Doctor of Medicine (MD)

Influences on and the impact of decision-making strategies for the management and surveillance of complex colonic polyps on patient outcomes

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February 2024

Summary

Background and aims

There is increasing awareness and recognition of complex colonic polyps and management across the UK is variable. Endoscopic treatments avoid the risks of surgery but require timely surveillance afterwards. There is a gap in evidence supporting team decision-making strategies introduced across the UK and surveillance guidelines have been recently updated. The aim of this thesis was to understand influences on decision-making, assess the potential impact of team strategies and identify areas to improve surveillance after treatment.

Materials and methods

A systematic review and focussed interviews were performed to assess the impact of and influences on decision-making. An observational study of patients managed through a multi-disciplinary team approach including a separate analysis of a novel technique, described their impact on clinical outcomes. A systematic review of surveillance guidance led to a linked data cohort study to assess the impact of colonoscopy quality on future risk of colorectal neoplasia.

Results

Systematic review of the literature suggested optimal decision-making strategies could reduce surgery for complex polyps. Positive experiences of team approaches were identified during clinician interviews. Increasing use of multi-disciplinary teams were identified with organ preservation achieved in 91.9% of patients. Colonic resections decreased and introduction of a novel technique avoided surgery in a further 80% of selected patients. Review of surveillance guidelines identified limited evidence regarding the impact of colonoscopy quality. In bowel screening colonoscopists, colorectal cancers were diagnosed in 0.9% after index examination, but limited impact was demonstrated above a threshold of stricter performance indicators on this risk.

Discussion

This thesis has demonstrated team decision-making strategies of complex polyps is effective, reduces unnecessary surgery and is endorsed by clinicians. Current surveillance guidelines can be safely utilised as decision-making tools. Quality standards set within a screening programme may be of importance in future surveillance recommendations and when comparing current diagnostic standards with new and emerging technology.

Acknowledgments

This thesis has been possible through the collaboration and guidance of many individuals. Firstly, I would like to express my gratitude to my supervisors for their ongoing support and mentorship during both my research and wider surgical career. Professor Sunil Dolwani has been invaluable as a supervisor, and I am extremely grateful for his expert guidance and attention to detail throughout. Professor Jared Torkington has provided continual encouragement and wisdom in helping me realise this achievement.

Dr Sunnia Gupta has been a great support during the methodology development and data collection within several aspects of this thesis. Her intelligence, pragmatism and good humour has been invaluable. I would also like to thank other members of the Screening Prevention and Early Detection Group within the Division of Population Medicine at Cardiff University including Lenira Semedo and Kate Lifford and for their expertise and time in ensuring high research standards were met during the qualitative aspects of this thesis. I am extremely grateful to all individuals across the UK involved for the complex polyp multi-centre study in the facilitation of data collection. My thanks also to members of Bowel Screening Wales and the Welsh Cancer Intelligence Unit for the expertise and guidance in obtaining data for the final research chapter of this thesis.

I have also had fantastic support from clinicians from Cardiff and Vale University Health Board. Lavanya Shenbagaraj as a fellow in gastroenterology was invaluable for her clinical expertise regarding complex colorectal polyps. I would also like to thank the consultants, colorectal research fellows and higher surgical trainees for their clinical and pastoral support during the thesis and the COVID pandemic. I am particularly grateful to Mr Michael Davies for assistance with the lap EMR aspect of the thesis and to Sally Keenan for her help accessing clinical information. The Medical Illustration team at Cardiff and Vale have been a credit in their provision of the excellent images in the introduction chapter.

Finally, I would like to acknowledge the collaboration of the Moondance Cancer Initiative with the Royal College of Surgeons of England in providing the funding for this research fellowship. This research would not have been possible without them, and I am so thankful for the wider opportunities and experiences I have gained because of it.

Publications and presentations

Peer reviewed publications

J PARKER, S Gupta, J Torkington, S Dolwani. Multi-disciplinary decision-making strategies may reduce the need for secondary surgery in complex colonic polyps - A systematic review and pooled analysis. Colorectal Disease, Dec 2021; 23(12): 3101-12 PMID 34473891.

J PARKER, J Torkington, M M Davies, S Dolwani. Laparoscopic-assisted endoscopic mucosal resection reduces the need for bowel resection for complex colonic polyps. British Journal of Surgery (BJS), May 2021; 108(5): 196-8 PMID: 33638645.

J PARKER, S Gupta, L Shenbagaraj, P Harborne, R Ramaraj, S Karandikar, M Mottershead, J Barbour, N Mohammed, M Lockett, A Lyons, R Vega, J Torkington, S Dolwani. Outcomes of complex colorectal polyps managed by multi-disciplinary team strategies – a multi-centre observational study. International Journal of Colorectal Disease, Feb 2023; 38(1): 28 PMID: 36735059.

J PARKER, S Gupta, J Torkington, S Dolwani. Comparison of recommendations for surveillance of advanced colorectal polyps – A systematic review of guidelines. Journal of Gastroenterology and Hepatology, Jan 2023; 38: PMID 36823764.

J PARKER, L Semedo, L Shenbagaraj, J Torkington, S Dolwani. Planning management for complex colorectal polyps – A qualitative assessment of factors influencing decision-making amongst colonoscopists. BMJ Open Gastroenterology, Apr 2023; 10: PMID 37217234.

Academic prizes

J PARKER. The impact of multi-disciplinary team management on complex colorectal polyp outcomes – a multi-centre observational study. Welsh Association of Gastroenterologists and. Endoscopists (WAGE) Annual Meeting, 2022 free paper presentations trainee prize winner

Presentations at national and international meetings

Oral presentations

J PARKER, J Torkington, M M Davies, S Dolwani. Laparoscopic-assisted endoscopic mucosal resection reduces the need for bowel resection for complex colonic polyps. Association of Coloproctology of Great Britain and Ireland (ACPGBI) Virtual Fringe Event, 2020.

Abstract published in Colorectal Disease, July 2020; 22(S1)

J PARKER, S Gupta, J Torkington, S Dolwani. Multi-disciplinary decision-making strategies may reduce the need for surgery in complex colonic polyps - a systematic review. Surgical Research Society (SRS) Virtual Annual Meeting, 2021.

Abstract published in BJS, July 2021; 108(S1)

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Video presentations

J PARKER, S Dolwani, J Torkington, M M Davies. Laparoscopic assisted endoscopic mucosal resection of a complex caecal polyp. ACPGBI Virtual Fringe Event, 2020.

Abstract published in Colorectal Disease, July 2020; 22(S1)

J PARKER, S Dolwani, J Torkington, M M Davies. Laparoscopic assisted endoscopic mucosal resection of a complex caecal polyp. British Society of Gastroenterology (BSG) Campus, 2021.

Abstract published in Gut, January 2021; 70 (S1)

Poster presentations

J PARKER, J Torkington, M M Davies, S Dolwani. Laparoscopic-assisted endoscopic mucosal resection reduces the need for bowel resection for complex colonic polyps. ESCP 15th Scientific and Annual Meeting, 2020.

Abstract published in Colorectal Disease, September 2020; 22(S3)

J PARKER, J Torkington, M M Davies, S Dolwani. Laparoscopic-assisted endoscopic mucosal resection reduces the need for bowel resection for complex colonic polyps. BSG Campus, 2021.

Abstract published in Gut, January 2021; 70 (S1)

J PARKER, S Gupta, J Torkington, S Dolwani. Multi-disciplinary decision-making strategies may reduce the need for secondary surgery in complex colonic polyps - a systematic review and pooled analysis. ACPGBI Annual Meeting, 2021.

Abstract published in Colorectal Disease, September 2021; 23(S1)

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Abstract published in Colorectal Disease, September 2022; 24(S2)

J PARKER, S Gupta, J Torkington, S Dolwani. Comparison of recommendations for surveillance of advanced colorectal polyps – a systematic review of guidelines. ACPGBI Annual Meeting, 2023.

Abstract published in Colorectal Disease, September 2023; 25(S1)

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Submitted abstracts

J PARKER, G Greene, A Gjini, D Huws, J Torkington, S Dolwani. The impact of colonoscopy key performance indicators on the risk of colorectal cancer and advanced polyps: an analysis of linked data in a screening population.

Submitted to ACPGBI Annual Meeting 2024 and BSG Live 24

Registered protocols

J PARKER, S Gupta, J Torkington, S Dolwani. A systematic review of the impact of decision-making strategies on the treatment outcomes of complex colonic polyps. PROSPERO 2020, CRD42020614.

J PARKER, S Gupta, J Torkington, S Dolwani. A systematic review of the surveillance recommendations and evidence base of international guidelines for advanced colorectal polyps. PROSPERO 2021, CRD42021189025.

List of abbreviations

ACPGBI	Association of Coloproctology of Great Britain and Ireland
ADR	Adenoma detection rate
AGREE II	Appraisal of guidelines for research and evaluation instrument 2nd edition
AKI	Acute kidney injury
ALF-ID	Anonymised linking field identifier
APC	Argon plasma coagulation
ASA	American Association of Anaesthesiologists
BCSP	Bowel cancer screening programme
BCUK	Bowel Cancer UK
BJS	British Journal of Surgery
BMI	Body mass index
BSG	British Society of Gastroenterology
BSW	Bowel Screening Wales
CANISC	Cancer Network Information System Cymru
CAVUHB	Cardiff and Vale University Health Board
CCA	Cancer Council Australia
CCI	Charlson comorbidity index
COREQ	Consolidated criteria for reporting qualitative research
CD	Clavien-Dindo classification system
CELS	Combined endoscopic laparoscopic surgery
CT	Computerised tomography
DVT	Deep vein thrombosis

EFTR	Endoscopic full thickness resection
EMR	Endoscopic mucosal resection
ESD	Endoscopic submucosal dissection
ESGE	European Society of Gastroenterology
EUA	Examination under anaesthetic
FIT	Faecal immunohistochemical test
FOBT	Faecal occult blood test
GRADE	Grading of recommendations, assessment, development and evaluations system
HGD	High grade dysplasia
IBD	Inflammatory bowel disease
ICD	International classification of disease
IDEAL	Idea, development, exploration, assessment, long term study
IQR	Interquartile range
IR	Interventional radiology
ITU	Intensive treatment unit
IV	Intravenous
JAG	Joint Advisory Group on Gastrointestinal Endoscopy
JGES	Japan Gastroenterological Endoscopy Society
KPI	Key performance indicator
Lap EMR	Laparoscopic assisted endoscopic mucosal resection
LGD	Low grade dysplasia
LNPCP	Large non pedunculated colorectal polyp
LST-G	Laterally spreading tumour granular
LST-NG	Laterally spreading tumour non-granular

MDT	Multi-disciplinary team
NG	Nasogastric
NHMRC	National Health and Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
PCCRC	Post colonoscopy colorectal cancer
PDR	Polyp detection rate
PE	Pulmonary embolism
PEDW	Patient Episode Data for Wales
PPS	Post polypectomy syndrome
PR	Per rectum
PRISMA	Preferred reporting items for systematic reviews and meta-analyses
PROSPERO	International prospective register of systematic reviews
QA	Quality assurance
RCT	Randomised controlled trial
SAIL	Secure anonymised information linkage databank
SIGN	Scottish Intercollegiate Guidelines Network
SMSA	Size morphology site access
SPDR	Serrated polyp detection rate
SPECC	Significant polyp and early colorectal cancers
SURE	Specialist Unit for Review Evidence
SRS	Surgical Research Society
STROBE	Strengthening the reporting of observational studies in epidemiology
TAMIS	Trans-anal minimally invasive surgery

TART	Trans-anal resection of tumour
TEMS	Trans-anal endoscopic microsurgery
USMSTF	US Multi-Society Task Force
WEO	World Endoscopy Organisation
WCISU	Welsh Cancer Intelligence and Surveillance Unit
WRRS	Welsh Results Reports Service

“*Decisions are more important than incisions*”

Mr Brendan Moran, 2021

Consultant colorectal surgeon

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Part One: Introduction, aims and hypotheses

1 Introduction

1.1 Epidemiology and pathogenesis of complex colorectal polyps

Colorectal cancer is the third most common cancer worldwide and the second commonest cause of cancer related mortality (1). In the UK it accounts for 11% of new cancer diagnoses annually (2). Alcohol, smoking, processed meat, weight and physical activity are all thought to affect an individual's risk of the disease (3, 4). It is estimated that 54% of colorectal cancers in the UK are preventable (5) and the chance of cure is best when the disease is caught early. Management options can include surgery, endoscopic treatment, chemotherapy or radiotherapy. If diagnosed early, outcomes are significantly improved with five year survival rates of 91% with stage 1 disease compared to 10% in those with stage 4 disease (6).

The development of colorectal polyps is widely accepted to be the precursor to colorectal malignancy (7) and their removal can reduce the incidence and mortality of bowel cancer (8). The prevalence of adenomas in those undergoing screening colonoscopy is estimated to be between 15% and 39% with higher rates seen in men over 70 (9). They are diagnosed on average ten years earlier than cancer (10). The adenoma carcinoma sequence as shown in figure 1.1, was first outlined by Fearon and Vogelstein in 1990 and is widely accepted as the major pathway to colorectal cancer (7). It describes a stepwise progression of genetic mutations from normal colonic mucosa to a benign colonic polyp then finally a carcinoma (7). This hypothesis forms the basis of colorectal cancer screening strategies which aim to detect cancer and polyps at an earlier, treatable stage.

1.2 Identification of complex colorectal polyps

Colorectal cancers or polyps are identified either when a patient seeks medical advice with bowel related symptoms or through a bowel cancer screening programme. Symptoms and signs leading to presentation can include a change in bowel habit, rectal bleeding or iron deficiency anaemia. Some individuals will be diagnosed whilst undergoing surveillance for other colorectal disorders or incidentally by investigations for other health problems. Confirmation of the diagnosis is usually achieved with an endoscopic examination in the form of colonoscopy or flexible sigmoidoscopy.

Screening programmes aim to detect early colorectal cancer to allow effective treatment and improve patient outcomes. In England and Wales, 9% and 12% of bowel cancers respectively are diagnosed through screening services (11). Structured programmes with stool based bowel cancer screening were introduced in the UK in 2006 as a result of collation of evidence from several UK and

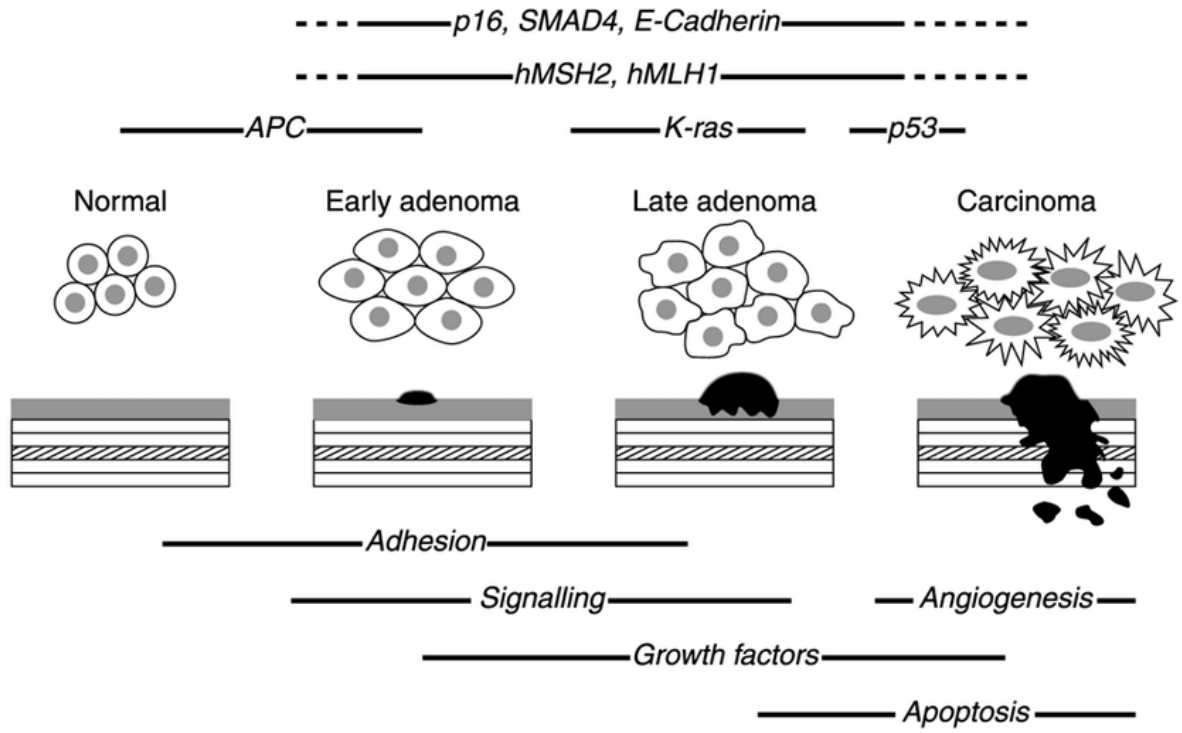

FIGURE 1.1 - THE ADENOMA CARCINOMA SEQUENCE

Image courtesy of Fearnhead et al 2002 (12)

international randomised control trials and a subsequent Cochrane Review demonstrating a 16% relative risk reduction in colorectal cancer mortality (13). Individuals are invited by post every two years to complete a sample to detect microscopic levels of blood in the stool. If this is positive, they are then invited for a colonoscopy to identify the underlying aetiology. This process aims to detect early-stage disease, improve outcomes and reduce mortality from colorectal cancer. A significant number of colorectal polyps are also identified through screening and removal of these in their pre-malignant phase also reduces the subsequent incidence of and prevents mortality from colorectal cancer (8, 14). At colonoscopy, adenomas and cancers are diagnosed in 50.8% and 12.4% respectively (11). An increasing proportion of bowel cancers are detected at an earlier stage as a result of screening (15).The uptake of colorectal cancer screening remains at around 65% of those invited. Males and those in socio-economically deprived areas are less likely to participate (16). Increasing awareness and endorsement by organisations or healthcare providers may all help improve participation (17). There have been ongoing modifications to the programme since its introduction to improve the uptake and accuracy of screening. This includes the change of the stool sampling kit from the faecal occult blood test (FOBT) to the faecal immunohistochemical test (FIT).

The FOBT detects the presence of haem through its peroxidase activity and requires three stool specimens from the patient. Test limitations included false positives resulting from ingested iron, red meat and some vegetables. In comparison, FIT uses antibodies to detect human globin. Only one sample is required from the patient and has a higher specificity of around 94% (18). The uptake of FIT by those invited seems to be higher compared to the FOBT. Screening across the UK is also aimed to gradually expand the age range and to begin invitations from the age of 50 rather than 60 to increase the number of participants and detected cancers in the near future.

1.3 Classification and definitions of complex colorectal polyps

There is a significant spectrum in the appearance and morphology of colorectal polyps and accurate lesion assessment is crucial in making management decisions. Lesions can be described in terms of their size, site within the colon and accessibility. The Paris system helps to classify morphology and separates lesions into polypoid (pedunculated or sessile) or non-polypoid (flat or depressed) lesions (19). Increasing size, ulcerated and depressed polyps have a higher chance of underlying malignancy. The surface appearance can also facilitate diagnosis using the Kudo pit pattern classification (20) with type V lesions having a 56% chance of invasive disease (21). Both the Paris and Kudo systems are outlined in figure 1.2 and 1.3.

There is no international consensus regarding the definition of a complex colorectal polyp and varying terminology has been reported. Other terms include difficult, advanced, refractory or large lesions. The term significant polyp and early colorectal cancers (SPECC lesions) has also been used. They are generally accepted to be polyps larger than 2cm or in a location that makes a stable platform for endoscopic removal difficult (22, 23). The size, morphology, site, access (SMSA) scoring system is a validated method of objectively determining the level of polyp complexity and difficulty of polypectomy (24). The use of this system may assist service delivery, training and management decisions. Less complex lesions are often easily removable at the time of colonoscopy with minimal risk. For complex lesions with a higher SMSA level, the decision-making and technical challenges of treatment are far greater. These complex polyps have a 10 to 15% risk of already containing a focus of cancer (25) so accurate assessment of the lesion and patient is required to guide optimal management.

Guidelines from the British Society of Gastroenterology (BSG) describe complex polyps as having a SMSA level of 4 or those with an increased risk of malignancy, incomplete resection or adverse

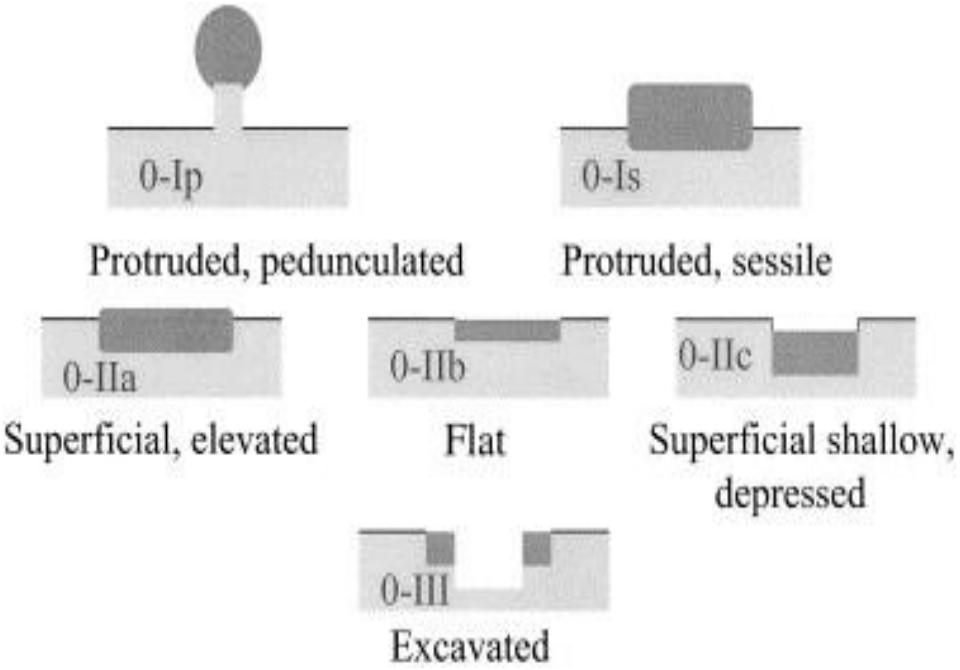

FIGURE 1.2 – THE PARIS MORPHOLOGY CLASSIFICATION

Image courtesy of Participants in the Paris Workshop 2022 (19)

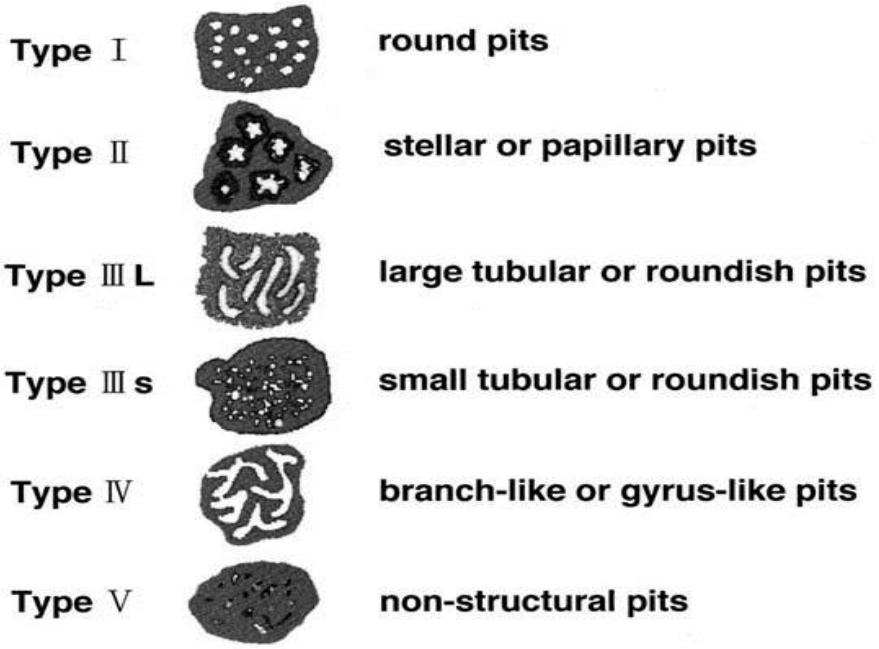

FIGURE 1.2 – THE KUDO SURFACE PIT PATTERN CLASSIFICATION

Image courtesy of Kudo et al 1996 (20)

TABLE 1.1 – THE SMSA SCORING SYSTEM

	Criteria	Points
Size	<1cm	1
	1-1.9cm	3
	2-2.9cm	5
	3-3.9cm	7
	>4cm	9
Morphology	Pedunculated	1
	Sessile	2
	Flat	3
Site	Left	1
	Right	2
Access	Easy	1
	Difficult	3

Levels are assigned as follows: level 1 = 4-5 points; level 2 = 6-9 points; level 3 = 10-12 points; level 4 = >12 points

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events (25). Internationally terminology and definitions are variable creating challenges to research in this field.

1.3.1 Recent advances in endoscopic imaging of colorectal polyps

There have been ongoing advances in the technology available to enhance the detection, assessment and characterisation of colorectal polyps. The progression from standard to high-definition white light endoscopy has been shown to improve both polyp and adenoma detection (26). The addition of image enhanced endoscopy aims to augment the appearance of the colonic surface to aid diagnostic accuracy. Traditional chromoendoscopy involves the application of dye or stains to enhance the surface appearances. Virtual chromoendoscopy includes techniques such as

narrow band imaging (NBI) and digital image processing technology. NBI uses the blue green light spectrum to enhance capillary patterns and mucosal surfaces. Image processing technology including I-SCAN digital contrast (I-SCAN), flexible spectral imaging colour enhancement (FICE), blue light imaging (BLI), and linked colour imaging (LCI) aim to enhance surface features and facilitate the differentiation between normal and abnormal mucosa.

All these techniques aim to facilitate the application of optical diagnosis for colorectal lesions and refine characterisation and management decisions. They allow a detailed assessment of mucosa, pit and vessel patterns to ascertain the histological nature of the lesion without the need for a tissue biopsy. As a result, appropriate treatment and surveillance decisions can be made without the additional burden of cost, delay and patient anxiety created by awaiting histological assessment (27). For complex polyps, avoiding biopsy has additional benefits. The process can inadvertently result in fibrosis in the lesion which creates a higher chance of difficulties or complications at subsequent endoscopic resection attempts. Conversely, a thorough optical assessment can also identify signs concerning for malignancy when a biopsy is benign which may influence the recommended management strategy. Documentation of these techniques using photos or videos can enable review by those with additional expertise at another time.

Endoscopic images technologies must balance the benefits of the strategy against the financial implications. Appropriate education and governance is also required to ensure reliability as performance can be influenced by training, available equipment and experience (28). The European Society of Gastroenterology (ESGE) recommend a core curriculum for optical diagnosis practice to facilitate high quality training and implementation (29).

1.4 Management options for complex colorectal polyps

Most colorectal polyps are often technically straightforward to remove at index colonoscopy by appropriately trained operators, but the management of complex lesions is more challenging. There are several options ranging from conservative management, organ preserving approaches such as endoscopy, trans-anal surgery through to colonic resection. Procedure related adverse events, utilisation of colonic resection, recurrence and unsuspected malignancies are key clinical outcomes for patients with complex polyps. The choice of management for complex polyps should be individualised and balance the risk of the procedure against the likely short and long-term outcomes.

1.4.1 Endoscopic procedures

A variety of endoscopy techniques can be used to resect polyps either whole (en bloc) or on piecemeal basis. They are usually performed with the patient awake or under light sedation. The

patient will require laxatives or an enema to clear the bowel before the procedure, but most are performed as a day case or short hospital stay. Risks after endoscopic management of complex polyps include readmission following the procedure (4.1%), post polypectomy bleeding (3%), and bowel perforation (0.5%) (30). Post polypectomy syndrome (PPS) which manifests as abdominal pain and fever can also occur.

1.4.2 Endoscopic mucosal resection (EMR)

As shown in figure 1.4, endoscopic mucosal resection (EMR) involves the injection of fluid in the submucosal space to raise the polyp from the underlying tissue (31). The endoscopist then places a snare around the lesion which is attached to diathermy. The cutting action of the snare as it tightens in conjunction with the diathermy then removes the polyp from the surface of the bowel with the plane of resection being the superficial or mid submucosa. This can be performed en bloc or in a piecemeal fashion for larger lesions. This is the standard endoscopic approach for most larger polyps.

1.4.3 Endoscopic submucosal dissection (ESD)

Endoscopic submucosal dissection (ESD) is a newer technique allowing en bloc resection of lesions in the colon (32). Like EMR, ESD also begins with a submucosal injection of fluid to raise the polyp. As shown in figure 1.5, an ESD knife is then used to incise around the lesion and dissect it from the underlying tissues. The plane of resection is usually the deep submucosa to enable it to be removed whole. In some scenarios, endoscopists will use a combination of both EMR and ESD techniques to achieve satisfactory polyp excision (hybrid EMR/ESD).

1.4.4 Combined endoscopic and laparoscopic surgery (CELS)

Combined endoscopic and laparoscopic surgery (CELS) procedures are emerging organ preserving techniques (33). They also have a variety of terminology to describe similar procedures. They utilise the benefits of both endoscopic and surgical approaches to facilitate complete endoscopic removal of polyps that may otherwise require colonic resection. A laparoscopic assisted full thickness polypectomy was first described in 1993 (34), and several series of combined techniques for complex polyps have since been reported (35). The procedures are performed under general anaesthetic with a short hospital stay. An overview of these techniques is shown in figure 1.6. Laparoscopic assisted endoscopic resection uses laparoscopic colonic mobilisation and manipulation to improve polyp access for assessment and resection by the colonoscopist. Figure 1.6.1 shows the surgeon assisting the endoscopic resection of the polyp by invaginating the bowel wall and enabling full polyp removal. The polyp can then be removed endoscopically using EMR or ESD as required. In

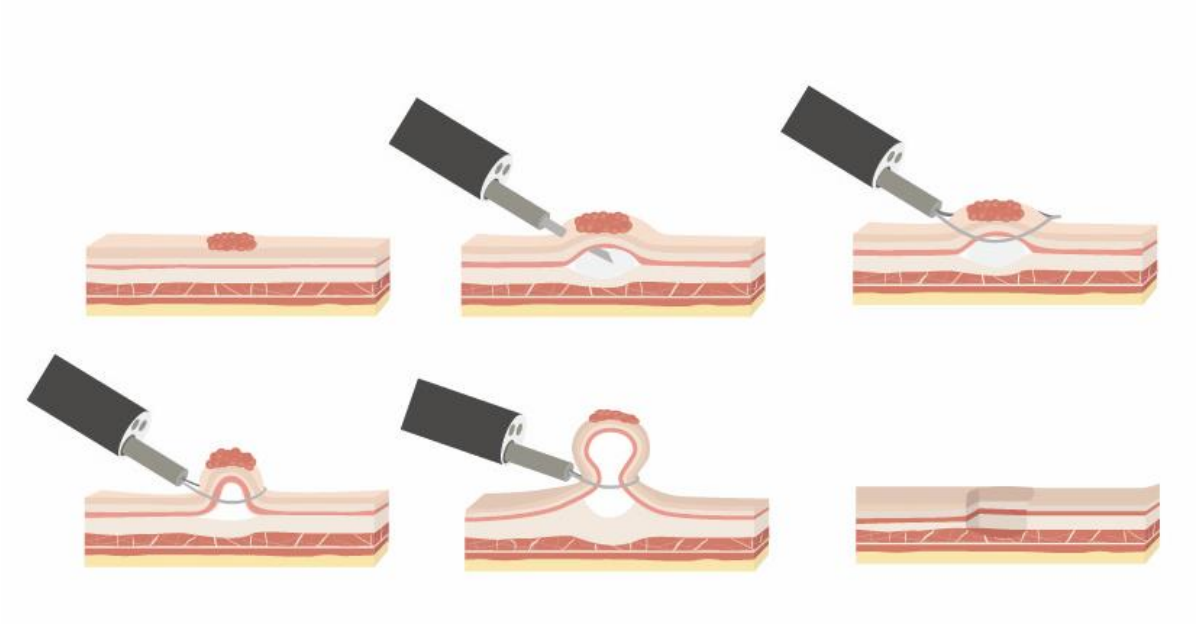


FIGURE 1.4 – ENDOSCOPIC MUCOSAL RESECTION (EMR)

Image courtesy of Medical Illustration, Cardiff and Vale University Health Board (CAVUHB)

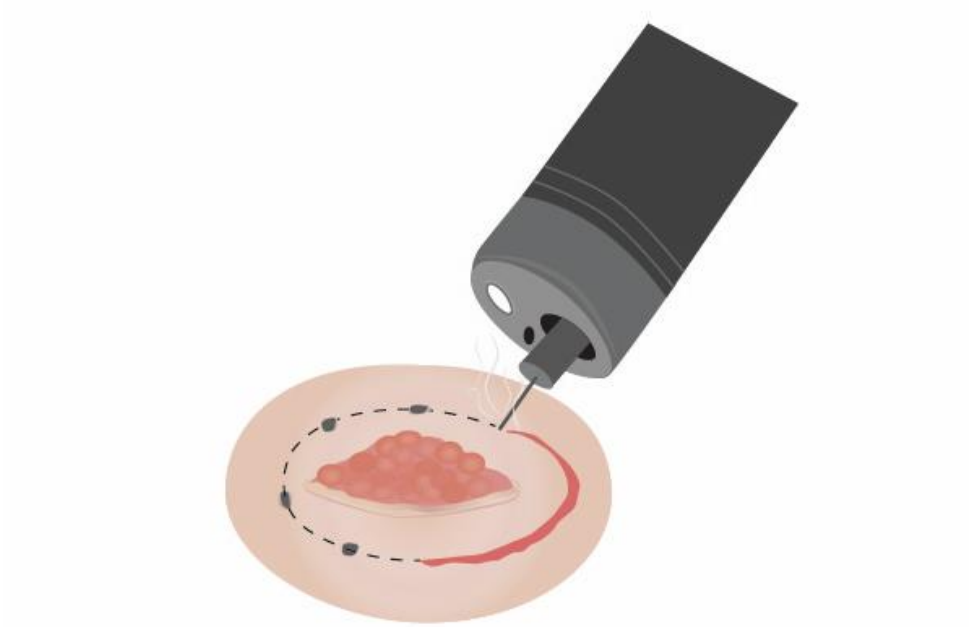


FIGURE 1.5 – ENDOSCOPIC SUBMUCOSAL DISSECTION (ESD)

Image courtesy of Medical Illustration, CAVUHB

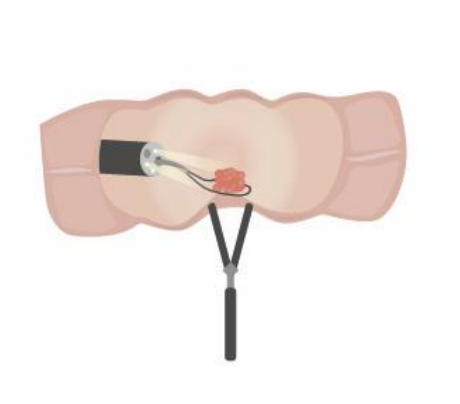


Figure 1.6.1 -

Laparoscopic assisted endoscopic resection

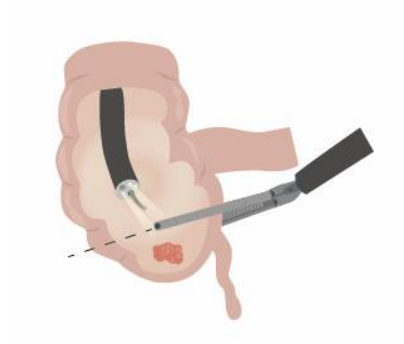


Figure 1.6.2 -

Endoscopic assisted laparoscopic resection

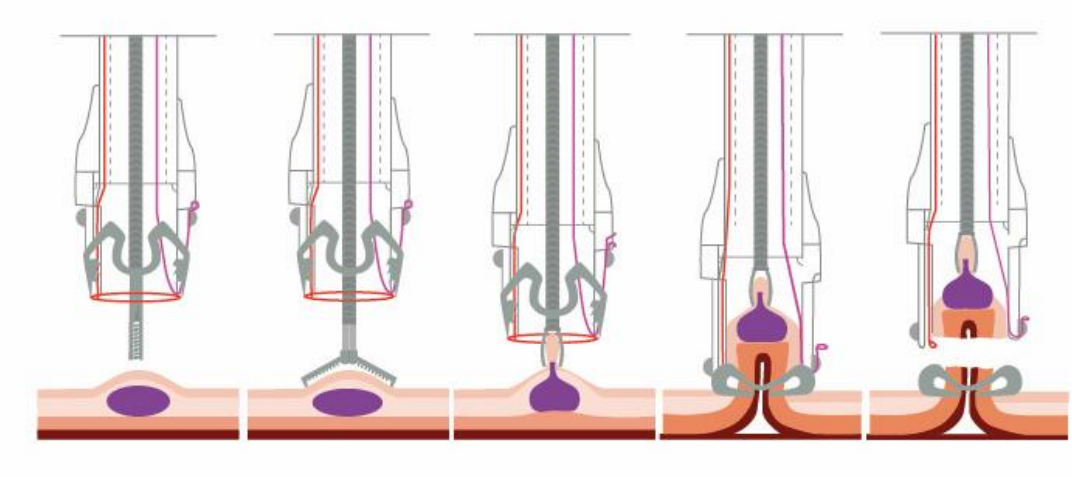


Figure 1.6.3 -

Full thickness endoscopic resection

FIGURE 1.6 – COMBINED ENDOSCOPIC AND LAPAROSCOPIC (CELS) PROCEDURES

Images courtesy of Medical Illustration, CAVUHB

endoscopic assisted laparoscopic resections, the endoscopist guides the surgeon to the location of the polyp to ensure complete removal during resection (figure 1.6.2). Its commonest use is for peri-appendiceal lesions and avoids a blind surgical procedure that could potentially result in a partial resection. The use of full thickness endoscopic resections has been described in several case series (36). This involves removing a small portion of the colon containing the polyp with an over the scope full thickness resection device (figure 1.6.3). The device is introduced with the endoscope which fully encompasses, and then removes the lesion. The feasibility of a similar technique to this combining laparoscopy with endoscopy has also been described. The full-thickness laparoendoscopic excision procedure (FLEX procedure) is also safe to use by appropriately trained teams within selected polyps (37). Laparoscopic and endoscopic lesion assessment are performed simultaneously. The borders of the lesion are marked endoscopically alongside placement of full thickness sutures which allow the section of the bowel containing the polyp to be everted. This section of the bowel can then be excised through a laparoscopic linear stapling device. Both these techniques are useful options where patients would have otherwise required bowel resection for their benign polyp and where the skills are available.

Combined procedures are not currently universally available with only a limited number of centres performing them. Indications vary between studies, but they are mostly used to avoid colonic resection where endoscopic management is unfeasible or has been previously unsuccessful. Complications can include bleeding, wound infection and complications of anaesthesia. Another benefit is the avoidance of an unrecognised perforation as this is ameliorated by laparoscopic assessment of the bowel wall throughout the procedure. Any full thickness breach can therefore be repaired at the time to avoid the consequences of a delayed presentation. Other advantages include the ability to convert to immediate colonic resection if polyp assessment reveals suspected malignancy, the resection is inadequate or in the event of procedure complications.

1.4.5 Surgical procedures

Surgical procedures can involve the resection of the colonic segment containing the polyp or organ preserving trans-anal techniques for rectal lesions. These are both illustrated in figure 1.7.

1.4.5.1 Trans-anal excisional techniques

Rectal polyps can be removed surgically via the trans-anal route. This can be performed with standard surgical instruments as a trans-anal resection of tumour (TART). Specialist equipment to improve access and visualisation of the lesion is known as trans-anal minimally invasive surgery (TAMIS). The TAMIS approach (figure 1.7.1) is performed under a general anaesthetic and is preferrable to a TART approach for complex polyps due to the accuracy and completeness of polyp

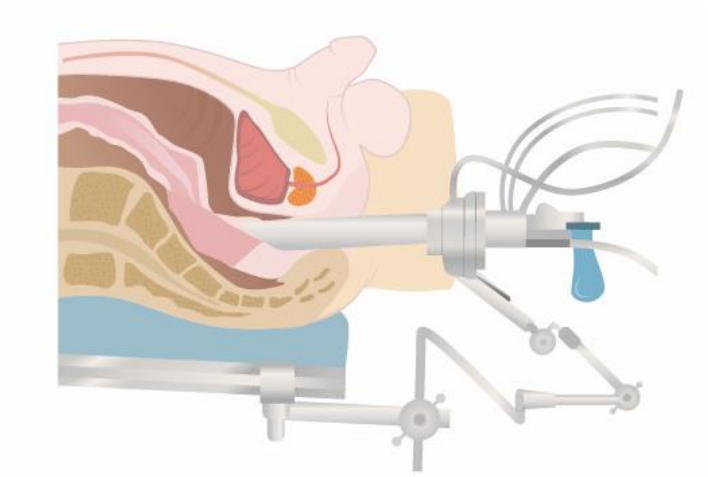


Figure 1.7.1 – Trans-anal minimally invasive surgery (TAMIS)

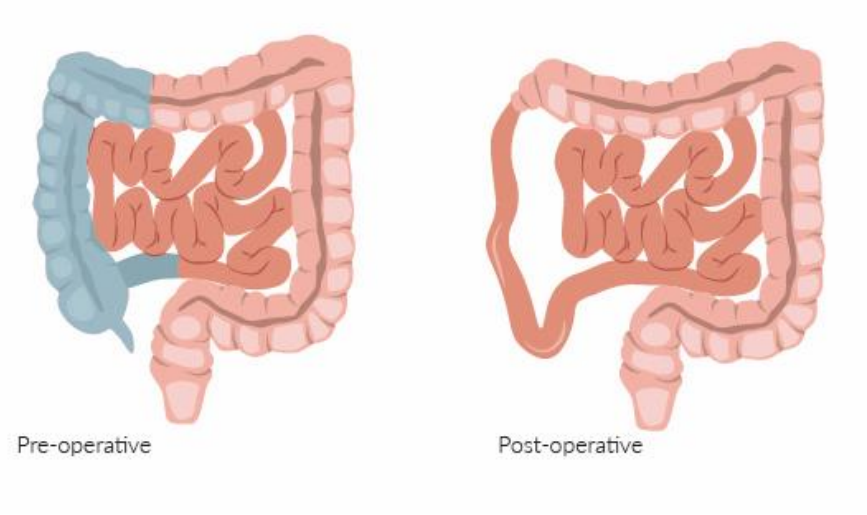


Figure 1.7.2 – Colonic resection (right hemicolectomy)

FIGURE 1.7 – SURGICAL PROCEDURES

Images courtesy of Medical Illustration, CAVUHB

resection. A recto-scope is introduced, and the lesion is removed from the lumen of the bowel using instruments introduced via the device. A bowel resection is not required. Complications of trans-anal procedures are similar to that of endoscopic methods with the additional risks of requiring a general anaesthetic, and a higher incidence of incontinence and post procedure symptoms as compared to endoscopic removal.

1.4.5.2 Colonic resection

Colonic resection involves the removal of the entire segment of colon containing the polyp along with its accompanying mesentery and lympho-vascular supply (figure 1.7.2). In most circumstances, the bowel is joined together with an anastomosis either using a sutured or stapled technique but

occasionally a temporary or permanent stoma is needed. Many colonic resections are now performed laparoscopically which has benefits in both patient recovery and length of stay, but some patients may still require an open operation. Colonic resection involves the risks of general anaesthesia, bleeding, post-operative infection, anastomotic leak and functional morbidity which can all have significant consequences to the patient. The duration of hospital stay and recovery is usually longer as compared to endoscopic, combined or trans-anal procedures.

1.4.6 Conservative management

There is little evidence describing outcomes after conservative management or surveillance for large or complex colorectal polyps. Given the inherent time taken for such polyps to transform to malignancy (38), it seems reasonable to recommend such management in those who have a limited life expectancy or where intervention would carry unacceptably high risks given patient function or comorbidities. Endoscopic or radiological surveillance may be offered depending on patient and clinician preferences.

1.5 Decision-making regarding complex polyp management

The detection and awareness of large, complex or higher risk polyps has increased (39) and this is likely due to the introduction of screening programmes, improvements in colonoscopy quality, education and training courses for health professionals and increasing public awareness of bowel cancer symptoms. Early cancer is found in 10-15% of these polyps (25), so treatment should logically be individualised and account for patient, polyp, and service-related factors in addition to balancing complete polyp removal against the risks of overtreatment.

1.5.1 The risks and benefits of different management options

Endoscopic therapy is the appropriate treatment for the majority of complex polyps providing there is no suspicion of cancer (25). It is the recommended first line treatment by several guidelines (25, 40, 41). Endoscopic resection of large polyps is internationally recognised as safe and can be successful in preventing surgery in 92% of selected cases (42). EMR and ESD can be used for complex polyps and both have lower adverse event rates and shorter duration of hospital stays as compared to surgery (42, 43). ESD procedures result in a higher complete resection rate, but its provision is limited by service availability in terms of operator expertise. Procedure duration is usually longer and there is a small increase in the risk of bowel perforation (44-47). As a result, its use tends to be reserved for lesions where there is suspicion of submucosal invasion or in those that cannot be satisfactorily removed by EMR (48). There also appear to be economic benefits to endoscopic first line management with significant cost savings compared to those managed surgically (49, 50).

Limitations of organ preserving techniques compared to colonic resection include the possibility of residual or recurrent disease and requirement of repeated surveillance. A meta-analysis of recurrence after endoscopic resection of large polyps reported rates in the region of 13.8% (range 0-68%) with most being definitively treatable with further endoscopy (51). Although the risk of significant endoscopic complications is low and often managed conservatively, some can require emergency surgical intervention. Another concern is the detection of unrecognised malignancy on final histology. This may require consideration of a secondary completion procedure usually in the form of colonic resection. In such cases however, survival and disease recurrence does not seem adversely affected by an initial endoscopic attempt (52).

Advanced therapeutic endoscopy increases the number of successful colonoscopic complex polyp resections (42, 43) but there remains a population where this is not possible. The reasons for this are commonly size or access difficulties but also where the risks of complications such as perforation may be unacceptably high. The application of CELS procedures in these scenarios seems promising and can avoid colonic resection in selected cases (33). Their use may become of greater importance with the increasing detection of complex lesions. A systematic review in 2015 reported an average reintervention rate of 9.5%, an adenocarcinoma incidence of 10.5% and a complication rate of 7.9% for laparo-endoscopic polyp procedures (35). The evidence for CELS is limited by the heterogeneity in studies with variability in their terminology, selection criteria and procedure techniques (53-57). Their use is also restricted by logistical issues, procedure duration and equipment requirements with cost benefit evidence and patient reported outcomes also required to validate their use.

Patients with benign polyps deemed too challenging for endoscopic resection may be offered surgery (58, 59) with the proportion requiring bowel resections being considered a key performance indicator (KPI) (25). Although there is no currently accepted rate, many polyps are still referred for surgery (30) with increasing use of colonic resections reported recently in certain geographical jurisdictions despite advances in organ preserving techniques (60). Indications for surgical intervention include polyps where the suspicion of malignancy is high or where endoscopic resection is unlikely to be complete (25). Large size and right sided locations are also a key factor for surgical referral (61, 62). Whilst bowel resection can offer definitive treatment by providing an oncology resection for those with subsequent unexpected malignancies and reduced surveillance requirements, this is at the cost of higher rates of adverse events, mortality and cost (50, 62, 63). A recent systematic review reported a complication and mortality rate of 24% and 0.7% respectively for resections performed for benign colonic polyps. Length of stay was on average 5.1 days which is significant longer than endoscopic or combined procedures. Risks of colonic resection including complications, duration of recovery and patient related outcomes must be carefully considered

against the benefits. For this reason, surgery for complex polyps should be reserved for those with clear indications.

1.5.2 Current utilisation of management options

Despite the recommendation for first line endoscopic treatment, the chosen management strategy for complex polyps varies considerably which may result in sub optimal patient outcomes. Lee et al described a wide range in use of primary surgery for complex polyps in screening programmes ranging from 7% to 36% (30). Increasing rates of surgery have been reported (60). Dattani identified that those not detected through screening had a higher risk of primary surgical treatment (64) and surgery could have potentially been avoided in 41% of patients with benign polyps in America (65). The reasons for recommending colonic resection are unclear (66, 67), but may reflect differences in service provision, expertise available or decision-making practices. Surgeons may still manage patients operatively despite knowing a polyp is benign suggesting this is not solely an issue surrounding accurate polyp assessment (68). Surgeons and non-experts in complex polypectomy seem more likely to refer patients for surgical intervention (68, 69). The individual endoscopist and treating centre have also been identified as risk factors for surgical intervention with clinicians referring a wide range of polyps (0 to 46.6%) larger than 20mm for bowel resection (70). Identifying the barriers in recommending endoscopic therapy at a clinician level could help direct strategies to resolve unnecessary surgical intervention for complex polyps. These factors may not only encompass clinical influences but could also include patient, logistical and service-related issues.

1.5.3 Surveillance after treatment

After treatment of a large or complex polyp, colonoscopic surveillance aims to identify and treat new or recurrent disease in attempt to reduce the impact of future cancer development further. The post colonoscopy colorectal cancer (PCCRC) rate is the principal outcome in monitoring the quality of a colonoscopy service (71). The exact risk of recurrence for every individual is different and depends on several factors including polyp number, size, location, gender and age (72). Decisions regarding whether an individual requires surveillance and the appropriate timing of this can be challenging. Surveillance intervals should balance the need for timely diagnosis against the risks of colonoscopy and its burden on the patient and health service.

Guidelines are decision-making tools that help clinicians provide evidence-based management for their patients. Several countries have recently published updated versions of their polyp surveillance guidelines (73-75). For large non-pedunculated colorectal polyps, one off surveillance at three years is recommended by the BSG guidelines providing the excision has been complete with interim check procedures recommended if the removal has been piecemeal (73). This is based mainly on patient

and polyp parameters including size, number or histology of polyps and patient age but the level of evidence available is limited. Patient wishes should be accounted for, and factors related to the quality of index colonoscopy may also be important. A Polish study has suggested a reduced risk of subsequent colorectal cancer in patients who have screening procedures performed by colonoscopists with high adenoma detection rates (ADR) (76). Studies by Kaminski (77) and Corley (78) also found lower ADRs were a predictor of interval colorectal cancers. As these studies were performed within programmes with a primary colonoscopy rather than faecal bowel screening system, they may not be directly applicable to screening programmes in the UK.

1.5.4 Strategies to improve decision-making

There is recognition of the potential importance of decision-making strategies in the management of complex polyps. BSG guidance recommends a multi-disciplinary team approach involving advanced endoscopists, laparoscopic colorectal surgeons and gastrointestinal pathologists using defined selection criteria (25). It is advised that colonic resection should only be used in selected cases and ideally discussed in a complex polyp multi-disciplinary team prior to being recommended. These recommendations are based on a very low grade of evidence but advise detailed assessment and shared decisions between patient and clinician as central to the process (25). In general the impact of clinical expertise and team decisions on clinical outcomes are unclear (79).The utility of strategies such as multi-disciplinary team decision-making meetings has been demonstrated in other settings (80, 81) but their impact on outcomes for complex polyps has not been assessed. It seems logical that the use of decision-making processes could improve outcomes in a field such as this where there is a wide range of treatment options and great variability in their application. Quality recommendations regarding surveillance are required to improve patient outcomes by balancing the risk of unidentified disease against the overuse of surveillance. Identification of the gaps in evidence supporting clinical guidelines and action on them is required to achieve this balance.

1.6 Conclusions

The detection of complex and large colonic polyps has increased since the introduction of screening programmes (39). The challenges of managing these are complex and current practices may not provide the optimal care for all patients. Understanding the process, effect and underlying evidence regarding decision-making strategies concerning management and surveillance warrants investigation. As the trend of increased screening uptake and better early detection continues, it is likely that improving outcomes for those with complex colorectal polyps will have an increasing impact on patients and health services.

2 Aims and hypotheses

The use of decision-making strategies may improve the clinical outcomes of patients with complex colorectal polyps by providing the optimal and individualised treatment method in the first instance followed by timely surveillance.

2.1 Aims and hypotheses of part one

The following aims will assess the status and impact of management decision-making strategies on complex polyp outcomes.

2.1.1 Aims

1. To perform a systematic review of the literature to assess and compare the current impact of clinical decision-making strategies on the treatment outcomes of complex colonic polyps.
2. To qualitatively assess and understand the influences on decision-making regarding complex polyp management amongst clinicians involved in their care.
3. To analyse the process, procedures performed and clinical outcomes of patients with colorectal polyps who are managed by a complex polyp multi-disciplinary team decision-making process.
4. To describe the structure of an individual team meeting and assess the impact of the introduction of a novel complex polyp resection technique on short and long term patient outcomes.

2.1.2 Hypotheses and research questions

1. Decision-making strategies for complex polyps are currently underreported and variable but can improve the clinical outcomes of patients with complex colorectal polyps.
2. The influences on decision-making when managing complex colorectal polyps by clinicians are not only clinical but are also impacted by service and non-clinical issues.
3. The utilisation of complex polyp multi-disciplinary teams is safe and can improve management of patients with complex polyps through providing optimal first line treatment and high standards of clinical outcomes.
4. A multi-disciplinary team decision-making process can facilitate the safe introduction of novel techniques to avoid surgical colonic resection whilst maintaining clinical outcomes for patients with complex colorectal polyps.
5.

2.2 Aims and hypotheses of part two

The following aims will assess current recommendations regarding advanced and complex colorectal polyp surveillance and their underlying evidence to develop new research that aids the improvement of these decision-making tools.

2.2.1 Aims

1. To perform a systematic guideline review to assess factors at index colonoscopy used for advanced and complex colorectal polyp surveillance recommendations.
2. To use data linkage and analysis to identify the effect of colonoscopy quality on the subsequent risk of colorectal cancer, advanced or complex colorectal polyps.

2.2.2 Hypotheses and research questions

1. International recommendations regarding surveillance for advanced and complex polyps are mostly based on patient and polyp factors at index colonoscopy with little consideration or evidence for operator or quality factors.
2. A higher quality of colonoscopy at index examination can reduce the future risk of developing colorectal cancer, advanced or complex polyps.

3 Definitions, classifications and statistical methods

3.1 Definitions and classifications

The definitions described below are applicable throughout the thesis unless otherwise stated.

3.1.1 Polyp definitions

3.1.1.1 Complex colonic polyp

These criteria used were developed based on national guidance, literature review and expert opinion. Complex polyps included those described as difficult, advanced, large, significant, refractory or endoscopically unresectable in this thesis. Non-pedunculated polyps larger than 20mm (22, 23), those with an SMSA level of 4 (25), with an increased risk of malignancy, incomplete resection or adverse events (25) or in a difficult location (22, 23) were also included.

3.1.1.2 Advanced colonic polyp

Based on BSG guidance (73), the criteria for advanced polyps included adenomatous polyps at least 10mm in size or with high grade dysplasia (HGD) and serrated polyps at least 10mm in size with any dysplasia.

3.1.1.3 Size morphology site access (SMSA) score

This classification system of colorectal polyps is described above in the introduction and in table 1.1. It was used to describe data collected on polyps throughout the thesis.

3.1.2 Comorbidities

Comorbidities throughout the thesis were described using the Charlson Comorbidity Index (CCI) (82). This is a widely used method of classifying comorbidities with a maximum score of 37. This can be used to predict an individual's 10 year survival rate and is shown in appendix 1.

3.1.3 Mode of presentation

Screening patients were those diagnosed through screening programmes. Symptomatic patients included those with a clinical presentation resulting in an indication for colonoscopy, incidental findings on other investigations or on a surveillance pathway for colorectal pathology.

3.1.4 Index screening colonoscopy

The first documented colonoscopy performed by a bowel screening programme after a positive faecal bowel screening test. This did not include individuals attending for surveillance procedures.

3.1.5 Polyp, adenoma and serrated polyp detection rate (PDR, ADR and SPDR)

The proportion of colonoscopies performed by a colonoscopist in which at least one polyp (PDR), adenoma (ADR) or serrated polyp (SPDR) was detected.

3.1.6 Colonoscopy completion rate

The proportion of colonoscopies successfully reaching the caecum for an individual colonoscopist.

3.1.7 Colonoscopy withdrawal time

The duration from maximal intubation to the caecum or terminal ileum to removal of the colonoscope in minutes described with or without any therapeutic intervention.

3.1.8 Primary and secondary procedures

The first procedure performed for a polyp was defined as the primary procedure. Primary surgery was defined as those referred directly for bowel resection without attempt at endoscopic therapy. Procedures for any indication thereafter for the same polyp were described as secondary or tertiary.

3.1.9 Outcomes

3.1.9.1 Length of stay

Length of stay was calculated as the total number of nights the patient spent in hospital before and after the procedure.

3.1.9.2 Adverse events

All adverse events reported were extracted described using the Clavien-Dindo (CD) classification system (83) as shown in appendix 2. Bleeding successfully controlled during an endoscopic or surgical procedure without the need for an additional intervention was not considered a complication. This is a surgical classification of complications based on the therapy required to treat the event and has also been used to classify endoscopic complications previously in the literature (64). This allowed comparisons to be made objectively between surgical and endoscopic treatments.

3.1.9.3 30-day readmissions

Unplanned readmissions within 30 days of the polyp procedure identified from hospital records were documented and classified as related or unrelated. Related readmissions to the polyp procedure were used to report the 30-day readmission rate.

3.1.9.4 Suspected and unsuspected malignancy

Suspected malignancies were lesions identified as such by endoscopic assessment or biopsy before or at the time of a primary procedure. Unsuspected malignancies were those only recognised on

final histological assessment of the excised specimen. If there was ambiguity, the Vienna classification was applied (84).

3.1.9.5 Residual and recurrent disease

Residual disease was that occurring at the resection site within 3 months of treatment as this is usually when first check procedures are recommended for complex polyps (25). Recurrent disease was defined as occurring after this.

3.2 Statistical methods

Quantitative data was collected throughout on pre-defined spreadsheets. Microsoft Excel Version 16.6 and SPSS version 26 (IBM, Chicago, Illinois, USA) were used for the descriptive statistics and data analysis. Median and interquartile range (IQR) were used for non-parametric data with mean and range for parametric data unless otherwise declared. Unpaired *t* and Mann-Whitney *U* tests were used to compare parametric and non-parametric data respectively. Chi squared tests were used for categorical data. Further statistical analyses were performed if required and described within the relevant chapter. Statistical analysis was performed with a *P* value of less than 0.05 being considered significant. All exclusions and missing data were declared in the results. Analysis of qualitative data is described separately in chapter 5.

Part Two: The status and impact of decision-making strategies on complex polyp outcomes

4 Review of the published literature – a systematic review and pooled analysis of the impact of decision-making strategies on complex colonic polyp outcomes

4.1 Introduction

A multi-disciplinary team decision-making process involves the application of selection criteria for discussion and subsequent management by a group of individuals with complementary expertise. The impact of such strategies on complex polyp outcomes is unclear (79), but utility has been demonstrated in other specific settings (80, 81). The result of good decision-making should involve the provision of the most appropriate management for a patient and their polyp at first attempt. The BSG guidelines recommend expert decision makers, defined selection criteria and the use of a multi-disciplinary team for complex polyp management but this is based on a very little evidence (25).

Decision-making strategies may have a more significant impact where management practices are highly variable. Given the variability of complex polyp management, the effect of group decision-making and defined selection criteria on patient outcomes merits investigation. The identification of the commonly reported clinical outcomes in the literature such as adverse events and recurrence is also of importance.

4.1.1 Aim

The primary aim of this systematic review was to assess and compare the impact of clinical decision-making strategies on the treatment outcomes of complex colonic polyps in the current literature. This review would also provide a reference point for clinical outcomes after treatment for complex polyps for subsequent aspects of the thesis.

4.2 Methods

Studies reporting complex colonic polyp treatment outcomes were systematically identified from the literature. Relevant full text articles were considered for final analysis and data extraction based on the inclusion and exclusion criteria. The study protocol was registered in the international prospective register of systematic reviews (PROSPERO) (85) and performed in line with the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines (86).

4.2.1 Literature search and search terms

A comprehensive search was performed to identify all potential articles concerning complex polyp management with the previously described definition from section 3.1.1.1 applied. Databases searched included PubMed, Web of Science, CINAHL and Scopus. Updates to identify new articles until the start of analysis in November 2020 were used. Experts in the field were approached for suggested articles to contribute to the review. Review articles and guidelines utilising systematic literature reviews were cross referenced to incorporate any missed articles of relevance to the study. No individual journals or country of publication were excluded. All articles were initially considered regardless of publication year or language.

The search terms were developed from those with expertise in complex polyps, colorectal surgery, systematic reviews and also utilised strategies from published guidelines (25). Terms included 'colonic polyps', 'complex', 'difficult', 'advanced', 'endoscopically unresectable', 'refractory', 'laterally spreading', 'large', 'polypectomy', 'endoscopic mucosal resection', 'endoscopic submucosal dissection', 'surgery', 'operate', 'laparoscopic', 'combined procedure', 'hybrid procedure' and 'laparoscopic facilitated'. Search terms were deliberately broad to capture all relevant articles considering the variability in complex polyp terminology. The full search strategy is shown in appendix 3. Articles with defined selection criteria were those using specified parameters such as size, location or morphology to justify their treatment choice. Undefined selection criteria were where treatment was chosen on the opinion of a clinician without elaboration of the factors considered.

4.2.2 Inclusion criteria

Articles reporting colonic polyp management were assessed against the complex polyp definition. Articles meeting this were then reviewed against the decision-making inclusion criteria which included the responsible clinician(s) making the decision and how the decision was reached. Finally, studies had to describe primary outcomes of adverse events, identified malignancies or surgery. Secondary outcomes including length of stay, residual or recurrent disease, functional outcomes and cost analysis were assessed if described.

4.2.3 Exclusion criteria

Studies reporting on only malignant polyps were excluded from this review as the decision-making regarding these have separate considerations. Malignancy carries the risk of nodal or metastatic disease requiring further assessment prior to management. Paediatric patients and those with polyposis syndromes or inflammatory bowel disease (IBD) were also not included. This was due to the wider implications of their underlying condition impacting decision-making for complex polyp

management. Studies reporting exclusively on rectal polyps were also excluded for several reasons. The justification for this predominantly concerned the implications of interventions involving rectal as opposed to colonic lesions that may have affected comparability of study findings within this review. There are additional treatment options for rectal lesions compared to colonic lesions including TART and TAMIS. The implications of treating rectal pathology can also be considerable. Intervention, especially surgical, can have a higher chance of immediate post operative complications and morbidity as compared to colonic lesions. Both endoscopic and surgical management can also have more significant functional implications. In addition to the higher comparable treatment risks, surgical management of rectal pathology also increases the possibility of a temporary or permanent stoma, and the quality of life implications this may have for the patient. All these factors can influence decision-making in such lesions which would not necessarily be influential in colonic lesions.

Reports on novel techniques or devices were not considered as their decision-making and patient selection may be biased by the new approach. Posters, presentations, case reports or editorials were excluded due to the unavailability of a full text article, unique nature of the article or individual opinion respectively. Narrative reviews were excluded as the articles referenced in these would have been captured by the cross referencing of systematic reviews. Despite considering all articles initially, some articles were unavailable despite all reasonable efforts to obtain them or lack of available language expertise. These articles were declared in the PRISMA flow chart.

4.2.4 Outcomes

Adverse events of CD 2 or higher were used to calculate the adverse event rate. CD 1 adverse events were not included in the final rate as they do not require any intervention that deviates from routine care. This decision was made to avoid confounding from the variability in reporting self-limiting post procedure rectal bleeds. These events were reported separately. Adverse event rate was described per number of patients included in the study.

Unsuspected malignancy rate was the primary outcome as further treatment would need to be considered and selected early cancers may be appropriately treated with endoscopy. This was described per number of lesions in the study.

Primary and secondary surgery rate was described per number of patients in the study. Indications for secondary surgery included unsuccessful or incomplete endoscopic resections, cancer suspected during polyp assessment, malignancy identified on final histology, polyp recurrence and procedure related adverse events. Residual and recurrent disease was described per number of patients followed-up in the study.

4.2.5 Article identification

Databases were searched with the previously described terms and downloaded into EndNote to identify duplicates. Abstracts were then exported to the Rayyan Systematic Review Web Application (87). Two independent, blinded researchers screened abstracts against the criteria. The researchers resolved conflicts and finalised articles for full text review. Conflicts at any stage of the review were referred to the senior supervisor for resolution. Full text articles were assessed by the same blinded reviewers and managed on separate EndNote files. Those meeting the inclusion criteria were selected for data extraction. Review articles and guidelines utilising systematic literature searches were cross referenced to identify additional studies. The abstracts identified were reviewed using the same process.

4.2.6 Data extraction and analysis

Data extraction was performed by the same two independent, blinded researchers onto separate, pre-defined spreadsheets. Variations in data extraction were resolved as previously described and finalised between the researchers and senior supervisor.

Data analysis was performed by one researcher and cross checked by a second. Articles were classified into three groups based on their decision-making strategies.

Group 1	Used defined selection criteria and multi-disciplinary decision-making
Group 2	Used defined selection criteria and individual decision-making
	Or
	Used undefined selection criteria and multi-disciplinary decision-making
Group 3	Used undefined selection criteria and individual decision-making

Given the clinical heterogeneity and small number of case series, a meta-analysis was deemed inappropriate. Statistical heterogeneity of the groups was assessed with chi-squared tests. A pooled analysis of primary outcomes was performed to allow group comparisons using chi-squared tests.

4.2.7 Assessment of study quality

The methodological quality of studies was assessed by the Specialist Unit for Review Evidence (SURE) questions to assist with the critical appraisal of case series (88). These questions are shown in appendix 4 and the assessment was performed independently by the two researchers. Conflicts were resolved as described previously. Study design and aims, setting and dates, selection criteria and enrolment, participant characteristics, outcome measures, statistical methods, participant flow,

results, conflict of interests and identified limitations were all appraised. A narrative description was performed due to the absence of evidence supporting scales in assessing study quality (89).

4.3 Results

4.3.1 Study selection

An overview of article identification is shown in the PRISMA diagram in figure 4.1. A total of 6,211 articles were screened after the removal of duplicates. Although most foreign language articles were translated, there were eleven where this was not possible and were excluded. Two articles could not be found after all reasonable attempts to locate them and were also excluded. There were 303 articles matching the complex polyp definition and describing treatment outcomes. Decision-making strategies were not described in 233 (76.9%), and there were 59 (19.5%) articles only partially describing their strategy. One article only reported mortality as its outcome and was excluded. Another article met the inclusion criteria but was published in 1977. As polyp therapy was very different at this time, a collaborative decision was made to exclude this. This left nine articles in the final analysis (53, 59, 90-96). Categorisation of excluded articles is described in appendix 5.

4.3.2 Study characteristics

A summary of characteristics of the nine included studies is shown in table 4.1. All were single centre, observational case series. Six studies were retrospective (53, 90, 92-94) and three prospective (91, 95, 96). Patient age ranged from 29 to 99 years. A total of 1,086 lesions in 1,037 patients were included and size ranged from 10mm to 160mm. Four studies described endoscopic treatments in the form of polypectomy, EMR or ESD (59, 92, 94, 95). Four studies described CELS procedures (53, 90, 93, 96) and one study both endoscopic and combined techniques (91).

There were no articles reporting outcomes for patients only treated by colonic resection for complex polyps that met the inclusion criteria. Most studies did not describe the patients in the centre that were referred straight for primary colonic resection after diagnosis of their complex polyp. Four of the included articles did report this (59, 91, 95, 97) and the numbers are shown in table 4.1. Only two of these studies included details of treatment outcomes for those having primary colonic resections (59, 91). Due to the variability in reporting between studies and the bias inclusion would introduce, a narrative description of patients referred for primary colonic resection was performed but they were excluded from the statistical analysis.

4.3.3 Decision-making strategies

A summary of the decision-making strategies used is shown in table 4.2. Group decisions (two or more clinicians) were used by three studies (90, 92, 94) with only one utilising multi-disciplinary

team decision-making (90). Six studies based management on the advice of an individual clinician. There were no articles comparing outcomes of groups using different decision-making strategies. All studies used endoscopists, therapeutic endoscopists, gastroenterologists or surgeons as their decision makers. Bulut et al also had input from radiology, histopathology and oncology as part of their team meeting (90).

None of the studies included or referenced a complex polyp definition. Six studies were categorised as having defined selection criteria (53, 90-94). Polyp factors were the commonest parameter used for decision-making. This included size (n=6), lesion location (n=6), surface changes and morphology (n=3), pre-intervention histology (n=3), evidence of malignancy (n=2), lifting sign (n=2), risk of incomplete resection (n=1) or recurrence (n=1). Two papers considered patient co-morbidities when deciding management. The remaining three studies used undefined selection criteria subject to a clinician's opinion (59, 95, 96). No study described the use of shared decision-making with the patient.

4.3.4 Primary outcomes

Table 4.3 shows a summary of the primary outcomes reported by the included studies.

4.3.4.1 Primary and secondary surgery rates

Three articles reported the number referred for primary colonic resection (59, 91, 95) (table 3.1) with a wide variation of 9.1% (95), 33.8% (59) and 57.8% (91). Two of these studies used individual decision-makers and undefined selection with secondary surgery rates of 8.2% (95) and 43.9% (59). The final study described an individual decision-maker with defined selection criteria and a secondary surgery rate of 5.3% (91). Only two included treatment outcomes for those having primary resections (59, 91). Due to this these patients were excluded, and further statistical analysis was not performed.The secondary surgery rate ranged considerably from 3.3% to 43.9%. The commonest indication for colonic resection was an unsuccessful or incomplete endoscopic resection (n=90). Other indications included cancer detected on final histology (n=20), cancer suspected at polyp assessment during procedure (n=19), recurrence (n=5) and perforation (n=3).

4.3.4.2 Adverse event rates

Adverse event rates across the studies ranged from 1.3 to 10%. The number of CD 1 events reported ranged widely from 2.6% (92) to 51.6% (59) with most being conservatively managed rectal bleeds. There was no mortality in any study. There were two CD 4 adverse events reported by a single study (53). These were an anaesthetic related anaphylaxis and pulmonary embolism (PE) in a single patient having a combined procedure.

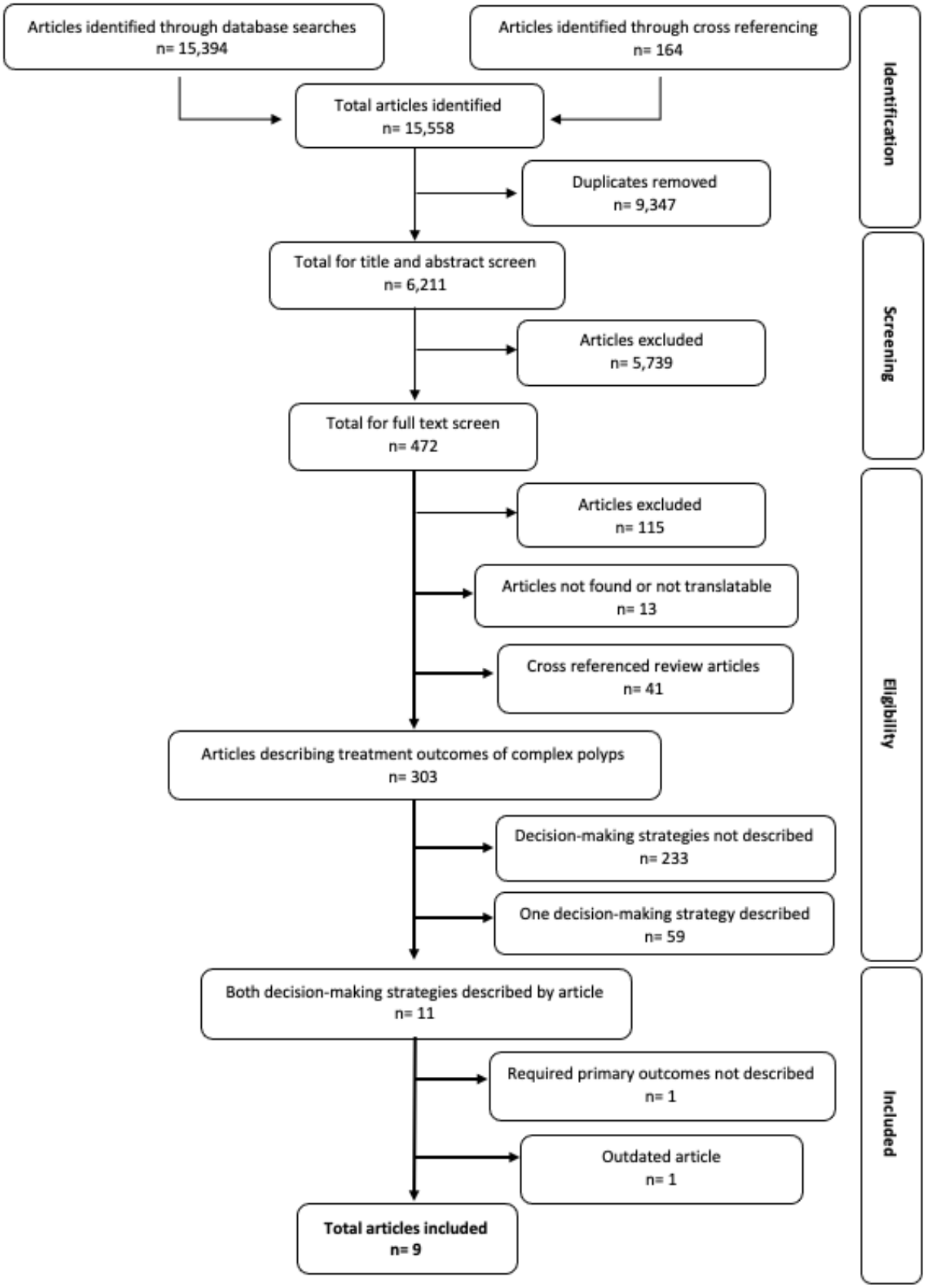


FIGURE 4.1 – PREFERRED REPORTING ITEMS FOR SYSTEMATIC REVIEWS AND META-ANALYSES (PRISMA) FLOW DIAGRAM

TABLE 4.1 – STUDY CHARACTERISTICS

Author	Title of paper	Country	Gender	Age (years)	Polyp size (mm)	Primary bowel resections	Total analysed (patients/lesions)		Treatment(s)
Bulut 2019 (90)	Combined endoscopic laparoscopic surgical treatment of advanced adenomas and early colon cancers	Denmark	Male 52% Female 48%	36 to 88 Median 71	10 to 80	Not described	25	25	CELS procedures
Emmanuel 2018 (92)	Combining eastern and western practices for safe and effective endoscopic resection of large complex colorectal lesions	UK	Male 57% Female 43%	33 to 99 Mean 71.8	20 to 160 Median 54.8	Not described	420	466	Endoscopic (EMR or ESD)
Kao 2011 (94)	Endoscopic excision of large colorectal polyps as a viable alternative to surgical resection	USA	Male 46% Female 54%	29 to 92 Mean 67	10 to 90 Median 33	Not described	104	104	Endoscopic (EMR)

Cohan 2020 (91)	Endoscopic step up: A colon-sparing alternative to colectomy to improve outcomes and reduce costs for patients with advanced neoplastic polyps	USA	Male 68% Female 32%	58 to 69 Median 65	20 to 31 Median 25	52 (57.8%)	38	38	Endoscopic (EMR or ESD) CELS procedures
Crawford 2015 (53)	Dynamic article: combined endoscopic-laparoscopic surgery for complex colonic polyps: postoperative outcomes and video demonstration of 3 key operative techniques	Canada	Male 66.7% Female 33.3%	32 to 81 Median 64	15 to 70 Median 40	Not described	30	30	CELS procedures
Goh 2013 (93)	Endo-laparoscopic removal of colonic polyps	UK	Male 60% Female 40%	61.6 to 73.5 Median 65.4	10 to 22 Median 14	Not described	30	30	CELS procedures
Longcroft-Wheaton 2013 (95)	Risk stratification system for evaluation of complex polyps can predict	UK	Male 61.6% Female 38.4%	44 to 86 Median 69	20 to 150 Mean 43	22 (9.1%)	220	220	Endoscopic (EMR)

	outcomes of endoscopic mucosal resection								
Voloyiannis 2007 (59)	Management of the difficult colon polyp referred for resection: resect or rescope?	USA	Male 56.1% Female 43.9%	Mean 65	10 to 100 Mean 32.27	80 (33.8%)	157	157	Endoscopic (polypectomy or EMR)
Wood 2011 (96)	Laparo-endoscopic resection for extensive and inaccessible colorectal polyps: a feasible and safe procedure	UK	1:2 male to female ratio	48 to 85	20 to 50	Not described	13	16	CELS procedures
						Total=	**1,037**	**1,086**	

4.3.4.3 Unsuspected malignancy rates

Unsuspected malignancies ranged from 2.4% to 15.4% across the articles. A complete overview of data is provided in appendix 6.

4.3.5 Secondary outcomes

Length of stay was reported in six studies. It was generally short with a range of averages between 0 and 2 days (53, 90-93, 96). Bulut was the only study reporting length of stay for colonic resections separately which ranged from 4 to 12 days (90).

Duration of follow-up ranged from 6 to 50 months with variability in surveillance timings and number receiving follow-up. One study did not state the duration of follow-up (96). Table 3.4 summarises residual and recurrent disease. Residual disease incidence ranged from 7.8% (92) to 20.4% (94) of the three reporting studies. Eight studies described recurrent disease ranging from 0% (93) to 34% (59). Only one paper reported on follow-up endoscopy for all study patients (93).

No study assessed functional, or patient reported outcomes. Two papers performed a cost analysis. Cohan compared costs for endoscopic step-up management against patients having planned colectomy demonstrating a cost saving for the former (91). Longcroft-Wheaton found a significant cost reduction with endoscopy compared to surgery (95).

4.3.6 Pooled analysis and comparison of decision-making groups

Studies were classified into three decision-making groups as previously described. Group 1 represented articles describing higher levels of decision-making strategies (group decisions and defined selection criteria) whereas group 3 utilised less robust decision-making strategies (undefined selection criteria and individual decision-making). Adverse event and secondary surgery rates were calculated per patient (n=1,037) and malignancy rates per lesion (n=1,086). Figures were given to one decimal place. There was no significant heterogeneity in adverse event rates (group 1 p=0.67, group 2 p=0.94, group 3 p=0.08) as calculated by chi-squared tests. The heterogeneity in unsuspected malignancies (group 1 p=0.00, group 2 p=0.98, group 3 p=0.30) and secondary surgery (group 1 p=0.00, group 2 p=0.05, group 3 p=0.00) varied within the groups.

The pooled adverse event and unsuspected malignancy rate across the three groups were similar ranging from 3.8% to 9.2% and 3.1% to 6.1% respectively (table 4.5). There were sequential decreases in secondary surgery with improving decision-making strategies. Pooled secondary surgery rate was 6.0% in those articles categorised into group 1 compared to 23.3% in group 3.

The reduction in secondary surgical intervention with improved decision-making strategies was significant (table 4.6). There was no difference in comparisons between groups regarding

TABLE 4.2 – OVERVIEW OF DECISION-MAKING STRATEGIES USED BY THE INCLUDED STUDIES

	Decision-maker			Selection criteria	
	Number	***Specialty***	***Meeting***	***Defined/undefined***	***Criteria used***
Bulut	Group	Surgeon, endoscopist, radiologist, histopathologist, oncologist	Yes	Defined	*Inclusion:* Large polyp size, difficult polyp location, non-lifting sign, co-morbidity excluding patient from standard bowel resection *Exclusion:* Not stated
Emmanuel	Group	Therapeutic endoscopists	No	Defined	*Inclusion:* Large size >20mm, difficult location, submucosal invasion on ultrasound, patient comorbidities, pit pattern assessed with narrow band imaging and chromoendoscopy *Exclusion:* Massive submucosal invasion or Kudo type Vn pit pattern
Kao	Group	Therapeutic endoscopists	No	Defined	*Inclusion:* Location, size, morphology, histology Exclusion: Difficult to visualise behind a fold or angulated flexure, deep ulceration

Cohan	Individual	Surgeon	No	Defined	*Inclusion:* Polyp size of 15 to 50mm, recurrent lesions, lesions with HGD *Exclusion:* Polyps <15mm or >50mm, rectal lesions, lesions suspicious for malignancy
Crawford	Individual	Therapeutic endoscopist	No	Defined	*Inclusion:* Large size, broad base, location, raised by submucosal saline injection, benign pre-operative histology, absence of lymphadenopathy/metastatic disease *Exclusion:* Malignant pre-operative histology, presence of lymphadenopathy/metastatic disease
Goh	Individual	Surgeon	No	Defined	*Inclusion:* Complex benign appearing polyps, could not be excised by attending colonoscopist, large size, broad base/base could not be observed, difficult location behind mucosal fold/tortuous segment, risk of thermal injury/incomplete removal/inadequate visualisation or combination of these *Exclusion:* Not stated

Longcroft-Wheaton	Individual	Endoscopist	No	Undefined	Were considered to be beyond the skills or resources of the referrer to remove
Voloyiannis	Individual	Surgeon	No	Undefined	The decision regarding repeat colonoscopy was made by the surgeon
Wood	Individual	Gastroenterologist or surgeon	No	Undefined	Considered unsuitable for conventional EMR by the referring clinician

TABLE 4.3 – PRIMARY OUTCOME RATES OF THE INCLUDED STUDIES

	Decision-making strategies	Adverse event rate	Unsuspected malignancy rate	Secondary surgery rate
Bulut	Group decision Defined selection criteria	8%	4%	16%
Emmanuel	Group decision Defined selection criteria	5.2%	2.4% *	3.3%
Kao	Group decision Defined selection criteria	3.8%	15.4% **	14.4%
Cohan	Individual decision Defined selection criteria	7.9%	2.6%	5.3%
Crawford	Individual decision Defined selection criteria	10%	3.3%	6.7%
Goh	Individual decision	10%	3.3%	30%

	Defined selection criteria			
Longcroft-Wheaton	Individual decision Undefined selection criteria	5.5%	7.7%	8.2%
Voloyiannis	Individual decision Undefined selection criteria	1.3%	3.8%	43.9%
Wood	Individual decision Undefined selection criteria	7.7%	6.3%	30.8%

***** *Unsuspected malignancy rate was not clearly described in this paper. Suspected cancers were defined as those with a type V pit pattern during endoscopic polyp assessment.*

*** *Carcinomas in situ were excluded from the malignancy rate in this paper as this is an alternative term for high grade dysplasia.*

TABLE 4.4 – FOLLOW-UP AND DETECTION OF RESIDUAL AND RECURRENT DISEASE BY THE INCLUDED STUDIES

	Patients	Length of follow-up	Follow-up at 3 months	Residual disease	Follow-up after 3 months	Recurrent disease
Bulut	25	6 months	-	-	17	11.8%
Emmanuel	420	Median 17.8 months	361	7.8%	254	10.2%
Kao	104	Median 12 months	98	20.4%	86	11.6%
Cohan	38	12 months	-	-	36	16.7%
Crawford	30	50 months	-	-	26	3.8%
Goh	30	Median 19 months	-	-	30	0%
Longcroft-Wheaton	220	Mean 3.2 years	179	15%	179	3.9%
Voloyiannis	157	9 to 16 months	-	-	44	34%
Wood	13	Not described	-	-	-	-

TABLE 4.5 – POOLED ADVERSE EVENT, UNSUSPECTED MALIGNANCIES AND SECONDARY SURGERY RATES ACROSS DECISION-MAKING GROUPS

Group	Criteria	Articles	Adverse event rate	Unsuspected malignancy rate	Secondary surgery rate
1	Defined selection criteria Group decision-making	Bulut Emmanuel Kao	5.1% (28 out of 549)	4.7% (28 out of 595)	6.0% (33 out of 549)
2	Defined selection criteria and individual decision-making Or Undefined selection criteria and group decision-making	Cohan Crawford Goh	9.2% (9 out of 98)	3.1% (3 out of 98)	13.3% (13 out of 98)
3	Undefined selection criteria Individual decision-making	Longcroft-Wheaton Voloyiannis Wood	3.8% (15 out of 390)	6.1% (24 out of 393)	23.3% (91 out of 390)

TABLE 4.6 – STATISTICAL COMPARISON BETWEEN DECISION-MAKING GROUPS.

	Adverse events		**Unsuspected malignancy**		**Secondary surgery**	
	Odds ratio	***P value***	***Odds ratio***	***P value***	***Odds ratio***	***P value***
Groups 1 vs 2	0.40 (0.17 – 0.93)	0.03	2.06 (0.61 – 7.00)	0.18	1.99 (1.06 – 3.73)	0.02
Groups 2 vs 3	1.88 (0.86 – 4.12)	0.09	0.64 (0.19 – 2.14)	0.34	2.39 (1.21 – 4.73)	0.01
Groups 1 vs 3	0.74 (0.39 – 1.41)	0.23	1.32 (0.75 – 2.30)	0.21	4.76 (3.12 – 7.26)	<0.01

Odds ratios are presented with (95% confidence intervals). Chi squared test was used to compare the proportions. Adverse event and secondary surgery rates were calculated per patient and malignancy rates per lesion. Figures are given to two decimal places.

unsuspected malignancy. Adverse events were significantly lower in group 3 as compared to group 2 but not in any other comparison in this category.

4.3.7 Assessment of study quality

The methodological quality of included studies was assessed by the SURE questions to assist with the critical appraisal of case series (88). This includes twelve questions regarding the areas outlined in the methods. The studies were classified into whether the article met the criteria, did not meet the criteria or was unclear. Most criteria were achieved by the articles and were deemed to be of reasonable to good quality by the researchers.

Criteria for the study aims and design, setting and dates, selection criteria, enrolment, participants characteristics, outcome measures and results were met by all articles. Two studies did not meet the criteria regarding participant flow due to inadequate follow-up (90, 96). The quality of statistical methods was not well described in most studies excluding Emmanuel and Kao (92, 94). This was due to either incomplete statistics or absence of discussion regarding missing data or confounding factors. Most articles identified the limitations of their research, but two studies did not (59, 96).

Only one paper declared a conflict of interest (91). The remaining articles either had no conflicts (53, 90, 92-95) or it was unclear (59, 96).

4.4 Discussion

The use of group decision-making and defined selection criteria for complex colonic polyp treatment may improve patient outcomes by avoiding the need of a secondary procedure. This is the first evidence attempting to assess the impact of such strategies. This review also demonstrates the lack of reporting of decision-making processes and variation in outcomes in the literature on complex colonic polyp management.

The outcome of good decision-making should be providing the most appropriate management for a patient and their polyp at the first attempt. This requires a thorough and accurate assessment to allow fully informed and shared decisions to be made. If this process is robust, the need for secondary procedures should be avoided and considered a reflection of good decision-making. Grouping of articles into a hierarchy of decision-making demonstrated a sequential reduction in the need of a secondary procedure with improving strategies. The arbitrary assignment of studies to decision-making groups is a surrogate for the true underlying process but was a pragmatic method of assessment.

The use of strict polyp selection criteria when identifying articles aimed to reduced variability in the study population. Differences remained in patient characteristics and selection criteria which affects generalisation and comparability of results. This may explain the wide ranges in outcomes but may also reflect significant variability in practice as reported previously (64, 98). The standardisation of articles concerning complex polyps is advocated. All studies should report the denominator stating those managed with other methods including conservative approaches or with surgery. A full description of the patient and polyp population, decision-making strategies involved and clear classifications of outcomes including surgery, complications, recurrence and adverse events should be reported with an adequate follow-up as a standardised minimum dataset (99). Qualitative assessments of decision-making in patients and clinicians regarding malignant polyps have been reported (100) and is likely these complexities also apply to benign polyps. Patient involvement in decision-making should be encouraged and reported as part of article standardisation.

4.4.1 Limitations

Decision-making strategies may have a higher impact in diseases where there is a wide variation in management (30, 64). This review aimed to identify evidence supporting these approaches in complex polyps but was challenging given the review's novel design and lack of preceding literature.

Group decisions utilising selection criteria are key features of multi-disciplinary team decision-making meetings and were therefore the chosen parameters. The description of group decision-making may have not truly reflected the team dynamics in these studies. Certain teams may have been significantly impacted by a single individual who may have influenced others with a dominant opinion. Additionally, robust team decision-making strategies are likely to be supported by high quality endoscopists which can make determining the exact influences on outcomes unclear. Qualitative or observational data collection on the dynamics of a team meeting may provide an interesting aspect to this dynamic. Understanding the psychological, communication and human factors amongst members could help facilitate improvement of team interactions and objective decision-making.

Of the many articles identified, only a small number were suitable for inclusion and only one used a multi-disciplinary team (90). They were mostly small case series with a variety of procedures described. This was recognised, but as they were all based on first line endoscopic resections and the comparator was decision-making, this was accepted. No studies compared outcomes of groups where different decision-making strategies were applied which is a significant limiting factor. The initial aim was to report primary surgery rates which is currently thought to be around 12.8% (64). Given only three studies reported it, this was not suitable for more than a descriptive assessment. Insight to surgically treated complex polyps is important as complication and mortality rates are 24% and 0.7% respectively (62) with readmission (7.8%) and stoma formation (2.2%) also a risk (63).

Guidance on performing systematic reviews of observational studies is conflicting (101) and created challenges regarding the analysis and reporting of findings. A pooled analysis to allow comparison of groups with assessment of heterogeneity was a pragmatic solution but we acknowledge the limitations of this. Given the limitations of the review and statistical heterogeneity within some groups, it is difficult to be certain whether these are true effects. It does provide the first evidence supporting decision-making in improving outcomes and identifies the need of further research to clarify.

4.5 Conclusion

Despite the limitations of this review, developing evidence in this field is required given the variability in management and increasing detection of complex polyps. Good decision-making practices may benefit patient outcomes. The evidence provided by this review suggests the use of multi-disciplinary decision-making with defined selection criteria may reduce the need for secondary surgical intervention in complex colonic polyps. Further evidence is required to draw definite

conclusions. Assessments of centres using a team approach and understanding the factors influencing decision-making on an individual clinician level is also important. The understanding of the parameters used by the articles in this review will help guide discussions during the qualitative and quantitative research in subsequent parts of the thesis.

5 Planning management for complex colorectal polyps – a qualitative assessment of factors influencing decision-making amongst colonoscopists

5.1 Introduction

The variability in complex polyp management remains unexplained with limited insight into the rationale behind a clinician's choice of management (66, 67). Decision-making can be complex and needs to balance the non-patient factors such as procedure risks, possibility of undiagnosed cancers and the chance of recurrence with patient specific factors such as functional capacity, comorbidities and lifestyle to avoid the risk of under or over treatment. Shared decision-making with individuals should enable patient insight into the details of treatment with the impact of follow up and surveillance tailored to their personal circumstances. Although not a direct focus of this research, it is still acknowledged as a crucial component of the decision-making process for managing complex polyps, especially given the range of potential treatment approaches.

Insight into the rationale behind a clinician's choice of management is limited and a significant variability in polyps larger than 20mm referred for surgery exists (0 to 46.6%) (66, 67). Advanced pre-malignant histology (e.g. high grade dysplasia on biopsy) or location can lead to a recommendation of primary colonic resection (70). Evidence is conflicting regarding whether surgeons (68, 69) or gastroenterologists (102) are more likely to recommend surgery. Surgeons may still recommend resection despite correctly identifying a polyp as benign (68), suggesting service related factors and availability of operator expertise may also be influential.

Understanding the influences on a clinician's decision-making when faced with a complex polyp are likely to be multi-factorial. As identified in the preceding systematic review, polyp factors such as size, location, surface changes and morphology are commonly considered. The subtleties and details of how decisions are made in everyday clinical practice will not be identified through such research. They may not only be clinical but could also have non-clinical, educational and service-related elements. A qualitative approach gives a unique and detailed insight into a clinician's choice of management and an opportunity to explore a range of factors that may have not been considered. Identifying barriers to clinicians for providing endoscopic treatment may improve patient care, service provision and reduce unnecessary surgical intervention.

5.1.1 Aim

The aim of this qualitative study was to explore the clinical and non-clinical factors influencing decision-making regarding management options amongst clinicians for complex colorectal polyp. Factors identified in the previous review were used to identify topics for discussion and experiences of decision-making strategies such as multi-disciplinary teams were explored. Comparisons were made in the factors favouring surgical intervention and attitudes towards team decision-making strategies between specialities.

5.2 Methods

This was a qualitative study utilising a thematic analysis to capture influences on decision-making by clinicians involved in the management of complex colonic polyps (103). It was undertaken in line with the Consolidated Criteria for Reporting Qualitative Research (COREQ) as shown in appendix 7.

5.2.1 Recruitment

Advertisement and dissemination were by email through professional associations and research collaborations of the study team to identify participants. Participants were recruited from National Health Service (NHS) trusts in England and Health Boards in Wales and interviews took place from May 2021 to September 2021. A provisional recruitment target of 15 to 20 participants was based on qualitative study sample sizes and information power (104) to achieve the study aims. This pragmatic target also allowed involvement of a variety of specialities and employment locations whilst also enabling an in-depth analysis of the interviews. Plans were made to extend recruitment in case the research team felt that data saturation had not been reached by this number.

5.2.2 Inclusion and exclusion criteria

Practicing colonoscopists with responsibility for decision-making in the management of complex colorectal polyps were eligible to participate. This included consultant colorectal surgeons, gastroenterologists and clinical endoscopists (nurses and other non-medical registered practitioners). Exclusion criteria included clinicians not meeting the eligibility criteria, incomplete interviews or withdrawal of consent at any time. Consent to participate in the study and have the transcript recorded were confirmed at the start of the interview.

5.2.3 Data collection

Participant characteristics including the individual's specialty, centre of employment and access to a complex polyp multi-disciplinary team was collected. The face to face, semi-structured interviews were conducted and recorded via Zoom (Zoom Version 5.7.6) at a location convenient to the

participant. Only the interviewer and participant were present, and field notes were not required. The interview focused on decision-making for complex colorectal polyps. These were defined for the participants as lesions requiring further management planning rather that those treatable at the time of endoscopy due to size, difficult access or other concerns regarding morphology or appearance. The discussion was guided by the interviewer with an interview guidance proforma as shown in appendix 8, to ensure three key topics were covered based on parameters identified through the preceding systematic review. This included clinical factors, non-clinical factors and any other influences. The interview structure was flexible and allowed for free discussion to develop points of interest. A pilot interview was performed to assess structure and acceptability of the interview. As this was successful, it was included in the final analysis. All interviews were performed by the lead author

after completion of training in qualitative interviewing and analysis. Audio recordings of the interviews were securely stored and transcribed verbatim by a transcription company into text for analysis. The transcripts were not returned to the participants for corrections as feedback would have been difficult due to time restrictions of the participating individuals.

5.2.4 Data analysis

NVivo qualitative data analysis software version 12 was used for storing and coding of transcripts to aid organisation of the qualitative data. Analysis was performed based on literature regarding thematic analysis (103, 105). Coding was completed by the lead author. Familiarisation with the information was performed by reading the transcripts several times to generate initial codes of the explored topics to describe the data. The codes were developed and refined during analysis and classified into major themes and sub themes regarding the influences on decision-making reported by participants. The themes were defined, named and a narrative description of responses within the themes was performed with quotations used where appropriate. Observation of the differences in the factors favouring surgical intervention between speciality and attitudes towards team decision-making strategies were performed.

5.2.5 Ethics and peer review

A favourable ethical opinion for this study was given by Cardiff University School of Medicine Research Ethics Committee prior to commencement of the study and is shown in appendix 9.

5.3 Results

A total of 20 participants were recruited from 14 different trusts across England and Wales. Invitations were sent via email to 49 individuals. There were no responses from 16 by the end of the

recruitment period. Reasons for those responding but not participating included having insufficient time (n=10) or not meeting the eligibility criteria (n=3). Final participants included gastroenterologists (n=10), colorectal surgeons (n=8) and clinical endoscopists (n=2). All participants were accredited colonoscopists performing independent procedures. Six of the twenty participants were also bowel screening colonoscopists. No repeated interviews were required, and their length ranged in duration from 12 to 29 minutes. Most participants worked in district general hospitals (n=13) with the remainder (n=7) being employed by larger teaching hospitals or tertiary centres. An overview of participant characteristics is shown in table 5.1. Four major themes were identified including gathering information regarding the patient and their polyp, aids to decision-making processes, barriers in achieving optimal management and improving services. Subthemes were identified within these and are outlined in table 5.2.

5.3.1 Thematic analysis of interviews

5.3.2 Gathering information regarding the patient and their polyp

The first major theme identified amongst clinicians was the need to assess the individual patient and their polyp. Size, morphology, surface appearance and pit pattern were frequently discussed parameters used to characterise complex polyps. All clinicians discussed that decisions made should consider the individual circumstances of the patient. Age, fitness, frailty, comorbidities, medication and performance status were all considered factors. Endoscopic treatment was widely considered to be the first line management approach where possible.

'I will do everything possible to resect endoscopically because endoscopy treatment is vastly superior in every way to surgery in most cases because surgery is bad. Surgery affects your quality of life and surgery is just miserable. If you can just remove a polyp endoscopically and do that safely then that patient's quality of life is not affected.'

Participant 11 – Surgeon

'I actually refer hardly anything which isn't malignant looking through for surgery.'

Participant 3 – Gastroenterologist

5.3.2.1 Risk of polyp malignancy

Reported lesion features considered likely to indicate malignancy were depression, tethering, ulceration, suspicious pit pattern or high-grade dysplasia. Several observed that biopsy results could potentially be misleading, and visual assessment based on international classifications should predominately guide management. Most would only biopsy a specific area of concern observing that the possibility of fibrosis could make future endoscopic management more challenging.

Identification of these features and high suspicion of cancer would lead the majority to recommend surgical resection.

'Anything which looks tethered, has a deep crater, is high grade or looks malignant - that would be my straight criteria for considering surgery.'

Participant 1 – Surgeon

For some, a lesion with a suspected focus of cancer was not necessarily a barrier to endoscopic management depending on the individual patient and chance of removing it completely. Use of techniques such as ESD was discussed in these circumstances. Some clinicians were more likely to consider the endoscopic resection of suspected cancers in polypoidal as opposed to flat lesions.

'I do remove polyps that I think have got cancer, but I always tattoo them. If I think I can get a clear margin of resection or resect through a normal stalk, I do remove them endoscopically. But if I tattoo them, they will have a staging CT (computerised tomography) *and they will always have MDT* (multi-disciplinary team) *discussion and a chat with a surgeon.'*

Participant 14 – Gastroenterologist

The approach towards polyps found to contain cancer after treatment was similar amongst participants. The automatic need for a completion colonic resection was not deemed necessary with participants stating this decision would be made on an individual basis. Factors such as staging investigations, histological findings, genetics and comorbidities would be considered. There seemed to be a general shift towards acceptance of surveillance in low-risk lesions.

'I remember patients who'd have a tiny little polyp cancer incidentally found, and they would automatically have a bowel resection. Whereas now I think as we are moving along. There are more studies looking at patients and tracking their pathway that have been through conservative management. Even in those that are high risk polyp cancers, there is still a relatively low risk of the cancer coming back.'

Participant 17 – Nurse endoscopist

5.3.2.2 Chance of achieving complete and safe endoscopic resection

Endoscopic treatment was widely considered to be the first line management approach where possible and the likelihood of complete and safe endoscopic removal was key to decision-making. Good access with a stable scope position were frequently mentioned requirements for endoscopic management. Polyps located over folds or within pathology such as diverticular disease swayed management decisions towards surgery. Right sided polyps were often discussed as a reason to

favour colonic resection. Justification for this included the thin colonic wall increasing the risk of perforation from the procedure and challenging access in lesions close to the appendix orifice or ileocaecal valve.

'Particularly if it's a proximal right-sided lesion where the bowel wall is a bit thinner, or it's close to the appendix or a difficult location. I think that in those cases if the patient is fit and well probably the risks of undergoing a lap right hemi aren't significantly greater than the risk of having a difficult polypectomy in a thin bit of bowel.'

Participant 6 – Surgeon

Increasing lesion size was acknowledged by most as a reason to consider surgical rather than endoscopic management. Very large laterally spreading or circumferential lesions were key features causing surgical management to be favoured in some. An exact measurement of size was infrequently quoted with clinicians observing that it was dependent on a combination of other patient and polyp factors.

'Size matters but perhaps not as much as some other characteristics of the polyp, because we do resect quite large lesions by piecemeal EMR.'

Participant 14 – Gastroenterologist

5.3.2.3 Influence of age and comorbidities

All clinicians discussed the importance of patient assessment when deciding on treatment. There was awareness amongst all that intervention for the polyp may be inappropriate in some. Poor quality of life, a limited functional capacity and short life expectancy were reasons to direct towards conservative management.

'Particularly in more elderly patients we look at the long-term benefits versus the immediate risks. We often then have to have discussions with other services like cardiology or elderly care because we want to know what the patient's prognosis is from their other comorbidities rather than jump in with two feet to take off this 2cm polyp that may never cause them any harm.'

Participant 16 – Nurse endoscopist

Younger patients with few comorbidities were more likely to be offered colonic resection, especially for challenging right sided lesions. The rationale was that this would reduce surveillance requirements and avoid uncertainty if a focus of cancer was identified.

'A right sided polyp which could potentially be taken on but has a very difficult colon and patient is fit, I may actually consider talking them into operation rather than having a repeated surveillance and a difficult experience.'

Participant 1 – Surgeon

The identification of multiple coexisting polyps, other symptomatic bowel pathology and genetic influences led some clinicians to consider colonic resection over endoscopic management. Medications including steroids and anticoagulants created concerns for some about endoscopic management.

'If they are otherwise fit then obviously you look at other factors. Have they got an underlying bowel disorder or inflammatory bowel disease? Are they on steroids? Things that I'd be concerned about managing it endoscopically.'

Participant 9 – Surgeon

5.3.2.4 Burden of treatment on the patient

Immediate and long-term burdens of endoscopic management on patients were frequently discussed. Difficult or poorly tolerated endoscopic examinations including the bowel preparation, would lead clinicians to consider other management strategies including surgical options or surveillance if the patient was unfit for operative intervention.

'It varies. I think that depends on patient's experience of endoscopy. You will get some patients who have had a bad experience and they do not want another endoscopy.'

Participant 9 – Surgeon

The impact of long-term consequences of endoscopic treatment were also considered important in the decision-making process. The risk of stenosis and recurrence in extremely large or circumferential lesions was discussed by some clinicians as a reason to advocate surgery in those fit enough.

'If it is a youngish patient with a carpet-like lesion, and the endoscopy is for eight hours and then bringing him back and forth with it turning into stenosis, it's no good.'

Participant 4 – Surgeon

The attitudes towards the management of recurrent lesions were variable. Some felt that a further endoscopic procedure to clear residual or recurrent disease was acceptable to patients. Others were more likely to seek definitive treatment with surgical resection, especially in those with several

TABLE 5.1 – SUMMARY OF PARTICIPANT CHARACTERISTICS

	Speciality	Hospital	Complex polyp meeting availability
Participant 1	Surgery	Tertiary/teaching	On site
Participant 2	Gastroenterology	Tertiary/teaching	On site
Participant 3	Gastroenterology	Tertiary/teaching	On site
Participant 4	Surgery	District general	On site
Participant 5	Gastroenterology	District general	No access
Participant 6	Surgery	District general	No access
Participant 7	Gastroenterology	District general	No access
Participant 8	Surgery	District general	No access
Participant 9	Surgery	District general	Separate site
Participant 10	Surgery	District general	No access
Participant 11	Surgery	District general	No access
Participant 12	Gastroenterology	District general	On site
Participant 13	Gastroenterology	Tertiary/teaching	On site
Participant 14	Gastroenterology	District general	No access
Participant 15	Surgery	District general	On site
Participant 16	Nurse endoscopist	District general	Separate site
Participant 17	Nurse endoscopist	District general	On site

Participant 18	Gastroenterology	Tertiary/teaching	On site
Participant 19	Gastroenterology	Tertiary/teaching	On site
Participant 20	Gastroenterology	Tertiary/teaching	On site

recurrences.

*'In those [*recurrence*] cases I often quite strongly counsel towards surgery, despite everything I've just been telling you. Multiple hospital visits and multiple polypectomies are high risk with anxiety that's actually killing the patient's quality of life.'*

Participant 11 – Surgeon

In the experience of most, they felt it was acceptable to the patient to undergo surveillance to avoid surgery, but this needed to be based on appropriate discussion with the patient.

'If there's the option of managing endoscopically and avoiding an operation, in my experience most of them are accepting of further surveillance colonoscopies.'

Participant 9 – Surgeon

Individual challenges posed by rectal lesions were recognised. The importance of other techniques such as trans-anal and ESD procedures were highlighted to preserve the rectum and avoid a potential stoma.

'I think I'd obviously be more inclined to try to tackle polyps in the rectum or give them to a colleague who does TAMIS for example, even if they look like they might be malignant.'

Participant 8 – Surgeon

5.3.3 Aids to decision-making

Participants described the involvement of patients and other clinicians through formal or informal pathways as important influencers on their final management strategy.

5.3.3.1 Opinions of colleagues and complex polyp team decision-making strategies

Most participants had access to complex polyp multi-disciplinary team decision-making meetings also known as multi-disciplinary teams (MDTs), but this varied between local or regional sites. Their

TABLE 5.2 – SUMMARY OF MAJOR AND MINOR THEMES FOR COMPLEX POLYP DECISION-MAKING IDENTIFIED FROM PARTICIPANT INTERVIEWS

1. Gathering information regarding the patient and their polyp
1.1. Risk of polyp malignancy
1.2 Chance of achieving complete and safe endoscopic resection
1.3 Influence of age and comorbidities
1.4 Burden of treatment on the patient
2. Aids to decision-making processes
2.1 Opinions of colleagues and complex polyp team decision-making strategies
2.2 Shared decision-making with patient
3. Barriers in achieving optimal management
3.1 Challenges of complex polyp team decision-making strategies
3.2 Endoscopy service provision
3.3 Referral to other sites for expertise
4. Improving services
4.1 Improving decision-making pathways
4.2 Education and training

effectiveness was generally seen as positive with benefits in the range of management options and avoidance of surgery.

'I think nowadays because we've got local expertise, talent, and an MDT, we're doing a lot more stuff endoscopically than we would have done some years ago. And I suspect that's not the same everywhere.'

Participant 3 – Gastroenterologist

In addition to patient outcomes, clinicians felt that multi-disciplinary team decision-making meetings were educational tools in developing confidence and understanding of complex polyp management. Surgeons involved in team meetings were observed by others to be more likely to recommend endoscopy. Multi-disciplinary team decision-making meetings provided opportunities for direct communication between clinicians, planning management and tracking of cases.

*And it'll be different than you'll get from people elsewhere who don't have established networks and local expertise. I feel almost very comfortable I've got that [*MDT*] around me. It's quite secure and I think I'd find life a little bit more vulnerable and scarier if I had to make decisions myself.'*

Participant 3 – Gastroenterologist

5.3.3.2 Shared decision-making with patient

All participants acknowledged the need for patient involvement and shared decision-making for managing complex polyps. References were made to informed consent, written information regarding choice of procedures and specific counselling clinics. The challenges of explaining the. complexities to the patient of the risks and benefits of different strategies were stated by several participants. One participant described the use of joint patient clinics involving surgeons and gastroenterologist after a multi-disciplinary team discussion. Another felt it was good practice to represent patient's wishes as part of this process.

'And clearly good clinical management is always to discuss with the patient before you discuss with an MDT. I think that's a really important part.'

Participant 3 – Gastroenterologist

Even though most advocated shared decision-making, many clinicians observed that patients were largely guided by their advice.

'I have to say the majority of patients will listen to what we say and say I'll be advised by whatever you think is best. Very occasionally you get a patient who doesn't want to have a further colonoscopy or doesn't want to have a bowel resection, but I would say that is not common.'

Participant 15 – Surgeon

It was observed that the speciality of the involved clinician could impact this.

'I've seen patients being very much swayed by who the initial consultant is. Let's say if they go to see a surgical consultant you can easily convince them to do laparoscopic intervention whereas if they come to see me, they can get swayed.'

Participant 12 – Gastroenterologist

Although generally patients seemed to be accepting of endoscopic intervention if it was recommended, there were a few scenarios where this may not be the case. Poor experience of endoscopic procedures and need to travel elsewhere for intervention were factors thought to deter patients from recommended endoscopic treatment.

'Occasionally patients will say I don't want to travel and in which case they're offered surgery as an alternative.'

Participant 20 – Gastroenterologist

Other participants did not perceive this be an issue in decision-making.

'Commuting for these distances is not a big issue for them. I've never come across to a patient who says that he can't go for polypectomy.'

Participant 4 – Surgeon

Patient awareness regarding the need for polyp surveillance and the risk of recurrent disease was considered important. Opinions from clinicians differed as whether definitive treatment in the form of bowel resection would be more acceptable as an alternative to endoscopic treatment.

'I've never spoken to anybody who wouldn't go through with the polypectomy because of the onward surveillance because I think if they've driven to have the polypectomy, then they're driven to have the surveillance.'

Participant 17 – Nurse endoscopist

'There's that bit of commitment from the patient, and I think there are definitely instances where on balance some patients would prefer to undergo a resection.'

Participant 6 – Surgeon

5.3.4 Barriers in achieving optimal management

Participants frequently commented on the challenges they faced in ensuring patients were managed optimally during their complex polyp treatment. Access to timely endoscopy, issues with technology and challenges in referring to other services were common themes.

5.3.4.1 Challenges of complex polyp team decision-making strategies

Several participants discussed challenges to their team decision-making service. Increasing referrals, frequency of meetings and the unavailability of participants due to other commitments were explanations. This was thought to result in inadequate time to discuss patients and delays in decision-making especially if meetings were not weekly. Some participants felt their meeting would benefit from additional expertise such as pathology or funding for administrational support.

'The complex rectal lesion MDT is probably the most challenged pathway in the trust because we have quite long waits. We only do the meeting once a fortnight and it does mean that it's logistically quite difficult.'

Participant 15 – Surgeon

Several observed that good decision-making by meetings was dependent on the quality of referral information including patient assessment, polyp description, photo or video documentation. The availability of expertise at the meeting could also affect the outcome.

'Often you get a letter and there's not even a size mentioned. The admin team then end up chasing the consultant. You don't want some communication going amiss and then a patient suffering. I try to encourage my own admin staff to try and chase things up rather than sending letters back and forth just creating delays.'

Participant 12 – Gastroenterologist

Those with no availability of team decision-making strategies felt patients would benefit by the availability of this service. Difficulties were reported when referring to a complex polyp multi-disciplinary team at another site. Limiting the selection of case referrals or attempting treatment at the local site in order to avoid overburdening the system was described.

'And then we will say let's refer to the complex polyp team which they can, but it overloads that service. So logistically we are going to pick three or four people to concentrate on. They are very good and they are quite quick, but we are very conscious they have a lot.'

Participant 9 – Surgeon

5.3.4.2 Endoscopy service provision

The Covid pandemic was observed to have created delays in diagnostics, therapeutics and surveillance for those with complex polyps. Although there were challenges to endoscopy services before, redeployment, cancellations and employee absences created service pressures. Shortage of available lists, endoscopy capacity and the lack of endoscopists performing complex polypectomy was frequently discussed by the participants.

*'Our trust is particularly bad at investing in estate and services. We were supposed to be having a new JAG (*Joint Advisory Group on Gastrointestinal Endoscopy*) accredited endoscopy unit built. We should have completed early this year, but it's now been put back to October next year. There's a lot of reasons. Some of it is staffing, some of it is estate.'*

Participant 15 – Surgeon

Some participants observed unacceptably long waits resulting in progression of polyps to endoscopically unresectable or even malignant lesions. This was mostly attributed to lack of available advanced endoscopy expertise or insufficient time on lists. Treatment of complex polyps were difficult to prioritise from an administration aspect as unlike suspected cancer criteria, there may be no waiting time targets.

'He's an asset to the service and that is a brilliant thing to have. The problem is he is one individual and there have been a few occasions where treatment has been delayed and by the time he has seen those patients he had said, sorry it's not suitable for EMR this is cancer.'

Participant 10 – Surgeon

Optical assessment of complex polyps was seen as crucial to informed decision-making. Individuals described technological problems in recording or storing photos and videos for the purpose of later discussion. This could result in the need for repeated procedures to assess the polyp prior to intervention creating a further burden on both the patient and the service.

'We've got a lot of endoscopists who work here, but we've also got a lot of people coming to do weekend-type lists. They are usually pretty good, but not always wonderful at taking video clips and assessments. So, then we have patients who need to have a second procedure.'

Participant 3 – Gastroenterologist

5.3.4.3 Referral to other sites for expertise

Individuals at sites without expertise such as advanced endoscopy, trans-anal surgery or endoanal ultrasound would have to refer elsewhere or manage the polyp with other techniques. Experiences in providing care across two sites were often challenged with delays in patient assessment and feedback to the referring centre. Logistics, communication and tracking issues were provided as an explanation for delays and could create concerns regarding responsibility and continuity of care.

'We don't have a complex polyp MDT. We do refer on occasionally and then they'll get heard about 15 months later which isn't very good.'

Participant 11 – Surgeon

Some would rely on informal discussion with colleagues and goodwill to avoid the lack of an established pathway.

'It is not very good and the system is still individually done. I think ideally what you want for these kinds of really complex, benign polyps is a much better set up where we can easily refer them on and get that advice.'

Participant 5 – Gastroenterologist

Lack of awareness of available services was also reported.

'We only in the last year became aware that we had a formal contractual arrangement in place. We had occasionally sent the odd case over, but there had always been a bit of uncertainty in the department about where we should be sending these. It wasn't until I did a little bit of digging around that we are actually paying for this, and we could use this service more than we had done.'

Participant 6 – Surgeon

At other sites, the experience of referrals to other centres were more positive with good communication and timely treatment, especially in those with pre-existing relationships or contractual agreements at other sites.

*'He offers a really good [*trans-anal endoscopic microsurgery - TEMS*] service actually, and I don't recall patients waiting a long time. He seems to offer a really good service with follow-up as well, clear advice and good communication.'*

Participant 11 – Surgeon

5.3.5 Improving services

Participants frequently commented on strategies that had been employed to improve their decision-making and management of patients with complex polyps.

5.3.5.1 Improving decision-making pathways

With increasing referrals, more frequent polyp multi-disciplinary team decision-making meetings had been introduced by some sites.

'What we've done is increase the number of complex polyp MDTs that we have in a month. We used to have two a month and now that's gone up to three so we're able to offer opinions a lot quicker than we were before.'

Participant 17 – Nurse endoscopist

Several sites thought that improvements in their referral pathways for multi-disciplinary team meetings had enhanced patient care. The availability of good clinical information, patient assessment and images on the referrals was felt to be crucial in efficient decision-making, list planning and avoidance of further assessment endoscopies. Structuring procedure information through designated proformas or referral criteria were methods that were improving this.

'There is now a really good process that the screening nurse fills in the referral and we get written feedback from the MDT. It's not just education about what the patient's management would be, but also education about what I've done and whether I've done the right things or not.'

Participant 3 – Gastroenterologist

One participant had started vetting high risk polyps as suspected cancer to ensure they were done in a timely fashion. Another described taking personal responsibility of a complex polyp database to track and ensure treatment and surveillance are performed.

'I've got complete oversight of when all these patients are booked. We cross-reference every patient that's discussed in a complex polyp meeting with my database waiting list. I can see at any one time how many patients are waiting to be dated and when their scope is going to be. I think we've got a fairly robust system and we've definitely got more capacity now than we did have. It's extra administration work but as the clinical service lead it doesn't really bother me too much that I've taken that on because it's quite good to have an overview.'

Participant 2 – Gastroenterologist

Increased endoscopy list capacity has been used to improve services at some sites.

'Pre-covid we had an alternate complex polyp list say every other week, and then we could see that actually the demand is going up. So, we have remodelled some of our services and now turned them into a weekly complex polyp list.'

Participant 2 – Gastroenterologist

Given the complexities of decision-making for complex polyp management, some participants had introduced the use of supplementary information to aid patient understanding. The use of information leaflets, letters or formal consent clinics were all described.

'What we've started to do when we find a big polyp is to give them all of the information on the day so that they know what the options are. They can pre-read it so whenever I ring them after their MDT, they have some idea of the options that are available to them and already have a kind of opinion in their head about what they would like to do and I think that's been really, really helpful.'

Participant 16 – Nurse endoscopist

5.3.5.2 Education and training

There was recognition of the importance of developing advanced polypectomy skills. The use of mentored practical sessions either in person or remotely was being used by some participants.

'One of the things that we don't do very well is continue training people in endoscopy, so you get signed off and that's it and unless you seek education or improvement yourself it doesn't come to you. We've got a development programme starting in December where we will actually attend the therapeutic list so we get that exposure and experience.'

Participant 16 – Nurse endoscopist

'Virtual mentoring will be good and I'm aware that our centre is starting to do that.'

Participant 13 – Gastroenterologist

Education regarding polyp assessment to improve the referral and decision-making process was also being performed.

'We have the journal club and try and do some education across the board. We do a lot of education about what pictures to take and what information we need.'

Participant 17 – Nurse endoscopist

Personal responsibility for education and improvement was taken by many. Attendance at endoscopy courses, training such as the SPECC development programme (106) and feedback from a

multi-disciplinary team decision-making meeting were all methods used to reinforce good decision-making.

'I voluntarily go to the MDT but it's not part of my job plan. I've been going to it because I think it's good to see cases and to see also the outcome of the cases I have done.'

Participant 15 – Surgeon

5.3.6 Comparisons between clinical specialities

Comparisons between surgical and medical clinicians for factors leading towards recommending surgical intervention are show in table 5.3. Similarities are seen with factors such as right sided lesions, difficult location, incidental cancers and young or fit patients leaning decision-making towards surgery. Other issues common between the groups that prevent endoscopic resection included patient preferences regarding management and disease progression as a result of treatment delays. Similarities are also seen in attitudes towards team decision-making strategies (table 5.4). Attitudes towards team decision-making were positive in nature with all negative observations being related to capacity, information and clinician availability.

5.4 Discussion

This is the first study assessing the influences on decision-making and barriers to ideal management for complex colorectal polyps. An explanation for the high utilisation of surgery for colonic polyps is needed (107), and this qualitative research gives a unique insight into clinical practice. As suspected, variability in current management may not solely be a result of knowledge. Clinicians advocated endoscopic management wherever possible in line with international recommendations (25, 40) but availability of expertise, timely endoscopy and challenges in referrals were all reported barriers in achieving optimal management.

Unlike the findings reported by Moon and colleagues (102), surgeons and gastroenterologists seemed equally engaged with endoscopic therapy. Polyp and patient features leading to a recommendation of surgery were consistent and based on the likelihood of malignancy, fitness and expectations of the patient. Lesions in the right colon were more likely to be offered surgery by some to avoid the risk of endoscopic perforation due to the thinner bowel wall. Such concerns need to be supported by evidence as the risk may not higher than those of colonic resection. There should be knowledge of and equity of access to alternatives such as combined procedures which can help avoid colonic resection (108). Lesions assessed as having HGD either endoscopically or histologically were a cause of concern for many participants. Although higher risk of, this finding is not synonymous with

TABLE 5.3 – COMPARISON IN FACTORS LEADING TOWARDS SURGICAL INTERVENTION BETWEEN MEDICAL AND SURGICAL CLINICIANS

Surgical clinicians	Medical clinicians (gastroenterology and nurse endoscopists)
Gathering Information regarding the patient and their polyp	
'When you have complex polyps in the right colon, there's always a debate. Is a right colectomy laparoscopically better than a complex polypectomy but then causing perforation and complications?' **Participant 10** 'Particularly if it's a proximal right-sided lesion where the bowel wall is a bit thinner, or it's close to the appendix or a difficult location. I think that in those cases if the patient is fit and well probably the risks of undergoing a lap right hemi aren't significantly greater than the risk of having a difficult polypectomy in a thin bit of bowel.' **Participant 6** 'Patients [*with incidental cancers*] who are higher risk, they go for surgery.' **Participant 4**	'If you're in your 40s with a [*incidental*] polyp cancer you'll either have very intense surveillance plus or minus genetics. Or you probably would push them potentially more to have a resection, to make sure that that segment of bowel has gone.' **Participant 7** 'We've had lesions where they're big things in the caecal pole, wrapping around the appendiceal orifice. That's not really going to be something for endoscopy, it's probably creeping down into the appendix. So that's the sort of thing that would go through that MDT and then on to surgery afterwards.' **Participant 3** 'I think caecal ones are almost as bad as the rectal ones. We seem to worry about them a lot more because of the increased risk of perforation. If they're in the caecal pole I always start to think up front with the patient that actually surgery might be the best option, rather than wasting three,

‘If you've got a young fit patient with an incidental cancer, we would tend to argue in the MDT that even if it's relatively low risk, they're probably better served by an offer of a resection.’

Participant 6

‘If they are otherwise fit then obviously you look at other factors. Have they got an underlying bowel disorder or inflammatory bowel disease? Are they on steroids? Things that I’d be concerned about managing it endoscopically.’

Participant 9

‘A right sided polyp which could potentially be taken on but has a very difficult colon and patient is fit, I may actually consider talking them into operation rather than having a repeated surveillance and a difficult experience.’

Participant 1

‘If it is a complete circumferential polyp, it can be done but we discuss this in MDT. If we do EMRs in different sittings, it can turn into fibrosis and lead to stenosis. In that case, we consider surgery as well.’

Participant 4

six, twelve months of repeated endoscopy, repeated surveillance and you end up with an operation anyway.’

Participant 7

‘A lesion in the right colon and in a young fit patient. I think they’re probably better served [by surgery].’

Participant 12

‘Especially with younger patients who may need to come back again and again, and we’re not going to clear that polyp. We have had cases where they’ve decided to go straightaway for surgery, because that’s a more permanent solution for them.’

Participant 17

‘If the patient is young with a suspected cancer and if perforated it will be T4, which is not a service to the patient. And his life will be shortened, just for the sake of argument that we can do this polyp with EMR.’

Participant 4

‘There are genetic factors as well. If they've got a background of multiple polyps, Lynch syndrome or something like that then you'd have a lower threshold for offering them a resection.’

Participant 6

‘We've certainly had some patients with caecal polyps that have been difficult to remove. They're still coming back several years down the line to have bits of polyp nibbled away, and you can't help think they would have been better just having an ileocecal resection and be done with it at that original time.’

Participant 6

‘Anything which looks tethered, has a deep crater, is high grade or looks malignant - that would be my straight criteria for considering surgery.’

Participant 1

‘In those [recurrence] cases I often quite strongly counsel towards surgery, despite everything I've just been telling you. Multiple hospital visits and

multiple polypectomies are high risk with anxiety that's actually killing the patient's quality of life.' **Participant 11**	
Aids to decision-making processes	
'There's that bit of commitment from the patient, and I think there are definitely instances where on balance some patients would prefer to undergo a resection.' **Participant 6** 'It varies. I think that depends on patient's experience of endoscopy. You will get some patients who have had a bad experience and they do not want another endoscopy.' **Participant 9**	'I've seen patients being very much swayed by who the initial consultant is. Let's say if they go to see a surgical consultant you can easily convince them to do laparoscopic intervention whereas if they come to see me, they can get swayed.' **Participant 12** 'So anecdotally I have heard that people have surgery as they haven't wanted to travel [for advanced endoscopic treatment].' **Participant 18** 'Occasionally patients will say I don't want to travel and in which case they're offered surgery as an alternative.' **Participant 20**
Barriers in achieving optimal management	

‘I think even when it is endoscopic resectable by a fairly straightforward EMR, because people don’t have the volume they won’t take them on.’

Participant 9

‘He’s an asset to the service and that is a brilliant thing to have. The problem is he is one individual and there have been a few occasions where treatment has been delayed and by the time he has seen those patients he had said, sorry it’s not suitable for EMR this is cancer.’

Participant 10

‘With Covid we've got all these delays and it makes me increasingly nervous. We had a guy who had a polyp diagnosed over a year ago and the endoscopist wasn't confident to take it out. We tried to get the patient back but Covid hit and patient didn't want to come back. He came for a colonoscopy last week, and you can see that the polyp is a cancer. But there's no doubt that patients' polyps have progressed.’

Participant 2

‘We had a guy who had a polyp diagnosed over a year ago. The endoscopist wasn't confident to take it out and left it. We tried to get the patient back, Covid hit and the patient didn't want to come back. He came for a colonoscopy last week, and you can see that is clearly a cancer.’

Participant 2

TABLE 5.4 – OVERVIEW OF ATTITUDES TO TEAM DECISION-MAKING STRATEGIES

Surgical clinicians	Other clinicians (gastroenterology and nurse endoscopists)
Positive attitudes	
'I voluntarily go to the MDT but it's not part of my job plan. I've been going to it because I think it's good to see cases and to see also the outcome of the cases I have done.' **Participant 15**	'I feel very comfortable I've got that [*polyp MDT*] around me. It's quite secure and I'd find life a more vulnerable and scarier if I had to make decisions myself.' **Participant 3**
And then if they are happy [*the polyp MDT*] they will get the patient across and bring them straight for the procedure. So they do it quite quickly.' **Participant 9**	'I've got complete oversight of when all these patients are booked. We cross-reference every patient that's discussed in a complex polyp meeting with my database waiting list…… I can see at any one time how many patients are waiting to be dated and when their scope is going to be.' **Participant 2**
'All of us have our own niche within that MDT. We work with people who do TEMS (trans-anal endoscopic microsurgery) and we have somebody who is interested in ESD. There are cases which are debated sometimes but I think it works quite well.' **Participant 1**	'Now they are discussed in MDTs and we will make sure they are done by an appropriate endoscopist.' **Participant 5**

‘Before that [*complex polyp MDT*] it was hit and miss and whoever can do it, can do it kind of thing.’

Participant 4

‘There is now a really good process that the screening nurse fills in the referral and we get written feedback from the MDT. It’s not just education about what the patient’s management would be, but also education about what I’ve done and whether I’ve done the right things or not.’

Participant 3

‘We would never send any polyps to the surgeons without having discussed in the complex polyp MDT, and our surgeons are part of that MDT as well.’

Participant 17

‘That’s one of the things you pick up from MDT so that that lesion can be thoroughly seen by anybody and there is no need for them to be scoped again.’

Participant 3

‘I found an enormous polyp about two weeks ago what I considered not to be endoscopically resectable but the opinion of my colleagues was the opposite.’

Participant 14

	‘I think it’s a great service and gone from strength to strength over the past couple of years. I run it alongside the gastro fellows and it’s really well attended. There’s lots of buy-in from both the surgical and the gastro teams in terms of referring patients along that pathway to the complex polyp MDT.’ **Participant 15**
Negative attitudes	
‘The complex rectal lesion MDT is probably the most challenged pathway in the trust because we have quite long waits. We only do the meeting once a fortnight and it does mean that it’s logistically quite difficult.’ **Participant 15** ‘We will say let’s refer to the complex polyp team, but it overloads that service.’ **Participant 9** ‘We need people who have got the time to properly participate in the MDT. Ours is the same day as our colorectal MDT, so we do find that people are torn between the two and it’s sometimes difficult to attend the whole meeting.’ **Participant 15**	‘Often you get a letter [*to the MDT*] and there’s not even a size mentioned. The admin team then end up chasing the consultant. You don’t want some communication going amiss and then a patient suffering. I try to encourage my own admin staff to try and chase things up rather than sending letters back and forth just creating delays.’ **Participant 12** ‘The original time slot is now inadequate, and it often impacts on the gastro meetings that follow straight after. It’s not that people aren’t getting done, but it’s impacting on other meetings in the morning.’ **Participant 18**

invasive disease and similar to other evidence (102) may lead clinicians to recommend surgical treatment where it is not required. International recommendations exist for optical diagnosis training (29), but it does not form part of colonoscopy accreditation in the UK. Exposure to training may enable confidence in clinicians to take on more challenging lesions endoscopically. The improvement of technology to capture images and videos was widely advocated. Improvements in virtual platforms could allow collaborative assessment at the time of or after diagnosis to facilitate good decision-making. Better understanding regarding those who wouldn't benefit from treatment based on the lesion and patient's life expectancy should also be explored. Differences in the experience of the colonoscopists may also impact decision-making. Given 30% of participants were bowel screening practitioners, these individuals may be more likely to have greater experience and confidence in lesion assessment and management. Advanced therapeutic endoscopists, dedicated fellowship training or regular participation in training courses may also skew the data towards favourability of endoscopic treatment and avoidance of surgery.

Contrary to the concept that decision-making is largely cognitive, literature has reported that emotional intelligence is linked clinical decision-making (64). Subtilties regarding the psychology of decision-making for the clinician and their interactions with patients have been alluded to in this study. It was suggested that the expertise of the endoscopist could influence the patient's decision, and many would agree to their clinician's recommendations. Several other influences on clinical judgement have been suggested, including the clinicians interaction with both his profession and relationship with the patient (109). Racial biases have also been reported amongst clinicians in other studies, but these do not seem to impact decision-making in clinical settings (110). Other psychological factors include the affective state of the clinician, with negative personal emotions potentially having a strong influence on the clinical reasoning and diagnostic process (111). This was not alluded to in our study group. To mitigate the potential adverse impact of this, collaboration and group decision-making may have an important role.

As speculated (107), challenges were reported in the utilisation, knowledge of and access to complex polyps expertise. This may explain a higher utilisation of surgical management where less invasive techniques may be possible. Given the known significant risks of surgery (63) and higher healthcare costs, it is important to avoid this unless clearly indicated. Development of relationships between departments in addition to the streamlining of agreed referral pathways and criteria to those with expertise are needed. This seems to be particularly important for techniques such as ESD and trans-anal endoscopic microsurgery (TEMS) where clear identification of service responsibility should help avoid individuals not being able to access potential organ preserving surgery. Challenges and barriers in training can also be restrictive (112). Increased multi-disciplinary team decision-making

meetings and endoscopy capacity, administration support, tracking of cases and treatment timelines were frequently called for by participants and could all help these non-clinical issues.

The use of complex polyp team decision-making strategies have been recommended by guidelines to aid management (25). The attitude towards collaborative discussion and decision-making was overwhelmingly positive by those with access to them despite limited underlying evidence. In addition to streamlining management, multi-disciplinary team decision-making meetings were reported as beneficial to service planning and as educational platforms. They were seen as supportive environments enabling clinicians to manage more complex cases and facilitate the introduction of new techniques. Some reported challenging the boundaries of treating early polyp cancers primarily endoscopically in the correct circumstances. There seemed to be a shift towards surveillance in those polyps with unexpected malignancies. Both strategies could help avoid the risk and burden of surgery in selected patients.

There were other areas identified by participants where improvements were being made to provide better care. Given the complexities of treatment and surveillance, improved knowledge for patients either through written information or dedicated clinics were reported to facilitate shared decision-making. Extra training such as the SPECC programme or collaboration between sites were also advocated in learning from each other's experience. A summary of recommendations to improve practice utilising the findings of this study is shown in figure 4.1.

5.4.1 Limitations

There are limitations to qualitative research. Bias may be introduced through participant selection and interview design. As a surgeon, the clinical and research interests of the lead researcher may have influenced the focus of the interviews. Efforts were made to avoid this with the use of a pre-written interview guide. As all participants were experienced endoscopists, they required limited guidance in discussing their opinions and it was felt the impact of the researcher's opinions was minimal. The use of a single analyser developing codes and themes may also have introduced bias, but guidance on how to perform thematic analysis is limited (113). Leading thematic analysis experts, Braun and Clarke, explicitly do not support the use of multiple coders for this type of research as quality of analysis may not be dependent on having more than one (114). More recent proposals suggest deviation from Braun and Clarke's model (115). It is possible that multiple coders may enhance findings and reduce the impact of an individual coder's interpretation, but there is little evidence to support these observations. Efforts were made to identify individuals from a range of sites and not just those with access to complex polyp expertise. Despite this, the results described may not accurately reflect all experiences or there may have been concerns about open discussion.

Reassurances of participant anonymity were made to hopefully avoid this. Although consistency in themes were identified, increasing the sample size could have found further factors. It was felt that data saturation had been achieved after the performance of 20 interviews, and that little further information would be gathered by recruiting more participants. The collected data may have also been limited by time constraints and availability of participants. Given the variability in health care systems internationally, the practice in the UK may not be generalisable to other countries.

The addition of patient interviews or patient representatives would have provided a wealth of further information and understanding in this area. Individuals could have been invited to participate after identification and treatment of a complex polyp through either endoscopy routes or a multi-disciplinary team discussion. Similar interviews could have been performed to enable comparison between their own influences on management choices and the clinicians. The absence of the patient's perspective is a limitation, with shared decision-making always an important consideration. Its role has been demonstrated amongst interviews of both patients and clinicians regarding decision-making for malignant polyps with uncertainty and information being key underlying themes (100). Patient involvement is also likely to be of great influence on the choice of management in complex polyps. This would have provided more insight into their perceptions regarding communication, understanding and beliefs in contrast to the clinical participants. Similarly, involvement of other professionals involved in the wider care of the patient may have provided additional insights. Polyp management may include input from a range of other individuals including general practitioners, nurse specialists, radiologists and surgeons. When designing the study, attention was focussed on the clinicians identifying these lesions at initial diagnosis and hence including solely practicing colonoscopists. Addition of a range of participants may have obscured outcomes and comparisons unless a high number were recruited. In addition, the decision not to incorporate patient participants was made considering similar research being undertaken by the wider research group at the time. Semedo et al demonstrated a positive experience reported through patient interviews who had complex polyps removed (116). Support initiatives were highlighted as a potential area to improve patient experience and adverse events after intervention were linked with quality of life outcomes afterwards. The most significant practical limiting factor on the involvement of other participants was the simultaneous Covid pandemic at the time of this study. Ethics and patient recruitment to any studies not related to the pandemic was challenging, and the burden on health professionals unprecedented. Keeping involvement concise was a pragmatic way of recruiting sufficiently without risking the possibility of the study not being completed.

5.5 Conclusions

Given the increasing recognition of complex colorectal polyps, good decision-making strategies and access to services are likely to have increasing importance. Colonoscopists from all backgrounds felt that endoscopic management should be the treatment of choice where possible. This study adds significant insight that access to clinical expertise, service provision, quality assessment and education is called for by health professionals to facilitate the shift towards avoiding surgical intervention and providing high standards of patient care. The role of collaborative decision-making strategies including the use of multi-disciplinary teams was perceived as useful in everyday practice despite the absence of evidence describing their outcomes or structure. Factors such as right sided lesion location and HGD on biopsy were a reason to advocate surgical intervention in some. Other factors should be considered in these situations to reassure that this approach should not be mandated due to this alone. Qualitative and quantitative evidence is required to assess the structure of polyp multi-disciplinary team decision-making meetings and their clinical outcomes including complications, risk of recurrence and unsuspected malignancies. They have the potential to improve the non-clinical challenges identified above and provide equality in treatment options for those with complex colorectal polyps.

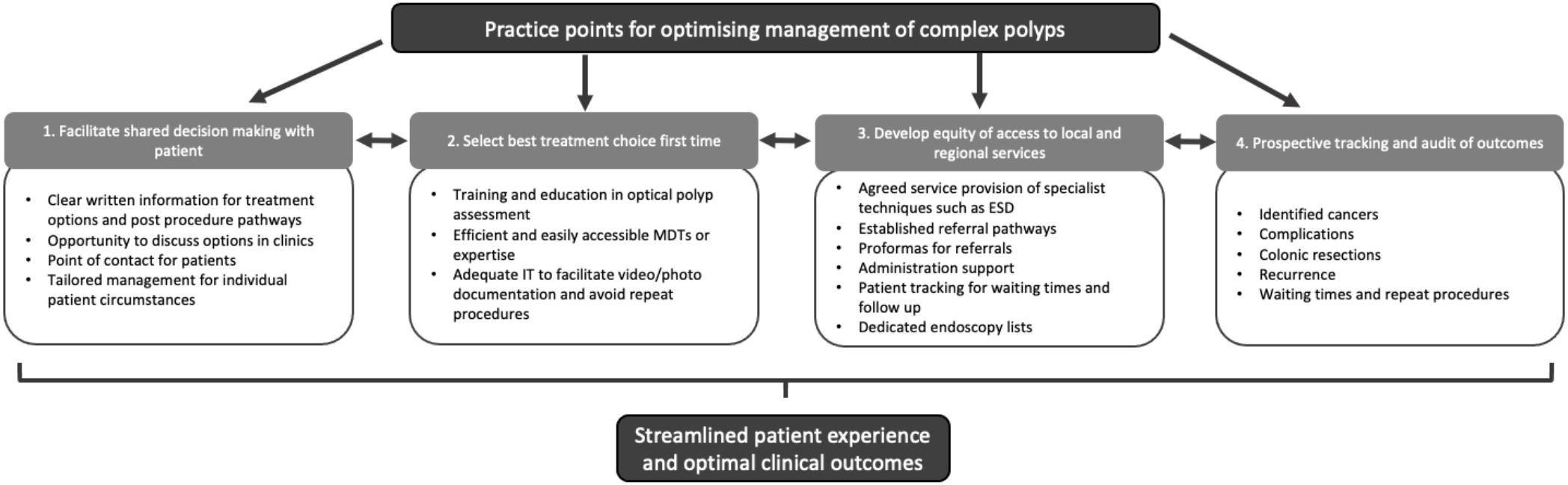


FIGURE 5.1 – RECOMMENDATIONS FOR IMPROVING PRACTICE FOR COMPLEX POLYPS

6 Outcomes of complex colorectal polyps managed by multi-disciplinary team decision-making strategies – a multi-centre observational study

6.1 Introduction

Endorsed by guidelines (25), multi-disciplinary team management meetings for complex colorectal polyps have been introduced across the UK. These meetings are synonymous to tumour boards used in other countries. The effectiveness of team management has been demonstrated in other settings (80, 81), but insight is limited regarding their impact on clinical outcomes for patients with complex polyps. Given the findings of the previous qualitative study, there are seen as having a positive role by clinicians with access to their services. It is not clear whether their initiation has translated into good clinical outcomes. There are currently no mandatory requirements for their structure, operation or monitoring of quality.

6.1.1 Aim

The primary aim of this multi-centre observational study was to assess the procedures performed and clinical outcomes of patients with colorectal polyps who are managed through these team decision-making approaches in the UK. Other objectives included an assessment of team structure, case referral volume, trends in primary procedures over time and comparisons between presentation and primary treatment modalities.

6.2 Methods

This was a retrospective, observational study of consecutive patients managed by complex polyp multi-disciplinary team management meetings in the UK utilising the STROBE (strengthening the reporting of observational studies in epidemiology) checklist recommendations as shown in appendix 10 (117). Lead clinicians involved in active meetings were approached for recruitment with all those invited agreeing to participate. Six separate and geographically widespread sites across the UK were included.

6.2.1 Data collection

All six centres provided complete, prospectively produced lists of patients referred to their complex polyp management meeting from its commencement for review. Individuals listed were assessed up

to March 2020 at the latest to ensure they met the required follow-up of at least one year after treatment at the time of data collection. All cases were initially considered and assessed against the inclusion and exclusion criteria from the information obtained from their digital hospital records. Information regarding the structure of the meeting was collected via questionnaire from a lead clinician involved in the service.

6.2.2.1 Team characteristics

Data were collected regarding the organisation of each management team including the participants, referral criteria, source and method of referral.

6.2.2.2 Patient and polyp demographics

Data were collected retrospectively for each patient from their digital hospital records and inputted onto pre-defined spreadsheets. All cases excluded from the analysis were classified and reported. Missing data and patients who did not receive surveillance after their procedure were also acknowledged in the results.

Data were collected regarding mode of presentation, date of first meeting discussion, age, gender, medical comorbidities, polyp size, morphology, location, access and pre-procedure histology. It was also noted if the polyp had been previously treated and if a repeat endoscopic assessment of the polyp was required prior to intervention. Medical comorbidities were described using the CCI and polyp complexity was determined using the SMSA scoring system.

6.2.2.3 Procedures

Treatments were categorised into endoscopic, CELS procedures, trans-anal techniques or colonic resection. If no primary procedure was recommended, the reason for this was documented. If a secondary or further procedure thereafter was recommended for the same polyp, the indication and type was described.

6.2.2.4 Outcomes

Documented adverse events were included regardless of level of severity. Data regarding length of stay, 30-day readmissions and final histology was collected for all procedures. If cancer was detected on final histology, the management plan following this was recorded. If residual or recurrent disease was identified, it was noted whether treatment was performed at the time of endoscopy or if an additional procedure was required. If the patient underwent colonic resection data on the indication, type of resection, type of access and requirement of a stoma was collected.

6.2.2 Inclusion and exclusion criteria

Inclusion and exclusion criteria were defined prior to the start of data collection and all cases listed for discussion at a team meeting were initially considered. Patients required at least one year between the procedure date (or meeting discussion if the patient was treated conservatively) and the time of data collection. This was to allow sufficient time for check or surveillance endoscopies to be performed to achieve an accurate assessment of residual or recurrent disease.

Patients with no available information regarding polyp management on hospital records and those without a documented discussion from the meeting were excluded. Lesions referred but on assessment there was no polyp in the area of concern, or the polyp did not meet the criteria for complexity were also excluded. Polyps categorised as non complex included lesions less than 10mm in size and without other indicators of complexity including difficult access or location, residual or recurrent lesions or indicators of advanced histology. Due to the alternative management considerations multiple small polyps, non-neoplastic pathology and suspected or known polyposis syndromes identified prior to intervention were not included in the analysis. The study focussed on lesions that were initially identified as being clinically and histologically benign. Individuals identified as having colorectal cancer before intervention and referred for management by the cancer management team were not included. Patients who had not received treatment by the end of March 2020 or were pending the required one year of follow-up after management were identified and reported in the results but not analysed further.

6.2.4 Ethics

Advice on ethical approval was sought from Cardiff University Research Integrity, Governance and Ethics Team. As this was classed as a retrospective service evaluation, they deemed that further ethical approval was not necessary. Local audit and research governance guidance was adhered to for each site throughout data collection.

6.3 Results

6.3.1 Team characteristics and referrals

An overview of the data collection period and team characteristics for each site is shown in table 6.1. All sites provided both symptomatic and screening endoscopy services and discussed cases from both in their meetings. Site 3 had separate meetings for symptomatic (site 3a) and screening (site 3b) presentations. All ran their meetings on a weekly or fortnightly basis. Three sites did not have agreed referral criteria and there was variability in the composition and method of referrals across

the sites. All sites offered both advanced therapeutic endoscopy including ESD and surgical techniques.

Referrals per year for each team are shown in figure 6.1. A total of 2749 patients were referred to a complex polyp team meeting during the data collection period with an increasing number of referrals each year. The figures are lower for 2020 as this was an incomplete year with data collection finishing in March at the latest. There were 640 excluded cases which are classified in appendix 11 leaving a total of 2109 patients for analysis.

6.3.2 Patient and polyp demographics

Patient and polyp characteristics are summarised in table 5.2. Of the 2109 patients included, the average age was 68.9 years with the majority presenting symptomatically (64.5%). There were more males in all categories but there was a higher proportion of women in symptomatic as compared to screening detected lesions (43% vs 33%, *P*<0.001). Symptomatic patients also had a significantly higher CCI (3.7 vs 3.1, *P*<0.001).

There were 2192 complex colorectal polyps identified within the included patients. Mean polyp size was 32.1mm with the largest proportion of lesions being SMSA level 4 (44.3%). A pre-intervention biopsy was documented in 52.1% (n=1142) of lesions. Of these biopsied polyps, 16.0% (n=183) had HGD, 78.5% (n=896) had low grade dysplasia (LGD) with the remainder having serrated pathology, hyperplastic pathology or normal mucosa (n=63, 5.5%).

There was no significant difference in the number of SMSA level 3 and 4 lesions (*P*=0.401), polyp location (*P*=0.920) or previously treated polyps (*P*=0.088) between screening and symptomatic groups. Polyps detected through screening were significantly larger (33.6mm vs 31.4mm, *P*=0.005) with a higher proportion of adenomas with HGD on pre-procedure histology (11% vs 7%, *P*=0.001). Further assessment endoscopy was performed in 10.4% of lesions prior to intervention.

6.3.3 Procedures

An overview of all procedures is shown in figure 6.2. A total of 2149 procedures were performed on the 2192 lesions analysed. Of these, 2010 were primary procedures with the remaining being either secondary (n=135) or tertiary interventions (n=4).

6.3.3.1 Primary procedures

Of the 2192 lesions analysed, primary endoscopic therapy was used in 1657 (75.6%) of lesions with the commonest technique being EMR. Surgical procedures were performed in 14.9% including trans-anal surgery (6.8%) or colonic resection (8.1%). Combined procedures were used in 1.1%. Conservative management was chosen in 182 lesions (8.3%). The commonest reason was that the

TABLE 6.1 – TEAM CHARACTERISTICS AND REFERRALS

Meeting	Participants	Referral criteria	Source and method of referral	Data collection	Total referrals
1	Gastroenterologist, colorectal surgeon, pathologist, team coordinator, gastro and surgical trainees, clinicians from other sites	No agreed criteria Photos and/or videos required	Own hospital, others within and outside of trust Email, telephone, face to face conversation Accepted from consultants, screening programme	Dec-17 to Mar-20 (28 months)	317
2	Gastroenterologist, colorectal surgeon, pathologist, radiologist, specialist colorectal nurse, team coordinator, gastro and surgical trainees, colorectal oncologists, clinical trial research nurse	Local guidelines: Polyps > 6mm Photos and/or videos required	Own hospital, others within and outside of trust, GP referral centres Specific complex polyp team proforma Accepted from registrars, consultants, specialist gastro or colorectal nurses, nurse endoscopists, screening programme	Feb-14 to Mar-20 (73 months)	527
3a	Gastroenterologist, colorectal surgeon, specialist colorectal nurse,	Local guidelines:	Own hospital, others within trust Specific complex polyp team proforma	Jan-15 to Feb-20 (61 months)	415

	team coordinator, gastro trainees	1. Laterally spreading tumour (LST) > 2cm regardless of site 2. Right sessile or flat elevated polyp > 2cm 3. Left sessile or flat elevated polyp > 4cm 4. Significant residual or recurrent polyps on scars ≥ 10mm 5. Polyps with difficult access 6. Other (e.g. large pedunculated polyps > 4cm) Photos and/or videos required	Accepted from junior doctors, registrars, consultants, specialist gastro or colorectal nurses, nurse endoscopists		
3b	Gastroenterologist, colorectal surgeon, pathologist, radiologist, specialist colorectal nurse,	Local guidelines as 3a Photos and/or videos required	Own hospital, others within and outside of trust, national referrals Specific complex polyp team proforma Accepted from junior doctors, registrars, consultants, specialist gastro or colorectal	Nov-11 to Jul-18 (80 months)	683

	team coordinator, gastro trainees		nurses, nurse endoscopists, screening programme		
4	Gastroenterologist, colorectal surgeon, radiologist, specialist gastro nurse, nurse endoscopist, team coordinator, clinicians from other sites	No definite criteria agreed Photos required	Own hospital, others outside of trust Formal letter Accepted from consultants, specialist gastro or colorectal nurses, nurse endoscopists, screening programme	Mar-14 to Mar-20 (72 months)	173
5	Gastroenterologist, colorectal surgeon, specialist gastro and colorectal nurses, nurse endoscopist, team coordinator, gastro and surgical trainees, endoscopy admin staff	Local guidelines: Polyps >2cm Photos required	Own hospital, others within and outside of trust Specific complex polyp team proforma Accepted from registrars, consultants, specialist gastro or colorectal nurses, nurse endoscopists, screening programme	Dec-17 to Mar-20 (27 months)	364
6	Gastroenterologist, nurse endoscopist, gastro and	No definite criteria agreed Photos preferred	Own hospital Email, electronic referral	Oct-18 to Mar-20 (17 months)	270

	surgical trainees, booking team member	Accepted from junior doctors, registrars, consultants, specialist gastro or colorectal, nurse endoscopists, screening programme			
			Total	**358 months**	**2749 patients**

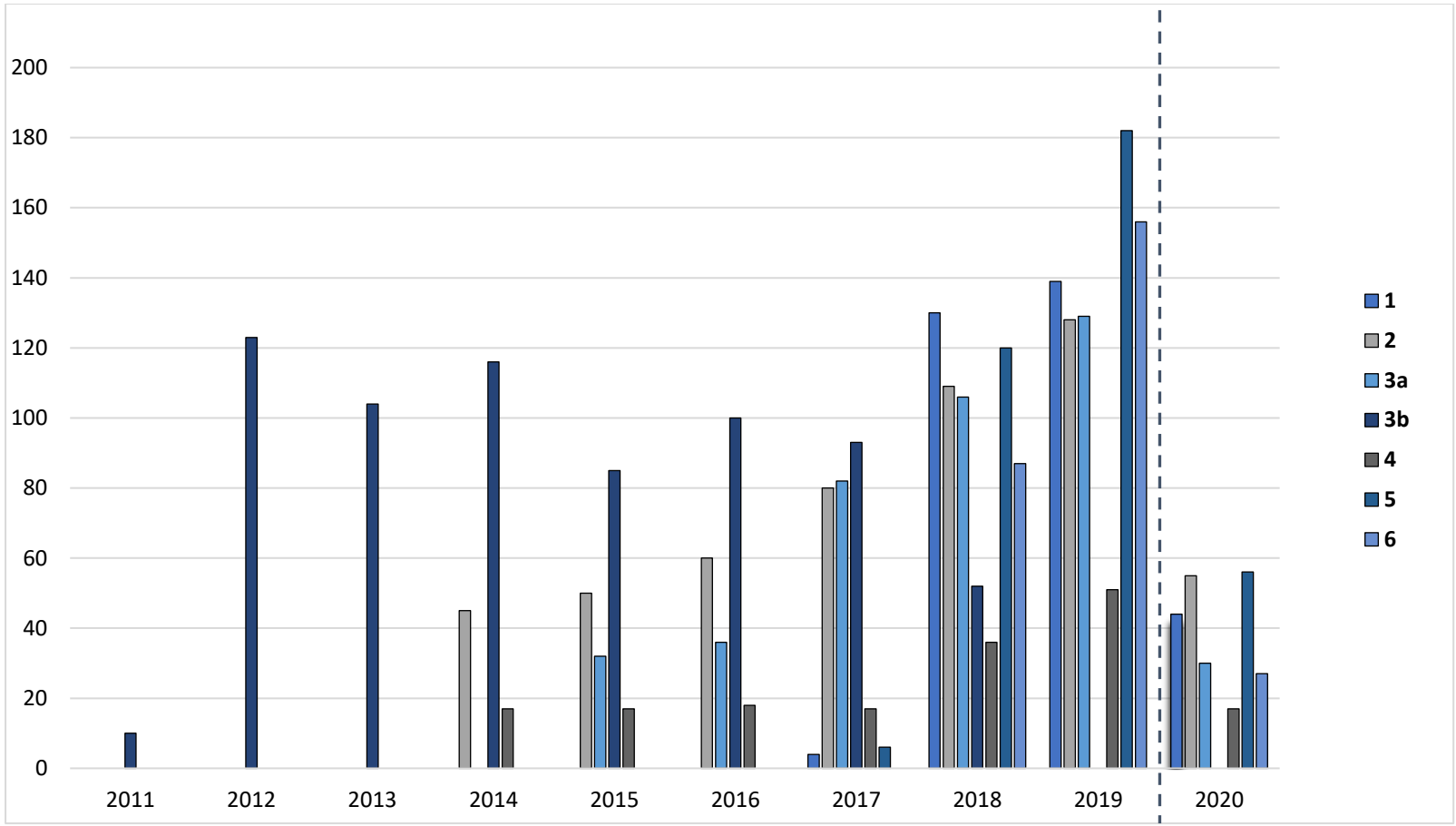


FIGURE 6.1 – ANNUAL REFERRALS TO COMPLEX POLYP MEETINGS

Each bar represents referrals to individual meetings. Numbers are given as total patient referrals each year before exclusions. To the right of the dotted line indicates an incomplete year of data as collection ceased in March 2020 at the latest.

TABLE 6.2 – PATIENT AND POLYP CHARACTERISTICS

	Total (n=2109)	**Screening (n=749)**	**Symptomatic (n=1360)**	***P* value**
Patient characteristics				
Age (years)	68.9 (23 to 97)	67.5 (50 to 78)	69.7 (23 to 97)	**<0.001**
Gender				
Female	832 (39.5%)	247 (33.0%)	585 (43.0%)	**<0.001**
Male	1277 (60.5%)	502 (67.0%)	775 (57.0%)	
CCI	3.5 (0 to 12)	3.1 (0 to 8)	3.7 (0 to 12)	**<0.001**
	Total (n=2192)	**Screening (n=758)**	**Symptomatic (n=1434)**	***P* value**
Polyp characteristics				
Polyp size (mm) *	32.1 (2 to 180)	33.6 (2 to 120)	31.4 (3 to 180)	**0.005**
Polyp morphology				

Flat	829 (37.8%)	238 (31.4%)	591 (41.2%)	
Sessile	1130 (51.6%)	455 (60.0%)	675 (47.1%)	
Pedunculated	228 (10.4%)	60 (7.9%)	168 (11.7%)	
Missing	5 (0.2%)	5 (0.7%)	0 (0%)	
Polyp location				
Right	980 (44.7%)	340 (44.9%)	640 (44.6%)	0.920
Left	1212 (55.3%)	418 (55.1%)	794 (55.4%)	
Polyp access				
Difficult	1024 (46.7%)	199 (26.3%)	825 (57.5%)	
Easy	1168 (53.3%)	559 (73.7%)	609 (42.5%)	
SMSA level				
4	971 (44.3%)	324 (42.7%)	647 (45.1%)	0.401

3	788 (35.9%)	278 (36.7%)	510 (35.6%)	
2	420 (19.2%)	144 (19.0%)	276 (19.2%)	**0.002**
1	8 (0.4%)	7 (0.9%)	1 (0.1%)	
Missing	5 (0.2%)	5 (0.7%)	0 (0%)	
Previously treated polyp				
Yes	117 (5.3%)	49 (6.5%)	68 (4.7%)	0.088
No	2075 (94.7%)	709 (93.5%)	1366 (95.3%)	
Pre procedure histology				
Biopsy not done	1050 (47.9%)	233 (30.7%)	817 (57%)	
Adenoma, LGD	896 (40.9%)	415 (54.8%)	481 (33.5%)	**0.001**
Adenoma, HGD	183 (8.4%)	83 (11.0%)	100 (7%)	
Serrated	40	13	7	

	(1.8%)	(1.4%)	(2.0%)
Hyperplastic	20 (0.9%)	11 (1.7%)	29 (0.5%)
Normal mucosa	3 (0.1%)	3 (0.4%)	0 (0%)
Further assessment endoscopy			
Yes	227 (10.4%)	84 (11.1%)	143 (10.0%)
No	1965 (89.6%)	674 (88.9%)	1291 (90.0%)

*Age, CCI and polyp size are given as mean and range. The remaining values are given as number and (%) to one decimal place. Unpaired t tests are used for continuous variables and chi-squared tests for categorical data. * Missing data, n=2*

patient was unfit for any intervention (51.1%). Other reasons included treatment being declined by the patient (40.7%), the patient dying from another cause awaiting intervention (4.4%), a recommendation for polyp surveillance only (3.3%) and moving out of the area (0.5%).

There was a higher number of primary colonic resections in the screening as compared to the symptomatic cohort (16% vs 4.7%, *P*<0.001). Patients undergoing primary colonic resection were similar in mean age (68.3 vs 68.4, *P*=0.862) and gender (59.7% vs 60.6% males, *P*=0.811) compared to those managed with other techniques. Polyps were larger (38.6mm vs 31.8mm, *P*<0.001) in those having colonic resections with more lesions on the right (68.5% vs 41.9%, *P*<0.001) and a higher proportion of SMSA level 3 and 4 lesions (88.2% vs 79.6%, *P*=0.006). Lesions managed with primary colonic resection had a higher proportion of adenomas with HGD on pre-intervention histology (23.2% vs 6.2%, *P*<0.001).

6.3.3.2 Secondary and tertiary procedures

After primary treatment, a secondary procedure was advised in 156 lesions (7.8%). Indications included an unsuccessful or incomplete primary procedure (n=60, 38.5%), suspicion of cancer during primary procedure (n=36, 23.1%), residual or recurrent polyp at surveillance (n=35, 22.4%) or cancer on final histology (n=25, 16%). Of these, 21 did not have a secondary procedure. Reasons included that the patient was unfit (57.1%), declined further intervention (38.1%) or had moved out of area (4.8%). The commonest secondary procedure was colonic resection (57.7%). Endoscopic management was performed in 16.0% with trans-anal techniques and combined procedures in 10.9% and 1.9% respectively.

Four polyps required a third procedure and three of these cases were due to polyp recurrence. One case was treated with ESD, and the other two underwent colonic resection. The remaining case was due to cancer detected on final histology after trans-anal surgery that was performed after an initial failed endoscopic resection. This individual went on to have a completion colonic resection. Despite a higher level of primary colonic resections in the screening cohort, there was no difference between the two presentation groups in the requirement for secondary or tertiary procedures (*P*=0.941).

6.3.3.3 Changes in recommended procedures over time

Figures 6.3 shows the changes in procedures over time. Figure 6.3.1 demonstrates an increasing use of primary organ preserving procedures such as EMR, ESD, hybrid ESD and trans-anal surgery from 62.7% in 2012 to 83.8% in 2020. The proportion of primary colonic resections fell consistently from 34.6% in 2012 to 1.7% over the same time period. More patients were managed conservatively with 2.7% in 2012 compared to 14.5% in 2020. This reduction in the primary surgery rates did not result in an increased number of secondary procedures with the total required falling from 7.3% in 2012 to 3.4% in 2020 (table 6.3.2).

6.3.4 Outcomes

6.3.4.1 Length of stay, adverse events and 30-day readmissions

A summary of length of stay, adverse events and 30-day readmissions is shown in table 6.3 with a comprehensive overview provided in appendix 12. Out of the 2149 procedures performed, most procedures were undertaken as a day case with a median length of stay of 0. Length of stay varied across the treatment modalities with it being significantly longer for patients having colonic resection compared to other organ preserving procedures (*P*<0.001). The median length of stay for endoscopic procedures was 0 days with 77.5% completed as day cases. Median length of stay was 5 days for colonic resections.

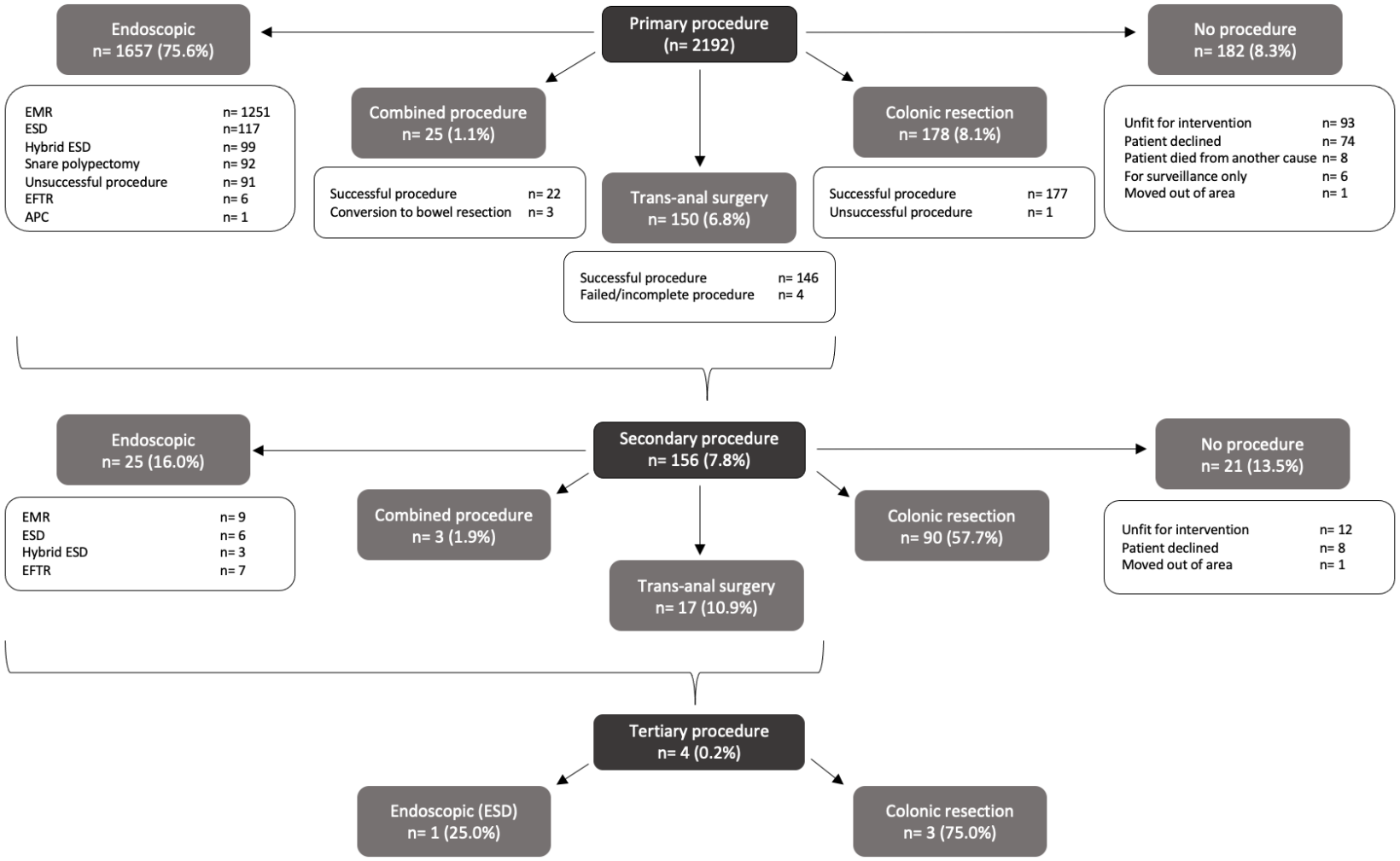


FIGURE 6.2 – FLOW DIAGRAM OF PRIMARY, SECONDARY AND TERTIARY PROCEDURES

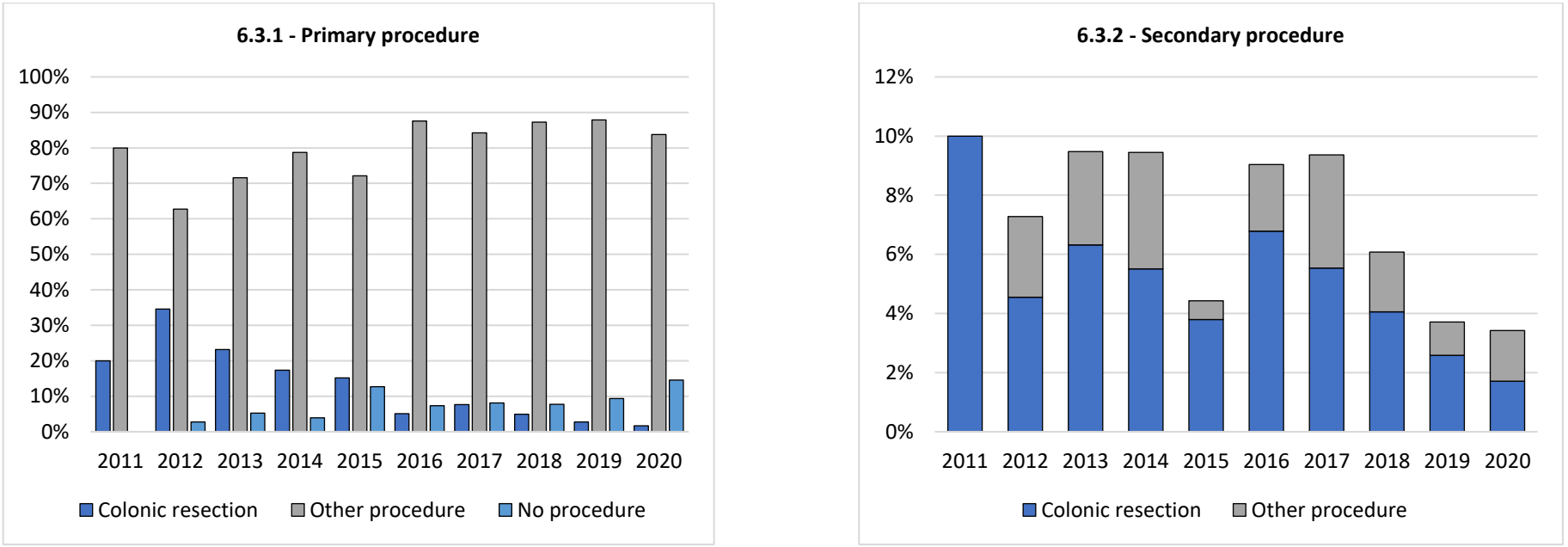


FIGURE 6.3 – CHANGE IN PROCEDURES OVER TIME

There were 193 adverse events identified (9.0%). Complications rates were similar for endoscopic (5.5%), combined (7.1%) and trans-anal procedures (7.2%) with the majority in all groups being minor (CD classification 1). Rectal bleeding after an endoscopic procedure was the commonest complication in this group (n=55, 3.3%) followed by perforation (n=14, 0.8%) and PPS (n=11, 0.7%). The management of post procedure bleeding was predominantly conservative (n=35, 63.6%) with a minority requiring intervention with endoscopy (n=12, 21.8%), transfusion (n=4, 7.3%), bowel resection (n=3, 5.5%) or interventional radiology (n=1, 1.8%). All perforations were CT diagnosed, delayed presentations as opposed to those identified during the procedure. Of the 14 perforations after endoscopy, the majority (n=9) occurred in left sided lesions. Most were conservatively managed with antibiotics (n=11, 78.6%) with 3 (21.4%) requiring surgical intervention in the form of bowel resection.

Complications in combined procedures were all due to urinary retention managed with a temporary catheter (n=2) which was also the commonest adverse event in trans-anal procedures (n=4). Other significant complications in trans-anal procedures included acute kidney injury (AKI) requiring admission to intensive care (n=1), rectal bleed requiring haemostasis under anaesthetic (n=1) and a perforation requiring surgical washout but no bowel resection (n=1). The remaining complications were minor and can be viewed in appendix 12.

Adverse events in those having colonic resections were significantly higher than other procedures (31.7%, $P<0.001$) with the majority being CD classification 2. The commonest adverse event was anastomotic leakage (n=17, 19.8%) which occurred in 11 left sided resections and 6 right. Four of the leaks were managed conservatively with antibiotics and surgical management was required in 13. Wound infection (n=13, 15.1%), respiratory tract infection (n=10, 11.6%) and ileus (n=10, 11.6%) were other frequent complications. All three 30-day mortalities occurred in those undergoing colonic resection.

Of the 2149 procedures performed, overall 30-day procedure related readmission was 3.3% (n=70). Readmission after colonic resection (4.8%) was higher than endoscopic (3.3%) and trans-anal procedures (1.2%) but this was not significant ($P=0.127$). There were no readmissions after combined procedures. The commonest reason for readmission was rectal bleeding after an endoscopic (n=40) or trans-anal (n=2) procedure. The other common indications were PPS (n=7), perforation after an endoscopic procedure (n=6), pain (n=3) and wound infection (n=3).

TABLE 6.3 – LENGTH OF STAY, ADVERSE EVENTS AND 30-DAY READMISSIONS

	Total (n=2149)	**Endoscopy (n=1683)**	**Combined procedure (n=28)**	**Trans-anal surgery (n=167)**	**Colonic resection (n=271)**	***P* value**
Length of stay	0 (0 to 1)	0 (0 to 0)	2 (2 to 3)	1 (1 to 2)	5 (4 to 8)	***P*<0.001**
Total adverse events	193 (9.0%)	93 (5.5%)	2 (7.1%)	12 (7.2%)	86 (31.7%)	***P*<0.001**
CD 1	65 (33.7%)	45 (48.4%)	2 (100%)	5 (41.7%)	13 (15.1%)	
CD 2	70 (36.3%)	27 (29.0%)	0	4 (33.3%)	39 (45.3%)	
CD 3	32 (16.6%)	15 (16.1%)	0	2 (16.7%)	15 (17.4%)	
CD 4	23 (11.9%)	6 (6.5%)	0	1 (8.3.%)	16 (18.6%)	
CD 5	3 (1.5%)	0	0	0	3 (3.5%)	
30-day readmission	70 (3.3%)	55 (3.3%)	0	2 (1.2%)	13 (4.8%)	*P*=0.127

Results are described for the total number of procedures performed (n=2149). Figures are given as median (IQR) for length of stay. The remaining values are given as number and (%) to one decimal place. P values are given for comparisons between colonic resections and all other organ preserving procedures using a Mann-Whitney U test for length of stay and chi-squared tests for adverse events and readmissions.

6.3.4.2 Final histology

A summary of final histology is shown in table 6.4. Of the 2192 lesions initially identified there were 1989 lesions successfully removed. Polyps not undergoing a primary procedure (n=182) and those with an unsuccessful primary and no secondary procedure (n=21) were excluded from this.

Malignancies were found in 8.8% (n=175) on final histology. This included 172 adenocarcinomas but there were also two neuroendocrine tumours and one squamous cell carcinoma. The number of malignancies were significantly higher in the screening cohort (12% vs 7%, *P*<0.001) and in those managed with primary colonic resection compared to organ preserving techniques (26% vs 7%, *P*<0.001). Of the 154 lesions identified as having HGD on pre-intervention biopsy and undergoing a successful procedure, 34.4% (n=53) had cancer identified on final histology compared to 8.3% of those with LGD on pre-intervention biopsies. Primary colonic resection was performed in 27.3% (n=42) of lesions with pre-intervention HGD with 57.1% (n=24) having benign histology confirmed on final histology.

In those who had cancer reported on final histology, 45.1% had already been managed with colonic resection. This rate was higher in the screening group (57.5% vs 33.0%). Completion colonic resection was recommended in 14.3% of those who had been treated by endoscopic, trans-anal or combined techniques before. This recommendation was higher in the symptomatic group (19.3% vs 9.2%). A total of 40.6% (n=71) were managed without completion colonic resection. Seven (9.9%) of these were treated for benign recurrence during surveillance with four having treatment at the time of their endoscopy. Three (4.2%) required further procedures. One individual had been initially treated with failed EMR followed by ESD and went on to have an anterior resection for benign recurrence. The other two were primary trans-anal procedures who were also successfully treated with this technique for their recurrence.

6.3.4.3 Residual or recurrent disease

The median duration of follow-up was 30.3 months (IQR 32.8 to 81.8 months). Of the 2192 initial included lesions, 618 were categorised as not requiring surveillance. The reasons included lesions that were managed conservatively, lesions managed with colonic resection or documented evidence that surveillance was inappropriate or not required. Of the remaining 1574, no surveillance was identified for 365 lesions during the follow-up period leaving 1209 (76.8%) of those eligible that had surveillance after their complex polyp treatment.

Benign recurrence was identified in 13.1% (n=158). Most patients had one episode (n=116) with two or more recurrences occurring in 42 patients. There was no significant difference in recurrent

TABLE 6.4 – FINAL HISTOLOGY

	Total (n=1989)	Screening (n=724)	Symptomatic (n=1265)	*P* value
Benign	**1814 (91.2%)**	**637 (88.0%)**	**1177 (93.0%)**	
Adenoma, LGD	1115	376	739	
Adenoma, HGD	464	175	289	
Serrated	138	30	108	
Hyperplastic	21	6	15	
Inflammatory	10	0	10	***P*<0.001**
Non polyp pathology *	12	6	6	
Histology not available	54	44	10	
Malignant	**175 (8.8%)**	**87 (12.0%)**	**88 (7.0%)**	
Adenocarcinoma	172	85	87	
Other malignancy **	3	2	1	

*Values are reported per number of successfully removed lesions and (%) to one decimal place. Comparisons are made between presentations for benign and malignant final histology using a chi-squared test. * Non polyp pathology included normal mucosa (n=2), lipoma (n=2), anal intraepithelial neoplasia (n=2), papilloma, mucosal prolapse, granulation tissue, fibrosis, fibroepithelial polyp and juvenile polyp (all n=1) ** Other malignancies included neuroendocrine tumour (n=2) and squamous cell carcinoma (n=1)*

disease between the screening and symptomatic cohorts (12.8% vs 13.2%, *P*=0.827). Of the 214 total episodes of recurrence, 82.2% were managed at the time of their endoscopic surveillance. Additional procedures were required in 38 (17.8%). Of these, 14 were managed with colonic

resection, 8 with ESD or hybrid ESD, 7 with trans-anal surgery, 6 with endoscopic full thickness resection (EFTR) and 3 with EMR.

6.3.4.4 Colonic resection

An overview of the colonic resections performed is shown in table 6.5. A total of 280 patients required a colonic resection related to their complex polyp treatment. The majority of these were performed based on the primary recommendation of the management team (63.6%). Other indications included an unsuccessful endoscopic or combined procedure (10.7%), cancer suspected during endoscopic treatment (9.3%), cancer on final histology (8.9%) or benign recurrence detected during surveillance (5%). Of the 26 lesions where cancer was suspected during endoscopic treatment, malignancy was confirmed in 25. Colonic resection was required for procedure complications in 7 individuals (2.5%). Six of these were performed after EMR and one after an ESD procedure. Indications included significant rectal bleeding post-procedure (n=3), colonic perforation (n=1 ascending colon lesions, n=2 sigmoid colon lesions) and bowel ischaemia after the use of interventional radiology for rectal bleeding (n=1).

6.3.4.5 Procedures and outcomes for rectal lesions

There were 642 lesions (29.3%) located in the rectum. The commonest chosen primary procedure type was endoscopic management (n=429, 66.8%) mostly in the form of either EMR (n=237, 36.9%), ESD (n=100, 15.6%) and hybrid ESD (n=71, 11.1%) techniques. Trans-anal surgery was performed in 22.7% (n=146), conservative management in 8.3% (n=53) and primary surgery in 2.2% (n=14).

Of the 589 rectal lesions treated, 7% (n=41) required a secondary procedure with one lesion requiring a third intervention. The indications for secondary or tertiary procedures included cancer suspected during primary treatment (n=12), recurrence (n=12), cancer on final histology (n=13) or an unsuccessful or incomplete primary procedure (n=8). Secondary interventions were mostly colonic resection (n=21, 51.2%) but also included trans-anal surgery (n=14, 34.2%), EMR (n=1, 2.4%) and ESD or hybrid ESD (n=5, 12.2%) techniques. The single tertiary intervention was a colonic resection performed for cancer identified on final histology. No colonic resections for rectal lesions were performed due to complications of treatment.

An anterior resection of the rectum was performed in 27 of the 36 (75%) rectal lesions treated surgically with abdominoperineal resection, panproctocolectomy and subtotal colectomy used in 7, 1 and 1 patients respectively. At the time of follow-up, 11 (29.7%) of these patients still had a stoma.

TABLE 6.5 – CHARACTERISTICS OF COLONIC RESECTIONS

	Total (n=280)	Screening (n=161)	Symptomatic (n=119)
Indication for bowel resection			
Meeting recommendation	178 (63.6%)	117 (72.7%)	61 (51.3%)
Unsuccessful endoscopic/combined procedure	30 (10.7%)	11 (6.8%)	19 (16.0%)
Cancer suspected during primary procedure	26 (9.3%)	14 (8.7%)	12 (10.1%)
Cancer on final histology	25 (8.9%)	8 (5.0%)	17 (14.3%)
Residual or recurrent polyp	14 (5.0%)	6 (3.7%)	8 (6.7%)
Procedure adverse events	7 (2.5%)	5 (3.1%)	2 (1.7%)
Resection performed			
Right hemicolectomy	144 (51.4%)	80 (49.7%)	64 (53.8%)
Anterior resection	74 (26.4%)	44 (27.3%)	30 (25.2%)
Sigmoid colectomy	20 (7.1%)	17 (10.6%)	3 (2.5%)
Appendicectomy or caecectomy	14 (5.0%)	5 (3.1%)	9 (7.6%)
Abdominoperineal resection	7 (2.5%)	1 (0.6%)	6 (5.0%)
Left hemicolectomy	8 (2.9%)	7 (4.3%)	1 (0.8%)
Subtotal colectomy	5 (1.8%)	3 (1.9%)	2 (1.7%)
Hartmann's procedure	4 (1.4%)	2 (1.2%)	2 (1.7%)

Pan proctocolectomy	4 (1.4%)	2 (1.2%)	2 (1.7%)
Access			
Laparoscopic	210 (75.0%)	116 (72.0%)	94 (79.0%)
Open	67 (23.9%)	42 (26.1%)	25 (21.0%)
Unknown	3 (1.1%)	3 (1.9%)	0
Stoma			
No	180 (64.3%)	91 (56.5%)	89 (74.8%)
Yes – reversed	19 (6.8%)	3 (1.9%)	16 (13.4%)
Yes – not reversed	19 (6.8%)	5 (3.1%)	14 (11.8%)
Unknown	62 (22.1%)	62 (38.5%)	0

Values are given as number and (%) to one decimal place

Cancers were identified on final histology in 11.7% of rectal lesions (n=69). Colonic resection had already been performed for 16 of the lesions. Of the remaining 53 identified cancers, a completion bowel resection was recommended in 9 (13.0%).

6.4 Discussion

This is the first multi-centre study of team management approaches for complex colorectal polyps assessing clinical outcomes and providing a comprehensive overview of all polyps referred to these services. Despite the current variability in structure, their use appears to deliver appropriate management with good clinical outcomes. As the sites covered a wide geographical area, this study gives a representative insight into current practice of complex polyp team management across the UK. The volume of cases referred is continuing to rise. Given other concomitant changes in practice likely to further increase detection such as the use of FIT and extension of bowel screening age, their use may be of increasing importance.

Organ preserving techniques were the primary treatment for most lesions. Primary surgery rate may reflect optimal decision-making, but the standard is not established (25). The overall (8.1%) and 2019 (2.7%) primary surgical resection rate is lower than reported (21.7%) (30). Secondary management (7.8%) was also lower than previous studies by Lee (16.1%) (30) and Dattani (13.2%) (64). This reduction conflicts the increasing or stable rates reported in American and European studies (60, 118). Tumour boards in America are analogous to multi-disciplinary team approaches (119), but are not standard practice for complex polyps. Their utilisation in the UK may explain the reduction in colonic resections and have implications for practice standards of professional guidelines (25). We acknowledge that ongoing developments in advanced endoscopy may confound the observed reduction in colonic resections despite this not having influenced other countries (60, 118). It also does not explain the increasing utilisation of conservative management seen in this study.

Contrary to previous evidence (64), screening detected polyps were more likely to have primary colonic resection. Some may have been anticipated cancers highlighting one limitation of retrospective data collection. The lower CCI in screening patients may reflect individual motivation regarding healthcare and could mean that surgical treatment is a viable option compared to the potentially more comorbid patients presenting through symptomatic routes. In general, bowel cancer screening programmes have a different structure as compared to symptomatic endoscopy provided by mainstream health services in the UK. There is more allocated time for the test and patients are counselled before their investigation. Bowel screening colonoscopists are an accredited group with higher levels of performance required to ensure screening standards are met. More time to perform the procedure, less conflicting external pressures, more experienced colonoscopists and the absence of trainee involvement may have impacted referrals to polyp meetings. It is reasonable to suggest that polyps meeting our complexity criteria may have been treated by screening colonoscopists without onward referral. This may also explain other discrepancies in this group including larger polyp size, greater proportion of HGD on pre procedure biopsy, more cancers on final histology and a higher rate of surgery. Conversely however, the proportion of SMSA level 3 and 4 lesions were similar between the groups. There are several options that may have improved understanding of these factors. Collection of screening data regarding all colonoscopies performed and polyps identified through this pathway would have allowed assessment of the denominator and the proportion of polyps being referred. Accessing this information for comparison in the symptomatic group would have been more challenging. Limiting study inclusion to a single parameter such as only SMSA level 4 lesions or a size of 20mm or more as previously used (64), may have allowed a more controlled comparative group between the screening and symptomatic groups.

The perceived correlation between HGD at biopsy and cancer on final histology could result in surgery being recommended. Only 34.4% of lesions with pre-intervention HGD were proven to contain cancer, similar to that reported by Dattani (37.5%) (64). Of lesions with HGD treated with resection, the majority (57.1%) were ultimately found to be benign. Biopsies can create diagnostic uncertainty through sampling error, burden pathology services and compromise endoscopic therapy (45). Identifying malignant features by optical polyp characterisation is vital for decision-making (95) and the ESGE now recommend a core curriculum to improve this (29). This can be challenging (120), but quality imaging and training allows final decisions regarding management to be made later by those with expertise in this field.

Endoscopic treatment has fewer adverse events, shorter hospital stays and lower costs (42, 43, 121) with the safety of procedures in this study being comparable. Post polypectomy bleeding (3.3%) was the commonest adverse event with similar rates reported by Moss (2.9%) and Buchner (7.2%) (45, 46). Perforation was low (0.8%) and within standards set by guidelines (25). The thinner right colonic wall may explain the higher resection rates in this group. Most perforations reported in this series were located on the left and managed conservatively. Despite colonic resection offering the security of complete lesion removal, it is overtreatment for most and associated with longer stays and more adverse events. A systematic review of surgical resections for benign polyps reported adverse event and mortality rates of 24% and 0.7% respectively (62). This studies adverse events (31.7%) including a leak rate of 19.8% and mortality of 1.1% are similar and reiterates the greater risks of resection. A leak rate of 19.8% seems relatively high. Even though quoted leak rates for the purpose of procedure consent are usually lower that this, the incidence is considerably varied in the literature. Reports range from as low as 2.8% up to 30% in colorectal surgery (122) which is comparable to what is found here. The risk factors for leak are well described and included older age, male gender, comorbidities, smoking, challenging surgery and anatomical location of the anastomosis (122, 123). Although this figure may seem alarming, it may be a more accurate reflection of real world outcomes across a range of larger units, outside of a trial setting.

Dattani reported a 10.7% risk of cancer in their study of significant polyps (64). The observed cancer rate in this study was 8.8%. Most were managed without completion resection and supports the safety of such management in selected patients. For malignant lesions, survival and recurrence is not adversely affected by endoscopic therapy initially (52) and completion bowel resection may not be superior (124). The reported benign recurrence rate in this study of 13.1% was acceptable. A meta-analysis in 2014 reported recurrence in 15% (125) with more recent evidence quoting 10.8% for large, non-pedunculated polyps (126).

There may be further benefits of team decision-making. It can increase capacity by modifying management, improve patient preparation and allocation of cases to those with expertise (127). Benefits in clinician education and confidence in choosing organ preserving techniques may result from involvement with meetings. With increasing referrals, ensuring efficiency and appropriate utilisation of polyp meetings is required. This study did not specifically assess repeat discussions regarding the same patient or polyp. More than one discussion regarding a patient may be required for several reasons. This may include not all investigations being available, lack of available expertise, new information that may affect management decisions, or the need to review treatment outcomes or histology. The utilisation of rediscussing must be balanced between facilitating good decision-making whilst keeping the efficiency of meetings. Vetting and tracking of referrals to only discuss once all required information is available may help. Good systems must be in place to ensure accountability and avoidance of losing individuals to follow up, which is time consuming amongst other challenges. Conversely, further discussions may have additional benefits. They may refine decision-making and therefore improve outcomes for the patient, but also facilitate learning for the team. Team reflection and feedback on both positive and negative outcomes can help the learning curve and allow accountability through audit, governance and quality improvement. Although there likely to be benefits of this, limitations on time and availability of the clinicians involved are likely to be a significant factor impacting its implementation.

Standardised referral criteria and completed proformas (99) are recommended to facilitate efficiency and uniformity. Evaluation of economic impact would also be valuable. Given the spectrum of options for complex polyps and their risks, the patient's voice is crucial and team management should advocate shared decision-making, with research regarding patient reported outcomes also required.

This data may guide KPIs for complex colorectal polyp treatment. The reduction in primary surgery over time suggests that team management of complex polyps contributes to the improvement of clinical outcomes. This effect may be due to a combination of group decision-making, clinical expertise, access to a full range of therapeutic modalities and optimisation of service provision. The importance of prospective data collection to facilitate quality assurance, outcome reporting and improvements is clear. Based on the data collected so far, a proposed polyp meeting template is shown in figure 6.3 which collects polyp parameters, recommended treatment and the outcomes. This also considers the BSG complex colorectal polyp minimum dataset. Designed to be a computer based document, aspects of the proforma can be copied and pasted into each discussion and a single, rolling document can be used. Discussions can also be added for multiple polyps. Sections are included to provide easy access links to images and results if appropriate.

COMPLEX POLYP TEAM MEETING PROFORMA		
PATIENT DETAILS	**DATE REFERRAL RECEIVED**	
	MEDICAL, SURGICAL AND MEDICATION HISTORY	

POLYP 1	**INITIAL DISCUSSION**				
DATE OF DISCUSSION		**MDT MEMBERS PRESENT**			
PRESENTATION	SCREENING	SYMPTOMATIC	INCIDENTAL		
RESIDUAL/RECURRENT	NO	YES			
POLYP LOCATION	CAECUM	ASCENDING	HEPATIC FLEXURE	TRANSVERSE	
	Appendix orifice /IC valve				
	SPLENIC FLEXURE	DESCENDING	SIGMOID	RECTUM	
				Height:	
POLYP DESCRIPTION					
KUDO PIT PATTERN	I	II	III	IV	V

OTHER SURFACE FEATURES											
SMSA CLASSIFICATION											
LEVEL 1 Score 4-5		LEVEL 2 Score 6-9			LEVEL 3 Score 10-12			LEVEL 4 Score > 12			
Site		**Morphology**			**Size**			**Access**			
Left Right	1 2	Pedunculated (Ip) Sessile (Is/Isp) Flat (II)	1 2 3		<1cm 1-1.9cm 2-2.9cm 3-3.9cm >4cm	1 3 5 7 9		Easy Difficult	1 3		
BIOPSY RESULTS		N/A	ADENOMA - LGD		ADENOMA - HGD		SERRATED	HYPERPLASTIC		CANCER	
		OTHER:									
IMAGING REVIEWED		ENDOSCOPY	CT		MRI		USS	PET			
		RESULTS:									
		LINKS:									
CONCERNS OF MALIGNANCY?		YES					NO				
PATIENT WISHES											
MEETING OUTCOME											
TREATMENT ADVISED ENDOSCOPIC TRANSANAL RESECTION BOWEL RESECTION		**FURTHER INVESTIGATION** ENDOSCOPY CT					**NO FURTHER MANAGEMENT ADVISED** REASON:				

		MRI USS		
	OTHER:			
TIMELINE FOR TREATMENT:	<4 WEEKS	<12 WEEKS	<6 MONTHS	<12 MONTHS
NEXT MDT DISCUSSION DUE:				

POLYP 1		**RE DISCUSSION (No 1/2/3/4/5)**	
DATE OF DISCUSSION		**MDT MEMBERS PRESENT**	
REASON FOR REDISCUSSION			
MEETING OUTCOME			
TREATMENT ADVISED ENDOSCOPIC TRANSANAL RESECTION BOWEL RESECTION	**FURTHER INVESTIGATION** ENDOSCOPY CT MRI USS PET	**NO FURTHER MANAGEMENT ADVISED**	REASON:
	OTHER:		
TIMELINE FOR TREATMENT:	<4 WEEKS	<12 WEEKS	<6 MONTHS	<12 MONTHS
NEXT MDT DISCUSSION DUE:				

POLYP 1		POST TREATMENT DISCUSSION	
DATE OF DISCUSSION		**MDT MEMBERS PRESENT**	
REASON FOR DISCUSSION			

FINAL TREATMENT PERFORMED				
ENDOSCOPIC SNARE EMR ESD HYBRID EFTR	**COMBINED** LAP EMR LAP ESD	**TRANSANAL** TART TEMS TEO	**BOWEL RESECTION** RESECTION + PRIMARY ANASTOMOSIS RESECTION, PRIMARY ANASTOMOSIS + DEFUNCTIONING STOMA NON RESTORATIVE RESECTION	**NO PROCEDURE** REASON:

	OTHER:	
COMPLICATIONS	NO	YES
	TYPE:	

CLAVIEN-DINDO CLASSIFICATION						
1	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions.					
2	Requiring pharmacological treatment with drugs other than such allowed for grade I complications.					
3	**A** Requiring surgical, endoscopic or radiological intervention under local anaesthesia					
	B Requiring surgical, endoscopic or radiological intervention under general anaesthesia					
4	**A** Life-threatening complication requiring intensive care management with single organ dysfunction					
	B Life-threatening complication requiring intensive care management with multi organ dysfunction					
5	Patient death					
30 DAY READMISSION	NO			YES		
	REASON:					
PROMS	NO			YES		
	OUTCOME:					
FINAL HISTOLOGY	N/A	ADENOMA - LGD	ADENOMA - HGD	SERRATED	HYPERPLASTIC	CANCER
	OTHER:					

MEETING OUTCOME		
FURTHER TREATMENT ADVISED ENDOSCOPIC MANAGEMENT TRANSANAL RESECTION BOWEL RESECTION	**SURVEILLANCE**	**NO SURVEILLANCE**
	DUE DATE:	REASON:

	OTHER:	
FOR DISCUSSION AT M&M	YES	NO

POLYP 1	***AUDIT OUTCOMES***	
FINAL PROCEDURE:		
TREATED WITHIN RECOMMENDED TIMELINES	*YES*	*NO*
NUMBER OF PROCEDURES:		
BOWEL RESECTION:	*YES*	*NO*
STOMA REQUIRED:	*YES*	*NO*
COMPLICATIONS:	*YES*	*NO*
30 DAY READMISSION:	*YES*	*NO*
CANCER:	*YES*	*NO*

FIGURE 6.4 – COMPLEX POLYP MEETING TEMPLATE

6.4.1 Limitations

This study's limitations include the retrospective design and absence of a control group. A comparator group was considered when designing the study but found not to be pragmatic. Simultaneous comparison to centres without a complex polyp meeting would make findings difficult to interpret and potentially misleading due to heterogeneity between sites. Data collection preceding the introduction of meetings would also have been difficult with limited digital records

and challenges in identifying a comparative cohort. Ideally prospective data collection before and after meeting introduction as described elsewhere should have been performed (81) but this would have required considerable time to achieve. All efforts were made to thoroughly assess and record data, but there could be missed adverse events, readmissions and surveillance procedures. Variability between team structure is also a confounder and possibly impacts both the decisions made and outcomes. Despite this, this study provides real world data that should reflect current clinical practice across the UK and outcomes for patients with complex colorectal polyps. Prospective data collection, audit and comparison to KPIs ideally on a national scale is advocated, to ensure the ongoing effectiveness of polyp meetings.

6.5 Conclusions

The clinical outcomes described for complex polyp multi-disciplinary team decision-making meetings across the UK are of high quality and comparable to other available data in the literature. The reduction in primary surgery over time suggests that a team management approach to complex polyps may improve clinical outcomes. This effect may be due to a combination of optimal decision-making, access to a full range of diagnostic and therapeutic modalities and optimisation of service provision. These findings support the positive attitudes reported by clinicians involved in the preceding qualitative research. As suggested, there may be wider benefits of implicating such decision-making strategies including the provision of expertise and facilities in the development of new techniques to further benefit patients. Strategies that enable further organ preservation in the most challenging complex colorectal polyps in particular warrants investigation.

The variability in the structure and processes for each multi-disciplinary meeting has been identified and there are no current recommendations regarding a suggested format. A detailed description of an established complex polyp multi-disciplinary team decision-making meeting and its experience in introducing a novel organ preserving technique shall be explored in the next chapter.

7 The Cardiff complex polyp multi-disciplinary team meeting and its impact on the outcomes of a novel complex polyp technique – a single-centre study

7.1 Introduction

As seen in the previous chapter, complex polyp multi-disciplinary team meetings may involve a range of expertise which can include endoscopists, colorectal surgeons, radiologists, specialist nurses and pathologists. Referral criteria and pathways were different across all meetings assessed. The Cardiff complex polyp multi-disciplinary team decision-making meeting was established in 2008 and became a national referral centre in 2011. It is one of the longest running meetings in the UK. It discusses approximately 250 screening and symptomatic cases each year. This meeting has introduced a CELS technique as an organ preserving treatment option and is one of laparoscopic assisted polypectomy utilising EMR (Lap EMR).

As described in section 1.2.2, CELS procedures are emerging techniques for the treatment of complex polyps. They utilise the benefits of both endoscopic and surgical approaches to facilitate complete endoscopic removal of the most challenging polyps with organ preservation. They may be particularly useful for complex right sided lesions. Those surrounding the appendix are often difficult to remove due to access challenges and the thinner wall of the caecum. Due to the risks of incomplete resection or perforation they are more likely to be managed surgically (128) even though EMR is safe in selected lesions (129). A CELS approach is one method of ameliorating these concerns. The colon can be mobilised and manipulated to ensure complete resection by the endoscopist whilst monitoring for a full thickness breach and performing immediate repair to avoid the consequences of an unrecognised perforation. EFTR is another endoscopic technique that helps avoid bowel resection for complex polyps. An endoscopic device to excise the whole bowel wall encompassing the polyp is utilised, rather than excision of just the polyp from the bowel wall as in CELS approaches (figure 1.6.3). The FLEX procedure is also described in the introduction chapter and is based on a similar principle of full thickness resection. Compared to the EFTR technique, the section of bowel is excised using a laparoscopic stapling device rather than through the lumen (37). This requires the presence of both laparoscopic surgeons and endoscopists. Indications for all these techniques are to provide an organ preserving option for those polyps that cannot be removed by traditional endoscopic techniques alone. Their utilisation across centres will depend on awareness, expertise,

training and the logistics of accessing such treatments. Good decision-making is important in balancing the benefits and risks of the various treatment approaches and it is recommended that such lesions be carefully assessed and managed by those with advanced endoscopic expertise (25, 40, 130).

Despite reassuring outcomes, CELS procedures are not widely utilised which may reflect service availability, knowledge of the techniques or concerns regarding its safety. A systematic review in 2015 reported an average reintervention rate of 9.5%, an adenocarcinoma incidence of 10.5% and an adverse event rate of 7.9% (35). As summarised in table 7.1, there is also significant heterogeneity in studies reporting this procedure with variability in their terminology, selection criteria and technique. As a result, drawing conclusions through comparison of studies and results can be challenging (53-57).

7.1.1 Aim

The aims of this research were to provide a detailed description of the format and referral processes of an established complex polyp multi-disciplinary team decision-making meeting and its selection criteria for Lap EMR. The technique of Lap EMR was described with a case study to illustrate its use. Data was collected to establish the short and long term outcomes of patients treated with Lap EMR procedures who are managed through this pathway.

7.2 Methods

A single centre, retrospective review was performed of all patients having Lap EMR procedures for complex colonic polyps between September 2008 and October 2018 who had been managed through the Cardiff complex polyp meeting. Outcomes included time from diagnosis to lap EMR procedure, nature of procedures performed, adverse events, length of stay, malignancies, residual and recurrent disease.

7.2.2 Data collection

Patient were assessed and selected for Lap EMR through the complex polyp team meeting. The format, referral processes and selection criteria used for Lap EMR by the team was described. The surgical technique was comprehensively illustrated with a case study and video presentation to supplement this.

Data for patients treated by Lap EMR was obtained through a thorough retrospective review of each patient's written notes, complex polyp meeting reports, theatre records, endoscopy reports and online clinical records. Cases after October 2018 were excluded to ensure the patients in the study

TABLE 7.1 – EXAMPLES OF STUDY VARIATION FOR CELS PROCEDURES

	Terminology	Procedure(s)	Selection criteria
Crawford 2015 (53)	Combined endoscopic laparoscopic surgery	Laparoscopic assisted snare polypectomy Colonoscopic assisted laparoscopic caecectomy	Unresectable or unsafe via colonoscopy by therapeutic endoscopist due to size, broad base or location
Cruz 2011 (128)	Laparoscopic assisted endoscopic polypectomy	Laparoscopically assisted hot snare polypectomy	Unsuccessful previous EMR attempt
Franklin 2009 (55)	Laparoscopically monitored colonoscopic polypectomy	Laparoscopically assisted hot snare polypectomy	Considered colonoscopically unresectable by referrer
Goh 2014 (93)	Endo-laparoscopic polypectomy	Laparoscopic assisted EMR with hot snare	Considered colonoscopically unresectable by referrer
Grunhagen 2011 (57)	Laparoscopically monitored colonoscopic polypectomy	Laparoscopic assisted snare polypectomy	Large and broad based polyps or those inaccessible for snare polypectomy with colonoscopy alone
Lee 2013 (131)	Combined endoscopic-laparoscopic surgery	Laparoscopic assisted EMR with hot snare	Unable to be excised by an expert endoscopist
Wood 2011 (96)	Laparo-endoscopic resection	Laparoscopic assisted EMR with hot snare	Various reasons by various endoscopists

had at least one year of follow-up after their procedure. Due to the innovative nature of this technique, the IDEAL (idea, development, exploration, assessment, long term study) framework recommendations were used to guide reporting of the study outcomes (132, 133). The STROBE checklist was also applied to this observational study (117). Outcomes included intra operative conversion to bowel resection, procedure duration, blood loss, intra and post-operative adverse events, length of stay, readmissions, suspected and unsuspected cancers, residual and recurrent disease.

7.2.3 Ethical approval

Advice on ethical approval was sought from Cardiff University Research Integrity, Governance and Ethics Team. As this was classed as a retrospective service evaluation, they deemed that further ethical approval was not necessary.

7.3 Results

7.3.1 The Cardiff complex polyp multi-disciplinary team meeting format, referral processes and selection criteria

The referral criteria to the team meeting and decision-making pathways for Lap EMR are outlined in figure 7.1. Fortnightly meetings take place involving individuals with expertise in laparoscopic colorectal surgery, gastroenterology, advanced therapeutic endoscopy, histopathology and radiology. All clinicians actively performing Lap EMR procedures are involved in the team meeting. Cases are discussed if the referral criteria are met, and complete information is provided on the meeting proforma. The referral proforma is based on BSG complex colorectal polyp minimum dataset guidance (99) as shown in appendix 13. The referrer is required to provide adequate imaging of the polyp and SMSA levels are calculated by the meeting as an objective assessment of complexity. In the absence of all required information, further requests or assessment at the national referral centre would be made by the team as necessary to allow fully informed decision-making. The meeting recommendation would then be implemented at the national referral or local assessment centre depending on the availability of expertise and patient wishes. Lap EMR would be considered when:

- endoscopic intervention alone was unlikely to be technically feasible due to polyp size or access difficulties;
- endoscopic intervention alone was unlikely to result in complete polyp resection;
- endoscopic intervention had been previously unsuccessful.

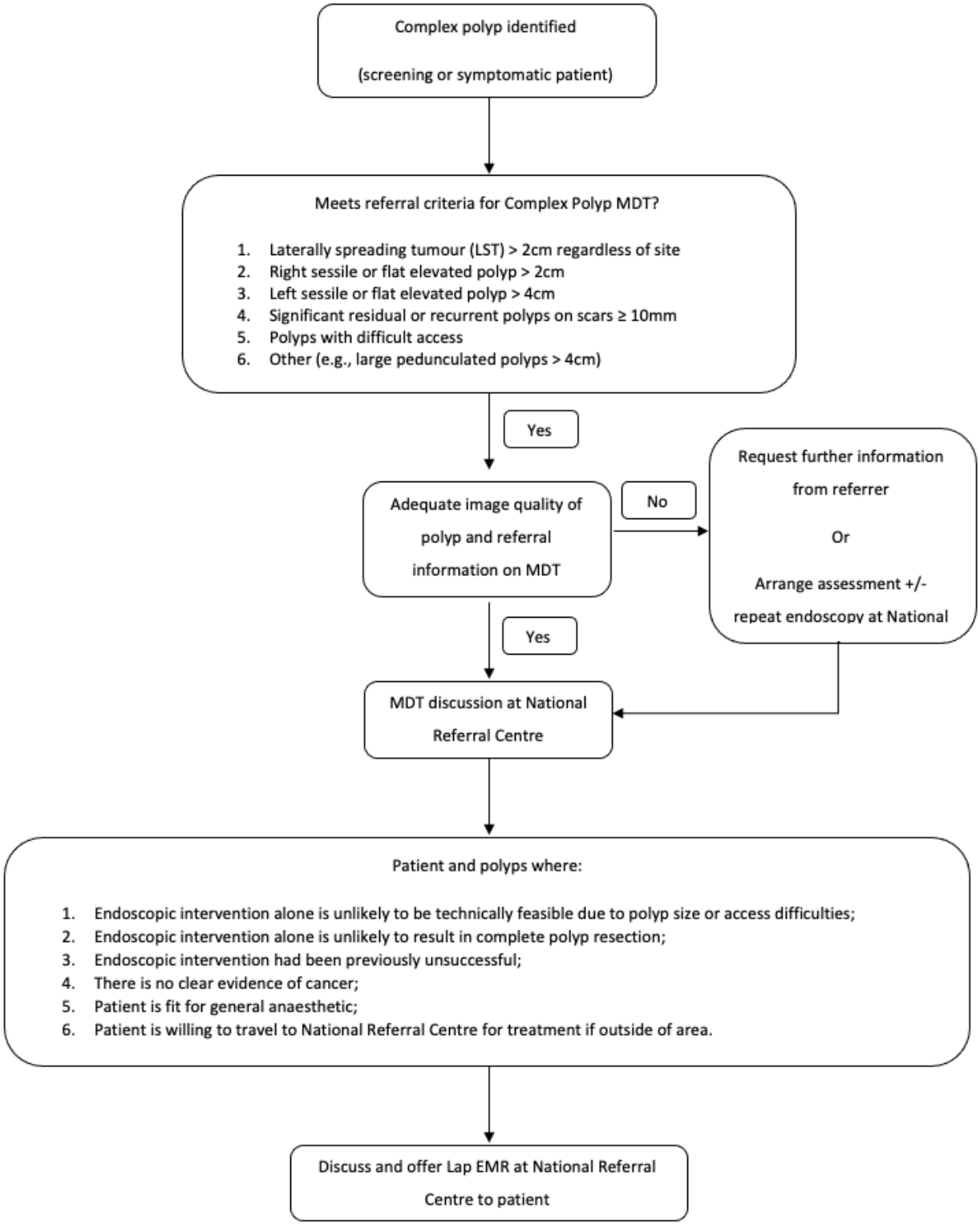


FIGURE 7.1 – CARDIFF COMPLEX POLYP MULTI-DISCIPLINARY TEAM DECISION-MAKING MEETING REFERRAL AND SELECTION PATHWAY FOR LAP EMR

Exclusion criteria for Lap EMR included patients not fit for a general anaesthetic, polyps with clear evidence of malignancy and patients declining the treatment.

7.3.2 Laparoscopic assisted endoscopic mucosal resection (Lap EMR) technique

7.3.2.1 Pre-operative preparation

In addition to the team discussion and recommendation, patients were reviewed by the operating laparoscopic colorectal surgeon and advanced endoscopist pre-operatively to allow shared decision-making. All Lap EMR procedures were performed at the national referral Centre in Cardiff. The nature of the operation would be explained including alternative treatment options. Full individual consent was taken regarding the nature of the operation, potential adverse events and conversion to colonic resection at the time if malignancy was suspected or the endoscopic procedure was unsuccessful. Patients were also warned about the possibility of a second operation if cancer was found in the resected polyp. They attended pre-operative assessment clinic and subsequently had an anaesthetic review or cardiopulmonary exercise testing if required. Standard bowel preparation was administered, and patients received thromboprophylaxis perioperatively. A urinary catheter was placed for all procedures and patients were given antibiotic prophylaxis.

7.3.2.2 Clinical expertise

All procedures were performed by a single advanced endoscopist and one of two laparoscopic colorectal surgeons. Both surgeons were experienced laparoscopic colorectal surgeons working at a tertiary centre with an active role in clinical and simulation training. The endoscopist had completed an advanced endoscopy fellowship at the National Cancer Centre Hospital in Tokyo with ongoing teaching and mentoring of others in complex EMR and ESD techniques. Although all involved endoscopist and surgeons were aware of other techniques such as EFTR and the FLEX procedure, these strategies were not practiced at this site and were not available management options. All were active participants in the complex polyp multi-disciplinary team.

7.3.2.3 Operative procedure

The procedures were performed under general anaesthetic with the patient in a Lloyd Davies position. Sterile preparation and draping of the abdomen were performed. An overview of the theatre set up is shown in figure 7.2. Pneumoperitoneum was established through a 12mm umbilical port. Two further 5mm ports would be inserted with their location depending on the site of the lesion. A full laparoscopy of the abdomen and the relevant section of bowel was performed next to ensure there were no signs suggesting more advanced disease. The bowel was then mobilised with the surgeons chosen energy device to allow sufficient manipulation to aid the colonoscopic procedure. Vascular pedicles were preserved throughout. A window was made in the mesentery

adjacent to the terminal ileum and a tape tied around the bowel to occlude the lumen. This prevented distension of the small bowel by the colonoscope which would limit the laparoscopic view during the procedure.

Colonoscopy was then performed. The lesion was identified and thoroughly assessed for any signs suggesting malignancy. Conversion to bowel resection was then performed if this was the case. An EMR technique was used for most lesions but Lap EMR at the centre also included the use of a hybrid EMR and ESD technique if appropriate. Standard EMR involved a submucosal injection of lifting solution and whole or piecemeal polypectomy using a hot snare. During this stage, the bowel would then be laparoscopically manipulated by the surgeon to facilitate complete polyp removal.

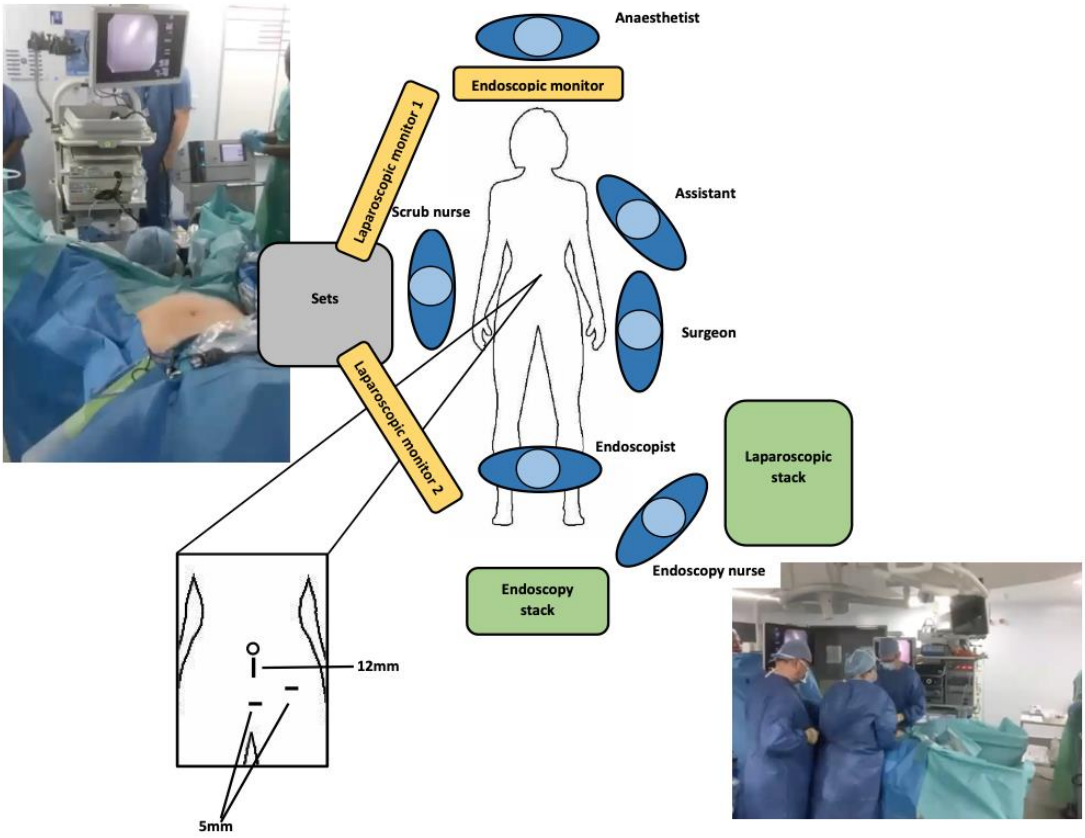


FIGURE 7.2 – THEATRE SET UP FOR LAP EMR PROCEDURES

For peri-appendiceal lesions, the appendix was invaginated to allow full excision of the polyp. If the involvement of the appendix was too extensive to allow endoscopic resection, an endoscopically assisted laparoscopic appendicectomy or caecectomy would be performed. Throughout the operation the bowel would be monitored for evidence of perforation which could then be treated immediately. Once excision was complete, careful haemostasis would be undertaken with diathermy and argon plasma coagulation (APC) as necessary. The mucosal defects were closed with endoscopic

clips and the specimen removed in a retrieval net by the colonoscope for histological analysis. A final laparoscopic inspection would then be performed to confirm bowel wall integrity before closure and removal of the ileal tape. The sheath of the 12mm port was closed and absorbable sutures were used for the skin. Local anaesthetic was infiltrated into the wounds.

7.3.2.4 Post-operative procedure

Post operatively the patients returned to the colorectal ward and would be encouraged to eat, drink and mobilise as soon as recovered from the general anaesthetic. The expected date of discharge was the first day after the procedure. Colonoscopic follow-up was in line with BSG guidelines with the first surveillance being performed at 3 months after treatment (134).

7.3.3 Outcomes of patients managed with Lap EMR

7.3.3.1 Patient and polyp characteristics

During the study period, 55 patients were treated with Lap EMR procedures. Median time from polyp diagnosis to Lap EMR procedure was 6 months (IQR 5 to 9 months). Table 7.2 shows the patient and polyp characteristics. Indications for Lap EMR included polyps unlikely to have complete endoscopic resection alone due to difficult access (n=28, 50.9%), size (n=13, 23.6%), both size and difficult access (n=11, 20%) or in a previously unsuccessful colonoscopic polyp excision (n=3, 5.5%). The SMSA level was 3 or 4 in most cases (90.9%). There were five SMSA level 2 lesions. Three of these were small (<1cm), sessile lesions extending into the appendix orifice. One lesion was a left sided sessile polyp measuring 1.5cm and proximal to a benign sigmoid stricture that was not passable without laparoscopic assistance. The final was a left sided, scarred sessile lesion measuring less than 2cm, where previous endoscopic resection had been unsuccessful.

7.3.3.2 Procedure outcomes

An overview of all procedures is shown in figure 7.3. Seven cases (12.7%) required a conversion to colonic resection during their Lap EMR procedure. The indications for conversion were an inability to gain complete polyp clearance during the procedure (n=4) or suspected malignancy during endoscopic assessment (n=3). Of these three patients with suspected malignancies, all were confirmed as having cancer in their polyp on final histology. The bowel resections performed were a right or extended right hemicolectomy in 6 patients and a sigmoid colectomy in one. A laparoscopic approach was used in all 6 patients with conversion to an open procedure in one patient due to adhesions.

TABLE 7.2 – PATIENT AND POLYP CHARACTERISTICS

	Total (n=55)
Patient characteristics	
Age (years)*	65 (62.5-69)
Gender	
Female	18 (32.7%)
Male	37 (67.3%)
ASA grade	
I	30 (36.4%)
II	27 (49.1%)
III	8 (14.5%)
BMI (kg/m^2)**	28.6 (26.2-32.8)
Smoker	
No	46 (83.6%)
Yes	9 (16.4%)
Mode of presentation	
Bowel screening	35 (58.2%)
Symptomatic	15 (27.3%)
Colorectal cancer surveillance	4 (7.3%)

Polyp characteristics	
Polyp size (mm) *	37.5 (20-48.8)
Polyp location	
Caecum	12 (21.8%)
Caecum – Appendix orifice	11 (20%)
Caecum – Ileocaecal valve	5 (9.1%)
Ascending colon	5 (9.1%)
Hepatic flexure	8 (14.5%)
Transverse colon	3 (5.5%)
Splenic flexure	5 (9.1%)
Sigmoid colon	6 (10.9%)
SMSA level	
1	0
2	5 (9.1%)
3	11 (20%)
4	39 (70.9%)

**Value is given as median (IQR) ASA – American Association of Anaesthesiologists, BMI – Body Mass Index*

TABLE 7.3 – POST-OPERATIVE COMPLICATIONS

	Complication	Management	CD classification
Patient 1	Rectal bleed	Transfusion and right hemicolectomy	3
	Respiratory tract infection	Antibiotics	2
Patient 2	Urinary retention	Temporary catheterisation	2
Patient 3	Urinary retention	Temporary catheterisation	2
Patient 4	Wound haematoma	None required	1

Four patients (7.3%) were treated with an endoscopic assisted laparoscopic appendicectomy. In three cases this was due to deep extension into the appendix lumen. In one case the polyp failed to lift after injection of EMR solution due to previous attempts at removal.

There was no intra operative colonic perforation. Estimated blood loss was documented as minimal in 50 (90.9%) cases. The five cases not documented as minimal were either converted to bowel resection (n=4) or appendicectomy (n=1). Median duration of all procedures (Lap EMR or resection) in the cohort was 156 minutes (IQR 127.5 to 185).

All patients returned to a colorectal ward postoperatively. There were five adverse events in four patients (7.3%) and an overview is shown in table 7.3. One patient had a significant post-operative rectal bleed that did not settle with conservative management. He required blood transfusion in addition to a right hemicolectomy and was subsequently identified as having an undiagnosed coagulation disorder despite a normal pre-operative clotting screen. There were no post-operative leaks, collections, wound infections or procedure related readmissions.

Median length of post-operative stay was 1 day (IQR 1 to 2). An overview of the final histology is shown in table 7.4 and cancer was found in 6 polyps in total (10.9%). The suspected cancer rate was 5.5% and these three patients had been converted to a resection (two right hemicolectomies and one sigmoid colectomy) during their Lap EMR procedure due to suspicion during polyp assessment. The unsuspected cancers all went on to have elective, uncomplicated laparoscopic bowel resections (two right hemicolectomies and one sigmoid colectomy) later. There was no requirement for a stoma in any patient requiring a bowel resection.

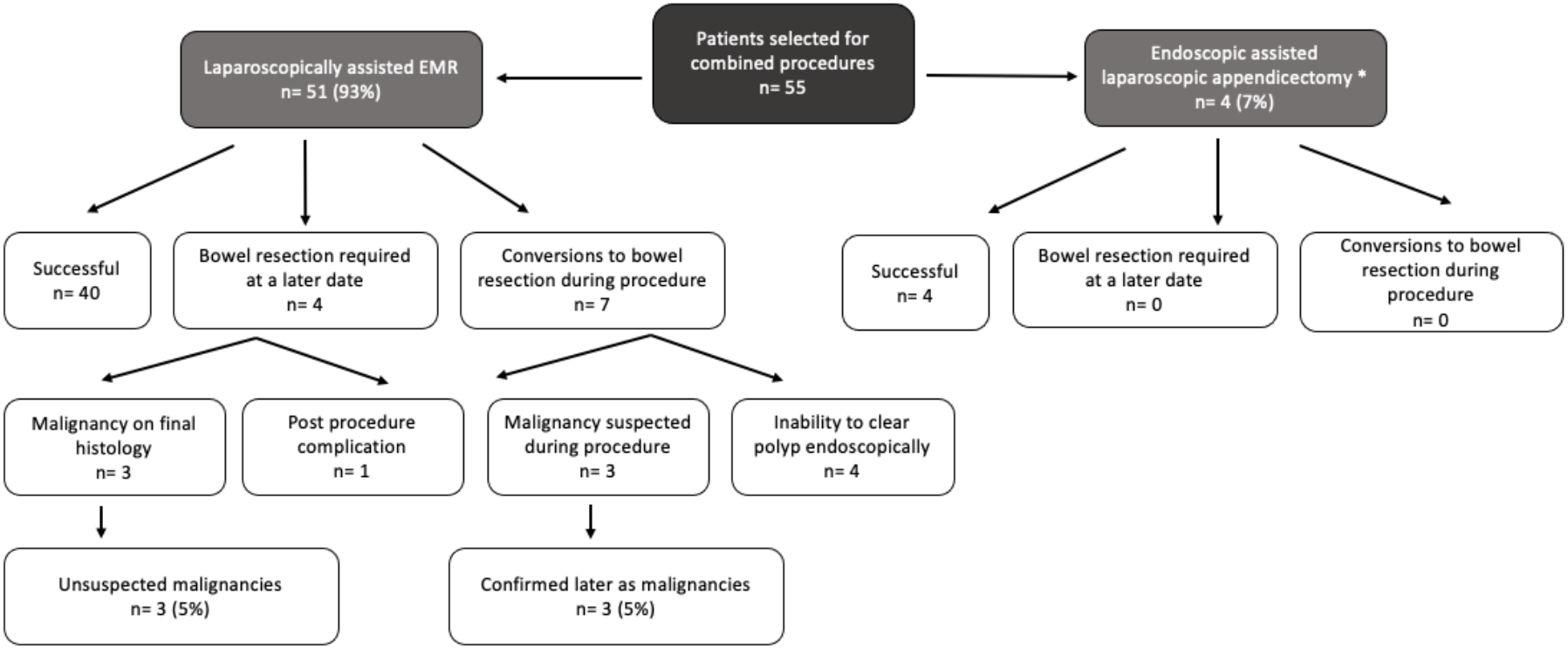


FIGURE 7.3 – STUDY FLOW DIAGRAM

**Indications for appendicectomy included deep extension into appendiceal lumen (3), and failure to lift after injection of EMR solution owing to previous removal attempts (1). All malignancies suspected during the procedure were subsequently confirmed histologically as cancer.*

TABLE 7.4 – FINAL POLYP HISTOLOGY

Histology	Total (n=55)
Adenocarcinoma	6 (10.9%)
Villous/tubular/tubulovillous adenoma	44 (80%)
Hyperplastic or serrated polyp	5 (9.1%)
Dysplasia	
Low grade	39 (70.9%)
High grade	8 (14.5%)
Not documented on report	2 (3.6%)

TABLE 7.5 – RESIDUAL AND RECURRENT DISEASE AFTER LAP EMR

	Residual disease	Recurrent disease
Patient 1	3 months	17 and 31 months
Patient 2	N/A	11 and 14 months
Patient 3	N/A	18 months
Patient 4	N/A	10 months
Patient 5	3 months	19 months
Patient 6	3 months	6, 9 and 11 months
Patient 7	3 months	4 months

The endoscopy and histology records of all patients were assessed for a median follow-up period of 76 months (IQR 62 to 91). Of the 44 patients who did not have a bowel resection, seven patients (15.9%) were identified as having either residual or recurrent disease at their previous polypectomy site. An overview is shown in table 7.5. All of these were benign and treated endoscopically within a median duration of 14 months (IQR 10.5 to 18.5) until successful complete clearance was achieved. No patient required a bowel resection for residual or recurrent disease. There was one mortality in the cohort (1.8%). This was unrelated to the treatment of his colonic polyp and due to the diagnosis of a primary lung cancer 18 months later.

7.3.4 Case study and Lap EMR video

A supplementary video demonstrating the Lap EMR technique was created during this project and illustrative pictures are shown in figure 7.4. A case study was performed of a 64 year old male diagnosed through bowel screening with a 25mm laterally spreading polyp in the caecum around the appendix orifice. The patient was assessed by a surgeon, an advanced endoscopist and discussed at the complex polyp multi-disciplinary team meeting. Due to the extent of appendix orifice involvement, endoscopic intervention alone was deemed unlikely to be successful and Lap EMR was recommended. On admission to hospital, the patient was consented for both the procedure and video recording (appendix 14). Video recordings of both the endoscopic and laparoscopic view were taken and edited on iMovie and Microsoft Movie Maker. Supplementary slides and a voiceover were added. There were no intra or post-operative complications. The patient was discharged the following day and histology confirmed a tubulovillous adenoma with LGD. The full video presentation can be viewed by scanning the QR code or visiting the link in figure 7.5.

7.4 Discussion

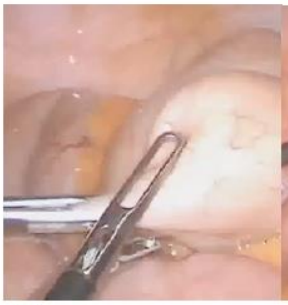
The use of Lap EMR for complex polyp removal avoided the need for bowel resection in 80% of patients selected through the Cardiff complex polyp multi-disciplinary team meeting. A low adverse event rate and short hospital stay was demonstrated for patients managed with this technique. It provides an option for patients where endoscopic excision alone of complex polyps is technically unfeasible. This research is the first describing outcomes for Lap EMR procedures managed through a systematic and objective criteria case selection by a multi-disciplinary team with a long term follow-up of up to 10 years. All patients were routinely followed up at 3 months after procedure. Subsequent follow ups were arranged in line with current BSG guidance at the time.

Comparison of these results to other series of patients having Lap EMR procedures is challenging due to their heterogeneity (53, 55, 56, 117, 131). As described previously, the terminology,

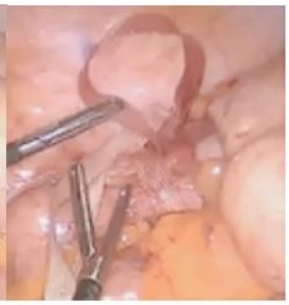
Laparoscopic assisted endoscopic mucosal resection procedure (Lap EMR)

Stage 1 – Laparoscopic assessment and mobilisation

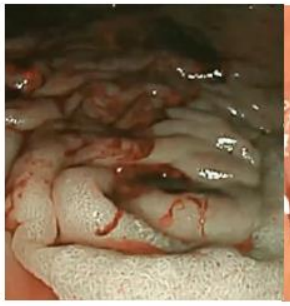
1.1 Laparoscopic assessment of the abdomen is performed with mobilisation of the caecum and appendix to facilitate endoscopic removal of the lesion.
1.2 A tape is tied around the terminal ileum to prevent small bowel distensions during colonoscopy which would obscure the laparoscopic view.



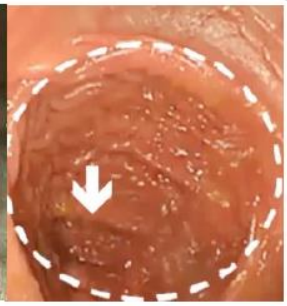
1.1



1.2



2.1



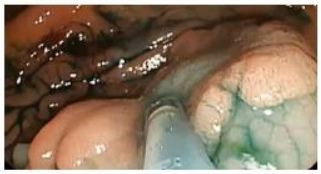
2.2

Stage 2 – Endoscopic assessment

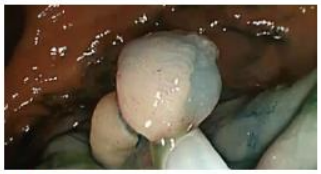
2.1 The polyp is shown on the left within the circle. The appendix orifice is marked with an arrow.
2.2 The lesions is assessed for malignancy including the use of narrow band imaging.

Stage 3 – Endoscopic mucosal resection (EMR)

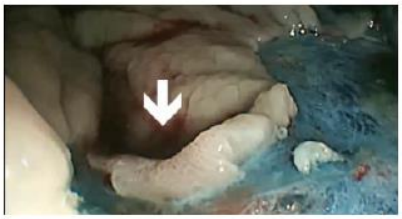
3.1 The polyp lifts easily with injection of EMR solution.
3.2 Piecemeal snare resection is performed with manipulation of the bowel by the surgeon to facilitate this.
3.3 Residual polyp remains around the appendix orifice.
3.4 The surgeon invaginates the appendix laparoscopically.
3.5 The remaining polyp can then be fully resected by the endoscopist.



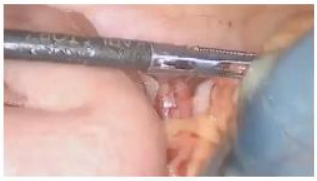
3.1



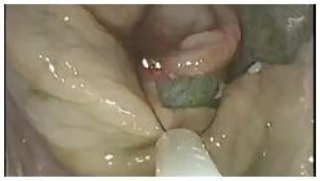
3.2



3.3



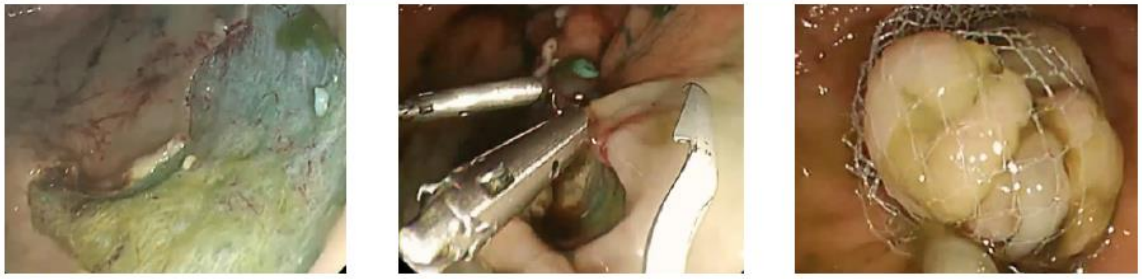
3.4



3.5

Stage 4 –Haemostasis and closure of the mucosal defect

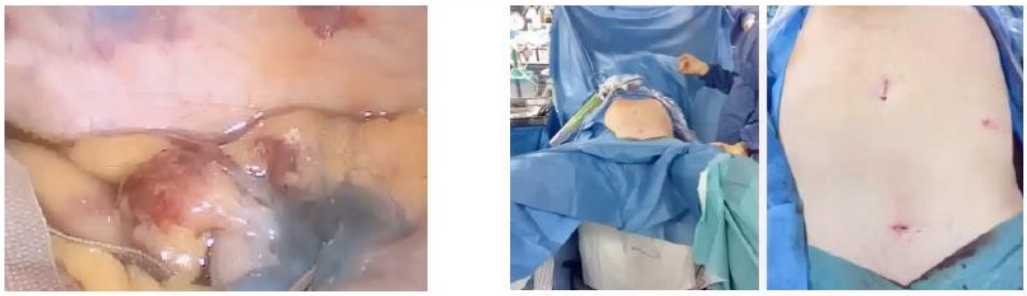
4.1 The base is carefully inspected to ensure full polyp excision. Diathermy and APC are used for haemostasis.
4.2 Clips are used to close the defect.
4.3 The specimen is removed in a net.



4.1 4.2 4.3

Stage 5 – Inspection for complications

5.1 The surgeon inspects the bowel for perforation or leak of EMR fluid which can be dealt with accordingly. There were no signs in this case.
5.2 After closure of the wounds with absorbable sutures, the patient is left with three small laparoscopic scars.



5.1 5.2

Link and QR code for lap EMR video

https://youtu.be/Uz7IOCprggU

FIGURE 7.4 – VIDEO PRESENTATION OF A LAP EMR PROCEDURE

procedures and selection criteria differ. Polyp characteristics are also variable with sizes ranging from 14 to 50mm with some studies not describing morphology (55, 96, 131). Decision-making is mostly by a single clinician which may cause bias in case selection. Some polyps may have been treatable by endoscopy alone with access to referral pathways, complex polyp expertise and advanced endoscopy. In this series, all cases underwent decision-making through the complex polyp team meeting to ensure endoscopic resection alone was unlikely to be feasible and to attempt to avoid the risks of bowel resection. The median polyp size was 37.5mm with over 90% having the highest level of complexity (SMSA level 3 and 4). The polyps classified as SMSA level 2 had justified explanations for the requirement of Lap EMR and highlights a limitation of this classification method. Most of these were peri appendiceal lesions which may be particularly suited to this technique due to challenges in their visualisation, accessibility and the risk of perforation during the endoscopic procedure (130). The median duration to treatment was 6 months with an IQR of 5 to 9 months. Performance of these interventions in a timely manner is important for several reasons. It is possible that significant delays may affect polyp resectability due to changes in size or even the development of cancer in the interim. It may also have an adverse impact on patient quality of life in terms of anxiety and dissatisfaction.

The intra operative conversion to colonic resection of 12.7% was lower than comparable studies with four describing rates more than 20% (55, 56, 96, 131). Full polyp visualisation may have not yet been achieved during diagnosis due to access difficulties without laparoscopic assistance. Lap EMR is a dynamic procedure that offers advantages in immediate assessment and decision-making throughout the procedure by two clinicians. Intra-operative conversion to colonic resection should not necessarily be deemed a failure but another key advantage of CELS techniques. The procedure time was longer than comparative studies (156 minutes vs 71.5 to 145 minutes) and may be explained by the inclusion of converted cases in the analysis and the high degree of complexity of the polyps in the series. Despite this, the length of stay was the same. Adverse events in these studies range from 4.4 to 15.3% (53, 55, 56, 96, 131) which is comparable to the figure of 7.3% reported here. The number of unsuspected cancers were low (5.5% vs 3.3 to 10.2%). The degree of complexity of polyps selected for Lap EMR and long follow-up may explain the marginally higher residual and recurrent disease rates (15.6% vs 0 to 10%) against similar studies.

The duration of follow-up reported is the longest documented for such procedures. This series has demonstrated that Lap EMR provides an effective long term treatment of selected complex polyps with minimal requirements for further intervention. It is likely that the utilisation of this technique could create significant benefits for patient recovery, functional outcomes and cost effectiveness as

compared to bowel resection. With increasing detection of complex lesions through screening programmes, this may provide better outcomes and improved cost effectiveness.

Lap EMR is not yet widely utilised. Explanations may include a lack of awareness, limited access to advanced endoscopy services or to complex polyp multi-disciplinary team decision-making. There could also be reticence in adopting the procedure due to concerns regarding unrecognised malignancy and subsequent delay in oncological staging and treatment. Clinicians may feel that a laparoscopic colonic resection provides similar outcomes and should remain the treatment for endoscopically unresectable polyps. A recent systematic review on surgically treated benign polyps reported unfavourable outcomes for patients both in terms of adverse events (24%) and mortality (0.7%) (62). A large cohort study also described 3.6% of patients needing further major surgery and 2.2% requiring a stoma (135). Other studies have similarly demonstrated high morbidity (31%) (136) and adverse events (56%) (137) for benign polyps treated by surgery. This study and others in the literature demonstrate a low risk of adverse events, major surgical reintervention, stoma formation and mortality for complex colonic polyps treated with Lap EMR when compared to bowel resection. The incidence of unexpected cancer in this series was 5.5%. The subsequent bowel resections for these patients were uncomplicated and none developed recurrent malignant disease suggesting their treatment was not compromised by the initial Lap EMR attempt.

A key characteristic of this series is the decision-making processes involving multi-disciplinary discussions with expertise in complex polyps and objective selection criteria. Patients with complex polyps should have equity of access to a full range of treatment options and the development of referral pathways and the utilisation of multi-disciplinary team decision-making may facilitate this. The rate of surgery for should be monitored in centres managing complex polyps to avoid its overuse and ensure alternative treatment modalities such as CELS have been explored.

7.3.1 Limitations

Limitations of this study include the analysis of a single centre, small cohort and its retrospective design. Cases were from a variety of centres referred onto the national referral centre but there was standardisation of patient assessment and management through meeting referral and selection criteria. Late recurrence after 16 months has been reported in some series (138), and the minimum 12 months of follow-up in this study may have been inadequate in duration to detect these.

The challenges of Lap EMR include the procedure duration, equipment requirements and need for two consultants. This can create logistical issues when planning these procedures. These limitations may be offset by the benefits of mutual decision-making by experts intraoperatively, the avoidance of bowel resection and reduction in cost associated with short hospital stays.

7.4 Conclusions

Lap EMR is an emerging CELS technique used to treat complex colorectal polyps. This study demonstrates Lap EMR provides a safe treatment modality, and the complex polyp multi-disciplinary team decision-making meeting is an appropriate decision-making process for this. It avoided bowel resection in 80% of patients with benefits of low morbidity, short length of stay and excellent long term outcomes. Further evidence regarding patient reported outcomes, quality of life and economic analyses are required for Lap EMR. Considering the variability in reporting of similar previous studies, the IDEAL recommendations for future research should be utilised. This will enable comparability and reliability of evidence for these emerging CELS techniques. Ideally direct prospective comparison between alternative treatment strategies for complex polyps is required but this may be difficult to achieve in clinical settings. The description of the complex polyp multi-disciplinary team decision-making meeting in Cardiff provides a template of an established meeting for service development or for recommendations by national guidelines.

To complete the cycle of complex polyp management, evidence-based surveillance strategies are required for the timely identification of recurrent or new disease. The current guideline recommendations for this will be reviewed in the next chapter to enable identification of evidence gaps for further research to improve their quality.

Part Three: After complex polyp treatment – understanding and improving evidence for decision-making recommendations regarding surveillance

8 A systematic review of published guidelines – influences on recommendations for surveillance of advanced or complex colorectal polyps

8.1 Introduction

The surveillance of patients after treatment of complex colorectal polyps aims to identify new, missed or recurrent lesions in a timely fashion. The risk of recurrent or metachronous disease is higher after identification of a complex polyp compared to those with simple lesions. As discussed previously, there is significant heterogeneity in the terminology and criteria for a complex polyp. In the context of international surveillance guidance, they are usually incorporated into the definitions of advanced or high risk polyps without a separate classification. The BSG define advanced polyps as sessile serrated lesions or adenomas at least 10mm in size, sessile serrated lesions with dysplasia or adenomas with evidence of HGD (73). Separate criteria are also given for large non pedunculated colorectal polyps (LNPCP) as those of 20mm or more in size. For this reason, the term advanced polyp was utilised in the design of this review to ensure it incorporated recommendations for complex polyps.

Surveillance frequency should balance the need for timely diagnosis and optimal outcomes against the risks of colonoscopy and its burden on the patient and health service. Guidelines are decision-making tools helping clinicians provide evidence-based patient management. Several international polyp surveillance guidelines have recently been updated (73-75). Recommendations for timing of surveillance should account for polyp features but also patient characteristics including overall health and their own individual preferences. Factors related to the index colonoscopy may also be important (76), with poor quality colonoscopy associated with a higher future risk of colorectal cancer (77, 78).

8.1.1 Aims

The aim of this systematic guideline review was to assess international surveillance recommendations and definitions for advanced and complex colorectal polyps. The factors considered in the development of their recommendations were compared including the patient, polyp and colonoscopy quality factors at index examination.

8.2 Methods

Guidelines with surveillance recommendations for colorectal polyps were systematically identified from the literature. The methodology was created in line with recent guidance (139). Relevant full text articles were considered for full analysis and data extraction based on the inclusion and exclusion criteria. The study protocol was registered on PROSPERO (140) and performed according to the PRISMA guidelines for systematic reviews (86).

8.2.2 Literature search and search terms

A systematic literature search was performed to identify all potential guidelines. Updates to identify new articles were used until the final analysis was performed. Databases searched included PubMed, Web of Science, Scopus and Trip Pro. Other resources as shown in appendix 15, were hand searched for further guidance and to ensure the most up to date versions had been identified.

The search terms were developed with input from specialists in the field of gastroenterology, colorectal surgery and systematic literature review. Search strategies from published guidelines were also utilised to guide the selection of terms (73). Search terms included 'guideline or practice guideline', 'recommendation', 'surveillance', 'intestinal polyps', 'colonic polyps', 'colorectal neoplasm', 'adenoma or adenomatous polyps' and 'polypectomy'. The full strategy is shown in appendix 16.

8.2.3 Inclusion criteria

Evidence-based national or international guidelines describing surveillance recommendations after colorectal polyp diagnosis in adults were considered. Those guidelines with specific recommendations regarding advanced polyps, complex polyps or an equivalent definition were included for full text review. The guidelines were deemed appropriate if exclusively describing advanced polyp surveillance or if the subject was part of a defined section in wider recommendations. If multiple guidelines were produced by the same group, the most recent was used for the analysis. No journals or countries of publication were excluded. All articles were initially considered regardless of the year of publication or language.

8.2.4 Exclusion criteria

Local or departmental guidelines were excluded from the review. Guidance exclusively for malignant or hereditary polyps were excluded due the specific considerations required for their surveillance. All articles were initially considered regardless of language but were excluded later if translation was not feasible. Guidelines published in draft form or as conference papers were not included due to the lack of peer review and unavailability of the full guideline respectively.

8.2.5 Guideline identification

Guidelines were identified with the same methodology as described in section 4.2.5 Any supplementary materials for the included guidelines were also obtained. Identified guidelines, article abstracts referring to a guideline, and systematic review articles were cross referenced to find other relevant articles. The identified articles were reviewed as above for inclusion or exclusion.

8.2.6 Data extraction and analysis

Data extraction was performed by the same two blinded researchers onto separate, standardised spreadsheets and variations were resolved as described in the previous systematic review. Information was collected and narrative descriptions and comparisons performed on the guideline characteristics, definitions of advanced and complex polyps, surveillance timings, levels of evidence, strength of recommendations and the polyp, patient and colonoscopy quality factors at index examination on which the recommendations were based. Data analysis was performed by one researcher and cross checked by a second using Microsoft Excel.

8.2.7 Assessment of guideline quality

The Appraisal of Guidelines for Research and Evaluation, 2nd Edition (AGREE II) instrument (141) is a validated tool designed to assess the quality of guideline development and methodology. As shown in table 8.1, it contains 23 items within 6 domains including scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability and editorial independence. Each item is scored out of 7 (1= strongly disagree, 7= strongly agree) to give a total across the domains. The final evaluation is an overall recommendation of the guideline for future use. Interpretation is determined by the users and the context of the review.

Guidelines were scored using the AGREE II criteria by two reviewers. Both reviewers completed the tutorials on the use of the instrument and utilised the handbook during the assessments. Each guideline was assigned a score for each item by the researchers allowing a scaled domain score to be calculated based on the AGREE II formula. Guidelines were included regardless of score and comparisons were made between them. The guidelines were classified based on the scaled domains scores into high quality (5 or more domains scoring 60% or more), average quality (3 to 4 domains scoring 60% or more) or poor quality (2 domains or less scoring 60% or more). A similar system has been used by other guideline reviews (142-144).

TABLE 8.1 – SCORING CRITERIA FOR THE APPRAISAL OF GUIDELINES FOR RESEARCH AND EVALUATION INSTRUMENT 2ND EDITION (AGREE II) INSTRUMENT

Domain	Item
Scope and purpose	1. The overall objective(s) of the guideline is (are) specifically designed 2. The health question(s) covered by the guideline is (are) specifically described 3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described
Stakeholder involvement	4. The guideline development group includes individuals from all the relevant professional groups 5. The views and preferences of the target population (patients, public, etc.) have been sought 6. The target users of the guideline are clearly described
Rigour of development	7. Systematic methods were used to search for evidence 8. The criteria for selecting the evidence are clearly described 9. The strengths and limitations of the body of evidence are clearly described 10. The methods for formulating the recommendations are clearly described 11. The health benefits, side effects, and risks have been considered in formulating the recommendations 12. There is an explicit link between the recommendations and the supporting evidence 13. The guideline has been externally reviewed by experts prior to its publication 14. A procedure for updating the guideline is provided
Clarity of presentation	15. The recommendations are specific and unambiguous 16. The different options for management of the condition or health issue are clearly presented 17. Key recommendations are easily identifiable
Applicability	18. The guideline describes facilitators and barriers to its application

	19. The guideline provides advice and/or tools on how the recommendations can be put into practice 20. The potential resource implications of applying the recommendations have been considered 21. The guideline presents monitoring and/or auditing criteria
Editorial independence	22. The views of the funding body have not influenced the content of the guideline 23. Competing interests of guideline development group members have been recorded and addressed

8.3 Results

8.3.1 Guideline selection

The PRISMA flowchart is shown in figure 8.1. A total of 6536 articles were identified and 73 guidelines concerning the surveillance of colorectal polyps were identified within these. Five of these fulfilled the inclusion criteria for full assessment and data extraction with a further guideline was identified through citation updates. These included guidance from the US Multi-Society Task Force (USMSTF) (75), BSG (73), Cancer Council Australia (CCA) (145), ESGE (74), Japan Gastroenterological Endoscopy Society (JGES) (146) and Asia-Pacific Working Group on Colorectal Cancer Screening (147).

The classification of excluded articles is shown in appendix 17. There were several guidelines that considered to have been replaced by more recent documents. The National Institute for Health and Clinical Excellence (NICE) (148) and Scottish Intercollegiate Guidelines Network (SIGN) (149) from 2011 and 2016 respectively were deemed to have been succeeded by the BSG guidance. Guidance from the Canadian Association of Gastroenterology (150) was excluded as they were based on the 2012 USMSTF recommendations and had not been modified since the American guidelines more recent update. The ESGE guidelines were utilised instead of several identified European documents as they were all outdated by this. They included French (151), Norwegian (152), Swiss (153), Spanish (154), German (155) and Dutch publications (156).

8.3.2 Guideline characteristics

An overview of guideline development method, assessment of evidence and recommendation gradings are given in table 8.2. All were published within the last three years and are updated

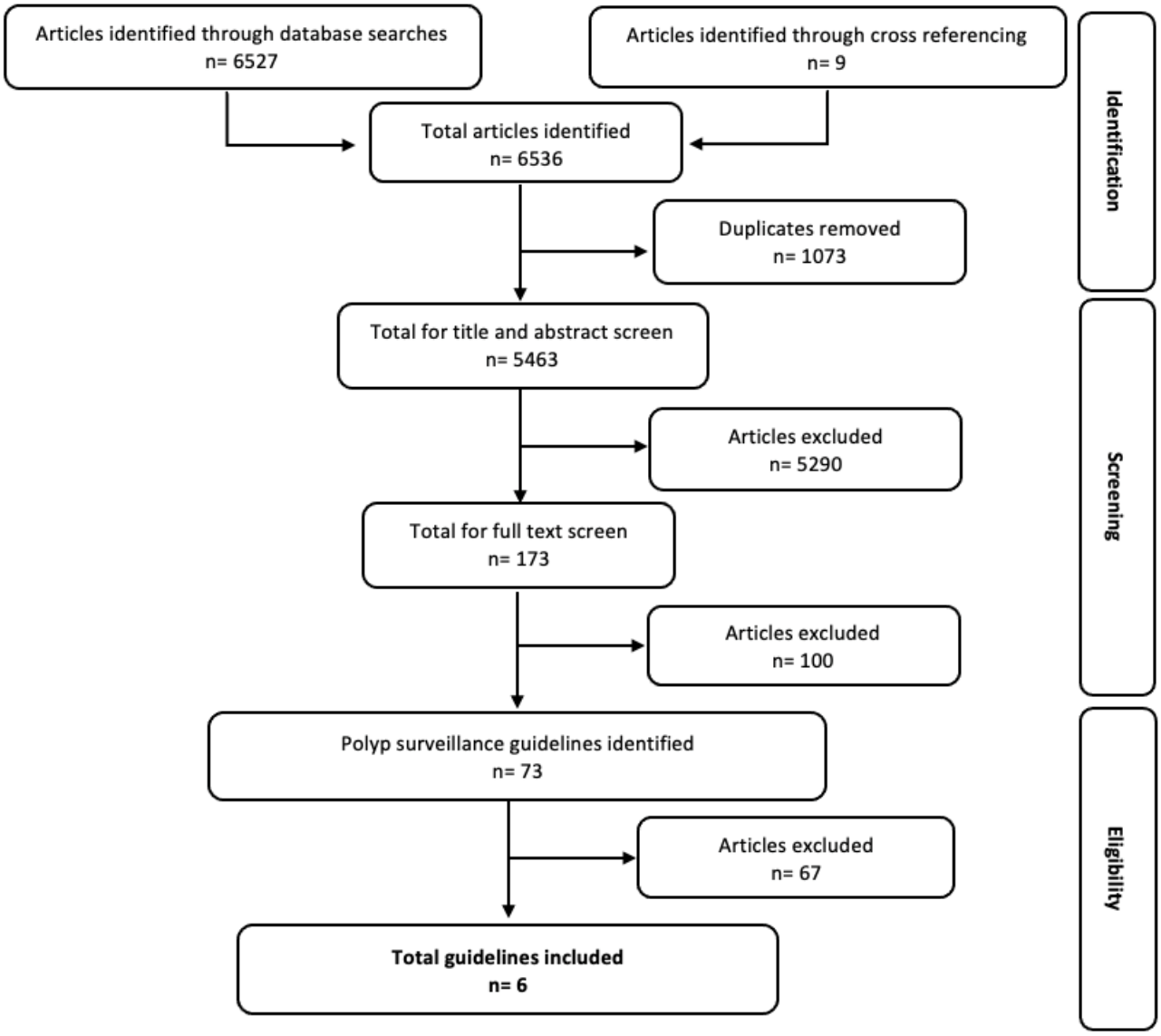


FIGURE 8.1 – PRISMA FLOW DIAGRAM

TABLE 8.2 – GUIDELINE CHARACTERISTICS

	Country	Year	Development method	Evidence assessment and recommendation grading
USMSTF	USA	2020	Recommendations produced through consensus discussion amongst authors	**GRADE system:** ***Strength of recommendation*** – rated strong or weak ***Quality of evidence*** – rated very low, low, moderate, or high
BSG	UK	2020	Recommendations produced according to BSG guideline development process utilising Delphi consensus	**GRADE system**
CCA	Australia	2019	Recommendations produced according to 2011 NHMRC* standard for clinical practice guidelines utilising consensus voting	**NHMRC levels of evidence and grades for recommendations for developers of guidelines:** ***Type of recommendation –*** Evidence-based, consensus based or practice point ***Grade of recommendation*** – A: Evidence trusted to guide practice, B: Evidence trusted to guide practice in most situations, C: Evidence provides some support but care should

				be taken in its application, D: Evidence is weak and recommendation must be applied with caution
ESGE	Europe	2020	Recommendations produced by consensus	**GRADE system**
JGES	Japan	2021	Recommendations produced through modified Delphi consensus	**2014 Minds Guide for Developing Clinical Practice Guidelines:** ***Recommendation strength* –** 1: highly, 2: weakly, none: cannot make a clear recommendation ***Evidence level* –** A: strong evidence, B: moderate evidence, C: weak evidence, D: minimal evidence
Asia-Pacific Working Group	Asia	2022	Recommendations produced through modified Delphi consensus	**Voting, quality of evidence and classification of recommendations** ***Likert scale level of agreement* –** A: Accept completely, B: accept with some reservation, C: accept with major reservation, D: reject with some reservation, E: reject completely ***Classification of recommendations* –** A: good evidence to support the statement, B: fair evidence to support the statement, C: poor evidence to support the statement, D: fair

evidence to refute the statement, E: good evidence to refute the statement

Quality of evidence – I: evidence obtained from at least one RCT**, II-1: evidence obtained from well-designed control trials without randomisation, II-2: evidence obtained from well-designed cohort or case–control study, II-3: evidence obtained from comparison between time or places with or without intervention, III: opinion of respected authorities, based on clinical experience and expert committees

** NHMRC - National Health and Medical Research Council, ** RCT - randomised controlled trial*

versions of previous guidance. A systematic literature review was performed by all during their development. Most used the grading of recommendations, assessment, development and evaluations (GRADE) system for their evidence assessment and recommendations, but the Australian, Japanese and Asia-Pacific guidelines used different standards.

8.3.3 Terminology and criteria for advanced polyps

8.3.3.1 Advanced adenomas

A summary of the advanced polyp definitions and surveillance recommendations for each guideline is shown in table 8.3. The JGES and USMSTF guidelines used the same term of advanced adenoma with the CCA and Asia-Pacific Working Group using high-risk adenoma. The BSG used advanced colorectal polyp. The ESGE guidelines did not use a definition for an advanced polyp but classified patients into those requiring surveillance or not. Criteria of size (≥10 mm) and inclusion of polyps with high-grade dysplasia to meet the definition of an advanced polyp were unanimous between all guidelines. Unlike the ESGE and BSG guidelines, the USMSTF, CCA, JGES and Asia-Pacific Working Group recommendations also included adenomas with villosity as part of their definition. Multiple lesions were included under the heading of advanced polyps in the CCA, Asia-Pacific Working Group and ESGE recommendations but with different criteria of 3 to 4, ≥3 lesions and ≥5 lesions respectively.

8.3.3.2 Advanced serrated lesions

A summary of the advanced serrated lesion definitions and surveillance recommendations for each guideline is shown in table 8.4. Polyps with serrated histology were inclusive of the advanced polyp definition provided by the BSG and ESGE guidelines. They both described these as lesions ≥10mm in size or with any grade of dysplasia. The JGES guidelines did not give a definition for an advanced serrated polyp. The USMSTF and Asia-Pacific Working Group recommendations provided separate surveillance recommendations for sessile serrated polyps ≥10 mm or with dysplasia but did not provide terminology for these. The Australian recommendations concerning serrated polyps were complex. They did not define an advanced serrated polyp and recommendations regarding surveillance depend on the size, number, presence of dysplasia and synchronous adenomas.

8.3.3.3 Large or complex polyps

The BSG and CCA guidelines also considered larger lesions separately within their recommendations. The definition of these were the same (size ≥20mm) but with different terminology. The British guidelines referred to these as LNPCPs whilst the Australian recommendations used large sessile or laterally spreading lesions.

8.3.4 Recommendations for surveillance

All guidelines recommended colonoscopy as the primary method of surveillance with the BSG and Australian guidelines accepting CT colonography as an alternative where colonoscopy was not appropriate. The USMSTF, CCA, ESGE, JGES and Asia-Pacific Working Group recommendations all advised a standard surveillance timing of three years after the diagnosis and removal of an advanced colorectal polyp. Although surveillance at 3 years is still recommended, the BSG guidance differs as at least 2 polyps, with one meeting the requirements of an advanced polyp or a single LNPCP must be identified. A shorter surveillance interval of 12 months is recommended by the CCA for large sessile or laterally spreading lesions and JGES for lesions ≥20mm.

For serrated lesions, the surveillance interval was 3 years for the USMSTF, BSG, ESGE and Asia-Pacific Working Group. The JGES did not provide specific recommendations for serrated lesions. The CCA recommendations for serrated lesions were complex with intervals ranging from 1 to 3 years depending on lesion characteristics. A comprehensive overview of these is provided in appendix 18.

Shorter surveillance intervals for piecemeal polyp removal in all guidelines were recommended for lesions meeting certain criteria. Similar to the ESGE recommendation of 3 to 6 months for piecemeal excisions of lesions greater than 20mm, the USMSTF also suggested a 6-month follow-up in polyps of this size. The BSG recommended that surveillance should be performed in 2 to 6 months where the excision completeness of an advanced polyp could not be determined or in piecemeal excisions of LNPCP's. The suggested interval by the CCA of 12 months for large sessile or laterally spreading lesions is reduced to 6 months in the case of piecemeal removal. The JGES state that a 6-month surveillance should be performed if any advanced adenomas are excised in a piecemeal nature. The Asia-Pacific Working Group did not provide specific recommendations for piecemeal excisions.

Most of the evidence regarding surveillance timings was assessed as low to moderate quality but despite this, the recommendations were mostly strong for those using the GRADE system. In contrast the JGES recommendations were classified as level 2 (weak). The CCA recommendations were consensus based which means admissible evidence on the clinical question was not found.

8.3.5 Factors at index colonoscopy guiding surveillance recommendations

8.3.5.1 Polyp factors

As all six guidelines based their surveillance recommendations predominantly on the polyp features at index examination, they are already described in detail above in the terminology and criteria for advanced polyps, recommendations for surveillance and in table 8.3.

TABLE 8.3 – DEFINITIONS AND RECOMMENDATIONS FOR SURVEILLANCE OF ADVANCED ADENOMAS

	Terminology and criteria	Surveillance recommendations	Recommendations for piecemeal excisions
USMSTF	**Advanced adenoma** Size ≥ 10mm, tubulovillous/villous histology or HGD	**3 years** (Strong recommendation, moderate to high GRADE evidence)	**6 months for lesions ≥ 20 mm** (Strong recommendation, moderate GRADE evidence)
BSG	**Advanced colorectal polyp** - Advanced adenomatous polyp - Size ≥10mm or HGD - Advanced serrated polyp - Size ≥10mm or any grade of dysplasia **LNPCP** Size ≥20mm	**3 years if ≥2 pre-malignant polyps including ≥1 advanced polyp or one LNPCP** * (Strong recommendation, low GRADE evidence)	**2-6 months in piecemeal excisions of LNPCP's [a] or where excision completeness cannot be determined in advanced polyps [b]** ([a] Strong and [b] weak recommendations, low GRADE evidence)
CCA	**High risk adenoma** Size ≥10mm, HGD, villosity or 3-4 adenomas **Large sessile/laterally spreading lesion**	**3 years for high-risk adenomas** (Consensus based recommendation**)	**6 months for large sessile or laterally spreading lesions** (Consensus based recommendation)

	Size >20mm	**12 months for large sessile or laterally spreading lesion** (Consensus based recommendation)	
ESGE	**Patients requiring surveillance** 1 adenoma ≥10 mm or HGD, serrated polyp ≥10 mm or with dysplasia, ≥5 adenomas	**3 years** (Strong recommendation, moderate GRADE evidence)	**3–6-months for lesions ≥ 20mm** (Strong recommendation, moderate GRADE evidence)
JGES	**Advanced adenoma** Size ≥ 10 mm, tubulovillous/villous histology or HGD	**3 years for advanced adenoma reduced to 1 for lesions ≥ 20mm** (Strength of recommendation 2, evidence level B)	**6 months**
Asia-Pacific Working Group	**High risk adenoma** Three or more adenomas, size >10mm, villous or HGD	**3 years** (Classification of recommendation A, quality of evidence II-2)	**No recommendation**

** If under 75 years ** A recommendation formulated in the absence of quality evidence, after a systematic review of the evidence was conducted and failed to identify admissible evidence on the clinical question*

8.3.5.2 Patient factors

The consideration of patient factors at index examination in the recommendations of surveillance intervals was varied between the included guidelines. A summary is shown in table 8.5. The American, Japanese and Asia-Pacific Working Group guidelines did not document any patient factors at index examination to be used in influencing surveillance timings for advanced polyps. The BSG, ESGE and CCA guidelines which did identify such factors recognised that this was based on limited evidence or opinion only.

The commonest patient factors considered were regarding the parameters where surveillance should not be performed. BSG guidance suggested that surveillance should only be performed in those with a life expectancy greater than 10 years and in general, not in those older than 75. The ESGE recommendations are similar suggesting stopping follow-up at the age of 80, or earlier if comorbidities are thought to limit life expectancy. These were both weak recommendations based on a low grade of evidence. The Australian guidelines are more complex. They promote the utilisation of shared decision-making in the elderly when considering surveillance. They advise the use of an objective method of assessing life expectancy such as the CCI score (82). With an age of 75 to 80 and score of four or less then surveillance should be considered, but not if greater than 4. Surveillance is not recommended in those over 80 years. The USMSTF or JGES guidelines did not provide recommendations for surveillance cessation. In addition, the BSG guidelines recommended balancing benefits of surveillance against its risk and cost to both patient and health services. They stated this should be explained to patients as part of shared decision-making regarding follow-up.

8.3.5.2 Colonoscopy quality factors

A summary of the factors considered by the guidelines regarding the quality of baseline colonoscopy is shown in table 8.6. All guidelines recognised the importance of quality in index colonoscopy in the applicability of their surveillance recommendations with the USMSTF, BSG, CCA and Asia-Pacific Working Group suggesting further research or benchmarking concerning this. The parameters required for quality colonoscopy were variable. The USMSTF, CCA and BSG all provided advice regarding completeness of examination with overall rates of greater than 95% and 90% quoted for the USMSTF and CCA guidelines respectively. The BSG stated that the individual colonoscopy should be complete to the caecum with an early repeat procedure if not, which is also advised in the case of poor bowel preparation. This advice is also given by the ESGE guidance. The USMSTF guidance advises overall adequate bowel preparation rates of greater than 85% to reliably detect lesions over 5mm. Both the CCA and USMSTF quote required ADRs for colonoscopists performing the index examination. The USMSTF guidelines advise an ADR of greater than 30% or 20% in men and women

TABLE 8.4 – DEFINITIONS AND RECOMMENDATIONS FOR SURVEILLANCE OF ADVANCED SERRATED LESIONS

	Terminology and criteria	**Surveillance recommendations**
USMSTF	**Not defined** Sessile serrated polyp ≥10mm or with dysplasia	**3 years** (Weak recommendation, very low quality of evidence)
BSG	**Advanced serrated polyp** Size ≥10mm or any grade of dysplasia	**3 years if ≥2 pre-malignant polyps including ≥1 advanced polyp or one LNPCP** * (Strong recommendation, low GRADE evidence)
CCA	**Not defined** Various criteria	**1 to 5 years** *
ESGE	**Patients requiring surveillance** Serrated polyp ≥10 mm or with dysplasia	**3 years** (Strong recommendation, moderate GRADE evidence)
JGES	**Not defined**	-
Asia-Pacific Working Group	**Not defined** Sessile serrated lesion >10mm or with cytological dysplasia	**3 years** (Classification of recommendation B, quality of evidence III)

**Full details can be seen in appendix 18*

respectively but this rate is greater than 25% in the Australian document. No reference to ADR requirements were made in the remaining guidelines. The USMSTF, BSG, CCA and ESGE documents agree that the colon should also be completely cleared of identified polyps. The JGES provide some background relating to quality indicators for colonoscopy, but without relation to their surveillance recommendations. They do suggest a withdrawal time of at least 6 minutes for baseline colonoscopy which is mirrored in the CCA document. Accepted withdrawal times are not given in the other three guidelines.

The ESGE guidelines quote recommendations from their own organisation and the World Endoscopy Organisation (WEO) regarding quality requisites for baseline colonoscopy (157, 158). Consensus was reached in the WEO recommendations regarding completeness of examination, quality of bowel preparation and completeness of polyp excision. The ESGE performance measures for lower gastrointestinal endoscopy included key performance measures of adequate bowel preparation rate (≥90%), caecal intubation rate (≥90%) and ADR of at least 25%.

The assessment of evidence regarding colonoscopy quality varied between the guidance. For the USMSTF, a formal assessment of evidence was not performed and the BSG assessed the evidence as low regarding bowel preparation and completion of examination. As the ESGE statements were based on preceding review documents, they gave strong recommendations regarding this but based on a moderate level of evidence. The CCA's statements regarding colonoscopy quality were given as practice points which are based on expert opinion and consensus only. The JGES was similar in assessing the level of evidence as weak. The USMSTF, BSG and CCA all recognised the importance of understanding colonoscopy quality factors through research in the improvement of surveillance recommendations. This included the effect of incomplete examination, poor bowel preparation, incomplete polyp removal and ADRs.

8.5.6 Assessment of guideline quality

The AGREE II instrument was used to assess the quality of the guidelines by two reviewers. An overview of the scores is shown in table 8.7. The BSG and CCA guidelines were rated as high quality with a scaled domain score of over 60% in all categories. The remaining guidelines were all rated as of average quality with scores less than 60% for all these guidelines in the stakeholder development and applicability domains. These low scores were explained in all guidelines by an absence in involvement of patient or public representatives in the stakeholder development domain. There were also low scores for resource implications of the recommendations and monitoring or auditing criteria in the applicability domains.

TABLE 8.5 – PATIENT FACTORS AT INDEX COLONOSCOPY

	Patient factors
USMSTF	None described
BSG	1. The benefits and risks of surveillance should be explained to patients, who should be involved in shared decision-making. The risks and benefits of non- adherence to surveillance should also be explained. 2. The impact of surveillance in terms of CRC risk reduction should be balanced with the risks of harm (for example, colonoscopy complications or psychological distress) and the costs to both the health service and patients. 3. Patients should be made aware of other evidence-based interventions that could reduce their risk of CRC and/or polyp recurrence. These could include lifestyle and behavioural modifications (e.g., stopping smoking and reducing red meat consumption) as well as medications (e.g. aspirin). 4. Age and life expectancy.
CCA	1. Patients with large sessile and laterally spreading lesions should be informed of the requirement for scheduled surveillance before proceeding to EMR (practice point). 2. Clinicians should advise patients that modification of lifestyle factors can reduce their risk of polyp recurrence (practice point).
ESGE	1. ESGE suggests that individuals with symptoms in the surveillance interval should be managed as clinically indicated (weak recommendation, low quality evidence).

JGES	None described
Asia-Pacific Working Group	None described

Both reviewers felt that all guidelines could be recommended for use despite the limitations in some areas of guideline quality.

8.4 Discussion

This review demonstrates that international surveillance guidelines for advanced colorectal polyps are of good quality but limited by their underlying evidence. The consistency in recommendations regarding surveillance timings is reassuring, but the terminology and criteria used for advanced polyps was variable. The emphasis on polyp factors as the key determinant for when surveillance should be performed was the same amongst all guidelines. Given the increasing detection of advanced polyps and a significant number of surveillance examinations in screening being inappropriate (159), improvement of the evidence base and guidance implementation is warranted.

The limited application of evidence regarding the influence of patient characteristics and the quality of baseline colonoscopy should be addressed as a significant area for improvement. The principles of informed choice and shared decision-making with patients should be applied when offering surveillance and be accounted for in recommendations. Three of the included guidelines discussed patient factors regarding surveillance timings but only the BSG and CCA involved representatives in their development process. Recommendations for when surveillance should not be performed were variable in the three documents discussing it reflecting the low quality of underlying evidence. The USMSTF and BSG both acknowledge further evidence is required for surveillance at the extremes of age with research concerning comorbidities also recommended by the USMSTF. The BSG stated the need to develop evidence in personalised surveillance algorithms, patient experience, preferences and compliance. The research gap regarding patient opinion and experience of endoscopy is significant (160), with knowledge in this field potentially having considerable effects on future recommendations provided. Individual patient assessment in terms of age, comorbidities and life expectancy should also be standardised. Based on the above, a proportion of patients will not develop clinically significant new or recurrent disease and should not be exposed to the risks of further examinations. This could economise surveillance further but must be evidence-based.

The quality of baseline colonoscopy may be the keystone to economising surveillance recommendations. If the risk of missed lesions is negligible after a high-quality colonoscopy and complete polyp removal, the need for further examination may be considerably reduced or not required at all. By not identifying lesions, low quality examinations may also underestimate the surveillance required. All guidelines recognised the importance of this but differed in their criteria for quality examination. Parameters such as ADR, completion rate, satisfactory bowel preparation

and withdrawal time were not standard between the guidelines and their applicability will vary depending on whether performed in a screening or symptomatic cohort. The association between ADR and risk of subsequent cancer or advanced adenomas has been reported (77, 78, 161). Efforts improving colonoscopy quality standards and KPIs may be challenging but could have considerable effects on surveillance resources. It should be noted that quality indicators for colonoscopy may also be provided through separate guidelines such as those provided by the Joint Advisory Group on Gastrointestinal Endoscopy (JAG) in the UK. The implementation and assurance of these are crucial with accountability needed to maintain quality both in screening and symptomatic services. This has been the focus of a recent American Gastroenterological Association review on strategies to improve quality of screening and surveillance colonoscopy (162). This provides standards and highlights the importance of measuring, tracking and providing feedback of colonoscopist specific quality measures including caecal intubation rate (≥90%), withdrawal time (≥6 minutes), ADR (≥30%) and serrated lesion detection rate (≥7%).

A recent narrative review comparing surveillance recommendations of the USMSTF, ESGE and BSG guidance for all colorectal polyps has been performed (163). This identified variability in surveillance recommendations for certain lesions but like these findings, found intervals specific for advanced lesions to be consistent. A challenge of this review has been the synthesis and comparison of guidelines due to inconsistent polyp terminology and classifications. The JGES and USMSTF guidelines and the CCA and Asia-Pacific Working Group were the only ones using the same term of advanced adenoma and high-risk adenoma respectively. The subclassification of larger polyps (≥20mm) was only performed by the BSG and CCA and inclusion of advanced serrated polyps, multiple lesions or villous features in advanced polyp definitions was different between all guidelines. This may result in challenges with interpretation and application to research and clinical practice. Gaps in knowledge of surveillance recommendations has been identified as a reason for non-compliance (164, 165) and the variability and complexity of definitions may explain this. Provisions to make recommendations user friendly should be implemented and feedback regarding the ease of guideline use by clinicians may be beneficial.

All guidelines were assessed as being average to high quality based on the AGREE II instrument. Limitations identified included the involvement of patient representatives, guideline implementation and variation in evidence assessment. Given the paucity of evidence on patient experience in surveillance, all guidelines should encourage the involvement of patient representatives during their development. Its use however, must be more than just a formality in meeting guideline quality standards. Only two of the included publications described patient or public involvement. The BSG guidelines describe the use of patient representatives but do not elaborate further on how they

contributed. The CCA guidelines sent their draft for a one month consultation period. Again, they do not describe the feedback from this or how it modified the final document. Despite the obvious benefits of patient involvement in such developments, their use and input must be formalised. Selection of those involved to avoid bias and ensure an accurate representation of the population concerned is important. Collection of information should be in an atmosphere that encourages honesty. Multiple rather than just a single individual may be required to avoid the impact of overwhelmingly positive or negative experiences. A recent editorial has recognised the importance, as well as the challenges, surrounding patient involvement in developing clinical guidelines and suggests three principles to optimise their involvement (166). The use of a range of available resources, not limited to only high levels of evidence, should be scrutinised in guideline development. A diverse selection of patients should also be accommodated, not only in terms of background, but also regarding stage of disease and its extent. Finally, measures should be taken to ensure equity considering not all individuals have equal healthcare access. All these principles could be easily applied to future polyp surveillance guidelines. Specific research in this field to develop protocols, guidelines and governance will be important to allow the best quality information to be utilised from patient participants.

Direct patient involvement in decision-making meetings is a further interesting concept. Delivery of a recommendation of treatment to a patient after the meeting itself, may disempower individuals and undermine shared decision-making (167). In other settings, patient participation in meetings have been described as positive, but intense (168). Although attendance of a patient at a meeting may have logistical and ethical challenges, a modified model may be required. This may change between settings but may also involve documented discussions with the patient before meetings, or a nominated patient representative.

Guidance and strategies to improve implementation and adherence is also crucial. A systematic review in 2019 identified that international adherence to polyp surveillance guidelines was remarkably low with over 50% of patients not receiving surveillance at an appropriate time (169). Within European guidelines, adherence for high risk lesions was 73.6%, but was significantly lower for low risk lesions at 24.4%. Implementation advice produced by guidelines may help this. Research assessing barriers to guideline adherence has identified three main areas affecting their implementation by physicians (170). Complexity of guidelines, weak or conditional recommendations and limited time due to clinical commitments all negatively impacted their use. The variability in the assessment of evidence by different guidelines also highlights potential inconsistencies in interpretation of data or impact of different rating systems. A standard instrument such as the GRADE system, which is an international applicable and endorsed method, may be

beneficial. Simplicity, awareness, ease of use and a robust evidence base for all guidelines should be considered in development to encourage their use and application.

8.4.1 Limitations

Limitations of this study included the review of only the most current international guidelines. Others may have been inappropriately excluded on the assumption there were no longer widely utilised. Given that the guidelines included covered a wide geographical area, this review should be representative. This review did not cover the recommendations for multiple lesions in detail, but these have been assessed recently elsewhere (163). The focus on advanced lesions was due to complexities of their management and higher risk of recurrent disease. It also provides a more detailed insight into the factors considered in the recommended timings to identify areas where improvement or future research is needed.

8.5 Conclusions

International surveillance guidelines for advanced colorectal polyps can be recommended for use. Standardisation in definitions would be valuable and potentially improve understanding and adherence by users. Better knowledge of patient experience and clinical factors in the identification of those who will never come to harm by future pathology is of great importance. Research into colonoscopist specific quality indicators is also highly recommended to further economise surveillance recommendations, minimise patient risk and reduce pressure on services and resources. This shall be the focus of the final chapter of this thesis.

TABLE 8.6 – QUALITY FACTORS OF INDEX COLONOSCOPY

	Colonoscopy quality factors	Standard of evidence
USMSTF	**High-quality colonoscopic examination** - Adequate bowel preparation rates >85% (to reliably detect lesions >5mm) - Colonoscopists with adequate ADR of >30% in men and >20% in women - Completion rates to caecum >95% - Attention to complete polyp excision - Parameters outlined above should be monitored as quality metrics in practice	Formal assessment of evidence not performed
BSG	**Acceptable minimum quality colonoscopy** - At least adequate bowel preparation - Complete colonoscopy to the caecum - Clearance of all identified premalignant polyps - Early re-examination if bowel preparation is poor or colonoscopy incomplete	Low GRADE evidence for bowel preparation and completion of examination
CCA	**High-quality colonoscopy** - Colonoscopists should maintain ADR >25% (patients >50 without diagnosis of IBD) - Unadjusted rates for caecal intubation ≥90%	Practice point *

	- Withdrawal time of >6 minutes (without polypectomy) - Colon has been cleared of all significant neoplasia - Colonoscopists should be certified, undergo regular re-certification and have training to increase PDRs	
ESGE	**High-quality colonoscopy based on ESGE and WEO guidance** - Repeat colonoscopy in one year if bowel preparation inadequate - Polyps completely removed	Strong recommendation, Moderate GRADE evidence
JGES	**Withdrawal time of at least 6 minutes (if no lesions)**	Strength of recommendation 2, evidence level C
Asia-Pacific Working Group	**Quality control of colonoscopy is mandatory for colorectal cancer screening programmes and benchmarks should be determined**	Classification of recommendation A, quality of evidence II-2

** A recommendation on a subject that is outside the scope of the search strategy for the systematic review, based on expert opinion and formulated by a consensus process*

TABLE 8.7 – AGREE II SCALED DOMAIN SCORES

	Domain 1 *Scope and purpose*	**Domain 2** *Stakeholder involvement*	**Domain 3** *Rigour of development*	**Domain 4** *Clarity of presentation*	**Domain 5** *Applicability*	**Domain 6** *Editorial independence*	**Overall quality**
USMSTF	97.2%	52.8%	74.0%	96.4%	29.2%	95.8%	Average
BSG	100%	97.2%	96.9%	100%	95.8%	91.7%	High
CCA	97.2%	94.4%	99%	97.2%	97.9%	100%	High
ESGE	97.2%	58.3%	75.0%	96.4%	31.3%	95.8%	Average
JGES	83.3%	50%	77.1%	88.9%	45.8%	91.7%	Average
Asia-Pacific Working Group	97.2%	41.7%	67.7%	88.9%	20.8%	91.7%	Average

Scaled domain scores were calculated using the formula: (Obtained score – Minimum possible score)/(Maximum possible score – Minimum possible score)x100

9 The potential impact of colonoscopy quality in a screening programme on the risk of future advanced polyps and cancer – an analysis of linked data

9.1 Introduction

Colorectal cancer screening programmes aim to reduce mortality from colorectal cancer through detecting malignancies at an earlier stage. A significant number of colorectal polyps, thought to be the precursors of cancer, are also identified through screening. In Wales, 13.3% of individuals attending bowel screening colonoscopies are found to have colorectal cancer and 70.1% have polyps identified (171).

The proportion of colonoscopies where a polyp or adenoma is identified during the examination is known as the PDR and ADR. They are considered a surrogate indicator of colonoscopy quality as they may represent a more thorough examination of the colon. Current evidence suggests that improving these rates in low detectors may reduce the risk of subsequent colorectal cancer diagnoses (77). It is unclear whether an upper threshold exists above which increases becomes less clinically meaningful. There is less evidence regarding the risk of developing advanced polyps after index screening colonoscopy. A recent study has estimated this to be up to 10% during surveillance in a screening population, but for those who had a polypectomy at index examination (172). There are likely to be better outcomes if high risk polyps rather than malignancies are identified and removed at surveillance, but this must be balanced against the resource and capacity consequences this may have within a surveillance programme. The detection of large colorectal polyps or those with advanced histology has increased with the introduction of bowel screening (39) and their consideration in the development of surveillance guidelines warrants investigation.

The established performance monitoring and standardised documentation of data from screening programmes provides a controlled dataset for research. Screening colonoscopists in the UK are an accredited group with higher levels of performance required for colonoscopy KPIs. Their performance is monitored to ensure screening standards are met through quality assurance (QA) and includes PDR, ADR and scope withdrawal time. It is currently unknown whether there is a threshold beyond which increases in PDR and ADR do not translate to significant additional gains in the detection and outcomes of colorectal cancer and polyps at surveillance. As identified in the previous chapter, evidence regarding thresholds relating to an upper limit for colonoscopist specific

quality indicators is limited. Understanding these could have a significant impact on economising surveillance, guiding training, improving endoscopy quality and predicting the utility of new technology such as artificial intelligence assisted colonoscopy.

9.1.1 Post colonoscopy colorectal cancer (PCCRC) definitions

PCCRC is a valid indicator of the quality of colonoscopy services and is defined as colorectal cancers appearing after a colonoscopy in which no cancer is diagnosed. Its use is endorsed by a WEO consensus statement recommending that PCCRC rate should be reported as a benchmark measure in the assessment of quality within a colonoscopy service (173). Although acceptable rates of PCCRC have not been standardised (173), a meta-analysis has reported a PCCRC of 8.2% at 3 years (174). Burr has described the considerable variation in PCCRC rates across the UK with an overall 3 year rate of 7.4% (162). Patients undergoing colonoscopies within screening programmes had a lower rate of 3.6%. In addition to the differences in colonoscopy services, another explanation for this variability may relate to range of calculation methods for PCCRC. Morris et al has described the impact of different methods on the values reported and proposes a standardised approach which has more relevance to patients undergoing a colonoscopy (175).

9.1.2 Aims

The aim of this study was to assess the impact of KPIs in a high polyp detector group on the future risk of advanced polyps and colorectal cancer diagnoses within 3 years of screening colonoscopy. The PCCRC and number of interval cancers or advanced polyps detected were also described for this cohort.

9.2 Methods

This was a retrospective cohort study of patients undergoing an index screening colonoscopy examination with the Bowel Screening Wales (BSW) Programme. BSW is a colorectal cancer screening programme providing a stool test for the assessment of blood in the faeces every 2 years to individuals between 55 and 74 years of age. This changed from FOBT to FIT in 2020. The current study is therefore based on an FOBT positive, asymptomatic cohort invited for screening colonoscopy rather than the current FIT programme. Individuals with a FIT level of greater than 120 micrograms of haemoglobin per gram of faeces are currently invited for a screening colonoscopy. These tests are performed by screening colonoscopists who must meet strict criteria for accreditation to ensure service quality and safety. Their performance is monitored through QA and KPIs including PDR, ADR, SPDR, completion rate and scope withdrawal time with and without therapy.

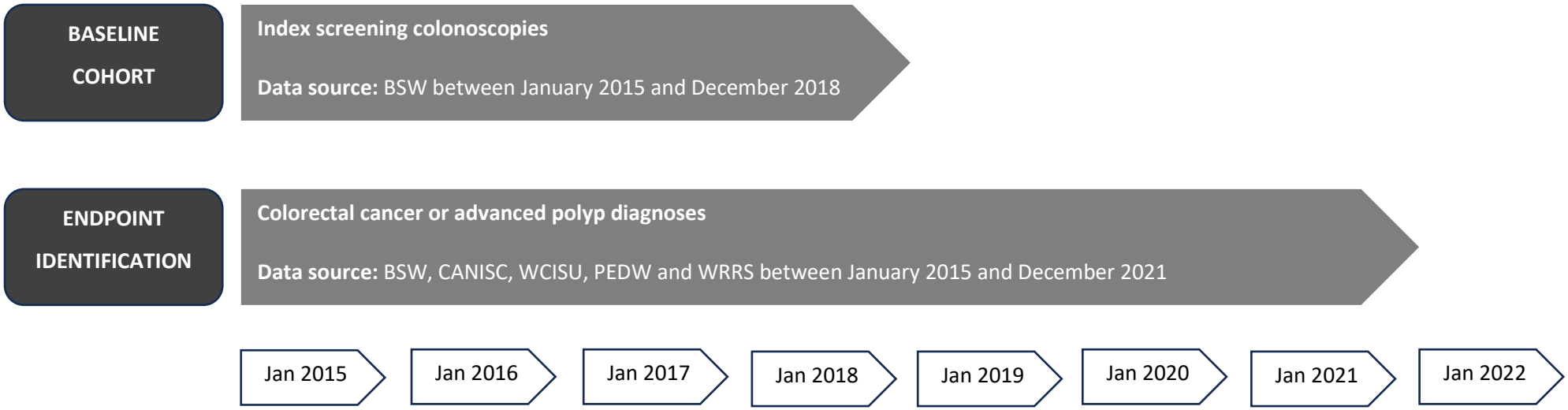


FIGURE 9.1 – OVERVIEW OF DATA COLLECTION TIMELINES AND SOURCES

9.2.1 Data collection

An overview of data collection and sources are illustrated in figure 9.1 and table 9.1. Four years of data was collected for the baseline cohort. Individuals having an index screening colonoscopy between January 2015 and December 2018 by BSW were included. For this study, the index screening colonoscopy was the first documented test performed by BSW after a positive faecal bowel screening test. It was not necessarily their first colonoscopy performed in any setting, but the test done after a positive stool screening test. This also did not include follow up tests performed after first colonoscopy for surveillance within the screening programme. This data was provided from routinely collected information through the screening programme. Patient demographics, date of colonoscopy and the diagnosis made during the investigation were extracted. Characteristics of identified polyps including size, number and histology were provided for the index examination. An advanced polyp was defined based on national guidance as adenomatous polyps at least 10mm in size or with HGD, and serrated polyps at least 10mm in size with any dysplasia (73). Multiple non advanced polyps were not included in this definition.

An anonymised identifier for the colonoscopist performing each procedure was provided. Individual KPIs for screening colonoscopists are issued every 6 months and are routinely collected by BSW. Time specific figures for each examination were matched from the colonoscopists KPIs to the 6-month window in which the colonoscopy was performed. KPIs included PDR, ADR, SPDR, completion rate and scope withdrawal time with and without therapy as defined in section 3.1.5. Number of colonoscopies performed by each endoscopist during the period of baseline data collected was also assessed.

9.2.1.1 Identification of endpoints

Data was collected to identify the endpoints of subsequent colorectal or advanced polyp diagnoses between January 2015 and December 2021. All patients included in the baseline cohort were followed up for 3 years after their index examination to assess for the endpoint outcomes. A colorectal cancer diagnosis or at least one advanced polyp diagnosis meeting the criteria described in section 9.2.1 identified between 6 and 36 months of index colonoscopy were included. Diagnoses within 6 months of baseline colonoscopy were categorised as index findings of the initial investigation.

Data regarding the follow-up colonoscopies performed through BSW for the identified cohort was provided within the same dataset. This included diagnoses of colorectal cancers and characteristics of polyps identified after index examination. This dataset was uploaded to the secure anonymised information linkage (SAIL) databank. This is a national bank of healthcare and

other related datasets for the Welsh population and allows linkage of resources via an individual Anonymised Linking Field Identifier (ALF-ID). Relevant resources were linked to allow identification of follow-up colonoscopies performed with diagnoses of colorectal cancers or advanced polyps after the index examination in the cohort. In addition to BSW, the included assets were Patient Episode Data for Wales (PEDW), Welsh Cancer Intelligence and Surveillance Unit (WCISU), Cancer Network Information System Cymru (CANISC) and the Welsh Results Reports Service (WRRS) pathology dataset. These sources were included to ensure endpoint identification was as complete as possible including any procedures identifying endpoints performed outside the screening programme surveillance pathway.

9.2.1.1.1 Calculation of interval cancers and PCCRC

Unadjusted interval cancers and advanced polyps were those diagnosed within 6 and 36 months of index colonoscopy. The PCCRC was calculated as per the method described by Morris et al (175). The number of cancers identified within 3 years including those identified at index colonoscopy (the true positives plus false negatives) was the gold standard and denominator for this calculation. The PCCRC rate was the number of cancers diagnosed within 6 to 36 months of follow-up after index examination (the false negatives) divided by the gold standard.

9.2.2 Inclusion and exclusion criteria

Individuals with diagnoses of colorectal cancer at index colonoscopy were used to calculate the PCCRC rate but excluded from the KPI analysis. As these individuals have different surveillance pathways, treatment including potentially surgery, and prognosis their inclusion may have confounded the results. All efforts were made to collect full information, but data without sufficient patient information to allow linkage between datasets was also excluded. The absence of a colonoscopist identifier was also an indication for exclusion. Colorectal cancers and advanced polyps identified after the 3 year follow-up period were also excluded.

9.2.4 Statistical analysis and comparisons

Descriptive statistics were performed to describe the patient and colonoscopist characteristics. Any values where the number of patients included were less than 5 were not used in compliance with the SAIL data usage policy to avoid a possibility of creating individual identifiable data. This was declared in the data if applicable, presented as a mean value or converted to a range to increase the number of values in that category. All data reported in the study was approved through the SAIL disclosure control process. A multivariate cox regression analysis including age, gender, polyp findings at index examination, PDR, ADR, SPDR completion rate and withdrawal time with or without

therapy was performed to assess the association between these factors and future diagnosis of colorectal cancer or advanced polyps.

9.2.5 Ethics

As a retrospective epidemiological analysis of anonymised data, advice from Cardiff University Research Integrity, Governance and Ethics Team deemed no further ethical approval was necessary.

9.3 Results

A total of 6576 patients were identified as having an index colonoscopy performed by BSW between January 2015 and December 2018. Colorectal cancers were identified in 684 patients (10.4%) at index examination and removed from the KPI analysis. Other exclusions were due to no ALF-ID being available for linkage (n=28, 0.4%) or an unknown colonoscopist identifier for the procedure (n=57, 0.9%). This left 5807 patients for data linkage and analysis of endpoint outcomes.

9.3.1 Patient characteristics

Patient characteristics are shown in table 9.2. There was a mean age of 67.0 years with a male preponderance in the cohort (62.1%). Most patients (64.6%) had at least one polyp identified at their index examination. Most of these were non advanced polyps (39.2%) with 25.4% advanced polyps (as defined in section 9.2.1) identified at index colonoscopy.

9.3.2 Colonoscopist characteristics

There were 24 colonoscopists performing screening procedures with BSW during the period of data collection. Median number of colonoscopies performed across all colonoscopists during the 4 years of baseline data collection was 186.5 (IQR 140.5 to 283.3). The median PDR, ADR and SPDR across all index procedures performed in the cohort were 62.2% (IQR 58.8 to 67.4), 50.9% (IQR 45.2 to 54.7) and 2.9% (IQR 1.1 to 5.0) respectively. Median withdrawal time with and without therapy was 17 minutes (IQR 15.0 -19.5) and 9 minutes (IQR 8.0 to 10.0) respectively. Unadjusted completion rate was 95.6% (IQR 93.5 to 97.0). Table 9.3 and figure 9.2 shows an overview of individual colonoscopist KPIs with box plots to illustrate variation between operators.

9.3.3 Interval colorectal cancers and advanced polyps

There were 27 individuals (0.5%) identified with a colorectal cancer within 3 years of index screening colonoscopy. Mean age in this group was 66.0 and 55.6% were males. Of those diagnosed with a colorectal cancer during follow-up, 22.2%, 59.3% and 18.5% respectively had no polyp, a non-advanced polyp or an advanced polyp at index examination.

TABLE 9.1 – DATA PARAMETERS REQUIRED FROM EACH SOURCE WITHIN THE SECURE ANONYMISED INFORMATION LINKAGE (SAIL) DATABANK

	Description	Outcomes identified	Method
BSW			
	Routinely collected data for patients undergoing colonoscopy through the screening programme	Date of colonoscopy after index investigation Date of cancer diagnosis after index investigation Date of colorectal polyp diagnoses after index investigation	Routinely collected data provided by BSW
PEDW via SAIL			
	Provides data for all inpatient and day case activity performed by NHS Wales	Date of colonoscopy after index investigation	OPCS-4* classification codes for interventions and procedures for endoscopic operations of the colon: - H18 - H21 to H25
WCISU via SAIL			
	National Cancer Registry for Wales	Date of colorectal cancer diagnosis after index investigation	ICD 10** classification codes for colorectal cancer: - C18 to C20
CANISC via SAIL			

	Multidisciplinary team diagnosis and summary of a patient's cancer record	Date of colorectal cancer diagnosis after index investigation	ICD 10** classification codes for colorectal cancer: - C18 to C20
WRRS via SAIL			
	Laboratory results for pathology requests across Wales	Date of colorectal polyp diagnoses after index investigation	SAIL lookup codes based on ICD 10 classification for: - Colonic polyp, biopsy or rectal biopsy - Colonoscopy - Benign tumour or neoplasm of large intestine HGD of colon Hand search of free text for identified linked patients

**Operating Procedure Codes Supplement version 4 ** ICD - International classification of diseases 10th revision codes*

Advanced polyps were diagnosed in 51 individuals (0.9%) within 3 years of index screening colonoscopy. Mean age in this group was 66.7 and 78.4% were males. Of those diagnosed with an advanced adenoma during follow-up, 5.9%, 31.4% and 62.8% respectively had no polyp, a non-advanced polyp or an advanced polyp at index examination.

The median time to diagnosis from index examination for advanced polyps and colorectal cancer was 12-15 months (IQR 12.5 – 18.0) and 21-24 months (IQR 12.6 – 26.5) respectively. These median figures are presented as ranges to avoid identifiable information and comply with the SAIL data usage policies.

9.3.3.1 Calculation of PCCRC rate

Cancers were diagnosed in 684 patients at index colonoscopy (true positives). Patients identified as having a colorectal cancer within 6 months of the index examination were included in this category. There were 27 patients identified as having colorectal cancer within 6 to 36 months from their index

TABLE 9.2 – PATIENT CHARACTERISTICS

	Total (n=5807)	**No polyp at index colonoscopy (n=2056, 35.4%)**	**Non advanced polyp at index colonoscopy (n=2277, 39.2%)**	**Advanced polyp at index colonoscopy (n=1474, 25.4%)**
Age in years	**67.0**	67.0	67.3	66.6
Gender				
Female	**2199 (37.9%)**	1008 (49.0%)	740 (32.5%)	451 (30.6%)
Male	**3608 (62.1%)**	1048 (50.9%)	1537 (67.5%)	1023 (69.4%)

Age is given as mean to one decimal place. Medians were not used to avoid potentially identifiable information. For this same reason, the range of values are also not presented. The remaining values are given as number and (%) to one decimal place.

TABLE 9.3 – KPIS FOR EACH COLONOSCOPIST

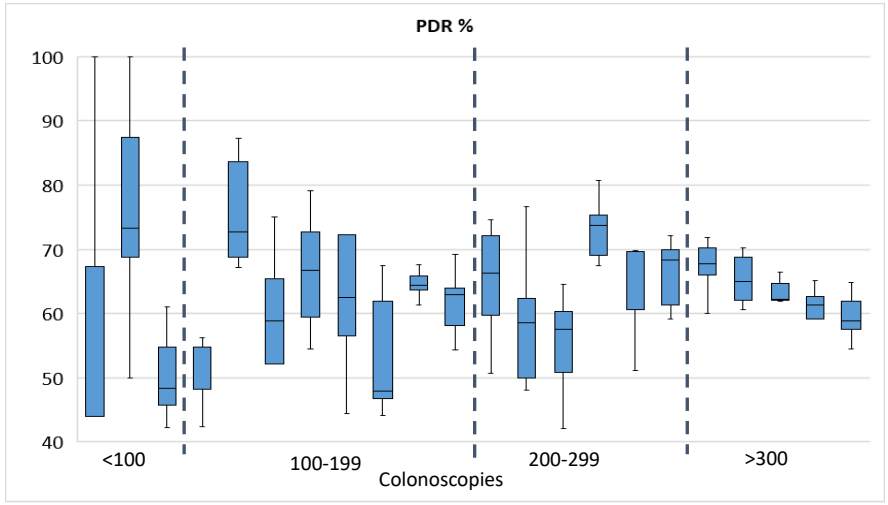
Colonoscopies performed	PDR %	ADR %	SPDR %	Completion rate %	Withdrawal time with therapy – minutes	Withdrawal time without therapy – minutes
<100	67.3 (44.0 – 67.3)	55.1 (44.0 – 55.1)	2.0 (0 – 2.0)	95.9 (95.9 – 96.0)	15.0 (15.0 – 20.0)	9.5 (9.0 – 9.5)
<100	48.4 (45.8 – 54.8)	42.1 (41.7 – 45.2)	0 (0 – 0)	96.8 (94.4 – 97.8)	15.0 (14.5 – 17.0)	7.5 (7.0 – 8.0)
<100	73.3 (68.8 – 87.5)	53.3 (50.0 – 60.0)	0 (0 - 0)	100 (100 – 100)	13.5 (11.0 – 14.0)	10.0 (9.0 – 11.0)
100-199	58.8 (52.2 – 65.4)	45.1 (41.3 – 48.7)	0 (0 – 1.0)	93.6 (93.6 – 94.1)	14.0 (14.0 – 15.0)	7.0 (7.0 -9.0)
100-199	72.7 (68.6 – 83.6)	60.4 (57.0 – 69.4)	7.3 (6.9 – 9.1)	93.7 (92.1 – 95.8)	28.5 (25.0 – 30.5)	13.0 (12.0 – 15.0)
100-199	47.9	40.9	4.2	95.7	15.0	9.0

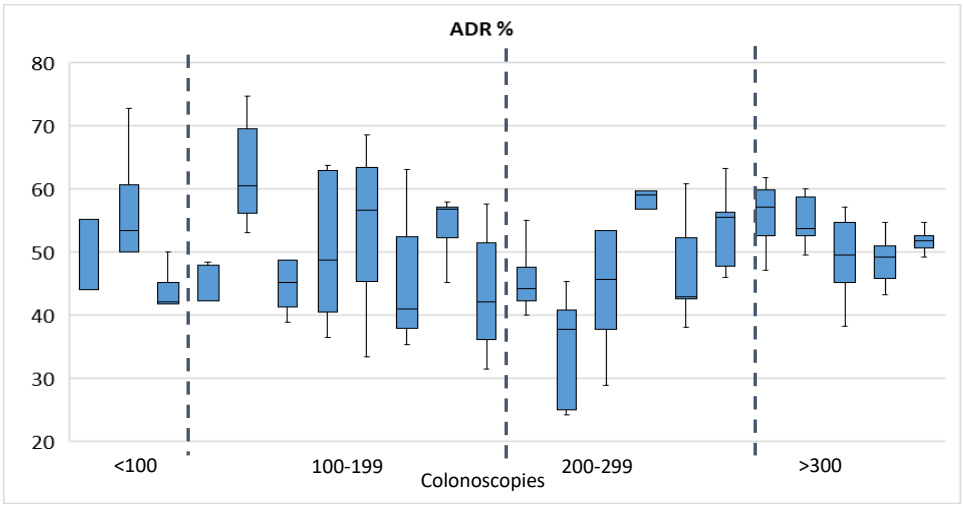
	(46.7 – 61.9)	(37.8 – 52.4)	(0 – 4.4)	(94.6 – 97.8)	(14.0 – 15.5)	(8.0 – 9.0)
100-199	66.7 (59.5 – 72.2)	48.6 (40.4 – 62.8)	2.3 (0 – 2.6)	94.6 (92.9 – 97.7)	18.0 (17.5 – 18.0)	9.0 (8.5 – 10.0)
100-199	62.9 (58.1 – 64.0)	42.0 (36.1 – 51.4)	0 (0 – 1.0)	93.9 (91.4 – 94.2)	12.0 (11.0 – 12.0)	7.0 (6.5 – 7.0)
100-199	62.5 (56.6 – 72.2)	56.6 (45.3 – 63.4)	1.8 (0 – 4.2)	97.6 (94.4 – 98.2)	13.0 (11.0 – 13.0)	7.0 (7.0 – 7.5)
100-199	48.2 (48.2 – 54.8)	42.2 (42.2 – 47.9)	0 (0 – 0)	93.1 (90.4 – 96.1)	12.0 (11.5 – 13.0)	9.0 (8.0 – 9.0)
100-199	64.4 (63.6 – 65.9)	56.8 (52.3 – 57.1)	2.4 (0 – 5.4)	95.7 (91.7 – 97.7)	19.0 (18.5 – 20.0)	9.0 (8.0 -10.0)
200-299	66.3 (59.8 – 72.1)	44.2 (42.3 – 47.6)	0 (0 – 2.2)	90.2 (89.9 – 91.5)	17.0 (17.0 – 18.0)	11.0 (11.0 – 11.5)
200-299	68.3	55.4	2	95.9	20.0	9.5

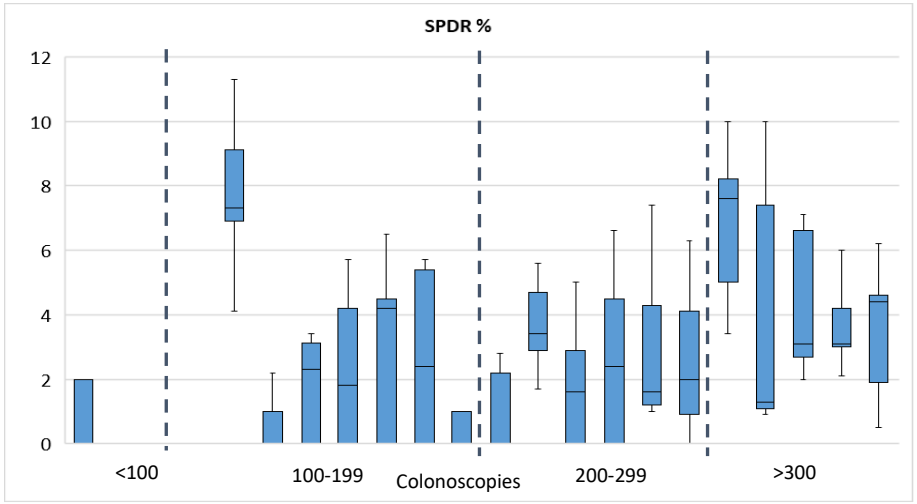
	(61.4 – 68.3)	(47.7 – 55.4)	(1.2 – 2.0)	(93.5 – 95.9)	(20.0 – 20.0)	(9.0 – 9.5)
200-299	60.6 (60.6 – 69.6)	42.9 (42.5 – 52.3)	1.6 (1.2 – 4.3)	96.5 (94.3 – 96.7)	16.0 (15.5 – 17.0)	9.0 (8.0 – 9.0)
200-299	73.7 (69.0 – 75.3)	59.0 (56.8 – 59.5)	2.4 (0 – 4.5)	96.7 (93.3 – 98.8)	13.0 (12.0 – 15.0)	8.0 (8.0 – 8.0)
200-299	57.5 (50.9 – 60.3)	45.6 (37.7 – 53.3)	1.6 (0 – 2.9)	90.2 (89.0 – 93.8)	18.0 (15.0 – 20.0)	8.5 (8.0 – 9.0)
200-299	58.6 (50.0 – 62.3)	37.7 (25.0 – 40.8)	3.4 (2.9 – 4.7)	93.0 (89.9 – 93.1)	12.5 (12.0 – 13.0)	7.5 (7.0 – 8.5)
≥300	67.7 (66.0 – 70.3)	57.0 (52.5 – 59.8)	7.6 (5 – 8.2)	99.1 (97.0 – 100)	21.0 (21.0 – 22.0)	14.0 (13.0 – 15.0)
≥300	62.2 (62 – 64.7)	49.5 (45.2 – 54.7)	3.1 (2.7 – 6.6)	95.8 (95.3 – 96.5)	15.0 (14.0 – 15.0)	9.0 (9.0 – 9.0)
≥300	58.8	51.7	4.4	94.7	19.5	10.0

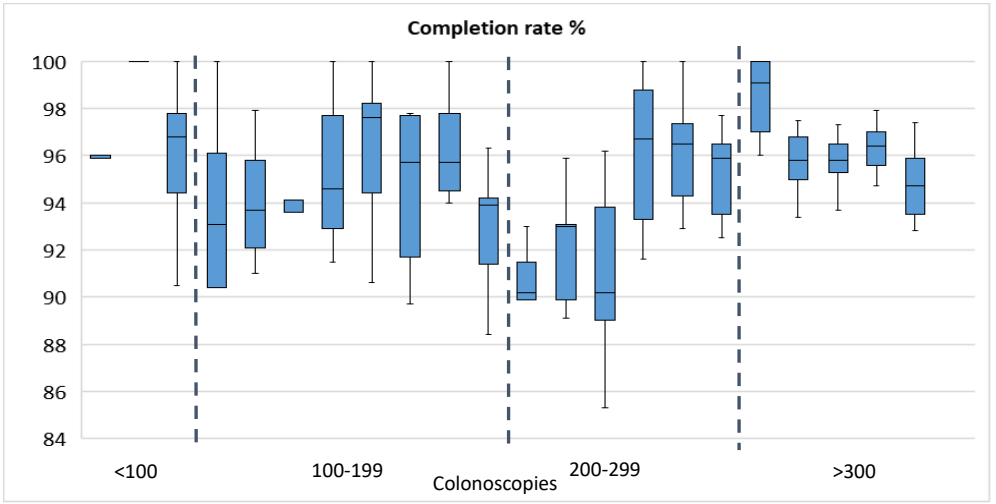
	(57.6 – 61.9)	(50.6 – 52.6)	(1.9 – 4.6)	(93.5 – 95.9)	(18.0 – 20.5)	(9.0 – 11.0)
≥300	61.4 (59.1 – 62.7)	49.1 (45.8 – 50.9)	3.1 (3.0 – 4.2)	96.4 (95.6 – 97.0)	17.0 (16.0 – 17.0)	9.0 (8.0 – 9.0)
≥300	65 (62.1 – 68.8)	53.7 (52.6 – 58.7)	1.3 (1.1 – 7.4)	95.8 (95.0 – 96.8)	19.0 (18.0 – 19.5)	7.0 (7.0 – 8.0)

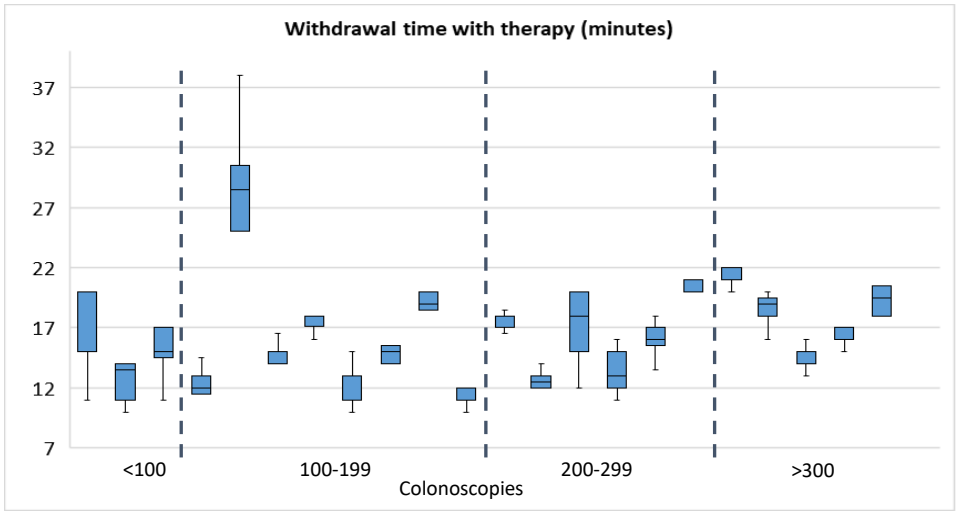
Number of colonoscopies are the total index examinations performed by each colonoscopist within the 4 years of data collection for the baseline cohort. KPIs are given as median and (IQR) for PDR, ADR, completion rate and withdrawal time with and without therapy. Two colonoscopists were excluded from this analysis to avoid presenting potentially identifiable data as per SAIL policies as they had performed less than 5 colonoscopies during the study period.


PDR %
100
90
80
70
60
50
40
<100
100-199
200-299
>300
Colonoscopies


ADR %
80
70
60
50
40
30
20
<100
100-199
200-299
>300
Colonoscopies


SPDR %
12
10
8
6
4
2
0
<100
100-199
200-299
>300
Colonoscopies


Completion rate %
100
98
96
94
92
90
88
86
84
<100
100-199
200-299
>300
Colonoscopies



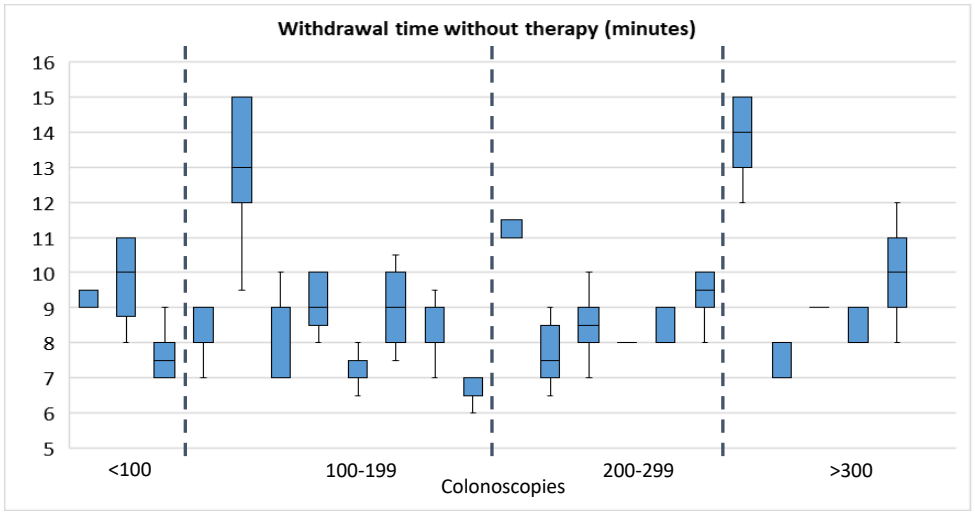


FIGURE 9.2 – BOX PLOTS SHOWING MEDIAN, RANGE AND IQR FOR EACH COLONOSCOPIST'S KPIS

Data is grouped into the number of index colonoscopies performed by each colonoscopist within the 4 years of data collection for the baseline cohort. Box plots display median, IQR and range for each KPI. Two colonoscopists were excluded from this analysis to avoid presenting potentially identifiable data as per SAIL policies as they had performed less than 5 colonoscopies during the study period.

TABLE 9.4 – COX REGRESSION ANALYSIS IN PATIENTS WITH AN INTERVAL DIAGNOSIS OF AN ADVANCED POLYP

	Hazard ratio	P value
Age	0.99 (0.93 – 1.05)	0.80
Gender	0.58 (0.29 – 1.13)	0.11
Polyp findings at index examination		
No polyp	1 (reference)	
Non advanced polyp	4.80 (1.39 – 16.59)	**0.01**
Advanced polyp	14.91 (4.52 – 49.19)	**<0.001**
Total colonoscopies performed	1.00 (0.99 -1.00)	0.47
PDR	0.98 (0.93 – 1.04)	0.51
ADR	0.98 (0.92 – 1.03)	0.38
SPDR	1.02 (0.92 – 1.12)	0.75
CR	0.98 (0.89 – 1.07)	0.59
Withdrawal time without therapy	0.92 (0.78 – 1.09)	0.35
Withdrawal time with therapy	1.08(0.99 -1.17)	0.09

Numbers are given as hazard ratios with (95% confidence intervals) to 2 decimal places

TABLE 9.5 – COX REGRESSION ANALYSIS FOR KPI'S IN PATIENTS WITH AN INTERVAL DIAGNOSIS OF COLORECTAL CANCER

	Hazard ratio	P value
Age	0.97 (0.88 – 1.06)	0.48
Gender	1.21 (0.52 – 2.83)	0.65
Polyp findings at index examination		
No polyp	1 (reference)	
Non advanced polyp	3.16 (1.02 – 9.80)	**0.05**
Advanced polyp	1.73 (0.46 – 6.55)	0.42
Total colonoscopies performed	1.00 (0.10 – 1.00)	0.84
PDR	1.03 (0.96 – 1.10)	0.40
ADR	0.99 (0.93 – 1.05)	0.74
SPDR	1.12 (0.98 – 1.27)	0.10
CR	1.03 (0.88 – 1.20)	0.70
Withdrawal time without therapy	0.90 (0.70 – 1.18)	0.45
Withdrawal time with therapy	0.92 (0.79 – 1.07)	0.28

Numbers are given as hazard ratios with (95% confidence intervals) to 2 decimal places

examination (false negatives). The 3 year PCCRC rate in this cohort was 3.8% ((false negatives/false negatives + true positives) x 100) using the method described by Morris et al (175).

9.3.4 Relationship between key performance indicators (KPI's) at index examination and future colorectal cancer or advanced polyps

Multivariate cox regression analysis was performed including age, gender, index polyp diagnosis, number of colonoscopies performed and the six KPIs included in the analysis. Tables 9.4 and 9.5 show the hazard ratios for each KPI for a follow-up diagnosis of advanced polyp or colorectal cancer respectively. Age and gender were not associated with an increased risk of future colorectal cancer or advanced polyp diagnoses within this group of screened patients. A significantly higher number of future advanced polyps were identified in those with any type of polyp found at index examination. Those with a non-advanced polyp at index were more likely to be diagnosed with a future colorectal cancer but this did not reach significance. The cox regression analysis did not show a significant impact of each percentage point increase in any of the selected colonoscopy KPIs on hazard ratios of subsequent diagnosis of an interval advanced polyp or colorectal cancer.

9.4 Discussion

International surveillance recommendations are based on polyp characteristics at index examination with an assumption of minimum standards for colonoscopy quality that may vary across settings and jurisdictions (176). ADR is an accepted measure and benchmark for a colonoscopists performance in the accurate detection of colonic lesions and prevention of future neoplasia. There was no observed association between the reported KPIs and the risk of colorectal cancer after index examination in this subset of screening colonoscopy practitioners with high ADRs. Similar findings for advanced polyps have also been demonstrated in this study. This suggests there may be a limit where improvements in KPIs beyond an upper threshold may become less clinically meaningful. The incidence of interval colorectal cancer and advanced polyp diagnosed within 3 years of an index screening colonoscopy in this UK based screening programme was 0.5% and 0.9% respectively, with a 3 year PCCRC rate of 3.8%.

Although acceptable rates of PCCRC have not been standardised (173), an international meta-analysis has demonstrated a rate of 8.2% at 3 years (174). Burr has described the considerable variation in PCCRC rates across the UK with an overall 3 year rate of 7.4% (177). Patients undergoing colonoscopies with screening programmes had a lower rate of 3.6% and these results are comparable to this figure. Methods for defining PCCRC rates are variable with no agreed single classification. This can result in variability in reporting depending on which method is used

(175). The method described by Morris et al has been utilised in this study and described in the methodology. It is a prospective method, and the results have more relevance to patients undergoing an index colonoscopy rather than those who have a colorectal cancer diagnosis afterwards. It is also not known whether definitions of PCCRC can also be safely applied to the reporting of polyps but the concept of a post colonoscopy advanced polyp rate warrants further investigation.

Previous studies by Kaminski (77) and Corley (78) have demonstrated ADR as a predictor of PCCRC. Although studies within screening programmes, the Polish and American systems use primary colonoscopy and this should be considered in any comparison to these results. Median ADR in these studies was between 12.2% and 17.9%. This is much lower than reported here where the median ADR is 50.9%. Figure 9.3 illustrates these observations and comparisons between studies. These figures are divided into subsequent colorectal cancer diagnoses in those with an ADR above or below the median value for this study. Although this is a simplified assessment and should be interpreted with caution given heterogeneity in patient cohorts and follow-up, it supports the theory that additional gains in ADR beyond a certain threshold may not translate to benefits in the reduction of future colorectal cancers. A formal systematic review of this may provide a more accurate assessment.

Although a higher ADR was previously the only performance indicator proven to be associated with PCCRC, the understanding of others is also increasing. Serrated lesions are often more challenging to identify at colonoscopy and their natural history and separate role in the carcinogenic pathway is of interest (178, 179). The FIT test is less sensitive for serrated lesions which may explain the differences in their prevalence between stool and colonoscopy based screening programmes (180). Their identification and removal may be of importance to endoscopy quality benchmarks and the incidence of PCCRC. A Dutch screening population study has demonstrated an inverse relationship with PCCRC and an increasing proximal SPDR (181). This was a large study assessing over 200,000 screening colonoscopies with a median proximal SPDR of 11.9%. Interestingly despite having a high ADR in this study, the reported SPDR of 2.9% here was comparatively lower than the Dutch series despite inclusion of all detected serrated polyps and not just proximal lesions. Several factors may explain this discrepancy. The Dutch study excluded any incomplete or poorly prepared colonoscopies and those performed by low volume colonoscopists. Comparison is also difficult given the international variation between screening programmes. Although a statistically relationship has not been demonstrated in this study, it seems reasonable to suggest that the low SPDR may contribute to some of the subsequently identified colorectal cancers or advanced polyps in this cohort. The comparatively

small sample size of the baseline cohort may have resulted in these associations not being demonstratable. This being considered, histological comparison of the identified colorectal cancers and polyps during follow-up would be of great interest but beyond the scope of this research. There were also observed differences in the SPDR of colonoscopists performing over 300 examinations during the study period with none in this group having a median SPDR of 0%. Six colonoscopists in total performing less that 300 colonoscopies during the study period had a median SPDR of 0% which may be of concern given the above observations. This may be a key area to focus on within this screening programme to reduce further the PCCRC. Although both seem to be associated with reducing PCCRC in other studies, ADR and SPDR seem to be only moderately associated with each other suggesting they should not be used as surrogates (181). Given the alternative carcinogenic pathways for adenomas and serrated lesions, it seems reasonable to suggest both may be required as quality indicators for colonoscopy. Although traditionally having been categorised together, the modern differentiation between hyperplastic polyps and serrated lesions is important due to the malignant potential of the latter. They are endoscopically, but also pathologically, challenging to assess with potential to be inaccurately classified (182, 183). Changes in criteria may not yet be reflected in everyday clinical practice. Assessment by an experience gastrointestinal pathologist may ameliorate this with a systematic review demonstrating a change in diagnosis rate from hyperplastic polyps to serrated lesions of 11% (182). This may also be a factor contributing to the 0% SPDR described in this study. Reporting criteria, adequate service provision, education and governance are all important in ensuring quality and accuracy in pathology reporting of colonic polyps.

The median withdrawal time without and with therapy described here was 9 and 17 minutes respectively in the included screening colonoscopies. Evidence initially suggested an optimal recommended withdrawal time of 8 minutes (184) to improve detection of adenomas, but further research suggests that 10 minutes may be more beneficial (185). Given the limited data on KPIs beyond ADR, further studies to build the body of evidence around the implications of withdrawal times in addition to all other performance indicators in large datasets is needed. This should be performed in a variety of settings to develop clear benchmarking standards for colonoscopy QA and reduction of future colorectal neoplasia.

The unadjusted incidence of interval colorectal cancer and advanced polyp diagnoses within 3 years of an index screening colonoscopy in this UK based screening programme was 0.5% and 0.9% respectively. This suggests that standards set by this service are of high quality ensuring a low risk of future colorectal neoplasia. This is similar to colorectal cancer rates of up to 0.5% described by Bonnington et al in their study during post polypectomy surveillance (172). The

heterogeneity between this and other studies including exclusion criteria and screening or symptomatic settings must be considered. Comparison to data regarding the incidence of advanced polyps is more challenging. An incidence of 0.9% within 3 years of screening colonoscopy seems acceptably low. A recent study has identified the incidence of advanced adenomas after polypectomy in the English screening programme (172). The identification of advanced adenomas during follow-up after polypectomy was 10%, 8.5% and 10.8% at first, second and third surveillance respectively. The data from this study included all index colonoscopies and not only those where polypectomy had been performed which may explain the lower rates observed. Unlike this study, advanced adenomas rather than polyps were described and these included lesions with a villous component (186) but excluded advance serrated lesions. This same definition was used by Hassan et al in a systematic review where advanced adenomas were detected in 5.6% of screening colonoscopies (187).

Patients with polyps, especially those with advanced features, at index examination were more likely to have another advanced polyp in the future. Given that the overall incidence of advanced polyps after index examination in this study may be lower than the general population, it is challenging to draw conclusions on how this may influence surveillance recommendations. It was also unclear from the data how many polyps identified at index were successfully removed which may affect interpretation. As expected, time to diagnosis from index colonoscopy was shorter for advanced polyps than colorectal cancers. A median duration of 12 to 15 months and 21 to 24 months from index examination to identification of either an advanced polyps or colorectal cancer was identified respectively. This was the time to presentation of the subsequent lesion and not necessarily the next scheduled surveillance procedure after index examination, and individuals may have had other interval surveillance procedures within this time frame. This could indicate the transition period to develop colorectal cancers from advanced adenomas may be around 9 months. This provides insight into their natural progression which is called for by international organisations (173) and may help guide standards for treatment timelines for managing such lesions. The importance of timely treatment of colorectal seems evident both in terms of clinical outcomes and health economics. Delayed assessment and treatment can result in polyps progressing to be endoscopically unresectable, or even malignant lesions. Treatment options required may be more invasive and as a result, more expensive with higher risks. Patients may also develop interim medical issues which make treatment more challenging. Quality of life and psychological impacts on patients are also likely with the uncertainty, anxiety and dissatisfaction of awaiting interventions. This may result in further presentations to the healthcare system and additional administrative tasks. Groups of experts within BCSPs or polyp

team meetings, are optimally placed to provide recommendations on treatment timelines and could be utilised as part of template illustrated earlier in this thesis. This should account for both the nature of the lesion and patient characteristics. A timeline like those utilised to prioritise surgical procedures could be instigated and adherence to this could be audited and improved. Administrative roles would be paramount in ensuring this was appropriately coordinated, tracked and delivered. This process could be performed locally through standard quality and service processes and outcomes recorded as part of the previously described template for ease of data collection. The National Bowel Cancer Audit (NBOCA) aims to monitor service quality and outcomes for patients diagnosed with colorectal cancer in the UK. A similar process may be applied to colorectal polyps, especially complex lesions or those managed through team meetings. This would allow assessments of the national provision of these services, benchmarking and comparison between centres. The challenges and costs of starting such a process may, however, restrict its introduction.

Given the low PCCRC rate and incidence of advanced polyps diagnoses within 3 years of index screening colonoscopy, this study suggests the KPI and QA standards set by BSW ensures quality for patients participating in the programme. International surveillance recommendations allude to the requirements of high standard of colonoscopy with minimum lower thresholds described, but without specific upper thresholds for criteria (176). These results may help define the standards of quality required by guidance and could help establish benchmarks for both training and technology. Artificial intelligence in endoscopy is a developing field and understanding of the translation of KPI rates into the risk of colorectal cancer may be crucial in quality and safety assurance.

9.4.1 Limitations

The applicability of this study is limited to screening colonoscopies in a stool based screening programme. Further research is needed to establish the impact of all KPIs for non-screening endoscopic practitioners. Despite a reasonable sample size, it is possible that the low numbers of colorectal cancer and advanced polyp diagnoses are insufficient to demonstrate a relationship. A power calculation was not utilised in the study. A longer period of data collection for the baseline cohort was considered but not performed due to the known incompleteness of BSW data before 2015. Individuals with cancers diagnosed at index screening colonoscopy were excluded from the study as these patients follow a different treatment and alternative surveillance pathway. Management of colorectal cancer patients with surgery, chemotherapy or radiotherapy may have affected comparability in this separate cohort of patients. Concepts such as colonoscopist blinding resulting in missed polyps after identification of a cancer may also be influential in this

group. A separate analysis would be beneficial to establish risks of future disease in this group which may have importance in colonoscopy surveillance after colorectal cancer.

Other limitations of this study include its retrospective design, potential missing data and inherent limitations of routine healthcare data linkage techniques. All reasonable efforts were made to minimise individuals with insufficient information to link between datasets. In line with the SAIL data usage policy, attempts to reidentify individuals for this purpose was not performed which limited options to minimise the exclusions and verification of outcomes. Only 1.4% were excluded due to this which would be unlikely to significantly impact the outcomes. Advanced polyp diagnoses made through other modalities such as CT colonography may not have been identified. Other influencing baseline demographics such as comorbidity, smoking and patient weight were not looked at. All efforts were made to ensure full data collection and careful data linkage and cleaning. It was assumed that all polyps were removed either at index examination or within 6 months of identification which may not accurately reflect actual practice. The WRRS dataset was particularly challenging and required searching of free text data to establish polyp parameters. The incidence of advanced polyp diagnoses may have been underestimated due to inaccurate data or coding.

The findings of this study need to be interpreted in context of updated UK surveillance guidelines being published within the follow-up period. Except for incomplete excision of polyps of 20mm or more, one off surveillance colonoscopy at 3 years as opposed to 12 months is now the recommended interval for polyps with high-risk findings. This study is also based on a FOBT based screening programme rather than the new FIT system. An update of this study after these changes is warranted.

9.5 Conclusions

QA and KPI standards set by this faecal bowel screening programme for training and accreditation seem appropriate with a low PCCRC rate and subsequent risk of advanced polyps. There has been no demonstrated impact of higher thresholds for KPIs including ADR, PDR, SPDR, withdrawal times and completion rate on this risk within a group of high polyp detectors. The current standards can be safely utilised in guiding surveillance recommendations, endoscopy training and the provision of screening services. Similar work is required to assess the influence of colonoscopy quality indications in large datasets across a variety of settings to enable the development of clear benchmarking standards for colonoscopy QA and reduction of future colorectal neoplasia. The investigation and improvement of indicators other than ADR, especially SPDR and proximal SPDR, is advocated in establishing their effect on PCCRC rates.

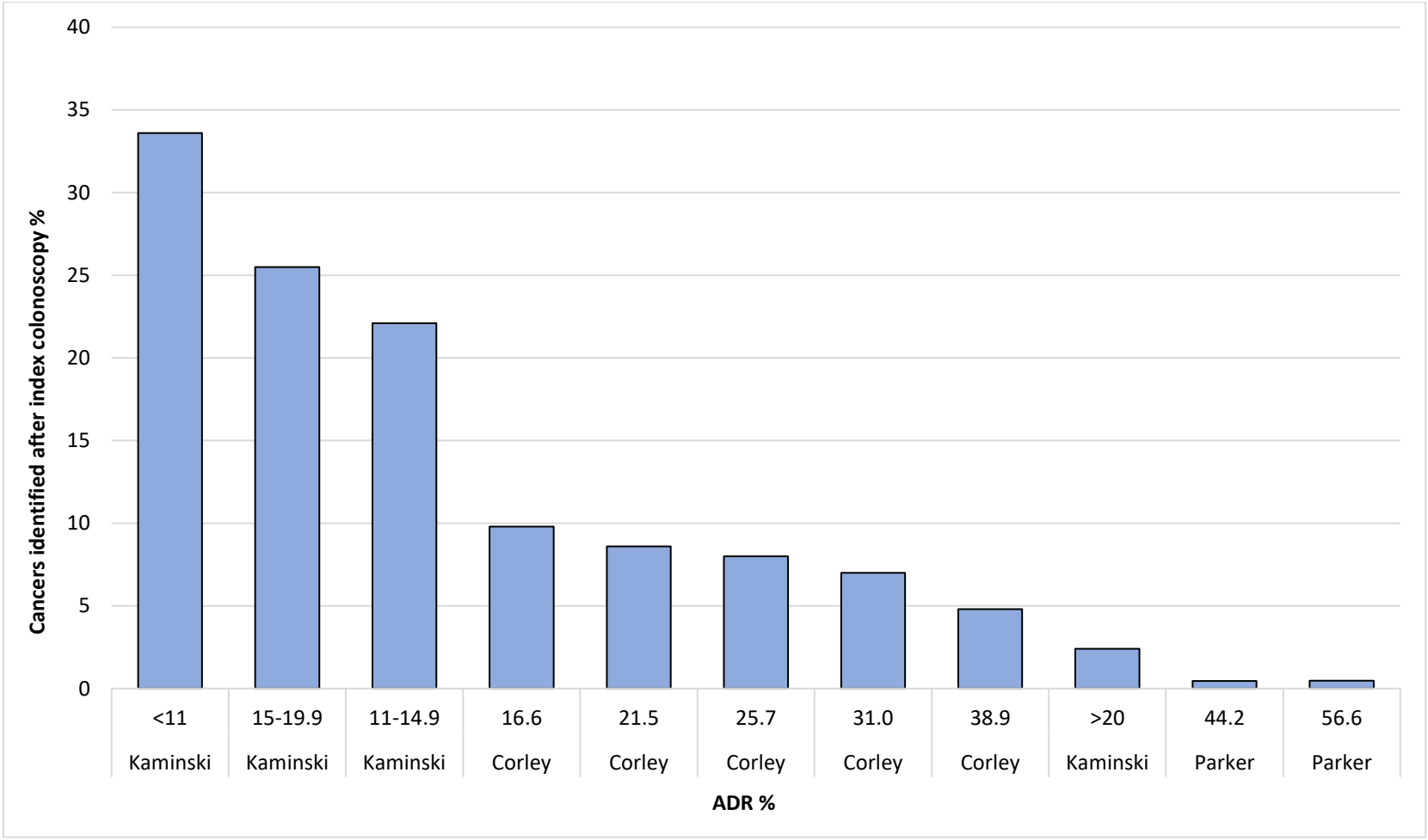


FIGURE 9.3 – COMPARISON OF ADR AND PERCENTAGE OF COLORECTAL CANCERS DIAGNOSED DURING FOLLOW BETWEEN THIS STUDY AND THOSE BY KAMINSKI (77) AND CORLEY (78)

Part Four: Summary of thesis and future work

10 Summary

Decision-making strategies through team management and objective selection criteria, benefit patient outcomes in the treatment of complex colorectal polyps. They are widely accepted and endorsed by clinicians but can be limited by logistical challenges and issues surrounding service provision. They can provide a safe platform to explore and introduce novel techniques and provide an opportunity for learning and education. There remain challenges to the performance of research in this field due to the variability in terminology and definitions of these lesions. Current international surveillance guidelines are high quality decision-making tools that can be safely applied by clinicians in managing patient follow-up after treatment. There are limited by the lack of underlying evidence concerning non polyp factors that may influence surveillance. Performance indicators at index colonoscopy such as ADR can affect the risk of future colorectal cancer, but there appears to be a threshold beyond which this influence plateaus.

The aims and hypotheses outlined at the start of this work have been addressed and are described below. Limitations are summarised and potential areas for future research proposed.

10.1 Conclusion of aims and hypotheses

10.1.1 Aims and hypotheses of part one

10.1.1.1 Chapter 4: Review of the published literature – a systematic review and pooled analysis of the impact of decision-making strategies on complex colonic polyp outcomes

Aim To perform a systematic review of the literature to assess and compare the current impact of clinical decision-making strategies on the treatment outcomes of complex colonic polyps.

Hypothesis Decision-making strategies for complex polyps are currently underreported and variable but can improve the clinical outcomes of patients with complex colorectal polyps.

The first aim of the thesis was to perform a systematic review of the current literature to identify if evidence existed demonstrating an impact of decision-making on complex polyp outcomes. As hypothesised and demonstrated in chapter 4, decision-making strategies and selection criteria for treatment are not well reported. The review demonstrated that better decision-making strategies may result in a lower rate of secondary surgery for complex colorectal polyps. There was no impact on other outcomes including adverse events and unsuspected malignancies. Given the limited and

heterogenous evidence available, it is difficult to be certain whether the results give a true reflection. Key complex colorectal polyp clinical outcomes including primary procedure choice, secondary procedure choice, adverse events, malignancies, length of stay, readmissions and recurrence identified from this literature review guided the qualitative and quantitative data collection for chapters 5, 6 and 7.

10.1.1.2 Chapter 5: Planning management for complex colorectal polyps – a qualitative assessment of factors influencing decision-making amongst colonoscopists

Aim To qualitatively assess and understand the influences on decision-making regarding complex polyp management amongst clinicians involved in their care.

Hypothesis The influences on decision-making when managing complex colorectal polyps by clinicians are not only clinical but are also impacted by service and logistical issues.

This study aimed to identify the influences on colonoscopists when planning the management of complex colorectal polyps. A qualitative assessment was performed as described in chapter 5 to reach this aim giving a unique insight of decision-making at a clinician level. Polyp and patient factors influencing decision-making were similar amongst those interviewed and colonoscopists from all backgrounds felt that endoscopic management should be the treatment of choice where possible. Concerns prohibiting endoscopic management included right sided lesion location and HGD on biopsy. As hypothesised, access to clinical expertise, service provision, timely decision-making and treatment were all challenges to optimal decision-making regarding management. The role of collaborative decision-making strategies including the use of multi-disciplinary teams was perceived as useful in everyday practice despite the absence of evidence or guidance regarding their expected outcomes or structure.

10.1.1.3 Chapter 6: Outcomes of complex colorectal polyps managed by multi-disciplinary team strategies – a multi-centre observational study

Aim To analyse the procedures performed and clinical outcomes of patients with colorectal polyps who are managed by a complex polyp multi-disciplinary team decision-making process.

Hypothesis The utilisation of complex polyp multi-disciplinary teams is safe and can improve management of patients with complex polyps through providing optimal first line treatment and high standards of clinical outcomes.

Chapter 6 utilised a multi-centre approach to describe patients with complex colorectal polyps managed through multi-disciplinary team strategies across the UK. Data on a large series of 2109

polyps was collected with information regarding procedures performed and clinical outcomes. As hypothesised, these teams were safe and effective with organ preservation being achieved in 91.9% of the included patients. The number of primary colonic resections decreased over the study period without a reciprocal increase in secondary procedures or recurrence. The rates of adverse events, malignancies, length of stay, readmissions and recurrence were similar, or better than comparative literature. There was variability in team organisation and guidance regarding team structure, referral pathways and quality monitoring is required to ensure ongoing effectiveness.

10.1.1.4 Chapter 7: The Cardiff complex polyp multi-disciplinary team decision-making meeting and its impact on the outcomes of a novel complex polyp technique – a single-centre study

Aim To describe the structure of an individual team meeting and assess the impact of the introduction of a novel complex polyp technique on short and long term patient outcomes.

Hypothesis A multi-disciplinary team decision-making process can facilitate the safe introduction of novel techniques that avoid colonic resection whilst maintaining clinical outcomes for patients with complex colorectal polyps.

Giving the findings of variability in team structure in chapter 6, this chapter firstly detailed the structure and referral pathway for an individual team meeting as a template for other centres. The novel technique of Lap EMR was also described as a method of achieving organ preservation in patients that would have otherwise required bowel resection. Outcomes were described and bowel resection was avoided in 80% of those selected. In keeping with the hypothesis, the procedure was safely introduced with minimal adverse events and excellent short and long term outcomes. Team decision-making pathways can provide a safe platform for the introduction of new techniques in the treatment of complex polyps.

10.1.2 Aims and hypotheses of part two

10.1.2.1 Chapter 8: Systematic review of published guidelines – influences on recommendations for surveillance of advanced colorectal polyps

Aim To perform a systematic guideline review to assess factors at index colonoscopy used for advanced and complex colorectal polyp surveillance recommendations.

Hypothesis International recommendations regarding surveillance for advanced and complex polyps are mostly based on patient and polyp factors at index colonoscopy with little consideration or evidence regarding operator or quality factors.

In addition to optimal initial management, patients with complex polyps require surveillance after treatment at an appropriate time interval. Given the variability in complex polyp definitions in the literature, this review aimed to compare international guidelines for their surveillance. Most do not define these separately but are incorporated into a wider definition of advanced polyps. Recommendation surveillance intervals were consistent despite terminology and classifications being variable. As hypothesised, timings were mostly based on polyp factors. Although some guidelines discussed the requirement of high quality colonoscopy, criteria and standards for this was lacking.

10.1.2.2 Chapter 9: The impact of variation in colonoscopy quality in a screening programme on the risk of future advanced polyps or cancer – an analysis of linked data

Aim To use data linkage and analysis to identify the effect of colonoscopy quality on the subsequent risk of colorectal cancer, advanced or complex colorectal polyps.

Hypothesis A higher quality of colonoscopy at index examination can reduce the future risk of developing colorectal cancer, advanced or complex polyps

The low number of identified colorectal cancers and advanced polyps after index colonoscopy suggests that standards set by this screening programme for training and accreditation are of high quality. Despite the original hypothesis, there was no demonstrable impact on PCCRC rates of higher threshold levels of KPIs within this colonoscopist group. Screening colonoscopists are a high polyp detector group. Other studies have demonstrated benefits in improving ADRs amongst colonoscopists but with much lower figures. This suggests there is a threshold where additional gains offer little clinically meaningful benefit in the future risk of colorectal neoplasia.

10.2 Limitations of thesis

The following provides a summary of limitations, and these are addressed in more detail in each individual chapter.

10.2.1 Limitations of part one

10.2.1.1 Limitations of chapter 4

- Low number and heterogeneity of papers for systematic review
- Lack of descriptions regarding selection criteria and decision-making strategies
- No papers comparing groups with different decision-making strategies
- No guidance regarding the performance of systematic reviews for observational studies
- Use of pooled analysis as statistical method

10.2.1.2 Limitations of chapter 5

- Limitations of qualitative data analysis including bias through participant selection, interview design and identification of themes
- Sample size and time limitations may have limited comprehensive data collection
- UK practice may not be generalisable to other countries
- Performance and comparison with interviews of patients was not performed

10.2.1.3 Limitations of chapter 6

- Retrospective data collection
- Absence of control or comparative arm
- Variability in team structure between centres

10.2.1.4 Limitations of chapter 7

- Retrospective data collection
- Absence of control or comparative arm
- Small sample size which describes only a single centre experience

10.2.2 Limitations of part two

10.2.2.1 Limitations of chapter 8

- Exclusion of non-evidence based and outdated guidelines
- No description of surveillance for multiple lesions

10.2.2.1 Limitations of chapter 9

- Retrospective data collection
- Only applicable to a stool based screening programme
- Demographics such as weight and smoking status were not assessed
- Limitations of linked data analysis and accurate identification of outcomes
- Small numbers of identified endpoints of colorectal cancers and advanced polyps may have resulted in inaccurate conclusions

10.2.3 Impact of the COVID-19 pandemic

In March 2020, two months after commencement of this research degree, the UK initiated a national lockdown to prevent the spread of COVID-19. As a higher trainee in general surgery, I returned to clinical practice on a full and then part time basis for 6 months to support the local surgical department during the pandemic. This clearly impacted the progress of projects resulting in delays and compromises in certain areas of the research and in the formulation of the thesis.

Accessing data from other sites for the multi-centre observational study in chapter 6 became very challenging. Remote access to IT systems had to be gained instead of visiting sites for data collection as planned. These processes were time consuming resulting in delays in starting data collection. The greatest impact was on accessing data for the assessment of colonoscopy performance indicators (chapter 9). As this data needed to be obtained through public health services, progress was not possible until the worst stages of the pandemic had settled. Significant delays resulted due to employees being redeployed limiting access to the data required from BSW.

Recruitment for interviews for the qualitative work chapter 5 were also significantly delayed. It was felt by myself and my supervisors that this had to wait until clinicians had recovered from the trials of the initial wave. Once started recruitment was straightforward, but it would have been possible to perform more interviews if not for the pandemic. The recruitment of patients would have been a valuable addition to this study. Given the delays already suffered, this aspect of the study was not pursued in the interest of time.

10.5 Future work

This thesis has identified further potential areas of importance to the field of decision-making in the management of complex colorectal polyps and are outlined below.

10.5.1 Development of an international consensus on complex polyp terminology

As noted throughout this thesis, the terminology and definitions of complex colonic polyps are variable. This has resulted in limitations in both the methodology and conclusions drawn. A consensus from leading international organisations regarding this is desirable to improve the performance of research in this field. It would also be greatly beneficial for the evidence underlying and recommendations of surveillance guidelines. Development and validation of a minimum dataset requirement for the methodology and reporting regarding complex polyp research would be a valuable contribution.

10.5.2 Development of standardised processes and monitoring for complex polyp team management approaches

Currently the structure of complex polyp management teams across the UK is variable. This will allow for the individual needs of each location, but guidance is required regarding team composition and referral processes to ensure service quality and equality in access. Research and guidance regarding the implementation of standardised referral pathways and selection criteria is warranted. Specific criteria are needed for access to and the safe introduction of specialist treatments such as ESD, TAMIS and CEL techniques. Work to develop the introduction of prospective data collection and

monitoring of patient outcomes for these services is needed. The identification, introduction and monitoring of appropriate KPIs should be performed similar to that required for bowel cancer outcomes through the National Bowel Cancer Audit. This may also allow evidence to be obtained into the economic benefits of such strategies. Research into educational and support strategies for the non-specialist colonoscopists for improving decision-making pathways and outcomes would also be of interest. The financial implications of specialist service provision are of inevitable importance in ensuring sustainability and cost effectiveness. Assessment of team meeting costs should be straightforward to collect in an UK setting. Sessional commitments for consultant staff can be calculated, in addition to hourly rates for other medical and administrative staff. This can then be assessed against the number of patients discussed per meeting. This must account for both the scheduled meeting in addition to any preparation or tasks resulting from it and would be important when generating figures for commissioning and reimbursement. There is limited evidence on this currently and it may be difficult to collect data on a comparative group to assess cost effectiveness. The alternative of ad hoc discussions, emails and enquiries when making decisions regarding patients is likely to be much more time consuming. It may be difficult to track but could be collected prospectively with careful planning to enable comparison between groups. Wider benefits of multi-disciplinary team meetings should also be accounted for including tracking and reporting of clinical outcomes, educational benefits and efficiency of management planning.

10.5.3 Assessment of patient reported outcomes after complex polyp treatment

This thesis has demonstrated the benefit of decision-making processes in the clinical management of patients with complex polyps. Of equal importance are the outcomes reported by patients and their involvement in the shared decision-making process. Qualitative and quantitative research is needed regarding patient experiences, quality of life and functional outcomes after complex polyp management. The comparison of treatment modalities and their impact on an individual will likely give an important insight into refining the best treatment options for patients. This is also highly applicable to the acceptability and duration of surveillance. Development of standardised patient information sheets for treatment options in collaboration with relevant organisations such as the BSG, Association of Coloproctology of Great Britain and Ireland (ACPGBI) and Bowel Cancer UK (BCUK) would be of value.

10.5.4 Identification of patients with complex polyps not suitable for treatment or surveillance

Given certain patient characteristics and the natural history of complex polyps, there are some patients where treatment or surveillance may not be beneficial. Identifying patient and polyp factors that predict where conservative management should be chosen is important and endorsed by

guidelines. The treatment of polyps in elderly patients may subject them to procedure risks for a condition that may never cause them harm. Prospective research of thresholds for treatment and surveillance based on age, life expectancy and patient wishes are warranted. The utilisation and effectiveness of less invasive methods such as CT or FIT testing in screening after treatment may also of importance.

10.5.5 Identification of optimal KPI standards for colonoscopy

Chapter 9 suggests that there is a threshold at which further improvements in colonoscopy KPIs do not translate to additional gains in reducing the risk of cancer or advanced polyps at a later date. A systematic literature review to assess this more thoroughly would be beneficial in additional to repeated studies like the one performed here. This evidence needs to be generated and interpreted in context of the setting including screening and symptomatic programmes. Benefits of identifying these standards will include to guidance regarding quality, endoscopy training and the introduction of technologies such as artificial intelligence.

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Appendices

Appendix 1 – The Charlson comorbidity index (CCI)

Score	Comorbidity
1	Myocardial infarction Congestive cardiac failure Cerebral vascular disease Peripheral vascular disease Dementia Chronic obstructive pulmonary disease Connective tissue disease Peptic ulcer disease Mild liver disease Age *
2	Diabetes/diabetes with end organ damage Hemiplegia Moderate/severe renal disease Any solid tumour, leukaemia, lymphoma
3	Moderate/severe liver disease
6	Metastatic solid tumour Acquired immunodeficiency syndrome

** For each decade after 40 years, a point is added (1 point for age group 41-50, 2 points for age group 51-60, 3 points for 61-70, 4 points for 71 or older*

Appendix 2 – The Clavien-Dindo (CD) classification of surgical complications

Grade	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions *
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications Blood transfusions and total parenteral nutrition are also included
Grade III	Requiring surgical, endoscopic or radiological intervention
Grade IV	Life-threatening complication (including CNS complications) requiring intermediate care or intensive care unit
Grade V	Death of a patient

**Allowed therapeutic regimens include drugs as antiemetics, antipyretics, analgesia, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside.*

Appendix 3 – Full search strategy for systematic review

(((("colonic polyps"[MeSH Terms] OR ("colonic"[All Fields] AND "polyps"[All Fields]) OR "colonic polyps"[All Fields] OR ("colonic"[All Fields] AND "polyp"[All Fields]) OR "colonic polyp"[All Fields]) AND (((((("laparoscopy"[MeSH Terms] OR "laparoscopy"[All Fields] OR "laparoscopic"[All Fields]) AND facilitated[All Fields]) OR (("chimera"[MeSH Terms] OR "chimera"[All Fields] OR "hybrid"[All Fields]) AND ("methods"[MeSH Terms] OR "methods"[All Fields] OR "procedure"[All Fields]))) OR (combined[All Fields] AND ("methods"[MeSH Terms] OR "methods"[All Fields] OR "procedure"[All Fields]))) OR ("laparoscopy"[MeSH Terms] OR "laparoscopy"[All Fields] OR "laparoscopic"[All Fields])) OR operate[All Fields]) OR ("surgery"[Subheading] OR "surgery"[All Fields] OR "surgical procedures, operative"[MeSH Terms] OR ("surgical"[All Fields] AND "procedures"[All Fields] AND "operative"[All Fields]) OR "operative surgical procedures"[All Fields] OR "surgery"[All Fields] OR "general surgery"[MeSH Terms] OR ("general"[All Fields] AND "surgery"[All Fields]) OR "general surgery"[All Fields]))) OR (("colonic polyps"[MeSH Terms] OR ("colonic"[All Fields] AND "polyps"[All Fields]) OR "colonic polyps"[All Fields] OR ("colonic"[All Fields] AND "polyp"[All Fields]) OR "colonic polyp"[All Fields]) AND ((("endoscopic mucosal resection"[MeSH Terms] OR ("endoscopic"[All Fields] AND "mucosal"[All Fields] AND "resection"[All Fields]) OR "endoscopic mucosal resection"[All Fields] OR ("endoscopic"[All Fields] AND "submucosal"[All Fields] AND "dissection"[All Fields]) OR "endoscopic submucosal dissection"[All Fields]) OR ("endoscopic mucosal resection"[MeSH Terms] OR ("endoscopic"[All Fields] AND "mucosal"[All Fields] AND "resection"[All Fields]) OR "endoscopic mucosal resection"[All Fields])) OR polypectomy[All Fields]))) OR (("colonic polyps"[MeSH Terms] OR ("colonic"[All Fields] AND "polyps"[All Fields]) OR "colonic polyps"[All Fields] OR ("colonic"[All Fields] AND "polyp"[All Fields]) OR "colonic polyp"[All Fields]) AND (((((large[All Fields] OR (laterally[All Fields] AND spreading[All Fields])) OR refractory[All Fields]) OR advanced[All Fields]) OR difficult[All Fields]) OR endoscopically unresectable[All Fields]) OR complex[All Fields]))

Appendix 4 – Specialist Unit for Review Evidence (SURE) checklist questions to assist with the critical appraisal of case series

Citation:

Are there other companion papers from the same study?

	Yes/Can't tell/No
1. Is the study design clearly stated? Consider if retrospective or prospective	
2. Does the study address a clearly focused question? Consider: population, exposure or intervention and outcomes (are these appropriate?)	
3. Are the setting, locations and relevant dates provided? Consider: recruitment period; follow-up & data collection; single or multiple centre	
4. Are there explicit inclusion/exclusion criteria?	
5. Were patients enrolled consecutively?	
6. Are participant characteristics provided? Consider if: sufficient details; a baseline table is included	
7. Are outcome measures appropriate? Consider if: the methods of assessment are valid & reliable	
8. Are the statistical methods well described? Consider: How missing data were handled; were potential sources of bias (confounding factors) considered/controlled for	

9. Is information provided on participant flow? Consider if following provided:

- numbers of participants in the series;

- number lost to follow-up;

- details of missing participant data;

- follow-up time.

10. Are the results well described? Consider if

- effect sizes, confidence intervals/standard deviations are provided;

- the results support the conclusions. Are they the same in the abstract and the full text?

11. Is any sponsorship/conflict of interest reported?

12. Finally...Did the authors identify any limitations and, if so, are they captured above?

Summary

Add comments relating to areas of concern that were avoidable and a statement indicating if the results are reliable and/or useful

Appendix 5 – Classifications of excluded articles for systematic review

Exclusion classification	Number of articles
Duplications	9,347
Exclusions based on study population	
Article not describing colonic polyp treatment(s)	5,411
Article did not meet complex polyp definition	86
Article only including malignant polyps	20
Article only including rectal polyps	10
Article describing a novel technique	7
Article describing treatment of polyposis syndromes	2
Exclusions based on article type	
Non-systematic review article	147
Editorials	67
Poster presentations	64
Cross referenced review article	41
Case reports	36
Book chapters	4
Exclusions based on article availability	

Article not found or not translatable	13
Exclusions based on decision-making or primary outcome inclusion criteria	
Decision-making strategy not described	233
Only one decision-making strategy described	59
Insufficient primary outcomes	1
Outdated article	1
Total exclusions =	**15,549**

Appendix 6 – Complete dataset for systematic review

Appendix 6.1 – Study characteristics

	Year	Title	Journal	Country, centres	Study design	Age	Polyp size (mm), location and morphology	Treatment(s)	Number of patients/ lesions	Referred for primary surgery	Total number analysed
Bulut	2019	Combined endoscopic laparoscopic surgical treatment of advanced adenomas and early colon cancers	Danish Medical Journal	Denmark 1	Case series Retrospective	Median 71 (range 36-88)	**Size:** Benign - Median 30 (range 10-80), malignant - Median 17 (range 15-70) **Location:** All **Morphology:** Not described	CELS	25 lesions in 25 patients	N/A	25 lesions in 25 patients
Cohan	2020	Endoscopic step up: A colon-sparing alternative to colectomy to improve outcomes and reduce costs for patients with advanced neoplastic polyps	Diseases of the Colon and Rectum	USA 1	Case series Prospective	Median 65 (range 58-69) (Endoscopic step up)	**Size:** Median 25 (range 20-31) **Location:** All **Morphology:** Not described	Compares straight to surgery vs 'endoscopic step up' (ESD/EMR/CELS)	90 lesions in 90 patients	52 (57.8%)	38 lesions in 38 patients

Crawford	2015	Dynamic article: combined endoscopic-laparoscopic surgery for complex colonic polyps: postoperative outcomes and video demonstration of 3 key operative techniques	Diseases of the Colon and Rectum	Canada 1	Case series Retrospective	Median 64 (range 32-81)	**Size:** Median 40 (range 15-70) **Location:** All **Morphology:** Sessile - 14 (46.7%), broad pedicle - 12 (40%), exophytic - 2 (6.7%), appendiceal mass - 2 (6.7%)	CELS	30 lesions in 30 patients	N/A	30 lesions in 30 patients
Emmanuel	2018	Combining eastern and western practices for safe and effective endoscopic resection of large complex colorectal lesions	European Journal of Gastroenterology and Hepatology	UK 1	Case series Retrospective	Mean 71.8 (range 33-99)	**Size:** Mean 54.8 (range 20-160) **Location:** All inc rectum **Morphology:** LST-G* or LST-NG**	EMR, ESD or hybrid procedure	466 lesions in 420 patients	N/A	466 lesions in 420 patients
Goh	2013	Endolaparoscopic removal of colonic polyps	Colorectal Disease	UK 1	Case series Retrospective	Median 65.4 (range 61.6-73.5)	**Size:** Median 14 (range 10-22) **Location:** All **Morphology:** Pedunculated -	CELS	30 lesions in 30 patients	N/A	30 lesions in 30 patients

							16 (53.3%), sessile - 14 (46.7%)				
Kao	2011	Endoscopic excision of large colorectal polyps as a viable alternative to surgical resection	The Archives of Surgery	USA 1	Case series Retrospective	Mean 67 (range 29-92)	**Size:** Median 33 (range 10-90) **Location:** All **Morphology:** Pedunculated - 33 (15%), sessile - 82 (37.2%), flat - 105 (47.7%)	EMR	104 lesions in 104 patients	N/A	104 lesions in 104 patients
Longcroft-Wheaton	2013	Risk stratification system for evaluation of complex polyps can predict outcomes of endoscopic mucosal resection	Diseases of the Colon and Rectum	UK 1	Case series Prospective	Mean 68, median 69 (range 44-86)	**Size:** Mean 43 (range 20-150) **Location:** All **Morphology:** Pedunculated - 33 (15%), sessile - 82 (37.2%), flat - 105 (47.7%)	EMR	242 lesions in 242 patients	22 (9.1%)	220 lesions in 220 patients
Voloyiannis	2007	Management of the difficult colon polyp referred for	Diseases of the Colon and Rectum	USA 1	Case series Retrospective	Mean 65	**Size:** Mean 32.27 (range 10-100) **Location:** All	Repeat colonoscopy and polypectomy	252 lesions in 237 patients	80 (33.8%)	157 lesions in 157 patients

		resection: resect or rescope?					**Morphology:** Pedunculated – 19, sessile - 218	(snare, hot forceps, EMR) or straight to colonic resection				
Wood	2011	Laparo-endoscopic resection for extensive and inaccessible colorectal polyps: a feasible and safe procedure	Annals of the Royal College of Surgeons of England	UK 1	Case series Prospective	Range 48-85	**Size:** 20-50 Location: All Morphology: 'Mostly sessile'	CELS	16 lesions in 13 patients	N/A	16 lesions in 13 patients	

The total number of patients analysed is included in the final column. For those studies describing referrals for primary surgery, this was excluded from this total.

*LST-G – Laterally spreading tumour granular

**LST-NG – Laterally spreading tumour non granular

Appendix 6.2 – Primary outcomes

	Malignancies (per lesion)			**Secondary surgery (per patient)**			**Adverse events (per patient)**	
	Total	***Suspected***	***Unsuspected***	***Number***	***Indications***	***Total***	***Type***	***CD 2-4***
Bulut	5 out of 25 (20%)	4 (16%)	1 (4%)	4 out of 25 (16%)	Cancer suspected during procedure: 3 Cancer on post-op histology: 1	4 out of 25 (16%)	**CD 1** Port site haematoma: 2 **CD 2/3/4**	2 out of 25 (8%)

							Micro-perforation (managed with Abx): 1 Post op abdominal pain and negative laparoscopy: 1	
Cohan	3 out of 38 (7.9%)	2 (5.3%)	1 (2.6%)	2 out of 38 (5.3%)	Cancer suspected during procedure: 2	5 out of 38 (13.2%)	**CD 1** PPS (no intervention): 1 Post procedure Ileus (no NG): 1 **CD 2/3/4** Blood transfusion: 1 Surgical site infection: 2	3 out of 38 (7.9%)
Crawford	1 out of 30 (3.3%)	0	1 (3.3%)	2 out of 30 (6.7%)	Cancer suspected during procedure: 1 Cancer on post-op histology: 1	3 out of 30 (10%)	**CD 1** Port site bleed (no intervention): 1 **CD 2/3/4** Urinary retention: 1 Anaphylaxis: 1 PE and subsequent haemorrhage from polypectomy site: 1	3 out of 30 (10%)
Emmanuel	34 out of 466 (7.3%)	23 (4.9%)	11 (2.4%)	14 out of 466 (3.3%)	Procedure related perforation: 2 Cancer on post-op histology: 7 Recurrence: 5	33 out of 420 (7.4%) ***	**CD 1** Post procedure bleeding (managed conservatively): 4 **CD 2/3/4**	22 out of 420 (5.2%)

	*						Post procedure bleeding (managed endoscopically): 4 Post procedure bleeding (requiring transfusion): 1 Procedure related perforation (managed with antibiotics): 1 Procedure related perforation (managed surgically): 2 Procedure related perforation (managed endoscopically): 10 Medical complication: 4	
Goh	2 out of 30 (6.7%)	1 (3.3%)	1 (3.3%)	9 out of 30 (30%)	Unsuccessful/incomplete resection: 7 Cancer suspected during procedure: 1 Cancer on post-op histology: 1	4 out of 30 (13.3%)	**CD 1** Post procedure bleeding (managed conservatively): 1 **CD 2/3/4** Urinary retention: 2 Post procedure Ileus: 1	3 out of 30 (10%)
Kao	16 out of 104 (15.4%) **	0	16 (15.4%)	15 out of 104 (14.4%)	Unsuccessful/incomplete resection: 14 Procedure related perforation: 1	7 out of 104 (6.7%)	**CD 1** Intra procedure bleeding (managed conservatively): 2 Post procedure bleeding (managed conservatively): 1 **CD 2/3/4** Post procedure bleeding (managed endoscopically): 3 Procedure related perforation (managed surgically): 1	4 out of 104 (3.8%)

Longcroft-Wheaton	22 out of 220 (10%)	5 (2.3%)	17 (7.7%)	18 out of 220 (8.2%)	Cancer suspected during procedure: 5 Unsuccessful/incomplete resection: 4 Cancer on post-op histology: 9	18 out of 220 (8.2%)	**CD 1** PPS (no intervention): 6 **CD 2/3/4** Post procedure bleeding (managed endoscopically): 5 Post procedure bleeding (managed with transfusion +/- endoscopy): 6 Micro-perforation (managed with Abx): 1	12 out of 220 (5.5%)
Voloyiannis	19 out of 157 (12.1%)	13 (8.3%)	6 (3.8%)	69 out of 157 (43.9%)	Unsuccessful/incomplete resection: 63 Cancer suspected during procedure: 6	83 out of 157 (52.9%)	**CD 1** Post procedure bleeding (managed conservatively): 81 **CD 2/3/4** Procedure related perforation (managed surgically): 2	2 out of 157 (1.3%)
Wood	2 out of 16 (12.5%)	1 (6.3%)	1 (6.3%)	4 out of 16 (30.8%)	Unsuccessful/incomplete resection: 2 Cancer suspected during procedure: 1 Cancer on post-op histology: 1	2 out of 13 (15.4%)	**CD 1** Post procedure bradycardia (managed conservatively): 1 **CD 2/3/4** Post procedure pneumonia: 1	1 out of 13 (7.7%)

***** Unsuspected malignancy rate was not clearly described in this paper. Suspected cancers were defined as those with a type V pit pattern during endoscopic polyp assessment.

** Carcinomas in situ were excluded from the malignancy rate in this paper as this is an alternative term for HGD. The Vienna classification of gastrointestinal neoplasia was applied where there was ambiguity (21).

** Delayed complications included seven post procedure strictures were excluded from this number

Appendix 7 – Consolidated criteria for reporting qualitative research (COREQ)

Item	Guide questions/description
Domain 1: Research team and reflexivity	
Personal Characteristics	
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?
2. Credentials	What were the researcher's credentials? *E.g. PhD, MD*
3. Occupation	What was their occupation at the time of the study?
4. Gender	Was the researcher male or female?
5. Experience and training	What experience or training did the researcher have?
Relationships with participants	
6. Relationship established	Was a relationship established prior to study commencement?
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic

Domain 2: study design	
Theoretical framework	
9. Methodological orientation and theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis
Participant selection	
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email
12. Sample size	How many participants were in the study?
13. Non-participation	How many people refused to participate or dropped out? Reasons?
Setting	
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace
15. Presence of non-participants	Was anyone else present besides the participants and researchers?
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date
Data collection	

17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?
20. Field notes	Were field notes made during and/or after the interview or focus group?
21. Duration	What was the duration of the interviews or focus group?
22. Data saturation	Was data saturation discussed?
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?
Domain 3: analysis and findings	
Data analysis	
24. Number of data coders	How many data coders coded the data?
25. Description of the coding tree	Did authors provide a description of the coding tree?
26. Derivation of themes	Were themes identified in advance or derived from the data?
27. Software	What software, if applicable, was used to manage the data?
28. Participant checking	Did participants provide feedback on the findings?

Reporting	
29. Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number
30. Data and findings consistent	Was there consistency between the data presented and the findings?
31. Clarity of major themes	Were major themes clearly presented in the findings?
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?

Appendix 8 – Interview guidance proforma

Explain to the participant that the purpose of the interview is to explore the influences affecting their management recommendations for a patient with a large or complex colorectal polyp. The topics are for guidance to prompt discussion only and there should be flexibility in discussing other topics of interest to the participant.

Time	Guidance
Before the interview	- Confirm eligibility and consent of participant - Notify of right to withdraw - Confirm that participant is happy with recording of interview
During the interview	- What factors do you assess and consider once a complex polyp has been found? - Are there any logistical considerations that would affect your chosen treatment? - Are there any other influences to mention? (e.g. colleagues, patient, evidence)
At the end of the interview	- Confirm the participant has study team contact details - Ask if they have any questions - Ask if they would like a copy of the study report when available

Appendix 9 – Ethical approval for qualitative study

School of Medicine
Yr Ysgol Meddygaeth

Cardiff University
Main Building
Heath Park
Cardiff CF14 4XN
Wales, UK
Prifysgol Caerdydd
Prif Adeilad
Parc y Mynydd Bychan
Caerdydd CF14 4XN
Cymru, Y Deyrnas Unedig

Wednesday 24th March 2021

Jody Parker
Division of Population Medicine
School of Medicine
Cardiff University

Dear Jody

Research project title: Why are benign polyps being operated on? A qualitative assessment of influences on decision making practices amongst colonoscopists.
SREC reference: 21/34

The School of Medicine Research Ethics Committee ('Committee') reviewed the above application at the meeting held on Wednesday 17th March 2021. A revised application was considered on Tuesday 23rd March 2021.

Ethical Opinion
The Committee gave a favourable ethical opinion of the above application on the basis described in the application form, protocol and supporting documentation.

Additional approvals
This letter provides an ethical opinion only. You must not start your research project until all appropriate approvals are in place.

Amendments
Any substantial amendments to documents previously reviewed by the Committee must be submitted to the Committee via email to Claire Evans (EvansCR9@cardiff.ac.uk) for consideration and cannot be implemented until the Committee has confirmed it is satisfied with the proposed amendments.

You are permitted to implement non-substantial amendments to the documents previously reviewed by the Committee but you must provide a copy of any updated documents to the Committee via email to Claire Evans (EvansCR9@cardiff.ac.uk) for its records.

Monitoring requirements
The Committee must be informed of any unexpected ethical issues or unexpected adverse events that arise during the research project. In addition to this, the Committee request an end of project report sent to the Committee via email to Claire Evans (EvansCR9@cardiff.ac.uk). This must be sent along with confirmation that your research project has ended and sent within the three months of the research project completion.

Documents reviewed by Committee
The documents reviewed by the Committee were:

Document	Version	Date
Application Form	V1	09/03/2020
Study Protocol	V1.1	January 2021
Recruitment Letter	V1.1	January 2021
Study Information and Eligibility Assessment	V1.1	January 2021
Consent Form	V1.1	January 2021
Participant Questionnaire	V1.1	January 2021
Interview Guidance Proforma	V1.1	January 2021
Email to Committee Secretary	-	22/03/2021
Consent Form	V1.1	January 2021
Participant Questionnaire	V1.1	January 2021
Recruitment Letter	-	18/01/2021
Study Information and Eligibility Assessment	V1.1	January 2021
Interview Guidance Proforma	V1.0	January 2021

Appendix 10 – Strengthening the reporting of observational studies in epidemiology (STROBE) statement

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with Title and abstract 1 a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls

		Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants (b) Cohort study—For matched studies, give matching criteria and number of exposed and unexposed Case-control study—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) Cohort study—If applicable, explain how loss to follow-up was addressed Case-control study—If applicable, explain how matching of cases and controls was

		addressed Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Cohort study—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	Cohort study—Report numbers of outcome events or summary measures over time Case-control study—Report numbers in each exposure category, or summary measures of exposure Cross-sectional study—Report numbers of outcome events or summary measures

Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity. of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

**Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.*

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine athttp://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Appendix 11 – Exclusion classifications

Reason for exclusion	Number of patients
Other pathology or simple polyp found on assessment *	175 (27.3%)
Redirected to cancer meeting for management	143 (22.3%)
Less than 1 year follow-up after primary procedure	92 (14.4%)
Complex polyp not found on assessment **	66 (10.3%)
Multiple small polyps or polyposis syndrome identified	59 (9.2%)
No documented discussion by complex polyp meeting	53 (8.3%)
Data unavailable	33 (5.2%)
Awaiting management	19 (3.0%)
Total	**640**

*Figures are given as number of patient and (%) to one decimal place * Simple polyps were lesions found to be less than 10mm in size with no other high-risk features (such as high-grade dysplasia, recurrent lesions or difficult access) when assessed by the complex polyp meeting ** Most cases were due to lesions detected on other investigations (such as CT colonography) and not identifiable at endoscopy*

Appendix 12 – Complications and reasons for 30-day readmissions

Complications

	Abx	*AntiC*	*Abx + IR drain*	*Abx + theatre debridement*	*Conservative*	*Endoscopic intervention*	*EUA*	*IR*	*ICU*	*IVF*	*Missing*	*NG*	*Colonic resection*	*Surgical washout*	*Temporary catheter*	*Transfusion*
Endoscopy	**21**	**0**	**0**	**0**	**44**	**12**	**0**	**1**	**0**	**2**	**0**	**1**	**7**	**1**	**0**	**4**
AKI	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Bleeding – Intra-abdominal	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Bleeding – PR	-	-	-	-	35	12	-	1	-	-	-	-	3	-	-	4
Bowel ischaemia	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Infection – Intra-abdominal	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Ileus	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Infection – Chest	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Infection – Wound	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Obstruction	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Pain causing readmission	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Perforation	11	-	-	-	-	-	-	-	-	-	-	-	3	-	-	-
PPS	4	-	-	-	7	-	-	-	-	-	-	-	-	-	-	-
Combined procedure	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**0**
Urinary retention	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2	-
Surgery – Trans-anal	**4**	**0**	**0**	**0**	**1**	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**0**	**1**	**4**	**0**
AKI	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Bleeding – PR	-	-	-	-	1	-	1	0	-	-	-	-	-	-	-	-
Infection –	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Intra-abdominal																
Infection – Chest	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Infection – Wound	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Perforation	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Urinary retention	-	-	-	-	-	-	-	-	-	-	-	-	-	-	4	-
Surgery – Colonic resection	**28**	**2**	**3**	**3**	**4**	**0**	**0**	**0**	**4**	**10**	**1**	**4**	**11**	**7**	**4**	**5**
AKI	-	-	-	-	-	-	-	-	-	5	-	-	-	-	-	-
Bleeding – Intra-abdominal	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1
Bleeding – PR	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	3
Bowel ischaemia	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-

DVT/PE	-	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Haematoma – Intra-abdominal	1	-	-	-	1	-	-	-	-	-	-	-	-	2	-	1
Haematoma – Wound	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Ileus	-	-	-	-	-	-	-	-	1	5	-	4	-	-	-	-
Infection – Intra-abdominal	-	-	1	-	-	-	-	-	-	-	-	-	-	1	-	-
Infection – Chest	10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Infection – Urine	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Infection – Wound	9	-	-	3	-	-	-	-	-	-	-	-	-	1	-	-
Leak	1	-	2	-	-	-	-	-	1	-	-	-	10	3	-	-
Obstruction	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Missing	-	-	-	-	-	-	-	-	2	-	1	-	-	-	-	-
Pain causing readmission	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-
Urinary retention	-	-	-	-	-	-	-	-	-	-	-	-	-	-	4	-

30-day readmissions

	Endoscopy	Trans-anal	Colonic resection	Total
Related	**55**	**2**	**13**	**70**
Bleeding – PR	40	2	-	42
Constipation	-	-	1	1
DVT/PE	-	-	1	1
Haematoma – Intra-abdominal	-	-	1	1
Ileus	-	-	1	1
Infection – Intra-abdominal	-	-	1	1
Infection – Urine	-	-	1	1
Infection – Wound	-	-	3	3
Missing	-	-	2	2
Obstruction	1	-	-	1
Pain	1	-	2	3
Perforation	6	-	-	6
PPS	7	-	-	7
Unrelated	**12**	**1**	**1**	**14**

Complete overview of all complications and their treatments divided into procedure type. Values are given as total number. All identified 30-day readmissions after polyp procedures classified into related or unrelated to treatment. The reasons for related readmissions are given as total number. Abx – antibiotics, AntiC – anticoagulation, AKI– acute kidney injury, EUA – examination under anaesthetic, DVT – deep vein thrombosis, IR – interventional radiology, ITU – intensive treatment unit, IV – intravenous, IVF – IV fluids, NG – nasogastric tube, PE – pulmonary embolism, PPS – post polypectomy syndrome PR – per rectum

Appendix 13 – British Society of Gastroenterology (BSG) complex colorectal polyp minimum dataset

Patient name:	**Gender:**	**DOB:**	**NHS no:**

Endoscopist + Centre	
Patient symptoms	
Additional colorectal pathology, e.g. IBD	
Significant comorbidity, e.g. ASA score, Schonberg Index	
Anticoagulation/antiplatelet use + indication	

Polyp details – ***Please record polyp details + indicate SMSA score. This will help determine the difficulty of achieving successful endoscopic resection***

	Details	**SMSA score *(circle/highlight)***
Site		Left=1; Right=2
Size		<1cm= 1; 1-1.9cm= 3; 2-2.9cm= 5; 3-3.9cm= 7; >4cm=9
Morphology (e.g. Paris/LST)		Pedunculated (Ip)= 1; sessile (Is/Isp)= 2; flat (II)= 3
Access issues		Proximal aspect of fold, difficult colonoscopy etc. Easy= 1; difficult= 3

Total SMSA score/level ***(circle/highlight)***	Level I: 4-5 Level 2: 6-9 Level 3: 10-12 Level 4: >12
Surface characteristic (e.g. pit pattern, Sano CP, NBI NICE classification)	
Features indicating high risk of malignancy ***Highlight all that apply***	Morphological: lesion depression (Paris 0-IIc or 0-IIa+c), LST-NG, LST-G with dominant nodule, non lifting sign Surface: ulceration, pit pattern V, Sano CP III, NBI NICE type 3
High risk of recurrence/incomplete excision ***Highlight all that apply***	≥ 40mm, difficult location (dentate line, ICV, appendix, diverticulum, anastomosis), previous failed attempts, other
Relevant histology results	
Relevant radiology results	

Additional information

Does the patient have any particular wishes/preferences? Is he/she prepared to travel to another centre?	
Specific questions regarding management?	

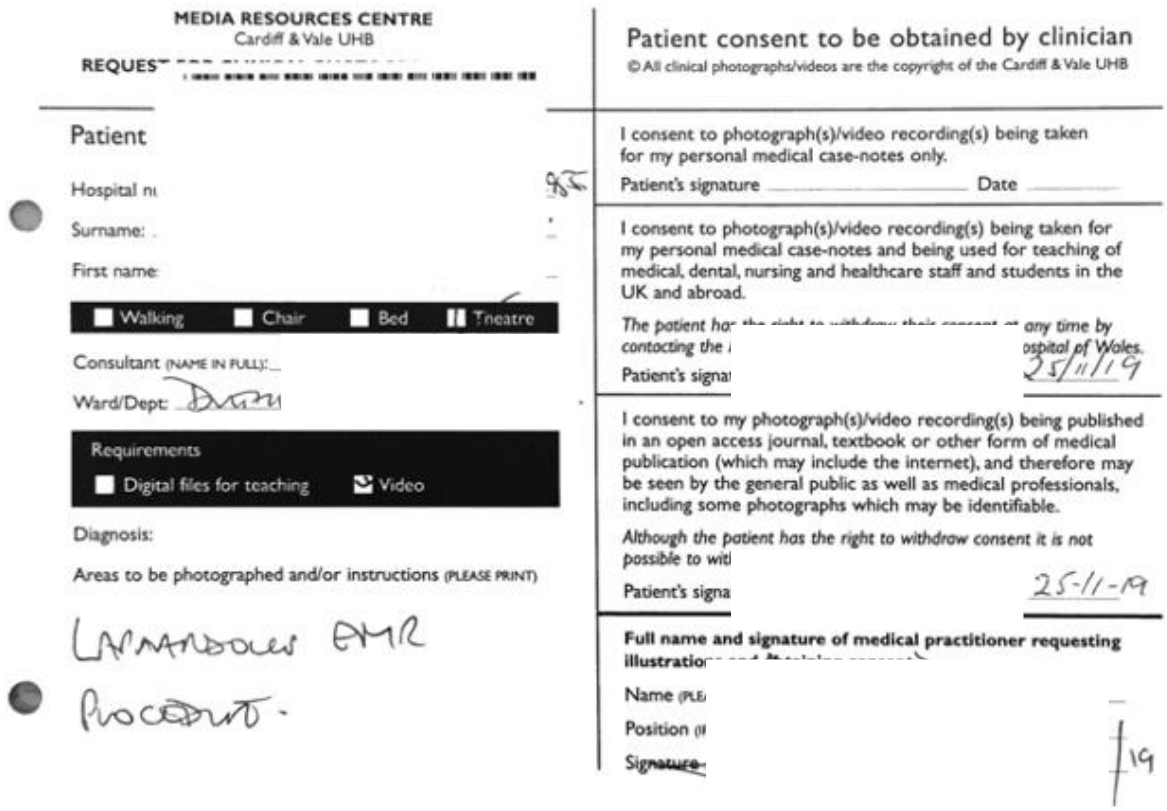
Please attach photos/video, including as a minimum: full lumen view, close-up lesion surface, close-up of any abnormal/ concerning focus

Additional desirable imaging: enhanced lesion surface imaging (e.g. NBI/FICE/I-Scan)

For rectal lesions please also include: retroflexed image and front facing image from anal verge

ASA, American Society of Anesthetists; CP, capillary pattern; G, granular; IBD, inflammatory bowel disease; ICV, ileocaecal valve; LST, laterally spreading tumours; NBI NICE, Narrow Band Imaging International Colorectal Endoscopic; NG, non-granular; SMSA, size, morphologv, site, access.

Appendix 14 – Patient consent for Lap EMR video



MEDIA RESOURCES CENTRE
Cardiff & Vale UHB

REQUES[redacted]

Patient

Hospital n[redacted]

Surname: [redacted]

First name: [redacted]

☐ Walking ☐ Chair ☐ Bed ☒ Theatre

Consultant (NAME IN FULL): [redacted]

Ward/Dept: [redacted]

Requirements
☐ Digital files for teaching ☒ Video

Diagnosis:

Areas to be photographed and/or instructions (PLEASE PRINT)

LAPAROSCOPIC EMR
PROCEDURE.

Patient consent to be obtained by clinician

© All clinical photographs/videos are the copyright of the Cardiff & Vale UHB

I consent to photograph(s)/video recording(s) being taken for my personal medical case-notes only.

Patient's signature [redacted] Date [redacted]

I consent to photograph(s)/video recording(s) being taken for my personal medical case-notes and being used for teaching of medical, dental, nursing and healthcare staff and students in the UK and abroad.

The patient ha[redacted] any time by contacting the [redacted] ospital of Wales.

Patient's signa[redacted] 25/11/19

I consent to my photograph(s)/video recording(s) being published in an open access journal, textbook or other form of medical publication (which may include the internet), and therefore may be seen by the general public as well as medical professionals, including some photographs which may be identifiable.

Although the patient has the right to withdraw consent it is not possible to wit[redacted]

Patient's signa[redacted] 25-11-19

Full name and signature of medical practitioner requesting illustratio[redacted]

Name (PLE[redacted]

Position ([redacted]

Signature [redacted] /19

For confidentiality purposes, the patient's details and signature have been removed

Appendix 15 – Other sources searched

Australian National Health and Medical Research Council (NHMRC) clinical practice guidelines
Guideline.gov
eGuidelines
Guidelines International Network (GIN)
New Zealand Guidelines Group
Scottish Intercollegiate Guidelines Network (SIGN)
US National Guidelines Clearing House
British Society of Gastroenterology (BSG)
National Institute for Health and Clinical Excellence (NICE)
European Society of Gastroenterology (ESGE)

Appendix 16 – Full search strategy

((((((recommendation) AND Abstract OR Guideline)) AND Abstract AND surveillance)) AND Abstract AND ((((polypectomy) AND Abstract OR adenoma) AND Abstract OR colorectal neoplasm) AND Abstract OR polyp) AND Abstract)

Appendix 17 – Classification of excluded articles

Exclusion classification	Number of articles
Duplications	**1073**
Title and abstract screen	**5290**
Full text screen	**100**
Cross referenced article	46
Guideline for bowel cancer screening only	17
Article not a guideline	15
Article not found or translatable	12
Guideline for technical issues	6
Guideline for other colorectal pathology	4
Guideline screen	**67**
Older version of guideline	30
Recommendations provided based on another guideline	16
Guideline not based on formal review of evidence	9
Succeeded by new guideline	9
Local or regional guideline	2
Specific surveillance timings not given by guideline	1
Total	**6530**

Exclusions that were for other colorectal pathology included guidelines only concerning colorectal cancer, inherited conditions or IBD. Excluded technical guidelines related to bowel preparation and endoscopy service delivery rather than timings for surveillance after polyp diagnosis.

Appendix 18 – Cancer Council Australia (CCA) guidance for surveillance intervals of sessile and traditional serrated adenomas

	Recommendation
Clinically significant serrated polyps only: ***1–2 sessile serrated adenomas all <10mm without dysplasia*** **Clinically significant serrated polyps and synchronous conventional adenomas:** ***2 in total, sessile serrated adenoma <10mm without dysplasia.***	5 years
Clinically significant serrated polyps only: ***3–4 sessile serrated adenomas, all <10mm without dysplasia*** ***1–2 sessile serrated adenomas ≥10mm or with dysplasia, or hyperplastic polyp ≥10mm*** ***1–2 traditional serrated adenomas, any size*** **Clinically significant serrated polyps and synchronous conventional adenomas:** ***3–9 in total, all sessile serrated adenomas <10mm without dysplasia*** ***2–4 in total, any serrated polyp ≥10mm and/or dysplasia*** ***2–4 in total, any traditional serrated adenoma*** **Synchronous high-risk conventional adenoma:** ***2 in total, sessile serrated adenoma <10mm, without dysplasia*** ***2 in total, serrated polyp ≥10mm and/or dysplasia*** ***2 in total, any traditional serrated adenoma***	3 years
Clinically significant serrated polyps only: ***≥5 sessile serrated adenomas <10mm without dysplasia***	1 year

3–4 sessile serrated adenomas, one or more ≥10mm or with dysplasia *3–4 traditional serrated adenomas, any size* **Clinically significant serrated polyps and synchronous conventional adenomas:** *≥10 in total, all sessile serrated adenomas <10mm without dysplasia* *≥5 in total, any serrated polyp ≥10mm and/or dysplasia* *≥5 in total, any traditional serrated adenoma* **Synchronous high-risk conventional adenoma:** *≥3 total adenomas, sessile serrated adenoma any size with or without dysplasia* *≥3 total adenomas, one or more traditional serrated adenoma*	

Appendix 19 – Peer reviewed publications

Received: 29 May 2021 | Revised: 28 July 2021 | Accepted: 23 August 2021

DOI: 10.1111/codi.15901

SYSTEMATIC REVIEW

Multidisciplinary decision-making strategies may reduce the need for secondary surgery in complex colonic polyps – A systematic review and pooled analysis

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Funding information
This project has been funded through a Pelican Cancer Foundation research grant and J Parker holds the Royal College of Surgeons of England Moondance Research Fellowship.

Abstract

Aim: The recognition of complex colonic polyps is increasing. Management varies considerably and the impact of this on clinical outcomes is unclear. The aim of this systematic review was to assess the impact of group decision-making strategies and defined selection criteria on the treatment outcomes of complex colonic polyps.

Method: A systematic literature review identified studies reporting complex polyp treatment outcomes and describing their decision-making strategies. Databases searched included PubMed, Web of Science, CINAHL and Scopus. Articles were identified by two blinded reviewers using defined inclusion criteria. The review protocol was registered on PROSPERO and performed in line with PRISMA guidelines.

Results: There were 303 identified articles describing treatment outcomes of complex colonic polyps. Only nine of these fully described the decision-making strategy and met the inclusion criteria. Adverse events ranged from 1.3% to 10% across the studies. Unsuspected malignancy and secondary surgery rates ranged from 2.4% to 15.4% and 3.3% to 43.9%, respectively. Grouping of articles into a hierarchy of decision-making strategies demonstrated a sequential reduction in secondary surgery rates with improving strategies. There were no differences in comparisons of adverse event or unsuspected malignancy rates.

Conclusions: There is limited description of decision-making strategies and variability in reporting of studies describing complex polyp treatment outcomes. The use of multidisciplinary decision-making and defined selection criteria may reduce the need for secondary surgical intervention in complex colonic polyps, but further evidence is required to draw definite conclusions.

KEYWORDS
complex colonic polyps, decision-making, outcomes

PROSPERO registration number: CRD42020157614.

INTRODUCTION

Colorectal cancer accounts for 11% of cancer diagnoses annually in the UK [1] with 54% estimated as being preventable [2]. Early detection improves outcomes and removal of premalignant polyps also reduces incidence of subsequent colorectal cancer as well as mortality associated with it [3].

Bowel cancer screening aims to detect asymptomatic cancer, but many polyps are also identified. Most are easily removable, but some are challenging and detection of complex polyps is increasing [4]. There is no internationally standardised definition, but they are generally accepted as those larger than 20 mm or in a location making endoscopic removal difficult [5, 6]. The British Society of Gastroenterology (BSG) guidelines also include polyps with a site morphology size access (SMSA) level of 4, or with increased risk of malignancy, incomplete resection or adverse events [7]. Early cancer is found in 10%–15% [7] so treatment should be individualised and balance complete polyp removal against the risks of intervention. Management strategies vary considerably [8, 9] and the reasons for this are unclear.

Guidelines recommend endoscopic therapy when cancer is not suspected [7] which has fewer adverse events and shorter hospital stays compared to surgery [10, 11]. Combined endoscopic and laparoscopic procedures can also avoid colonic resection in selected cases [12, 13]. Surgery for benign polyps may be indicated for some but the proportion having bowel resections is considered a key performance indicator [7, 14]. In those found to have malignancy on final histology, survival and disease recurrence does not seem adversely affected by an initial endoscopic attempt [15].

A multidisciplinary decision-making process involves defined selection criteria for treatment applied by a group of individuals with complementary expertise. The impact of such strategies on complex polyp outcomes is unclear [16] but utility has been demonstrated in other settings [17, 18]. The outcome of good decision-making should be providing the most appropriate management for a patient and their polyp at first attempt. BSG guidelines recommend the use of multidisciplinary teams (MDT) for complex polyp management but based on very little evidence [7].

Given the variation in practice for complex polyp management, the effect of group decision-making and selection criteria merits investigation. The primary aim of this review was to assess the impact of these clinical decision-making strategies on the treatment outcomes of complex colonic polyps.

METHODS

A systematic literature review was performed to identify studies reporting treatment outcomes of complex colorectal polyps and describing decision-making strategies for management.

Definitions

Complex colonic polyp

The definition of complex polyps included those described as difficult, advanced, large, significant, refractory or endoscopically unresectable in literature. Nonpedunculated polyps larger than 20 mm [5, 6], those with an SMSA level of 4 [7], with an increased risk of malignancy, incomplete resection or adverse events [7] or in a difficult location [5, 6] were also included.

Defined and undefined selection criteria

Defined selection criteria were articles using specified parameters such as size, location or morphology justifying their treatment choice. Undefined selection criteria were where treatment was chosen on the opinion of a clinician without elaboration of the factors considered.

Adverse event rate

Adverse events were described using the Clavien-Dindo (CD) classification system [19]. Adverse events of CD 2 or higher were used to calculate the adverse event rate. As CD 1 events do not require intervention, they were not included. This was described per number of patients in the study.

Suspected and unsuspected malignancy rates

Suspected malignancies were lesions identified as such by endoscopic assessment or biopsy before or at the primary procedure. Unsuspected malignancies were those recognised on final histology. If there was ambiguity, the Vienna classification was applied [20]. Unsuspected malignancy rate was the primary outcome as further treatment would need to be considered and selected early cancers may be appropriately treated with endoscopy. This was described per number of lesions in the study.

Primary and secondary surgery rate

Primary surgery rate was those referred directly without attempt at endoscopic therapy. Secondary surgery were patients having a colonic resection for any indication thereafter. This was described per number of patients in the study.

Residual and recurrent disease

Residual disease was that occurring at the resection site within 3 months of treatment [7]. Recurrent disease was defined as occurring after this. This was described per number of patients followed-up in the study.

Literature search and search terms

Relevant full text articles were systematically identified from the literature based on the inclusion and exclusion criteria. The study protocol was registered in PROSPERO [21] and performed in line with the PRISMA guidelines [22].

Databases searched included PubMed, Web of Science, CINAHL and Scopus. Updates to identify new articles until the start of analysis in November 2020 were used. No individual journals or country of publication were excluded. All articles were initially considered regardless of publication year or language.

The search terms were developed with expertise in complex polyps and utilised strategies from published guidelines [7]. Terms included "colonic polyps", "complex", "difficult", "advanced", "endoscopically unresectable", "refractory", "laterally spreading", "large", "polypectomy", "endoscopic mucosal resection", "endoscopic submucosal dissection", "surgery", "operate", "laparoscopic", "combined procedure", "hybrid procedure" and "laparoscopic facilitated". Search terms were broad considering the variability in complex polyp terminology. The full strategy is shown in Appendix S1.

Inclusion criteria

Articles reporting colonic polyp management were assessed against our complex polyp definition. Articles meeting this were then reviewed against the decision-making inclusion criteria which included the responsible clinician(s) making the decision and how the decision was reached. Finally, studies had to describe primary outcomes of adverse events, malignancies, or surgery. Secondary outcomes including length of stay, residual or recurrent disease, functional outcomes and cost analysis were assessed if described.

Exclusion criteria

Studies reporting on malignant polyps, rectal polyps, paediatric patients, polyposis syndromes or inflammatory bowel disease were excluded due to the separate considerations required in these circumstances.

Reports on novel techniques or devices were not considered as decision-making and patient selection may be biased. Posters, presentations, case reports or editorials were excluded. Despite considering all articles, some were unavailable despite reasonable efforts to obtain them or lack of language expertise.

Article identification

Database search results were downloaded into EndNote to identify duplicates. Abstracts were then exported to the Rayyan Systematic Review Web Application [23]. Two independent, blinded researchers screened abstracts against our criteria. The researchers resolved conflicts and finalised articles for full text review. Any unresolved conflicts were referred to the senior researcher. Full text articles were assessed by the same blinded reviewers and managed on separate EndNote files. Those meeting the inclusion criteria were selected for data extraction. Review articles and guidelines utilising systematic literature searches were cross referenced to identify additional studies. The abstracts identified were reviewed using the same process.

Data extraction and analysis

Data extraction was performed by the same blinded researchers onto separate, predefined spreadsheets. Variations in data extraction were resolved and finalised between the researchers and senior author.

Analysis was performed by one researcher and cross checked by a second using Microsoft Excel and SPSS. Articles were classified into three groups based on their decision-making strategies.

Group 1	Used defined selection criteria and multidisciplinary decision-making
Group 2	Used defined selection criteria and individual decision-making
	Or
	Used undefined selection criteria and multidisciplinary decision making
Group 3	Used undefined selection criteria and individual decision-making

Given the clinical heterogeneity and small number of case series, a meta-analysis was deemed inappropriate. Statistical heterogeneity of the groups was assessed with chi-squared tests. A pooled analysis of primary outcomes was performed to allow group comparisons using chi-squared tests. A p-value of <0.01 was accepted as statistically significant.

Assessment of study quality

The methodological quality of studies was assessed by the Specialist Unit for Review Evidence (SURE) questions to assist with the critical appraisal of case series [24] independently by two researchers (Appendix S2). A narrative description was performed due to the absence of evidence supporting scales in assessing study quality [25].

RESULTS

Study selection

A total of 6211 articles were screened and an overview is shown in Figure 1. There were 303 articles matching our complex polyp definition and describing treatment outcomes. Decision-making strategies were not described in 233 (76.9%), and there were 59

(19.5%) articles only partially describing their strategy. One article only reported mortality as its outcome and was excluded. Another article met the inclusion criteria but was published in 1977. As polyp therapy was very different at this time, a collaborative decision was made to exclude this. This left nine articles in the final analysis [26–34]. Categorisation of excluded articles is described in Appendix S3.

Study characteristics

A summary of the studies is shown in Table 1. All were single centre, observational case series. Six studies were retrospective [26, 28–31,] and three prospective [27, 32, 34]. Patient ages ranged from 29 to 99 years. A total of 1086 lesions in 1037 patients were included and size ranged from 10 mm to 160 mm. Four studies described endoscopic treatments in the form of polypectomy, endoscopic mucosal resection or endoscopic submucosal dissection [29, 31–33]. Four studies described combined endoscopic and laparoscopic procedures [26, 28, 30, 34] and one study both endoscopic and combined techniques [27].

Decision-making strategies

Table 2 summarises the decision-making strategies used. Group decisions (two or more clinicians) were used by three studies [26, 29, 31] with only one utilising an MDT [26]. Six studies based management on the advice of an individual clinician. There were no articles comparing outcomes of groups using different decision-making strategies.

Six studies were categorised as having defined selection criteria [26–31]. Polyp factors were the commonest parameter used for decision-making. This included size (n = 6), lesion location (n = 6), surface changes and morphology (n = 3), preintervention histology (n = 3), evidence of malignancy (n = 2), lifting sign (n = 2), risk of incomplete resection (n = 1) and recurrences (n = 1). Two studies considered patient comorbidities when deciding management. The remaining three studies used undefined selection criteria subject to a clinician's opinion [32–34]. No study described the use of shared decision-making with the patient.

Primary outcomes

Table 3 shows a summary of the primary outcomes reported by the included studies.

Primary and secondary surgery rates

Three articles reported the number referred for primary colonic resection [27, 32, 33] (Table 1) with a wide variation of 9.1% [32], 33.8% [33] and 57.8% [27]. Two of these studies used individual decision-makers and undefined selection with secondary surgery rates of 8.2% [32] and 43.9% [33]. The final study described individual decision-makers with defined selection criteria and a secondary surgery rate of 5.3% [27]. Only two included treatment outcomes for those having primary resections [27, 33]. Due to this these patients were excluded, and further statistical analysis was not performed.

The secondary surgery rate ranged considerably from 3.3% to 43.9%. The commonest indication for colonic resection was an unsuccessful or incomplete endoscopic resection (n = 90). Other indications included cancer detected on final histology (n = 20), cancer suspected at polyp assessment during procedure (n = 19), recurrence (n = 5) and perforation (n = 3).

Adverse event rates

Adverse event rates across the studies ranged from 1.3% to 10%. The number of CD 1 events reported ranged widely from 2.6% [29] to 51.6% [33] with most being conservatively managed rectal bleeds. There was no mortality in any study. There were two CD 4 adverse events reported by a single study [28]. These was an anaesthetic-related anaphylaxis and pulmonary embolism in a single patient having a combined procedure.

Unsuspected malignancy rates

Unsuspected malignancies ranged from 2.4% to 15.4% across the articles. A complete overview is provided in Appendix S4.

Secondary outcomes

Length of stay was reported in six studies. It was generally short with a range of averages between 0 and 2 days [26–30, 34,]. The study by Bulut et al. was the only one which reported length of stay for colonic resections separately which ranged from 4 to 12 days [26].

Duration of follow-up ranged from 6 to 50 months with variability in surveillance timings and number receiving follow-up. One study did not state the duration of follow-up [34]. Table 4 summarises residual and recurrent disease. Residual disease incidence ranged from 7.8% [29] to 20.4% [31] of the three reporting studies. Eight studies described recurrent disease ranging from 0% [30] to 34% [33]. Only one study reported follow-up endoscopy for all study patients [30].

No study assessed functional, or patient reported outcomes. Two studies performed a cost analysis. Cohan compared costs for endoscopic step-up management against patients having planned colectomy [27] demonstrating a cost saving for the former.

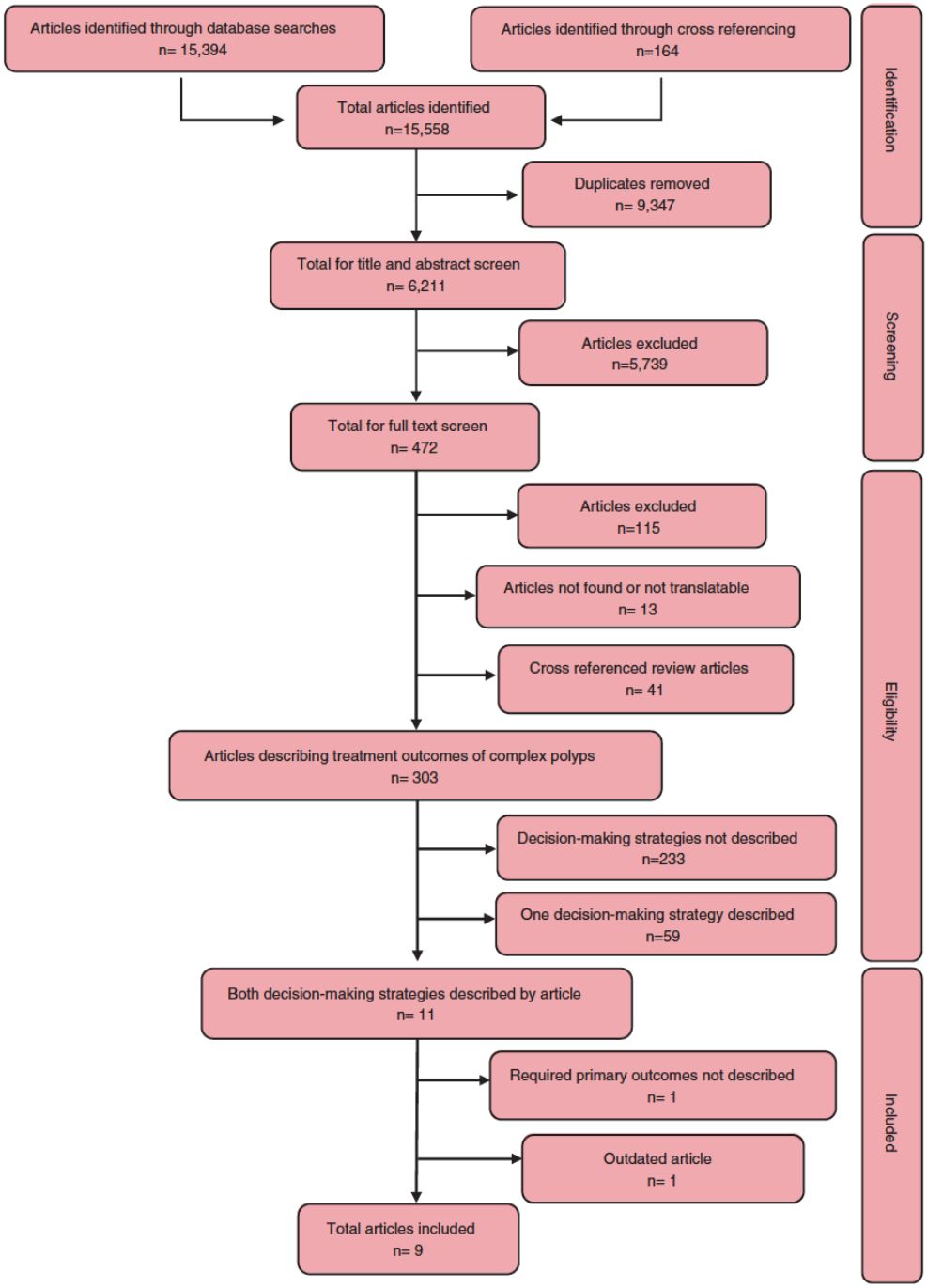

FIGURE 1 PRISMA flowchart

TABLE 1 Study characteristics

Author and year	Title of article	Country	Gender	Age (years)	Polyp size (mm)	Referrals for primary bowel resection	Total analysed in review		Treatment(s)
							Patients	Lesions	
Bulut et al. 2019 [26]	Combined endoscopic laparoscopic surgical treatment of advanced adenomas and early colon cancers	Denmark	Male 52% Female 48%	36–88 Median 71	10–80	Not described	25	25	Combined endoscopic/ laparoscopic procedures
Emmanuel et al. 2018 [29]	Combining eastern and western practices for safe and effective endoscopic resection of large complex colorectal lesions	UK	Male 57% Female 43%	33–99 Mean 71.8	20–160 Median 54.8	Not described	420	466	Endoscopic (EMR or ESD)
Kao et al. 2011 [31]	Endoscopic excision of large colorectal polyps as a viable alternative to surgical resection	USA	Male 46% Female 54%	29–92 Mean 67	10–90 Median 33	Not described	104	104	Endoscopic (EMR)
Cohan et al. 2020 [27]	Endoscopic step up: A colon-sparing alternative to colectomy to improve outcomes and reduce costs for patients with advanced neoplastic polyps	USA	Male 68% Female 32%	58–69 Median 65	20–31 Median 25	52 (57.8%)	38	38	Endoscopic (EMR or ESD) Combined endoscopic/ laparoscopic procedures
Crawford et al. 2015 [28]	Dynamic article: combined endoscopic-laparoscopic surgery for complex colonic polyps: postoperative outcomes and video demonstration of 3 key operative techniques	Canada	Male 66.7% Female 33.3%	32–81 Median 64	15–70 Median 40	Not described	30	30	Combined endoscopic/ laparoscopic procedures
Goh et al. 2013 [30]	Endolaparoscopic removal of colonic polyps	UK	Male 60% Female 40%	61.6–73.5 Median 65.4	10–22 Median 14	Not described	30	30	Combined endoscopic/ laparoscopic procedures
Longcroft-Wheaton et al. 2013 [32]	Risk stratification system for evaluation of complex polyps can predict outcomes of endoscopic mucosal resection	UK	Male 61.6% Female 38.4%	44–86 Median 69	20–150 Mean 43	22 (9.1%)	220	220	Endoscopic (EMR)
Voloyiannis et al. 2007 [33]	Management of the difficult colon polyp referred for resection: resect or rescope?	USA	Male 56.1% Female 43.9%	Mean 65	10–100 Mean 32.27	80 (33.8%)	157	157	Endoscopic (polypectomy or EMR)
Wood et al. 2011 [34]	Laparo-endoscopic resection for extensive and inaccessible colorectal polyps: a feasible and safe procedure	UK	1:2 male to female ratio	48–85	20–50	Not described	13	16	Combined endoscopic/ laparoscopic procedures
						Total=	1,037	1,086	

Abbreviations: EMR, endoscopic mucosal resection; ESD, endoscopic submucosal dissection.

TABLE 2 Overview of decision-making strategies used by the included studies

	Decision maker			Selection criteria	
	Number	**Specialty**	**MDT**	**Defined/undefined**	**Criteria used**
Bulut et al. [26]	Group	Surgeon, endoscopist, radiologist, histopathologist, oncologist	Yes	Defined	Inclusion Large polyp size, difficult polyp location, nonlifting sign, comorbidity excluding patient from standard bowel resection Exclusion Not stated
Emmanuel et al. [29]	Group	Therapeutic endoscopists	No	Defined	Inclusion Large size >20 mm, difficult location, submucosal invasion on ultrasound, patient comorbidities, pit pattern assessed with narrow band imaging and chromoendoscopy Exclusion Massive submucosal invasion or Kudo type Vn pit pattern
Kao et al. [31]	Group	Therapeutic endoscopists	No	Defined	Inclusion Location, size, morphology, histology Exclusion Difficult to visualise behind a fold or angulated flexure, deep ulceration
Cohan et al. [27]	Individual	Surgeon	No	Defined	Inclusion Polyp size of 15–50 mm, recurrent lesions, lesions with high grade dysplasia Exclusion Polyps <15 mm or >50 mm, rectal lesions, lesions suspicious for malignancy
Crawford et al. [28]	Individual	Therapeutic endoscopist	No	Defined	Inclusion Large size, broad base, location, raised by submucosal saline injection, benign preoperative histology, absence of lymphadenopathy/metastatic disease Exclusion Malignant pre-operative histology, presence of lymphadenopathy/metastatic disease

(Continues)

TABLE 2 (Continued)

	Decision maker			Selection criteria	
	Number	Specialty	MDT	Defined/undefined	Criteria used
Goh et al. [30]	Individual	Surgeon	No	Defined	Inclusion Complex benign appearing polyps, could not be excised by attending colonoscopist, large size, broad base/base could not be observed, difficult location behind mucosal fold/tortuous segment, risk of thermal injury/incomplete removal/ inadequate visualisation or combination of these Exclusion Not stated
Longcroft-Wheaton et al. [32]	Individual	Endoscopist	No	Undefined	Were considered to be beyond the skills or resources of the referrer to remove
Voloyiannis et al. [33]	Individual	Surgeon	No	Undefined	The decision regarding repeat colonoscopy was made by the surgeon
Wood et al. [34]	Individual	Gastroenterologist or surgeon	No	Undefined	Considered unsuitable for conventional EMR by the referring clinician

Longcroft-Wheaton found a significant cost reduction with endoscopy compared to surgery [32].

Pooled analysis and comparison of decision-making groups

Articles were classified into three groups as described previously. There was no significant heterogeneity in adverse event rates (group 1 $p = 0.67$, group 2 $p = 0.94$, group 3 $p = 0.08$) as calculated by chi-squared tests. The heterogeneity in unsuspected malignancies (group 1 $p = 0.00$, group 2 $p = 0.98$, group 3 $p = 0.30$) and secondary surgery (group 1 $p = 0.00$, group 2 $p = 0.05$, group 3 $p = 0.00$) varied within the groups.

The pooled adverse event and unsuspected malignancy rate across the three groups were similar ranging from 3.8% to 9.2% and 3.1% to 6.1%, respectively (Table 5). There were sequential decreases in secondary surgery with improving decision-making strategies. Pooled secondary surgery rate was 6.0% in those articles categorised into group 1 compared to 23.3% in group 3.

The reduction in secondary surgical intervention with improved decision-making strategies was significant (Table 6). There was no difference in comparisons between groups regarding unsuspected malignancy. Adverse events were significantly lower in group 3 as compared to group 2 but not in any other comparison in this category.

Assessment of article quality

The studies were assessed by the SURE questions and classified into whether the article met the criteria, did not meet the criteria or was unclear. Most criteria were achieved by the articles and were deemed to be of reasonable to good quality by the researchers.

Criteria for the study aims and design, setting and dates, selection criteria, enrolment, participants characteristics, outcome measures and results were met by all articles. Two studies did not meet the criteria regarding participant flow due to inadequate follow-up [26, 34]. The quality of statistical methods was not well described in most studies excluding Emmanuel and Kao [29, 31]. This was due to either incomplete statistics or absence of discussion regarding missing data or confounding factors. Most articles identified the limitations of their research, but two studies did not [33, 34]. Only one article declared a conflict of interest [27]. The remaining articles either had no conflicts [26, 28–32,] or it was unclear [33, 34].

DISCUSSION

MDT strategies involving group decision-making and defined selection criteria for complex colonic polyps may improve patient

TABLE 3 Primary outcome rates of the included studies

	Decision-making strategies	Adverse event rate	Unsuspected malignancy rate	Secondary surgery rate
Bulut et al. [26]	Group decision Defined selection criteria	8%	4%	16%
Emmanuel et al. [29]	Group decision Defined selection criteria	5.2%	2.4%[a]	3.3%
Kao et al. [31]	Group decision Defined selection criteria	3.8%	15.4%[b]	14.4%
Cohan et al. [27]	Individual decision Defined selection criteria	7.9%	2.6%	5.3%
Crawford et al. [28]	Individual decision Defined selection criteria	10%	3.3%	6.7%
Goh et al. [30]	Individual decision Defined selection criteria	10%	3.3%	30%
Longcroft-Wheaton et al. [32]	Individual decision Undefined selection criteria	5.5%	7.7%	8.2%
Voloyiannis et al. [33]	Individual decision Undefined selection criteria	1.3%	3.8%	43.9%
Wood et al. [34]	Individual decision Undefined selection criteria	7.7%	6.3%	30.8%

Adverse event and secondary surgery rates are described per patient and malignancy rate per lesion for each study. Complications are inclusive of CD classifications 2, 3 and 4. A full summary of the extracted data is given in the supplementary material (Appendix S4).

[a]Unsuspected malignancy rate was not clearly described in this article. Suspected cancers were defined as those with a type V pit pattern during endoscopic polyp assessment.

[b]Carcinomas in situ were excluded from the malignancy rate in this article as this is an alternative term for high grade dysplasia. The Vienna classification of gastrointestinal neoplasia was applied where there was ambiguity [19].

TABLE 4 Follow-up and detection of residual and recurrent disease by the included studies

	Patients in study	Length of follow-up	Number followed up at 3 months	Residual disease	Number followed up after 3 months	Recurrent disease
Bulut et al. [26]	25	6 months	–	–	17	11.8%
Emmanuel et al. [29]	420	Median 17.8 months	361	7.8%	254	10.2%
Kao et al. [31]	104	Median 12 months	98	20.4%	86	11.6%
Cohan et al. [27]	38	12 months	–	–	36	16.7%
Crawford et al. [28]	30	50 months	–	–	26	3.8%
Goh et al. [30]	30	Median 19 months	–	–	30	0%
Longcroft-Wheaton et al. [32]	220	Mean 3.2 years	179	15%	179	3.9%
Voloyiannis et al. [33]	157	9–16 months	–	–	44	34%
Wood et al. [34]	13	Not described	–	–	–	–

outcomes by avoiding the need for secondary procedures. This is the first evidence attempting to assess the impact of such strategies. This review also demonstrates the lack of decision-making and variation in outcome reporting concerning complex polyp management.

Decision-making strategies may have a higher impact in diseases with wider variation in management [9, 35]. This review aimed to identify evidence supporting these approaches to complex polyps but there were challenges given the review's novel design and lack of preceding literature. Group decisions utilising selection criteria are key features of an MDT and were therefore the chosen parameters. Of the many articles identified, only a small number were suitable for inclusion and only one used an MDT [26]. They were mostly small, case series with a variety of procedures described. This was recognised, but as they were all based on first line endoscopic resections and the comparator was decision-making, this was accepted by the study team. No studies compared outcomes of groups where different decision-making strategies were applied which is a significant limiting factor. Our initial aim was to report primary surgery rates which is currently thought to be around 12.8% [9]. Given only three studies reported it, this was not suitable for more than a descriptive assessment.

TABLE 5 Pooled adverse event, unsuspected malignancies and secondary surgery rates across the decision-making groups

Group	Criteria	Articles	Adverse event rate	Unsuspected malignancy rate	Secondary surgery rate
1	Defined selection criteria Group decision-making	Bulut [26], Emmanuel [29], Kao [31]	5.1% (28 out of 549)	4.7% (28 out of 595)	6.0% (33 out of 549)
2	Defined selection criteria individual decision-making Or Undefined selection criteria Group decision-making	Cohan [27], Crawford [28], Goh [30]	9.2% (9 out of 98)	3.1% (3 out of 98)	13.3% (13 out of 98)
3	Undefined selection criteria Individual-decision making	Longcroft-Wheaton [32], Voloyiannis [33], Wood [34]	3.8% (15 out of 390)	6.1% (24 out of 393)	23.3% (91 out of 390)

Note: Studies were classified into three decision-making groups. Group 1 represented articles describing higher levels of decision-making strategies (i.e., group decisions and defined selection criteria) whereas group 3 utilised less robust decision making strategies (undefined selection criteria, individual decision making). Adverse event and secondary surgery rates were calculated per patient ($n = 1037$) and malignancy rates per lesion ($n = 1086$). Figures are given to one decimal place.

Insight to surgically treated complex polyps is important as complication and mortality rates are 24% and 0.7%, respectively [36] with readmission (7.8%) and stoma formation (2.2%) also a risk [37].

Guidance on performing systematic reviews of observational studies is conflicting [38] and created challenges regarding the analysis and reporting of findings. A pooled analysis to allow comparison of groups with assessment of heterogeneity was a pragmatic solution but we acknowledge the limitations of this.

The outcome of good decision-making should be providing the most appropriate management for a patient and their polyp at first attempt. This requires a thorough and accurate assessment to allow fully informed and shared decisions to be made. If this process is robust, the need for secondary procedures should be avoided and could be considered a reflection of good decision-making. Grouping of articles into a hierarchy of decision-making demonstrated a sequential reduction in the need of a secondary procedure with improving strategies. The arbitrary assignment of studies to decision-making groups is a surrogate for the true underlying process but was a pragmatic method of assessment. Given the limitations of the review and statistical heterogeneity within some groups, we cannot be certain these are true effects. It does provide the first evidence supporting decision-making in improving outcomes and will hopefully promote generation of further research.

The use of strict polyp selection criteria when identifying articles aimed to reduced variability in the study population but differences remained in patient characteristics and selection criteria which affects generalisation and comparability of results. This may explain the wide ranges in the outcomes but may also reflect significant variability in practice as reported previously [8, 9]. We advocate standardisation of articles concerning complex polyps. Studies should include the denominator stating those managed with other methods including conservatively or with surgery. We suggest that a full description of the patient and polyp population, decision-making strategies involved and clear classifications of outcomes including surgery, complications, recurrence and adverse events should be reported with an adequate follow-up as a standardised minimum dataset [39]. Qualitative assessments of decision-making in patients and clinicians regarding malignant polyps have been reported [40] and is likely these complexities also apply to benign polyps. Patient involvement in decision-making should be encouraged and reported as part of article standardisation.

Despite the limitations of this review, developing evidence in this field is required given the variability in management and increasing detection of complex polyps. Good decision-making practices may benefit patient outcomes. Further evidence is required directly comparing decision-making strategies using standardised reporting. Assessments of centres using an MDT and understanding decision-making on an individual level are also important. In addition to the treatment outcomes, assessment on patient quality of life and experience, functional outcomes and financial impacts also need to be evaluated.

TABLE 6 Statistical comparison between the decision-making groups

	Adverse events		Unsuspected malignancy		Secondary surgery	
	Odds ratio (CI)	*p*-value	Odds ratio (CI)	*p*-value	Odds ratio (CI)	*p* value
Groups 1 vs. 2	1.88 (0.86–4.12)	0.91	0.64 (0.19–2.15)	0.34	2.30 (1.2–4.73)	0.01
Groups 2 vs. 3	0.40 (0.17–0.93)	0.03	2.06 (0.61–7.0)	0.18	1.99 (1.06–3.73)	0.018
Groups 1 vs. 3	0.74 (0.39–1.41)	0.23	1.32 (0.75–2.30)	0.21	4.76 (3.12–7.26)	0.00

Note: Odds ratios are presented with 95% confidence intervals (CI). Chi squared test was used to compare the proportions. Adverse event and secondary surgery rates were calculated per patient and malignancy rates per lesion. Figures are given to two decimal places.

ACKNOWLEDGMENTS

We would like to thank Mala Mann (Specialist Unit for Review Evidence, Cardiff University) for her advice and expertise in the production of this review.

CONFLICT OF INTEREST

There are no conflicts of interest.

ETHICAL APPROVAL

Not required.

DATA AVAILABILITY STATEMENT

Data available in article supplementary material.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of the article at the publisher's website.

How to cite this article: Parker J, Gupta S, Torkington J, Dolwani S. Multidisciplinary decision-making strategies may reduce the need for secondary surgery in complex colonic polyps – A systematic review and pooled analysis. Colorectal Dis. 2021;23:3101–3112. https://doi.org/10.1111/codi.15901

BMJ Open Gastroenterology

Planning management for complex colorectal polyps: a qualitative assessment of factors influencing decision-making among colonoscopists

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To cite: Parker J, Semedo L, Shenbagaraj L, *et al*. Planning management for complex colorectal polyps: a qualitative assessment of factors influencing decision-making among colonoscopists. *BMJ Open Gastro* 2023;**10**:e001097. doi:10.1136/bmjgast-2022-001097

► Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/bmjgast-2022-001097).

Received 6 January 2023
Accepted 1 April 2023

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ABSTRACT

Objective Endoscopic therapy is the recommended primary treatment for most complex colorectal polyps, but high colonic resection rates are reported. The aim of this qualitative study was to understand and compare between specialities, the clinical and non-clinical factors influencing decision making when planning management.

Design Semi-structured interviews were performed among colonoscopists across the UK. Interviews were conducted virtually and transcribed verbatim. Complex polyps were defined as lesions requiring further management planning rather than those treatable at the time of endoscopy. A thematic analysis was performed. Findings were coded to identify themes and reported narratively.

Results Twenty colonoscopists were interviewed. Four major themes were identified including gathering information regarding the patient and their polyp, aids to decision making, barriers in achieving optimal management and improving services. Participants advocated endoscopic management where possible. Factors such as younger age, suspicion of malignancy, right colon or difficult polyp location lead towards surgical intervention and were similar between surgical and medical specialties. Availability of expertise, timely endoscopy and challenges in referral pathways were reported barriers to optimal management. Experiences of team decision-making strategies were positive and advocated in improving complex polyp management. Recommendations based on these findings to improve complex polyp management are provided.

Conclusion The increasing recognition of complex colorectal polyps requires consistency in decision making and access to a full range of treatment options. Colonoscopists advocated the availability of clinical expertise, timely treatment and education in avoiding surgical intervention and providing good patient outcomes. Team decision-making strategies for complex polyps may provide an opportunity to coordinate and improve these issues.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The treatment of complex colorectal polyps is variable but the underlying factors for this at an individual clinician level are not understood.

WHAT THIS STUDY ADDS

⇒ The factors identified were not only clinical, and endoscopists advocated availability of expertise, timely treatment and education in avoiding surgical intervention and providing good patient outcomes.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Recommendations to improve practice are provided and the use, access to and monitoring of team decision-making strategies for complex polyps are advocated on a national level.

INTRODUCTION

Colorectal polyps are precursors to colorectal cancer development.[1] Their morphological spectrum is considerable[2] and in larger or more complex lesions, the decision-making and technical challenges of treatment are significant.

Endoscopic treatment is recommended first line for most polyps.[3] There remains considerable variability in the management of complex lesions[4 5] with overutilisation of colonic resection reported.[6 7] Insight into the rationale behind the choice of management is limited.[8 9] There is wide variability in polyps larger than 20 mm referred for surgery (0%–46.6%) with advanced histology or site within the colon often resulting in a recommendation of colonic resection.[10] Evidence is conflicting regarding whether surgeons[11 12] or gastroenterologists[13] are more likely to recommend surgery. Surgeons may still recommend resection despite correctly identifying a polyp as benign,[12] suggesting service-related factors may also be influential. The use of team approaches to decision-making may reduce the utilisation of colonic resection,[14] but these are not available in all centres. Shared decision- making should also

be considered, with importance demonstrated regarding the management of malignant polyps.[15] Understanding these factors may improve patient care, service provision and reduce surgical intervention.

The aim of this qualitative study was to explore the clinical and non-clinical factors impacting decision-making regarding complex colorectal polyp management. Comparisons were made in the factors favouring surgical intervention and attitudes towards team decision-making strategies between specialities.

METHODS

This was a qualitative study using thematic analysis and performed in line with the consolidated criteria for reporting qualitative research (COREQ).[16]

Recruitment

Advertisement and dissemination were by email through professional associations and research collaborations of the study team. Recruitment from NHS trusts in the UK lasted from May 2021 to September 2021. A provisional recruitment target of 15–20 participants was based on qualitative study sample sizes and information power[17] to achieve the aims. Plans were made to extend recruitment in case the research team felt that data saturation had not been reached by this number.

Inclusion and exclusion criteria

Practicing colonoscopists including colorectal surgeons, gastroenterologists and clinical endoscopists (nurses and non-medical practitioners) involved in decision-making for managing complex colorectal polyps were eligible. Exclusions included incomplete interviews or withdrawal of consent. Consent to participate in the study and to record the transcript was confirmed at the start of the interview.

Data collection

The semi-structured interview was recorded via Zoom (Zoom V.5.7.6). The interview focused on decision-making for complex colorectal polyps. These were defined for the participants as lesions requiring further management planning rather than those treatable at the time of endoscopy due to size, difficult access or other concerns regarding morphology or appearance. Discussions were guided by an interview guidance proforma to cover three key topics including clinical factors, non-clinical factors and any other influences (online supplemental material 1). The interview allowed free discussion to develop points of interest. A pilot interview to assess structure and acceptability was performed and included in the analysis. All were conducted by the lead author after completion of training in qualitative interviewing and analysis. Audio recordings of the interviews were securely stored and transcribed verbatim by a transcription company into text.

Data analysis

NVivo qualitative data analysis software V.12 was used for storing, coding and organisation of transcripts and qualitative data. Analysis was performed based on literature regarding thematic analysis.[16 18] Coding was completed by the lead author. Familiarisation with the information was performed by reading the transcripts repeatedly to generate initial codes of the topics and describe the data. The codes were developed and refined during analysis and classified into major themes and subthemes. The themes were defined, and a narrative description was performed with quotations. Observation of the differences in the factors favouring surgical intervention between specialty and attitudes towards team decision-making strategies was performed.

Ethics and peer review

A favourable ethical opinion was given by Cardiff University School of Medicine Research Ethics Committee (online supplemental material 2).

RESULTS

Twenty participants were recruited from 14 trusts across the UK. Email invitations were sent to 49 individuals. There were no responses from 16 by the close of the recruitment. Reasons for those responding but not participating included having insufficient time (n=10) or not being eligible (n=3).

An overview of participant characteristics is shown in table 1. The interview length ranged from 12 to 29 min. The identified themes are shown in table 2.

Thematic analysis of interviews

Gathering information regarding the patient and their polyp

The first major theme was the need to assess the patient and their polyp. Size, morphology, surface appearance and pit pattern were frequently discussed parameters. All clinicians discussed that decisions made should consider age, fitness, frailty, comorbidities, medication and performance status.

Risk of polyp malignancy

Features considered likely to be indicative of malignancy were depression, tethering, ulceration, suspicious pit pattern or high-grade dysplasia. Several observed that biopsies could potentially mislead, and visual assessment should predominately guide management. A high suspicion of cancer would lead the majority to recommend surgical resection. For some, a lesion with possible cancer could be managed endoscopically depending on the patient and the chance of complete removal.

> I do remove polyps that I think have got cancer, but I always tattoo them. If I think I can get a clear margin of resection or resect through a normal stalk, I do remove them endoscopically. (Participant 14—gastroenterologist)

The approach towards polyps with cancer after treatment was similar with the automatic need for a complete resection not being deemed necessary. Participants stated this decision should be made individually considering

Table 1 Summary of participant characteristics

Participant	Specialty	Hospital	Complex polyp team decision-making availability
Participant 1	Surgery	Tertiary/teaching	On site
Participant 2	Gastroenterology	Tertiary/teaching	On site
Participant 3	Gastroenterology	Tertiary/teaching	On site
Participant 4	Surgery	District general	On site
Participant 5	Gastroenterology	District general	No access
Participant 6	Surgery	District general	No access
Participant 7	Gastroenterology	District general	No access
Participant 8	Surgery	District general	No access
Participant 9	Surgery	District general	Separate site
Participant 10	Surgery	District general	No access
Participant 11	Surgery	District general	No access
Participant 12	Gastroenterology	District general	On site
Participant 13	Gastroenterology	Tertiary/teaching	On site
Participant 14	Gastroenterology	District general	No access
Participant 15	Surgery	District general	On site
Participant 16	Nurse endoscopist	District general	Separate site
Participant 17	Nurse endoscopist	District general	On site
Participant 18	Gastroenterology	Tertiary/teaching	On site
Participant 19	Gastroenterology	Tertiary/teaching	On site
Participant 20	Gastroenterology	Tertiary/teaching	On site

factors such as staging, histological findings, genetics and comorbidities. There was consensus towards surveillance in low-risk lesions.

> I remember patients who'd have a tiny little polyp cancer incidentally found, and they would automatically have a bowel resection. Whereas now I think we are moving along. There are more studies looking at patients and tracking their pathway that have been through conservative management. (Participant 17—nurse endoscopist)

Chance of achieving complete and safe endoscopic resection

Endoscopic treatment was widely considered to be the first-line management approach where possible and the likelihood of complete and safe removal was key to decision-making. Good access with a stable scope position were frequently mentioned requirements. Polyps located over folds or within pathology such as diverticular disease swayed management towards surgery. Right-sided polyps were often discussed as a reason to favour colonic resection. Justification for this included an increased

Table 2 Summary of major and minor themes for complex polyp decision-making identified from participant interviews

Major theme	Sub-themes
1. Gathering information regarding the patients and their polyp	1.1 Risk of polyp malignancy 1.2 Chance of achieving complete and safe endoscopic resection 1.3 Influence of age and comorbidities 1.4 Burden of treatment on the patient
2. Aids to decision-making processes	2.1 Opinions of colleagues and complex polyp team decision-making strategies 2.2 Shared decision-making with patient
3. Barriers in achieving optimal management	3.1 Challenges of complex polyp team decision-making strategies 3.2 Endoscopy service provision 3.3 Referral to other sites for expertise
4. Improving services	4.1 Improving decision-making pathways 4.2 Education and training

perforation risk and challenging access to the appendix orifice or ileocaecal valve lesions.

> Particularly if it's a proximal right-sided lesion where the bowel wall is a bit thinner, or it's close to the appendix or a difficult location. I think that in those cases if the patient is fit and well probably the risks of undergoing a lap right hemi aren't significantly greater than the risk of having a difficult polypectomy in a thin bit of bowel. (Participant 6—surgeon)

Influence of age and comorbidities

All clinicians discussed the importance of patient assessment with an awareness that intervention may be inappropriate in some. Poor quality of life and short life expectancy were reasons to direct towards conservative management.

> We often have discussions with other services like cardiology or elderly care because we want to know what the patient's prognosis is from their other comorbidities rather than jump in with two feet to take off this 2 cm polyp that may never cause them any harm. (Participant 16—nurse endoscopist)

Younger patients with few comorbidities were more likely to be offered surgery, especially for challenging right-sided lesions. The rationale was the reduction in surveillance requirements and avoidance of uncertainty if a cancer was identified. The identification of multiple polyps, other bowel pathology and genetic influences led some to consider colonic resection. Medications including steroids and anticoagulants were concerning for some in considering endoscopic management.

Burden of treatment on the patient

The burden of endoscopic management on patients was frequently discussed. Poorly tolerated endoscopic examinations including the bowel preparation would lead clinicians to consider other management including surgical options or surveillance if the patient was unfit for operative intervention. The impact of long-term consequences of endoscopic treatment was also considered. Stenosis or recurrence in extremely large or circumferential lesions was discussed by some clinicians as a reason to advocate surgery in those fit enough. Attitudes towards managing recurrent lesions were variable. Some felt that further endoscopy to clear residual or recurrent disease was acceptable. Others were more likely to seek definitive treatment, especially in multiple recurrences. For most, they felt it was acceptable for the patient to undergo surveillance and avoid surgery, but this needed to be based on appropriate discussions with them.

> If there's the option of managing endoscopically and avoiding an operation, in my experience most of them are accepting of further surveillance colonoscopies. (Participant 9—surgeon)

The specific challenges posed and the burden of treatment on patients for rectal lesions were recognised. The importance of techniques such as trans-anal and endoscopic submucosal dissection procedures were highlighted to preserve the rectum and avoid a stoma.

Aids to decision-making processes

Participants described the involvement of patients and colleagues as important influencers on their management strategies.

Opinions of colleagues and complex polyp team decision-making strategies

Most participants had access to complex polyp team decision-making meetings also known as multidisciplinary teams (MDTs), but this varied between local or regional sites. Their effectiveness was generally seen as positive with benefits in the range of management options and avoidance of surgery.

Clinicians felt team meetings were educational and developed confidence and understanding of complex polyp management. Surgeons involved were observed to be more likely to recommend endoscopy and enabled communication between clinicians, management planning and tracking of cases.

> I feel almost very comfortable I've got that (MDT) around me. It's quite secure and I think I'd find life a little bit more vulnerable and scarier if I had to make decisions myself. (Participant 3—gastroenterologist)

Shared decision-making with the patient

All participants acknowledged the need for shared decision-making. References were made to informed consent, written information and counselling clinics. The challenges of explaining the complexities of different management strategies were stated by several participants. One described the use of joint patient clinics involving surgeons and gastroenterologists. Another felt it was good practice to represent patients' wishes as part of the complex polyp team decision-making process. Many clinicians observed that patients were largely guided by their advice, but it was also observed that the specialty of the involved clinician could impact this.

> Let's say if they go to see a surgical consultant you can easily convince them to do laparoscopic intervention whereas if they come to see me, they can get swayed. (Participant 12—gastroenterologist)

Although patients seemed to accept endoscopic intervention, there were a few exceptions. Poor experience of endoscopy and the need to travel elsewhere were factors thought to deter patients, but other participants did not perceive this as an issue in decision-making. Patient awareness regarding surveillance and the risk of recurrence was considered important.

Barriers in achieving optimal management

Participants observed challenges in optimal management. Access to timely endoscopy, poor technology and barriers for referrals were common issues.

Challenges of complex polyp team decision-making strategies

Several discussed challenges to their team decision-making service. Increasing referrals, meeting frequency and the unavailability of participants were explanations for delaying decision-making. Some participants felt their meeting would benefit from additional expertise such as pathology, or administrational support.

> The complex rectal lesion MDT is probably the most challenged pathway in the trust because we have quite long waits. (Participant 15—surgeon)

Several observed that good decision-making was dependent on the quality of referral information including patient assessment, polyp description and photo or video documentation. The availability of expertise at the meeting could also affect the outcome. Those with no availability of team decision-making strategies felt patients would benefit from this service. Difficulties were reported when referring to another site. Limiting referrals or attempting alternative treatment to avoid overburdening the system was described.

Endoscopy service provision

The COVID-19 pandemic created delays in diagnostics, therapeutics and surveillance for complex polyps with redeployment, cancellations and employee absences creating service pressures. The shortage of available lists, endoscopy capacity and the lack of endoscopists performing complex polypectomy were frequently discussed.

Some observed long waits due to limited advanced endoscopy expertise or insufficient lists resulting in polyp progression to endoscopically unresectable or even malignant lesions. Complex polyp treatment was difficult to prioritise in the absence of waiting targets.

> The problem is he is one individual and there have been a few occasions where treatment has been delayed and by the time he has seen those patients he had said, sorry it's not suitable for EMR this is cancer. (Participant 10—surgeon)

The optical assessment was seen as crucial to informed decision-making. Individuals described technological problems in recording photos or videos and resulting in repeat procedures which created a further burden on both the patient and the service.

Referral to other sites for expertise

Individuals at sites without expertise such as advanced endoscopy or trans-anal surgery would have to refer elsewhere. Experiences in providing care across two sites were often challenged with delays in patient assessment and feedback. Logistics, communication and tracking issues were provided as explanations and created concerns regarding responsibility and continuity of care.

Some would rely on informal discussions with colleagues and goodwill in the absence of established pathways. For some, the referral experience was positive with good communication and timely treatment, but poor awareness of available services was also reported.

> It wasn't until I did a little bit of digging around that we are paying for this, and we could use this service more than we had done. (Participant 6—surgeon)

Improving services

Participants frequently commented on strategies to improve decision-making and management.

Improving decision-making pathways

With increasing referrals, more frequent polyp team meetings had been introduced by some sites. Several sites thought that improved referral pathways had enhanced patient care. Good clinical information, patient assessment and images for referrals were felt to be crucial in efficient decision-making, list planning and avoiding repeated endoscopy.

> There is now a really good process that the screening nurse fills in the referral and we get written feedback from the MDT. It's not just education about what the patient's management would be, but also education about what I've done. (Participant 3—gastroenterologist)

One participant vetted high-risk polyps as suspected cancer to ensure timely treatment. Another described taking personal responsibility for tracking patients to ensure treatment and surveillance were performed. Increased endoscopy list capacity had been employed by some. Given the complexities of decision-making, some participants had introduced supplementary information to facilitate patient understanding. The use of information leaflets, letters or formal consent clinics was all described.

> What we've started to do when we find a big polyp is to give them all the information on the day so that they know what the options are. They can pre-read it so whenever I ring them after their MDT, they have some idea of the options that are available and already have a kind of opinion in their head about what they would like to do and I think that's been really, really helpful. (Participant 16—nurse endoscopist)

Education and training

The importance of developing advanced polypectomy skills was recognised with mentored sessions either in person or remotely being used by some participants. Education regarding polyp assessment to improve referrals and decision-making was also being performed.

Table 3 Comparison in factors leading towards surgical intervention between medical and surgical clinicians

Surgical clinicians	Medical clinicians (gastroenterology and nurse endoscopists)
Gathering Information regarding the patient and their polyp	
'If you've got a young fit patient with an incidental cancer, we would tend to argue in the MDT that even if it's relatively low risk, they're probably better served by an offer of a resection.' **(Participant 6)** 'If they are otherwise fit then obviously you look at other factors. Have they got an underlying bowel disorder or inflammatory bowel disease? Are they on steroids? Things that I'd be concerned about managing it endoscopically.' **(Participant 9)** 'A right sided polyp which could potentially be taken on but has a very difficult colon and patient is fit, I may actually consider talking them into operation rather than having a repeated surveillance and a difficult experience.' **(Participant 1)** 'If it is a complete circumferential polyp, it can be done but we discuss this in MDT. If we do EMRs in different sittings, it can turn into fibrosis and lead to stenosis. In that case, we consider surgery as well.' **(Participant 4)** 'Sometimes when you have complex polyps in the right colon, there's always debate. Is a right colectomy laparoscopically better than complex polypectomy and then causing perforation and complications?' **(Participant 10)** 'There are genetic factors as well. If they've got a background of multiple polyps, Lynch syndrome or something like that then you'd have a lower threshold for offering them a resection.' **(Participant 6)** 'We've certainly had some patients with caecal polyps that have been difficult to remove. They're still coming back several years down the line to have bits of polyp nibbled away, and you can't help think they would have been better just having an ileocecal resection and be done with it at that original time.' **(Participant 6)** 'In those (recurrence) cases I often quite strongly counsel towards surgery, despite everything I've just been telling you. Multiple hospital visits and multiple polypectomies are high risk with anxiety that's actually killing the patient's quality of life.' **(Participant 11)**	'If you're in your 40s with a (*incidental*) polyp cancer you'll either have very intense surveillance plus or minus genetics. Or you probably would push them potentially more to have a resection, to make sure that that segment of bowel has gone.' **(Participant 7)** 'We've had lesions where they're big things in the caecal pole, wrapping around the appendiceal orifice. That's not really going to be something for endoscopy, it's probably creeping down into the appendix. So that's the sort of thing that would go through that MDT and then on to surgery afterwards.' **(Participant 3)** 'I think caecal ones are almost as bad as the rectal ones. We seem to worry about them a lot more because of the increased risk of perforation. If they're in the caecal pole I always start to think up front with the patient that actually surgery might be the best option, rather than wasting three, six, twelve months of repeated endoscopy, repeated surveillance and you end up with an operation anyway.' **(Participant 7)** 'A lesion in the right colon and in a young fit patient. I think they're probably better served (by surgery).' **(Participant 12)** 'Especially with younger patients who may need to come back again and again, and we're not going to clear that polyp. We have had cases where they've decided to go straightaway for surgery, because that's a more permanent solution for them.' **(Participant 17)**
Aids to decision-making processes	
'There's that bit of commitment from the patient, and I think there are definitely instances where on balance some patients would prefer to undergo a resection.' **(Participant 6)** 'I think that depends on patient's experience of endoscopy. You will get some patients who have had a bad experience and they do not want another endoscopy.' **(Participant 9)**	'I've seen patients being very much swayed by who the initial consultant is. Let's say if they go to see a surgical consultant you can easily convince them to do laparoscopic intervention whereas if they come to see me, they can get swayed.' **(Participant 12)** 'Occasionally patients will say I don't want to travel and in which case they're offered surgery as an alternative.' **(Participant 20)**
Barriers in achieving optimal management	
'I think even when it is endoscopic resectable by a fairly straightforward EMR, because people don't have the volume they won't take them on.' **(Participant 9)** 'He's an asset to the service and that is a brilliant thing to have. The problem is he is one individual and there have been a few occasions where treatment has been delayed and by the time he has seen those patients he had said, sorry it's not suitable for EMR this is cancer.' **(Participant 10)**	'With Covid we've got all these delays and it makes me increasingly nervous. We had a guy who had a polyp diagnosed over a year ago and the endoscopist wasn't confident to take it out. We tried to get the patient back but Covid hit and patient didn't want to come back. He came for a colonoscopy last week, and you can see that the polyp is a cancer. But there's no doubt that patients' polyps have progressed.' **(Participant 2)**

MDT, multidisciplinary team.

We have the journal club and try and do some education across the board. We do a lot of education about what pictures to take and what information we need. (Participant 17—nurse endoscopist)

Personal responsibility for improvement was taken by many. Attendance at endoscopy courses, development programmes and feedback from meetings were all methods used to reinforce good decision-making.

Comparisons between clinical specialities

Comparisons of factors between surgical and medical clinicians for recommending surgery and attitudes towards team decision-making strategies are shown in tables 3 and 4. Similarities are seen with factors such as right-sided lesions, difficult location, suspected cancers and young or fit patients leaning decision-making towards surgery. Other issues common between groups

Table 4 Comparison in attitudes towards team decision-making strategies between medical and surgical clinicians

Surgical clinicians	Other clinicians (gastroenterology and nurse endoscopists)
Positive attitudes	
'I voluntarily go to the MDT but it's not part of my job plan. I've been going to it because I think it's good to see cases and to see also the outcome of the cases I have done.' **(Participant 15)** 'And then if they are happy (*the polyp MDT*) they will get the patient across and bring them straight for colonoscopy with procedure. So that they do it quite quickly.' **(Participant 9)** 'All of us have our own niche within that MDT. We work with people who do TEMS and we have somebody who is interested in ESD. There are cases which are debated sometimes but I think it works quite well.' **(Participant 1)** 'Before that (*complex polyp MDT*) it was hit and miss and whoever can do it, can do it kind of thing.' **(Participant 4)**	'I feel very comfortable I've got that (*polyp MDT*) around me. It's quite secure and I'd find life a more vulnerable and scarier if I had to make decisions myself.' **(Participant 3)** 'I've got complete oversight of when all these patients are booked. We cross-reference every patient that's discussed in a complex polyp meeting with my database waiting list…… I can see at any one time how many patients are waiting to be dated and when their scope is going to be.' **(Participant 2)** 'Now they are discussed in MDTs and we will make sure they are done by an appropriate endoscopist.' **(Participant 5)** 'There is now a really good process that the screening nurse fills in the referral and we get written feedback from the MDT. It's not just education about what the patient's management would be, but also education about what I've done and whether I've done the right things or not.' **(Participant 3)** 'We would never send any polyps to the surgeons without having discussed in the complex polyp MDT, and our surgeons are part of that MDT as well.' **(Participant 17)** 'That's one of the things you pick up from MDT so that that lesion can be thoroughly seen by anybody and there is no need for them to be scoped again.' **(Participant 3)** 'I found an enormous polyp about 2 weeks ago what I considered not to be endoscopically resectable but the opinion of my colleagues was the opposite.' **(Participant 14)** 'I think it's a great service and gone from strength to strength over the past couple of years. I run it alongside the gastro fellows and it's really well attended. There's lots of buy-in from both the surgical and the gastro teams in terms of referring patients along that pathway to the complex polyp MDT.' **(Participant 15)**
Negative attitudes	
'The complex rectal lesion MDT is probably the most challenged pathway in the trust because we have quite long waits. We only do the meeting once a fortnight and it does mean that it's logistically quite difficult.' **(Participant 15)** 'We will say let's refer to the complex polyp team, but it overloads that service.' **(Participant 9)** 'We need people who have got the time to properly participate in the MDT. Ours is the same day as our colorectal MDT, so we do find that people are torn between the two and it's sometimes difficult to attend the whole meeting.' **(Participant 15)**	'Often you get a letter (*to the MDT*) and there's not even a size mentioned. The admin team then end up chasing the consultant. You don't want some communication going amiss and then a patient suffering. I try to encourage my own admin staff to try and chase things up rather than sending letters back and forth just creating delays.' **(Participant 12)** 'The original time slot is now inadequate, and it often impacts on the gastro meetings that follow straight after. It's not that people aren't getting done, but it's impacting on other meetings in the morning.' **(Participant 18)**

ESD, endoscopic submucosal dissection; MDT, multidisciplinary team.

preventing endoscopic resection included patient preferences and disease progression. Attitudes towards team decision-making were positive in nature with all negative observations being related to capacity, information and clinician availability.

DISCUSSION

To our knowledge, this is the first study assessing the influences on decision-making for complex colorectal polyps. An explanation for the high surgery rates for colonic polyps is needed,[19] and qualitative research gives a unique insight into practice. Clinicians advocated endoscopic management wherever possible but the availability of expertise, timely endoscopy and challenges in referrals were all reported barriers in achieving optimal management.

Unlike the findings of Moon *et al*,[15] surgeons and gastroenterologists seemed equally engaged with endoscopic therapy. Polyp and patient features leading to a recommendation of surgery were consistent and based on the likelihood of malignancy, fitness and wishes of the patient. Lesions in the right colon were more likely to be offered surgery to avoid perforation in the thinner bowel wall. Such concerns need to be supported by evidence as the risk may not be higher than those of colonic resection. Alternative colon sparing treatments such as combined procedures should be available.[20] Lesions assessed as having high grade dysplasia were a cause of concern for many participants. This finding is not synonymous with invasive disease and similar to other evidence[13] may lead to unnecessary surgical treatment. International recommendations exist for optical diagnosis training.[21] The improvement of technology to capture images and videos was widely advocated. Virtual platforms could allow collaborative assessment to facilitate good decision-making and confidence in taking on more challenging lesions endoscopically.

As speculated,[19] challenges were reported in the knowledge of and access to complex polyps expertise. This may explain utilisation of surgical management where less invasive techniques may be possible. Given the known risks of surgery[22] and higher healthcare costs, it is important to avoid unless clearly indicated. Development of relationships in addition to streamlined referral pathways is needed. This is particularly important for specialist techniques where clear identification of service responsibility could help access organ preserving procedures. Challenges regarding training can also be restrictive.[23] Increased team meeting and endoscopy capacity, administration support, tracking of cases and treatment timelines were frequently called for by participants.

The use of complex polyp team decision-making strategies has been recommended by guidelines.[5] The attitude towards collaborative discussion and decision-making was overwhelmingly positive despite limited underlying evidence. Meetings were reported as beneficial to service planning and education. They were viewed as supportive environments enabling clinicians to manage complex cases and facilitate the introduction of new techniques.

There were other areas identified where improvements were being made. Given treatment complexities, improved knowledge for patients through written information or dedicated clinics was reported. Collaboration between sites was advocated to learn from each other's experience. A summary of recommendations to improve practice using the findings of this study is shown in figure 1. The introduction of structured team decision-making could facilitate these recommendations in optimising complex polyp management and avoiding inappropriate surgery. We advocate their use and recommend professional organisations provide guidance on their structure and monitoring.

There are limitations to qualitative research. Bias may be introduced through participant selection and interview design. As a surgeon, the clinical and research interests of the lead author may have influenced the focus of the interviews. Efforts were made to avoid this with the use of a pre-written interview guide. We observed that as all participants were experienced endoscopists, they required limited guidance in discussing their opinions and we felt the impact of the researcher's opinions was minimal. The use of a single researcher developing codes and themes may also have introduced limitations, although quality is not necessarily dependent on multiple coders.[24] Efforts were made to identify individuals from a range of sites and not just those with access to complex polyp expertise. Despite this, the results described may not accurately reflect all experiences or there may have been concerns about open discussion. Reassurances of participant anonymity were made to hopefully avoid

Figure 1 Recommendations for improving practice for complex colorectal polyp management. ESD, endoscopic submucosal dissection.

this. Although consistency in themes was identified, increasing the sample size could have found further factors. Collectively the research team felt that data saturation had been achieved after the performance of 20 interviews, and that little further information would be gathered by recruiting more participants. The collected data may have also been limited by time constraints and availability of participants. Given the variability in healthcare systems internationally, our practice in the UK may not be generalisable to other countries.

The absence of the patient's perspective and shared decision-making is an important consideration. Its role has been demonstrated regarding decision-making for malignant polyps with uncertainty and information being key underlying themes.[15] Patient involvement is also likely to be of great influence on the choice of management in complex polyps. This would have provided more insight into their perceptions regarding communication, understanding and beliefs in contrast to the clinical participants. The decision not to incorporate patient participants was made considering similar research being undertaken by the wider research group at the time. Semedo *et al* demonstrated a positive experience of patients having complex polyps removed.[25] Support initiatives were highlighted as a potential area to improve patient experience and adverse events after intervention were linked with quality of life outcomes afterwards.

Given the increasing recognition of complex colorectal polyps, good decision-making and service access are likely to have increasing importance. Colonoscopists from all backgrounds feel that endoscopic management should be the treatment of choice where possible. Access to clinical expertise, service provision, quality assessment and education is called for by our health professionals to facilitate the shift towards avoiding surgical intervention and providing high standards of patient care. Multidisciplinary team decision-making processes are likely to be of central importance to these improvements.

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Contributors JP planned the study, recruited subjects, collected and analysed data, wrote and revised the manuscript. LSe, LSh planned the study and revised the manuscript. JT and SD planned the study, recruited subjects, revised the manuscript and acted as overall supervisors of the project. SD was the author responsible for the overall content as the guarantor.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Cardiff University School of Medicine (SREC reference: 21/34). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement The data underlying this article will be shared on reasonable request to the corresponding author.

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International Journal of Colorectal Disease (2023) 38:28
https://doi.org/10.1007/s00384-022-04299-0

RESEARCH

Outcomes of complex colorectal polyps managed by multi-disciplinary team strategies—a multi-centre observational study

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Accepted: 28 November 2022

Abstract

Purpose Team management strategies for complex colorectal polyps are recommended by professional guidelines. Multi-disciplinary meetings are used across the UK with limited information regarding their impact. The aim of this multi-centre observational study was to assess procedures and outcomes of patients managed using these approaches.

Method This was a retrospective, observational study of patients managed by six UK sites. Information was collected regarding procedures and outcomes including length of stay, adverse events, readmissions and cancers.

Results Two thousand one hundred ninety-two complex polyps in 2109 patients were analysed with increasing referrals annually. Most presented symptomatically and the mean polyp size was 32.1 mm. Primary interventions included endoscopic therapy (75.6%), conservative management (8.3%), colonic resection (8.1%), trans-anal surgery (6.8%) or combined procedures (1.1%). The number of primary colonic resections decreased over the study period without a reciprocal increase in secondary procedures or recurrence. Secondary procedures were required in 7.8%. The median length of stay for endoscopic procedures was 0 days with 77.5% completed as day cases. Median length of stay was 5 days for colonic resections. Overall adverse event and 30-day readmission rates were 9.0% and 3.3% respectively. Malignancy was identified in 8.8%. Benign polyp recurrence occurred in 13.1% with a median follow up of 30.4 months. Screening detected lesions were more likely to undergo bowel resection. Colonic resection was associated with longer stays, higher adverse events and more cancers on final histology.

Conclusion Multi-disciplinary team management of complex polyps is safe and effective. Standardisation of organisation and quality monitoring is needed to continue positive effects on outcomes and services.

Keywords Large or complex colorectal polyp · Multi-disciplinary team management · Decision-making · Outcomes

Introduction

Colorectal polyps are often a precursor to malignancy [1] and removal can reduce the incidence of bowel cancer [2]. Increasing detection is likely due to colorectal cancer screening programmes [3], improvements in colonoscopy and increasing awareness of symptoms. The morphological spectrum of colorectal polyps is considerable. The size, morphology, site, access (SMSA) scoring system is validated in determining lesion complexity and difficulty of polypectomy [4]. For those with a higher SMSA level, the decision-making and technical challenges of treatment are significant. With a 10 to 15% risk of containing a focus of cancer [5], accurate lesion and patient assessment is required. Management should be individualised, and options include endoscopic resection, combined procedures, conservative management or surgery including trans-anal approaches and colonic resection. Endoscopic intervention is recommended first line [5], but variability remains in the management of these lesions [6, 7]. Static or increasing use of colonic resection has been reported despite advances in organ preserving techniques [8, 9].

Endorsed by guidelines, multi-disciplinary management meetings for complex colorectal polyps are used across the UK [5]. These meetings are synonymous to tumour boards used in other countries. Effectiveness has been demonstrated elsewhere [10, 11], but understanding of their impact on complex polyp outcomes is limited. The primary aim of this

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Published online: 03 February 2023

multi-centre observational study was to assess procedures and clinical outcomes of patients managed through these approaches. Other objectives included assessment of referral volume, trends in primary procedures and comparisons between presentation and treatment modality.

Method

This was a retrospective, observational study of consecutive patients managed by six complex polyp multi-disciplinary team meetings in the UK utilising the STROBE recommendations [12].

Data collection

Each centre provided prospective lists of patients referred to meetings from commencement for review and assessed until March 2020 at the latest. Data were collected from digital hospital records onto pre-defined spreadsheets.

Patient and polyp demographics

Data were collected regarding patient and polyp characteristics. Screening patients were diagnosed through colorectal cancer screening programmes. Symptomatic patients included those diagnosed through symptomatic presentations, incidental findings, or through surveillance programmes. Comorbidities were described using the Charlson Comorbidity Index (CCI) [13] and polyp complexity defined by the SMSA scoring system [4].

Outcomes

Length of stay was the total nights in hospital. Adverse events were classified using the Clavien-Dindo (CD) system [14]. Bleeding controlled during a procedure without additional intervention was not considered an adverse event. Readmission rate was unplanned readmissions related to the polyp procedure within 30 days. Residual or recurrent disease included histologically confirmed lesions at or adjacent to the original excision site identified at follow-up colonoscopy.

Inclusion and exclusion criteria

Standardised criteria for case selection were used with at least one year follow-up to allow time for surveillance to be performed. Patients with no documentation regarding meeting discussion were excluded. Lesions referred but on assessment were absent or did not meet complexity criteria were also excluded. This included those below 10 mm and without other complexity indicators such as difficult access, recurrence or advanced histology signs. Non-neoplastic pathology, multiple small polyps and polyposis syndromes were excluded. The study focussed on lesions initially assessed as benign so confirmed cancers before intervention were excluded. Patients pending treatment or follow-up were reported but not analysed.

Statistical analysis and comparisons

Descriptive statistics were performed with unpaired *t* and Mann–Whitney *U* tests for parametric and non-parametric data respectively. Chi-squared was used for categorical data. Comparisons were made between presentation type and colonic resections against organ sparing procedures. Statistical analysis was performed with SPSS version 26 (IBM, Chicago, IL, USA). A P value < 0.05 was considered significant.

Ethics

As a service evaluation, further ethical approval was deemed unnecessary by Cardiff University Research Integrity, Governance and Ethics Team. Local research governance guidance was followed at each site.

Results

Patient and polyp demographics

A total of 2749 patients were referred with increasing numbers each year. Exclusion of 640 cases left 2109 patients for analysis (Supplementary materials 1 and 2).

Table 1 summarises patient and polyp characteristics. The mean age was 68.9 years with most presenting symptomatically. There was a male preponderance in all categories and symptomatic patients had a significantly higher CCI. Supplementary material 3 shows characteristics of each centres team structure.

There were 2192 complex colorectal polyps identified in the 2109 patients. Mean size was 32.1 mm and most were SMSA level 4 (44.3%). A pre-intervention biopsy was documented in 52.1% and histology showed high grade dysplasia (HGD) in 16.0% of these.

There was no difference in the number of SMSA level 3 and 4 lesions ($P = 0.401$), polyp location ($P = 0.920$) or previous treatment attempts ($P = 0.088$) between screening and symptomatic groups. Screen detected polyps were larger (33.6 mm vs 31.4 mm) and had more lesions with HGD (11% vs 7%).

Table 1 Patient and polyp characteristics

PATIENT CHARACTERISTICS				
	Total ($n=2109$)	**Screening ($n=749$)**	**Symptomatic ($n=1360$)**	***P* value**
Age (years)	68.9 (23 to 97)	67.5 (50 to 78)	69.7 (23 to 97)	<0.001
Female	832 (39.5%)	247(33.0%)	585(43.0%)	<0.001
Male	1277 (60.5%)	502 (67.0%)	775(57.0%)	
CCI	3.5 (0 to 12)	3.1 (0 to 8)	3.7 (0 to 12)	<0.001
POLYP CHARACTERISTICS				
	Total ($n=2192$)	**Screening ($n=758$)**	**Symptomatic ($n=1434$)**	***P* value**
Polyp size (mm)*	32.1 (2 to 180)	33.6 (2 to 120)	31.4 (3 to 180)	0.005
Polyp morphology				
Flat	829 (37.8%)	238 (31.4%)	591 (41.2%)	
Sessile	1130 (51.6%)	455 (60.0%)	675 (47.1%)	
Pedunculated	228 (10.4%)	60 (7.9%)	168 (11.7%)	
Missing	5 (0.2%)	5 (0.7%)	0	
Polyp location				
Right	980 (44.7%)	340 (44.9%)	640 (44.6%)	0.920
Left	1212 (55.3%)	418 (55.1%)	794 (55.4%)	
Polyp access				
Difficult	1024 (46.7%)	199 (26.3%)	825 (57.5%)	
Easy	1168 (53.3%)	559 (73.7%)	609 (42.5%)	
SMSA level				
4	971 (44.3%)	324 (42.7%)	647 (45.1%)	0.401
3	788 (35.9%)	278 (36.7%)	510 (35.6%)	
2	420 (19.2%)	144 (19.0%)	276 (19.2%)	0.002
1	8 (0.4%)	7 (0.9%)	1 (0.1%)	
Missing	5 (0.2%)	5 (0.7%)	0	
Previously treated polyp				
Yes	117 (5.3%)	49 (6.5%)	68 (4.7%)	0.088
No	2075 (94.7%)	709 (93.5%)	1366 (95.3%)	
Pre procedure histology				
Biopsy not done	1050 (47.9%)	233 (30.7%)	817 (57%)	
Adenoma, LGD	896 (40.9%)	415 (54.8%)	481 (33.5%)	0.001
Adenoma, HGD	183 (8.4%)	83 (11.0%)	100 (7%)	
Serrated	40 (1.8%)	13 (1.4%)	7 (2.0%)	
Hyperplastic	20 (0.9%)	11 (1.7%)	29 (0.5%)	
Normal mucosa	3 (0.1%)	3 (0.4%)	0	
Further assessment endoscopy				0.417
Yes	227 (10.4%)	84 (11.1%)	143 (10.0%)	
No	1965 (89.6%)	674 (88.9%)	1291 (90.0%)	

Age, CCI and polyp size are given as mean and range. The remaining values are given as number and (%) to one decimal place. Unpaired *t* tests are used for continuous variables and chi-squared tests for categorical data

*Missing data, $n=1$

Procedures

A total of 2149 procedures were performed on 2192 lesions (Fig. 1). Of these, 2010 were primary procedures with the remainder being secondary ($n=135$) or tertiary interventions ($n=4$).

Primary procedure

Primary endoscopic therapy was performed in 1657 (75.6%) polyps. Surgical procedures were performed in 14.9% including trans-anal surgery (6.8%) or colonic resection (8.1%). Combined endoscopic-surgical procedures and

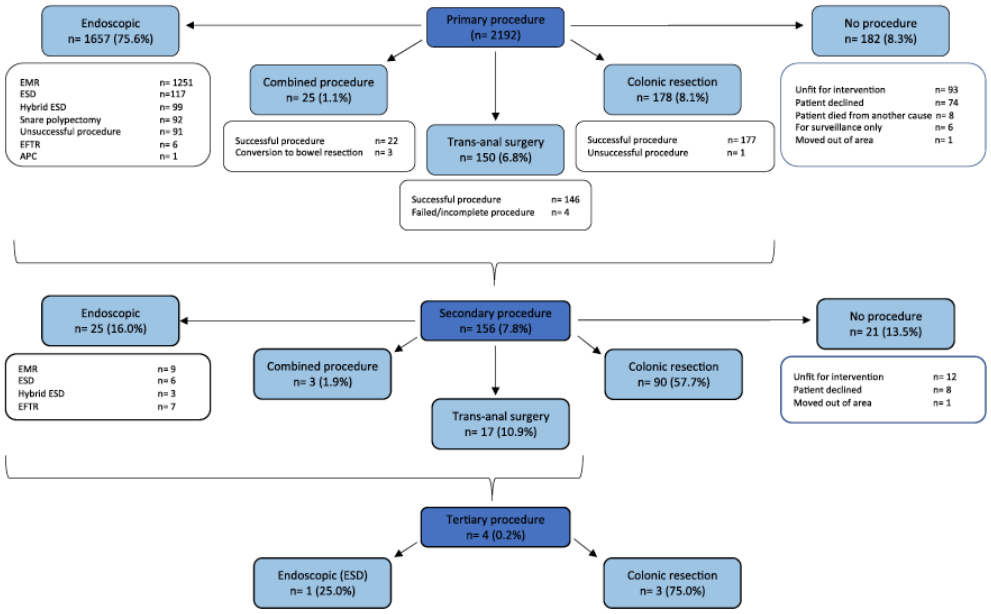

Fig. 1 Flow diagram of primary, secondary and tertiary procedures

conservative management were used in 1.1% and 8.3% respectively. Reasons for no intervention were mostly due to patients being unfit (51.1%). Other reasons included patients declining treatment (40.7%), opting for surveillance only (3.3%), dying from another cause before treatment (4.4%) or moving out of area (0.5%).

More primary colonic resections were performed in the screening cohort (16% vs 4.7%, $P<0.001$). Patients undergoing resection were similar in age (68.3 vs 68.4, $P=0.862$) and gender (59.7% vs 60.6% males, $P=0.811$) compared to those with organ preservation. Polyps were larger (38.6 mm vs 31.8 mm, $P<0.001$) in those treated by resection with more right (68.5% vs 41.9%, $P<0.001$) and SMSA level 3 or 4 lesions (88.2% vs 79.6%, $P=0.006$). There were more adenomas with pre-intervention HGD in the resection group (23.2% vs 6.2%, $P<0.001$).

Secondary and tertiary procedures

Secondary procedures were advised in 156 lesions (7.8%). Indications included unsuccessful primary intervention (38.5%), suspicion of cancer during procedure (23.1%), recurrence (22.4%) or cancer on final histology (16%). Of these, 21 did not have a secondary procedure mostly due to the patient being unfit (57.1%). The commonest secondary procedure was colonic resection (57.7%). Endoscopic management was performed in 16.0% with trans-anal and combined procedures in 10.9% and 1.9% respectively.

Four polyps required a third procedure. Three were due to recurrence and one for cancer detected on final histology. Despite more primary resections in the screening cohort, there was no difference in further procedures between the two presentations ($P=0.941$).

Change in recommended procedures over time

The proportion of primary colonic resections fell from 34.6% in 2012 to 1.7% in 2020 with organ preserving procedures or conservative management having an increasing role (Fig. 2). Over the same time, the use of organ preserving procedures increased from 62.7 to 83.8%. More patients were managed conservatively with 2.7% in 2012 compared to 14.5% in 2020. There was no reciprocal increase in secondary procedures or recurrences as a result of the increasing use of primary organ preserving procedures (Figs. 2 and 3).

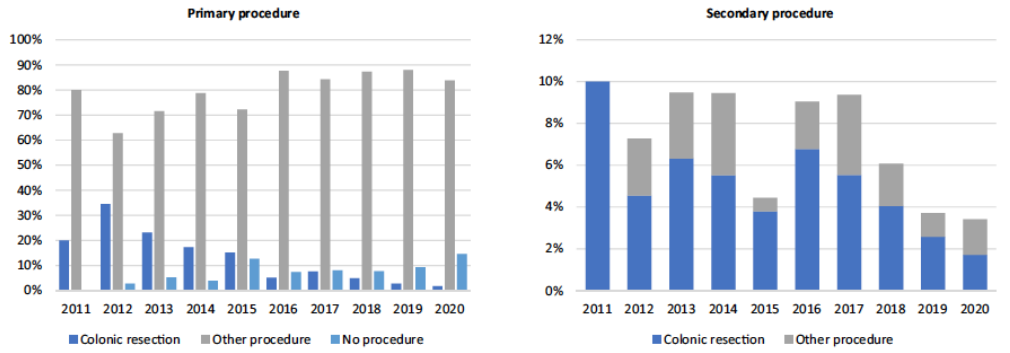

Fig. 2 Change in procedures over time

Outcomes

Length of stay, adverse events and 30-day readmissions

Most procedures were day cases with a longer length of stay for colonic resections ($P < 0.001$). Adverse events were identified in 9.0% (Table 2) with rates being similar for endoscopic (5.5%), combined (7.1%) and trans-anal procedures (7.2%). Rectal bleeding was the commonest adverse event after endoscopic procedures (3.3%), followed by perforation (0.8%) and post polypectomy syndrome (PPS) (0.7%). Management of bleeding was predominantly conservative (63.6%). A minority required endoscopic intervention (21.8%), transfusion (7.3%), bowel resection (5.5%) or interventional radiology (1.8%). Most perforations occurred in left sided lesions (64.3%) and were managed with antibiotics or surgical intervention in 78.6% and 21.4% respectively.

There were significantly more adverse events for colonic resections (31.7%). The commonest was anastomotic leak (19.8%) which occurred in 11 left and 6 right sided resections. Four were managed conservatively and surgical intervention was required in 13. Wound infection (15.1%), respiratory tract infection (11.6%) and ileus (11.6%) were other frequent adverse events. All three 30-day mortalities occurred in those undergoing colonic resection.

Thirty-day procedure-related readmission was 3.3%. Readmission after colonic resection (4.8%) was higher than endoscopic (3.3%) and trans-anal procedures (1.2%) but not significantly ($P = 0.127$). The commonest readmission reason was rectal bleeding after endoscopic or trans-anal procedures.

Final histology

Of the 1989 removed lesions, malignancy was found in 8.8%. Malignancy was significantly higher in the

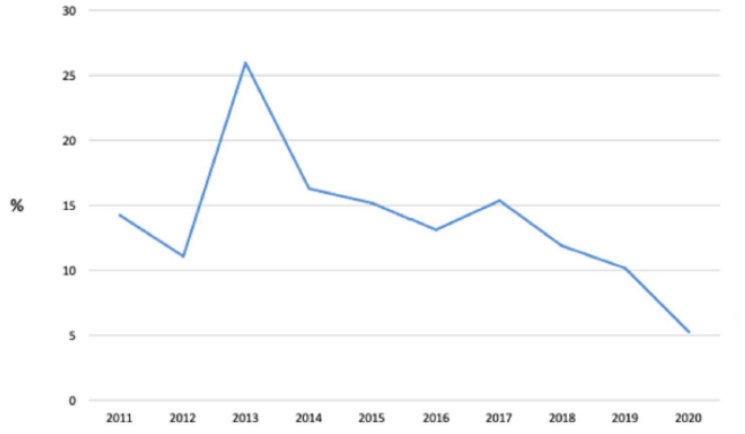

Fig. 3 Change in recurrence rates over time

Table 2 Length of stay, adverse events and 30-day readmissions

	TOTAL (*N* = 2149)	ENDOSCOPY (*N* = 1683)	COMBINED PROCEDURE (*N* = 28)	TRANS-ANAL SURGERY (*N* = 167)	COLONIC RESECTION (*N* = 271)	*P* VALUE
LENGTH OF STAY	0 (0 to 1)	0 (0 to 0)	2 (2 to 3)	1 (1 to 2)	5 (4 to 8)	*P* < 0.001
TOTAL ADVERSE EVENTS	193 (9.0%)	93 (5.5%)	2 (7.1%)	12 (7.2%)	86 (31.7%)	*P* < 0.001
CD 1	65 (33.7%)	45 (48.4%)	2 (100%)	5 (41.7%)	13 (15.1%)	
CD 2	70 (36.3%)	27 (29.0%)	0	4 (33.3%)	39 (45.3%)	
CD 3	32 (16.6%)	15 (16.1%)	0	2 (16.7%)	15 (17.4%)	
CD 4	23 (11.9%)	6 (6.5%)	0	1 (8.3.%)	16 (18.6%)	
CD 5	3 (1.5%)	0	0	0	3 (3.5%)	
30-DAY READMISSION	70 (3.3%)	55 (3.3%)	0	2 (1.2%)	13 (4.8%)	*P* = 0.127

Results are described for the total number of procedures performed ($n = 2149$). Figures are given as median (interquartile range) for length of stay. The remaining values are given as number and (%) to one decimal place. *P* values are given for comparisons between colonic resections and all other organ preserving procedures using a Mann–Whitney *U* test for length of stay and chi-squared tests for adverse events and readmissions. A complete overview of adverse events and reasons for 30-day readmissions can be viewed in Supplementary material 4

screening cohort (12% vs 7%, $P < 0.001$) and in those having primary colonic resection (26% vs 7%, $P < 0.001$). Of those with HGD on biopsy, 34.4% were identified as cancer on final histology compared to 8.3% with LGD (Supplementary material 5).

Of the cancers, 45.1% had been managed with primary resection. Completion colonic resection was recommended in 14.3% of those treated with organ preservation and 40.6% underwent surveillance only. Seven (9.9%) of these had benign recurrence with four treated during surveillance endoscopy. Three (4.2%) required further procedures with trans-anal surgery ($n = 3$) or colonic resection ($n = 1$).

Residual or recurrent disease

The median duration of follow up was 30.3 months (IQR 32.8 to 81.8 months). Of the 2192 lesions, 618 were categorised as not requiring surveillance. Of the remaining 1574, 1209 (76.8%) had a colonoscopy during follow up. Benign recurrence was identified in 13.1% ($n = 158$). Most patients had one episode ($n = 116$) with two or more recurrences in 42 patients. There was no difference in recurrence between screening and symptomatic cohorts (12.8% vs 13.2%, $P = 0.827$). Of the 214 total recurrence episodes, 82.2% were managed at the time of surveillance. Additional procedures were required in 38 (17.8%). Figure 3 demonstrates the reduction in recurrence rates over the study period.

Colonic resection

Colonic resection was required in 280 patients. Most were the recommended primary intervention (63.6%). Other indications included unsuccessful primary procedures (10.7%), cancer suspected during treatment (9.3%), cancer on final histology (8.9%) and recurrence (5%). Of the 26 lesions where cancer was suspected during treatment, malignancy was confirmed in 25. Colonic resection was required for adverse events in 2.5% ($n = 7$) (Supplementary material 6).

Procedures and outcomes for rectal lesions

There were 642 (29.3%) rectal lesions and endoscopy was the commonest primary procedure (66.8%) Trans-anal procedures were performed in 22.7%, conservative management in 8.3% and colonic resection in 2.2%. Secondary procedures were required in 7% which were mostly colonic resection (51.2%) but also included trans-anal surgery or endoscopy (14.6%). There were no resections performed for adverse events. At the time of follow up, 29.7% of patients with rectal lesions treated surgically still had a stoma.

Discussion and conclusions

This is the first multi-centre study of team approaches for complex colorectal polyps and demonstrates the delivery of appropriate management with good outcomes. As the case volume is rising and early detection improving, their use may be of increasing importance.

Organ preserving techniques were the primary treatment for most lesions. Primary surgery rate may reflect optimal decision-making, but the standard is not established [5]. Our overall (8.1%) and 2019 (2.7%) primary surgical resection rate is lower than reported (21.7%) [6]. Secondary management (7.8%) was also lower than previous studies by Lee (16.1%) [6] and Dattani (13.2%) [7]. This reduction conflicts the increasing or stable rates reported in American and European studies [8, 9]. Tumour boards in America are analogous

to multi-disciplinary team approaches [15], but are not standard practice for complex polyps. Their utilisation in the UK may explain the reduction in colonic resections and have implications for practice standards of professional guidelines [5]. We acknowledge that ongoing developments in advanced endoscopy may confound the observed reduction in colonic resections despite this not having influenced other countries [8, 9]. It also does not explain the increasing utilisation of conservative management seen in this study.

Contrary to previous evidence [7], screening detected polyps were more likely to have primary colonic resection. Some may have been anticipated cancers highlighting one limitation of retrospective data collection. Time allocation for screening lists and more experienced endoscopists may result in lesions being treated without referral to meetings. This could explain the higher number of larger lesions and those with HGD in screening presentations. The lower CCI in screening patients may reflect individual motivation regarding healthcare and mean that surgical treatment is a viable option compared to the comorbid.

The perceived correlation between HGD and cancer on final histology [7] could result in surgery being recommended. Only 34.4% of lesions with pre-intervention HGD were proven to contain cancer, similar to that reported by Dattani (37.5%) [7]. Of lesions with HGD treated with resection, the majority (57.1%) were ultimately found to be benign. Biopsies can create diagnostic uncertainty through sampling error, burden pathology services and compromise endoscopic therapy [16]. Identifying malignant features by optical polyp characterisation is vital for decision-making [17] and the European Society of Gastroenterology now recommend a core curriculum to improve this [18].This can be challenging [19], but quality imaging and training allows final decisions to be made later by those with expertise in this field.

Endoscopic treatment has fewer adverse events, shorter stays and lower costs [20–22] and the safety of procedures in our study being comparable. Post polypectomy bleeding (3.3%) was the commonest adverse event with similar rates reported by Moss (2.9%) and Buchner (7.2%) [16, 23]. Perforation was low (0.8%) and within standards set by guidelines [5]. The thinner right colonic wall may explain the higher resection rates in this group. Most perforations reported in our series were located on the left and managed conservatively. Despite colonic resection offering the security of complete lesion removal, it is overtreatment for most and associated with longer stays and more adverse events. A systematic review of surgical resections for benign polyps reported adverse event and mortality rates of 24% and 0.7% respectively [24]. Our adverse events (31.7%) including a leak rate of 19.8% and mortality of 1.1% are similar and reiterates the greater risks of resection.

Dattani reported a 10.7% risk of cancer in their study of significant polyps [7]. Our cancer rate was 8.8%. Most were managed without completion resection and supports the safety of such management in selected patients. For malignant lesions, survival and recurrence is not adversely affected by endoscopic therapy initially [25] and completion bowel resection may not be superior [26]. Our benign recurrence rate of 13.1% was acceptable. A meta-analysis in 2014 reported recurrence in 15% [27] with more recent evidence quoting 10.8% for large, non-pedunculated polyps [28].

Study limitations include the retrospective design and absence of a control group. A comparator group was considered when designing the study but found not to be pragmatic. Heterogeneity between centres without a meeting could have been misleading. Data collection preceding the introduction of meetings would also have been difficult with limited digital records and challenges in identifying a comparative cohort. Prospective data collection before and after meeting introduction could have been performed but would require considerable time to achieve. All efforts were made to thoroughly assess and record data, but there could be missed adverse events, readmissions and surveillance procedures. Variability between team structure is also a confounder and possibly impacts both the decisions made and outcomes. Despite this, our study provides real world data that should reflect current clinical practice across the UK and outcomes for patients with complex colorectal polyps. We advocate prospective data collection, audit and comparison to key performance indicators ideally on a national scale, to ensure the ongoing effectiveness of polyp meetings.

There may be further benefits of team decision-making. It can improve capacity by modifying management, improving patient preparation and allocating cases to those with expertise [29]. Benefits in clinician education and confidence in choosing organ preserving techniques may result from involvement with meetings. With increasing referrals, ensuring efficiency and appropriate utilisation of polyp meetings is required. Standardised referral criteria and completed proformas [30] are recommended to facilitate efficiency and uniformity. Evaluation of economic impact would also be valuable. Given the spectrum of options for complex polyps and their risks, the patient's voice is crucial and team management should advocate shared decision-making, with research regarding patient reported outcomes also required.

This data may guide key performance indicators for complex colorectal polyp treatment. The reduction in primary surgery over time suggests that team management of complex polyps contributes to the improvement of clinical outcomes. This effect may be due to a combination of group decision-making, clinical expertise, access to a full range of therapeutic modalities and optimisation of service provision.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00384-022-04299-0.

Acknowledgements We would like to express our gratitude to Simon Cavan, Alexander Johnston, Jonathan Fawkes, Michael Davies and the Leeds Large Polyp Multi-Disciplinary Team Meeting for their invaluable time and assistance in the completion of this study.

Authors' contributions Jody Parker designed the study, collected data, analysed data, drafted and revised the manuscript. Sunnia Gupta and Lavanya Shenbagaraj collected data, analysed data, and revised the manuscript. Phillip Harborne, Rajeswari Ramaraj, Sharad Karandikar, Marcus Mottershead, Jamie Barbour, Noor Mohammed, Melanie Lockett, Ann Lyons and Roser Vega collected data and revised the manuscript. Jared Torkington and Sunil Dolwani designed the study, revised the manuscript and supervised the overall project. All authors read and approved the final manuscript.

Funding J Parker holds the Royal College of Surgeons of England Moondance Research Fellowship.

Data availability Data is available on request to the lead (JP) and senior (SD) authors.

Declarations

Ethics approval and consent to participate Not required.

Competing interests The authors declare that they have no competing interests.

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OXFORD

BJS, 2021, 108, e196–e198
DOI: 10.1093/bjs/znab053
Advance Access Publication Date: 26 February 2021
Research Letter

Laparoscopically assisted endoscopic mucosal resection reduces the need for bowel resection for complex colonic polyps

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Presented to the Association of Coloproctology of Great Britain and Ireland Virtual Fringe, July 2020

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Dear Editor

Complex polyps are defined as those with an increased risk of malignancy, incomplete resection, adverse events, or with an SMSA (size morphology site access) level of 4[1]. They can be challenging to treat and have a 10–15 per cent risk of developing into cancer[1]. Patients perceived to have endoscopically unresectable polyps may be offered surgery. Combined laparoscopic colonic mobilization with endoscopic resection can avoid bowel resection. A systematic review[2] of laparoscopically assisted endoscopic mucosal resection (EMR) reported the need for reintervention in 9.5 per cent of patients, an adenocarcinoma incidence of 10.5 per cent, and a complication rate of 7.9 per cent. Significant heterogeneity exists in these studies, with variability in terminology, selection criteria, and procedural technique. The authors' tertiary centre coordinates a complex polyp multidisciplinary team (MDT). The aim was to assess short- and long-term outcomes of laparoscopically assisted EMR procedures managed through the MDT pathway.

The complex polyp MDT was established in 2008 and discusses approximately 250 cases annually. Referral criteria and decision-making pathways are based on national guidance[3]. A retrospective review was performed of all laparoscopically assisted EMR procedures undertaken by the MDT between September 2008 and October 2018. The IDEAL framework recommendations[4] and STROBE checklist[5] were applied. Laparoscopically assisted EMR was considered when endoscopic intervention alone was considered not feasible owing to size or access difficulties, would not achieve complete resection, or had been unsuccessful previously. Exclusion criteria were: patients unfit for general anaesthetic, polyps with clear evidence of malignancy, and patients who declined treatment.

All procedures were undertaken at the national referral centre in Cardiff. Patients were consented for the possibility of conversion to segmental resection or a second operation. Procedures were performed by an advanced endoscopist and one of two colorectal surgeons. All were active members of the MDT. Patients received standard bowel preparation, thromboprophylaxis, a urinary catheter, and antibiotic prophylaxis.

Laparoscopy was performed and the bowel mobilized sufficiently to aid the colonoscopic procedure. A tape was tied around the terminal ileum to prevent small bowel distension during colonoscopy. Lesions were assessed for signs suggesting malignancy and converted to bowel resection in this situation. An EMR technique was mostly used, but a hybrid EMR endoscopic submucosal technique was used where necessary. EMR involved injection of lifting solution and whole or piecemeal polypectomy using a hot snare. The bowel was manipulated simultaneously by the surgeon to facilitate removal. For periappendiceal lesions, invagination of the appendix by the surgeon allowed full polyp excision. If too extensive, an appendicectomy was carried out. Haemostasis was ensured and mucosal defects were closed with endoscopic clips. Laparoscopic inspection was done to confirm bowel wall integrity before removal of the tape and closure. First colonoscopic surveillance was undertaken 3 months after treatment. As a retrospective service evaluation, Cardiff University Research Integrity, Governance and Ethics Team confirmed that ethical approval was not necessary.

During the study interval, 55 patients underwent laparoscopically assisted EMR (*Table 1* and *Fig. 1*). There were no intraoperative perforations and estimated blood loss was minimal in 50 patients (91 per cent). Median procedure duration was 156 (i.q.r. 128–185) min. Median duration of postoperative hospital stay was 1 (i.q.r. 1–2) day. There were five complications in four

Received: January 12, 2021. **Accepted:** January 24, 2021

Table 1 Patient and polyp characteristics

	No. of patients*
Patient characteristics	
Age (years)†	65 (63–69)
Sex ratio (M : F)	37 : 18
ASA fitness grade	
I	20 (36)
II	27 (49)
III	8 (15)
BMI (kg/m^2)†	28.6 (26.2–32.8)
Smoker	
No	46 (84)
Yes	9 (16)
Mode of presentation	
Bowel screening	32 (58)
Symptomatic	15 (27)
Colorectal cancer surveillance	4 (7)
Polyp surveillance	4 (7)
Indication for laparoscopically assisted EMR	
Difficult access to polyp	28 (51)
Polyp size	13 (24)
Polyp size and difficult access	11 (20)
Previously unsuccessful endoscopic excision	3 (5)
Polyp characteristics	
Size (mm)†	37.5 (20.0–48.8)
Location	
Caecum	12 (22)
Caecum: appendiceal orifice	11 (20)
Caecum: ileocaecal valve	5 (9)
Ascending colon	5 (9)
Hepatic flexure	8 (15)
Transverse colon	3 (5)
Splenic flexure	5 (9)
Sigmoid colon	6 (11)
Size morphology site access level	
1	0
2‡	5 (9)
3	11 (20)
4	39 (71)
Final histology	
Villous/tubular/tubulovillous adenoma	44 (80)
Hyperplastic or serrated polyp	5 (9)
Adenocarcinoma	6 (11)
Dysplasia	
Low grade	39 (71)
High grade	8 (15)
Not documented on report	2 (4)

* With percentages in parentheses unless indicated otherwise; †values are median (i.q.r.). ‡ Indications for laparoscopically assisted endoscopic mucosal resection (EMR) in these polyps were extension into the appendix orifice (3), lesion proximal to a sigmoid stricture not passable without laparoscopic assistance (1), and previously unsuccessful endoscopic excision (1). SMSA, size morphology site access.

patients (7 per cent). One patient had a postoperative bleed requiring blood transfusion and a right hemicolectomy; he was subsequently diagnosed with a coagulation disorder. Other complications included urinary retention (2), chest infection (1), and wound haematoma (1). There were no readmissions. Cancer was found in six polyps (11 per cent), and for three of these the procedure was converted to resection owing to suspicion of malignancy. The three cancers diagnosed on final histology were all removed in uncomplicated laparoscopic bowel resections at a later date. Endoscopic and histological records were assessed for a median follow-up of 76 (i.q.r. 62–91) months. Of 44 patients who did not undergo bowel resection, seven had either residual (at 3 months) or recurrent (after 3 months) disease at the polypectomy site. All such disease was benign and treated successfully endoscopically.

Laparoscopically assisted EMR for complex polyps avoided surgery in 80 per cent of patients selected by the MDT with a low complication rate, short hospital stay, and good long-term outcomes. The rate of intraoperative conversion to resection (13 per cent) was lower than that in comparable studies, with some describing rates exceeding 20 per cent[6–8], but complication rates were similar (7 *versus* 4.4–15.3 per cent[6–9]). A smaller percentage of unsuspected cancers was reported here (5 *versus* 3.3–10.2 per cent).

Laparoscopically assisted EMR is not widely used. Reasons for this may include lack of awareness, concerns regarding unrecognized malignancy or access to advanced endoscopy. A recent systematic review[10] of surgically treated benign polyps reported unfavourable outcomes in terms of rates of complications (24 per cent) and mortality (0.7 per cent). Laparoscopically assisted EMR is an effective long-term treatment for selected complex polyps with minimal need for reintervention. Compared with bowel resection, this technique is potentially beneficial in terms of patient recovery, functional outcomes, and cost-effectiveness.

Limitations of this study include its single-centre, retrospective, and observational design. Laparoscopically assisted EMR has logistical challenges, including equipment requirements and the need for two consultants. This may be offset by the avoidance of bowel resection and cost reduction, but further evidence regarding quality of life and economic outcomes is required. Considering study heterogeneity, the authors support adherence to the IDEAL recommendations for future research.

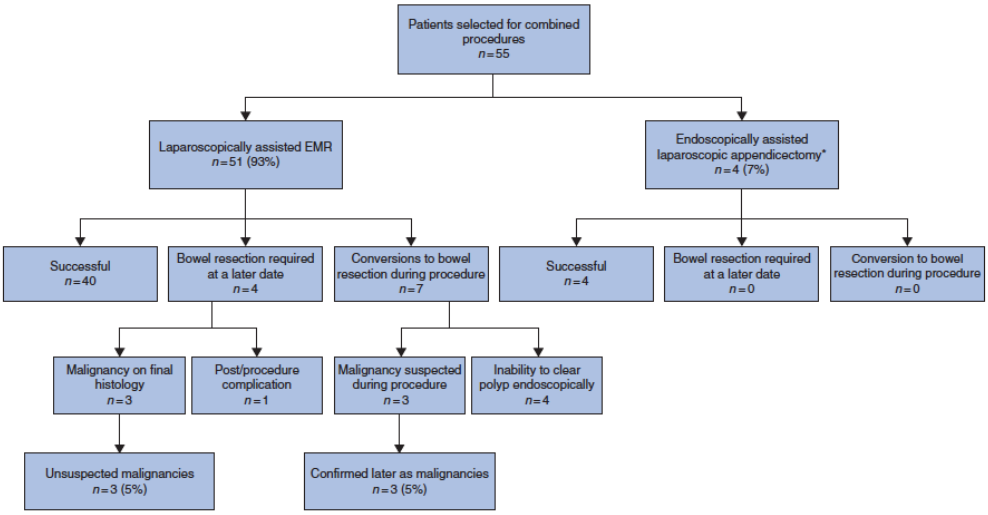

Fig. 1 Study flow diagram

*Indications for appendicectomy included deep extension into appendiceal lumen (3), and failure to lift after injection of endoscopic mucosal resection (EMR) solution owing to previous removal attempts (1). †All malignancies suspected during the procedure were subsequently confirmed histologically as cancer.

Funding

J.P. is in receipt of a Research Fellowship funded by the Royal College of Surgeons of England.

Acknowledgements

The authors thank S. Gupta, S. Keenan, and L. Shenbagaraj for invaluable assistance in collecting data for this study.

Disclosure. The authors declare no conflict of interest.

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Journal of Gastroenterology and Hepatology
JGHF
doi:10.1111/jgh.16157

SYSTEMATIC REVIEW

Comparison of recommendations for surveillance of advanced colorectal polyps: A systematic review of guidelines

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Key words
Advanced colorectal polyp, Guidelines, Surveillance.

Accepted for publication 17 February 2023.

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Financial support: J. Parker holds the Royal College of Surgeons of England Moondance Research Fellowship.
Category in which manuscript is being submitted: Systematic review.

Abstract

Background and Aim: Patients diagnosed with advanced colorectal lesions have a higher risk of developing colorectal cancer. International polyp surveillance guidelines have recently been updated. The aim of this systematic review was to assess surveillance recommendations for advanced colorectal polyps and compare the patient, polyp, and colonoscopy quality factors considered in their recommendations.

Methods: Guidelines with surveillance recommendations for colorectal polyps were identified. Databases searched included PubMed, Web of Science, Scopus, TripPro, and guidelines identified by two blinded reviewers. The review protocol was registered on PROSPERO and performed in line with PRISMA guidelines.

Results: Six guidelines from the US Multi-Society Task Force, British Society of Gastroenterology, Cancer Council Australia, European Society of Gastrointestinal Endoscopy, Japan Gastroenterological Endoscopy Society, and Asia-Pacific Working Group on Colorectal Cancer Screening were included. The recommended surveillance interval of 3 years was consistent, but the criteria used for advanced polyps were variable. Polyp factors were the key determinant for when surveillance should be performed. Although all guidelines recognized their importance, the application of and evidence underlying patient characteristics and the quality of baseline colonoscopy were limited. All included guidelines were rated of average to high quality by the AGREE II instrument.

Conclusion: Surveillance guidelines for advanced colorectal polyps are of good quality but limited by their underlying evidence. Standardization of definitions would be valuable for both research and clinical application. Better knowledge of colonoscopist quality indicators and patient factors is recommended to further economize surveillance recommendations, minimize patient risk, and achieve optimal outcomes without increasing pressure on services.

Introduction

The surveillance of patients diagnosed with colorectal polyps aims to identify and treat new, missed, or recurrent lesions to reduce the chance of developing colorectal cancer.[1] The spectrum in polyp morphology affects the level of this risk, and factors include number, size and location of polyps, gender, and age.[2]

The risk of recurrent or metachronous disease is higher after identification of advanced colorectal lesions. The British Society of Gastroenterology (BSG) define these as sessile serrated lesions or adenomas at least 10 mm in size, sessile serrated lesions with dysplasia or adenomas with evidence of high-grade dysplasia.[3] Due to their increasing detection,[4] surveillance frequency should balance the need for timely diagnosis and optimal outcomes against the risks of colonoscopy and its burden on the patient and health service. Guidelines are decision-making tools helping clinicians provide evidence-based patient management, and several international polyp surveillance guidelines have recently been updated.[3,5,6] Recommendations for timing of surveillance should account for polyp features but also patient characteristics including overall health and their own preferences. Factors related to the index colonoscopy may also be important,[7] with poor quality colonoscopy associated with a higher future risk of colorectal cancer.[8,9]

The aim of this systematic guideline review was to assess the surveillance recommendations and definitions specifically for advanced colorectal polyps and compare the patient, polyp, and colonoscopy quality factors at index examination considered in their development.

Methods

Guidelines with surveillance recommendations for colorectal polyps were systematically identified from the literature. The methodology was created in line with recent guidance.[10] Relevant full-text articles were considered for full analysis and data

extraction based on the inclusion and exclusion criteria. The study protocol was registered on PROSPERO[11] and performed according to the PRISMA guidelines for systematic reviews.[12]

Literature search and search terms. A systematic literature search was performed to identify all potential guidelines. Updates to identify new articles were used. Databases searched included PubMed, Web of Science, Scopus, and TripPro. Other resources as shown in Supporting information Table S1, were hand searched for further guidance and to ensure the most up to date versions had been identified.

The search terms were developed with input from specialists in the field of gastroenterology, colorectal surgery and systematic literature review. Search strategies from published guidelines were also utilized to guide the selection of terms.[3] Search terms included "guideline or practice guideline," "recommendation," "surveillance," "intestinal polyps," "colonic polyps," "colorectal neoplasm," "adenoma or adenomatous polyps," and "polypectomy." The full strategy is shown in Table S2.

Inclusion criteria. Evidence based national or international guidelines describing surveillance recommendations after colorectal polyp diagnosis in adults were considered. Those guidelines with specific recommendations regarding advanced polyps or an equivalent definition were included for full-text review. The guidelines were deemed appropriate if exclusively describing advanced polyp surveillance or if the subject was part of a defined section in wider recommendations. If multiple guidelines were produced by the same group, the most recent was used for the analysis. No journals or countries of publication were excluded. All articles were initially considered regardless of the year of publication or language.

Exclusion criteria. Local or departmental guidelines were excluded from the review. Guidance exclusively for malignant or hereditary polyps were excluded due the specific considerations required for their surveillance. All articles were initially considered regardless of language but were excluded later if translation was not feasible. Guidelines published in draft form or as conference papers were not included due to the lack of peer review and unavailability of the full guideline respectively.

Guideline identification. Databases were searched with the previously described terms and downloaded into EndNote to identify duplicates. Abstracts were then exported to the Rayyan Systematic Review Web Application.[13] Two independent, blinded researchers screened abstracts using the described inclusion and exclusion criteria. The researchers met to resolve decision conflicts at this stage and to finalize the guidelines for full-text review. Conflicts at any stage were referred to the senior researcher for resolution.

Full-text guidelines were assessed by the same blinded reviewers. This was managed on separate EndNote files, and reasons for exclusion were classified. Decision conflicts were resolved at this stage and the final articles confirmed. Any supplementary materials for the included guidelines were also obtained. Identified guidelines, article abstracts referring to a guideline, and systematic review articles were cross referenced to find other relevant articles. The identified articles were reviewed as above for inclusion or exclusion.

Data extraction and analysis. Data extraction was performed by the same two blinded researchers onto separate, standardized spreadsheets, and variations were resolved as previously described. Information was collected and narrative descriptions and comparisons performed on the guideline characteristics, advanced polyp definitions, surveillance timings, levels of evidence, strength of recommendations, and the polyp, patient, and colonoscopy quality factors at index examination on which the recommendations were based. Data analysis was performed by one researcher and cross checked by a second using Microsoft Excel.

Assessment of guideline quality. The Appraisal of Guidelines for Research and Evaluation, 2nd Edition (AGREE II) instrument,[14] is a validated tool designed to assess the quality of guideline development and methodology. As shown in Table 1, it contains 23 items within six domains including scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence. Each item is scored out of 7 (1 = *strongly disagree*, 7 = *strongly agree*) to give a total across the domains. The final evaluation is an overall recommendation of the guideline for future use. Interpretation is determined by the users and the context of the review.

Guidelines were scored using the AGREE II criteria by two reviewers. Both reviewers completed the tutorials on the use of the instrument and utilized the handbook during the assessments. Each guideline was assigned a score for each item by the researchers allowing a scaled domain score to be calculated based on the AGREE II formula. Guidelines were included regardless of score, and comparisons were made between them. The guidelines were classified based on the scaled domains scores into high quality (5 or more domains scoring 60% or more), average quality (3 to 4 domains scoring 60% or more), or poor quality (2 domains or less scoring 60% or more). A similar system has been used by other guideline reviews.[15–17]

Results

Guideline selection. The PRISMA flowchart is shown in Figure 1. A total of 6536 articles were identified, and 73 guidelines concerning the surveillance of colorectal polyps were identified within these. Five of these fulfilled the inclusion criteria for full assessment, and data extraction with a further guideline was identified through citation updates. These included guidance from the US Multi-Society Task Force (USMSTF),[6] British Society of Gastroenterology (BSG),[3] Cancer Council Australia (CCA),[18] European Society of Gastrointestinal Endoscopy (ESGE),[5] Japan Gastroenterological Endoscopy Society (JGES),[19] and Asia-Pacific Working Group on Colorectal Cancer Screening.[20]

The classification of excluded articles is shown in Table S3. There were several guidelines that considered to have been replaced by more recent documents. The National Institute for Health and Clinical Excellence (NICE)[21] and Scottish Intercollegiate

Table 1 Scoring criteria for the AGREE II instrument

Domain	Item	
Scope and purpose	1.	The overall objective(s) of the guideline is (are) specifically designed.
	2.	The health question(s) covered by the guideline is (are) specifically described.
	3.	The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.
Stakeholder involvement	4.	The guideline development group includes individuals from all the relevant professional groups.
	5.	The views and preferences of the target population (patients, public, etc.) have been sought.
	6.	The target users of the guideline are clearly described.
Rigor of development	7.	Systematic methods were used to search for evidence.
	8.	The criteria for selecting the evidence are clearly described.
	9.	The strengths and limitations of the body of evidence are clearly described.
	10.	The methods for formulating the recommendations are clearly described.
	11.	The health benefits, side effects, and risks have been considered in formulating the recommendations.
	12.	There is an explicit link between the recommendations and the supporting evidence.
	13.	The guideline has been externally reviewed by experts prior to its publication.
	14.	A procedure for updating the guideline is provided.
Clarity of presentation	15.	The recommendations are specific and unambiguous.
	16.	The different options for management of the condition or health issue are clearly presented.
	17.	Key recommendations are easily identifiable.
Applicability	18.	The guideline describes facilitators and barriers to its application.
	19.	The guideline provides advice and/or tools on how the recommendations can be put into practice.
	20.	The potential resource implications of applying the recommendations have been considered.
	21.	The guideline presents monitoring and/or auditing criteria.
Editorial independence	22.	The views of the funding body have not influenced the content of the guideline.
	23.	Competing interests of guideline development group members have been recorded and addressed.

Guidelines Network (SIGN)[22] from 2011 and 2016, respectively, were deemed to have been succeeded by the BSG guidance. Guidance from the Canadian Association of Gastroenterology[23] was excluded as they were based on the 2012 USMSTF recommendations and had not been modified since the American guidelines more recent update. The ESGE guidelines were utilized instead of several identified European documents as they were all outdated by this. They included French,[24] Norwegian,[25] Swiss,[26] Spanish,[27] German,[28] and Dutch publications.[29]

Guideline characteristics. An overview of guideline development method, assessment of evidence, and recommendation gradings is given in Table 2. All have been published within the last 3 years and are updated versions of previous guidance. A systematic literature review was performed by all during their development. Most used the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) system for their evidence assessment and recommendations, but the Australian, Japanese, and Asia-Pacific guidelines used different standards.

Terminology and criteria for advanced polyps

Advanced adenomas. A summary of the advanced polyp definitions and surveillance recommendations for each guideline is shown in Table 3. The JGES and USMSTF guidelines used the same term of advanced adenoma with the CCA and Asia-Pacific Working Group using high-risk adenoma. The BSG used advanced colorectal polyp. The ESGE guidelines did not use a definition for an advanced polyp but classified patients into those requiring surveillance or not. Criteria of size (≥ 10 mm) and inclusion of polyps with high-grade dysplasia to meet the definition of an advanced polyp were unanimous between all guidelines. Unlike the ESGE and BSG guidelines, the USMSTF, CCA, JGES, and Asia-Pacific Working Group recommendations also included adenomas with villosity as part of their definition. Multiple lesions were included under the heading of advanced polyps in the CCA, Asia-Pacific Working Group, and ESGE recommendations but with different criteria of 3 to 4, ≥ 3 lesions and ≥ 5 lesions, respectively.

Advanced serrated lesions. A summary of the advanced serrated lesion definitions and surveillance recommendations for each guideline is shown in Table 4. Polyps with serrated histology were inclusive of the advanced polyp definition provided by the BSG and ESGE guidelines. They both described these as lesions ≥ 10 mm in size or with any grade of dysplasia. The JGES guidelines did not give a definition for an advanced serrated polyp. The USMSTF and Asia-Pacific Working Group recommendations provided separate surveillance recommendations for sessile serrated polyps ≥ 10 mm or with dysplasia but did not provide terminology for these. The Australian recommendations concerning serrated polyps were complex. They did not define an advanced serrated polyp and recommendations regarding surveillance depend on the size, number, presence of dysplasia, and synchronous adenomas.

Large or complex polyps. The BSG and CCA guidelines also considered larger lesions separately within their recommendations. The definition of these were the same (size ≥ 20 mm) but with different terminology. The British guidelines referred to these as large non-pedunculated colorectal polyps (LNPCP) while the Australian used large sessile or laterally spreading lesions.

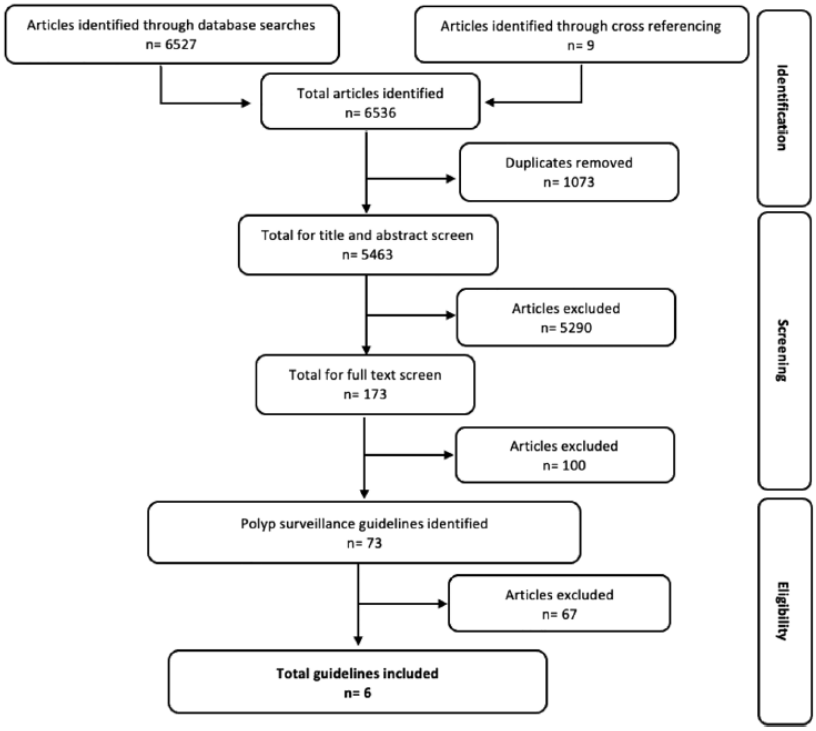

Figure 1 PRISMA flow chart.

Table 2 Guideline characteristics

	Country	Year	Development method	Evidence assessment and recommendation grading
USMSTF	USA	2020	Recommendations produced through consensus discussion among authors	GRADE system: *Strength of recommendation*—rated strong or weak *Quality of evidence*—rated very low, low, moderate, or high
BSG	UK	2020	Recommendations produced according to BSG guideline development process utilizing Delphi consensus	GRADE system
CCA	Australia	2019	Recommendations produced according to 2011 NHMRC† standard for clinical practice guidelines utilizing consensus voting	NHMRC levels of evidence and grades for recommendations for developers of guidelines: *Type of recommendation*—evidence based, consensus based or practice point *Grade of recommendation*—A: evidence trusted to guide practice; B: evidence trusted to guide practice in most situations; C: evidence provides some support but care should be taken in its application; D: evidence is weak and recommendation must be applied with caution
ESGE	Europe	2020	Recommendations produced by consensus	GRADE system

(Continues)

	Country	Year	Development method	Evidence assessment and recommendation grading
JGES	Japan	2021	Recommendations produced through modified Delphi consensus	2014 Minds Guide for Developing Clinical Practice Guidelines: *Recommendation strength*—1: highly; 2: weakly; none: cannot make a clear recommendation *Evidence level*—A: strong evidence; B: moderate evidence; C: weak evidence; D: minimal evidence
Asia-Pacific Asia Working Group		2022	Recommendations produced through modified Delphi consensus	Voting, quality of evidence and classification of recommendations *Likert scale level of agreement*—A: accept completely; B: accept with some reservation; C: accept with major reservation; D: reject with some reservation; E: reject completely *Classification of recommendations*—A: good evidence to support the statement; B: fair evidence to support the statement; C: poor evidence to support the statement; D: fair evidence to refute the statement; E: good evidence to refute the statement *Quality of evidence*—I: evidence obtained from at least one RCT[‡]; II-1: evidence obtained from well-designed control trials without randomization; II-2: evidence obtained from well-designed cohort or case–control study; II-3: evidence obtained from comparison between time or places with or without intervention; III: opinion of respected authorities, based on clinical experience and expert committees

BSG, British Society of Gastroenterology; CCA, Cancer Council Australia; ESGE, European Society of Gastrointestinal Endoscopy; JGES, Japan Gastroenterological Endoscopy Society; USMSTF, US Multi-Society Task Force.
[†]National Health and Medical Research Council.
[‡]Randomized controlled trial.

Table 3 Definitions and recommendations for surveillance of advanced adenomas

	Terminology and criteria	Surveillance recommendations	Recommendations for piecemeal excisions
USMSTF	Advanced adenoma: Size ≥ 10 mm, tubulovillous/villous histology or HGD	3 years (Strong recommendation, moderate to high GRADE evidence)	6 months for lesions ≥ 20 mm (Strong recommendation, moderate GRADE evidence)
BSG	Advanced colorectal polyp: • Advanced adenomatous polyp—size ≥ 10 mm or HGD • Advanced serrated polyp—size ≥ 10 mm or any grade of dysplasia Large non-pedunculated colorectal polyp (LNPCP): Size ≥ 20 mm	3 years if ≥ 2 pre-malignant polyps including ≥ 1 advanced polyp or one LNPCP[†] (strong recommendation, low GRADE evidence)	2–6 months in piecemeal excisions of LNPCP's[§] or where excision completeness cannot be determined in advanced polyps[¶] ([§]strong and[¶] weak recommendations, low GRADE evidence)
CCA	High-risk adenoma: Size ≥ 10 mm, HGD, villosity or 3–4 adenomas Large sessile/laterally spreading lesion: Size > 20 mm	3 years for high-risk adenomas (consensus-based recommendation[‡]) 12 months for large sessile or laterally spreading lesion (consensus-based recommendation)	6 months for large sessile or laterally spreading lesions (consensus based recommendation)
ESGE	Patients requiring surveillance: 1 adenoma ≥ 10 mm or HGD Serrated polyp ≥ 10 mm or with dysplasia ≥ 5 adenomas	3 years (strong recommendation, moderate GRADE evidence)	3–6-months for lesions ≥20 mm (strong recommendation, moderate GRADE evidence)
JGES	Advanced adenoma: Size ≥ 10 mm Tubulovillous/villous histology or HGD	3 years for advanced adenoma reduced to 1 for lesions ≥ 20 mm (strength of recommendation 2, evidence level B)	6 months

(Continues)

	Terminology and criteria	Surveillance recommendations	Recommendations for piecemeal excisions
Asia-Pacific Working Group	High-risk adenoma Three or more adenomas Size > 10 mm Villous or high-grade dysplasia	3 years (classification of recommendation A, quality of evidence II-2)	No recommendation

BSG, British Society of Gastroenterology; CCA, Cancer Council Australia; ESGE, European Society of Gastrointestinal Endoscopy; HGD, high-grade dysplasia; JGES, Japan Gastroenterological Endoscopy Society; USMSTF, US Multi-Society Task Force.
[†]If under 75 years.
[‡]A recommendation formulated in the absence of quality evidence, after a systematic review of the evidence was conducted and failed to identify admissible evidence on the clinical question.
[§]refers to '2–6 months in piecemeal excisions of LNPCP's' being based on strong evidence.
[¶]refers to 'where excision completeness cannot be determined in advanced polyps' being based on weak evidence.

Table 4 Definitions and recommendations for surveillance of advanced serrated lesions

	Terminology and criteria	Surveillance recommendations
USMSTF	Not defined: Sessile serrated polyp ≥ 10 mm or with dysplasia	3 years (weak recommendation, very low quality of evidence)
BSG	Advanced serrated polyp: Size ≥ 10 mm or any grade of dysplasia	3 years if ≥ 2 pre-malignant polyps including ≥ 1 advanced polyp or one LNPCP[†] (strong recommendation, low GRADE evidence)
CCA	Not defined: Various criteria	1 to 5 years[†]
ESGE	Patients requiring surveillance: Serrated polyp ≥ 10 mm or with dysplasia	3 years (strong recommendation, moderate GRADE evidence)
JGES	Not defined	—
Asia-Pacific Working Group	Not defined: Sessile serrated lesion > 10 mm or with cytological dysplasia	3 years (classification of recommendation B, quality of evidence III)

BSG, British Society of Gastroenterology; CCA, Cancer Council Australia; ESGE, European Society of Gastrointestinal Endoscopy; JGES, Japan Gastroenterological Endoscopy Society; USMSTF, US Multi-Society Task Force.
[†]Full details can be seen in Table S4.

Recommendations for surveillance. All guidelines recommended colonoscopy as the primary method of surveillance with the BSG and Australian guidelines accepting CT colonography as an alternative where colonoscopy was not appropriate. The USMSTF, CCA, ESGE, JGES, and Asia-Pacific Working Group recommendations all advised a standard surveillance timing of 3 years after the diagnosis and removal of an advanced colorectal polyp. Although surveillance at 3 years is still recommended, the BSG guidance differs as at least two polyps, with one meeting the requirements of an advanced polyp or a single LNPCP must be identified. A shorter surveillance interval of 12 months is recommended by the CCA for large sessile or laterally spreading lesions and JGES for lesions ≥ 20 mm.

For serrated lesions, the surveillance interval was 3 years for the USMSTF, BSG, ESGE, and Asia-Pacific Working Group. The JGES did not provide specific recommendations for serrated lesions. The CCA recommendations for serrated lesions were complex with intervals ranging from 1 to 3 years depending on lesion characteristics. A comprehensive overview of these is provided in Table S4.

Shorter surveillance intervals for piecemeal polyp removal in all guidelines were recommended for lesions meeting certain criteria. Similar to the ESGE recommendation of 3 to 6 months for piecemeal excisions of lesions greater than 20 mm, the USMTF also suggested a 6-month follow-up in polyps of this size. The BSG recommended that surveillance should be performed in 2 to 6 months where the excision completeness of advanced polyps cannot be determined or in piecemeal excisions of LNPCPs. The suggested interval by the CCA of 12 months for large sessile or laterally spreading lesions is reduced to 6 months in the case of piecemeal removal. The JGES state that a 6-month surveillance should be performed if any advanced adenomas are excised in a piecemeal nature. The Asia-Pacific Working Group did not provide specific recommendations for piecemeal excisions.

Most of the evidence regarding surveillance timings was assessed as low to moderate quality, but despite this, the recommendations were mostly strong for those using the GRADE system. In contrast, the JGES recommendations were classified as level 2 (weak). The CCA recommendations were consensus based, which means that admissible evidence on the clinical question was not found.

Factors at index colonoscopy guiding surveillance recommendations

Polyp factors. As all six guidelines based their surveillance recommendations predominantly on the polyp features at index

examination, they are already described in detail above in the terminology and criteria for advanced polyps, recommendations for surveillance, and in Table 3.

Patient factors. The consideration of patient factors at index examination in the recommendations of surveillance intervals was varied between the included guidelines. A summary is shown in Table 5. The American, Japanese, and Asia-Pacific Working Group guidelines did not document any patient factors at index examination to be used in influencing surveillance timings for advanced polyps. The BSG, ESGE, and CCA guidelines, which did identify such factors, recognized that this was based on limited evidence or opinion only.

The commonest patient factors considered were regarding the parameters where surveillance should not be performed. BSG guidance suggested that surveillance should only be performed in those with a life expectancy greater than 10 years and in general, not in those older than 75 years. The ESGE recommendations are similar suggesting stopping follow-up at the age of 80 years, or earlier if comorbidities are thought to limit life expectancy. These were both weak recommendations based on a low grade of evidence. The Australian guidelines are more complex. They promote the utilization of shared decision making in the elderly when considering surveillance. They advise the use of an objective method of assessing life expectancy such as the Charlson score.[30] With an age of 75 to 80 years and score of four or less, then surveillance should be considered, but not if greater than 4. Surveillance is not recommended in those over 80 years. The USMSTF or JGES guidelines did not provide recommendations for surveillance cessation. In addition, the BSG guidelines recommended balancing benefits of surveillance against its risk and cost to both patient and health services. They stated that this should be explained to patients as part of shared decision making regarding follow-up.

Colonoscopy quality factors. A summary of the factors considered by the guidelines regarding the quality of baseline colonoscopy is shown in Table 6. All guidelines recognized the importance of quality in index colonoscopy in the applicability of their surveillance recommendations with the USMSTF, BSG, CCA, and Asia-Pacific Working Group suggesting further research or benchmarking concerning this. The parameters required for quality colonoscopy were variable. The USMTF, CCA, and BSG all provided advice regarding completeness of examination with overall rates of $> 95\%$ and $> 90\%$ quoted for the USMSTF and CCA guidelines, respectively. The BSG stated that the individual colonoscopy should be complete to the caecum with an early repeat procedure if not, which is also advised in the case of poor bowel preparation. This advice is also given by the ESGE guidance. The USMSTF guidance advises overall adequate bowel preparation rates of $> 85\%$ to reliably detect lesions over 5 mm.

Both the CCA and USMSTF quote required adenoma detection rates (ADR) for colonoscopists performing the index examination. The USMSTF guidelines advise an ADR of $> 30\%$ and $> 20\%$ in men and women, respectively, but this rate is $> 25\%$ in the Australian document. No reference to ADR requirements were made in the remaining guidelines. The USMSTF, BSG, CCA, and ESGE documents agree that the colon should also be completely cleared of identified polyps. The JGES provide some background relating to quality indicators for colonoscopy, but without relation to their surveillance recommendations. They do suggest a withdrawal time of at least 6 min for baseline colonoscopy, which is mirrored in the CCA document. Accepted withdrawal times are not given in the other three guidelines.

The ESGE guidelines quote recommendations from their own organization and the World Endoscopy Organization (WEO) regarding quality requisites for baseline colonoscopy.[31,32] Consensus was reached in the WEO recommendations regarding completeness of examination, quality of bowel preparation, and completeness of polyp excision. The ESGE performance measures for lower gastrointestinal endoscopy included key performance measures of adequate bowel preparation rate ($\geq 90\%$), caecal intubation rate ($\geq 90\%$), and ADR of at least 25%.

Table 5 Patient factors at index colonoscopy

USMSTF	None described
BSG	1. The benefits and risks of surveillance should be explained to patients, who should be involved in shared decision-making. The risks and benefits of non-adherence to surveillance should also be explained. 2. The impact of surveillance in terms of CRC risk reduction should be balanced with the risks of harm (e.g., colonoscopy complications or psychological distress) and the costs to both the health service and patients. 3. Patients should be made aware of other evidence-based interventions that could reduce their risk of CRC and/or polyp recurrence. These could include lifestyle and behavioral modifications (e.g., stopping smoking and reducing red meat consumption) as well as medications (e.g., aspirin). 4. Age and life expectancy.
CCA	1. Patients with large sessile and laterally spreading lesions should be informed of the requirement for scheduled surveillance before proceeding to EMR (practice point). 2. Clinicians should advise patients that modification of lifestyle factors can reduce their risk of polyp recurrence (practice point).
ESGE	1. ESGE suggests that individuals with symptoms in the surveillance interval should be managed as clinically indicated (weak recommendation, low-quality evidence).
JGES	None described
Asia-Pacific Working Group	None described

BSG, British Society of Gastroenterology; CCA, Cancer Council Australia; ESGE, European Society of Gastrointestinal Endoscopy; JGES, Japan Gastroenterological Endoscopy Society; USMSTF, US Multi-Society Task Force.

Table 6 Quality factors of index colonoscopy

	Colonoscopy quality factors	Standard of evidence
USMSTF	High-quality colonoscopic examination: • Adequate bowel preparation rates > 85% (to reliably detect lesions > 5 mm) • Colonoscopists with adequate adenoma detection rate (ADR) of > 30% in men and > 20% in women • Completion rates to caecum > 95% • Attention to complete polyp excision • Parameters outlined above should be monitored as quality metrics in practice	Formal assessment of evidence not performed
BSG	Acceptable minimum quality colonoscopy: • At least adequate bowel preparation • Complete colonoscopy to the caecum • Clearance of all identified premalignant polyps • Early re-examination if bowel preparation is poor or colonoscopy incomplete	Low GRADE evidence for bowel preparation and completion of examination
CCA	High-quality colonoscopy: • Colonoscopists should maintain ADR > 25% (patients > 50 without diagnosis of inflammatory bowel disease) • Unadjusted rates for caecal intubation ≥ 90% • Withdrawal time of > 6 min (without polypectomy) • Colon has been cleared of all significant neoplasia • Colonoscopists should be certified, undergo regular recertification and have training to increase polyp detection rates	Practice point†
ESGE	High-quality colonoscopy based on ESGE and WEO guidance: • Repeat colonoscopy in 1 year if bowel preparation inadequate • Polyps completely removed	Strong recommendation, Moderate GRADE evidence
JGES	Withdrawal time of at least 6 min (if no lesions)	Strength of recommendation 2, evidence level C
Asia-Pacific Working Group	Quality control of colonoscopy is mandatory for colorectal cancer screening programs and benchmarks should be determined	Classification of recommendation A, quality of evidence II-2

BSG, British Society of Gastroenterology; CCA, Cancer Council Australia; ESGE, European Society of Gastrointestinal Endoscopy; JGES, Japan Gastroenterological Endoscopy Society; USMSTF, US Multi-Society Task Force; WEO, World Endoscopy Organization.
†A recommendation on a subject that is outside the scope of the search strategy for the systematic review, based on expert opinion and formulated by a consensus process.

The assessment of evidence regarding colonoscopy quality varied between the guidance. For the USMSTF, a formal assessment of evidence was not performed, and the BSG assessed the evidence as low regarding bowel preparation and completion of examination. As the ESGE statements were based on preceding review documents, they gave strong recommendations regarding this as based on a moderate level of evidence. The CCA's statements regarding colonoscopy quality were given as practice points, which are based on expert opinion and consensus only. The JGES was similar in assessing the level of evidence as weak. The USMSTF, BSG, and CCA all recognized the importance of understanding colonoscopy quality factors through research in the improvement of surveillance recommendations. This included the effect of incomplete examination, poor bowel preparation, incomplete polyp removal, and ADRs.

Assessment of guideline quality. The AGREE II instrument was used to assess the quality of the guidelines by two reviewers. An overview of the scores is shown in Table 7. The BSG and CCA guidelines were rated as high quality with a scaled domain score of over 60% in all categories. The remaining guidelines were all rated as of average quality with scores less than 60% for all these guidelines in the stakeholder development and applicability domains. These low scores were explained in all guidelines by an absence in involvement of patient or public representatives in the stakeholder development domain. There were also low scores for resource implications of the recommendations and monitoring or auditing criteria in the applicability domains. Both reviewers felt that all guidelines could be recommended for use despite the limitations in some areas of guideline quality.

Discussion

This review demonstrates that international surveillance guidelines for advanced colorectal polyps are of good quality but limited by their underlying evidence. The consistency in recommendations regarding surveillance timings is reassuring, but the terminology

Table 7 AGREE II scaled domain scores

	Domain 1 Scope and purpose	Domain 2 Stakeholder involvement	Domain 3 Rigor of development	Domain 4 Clarity of presentation	Domain 5 Applicability	Domain 6 Editorial independence	Overall quality
USMSTF	97.2%	52.8%	74.0%	96.4%	29.2%	95.8%	Average
BSG	100%	97.2%	96.9%	100%	95.8%	91.7%	High
CCA	97.2%	94.4%	99%	97.2%	97.9%	100%	High
ESGE	97.2%	58.3%	75.0%	96.4%	31.3%	95.8%	Average
JGES	83.3%	50%	77.1%	88.9%	45.8%	91.7%	Average
Asia-Pacific Working Group	97.2%	41.7%	67.7%	88.9%	20.8%	91.7%	Average

Scaled domain scores were calculated using the formula: (obtained score − minimum possible score)/(maximum possible score − minimum possible score) × 100.

BSG, British Society of Gastroenterology; CCA, Cancer Council Australia; ESGE, European Society of Gastrointestinal Endoscopy; JGES, Japan Gastroenterological Endoscopy Society; USMSTF, US Multi-Society Task Force.

and criteria used for advanced polyps was variable. The emphasis on polyp factors as the key determinant for when surveillance should be performed was the same among all guidelines. Given the increasing detection of advanced polyps and a significant number of surveillance examinations in screening being inappropriate,[33] improvement of the evidence base and guidance implementation is warranted.

The authors feel that the limited application of evidence regarding the influence of patient characteristics and the quality of baseline colonoscopy should be addressed as a significant area for improvement. The principles of informed choice and shared decision making with patients should be applied when offering surveillance and be accounted for in recommendations. Three of the included guidelines discussed patient factors regarding surveillance timings but only the BSG and CCA involved representatives in their development process. Recommendations for when surveillance should not be performed were variable in the three documents discussing it, reflecting the low quality of underlying evidence. The USMSTF and BSG both acknowledge that further evidence is required for surveillance at the extremes of age with research concerning comorbidities also recommended by the USMSTF. The BSG stated the need to develop evidence in personalized surveillance algorithms, patient experience, preferences, and compliance. The research gap regarding patient opinion and experience of endoscopy is significant[34] with knowledge in this field potentially having significant effects on future recommendations provided. Individual patient assessment in terms of age, comorbidities, and life expectancy should also be standardized. Based on the above, a proportion of patients will not develop clinically significant new or recurrent disease and should not be exposed to the risks of further examinations. This could economize surveillance further but must be evidence based.

The quality of baseline colonoscopy may be the keystone to economizing surveillance recommendations. If the risk of missed lesions is negligible after a high-quality colonoscopy and complete polyp removal, the need for further examination may be considerably reduced or not required at all. By not identifying lesions, low-quality examinations may also underestimate the surveillance required. All guidelines recognized the importance of this but differed in their criteria for quality examination. Parameters such as ADR, completion rate, satisfactory bowel preparation, and withdrawal time were not standard between the guidelines, and their applicability will vary depending on whether performed in a screening or symptomatic cohort. The association between ADR and risk of subsequent cancer or advanced adenomas has been reported.[8,9,35] Efforts improving colonoscopy quality standards and key performance indicators may be challenging and have considerable effects on surveillance resources. It should be noted that quality indicators for colonoscopy may also be provided through separate guidelines such as those provided by the Joint Advisory Group on Gastrointestinal Endoscopy (JAG) in the UK. The implementation and assurance of these are crucial with accountability needed to maintain quality both in screening and symptomatic services. This has been the focus of a recent American Gastroenterological Association review on strategies to improve quality of screening and surveillance colonoscopy.[36] This provides standards and highlights the importance of measuring, tracking and providing feedback of colonoscopist specific quality measures including caecal intubation rate (≥ 90%), withdrawal time (≥ 6 min), ADR (≥ 30%), and serrated lesion detection rate (≥ 7%).

A recent narrative review comparing surveillance recommendations of the USMTF, ESGE, and BSG guidance for all colorectal polyps has been performed.[37] This identified variability in surveillance recommendations for certain lesions but like our findings found intervals specific for advanced lesions to be consistent. A challenge of these reviews has been the synthesis and comparison of guidelines due to inconsistent polyp terminology and classifications. The JGES and USMSTF guidelines and the CCA and Asia-Pacific Working Group were the only ones using the same term of advanced adenoma and high-risk adenoma respectively. The subclassification of larger polyps (≥ 20 mm) was only performed by the BSG and CCA and inclusion of advanced serrated polyps, multiple lesions, or villous features in advanced polyp definitions was different between all guidelines. This may result in challenges with interpretation and application to research and clinical practice. Gaps in knowledge of surveillance recommendations have been identified as a reason for non-compliance,[38,39] and the variability and complexity of definitions may explain this. Provisions to make recommendations user friendly should be implemented, and feedback regarding the ease of guideline use may be beneficial.

All guidelines were assessed as being average to high quality based on the AGREE II instrument. Limitations identified included the involvement of patient representatives, guideline implementation, and variation in evidence assessment. Given the paucity of evidence on patient experience in surveillance, all guidelines should mandate the involvement of patient representatives during their development. Guidance on implementation and adherence is also crucial. A systematic review identified that international adherence to surveillance guidelines was remarkably low with over 50% of patients not receiving surveillance at an appropriate time.[40] Implementation advice produced by guidelines may help this. The variability in the assessment of evidence by different guidelines also highlights potential inconsistencies in interpretation of data or impact of different rating systems. A standard instrument such as the GRADE system, which is an international applicable and endorsed method, may be beneficial.

Limitations of this study included the review of only the most current international guidelines. Others may have been inappropriately excluded on the assumption that there were no longer widely utilized. Given that the guidelines included covered a wide geographical area, we believe our review should be representative. Our review did not cover the recommendations for serrated or multiple lesions in detail, but these have been assessed recently elsewhere.[37] The focus on advanced lesions was due to complexities of their management and higher risk of recurrent disease. It also provides a more detailed insight into the factors considered in the recommended timings to identify areas where improvement or future research is needed.

International surveillance guidelines for advanced colorectal polyps can be recommended for use. All had merits and can be safely utilized given consistency in recommended surveillance timings. Overall, we would recommend the use of the BSG guidance given the high quality of methodology, ease of use, and patient involvement during development. Standardization in definitions would be valuable and potentially improve understanding and adherence by users. Better knowledge of patient experience and clinical factors in the identification of those who will never come to harm by future pathology is of great importance. Research into colonoscopist-specific quality indicators is also highly recommended to further economize surveillance recommendations, minimize patient risk, and reduce pressure on services and resources.

Data availability statement. Data available on request to the lead (J. P.) and senior author (S. D.).

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Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1. Other sources searched.
Table S2. Full search strategy.
Table S3. Classification of excluded articles.
Table S4. CCA guidance for surveillance intervals of sessile and traditional serrated adenomas.

Appendix 20 – Registered protocols

NIHR | National Institute for Health Research

PROSPERO
International prospective register of systematic reviews

A systematic review of the impact of decision making strategies on the treatment outcomes of complex colonic polyps

Citation

Jody Parker, Sunnia Gupta, Sunil Dolwani. A systematic review of the impact of decision making strategies on the treatment outcomes of complex colonic polyps. PROSPERO 2020 CRD42020157614 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42020157614

Review question [1 change]

What is the variation in decision making strategies concerning the management of complex colonic polyps, and how does this impact on patient's treatment outcomes?

Searches [1 change]

A comprehensive search with defined terms will be performed to identify all potential articles concerning complex polyp management.

The databases to be searched will include PubMed, MEDLINE via Ovid, Web of Science, CINAHL and Scopus.

Review articles and guidelines identified by the searches and based on systematic literature reviews will also be cross-referenced for missed articles of relevance to the study.

No individual journals or country of publication will be excluded.

All articles will be initially considered regardless of the year of publication or language.

Experts in the field will be approached for suggested articles that may contribute to the review.

Additional search strategy information can be found in the attached PDF document (link provided below).

Types of study to be included [1 change]

Given the nature of the review and knowledge of the subject, the studies included will be case control and cohort studies. We are not aware of any randomised control trials (RCT'S) in this area.

Condition or domain being studied [1 change]

The detection and recognition of complex colonic polyps has increased since the introduction of Bowel Screening Programmes.

A proportion of these will progress to cancer if left untreated and management strategies range from active monitoring to bowel resection.

Decision making requires consideration of patient and polyp characteristics, the individual's wishes and available

expertise to balance optimum management and avoid unnecessary risk.

There is significant variability in the management of complex polyps often resulting in suboptimal patient outcomes.

As there is no international consensus on definition, the following terms or descriptions based on current literature and guidance will be accepted as 'complex polyps' for this review and are inclusive for the remainder of the document:

• Polyps described as 'difficult', 'laterally spreading', 'advanced', 'large' or 'refractory';

• Non pedunculated polyps larger than 2cm;

• Polyps assessed to be in a difficult location by the operator;

• Polyps with a Site Morphology Site Access (SMSA) level of III or IV;

• Polyps defined as having an increased risk of a) malignancy b) incomplete resection or c) adverse events.

Participants/population [1 change]

Inclusion criteria:

Published studies describing outcomes after any mode of treatment for patients with complex colonic polyps will be considered. Internationally accepted guidelines advise that pre intervention decision making should incorporate detailed polyp assessment and involve individuals with expertise in this field. The use of objective selection criteria and shared decision making may improve outcomes. Based on this, the articles chosen for full analysis will be those describing both of the following in their methodology or results:

• Pre intervention selection strategies or criteria used for choosing the management option of complex colonic polyps;

And

• The responsible clinician(s) making the decision.

Exclusion criteria:

• Papers not concerning the treatment outcomes of complex colonic polyps;

• Malignant polyps;

• Rectal polyps;

• Paediatric patients;

• Polyposis syndromes or inflammatory bowel disease patients;

• Posters, presentations, case reports, editorials or narrative reviews.

Intervention(s), exposure(s) [1 change]

All modes of treatment for complex polyps will be considered.

Treatment modalities included will be active monitoring, endoscopic (such as polypectomy, endoscopic mucosal resection or submucosal dissection), surgical (open or laparoscopic) and combined procedures.

Treatment modalities not to be included are feasibility studies or novel techniques with only observational, pilot or preliminary data.

Comparator(s)/control [1 change]

The review will assess the differences in outcomes between two categories.

Comparison 1:

Data will be extracted from the studies regarding the nature of selection strategies used. This will be categorised into the use of objective and quantifiable criteria (such as size, location or morphology) or subjective criteria (such as individual opinion).

Comparisons of treatment outcomes will be performed across the two groups.

Comparison 2:

Information regarding the clinician(s) making the decision will be compared. This will be categorised into either a single decision maker or shared/multiple decision makers.

Comparisons of treatment outcomes will be performed across these two groups.

Context [1 change]

Inclusion criteria:

There is no international consensus on the definition of a complex polyp. Size alone (usually 20mm or more) is often used but other definitions utilise location, polyps with an increased risk of malignancy or scoring systems. The descriptions in section 18 reflect terms used currently in guidelines and literature and will be used to identify suitable articles. As complex polyps are treated globally, all countries and languages will be considered.

Treatment options for complex polyps vary and decisions regarding the most appropriate must consider many factors. All established treatment options will be assessed unless the technique is novel, emerging or part of a feasibility study.

Exclusion criteria:

Studies not involving a defined complex polyp population will be excluded. Malignant and rectal polyps are also excluded as the decision making regarding these have separate considerations. Malignancy carries the risk of nodal or metastatic disease requiring full assessment prior to management. Rectal lesions have a wider range of treatment options and there are the implications of a temporary or permanent stoma if treated operatively.

Paediatric patients and those with polyposis syndromes or inflammatory bowel disease will also be excluded. The wider considerations of their underlying condition will impact decision making for complex polyp management. Excluded publications types include posters or presentations, case reports and editorials due to the unavailability of a full text article, unique nature of publication and individual opinion respectively. Narrative reviews shall be excluded as the articles used in these will likely be captured by the systematic review cross referencing.

Main outcome(s) [1 change]

Outcome 1 - A description of the variability in decision making strategies used by the studies:

• Were the selection strategies or criteria used by the studies objective and quantifiable or subjective?

• If objective, what criteria was used (size, location, morphology etc)?

• Were guidelines or complex polyp definitions used by the studies?

• Was a single or shared decision makers involved?

• What was the expertise of the involved decision makers?

• Was there documented use of a multi-disciplinary team?

Outcome 2 - Assessment of the impact of decision making strategies on patient's treatment outcomes:

• Differences in treatment outcomes of studies with objective and quantifiable vs. subjective selection criteria;

• Differences in treatment outcomes of studies with single vs. shared decision making

Measures of effect

Not applicable.

Additional outcome(s) [1 change]

None.

Measures of effect

Not applicable.

Data extraction (selection and coding) [1 change]

Identification of articles:

Databases will be searched and articles downloaded into EndNote to identify duplicates. Abstracts will be exported to the Rayyan Systematic Review Web Application. Two independent, blinded researchers will screen abstracts against the inclusion and exclusion criteria. The researchers will resolve decision conflicts at this stage and finalise the articles for full text review. Unresolved conflicts at any stage will be referred to the senior researcher for resolution

Full text articles will be assessed by the same blinded reviewers and managed on separate EndNote files. Those describing both parameters in the inclusion criteria will be selected for data extraction. The articles describing only one criteria will be included in the PRISMA flowchart. Decision conflicts will be resolved and the final articles confirmed.

Review articles or guidelines identified and based on a systematic literature review will be hand searched for additional articles. Articles identified will undergo the same process as described above.

Data extraction:

This will be performed by two independent, blinded researchers onto pre-defined Excel Spreadsheets managed on a Cardiff University networked computer. Variations in data extraction will be resolved as previously described. The data to be extracted is outlined below.

Domain 1 - Study characteristics:

• Authors, title, journal and date of publication;

• Country, type and number of centres involved;

• Study design;

• Patient and polyp demographics;

• Treatments.

Domain 2 - Decision making strategies (selection criteria):

• Objective or subjective selection criteria used;

• Nature and parameters of selection criteria;

• Guidelines used for selection criteria;

• Definition of complex polyp used.

Domain 3 - Decision making strategies (responsible clinicians):

• Number of clinicians making the decision;

• Speciality of the responsible clinician;

• Use of a multi-disciplinary team meeting.

Domain 4 - Treatment outcomes:

• Complication rates;

• Length of hospital stay;

• Surgical referral rate;

• Need for re intervention;

• Number of polyps found to be malignant;

• Recurrence/residual disease rate;

• Functional outcomes.

Risk of bias (quality) assessment [1 change]

The review will involve cohort or case control studies. The quality of included studies will be assessed by the Newcastle-Ottawa Scale independently at a study level by two researchers. It is unlikely RCT's will be included in the final analysis

due to the known paucity in this field and decision making in the study design being overruled by the randomisation process. If RCT's are included, a suitable tool will be applied. An overview of study quality will be outlined, but all articles will be included regardless of score. Discrepancies will be resolved as previously described. Other potential sources of bias are outlined below.

Paper selection and data extraction bias:

This will be minimised by using two independent, blinded researchers using defined inclusion criteria, exclusion criteria and data extraction proformas. Expertise in systematic reviews through Cardiff University have been used in developing the protocol and search terms.

Absence of decision making:

The absence of a description of decision making processes in a centre which has defined strategies may occur. If absent, this data will not be requested as inaccuracies may occur due to recall bias or process changes.

Language bias:

The inclusion of non English articles may be limited by the feasibility of translation.

Strategy for data synthesis [1 change]

Data analysis will be performed by one researcher and cross checked by a second. Microsoft Excel and SPSS will be used for the statistical analysis. A P value of <0.05 will be accepted as significant for any statistical tests applied. The following describes how the collected data will be synthesised and reported.

Study characteristics:

A narrative description of the studies characteristics, patient demographics, polyp characteristics and treatments will be performed. This will be summarised in tabular form.

Decision making strategy (selection criteria):

A narrative description of the variation in selection criteria will be performed. The proportion of studies using subjective and objective strategies will be assessed. For those studies using objective criteria, the nature and parameters of these will be described and summarised. If studies have used guidelines as part of their selection criteria or stated a complex polyp definition, this will also be included.

Decision making strategy (responsible clinicians):

The proportion of studies using single or shared decision makers will be documented and the speciality of those involved will be summarised. The number of studies involving a multi-disciplinary team meeting in their decision making process will be reported.

Treatment outcomes:

A summary of the outcomes reported by each study will be reported in tabular form.

Comparison of data:

Outcomes of studies will be compared across two groups. These will include those reporting objective vs subjective selection criteria and those with single vs shared decision making. An unpaired T test will be used to identify any significant differences between the studies based on the decision making strategies described.

Analysis of subgroups or subsets [1 change]

Depending on the studies extracted for full review, a subgroup of patients with caecal or peri appendiceal lesions may be analysed. We expect these to be included in the main dataset under size, location or difficult access criteria. These lesions are often more challenging to treat endoscopically due to their location. As a result, there may be a higher surgery rate which may adversely effect outcomes. The analysis used will be the same as previously described.

Contact details for further information

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Organisational affiliation of the review [1 change]

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Review team members and their organisational affiliations [1 change]

Ms Jody Parker. Division of Population Medicine, Cardiff University

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Dr Sunil Dolwani. Division of Population Medicine, Cardiff University

Collaborators [1 change]

Mr Jared Torkington. Department of Colorectal Surgery, Cardiff and Vale University Health Board

Mike Davies. Department of Colorectal Surgery, Cardiff and Vale University Health Board

Type and method of review

Intervention, Methodology, Systematic review

Anticipated or actual start date [1 change]

01 May 2020

Anticipated completion date [1 change]

31 December 2020

Funding sources/sponsors

The Research Fellowship for Jody Parker is funded by the Royal College of Surgeons of England

Conflicts of interest

Language

English

Country

Wales

Stage of review [2 changes]

Review Completed published

Details of final report/publication(s) or preprints if available [1 change]

https://PubMed.ncbi.nlm.nih.gov/34473891/

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Adult; Clinical Decision-Making; Colon; Colonic Polyps; Decision Making; Humans; Medical History Taking; Patient Care; Therapeutics; Treatment Outcome

Date of registration in PROSPERO

03 June 2020

Date of first submission

07 November 2019

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Versions

03 June 2020

10 March 2021

10 September 2021

A systematic review of the surveillance recommendations and evidence base of international guidelines for advanced colorectal polyps

Citation

Jody Parker, Sunnia Gupta, Jared Torkington, Sunil Dolwani. A systematic review of the surveillance recommendations and evidence base of international guidelines for advanced colorectal polyps. PROSPERO 2021 CRD42021189026
Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021189026

Review question

What is the variability in definition and surveillance recommendations for advanced colorectal polyps and what is the scope and quality of evidence on which this is based?

Searches

- A comprehensive literature search will be performed to identify all potential guidelines.

- Databases searched will include PubMed, MEDLINE via Ovid, Web of Science, Scopus and Trip Pro.

- Identified guidelines and articles referencing guidelines in their abstract will be cross-referenced.

- No individual journals or country of publication will be excluded.

- All articles will be initially considered regardless of the year of publication or language.

- Experts in the field will be approached for suggested articles that may contribute to the review.

PubMed search strategy:

(((((recommendation) AND Abstract OR Guideline)) AND Abstract AND surveillance)) AND Abstract AND ((((polypectomy) AND Abstract OR adenoma) AND Abstract OR colorectal neoplasm) AND Abstract OR polyp) AND Abstract

Types of study to be included

Inclusion criteria:

Evidence based national or international guidelines describing surveillance recommendations after the diagnosis of benign colorectal polyps in adults will be considered. Those guidelines with specific recommendations regarding advanced polyps (or an equivalent definition) will be included for full text review. Guidelines will be deemed appropriate if exclusively describing advanced polyp surveillance or if the subject is part of a defined section in wider recommendations. If multiple guidelines are produced by the same group, the most recent will be used for analysis. No journals or countries of publication will be excluded. All articles will be initially considered regardless of the year of publication or language.

Exclusion criteria:

Local or departmental guidelines will be excluded from the review. Guidance only for malignant or hereditary polyps will also be excluded due the specific considerations required for their management and follow up. All articles will be considered regardless of publication language but excluded later if translation is not feasible. Those guidelines published in draft form or as conference papers will not be included due to the lack of peer review and unavailability of the full guideline respectively.

Condition or domain being studied

The aim of surveillance of patients diagnosed with colorectal polyps is to detect new or recurrent disease at an early, treatable stage. The appropriate timing of this will depend on the characteristics of the polyp and the method used for its removal. Patient factors may also be considered in the ongoing appropriateness of surveillance.

Colonoscopy and associated therapy carry risks of bleeding and perforation in addition to discomfort and inconvenience of the test. The overuse of surveillance can create a burden for both the patient and health service. Appropriate surveillance intervals should balance the timely need for diagnosis against the risks of colonoscopy.

Advanced colorectal polyps pose additional challenges in management and follow up and their detection has increased with the introduction of screening. With this increasing burden, evidence-based recommendations regarding their classification, management and follow up are required to ensure good quality of care.

Guidelines are decision making tools that help clinicians to provide evidence-based treatment for their patients. Several countries have recently published updated versions of their polyp surveillance guidelines with specific recommendations for advanced polyps.

Participants/population

Adults following a diagnosis of benign colorectal polyps.

Intervention(s), exposure(s)

Inclusion criteria:

Evidence based national or international guidelines describing surveillance recommendations after the diagnosis of benign colorectal polyps in adults will be considered. Those guidelines with specific recommendations regarding advanced polyps (or an equivalent definition) will be included for full text review. Guidelines will be deemed appropriate if exclusively describing advanced polyp surveillance or if the subject is part of a defined section in wider recommendations. If multiple guidelines are produced by the same group, the most recent will be used for analysis. No journals or countries of publication will be excluded. All articles will be initially considered regardless of the year of publication or language.

Exclusion criteria:

Local or departmental guidelines will be excluded from the review. Guidance only for malignant or hereditary polyps will also be excluded due the specific considerations required for their management and follow up. All articles will be considered regardless of publication language but excluded later if translation is not feasible. Those guidelines published in draft form or as conference papers will not be included due to the lack of peer review and unavailability of the full guideline respectively.

Comparator(s)/control

A narrative description and comparison of the variability in advanced polyp terminology, definitions, recommendations

for surveillance, level of evidence used and strength of recommendations across the guidelines will be performed and summarised.

Guidelines will be assessed and compared for the factors and evidence considered in making their recommendations across the following groups:

Polyp factors - Such as size, morphology and histology;

Patient factors - Such as age, comorbidities and patient wishes;

Operator factors - Such as quality of endoscopy, adequacy of resection.

Context

The development of early bowel cancer detection and screening has resulted in the development of surveillance strategies. Most developed countries have now published their own surveillance recommendations which provides the overriding basis for service provision across the country. Local guidelines are therefore unlikely to be available or of no relevance. Malignant or hereditary polyps have their own management considerations due to the wider implications of their condition and will not be included as part of this review.

Main outcome(s)

Outcome 1 - What is the variability in definition of advanced polyp across the guidelines?

Outcome 2 - What is the variability in recommended timing intervals for surveillance for advanced polyps across the guidelines?

Outcome 3 - What polyp, patient and operator factors are considered in making these recommendations and what is the quality of evidence on which this is based?

Measures of effect

Not applicable.

Additional outcome(s)

None.

Measures of effect

Not applicable.

Data extraction (selection and coding)

Identification of articles:

Databases will be searched with the previously described terms and downloaded into EndNote to identify duplicates. Abstracts will then be exported to the Rayyan Systematic Review Web Application. Two independent, blinded researchers will screen abstracts using the described inclusion and exclusion criteria. The researchers will meet to resolve decision conflicts at this stage and to finalise the guidelines for full text review. Conflicts at any stage will be referred to the senior researcher for resolution.

Full text guidelines will then be assessed by the same blinded reviewers. This will be managed on separate EndNote files and reasons for exclusion classified. Decision conflicts will be resolved at this stage and the final articles confirmed. Any supplementary material for the included guidelines will also be obtained. The identified guidelines will be hand searched for additional articles in their references and the abstracts identified reviewed as above for inclusion or exclusion.

Data extraction:

Data extraction will be performed by the same two independent, blinded researchers onto separate, standardised Excel Spreadsheets. Variations will be resolved as previously described. The following information will be extracted.

Guideline characteristics:

- Title and authors

- Year of publication

- Country of publication

- Publishing organisation

- Main focus of the guideline

- New or updated guideline

- Method of guideline development

- Sources of funding

Definitions:

- The terminology and definition used for advanced polyps by the guideline and the parameters

Recommendations for complex polyp surveillance:

- The recommended timing intervals for surveillance

- The recommended surveillance method

- The patient, polyp and operator factors to consider when recommending surveillance

- The recommended parameters for cessation of surveillance

- The level of evidence for the above recommendations

- The strength of the above recommendations.

Risk of bias (quality) assessment

Guidelines will be scored against the AGREE II criteria to assess quality by two reviewers. Both reviewers will complete the tutorials on the use of the instrument and utilised the handbook during the assessments. Each guideline will be assigned a total score and a score for each domain by each researcher allowing percentages to be calculated. Guidelines will be included regardless of score.

Comparisons of the AGREE II assessments and scores across the domains will be made between the guidelines. Recommendations on use of the guidelines based on the AGREE II instrument will be classified into strongly recommended (total score of over 60%), recommended with modifications (30-60%) and not recommended (less than 30%). A similar system has been used by other guideline reviews.

Strategy for data synthesis

Data analysis will be performed by one researcher and cross-checked by a second.

Microsoft Excel will used for the statistical analysis.

Most of the synthesis will be narrative and summarised in tabular form.

Analysis of subgroups or subsets

None planned.

Contact details for further information

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Dr Sunil Dolwani. Cardiff University

Type and method of review

Diagnostic, Service delivery, Systematic review

Anticipated or actual start date

31 March 2020

Anticipated completion date

31 October 2021

Funding sources/sponsors

J Parker's Research Fellowship is funded through the Royal College of Surgeons of England

Conflicts of interest

Language

English

Country

Wales

Stage of review

Review Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Adult; Aftercare; Colonic Polyps; Delivery of Health Care; Diagnostic Screening Programs; Early Diagnosis; Guidelines as Topic; Humans; Intestinal Polyposis; Practice Guidelines as Topic

Date of registration in PROSPERO

10 March 2021

Date of first submission

10 March 2021

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

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Versions

10 March 2021