



# TME for rectal cancer: consecutive 70 patients treated with laparoscopic and robotic technique—cumulative experience in a single centre

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## Abstract

From January 2011 to December 2015, 70 consecutive patients underwent either laparoscopic surgery (LS) or robotic surgery (RS) total mesorectal excision (TME) for malignancy. Data were prospectively recorded in a dedicated local database including ASA score, age, operative time, conversion rate, re-operation rate, early complications, length of stay, and pathological results. We enrolled 70 consecutive patients, 35 treated with LS (18 M, 17 F), 35 treated with RS (23 M, 12 F). Median total operative time was 225 min in LS group (IQR 194–255) and 252.5 min for RS group (IQR 214–300). Median first flatus time was 2 days for LS group (IQR 1–3) and 1 day for RS group (IQR 1–2). Stool discharge time (median) was 4 days for LS group (IQR 2–5) and 2 days for RS group (IQR 1–3). Length of stay (median) was 8 days in LS group (IQR 7–10) and 7 days in RS group (IQR 5–8). It was not found any statistically significant difference between the two groups when we analyzed the number nodes harvested the postoperative complications. The 30 day mortality was 0% in both two groups. The conversion rate for LS group was 23% (8/35 pts) and that for RS group was 0% (0/35). The RS may overcome technical limitations of LS. In our experience, it is a feasible and safe technique, it achieves better clinical outcomes due to the lower conversion rate compared to LS, although with higher costs.

**Keywords** Rectal cancer · Total mesorectal excision · Robotic surgery · Single docking · Low rectal anterior resection

## Introduction

Minimally invasive techniques have revolutionized general surgery, especially in the field of gastrointestinal surgery. The first hemicolectomy was performed laparoscopically in 1990 [1]. Since then, despite early skepticism towards this technique, laparoscopic technique for malignancy has been gradually performed. Since 2002, a series of randomized clinical trials compared the laparoscopic and the open technique, whose results definitely eliminated any doubts concerning the oncological adequacy of laparoscopic technique [2–7]. The advantages of minimally invasive approach in colorectal cancer surgery have been demonstrated

in both pathophysiological (decreased inflammatory response → decreased immune response → decreased post-operative morbidity/comorbidity) and oncological aspects (similar results in terms of survival and outcome) [4–9].

Many advantages over traditional techniques have been reported, including less pain, quicker return to daily activities, minimal scarring, reduced recovery time, and less injury to tissue. Oncologic surgery is feasible with at least the same long-term results as the traditional open approach [10, 11].

The laparoscopic approach for colorectal disease, however, has both technical and “anatomical” disadvantages: long learning curve, presence of a large surgical field that requires a skilled camera assistant surgeon, constant dialog between the operator and the assistant, loss of three-dimensional vision, reduced ergonomics during specific phases of the procedure (need to take uncomfortable positions), poor dexterity of the laparoscopic instruments and decreased range of motion due to the rigidity of the insertion of the trocars site, amplification of physiological tremor, and the fulcrum effect [1, 12–14].

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Compared with laparoscopy, surgery with robotic systems is known to have several advantages, including a more ergonomic position, a stable camera platform, a stereoscopic view under the surgeon's direct control, elimination of tremors, and improved dexterity because of instruments with seven degrees of freedom that mimic hand movements. Robotic arms follow the slightest movement of the surgeon's hands; it also can scale down hand movements when the tiniest dissections are needed and it eliminates hand tremors, which further enhances technology's precision and control during surgical procedures [12, 15, 16].

Many works have been published regarding open and laparoscopic surgery [17, 18]; in the last few years, a lot of papers regarding robotic surgery have been published and we aim to contribute, with our experience gained in a single operative unit of general surgery, to the treatment of rectal cancer.

## Materials and methods

We report our cumulative experience with TME for malignancy in a 5-year period, in relation to surgical technique evolved from LS into RS.

From January 2011 to December 2015, 70 patients underwent TME with LS or RS (since March 2012) with the DaVinci® System (Intuitive Surgical Inc., Sunnyvale, CA, USA).

Patients data including ASA score (American Society of Anesthesiologists'), age, BMI, previous abdominal surgery, comorbidity, tumor distance to anal verge, preoperative radio-chemotherapy operative time, conversion rate, re-operation rate, early complications, length of stay, and pathological results were prospectively recorded in a database.

We reviewed the prospectively collected records of patients with mid or low rectal cancer. The inclusion criteria were as follows: histologically proven adenocarcinoma located  $\leq 15$  cm from the anal verge; no evidence of distant metastasis at the time of surgery.

Tumor location was defined as the distance between the distal margin of the tumor and the anal verge as measured using a flexible colonoscopy.

All patients with a primary rectal cancer within 15 cm from the anal verge who were seen by a cancer surgeon and who were determined to be a candidate for laparoscopic or robotic-assisted resection were included. These patients underwent laparoscopic or robotic-assisted, and total mesorectal excision with primary anastomosis with or without diverting loop ileostomy. Neoadjuvant chemoradiotherapy was applied if necessary.

The Da Vinci® Robotic System (Intuitive Surgical Inc., Sunnyvale, CA, USA) was introduced in the Department of General Surgery, San Pio X Hospital in Milan, in

January 2012 with the purpose of a multidisciplinary adoption (General Surgery, Urology, ORL, Gynecology). After being informed in detail about the procedure, patients were recruited for robot-assisted TME, instead of a traditional laparoscopic TME, according to patients' wish. An informed consent was obtained. There were not any exclusion criteria for robotic surgery. All the patients underwent "fast track surgery" protocol according to ERAS guidelines, including bowel preparation during the 4 days before surgery. Before induction of general anesthesia, an epidural catheter for postoperative analgesia was positioned in selected cases and a urinary catheter was positioned in all patients. Standard DVT with Enoxaparin and antimicrobial with Cefazolin and Metronidazole prophylaxis was adopted.

## Robotic surgery technique [15]

Surgery starts with the introduction of a trocar for the camera, three robotic trocars, and additional trocar for the assistant.

The previous laparotomies do not exclude by rule mini-invasive surgery because adhesions can be treated laparoscopically by the assistant surgeons before docking.

We usually perform a totally single docking technique; without repositioning the arms, such schemes have been modified to achieve an optimal positioning that has allowed us to perform left colectomy, R-LAR, and Miles procedures without conflicts. The trocars' position is different between robotic and laparoscopic techniques, because the robotic trocar must have a minimum distance between them of at least 8–10 cm to avoid the conflict between the arms (Fig. 1). With the single docking technique, it is very important to ensure that the trocar is not aligned with each other on the same axis in relation to the three anatomic target (the splenic

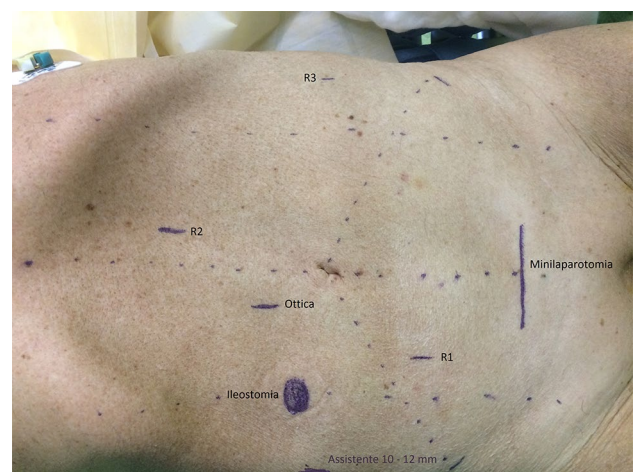


Fig. 1 Robotic trocars placement

flexure, mesenteric vessels, and pelvis); if this was to occur, the conflict of arms would not allow the continuation of the procedure; in that case, the only remedy is to move the trocar during surgery or make more docking. It is a goaded to simulate the correct accesses positioning during the various phases of the operation, before their insertion. The robotic instruments used are the mono-polar scissors, bipolar forceps, the grasper (Prograsp or Cadriere), the robotic 30° scope oriented from top to bottom in the periumbilical 10–12 mm trocar, laparoscopic forceps, clips, and the linear stapler all inserted into the trocar in the right flank. The use of energy devices in robotic surgery is not necessary as in laparoscopic technique.

The patient is tilted into a deep Trendelenburg position with the left side maximally elevated. The patient cart is brought to the operating table following an oblique imaginary line joining the trocar of the camera, the left ASIS, and the camera arm aligned with the support of the cart plant. The robotic arms are then docked. The operative steps are the same than in laparoscopic technique as follows. We start the surgery with the opening of the colo-epiploic ligament from the middle third of the transverse colon to the left corner. The splenic flexure is taken down by spleno-colic ligament dissection with exposure of the pancreatic tail and Gerota fascia, and an initial detachment of the descending colon. A gauze is then inserted on the pancreas' tail which will serve as a marker addressing the subsequent dissection from medial to lateral.

The Treitz's ligament is identified, the posterior parietal peritoneum is opened, and the inferior mesenteric vein (IMV) is detected, dissected, and closed with hemostatic clips near the splenorenal mesenteric confluence; we proceed in the dissection of the medial side of the space underlying the IMV detaching the Toldt's fascia from the Gerota's fascia and cranially to the lower border of the pancreas rejoining the epiploon cavity identified by the gauze previously placed; the IMV is then sectioned. The incision of peritoneum is carried down by the IMV window to the promontory; the dissection of the preaortic space allows for the hypogastric branch identification and the IMA dissection approximately 1–1.5 cm from its origin. We routinely perform flush IMV and IMA ligation mainly to optimize mesenteric nodal dissection, and to achieve better colon mobilization and splenic flexure takedown. The IMA is closed with hemostatic clips and sectioned. The detachment of the Toldt's fascia by gonadal vessels and ureter proceeds downward and laterally to complete the mobilization of the descending and sigmoid colon.

After the colon mobilization, the mesorectal plane is exposed. The holy plane between the mesorectal fascia and the presacral is dissected. The left and right branches of the inferior hypogastric plexus are identified and saved. Mesorectal dissection is performed posteriorly and on the right

side (270°) down to the elevators muscles; the left lateral dissection is completed tractioning the rectum to the right side of the pelvis. The opening of the anterior peritoneal reflection is performed and the dissection of the recto vaginal septum, in women, or of the seminal vesicles and Denonvilliers' fascia in men is completed.

Once the circumferential dissection of the rectum is completed, the linear stapler is introduced for rectal section which is not always easy, especially in cases of narrow pelvis. The last step of the intervention, before the extraction of the surgical specimen, is the preparation of the descending mesocolon: starting from the IMA stump.

A Pfannenstiel mini-laparotomy is executed and a wall protector is inserted; the specimen is extracted and cut; the anvil of the circular stapler is inserted into the proximal colon stump, which is then reduced in the abdomen. The mini-laparotomy is sutured. In cases of Miles procedure, the specimen is extracted from the perineal wound.

The pneumoperitoneum is created and a robot-assisted Knight–Griffen colorectal anastomosis is performed. When necessary, it is possible to put some stitches on the suture line. The operation is completed with the placement of a pelvic drainage, the identification of the last ileal loop for the ileostomy, which is always performed for ultra-low TMEs and in patients who underwent neo adjuvant therapy.

## Statistical analysis

Numeric variables were summarized by their median and Inter-Quartile Range (IQR: first quartile–third quartile), categorical variables were summarized by absolute frequencies and percentages.

Differences among means were evaluated by non-parametric ANOVA or Mann–Whitney test. The Odds Ratios between groups were fitted by logistic regressions. *P* values were computed by permutation methods, to avoid any asymptotic approximation or distributional assumption, and adjusted for False Discovery Rate (*p*-adj), when appropriate. *P* values < 0.05 were considered significant. All analyses were computed in R environment (ver. 3.2.2).

## Results

We enrolled 70 consecutive patients, 35 treated with LS (18 M, 17 F), 35 treated with RS (23 M, 12 F).

The median age for each group was 66 years (LS) and 70 years (RS).

We analyzed preoperative parameters like median BMI, number of comorbidity, number of patient with previous abdominal surgery, tumor distance to anal verge, ASA score, T stage, and type of surgery in both of two groups, and no statistical difference appeared (Table 1).

**Table 1** Preoperative parameters

Preoperative parameters	Robot ( <i>n</i> = 35)	Laparoscopy ( <i>n</i> = 35)	<i>p</i> value
Age (year) median	70	66	n.s.
Gender			
Male number	23	18	n.s.
Female number	12	17	n.s.
Body mass index (kg/m <sup>2</sup> ) median	24.6	25	n.s.
Comorbidity number	41	30	n.s.
Previous abdominal surgery number	4	8	n.s.
ASA score			
ASA 1	6	5	n.s.
ASA 2	22	24	n.s.
ASA 3	7	6	n.s.
Tumor distance from AV median (cm)	8	8	n.s.
T stage			
T0	6	7	n.s.
T1	2	3	n.s.
T2	12	8	n.s.
T3	14	17	n.s.
T4	1	0	n.s.
Preoperative CRT number	11	4	n.s.
Operative procedure number			
RAR	28	30	n.s.
Hartmann's operation	1	0	n.s.
Miles' operation	6	5	n.s.

Distribution according to ASA Score (American Society of Anesthesiologists') was as follows:

LS group: ASA1 17% (6/35),  
ASA2 63% (22/35), ASA3 20% (7/35),

RS group: ASA1 14% (5/35),  
ASA2 69% (24/35), ASA3 17% (6/35).

All patients underwent TME for malignancy diagnosed at endoscopic biopsy.

In LS group, rectal anterior resection (L-RAR) was performed in 28 (80%) patients, whereas Hartmann's operation was performed in one patient (3%) and Miles' operation was performed in six patients (17%).

In RS group, rectal anterior resection (R-RAR) was performed in 30 (86%) patients, whereas Hartmann's operation was not performed in any patient (0%) and Miles' operation was performed in five patients (14%).

The conversion rate for LS group was 23% (8/35 pts) and that for RS group was 0% lesion (one case), pelvic involvement (one case), no tumor identification (one case), and hypercapnia (one case). According to the Clavien–Dindo

**Table 2** Analysis of complications; Clavien–Dindo Score

Grade	LS	RS	Tot
I	6	2	8
II	7	5	12
IIIa	2	2	4
IIIb	3	3	6
IVa	0	0	0
IVb	1	1	2
V	0	0	0
Tot	19	13	32

Classification [19] (Tables 2, 3), we considered the complications of grade I and II like minor complications; instead, the adverse events of grade III and IV are considered like major complications. No death (grade V) occurred nor in robotic neither in laparoscopic group.

The perioperative complications in LS group were: four anastomotic leakage requiring one revisional surgery, one percutaneous drainage and two conservative treatment, three anastomotic bleeding (one endoscopic and two conservative treatment), one duodenal ulcer perforation treated with surgery, and two patients had mechanical postoperative ileus (one required surgery, one conservative treatment), and one

**Table 3** Intra-operative and post-operative parameters

Postoperative parameters	Robot ( <i>n</i> = 35)	Laparoscopy ( <i>n</i> = 35)	<i>p</i> value
Day to oral feeding (median)	1	1	n.s.
Day to first flatus (median)	1	2	< 0.001
Day to first evacuation (median)	2	4	< 0.002
Day to discharge (median)	7	8	< 0.002
Major complications (n°/percentage)	6/17%	7/20%	n.s.
Minor complications (n°/percentage)	6/17%	13/37%	n.s.
Harvested nodes (median)	16	20	n.s.
Tumor distance to distal margin (cm) (median)	2	2.1	n.s.
Conversion rate (n°/percentage)	0	8/23%	< 0.001
Mortality at 30 days	0	0	n.s.
Readmission rate at 30 days	0	0	n.s.
Operation time (min) (median)	252.5	225	< 0.05

patient had multiorgan failure and required recovery in Intensive-Care Unit.

We performed three reoperations: one percutaneous drainage, one endoscopic treatment, and one patient which had an MOF; according to Clavien–Dindo Classification grade III and IV, there were six major complications in the laparoscopic group.

The 30 day mortality rate was 0% in the LS group.

The perioperative complications in RS group were: one anastomotic leakage requiring revisional surgery, two anastomotic bleeding (one endoscopic and one conservative treatment), one pelvic bleeding treated with surgery, two patients had mechanical postoperative ileus (one required surgery, one endoscopic treatment), and one patient had multiorgan failure and required recovery in Intensive-Care Unit.

We performed three reoperations, six endoscopic treatments, and one patient had an MOF; according to Clavien–Dindo Classification grade III and IV, there were six major complications in the robotic group. The 30 day mortality rate was 0% in the RS group.

Median total operative time was 225 min in LS group (IQR 194–255) and 252.5 min for RS group (IQR 214–300).

We considered the median operative time of the first 17 and the last 18 patients, according to the date of operation, treated with LS and RS to evaluate the learning curve. The results in LS were 220 min (IQR 175–252.5) for the first 17 and 225 min (IQR 210–257.5) for the last 18 patients, while the results in RS were 272.5 min for the first 17 (IQR 220–310) and 222.5 min (IQR 197.5–255) for the last 18 patients.

Median first flatus time was 2 days for LS group (IQR 1–3) and 1 day for RS group (IQR 1–2).

Stool discharge time (median) was 4 days for LS group (IQR 2–5) and 2 days for RS group (IQR 1–3).

Length of stay (median) was 8 days in LS group (IQR 7–10) and 7 days in RS group (IQR 5–8).

The median number of nodes harvested was 20 in LS group (IQR 10.75–23.5) and 16 in RS group (IQR 13–19.5) (Table 2).

## Discussion

The first robotic colectomies were reported by Weber et al. [1]. Since then, a wide range of colorectal operations have been performed, including right and left colectomies, sigmoid resections, rectal anterior resections, abdominoperineal resections, and total colectomies. These operations were performed mainly on benign diseases [20]. Colorectal robotic surgery also seems to be feasible for malignant disease [15, 21, 22] with comparable results, in terms of oncologic radicality and surgical accuracy and in terms of short-term outcomes, compared to the standard laparoscopy.

The experience of our Department of Surgery is reported in this study. The goal was to evaluate the feasibility and the safety of robotic TME for cancer.

The layout for trocars placement, previously described by authors skilled in robotic surgery, was applied with some adjustments due to patient conformation to avoid arms collisions and achieve a single docking procedure.

We compared 70 consecutive patients treated with two different techniques (LS 35 pts and RS 35 pts) to evaluate whether the robotic approach to rectal surgery was as successful as the laparoscopic surgery. The LS and RS groups of patients, even if not randomly selected, were similar in terms of demographic and clinical characteristics (Table 1).

All the patients suffered from rectal cancer.

No statistically significant differences ( $p = 0.588$ ) were found between the two groups in the number of harvested nodes.



The median operative time was significant lower in LS group (225 min) than RS group (252.5 min).

In many works, operative time in LS for malignancy is reported to be shorter than RS. RS has a high variable total operative time in different series (range 204–441 min) [15, 23–28] and the median operative time, in a recent meta-analysis, was found to be the same for both RS and LS for rectal cancer [29]. A recent retrospective multicenter analysis on data of 425 patients who underwent robotic total mesorectal excision for rectal lesions has shown a mean operative time of 240 min; that time differs only on 12 min from our data [30].

Our data are aligned with the most recent papers on the topic and we can affirm that the shorter operative time is the main advantage of LS compared to RS; nevertheless, in a growing number of articles, the operative time is the same for both RS and LS [31]; this is probably related to the faster learning curve of the RS compared with LS [32].

We observed that the total operative time in RS decreases significantly during the learning curve of the surgeon and the team (Fig. 2): we analyzed the operative median time of the first 17 patients of the laparoscopic and robotic group with the last 18 patients of the same groups. Comparing the two subpopulation of LS, we did not find any statistical difference in time of median operating time (215 min and 225 min) between the two groups; conversely, comparing the two subpopulation in RS, we recognized a significant statistical difference ( $p < 0.05$ ) in the median operative time between the first 17 and the last 18 patients (272.5 min and 225.5 min) who underwent surgery. Moreover, comparing the group of the last patients who underwent RS with the LS, we did not find any statistical difference. This result confirm our hypothesis about the different operative time of RS comparing with LS: however, we found that, after an adequate learning curve, there was no difference among RS and LS.

We observed that the recover of the bowel function and the length of stay are significantly reduced in RS than LS groups (respectively,  $p < 0.001$  and  $p < 0.002$ ).

The median first flatus time was 1 day for RS group and 2 days for LS group ( $p < 0.001$ ).

The rapid recovery of the first flatus time with minimally invasive procedures, especially with robotic techniques, agrees with the results found in the literature [27, 28, 33].

Rapid bowel recovery after surgery allows for shorter length of stay; in fact, in RS, patients are dismissed 7 days after surgery compared to 8 days in LS. The better outcome for RS is statistically significant ( $p < 0.002$ ).

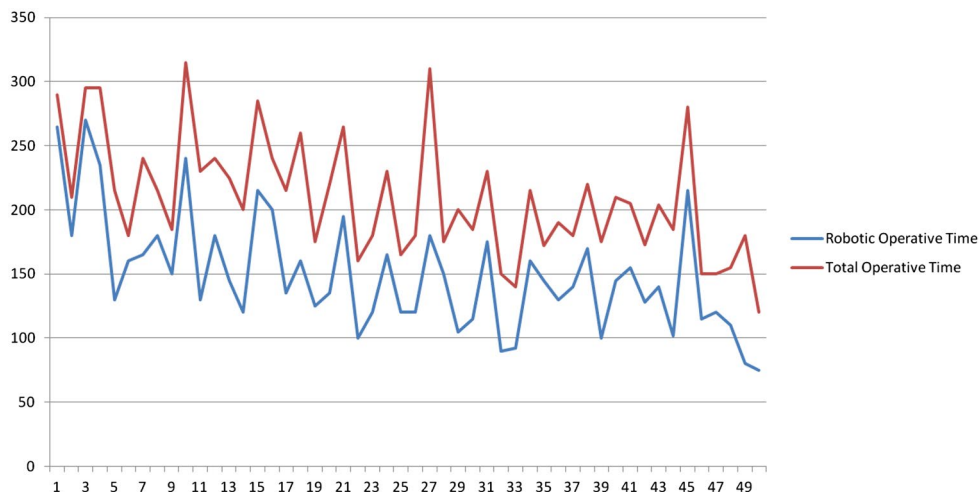
The increased operative time is justified either in terms of clinical benefit to the patient or costs of hospitalization. The early resumption of intestinal function can be attributed to less trauma due to the absence of conversion to laparoscopic or open surgery, due to robotic instruments that act on a fulcrum located in the abdominal wall thickness and by the lower traction of colon which is guaranteed by the presence of a fixed and stable field, with robotic instruments able to perform the most delicate and fragmented traction during surgery. In no case in the RS group was it necessary to place additional laparoscopic or robotic trocars to overcome conflicts of instruments or robotic arms, reducing abdominal wall trauma.

A substantial difference was observed in the conversion rate if we compare the two groups of minimally invasive surgery.

In the literature, between the various patient series, we found a significant variability of the conversion rate from laparoscopy to open surgery. Recent papers attest this value between 10 and 31% [17–34].

In our experience, the conversion rate in LS group was 23% (8/35) compared to 0% (0/35) in the RS group ( $p < 0.001$ ).

**Fig. 2** Learning curve for robotic surgery



In all cases treated with robotics, the procedures were performed totally robotically.

The best result in favor of RS group, in terms of conversion, was statistically significant ( $p < 0.001$ ).

The robotic technique allows us to carry out easily all the cases of difficult TME without need of conversion to open surgery, even if with longer operative time.

In a recent paper, 776,007 patients were analyzed, of which nearly 1000 underwent laparoscopic TME; compared with patients who had a complete laparoscopic operations, patients who had conversion to open surgery (about 31%) had a higher mortality, higher overall morbidity, longer length of hospitalization, and increased hospital charges [34].

Between January 20, 2004, and May 4, 2010, 1044 patients with rectal cancer enrolled in the COLOR II trial and were randomized to either laparoscopic or open surgery. Of 693 patients who had laparoscopic surgery, 114 (16%) were converted to open surgery [17].

This result emphasizes the importance of the low conversion rate which is allowed by the robotic surgery and means reduced need for medical and surgical short- and long-term cares, with an earlier resumption of normal social and work activities like shown in three recent meta-analysis [35–37].

The laparoscopic surgery for rectal cancer is technically demanding for the anatomical conformation of the pelvis, especially for narrow pelvis in male patients and for the loss of correct visual and often for the position of the surgeons on the operative field. The robotic surgery exceeds these limitations and offers an effective solution for patients and surgeon.

In our laparoscopic group, the major cause of conversion to open surgery is due to a difficult TME in male's narrow pelvis (four cases). The R.O.L.A.R.R. randomized clinical trial reports a higher, but not statistically significant, conversion rate in laparoscopic than robotic technique (12.2% vs 8.1%,  $p = 0.16$ ); in the obese and male patients subpopulation, the conversion rate is significant higher in laparoscopy than robotics ( $p < 0.01$ ) [38].

We do not found a statistically significative difference between the two mini-invasive techniques (LS and RS) regarding postoperative complications.

The 30 day mortality was 0% for LS and RS groups.

The statistical analysis did not show significant differences between the groups in terms of anastomotic bleeding and anastomotic leakage.

## Conclusions

In our experience, the two techniques obtain the same pathological outcomes.

It seems that the operative time is the main advantage shown by the LS group; however, we found that, after an adequate learning curve, the two techniques achieved the same operative time.

RS group obtained the best results in terms of postoperative outcomes, such as the more rapid recovery of the intestinal functionality and a lower postoperative length of stay. The RS group had a 0% conversion rate and this fact is of considerable importance, because we know from the literature that patients who had conversion to open surgery had a higher mortality, higher overall morbidity, longer length of hospitalization, and increased hospital charges.

The RS may exceed the limitation of traditional laparoscopic surgery. In our experience, it is a feasible and safe technique; it achieves better clinical outcomes and obtains the same pathological results compared to LS and OS, although with higher costs. RS permits to perform difficult dissections with greater precision and safety with all the advantages guaranteed by the minimally invasive access.

The authors assume that robotic TME for rectal cancer could find its specific indication to perform nerve sparing TME routinely to reach better functional outcomes and to treat male patients after neoadjuvant chemoradiation therapy.

Further studies are needed.

## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Research involving human participants and/or animals** We declare that the study has been conducted according to GCP and ethical standard with no adoption of human or animal source of experimental investigation. This is a retrospective study.

**Informed consent** Informed consent was obtained by all patients as per local protocol.

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