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Factors impacting time to ileostomy closure after anterior resection: The UK CLOSure of Ileostomy Timing cohort study (CLOSE-IT)

The Dukes' Club Research Collaborative

Corresponding Author:

Mr Peter Vaughan-Shaw, The Dukes' Club, Association of Coloproctology of Great Britain and Ireland, Royal College of Surgeons of England, *London*

Email: pvaughan@ed.ac.uk

STRUCTURED ABSTRACT

Background

Delay to closure of ileostomy following anterior resection for rectal cancer may impair post-operative bowel function and quality of life (QoL). We analysed time to ileostomy closure across the UK and investigated factors delaying closure.

Methods

Retrospective cohort: We assessed time to closure and incidence of non-closure for patients who underwent anterior resection with defunctioning ileostomy during 2015. Multivariate linear/ cox-regression analyses were performed.

Prospective cohort: We captured patients undergoing ileostomy closure during a 3-month period to validate retrospective findings.

Results

Retrospective cohort: Of 788 patients, 669 (84.9%) had bowel continuity restored, median time to closure 259 days. Recognised factors associated with delay and risk of non-closure, included anastomotic leak (HR 3.65, 2.61-5.08), chemotherapy (HR 2.62, 2.17-3.15) and cancer progression (HR 2.05, 1.62-2.58). Crucially, specific aspects of the surgical pathway were associated with time to closure, e.g. waiting list entry prior to outpatient clinic review/imaging was associated with an estimated 133-day shorter interval to closure (P < 0.001).

Prospective cohort: 288 patients underwent closure, at median 271 days. Chemotherapy use and cancer progression were associated with delay to closure while listing for surgery prior to clinic and imaging was associated with estimated shorter interval to closure of 168 days (P=0.008).

Conclusions

Delays to closure of ileostomy are common in the UK. Listing patients for surgery only after follow-up outpatient appointment, imaging or chemotherapy, delays closure. Findings will inform consensus guidelines towards an optimum treatment pathways to reduce delay and improve post-closure QOL.

What does this paper add to the literature?

Interval to ileostomy closure is ~9-months in the UK yet streamlining patient pathways could reduce interval by up to 5-months. COVID-19 risks further delays, supporting integration of ileostomy closure into target-driven pathways and strategies to reduce delays. Prospective waiting-list entry before outpatient review, imaging or chemotherapy may achieve timely closure, benefiting bowel function and QOL.

INTRODUCTION

Total mesorectal excision is the gold standard surgical treatment for cancer of the middle and lower rectum, enabling sphincter preservation, while affording low rates of local recurrence [1]. A defunctioning ileostomy is commonly formed to reduce risk and sequelae of leak from a low colorectal or coloanal anastomosis [2, 3], and can usually be closed once the anastomosis has healed. Between 2011 and 2014 in England & Wales, some 5406 (63%) patients undergoing anterior resection for rectal cancer had a defunctioning ileostomy formed [4]. Despite being formed to reduce the burden of a potential complication, an ileostomy itself has associated morbidity. Patients may experience high stoma output and subsequent renal failure requiring readmission for intravenous fluid support [5-7], while parastomal hernia, stoma prolapse or retraction, chronic renal impairment and psychosocial sequelae are not uncommon [8-10].

Crucially, emerging evidence indicates that *delay* to closure of ileostomy after rectal cancer resection is associated with greater risk of developing low anterior resection syndrome (LARS) [11-13]. LARS is a spectrum of symptoms including faecal incontinence or urgency, stool fragmentation, frequency and emptying difficulties [14], and is associated with lower overall quality of life [15].

Despite a 3-fold increase risk of major bowel dysfunction after delayed restoration of bowel continuity [11], time to closure of ileostomy varies widely across Europe, and is not subject to national targets or financial incentives within the NHS in the UK. The focus of targets is on commencement of cancer treatment, rather than the completed patient pathway. In mainland Europe and the USA, median time to closure is around 4 months [16-18], with the recently reported *EASY* trial defining late closure as greater than 12 weeks [19]. Meanwhile, in the UK 34% of ileostomies (following anterior resection) have not been closed at 18 months [4]. Clinical factors might preclude timely closure, yet surgeon and patient preference, or service pressures due to competing targets, could impact time to closure. No study to date has evaluated such factors. We performed a UK-wide, multicentre audit to determine median time to ileostomy closure, incidence of non-closure, and to explore the patient pathway to closure in order to identify factors contributing to delays.

METHODS

This multicentre, observational study was led by the Dukes' Club Research Collaborative, a national colorectal trainee research group, affiliated with the Association of Coloproctology of Great Britain & Ireland (ACPGBI). Trainee-led research networks are now well established in the UK [20], and have been shown to facilitate the delivery of high-quality studies. The study protocol was published prior to study completion [21], and STROBE guidelines followed [22].

CLOSE-IT consisted of two elements: Part 1) a retrospective analysis of patients who underwent anterior resection for rectal cancer with ileostomy formation in 2015 (12-month period); Part 2) a prospective 3-month data collection of all patients undergoing closure of ileostomy following previous anterior resection for rectal cancer in order to validate findings from the retrospective arm (study period was any consecutive 3-month period between April and November 2018). Patients were identified prospectively as they underwent ileostomy closure and data collected on their previous and current clinical episodes.

Baseline demographic and clinical data including potential confounders, and effect modifiers were collected from electronic hospital and theatre records, MDT notes and radiology imaging systems and entered onto Clinical Report Forms (CRFs) [Appendix 1] at source, de-identified and returned through the secure REDCap (Research Electronic Data Capture)[23] server. Number of days from primary surgery to post-operative outpatient clinic review, imaging, waiting list entry and closure were collected with the '*pathway to closure*' (i.e. straight onto waiting list after index surgery, onto waiting list after clinic etc.) and inferred or documented reasons for any delays to closure also collected. A pilot study during January 2018 successfully tested the procedures and processes for data collection via REDCap.

Statistical analysis

Data were stored in Excel™ (Microsoft Inc., Seattle, USA). Data handling and analysis was conducted in Microsoft Excel and R [24], providing median and inter-quartile range for relevant variables unless otherwise stated. Continuous variables were not normally distributed (days to closure, days on waiting list) and were therefore log-transformed before statistical modelling. Analysis of retrospective data was performed using Cox proportional hazards models to calculate hazard ratios (HRs) for 'non-closure' within the R '*survival*' package, adjusting for patient- and pathway-related factors hypothesised to influence time to closure (age, sex, ASA grade, cancer progression, adjuvant therapy, and pathway to

closure). Cases with missing data were excluded from multivariate analysis. In order to explore clinically relevant cut-off values for age and ASA grade, these variables were dichotomized to age >70years and ASA >3 and entered as factors into the model as a secondary analysis. Linear regression modelling was performed in those retrospective patients who had undergone closure and in the prospective dataset (who all underwent closure), to identify factors associated with time to closure. Variables included in the model were as stated above, with all factors included in multivariate analysis.

Data validation methods

Included sites were asked to complete CRFs for at least one randomly selected patient included in the original submission. These were completed by researchers independent to the original research team at each site who were blinded to the REDCap data from the original submission. CRFs cross-referenced against the REDCap data independently by 2 researchers, independent to the main study team. Concordance of 11 key fields was assessed: gender; neo-adjuvant therapy use; date of index surgery; anastomotic leak; adjuvant therapy; cancer progression; imaging performed prior to ileostomy closure (Y/N); date of imaging; clinic (Y/N) and date; date of entry onto waiting list; date of ileostomy closure.

Ethical Approval

Ethical approval was obtained from the Proportionate Review Sub-committee of the South West - Exeter Research Ethics Committee (reference 18/SW/0024) and the study received portfolio adoption from the UK Health Research Authority. All collaborators registered the study with their local audit and local Caldicott Guardian. Informed consent from included patients was not required as per the above committee recommendations.

Public and patient involvement

Functional outcomes and quality of life after bowel surgery and temporary stomas were highly ranked issues in a comprehensive patient and public consultation exercise, defining the current research question [25]. Lay representatives from the 'Involving People' network, supported by NIHR INVOLVE, reviewed and informed the study design prior to application for funding and ethical approval. Given that consent was not required for this observational

study, PPI was not deemed necessary for the conduct of the study. The ACPGBI patient liaison group and Ileostomy and internal pouch Support Group will help future dissemination and development of consensus guidelines for ileostomy closure.

RESULTS

A total of 192 researchers from 53 NHS hospitals submitted data on 1037 patients. 21 incomplete records containing no usable data were excluded from analysis (Figure 1).

Retrospective study– Demographics and patient pathway

788 patients who underwent anterior resection and ileostomy formation in 2015 were included (details in Supplementary Table 1). Ileostomy closure occurred in 669 patients over the follow-up period (median 294, interquartile range (IQR) 315 days). Median days to closure was 259 (IQR 214) days from index anterior resection. 305 patients (39%) had not undergone closure 12 months following anterior resection.

Pre-closure pathway was assessed, with just 18 patients (3%) booked for closure before any clinic appointments or imaging studies (Supplementary Table 2). In total 639 (96%) patients underwent imaging, commonly water-soluble contrast enema (622, 79%), with median days from imaging request to completion of 28 (IQR 26, maximum 328) days. In total, 567 patients (73%) were seen in clinic at least once while 154 (23%) were seen in clinic at least twice before being booked for closure.

Risk of non-closure

Non-closure was more common in those with anastomotic leak (HR 3.65, 2.61 to 5.08), cancer progression (HR 2.05, 1.62 to 2.58), or undergoing adjuvant therapy use (HR 2.62, 2.17 to 3.15) (Table 1). There was no association with patient gender or case frequency. Stratification by age over 70 and ASA≥3 indicated that risk of non-closure was markedly greater in older and comorbid patients. Indeed, in 9 patients with ASA≥3 and over 70 years of age who had an anastomotic leak, only 4 had undergone reversal of ileostomy at end of follow-up.

Delay to closure in retrospective cohort

In those undergoing closure, adjuvant therapy, increasing age, anastomotic leak and cancer progression were associated with longer interval to ileostomy closure (Table 2). Median interval to closure was 364 (IQR 175.75) days in those who underwent adjuvant therapy and median 182.5 (IQR 132.75) days in those who did not (P < 0.001; Supplementary Figure 1).

Just 18 patients (3%) were booked for closure before any clinic appointments or imaging was performed with 157 (23%) seen in clinic at least twice before being booked for closure (Supplementary Table 3). A more streamlined pre-order closure pathway was associated with shorter interval to closure, with patients being booked straight after index or adjuvant therapy having an estimated 133-day shorter interval compared with those seen in clinic, undergoing imaging and seen in clinic again before being entered onto waiting list (P < 0.001; Figure 2; estimates with 95%CI given in Supplementary Table 3). No association between interval to closure and number of cases submitted or reported annual rectal cancer cases was seen (Table 2, Supplementary Figure 2). Time on the waiting list was modestly correlated with interval from anterior resection to closure (R=0.44, P < 0.001; Supplementary Figure 3). The commonest documented or inferred factors identified in patient notes impacting interval to closure were patient comorbidity (19%), need for chemotherapy (15%) and patient preference (8%). Long waiting list and procedure cancellation due to lack of hospital beds or staffing was specifically identified in 8% and 5% respectively (Table 3).

Prospective cohort–Patient pathway

228 patients undergoing closure of ileostomy were included (Supplementary Table 1). Interval from anterior resection to closure was median 271 (IQR 198) days from anterior resection, interval >365 days in 62 (27%). Just 5 patients (2%) were booked for closure before any clinic appointments or imaging was performed. In total 220 (96%) patients underwent imaging, 187 (82%) were seen in clinic at least once and 55 (24%) were seen in clinic at least twice before being booked for closure (Supplementary Table 4).

Factors associated with delay to closure in prospective cohort

Findings replicated those in the retrospective cohort with patients booked straight after index surgery or adjuvant therapy having an estimated 168-day shorter interval to closure (P=0.009; Table 2) and those imaged but not seen in clinic before listing, having an

estimated 54-day shorter wait for closure (Table 2; P < 0.001). No association between interval to closure and number of cases submitted, or reported annual rectal cancer cases was seen (Table 2, Supplementary Figure 4). Interval to closure was correlated with days on waiting list R=0.41, P < 0.001 (Supplementary Figure 5).

The commonest documented or inferred factors identified in patient case notes as impacting interval to closure were patient comorbidity (15%), need for chemotherapy (14%) and patient preference (11%). Long waiting list and procedure cancellation due to lack of hospital beds or staffing were present in 14% and 4% respectively (Table 3).

Data validation results

Validation case report forms were received for 64 cases from the retrospective arm. Analysis of these for agreement with the REDCap data revealed a concordance of >95% for all variables except for 'Clinic' appointment' ('yes' or 'no' and date; 90%) and 'entry onto waiting list' (89%) (Supplementary Table 5). Date of entry onto waiting list was often different by a small number of days which is likely to be because this is not always clearly recorded within electronic case records and may have been approximated based on clinic letters or waiting list office records. Nevertheless, these were coded as 'incorrect' for purposes of validation.

DISCUSSION

This multifaceted UK wide study is the first to explore reasons for delay to ileostomy closure and to provide a template by which to analyse and optimise this patient treatment pathway in the NHS. Median time to ileostomy closure is prolonged, at ~9 months, with a high incidence of non-closure of ~40% at 12 months, and 20% at 18 months following anterior resection. Crucially, streamlined pathways to closure were associated with markedly shorter intervals to restoration of bowel continuity.

This study provides clear evidence for an optimum treatment pathway which could be readily and easily implemented in NHS practice to improve patient outcomes and reduce stoma-related expenditure. There were significant associations between steps in the patient pathway and time to closure, with the most streamlined pathway of care seen in patients who were listed for closure before any post-operative clinic or imaging, with an estimated 4-month reduction in interval to closure. Similarly, time to closure was ~2 months shorter in patients who: a) had imaging of their anastomosis but were *not* seen in clinic prior to being listed for closure, or b) were seen in clinic just once prior to listing with imaging performed before/ after clinic; compared to patients who were seen twice in clinic before being added to the waiting list. Furthermore, we found that the time on the waiting list was correlated with the overall delay from anterior resection to closure, suggesting that pre-emptively booking patients for closure immediately after index surgery could decrease delay to closure.

Findings from the current study are consistent with a previous study that provided patients with an agreed date for closure on discharge from hospital after their index operation resulting in a significant reduction in interval to closure[26]. Such an approach appears both attractive and safe, with a recent meta-analysis reporting no significant difference in morbidity or anastomotic leak rate with early closure but reduced stoma related complications[27].

Exploring documented or inferred reasons for delay demonstrated a small proportion of patients who *requested* a longer interval to closure. It is important that such patients are appropriately counselled on the association between delay to closure and LARS, as well as other ileostomy-related complications, when making this decision. Adjuvant chemotherapy use was the most important factor delaying ileostomy reversal. The Royal College of Surgeons of England and NHS improvement report '*Getting it Right First Time'* reported huge variation in time to closure between trusts and divergent views on closure and adjuvant therapy use[28]. Crucially, a recent meta-analysis comparing closure during or after

chemotherapy found no difference in overall perioperative complications or outcomes [29], supporting the concept of pre-chemotherapy closure. Addressing these differences in clinical decision-making both locally and nationally are key to streamlining the process.

The responses from consultants at exemplar sites may allow clinicians at other sites to identify key processes or priorities to enable them to improve their management of such patients or introduce pathways to closure within their unit.

With significant improvements in survival from cancer surgery, increasing emphasis has been placed on the importance of patient experience and survivorship. Patient reported outcome measures following rectal cancer surgery including quality of life, bowel, bladder and sexual function and psychosocial issues around body image, have all gained significant attention over the last decade. Crucially, the National Bowel Cancer Survivorship initiative reports that almost 20% of patients have significant bowel dysfunction following colorectal resection [15]. Our findings support data from the National Bowel Cancer Audit [4] with markedly longer interval to closure than is reported in Europe or the USA [16-18]. There is evidence suggesting that prolonged colonic redundancy (i.e. time to restoration of bowel continuity) is associated with higher rates of bowel dysfunction [11-13], supporting the need for a better understanding of delaying factors and the implementation of strategies to reduce delays.

As expected, major post-operative morbidity, adjuvant chemotherapy and cancer progression were independently associated with a delay to closure and risk of non-closure, as were increasing age and ASA grade. These findings are pertinent to inform the pre-operative counselling of those patients who may be unlikely to ever undergo ileostomy closure, especially if they suffer an anastomotic leak. Crucially, these findings should also guide the choice of index surgical procedure offered to such patients, as a low Hartmann's procedure or intersphincteric APER with end colostomy, rather than anterior resection with permanent ileostomy, may yield better quality of life outcomes and reduced risk of stoma-related complications in the elderly and co-morbid.

The Montgomery ruling necessitates that surgeons provide patients with accurate, realistic information on all aspects of their surgery. It is critical that clinicians consider whether patients would make a different decision if they were provided with more information, or if they would be more demanding for a closure if they knew that delay to closure impacted bowel function. A defunctioning ileostomy is typically explained as one that is 'temporary', yet the timing of the closure may not be indicated or may be grossly unrealistic. Making

ileostomy closure part of the cancer pathway may risk patient centred care, with a "patient pathway" focussing on the most appropriate treatment for each individual more preferable. Given the seismic impact of COVID-19 on NHS services, and the prediction that NHS waiting lists could reach 10 million by the of the year [31], patients must be realistically counselled on likely timing of closure of their ileostomy and national strategies to ensure timely closure must be urgently discussed. While a target-driven pathway dictating a maximum acceptable interval to closure may seem attractive, this may be unwelcomed and unachievable in the current climate.

The current study is a paradigm for the investigation of patient treatment pathways in the NHS. There is marked variation in median time to ileostomy closure following anterior resection across the UK. Given the significant association between patient pathway and time to closure, colorectal units should consider simple measures to create a coordinated streamlined pathway to closure. Such an approach is consistent with the 'optimal care pathways' recommended in the *GIRFT* report, to reduce cost, stoma-related morbidity and QOL impact of delay to stoma closure. Of course, integration of ileostomy closure into national target-driven pathways may preclude a patient-centred approach yet may be required in a peri/post-COVID-19 era as elective waiting lists mount.

Findings presented here will inform future work focussing on the development and implementation of streamlined pathways to ileostomy closure. Stakeholders must include patients, surgeons, oncologists and stoma nurses to ensure that derived pathways are realistic, patient-centred and safe. It is clear that further research is required to define the optimal timing of ileostomy closure in respect of both the index operation and adjuvant chemotherapy, assessing both patient-reported, surgical and oncological outcomes.

We acknowledge some limitations of the current study. First, it relies on the quality of data provided by local centres. Although independently submitted validation datasets indicate high levels of data validity, we cannot determine evidence of selection bias as we did not request numbers of potentially eligible patients. Meanwhile, we acknowledge that not all centres and patients are included, i.e. there is risk of selection bias with poorly performing centres failing to submit data for inclusion. Next, whilst the prospective dataset appeared to replicate findings seen in the retrospective cohort, associations often lacked statistical significance, which may reflect inadequate statistical power. Finally, there is risk of confounding in our results and we cannot definitively attribute causation to the observed associations as this is an observational study. Despite these limitations, this paper provides novel and important findings in relation to delays to ileostomy closure. It demonstrates the

value of a multifaceted approach to the study of patient treatment pathways, the power of national research collaborative groups, and the role of social media in engaging and enthusing trainees to contribute.

TABLES

Table 1 - Factors significantly associated with non-closure of ileostomy at completion of follow-up in retrospective group

	Unadjusted model			Multivariate model		
Factor	HR	95%CI	P value	HR	95%CI	P value
Adjuvant therapy use	1.89	1.61-2.22	< 0.001	2.62	2.17-3.15	< 0.001
Age	1.01	1.00-1.01	0.11	1.02	1-1.02	< 0.001
Age >70 years	1.22	1.04-1.45	0.01	1.48	1.23-1.79	< 0.001
ASA	1.10	0.98-1.23	0.11	1.13	0.98-1.29	0.07
ASA>=3	1.21	0.98-1.50	0.08	1.28	1.02-1.61	0.03
Age>70 years & ASA>=3	1.27	0.96-1.66	0.09	1.43	1.08-1.90	0.01
Cases submitted to CLOSE-IT	1.00	0.97-1.02	0.98	0.98	0.95-1	0.22
Gender (male)	1.10	0.93-1.28	0.26	0.90	0.75-1.07	0.24
Anastomotic leak	2.63	1.92-3.57	< 0.001	3.65	2.61-5.08	< 0.001
Cancer progression	1.89	1.61	< 0.001	2.05	1.62-2.58	< 0.001

Multivariate model adjusted for Age, Sex, ASA grade, Cases submitted to CLOSE-IT per unit, Anastomotic leak, Adjuvant therapy and Cancer progression. Dependent factors entered into separate models (e.g. 'ASA>=3' not entered into the same model as 'Age>70 years & ASA>=3')

Table 2 - Clinical and patient pathway factors associated with delay to closure in the retrospective and prospective cohorts

Factor	Retrospective cohort			Prospective cohort		
	N(%)/ Median	Estimate (days)	P	N(%)/ Median	Estimate (days)	P
Number undergoing closure	669	-	**-**	228	-	**-**
Baseline data						
Age	65 (13)	2	**< 0.001**	64.5 (15)	2	0.066
Sex (Male)	416 (62%)	-13	0.457	145 (64%)	-33	0.085
ASA	2 (0)	-6	0.728	2 (0)	-11	0.578
Cases submitted to CLOSE-IT per unit	5 (4)	-1	0.244	5 (5)	3	0.652
Anastomotic leak	43 (6%)	136	**< 0.001**	17 (7%)	63	0.214
Adjuvant therapy	280 (42%)	187	**< 0.001**	88 (39%)	179	**< 0.001**
Cancer progression	108 (16%)	28	0.418	9 (4%)	-78	0.398
Pre-closure order						
Clinic, imaging, clinic then waiting list	154 (23%)	0 *(ref)*	-	55 (24%)	0 *(ref)*	-
Imaging then waiting list	90 (13%)	-58	**0.002**	39 (17%)	-54	**< 0.001**
Imaging, clinic then waiting list	120 (18%)	-59	**< 0.001**	37 (16%)	13	0.567
Clinic, imaging then waiting list	161 (24%)	-61	**< 0.001**	66 (29%)	-34	0.357
Clinic then waiting list	62 (9%)	-17	0.172	14 (6%)	153	0.142
Straight onto waiting list	17 (3%)	-133	**< 0.001**	5 (2%)	-168	**0.008**

Pre-closure order represents over of events prior to placing patient onto waiting list. Estimate of days' difference associated with each factor given with corresponding p value derived from multivariate linear regression model. Negative estimate indicates that factor is associated with shorter interval to closure. Figures in brackets represent % or I.Q.R. Ref – reference group. Subgroup analysis of retrospective cohort patients without anastomotic leak or cancer progression (i.e. patients with uncomplicated post-operative course, n=526) showed no substantial change in results with pre-closure order still significantly associated with time to closure.

Table 3 - Factors identified in case notes as impacting interval to closure

Factor causing delay	Retrospective cohort	Prospective cohort
None reported	467 (59%)	110 (48%)
Patient comorbidity	150 (19%)	34 (15%)
Chemotherapy	116 (15%)	32 (14%)
Patient preference	66 (8%)	26 (11%)
Cancer Progression	66 (8%)	7 (3%)
Waiting list	64 (8%)	31 (14%)
Cancellation on the day	36 (5%)	8 (4%)
Anastomotic leak	30 (4%)	14 (6%)
Anastomotic stricture	21 (3%)	6 (3%)
Delay to clinic	3 (0%)	0 (0%)
Delay to imaging	2 (0%)	5 (2%)
Administrative error	1 (0%)	0 (0%)

Documented and inferred factors for delay were combined for each cohort. Multiple factors may have been reported for each patient, resulting in sum exceeding the total cohort number

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FIGURES

Figure 1 Flow chart of included patients

Figure 2 Kaplan-Meier plot for time to closure stratified by pre-closure patient pathway in retrospective cohort

P value for univariate longitudinal analysis (cox regression) of time to closure when compared to those patients seen in clinic, imaging performed, seen again in clinic before being placed on waiting list

TRANSPARENCY DECLARATION

The lead author (JC) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

CONTRIBUTORSHIP STATEMENT

The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. The authors' contributions are as follows, with collaborative authors given in the supplementary files:

Study concepts: PGVS, KG, JAC
Study design: PGVS, KG, JAC
Data acquisition: PGVS, KG, JAC, JB, AEV, KA
Statistical analysis: PGVS, KM
Manuscript preparation: PGVS, KG,
Manuscript editing: PGVS, KG, JAC
Manuscript review: JB, KA, JT, KM, AEV, KA
Funding acquisition: JAC, PGVS, KG
Project administration: JAC

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Supervision: JAC, JT

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ETHICAL APPROVAL

Ethical approval was obtained from the Proportionate Review Sub-committee of the South West - Exeter Research Ethics Committee (reference 18/SW/0024) and the study received portfolio adoption from the UK Health Research Authority.

DISSEMINTATION

Results will be disseminated through the Association of Coloproctology of Great Britain and Ireland, including their Patient Liaison Group. Individual patients in the current study were not consented to receive results and thus it would not be appropriate to contact them.

DATA SHARING

Data and respective statistical code available on reasonable request to the corresponding author.

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