

TAMIS without Closure of the Surgical Defect

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ABSTRACT

Background: Transanal Minimally Invasive Surgery (TAMIS) is a technique that is especially useful in extraperitoneal rectum injuries difficult to be anteriorly approached.

Currently, the closure of the rectal defect below peritoneal reflection is still controversial. The endoluminal suture is one of the most challenging aspects of the procedure and the literature is discordant regarding the closure of the defect.

Objective: Our goal is to carry out a descriptive study of a consecutive series of patients with extraperitoneal rectum injuries, who undergone TAMIS surgery, leaving the surgical defect open.

Design: A prospective longitudinal descriptive study.

Material and Method: Between August 2013 and July 2019, all patients with extra peritoneal rectum lesions, operated using the TAMIS technique, were consecutively included. The presented lesions were: benign lesions ≥ 3 centimeters difficult to endoscopic resolution, neuroendocrine tumors ≤ 2 cm, T1N0 adenocarcinomas without histological signs for poor prognosis, T2N0 adenocarcinomas with high surgical risk or patients reluctant to radical surgery and others with doubtful about a complete remission after neoadjuvant therapy.

All the procedures were performed by the same surgeon and in all of them, the surgical defect was left open.

Results: In a 6-year period, 35 patients were treated using TAMIS technique, with an average age of 61 years ± 12 . The average size of the lesions was 3.68 ± 2.1 cm (0.7-9 cm) and the distance from the anal margin to the distal end of the lesion was 5.7 ± 1.48 cm (3 to 8.5 cm). The operative time was 39.2 ± 20.5 min and the hospitalization time was 33 ± 28.2 hours. The pathological anatomy of the resected lesions was: 15 adenomas, 3 carcinoid tumors and 17 adenocarcinomas. 1 ypT0, 4 carcinomas in situ, 4 T1 tumors and 8 T2 tumors. In all cases, the rectal defect was left open, with a minimum post-operative follow-up of 9 months. There were no deaths and the overall morbidity was 14.2% (5 patients). Two patients were admitted for pain treatment (Clavien-Dindo II) and 3 patients (8.5%) were assisted for postoperative bleeding, out of which only 1 (2.8%) required reoperation (Clavien-Dindo III). There were no infectious complications, postsurgical rectum stenosis, or perforations into the abdominal cavity.

Conclusion: Our results allow us to describe TAMIS technique, leaving the surgical defect open, as a technique with good results, high feasibility and low complication rate.

Key words: TAMIS; Transanal Surgery; Closure; Surgical Defect; Complications

INTRODUCTION

Rectal resection with total mesorectal excision via the abdominal approach remains the standard treatment for rectal cancer.^{1,2} However, postoperative morbidity and functional sequelae are high with 10-30% of patients requiring a definitive ostomy.³⁻⁵

Early stage benign and malignant tumors of the lower rectum have traditionally been managed with local excision with the Parks technique. But this approach has important limitations in terms of exposure and visibility of the rectal lumen.⁶ Buess et al.,⁷ described Transanal Endoscopic Microsurgery (TEM) in 1984 and it was established as the treatment of choice for benign and early stage malignant tumors of the rectum not suitable for resection with the Parks technique or flexible endoscopy.^{8,9} However, several factors prevented this technique from becoming popular, such as the need for special high-cost instruments and a long learning curve.^{10,11}

Transanal Minimally Invasive Surgery (TAMIS) de-

scribed by Atallah et al., in 2009,¹² overcame these limitations using a flexible transanal device and standard laparoscopic instruments, obtaining similar results to TEM.^{13,14} TAMIS is especially useful in extraperitoneal rectal lesions difficult to approach via the anterior approach and with a low risk of perforation into the peritoneal cavity.

Currently, closure of the rectal defect below peritoneal reflection remains controversial and there is no consensus among colorectal surgeons on this point.¹⁵ One of the most challenging aspects of the procedure is endoluminal suturing, which may take longer than dissection itself. The inability to suture through the platform has been a barrier to the adoption of this technique.¹⁶⁻¹⁸ The literature is discordant regarding the closure of the surgical defect and it is difficult to reach conclusions due to the heterogeneity of the studies which compare different surgical techniques with decisions left to the intervening surgeon's choice and patients operated on using disparate selection criteria by surgeons with different levels of experience.^{15,19}

Our objective was to carry out a descriptive study of a consecutive series of patients with extraperitoneal rectal lesions who underwent TAMIS surgery, leaving the surgical defect open.

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MATERIAL AND METHODS

This is a longitudinal, prospective, descriptive study conducted between August 2013 and July 2019 at two private and one public institution in the city of Mar del Plata. All patients with extraperitoneal rectal lesions operated on with the TAMIS technique, were consecutively included. The indications were benign lesions ≥ 3 cm difficult for endoscopic treatment, neuroendocrine tumors ≥ 2 cm, T1N0 adenocarcinomas without histological signs of poor prognosis, T2N0 adenocarcinomas with high surgical risk, doubts about complete remission after neoadjuvant treatment and patients who refused radical surgery.

Preoperative staging was performed with digital rectal examination, colonoscopy, abdominal and pelvic high-resolution magnetic resonance imaging (MRI) of at least 1.5 Tesla, computed tomography of the chest (CT), and carcinoembryonic antigen in malignant lesions. For patients with neoadjuvant therapy re-staging was performed between 6 to 8 weeks after the end of treatment.

Bowel preparation with phosphates and general and/or spinal anesthesia was used. Antibiotic prophylaxis was performed with metronidazole and gentamicin during hospitalization, completed in most cases with oral amoxicillin-clavulanic acid for 5 days after hospitalization.

Procedures were performed by the same surgeon with a 15 mmHg CO₂ insufflation pressure and SILS Port® (Covidien, Mansfield, MA, United States) or GelPointPath® (Applied Medical Rancho Santa Margarita, CA, United States) transanal devices, standard laparoscopic instruments and harmonic scalpel (Ultracision Harmonic Scalpel®, Ethicon Endosurgery Inc. Cincinnati, OH, USA) in all cases. The surgical defect was left open, regardless of lesion size or location.

Postoperative complications were the most important parameter assessed. Rectal bleeding, infectious complications (defined as the presence of at least two of the following parameters: fever $> 38.5^{\circ}$, rectal pain, leukocytosis $> 11 \times 10^9$ c/L, images compatible with perirectal collection or clinical diagnosis of infection), perforation into the peritoneal cavity, rectal stenosis that required some type of dilation and mortality were analyzed.

RESULTS

In a 6-year period, 35 patients were treated with the TAMIS technique without closure of the rectal defect. The average age of patients was 61 ± 12 (range: 30-86) years and 51.4% were female. Five patients had received neoadjuvant therapy.

The mean size of the lesions was 3.7 ± 2.1 (range: 0.7-9) cm and the distance from the anal margin to the distal

end of the lesion was 5.7 ± 1.5 (range: 3 -8.5) cm. Operative time was 39.2 ± 20.5 (range: 17-90) min and hospital stay was 33 ± 28.2 hs (range: 1 to 7 days) (Table 1). There were no perforations into the abdominal cavity.

The histopathology of the resected lesions reported 43% adenomas, 8% carcinoid tumors and 49% adenocarcinomas (Table 1). Within this last group, there was a patient who received preoperative chemo-radiotherapy who had the scar removed to confirm complete remission (ypT0). Of the patients with T2 tumors, one had a biopsy informed as adenoma, 3 refused radical surgery, and 4 were sub-staged by MRI, of which 2 underwent Miles operation.

There was no mortality and the overall morbidity was 14.3% (Table 2). Two patients (5.7%) who had received neoadjuvant treatment were readmitted for pain treatment (Clavien-Dindo II). Three patients (8.5%) had postoperative bleeding, 1 self-limited on 80 day (Clavien-Dindo I), 1 required transfusion with 2U of red blood cells (Clavien-Dindo II) and only 1 (2.8 %) was reoperated (Clavien-Dindo III). There were no infectious complications or rectal stenosis. The minimum postoperative follow-up was 9 months.

DISCUSSION

TEM was the procedure that radically changed the way of performing transanal excision of rectal lesions,²⁰ however, several factors prevented this technique from becoming popular.^{10,11} TAMIS surgery managed to overcome these limitations, achieving results similar or even better than TEM in some aspects, such as operative time and anal sphincter dysfunction.^{13,21,22} The patient is always placed in the lithotomy position regardless of the location of the lesion, allowing a rapid abdominal approach if necessary. These advantages, along with lower cost and a shorter learning curve, resulted in the possibility of more surgeons incorporating mini-invasive transanal resection techniques.^{23,24}

In our series, all resections were performed with full-thickness excision of the rectal wall. This is mandatory for interventions performed on malignant lesions and highly recommended for benign lesions, due to the possibility that the specimen contains an invasive component which can occur in up to 30% of cases.^{25,26}

Regarding staging, 4 patients, 3 of whom had received neoadjuvant therapy, were under-staged by MRI, reflecting the difficulty for evaluating these lesions. Although transanal ultrasound has shown its value in differentiating T1 from T2 tumors, it was not used in our series because this diagnostic method was not available in our setting. On the other hand, we use in all cases high-reso-

lution MRI with specific protocols for the rectum, which in recent years has achieved equal results than transanal ultrasound in the staging of early tumors, with the advantage of allowing the evaluation of poor prognostic factors for local resection and the re-staging after neoadjuvant treatment.²⁷⁻³⁰

Despite efforts to standardize the technique in mini-

TABLE 1: CHARACTERISTICS OF THE POPULATION.

Patients n	35
Female gender, n (%)	18 (51.4)
Age, yrs (mean ± SD)	61±12
Tamaño de la lesión, cm (mean ± SD)	3.7 ± 2.1
Distance from the anal verge, cm (mean ± SD)	5.7 ± 1.5
Operative time, min (mean ± SD)	39.2 ± 20.5
Hospital stay, h (mean ± SD)	33 ± 28.2
Histopathology	
Adenoma, n (%)	15 (43)
Carcinoide tumor, n (%)	3 (8)
Adenocarcinoma, n (%)	17 (49)
yT0	1
Tis	4
T1	4
T2	8

TABLE 2: POSTOPERATIVE COMPLICATIONS: CLAVIEN-DINDO CLASSIFICATION.

Complications	n (%)	Grade I	Grade II	Grade III
Pain	2 (5.7)	0	2	0
Bleeding	3 (8.5)	1	1	1
Reinterventions	1 (2.8)	0	2	1
Total	5 (14.3)	2.8%	8.5%	2.8%

mally invasive transanal resections,^{31,32} the closure of the rectal defect remains one of the most controversial points, especially in lesions located below the peritoneal reflection where these techniques are more useful and there is less risk of perforation to the peritoneal cavity.¹⁵ The benefits of rectal defect closure are not well understood as the rectum and mesorectum are well Given the limited space, the suture of the defect is technically difficult, especially the approximation of the edges without tension; it takes a long time, sometimes even longer than the dissection itself, doubling the duration of the procedure.¹⁸⁻²⁰ Different types of suturing techniques were used, such as continuous intracorporeal suture, separate suture with extracorporeal knots and metal clips to avoid knotting,^{16,18,33-35} but it is still considered that 30% of the defects cannot be closed.²⁰

The reports in the literature are contradictory, both in the comparative studies, the randomized ones and the meta-analyzes; in the majority there are no statistically significant differences in complications between those who leave the defects open and those who close them. Hahnloser et al.,²⁰ found no significant differences in postoperative complications (bleeding or infection). Conversely, Brown et al.,¹⁶ showed that patients in whom the defect was closed after TEM had fewer complications and readmissions, although the open group had significantly lower lesions. A third observational study by Noura et al.,³⁶ was associated with higher morbidity and more severe complications when the defect was closed. Menahem et al.,¹⁵ in their meta-analysis of 503 patients found no significant differences regarding overall morbidity, including bleeding and infections, same conclusion reached by Lee et al.,¹⁹ in a later communication (Table 3).

There are important limitations in the published studies. Most are multicenter studies in which perioperative management is not standardized. There are different inclusion criteria based on the height or size of the lesions, or whether or not they received neoadjuvant treatment. Patients operated on by surgeons with different levels of experience, different techniques and diverse instruments/equipment are compared. Finally, in many studies the decision to close the rectal wall defect is left to the discretion of the intervening surgeon.^{15,19,20}

In our series, all patients received the same perioperative management and were operated on by the same surgeon. Patients with and without neoadjuvant treatment were included and in no case was the defect closed, regardless of the height or size of the lesion. The harmonic scalpel was used in all interventions, since it has been associated with less postoperative bleeding than when diathermy alone is used.³⁷

Overall morbidity was 14.3% (5 patients), in line with published series. Most complications were mild and only 1 (2.8%) was grade III of the Clavien-Dindo classification, the only case that required reoperation due to postoperative inpatient bleeding. The patient was reoperated by TAMIS, achieving hemostasis with a harmonic scalpel.

When analyzing the patients who received neoadjuvant treatment, we observed that 2 of the 5 were readmitted for pain management (Clavien-Dindo grade II). Although some series describe a higher rate of complications in patients who received chemo-radiotherapy, local resection has a precise indication, is very useful in cases of doubt of complete remission and safe from the oncological point of view.³⁸⁻⁴⁰ Our series allowed the identification of residual tumor in 2 patients who subsequently underwent abdominoperineal resection.

A suture dehiscence rate of 47% has been described,

TABLA 3: RESULTS OF TREATMENT OF RECTAL CANCER WITH TAMIS IN DIFFERENT SERIES OF THE LITERATURE.

Authors	Patients (n)	Overall mortality (%)	Morbidity (%)		Bleeding (%)		Infection (%)		Reoperation (%)	
			C	O	C	A	C	O	C	O
RAMIREZ	40	10	15	5	0	0	5	5	0	0
HANLOSER	75	19	12.5	17.1	3	11	10	6	2.5	0
NOURA	43	18.6	33.3	1.5	23.8	0	4.6	0	19	0
BROWN	341	11.7	8.4	19	4.7	7.6	2.1	6.7	0.4	1.9
LEE	220	13.6	12	15	9	5	5	3	3	2

C: Closed defect. O: Open defect.

which approaches 60% in patients with neoadjuvant treatment. However, it is not clear whether postoperative pain is associated to dehiscence, and it is even possible that leaving the defect open for closure by secondary intention could reduce this complication.³⁸

We did not have postoperative infections, probably due to the fact that leaving the surgical defect open prevented the creation of a contaminated closed cavity and to the indication of antibiotic prophylaxis against gram positive and negative infections in the intra and postoperative period.

Additionally, we had an average operative time of 39.2 ± 20.5 minutes. Since it was a brief procedure we used spinal anesthesia in most patients, which allowed them rapidly resuming oral intake and ambulation and having an average hospital stay of 33±28.2 hs.

All patients received endoscopic controls at least up to the 9th month after surgery and there were no postoperative stenoses, even with resections of lesions 9 cm in diameter. It is very difficult to close defects of such magnitude without narrowing the rectal lumen, complication that does not occur when they are left open waiting for closure by second intention.

Despite performing all full-thickness resections, we did not have perforations to the abdominal cavity, which have been reported in other series in about 6% of cases.^{41,42} This is partly due to the fact that we selected patients with lesions in the middle and lower rectum in whom the possibility of this complication is much lower.

Mortality rates in this type of intervention are low and reported in up to 2%.^{43,44} We did not have mortality in our series.

Analyzing our results and those of most studies that do

not report significant differences in complications whether the surgical defect is sutured or not, the benefit of closure should be reconsidered, especially when it involves a laborious stage that prolongs surgery. Additionally, it is possible that a technically less demanding procedure could be performed by a greater number of surgeons.

The limitation of this study is that no comparison with a procedure that closes the rectal defect with the same equipment, technique and surgical team was made

However, the results of this study serve as a first step and raise the need to carry out a comparative study of different techniques in order to reach clearer conclusions regarding the benefits of the TAMIS with no rectal defect closure.

CONCLUSION

In extraperitoneal rectal lesions, the results of this study show that the TAMIS technique with the surgical defect left open is highly feasible and has good results with a low rate of complications.

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