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ORIGINAL ARTICLE

The role of transanal compared to laparoscopic total mesorectal excision (taTME vs. lapTME) for the treatment of mid-low rectal cancer in obese patients: outcomes of a multicenter propensity-matched analysis

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Abstract
To compare the rate of sphincter-saving interventions between transanal and laparoscopic Total Mesorectal Excision in this particular group of patients. A multicentre observational study was conducted using a prospective database, including patients diagnosed with rectal cancer below the peritoneal reflection and BMI ≥ 30 kg/m^2, who underwent minimally invasive elective surgery over a 5-year period. Exclusion criteria were (1) sphincter and/or puborectalis invasion; (2) multi-visceral resections; (3) palliative surgeries. The study population was divided into two groups according to the intervention: transanal or laparoscopic total mesorectal excision. The primary outcome was the rate of sphincter-saving surgery. Secondary outcomes included conversion, postoperative complications, quality of the specimen, and survival. A total of 93 patients were included; 40 (43%) transanal total mesorectal excision were compared to 53 (57%) laparoscopic. In addition, 35 cases of transanal approach were case-matched with an equal number of laparoscopic approaches, based on gender, tumor's height, and neoadjuvant therapy. In both groups, 43% of the patients had low rectal cancer; however, the rate of sphincter-saving surgery was significantly higher in the transanal group (97% vs. 71%, $p = 0.003$). There were no conversions to open surgery in the transanal group, compared to 2 cases in the laparoscopic group (6%) ($p = 0.246$). The percentage of major complications was similar, including the rate of anastomotic leakage (10% transanal vs. 19% laparoscopic, $p = 0.835$). In our experience, higher percentages of sphincter-saving procedures and lower conversion rates are potential benefits of using the transanal approach in a complex surgical setting population of obese patients with mid-low rectal tumors when compared to laparoscopic.

Keywords Laparoscopic surgery · Rectal cancer · Transanal total mesorectal excision · TaTME · Total mesorectal excision

Introduction

Total mesorectal excision (TME) represents the gold standard technique for patients with rectal cancer [1]. The TME procedure can be performed either by open or minimally invasive (MI) laparoscopic or robot-assisted techniques ("top to down" approach) or by a combination of both abdominal and transanal techniques ("down to up" approach). The MI approaches have demonstrated several advantages compared to open surgery, such as reduced postoperative pain, shorter hospital stay, and a faster return to normal activities [2]. On the contrary, recent oncological outcomes published by large clinical trials are controversial on whether MI approaches are non-inferior to open surgery [2–4]. As a result, the ideal MI approach to TME is also a matter of ongoing

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consideration, which has aroused much debate throughout the past few years resulting in a lack of consensus about which is the best way to perform the TME procedure.

The laparoscopic TME (lapTME) technique carries technical difficulties and obesity by itself (BMI > 30 kg/m^2) has been demonstrated to have a negative impact on surgical outcomes by reducing the possibility of performing sphincter-saving procedures for distal rectal tumors in male patients. A proctectomy in obese patients is also associated with a higher risk of conversion, increased postoperative complications, and anastomotic leakages in comparison with nonobese patients [5]. In addition, the worst oncological outcomes have been reported in obese patients with rectal cancers due to a higher risk of positive circumferential radial margins, regardless of the surgical approach [6].

The robotic-assisted TME (rTME) and transanal TME (taTME) have risen as MI approaches in the last decade and have found new ways to overcome some of the previously mentioned limitations. The taTME results are found to be especially useful in obese patients with a narrow pelvis and low rectal tumors, whereas the other MI approaches carry technical difficulties such as the moment of ensuring a secure rectal transection below the tumor´s edge [7, 8].

An unanswered question remains as to whether the taTME has brought new potential advantages in contrast to lapTME, specifically for the most challenging cases. Therefore, we designed the present study with the aim of comparing the rate of sphincter-saving interventions of taTME vs. lapTME in a prospective, multicenter group of obese patients diagnosed with mid-low rectal cancers.

Methods

A multicenter, prospective cohort study was performed selecting consecutive patients diagnosed with mid-low rectal cancers located below the peritoneal reflection and with a BMI > 30 kg/m^2, who underwent MI elective rectal cancer surgeries at four tertiary centers in Spain (1. University Hospital Gregorio Marañon, Madrid, 2. University Clinic of Navarre, Madrid & Pamplona, 3. University Hospital Rio Hortega, Valladolid, 4. University Hospital of Leon, Leon).

The inclusion criteria were (1) patients undergoing surgery for rectal tumors located below the peritoneal reflection and requiring a TME procedure 2) BMI > 30 kg/m^2. Exclusion criteria included: (1) emergency surgeries; (2) extended en-bloc resections (cT4b tumors requiring multivisceral resections); (3) tumors with infiltration of the external sphincter or puborectalis muscle (requiring an abdominoperineal resection -APR-); (4) palliative surgeries. The study was initiated after obtaining approval by the local Ethics Research Committee and all participants gave written informed consent to use their clinical data prior to study inclusion.

The primary objective is to analyze the rate of sphincter-saving surgery and to compare it between the two groups of the study. As secondary outcomes, we analyzed short-term postoperative results and oncological outcomes.

Surgical procedures

We allocated the study population into two groups based on the type of surgery: a study group of patients who underwent taTME and a retrospective control group of patients treated by lapTME. From the beginning of the study, our group was regularly performing lapTME; however, taTME was progressively implemented as the primary option for low rectal cancers in all centers. Both techniques included the same laparoscopic abdominal phase by using a 4–5 trocar approach. By protocol, we standardized the procedure including a complete medial-to-lateral mobilization of the splenic flexure and a high ligation of the inferior mesenteric vessels. For the pelvic phase, we followed the oncological principles of the TME technique, performing the dissection from the posterior and lateral sides of the mesorectum to the anterior plane.

In the lapTME technique, once the dissection was carried out below the tumor´s edge, we transected the rectum using linear staplers across the rectum in a transverse orientation. Then, the specimen was extracted through a Pfannenstiel suprapubic incision and lastly, an intracorporeal end-to-end or side-to-end double-stapled colorectal anastomosis was created. If an intersphincteric dissection is needed, it is performed according to Rullier´s technique [10].

In the taTME technique, we used one or two teams combining the abdominal and transanal approaches as we reported previously [9]. The pelvic dissection was performed in the TME plane to the level of the puborectalis sling posteriorly and of the seminal vesicles or the rectovaginal septum anteriorly. Transanally, an intersphincteric dissection was performed for type II Rullier´s Classification tumors [10]. For type I tumors, a purse-string suture was done ensuring the distal margin and a complete closure of the rectum. Afterwards, a complete circumferential full-thickness rectotomy was performed facing the dissection proximally through the TME plane until connecting to the abdominal dissection. The specimen extraction was carried out through a suprapubic incision (Pfannenstiel) or transanally. Then, the anastomosis was performed either by a circular stapler or hand-sewn anastomosis [11]. Finally, in both groups, a loop ileostomy was performed if considered necessary by the surgical team.

Study variables

The data obtained for analysis included variables related to the patient´s preoperative characteristics (age, gender, previous comorbidities, preoperative staging, neoadjuvant chemoradiotherapy -nCRT-). To define the tumors' height, the length from the distal edge of the tumor to the anal verge was measured by MRI, based on the anatomical landmarks from the LOREC definitions [12]. We also recorded the following intraoperative variables: type of intervention, the sphincter-saving procedures, the type of anastomosis, the need for a stoma (whether a loop or terminal stoma) and the rates and reasons for conversion. Conversion to open surgery was defined as an intraoperative change from a laparoscopic (either abdominal or transanal) approach to an unplanned laparotomy. Short-term postoperative complications were graded as minor vs. major categories using the Clavien-Dindo classification [13]. Patients with either clinically suspected or confirmed radiological leakage, reported by a CT scan were included as anastomotic leakages (AL). AL was defined following the criteria of the International Study Group of Rectal Cancer [14]. The length of hospital stay (LOS) and the rate of readmission during the first 30-day postoperative period were also documented.

The following data was extracted from the pathological report; postoperative staging based on the American Joint Commission on Cancer classification (AJCC 8th) [15], distal resection margin (DRM), circumferential resection margin (CRM), median of lymph nodes harvested, presence of lymphovascular invasion and the quality grade of the mesorectum on the surgical specimen. A positive DRM or CRM was defined as ≤ 1 mm of margins free of disease.

We standardized the follow-up protocol of 5 years for every participating center. Adjuvant chemotherapy was given based on the patient's status and the pathological report after a recovery period of approximately one month. Evidence of distant recurrent disease was accepted when metastases were confirmed on ultrasound, CT scan, PET-CT scan or MRI with a positive biopsy. We defined local recurrence (LR) as the detection of tumor recurrence in the pelvis, anastomosis or the perineal area. Disease-free survival (DFS) was defined as the length of time after treatment during which no evidence of disease was found. Overall Survival (OS) was defined as the percentage of patients diagnosed with rectal cancer at the start of the study who were alive at the time of evaluation. Patients with stage IV disease at the time of diagnosis were excluded from the survival analysis.

Statistical analysis

Descriptive statistics were calculated with mean and standard deviation (SD) or median and interquartile range (LQR-UQR) for quantitative variables.

A case–control 1:1 design was applied to minimize baseline differences between the Study and Control groups. Patients were matched into those 2 groups using nearest-neighbor propensity matching, with a matched tolerance of 0 for all the covariates included. Confounding variables used to compute the propensity score were gender, tumor's height, and the presence of nCRT. After matching was completed, we checked whether the balance on the covariates was truly achieved through the matching procedure, by calculating the standardized mean differences or Cohen's d before and after matching. The rest of the analysis was performed using the already matched patients by surgical approach.

Comparison of differences between group medians was carried out using the Mann–Whitney U test for quantitative variables with non-parametric distribution. We used Chi-Squared analysis with Fisher's exact test when any value observed in the contingency table was less than 5 to compare proportion variables. A time-to-event analysis was performed using the Kaplan–Meier method. Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-sided test, 28 subjects were necessary for the study group (taTME) to be recognized as statistically significant with a difference greater than or equal to 25% in sphincter-saving surgery. A proportion in the control group (lapTME) was estimated to be 70%. A drop-out rate of 0% was anticipated. All statistical analyses were conducted using SPSS® version 26 software (SPSS, Inc., Chicago, IL) and p-values of < 0.05 were considered statistically significant.

Results

A cohort of 93 patients who met inclusion criteria over a 5-year period (2016–2021) were initially included in the study. Of them, 53 underwent lapTME (57%) and 40 taTME (43%). The median age was 67 (56–75) years, 66% were male, and the median BMI was 32 (31–33) Kg/m^2. Median tumor's height was 6 (5–8) cm, 61% received nCRT, with an overall percentage of sphincter-saving surgery of 83%.

A total of 35 patients who underwent taTME were case-matched 1:1 with 35 patients who underwent lapTME. In each group, the ratio of male to female was 57:43, with a mean BMI of 32 (31–34) Kg/m^2. The same proportion of 60% of patients received nCRT in the taTME and lapTME. A total of 43% of the patients had low rectal cancers in both groups. The standardized mean differences or Cohen's d were calculated before and after matching, and no imbalances remained after matching, with a value of $d = 0$ for the

Fig. 1 Dotplot of standardized mean differences (Cohen's d) for all covariates before and after matching

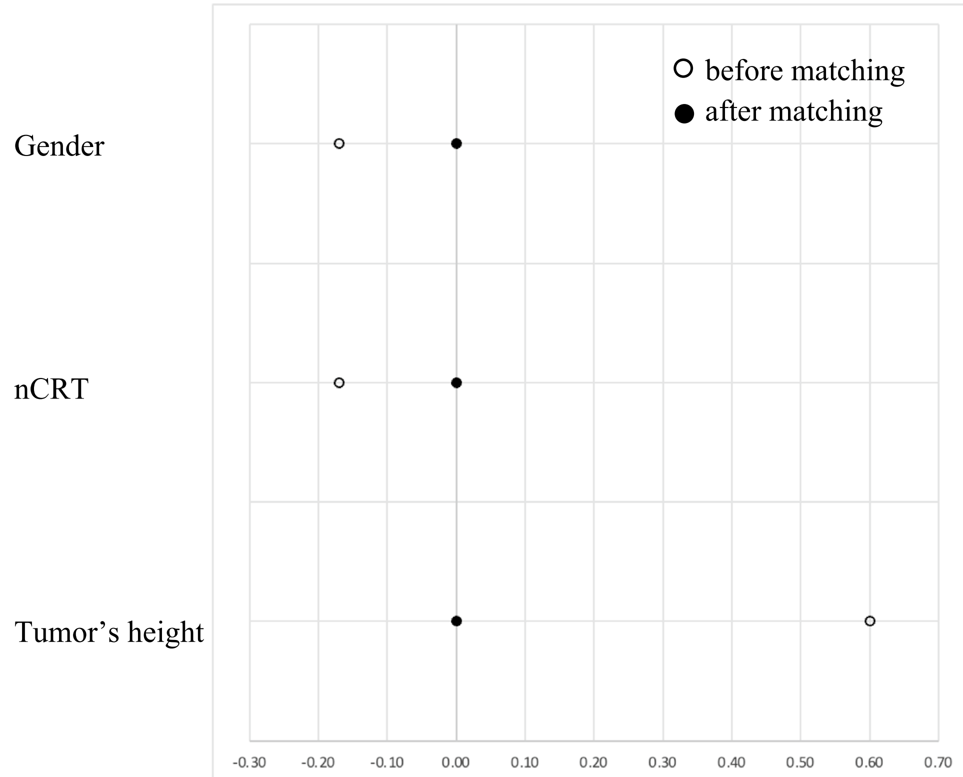


Table 1 Patients' perioperative characteristics of both groups before and after matching

	Before propensity-matched			After propensity-matched		
	lapTME $n=53$	taTME $n=40$	p value	lapTME $n=35$	taTME $n=35$	p value
Age (median, IQR) (years)	69 (61–77)	61 (52–71)	0.002	70 (63–75)	61 (52–71)	0.005
Gender (M:F) (%)	72:28	60:40	0.236	57:43	57:43	1
BMI (median, IQR)	32 (31–33)	32 (31–34)	0.823	32 (31–34)	32 (31–34)	0.934
ASA			0.230			0.357
I–II	33 (62%)	20 (50%)		23 (66%)	21 (60%)	
III	18 (34%)	17 (43%)		11 (31%)	12 (34%)	
Missing	2 (4%)	3 (7%)		1 (3%)	2 (6%)	
cT			0.102			0.262
< 2	14 (26%)	16 (40%)		10 (29%)	15 (44%)	
3	17 (32%)	22 (55%)		9 (26%)	18 (51%)	
4	5 (20%)	0		2 (6%)	0	
Missing	17 (32%)	2 (5%)		14 (40%)	2 (6%)	
cN +	18 (34%)	24 (60%)	0.576	13 (37%)	20 (57%)	0.835
cM +	1 (2%)	4 (10%)	0.302	1 (3%)	4 (11%)	0.497
Tumor location			0.052			1
Mid rectum (6–10 cm)	37 (70%)	20 (50%)		20 (57%)	20 (57%)	
Low rectum (0–5 cm)	16 (30%)	20 (50%)		15 (43%)	15 (43%)	
nCRT	30 (57%)	26 (65%)	0.413	21 (60%)	21 (60%)	1

three covariates analyzed, as shown in Fig. 1. Demographics and patient´s baseline characteristics after the matching are presented in Table 1.

Information regarding operative details and postoperative outcomes is shown in Table 2. The most frequently performed surgery was a Low Anterior Resection (LAR) (88%

Table 2 Intra- and postoperative outcomes of both groups, after matching

	After propensity-matched		
	lapTME $n=35$	taTME $n=35$	*p* value
Surgery (*n*, %)			0.004
LAR	25 (71%)	31 (88%)	
ISR	0	3 (9%)	
APR	10 (29%)	1 (3%)	
Sphincter-saving (*n*, %)	25 (71%)	34 (97%)	0.003
Anastomosis (*n*, %)			0.009
E-E	7 (28%)	6 (24%)	
S-E	6 (24%)	14 (41%)	
Hand-sewn	6 (24%)	10 (29%)	
Missing	6 (24%)	4 (12%)	
Stoma (*n*, %)			0.000
Diverting	13 (52%)	33 (97%)	
Permanent	10 (29%)	1 (3%)	
Conversion (*n*, %)	2 (6%)	0 (0%)	0.246
Complications (*n*, %)			0.502
Dindo-Clavien I-II	8 (23%)	5 (14%)	
Dindo-Clavien III-V	2 (6%)	4 (11%)	
Leak[a] (*n*, %)	6/31 (19%)	4/38 (10%)	0.835
Clinical	4 (16%)	3 (9%)	
Radiological findings	2 (8%)	1 (3%)	
Management of the leak[b]			
A	2 (6.5%)	0	
B	2 (6.5%)	3 (8%)	
C	2 (13%)	1 (2%)	
LOS (median, IQR) (days)	6 (4–12)	6 (4–10)	0.627
30-day readmission (*n*, %)	2 (6%)	1 (3%)	0.106
Stoma reversal (*n*, %)	11/13 (85%)	30/33 (91%)	0.439
90-day exitus (*n*, %)	0	0	0.600

[a]AL excluding APR cases

[b]According to the International Study Group of Rectal Cancer classification

Table 3 Pathological outcomes of both groups, after matching

	After propensity-matched		
	lapTME $n=35$	taTME $n=35$	*p* value
DRM (median, IQR) (mm)	8 (5–25)	12 (5–29)	0.349
DRM[a] + (*n*, %)	2 (6%)	0	0.207
CRM[a] + (*n*, %)	2 (6%)	1 (3%)	0.421
Mesorectum (*n*, %)			0.399
Complete	11 (31%)	26 (74%)	
Nearly complete	1 (3%)	3 (9%)	
Incomplete	2 (6%)	1 (3%)	
Missing	21 (60%)	5 (14%)	
pT (*n*, %)			0.121
0–2	17 (48%)	18 (51%)	
3	10 (29%)	16 (46%)	
4	8 (23%)	1 (3%)	
pN + (*n*, %)	6 (17%)	13 (37%)	0.138
Lymph nodes harvested	12 (8–20)	15 (10–19)	0.210
Lymphatic invasion (*n*, %)	8 (23%)	9 (26%)	0.776
Venous invasion (*n*, %)	7 (20%)	11 (31%)	0.380

[a]Defined as ≤ 1 mm

in taTME vs. 71% in lapTME), followed by APR (3% in the taTME group vs. 29% in the lapTME group) ($p=0.004$). In the taTME group, the case was a male patient, and the APR was performed due to technical difficulties. On the contrary, in the lapTME group, most of the APR (8/10, 80%) were performed due to technical difficulties in completing the pelvic dissection and ensuring negative distal margins. Four cases were located in the distal rectum and five in the mid-rectum, with similar distribution between genders. The remaining 2 cases underwent an APR due to functional reasons, as the patient was already incontinent before surgery. In addition, the rate of sphincter-saving surgery was significantly higher in the taTME group (97% vs. 71%, $p=0.003$), requiring an intersphincteric dissection (ISR) in 3 cases (9%). There were no conversions to open surgery in the taTME group compared to 2 (6%) cases in the lapTME group ($p=0.246$), mainly due to technical difficulties. A hand-sewn anastomosis was performed in 10 patients (29%) in the taTME group vs. 6 (24%) in the lapTME, $p=0.009$. The percentage of loop stoma was significantly higher in the taTME group (97% vs. 52% in lapTME $p=0.000$), while the rate of terminal stoma was lower (3% vs. 29%, $p=0.000$). Nevertheless, a similar percentage of temporary stomas was reversed in both groups at the time of completion of the study (91% taTME vs 85% lapTME, $p=0.439$.

The percentage of major complications (Dindo-Clavien III-IV) was comparable between groups (11% taTME vs. 6% lapTME, $p=0.502$); however, the rate of AL was lower in the taTME group, although not statistically significant (10% vs. 19% in the lapTME group, $p=0.835$). Management of the leaks included two cases of type A, five cases of type B (antibiotics plus the use of endosponge in three cases), and three cases of type C (2 primary closures via transanal and 1 laparoscopic lavage). The length of hospital stay (LOS) was equivalent between groups (6 (4–10) taTME vs. 6 (4–12) lapTME days, $p=0.627$), with a similar rate of 30-day readmission (3% vs. 6%, $p=0.106$). A total of three patients were readmitted, two of them due to an abdominal collection, both managed with antibiotics, and one requiring percutaneous drainage; the third case was readmitted due to postoperative ileus, managed conservatively.

In Table 3, we report the pathological outcomes for both groups. The median distal resection margin (DRM) was similar between groups (12 (5–29) vs. 8 (5–25) mm, $p = 0.349$). However, a free DRM was obtained in all taTME patients while positive in 2 (6%) cases in the lapTME group ($p = 0.207$). There were no differences regarding CRM (1 (3%) vs. 2 (6%), $p = 0.421$). Pathological staging showed no differences in pT staging after surgery ($p = 0.121$), however, there was one case of pT4a in the lapTME group due to the presence of infiltration of the peritoneal reflection. The quality of the mesorectum and the number of harvested lymph nodes were similar between groups.

The oncological outcomes for both groups are reported in Table 4, excluding patients with metastatic disease at diagnosis. No differences were found between groups regarding recurrences after a similar follow-up period (31 (15–44) months taTME vs. 40 (25–60) months lapTME, $p = 0.881$); a total of 10 patients developed distant metastasis (4 (13.3%) in the taTME group vs. 6 (18.2%) in the lapTME, $p = 0.430$), and five patients were diagnosed with locoregional recurrence (LR) during follow-up (3 cases (10%) in the taTME group vs. 2 (6%) in the lapTME group, $p = 0.454$).

Of the taTME LR cases, two were detected at the level of anastomosis while the remaining one was retroperitoneal. LR DFS at 3-year follow-up was 93% in the lapTME vs. 79% in the taTME group, $p = 0.459$. A total of 7 cases died during follow-up; 3 patients developed distant metastasis and died due to disease progression and one developed a lung tumor. The remaining three cases died for unknown reasons. OS at 3-year follow-up was 70% in the lapTME vs. 84% in the taTME group, $p = 0.305$. Survival curves are shown in Fig. 2.

Lastly, we analyzed the subgroup of 30 patients who had low rectal tumors (below 5 cm from the anal verge included in the study), 15 from each group. Of them, 73% were male and 53% received nCRT. To be highlighted, 100% of the low rectal cancer cases in the taTME group had a sphincter-saving procedure vs. 60% in the lapTME ($p = 0.008$), with only one radiological AL in the lapTME group. None of the 15 taTME cases had positive DRM or CRM, vs. one positive DRM and one positive CRM in the lapTME group ($p = 0.440$ and $p = 0.478$, respectively).

Discussion

Our study showed significant advantages of using the taTME technique for the treatment of mid and low-rectal tumors in a particularly challenging group of obese patients in comparison to a propensity-case matched lapTME control group. We have shown higher sphincter-saving procedures when using taTME compared to lapTME, and significantly lower rates of conversion. Short-term outcomes and postoperative complications were comparable between groups and oncological results did not show differences at the 3-year follow-up.

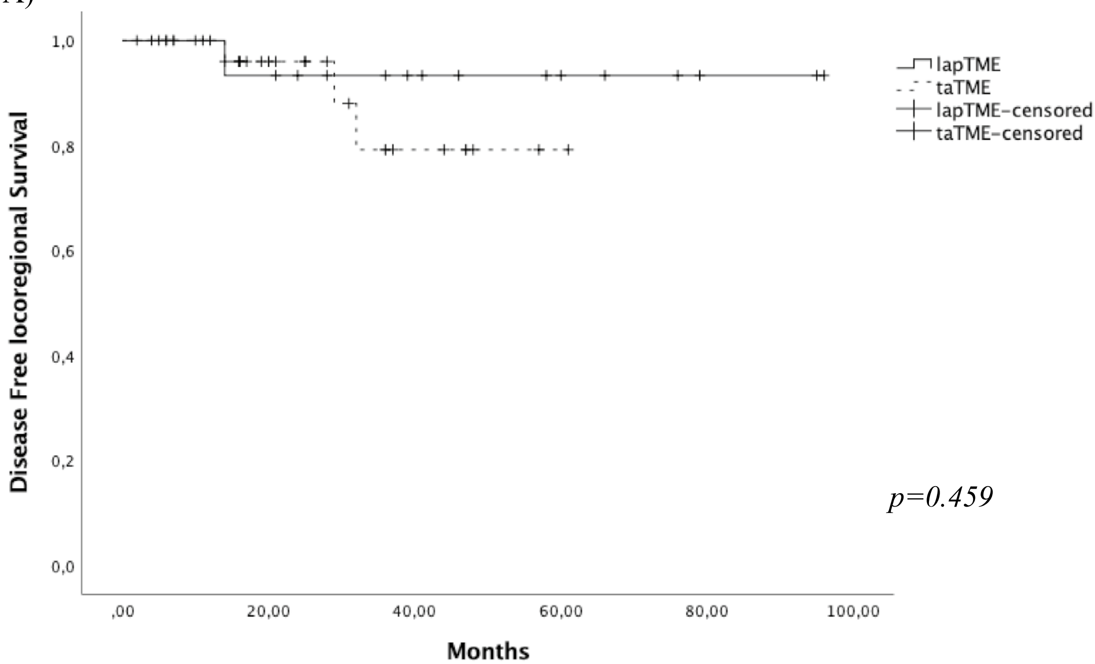
With this study, we identified that the use of taTME in obese patients achieves a higher rate of sphincter-saving procedures compared to lapTME (97% vs. 71%). It is important to highlight that in the subset analysis of 30 patients with low rectal tumors (below 5 cm from the anal verge), we observed even higher differences between groups (100% in the taTME group vs. 60% in the lapTME group). A BMI ≥ 30 kg/m^2 has been reported as an independent risk factor for undergoing a non-preserving procedure [6]; as a consequence, 29% of patients in our lapTME group underwent an APR due to technical issues or bulky tumors. On the other hand, the taTME patients requiring a terminal colostomy were only 3%. In the literature, taTME has previously been shown to increase the chance of having a sphincter-saving surgery up to 84%, with higher rates when compared to lapTME and similar rates to rTME [16]. We believe that achieving a correct dissection in the last 4–5 cm of the mesorectal space is a critical point in lapTME that has been overcome by taTME and rTME. In addition, the expanding experience in transanal surgery makes the surgeons more confident in performing intersphincteric dissections when required. However, due to the higher percentage of sphincter-saving surgery with ultralow anastomosis, there is an increased number of patients requiring a diverting stoma after taTME [17], as shown in our series (97%); nevertheless, the percentage of stoma reversal at the time of the study closure was also very high, reaching 90%.

Another advantage that we have identified is the lower rate of conversion to open surgery with taTME. Conversions are associated with a negative impact on postoperative

Table 4 Oncological outcomes of both groups, after matching. Patients with M1 disease at diagnosis have been excluded from the survival analysis

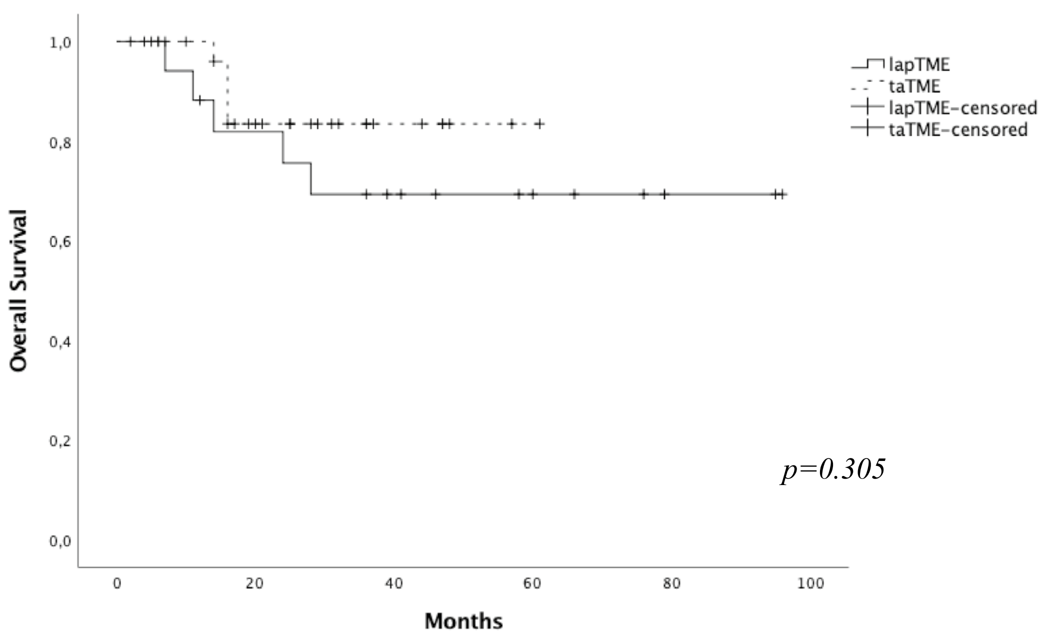
	After propensity-matched		
	lnapTME $n = 33$	taTME $n = 30$	p value
Locoregional recurrence	2 (6.1%)	3 (10%)	0.454
Distant metastasis	6 (18.2%)	4 (13.3%)	0.430
3y locoregional DFS	93%	79%	0.459
3y OS	70%	84%	0.305
Follow-up (median, IQR) (months)	40 (25–60)	31 (15–44)	0.881
Exitus (n, %)	5 (15.2%)	2 (6.7%)	0.254

A)



Number at risk					
LapTME	18	13	9	5	2
TaTME	29	16	6	1	

B)



Number at risk					
LapTME	18	13	9	5	2
TaTME	29	16	6	1	

Fig. 2 Comparison of survival curves between lapTME and taTME. **A** Locoregional DFS. **B** OS. Patients with M1 disease have been excluded from the survival analysis

morbidity, a higher incidence of wound infections and AL, and also a possible effect on long-term oncological outcomes [18]. Overall, the reported percentage of conversion when performing lapTME in the literature varies from 0 to 34% [2, 16, 18, 19]. The conversion rate may be influenced by independent risk factors such as the surgeon´s learning curve, radiated or locally advanced tumors in male, obese patients. New techniques have arisen in the last decade such as the rTME and the taTME, reporting lower conversion rates compared to lapTME. The robotic platform adds many advantages to the lapTME such as better visualization and accurate dissection, especially in distal rectal cancers. In cases of rTME, the ROLARR trial reported an overall conversion rate of 8.1%, with an increased risk when analyzing the subgroup of obese patients, reaching 18.9% (OR = 4.69 [95% CI, 2.08 to 10.58]). Regarding taTME, conversions seem to be lower, ranging between 0 and 11% [20, 21], and in our data, we had no cases of conversion in the taTME group vs. 6% in the lapTME. Similarly, a recently published nationwide study including 11 experienced centers in the Netherlands and reported a 2% conversion rate in taTME compared to a 7% in lapTME and 6.9% in rTME [16]. When focusing on obese patients, the rate of conversion may increase to 10% as recently reported by Gardner et al. in complex obese patients with advanced rectal tumors [22].

Our study did not find differences in short-term complications between groups, including major complications, AL, and 30-day readmissions. Some concerns were raised at the beginning of the taTME implementation, such as the emergence of specific procedure-related complications (i.e., urethral injuries), mainly due to a wrong dissection plane during the learning curve. Nevertheless, with the full implementation of the technique, different systematic reviews and meta-analyses have compared taTME and lapTME postoperative outcomes without showing significant differences including AL rates [23, 24]. Similar data has been observed in the first RCT published to date comparing both techniques (TaLaR trial) [25]. Our study has included cases from surgeons' early learning curve in taTME, but we believe that the fact that all procedures were performed in expert centers, diminished the learning curve effect.

The occurrence of AL after a LAR is an unsolved problem for colorectal surgeons. Creating a safe anastomosis is a key point during taTME and it may be performed in four different ways as previously reported by our group: by creating a single-stapled double pure string anastomosis via abdominal or transanally, by performing a hand-sewn coloanal anastomosis or with a pull-through technique or by a delayed hand-sewn coloanal suture [11]. Based on our data, we observed a 50% reduction in AL in the taTME group compared to the lapTME group from 19 to 10% in clinical AL requiring an intervention. According to our data, the previously reported incidence varies between 10 and 20% based on systematic reviews and the data from the International taTME registry [20, 23]. In a recently published meta-analysis including 8 studies with 437 patients comparing taTME vs. lapTME, a significant decrease of AL was observed in favor of taTME [24]. Moreover, a multicenter cohort study published in the Netherlands including a comparison between lapTME, taTME, and rTME reported nearly equal rates of AL between lapTME and rTME; 23.6 and 21.6%, respectively, in comparison to a lower incidence in taTME (17.6%) [16].

Previous studies comparing open TME with lapTME showed some benefits of the open approach regarding CRM [3, 4]. With the introduction of the taTME, we have overcome some of these lapTME drawbacks [23, 26, 27]; Although we could not find statistical differences in our series, there was a trend toward a lower rate of positive CRM in the taTME group (3% vs. 6%), and our data is in line with other taTME series [28]. No significant differences have been found in the literature regarding the number of lymph nodes harvested after lapTME or taTME; [23], according to our results. In terms of DRM, we believe that one of the main advantages of taTME surgery is the possibility of achieving higher rates of negative DRM by choosing an adequate distance to the tumor under direct visualization. Although previous studies did not find differences in DRM [23, 26], in our series, DRM was similar, but there were no cases of positivity in the taTME group compared to 2 positive cases (6%) in the lapTME group.

Without data coming from randomized controlled trials concerning oncological safety on performing taTME for rectal cancer, there currently remains a lack of evidence in the literature and some results are controversial. Some concerns have been recently raised with regard to the oncological outcomes after taTME surgery especially from 2019 when the Norwegian taTME data reported LR rate as high as 11.6% [29]. This data led to a moratorium on taTME in Norway. However, during the last 2–3 years many multicenter collaborative studies, systematic reviews, and meta-analysis have reported LR ranging from 2 to 6.2% [21]. In our data we did not find significant differences in terms of distant or local recurrence percentages, but 3 patients in taTME (10%) vs. 2 patients (6%) in lapTME developed LR with a median follow-up of 3 years. To note, two cases were at the level of the anastomosis, while the remaining case was a retroperitoneal recurrence. This observed percentage was higher than observed in our previous publication based on our global experience with taTME [10]; however, we believe that LR was expected to be higher in this particularly challenging group of obese patients, predominantly males with 50% of low rectal tumors stage 3 disease. Nevertheless, locoregional DFS at 3 years was similar between groups.

Regarding OS, there were no significant differences between the two groups, with a slightly higher percentage of distant metastasis in the lapTME group of patients.

Limitations

This study has some limitations that deserve to be mentioned. Firstly, our study was not a randomized controlled trial; however, we introduced a propensity-matched analysis to obtain two homogeneous groups to be compared. The sample size may be considered small, but we performed a sample size calculation to estimate the number of patients needed to detect statistical differences. Additionally, we were unable to take the learning curve into account as the implementation of the technique was not equivalent for all the centers; however, all participant centers performed both procedures from the beginning of the study. Surgeons were experts in MI TME and they all completed the Structured taTME Training Curriculum defined by Francis et al.[30] There was also a lack of data in our study about functional outcomes for both groups of the study and further work is required to establish the impact of taTME and sphincter-saving procedures on functional outcomes. Future studies more focused on long-term oncological outcomes will be interesting to strictly compare both techniques.

Conclusions

In our experience, lower conversion rates and higher percentages of sphincter-saving procedures are potential benefits of using taTME in a complex surgical setting population of mainly male and obese patients with mid-low rectal tumors when compared to lapTME. Additionally, we did not observe significant differences in short-term outcomes and survival at 2-year follow-up.

Although we believe that taTME may be considered a gold standard approach for this particular population, it must be highlighted that previous experience in minimally invasive and transanal procedures is essential for surgical teams before beginning with taTME.

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Data availability The data that support the findings of this study are available from the corresponding author, [PT], upon reasonable request.

Declarations

Conflict of interest The authors have no conflict of interest.

Informed consent Informed consent was obtained from all participants.

Research involving human and animal participants All procedures performed in studies involving humans were in accordance with the ethical standards of the institutional research committee and the 1964 Helsinki Declaration and its later amendments.

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