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Transanal Endoscopic Microsurgery (TEM) Facilitated by Video-Assistance and Anal Insertion of a Single-Incision Laparoscopic Surgery (SILS®)-Port: Preliminary Experience

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Abstract

Objective Transanal endoscopic microsurgery (TEM) is an established method for the resection of benign and early malignant rectal lesions. Very recently, TEM via an anally inserted single incision laparoscopic surgery (SILS®)-port has been proposed to overcome remaining obstacles of the classical TEM equipment.

Methods Nine patients with a total of 12 benign or early stage malignant rectal polyps were operated using the SILS®-port for TEM. Patients' and polyps' characteristics, perioperative and postoperative complications, as well as operating and hospitalization time were recorded.

Results All 12 polyps (ten low-grade adenoma, one high-grade adenoma, one pT_2 carcinoma [preoperatively staged as T_1]) were resected. Local full-thickness bowel wall resection was performed for three lesions and submucosal resection for nine lesions. Median operating time was 64 (range 30–180) min. No conversion to laparoscopic or open techniques was necessary. The median maximum diameter of the specimen was 25 (range 3–60) mm, fragmentation of polyps was avoidable in 11 of 12 (92 %) lesions, and resection margins were histologically clear in 11 of 12 (92 %) polyps. Only one patient, in whom three lesions were resected, experienced a complication as postoperative hemorrhage. No mortality occurred. Median hospitalization time was four (range 1–14) days.

Conclusions SILS®-TEM is a feasible and safe method, providing numerous advantages in application, handling, and economy compared with the classical TEM technique. SILS®-TEM might become a promising alternative to classical TEM. Randomized, controlled trials comparing safety and efficacy of both instrumental settings will be needed in the future.

Abbreviations

TEM	Transanal endoscopic microsurgery
NOTES	Natural orifice transluminal endoscopic surgery
SILS	Single incision laparoscopic surgery
EMR	Endoscopic mucosal resection
ESD	Endoscopic submucosal dissection

Introduction

Transanal endoscopic microsurgery (TEM), which was described as an innovation in 1983 by Buess et al. [1, 2], can be regarded as the first approach to pure natural orifice transluminal endoscopic surgery (NOTES) and single-port surgery (SPS) [3, 4]. Despite the advantages of classical TEM and its superiority compared with conventional transanal excision [5, 6], including our own concept [7], some difficulties remain, detaining this technique from

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widespread adoption. The main reasons are the high costs of investment for the required specific TEM devices [8, 9], the long learning curve due to the demanding and inconvenient technique [10, 11], and the at least temporary fecal incontinence in some patients caused by anal dilatation and insertion of the large metal tube [11, 12].

Transanal excision of rectal adenomas via a laparoscopic single access port device was described for the first time in 2010 by Khoo et al. and Demirbas et al. (accepted 2010, published 2012) [13, 14]. Several case reports [15, 16] and case series followed, investigating different laparoscopic single port devices [10, 12, 17–19].

For the TEM procedure, we used a SILS®-port, which is made of a mixture of elastic polymers and therefore has a soft and spongy consistency. The measures and shape of the SILS®-port fit optimally into the human anal canal. Due to its ability to be compressed (Fig. 1), it can be inserted easily into the anal canal without previous dilatation.

The purpose of this prospective case series was to investigate the feasibility and the short-term results of the new SILS®-TEM method, to discuss its advantages over the conventional Buess technique, and to provide some practical tips.

Patients and methods

During the period of August 2010 to December 2012, patients with rectal polyps not amenable to colonoscopic or standard transanal excision due to tumor size (usually >3 cm), location (located within 6–7 cm from anal verge, on or behind a fold of Kohlrausch), or morphology (sessile, high-grade dysplasia, or cT_1 $G_{1\text{-}2}$-cancer) but eligible for TEM were offered the option to undergo SILS®-TEM. Eligibility criteria were comprised of sessile rectal adenomas of any degree of dysplasia or cT1-carcinomas with low risk for metastasis, i.e., well or moderately differentiated carcinomas without venous or lymphatic invasion in the biopsy specimen, in elderly patients. Informed consent was obtained from all patients. Patients' characteristics, perioperative data, clinicopathological findings, and postoperative outcomes were assessed. Complications, such as (haemodynamic relevant) hemorrhage, bowel perforation, suture dehiscence with consecutive leakage, stenosis, fecal incontinence, abscesses, fistulae, urinary tract infection, and mortality, were registered.

Preoperative investigations included rectal digital examination, colonoscopy with biopsy of the polyps, and endorectal ultrasound. The polyps' site within the rectum and the distance from the caudal border of the polyps to the anal verge were assessed by use of a rigid proctoscope. In the case of suspected malignancy, magnetic resonance imaging (MRI) of the pelvis as well as computed tomography (CT) of the abdomen and thorax were performed additionally. Pre- and postoperatively, Miller's anal incontinence score (complete incontinence: 18/18 points, complete continence: 0/18 points), which is based on the frequency of incontinence of gas, solid stool, and liquid stool [20, 21], was assessed in all patients.

Surgical technique

For prophylaxis of venous thromboembolism, low-molecular-weight heparin was administered at a dose of 5,000 IU subcutaneously the evening before surgery. Mechanical bowel preparation was performed the day before surgery by means of a 4-liter electrolyte solution. Single-shot cefuroxime and metronidazole were used as antibiotic prophylaxis for patients with submucosal resection. The procedure was performed under general anesthesia, and all patients were placed in the lithotomy position (Fig. 2a), independent of the site of the polyp within the rectum. All

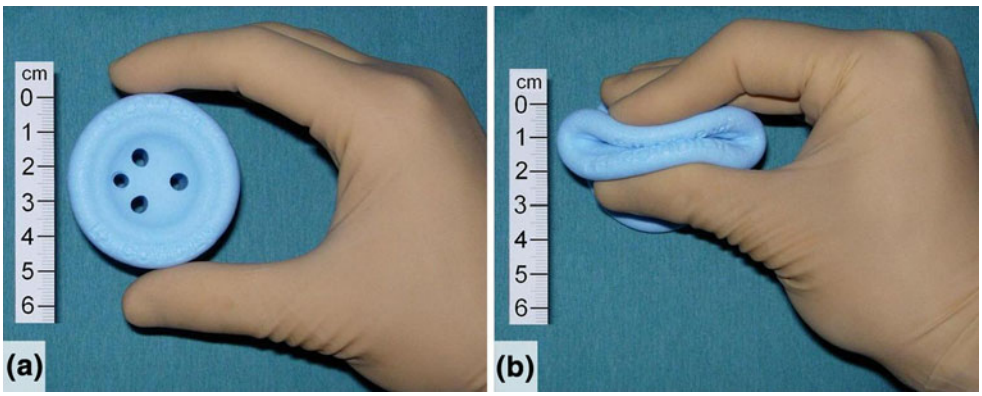

Fig. 1 **a** SILS®-port without inserted instruments and without gas tube (*front view*). The sizes are 50 mm in length, 50 mm maximum diameter at the edges, and 30 mm minimum diameter in the middle. The SILS®-port channels are accessible for 5–15 mm cannulae. **b** Note the high flexibility—the port may be compressed to approximately 60 % of its original diameter (50–20 mm), allowing an easy insertion and fitting into the anal canal

procedures were performed by the same surgeon (CAM) with the assistant standing on the left and the scrub nurse on the right side at the lower end of the patient. A SILS®-port (Covidien, Mansfield, MA) was lubricated and introduced into the anal canal without prior dilatation. A 5-mm, 30-degree optic with a shank length of 50 cm was introduced via one of the three 5-mm cannulae within the SILS®-port and stable pneumorectum was established by CO_2-insufflation with a pressure of 10 and 15 mm Hg via the gas tube belonging to the SILS® set (Figs. 2b, 3). If required, luxation of the port was prevented manually, not using any perianal temporary fixation sutures. Standard (nonarticulating and noncurved) laparoscopic 5-mm instruments, such as graspers, thermal energy devices, needle drivers, and suction/irrigation devices, were used via the two remaining 5-mm cannulae (Fig. 3). Polyps were resected by means of diathermy scissors, diathermy hook or Harmonic Ace® scalpel (Ethicon Endo-Surgery, Cincinnati, OH). If required, selective argon plasma coagulation was applied. A safety margin of at least 2–3 mm grossly normal mucosa was always left during the procedure (Fig. 4). A local full-thickness bowel wall excision was performed if malignancy was suspected. Otherwise, a submucosal resection of the polyp was performed. The specimen was removed together with the SILS®-port and pinned in a stretched way on a cork tablet. Following extensive rectal washout with cytotoxic 1:10 diluted polyvidon iodide solution (10 × 50 ml) via a Foley-catheter, the SILS®-port was reinserted in the anal canal. The rectal defect was closed in full-thickness resections, using only a resorbable monofilament 3.0 running suture (glycolide, dioxanone, and trimethylene carbonate). For this purpose, the V-Loc™ suture concept (VLOCM0604, Covidien, Mansfield, MA) proved to be helpful.

Postoperative care

Postoperatively, patients were allowed to take light food on the evening of the operation and normal food from the first postoperative day onwards. Stool consistency was optimized by daily oral application of liquid paraffin. The patients, who underwent submucosal resection, as mentioned, received a preoperative antimicrobial single-shot prophylaxis with 1,500 mg of cefuroxime and 500 mg of metronidazole according to the actual guidelines [22]. However, patients with local full-thickness bowel wall resection and primary suture of the defect and thus having a risk for pararectal abscess received an empirical preemptive antibiotic therapy with 500 mg of ciprofloxacin and 500 mg of metronidazole twice a day for 5 days. The Miller incontinence score was assessed again. Control colonoscopy was recommended 3–6 months after SILS®-TEM for all patients. All values are presented as median (range).

Results

In 9 patients (7 males, 2 females) who underwent SILS®-TEM, 12 rectal lesions were resected. During the same time period, we removed 21 rectal polyps by conventional transanal surgical resection and 342 polyps of the colorectum were removed by means of a conventional endoscope at the department of gastroenterology. In addition to SILS®-TEM, one patient underwent a synchronous left hemicolectomy and wedge resection of the liver for stage IV colon cancer according to Union International Against Cancer (UICC) [23]. The patients' and polyps' characteristics as well as the procedure-related results are summarized in Tables 1 and 2. No patient had had anal surgery

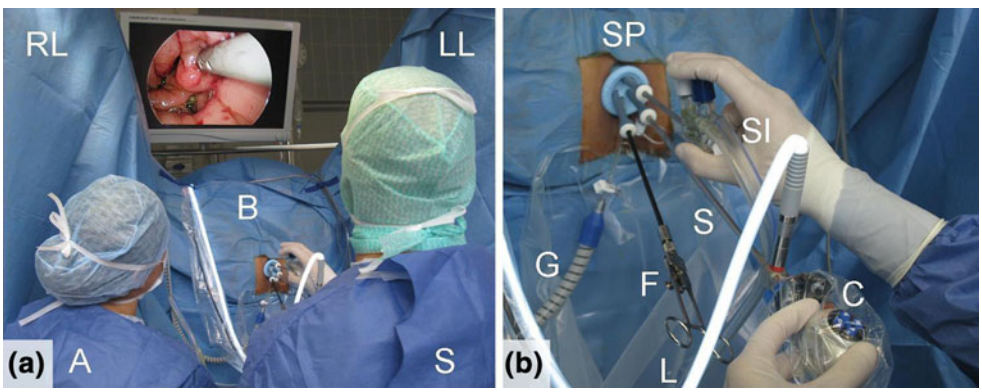

Fig. 2 **a** SILS®-TEM with surgeon (S), assistant (A), and patient in lithotomy position. *RL* right leg; *LL* left leg; *B* belly. **b** SILS®-TEM instruments in situ. SILS®-port (SP), gas supply (G), 30°-endoscope with a 50-cm shank (S), connected camera (C) and light supply (L), suction/irrigation device (SI), and french grasper (F). Note the staggered position of the instruments with regard to the bulky camera allowing comfortable handling

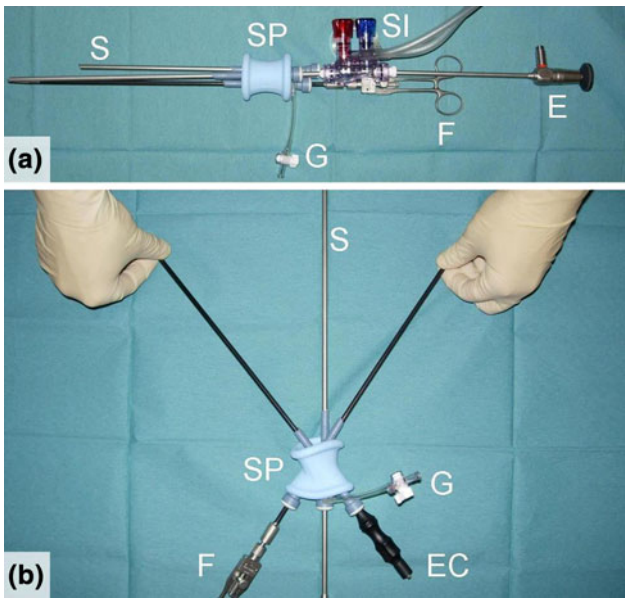

Fig. 3 **a** SILS®-port with inserted instruments and endoscope ex situ (lateral view). SILS®-port (SP), gas supply (G), 30°-endoscope (E) with a 50-cm shank (S), suction/irrigation device (SI), and French grasper (F). Note the staggered position of the instruments with regard to the endoscope. **b** SILS®-port with inserted instruments ex-situ. SILS®-port (SP), gas supply (G), 30°-endoscope with a 50-cm shank (S), French grasper (F), and electrocautery device (EC). Note the high flexibility of the SILS-port allowing a wide range of instruments' angulation

before. No conversion to standard transanal excision, laparoscopic, or open techniques was performed.

In one patient, a polyp preoperatively staged as low-risk cT_1-cancer turned out to be a moderately differentiated pT_2-carcinoma with carcinomatous lymphangiosis at histological examination. Because this patient refused to undergo radical rectal resection, combined chemoradiotherapy was performed. Up to date, the patient is without evidence for local recurrence 11 months after SILS®-TEM.

Except in the T_2-carcinoma, all other resection margins were clear. No mortality occurred and no patient needed reoperation due to complications specific to the procedure during the hospital stay. The longest hospitalization time was 14, 10, and 8 days, respectively, which were necessary for one patient with bladder tamponade requiring blood transfusion, who underwent transurethral resection of the prostate 2.5 weeks before SILS®-TEM, for one patient who underwent synchronous left hemicolectomy, and for one patient with a syndrome of inappropriate antidiuretic hormone secretion (SIADH), requiring electrolyte substitution. Actually, the shortest hospitalization time for patients receiving sole SILS®-TEM was 4 days. However, one readmission was necessary on day 11 to control a secondary hemorrhage for one patient, who was under anticoagulation with marcoumar. Postoperatively, Miller's anal incontinence score remained unchanged compared

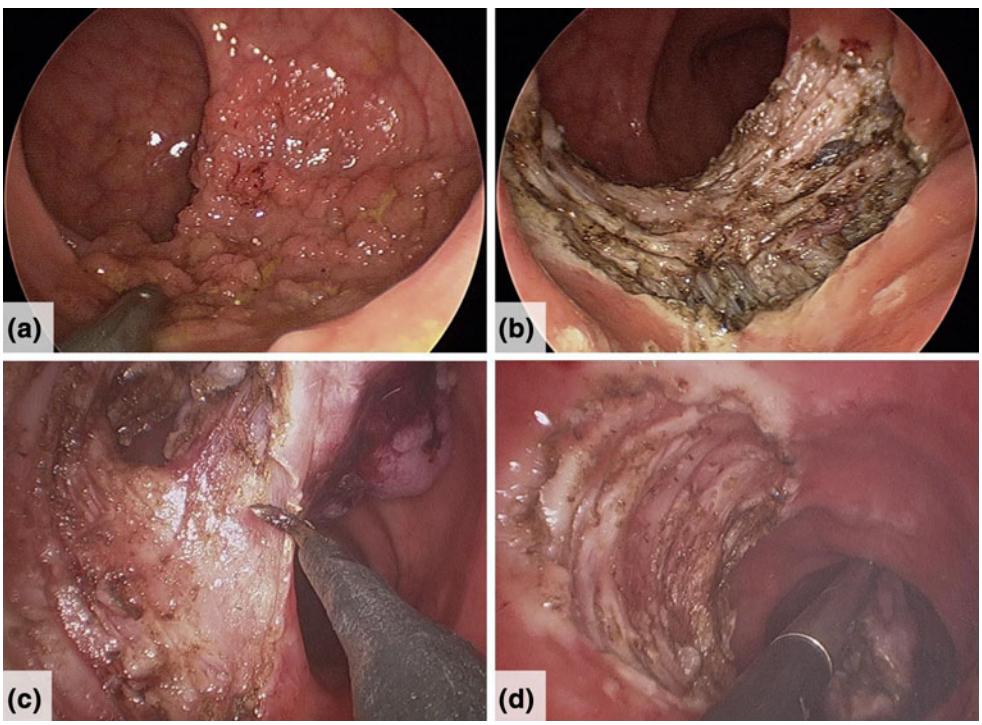

Fig. 4 **a**, **b** Intraoperative endoscopic view showing a large sessile rectal adenoma (50 × 45 × 8 mm) before and after submucosal resection, done with cautery. **c**, **d** Intraoperative endoscopic view showing a large sessile adenoma (35 × 30 × 10 mm) right before complete submucosal resection (note the polyp in the *upper right corner* and the associated safety margin) and the resection area after resection was completed

Table 1 Clinical variables and characteristics of polyps

Patients: $n = 9$; Rectal polyps: $n = 12$
Male:female ratio—7:2 (78:22 %)
Age, median (range): 66 (54–78)
ASA classification
1:1
2:6
3:2
4:0
Body mass index (kg/m^2), median (range): 25.4 (22.7–29.8)
Distance of lower polyp border from anal verge in cm, median (range): 6 (4.5–13)
Distance of upper polyp border from anal verge in cm, median (range): 10 (8–15)
Site within rectum
Posterior: 3
Anterior: 2
Lateral (left): 3
Lateral (right): 3
Circumferential: 1
Preoperative staging, and histology according to biopsy, $n = 12$
Adenoma with low-grade dysplasia: 10
Adenoma with high-grade dysplasia: 1
T1-cancer: 1
T2-cancer: 0

Table 2 Procedure-related results

Operation time in min, median (range): 64 (30–180)
Conversion to other technique: 0/9 (0 %)
Full-thickness bowel wall resection: 3/12 (25 %)
Suture closure of bowel wall defect: 5/12 (42 %)
Blood loss in ml, median (range): 5 (2–10)
Hospitalization time in days, median (range): 4 (1–14)*
No fragmentation of specimen: 11/12 (92 %)**
Maximum diameters of specimens (mm), median (range)
Length, mm: 25 (3–60)
Width, mm: 24 (8–50)
Depth, mm: 8 (3–35)
Calculated volume of specimens (L × W × D) (cm), median (range): 7.2 (1.2–10.5)
Histologically clear resection margins (%): 11/12 (92 %)**
Minimum mucosal safety margin (mm), median (range): 3 (2–3)
Histology of SILS®-TEM specimens, $n = 12$
Adenoma with low grade dysplasia: 10
Adenoma with high grade dysplasia: 1
T1-cancer: 0
T2-cancer: 1 (preoperatively staged as T1)

* Including one patient who had concomitant left hemicolectomy and hepatic wedge resection and another one with postoperative inadequate secretion of antidiuretic hormone, requiring a hospital stay of 10 and 14 days, respectively

** Criterion not fulfilled for the T2-cancer specimen

with the preoperative score in all patients. Control proctoscopy was done for 11 polyps: with the exception of the (pseudo-)recurrence of the T2-cancer, no recurrent polyp was detected at the site of resection.

Discussion

Since its description in 1983, TEM increasingly has become the standard therapy for the treatment of benign rectal lesions of the middle and upper third of the rectum, as well as for some early rectal cancers in elderly patients. Very recently, some technical problems had been overcome by the use of a single access (laparoscopic) port device instead of the specialized classical TEM equipment. We report our first experiences with TEM facilitated by video-assistance and anal introduction of a SILS®-port. Other ports, such as the Single-Site Laparoscopic Access System® (SSL; Ethicon Endo-Surgery, Cincinnati, OH) [17] and the TriPort/TriPort+® (Olympus KeyMed, Southend, UK) [24] have been used for this purpose and proved suitable as well.

Our data confirm the feasibility, safety, and reliability of this new technique. The conversion rate to another technique was zero in this series, and no major complications occurred. Operation times were similar to those of recent publications reporting median operating times between 66 and 86 min [11, 19, 25]. The hospitalization time took up to 14 days, because three patients needed treatment for additional diseases as mentioned in the "Results" section. In the remaining patients, we refrained from early discharge to prevent missing postoperative complications. With increasing experience, shorter hospitalization times might be expected in the future.

Reliability of SILS®-TEM in this series may be expressed by the low fragmentation rate of the specimens, as well as the high rate of clear histological margins. Until now, there is no prospective data about (SILS®-)TEM compared with other, even less invasive methods, such as endoscopic mucosal resection (EMR) or endoscopic submucosal dissection (ESD). At present, the TREND-study is running, comparing safety (recurrence rate, morbidity, mortality, quality of life) and cost-effectiveness of EMR vs. the dated classical TEM [26]. A direct comparison of a new promising technique, such as SILS®-TEM with EMR, seems necessary in the future. The rectal polyps resected by SILS®-TEM in the present series represents 3.5 % of all endoscopically resected polyps of the colorectum during the same period, because surgeons in Switzerland do not perform colonoscopies; they are done almost exclusively by gastroenterologist as in the author's hospital. All referrals

for transanal surgical resection were done by gastroenterologists in patients with challenging rectal polyps, e.g., large and/or bulky polyps or polyps close to the anal canal, i.e., the lower border of the polyp being at 4–7 cm from the anal verge. Indeed, the resection of large rectal polyps by SILS®-TEM might be more efficient, reliable, and satisfying than the conventional piecemeal technique.

According to our experience, video-assisted SILS®-TEM has several advantages compared with classical TEM with the specialized Buess instruments. First, the handling of the equipment is more comfortable. Transducing the endorectal image via an endoscopic camera to a high-definition television screen allows the surgeon to obtain an optimum, enlarged, and comfortable view of the surgical field (Fig. 2a). Because this equipment and the instruments are the same as in conventional laparoscopy or thoracoscopy, surgeons adopting the SILS®-TEM technique will be familiar with these devices from the very beginning, with a shorter learning curve and a better and faster adoption of the SILS®-TEM technique. For resection, e.g., we also used the harmonic scalpel occasionally, as shorter operation times and fewer bleeding complications have been described [27, 28]. Indeed, we soon stopped using the harmonic scalpel as we did not see any advantage and the use of it has been described to result in oblique and conical instead of cylindrical specimen resection [10].

The corresponding author (CAM), who also was responsible for all SILS®-TEM procedures in the present series, had a personal experience with TEM instruments of 1.5 years.

Second, the sponge-like consistence of the SILS®-port proved to be very flexible (Fig. 1b), allowing optimum angulation of the inserted instruments (Fig. 3b), differently than the long metal tube of Buess, independently of the distance of the polyp from the anal verge. We recommend using an overlong endoscope, e.g., with a 50-cm long shank, to avoid interference of the bulky camera with the handles of surgical instruments (Figs. 2b, 3a).

Some surgeons used to fix the port with temporal sutures to the perianal skin [12, 25], avoiding its luxation during higher pressure CO_2 insufflation (note: the TEM instrumentarium is fixed to the operation table). In contrast, we purposely abandoned this option to preserve full flexibility, i.e., rotation and articulation of the port. Furthermore, we kept the possibility of port luxation as a safety measure, because this may help to avoid overpressure within the colorectum with its risk of colonic burst, especially in patients with competent ileocecal valve.

Third, regarding the reach of SILS®-TEM, there seems to be no disadvantage compared with classical TEM. Lesions may be resected up to 25 cm from the anal verge with classical TEM [10]. With SILS®-TEM, resections of polyps up to 15 cm were reported [18]. In the present series, we were able to confirm this finding. Furthermore, advancement of the 5-mm endoscope as well as the other instruments was easily feasible for another 7–10 cm in our patients. So far, only van den Boezem and colleagues described a resection beyond 15 cm, however, using stapler devices [12]. We were able to resect lesions with a distal polyp border located as low as 4.5 cm from the anal verge without dislocation of the port. This is in accordance with the limits already reported [25]. In addition, for very large longitudinal polyps, e.g., those located 3–11 cm from anal verge, an option to optimize the resection conditions might be to use a combination of two techniques: conventional transanal resection for the lower parts of such a polyp followed by SILS®-TEM for the upper parts.

Fourth, due to the port's softness, the incidence of dilatation-induced sphincter lesions, which were documented after procedures performed via the classical 40-mm diameter TEM rectoscope [11, 12, 29, 30], may be reduced. None of the patients in the present series complained of altered anal continence after the operation.

Fifth, using classical TEM equipment, patient positioning depends on the location of the lesion. Prone is used for anterior wall lesions, lithotomy for posterior wall lesions, and side positioning for lateral lesions [10]. The SILS®-TEM-technique allows for the comfortable resection of all rectal polyps of any location in lithotomy position, as was done in the present series. This may reduce the risk of position related nerve injuries and loss of airway control, as described for prone positioning [31–33]. Also, the positioning and setup time in the operation theater may be reduced by defining the lithotomy position as the standard position for SILS®-TEM.

Finally, the acquisition costs are lower, being €300–400/$500–600 for a one-way SILS®-port device compared to €40,000–50,000/$75,000–85,000 for the specialized TEM rectoscope and insufflation system [10, 17].

We feel that this procedure, apart from its advantages compared with classical TEM, might be especially beneficial for patients in poor general condition and with comorbidities, not eligible for laparoscopic procedures or standard transanal excision [12]. Therefore, wide adoption of this technique might become a reality for an elderly and comorbid patient population in the future.

In summary, this prospective series on patients undergoing SILS®-TEM provided a satisfying preliminary experience; larger and randomized trials are warranted to confirm these findings.

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