

# NOTES transanal rectal cancer resection using transanal endoscopic microsurgery and laparoscopic assistance

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## Abstract

**Background** The feasibility and safety of Natural Orifice Transluminal Endoscopic Surgery (NOTES) transanal endoscopic rectosigmoid resection using transanal endoscopic microsurgery (TEM) was previously demonstrated in human cadavers and a porcine survival model. We report the first clinical case of a NOTES transanal resection for rectal cancer using TEM and laparoscopic assistance, performed by a team of surgeons from Barcelona and Boston with extensive experience with NOTES and minimally invasive approaches to colorectal diseases.

**Methods** Transanal endoscopic rectal resection with total mesorectal excision using the TEM platform was performed in a 76-year-old woman with a T2N2 rectal cancer treated with preoperative chemoradiation. Laparoscopic visualization and assistance with retraction and exposure during rectosigmoid mobilization was provided through one 5-mm port, which was later used as the stoma site, and 2-mm needle ports, one of which was used as a drain site. The specimen was transected transanally followed by handsewn coloanal anastomosis.

**Results** The procedure was completed successfully with an operative time of 4 hours and 30 minutes. Mesorectal excision was complete. The postoperative course was

uneventful, and the patient was discharged on the fourth postoperative day. The final pathology demonstrated pT1N0 with 23 negative lymph nodes and negative proximal, distal, and radial margins.

**Conclusions** NOTES transanal endoscopic rectosigmoid resection using TEM and laparoscopic assistance is feasible and safe. Careful patient selection and improvement in NOTES instrumentation are critical to optimize this approach before widespread clinical application.

**Keywords** Natural Orifice Transluminal Endoscopic Surgery · Transanal endoscopic microsurgery · Transanal · Rectal cancer

Since the report of the first human incisionless transgastric endoscopic appendectomy in 2005 [1], NOTES has been anticipated to represent the next step in the evolution of minimally invasive surgery. There are a number of potential benefits to using NOTES compared with traditional surgical techniques, which are associated with the integrity of the abdominal wall. However, NOTES shares the potential for many of the complications associated with laparoscopic surgery, all them related with technical limitations [2].

Marescaux et al. described the first clinical report of hybrid NOTES transvaginal cholecystectomy in 2007 [3]. Since then, transvaginal access has become the preferred route for NOTES procedures with the international experience now numbering several hundred cases performed, including cholecystectomy, nephrectomy, sleeve gastrectomy, and segmental colon resection [4–9]. The major limitation of the approach is that it can only be performed in women. Relative to other types of transluminal access, transrectal and transcolonic NOTES have been described in few reports, mainly due to concerns related to fecal

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contamination of the abdominal cavity. There are specific theoretical advantages of the transcolonic approach: upper abdominal intervention allows for en-face visualization; colorectum is much more compliant than upper gastrointestinal tract and an adequate colotomy closure can be achieved. Recent reports have described transcolonic procedures, including peritoneoscopy, cholecystectomy, ventral hernia repair, and distal pancreatectomy in survival swine models with minimal septic complications [10–13]. However, different studies have shown an increased risk of infection in the transcolonic access site [12], and different groups are investigating for a safe and sterile colonic access for NOTES [14].

One of the major advantages of transanal NOTES is the availability of transanal endoscopic microsurgery (TEM) as a stable endoscopic platform. TEM was designed more than 20 years ago to perform endoscopic full-thickness excision of mid to high rectal lesions not amenable to standard colonoscopic or transanal resection. Mucosal or full-thickness excision of mid and high rectal lesions can be performed followed by closure of the defect using adapted suturing devices. TEM represents an attractive minimally invasive alternative to more radical resections of benign and carefully selected malignant rectal lesions. Clinical reports have demonstrated a conversion to open surgery rate of <1% with a complication rate within 4–28%; the TEM complication rate is still far lower than the approximately 50% rate reported with radical excision [15–17]. Even for cases in which full-thickness resection above the peritoneal reflection results in peritoneal entry, no significant increases in infectious complications were noted, granted adequate closure of the colotomy was accomplished [17–19]. This supports the concept that purposeful entry into the peritoneal cavity using NOTES procedures via the anus, rectum, and colon might be safe.

One particularly attractive target for NOTES transanal procedures is rectosigmoid resection. Laparoscopic colorectal resections, through the use of smaller abdominal incisions relative to open surgery, have been associated with decreased incisional pain, reduced length of hospital stay, and faster return to work. However, sizeable abdominal incisions are still required to insert laparoscopic equipment and to exteriorize specimens. These incisions are associated with substantial infectious and bleeding complications, incisional pain, and long-term risks of hernia formation. On the other hand, NOTES transanal rectosigmoid resection using TEM offers the potential of performing transluminal colorectal resections through significantly smaller, or without, abdominal incisions.

The clinical report presented here was preceded by extensive laboratory experience with NOTES transanal rectosigmoid resection in swine and human cadavers. After the first report of transanal sigmoid resection in three

human cadavers by Whiteford et al. [19], our group subsequently demonstrated the feasibility of NOTES transanal endoscopic rectosigmoid resection using TEM in a swine cadaver model with or without transgastric endoscopic assistance [20], as well as the safety of this approach in a swine survival model [21]. The same technique was successfully replicated in human cadavers using commercially available TEM, with endoscopic and laparoscopic instrumentation. In a series of male and female cadavers, we found that this approach was not only feasible, but most importantly, that complete rectal dissection with total mesorectal excision could be performed transanally [20]. As in the swine model, combining transgastric and/or transanal endoscopic assistance through flexible endoscopes during transanal procedures can help overcome technical limitations, preventing more proximal colon mobilization, which include difficulties with endoscopic visualization, tissue retraction, and limitations in specialized instrumentation (unpublished data).

### Surgical technique

The procedure was performed at the Hospital Clinic of Barcelona, Spain, by a team of colorectal surgeons from Barcelona and Boston, MA, USA, with clinical expertise in minimally invasive approaches to colon and rectal cancer and extensive experience with NOTES in swine and human cadavers. In an effort to avoid potential complications related to transgastric endoscopic access and closure, clinical application of NOTES transanal rectosigmoid resection using TEM included transabdominal laparoscopic assistance for visualization, dissection, and retraction as needed during transanal endoscopic dissection. Institutional review board approval at the Hospital Clinic of Barcelona was obtained to perform the first human case of NOTES transanal endoscopic rectal cancer resection with total mesorectal excision using TEM, under laparoscopic visualization, with or without laparoscopic assistance.

### Clinical description

The patient was a 76-year-old woman with a body mass index (BMI) of 20 kg/m<sup>2</sup> and no significant past medical history, who was found to have a rectal mass approximately 8 cm from the anal verge on screening colonoscopy. The patient's previous surgical history included two femoral hernia repairs and no other abdominal or pelvic surgery. Biopsies demonstrated a moderately differentiated adenocarcinoma. On rigid sigmoidoscopy, the lesion consisted of a 3-cm mobile sessile mass located on the anterior rectal wall and located 6 cm from the anal verge. Preoperative workup included a staging pelvic MRI that showed

a concentric thickening of the walls of the rectum located 8 cm from the anal margin. No images of infiltration of the perirectal fat were appreciated. Multiple lymph nodes in the perirectal fat (approximately 8–10) were observed, suggestive of a T2N2 tumor. CT scans of the chest, abdomen, and pelvis were negative for metastasis, and the carcinoembryonic antigen (CEA) level was 1.0 ng/ml.

The patient underwent neoadjuvant treatment with radiotherapy, which was delivered to the pelvis with a three-field technique (posterior and two lateral fields), using an energy of 6 or 18 MV from a linear accelerator while the patient was in the prone position. The total dose was 45 Gy, with a daily dose of 1.8 Gy administered 5 days each week and chemotherapy with continuous 5-FU infusion, 225 mg/m<sup>2</sup>/day, during 5 days, concomitant with radiotherapy, which she tolerated well.

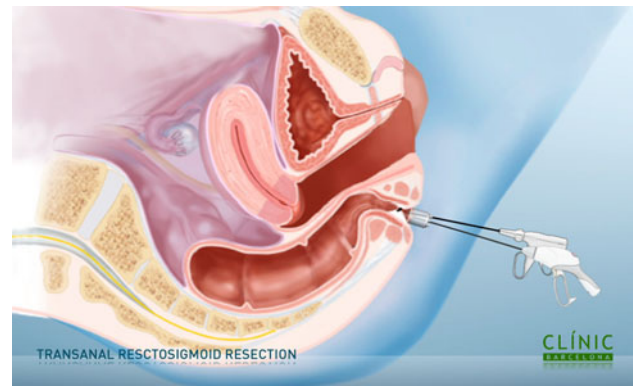
Informed consent was obtained for the procedure, which also included a protective diverting loop ileostomy.

#### Preoperative preparation

Preoperatively, the patient received full mechanical bowel preparation with oral sodium phosphosoda. In the preoperative area, an epidural catheter was inserted for postoperative pain control and preoperative antibiotics (Cefoxitin 2 g) were administered intravenously. After general anesthesia, a central line, arterial line, and Foley catheter were inserted, and the patient was placed in lithotomy position in stirrups. Both arms were tucked to the sides and the rectum was irrigated with diluted Betadine solution. A Veress needle was inserted through the umbilicus and used to insufflate the abdomen to a pressure of 12 mmHg. It was then removed and a 2-mm needle port was inserted through the same incision. A 5-mm port was inserted through the site previously marked for ileostomy creation in the right lower quadrant for the laparoscope, and the abdomen and pelvis were inspected laparoscopically using a 2-mm needle grasper though the umbilical needle port. After confirming that the sigmoid colon was redundant with no evidence of pelvic adhesions, the laparoscopic camera and instrument were removed and transanal dissection was initiated.

#### Transanal endoscopic rectal mobilization using TEM

The patient was placed in lithotomy position and the PPH anoscope (Ethicon Endo-Surgery, Cincinnati, OH) was inserted transanally and sutured to the perianal skin. Starting approximately 4 cm from the anal verge, a pursestring suture was placed through the rectal mucosa to tightly occlude the rectum. The 7.5-cm TEM proctoscope (Karl Storz, Tuttlingen, Germany) was inserted and sealed with the faceplate, and CO<sub>2</sub> was insufflated to a pressure of 9 mmHg. The rectal mucosa was scored circumferentially starting just distal to



**Fig. 1** Rectal dissection by transanal approach using TEM

the pursestring, and full-thickness rectal transection was initiated circumferentially using the Harmonic scalpel (Ethicon) and TEM dissecting instruments (Storz). Posteriorly, care was taken to avoid dividing residual internal sphincter muscle fibers. The presacral plane was entered and the mesorectum was mobilized sharply using the Harmonic scalpel and a flexible bipolar spatula (Novare, Cupertino, CA). Posterior dissection proceeded cephalad in the avascular presacral plane in accordance with the principles of a total mesorectal excision. This plane of dissection was extended medially, laterally, and anteriorly to achieve circumferential rectal mobilization, which was extended cephalad. The shorter proctoscope was replaced with the 15-cm proctoscope to improve exposure. The peritoneal reflection was visualized and divided anteriorly, and the peritoneal cavity was entered. The peritoneal attachments of the rectosigmoid were divided using a flexible bipolar spatula and flexible Themaseal device (Novare; Fig. 1).

#### Combined transanal and laparoscopic sigmoid mobilization

More proximal dissection of the peritoneal attachment of the rectosigmoid junction through the TEM was performed under laparoscopic visualization. A Keith needle was inserted above the pubis into the abdominal cavity and used to retract the uterus. A second 2-mm needle port was inserted in the right lower quadrant. Using a mini-grasper and mini-hook dissector through the umbilical and suprapubic needle ports, assistance with lateral and proximal sigmoid mobilization was provided to the transanal approach. The inferior mesenteric vessels and left ureter were identified laparoscopically, and the mini-grasper was used to retract the rectosigmoid and expose the vascular pedicle, which was transected at its base using one vascular load of the EndoGIA stapler inserted transanally through the largest TEM port. Additional sigmoid mesentery was divided transanally using the flexible Themaseal (Novare). After confirming that sufficient length of sigmoid colon

had been mobilized, the TEM proctoscope was removed and the rectosigmoid was exteriorized transanally.

#### Coloanal anastomosis and diverting loop ileostomy

The sigmoid colon was transected transanally well above the tumor and the specimen was passed off the field. The Lone Star Retractor<sup>TM</sup> was positioned. A transverse coloplasty was made, and a longitudinal incision of 7 cm was made of the sigmoid colon starting 2–3 cm above the rim of the stapler anvil. The incision was closed transversely with a double layer of 4/0 Vicryl running suture, and hand-sewn coloanal anastomosis was performed between the proximal sigmoid colon and the distal anorectal cuff. A loop of terminal ileum was identified laparoscopically in preparation for ileostomy creation. The 5-mm right lower quadrant camera port site was enlarged to create the stoma site through which the loop of ileum was exteriorized and matured in a standard Brooke's fashion. A small suction drain was placed in the deep pelvis and exteriorized through the right lower quadrant 2-mm needle port site.

#### Results

Endoscopic dissection of the rectum and mesorectum could be achieved entirely transanally through the TEM platform up to the level of the rectosigmoid junction above the peritoneal reflection. During early mobilization of the anterior rectal wall from the posterior vaginal wall, a small tear of the rectal wall was noted, which was quickly sutured closed using the Endostich device inserted through the TEM platform (US Surgical, Norwalk, CT). Laparoscopic assistance with visualization and proximal sigmoid mobilization was achieved through a total of three ports, including a 5-mm port site, which was used as the stoma site, and two 2-mm needle ports, one of which was used as a drain site. An oncologic resection was made, with section of inferior mesenteric artery in the origin, and a total



**Fig. 2** Surgical specimen. Section of IMA in the origin

mesorectal excision was achieved with an intact mesorectal specimen (Fig. 2). The operative time was 4.5 hours, and the patient's postoperative course was uneventful. The epidural catheter was removed the second postoperative day, and pain was controlled with oral analgesia. She was tolerating a regular diet by postoperative day 1 and was discharged home on the fourth postoperative day. Final pathology demonstrated pT1N0 (of 23 sampled lymph nodes) with negative proximal, distal, and radial margins.

#### Discussion

Since the first clinical report on NOTES transgastric appendectomy in 2005, significant research efforts have focused on developing safe and easily reproducible transluminal endoscopic approaches to perform various intra-abdominal surgical procedures. Transgastric and transvaginal access have been largely favored over transcolonic and transanal approaches, primarily due to concerns of infectious complications from fecal contamination of the abdominal cavity [2, 22]. With respect to colorectal resections, this risk is not specific to a NOTES approach but also applies to laparoscopic, open, and TEM resections where microscopic fecal contamination routinely occurs. One of the attractive features of transanal NOTES for colorectal resections is the fact that rather than creating an enterotomy through an otherwise healthy viscera to access a remote organ, as in transgastric and transvaginal cholecystectomy, the colotomy or proctotomy is created through the diseased organ itself and is closed by incorporating it into a standard colorectal handsewn or stapled anastomosis.

The Gastrointestinal Surgery Unit of The Hospital Clínic of Barcelona has had extensive experience with minimally invasive approaches to colon and rectal cancer. More recently, efforts to develop NOTES approaches to the colon and rectum have led to the first report of MA-NOS (minilaparoscopic-assisted natural orifice surgery) transvaginal radical sigmoid resection for cancer by Lacy et al. in 2008 [4]. With respect to colorectal resections, a transanal endoscopic approach offers substantial advantages over transvaginal access, including avoidance of a vaginotomy, which would not otherwise be indicated and its applicability to both men and women patients. As illustrated by more than 20 years of published clinical experience, full-thickness local excision of rectal lesions can be safely performed endoscopically using TEM [23]. More recently, TEM was reappraised as an ideal NOTES platform to access to the peritoneal cavity endoscopically through the anus [19, 24], and specifically to perform colorectal resections [19, 20]. The TEM proctoscope is equipped with excellent optics and CO<sub>2</sub> insufflation, which greatly facilitates dissection along tissue planes, and can



accommodate rigid and flexible dissecting instruments as well as flexible endoscopes. Magnified visualization of the rectal wall and direct tissue manipulation with TEM instruments allows for precise suture closure of colon wall, and a transanal approach will permit delivery of much large specimens than transgastric access [22, 24]. In swine and human cadavers, the NOTES group at the Massachusetts General Hospital in Boston and Whiteford et al. have demonstrated that full-thickness endoscopic rectal dissection using TEM can be extended beyond the rectal wall to incorporate the mesorectum and perirectal fat to achieve complete circumferential rectal mobilization [19, 20]. The safety of this approach was recently demonstrated in a swine survival model [21].

In experimental NOTES transanal resection models, complete rectal mobilization is consistently achieved using a pure transanal endoscopic NOTES approach using TEM [19]. More proximal colon mobilization, however, is limited by a narrow pelvis in swine, which cannot accommodate the full length of the proctoscope, and by difficulty achieving effective tissue retraction and endoscopic visualization in both swine and human cadavers due to limitations in current NOTES instrumentation. In the experimental models, some of these limitations can be overcome in part by combining transgastric endoscopic access to assist with proximal colon mobilization, which substantially extends the length of rectosigmoid colon mobilized transanally [20, 21]. In human cadavers, flexible endoscopes inserted transanally through the TEM platform can both improve endoscopic visualization and be used to assist with endoscopic dissection [24].

The same findings were replicated in this first clinical case of transanal endoscopic rectal dissection where complete rectal and mesorectal dissection could be achieved entirely transanally using TEM, and more proximal sigmoid mobilization was facilitated by laparoscopic assistance. Independent of the surgical approach for this particular patient, a protective diverting loop ileostomy was indicated given the location of the tumor in the lower rectum, and the fact that the patient was treated with preoperative chemoradiation. Therefore, transabdominal laparoscopic assistance was a logical adjunct for the safe completion of the procedure and helped to improve exposure during transanal lateral rectosigmoid mobilization, avoid inadvertent injury to the left ureter, and dissect and expose the inferior mesenteric pedicle for transanal transection. Similar to clinical NOTES transvaginal cholecystectomy, which is performed under laparoscopic visualization with varying degrees of transabdominal assistance through a single trocar, until longer, more flexible, and better adapted instruments become available to address the specific needs of NOTES transanal procedures, laparoscopic assistance should be provided, at the very

least to assist with visualization and retraction [25]. This is particularly important in cases where splenic flexure mobilization is required to achieve a tension-free colorectal anastomosis. Based on prior work in human cadavers, splenic flexure mobilization can be difficult to achieve transanally due to limitations in length, flexibility, and maneuverability of available NOTES instrumentation to achieve adequate retraction [20].

The combined experience from cadaver work and from this first human case of NOTES transanal rectosigmoid resections using TEM highlight potential strengths and limitations of this approach. Cosmetic results, with two-needle port site incisions in addition to the planned diverting loop ileostomy in this patient, can be predicted to be superior to those from both open and laparoscopic approaches; however, potential benefits with regards to pain, recovery time, and patient satisfaction are unknown. Perineal proctosigmoidectomy for rectal prolapse as well as TEM procedures for rectal lesions are associated with substantially lower pain, morbidity, recovery time, and length of hospital stay (LOS) than transabdominal resections [17]. The same benefits might be observed with NOTES transanal rectosigmoid resections. However, the potential effects of prolonged TEM platform insertion on short- and long-term anal sphincter function will have to be evaluated [18]. Careful patient selection will be critical to ensure the technical success of this approach. In human cadavers, obesity and adhesions from prior abdominal or pelvic surgery were associated with much more difficult transanal rectal dissection and higher risk of bowel injury (unpublished data). With respect to selection criteria for transanal NOTES approach rather than transanal local excision or abdominal procedures, this approach represents an attractive and less morbid alternative for the management of benign or premalignant lesion of the rectosigmoid, such as large unresectable polyps or dysplastic lesions. Complete or partial mesorectal excision with lymph node sampling also can be achieved, which is a significant advantage relative to transanal local excisions and TEM. Patients selected for this approach, however, should have a clear indication to undergo low anterior resection. As described in this clinical report, rectosigmoid resection using a NOTES transanal endoscopic approach entails that initial rectal dissection and colorectal anastomoses be performed 4–5 cm from the anal verge. Although sigmoid resection can be performed in patients with some redundancy in their sigmoid colon, routine resection of the rectum not otherwise indicated is associated with lesser functional outcomes.

With respect to the oncologic adequacy of this approach for curable rectal cancer, although this clinical case demonstrates the feasibility and safety of adequate TME with excellent lymph node harvest, the long-term oncologic

outcomes with respect to local recurrence and survival will need to be closely monitored and formally investigated in the form of clinical trials. Until then, this approach for rectal cancer should be considered strictly investigational and should be performed by surgeons with extensive expertise in rectal cancer and NOTES.

## Conclusions

In this first clinical report, we have demonstrated the feasibility and safety of NOTES transanal rectal cancer resection with total mesorectal excision using TEM and laparoscopic assistance. The potential clinical benefits of this approach for resection of benign and malignant diseases of the rectosigmoid are significant but need to be formally evaluated. Careful patient selection, evaluation of long-term oncologic outcomes of this approach in rectal cancer, and improvement in NOTES instrumentation are critical to optimize this approach before widespread clinical application.

## Disclosures

Dr. Sylla is a consultant for Covidien, Dr. Rattner is a consultant for educational conferences for Olympus Medical, Dr. Delgado has no conflicts of interest or financial ties to disclose, and Dr. Lacy is a consultant for Covidien and for Olympus Medical.

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