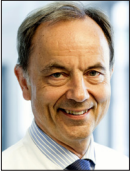


ADVANCES IN ENDOSCOPY

Current Developments in Diagnostic and Therapeutic Endoscopy

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The Potential Role of Motorized Spiral Enteroscopy in Small Bowel Evaluation



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G&H What are the main indications for spiral enteroscopy of the small bowel?

HN The indications for spiral enteroscopy are not different from those for other technologies and methods for enteroscopy. These indications are mainly seen in patients with obscure or overt gastrointestinal (GI) bleeding, and spiral enteroscopy is useful for diagnostic purposes or for therapeutic interventions (Figure). The main indications are presentations suspicious of Crohn's disease, based on other imaging findings (capsule endoscopy or small

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bowel imaging) as well as findings suspicious of small bowel tumors, shown in particular by magnetic resonance enteroclysis or computed tomography scan, for further evaluation or treatment of polyps. In patients with Peutz-Jeghers syndrome, usually with multiple small bowel polyps, spiral enteroscopy may be used for therapeutic intervention and removal of these polyps.

Also, in terms of obscure GI bleeding, for patients who have indeterminate iron deficiency anemia with

normal findings on upper and lower GI endoscopy, usually the recommendation is to perform capsule endoscopy first before spiral enteroscopy. This provides the advantage of having a better, full image of the small bowel. These findings direct the decision whether to approach the small bowel with spiral enteroscopy from the upper side or from the anal side. For example, when patients have obscure GI bleeding and capsule endoscopy shows that angiodysplasias are located only in the upper part of the small bowel in the jejunum, then spiral enteroscopy is done from the oral side. A total enteroscopy is not needed in these cases because capsule endoscopy ruled out the presence of lesions in the distal bowel. This is an advantage of having more information before doing the invasive spiral enteroscopy procedure.

G&H What are the advantages of the motorized spiral endoscope in the examination of the small bowel?

HN There are 2 main advantages. First, when comparing motorized spiral enteroscopy (MSE) with standard technologies, in particular double-balloon or single-balloon enteroscopy, there is no doubt that the learning curve is shorter. Balloon-assisted enteroscopy is quite complex and takes more time to learn. Second, MSE is also faster and may allow for a deeper insertion depth. In evaluating deep parts of the small bowel, to approach the deepest point of interest, MSE is an easier and faster approach. The diagnostic and therapeutic yields are probably comparable, although no prospective randomized controlled trials have compared these 2 techniques.

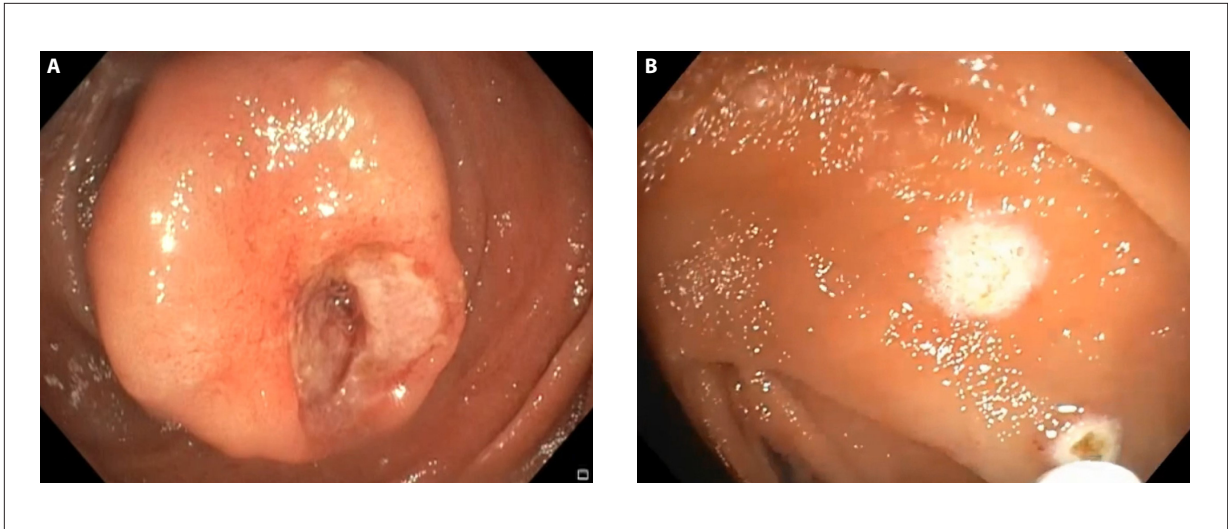


Figure. Views from motorized spiral enteroscopy show a jejunal gastrointestinal stromal tumor with ulceration (A) and argon plasma coagulation of an arteriovenous malformation in the ileum (B).

There are data for tube-based spiral enteroscopy, which has not been motorized. The tube-based procedure is the same concept as the motorized version in that a spiral is mounted on a tube, but the tube must be rotated by a second endoscopist outside of the patient at the proximal end of the endoscope. More than 10,000 procedures have been done with the manually driven tube with an integrated spiral. Comparisons with balloon-assisted enteroscopy show that tube-based spiral enteroscopy is faster. However, there are also no prospective randomized controlled trials of tube-based spiral enteroscopy, and it is more complicated without motorization. The motorization simplifies the procedure.

Another advantage of the motorized technique is that the instrument is like a pediatric colonoscope in that it is only 168-cm long and has a 3.2-mm working channel. This means that accessories used for colonoscopy, for example, can be used for MSE. There is no need for specially designed and modified devices, which is cost saving.

G&H What are the risks of MSE compared with other enteroscopy techniques?

HN The spiral has a relatively large diameter, and although the fins on the spiral are very soft, sometimes mucosal laceration occurs. When the endoscopist passes the upper esophageal sphincter or narrow parts of the small bowel, the spiral endoscope may cause some trauma of the mucosa. These adverse effects are rarely clinically relevant; however, they are probably more frequently seen with MSE than with balloon-assisted enteroscopy. On the other hand, there have been no cases of pancreatitis using

this technique in contrast to balloon-assisted enteroscopy. Perforations may rarely happen. Again, there are no data showing a significant difference in the rate of these adverse effects with MSE. The rate of severe complications is very low at approximately 2% and complies with standards according to European guidelines, which state the rate of complications should be less than 1% for diagnostic procedures and less than 5% for therapeutic interventions. All studies that have been performed so far with MSE have shown that the rate of severe adverse events is below this threshold.

G&H How would you summarize the key data on MSE?

HN When summarizing the data, it is important to note that there is the conventional way of spiral endoscopy, the manually driven tube with an integrated spiral, and MSE (also called power spiral enteroscopy), which is a different technology. The first motorized spiral enteroscopic examination in the world was performed in our department in Germany in November 2015. Shortly after that, my colleagues and I initiated a bicentric feasibility trial. Because MSE is a complex technology, it does take time to provide medical centers with the system. Since 2019, it has been distributed more but so far has been used only in Europe. The system has yet to launch in the United States.

Initially, we performed a feasibility trial in 2 centers in Düsseldorf and in Brussels for evaluation of the diagnostic therapeutic yield of the motorized technique. The trial involved 132 patients with the indications I mentioned earlier. At that time, we excluded patients with previous abdominal surgery or those with altered GI

anatomy. The results were very promising. There was a diagnostic yield of 74%, which is higher compared with any previous studies on balloon-assisted enteroscopy, and the rate of serious adverse events (SAEs) was 1.5%. The mean procedure time was less than 1 hour, with a median time of 45 minutes, which is relatively short for such an intervention with a deep insertion depth. It is always difficult to measure how deep the endoscopist can penetrate the small bowel. We estimated insertion depth to be in a medium level, 450 cm, and deeper probably compared with balloon-assisted enteroscopy. In 11% of these cases, we approached the large bowel, in that we passed the

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ileocecal valve from the antegrade approach, although this was not the primary endpoint. As I said before, when there were indications that bleeding sites were only located in the upper part of the small bowel according to capsule endoscopy, we did not attempt to examine the whole small bowel. In those cases, MSE of the entire small bowel is unnecessary and a risk for the patient.

After that trial, we performed a prospective trial of total spiral enteroscopy in patients in whom there was an indication for evaluation of the whole small bowel. This trial also took place at the same centers; again, patients with previous abdominal surgery were excluded. According to the protocol, an integrated approach was attempted to advance the enteroscope as deep as possible into the small bowel, and when we could not approach the large bowel, then we placed a small tattoo with injection of ink at the deepest point of insertion. On the next day, we performed MSE from the anal side and tried to reach this tattoo. The results showed that in 70% of all cases, a total enteroscopy was achieved. Of those cases, this was achieved in 17% with just the integrated approach and in 53% with a combination integrated and retrograde approach. A trial done in India involving 61 patients and studies done by other institutions have been published showing similar results.

In a large prospective observational multicenter study, the SAMISEN trial, 298 patients from 10 reference centers were evaluated with the motorized technique performed by not only expert endoscopists but also beginners who had limited experience with the

motorized technique (defined as fewer than 20 MSE procedures). The trial included patients without previous abdominal surgery as well as those with previous abdominal surgery (21.5%) and those with altered GI anatomy (10%), which are considered difficult to approach. The beginners underwent a training phase on MSE. The anatomic region of interest could be reached in 88% (250) of 284 procedures. Success meant passing at least the upper part of the small bowel. The diagnostic yield was 84%. This was comparable with our feasibility study results. The overall SAE rate per patient was 2.3%, which complies with standard guidelines. It is important to mention that of the 298 patients, SAEs occurred in 7, of whom 6 underwent therapeutic procedures and only 1 underwent a diagnostic procedure. I think this event rate is acceptable because it is known that complications can occur during treatment with polypectomy or ablation of arterial venous malformations. Interestingly, the SAE rate was a little higher during the training phase at 4.3%.

G&H Has there been further study of MSE in patients with altered GI anatomy?

HN We recently published a retrospective trial on using MSE for endoscopic retrograde cholangiopancreatography (ERCP) and altered GI anatomy in 36 patients. The reconstructed anatomy was from surgeries such as digestive anastomosis, Roux-en-Y, and Billroth II. The intention-to-treat success rate of ERCP with MSE was 72%, and there was only 1 SAE of bleeding after sphincterotomy, thus, not directly related to enteroscopy. For further evaluation of MSE for ERCP, we initiated another registry in Europe, with the aim of enrolling approximately 100 patients in 5 centers. In these 5 experienced centers, all patients who have an altered GI anatomy (ie, previous surgery) undergo ERCP using MSE. So far, more than half of the patients have been enrolled, and we hope to finalize this study in 5 or 6 months.

G&H What is the learning curve for MSE?

HN As I mentioned, the learning curve is relatively short. However, the SAMISEN study showed that there is a higher rate of adverse events in the initial phase during training, and the success rate of therapeutic interventions (eg, removal of a polyp and management of a bleeding site) is lower compared with endoscopists who have more experience after passing the learning curve, but this is not unexpected. As with other technologies, it is strongly recommended that physicians undergo in-person MSE training. Olympus provides a 2-day training course on the technique, which our unit regularly offers. This includes a hands-on model, during which trainees perform 3 or

4 procedures. The trainees are instructed together in the same room, and all the challenges of this technique are explained. Of course, a proctorship with an experienced endoscopist is also recommended. It is not a requirement, but I would recommend having an experienced endoscopist watch the trainee perform his or her first procedure.

G&H Do you see future applications of MSE outside of the small intestine?

HN We performed a feasibility study on use of this technique for colonoscopy in 30 patients. For the transanal approach, the examiner must pass the colon anyway. Of course, the motorized spiral endoscope shortens the colon by pleating. This is the concept of this spiral technique to pleat the bowel onto the tube of the endoscope. The results were good; however, we have no direct comparison with standard colonoscopy. It would be interesting to perform a study just in patients in whom standard colonoscopy failed to see if there is any advantage (eg, to shorten the colon and avoid loop formation). Other studies on using this technique in Crohn's disease in comparison with balloon enteroscopy have been published.

G&H What are the concerns or challenges in performing the technique?

HN It could be a challenge for the endoscopist initially to pass the level of the upper esophageal sphincter. As I have mentioned, the spiral has a relatively large diameter. In order to pass that point, the head of the patient must be overextended, and this must be done very carefully. In addition, at the proximal part of the jejunum, at the ligament of Treitz, is a relatively sharp undulation, and there may be a higher resistance, which I think requires some experience to navigate successfully.

During MSE, when the risk resistance is too high, the motor stops automatically to minimize the risk of traumatization, even perforation. When there are several motor stops, it is better for the endoscopist to discontinue the motorized procedure and change to other

techniques. Thus, MSE is not expected to replace other methods completely.

G&H Is MSE a revolution in small bowel examination?

HN Absolutely. The motorized technique is not only for small bowel enteroscopy, and it is a disruptive technology in endoscopy because it is the first active endoscope. With current endoscopy techniques, the endoscopist has to push and pull the endoscope, whereas with MSE, the endoscopist more or less in some parts holds the endoscope, driving the spiral tube through the bowel as the mucosa cleaves onto the spiral-shaped fins.

Disclosures

Professor Neuhaus has received consultant honoraria and speaker fees from Olympus Medical Systems Corporation.

Suggested Reading

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