



Robotic versus laparoscopic sphincter-saving total mesorectal excision for mid or low rectal cancer in male patients after neoadjuvant chemoradiation therapy: comparison of long-term outcomes

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Abstract

The aim of our study was to compare long term outcomes of robotic and laparoscopic sphincter-saving total mesorectal excision (TME) in male patients with mid-low rectal cancer (RC) after neoadjuvant chemoradiotherapy (NCRT). The study was conducted as a retrospective review of a prospectively maintained database, and we analyzed 14 robotic and 65 laparoscopic sphincter-saving TME (R-TME and L-TME, respectively) performed by one surgeon between 2005 and 2013. Patient characteristics, perioperative recovery, postoperative complications and pathology results were compared between the two groups. The patient characteristics did not differ significantly between the two groups. Median operating time was longer in the R-TME than in the L-TME group (182 min versus 140 min). Only two conversions occurred in the L-TME group. No difference was found between groups regarding perioperative recovery and postoperative complication rates. The median number of harvested lymph nodes was higher in the RTME than in the L-TME group (32 versus 23, $p=0.008$). The median circumferential margin (CRM) was 10 mm in the R-TME group, 6.5 mm in the L-TME group ($p=0.047$). The median distal resection margin (DRM) was 27.5 mm in the R-TME, 15 mm in the L-TME group ($p=0.014$). Macroscopic grading of the specimen in the R-TME group was complete in all patients. In the L-TME group, grading was complete in 52 (80%) and incomplete in 13 (20%) cases ($p=0.109$). Median follow-up 87 months (1–152). Whereas local recurrence was seen in eight cases (10.12%) and distant metastasis was seen in 18 cases (22.7%). Overall, 5 years survival was 83.3% in R-TME, 75% in L-TME groups. R-TME is a safe and feasible procedure that facilitates performing of TME in male patients with mid to low RC after NCRT.

Keywords Rectal cancer · Robotic · Laparoscopic · Sphincter-saving procedure · Total mesorectal excision

Introduction

Over the last two decades, the management of rectal cancer (RC) has evolved with a fall in local recurrence rates and improvement in disease-free survival. This can be attributed

to improved radiological staging, neo-adjuvant chemoradiotherapy, and surgical technique [1–4]. Neoadjuvant long-course chemoradiotherapy downstages tumor, achieves complete response rates in 15–20% patients depending on the waiting period, and may improve sphincter preservation rate

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[5, 6]. However, operating on patients who have mid or low RC after neoadjuvant chemoradiotherapy (NCRT) is challenging with minimal invasive surgery. Additionally, laparoscopic resection of RC is a more technically demanding and has a steep learning curve because it is performed in the narrow pelvic cavity [7, 8]. Results of the United Kingdom Medical Research Council Conventional vs Laparoscopic-Assisted Surgery in Colorectal Cancer (MRC-CLASICC) showed that laparoscopic surgery for RC was associated with high rates of conversion, circumferential resection margin (CRM) positivity, and urinary/sexual dysfunction especially in male patients. Additionally, converted individuals had more complications from surgery [9]. Additionally, conversion rates decrease with the learning curve but are still high at Classic 34%, Color II (17%), ACOSOGZ51 (11.3%) and Alacart (9%) studies [10–13]. Considering the particular advantage of the robot in pelvic procedures, it is believed that the robotic system will overcome the limitations of laparoscopy in the narrow pelvis and could result in a benefit to the patient in the meaning of improved oncologic and functional outcomes. However, most of the published studies comparing robotic versus laparoscopic surgery for mid or low RC did not specifically focus on male mid or low RC patients received NCRT [14–17]. We have already published our study to compare perioperative and oncological short-term outcomes of laparoscopic and robotic sphincter-saving resections for mid or low RC in male patients after NCRT [18]. In the present study, we share our long term oncologic outcome in the same group of patients.

Patients and methods

A retrospective analysis was carried out based on a RC database collected prospectively between January 2005 and December 2013. Fourteen robotic rectal resections with total mesorectal excision (TME) (R-TME) were compared to the 65 laparoscopic rectal resections with TME (L-TME) for the 306 patients who underwent minimally invasive TME performed from 2005 to 2013. Robotic procedures were performed from January 2013 to December 2013. Robotic and laparoscopic resections were performed by a single surgeon (OA) at two different centers (Istanbul University Faculty of Medicine, Department of General Surgery, Istanbul, Turkey and Liv Hospital, Department of General Surgery, Istanbul, Turkey). Patients with male gender, mid or low RC, cT3-4, N(-)/(+) lesions without distant metastasis, having a sphincter-saving TME after NCRT were included in the study. The RC was defined as pathologically demonstrated adenocarcinoma located in the rectum, 10 cm or less from the anal verge with the rigid sigmoidoscope. All patients were carefully assessed preoperatively. Patient characteristics, BMI, and American Society of Anesthesiologists (ASA) scores [19] were evaluated. The preoperative staging

included chest X-ray, assessment of carcinoembryonic antigen (CEA) levels, total colonic examination with flexible or virtual colonoscopic technique, abdominal computed tomography (CT), pelvic-phased array magnetic resonance imaging (MRI), and/or endorectal ultrasound. Patients with clinical T3, T4 or node-positive disease (stage II and III) initially treated with either neoadjuvant long-course chemoradiotherapy [45–50.4 Gy pelvic irradiation with concomitant 5-fluorouracil (5-FU) and leucovorin (FUFA)], or short-course radiotherapy (25 Gy pelvic irradiation). Short-course radiotherapy was preferred in a selected 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. After the completion of surgery, all patients treated with neoadjuvant protocol and diagnosed with pT3 and/or any N positivity were treated with four courses of FUFA. Our technique of L-TME and R-TME has been described before [20–22]. Perioperative outcomes included operation time, conversion to an open procedure, the time to first passage of flatus, the time to a resumed a soft diet, and the length of hospital stay. Conversion was defined as any unplanned laparotomy at any time during surgery, regardless of the incision length. Postoperative complications were defined as adverse events that occurred within 30 days after surgery. All pathology specimens were examined to determine tumor size, the number of lymph nodes harvested, microscopic proximal, distal and circumferential resection margins (PRM, DRM and CRM, respectively), and the integrity of the mesorectum. Surrogates of oncologic outcome were then compared between L-TME and R-TME groups.

Statistical analysis

All statistical analyses were performed using SPSS software, version 18.0 (SPSS, Chicago, IL). Categorical variables were analyzed using the χ^2 or Fisher's exact test, and continuous variables were analyzed using the Student's *t* test/Mann–Whitney *U* rank tests. *p* values < 0.05 were considered statistically significant.

Results

Between January 2005 and December 2013, minimal invasive surgery was applied in 306 patients with RC by a single surgeon. Seventy-nine patients met the study inclusion criteria; 65 had L-TME and 14 had R-TME. Characteristics of the entire study population are presented in Table 1. No significant difference in age, BMI, and ASA score was observed between the two groups. Table 2 summarizes perioperative outcomes. There was no conversion noted in RTME group whereas two (3%) patients in the L-TME group were

Table 1 Patient characteristics

	R-TME (<i>n</i> = 14)	L-TME (<i>n</i> = 65)	<i>p</i> value
Age (years) ^a	54 (41–71)	57 (28–80)	0.554
BMI ^a	24.7 (23–27)	26 (21–32)	0.068
ASA score ^a	2 (1–3)	2 (1–4)	0.078

^aValues are expressed as median with interquartile range

Table 2 Perioperative outcomes

	R-TME (<i>n</i> = 14)	L-TME (<i>n</i> = 65)	<i>p</i> value
Sphincter saving procedures (<i>n</i>)			
Low anterior resection	4	41	
Intersphincteric resection	10	24	
Conversion to open (<i>n</i>)	0	2	
Operative time (min) ^a	182 (140–220)	140 (90–300)	0.033
Days to 1st flatus (days) ^a	2 (1–5)	1 (0–11)	0.410
Oral reintake (days) ^a	2 (1–5)	2 (1–12)	0.939
Hospital stay (days) ^a	5 (4–10)	6 (2–32)	0.175

^aValues are expressed as median with interquartile range

Table 3 Postoperative complications

	R-TME (<i>n</i> = 14)	L-TME (<i>n</i> = 65)	L-TME (<i>n</i> = 65)
Anastomotic leak, <i>n</i>	1	6	
Stoma complications, <i>n</i>	0	2	
Wound infection, <i>n</i>	1	3	
Subileus, <i>n</i>	0	1	
Urinary retention, <i>n</i>	0	1	
Urinary tract infections, <i>n</i>	0	2	
Intra-abdominal abscess, <i>n</i>	0	1	
Overall, <i>n</i> (%)	2 (14.3)	16 (24.6)	0.504

Table 4 Pathological findings

	R-TME (<i>n</i> = 14)	L-TME (<i>n</i> = 65)	<i>p</i> value
Lymph node harvested	32 (17–56)	23 (4–67)	0.008
Specimen length (cm)	20.5 (15–45)	21 (20–50)	0.656
Proximal resection margin (cm)	14.8 (4.5–35)	16 (2.4–30)	0.230
Distal resection margin (mm)	27.5 (5–60)	15 (10–70)	0.014
Circumferential resection margin (mm)	10 (1–30)	6.5 (0–35)	0.047
Tumor diameter (mm)	32.5 (20–70)	30 (0–75)	0.081
Macroscopic quality of TME specimen			0.109
Complete	14 (100%)	52 (80%)	
Incomplete	0 (%)	13 (20%)	
Stage 0	2 (%14.3)	10 (%15.4)	0.767
Stage 1	4 (%28.6)	11 (%16.9)	
Stage 2	4 (%28.6)	19 (%29.2)	
Stage 3	4 (%28.6)	25 (%38.5)	

R-TME robotic total mesorectal excision, L-TME laparoscopic total mesorectal excision

converted to open surgery. The median operation time was significantly longer in the R-TME group than in the L-TME group ($p = 0.05$). The median time to the first passing of flatus was 2 days in the R-TME group (range 1–5 days) and 1 day in the L-TME group (range 1–11 days) ($p = 0.4$); the median time to resume a soft diet was 2 days (range 1–5 days) in the R-TME group and 2 days (range 1–12 days) in the L-TME group ($p = 0.9$). There was no difference with regard to the length of hospital stay [5 days (range 4–10 days) in R-TME group vs 6 days (range 4–32 days) in LTME group].

Overall complication rate was 14.3% for the R-TME group and 24.6% for the LTME group ($p = 0.502$) (Table 3). There were one (7.1%) anastomotic leak in the R-TME group and 6 (9.2%) in the L-TME group. All patients with leakage was treated conservatively, by maintaining pelvic drainage until the infection that was present had resolved clinically. In the L-TME group, three wound infections, two ileostomy-related complications, and two urinary tract infections occurred. Detailed evaluation of postoperative complications is summarized in Table 3.

Pathological findings are presented in Table 4. Tumor size and specimen length were similar in both groups.

The median number of harvested lymph nodes was 32 (range 17–56) in the R-TME group and 23 (range 4–67) in the L-TME group ($p=0.008$). The median PRM did not differ significantly between the two groups. The median DRM was 27.5 mm (range 5–60 mm) for R-TME and 15 mm (range 10–70 mm) for L-TME ($p=0.014$). The median CRM (CRM) were 10 mm (range 1–30 mm) in the R-TME group and 6.5 mm (range 0–35 mm) in the L-TME group ($p=0.047$). The CRM was positive in a one patient in R-TME group (1 mm) and 3 patients in L-TME group (1 mm in a one and 0 mm in the other two patients). Macroscopic grading of the specimen in the R-TME group was complete in all patients. In the L-TME group, grading was complete in 52 (80%) cases and incomplete in 13 (20%) cases. The difference between two groups was not found statistically significant.

With a mean follow-up of 66 months (range 27–88) in R-TME, 92 months (1–152) in L-TME, the 5-year disease free survival rate (DFS) was comparable between groups: 74.4% (laparoscopic surgery) vs. 81.8% (robotic surgery ($p=0.662$)). The 5-year OS rate for the laparoscopic and robotic groups was 75.4% and 83.3%, respectively ($p=0.550$) (Fig. 1). With a mean follow-up of 87 months (range 1–152) the local recurrence rate was 10.12% (8 patients) and distant metastasis rate was 22.7% (18 patients). The local recurrence was seen in 5 patients in the L-TME and 3 in the R-TME. Systemic recurrence was seen 16 cases in the L-TME and 2 cases in the R-TME.

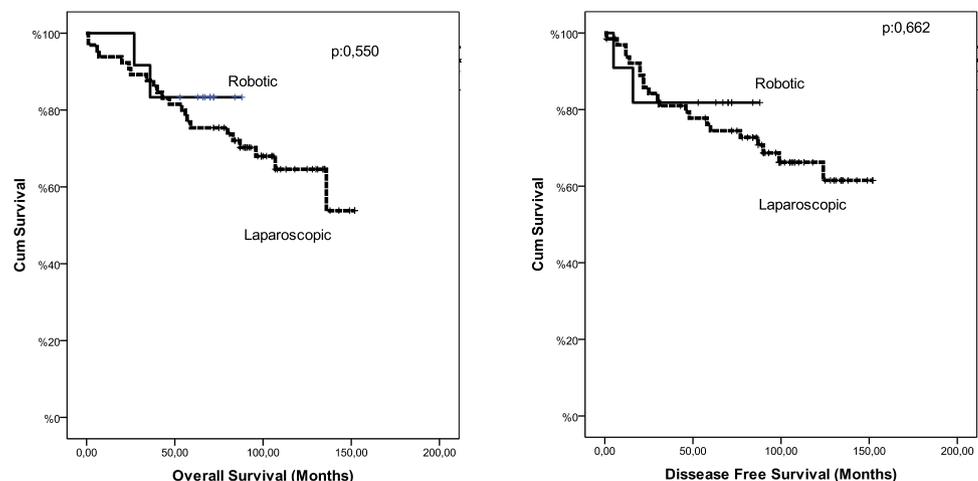
Discussion

Achieving a TME is a key oncological principle when resecting the rectum for mid or low cancer, and is particularly challenging when laparoscopically attempting sphincter-saving TME in male patients after NCRT. This is because performing a L-TME with meticulous and precise dissection of the mesorectum in a previously irradiated rectum down to the pelvic floor within the confines of a narrow pelvis requires a series of complex moves, which are not only operator but also assistant/camera-man dependent and demands a high level of experience and has a significant learning curve, which has been required 156 laparoscopic TME surgery [23, 24]. In addition, laparoscopic instruments are known to have several limitations such as inability to perform high precision suturing, poor ergonomics, and fixed tips with limited dexterity.

The average conversion rate of the studies was $17.9 \pm 10.1\%$. A recent meta-analysis showed that complete laparoscopic surgery favoured lower 30-day mortality rate, lower long-term disease recurrence and lower overall mortality. Factors negatively associated with the completion of laparoscopic surgery were male gender, rectal tumour, T3/T4 tumour, and node positive disease [24].

I have been previously published my personal cases, laparoscopic sphincter-preserving TME was attempted in 217 unselected patients with rectal cancer, from 2005 to June 2012, with a 6.5% conversion rate. There were 91 women and 126 men, Complication rate was 17.05%. The mean follow-up time of all patients was 36.12 months (range,

Fig. 1 R-TME vs L-TME OS and DFS



	Overall survi 5 years	p	DFS 5 years	p
Robotic	%83,3	0,550	%81,8	0,662
Laparoscopic	%75,4		%74,4	

1–89 months). Local recurrence rate was 3.6% and distant recurrence rate was 8.7%. The 5-year DFS rate was 81.5% [21]. We evaluated the same group of patients 5 years later to show long-term oncological outcome. The mean follow-up of all patients was a median of 91 months (range, 3–164 months). The local recurrence rate was 6.5%, and the distant recurrence rate was 19.8%. The 10-year DFS rates were 67.1%, and overall survival (OS) was 76.4%. In 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 [25].

Similar results were seen in another study. Rottoli et al. analyzed long-term oncological outcome was analyzed, with a mean follow-up of 46 months in converted group and 36 months in non-converted group. Cumulative 5-year disease free survival was significantly lower in converted patients (55.7%) when compared to laparoscopically completed cases (79.2%) [26]. The conversion rate in Color II study remained 16% throughout the study period, whereas a decline in the conversion rate from 38% in the first year to 16% in the last year of the trial was reported by the CLASICC group. A similar reduction in conversion rates with time has been reported in other conventional laparoscopic rectal cancer trials: ACOSOG Z6051, 11%; and ALaCaRT, 9%. Conversion, which has been related not only tumoral factors but also learning curve effect, has impaired survival in patients with rectal cancer in long term follow-up. Robotic rectal resection has been suggested as a means of overcoming the difficulties of the laparoscopic approach and improving the adoption of minimally invasive rectal surgery [14–17].

Previous meta-analyses have failed to show superiority for robotic-assisted surgery over conventional laparoscopic surgery with respect to short-term outcomes due to intrinsic design limitations of the included studies but recent reports from a few centers claim outcome benefits with robotic approach [14–16]. The latest study results coming out from Kim's phase II open label prospective randomized controlled trial (RCT) study, and the multicenter, randomized ROLARR trial showed a reduced need to convert to open surgery with the robotic approach, there is a need to include most recent and largest trial data in line with currently available RCTs to evaluate the safety and efficacy of rectal cancer surgery in adults undergoing robotic surgery in comparison with traditional laparoscopic surgery, with regards to short-term clinical and pathological outcomes. Conversion rate was described in six of the included RCTs [27]. Pooled conversion rate of (11.89%) was reported in 49 of 412 patients who underwent laparoscopic resection and in 23 (5.72%) of 402 patients who underwent robotic resection [28].

ROLARR study showed that no significant differences in conversion rate between robotic surgery (8.1%) and laparoscopic surgery (12.2%) in RCT of 471 patients undergoing

surgery for rectal cancer. In the same RCT, Robotic-assisted laparoscopic surgery performed by surgeons with varying experience with robotic surgery did not reduce the odds of conversion to laparotomy when compared to stand-alone laparoscopic surgery. There was no statistically significant difference between robotic-assisted and laparoscopic surgery with regards to odds of conversion. The actual overall conversion rate in the ROLARR RCT was 10.1% [27].

Upon sex 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 8 out 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%) [27]. Similarly, the higher overall conversion rates for men (as compared with women) and obese patients (as compared with underweight or normal-weight patients) probably reflect the increasing technical difficulty in these patients.

In almost all of the subgroup analyses, there were insufficient numbers of patients to produce statistically meaningful comparisons between the groups regarding the need to convert to an open operation. However, 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.

In another single center study, a statistically significant difference was reported between the two series regarding the rate of conversion, which was more frequent in the L-TME group (2% in the 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 group) and patients who underwent low anterior resection (1.3% vs. 9.5%, respectively) [29].

The ROLARR RCT showed that operating surgeon had a small impact on odds of conversion. Sensitivity analyses accounting for a potential learning effect suggest that the benefit of robotic-assisted laparoscopic surgery compared with ordinary laparoscopic surgery, with respect to conversion rate, is greater when performed an operating surgeon with a substantial level of previous experience in standard laparoscopic surgery [24].

I have been previously published my personal cases, where I had evaluated shorth term oncologic outcome [18]. In the present series, none of the R-TME patients and two of the L-TME patients were converted to laparotomy. Despite the challenges posed by the more complex surgical cases, the low number of conversions and the good pathological

outcomes in our series might reflect the surgeon who completed the learning curve. We evaluated the same group of patients to show long-term oncological outcome. We found that no statistically significant differences of pathology outcomes, 5-year DFS (81.8%, 74.4%) or OS (83.3%, 75.4%) between both groups in the intention-to-treat analysis, however, point estimates were in favor of robotic TME, and the observed difference of 7% would be clinically important (Fig. 1).

A previous single center series had similar cumulative disease-specific survival for L-TME of 79.6%, and for R-TME of 81.8% at 52 months of median follow-up [29].

This study had important limitations. First, it was a retrospective study of prospectively collected data from a single surgeon highly experienced in performing laparoscopic colorectal resection, and there was a definite difference between the two operative techniques with regard to the surgeon's expertise. Second, the number of performed procedures is quite low because of the restricted study population and this study was not a randomized trial so we included a special group of patients to study to obtain homogenization between the groups and achieve reliable results.

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Conclusion

Rectal cancer surgery is demanding, due to staging and location of the tumor, receiving NCRT, furthermore choosing tools as laparoscopic and robotic procedures. To achieve a good oncological outcome, the following issues should be addressed: free surgical margins (R0), decreasing conversion to open surgery, and complete mesorectal excision should be performed. For this purpose, the specialization

and experience of the surgeons dealing with rectal surgery will determine which tool will be the most appropriate. Considering the extra financial and time expenses of the robotic procedure, but the clinical plausibility of the robot facilitating dissections in the narrower male pelvis with more operator-controlled retraction, better optics, and instrument precision this novel technology should be selectively applied. To achieve the goal in laparoscopic and robotic sphincter-preserving rectal surgery in the male patient with mid and distal tumor location, the number of performed cases should be at least 152 and 68, respectively, for learning curve and to obtain good oncological outcome. Further higher scale studies into the potential benefit of robotic-assisted laparoscopic surgery in this subgroup of technically challenging patients are thus warranted.

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Compliance with ethical standards

Conflict of interest Author Oktar Asoglu, Author Handan Tokmak, Author Baris Bakir, Author Vusal Aliyev, Author Sezer Saglam, Author Yalin Iscan, Author Suleyman Bademler, and Author Serhat Meric declare that they have no conflicts of interest or financial ties to disclose.

Ethical approval All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

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