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HOW I DO IT

Transanal Minimally Invasive Surgery (TAMIS): Standardizing a Reproducible Procedure

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Abstract
Background The recent introduction of transanal minimally invasive surgery (TAMIS) offers a safe and cost-effective method for the local resection of rectal neoplasms. The ability to standardize a technique for TAMIS will lead to the most reproducible outcomes and enable teaching.
Methods A retrospective, IRB-approved chart review was conducted of 32 patients who underwent the TAMIS procedure at one institution over a 3-year period.
Results TAMIS was performed for 11 benign and 21 malignant lesions. The majority of resections were full thickness (29/32) and all were R0. Average distance from the anal verge was 7.5±3 cm, defect circumference was 43.7±10 %, operative time was 131±80 min, and length of stay was 1.1±1 days. Two patients had morbidities requiring readmission and further treatment for (1) an aspiration pneumonia with CHF exacerbation and (2) a rectal abscess.
Conclusions This report outlines an operative technique for TAMIS that is reproducible for the excision of rectal lesions, associated with low morbidity.

Keywords Transanal minimally invasive surgery · Laparoscopy · Rectal neoplasms

Introduction

Transanal full thickness local resection techniques, such as transanal minimally invasive surgery (TAMIS), are not new procedures but have been evolving for many years[1] as alternative methods of providing curative surgical therapy for benign and early stage malignant lesions of the rectum. In select high-risk patients, a transanal approach has the potential to aid in the management of local disease as part of a multimodal approach with chemoradiation therapy. Without a transanal approach, these lesions would otherwise only have resection options which involve a more morbid procedure requiring an anastomosis and/or an ostomy. Such resections which provide a total mesorectal excision include an intraabdominal low anterior resection, abdominoperineal resection (APR), abdominal sacral resection (ASR), and Kraske approach.[1] Another alternative without a transanal approach for the local management in high-risk patients with malignant rectal lesions is primary radiation therapy which also has attendant morbidities. Traditional transanal excision (TAE) has the primary goal of preserving the anus and avoiding the associated morbidity of resection, but requires standard anal retraction devices, scopes, and instruments that may limit a surgeon's ability to visualize lesions that are very proximal or very distal.[1] This led to the development in the 1980s of transanal endoscopic microsurgery (TEMS). Long-term results from this method

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showed that TEMS was superior in overall outcomes to TAE in terms of lower recurrence and better R0 margins.[1] However, despite the enhanced visibility and ease of removing a wider variety of lesions with TEMS, TAE has remained a more common procedure.[1] The limitation of TEMS includes its cost, specialized equipment, and increased technical training time for proficiency.[1]

The advent of laparoscopic approaches in the 1990s again changed the landscape in the management of rectal disease.[1] TAMIS was started in 2009, with selection criteria for the management of lesions being similar to that of endoscopic and TEMS platforms. TAMIS use is not designed therefore to replace the indications for APR, Kraske, or ASR. TAMIS offers the advantages of greater technical maneuverability and simplicity of instrumentation, in an effort to develop a minimally invasive transanal resection technique that would allow for full thickness local excision of rectal lesions with the visibility and superior outcomes of TEMS, but that would also be more cost effective and teachable.[1] The cost structure is changed from TEMS given the use of different trocars and platforms.[1] Several authors have reported their early experience with the TAMIS technique as a modification of a single site laparoscopic port platform, which was developed for transabdominal surgery, as the predecessor to the GelPOINT (Applied Medical, Rancho Santa Margarita, CA).[2] For example, Hompes et al. report the use of an anal dilator with wound protector and glove to create a port for trocars which also allowed for CO_2 insufflation of the rectum.[3] Many surgeons also report using single port access techniques to modify the TEMS procedure, such as the SILS port (Covidien Norwalk, CT) or TriPort (Olympus KeyMed Southend, UK), and ultimately switched from endoscopic to laparoscopic instruments in the advent of the TAMIS concept.[4–6] There are approximately eight different platforms described in the literature, which has led to the creation of what is known as the TAMI S device or GelPOINT Path.[1]

Although TAMIS has been introduced in the literature, there are only a few series and adoption has been modest for the surgical management of benign and early stage, low-risk profiled malignant rectal lesions. The data published thus far supports local resection of rectal lesions in a safe and effective manner, although the data are short term. With its growing adoption and favorable clinical results, the TAMIS procedure can benefit from a standardized technical approach.

The only comparison for the technique of TAMIS is with endoscopic snaring therapy and not TEMS. TAMIS gives us dexterity from different angles, while endoscopic methods can only pass devices in a linear fashion along the scope working channel. Herein, we offer our set-up and step-by-step operative technique, in an effort to increase adoption by surgeons with basic laparoscopy skills and equipment, which will ultimately lead to greater availability to patients.

Preoperative Evaluation

Thirty-two patients underwent TAMIS from December 2011 to October 2014 (Table 1). Most patients had an endoscopic attempt at biopsy or resection of an identified lesion and their pathology confirmed. Of the 18 patients who underwent preoperative imaging to assess depth of invasion or identify any lymph node disease, 7 had both pelvic MRI and endorectal ultrasound (ERUS) while 3 had only MRI and 8 had only the ERUS. Of note, one patient had presented after a prior TEMS attempt at removal of the lesion and one patient had a sessile lesion that was unable to be biopsied. One patient underwent two TAMIS excisions. One patient underwent preoperative neoadjuvant chemoradiation for a locally advanced rectal adenocarcinoma prior to undergoing TAMIS.

Patients with rectal adenocarcinoma were offered TAMIS as an alternative to segmental resection if the rectal lesion had favorable histopathologic features. These features included T1 rectal lesions lacking evidence of lymph node metastases characterized by ERUS or pelvic MRI, located 2–13 cm from the anal verge, and lacking high-risk pathologic features including poor differentiation, lymphovascular invasion (LVI), perineural/venous invasion (PNI), signet cells, and mucinous subtype. In addition, patients deemed high risk for transabdominal resection with an ASA classification of 4 were offered a TAMIS procedure for resection of high-risk T1, T2, or T3 lesions. One patient was a conversion to TAMIS from an endoscopic transanal resection attempt in the operating room.

A standard mechanical bowel preparation preoperatively included a regimen of 238 g of oral powder Miralax, two 32 oz bottles of Gatorade, one bottle of magnesium citrate,

Table 1 Patient and preoperative demographics

Demographic	Range	Mean	SD
Age (years)	44–87	65	+/−12
ASA class	2–4	2.6	+/−1
BMI	18–41	27	+/−6
Demographic		*N*=32	%
Male		17	53
Female		15	47
Endoscopic biopsy or resection		30	94
Imaging (ERUS and/or pelvic MRI)		19	59
Neoadjuvant therapy		1	3
Adenocarcinoma		14	44
Tubulovillous adenoma		9	28
Carcinoid		4	12.5
Tubular adenoma		3	9
Solitary rectal ulcer		1	3
Sessile adenoma		1	3

ASA American Society of Anesthesiologists physical status classification, *BMI* body mass index (kg/m^2), *ERUS* endorectal ultrasound, *MRI* magnetic resonance imaging

Dulcolax laxative tablets, oral neomycin, and oral Flagyl, all taken on the day prior to surgery.

Operative Technique

The principle steps to TAMIS are as follows: exposure, excision, and defect closure.

After appropriate consent and time out procedures are done, the patient is given single doses of weight-based cefazolin and metronidazole as a prophylactic intravenous perioperative antibiotic coverage for enteric flora. For patients with a penicillin allergy, we substitute these antibiotic choices with clindamycin and aztreonam (based upon our institution's pharmacy recommendations). In our practice, we do not routinely give preoperative chemoprophylaxis for venous thromboembolism; however, sequential compression devices are placed prior to induction of general endotracheal anesthesia. Patients are given appropriate neuromuscular blockade to minimize battling with the Valsalva effects of intraabdominal pressure. The patient is placed in high lithotomy and slight Trendelenburg. An advantage of TAMIS is that lesion location does not alter the patient positioning, as all lesions are can be accessed with the patient in lithotomy (Fig. 1). A single monitor is placed over the patient with surgeon on patient right and assistant on patient left. Clipping is done perianally as indicated. Wide perineal and perianal skin preparation and draping are done in standard fashion.

The required equipment is commonly found in laparoscopic surgical suites (Fig. 2a, b). We routinely examine the perianus and perform a digital rectal exam with gentle anal dilation prior to insertion of the TAMIS device into the anus. The GelPOINT Path TAMIS device is anchored in the anal canal with a 0-silk suture on opposite sides laterally (Fig. 1). The GelPOINT Path is oriented in the patient such that the camera port is superior and the two working ports are inferior in a triangular pattern. We recommend use of the SurgiQuest device (AirSeal Milford, CT) as it allows for retention of pneumorectum with smoke evacuation, allowing for optimal visualization during the procedure over standard laparoscopic insufflation. The increased circulating CO_2 aids in clearing the condensation generated when using diathermy on the mucosa. We recommend suturing the SurgiQuest device to the gel pad to anchor it. We use two 5 mm ports and a 5 mm/30° scope. A 30° scope is recommended for optimal visualization. CO_2 insufflation of 10–15 mmHg is used, and occasionally, short periods of up to 18–20 mmHg of pressure may be useful for visualization.

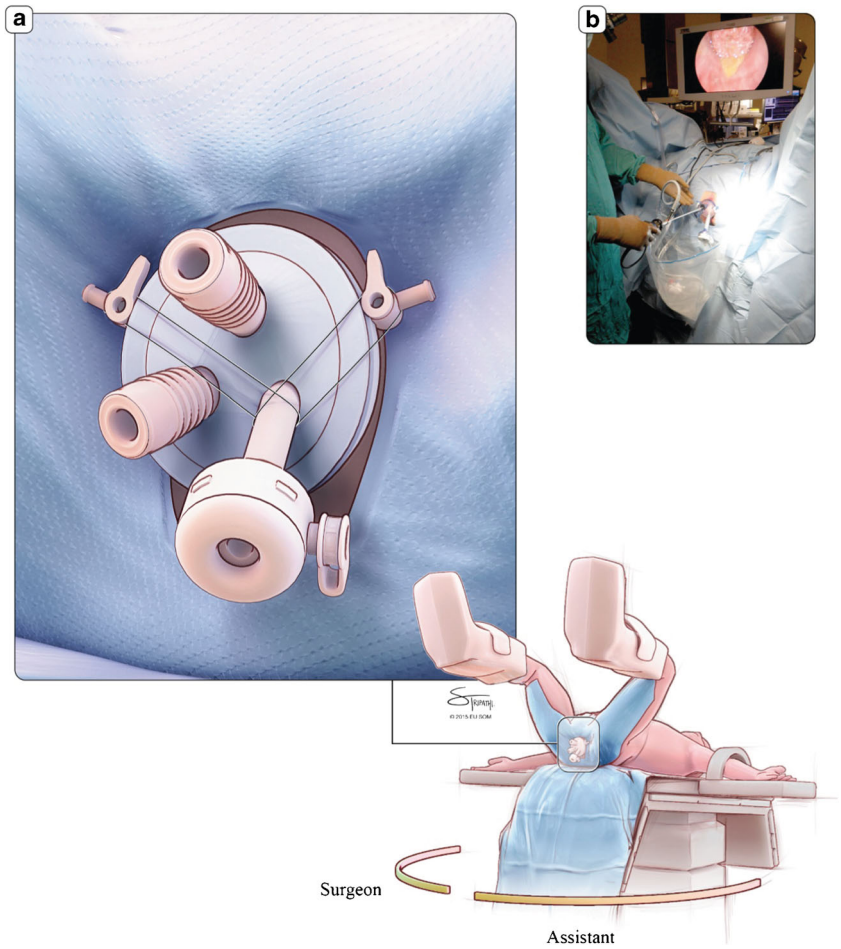

Fig. 1 Patient positioning and TAMIS device setup. Patient is positioned in lithotomy with TAMIS device in place. The surgeon stands to the patient's right side while the assistant stands on the patient's left side. Monitors can be set up above the patient's torso over either shoulder close to midline view. **a** The *inset* provides a magnified view of the components of the TAMIS device, namely two 5 mm trocars and a SurgiQuest device kept in place with stay sutures. **b** Intraoperative photo of patient positioning with TAMIS device in place

Fig. 2 Laparoscopic instruments and equipment necessary to perform a TAMIS. **a** From *top to bottom*: laparoscopic needle driver, loaded Lapraty, 2-0 vicryl suture cut to 15 cm with Lapraty, laparoscopic grasper, laparoscopic scissors, laparoscopic hook, 5 mm suction irrigator tip, and a 5 mm/30° laparoscope. **b** Sample preference card listing the necessary equipment to perform a TAMIS

Hook diathermy is used for lesion excision (Fig. 3). The laparoscope is kept as far distal in the rectum as possible to allow for visualization but avoid collisions with the working instruments. Once the lesion is identified, the lesion is lifted with an open jaw grasper technique to avoid bleeding and breaking which is possible if it is mishandled. The mucosa is marked by a hook cautery device to ensure the desired margin of resection. We mark the mucosa where there is normal looking mucosa, but prefer 0.5 cm margins when possible. In our experience, the hook diathermy most easily facilitates the excision of all lesions regardless of size or location. Energy devices such as the Harmonic scalpel (Ethicon), EnSeal (Ethicon), and LigaSure (Covidien) are more bulky in their space requirements and also do not facilitate margin marking as a hook device does. A stapling device would not only be bulky and have awkward angulation, but it would be difficult to ensure a full thickness excision. A straight plane down to mesorectal fat for a full thickness excision of the rectal wall is then completed. It is important to identify the yellow adipose tissue of the mesorectum as this signifies a full thickness resection. We can do a mucosal excision if we know on ERUS or MRI that this is benign disease and the disease is limited to the mucosa. Often when using diathermy on the mucosa, condensation is produced and although commonly cleared with the SurgiQuest; it occasionally can be additionally cleared for a more optimal view by use of a suction-irrigator device kept in the rectum. Gentle suctioning will evacuate the obscuring condensation while maintaining pneumorectum.

The excised specimen can be marked for orientation as desired. Additional margins can be excised as desired, but we have not yet had to do this in our experience thus far. Deep excision into the mesorectum should be avoided as this may result in retroperitoneal air tracking in the mesorectal plane. The anterior peritoneal reflection can be low (7–8 cm from the anal verge) especially in females, and the surgeon should exercise caution as a full thickness resection may result in entry into the peritoneal cavity. We have not yet

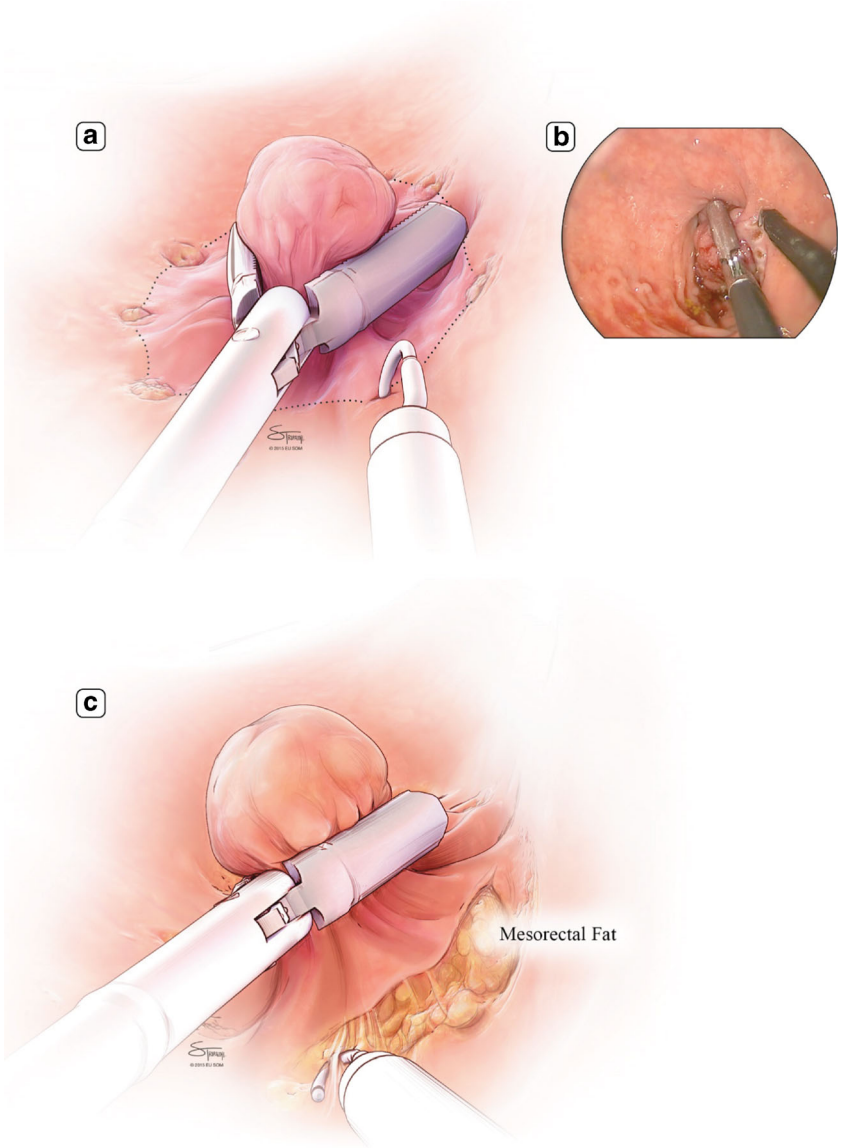

Fig. 3 Hook diathermy is used for lesion excision. **a** First the lesion with margins is marked with cautery. **b** Intraoperative photo of hook cautery usage for marking around lesion. **c** Then the lesion is excised in a full thickness fashion with cautery down to mesorectal fat (labeled)

encountered this issue. If the peritoneal cavity is entered, however, a laparoscope can be easily inserted into the abdominal cavity to facilitate performance of a leak test after closure of the rectal defect. If a lesion is located very proximal, it can be brought into view by ensnaring it with an Endoloop (Ethicon Somerville, NJ) (Fig. 4). We have employed this technique with success on several occasions.

Closure of the defect is best accomplished with 2-0 free vicryl sutures cut to a length of 15 cm and Lapraty (Ethicon) preformed knots (Fig. 5). Bulkier instruments such as an Endo Stitch (Covidien) may require more skill and also make some angles difficult to achieve. The Lapraty avoids the need for intra- or extracorporeal knot tying skills. The suture should approximate but not induce ischemia of the tissues and full thickness bites of the rectal wall should be used. The closure is most easily accomplished by first placing a simple interrupted or figure-of-eight suture at the middle of the defect. Either side of the defect can then be closed with either interrupted or continuous suture closure. Longer running suture lines have the tendency to lose tension and unravel if continuous tension is not applied. The closed defect is inspected and simple interrupted sutures can be placed if needed in areas requiring additional closure.

A suction-irrigator device is a good tool to have on hand to aid in visualization. We have not had any major bleeding complications intraoperatively but standard laparoscopic hemostasis techniques can be utilized in such a situation. We routinely perform a colonoscopy with air insufflation at the conclusion of the operation to demonstrate easy passage of the scope and ensure no

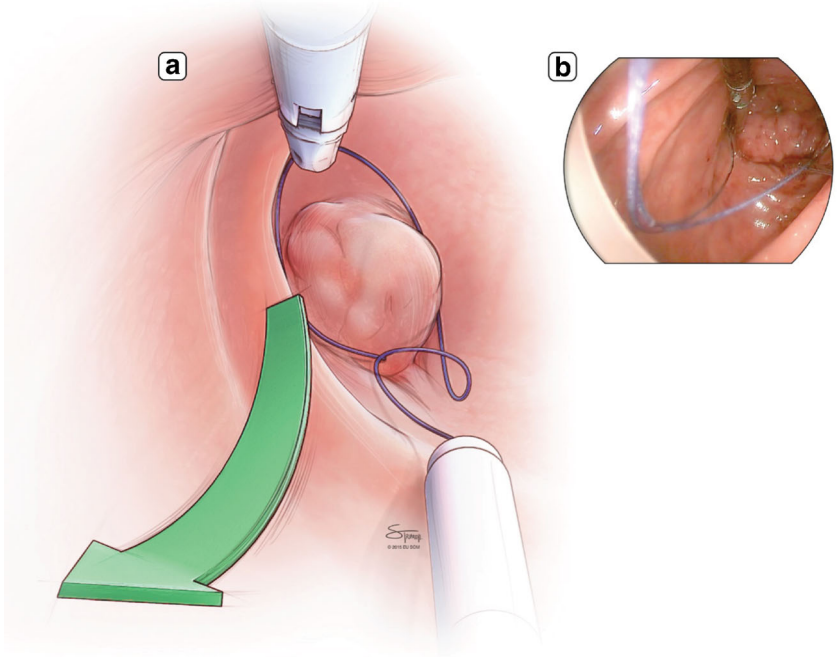

Fig. 4 The usage of an endoloop is depicted. **a** The endoloop is used to aid in the exposure of very proximal lesions. It can be cinched around the stalk of the lesion in order to bring the lesion down into view, as suggested by the *arrow*, and provide traction for excision. **b** Intraoperative photo showing the usage of an endoloop

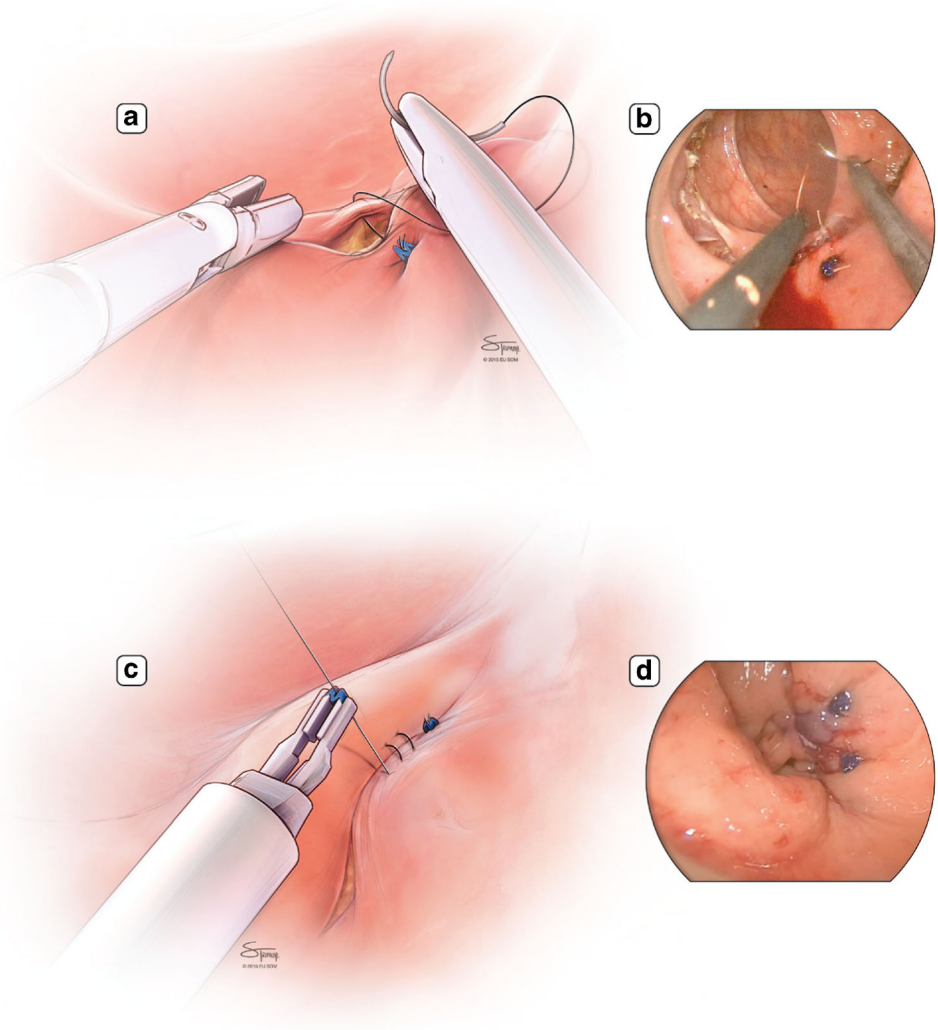

Fig. 5 Closure of the rectal defect is done with a free suture and Lapratys. **a** The defect is first brought together in the middle by an interrupted suture. **b** Intraoperative photo of defect closure with suturing and Lapraty. **c** Running sutures then complete the closure and Lapratys are used to avoid the need for knot-tying. **d** Intraoperative photo of completed defect closure

narrowing has been done to the rectum at our area of closure. After cleaning the perineum with saline, we place an ABD pad and mesh panties.

Postoperative Care

Patients are discharged the same day or admitted for 23 h observation if there are any concerns. There are no diet restrictions. Oral narcotic pain medication is prescribed if needed for perianal pain. If admitted for observation, no fluids or subcutaneous DVT prophylaxis is given routinely. Patients are scheduled for follow-up in 6 weeks. A physical exam and digital rectal examination with anoscope are done routinely at the postoperative visit. The pathology is reviewed and the recommended surveillance is scheduled. If the pathology shows high-risk features or positive margins, T2 or higher invasion, or lymph node disease, we would recommend immediate segmental resection. There has not yet been long-term follow-up for us to adequately address the topic of recurrence.

Operative and Postsurgical Outcomes

Perioperative results are summarized in Table 2. Following the initial endoscopic biopsy or attempted excision, residual lesions were found in 22 patients undergoing TAMIS while 10 had no residual disease on pathology. Two patients had multiple sites/lesions resected in the same procedure, but the larger/more concerning lesion is reported here. For patients with adenocarcinoma, their pathology was T_{IS} or T1 with low-risk features as detailed previously. For patients with carcinoid, these were all low grade (grade 1), well differentiated, and the greatest depth was to the muscularis propria. R0 margin resections were achieved for all malignant lesions if not full thickness resections. Two patients had non-local recurrent disease, which was a distant metastasis, and a second primary. One of these patients had familial adenomatous polyposis. One patient was found to have a synchronous sigmoid cancer and opted for a TAMIS of the rectal lesion to limit the segmental resection required for the more proximal colonic sites. Our follow-up is limited to a mean time of 2.72±4.11 months (range 0–19 months). Some patients were also lost to follow-up, as in our Veterans Administration Medical Center patients.

Even with a less invasive operation, there were complications observed within our cohort (Table 3). The patients who suffered major morbidities requiring readmission were of an ASA class 2 or 3. One patient experienced immediate postoperative tachycardia, leukocytosis, and hematuria which all resolved but required an initial stay of 4 days and then was readmitted for an aspiration pneumonia and congestive heart failure exacerbation which were treated medically and required a course of outpatient oral antibiotics after a 4-day hospital stay. One patient with a rectal abscess due to a posterior rectal sinus had an initial 1-day stay with perianal pain and then required a 14-day hospital stay which included concomitant acute kidney injury and urinary tract infection, a diverting Hartman's procedure, and subacute rehabilitation disposition. This patient had a BMI of 33, was an ASA 3, and had

Table 2 Summary of operative and postoperative results

Result	Mean	SD	Range
Results reported by average			
Tumor size (cm)	2.1	+/−1	0.3–5
Distance from anal verge (cm)	7.5	+/−3	2–13
% Rectal circumference of defect	43.7	+/−10	25–60
Operative time (min)	131	+/−80	60–360
Estimated blood loss (ml)	21.7	+/−32	0–100
Length of stay (days)	1.1	+/−1	0–4
Result		*N*=32	%
Results reported by percentage			
Location of tumor			
Anterior		15	47
Anterolateral		4	12.5
Lateral		1	3
Posterolateral		1	3
Posterior		7	22
Undocumented[a]		2	6.3
Pathology			
Malignant		21	66
Benign		11	34
Adenocarcinoma		15	47
Carcinoid		4	12.5
Hamartomatous polyp		1	3
Hyperplasia		1	3
Tubulovillous adenoma		7	22
Tubular adenoma		4	12.5
Concordance of diagnosis		25	78
Full thickness excision		29	91
R0 resection for malignancy		21	100
Specimen fragmentation		0	0
Lymph node in specimen		4	12.5
Operative data			
Lithotomy positioning		27	84
GETA		32	100
Conversion		0	0
Postoperative data			
Readmission		2	6.25
Follow-up with surveillance		9	28
Recurrence		2	6.25
Mortality		0	0

GETA general endotracheal anesthesia

[a] The location was not documented in the operative report

Table 3 Complications

Complication	*N*=32	Percent
Minor morbidity (resolution in immediate postop period)	14	44
Urinary retention	3	9
Fecal incontinence	1	3
Perianal pain	2	6.25
Blood per rectum	4	12.5
Other (diarrhea, ulceration at resection site, hypovolemia)	4	12.5
Major morbidity (requiring readmission)	2	6.25
Aspiration pneumonia, CHF exacerbation	1	3
Rectal abscess	1	3

undergone neoadjuvant chemoradiation therapy after ERUS with good response for a T2N0 lesion that was then restaged as T1N0. The case was presented at a multidisciplinary oncology conference prior to undergoing TAMIS for full thickness resection. Operative pathology showed 1/1 negative lymph nodes and a low grade moderately differentiated 0.6-cm T1 adenocarcinoma lesion without LVI or PNI and with negative margins. The patient subsequently went on to have a stage 4 disease, confirmed on CT scan at 9 months follow-up from the initial TAMIS resection. This case represents our only major, and significant, complication.

Our outcomes for this technique are comparable to what is reported in the literature (Table 4). Our series is small and follow-up is short in length. Our outcomes appear no worse than endoscopically treated lesions; however, interpretation of our data is limited in that long-term outcomes are not yet available.

The curative results for early stage and low-risk malignant lesions, including neuroendocrine tumors, are promising with respect to the published data for TAMIS. Most published results are short term, but thus far show minimal local recurrence and that preoperative radiation therapy does not increase complication rates.[1,7] Full thickness, negative margin resections seem to be the standard with this approach as well.[1,7] One of the largest single institution published series by Albert et al.,[7] had a median of 20 months follow-up for 50 patients between 2009 and 2011. Half of the lesions they resected were for malignancy. They report complete excisions for all, except in three patients with microscopic positive margins, and two recurrences at 6- and 18-month follow-up periods. The recurrences were noted to be in a patient with a positive margin after villous adenoma resection and in a patient with pT1 with LVI. Both patients had further surgical excision and suffered no adverse sequelae. The patients with positive margins or found to have upstaged tumors of pT2 or pT3 on final pathology were offered further medical and surgical therapy as appropriate and did not experience adverse sequelae. The results of this series suggest the potential for the use of TAMIS in the management of low-risk, early stage malignant lesions of the rectum with curative intent but there were two recurrences in this study. We also note that in this series, TAMIS was offered to patients with high comorbid risks to an intraabdominal resection for a malignant lesion. So far, these patients have not exhibited recurrence. Hence, there is current discussion of the appropriate patient population to which TAMIS should be utilized in the setting of an oncological approach of rectal adenocarcinoma which are T_{IS} (invasion to the lamina propria) and T1 (invasion to the submucosa), without high-risk features (lymph node disease, PNI, LVI).

Currently, TAMIS has been reported to include robotics[8] and combined abdominal approaches.[9] It is also being employed in the removal of foreign bodies, in the repair rectourethral fistulas, and in the ligation of Dieulafoy lesions.[9] It does however have limitations, such as the requirement of a first assistant to hold and manipulate the laparoscope. TAMIS also does not avoid the need for general endotracheal anesthesia in high-risk surgical candidates. Advantages however are low operative times and avoidance of the morbidity of major abdominal/perineal approaches. It has also been shown to lack complications when performed in patients after undergoing neoadjuvant radiation therapy.[1,7] The TAMI S device is also cost-effective compared to the TEMS

Table 4 Reported published outcomes

Author-year	No.	Platform	Location from anal verge (cm)	Size (cm)	Mean OR time (min)	Margin status	Pathology	Complications
McLemore et al. 2014[1]	32	GelPOINT Path	1–11	0.5–8.5	123	Positive (1)	Benign (13) Adenoca (16) Carcinoid (3)	5; UTI, C. diff, Afib, Rectal stenosis, bleeding
Albert et al. 2013[2]	50	GelPOINT Path	3–14	0.7–6	75	Positive (3)	Benign (25) Adenoca (23) Carcinoid (2)	3; scrotal emphysema, COPD exacerbation, bleeding

platform,[1] largely due to its multichannel port capability which utilize basic and familiar laparoscopic instruments. Overall, the use of CO_2 insufflation with a laparoscope enables the excision of large lesions, both proximal and distally located, in a full thickness manner due to a wide workspace and 360° view.

In summary, our data suggests favorable outcomes when applied to well-selected rectal lesions. The results of TAMIS are promising and the interest in it continues to grow amongst surgeons. Thus, this complex procedure needs standardization to allow for more widespread adoption, adherence to oncologic principles, and maintain low morbidity compared with other approaches. We have described here our operative technique for the local excision of benign, pre-malignant and early stage malignant rectal tumors using the TAMIS method. Our approach, although not easy, is feasible, reproducible, safe and effective, and can serve as a guide to other surgeons who wish to offer this approach to suitable patients.

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