Inspecting the total gastrointestinal tract by consecutive bidirectional double-balloon enteroscopy in patients with suspected small bowel bleeding

Liang Zhao, Anning Yin*, Fei Liao, Yijuan Ding, Honggang Yu*

Department of Gastroenterology, Renmin Hospital of Wuhan University, Wuhan, Hubei, China

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ABSTRACT

Background/Aims: *This study aimed to investigate the feasibility, efficiency, and clinical significance of examining the total gastrointestinal (GI) tract by consecutive bidirectional double-balloon enteroscopy (DBE) within 1 day in patients with suspected small-bowel bleeding.*

Materials and Methods: *From January 2016 to January 2018, the clinical and endoscopic data of 41 patients with suspected small-bowel bleeding undergoing DBE aimed at inspecting the total GI tract within 1 day.*

Results: *A success rate of 87.8% (36/41) for examining the total GI tract with no adverse event was achieved by consecutive bidirectional DBE performed within 1 day. The total examination time was 140.61±36.41 (range, 82-270) minutes. Positive or negative findings of bleeding were detected in 51.2% (21/41) and 48.8% (20/41) patients, respectively. Single bleeding etiology with non-small-bowel lesions (NSBLs) or small-bowel lesions (SBLs) was detected in 12.2% (5/41) and 26.8% (11/41) of patients, respectively. Dual bleeding etiologies, including NSBLs and SBLs, were detected in 12.2% (5/41) of patients. A re-bleeding rate of positive or negative findings was different (4.8% vs. 40.0%; p<0.05).*

Conclusion: *Consecutive bidirectional DBE within 1 day can achieve complete vision of the total GI tract with a considerable success rate and high safety. This strategy may provide an option for detecting bleeding etiology throughout the GI tract. A negative finding with this method cannot absolutely exclude missed bleeding etiology and re-bleeding.*

Keywords: *Gastrointestinal hemorrhage, double-balloon enteroscopy*

INTRODUCTION

Obscure gastrointestinal bleeding (OGIB) is traditionally defined as bleeding from the gastrointestinal (GI) tract that persists or recurs without an obvious etiology after esophagogastroduodenoscopy (EGD), colonoscopy, and radiologic evaluation of the small bowel (1). It accounts for 5%-10% of GI bleeding, with the majority of the bleeding source (70%-80%) originating from the small bowel (2-4). Owing to the concurrent advances in small-bowel imaging, including capsule endoscopy (CE), deep enteroscopy, and computed tomography enterography (CTE), the diagnosis of small-bowel lesions (SBLs) has dramatically improved. The term "suspected small-bowel bleeding" has been recently recommended as a replacement for the former definition of OGIB (3). Accordingly, the term "OGIB" should be reserved for patients in whom a source of bleeding has not been found anywhere in the GI tract after EGD, colonoscopy, small bowel evaluation with CE and/or enteroscopy, and radiographic testing (3). Deep enteroscopy is an important approach among the diagnostic algorithms of suspected small-bowel bleeding. Total deep enteroscopy is recommended if there is a strong suspicion of an SBL on the basis of clinical presentation or abnormal CE study (3). This usually depends on the discretion of the endoscopist, the degree of clinical suspicion of SBL, and the inability to detect the lesion using a single approach. It is generally accepted that double-balloon enteroscopy (DBE) provides the highest success rate in total enteroscopy, mostly achieved by a combination of antegrade and retrograde approaches (1, 3, 5-7). Routinely, the alternative insertion procedure is scheduled on the next day or on another day within a week (8-11).

It should be emphasized that a significant percentage of the patients with suspected small-bowel bleeding actually have bleeding sources within the reach of EGD and colonoscopy, and are non-small-bowel lesions (NSBLs)

#The first two authors contributed equally to this study.

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Corresponding Author: ***Liang Zhao; zhyscopy@yeah.net***

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(12-17). Therefore, a second-look EGD and/or colonoscopy in patients with a high suspicion of NSBLs or incomplete initial examination is recommended (3). However, the effectiveness of this strategy has been doubted, and not all patients are willing to finish the second-look endoscopy (4). It is noteworthy that NSBLs can be effectively detected and newly diagnosed during DBE (15-16).

Theoretically, we can have a comprehensive understanding of the presence, amount, phenotype, and distribution of all NSBLs and SBLs, potentially accounting for GI bleeding, only when the total GI tract has been inspected. DBE is an effective method for detecting NSBLs as well as SBLs and has the potential for inspecting the total GI tract. This study aimed to investigate the feasibility, efficiency, and clinical significance of examining the total GI tract by performing consecutive bidirectional DBE within 1 day in patients with suspected small-bowel bleeding.

MATERIALS AND METHODS

Data Collection and Analysis

Clinical and endoscopic data of patients with suspected small-bowel bleeding undergoing DBE at Renmin hospital of Wuhan university, China, from January 2016 to January 2018 were collected and analyzed retrospectively. Patients planning a complete vision of the total GI tract by DBE were included. Inclusion criteria were complete vision of the total GI tract by DBE requisite for establishing a definite diagnosis, EGD and colonoscopy performed earlier at least once, and CE and/or CTE performed before DBE. Exclusion criteria were presence of etiology definitely accounting for GI bleeding and thus further insertion found unnecessary and lesions obviously preventing further insertion (huge mass and lumen stricture). The data, including baseline characteristics, indications, initial and subsequent insertion routes, examination time for the entire procedure, success rate, findings and diagnosis, and adverse events. were specially reviewed and analyzed. This study was performed in conformity with the Declaration of Helsinki.

MAIN POINTS

- *In this study, a special DBE (consecutive bidirectional procedure without X-ray fluoroscopy guidance) was performed to inspect the total GI tract.*
- *This is the first report demonstrating the feasibility and efficiency of achieving complete vision of the total GI tract by a consecutive bidirectional DBE procedure within one day.*
- *No guideline is currently available on the diagnosis and treatment for dual bleeding etiologies. In our opinion, the decision should be made on a case-by-case basis.*

DBE Procedure

DBE was performed with the EN-530T enteroscopy system (Fujinon Inc., Saitama, Japan). The endoscope tip cap was not used in the procedure. All the patients were told to fast for 12 hours before the DBE and bowel preparation (polyethylene glycol electrolyte mixed with 2,000 mL water) was administered 4-5 hours before the procedure. General anesthesia (intravenous propofol, 2-3 mg/kg/hour) was administered by anesthesiologists monitoring cardiorespiratory parameters. All the patients had intubation and mechanical ventilation. DBE was manipulated by three endoscopists with an experience of at least 50 DBE procedures for each endoscopist (18). Carbon dioxide insufflation was used without X-ray fluoroscopy guidance.

The initial insertion route was directly determined according to the clinical information and/or previous findings. The furthest insertion point was tattooed by submucosal injection with 10% methylene solution (3-5 mL) as a marker. The opposite route was performed subsequently. Further insertion was not performed if further advancement of the scope was over 20 minutes (10). Total enteroscopy was confirmed by reaching the mark made by the initial insertion. The success rate was defined as the ratio of the number of patients achieving complete vision of the entire GI tract to the total patients in whom an attempt was made to examine the entire GI tract (7). The total examination time required for the total GI tract was calculated by adding the insertion time of both insertion routes (19, 20).

DBE Findings, Diagnosis, and Follow-up

DBE findings with active bleeding, recent evidence of bleeding (adhered clot, non-bleeding visible vessels, and pigmented material at lesion base), polyps/tumors more than 20 mm in diameter, and ulcers more than 10 mm in diameter are considered as lesions definitely accounting for GI bleeding. Lack of evidence of active or recent bleeding was as attributed to lesions possibly accounting for GI bleeding (21, 22). The definition of "positive findings" was abnormalities or lesions noted on complete vision of the total GI tract. Absence of abnormalities or lesions were regarded as "negative findings," complete vision of the total GI tract as "normal," and incomplete vision of the total GI tract as "inconclusive." NSBLs were defined as lesions from regions proximal to the ampulla of Vater or distal to the ileocecal valve, which were within the reach of EGD and colonoscopy (15, 16). Vascular lesions of the small bowel were classified on the basis of

the Yano-Yamamoto classification (23). Follow-up was carried out by email contact or telephone interview.

Adverse Events

DBE adverse events were any adverse event that negatively altered the health condition of the patient during or after the procedure. They can be divided into minor and major categories according to the severity (14).

Statistical Analysis

Continuous variables, expressed as mean±standard deviation, were compared by the Studentt-test. For comparison of categorical variables, chi-squared test and/or the Fisher exact test were used when appropriate. Differences were considered significant for a p value of <0.05. Statistical analysis was performed using the IBM Statistical Package for the Social Sciences (SPSS) version 22.0, (IBM Corp.; Armonk, NY, USA) software.

Table 1. Baseline characteristics of patients with suspected small bowel bleeding aiming at examining the total GI tract by DBE

Baseline characteristics	n (%)
Age (yrs), mean ± SD (range)	48.70 ± 14.94 (15-65)
Gender (M/F)	28 (68.2%)/13 (31.8%)
Previous surgery	
Appendectomy	3 (7.3%)
BillrothIIgastrectomy	1 (2.4%)
Ovarian cystectomy	1 (2.4%)
Comorbidity	
Cardiovascular disease	9 (21.9%)
Respiratory disease	5 (4.9%)
Chronic renal disease	2 (4.9%)
Chronic liver disease	1 (2.4%)
Use of anticoagulant	0 (0%)
Use of nonsteroid anti-inflammatory drug	0 (0%)
Presenting symptom	
Melena	65 (66.3%)
Hematochezia	33 (33.7%)
Occult bleeding	0 (0%)
Initial insertion	
anal route	35 (85.3%)
Oral route	6 (14.7%)
Time from last bleeding to	
DBE (d) mean ± SD (range)	22.46 ± 14.68 (7-60)
Blood transfusion	73 (74.4%)
Small bowel investigation before DBE	
CE	10 (24.4%)
CTE	23 (56.0%)
CE and CTE	8 (19.6%)

GI: gastrointestinal; DBE: double-balloon enteroscopy; CE: capsule endoscopy; CTE: computed tomography enterography.

RESULTS

Baseline Characteristics and Recruitment of Patients for Inspecting the Total GI Tract by DBE

From January 2016 to January 2018, DBE was performed on 118 patients with suspected small-bowel bleeding at Renmin Hospital of Wuhan University, China. Of these patients, 41 patients were scheduled for inspection of the total GI tract. Baseline characteristics of the patients are summarized in Table 1, and recruitment for this plan is illustrated in Figure 1.

DBE Procedures

During bidirectional DBE, initial retrograde and anterograde insertions were planned for 85.3 % (35/41) and 14.7% (6/41) of the patients, respectively (Table 1). The success rate for the complete vision of the total GI tract was 87.8 % (36/41). The total examination time for this procedure was 140.61±36.41 (range, 82-270) minutes. The average procedure time of each initial insertion route was 116.71±30.46 (retrograde, range 80-240) and 109.17±26.54 (anterograde, range 60-135) minutes; however, the difference was not statistically significant (p=0.974). No adverse events occurred.

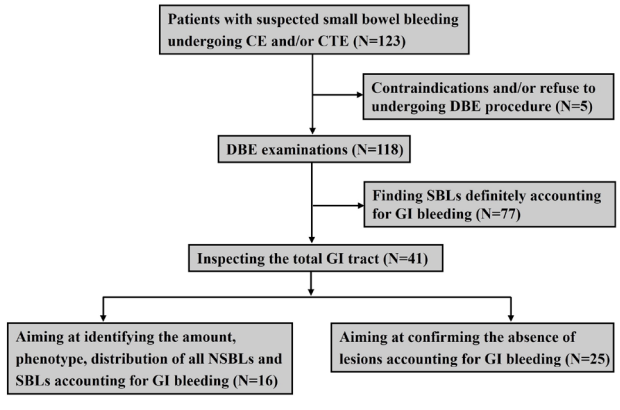

Figure 1. Flowchart of recruitment of patients with suspected small-bowel bleeding aiming to achieve complete vision of the total gastrointestinal tract.

Table 2. The DBE findings, diagnosis, treatment and clinical outcome of patients aiming at achieving complete vision of total GI tract

			Clinical Outcome	
DBE Findings	Diagnosis	Treatment	Controlled	Uncontrolled
NSBLs (n=5)				
Single NSBL (n=2)				
Colonic diverticulum (n=1)	Colonic diverticulum (n=1)	Observation	1	
Duodenal diverticulum (n=1)	Duodenal diverticulum (n=1)	Observation	1	
Multiple NSBLs (n=3)				
Colonic angioectasias (n=1)	Colonic angioectasias (n=1)	APC	1	
Fundic angioectasias (n=1)	Fundic angioectasias (n=1)	APC+Clipping	1	
Duodenal angioectasias (n=1)	Duodenal angioectasias (n=1)	APC	1	
SBLs (n=11)				
Single SBL (n=4)	Traditional serrated polyp (n=1)	EMR	1	
Jejunal polyp (n=2)	Adenoma (n=1)	EMR	1	
Ileal diverticulum (n=1)	Diverticulum (n=1)	Surgical resection	1	
Jejunal anastomotic ulcer (n=1)	anastomotic ulcer (n=1)	Observation	1	
Multiple SBLs (n=7)				
Jejunal erosion (n=2)	Ancylostomiasis (n=2)	Alendazole	2	
Ileal angioectasias (n=2)	Ileal angioectasias (n=2)	APC+thalidomide	1	1
Jejunal diverticulum (n=1)	Jejunal diverticulum (n=1)	Observation	1	
Ileal ulcer (n=1)	non-specific ulcer (n=1)	Observation	1	
Single ileal polyp+Single ileal diverticulum (n=1)	Adenoma+diverticulum (n=1)	Surgical resection	1	
NSBLs +SBLs (n=5)				
Single NSBL+Single SBL (n=3)				
Duodenal polyp+Ileal diverticulum (n=1)	Diverticulum	Surgical resection	1	
Jejunal protrusion+cecal protrusion (n=1)	Jejunal lymphoma+cecal schistosomal granuloma (n=1)	Chemotherapy	1	
Duodenal diverticulum+ ileal ulcer (n=1)	Duodenal diverticulum+ ileal ulcer (n=1)	Observation	1	
Multiple NSBLs+Multiple SBLs (n=2)				
Gastric erosion+ileal erosion (n=1)	Henoch-Schonlein purpura (n=1)	Prednisone	1	
Cecal polyp+ileal angioectasias (n=1)	Angioectasias (n=1)	APC+thalidomide	1	
Negative findings (n=20)				
Normal (n=17)	Normal (n=15)	Observation	10	5
	GIST* (n=2)	Surgical resection	2	
Inconclusive (n=3)	Inconclusive (n= 3)	Observation	1	2

*Small bowel mass is detected by CTE before DBE examination in two patients.
They are submitted to surgery resection and are diagnosized as GIST by pathology.
GI: gastrointestinal; DBE: double-balloon enteroscopy; NSBL: non-small-bowel lesions; SBL: small-bowel lesions; CTE:computed tomography enterography; GIST: gastrointestinal stromal tumor.

DBE Findings, Diagnosis, Treatment, and Clinical Outcome

DBE findings, diagnosis, treatment, and clinical outcome are listed in Table 2. There were 6 patients who were given treatment with "observation", in which the positive findings were considered as lesions possibly accounting for GI bleeding. NSBLs were newly diagnosed in 24.3% (10/41) of patients, SBLs newly diagnosed (not detected by CE and/or CTE) in 34.1% (14/41). And 5 patients (12.1%, 5/41) had possible dual bleeding etiologies with both SBLs and NSBLs. No bleeding etiology was detected in 48.8% (20/41) of patients, including 44.4% (16/36) achieving complete vision of the total GI tract. All the patients were followed up for 9 to 32 months. Re-bleeding occurred in 4.8% (1/21) of patients with positive findings and in 40.0% (8/20) of patients with negative findings (difference was significant, p=0.0189). Moreover, 1 patient with re-bleeding after positive findings was treated with conservative therapy. The subsequent examination and treatment of negative findings for re-bleeding are illustrated in Figures 2 and 3.

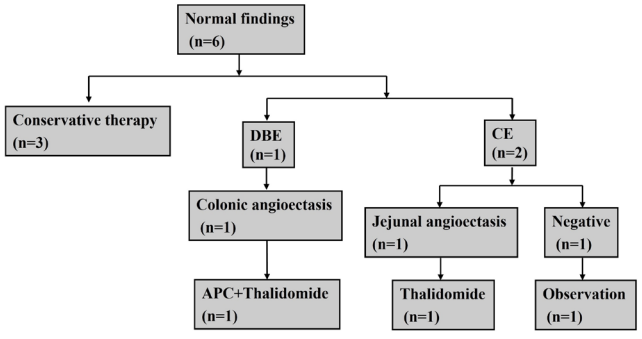

Figure 2. Examination and treatment of patients with re-bleeding with normal findings by double-balloon enteroscopy (n=6).

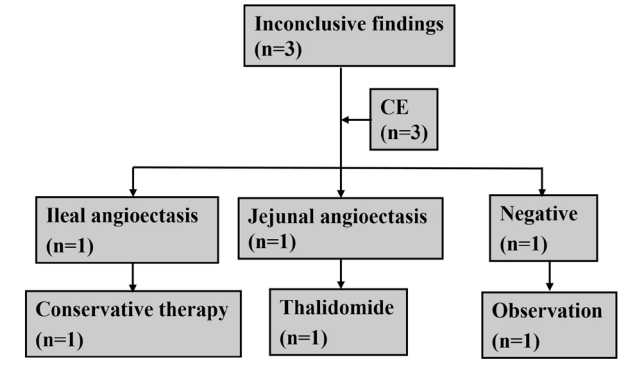

Figure 3. Examination and treatment of patients with re-bleeding with inconclusive findings by double-balloon enteroscopy (n=3).

DISCUSSION

Despite technical advancements in small-bowel imaging, accurate diagnosis of suspected small-bowel bleeding still presents a significant challenge for the gastroenterologist. Endoscopic inspection of the total GI tract in patients with suspected small-bowel bleeding is routinely scheduled for at least three different days including, one day for a second-look using EGD and colonoscopy, one day for the initial insertion procedure of deep enteroscopy, and one day for the alternative insertion procedure. This arrangement usually presents a substantial stress on the utilization of endoscopy and human resources and also causes great inconvenience to patients. As DBE has the potential to inspect the total GI tract, is it possible to check the total GI tract completely by consecutive bidirectional DBE?

In this study, a special DBE (consecutive bidirectional procedure without X-ray fluoroscopy guidance) was performed to inspect the total GI tract. This strategy achieved a success rate of 87.8% (36/41) in examining the total GI tract with no adverse events. The total examination time required for the complete vision of the total GI tract was 140.61±36.41 (range 82–270) minutes. This is the first report demonstrating the feasibility and efficiency of achieving complete vision of the total GI tract by a consecutive bidirectional DBE procedure within one day. Our data provides evidence that consecutive bidirectional DBE can achieve complete vision of the total GI tract with a satisfactory success rate and safety, which are comparable with the outcome of two previous studies aimed at achieving total enteroscopy by bidirectional DBE (with X-ray fluoroscopic guidance) performed on two different days (11, 21). We propose that this method exhibits several advantages over the traditional arrangement of endoscopic examination, including a second-look using EGD and colonoscopy; avoiding repeat fasting, bowel preparation, anesthesia, and radiation exposure; shorter duration of hospitalization; and accurate and prompt diagnosis depending on the data of all possible lesions accounting for GI bleeding.

Our data indicated that complete vision of the total GI tract was required in 34.7% (41/118) of patients with suspected small-bowel bleeding during DBE, which reflects a considerable clinical demand for it. Detection of both NSBLs and SBLs has been described earlier; however, whether complete vision of the total GI tract was achieved during DBE has not been mentioned (14-15). Our study showed a single bleeding etiology with either NSBL (13.8%, 5/36) or SBL (30.5%, 11/36) in patients

achieving complete vision of the total GI tract by DBE. As complete vision of the total GI tract is achieved, the detected lesions are considered to be the only possible etiology causing bleeding and subsequently submitted for appropriate treatment or surveillance. Furthermore, 12.1% (5/41) of these patients in our study had possible dual bleeding etiologies with both SBLs and NSBLs. This percentage was similar to that in another study (10.5%) (15). Therefore, the need to inspect the total GI tract may be necessary and vital for a certain subgroup of patients with GI bleeding. No guideline is currently available on the diagnosis and treatment for dual bleeding etiologies. In our opinion, the decision should be made on a case-by-case basis. The diagnosis should be accurately made on the complete evaluation of the phenotype, size, appearance, behavior, malignant potential of all detected lesions, and careful analysis of their correlation with GI bleeding. The lesion that is most likely responsible for the GI bleeding or having malignant potential should be treated preferentially. Follow-up and repeat examination at an appropriate time upon re-bleeding is essential in any condition.

In our study, no bleeding etiology was detected in a significant percentage (44.4%, 16/36) of the patients and met the criteria for "OGIB" in 2015 (3). Less data are available for the clinical outcome of that condition. During the follow-up period ranging from 9 to 32 months, no re-bleeding occurred in 68.8% (11/16) of patients. The possible explanation may be that these were self-limited or self-healed lesions caused by acute infection, ischemia, drug-induced damage, or other causes, which may have been invisible during DBE. Alternatively, re-bleeding occurred in 31.3% (5/16) of patients. Small-bowel gastrointestinal stromal tumor (GIST) missed by DBE was revealed by CTE before performing DBE in two patients. Subsequent CE or DBE after re-bleeding revealed intestinal vascular lesions in two other patients (Table 2). There were similar findings in previous research; however, the diagnosis for re-bleeding in patients achieving total enteroscopy was not mentioned in detail (24, 25). Negative findings throughout the total GI tract cannot absolutely exclude the possibility of a bleeding etiology being missed and the occurrence of re-bleeding. The possibility of an extraluminal mass in the small bowel and vascular lesions with intermittent bleeding should be considered, which may be detected by complimentary CTE or repeat endoscopy.

The success rate in identifying the bleeding source was 51.2%, which was owing to the fact that the period from final bleeding to DBE was as long as 22.46 days on average. This percentage was similar to that of another study (26) with 44.8% success rate. The average time of more than three weeks for patients to complete a DBE in our hospital is mainly spent on the patients' appointment for hospitalization and DBE and the completion of relevant examinations after admission. For most patients hospitalized in community hospitals for the first time, small-bowel endoscopy (including CE and/or deep enteroscopy) and CTE are not routine examination methods. The schedule for the examination would not be delayed by performing both anterograde and retrograde DBE on the same day, whereas we could arrange more than one patient who needed to undergo DBE in a day, whether retrograde and/or anterograde.

In the study, there were 24 patients with melena (58.5%) and 17 patients with hematochezia (41.5%). However, retrograde DBE was chosen more often (35/41, 85.3%) as the initial insertion route owing to several reasons. First, the results of CE and/or CTE of some patients showed the suspicious bleeding lesion was close to the proximal and ileocecal valves. Second, the priority was to complete retrograde DBE where insertion was more difficult than in anterograde DBE. Finally, the possibility of acute pancreatitis and medical history of some patients was also considered.

Our study had some limitations. First, this was a single-center retrospective analysis with a relatively small sample size and short follow-up period. Possible bias may have existed in evaluating the value of this study. Second, there is a statement in the recent technical review by European Society of Gastrointestinal Endoscopy on small-bowel enteroscopy recommending against performing bidirectional enteroscopy on the same day (27). Out study data came from a single-center retrospective analysis, and the insertion depth achieved is mainly an index to compare between retrograde DBE when performed as an isolated procedure and when performed immediately after anterograde DBE (28). More evidence, such as from randomized controlled trials, may be needed to confirm the conclusions.

In conclusion, a consecutive bidirectional DBE procedure within 1 day can achieve complete vision of the total GI tract with a considerable success rate and high safety. This strategy provides an option for detecting all possible bleeding etiologies throughout the total GI tract. Negative findings cannot exclude the presence of bleeding etiology and the occurrence of re-bleeding. Alternative

or complimentary approaches to this strategy should be evaluated in further research aimed at further increasing the diagnostic yield of suspected small-bowel bleeding.

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