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CLINICAL RESEARCH

Double-balloon endoscopy in the diagnosis and management of GI tract diseases: Methodology, indications, safety, and clinical impact

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Abstract

AIM: To prospectively evaluate the indications, methodology, safety, and clinical impact of double-balloon endoscopy.

METHODS: A total of 60 patients with suspected or documented small- or large-bowel diseases were investigated by double balloon endoscopy. A total of 103 procedures were performed (42 from the oral route, 60 from the anal route, and 1 from the stoma route). The main outcome measurements were the time of insertion and the entire examination, complications, diagnostic yields, and the ability to successfully perform treatment.

RESULTS: Observation of the entire small intestine was possible in 10 (40%) of 25 patients with total enteroscopy. The median insertion time was 122 min (range, 74-199 min). Observation of the entire colon was possible in 13 (93%) of 14 patients after failure of total colonoscopy using a conventional colonoscope. Small-intestine abnormalities were found in 20 (43%) of 46 patients with indications of suspected or documented small bowel diseases, obscure GI tract bleeding, or a history of ileus. Endoscopic procedures including tattooing (n = 33), bite biopsy (n = 17), radiographic examination (n = 7), EUS (n = 5), hemostasis (n = 1), polypectomy (n = 5), balloon dilatation (n = 1), endoscopic mucosal resection (n = 1) and lithotripsy (n = 1) were all successfully performed. No relevant technical problems or severe complications were encountered.

CONCLUSION: Double balloon endoscopy is a feasible technique that allows adequate small and large bowel examination and potentially various endoscopic procedures of small-intestinal lesions. It is safe, useful, and also provides a high clinical impact.

Key words: Double-balloon endoscopy; GI tract disease; Endoscopic therapy

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INTRODUCTION

Due to the development of endoscopic instruments and techniques, endoscopy has played an important role in the diagnosis and treatment of disorders in the esophagus, stomach, duodenum, and colon. However, diseases occurring in more hidden areas of the gastrointestinal tract have long remained a gastroenterological problem. Unfortunately, endoscopic small bowel examination has commonly been limited to the proximal jejunum[1,2]. Therefore, more distal lesions have not usually been identified endoscopically. Recently, a new wireless capsule endoscope was introduced. Capsule endoscopy can provide an endoscopic image from the entire GI-tract without requiring a surgical laparotomy. It is undoubtedly an important improvement in diagnostic endoscopy of the small intestine and also offers advances the diagnostic workup of small bowel diseases[2,3]. Nevertheless, this method is limited because it cannot provide for air insufflations, tissue rinsing, biopsies, or therapeutic interventions. Double-balloon endoscopy (DBE), developed by Yamamoto and colleagues in 2001[4], is an exciting new endoscopic technique that allows for complete visualization and therapeutic interventions in the entire small intestine. Preliminary experiences with DBE have illustrated the capability to perform total small-bowel enteroscopy with a good safety profile and patient tolerance for this procedure[4-11]. The aim of this study was to prospectively determine the indications, safety, diagnostic and therapeutic impact of DBE in patients with known or suspected GI-tract disorders.

MATERIALS AND METHODS

Patients

Between July 2004 and November 2005, 103 endoscopies, including 42 antegrade and 61 retrograde procedures, were performed on 60 patients in our hospital using the DBE system. The patients were being tested for gastrointestinal bleeding, abdominal pain, diarrhea, inflammatory bowel diseases, suspected small-bowel tumors or polyps, and unsuccessful total colonoscopy using a conventional colonoscope (Table 1). Most patients had undergone at least one esophagogastroduodenoscopy and colonoscopy. DBE was performed when small bowel disease was suspected after negative upper and lower endoscopy and radiographic evaluation of the GI tract, or was previously documented by various imaging investigation [small bowel enema study (n = 20), transabdominal US (n = 10), CT (n = 22), angiography (n = 4), and radionuclide scanning (n = 7)]. In some patients, more than 1 enteroscopy was performed for endoscopic treatment of small-intestinal lesions or patients were reexamined for obscure GI bleeding by DBE previously. The median age of the 60 patients (35 men, 25 women) was 64 years (range, 19 to 83 years). Written informed consent was obtained from all patients. The indications included the following: suspected or documented small intestinal lesions (24 patients), obscure GI bleeding (20 patients), unsuccessful total colonoscopy using a conventional colonoscope (14 patients), and other indications (2 patients). This study was reviewed and approved by our institutional review board.

Methods

The DBE system (Fujinon-Toshiba ES system Co, Tokyo, Japan) is a high resolution video endoscope with a flexible overtube. The videoendoscope has a working length of 200 cm and a detachable balloon at its tip. It is used with a soft overtube measuring 145 cm in length with another balloon at the distal end. The endoscope and overtube balloons are made from latex that is 0.1 mm thick, very soft, and can be inflated or deflated by a specially designed air pump controller with one-touch controls while monitoring air pressure. The balloons are used at 45 mmHg, which is the lowest possible pressure needed to hold the intestine for endoscope insertion, and the balloon is designed not to cause pain or discomfort to the subjects due to balloon dilation (PB-10, Fujinon-Toshiba ES system Co, Tokyo, Japan)[4]. There are two types of DBE, i.e., one for general use (EN-450P5) and one for treatment (EN-450T5) (Figure 1). The major difference between the EN-450P5 and EN-450T5 is the diameter. EN-450P5 is a thinner endoscope with an external diameter of 8.5 mm and forceps channel diameter of 2.2 mm. It is used with an overtube that has an external diameter of 12.2 mm and an internal diameter of 10 mm. The EN-450T5 has an external diameter of 9.4 mm and forceps channel diameter of 2.8 mm and it is used with an overtube that has an external diameter of 13.2 mm and an internal diameter of 11 mm.

Antegrade DBE was performed transorally after overnight fasting. Retrograde DBE was performed transanally after the patients were prepared with the same oral electrolyte lavage solution as that used for regular colonoscopy. The patients were prepared by continuous intravenous infusion and then were examined by DBE under conscious sedation with intravenous flunitrazepam coupled with 35 mg of petidine chloride. During DBE, blood pressure and oxygen saturation were monitored and, when necessary, intravenous sedatives were added. DBE was carried out under fluoroscopy by experienced endoscopists, and the endoscope was advanced as far as possible in the manner described below. With the endoscope in the intestine

Table 1 Indications for and the clinical Impact of DBE

Indications	DBE diagnosis	*n* (%)	Clinical impact
Suspected or documented small bowel diseases		24 (40)	
	Crohn's disease	5 (8)	Medical and Endoscopic treatment
	Jejunal cancer	2 (3)	Surgical treatment
	Malignant lymphoma	1 (1.7)	Medical treatment
	Enterolithiasis	1 (1.7)	Endoscopic treatment
	Peutz-Jeghers syndrome	1 (1.7)	Endoscopic treatment
	Intestinal Behçet disease	1 (1.7)	Medical treatment
	Cronkhite-Canada syndrome	1 (1.7)	Medical treatment
	Jejunal lipoma	1 (1.7)	No treatment
	NSAIDs ulcers	1 (1.7)	Medical treatment
	Stomal ulcer	1 (1.7)	Medical treatment
	Negative findings	9 (15)	Symptomatic approaches
Obscure GI tract bleeding		20 (33)	
	Ileal angiodysplasia	1 (1.7)	Endoscopic treatment
	Jejunal cancer	1 (1.7)	Surgical treatment
	NSAIDs ulcer	1 (1.7)	Medical treatment
	Solitary Peutz-Jeghers type polyp	1 (1.7)	Surgical treatment
	Idiopathic small intestinal ulcer	1 (1.7)	Medical treatment
	Negative findings	15 (25)	Follow-up
Incomplete conventional colonoscopy		14 (23)	
	Colonic polyp	5 (8)	Endoscopic treatment
	Colonic diverticula	3 (5)	Synmptomatic approaches
	Colonic cancer	1 (1.7)	Surgical treatment
	Colonic submucosal tumor	1 (1.7)	Follow-up
	Colonic tuberculosis	1 (1.7)	Medical treatment
	Negative findings	3 (5)	Follow-up
History of ileus		2 (3)	
	Negative findings	2 (3)	Follow-up

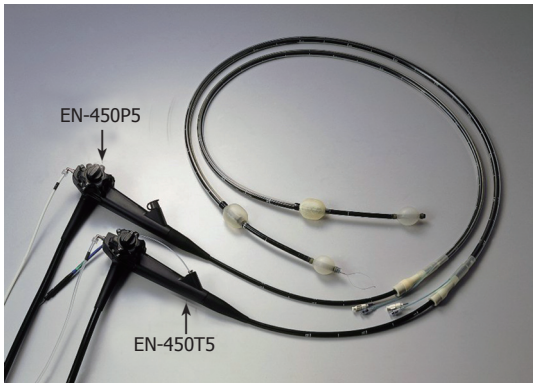

Figure 1 Two types of double-balloon videoenteroscopes (EN-450P5 and EN-450T5).

Table 2 Clinical data of patients who underwent DBE

Indications	Approach	*n*	Median insertion time (range, min)	Successful insertion
Panenteroscopy	Antegrade + Retrograde	25	122 (74-199)	40% (10/25)
Partial enteroscopy for suspected or documented lesion	Antegrade	9	40 (11-99)	67% (6/9)
	Retrograde	12	55 (10-87)	75% (9/12)
	Total	21	46 (10-99)	71% (15/21)
Total colonoscopy	Retrograde	14	47 (15-78)	93% (13/14)

and the balloon of the overtube inflated and anchoring the position, the endoscope can thus be advanced. When the endoscope is advanced to its most distal point, the endoscope balloon is inflated to hold the insertion point. The overtube can be advanced after deflating the overtube balloon until the proximal end of the overtube reaches a set mark on the endoscope (150 mm); this corresponds to the distal end striking the rubber ring that holds the balloon onto the endoscope (which acts as a stopper for overtube advancement). The overtube balloon is inflated to maximum pressure and then both the enteroscope and the overtube are slowly withdrawn to reduce the GI-tract loops on the overtube and straighten the lumen for advancement. The endoscope balloon is then deflated, and insertion into the GI tract continues. This process is repeated until advancing the endoscope any further becomes difficult. The insertion route was chosen according to the estimated location of the suspected lesions, e.g., antegrade DBE was chosen when jejunal lesions were suspected and retrograde DBE was chosen when ileal lesions were suspected. A combination of both approaches was used if the indication required inspection of the whole length of the small intestine. However, examination of the entire small intestine is uncertain because there is no landmark in the small intestine. Therefore, an india-ink tattoo is left as a landmark for a subsequent retrograde DBE[4]. Fluoroscopy was used when advancement came to an unexpected halt. Gastrografin (Nihon Schering, Osaka, Japan) was injected via the working channel to allow for a radiographic assessment of the nature of the lesion. Instrumentation with a wide range of instruments is possible; e.g., ultrasound catheter probe, snares, biopsy, clip or injection needle.

RESULTS

Technical aspects

In our study, endoscopic observation of the entire small intestine was successful in 10 (40%) of the 25 patients with total enteroscopy by a combination of both approaches (anterograde and retrograde) (Table 2). The median insertion time was 122 (range, 74-199) min. Insertion of the endoscope and endoscopic observation of the target lesion was successfully achieved using DBE in 15 (71%) of the 21 patients with partial enteroscopy for suspected or documented lesion. The main reasons for failing to complete total enteroscopy or to reach the region of the target lesion was marked intestinal adhesion caused by previous laparotomy. The median insertion time was 46 (range, 10-99) min. Observation of the entire colon was possible in 13 (93%) of 14 patients in whom total colonoscopy failed using a conventional colonoscope. The median insertion time was 47 (range, 15-78) min.

Table 3 Managements during or after DBE in 60 patients

	n	%
Endoscopic	9	15
Surgical	5	8
Medical	12	20
Symptomatic approaches or follow-up	34	56

Table 4 Endoscopic procedures using DBE

Procedure	*n*	%
Tattooing	33	55
Biopsy	17	28
Radiographic examination	7	12
EUS	5	8
Polypectomy	5	8
Hemostasis	1	2
Balloon dilation	1	2
Lithotripsy	1	2
Endoscopic mucosal resection	1	2

Indications and clinical impacts of DBE

The indications and clinical impact of DBE are presented in Table 1. Small-intestine abnormalities were found in 20 patients (43%); i.e., 15 (63%) of 24 patients with suspected or documented small bowel diseases, 5 (25%) of 20 patients with obscure GI bleeding and neither (0%) of two patients with a history of ileus. Colonic abnormalities were observed in 11 (79%) of 14 patients who underwent incomplete conventional colonoscopy. DBE resulted in a therapeutic intervention (endoscopic, medical or surgical therapy, excluding symptomatic approaches) in 43% of the patients (26/60) (Table 3). In 9 patients (15%), an endoscopic intervention was carried out during the DBE procedure (polypectomy, $n = 5$; endoscopic injection of hypertonic saline-solution-epinephrine, $n = 1$; endoscopic balloon dilation, $n = 1$; endoscopic lithotoripsy, $n = 1$; endoscopic mucosal resection, $n = 1$). In one patient with Peutz-Jeghers syndrome, it was possible to resect seven small intestinal polyps (without complications in three DBE sessions) by endoscopic polypectomy with clipping, with the sizes of the polyps ranging from 0.7 to 2 cm (Figure 2). In one patient with obstructive symptoms due to a huge enterolith (7 cm), it was possible to crush the enterolith using a large polypectomy snare (Captivator Ⅱ, Boston Scientific Japan, Tokyo, Japan) and remove it (Figure 3). Five patients (8%) underwent surgery for a resection of jejunal cancer (Figure 4), with one patient incurring a resection of a large solitary Peutz-Jeghers type polyp of the jejunum and another incurring a resection of advanced ascending colon cancer.

Endoscopic procedures using DBE

DBE intervention and therapeutics are summarized in Table 4. Thirty-three underwent tattooing, 17 underwent

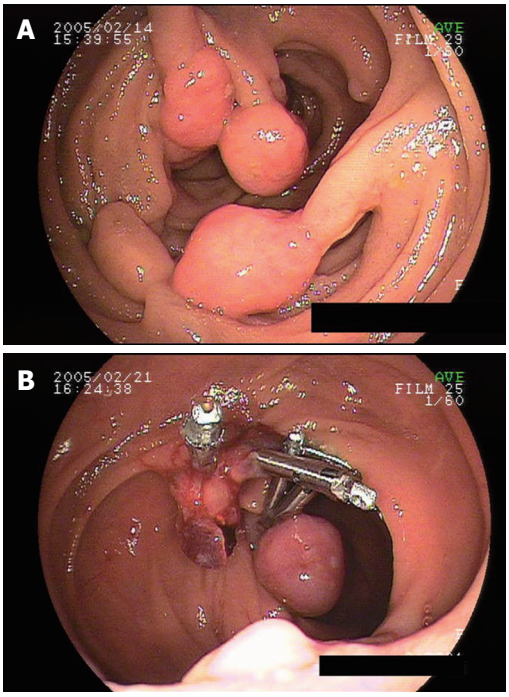

Figure 2 The successful endoscopic removal of polyps from the mid small bowel in a patient with Peutz-Jeghers syndrome. **A**: Endoscopic view of multiple pedunculated small intestinal polyps; **B**: Endoscopic view of the region after endoscopic polypectomy using clipping.

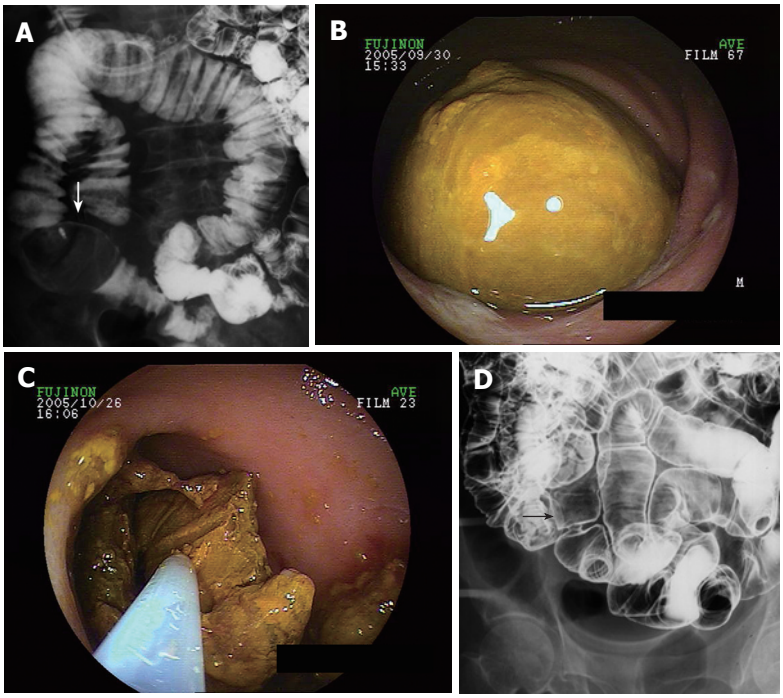

Figure 3 Successful endoscopic lithotripsy for a huge enterolithiasis. **A**: Radiographic view of the ileum showing a huge enterolith (arrow); **B**: Endoscopic view of a huge enterolith; **C**: Endoscopic view of the lesion during lithotripsy; **D**: Radiographic view of the region after endoscopic lithotripsy showing no enterolith (arrow).

bite biopsy, 7 underwent a selective radiographic examination (Figure 4B), 5 underwent EUS using an ultrasound catheter probe (Figure 4C), 5 underwent endoscopic polypectomy, 1 underwent endoscopic hemostasis (Figure 5), 1 underwent endoscopic balloon dilation, 1 underwent endoscopic lithotripsy using a polypectomy snare, and 1 underwent endoscopic mucosal resection. All endoscopic procedures were successfully performed.

Complications

No severe complications, such as perforation, occurred. DBE was well tolerated by all patients.

DISCUSSION

Although EGD and total colonoscopy have become unequivocal procedures for the diagnosis and the treatment of GI tract diseases, enteroscopy has not yet been widely accepted by gastroenterologists. This may be partly explained by failures in total enteroscopy and the inconvenience of the procedure in push enteroscopy[1,2,12]. While video capsule endoscopy now permits the direct and painless visualization of small bowel mucosa, it does not provide a histological diagnosis and treatment of small-intestinal pathology at present[4,5,12]. A new insertion method of enteroscopy, i.e., the DBE method, has been reported to enable the endoscopic scrutiny of the entire small bowel with intervention capabilities[4-11].

Total enteroscopy using the antegrade route alone is not usually achieved, but it is possible in rare cases[4,9]. This was not achieve in this study. The strategy of combining antegrade and retrograde approaches with DBE allows total enteroscopy more frequently. To achieve this, the deepest point reached during the antegrade procedure is marked by injecting india ink so that the same point can be reached again using the retrograde approach. When total enteroscopy is intended, previous studies[4-6,8-11] have demonstrated that this mark can be reached in from 0% to 86% of all cases. In our study, this point could only be reached in 40% of the cases. The median insertion time required for panenteroscopy was 122 minutes, which was almost the same as the time reported by Yamamoto *et al* (123 min)[4]. This is certainly longer than with push enteroscopy, in which the examination times are usually approximately 30 min[10,12]. As a result, DBE is certainly a time-consuming procedure that also requires a high level of staffing, with two assistants needed in addition to a well-trained endoscopist (one assistant to help perform the DBE and one to provide patient care). However, we think that, if possible, total enteroscopy is as desirable as total colonoscopy because small bowel diseases sometimes have multiple lesions. To minimize the total effort and costs of this procedure, further technical and mechanical refinements are required.

At present, the main indications for DBE are the investigation of gastrointestinal bleeding and inflammatory bowel disease[4-12]. Other indications for DBE include an evaluation of suspected small-bowel diarrhea, abdominal pain, abnormal radiographic studies, small-bowel intussusception, the removal of small-bowel polyps, treatment for angiodysplasias, the retrieval of tissue samples, accessing Roux-en-Y anastomoses, and most

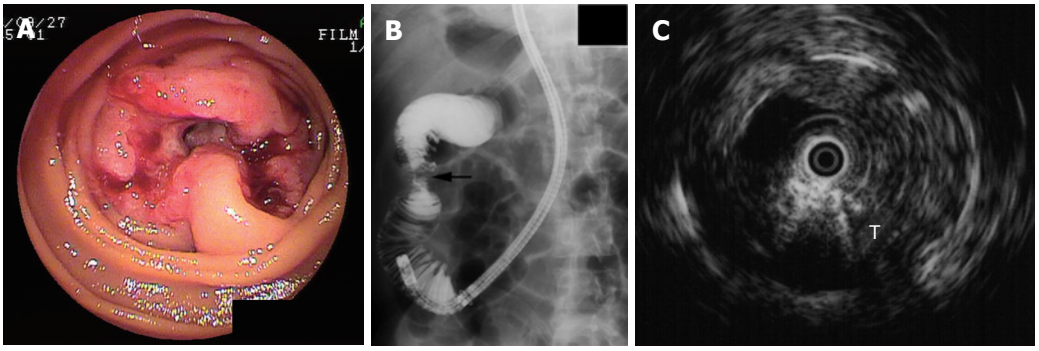

Figure 4 Primary advanced jejunal cancer. **A**: Endoscopic image; **B**: Selective radiographic image using DBE revealing a stenotic lesion (arrow) suggestive of jejunal cancer; **C**: EUS image using ultrasound catheter probe showing a hypoechoic tumor (T), which extended into the serosal layer (T3).

recently, the evaluation of abnormal capsule endoscopy findings[4-6,8-11]. The indications for the patients examined in our study included suspected or documented small bowel diseases, obscure GI tract bleeding, incomplete conventional colonoscopy, and history of ileus. At present, conventional colonoscopy is the reference standard for evaluating the colon, especially for the screening, diagnosis, and treatment of colorectal tumors. However, the entire colon cannot be visualized during endoscopic colonoscopy in 5%-15% of patients[13,14]. Even an experienced endoscopist may be unable to intubate the colon in its entirety as far as the cecum for a variety of reasons, including a redundant or tortuous colon, marked diverticulosis, angulation or fixation of colonic loops, or spasm[14]. In this study, observation of the entire colon was possible in 93% of the patients for whom total colonoscopy failed using a conventional colonoscope, even though the median insertion time was 47 min. Using the DBE technique, especially *via* the anal route, it is possible to reach deep portions of the terminal ileum. As a result, it is considered to be an effective alternative method for patients who previously underwent incomplete colonoscopy using a standard colonoscope. DBE is much thinner, longer and less stiff than a conventional colonoscope. Therefore, colonoscopy in a "normal"patient appears to be more difficult with the DBE than with the standard colonoscope. We think that the best indication of DBE for total colonoscopy is in difficult cases when using a standard colonoscope.

In the report of Yamamoto *et al* (123 patients)[4], multiple perforations occurred after DBE in a patient with lymphoma who was actively undergoing chemotherapy. A second patient, with Crohn's disease, developed abdominal pain and fever after DBE, but no perforation was found after further investigation. May *et al* (137 patients)[10] demonstrated DBE to be a safe procedure with none of the patients experiencing bleeding or perforation. In the Heine series (275 patients)[9], severe complications were recognized in three patients, all cases involved pancreatitis. In this study, we encountered no complications. Complications have been reported relatively rarely. The reported incidence of severe complications associated with DBE has ranged from 0% to 2.5%[4-12,15].

DBE was clinically useful for making an endoscopic and histologic diagnosis as well as for providing appropriate therapy[4-12,16-21]. DBE was found to be a useful and safe method for obtaining tissue specimens, EUS images using an ultrasound catheter probe, selective

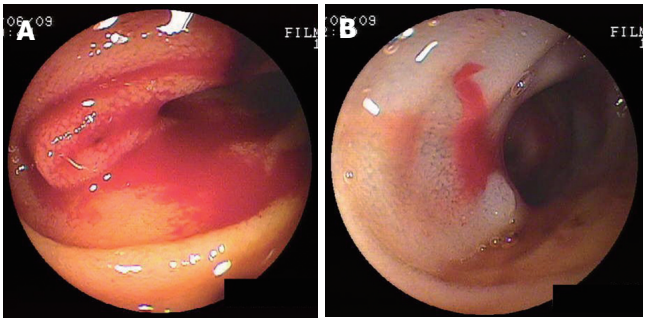

Figure 5 Endoscopic hemostasis using hypertonic-saline solution epinephrine injection. **A**: Endoscopic image of bleeding angiodysplasia; **B**: Endoscopic image of the region after hemostasis.

radiologic images for making a diagnosis, for perfoming hemostasis, crushing enterolithiasis, performing balloon dilation, and carrying out polypectomies. Furthermore, all patients who underwent these endoscopic therapeutic procedures had an excellent outcome, thereby allowing them to avoid surgical intervention. More importantly, beyond its diagnostic value, the therapeutic value of DBE and its impact on clinical decision-making were favorable in 43% of the patients studied. This technique was also confirmed to have a high diagnostic yield in comparison to previous methods of small-bowel imaging and evaluation[4-12,20,21]. The therapeutic impact of the procedure was evident since the findings associated with this new modality resulted in decisions to start new treatments, change existing ones, and carry out surgical intervention or perform therapeutic endoscopy.

Because DBE is a new diagnostic and therapeutic procedure, it is currently not known when it should be performed during the evaluation of the small bowel. If information from prior tests is available, it is helpful in choosing the type of enteroscope (i.e. thinner type scope, EN-450P5 or therapeutic type scope, EN-450T5) and the type of approach (i.e. from oral route or anal route). Compared with other diagnostic radiologic tests, wireless capsule endoscopy has a significantly higher yield in patients[3,22]. While capsule endoscopy appears to be a reasonable initial diagnostic imaging test, miss rates of up to 36% have been reported with the capsule because of the limited 140° field of view[23]. It is limited in its inability to provide diagnostic sampling and therapeutic intervention for small-bowel lesions. Therefore, if the lesion was suspected or found by capsule endoscopy, the subsequent DBE is vital for confirming the lesion,

including biopsy, and if possible performing endoscopic therapy. Tests prior to DBE are time consuming and increase costs. At present, there are no investigation algorithms for suspected small bowel diseases. From the results of previous studies[4-12, 16-21] and ours, DBE is safe and the most accurate diagnostic modality and is able to deliver endoscopic biopsy and therapy in addition. We believe that DBE should be performed as soon as possible if small bowel disease is suspected after negative upper and lower endoscopy. However, assessing the significance of DBE in small-bowel diseases requires prospective studies comparing DBE with other currently available imaging modalities[24].

In our preliminary study, this new method was found to assist in the diagnosis and treatment of small intestine diseases and any part of the GI tract where conventional endoscopic access is otherwise difficult. It is likely that the indications for this procedure will increase in the future and that novel uses of DBE will be developed for diagnosing, monitoring, and treating entire GI tract diseases.

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