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Local excision for Rectal Cancer.

A Minimally Invasive Option.

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Key words

- Conventional transanal excision
- Transanal endoscopic microsurgery
- Transanal Endoscopic Operation
- Transanal Minimally Invasive Surgery
- Full-thickness excision
- Early Rectal cancer
- Lymph nodes
- Chemoradiation therapy
- Total mesorectal excision

Abstract

Transanal excision (TAE) with conventional retractors and transanal endoscopic microsurgery (TEM) are two well established minimally invasive surgical options for the treatment of selected rectal cancers. TEM is nowadays considered the standard of care for the transanal excision of rectal tumors, since it is associated with significantly better quality of excision and lower rates of recurrence than TAE. When compared with rectal resection and total mesorectal excision, TEM has lower postoperative morbidity and better functional outcomes, with similar long-term survival rates in selected early rectal cancers. More recently, transanal minimally invasive surgery (TAMIS) has been developed as an alternative to TEM. Possible benefits of TAMIS are under evaluation.

Introduction

During the last three decades, the wide introduction of screening population programs has led to a significant increase in the early detection of rectal cancers. This was paralleled by major technological improvements in the field of both staging and treatment modalities of rectal cancer, thus stimulating the development of several multimodal organ-preserving strategies in patients with early rectal cancer (ERC), including the use of local excision (LE)¹ and chemoradiation therapy (CRT)².

Until the 1990s, transanal excision (TAE) with conventional retractors was considered oncologically adequate for the treatment of ERC³. However, the implementation of the total mesorectal excision (TME)⁴ and the development of new endoscopic rigid platforms, such as transanal endoscopic microsurgery (TEM) and Transanal Endoscopic Operation (TEO), have challenged the role of conventional TAE. Nowadays, abdominal rectal resection combined with TME is the surgical standard of care for patients with rectal cancer. However, it is burdened by high rates of postoperative complications and impaired quality of life.⁵

Conceived in the early 1980s, TEM has become a valuable alternative option in selected cancer patients, being associated with significantly lower postoperative morbidity and better functional outcomes than abdominal rectal resection with TME; in addition, it provides better quality of the excision, lower risk of recurrence and better survival than conventional local excision. More recently, the TEO platform was designed, reporting similar intraoperative and postoperative outcomes when compared to TEM platform.⁶ Lastly, a novel flexible platform has been developed in 2009 as an alternative to TEM, the TransAnal Minimally Invasive Surgery (TAMIS).⁷

The aim of this paper is to review the outcomes of conventional TAE, TEM/TEO and TAMIS for early rectal cancer.

Literature search

The critical appraisal of the literature was performed searching the electronic PubMed/Medline databases and the Cochrane Library for articles published in English language between January 1985 and January 2018. The following medical subject headings (MeSH) and free-text words alone or in combination were used: "transanal endoscopic microsurgery", "transanal excision", "full thickness excision", "rectal cancer", "total mesorectal excision", "transanal", "laparoscopic", "neoadjuvant chemoradiation therapy", "function", "quality of life", "Transanal Minimally Invasive Surgery", "TAMIS"; "Transanal Endoscopic Operations", "TEO", "endoscopic posterior mesorectal resection", "learning curve", "cost", "sentinel lymph node". Reference lists from the included articles were manually checked, and additional studies were included when appropriate. Studies were included if they reported on TEM for the treatment of

rectal cancer.

Endoscopic platforms

Rigid

Two different rigid platforms used to perform transanal endoscopic surgery for ERC are available: the TEM and the TEO platforms. Both allow to remove lesions in the lower, mid and upper rectum that are not attainable with conventional TAE, with a better visualization of the rectal lumen than TAE. The TEM (Richard Wolf, Knittlingen, Germany) equipment (**Figure 1**) was originally conceived by Gerhard Buess in the early 80s and includes:

- An operating proctoscope that is 4 cm in diameter and is available in three different lengths with correspondent obturators that allows insertion of the proctoscope.
- A working adapter and a working insert to connect the proctoscope to working instruments, camera and insufflator.
- > A Martin arm to fix the proctoscope to the operating table.
- A light source and a stereoscopic angled telescope which allows dissection under microsurgical conditions with 3D visualization.
- > The surgical tools include suction and irrigation tubes, curved and straight monopolar grasping forceps, suture clips forceps, electrocautery, needle holder.

The TEO Instrumentation by Karl Storz GmbH (Tuttlingen, Germany) (**Figure 2**) is an alternative to the TEM platform that has gained wide acceptance worldwide. TEO instrumentation includes a 7 or 15-cm proctoscope (4 cm in diameter) with 3 working channels (12, 5 and 5 mm) for dedicated or conventional laparoscopic instruments, and a 5-mm channel for a 30° 2D camera. The shape of the TEO proctoscope tip allows manipulation and suturing of the rectal wall on a 360° surface. A standard laparoscopic unit is used in combination with this system, with the imaging being displayed on a screen.

Flexible

In 2009, the first use of flexible platform for transanal excision (TAMIS) was reported.⁷ Even though the outcomes using several multichannel ports have been published,⁸ currently the Food

& Drug Administration has approved in the United States only two ports for TAMIS: the SILS Port (Covidien, Mansfield, MA, USA) and the GelPOINT Path Transanal Access Platform (Applied Medical, Rancho Santa Margarita, CA, USA), with the latter being the only multiport specifically developed for TAMIS procedures. The SILS Port (**Figure 3**) has a neck of 3 cm and includes three 5-mm ports (one can be changed to a 11-mm port), through with standard laparoscopic tools are inserted, and a dedicated access for CO₂ insufflation. The material that the SILS port is made of is soft, flexible and sponge-like, thus allowing a smooth and atraumatic insertion of the port into the anal canal.

The GelPOINT path transanal access platform (**Figure 4**) includes 3 ports with self-retaining sleeves that accommodate 5-mm and 10-mm standard laparoscopic tools; the insufflation Stabilization Bag that is connected to standard insufflation tubes stabilizes the surgical space with an elastic CO₂ reservoir that effectively absorbs the pulsing motion of an insufflated rectum. The access channel is available in 3 sizes to meet procedural needs, offers a 4-cm atraumatic retraction to enhance endorectal exposure and access, and includes suture ties to maximize the security during the entire operation. Lastly, the GelSeal cap provides a flexible fulcrum for unmatched triangulation of standard laparoscopic instrumentation, allows to keep the exposure stable during the operation by accommodating two interchangeable insufflation/smoke evacuation ports and facilitates the specimen removal with simple detachment from the access channel.

Surgical technical points

Positioning of the patient on the operating table

Both TEM/TEO and TAMIS procedures can be performed either under general or spinal

anesthesia.⁹⁻¹² A recent prospective observational including 50 patients treated with TEO platform for rectal tumors showed that TEO[®] under spinal anaesthesia is safe and feasible. No intraoperative complications occurred, and no procedure required conversion to general anesthesia. The median duration of operation was 60 (range 20-165) min. No opioids were administered during the perioperative or postoperative period. The median postoperative pain score was 0 at 4, 8, 24 and 48 h after surgery. No significant postoperative changes were observed in hemodynamic parameters.¹³

The patient is placed either prone or supine in order to keep the lesion as close to the 6 o'clock position as possible. Patients with lateral rectal tumors are placed in the supine position unless the lesion is located on the anterolateral wall (12 to 3 o'clock position or 9 to 12 o'clock position) or close to the peritoneal reflection. When the peritoneum is opened, the prone position allows to reduce the descent of small bowel loops into the surgical field and the air leak into the peritoneal cavity, thus facilitating the suture of the peritoneal opening.

Step 1: Dissection

After insertion of the proctoscope into the rectum and identification of the rectal tumor, the proctoscope is fixed to the operating table. Carbon dioxide (CO_2) is inflated to maintain an 8-mmHg endorectal pressure that in some cases might be increased up to 16 mmHg.

- The operation starts by marking the lesion circumferentially with the electrocautery, thus ensuring at least 5-mm clear circumferential margins.
- > The dissection begins at the right lower border of the tumor, and then is continued proximally around and under the tumor until a circumferential dissection is achieved and the tumor en bloc excised. Tumor excision can be safely performed by using monopolar

electrocautery. Ultrasonic shears or a Electrothermal Bipolar Vessel Sealing System might be useful in difficult cases to complete the dissection. Due to the limited accuracy of the preoperative staging tools, a full-thickness excision down to the perirectal fatty tissue should be routinely performed. Female and male patients who had previous prostactectomy who undergo a TEM/TEO procedure for an anteriorly located rectal tumor are at higher risk of developing a rectovaginal or rectovescical fistula.

- The specimen is then retrieved transanally and is oriented and pinned to a corkboard to preserve the margins of normal rectal mucosa surrounding the tumor.
- In case of intraoperative peritoneal opening the surgeon's learning curve and case volume are the two factors that mainly influence the treatment strategy. In our experience, the prone position of the patient on the operating table and the particular shape of the tip of the TEO proctoscope help suture the rectal wall on a 360° surface, thus minimizing the risk of conversion to open surgery or the need for a stoma.

Step 2: Wall defect suturing

The optimal management of the rectal wall defect is controversial, with some studies suggesting the closure, others favouring leaving the defect open and others showing no differences. A systematic review and metanalysis of the literature published in 2017 included 4 studies (489 patients: 317 in the closed group and 182 in the open group): no significant differences were found in overall morbidity, postoperative local infection, postoperative bleeding and reintervention.¹⁴ Similar results were obtained by Lee et al. in a multi-institutional matched analysis published in 2018, suggesting that the decision to close the rectal wall defect should represent a tailored approach.¹⁵

We believe that the closure of the rectal wall represents one of the technical advantages of TEM/TEO procedure compared to classical transanal excision and might reduce early postoperative morbidity and the risk of complications in case of later rectal resection with total mesorectal excision. This practice is supported by the results of a prospective study that demonstrated that the rate of grade 3 complications according to the Clavien Dindo classification was significantly reduced when the rectal wall defect was sutured by TEM.¹⁶

- > The wall defect is first irrigated with iodopovidone solution to reduce septic complications and the risk of tumor cell implantation.
- The rectal wall defect is then closed with one or more monofilament absorbable running sutures, usually from right to left. For large wall defects, a midline stitch is placed to approximate proximal and distal margins, thus reducing the tension of the suture. Dedicated silver clips are used to secure the suture since knot tying during the procedure is challenging. At the end of the procedure, patency of the rectal lumen is carefully checked through the TEM/TEO proctoscope.

Post-operative complications

Postoperative complications occur in 2% to 15% of patients. Most frequent local complications are rectal bleeding and suture dehiscence. Rectal bleeding is self-limiting in most cases. Treatment options include blood transfusions and endoscopic clipping. Suture dehiscence occurs more frequently after neoadjuvant radiation therapy in patients preoperatively staged as cT2N0. Patients with suture dehiscence experience severe rectal pain, tenesmus and fever. An endoscopy or cross sectional imaging is always obtained to check the suture line and the size of the perirectal collection for possible drainage. Conservative treatment includes intravenous antibiotics and 10% iodine solution enemas and leads to healing in about 90% of cases.¹⁷ Further

treatment tools such as the endoscopic vacuum system (Endosponge[®], B Braun Medical BV, Melsungen AG, Tuttlingen, Germany) are rarely use. The need for a stoma creation to control sepsis is very uncommon.

Evidence from the literature

1. Local excision for selected T1 N0 rectal cancer: conventional TAE or TEM?

Several studies have compared surgical outcomes of patients undergoing TEM versus TAE for T1 N0 rectal cancers, reporting significantly higher rates of tumor fragmentation and positive resection margins after TAE than TEM, thus leading to higher and unacceptable local recurrence rates.¹⁸ For instance, Langer et al.¹⁹ reviewed 38 T1 rectal cancer patients treated by TAE (18 patients) or TEM (20 patients). The rates of positive or indeterminate resection margins were higher after TAE than TEM (37% vs. 19%, positive; 16% vs. 5%, indeterminate). Christoforidis et al.²⁰ found similar results comparing 42 stage 1 rectal cancer patients treated by TEM and 129 stage 1 rectal cancer patients treated by TAE. TAE was associated with significantly higher rates of positive resection margins than TEM (16% vs. 2%; P=0.017). A recent systematic review and meta-analysis of studies comparing TAE and radical resection for T1N0M0 rectal cancer showed that TAE had higher local recurrence rates and poorer 5-year survival.²¹

The evidence that TAE compromises survival in patients with ERC has led to a decrease in the use of this approach during the last 15 years, favoring the implementation of TEM.^{22,23} TEM does not jeopardize the long-term survival in "low risk" T1 carcinoma according to Hermanek criteria.²⁴ Heintz et al.²⁵ showed no significant differences in local recurrence between patients who had a TEM or TME for a T1 "low-risk" cancer (4% vs. 3%, respectively), while higher local recurrence rates were observed after TEM than TME in "high risk" rectal cancer patients (33%)

vs. 18%). Similarly, Lee et al.²⁶ reported similar local recurrence rates in 52 patients treated by TEM and in 17 patients who had undergone rectal resection with TME for G1 or G2 rectal cancers (4% vs. 0%; P=0.95). Borschitz et al.²⁷ studied recurrence rates and ten-year cancer-free survival in 105 pT1 cancer patients treated by TEM. Patients were divided into two groups: "low-risk" cancers and "high-risk". Local recurrence rates were 6% after R0 TEM in the low-risk cancer patients and 39% in the high risk group of patients. The recurrence rate was significantly reduced to 6% in those high risk patients who underwent an immediate reoperation (P=0.015).

Submucosal tumor invasion is a strong prognostic factor for long-term survival in rectal cancer patients undergoing TEM for T1 N0 rectal cancer^{28,29}. Bach et al.²⁸ analysed the outcomes of 487 rectal cancer patients treated by TEM. They found that T1 rectal cancers with a submucosal tumor invasion less than 1000 μ (T1sm1) had the lowest risk of recurrence, while sm2-3 T1 and T2 rectal cancers had similar recurrence rates. Local recurrence rate was less than 5% for pT1 Sm1 rectal cancers with no evidence of lymphovascular invasion and a diameter of 3 cm or less.

Even though TEM was initially developed for the treatment of tumors located in the mid and lower rectum, to date the distance of rectal cancer from the anal verge does not represent an absolute contraindication to a full thickness TEM procedure. There are several data supporting the use of this platform also for the treatment of selected intraperitoneal rectal cancers, with no increased short-term morbidity or mortality and no adverse oncologic outcomes even in case of inadvertent peritoneal opening.³⁰⁻³⁵ The experience of the surgeon is key in the decision making process for the treatment strategy to be adopted when the peritoneum is entered.³⁶ In conclusion, TAE should be abandoned for the treatment of rectal cancer. TEM should be considered in selected T1 (sm1) rectal cancer patients, thus avoiding unnecessary rectal resection without affecting survival.

2. Is local excision of T2 N0 rectal cancer a valuable option?

The assessment of perirectal lymph node status is the main challenge of LE as treatment modality for rectal cancer, and the risk of lymph node metastases increases with tumor stage: from 0% to 3% for T1 sm1, to 15% for T1 sm2-3 and to 25% for T2 rectal cancers.^{37,38} As a consequence, "high risk" T1 and T2 rectal cancer patients have a significantly higher risk of recurrence after LE alone than after radical surgery.

During the last decade, a multimodal organ-preserving approach including neoadjuvant CRT followed by LE has been proposed in selected T1-T2 N0 rectal cancer patients aiming at avoiding the postoperative morbidity and mortality associated with rectal resection and TME without affecting survival.³⁹⁻⁴² For instance, Bhangu et al.⁴⁰ reviewed 7,378 patients undergoing LE and 36,116 patients treated with major rectal resection for T0-2N0M0 rectal cancer. LE had similar oncologic outcomes compared to abdominal surgery in T0-1 rectal cancer patients, while poor results were obtained in T2 rectal cancer patients. However, neoadjuvant therapy followed by LE for T2 rectal cancer led to oncologic outcomes that were similar to those achieved in T2 rectal cancer patients treated with abdominal surgery.

The impact of a multidisciplinary strategy including neoadjuvant CRT followed by TEM for the treatment of T2 N0 M0 is gaining increasing interest in the surgical community, since preliminary oncologic results are promising.^{2,26,43,44} For instance, in a randomized controlled trial

published by Lezoche et al.² cancer-related and overall survival rates were similar in 50 patients treated by TEM and 50 patients undergoing rectal resection after long-course CRT for G1-G2 tumors preoperatively staged as T2 N0 M0, smaller than 3 cm and located within 6 cm of the anal verge: 89% vs. 94% (P=0.687), and 72% vs. 80% (P=0.609) with a median follow-up of 9.6 years. In both groups, local or distant recurrences were reported only in partial or non-responders to neoadjuvant CRT. More recently, Garcia-Aguilar et al.⁴⁵ published the results of a an open-label, single-arm, multi-institutional, phase 2 trial (ACOSOG Z6041). The estimated 3-year disease-free survival in 72 patients treated by neadjuvant log-course CRT and TAE or TEM was 86.9% (95% CI, 79.3-95.3). The authors concluded that neoadjuvant CRT followed by LE might be considered as an organ-preserving alternative in carefully selected patients with clinically staged T2N0 tumors who refuse, or are not fit for radical rectal resection.

However, this strategy has some potential drawbacks. Significant rectal wound-related morbidity (up to 70%) has been reported in patients undergoing neoadjuvant treatment followed by TEM.^{17,46,47} Marks et al.¹⁷ compared retrospectively 43 rectal cancer patients who underwent neoadjuvant radiation therapy followed by TEM and 19 were treated with TEM alone. A wound complication was experienced by 25.6% patients in the radiotherapy group while no patients treated by TEM alone experienced such a complication (P=0.015). In a study comparing 30-day outcomes in 23 patients treated by neoadjuvant CRT followed by TEM and 13 patients undergoing TEM alone, Perez et al.⁴⁶ found significantly higher rates of rectal suture dehiscence (70% vs 23%; P=0.03), and readmissions (43% vs. 7%; P=0.02) after CRT.

Suturing irradiated tissue could be the reason of the high incidence of rectal wall dehiscence observed in patients undergoing TEM after neoadjuvant radiation therapy. Optimal management of the rectal wall defect following TEM after neoadjuvant radiation therapy remains debated.

This multidisciplinary approach is also associated with poor functional outcomes that are similar to those observed after radical rectal resection.^{48,49} In a retrospective study comparing the functional outcomes at 1 year after surgery by using a self-administered non-validated questionnaire in T2 N0 rectal cancer patients undergoing neoadjuvant radiation therapy followed by full-thickness LE or anterior resection alone, Gornicki et al.⁴⁸ found no differences in the mean number of bowel movements, occurrence of gas and fecal incontinence, clustering of bowel movements and urgency between the 2 groups of patients. Thirty-eight percent of patients after LE claimed anorectal dysfunction affecting their quality of life. Sexual life was impaired in 19% of men and 20% of women.

In conclusion, this multimodality strategy should be proposed only in the setting of clinical trials while awaiting the long-term results of large randomized controlled trials.⁵⁰ An European multicenter prospective study, Transanal Endoscopic Microsurgery After Radiochemotherapy for Rectal Cancer (CARTS)⁵¹ is investigating the outcomes of TEM performed 8-10 weeks after preoperative long-course CRT. The TREC (Transanal endoscopic microsurgery and radiotherapy in Early rectal Cancer)⁵² is an ongoing phase II open, multicentre randomised controlled trial that compares radical rectal resection by TME with short-course radiotherapy followed by delayed (8-10 weeks) TEM for ERC. The TREC and CARTS groups have combined their phase II protocols (STAR-TREC) to produce a single phase III trial that will randomise patients to (a) radical surgery, (b) short-course radiotherapy followed by TEM, or (c) CRT followed by TEM.

3. TEM or TEO?

To date, only one randomized controlled trial has compared TEM and TEO for rectal tumors.

Serra-Aracil et al.⁶ included patients with a rectal adenoma or cancer staged T1-2 N0 with a diameter between 2 and 6 cm, the lower margin at least 2 cm from the anal verge and the upper margin within 15 cm from the anal verge. A total of 34 patients were randomized: 17 to TEM and 17 to TEO. No significant differences were observed in time necessary to assemble the instrumentation, time necessary for excision and rectal wall suturing and total operative time. No patients required conversion from one platform to the other or to abdominal surgery. Postoperative morbidity rates were 21% after TEM and 18% after TEO (p=0.83). There was no mortality and median hospital stay was 3 days in both groups. The overall cost analysis revealed that mean costs associated with TEO were significantly lower than those associated with TEM (€ 2031 ± 440 vs. $\notin 2603\pm507$, p=0.003).

4. Rigid or flexible platform?

TAMIS was first conceived in 2009 as an alternative to TEM, aiming at overcoming some potential drawbacks of the rigid platforms, such as costs, steep learning curve and impaired anorectal function. Since the publication of the first 6 cases in 2010, a wide and quick diffusion of the TAMIS platforms occurred worldwide with about 400 TAMIS procedures being performed in the following 4 years. Martin-Perez et al.⁵³ published in 2014 a systematic review of 33 small retrospective studies (the largest including 50 patients) and case reports and 3 abstracts published between 2010 and 2013 from 16 countries. Main indications for TAMIS were cancers (53.5%) and adenomas (39%). The mean tumor size was 3.1 cm (range, 0.8-4.75), and the mean distance from the anal verge 7.6 cm (range, 3-15). Mean operative time was 76 minutes (range, 25-162) and estimated blood losses were minimal. Overall positive margin rate was 4.4% and specimen fragmentation occurred in 4% of TAMIS. Overall postoperative complication rate was 7.4%.

Based on these preliminary results, TAMIS was defined a "giant leap forward" compared to TEM, since it requires minimal setup time, allows the adaptation of standard laparoscopic instruments and the cost of each disposable device is relatively low. However, the interpretation of the results published in 2014 is limited by the small number of patients included in most case series, and the very short mean follow-up (only 7 months), so no definitive conclusions regarding the oncologic soundness of TAMIS were drawn; in addition, a full thickness excision was performed in 60% of cases only. During the following 3 years, several large series of TAMIS procedures with longer follow-up have been published, suggesting that TAMIS is a viable option for excision of both benign and early rectal tumors, with minimal postoperative morbidity and acceptable recurrence rates.⁵⁴⁻⁵⁶ However, very few studies have compared TEM and TAMIS. Since TAMIS had a wide adoption without clear evidence of safety and efficacy, our group conducted in 2012 a comparative experimental study using a dedicated trainer box for transanal procedures.⁵⁷ Ten surgeons without experience in transanal surgery performed a dissection and suture task by using both TEM and TAMIS platforms in a random order. Accuracy of dissection was similar, while the time needed to dissect and suture was significantly shorter in the TEM group. In addition, the surgeon had to switch from TAMIS to TEM in three cases to complete the suture. Subjective surgeon's appreciation was higher for TEM.

In 2016, Melin et al.⁵⁸ retrospectively compared the short-term outcomes of 40 TEM procedures and 29 TAMIS. The two groups of patients were similar in terms of patients' baseline and tumor characteristics. Operative time and the rate of positive margins were similar. Postoperatively, no differences in morbidity were observed.

In 2017, Mege et al.⁵⁹ published the results of a case-matched study including 74 patients: 33 patients underwent a TAMIS procedure and 41 a TEO procedure. More frequently, adenocarcinoma was the indication in the TEO group (42% vs. 27%); a full-thickness excision was less frequently performed in the TAMIS group (85% vs. 100%). There were no differences in the two groups in median operative time, major morbidity, and recurrence rate; similar outcomes were observed also in terms of anorectal function. Interestingly, R1 resection rates after TAMIS were two-fold those observed after TEO (21% vs. 10%); however, the difference was not statistically significant.

Lastly, a retrospective multicenter matched analysis including 247 TEM procedures and 181 TAMIS procedures showed that both operations are similar in terms of postoperative complications, R1 resection rates, fragmentation rates and cumulative 5-year survival.⁶⁰

The results of these studies show that TEM and TAMIS are equivalent in achieving highquality local excision and the choice of using a rigid or flexible platform should be based on the surgeon preference and equipment availability. Indeed, costs and the steepness of the learning curve should not be considered the reasons to prefer TAMIS over TEM/TEO. To date, there are no comparative cost analyses; however, it has been calculated that the costs of both platforms become equivalent after 18 procedures, considering the cost of each disposable TAMIS device, the costs of specific automated suturing devices used during a TAMIS, and the fact that two surgeons are involved in a TAMIS procedure while TEO is a one-surgeon procedure.⁵⁷ Similarly, a cost analysis comparing TEM and open surgery for rectal tumors demonstrated that the high equipment costs of the TEM platform are amortized after only 12 TEM procedures.⁶¹ Supporters of the flexible platforms claim that TAMIS has a shorter learning curve than TEM/TEO. Actually, in the absence of comparative studies, the current evidence does not show significant differences between the two platforms. Helewa et al.⁶² have recently demonstrated that 16 TEM procedures are necessary to significantly lower operative time. These results compare favorably with those reported by Lee et al.⁶³ in a series of 254 TAMIS, showing that 14 to 24 TAMIS procedures are required to achieve stabilization of the operative time.

Conclusions

TEM/TEO is the standard of care for LE of selected rectal cancers, since postoperative complications and mortality rates are significantly lower than after abdominal rectal resection with TME and oncologic outcomes are similar. Conventional TAE should be used only in highly selected distal rectal tumors if TEM is not feasible for technical reasons. The role of neoadjuvant CRT followed by TEM in highly selected T2 N0 rectal cancer is still under evaluation. To date, there is no evidence supporting the superiority of flexible over rigid platforms. The wide and quick diffusion of TAMIS in many centers might impair quality of surgery if performed by surgeons with low volume and limited expertise in the management of rectal tumors and postoperative surgical complications.

Legends for figures

Figure 1. TEM equipment

Figure 2. TEO equipment

Figure 3. The SILS Port

Figure 4. The GelPOINT path transanal access platform

References

1. You YN, Baxter NN, Stewart A, et al. Is the increasing rate of local excision for stage I rectal cancer in the United States justified?: a nationwide cohort study from the National Cancer Database. Ann Surg. 2007;245:726-33

2. Lezoche E, Baldarelli M, Lezoche G, et al. Randomized clinical trial of endoluminal locoregional resection versus laparoscopic total mesorectal excision for T2 rectal cancer after neoadjuvant therapy. Br J Surg 2012;99: 1211-1218

3. Steele GD Jr, Herndon JE, Bleday R, et al. Sphincter-sparing treatment for distal rectal adenocarcinoma. Ann Surg Oncol. 1999;6:433-41

4. Heald RJ, Moran BJ, Ryall RDH, et al. The Basingstoke experience of total mesorectal excision, 1978–1997. Arch Surg 1998.7;133: 894–899

5. Hupkens BJP, Martens MH, Stoot JH, Berbee M, Melenhorst J, Beets-Tan RG, et al. Quality of Life in Rectal Cancer Patients After Chemoradiation: Watch-and-Wait Policy Versus Standard Resection - A Matched-Controlled Study. Dis Colon Rectum. 2017;60(10):1032-1040.

 Serra-Aracil X, Mora-Lopez L, Alcantara-Moral M, et al. Transanal endoscopic microsurgery with 3-D (TEM) or high-definition 2-D transanal endoscopic operation (TEO) for rectal tumors. A prospective, randomized clinical trial. Int J Colorectal Dis 2014; 29:605-610

7. Atallah S, Albert M, Larach S. Transanal minimally invasive surgery: a giant leap forward. Surg Endosc. 2010;24(9):2200-5.

8. 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(9):775-88

9. Albert M, Atallah S, deBeche-Adams T, Izfar S, Larach S. 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

10. Demırbaş S, Cetiner S, Ozer TM, Oztaş M, Duran E. The use of single port surgery for polyps located in the rectum. Turk J Gastroenterol 2012;23:66–71

11. Hayashi S, Takayama T, Yamagata M, Matsuda M, Masuda H. Single-incision laparoscopic surgery used to perform transanal endoscopic microsurgery (SILSTEM) for T1 rectal cancer under spinal anesthesia: report of a case. Surg Today 2013;43:325–328

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

13. Arezzo A, Cortese G, Arolfo S, et al. Transanal Endoscopic Operation under spinal anaesthesia. Br J Surg. 2016;103(7):916-20

14. Menahem B, Alves A, Morello R, Lubrano J. Should the rectal defect be closed following transanal local excision of rectal tumors? A systematic review and meta-analysis. Tech Coloproctol. 2017;21(12):929-936.

15. Lee L, Althoff A, Edwards K, Albert MR, Atallah SB, Hunter IA, et al. Outcomes of Closed Versus Open Defects After Local Excision of Rectal Neoplasms: A Multi-institutional Matched Analysis. Dis Colon Rectum. 2018;61(2):172-178.

16. Marques CF, Nahas CS, Ribeiro U Jr, Bustamante LA, Pinto RA, Mory EK, et al. Postoperative complications in the treatment of rectal neoplasia by transanal endoscopic microsurgery: a prospective study of risk factors and time course. Int J Colorectal Dis. 2016;31(4):833-841. 17. Marks JH, Valsdottir EB, DeNittis A, et al. Transanal endoscopic microsurgery for the treatment of rectal cancer: comparison of wound complication rates with and without neoadjuvant radiation therapy. Surg Endosc 2009;23: 1081-1087

18. Clancy C, Burke JP, Albert M, et al. Transanal Endoscopic Microsurgery versus standard transanal excision for the removal of rectal neoplasms: a systematic review and meta-analysis. Dis Colon Rectum 2015;58:254-261

19. Langer C, Liersch T, Süss M, et al. Surgical cure for early rectal carcinoma and large adenoma: transanal endoscopic microsurgery (using ultrasound or electrosurgery) compared to conventional local and radical resection. Int J Colorectal Dis 2003;18: 222-229

20. Christoforidis D, Cho HM, Dixon MR, et al Transanal endoscopic microsurgery versus conventional transanal excision for patients with early rectal cancer. Ann Surg 2009;249:776-782

21. Kidane B, Chadi SA, Kanters S, et al. Local resection compared with radical resection in the treatment of T1N0M0 rectal adenocarcinoma: a systematic review and meta-analysis. Dis Colon Rectum 2015;58:122-140

22. Atallah S, Keller D. Why the Conventional Parks Transanal Excision for Early Stage Rectal Cancer Should Be Abandoned. Dis Colon Rectum 2015;58:1211-4

23. Gillern SM, Mahmoud NN, Paulson EC. Local excision for early stage rectal cancer in patients over age 65 years: 2000-2009. Dis Colon Rectum 2015;58:172–178

24. Hermanek P, Gall FP. Early (microinvasive) colorectal carcinoma. Pathology, diagnosis, surgical treatment. Int J Colorectal Dis 1986;1:79–84

25. Heintz A, Mörschel M, Junginger T. Comparison of results after transanal endoscopic microsurgery and radical resection for T1 carcinoma of the rectum. Surg Endosc 1998;12:1145-1148,

26. Lee W, Lee D, Choi S, Chun H. Transanal endoscopic microsurgery and radical surgery for T1 and T2 rectal cancer. Surg Endosc 2003;17:1283-1287

27. Borschitz T, Heintz A, Junginger T. The influence of histopathologic criteria on the longterm prognosis of locally excised pT1 rectal carcinomas: results of local excision (transanal endoscopic microsurgery) and immediate reoperation. Dis Colon Rectum 2006;49:1492-1506

28. Bach SP, Hill J, Monson JR, et al; Association of Coloproctology of Great Britain and Ireland Transanal Endoscopic Microsurgery (TEM) Collaboration. A predictive model for local recurrence after transanal endoscopic microsurgery for rectal cancer. Br J Surg 2009;96:280-290

29. Morino M, Allaix ME, Caldart M, et al. Risk factors for recurrence after transanal endoscopic microsurgery for rectal malignant neoplasm. Surg Endosc 2011;25: 3683-3690

30. Gavagan JA, Whiteford MH, Swanstrom LL. Full-thickness intraperitoneal excision by transanal endoscopic microsurgery does not increase short-term complications. Am J Surg 2004;187:630-634

31. Ramwell A, Evans J, Bignell M, et al. The creation of a peritoneal defect in transanal endoscopic microsurgery does not increase complications. Colorectal Dis 2009;11: 964-966

32. Baatrup G, Borschitz T, Cunningham C, et al. Perforation into the peritoneal cavity during transanal endoscopic microsurgery for rectal cancer is not associated with major complications or oncological compromise. Surg Endosc 2009;23:2680-2683

33. Morino M, Allaix ME, Famiglietti F, et al. Does peritoneal perforation affect short- and long-term outcomes after transanal endoscopic microsurgery? Surg Endosc 2013;27:181-188

34. Eyvazzadeh DJ, Lee JT, Madoff RD, et al. Outcomes after transanal endoscopic microsurgery with intraperitoneal anastomosis. Dis Colon Rectum 2014;57:438-441

35. Marks JH, Frenkel JL, Greenleaf CE, et al. Transanal endoscopic microsurgery with entrance into the peritoneal cavity: is it safe? Dis Colon Rectum 2014;57:1176-1182

36. Salm R, Lampe H, Bustos A, et al. Experience with TEM in Germany. Endosc Surg Allied Technol 1994;2:251–254

37. Yamamoto S, Watanabe M, Hasegawa H, et al. The risk of lymph node metastasis in T1 colorectal carcinoma. Hepatogastroenterology 2004;51:998-1000

38. Saraste D, Gunnarsson U, Janson M. Predicting lymph node metastases in early rectal cancer. Eur J Cancer 2013;49:1104-1108

39. Garcia-Aguilar J, Shi Q, Thomas Jr. CR, et al. A Phase II trial of neoadjuvant chemoradiation and local excision for T2N0 rectal cancer: preliminary results of the ACOSOG Z6041 trial. Ann Surg Oncol 2012;19:384-391

40. Bhangu A, Brown G, Nicholls RJ, et al. Survival outcome of local excision versus radical resection of colon or rectal carcinoma: a Surveillance, Epidemiology, and End Results (SEER) population-based study. Ann Surg 2013;258:563-569

41. Pucciarelli S, De Paoli A, Guerrieri M, et al. Local excision after preoperative chemoradiotherapy for rectal cancer: results of a multicenter phase II clinical trial. Dis Colon Rectum 2013;56:1349–1356

42. Shaikh I, Askari A, Ourû S, et al. Oncological outcomes of local excision compared with radical surgery after neoadjuvant chemoradiotherapy for rectal cancer: a systematic review and meta-analysis. Int J Colorectal Dis 2015;30:19–29.

43. Allaix ME, Arezzo A. Giraudo G, et al. Transanal endoscopic microsurgery vs. laparoscopic total mesorectal excision for T2N0 rectal cancer. J Gastrointest Surg 2012;16:2280-2287

44. Sajid MS, Farag S, Leung P, et al. Systematic review and meta-analysis of published trials comparing the effectiveness of transanal endoscopic microsurgery and radical resection in the management of early rectal cancer. Colorectal Dis 2013;16;2-16

45. Garcia-Aguilar J, Renfro LA, Chow OS et al. Organ preservation for clinical T2N0 distal rectal cancer using neoadjuvant chemoradiotherapy and local excision (ACOSOG Z6041): results of an open-label, single-arm, multi-institutional, phase 2 trial. Lancet Oncol. 2015;16:1537-46

46. Perez RO, Habr-Gama A, São Julião GP, et al. Transanal Endoscopic Microsurgery for residual rectal cancer after neoadjuvant chemoradiation therapy is associated with significant immediate pain and hospital readmission rates. Dis Colon Rectum 2011;54: 545-551

47. Arezzo A, Arolfo S, Allaix ME, et al. Results of neoadjuvant short-course radiation therapy followed by transanal endoscopic microsurgery for T1-T2 N0 extraperitoneal rectal cancer. Int J Radiat Oncol Biol Phys. 2015;92:299-306

48. Gornicki A, Richter P, Polkowski W, et al. Anorectal and sexual functions after preoperative radiotherapy and full-thickness local excision of rectal cancer. Eur J Surg Oncol 2014;40:723-730

49. Restivo A, Zorcolo L, D'Alia G, et al. Risk of complications and long-term functional alterations after local excision of rectal tumors with transanal endoscopic microsurgery (TEM). Int J Colorectal Dis 2016;31:257-66

50. Morino M, Risio M, Bach S, et al. Early rectal cancer: the European Association for Endoscopic Surgery (EAES) clinical consensus conference. Surg Endosc 2015;29:755-773

51. Verseveld M, de Graaf EJ, Verhoef C et al.; CARTS Study Group. Chemoradiation therapy for rectal cancer in the distal rectum followed by organ-sparing transanal endoscopic microsurgery (CARTS study). Brit J Surg 2015;102:853-860

52. TREC study. Available at: http://www.controlled-trials.com/isrctn 14422743.

53. 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;18:775-88.

54. 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 2014;17:397-402

55. Keller DS, Tahilramani RN, Flores-Gonzalez JR, Mahmood A, Haas EM. Transanal minimally invasive surgery: review of indications and outcomes from 75 consecutive patients. J Am Coll Surg 2016;222:814-822

56. Lee L, Burke JP, deBeche-Adams T, Nassif G, Martin-Perez B, Monson JR, Albert MR, Atallah SB. Transanal Minimally Invasive Surgery for Local Excision of Benign and Malignant Rectal Neoplasia: Outcomes From 200 Consecutive Cases With Midterm Follow Up. Ann Surg. 2017 Mar 1. doi: 10.1097/SLA.00000000002190. [Epub ahead of print]

57. 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(10):3762-8

58. Melin AA, Kalaskar S, Taylòor L, Thompson JS, Ternent C, Langenfeld SJ. Transanal endoscopic microsurgery and transanale minimally invasive surgery: is one technique superior? Am J Surg 2016;212:1063-1067

59. Mege D, Bridoux V, Maggiori L, Tuech JJ, Panis Y. What is the best tool for transanal endoscopic microsurgery (TEM)? A case-matched study in 74 patients comparing a standard platform and a disposable material. Int J Colorectal Dis. 2017;32(7):1041-1045

60. Lee L, Edwards K, Hunter IA, Hartley JE, Atallah SB, Albert MR, Hill J, Monson JR. Quality of Local Excision for Rectal Neoplasms Using Transanal Endoscopic Microsurgery Versus Transanal Minimally Invasive Surgery: A Multi-institutional Matched Analysis. Dis Colon Rectum. 2017;60(9):928-935

61. Maslekar S, Pillinger SH, Sharma A, Taylor A, Monson JR. Cost analysis of transanal endoscopic microsurgery for rectal tumours. Colorectal Dis. 2007;9(3):229-34

62. Helewa RM, Rajaee AN, Raiche I, Williams L, Paquin-Gobeil M, Boushey RP et al. The implementation of a transanal endoscopic microsurgery programme: initial experience with surgical performance. Colorectal Dis. 2016;18(11):1057-1062

63. Lee L, Kelly J, Nassif GJ, Keller D, Debeche-Adams TC, Mancuso PA, et al. Establishing the learning curve of transanal minimally invasive surgery for local excision of rectal neoplasms. Surg Endosc. 2018;32(3):1368-1376.