

Transanal total mesorectal excision (taTME) for rectal cancer: a training pathway

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Abstract

Background With increasing interest in natural orifice surgery, there has been a dramatic evolution of transanal and endoluminal surgical techniques. These techniques began with transanal endoluminal surgical removal of rectal masses and have progressed to transanal radical proctectomy for rectal cancer. The first transanal total mesorectal excision (taTME) was performed in 2009 by Sylla, Rattner, Delgado, and Lacy. The improved visibility and working space associated with the taTME technique is intriguing. This video manuscript outlines the training pathway followed by pioneers in the taTME technique, the

process of implementation into clinical practice, and initial case report.

Methods A double board-certified colorectal surgeon with expertise in rectal cancer, minimally invasive total mesorectal excision, transanal endoscopic surgery (TES), and intersphincteric dissection, underwent taTME training in male cadaver models. Institutional review board (IRB) approval for a phase I clinical trial was achieved. The entire operative team including surgeons, nurses, and operative staff underwent taTME cadaver training the day prior to the first clinical case. The case was proctored by an expert in taTME.

Results A 66-year-old male with uT3N1M0 rectal cancer located in the posterior distal rectum, underwent taTME with laparoscopic abdominal assistance, hand sewn coloanal anastomosis, and diverting loop ileostomy. The majority of the TME was performed transanally with laparoscopic assistance for exposure, splenic flexure mobilization, and high ligation of the vascular pedicles. Operative time was 359 min. There were no intraoperative complications. Pathology revealed a ypT2N1 moderately differentiated invasive adenocarcinoma, grade I TME, 1 cm circumferential radial margin, and 2/13 positive lymph nodes.

Conclusion Implementation of taTME into practice can be achieved by surgeons with expertise in minimally invasive TME, TES, pre-clinical taTME training in cadavers, case observation, proctoring, and ongoing mentorship. IRB peer review process and participation in a clinical registry are additional measures that should be employed.

Keywords Transanal · Total mesorectal excision · Rectal cancer · Training

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Background

The surgical technique associated with the highest rate of cure and lowest rate of rectal cancer recurrence is called “low anterior resection (LAR) with total mesorectal excision (TME)” [1]. The execution of LAR with TME using a minimally invasive surgical approach (laparoscopic, robotic) is a technically challenging operation with reduced working space, retraction capabilities, and visibility. There has been an exceedingly slow adoption rate of this technique with <10 % minimally invasive surgical procedures being performed for rectal cancer in the USA by 2011 [2]. These challenges led to the trend toward increased interest and utilization of robotic rectal surgery. However, even with robotic visualization and instrumentation, there remain several technical hurdles in the minimally invasive approach to rectal cancer. Most notably, the division of the distal rectum remains technically challenging due to the limitations of the pelvic working space and articulation of modern stapler technology.

The standard approach for both minimally invasive and open laparotomy TME for rectal cancer is performed using incisions in the abdomen to access the rectum located deep in the pelvis. Alternatively, the TME can be performed using the anus, a natural orifice, and portal to access the pelvic dissection. Transanal pelvic access for rectal cancer has many potential advantages compared to the transabdominal surgical approach. (1) A transanal approach utilizes pneumatic pressure to assist with the dissection through the avascular embryologic tissue plane surrounding the rectum. This pneumatic pressure dissection does not occur when using a transabdominal approach to rectal surgery. (2) The retraction of the rectum is technically less difficult from the transanal approach as rectal retraction is a “forward pushing motion” for transanal rectal surgery compared to a “pulling up and out of the pelvis motion” required for transabdominal rectal surgery. (3) Rectal division can be performed without using modern endoscopic staplers with a transanal approach. This allows the surgeon to more precisely select the distal margin transection site and perform the transection in a more precise, linear fashion under direct visualization. (4) the low pelvic anastomosis can be performed using a double circular stapler technique or hand sewn technique, thereby avoiding the multiple staple line and staple cross over lines when creating a low pelvic anastomosis that may be associated with an increased rate of anastomotic leak.

The combined transabdominal–transanal (TATA) approach for the surgical management of low-lying rectal cancers was initially described by Marks et al. [3, 4]. The TATA technique was developed in 1984 by Dr. Gerald

Marks at Thomas Jefferson University Hospital as an alternative to abdominal perineal resection with permanent end colostomy in patients with low-lying rectal cancers located in the distal third of the rectum [3]. In 2010, Marks et al. [4] reported their laparoscopic TATA experience over a 10-year period. A total of 79 patients underwent laparoscopic TATA resection for locally advanced low-lying rectal cancer located within 3 cm or less of the anorectal ring. There were no perioperative mortalities. The conversion rate was very low (2.5 %), as was the local recurrence rate (2.5 %). All patients underwent a temporary diverting ileostomy at the time of the laparoscopic TATA procedure. After completion of systemic chemotherapy and interval follow-up, 90 % of the patients were able to undergo ileostomy reversal [4].

With increasing interest in natural orifice surgery, there has been an increased interest in the evolution of transanal natural orifice and endoluminal surgical techniques. These techniques began with transanal endoluminal surgical removal of rectal masses [5–11] and have progressed to transanal endoscopic surgical resection of the rectum without abdominal laparoscopic assistance [12–14]. Investigative activity has escalated in the evaluation of proctectomy via a completely transanal approach [15]. The feasibility and safety of transanal proctectomy and transrectal rectosigmoid resection has been demonstrated in human cadavers and porcine survival models using the rigid transanal endoscopic platform [16–24].

The largest cadaveric series investigating transanal rectosigmoid resection for rectal cancer via natural orifice transluminal endoscopic surgery (NOTES) with TME using a rigid transanal endoscopic platform in 32 cadavers was published by Telem and Sylla et al. in 2012 [25]. The majority of patients were male, mean operative time was 5.1 h, and mean specimen length was 53 cm. Transanal dissection alone using the TEM platform was performed in 19 cases (17 cases with the use of a gastroscope). Intra-abdominal assistance was performed using multi-port laparoscopy in eight cases and transgastric endoscopic assistance in five cases. The mesorectum was intact in all of the specimens [25].

The first clinical case utilizing a rigid transanal endoscopic platform to perform a transanal total mesorectal excision (taTME) with laparoscopic assistance in a 76-year-old woman with uT2N2M0 stage III rectal cancer was safely executed by Sylla, Rattner, Delgado, and Lacy in 2009 and published in 2010 [26]. The outcome of this case demonstrated patient safety, accelerated recovery, and equivalent short-term oncologic outcomes. At nearly 4 years of survivorship screening and surveillance, the patient has demonstrated no evidence of locally recurrent or metastatic disease.

However, there are limitations to rigid transanal endoscopic platforms like the transanal endoscopic microsurgery (TEM; Richard Wolf Medical Instruments Corporation, Vernon Hills, IL, USA) and transanal endoscopic operation (TEO; Karl Storz GmbH & Co, Tuttlingen, Germany) platforms including large platform size, rigidity, and prolonged setup time. Atallah et al. [27] demonstrated the innovative use of a single incision laparoscopic (SIL™) port for transanal access in 2010 as an alternative to rigid transanal endoscopic platforms. A new term, transanal minimally invasive surgery (TAMIS) [27], was coined by the group, and the technique has gained widespread interest in the field of colorectal surgery at the national and international level. Many of the disadvantages of the rigid transanal endoscopic platforms have been overcome by the development of soft, disposable transanal endoscopic platforms with the largest taTME experience and series published to date by Antonio Lacy, Barcelona, Spain [27–36].

Training pathway

There are six key elements that should be acknowledged and emphasized in the process of taTME training and implementation of the technique into surgical practice: (1) expertise in TME for rectal cancer in your surgical practice [37, 38], (2) expertise in minimally invasive (laparoscopic and/or robotic) TME from the abdominal approach, (3) expertise in transanal endoscopic surgery, (4) experience in intersphincteric dissection for very low rectal invasive neoplasms, (5) practice in taTME techniques in human cadaver models, and (6) institutional review board (IRB) approved data collection with publication of outcomes and/or participation in a clinical registry.

After a few years of experience with laparoscopic and robotic TME for rectal cancer including intersphincteric dissection, the first author trained in TEM and TAMIS [31–34]. Thereafter, following the pathway of pioneers in the taTME technique, the first author and surgical team underwent cadaver training in taTME in 2012. A grade I TME dissection quality was achieved in all eight male cadaver models, of which the results of the first five were published in 2013 [35].

Following cadaver training, a prospective, phase I, clinical trial was then submitted to the IRB and approved. The inclusion criteria were T1–3 N0–2 rectal cancer determined by clinical staging computed tomography (CT) scans and transrectal ultrasound (TRUS), or rectal cancer protocol pelvic MRI. Distal edge of tumor is located within the mid-to-distal rectum (distal edge of tumor no higher than 8–10 cm from the anal verge). Additional inclusion criteria in patients with T3N0 or T1–2N1–2 clinical stage

rectal cancer included completion of pre-operative combined 5-FU-based chemotherapy and radiation therapy prior to surgery. Patients with T4, metastatic disease, or primarily anterior lesions were not eligible for this phase I clinical trial. Patients with sphincter involvement on clinical staging TRUS or pelvic MRI were also not eligible.

The day prior to the first scheduled taTME clinical case, a taTME cadaver training day was scheduled to introduce the operating room staff to the steps of the taTME technique. The entire operating room team including surgeons, residents, and nursing staff was present for the taTME cadaver training in which the procedure was performed from incision to closure as it would be in the operative theater (Video 1). A grade I TME dissection was achieved (Fig. 1). An expert in taTME dissection technique proctored the first clinical taTME case at the University of California, San Diego Medical Center in 2013.

Case report

A 66-year-old male with a body mass index (BMI) of 32 kg/m² was referred for evaluation of rectal bleeding and hemorrhoids and discovered to have a posterior suspicious mass just above the sphincter muscle complex on digital rectal examination. A colonoscopy was performed and confirmed the presence of an invasive adenocarcinoma. Clinical staging was completed and revealed a stage III (uT3N1M0) rectal cancer located in the posterior distal rectum, 2 cm from the anal verge, and occupying approximately 30 % of the circumference of the rectum. The patient underwent combined radiation chemotherapy (4500 cGy with 540 cGy boost; concurrent 5-FU-based radio-sensitizing chemotherapy).

Approximately 10 weeks after completing combined radiation chemotherapy, the patient underwent taTME with laparoscopic abdominal assistance, hand sewn coloanal anastomosis, and diverting loop ileostomy using a two-team approach in August of 2013. The splenic flexure mobilization and high ligation of the inferior mesenteric vein and artery were performed laparoscopically. The TME was performed primarily via a transanal approach with laparoscopic visualization and assistance (Video 2). The operative time was 5 h 59 min (359 min). There were no intraoperative complications. The final pathology revealed ypT2N1 moderately differentiated invasive adenocarcinoma, negative lymphovascular invasion, grade I TME (Fig. 1), 1 cm circumferential radial margin, 0.3 cm distal margin, MSI stable, and 2/13 lymph nodes positive for disease.

The patient's post-operative course was complicated by high output ileostomy and abdominal abscess which was located at the pelvic brim requiring percutaneous drainage and antibiotic therapy. The abscess may have been due to

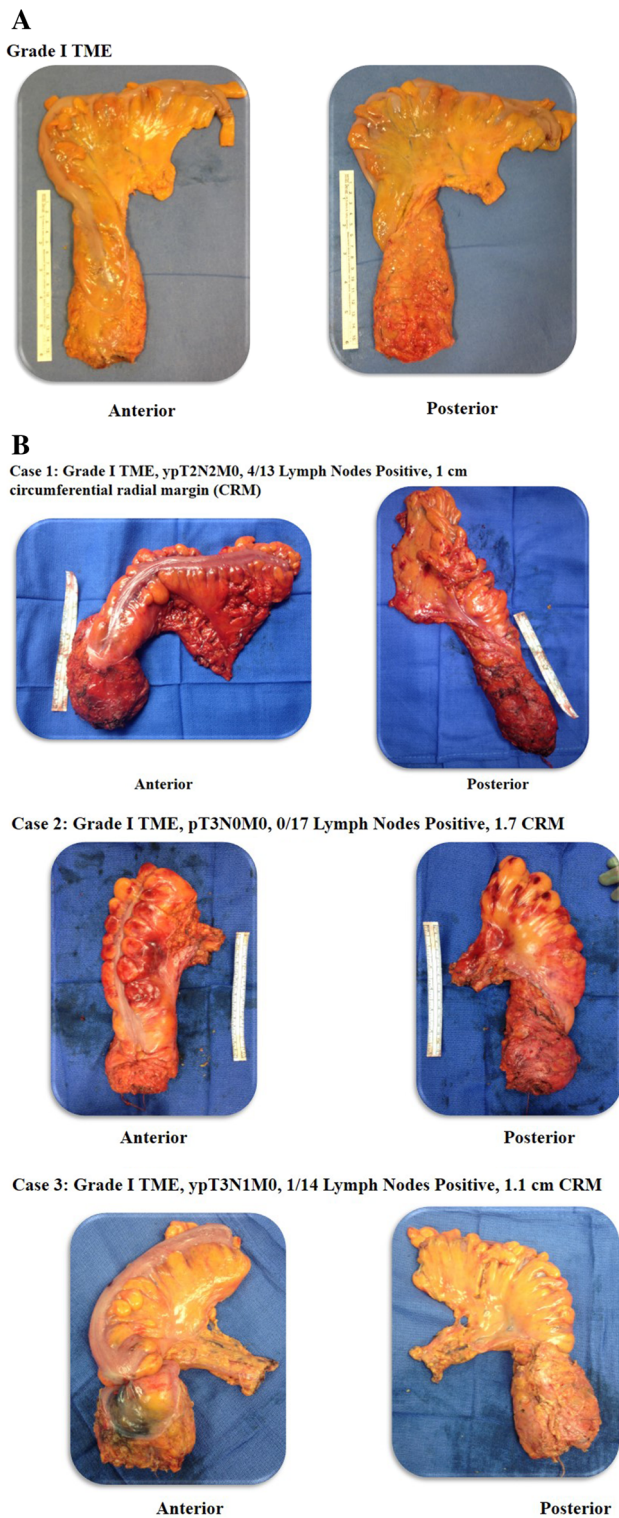


Fig. 1 TME specimen quality. Anterior and posterior TME specimen photo documentation of cadaver (A) and clinical (B) transanal total mesorectal excision (taTME)

pulling the completed proctectomy out of the pelvic dissection field and up into the abdominal cavity to inspect the quality of the pelvic dissection after taTME. This

maneuver is no longer performed, and there have been no subsequent post-operative abdominal abscess formation. The Foley catheter was removed on post-operative day 3 without urinary retention, and the hospital length of stay was 7 days. The patient completed eight cycles of mFOLFOX6 systemic chemotherapy and has undergone ileostomy reversal. At this time, just over 2 years, the patient does not have any evidence of local recurrence or distant metastasis.

The clinical trial was closed earlier than anticipated due to the recruitment of the primary investigator to another healthcare system. A total of three taTME cases were completed prior to closure of the clinical trial. All three cases were completed without intraoperative complication, grade I TME dissection quality, negative distal margins, circumferential radial margins >1 cm, and lymph node harvests >12. All patients have subsequently undergone ileostomy reversal. The first author has continued to perform taTME in the new healthcare system using a two-team transanal–transabdominal approach for low-lying rectal cancers (10 cm or less from the anal ring) achieving a grade I TME in all twelve cases to date. The second surgeon is a double board-certified colon and rectal surgeon who also underwent taTME cadaver training in May 2014 at the UC San Diego Center for the Future of Surgery. IRB retrospective data collection approval has been obtained, and the perioperative outcome data and short-term oncologic outcomes in a case series report will be submitted for peer review in the future. The first author plans to foster the training and implementation of the taTME technique into the other medical centers within the Southern California Kaiser Permanente Health System in a prospective phase I observational clinical trial setting using the model outlined in this manuscript.

Discussion

taTME is an attractive alternative to current standard minimally invasive TME techniques as the number of abdominal access ports is reduced, the abdominal extraction incision can be avoided in the majority of cases, and the technical difficulty of performing the TME is reduced. Antonio Lacy has the largest experience with taTME for rectal cancer and has published the outcomes of the first 140 taTME cases for rectal cancer [35]. Compared to his laparoscopic experience, the taTME technique is associated with a lower conversion rate (0 vs. 20 %) and shorter TME mean operative times (154 vs. 179 min) [36]. The rate of ileus (4.1, 1.3 %), anastomotic leakage (8.2, 7.3 %), pelvic fluid collection (4.1, 1.3 %), and urinary retention (1.8, 2.7 %) were similar after taTME and laparoscopic TME, respectively.

The order of the surgical steps is widely variable in the literature. The first author prefers to complete the high ligation of the inferior mesenteric vein and artery, splenic flexure mobilization, and proximal mesenteric division laparoscopically followed by a two-team combined trans-abdominal–transanal TME approach with specimen extraction via the anus when feasible, low pelvic anastomosis, and diverting loop ileostomy when indicated. This combined transanal–transabdominal TME dissection approach has resulted in similar findings of shorter operative times with early initial experience, with the shortest operative time being 295 min thus far (4 h, 55 min; 10–20 taTME case learning phase; unpublished data).

The implementation of this new technique into clinical practice can safely and effectively be achieved by surgeons with expertise in the management of rectal cancer, minimally invasive TME, and transanal endoscopic surgery. Surgeons interested in learning this new technique should have experience with rectal cancer in their surgical practice, expertise in achieving negative circumferential radial margins and grade I TME specimens after a minimally invasive approach to TME, and mastery of transanal endoscopic surgery. Given the relatively recent introduction of the taTME technique, the paucity of long-term oncologic and functional outcomes, and the lack of prospective comparative trials, additional key elements that should be acknowledged and emphasized in the process of taTME training and implementation include pre-clinical taTME cadaver training, case observation, proctoring, mentorship with ongoing feedback, participation in a clinical registry [39], ongoing peer review, and publication of the outcomes after taTME.

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Compliance with ethical standards

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