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The Utility of Magnetic Resonance Enterography and Double Balloon Enteroscopy-Assisted Endoscopic Balloon Dilatation for Small Bowel Strictures in Crohn's Disease: A Retrospective Observational Study

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Keywords
Crohn's disease · Magnetic resonance imaging · Double balloon enteroscopy · Small bowel · Stricture

Abstract

Introduction: Crohn's disease (CD) of the small bowel is associated with a severe course and increased risk of complications. Strictures at this location are challenging to diagnose and out-of-reach of colonoscopy. We aimed to evaluate the detection rate of small bowel strictures with magnetic resonance enterography (MRE) and assess the efficacy of double balloon enteroscopy-assisted endoscopic balloon dilatation (DBE-assisted EBD) in managing these strictures. ***Methods:*** A retrospective study included all patients with DBE-assisted EBD of small bowel strictures in CD in our facility. All patients had MRE to detect strictures prior to the dilatation. Sequential dilatation protocol was performed using through-the-scope (TTS) working channel balloons. The outcomes included technical success defined by the passage of the enteroscope post-dilatation, resolution of symptoms, and the requirement of repeated procedures or surgery during 12 months of follow-up. ***Results:*** Twenty DBE-assisted EBDs of small bowel strictures were attempted during 13 DBE procedures in 10 patients (6 males, median age 42). MRE identified 75% of the strictures with 100% accuracy in localisation. Retrograde DBE was the approach in 16/20 (80%) strictures. Anaesthetic intubation was used in 8/20 (40%). DBE reached 19/20 strictures. All the reached strictures were dilated successfully; the technical success following dilatation was 72.2%. The median DBE insertion time with TTS balloon dilatation was 66 min. Three patients required follow-up dilatations within 2–3 months. Surgery was not needed during the follow-up period. ***Conclusions:*** MRE is essential in diagnosing and localising small bowel strictures in CD. DBE reached 95% of strictures with successful dilatation. Immediate technical success was high, and safety was demonstrated. Planned repeat procedures for sequential dilatation were performed in a few patients. Surgical resection was avoided in all patients.

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Introduction

Crohn's disease (CD) is an inflammatory bowel disease characterised by its chronic, relapsing-remitting nature that can affect any part of the gastrointestinal tract, from the mouth to the anus. The Montreal revision of the Vienna classification is considered the main classification system for CD. It classifies the disease according to age at diagnosis, location, and disease behaviour [1, 2]. The prevalence of patients with CD involving the proximal gastrointestinal tract is reported to be between 8 and 19% of all patients [3]. CD in these patients involves the esophagogastroduodenum in 51% of the patients, small bowel in 33%, and a combined involvement in 16%. They have a concurrent Montreal L1–L3 disease in 93% of the cases [4].

Up to 50% of all patients with CD develop stricturing or penetrating intestinal complications 20 years after diagnosis [5]. Involvement of the proximal gastrointestinal tract is a known predictor of more severe disease with a higher rate of adverse events and recurrence, and they tend to have a more stenosing and stricturing (Montreal B2) behaviour [6]. Additionally, real-world data show that patients with fibro-stenotic disease had overall higher healthcare utilisation costs, including a higher risk of hospitalisation, repeated endoscopy, and abdominal surgery [7]. Medical therapy, such as biological agents, can alleviate inflammation but cannot resolve fibro-stenotic strictures completely [8]. Thus, endoscopic balloon dilatation (EBD) and surgery remain the cornerstone treatments despite a high recurrence rate, which indicates the need to refine our approach to managing CD strictures [9]. With the advent and availability of new technologies, primarily diagnostic and therapeutic modalities, precise assessment of small bowel involvement in CD is considered an objective goal, aiming for mucosal or transmural healing as the ultimate target [10].

Magnetic resonance enterography (MRE) has evolved over the last 2 decades, and it is considered the preferred imaging modality to assess stricturing small bowel disease in CD; it identifies the presence of adverse events (e.g., fistulae and perforations). The advantages of MRE include precise evaluation of disease activity, differentiating between inflammatory and fibrous strictures and avoiding radiation exposure. Its widespread use is limited by cost, availability, and the expertise required to interpret the images [11, 12]. A prospective study from Japan of 100 patients reported the sensitivity and specificity of MRE in detecting CD-related active lesions and stenoses compared to enteroscopy performed within 3 days. MRE was an advantageous, non-invasive tool in detecting ulcerative lesions (sensitivity 82.4, specificity 87.6%) and all mucosal lesions (sensitivity 67.5, specificity 94.8%) in the small intestine. However, a disadvantage of MRE was the low detection rate of major stenosis (sensitivity 58.8, specificity 90.0%) and all stenoses (sensitivity 40.8, specificity 93.7%). The low detection rate of stenoses was thought to be related to the lack of proper distension of the small bowel during MRE in some patients. This observation concluded that enteroscopy remains the gold standard in detecting stenoses, especially when there is a high clinical suspicion [13].

Double balloon enteroscopy-assisted endoscopic balloon dilatation (DBE-assisted EBD) has become a popular intervention for managing CD-associated small intestinal strictures in the past 2 decades. It is safe, efficacious, and minimally invasive [14]. It is the first-line management of strictures 4–5 cm long. EBD improves the symptoms of obstruction associated with small bowel strictures and can be repeated safely without the risk of short bowel syndrome and with less peri-procedural morbidity and mortality compared to surgery; this is of particular importance in conditions like CD, where it is incurable and relapsing.

We aim to review the utility, safety, and efficacy of the conjugate use of MRE and DBE-assisted EBD in patients with small bowel CD strictures in our facility. We will specifically assess the detection rate of small bowel strictures by MRE compared to enteroscopy, the safety of DBE-assisted EBD, and the requirement for repeated procedures or surgery during the follow-up period.

Methods

This was a retrospective study of DBE-assisted EBD for small bowel CD strictures. We searched the endoscopy unit database (Endobase) at Macquarie University Hospital for all adult patients who underwent the procedure for over 12 months between July 2022 and July 2023. Patients with small bowel strictures secondary to other causes and patients under 18 years old were excluded; there were no other specific exclusion criteria. We obtained the corresponding MRE studies and baseline patient characteristics, including obstructive symptoms, use of biological agents, and history of previous surgical resection. Then, we reported follow-up based on clinic visits for 12 months.

As a standard of care, all patients had MRE within 3 months prior to the intervention, and their presentation was discussed in a multi-disciplinary team (MDT) meeting with a consensus to proceed with DBE-assisted EBD. The DBEs were performed by one enteroscopist who decided on the DBE approach; strictures in the jejunum and proximal ileum were approached through antegrade DBE, while more distal strictures were approached retrograde. A therapeutic Fujifilm enteroscopy with a controlled radial expansion wire-guided balloon dilator was used for dilatation; the duration of dilatation was 60 s. DBE-related extracted

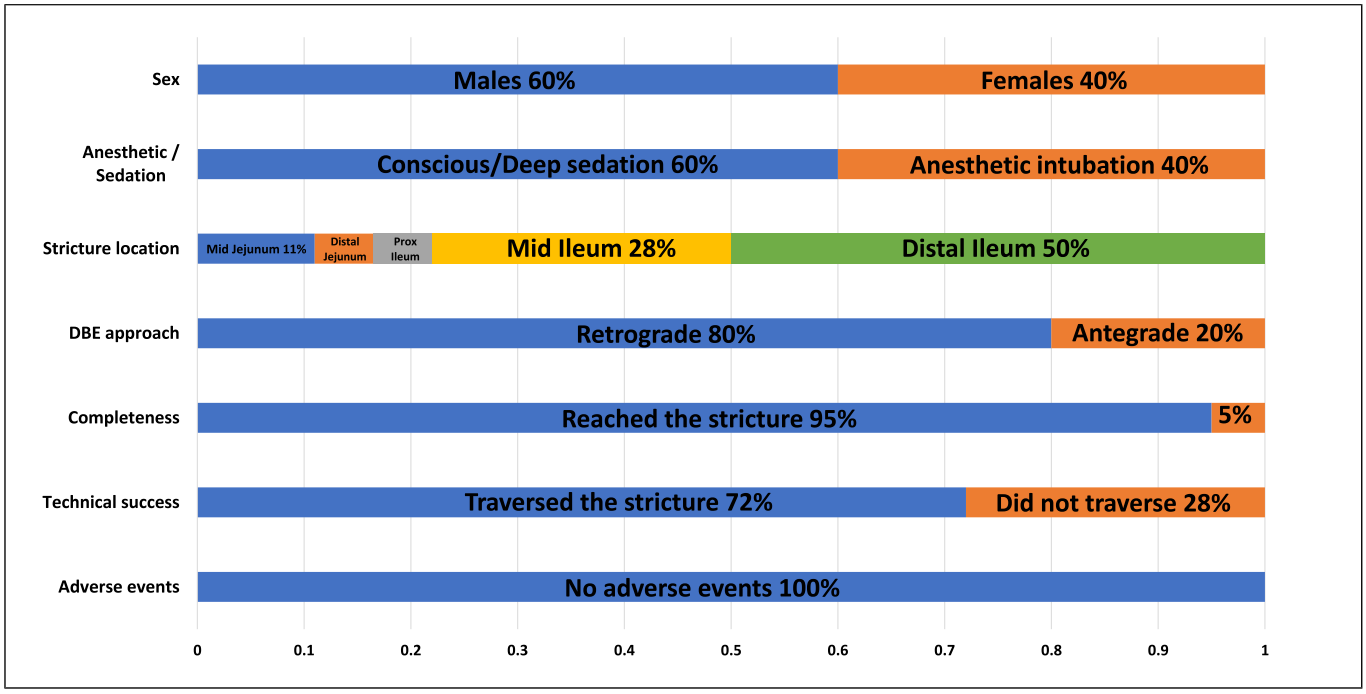

Fig. 1. Patient characteristics and outcomes of DBE-assisted EBDs for CD small bowel strictures.

data included the balloon enteroscopy approach, type of anaesthetics used, completeness of the procedure (defined as reaching the intended stricture area), number of strictures per patient, the diameter of dilatation, and adverse outcomes. DBE-assisted EBD was performed sequentially for 3 mm above the estimated diameter; in cases where the achieved dilatation was less than 15 mm, a staged repeat DBE-assisted EBD was planned in a few months following the initial procedure.

We compared the details and findings of DBE and MRE. The detection rate of small bowel strictures by MRE was assessed (using cine motility, coronal and axial T2 HASTE, coronal T2FS HASTE, axial DWI, T1 DIXON, pre- and contrast-enhanced coronal and axial T1 VIBE). The short-term outcome of DBE-assisted EBD was the passage of the enteroscope post-dilatation (technical success); the longer term outcome was the resolution of symptoms and avoidance of surgery.

This study was approved by the Clinical Innovation and Audit Committee (CIAC) at Macquarie Health. Pearson's correlation coefficient (Pearson's r) and independent sample *t* test were used to correlate between variables. A p value of <0.05 was considered statistically significant. IBM SPSS 29 (Armonk, NY, USA) was used for statistical analysis. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement guidelines were used to report this study.

Results

A total of 10 patients (6 males, median age of 42 with an age range between 31 and 77 years) underwent 13 DBE procedures, and 18 DBE-assisted EBDs of small bowel strictures were performed (mean number of stricture dilatation per patient 1.8). All patients had follow-up clinic visits for a minimum of 12 months. The summary of the main results is shown in Figure 1.

Out of the 18 stricture dilatations, one stricture was dilated on two occasions, and another was dilated three times. One patient had per rectal bleeding noted during the bowel preparation before the procedure; retrograde DBE then identified a bleeding ulcerated stricture; dilatation was not performed at this stricture (shown in Fig. 2). A second patient had a retrograde DBE that could not reach the stricture due to looping and technical difficulties. This brings the total number of strictures attempted to be dilated to 20.

Seven patients had previous surgical resections to manage CD-related adverse events. All patients were treated with biological agents, either infliximab or ustekinumab; none were prescribed small-molecule medications. Obstructive symptoms related to the strictures were present in 7/10 patients. The other 3 patients underwent dilation as a planned procedure; two of them had previous strictures with perforations requiring surgical resection, and one had a fistulising disease related to the stricture. Table 1 shows patient characteristics.

MRE identified 15/20 (75%) of the strictures; three strictures were at previous surgical anastomosis, while twelve were de novo strictures. The median stricture

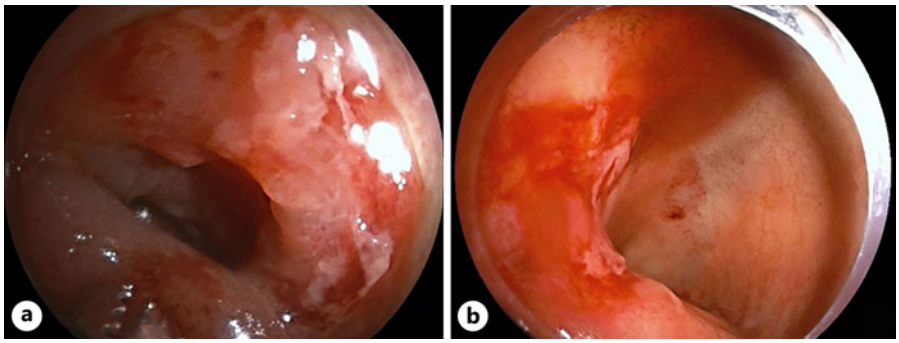

Fig. 2. a, **b** An ulcerated stricture with active oozing; no intervention was performed at this stricture. The patient was treated with intravenous hydrocortisone, which stopped the bleeding. The patient continued ustekinumab medical therapy and is scheduled for a repeat retrograde DBE with EBD.

length on MRE was 4 cm (a range between 1.5 and 7 cm). All the strictures were associated with upstream dilatation, indicating a mechanical obstruction; the median dilatation was 4 cm (a range between 3.6 and 8 cm). The simplified MARIA score in 8/15 strictures was ≤1, indicating a fibrotic stricture with no disease activity, and seven strictures had a score of ≥2, indicating an inflammatory stricture with active CD-related inflammation. MRE was excellent in identifying the location of the strictures; Pearson's r between the location of strictures found on MRE and its site on DBE was 1 (p value <0.001). Upstream dilatation on MRE was significantly correlated with the location of the stricture (Pearson's r −0.800, p value 0.003), with proximal jejunal strictures having minimal dilatation while strictures in the distal jejunum and proximal ileum having more dilated loops of up to 6–8 cm (shown in Fig. 3). MRE did not detect five strictures (false-negative rate of 25%), and these patients underwent DBE due to high clinical suspicion. Two of the five missed strictures were associated with a complex ileal segment due to fistulation between the ileum and the sigmoid; MRE showed the fistulisation (shown in Fig. 4). The other three missed strictures were mid-ileal strictures that were not visualised on MRE despite a good quality imaging. On MRE, the radiological definition of a stricture is a segment of narrowing associated with unequivocal upstream small bowel dilatation of more than 3 cm. It is a known limitation of MRE that in cases of multiple strictures, a downstream stricture may not be associated with bowel dilatation. Therefore, this is the likely explanation for not visualising all strictures in these 2 patients. Table 2 shows MRE findings for each patient.

Retrograde DBE was the approach in 16/20 (80%) of the strictures. DBE reached 19/20 strictures (95%); this was assessed based on reaching the stricture location seen on MRE. Anaesthetic intubation was used in 8/20 (40%) of all the procedures. Dilatation was performed in the mid jejunum (2 strictures, 11.1%), distal jejunum (one stricture, 5.5%), proximal ileum (one stricture, 5.5%), mid ileum (5 strictures, 27.9%), and distal ileum (9 strictures, 50%). All strictures were dilated sequentially by 3 mm; the median diameter of dilatation was 12 mm (a range between 9 and 18 mm). Technical success following dilatation was achieved in 13/18 strictures (72.2%). Ulceration at the stricture site was present in 14/18 strictures, and one stricture was associated with a fistula (shown in Fig. 5); all these strictures were dilated successfully. The median DBE insertion time with EBD was 66 min. No immediate or delayed adverse events were reported, and all patients tolerated the procedure well. Table 3 shows the DBE features of each stricture.

All symptomatic patients had improvement of their symptoms post-dilatation on follow-up for a minimum of 12 months. All patients avoided surgery during the period of follow-up, with only 3 patients (5 strictures) having planned follow-up dilation within 3 months of the previous dilatation; one stricture could not be reached on repeated retrograde DBE, the patient remained well and is planned for further intervention, two strictures were patent and traversed without intervention, and the other two were dilated to a larger diameter. Technical success did not have a statistically significant correlation with different variables, including the length of the stricture on MRE (p value 0.658), the maximum diameter of dilatation (p value 0. 058), DBE approach (p value 0.572), location of the strictures (p value 0.267), sMARIA score (p value 0.269), whether de novo or anastomotic stricture (p value 0.695).

Discussion

Small bowel strictures secondary to CD have been complex to diagnose and manage. Surgical resection, with its associated peri-operative risks, was the only available

Table 1. Characteristics of patients who underwent DBE-assisted EBD

Patient No.	Age	Sex	Obstructive symptoms	Use of biologics	Previous bowel resection
1	58	M	No	Yes	Yes
2	42	M	No	Yes	No
3	35	M	Yes	Yes	Yes
4	42	F	Yes	Yes	Yes
5	48	M	Yes	Yes	Yes
6	77	M	Yes	Yes	No
7	47	F	Yes	Yes	No
8	31	M	No	Yes	Yes
9	58	F	Yes	Yes	Yes
10	32	F	Yes	Yes	Yes

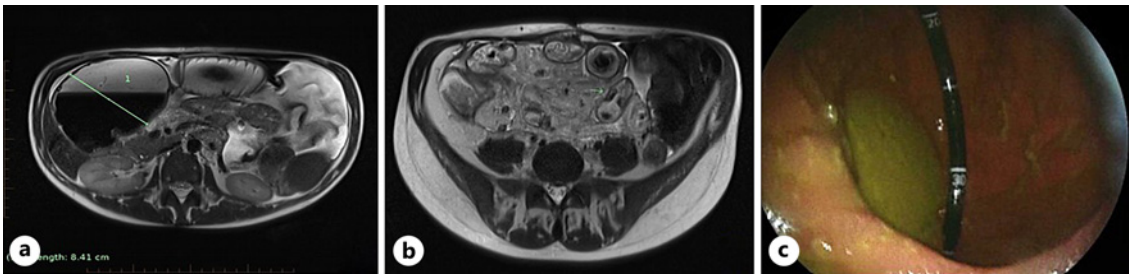

Fig. 3. a Axial T2 sequence showing upstream jejunal dilatation of 8 cm proximal to a stricture in the distal jejunum (green measurement marker). **b** An axial T2 sequence shows one of the many strictures in the ileum with a concentric bowel wall thickening (green arrow). **c** Endoscopic images showing the ability of the enteroscope to retroflex in the severely dilated segment.

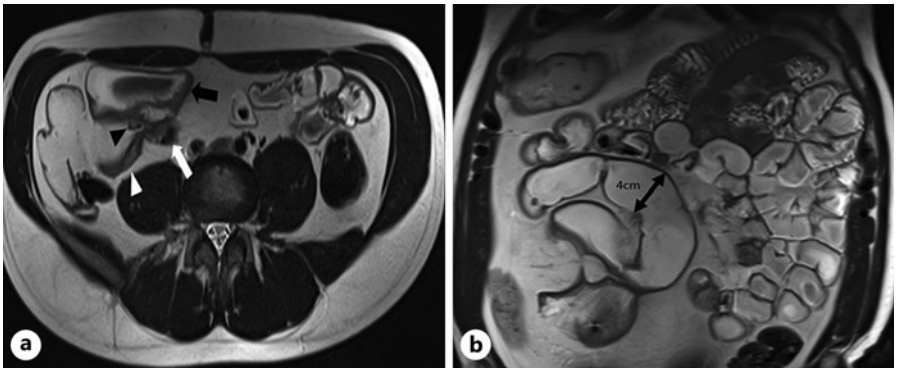

Fig. 4. a Axial T2 sequence demonstrating fistulation (black arrowhead) between the terminal ileum (white arrowhead), distal ileum (black arrow), and the sigmoid colon (white arrow). **b** Coronal T2 sequence demonstrating upstream ileal dilatation to 4 cm proximal to the stricture (black arrow).

option for managing symptomatic strictures for decades, but the increasing use of MRE and DBE-assisted EBD has transformed the management approach to this condition.

Traditionally, surgical management of small bowel CD involves small bowel resection or strictureplasty [15]. Small bowel resection is considered the first-line surgical approach and is the more common of the two procedures. It has good outcomes in isolated mild ileocolonic CD [16]. This does not necessarily apply to patients with a more proximal disease, where patients usually have a multifocal disease with short strictures distributed over multiple segments in the jejunum and ileum; these patients require extensive resections of large portions of their small bowel. Major adverse event rate of surgical management for CD can be as high as 20% [17], including abscess formation or

Table 2. Details of the strictures and other findings on MRE for each patient

Patient No.	Strictures, *n*	Location	Stricture length	Type	Upstream dilatation	De novo versus anastomotic	sMARIA score
1	1[a]	Distal ileum	2 cm	Fibrotic	3.7 cm	Anastomotic	1
2	1[b]	Distal ileum	N/A	Inflammatory (with fistula)	3.7 cm	De novo	4
3	3[c]	Mid jejunum and ileum	N/A	Inflammatory	4 cm	De novo	5
4	12[d]	Jejunum and ileum	1.5 cm[d]	Fibrotic	8 cm	De novo	0
5	2	Distal ileum	6 cm and 3 cm	Fibrotic	5 cm and 3.6 cm	Anastomotic and de novo	1
6	Not seen on MRE	N/A	N/A	N/A	N/A	N/A	N/A
7	1	Mid ileum	5 cm	Fibrotic	Yes, not measured	De novo	1
8	1	Distal ileum	5 cm	Inflammatory	Yes, not measured	De novo	2
9	1	Distal ileum	2.5 cm	Fibrotic	Yes	De novo	0
10	1	Distal jejunum	7 cm	Fibrotic	6.6 cm	De novo	1

[a]Failed to reach this stricture on a second occasion due to looping and technical difficulties. [b]This stricture was dilated on two occasions. MRE did not find the other two strictures of this patient that were found on DBE. [c]One of the strictures was dilated on two occasions. [d]The length of the dilated stricture.

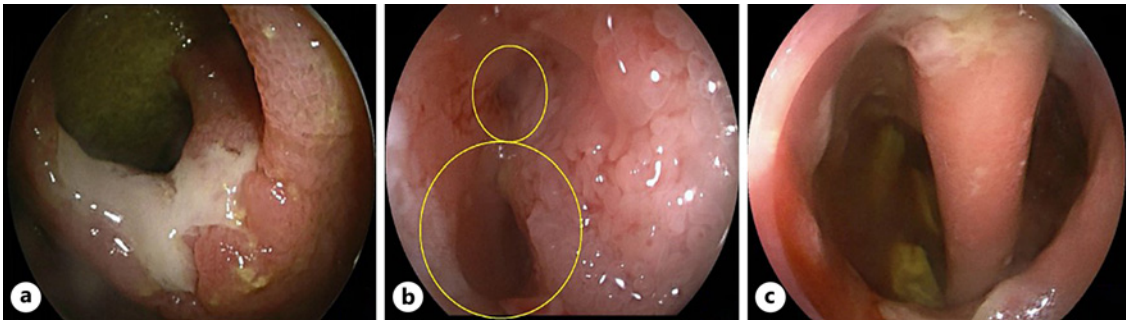

Fig. 5. a Severely ulcerated stricture in the distal ileum. **b** Strictured lumens in the distal ileum prior to dilatation. **c** After dilatations of both strictures, multiple lumens were found, including the ileal lumen and a fistular lumen connected to the sigmoid.

fistulisation, anastomotic leak, recurrence post-resection, and further requirement for surgical management and resection with consequent short bowel and malabsorption syndromes. Strictureplasty is considered a second-line surgical procedure for a recurrent disease where bowel preservation is a priority; it is reported to have a postoperative adverse event rate of 10–13%, including fistula formation, abscess development, gastrointestinal bleeding, and wound infection. The recurrence rate post-strictureplasty and the need for re-operation at the same or a different site are around 25% [18, 19].

Table 3. Details of the DBE-assisted EBD

Patient no.	Stricture	DBE approach	Anaesthetics[a]	Completeness	Location	Extra features	Maximum dilatation	Technical success	Adverse outcomes	Insertion time
1	1A	Retrograde	Deep sedation	Yes	Distal ileum	Ulceration	9 mm	No	No	120 min
	1A (re-dilatation	Retrograde	Deep sedation	No	Distal ileum	N/A	N/A	N/A	N/A	111 min
2	2A	Retrograde	GA	Yes	Distal ileum	Nil	12 mm	Yes	No	55 min
	2B	Retrograde	GA	Yes	Distal ileum	Fistula, ulceration	12 mm	Yes	No	
	2C	Retrograde	GA	Yes	Distal ileum	Nil	12 mm	No	No	
	2B (re-dilatation)	Retrograde	GA	Yes	Distal ileum	Fistula, ulceration	15 mm	Yes	No	48 min
3	3A	Retrograde	Conscious sedation	Yes	Mid ileum	Ulceration	10 mm	No	No	66 min
	3A (re-dilatation)	Retrograde	Deep sedation	Yes	Mid ileum	Ulceration	12 mm	No	No	40 min
	3B	Antegrade	GA	Yes	Mid jejunum	Ulceration	12 mm	Yes	No	
	3C	Antegrade	GA	Yes	Mid jejunum	Ulceration	11 mm	Yes	No	
4		Antegrade	GA	Yes	Proximal ileum	Ulceration	12 mm	Yes	No	74 min
5	5A	Retrograde	Conscious sedation	Yes	Distal ileum	Nil	15 mm	Yes	No	43 min
	5B	Retrograde	Conscious sedation	Yes	Distal ileum	Nil	15 mm	Yes	No	
6	6A	Retrograde	Conscious sedation	Yes	Mid ileum	Ulceration	11 mm	Yes	No	64 min
	6B	Retrograde	Conscious sedation	Yes	Mid ileum	Ulceration	11 mm	Yes	No	
	6C	Retrograde	Conscious sedation	Yes	Mid ileum	Ulceration	12 mm	Yes	No	
7		Retrograde	Deep sedation	Yes	Proximal ileum	Actively bleeding	N/A	N/A	N/A	82 min
8		Retrograde	Conscious sedation	Yes	Distal ileum	Ulceration	10 mm	Yes	No	74 min

Table 3 (continued)

Patient no.	Stricture	DBE approach	Anaesthetics[a]	Completeness	Location	Extra features	Maximum dilatation	Technical success	Adverse outcomes	Insertion time
9		Retrograde	Conscious sedation	Yes	Distal ileum	Ulceration	18 mm	Yes	No	34 min
10		Antegrade	GA	Yes	Distal jejunum	Ulceration	10 mm	No	No	90 min

[a]Conscious sedation: fentanyl + midazolam, deep sedation: propofol, GA: anaesthetic intubation.

DBE was first introduced into practice by Yamamoto et al. [20] in 2001. It revolutionised the management of small bowel disorders between the duodenum and the ileocecal valve, and it is considered the most well-studied endoscopic modality for obtaining biopsies and for therapeutic purposes in the small bowel. DBE is performed either in an antegrade (oral) or retrograde (anal) approach. It is considered a very safe procedure; the overall adverse outcomes associated with EBD in the small bowel are 4.8% per patient and 2.6% per dilatation [21]. Perforation is the most reported adverse outcome, and it is associated with active disease at the time of dilatation and the use of an oversized balloon. Reported cases of severe bleeding due to EBD suggest that it responds to conservative management with no need for surgical interventions. EBD could be performed safely for de novo and anastomotic strictures; however, it should be avoided or carefully performed in strictures with active disease, abscesses, fistulae, or strong angulation or adhesions. Pancreatitis can happen in 0.3% of the antegrade DBE, which is thought to be related to ischemic injury to the pancreas at the time of the push and pull manoeuvres during prolonged procedures and the mechanical impact on the pancreatic sphincter by repeated inflations of the overtube balloon, in addition to the constant compression and rubbing by the shaft of the overtube [22]. A systematic review of 13 studies, including 310 patients followed up for an average of 31.8 months, showed that DBE-assisted EBD is efficacious for small bowel CD strictures and helped avoid surgery in 80% of patients, with re-dilatation required in 46% of patients [23].

In our study, we demonstrated the significance of MRE in detecting strictures, identifying stricture-related adverse events, and an optimal localisation of strictures, which is essential to guide the choice of the DBE approach. It is necessary to highlight that in our cohort, DBE identified five strictures that were not seen on MRE; this indicates that a high clinical suspicion for the presence of small bowel strictures should be investigated by enteroscopy in these circumstances. A potential explanation for MRE's failure to detect strictures is the strict radiological definition of stricture, which is defined as a segment of narrowing that must be associated with upstream bowel dilatation of more than 3 cm in diameter [11]. As such, a stricture identified endoscopically may not meet the criteria for a stricture radiologically.

We also demonstrated the efficacy of DBE-assisted EBD with a technical success above 70%, symptomatic improvement, and avoidance of surgery in all patients over the 12 months of follow-up. Our cohort had no adverse events or perforations as patients were carefully selected, and a graded approach to EBD was used. Bleeding occurred

in 1 patient; however, it was noted prior to performing EBD and thus not directly related to the intervention. Most strictures were <5 cm long, and EBD for de novo and anastomotic strictures were performed. In our cohort, DBE-assisted EBD was performed in ulcerated strictures and a fistulising stricture with good technical and clinical outcomes.

All the DBE procedures were performed by one enteroscopy expert, which can be considered a limitation of our study. Other limitations include the short duration of follow-up of 12 months, the relatively small number of patients, due to the study's retrospective nature, we had no control group of surgery, and no other imaging modalities for comparison, such as intestinal ultrasound or CT. The patients included in this study were selected from the database of patients who had DBE-assisted EBD after discussing their presentation in an MDT meeting. The study did not include all patients who had MRE in our institution. Hence, selection bias must be considered when applying this study's results to all patients with CD-related small bowel strictures.

In conclusion, managing small bowel CD stricture remains challenging. MRE is an essential tool for investigating these patients and aids in characterising and localising strictures. We recommend discussing the clinical and MRE results in an MDT meeting to stratify and select suitable patients who will benefit from the procedure. DBE-assisted EBD should be considered a first step in managing these strictures due to its high efficacy and safety profile. A careful patient selection and individualising therapies will lead to patients achieving the goals of relieving obstructive symptoms, preserving bowel integrity, and avoiding surgery.

Statement of Ethics

This study was approved by the Clinical Innovation and Audit Committee (CIAC) at Macquarie Health, Sydney, Australia, approval number [MQCIAC2018012]. Due to the retrospective nature of the study, consent to participate was not required by CIAC. We have received written consent from patients for the publication of their medical details and any accompanying images.

Conflict of Interest Statement

Rupert W Leong reports advisory board membership of AbbVie, Aspen, BMS, Celgene, Celltrion, Chiesi, Ferring, Glutagen, Hospira, Janssen, Lilly, MSW, Novartis, Pfizer, Prometheus Biosciences, and Takeda, and research grant support from McCusker Charitable Foundation, Joanna Tiddy grant University of Sydney, Celltrion, Shire, Janssen, Takeda, Gastroenterological Society of Australia, MRFF, NHMRC, Gutsy Group, and Pfizer. All other authors (A.A., A.A., J.Y., H.L., and E.V.) have no conflicts of interest to declare.

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Author Contributions

Arteen Arzivian: acquisition, analysis and interpretation of data, drafting the manuscript, and final approval. Ahmad Alrubaie: concept and design of the study, critically reviewing, and final approval. Jessica Yang: concept and design of the study, critically reviewing, especially the radiology data, and final approval. Huiyu Lin: interpretation of data, critically reviewing and providing resources and references, and final approval. Eva Zhang: acquisition of data, reviewing, and final approval of the manuscript. Rupert Leong: design and concept of the study, interpretation of data, critically reviewing, and final approval. All authors agreed to be accountable for all aspects of the work.

Data Availability Statement

The data that support the findings of this study are not publicly available due to containing patients' information but are available from the corresponding author A.A. upon reasonable request.

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