# Robotic Sphincter-Saving Total Mesorectal Excision for Rectal Cancer Treatment: A Single-Surgeon Experience in 103 Consecutive Male Patients

Vusal Aliyev, MD
General Surgeon
Department of General Surgery
Istanbul Florence Nightingale Hospital
Istanbul, Turkey

Handan Tokmak, MD
Associate Professor
Department of Nuclear Medicine,
Maslak Acibadem Hospital
Istanbul, Turkey

Baris Bakir, MD
Professor of Radiology
Department of Radiology
Istanbul University Faculty of Medicine
Istanbul, Turkey

Suha Goksel, MD
Professor of Pathology
Department of Pathology
Maslak Acibadem Hospital
Istanbul, Turkey

Hakan Kaya, MD
General Surgeon
Department of General Surgery
Maslak Acibadem Hospital
Istanbul, Turkey

Koray Guven, MD
Professor of Radiology
Department of Radiology
Acibadem Mehmet Ali Aydinlar University School of Medicine
Istanbul, Turkey

Oktar Asoglu, MD
Professor of Surgery
Bosphorus Clinical Research Academy,
Istanbul, Turkey

## ABSTRACT

**Background: A robotic surgical approach provides advantages compared to laparoscopy in male patients with mid- and low-lying rectal cancer located in the narrow pelvic space. The aim of this report is to present a single-surgeon experience with robotic sphincter-saving total mesorectal excision of rectal cancer in male patients.**

**Methods: A series of 103 consecutive male patients who underwent robotic rectal surgery between January 2012 and June 2019 were analyzed retrospectively in terms of demographics, histopathological data, and surgical and oncological outcomes.**

**Results: All of the patients underwent robotic sphincter-saving resection: 76 (73.8%) underwent low-anterior resection and 27 (26.2%) underwent ıntersphincteric resection with colo-anal anastomosis. There was no conversion. The median distal resection margin of the operative specimen was 3 (0.2-7) cm. The circumferential resection margin was positive in 3 (2.91%) cases. The median number of retrieved lymph nodes was 22 (18-42). The median hospital stay was 4 (3-16) days. Whereas the overall morbidity was 13%, there was no in-hospital or 30-day mortality. The median length of follow-up was 48 (9-80) months. The 5-year overall survival rate was 87%. The 5-year disease-free survival rate was 84%. Local and distant recurrence rates were 3.8% and 5.82%, respectively.**

**Conclusions: In male patients with rectal cancer, a robotic approach is a promising alternative and is expected to overcome the low penetration rate of laparoscopy in this field.**

## INTRODUCTION

Over the past three decades, the management of rectal cancer (RC) has evolved, with a fall in local recurrence rates and improvements in disease-free survival. This can be attributed to improvements in radiological staging, neo-adjuvant chemoradiotherapy, and surgical technique.[1,2] Laparoscopic resection of RC is more technically challenging and has a steep learning curve because it is performed in the narrow pelvic cavity.[3] Additionally, while conversion rates decrease with the learning curve, they are still high, as shown in the ALaCaRT (9%), ACOSOG Z6051 (11.3%), COLOR II (17%) and CLASICC (34%) studies.[4-7] A robotic approach may overcome the limitations of laparoscopy in the narrow pelvis, and could provide better oncologic and functional outcomes.[8,9] We previously compared perioperative and oncological short- and long-term outcomes of laparoscopic and robotic sphincter-saving resection for mid- or low-lying RC in male patients after neoadjuvant chemoradiotherapy (nCRT).[10,11]

## MATERIALS AND METHODS

One hundred three consecutive male patients who underwent robotic rectal resection for cancer between January 2012 and June 2019 were analyzed retrospectively. All of the patients gave their written informed consent. All procedures were performed by a single surgeon (OA) who is experienced in advanced laparoscopy and robotic surgery. We excluded patients with carcinomatosis or T4 tumors that required multiorgan resection. Preoperative staging included assessment of carcinoembryonic antigen (CEA) levels, total colonic examination with a flexible or virtual colonoscopic technique, thoracoabdominal computed tomography (CT), and pelvic phased-array magnetic resonance imaging (MRI). Preoperative clinical data included the patient characteristics and TNM staging. The final treatment plan was decided upon by a multidisciplinary team that included colorectal surgeons, radiologists, nuclear medicine specialists and oncologists, and followed the NCCN guidelines for rectal cancer. Patients with clinical T3, T4 or node-positive disease (stage II and III) were initially treated with either neoadjuvant long-course chemoradiotherapy (45-50.4 Gy pelvic irradiation with concomitant 5-fluorouracil (5-FU) and leucoverin (FUFA)), or short-course radiotherapy (25 Gy pelvic irradiation). Short-course radiotherapy was preferred in a select group of patients without any risk of lateral margin positivity. The waiting period was 4-8 weeks for long-course radiotherapy and 1-4 weeks for short-course radiotherapy. Perioperative clinical data included general patient characteristics and tumor location. The intraoperative results consisted of the type of surgical procedure (low anterior resection (LAR), intersphincteric resection (ISR)), operative time for each type of procedure, and volume of blood loss. The postoperative results included pathological data (tumor diameter, distal resection margins, number of retrieved lymph nodes, status of the circumferential resection margin (CRM) and TNM stage), postoperative complications, hospital stay and duration of follow-up. CRM positivity was defined as positivity ≤1mm from the circumference margin. Follow-up included a clinical examination within 1 month after surgery, examinations every 3-6 months with tumor markers, and thoracoabdominal CT at 6 and 12 months. Colonoscopy was performed at the end of the first year and every 2 years thereafter. In patients with postoperative chemoradiotherapy, abdominal/pelvic CT, MRI or PET-CT was performed at the end of treatment. Operative techniques have been described previously.[10]

### Statistical analysis

Data are expressed as the median (range) for continuous variable and number (percentage) for categorical variables. Overall and disease-free survival were assessed using the Kaplan-Meier method.

## RESULTS

The clinical characteristics of the patients are listed in Table I. All 103 patients were male and the median age was 60 years (range 32-80). Median BMI was 26.4 kg/m$^2$ (range 17.4-38). Seventy-two (69.90%) patients received nCRT. The tumor was located in the lower rectum in 64 (62.14%) cases and in the mid rectum in 39 (37.86%).

Seventy six (73.8%) patients underwent LAR for mid-distal rectal cancer, and ISR with hand-sewn colo-anal anastomosis was performed in 27 (26.2%) (Table II). Two patients with stage 4 rectal cancer showed multiple liver metastases, and these patients underwent robotic rectal resection due to bleeding and symptoms of obstruction. Diverting loop ileostomy was performed in 97 (94.17%) cases. There was no

conversion. The median console operative time for sphincter-saving procedures was 130 (range 80-220) min. Estimated blood loss was 120 ml (range 10-230).

A surgical complication occurred in 13% of the patients (Table III). In 13 patients, these complications were managed conservatively. The most frequent cause of postoperative morbidity (3 cases, 2.91%) was anastomotic leakage. All of these patients underwent diverting ileostomy, and completely recovered with CT drainage. Additionally, in one patient who underwent a revision surgery for ischemic colon, laparoscopic left colectomy and colo-anal anastomosis were performed. There was no in-hospital or 30-day mortality.

Histopathological outcomes are presented in Table IV. The median distal margin of the operative specimen was 3 cm (range 0.2-7). The median number of harvested lymph nodes was 22 (range 18-42). The CRM was positive in 3 (2.91%) cases. Six patients (5.82%) presented transitory postoperative urinary dysfunction, and all of them were treated medically (alpha-1 adrenergic receptor antagonist). Only 2 patients were discharged with a urinary catheter; the catheter was removed after 10 days following surgery in both patients.

Regarding oncological outcomes, the median follow-up time was 48 months (range 9-80). The 5-year overall survival (OS) and disease-free survival (DFS) rates were 87% and 84%, respectively (Figs. 1, 2). The local recurrence rate was 3.8% (n=4); 3 of them underwent abdominoperineal resection (APR) and one underwent cytoreductive surgery with hyperthermic chemotherapy (HIPEC) because of localized pelvic carcinomatosis and locally recurrent rectal cancer. Distant metastases occurred in 5.82% (n=6): 4 in the liver and 2 in the lung. There were 5 deaths during the follow-up period: 2 patients with stage 4 rectal cancer, 2 with stage 3 rectal cancer, and one with stage 1 rectal cancer.

## DISCUSSION

Achieving a total mesorectal excision (TME) is a key oncological principle for mid- or low-lying localized rectal cancer, and laparoscopic sphincter-saving TME is especially challenging in male patients.[11] Laparoscopic TME (L-TME) with

**Table I**
**Patient characteristics (n=103)**

| | n or median | % or range |
|---|---|---|
| Male | 103 | 100% |
| Age (years) | 60 | 32-80 |
| BMI (kg/m$^2$) | 26.4 | 17.6-38 |
| ASA class | | |
| 1 | 36 | 34.95% |
| 2 | 52 | 50.48% |
| 3 | 15 | 14.56% |
| History of abdominal surgery | 19 | 18.44% |
| Tumor location (from anal verge) | | |
| Low (<5 cm) | 64 | 62.14% |
| Mid (5-10 cm) | 39 | 37.86% |
| Preoperative CRT | 72 | 69.90% |

**Table II**
**Surgical outcomes (n=103)**

| Type of Operation | n (%) or median (range) |
|---|---|
| LAR | 76 (73.8%) |
| ISR with colo-anal anastomosis | 27 (26.2%) |
| Diverting loop ileostomy | 97 (94%) |
| Conversion | 0 |
| Operative time, LAR (min) | 180 (140-280) |
| Console time (min) | 130 (80-220) |
| Docking time (min) | 5 (3-15) |
| Undocking time (min) | 4 (3-15) |
| Estimated blood loss (ml) | 120 (10-230) |
| Postoperative stay (days) | 4 (3-16) |
| Follow-up (months) | 48 (9-80) |

LAR, low anterior resection; ISR, intersphincteric resection

**Table III**
**Postoperative complications (n=14; 13.6%)**

| Surgical complications | n or median | % or range |
|---|---|---|
| Anastomotic leak | Conservative treatment<br>CT drainage | 3 (2.91%) |
| Ischemic colitis | Laparoscopic partial colonic resection with colo-anal anastomosis | 1 (0.97%) |
| Bowel obstruction | Conservative<br>NG decompression | 3 (2.91%) |
| Pelvic hematoma | Conservative<br>CT drainage | 2 (1.94%) |
| Pelvic abscess | Conservative<br>CT drainage | 3 (2.91%) |
| Wound infection | Conservative | 2 (1.94%) |

**Table IV**
**Histopathological outcomes**

| Type of Operation | n (%) or median (range) |
|---|---|
| Tumor diameter (cm) | 3.45 (0.5-10) |
| Distal resection margins (cm) | 3 (0.2-7) |
| CRM positive, ≤1mm | 3 (2.91%) |
| Retrieved lymph nodes | 22 (18-42) |
| pT stage | |
| 0 | 6 (5.82%) |
| I | 36 (34.95%) |
| II | 46 (44.66%) |
| III | 13 (12.62%) |
| IV | 2 (1.94%) |
| Tumor differentiation and histology | |
| Well | 23 (22.33%) |
| Moderate | 62 (60.19%) |
| Poor | 18 (17.47%) |
| Macroscopic quality of TME specimen | |
| Complete | 96 (93.20%) |
| Near Complete | 4 (3.88%) |
| Incomplete | 3 (2.91%) |

CRM, circumferential resection margin; TME, total mesorectal excision.

meticulous and precise dissection of the mesorectum in a previously irradiated rectum down to the pelvic floor, within the confines of a narrow male pelvis, requires a series of complex maneuvers that are both operator- and assistant/cameraman-dependent, and demand a high level of experience and require a significant learning curve, which can involve 152 L-TME surgeries.[12,13] Additionally, laparoscopic instruments have several limitations, such as an inability to perform high-precision suturing, poor ergonomics, and fixed tips with limited dexterity. Conversion, which has been related to not only tumoral factors but also the learning curve, reduces survival in patients with rectal cancer in long-term follow-up.[11,13] The average conversion rate in these studies was 17.9 ± 10.1%. A recent meta-analysis showed that complete laparoscopic surgery favored a lower 30-day mortality rate, lower long-term disease recurrence, and lower overall mortality. Factors that were negatively associated with the completion of laparoscopic surgery were male gender, rectal tumor, T3/T4 tumor, node-positive disease, and patients requiring sphincter-preserving surgery.[13-15] We previously published our personal cases: from 2005 to June 2012, laparoscopic sphincter-preserving TME was attempted in 217 unselected patients with rectal cancer, with a 6.5% conversion rate.[16] These patients consisted of 91 women and 126 men, with a complication rate of 17.05%. The mean follow-up time for all patients was 36.12 months (range 1-89). The local and distant recurrence rates were 3.6% and 8.7%, respectively. The 5-year DFS rate was 81.5%.[16] We evaluated the same group of patients 5 years later to determine the long-term oncological outcome [17]. The median follow-up of all patients was 91 months (range 3-164). The local and distant recurrence rates were 6.5% and 19.8%, respectively. The 10-year DFS was 67.1%. and overall survival (OS) was 76.4%. In a subgroup analysis, in the converted group, DFS and OS were 46.7%, and 50%, respectively. In the laparoscopic group, DFS and OS were 68.5% and 78.3%, respectively.[17]

While the conversion rate in the COLOR II study was 16% throughout the study period, the conversion rate in the CLASICC study decreased from 38% in the first year to 16% in the last year of the trial. A similar reduction in the conversion rate with time has been reported in other conventional laparoscopic rectal cancer trials: ACOSOG Z6051 (11%) and ALaCaRT (9%). Robotic rectal resection has been suggested as a means of overcoming the difficulties of the laparoscopic approach, thus expanding the adoption of minimally invasive rectal surgery, and decreasing conversion rates, compared to laparoscopic or open surgery.[18,19] Pooled conversion rates were reported in other studies: 49 of 412 patients (11.89%) who underwent laparoscopic resection and 23 of 402 patients (5.72%) who underwent robotic resection.[20] The ROLARR study found no significant difference in the conversion rate between robotic surgery (8.1%) and laparoscopic surgery (12.2%) in an RCT of 471 patients who underwent surgery for rectal cancer.[13] The actual overall conversion rate in the ROLARR RCT was 10.1%.[13] In a sex-

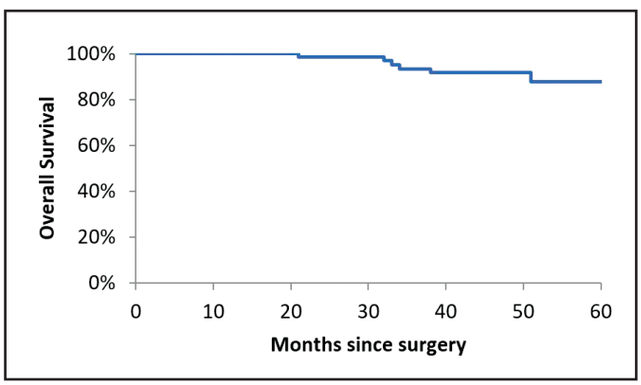


**Figure 1. 5-Year overall survival of 103 male patients with rectal cancer.**

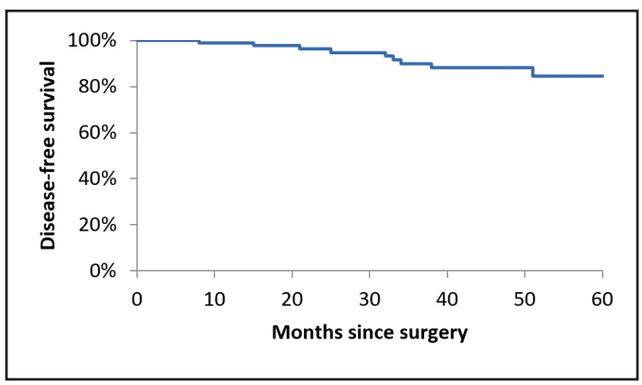


**Figure 2. 5-Year disease-free survival of 103 male patients with rectal cancer.**

**Table V**
**Oncological outcomes after R-TME**

| Study | Country (year) | LR (%) | DM (%) | DFS (%) | OS (%) |
|---|---|---|---|---|---|
| Cho et al.[22] | S. Korea (2012) | 1.8 | 12.2 | 81.8% (5-year) | 92.2% (5-year) |
| Hara et al.[25] | S. Korea (2014) | 4.5 | 10 | 81.7% (5-year) | 92.0% (5-year) |
| Pai et al.[26] | USA (2015) | 4 | 17 | 79.2% (3-year) | 90.1% (3-year) |
| Park et al.[27] | S. Korea (2015) | 2.3 | 12.0 | 81.9% (5-year) | 92.8% (5-year) |
| Kim et al.[28] | S. Korea (2016) | 1.9 | 26.4 | 72.8% (4-year) | 87.7% (4-year) |
| Aliyev et al.[29] | Turkey (2019) | 3.57 | 2.85 | 90% (5-year) | 92.7% (5-year) |
| Present study | Turkey (2020) | 3.8 | 5.82 | 84% (5-year) | 87% (5-year) |

R-TME, robotic total mesorectal excision; LR, local recurrence; DM, distant metastasis; DFS, disease-free survival; OS, overall survival

subgroup analysis, the ROLARR RCT also showed increased odds of conversion in men as compared with women: 39 of 317 men (12.3%) underwent conversion to laparotomy, 25 of 156 (16.0%) in the conventional laparoscopic group and 14 of 161 (8.7%) in the robotic-assisted laparoscopic group (unadjusted difference in proportions = 7.3%), while only 8 of 149 enrolled women (5.4%) underwent conversion to laparotomy, 3 of 74 (4.1%) in the conventional laparoscopic group and 5 of 75 (6.7%) in the robotic-assisted laparoscopic group (unadjusted difference in proportions = 2.6%).[13] Differences were apparent in the conversion rates for the conventional and robotic-assisted laparoscopic groups in men, with robotic-assisted laparoscopic surgery appearing to offer a benefit. Another cohort study used the National Cancer Database, in which 2472 patients underwent surgery under a robotic approach. The overall conversion rate was 13%, and was higher in the laparoscopic group (LAP: 15% vs. ROB: 8%; OR 0.47; 95% CI (0.39, 0.57).[14] In another single-center study, a statistically significant difference was found in the rate of conversion, which was more frequent in the L-TME group (2% in the robotic (R)-TME series vs. 9.5% in the L-TME series, p = 0.001). The risk of conversion was also significantly higher in the L-TME group for two known high-risk subgroups of patients: males (3.1% vs 9.6% in the R-TME and L-TME groups, respectively) and patients who underwent LAR (1.3% vs. 9.5%, respectively).[15] In the present series, none of the 103 R-TME patients were converted to laparotomy. Despite the challenges posed by the more complex surgical procedures, the low number of conversions and the good pathological outcomes in our series might reflect that the surgeon had completed the learning curve. Similar results were seen in single-center series that had only 1.23% (1/81) and 0.35% (1/278) conversions.[21,22] Conversion to open surgery is a complication that not only increases the risk of short-term morbidity and mortality, but may also be associated with long-term disease recurrence.[10,12,13] This finding indicates that robotic rectal surgery (RRS) provides better management of complex procedures, and increases the number of patients who may benefit from a minimally invasive approach. To achieve the desired results in robotic sphincter-preserving rectal surgery in male patients with mid-lying and distal tumor, surgeons should expect a learning curve of at least 68 procedures to obtain good oncological outcomes.[13]

The quality of the TME specimen is considered to be a parameter for evaluation of the prognosis. The integrity of the mesorectum and a clear CRM and distal resection margin (DRM) are important oncological and surgical end-points. The impact of the robotic learning curve on histopathology has been previously described by Gachabayov et al.[23] Kim et al. showed a TME qualityof 80.3% complete, 18.2% near-complete, 1.5% incomplete.[21] The TME quality in our study was rated as complete in 93.20% (n =96) of patients, nearly complete in 3.88% (n=4), and incomplete in 2.91% (n=3). CRM positivity, which has been reported to be associated with local recurrence, can be used as an indicator of the quality of TME.[24] In the present study, CRM positivity was found in three patients (2.91%). All three patients with positive CRM were pathologically T3. Two of these patients developed local recurrence during follow-up of 24 and 32 months, respectively. Other studies have shown CRM-positive rates of 6.1% (n=4/81),[21] and %5 (n=13/278).[22]

Local recurrence has been the most common major morbidity in patients with rectal cancer. In our study, the local recurrence rate was 3.8 % (n=4/103). In previous studies on R-TME, the local recurrence rate ranged from 1.8 to 4.5%, and the distant metastasis rate ranged from 6 to 26.4%, with a mean follow-up period of 3 to 5 years.[22,25-29] We obtained similar results, and our study only included male patients who had undergone sphincter-saving surgery. There are some studies on the survival of patients after robotic TME for rectal cancer. The oncological outcomes of the present study, which included only male patients, are comparable to those of other studies (Table V).

A limitation of our study is that it was retrospective. It also lacks reproducibility and external validity, because the patients were all operated upon by just one surgeon. Urogenital assessment after surgery was not included in this study.

## CONCLUSION

Laparoscopic TME carries a high conversion risk in male patients who undergo a sphincter-saving surgery. Robotic surgery provides an advantage in this regard. Conversion not only influences long-term oncologic outcomes, but also provides a poor

surgical specimen. However, an important result is the steep learning curve of minimally invasive surgery for TME. Robotic TME is superior, especially in male patients undergoing a sphincter-saving procedure. To achieve the desired results in robotic sphincter-preserving rectal surgery in male patients with mid-lying or distal tumor, the number of procedures performed for robotic TME and laparoscopic TME should be at least 68 and 152, respectively, to address the learning curve and to obtain good oncological outcomes. **STI**

## AUTHORS' DISCLOSURES

The authors declare that there are no conflicts of interest.

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