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Psychosocial outcomes following emergency laparotomy (POLO) study: a study protocol for a multicentre mixed-methods prospective cohort study assessing the psycho-social outcomes following emergency laparotomy in adults

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ABSTRACT

Introduction Morbidity from an emergency laparotomy (EmLap) is difficult to define and poorly understood. Morbidity is a holistic concept, reliant upon an interplay of bio-psychosocial outcomes that evolve long after discharge. To date, no previous study has explored the psychosocial outcomes following EmLap as a collective, nor their change over time. This study aims to describe the holistic morbidity following EmLap within the first year following surgery.

Methods and analysis This is a multicentre, mixed-methods prospective 12-month cohort study with two participant populations: patient participants and family caregivers (FCGs). A target of 160 adult patients who undergo EmLap and can give informed consent will be included in the patient participant group. Patient participants will be asked to complete three patient surveys, incorporating validated patient-reported outcome measures (PROMs) to assess bio-psychosocial outcomes (EuroQol five-dimension five-level (EQ5D-5L), Gastrointestinal Quality Life Index-36, Patient Health Questionnaire-9, Generalised Anxiety Disorder 7, International Trauma Questionnaire, Caregiver Interaction Scale and Fatigue Severity Scale) in the 12 months following surgery. A subgroup of 15 patient participants will be asked to take part in two semistructured interviews at 6 and 12 months. A target of 15 associated family caregivers will be included in the FCG group. FCGs will be asked to take part in a semi-structured interview at 6 months to assess the EmLap impact on the wider support network. The primary outcome will be a change in quality of life (EQ5D-5L) at 12 months. Secondary outcomes will be changes in bio-psychosocial status at 3 and 12 months. Qualitative analysis will allow contextualisation of PROMS and further explore themes of EmLap morbidity. It is anticipated that the results of this study will help inform and develop standards of aftercare for future EmLap patients.

STRENGTHS AND LIMITATIONS

⇒ This novel study will provide medium-term outcome data for an underrepresented patient population.
⇒ We anticipate that the study will inform the design of appropriate interventions for future studies.
⇒ The study relies on patient-reported outcome measures (PROMs) that have not been developed nor validated in an emergency laparotomy (EmLap) cohort. This is a recognised limitation, but currently no such PROM exists.
⇒ The exclusion of non-English speaking patients is a limitation of the study. This is due to funding constraints and the availability of validated measures in different languages. We will seek to address this in future funding applications and projects.
⇒ This study has coincided with the COVID-19 pandemic, which may impact recruitment and data collection.

Ethics and dissemination This study has received ethical approval (Wales REC7;12/WA/0297) and will be undertaken in accordance with the principles of Good Clinical Practice. We intend to disseminate study results in peer-reviewed journals and medical conferences, as well as a lay report to study participants.

Trial registration number Clinical Trials.gov NCT05281627.

INTRODUCTION

Each year, more than 25 000 emergency laparotomies (EmLaps) are performed in England and Wales.[1] The associated 30-day and 90-day mortality from an EmLap has been the focus of much research and national quality improvement projects.[1 2]

Conversely, the rate of morbidity associated with an EmLap is less well understood. Perhaps, this is in part because the concept of 'morbidity' is difficult to define. Previous attempts to describe EmLap morbidity have quantified distinct objective outcomes; for example, the average length of stay following EmLap is reported as 15.4 days[1]; the rate of unplanned return to theatre is 4.8%[3]; the rate of chronic postsurgical pain is considered to be 19%[4] and the rate of postoperative unemployment is published as 15%.[5]

However, the Oxford English Dictionary defines morbidity as 'the state of suffering from a disease' (or, in this case, from an EmLap).[6] This suggests that morbidity is both subjective and holistic; morbidity outcomes should not be limited to a biological domain but should represent a bio-psychosocial whole. A clinician is well qualified to describe biological outcomes, but a clinician is not omniscient; a clinician is limited to appreciating the full impact on a patient's being, i.e. psychosocial outcomes. It is, therefore, the patient who is most qualified to describe their own morbidity.

Patient-reported outcome measures (PROMs) are a recognised means of describing patient morbidity, but they are not without limitations. Effectiveness is dependent on both the sensitivity of inquiry across all bio-psychosocial domains and the specificity of the condition in question. At present, there is no PROM specific to EmLap. However, a handful of studies have reported an array of generic PROMs following EmLap; the majority of these are feasibility studies,[7 8] limited by short-term follow-up,[4 9 10] a single-method approach,[11–14] retrospective, or focusing solely on the elderly.[15] The holistic morbidity following EmLap continues to be poorly understood.

This is a multicentre mixed-methods prospective cohort study, aiming to profile the holistic morbidity of EmLap. The objectives of the study are to (1) describe psychosocial outcomes in the 12 months following EmLap and (2) understand their integrated relationship to one another.

METHODS

Study design and setting

This is an observational multicentre mixed-methods prospective cohort study. The objectives are to profile the psychosocial outcomes of adult EmLap patients and their caregivers in the 12 months following surgery with the use of validated PROMs and semistructured interviews.

The study has three stems:

1. Patient surveys at baseline, +3 months and +12 months from discharge, in addition to +12 months of clinical assessment, for EmLap patients.
2. Semistructured interviews at +6 months and +12 months from discharge for a subgroup of EmLap patients.
3. Semistructured interviews at +6 months from discharge for EmLap family caregivers (FCGs).

The study will be conducted at two tertiary centres in the UK: University Hospital Wales, Cardiff and Vale University Health Board and the Royal Alexandra Hospital, NHS Greater Glasgow and Clyde. The study will run between November 2021 and February 2024.

Participants

The study has two populations: patients and FCGs. Purposive sampling of patients will identify a subgroup to undergo semistructured interviews. This will mean there will be a total of three study groups: all patients (group 1), a sampled patient subgroup (group 2) and FCGs (group 3).

Group 1: patients (total 160 participants)

Inclusion criteria for patients

- 18 years or above.
- Able to communicate in English.
- Cognitively able to complete the survey.
- Able to provide informed, voluntary consent.
- Undergone an EmLap during admission.
- The clinical team anticipates being 'medically fit for discharge' within 48 hours.

Exclusion criteria for patients

- Any terminal diagnosis in which the clinical team does not anticipate life expectancy to exceed 6 months from the time of surgery.
- Acutely unwell at the time of recruitment. These patients may still be eligible and can be rescreened and recruited later, should their condition improve.

Group 2: patient subgroup (total 15 participants)

Purposive sampling by the research team will identify a subgroup of patients in group 1 for semistructured interviews. This will take place at the time of enrolment. This is on account of the patient population being hugely heterogeneous and to ensure that a range of phenomena are explored. Efforts will be made to select patients for the semistructured interviews to cover a range of variables, such as:

- Patient variables (age <65 years or >65 years, sex, affluence and premorbid employment status).
- EmLap operation (adhesiolysis, Hartmann's, right hemicolectomy and perforated duodenal ulcer repair).
- New comorbidity (colorectal cancer, inflammatory bowel disease and new stoma).
- Severity of acute illness (ITU admission, return to theatre).

Group 3: FCGs (total 15 participants)

An FCG, who takes care of and supports the patient for most of the time (whether physical or non-physical) in a non-professional capacity, will be identified by the recruited patient. FCGs do not necessarily need to be relatives.

Inclusion criteria for FCGs

- Identified by the patient participant.
- 18 years or above.
- Able to communicate in English.
- Able to provide informed, voluntary consent.

Outcomes

The primary outcome is a change in EuroQol five-dimension five-level (EQ5D-5L) score at 12 months following EmLap. Currently, there is no validated PROM to measure holistic morbidity following EmLap. EQ5D-5L was therefore decided as the primary outcome on account of its simplicity, its scope of inquiry and its wide application in a clinical and health-economic setting.[16] Additional outcomes and validated PROMs are summarised in table 1. The authors decided upon these outcomes and the use of validated PROMs based on the expansion of key themes that were identified from previous patient focus group work. These themes included communication

Table 1 Psychosocial outcomes following EmLap outcomes, measures and endpoints

		Endpoint(s)			
Outcome	**Measure**	**Baseline (discharge)**	**+3 months**	**+6 months**	**+12 months**
Primary outcome					
Change in quality of life in the 1 year following EmLap	EuroQol five-dimension five-level	X	X		X
Secondary outcome					
Patient definition of EmLap recovery following EmLap	Patient definition of recovery	X			X
	Time to patient reported recovery		X		X
	Patient reported factors that influence recovery	X	X	X	X
Change in physical health in the 1 year following EmLap	Fatigue severity score	X	X		X
	Gastrointestinal Quality of Life Index	X	X		X
	Prevalence of incisional hernia				X
	Rookwood Frailty Score (over 65 years only)	X			X
	Body mass index	X			X
Change in mental health status in the 1 year following EmLap	International Trauma Questionnaire		X		X
	Patient Health Questionnaire	X	X		X
	Generalised Anxiety Disorder assessment	X	X		X
	Body Image Perception (Likert scale)	X	X		X
Change in social status in the 1 year following EmLap	Community Integration Questionnaire	X	X		X
	Time to return to premorbid sexual function				X
	Time to return to premorbid employment status				X
	New use of income support				X
Tertiary objectives					
To describe the provision of EmLap aftercare and patient's experiences	NHS Wales Experience Questionnaire	X	X		X
	Number of points of care: scheduled/unscheduled and multiprofessionals (patient diary)		X		
	Patient-defined care priorities for future rehabilitation programme	X		X	X

EmLap, emergency laparotomy.

and relationships, incisional hernia, mental health, diet and employment. All validated PROMs (except for the International Trauma Questionnaire for post-traumatic stress disorder (PTSD), where there will be no baseline measure) will be reported by patients at three endpoints to understand the trend of morbidity in the 12 months following EmLap. Patient definitions of recovery and time to recovery will be recorded both using open questions in the patient survey and semistructured interviews. A mixed-methods approach will allow the contextualisation of validated PROMs.

Participant timeline

Baseline assessments

Patient participants will complete a baseline survey in the hospital at the time of enrolment. Clinical variables will be obtained from the medical notes and documented in the case report form (Online supplemental material 1) by the research team. Patient participants will be provided with a diary at the time of discharge and asked to record any further interaction with healthcare and social care professionals prospectively for the forthcoming 3 months on a weekly basis (online supplemental material 2). FCG participants will complete a baseline questionnaire to gather demographics via post once enrolled in the study. The reporting structure for the surveys is described in the Strengthening the Reporting of Observational Studies in Epidemiology statement (online supplemental material 3).[17]

Follow-up assessments

Follow-up surveys will be posted to participants at +3 months and +12 months from discharge. Participants will be asked to return surveys in a prepaid and addressed envelope to the sponsor. An end-of-study clinical assessment for patient participants will occur +12 months after discharge and will include BMI calculation, screening for incisional hernia and frailty assessment by a member of the research team.

Semistructured interviews

Interviews will be conducted by trained clinical researchers within the POLO study group and are scheduled to last between 30 and 60 min. Interviews for FCGs will occur at +6 months only; interviews for patient participants will be repeated at +6 and +12 months. Interviews will either be face-to-face or virtual via secure videoconferencing, depending on the participant's preference. Non-participants will be permitted to attend. All interviews will be recorded and transcribed by an internal third party (Cardiff and Vale staff member trained in transcription). A semistructured interview technique will not only enable the discussion of known core themes but also facilitate the exploration of other themes not yet understood at this stage of the study (online supplemental material 4). The reporting structure for the interviews is outlined in the Consolidated criteria for Reporting Qualitative research statement (online supplemental material 5).[18]

Sample size

We aim to recruit 160 patient participants (group 1). This figure is reflective of a target 12-month recruitment time (total length of study: 24 months), a combined EmLap annual frequency of 400 and an estimated pickup rate of 40%. 15 of these will be included in the patient semi-structured interviews (group 2). A further 15 participants will be recruited for the FCG semistructured interviews (group 3). Previous literature suggests that this should generate enough thematic data for qualitative analysis.[19] However, if there is a need for further investigation of themes, additional participants will be interviewed until saturation is reached.

Recruitment

All patients who have undergone an EmLap will be screened and approached by the research team with a patient information sheet (PIS; Online supplemental material 6) and given a minimum of 24 hours for consideration. Patients will be recruited by the research team if they meet the eligible criteria and provide written informed consent (online supplemental material 7). If a recruited patient's clinical condition deteriorates shortly after recruitment, causing a delay in discharge, the patient will remain in the study. Baseline survey responses relate to preadmission status and therefore will not need to be repeated, nor will consent. The research team will be required to update medical history, for example, inpatient complications, and the 'start clock' for follow-up surveys and interviews will need to be reset to the actual day that the patient is discharged from the hospital. There is no time limit for reinclusion.

Once a patient has been enrolled in the study, they will be asked to identify one potential FCG and provide their contact details. A patient may be recruited even if they do not wish to or cannot identify an FCG for screening. If a potential FCG is identified, the research team will approach the FCG via telephone about the study. Should the potential FCG show interest at the initial telephone call, a PIS (online supplemental material 8) and consent form (online supplemental material 9) will be posted to the potential FCG for further information. FCGs will be enrolled upon receipt of written consent.

Data collection

Participants will be assigned a subject identification number (SID). Their corresponding data will be kept anonymous and coded with the same assigned SID for consistency. All data will be collected, handled and stored in accordance with the Data Protection Act (2018).

Patient surveys will incorporate a total of nine validated questionnaires as instrument measures (online supplemental table 1). All survey assessments will be carried out by the participants themselves to minimise bias. The research team will review all surveys to ensure completeness. If any incomplete surveys are returned, efforts will be made by the research team to obtain these from the participant as soon as possible via telephone (follow-ups)

or face-to-face (baseline). A maximum of two telephone reminders will be made if there are delays in returning postal surveys to minimise attrition bias. All exit 12-month clinical assessments will be completed by Good Clinical Practice-trained surgical practitioners.

Data analysis

Quantitative analysis

Validated PROMs will be scored in accordance with their scoring manuals. Missing data within each PROM response will be handled using mean substitution. Drop-outs will be handled with case deletion for that endpoint only.

In general, demographic variables will be presented as descriptive summaries; non-parametric data will be presented as median and IQR; parametric data will be presented as mean and SE of the mean; categorical data will be described in percentage or frequency. For inferential analysis, univariate and multivariate linear regression analyses will be conducted to determine associations for continuous variables (change in EQ5D-5L score at 12 months, change in FSS at 12 months and change in CIS at 12 months) and logistical regression for dichotomous outcomes (new diagnosis of PTSD, depression, anxiety and new unemployment). P values of <0.05 will be considered statistically significant.

Qualitative analysis

Transcribed data and field notes will be analysed using Clark and Braun's approach to thematic analysis[20] by two researchers. Patterns will be identified initially by the repetitive reading of transcripts to ensure data familiarity and construct summary notes. Systematic coding will capture elements of the data relevant to the research aim. Initial themes and subthemes will be developed and refined until the identification of final themes that capture meaningful patterns in relation to the research aim.

Patient and public involvement

All participant material has been reviewed by two patient and public involvement representatives, supported by Involving People, Wales.

Ethics and dissemination

This study has been reviewed and received ethical approval from NHS Wales REC7 (ref. 21/WA/0297) as well as Health Research Authority/Health and Care Research Wales. The study will be conducted in accordance with the principles of Good Clinical Practice and all other appropriate regulatory guidance.

All participants will be required to provide valid informed consent in writing before enrolment into the study. We intend to publish the results of this research in peer-reviewed medical and scientific journals. Results will also be presented at medical conferences at a regional, national and an international level. Participants will have the opportunity to receive newsletters with study updates and results.

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Contributors JC conceived the study. LS designed the study, wrote the protocol and ethical application. SA, SM, JT, JIB, TW and AM helped with study design and protocol development; AM and JHN were involved in study management. All authors have reviewed and approved this manuscript.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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REFERENCES

1 NELA. Sixth Patient Report of the National Emergency Laparotomy Audit. London: RCoA, 2020.
2 Parmar KL, Law J, Carter B, *et al*. Frailty in older patients undergoing emergency laparotomy: results from the uk observational emergency laparotomy and frailty (ELF) study. *Ann Surg* 2021;273:709–18.
3 NELA. Seventh Patient Report of the National Emergency Laparotomy Audit. London: Royal College of Anaesthetists, 2021.
4 Tolstrup M, Thorup T, Gögenur I. Chronic pain, quality of life, and functional impairment after emergency laparotomy. *World j Surg* 2019;43:161–8.
5 Thygesen LC, Gögenur I. Labour market participation after emergency laparotomy: a nationwide cohort study with long-term follow-up. *World J Surg* 2019;43:763–71.
6 Oxford Dictionary of English. USA: Oxford University Press, 2012.
7 Mason JD, Blencowe NS, McNair AG, *et al*. Investigating the collection and assessment of patient-reported outcome data amongst unplanned surgical hospital admissions: a feasibility study. *Pilot Feasibility Stud* 2015;1:16.
8 Saunders DI, Sinclair RCF, Griffiths B, *et al*. Emergency Laparotomy follow-up study (ELFUS): prospective feasibility investigation into postoperative complications and quality of life using patient-reported outcome measures up to a year after emergency Laparotomy. *Perioper Med* 2021;10:22.
9 Kwong E, Neuburger J, Murray D, *et al*. Feasibility of collecting and assessing patient-reported outcomes for emergency admissions: Laparotomy for gastrointestinal conditions. *BMJ Open Gastroenterol* 2018;5:e000238.

10 Tengberg LT, Foss NB, Lauritsen ML, *et al*. The impact of acute high-risk abdominal surgery on quality of life in elderly patients. *Dan Med J* 2017;64:A5371.
11 Jones CH, O'Neill S, McLean KA, *et al*. Patient experience and overall satisfaction after emergency abdominal surgery. *BMC Surg* 2017;17:76.
12 Thomsen T, Vester-Andersen M, Nielsen MV, *et al*. Pastients' experiences of postoperative intermediate care and standard surgical ward care after emergency abdominal surgery: a qualitative sub-study of the Incare trial. *J Clin Nurs* 2015;24:1280–8.
13 Law J, Welch C, Javanmard-Emamghissi H, *et al*. Decision making for older patients undergoing emergency laparotomy; defintiing patient ANC clinician values and priorities. *Colorectal Dis* 2020;22:1694–703.
14 Park B, Barazanchi A, Rahiri J-L, *et al*. Patient experiences of the emergency laparotomy pathway: a qualitative study. *World J Surg* 2021;45:1362–9.
15 Gazala S, Tul Y, Wagg A, *et al*. Quality of life and long-term outcomes of octo- and nonagenarians following acute care surgery: a cross sectional study. *World J Emerg Surg* 2013;8:23.
16 Herdman M, Gudex C, Lloyd A, *et al*. Development and preliminary testing of the new five-level version of Eq-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727–36.
17 Elm E von, Altman DG, Egger M, *et al*. The strengthening the reporting of observational studies in epidemiology (Strobe) statement: guidelines for reporting observational studies. *BMJ* 2007;335:806–8.
18 Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care* 2007;19:349–57.
19 Saunders MNK, Townsend K. Reporting and justifying the number of interview participants in organization and workplace research. *British J of Management* 2016;27:836–52.
20 Braun V, Clarke V. "What can "thematic analysis" offer health and wellbeing researchers". *Int J Qual Stud Health Well-Being* 2014;9:26152.