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Double Balloon Enteroscopy: Current Status and Indications



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INTRODUCTION

The double balloon enteroscopy (DBE) system (Fujinon Inc., Saitama, Japan) has been available for use in the United States since 2004 following initial development by Yamamoto et al.¹ This system combines an enteroscope and overtube, both equipped with latex balloons which are insufflated/deflated in alternating cycles to pleat the bowel onto the overtube. DBE technique allows for intubation in the deep small bowel with therapeutic capability and access to the entire gastrointestinal tract lumen in many cases.

Evolution of Device Assisted Enteroscopy (DAE)

Following the introduction of DBE, additional technologies were developed for intubation of the deep small bowel applying the same principle of small bowel pleating. Single balloon enteroscopy (SBE) (Olympus Optical Co, Tokyo, Japan) was introduced in 2007 followed by spiral enteroscopy (SE) in 2008 (Spirus Medical LLC,

West Bridgewater, MA, USA).^{2,3} More recently, the NaviAid device (SMART Medical Systems Ltd., Ra'anana Israel) was approved as a through-the-scope balloon catheter which facilitates advancement of a standard colonoscope into the deep small bowel for “balloon-guided endoscopy (BGE)”.⁴ An enteroscope with a motorized, spiral tip is currently in development which may decrease procedure time and increase total enteroscopy rates.⁵ These techniques are all collectively known as device assisted enteroscopy (DAE) procedures.

Double Balloon Enteroscopy Equipment

DBE requires a base Fujinon endoscopy processor and light source combined with a balloon pump controller and DBE enteroscope (Figures 1a,1b,1c). The utilization of DBE in the U.S. has been somewhat limited by the prevalence of Olympus endoscopy equipment compared to that of Fujinon. In facilities in which an Olympus or other non-Fujinon system is already in use, it may be challenging to justify the capital expense of a second endoscopy system for this specialized procedure.

- Double Balloon Endoscope Models (Table 1)
The double balloon enteroscope is currently

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available in a standard, 200cm length with 3.2mm (therapeutic) accessory channel (EN-580T) as well as a shorter, 155cm length with a 3.2mm accessory channel for altered anatomy ERCP procedures (EI-580BT). The 3.2mm channel, as well as the 2.8mm channel found in older models (EN-450T5), allows for passage of nearly all standard instruments.⁶ A slim-version 200cm enteroscope (EN-580XP) is also currently available for pediatric procedures. This model has a reduced diameter but a smaller accessory channel.

• Additional Equipment

A pressure-regulated air pump controls the exchange of air to and from the balloons for insufflation/deflation. This pump system includes tubes and diaphragms which are multiuse. Carbon dioxide insufflation of the small bowel lumen has been found to increase insertion depth while decreasing symptoms of abdominal distension post-procedure compared to examinations using air.^{7,8} Therefore, a CO₂ controller should be employed. Complementary equipment for DBE includes a Fujinon ST-10 balloon setting tool (Figure 2a), Zutron stiffening device (Figure 2b) and instrument cap with irrigation port (Figure 2c).

• Other Considerations

The choice of sedation is dependent on the length of the procedure, patient characteristics and individual preference. Endotracheal intubation is often appropriate for long antegrade DBE procedures while moderate sedation is safe for retrograde exams and shorter antegrade exams. Fluoroscopy is no longer commonly used as a complement to DBE but may be beneficial in select cases.

Standard Performance of DBE

Double balloon enteroscopy may be performed via antegrade or retrograde route. Total enteroscopy rates (TER) for DBE range from 16-86% with a pooled rate of 44% reported in a recent, large meta-analysis.^{9,10} Although total enteroscopy is achievable through antegrade DBE alone, it is most commonly accomplished using a combination of antegrade and retrograde approaches with a submucosal ink tattoo placed at the maximal insertion site of the initial approach. Total enteroscopy rates with DBE are impacted by

Figures 1a, 1b, & 1c. Fujinon endoscopy processor & light source (1a), balloon pump controller (1b) and enteroscope (1c) *with permission from Fujinon*

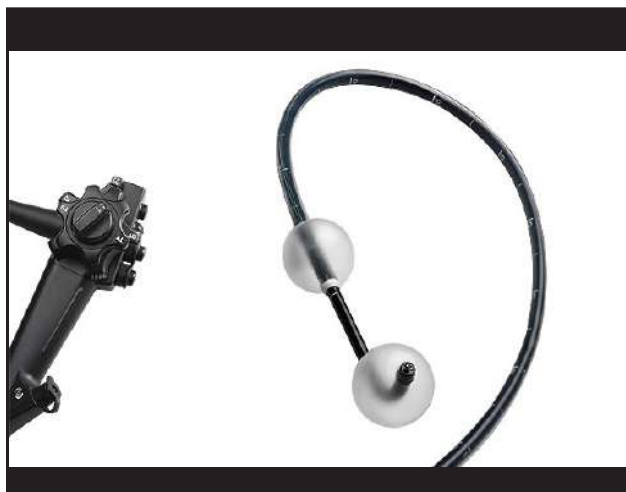


Table 1. Double Balloon Endoscope Models (Fujinon Inc., Saitama, Japan)

Model	Working length	Outer Diameter	Accessory Channel	Primary Use
EN-450T5	200cm	9.4mm	2.8mm	Enteroscopy
EI-580BT	155cm	9.3mm	3.2mm	Altered anatomy ERCP
EN-580T	200cm	9.3mm	3.2mm	Therapeutic Enteroscopy
EN-580XP	200cm	7.5mm	2.2mm	Pediatric Enteroscopy

Table 2. Indications for Double Balloon Enteroscopy^{9,10,15}

Indication	Intervention
Abnormal Video Capsule Endoscopy (VCE) <ul style="list-style-type: none"> • Small bowel angioectasias or Dieulafoy • Small bowel ulceration • Small bowel tumor 	<ul style="list-style-type: none"> • Endoscopic ablation • Biopsy • Biopsy and ink tattoo
Abnormal small bowel imaging (ex: CTE/MRE)	Evaluation for SB tumor or enteritis
Suspected small bowel bleeding after negative VCE	Diagnosis of missed tumors and vascular lesions
Suspected bleeding in altered anatomy	Treatment of bleeding sources in the afferent limb
Altered anatomy ERCP	Stone removal, stent placement, stricture dilation
Enteral feeding in altered anatomy	Jejunostomy; PEG placement in remnant stomach
Retained foreign bodies (ex: video capsules)	Foreign body removal
Management of small bowel strictures	TTS balloon dilation
Surveillance of intestinal polyposis	Prophylactic polypectomy
Incomplete colonoscopy	Complete colonoscopy +/- polypectomy

experience of the endoscopist as observed in one study which demonstrated a TER of 8% in the first 50 cases then 63% after 150 cases.¹¹ Total enteroscopy may be easier to achieve in patients who are short in stature and thin considering that small bowel length correlates positively with height and body mass index (BMI). Other patient dependent factors which may affect TER include previous abdominal surgery and excess visceral fat.¹²

DBE is considered a low-risk procedure by current society guidelines including interventions such as endoscopic biopsy, argon plasma coagulation (APC) and hemoclip placement.¹³ Study of DAE performed in patients on active

thienopyridine therapy, such as clopidogrel, has failed to show any increase in risk of procedural complication and may even increase diagnostic yield in DAE indicated for small bowel bleeding.¹⁴ The pooled rate of major complication in all applications of DBE is 1.2% with the two most common being pancreatitis, observed in 0.3 - 1% of all cases, and perforation, observed primarily in cases of polypectomy.^{10,15,16}

Procedural Indications

DBE is most commonly employed for the evaluation of known or suspected small bowel bleeding. This procedure is valuable in the evaluation of other

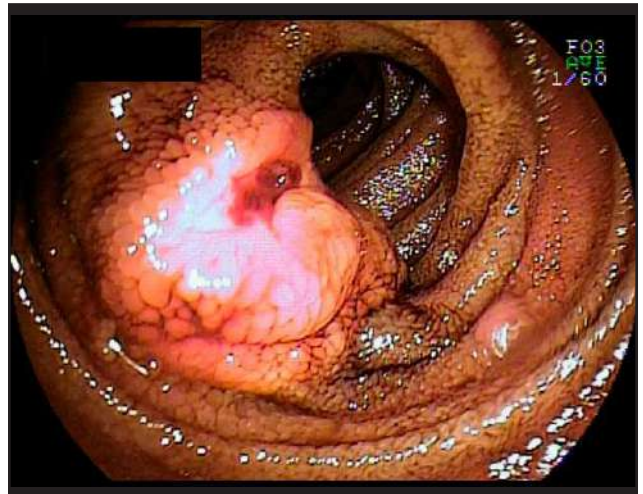
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Figures 2a, 2b, & 2c. Additional Equipment including Fujinon balloon set tool (2a), Zutron stiffening device (2b) and US Endoscopy instrument cap with irrigation port (2c)



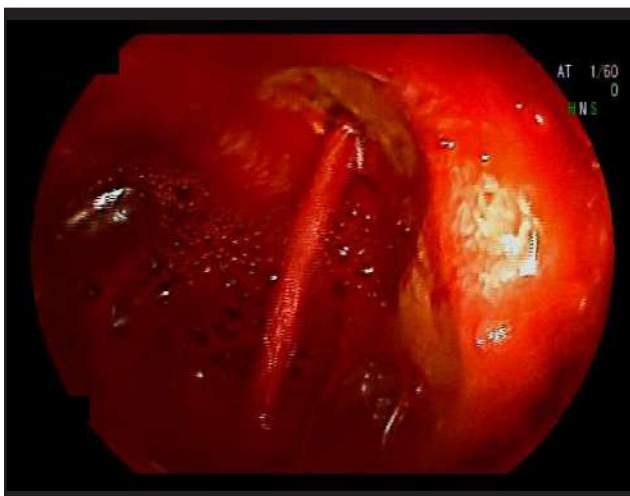
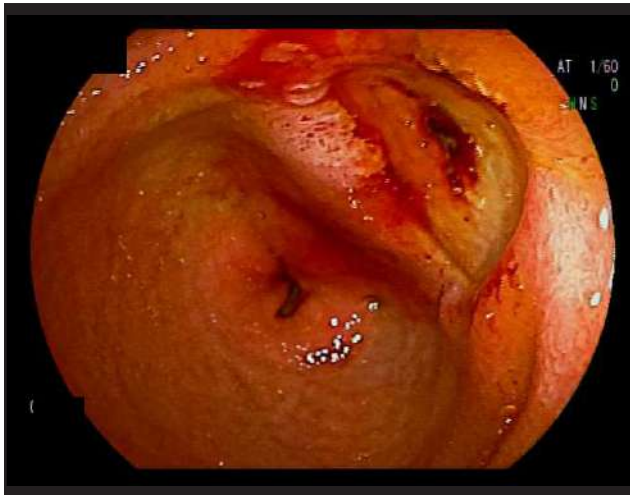
Figures 3a & 3b. Small bowel tumors missed by VCE including carcinoid (3a) and GIST (3b)



small bowel pathology as well as access to the diverted stomach and ampulla in patients with surgically altered anatomy. It has also been shown to be effective in completing difficult colonoscopy examinations such that the adoption of DBE for this indication has expanded over time. A list of DBE indications is included in Table 2.

There are several conditions in which DBE has little or no demonstrated utility but is often contemplated. DBE is not routinely indicated in the evaluation of patients with disorders of gut-brain interaction (DGBIs), formerly functional gastrointestinal disorders (FGIDs).¹⁷ Small bowel obstruction due to adhesions or intestinal carcinomatosis is not managed with DBE, although one series of 4 cases has been published describing

Figure 4a & 4b. Duodenal ulcer with visible vessel in RYGB before & after attempt at cauterity (unsuccessful)



the benefit of push enteroscopy in treating early post-operative bowel obstruction.¹⁸ DBE is not indicated to exclude a diagnosis of small bowel Crohn's disease after negative video capsule endoscopy (VCE) as VCE has a high negative predictive value for this indication.¹⁹

• Small Bowel Bleeding

DBE has a diagnostic yield of up to 60-80% in cases of suspected small bowel bleeding. VCE produces a similar diagnostic yield for this indication but is less invasive.⁹ Therefore, DBE is generally recommended after abnormal VCE as a therapeutic procedure to treat identified bleeding sources. DBE is indicated after normal VCE in patients under the age of 50 as small bowel tumors may be missed by VCE in 18% of cases.^{20,21} (Figures 3a & 3b)

DBE is also indicated after normal VCE in patients older than age 50 who experience continued blood loss as evidence by a drop in hemoglobin by > 4gm/dl or overt bleeding.^{9,22} Finally, DBE may be required to evaluate the pancreatobiliary intestinal limb and diverted stomach for bleeding sources in patients with altered anatomy such as long Roux-en-y gastric bypass.²³ (Figures 4a & 4b)

• Abnormal Small Bowel Imaging

In patients with small bowel ulceration observed on VCE, DBE is often required to obtain tissue samples to confirm a diagnosis of Crohn's disease, NSAID enteropathy or small bowel lymphoma. (Figures 5a, 5b, 5c) DBE may be performed as an alternative to VCE in patients with suspected small bowel Crohn's disease who are at high risk for capsule retention. Abnormal small bowel imaging of the small bowel is also an indication for DBE when suggestive of a new diagnosis of small bowel tumor or other pathology. (Figures 6a & 6b)

• Altered Anatomy ERCP

Altered anatomy ERCP is an indication for DBE which requires a specialized skillset and equipment. The reported success rates of DBE-assisted ERCP in surgically altered anatomy varies by type of post-surgical anatomy. Success rates of up to 100% have been reported with DBE-ERCP in cases of Billroth II, Whipple pancreaticoduodenectomy and short-limb Roux-en-y anatomy. In patients with long-limb Roux-en-y anatomy, success rates for cannulation are much lower at 60-84%. (Figure 7) When considering DBE-ERCP, it is important to appreciate that the risk of post-ERCP pancreatitis is higher in altered anatomy ERCP due to challenging cannulation which often requires pre-cut sphincterotomy.^{24,25,26}

The utility of DBE and other DAE methods in facilitating biliary access in long-limb Roux-en-y gastric bypass (RYGP) anatomy, has recently been studied head-to-head with alternative methods such as laparoscopic-assisted ERCP (LA-ERCP) and EUS-assisted transgastric ERCP (EDGE). In a recent cohort study comparing DAE-ERCP, LA-ERCP and EDGE in 130 patients, DAE-ERCP was successful in only 59% of patients in comparison with success rates of 98% for LA-ERCP and 100% for EDGE. EDGE was also associated with shorter

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Table 3. Comparison of Enteroscopy Techniques ^{1,2,3,4,9,10,12,39,40,41,42,43,44,48}

Technique	Double Balloon (DBE)	Single Balloon (SBE)	Spiral Enteroscopy (SE)	Balloon Guided Enteroscopy (BGE)	Push Enteroscopy (PE)
Equipment	Fujinon System with Enteroscope	Olympus System with Enteroscope	Fujinon System with DBE or SBE Enteroscope	Standard Colonoscope with NaviAid Balloon	Pediatric Colonoscope or Enteroscope
Total Enteroscopy Rate (TER)	34 +/- 10%	12 +/-10%	3 +/-5%	0%	0%
Procedure Time: Anterograde	76 +/- 6min	60 +/- 10min	41 +/- 4min	15 – 52min	10 – 45min
Procedure Time: Retrograde	85 +/- 8min	69 +/- 10min	46min	31min	N/A
Overall Diagnostic Yield	40-80%	41-65%	33-59%	44%	20-80%

hospitalization and fewer adverse events.²⁷ Many therapeutic endoscopists have adopted EDGE as their method of choice for biliary access in patients with long-limb RYGP as a result of this and similar studies.²⁸

• Foreign Body Removal

Foreign bodies may be removed from the deep small bowel using DBE, including retained video capsules, motility capsules, self-expandable metal stents, intragastric bariatric balloon, dentures and other objects.²⁹ A pooled success rate of 86.5% was reported in one large review of video capsule retrieval by DBE. Anterograde approach and jejunal location were predictors of success compared to retrograde approach and ileal location. The performance of DBE for video capsule retrieval also reduced the need for surgery for benign strictures and helped define strictures due to malignancy.³⁰ Video capsule retention may be considered as a positive event in cases in which retention aids in localization of pathology. (Figure 8) Finally, DBE

has a limited role in dilation of strictures of the small bowel related to Crohn’s disease, NSAID enteropathy or other benign etiologies.³¹ (Figures 9a, 9b & 9c)

• Intestinal Polyposis

Surveillance of intestinal polyposis syndromes including Peutz-Jeghers Syndrome (PJS) and Familial Polyposis (FAP) is an infrequent indication for DBE due to the rarity of these conditions. In patients with PJS, prophylactic resection of hamartomatous small bowel polyps >10mm in size may decrease the risk of repeated laparotomy require to treat intussusception, obstruction or bleeding.^{32,33,34} (Figures 10a & 10b) Each laparotomy increases the risk of future surgeries as well as risk of complications such as short bowel and intestinal obstruction due to adhesions.³⁵ DBE may be useful in the surveillance of adenomatous polyps of the proximal small bowel in FAP.³⁶

• Balloon-Assisted Colonoscopy

Double-balloon enteroscopy equipment has proven to be valuable in the completion of colonoscopy after failure of colonoscopy with standard equipment. A 2017 meta-analysis of 18 studies, including a total of 667 patients, described a successful completion

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Figures 5a, 5b, & 5c. Small bowel ulceration with stricture formation observed in Crohn's disease (5a), NSAID diaphragm disease (5b) and follicular lymphoma (5c)

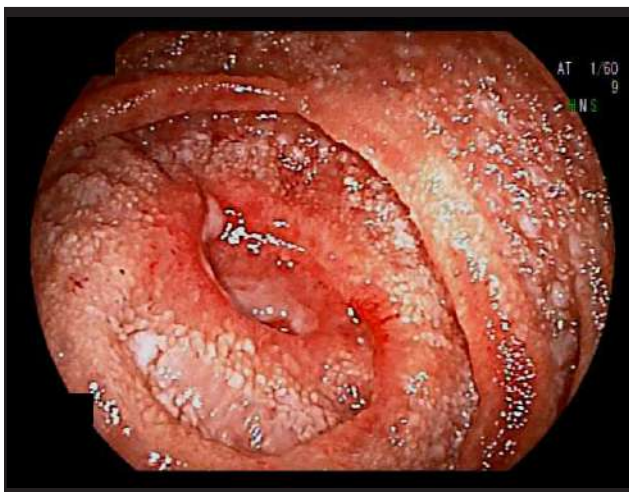
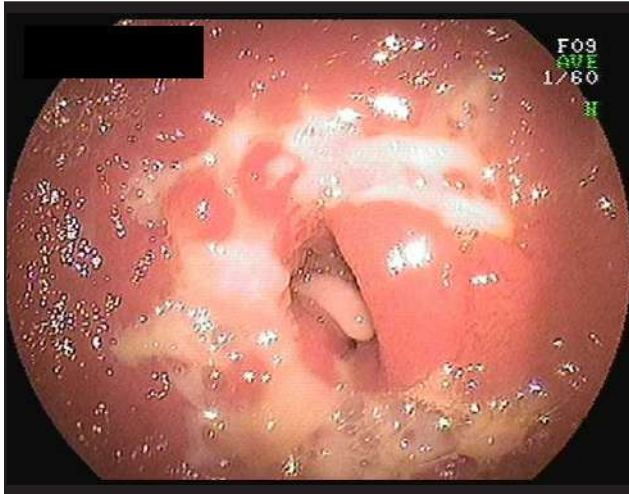
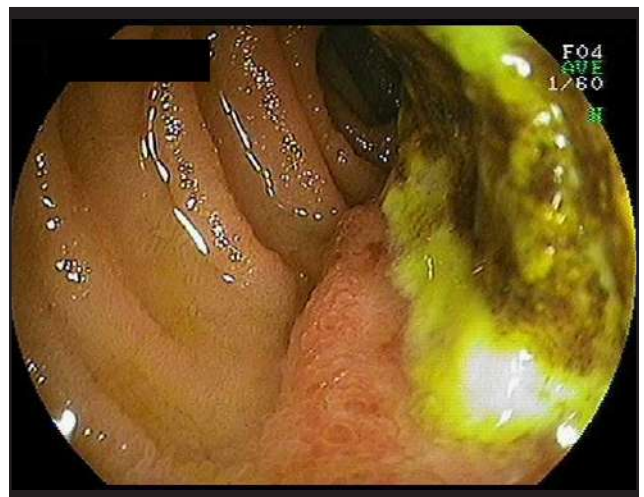
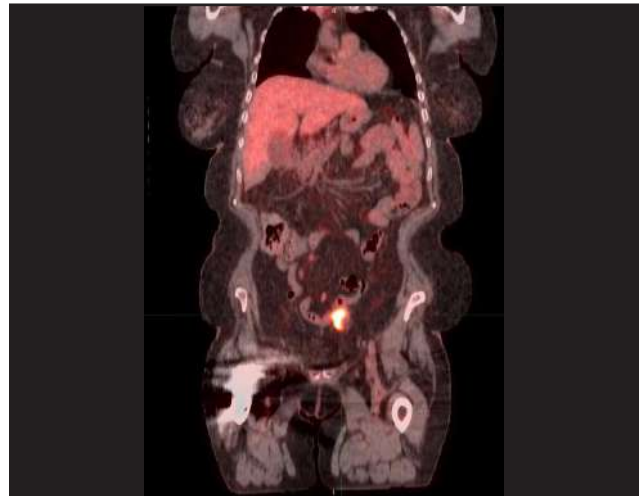


Figure 6a & 6b. Metastatic colon cancer to the small bowel observed on PET/CT and DBE



rate of >97% with DBE.³⁷ A more recent study of 122 cases produced similar results with a 92% completion rate.³⁸

Comparison of DAE Techniques

DBE, SBE, SE and BGE may all be considered for the above indications with advantages, disadvantages and limitations with each technique. Comparison trials have been performed for several of these indications which are useful for reference. However, the primary deciding factors in selection of DAE technique are: availability of the required equipment in the endoscopy unit and experience of the endoscopist. A summary of important comparisons are listed in Table 3.

Figure 7. DBE-Assisted ERCP with cholangiogram
Image Courtesy of Dr. Janak Shah



Figure 8. Video capsule retained proximal to a submucosal (carcinoid) tumor



- **Total Enteroscopy Rate (TER)**
Total enteroscopy with DBE using a combination of anterograde and retrograde exams was reported as achievable in 86% of patient in the initial study.¹ Although TERs have been lower in subsequent studies, DBE has been demonstrated to outperform SBE, SE and BGE in this regard. The average TER with DBE is 34% compared to 12% with SBE and 3% with SE, considering data from across multiple studies.^{39,40,41,42,43}

- **Procedure Time**
Average procedure time with anterograde DBE is significantly longer at 76 +/- 6min compared to 60 +/- 10min for anterograde SBE and 41 +/- 4min for anterograde SE. Procedure times for retrograde DBE are also longer than SBE and SE.⁴⁴

- **Diagnostic Yield**
The diagnostic yield of device-assisted enteroscopy is similar across all techniques at ~40 – 60% despite differences in TER.^{45,46,47} Lack of correlation between diagnostic yield and TER may be related to inclusion of upper GI tract abnormalities when calculating diagnostic yield for anterograde enteroscopy. The overall diagnostic yield of push enteroscopy ranges from 20-80% but half of abnormalities are found within reach of a standard gastroscope. Distribution of pathology within the small bowel may also explain similar diagnostic yield across techniques.⁴⁸ Angiectasias, the most common pathology found on DAE, are most frequently observed in the proximal 1/3

of the small bowel which is within reach of all anterograde enteroscopy techniques.⁴⁹ (Figure 11a & 11b). The diagnostic yield of anterograde DAE is comparatively higher than that of retrograde DAE likely for these same reasons.⁵⁰

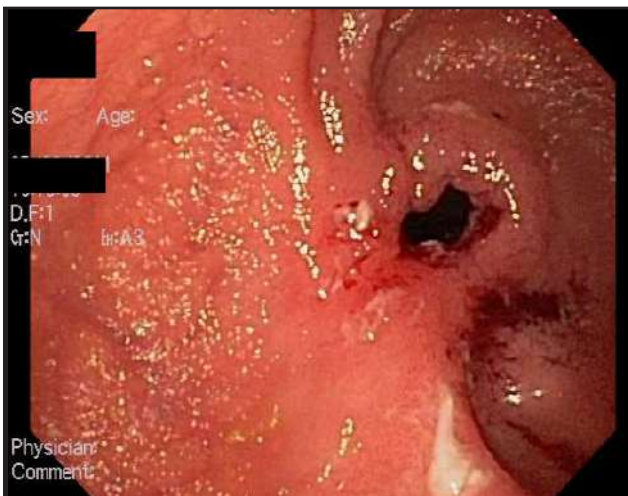
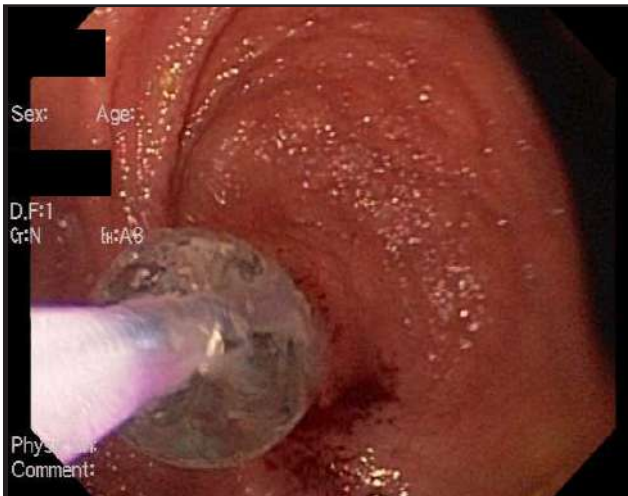
- **Altered Anatomy ERCP**
Successful completion of DAE-ERCP appears to be equal between DBE, SBE and SE techniques when studied in all types of surgically altered anatomy.²⁸ There is a practical advantage to using a short (155cm) model enteroscope, now available for DBE and SBE, as it allows for the use of all accessories of standard length. For the challenging indication of DAE-ERCP in long limb surgical bypass, DBE, SBE and SE were compared within a cohort of 129 patients. Cannulation by DAE-ERCP was successful in 63% of cases overall with similar success rates between all three methods.⁵¹ These results are consistent with previous studies of DBE, SBE and SE in the performance of DAE-ERCP.

- **Device-Assisted Colonoscopy**
The success rate of colonoscopy with DAE equipment approaches 100% in individual as well as comparison studies regardless of DAE technique. The largest comparison study of double balloon and single balloon technique for colonoscopy in patients with previous incomplete exams using standard equipment demonstrated success rates of 93% & 100%, respectively with each method.⁵²

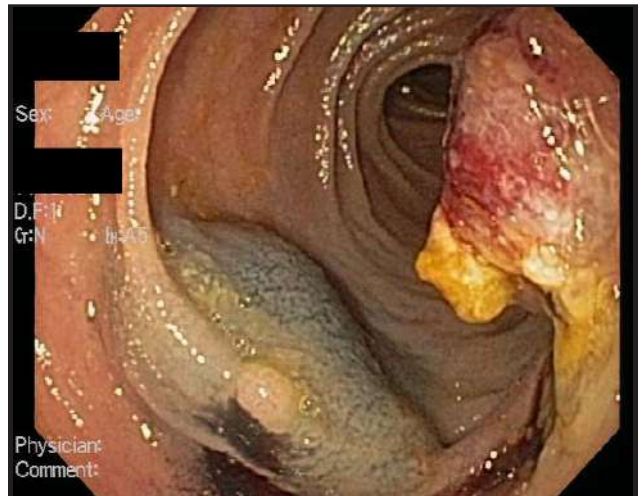
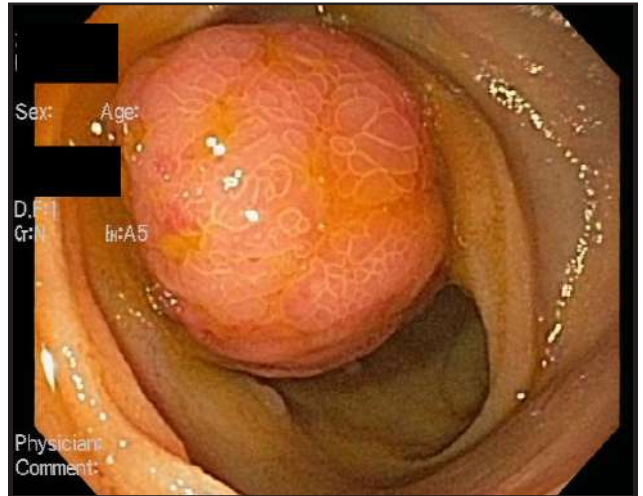
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Figures 9a, 9b & 9c. Ileal stricture due to Crohn's disease treated with TTS balloon dilation



Figures 10a & 10b. Large hamartoma removed from the distal jejunum by saline injection-hot snare



Spiral enteroscopy and through-the-scope balloon catheters have also been utilized with success in completion of difficult colonoscopy cases.

CONCLUSION

The advent of double balloon enteroscopy in Japan (2001) then in the U.S. (2004) was an important milestone in gastrointestinal endoscopy as this technology allows for access to the entire small bowel for therapeutic intervention. This procedure is well tolerated and low risk, especially when compared to intraoperative enteroscopy. DBE equipment is currently utilized for a variety of endoscopic indications in addition to the common

Figure 11a & 11b. Angioectasias in the proximal jejunum (11a) including a lesion with active bleeding (11b)



indication of small bowel bleeding. Although additional technologies for DAE have been subsequently developed, DBE has an advantage over other DAE techniques in regard to rate of total enteroscopy. The performance of DBE in the U.S. may be inhibited by availability of Fujinon endoscopy systems. However, the DBE system should be considered as an essential tool for centers which manage a significant volume of patients with small bowel bleeding or other small bowel pathology. ■

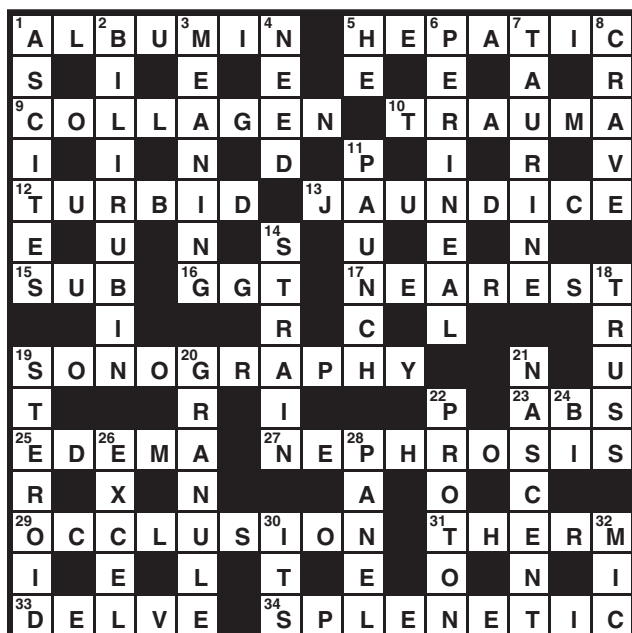
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Answers to this month's crossword puzzle:





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Academic Gastroenterology Position

The Division of Gastroenterology and Hepatology of the Johns Hopkins School of Medicine is seeking a Therapeutic Endoscopist to join our Faculty at Sibley Memorial Hospital, Washington DC., to work as a full-time clinical gastroenterologist & instructor with a special focus in therapeutic endoscopy, including teaching fellows and residents in advanced endoscopic procedures & techniques. Suitable candidates should have completed 2 years of training in GI plus at least 1 year of advanced training in therapeutic endoscopy. Candidates should be trained in EUS, ERCP, and advanced resection.

Johns Hopkins Division of Gastroenterology is routinely ranked among the top 5 in the nation. The Johns Hopkins - Sibley Memorial Hospital is a 318 bed hospital, located in Washington DC, and provides comprehensive care to the National Capital Region of 6.2 million people. Johns Hopkins School of Medicine is an equal opportunity, affirmative action employer. Women and minority candidates are strongly encouraged to apply. Qualified applicants should submit a cover letter and curriculum vitae to mkhasha1@jhmi.edu

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