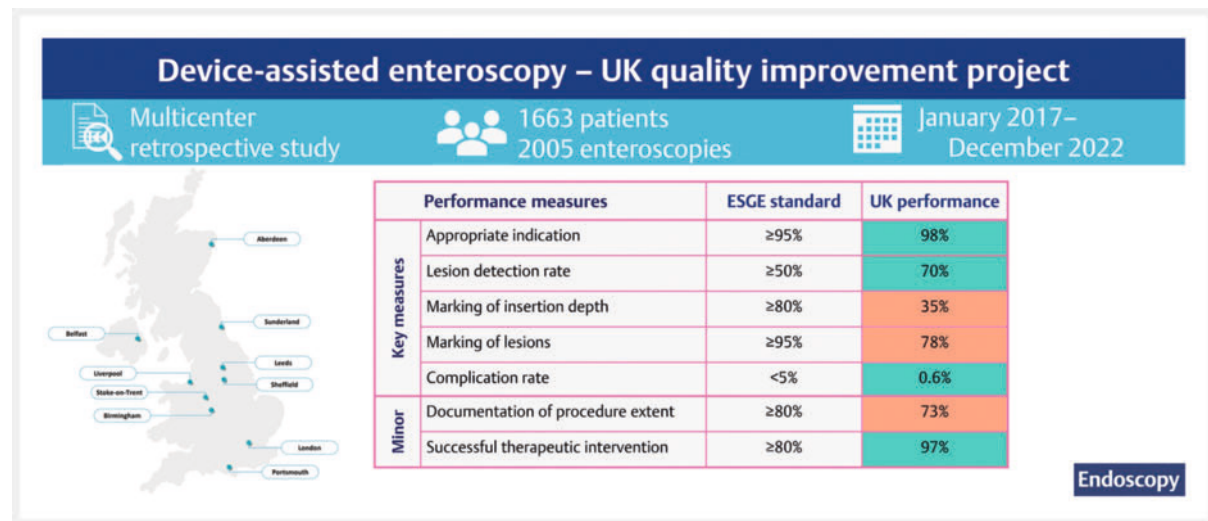


Device-assisted enteroscopy performance measures in the United Kingdom: DEEP-UK quality improvement project

GRAPHICAL ABSTRACT



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ABSTRACT

Background Device-assisted enteroscopy (DAE) has become a well-established diagnostic and therapeutic tool for the management of small-bowel pathology. We aimed to evaluate the performance measures for DAE across the UK against the quality benchmarks proposed by the European Society of Gastrointestinal Endoscopy (ESGE).

Methods We retrospectively collected data on patient demographics and DAE performance measures from electronic endoscopy records of consecutive patients who underwent DAE for diagnostic and therapeutic purposes across 12 enteroscopy centers in the UK between January 2017 and December 2022.

Results A total of 2005 DAE procedures were performed in 1663 patients (median age 60 years; 53% men). Almost all procedures (98.1%) were performed for appropriate indications. Double-balloon enteroscopy was used for most procedures (82.0%), followed by single-balloon enteroscopy (17.2%) and spiral enteroscopy (0.7%). The estimated depth of insertion was documented in 73.4% of procedures. The overall diagnostic yield was 70.0%. Therapeutic interventions were performed in 42.6% of procedures, with a success rate of 96.6%. Overall, 78.0% of detected lesions were marked with a tattoo. Patient comfort was significantly better with the use of deep sedation compared with conscious sedation (99.7% vs. 68.5%; $P < 0.001$). Major adverse events occurred in only 0.6% of procedures.

Conclusions Performance measures for DAE in the UK meet the ESGE quality benchmarks, with high diagnostic and therapeutic yields, and a low incidence of major adverse events. However, there is room for improvement in optimizing sedation practices, standardizing the depth of insertion documentation, and adopting marking techniques to aid in the follow-up of detected lesions.

Introduction

At the turn of the millennium, the introduction of the disruptive technologies of small-bowel capsule endoscopy (SBCE) and device-assisted enteroscopy (DAE) led to a paradigm shift in the diagnosis and management of small-bowel disease. While SBCE offers a noninvasive means to visualize of the entire length of the small bowel, DAE allows for detailed, direct endoscopic assessment of suspected lesions, the acquisition of targeted biopsies, and the delivery of endotherapy [1]. These two technologies, along with similar advances in dedicated small-bowel cross-sectional imaging, are complementary. Their tandem use, with SBCE and/or cross-sectional imaging often guiding the need for DAE, has revolutionized our minimally invasive endoscopic approach to the management of small-bowel pathology.

Since first described by Yamamoto et al. over two decades ago, the repertoire of DAE techniques has expanded to include double-balloon enteroscopy (DBE), single-balloon enteroscopy (SBE), manual spiral enteroscopy, and latterly motorized-spiral enteroscopy (MSE) [2, 3, 4]. DAE has become well established as the procedure of choice for patients requiring further endoscopic evaluation, biopsy, or endotherapy of small-bowel pathology. However, despite its increasing use in clinical practice, large-scale data regarding performance measures for DAE remain limited.

Key performance indicators (KPIs) have been established to improve and standardize the quality of care for several endoscopic procedures [5, 6, 7]. These KPIs provide endoscopy services and endoscopists with measurable benchmarks to audit their performance, identify areas for improvement, and ensure the delivery of consistent, high quality care. In 2019, the European Society of Gastrointestinal Endoscopy (ESGE) proposed a set of quality performance measures for small-bowel endoscopy [8]. Nonetheless, to date, no large-scale studies have evaluated the utility and impact of these performance measures in clinical practice.

The aim of the “DEEP-UK” quality improvement project was to evaluate the performance measures for DAE across the UK against the quality benchmarks proposed by the ESGE.

Methods

Study design and participants

This was a multicenter retrospective quality improvement project conducted at 12 enteroscopy centers in the UK, including England, Scotland, and Northern Ireland (► **Fig. 1**). All consecutive adult patients (≥ 18 years of age) who underwent DAE for diagnostic and/or therapeutic indications between January 2017 and December 2022 were included in the analysis. Endoscopy data from the participating centers are prospectively collected and uploaded to the National Endoscopy Database [9].



► **Fig. 1** A map of the UK showing the 10 cities where the 12 participating sites were located.

Demographic, clinical, and endoscopic data were extracted from electronic endoscopy databases in each center using a standardized Excel spreadsheet (Microsoft Co., Redmond, Washington, USA). Anonymized data from all centers were collated into a single database for the final analysis. The audit departments of all of the included sites approved the study (host site, Sheffield Teaching Hospitals; registration no. CEU 7073).

Performance measures

We compared the performance measures of DAE against the quality benchmarks proposed by the ESGE [8], and among the different centers to evaluate variations in practice. The performance measures of DAE in this study included: (i) indication for DAE; (ii) diagnostic and therapeutic yields; (iii) completeness of procedure; (iv) patient comfort; and (v) adverse events (AEs).

Patient comfort levels were recorded by the endoscopists immediately after the procedures and were assessed on a scale from 0 (comfortable) to 4 (severe discomfort). AEs during or after the procedures were classified as minor and major AEs. Minor AEs included self-limited or transient symptoms that did not require extended treatment or hospitalization. Major AEs included severe complications, such as perforation, bleeding, and pancreatitis, or unplanned hospital admission related to the procedure.

Statistical analysis

We used descriptive statistics to present the patient characteristics and procedural outcomes. Continuous data were expressed as the median and interquartile range (IQR), and categorical data were expressed as counts and percentages. Comparisons between categorical outcomes were performed using the Fisher's exact test or the chi-squared test, and between continuous variables using the Mann–Whitney *U* test. A two-tailed *P* value of <0.05 was considered significant. The variations in practice between different centers were assessed using funnel plots. No correction was done for multiple testing owing to the exploratory nature of the study and the high value of reporting rare outcomes. Statistical analyses were performed with Stata version 17 (StataCorp., College Station, Texas, USA).

Results

Patient characteristics

Between January 2017 and December 2022, a total of 1663 patients (53.1% men) underwent 2005 DAE procedures; their median age was 60 years (range 18–93 years), and 22.0% of patients had an American Society of Anesthesiologists (ASA) score of ≥ 3 . The most common medical co-morbidities were: hematological disease (44.0%), cardiovascular disease (27.4%), and respiratory disease (11.5%). In addition, surgically altered anatomy was present in 235 patients (14.1%), of whom 98 (41.7%) had undergone small-bowel resections. The characteristics of the patients are listed in ► **Table 1**.

DAE trends and indications

Royal Free Hospital, St. Mark's Hospital, and Sheffield Teaching Hospitals were the high volume centers. There was a large reduction in the number of annual procedures during the COVID-19 pandemic, which subsequently displayed a recovery trend and exceeded the prepandemic level by 2022 (► **Fig. 2**). Almost all procedures (98.1%, 95%CI 97.4%–98.6%) were performed for appropriate indications as published in international guidelines. Antecedent SBCE was performed in 56.1% of cases, and cross-sectional or magnetic resonance imaging in 51.1% of cases. The route of insertion was decided on the basis of prior imaging in 84.1% of cases. The most common indications for DAE were small-bowel bleeding (38.7%), tumors or polyps (21.1%), and suspected Crohn's disease (14.4%) (► **Table 1**).

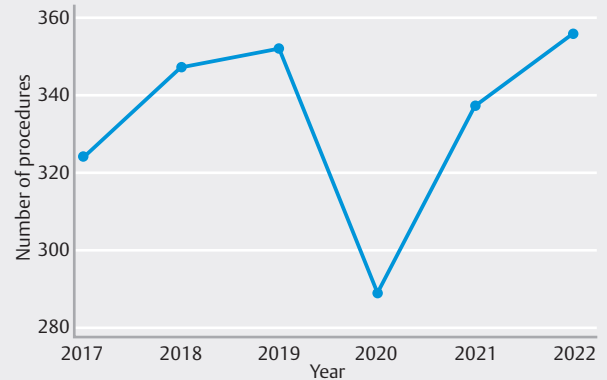
DAE procedures and technical success rate

DBE was used for most procedures (82.0%), followed by SBE (17.2%) and spiral enteroscopy (14 manual spiral enteroscopies and one MSE) (0.7%). The antegrade and retrograde routes were used in 73.7% and 25.9% of cases, respectively. Only eight procedures (0.4%) were performed with laparoscopic assistance (► **Table 2**). Hyoscine n-butyl bromide (median dose 20 mg) was used as an intravenous antispasmodic agent in 802 procedures (40%); glucagon (median dose 1 mg) was used as an alternative antispasmodic in 65 procedures (3.2%). The overall technical success rate was 98.0%. Failed procedures were

► **Table 1** Characteristics of the 1663 patients who underwent a total of 2005 device-assisted enteroscopies (DAEs), and the procedure indications.

Patient characteristics, and indications	
Sex, n (%)	
▪ Male	883 (53.1)
▪ Female	780 (46.9)
▪ Age, median (IQR), years	60 (44–71)
ASA score, n (%)	
▪ 1	595 (35.8)
▪ 2	701 (42.2)
▪ 3	348 (20.9)
▪ 4	19 (1.1)
Co-morbidities, n (%)	
▪ Hematological disease	732 (44.0)
▪ Cardiovascular disease	455 (27.4)
▪ Respiratory disease	192 (11.5)
▪ Liver disease	48 (2.9)
▪ Diabetes	184 (11.1)
▪ Cerebrovascular and neurological disease	81 (4.8)
▪ Polyposis syndromes	93 (5.6)
▪ Hereditary hemorrhagic telangiectasia	18 (1.1)
▪ History of gastrointestinal malignancy	59 (3.5)
▪ Surgically altered anatomy, n (%)	235 (14.1)
Medication, n (%)	
▪ Anticoagulation or antiplatelet therapy	147 (8.8)
Indication for DAE, n (%)	
▪ Small-bowel bleeding/anemia	775 (38.7)
▪ Small-bowel tumor or polyp	423 (21.1)
▪ Suspected Crohn's disease	289 (14.4)
▪ Established Crohn's disease	63 (3.1)
▪ Refractory celiac disease	31 (1.5)
▪ Stricture dilation	89 (4.4)
▪ Placement of PEJ	70 (3.5)
▪ Foreign body removal	19 (0.9)
▪ Access for altered anatomy for ERCP	1 (0.05)
▪ Other indications	245 (12.2)

IQR, interquartile range; ASA, American Society of Anesthesiologists; PEJ, percutaneous endoscopic jejunostomy; ERCP, endoscopic retrograde cholangiopancreatography.



► **Fig. 2** Line graph of the total number of device-assisted enteroscopies performed per year.

► **Table 2** Procedure characteristics and performance measures for device-assisted enteroscopy (DAE).

Procedure characteristics	
Type of enteroscopy, n (%)	
▪ Double-balloon enteroscopy	1645 (82.0)
▪ Single-balloon enteroscopy	345 (17.2)
▪ Spiral enteroscopy	15 (0.7)
Route of insertion, n (%)	
▪ Antegrade	1477 (73.7)
▪ Retrograde	520 (25.9)
▪ Laparoscopy assisted	8 (0.4)
Type of sedation, n (%) [*]	
▪ General anesthesia	956 (47.7)
▪ Deep sedation	404 (20.1)
▪ Conscious sedation	614 (30.6)
Patient comfort score, n (%) [‡]	
▪ 0, comfortable	604 (59.7)
▪ 1, minimal discomfort	214 (21.1)
▪ 2, mild discomfort	137 (13.5)
▪ 3, moderate discomfort	38 (3.7)
▪ 4, severe discomfort	18 (1.7)
Depth of insertion, median (IQR), cm	
▪ Antegrade approach (n = 1016)	180 (120–220)
▪ Retrograde approach (n = 456)	90 (50–150)
Procedure time, median (IQR), minutes	
▪ Antegrade approach (n = 748)	55 (39–76)
▪ Retrograde approach (n = 259)	50 (34–80)
Diagnoses, n (%)	
▪ Inflammatory lesions	510 (25.4)

► **Table 2** (Continuation)

Procedure characteristics	
▪ Vascular lesions	489 (24.4)
▪ Mass lesions	338 (16.9)
▪ Anatomical alteration	36 (1.8)
▪ Other diagnoses	12 (0.6)
▪ Normal	606 (30.2)
Therapeutic interventions, n (%)	
▪ Argon plasma coagulation	444 (22.1)
▪ Endoscopic clipping	244 (12.2)
▪ Polypectomy	184 (9.2)
▪ Stricture dilation	76 (3.8)
▪ PEJ insertion	70 (3.5)
▪ Adrenaline injection	49 (2.4)
▪ Foreign body removal	19 (0.9)
Adverse events, n (%)	
▪ Minor	32 (1.6%)
▪ Major	13 (0.6%)

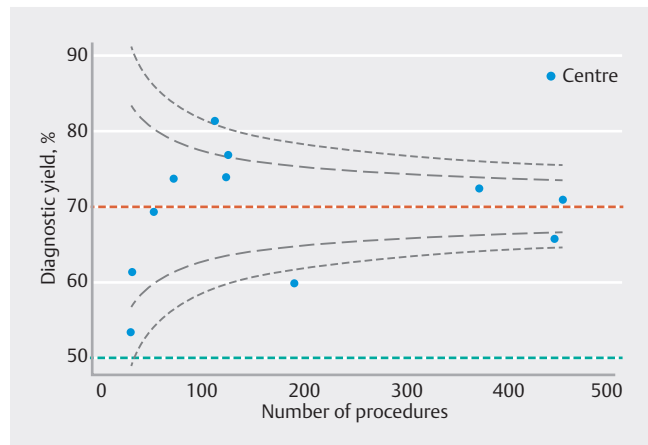
IQR, interquartile range; PEJ, percutaneous endoscopic jejunostomy.
 * Type of sedation not documented (n = 31).
 ‡ Procedures performed under general anesthesia or where sedation type was not documented were excluded; patient comfort score not documented (n = 7).

more likely to be retrograde than antegrade (5.7% vs. 1.0%; $P < 0.001$), owing to poor bowel preparation or excess looping.

Diagnostic and therapeutic yield

The overall diagnostic yield was 70.0% (95%CI 67.8%–72.0%), with evidence of variations between centers (► **Fig. 3**). Inflammatory lesions, such as ulcers, erosions, and strictures, were the most common findings (25.4%), followed by vascular lesions, such as small-bowel angioectasias and Dieulafoy lesions (24.4%), and polyps (11.0%) or other mass lesions (5.8%). Anatomical alterations, such as small-bowel/Meckel's diverticula, accounted for 1.8% of findings (► **Table 2**). Biopsies were obtained in 35.8% (95%CI 33.7%–38.0%) of procedures, and detected lesions were marked with a submucosal tattoo of sterile carbon particles in 78.0% (95%CI 69.4%–85.0%) of cases. There were no significant differences in the diagnostic yield between antegrade and retrograde procedures (70.4% vs. 68.2%; $P = 0.37$), nor between DBE and SBE procedures (70.0% vs. 69.3%; $P = 0.83$). The diagnostic yield of procedures performed for ESGE-guided indications for DAE was significantly higher than those performed for other nonspecific indications ($P < 0.001$) (**Table 1s**, see online-only Supplementary material).

Therapeutic interventions were performed in 855 procedures (42.6%, 95%CI 40.4%–44.8%) procedures and included argon plasma coagulation, endoscopic clipping, polypectomy, adrenaline injection, stricture dilation, direct percutaneous



► **Fig. 3** Funnel plot showing the variation in the diagnostic yield between centers, with the blue line representing the ESGE minimum quality standard and the orange line representing the overall diagnostic yield (centers with <10 procedures were excluded).

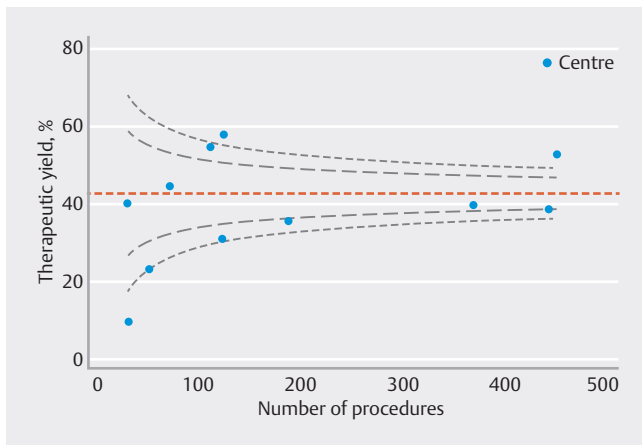
endoscopic jejunostomy insertion, and foreign body retrieval (► **Table 2**). There were variations in the therapeutic yield between centers (► **Fig. 4**). The overall therapeutic success rate was 96.6% (95%CI 95.1%–97.7%), based on intention to treat.

DAE procedure time and extent

The total procedure time was documented in 50.2% (95%CI 40%–52.4%) of cases. Where it was documented, the median time for procedures was of 54 minutes (IQR 37–78). Procedure time was not significantly different between antegrade and retrograde procedures ($P = 0.30$). The extent of the procedure was documented in 73.4% (95%CI 71.4%–75.3%) of cases, with a median depth of insertion of 160 cm (IQR 90–200). The estimated depth of insertion was 180 cm and 90 cm for the antegrade and retrograde procedures, respectively ($P < 0.001$). Total enteroscopy was achieved in 17 procedures (0.8%, 95%CI 0.5%–1.3%), of which six were in patients with previous small-bowel resections. The maximum point of insertion was marked with a tattoo in 34.5% (95%CI 32.4%–36.6%) of procedures.

Sedation and patient comfort

Almost half the DAE procedures were performed with the patient under general anesthesia (47.7%), while deep sedation with propofol and conscious sedation were used in 20.1% and 30.6% of cases, respectively (► **Table 2**). The median propofol dose was 902.5 mg (IQR 678.5–1148), with higher doses administered to younger patients (<70 years of age) compared with older patients (1055 mg vs. 784 mg; $P = 0.002$). The median midazolam dose was 4 mg (IQR 3–5) and, similarly, younger patients received higher doses than older patients (4 mg vs. 3 mg; $P < 0.001$). Additionally, the median dose of fentanyl was 75 mcg (IQR 50–100), with higher doses used for younger patients compared with older patients ($P < 0.001$). Poor patient tolerance limited 6% of the procedures performed under conscious sedation, despite a median midazolam dose of 4 mg and a median fentanyl dose of 75 mcg being used. Overall, patient comfort



► **Fig. 4** Funnel plot showing variation in the therapeutic yield between centers, with the orange line representing the overall therapeutic yield (centers with <10 procedures were excluded).

(comfort scores 0–1) was significantly better with the use of deep sedation than with conscious sedation (99.7% vs. 68.5%; $P<0.001$).

Adverse events

Minor AEs occurred in 32 cases (1.6%, 95%CI 1.0%–2.2%) and were mainly self-limited oxygen desaturation or bradycardia and hypotension secondary to sedation. Major AEs occurred in 0.6% (95%CI 0.3%–1.1%) of procedures; these included six cases of perforation, three of pneumonia requiring hospitalization, two of post-polypectomy bleeding, and one each of severe pancreatitis and unstable cardiac arrhythmia. Only one case of perforation was related to therapy (post-polypectomy); two occurred during the insertion or removal of the endoscope at the upper esophagus, and three after biopsy of friable malignant tissue.

Comparison between high volume and low volume centers

The overall diagnostic and therapeutic yields were comparable between the three high volume centers (>50 annual procedures) and the low volume centers (<50 annual procedures). However, at the high volume centers, a greater proportion of cases were found to have an appropriate indication, and to have had the depth of insertion and detected lesions marked with tattoos, and the procedure extent documented (**le 2s**).

Only 19.4% of procedures at high volume centers were performed with the patient under conscious sedation compared with 51.4% of procedures at low volume centers. Patient comfort at high volume centers was better than at low volume centers when conscious sedation was used (78.0% vs. 62.2%), but not when deep sedation was used (99.7% vs. 100%); however, deep sedation was used in only 3.7% of cases at low volume centers compared with 29.8% at high volume centers.

Discussion

This is the largest study to report DAE performance and outcomes, and the first multicenter study to evaluate the performance measures for DAE against the ESGE quality benchmarks. We included 1663 patients who underwent 2005 DAE procedures for diagnostic and therapeutic purposes across 12 enteroscopy centers in the UK. Although DAE had high diagnostic and therapeutic yields, with a low incidence of AEs, there was evidence of variations in practice and room for improvement in optimizing sedation practices, increasing standardization of depth of insertion documentation, and adopting marking techniques to aid in the follow-up of detected or treated lesions.

The overall diagnostic yield for DAE in our study was 70%, and all participating centers exceeded the ESGE minimum standard of 50%. A meta-analysis of early studies evaluating the performance of DBE over its first decade of use, reported a similar pooled diagnostic yield of 68.1% [10]. Furthermore, our findings confirm the results of a more recent meta-analysis by Lipka et al. [11], who found a comparable diagnostic yield between DBE and SBE procedures. The high diagnostic yield in our study can be attributed to two main factors: appropriate patient selection and the use of DAE as a second-line modality after abnormal SBCE or dedicated cross-sectional imaging findings. However, we observed variations in the diagnostic yield for DAE among centers, which ranged from 53.3% to 81.2%. This is consistent with the diagnostic yields for DAE reported in recent studies, which range from 59% to 76.5% [12, 13, 14, 15]. These variations are likely a reflection of the differences in diagnostic yield among the various indications for DAE and the different levels of experience between endoscopists. In the current study, adherence to the list of ESGE-guided indications for DAE was associated with significantly higher diagnostic yields compared with procedures performed for other nonspecific indications.

The rate of therapeutic intervention was not included in the ESGE performance measures owing to a lack of supporting data [8]. We found that therapeutic interventions were performed in 42.6% of procedures, with variations among centers, although only one center had a therapeutic yield of less than 20%. A recent multicenter study in the USA reported a higher rate of therapeutic interventions at 49.5% [14]. Therefore, the present data suggest that centers might aim for a minimum therapeutic yield of 20%.

There is a paucity of evidence regarding the number of DAE procedures required to achieve competence during training and the minimum number of annual procedures required to maintain competence [8]. An interesting finding in the current study is that the diagnostic and therapeutic yields of DAE were not directly related to the volume of procedures in each center, as shown in ► **Fig. 3** and ► **Fig. 4**. This suggests that other factors, beyond procedural volume, such as the endoscopists' experience in advanced upper and lower gastrointestinal endoscopy and appropriate patient selection may have a major influence on the outcomes of DAE.

The estimated depth of enteroscope insertion was reported in 73.4% of procedures, compared with the minimum ESGE standard of ≥80%. This benchmark was however based on very

low quality evidence as the estimated depth of insertion is often inaccurate in clinical practice and varies between endoscopists, despite early promising results of accurate estimations in porcine models [16, 17]. Similarly, submucosal tattooing of the point of maximal insertion in $\geq 80\%$ of procedures was proposed as a quality benchmark, but was performed in only 34.5% of procedures in our study. Moreover, tattooing of lesions that might require surgical intervention was performed in 78% of cases, compared with the minimum ESGE standard of $\geq 95\%$ [8]. These findings highlight areas for improvement in procedure documentation and marking techniques, to aid in the follow-up of detected or treated lesions.

The invasive nature of DAE coupled with the relatively long procedure time requires high doses of sedation to ensure patient comfort. A study of 956 patients undergoing different endoscopic modalities under conscious sedation showed that the tolerability of DBE was worse than other endoscopic modalities, including ERCP, despite high doses of sedation [18].

Conscious sedation was regularly used in our study; however, even with relatively high doses of midazolam and fentanyl, approximately a third of procedures were poorly tolerated by patients (comfort scores ≥ 2), and 6% of procedures had to be terminated early because of poor patient tolerance and withdrawal of consent. Conversely, almost all procedures performed under deep propofol sedation were well tolerated. In two previous multicenter studies in Portugal and the Netherlands, most DAE procedures were performed under anesthesiologist-administered propofol sedation [13, 19]. This highlights the varying practice approach in the UK with respect to using moderate sedation compared with other countries where monitored anesthesia care (MAC) is the preferred approach. While performing all DAE procedures under general anesthesia or propofol sedation poses a challenge in the UK because of the logistical complexities associated with the provision of MAC for advanced endoscopy, our results suggest that DAE should not be routinely performed with patients under conscious sedation.

We observed a low rate of major AEs (0.6%), which is well below the 5% benchmark proposed by the ESGE. This rate is comparable with pooled AE rates from meta-analyses and more recent multicenter studies from Portugal and the USA [10, 11, 13, 14]. Such findings reinforce the high safety profile and low complication rate of DBE and SBE procedures, and support adopting a lower major AE benchmark in future guidelines. There was only one MSE procedure in our study, and this resulted in an upper esophageal perforation on withdrawal of the device. MSE has not been used in the UK following this unfortunate incident. A case-matched study comparing MSE and DBE found that MSE did not offer diagnostic or therapeutic advantages over DBE, and was associated with more frequent AEs [20]. More recently, serious safety concerns, including fatalities, with regard to the MSE device have led to its withdrawal and recall from clinical practice and the market worldwide [21].

There are several strengths to our study. First, we provide a comprehensive overview of small-bowel endoscopy practices in the UK, which captures the impact of the COVID-19 pandemic on enteroscopy services and the road to recovery over the last 3 years. Second, this is the first study to evaluate performance

measures for DAE against the ESGE quality benchmarks with >2000 procedures performed across 12 different sites. Third, we showed that variations in practice exist between different centers. Fourth, we provided evidence to support the use of general anesthesia or deep sedation over conscious sedation for DAE. Importantly, the results of this study set an evidence-based framework for the development of future performance measures and challenge some of the existing quality benchmarks for DAE, akin to the precedent set with SBCE [22].

The limitations of this study include the retrospective nature of the analysis, which has inherent limitations, such as the presence of confounding factors and selection bias. The lack of adequate sedation in a proportion of procedures in the current study may have influenced the length of small-bowel explored and, consequently, the diagnostic and therapeutic outcomes of these procedures. Furthermore, our study focused on assessing patient comfort levels during DAE procedures as recorded by the endoscopists, which may have introduced further bias. Future prospective studies should use validated questionnaires, such as the Global Rating Scale (GRS), to gain a more comprehensive understanding of overall patient experience [23].

Another important limitation that should be considered when interpreting the results of this study is that some patients underwent repeated DAE procedures, which means that not all observations were statistically independent. However, each endoscopic procedure is inherently unique and all established performance measures in endoscopy account for the total number of procedures, including repeated procedures, as certain findings, therapies, or complications may have occurred in only one of several endoscopies a patient has had over an extended period of time. Therefore, correcting for multiple testing might have provided misleading results for rare outcomes such as DAE complications. Finally, we were unable to assess the rates of accurate photodocumentation and the quality of bowel preparation, both of which are minor performance indicators for DAE [8].

In conclusion, DEEP-UK is the first study to evaluate the performance measures for DAE against the ESGE quality benchmarks. DAE performance measures in the UK meet the ESGE standards with high diagnostic and therapeutic yields, and a low complication rate; however, variations in practice exist between different centers, highlighting potential areas for quality improvement.

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Conflict of Interest

E.J. Despott has received educational and travel grants and speaker's honoraria from Fujifilm, Aquilant, Diagmed, Laborie, and Medtronic (2007 to present); his department has received educational grants from Fujifilm, Pentax, Olympus, ERBE, Norgine, and Medtronic (2012 to present). The remaining authors declare that they have no conflict of interest.

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