

Chapter

Local Excision for the Management of Early Rectal Cancer

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Abstract

Transanal endoscopic microsurgery (TEM) is a minimally invasive technique introduced in the 1980s to overcome the technical difficulties in the management of low rectal tumors. The TEM system includes a dedicated rigid rectoscope and platform with a dedicated expensive instrumentation. The transanal minimally invasive surgery (TAMIS) technique was introduced to overcome these limitations. Transanal surgery consists of three main steps: exposure of the lesion, tumor excision, and defect closure. Traditional indications are benign adenomas and selected T1 rectal cancers. However, when combined with neoadjuvant chemoradiotherapy (n-CRT), the indications may be extended to patients with selected T2-T3 rectal cancers responsive to n-CRT. Intraoperative complications may be difficult to deal with, but peritoneal entry is adequately managed by endoluminal direct closure of the defect by expert surgeons. Concerning the indications for defect closure, there is no evidence of better results to prevent complications such as bleeding; the indication for defect closure should be evaluated according to multiple variables. The management of other complications is safe and does not affect TEM's oncological and functional outcomes. Transanal excision of rectal tumor is a safe and effective alternative to conventional resection to avoid the low anterior resection syndrome, with comparable oncological results and with the advantages of an organ-sparing strategy for better patients' QoL.

Keywords: early rectal cancer, local excision, transanal endoscopic microsurgery, TEM, transanal minimally invasive surgery, TAMIS, complication, prevention, managements

1. Introduction

Transanal endoscopic microsurgery (TEM) is a minimally invasive technique introduced in 1983 by Professor G. Buess [1]. By merging endoscopy with microsurgery [2], Buess developed this natural orifice instrumentation and technique to overcome the technical difficulties that are inherent in the management of low rectal tumors, avoiding an invasive surgical procedure such as low anterior resection but with disease-free margins, unlike traditional local excision techniques. Before the development of TEM, the available methods for the management of rectal tumors included abdominal invasive surgery, in the form of anterior or posterior approach,

and traditional transanal local excision techniques. In the anterior approach, the anatomic and technical difficulties restricted the surgeon; the posterior approaches were extremely radical with significant morbidity and mortality. These methods included the York Mason para-sacrococcygeal trans-sphincteric approach [3] for middle rectal tumors and the trans-coccygeal Kraske approach [4] for upper rectal lesions. Both the posterior techniques had high rates of complications: wound infection, fistulae, chronic pain, fecal incontinence, stenosis, high incidence of permanent stoma [5, 6]. Traditional transanal local excision techniques had several disadvantages such as poor exposure and lighting, with consequently increased risk of local recurrence. These techniques included the Parks transanal [7] approach and its variations according to Francillon [8] and Faivre [9]. In the Parks' procedure [7] after positioning of Parks' retractor, adrenaline submucosal injection was performed to raise the submucosa from the muscle plane, then two sutures were placed for traction, the mucosa was marked at about 1 cm from the tumor with diathermy, and it was excised following the muscle plane until complete tumor removal, with subsequent closure of the defect. According to the Francillon's technique [8], several stitches were positioned on healthy mucosa at about 1 cm from the tumor, and their traction acted like a "parachute," whereby the rectal wall harboring the tumor could be excised together with adjacent perirectal fat. Finally, in the Faivre technique [9], a flap of ano-rectal mucosa hosting the tumor was created and excised.

Buess, together with Richard Wolf Medical Instruments Division, developed a specific rectoscope and dedicated instrumentation to accomplish a revolutionary, highly technological, and new technique of rectal tumors excision by a transanal organ sparing minimally invasive approach but preserving oncological radicality, due to a magnified binocular 3D vision and excellent lighting [10].

2. TEM instrumentation and technique

The TEM system consists of a beveled rigid rectoscope of 4 cm in diameter and available in two sizes: 12 cm – short – or 20 cm – long – (**Figure 1**), depending on the preoperative location of the rectal lesion.

The rectoscope is fixed to the operating table with a multidirectional bearing, the Martin's Arm, and a constant pneumorectum is obtained by an insufflation unit providing carbon dioxide insufflation, suction, and irrigation (**Figure 2**).

The removable faceplate of the rectoscope has a port system to accommodate long curved instruments, the suction and coagulation cannula, and for placing the stereoscope with gas sealing (**Figure 3**). Through the stereoscope the surgeon obtains a magnified, three-dimensional vision of the rectal lesion with high-intensity lighting.

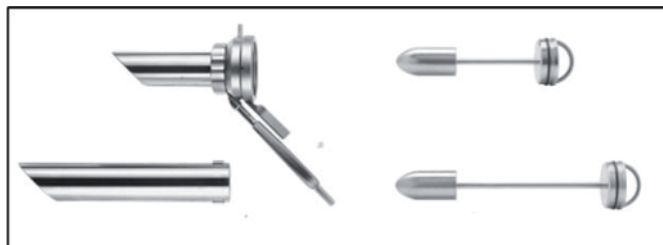


Figure 1.
Rectoscope © Richard Wolf GmbH. All rights reserved.

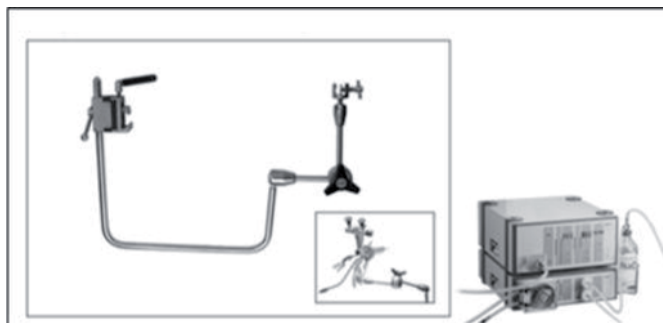


Figure 2.
Martin's Arm and insufflation system © Richard Wolf GmbH. All rights reserved.

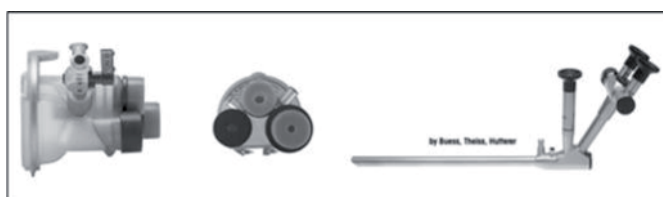


Figure 3.
Port System and Stereoscope © Richard Wolf GmbH. All rights reserved.

The stereoscope can also be connected to a laparoscopic video unit, for procedure recording and teaching purposes.

Given the instrumentation design, the lesion must always be located in the inferior part of the operative visual field. Therefore, a precise preoperative assessment of the rectal tumor position is of utmost importance because the patient's position on the operative table depends on the localization of the rectal lesion: for anteriorly located lesions, a prone jack-knife position (**Figure 4**) is required, whereas a lithotomy position is needed for posterior lesions (**Figure 5**). These positions may have to be coupled with a lateral tilt of the operative table on one side or the other in case of lesions that are located on the lateral rectal wall. The patient's position and the instrumentation settings may sometimes have to be changed during the procedure; therefore, an excellent supporting working team is fundamental.

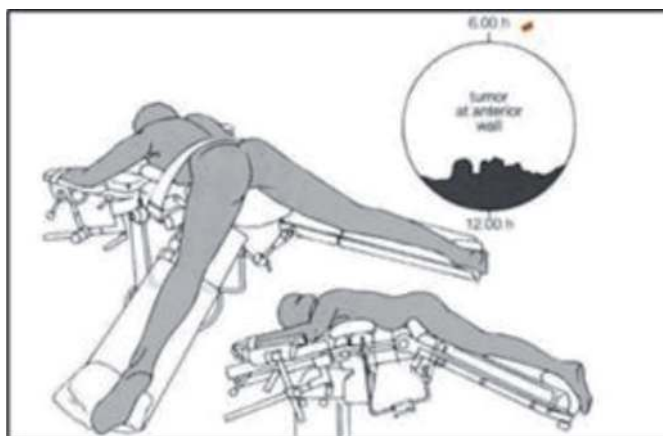


Figure 4.
The prone jack-knife position for anterior lesions.

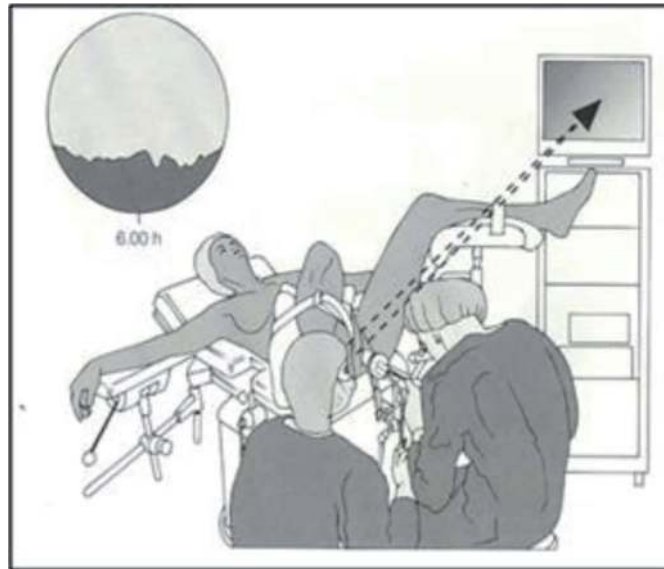


Figure 5.
The lithotomy position for posterior lesions.

Once the correct patient position and lesion exposure are obtained, the surgeon gets a magnified view of the distended rectum and can take advantage of a wide set of angled instruments (monopolar grasping forceps, scissors, needle holder, hook, silver clip applier, suction/irrigation, and coagulation cannula) to excise the lesion with adequate margins. The surgeon may therefore perform a full-thickness resection of the rectal lesion including the perilesional mesorectal fat, if necessary, and to close the residual defect with a running suture.

3. TAMIS instrumentation and technique

With the increase in laparoscopic experience, some limitations of TEM, such as costs, need for specific technical training, dedicated equipment, and instrumentation, encouraged the development of the transanal minimally invasive surgery (TAMIS) platform in 2009 [11]. TAMIS needs only a single-incision laparoscopic surgery port (SILSTM Port, Covidien, Mansfield, MA) that is first lubricated and then introduced into the anal canal (**Figure 6**). Through the SILS port, a standard



Figure 6.
SILS™ port and modified laparoscopic instrument for TAMIS ©Medtronic.

bidimensional laparoscope and instrumentation are inserted into the rectum, and pneumorectum is achieved with a conventional laparoscopic insufflator. Therefore, TAMIS provides similar, although not equivalent, visibility as TEM without the need for expensive and specialized equipment.

Furthermore, TAMIS enables dissection from different angles in multiple quadrants, avoiding the changes in patient's position that may sometimes be required during TEM: all resections in TAMIS can be done in the lithotomy position. Initially TAMIS was employed only for local excision of distal rectal lesions, but it is reported to be a feasible option also for higher lesions with satisfactory outcome [12]. So, nowadays TAMIS is considered to be a valuable alternative to TEM, with technical advantages and same prognosis for full-thickness local excision of rectal lesions [13, 14].

4. Surgical technique

The essential steps for both TEM and TAMIS are similar. They include: operative field exposure, tumor excision, and defect closure.

The first step is the positioning of the rectoscope or of the SILS Port, then the lesion is identified, and the rectoscope or SILS port is fixed in place in the correct position. CO₂ insufflation is then started to create pneumorectum until reaching an endoluminal pressure of 8–10 mmHg.

Once the lesion is identified, the line of excision is circumferentially marked by electrocautery with at least a 5–10 mm safety margin from the lesion, and dissection then starts at its caudal margin. Tumor resection can be performed by monopolar hook, ultrasonic instruments, or electrothermal bipolar energy devices. Dissection is carried around the lesion until the yellow adipose tissue of the mesorectum is identified and reached for a full-thickness resection. Full-thickness resection with adequate safety margins is performed routinely, with preservation of sphincter muscles (**Figure 7**). Full-thickness resection could be the cause of inadvertent entry into the peritoneal cavity. Should this occur, a laparoscope can be inserted into the abdominal cavity during TAMIS or in a TEM performed in lithotomy position, for better control of the peritoneal repair. If TEM is performed in the prone position, the patient will have to be turned in lithotomy position for diagnostic laparoscopy. After tumor removal, a suction-irrigation cannula is used for irrigation of the residual cavity and to check the hemostasis. Bleeding is controlled by monopolar or radiofrequency coagulation.

Following the tumor excision, the residual defect in the rectal wall can either be closed or be left opened. In the literature, no difference between these two techniques



Figure 7.
Step-by-step dissection technique for full-thickness excision and residual defect.

is reported in terms of intraoperative results and final outcome [15]. Our personal preference is to close the defect, as previously reported [16, 17]. The closure can be performed with one or more interrupted or continuous sutures, with Lapraty (Ethicon®) preformed knots and with dedicated silver clips. In case of large defects, the closure can be carried out first by placing a single interrupted or figure of eight suture in the middle of the defect to draw the margins closer. At this stage, the endoluminal pressure can be reduced to facilitate suturing the margins of the defect with either single stitches or, preferably, with a running suture. The suture line should be closed without excessive tension not to cause tissue ischemia. Once the suture is completed, it is necessary to make sure that the rectal lumen has not been inadvertently closed. A suction-irrigation device is helpful in the final correct visualization of the suture.

5. Indications

Traditional indications of TEM and TAMIS are benign lesions and selected T1 rectal tumors, defined by Buess as sessile rectal adenomas and pT1 stage low-risk adenocarcinomas [1, 2].

5.1 Benign adenomas

The standard procedure for the management of benign adenomas with size and morphology that do not allow a complete endoscopic removal is now considered a full-thickness excision by TEM. In these patients, TEM may avoid the morbidity of major surgery with a low recurrence rate [2, 18].

Nowadays, however, with appropriately selected indications, endoscopic mucosal resection (EMR) or endoscopic submucosal dissection (ESD) can be suitable alternative to surgery for subinvasive rectal tumor. In case of R1 endoscopic removal at final pathology, a subsequent salvage endoluminal loco-regional resection by TEM can be obtained aimed at achieving R0 resection [19].

5.2 Selected T1 rectal adenocarcinomas

In case of rectal cancer, a number of factors should be considered to set the indications for tumor excision by TEM. These factors include physical examination findings, preoperative imaging, and histopathological characteristics [20–22].

Preoperative staging examinations include:

- total colonoscopy and rigid rectoscopy with biopsies of the lesion to evaluate distance and circumferential position of the lesion;
- digital examination to evaluate mobility or fixity of the tumor;
- endorectal ultrasound scan;
- magnetic resonance imaging (MRI) with 3 mm sections of abdomen and pelvis;
- Total body computed tomography (CT).

Several studies concluded that in carefully selected low-risk T1 patients, TEM had a similar local recurrence rate than total mesorectal excision [23]. Criteria to set the indications for tumor excision by TEM are summarized in **Table 1**.

TEM and TAMIS are also effective for patients' management after R1 polypectomy, after either EMR or ESD [24], avoiding total mesorectal excision, which would be an overtreatment. The oncological outcomes of transanal minimally invasive procedures in these patients are equal to more invasive surgery, with R0 status in all cases, low morbidity, and 0% mortality rate at a minimum 12 months follow-up [19].

5.3 Extended indications in rectal tumors: TEM after neoadjuvant chemoradiotherapy

Neoadjuvant chemoradiotherapy (n-CRT) is recommended by the European Society of Medical Oncology (ESMO) in cases of: advanced disease (T3c/T3d and over), MRI-predicted circumferential radial margin (CRM) (<1 mm), and lymph node involvement at MRI [25]. These characteristics of the tumor define the risk of local recurrence and metastatic disease, so the goal of n-CRT is to downsize or downstage the tumor and to avoid disease progression. Short-course neoadjuvant radiation therapy involves 25 Gy administered in doses of 5 Gy daily in 1 week, followed by surgery 1 week after completing neoadjuvant therapy; in 1997, the Swedish Rectal Cancer Study Group found a significant reduction in local recurrence rates between irradiated and control group [26]. Neoadjuvant long-course chemoradiation therapy described by Marks et al. [27] includes an overall administration of 50, 40 Gy in 28 fractions over 5 weeks, with concurrent continuous intravenous infusion of 5-FU. The radiation is administered in the areas of the anus, rectum, mesorectum, regional and iliac lymph nodes. Surgery is performed between 45 and 55 days after completion of chemoradiotherapy.

The standard treatment for T2–T3 rectal cancer after neoadjuvant chemoradiotherapy (n-CRT) is low anterior resection (open or laparoscopic approach) with total mesorectal excision (TME) [28, 29]. However, some studies report that combination of n-CRT with TEM is feasible in T2 and T3 rectal cancers [30, 31]. In a prospective randomized controlled trial, at a 5-year follow-up in selected post n-CRT patients with T2 rectal cancers, the local recurrence rates, the disease-free survival, and distant metastases rates showed no statistical difference in patients receiving TEM or TME [32]. Furthermore, the combination of n-CRT with TEM showed also advantages in preserving patients' anal function and in lower disruption of patients' quality of life [33–35].

Anatomic	Histologic	Staging
<ul style="list-style-type: none"> • <40–50% circumference of rectum • <3 cm in size • Mobile, not fixed • Within 20 cm from the anal verge 	<ul style="list-style-type: none"> • T1 • Sm1 or Sm2 • Absence of tumor budding • Absence of lymphovascular invasion • Moderate to well-differentiation 	<ul style="list-style-type: none"> • cT1N0 without neural /lymphovascular infiltration

Sm: submucosal layer invasion [21].

Table 1.
 Criteria of inclusion for TEM.

Nevertheless, despite extensive mesorectal fat dissection during endoluminal loco-regional resection (ELRR) by TEM, in these patients the N parameter may remain incompletely defined, which may be a cause of concern. In the literature, an original modified sentinel lymph node procedure called nucleotide-guided mesorectal excision (NGME) [36] is described, which can improve the lymph node harvest during endoluminal resection by TEM/TAMIS and consequently obtain a better staging accuracy. During NGME, injection of 99 m-technetium-marked nanocolloid is performed in the peritumoral submucosa before starting the procedure. After specimen removal, the residual cavity is probed with a gamma camera in order to survey any residual radioactive area. In case of positivity, these areas are excised by TEM/TAMIS.

TEM may also be used when the focus is on palliation, if a curative treatment is impossible, in > T3 tumors in patients with unresectable metastases.

5.4 Other indications

Other types of rectal tumors can also be treated with TEM or TAMIS approaches, such as neuroendocrine tumors, leiomyoma, gastrointestinal stromal tumors [25, 23].

TEM can also be used for treatment of iatrogenic fistulae after general surgery and gynecological or urological procedures, such as after prostatectomy or for management of recto-vaginal and recto-urinary fistulae [37–39]. Benign rectal strictures can also be treated by TEM [40, 41].

6. Complications management

6.1 Intraoperative complications

6.1.1 Peritoneal entry

Accidental peritoneal entry during full-thickness TEM excision was in the past considered a serious complication requiring an aggressive management by conversion to standard laparotomy anterior resection (LAR) and fecal diversion [18, 42, 43]. More recently, larger transanal minimally invasive resection series showed a rate of peritoneal entry ranging from 0 to 32% [44, 45]. Proposed risk factors for accidental peritoneal opening include full-thickness TEM excision of lesions located in the upper rectum and in the anterior and lateral rectal wall [46–48]. These papers also demonstrated that for a surgeon with appropriate skills in transanal surgery, peritoneal entry during TEM can be safely closed transanally with direct defect sutures without the need for abdominal exploration [45, 46] and was not followed by increased postoperative morbidity [45, 48, 49]. As previously demonstrated in large TEM series, [47, 48], the occurrence of peritoneal entry was not associated with increased risks of infectious or other postoperative complications, or longer hospital stay. Several series have also demonstrated that peritoneal entry during TEM resection of rectal cancer was not associated with worse oncologic outcomes [48, 49]. Peritoneal entry during TAMIS has not been as frequently reported as during TEM procedures. In a TAMIS systematic review of 390 patients published in 2014, only four cases of inadvertent peritoneal opening have been documented during dissection of low rectal lesions, and only one required laparoscopic assistance for closure of the defect [50]. TAMIS experience for resection of upper rectal lesion is still limited in

the literature, and among recent TAMIS series, the rate of peritoneal entry ranged from 0 to 10% [51–53]. However, a total of seven cases of peritoneal entry during TAMIS for upper rectal tumors have been described, six of which required conversion to laparoscopy or laparotomy. A recently published systematic review of 12 series of TEM procedures, including 4395 patients report that the rate of perforation into the peritoneal cavity was 5.1%, and conversion to an abdominal approach was required in 0.8% of cases [54]. Risk factor analysis identified anterior [46, 47] and upper rectal [45] tumor locations as significant risk factors for peritoneal entry. Also female sex during excision of anteriorly located lesions has been advocated as a risk factor due to the lower reflection of the anterior peritoneum in the female pelvis. Some authors state that in experienced hands, the majority of peritoneal defects could be closed transanally with significant decrease in conversion rate [49]. It is important to note that the definition used for peritoneal entry across different series is really heterogeneous, including: “major leakage of CO₂ into the abdominal cavity resulted in significant technical difficulties” [55], “visible entrance into the peritoneal cavity” [46], “direct visualization of the defect during surgery” [45], while many studies do not explicitly state how they defined peritoneal entry [47, 48].

Transanal endoscopic direct closure of peritoneal defects appears to be feasible in more than 90% of cases, but it requires a significantly longer operating time (207.5 vs. 131.5 min) [55] from the increased technical complexity due to the loss of pneumorectum, producing a limited endoluminal vision and a troublesome reach of the peritoneal defect by the surgical instruments [49]. Authors experienced in both TEM and TAMIS transanal tumor excision have also suggested to shift to the TEM platform in case of peritoneal entry during TAMIS dissection, particularly for anterior and upper rectal lesions, to better manage the transanal peritoneal suture. This is due to the advantage offered by the rigid and longer rectoscope that is included in the TEM platform, which maintains the rectal wall stented allowing to suture the defect without the need for conversion [55]. In conclusion, peritoneal entry during local excision of a rectal tumor is a recognized intraoperative complication that can be adequately managed by endoluminal direct closure of the defect, not affecting the short- and long-term oncological results. However, extensive surgeon experience in transanal minimally invasive resection is required, together with the ability to use different transanal platforms. In the decision-making process for patient selection, the risk factors for peritoneal entry should be evaluated, considering the upper and anterior location of the lesion as an increased risk factor for this complication.

6.2 Postoperative complications

6.2.1 Bleeding, suture dehiscence, and pelvic abscess: to close or not to close the defect?

Postoperative rectal bleeding after TEM or TAMIS is the most frequently reported complication with a variable incidence ranging between 1.7% and 10.8% [56–58]. Nevertheless, in the literature the definition of rectal bleeding as a complication is heterogeneous, because the presence of a wound inside the rectum, whether completely sutured, partially sutured, or left open, causes variable blood emission after contact with the stools and with increasing internal pressure inside the rectum during defecation. This is a common occurrence, and it may be considered normal within the process. Therefore, rectal bleeding should be considered a cause of concern when the amount of blood loss produces anemia requiring blood transfusions and those requiring surgical revision, considering that more than 50% of post TEM/TAMIS bleeding

episodes are self-limited. Some authors observed that bleeding is more consistent if it is associated with suture line dehiscence in patients with defect closure, and it is more frequent in patients whose defect was left open [59, 60]. Other authors instead did not observe a correlation between defect closure and risk for postoperative bleeding [15, 44]. Postoperative bleeding seems to be significantly reduced following the use of ultrasonic dissection during local excision, as compared with diathermy (1.1% vs. 6.3%) [44, 61]. According to Lee et al., postoperative bleeding was less common in sutured defects [12]. A retrospective analysis of 220 patients with full-thickness excision and 210 patients with partial-thickness excision showed an incidence of 30-day complications analogous for open and closed defects after full-thickness (15% vs. 12%, $p = 0.432$) and partial-thickness excisions (7% vs. 5%, $p = 0.552$). Although full-thickness excision in patients with open defects had a higher rate of clinically relevant postoperative bleeding complications (9% vs. 3%, $p = 0.045$) [62].

Use of hemostatic agents at the end of the resection is commonly part of the clinical practice; however, no focused trials have been published reporting its effectiveness in prevention of postoperative bleeding. In patients with consistent bleeding, usually endoscopic hemostatic techniques (argon, clipping, adrenaline injection), or TEM/TAMIS revision with defect suturing (or resuturing) may be effective in managing this complication without the need for creation of a diverting stoma or resorting to an anterior resection procedure [54, 57, 59].

The suture line dehiscence rate after full-thickness TEM and TAMIS is not negligible, and in the literature, it ranges between 2% and 22.7% [16, 17, 44, 63, 64]. Its clinical presentation may range from paucisymptomatic cases to a variable symptoms' collection including rectal pain, bleeding, fever, and development of a pelvic abscess. Endoscopy is the primary investigation to assess the presence of suture line dehiscence, whereas transanal ultrasound, MRI, and CT scan should be reserved to the patients suspected for having developed a pelvic abscess. Many factors have been considered responsible for suture line dehiscence: tumor size and location [44], type of resection (full thickness), depth of excision, degree of tension on the suture line [16], type of suture (multiple interrupted sutures or single running suture) [60], previous neoadjuvant therapy [63, 64], and rectal wall ischemia [17]. Lateral or anterior location of the tumor associated with a defect size of 2 cm or more seems related to an increased risk of postoperative bleeding and pelvic collection with sepsis [56]. Bignell et al. reported that for lesions sited within 2 cm from the anal verge, an increased rate of complications occurs [44]. The risk of postoperative complications after neoadjuvant chemoradiotherapy was also reported by several authors [63, 64]. The high rate of suture line dehiscence in irradiated patients who underwent TEM/TAMIS could be a consequence of the detrimental effects of radiotherapy on the tissue, (free radical formation, DNA damage, tissue fibrosis, vascular thrombosis), with a consequently higher risk of suture line dehiscence and infection [65]. Moreover, in TEM irradiated patients, both sutured wound edges were previously irradiated, presenting all listed detrimental causes of damage, therefore the risk of wound complication is increased [63]. Some authors [16] suggested the degree of tension on the suture line and perirectal collection formation as primary causes for suture line dehiscence. This is particularly relevant in relation to extended endoluminal resection partially including perirectal fat, in which not only defect closure is mandatory to avoid pelvic contamination but the lack of tissue around the rectal wall resection becomes a "locus minoris resistentiae" where fluids collect increasing the suture line tension. With the aim of avoiding perirectal fluid collection, these authors proposed to stuff the rectal ampulla with two iodoform gauzes and to

place a transanal Foley catheter with its tip well above the suture line for postoperative gas evacuation to be kept in place for 48 h. The rationale is to prevent overdistention of the rectal ampulla and at the same time obtain a moderate pressure to obliterate the remaining perirectal cavity. A wider residual cavity is subject to collection of larger amounts of fluids, which may lead to infection. This infected collection may spontaneously drain through the suture line, which in turn may lead to wound separation. The described technical details have reduced the dehiscence rate in the authors' series from 12 to 0% for wide endoluminal resection independently of tumor location and previous radiation treatment.

Pelvic abscess occurs due to intraoperative seeding of bacteria aided by dissection into the retroperitoneum and diffusion from carbon dioxide insufflation. Extension of infection from the anal region into the retroperitoneum has been reported in the literature. Bacterial seeding may cause presacral and perirectal abscess that can extend into the perineal space or to the retroperitoneum along the psoas muscle. Its clinical presentation includes pelvic and anal pain, fever, increased inflammatory markers up to sepsis. Diagnosis requires radiological confirmation by CT scan or MRI to evaluate the extension of the infectious process and the involvement of pelvic and retroperitoneal structures. The occurrence of suture line dehiscence in full-thickness excision is considered a risk factor for pelvic abscess development. Bignell et al. series of 262 patients who underwent TEM for lesions located within 2 cm from the dentate line was associated with a higher incidence of pelvic sepsis ($p < 0.02$). Surprisingly, no statistical correlation between defect closure and pelvic abscess was found [44]. Many patients with pelvic sepsis were managed with diverting colostomy aimed at reducing perineal contamination [44, 63, 66]. Interventional radiology (IR) development, together with the extension of indications for percutaneous drainage, has progressively replaced the need for surgical revision in a large part of retroperitoneal and pelvic collections. Generally, retroperitoneal abscess management strategies include conservative treatment with antibiotics in association with radiologically guided percutaneous drains, versus traditional surgical exploration with abscess drainage and eventually fecal diversion [44, 63, 64, 66, 67]. The need for protective stoma should be evaluated and considered particularly in relation to the abscess extension and patients' septic state. Small retroperitoneal abscesses (less than 3 cm in diameter) in a hemodynamically stable patient may be effectively treated with an extended course of antibiotics alone. However, larger abscesses or unresolving smaller abscesses must be drained either by percutaneous drain placement or by surgical exploration and drainage. Microbiological examination is required to shift from empirical antibiotic therapy to a tailored one. Surgery offers several advantages over IR drainage, including the ability to fully explore the anatomy and extent of the infection as well as the ability to remove fistulous tracts [68]. However, surgery does carry more significant risks, delays, and morbidity. Resolution and recurrence are similar between the surgical and IR approaches [68].

Concerning the issue of defect closure indications, several studies have directly compared the outcomes of leaving the defect open versus suture closure, reporting variable results. The first randomized controlled trial (RCT) on this subject, with short follow-up at 30 days [15], showed postoperative bleeding to be the only complication encountered, and both techniques were judged to be equally safe. This result was confirmed by a large multicenter comparative study in which the rectal defects were left open in 47% of patients, without increased complications [52]. However, a more recent study has postulated that open management of the rectal defect after TEM may be associated with a higher postoperative complications rate (19% vs. 8.4% $p = 0.03$)

but also with lower readmission rates (4.7 vs. 12.4%, $p = 0.01$) [60]. Brown et al. also underlined the importance of performing defect closure as a surgical training modality to achieve rectal wall suturing skills, because involuntary opening of the peritoneum during transanal excision does require such technical skills to manage this complication without conversion.

Another topic of concern has been the association of TEM defect management and increased postoperative pain. This was reported by a 2011 study, stating that postoperative pain after defect suture closure was associated with a high readmission rate and a high incidence of wound dehiscence [69]. However, a more recent multicenter RCT has refuted these results, reporting no difference in postoperative pain between sutured or open defect management [70]. In conclusion, there is no evidence that closure of the defect will prevent complications, both approaches being equally safe. Nevertheless, the decision to close or not the defect, particularly after full-thickness excision, should be evaluated according to multiple parameters, including tumor position and size, extension and depth of resection, and surgeon's technical skills.

6.2.2 Rectovaginal fistula (RVF)

Rectovaginal fistula after transanal excision is a rare iatrogenic complication, but a particularly challenging one to treat. In the literature it has been reported in a few series with an incidence rate of 0.5%–2.3% [62, 66]. It usually occurs after excision of anteriorly located lesions in women. The integrity of the rectovaginal septum should be monitored during surgery, and a vaginal examination is performed in case of doubt. Vaginal fistulas can result also from suture line dehiscence after defect closure of anterior lesion with development of a perirectal collection draining through the vaginal orifice, due to the poor vascularization and fragility of the rectovaginal septum, to the higher intraluminal rectal pressure and to the even higher pressure exerted on it during defecation. These fistulas are difficult to treat, requiring in many cases multiple reinterventions, starting with creation of a temporary stoma and subsequent repair of the fistula, which may be subject to failure. Typical clinical presentations include vaginal passage of air, stool, purulent drainage, or ill-smelling discharge, often associated with urinary infection. Diagnosis includes digital rectovaginal bimanual examination, vaginoscopy and proctoscopy, transanal blue methylene test, or transanal injection of iodine contrast agent followed by conventional X-ray or CT scan and MRI. Across the years, different techniques have been proposed for the surgical management of this complication: skin flaps, muscle flaps, musculo-cutaneous flaps, intestinal flaps, and the Martius flap, including subcutaneous tissue and bulbocavernosus muscle from one of the labia minora, and graciloplastica. The success rates ranged from 62–92% for patients not previously treated by radiotherapy and not affected by inflammatory bowel disease [71–77]. Among the unusual indications for TEM, there is also the possibility to close the fistula orifice after fecal diversion by a deferred transanal approach, as described by some authors in small series with good results [78–80].

6.2.3 Pneumoretroperitoneum

Under physiologic conditions, rectal intraluminal air pressure ranges between 5 and 25 cm H₂O, but during transanal procedures, the intraluminal pressure increases due to gas insufflation [81]. Common to all cases of pneumo-mediastinum and pneumo-retroperitoneum, the pathophysiological mechanism begins with gas

migrating from the pelvis to the retroperitoneum and then to the cervical spaces, passing through the diaphragmatic hiatus, the posterior mediastinum, following the course of tracheal and esophageal walls, and then through any space delimited by skull, diaphragm, and both anterior and posterior cervical fasciae (the so-called Godinsky's space) or the retropharyngeal space [81]. Air migration might be limited in overweight and obese subjects, as fat fills in all anatomical spaces. In patients who underwent general anesthesia, it is very important to exclude other causes of extraluminal gas, such as esophageal or tracheobronchial perforations that may occur intraoperatively during nasogastric tube positioning or endotracheal intubation. In most cases, treatment may be conservative with restricted diet, intravenous antibiotics administration, and close observation [12, 82–85], although some authors prefer to treat this condition by fecal diversion [86, 87]. The presence of perirectal fluid and gas collection aerosol dissemination of bacteria and the subsequent risk of cardiac and respiratory infection or generalized sepsis must be considered in evaluating the opportunity of operative management. Frequent clinical symptoms reported in the literature are fever, pain, and subcutaneous emphysema, together with other less frequent symptoms such as dyspnea, dysphagia, or positive Kernig's sign. Fever seems to be a recurrent finding especially during the first postoperative day, without specific correlation with a septic state in patients who do not present with fluid collection or abscess [12, 82–85]. Fever could be related to transient aerosol dissemination of enteric bacteria through the fascial spaces. Asymptomatic fever with no clinical evidence of infectious site has been described also in patients not presenting with pneumoretroperitoneum or subcutaneous emphysema, showing a self-limited trend with resolution within 2–3 days [50, 54, 66, 88].

6.2.4 Urinary complications

Urinary complications are the second most frequent short-term complication after bleeding and have been reported in 5–10.8% of patients after transanal surgery [12, 54, 57, 66]. Urinary retention is a common complication after transanal procedures, especially in anterior resection, mainly occurring in male patients. Often it is classified as a Clavien-Dindo [89] grade II sequel, and it is easily managed by placement of a transurethral catheter [12, 54, 57, 66]. Reasons may be related to different factors: the anterior location of the excised lesion, preexisting prostatic hypertrophy, spinal anesthesia, and premature removal of the bladder catheter.

6.2.5 Rectal stenosis

Rectal stenosis is relatively infrequent complication after transanal excision of rectal lesions, poorly reported in the literature with an incidence rate of 1.5–5.8% [44, 90–93]. Rectal stenosis is associated with fecal urgency and incontinence, and it has a negative impact on the patients' quality of life [64]. In a recently published series of 761 patients undergoing TEM, the overall stenosis rate was 3.2%; analyzing the correlation between tumor size and subsequent stenosis development, the authors did not find postoperative stenosis in tumors measuring less than 5 cm in diameter, but it appeared in 6.8% of very large tumors (5–9 cm) and in 13.9% of ultralarge tumors (>10 cm) [93]. Altaf et al. report an incidence of stenosis of 5.8% following transanal surgery, but it did not become obstructive in any patient [91], therefore not requiring endoscopic treatment. Bignell et al. reported a 1.5% rate of rectal stenosis underlining that none of the patients

received neoadjuvant therapy before surgery, but 50% of them underwent four quadrants lesion's excision [44].

The etiology of stenosis following anterior resection and total mesorectal excision is multifactorial, and it includes postoperative leaks and pelvic sepsis. It is also widely believed that ischemia plays an important role in stenosis formation. On the contrary, transanal excision is not associated with major alteration of blood supply; therefore, it appears that the only factor that may play a role is mucosal ischemia in association with the extension of the dissection. Several authors agree on the fact that circumferential excision or resection of lesions measuring more than 5 cm in diameter is the main risk factor for rectal stenosis, independently from the distance of the tumor from the anal verge or from neoadjuvant radiotherapy [44, 90, 91]. Once stenosis has occurred, there are several treatment options that have been already described in the setting of rectal stenosis following anterior resection. These options include surgical resection, transanal strictureplasty, balloon or surgical dilatation, and stenting [90, 92, 94]. In the literature, the majority of cases of rectal stenosis following transanal surgery can be easily treated by endoscopic balloon dilatation or with a day-case procedure under general anesthesia using Hegar's dilators by single or multiple sessions [56, 90, 92, 94]. Surgical resection of the stenotic tract or fecal diversion should be reserved only to those patients who are refractory to endoscopic conservative treatment.

6.3 Functional outcomes

Despite the large diffusion of TEM and TAMIS for organ-sparing tumor resection in rectal cancer, several issues have been investigated to assess the safety of both techniques concerning the postoperative functional outcomes. This is due to the risk that rectal and anal stretching produced by the introduction of a wide proctoscope or platform during surgery, as well as partial organ resection reducing rectal compliance, might be the cause of postoperative functional disorders such as fecal incontinence, urgency, and soiling, with subsequent impairment of the patient's quality of life (QoL). A recently published systematic review including 29 studies reporting the functional results following TEM or TAMIS surgery and including almost 1300 patients reveals that several studies reported some deterioration in manometric scores after both TEM and TAMIS and suggested worsening function, at least in some items of the used scores, including de novo incontinence development in some patients. However, globally the QoL does not seem to be significantly impaired after either procedure [95]. After tumor resection, continence was recovered or improved in several series following both TEM [33, 96–100] and TAMIS [101, 102]. On the contrary, worsening of fecal continence scores was reported by some studies assessing TEM functional outcomes [102–106]. Sphincter damage caused by anal dilation during surgery with the rigid TEM rectoscopes or platforms that are 4 cm in diameter [107, 108] has been advocated as a risk factor for postoperative incontinence, as well the surgical duration [108]. Moreover, partial rectal wall resection reduces rectal compliance, which might also result in later development of fecal symptoms as incontinence and urgency [33]. However, it should be underlined that some studies, including the authors' previous series [33, 100], reported that postoperative incontinence after TEM was transient in many patients and improved at long term postoperative follow-up [97, 107, 109, 110, 111]. All these changes in anorectal

physiology are mainly detected within the first 30 postoperative days and seem to significantly improve at 1 year after surgery; hence, they might not be clinically relevant to the patients in the long run [33, 104]. Mora Lopez et al. [104] found that only closer distance to the anal verge seemed to affect continence. Other reported risk factors for fecal incontinence included male gender, age at surgery, surgical time, extended resection, and full-thickness resection [103, 105, 110]. Khoury et al. [112] found that continence can be also affected by repeated TEM procedures, as the result of multiple anal sphincter complex traumas. There are very few available studies that included patients who underwent chemoradiotherapy before TEM [35, 64, 110, 113] and TAMIS [108], hence no conclusive data are available, although worsening functional outcomes have been reported in this group of patients as compared with those who underwent transanal surgery alone [35, 110, 113]. A possible explanation for worse results in irradiated patients can be postulated due to radiotherapy impairment of muscles and nerve fiber integrity and reduced rectal wall elasticity [114, 115]. This was reported by the authors [35] and Ghiselli et al. [110] after TEM surgery and by Clermonts et al. after TAMIS procedures [108]. In conclusion, TEM and TAMIS can be considered safe in terms of long-term functional outcomes, with only transient impairment of fecal continence and worsening QoL, showing almost complete anorectal physiology recovery within 1 year from surgery. Nevertheless, the duration of surgery together with tumor features (location, stage, and size) can be considered as a risk factor for deterioration of functional results together with combination of radiation treatment.

7. Conclusion

Transanal excision of rectal tumors is a valid, safe, and reproducible alternative to conventional anterior resection for the treatment of early rectal cancer, showing comparable oncological results with the advantages of an organ-sparing surgical strategy favorably impacting on overall patients' QoL as compared with low anterior resection. Encouraging results have been obtained also in the treatment of locally advanced tumors in association with n-CRT, although randomized controlled trials with long-term follow-up and shared protocols are still needed to definitely assess the role of TEM and TAMIS in non-early rectal cancer. Globally, the morbidity rate of both techniques is lower than after anterior resection, and their main complications including postoperative bleeding, suture line dehiscence, and urinary complications can be safely managed in most cases without conventional surgical revision or fecal diversion. The functional outcomes are also satisfactory, with mainly transient disturbance of anorectal physiology and progressive functional recovery. In conclusion, transanal excision techniques must be rightfully included in the armamentarium of the technical skills of any colorectal surgeon for the multimodality treatment of rectal cancer.

Conflict of interest

The authors declare no potential conflicts of interest with respect to research, authorship, and/or publication of this manuscript.

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