The American Journal of Surgery 217 (2019) 53–58

Contents lists available at ScienceDirect

The American Journal of Surgery

journal homepage: www.americanjournalofsurgery.com

How to deal with rectal lesions more than 15 cm from the anal verge through transanal endoscopic microsurgery

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ARTICLE INFO

Article history:
Received 10 January 2018
Received in revised form
12 April 2018
Accepted 17 April 2018

Keywords:
Transanal endoscopic microsurgery
Transanal endoscopic operation
Upper rectum
Rectosigmoid colon
Colorectal cancer

ABSTRACT

Background: The aim of this study is to assess postoperative morbidity and mortality in tumors with a proximal margin 15 cm or more from the anal verge operated with transanal endoscopic microsurgery (TEM).

Methods: This observational study of consecutive rectal tumor patients undergoing TEM was carried out from July 2004 to June 2017. We compared the results of rectal tumors at distances of ≥15 cm (group A) and <15 cm (group B) from the anal verge.

Results: During the study period 667 patients were included: 118 in group A and 549 in group B. In the comparative analysis there were no significant differences in morbidity ($p = 0.23$), mortality ($p = 0.32$) or free margin involvement ($p = 0.545$). Differences were observed in terms of lesion size ($p < 0.001$), surgical time ($p < 0.001$) and peritoneal cavity perforation, which were all increased in group A.

Conclusion: TEM for lesions in the rectosigmoid junction is feasible and is not associated with higher morbidity or mortality.

Introduction

Traditionally, an abdominal approach has been used in tumors of the rectosigmoid junction. Anterior resection (either high, or, less frequently, low) is performed in conjunction with anastomosis, either via laparoscopy or laparotomy. These techniques have morbidity rates of up to 33% and a mortality rate of 2%,[1] with occasional ostomy, a risk of anastomotic dehiscence and genito-urinary alterations or sexual dysfunction in up to 20–30% of patients.[2–6] Transanal endoscopic microsurgery (TEM), introduced by Buess[7] in the 1980s, is a minimally invasive surgical technique that facilitates excision of rectal tumors up to 20 cm from the anal verge.

In abdominal rectal surgery, tumors are usually measured in terms of the distance from the distal margin of the lesion to the anal verge. However, in TEM the reference point should be the proximal margin of the lesion, the one farthest from the anal verge, since this is the highest point that the local excision must reach.

In the early days of the TEM technique, lesions on the anterior or lateral surfaces of the rectum at heights of 12–15 cm were considered unsuitable for excision because of the risk of perforation into the peritoneal cavity.[8] In this situation, inadequate repair may cause postoperative fecaloid peritonitis. Another theoretical risk is the worsening of the cancer prognosis due to a possible seeding of cancer cells inside the peritoneum.[9]

As the experience with the technique has increased over the years, reductions in morbidity and complications have been reported[10] and new indications for TEM have been published.[11] However, the local excision of rectal tumors in the upper rectum, its intraperitoneal segment or the rectosigmoid junction (that is, at heights above 15 cm) remains controversial. TEM may be a good alternative in frail patients in whom abdominal surgery represents a high risk; however, the few studies of the subject carried out so far have only included small groups and their results have been inconsistent.[9,12–16]

Our group has many years of experience in transanal endoscopic surgery. We believe that suturing of the defect after TEM is mandatory, especially in lesions in the upper third of the rectum and the rectosigmoid junction. We also contend that primary repair of a perforation into the peritoneal cavity need not entail a greater complication rate.

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https://doi.org/10.1016/j.amjsurg.2018.04.014
0002-9610/

The aim of this study is to assess immediate postoperative morbidity and mortality of tumors with a proximal margin 15 cm or more from the anal verge in patients operated with TEM, and to compare the results with those recorded in lesions at lower heights.

Materials and methods

Design

Observational study with collection of prospective data from July 2004 to June 2017. The data obtained from all consecutive patients undergoing TEM were analyzed. Patients were assigned to group A (rectal tumors with proximal margin ≥15 cm from the anal verge) or group B (rectal tumors with proximal margin <15 cm from the anal verge), and data from the two groups were compared.

Patients

Candidates for TEM underwent the preoperative study included in the protocol[17]: clinical history with rectal examination, colonoscopy and biopsy, rectal examination, rigid rectoscopy, endorectal ultrasound (u) and pelvic magnetic resonance imaging (mri), sphincter function test (Wexner[18]) and anal manometry if the Wexner score was 6 or above. If the biopsy indicated adenocarcinoma, chest x-ray and abdominal CT were performed and oncological markers CEA and CA 19.9 assessed. After the preoperative study, patients were classified into five groups: group I with curative intent (benign tumor, u-mriT0-1 and u-mriN0); group II, with curative intent (low grade adenocarcinomas, u-mriT0-1 and u-mriN0); group III, consensus indication (low-grade adenocarcinomas, u-mriT2 and u-mriN0, who reject radical surgery); group IV, palliative (adenocarcinomas of any stage with palliative indication) and group V, atypical indications.[11]

The height and size of the lesion were defined by rigid rectoscopy, which confirmed the lesion's location according to quadrant and determined its upper and lower margins.

Inclusion criteria

Patients undergoing TEM for rectal lesion (indication groups I to IV), and size limits of three quadrants, or four quadrants but very short in length were divided into two groups:

Group A: All patients undergoing TEM with proximal margin of the tumor 15 cm or more from the anal verge. Group B: patients undergoing TEM with the upper margin of the lesion less than 15 cm from the anal verge.

Exclusion criteria

Atypical indications of TEM (with the exception of neuroendocrine tumors, which were included).

Surgical technique

All patients scheduled for TEM underwent mechanical preparation of the colon prior to surgery according to our service's protocol.[17] All were operated by the colorectal surgery unit team, which consists of five surgeons. The position of the patient on the operating table was determined by the quadrant affected. The techniques used for local excision were TEM® (Richard Wolf, Knittlingen, Germany) or transanal endoscopic surgery (TEO®) (Karl Storz GmbH, Tüttlingen, Germany).[19] In all cases, full-thickness excision of the rectal wall was performed as previously described, and the defect was closed with a continuous PDS 3/0 suture.[17]

Three different ways were used to reach lesions at heights above 15 cm using TEM/TEO. The choice of technique depended mainly on the characteristics of the lesion and the surgeon's preference:

Intussusception of the lesion inside the rectoscope, indicated in small lesions (less than 3 cm in diameter and located between 4 and 5 cm above the rectosigmoid junction). With the 20-cm TEM/TEO rectoscope in place above the rectosigmoid junction, the healthy mucosa is pulled proximally to the lesion with the forceps towards the rectoscope, in the same way as in an intussusception. Maintaining the traction inside the rectoscope, the lesion is excised and the defect sutured (video 1).

Supplementary video related to this article can be found at https://doi.org/10.1016/j.amjsurg.2018.04.014.

Rectoscope advancement technique, indicated in large lesions that advance from the rectum to the rectosigmoid junction. With the 20-cm rectoscope, full-thickness wall excision is started and the rectoscope is moved forward to the proximal part of the lesion. This approach is indicated in wide rectosigmoid junctions that allow the introduction of the rectoscope beyond the rectum. It is important to keep the patient in the Trendelenburg position so that the lesion is inserted inside the sigma as we remove it and does not block the view inside the rectoscope. Subsequently, the defect is sutured. To facilitate closure, the pneumorectum pressure is decreased from 12-14 mmHg to 8–10 mmHg with several continuous sutures (video 2).

Supplementary video related to this article can be found at https://doi.org/10.1016/j.amjsurg.2018.04.014.

Combined rectovision® (Karl Storz GmbH, Tüttlingen, Germany) and TEO®. This approach is indicated mainly in small lesions located above 20–22 cm, with narrow rectosigmoid junctions less than 4 cm in diameter which prevent the passage of the TEM/TEO rectoscope. The rectovision, with a length of 25 cm and a diameter of 2.5 cm, allows the creation of a traction stitch close to the lesion through its working windows. Subsequently, with the introduction of TEM/TEO rectoscope, we pull from the stitch and perform the excision and suture (video 3).

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The excised surgical specimen is mounted with needles on a cork base and is referred to the pathology laboratory. If there are no complications, patients are discharged on the same day or within 24 h. Postoperative morbidity was recorded up to 30 days after surgery, using the Clavien-Dindo classification system[20] and the Comprehensive Complication Index (CCI).[21] Patients in the preoperative indication groups I and II (curative intent) who were ≥ pT2 after the pathology study were rescued by radical abdominal surgery in the following weeks.[22]

Study variables and statistical analysis

Patients' demographics, ASA (American Society of Anesthesiologists) classification of surgical indication by groups, intraoperative findings (size, location [upper or lower margin]), surgical technique (TEM/TEO, type of technique, surgical time, full-thickness wall resection, perforation in the peritoneal cavity, conversion to abdominal surgery), postoperative events (overall morbidity, clinical morbidity defined by Clavien-Dindo degrees II to IV, type of morbidity, postoperative mortality, CCI, hospital stay) and pathology study of the specimen.

The study was approved by the local Institutional Ethics Committee (CEIC: 2016–36) and was carried out in accordance with the Declaration of Helsinki. The STROBE guidelines for observational studies were followed.

Data processing and analysis were performed with the IBM 21 SPSS Statistics Data Editor program. For the quantitative variables, means (SD) were used when the distribution was considered

normal; otherwise, the median and interquartile range (IQR) were used. Categorical variables were reported in absolute numbers and percentages. The parametric "t" test was used for statistical analysis of the quantitative variables with independent groups if the conditions for its application were met; otherwise, the Mann Whitney *U* test was applied. For categorical variables, the Pearson χ^2 test was used. The results of the statistical tests are given, whenever possible, with a 95% confidence interval (95%CI), and $p < 0.05$ was considered statistically significant.

Results

During the study period, 715 patients were treated with TEM/TEO. Forty-eight with atypical indications were excluded, though neuroendocrine tumors were included. Fig. 1 shows the distribution of the 667 remaining patients according to the height of the upper margin of the lesion. Group A included 118 patients (17.7%) and group B 549 (82.3%).

Table 1 displays the descriptive variables of patients in group A. Thirty patients in this group were female (24.4%) and 88 male (74.6%). Mean age was 71.3 (SD 10.4) years. The biopsy indicated adenoma in 92 patients (78%), who were scheduled for surgery with curative intent: this was the most frequent therapeutic indication. The median height of the upper margin of the lesion was 17 cm with an IQR of 3.6 cm (range 15–26 cm). In 15 patients (12.7%), the distal margin was located in the mid-rectum (5–10 cm from the anal verge). The median size of the lesions was 5 cm with an IQR of 3 cm (range 1–11 cm). Lesion location by quadrant was quite evenly distributed: the most frequent location was the posterior quadrant, in 33 patients (28%). One hundred and three patients (97%) were ASA II and III. TEM equipment was used in 79 patients (66.9%). The most frequently performed technique was rectoscope advancement, carried out in 95 patients (80.5%). The resection was full-thickness wall excision in 114 patients (96.6%). Perforation of the peritoneal cavity was performed in 28 patients (23.7%), of whom only seven presented morbidity. None of these patients had postoperative complications in the form of intra-abdominal infection.

Overall morbidity in group A was 22 patients (18.6%); seven (5.9%) presented clinical morbidity (Clavien-Dindo ≥ II) (Table 1). The intussusception and combined rectovision and TEO techniques were not associated with morbidity. In the definitive pathology study, ten of the 35 adenocarcinomas were pT ≥ 2 (eight in preoperative indication group I and two in preoperative indication group II) who required radical salvage surgery in the following weeks. Only one patient (0.8%) was converted to abdominal surgery with laparoscopically-guided high anterior resection, and presented satisfactory postoperative evolution. One patient (0.8%) died: a 54-year-old man with a history of liver cirrhosis awaiting liver transplantation, in whom an 11-cm villous adenoma was

Table 1
Descriptive variables in group A (≥15 cm).

Variable	N Patients (%)/Median, SD (range)
Sex	30 women (24.4%)
	88 men (74.6%)
Age (years)	71.3, SD 10.4 (47)
Indication group	Group I, Curative intent (ADN): 92 (78%)
	Group II, Curative intent (ADK): 14 (11.8%)
	Group III, Consensus (ADK): 4 (3.4%)
	Group IV, Palliative (ADK): 7 (5.9%)
	Group V, Atypical: 1 (0.8%)
Lesion size	5 cm, IQR 3 cm (1–11 cm)
Location by quadrant	Anterior: 31 (26%)
	Posterior: 33 (28%)
	Right lateral: 23 (20%)
	Left lateral: 30 (25%)
ASA	- ASA I: 1 (0.8%)
	- ASA II: 53 (45%)
	- ASA III: 50 (42.4%)
	- ASA IV: 14 (12%)
Surgical time	98.9 min, SD 42.3 min (215)
Intraoperative perforation	28 (23.7%)
TEM/TEO	TEM: 79 (66.9%)
	TEO: 39 (33.1%)
Technique used	- Intussusception: 15 (13%)
	- Rectoscope advancement: 95 (80%)
	- Rectovision + TEM/TEO: 8 (7%)
Type of resection	- Full wall: 114 (96.6%)
	- Non full wall: 4 (3.4%)
Overall morbidity	22 (18.6%)
Clinical morbidity ≥ II D-CL	7 (5.9%)
CCI	3.73, SD 11.5 (100)
Mortality	1 (0.8%)
Pathology	- Adenoma: 76 (64.4%)
	- Adenocarcinoma: 35 (29.7%)
	- Neuroendocrine: 1 (0.8%)
	- No pathology: 6 (5.1%)

SD: Standard deviation. ADN: Adenoma. ADK: Adenocarcinoma. IQR: Interquartile range. ASA: ASA (American Society of Anesthesiologists) classification TEM: Transanal Endoscopic Microsurgery.

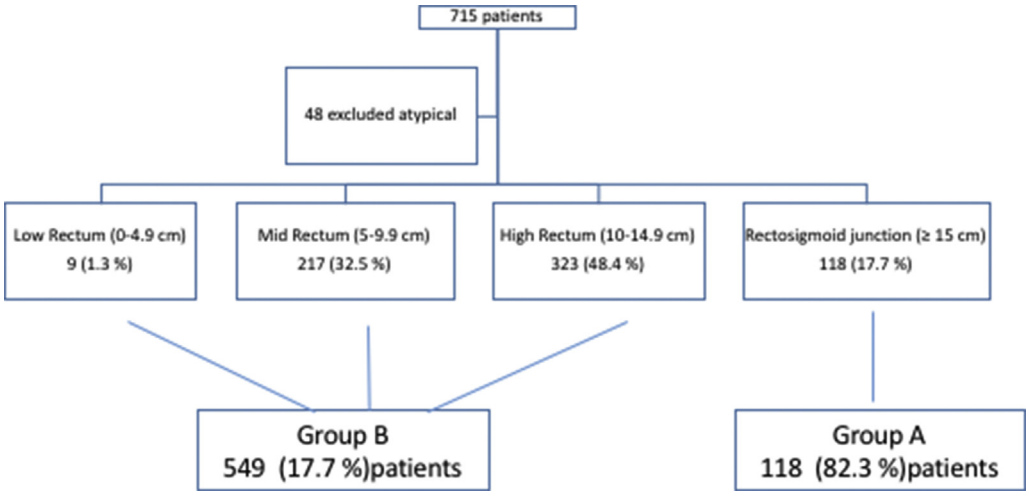

Fig. 1. Distribution of patients according to the height of the upper margin of the tumor with respect to the anal verge. 667 patients.

identified with an upper margin 22 cm from the anal verge. TEM was laborious, with perforation into the peritoneal cavity, but there were no postoperative complications related to TEM. In the third postoperative week the patient developed digestive hemorrhage and coagulopathy, which was the cause of death. Of the patients with peritoneal perforation, 7 had adenocarcinomas and 21 adenomas. No patient presented peritoneal recurrence. Two patients presented local recurrence: one was a pT3 with unresectable bilobar hepatic metastasis, and the other an initial adenoma and a subsequent recurrence with biopsy of adenocarcinoma which was converted to radical surgery.

Table 2 shows the type of morbidity and mortality in group A, in relation to the indication group, Clavien-Dindo grade of complication, CCI, location by quadrant and definitive pathology study of the 22 patients who presented complications. The most frequent were rectal bleeding in 16 patients (72.2%) and urinary pathology in five (22.7%). The CCI was low, with a median of 12.2 (range 8.7–34.8) excluding the exitus.

Table 3 shows the bivariate analysis between study groups A and B. There were no statistically significant differences regarding preoperative surgical indication between the groups. Group A patients presented significantly greater lesion size ($p < 0.001$), longer surgical time ($p < 0.001$) and more perforations in the peritoneal cavity during the procedure than group B patients. However, there were no differences in overall morbidity ($p = 0.23$), clinical morbidity ($p = 0.36$), CCI ($p = 0.48$), mortality ($p = 0.32$) or free margins ($p = 0.54$). As regards experience with the technique, all the surgeons at the Unit had operated on at least 35 cases. Surgeon 1 was the one with most experience and the best results in postoperative morbidity, though the differences with regard to the other surgeons were not statistically significant.

Discussion

Local excision of rectal tumors is indicated in adenomatous lesions and T1 adenocarcinomas with histological characteristics indicating good prognosis. Lesions of this type located at the rectosigmoid junction have classically been treated by open abdominal surgery or laparoscopy with colorectal anastomosis. Since the introduction of TEM, these lesions can now be reached with a 20-cm rectoscope. TEM[7] provides an excellent view of the working area, allowing dissection, cutting, coagulation, suturing, preservation of the sphincter apparatus and full-thickness wall resection, thus reducing the morbidity rates associated with this type of surgery.[7] Other transanal endoscopic surgery procedures such as TEO[19] and TAMIS (minimally invasive transanal surgery)[23] have also been described with the intention of simplifying the technique and equipment required.

TEM and TEO are used interchangeably for transanal surgery. As we have shown previously, from the technical point of view the two systems are similar, since 20-cm rectoscopes can be used in both.[24] In this study we used TEM more frequently, but TEO has recently grown in popularity because of the greater simplicity of the apparatus and the 30° view provided by the telescope.[25] TAMIS is not recommended for these lesions, as some authors report a risk of complicated peritoneal entry which may require conversion to a rigid platform.[26]

The distance from the upper margin of the lesion to the anal verge is of vital importance for defining the limits of TEM with regard to lesion height. Using TEM, the limits were traditionally established by the risk of perforation of the peritoneal cavity, but today perforation is no longer considered a contraindication[14]; therefore, there are no limits regarding the location of the lesion according to quadrant, and the excision can be performed up to and beyond 18–20 cm. The actual height limit is determined by the length of the rectoscope and the patient's anatomical characteristics: for instance, narrow rectosigmoid junctions with a small rectum, or previous abdominal surgery that immobilizes the rectosigmoid junction and prevents its intussusception, may rule out the use of TEM in these situations.[17]

In lesions at certain heights it is not easy to decide whether a particular lesion requires TEM or abdominal surgery. The issue should first be evaluated with all the members of the unit. Then the surgery is scheduled, the two sets of equipment (TEM and laparoscopic surgery) are prepared, and the patient, anesthetists and surgical nursing teams are informed of the two possibilities. Before surgery, the tumor is reassessed by rigid rectoscopy in the operating room. Unless it is clearly impossible to perform TEM, we

Table 2
Type of postoperative morbidity and mortality in group A (≥15 cm).

TYPE OF MORBIDITY	Nº Patients	CCI	Therapeutic indication group	C-D grade	Pathology	T	Quadrant	Perforation
Rectal hemorrhage	2	8.7	I: Curative. Benign tumor	I	ADENOMA	0	anterior	0
Rectal hemorrhage	1	8.7	I: Curative. Benign tumor	I	ADENOMA	0	anterior	1
Rectal hemorrhage	1	8.7	IV: Palliative	I	CARCINOMA	2	left lateral	0
Rectal hemorrhage	1	8.7	I: Curative. Benign tumor	I	ADENOMA	0	left lateral	0
Rectal hemorrhage	2	8.7	I: Curative. Benign tumor	I	ADENOMA	0	posterior	0
Rectal hemorrhage	1	8.7	I: Curative. Benign tumor	I	CARCINOMA	3	posterior	1
Vomiting	1	8.7	III: Consensus-Carcinomas	I	CARCINOMA	2	anterior	0
AUR	1	12.2	I: Curative. Benign tumor	I	ADENOMA	0	right lateral	1
AUR + rectal hemorrhage	1	12.2	I: Curative. Benign tumor	I	ADENOMA	0	anterior	0
Rectal hemorrhage (2 episodes)	1	12.2	I: Curative. Benign tumor	I	ADENOMA	0	right lateral	1
Rectal hemorrhage (2 episodes)	1	12.2	IV: Palliative	I	CARCINOMA	1	left lateral	0
Rectal hemorrhage (2 episodes)	1	12.2	I: Curative. Benign tumor	I	CARCINOMA	3	posterior	0
Rectal hemorrhage + bradycardia + AUR	1	17.3	I: Curative. Benign tumor	I	ADENOMA	0	posterior	0
Urine infection	1	20.9	I: Curative. Benign tumor	II	ADENOMA	0	anterior	0
AUR with cystostomy	1	20.9	I: Curative. Benign tumor	II	ADENOMA	0	posterior	0
Rectal hemorrhage	1	26.2	IV: Palliative	IIIa	CARCINOMA	3	posterior	0
Perianal abscess, rectal hemorrhage and retropneumo	1	30.8	I: Curative. Benign tumor	II	CARCINOMA	2	anterior	1
Exploratory laparotomy	1	33.7	II: Curative. Carcinoma	IIIb	CARCINOMA	1	left lateral	1
Exploratory laparotomy	1	33.7	I: Curative. Benign tumor	IIIb	CARCINOMA	3	right lateral	0
Rectal hemorrhage reintervention with TEM	1	34.8	I: Curative. Benign tumor	IIIb	ADENOMA	0	anterior	1
TYPE OF MORTALITY	Nº Patients	CCI	Therapeutic indication group	C-D grade	Pathology	T	Quadrant	Perforation
Digestive hemorrhage, liver failure	1	100.0	I: Curative. Benign tumor	V	ADENOMA	0	left lateral	1

C-D: Clavien-Dindo. CCI: Comprehensive Complication Index. AUR: Acute Urine Retention.

Table 3
Bivariate analysis.

Variable		Group A (≥15 cm) 118 patients	Group B (<15 cm) 549 patients	P
Indication group	I-Curative intent (ADN)	92 (78%)	377 (68.7%)	0.25
	II-Curative intent (ADK)	14 (11.9%)	94 (17.1%)	
	III-Consensus (ADK)	4 (3.4%)	40 (7.3%)	
	IV-Palliative (ADK)	7 (5.9%)	30 (5.5%)	
	V-Atypical [11]	1 (0.85)	8 (1.5%)	
Surgeon	1	73 Morbidity: 10 (14%)	276	0.52
	2	20 Morbidity: 5 (25%)	114	
	3	10 Morbidity: (30%)	57	
	4	11 Morbidity: 3 (27.3%)	85	
	5	4 Morbidity: 1 (25%)	65	
Lesion size		4.93 cm SD 2 cm	3.88 cm SD 1.7 cm	<.001
Surgical time		98.82′ SD 42.3′	76.95′ SD 38′	<.001
Free margins		112 (94.9%)	508 (92.9%)	0,545
Perforation		28 (23.7%)	18 (3.3%)	<.001
Overall morbidity		22 (18.6%)	132 (24%)	0.230
Clinical morbidity C-D > II		7 (5.9%)	49 (8.9%)	0.361
CCI		3.7 SD 11.4	4.5 SD 10.7	0.486
Mortality		1 (0.8%)	1 (0.2%)	0.323

ADN: Adenoma. ADK: Adenocarcinoma. SD: Standard deviation. C-D: Clavien-Dindo. CCI: Comprehensive Complication Index.

always start with this approach. The combination of the two approaches may be a good solution in selected cases. In the study presented here, only one case was converted to abdominal surgery.

We performed full thickness rectal wall excision in all the lesions, even in those with biopsies indicating adenomas. This was because of the high incidence of infiltrating adenocarcinoma which we reported in a previous study.[27]

The present study is one of the largest reports in the literature of the use of TEM in cases of rectosigmoid lesions. We have not found any prior descriptions of the use of transanal surgery to treat rectosigmoid junction lesions. We believe that the three approaches we describe here can provide solutions for the treatment of these lesions, as they use minimally invasive techniques and achieve minimal morbidity. However, we stress that these techniques are demanding and should be performed by surgeons with extensive experience in transanal endoscopic surgery: that is, surgeons who have completed the learning curve, estimated to be around 35 procedures.[28]

Overall morbidity in our group of rectosigmoid lesions (18.6%) is comparable to that of the rest of series (24%) – in fact it is slightly lower, although the differences were not statistically significant. Nor were differences found with regard to clinical morbidity (5.9% vs. 8.9%). The most common complications were rectal bleeding and urinary pathology, though the rates of these complications were within the ranges published in the literature in similar lesions.[29,30]

Rates of peritoneal cavity perforation during TEM were higher in the rectosigmoid lesion group (23.7%, 28/118) than in the rest of the series (3.3%, 18/549). However, only one patient required conversion to abdominal surgery. There were no postoperative septic complications and no patient in the study required fecal derivation.[31]

The use of TEM/TEO for the resection of intraperitoneal rectal lesions represents an intermediate step on the way toward minimally invasive natural orifice surgery (NOTES). Our experience with the treatment of these lesions has allowed us to develop our hybrid NOTES technique with intracorporeal resection and anastomosis through TEO.[25]

The limitations of the present study are its observational, single-center design and the fact that it was performed by a group of experts in TEM/TEO; this may mean that is excessively demanding for surgeons who are new to the technique.

Conclusions

Resection of rectal lesions above 15 cm of the anal verge using TEM/TEO is feasible and safe. Patients must be rigorously preselected and operated upon by experienced surgeons. Despite the greater technical difficulty, rates of complications and postoperative mortality have not increased. Although it is true that there is a risk of perforation into the peritoneal cavity, this does not entail greater morbidity for the patient provided that the defect is correctly sutured.

Conflicts of interest

The authors have no competing interests to declare.

Acknowledgments

We thank the rest of the members of the Coloproctology Unit for applying the study protocol. We thank Cristina Gomez Vigo for correcting the manuscript and Michael Maudsley for helping with the English.

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