

# Transanal Minimally Invasive Surgery for Rectal Lesions

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## ABSTRACT

**Background and Objectives:** Transanal minimally invasive surgery (TAMIS) has emerged as an alternative to transanal endoscopic microsurgery (TEM). The authors report their experience with TAMIS for the treatment of mid and high rectal tumors.

**Methods:** From November 2011 through May 2016, 31 patients (21 females, 68%), with a median age of 65 years who underwent single-port TAMIS were prospectively enrolled. Mean distance from the anal verge of the rectal tumors was 9.5 cm. Seventeen patients presented with T1 cancer, 10 with large adenoma, 2 with gastrointestinal stromal tumor (GIST) and 2 with carcinoid tumor. Data concerning demographics, operative procedure and pathologic results were analyzed.

**Results:** TAMIS was successfully completed in all cases. In 4 (13%) TAMIS was converted to standard Park's transanal technique. Median postoperative stay was 3 days. The overall complication rate was 9.6%, including 1 urinary tract infection, 1 subcutaneous emphysema, and 1 hemorrhoidal thrombosis. TAMIS allowed an R0 resection in 96.8% of cases (30/31 cases) and a single case of local recurrence after a large adenoma resection was encountered.

**Conclusion:** TAMIS is a safe technique, with a short learning curve for laparoscopic surgeons already proficient in single-port procedures, and provides effective oncological outcomes compared to other techniques.

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All authors contributed to the conception, design of the work; acquisition, analysis, and interpretation of data; and drafting of the manuscript and revising it critically for important intellectual content and final approval of the version to be published. All agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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DOI: 10.4293/JSLS.2016.00032

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**Key Words:** Colorectal surgery, Natural orifice transluminal endoscopic surgery (NOTES) Single-site laparoscopic surgery (SILS), Surgical oncology, Transanal minimally invasive Surgery (TAMIS).

## INTRODUCTION

Over the past 30 years, significant improvements in transanal surgery have been reported in an increasing number of minimally invasive organ-sparing procedures performed for rectal tumors. In 1983, Buess et al<sup>1</sup> introduced the transanal endoscopic microsurgery (TEM) for the treatment of giant sessile polyps and early rectal cancer. Since its introduction, TEM seemed to be a suitable alternative to the conventional transanal excision (TAE), showing better outcomes in R0 resection and local recurrence rate.<sup>2</sup> The technical advantages provided by TEM instrumentation, as the better exposition, the magnified 3D vision and the operative field illumination allowed the improved clinical outcomes. Despite this, TEM did not gained large favor within the surgical community, being routinely performed in only a few dedicated centers, mainly because of the long and challenging learning curve, the high instrumentation costs, and the relative limited number of patients suitable for the procedure.<sup>3</sup>

Transanal minimally invasive surgery (TAMIS), since the first report by Atallah et al.<sup>4</sup> has progressively gained popularity for the treatment of mid and high rectal lesions, offering a feasible alternative to TEA, TEM, and endoscopic submucosal dissection (ESD) in early rectal cancer, despite the lack of comparative trials. This technique is performable by a disposable single-port device adapted for transanal insertion (SILS Port; Covidien, Mansfield, Massachusetts, USA; and GelPath Transanal Access Platform; Applied Medical, Inc., Rancho Santa Margarita, California, USA), and the dissection is performed by standard laparoscopic instruments.

TAMIS offers several technical advantages compared with the TEM technique, as the shape of the operative channel allowing a circumferential dissection without the need to change patient position and, mainly, the possibility of using instruments already available in the operative set-

ting. Moreover, the soft transanal access platform is supposed to be safer in postoperative functional outcomes because of the minor sphincter traction compared to that in TEM proctoscopy, although incomplete comparative functional data have been reported.

The purpose of the present study is to investigate TAMIS technique feasibility and safety in a prospective series of 31 patients with benign and malignant tumors located in medium and high rectum.

## MATERIALS AND METHODS

From November 2009 through May 2016, 31 consecutive patients with rectal tumors have been treated with single-port TAMIS. Data collection for all colorectal procedures was approved by the institutional review board. All procedures were performed by the same surgical team, according to a standardized surgical protocol. Informed consent for the procedure was obtained from all patients.

Data concerning demographics, operative procedure, and pathologic results were analyzed. Complications were graded according to the Clavien-Dindo classification.<sup>5</sup>

### Preoperative Evaluation

All patients underwent full colonoscopy with biopsy and transanal endoscopic ultrasonography. In the case of cancer, regional staging was completed by magnetic resonance imaging and computed tomographic (CT) scan. Patients presenting with suspected lymph nodal involvement or known T2–T3 cancer were excluded from the study.

### Surgical Technique

A full-bowel mechanical preparation was administered the day before surgery. All patients received preoperative antibiotics (cephalosporin+metronidazole) and thromboembolic prophylaxis with low-molecular-weight heparin. In case of peritoneal perforation, antibiotics were continued for 3 days. All but one patient underwent general anaesthesia. A single-incision laparoscopic surgery port (SILS PORT, Covidien) was used in 19 cases and a Gelpath (Applied Medical Corp.) was used 12 cases performed since 2015. Surgery was performed with the patient placed in the Lloyd-Davies position, also in cases of anterior lesion. After platform insertion, a pneumorectum at 10–12 mmHg was set. Wet gauze was used above the lesion to reduce cranial colonic distension. Conventional laparoscopic instruments were used. A hook-type monopolar electrocautery or the harmonic scalpel was used for dis-

section and coagulation. After marking the area of resection, the dissection was started on health tissue ~1 cm all around the lesion margins and carried to obtain a full-thickness excision. The rectal full-thickness defects were always closed by interrupted or running barbed sutures (monofilament 3-0); for this purpose, a pneumorectum reduction (7–8 mm Hg) is useful to avoid increasing the tension during suturing. In one case, the lesion was closed with a GIA universal stapler with a 60-mm purple cartridge.

### Follow-up and Oncological Outcomes

The patients were examined at 3–6- and 12-month follow-ups during the first year, then once a year. Endoscopy and MRI evaluation were performed for the first time 6 months after surgery and then once a year.

## RESULTS

The TAMIS procedure was performed for: (1) T1 adenocarcinoma in 17 patients (54.8%), (2) large adenomas in 10 patients (32.2%), (3) GIST in 2 patients (6.5%), and (4) carcinoid in 2 patients (6.5%). The median age of rectal tumor patients at the time of surgery was 65 years (range, 36–82) with 21 women (68%) and 10 men (22%). The mean distance of the lesions from the anal verge was 9.5 cm (range, 6–15 cm), and the mean tumor diameter was 2.4 cm (range, 1–5). Sixteen patients were referred from other centers and departments after failed endoscopic resection. TAMIS was successfully completed in all cases, without the need to conversion to transabdominal surgery. In 2 cases, TAMIS was converted to a standard transanal technique (6.5%): 1 case of bleeding precluding the camera view and 1 case of difficult Douglas peritoneal suture requiring anal Parks dilators and vaginal valves for correct exposure.

The abdominal cavity was entered in 5 cases (16.2%), a suture of a Douglas peritoneal defect was performed with the TAMIS procedure in 4 cases and by conventional transanal access in another case, without adverse clinical consequences. Abdominal cavity entry was more frequent in upper lesions (distance from the anal verge more than 10 cm) and anterior lesions located >8 cm from the anal verge. Median postoperative length of stay was 3 days (range, 2–7).

Complications according to Clavien-Dindo classification<sup>5</sup> are listed in **Table 1**. The overall complication rate was 9.6% (3 patients, and excluding the intraoperative Douglas peritoneum opening) including 1 urinary tract infection, 1

**Table 1.**  
Complications According to Clavien Classification 5

Complications	Number of Patients (%)	Treatment	Clavien-Dindo Classification
Peritoneum perforation during surgery	5 (16.2)	Intraoperative suture	NC
Urinary tract infection	1 (3.2)	Antibiotics	II
Subcutaneous emphysema	1 (3.2)	None	I
Hemorrhoid thrombosis	1 (3.2)	Flavonods drugs	II

NC, not classified.

subcutaneous emphysema, and 1 hemorrhoidal thrombosis. Urinary infection was treated with oral antibiotics; subcutaneous emphysema did not require any treatment and was spontaneously reabsorbed in 4 days. The hemorrhoidal thrombosis resolved in 5 days with administration of a flavonoid drug.

Definitive pathology confirmed the preoperative tumor histology and staging. TAMIS allowed an R0 resection in 96.8% of cases (30/31 cases). An R1 resection was encountered in a patient affected by a rectal adenoma (moderated dysplasia), treated successfully with an endoscopic resection of residual tumor.

At mean follow-up of 30 months (range, 1–79) there was 1 local recurrence after large adenoma resection 18 months after surgery treated with endoscopic removal of a 1-cm flat polyp with moderated dysplasia. No cases of abdominal recurrence related to tumor cell seeding were recorded in cases of peritoneal entry.

## DISCUSSION

TAMIS is a new transanal platform for local excision of rectal benign and malignant tumors. In past years, TAMIS has become more popular, and several other studies have been published, confirming safe and effective results in early and oncologic outcomes (**Table 2**).<sup>4,6–28</sup> In a recent 4-year review of available clinical data on TAMIS, Martin-Perez and colleagues,<sup>6</sup> reported that early results were encouraging and that the use of this new approach to transanal surgery is undergoing significant global growth.

This paper presents a short and preliminary single-center series of 31 patients affected by medium and high rectal tumors, including early rectal cancer, treated by TAMIS. The surgical team had no previous significant experience with the TEM technique but was recognized as having substantial laparoscopic single-port device procedure expertise.

The primary purpose of the study was to establish the safety of the technique, and the authors found an overall complication rate of 9.6% (including minor and major complications) comparable to those reported by the literature.<sup>7–10</sup> None of the complications encountered required a reoperation or an invasive treatment.

The literature review presented in **Table 2**, including 513 patients with benign and malignant rectal tumors, demonstrated a 16.8% postoperative complication rate (range, 0–23%).<sup>4,7–15,17–28</sup>

All the TAMIS procedures presented in this paper have been completed by the transanal approach and also intraoperative complications such as bleeding or peritoneal perforation did not required conversion to an invasive transabdominal procedure. The data seem to be comparable to those in the literature, presenting a mean 3.1% of conversion to the laparotomic/laparoscopic approach because of intraoperative complications.

In the present series, the en bloc resection and R0 resection rates were 100% and 96.8%, respectively, and these outcomes are comparable to the literature data for TAMIS technique, describing a 5.6% R1 rate (29/513; **Table 2**).<sup>4,7–15,17–28</sup>

In some institutions, TAMIS is applied in the treatment of well-selected cases of stage I rectal cancer.<sup>11,12</sup> One argument for this has been the ability to obtain an en bloc resection with well-defined margins. In a recent study published by Haugvik and colleagues,<sup>13</sup> there was a high number of positive-resection margins (22%) in the final pathology specimens. In a systematic review of 266 TAMIS procedures from 28 studies by Martin-Perez and colleagues,<sup>6</sup> a positive-resection margin was observed in 5% only, but in almost one-third (31%) of the surgical specimens, the microscopic resection status could not be defined because of frequent tissue fragmentation.<sup>6</sup>

**Table 2.**  
Published TAMIS Series With at Least 5 Patients

Authors	Year	Device	Pts (n)	B:M:O*	Conversion (n)	Complications (n)	R1 (n)	LR <sup>†</sup> (%)	Follow up (months)
Atallah et al <sup>4</sup>	2010	SILS <sup>‡</sup>	6	3:2:1	0	0	1	NA	1.5
Cid et al <sup>11</sup>	2010	SILS	5	4:1:0	0	0	NA	NA	3
Van den Boezem et al <sup>21</sup>	2011	SILS	12	9:3:0	2	2	0	NA	NA
Lorenz et al <sup>22</sup>	2011	SILS/TriPort	13	0:13:0	0	0	—	NA	0.5
Carrara et al <sup>17</sup>	2012	Glove	8	5:3:0	0	0	0	NA	5
Lim et al <sup>12</sup>	2012	SILS	16	0:11:5	0	0	0	NA	3
Hompes et al <sup>23</sup>	2012	Glove	14	7:6:1	2	2	2	1	5.7
Ragupathi et al <sup>14</sup>	2012	SILS	20	14:6:0	0	1	1	1	NA
Canda et al <sup>24</sup>	2012	SILS	6	5:1:0	0	0	0	NA	3.8
Cantero and Delgado <sup>25</sup>	2012	SILS	20	0:20:0	0	0	NA	NA	NA
Barendse et al <sup>26</sup>	2012	SSL <sup>‡</sup>	15	9:4:2	2	2	0	NA	NA
Albert et al <sup>15</sup>	2013	SILS/GelPath	50	25:23:2	0	4	3	2	20
Lee and Lee <sup>19</sup>	2013	SILS	25	6:9:10	0	1	0	0	9.8
Gorgun et al <sup>10</sup>	2013	GelPath	12	10:1:1	2	3	NA	NA	NA
Mendes et al <sup>20</sup>	2013	SSL <sup>‡</sup>	11	4:2:5	0	1	0	0	9.2
Bridoux et al <sup>27</sup>	2013	Endorectal trocar	14	10:4:0	0	3	1	1	NA
McLemore <sup>8</sup>	2014	SILS/GelPath	32	13:16:3	3 (Leak test)	5	0	0	3–23
Hahnloser et al <sup>9</sup>	2014	SILS	75	25:49:1	3 (Peritoneal suture)	23	3	NA	NA
Gill et al <sup>7</sup>	2015	GelPath	32	11:16:5	0	16	0	1 distant	NA
Sumrien et al <sup>28</sup>	2016	SILS/GelPath	28	17:11:0	2	7	6	2	NA
Haugvik et al <sup>13</sup>	2016	SILS/GelPath	51	43:8:0	0	6	11	0	48
Verseveld et al <sup>18</sup>	2016	SSL	24	4:20:0	0	1	0	0	NA
Present series	2016	SILS/GelPath	31	10:17:4	0	8	1	1	30
TOTAL	—	—	513	233:240:40	16 (3.11%)	85 (16.5%)	29 (5.6%)	8 (1.5%)	—

\*Ratio benign:malignant:other; <sup>†</sup>local recurrence; <sup>‡</sup>single-site laparoscopic port.

Highlighting the advantages of the TAMIS procedure, Haugvik et al<sup>13</sup> demonstrated that one-third of the specimens were upgraded on final histology when compared with preoperative biopsies. This outcome indicates an advantage of TAMIS in optimal specimen quality for histologic analysis of large rectal polyps, compared with conventional piecemeal endoscopic mucosal resection, where resection margins are undefined and en bloc resections are lacking.

Standardization of the technique should be considered the primary outcome at the beginning of the learning curve,

even if surgery is performed by an experienced laparoscopic surgeon. The first aspect to evaluate is the lesion distance from the anal verge, many authors indicated an ideal range from 6 to 10 cm.<sup>14,15</sup> In this condition, the instruments manoeuvrability and the vision are optimal for the dissection independently from the anatomical lesion location.

The best method for closure of the rectal wall defect after a full-thickness excision is still debated. A recent multicenter trial published by Hahnloser et al<sup>9</sup> comparing morbidity and incontinence rates between patients undergo-

ing the suture of the rectum or a left-open technique, failed to demonstrate any significant differences between the 2 groups of patients. In the present series all the defects were surgically closed, with the intent to improve the learning curve in suturing during transanal single-port surgery.

No comparative clinical studies or randomized control trials are available to establish the equivalence or the superiority of TAMIS to the TEM procedure, although a preliminary evaluation on a phantom model has been published by Rimonda and colleagues.<sup>16</sup> In this study, several surgeons were asked to perform a rectal lesion excision by the TEM and TAMIS procedures in a phantom model with the intent to evaluate the difficulty of dissection and suture and the quality of the vision and the conflict between the instruments. TEM results were superior to those of TAMIS in all the investigated items. However, these data are in contrast to the relatively rapid spread of the use of TAMIS in clinical practice, especially among colorectal surgeons who do not routinely performed TEM.<sup>14,15,17</sup> Moreover, some authors with experience in TEM surgery have started to publish TAMIS surgery reports with encouraging data on functional results.<sup>18</sup>

## CONCLUSIONS

Despite the encouraging technical and preliminary oncological outcomes obtained by the TAMIS procedure, short-term follow-up data<sup>8,15,19,20</sup> are not yet able to establish its equivalence to the TEM procedure in long-term oncological outcomes. Further multicenter prospective randomized studies are needed.

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