

True NOTES TME resection with splenic flexure release, high ligation of IMA, and side-to-end hand-sewn coloanal anastomosis

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Abstract

Introduction Natural orifice transluminal endoscopic surgery (NOTES) represents the ultimate expression of minimally invasive surgery. We have developed and present here an initial feasibility and safety study of transanal total mesorectal excision (TME) with splenic flexure release, high ligation of the IMA and IMV, and side-to-end coloanal anastomosis with temporary diverting ileostomy for rectal cancer.

Methods A program of full NOTES TME resection with release of the splenic flexure, high ligation of the IMA/IMV, with side-to-end coloanal anastomosis was performed transanally from December 2013 to July 2014. Demographics, preoperative, perioperative, and postoperative data were prospectively obtained. Operative components were broken into TME, colonic mobilization, splenic flexure release, IMA/IMV transection, transanal extraction of specimen, and coloanal anastomosis for analysis of performance completion.

Results There were 3 women and 1 man on whom we operated. Mean age was 56 (46–65). Mean BMI was 26

(23.8–30.2). The operation was completed entirely transanally in 2 patients. Transanal component completion of the operation was as follows: TME in 3/4; colonic mobilization in 4/4; splenic flexure release in 3/4; IMA/IMV transection in 3/4; transanal specimen extraction in 4/4; coloanal anastomosis in 4/4. Abdominal time for completion of component parts was: splenic flexure release 4:53 (min:s), IMA/IMV 19:43, completion of TME 13:41. Mean EBL was 194 cc (25–500). Aside from stoma site, there were no abdominal incisions. There were no mortalities. Mesorectum was intact in all 4 patients and with negative circumferential and distal margins.

Conclusion This experience supports the feasibility and safety of a true NOTES TME. The critical anatomic views demonstrated on video affirm the potential of this approach for distal rectal cancer. Colorectal surgery represents the most logical application for NOTES. While highly promising, a great deal of work remains to develop the technique and applicability of NOTES colorectal surgery.

Keywords Transanal TME · Rectal cancer · NOTES · TATA · Laparoscopic

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Management of rectal cancer continues to evolve with the focus on an oncologic cure while maintaining the highest quality of life. When addressing rectal cancer, the principal goals of treatment are to achieve resection of tumor with negative margins, decreasing the associated morbidity and mortality, maintaining quality of life, and avoidance of a permanent stoma if possible. Since the abdominoperineal resection (APR) introduced by Sir Earnest Miles in 1908, management of cancer in the distal third of the rectum has evolved tremendously. The use of chemoradiation along with advances in surgical technique has led to a shift in the

treatment of rectal cancer from APR with a permanent colostomy to a sphincter-preserving surgery using minimally invasive techniques [1].

Transanal excision of rectal lesions has advanced tremendously. The introduction of transanal microscopic surgery (TEM) pioneered by Dr. Gerhard Buess in 1983 revolutionized the transanal approach [2]. It ushered in the era of endoluminal surgery well before NOTES. His technique offered optimal visualization and access to proximal lesions by using rectal distention with carbon dioxide, laparoscopic instruments, and magnified views. It did not involve excision of lymph nodes in the mesorectum; therefore, its use was limited for resection of benign lesions and carefully selected rectal cancers.

With the goal of avoiding abdominal incisions, a new technique of natural orifice transluminal endoscopic surgery (NOTES) has developed. Since first described in animal models by Dr. Kalloo, NOTES has been viewed as the ultimate step in minimally invasive surgery [3]. We and others have questioned the widespread applicability of NOTES as it generally requires injury of a healthy organ to access the diseased organ [4]. The application of NOTES for distal rectal cancers is very practical since it requires access to the mesorectum through a diseased organ that will eventually be removed [5]. Studies have shown the safety and effectiveness of integrating transvaginal and transanal specimen extraction for colorectal resections [6, 7]. Leroy and Wolthius have published their original experiences with transanal NOTES resections with laparoscopic assistance for rectal cancer [8, 9]. Others have shown a hybrid transanal/laparoscopic approach is feasible, reproducible, safe and provides adequate resection of lymphoid tissue and total mesorectal excision (TME) [10–12].

These surgeries have been carried out with abdominal laparoscopic surgery to achieve mobilization of the splenic flexure as well as dissection and division of the inferior mesenteric vessel. Since 1998 at our institution, Lankenau Hospital and Institute for Medical Research, cancers in the distal 3 cm of the rectum that are mobile 8–12 weeks after neoadjuvant therapy have been managed by a laparoscopic transanal abdominal transanal radical proctosigmoidectomy and a descending coloanal hand-sewn anastomosis (TATA). Transanal surgery via a transanal MIS approach for benign disease was first performed in our institution in 2009. Starting in 2012, selective usage of transanal TME surgery (taTME) has been utilized for rectal cancer and prospectively entered into a database. This experience has subsequently evolved and expanded into an entirely transanal NOTES TME. We present here our initial experiences and video to demonstrate visually the initial feasibility and safety of performing a taTME and then proceeding with transanal splenic flexure release, high

ligation of the IMA and IMV, and side-to-end coloanal anastomosis with temporary diverting ileostomy for low rectal cancer after neoadjuvant therapy.

Methods

As part of an ongoing program of minimally invasive rectal cancer surgery, a program of NOTES TME resection was begun in December 2013 for patients with low rectal cancer. Inclusion criteria for performing NOTES TME, taTME, and laparoscopic TATA are similar. The decision regarding sphincter preservation is based on the cancer after completion of neoadjuvant therapy and included patients with mobile rectal cancers located up to 3.0 cm proximal to the anorectal ring. Patients with a tumor more than 3 cm from the anorectal ring and patients not undergoing neoadjuvant therapy were excluded. ASA status, BMI, or previous abdominal surgery was not used for selection.

Evaluation prior to treatment included clinical examination, blood cell count, serum chemistries, and carcinoembryonic antigen (CEA) levels. Patients underwent a full colonoscopy preoperatively to rule out synchronous disease. Staging was assessed by endorectal ultrasound, chest, abdominal and pelvic computed tomography (CT), or magnetic resonance imaging (MRI). Tumor characteristics including level in the rectum, size, fixity, clinical stage, degree of ulceration, position, and configuration were assessed at presentation and again 8–12 weeks after completion of neoadjuvant chemoradiation by digital examination and flexible sigmoidoscopy.

Proctosigmoidectomy with release of the splenic flexure, high ligation of the IMA/IMV, and a side-to-end coloanal anastomosis was performed transanally. Demographics, preoperative, perioperative, and postoperative data were prospectively obtained. Video documentation of all cases was performed. The operative components of the procedure were broken into TME excision, colonic mobilization, splenic flexure release, IMA/IMV transection, transanal extraction of specimen, and coloanal anastomosis for analysis of performance completion. As in standard laparoscopic TATAs, all patients were diverted with a loop ileostomy. In cases in which the procedure could not be completed transanally, the component task was finished via a SILS port at the ileostomy site, and time for completion was noted.

A detailed description of the procedure is given to patients prior to surgery, and informed consent is obtained. Patients received mechanical bowel preparation the day before the procedure. All patients received preoperative intravenous antibiotic prophylaxis. Patients were placed in lithotomy position using Allen stirrups with all pressure

points padded. A Foley catheter was placed in usual sterile fashion. The abdomen and perineum were prepped in routine sterile fashion using Betadine. In addition to bariatric length laparoscopic instruments, the procedure was performed using a Gelpoint path (Applied Medical, Rancho Santa Margarita, CA, USA), a 5-mm LigaSure (Covidien, Mansfield, MA, USA), and a Olympus flexible scope (Olympus America, Center Valley, PA).

The TATA procedure has been described by us previously [13]. As demonstrated in Video 1, Allis-Adair clamps were used to evert the anal canal to demonstrate the dentate line. Electrocautery was used to incise at the dentate line circumferentially. Metzenbaum scissors were used to incise circumferentially in a full-thickness fashion through the upper half of the internal sphincter to enter the intersphincteric plane. The key element of showing the glistening white of the puborectalis muscle is shown. The rectum was dissected transanally to the level of the seminal vesicles in the male and the cervix in females. The rectum was oversewn with a purse-string suture, and then, a SILS transanal port was placed per anus and air insufflated to a pressure of 10–12 mmHg. A flexible tip laparoscope was used for visualization.

Video 2 shows how scissors, electrocautery, and LigaSure were used to dissect in the proper avascular TME plane starting posteriorly and then carried circumferentially maintaining a balance between all sides. Once the mesorectal excision was completed in a transanal bottom-up fashion, the peritoneal reflection was opened anteriorly and the abdominal cavity was entered.

In Video 3, we demonstrate how the rectum is delivered into the abdominal cavity, and subsequently, the sigmoid colon mobilization was carried in a lateral to medial fashion identifying key anatomic landmarks including the ureter. In order to achieve this, the operating table is positioned in a Trendelenburg and right side down. An incision is made at the base of the lateral aspect of the left colon along the white line of Toldt with the left colon retracted medially. Once the colon was mobilized, attention was carried toward dissection and high ligation of the IMA and IMV using the energy device.

Video 4 shows complete mobilization of the splenic flexure with transanal extraction of the specimen, maintaining adequate orientation at all times. Of note, the video shows how a loop of ileum is grasped from a port placed in the ileostomy site and is brought out and matured in a standard Brooke fashion. A GIA stapler was used to transect the descending colon after the mesentery was divided. An incision was made 3 cm proximal to the staple line on the anti-mesenteric border of the colon, and a hand-sewn anastomosis was then performed in an side-to-end fashion.

Nineteen patients underwent a taTME during the period between December 2013 and July 2014. NOTES TME was

considered at the time of surgery for all patients undergoing a taTME. The decision to proceed in a full NOTES fashion was made in the operating room based on the intraoperative findings, including bulk of the lesion, height of the pelvic brim, intrapelvic adhesions, and patient course. In four of these patients, we decided to proceed in a NOTES fashion and they are presented herewith. In an attempt to measure what was left to be done when we were unsuccessful in completing a defined component of the operation transanally, we used the metric of time to completion abdominally using a single-port approach through the eventual stoma site.

Results

Demographics

Between December 2013 and July 2014, three women and one man were operated on by NOTES taTME. The mean age was 56 years (46–65) with a mean BMI of 26 kg/m² (23.8–30.2). All four patients had a history of previous abdominal surgery.

Preoperative tumor characteristics

The tumor was located in the distal third of the rectum in all cases. The mean level in the rectum superior to the anorectal ring was 1.1 cm (0.0–3.0). Preoperative staging was T2N0, T2N1, T3N0, and T3N1. In terms of fixity, 3 were mobile and 1 had early fixation. Ulceration was deep in 1 case, superficial in 2 cases, and minimal in 1 case.

Neoadjuvant treatment

All patients received chemoradiation [Xeloda ($n = 4$); 5580 cGy ($n = 1$), 5400 cGy ($n = 1$) 5040 cGy ($n = 2$)]. Post radiation response was assessed clinically for all patients before surgery. All patients were able to complete radiation therapy without significant morbidity.

Surgery

The median time from completion of treatment to surgery was 11.6 weeks (10.1–11.9). There were no conversions to open surgery. The operation was completed entirely transanally in 2 patients. Component completion of the operation was as follows: TME excision in 3 of 4; colonic mobilization in 4 of 4; splenic flexure release in 3 of 4; IMA/IMV transection in 3 of 4; transanal specimen extraction in 4 of 4; coloanal anastomosis in 4 of 4. In one patient, completion of the TME required laparoscopic assistance via a single port placed in the future ileostomy

site, which took 13:41 (min:s). Another patient required abdominal assistance for completion of the splenic flexure mobilization and transection of the IMA and IMV. The abdominal time for completion of the splenic flexure release took 4:53 and transection of the IMA/IMV took 19:43. Mean operative duration for the transanal TME was 135 min (range 113–160). Mean EBL was 194 cc (25–500). Outside of the stoma site, there were no abdominal incisions.

Pathology

In all four patients, there was a completely intact mesorectum and there were no positive distal or circumferential margins, with the definition of a clear margin being greater than 2-mm clearance. The ypT stages included 3 complete responses and one ypT3N0. Mean number of lymph nodes harvested was 6 (4–8).

Clinical Outcomes

The mean LOS was 5 days (3–8) with median return of bowel function at 2 days (1–6). There were no perioperative blood transfusions. Mean follow-up was 10.5 months (6.7–14.1). There were no local recurrences, and none of the patients developed distant metastasis. One patient after an unremarkable postoperative course underwent a routine digital dilatation of a mild anastomotic stricture by rectal examination in the office 6 months postoperatively and developed severe rectal bleeding. The bleeding required blood transfusion and an examination under anesthesia in the operating room with ligation of a single bleeding vessel. The patient had an uneventful recovery from this unusual presentation and has since had his stoma closed and enjoyed good function. All other stomas have also been reversed without complications.

Discussion

A great deal of enthusiasm has developed in the surgical community regarding the transanal approach to rectal cancer. Albert, Attalah, and Larach started the process with the introduction of the TAMIS approach for rectal lesions [14]. From here the taTME approach evolved in the management of rectal cancer via minimally invasive methods. Multiple small series of publications from across the world have demonstrated the feasibility, reproducibility, and safety of a transanal approach in resection of low-lying rectal cancers with a combined laparoscopic abdominal approach [10–12]. This is a natural extension of our laparoscopic TATA experience dating back to 1998, with the TME dissection extended cephalad, from the seminal

vesicles or cervix utilizing transanal single-port surgery [15].

The transanal approach offers multiple technical advantages in performing a TME resection. Initiation of the resection at the dentate line, for very low-lying tumors, ensures a known distal margin and allows preservation of sphincter function avoiding a permanent colostomy. Transabdominally operating on the rectum from above, the most challenging aspect of rectal cancer surgery remains the dissection of the distal 1/2 to 1/3 of the rectum. This challenge has been offered as the reason for such low adoption of minimally invasive techniques for rectal cancer surgery and contributes to the high APR rates. Clearly, it is the technical challenge of operating in the distal half of the rectum which has led to the interest in the robotic approach as well as the interest in bottom-up TME or taTME [for rectal cancer [16].

With the advancements in endoscopic technological instrumentation, the transanal platform offers a better in-line visualization of the pelvis, leading to an efficient and complete TME [17]. This has been offered as one of the most important benefits of this approach as the pelvic dissection is the most challenging part of the surgery via an abdominal approach, whether performed open, laparoscopic, or robotic.

Recognizing the challenge of the distal 3 cm of the rectal dissection, the TATA procedure was first developed in our unit in 1984 [18]. We have been performing the laparoscopic TATA since 1996 with excellent results [15]. The transanal approach of the TATA is excellent for dissection of the distal rectum, and the taTME approach extends this dissection into the mid- and upper rectum. Our video presentation of a NOTES technique transanally extends the aim of the transanal approach. We endeavored to demonstrate the feasibility of this technique with the aim to show that the critical anatomy can be visualized and safely dissected via a transanal approach and present the data surrounding this small initial series. It should be noted that the technique was started in a unit with an extensive experience in rectal cancer surgery, TEM surgery as well as single-port colon surgery. This represents a gradual extension of all of these techniques converging in a goal to routinely perform colonic NOTES surgery. In the series presented, we have continued our taTME surgery via the transanal approach to dissect the splenic flexure, ligate the inferior mesenteric vessels, and deliver the specimen via the anus.

Along with a few other units worldwide, we are working to see whether it is reproducible and safe to perform a completely transanal proctosigmoidectomy. While most studies have indicated the use of abdominal laparoscopic instruments to aid the transanal TME, our series is one of the first to report a total transanal approach in the surgical

management of rectal cancer after neoadjuvant chemoradiotherapy [8, 9, 19]. The first pure transanal NOTES TME with coloanal anastomosis was reported by Leroy, a true pioneer in the field, in a 56-year-old woman with a large tubulovillous adenoma. Chouillard describes a similar transanal approach in 16 patients with rectal neoplasia. They were able to perform a pure NOTES transanal TME in 10 patients with coloanal anastomosis. They excluded patients with previous abdominal surgery and patients who received chemoradiotherapy. Similar to our findings, they stressed the challenge of the splenic flexure dissection from the transanal approach, which is one of the main limiting factors in performing a true NOTES TME with the current instrumentation. Wolthuis as well reports performing transanal rectal excision for benign disease or early rectal carcinoma without neoadjuvant treatment. His experience also required laparoscopic assistance in cases where length was required after the transanal dissection, however, did not continued into the abdomen requiring.

All of our experiences are converging on the same areas of challenge. The taTME can be performed with excellent visualization. Training and development of technique to demonstrate reliably the critical anatomy for the procedure need to be carried out. We attempted to show this via the enclosed video. The extension of the transanal approach to complete the additional component parts of the operation remains challenging. While we were able to complete our surgery entirely via the transanal approach in two of the four patients and the components remaining to be done from above were quite small, as evidenced by the 15 min it took to complete the TME in the one patient via an abdominal SILS port at the site of the future ileostomy, this approach is technically very challenging for both the surgeon and the camera holder. Reach and retraction to the splenic flexure is a limiting issue. The angle of the line from the anus to the bony pelvic inlet makes it at times difficult to dissect in the retroperitoneum. Furthermore, exchange of instruments into the abdominal cavity remains problematic. Clearly, the absence of additional abdominal incisions apart from the ileostomy would build on the well-established benefits of minimally invasive surgery including reduced postoperative pain, shorter hospital course, and better cosmetics [20]. It is this goal, while maintaining the oncologic principles of rectal cancer surgery that drives us and others to move forward to develop the transanal NOTES approach.

While postoperative complications play an important role in determining the feasibility and applicability of any new procedure, there were no acute morbidities encountered with this approach. In this series, we did not have any perioperative morbidity or mortality. The only significant morbidity was a patient with severe bleeding after dilation

of a mild anastomotic stricture in the office 6 months after surgery.

Although technical feasibility is of great significance, it is most important to compare the oncologic outcomes of this approach. It is well documented that achieving a negative CRM is essential as well as achieving a negative distal margin [21, 22]. In our current series, the TME specimen was intact in all four patients. We achieved negative proximal and distal margins, as well as a negative CRM. Short-term oncologic outcomes in terms of locoregional recurrences have been favorable in previous transanal TME series ranging from no recurrences [12, 23, 24] up to 13 % in the high-risk group of Rouanet et al. [11]. While long-term outcomes are still being compiled, it cannot be stressed enough that careful patient selection has a major role in achieving a good oncologic result.

The ultimate purpose of this dynamic paper is to share our early experience, with video demonstration of the critical steps, of a successful attempt at a NOTES transanal proctosigmoidectomy with coloanal anastomosis in the hopes that it will encourage others to help develop the field. The transanal release of the splenic flexure, mobilization of the colon, and transection of the IMA and IMV are demonstrated clearly on video but remain a great challenge. It will certainly take a partnering with industry to produce instruments that are capable of addressing our evolving needs of expanded transanal surgery.

Conclusion

This experience supports the feasibility and safety of a true NOTES TME. The critical anatomic views demonstrated on video affirm the potential of this approach for distal rectal cancer. Colorectal surgery represents the most logical application for NOTES. The distal rectal cancer allows the most logical place to start as we are already operating transanally for this problem. While highly promising, a great deal of work remains to develop the technique and applicability of NOTES colorectal surgery.

Compliance with ethical standards

Disclosures Drs. John Marks, Nicolas Lopez-Acevedo, Barath Krishnan, Grace Montenegro, Gerald Marks, and Mr. Matthew Johnson have no conflicts of interest or financial ties to disclose.

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