Transanal Total Mesorectal Excision

International Registry Results of the First 720 Cases

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Objective: This study aims to report short-term clinical and oncological outcomes from the international transanal Total Mesorectal Excision (taTME) registry for benign and malignant rectal pathology.

Background: TaTME is the latest minimally invasive transanal technique pioneered to facilitate difficult pelvic dissections. Outcomes have been published from small cohorts, but larger series can further assess the safety and efficacy of taTME in the wider surgical population.

Methods: Data were analyzed from 66 registered units in 23 countries. The primary endpoint was ''good-quality TME surgery.'' Secondary endpoints were short-term adverse events. Univariate and multivariate regression analyses were used to identify independent predictors of poor specimen outcome.

Results: A total of 720 consecutively registered cases were analyzed comprising 634 patients with rectal cancer and 86 with benign pathology. Approximately, 67% were males with mean BMI 26.5 kg/m^2. Abdominal or perineal conversion was 6.3% and 2.8%, respectively. Intact TME specimens were achieved in 85%, with minor defects in 11% and major defects in 4%. R1 resection rate was 2.7%. Postoperative mortality and morbidity were 0.5% and 32.6% respectively. Risk factors for poor specimen outcome (suboptimal TME specimen, perforation, and/or R1 resection) on multivariate analysis were positive CRM on staging MRI, low rectal tumor <2 cm from anorectal junction, and laparoscopic transabdominal posterior dissection to <4 cm from anal verge.

Conclusions: TaTME appears to be an oncologically safe and effective technique for distal mesorectal dissection with acceptable short-term patient outcomes and good specimen quality. Ongoing structured training and the upcoming randomized controlled trials are needed to assess the technique further.

Keywords: poor histological outcomes, rectal cancer, registry, risk factors, transanal total mesorectal excision

(*Ann Surg* 2017;266:111–117)

Colorectal cancer is the third most common cancer in the world.[1] Rectal cancer in particular poses unique challenges and major changes have occurred over the past few decades. The gold standard approach to rectal cancer surgery is total mesorectal excision (TME) as popularized by Heald in 1979.[2] Neoadjuvant therapy and accurate dissection along the fascia propria obtaining intact mesorectum with negative distal (DRM) and circumferential resection margins (CRM), can improve local recurrence rate and cancer-free survival.[3–5] Oncological benefits were originally shown with open surgery.[4–7] After increasing adoption of laparoscopy, randomized controlled trials (RCT) showed largely equivalent outcomes.[6,7] However, two recent RCTs, ACOSOG Z6051[8] and ALaCaRT,[9] failed to show noninferiority of laparoscopy compared with open surgery for oncological outcomes. Patient-related factors predicting intraoperative difficulty and potentially increased risk of local recurrence include male sex, high body mass index (BMI), visceral obesity, and a narrow pelvis.[10] Bulky tumors and advanced T-stage have also been identified as risk factors for a positive CRM.[11] These anatomical features pose technical challenges during both laparoscopic and open surgery, with

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Disclosure: The TaTME registry was funded by the Pelican Cancer Foundation, UK. The Oxford Colon Cancer Trust (OCCTOPUS) is funding Marta Penna's research post. Ethical approval for the taTME registry and publication of its results was obtained from the UK Health Research Authority (REC reference 15/LO/0499, IRAS project ID 156930). The authors declare no conflicts of interest.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.annalsofsurgery.com).

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ISSN: 0003-4932/16/26601-0111
DOI: 10.1097/SLA.0000000000001948

poor visualization of mesorectal planes and difficult introduction of instruments into a narrow pelvis; increasing the risk of an incomplete mesorectal excision and poor oncological outcomes. High conversion rates have also been reported for laparoscopy—16% and 11.3% in COLOR II[7] and ACOSOG Z6051[8] trials, respectively—indicating technical challenges of achieving a successful laparoscopic TME.

Transanal approaches to pelvic dissection have attracted attention with expectations to improve clinical, oncological, and functional outcomes by providing better visualization and more accurate distal TME dissection. Transanal TME (taTME) is not a completely new concept, but rather, an amalgamation of important surgical techniques; transanal endoscopy microsurgery (TEM),[12] transabdominal transanal (TATA) approach,[13] and transanal minimally invasive surgery (TAMIS).[14] Since Sylla and Lacy reported their early experience in 2010,[15] numerous case series have been published, showing encouraging results in terms of safety and efficacy of taTME.[16–18]

The aim of the current study is to report short-term outcomes of initial cases reported on the international taTME registry.[19] These data give insight into the experience with this new technique in everyday practice from a wide community of rectal surgeons across the globe.

METHODS

The taTME Registry

The registry is a secure online database funded by Pelican Cancer Foundation[19] and accessed via the Low Rectal Cancer Development (LOREC) website (http://www.lorec.nhs.uk). Registration is voluntary and surgeons performing taTME worldwide are invited to join. The dataset collected consists of nine sections: patient demographics, staging and neoadjuvant treatment, operative details, postoperative clinical and histological outcomes, readmissions details, late morbidity, and long-term oncologic follow-up. Ethical approval for the registry and publication of results was obtained from the UK Health Research Authority (REC reference 15/LO/0499, IRAS project ID 156930).

Study Design and Patient Population

Cases registered between July 2014 and December 2015 were analyzed. These results were recorded in 66 surgical units from 23 different countries (Appendix 1, http://links.lww.com/SLA/B80). Three months before data analysis, registered surgeons were invited via email to update their records with two subsequent reminders to minimize missing data. Surgeons were individually contacted to clarify unexpected or possibly erroneously entered results. Data were gathered on rectal cancer and benign cases that underwent taTME. Data from cancer cases focused on preoperative staging, neoadjuvant treatment and histopathological results. Definitions of variables and outcomes are outlined in Appendix 2, http://links.lww.com/SLA/B80. Missing data did not exceed 15% for each variable and percentages shown represent data available excluding missing values. The primary endpoint of the study was ''good-quality TME surgery'' defined as a TME dissection that was classed as intact or with minor defects and with clear CRM and DRM (R0 resection). Quality of the TME specimens was categorized using descriptions by Quirke et al.[20] Secondary endpoints included short-term patient and procedure-related adverse events.

Statistical Analysis

Categorical data are presented as number of cases and percentages, whereas continuous data are shown as either mean ± standstandard deviation (range) or median with range. Univariate and multivariate analyses were performed to identify possible risk factors associated with poor histological features (composite of R1 resection and poor TME/perforated specimen). Dependent variables were subdivided into patient-related, tumor-related, and technical risk factors. Univariate analysis comparing categorical variables was performed using the Pearson χ^2 test, and continuous variables were analyzed using Mann-Whitney U test. Multivariate analysis was subsequently performed using logistic binary regression for variables that achieved a $P \leq 0.100$ on univariate analysis. On multivariate analysis, $P < 0.05$ was considered statistically significant. The Statistical Package for Social Sciences (SPSS) of IBM Statistics, version 20, was used for the statistical analysis.

RESULTS

A total of 720 cases were recorded on the taTME registry during an 18-month period. Caseload distribution was as follows: 0–5, 6–10, 11–20, and >20 cases in 33 (50%), 12 (18%), 8 (12%), and 13 (20%) units, respectively. The indication for surgery was rectal cancer in 634 cases (88.1%), whereas 86 patients (11.9%) had benign pathology. Patients' characteristics are outlined in Table 1.

Cancer Cases: Preoperative Staging and Neoadjuvant Therapy

Preoperative tumor characteristics and neoadjuvant therapy are outlined in Table 2. Low rectal cancer, ≤6 cm from anal verge, accounted for 62% of cases. Mid (7–10 cm) or high (>10 cm) rectal cancer was present in 37% and 1%, respectively. Preoperative MRI revealed threatened (CRM) in 115 cases (21.1%); 8.3% showed nodal involvement, 11% tumor involvement, and 1.8% both nodal and tumor involvement. Baseline MRI staged 185 (33.1%) as T1–T2 rectal cancer, 343 (61.4%) T3, and 31 (5.5%) T4 cancer. Nodal status was reported as N0, N1, and N2 in 232 (41.8%), 221 (29.8%), and 102 (18.4%) cases, respectively. Synchronous metastatic disease was present in 40 patients (6.6%).

TABLE 1. Patient Characteristic

Patient Characteristic	TaTME Registry Data Results
Factor	**Total: 720 Cases**
Sex, n (%)	
Males	489 (67.9)
Females	231 (32.1)
Age in years, mean ± SD (range)	62.4 ± 13.0 (18–91)
ASA score, median (range)	2.0 (1–4)
BMI in kg/m^2, mean ± SD (range)	26.5 ± 4.3 (16.5–42.7)
Smoking, n (%)	
Smoker	90 (12.5)
Nonsmoker	630 (87.5)
Presence of comorbidities, n (%)	
Diabetes mellitus	85 (11.8)
Ischemic heart disease	97 (13.5)
Active inflammatory bowel disease	42 (5.8)
Steroid use at time of surgery	13 (1.8)
Previous abdominal surgery, n (%)	
Non-cancer related surgery	134 (19.0)
Hysterectomy	23 (3.2)
Prostatectomy	12 (1.7)
Laparoscopic ventral mesh rectopexy	1 (0.1)
Previous pelvic radiation therapy, n (%)	15 (2.1)

ASA indicates American Society of Anesthesiologists; BMI, body mass index; SD, standard deviation.

TABLE 2. Cancer Cases: Preoperative Staging and Neoadjuvant Therapy

Preoperative Staging Factor	TaTME Registry Data Results Total: 634 Cancer Cases
Clinical tumor height from anal verge on rigid sigmoidoscopy in cm, median (range)	6.0 (0–13)
Tumor height from anorectal junction on MRI in cm, median (range)	3.0 (0–11)
Predominant tumor location, n (%)	
Anterior	243 (43.3)
Posterior	233 (41.5)
Lateral	85 (15.2)
Missing	73 (11.5)
Circumferential extent of tumor, n (%)	
1 to 2 quadrants	399 (70.1)
3 to 4 quadrants	170 (29.9)
Missing	65 (10.3)
Preoperative MRI staging, n (%)	
≥T3	374 (66.9)
N+	323 (58.2)
Preoperative CRM involvement on MRI, n (%)	115 (21.1)
Neoadjuvant therapy	
Received neoadjuvant therapy, n (%)	355 (57.1)
Short course radiotherapy	56 (15.8)
Long course chemoradiotherapy	255 (71.8)
Long course radiotherapy alone	27 (7.6)
Chemotherapy alone	48 (13.5)
Contact radiotherapy	1 (0.3)
TRG response post neoadjuvant therapy, n (%)	
mTRG 1 & 2 (No or small residual tumor)	136 (38.3)
mTRG 3 (Mixed fibrosis and tumor)	103 (29.0)
mTRG 4 & 5 (Mainly or only tumor)	116 (32.7)

CRM indicates circumferential resection margin; MRI, magnetic resonance imaging; N+, positive nodal status (N1 or N2); TRG, tumor regression grading on MRI.

Percentages for missing values use the total number of cancer cases as the denominator (ie, 634). Percentages for the variables are calculated out of the total number of actual results available excluding the missing values.

Operative Details

A total of 634 cancer and 86 benign taTME operations were performed. Table 3 outlines operative features.

Abdominal Phase

A minimally invasive approach was adopted for the abdominal phase in 650 (96.9%) patients, with splenic flexure mobilization in 72%. In cancer resections, the anterior extent of pelvic dissection in males reached the pouch of Douglas (POD), seminal vesicles and prostate in 53%, 38%, and 9%, respectively. In female patients, most surgeons (67%) terminated anterior dissection at the POD, whereas the lowest level reached was mid-vagina in 7.1% of cases. Posterior abdominal TME dissection in cancer cases reached a level of 8 to 10 cm, 5 to 7 cm, and <5 cm from anal verge in 56%, 31%, and 13%, respectively. In benign cases, pelvic dissection was continued to a lower level more frequently: 42% to POD, 53% seminal vesicles, and 5.6% down to the prostate level. Female anterior dissection reached mid-vagina in 8%, but most surgeons (68%) stopped at the POD. Posterior dissection reached 8 to 10 cm, 5 to 7 cm, and <5 cm from anal verge in 44%, 36%, and 20% of cases, respectively. A defunctioning stoma was created in 538 patients (91%) who underwent anterior resection with primary anastomosis.

TABLE 3. Operative Details

Operative Characteristic Factor	TaTME Registry Data Results n (%)	
Total number of cases	720	
Indication		
Benign	86 (11.9)	
Cancer	634 (88.1)	
Operations performed		
Cancer cases:		
High anterior resection	30 (4.8)	
Low anterior resection	537 (86.2)	
Abdominoperineal excision	14 (2.2)	
Intersphincteric APE	42 (6.8)	
Missing	11 (1.7)	
Benign cases		
Low anterior resection	3 (3.7)	
Standard APE	4 (4.9)	
Intersphincteric APE	48 (58.5)	
Proctectomy (close rectal) + IPAA	3 (3.7)	
Proctectomy (TME plane) + IPAA	24 (29.2)	
Missing	4 (4.7)	
Simultaneous abdominoperineal operating	227 (32.3)	
Surgical approach		
Abdominal phase		
Open	21 (3.1)	
Laparoscopic	553 (82.4)	
SILS	93 (13.9)	
Robotic	4 (0.6)	
Missing	49 (6.8)	
Transanal phase	Benign	Cancer
Mucosectomy	3 (3.9)	49 (8.2)
Total intersphincteric	29 (28.2)	37 (6.2)
Partial intersphincteric	2 (2.6)	120 (20.0)
Pursestring	40 (52.6)	375 (62.5)
Other*	2 (2.6)	19 (3.2)
Missing	10 (11.6)	34 (5.4)
Conversion		
Abdominal	40 (6.0)	
Perineal	20 (2.8)	
Stoma		
No stoma	51 (7.3)	
Ileostomy	580 (83.3)	
Colostomy	65 (9.3)	
Missing	24 (3.3)	
Specimen extraction site		
Pfannenstiel	99 (14.7)	
Umbilical	61 (9.0)	
Right or left iliac fossa	75 (11.1)	
Transanal	340 (50.4)	
Other†	92 (13.6)	
Missing	53 (7.4)	
Anastomotic technique	Benign	Cancer
Manual	3 (13.6)	249 (44.7)
Stapled	19 (86.4)	308 (55.3)
Missing	8 (26.7)	10 (1.8)
Height of anastomosis from anal verge in cm, median (range)	Benign	Cancer
Manual	2 (1–4)	3 (0–5)
Stapled	4 (2–6)	4 (0–10)
Operative time in minutes, mean ± SD (range)		
Total operative time	277 ± 83 (62–685)	
Perineal phase time	128 ± 70 (15–467)	
Intraoperative adverse events		
Technical problems	283 (39.3)	
Incorrect dissection plane	56 (7.8)	
Pelvic bleeding	50 (6.9)	

TABLE 3. (*Continued*)

Operative Characteristic Factor	TaTME Registry Data Results n (%)
Visceral injury	11 (1.5)

APE indicates abdominoperineal excision; IPAA, ileal pouch-anal anastomosis; SD, standard deviation; SILS, single incision laparoscopic surgery; TME, total mesorectal excision.

*Other transanal phase surgical approaches include extralevator dissection and abdominoperineal excision.

†Other sites of specimen extraction: Single port incision (n = 44, 6.1%), midline laparotomy incision (n = 40, 5.6%), and previous stoma site (n = 8, 1.1%).

Percentages for Missing values use the total number of cases as the denominator (ie, 720). Percentages for the variables are calculated out of the total number of actual results available excluding the missing values.

Perineal Phase

Rigid and flexible transanal access platforms were used in 14.4% and 85.6%, respectively. A rectal purse-string technique was adopted before full rectotomy in the majority of cancer and benign cases, 62.5% and 52.6%, respectively. Median purse-string height from anorectal junction was 4.0 cm (range = 0–9) in cancer cases and 4.0 cm (range = 0–7) in benign cases. Anterior dissection in males was performed anterior to Denonvilliers fascia in 66.7% of patients with an anterior tumor.

Bowel anastomosis was performed manually in 252 cases (43.6%) and stapled in 327 cases (56.5%). In cancer cases with a stapled anastomosis, the configuration was side-to-end, end-to-end, colonic-J-pouch, and ileal pouch-anal anastomosis (IPAA) in 49.2%, 46.9%, 3.3%, and 0.7% of cases, respectively. The stapler diameters used were 28/29 mm in 30.6%, 31 mm in 12.4%, and 33 mm in 57% of cases. For manual anastomoses in cancer patients, configurations performed included end-to-end, side-to-end, colonic-J-pouch, and IPAA in 67.9%, 27.3%, 4.4%, and 0.4%, respectively. In benign cases, side-to-end or IPAA were performed in 10.5% and 89.5% of stapled cases. Three different stapler diameters were used: 28 mm (5.3% cases), 29 mm (73.7%), and 31 mm (21.1%). Manual anastomosis configurations recorded for 3 benign cases were one end-to-end and two IPAA.

Adverse Events

Intraoperative Difficulties and Complications

Abdominal conversion (Appendix 2, http://links.lww.com/SLA/B80) occurred in 40 cases (6.3%): strategic conversion in 31 cases and reactive in 9 cases. Significant adverse events reported during the abdominal phase included two ureteric transections, iatrogenic enterotomy on insertion of a laparoscopic instrument, splenic injury, and bladder injury during simultaneous laparoscopic hysterectomy for myomatosis.

Perineal conversion (Appendix 2, http://links.lww.com/SLA/B80) to a more extensive abdominal dissection was required in 20 cases (2.8%): strategic and reactive conversions in 11 and 9 cases, respectively. There were 4 cases (0.6%) of reported failure of the pursestring, with leakage, requiring a repeat pursestring. Problems encountered during perineal dissection included difficulty maintaining a stable pneumopelvis (15.6%), excessive smoke obscuring the view (21.9%), incorrect planes (7.8%), and problematic pelvic bleeding difficult to control (6.9%). Visceral injuries during perineal dissection included 5 urethral injuries (0.7%), 2 bladder injuries (0.3%), 1 vaginal perforation (0.1%), 1 unilateral resection of hypogastric nerves (0.1%), and 2 rectal tube perforations (0.3%). Intraoperative blood loss of <100 mL occurred in 61.2%, with 6 cases (1%) losing more than 1 litre.

Postoperative Clinical Outcomes

Table 4 outlines the short-term outcomes with overall postoperative mortality rate of 2.4% (n = 17) and morbidity rate of 32.6% (n = 213). All deaths occurred in cancer patients, three of which occurred during index admission. Median time of death after surgery was 248 days (range 4–1857 days). Specific causes of death were not recorded, but categorized as cancer-related (n = 6), not cancer related (n = 5), postoperative (n = 3), or unknown (n = 1) with 2 missing results.

Anastomotic leaks were recorded in 40 cases (6.7%); 32 (5.4%) cases were identified early, the remaining 8 cases identified at a later stage (>30 days). Surgical or radiological reintervention was required in 14 (44%) of the 32 patients, and 10 (31%) of these patients required unplanned readmission. An abdominal or pelvic abscess was recorded in an additional 17 patients without evidence of anastomotic leak.

Unplanned surgical or radiological interventions were required in 66 (10.1%) patients. Reoperations during the index admission included 3 laparotomies for ischemic left colon, 1 laparotomy for fecal peritonitis, 3 examinations under anesthesia for anastomotic leak, 2 evacuations of hematoma, 1 negative laparotomy for severe sepsis on day 1 postresection, 1 incarcerated hernia repair, and 1 case requiring bilateral fasciotomies for compartment syndrome.

Fifty patients (6.9%) had unplanned readmissions into hospital. Thirty (60%) readmitted patients were treated either conservatively or medically for general malaise, abdominal pain, high stoma output with acute kidney injury, pulmonary embolism, prolonged ileus, and delayed anastomotic leak diagnosed during chemotherapy. Fifteen patients underwent a surgical intervention during their readmission: 1 laparotomy for small bowel obstruction requiring small bowel resection, 1 laparotomy for a coloplasty leak 1 parastomal hernia repair, 1 drainage of a perineal abscess, 1 abdominal wound debridement, 1 pull-through procedure for anastomotic leak, and 9 examinations under anesthesia; with resuturing of partial anastomotic dehiscence (3 cases), redo of coloanal

TABLE 4. Post-operative Short-term Clinical Outcomes

Postoperative Clinical Outcomes Factor	TaTME Registry Data Results Total: 720 Cases
Length of hospital stay in days, median (range)	8.00 (2–97)
Postoperative morbidity at 30 days, n (%)	213 (32.6)
Clavien-Dindo classification at 30 days, n (%)	
I or II	142 (21.7)
III	66 (10.1)
IV	5 (0.8)
V	3 (0.5)
Missing	68 (9.4)
Overall Mortality Rate*, n (%)	17 (2.4)
Pelvic sepsis, n (%)	
Anastomotic leak:	
Early	32 (5.4)
Delayed	8 (1.3)
Intraabdominal / pelvic abscess	17 (2.4)
Surgical reinterventions	44 (6.1)
Unplanned hospital readmissions	50 (6.9)

*Overall mortality rate refers to reported deaths occurring at any time point during the study period.

anastomosis (1 case), dilatation of a strictured handsewn anastomosis (1 case), placement of endo-VAC therapy (2 cases) for pelvic abscess and chronic presacral sinus, transanal lavage of the presacral collection after anastomotic dehiscence (1 case), or no further action (1 case). The remaining 5 readmitted patients underwent radiologically guided drainage of pelvic collections.

Histopathological Results

A total of 634 (88%) cancer cases were analyzed. Table 5 outlines key pathological outcomes. R0 resection was obtained in 97.3% of cases. Sixteen cases (2.7%) were reported as R1 because of positive DRM, positive CRM by tumor, and positive CRM by an adjacent malignant lymph node in 2 (0.3%), 10 (1.7%), and 4 (0.7%) cases, respectively. A poor TME specimen was reported in 24 (4.1%) cases. Twelve specimens were found to have a rectal tube perforation but only 6 of these were recorded as poor TME specimens. Although the perforation was not necessarily at the tumor site or through the mesorectum, we have included all rectal perforations into the ''poor TME specimen'' category for further analysis.

Risk Factors for a Poor Pathological Composite Outcome: Univariate and Multivariate Analysis

R1 resections were combined to those with a poor TME specimen to form a composite endpoint of poor pathological features (n = 44, 7.4%). Possible risk factors were divided into patient-related, tumor-related, and technical variables. On univariate analysis, the following factors achieved a $P \leq 0.100$. Patient-related factors: none; tumor-related factors: (i) tumor height from anorectal junction, (ii) tumor location, (iii) preoperative T-staging on MRI, (iv) positive CRM on preoperative MRI, (v) metastatic disease on staging CT, (vi) neoadjuvant long course radiotherapy. Technical factors: (i) simultaneous abdomino-perineal operating, (ii) anterior resection versus abdomino-perineal excision (APE), (iii) abdominal and perineal conversion, (iv) blood loss over 1 L, (v) extent of posterior pelvic dissection abdominally, and (vi) total transanal operative time.

Multivariate analysis identified three statistically significant risk factors (Table 6). Poor pathological features are more likely to occur when the posterior pelvic dissection performed by the abdominal ''top-down'' approach extends to less than 4 cm from the anal verge. Lower tumors, with a tumor height of $\leq$2 cm from the anorectal junction, and preoperative positive CRM on staging MRI significantly increase the risk of obtaining a poor histological outcome.

TABLE 5. Histopathological Data

Histopathological Data Factor	TaTME Registry Data Results
Total number of cancer cases	634
Pathological T stage, n (%)	
T0	82 (14.1)
T1	70 (12.1)
T2	197 (34.0)
T3	222 (38.3)
T4	9 (1.6)
Missing	54 (8.5)
Pathological N stage, n (%)	
N0	406 (69.2)
N1	122 (20.8)
N2	59 (10.1)
Missing	47 (7.4)
Quality of TME specimen, n (%)	
Intact	503 (85.0)
Minor defects	65 (11.0)
Major defects	24 (4.1)
Rectal perforation	12 (2.0)
Missing	42 (6.6)
Number of lymph nodes harvested	
Mean ± SD	16.5 ± 9.2
Median (range)	15 (0–70)
Maximum tumor size in mm	
Mean ± SD	27.6 ± 16.7
Median (range)	25 (0–95)
Distal margin in mm	
Mean ± SD	19.0 ± 14.3
Median (range)	15 (0–97)
Positive DRM, n (%)	2 (0.3)
Missing	45 (7.1)
Circumferential resection margin in mm	
Mean ± SD	9.19 ± 8.6
Median (range)	8 (0–90)
Positive CRM, n (%)	14 (2.4)
Missing	45 (7.1)
Composite poor pathological outcome	
R1 + poor TME specimen	44 (7.4)
Missing	42 (6.6)

CRM indicates circumferential resection margin; DRM, distal resection margin; SD, standard deviation; TME, total mesorectal excision.

Percentages for Missing values use the total number of cancer cases as the denominator (ie, 634). Percentages for the variables are calculated out of the total number of actual results available excluding the missing values.

DISCUSSION

The taTME registry is an international database with strong collaboration among 66 surgical units in 23 different countries. The current study reports the initial 720 taTME cases recorded, which represent the largest patient cohort published to date. Low anterior resection was performed in 77% of cases with most surgeons adopting a laparoscopic approach for the abdominal phase. The conversion rate from laparoscopic to open or transanal was 6.3% with an even lower perineal conversion rate of 2.8%, which is encouraging given the higher rates reported in earlier studies.[7,8,21,22] This may be due to increased experience in laparoscopic surgery. However, the 3 commonest reasons for conversion in the COLOR II trial were a narrow pelvis (22%), obesity (10%), and tumor fixation (9%). Similar risk factors for conversion were also apparent in the more recent ROLARR (RObotic versus LAparoscopic Resection for Rectal Cancer) trial[23] with 471 patients randomized to either laparoscopy (234) or robotic (237) TME. The overall conversion rates were 12.2% and 8.1% for laparoscopic and robotic TME surgery, respectively. However, 27.8% of obese patients undergoing laparoscopic TME and 18.9% in the robotic arm required conversion. Lower rectal cancer and male sex were also associated with increased conversion rates. These risk factors can potentially be overcome by taTME as constraints and challenges posed by anatomical features are reduced when approached from below. Veltcamp-Helbach et al[24] reported on 80 taTME cases and reported a conversion rate of 5%; unlike Lacy et al[16] who had no conversions in 140 cases.

The most frequently reported intraoperative problems during the transanal phase were an unstable pneumopelvis and poor smoke evacuation. In these cases, conventional laparoscopic insufflation devices were used that are unable to evacuate smoke effectively and prevent bellowing. This emphasizes the importance of using optimal equipment available for taTME.[25] Failure of the pursestring with subsequent spillage was also reported, potentially leading to sepsis, and even tumor implantation. This hypothesis will require further evaluation and long-term follow-up. Eleven visceral injuries, including 3 urethral injuries during taTME alone were recorded. Two further urethral injuries occurred during combined rectal and partial

TABLE 6. Multivariate Analysis of Risk Factors for Poor Composite Histological Features (R1 Resection + Poor TME Specimen)

Multivariate Analysis				
Factor	**Event Rate %**	**Adjusted Odds Ratio**	**95% Confidence Interval**	***P***
Tumor height from anorectal junction				
>2 cm	3.8			
0 to 2 cm	11.6	4.561	1.167–17.826	0.029
Positive CRM on staging MRI				
Clear CRM	4.4			
Positive CRM	12.3	4.930	1.364–17.816	0.015
Abdominal extent of posterior pelvic dissection				
>4 cm	3.1			
≤4cm	10.4	5.849	1.424–24.024	0.014

CRM indicates circumferential resection margin; MRI, magnetic resonance imaging.

prostatic resections. Urethral injury has not been reported with abdominal approaches and, even in APE, is an uncommonly reported event. Likewise, 12 (2%) rectal perforations were documented on histological analysis, of which only 2 were identified intraoperatively. This clearly is a serious concern that must be addressed. Every operation carries risks; just as ureteric injury can occur during abdominal anterior resections, urethral injury has been identified as an important risk during taTME. Therefore, it is crucial for surgeons who wish to adopt taTME to have appropriate education and training. Surgeons must also inform patients of specific risks as part of the consenting process.

Postoperative morbidity and mortality at 30 days, 32.6% and 0.5%, respectively, were similar to those reported in previous rectal surgery trials[7,21] and to other large taTME studies.[16,26,27] The 6.3% overall anastomotic leakage rate compares favorably to the rate observed in other series (7% in CLASICC,[21] 13% in COLOR II,[7] 8.6% in Lacy's series[16]). A hospital stay of 8 days is acceptable, although the use of enhanced recovery protocols was not recorded.

Histopathological results are comparable to the best published literature, with an incomplete specimen in only 4.1% and R1 resection in 2.7% (16 cases). R1 was secondary to a positive CRM in 14 cases. In COLOR II,[7] using the limit of 1 mm for comparison, positive margins were seen in 7% of laparoscopic and 9% of open resections; most of which were cases with more proximal tumors. ROLARR[23] found no statistically significant oncological or clinical advantage to robotic over laparoscopic TME surgery, with positive CRM rates of 5.1% and 6.3%, respectively. In taTME series by Lacy et al,[16] Burke et al,[26] and Veltcamp–Helbach[24] CRM positivity was 6.4%, 4%, and 2.5%, respectively. Small cohorts and registry data do have limitations outlined below, and caution should be exercised when comparing with well stratified RCTs. A RCT comparing laparoscopic TME to hybrid-taTME in 100 patients with low rectal cancer, showed significantly lower positive CRM rates (18% vs 4%, $P = 0.025$), with similar surgical morbidity (14% vs 12%, $P = 0.766$).[27] It is important to note that most surgeons performing taTME are still at the early stage of their learning curve and despite this, results are very promising. Also, most registry patients had risk factors for difficult pelvic dissections,[10] being predominantly overweight males (61.2% overweight and obese) with low rectal tumors receiving neoadjuvant chemoradiotherapy.

Interestingly, none of the patient characteristics, including increased BMI or male sex, were significant risk factors for poor histological results. This suggests the transanal approach may overcome patient characteristics that traditionally created a difficult pelvic dissection from the abdominal approach. On multivariate analysis, three risk factors for poor histological features were significant: positive CRM identified on staging MRI, tumor height less than 2 cm from the anorectal junction, and a posterior dissection to less than 4 cm from the anal verge performed transabdominally. The first 2 of these findings agree with results from the observational, multicenter MERCURY II study that predicted a positive pathological CRM by anteriorly located tumors, presence of extramural venous invasion, tumors either within 4 cm of anal verge or 1 mm from the CRM.[3,28] Further analysis of long-term registry data will allow assessment recurrence and survival rates.

The only technical risk factor for poor quality specimens identified on multivariate analysis was extensive trans-abdominal dissection and the chances of obtaining a worse specimen is 6 times greater than if the dissection is performed transanally. The extent of transanal dissection did not increase the risk of poor histological outcome, suggesting that a better oncological resection is likely to be achieved for low rectal tumors via the transanal approach.

Limitations of registry data include the potential for selection bias and relying on accurate, reliable, and all-inclusive data recording from centers in different countries. This is a voluntary registry with no formal documentation of the total denominator of all rectal cancer cases performed in each unit during the time-period of the study. Thus, the outcomes cannot be applied to all patients with rectal cancer and further work is needed to establish exact indications and outcomes. Recording data is also time consuming and needs to be inputted at different intervals following the patient's progress. Perioperative outcomes in particular may therefore be under-reported. However, at present, the registry is the largest data source available and its results add to the current body of evidence that is needed to establish an identity for this new procedure. The advantages of an international registry are that it assesses the therapeutic effectiveness and safety of taTME in the ''real world,'' with surgeons at different stages in their learning curve. It also offers a rapid evaluation of new technologies with data from a large number of patients. Furthermore, an open and transparent collaborative is formed amongst contributing centers that are able to share experiences and advice.

Further analysis of registry data will form a prognostic model for key pathological outcomes, pelvic sepsis, and other major complications. Once short-term clinical and oncological safety has been confirmed in randomized controlled trials, such as the upcoming COLOR III trial,[29] the focus will shift to long-term oncological results, functional outcomes and quality of life after taTME. The online registry continues to record these long-term outcomes and will be reported at 3 years follow-up. The opportunity to record quality of life and functional survey data will also be available. As the interest and uptake of taTME continues to grow, monitoring of outcomes remains vitally important to provide patients with the best possible care.

In conclusion, the initial results of the international TaTME Registry suggest that TaTME is predominantly an oncologically safe and effective technique, resulting in low involved margin- rates, and good specimen quality with acceptable short-term patient outcomes. Structured training, standardization of the technique and reducing the learning curve are all necessary. Well-designed trials are needed to assess the efficacy of taTME compared with laparoscopic, robotic, and open TME surgery.

ACKNOWLEDGMENTS

The authors would like to thank all participating centers registered on the TaTME registry for inputting and updating their data. Thanks also to the Pelican Cancer Foundation for funding the registry and to OCCTOPUS–Oxford Colorectal Cancer Trust for funding the latest registry quality of life/funtional survey additions and funding Marta Penna's research.

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