



## Transanal Surgery: New Therapeutic Tools

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### Abstract

The standard care treatment for rectal cancer is radical surgery, including total mesorectal excision (TME). The management of early stage rectal cancer is based on finding the right balance between optimal oncologic outcomes and acceptable adverse effects for the patient. Trying to minimize the morbidity associated with radical surgery, alternative approaches have been created, including transanal endoscopic microsurgery (TEM) transanal endoscopic operation (TEO) and transanal minimally invasive surgery (TAMIS). Transanal minimally invasive surgery is a safe and effective technique for the resection of lesions located in the middle and upper third of the anus, so benign nature and neoplastic lesions T1N0 stage. The use of this technique in T2 lesions, today is controversial, and requires individual assessment of each case. The correct patient selection allows transanal resections having similar oncological long-term results versus conventional surgery, with a significant reduction in complications. In our experience, long-term oncologic results, and low morbidity and mortality let transanal minimally invasive surgery applicable for rectal lesions, also lower costs and shorter learning curve make a better option than TEM, due to the use of laparoscopic instruments in this field.

### Introduction

Rectal cancer is the fifth most frequent worldwide, in the US there are around 40.000 patients diagnosed each year. The screening programs have decreased the incidence of rectal cancer, in the last decade, 1.5% in patients between 50 and 64 years and 4.3% over 65 years old, with a 5 years survival rate around 66.5% [1,2]. Furthermore, routine colonoscopies have advanced the diagnosis of adenocarcinoma earlier stages and facilitated the identification of premalignant lesions. Actually, the rate of patients with an early stage diagnose of colorectal cancer (CRC) is around 40%, this group is associated with a better survival rate [3]. Early stage of CRC includes lesions localized in submucosa (T1) o muscularis mucosae (T2) or without lymphatic affection (N0).

Within this, new and different therapeutic options had emerged, allowing us a complete resection or the tumor, with good survival rates and with less morbidity compared to conventional surgery. In 1984, Dr. Buess [4] developed TEM "Transanal Endoscopic Microsurgery", as an alternative in patients with rectal cancer. This technique, was a real change in surgery, it could achieve complete excision of rectal endoluminal lesions located between 4 and 20 cm from anus, using a rigid sigmoidoscope. Despite all advantages, implementation of this technique was less than expected, due to the important learning curve and the high cost of the materials.

The outcomes of new technology in the last decade, and the acquisition of skills in minimally invasive surgery by colorectal surgeons, have developed a novel therapeutic approach, TAMIS "Transanal Minimal Invasive Surgery". It employs standard laparoscopic instruments, preserving principles describes by Buess [4], through the creation of pneumorectum, across a transanal single port and the same principles of TEM. This technique, first described in 2010, had allowed the reduction of the learning curve in colorectal surgeons, and the decrease in instrumental costs.

On the other hand, over the last few years, some endoscopic techniques such as endoscopic submucosal dissection (ESD) have shown to be effective in the management of early colorectal neoplasms, particularly in Asian countries where these techniques were born. In Western world, implementation of ESD is slow and laborious but can be an alternative to surgical treatment option in selected cases [5].

### TEM and TEO

Transanal Endoscopic Microsurgery (TEM) approach involves a technique for lesions located at upper and medium third of the rectum using a rigid sigmoidoscope designed by Wolf

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Figure 1 and 2: SILS® device (Covidien).



Figure 3 and 4: Gel Point Path® device (Applied).



Figure 5: SSL® device (Ethicon).



Figure 6: Triport® device (Olympus).

(Tuttlingen, Germany) [4], of 4 cm diameter and length between 12 and 20 cm, associated to a CO<sub>2</sub> insufflation system. This equipment is connected to a binocular vision system that allows the surgeon a three-dimensional view with an optical magnification of up to 6, connected to a camcorder and three working channels. Before intervention, a rectoscopy is mandatory [6,7], so that the patient

should be positioned such that the lesion to be removed will be at the bottom of the rectoscope. Rectal distension, complete excision of rectal wall thickness is achieved, usually using ultrasonic scalpel (Ultracision Harmonic Ethicon Endo-Surgery, Karl Storz, Germany) for a better hemostasis. Because the material used is rigid, this technique has limited application in patients with rectal stricture or those with higher-level concavity of the sacrum [8]. TEM and TEO “Transanal Endoscopic Operation” system uses the same equipment, differing only that TEO use a laparoscopic optic as a display system. Recent indications of TEM/TEO are benign lesions unresectable through endoscopy and early stages of malignant tumors T1 without lymphovascular invasion. Some groups have developed this as a palliative treatment in those patients dismissed for a regular surgery. The piece resection must be the full thickness of the wall, allowing a proper study of the surgical specimen.

The most frequent postoperative complications are urinary retention and rectal bleeding. Despite the use of a rigid rectoscope with a diameter of 4 cm, there is no fecal incontinence after TEM use reported [9,10].

The tumor recurrence is between 5 and 7% for patients with stage T1N0 complete tumor excision and resection margins free of disease [11,12].

## TAMIS

TAMIS “Transanal minimally invasive surgery” was developed by Dr. Matthew Albert and Dr. Sam Atallah in Orlando, Florida, and presented in 2010 in the American Society of Colon and Rectal Surgeons Annual Meeting. Based on the principles proposed by Buess [4], TAMIS use conventional laparoscopy materials. It allows local excision of rectal tumors of middle and proximal third and those benign lesions endoscopically unresectable. In the same way, it allows excision node through the rectal defect.

Today, several single-port devices are used for TAMIS [8,13].

1. SILS (Single Incision Laparoscopic Surgery) of Covidien, Mansfield, MA. Among other advantages, the SILS device is elastic and soft so it facilitates the easy insertion and removal in the anus, and generates a minimum sphincter injury [14]. Given the proximity of the working ports, is less ergonomic than other devices, because it occur smaller triangulation movements. Figure 1 and 2.

2. Gel Point Path® (Applied Medical Inc® Rancho Santa Margarita, CA), was designed especially for TAMIS [8]. Given the position of the working ports, it allows greater triangulation of the movements, facilitating the operation. Figure 3 and 4.

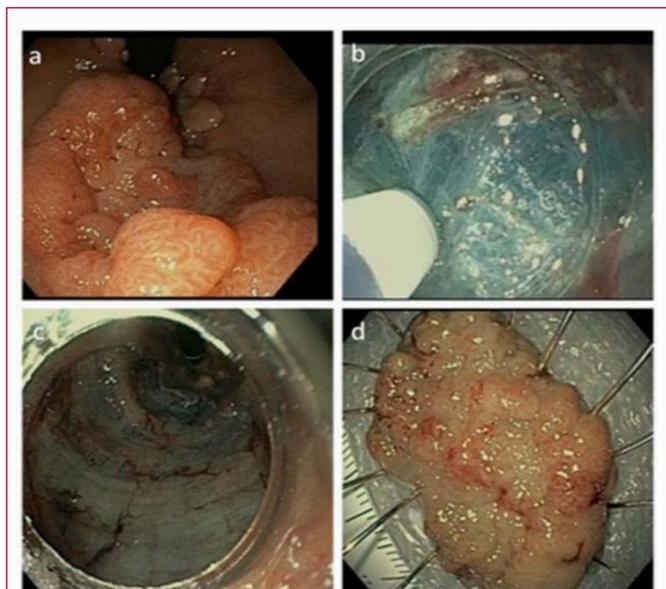
3. SSL Single-site laparoscopic® (Ethicon Endo-surgery®, Cincinnati, OH) available in 2 and 4 cm width. Figure 5.

4. Triport (Olympus KeyMed®, Southend, UK). Figure 6.

5. Gloveport®: It combines the application of a retractor Alexis® (ALEXIS Wound Protector/Retractor Medium, Applied Medical, Rancho Santa Margarita, CA) and a surgical glove.

6. Triport (Olympus KeyMed®, Southend, UK).

7. Mechanical preparation of the colon is done, after which the patient is always placed in lithotomy position. In contrast to TEM technique, the time of preparation of the operation field is considerably less (1.9 minutes), and surgical time is less than 1 hour in expert hands [8,15,16].



**Figure 7:** Rectal ESD procedure: (a) Rectal 4 cm lesion Paris 0-IIa+IIc LST-Granular type. (b) Submucosal dissection. (c) Resection bed. (d) Excised lesion.

8. After lubricating the working port, it is inserted through the anus and attached to perianal skin. CO2 is insufflated at 20 Lt/minute with pressure of 15-20 mm Hg.

9. The material we use are the same as conventional laparoscopy and the devices could be Ultracurion<sup>®</sup>, Ligasure<sup>®</sup>, Thunderbeat<sup>®</sup> or monopolar energy. Unlike TEM, which employs a rigid sigmoidoscope, this port leads to less anorectal injury; on the other hand, it achieves better adaptation in patients with fibrotic tissue [8].

10. Indications are the same to TEM, used as a proven technique in benign lesions, patients with carcinoid, adenocarcinoma T1N0 stage, diameter of the lesion less than 3 cm or covering less than 40%, as well those in which there is no lymphovascular invasion [17-19].

11. Depending on the size of the excised lesion and patient characteristics, this technique can be performed on an outpatient or inpatient.

**Endoscopic Techniques: ESD**

Endoscopic submucosal dissection (ESD) is a well-established technique of endoscopic resection that allows en bloc removal of gastrointestinal epithelial lesions. ESD differs from endoscopic



**Figure 8:** Rectal defect after tumor removal.

mucosal resection (EMR), another type of endoscopic resection. Both techniques involve injection of a substance under the targeted lesion to act as a cushion. With EMR, the lesion is then removed with a snare or suctioned into a cap and snared. While ESD, submucosa is instead dissected below the lesion with a specialized electrosurgical knife (Figure 7). This enables the en bloc removal of large lesions and even those showing shallow submucosal invasion with a curative intent than can be accomplished with EMR [20].

ESD needs a specialized training to achieve competence and it can be a lengthy procedure for non experts, especially in Western countries. However, in expert hands, it has some advantages over surgery: shorter procedure duration and hospital stay, low profile of invasiveness and less need for general anaesthesia [5]. Furthermore, TEM lacks a good-view of the operative field near the dentate line which is not an issue in ESD.

Indications for colorectal ESD are shown in the Table 1 [21,22]. ESD in colon and rectum has generally been used for laterally spreading tumors (LST) larger than 2 cm in diameter have a higher risk of submucosal invasion. By using image-enhanced endoscopy, specific dyes and optical magnification, the endoscopist can evaluate the lesion through its macro- and microscopic appearance (lesion colour, surface unevenness, presence of depression, and fold convergence) to assess the presence of signs of deep submucosal invasion. Staging with either EUS and/or MRI can be considered for rectal lesions showing the aforementioned signs [5].

The most frequent complications of ESD are bleeding and perforation. Intraprocedural bleeding is a common and expected event during ESD, and it can be typically managed endoscopically. Delayed bleeding has been reported in 2% of patients in a meta-analysis of colorectal ESD [23]. Perforation rate in this meta-analysis of colorectal ESD was 4.8% [23] but in some studies reaches up to 18%

**Table 1:** Indications for Colorectal ESD.

1	large lesions (>20mm in diameter) where en bloc resection is required
a	LST-NG (Particularly flat-depressed type)
b	Lesions showing Kudo's Vi pit pattern
c	Carcinoma with predicted shallow submucosal invasion
d	Large depressed-type tumors
e	Large-protuded-type lesions suspected to be a carcinoma. Including LST-G, nodular mixed type
2	Mucosal tumors with submucosal fibrosis as a result of previous biopsy or prolapse caused by intestinal peristalsis
3	Flat dyplastic lesions associated with Ucleractive Colitis non respectable by EMR
4	Local residual or recurrent early carcinomas after endoscopic resection

**Table 2:** Study results. 2,077 patients.

Results (Arezzo et al)	ESD (n=11 series)	TEM (n=11 series)
En bloc resections	87.80%	98.70%
RO resections	74.60%	88.50%
Procedure time	96 min	67 min
Postoperative complications	8%	8.40%
Recurrences	2.60%	5.20%
Rate of overall need of further abdominal treatment	8.40%	1.80%

**Table 3:** Study results. 63 patients.

Results Park et al)	ESD (n=30)	TEM (n=33)
En bloc resections	96.70%	100.00%
RO resections	96.70%	97.00%
Curative resections	77.00%	79.00%
Procedure time	84 min	116 min
Postoperative complications	3.3% (no significant differences)	6.1% (no significant differences)
Hospital stay	3.6 days	6.6 days
Local recurrence in 2 years of follow up (in curative reaction)	NO	NO

[24]. Fortunately, most perforations are recognized intraprocedurally and are amenable to clip closure.

The 2010 guidelines from the Japanese Society for Cancer of the Colon and Rectum define R0 resections as curative when none of the following are present: depth of submucosal invasion greater than 1000 mm, lymphovascular invasion, poor differentiation, or higher grade (2 or 3) tumor budding at the site of deepest invasion [25].

The efficacy of ESD in the colon and the rectum has been well documented in many studies. A systematic review published in 2012 by Repici et al. [23] including 2841 lesions, reported a complete resection rate of 96% (95%CI 91%-98%), R0 resection rate of 88% (95 %CI 82 % – 92 %) and a negligible local recurrence rate (<0.1%). Another report by Lee et al. [26] that gathered 1000 cases showed similar results. Nevertheless western endoscopists have also published results that differ from those reported by more experienced centres, like the multicenter study published by Rahmi et al. [24] that gathered 45 cases with an en bloc resection rate of 64%, R0 resection rate of 53% and a local recurrence rate of 7%.

## Discussion

Conventional treatment of rectal cancer involves the complete mesorectal excision within a recurrence rates below 5%, a morbidity rate around 30-68% and 2-7% mortality [8,27,28]. The Parks transanal access technique is the choice for early lesions in the lower rectum [29]. The difficulty comes within the middle and upper third rectum lesions in which the transanal approach becomes limited by the surgery field [8].

The TEM and TAMI's transanal surgery allow us the resection of large benign lesions and early stages rectal adenocarcinoma. It is used is mostly in T1N0 lesions. The indication in T2 lesions is controversial. Although it is technically possible, the discussion appears regarding cancer outcomes due to the lack of mesorectal resection. We must consider that between 0-12% of T1 stage patient's present lymph node metastasis, and 10 to 22% of those with T2 injuries [30].

The accurate tumor staging and the lymphovascular invasion

are clue factors for transanal surgery indication. From our point of view the adequate preoperative patient assessment by endoscopic ultrasound, abdominopelvic MRI as well as CT scan and adequate patient selection are crucial. We must know the lesion size and location as well as the presence of lymphovascular invasion [27,30,31].

The endoscopic ultrasound and magnetic resonance imaging (MRI) are the tests of choice. Sensitivity and specificity are superior in MRI and there is no inter-observer bias [32]. Both tests can miss the presence of distant metastases, so the preoperative study should be completed with the completion of a CT scan.

In experienced centers oncological results are similar to conventional surgery, within tumor recurrence between 5 and 7% in T1N0 stage patients in which a complete tumor excision with free resection margins was performed [11,12,27]. On the other hand, important complications such as anastomotic dehiscence, postoperative sepsis, surgical wound complications, sexual dysfunction, and urinary or gastrointestinal complications arising from the realization of a stoma are still present, with significant reduction in quality of life [27]. The correct patient selection allows transanal resections having similar oncological long-term results versus conventional surgery [30], with a significant reduction in complications. Regarding cancer follow up, current clinical guidelines recommend performing colonoscopy every 6 months the first 5 years after resection in T1 lesions patients and a CT chest-abdominal-pelvic annually during the first three years [30,33]. In T2 or higher stage patients we can perform the transanal surgery as a palliative option in patients with comorbidities, disseminated stage or patient election.

The second place would be for those patients with higher lesions than T2, which have undergone adjuvant treatment. According to the series in the literature, about 20% of patients have complete pathological response, and this is where the dilemma arises. Many authors advocate complete mesorectal resection, despite tumor response, others suggest the possibility of close monitoring without surgical resection in cases with tumor regression with complete clinical response [34], with similar long term survival rates. In this field, the TEM or TAMI's resection of tumor scar, in those patients with good response to neoadjuvant therapy, would allow us to reduce

the local recurrence possibility and confirm complete pathological response in the analysis of the tumor scar.

Unfortunately, nowadays, there is insufficient scientific evidence around T2 patient. There are few studies in the literature that assess the cancer outcomes of these patients in the short and med term. The trial of the American College of Surgeons Oncology Group (ACOSOG) Z6041 is a prospective and multicenter study of efficacy and safety (Phase II) of chemo-radiotherapy and local resection of patients with T2N0 lesions. It included 90 patients and observed complete response in 44% of surgical specimens, and partial response in 64% (ypT0/1) [35].

The long-term oncologic outcomes in patients with T2N0 lesions are not yet known, which calls for the design of clinical trials and the selection and close monitoring of these patients [35,36]. In this line include the study of Lezoche compares local recurrence, distant metastasis and survival of patients with rectal adenocarcinoma stage T2N0. This study of two randomized groups compares patients with total excision of mesorectum performed against those with a transanal resection, in both cases after neoadjuvant therapy. After a follow up of 84 months, it was observed that oncologic results were similar in both groups [37]. Some authors suggest that TEM and TAMIS after chemoradiotherapy increases the postoperative pain and surgical wound dehiscence, so the patients should be carefully selected [38].

Regarding closure of the defect after resection, there is no consensus in the literature. Closure can be performed by continuous or interrupted suture, with intracorporeal or extracorporeal knotting. The most important study of literature includes 75 operated patients, of which 53% closure was performed. There are no statistically significant differences in the postoperative period in both groups concerning long-term continence. On the other hand, defect closure is time consuming (an average of 38 minutes in the hands of expert surgeons). What is undeniable is that in patients with an abdominal inlet cavity, it is mandatory the rectal closure, either via transanal or combined with laparoscopy [15].

In addition, we can say that both techniques are important tools for other rectal diseases. It is useful for resection of rectal adenoma, tumors of neuroendocrine line or anal warts [39]. It can also be used to close the defect in rectal iatrogenic perforations. Also, it is a useful tool in treating complex rectal fistulas, especially those with high location, such as the urinary fistulas, with good outcomes and low morbidity [40].

Finally, the data comparing ESD with surgical treatments for colorectal neoplasia are retrospective and limited in the literature. In a large systematic review published in 2014 by Arezzo [41], the ESD procedure appears to be a safe technique, but TEM achieves a higher R0 resection rate when performed in full-thickness fashion, significantly reducing the need for further abdominal treatment. In a single-centre South Korean retrospective study [42], both ESD and TEM are effective and oncologically safe for treating non-polypoid rectal high grade dysplasia and submucosa-invading cancers, and ESD has the additional advantages of minimal invasiveness and avoidance of anaesthesia. These results are shown in the Table 2 and 3.

Probably, in an ideal scenario, ESD might be a great option for early colorectal neoplasia but frequently this is not the case in most institutions in Western countries and surgical techniques are commonly more accessible to physicians [43]. Recent European

guidelines for early rectal cancer do recommend either ESD or TEM, both with optimal curative resection rate [44]. By last, we must not forget that some techniques can be used in combination. Our group has published [45] the utility of combining simultaneous flexible endoscopy with TEM.

## Conclusion

Transanal minimally invasive surgery is a safe and effective technique for the resection of lesions located in the middle and upper third of the anus, so benign nature as neoplastic lesions T1N0 stage. The use of this technique in T2 and T3 lesions, today is controversial, and requires individual assessment of each case. Long-term oncologic results and low morbidity and mortality make this technique applicable for rectal lesions, and lower costs and shorter learning curve in TAMIS make a better option than TEM (Transanal Endoscopic Microsurgery), due to the use of laparoscopic instruments. Endoscopic procedures such as ESD could be an alternative in selected cases. The application of this technique is developing in other rectal lesions.

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