

## Original research

# Positioning intestinal ultrasound in a UK tertiary centre: significant estimated clinical role and cost savings

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## ABSTRACT

**Objective** Intestinal ultrasound (IUS) is an inexpensive, non-invasive method of diagnosing and monitoring inflammatory bowel disease (IBD). We aimed to establish the proportion of lower gastrointestinal endoscopies (LGIEs) and magnetic resonance enterographies (MREs) that could have been performed as IUS, the potential pathology miss-rates if IUS was used and the associated cost savings.

**Methods** All MREs and LGIEs performed for either assessment of IBD activity or investigation of possible IBD, performed at a single UK tertiary centre in January 2018, were retrospectively reviewed against predetermined criteria for IUS suitability. Case outcomes were recorded and cost of investigation if IUS was performed instead was calculated.

**Results** 73 of 260 LGIEs (28.1%) and 58 of 105 MREs (55.2%) met the criteria for IUS suitability. Among potential IUS-suitable endoscopy patients, one case each of a <5 mm adenoma and sessile serrated lesion were found; no other significant pathology that would be expected to be missed with IUS was encountered. Among IUS-suitable MRE patients, no cases of isolated upper gastrointestinal inflammation likely to be missed by IUS were found, and extraintestinal findings not expected to be seen on IUS were of limited clinical significance. The predicted cost saving over 1 month if IUS was used instead was £8642, £25 866 and £5437 for MRE, colonoscopy and flexible sigmoidoscopy patients, respectively.

**Conclusion** There is a significant role for IUS, with annual projected cost savings of up to almost £500 000 at our centre. Non-inflammatory or non-gastrointestinal pathology predicted to be missed in this cohort was of limited clinical significance.

## WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Intestinal ultrasound is capable of assessing enteric inflammation and associated complications, performing comparably with modes of investigation including magnetic resonance enterography (MRE) and endoscopy; however, it is cheaper than these investigations, is non-invasive, does not require bowel preparation and can be used at point of care.

## WHAT THIS STUDY ADDS

⇒ This study presents the predicted clinical role and associated cost savings of introducing intestinal ultrasound into a UK centre.  
⇒ A significant proportion of MREs (55%) and lower gastrointestinal endoscopies (28%) could reasonably have been performed as intestinal ultrasounds instead, with annual predicted cost savings of up to almost £500 000.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The findings support consideration of incorporating intestinal ultrasound into clinical practice in the UK from both a clinical and financial perspective.

## INTRODUCTION

Investigations used in the diagnosis and monitoring of inflammatory bowel disease (IBD) are evolving, with a drive towards tests that are not only accurate but are also cost-effective and acceptable to patients. Colonoscopy is the gold standard for assessing ileocolonic inflammation, but is invasive, risks bowel perforation and requires bowel preparation.<sup>1</sup> Furthermore, inflammation or

strictures may be out of reach of a colonoscope and extraluminal findings will not be identified. Accordingly, small bowel imaging is often also required.<sup>2</sup> In many centres, magnetic resonance enterography (MRE) is the standard imaging technique used to assess the small bowel<sup>3</sup>; however, it is expensive, can be poorly tolerated and has limited availability.

Transabdominal intestinal ultrasound (IUS) is increasingly used to assess gastrointestinal inflammation. It is best at assessing ileocolonic inflammation proximal to the rectum,<sup>4</sup> is cheap and non-invasive, and can be employed at point of care, enabling immediate therapeutic decisions to be made. Accordingly, it has the potential to obviate the need for other more expensive and invasive tests.

Compared with MRE, IUS performs favourably, with comparable diagnostic accuracy in detecting inflammation in multiple systematic reviews and meta-analyses, except with respect to inflammation proximal to the ileum.<sup>5–8</sup> In the Diagnostic accuracy of magnetic resonance enterography and small bowel ultrasound for the extent and activity of newly diagnosed and relapsed Crohn's disease (METRIC) study, the sensitivity of IUS for presence of small bowel disease was clinically comparable, although statistically inferior, with MRE (92% vs 97%,  $p=0.025$ ), with a non-statistically significant difference of 12% in specificity (96% vs 84%,  $p=0.054$ ).<sup>3</sup> However, IUS was more sensitive for presence of colonic Crohn's disease (CD) (74% vs 64%, NS) and statistically superior when assessing for a new diagnosis of CD (67% vs 47%, 20% difference, 95% CI 1% to 29%), with similar specificity (96% vs 96%). Importantly, the sensitivity (80% vs 70%,  $p=0.027$ ) and specificity (95% vs 81%,  $p=0.039$ ) of MRE in assessing the extent of small bowel disease were greater than IUS. When management strategies in CD have been compared in the face of IUS or MRE findings in the same patients, high concordance has been shown ( $\kappa$  coefficient=0.80).<sup>9</sup> Furthermore, in the Transabdominal ultrasonography of the bowel in subjects with IBD to monitor disease activity (TRUST) studies, IUS was shown to be useful in the assessment of response to treatment in CD, and it has been proposed for the diagnosis and assessment of activity and disease extent in ulcerative colitis, despite limited views of the rectum.<sup>4 10 11</sup>

Noting these recommendations, we aimed to (1) establish the proportion of lower gastrointestinal endoscopies and MREs performed at a tertiary UK centre that could be performed as IUS instead; (2) evaluate the potential pathology miss-rates if IUS was to be substituted for MRE and colonoscopy; and (3) calculate the potential cost savings.

## METHODS

### Study design and population

A single-centre, retrospective study was performed examining the potential role of IUS in place of MRE or lower gastrointestinal endoscopy in January 2018.<sup>12</sup>

All patients who underwent MRE were considered for IUS suitability. In patients undergoing lower

gastrointestinal endoscopy (colonoscopy or flexible sigmoidoscopy), only those in whom the procedure was performed for assessment of IBD activity or investigation of luminal gastrointestinal symptoms potentially consistent with inflammation were considered. Specific symptoms included diarrhoea, alternating diarrhoea and constipation, constipation, abdominal pain, or a combination thereof.

Demographics, indication for MRE/endoscopy, IBD history and characteristics, surgical history, and investigation findings were collected, including extraintestinal findings for MRE. Performance of biopsies, caecal and ileal intubation rates, and need for repeat procedure or subsequent imaging were also collected.

### IUS suitability criteria for MRE patients

Indications deemed suitable for IUS included assessment of activity of known small bowel CD, assessment for presence of small bowel disease in known IBD and investigation for small bowel disease in patients without known IBD. Factors rendering a patient unsuitable for IUS included obesity (body mass index (BMI) >30), complicated surgical history (more than one resection or strictureplasty involving different intestinal segments or presence of stoma) and known proximal small bowel disease.

### IUS suitability criteria for lower gastrointestinal endoscopy patients

IUS was considered suitable only in patients with IBD without the following characteristics: dysplasia surveillance or stricture dilatation, consideration of treatment withdrawal dependent on the result of the endoscopy, initial assessment of acute severe ulcerative colitis, history of isolated proctitis or performance of endoscopy as part of a trial. The performance of biopsies was not itself considered a factor deeming a patient with IBD unsuitable for IUS, given that histological remission is currently not a treatment target.<sup>13</sup>

In patients being investigated for symptoms, in order to exclude those who would likely undergo endoscopy regardless of IUS due to high pretest probability of malignancy or IBD, only those aged less than 40 without calprotectin >250  $\mu\text{g}/\text{mg}$ , C-reactive protein (CRP) >5  $\text{mg}/\text{L}$ , anaemia, rectal bleeding or documented family history of colorectal cancer were deemed appropriate for IUS. Patients with obesity or a complex surgical history were again considered inappropriate. Given microscopic colitis is rare in patients under 40, the need for biopsies to exclude this condition was not considered a criterion for unsuitability for IUS.<sup>14</sup>

### Statistical analysis

Descriptive statistics were used for demographic and clinical characteristics. Costing analysis was based on the following National Health Service tariff costs, inclusive of reporting, current as of February 2021: IUS £41; MRE £190; flexible sigmoidoscopy with biopsies £395; flexible

sigmoidoscopy without biopsies £310; colonoscopy with biopsies £528; and colonoscopy without biopsies £460. Our MRE protocol has been published elsewhere,<sup>15</sup> although the cine sequence is no longer performed routinely. Cost saving was generated by calculating the differential costs of the procedures performed compared with IUS and projected for the course of a year.

## RESULTS

### Patient characteristics

There were 260 lower gastrointestinal endoscopies performed in January 2018 for the purpose of IBD assessment (n=108, 41.5%) or investigation of gastrointestinal symptoms (n=152, 58.5%); patient characteristics are summarised in table 1. The majority (n=74, 68.5%) of IBD cases were being assessed for response to therapy, as opposed to investigation of clinical relapse (n=34, 31.5%). Adjunctive indications included dysplasia surveillance (n=27), planned dilatation (n=3) or performance as part of a trial (n=4).

Of patients being investigated for symptoms, primary symptoms included diarrhoea (n=77, 50.7%), constipation (n=17, 11.2%), alternating diarrhoea and constipation (n=29, 19.1%), and abdominal pain (n=78, 51.3%), the latter occurring with or without one of the other primary indications. Adjunctive case features included rectal bleeding (n=25, 16.4%), bloating (n=32, 21.1%), weight loss (n=23, 15.1%), elevated calprotectin (n=5, 3.3%), elevated CRP (n=23, 15.1%), anaemia (n=15, 9.9%) and family history of bowel cancer (n=11, 7.2%).

In the same period, 105 MREs were performed for all indications. Half of the scans were performed for assessment of known CD (n=53, 50.5%), while 19 (18.1%) were performed to assess for new small bowel inflammation in patients with IBD and 21 (20%) for investigation of gastrointestinal symptoms without a background of IBD; 12 (11.4%) were performed for other indications (table 1).

### Endoscopic examinations suitable for IUS

In total, 73 of 260 (28.1%) endoscopy patients met the criteria for IUS suitability (figure 1). These included 55 out of 220 colonoscopies (25%) and 18 out of 40 flexible sigmoidoscopies (45%), of which 23 of 55 and 7 of 18 cases, respectively, underwent biopsies. A larger proportion of IBD cases met the IUS criteria compared with patients being investigated for symptoms (46 of 108 (42.6%) IBD; 27 of 152 (17.8%) symptoms).

The reasons for unsuitability for IUS are summarised in table 2. The most common reasons for IUS unsuitability among patients with IBD included requirement for dysplasia surveillance (n=27, 25%), obesity (n=13, 12%) and consideration of withdrawal of treatment based on the endoscopy result (n=10, 9.3%). Among patients investigated for symptoms, age ≥40 (n=104, 68.4%) and obesity (n=28, 18.4%) were the most common reasons for IUS unsuitability.

**Table 1** Demographics of endoscopy and MRE cases

Variable	Endoscopy cases (n=260)	MRE cases (n=105)
Female, n (%)	137 (52.7)	57 (54.3)
Age, mean (SD)	45.9 (15.3)	38.4 (15.6)
Colonoscopies, n(%)	220 (84.6)	
Flexible sigmoidoscopies, n(%)	40 (15.4)	
Indication, n(%)		
Endoscopy		
Assessment of IBD activity	108 (41.5)	
Assessment of gastrointestinal symptoms	152 (58.5)	
MRE		
Assessment of Crohn's disease activity		53 (50.5)
Assessment for small bowel disease (previously not known)		19 (18.1)
Investigation of gastrointestinal symptoms without previous diagnosis of IBD		21 (20)
Other		12 (11.4)
Diagnosis of IBD, n (%)		
None	152 (58.5)	32 (30.5)
Crohn's disease	51 (19.6)	62 (59)
Ulcerative colitis	54 (20.8)	8 (7.6)
IBD-U	3 (1.2)	3 (2.9)
Crohn's disease cases, Montreal classification, n (%)		
Age		
A1	9 (17.6)	12 (19.4)
A2	37 (72.5)	44 (71)
A3	5 (9.8)	6 (9.7)
Behaviour		
Inflammatory	19 (37.3)	23 (38.3)
Strictureing	24 (47.1)	26 (43.3)
Penetrating	8 (15.7)	10 (16.7)
Location		
Ileal	15 (29.4)	20 (32.8)
Colonic	11 (21.6)	7 (11.5)
Ileocolonic	25 (49.0)	34 (55.7)
Perianal disease	12 (23.5)	17 (27.4)
Upper gastrointestinal disease	2 (3.9)	9 (14.5)
Ulcerative colitis/IBD-U cases, Montreal disease extent, n (%)		
Proctitis	9 (15.8)	2 (18.1)
Left-sided	21 (36.8)	3 (27.3)
Extensive	26 (45.6)	6 (54.5)
Body mass index, mean (SD)	26.6 (5.8)	25.0 (5.6)
Obesity, n (%)	41 (15.8)	14 (13.3)

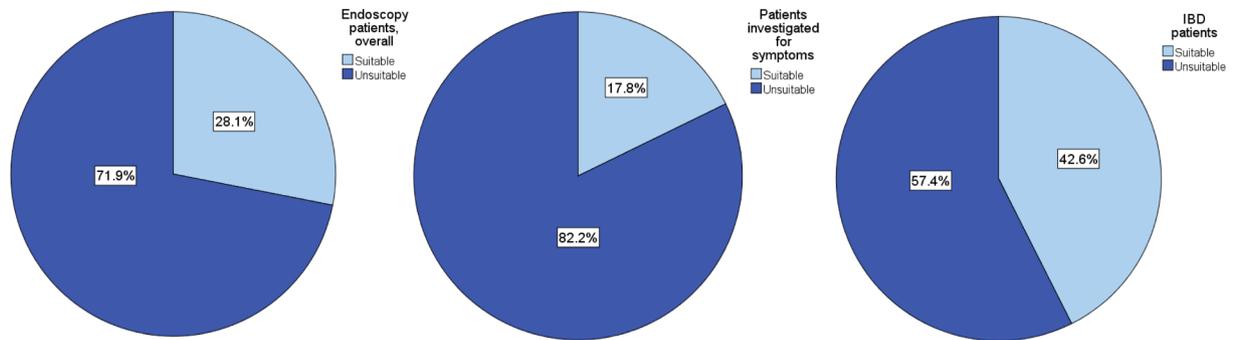
IBD, inflammatory bowel disease; IBD-U, inflammatory bowel disease unclassified; MRE, magnetic resonance enterography.

### Endoscopy findings

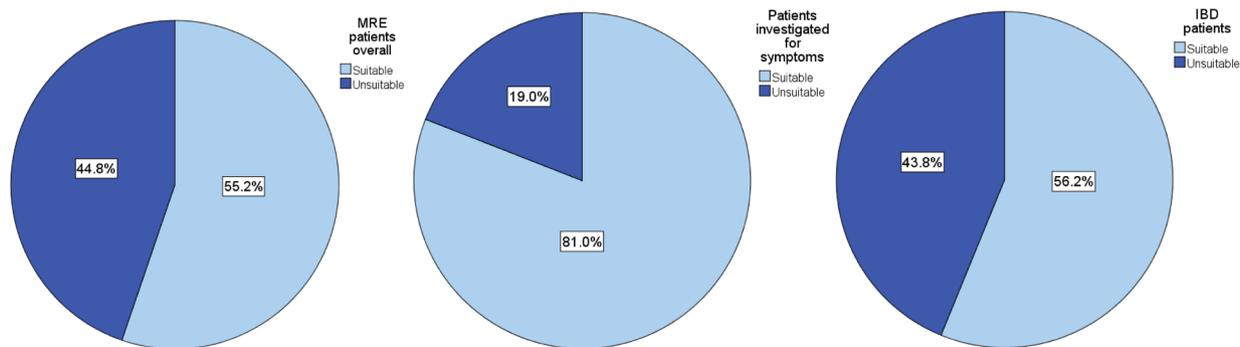
Out of 220 colonoscopies, the majority achieved caecal (n=207, 94%) and ileal (n=154, 70%) intubation. All flexible sigmoidoscopies were completed successfully.

Disregarding inflammation in patients known to have IBD, a significantly smaller proportion of IUS-suitable

## A. Endoscopy patients



## B. MRE patients



**Figure 1** Proportion of endoscopy (A) and MRE (B) patients suitable (light blue) and unsuitable (dark blue) for intestinal ultrasound, overall and stratified by pretest IBD status. IBD, inflammatory bowel disease; MRE, magnetic resonance enterography.

patients had pathology detected than those who were IUS-unsuitable (16.4% vs 35.8%,  $p=0.002$ ). The majority of findings in IUS-suitable patients were either of no or limited clinical significance (one case each of a <5 mm adenoma and <5 mm sessile serrated lesion), or would be expected to be found on IUS (new inflammatory stricture). In contrast, significant pathologies including malignancy ( $n=4$ ) and new diagnosis of IBD ( $n=8$ ) were found in IUS-unsuitable patients (table 3). Further, there were 19 cases with adenomatous polyps in the unsuitable group, including 5–10 mm ( $n=6$ ) or >20 mm ( $n=1$ ) polyps.

Among IUS-suitable patients being assessed for IBD activity, inflammation was detected endoscopically in ileal only ( $n=8$ ), colonic only ( $n=4$ ), ileal and rectal ( $n=1$ ), colonic and rectal ( $n=15$ ), and ileocolonic and rectal ( $n=1$ ) distributions. Importantly, there were no cases of isolated proctitis, a distribution likely to be missed with IUS.

A repeat colonoscopy was required in 10 (4.5%) patients, predominantly due to poor bowel preparation ( $n=8$ ); 3 of these patients met the criteria for IUS, none of whom had pathology detected on repeat colonoscopy. A CT pneumocolon was ordered for seven patients with incomplete procedures, none of whom met the criteria for IUS suitability. Of 39 patients who underwent an MRE within 3 months of endoscopy, 14

were suitable for IUS, potentially obviating the need for MRE in these patients as well.

**MRE examinations suitable for IUS**

Of 105 MREs performed, 58 (55.2%) met the criteria for IUS suitability. These included 26 (45.6%) for assessment of CD activity, 15 (26.3%) patients with IBD being assessed for presence of a new small bowel disease and 17 (29.8%) investigations for symptoms without a previous diagnosis of IBD (figure 1). The most common reason for IUS unsuitability was complex surgical history ( $n=18$ ), followed by obesity ( $n=14$ ) and non-inflammatory indication for scan ( $n=12$ ) (table 2).

**MRE findings**

With respect to IUS-suitable patients, 31 (53.4%) had inflammatory findings, including isolated ileal ( $n=18$ ), ileocolonic ( $n=6$ ) and isolated colonic ( $n=6$ ) inflammation. In one case of a new diagnosis of Crohn's being investigated for small bowel disease for the first time, both ileal and jejunal disease were found, the latter likely to be underappreciated with IUS. No cases of isolated upper gastrointestinal inflammation were found.

Extraluminal findings are summarised in table 3. There were a similar number of extraluminal findings

**Table 2** Reasons for unsuitability for intestinal ultrasound

Patient group	Reason for IUS unsuitability	Cases, n (%)
Endoscopy cases		
Assessment of inflammatory bowel disease	Surveillance	27 (25)
	Obesity	13 (12)
	De-escalation proposed	10 (9.3)
	Proctitis only	9 (8.3)
	Trial	4 (3.7)
	Complex surgical history	4 (3.7)
	Dilatation planned	3 (2.8)
	Stoma	2 (1.9)
Investigation of symptoms	Age $\geq$ 40	104 (68.4)
	Obesity	28 (18.4)
	Per rectal bleeding	25 (16.4)
	Elevated CRP	23 (15.1)
	Anaemia	15 (9.9)
	Family history of bowel cancer	11 (7.2)
	Elevated calprotectin	5 (3.3)
	MRE cases	
All	Complex surgical history	18 (37.5)
	Obesity	14 (29.2)
	Other indication	12 (25)
	Known upper gastrointestinal disease	9 (19.1)
	Stoma	5 (10.4)

CRP, C-reactive protein; IUS, intestinal ultrasound; MRE, magnetic resonance enterography.

in both IUS-suitable and IUS-unsuitable groups (24 findings in 21 IUS-suitable patients compared with 24 findings among 20 IUS-unsuitable patients). Among IUS-suitable patients, the majority of findings were either benign or expected to be seen on IUS (ie, diverticular abscess, periluminal collection and lymphadenopathy). In two IUS-suitable cases, pancreatic cysts were detected necessitating further investigation with serial MRIs and endoscopic ultrasound, yielding diagnoses of a side-branch intraductal papillary mucinous neoplasm and a benign serous cystadenoma. In one IUS-suitable case, multiple high T2 skeletal lesions were detected; these were deemed clinically insignificant following further investigation.

### Cost analysis

With a cost difference of £149 between IUS and MRE, the predicted potential saving in January 2018 if all IUS-suitable MRE patients (n=58) underwent IUS instead would be £8642. Projected annually, this equates to £103 704. With respect to colonoscopy, considering a cost difference with IUS of £487 or £419, depending on whether biopsies are taken, the predicted cost saving in January 2018 if all IUS-suitable colonoscopy patients underwent IUS instead is up to £25 866. For

**Table 3** New inflammatory and non-inflammatory MRE and endoscopic findings

Finding	Potential US cohort n=58	Non-US cohort n=47
<b>MRE cases</b>		
New small bowel inflammation	6	0
Diverticular abscess	1	0
Renal cortical atrophy	1	0
Prominent renal collecting system	0	1
Benign liver cyst(s)	3	4
Benign renal cyst(s)	3	0
Duplex kidney	1	0
Benign ovarian cyst(s)	3	0
Endometriosis	1	0
Periluminal collection	1	0
Small lymph nodes	4	1
Enlarged lymph nodes	1	3
Gall stones	1	0
Mesenteric panniculitis	1	0
Pancreatic pseudocyst	0	2
Non-suspicious pancreatic cysts	0	1
Pancreatic cysts requiring further investigation	2	0
Multiple high T2 axial skeleton lesions	1	0
Enterocutaneous fistula	0	1
Abdominal wall hernia	0	1
Multiple intra-abdominal abscesses	0	1
Intrahepatic and extrahepatic duct dilatation	0	1
Fatty liver	0	3
Adhesions	0	4
Fibroid uterus	0	1
<b>Endoscopy cases</b>		
Adenomatous polyps	1	19
Sessile serrated lesion	1	0
Haemorrhoids	2	8
Diverticular disease	1	21
Malignancy	0	4
Pseudopolyps	6	13
New inflammatory stricture	1	0
New diagnosis of IBD	0	8
Intestinal spirochaetosis	0	1
Mucosal prolapse	0	1
Lipoma	0	1
Microscopic colitis	0	0

IBD, inflammatory bowel disease; MRE, magnetic resonance enterography; US, ultrasound.

flexible sigmoidoscopy, considering a cost difference of £354 and £269 for biopsy-requiring and non-requiring procedures, respectively, the predicted cost saving for January 2018 is up to £5437. The projected annual cost saving if all IUS-suitable endoscopy cases

underwent IUS instead is £381 073; including MRE cases, the total annual projected saving is £484 777.

## DISCUSSION

This retrospective study provides insight into the proportion of MREs and lower gastrointestinal endoscopies at a large UK tertiary centre that could potentially be replaced with IUS; the associated cost savings suggest that a change in strategy is worth consideration. Over 50% of MREs and almost 30% of selected lower gastrointestinal endoscopies met our criteria for suitability for IUS, with predicted cost savings of almost £500 000 annually. Furthermore, when used in the clinical scenarios proposed in this specific cohort, incidental pathology predicted to be missed was of limited clinical significance.

Incorporating IUS into a gastroenterology service has a number of advantages. While different models of service delivery for IUS exist, it has the ability to be performed at point of care. This has several potential advantages, including immediate decision making in the case of an IBD flare<sup>16 17</sup>; endoscopic triage based on positive scans reducing diagnostic delay<sup>18</sup>; and avoidance of invasive tests in cases with low pretest probability.<sup>4 18</sup> Furthermore, considering the recent Selecting therapeutic targets in IBD (STRIDE) 2 recommendations for frequent endoscopic evaluation of IBD activity,<sup>13</sup> IUS provides an easily repeatable, objective measure of disease activity that does not burden overstretched endoscopy services. From a patient perspective, IUS is non-invasive, requires no bowel preparation, is better tolerated than MRE and colonoscopy, and may even add to the IBD-specific knowledge of patients with IBD.<sup>17 19–21</sup>

From a cost perspective, it is already recognised that an IUS-based diagnostic approach is significantly cheaper than MRE and endoscopy.<sup>22</sup> However, the current cost analysis highlights the magnitude of opportunity for financial savings. Set-up costs are limited; ultrasound machines are readily available at most centres, and while there are no published learning curve studies, 100 scans are estimated to be sufficient to obtain a minimum degree of proficiency.<sup>23</sup>

There are a number of barriers to overcome in order to incorporate IUS into a service. With regard to training, the International Bowel Ultrasound Group ([www.ibus-group.org](http://www.ibus-group.org)) has proposed a curriculum involving theoretical components, supervised hands-on training and a summative assessment<sup>4</sup>; unfortunately, there are currently no accredited training centres in the UK. Furthermore, a lack of awareness of the role of IUS among gastroenterologists restricts its use and acceptability in the UK and some other parts of the world.<sup>8 24</sup> While IUS is performed by gastroenterologists in some countries, in the UK ultrasound is traditionally the domain of radiologists and sonographers. However, an appetite for the technique among UK

gastroenterologists is growing<sup>8 25</sup> and a framework for establishing an IUS service has been proposed elsewhere.<sup>4</sup>

There are a number of limitations to this study. First, the cost analysis is an estimate, most accurately applicable to our centre. Predicted cost savings are dependent on case-mix and pricing and may also be influenced by factors not addressed within the methodology we used. However, we predict that there would be a role for IUS in most UK centres with associated cost savings. Second, the cost analysis does not include costs associated with IUS training, which would vary depending on specialty (radiology vs gastroenterology) and stage of training. However, akin to other countries, we predict this training could be incorporated into established specialty training programmes. Third, due to the retrospective nature of this study, the criteria used for IUS suitability among symptomatic endoscopy patients are necessarily conservative, with the emphasis being on selecting patients at low pretest probability of IBD in whom endoscopic exclusion of colonic malignancy was not required; these criteria need to be prospectively validated. Accordingly, there are likely to have been patients deemed IUS-unsuitable who may in fact have been suitable for IUS. Furthermore, while obesity may limit the utility of IUS due to the variability in sonographic properties of adipose tissue, there is currently no defined BMI cut-off at which point IUS is not recommended; hence, some such patients deemed unsuitable may, in reality, still have been suitable for IUS.<sup>4</sup> Finally, the costing analysis does not take into account the test characteristics of IUS, rather presenting a maximum estimated cost saving. In reality, some patients undergoing IUS may need a subsequent MRE or colonoscopy. These decisions will also be dependent on the managing clinician's confidence in the IUS result and hence whether further investigations are required; this is worthwhile exploring in future studies and may change as UK clinicians become more comfortable with IUS. However, the financial costs associated with doing extra tests are expected to be minimal relative to the overall savings.

In conclusion, this retrospective analysis of MRE and lower gastrointestinal endoscopy cases shows a significant potential role for IUS, with annual potential cost savings of up to almost £500 000 at our centre. Prospective validation of these findings would strengthen the financial case for incorporating IUS into clinical practice and should support the institution of training programmes in the UK.

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**Contributors** The study was conceived by RL, PMI, KBG and NG, with data collection performed by RL, BP, SM, SH and SZ. The data were analysed and the manuscript drafted by RL, KBG and PMI. All authors reviewed and approved the final version. PMI is the guarantor of the article.

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