Robotic-assisted laparoscopic low anterior resection versus trans-anal total mesorectal excision for malignant rectal lesion: a prospective cohort trial

Ahmed F.A. Farag[a], Ahmed M.A. Mahmoud[b], Haitham M. Azmy[a], Abdrabbou N. Mashhour[a], Ahmed S. Khalifa[c], Yasser Debakey[b], Mohamed Y. Elbarmelgi[a]

[a]General Surgery, Faculty of Medicine, Cairo University, [b]Surgical Oncology, National Cancer Institute, Cairo University, [c]General Surgery Department, Cairo University, Cairo, Egypt

Correspondence to Mohamed Y. Elbarmelgi, MD, MRCS, General Surgery, Faculty of Medicine, Cairo University, Cairo, 68 3rd neighborhood, 7th discreet, Sheik Zayed city. Giza, Postal code: 3240001, Egypt. Tel: +0020 100 149 2942; Fax: 00237881227; e-mail: dr.yeho@yahoo.com, dr.yeho@cu.edu.eg

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Introduction
Colorectal carcinoma is one of the most common malignancies of the gastrointestinal tract. The aim of the present study was to compare the trans-anal total mesorectal excision (TaTME) to the robotic-assisted laparoscopic resection of mid- and low rectal carcinoma regarding the clinical and oncological outcome.

Methods
This was a prospective cohort study. This study was held on patients presenting with rectal cancer. Eighty patients were included divided into two groups, 40 patients were subjected to TaTME and 40 patients were subjected to robotic-assisted resection.

Results
Rectal resection was performed in both groups and the results were compared; total time was significantly less in TaTME group (mean time was 179.10 min in TaTME and 266.35 in robotic, *P* value $<$ 0.001), estimated blood loss was significantly less in TaTME group (mean was 130.50 ml in TaTME and 212 ml in robotic, *P* value=0.017), cost was significantly less in TaTME group (mean cost ×1000L.E was 46.15 in TaTME and 110.70 in robotic, *P* value less than 0.001), distal margin was significantly more in the robotic group (mean was 2.68 compared with 2.02 in TaTME, *P* value = 0.002), hospital stay was significantly less in the robotic group (mean of 4.6 days compared with 5.1 for TaTME, *P* value = 0.014) and there was no statistically significant difference concerning the total number of lymph nodes, proximal and circumferential margins.

Conclusion
This study suggests that robotic surgery is safe and effective and has some advantages concerning distal margins of low rectal resections. Also, TaTME can be compared with robotic surgery and represents an effective and less expensive alternative for robotic surgery.

Keywords:
cancer, cost, rectum, robotic surgery, trans-anal resection

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Introduction

Colorectal carcinoma is one of the most common malignancies of the gastrointestinal tract. Currently, colorectal cancer is the third leading cause of cancer deaths among both sexes [1]. Surgery is the main line of treatment for patients with colorectal cancer. The concept of total mesorectal excision (TME), which was first described during the 1980s by Heald and Ryall, has significantly improved the outcome of management of rectal cancer, particularly the incidence of local recurrence [2].

The adoption of TME technique has markedly improved the oncological outcomes of rectal cancer resection [3–5]. Surgical resection of rectal cancer represents a significant technical challenge for surgeons due to limited access to the relatively narrow space within the bony pelvis that can jeopardize the meticulous oncological dissection and lead to damage to critical neurovascular structures [6,7]. Also, there are many other patient and tumor-related factors that can further add more complexity to the procedure. Therefore, throughout history, surgeons have switched between abdominal and perineal approaches to improve access and outcomes [8].

Trans-anal total mesorectal excision (TaTME) has emerged as an alternative 'down-to-up' solution in recent years. TaTME has become a major topic of research in the field of colorectal surgery since a lot of studies have proven its feasibility and advantages [9,10]. From the perspective of surgical technique, the utility of articulating instruments in the robotic system may to some extent ease some difficult situations during surgery such as bulky mesorectum, enlarged prostates and irradiated pelvises [11].

The introduction of robotic surgical system led to revolution in the field of minimally invasive surgery, it has overcome many drawbacks of conventional laparoscopic surgery such as physiologic tremor, fatigue and provides better ergonomics [12,13].

What this study adds to literature?

This study compares 2 recent techniques of rectal resection, which are TaTME and robotic-assisted laparoscopic rectal resection regarding short-term oncological outcome and immediate clinical outcome. Comparison of cost per case is unique to this work.

Patients and methods

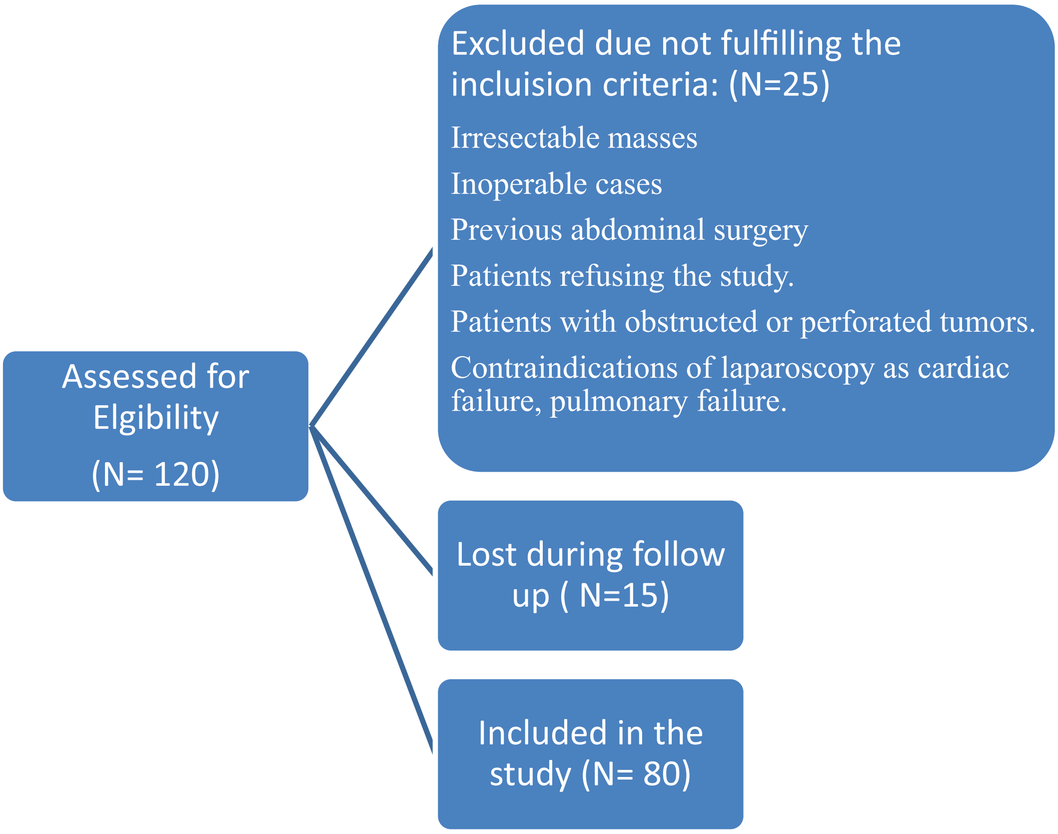
Design, setting and population of the study

This was a prospective cohort study that included 80 patients of both sexes and all age groups who present with mid- and low rectal cancer to the outpatient clinics of our hospitals from May 2018 to May 2021. The patients were divided into two groups, the first group included 40 patients who have been subjected to robotic-assisted laparoscopic rectal resection 'the robotic system that we used is the da Vinci Si system (Intuitive Surgical, Inc., Sunnyvale, CA)'. The other group also included 40 patients and have been subjected TaTME for which we used conventional laparoscopy for the abdominal part, and GelPOINT Mini Advanced Access Platform for the trans-anal part. The 2 arms of the study ran in 2 consecutive periods, the first arm of the TaTME group ran in the period from May 2018 to February 2020 and the other arm from February 2020 to May 2021. All the surgeries were done by the same surgical team with adequate level of training on both techniques.

Inclusion criteria

All patients from both sexes and all age groups presenting with mid- or low rectal cancers during the allocated period were included in the study.

Chart 1



Included and excluded patients.

Exclusion criteria

Look at the flow chart below (Chart 1).

Methods

Preoperative

All patients were subjected to full history taking, full examination, full colonoscopy, MRI rectal protocol and pan-computed tomography (CT) scan for proper localization and staging of the tumour. Two rectal enemas were done the day before surgery as mechanical preparation, also prophylaxis against thromboembolism was administered. All patients received single-dose antibiotic prophylaxis against both anaerobes and aerobes about 1 h before surgery.

Operative details

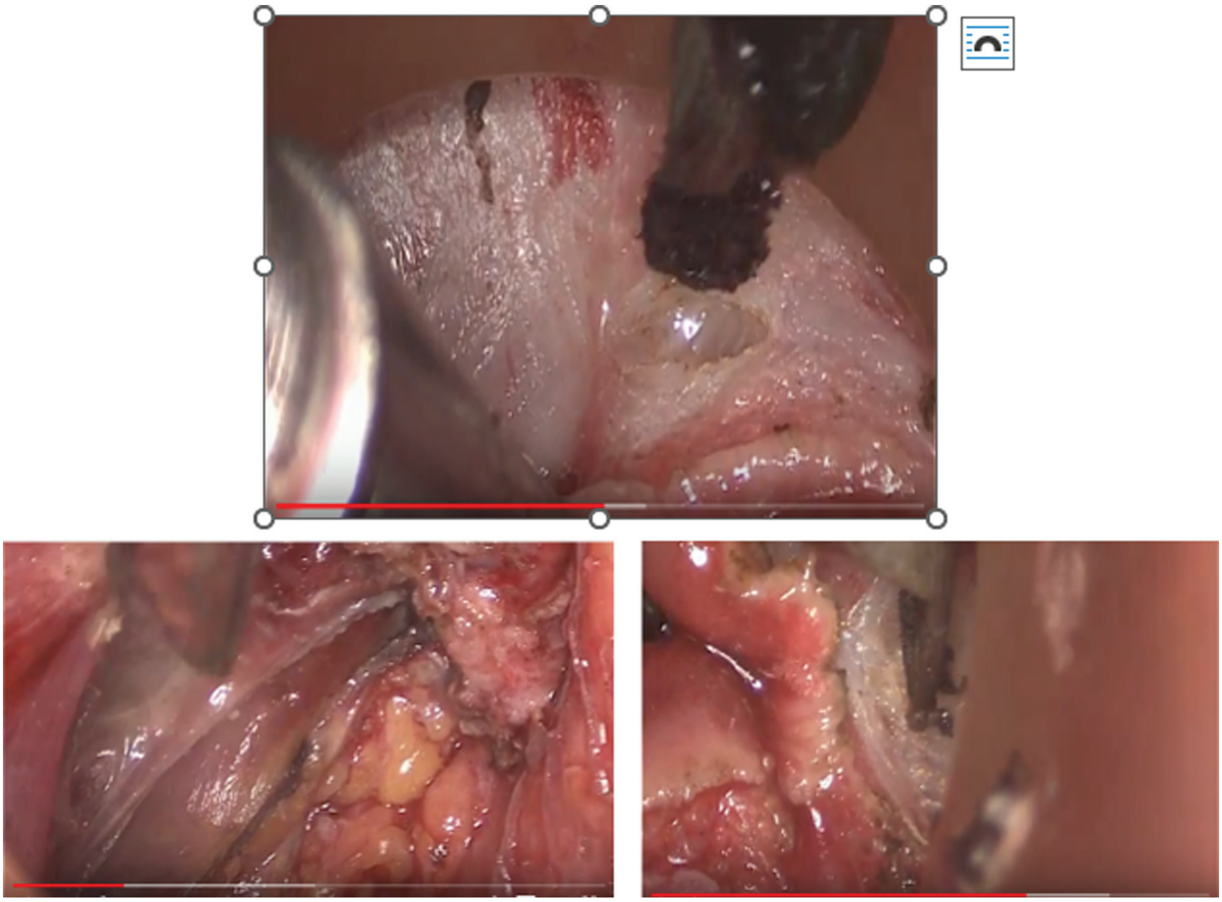
Robotic group: The patient was positioned in a modified lithotomy position with both arms tucked. We adopted the same technique of robotic rectal resection described in literature [11,14].

TaTME group: The patient was positioned in a modified Lloyd Davis position with both arms tucked. Then, abdominal and pelvic dissection was carried on by the same technique as the robotic group.

Trans-anal technique: First, we do proper exposure of the anal canal by taking four silk sutures at 12, 3, 6 and 9 o'clock followed by a purse string suture distal to the tumour, which is applied at an adequate safety margin. A circumferential rectotomy was then placed distal to the purse string to reach our dissection plane just outside the mesorectum. Then dissection started around the previous rectotomy outside the mesorectum to achieve a TME till we reach the dissection from above (Fig. 1). Finally, the specimen was either delivered trans-anally, so it is considered the last step in the evolution of rectal resections being a real NOS 'Natural orifice Surgery' or through a small Pfannenstiel incision if the specimen was quite large.

Anastomotic technique: In both groups, a double-stapled anastomosis is performed using standard EEA stapler and circular stapler. When the endoscopic stapler could not be applied with an adequate margin below the tumour, trans-anal

Figure 1



TaTME dissection. a. Dissection from above. b. Right c. Left.

resection and coloanal hand-sewn anastomosis is performed.

A diverting loop ileostomy was routinely used in all patients with low (below the anterior peritoneal reflection) anastomoses. Consideration for ileostomy reversal occurs 3 months after the index operation or once any potential adjuvant therapy is completed.

Postoperative policy

We adopted during this work an enhanced recovery care protocol for patients following either robotic or transanal approach for rectal cancer. The patients were discharged when they fulfilled the discharge criteria that include tolerance to oral diet, adequate pain control with oral analgesics, patient ambulating independently, afebrile without tachycardia and nonrising inflammatory markers.

Postoperative follow-up

Immediate postoperative outcome within one month was reported, this includes hospital stay, complications (if any, like anastomotic leakage, ileus, wound problems, re-operation, 30-day mortality and others), total operative time including preparation (which includes time out, draping of the patient and docking time in robotic surgery) and actual time which we identify as time from the skin, intraoperative bleeding that was estimated by using 'Blood loss estimation using gauze visual analogue' [14] plus what was obtained in the OR suction device and cost per case (calculated in 1000 × LE including all expenses).

The pathological reports of all specimens were collected, and the following data were collected for statistical analysis: gender, age, proximal margin, distal margin, circumferential margin, number of lymph nodes retrieved and positive ones.

N.B. The postoperative management and follow-up were standardized between both groups and both centres to minimize bias and make a reasonable comparison.

Aim

Primary endpoint

The main outcome of this study was to compare the TaTME technique to robotic-assisted laparoscopic resection of rectal carcinoma as regards short-term oncological outcome; in terms of circumferential resection margin, longitudinal resection margins (proximally and distally) and lymph node retrieval.

Secondary endpoints

Also, both techniques were compared as regards to operative time, estimated blood loss, the length of hospital stay and cost per case.

Statistical methods

Data were coded and entered using the statistical package for the Social Sciences (SPSS) version 26 (IBM Corp., Armonk, NY, USA). Data were summarized using mean, standard deviation, median, minimum and maximum in quantitative data and using frequency (count) and relative frequency (percentage) for categorical data. Comparisons between quantitative variables were done using the nonparametric Mann-Whitney test [15]. For comparing categorical data, Chi-square (χ^2) test was performed. Fisher's Exact test was used instead when the expected frequency is less than 5 [16]. *P* values less than 0.05 were considered statistically significant.

Results

Demographic features and ASA grades for both groups are shown in (Table 1), there was no statistical difference, which means that both groups are comparable.

According to histopathology of the tumours, 56 (70%) patients of cases were adenocarcinoma [29 (72.5%) in TaTME group and 27 (67.5) in the robotic group], there was no statistically significant difference between both groups (*P* value 0.334). Sixteen patients (20%, 8 in each group) were mucoid adenocarcinoma and 8 patients (10%, 5 in TaTME group and 3 in the robotic group) showed complete pathological response after neoadjuvant chemo-radiation.

Table 1 Demographic features and patient characteristics

	Mean	Standard deviation	*P* Value
Age (years)			
Both groups	52.43	9.7	0.216
TaTME	50.33	8.9	
Robotic	48.6	9.8	
Sex (Male)	Number (%)		0.421
TaTME	29 (72.5%)		
Robotic	27 (67.5%)		
BMI	Mean	SD	0.089
TaTME	29.3 kg/m^2	1.5	
Robotic	28.8 kg/m^2	1.7	
ASA			
TaTME	ASA 1 . . . .14 patients, ASA 2 . . . 15, ASA 3 . . . 11		1.000
Robotic	ASA 1 . . . 13 patients, ASA 2 . . . 14, ASA 3.13		

According to clinical staging (AJCC) of the rectal cancer, there were 8 patients (10%, 4 in each group) with tumours of stage I, 34 (42.5%) patients of stage II and 38 (47.5%) patients of stage III.

According to preoperative systemic treatment (neoadjuvant chemoradiation), all TaTME patients (100%) and 30 patients from the robotic group received preoperative neoadjuvant chemo-radiotherapy (75%), which shows statistical difference (*P* value 0.047).

As for the analytical results, firstly, according to operative time, (Table 2) shows comparison between both groups regarding different times. TaTME group showed statistically significant shorter time (*P* value < 0.001 for total and preparation time, 0.003 for actual operative time).

Then, according to the intraoperative estimated blood loss, although not clinically obvious, the estimated blood loss was statistically significantly lower in the TaTME group than the robotic group (*P* value 0.017). Also, regarding the length of hospital stay, there was statistically significant less hospital stay in favour of the robotic group (*P*-value 0.014). This is shown in Table 3.

The mean cost in the trans-anal group was 46.15 and the mean cost in the robotic group was 110.7, which is less in the trans-anal group with a statistically significant value (*P* value < 0.001). Total hospital cost/case (in 1000 USD) in the trans-anal group was 2.93 and the mean cost in the robotic group was 7.04, which is less in trans-anal group with a statistically significant (*P* value < 0.001) (Table 3).

The mean distal safety margin was statistically significantly higher in the robotic group (*P* value = 0.002). The mean proximal safety margin showed no statistically significant value (*P* value = 0.698) (Table 4).

Regarding the quality of circumferential margin (complete vs. partly complete). Although the circumferential resection margin (CRM) was complete in 36 patients, only (90%) in the robotic group (4 patients had had positive CRM) in contrast

Table 2 Operative time

	Mean	Standard deviation	Median	Minimum	Maximum	*P* Value
Total time						
Both groups	222.72	67.12	195.50	139.00	371.00	<0.001
TaTME	179.10	23.45	177.50	139.00	225.00	
Robotic	266.35	68.48	263.00	182.00	371.00	
Preparation time						
Both groups	46.35	25.45	36.00	19.00	113.00	<0.001
TaTME	26.75	2.83	27.50	19.00	31.00	
Robotic	65.95	22.65	56.50	41.00	113.00	
Actual time						
Both groups	176.37	44.91	151.00	113.00	280.00	0.003
TaTME	152.35	22.82	149.00	113.00	198.00	
Robotic	200.40	49.03	201.50	140.00	280.00	

Table 3 Statistical analysis of intraoperative bleeding, Hospital stay and cost per case (x1000 LE)

	Mean	SD	Median	Minimum	Maximum	*P* Value
Bleeding (ml)						
TaTME	130.50	75.76	110.00	50.00	400.00	0.017
Robotic	212.00	141.15	170.00	50.00	650.00	
Both groups	171.25	119.18	137.50	50.00	650.00	
Hospital Stay						
Total	4.85	2.60	5.00	2.00	14.00	0.014
TaTME	5.10	0.64	5.00	4.00	7.00	
Robotic	4.60	3.65	3.00	2.00	14.00	
Cost						
Total	78.43	33.01	77.50	44.00	128.00	< 0.001
TaTME	46.15	1.14	46.00	44.00	49.00	
Robotic	110.70	6.47	108.00	106.00	128.00	

Table 4 End margins and retrieved and positive lymph nodes comparison

	Mean	Standard deviation	Median	Minimum	Maximum	*P* Value
Distal margin						
Total	2.35	0.64	2.35	1.40	4.00	0.002
TaTME	2.02	0.42	1.90	1.50	2.90	
Robotic	2.68	0.67	2.75	1.40	4.00	
Proximal margin						
Total	14.30	2.66	14.00	10.00	20.00	0.698
TaTME	14.55	2.95	14.00	10.00	19.00	
Robotic	14.05	2.39	13.50	10.00	20.00	
Number of lymph nodes harvested						
Total	13.77	4.96	13.50	6.00	25.00	0.678
TaTME	13.60	6.44	12.00	6.00	25.00	
Robotic	13.95	3.02	14.00	8.00	20.00	
Positive lymph nodes						
Total	4.13	3.84	3.50	0.00	13.00	<0.001
TaTME	1.60	3.28	0.00	0.00	13.00	
Robotic	6.65	2.46	6.00	2.00	12.00	

to 40 patients (100%) in the TaTME group, it did not differ statistically with a *P*-value = 0.487.

According to the lymph node retrieved. There was no statistically significant difference in the number of retrieved lymph nodes. On the other hand, positive lymph nodes showed statistically significant increase in the robotic group (P value < 0.001) (Table 4).

The overall complication rates were not statistically different between the two groups (P value = 0.601). The overall complication rate was 10% in TaTME (4 cases) and 20% in robotic (8 cases). Anastomotic leakage occurred twice in each group; in the robotic group, the leakage was minimal and was successfully managed nonoperatively, but in the TaTME, one patient was managed operatively by exploration and the other patient was managed nonoperatively. In the robotic surgery group, postoperative ileus occurred in 4 patients compared with no patients in the TaTME group, which may be related to prolonged operative time, they were both managed conservatively. Despite our initial experience in these recent approaches, there were only 2 cases in each group that was converted to an open approach (5%).

Discussion

Rectal surgery has changed tremendously during the past 40 years. This can be summarized in the shift from open to minimally invasive and robotic techniques, a worldwide application of neoadjuvant chemoradiation therapy for locally advanced disease as well as adoption of surgical technique of nerve preservation and of total mesorectal excision (TME), which was a major step towards better oncological outcomes [3].

Our results showed superiority of TaTME as regards the intraoperative time and cost, whereas the robotic technique was superior in terms of hospital stay and distal margins that may be referred to better and magnified visualization in the robotic system. There was no difference between both techniques as regards distal margins, circumferential margins, number of lymph nodes harvested and incidence of complication.

Actually, we find only very few studies comparing both techniques, we compared between our study and articles discussing the same issue from different prospectives:

An obvious finding of this trial is the longer preparation and operative time of the robotic group as shown in the results section. These results are justified by the time used to dock and undock the robotic system during repositioning of the patient. Undoubtedly, continuous training of the whole surgical team on the step-by-step procedure can lead to a progressive reduction of the operative time. The mean total time in the trans-anal group was 179.10 ±23.45 min and in the robotic group was 266.35 ±68.48 min, which is statistically significantly less in the trans-anal group (P value < 0.001).

In contrast to our results, Perez *et al.* [17], in 2018 reported that median operating time was 276 (145–525) minutes in the robotic technique, whereas it was 291(150–600) min in the TaTME group, which is 15 min longer in the TaTME, which did not reach statistical significance, but he did not take into consideration the preparation time for docking and undocking of the robotic system. Also, Lee *et al.* [18], in 2018 in a similar comparative study on 45 patients

(21 TaTME, 24 robotic) reported mean time in TaTME 267±77.6 and in robotic 252±77.3, which is also longer in TaTME that contradicts our study too. In 2017, Bravo and colleagues in a case report combined robotic and TaTME procedures simultaneously through operating by 2 teams, he reported that total time was 160 min, whereas actual time was 90 min, while the other 70 min was for docking, undocking and the anastomosis [17–19].

As for the estimated blood loss, this trial reported a significantly lower estimated blood loss during TaTME (*P*-value =0.017). In contrast to our results, Perez and colleagues in 2018 reported 2 cases of major bleeding in the robotic group and a single case of major bleeding in TaTME, whereas we did not report any case with major bleeding. In their study, they did not report overall estimated intra-operative blood loss. Also, in 2018, Lee and colleagues in a similar comparative study reported estimated blood loss in the TaTME group of 283±277.6 cc and 155±118.5 cc in the robotic group with no statistical significance (*P*-value 0.061). There was more bleeding in the TaTME group, which contradicts our results [17,18].

Regarding safety margins and lymph nodes, Perez *et al.* [17], in 2018 also had no difference between both groups concerning the number of lymph nodes retrieved with a median of 15 (7–30) in robotic and 15 (8–55) in TaTME, which was very close to our results. They also reported no difference between both groups regarding distal safety margin with a median 31 (19–45 mm) in the robotic group and 19 (8-30 mm) in the TaTME group (*P*-value 0.007), these results were comparable to our results. As for CRM, they reported superiority of clearance of CRM in the robotic group with statistical significance, whereas we had better CRM in TaTME with no statistical significance [17].

As for Lee and colleagues also in 2018, they showed no statistical significance between both groups concerning distal safety margin, circumferential radial margin nor number of retrieved lymph nodes. The mean number of lymph nodes in the TaTME group was 10.7±6.28, mean distal margins was 2.2±1.28 and quality of CRM was 90.5%. Mean number of lymph nodes retrieved in the robotic group in their study was 13.6±6.29, mean distal margins was 1.9±1.06 and quality of CRM in robotic was 100%. These results were comparable to our results discussed above [18].

For the hospital stay, in our study, we had statistically significant shorter hospital stay in the robotic group, thanks to adoption of fast-track surgery with a (*P* value 0.014). In 2018, Perez and colleagues had had no statistical difference between both groups with a median of 8 (4-36) days in the robotic group and a median of 7 (5-53) days in the TaTME group, they were both more than our medians in both groups (3 (2-14)) in the robotic group and (5(4-7)) in the TaTME group [17].

Lee and colleagues also had no statistical difference between both groups with a mean of (7.7±3.22) in the robotic group and a mean of (8.0±4.86) in the TaTME group. They also showed less hospital stay in the robotic group as our results but with no statistical significance [18].

Also, regarding complication rate, Perez and colleagues, in 2018, had no differences found between intraoperative complications and conversion rates between both groups, they reported 10% conversion in the robotic group and 3.6% in the TaTME group. They also reported major complications (as anastomotic leakage) of 30% in the robotic group and 50.9% in the TaTME group [17]. Lee and colleagues noted no differences in intraoperative complication and conversion rates between both groups. He reported 4.2% conversion in the robotic group and no conversion (0%) in the TaTME group. They also reported major complication rate (such as anastomotic leakage) of 29.2% in the robotic group and 28.6% in the TaTME group [18].

Lastly regarding the cost, the two similar comparative studies done by Perez and colleagues [17] and Lee and colleagues [18] did not study the cost. Regarding TaTME technique, we did not find a single study assessing the total hospital cost using the TaTME approach in low rectal resection. As for robotic technique, in 2003, Delaney and colleagues in their study on 6 patients had found mean total hospital cost of $3721.5, which is less than our mean [20]. Finally, the cost of robotic surgery is still variable between the countries and different centres. However, minimal invasive surgeries carry the advantage of faster recovery and earlier return to work.

More recent studies as that of Law and Foo [21] who compared both techniques and they concluded that both robotic and TaTME can reach favourable rectal cancer resection outcomes, however, TaTME is associated with a shorter operating time, less intraoperative blood loss and better trans-anal specimen extraction.

Also, in 2019, Gachabayov and colleagues compared histopathological metrics and complication rates between TaTME and robotic technique rectal cancer. They performed a systematic search and included six observational studies involving 1572 patients (TaTME: 811, robotic TME: 761) in their meta-analysis. The CRM involvement rate, distal resection margin and complication rates did not differ between both procedures, and they concluded that performing TaTME for rectal cancer does not improve histopathological outcomes or complication rates [22].

Conclusion

TaTME represents a promising complementary technique to laparoscopic TME in the step of low rectal dissection, especially for difficult cases where laparoscopy is too demanding. This study also suggests that robotic surgery is safe and effective and has some advantages concerning distal margins of low rectal resections. Also, TaTME can be compared with robotic surgery and represents an effective and less expensive alternative for robotic surgery.

Strengths and limitations of the study

From the strengths of this work that it was done on a considerable number of patients who were included in this study. However, a larger number of patients is needed to assess the efficacy of TaTME and robotic techniques in rectal resection. Also, discussing cost is a point of strength in this study.

From the limitations of this study, operating in 2 different periods, however, we tried to overcome this by comparing both groups demographically and regarding tumour characteristics and found them comparable. Also, from the limitations of that study was the lack of assessment of postoperative functional; urological, sexual and continence outcomes that my need longer period of follow-up. Also, long-term oncological outcomes and survival rates were not addressed by this study as we focused mainly on the clinical outcomes and the quality of radical oncological resection.

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All authors have contributed to the conception or design of the work, interpretation of data for the work, drafting the work or revising it critically for important intellectual content, final approval of the version to be published and agreement to be accountable for all aspects of the work.

Information and consent: All patients signed a written informed consent for the operation and the technique to which they are subjected.

Data Availability statement: The data are available with the corresponding author upon request.

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Conflicts of interest

All authors declare that there are no conflicts of interest.

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