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Efficacy and Safety of Single-Balloon Versus Double-Balloon Enteroscopy: A Single-Center Retrospective Analysis

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Background: Single-balloon endoscopy (SBE) has been introduced as a simplified endoscopy technique after the promotion of double-balloon endoscopy (DBE). The difference in clinical performance between DBE and SBE is still not very clear. In this study, we aimed to compare the efficacy and safety between these 2 endoscopic procedures.

Material/Methods: A total of 173 patients with suspected small bowel disease were enrolled into this study from January 2007 to December 2011. All cases were divided into DBE or SBE groups according to the endoscopic procedures they underwent. We then compared the diagnostic yield, the influence of DBE and SBE on the diagnostic/therapeutic course, the examination time, and post-procedure discomfort between DBE and SBE groups.

Results: We observed no notable adverse events during or after the examinations. Additionally, SBE displays a significantly higher diagnostic rate (62.0%) than DBE (35.6%) via the anal approach (P=0.0137), while there was no difference in positive diagnostic rate between DBE and SBE via the oral route. Remarkably, it takes significantly less time to perform SBE examinations (38.86±5.64 minutes) than DBE procedures (41.80±6.50 minutes) via the oral route (P=0.048), although the average examination time for DBE is close to that for SBE via the anal route (P=0.952). However, DBE and SBE are similar in terms of their impact on the diagnostic/therapeutic course and complication rate.

Conclusions: Both SBE and DBE are very safe procedures to perform and SBE is a preferred choice for the evaluation of small bowel diseases in terms of diagnostic rate via the anal route compared with DBE.

MeSH Keywords: Double-Balloon Enteroscopy • Inflammatory Bowel Diseases • Postoperative Complications

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Background

It used to be a great challenge to diagnose and treat patients with small intestinal diseases, since most parts of the small bowel were not accessible to conventional endoscopy techniques due to its long length and the presence of multiple complex loops [1]. Double-balloon enteroscopy (DBE) developed by Yamamoto and colleagues has allowed us to tackle this issue and perform deep enteroscopy to examine the entire small intestine [2]. Compared with traditional small bowel endoscopic techniques such as push endoscopy and capsule endoscopy, DBE can not only allow for the visualization of the entire small bowel, but also provide biopsy of the lesions or therapeutic interventions of small bowel diseases if necessary [2,3]. Hence, DBE has been widely used in gastroenterological practice [2]. However, DBE also exhibits some technical issues, such as the complex and cumbersome process of preparing and handling the double-balloon enteroscope [4]. To simplify the enteroscopy procedure, another novel balloon-based enteroscope system, single-balloon enteroscopy (SBE), was designed in 2007 and has been routinely used in clinical settings for the diagnosis and management of small bowel diseases [4]. SBE system is easier to manipulate than DBE since it avoids attaching the enteroscope balloon to the distal tip of the endoscope and eliminates the need to inflate and deflate 2 balloons [4,5]. As a result, the time consumption and complexity for the preparation of the SBE system and for the examination itself may be substantially reduced [4,5]. Nevertheless, it has been suggested that SBE manifests less efficiency for deep intubation of the small bowel, compared with DBE, and may even cause adverse effects due to the hooking technique during straightening of the single-balloon endoscope [5].

Several studies have investigated the efficacy and safety of the 2 balloon-assisted enteroscope systems [6–9]. However, the difference in the clinical performance, including the depth of intubation, procedure time, diagnostic yields and complication rates, between the DBE and SBE systems remains controversial [6–8]. Therefore, in this study, we aimed to compare the diagnostic yield, the impact of DBE and SBE procedures on the diagnostic/therapeutic course of small bowel diseases, the examination time and post-procedure discomfort between DBE and SBE. Our findings may offer important guidelines for the use of DBE and SBE in the management of patients with small bowel diseases in the future.

Material and Methods

Patients

A total of 173 inpatients enrolled in our hospital from January 2007 to December 2011 were selected for this retrospective study. Forty-five cases of DBE and 50 procedures of SBE were performed via the anal approach, while 78 patients received the per-oral procedures, including 49 and 29 cases of DBE and SBE, respectively. The patients included for this study met the following criteria: (1) The patients were suspected of having small bowel diseases; (2) No final diagnosis was made before the endoscopy examinations. On the contrary, patients who underwent a previous small bowel endoscopy or exhibited contradictions to an endoscopic procedure were excluded from this study. The chief complaints of the patients enrolled in this study included fever, poor appetite, vomiting, abdominal pain, back pain, diarrhea, melena, bloody stool, changes in stool property, ascites, abdominal mass, abdominal distention, weight loss, anemia, elevation of tumor markers, and postoperative checkup. Some patients may have presented with more than one chief complaint. Whether the patients received the SBE or DBE via the anal or oral route was mainly based on the chief complaints of the patients. Cases were assigned to either DBE or SBE group according to the type of endoscopic examinations, and were further assigned to per-anal or per-oral subgroup according to the route of the examinations.

The study was conducted according to the Declaration of Helsinki [10]. Written informed consent was obtained from each patient prior to each endoscopic procedure and the study protocol was approved by the Ethics Committee of the Shanghai Jiaotong University.

Endoscopic procedure

DBE and SBE were performed using EN-450P5 (Fujinon Medical Co, Ltd., Tokyo, Japan) and SIF-Q260 (Olympus Medical Systems, Tokyo, Japan), respectively. All of the procedures were carried out by one operator with more than 10 years of experience in performing gastrointestinal endoscopy, including about 5 years of clinical practice in small bowel endoscopy such as push enteroscopy, DBE and SBE. The parameter settings for operating the enteroscope systems DBE and SBE were illustrated in Table 1. Patients who received the endoscopic procedure via the anal approach were administered 2 L of polyethylene glycol solution for bowel preparation 6 hours prior to the procedures. Otherwise, patients who underwent the per-oral enteroscopy were fasted for at least 12 hours. Aperients may be given to patients suspected of having slow transmission. During the procedure, the patients underwent general anesthesia intravenously or by inhalation. All procedures started with left lateral position and the position may be changed according to the progress of the examination. The endoscope was advanced into the small bowel as deeply as possible and the procedure was stopped if any of the following occurred: (1) A significant lesion was detected; (2) Endoscopic intervention was indicated; (3) The procedure time exceeded 90 minutes; (4) The procedure was discontinued at the anesthetist's request.

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Table 1. Parameter settings of the endoscopic examinations.

	Outer diameter (mm)	Working length (mm)	Working channel (mm)	Length of overtube (mm)	Outer diameter of overtube (mm)
Olympus SIF-Q260	9.2	2000	2.8	1400	13.2
Fujinon EN-450P5	8.5	2000	2.2	1450	12.2

Table 2. Baseline characteristics of the patients.

	Per-anal			Per-oral		
	DBE	SBE	P value	DBE	SBE	P value
Sex						
Male	21	28	0.414	31	14	0.239
Female	24	22		18	15	
Age						
Minim	17	15		17	27	
Max	82	84		82	62	
Average	48.36±15.19	52.02±16.93	0.272	50.29±18.98	52.62±10.84	0.547
Chief complaint						
Abdominal pain	11	10	0.629	9	5	1.000
Diarrhea	8	10	0.800	11	3	0.231
Melena	11	10	0.629	11	12	0.122
Bloody stool	6	5	0.751	5	1	0.403
Changes of stool	4	4	1.000	3		0.290
Abdominal mass				1		1.000
Vomiting	1	2	1.000	3	2	1.000
Fever	1	1	1.000		1	0.372
Ascites	1	1	1.000	1		1.000
Loss of weight	1	1	1.000	1	1	1.000
Anemia					2	0.135
Back pain		1		1		1.000
Elevation of tumor marker	2	1	0.602	1	1	1.000
Poor appetite or distention	5	6	1.000	6	4	1.000
History of GI surgery	2	2	1.000	2	1	1.000
Total	45 (53)	50 (54)		49 (55)	29 (33)	

DBE – double-balloon enteroscopy; SBE – single-balloon enteroscopy.

Statistical analysis

All statistical analyses were performed using SPSS (Version 13.0 for Windows, SPSS Inc., Chicago, IL). Chi-square or Fisher exact tests were used to analyze categorical data, including constituent ratio of chief complaints, constituent ratio of diagnosis, and diagnosis rate. Continuous variables were compared using the Student's t-test. The Mann-Whitney U test was performed to compare the differences in the procedure time between DBE and SBE. Differences with $p<0.05$ were considered statistically significant.

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Table 3. Diagnostic yield of DBE and SBE.

	Per-anal			Per-oral		
	DBE	SBE	*P* value	DBE	SBE	*P* value
Total	45	50		49	29	
Crohn's disease	6	7		4	1	
Intestinal tuberculosis		2				
Angiotelectasis/vascular malformation	4	5				
Ulcer	2	2		3	5	
Stromal tumor	2	3		4	1	
Inflammation		7		2	2	
Malignant stromal tumor					2	
Diverticula	1	1		2	2	
Diverticulitis					1	
Polyp		3		2	2	
Adenocarcinoma		1		2		
Lymphoma					1	
Behçet's disease	1			1		
Normal	29	19		29	12	
Positive diagnosis rate (%)	35.6	62.0	0.0137	40.8	58.6	0.1617

DBE – double-balloon enteroscopy; SBE – single-balloon enteroscopy.

Results

Patient characteristics

A total of 173 patients were included for this study. Per-anal DBE and SBE procedures were performed on 45 and 50 patients, respectively, whereas 49 and 29 patients received DBE and SBE via the oral route, respectively. There were no significant differences in the baseline patient characteristics, including age, gender, and the ratio of chief complaints, between the DBE and SBE groups who received ether per-anal or per-oral procedures ($P>0.05$) (Table 2). All procedures were performed smoothly without any notable complications such as bleeding, perforation and acute pancreatitis.

Diagnostic yield

To compare the clinical performance between DBE and SBE, we first examined the diagnostic yield of these 2 enteroscopy systems in patients with small bowel diseases. As shown in Table 3, common findings from the endoscopic examinations included Crohn's disease, intestinal tuberculosis, angiotelectasis or vascular malformation, benign or malignant stromal tumor, diverticulitis, inflammation, adenocarcinoma, lymphoma, Behçet's disease, and polyp. Remarkably, the diagnostic yield of SBE (62.0%) was significantly higher than that of DBE (35.6%) via the anal approach ($P=0.0137$). However, there was no significant difference in the diagnostic yield between DBE (40.8%) and SBE (58.6%) ($P=0.1617$) via the oral route (Table 3).

Influence of DBE and SBE on the diagnostic/therapeutic course

As described above, both DBE and SBE are extremely safe procedures to perform and do not cause serious adverse events such as bleeding, perforation, and acute pancreatitis. We also determined whether the endoscopic procedures make any difference in the diagnostic and therapeutic schemes for patients with small bowel diseases. As shown in Table 4, there was no significant difference between the DBE and SBE endoscopic examinations in the number of patients whose diagnostic or therapeutic schemes were adjusted following the endoscopic procedures ($P>0.05$).

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Table 4. The impact of DBE and SBE on the diagnostic/therapeutic courses.

	DBE (changed/total)	SBE (changed/total)	*P* value
Abdominal pain	8/20	6/15	1.000
Diarrhea	2/19	3/13	0.375
Melena	7/22	5/22	0.736
Bloody stool	1/11	1/6	1.000
Vomiting	0/4	0/4	
Poor appetite or distention	4/11	6/10	0.395
Other symptoms	5/21	5/17	0.727

DBE – double-balloon enteroscopy; SBE – single-balloon enteroscopy.

Table 5. Examination time and post-procedure discomfort.

	Per-anal			Per-oral		
	DBE	SBE	*P* value	DBE	SBE	*P* value
Time of examination	51.13±10.97	50.62±10.08	0.952	41.80±6.50	38.86±5.64	0.048
Discomfort or aggravation of pain 24 h after procedure	6	7	1.000	4	2	1.000

DBE – double-balloon enteroscopy; SBE – single-balloon enteroscopy.

Examination time and post-procedure discomfort

Examination time and post-procedure discomfort are 2 important factors that we should take into considerations when we compare the advantages and limitations of DBE and SBE in the diagnosis and therapeutic intervention in patients with small bowel diseases. Our data show that the average examination time for the per-anal DBE (51.13±10.97 minutes) is very comparable to that for the per-anal SBE (50.62±10.08 minutes) (*P*=0.952) (Table 5). However, the average examination time for SBE (38.86±5.64 minutes) is significantly shorter than that for DBE (41.80±6.50 minutes) via the oral approach (*P*=0.048). Notably, there was no significant difference in post-procedure discomfort between the 2 groups (*P*=1.000) (Table 5).

Discussion

The development of balloon-assisted enteroscopy, including DBE and SBE, revolutionized the diagnosis and treatment of small bowel disorders such as occult gastrointestinal bleeding, small intestinal obstruction, and chronic diarrhea [5,11]. The main difference between DBE and SBE lies in the number of balloons [6]. DBE is composed of an endoscope and a soft overtube whose tips are both attached by a balloon. By contrast, SBE was simplified to possess only 1 balloon at the tip of the overtube [2,4]. Thus, it has been suggested that SBE requires less preparation and examination time than DBE [7]. Consistently, our data demonstrated that the average examination time for SBE is significantly shorter than that for DBE via an anterograde approach through the mouth. Additionally, there is no significant difference in the diagnostic yield between DBE and SBE via the oral route. Thus, our findings indicate that SBE is a favored choice for the management of small bowel diseases as compared to DBE via the oral route if examination time is one of the main concerns. However, DBE and SBE are very similar in the average examination time via a retrograde approach through the anus. Strikingly, SBE also displays a significantly higher diagnostic yield than DBE via the anal route. Similarly, SBE also appears to perform better than DBE via the oral route, although the difference is not statistically significant and it may need future studies with larger sample size to verify these data. Therefore, although the reasons for the increased diagnostic yield from SBE are still unknown, our findings also favor SBE as a better choice compared with DBE via the anal route, since both DBE and SBE are very safe procedures to perform.

Several studies have compared the efficacy and safety of DBE and SBE in the management of patients with small bowel diseases [6–9,11,12], but the findings from those studies yielded inconsistent results. For example, consistent with our findings, Lenz et al. reported a higher diagnostic yield from SBE than from DBE, whereas a meta-analysis by Lipka et al. found no difference in this regard. The inconsistent findings may result from different levels of experiences of the endoscopists who performed

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the enteroscopy DBE and SBE procedures. Additionally, the DBE and SBE procedures were carried out by more than one endoscopist in some studies [7–9], which can further increase the inconsistency. Balloon-assisted enteroscopy DBE and SBE are a challenging procedure and usually associated with a steep learning curve [13]. It was reported that experienced endoscopists who received previous DBE training could only achieve ~69% of success rate in the stable insertion of the DBE endoscope through the ileocecal valve into the terminal ileum in the first year of DBE procedures they performed [14]. Thus, it is reasonable to expect that, in previous studies, endoscopists with different levels of experience may have reported inconsistent findings on the efficacy and safety of DBE and SBE, including diagnostic yield and complication rate. Notably, in our study, all of the DBE and SBE procedures were carried out by one endoscopist with more than 10 years of experience in performing gastrointestinal endoscopy, including about 5 years of clinical practice in small bowel endoscopy such as push enteroscopy, DBE and SBE and thus the operator was very proficient in performing both DBE and SBE procedures. Hence, in our study, we rule out the impact of performance bias of the operators on the results of our study, which definitely helps to reveal the true advantages and limitations of DBE and SBE.

Depth of insertion for endoscopic examinations is of great interest to endoscopists. It is important to note that the endpoints of our examinations were when a significant lesion was detected or when the time limit of the procedures was reached. Thus, the depth of insertion was not determined in our study. Several studies have compared the depth of insertion of total endoscopy using DBE and SBE, but the findings have not reached a consistent conclusion regarding the total endoscopy rate of DBE and SBE [2,8,9]. Previous evidence from 2 randomized trials indicates that the total endoscopy rate of DBE can be close to 66%, which is significantly higher than that of SBE [8]. Nevertheless, it was also reported that no statistical difference in the insertion depth between SBE and DBE [9]. Different methods used to measure the insertion depth may have led to the inconsistent results. The net insertion of the overtube of enteroscopes was measured to calculate the depth with each 5 cm of overtube advancement corresponding to approximately 40 cm of endoscope advancement [15]. Another method is to count the number of folds, and the average distance between folds was 0.9 cm [9]. It will be very interesting to include depth of insertion using either method as described above in our future study to determine its effect on the results of our endoscopic examinations.

It is also worth noting that we did not observe any notable complications such as bleeding, perforation and acute pancreatitis after the DBE and SBE examinations in our study, although the patients may have experienced certain degrees of abdominal discomfort. The abdominal pain/discomfort may be caused by insufflation of air in the enteral lumen. Thus, as recommended by a previous study [16], we employed carbon dioxide (CO_2) insufflation to reduce post-procedure pain and bowel distention. Intriguingly, previous studies have shown that CO_2 insufflation can even improve the intubation depth and total endoscopy rate of SBE [16,17]. Hence, it will also be interesting to examine the effect of CO_2 insufflation on the efficacy and safety of DBE and SBE in the future.

One of the major limitations regarding our work is that this was a retrospective study. Additionally, this study was conducted in a single center and the subjects enrolled in this study were only Chinese patients. Therefore, it will be very important to perform additional studies with larger sample sizes in different ethnic populations and from multiple centers to validate these findings in the future.

Conclusions

Our findings indicate that both DBE and SBE are extremely safe procedures. SBE exhibits a significant shorter examination time than DBE via the oral route, while DBE and SBE are similar in the examination time via the anal approach. Additionally, SBE also displays a significantly higher diagnostic yield than DBE via the anal route. These findings may provide important guidance on the use of DBE and SBE in the management of patients with small bowel diseases in the future.

Conflicts of interest

The authors declare that they have no conflicts of interest regarding this article.

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