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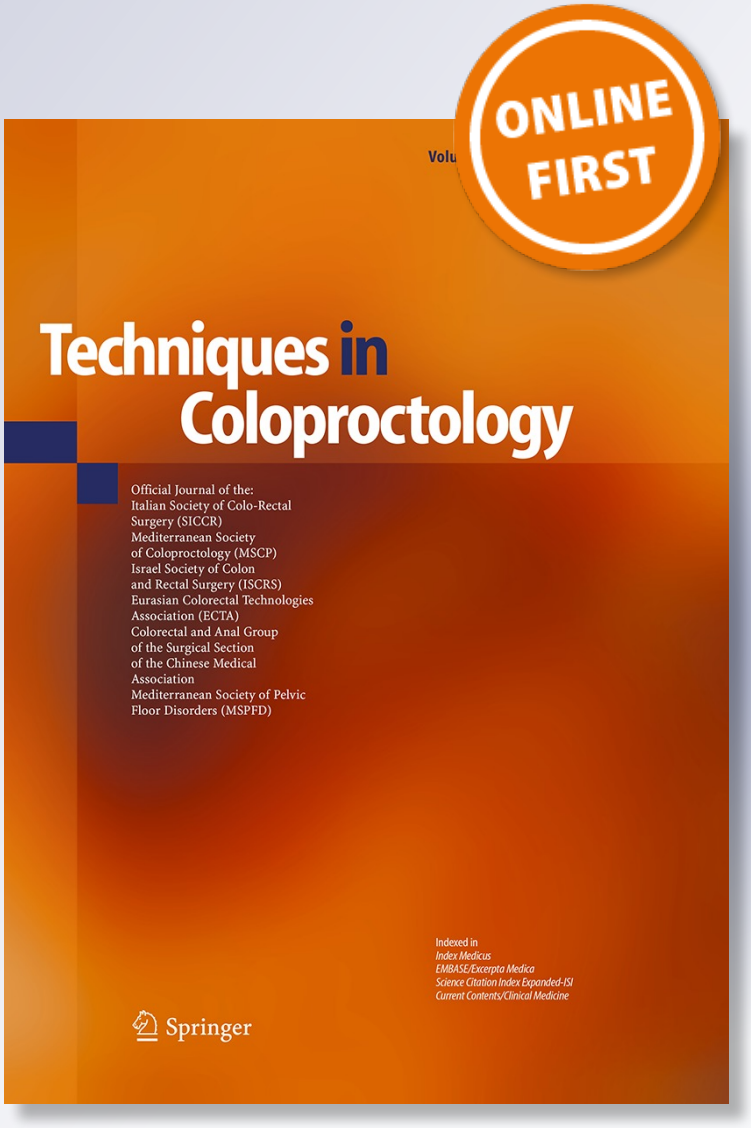

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TECHNICAL NOTE

Transanal minimally invasive surgery (TAMIS) using a new disposable device: our initial experience

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Abstract Disposable single-port surgery devices have been used for transanal minimally invasive surgery (TAMIS). Their advantage, compared to transanal endoscopic microsurgery, is that they do not require special equipment or training. The aim of this study was to assess our initial experience using the single-site laparoscopic (SSL^{TM}) access system (Ethicon Endo-Surgery, Cincinnati, OH, USA) for TAMIS. Five patients eligible for local excision of rectal tumors, four males and one female, mean age 58 years (range 50–78), underwent surgery using the SSL^{TM} device. The average distance from anal verge was 4 cm (range 1–6). Four patients had an initial diagnosis of adenoma, and one had a previous endoscopic excision of a T1 adenocarcinoma with positive margins. In one patient, due to the lack of exposure, the procedure was converted to a low anterior resection. In the remaining four patients, average setup time was 7 minutes (range 4–15) and average operative time was 52 minutes (range 38–72). All resection margins were tumor free. There were no postoperative complications. Two of the presumed adenomas were intramucosal adenocarcinomas, while one patient had a T2 tumor and underwent radical surgery. Although at the present time the appropriate use of local excision is still under debate, TAMIS is a technique with great potential. Because of its simplicity and similarity with conventional laparoscopic surgery, it can be learned easily by surgeons not trained in transanal endoscopic microsurgery.

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Introduction

As screening has substantially increased the early diagnosis of tumors, there is a need for local treatments that are oncologically equivalent to radical surgery, but safer and functionally superior [1]. Local excision of rectal tumors has been performed since the early 1800s, when Lisfranc described a local excision for rectal carcinoma [2].

Compared to local excision, transanal endoscopic microsurgery (TEM) provides superior quality of resection, decreased local recurrence, and improved survival, particularly among patients with adenomas [3] and histologically favorable stage I rectal cancer [4, 5]. In long-term follow-up, TEM excision of rectal tumors has proven to be safe and effective, with morbidity and mortality similar to that of conventional transanal excision [5, 6].

However, although TEM has been in use for more than 20 years, it has been slow to become universally adopted by colorectal surgeons, partly due to a long learning curve, but also because of the significant cost of the highly specialized equipment and instrumentation [2, 4].

As technology continues to undergo rapid evolution, minimally invasive surgical techniques develop quickly. Recently, single-incision laparoscopic surgery (SILS) has provided technology for developing permanent and disposable equipment and instruments that can be used for both abdominal and pelvic operations through a single incision. These devices have facilitated a wide range of operations, including bariatric and various transanal colorectal applications using a single-incision multiport device.

The working angles in single-access laparoscopy are essentially identical to those used in TEM. Therefore, crossover exists between the skills necessary to perform single-port laparoscopy and TEM. The considerable up-front cost of TEM instrumentation, however, remains a significant barrier to its widespread use [4].

Transanal minimally invasive surgery (TAMIS) was first described by Drs Atallah et al. from Orlando, USA [4], using an elastomer device (SILS™ Port, Covidien, Mansfield, MA, USA) and reported to be effective and safe for early rectal cancer and adenomas, with excellent operative field visibility and moreover not technically difficult. As the authors say, TAMIS is a "giant leap forward" when compared to TEM. Mounting is easier and demands less time prior to beginning surgery. Since a disposable device is used, the cost is lower and manipulation is much more comfortable than with TEM.

Recently, Ethicon Endo-Surgery (Cincinnati, OH, USA) presented their single-site laparoscopic (SSL™) access system. We report the clinical application of this device and present preliminary data showing SSL™ to be an effective tool for the excision of rectal neoplasms.

Materials and methods

Over a 6-month period, TAMIS was offered to all patients with rectal adenomas who were candidates for transanal local excision. Informed consent was obtained, and all patients were given the option to undergo conventional surgery. Five patients, four males and one female, mean age 58 years (range 50–78), were included in the study.

Prior to surgery, all patients undergo mechanical bowel preparation and receive a single 3-g dose of intravenous Unasyn® (Pfizer, Brazil), at induction of anesthesia.

Single-site laparoscopic™ is an abdominal access system consisting of a seal cap with accessories (silicone retractor, retractor insertion tool, and reducer cap) and a fixed-length retractor. The 4-cm retractor was used in all cases. The assembled device maintains gas pressure while allowing for insertion of multiple surgical instruments. The seal cap has a separate insufflation-dedicated access, two 5-mm seals, and one 12-mm seal, which are to be used without trocars, eliminating possible interference of trocar cannulas in the rectum. The seal cap has 360° rotation that allows quick reorientation of the instrumentation and camera throughout the procedure, and there is no need for the device to be fixed to the patient or to the table. The removable seal cap makes it easy to extract large specimens without removing the device.

The procedure is performed under general anesthesia.

The patient's position is ideally one in which the lesion is facing the surgical table. When the lesion is in the posterior rectal wall, the patient is in lithotomy position, with legs up; when the tumor is in the right lateral wall, the patient must be turned with the right side down. Although not mandatory, this is the most comfortable way to perform this procedure.

After the patient is correctly positioned, the retractor is gently inserted into the anal canal and tested with a finger for good positioning of the internal ring of the retractor in the rectum, right above the anorectal ring (Fig. 1a). Then the seal cap is fixed in place in the external ring, and the inner part of the cap rotated up to the desired position (Fig. 1b). Once in position, pneumorectum can be established and endoscopic access to the rectum is achieved. There is no need for trocars, since the cap has its own seals, and there is no need for fixation, as the device remains in place for the entire procedure. There is also no need for special instruments.

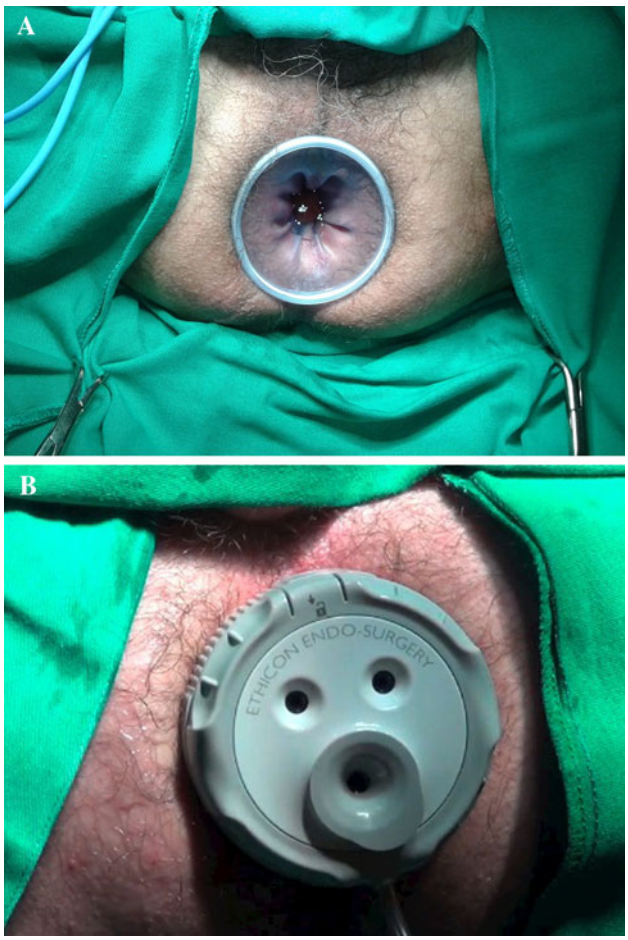

Fig. 1 **a** The single-site laparoscopy (SSL) retractor in place for transanal minimally invasive surgery (TAMIS) excision. **b** SSL with cap. Originally designed to facilitate single-incision laparoscopy, it fits well in the anal canal for TAMIS access. It has two 5-mm ports and one 5–15-mm port. As it already comes with a seal, trocars are not used in any of the ports

Regular straight laparoscopic graspers, scissors, clip appliers, and needle drivers can be used with no technical difficulty (Fig. 2). Sometimes, an articulated or curved-tip instrument can be used in order to make the procedure technically easier.

As a first step, a monopolar marking is made at least 5 mm far from the tumor margins (Fig. 3). After that, a full-thickness resection including mesorectal fat resection is performed, and absorbable monofilament running sutures are used to close the rectal wall defect approximating the rectal wall borders (Fig. 4). The edges of the suture line are either tied or clipped. Excision specimens are measured, stretched, and pinned on cardboard by the surgeon before immersion into formalin (Fig. 5).

Results

Five patients underwent TAMIS excision of rectal lesions (Table 1). The average distance from anal verge was 4 cm (range 1–6 cm), and the mean tumor diameter estimated by endoscopy was 4 cm (range 2.5–6 cm). Four patients had an initial diagnosis of adenoma. One patient had undergone a previous endoscopic resection of a T1 adenocarcinoma (case C) with positive margins.

One patient (case D) could not be operated using TAMIS with SLL. Expansion of the retractor into rectal lumen was not possible. The size of the prostate probably did not allow the device to open to the anterior rectal wall, and a conventional low anterior resection was used in this case.

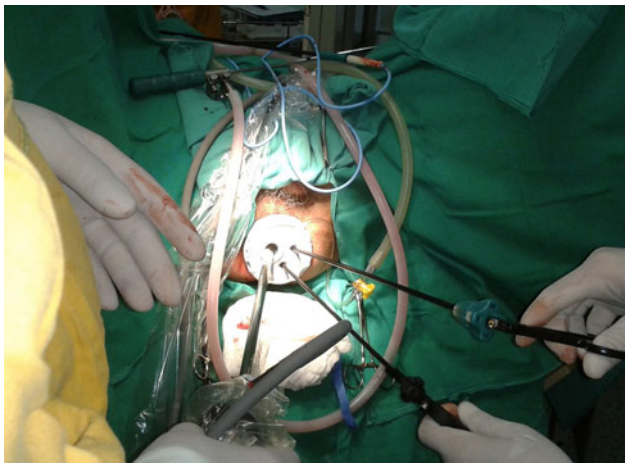

Fig. 2 Single-site laparoscopy (SSL) device is used with regular straight instruments; 5-mm ports are used for instruments, and 15-mm port was used for 10-mm 30° lens. If a 5-mm laparoscope is used, there is no need to take the reduction seal out

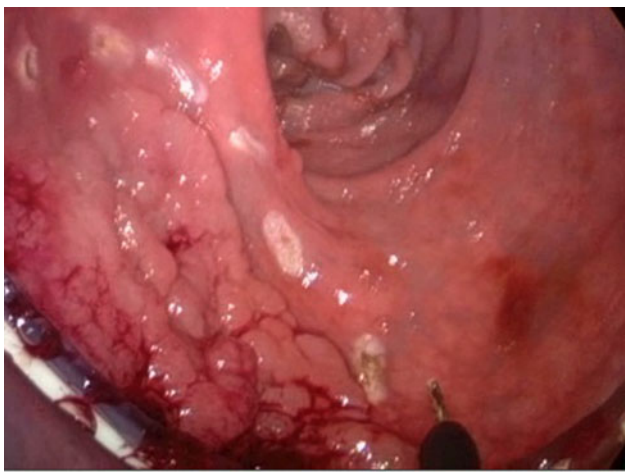

Fig. 3 Endoscopic view of adenoma with central focal pT1/N0 prior to excision after monopolar marking of 1 cm from tumor margins

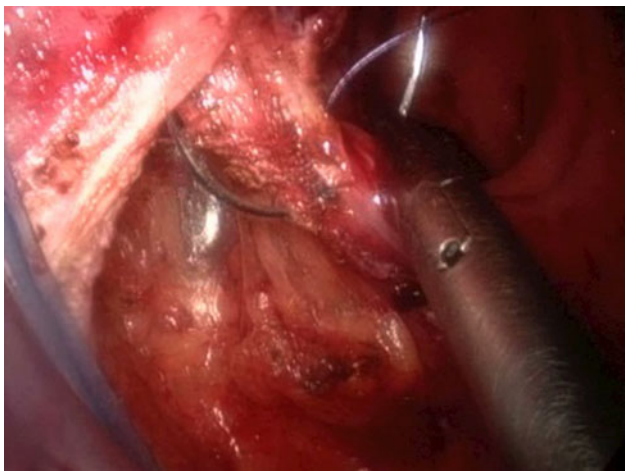

Fig. 4 After full-thickness excision of a 5-cm adenoma with T1 focal adenocarcinoma, with negative pathological margins, suture begins with regular straight laparoscopic needle driver

Fig. 5 Surgical specimen. Margins are tumor free and 8 mm circumferential. In this case most of the mesorectum was removed in the dissection, and three benign nodes were retrieved

Table 1 Tumor characteristics

Case, age/sex	Tumor location (cm from anal verge)	Initial tumor pathology	Position	Tumor diameter (cm)	Resection margin	Final pathology
A, 51/M	1	Villous adenoma	Posterior	5	Free	Adenocarcinoma Tis
B, 76/M	6	Villous adenoma	Left lateral	5	Free	Adenocarcinoma Tis
C, 50/F	5	Adenocarcinoma T1, resected with endoscopic mucosectomy, focally compromised margins	Left lateral (no visible tumor, only scar)	2 cm (scar)	Free	Tumor free
D, 56/M	2	Tubulovillous adenoma, high-grade dysplasia	Circumferential[a]	Not excised	Not excised	Not excised
E, 78/M	5	Tubulovillous adenoma	Posterior	6	Free	Adenocarcinoma T2

[a] After positioning the patient, the device could not be positioned and the technique was changed to standard low anterior resection

Table 2 Clinical and operative results

Case	Operative time (min)	Hospital stay (days)	Morbidity/mortality	Setup time (min)
A	53	1	None	15
B	44	1	None	5
C	38	1	None	4
D	Low anterior resection	–	–	–
E	72	1	None	4

Key intra- and postoperative data are shown in Table 2. There was no postoperative mortality. In one patient partial dehiscence of the suture line in the distal rectum was diagnosed by digital rectal examination on postoperative day 9, confirmed by anuscopy, and treated conservatively as outpatient. In this patient, endoscopy revealed a complete scar at 45 days.

The patient with a previous T1 tumor had no residual cancer. Of the remaining three patients, two had intramucosal adenocarcinomas (Tis) and one had a T2 adenocarcinoma. This patient underwent laparoscopic anterior resection with coloanal anastomosis 6 weeks after neoadjuvant chemoradiation, and pathology showed no carcinoma (pT0 N0) in the surgical specimen. All patients were followed up clinically for an average of 21 weeks (range 12–53) and underwent CT scan on week 12 and colonoscopy at 11–12 months. There were no complications, and no recurrence was identified.

Discussion

Although TEM has been proven to be an effective alternative for local excision and has been performed for more than 20 years, before the widespread use of laparoscopic techniques for abdominal surgery, the advances made in the TEM technique were limited and did not follow to the developments in abdominal laparoscopy. Before TAMIS was presented in 2009, the only evolution in transanal surgery was the development of rigid metal or transparent [7] proctoscopes for TEM. When TAMIS was first described, colorectal surgeons became aware of a completely new technique using an affordable, simple, and effective device.

Care must be taken in patient selection, as local excision must be considered only for early rectal cancer with no evidence of nodal metastasis [5, 8], parameters that can be predicted by clinical and radiological evaluation [9]. Even after adequate evaluation, up to 44.3 % of T1 tumors may be understaged preoperatively [1]. Although three of our patients went for surgery with a tumor thought to be benign, one had a T2 tumor. As oncological safety of local excision for T2 tumors is not well established [1, 10], this patient underwent laparoscopic anterior resection after neoadjuvant therapy.

Considering the minimal setup time, low cost, and especially the adaptation of regularly used laparoscopic instruments, TAMIS provides an ideal platform for transseptal or transanal excision [11]. It has also been used for high fistulas, distal rectal mobilization for coloanal anastomosis [12], and carcinoid tumors [13, 14]. Other indications that still lack consensus are re-excision following endoscopic removal of malignant polyps [15] and excision of a downstaged tumor or scar after complete response to neoadjuvant chemo/radiotherapy [16, 17]. Total mesorectal excision (TME) is also an indication being considered for the use of TAMIS technique [18].

In this series, the maximum distance from tumor to anal verge was 6 cm. This patient had a 5-cm-diameter tumor, so resection was performed to a level of 12 cm from the anal verge without difficulties, showing that TAMIS must not be restricted to low tumors, as has been suggested [19].

The advantages of TAMIS over TEM are well described [4, 20]: (1) Devices used for TAMIS are pliable and allow well-fitted positioning at the anal canal, possibly leading to less impairment of sphincter function than the 40-mm rigid scope used for TEM; (2) setup time is significantly lower for TAMIS; (3) in TAMIS regular straight laparoscopic instruments and a standard 30° laparoscope can be used, as

opposed to the fixed eyepiece of the TEM rectoscope, making it possible to advance the scope into the proximal rectum and sigmoid and allowing the surgeon to look beyond the tumor; (4) TAMIS is easily learned by surgeons not used to TEM due to its potential instrumental simplicity and similarity with conventional laparoscopic surgery; (5) a 15-mm port is available only for TAMIS devices, and it can be very helpful when a 10-mm instrument or lens or even a 12-mm stapler is needed (e.g., for safe excision of a big pedunculated polyp); and (6) it is a cost-effective alternative to TEM [21]. When local excision is considered for adenomas or T1 tumors located in the area from dentate line up to higher rectum, or if future studies show that selected T2 and T3 tumors can be locally excised [1, 22, 23], TAMIS can be a remarkable cost-effective alternative.

The potential advantages of SSL over other devices are also remarkable [11, 20]: (1) The cap can be removed and reinserted quickly when needed and can be removed for specimen retrieval and repositioned in less than one minute for suturing; (2) positioning the SSL^{TM} is quick and there is no need of fixing it to the patient's skin; and (3) there is no need for trocars, as there is a seal on each port, which makes instrumentation much easier, when compared to single-incision laparoscopic surgery (SILS^{TM}) or TEM. As the device is basically a hollow sleeve with a cap in which the ports are located, there is no resistance when moving around the laparoscopic instruments, as may happen with SILS, which is solid. This makes the use of regular straight laparoscopic instruments easier than when using SILS. Also, the rotating cap allows changing instrument position without having to reinsert the device or changing its position.

Conclusions

Although at the present time the appropriate use of local excision is still under debate, TAMIS is a technique that has a potential of increased application and much remains to be learned [4, 20]. It is our opinion that TAMIS will prove to be a good alternative to TEM and one of the most import contributions made to transanal surgery for years.

Conflict of interest None.

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