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Original Article

Transanal *versus* conventional total mesorectal excision for rectal cancer using the IDEAL framework for implementation

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Abstract

Background: Transanal total mesorectal excision (TaTME) is an innovative technique for distal rectal cancer dissection. It has been shown to have similar short-term outcomes to conventional open and laparoscopic total mesorectal excision (cTME), but recent studies have raised concern about increased morbidity and local recurrence rates. The aim of this study was to assess outcomes after TaTME *versus* cTME for rectal cancer.

Methods: TaTME was implemented in 2014 using IDEAL principles in a single institution. The institution maintains databases for all patients undergoing rectal cancer surgery. This retrospective review compared data collected from all patients who had TaTME with those from a propensity-matched cohort of patients who underwent cTME. The primary outcome was a composite pathological measure combining margin status and quality of total mesorectal excision (TME). Short-term clinical and survival outcomes were also measured.

Results: Propensity matching created 109 matched pairs for analysis. Nine patients (8.3 per cent) undergoing TaTME had positive margins and/or incomplete TME, compared with 11 (10.5 per cent) undergoing cTME ($P = 0.65$). There were no significant differences in morbidity between the TaTME and cTME groups, including number of anastomotic leaks (13.8 *versus* 18.3 per cent; $P = 0.37$). The estimated 3-year local recurrence-free survival rate was 96.3 per cent in both groups ($P = 0.39$). Estimated 3-year overall (93.6 per cent for TaTME *versus* 94.5 per cent for cTME; $P = 0.09$) and disease-free (88.1 *versus* 76.1 per cent; $P = 0.90$) survival rates were similar.

Conclusion: TaTME provided similar outcomes to cTME for rectal cancer with the application of IDEAL principles.

Introduction

Transanal total mesorectal excision (TaTME) is an innovative approach to distal rectal dissection that is particularly useful for low rectal cancer in selected patients. The approach has several potential benefits that may overcome well recognized challenges associated with conventional laparoscopic and open total mesorectal excision (cTME)[1]. Delineation of the distal resection margin (DRM), enhanced visualization of circumferential resection planes, and improved sphincter-sparing are all proposed advantages[1–3]. Initial reports[3,4] from expert centres and the international TaTME registry suggest the procedure has acceptable short-term perioperative and pathological features that are surrogates for long-term oncological outcomes. However, TaTME is a technically challenging procedure with a long learning curve[5,6]. Recent publications[7,8] have raised concern about the safety of TaTME with regard to local recurrence (LR), suggesting that surrogate features may not be adequate for assessment of safety. Similarly, new data from the TaTME registry[9] suggest that more widespread adoption may be associated with higher morbidity rates and less favourable outcomes than initially reported.

The association between innovative techniques such as TaTME and the potential for new complications and adverse outcomes is well established[10]. Thus, it is important to implement methods to ensure safe adoption and minimize risks to patients[10,11]. The IDEAL framework[10–13] was proposed to improve the systematic adoption and assessment of surgical innovation. IDEAL proposes that surgical innovation and evaluation should occur concurrently during the development process along pre-existing adoption curves. The IDEAL recommendations were introduced in 2009, and have become a widely accepted framework for the process and assessment of innovation[14,15]. However, specific use of the recommendations in reporting has remained poor. A recent systematic review[14] identified 522 unique papers with IDEAL citations, with only 38 publications explicitly using IDEAL principles in their study design and reporting.

With conflicting reports in the TaTME literature, the safety and long-term outcomes of the procedure have yet to be proven. As TaTME continues to move through its adoption curve, more data will be forthcoming. Recruitment is under way for the COLOR III trial[16], the first RCT to compare TaTME with laparoscopic total mesorectal excision (TME). Until robust data are

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available from randomized trials, ongoing assessment of non-randomized prospectively collected data can add to the understanding of TaTME outcomes. TaTME was first performed in 2014 at St Paul's Hospital (SPH) in Vancouver. The procedure was adopted carefully with a systematic approach using IDEAL framework principles. SPH presented a unique environment for the study of the programmatic adoption of TaTME into clinical practice, and the impact of this on patient outcomes. In this study, the early experience of patients undergoing TaTME at SPH using rigorous adherence to IDEAL principles was compared with results from a propensity-score matched cohort of patients with rectal cancer who had cTME.

Methods

TaTME was adopted into practice at SPH in October 2014. IDEAL principles were considered during each step of adoption and reporting. The procedure was performed by four colorectal surgeons, all of whom were proficient in advanced laparoscopic surgery for low rectal cancer and transanal endoscopic surgery before starting TaTME. All four surgeons participated in a proctored TaTME course before offering the procedure. Patient selection criteria and procedural methods were developed and agreed on between surgeons before instituting the procedure.

Patient selection and counselling

A systematic approach was used to select patients for TaTME. All patients referred with rectal cancer have been reviewed at existing multidisciplinary oncology rounds since 2014. Patient consideration and selection for TaTME was included and documented as a discussion point during rounds. Surgeon consensus on patient suitability for TaTME was required for the patient to be offered this procedure over conventional approaches. This decision was guided by the potential for patient benefit based on clinical factors (obesity, mid–low tumours, narrow pelvis, previous transanal excision), thereby selecting patients whose surgery was considered technically difficult from an abdominal approach. Decisions regarding neoadjuvant treatment were also determined at multidisciplinary rounds. Patients with cT1–T3 Nx low to mid rectal cancer were considered for TaTME; those with T4 disease or a threatened circumferential resection margin (CRM) were not eligible. Clinical T category and CRM status were assessed by MRI, and reviewed at multidisciplinary rounds for all patients. Patients offered TaTME were counselled before operation as part of the informed consent process regarding the novel nature of TaTME, and lack of data on long-term outcomes compared with cTME.

Intraoperative factors

TaTME procedures required two operating surgeons. The transanal portion of the operation was performed first, with both primary and secondary surgeons attending to the transanal dissection. A Transanal Endoscopic Microsurgery (TEM) Platform (Karl Storz, Tuttlingen, Germany) and ENDOmotion arm (Richard Wolf, Knittlingen, Germany) were used. This platform was used exclusively at SPH and all surgeons were experienced in its use for transanal endoscopic surgery before implementing TaTME. Purse-string closure of the rectum was followed by full-thickness proctotomy via the TEM port. Initial proctotomy followed by purse-string closure was performed if a low distal margin or intersphincteric dissection was required (generally for Rullier type II or III distal tumours)[17]. TaTME dissection was undertaken proximally until the anterior peritoneal reflection had been reached, or to a level at the discretion of the surgeons when it was felt best to proceed to the abdominal portion of the procedure owing to technical factors. The abdominal portion of the operation was then performed laparoscopically or via an open approach, followed by anastomosis and diverting ileostomy. Specimens were extracted transabdominally. Both surgeons were present for the anastomosis, which was done by a 28-mm end-to-end or side-to-end stapled technique where feasible. Hand-sewn anastomoses were fashioned when the distal margin was too low for stapled anastomosis. All patients who underwent TaTME received a diverting ileostomy. To ensure surgical quality, all TME specimens were photographed and the entire procedure video-recorded.

Data collection

Institutional ethics approval for this study was obtained from the University of British Columbia Research Ethics Board. SPH has maintained a database of all patients with rectal cancer undergoing surgery since 2006. Patients who had TaTME have been accrued in a separate database since 2014. A retrospective review of these databases was completed in May 2019, to compare data collected on patients who had TaTME with a propensity-matched cohort of patients who underwent cTME. In addition to routine surgical follow-up and surveillance, patients with rectal cancer at SPH have bi-yearly follow-up overseen by a nurse navigator. Standardized synoptic operative and pathology reports used for rectal cancer also assisted with data collection. All TaTME procedures were submitted to the international TaTME registry[2,4].

Outcomes

The primary outcome was a composite measure of surgical quality consisting of CRM, distal DRM, and completeness of TME. The outcome variable was selected during study design to assess whether there were differences in surgical quality provided to patients undergoing TaTME at SPH compared with those having cTME. This outcome variable has been used by other studies as a marker of adequate surgical resection[18]. Margins were considered involved if tumour cells were measured within 1 mm from the margin[19]. TME quality was measured as incomplete, near-complete or complete, in accordance with the Quirke grading system[20]. Completeness of TME was reviewed independently by a pathologist, and was included in the synoptic pathology report. A score of 1 was assigned if the patient had any one of: involved DRM, involved CRM, and/or incomplete TME. The score was 0 if the margins were clear and the TME was near-complete or complete. Secondary outcomes included: intraoperative events such as conversion to open surgery and urethral injuries, postoperative complications, overall in-hospital morbidity, duration of hospital stay, and 30-day mortality. Perioperative complications were graded according to the Clavien–Dindo classification, and included anastomotic leak (AL), venous thromboembolism, myocardial infarction, surgical-site infection, ileus, and urinary retention. AL was diagnosed by clinical and/or radiographic criteria. Long-term oncological outcomes, including LR, overall survival (OS), and disease-free survival (DFS) were captured and analysed.

Statistical analysis

Propensity scores were estimated for each patient using a multivariable logistic regression model. In the model, the treatment group was the dependent variable, and patient's age, BMI, sex, ASA fitness grade, tumour height, preoperative radiation, pT category, and operating surgeon were the independent variables.

All patients in the cTME and TaTME databases with sufficient available regression variable data were included for matching. Patients who had TaTME were matched to those having cTME using a 1 : 1 optimal matching algorithm, with a caliper of 0.25 standard deviations of the propensity score.

After matching, outcomes between groups were compared using McNemar's test for categorical variables and Wilcoxon signed-rank test for continuous variables. Kaplan–Meier curves for the two groups were constructed to estimated 3-year OS, DFS, and recurrence-free survival, and were compared using the log rank test.

Results

More than 30 TaTME procedures have been performed annually at SPH since 2016 (*Fig. 1*). At the time of propensity matching in June 2019, there were 484 patients from 2006 to 2019 in the cTME database, and 133 patients from 2014 to 2019 in the TaTME database. Of these, 300 patients in the cTME group and 114 patients in the TaTME group had sufficient data to be included for matching (*Table 1*). For both groups, there were no significant differences in the characteristics of patients with sufficient data for matching compared with all patients in the databases. Patient characteristics between the unmatched TaTME and cTME groups were similar in terms of age, sex, BMI, and ASA grade (*Table 1*). Before matching, tumours were on average lower and of less advanced pT category for TaTME than cTME. Patients in the TaTME group had higher rates of neoadjuvant treatment.

Propensity matching generated 109 matched pairs for analysis. Characteristics of the matched cohorts are shown in *Table 1*. Matching adequately adjusted for the differences between the two groups (*Table S1*). For example, there was an apparent

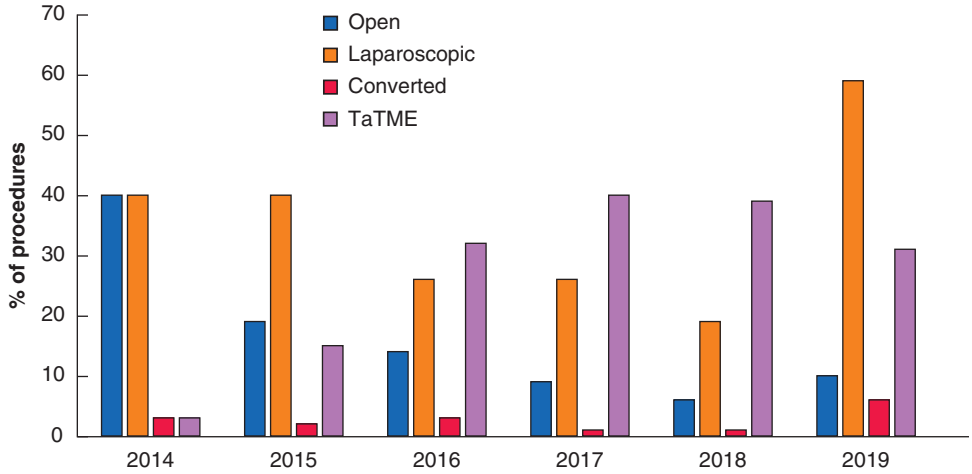

Fig. 1 Proportion of low anterior resections for rectal cancer performed by laparoscopic, converted, open and transanal total mesorectal excision approach at St Paul's Hospital by year

TaTME, transanal total mesorectal excision.

Table 1 Characteristics of patients in total cohorts and propensity-matched pairs

	Patients with complete data		Propensity-matched pairs	
	cTME (*n* = 300)	TaTME (*n* = 114)	cTME (*n* = 109)	TaTME (*n* = 109)
Age (years)*	62.0 (54.0–69.0)	62.5 (53.0–70.0)	62.0 (54.0–68.0)	63.0 (54.0–70.0)
Sex ratio (F : M)	109 : 191	38 : 76	34 : 75	36 : 73
BMI (kg/m^2)*	25.8 (22.7–28.6)	26.10 (23.7–29.9)	26.6 (23.2–30.9)	26.2 (23.8–29.9)
ASA fitness grade				
I	11 (3.7)	3 (2.6)	1 (0.9)	3 (1.8)
II	154 (51.3)	62 (54.4)	55 (50.5)	60 (55.0)
III	126 (42.0)	47 (41.2)	51 (46.8)	45 (109)
IV	9 (3.0)	2 (1.8)	2 (1.8)	2 (1.8)
Pathological tumour category				
pT0	24 (8.0)	27 (23.7)	20 (18.3)	25 (22.9)
pT1	26 (8.7)	11 (9.6)	9 (8.3)	11 (10.1)
pT2	82 (27.3)	27 (23.7)	32 (29.4)	27 (24.8)
pT3	142 (47.3)	36 (31.6)	43 (39.4)	34 (31.2)
pT4	22 (7.3)	2 (1.8)	1 (0.9)	2 (1.8)
pTx	4 (1.3)	11 (9.6)	4 (3.7)	10 (9.2)
Tumour height (cm)*	5.0 (3.0–7.0)	3.0 (2.5–4.0)	3.0 (2.0–4.0)	3.0 (2.5–4.0)
Radiotherapy				
No	143 (47.7)	39 (34.2)	30 (27.5)	38 (34.9)
Yes	157 (52.3)	75 (65.8)	79 (72.5)	71 (65.1)

Values in parentheses are percentages unless indicated otherwise; continuous variables are presented as the mean value (%)*values are presented as median (IQR),. cTME, conventional total mesorectal excision; TaTME, transanal total mesorectal excision.

decrease in the proportion of patients with T4 disease in the propensity-matched cTME group compared with the overall cTME cohort (0.9 per cent *versus* 7.3 per cent). Two patients in the TaTME group had tumours understaged by MRI and had pT4 tumours on final pathology.

There was no significant difference in the composite pathological outcome between TaTME and cTME (*Table 2*). In the TaTME group, nine patients (8.3 per cent) had a positive composite score compared with 11 (10.5 per cent) who had cTME ($P = 0.65$). The CRM was positive in three and six patients respectively (2.8 *versus* 5.5 per cent; $P = 0.32$). The DRM was positive in one patient in the TaTME group owing to a positive anastomotic doughnut, compared with four who had cTME (0.9 *versus* 3.7 per cent; $P = 0.18$). TME quality was incomplete in 10 TaTMEs and 16 cTMEs (9.2 *versus* 15.2 per cent; $P = 0.22$).

There were no significant differences in perioperative morbidity between groups (*Table 2*), and no 30-day mortality in either group. The overall morbidity rate was 45.8 per cent (50 of 109) for TaTME and 44.0 per cent (48 of 109) for cTME. There were no urethral injuries. The AL rate was 13.8 per cent (15 of 109) for TaTME and 18.3 per cent (20 of 109) for cTME. AL graded as Clavien–Dindo grade III or higher occurred after 8.3 per cent of TaTMEs and 10.1 per cent of cTMEs. Four of the 15 ALs after TaTME occurred within the first year after introduction the procedure. Clavien–Dindo grade III or higher AL requiring further intervention occurred in 11/20 TaTME AL and in 9/15 cTME AL. Seven patients who had TaTME returned to the operating room for further management, and two underwent percutaneous drain placement. Two patients were treated with antibiotics, and the remaining four were diagnosed with radiographic Clavien–Dindo I leaks.

Forty-one of 109 patients (37.6 per cent) had laparoscopic surgery in the cTME group compared with 99 of 109 (90.8 per cent) in the TaTME cohort. The procedure was converted to open surgery in seven of 106 patients (6.6 per cent) in the TaTME group and three of 44 (7 per cent) in the cTME group. The hospital stay was shorter for TaTME (*Table 3*). In analysis of laparoscopic matched pairs, duration of hospital stay remained significantly reduced by 1 day in the TaTME group.

There were no differences in survival outcomes between the two groups. Median follow-up was 1.3 (IQR 0.7–2.1) years for TaTME and 4.0 (IQR 2.2–6.1) years for cTME. Estimated 3-year OS rates from Kaplan–Meier curves were 93.6 per cent for TaTME and 94.5 per cent for cTME ($P = 0.09$), and DFS rates were 88.1 and 76.1 per cent respectively ($P = 0.90$) respectively (*Fig. 2*). The estimated 3-year LR-free survival rate was 96.3 per cent in both groups ($P = 0.39$). Characteristics of LRs after TaTME are summarized in *Table 4*. Three of the patients had synchronous local and distant recurrences. Two patients with LR experienced AL, and a third patient had a pelvic haematoma requiring percutaneous drainage. One patient had a positive CRM with near-complete TME, and another underwent incomplete TME.

Table 2 Outcomes for propensity-matched pairs

	cTME ($n = 109$)	TaTME ($n = 109$)	$P^{\dagger}$
Composite score			0.65
0	94 of 105 (89.5)	100 (91.7)	
1	11 of 105 (10.5)	9 (8.3)	
Missing	4	0	
Circumferential resection margin			0.32
Negative	103 (94.5)	106 (97.2)	
Positive	6 (5.5)	3 (2.8)	
Distal resection margin			0.18
Negative	105 (96.3)	108 (99.1)	
Positive	4 (3.7)	1 (0.9)	
TME quality			0.22
Complete*	89 of 105 (84.8)	99 (90.8)	
Incomplete	16 of 105 (15.2)	10 (9.2)	
missing	4	0	
Secondary outcomes			
Anastomotic leak			0.37
Yes	20 (18.3)	15 (13.8)	
No	89 (81.7)	94 (86.2)	
Clavien–Dindo grade			
I–II	9 (8.3)	6 (5.5)	
IIIa/b	11 (10.1)	9 (8.3)	
Surgical-site infection			0.13
Yes	15 (13.8)	8 (7.3)	
No	94 (86.2)	101 (92.7)	
Ileus			0.86
Yes	21 (19.3)	22 (20.2)	
No	88 (80.7)	87 (79.8)	
Urinary retention			0.13
Yes	6 (5.5)	12 (11.0)	
No	103 (94.5)	97 (89.0)	

Values in parentheses are percentages. *Includes total mesorectal excision (TME) specimens graded as complete or nearly-complete. cTME, conventional TME; TaTME, transanal TME. †McNemar's test.

Discussion

TaTME has several potential benefits over cTME, but remains technically challenging with a significant learning curve[5,9]. Similar to other surgical innovations, there is a risk of increased morbidity during adoption. Recent publications[7,8] have raised concern regarding high LR and complication rates with TaTME. In Norway, TaTME was associated with a six-fold increase in LR compared with cTME (LR 7.9 per cent for TaTME), with half of these patients presenting with multifocal pelvic recurrences not seen with cTME[8,21]. Van Oostendorp and colleagues[7] reported LR in 10 per cent of patients undergoing TaTME in the early phase of implementation. Similarly, most LRs were multifocal pelvic recurrences, despite a structured training programme and good pathological outcomes. However, many other series and data from the TaTME registry have shown TaTME to be safe, with clinical and pathological outcomes similar to those of cTME (*Table 5*)[4,8,22–32]. The largest TaTME series[24] to date assessing LR in 767 patients at six high-volume centres had a LR rate of 3.1 per cent. These findings have created much debate surrounding the safety of TaTME, how and when it should be performed, and what methods are available for safe adoption of the technique[33,34].

At SPH, TaTME provided equivalent outcomes to those of a propensity-matched group of patients who underwent cTME.

Table 3 Duration of hospital stay for all matched patients and those who had a laparoscopic procedure

	Duration of hospital stay (days)		P^{*}
	cTME	TaTME	
All matched pairs	9.0 (6.0–14.5)	6.0 (4.0–9.0)	< 0.001
n	108	109	
All laparoscopic procedures	6.0 (5.0–9.0)	6.0 (4.0–10.0)	0.08
n	41	99	
Laparoscopic matched pairs	6.0 (5.0–9.0)	5.0 (4.0–7.0)	0.050
n	41	41	

Values are median (i.q.r.). cTME, conventional total mesorectal excision; TaTME, transanal total mesorectal excision. *Wilcoxon signed-rank test.

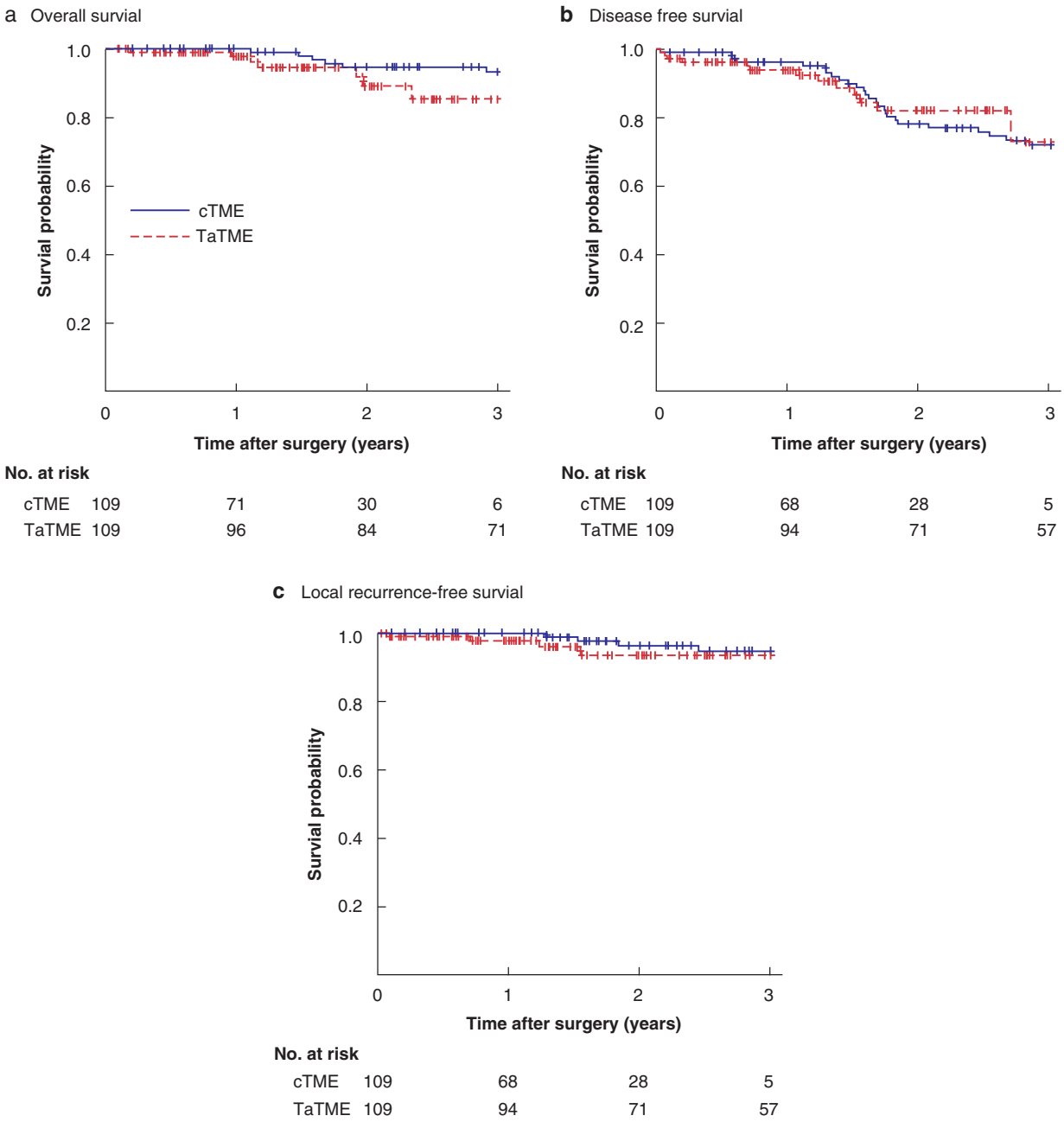

Fig. 2 Estimated 3-year survival outcomes for transanal and conventional total mesorectal excision surgery for rectal cancer at St Paul's Hospital

a Overall survival, **b** disease-free survival, and **c** local recurrence-free survival. cTME, conventional total mesorectal excision; TaTME, transanal total mesorectal excision. **a** $P = 0.09$, **b** $P = 0.90$, and **c** $P = 0.39$ (log rank test).

Table 4 Characteristics of local recurrences after transanal total mesorectal excision

Year of surgery	Distance from anal verge(cm)	pT	CRM	TME quality	nCRT	Anastomotic leak	Type of recurrence	Time to local recurrence (months)	Treatment	Status at end of study
2015	3	T3	+	Near-complete	Yes	Yes	Synchrono-us (lung)	19	Chemo-therapy	Lost to follow-up
2015	3	T3	–	Complete	No	No	Local	15	Chemo-therapy	Dead
2016	5	T3	–	Complete	Yes	No	Synchrono-us (bone, liver)	1	chemo-therapy	Dead
2017	3	T3	–-	Incomplete	Yes	Yes	Synchrono-us	9	chemo-therapy	Dead

CRM, circumferential resection margin; TME, total mesorectal excision; nCRT, neoadjuvant chemoradiation.

Table 5 Summary of short-term outcomes of published series of transanal total mesorectal excision

Reference	*n*	Study duration (months)	cT category	Distance from anal verge (cm)	Neoadjuvant treatment	Incomplete TME	Positive CRM	Positive distal margin Length (mm)	No. with local recurrence Follow-up (months)	Anastomotic leak
Atallah *et al.*[22]	20	32	cT2: 3 (15) cT3: 12 (60) cT4: 5 (25)	5 (1–9)*	17 (85)	3 (15)	1 (5)§	1 (5)§	0 6 (1–24)*	1 (7)
Buchs *et al.*[27]	40	24	≥ cT3: 23 (58)	3 (0–10)*	12 (30)	1 (3)	2 (5)	0 (0)	0 10.7*	3 (10)
Burke *et al.*[28]	50	41	T1: 1 (2) T2: 6 (12) T3: 35 (70) T4: 8 (16)	4.4 (3–6)†	43 (86)	1 (2)	2 (4)	1 (2)	4.0 15.1 (7–23)†	3 (7)
Fernandez–Hevia *et al.*[25]	37	17	T2: 8 (22) T3: 26 (72) T4: 2 (6)	Mid: 8.1 (2)‡ Low: 3.5 (1)‡	27 (73)	1 (3)	0 (0)	0 (0) 28(18)‡	n.r.	2 (5)
Hol *et al.*[26]	159	53	T1: 2 (1.3) T2: 39 (24.5) T3: 103 (64.8) T4: 11 (6.9)	5.7 (3.5)‡	112 (70.4)	4 (2.5)	1 (0.6)	0 (0)	6 (3.8) 54.8 (36–88)*	10 (6.3)
Lacy *et al.*[23]	140	37	T1: 2 (1.4) T2: 27 (19.3) T3: 90 (64.3) T4: 11 (7.9)	7.6 (3.6)‡	94 (67.1)	1 (0.7)	9 (6.4)	0 (0) 28(21)‡	3 (2.1) 15 (7.1–20.7)†	12 (8.6)
Kang *et al.*[31]	211	72	T1: 11 (5.2) T2: 56 (26.5) T3: 106 (50.2) T4: 29 (13.7)	5.9 (2.0)‡	58 (27.5)	3 (1.4)	5 (2.3)	0 (0) 1.9(0.9)‡	13 (6.2) 35 (2–86)*	17 (8.1)
Perdawood *et al.*[30]	100	22	T2: 56 (56.0) T3: 43 (43.0) T4: 1 (1.0)	7.5 (1.9)‡	18 (18.0)	14 (14.0)	7 (7.0)	0 (0) 25(14)‡	n.r.	6 (9.5)
Roodbeen *et al.*[24]	767	84	T1: 23 (3.0) T2: 196 (25.6) T3: 421 (54.9) T4: 52 (6.8)	3.0 (1–5)†	527 (68.7)	62 (8.1)	56 (7.3)	14 (1.8)	24 (3.1) 25.5 (15–39)†	n.r.
Rouanet *et al.*[29]	30	29	T1: 1 (3) T2: 1 (3) T3: 21 (70) T4: 7 (23)	1 (0–7)*	29 (97)	0 (0)	4 (13)	0 (0) 9 (3–40)*	4 (13) 21 (10–41)*	n.r.
Simó *et al.*[32]	100	59	T1: 20 (20.0) T2: 27 (27.0) T3: 50 (50.0) T4: 3 (3.0)	4.9 (1.3)‡	58 (58.0)	4 (4.0)	2 (2.0)	0 (0.0) 15 (5–24)†	2 (2.0) 24 (13–39)†	12 (12.0)
Wasmuth *et al.*[8]	157	48	n.r.	8.0 (2–13)†	33 (21.0)	n.r.	8 (5.1)	12 (7.6)¶	12 (7.9)	11 (8.4)

Values in parentheses are percentages unless indicated otherwise; values are *median (range), †median (i.q.r.), and ‡mean(s.d.). §Positive margin defined as 2 mm or less; all others used 1 mm or less.n, number of transanal total mesorectal excisions (TMEs) reported; n.r., not reported.

Pathological outcomes were favourable for TaTME, and the estimated 3-year LR-free survival rate was 96.3 per cent. However, other studies have highlighted that good pathological outcomes may not be reflective of actual LR rates[7]. Thus, more follow-up is required to establish the true LR rate and long-term outcomes of TaTME. Of note, there were no multifocal pelvic recurrences, and nearly all LRs after TaTME were associated with high-risk features such as positive margins, incomplete TME, or AL. The AL rate for TaTME was 13.8 per cent, which is similar to the rate of anastomotic failure in the TaTME registry (15.7 per cent of 1594 patients)[9]. This was not significantly different from the AL rate of 18.3 per cent in the propensity-matched cTME cohort. AL in the cTME cohort was much higher than the overall rate of AL in the SPH database, which was 5.4 per cent. Patients selected for TaTME at SPH are a subset at increased risk of AL by design. Furthermore, the definition of AL included lower-grade leaks. The rate of AL requiring intervention after TaTME was 8.3 per cent, which is within the acceptable range for rectal cancer, particularly for high-risk patients in the TaTME group[9]. Overall, four of the 15 ALs at SPH among patients who had TaTME occurred in the first year of implementation, consistent with evidence showing increased morbidity during the learning curve[5].

When instituting TaTME at SPH, criteria from the IDEAL framework were used to ensure systematic adoption, with stringent patient selection criteria, and methods to ensure surgical quality. Undertaking the perineal dissection first may have optimized the quality of dissection and ensured closure of the distal rectum before dissection of other planes. The presence of two operating surgeons for the perineal dissection likely contributed to favourable outcomes. The perineal dissection is the novel aspect of TaTME; collaboration and communication between two expert surgeons subjectively shortened the learning curve and mitigated the risk of surgery in the wrong plane. Similar to other technically challenging operations, TaTME may have better outcomes when performed at specialized high-volume centres. Surgical volumes for rectal cancer are associated with improved outcomes[35–37]. It seems logical that a challenging innovative approach like TaTME be restricted to high-volume, expert pelvic surgeons until long-term oncological equivalence is proven in principle. In series reporting suboptimal TaTME outcomes, procedure numbers at individual institutions have been low. Wasmuth *et al.* reported on four high-volume centres where TaTME volumes averaged fewer than 10 procedures per year[7,8]. No mention was given to assessment of surgical quality, and inclusion for TaTME had no specified selection criteria. Van Oostendorp and colleagues[7] looked at only the first 10 TaTME procedures at any institution. At four high-volume centres that performed more than 45 procedures, the LR rate dropped to less than 5 per cent after 10. The learning curve for TaTME has been shown to be upwards of 40 procedures, so it is possible that outcomes were related to lack of completion of the learning curve[5,7,38]. This highlights the need for structured training and proctoring when adopting TaTME[1,2]. Similar to laparoscopic colonic surgery, where early concerns were raised about port-site metastases and safety, these findings do not undermine TaTME as an important surgical advance in rectal cancer treatment[33,39].

There are several limitations to the present study. The results are from a single-institution cohort study and can be generalized only to other high-volume centres that employ a similarly rigorous IDEAL-driven adoption strategy. Robust short- and long-term data are needed to ensure the safety of TaTME, and will hopefully be forthcoming in randomized trials such as COLOR III[16]. In the interim, more prospective, appropriately case-matched cohort studies are needed to critically assess the safety and efficacy of TaTME. Studies should report on strategy for TaTME implementation, as it is clear that these factors contribute to outcomes and understanding of the safety of this new procedure. Although the inherent biases of observational cohort studies apply to this work, the reporting of the implementation process, along with use of propensity score matching to ensure these difficult procedures have an appropriate comparator group, is consistent with the recommendations of the IDEAL framework[12].

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Supplementary material

Supplementary material is available at *BJS Open* online.

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