

A multicenter experience of through-the-scope balloon-assisted enteroscopy in surgically altered gastrointestinal anatomy

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Received: 27 May 2016 / Accepted: 4 October 2016 / Published online: 30 December 2016
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Abstract

Background Surgically altered gastrointestinal anatomy poses challenges for deep enteroscopy. Current overtube-assisted methods have long procedure times and utilize endoscopes with smaller working channels that preclude use of standard accessories. A through-the-scope balloon-assisted enteroscopy (TTS-BAE) device uses standard endoscopes with a large working channel to allow metallic and plastic stent insertion. We aim to determine the efficacy and safety of TTS-BAE in patients with altered surgical anatomy.

Methods A retrospective, multicenter study of TTS-BAE in altered anatomy patients at two USA and one German institution was performed between January 2013 and December 2014. Type of anatomy, procedure indication and duration, adverse events, and target, technical, and clinical success were recorded.

Results A total of 32 patients (mean age 54 years, Caucasian 81.6%, female 42.1%, mean BMI 25.4 kg/m²) underwent 38 TTS-BAE procedures. Thirty-two percent of

cases had a prior attempt at conventional enteroscopy which failed to reach the target site. The target was successfully reached in 23 (60.5%) cases. Of the 23 cases that reached the intended target, 22 (95.7%) achieved technical success and 21 (91.3%) achieved clinical success. The median procedure time was 43 min. Target, technical, and clinical success rates for TTS-BAE-assisted ERCP ($n = 31$) were 58.1, 54.8 and 54.8%. Seven self-expandable metallic stents (five biliary, two jejunal) were attempted, and all successfully deployed. Adverse events occurred in 4 (10.4%) cases, including one luminal perforation.

Conclusion TTS-BAE is an alternative to overtube-assisted enteroscopy that is comparable in safety in patients with surgically altered anatomies. Technical success in the instances where the target had been reached was excellent. TTS-BAE confers an advantage over overtube-assisted enteroscopy as it can facilitate the deployment of self-expandable metallic stents in the biliary tree and deep small bowel.

Keywords Enteroscopy · Altered surgical anatomy · Roux-en-Y gastric bypass · ERCP

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In recent years, there have been an increasing number of individuals with surgically altered gastrointestinal anatomy following pancreaticobiliary surgery, liver transplantation, and bariatric surgery [1, 2]. The need for endoscopic solutions to both postoperative complications as well as intrinsic disease in these patients poses significant challenges for deep enteroscopy due to a long length of insertion and the presence of anastomoses that create sharp angles which are difficult to navigate by traditional instruments [3].

Current methods of performing enteroscopy in surgically altered anatomy include overtube-assisted double-balloon enteroscopy (DBE) as the first available technique developed in 2001, followed by single-balloon (SBE) and spiral (SE) platforms in 2007 and 2008, respectively. Successful outcomes among these methods have been reported in 61–98% of cases while the rate of adverse events in all overtube-assisted enteroscopy (OAE) platforms ranges from 3.4 to 12%, mostly consisting of cholangitis, pancreatitis, bleeding, and perforation [4–13].

These conventional techniques, however, lack widespread availability outside of tertiary endoscopic referral centers, require specialized training, have long procedure times, and rely on endoscopes with a 2.8-mm working channel that has limited therapeutic potential because it precludes the use of many standard endoscopic accessories [7, 14].

Through-the-scope balloon-assisted enteroscopy (TTS-BAE), marketed as NaviAid™ AB (SMART Medical Systems Ltd., Ra'anana, Israel), is a novel technique that utilizes standard endoscopes to traverse the deep small bowel in either an antegrade or retrograde fashion [15–18]. In a retrospective study, TTS-BAE was found to have mean diagnostic and therapeutic yields of 45 and 36% for antegrade enteroscopy and 59–47% for retrograde enteroscopy, respectively, with a technical success rate of 100% [15]. No adverse events have been reported; the soft and flexible nature of the balloon catheter may protect against mucosal perforation [15, 19]. The advantages of TTS-BAE include its short learning curve, low cost, on-demand feature that allows its use if an unexpected finding occurs during standard endoscopy, shorter procedure times compared with OAE, and ability to perform therapy utilizing the large working channel that can facilitate a broader range of interventions including the deployment of metallic and 10-Fr plastic stents [15, 20]. However, to our knowledge, the use of TTS-BAE has only been described in cases of normal GI anatomy. We hypothesized that this device may also be a suitable alternative to current deep enteroscopy systems in patients with altered anatomy. Therefore, in this multicenter study, we aim to examine the efficacy and safety of through-the-scope balloon-assisted enteroscopy in the surgically altered population.

Materials and methods

Study population

This was a retrospective multicenter study of TTS-BAE in patients with surgically altered anatomy at three tertiary academic institutions (two USA and one German) over a 2-year period. It was approved by the Institutional Review

Board for Human Research and complied with Health Insurance Portability and Accountability Act (HIPAA) regulations at each institution. At participating centers, endoscopic records were reviewed to identify all TTS-BAE procedures between January 2013 and December 2014. Adult patients with prior small bowel resection, surgery resulting in an altered gastrointestinal anatomy, or deep enteroscopy for endoscopic retrograde cholangiopancreatography (ERCP) were included in this study. Altered anatomy was defined as having surgical reconstruction that would affect the length, angle, or overall trajectory of the endoscope during the intended approach.

Data were collected on the following: (1) patient demographics, (2) clinical indication, (3) type of surgical anatomy, (4) alternative platforms attempted prior to TTS-BAE, (5) procedure time, (6) endoscopic approach, (7) endoscopic target, (8) type of therapeutic intervention if any, (9) type of stent and location if any, (10) whether the target was reached, (11) technical success, (12) clinical success, and (13) adverse events.

Device

The NaviAid™ AB device consists of a single-use, on-demand balloon catheter supported by an inflation–deflation apparatus (NaviAid™ SPARK system) that is inserted through a working channel diameter of at least 3.7 mm (Fig. 1). The latex-free balloon catheter has a soft, flexible tip that allows for safe negotiation of bends. The balloon is assembled upon a 350-cm catheter and reaches a maximum diameter of 4 cm when fully inflated. A pressure of 60 ± 10 mbar is used to maintain inflation of the balloon using the NaviAid™ SPARK system. A foot pedal is provided to control the inflation/deflation process.

Endoscopic procedure

All procedures were performed by or under the direct supervision of four endoscopists who are experienced in OAE and ERCP. No endoscopist had undergone any previous specialized training related to the use of the NaviAid system. Enteroscopy was performed with the patient in the left lateral or supine position. Carbon dioxide was used for luminal insufflation. Either an adult colonoscope or therapeutic gastroscope was used.

The deflated balloon was passed through the working channel 20–30 cm ahead of the standard endoscope. Direct visualization was not required and was commonly lost when the balloon proceeded around a bend. It was then inflated to anchor itself to the small bowel wall. Once inflated ahead of the endoscope and anchored against the small bowel wall, the endoscope was pushed forward while simultaneous counter

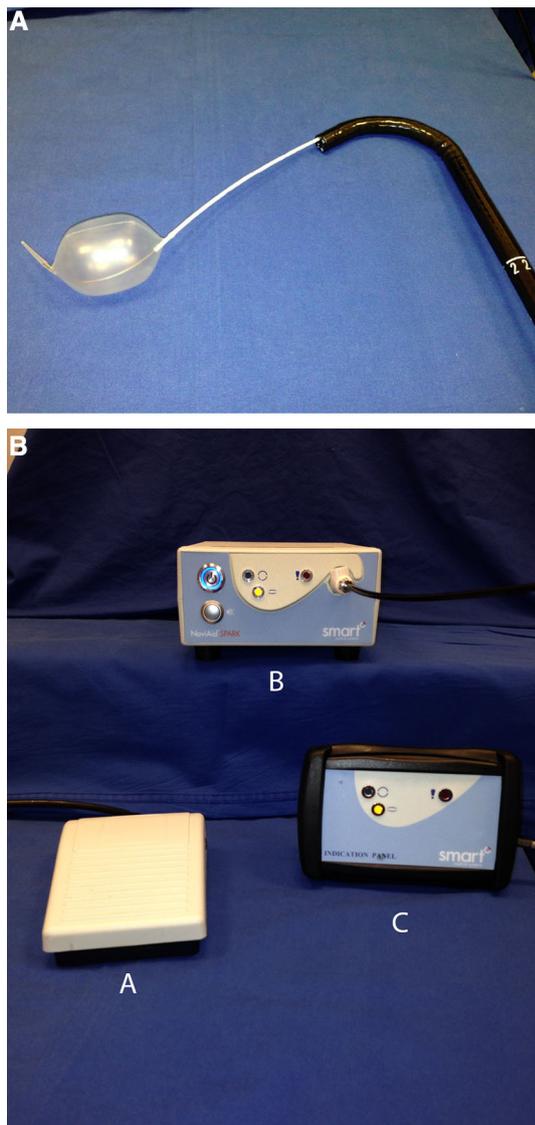


Fig. 1 **A** Through-the-scope balloon catheter has been passed through the working channel of a colonoscope, and the balloon is inflated, **B** Through-the-scope balloon-assisted enteroscopy setup: **A** foot pedal to inflate/deflate the balloon, **B** air supply unit, and **C** indication panel

traction is provided on the balloon catheter. Hence, the device was used as a rail on which the endoscope is advanced. Once the endoscope met the balloon catheter, the balloon was deflated to allow for the next cycle of advancement. At any point during the procedure, the balloon catheter could be removed to allow for passage of accessories through the working channel of the endoscope and then later reinserted to continue the procedure. During balloon deflation or removal, the unpleating or slippage of the endoscope over the small bowel was negligible.

Stents deployed included 10 × 40 mm and 22 × 90 mm fully covered self-expanding metal stents (WallFlex, Boston

Scientific, Natick, MA, USA) as well as 10-Fr plastic stents (Cook Medical, Bloomington, IN, USA).

Outcomes

For cases involving ERCP, target success was defined as intubation of the biliopancreatic limb and the ability to identify and access the papilla of Vater or anastomotic site, either bilioenteric or pancreaticoenteric [7]. Technical success was defined as successful duct cannulation, cholangiogram leading to a diagnosis, stent removal or insertion, and completion of other diagnostic and therapeutic interventions [7]. Clinical success in ERCP was defined as greater than 50% reduction in abdominal pain, greater than 50% reduction in hepatic enzyme levels, and resolution of jaundice and other obstructive symptoms including nausea and recurrent vomiting [4].

Among cases that did not utilize ERCP, target success was defined as the ability to reach the intended target (i.e., jejunojunal anastomosis, ileum) [21]. Technical success was defined as reaching the part of the anatomy that was the goal of the procedure and providing diagnostic or therapeutic intervention if indicated (i.e., stricture dilation, stent placement, argon plasma coagulation, and endoscopic clips for bleeding). Clinical success in non-ERCP cases was defined as greater than 50% reduction in abdominal pain, resolution of obstructive symptoms, and no biochemical evidence of rebleeding [22]. Adverse events were graded according to the American Society for Gastrointestinal Endoscopy lexicon's severity grading system of mild, moderate, severe, or fatal [23].

Statistical analysis

Target, technical, and clinical success rates were compared between groups using Pearson's Chi-square test. Mood's median test was used to compare procedure duration times across different types of surgical anatomy. All analyses were performed using STATA version 13.1 software (StataCorp, College Station, TX).

Results

A total of 32 patients with altered surgical anatomy who underwent 38 TTS-BAE procedures were included for analysis. All cases were performed under monitored anesthesia care with 84.2% ($n = 32$) under general anesthesia and 15.8% ($n = 6$) under conscious sedation. The baseline demographics and clinical characteristics of the study cohort are presented in Table 1.

Our study represented a diverse array of altered surgical anatomy including transplant and non-transplant Roux-en-

Table 1 Patient demographic and clinical characteristics

<i>Demographic characteristics</i>	
Age, mean \pm SD (years)	53.7 \pm 16.1
Female sex, <i>n</i> (%)	16 (42.1)
Race, <i>n</i> (%)	
Caucasian	31 (81.6)
African-American	2 (5.3)
Hispanic	2 (5.3)
Asian	1 (2.6)
BMI, mean \pm SD (kg/m ²)	25.4 \pm 5.3
<i>Patients with prior failed intervention, n (%)</i>	
SBE	7 (18.4)
DBE	1 (2.6)
Push enteroscopy	4 (10.5)
Total	12 (31.6)
<i>Type of surgical anatomy, n (%)</i>	
RYGB	8 (21.1)
Transplant RYHJ	4 (10.5)
Non-transplant RYHJ	14 (36.8)
Whipple	10 (26.3)
Small bowel resection	2 (5.3)
<i>Indication for TTS-BAE, n (%)</i>	
Biliary stricture	18 (47.4)
Choledocholithiasis	6 (15.8)
Small bowel stricture	3 (7.9)
Malignant	2 (5.3)
Benign	1 (2.6)
GI bleeding	4 (10.5)
Pancreatic stricture	2 (5.3)
<i>Target of TTS-BAE, n (%)</i>	
Hepaticojejunostomy	27 (71.1)
Jejunojunctionostomy	2 (5.3)
Deep small bowel (proximal ileum/jejunum)	4 (10.5)
Biliopancreatic limb	4 (10.5)
Excluded stomach	1 (2.6)

SD standard deviation, RYGB Roux-en-Y gastric bypass, RYHJ Roux-en-Y hepaticojejunostomy, ERCP endoscopic retrograde cholangiopancreatography, TTS-BAE through-the-scope balloon-assisted enteroscopy, SBE single-balloon enteroscopy, DBE double-balloon enteroscopy, SE spiral enteroscopy

Y hepaticojejunostomy, Whipple, Roux-en-Y gastric bypass, and small bowel resection. The most common indication for TTS-BAE was for treatment of biliary stricture ($n = 18$, 47.4%), followed by choledocholithiasis ($n = 6$, 15.8%) and small bowel strictures ($n = 3$, 7.9%). The most frequent target of TTS-BAE was at the surgical anastomosis, either the hepaticojejunostomy ($n = 27$, 71.1%) or jejunojunctionostomy site ($n = 2$, 5.3%). Over 31% ($n = 12$) of all cases had failed to reach the target site by endoscopic intervention prior to TTS-BAE; two thirds of

these failed prior OAE, while one third failed prior push enteroscopy.

Overall, the target success was 60.5%, technical success was 57.9%, and clinical success was 55.3% (Table 2). Of the 23 cases that reached the intended target, 95.7% ($n = 22$) were technically successful and 91.3% ($n = 21$) were clinically successful (Table 3).

TTS-BAE-assisted ERCP

TTS-BAE-assisted ERCP consisted of 81.6% ($n = 31$) of all procedures performed. The papilla of Vater or anastomotic site was reached in 58.1% ($n = 18$), of which 94.4% ($n = 17$) were both technically and clinically successful (Table 3; Fig. 2). ERCP procedures that involved patients with Roux-en-Y anatomy did not differ in their target, technical, and clinical success rates when compared with ERCPs on patients with non-Roux-en-Y anatomy ($p = 0.535$, $p = 0.397$, $p = 0.397$, respectively). Similarly, TTS-BAE-assisted ERCPs on patients with native papillae (including RYGB and small bowel resection) did not significantly differ in rates of success from that of ERCPs in patients with hepaticojejunostomies ($p = 0.751$, $p = 0.665$, $p = 0.665$, respectively). Other successful interventions in TTS-BAE-assisted ERCP included stent removal ($n = 7$), sludge removal ($n = 5$), dilation of stricture ($n = 1$), and cholangiography ($n = 1$) (Table 4).

Non-ERCP TTS-BAE

There were seven TTS-BAE procedures that did not utilize ERCP. Indications included GI bleeding ($n = 3$), malignant ($n = 2$) and benign ($n = 1$) small bowel stricture, and pancreatic stricture ($n = 1$). The target success was 71.4% ($n = 5$), of which 100% ($n = 5$) were technically successful and 80% ($n = 4$) were clinically successful (Table 3). Successful intervention in non-ERCP TTS-BAE included deployment of jejunal metallic stents ($n = 2$), placement of endoscopic clips ($n = 1$), and benign stricture dilation ($n = 1$) (Table 4). Compared to that of ERCP procedures, these cases did not have statistically different rates of target, technical, nor clinical success.

Through-the-scope stent insertion

Insertion of a stent was one of the most common therapeutic interventions performed (Table 4). A total of seven self-expanding metallic stents and one 10-Fr plastic stent were successfully deployed. Of the metallic stents, five were biliary and targeted strictures at the hepaticojejunostomy. Four of the five cases (80%) had failed to clinically respond to prior plastic stenting with 7 Fr \times 7 cm double-pigtail catheters as well as serial

Table 2 Target, technical, and clinical success rates of TTS-BAE

	Target success, <i>n</i> (%)	Technical success, <i>n</i> (%)	Clinical success, <i>n</i> (%)
Total cases (<i>n</i> = 38)	23 (60.5)	22 (57.9)	21 (55.3)
ERCP cases (<i>n</i> = 31)	18 (58.1)	17 (54.8)	17 (54.8)
RY anatomy (<i>n</i> = 22)	12 (54.5)	11 (50)	11 (50)
Non-RY anatomy (<i>n</i> = 9)	6 (66.7)	6 (66.7)	6 (66.7)
<i>p</i> value	0.535	0.397	0.397
Native papilla (<i>n</i> = 3)	2 (66.7)	2 (66.7)	2 (66.7)
Anastomotic site (<i>n</i> = 28)	16 (57.1)	15 (53.6)	15 (53.6)
<i>p</i> value	0.751	0.665	0.665
Non-ERCP cases (<i>n</i> = 7)	5 (71.4)	5 (71.4)	4 (57.1)
<i>p</i> value*	0.514	0.422	0.912

* Compares the success rates of all non-ERCP and all ERCP cases

Table 3 Technical and clinical success rates of TTS-BAE in those that achieved target success

	Target success, <i>n</i> (%)	Technical success, <i>n</i> (%)	Clinical success, <i>n</i> (%)
Total cases (<i>n</i> = 38)	23 (60.5)	22 (95.7)	21 (91.3)
ERCP cases (<i>n</i> = 31)	18 (58.1)	17 (94.4)	17 (94.4)
RY anatomy (<i>n</i> = 22)	12 (54.5)	11 (91.7)	11 (91.7)
Non-RY anatomy (<i>n</i> = 9)	6 (66.7)	6 (100)	6 (100)
Native papilla (<i>n</i> = 3)	2 (66.7)	2 (100)	2 (100)
Anastomotic site (<i>n</i> = 28)	16 (57.1)	15 (93.8)	15 (93.8)
Non-ERCP cases (<i>n</i> = 7)	5 (71.4)	5 (100)	4 (80)

ERCP endoscopic retrograde cholangiopancreatography, RY Roux-en-Y

balloon dilations. The remaining two metallic stents targeted the deep small bowel in the setting of malignant strictures but did not involve ERCP (Fig. 3). Through-the-scope deployment of these metallic stents would not have been possible using conventional OAE platforms.

Procedure duration

The median duration of all TTS-BAE procedures was 43 min. When stratified by type of surgical anatomy, patients with prior Whipple surgery were found to have the longest median procedure time of 50.5 min, followed by patients with RYGB at 46.5 min (Table 5). Procedures in individuals with small bowel resections took the shortest median amount of time at 32.5 min. There was no difference in median procedure duration between ERCP (43 min) and non-ERCP cases (35 min, $p = 0.572$).

Adverse events

Four (10.4%) adverse events occurred including aspiration pneumonia ($n = 1$, mild), cholangitis ($n = 1$, mild), luminal perforation ($n = 1$, severe), and device malfunction with balloon-catheter separation ($n = 1$, mild) (Table 6). The perforation event occurred in a patient with a non-transplant RYHJ with an anastomotic biliary

stricture. During insertion, the balloon ruptured near the intended target with blood oozing ahead of the endoscope. SBE was subsequently used and found a deep mucosal tear adjacent to the hepaticojejunostomy consistent with recent trauma. Several unsuccessful attempts using endoscopic clips were made to close the defect, but the patient ultimately required an emergent exploratory laparotomy with resection and recreation of the surgical anastomosis.

Discussion

This study describes the first multicenter experience on the use of through-the-scope balloon-assisted enteroscopy in patients with surgically altered GI anatomy. The evaluation of the efficacy and safety of TTS-BAE in a variety of altered anatomical settings is important in an era of increasing volume of patients who desire treatment strategies that remain minimally invasive and avoid costly and risk-prone resurgical or percutaneous interventions. As a one-time investment of approximately \$6000 to \$7000 USD for the inflation–deflation system and each disposable balloon costing \$200 USD, TTS-BAE is an affordable alternative to deep enteroscopy, particularly in centers where OAE is not available.

Fig. 2 Sixty-five-year-old male with Roux-en-Y hepaticojejunostomy following choledochal cyst resection suffered recurrent episodes of cholangitis with placement of a percutaneous drain and unsuccessful stricture dilation by interventional radiology. He underwent TTS-BAE-assisted ERCP for endoscopic stricture management. **A** Endoscopic view of balloon catheter being passed ahead of the endoscope into the biliopancreatic limb, **B** fluoroscopic view of inflated balloon when during passage through the biliopancreatic limb toward the percutaneous biliary pigtail drain, **C** the balloon touches the internal curl of the biliary drain. The endoscope traverses multiple bowel loops, and **D** TTS-BAE has reached the hepaticojejunostomy. The endoscope is shortened with the balloon inflated to maintain its position

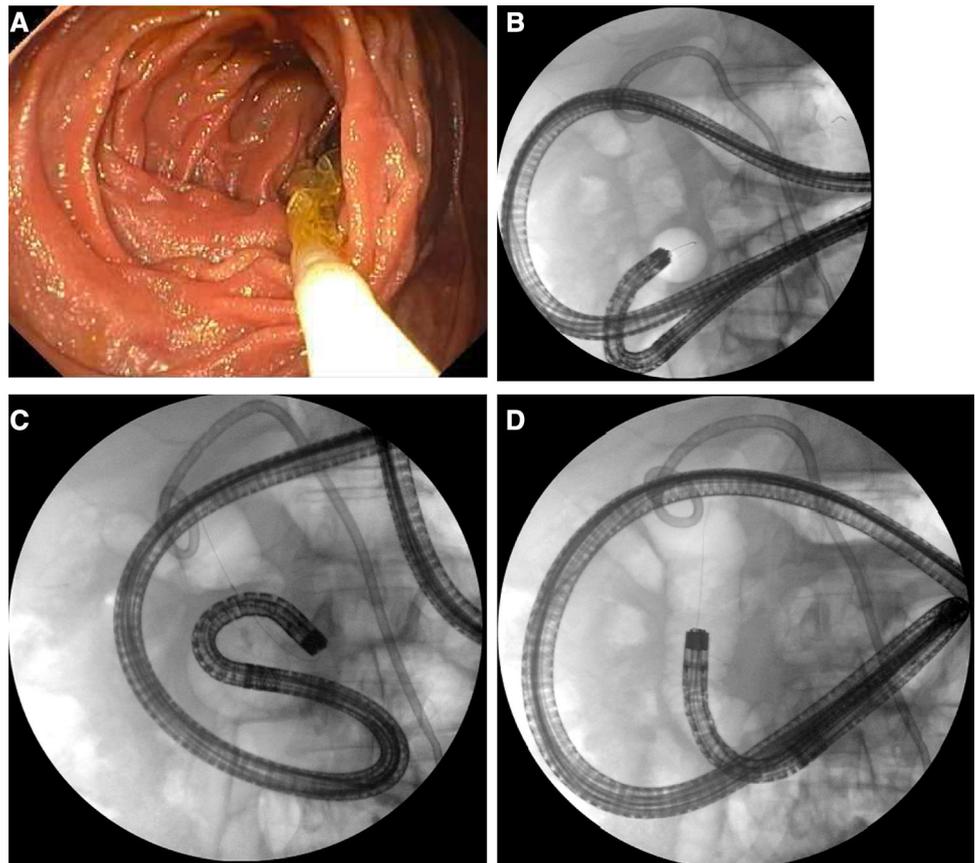


Table 4 Interventions performed in technically successful procedures

Interventions performed (<i>n</i> = 24)	<i>n</i> (%)
ERCP	20 (83.3)
Stent insertion	6 (25)
Metallic biliary stent	5 (20.8)
10 Fr plastic biliary stent	1 (4.2)
Stent removal	7 (29.2)
Sludge removal	5 (20.8)
Stricture dilation	1 (4.2)
Cholangiography	1 (4.2)
Non-ERCP	4 (16.7)
Metallic jejunal stent insertion	2 (8.3)
Endoscopic clips placement	1 (4.2)
Stricture dilation	1 (4.2)

ERCP endoscopic retrograde cholangiopancreatography

In this study, our analysis revealed overall technical and clinical success rates of 57.9 and 55.3%, respectively. This is reflective of the target success rate of 60.5%, which appears to be slightly lower than what has been reported in previous studies on OAE in altered bowel anatomy. Among

studies that examined DBE, the diagnostic yield ranged from 61 to 96% [4–7, 9, 12, 13]. Similarly, among studies that utilized SBE, the diagnostic yield ranged from 65.4 to 100% [4, 6–8, 10, 11]. Spiral enteroscopy had less robust data in this patient population, and a few systematic reviews reported a target success rate of 72–76% of cases [4, 7, 24].

One potential reason why TTS-BAE did not reach the intended target as frequently as OAE is a shorter depth of insertion with the standard adult endoscope. Either an adult colonoscope or therapeutic gastroscope was used. The choice depended on the location of the intended target and the planned therapy (for example, a therapeutic gastroscope was used to deploy a metallic biliary stent in a patient with an anastomotic biliary stricture). The mean maximum depth of insertion (DMI) of TTS-BAE has been reported in two studies: 1.2 m from the ligament to Treitz [15] and 1.6 m from the pylorus in the antegrade approach. This is significantly less when compared with SBE and spiral enteroscopy with mean DMI of approximately 2.0 and 2.4 m, respectively [25–33]. A shorter DMI may be the result of the shorter standard endoscope as well as the absence of an overtube preventing gastric looping. In addition, there may be a selection bias against TTS-BAE given that nearly 32% of cases had failed some form of prior endoscopic attempt.

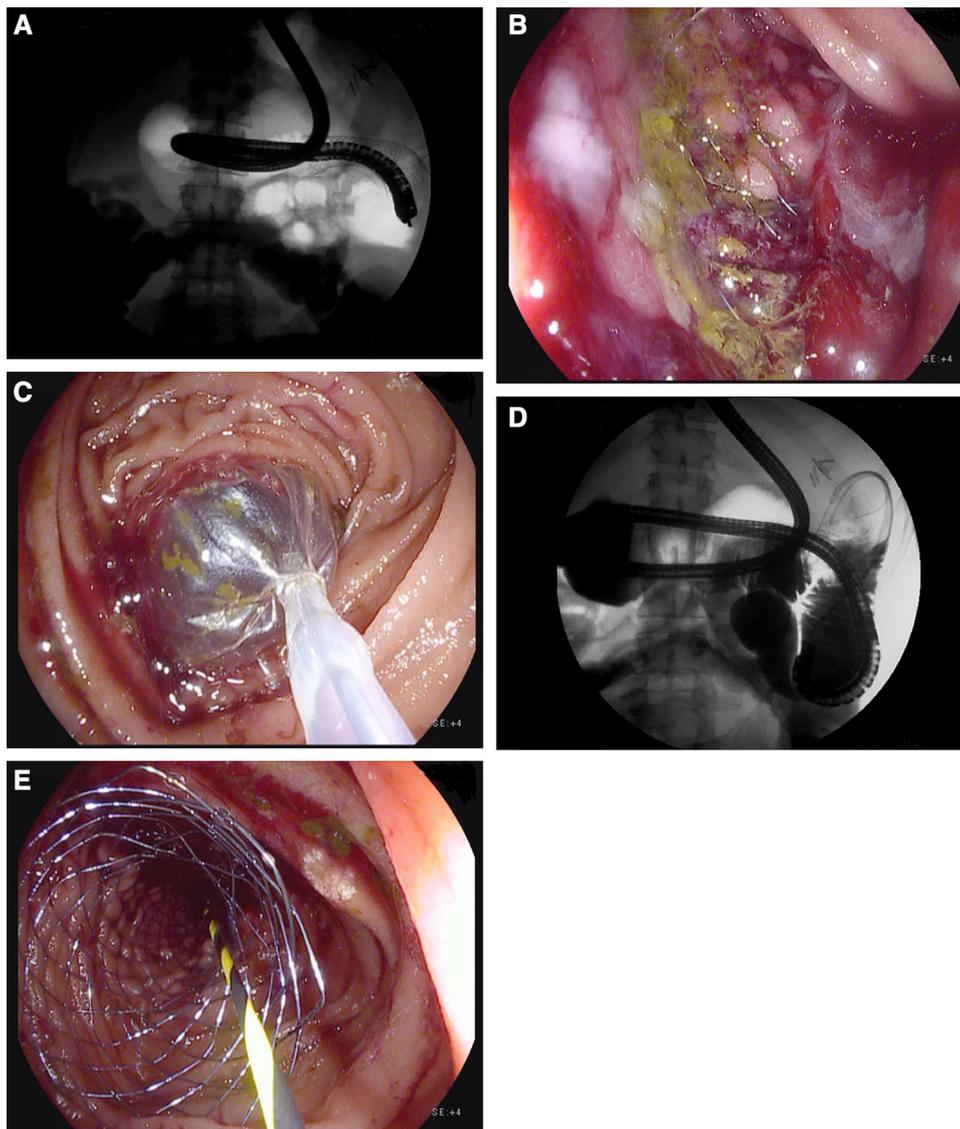


Fig. 3 Forty-eight-year-old male undergoing palliative chemotherapy for metastatic colorectal carcinoma after prior resection underwent TTS-BAE and jejunal stent (22 × 90 mm) insertion for a malignant stricture at the duodenal-jejunal flexure. He had inadequate symptom control and subsequently had upper GI series which revealed a second, downstream stricture in the left upper quadrant at the site of the previously placed surgical clips. **A** Fluoroscopic view of endoscope through the previously placed proximal jejunal stent, **B** endoscopic view of previously placed proximal jejunal stent. The

colonoscope, aided by TTS-BAE, is able to pass through the stent, and **C** the endoscope tip is distal to the previously placed jejunal stent. The balloon catheter is advanced ahead of the endoscope and the balloon is inflated. Apposition to the jejunal wall is achieved allowing the catheter to be used as a rail to further advance the endoscope, **D** fluoroscopic image during deployment of a 22 × 90 mm enteral stent in the mid jejunum. The waist of the stent is seen near the surgical clips, **E** through-the-scope deployment of the mid-jejunal uncovered metallic stent over a guidewire using an adult colonoscope

Of the TTS-BAE procedures that reached the intended target, however, 95.7 and 91.3% were found to achieve technical and clinical success, respectively, whereas technical success rates reported for DBE, SBE, and SE ranged from 78 to 100% [4, 6, 7]. This suggests that despite a slightly lower target success rate as compared to other platforms, TTS-BAE is shown to be a very effective modality to successfully deliver intervention. In particular,

the outcomes of TTS-BAE-assisted ERCP in patients with RY anatomy were comparable to OAE that report successful intervention in 44–73% of RY cases [4, 7, 8]. Furthermore, the high technical and clinical success in ERCP cases compares favorably to the outcomes reported in OAE. In OAE, cannulation of the native papilla is thought to be much more difficult because the extended length of the standard DBE enteroscope makes endoscopic

Table 5 Median duration of TTS-BAE stratified by type of surgical anatomy and procedure

	Duration, median \pm SD (min)
Total cases	43 \pm 48
Type of surgical anatomy	
RYGB	46.5 \pm 65.4
Transplant RYHJ	42 \pm 7.1
Non-transplant RYHJ	36.5 \pm 17.7
Whipple	50.5 \pm 65
Small bowel resection	32.5 \pm 0.7
Type of procedure	
ERCP	43 \pm 48.6
Non-ERCP	35 \pm 48.6
<i>p</i> value	0.572

SD standard deviation, RYGB Roux-en-Y gastric bypass, RYHJ Roux-en-Y hepaticojejunostomy, ERCP endoscopic retrograde cholangiopancreatography

Table 6 Adverse events

Adverse event	<i>n</i> (%)	Severity
Aspiration pneumonia	1 (2.6)	Mild
Cholangitis	1 (2.6)	Mild
Device malfunction	1 (2.6)	Mild
Perforation	1 (2.6)	Severe

manipulation cumbersome, ERCP accessories are not compatible, and its forward-facing direction provides suboptimal views. TTS-BAE solves the first two problems, potentially contributing to the trend toward greater ERCP success after navigating to the papilla of Vater.

An important and potentially cost-saving benefit to using TTS-BAE, particularly in ERCP procedures, is the ability to deploy self-expanding metallic stents (SEMS), which is currently not possible in traditional OAE due to the smaller working channel that only permits 7-Fr plastic stent placement. Metallic biliary stents feature a larger diameter with a narrow deployment system that does not require extensive dilation prior to placement. In addition, there is a lower risk of stent occlusion resulting in a longer duration of stent patency and theoretically, fewer ERCP procedures than that of plastic stents [34, 35]. There are currently no studies that compare the efficacy of metallic and plastic stenting in this patient population. Skinner et al. [36] describe using DBE-ERCP to deliver a guidewire in a patient with Billroth II reconstruction before the endoscope was removed, leaving the overtube and guidewire in place. A metallic stent was then placed over the wire under fluoroscopy with the overtube serving as a larger diameter working channel. Several studies describe the use of

metallic stents in treating both malignant and benign small bowel strictures, one of which utilized the overtube employed spiral enteroscopy to deploy a partially covered SEMS via a guidewire into the jejunum [37–39]. In contrast, TTS-BAE was able to successfully deploy five biliary and two jejunal metallic stents under endoscopic and fluoroscopic visualization using the through-the-scope system in this study.

More recently, short DBE has come to the market as a way to use standard accessories (including metal stent deployment) via the shorter 152 cm endoscope length and 3.2-mm working channel (Fujifilm, Tokyo, Japan). A systematic review of short DBE-assisted ERCP in altered anatomy shows high technical success rates of 81–100% [40, 41]. Therefore, similar to TTS-BAE, the short DBE represents another viable option for altered anatomy patients who may benefit from ERCP and metallic biliary stenting.

The efficiency of TTS-BAE is further reflected in its shorter procedure duration. Our study found a median procedure time of 43 min compared with 70–111 min for DBE, 45–120 min for SBE, and 43 min for SE [4, 7, 8]. The fact that TTS-BAE utilizes a standard colonoscope and accessories while requiring no specialized endoscopist training beyond familiarity with the device likely facilitates this dramatic decrease in procedure duration with little compromise in overall technical success.

The rate of adverse events in TTS-BAE was similar to that of OAE, between 3.4 and 12%; however, one case was due to device malfunction and did not cause any clinical deterioration. All events were mild except one severe perforation (2.6%) that required surgical intervention. This is comparable to the rates of perforation found in DBE and SE, ranging between 1.6 and 6.7% [7]. Endoscopic-related perforations may be minimized with by using pediatric colonoscopes with a 3.8-mm working channel (Pentax EC3490 LK, Pentax Medical Corp., Montvale, NJ) that accommodates the device as well as with improved experience with the TTS-BAE platform to mitigate future malfunctions. TTS-BAE also avoids adverse events related to allergic reactions given its latex-free composition and may be a good alternative for latex-allergic patients who cannot undergo DBE.

Our study was limited by its retrospective design. Additionally, all participating institutions routinely utilized other deep enteroscopy platforms and the procedures included in our study were not consecutive patients that underwent deep enteroscopy in patients with altered surgical anatomy. As there was no pre-defined criteria which dictated which patient would undergo OAE versus TTS-BAE, there is a potential selection bias.

In conclusion, given its lower overall target success, TTS-BAE may not yet be able to replace current OAE

methods. However, given its very high technical and clinical success rates once the target is reached, the device may be a reasonable first-line platform with the option to switch back to OAE if the intended target is not reached. As the first study examining TTS-BAE in altered anatomy, we are early in our clinical experience with the device and anticipate increased success rates over time. Our results suggest that TTS-BAE may be an alternative to OAE that is comparable in safety with excellent rates of technical success in the diagnostic and therapeutic management of a diverse range of surgically altered anatomies and appears particularly useful in facilitating metallic stent deployment in this patient population. Prospective studies are needed to further validate our data.

Compliance with ethical standards

Disclosures Dr. Mouen A. Khashab is a consultant for Boston Scientific and Olympus America, and has received research support from Cook Medical. Drs. Jennifer X. Cai, David L. Diehl, Ralf Kiesslich, Andrew C. Storm, Mohamad H. El Zein, Alan H. Tieu, Arthur Hoffman, Vikesh K. Singh, Patrick I. Okolo III, and Vivek Kumbhari have no conflicts of interest or financial ties to disclose.

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