

Review

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Conventional and robotic transanal minimally invasive surgery for rectal neoplasia

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Abstract

The treatment of rectal cancer is evolving at a rapid pace in parallel with advancements in surgical technique. One such advancement is the application of the laparoscopic platform to the transanal approach, coined transanal minimally invasive surgery (TAMIS). TAMIS overcomes many of the shortcomings of the traditional transanal approach to the local resection of rectal neoplasia, offering greater visualization and access to the middle and upper rectum with improved oncologic outcomes. Following the introduction of conventional TAMIS, the robotic platform was introduced and applied in analogous fashion. Over the past decade, data have accumulated enabling the comparison of the two approaches most notably with regard to patient morbidity, mortality, and oncologic outcomes. This review discusses the most recently available outcomes regarding conventional and robotic TAMIS and provides a comparison of the two platforms in the treatment of rectal neoplasia. While randomized controlled trials comparing the two platforms are lacking, important differences have been identified. Conventional TAMIS is the more cost-effective approach while advancements in the robotic platform allow the surgeon to be seated and ergonomically optimized, allowing greater visualization and ease of suturing. Differences in oncologic outcomes between the two platforms have not been identified. Head-to-head randomized controlled trials are required to determine if any differences in functional or oncologic outcomes exist.

Keywords: Rectal cancer, transanal minimally invasive surgery(TAMIS), laparoscopy, robotic surgery



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INTRODUCTION

Our understanding of rectal cancer is advancing at a rapid pace. Treatment options have expanded requiring surgeons to be facile at not only traditional open surgery, but also minimally invasive techniques, such as the laparoscopic and robotic platforms. Minimally invasive surgery techniques have been applied not only to the intra-abdominal approach, but also transanal approach as well. Atallah, Albert and Larach were the first to report this application in their seminal paper describing the approach of single-port laparoscopy, coining the term transanal minimally invasive surgery (TAMIS) in 2009^[1]. TAMIS was established to serve as an alternative to transanal endoscopic microsurgery (TEM). Both TEM and TAMIS demonstrate superior oncological results over traditional transanal excision (TAE)^[2]. While TEM is safe and effective for the treatment of early rectal cancer, its widespread use has been hampered by its high cost of specialized instrumentation and steep learning curve^[3,4]. TAMIS is a technique of single-port laparoscopy enabling the use of widely used laparoscopic instruments with the access of TEM, with reduced cost and possibly less trauma to the anal sphincter^[1,5]. The TEM platform offers improved access to higher lesions with retraction of the rectal valves.

INDICATIONS FOR TAMIS

The indications for TAMIS have traditionally followed the same guidelines as for open transanal excision of rectal tumors set forth by the National Comprehensive Cancer Network (NCCN)^[6]. Tumors should be < 3 cm in size and encompass less than one-third of the circumference of the bowel lumen. However, TAMIS overcomes many of these historical limitations of TAE by offering greater access to middle and upper rectal lesions and improved visualization in a confined operating field. Lesion location is usually < 15 cm from the anal verge and because of the seating of the transanal platform (discussed below), tumors less than 4 cm from the anal verge may require a hybrid approach with traditional TAE. Tumor pathology must be favorable. Thus, benign disease (polyps without submucosal invasion or excisional biopsy for masses of uncertain malignant potential) or uT1 malignant disease with favorable tumor characteristics (no lymphovascular invasion, perineural invasion, or mucinous component) are appropriate^[7,8]. TAMIS also has a role in local excision following incomplete polypectomy to provide negative margins, as well as in cases of palliative resection in patients who are unfit for total mesorectal excision (TME)^[9]. The quality of local excision appears to be equally achieved as that by TEM^[10]. Following excision, if any high-risk features are identified, such as sm3 invasion, lymphovascular invasion, or positive margins, further treatment is recommended^[11]. Notably, no negative effects are seen on oncologic outcomes for subsequent radical resection^[12].

OPERATIVE OVERVIEW

TAMIS is traditionally performed under general anesthesia, but spinal anesthesia has also been described^[13-16]. Advocates for spinal anesthesia have suggested that this modality offers more stable pneumorectum due to improved rectal wall relaxation^[14]. Once the transanal port is inserted and pneumorectum is established, the lesion is identified, and a 0.5-1.0 cm margin is marked circumferentially using electrocautery. Either full thickness or submucosal dissection ensues. Once excised, the specimen is oriented and sent to pathology. Pneumorectum is reestablished under slightly reduced pressure to allow for closure of the defect^[17]. Should there be inadvertent intraperitoneal entry, standard laparoscopic abdominal access can then be established with ports placed to assist with retraction for excision of the specimen as well as closure of the defect^[1,17]. It has also been shown that the defect may be left open, in the absence of peritoneal entry, and it is generally done if a tension-free repair is not deemed possible^[18]. However, if left open, there may be an increased risk of postoperative bleeding^[19,20]. Although an increased risk of infection may also be a concern with an open defect, this has not been conclusively shown^[18-20].

TECHNICAL DETAILS

Patients may be positioned according to surgeon preference. Some prefer to always position patients in high dorsal lithotomy regardless of tumor location ensuring abdominal access, should there be inadvertent peritoneal entry^[1,11,15,21]. Others prefer patients to be positioned to allow the target lesion to be centered at the 6 o'clock position. Thus, patients with anterior tumors are placed in prone jackknife, and patients with posterior tumors are placed in dorsal lithotomy^[17,22,23]. Lateral decubitus position is utilized for lateral tumors^[23]. Split-leg position is necessary to facilitate exposure in lateral decubitus or prone jackknife^[17].

Multiple ports have been described and utilized. Currently, there are two FDA-approved devices. Atallah *et al.*^[1] initially described TAMIS with a single-incision laparoscopic surgery port (SILS™ Port, Covidien, Mansfield, MA), which is lubricated and introduced into the anal canal by steady manual pressure anchoring just above the anorectal ring. Once in place, endoscopic access is gained and pneumorectum is established. The SILS port is made of a soft, flexible thermoplastic elastomer allowing for conformity and provides for three cannulas enabling instrumentation with commonly used laparoscopic instruments. It is 35 mm in diameter and 37 mm in length. The second FDA-approved port is the GelPOINT Path Transanal Access Platform (Applied Medical, Rancho Santa Margarita, CA) and is the only disposable multichannel port specifically designed for TAMIS^[7,13,24]. It comes in three access channel sizes: 4 cm × 4 cm, 4 cm × 5.5 cm, and 4 cm × 9 cm. The GelPOINT Path Long Channel is also available and allows reach of lesions up to 15 cm from the anal verge, and for visually obstructed lesions at rectal folds^[17]. Similar to SILS, the GelPOINT Path port is lubricated and seated into the anal canal with steady manual pressure. The SILS port is advantageous for use in patients with narrow or fibrotic anal canals that prohibit the placement of the GelPOINT Path^[17]. In addition to the SILS and GelPOINT Path ports, multiple other transanal ports have been described [Table 1]^[11,13,14,17,18,21,25-29].

CONVENTIONAL TAMIS [TABLE 1]

In the 6 patients included in their initial publication, Atallah *et al.*^[1] described tumor locations ranging from 6 to 11.5 cm from the anal verge, with operative times of 4 patients that were less than 60 min, one patient of 121 min (difficulty maintaining insufflation) and another patient of 192 min (difficult anterior intraperitoneal lesion). Set up times averaged less than 2 min per patient. One patient had positive margins and underwent fulguration. There were no complications through six postoperative weeks, and all patients were discharged by postoperative day two (average 0.83 days).

A systematic review was published in 2014 by Martin-Perez *et al.*^[13] analyzing 33 retrospective studies and case reports and 3 abstracts, amounting to 390 TAMIS procedures for local excision of rectal neoplasia from 16 countries. Of these, 152 (39%) resections were performed for benign disease (adenomas and high-grade dysplasia), 209 (53.5%) for malignancy (carcinoma in situ and invasive disease), and 29 (7.5%) for other pathology. Average size of lesions was 3.1 cm (range 0.8-4.75 cm), mean distance was 7.6 cm (range 3-15 cm) from the anal verge. Twenty-five studies reported on margin positivity, present in 12 of 275 cases (4.36%), and tumor fragmentation occurring in 4.1% of cases. Mean operative time was 76 min (range 25-162 min). Nine of 390 cases required conversion to TAE, TEM or abdominal laparoscopy. Average length of stay was 2 days. Complications occurred in 29 cases (7.4%), with 10 cases of self-limited bleeding and 4 cases of peritoneal entry. Recurrence was described in 16 publications, totaling 259 cases, and occurred in 7 (2.7%) cases at a 7.1-month mean follow-up^[13].

Since these early studies, larger series have been published shedding more light on intermediate outcomes^[11,17,18,21,23,25-27,30]. The largest series to date was published by Lee *et al.*^[11] in 2018, who reported their intermediate outcomes in 200 consecutive resections in 196 patients. Notably, 185 (92%) of cases were performed with laparoscopic instrumentation while 15 (8%) were performed with the da Vinci Si robotic

Table 1. Outcomes of selected cases following laparoscopic TAMIS

Author, Publication	Transanal Port	Patients (n)	Indications (Pathology)	Operative Time (min)	Tumor Distance from AV (cm)	Tumor Size (cm)	Defect Closure	Margins Positive (n)	Length of Stay (days)	Conversions/Complications	Recurrence (n)	Follow Up
Martin-Perez et al. ^[13] , <i>Tech Coloproctol</i> 2014	Multiple	390	152 benign, 209 malignant, 29 others	76	7.6	3.1	-	12 (4 additional fragmented)	1.9	9 conversions, 34 complications	7	7.1 months
Hahnloser et al. ^[18] , <i>Colorectal Dis</i> 2014	SILS	75	42 benign, 32 malignant, 1 carcinoid	median 77 (25-245)	6.4 (± 2.3)	3.9 (± 1.6)	40 (53%) closed, 35 (47%) open	3 (4%)	Median 3.4 (range 1-21)	0 conversions; 7 (9%) Intraop; 15 (19%) Postop	0	median 385 (67-884) days
McLemore et al. ^[17] , <i>Am J Surg</i> 2014	GePOINT Path, Long Channel, SILS	32	10 benign, 22 malignant	123 (± 62)	4.0 (± 3.0)	3.0 (± 2.0)	32 (100%)	1 (3%)	2.5 (± 2.0)	3 (10%) with lap assistance; 25% morbidity	0	range 3 to 23 months
Schiphorst et al. ^[28] , <i>DCR</i> 2014	SILS	37	23 benign, 13 malignant	median 64 (17-211)	median 7 (0-19) from dentate line	Median 18 cm ²	27 (73%)	6 (16%)	1 (1-23)	1 (3%) conversion; 14% morbidity	1	median 11 (3-19)
Sumrien et al. ^[29] , <i>Anticancer Res</i> 2016	GePOINT Path or SILS	28	17 benign, 11 malignant	all cases < 60 min	not reported	benign 5 (1.2-11.5); malignant 4.3 (1.2-9.5)	28 (100%)	5 (18%)	1.5	10% conversion; 25% morbidity	1 benign, 1 malignant	3 months
Quaresima et al. ^[25] , <i>JSL</i> 2016	GePOINT Path or SILS	31	17 benign, 10 malignant, 4 others	not reported	9.5 (6-15)	2.4 (1-5)	31 (100%)	3.2%	Median 3 (2-7)	0% conversion; 9.6% complication	1 benign	30 (1-79) months
Keller et al. ^[21] , <i>J Am Coll Surg</i> 2016	GePOINT Path or SILS	75	59 benign, 17 malignant	76 (± 36.1)	median 10 (6-16)	3.2 (± 3.1)	69 (92%)	5 (6.7%)	median 1 (0-6)	3 (4%) peritoneal entries w/2 loop ileostomies; 3 (4%) postop	1	median 39.5 (10.5-65.3) months
García-Flores et al. ^[26] , <i>Surg Innov</i> 2017	GePOINT Path	32	15 benign, 12 malignant, 5 others	69 (35-210)	5.6 ± 1.5	14.5 (± 14.4) cm ²	32 (100%)	1	3.9 (2-26)	22% complication	1 benign, 2 malignant (10.3%)	median 26 months
Chen et al. ^[27] , <i>World J Gastrointest Oncol</i> 2018	SILS	25	3 benign, 22 malignant	61.3 (± 25.5)	8.4 (± 1.6)	1.1 (± 0.5)	25 (100%)	0 benign, 5 malignant (20%)	2.7 (± 1.4)	0% conversion; 0% complications	0	8 weeks
Lee et al. ^[11] , <i>Ann Surg</i> 2018	GePOINT Path or SILS	200	90 benign, 110 malignant	69.5 (± 37.9)	7.2 (± 3.3)	2.9 (± 1.5)	188 (94%)	14 (7%); 9 (5%) fragmentation	76% POD 0, 28% POD 1, 20% POD 2	4% peritoneal entry, 2% abdominal assistance; 4% intraop, 11% postop	6% (distant in 2%)	14.4 (± 17.4)
Lee et al. ^[4] , <i>Surg Endosc</i> 2019	GePOINT Path	21	15 benign, 4 malignant, 2 others	100 (± 55)	7.8 (± 2.3)	17 (2.1-55.0) cm ²	100%	2 (9.5%)	median 5 (± 18) hours	1 (5%) peritoneal entry with abdominal assistance	not recorded	not recorded

Mean unless otherwise stated in column header

system (Intuitive Surgical Inc., Sunnyvale, CA). Operations were performed with either the SILS port or GelPOINT Path port. Indications for operation were benign rectal lesions not amenable to endoscopic resection, namely low-grade neuroendocrine tumors ≤ 2 cm in diameter, node-negative cT1 rectal cancer ≤ 3 cm in diameter, well-differentiated, and no lymphovascular invasion present. Palliative indications included patients with more advanced cancer (cT2, cT3) or histologically unfavorable cT1 lesions who were unwilling or unfit to undergo radical excision, and patients who exhibited endoscopic evidence of complete clinical response following neoadjuvant therapy. Final surgical pathology revealed 90 benign lesions and 110 malignant lesions. Notably, 11 of 110 patients with malignant lesions received neoadjuvant therapy. Twenty patients had pT2-3 or ypT2-3 tumors and underwent subsequent radical resection, received adjuvant treatment, or refused further treatment. Mean tumor size was 2.9 ± 1.5 cm, and distance from anal verge was 7.2 cm (range 2-17 cm). Fourteen patients (7%) had positive margins, of which 9 patients had malignant lesions. Eight of these 9 patients with malignancy were pT2 or higher and radical resection was recommended. Ninety-five percent of specimens were submitted without fragmentation. Mean operative time was 69.5 ± 37.9 min. Defects were closed in 188 (94%) cases and were left open due to the inability to obtain a tension-free closure. Peritoneal entry occurred in 8 (4%) cases, of which half were amenable to closure by TAMIS while the other half required abdominal access. Intraoperative complication rate was 8%. Morbidity was 11%, most commonly due to hemorrhage (9%), urinary retention (4%), and scrotal or subcutaneous emphysema (3%). Three patients suffered major morbidity. One patient required a diverting ileostomy for a symptomatic nonhealing rectal wound with fistula formation to the perineum. One patient was readmitted on postoperative day 3 with significant perirectal inflammation which resolved with medical management. One patient developed a rectovaginal fistula after a repeat TAMIS excision of a local recurrence. This resolved with conservative management after two months. Most patients (76%) were discharged following the procedure from the postanesthesia care unit. Mean follow-up for patients with benign and malignant lesions undergoing TAMIS for curative intent was 13.6 ± 17.3 months and 14.4 ± 17.4 months, respectively, with local recurrence rates of 3 and 6%, with distant metastases in 2%. Mean time to recurrence following resection of both benign and malignant lesions was 17 months. Cumulative disease-free survival for patients undergoing resection of benign neoplasms was 98, 94, and 94% and for malignant neoplasms 96, 93, and 84% at 1-, 2-, and 3-year follow-up, respectively.

Keller *et al.*^[21] published their series of 75 consecutive patients undergoing 76 resections. Indications followed NCCN guidelines for TAE, as well as patients unfit or unwilling to undergo radical resection for more advanced pathology. Median lesion distance from anal verge was 10 cm (range 6 to 16 cm). The GelPOINT PATH or SILS port was used for access. Mean operative time was 76 ± 36.1 min. Only 1 lesion was fragmented. Inadvertent peritoneal entry occurred in 3 cases, with 2 of these 3 patients undergoing creation of a protective loop ileostomy to assure healing. Postoperatively, there were 3 complications (4%); one each of bleeding, rectovaginal fistula, and rectal stricture. One case was aborted after intraoperative assessment deemed it unresectable by the transanal approach. Defects were closed in 69 cases, with no complications noted in the 6 cases in which the defect was left open. There were no functional complications noted following resection. Median length of stay was 1 day (range 0-6 days). Fifty-nine resections were performed for benign disease, while 17 resections were performed for malignancy. Of the malignant resections, final pathology yielded 4 pT2 lesions and 1 pT3 lesion, and all of these patients underwent further treatment without apparent oncologic or technical compromise. There were 5 cases of positive margins following resection, 3 of which were pT2 lesions, 1 pT1 lesion and 1 gastrointestinal stromal tumor (GIST). Thus, an important point of emphasis in this study was the high rate of margin positivity in T2 lesions, positive in 3 of 4 cases. Mean follow-up was 36.5 ± 14.8 months. In the 17 malignant cases in the patients who did not undergo immediate radical resection, there was 1 recurrence (5.8%), occurring locally at 9 months after excision. No mortalities were recorded during the study follow-up period.

ROBOTIC TAMIS [TABLE 2]

Following the utilization of standard and advanced laparoscopic tools for transanal surgery came the application of the robotic platform to transanal surgery^[8,23,31-37]. By utilizing the robotic platform, one can take advantage of its three-dimensional imaging and multidegree movement which may be limited in the narrow working space of the rectum. Tasks such as full thickness dissection and closure of rectal wall defects that may otherwise be technically and ergonomically challenging laparoscopically might be more easily performed. Robotic TAMIS allows the working surgeon to be seated and ergonomically optimized, enabling greater ease of suturing^[23]. It has also been suggested that the robotic platform permits better visualization and maneuverability, which may allow for more aggressive resection^[23].

Preclinical cadaveric studies began in 2010 and confirmed the feasibility of applying the da Vinci system and illustrated the possibility of side or parallel approach to docking the da Vinci robotic cart^[38,39]. Hompes *et al.*^[39,40] applied a glove port, which they had previously described for TAMIS, for use with the robot. Creatively designed, the port consisted of a circular anal dilator, a standard wound retractor, and a surgical glove allowing for greater working room which minimized arm collisions^[39,40]. The first human study was published by Atallah *et al.*^[41], which described the resection of a 3-cm tubulovillous adenoma 7 cm from the anal verge in a 58-year-old female. The patient was in modified lithotomy, and the GelPOINT port was utilized, along with three arms of the da Vinci robot via 8-mm trocars placed in the port cannulas. The robot was docked over the patient's right shoulder. The defect was closed with a V-Loc 180 Absorbable Wound Closure Device (Covidien, Mansfield, MA). Operative time was 105 min and there were no complications. Initial publications following these initial experiences were primarily case reports, but since then larger series have been published^[42-44].

Hompes *et al.*^[35] described their initial experience in 16 patients among three sites. One case required conversion to TAMIS due to problems with the glove port. The da Vinci Si platform was utilized. Mean docking and operative duration were 36 (18-75) and 108 (40-180) min, respectively. Patients were positioned prone or left lateral depending on tumor location. Problems included tearing of the glove in four procedures, which required replacement and subsequent completion. There were no cases of peritoneal entry reported, and one patient developed pneumoperitoneum managed conservatively. One patient developed urinary retention requiring catheterization. Median hospital stay was 1.3 days (0-4 days). Positive margins were identified in 2 patients who were found to have more advanced lesions and underwent further resection. No other complications occurred.

Liu *et al.*^[36] described the application of the newest robotic platform, the da Vinci Xi platform (Intuitive Surgical Inc., Sunnyvale, CA), in 34 patients. Lesions were located from 2 to 15 cm from the dentate line and up to 5.5 cm in diameter, average operative time was 100 ± 70 min, and robotic console time was 76 ± 67 min, with a docking time of 25 ± 14 min. Most patients ($n = 32$) were positioned lithotomy versus prone ($n = 2$). There were no intraoperative complications or operative conversions, and the only postoperative complication was a case of *Clostridium difficile* infection in one patient managed medically. Preoperative evaluation consisted of colonoscopy and imaging with use of either endorectal ultrasound or pelvic Magnetic Resonance Imaging (MRI) for local staging. Patients with early-stage rectal neoplasms (uTis or uT1N0M0) and low-risk histology (no lymphovascular invasion) were considered candidates. Patients also included were those with T1 carcinoid tumors, incomplete endoscopically resected rectal polyps, and one case of partial resection for palliative control of bleeding in the setting of metastatic disease^[36]. No patients had received neoadjuvant therapy. The GelPOINT Path port was utilized, and the robotic cart was docked from the side of the patient. A 30° 8-mm robotic camera was placed in the middle trocar and two robotic instruments were used along with an additional assistant trocar. Final pathology yielded 22 (65%) patients with adenoma, 7 (21%) with carcinoma, and 4 (12%) with carcinoid tumors. Three patients were identified as T2 and underwent formal low anterior resection. Notably, severe obesity (BMI > 35) was a predictor of

Table 2. Outcomes of selected cases following robotic TAMIS

Author, Publication	Transanal Port	Patients (n)/ Positioning	Indications (Pathology)	Operative Time (min)/Platform	Tumor Distance from AV (cm)	Tumor Size (cm)	Defect Closure	Margins Positive (n)	Length of Stay (days)	Conversions/Complications	Recurrence (n)	Follow Up
Hompes et al. ^[35] , <i>Br J Surg</i> 2014	Transanal 16 (15 Glove successful)/prone or left lateral decubitus	6 benign, 4 cancer, 5 scar	median 108 (40-180)/da Vinci Si	8 (3-10)	5.3 (0.5-21) cm ²	13 (87%)	2 (13%)	median 1.3 (0-4)	1 conversion to TAMIS; 2 complications (13%)	not recorded	not recorded	
Atallah et al. ^[31] , <i>Tech Coloproctal Surg</i> 2015	GelPOINT 9/modified dorsal lithotomy	6 benign, 3 malignant	124/da Vinci S or Si	6.6 (3-11)	2.8 (0.9-5.7)	56%	1 (11%)	0.8	1 requiring diagnostic laparoscopy to eval perforation; 2 (22%) complications	0	11.4 months	
Liu et al. ^[36] , <i>Surg Endosc</i> 2018	GelPOINT 34 (32 lithotomy, 2 prone)	22 benign, 7 malignant, 4 others	100 (±70)/da Vinci Xi	8.6 (±3.6) from dentate line	2.6 (±1.1)	100%	1 (3%)	1.8 (±0.83)	0 conversions; 1 complication	not recorded	188 (±209) days	
Tomassi et al. ^[8] , <i>DCR</i> 2019	GelPOINT 58 (5 lithotomy, 45 lateral, 8 prone)	18 benign, 28 malignant, 12 others	66.2 (17-180)/da Vinci Si (40) or Xi (18)	8.8 (4-14)	3.3 (1.3-8.2)	100%	3 (5.2%), one fragmented	52 (89.7%), discharged POD 0; 6 (10.3%) discharged POD1	0 conversions; 6 (10.3%) complications	3 (5.5%)	11.5 (0.3-33.3) months	
Paull et al. ^[32] , <i>J Robot Surg</i> 2019	SILS and GelPOINT Path	10 da Vinci® Si; 11 Flex® Colorectal Drive/Prone jackknife or high lithotomy	da Vinci Si: 167 (±84.2); Flex Colorectal Drive: 110.1 (±39.9)	da Vinci: 11.1 (±3.8); Flex: 9.58 (±3.6)	not recorded	100% in both	da Vinci: 1 fragmented	not recorded	da Vinci: 4 conversions and 1 complication; Flex: 1 case aborted	da Vinci: 6 months; Flex: not recorded	not recorded	
Lee et al. ^[23] , <i>Surg Endosc</i> 2019	GelPOINT 19/16 prone, 3 lithotomies	14 benign, 5 malignant	100 (±22)/da Vinci Si or Xi	8.2 (±2.1)	17 (3.2-28.4) cm ²	100%	1 (5.3%)	median 4 (±12) h	0 conversions; 1 complication	not recorded	not recorded	
Baker et al. ^[33] , <i>Colorectal Dis</i> 2020	GelPOINT 11/all lithotomy	5 benign, 6 malignant	64 (40-100)/da Vinci Xi	7.5 (3-14)	3.6 (2.0-6.0)	6/11 (56%) only full thickness defects	1 (11%)	1 (8 on POD 1, 2 on POD 2, 1 on POD 4)	0 conversions; 1 complication	not recorded	not recorded	
Huang et al. ^[37] , <i>Asian J Surg</i> 2020	GelPOINT 23/prone	8 benign, 13 malignancy, 2 other	median 107 (15-220)/da Vinci Si (19) or Xi (2)	median 5 (2-8)	median 2.5 (1.1-4.5)	100%	2 (8.7%)	median 3 (1-10)	0 conversions and 0 complications	0	median 9.6 months	
Yao et al. ^[34] , <i>Surg Inn</i> 2020	GelPOINT 24/lithotomy	3 benign, 15 malignant, 6 others	129.6 (60.0-240.0)/da Vinci Si (7) or Xi (17)	5.9 (3.5-12.0)	median 2.4 (1.0-5.2)	100%	0	4.6 (3-11)	0 conversions and 0 complications	1 (4%)	median 23.6 (4-45) months	

Mean unless otherwise stated in column header

significantly longer total operative time, requiring on average twice the operative and robotic console time. Average hospital stay was 1.18 ± 0.83 days, and all patients remained disease-free and alive at follow-up (mean follow-up 188 days), with the exception of the lone patient who underwent palliative resection for bleeding^[36].

Tomassi *et al.*^[8] published their experience with robotic TAMIS in 58 consecutive patients. The first 40 patients were completed with the da Vinci Si platform, and the last 18 with the Xi platform. Patients were most commonly placed in the lateral decubitus hockey stick position ($n = 45$), as opposed to lithotomy ($n = 5$) or prone ($n = 8$), allowing the legs to be moved away from the operative field enabling more range of motion for the robotic arms. While excision was performed as previously described, the proctotomy was closed in a transverse fashion with running 3-0 V-lock Maxon sutures (Medtronic, Minneapolis, MN). Floseal Hemostatic Matrix (Baxter International, Deerfield, IL) was selectively injected below the rectal wall of larger or previously radiated defects. Indications for TAMIS varied widely and included uT1N0 rectal cancer (41.4%), uT2N0 (3.4%), stage III rectal cancer with complete clinical response following neoadjuvant therapy (3.4%), rectal polyps (31%), carcinoid (19%), and GIST (1.7%). Tumor distance from anal verge ranged from 4 to 14 cm and mean operative time on robot was 66 (range 17-180) min. No cases required conversion. Ninety percent of patients were discharged home the same day following surgery, and the remaining patients were discharged on postoperative day 1. Complications included two patients unable to void in recovery and one patient with nausea in a case combined with laparoscopic cholecystectomy. Three patients presented with delayed complications: two patients with lower gastrointestinal bleeding required further endoscopic intervention, and one patient with mucus drainage and tenesmus from suture line dehiscence was treated with antibiotics. Final pathology confirmed preoperative staging in 79.3% of patients, with appropriate oncologic treatment in 88%. Seven patients required further treatment due to upstaging or high-risk features. Fifty-three patients underwent surveillance for a mean follow-up of 11.5 months with 3 local recurrences (5.5%). Overall, 54 (93.1%) have not required radical resection^[8].

HEAD-TO-HEAD COMPARISONS

A single institution head-to-head comparison of conventional and robotic TAMIS was published by Lee *et al.*^[23]. The study was a retrospective analysis of a prospectively collected database of 40 consecutive patients undergoing TAMIS. For conventional resection ($n = 21$), patients were positioned such that the lesion was in the dependent position to allow for laparoscopic suturing. Patients undergoing robotic-assisted resection ($n = 19$) were either in lithotomy or prone depending on tumor location. Platform was selected based on robot availability and surgeon preference. The GelPOINT Path port was utilized for both platforms. Median times for resection were similar between the two platforms, as were for distance of neoplasms from anal verge, R0 resection rate, and indications for resection (with the most common reason being adenoma). Perioperative morbidity was similar as well, with one patient in each group experiencing urinary retention requiring catheterization, and one patient in the conventional group requiring laparoscopic abdominal assistance in repairing a defect with inadvertent peritoneal entry. There were no readmissions or mortalities in either group.

COST

While perioperative and postoperative outcomes appear largely similar, cost appears to consistently favor the use of laparoscopic instruments. The primary cost is the transanal port; the cost of the GelPOINT Path is approximately \$600-800 and the SILS port is \$500^[11,17]. The addition of the robotic platform adds to the cost due to the additional instrumentation.

Hompes *et al.*^[35] identified an additional cost of €837 in comparison to conventional TAMIS. In their head-to-head study, Lee *et al.*^[23] demonstrated an average of \$880 (conventional-\$3563 vs. robotic-\$4440.92). This

was the only difference in outcomes identified between the two procedures. At the Taiwan Medical Center in Taipei, Huang *et al.*^[37] identified an approximate difference of \$2000 in favor of laparoscopy due to their current payment system. It has been proposed that robotic TAMIS may have a supplementary role in more complex rectal lesions in which the gained dexterity of the platform would further support and justify its utility^[41].

FUNCTIONAL OUTCOMES

Overall, TAMIS is very well tolerated^[28,29,45-47]. Studies published thus far have focused only on the conventional platform. Schiphorst *et al.*^[28] examined 37 patients who underwent conventional TAMIS. Patients were placed in lithotomy and the SILS port or the single-site laparoscopic access system (SSL, Ethicon Endo-Surgery, Cincinnati, OH) were utilized for transanal access. Full thickness rectal excisions were performed and defects, when closed, were done so using a V-loc absorbable suture. TAMIS was completed in 36 patients. There were two cases of rectal perforation with peritoneal entry, with one patient converted to laparoscopic anterior resection due to a large rectal defect and pneumoperitoneum. In 7 cases, a hybrid approach with traditional transanal excision was required due to distal lesion location. Three (8%) patients experienced postoperative complications which included hemorrhage ($n = 2$) and abscess ($n = 1$). Long-term morbidity was also experienced in 3 (8%) patients, including local recurrence ($n = 2$) and rectal stricture ($n = 1$). The rectal defect was closed in 27 (73%) patients [Table 2]. Functional outcomes were assessed using the Fecal Incontinence Severity Index (FISI) Score, which takes into account leakage from gas, mucus, liquid and solid stool, and ranges from 0 (total continence) to 61 (complete incontinence). Mean FISI scores before and after surgery decreased from 10 to 5 ($P = 0.01$) at median follow-up of 11 months, consistent with an overall significant improvement in anorectal function following TAMIS. The same cohort was then evaluated again after a median follow-up of 3 years in 44 patients^[45]. Mean preoperative FISI scores were 8.3 (range 0-35) vs. 5.4 (range 0-20) at one-year post-TAMIS ($P = 0.5$). At 3 years, mean FISI score increased to 10.1. This was not statistically significant relative to preoperative FISI. Quality of life was not evaluated in the study.

Sumrien *et al.*^[29] described the Bristol conventional TAMIS series of 28 patients evaluating feasibility and quality of life associated with incontinence. Either the GelPOINT Path or SILS port was used. Full thickness defects were closed. All patients underwent endoscopic evaluation at 3 months along with evaluation of quality of life with the International Consultation on Incontinence Modular Questionnaire (ICIQ). In all, TAMIS was unable to be completed in 3 cases due to extent of tumor. Seventeen cases were performed for benign neoplasia, with R0 resection achieved in 12 (71%). Eleven cases were for malignancy, of which 9 were palliative. In all of these cases, R0 resection was achieved, with one person experiencing recurrence at 11 months. Two patients developed urinary retention and were sent home with a catheter, while 4 patients who developed urinary retention showed resolution prior to discharge. Notably, they modified their practice in favor of a one-time in-out catheterization at the start of the procedure and then noticed a reduction in the incidence of postoperative urinary retention. One patient was readmitted with bleeding at 2 weeks following surgery and managed conservatively. One patient had full thickness perforation amenable to closure by TAMIS. ICIQ was completed in 13 of 26 patients following surgery. Within the questionnaire, the highest score is 60 and a higher score correlates with worsening severity of symptoms. Median score was 15, and 11 of 13 patients scored under 30, while 2 scored higher. They concluded that functional results were consistent with an acceptable quality of life.

Verseveld *et al.*^[46] evaluated quality of life and functional outcomes following TAMIS in 24 patients 6 months following resection. Indications for resection were adenoma ($n = 20$) or low-risk T1 carcinomas ($n = 4$). The SSL port was used for transanal access and patients were in lithotomy. Full thickness excisions were performed and all defects were closed. Mean operative time was 32 (13-94) min and median length of stay was 1 (1-3) day. There was one complication of hemorrhage requiring reoperation. Functional outcomes

were evaluated with the FISIQ questionnaire, and quality of life was evaluated with the EuroQol EQ-5D/EG-VAS and Fecal Incontinence Quality of Life (FIQL) scores. Mean FISIQ did not significantly change pre-resection to six months post-resection. Prior to surgery, 13 patients had abnormal FISIQ scores, while 11 had normal scores. Fifteen patients were continent following surgery, while 5 patients had minor deterioration. These 5 patients also had tumors that were larger and at a shorter distance from the dentate line. FIQL score trended towards improvement following resection and was significantly improved in the area of “coping behavior”. EQ-VAS scores were significantly higher following resection, consistent with an improvement in quality of life, while there was no change in the EQ-5D score, suggesting no change from a social perspective. Overall, the authors concluded that quality of life is generally improved following resection and is equal to the general population at 6 months post-resection.

Karakayali *et al.*^[47] evaluated anorectal function in 10 patients undergoing TAMIS for benign neoplasia or low-risk T1 rectal adenocarcinoma. All procedures were performed in lithotomy, the SILS port was used for transanal access, and all defects were closed. Follow-up consisted of digital rectal examination at 1 week and proctoscopy at 3 weeks following surgery. Anorectal manometry was performed prior to and at 3 weeks following surgery. Mean distance of tumor from anal verge was 5.6 cm (3-10 cm). Mean operative time was 98.8 min. All patients had R0 resections. There were no complications through a mean follow-up period of 27 weeks. Patients were evaluated for function by the Cleveland Clinic Incontinence Score questionnaire. All patients were continent prior to surgery with a score of 0. At 3 weeks postoperative, only one patient complained of incontinence to flatus and fecal urgency for a score of 3. This resolved by 6 weeks following surgery. All 9 other patients had scores of 0. Anorectal manometry prior to surgery was normal for all patients. At postoperative week 3, there were no significant differences seen in mean resting anal pressure, maximum squeeze pressure, or squeeze endurance. However, minimum rectal sensory volume was significantly reduced from 37 ± 8.23 preoperatively to 24 ± 5.15 following surgery ($P = 0.004$). There were no changes in rectoanal inhibitory reflex or sphincter reflex contractions. Thus, the authors concluded that conventional TAMIS is safe without impairment of anorectal function.

LEARNING CURVE

The learning curve for conventional TAMIS appears reasonable and attainable^[27,48,49]. Lee *et al.*^[48] performed a cumulative summation (CUSUM) analysis to determine the number of cases required to reach proficiency. Overall, 254 TAMIS procedures were included with an R1 resection rate of 7%. CUSUM analysis reported that an acceptable R1 rate was achieved between 14 and 24 cases. Clermonts *et al.*^[49] identified a learning curve between 18 to 31 procedures to reach proficiency. They also pointed out that with the establishment of standardized protocols and proctorship a shorter learning curve with fewer cases (6 to 10) may be achieved. Chen *et al.*^[27] reached a similar conclusion, with a minimum of 10 cases required for proficiency. A learning curve has not been established for the robotic platform. In comparison to TEM, our group has evaluated the TEM learning curve, performed by the senior author in 23 patients^[50]. A CUSUM analysis was conducted taking into account the size of lesion and the operating time. The rate of excision was extrapolated. The CUSUM curve stabilized following the four-case mark, after which the rate of excision declined indicating the surmounting of the learning curve.

CONCLUSION

A decade following its introduction, TAMIS appears to be a safe, cost-effective and clinically appropriate approach to the treatment of benign and early malignant (T1) rectal neoplasia with low-risk features. It overcomes several of the limitations of TEM, while matching its efficacy and advantages over resection by traditional TAE. Most importantly, it has an acceptable rate of achieving R0 resection with a low rate of disease recurrence, while maintaining a low rate of morbidity. Oncologic outcomes are not affected should disease recur. The majority of patients are now undergoing TAMIS as an outpatient procedure and many are spared the morbidity associated with TME.

While randomized control trials and head-to-head studies are lacking, the accumulated evidence suggests that the conventional and robotic approaches are similar in their clinical efficacy. However, differences exist and are mostly related to the higher cost of the robotic platform. While proponents of laparoscopy would highlight these cost-related factors, one cannot overlook the improved ergonomics of robotic surgery given the physical constraints of transanal surgery. Also, the gained articulation and dexterity not only allow for easier closure of defects, but may also facilitate the resection of larger lesions in multiple quadrants^[8,36]. Future advancements in robotic technology, particularly with the introduction of single-port robotic systems, will continue to make this platform an attractive alternative in rectal surgery.

It is important to note that in either approach, obesity still remains a factor in contributing to longer operative times^[36,51]. Undoubtedly, transanal surgery will continue to evolve as both conventional and robotic technologies advance and evolve, creating for an everchanging landscape for the colorectal surgeon. Should the clinical efficacy of the two approaches remain similar, the most important factors that remain will then be surgeon preference and comfort level.

DECLARATIONS

Authors' contributions

Made substantial contributions to conception and design of the study and performed data analysis and interpretation: Jahansouz C, Arsoniadis EG, Sands DR

Performed data acquisition, as well as provided administrative, technical, and material support: Jahansouz C, Sands DR

Availability of data and materials

Not applicable.

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Conflicts of interest

All authors declared that there are no conflicts of interest.

Ethical approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

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