



Transanal versus laparoscopic total mesorectal excision: a comparative study of long-term oncological outcomes

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Abstract

Background Transanal total mesorectal excision (TaTME) is the most recent approach developed to improve pelvic dissection in surgery for mid and low rectal tumors. There are still inconsistencies regarding the technique's oncological results. The aim of this study was to analyze clinical and oncological outcomes of the learning curve of TaTME in comparison to laparoscopic TME (lapTME).

Methods Rectal cancer patients who had TaTME and lapTME in two Portuguese colorectal units between March 2016 and December 2018 were eligible. Primary endpoints were 5-year overall survival, disease-free survival, and local recurrence. Secondary endpoints were clinical and pathological outcomes.

Results Forty-four patients underwent TaTME (29 men) and 39 lapTME (27 men) with a median age of 69 and 66 ($p=0.093$), respectively. No differences were observed concerning baseline characteristics, emphasizing their comparability. In the TaTME group, there were more hand-sewn anastomosis (0 lapTME versus 7 TaTME, $p=0.018$) with significantly less distance to the dentate line (40 mm lapTME versus 20 mm TaTME, $p=0.005$) and significantly more loop ileostomies performed (28 lapTME versus 41 TaTME, $p=0.001$). There were no differences in post-operative mortality, morbidity, readmissions, and stoma closure. Groups were similar in relation to specimen quality, margins, and resectability; however, TaTME had a significantly higher node yield (14 lapTME versus 20 TaTME, $p=0.002$). Finally, no disparities were noted in oncological outcomes, namely local and distant recurrence, 5-year overall survival, and disease-free survival.

Conclusions Even with the disadvantage of the learning curve of a new technique, TaTME appears to be comparable to lapTME, with similar long-term oncological outcomes. It has, however, a demanding learning curve, significant risk for morbidity and should be used only for selected patients.

Keywords Rectal cancer · lapTME · TaTME · Oncological outcomes

Introduction

Impressive improvements have been introduced in the last decades in the surgical approach to rectal cancer (RC) and treatment evolved from one single technique performed in all RC patients to a multitude of procedures, individually selected according to patient performance status, oncological risk, or even response to neoadjuvant therapies. Still, the gold standard treatment of this malignancy is total mesorectal excision (TME) that can be very challenging, especially in obese male patients with a narrow pelvis and distal tumors. In fact, these characteristics are the principal risk factors for a positive circumferential resection margin (CRM) and intraoperative technical difficulties [1, 2].

Transanal total mesorectal excision (TaTME) was developed to improve visualization and facilitate exposure of

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the pelvic compartment, enhancing the minimally invasive approach and all its known advantages. Other advantages of TaTME are improved margin definition and avoidance of the double stapling technique [3, 4].

Good TaTME short-term clinical outcomes have already been reported [5] but there are inconsistencies regarding oncological outcomes. The primary goal of the present study was to investigate the long-term oncological outcomes of the introduction of TaTME in a Portuguese colorectal unit and to compare it to a historical cohort of patients treated by laparoscopic TME (lapTME) by the same surgeons. Primary endpoints were oncological outcomes, namely overall survival (OS), disease-free survival (DFS), and local recurrence (LR). Secondary endpoints were clinical, pathological outcomes, and parameters of specimen quality.

Materials and methods

This was a retrospective comparative study. The data analyzed were collected from Hospital Beatriz Ângelo and Hospital da Luz informatics database.

Consecutive patients with mid and low RC, stage I–III (American Joint Committee on Cancer) who had TaTME between March 2016 and December 2018 in Hospital Beatriz Ângelo and Hospital da Luz in Lisbon were compared to a historical group of consecutive patients with mid and low RC, stage I–III, treated with lapTME in the same institutions between June 20 and December 2016, by the same surgeons. The TaTME patients reflected the learning curve of the technique [6–9]. Stage IV patients were not included. Prior to TaTME implementation, the surgeons observed live procedures and had hands-on modular training courses and proctored learning. Data regarding TaTME cases were introduced in the International TaTME Registry.

Patient characteristics and demographics

Tumors were defined as being in the mid or low rectum if located between 5 and 10 cm and less than 5 cm from the anal verge, respectively, by magnetic resonance imaging (MRI) and rigid sigmoidoscopy.

The pathological specimen plane was defined according to Quirke et al. as ‘mesorectal’, ‘intramesorectal’, or ‘muscularis propria plane’ [10].

In this study, anastomotic leak was defined according to the International Study Group of Rectal Cancer, including clinical leak, radiological leak, pelvic, and perianastomotic abscess [11].

Post-operative morbidity was assessed according to the Clavien–Dindo Classification and included all complications related to the initial surgery, even after 0 days [12].

Surgical technique

The TaTME procedure was performed with 2 teams, trans-abdominal and transanal, working synchronously, with complete mobilization of the splenic flexure in all cases, using *Lone Star*[®] Retractor (Cooper Surgical, USA) and *GelPOINT*[®] Path Transanal Access Platform (Applied Medical, USA) for the transanal approach. There were no adjustments to the initial technique during the learning curve.

Statistical analysis

In this retrospective study, continuous variables were reported as *n*, median, first and third quartiles (Q1, Q3). To compare characteristics between patients that performed lapTME or TaTME, independent *t* test for equal and unequal variances, proportion test, chi-squared test, and Fisher exact test were applied, as appropriate. Analysis time to event data was performed through Kaplan–Meier (KM) curves. Overall survival (OS) was calculated considering surgery date until death date. Disease-free survival (DFS) was estimated considering surgery date until the appearance of recurrence, local or distant. Local recurrence-free survival (LRFS) was assessed measuring time from surgery till the appearance of LR. Finally, distant progression-free survival (DPFS) was calculated considering surgery date until the appearance of distant progression. Estimated median time to event, 25th–75th percentiles and correspondent 95% confidence interval (CI) were presented. Probability of survival for these time points and respective 95% CI were also disposed. For comparing survival times between groups, log-rank test was used. The significance level was set at $p \leq 0.05$. Data were analyzed with R (version 4.0.2, 2020-06-22, “Taking Off Again”).

Results

Patient characteristics and demographics

During the selected period, a total of 44 patients had TaTME and 39 had lapTME with a predominance of male sex, performance status (PS) Eastern Cooperative Oncology Group (ECOG) 0 and American Society of Anesthesiologists (ASA) class 2 in both groups. There were no significant differences between cohorts in terms of baseline characteristics (Table 1).

Patients with RC were staged with pelvic MRI and computed tomography (CT) scan of the chest, abdomen, and pelvis except for two that underwent endorectal ultrasound (ERUS) due to the presence of metallic prosthesis. There

Table 1 Patient characteristics and demographics

Clinical parameters	LapTME (<i>n</i> = 39)	TaTME (<i>n</i> = 44)	<i>p</i> Value
Sex			
Female	12 (31)	15 (34)	0.747
Male	27 (69)	29 (66)	
Age, years, median (range)	69 (61–76)	66 (59–74)	0.093
BMI, kg/ m ² , median (range)			
	27 (24–29)	26 (23– 28)	0.162
<25	11 (30)	21 (48)	0.246
≥25	26 (70)	23 (52)	
ND	2	0	
PS (ECOG), <i>n</i> (%)			
0	30 (83)	42 (96)	0.180
1	2 (6)	0 (0)	
2	3 (8)	2 (4)	
3	1 (3)	0 (0)	
ND	3	0	
ASA score, <i>n</i> (%)			
1	0 (0)	2 (5)	0.596
2	21 (66)	28 (67)	
3	11 (34)	12 (28)	
ND	7	2	

BMI=body mass index, *PS*=performance status, *ECOG*=Eastern Cooperative Oncology Group, *ASA*=American Society of Anesthesiologists, *TaTME*=transanal total mesorectal excision, *LapTME*=laparoscopic total mesorectal excision, *ND*=not discriminated, *NA*=not applicable,

were no differences between groups regarding tumor location, extension, distance to the anal verge, cT, cN, cM, clinical stage, circumferential resection margin (CRM) status, extramural vascular invasion (EMVI) and levels of carcinoembryonic antigen (CEA). The majority were patients in stage III, without EMVI and with free CRM. Likewise, the majority of patients in both groups underwent neoadjuvant therapy, mostly with long-course chemoradiotherapy (LCCRT). There were no differences between TaTME and lapTME groups regarding tumor characteristics, stage, neoadjuvant regimen chosen and tumor regression grade assessed by MRI (mrTRG) (Table 2).

Surgical outcomes

All patients had preoperative mechanical oral bowel preparation and underwent surgical procedure in a median of 12 weeks after chemoradiotherapy (CRT) (lapTME range 10–13 weeks and TaTME range 11–13 weeks, *p*=0.287).

TaTME was done laparoscopically in 36 (82%) patients and robotically in 4 (9%) cases, for a total of 40 (91%) procedures with a minimally invasive approach. With no transanal conversions, there were four (9%) abdominal conversions to midline laparotomy, one due to presacral bleeding, one for pneumoperitoneum intolerance and two for obesity-related technical difficulties.

There were no differences between groups related to the number of anastomoses performed with a predominance of mechanical, side-to-end anastomosis in both. Groups were comparable regarding intraoperative blood loss, complications, and operative time. There were, however, more hand-sewn anastomoses in the TaTME group (0 lapTME versus 7 TaTME, *p*=0.018) with significantly less distance from the dentate line (40 mm lapTME versus 20 TaTME, *p*=0.005). Also, significantly more loop ileostomies (28 lapTME versus 41 TaTME, *p*=0.001) were used in the TaTME group. The specimen was preferentially extracted through a Pfannenstiel incision in both groups (Table 3).

Post-operative period and follow-up

There were no differences between groups related to 30-day mortality (2 lapTME versus 0 TaTME, *p*=0.218) or overall post-operative morbidity (20 lapTME versus 18 TaTME, *p*=0.178) (Table 4).

In the lapTME group, eight patients had to be re-operated, three for anastomotic leak and five for problems non-related with the anastomosis (epigastric vessels bleeding, intra-abdominal hematoma, small bowel internal hernia, colostomy ischemia and jejunal perforation).

In the TaTME, ten patients had to be surgically revisited, six due to anastomotic leak, and four for complications

Table 2 Pre-operative staging and neoadjuvant therapy

Pre-operative staging and neoadjuvant therapy	LapTME (<i>n</i> = 39)	TaTME (<i>n</i> = 44)	<i>p</i> value
Location, rectum (%)			
Middle 1/3	28 (72)	27 (61)	0.359
Lower 1/3	11 (28)	17 (39)	
Tumor extension (mm), median (range)	45 (30–60)	40 (34–50)	0.760
Distance to anal verge (mm), median (range)	80 (70–90)	70 (50–80)	0.189
cT			
Tx	1 (3)	2 (5)	0.756
T1	1 (3)	3 (7)	
T2	10 (27)	15 (33)	
T3	23 (62)	21 (48)	
T4	2 (6)	3 (7)	
ND	2	0	
cN			
N0	11 (28)	20 (46)	0.272
N+	28 (72)	24 (54)	
cM			
M0	39 (100)	44 (100)	NA
M1	0 (0)	0 (0)	
Stage			
Stage I	6 (15)	15 (34)	
Stage II	5 (13)	6 (14)	0.141
Stage III	28 (72)	23 (52)	
CRM, <i>n</i> (%)			
Free	25 (76)	35 (79)	0.784
Threatened	4 (12)	3 (7)	
Invaded	4 (12)	6 (14)	
ND	6	0	
EMVI, <i>n</i> (%)			
Negative	24 (83)	36 (92)	0.272
Positive	5 (17)	3 (8)	
ND	10	5	
CEA (ng/mL)	1.7 (0.5–2.6)	1.3 (0.8–2.3)	0.999
CRT			
LCCRT	28 (93)	22 (100)	0.502
SCRT	2 (7)	0 (0)	
NA	9	22	
mTRG, <i>n</i> (%)			
mTRG 1	5 (50)	2 (17)	0.295
mTRG 2	4 (40)	8 (66)	
mTRG 3	1 (10)	2 (17)	
NA/ND	9/20	22/10	
cCR, <i>n</i> (%)			
Negative	26 (87)	19 (86)	0.999
Positive	4 (13)	3 (14)	
NA	9	22	

cT cN cM TNM Staging Classification for Rectal Cancer 8th ed., 2017. NA in “CRT”, “mTRG” and “cCR” relates to patients that did not have neoadjuvant therapy

CEA carcinoembryonic antigen, CRM magnetic resonance accessed circumferential resection margin, EMVI magnetic resonance accessed extramural vascular invasion, CRT chemoradiotherapy, LCCRT long-course chemoradiotherapy, SCRT short-course chemoradiotherapy, mTRG magnetic resonance tumor regression grade, cCR clinical complete response, TaTME transanal total mesorectal excision, LapTME laparoscopic total mesorectal excision, NA not applicable, ND not discriminated

Table 3 Surgical outcomes

Surgical outcomes	LapTME (<i>n</i> = 39)	TaTME (<i>n</i> = 44)	<i>p</i> value
Type of surgery, <i>n</i> (%)			
Anterior resection	8 (20)	0 (0)	< 0.001*
Low anterior resection	31 (80)	0 (0)	
TaTME	0 (0)	44 (100)	
CRT- surgery, weeks, median (range)	12 (10–13)	12 (11–13)	0.287
Abdominal approach, <i>n</i> (%)			
Laparoscopy	39 (100)	36 (82)	0.014*
Laparotomy	0 (0)	4 (9)	
Robotic	0 (0)	4 (9)	
Anastomosis, <i>n</i> (%)			
Yes	33 (85)	41 (93)	0.294
No	6 (15)	3 (7)	
Anastomosis, type, <i>n</i> (%)			
Mechanical	30 (100)	34 (83)	0.018*
Hand-sewn	0 (0)	7 (17)	
ND/ NA	3/6	0/3	
Anastomosis, type, <i>n</i> (%)			
Side-to-end	18 (69)	21 (66)	0.999
End-to-end	8 (31)	10 (31)	
Ileoanal pouch-anal	0 (0)	1 (3)	
ND /NA	7/6	9/3	
Anastomosis distance from dentate line, mm, median (range)	40 (28–60)	20 (5–40)	0.005*
Specimen extraction site, <i>n</i> (%)			
LIF	12 (44)	6 (15)	0.020*
Pfannenstiel	15 (56)	32 (80)	
Transanal	0 (0)	2 (5)	
ND/ NA	12/ 0	4	
Operative morbidity, <i>n</i> (%)	0 (0)	3 (7)	0.244
Abdominal approach			
Pre-sacral bleeding	0	1	
Transanal approach			
Vaginal lesion	0	1	
Urethral lesion	0	1	
Stoma, <i>n</i> (%)			
No stoma	5 (13)	0 (0)	0.001*
Loop ileostomy	28 (72)	41 (93)	
Terminal colostomy	6 (15)	3 (7)	
Drains, <i>n</i> (%)			
Yes	25 (64)	20 (46)	0.089
No	14 (36)	24 (54)	
Blood loss, mL, median (range)	150 (100–200)	200 (100–300)	0.105
Operative time, minutes, median (range)	287 (246–320)	285 (255–338)	0.641

NA in “Anastomosis type” relates to nine patients that did not have an anastomosis, NA in “Specimen extraction site” relates to 4 TaTME patients that were converted to laparotomy

CRT chemoradiotherapy, LIF left iliac fossa, TaTME transanal total mesorectal excision, LapTME laparoscopic total mesorectal excision, ND not discriminated, NA not applicable

**p* value < 0.05

Table 4 Post-operative period and follow-up

Post-operative period	LapTME (<i>n</i> =39)	TaTME (<i>n</i> =44)	<i>p</i> value
Admission (days), median	7 (5–13)	7 (4–14)	0.976
30-day mortality, <i>n</i> (%)	2 (5)	0 (0)	0.218
30-day readmission, <i>n</i> (%)	3 (8)	5 (11)	0.721
Post-operative complications (treatment), <i>n</i> (%)			
No complications	19 (49)	26 (59)	0.178
Clavien–Dindo I	5 (13)	1 (2)	
Clavien–Dindo II	7 (18)	7 (16)	
Clavien–Dindo III	6 (15)	10 (23)	
Abdominal wall dehiscence (closure abdominal wall)	–	1	
Intra-abdominal bleeding (ligation of epigastric vessels)	1	–	
Intra-abdominal hematoma/ collection (drainage)	1	1	
Parastomal hernia (suture)	–	1	
Internal hernia (reduction)	1	–	
Small bowel injury (enterorrhaphy)	–	1	
Necrosis of colostomy (segmental resection)	1	–	
Anastomotic leak (Transanal drainage)	1	4	
(Transabdominal drainage)	–	1	
(End colostomy)	1	1	
Clavien–Dindo V	2 (5)	0 (0)	0.109
Small bowel perforation (segmental enterectomy)	1	–	
Anastomotic leak (colostomy)	1	–	
Overall anastomotic leak	3 (9)	7 (17)	0.326
Follow-up			
Ileostomy closure, <i>n</i> (%)			
Yes	24 (86)	36 (88)	0.999
No	4 (14)	5 (12)	
NA	11	3	
Adjuvant CT, <i>n</i> (%)			
Yes	23 (59)	21 (48)	0.380
No	16 (41)	23 (52)	

Leak defined according to International Rectal cancer Study Group [10] and complications classified according to Clavien–Dindo classification [11]

TaTME transanal total mesorectal excision, LapTME laparoscopic total mesorectal excision, AB antibiotic treatment, CT chemotherapy

non-related with the anastomosis (abdominal wall dehiscence, intra-abdominal hematoma, parastomal hernia and small bowel injury).

There were 3 (9%) anastomotic leaks in the lapTME group versus 7 (17%) in the TaTME group ($p=0.326$). All three patients in the lapTME group underwent surgical re-exploration with two end colostomies and one case of transabdominal drainage. There was a mortality case consequent to leak in an 81-year-old patient that, despite early re-intervention, developed irreversible multiorgan failure. In the TaTME group, 6 of 7 patients with anastomotic leak were re-operated, resulting in 1 end colostomy, 1 trans-abdominal and 4 cases of transanal drainage. Overall, 31 (94%) and 40 (98%) patients maintained their anastomosis in the lapTME and TaTME groups, respectively.

No differences were found regarding length of hospital stay, readmission rate, stoma closure and number of patients undergoing adjuvant therapy. By the final date of this study, 24 (86%) lapTME and 36 (88%) TaTME patients had had their ileostomies closed ($p=0.999$) (Table 4).

Oncological outcomes

Median follow-up time was 38 (range 24–63) and 40 (31–48) months in the lapTME and TaTME groups, respectively ($p=0.309$).

In the lapTME group, there was 1 (3%) case of LR at 16 months, in the presacral area in a patient with previous distant disease. There were 3 (8%) cases of distant progression (DP) after a median of 23 months in patients that

were initially in stage III. There were 5 (13%) deaths, 2 to complications of index surgery and 3 for non-oncological co-morbidities (vascular, hepatic, and cardiac insufficiency) (Table 5). Five-year OS and DFS were 86% (CI 0.753–0.983) and 86% (CI 0.721–1), respectively. Also, 5-year DPFS and LRFS were 86% (CI 0.721–1) and 96% (CI 0.890–1), correspondingly (Fig. 1).

In the TaTME group, there were 2 (5%) cases of LR at 8 and 22 months. Recurrences were presacral and anastomotic, respectively, with no pelvic sidewall pattern. The patient with a presacral recurrence had synchronous hepatic metastasis and a specimen with an incomplete mesorectum following a procedure with long operative time and an intraoperative urethral lesion. There were 8 (18%) cases of distant disease, one synchronous with LR and seven metachronous, after a median of 9 months. Patients who developed distant metastasis were initially in stage III. Metastatic disease involved the lung, liver, brain, bone, and inguinal nodes. In the TaTME group, there are five deaths, all related to distant disease progression (Table 5). Five-year OS and DFS were 87% (CI 0.765–0.984) and 81% (CI 0.699–0.938), respectively. Finally, 5-year DPFS and LRFS were 81% (CI 0.699–0.938) and 94% (CI 0.867–1), correspondingly (Fig. 1).

Overall, there were no differences between and TaTME groups related to mortality ($p=0.999$), LR ($p=0.999$), and DP ($p=0.204$). Likewise, cohorts presented similar 5-year OS, DFS, LRFS, and DPFS ($p=0.7$, $p=0.2$, $p=0.7$, and $p=0.2$, respectively) (Fig. 1).

Pathological outcomes

There were no differences between groups related to pathological stage, circumferential, proximal and distal margins, resectability, and specimen quality (Table 6). However, TaTME had a higher node yield (14 lapTME versus 20 TaTME, $p=0.002$).

Discussion

Despite the great advance in rectal surgery brought by lapTME in terms of short- and long-term outcomes, this technique can be very demanding, particularly in male patients with obesity and distal bulky tumors. In previous randomized controlled trials, lapTME for mid and low RC has been associated with a high rate of anastomotic leak, conversion to laparotomy, and incomplete TME specimens, with known deleterious oncological consequences [1, 10, 13, 14]. The difficulty relates to operating in the low pelvic compartment with restricted working space, limited vision and maneuverability.

Surgeons have tried to develop alternatives to overcome these problems and TaTME was introduced in 2010 to improve the pelvic approach [3]. The technique has several potential advantages, namely a better view of the prostate and rectovaginal septum with ability to decide whether to stay in front or behind Denonvillier's fascia in anterior tumors, better visualization of neurovascular bundles and pelvic floor muscles, reduced manipulation due to pneumorectum, and surgeon's definition of the appropriate distal

Table 5 Oncological outcomes

	LapTME ($n=39$)	TaTME ($n=44$)	p Value
Follow-up time, months, median (range*)	38 (24–63)	40 (31–48)	0.309
Local recurrence, n (%)	1 (3)	2 (5)	0.999
Pre-sacral	1	1	
Anastomotic	–	1	
Distant progression, n (%)	3 (8)	8 (18)	0.204
Lung	2	3	
Liver	1	3	
CNS + bone	–	1	
Inguinal node	–	1	
Overall mortality, n (%)	5 (13)	5 (11)	0.999
5y OS probability, % (CI)	86 (0.753–0.983)	87 (0.765–0.984)	0.7
5y DFS probability, % (CI)	86 (0.721–1)	81 (0.699–0.938)	0.2
5y DPFS probability, % (CI)	86 (0.721–1)	81 (0.699–0.938)	0.2
5y LRFS probability, % (CI)	96 (0.890–1)	94 (0.867–1)	0.7

TaTME transanal total mesorectal excision, LapTME laparoscopic total mesorectal excision, CNS central nervous system, OS overall survival, DFS disease-free survival, DPFS distant progression-free survival, LRFS local recurrence-free survival, CI confidence interval

*Interquartile range

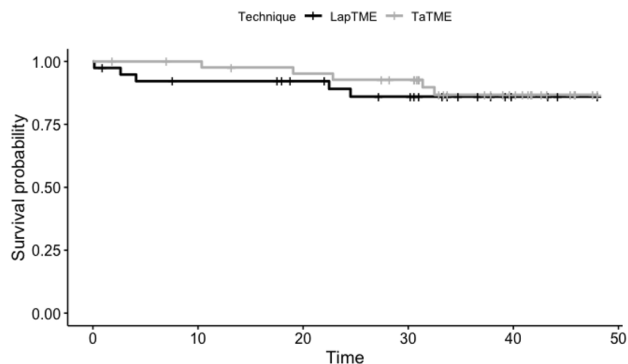
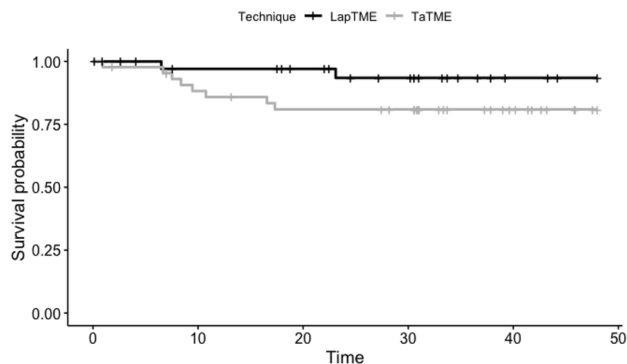
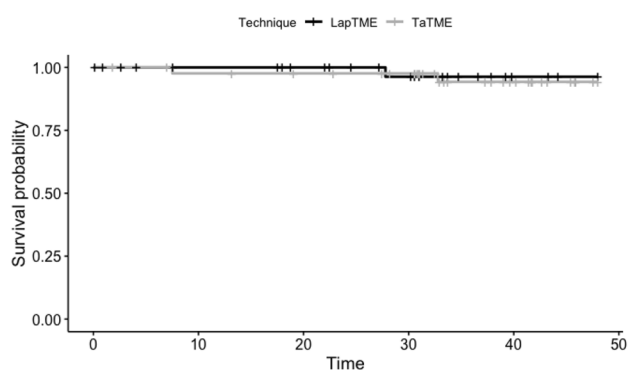
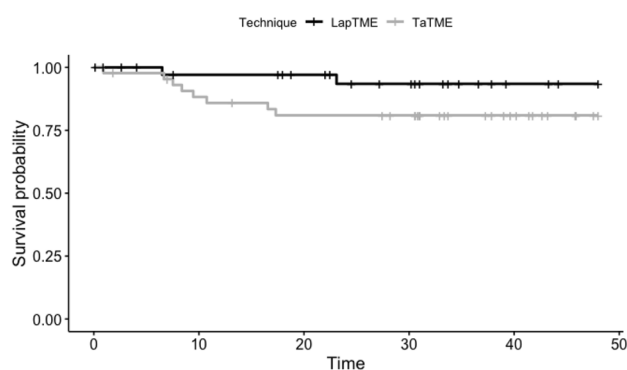
(a) Overall survival**(b) Disease-free survival****(c) Local recurrence-free survival****(d) Distant progression-free survival**

Fig. 1 Oncological outcomes of Kaplan–Meier curves for **(a)** overall survival (OS), **(b)** disease-free survival (DFS), **(c)** local recurrence-free survival (LRFS), and **(d)** distant progression-free survival (DPFS) according to the technique, TaTME: transanal total mesorectal excision, LapTME laparoscopic total mesorectal excision. There were no differences between groups related to 5-year OS ($p = 0.7$),

DFS ($p = 0.2$), LRFS ($p = 0.7$) and DPFS ($p = 0.2$). **a** LapTME 5-year OS was 86% (CI 0.753–0.983), **b** 5-year DFS was 86% (CI 0.721–1), **c** 5-year LRFS was 96% (CI 0.890–1) **d** 5-year DPFS was 86% (CI 0.721–1); **a** TaTME 5-year OS was 87% (0.765–0.984), **b** 5-year DFS was 81% (CI 0.699–0.938), **c** 5-year LRFS was 94% (0.867–1), **d** 5-year DPFS was 81% (CI 0.699–0.938)

margin [4, 15]. Potential gains from this technique are an easier dissection in the narrow male pelvis, a decrease in conversion, an increase in sphincter saving resections, better anastomotic techniques with subsequent lower morbidity, improved specimen quality and a decrease in surgical site infection [16–18]. Also, TaTME does not require stapling of the rectum distally to the tumor, avoiding imperfect firing (due to the limitation of staplers' 45° angulation), “dog ears” and crossing of staple lines. In classic laparoscopy, low pelvic tumors frequently need several staplings and this is known to be associated with anastomotic leak [19]. However, TaTME has specific challenges associated with the change in anatomic perspective and the demands of a single-port technique. Likewise, it also introduced new complications, not associated with the open or laparoscopic approaches, namely urethral injuries, carbon dioxide embolism, and reverse coning [20, 21].

TaTME was started in our Colorectal Unit in March 2016. Prior to the introduction of the technique, institutional

protocols and procedural guidelines were developed, and surgeons had hands-on courses, observation of live procedures, and didactic learning through *iLapp* platform, with the first cases performed mentored by international proctors.

Since our group had already studied the short-term outcomes [22], the aim of our present study was to analyze the long-term clinical and oncological outcomes of the learning curve of TaTME in our institution and to compare these outcomes to the ones of a historical group of patients treated with lapTME by the same surgeons.

In this study, TaTME and lapTME groups were comparable in terms of demographic and clinical characteristics with no differences in terms of sex, age, body mass index, PS, ASA class, baseline tumor characteristics, neoadjuvant therapy and subsequent response. Groups were also surgically comparable with the exception that in the TaTME group there were more hand-sewn anastomosis (0 lapTME versus 7 TaTME, $p = 0.018$), significantly less distance from the dentate line (40 mm lapTME versus 20 TaTME, $p = 0.005$)

Table 6 Pathological outcomes

	LapTME (n = 39)	TaTME (n = 44)	p Value
Stage, n (%)			
TxNOM0			
I	7 (18)	4 (9)	0.437
II	15 (40)	21 (48)	
III	6 (16)	4 (9)	
ND	10 (26)	15 (34)	
	1	–	
Resectability, n (%)			
R0	38 (97)	44 (100)	0.470
R1	1 (3)	0 (0)	
Specimen plane, n (%)			
Mesorectal	24 (77)	33 (75)	0.916
Intramesorectal	5 (16)	9 (21)	
<i>Muscularis propria</i>	2 (7)	2 (5)	
ND	8	0	
Proximal margin, n (%)			
Free	39 (100)	44 (100)	NA
Invaded	0	0	
Distal margin, n (%)			
Free	39 (100)	44 (100)	NA
Invaded	0	0	
CRM, n (%)			
Free	37 (95)	44 (100)	0.218
Threatened/Invaded	2 (5)	0	
Distal margin, mm, median (range)	26 (17–30)	23 (12–25)	0.365
Nodes, median (range)	14 (9–18)	20 (15–24)	0.002

Pathological staging according to the American Joint Committee on Cancer TNM Staging Classification for Rectal Cancer 8th ed., 2017. Specimen quality/mesorectal plane classified according to P. Quirke [9]

TaTME transanal total mesorectal excision, LapTME laparoscopic total mesorectal excision, CRM circumferential resection margin, ND not discriminated, NA not applicable

and significantly more loop ileostomies (28 lapTME versus 41 TaTME, $p = 0.001$) (Table 3).

So far, the literature shows that TaTME has short-term clinical outcomes similar or better than lapTME regarding conversion, anastomotic leak, distal and circumferential margins, mesorectal integrity, lymph-node yield, operative time, blood loss, morbidity, length of hospital stay and readmission rates [23–33]. Outcomes regarding function are still controversial, although most studies present comparable results [34–36].

In our study, we obtained similar early outcomes regarding length of stay, readmission rates, morbidity and overall leak rate. Anastomotic leak included early and late radiological and clinical leak, pelvic and perianastomotic abscess. Although not statistically different between cohorts (9% lapTME versus 17% TaTME, $p = 0.326$), the high anastomotic leak rate in the TaTME group was probably a consequence of this broad leak definition and the initial learning curve. Also, the lower ileostomy rate in the lapTME group might explain the fatal outcome of one anastomotic leak.

Regarding pathological outcomes, TaTME had significantly higher node sampling rate (14 lapTME versus 20

TaTME, $p = 0.002$) but there were no disparities between groups concerning stage, resectability, circumferential, proximal, distal margins and specimen integrity. Both techniques showed good quality specimens with appropriate margins and lymphadenectomies.

Although TaTME short-term clinical outcomes seem to be well established, inconsistencies remain regarding oncological outcomes and some authors have even reported disturbing results of early sidewall and multifocal pelvic cavity recurrence [37]. In this study, we did not experience these negative outcomes, which, in our opinion, may be due to the use of a non-standardized procedure, surgeons endorsing TaTME prior to being proficient in the technique or even technical differences between surgical teams. In fact, we still cannot fully comprehend the discrepancy of results between publications.

So far, very few studies that report on TaTME have a follow-up longer than 3 years. Marks et al. analyzed 373 patients who underwent a trans-abdominal transanal approach (TATA) with the abdominal dissection done via a pure transanal, laparoscopic, robotic or open approach. With 66 (range 0–300) months of mean follow-up, 5-year

LR was 7.4% and OS was 90% [38]. Recently, Hol et al. reported on 159 TaTME patients with 5-year 4% LR, 77% OS and 81% DFS [39]. Finally, in a trial with 100 patients randomly assigned to TaTME and lapTME, Denost et al. reported that there was no difference in 5-year LR or DFS between groups [40]. The fact that most other studies only report short-term oncological outcomes makes it impossible to draw definitive conclusions.

In our study, the lapTME group had 1 (3%) case of LR, happening at 16 months, in the presacral area in a patient with prior distant progression. In the TaTME group there were 2 (5%) cases of LR, presacral and anastomotic, none multifocal or in the pelvic sidewall. Overall, no differences were perceived regarding LR ($p=0.999$). In the lapTME group, 5-year OS and DFS were 86% (CI 0.753–0.983) and 86% (CI 0.721–1), respectively, similar to the 87% (CI 0.765–0.984) and 81% (CI 0.699–0.938) presented by the TaTME group. Also, lapTME 5-year LRFS and DPFS were 96% (CI 0.890–1) and 86% (CI 0.721–1), respectively, parallel to the 94% (CI 0.867–1) and 81% (CI 0.666–0.938) of the TaTME group. Overall, no differences occurred related to 5-year OS, DFS, LRFS, and DPFS ($p=0.7$, $p=0.2$, $p=0.7$ and $p=0.2$ respectively).

In this context, the question is no longer “can good results be obtained by gifted surgeons appropriately trained?” It has moved on to “can this technique be performed reliably, safely and with good outcomes by the average surgeon on the common patient?” Reflecting the learning curve of the technique, accepted to be 20 cases per surgeon [41], our results show similar pathological and oncological outcomes between lapTME and TaTME, in accordance to what has been the generalized perception of TaTME. It must be emphasized, however, that TaTME has a demanding learning curve and significant risk for morbidity. For its safe introduction, it is fundamental to understand the different anatomical perspective involved [42–45], to implement an intensive multimodal training with hands-on cadaver training and proctored application, to follow international guidelines and apply it to carefully selected patients [46, 47]. Also, it is imperative that surgeons are experienced not just in laparoscopy but also in single-port and low pelvic surgery. Finally, transparent scrutiny of the TaTME technique involves reporting one’s results, participating in ongoing multicenter randomized trials and in international Registries.

The main limitation of this work is its non-randomized methodology and also the non-inclusion of data regarding functional outcomes. Notwithstanding, the similarity observed between groups with respect to baseline characteristics emphasizes their comparability. Moreover, our follow-up is longer than what most studies have published so far.

Conclusions

Our study showed that the TaTME can produce long-term oncological safe outcomes, comparable to lapTME. Our results also reflect how demanding this new technique can be and the consequent need for a strict patient selection and proper learning curve. In our opinion, TaTME should not replace other established approaches to rectal surgery, but should be considered a new alternative to address difficult cases.

Author contributions SO: study conception and design, acquisition, analysis and interpretation of the data, drafting of the article, critical revision of the article for important intellectual content, and final approval of the article. MF: interpretation of the data, critical revision of the article for important intellectual content, and final approval of the article. PR: interpretation of the data, critical revision of the article for important intellectual content, and final approval of the article. RM: critical revision of the article for important intellectual content and final approval of the article.

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Availability of data and materials The datasets analyzed during the current study are available in the Hospital Beatriz Ângelo e Hospital da Luz informatics hospital database (Soarien), available from the corresponding author on reasonable request.

Code availability Not applicable

Declarations

Conflict of interest The authors declare no conflicts of interest or disclosures.

Ethical approval The present study was approved by the Ethics Committee and Institutional Review Board of Hospital Beatriz Ângelo and Hospital da Luz with no formal Informed consent required due to its methodology and anonymity. The study protocol was performed in accordance with the ethical standards of the 1964 Declaration of Helsinki and its later amendments.

Informed consent For this type of study formal consent is not required.

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