# Deep enteroscopy with standard endoscopes using a novel through-the-scope balloon

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**Background and study aims:** A new on-demand enteroscopy (ODE) device has been designed to allow deep enteroscopy using a standard adult colonoscope with the aid of a novel through-the-scope balloon. The aims of the current study were to establish the feasibility, efficacy, and safety of ODE in performing anterograde and retrograde enteroscopy.

**Patients and methods:** A retrospective, single-center study of 28 consecutive deep ODE procedures (11 anterograde and 17 retrograde) was performed. Diagnostic yield, therapeutic yield, technical success, procedure time, depth of maximal insertion (DMI), time to DMI, and adverse events were recorded.

**Results:** The mean diagnostic and therapeutic yields were 45 % and 36 % for anterograde enteroscopy and 59 % and 47 % for retrograde enteroscopy, respectively. Technical success was achieved in 100 %. For anterograde enteroscopy, the mean total procedure time was 24 minutes, with a mean DMI of 1.2 m. For retrograde enteroscopy, the mean total procedure time was 31 minutes, with a mean DMI of 1.1 m. No adverse events were recorded.

**Conclusion:** Deep enteroscopy using a novel through-the-scope balloon and standard endoscope appeared to be feasible and safe, with rapid procedures times.

## Introduction

The three established deep enteroscopy platforms are double-balloon enteroscopy (DBE), single-balloon enteroscopy (SBE), and spiral enteroscopy. All three techniques require specialized equipment and accessories (e.g. enteroscopes, overtubes, pumps etc) [1]. In addition, these deep enteroscopy techniques are time consuming and require dedicated training [2].

A new on-demand enteroscopy (ODE) device (NaviAid AB; Smart Medical Systems Ltd., Ra'anana, Israel), which is a through-the-scope, balloon-assisted enteroscopy device, has recently gained Food and Drug Administration approval and Conformité Européenne certification. The device utilizes a push – pull technique to permit deep enteroscopy by means of a balloon catheter inserted through the working channel of a standard adult colonoscope. The aims of the current study were to assess the diagnostic yield, therapeutic yield, technical success, procedure duration, depth of maximal insertion (DMI), time to reach DMI, and adverse events in patients undergoing ODE.

## Patients and methods

### Study population

A retrospective review was performed of a prospectively maintained database containing all patients who underwent anterograde or retrograde ODE at a single tertiary referral center between March and July 2013.

Adult patients with suspected small-bowel disease not within reach of standard esophagogastroduodenoscopy or colonoscopy were included in this study. Exclusion criteria included prior small- or large-bowel resection, surgery resulting in an altered gastrointestinal anatomy, or deep enteroscopy for endoscopic retrograde cholangiopancreatography (ERCP).

The electronic medical records were reviewed, and patient demographic and clinical data were recorded. The study was approved by the Johns Hopkins Institutional Review Board for Human Research.

### Device

The NaviAid AB ODE device is a single-use balloon catheter (**Fig. 1 a**) supported by inflation – deflation apparatus (**Fig. 1 b**). The latex-free

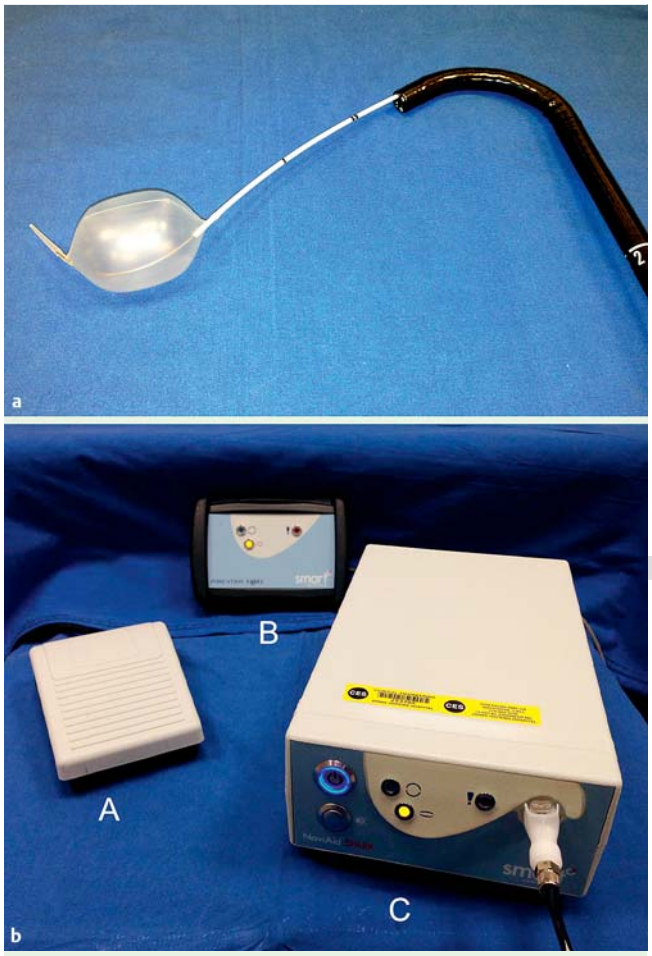


**Fig. 1** The 3.5-m through-the-scope balloon catheter is passed through the working channel of the colonoscope. **a** The balloon can be inflated to a maximum of 40 mm. **b** NaviAid AB set up: (A) foot pedal to inflate or deflate the balloon; (B) indication panel; (C) air supply unit.

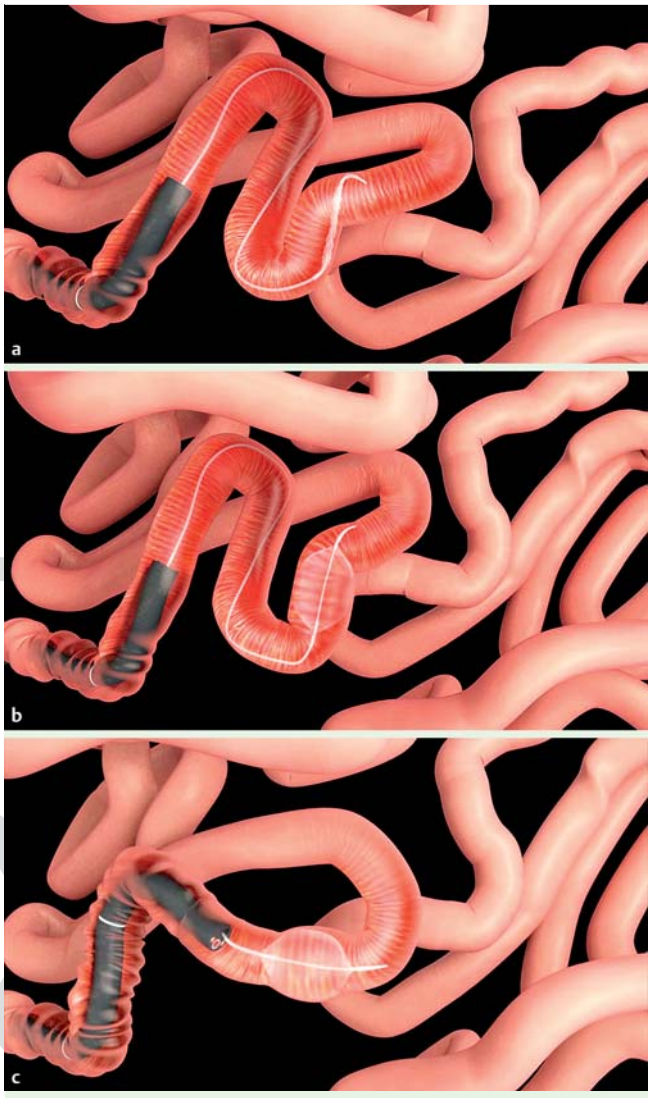


**Fig. 2** Endoscopic procedure. **a** The flexible through-the-scope balloon allows safe insertion ahead of the endoscope without direct visualization. **b** The inflated balloon acts as an anchor in the small bowel. **c** Endoscope advancement to the balloon, with concertina of the small-bowel loops.

balloon catheter requires a working channel diameter of at least 3.7 mm, and has a soft flexible tip allowing it to negotiate bends safely.

## Endoscopic procedure

All procedures were performed by or under the direct supervision of one of two endoscopists (P.I.O and M.A.K) who were experienced in SBE and spiral enteroscopy. Neither endoscopist had previously used the ODE device nor had they undergone any specialized training. An assistant was present to aid with manipulation of the balloon catheter. Carbon dioxide was used for luminal insufflation. Fluoroscopy was not utilized in any case.

The balloon catheter was deployed when the endoscope reached the ligament of Treitz for anterograde enteroscopy, and immediately after intubation of the ileocecal valve (ICV) for retrograde enteroscopy. The balloon catheter was then advanced ahead of the endoscope (**Fig. 2a**). Direct visualization of the catheter tip was commonly lost, and the balloon was inflated at the point where resistance was discerned (**Fig. 2b**). After the balloon had been inflated, the endoscope was pushed forward with simultaneous counter traction provided on the balloon catheter (**Fig. 2c**). Once the endoscope met the balloon, the balloon was deflated and the cycle was repeated (**Video 1**).

The point of maximal insertion was routinely tattooed using a suspension containing carbon particles (Spot; GI Supply, Camp Hill, Pennsylvania, USA). Controlled endoscope withdrawal was performed using a novel technique to facilitate the measurement of the DMI. A single circumferential mark was placed at 5 cm and a double mark at 10 cm from the proximal end of the balloon. Once the DMI was reached, the balloon was inflated immediately

**Video 1**

Demonstration of the on-demand enteroscopy NaviAid AB device, animation of its use, and demonstration of endoscope advancement and controlled withdrawal.

**Online content including video sequences viewable at:** www.thieme-connect.de

| | Anterograde (n = 11)[1] | Retrograde (n = 17)[2] |
|---|---|---|
| Age, mean ± SD, years | 66.0 ± 14.3 | 60.9 ± 16.1 |
| Male sex, n (%) | 6 (54.5) | 4 (23.5) |
| Race, n (%) | | |
| Caucasian | 7 (63.6) | 13 (76.5) |
| African American | 4 (36.4) | 3 (17.6) |
| Other | 0 (0) | 1 (5.9) |
| Indication, n (%) | | |
| Melena | 2 (18.2) | 2 (11.8) |
| Occult gastrointestinal bleeding | 3 (27.3) | 3 (17.7) |
| Iron deficiency anemia | 3 (27.3) | 2 (11.8) |
| Protein losing enteropathy | 1 (9.1) | 1 (5.9) |
| Chronic diarrhea | 1 (9.1) | 4 (23.5) |
| Polyposis screening | 1 (9.1) | 1 (5.9) |
| Stent retrieval | 0 (0) | 1 (5.9) |
| Abnormal CT imaging | 0 (0) | 2 (11.8) |
| Abnormal capsule study | 0 (0) | 1 (5.9) |
| Prior capsule, n (%) | 8 (72.7) | 10 (58.8) |
| Height, mean (m) | 1.7 ± 0.1 | 1.6 ± 0.1 |
| Weight, mean ± SD, kg | 79.8 ± 15.5 | 69.7 ± 17.4 |
| BMI, mean ± SD, kg/m$^2$ | 27.0 ± 5.0 | 25.8 ± 5.0 |
| ASA score, median (IQR) | 3 (2 – 3) | 2 (2 – 3) |

CT, computed tomography; BMI, body mass index; ASA, American Society of Anesthesiologists; IQR, interquartile range.
[1] Number of procedures.
[2] Number of procedures.

**Table 1** Demographic and clinical characteristics of patients in the anterograde and retrograde cohorts.

| | Anterograde (n = 11)[1] | Retrograde (n = 17)[1] |
|---|---|---|
| Technical success, n (%) | 11 (100) | 17 (100) |
| Diagnostic yield, n (%) | 5 (45.5) | 10 (58.8) |
| Therapeutic yield, n (%) | 4 (36.4) | 8 (47.1) |
| Procedure time, mean ± SD, minutes | 24.1 ± 6.4 | 31.4 ± 5.3 |
| DMI, mean ± SD, m | 1.2 ± 0.3 | 1.1 ± 0.3[2] |
| Mean time to DMI, mean ± SD, minutes | 15.1 ± 4.6 | 19.7 ± 4.0[2] |
| Adverse events, n (%) | 0 (0) | 0 (0) |

[1] Number of procedures.
[2] These mean values are calculated for the 15 patients who did not have obstructing lesions identified.

**Table 2** Technical characteristics of anterograde and retrograde procedures.

ahead of the endoscope tip and used as an anchor as the endoscope was withdrawn until the 10 cm mark became visible. The balloon would then be deflated and brought back to the tip of the endoscope and the procedure repeated (▶ **Video 1**). For tattooing, biopsy, and endoscopic therapy, the balloon catheter would be removed to allow passage of accessories, and then reinserted to continue the procedure.

## Outcomes

The diagnostic yield was defined as the proportion of enteroscopies in which clinically significant findings (e.g. angiodysplasia, polyp) were identified or if histopathology yielded a diagnosis. The therapeutic yield was defined as the proportion of enteroscopies in which a therapeutic intervention (e.g. argon plasma coagulation, polypectomy) was undertaken.

Technical success was defined as endoscope advancement > 60 cm beyond the ligament of Treitz for anterograde and > 30 cm beyond the ICV for retrograde procedures [3]. The DMI was measured on withdrawal from the point of maximal insertion to the ligament of Treitz or the ICV. Cases in which the DMI was limited by the presence of pathology (e.g. obstructing lesion) were excluded from calculations of the DMI and the time to reach DMI. Adverse events were graded according to the American Society for Gastrointestinal Endoscopy severity grading system [4].

## Statistical analysis

Descriptive statistics were calculated for all measured variables and derived parameters. The results were tabulated as means and medians, standard deviation, and interquartile ranges for continuous data, and absolute and relative frequencies for categorical data. All statistical analyses were performed using SPSS version 19 (IBM SPSS Statistics, Armonk, New York, USA).

## Results

Over the 5-month period, 23 patients who underwent 28 procedures (11 anterograde, 17 retrograde) were included for analysis. Five patients underwent both anterograde and retrograde enteroscopy. The baseline demographics and clinical characteristics of the study cohort are presented in ▶ **Table 1**.

## Anterograde enteroscopy

The diagnostic yield was 45 % (5/11) and therapeutic interventions were performed in 36 % (4/11) (▶ **Table 2**). The most common diagnosis was angiodysplasia in 27 % (3/11) (▶ **Table 3**). Technical success was achieved in 100 % (11/11). The mean total procedure time was 24.1 ± 6.4 minutes. The mean DMI was 1.2 ± 0.3 m beyond the ligament of Treitz. The mean time to DMI was 15.1 ± 4.6 minutes. There were no procedure-related complica-

**Table 3** Pathology encountered and therapy applied among the patients in the anterograde and retrograde cohorts.

| | Anterograde (n = 11)[1] | Retrograde (n = 17)[1] |
|---|---|---|
| Diagnosis, n (%) | | |
| Angiodysplasia(s) | 3 (27.3) | 4 (23.5) |
| Polyp(s) | 1 (9.1) | 3 (17.6) |
| Migrated stent | 0 (0) | 1 (5.9) |
| Stricture | 0 (0) | 1 (5.9) |
| Non-specific findings | 1 (9.1) | 1 (5.9) |
| Therapy, n (%) | | |
| APC | 3 (27.3) | 3 (17.6) |
| Clipping | 0 (0) | 1 (5.9) |
| Polypectomy | 1 (9.1) | 3 (17.6) |
| Stent retrieval | 0 (0) | 1 (5.9) |

APC, argon plasma coagulation.
[1] Number of procedures.

tions, such as perforation, bleeding, acute pancreatitis or anesthesia-related events.

## Retrograde enteroscopy

The diagnostic yield was 59% (10/17) and therapeutic interventions were performed in 47% (8/17) (**Table 2**). Technical success was achieved in 100% (17/17). The mean total procedure time was 31.4 ± 5.3 minutes. Two patients had obstructing lesions identified (Crohn's-related inflammatory stricture and migrated enteral stent) (**Table 3**). The mean DMI in the remaining 15 patients was 1.1 ± 0.3 m beyond the ICV. The mean time to DMI was 19.7 ± 4.0 minutes. There were no procedure-related complications, such as perforation, bleeding, or anesthesia-related events. Endoscopic visualization of the entire small bowel was not accomplished in any of the five patients who underwent both anterograde and retrograde enteroscopy.

## Discussion

This is the first reported experience of the ODE device, which enables deep enteroscopy without the need for specialized endoscopes and processors. Technical success was achieved in 100%, which compares favorably with retrograde enteroscopy using DBE, which has a failure rate of up to 21% in Western populations, primarily due to the inability to advance into the terminal ileum [5]. The use of a colonoscope for ileal entry (compared with the more flaccid enteroscope), and the absence of an overtube, probably simplify intubation of the ICV.

The diagnostic yield of ODE was similar to published rates of 40% – 75% for anterograde [3,6 – 13] and 25% – 56% for retrograde enteroscopy [8,9,11,13]. The therapeutic yield was also similar to published rates of 40% – 73% for anterograde [3,6 – 13] and 8% – 41% for retrograde enteroscopy [8,9,11,13]. For each therapeutic intervention, the balloon catheter was exchanged for an accessory, with endoscope stability being maintained without loss of position. This stability, even when the balloon catheter was not functioning as an anchor, allowed the endoscope to advance and withdraw efficiently without slippage.

The DMI is often used as a performance measure when evaluating an enteroscopy platform. Commonly used methods of calculating the DMI are counting folds or estimating 10-cm increments on endoscope withdrawal [3,14]. In the current study, a novel method of calculating the DMI was adopted by using a marker to measure the distance withdrawn. Our method could not be validated as no patient had subsequent surgical therapy.

Insertion was rapid for anterograde procedures, although the DMI was considerably less compared with the other established deep enteroscopy techniques. For example, SBE and spiral enteroscopy have a mean DMI of approximately 2.0 and 2.4 meters, respectively [3,6 – 13]. However, when comparing ODE using NaviAid AB with a similar device reported by Adler et al., the current results are not disparate with their mean depth of insertion of 1.5 meters [15]. It is possible that the absence of the overtube results in increased looping of the endoscope in the stomach.

For retrograde procedures, the mean DMI in this study appeared to be slightly deeper than SBE and spiral enteroscopy studies, where the depths of insertion range from 0.7 to 1.0 meters [8,9, 11,13]. However, the DMI appeared equivalent to that reported in the DBE literature (0.7 – 1.3 meters), making ODE a suitable platform for retrograde enteroscopy [3,16,17].

The mean procedure times for ODE were substantially faster than other deep enteroscopy techniques, which have times ranging from 47 to 76 minutes for anterograde [3,6 – 13] and 55 to 111 minutes for retrograde procedures [5,13,15,17,18]. Reasons for this may include the simplicity of a single-balloon cycle, the shorter DMI achieved during anterograde enteroscopy, and the use of the adult colonoscope for traversing the colon and intubating the terminal ileum. These rapid procedure times may even permit both anterograde and retrograde enteroscopy under the same anesthetic, although we believe that complete endoscopic visualization of the entire small bowel is unlikely to be achieved using this platform alone (primarily due to the shorter DMI attained during anterograde enteroscopy).

There were no adverse events encountered during the study. The balloon catheter did not cause mucosal injury or perforation, despite often being advanced without direct vision. This is likely to be due to the soft, flexible nature of the balloon catheter. Indeed, the first case report of this device demonstrated the safety of advancement without direct vision in a patient with multiple large small-bowel diverticula [19].

Novel applications of ODE (3.7-mm working channel) over the current deep enteroscopy techniques (2.8-mm working channel) may include placement of self-expandable metal stents for the relief of enteral obstruction, or biliary obstruction in the setting of ERCP for altered anatomy. Second, ODE can be used in an on-demand manner, allowing its use if an unexpected finding were to be noted during standard endoscopy, obviating the need to return for a second procedure.

There are several limitations to this study. First, it was a retrospective study with a limited sample size. However, data were collected prospectively among all consecutive patients who underwent ODE. Second, selection bias may have occurred, as other deep enteroscopy techniques (SBE and spiral enteroscopy) were available at the institution.

In conclusion, this is the first study to describe the clinical utility and safety of ODE using the NaviAid AB device. The results suggest that ODE may be an effective, rapid, and safe method of performing deep enteroscopy using a standard adult colonoscope. Future multicenter, randomized, comparative studies in both tertiary and community hospital settings are required to validate this novel platform.

**Competing interests:** Dr. Singh is a Consultant for Abbvie, D-Pharm, Santarus, and Boston Scientific. Mouen A. Khashab is a consultant for Boston Scientific and Olympus America and has

received research support from Cook Medical. Payal Saxena has received consulting fees from Boston Scientific and has received research support from Cook Medical. Anne Marie Lennon is a consultant for Boston Scientific

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