RESEARCH

Device-assisted enteroscopy in the UK: description of a large tertiary case series under conscious sedation

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Received 29 March 2017

Revised 20 June 2017

Accepted 3 July 2017

Published Online First

16 August 2017

ABSTRACT

Objective Device-assisted enteroscopy (DAE) has developed rapidly, particularly with the advent of double-balloon enteroscopy (DBE). This study reports a case series from a UK tertiary centre for DAE across two modalities—DBE and spiral enteroscopy (SE)—under conscious sedation.

Design Retrospective observational study of 257 enteroscopy procedures from 2008 to 2014. Data were collected on demographics, indications, diagnosis, sedation requirements, duration, complications, tolerance, therapy performed and completion rate. Procedures were performed under conscious sedation using a combination of midazolam, pethidine and fentanyl in a solely outpatient setting.

Results Obscure gastrointestinal bleeding (OGIB) was the commonest indication for DAE (n=164, 63.8%). Overall, yield of DAE was 47.2% and varied significantly across the indications (p=0.003). There was a greater likelihood of positive findings if the indication was polyposis syndrome (75%), abnormal capsule endoscopy (67%) or OGIB (53%) and in older patients (mean age normal exam 60.3 vs abnormal exam 67.9 years, p<0.001). Higher mean doses of midazolam were used for DBE from above (5.4 mg, SD 2.24) and SE (5.6 mg, SD 2.9) to DBE from below (4.4 mg, SD 1.8). No serious complications were recorded. Tolerance of DAE was good with the majority (240/257, 93.4%) of procedures tolerated with comfort scores 0 or 1. Therapy was performed in 121/257 (47.1%) of procedures. The strongest predictor indications for therapy to be performed at DAE were abnormal capsule endoscopy (88.9%) and occult gastrointestinal (GI) bleeding (54.9%). Completion rates were higher in DBEb (91.8%) compared to DBEa (76.5%) and SE (81.6%).

Conclusion DAE under conscious sedation is safe and well tolerated. DAE has a high yield if performed for recognised indications and may be safely used to provide therapy where a diagnosis has been made using other modalities.

INTRODUCTION

Device-assisted enteroscopy (DAE) is a rapidly evolving field with multiple techniques established.¹ The most prominent of these are single balloon enteroscopy (SBE), double-balloon enteroscopy (DBE) and spiral enteroscopy (SE).

Two techniques offer the possibility of total small bowel examination. DBE was introduced by Yamamoto in 2001.² SE was more recently introduced (2008) and has been shown to be of similar utility in complete investigation of the small bowel³ with perhaps shorter duration at the expense of depth of insertion. Push enteroscopy (PE) is a long-standing technique to examine the proximal jejunum, but does not enable total small bowel examination⁴ and is not considered as a form of DAE. Data from PE procedures have therefore been excluded from this study. Sedation for DAE is commonly propofol-based conscious sedation or general anaesthetic, particularly in Western centres and for anterograde procedures.⁵

The aim of the current study was to describe the 7-year experience of DAE at Southmead Hospital, Bristol—a large tertiary referral centre in the South West of the UK serving a population of around 1 million people. Procedures are performed solely under conscious sedation.

PATIENTS/MATERIALS AND METHODS

Recruitment

The current study is a retrospective observational analysis of patients referred for device-assisted enteroscopy (DAE) at Southmead Hospital from September 2008 to November 2014. DAE performed at the centre consists of SE from above and below and DBE from above and below. There were two

To cite: Pattni V, Tate DJ, Terlevich A, et al. *Frontline Gastroenterology* 2018;9:122–128.

Table 1 Patient and procedural factors, tolerance and outcome of small bowel endoscopy split by the techniques described

		Procedure performed						p Value
		DBEa		DBEb		SE		
		Mean/count	(%/SD)	Mean/count	(%/SD)	Mean/count	(%/SD)	
Patient factors								
Age of patient		64.5	2.72	58.7	4.29	69.5	3.76	<0.001
Procedure factor								
Endoscopist	AT	18	12.9	2	3.1	0	0.0	<0.001
	PFM	56	40.3	29	45.3	13	24.1	
	SH	65	46.8	33	51.6	41	75.9	
Midazolam dose (mg)		5.4	2.2	4.4	1.8	5.6	2.9	<0.001
Pethidine dose (mg) (median)		50	25	50	0	50	0	0.284
Indication	Abnormal VCE	8	5.8	1	1.6	0	0.0	0.002
	Abnormal imaging (not VCE)	7	5.0	3	4.7	1	1.9	
	Coeliac disease	0	0.0	0	0.0	0	0.0	
	OGIB	89	64.0	32	50.0	43	79.6	
	Other	0	0.0	1	1.6	1	1.9	
	Polyposis syndrome	5	3.6	3	4.7	0	0.0	
	SBO	6	4.3	5	7.8	0	0.0	
	Suspected polyp	6	4.3	1	1.6	6	11.1	
	Suspected CD	10	7.2	7	10.9	1	1.9	
Symptoms/signs		8	5.8	11	17.2	2	3.7	
Procedure outcomes								
Diagnosis	Angiodysplasia	36	25.9	8	12.5	20	37.0	<0.001
	BRBNS	0	0.0	0	0.0	1	1.9	
	Coeliac disease	0	0.0	0	0.0	0	0.0	
	CD	6	4.3	4	6.3	0	0.0	
	Did not reach SB	0	0.0	6	9.4	1	1.9	
	Dieulafoy	0	0.0	0	0.0	0	0.0	
	Jejunal diverticulosis	1	0.7	0	0.0	0	0.0	
	Normal	67	48.2	39	60.9	25	46.3	
	Peutz-Jeghers syndrome	2	1.4	1	1.6	0	0.0	
	SB polyp	7	5.0	0	0.0	0	0.0	
	SB tumour	4	2.9	2	3.1	4	7.4	
	Stricture	3	2.2	3	4.7	0	0.0	
	Ulceration	4	2.9	1	1.6	1	1.9	
	UGI pathology	9	6.5	0	0.0	2	3.7	
Median distance (m)		2.4	0.82	1.5	0.82	2.0	0.68	<0.001
Duration (min)		52.4	3.71	70.1	7.80	40.1	4.65	<0.001
Normal exam	Abnormal	71	51.1	19	32.8	28	52.8	0.041
	Normal	68	48.9	39	67.2	25	47.2	
Therapy	No	63	45.3	46	71.9	27	50.0	0.002
	Yes	76	54.7	18	28.1	27	50.0	
Objective met?	No	27	23.5	4	8.2	7	18.4	0.071
	Yes	88	76.5	45	91.8	31	81.6	
Tolerance of procedure								
Tolerance	Fair	12	8.6	6	9.4	7	13.0	
	Good	119	85.6	54	84.4	42	77.8	
	Poor	8	5.8	4	6.3	5	9.3	

BRBNS, blue rubber bleb nevus syndrome; CD, Crohn's disease; CE, capsule endoscopy; DBE, double-balloon endoscopy; DBEa, DBE from above; DBEb, DBE from below; OGIB, occult gastrointestinal bleeding; SB, small bowel; SBO, small bowel obstruction; SE, spiral enteroscopy; UGI, upper gastrointestinal; VCE, video capsule endoscopy.

Figure 1 Yield of device-assisted enteroscopy by indication. CD, Crohn's disease; CE, capsule endoscopy; OGIB, occult gastrointestinal bleeding; SB, small bowel; SBO, small bowel obstruction. Value presented n%.

consistent consultant operators throughout the study period (SH and PFM) and one new consultant operator (AT) who started after 2 years as a small bowel fellow in the department in 2010. All patients who had procedures during the study period were included in the analysis. All procedures were performed in an elective outpatient, non-emergency setting.

The endoscopy database at Southmead Hospital was retrospectively analysed for all procedures performed in enteroscopy (DBE, SE) over the study period. The following outcome measures were recorded: indication, patient age, dose of sedation agents (midazolam, pethidine and fentanyl), extent of procedure, diagnosis, duration and depth of insertion, endoscopist and nursing recorded comfort score, complications, yield of the procedure, whether therapy was performed and the type of therapy. Details that were unclear from the database were clarified by manual review of the medical record. Ethical review was obtained from the North Bristol NHS trust local ethics committee for the project.

Enteroscopy procedures

The DBE system (Fujinon, Saitama, Japan) consists of a high-resolution video endoscope with a length of

Table 3 Comfort scale for endoscopic procedures

0	No pain (mild transient discomfort only)
1	Mild pain (short-lived pain, not requiring intervention)
2	Moderate pain (significant pain requiring intervention)
3	Severe pain

200 cm and a flexible overtube made of polyurethane with a length of 145 cm. The principle of the DBE technique is described elsewhere.²

SE was performed using the overtube known as the Discovery Small Bowel (Spirus Medical, Stoughton, Massachusetts, USA). The overtube consists of polyvinyl chloride and is 118 cm long, with an outer diameter of 16 mm and an internal diameter of 9.8 mm. The device was used with a Fujinon enteroscope. The principle of the SE technique is described elsewhere.³

DBE and SE were performed from above and below. SE was performed only six times from below over the study period and, as such, is considered a single procedure; DBE was considered as a separate procedure from above and below as much higher numbers were performed. The operator or referrer determined the initial routes for DBE and SE after consideration of symptom and/or imaging findings. Preparation for DBE from below (DBEb)/SE from below (SEb) was with standard split dose colonoscopic bowel preparation.

The sedation agents used at our centre are predominantly midazolam together with pethidine. Fentanyl is occasionally used but not frequently enough for meaningful analysis. Propofol sedation and general anaesthetic are not used. American Society of Anesthesiologists (ASA) scores were therefore not routinely collected for patients undergoing DAE.

Therapeutic manoeuvres performed were divided into argon photocoagulation (APC), biopsy, polypectomy, clip placement and epinephrine injection. APC was performed using an ERBE device (ERBE Medical, Leeds, UK) with settings at the discretion of the endoscopist. Biopsy was included as a therapy as this is often the primary purpose of the procedure. Snare polypectomy was performed using standard techniques described elsewhere. Epinephrine injection was with 1/100 000 epinephrine in saline.

Table 2 Pivot table showing dosing of midazolam and pethidine split by procedure type and age

Procedure	Age	n	Max midazolam (mg)	Mean midazolam (mg)	Median pethidine (mg)
DBEa	≥70	64	10	4.5	25
	<70	75	12	6.1	50
DBEb	≥70	17	7	3.7	25
	<70	47	10	4.6	50
SE	≥70	30	10	5.5	50
	<70	24	12	5.7	50

DBEa, double-balloon endoscopy from above; DBEb, double-balloon endoscopy from below; SE, spiral enteroscopy.

Figure 2 Endoscopist assigned comfort score for enteroscopy procedures. See Table 3 for discomfort rating scale used at the study institution.

Patients were monitored in the endoscopy unit recovery area for at least 2 hours postprocedure or until recovered.

Definitions

Indications for DAE were categorised as follows: abnormal video capsule endoscopy (VCE), abnormal imaging not VCE, coeliac disease, obscure gastrointestinal bleeding (OGIB), polyposis syndrome, small bowel obstruction (SBO), suspected polyp, suspected Crohn's disease (CD), symptoms/signs suggestive of small bowel disease only. OGIB encompassed occult and overt gastrointestinal (GI) bleeding, including iron deficiency anaemia. SBO defined as a syndrome of abdominal pain, vomiting and constipation in the presence of suggestive imaging findings. Symptoms/signs defined as an indication where there were significant symptoms, for example, diarrhoea, weight loss, vomiting or signs to warrant DAE but no objective imaging or VCE finding to support this.

Yield was defined as a DBE examination that was not normal. Whether the outcome of the procedure had been achieved was also recorded as completion rate. Completion was achieved if the clinical question posed by the

Table 5 Suggested quality improvement parameters for device-assisted enteroscopy

Midazolam range	DBEa 5 mg, max 10 mg DBEb 4 mg, max 8 mg SE 5 mg, max 10 mg
Pethidine range	DBEa, DBEb, SE 50 mg
Prior capsule endoscopy	All procedures, particularly if indication OGIB
Consider alternative investigation	All procedures, particularly if indication symptoms/signs

DBEa, double-balloon endoscopy from above; DBEb, double-balloon endoscopy from below; OGIB, obscure gastrointestinal bleeding; SE, spiral enteroscopy.

referrer was answered or if performing DAE changed patient management. Completion rate was assessed on a per patient basis as some patients had more than one procedure.

Study endpoints

To determine referral pathways, sedation requirements, procedural aspects and complications of DAE in a tertiary referral setting in the UK.

Statistical

Summary of numerical data was by mean for symmetrical distributions and median for skewed distributions. Comparison of numerical data was performed using t-test or one-way analysis of variance for comparison of multiple means. Comparison of categorical data was performed using χ^2 testing or correlation testing. Data were analysed using SPSS statistics V22. Results were considered significant when p was less than or equal to 0.05.

RESULTS

Two hundred and fifty-seven procedures were performed over the study period (6.5 years) in 202 patients. Age of patients ranged from 17 to 96 years, mean 62.7 years (SD 16.4 years). One hundred and thirty-nine DBE from above (DBEa), 64 DBEb and 54

Table 4 Summary of therapy performed during enteroscopy procedures

		Procedure performed						
		DBEa		DBEb		SE		
		n	n %	n	n %	n	n %	p Value
Therapy performed	No	63	45.3%	46	71.9%	27	50.0%	0.002
	Yes	76	54.7%	18	28.1%	27	50.0%	
Type of therapy	APC	48	63.2%	9	50.0%	21	77.8%	
	Biopsy	19	25.0%	6	33.3%	4	14.8%	
	Polypectomy	6	7.9%	2	11.1%	0	0.0%	
	Clip	0	0.0%	0	0.0%	1	3.7%	
	Multiple	2	2.6%	0	0.0%	0	0.0%	
	Epinephrine injection	1	1.3%	1	5.6%	1	3.7%	

DBEa, double-balloon endoscopy from above; DBEb, double-balloon endoscopy from below; SE, Spiral Enteroscopy.

SE (48 from above, six from below) were recorded. The mean number of procedures per 3 months was 9.9. Over the study period, DBE was performed throughout and SE between 2009 and 2011.

SH performed 139 procedures, PFM 98 and AT 20 as the named consultant operator. These numbers reflect experience of the endoscopists at enteroscopy.

Indications

The most common indications for SBE over the study period were OGIB (164/63.8%), symptoms/signs (21/8.2%), suspected CD (18/7.0%) and small bowel polyps (13/5.1%). The full range of indications split by procedure is found in [table 1](#).

Diagnoses

Seven procedures did not reach the small bowel (1 SE, 6 DBEb). In the 250 completed procedures, the top five diagnoses were normal (131/52.4%), angiodysplasia (64/25.6%), incidental pathology above the pylorus (11/4.4%), small bowel tumour (10/4.0%) and CD (10/4.0%). The yield for all procedures combined was 47.2%; this was similar for DBEa (51.1%) and SE (52.8%) and lower for DBEb (32.8%) and this was statistically significant ($p=0.041$).

Normal was the most frequent diagnosis at DAE (131/250, 52.4%). Older patients were more likely to have an abnormal examination (mean age normal exam 60.3 vs abnormal exam 67.9 years, $p<0.001$). Yield varied over the range of indications ([figure 1](#)). The yield was greatest for patients with polyposis syndrome (75%), abnormal VCE (67%) and OGIB (53%). Yield was lowest in patients with symptoms/signs only (14.3%) and if imaging other than VCE suggested small bowel pathology (10%) ([figure 1](#)).

Sedation requirements

Mean and median sedation doses for all procedures are described in [table 1](#). Higher mean doses of midazolam were used for DBEa (5.4mg, 2.24) and SE (5.6mg, 2.92) with lower doses for DBEb (4.4mg, 1.83). Similar median pethidine dosing was observed for DBEa, DBEb and SE (50mg). The dose of sedation decreased for midazolam with increasing age ($p<0.001$); however, this trend was not significant with increasing age in pethidine doses ($p=0.284$) ([table 2](#)).

Adverse events/complications

An episode of hypotension was described in an 80-year-old undergoing spiral endoscopy who was given 2mg midazolam and 25mg pethidine with improvement after intravenous fluid therapy. No other adverse sedation events were described over the period under investigation. In particular, there was no 8-day mortality, 30-day readmissions or pancreatitis.

Comfort scores

Comfort scores were agreed by endoscopists and nursing staff and recorded as 0–3. The comfort scale used for endoscopic procedures at NBT is summarised in [table 3](#).

Procedures were generally well tolerated with 240/257 procedures tolerated with score 0 or 1. SE and DBEb were significantly less likely to be tolerated with an endoscopist pain score of 0 (28.1% and 33.3%, respectively, $p<0.001$) as compared with DBEa (59.7%). [Figure 2](#) shows comfort scores split by procedure. Tolerance of the procedure did not vary across indications ($p=0.13$) but was better tolerated in older patients age ($p=0.010$).

Extent and duration of procedure

Mean durations of procedures including therapy were 52 ± 18.8 min (range 20–130) for DBEa, 70 ± 23.8 (range 30–125) min for DBEb and 40 ± 15.3 (range 15–90) min for SE. Duration of SE procedures was significantly shorter than DBEa procedures ($p<0.001$).

Distances reached into the small bowel were recorded for 117/257 procedures. The median distance for DBEa was 2.4 m (IQR 1, range 0.2–4), for DBEb was 1.5 m (IQR 1.1, range 0.1–3) and for SE was 2.0 (IQR 1, range 0.5–3). DBEa reached significantly further into the small bowel than SE ($p=0.03$).

Completion rates and therapy

Completion rates were 81.6% for SE, 91.8% for DBEb and 76.5% for DBEa. Completion rates did not vary across different ages of patient ($p=0.238$) or endoscopists ($p=0.476$). No particular indication predicted completion. Longer procedure duration predicted increased likelihood of completion (completion 97.9% if procedure ≥ 60 min vs 70.5% if < 60 min, $p<0.001$), although this is probably just a reflection of the additional time taken for therapy.

Therapy was performed in 121/257 (47.1%) of procedures ([table 4](#)). The most common therapies (121) were APC (78, 64.5%), biopsy (29, 24.0%) and polypectomy (8, 6.6%). The therapy rate was 54.7% for DBEa, 50.0% for SE and 28.1% for DBEb. The therapy rate did not vary between endoscopists ($p=0.193$). Older patients were more likely to undergo therapy at DAE (therapy rate 78.5% if age ≥ 75 vs 37.9% if < 75 , $p<0.001$). The strongest predictor indications for therapy to be performed at DAE were abnormal capsule endoscopy (88.9%) and occult GI bleeding (54.9%).

DISCUSSION

This retrospective observational study represents one of the largest Western experiences of DAE under conscious sedation in the medical literature. The most common indication for DAE was OGIB in keeping with most other series.^{6–9}

DAE yield is 47.2% in this study. The yield of DBEa and SE in this study was similar to each other and other recently published reports.¹⁰ The lower yield of DBEb in this study was unexpected but is not often reported separately from DBEa. This study shows that the yield of DAE is highest where patients had polyposis syndrome (75%), where capsule endoscopy had shown a lesion (67%) and was also higher (53%) where the indication was OGIB. This is in keeping with a recent meta-analysis on DAE in OGIB.¹¹ DAE was of significantly lower yield in this study if undertaken simply on the basis of symptoms/signs (14.3%) and imaging other than capsule endoscopy suggested small bowel pathology (10%). Taken together, these results support the use of capsule endoscopy wherever possible prior to DAE in the investigation of small bowel disorders. In further support of this, the therapy rate in this study was 47.1%, but increased to 88.9% with a prior abnormal capsule endoscopy.

An attempt was made to assess the clinical relevance of the findings by the use of completion rate. A particular benefit of this approach is that a normal study is often clinically useful, for example, in excluding inflammatory bowel disease or an abnormality seen in imaging. Using completion rate, DBEb was the most clinically useful investigation, changing patient management in 91.8% of cases. DBEa and SE demonstrated similar rates. These data suggest that the utility of DAE is undervalued by simple measurement of yield.

Midazolam and pethidine were the predominant sedation agents used in this study. This is in keeping with Japanese and Korean centres, but unusual for Western centres where propofol is often used in addition. Use of heavier sedative agents, while reported safe in the hands of proceduralists,¹² requires at the very least extra training and often the presence of anaesthetic-trained personnel. Indeed, in many series, general anaesthetic is administered for small bowel enteroscopy, particularly antegrade.⁵ It is therefore of considerable interest that patients in this study tolerated DAE very well under conscious sedation, with the majority (240/257, 93.4%) of procedures tolerated with comfort score 0 or 1 (out of 3). Nursing scores were also obtained for 73/257 procedures and were statistically similar to endoscopist scores, validating this method of assessing patient tolerance.

Few studies have previously reported comprehensive sedation dosing for DAE. In the present study, mean midazolam dosing was 5.4 mg for DBEa and 5.6 mg for SE; dosing was lower for DBEb (4.4 mg). Pethidine dosing was median 50 mg for DBEa, DBEb and SE. It is noted that DBEa was tolerated better on endoscopist ratings but required higher doses of sedation than DBEb, which has historically been the better tolerated procedure.¹

The demonstrated safety and tolerability of conscious sedation in DAE challenges the need for heavier

sedative agents and the associated higher healthcare costs. This is particularly relevant in the current light of difficulty with healthcare budgets.

A recent study addressed the role of DBE in elderly patients (>65 years), finding the yield and rate of therapy performed to be higher in this group and complications to be similar.¹³ Sedation doses were also found to be lower in the elderly population. The present study supports these statements. We used age ≥ 70 to define elderly and found higher yield and therapy rates to be in this group throughout all modalities of DAE. However, the sedation-related complication in the study was also in the elderly group so caution must be exercised. The data support the use of DAE in elderly patients and suggest that it may be of even greater utility than the younger age group.

Our study demonstrates a very low rate of complications, 1/257 procedures (0.4%), related to sedation in an elderly patient; this is in keeping with other small series that have shown similarly low rates.⁵ There was no incidence of pancreatitis or perforation. This may be explained by the fact that all procedures were performed in an outpatient, non-emergency setting, reflecting a possible reduction in complexity and severity of a patient's clinical status. The published literature indicates that DBE and DAE are not benign procedures, however, with published rates of serious complications of 1.7%.¹⁴

The predominant weakness of the study is its retrospective nature. OGIB was not further subdivided into occult and overt bleeding; however, this is consistent with many other studies; we anecdotally predict that the majority of patients had occult bleeding.⁴ Spiral enteroscopy was not performed throughout the whole study period, which may have skewed the later results. Rates of complete enteroscopy were not assessed due to the lack of available data regarding placement of tattoo. Duration and extent were not recorded for all procedures and reporting bias may have skewed the results of these parameters. ASA grades were not recorded for patients in this study. This may have been helpful in further predicting procedural risk. Data on comorbidities, including cardiac risk factors, obstructive sleep apnoea and body mass index were not routinely recorded. Further studies should aim to include these data as they may play a significant role in triaging patients to either conscious sedation or anaesthesia-directed sedation.

In conclusion, the dataset presented represents one of the largest UK experiences of enteroscopy in the medical literature and is particularly notable that all procedures were performed under conscious sedation. The data support the fact that deep enteroscopy in this setting is safe and well tolerated. Colonoscopy in the UK has

Significant of this study

What is already known on this topic?

- ▶ Traditionally, full visualisation of the small bowel has been challenging. Device-assisted enteroscopy is a rapidly evolving field which allows the gastroenterologist the possibility of total small bowel examination and is typically performed under deep sedation or general anaesthetic.

What this study adds?

- ▶ This study represents one of the largest UK experiences of enteroscopy in the medical literature and demonstrates that device-assisted enteroscopy is safe and well tolerated under conscious sedation.

How might it impact on clinical practice in the foreseeable future?

- ▶ Device-assisted enteroscopy can safely be performed under conscious sedation and is important for providing therapy once a diagnosis has been made by other modalities. We call for improved UK-wide reporting of enteroscopy procedures with a view to quality assurance, particularly of reporting parameters.

undergone a transformation with the introduction of quality assurance parameters, particularly around reporting, sedation and adenoma detection rates. We call for improved UK-wide reporting of enteroscopy procedures with a view to quality assurance, particularly of reporting parameters. The data recorded here provide a robust basis on which such factors could be developed and some suggestions are shown in [table 5](#). The European Society of Gastrointestinal Endoscopy has also published some guidance recently which is complementary to this objective.⁴

Acknowledgements We would like to thank the Departments of Gastroenterology, Radiology and Audit at North Bristol NHS Trust for all their kind assistance in this project.

Contributors VP, DJT, PM and SH helped in the conception and design of the study. VP collated and organised data from the departmental database. DJT performed statistical analysis of the data, helped write the original manuscript, which was also edited by VP. AT, PM and SH reviewed the final manuscript, which was then further revised by VP. VP submitted the final manuscript and is therefore responsible for the overall content of the submission as a guarantor. VP and DJT contributed equally to the overall study and therefore are denoted as joint first authors.

Competing interests None declared.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Local ethics approval gained from audit department to access departmental database. Push enteroscopy unpublished data can be accessed by written request by email correspondence to department/authors if needed.

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