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Double-balloon enteroscopy (DBE) in patients presenting with obscure gastrointestinal bleeding (OGIB)

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ABSTRACT

Background and study aims: Obscure gastrointestinal bleeding (OGIB) is defined as bleeding of unknown origin that persists or recurs after an initial negative investigation. Identifying the source of OGIB represents a diagnostic challenge that is frequently focused on visualizing the small intestine. Conventional diagnostic methods, such as push enteroscopy, small-bowel follow-through, radionuclide scanning, and angiography, each exhibit inherent limitations. Double balloon enteroscopy (DBE) was designed specifically to evaluate the entire small bowel. DBE allows for better visualization, biopsy of the identified lesions and application of therapeutic techniques. This study sought to assess the role of DBE in the diagnosis and management of patients with OGIB.

Patients and methods: This prospective study was conducted to analyse data from 31 patients presenting with OGIB referred for DBE in the Endoscopy Unit at the Internal Medicine Department of the Faculty of Medicine, Cairo University.

Results: Five patients had lesions in locations other than the small intestine that accounted for GI bleeding. Thus, the potential source of OGIB was defined as the small intestine in 18 of 26 patients (69.2%), and negative DBE findings were noted in eight patients (30.8%). Major findings included small intestinal tumours in eight patients, vascular bleeding lesions in 8 patients and ulcerations in 2 patients. Endoscopic haemostasis was performed in eight patients with vascular lesions. The three patients with Petuz-Jegher syndrome underwent polypectomy of their major polyps. Patients with gastrointestinal tumours were referred for surgery.

Conclusion: DBE is an excellent endoscopic procedure that has a relatively high diagnostic and therapeutic yield. The procedure is feasible and exhibits a high safety profile with a low complication rate when performed by an experienced endoscopist.

Introduction

The source of gastrointestinal (GI) bleeding is identified in more than 95% of cases by either conventional upper or lower GI endoscopy [1,2]. However, in approximately 5% of all GI bleeds, the source of bleeding remains unidentified [3,4]. Hence, obscure GI bleeding (OGIB) is defined as bleeding of unknown origin that persists or recurs after an initial negative investigation [5]. The initial investigation refers to upper or lower endoscopy, radiologic imaging with small bowel follow-through (SBFT) or enteroclysis [6]. OGIB can be further classified as overt or occult OGIB. Obscure overt GI bleeding in patients presents as clinically visible bleeding such as haematemesis, melena or haematochezia [7,8]. In contrast, the obscure type presents as persistent/recurrent iron deficiency anaemia or a positive occult blood test in the stool [9,10].

Identifying the source of OGIB represents a diagnostic challenge that is frequently focused on visualizing the small intestine [11,12]. Moreover, even after the source has been identified, the accessibility of the bleeding source hinders management. Conventional diagnostic methods, such as push enteroscopy, SBFT, radionuclide scanning, and angiography, each exhibit inherent limitations [13]. Wireless capsule endoscopy was demonstrated to be superior to other conventional diagnostic modalities, including push enteroscopy and small-bowel radiography, for the evaluation of small-intestinal diseases [14]. The currently available capsule, however, is not useful for biopsy or for providing therapeutic interventions, such as argon plasma coagulation [15].

Double balloon enteroscopy (DBE) was designed specifically by Hironori Yamamoto in 2001 to evaluate the entire small bowel [16]. DBE offers valuable advantages over the other conventional

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methods mentioned above [17]. DBE allows for better visualization of the small bowel, biopsy of the identified lesions and application of therapeutic techniques. This study focused on the diagnostic and therapeutic yield of DBE in the management of cases of OGIB [18]. The main aim of this study was to evaluate the diagnostic yield of DBE and its impact on the treatment and clinical outcomes of patients with OGIB in an Egyptian population.

Patients and methods

Study design and study population

This prospective study was conducted to analyse data from 31 patients presenting with OGIB referred for DBE in the Endoscopy Unit at the Internal Medicine Department of the Faculty of Medicine, Cairo University.

The study included 31 patients: 20 (64.5%) males and 11 (35.5%) females. Patient age ranged from 15-80 years with a mean (SD) of 41.2 (20.1) years.

Inclusion criteria

All patients fulfilled the following inclusion criteria:

1. Age older than 15 years;
2. Patients with OGIB for whom the source of bleeding could not be identified through conventional upper gastrointestinal endoscopy and colonoscopy performed at least once at one of our affiliated facilities;
3. Patients with no episode of GI bleeding but with positive faecal occult blood and a decrease in haemoglobin levels of more than 2 g/dL for a period of 2 months despite a negative colonoscopy and EGD.

Exclusion criteria

Serious physical condition, suspected perforation of the GI tract, severe bleeding tendency, and lack of informed consent.

Methodology in details

All patients were subjected to the following: A thorough history and physical examination, including the clinical presentation, duration of gastrointestinal bleeding, bleeding type, number of blood transfusion units, presence of any medical illnesses (particularly chronic renal or liver disease), use of nonsteroidal anti-inflammatory drugs (NSAIDs) and bleeding from other body sites, were obtained. All patients were subjected to the following investigations: full blood count (FBC), liver function tests (LFTs), renal function tests (RFTs), coagulation profile, iron studies and occult blood from stool that was proven to be positive. Upper and lower GI endoscopies were performed twice in all patients. At least one examination was performed in our unit prior to DBE. Only 4 patients had a capsule endoscopy performed before referral for DBE.

The patients had three different presentations:

1- Overt OGIB that presented as active bleeding at the time of endoscopy (10 patients);
2- Overt OGIB with a history of bleeding without bleeding at the time of DBE;
3- Occult OGIB bleeding in patients with positive faecal occult blood and a reduction in the haemoglobin level greater than 2 g/dL over a period of 2 or more months without visible blood loss.

Preparation of the patient

The DBE endoscope was inserted via either the oral (anterograde) or the anal (retrograde) route and, on average, reached roughly a half to two-thirds into the entire length of the small intestine. Anterograde DBE examination was performed after an overnight fast, and retrograde DBE was performed after standard bowel cleansing with clear liquids for 24 h before the procedure. Four tablets of Bisacodyl were administered the night before the procedure, and 1000 ml of 10% mannitol was administered 5 h before the procedure.

DBE system

The double balloon endoscope consisted of a working enteroscope and an over tube. The over tube was filled with water to reduce the friction between the plastics and to allow the inner enteroscope to move easily. A soft latex balloon was placed on the end of the enteroscope once the over-tube was positioned. The over tube was fitted with a larger soft latex balloon. Both balloons were inflated and/or deflated independently to an established pressure using an external pump device [16,17]. All the procedures were performed by a single endoscopist using a double balloon enteroscope (Fujinon EN-450-T5, Fuji Photo Optical Co. Ltd., Omiya, Japan; diameter of biopsy channel 2.8 mm, length 200 cm). The instrument was used together with a soft over tube (Fujinon TS-13140, Fuji Photo Optical Co. Ltd., Omiya Japan; outer diameter 13.2 mm, length 145 cm).

DBE examinations

All procedures were performed in the left lateral position, and the patients received monitored conscious sedation by an anaesthetist using midazolam and propofol. Advancement of the endoscope was stopped when the lesion of interest was reached or when intestinal loops precluded an efficient forward progression of the endoscope. Fluoroscopy was used intermittently when the endoscopist encountered difficulty in advancing the scope. Failure to advance was defined as inability to advance the endoscope for greater than 30 cm after three exchanges using the standard technique.

Choice of the route of DBE

The DBE endoscope was inserted via either the oral (anterograde) or the anal (retrograde) route and, on average, reached roughly a half to two-thirds into the entire length of the small intestine. Anterograde (oral) and retrograde (anal) approaches were used depending on the clinical presentation of each patient. Patients with melena, upper abdominal symptoms or haematemesis were initially evaluated with the anterograde route. If negative, the retrograde approach was performed. Patients with haematochezia were evaluated by the retrograde route. For cases where the source of bleeding was not identified during the first DBE session, a second DBE session was performed from the opposite end. In patients for whom the source of bleeding was identified during the first DBE session, the second DBE session was omitted. Total procedure time, endoscopic findings, endoscopic interventions and complications were evaluated.

As shown in Fig. 1 39 procedures were performed in the 31 patients studied. Eight patients required repeating the procedure from the other route when the first study failed to explain their OGIB. In 23 patients, only one procedure was required for diagnosis. Diagnostic biopsies and therapeutic procedures were performed during DBE as necessary for any lesions discovered.

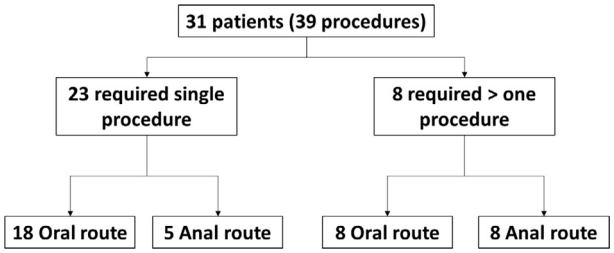

Fig. 1. Diagram presenting the number and routes of DBE.

Definition of the bleeding source in the small intestine

Any tumours associated with ulcers or vascularization were regarded as the bleeding focus. The tumours were then biopsied or resected by endoscopy during DBE, surgically removed, and diagnosed by a pathologist. Angiectasias as well as any varices, ulcerations, and erosions that bled in the course of an endoscopy or bled on contact were also diagnosed as the source of bleeding. The presence of any varices, ulceration, or angiectasia was also considered to be the source of bleeding when the focus could not be otherwise determined after thorough examination of the small intestine. In contrast to other studies, lesions that did not bleed during examination, such as erosions and red spots of uncertain significance, were not regarded as the source of OGIB bleeding in the present study.

Study ethics

The ethics committee at our facility approved this study. Full written informed consent was obtained from each patient undergoing any procedure.

Compliance with the study

All patients were compliant with the study.

Statistical analysis

The statistical software package SPSS for Windows, version 19 (SPSS, Inc., Chicago, Ill) was used to analyse the data. Means and ranges were used to summarize data for continuous variables, whereas percentages were used for categorical variables. Univariate associations between categorical variables and outcome were assessed using chi-square tests. Alternatively, when expected cell sizes were <5, the Fisher exact test was used. The *t* test was used to test for differences between groups in the distribution of continuous variables. Odds ratios (OR) and their 95% confidence intervals (CI) were used to quantify the extent of an association. Two-tailed tests with a significance level of 5% were used throughout the analysis.

Results

The mean duration of OGIB upon enrolment in the study was 21 months ± SD (±27), with a range of 1–120 months. The mean haemoglobin level of the patients was 6.6 mg/dl ± SD (±1.7), with a range of 4–10 g/dL. Twenty-seven patients had a history of blood transfusion. The mean unit of blood transfusion was 11 units ± SD (±18), with a range of 0–92 units. Table 1 summarizes the demographic data, clinical characteristics and bleeding history of the subjects studied. Table 2 presents the mean duration of the DBE examination with no significant difference between the oral and anal routes.

Table 1
Demographic data, clinical characteristics and bleeding history of the subjects studied.

Demographic data	
No. of patients	31
Mean age (years)	41.2 ± 20.1, range (15–80)
Sex (male/female)	20/11
Severity of bleeding	
Blood haemoglobin (g/dL)	6.6 ± 1.7, range (4–10)
No. of transfusions (units)	11 ± 18, range (0–92)
Mean duration of bleeding (months)	21 ± 27.05, range (1–120)

Table 2
Route and duration of DBE procedures.

Route	Number	Mean duration (min)	Mean depth of insertion in cm
Oral	26	42.5	247 (SD ± 110.5), range (60–470)
Anal	13	64.1	
Total	39	47.8 (SD ± 27), range (12–122)	
P-value		0.835	

Diagnostic yields of DBE in patients with OGIB

Five patients had lesions in places other than the small intestine that accounted for GI bleeding. We excluded those five patients from all subsequent analyses of small-intestinal lesions diagnosed by DBE. Thus, the potential source of OGIB in the small intestine was defined in 18 of 26 patients (69.2%), with negative DBE findings in eight patients (30.8%). Table 3 lists the lesions identified during DBE.

Major findings included small intestinal tumours in eight patients, vascular bleeding lesions in 8 patients and ulcerations in 2 patients. Two patients had Celiac disease; one of these patients was complicated by adenocarcinoma. Small bowel ulcerations were noted in two patients. Of these patients, one was diagnosed with Crohn's disease, and one was diagnosed with NSAID-induced ulcerations. The tumours found included one gastrointestinal stromal tumour (GIST), 3 hamartomas of Petuz-Jegher syndrome, 3 adenocarcinomas and one lymphoma. Fig. 2 presents a list of the lesions discovered during the study.

Lesions found outside the small intestine

Five patients presented lesions located in sites other than the small intestine that accounted for GI bleeding, including one Cameron ulcer in a large sliding hiatus hernia, one duodenal ulcer,

Table 3
Lesions found during DBE examination.

Type of lesion	Number of patients
Ulcers	(2)
Crohn's disease	1
NSAID induced	1
Tumors	(8)
GIST	1
Peutz-Jegher hamartomas	3
Lymphoma	1
Adenocarcinoma	3
Vascular bleeding lesion	(8)
Extra-intestinal lesion	(5)
Cameron ulcer	1
Erosive gastritis	1
Duodenal ulcer	1
Rectal varices	1
Gastric purpura	1

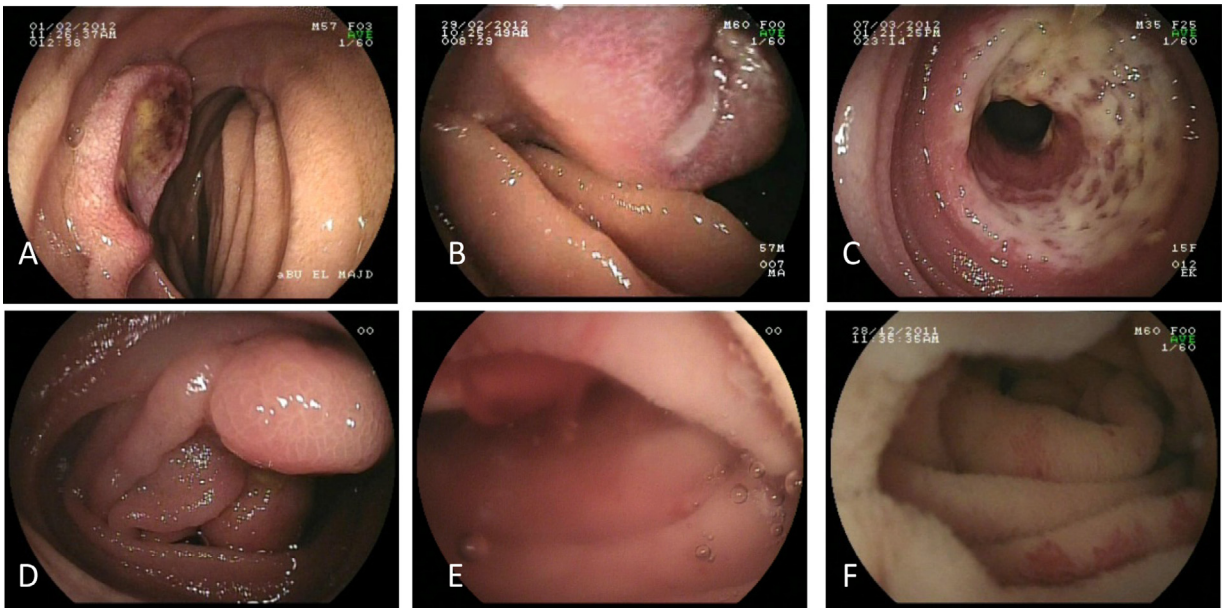

Fig. 2. Lesions encountered during DBE.

one gastric purpura, one rectal varices accompanied by congestive colopathy and one erosive gastritis. Fig. 2 presents photographic examples of the lesions captured during DBE.

Therapeutic yield of DBE

Endoscopic haemostasis was performed in eight patients with vascular lesions. This procedure mainly involved argon plasma coagulation (APC) of angioectasia. One patient required injection of 1/10,000 diluted adrenaline to stop bleeding from a spurting vascular malformation. The three patients with Petuz-Jegher syndrome underwent polypectomy of their major polyps. Patients with gastrointestinal tumours were referred to surgery. Standard medical treatment was instituted for patients with NSAID-induced ulcers and Crohn's disease. Fig. 3 presents the therapeutic interventions performed during DBE. Fig. 4 presents photographic examples of some interventions used during DBE.

Complications

No serious complications were encountered during the procedure. Two minor complications occurred during the study, resulting in a 5.2% incidence of minor complications. One patient developed unexplained shivering at the end of the procedure, which was considered a pyrogenic reaction to medications. One patient had hypotension that recovered soon after the procedure and was mostly caused by vasovagal reflex.

Discussion

Although representing a smaller proportion of patients than those with upper or lower GI bleeding [19], patients with OGIB consume many resources and experience a delay in their diagnosis and management [13]. Searching for the source of OGIB typically constitutes an extensive work-up for visualizing the small bowel. Moreover, the American College of Gastroenterology (ACG) proposed the term small intestinal bleeding to replace the term OGIB, reserving OGIB for patients in whom a source of bleeding cannot be identified anywhere in the GI tract [20].

The introduction of video capsule endoscopy (VCE) and other means to examine and treat lesions of the small bowel has led to great advances in the field of gastroenterology [21,22]. VCE is superior to standard radiographic studies (SBFT, enteroclysis, or computed tomography (CT) enterography) and push enteroscopy for

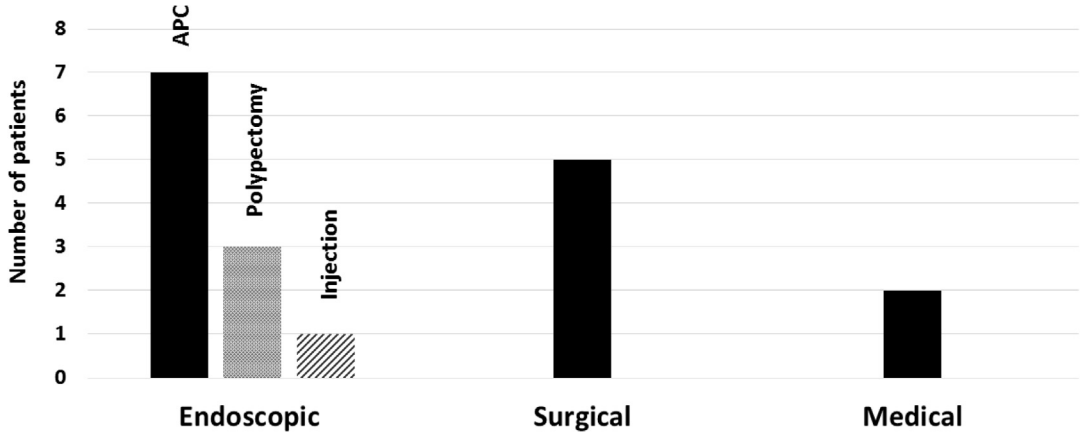

Fig. 3. Therapeutic interventions required during DBE.

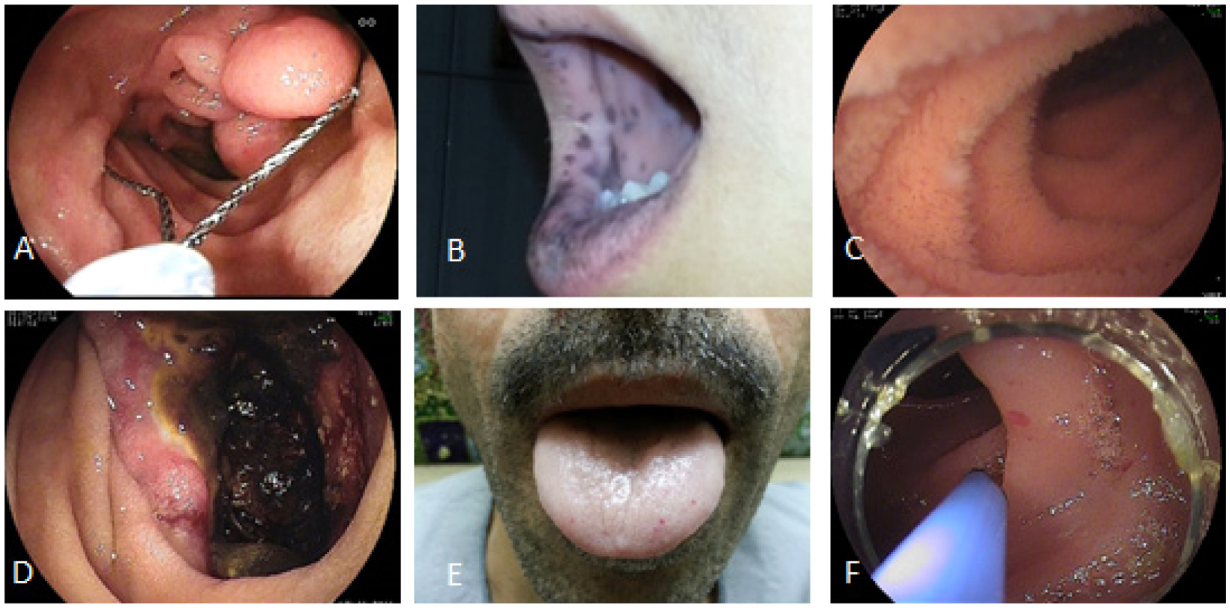

Fig. 4. Examples of therapeutic interventions during DBE.

the detection of small bowel lesions [23]. However, the ability of VCE to precisely locate small intestinal lesions has been questioned. Some studies have evaluated the VCE transient time in determining the route of DBE [24]. Moreover, VCE is recommended as the first-line investigation in patients with OGIB[25].

In this study, only four patients underwent capsule endoscopy prior to DBE. The findings revealed telangiectasias in two patients, and the results were negative in the other two patients. Given that the sensitivity and diagnostic yield of capsule endoscopy in such patients exhibit a high positive rate [26], this technique requires less time and resources compared with less sensitive studies, such as barium studies that have a very low yield. For example, enteroclysis does not detect mucosal lesions, such as vascular ectasias, with a sensitivity less than 2% [27,28]. The reason for the low use of capsule endoscopy is its high cost. In addition, this procedure is not available in our centre and is typically not covered by the health insurance of Egyptian patients. These features prohibit the regular use of capsule endoscopy in most cases. Moreover, capsule endoscopy is not widely available in Egypt, and the number performed annually by each centre is low.

There were more patients in the occult OGIB group than in the overt group. Most of the patients with ongoing-overt OGIB showed positive findings via endoscopy. The cause could not be identified in only two patients. However, given the small number of patients, we did not perform subgroup analysis because any conclusions from the statistical analysis of the small subgroups would have lacked precision. Studies that have included more patients have reported similar findings, namely, increased positive outcomes in patients with overt-ongoing bleeding compared to patients with occult OGIB [25]. This finding may suggest that a prior capsule endoscopy is the best choice for such patients to save the patient from a potentially invasive procedure. However, in cases of active ongoing bleeding, DBE would be more appropriate given the potential therapeutic advantage.

DBE is an invasive procedure, and this is one respect in which capsule endoscopy is superior to DBE. However, this study revealed the high safety profile of DBE when performed by an experienced endoscopist. We encountered no serious complications in our series, and only two minor complications were noted. This finding is consistent with other studies [29,30] and confirms the safety of the procedure.

In this study, we could identify the potential source of OGIB in the small intestine in 18 of 26 patients (69.2%), with negative DBE findings in 8 patients (30.8%). This value is between those reported in other studies for other patient groups. The diagnostic yield of DBE in patients with OGIB ranges from 50 to 80% in different studies, and this test enables successful endoscopic therapeutics in up to 75% of patients [31]. The most commonly encountered lesions were angioectasias followed by GI tumours (8 patients 30.8%, 5 patients 19.2%, respectively). However, different groups have reported different results. For instance, Fujita et al., in 2010, reported that the most frequent sources of bleeding were ulcers and erosions (18.4%) [32], and Tanaka et al., in 2008, found that the most common sources of bleeding were ulcers and tumour lesions [29].

The diagnostic yield in the current study was between the reported yields of capsule studies in different papers. Positive findings in capsule endoscopy have been reported to range from as low as 41.7% [33] to as high as 74.7% [34]. Studies that compared capsule endoscopy with DBE head to head have reported similar diagnostic yields. In these studies, using DBE, the lesion could be biopsied and therapeutic interventions could be performed.

We still identified lesions outside the small bowel that could be reached by conventional upper and lower GI endoscopy. Five such lesions were observed in the present study, including one Cameron ulcer in a large sliding hiatus hernia, one duodenal ulcer, one gastric purpura, one rectal varices accompanied by congestive colopathy and one case of erosive gastritis. Collectively, in the current study, 16.1% of lesions were observed outside the small bowel. Similar results were reported by other groups [25]. By identifying these lesions, DBE offers a greater diagnostic advantage.

A major advantage of DBE over capsule endoscopy is its ability to manage lesions discovered during the procedure. Overall, the therapeutic yield of the procedure was 69.2%. In the current study, several therapeutic interventions that are common to regular upper and lower GI endoscopy were performed for small intestinal lesions. We performed Argon plasma coagulation for 7 of the patients with vascular lesions. One patient required injection of diluted adrenaline to stop bleeding from a spurting vascular malformation. Three patients with Petuz-Jegher underwent polypectomy of their major polyps. Five patients with gastrointestinal tumours were referred for surgery. In addition, medical treatment

for NSAID-induced ulcers and Crohn's disease was instituted. Collectively, the therapeutic yield of the procedure was 69.2% based on 18 patients in whom small intestinal lesions were discovered. A high therapeutic yield has been reported in other studies, enabling successful endoscopic therapeutics in up to 75% of patients [27]. These findings demonstrate that DBE is an excellent endoscopic procedure that has a relatively high diagnostic and therapeutic yield. The procedure is both feasible and exhibits a high safety profile with a low complication rate when performed by an experienced endoscopist. Thus, this technique represents an advance in the diagnosis and treatment of patients with OGIB.

The authors whose names are listed certify that they have NO conflict of interest with any organization or entity with any financial or non-financial interest in the subject matter or materials discussed in this manuscript.

COI statement

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