

Predictors for outcomes and readmission rates following double balloon enteroscopy: a tertiary care experience



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ABSTRACT

Aim The objectives of this study are to examine clinical characteristics of patients undergoing anterograde and retrograde double balloon enteroscopy (DBE) and to assess factors predicting positive diagnostic yield, therapeutic yield, and readmission.

Methods We conducted a retrospective cohort study of patients ($n=420$) who underwent DBE at a tertiary care center between 2012 and 2016 at a tertiary referral center. Measures of central tendency and frequency distributions were used for univariate analysis. Chi-square and t-test analyses were used to compare patient characteristics. Logistic regression was used to predict outcomes of interest.

Results Of patients included in the study, 59% were male with a mean age of 61.49 (SD=15.15). Altered anatomy was noted in 14%, while 5% and 13% of patients had end stage renal disease (ESRD) and current use of anticoagulation, respectively. The most common indication for DBE was obscure gastrointestinal bleed (OGIB) (33%). Forty-nine patients had obscure and overt gastrointestinal bleeding (GIB) and 22% had occult GIB with iron deficiency. The cohort's rate of positive diagnostic yield was 73% and 35% for therapeutic yield. The 30-day and 6-month readmission rates were both 11%. A higher proportion of those readmitted were male (75% vs 57%, $P=0.027$) and had longer procedural time (38.68 vs 46.57, $P=0.011$). Likewise, occult GIB with iron deficiency anemia and iron deficiency alone (OR=2.45, CI: 1.233–4.859, $P=0.011$), inpatient status (OR 2.42, CI 1.344–4.346, $P=0.003$), and longer procedural time (OR=1.02, CI: 1.004–1.029, $P=0.008$) were associated positively with readmission.

There were no statistically significant predictors of positive diagnostic yield, however procedural time (OR=1.01, CI: 1.03–1.026; $P=.0017$) and older age (OR=1.03, CI: 1.009–1.045, $P=0.003$) were positively associated with therapeutic yield. Retrograde procedure (OR=0.230, CI 0.125–0.422, $P=0.000$) was negatively associated with therapeutic yield.

Conclusion DBE procedures have relevant efficacy for both diagnostic and therapeutic yield while evaluating small bowel disease. Readmission rates are low and more in those with GI bleed and iron deficiency with longer index procedural times.

Introduction

The indications for enteroscopy have continued to expand. Among these include evaluation for iron deficiency anemia, inflammatory bowel disease, and small bowel masses [1, 2]. Enteroscopy also allows for therapeutic procedures such as endoscopic retrograde cholangiopancreatography (ERCP), jejunal tube placement, and investigating surgically altered anatomy [3–5]. So far, evaluation for suspected small bowel bleeding is the most common indication despite negative endoscopic evaluation [2]. Current guidelines reserve the term obscure gastrointestinal (GI) bleeding (OGIB) to identify patients not found to have a source of bleeding after performance of standard upper and lower endoscopic examinations, small bowel evaluation with video capsule endoscopy (VCE), or radiographic testing [6, 7].

The diagnostic workup of such OGIB can be extensive and require longer hospital stays, blood transfusions, and multiple investigative procedures [8, 9]. In a prospective study of 60 patients, Kaffes et al. found significant reductions in transfusion requirements and re-bleeding events after interventional double-balloon enteroscopy (DBE) at 10 ± 5.2 mo postprocedure [10]. Thus, identifying factors early during admission that are associated with higher risk of re-bleeding or readmission would be advantageous from both a resource utilization and clinical outcomes perspective. A number of retrospective cohort studies have explored various aspects of DBE's performance and utility [11, 12]. However, the literature lacks evidence in identifying useful predictors of DBE success and outcomes, especially with regards to readmission rates after initial endoscopic evaluation. This study aims to characterize patient and procedural variables that impact both DBE diagnostic and therapeutic yield for various indications. Additionally, we explore whether certain patient characteristics can predict readmission rates.

Methods

Data collection and study design

We conducted a retrospective chart review of patients who underwent DBE at the University of Alabama at Birmingham, an academic tertiary center, between November 2012 and August 2016. We excluded patients aged <18 years and pregnant patients. The study was approved by the institutional review board. All procedures were performed under monitored anesthesia care using the diagnostic Fujinon Double-Balloon Enteroscopy System (Fujinon Inc., Saitama, Japan) with a 2.2-mm endoscopy accessory channel. Sedation was administered by trained anesthesia personnel for ambulatory care. Routinely, the preferred anesthesia for anterograde procedures was intubation and general anesthesia, while propofol sedation was predominately used for retrograde procedures. Procedures were performed by expert gastroenterologists with extensive experience in interpreting VCE and in performing DBE.

Demographic, clinical, and endoscopic data were extracted during chart review. Indications for the DBE procedures were noted. Obscure GI bleeding or suspected small bowel bleeding, either overt or occult, were classified per recent guidelines [6].

Outcomes of interest were rates and predictors of positive diagnostic yield, therapeutic yield, and readmission. Differences among these outcomes with respect to anterograde or retrograde DBE procedures were examined as well. Positive diagnostic yield was defined as a significant endoscopic finding on DBE that was considered to be clinically relevant to the indication for endoscopy. Therapeutic yield was defined as an endoscopic intervention. Readmission rates were calculated as those who were admitted for a GI-related cause such as GI bleeding overt or occult with iron deficiency. Early readmission was defined as hospital readmission as bedded outpatient or inpatient 30 d or 6 mo status post initial DBE.

Statistical analysis

Measures of central tendency and frequency distributions were calculated. Independent t-tests and chi-squared statistics were used for bivariate comparisons between anterograde and retrograde procedures. Logistic regression was used to predict positive diagnostic yield, therapeutic yield, and readmission. All analyses were conducted using SPSS version 22.0 statistical software and statistical significance was set at $P < 0.05$.

Results

Of all patients ($n = 420$) included in the study, 59% were male with a mean age of 61.49 years (standard deviation [SD] = 15.15), and 72% of procedures were performed in outpatient settings (► **Table 1a**). Thirty-three percent of patients had a body mass index (BMI) ≥ 30 and 88% had ASA III/IV classifications. Fourteen percent of patients had altered anatomy, while 5% and 13% had end-stage renal disease (ESRD) and current use of anticoagulation (vitamin K inhibitor, factor Xa inhibitor, direct thrombin inhibitor, or antiplatelet medication), respectively. Of those patients evaluated for suspected small bowel bleeding, 207 (49%) had overt and 93 (22%) had occult GI bleeding. The mean procedural time was 39.58 min (SD = 20.08), and 74% of DBE patients received anterograde procedures. In terms of retrograde procedures, cecal intubation and ileal examination was successful in 91.7% of patients. Reasons for incomplete examination were incomplete preparation, adhesions, and strictures. Total enteroscopy was achieved in 3 patients only, as the strategy was to target and treat the findings or lesion either by anterograde or retrograde approach. This was thought to be a reason for not pursuing total enteroscopy in most of the patients. Tattooing of the distal site of intubation was performed routinely in all included patients.

Compared to retrograde procedures, a higher proportion of DBE patients with anterograde procedures had altered anatomy (18% vs. 4%, $P = 0.000$), positive diagnostic yield (77% vs. 62%, $P = 0.003$), and therapeutic yield (41% vs. 16%, $P = 0.000$) (► **Table 1b**). Compared to anterograde procedures, a higher proportion of DBE patients with retrograde procedures were on anticoagulation (20% vs. 11%, $P = 0.010$) and received MAC anesthesia (34% vs. 8%, $P = 0.000$). There were no significant differences in procedural times between anterograde and retrograde procedures (38.84 vs. 41.73, $P = 0.202$). The most common kind of altered anatomy was Roux-en-Y gastric bypass.

► Table 1a Characteristics of DBE patients.

Variables (categories)	n (%) / mean (SD)
Sex	
▪ Male	249 (59%)
▪ Female	171 (41%)
Age, range: 16–93, mean (SD)	61.49 (15.15)
Patient type	
▪ Outpatient	303 (72%)
▪ Inpatient	117 (28%)
BMI (rank)	
▪ <18.5	17 (4%)
▪ 18.5–24.9	126 (30%)
▪ 25–29.5	119 (28%)
▪ 30+	153 (36%)
▪ n/a	5 (1%)
ASA class (rank)	
▪ I	1 (0%)
▪ II	49 (12%)
▪ III	321 (77%)
▪ IV	47 (11%)
Altered anatomy	
▪ No	361 (86%)
▪ Yes ¹	59 (14%)
Anticoagulation	
▪ No	363 (87%)
▪ Yes	55 (13%)
ESRD	
▪ No	398 (95%)
▪ Yes	22 (5%)
Anesthesia type	
▪ General	359 (86%)
▪ MAC (monitored anesthesia care)	61 (15%)
Pill capsule	
▪ No	212 (51%)
▪ Yes	207 (49%)
DBE type	
▪ Anterograde	311 (74%)
▪ Retrograde	109 (26%)
Total procedural time, range 1–149, mean (SD)	39.58 (20.08)
Indications	
▪ Obscure/overt GIB	207 (49%)

► Table 1a (Continuation)

Variables (categories)	n (%) / mean (SD)
▪ Occult GIB w/ iron deficiency and iron deficiency alone	93 (22%)
▪ Others ²	120 (29%)
Positive diagnostic yield	
▪ No	112 (27%)
▪ Yes	308 (73%)
Types of findings	
▪ Normal	112 (21%)
▪ Angioectasia/AVM	104 (20%)
▪ Fresh blood, erosions	53 (10%)
▪ Abnormal mucosa	34 (6%)
▪ Others ³	230 (43%)
Therapeutic yield	
▪ No	275 (65%)
▪ Yes	145 (35%)
Types of interventions	
▪ Nothing	275 (65%)
▪ APC	104 (22%)
▪ Epinephrine injection	24 (5%)
▪ Others ⁴	64 (14%)
30-d readmission following initial DBE intervention	
▪ No	373 (89%)
▪ Yes	47 (11%)
Reason: 30-d readmission	
▪ Non-GI-related reason	5 (11%)
▪ GI-related reason	42 (89%)
6-mo readmission following initial DBE intervention	
▪ No	372 (89%)
▪ Yes	48 (11%)
Reason: 6-mo readmission	
▪ Non-GI-related reason	8 (17%)
▪ GI-related reason	40 (83%)

¹ Roux-en-Y gastric bypass (29%), Billroth (17%), post-orthotopic liver transplant (OLT) with hepatico-jejunostomy (14%), others (24%): Whipple procedure, esophago-jejunostomy, partial gastrectomy-jejunostomy, hemigastrectomy, ileo-sigmoid anastomosis, hepatico-jejunostomy with Roux-en-Y, sleeve gastrectomy, post-OLT with Roux-en-Y, ileo colonic anastomosis, ileostomy, jejunum duodenal anastomosis.

² ERCP, abnormal computed tomography (CT), inflammatory bowel disease, polyps, weight loss, incomplete colonoscopy, small bowel obstruction, bile leak/stent exchange, G/J tube malfunction/removal, small bowel ulcers/lesions/mass, stricture, retained VCE capsule, nausea/vomiting, endoscopic feeding tube placement, surveillance s/p malignancy, diarrhea, stent migration, abnormal X-ray findings.

³ Diverticulosis, stricture/stenosis, adhesions, polyps, prominent lymphatics, scattered ulcers, healing ulcers, ulcer at small bowel anastomosis, CBD dilation/CBD stones/bile leak, marginal ulcer, Dieulafoy lesion, varices, nodules, small bowel dilation, small bowel mass, retained capsule, external compression, Meckel diverticulum poor prep, small bowel obstruction, fistulas, mucosal ring, dislodged stent, poor study/food debris.

⁴ Hemoclipping, stent removal/exchange/placement, balloon dilation, jejunostomy tube placement/removal, polypectomy, multipolar electrocoagulation, banding, sphincterotomy, fistula closure, endoscopic mucosal resection.

► **Table 1b** Bivariate comparison of clinical characteristics between patients with antegrade and retrograde DBE procedures.

	Antegrade	Retrograde	P-value
Sex			0.051
▪ Male	193 (62%)	56 (51%)	
▪ Female	118 (38%)	53 (49%)	
Age, range: 35–93, mean (SD)	61.72 (14.89)	60.83 (15.90)	0.601
Patient type			0.114
▪ Outpatient	218 (70%)	85 (78%)	
▪ Inpatient	93 (30%)	24 (22%)	
BMI			0.966
▪ <30	193 (63%)	69 (63%)	
▪ ≥30	113 (37%)	40 (37%)	
ASA class (rank)			0.680
▪ I/II	35 (11%)	14 (13%)	
▪ III/IV	273 (89%)	95 (87%)	
Altered anatomy			0.000¹
▪ No	256 (82%)	105 (96%)	
▪ Yes	55 (18%)	4 (4%)	
Anticoagulation			0.010¹
▪ No	277 (89%)	86 (80%)	
▪ Yes	33 (11%)	22 (20%)	
ESRD			0.723
▪ No	294 (95%)	104 (95%)	
▪ Yes	17 (5%)	5 (5%)	
Anesthesia type			0.000¹
▪ General	287 (92%)	72 (66%)	
▪ Mac	24 (8%)	37 (34%)	
Pill capsule			0.416
▪ No	161 (52%)	51 (47%)	
▪ Yes	150 (48%)	57 (53%)	
Total procedural time, mean (SD)	38.84 (20.01)	41.73 (20.21)	0.202
Positive diagnostic yield			0.003¹
▪ No	71 (23%)	41 (38%)	
▪ Yes	240 (77%)	68 (62%)	
Therapeutic yield			0.000¹
▪ No	183 (59%)	92 (84%)	
▪ Yes	128 (41%)	17 (16%)	
Readmission 30-d			0.433
▪ No	273 (88%)	100 (92%)	

► **Table 1b** (Continuation)

	Antegrade	Retrograde	P-value
▪ Yes	36 (12%)	9 (8%)	
Readmission 6-mo			0.873
▪ No	275 (88%)	97 (89%)	
▪ Yes	36 (12%)	12 (11%)	
¹ P<0.05			

The rates of positive diagnostic yield and therapeutic yield were 73% and 35%, respectively, for the procedure. The most frequent findings were GI angiodysplasia (GIAD) (20%), fresh blood erosions (10%), and diverticulosis (5%). Fresh blood erosions were defined as erosion of mucosa with evidence of bleeding. The general term “abnormal mucosa” was used to describe erythema, granularity, thickened folds, and/or edematous mucosa. The most frequent interventions were argon plasma coagulation (APC) (22%) and epinephrine injection (5%). One patient had a colonic perforation during a retrograde procedure secondary to adhesive disease requiring surgical intervention. Otherwise, there were no reported major complications such as pancreatitis or cardiorespiratory events.

In multivariable analysis, there were no independent significant predictors of positive diagnostic yield (table not shown). However, older age (odds ratio [OR]=1.03, confidence interval [CI]: 1.009–1.045, $P=0.003$) and longer procedural time (OR=1.01, CI: 1.03–1.026, $P=0.017$) were associated positively with therapeutic yield. Likewise, retrograde procedure (OR=0.230, CI: 0.125–0.422, $P=0.000$) was associated negatively with therapeutic yield (► **Table 2**).

The 30-d and 6-mo readmission rates were both 11%. Readmission rates were calculated as those who were admitted for a GI-related cause such as GI bleeding overt or occult with iron deficiency.

Compared to patients without 30-d readmission, a higher proportion of patients with 30-d readmission was male (75% vs. 57%, $P=0.027$) and had longer procedural time (38.68 vs. 46.57, $P=0.011$). Patients with and without 30-d readmission did not differ in any other clinical characteristic. In multivariable analysis, occult GIB with iron deficiency anemia (OR=2.45, CI: 1.233–4.859, $P=0.011$), inpatient status (OR=2.42, CI: 1.344–4.346, $P=0.003$), and longer procedural time (OR=1.02, CI: 1.004–1.029, $P=0.008$) were associated positively with readmission (► **Table 3**). Mean hemoglobin before initial DBE and at time of readmission was 8.41 (SD=1.8) and 9 (SD=2.3), respectively.

Discussion

Our study demonstrates that DBE is an effective means to investigate small bowel lesions that were previously unattainable with traditional endoscopy. This corroborates previously published studies describing effectiveness of DBE. Its primary advantage lies in its ability to examine the small bowel in its en-

► **Table 2** Multivariate logistic regression predicting therapeutic yield among DBE patients.

Variables	Categories	OR	95% CI	P-value
Sex	Male	1		
	Female	1.001	0.635 – 1.578	0.998
Age		1.027	1.009 – 1.045	0.003 ¹
BMI	≤ 29	1		
	≥ 30	0.876	0.550 – 1.394	0.576
ASA class	I/II	1		
	III/IV	1.677	0.735 – 3.826	0.219
ESRD	No	1		
	Yes	0.977	0.356 – 2.680	0.964
Pill capsule	No	1		
	Yes	1.238	0.766 – 2.002	0.383
Patient type	Outpatient	1		
	Inpatient	0.993	0.592 – 1.664	0.978
Total surgery minutes		1.014	1.003 – 1.026	0.017 ¹
Indication	Obscure/overt GIB	1		
	Occult GIB w/ iron deficiency and iron deficiency alone	0.854	0.479 – 1.524	0.593
	Other	1.401	0.778 – 2.524	0.261
DBE type	Anterograde	1		
	Retrograde	0.230	0.125 – 0.422	0.000 ¹

¹ P<0.05

► **Table 3** Multivariate logistic regression of predicting readmission among DBE patients.

Variables	Categories	OR	95% CI	P-values
Intervention	No	1		
	Yes	1.204	0.673 – 2.154	0.531
Finding	No	1		
	Yes	1.385	0.693 – 2.766	0.356
Indication	Obscure/overt GIB	1		
	Occult GIB bleed w/ iron deficiency and iron deficiency alone	2.448	1.233 – 4.859	0.011 ¹
	Other	1.381	0.729 – 2.617	0.322
Patient type	Outpatient	1		
	Inpatient	2.417	1.344 – 4.346	0.003 ¹
Total surgery minutes		1.016	1.004 – 1.029	0.008 ¹

¹ P<0.05

tirety. With the various therapeutic inventions DBE provides, DBE has become a mainstay in evaluation and treatment of suspected small bowel bleeding, abdominal pain, diarrhea, and in patients with altered surgical anatomy. Our study serves to highlight the utility of DBE from a diagnostic and therapeutic

standpoint, as well as to characterize factors that impact success rates. In line with prior studies [5, 13 – 16], the most common indication for DBE in our patient population was overt GIB (49%). Not surprisingly, the most frequent findings were GIAD and fresh blood erosions (20% and 10%, respectively) and the

most commonly employed interventions were APC and epinephrine injection.

DBE is known to be labor intensive with prolonged endoscopy times. In a study evaluating outcomes of patients with OGIB, Hussan et al. reported average procedural times between 60 and 90 min [17]. In our experience, the mean procedural time was 39.58 min. However, unlike other cases reported in the literature [18], our study found that the longer procedural times and older age were associated with higher odds of therapeutic yield. The longer procedural time seemed to account for a positive outcome and correlates to the time taken for diagnosis and for appropriate intervention.

Readmission rates, after endoscopy at 30 d and 6 mo, were low, both at 11%. Nonetheless, presentation of occult GI bleeding with iron deficiency anemia, inpatient status, and longer procedural times during the initial enteroscopy increased the odds of readmission. The underlying factors associated with the aforementioned readmission rates are unclear. It is plausible that the cases involved were inherently either more significant in terms of degree or number of bleeding foci, were more technically difficult, had ineffective initial therapy, or had lesions that were missed or inaccessible during initial DBE. Inability to locate the “culprit” lesions during the initial endoscopy could account for the longer operator time required. The duration of enteroscopy can be affected by other factors such as obesity, surgical history, presence of adhesions, and other technical factors, though we did not specifically sub-analyze these [19]. On the other hand, it is important to note that prolonged procedural time was conversely correlated with higher therapeutic yield as previously mentioned.

Surprisingly, overt GI bleed did not predict readmission; this could suggest that the culprit lesions were effectively treated in the first place and therefore recurrence in this group was minimal. Inpatient status seemed to affect readmission and this could be attributed to more overt clinical symptoms warranting admission and thus more significant pathology. These factors are important as to effectively minimize cost as well as provide timely intervention. From a large national database study, weekend admissions for bleeding secondary to GIAD were associated with higher odds of mortality, intensive care unit admissions, higher rates of delayed endoscopic procedures, longer lengths of stay, and higher hospital charges [20]. To our knowledge, there are few published studies examining patient variables impacting readmission rates post-DBE. From a recent meta-analysis, in patients treated for small bowel angioectasias after endoscopic therapy, the pooled re-bleeding rate was 34% after a mean of 22 ± 13 mo [21]. For vascular lesions, age > 65 years, cardiac valvular lesions, renal disease, and use of anticoagulation increased the odds for readmission and thus differed from the predictors that we found [6, 22]. However, our study was not limited to patients with GI bleeding as the sole indication for DBE. Our study is therefore unique with regards to characterizing patient presentations and procedural modalities that impact short-term and long-term readmission for various indications.

Our study also unearths the contrast between the diagnostic and therapeutic yield of anterograde compared to retrograde

endoscopy. While the majority of our patients underwent anterograde endoscopy (74%), retrograde endoscopy was negatively associated with therapeutic yield. It is well known that retrograde endoscopy proves to be more difficult with failure to intubate the terminal ileum in 21% of DBE cases [23]. It is frequently used to evaluate lesions in the distal small intestine; however, the anterograde approach enables endoscopists to traverse twice as far into the small bowel [6]. It could be inferred that this technical difference accounts for the discrepancies seen. In our case, anterograde endoscopy had a higher rate of diagnostic yield than retrograde endoscopy. Additionally, we encountered that anterograde DBE was useful in evaluation of patients with altered anatomy, specifically in patients with Roux-en-Y anastomoses (28.8%).

As stated above, our overall diagnostic yield for anterograde DBE was 77%. Previous reports in the literature indicate DBE diagnostic yield for OGIB ranges from 60–80% [2]. In a systematic review of 66 published studies, anterograde DBE had a pooled detection rate of 68.1% of all small bowel disease [14]. In regards to the retrograde approach, the diagnostic yield reportedly ranges from 39% to 47% [6], which was less than our overall retrograde DBE of 62%. The average pooled therapeutic rate in published literature is approximately 40% [24], which is in keeping with our study at 35%. In effect, our proficiency and the utility of DBE prove to be clinically comparable to other similar reports in the literature [19].

There were noteworthy limitations and strengths of our study. Our study was retrospective and conducted at a single tertiary care center, thus limiting the generalizability of findings to smaller community settings. Although the multivariable analysis found several findings of statistical significance, the analysis was unable to determine independent predictors of diagnostic yield. Notwithstanding, our study comprised a relatively large clinical sample of patients undergoing DBE ($n = 420$). To our knowledge, this was one of the larger cohort studies designed to evaluate the diagnostic and therapeutic yield of DBE to date. There was also incomplete follow-up in some of the cases, as our study did not account for those who were not readmitted. Another limitation of the study was that we did not collect other metrics reflecting degree of GI bleed (i. e., transfusion requirement) to establish a pre- and postprocedural analysis of these variables.

In summary, our study reinforces the diagnostic and therapeutic utility of DBE in a large cohort of patients in evaluation of various small bowel conditions including luminal bleeding, abdominal pain, and iron deficiency anemia. Our study highlights important predictors that are positively and negatively associated with therapeutic yield and readmission. Our results indicate that procedural time and increasing age were predictors of therapeutic yield. Moreover, inpatient status, those with GI bleeding with iron deficiency, and longer procedural times at index were more likely to have readmission. DBE is clearly an important modality for diagnosis and treatment of small bowel disorders. Despite its capabilities, there are a substantial number of patients who require readmission and further treatment. Identifying factors associated with readmission will aid in understanding and implementing the most cost-ef-

fective strategy with appropriate resource utilization in the algorithmic approach to managing small bowel disorders. Future studies can help in predicting those patients who require long-term follow-up and thereby prevent the need for further interventions.

Competing interests

None

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