World Journal of Gastroenterology

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World J Gastroenterol 2019 July 21; 25(27): 3538-3545

DOI: 10.3748/wjg.v25.i27.3538

ISSN 1007-9327 (print) ISSN 2219-2840 (online)

MINIREVIEWS

Device-assisted enteroscopy: A review of available techniques and upcoming new technologies

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Author contributions: Schneider M, Höllerich J and Beyna T wrote the review.

Conflict-of-interest statement: Schneider M and Höllerich J have nothing to disclose; Beyna T reports personal fees from Olympus, personal fees from Medronic, personal fees from Falk, personal fees from Cook, personal fees from Boston Scientific, during the conduct of the study.

Manuscript source: Invited manuscript

Received: March 27, 2019
Peer-review started: March 28, 2019
First decision: April 16, 2019
Revised: May 1, 2019
Accepted: May 31, 2019
Article in press: June 1, 2019
Published online: July 21, 2019

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Abstract

The advent of video capsule endoscopy into clinical routine more than 15 years ago led to a substantial change in the diagnostic approach to patients with suspected small bowel diseases, often indicating a deep enteroscopy procedure for diagnostical confirmation or endoscopic treatment. Device assisted enteroscopy was developed in 2001 and for the first time established a practicable, safe and effective method for evaluation of the small bowel. Currently with double-balloon enteroscopy, single-balloon enteroscopy and spiral enteroscopy three different platforms are available in clinical routine. Summarizing, double-balloon enteroscopy seems to offer the deepest insertion depth to the small bowel going hand in hand with the disadvantage of a longer procedural duration. Manual spiral enteroscopy seems to be a faster procedure but without reaching the depth of the DBE in currently available data. Finally, single-balloon enteroscopy seems to be the least complicated procedure to perform. Despite substantial improvements in the field of direct enteroscopy, even nowadays deep endoscopic access to the small bowel with all available methods is still a complex procedure, cumbersome and time-consuming and requires high endoscopic skills. This review will give an overview of the currently available techniques and will further discuss the role of the upcoming new technology of the motorized spiral enteroscopy (PowerSpiral).

Key words: Small bowel disease; Capsule endoscopy; Enteroscopy; PowerSpiral enteroscopy; Endoscopy

Core tip: This review will give an overview of the currently available techniques especially the double balloon-enteroscopy, the single balloon-enteroscopy and the manual spiral enteroscopy. Further the role of the upcoming new technology of the PowerSpiral will be discussed. Available preliminary data on novel PowerSpiral

P-Reviewer: Chiba T, Suzuki H
S-Editor: Yan JP
L-Editor: A
E-Editor: Liu JH

Enteroscopy promise a safe and effective tool for deep enteroscopy with a possible faster, deeper and less invasive approach. Further careful evaluation in larger prospective randomized clinical trials is needed to determine the further role of PSE in diagnostic and therapeutic approach to the small bowel.

Citation: Schneider M, Höllerich J, Beyna T. Device-assisted enteroscopy: A review of available techniques and upcoming new technologies. *World J Gastroenterol* 2019; 25(27): 3538-3545
URL: https://www.wjgnet.com/1007-9327/full/v25/i27/3538.htm
DOI: https://dx.doi.org/10.3748/wjg.v25.i27.3538

INTRODUCTION

Development of endoscopic methods for evaluation of the small bowel started almost simultaneously with flexible colonoscopy. First successful total enteroscopy was reported in 1971 using a ropeway and also a "sonde" method[1]. However, both methods were cumbersome, time-consuming and technically challenging and thus did not achieve wide acceptance in clinical routine. For approximately 30 years, "push"-enteroscopy was the preferred method, leaving the deep portion of the small intestine in-visible and in-accessible to endoscopic evaluation. The advent of video capsule endoscopy (VCE) as a novel non-invasive and reliable method for visualization of the entire mucosal surface of the small bowel in 2000 led to a substantial change in diagnostic assessment of patients with suspected small bowel disorders[2]. The increased detection rate of small bowel diseases consecutively led to an increasing need for a reliable method for direct endoscopic access to the small bowel for histopathological confirmation and/or performance of endoscopic treatment, that is practicable in clinical routine. The development of device-assisted enteroscopy (DAE) in 2001 by Yamamoto[3] established a practical method for examination of the small bowel and resulted in a paradigm shift in diagnostic and therapeutic approach in patients with suspicion of small bowel diseases. Currently three platforms for deep enteroscopy exist: Double-balloon enteroscopy (DBE, Fujifilm, Tokyo, Japan) was first described by Yamamoto in 2001[3], single-balloon enteroscopy (SBE, Olympus Medical Systems Corporation, Tokyo, Japan) in 2007[4] and spiral enteroscopy (SE, Spirus Medical, LCC, West Bridgewater, MA, United States) in 2008[5]. Balloon-guided enteroscopy (BGE, NaviAid, SMART Medical Systems Ltd, Ra'anana, Israel) is not well established in clinical routine, despite a few published trials report a diagnostic yield and DMI not inferior to standard DAE[6,7]. The double-balloon (Fujifilm, Tokyo, Japan)[3] and single-balloon (Olympus Medical Systems Corporation, Tokyo, Japan)[4] enteroscopy systems are the most commonly used devices in Europe. After thorough clinical evaluation SE has gained wide acceptance in North America but less in Europe. Despite these substantial improvements in the field of direct enteroscopy, even nowadays deep endoscopic access to the small bowel with all available methods is still a complex procedure, cumbersome and time-consuming and requires high endoscopic skills. Thus, technique of deep enteroscopy was further developed. In November 2015 clinical evaluation of a novel motorized version of the SE system started with the first in human case of PowerSpiral Enteroscopy (PSE, Olympus Medical Systems Corporation, Tokyo, Japan) being performed by our group[8]. The role of small-bowel capsule endoscopy and DAE for diagnosis and treatment of small bowel disorders was recently addressed in clinical guidelines and technical reviews by the European Society of Gastrointestinal Endoscopy (ESGE)[9,10], American Society of Gastrointestinal Endoscopy[11] and Japanese Gastroenterological Endoscopy Society[12]. This review will give an overview of currently available techniques for deep enteroscopy and will further discuss the role of the upcoming technologies with focus on PSE.

TECHNIQUES

Generally direct endoscopic approach to the small bowel can be achieved from the per-oral route (antegrade) or the per-anal route (retrograde). Enteroscopy has unique challenges due to the length of the small bowel and the difficulties encountered when attempting to push a slim, flexible instrument through as much as 300 cm to 400 cm of

small intestine. Various devices and techniques for enteroscopy have evolved to facilitate endoscope insertion into the small intestine. They are designed to help minimize looping which is the rate limiting step for push enteroscopy. For antegrade approach the endoscope is inserted *via* the mouth passing the esophagus and the stomach before the small bowel can be entered. Insertion depth to the small bowel is usually referenced to the pylorus or the Ligament of Treitz. For the retrograde approach the enteroscope first has to pass the colon before passage of the ileocecal valve facilitates access to the ileum. Non-invasive small bowel imaging modalities, *e.g.*, VCE or magnetic resonance imaging (MRI), are usually performed prior to direct enteroscopy to: First, identify any mucosal or subepithelial lesions indicating direct enteroscopy and thus, improving diagnostic yield of DAE; Second, to decide whether to start with antegrade or retrograde approach, and third, to rule out contra-indications for deep enteroscopy, *e.g.*, severe strictures. DAE with DBE, SBE and conventional SE allows for diagnostic and therapeutic deep enteroscopy and also endoscopic retrograde cholangio-pancreaticography (ERCP) in patients with altered anatomy[13,14]. However, currently available single- and double-balloon enteroscopes with a working length of 200 cm have a working channel of 2.8 mm or less, making the advancement of accessory material sometimes difficult or even impossible[15]. Conventional SE is liable to the same limitations, because the Endo-Ease overtube (Spirus Medical, LCC, West Bridgewater, MA, United States) is usually used with the standard slim 200 cm double- and single-balloon enteroscope[16]. To overcome these limitations, recently new therapeutic enteroscopes for double- and single-balloon platform have been developed with larger working channels of 3.2 mm to reduce friction during introduction of accessory material and facilitate therapeutic interventions[17,18]. Short length of the insertion portion additionally allows for utilization of standard instruments for therapeutic interventions, *e.g.*, sphincterotomes or delivery systems for plastic or self-expandable metal stents.

The choice of the device utilized for DAE mainly depends on the experience and equipment of the endoscopic center and the indication for enteroscopy in the individual patient. In principle, balloon-based techniques, comprising of balloon-assisted enteroscopy (DBE, SBE) and BGE, have to be distinguished from spiral-based technique (SE, PSE). Double-balloon (DBE), single-balloon (SBE) and SE have been studied in numerous uncontrolled and a limited number of controlled trials[19-29]. Advantages and disadvantages of current technologies have been summarized in several reviews and discussed in recent editorials[15,30-36]. In the following technical details of the DAE procedures will be explained. Currently available endoscopes for each technique are listed in Table 1.

Double-balloon enteroscopy (Fujifilm Inc, Tokyo, Japan)

DBE was introduced in 2001 in Japan by Yamamoto as the first method for device assisted enteroscopy[3]. The DBE system combines a flexible endoscope, an overtube and a balloon-pump-system. DBE utilizes a distal and proximal balloon mounted onto the endoscope and overtube tip, respectively, that can be inflated and deflated independently from each other to "anchor" and move the bowel, thereby assisting the operator in advancing the endoscope while gathering the bowel onto the overtube shaft by insertion and retraction ("push-and-pull"-method).

There are three types of DBE available and they include a diagnostic, a therapeutic and a short model (EN-580T, EN-580XP, EI-580BT). The "short" Double Balloon Endoscope is engineered to overcome technically-challenging therapeutic ERCP procedures in patients with surgically-altered anatomy such as Roux-en-Y reconstruction after biliopancreatic, gastric or bariatric surgery.

Single-balloon enteroscopy (Olympus Medical Systems Corporation, Tokyo, Japan)

Beside DBE, SBE is the most popular DAE device used in Europe. In contrast to DBE, SBE has only one balloon at the distal end of the overtube, what simplifies the preparation of the scope prior to start the procedure[4]. On the other hand technique for anchoring the endoscope's tip differs from DBE, because SBE uses scope tip angulation and suction instead of balloon inflation to maintain a stable position ("hook-and-suck"-technique) while advancing the overtube. One diagnostic and one therapeutic model of endoscope are available (SIF-Q180 and SIF-H290S).

Balloon-guided endoscopy (NaviAid, SMART Medical Systems Ltd, Ra'anana, Israel)

BGE utilizes a dedicated through-the-scope balloon which is inserted in the working channel of the endoscope. The balloon aids to anchor a standard endoscope, *e.g.*, colonoscope, in the small-bowel. Progression is achieved by repeated push-and-pull maneuvers. In the resent published studies the BGE is used form the antegrade and retrograde route. For therapeutic maneuvers the balloon catheter can be extracted. If

Table 1 Currently available device-assisted endoscopes: Technical characteristics

DAE System type	Single-balloon enteroscopy	Short-single balloon	Double-balloon enteroscopy	Double-balloon enteroscopy	Short-double balloon	Balloon-guided enteroscopy	Spiral enteroscopy	PowerSpiral enteroscopy
Company	Olympus Tokyo, Japan	Olympus Tokyo, Japan	Fujifilm Corporation Tokyo, Japan	Fujifilm Corporation Tokyo, Japan	Fujifilm Corporation Tokyo, Japan	Smart Medical Systems Raanana, Israel	Spirus Medical, Stoughton, Massachusetts, United States	Olympus Tokyo, Japan
Endoscope model	SIF-Q 180	SIF-H290S	EN-580T	EN-580XP	EI-580BT	No specific scope	No specific scope	PSF-1
Outer diameter distal end of endoscope	9.2 mm	9.2 mm	9.4 mm	7.5 mm	9.4 mm			11.2 mm
Instrument channel inner diameter	2.8 mm	3.2 mm	3.2 mm	2.2 mm	3.2 mm			3.2 mm
Outer diameter of overtube	13.2 mm	13.2 mm	13.2 mm	11.6 mm	13.2 mm		14.5 mm	18.1 mm 31.1 mm (with spiral)
Total length	2345 mm	1830 mm	2300 mm	2300 mm	1850 mm			2015 mm
Working length	2000 mm	1520 mm	2000 mm	2000 mm	1560 mm			1680 mm
Image Enhancement	NBI (Narrow band imaging)	NBI	FICE (Flexible spectral imaging color enhancement)	FICE	FICE	Depend on endoscope used	Depend on endoscope used	NBI

NBI: Narrow band imaging; FICE: Flexible spectral imaging color enhancement.

necessary, it can be reinserted for ongoing the procedure. BGE is also used as an "on-demand" enteroscopy system, as it can be added to every standard endoscope if needed[6,7,37].

Spiral enteroscopy (Spirus Medical, LCC, West Bridgewater, Massachusetts, United States)

Spiral assisted endoscopy is based on a completely different concept of advancing an endoscope by pleating of the bowel on the instrumentation shaft by active rotation instead of applying pushing force. Principle of SE is the conversion of rotational energy of the spiral into linear force to pull the intestine on the enteroscope[16]. This technique has been widely used for anterograde enteroscopy[20,21,24,26,28]. For this purpose the manually rotatable Endo-Ease Overtube (Spirus Medical, LCC, West Bridgewater, MA, United States) is used with a standard thin flexible enteroscope. The distal end of this dedicated overtube harbors a flexible spiral thread for pleating the small intestine over the overtube. By manually rotating the overtube, the spiral engages the small bowel which is thus pleated onto or unpleated from the overtube, respectively, depending on the direction of the spiral rotation. Spiral assisted endoscopy has been also approved and evaluated for retrograde enteroscopy *via* the anal route[24]. However, use of the Endo-Ease Overtube requires assistance by a second endoscopist for its appropriate use.

Upcoming Novel Technology: PowerSpiral Enteroscopy (Olympus Medical Systems corporation, Tokyo, Japan)

A novel motorized spiral endoscope (Olympus Medical Systems Corporation, Tokyo, Japan) has been introduced into clinical evaluation in November 2015[8]. The PSE consists of a 168 cm long flexible endoscope and is fully compatible with the latest EXERA III endoscopy system (Olympus Medical Systems Corporation, Tokyo, Japan). It is similar to other currently marketed endoscopes in that it incorporates a flexible insertion tube, 4-way deflection capabilities, high-definition imaging, optical image enhancement technology capabilities (narrow band imaging), a large caliber accessory channel of 3.2 mm and a separate dedicated irrigation channel. The system is unique in that it incorporates a user-controlled integrated electric motor embedded in the endoscope's handle to rotate a short flexible, disposable spiral overtube, that is attached to a rotation coupler located on the endoscope's insertion tube. Clockwise and counterclockwise rotation is activated by a foot pedal switch. Motorized, active

rotation of this spiral overtube pleats the bowel on to the endoscope's insertion tube. The system measures and feedbacks the resistance that the spiral rotation applies to the tissue *via* a LED display in order to prevent damage to the bowel[38]. PSE is currently been evaluated for its efficacy and safety in two prospective clinical trials in Europe. Preliminary data is currently only available in abstract form[39]. These show, that PSE seems to be safe and effective for deep enteroscopy. Diagnostic yield of antegrade PSE seems at least equal to standard DAE techniques while PSE seems to offer a faster and deeper approach to the small bowel.

DISCUSSION

In the clinical practice there are three well established device assisted enteroscopy platforms: DBE, SBE and the SE[4,5,40]. There is a couple of uncontrolled and only a limited number of controlled trials comparing the different DAE techniques[10,15,19-36]. The comparison of these techniques is difficult in particular due to differences in selection criteria for indications and study endpoints among the available trials.

Depth of maximum insertion (DMI) is used as an indicator of the capability of each device for deep access to the small bowel and to compare the different techniques. On closer inspection of the DMI there are several limitations of an exact measurement, and thus, leading to only an estimation of the covered distance in most trials[31]. An ESGE technical review of 2018 reports, that DBE seems to be associated with a higher DMI, however, the diagnostic yield as well as the safety profile of DBE, SBE and SE seem to be comparable. ESGE concludes, that these techniques appear equivalent for routine clinical practice[10]. A systematic review by Baniya *et al*[15] of 8 studies including 615 procedures found no significant difference between balloon-assisted enteroscopy and conventional SE in terms of DMI, diagnostic and therapeutic yield as well as AE rate, despite a significant shorter procedure time for SE. Another prospective randomized controlled trial by Moran *et al*[35] showed no significant differences in DMI, diagnostic yield, procedure time and adverse events (AEs) comparing antegrade SBE with SE. In this trial the medium DMI varied from 330 cm for SE comparing to 285 cm for SBE beyond the pylorus. Concerning the DMI and the total enteroscopy rate (TER) the most of the published trials showed a benefit for the DBE comparing to SBE and SE. In contrast a systematic review of 68 trials and two meta-analyses of only randomized controlled studies reported on similar results for depth of insertion, diagnostic and therapeutic yield and complications[29,41,42]. Two back-to-back trials compared manual SE with anterograde DBE. Summarizing, DBE seems to achieve a deeper insertion to the small bowel compared to SE[24,43]. Despite of all benefits of the DBE on the other hand, many trials show a longer procedure time in relation to SBE and SE[9,10,22,24,26,29,33,35,43,44].

On closer consideration to the TER several trials compare the various DAE techniques. A 2011 published systematic review of 23 studies including 1143 procedures showed a TER of only 1% for antegrade DBE. Nevertheless in 44% a total visualization of the entire small-bowel was subsequently possible by adding the retrograde approach[44]. A meta-analysis of 2015 compared four randomized clinical trials (RCTs) and confirmed that DBE had a higher TER than the SBE[29]. In keeping with this, in comparison to SE, DBE showed a significantly higher rate for total enteroscopies in a prospective RCT[26].

DAE generally is considered to be a very safe procedure with an overall AE rate of 0.8% for diagnostic procedures[1]. However, most adverse advents occurred in relationship to therapeutic interventions resulting in higher AE rates of up to 10% in therapeutic situations, mainly comprising of perforations and bleedings[10,44,45-48]. Xin *et al*[44] showed in a systematic review of 12823 procedures of DBE a minor complication rate of 9.1%. The rate of major complications were 0.72%. That included perforation (0.24%), pancreatitis (0.2%), bleeding (0.07%) and other (0.21%)[44]. Comparing DBE and SE, Despott *et al*[49] reported in a multicenter DBE registry a major complication rate of 0.8% in 950 procedures. The German DBE register offered a higher rate of major complications of 1.2% in 3894 cases[46]. Maybe a higher inclusion-rate of therapeutic procedures in this trial was the reason for a higher AE rate. Acute pancreatitis occurred in 9 patients. In all of these patients the DBE was performed by the per-oral route. Regarding conventional SE Akerman *et al*[5,16,32,50] reported a major complication rate of 0.3%. In 2950 patients there were 8 perforations but on the other hand no incidence of an acute pancreatitis[50]. The data allows the assumption, that SE has a lower risk of acute pancreatitis than DBE and SBE.

Summarizing, DBE seems to offer the deepest insertion depth to the small bowel going hand in hand with the disadvantage of a longer procedural duration. Manual SE seems to be a faster procedure but without reaching the depth of the DBE in

currently available data. Finally, SBE seems to be the least complicated procedure to perform. The novel PSE may promise a solution for the dilemma and help to overcome the limitations of currently available DAE techniques, as it seems to have adopted lessons learned from the development of DAE systems. In a first prospective bi-centric trial on antegrade PSE aiming for diagnostic yield of PSE 140 procedures were performed in 132 patients without prior abdominal surgery with suspected small bowel disease. Diagnostic yield was shown not to be inferior to standard DAE. Secondary endpoints of the trial promise a potential for deeper and faster approach. Motorization of the spiral enteroscope seems to simplify the procedure of SE while maintaining the beneficial features of SE promising an even further reduction of procedural duration and providing deeper access to the small bowel. Data on efficacy for total enteroscopy and retrograde approach will be available soon. However, data on PSE in patients after abdominal surgery and with altered anatomy as well as for enteroscopy-assisted biliopancreatic interventions are lacking. An international prospective multicenter trial will soon start enrolling patients to answer these questions.

CONCLUSION

DAE complements non-invasive small bowel imaging technologies like VCE and MRI and offers safe and effective deep direct endoscopic access to the small bowel for diagnostic evaluation and therapeutic interventions. However, available standard techniques are still time consuming and cumbersome to use. Available preliminary data on novel PSE promise a safe and effective tool for deep enteroscopy with a possible faster, deeper and less invasive approach. Further careful evaluation in larger prospective randomized clinical trials is needed to determine the further role of PSE in diagnostic and therapeutic approach to the small bowel.

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