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.

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 al1 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.2 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.3

Transanal minimally invasive surgery (TAMIS), since the first report by Atallah et al,4 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.5

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 dissection 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 classification5 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
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).4,6–28 In a recent 4-year review of available clinical data on TAMIS, Martin-Perez and colleagues,6 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.7–10 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%).4,7–15,17–28 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).4,7–15,17–28 In some institutions, TAMIS is applied in the treatment of well-selected cases of stage I rectal cancer.11,12 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,13 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,6 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.6

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**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)                | Flavonoids drugs   | II                           |

NC, not classified.
Highlighting the advantages of the TAMIS procedure, Haugvik et al\textsuperscript{13} 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.\textsuperscript{14,15} 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\textsuperscript{9} comparing morbidity and incontinence rates between patients undergoing

| Authors                     | Year | Device          | Pts (n) | B:M:O* | Conversion (n) | Complications (n) | R1 (n) | LR † (%) | Follow up (months) |
|-----------------------------|------|-----------------|---------|--------|----------------|-------------------|--------|----------|-------------------|
| Atallah et al\textsuperscript{4} | 2010 | SILS\textsuperscript{2} | 6       | 3:2:1  | 0              | 0                 | 1      | NA       | 1.5               |
| Gid et al\textsuperscript{11} | 2010 | SILS            | 5       | 4:1:0  | 0              | 0                 | NA     | NA       | 5                |
| Van den Boezem et al\textsuperscript{21} | 2011 | SILS            | 12      | 9:3:0  | 2              | 2                 | 0      | NA       | NA               |
| Lorenz et al\textsuperscript{122} | 2011 | SILS/TriPort    | 13      | 0:13:0 | 0              | 0                 | —      | NA       | 0.5              |
| Carrara et al\textsuperscript{17} | 2012 | Glove           | 8       | 5:3:0  | 0              | 0                 | 0      | NA       | 5                |
| Lim et al\textsuperscript{12} | 2012 | SILS            | 16      | 0:11:5 | 0              | 0                 | 0      | NA       | 3                |
| Hompes et al\textsuperscript{23} | 2012 | Glove           | 14      | 7:6:1  | 2              | 2                 | 2      | 1        | 5.7              |
| Ragupathi et al\textsuperscript{14} | 2012 | SILS            | 20      | 14:6:0 | 0              | 1                 | 1      | 1        | NA               |
| Canda et al\textsuperscript{24} | 2012 | SILS            | 6       | 5:1:0  | 0              | 0                 | 0      | NA       | 3.8              |
| Cantero and Delgado\textsuperscript{25} | 2012 | SILS            | 20      | 0:20:0 | 0              | 0                 | NA     | NA       | NA               |
| Barendse et al\textsuperscript{26} | 2012 | SSL\textsuperscript{4} | 15      | 9:4:2  | 2              | 2                 | 0      | NA       | NA               |
| Albert et al\textsuperscript{15} | 2013 | SILS/GelPath    | 50      | 25:23:2| 0              | 4                 | 3      | 2        | 20               |
| Lee and Lee\textsuperscript{19} | 2013 | SILS            | 25      | 6:9:10 | 0              | 1                 | 0      | 0        | 9.8              |
| Gorgun et al\textsuperscript{10} | 2013 | GelPath         | 12      | 10:1:1 | 2              | 3                 | NA     | NA       | NA               |
| Mendes et al\textsuperscript{20} | 2013 | SSL\textsuperscript{4} | 11      | 4:2:5  | 0              | 1                 | 0      | 0        | 9.2              |
| Bridoux et al\textsuperscript{27} | 2013 | Endorectal trocar | 14      | 10:4:0 | 0              | 3                 | 1      | 1        | NA               |
| McLemore\textsuperscript{8} | 2014 | SILS/GelPath    | 32      | 13:16:3| 3 (Leak test)  | 5                 | 0      | 0        | 3–23             |
| Hahnloser et al\textsuperscript{9} | 2014 | SILS            | 75      | 25:49:1| 3 (Peritoneal suture) | 23 | 3       | NA       | NA               |
| Gill et al\textsuperscript{7} | 2015 | GelPath         | 32      | 11:16:5| 0              | 16                | 0      | 1 distant | NA               |
| Sumrjen et al\textsuperscript{28} | 2016 | SILS/GelPath    | 28      | 17:11:0| 2              | 7                 | 6      | 2        | NA               |
| Haugvik et al\textsuperscript{13} | 2016 | SILS/GelPath    | 51      | 43:8:0 | 0              | 6                 | 11     | 0        | 48               |
| Verseveld et al\textsuperscript{18} | 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; †local recurrence; ‡single-site laparoscopic port.
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. 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. Moreover, some authors with experience in TEM surgery have started to publish TAMIS surgery reports with encouraging data on functional results.

CONCLUSIONS

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

References
1. Buess G, Hutterer F, Theiss J, Böbel M, Isselhard W, Pichlmair H. A system for a transanal endoscopic rectum operation. Chirurg. 1984;55:677–680.
2. Moore JS, Cataldo PA, Osler T, Hyman NH. Transanal endoscopic microsurgery is more effective than traditional transanal excision for resection of rectal masses. Dis Colon Rectum. 2008;51:1026–1030; discussion 1030–1031.
3. Arezzo A, Passera R, Saito Y, et al. Systematic review and meta-analysis of endoscopic submucosal dissection versus transanal endoscopic microsurgery for large noninvasive rectal lesions. Surg Endosc. 2014;28:427–438.
4. Atallah S, Albert M, Larach S. Transanal minimally invasive surgery: a giant leap forward. Surg Endosc. 2010;24:2200–2205.
5. Clavien PA, Barkun J, de Oliveira ML, et al. The Clavien-Dindo classification of surgical complications: five-year experience. Ann Surg. 2009;250:187–196.
6. Martin-Perez B, Andrade-Ribeiro GD, Hunter L, Atallah S. A systematic review of transanal minimally invasive surgery (TAMIS) from 2010 to 2013. Tech Coloproctol. 2014;18:775–788.
7. Gill S, Stetler JL, Patel A, et al. Transanal minimally invasive surgery (TAMIS): standardizing a reproducible procedure. J Gastrointest Surg. 2015;19:1528–1536.
8. McLemore EC, Weston LA, Coker AM, et al. Transanal minimal invasive surgery for benign and malignant rectal neoplasia. Am J Surg. 2014;208:372–381.
9. Hahnloser D, Cantero R, Salgado G, Dindo D, Rega D, Delrio P. Transanal minimal invasive surgery for rectal lesions: should the defect be closed? Colorectal Dis. 2015;17:397–402.
10. Gorgun IE, Aytac E, Costedio MM, Erem HH, Valente MA, Stocchi L. Transanal endoscopic surgery using a single access port: a practical tool in the surgeon’s toybox. Surg Endosc. 2014;28:1034–1038.
11. Cid RC, Pérez JC, Elosua TG, et al. Transanal resection using a single port trocar: a new approach to NOTES (in Spanish). Cir Esp. 2011;89:20–23.
12. Lim SB, Seo SI, Lee JL, et al. Feasibility of transanal minimally invasive surgery for mid-rectal lesions. Surg Endosc. 2012;26:3127–3132.
13. Haugvik SP, Groven S, Bondi J, Vågan T, Brynhildsvoll SO, Olsen OC. A critical appraisal of transanal minimally invasive surgery (TAMIS) in the treatment of rectal adenoma: a 4-year experience with 51 cases. Scand J Gastroenterol. 2016;51:855–859.
14. Ragupathi M, Vande Maele D, Nieto J, Pickron TB, Haas EM. Transanal endoscopic video-assisted (TEVA) excision. Surg Endosc. 2012;26:3528–3535.
15. Albert MR, Atallah SB, DeBeche-Adams TC, Izfar S, Larach SW. Transanal minimally invasive surgery (TAMIS) for local excision of benign neoplasms and early-stage rectal cancer: efficacy and outcomes in the first 50 patients. Dis Colon Rectum. 2013;56:301–307.
16. Rimonda R, Arezzo A, Arolfo S, Salvai A, Morino M. Transanal Minimally Invasive Surgery (TAMIS) with SILS™ port versus Transanal Endoscopic Microsurgery (TEM): a comparative experimental study. Surg Endosc. 2013;27:3762–3768.
17. Alessandro C, Daniela M, Michele M, et al. Glove port technique for transanal endoscopic microsurgery. Int J Surg Oncol. 2012;2012:383025.
18. Verseveld M, Barendse RM, Gosselink MP, Verhoef C, de Graaf EJ, Doornebosch PG. Transanal minimally invasive sur-
surgery: impact on quality of life and functional outcome. Surg Endosc. 2016;30:1184–1187.

19. Lee TG, Lee SJ. Transanal single-port microsurgery for rectal tumors: minimal invasive surgery under spinal anesthesia. Surg Endosc. 2014;28:271–280.

20. Silveira Mendes CR, Miranda Ferreira LS, Aguiar Sapucaia R, Andrade Lima M, Alonso Araujo SE. Transanal minimally-invasive surgery (TAMIS): technique and results from an initial experience. J Coloproctol. 2013;33:191–195.

21. van den Boezem PB, Kruyt PM, Stommel MW, Tobon Morales R, Cuesta MA, Sieteses C. Transanal single-port surgery for the resection of large polyps. Dig Surg. 2011;28:412–416.

22. Lorenz C, Nimmesgern T, Langwieler TE. Transanal endoscopic surgery using different single-port devices. Surg Technol Int. 2011;21:107–111.

23. Hompes R, Ris F, Cunningham C, Mortensen NJ, Cahill RA. Transanal glove port is a safe and cost-effective alternative for transanal endoscopic microsurgery. Br J Surg. 2012 Oct;99:1429–1435.

24. Canda AE, Terzi C, Sagol O, Sarioglu S, Obuz F, Fuzun M. Transanal single-port access microsurgery (TSPAM). Surg Laparosc Endosc Percutan Tech. 2012;22:349–353.

25. Cantero R, Salgado G. Transanal access for rectal tumors: the simultaneous use of a flexible endoscope and SILS. Tech Coloproctol. 2014;18:301–302.

26. Barendse RM, Doornebosch PG, Bemelman WA, Fockens P, Dekker E, de Graaf EJ. Transanal employment of single access ports is feasible for rectal surgery. Ann Surg. 2012;256:1030–1033.

27. Bridoux V, Schwarz L, Suau L, Dazza M, Michot F, Tuech JJ. Transanal minimal invasive surgery with the Endorec(TM) trocar: a low cost but effective technique. Int J Colorectal Dis. 2014;29:177–181.

28. Sumrien H, Dadnam C, Hewitt J, McCarthy K. Feasibility of transanal minimally invasive surgery (TAMIS) for rectal tumours and its impact on quality of life: the Bristol Series. Anticancer Res. 2016;36:2005–2009.