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Prospective Multicenter Trial Comparing Push-and-Pull Enteroscopy With the Single- and Double-Balloon Techniques in Patients With Small-Bowel Disorders

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OBJECTIVES: **Double-balloon enteroscopy (DBE) is now an established method for diagnostic and therapeutic small-bowel endoscopy. Single-balloon enteroscopy (SBE) has been introduced to simplify the technique. A prospective randomized study was carried out to compare the two methods.**

METHODS: **The study included 100 patients (50 in each group; 63 men, 37 women; mean age 55 years), with no previous small-bowel or colon surgery. The indications for enteroscopy were (suspected) mid-gastrointestinal bleeding, Crohn's disease, small-bowel masses, chronic diarrhea or abdominal pain or both, and other conditions. Fujinon instruments were used, with either two balloons or one. The end point of the study was complete enteroscopy as the most objective parameter.**

RESULTS: **No severe complications such as perforation, bleeding, or pancreatitis occurred. Instrument preparation time was significantly faster with SBE than with DBE ($P<0.0001$). Complete enteroscopy was achieved with the DBE technique in 66% of cases (33 patients), either with the oral route alone or with combined oral and anal approaches. With the SBE technique, the complete enteroscopy rate was significantly lower at 22% ($P<0.0001$; 11 patients, only with oral and anal routes combined). The rate of therapeutic consequences for the patients based on diagnostic yield and negative complete enteroscopy was significantly higher ($P=0.025$) in the DBE group at 72%, compared with 48% in the SBE group.**

CONCLUSIONS: **The complete enteroscopy rate was three times higher with DBE than with SBE, accompanied by a higher diagnostic yield. DBE must therefore continue to be regarded as the nonsurgical gold standard procedure for deep small-bowel endoscopy.**

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INTRODUCTION

Until only a few years ago, it was not possible to access most of the small bowel using endoscopic techniques that avoid the need for surgical interventions. Video capsule endoscopy and balloon enteroscopy were therefore decisive breakthroughs in this field. Balloon enteroscopy using the double or single balloon technique is a more invasive procedure in comparison with capsule endoscopy. However, it provides all the advantages of conventional endoscopy. In optimal cases, the entire small bowel, or at least considerable proportions of it, can be visualized using balloon enteroscopy (1). Depending on the endoscopist's level of experience, the rate of complete enteroscopy using the double-balloon method is around 40–80% (2,3). With single-balloon enteroscopy (SBE), the rates are currently 12–25% (4,5). The double-balloon enteroscopy (DBE) system, developed by Dr Yamamoto, was presented for the first time in Japan in 2001, and by our own research group in Germany in 2003 (1,6). In the meantime, the system has become established throughout the world for diagnostic and therapeutic small-bowel examinations, and it is now used universally in routine clinical work. In addition to the classic indication for small-bowel endoscopy, the DBE technique has a variety of other potential uses as well—in

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difficult colonoscopies, for access to the pancreatic and biliary tract in patients with a surgically modified gastrointestinal tract, and for access to the stomach in patients who have undergone obesity surgery (7–12).

Another balloon enteroscopy system was recently introduced in which only one balloon is attached at the tip of the overtube; the method is therefore known as SBE (4). SBE is a simplification of the double balloon method, and its value has already been confirmed for difficult colonoscopies (13). The question of whether similar results can be achieved with the single balloon method in the more complex situation of the small bowel has not yet been answered. A prospective, randomized multicenter study comparing the double and single balloon techniques was therefore carried out, the results of which are presented here.

METHODS

Patients

The inclusion criteria were suspected or known small-bowel disorders for diagnostic balloon enteroscopy or therapeutic enteroscopy with argon plasma coagulation of up to five angiodysplasias. The exclusion criteria were age under 18, pregnancy, coagulation disorders (thrombocytes < 100,000 per ml, Quick < 60%, partial thromboplastin time > 50 s), prior surgery of the small bowel and colon, and patients in whom the following procedures were anticipated or performed: polypectomy, dilation of stenoses, argon plasma coagulation of more than five angiodysplasias, or foreign body extraction. These therapeutic balloon enteroscopies were excluded, as the time needed for treatment cannot be used for further advancement of the instrument to achieve complete enteroscopy. The end point of the comparative study was the rate of complete enteroscopy, as this is the most objective parameter. The patients were randomly assigned to undergo either DBE or SBE technique using computer-generated sealed envelopes.

Push-and-pull enteroscopy with the double balloon technique

The DBE system (Fujinon, Saitama, Japan) consists of a high-resolution video endoscope with a working length of 200 cm and a flexible overtube made of polyurethane. Latex balloons are attached both at the tip of the enteroscope and also on the overtube and can be inflated with air or deflated using a pressure-controlled pump. The principle of the DBE technique is based on alternating pushing and pulling maneuvers, allowing the small bowel to be threaded onto the overtube step by step (1,6). Two types of device are currently available with the double balloon system. For this study, the EN450-P5 model with a working channel of 2.2 mm and an outer diameter of 8.5 mm was used, as the P-type is the standard model used for diagnostic procedures. The overtube has a diameter of 12.2 or 13.2 mm and an overall length of 145 cm.

Push-and-pull enteroscopy with the single balloon technique

The EN450-P5 model was also used for single balloon examinations, as the system can also be used with a single balloon by detaching the balloon from the enteroscope tip (14,15). In contrast to the double balloon technique, stable positioning in the small bowel is achieved during withdrawal of the scope by angling the tip of the endoscope or power suction (16), rather than by inflating the balloon on the scope. Insufflation of the overtube balloon is also carried out using the pressure-controlled pump.

Examination procedure

For both DBE and SBE, the patients generally needed only to fast before the oral examination (approximately 12 h for food and 4 h for clear liquids). Laxative measures before oral examinations were only administered in patients with signs of intestinal obstruction or diabetic neuropathy with delayed transit. For the anal examination, patients received bowel preparation in the same way as for colonoscopy, including splitting—taking half of the bowel cleansing solution on the day before enteroscopy and half on the day of the enteroscopy.

Before the procedure, the sealed envelope was opened by an assistant and the patient was assigned to one or the other method in accordance with the randomization. The examination itself was carried out either with conventional sedoanalgesia or with propofol sedation. All the balloon enteroscopy examinations were carried out by experienced investigators, each of whom had previously conducted at least 50 DBE procedures. Training in the single balloon technique had been provided for 2 months beforehand. Oral balloon enteroscopy was performed first, followed by anal balloon enteroscopy if the oral examination did not reach the cecum. Depending on the individual patient's condition, the anal procedure was conducted on the next day or the day after. Complete enteroscopy was achieved if the India ink mark made at the deepest point reached during oral balloon enteroscopy was clearly identified. The examinations were not allowed to exceed more than 2 h. The start of the examination was defined as the beginning of sedoanalgetic medication. The examination had to be stopped if no further advancement of the scope into the small bowel was achieved for a 20 min period. Fluoroscopy—to obtain a better position by straightening the enteroscope under radiographic guidance—was an additional option during the examination.

Although a previous prospective two-center study showed substantial advantages about patient comfort and insertion depth with the use of CO_2 insufflation in DBE (17), air insufflation was used for this study, as CO_2 is not yet generally established and was not available in all the participating centers.

A standardized data collection form was completed after each examination to record the following data: all information about the patients, including age, sex, prior diagnostic work-up and examination date; and enteroscopy data, including randomization, the times required for preparation of the device, for insertion to the deepest point, and for the whole examination; the amount of sedoanalgetic medication, X-ray exposure time (if used; in minutes and dGy/cm^2); findings, and acute complications during the investigation and on the day after. All the patients were admitted to hospital for at least 2 days.

Statistical analysis and ethical considerations

Descriptive statistics were calculated for the patients' data and clinical parameters, and are presented as means and medians, as well as standard deviation and range (minimum–maximum) for continuous data and absolute and relative frequencies for categorical data. For continuous data, comparisons between the two groups were carried out using the Mann–Whitney *U*-test. A *P* value of ≤0.05 was considered to be statistically significant. The χ^2-test was used for categorical data.

The null hypothesis of the test was that the double balloon technique is superior to the single balloon technique, with at least double the rate of complete enteroscopies. On the basis of previous experience, it was assumed that complete enteroscopy could be achieved in at least 40% of the patients with DBE, whereas with SBE the complete enteroscopy rate was expected to be 15%. This difference can be detected with 80% power in a one-sided χ^2-test at the 2.5% level if 49 patients are included in each of the two groups.

Randomization was carried out centrally at the HSK Wiesbaden hospital using a computer-generated list for each participating study center. The study nurse at HSK Wiesbaden produced the corresponding envelopes with labels (center number and patient number) and sent them to the participating study centers in blocks. All the data were collected at the leading study center, HSK Wiesbaden.

Approval for administering balloon enteroscopy in patients with suspected or confirmed small-bowel disease was received from the ethics committee of the state of Hesse, Germany.

RESULTS

Between October 2007 and November 2008, 123 patients with suspected or known small-bowel disorders were enrolled in the study after providing written informed consent. Of them, 100 patients (63 men, 37 women) with a mean age of 55±18 years (range 18–88) completed the study. The indications for small-bowel endoscopy were (suspected) mid-gastrointestinal bleeding ($n=60$), (suspected) Crohn's disease ($n=12$), suspected small-bowel masses ($n=7$), chronic diarrhea and/or abdominal pain combined with other pathologies such as enlarged abdominal lymph nodes ($n=19$), and others ($n=2$).

Of the 123, 23 patients originally enrolled in the five participating centers had to be excluded after the first examination (12 in the DBE group and 11 in the SBE group) for the following reasons: the patient decided not to undergo anal balloon enteroscopy after the diagnosis was made with oral balloon enteroscopy ($n=9$); oral enteroscopy had to be stopped due to impassable strictures due to Crohn's disease or malignant stenosis ($n=6$); endoscopic treatment of more than five angiodysplasias and polypectomy of a hyperplastic polyp that was considered to be responsible for the mid-gastrointestinal bleeding were carried out ($n=4$); a technical complication occurred ($n=1$, tearing of the cable control); a complication of sedation meant that the enteroscopy had to be stopped ($n=1$); and the maximum investigation time of 120 min was exceeded ($n=2$).

Balloon enteroscopies were carried out successfully in all the remaining 100 patients (50 patients in each group), with no further relevant technical problems. The course of the study is listed in a flow chart in **Figure 1**. No severe balloon-enteroscopy-associated complications such as perforation, bleeding induced by mucosal injury, or pancreatitis were observed. In three patients (3%; one in the DBE group, two in the SBE group), severe abdominal pain occurred for several hours after balloon enteroscopy and resolved by the following morning. No fever occurred. One of these three patients underwent argon plasma coagulation for treatment of angiodysplasias; in the other two patients, only a diagnostic balloon enteroscopy was performed, which revealed several ulcerations and erosions in one patient and a Meckel's diverticulum

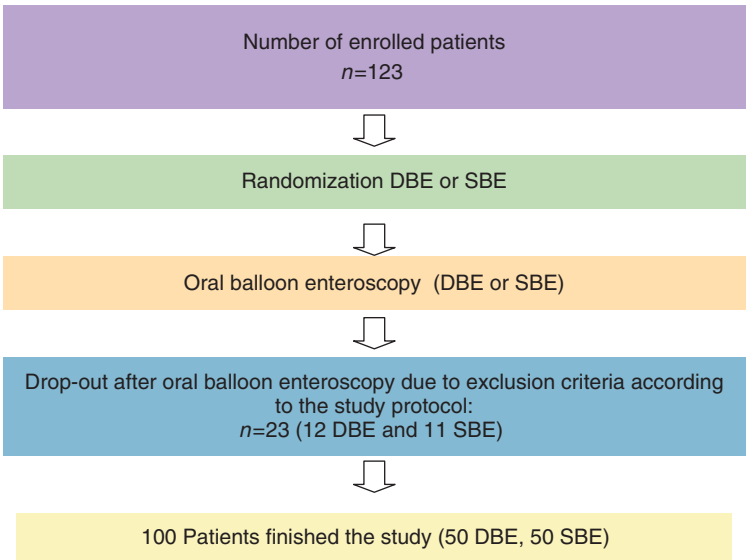

Figure 1. Flow chart of the course of the study. DBE, double-balloon enteroscopy; SBE, single-balloon enteroscopy.

in the other. There were no signs of perforation or pancreatitis (on laboratory tests, abdominal ultrasound, or radiography). The pain was probably caused by the insufflated air and argon gas during argon plasma coagulation. In one patient in the DBE group (2%), a brief drop in oxygen saturation to 78% occurred, but there was no need to carry out tracheal intubation or stop the balloon enteroscopy.

There were no differences between the two groups about the patients' demographic data, including sex, age, body mass index, and earlier abdominal surgery (**Table 1**). Details of the investigation parameters, such as the time needed for preparation of the balloon enteroscopy devices, procedure time and total investigation time, the rate of complete enteroscopy, and the overall diagnostic yield are listed in **Table 2**. Detailed information on the relevant findings is given in **Table 3**. Generally, a combination of midazolam (Dormicum) and/or fat-soluble diazepam (Stesolid) and meperidine (pethidine, Dolantin) or piritramide (Dipidolor) was chosen for conscious sedation. Propofol was administered alone or in combination with meperidine only in young patients.

Statistically significant differences were seen between the two groups about the time required for preparation of the devices, investigation time, and complete enteroscopy rate, as well as the rate of therapeutic consequences of the patients based on the diagnostic yield and negative complete enteroscopies. Preparation of the scope using the single balloon technique was significantly faster in comparison with the double balloon technique (mean 6 vs. 10 min; $P<0.0001$). The overall investigation time as well as the procedure time with the oral approach in the SBE group was also significantly shorter in comparison with the DBE group ($P=0.0013$ and 0.0005). Conversely, the rate of complete enteroscopy was three times higher in the DBE group than in the SBE group. This result was achieved in the group including all randomized patients (intent-to-treat group, $n=123$, 35 of 62 patients, 56% vs. 11 of 61 patients, 18%) as well as in the study group ($n=100$, 33 of 50 patients, 66% vs. 11 of 50 patients, 22%; $P<0.0001$). After the exclusion of 23 patients, a substantial percentage of whom had relevant positive findings (see above), the diagnostic yield for relevant findings in the remaining 100 patients who completed the study was higher in the DBE group (52%, 26 of 50 patients) than in the SBE group (42%, 21 of 50 patients). The difference was not statistically significant ($P=0.42$), but this rate only includes relevant findings confirming the suspected diagnosis or providing a new diagnosis and explaining the

Table 1. Characteristics of the patients

	DBE (n=50)	SBE (n=50)	*P*
Sex (M/F)	28/22	33/17	NS*
Age (years; mean±s.d.)	53±18	56±18	NS**
BMI	24.7±4.8	25.9±4.0	NS*
Prior surgery (n, %)	16 (32%)	19 (38%)	NS*

BMI, body mass index; DBE, double-balloon enteroscopy; NS, not significant; SBE, single-balloon enteroscopy.
*χ^2-Test.
**Student's *t*-test.

Table 2. Enteroscopy data

	DBE		SBE		*P*
	Oral	Anal	Oral	Anal	
Preparation time for the instruments (min)					
Mean±s.d.	9.7±2.4	10.0±3.2	6.4±1.9	6.2±2.1	<0.0001*
Minimum–maximum	5–15	5–20	4–10	3–15	
Investigation time (min)					
Procedure					
Mean±s.d.	66.5±17.7	62.0±22.7	53.6±16.7	60.3±19.6	0.0005 *(only oral route)
Minimum–maximum	38–100	22–115	23–90	20–100	
Total					
Mean±s.d.	88.5±21.8	80.5±25.7	72.4±25.3	76.5±23.8	0.0013*(only oral route)
Minimum–maximum	47–120	27–120	30–120	32–100	
Complete enteroscopy (n, %)	33/50 (66%)		11/50 (22%)		<0.0001**
Diagnostic yield	26/50 (52%)		21/50 (42%)		NS
Rate of negative complete enteroscopies influencing the further therapy	10/50 (20%)		3/50 (6%)		
Therapeutic yield (n, %)	36/50 (72%)		24/50 (48%)		0.025**

DBE, double-balloon enteroscopy; SBE, single-balloon enteroscopy.
*χ^2-Test.
**Student's *t*-test.

Table 3. Relevant findings in the small bowel with balloon enteroscopy

	DBE (*n*=50)	SBE (*n*=50)
Vascular malformations		
Angiodysplasias	6	9
Hemangiomas	1	—
Erosions and ulcerations		
Nonspecific	3	3
Crohn-like (including stenosis)	6	3
NSAID-like	—	1
Scar tissue	—	1
Diverticula		
Meckel's	3	—
Diffuse	1	2
Bleeding colonic	1	—
Polyps (adenoma)	1	1
Malignancy		
Lymphoma	1	1
Neuroendocrine carcinoma	1	
GIST	1	
Other (Cronkhite–Canada syndrome)	1	
Total	26/50 (52%)	21/50 (42%)

DBE, double-balloon enteroscopy; GIST, gastrointestinal stromal tumor; NSAID, nonsteroidal anti-inflammatory drug; SBE, single-balloon enteroscopy.

patient's symptoms. In addition, in 13 of 18 patients (72%; 10 in the DBE group and 3 in the SBE group) with normal or nonrelevant findings (e.g., isolated lymphangiectasia, lipoma) and total balloon enteroscopy, complete enteroscopy was important for subsequent management.

Two patients had recurrent severe hematochezia. One of them had colonic diverticula (with no active bleeding during colonoscopy), and was at increased surgical risk due to concomitant conditions. In the other patient, a fistula between the stump of the left renal artery and the proximal jejunum following nephrectomy had been suspected on push enteroscopy and abdominal computed tomography, but this was not confirmed by bleeding during the examinations. In both of these cases, complete DBE excluded other bleeding sources in the small bowel. The post-nephrectomy patient was referred for surgery, which confirmed the suspected diagnosis of a fistula. The patient with colonic diverticula was scheduled for surgery.

In two patients with known celiac disease and suspected thickening of the small-bowel wall on abdominal computed tomography, lymphoma of the small bowel was excluded. In seven patients with chronic diarrhea and/or abdominal pain and/or slight iron-deficiency anemia without signs of bleeding and additional pathology in either laboratory tests or imaging methods (abdominal computed tomography, abdominal ultrasound, abdominal magnetic resonance imaging), suspected Crohn's disease or enteritis was excluded and/or a suspected irritable bowel syndrome was confirmed. In one patient with protein-losing enteropathy and chronic suspected mid-gastrointestinal bleeding (with a positive fecal occult blood test), pathological ectasia of the lymph vessels and blood vessels was diagnosed in the duodenum, and involvement of the remaining small bowel was excluded. In one patient with an unclear polyposis syndrome (Peutz–Jeghers syndrome was suspected), no polyps were found in the small bowel. Complete enteroscopy excluded small-bowel lesions or determined the extent of a disease in 13 patients (10 in the DBE group and 3 in the SBE group). Altogether, the rate of therapeutic consequences in the DBE group was significantly higher at 72% (36 of 50 patients) than in the SBE group at 48% (24 of 50 patients; $P=0.025$).

DISCUSSION

Mid-gastrointestinal bleeding is defined as small-bowel bleeding located between the papilla and the ileocecal valve (18) and is the main indication for small-bowel endoscopy (19–23). In comparison with push enteroscopy, a much higher diagnostic yield (including both the diagnosis and the number of detected lesions) can be achieved with DBE—as expected, because much more of the small bowel can be visualized (24,25). The high diagnostic yield of DBE, at around 60–80%, is also associated with a high proportion of direct treatment implications for the patient (2,19–23). Most studies on DBE have reported a high rate of endoscopic interventions, at between 35 and 65%. The first original studies in Asia on SBE reported a lower diagnostic yield of around 40–50% (4,5), whereas the rate of endoscopic interventions was only 5–20%. This rate appears to be very low, and various explanations are possible. On the one hand, it is well known that angiodysplasias, which can generally be well treated endoscopically, are much more frequent in the Western hemisphere than in Asia. Conversely, the insertion depth reached with the SBE technique might be markedly lower than with the DBE technique, so that SBE might therefore be associated with a lower diagnostic yield, as in push enteroscopy.

No studies comparing push-and-pull enteroscopy using the double balloon and single balloon techniques have previously been reported to confirm or disprove this hypothesis. This report describes the first prospective comparative multicenter trial, and the results are in good agreement with results previously reported for the different balloon enteroscopy techniques separately. In this study, the rate of complete enteroscopy was three times higher in the DBE group in comparison with the SBE group (66 vs. 22%), associated with a higher diagnostic yield in the DBE group. The higher diagnostic yield is certainly due to the greater insertion depth possible with DBE; the deeper the insertion, the larger the percentage of the small bowel that can be visualized endoscopically.

The end point of the present comparative study was the rate of complete enteroscopy, as this is the most objective parameter. Measurement of the insertion depth always involves an estimate

and is dependent on the endoscopist. In addition, using the published technique (25), it is more difficult to measure the insertion depth in SBE. It might be debated whether the diagnostic yield would have been a better end point for the study. If both enteroscopy techniques were performed in the same patient, this would have been a good alternative study end point. However, the trial was a randomized one, and the situation was therefore different and more difficult. However, there is still a lack of generally accepted and widely used classifications and definitions of relevant bleeding sources—e.g., for vascular malformations—and these are therefore dependent on the endoscopist's assessment. Furthermore, not only the diagnosis of disease but also its extent is becoming increasingly important. The insertion depth thus has an important role. A correlation between the insertion depth and the number of lesions diagnosed has already been reported previously (13).

At the start of the DBE era, there were large numbers of patients with suspected or known small-bowel diseases awaiting the option of a nonsurgical approach to the small bowel using the new method. Nowadays, balloon enteroscopy has become an established technique that is routinely accepted and is an essential part of the diagnostic and therapeutic work-up for small-bowel diseases (26). It is increasingly being used to exclude small-bowel lesions and diseases without the need to resort to surgery, and to assess the extent of known small-bowel diseases. It is therefore important for the further management of patients in whom there are diagnostic questions that can only be answered by complete enteroscopy. The results of this study illustrate this well, as the overall diagnostic yield of 72% in the DBE group consisted of two subgroups of patients—52% with relevant findings and 20% in whom a normal complete enteroscopy was the outcome influencing the further management of the patient. The corresponding data for the SBE group were lower, at 42 and 6%.

The time needed for preparation of the enteroscope using the single balloon technique was significantly shorter than with the double balloon technique. However, the difference only amounted to a couple of minutes. The examination time in the SBE group was also significantly shorter in comparison with the DBE group. This can be explained by the greater difficulty of the SBE procedure in the deeper parts of the small bowel, as the small bowel slips off the overtube more easily during pushing and pulling maneuvers when the second endoscope balloon is not attached. During insertion, therefore, the point at which no further advancement can be achieved is reached earlier with SBE in comparison with the DBE technique.

As to the complication rate in the two balloon enteroscopy techniques, no severe complications such as bleeding, perforation, or pancreatitis occurred in this trial. On the basis of the reported data, however, including the German Double Balloon Registry, including nearly 4,000 DBE procedures, relevant complications can be expected in diagnostic double balloon enteroscopies in approximately 1% of cases. The most severe complication here is certainly pancreatitis, with a risk of approximately 0.3% in oral DBE (27,28). Insufficient data are currently available regarding the expected complication rates in SBE. Perforation as a severe complication in a diagnostic examination has only been reported in one of the two original studies that have been published to date (one of 37 examinations in 27 patients) (5). In the other study (4), a deep mucosal tear was described, which was treated with clips (one of 78 examinations in 41 patients). This was caused by the flexed endoscope tip during advancement of the overtube. It is conceivable that the inverted endoscope tip technique might in fact lead to a higher rate of relevant mucosal injuries, but due to the limited numbers of cases this question cannot be answered as yet.

This study has potential limitations. First, the 2-month training for the SBE technique might be considered to be too short. However, only investigators with extensive experience (≥50 DBEs) with the push-and-pull technique used in both DBE and SBE were allowed to perform the enteroscopy. Mehdizadeh *et al.* (29) showed that even investigators with no experience in balloon enteroscopy were able to achieve a significant reduction in the investigation time after 10 DBEs. It can therefore be assumed that with more than 50 DBEs, the investigators were able to learn the easier handling needed in the SBE technique within a short time. Second, only experienced endoscopists performed the examinations. However, we believe that the differences between the two methods regarding the complete enteroscopy rates would have also been observed if less experienced investigators had conducted the examinations—probably with a lower rate for both techniques. Third, DBE and SBE were compared using a single type of enteroscope (Fujinon). It could be argued that differences in scope type (Olympus, Tokyo, Japan) may influence the depth of intubation and the rates of complete enteroscopy achieved. However, there appear to be no differences, as the rates for the diagnostic yield of relevant findings and complete enteroscopy achieved with Fujinon SBE in this study (48 and 22%, respectively) are in good agreement with results previously reported for the Olympus SBE system (40–50 and 12.5–25%, respectively) (4,5).

Double balloon enteroscopy has become established throughout the world for diagnostic and therapeutic examinations of the small bowel, and is now used universally in clinical routine work. The recently introduced technique of single balloon endoscopy represents a simplification of the method. This prospective randomized trial showed that the rate of complete enteroscopy with DBE was three times higher than with SBE and that DBE was associated with a higher diagnostic yield. On the basis of these results, DBE must continue to be regarded as the nonsurgical gold standard procedure for deep small-bowel endoscopy at present.

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CONFLICT OF INTEREST

Guarantor of the article: Andrea May, MD, PhD.

Specific author contributions: Study protocol, ethics approval, enteroscopies, and manuscript preparation: Andrea May; patient enrollment, data collection, statistics, and randomization: Michael Färber and Insa Aschmoneit; manuscript preparation: Christian Ell; enteroscopies: all of the remaining authors.

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Potential competing interests: None.

Study Highlights

WHAT IS CURRENT KNOWLEDGE

- ✓ Double-balloon enteroscopy (DBE) has become the standard investigation technique for deep small-bowel endoscopy in patients with known or suspected small-bowel disorders.
- ✓ Single-balloon enteroscopy (SBE) is a simplification of this balloon enteroscopy technique and is said to be easier and faster with the same results, e.g., regarding insertion depth.

WHAT IS NEW HERE

- ✓ We carried out a prospective comparison of the single- and double-balloon techniques.
- ✓ Preparation time of the SBE is significantly faster than that of the DBE.
- ✓ Rate of complete enteroscopy is threefold higher using the DBE technique compared with the SBE technique.

REFERENCES

1. Yamamoto H, Sekine Y, Sato Y *et al.* Total enteroscopy with a nonsurgical steerable double-balloon method. Gastrointest Endosc 2001;53:216–20.
2. Yamamoto H, Kita H, Sunada K *et al.* Clinical outcomes of double-balloon endoscopy for the diagnosis and treatment of small-intestinal diseases. Clin Gastroenterol Hepatol 2004;2:1010–6.
3. Pohl J, Blancas JM, Cave D *et al.* Consensus report of the 2nd International Conference on Double Balloon Endoscopy. Endoscopy 2008;40:156–60.
4. Tsujikawa T, Saitoh Y, Andoh A *et al.* Novel single-balloon enteroscopy for diagnosis and treatment of the small intestine: preliminary experiences. Endoscopy 2008;40:11–5.
5. Kawamura T, Yasuda K, Tanaka K *et al.* Clinical evaluation of a newly developed single-balloon enteroscope. Gastrointest Endosc 2008;68:1112–6.
6. May A, Nachbar L, Wardak A *et al.* Double-balloon enteroscopy: preliminary experience in patients with obscure gastrointestinal bleeding or chronic abdominal pain. Endoscopy 2003;35:985–91.
7. Kaltenbach T, Soetikno R, Friedland S. Use of a double balloon enteroscope facilitates caecal intubation after incomplete colonoscopy with a standard colonoscope. Dig Liver Dis 2006;38:921–5.
8. Mönkemüller K, Knippig C, Rickes S *et al.* Usefulness of the double-balloon enteroscope in colonoscopies performed in patients with previously failed colonoscopy. Scand J Gastroenterol 2007;42:277–8.
9. Pasha SF, Harrison ME, Das A *et al.* Utility of double-balloon colonoscopy for completion of colon examination after incomplete colonoscopy with conventional colonoscope. Gastrointest Endosc 2007;65:848–53.
10. Haruta H, Yamamoto H, Mizuta K *et al.* A case of successful enteroscopic balloon dilation for late anastomotic stricture of choledochojejunostomy after living donor liver transplantation. Liver Transpl 2005;11:1608–10.
11. Aabakken L, Bretthauer M, Line PD. Double-balloon enteroscopy for endoscopic retrograde cholangiography in patients with a Roux-en-Y anastomosis. Endoscopy 2007;39:1068–71.
12. Kuga R, Safatle-Ribeiro AV, Faintuch J *et al.* Endoscopic findings in the excluded stomach after Roux-en Y gastric bypass surgery. Arch Surg 2007;142:942–6.
13. May A, Nachbar L, Schneider M *et al.* Prospective comparison of push enteroscopy and push-and-pull enteroscopy in patients with suspected small-bowel bleeding. Am J Gastroenterol 2006;101:2016–24.
14. May A, Nachbar L, Ell C. Push-and-pull enteroscopy using a single-balloon technique for difficult colonoscopy. Endoscopy 2006;38:395–8.
15. Mönkemüller K, Fry LC, Bellutti M *et al.* ERCP using single-balloon instead of double-balloon enteroscopy in patients with Roux-en-Y anastomosis. Endoscopy 2008;40:E19–20.
16. Kav T, Balaban Y, Bayraktar Y. The power suction maneuver in single balloon enteroscopy. Endoscopy 2008;40:961–2.
17. Domagk D, Bretthauer M, Lenz P *et al.* Carbon dioxide insufflation improves intubation depth in double-balloon enteroscopy: a randomized, controlled, double-blind trial. Endoscopy 2007;39:1064–7.
18. Ell C, May A. Mid-gastrointestinal bleeding: capsule endoscopy and push-and-pull enteroscopy give rise to a new medical term. Endoscopy 2006;38:73–5.
19. Ell C, May A, Nachbar L *et al.* Push-and-pull enteroscopy in the small bowel using the double-balloon technique: results of a prospective European multicenter study. Endoscopy 2005;37:613–6.
20. May A, Nachbar L, Ell C. Double-balloon enteroscopy (push-and-pull enteroscopy) of the small bowel: feasibility and diagnostic and therapeutic yield in patients with suspected small bowel disease. Gastrointest Endosc 2005;62:62–70.
21. Heine GD, Hadithi M, Groenen MJ *et al.* Double-balloon enteroscopy: indications, diagnostic yield, and complications in a series of 275 patients with suspected small-bowel disease. Endoscopy 2006;38:42–8.
22. Sun B, Rajan E, Cheng S *et al.* Diagnostic yield and therapeutic impact of double-balloon enteroscopy in a large cohort of patients with obscure gastrointestinal bleeding. Am J Gastroenterol 2006;101:2011–5.
23. Zhong J, Ma T, Zhang C *et al.* A retrospective study of the application on double-balloon enteroscopy in 378 patients with suspected small-bowel diseases. Endoscopy 2007;39:208–15.
24. Matsumoto T, Moriyama T, Esaki M *et al.* Performance of antegrade double-balloon enteroscopy: comparison with push enteroscopy. Gastrointest Endosc 2005;62:392–8.
25. May A, Nachbar L, Schneider M *et al.* Push-and-pull enteroscopy using the double-balloon technique: method of assessing depth of insertion and training of the enteroscopy technique using the Erlangen Endo-Trainer. Endoscopy 2005;37:66–70.
26. Gerson LB, Flodin JT, Miyabayashi K. Balloon-assisted enteroscopy: technology and troubleshooting. Gastrointest Endosc 2008;68:1158–67.
27. Mensink PB, Haringsma J, Kucharzik T *et al.* Complications of double balloon enteroscopy: a multicenter survey. Endoscopy 2007;39:613–5.
28. Möschler O, May AD, Müller MK, *et al.*, DBE-Studiengruppe Deutschland. Complications in double-balloon enteroscopy: results of the German DBE registry; in German. Z Gastroenterol 2008;46:266–70.
29. Mehdizadeh S, Ross A, Gerson L *et al.* What is the learning curve associated with double balloon enteroscopy? Technical details and early experience in 6 US tertiary care centers. Gastrointest Endosc 2006;64:740–50.