



Surgery is the Standard of Care for Early Rectal Cancer

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‘When I use a word’, Humpty Dumpty said in a rather scornful tone, ‘it means just what I choose it to mean – neither more nor less’. Lewis Carrol, *Through the Looking Glass*, 1934.

Unfortunately, the term ‘early rectal cancer’ has been taken to describe various stages of rectal cancer with no uniformity as to its meaning. Although most pathologists and clinicians use the Tumour Node Metastasis (TNM) system of cancer staging [1], the term ‘early rectal cancer’ may include tumours that are T1,N0 or T1-2,N0 or T1-3,N0. This makes it difficult to compare outcomes from different series. Furthermore, the TNM classification system is updated repeatedly [2] and, hence, current and historical reports may include different tumour stages under the same category.

Therefore, the importance of pre-treatment staging cannot be overemphasised. This is important both for informing individual patients of their likely prognosis, but also for allowing comparison between the outcomes of different treatment approaches. Pre-treatment investigation and staging is a multidisciplinary process whereby radiology, pathology, gastroenterology and surgery may all contribute to the decision making.

Pre-treatment investigation of early rectal cancer includes clinical examination, radiological investigation and pathological assessment. The latter is intended to confirm the diagnosis of adenocarcinoma and confirm any adverse features. These include poor differentiation, lymphovascular or perineural invasion, mucinous component, tumour ulceration and tumour budding [3–10]. Although it is now more common for pathologists to report at least a minimum dataset for all cancers, there are geographical and historical variations in the domains and degree of detail reported. Therefore, it is very difficult to assess and compare different case series or clinical trials reported in the literature, as

outcomes may be related to the types of cancer selected rather than the treatment applied.

Likewise for radiological staging, where both the modalities of investigation and the detail provided in reports vary significantly. It is recommended that all patients with early rectal cancer undergo computed tomography of the thorax, abdomen and pelvis, together with magnetic resonance imaging of the rectum and an endorectal ultrasound scan [11]. Although high-quality computed tomography scanning is available in most centres in the developed world, magnetic resonance imaging quality may vary due to differences in both the equipment and the scan protocols, while endorectal ultrasound is operator dependent.

The quality of the evidence on which to decide on the merits of different treatment approaches for early rectal cancer is therefore variable, due to differing approaches to the investigation of these cases and the interpretation of both histology and radiology results. Furthermore, there is selective reporting of case series, with a bias towards reporting of specific techniques by enthusiasts with no control group. Inclusion and exclusion criteria are set by individual authors and there is no standardisation of case selection. Very few clinical trials have been reported, and these are limited by difficulties in ascertaining that cases are indeed comparable.

Traditionally, surgery, involving resection of the rectum, has been considered the standard of care for early rectal cancer. Standard of care is a phrase that carries legal and professional connotations. The medical definition of standard of care is ‘a diagnostic and treatment process that a clinician should follow for a certain type of patient, illness or clinical circumstance’ [12]. The legal definition of standard of care is ‘what a minimally competent physician in the same field would do in the same situation, with the same resources’ [13]. It should be noted that standard of care is not the same as absolute perfection, and indeed the accepted standard of care will change over time.

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The current standard of care for rectal cancer is resection of the rectum, with restoration of continuity by anterior resection, or abdominoperineal resection (APR) with permanent colostomy, depending on the location of the tumour and the integrity of the patient's sphincters. There is a wealth of historical evidence in favour of the benefits of surgery, which form the standard against which newer treatments, of which there have been many in recent decades, can be assessed. APR of the rectum was popularised by Ernest Miles [14] over 100 years ago and it is an operation that has stood the test of time. Henri Hartmann described his eponymous operation in 1921 [15]. The anterior approach for this procedure was enabled by concurrent developments in anaesthesia and the absence of an anastomosis ensured that there was no risk of anastomotic leakage and the devastation that this complication can cause. In 1948, Claude Dixon [16] described restorative anterior resection with anastomosis, which has become the standard procedure for most rectal cancers worldwide today. In the 1980s, the British surgeon Professor Bill Heald reported a consecutive series of rectal cancer cases with a remarkably low local recurrence rate [17–19] and he advocated and popularised the technique of total mesorectal excision. His efforts have transformed the quality of rectal cancer surgery in many parts of the world over the last three decades.

The quality of resectional surgery, and therefore the standard against which other treatment modalities are compared, is measured by mortality rates (operative mortality and 5-year survival), positive circumferential resection margin (CRM) rates, local recurrence rates and morbidity. Table 1 shows the historic mortality and local recurrence rates for the series mentioned in above paragraph. The way in which individual authors report their outcomes varies such that there is no standardised dataset of reported outcomes. Even today, when the importance of being able to compare outcomes is recognised, many authors report survival at differing time points or use differing end points, such as disease-specific survival and progression-free survival or exclude significant proportions of patients, rather than overall survival of all the original patients.

Although resectional surgery has been accepted as the standard of care for a least the last 40 years, there has been debate as to whether anterior resection or APR is more appropriate for cancers in the lower rectum. Although standards of surgery and surgical care have gradually improved over many years, there was, and remains, a discrepancy in outcomes between the two techniques.

Mortality rates for resectional surgery vary in different reports but, in general, operative mortality is reported at 0–6.5%, with a 5-year survival rate of about 80% overall. The positive CRM rates vary significantly between the two techniques, such that anterior resection should yield a positive CRM of <5%, whereas APR is associated with a positive CRM of about 8–10%. This translates into local recurrence rates of 5–8% for anterior resection and about 10% for APR in good centres. Whether these differences are due to the differing nature of those tumours that require APR, intrinsic issues with the nature of the surgery or due to poorer surgical technique remains controversial and beyond the scope of this presentation. However, the fact remains that both of these operations carry a significant morbidity and mortality risk and therefore it is reasonable to explore alternative treatments for early rectal cancer that might achieve equivalent cure rates but with lesser morbidity.

One of the problems with determining whether resectional surgery, or indeed any other form of treatment, should be considered 'standard of care' is the fact that outcomes vary widely. The literature has multiple reports of the outcome of particular case series and clinical trials, which confirm that there remains significant variation between different centres. Figure 1 shows the range of 5-year survival rates after anterior resection or APR of the rectum, taken from large series in the English literature over the last 20 years.

Allowing for the fact that these series represent heterogeneous groups of patients and some of the operations reported as anterior resections may have been done for tumours at or above the recto-sigmoid junction, it is evident that there is still widespread variation in 5-year survival for both procedures. Whether this is due to variation in the standard of surgery or to differences in the use of adjuvant therapies is a matter of research and debate.

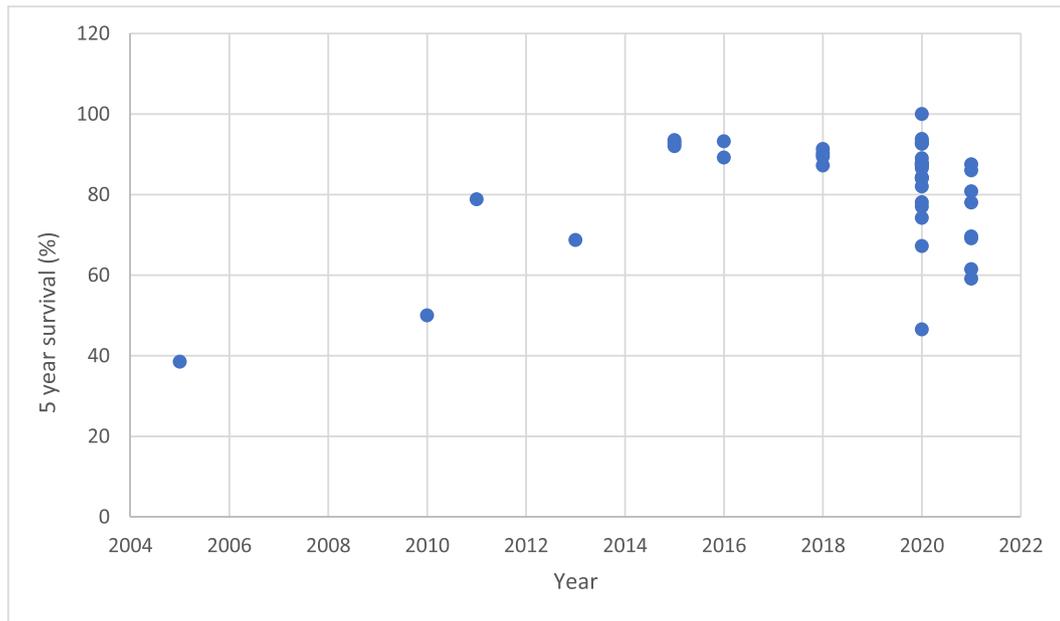
With respect to outcome measures that may be more closely aligned to quality of surgery, Figures 2 and 3 show that positive CRM rates and local recurrence rates vary widely, both between the two operations and among different centres. The reasons for this are multifactorial and may in part relate to differing tumour characteristics. However, it is evident that APR is associated with a generally higher rate of CRM positivity and local recurrence in many series. Whether these problems would be relevant to tumours classified as 'early rectal cancers' is a matter for debate, as the CRM should not be threatened in such cases. However, positive CRM is taken as a marker of surgical quality, together with lymph node harvest and specimen

Table 1
Outcome results for historic rectal cancer series

Year	Surgeon	Operation	Survival	Local recurrence	Reference
1907	Miles	APR	58% 1 year	30%	[14]
1910	Balfour	Anterior resection	64%	20.8%	[20]
1948	Dixon	Anterior resection	64% 5 years	~20%	[16]
1978–1997	Heald	TME	80% 5 years	4%	[17–19]

APR, abdominoperineal resection of rectum; TME, total mesorectal excision.

A



B

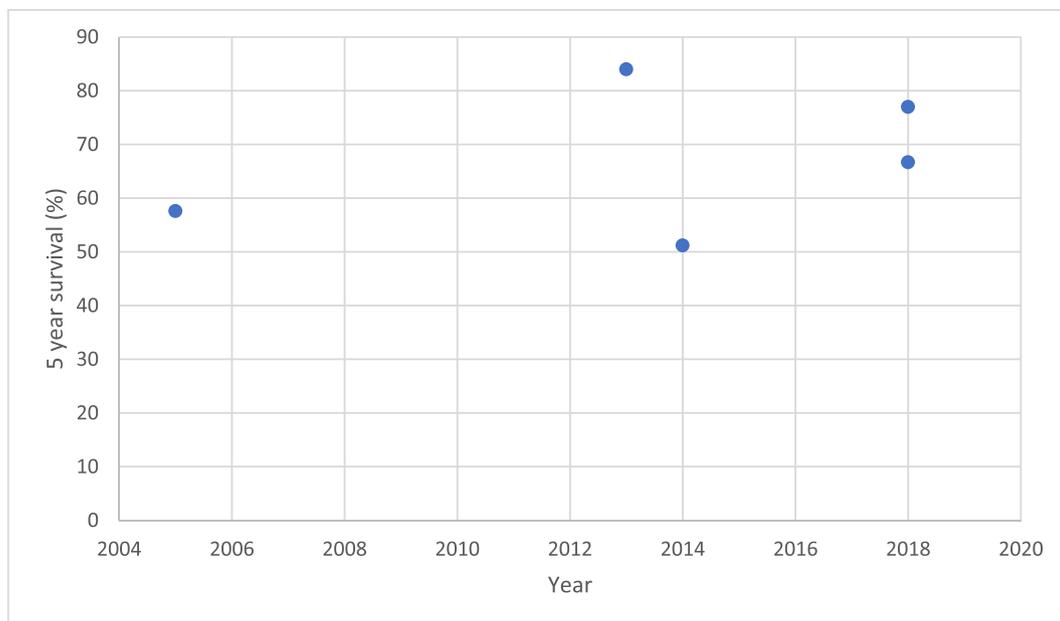


Fig 1. Five-year survival after resectional surgery for rectal cancer. (A) Five-year survival after anterior resection. (B) Five-year survival after abdominoperineal resection.

perforation and APR is reported to have worse quality markers than anterior resection, although both operations vary in different centres. Rectal specimen perforation is known to be a risk factor for recurrence, irrespective of the original stage of the tumour.

Although the term ‘standard of care’ does not mean that the care delivered is absolute perfection, the wide variation in outcomes shown above does lead to problems for patients, but also for professionals, when trying to determine

the relative value of different treatment options. Professional organisations and individuals have attempted to deal with variations in standard of care by several methods.

Clinical practice guidelines are published by many organisations [21]. Some guidelines are mandatory and impose certain standards on clinical teams. For example, the National Institute for Health and Care Excellence (NICE) generate guidelines that are mandatory for clinicians in England and Wales. NICE’s most recent guidance on the

hospital stay and postoperative recovery. However, there is one domain for which resectional surgery will always maintain the advantage and that is regarding accurate pathological staging. Examination of the resected specimen may result in upstaging of the tumour and allow the opportunity for adjuvant treatment that would never be available if an ablative approach had been undertaken.

Conclusion

In summary, the treatment of early rectal cancer remains controversial. Despite improvements in the standard of surgical care and anaesthesia in recent years, rectal resection is a major procedure with attendant risks. The evidence base for the utility of resectional surgery is well established and this approach is associated with long-term survival, definitive staging and treatment of the nodal drainage areas and is also a service that is easy to access for all patients in developed countries. By contrast, newer techniques for the treatment of early rectal cancer are aimed at sphincter preservation and reduced operative morbidity (and mortality). Recovery from such procedures is generally quicker and the overall cost may be lower. However, these techniques are less widely available to patients and there remain questions over the long-term survival rates and risk of local recurrence. For these reasons, surgery remains the standard of care for early rectal cancer, but research into options that achieve equivalent, or improved, cancer outcomes with lesser morbidity should continue to be pursued.

Conflicts of Interest

The authors declare no conflict of interest.

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