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TAMIS Assisted Laparoscopic Low Anterior Resection with Total Mesorectal Excision in a Cadaveric Series

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Abstract

Background—The purpose of this study is to demonstrate the feasibility of an innovative technique for the surgical management of rectal cancer: trans anal minimally invasive surgery assisted low anterior resection with total mesorectal excision (TAMIS assisted LAR TME) in a cadaver model. Trans anal endoscopic low anterior resection via natural orifice transluminal endoscopic surgery (NOTES) has been reported in cadaveric series using rigid trans anal endoscopic platforms. This procedure has not been described using a combination of a single incision laparoscopy and TAMIS soft trans anal endoscopic platform. Herein, we describe the first cadaveric series of TAMIS assisted single incision laparoscopic LAR with TME.

Methods—TAMIS assisted laparoscopic single incision LAR with TME was successfully performed in 5 fresh male human cadavers. The procedure was performed using the mini-Gelpoint single incision platform and the Gelpoint Path TAMIS platform (Applied Medical, Rancho Santa

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Margarita, CA). The variables recorded were age, body mass index (BMI in kg/m²), operative time, complications, and specimen length. The grade of the TME was determined by evaluation of the specimen by photo documentation by a gastrointestinal pathologist.

Results—All cadavers were male with a mean age of 71 $\pm$ 8 years and mean BMI of 28 $\pm$ 3 kg/m². The mean operative time was 200 $\pm$ 55 minutes (range 128 – 249 min). The quality of the TME was Grade I (complete) with intact mesorectum in all five cases. The mean specimen length was 36.8 $\pm$ 3.4 cm. Intra-operative complications included one bowel injury and one splenic capsular tear.

Conclusions—TAMIS assisted laparoscopic LAR with TME is feasible in this pre-clinical cadaveric series. We have also demonstrated that a high quality TME can be achieved with this technique. Trans anal endoscopic techniques employed to perform total mesorectal dissection may revolutionize the surgical management of rectal cancer. However, phase II clinical trials are needed to further evaluate the oncologic safety and surgical outcomes of trans anal endoscopic TME using various platforms prior to widespread application of this new technique.

Introduction

The combined trans abdominal, trans anal (TATA) approach for the surgical management of low lying rectal cancers was initially described by Dr. Marks and colleagues.^{1,2} The 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.¹ In 2010, Marks et al. reported their laparoscopic TATA experience over a ten year period.² 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 peri-operative mortalities. The conversion rate was very low (2.5%) as was the local recurrence rate (2.5%). All of the patients underwent a temporary diverting ostomy 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 ostomy reversal.²

With increasing interest in natural orifice surgery, there has been an increased interest in the evolution of trans anal natural orifice and minimally invasive surgical techniques. These techniques began with trans anal intraluminal surgical removal of rectal masses^{3–9} and have progressed to trans anal endoscopic surgical resection of the rectum without abdominal laparoscopic assistance.^{10–12} Investigative activity as escalated in the evaluation of proctectomy and left colectomy via a completely trans-anal approach.¹³ The feasibility and safety of trans-anal proctectomy and trans-rectal rectosigmoid resection has been demonstrated in human cadavers and porcine survival models using the rigid trans anal endoscopic platform.^{14–22} The first clinical case utilizing a rigid trans anal endoscopic platform to perform trans-anal total mesorectal excision with laparoscopic assistance in a 76 year old woman with rectal cancer (pre-operative clinical stage T2N2M0) was published in 2010.²³ The outcome of this case demonstrated patient safety, accelerated recovery, and good short term oncologic outcomes. At nearly 3-year follow up, the patient has undergone ileostomy reversal and has demonstrated no evidence of disease during her oncologic surveillance.

The largest cadaveric series investigating trans anal rectosigmoid resection for rectal cancer via natural orifice transluminal endoscopic surgery (NOTES) with total mesorectal excision using a rigid trans anal endoscopic platform in 32 cadavers was published by Telem et al. in 2012.²⁴ The majority of patients were male, mean operative time of 5.1 hours, and mean specimen length of 53 cm. Trans anal 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 trans-gastric endoscopic assistance in five cases. The mesorectum was intact in all of the specimens.²⁴

However, there are limitations to rigid trans anal endoscopic platforms including large platform size, rigidity, and prolonged set up time. Atallah et al. demonstrated the innovative use of a SILTM port for trans anal access in 2010 as an alternative to rigid trans anal endoscopic platforms.²⁵ A new term, trans anal minimally invasive surgery (TAMIS)²⁵ 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 trans anal endoscopic platforms have been overcome by the development of disposable trans anal endoscopic platforms.^{12,25–28} Zhang et al reported the use of a disposable trans anal endoscopic platform to perform a completely trans anal proctectomy for rectal cancer in a 48 year old female, BMI 20 kg/m², and intact mesorectal fascia.¹²

As the incidence of obesity is rising, maintaining abdominal access to assist the trans anal operative approach is appealing as the surgical management of many patients with lower third rectal cancers includes the creation of a temporary diverting ileostomy which can be used as the trans-abdominal access site. To date, trans anal rectosigmoid resection using a combination of a single incision abdominal laparoscopic approach and disposable platform for trans anal minimally invasive surgery has not been described in the literature.²⁷ The aim of this study is to demonstrate the feasibility of TAMIS assisted laparoscopic LAR with TME in a cadaveric model.

Methods

TAMIS assisted laparoscopic low anterior resection with total mesorectal excision (TAMIS assisted TME) was successfully performed in five fresh human male cadaver subjects. The procedure was performed using a mini-Gelpoint single incision platform (Applied Medical, Rancho Santa Margarita, CA) placed in the right lower quadrant, a typical location for creation of a temporary diverting ileostomy in conjunction with a low anterior resection for locally advanced rectal cancer (Figure 1). This is the first time the mini-Gelpoint single incision device has been utilized. A 5-mm Kii balloon blunt tip port (Applied Medical, Rancho Santa Margarita, CA) was placed in the left lower quadrant, a typical location for pelvic drain abdominal insertion site (Figure 1). A Gelpoint Path TAMIS platform (Applied Medical, Rancho Santa Margarita, CA) was utilized for trans anal endoscopic access (Figure 2).

The variables recorded were age, body mass index (BMI in kg/m²), operative time, complications, length of mobilized specimen, and the quality of the specimen. The grade of the TME was determined by a single, un-blinded surgeon at the time of the operation. The

grade of the TME was also evaluated by a single gastrointestinal pathologist based on evaluation of photo documentation of the individual specimens.

Operative Technique

The fresh human male cadaver torso is placed in the supine position. The Gelpoint Path (Applied Medical, Rancho Santa Margarita, CA) anal retractor is placed into the anus. The proximal rectum is occluded transanally with an 0-Silk purse-string suture approximately 3–4 cm from the dentate line. A circumferential full thickness dissection is then performed using manual cautery. The Gelpoint Path cap is then secured to the anal retractor component. A pneumo-rectum is then established with CO₂ (10 – 15 mm Hg) and the proximal occluding purse string suture is evaluated for complete closure and exclusion of the proximal colon and rectum.

A right lower quadrant trans rectus abdominus muscle splitting incision is made using sharp and blunt dissection with direct visual entry into the peritoneal cavity. A mini-Gelpoint single incision platform (Applied Medical, Rancho Santa Margarita, CA) is placed at this site and a pneumoperitoneum is established with CO₂ (15 mm Hg). A 5-mm port is placed in the left lower quadrant under laparoscopic vision in order to facilitate splenic flexure mobilization. The pneumoperitoneum is then reduced to 5 mm Hg so as not to interfere with the pelvic dissection CO₂ pressure.

The trans anal minimally invasive surgical (TAMIS) circumferential dissection of the rectum is then initiated at a level above the sphincter muscle complex using sharp scissor dissection and standard laparoscopic instruments in the first three cadavers. In the last two cadavers, dissection was performed with an energy device (Harmonic®, Ethicon Endo-Surgery, Cincinnati, OH). The posterior mesorectal dissection is facilitated by CO₂ insufflation and continued cephalad in the pre-sacral avascular space to the level of the sacral promontory. The left and right iliac vessels and ureters are identified at this point. The lateral dissection plane is then thinned out with anterior blunt traction and dissection. The anterior dissection is then performed with sharp dissection posterior to Denonvilliers fascia (harmonic energy device used for dissection in the last two cases). The dissection is monitored from the abdominal laparoscope and the small intestine is mobilized out of the pelvis. The peritoneal cavity is entered from the anterior TAMIS dissection plan. Once the peritoneal cavity is entered, the CO₂ pressure is equalized and thereafter maintained at 15 mm Hg from both insufflations sites. The seminal vesicles and the right and left ureters are identified and spared from injury. The anterior dissection plane is continued laterally, further thinning out the remaining lateral stalks, taking care to preserve the lateral pelvic nerve bundles. The lateral stalks are divided with a vessel sealing energy device.

The remainder of the procedure is then performed primarily from the abdominal approach with TAMIS assistance. The remaining proximal lateral peritoneal attachments of the rectosigmoid are dissected using the mini-Gelpoint single incision platform. The circumferential mobilization of the rectum is then complete. The dissection is carried proximally with TAMIS assistance in an infra-mesocolic dissection plane identifying the avascular plane caudal and cranial to the inferior mesenteric artery (similar to medial to lateral dissection technique). The inferior mesenteric artery (IMA) is then divided using a

vessel sealing energy device (Enseal®, Ethicon Endo-Surgery Inc., Cincinnati, OH) via the TAMIS platform. Splenic flexure mobilization is then continued using the abdominal single incision platform and 5-mm abdominal port. The inferior mesenteric vein is divided using a vessel sealing energy device (Enseal®, Ethicon Endo-Surgery Inc., Cincinnati, OH) via the abdominal single incision platform.

After complete mobilization of the splenic flexure, the TAMIS platform is removed from the anus. The specimen is extracted through the anus and transected extracorporeally. The specimen is then measured and photo documentation of the posterior and anterior mesorectal excision is performed for pathologic evaluation and grading of the total mesorectal excision dissection technique. A colo-anal anastomosis is then performed. A variety of techniques were evaluated and included single staple circular stapler anastomosis using the 29 mm circular stapler (Ethicon Endo-Surgery Inc., Cincinnati, OH), double staple using the 3.5 mm depth linear stapler and 29 mm circular stapler (Ethicon Endo-Surgery Inc., Cincinnati, Ohio), and hand sewn colo-anal anastomosis with interrupted 2-0 braided, polyglactin suture. The integrity of the anastomosis is evaluated laparoscopically with an air leak test.

Grading of the Quality of Total Mesorectal Excision

The quality of total mesorectal excision for each specimen was evaluated using the grading system used by The American College of Surgeons Oncology Group (ACOSOG, now ALLIANCE) Z6051²⁹ Phase III prospective randomized trial comparing laparoscopic-assisted resection versus open resection for rectal cancer. A complete TME is defined as a rectal resection specimen with an intact mesorectum and covering peritoneal envelope all the way to the level of rectal transection with no coning in of the mesorectum above the point of transection. The surface of the peritoneal covering should be smooth and shiny with no defects exposing the underlying fat (Table I).^{29,30} At the time of specimen extraction, photo documentation of the posterior and anterior mesorectal excision including the inferior mesenteric pedicle is performed for pathologic evaluation and grading of the total mesorectal excision dissection technique. The circumferential radial margin criteria were excluded in this pre-clinical cadaveric series. The grade was determined by the surgeon at the time of the procedure and recorded. The photos of the specimen were also separately evaluated by a pathologist and the grade was determined and recorded.

Results

All cadaveric subjects were male with a mean age of 71 $\pm$ 8 years and mean BMI of 27.6 $\pm$ 2.7 kg/m² (Table II). The mean operative time was 200 $\pm$ 55 minutes (range 128 – 249 min). The quality of the total mesorectal excision (TME) was Grade I (complete) with intact mesorectum in all five cases graded by the gastrointestinal pathologist and Grade I (complete) in four cases and Grade II for mild coning in one case by the colorectal surgeon (Figure 3). The mean specimen length was 36.8 $\pm$ 3.4 cm and width 10.1 $\pm$ 1.5 cm.

Complications included one large bowel injury and one splenic capsular tear. The large bowel injury occurred in the descending colon during laparoscopic splenic flexure mobilization phase of the procedure and was utilized as the site of colo-anal anastomosis. The injuries occurred in different patients the first and second cases. No complications

occurred in the final three operations. There were no anastomotic leaks based on air leak testing.

The right and left ureters were identified in all cases except one case in which the cadaver had undergone a radical right nephrectomy. The left ureter was identified first in most cases with a mean time for trans-anal ureter identification of 69.8 $\pm$ 32 min. The mean time for trans-anal identification of the right ureter was 86.2 $\pm$ 26 min.

The mean time of trans-anal anterior peritoneal entry was 66 $\pm$ 19.6 minutes. The trans-anal IMA ligation mean time was 106 $\pm$ 40.8 minutes. The mean time to completion of the splenic flexure mobilization was 148 $\pm$ 50.5 minutes. The IMV was typically divided near the completion of the splenic flexure mobilization with a mean division time of 142 $\pm$ 59.3 minutes. The distal rectal division distance from the dentate line ranged from 2 – 4 cm. The anastomosis distance from the dentate line ranged from 2 – 3 cm.

Discussion

Trans anal minimally invasive surgery (TAMIS) assisted laparoscopic low anterior resection with total mesorectal excision (TME) is a feasible approach for the surgical management of rectal cancer. A single incision abdominal approach is appealing as the surgical management of many patients with low lying rectal cancers includes the creation of a temporary diverting ileostomy. Appropriate training will be essential for safe adoption of this technique as a poor quality TME for rectal cancer is associated with poor quality oncologic outcomes including increased local recurrence rates and earlier cancer related mortality.

The feasibility and safety of natural orifice surgery such as trans-anal proctectomy and trans-rectal rectosigmoid resection has been demonstrated in human cadavers, porcine survival models, and human subjects using the rigid trans anal endoscopic platforms.²⁻¹⁰ There was initial speculation that the shorter length of the soft platform Gelpoint Path used in this investigation would limit proximal reach and dissection. The longer channel Gelpoint Path platform was evaluated (unpublished data) and did not improve proximal reach or assist in rectal dissection in the preliminary cadaveric experimental cases. The longer channel was not used in this cadaveric series of five. The longer channel was subjectively more difficult to maneuver and limited dissection and traction ability with the use of the long channel and standard laparoscopic instrumentation.

The mean specimen length was longer in the trans anal rectosigmoid resection for rectal cancer via natural orifice transluminal endoscopic surgery (NOTES) with total mesorectal excision using the TEM platform cadaveric series compared to this series.¹¹ This may be due to the difference in technique in specimen length measurement. In the TEM cadaveric series, the specimen was measured prior to proximal division with some tension and stretching on the specimen, thereby elongating the specimen.¹¹ In this series, the specimen was measured on the back table after proximal division, without any gravitational traction.

The wide range in operative time in this series was likely due to variation in dissection technique and a reflection of the learning curve. In the first three cases, dissection was carried out with scissors primarily with the use of energy vessel sealing devices for division

of named vascular structures only. There was a trend towards reduced operative time with each case in these first three cases. In the last two cases, tissue dissection was carried out using energy vessel sealing devices for the as well as division of major vascular structures (249 min vs. 128 min, Table II). Again, there was a trend towards reduced operative time in the last two cases (259 min vs. 172 min, Table II).

A potential criticism of this study may be that the abdominal portion of the operation is not a pure single incision approach as two incisions are utilized: an incision at the site of the temporary ileostomy, and a second incision where a pelvic drain may exit the abdominal cavity. At this time, the surgical management of the majority of patients with low lying rectal cancers includes the creation of a temporary diverting ileostomy and the use of a pelvic drain exiting the abdominal cavity in the opposite quadrant. The authors elected to utilize these two sites for abdominal incisions for this study to assist with splenic flexure mobilization. This technique has also been reported using a rigid trans anal endoscopic platform.²⁷

Compared to current minimally invasive abdominal approaches (including robotic surgery), the authors have observed improved low pelvic visualization and dissection with the TAMIS approach. Specifically, the visualization is improved dramatically during the anterior dissection for TAMIS total mesorectal excision. In addition, visualization of the lateral pelvic nerves subjectively appears to be significantly improved compared to current minimally invasive abdominal TME dissection techniques. However, definitive conclusions for or against improved visualization is limited to this cadaveric series and will need to be further evaluated in the clinical setting.

Conclusions

While the results of national and international randomized clinical trials comparing open and minimally invasive total mesorectal excision (TME) for rectal cancer are long-awaited, a trans anal assisted endoscopic approach may represent the next step in the evolution of minimally invasive colorectal cancer surgery. The safety and oncologic outcomes of trans anal assisted endoscopic TME using various platforms need to be further investigated in the setting of carefully conducted phase II clinical trials.

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Figure 1.
Abdominal Port Placement

Figure 2.
Combined Set Up

Figure 3.
Specimen

Table IGrading System for Quality of Total Mesorectal Excision for Rectal Cancer¹⁴

	Mesorectum	Defects	Coning
I – Complete	Intact, smooth	Not deeper than 5 mm	None
II – Nearly Complete	Moderate bulk, Irregular	No visible muscularis propria	Moderate
III - Incomplete	Little bulk	Down to muscularis propria	Moderate – marked

Modification Note: Circumferential Radial Margin (CRM) not applicable in this cadaveric series

Table II

TAMIS assisted Laparoscopic TME Operative Results

Case #	Sex	Age (yr)	BMI (kg/m ³)	Operative Time (min)	Distance From Dentate Line		Specimen Length (cm)	TME Grade (pathologist)
					Distal Rectal Division (cm)	Anastomosis (cm)		
1	M	72	27	249	2	2	38	I
2	M	69	30	192	4	2.5	32	I
3	M	82	23	128	3	2	41	I
4	M	72	29	259	2	2	38	I
5	M	60	29	172	3	2.5	35	I