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Transanal hybrid colon resection: from laparoscopy to NOTES

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Abstract
Background Reducing access size and trauma are important issues in natural orifice transluminal endoscopic surgery (NOTES). The combination of experience with laparoscopic colorectal surgery and transanal endoscopic microsurgery has helped in the use of the transanal approach as a realistic option of NOTES techniques to introduce transanal hybrid laparoscopic-assisted colon resection into clinical practice. The purpose of this study was to assess the clinical introduction of transanal hybrid colon resection in terms of feasibility and patient safety.
Methods Patients with pelvic floor disorders, prolapse, and slow-transit constipation in whom a colon resection was indicated were recruited. Patients were followed prospectively with a postoperative well-being score, a pain score, and a quality-of-life score. All complications were prospectively documented. The essential change was the reduction of the number and size of ports by using the transanal route. A camera and two 5-mm ports for grasping forceps and delivering ultrasonic energy were the laparoscopic components. All tasks requiring a port diameter of >5 mm were applied via the transanal route, such as positioning of the proximal stapler anvil, application of linear stapling for resection, specimen retrieval, stapler anastomosis, and closing the bowel.
Results Fifteen patients with benign colorectal disease underwent transanal hybrid colon resection, and 11 had additional rectopexy. All patients were women with a mean age of 61 (range, 28–86) years and a body mass index of 26 kg/m^2. One patient was converted to full laparoscopy. One complication—bleeding that required no reintervention—was recorded. The procedure lasted a mean of 131 (range, 55–184) min. The Gastrointestinal Quality of Life Index was 96 before surgery and 117 after surgery.
Conclusions From this initial experience, transanal hybrid colon resection seems a feasible and safe hybrid NOTES procedure that can be usefully introduced into clinical practice.

Keywords Laparoscopic colorectal surgery · NOTES colorectal surgery · Rectopexy · Transanal hybrid sigmoid resection · Transanal hybrid subtotal colectomy

Natural orifice transluminal endoscopic surgery (NOTES) has stimulated centers around the world to assess various possibilities to transform this new idea from the experimental setting into clinical practice [1]. Experimental technical feasibility has been determined for several indications, including cholecystectomy and bowel resection. In patients, the transvaginal approach has been used most frequently in the past, usually for transvaginal cholecystectomy [2]. Initial experimental experience has been gathered with transvaginal and transanal colorectal procedures [3–7]. Worldwide, very few centers have begun applying this technique in patients; when performed, it is mostly for transanal rectal resection [8, 9].

These techniques are developed from the experience with transanal endoscopic microsurgery (TEM), which was introduced three decades ago [10]. Extensive experimental

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training and studies regarding the transanal route for colorectal resections, as well as the first clinical reports, stimulated our team to explore and gather experimental experience [3–9]. On the basis of our previous experimental training of transgastric, transvaginal, and transanal NOTES procedures such as cholecystectomy, cardiomyotomy, and bowel resection [11, 12], and on the basis of our clinical experience with TEM operations, we focused on evaluating the transanal hybrid NOTES approach for colorectal surgery. We sought to find how this transanal hybrid NOTES technique could be introduced safely into clinical practice. Because pure NOTES procedures are currently not particularly feasible because of the lack of adequate instruments and endoscopes, hybrid NOTES procedures could provide the necessary bridge between traditional laparoscopic techniques and NOTES procedures.

The purpose of this study was to evaluate the clinical feasibility of transforming laparoscopic sigmoid resection into a transanal hybrid technique with the aim of minimizing access trauma by using the natural orifice of the anus and by reducing the size and number of ports.

Methods

Modified technical concept

The principle of NOTES is to use a natural orifice as an entry port into the abdominal cavity and to prevent additional access trauma through the abdominal wall. Because endoscopic technology is not available to perform complex operations such as a colon resection inside the abdomen exclusively via a natural orifice such as the mouth or the anus, a hybrid solution has emerged. This hybrid technique uses the natural orifice for instruments and tasks that need a larger diameter of access (>5 mm) to the abdominal cavity; the technique also allows for a laparoscopic assistance via small-size ports to avoid access trauma and morbidity.

Patients

Patients were recruited from referred cases for surgical therapy of pelvic floor and colorectal benign disorders in whom a colon resection was indicated. The protocol was approved by the hospital review board after appropriate preparation. For this prospective pilot study, all patients were included who gave informed consent for these indications to undergo this new minimally invasive surgical procedure and who were more than 18 years old. The patients were informed by the investigators in detail, and sufficient time was provided to allow for reflection and questions. Patients with limitations in understanding the information were excluded from this study, as were patients with acute sigmoid diverticulitis and possible penetration and/or perforation.

Extensive preoperative diagnostic assessment was performed in all cases of benign functional disease such as slow-transit constipation and pelvic floor disorders with rectal prolapse. All necessary investigations (Hinton test, anorectal manometry, proctologic investigations, rectoscopy, colonoscopy) were performed in our specialized gastrointestinal and colorectal function laboratory. Dynamic magnetic resonance imaging defecography was performed by the department of radiology.

The indication in these patients was obstructed defecation due to an internal intussusception of rectum, often in combination with sigmoid kinking and adhesions; full external rectal prolapse; or therapy-refractory slow-transit constipation. Therefore, a sigmoid resection combined with a rectopexy was necessary in the prolapse patients, and a subtotal colectomy with ileosigmoidostomy was indicated in patients with slow-transit constipation. Care was taken to extensively evaluate the patients before surgery for optimal preparation and selection.

The patients underwent a preoperative bowel preparation in order to have a clean bowel during the operation, when intraabdominal opening and manipulation of the bowel were necessary. Before surgery, prophylactic intravenous antibiotics (cephalosporin and metronidazole) were provided. General anesthesia was administered, and the patient was placed supine for the operation.

Before the pilot study, the team surgeons underwent extensive experimental training in several NOTES techniques involving transgastric, transvaginal, and transanal procedures. In addition, the team members had extensive experience with both open and laparoscopic gastrointestinal and colorectal surgery, interventional flexible endoscopy, and TEM.

Technique of transanal hybrid colon resection

After establishing a capnoperitoneum via a Veress needle and after necessary safety tests, a periumbilical port was introduced in the abdominal cavity. Two additional 5-mm ports were brought in the right lower quadrant for dissection of the colon and rectum (Fig. 1). The dissection of the anastomotic site, all necessary hemostasis, and energy delivery via the SonoSurg system (Olympus Holding Europe, Hamburg, Germany) were applied via these ports. The dissection of the mesentery was performed in a stepwise manner under careful laparoscopic control to ensure that the pelvic nerve plexus was not in danger and that the dissection planes could be followed.

In cases of sigmoid resection for prolapse surgery, the colon–lumen was clamped at the level of the descending

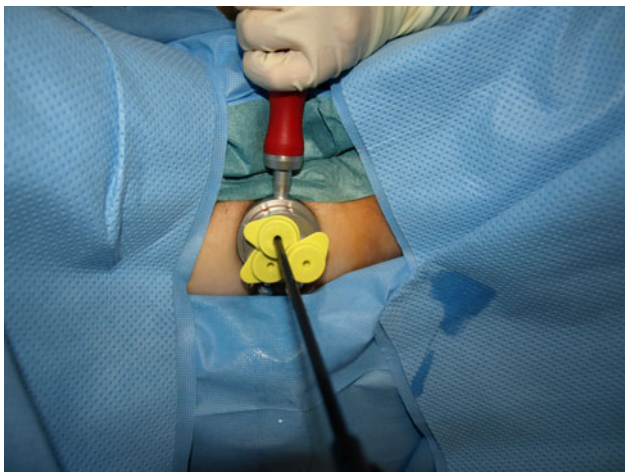

Fig. 1 Operative site with three ports in the lower part of the abdomen

Fig. 2 Transanal endoscopic applicator during transanal maneuvers

segment, and a sigmoidoscopy was performed to make sure that this bowel segment was clean, which was ensured by rinsing the rectum and colon. After removing the scope, bougies of size 25, 28, and 33 were introduced into the anus, rectum, and sigmoid colon. A careful bougienage of the rectum facilitates the following maneuvers. The next step was the transanal introduction of a transanal endoscopic applicator (TEA), which allows for safe introduction of endoscopes, linear staplers, and grasping devices, and also permits specimen removal (Fig. 2). Then the anvil of a 28-mm circular stapler was introduced into the TEA and rectum with a special grasper and maneuvered more proximally up to the descending colon to the future anastomotic site (Fig. 3).

This was followed by an incision of the colon—usually the distal sigmoid—at the distal anastomotic site. Here, a transanally introduced linear stapler could exit the colon into the abdominal cavity and was used to transect the

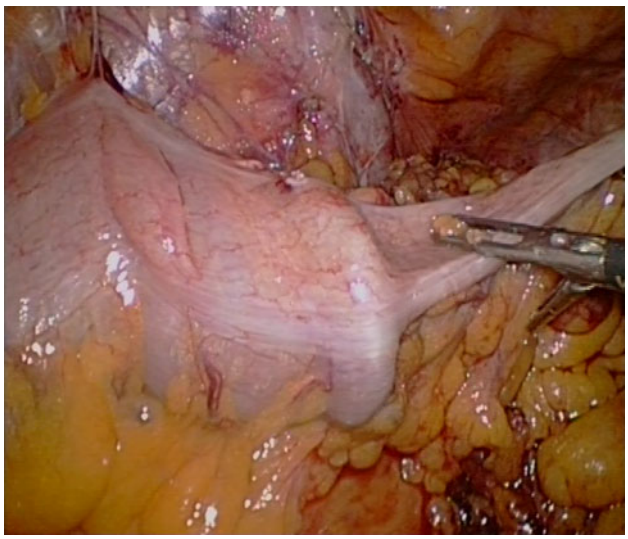

Fig. 3 The anvil of the circular stapler is advanced transanally toward the proximal anastomotic site

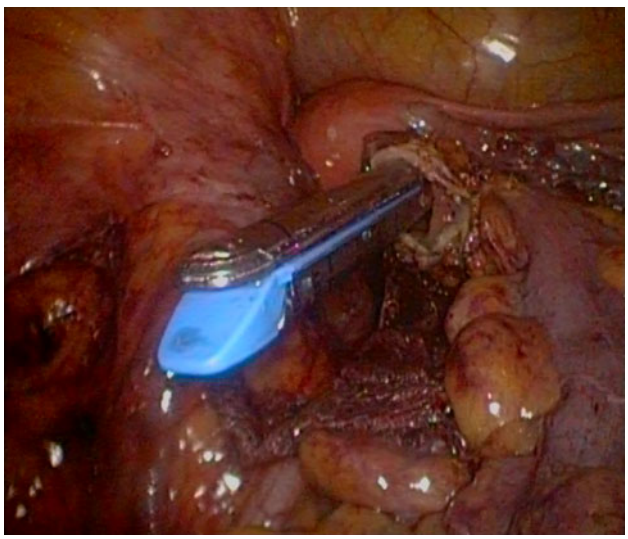

Fig. 4 The sigmoid colon is opened and the linear stapling device is advanced transcolonic into the abdominal cavity

proximal end of the sigmoid segment, which needed to be removed for shortening the colon (Fig. 4). Via the transanal position, it was possible to deploy the TEA instruments and to apply, remove, and change the stapling cartridges (Fig. 5). At the proximal colon stump, the intraluminal anvil was grasped through the bowel wall and stabilized. The central pin of the anvil was penetrated through the bowel wall at the stapled line to be available for later anastomosis. The penetration of the pin was facilitated by creating a small hole at the stapled line with the ultrasound cutting device.

Once the sigmoid segment was resected and free of detachments, a grasper was advanced via the TEA to reach for

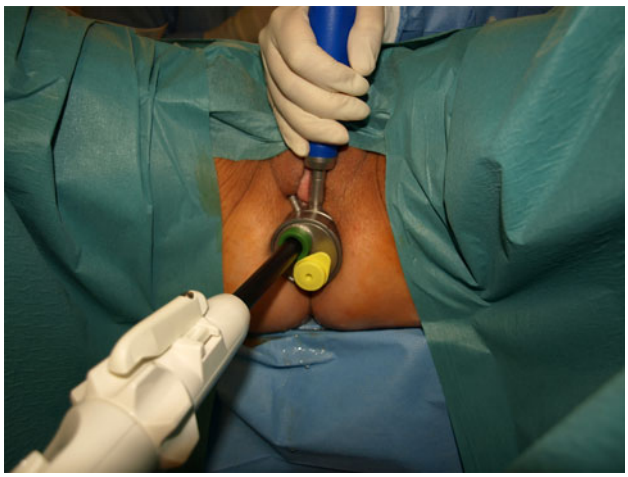

Fig. 5 The linear stapler is positioned in the abdominal cavity via the transanal route

the specimen in the abdomen. Then the specimen was pulled through the luminal opening at the distal rectosigmoid stump via the rectal lumen and via the TEA transanally to the outside.

After transanal removal of the specimen, a purse-string suture was placed at the distal rectosigmoid stump to complete the anastomosis with the circular stapling device. The TEA was removed, and a circular stapler was inserted transanally and advanced to the distal rectosigmoid opening, carrying the purse-string suture. The central pin was opened, and the purse-string suture was tied down around the central pin. The anvil was connected to the stapler, followed by approximating and firing the device in the usual manner under laparoscopic visual control. Thus, the actual anastomosis could be performed under the same optimal conditions that laparoscopic surgery can provide.

In cases of rectal prolapse, a rectopexy was added in the usual technique with nonabsorbable sutures between peritoneal, pararectal tissue, and the sacral bone at the promontorium using 5-mm ports, straight needles, and mini instruments.

In cases of slow-transit constipation, a subtotal colon resection was performed by dissecting and severing the complete colon mesentery with the 5-mm SonoSurg device, usually via two 5-mm ports, occasionally assisted by another 3-mm grasper without trocar. The ileum and the sigmoid colon were transected via a transanal linear stapler. Then the complete colon was removed transanally. The anvil was advanced transanally to the distal ileum and inserted into the lumen, followed by penetration of the central pin through the antimesenteric ileal wall for later anastomosis. The ileum was closed via a transanal linear stapler. The tissue remnant was removed transanally. The ileosigmoidostomy was performed in a similar manner as that described above. After control of hemostasis, inspection of the anastomosis, leak test with air and water, and placement of drainage, the procedure was finished by removal of the three ports.

The patients were provided a standardized postoperative pain medication program consisting of metamizol 4 g per day and additional piritramide 15 mg up to four times a day. The patients could drink water and tea on the evening of the operation and were given fluids, including protein drinks, the first few days after surgery. Usually on the third postoperative day, enteral feeding started with soup, semisolid food, and, if well tolerated, solid food.

Data management

All data were prospectively documented. All intraoperative problems and postoperative complications were recorded so the safety of the technique could be assessed. We also assessed the feasibility of the different steps by recording the conversions to more trocars. Assessments of learning curve and proficiency gain were also important; we monitored these by recording the intraoperative handling problems of the surgeons/endoscopists and the duration of the operations.

We took special care to record the postoperative condition of the patients, such as pain assessment (visual analog scale of 0–10 with daily measurements, with 0 = no pain and 10 = maximum pain), differentiating in score assessment at rest and during body activity. This scale is used daily in our clinical routine, following our policy of a pain-free hospital according to the Quality Care Management Criteria for Certification in German hospitals. Prospective documentation and assessment of consumption of pain medication were performed.

In addition, all postoperative symptoms were documented daily by means of a well-being score (Table 1), evaluating the eight most frequent postoperative symptoms by a previously published questionnaire [13]. All data were monitored by a study nurse and coordinator.

All patients underwent preoperative and postoperative assessment of quality of life, which was evaluated by the Gastrointestinal Quality of Life Index (GIQLI) [14].

Statistical analysis

Proportions were compared by the Chi-square test or Fisher's exact test, as appropriate. A p value of ≤ 0.05 was considered statistically significant.

Results

Patient characteristics

Fifteen patients entered this pilot study on transanal hybrid colon resections. The median age of these patients was 61

Table 1 Symptom analog scale for postoperative assessment of patient well-being

Item	Scale					
	0	1	2	3	4	5
Belly pain	0	1	2	3	4	5
Bloating	0	1	2	3	4	5
Belching	0	1	2	3	4	5
Fullness	0	1	2	3	4	5
Nausea	0	1	2	3	4	5
Vomiting	0	1	2	3	4	5
Pain during defecation	0	1	2	3	4	5
Fear	0	1	2	3	4	5
Other	0	1	2	3	4	5
Sum						

Summarized in an evaluation form for daily assessment (per day: minimum = 0; maximum = 45). From [13]

(range, 28–86) years. Body weight was a median of 78 kg, and median body mass index was 26 kg/m^2. The patients were all women and had an American Society of Anesthesiology (ASA) classification score of I or II, with the exception of one patient, who had an ASA score of III as a result of previous cardial disease.

The indication for surgery was in two cases a recurrent sigmoid diverticulitis after multiple inflammatory episodes, in seven cases an external rectal prolapse, in four patients an internal rectal intussusception with pelvic obstruction, and in two patients severe slow-transit constipation.

Intraoperative course

The transanal hybrid procedures could be performed as planned in all but one patient after diverticulitis. In this patient, a conversion to a full laparoscopic approach was necessary, including a minilaparotomy to remove the specimen. The bulky sigmoid inflammatory tumor was too large to risk the transanal passage.

There were no intraoperative complications; however, there were a few handling problems, which were solved by additional instruments. In four patients, an additional 3-mm grasper without a port was necessary to assist the procedure, one in a subtotal colectomy in the left upper quadrant and the others in the prolapse patients in the left lower quadrant. In these patients, the smooth pulling through of the specimen through the open distal sigmoid colon opening was not possible without having a third grasper to keep the lumen wide open for the passage.

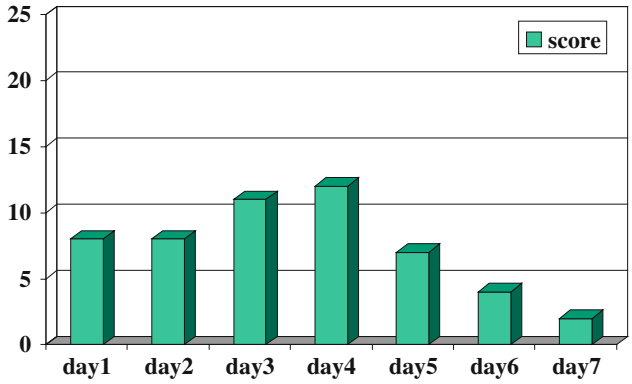

Fig. 6 Postoperative development of the well-being score of the patients

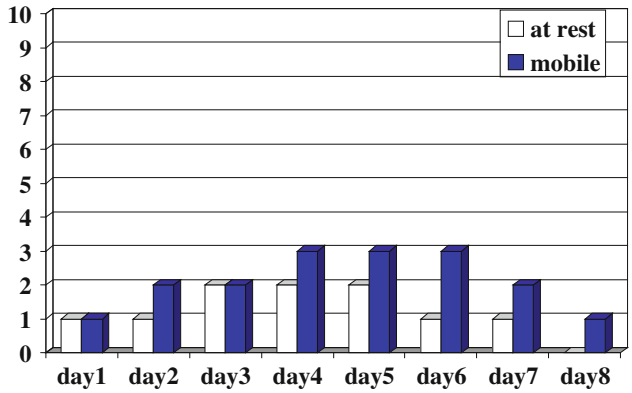

Fig. 7 Postoperative development of patient pain score

Postoperative course

The postoperative course in all patients was uneventful, with the exception of two patients, both of whom underwent transanal hybrid resection rectopexy. One patient experienced postoperative ileus for 4 days before conservative treatment became effective and the situation resolved. Another patient experienced postoperative intra-abdominal bleeding on the first postoperative day and required a transfusion, but there was no need for repeat intervention.

In this preliminary series, the postoperative well-being score, which characterized the patients' usual symptoms, was favorable (Fig. 6). In addition, the daily pain score of these patients showed marked improvement after a few days (Fig. 7). Patients required analgesic pain medication the first few days after surgery, but the amounts required were reduced after the third postoperative day. Usually patient complaints of pain were low in the first 2 days, then increased on postoperative days 3 and 4, only to decrease again after postoperative day 5. With the exception of two patients, all were dismissed after 10 days in the hospital. The length of hospital stay often depended on the national

reimbursement system as well as on the individual hospital policy. Patients entering our pilot study, with its application of innovative procedures, were kept under hospital observation longer than usual for safety reasons.

The patients were assessed at an office visit within 2 weeks after they were released from the hospital. No further complications occurred. After 6 months, the patients were contacted so we could evaluate their quality of life. The preoperative GIQLI evaluation was a median of 96 (range, 78–112). At 6 months after surgery, the median GIQLI score was 117 (range, 110–131). This difference was statistically significant ($p < 0.05$). None of the patients experienced any functional problems due to the application of bougies or TEA.

As a consequence of our positive findings, the method was successfully introduced in our clinical practice, although further comparative studies are necessary.

Discussion

Marked improvements were made in postoperative convalescence by the introduction of minimal-access surgery, when large abdominal incisions were avoided. However, laparoscopic operations may also require port sizes of 10–15 mm for stapler applications and minilaparotomies for removal of specimens. This can cause wound problems, as well as hernias in up to 22 % of patients [15–17].

The central idea of the NOTES concept is the complete avoidance of access trauma at the abdominal wall by using natural orifices for the approach to the abdominal cavity. Both experimental and clinical experience have shown that complex operative techniques are difficult, if not impossible, with current flexible endoscopes, and multitasking platforms are not yet available [18, 19]. As a consequence, successful hybrid NOTES techniques, which use some assistance from laparoscopic techniques such as energy delivery, camera control view, and triangulation by an assisting grasper, have been applied in the past few years [2, 12, 20–22].

After adequate experimental training, we explored the possibility of transforming current laparoscopic standard colectomy procedures, such as sigmoid resection and subtotal colectomy, into transanal hybrid NOTES procedures. As a prerequisite, this process must be a safe, stepwise transformation from a current laparoscopic procedure, with four ports and a minilaparotomy for specimen retrieval, to a transanal hybrid NOTES procedure, with fewer ports and no incision for specimen retrieval. Via the transanal approach, we could use our experience with transanal endoscopic procedures with an operative rectoscope for this purpose, our experience with laparoscopic advanced colorectal surgery, and our experience in flexible endoscopy. The commercially available operative rectoscopes for TEM have a diameter of 4 cm, which may create some functional problems after the operation [10, 23]. With the introduction of transanal hybrid colon resections, long-term anorectal functional problems would not be acceptable. We thus developed a special TEA with a smaller diameter of 3 cm; we do not expect anorectal functional problems to result from its use. A 33 bougie is the most frequently used in colorectal surgery for stapling with an absolute minimum number of adverse effects for functional problems. Thus, we chose a diameter of 30 mm for the TEA to be in the safe range. None of the patients developed more severe postoperative functional defects, especially regarding incontinence.

NOTES and hybrid NOTES approaches have been reported in the literature for colorectal surgery [3–5, 8, 9]. Leroy et al. [5] have performed early experimental work with bowel resections. We gathered experience with transgastric small bowel resections, both with hybrid techniques and with a prototype of a multitasking platform [19]. The important idea came from authors who reported their initial experimental work on transanal techniques when operating in the abdomen [3, 4, 8, 9]. Their experience demonstrated that the transanal approach to dissect the rectum and further up into the abdominal cavity is possible and safe. If pure NOTES is required, the transanal approach is feasible, but it is quite difficult to advance into the upper abdomen purely by transanal instrumentation and manipulation. In this case, long instruments, solutions for triangulation, and more complex devices are necessary.

However, if one combines the advantages of the transanal route (reduced diameter and easy access to the pelvis with longer devices) with the advantages of laparoscopy (excellent overview from transumbilical camera position, excellent maneuverability and triangulation from 3- and 5-mm graspers, good exposure for 5-mm energy devices), the result is a true hybrid NOTES, with the advantages of both.

Morbidity related to the use of 5-mm ports is minimal, and that of 3-mm ports is negligible [15–17]. The use of any ports at all violates the spirit of NOTES, but the above-described compromise fulfills the criteria of NOTES to a high degree. If the transanal orifice approach can be used for all tools with a diameter of >5 mm and in addition the actual opening in the bowel for transanal intraabdominal access can be later used for anastomosis, an ideal compromise is achieved. With the current available instruments, this is an applicable and safe solution.

Possible benefits of this hybrid NOTES technique compared to traditional laparoscopic colectomies are fewer wound infection problems, less frequent hernias, and possibly quicker recovery for daily activities. However, this remains to be conclusively demonstrated in comparative studies.

The necessary technical steps to perform this procedure are quite easy and are not a major problem for an experienced laparoscopic surgeon, indicating that this hybrid NOTES procedure does not require a long learning curve or the acquisition of new, specialized skills.

Conclusion

From our initial experience, transanal hybrid colon resection seems to be a feasible and safe hybrid NOTES procedure that can be introduced into clinical practice. On the one hand, the good quality of laparoscopic overview, the delivery of energy for safe dissection, and the advantages of instrument triangulation can be used; on the other hand, abdominal access trauma is limited to maximum 5-mm ports with low probability of subsequent morbidity by using a natural orifice via the transanal route for all other manipulations requiring an access larger than 5 mm, such as deploying devices like staplers and endoscopes and performing procedures like specimen retrieval.

Disclosures Karl Hermann Fuchs is consultant to Olympus Europe Holding Hamburg. Karl-Hermann Fuchs, Wolfram Breithaupt, Gabor Varga, Thomas Schulz, and Alexander Reinisch have no conflicts of interest or financial ties to disclose.

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