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ORIGINAL CONTRIBUTION

Oncologic Outcomes After Transanal Total Mesorectal Excision for Rectal Cancer

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BACKGROUND: Recent series have raised concerns about the oncologic outcomes of transanal total mesorectal excision for mid and low rectal cancer. There is a paucity of large data sets from the United States to contribute to the ongoing international discourse.

OBJECTIVE: This study aimed to investigate the rate of local recurrence and other oncologic outcomes in patients undergoing transanal total mesorectal excision for rectal adenocarcinoma.

DESIGN: This study is a retrospective review of patients undergoing transanal total mesorectal excision for primary rectal cancer from January 2014 to December 2019.

SETTINGS: This study was conducted at a single academic tertiary care medical center in the United States.

PATIENTS: Consecutive patients aged ≥18 years undergoing surgical resection for primary rectal cancer were selected.

INTERVENTION: The transanal total mesorectal excision procedures were performed utilizing a 2-team approach.

MAIN OUTCOME MEASURES: Primary outcomes were pathologic quality, local and distant recurrence, treatment-related complications, and overall- and cancer-specific survival.

RESULTS: Seventy-nine consecutive patients were included. The median age was 58 years (interquartile range, 50–64), and median BMI was 28 kg/m^2 (interquartile range, 24.6–32.4). The mesorectum was complete in 69 patients (87.3%), nearly complete in 9 (11.4%), and incomplete in 1 (1.3%). There was circumferential resection margin involvement (<1 mm) in 4 patients (5.1%), and no patients had a positive distal margin (<1 mm) or intraoperative rectal perforation. Composite optimal pathology was achieved in 94.9% of specimens. Median follow-up was 29 months (range, 6–68). There were no local recurrences. Distant metastases were found in 10 (13.5%) patients and diagnosed after a median of 14 months (range, 0.6–53). Disease-free survival was 91.2% at 2 years, and overall survival was 94.7% at 2 years.

LIMITATIONS: Retrospective design, a single center, and relatively short follow-up period were limitations of this study.

CONCLUSION: The oncologic outcomes of this cohort support the use of transanal total mesorectal excision in the surgical management of mid to low rectal cancer at centers with appropriate expertise. See **Video Abstract** at http://links.lww.com/DCR/B723.

Funding/Support: None reported.

Financial Disclosures: Dr Maykel is an Applied Medical clinical educator.

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Dis Colon Rectum 2022; 65: 827–836
DOI: 10.1097/DCR.0000000000002173

RESULTADOS ONCOLÓGICOS DESPUÉS DE LA EXCISIÓN TOTAL DEL MESORRECTO POR VÍA TRANSANAL EN CASOS DE CÁNCER RECTAL

ANTECEDENTES: Estudios recientes han suscitado preocupación sobre los resultados oncológicos de la excisión total del mesorecto por vía transanal en casos de cáncer de recto medio y bajo. Existe una gran escasez de conjuntos de datos en los Estados Unidos, para contribuir en el actual discurso internacional sobre el tema.

OBJETIVO: Investigar la tasa de recurrencia local y otros resultados oncológicos en pacientes sometidos a una excisión total del mesorrecto por vía transanal por adenocarcinomas de recto.

DISEÑO: Revisión retrospectiva de pacientes sometidos a excisión total del mesorecto por vía transanal en casos de cáncer de recto primario desde enero de 2014 hasta diciembre de 2019.

AJUSTE: Centro médico Universitario de atención terciaria único en los Estados Unidos.

PACIENTES: Aquellos pacientes consecutivos de ≥ 18 años de edad, sometidos a resección quirúrgica por cáncer de recto primario.

INTERVENCIÓN: Los procedimientos de excisión total del mesorecto por vía transanal se realizaron utilizando un enfoque de dos equipos.

PRINCIPALES MEDIDAS DE RESULTADO: Los resultados primarios fueron la calidad anatomo-patológica de las piezas, la recidiva local y a distancia, las complicaciones relacionadas con el tratamiento y la sobrevida global específica para el cáncer.

RESULTADOS: Se incluyeron 79 pacientes consecutivos. La mediana de edades fue de 58 años (IQR, 50–64) y la mediana del índice de masa corporal fue de 28 kg / m (IQR, 24,6–32,4). El mesorrecto se encontraba completo en 69 pacientes (87,3%), casi completo en 9 (11,4%) e incompleto en 1 (1,3%). Hubo afectación de CRM (<1 mm) en 4 pacientes (5,1%) y ningún paciente tuvo un margen distal positivo (<1 mm) o perforación rectal intraoperatoria. La histopatología óptima compuesta se logró en el 94,9% de las muestras. La mediana de seguimiento fue de 29 meses (rango 6–68). No se presentaron recurrencias locales. Se encontraron metástasis a distancia en 10 (13,5%) pacientes y se diagnosticaron después de una mediana de 14 meses (rango 0,6–53). La sobrevida libre de enfermedad fue del 91,2% a los 2 años y la sobrevida global fue del 94,7% a los 2 años.

LIMITACIONES: Diseño retrospectivo, unicéntrico y período de seguimiento relativamente corto.

CONCLUSIÓN: Los resultados oncológicos de este estudio de cohortes, apoyan la realización de excisión total del mesorecto por vía transanal para el tratamiento quirúrgico del cáncer de recto medio y bajo, en centros con la experiencia adecuada. Consulte **Video Resumen** en http://links.lww.com/DCR/B723. (*Traducción—Dr. Xavier Delgadillo*)

KEY WORDS: Low anterior resection; Proctectomy; Rectal cancer; Transanal total mesorectal excision.

Total mesorectal excision (TME) is the standard surgical technique for rectal cancer because it is associated with reduced local recurrence and improved cancer-free survival rates.[1,2] Randomized prospective clinical trials, including COLOR II, COREAN, and CLASICC, demonstrated better short-term and long-term perioperative outcomes for laparoscopic TME with no significant differences in local recurrence and disease-free survival compared with the open approach.[3–5] More recently, however, oncologic outcomes of the laparoscopic approach have been challenged because the American College of Surgeons Oncology Group (ACOSOG) Z6051[6] and the Australasian Laparoscopic Cancer of the Rectum Trial (ALaCaRT)[7] failed to demonstrate the noninferiority of laparoscopic surgery compared with open surgery on pathologic outcomes.

Transanal TME (TaTME) arose as an alternative surgical approach to address the technical challenges encountered during open, laparoscopic, and robotic rectal mobilization and resection of tumors of the mid and low rectum.[8] Compared with laparoscopic and robotic approaches, TaTME may be advantageous for patients with unfavorable anatomic characteristics, such as a narrow pelvis, previous pelvic irradiation, male sex, and high BMI.[9] Early studies demonstrated safety and feasibility with satisfactory short-term oncologic results in highly experienced centers,[10,11] and consequently TaTME was met with rapid, widespread interest and adoption[12] despite a lack of evidence from multicenter, randomized controlled trials. When the first long-term outcome data from an expert center demonstrated low local recurrence rates of 2% in 3 years of follow-up,[13] this further encouraged the global adoption of TaTME.

Despite the proposed advantages, TaTME is technically challenging with a steep learning curve and procedure-specific morbidity.[14] Despite attempts at introduction via structured surgeon-training programs, the early global adoption has not been regulated, resulting in reports of both adverse perioperative complications and concerns for oncologic inferiority.[15] Most recently, Larsen et al[16] raised concern by reporting a 9.5% local recurrence rate in 110 patients from multiple institutions at a median follow-up of 11 months, leading to a national moratorium for TaTME in Norway and abandonment or suspension of the technique in other countries.[16,17]

Although TaTME has been met with some degree of enthusiasm in the United States, published data on the US experience for rectal cancer are lacking.[18,19] These 2 studies showed favorable histopathologic and oncologic outcomes; however, Marks et al[18] included patients undergoing both transanal abdominal transanal proctosigmoidectomy (n = 335) and TaTME (n = 38), and Burke et al[19] was limited to 50 patients with a median follow-up of 15.1 months. This study aimed to build on the collective US experience by reporting on longitudinal outcomes for consecutive patients with mid and low rectal cancer from a single, high-volume US center that was an early adopter of the technique.

MATERIALS AND METHODS

Data Source

A retrospective cohort was identified from a prospectively maintained, longitudinal database of all patients

undergoing TaTME since 2014 at a single academic institution. Data were collected from the electronic medical record and entered into a secure database (Research Electronic Data Capture; REDCap, Version 9.3.0, 2019 Vanderbilt University, Nashville, TN). This study was reviewed and approved by the Institutional Review Board at the University of Massachusetts Medical School.

Study Population

General inclusion criteria included a TaTME procedure performed by 2 surgeons within the Division of Colon and Rectal Surgery at the University of Massachusetts Memorial Medical Center from January 2014 through December 2019. Only elective, nonemergent surgeries were included in the study. The series included patients with all stages of primary rectal cancer of the mid or low rectum, including those with T4 tumors, those with a threatened circumferential resection margin (CRM) on MRI, 2 cases with contained rectal cancer perforations, and those with metastatic disease considered appropriate for resection.

Variables and Outcomes of Interest

Patient characteristics included standard demographic data, presentation and diagnosis, and comorbidity. Preoperative assessment included colonoscopy and biopsy, MRI of the pelvis, endorectal ultrasound (ERUS), and CT scan of the chest, abdomen, and pelvis. Over the course of this series, our protocol for locoregional staging has transitioned from ERUS performed by the primary surgeon to rectal cancer–protocol MRI. Threatened CRM was defined as tumor or malignant lymph nodes that were present at or within 1 mm of the mesorectal fascia (MRF) on baseline MRI. Each case was reviewed by a multidisciplinary tumor board, and patients were offered neoadjuvant therapy per National Comprehensive Cancer Network guidelines. Patients who underwent neoadjuvant therapy received chemotherapy and long-course radiation treatment or total neoadjuvant therapy as per institution protocol. An MRI was performed for restaging after neoadjuvant therapy when applicable. Patients with evidence for a complete clinical response were offered a "watch and wait" approach as an alternative to radical resection. Details regarding tumor characteristics, neoadjuvant therapy, surgical details, postoperative complications, and adjuvant therapy were analyzed.

The primary outcome of interest for this study was local recurrence of rectal cancer. Local recurrence was defined as any recurrent disease in the pelvis, along previous surgical dissection planes, or at the anastomosis or pelvic nodal disease. Additional outcomes of interest included the development of distant metastatic disease, treatment-related complications, and survival (overall and cancer-specific).

Surgical Technique

Transanal TME was performed as previously reported by our group.[20,21] A 2-team approach was utilized, with simultaneous abdominal and transanal mobilization. The transanal phase was performed exclusively by either of 2 faculty (K.A. and J.M.). Specimen extraction was usually performed transabdominally through a small Pfannenstiel incision to extract large, bulky specimens and to prevent both disruption of the mesorectal envelope and tearing of the marginal artery with transanal extraction.

Pathology and Surveillance

Histopathologic processing and assessment of the specimen was performed by pathologists with expertise in rectal cancer specimen assessment. Quality of the specimen was categorized as previously described by Nagtegaal et al.[22] "Composite optimal pathology" was defined as: (1) complete or nearly complete TME, (2) a clear circumferential margin (>1 mm), and (3) a clear distal resection margin (>1 mm).[6]

Postoperative cancer surveillance regimen included clinical visits at 3- or 6-month intervals with digital rectal examination and CEA levels, annual CT scans of the abdomen and pelvis, and routine endoscopy. Adjunctive MRI and/or PET-CT were performed based on clinical indications.

Statistical Analysis

Analyses were performed using SAS statistical software (version 9.4; SAS Institute Inc, Cary, NC). Descriptive statistics were generated for patient, tumor, treatment characteristics, and clinical outcomes. Kaplan-Meier survival analysis was performed for disease-free survival rates and overall survival rates. The log-rank test was used to test for differences between strata.

RESULTS

Patient and Tumor Characteristics

A total of 79 patients with mid to low rectal cancer underwent TaTME. Table 1 provides baseline patient and tumor characteristics. The median age was 58 (interquartile range [IQR], 50–64), and 62% of patients were men. The median BMI was 28 (IQR, 24–32); 31% patients had a BMI of 30 or greater. The median tumor height was 7.0 cm from the anal verge (range, 2.5–13.0). Twelve patients (15%) had a tumor <4 cm from the anal verge. A quarter of patients (n = 21; 27%) had an anterior tumor, and a quarter (n = 20; 25%) had a circumferential lesion. Fifty-four (68.4%) patients underwent baseline MRI, of whom 10 (18.5%) had an MRF and 7 (8.8%) had extramural vascular invasion. Eighteen (22.8%) patients had a baseline ERUS. No patients underwent both MRI and ERUS, whereas 6 (7.6%) were staged with CT scan only. Most patients

TABLE 1. Patient and tumor characteristics

Patient and tumor characteristics	*n = 79*
Sex, male, n (%)	49 (62.0)
BMI, median (IQR)	28 (24–32)
BMI ≥30, n (%)	31 (39.2)
Age, y, median (IQR)	58 (50–64)
ASA, n (%)	
I	1 (1.3)
II	52 (66)
III	26 (33)
Height from AV, cm	
Mean	6.9
Median (range)	7.0 (2.5–13)
Height from AV <4 cm, n (%)	12 (15.2)
Tumor location at diagnosis, n (%)	
Anterior	21 (26.6)
Posterior	12 (15.2)
Lateral	23 (29.1)
Circumferential	20 (25.3)
Unknown	3 (3.8)
MRI or ERUS performed, n (%)	72 (91.1)
Baseline clinical T stage, n (%)	
T1	5 (6.3)
T2	8 (10.1)
T3	60 (75.9)
T4	5 (6.3)
Missing	1 (1.2)
Baseline clinical N stage, n (%)	
N0	19 (24.1)
N1	38 (48.1)
N2	18 (22.8)
Nx	3 (4.8)
Missing	1 (1.3)
Baseline clinical M stage, n (%)	
M0	71 (89.9)
M1	7 (8.9)
Missing	1 (1.3)
EMVI on baseline MRI, n (%)	7/54 (7.4)
Threatened MRF on baseline MRI, n (%)	10/54 (18.5)
Received neoadjuvant treatment (n = 69) , n (%)	69/79 (87.3)
Chemoradiation	64/69 (92.8)
Radiation	1/69 (1.4)
Chemotherapy	2/69 (2.9)
Total neoadjuvant therapy	2/69 (2.9)
Downstaged after neoadjuvant treatment, n (%)	56/69 (81.2)

Percentages for variables are calculated out of the total number of actual results available, excluding missing values.
AV = anal verge; EMVI = extramural vascular invasion; ERUS = endorectal ultrasound; IQR = interquartile range; MRF = mesorectal fascia; Nx = stage unknown.

received neoadjuvant chemoradiotherapy treatment (n = 69; 87.3%). Two patients received total neoadjuvant therapy. Fifty-six (81.2%) were noted to have tumor regression on posttreatment MRI.

There were 7 patients with M1 disease on preoperative staging. Of these, 4 patients had limited liver metastases that were treated with metastectomy. One patient had regression of metastatic disease following neoadjuvant therapy. Two patients had contained tumor perforation leading to resection to proceed with chemotherapy.

Clinical Outcomes

Table 2 shows operative details and postoperative clinical outcomes. The vast majority of TaTME procedures were low anterior resections (n = 74, 94%). Primary anastomosis was performed in 74 patients (93.7%); most patients underwent a stapled anastomosis (n = 62, 83.8%), and the remainder of anastomoses were handsewn (n = 9, 12.2%). Median total operative time was 309 minutes (IQR, 262–380). There was 1 unplanned abdominal conversion to midline laparotomy due to difficulty mobilizing a perforated, bulky tumor and maintaining pneumopelvis.

With regard to TaTME-specific intraoperative complications, there were 2 identified cases of intraoperative carbon dioxide embolism (2.4%), which were managed wwith

TABLE 2. Operative details and clinical outcomes

Operative details	*n = 79*
Primary procedure performed, n (%)	
LAR	74 (93.7)
APR	4 (5.1)
TPC + ileostomy	1 (1.3)
Operative time, min, median (IQR)	309 (262–380)
Transanal specimen extraction, n (%)	17 (21.5)
Estimated blood loss, mL, mean (SD)	143 (252)
Abdominal approach, n (%)	
Multiport laparoscopy	77 (97.5)
Robot-assisted laparoscopy	2 (2.5)
Type of anastomosis, n (%)	
Handsewn	9/74 (12.2)
Stapled	62/74 (83.8)
Intraoperative complications, n (%)	
Organ injury (eg, urethra)	0 (0)
Bleeding >400 mL	2 (2.5)
Unplanned abdominal conversion	1 (1.3)
Carbon dioxide (CO_2) embolism	2 (2.5)
Postoperative course	
Hospital stay, days, median (IQR)	4 (4–5)
Morbidity	
Clavien-Dindo grade 3+ complications, n (%)	11 (13.9)
Postoperative ileus	13 (16.5)
Urinary retention	4 (5.1)
SSI	4 (5.1)
Bowel obstruction	2 (2.5)
UTI	1 (1.3)
Anastomotic leak	3 (3.8)
Pelvic abscess	8 (10.1)
Renal failure	1 (1.3)
Pneumonia	0 (0)
Cardiovascular event	0 (0)
Deep vein thrombosis	0 (0)
Pulmonary embolism	0 (0)
Sepsis	2 (2.5)
Reoperation	2 (2.5)
Unplanned ICU admission	5 (6.3)
Readmission within 30 days	21 (26.6)
Other	8 (10.1)

APR = abdominoperineal resection; ICU = intensive care unit; IQR = interquartile range; LAR = low anterior resection; SSI = surgical site infection; TPC = total proctocolectomy; UTI = urinary tract infection.

immediate release of pneumopelvis and pneumoperitoneum, hemodynamic support with crystalloid or vasopressors, and placement of the patient in the Trendelenburg position with left side down. All patients had return of baseline blood pressure, heart rate, O_2 saturation, and end tidal CO_2 to pre-event levels within 10 minutes. There were no intraoperative or postoperative sequelae. There were no injuries to adjacent organs, including urethra, prostate, bladder, and vagina. Postoperatively, Clavien-Dindo grade 3 or higher complications were encountered in 11 (13.9%) patients. There were 3 anastomotic leaks (3.8%) within 30 days; all were managed with reoperation, of which 1 patient required an end sigmoid colostomy. There was one other reoperation; a patient underwent lysis of adhesions for adhesive small-bowel obstruction. Median hospital length of stay was 4 days (IQR, 4–5). There were no 30-day mortalities.

Histopathologic Outcomes

Table 3 shows histopathologic outcomes. The median tumor size was 2.0 cm (IQR, 1.2–3.0). The TME specimen was graded as complete in 69 (87.3%) patients and nearly complete in 9 (11.4%) patients. The CRM was positive in 4 (5.1%) patients, and one of these had threatened MRF on preoperative MRI. No patients had a positive distal resection margin. There were no cases of rectal perforation. The composite endpoint of "optimal pathology" was 94.9%.

Oncologic Outcomes

There were no local recurrences identified after a median follow-up of 29 months (range, 7–60). Further oncologic outcomes are summarized in Table 4. Fifty-eight (73.2%) patients received adjuvant chemotherapy. Distant recurrence was identified in 10 (13.5%) patients, all underwent adjuvant therapy, and 2 underwent interventional procedures, such as metastectomy or radiofrequency ablation. There were no intraperitoneal recurrences. Median time to distant metastases was 14 months (range, 0.6–53). Sixty-two patients (78.5%) were alive with no evidence of disease. For this interim analysis, total cohort survival rate was 85.7% with a total of 10 deaths. Four mortalities (5.1%) were due to progression of disease.

Overall survival (OS) was 94.7% at 2 years and 86.6% at 3 years. Figure 1 shows a Kaplan-Meier curve of OS. Disease-free survival (DFS) was 91.2% at 2 years and 82.6% at 3 years. Figure 2 shows a Kaplan-Meier curve of DFS. Stage-specific OS is shown in Figure 3, and stage-specific DFS is shown in Figure 4.

Table 3. Histopathologic outcomes

Histopathologic characteristics	*n = 79*
No neoadjuvant therapy	n = 10
Pathologic T-stage, n (%)	
pT0	0
pT1	7 (8.9)
pT2	3 (3.8)
pT3	0 (0)
pT4	0 (0)
Pathologic N-stage, n (%)	
pN0	9 (11.4)
pN1	1 (1.3)
pN2	0 (0.0)
Underwent neoadjuvant therapy	n = 69
Pathologic T-stage, n (%)	
(y)pT0	12 (15.2)
(y)pT1	2 (2.9)
(y)pT2	22 (32)
(y)pT3	32 (46)
(y)pT4	1 (1.5)
Pathologic N-stage, n (%)	
(y)pN0	42 (53.2)
(y)pN1	22 (27.8)
(y)pN2	5 (6.3)
Number of lymph nodes examined, median (IQR)	16 (13–20)
Tumor size, cm, median (IQR)	2.0 (1.2–3.0)
TME specimen	
Completeness of mesorectum resection, n (%)	
Complete	69 (87.3)
Nearly complete	9 (11.4)
Incomplete	1 (1.3)
CRM involved (<1 mm), n (%)	
No	75 (94.9)
Yes, direct tumor	4 (5.1)
DRM involved (<1 mm), n (%)	
No	79 (100)
Rectal perforation, n (%)	0
Composite optimal pathology, n (%)	75 (94.9)

Percentages for variables are calculated out of the total number of actual results available, excluding missing values. Composite optimal pathology: CRM not involved, DRM not involved, and complete or nearly complete TME specimen and no rectal perforations.
CRM = circumferential resection margin; DRM = distal resection margin; IQR = interquartile range; TME = total mesorectal resection.

DISCUSSION

As the largest series from one of the few high-volume TaTME sites in the United States, our results provide long-awaited data on safety and oncologic local control. As early adopters of TaTME, we demonstrate in this consecutive, longitudinal series both the safety and excellent short- and mid-term oncologic outcomes for mid to low rectal cancer,[13,18] with few involved circumferential margins (5%), no involved distal margins, and no local recurrences. Although not mature enough to report on 5-year oncologic outcomes, our follow-up of 29 months (range, 7–60) represents the longest time period from any US site, further supporting the oncologic durability of the TaTME procedure.

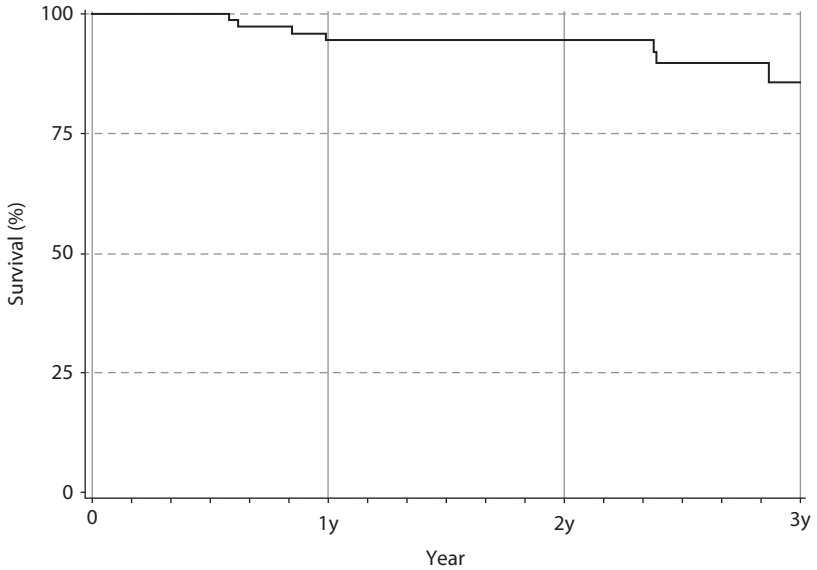
These findings are particularly relevant in the context of the ongoing global debate regarding the oncologic safety of TaTME. The negligible recurrence rate in this study is far lower than reported by Larsen et al[16] in the Norwegian study. Although surgeon expertise and center volume

Table 4. Oncologic outcomes

Oncologic outcomes	*n = 79*
Postoperative follow-up, mo, n (%)	
Mean	29
Median (min–max)	28 (6–68)
Received adjuvant chemotherapy, n (%)	58 (73.4)
Local recurrence, n (%)	0/79 (0)
Distant recurrence, n (%)	
No	64 (81.0)
Yes	10 (13.5)
Interval to distant recurrence, mo, n (%)	
Mean	18
Median (min–max)	14 (0.6–53)
Overall survival, n (%)	
Alive with no evidence of disease	62 (78.5)
Alive with disease	6 (7.6)
Lost to follow-up	1 (1.3)
Deceased	10 (12.7)
Interval to death, mo	
Mean	27
Median (min–max)	29 (7.0–51)

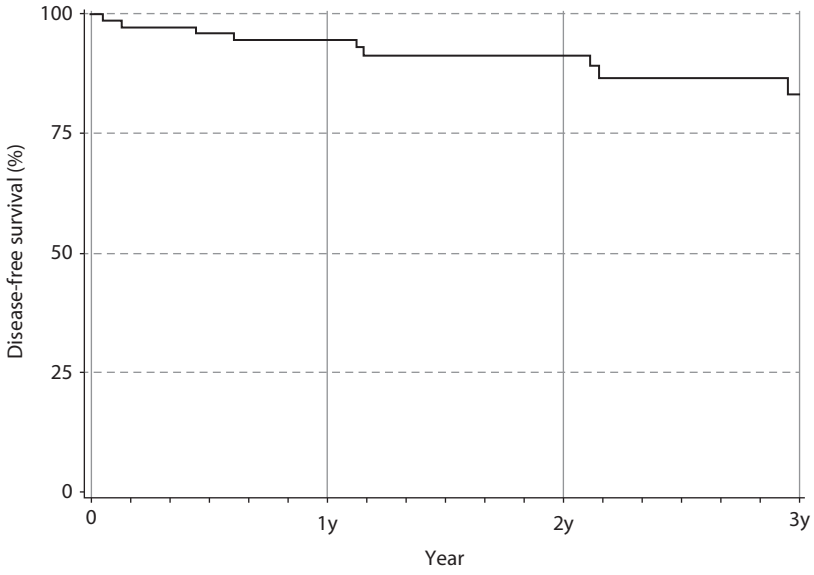
have been hypothesized to play a role in the Norwegian outcomes,[23] a multidisciplinary approach to rectal cancer remains critical. Our center followed a standard protocol according to National Comprehensive Cancer Network guidelines, resulting in 87% of patients receiving neoadjuvant chemoradiotherapy, in stark contrast to the 21% of patients in the Norwegian trial. Although surgical technique clearly impacts patient outcomes,[1] the multidisciplinary approach itself, including the administration of up-front chemotherapy and radiotherapy, has been proven to impact local recurrence and survival rates.[24,25] The technical advantages of the TaTME approach are further supported by our favorable rectal specimen results, including specimen grading (98.7% complete/near complete grade), no positive distal margins, low CRM positivity rate (5.1%), and no rectal perforations. The ACOSOG and ALaCaRT trials defined "optimal pathology" as a surrogate for surgical quality by meeting the following criteria: complete or nearly complete TME, clear (>1 mm) CRM, and clear (>1 mm) distal margin. Our series compares favorably to benchmarks because this composite score was achieved in 95% (n = 75) of the consecutive patients in this study, compared with 82% in the laparoscopic surgery group and 89% in the open surgery group in the ALaCaRT trial.[7] Although tumor exposure at the CRM predicts a higher rate of local recurrence and poorer DFS,[26] the CRM was negative in 95% of specimens in this study. Because 78.4% of patients were alive with no evidence of disease at the end of follow-up and the total cohort survival rate was 86.6%, these favorable histopathologic outcomes support the role of TaTME related to patient outcomes.

Our study had a 2-year DFS of 91.2% and OS rate of 94.7%. There was no local recurrence, and 13.5% of patients experienced distant recurrence at a median of 14 months (range, 0.6–53) after TaTME. Our 2-year survival rates are



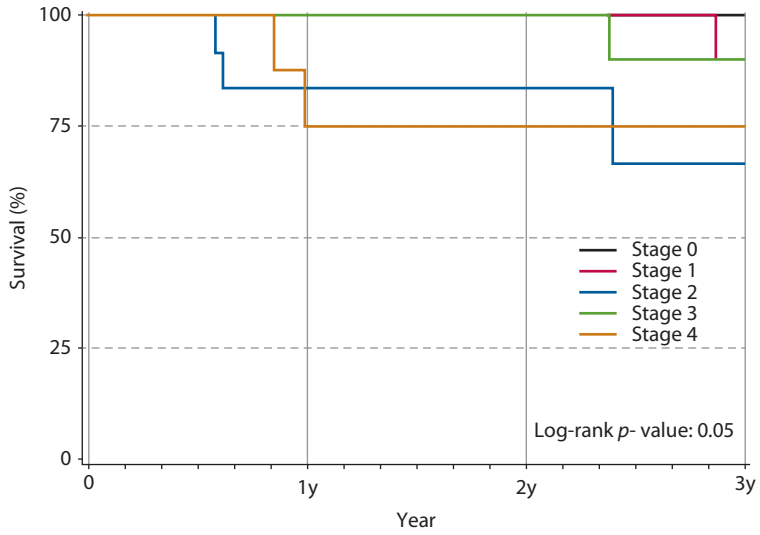
	Baseline	Year 1	Year 2	Year 3
Number at risk	79	68	46	27
Survival (%)	100	94.7	94.7	86.6

FIGURE 1. Kaplan-Meier curve of overall survival after transanal total mesorectal excision.



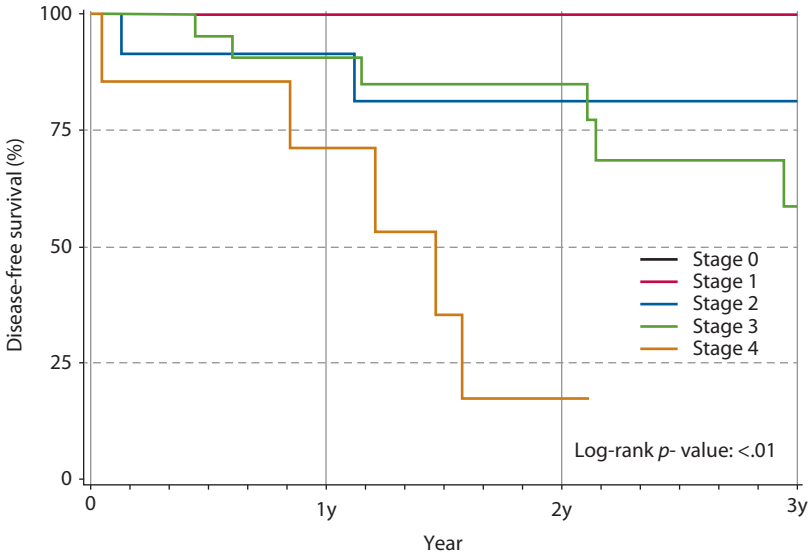
	Baseline	Year 1	Year 2	Year 3
Number at risk	72	61	40	23
Survival (%)	100	94.4	91.2	82.6

FIGURE 2. Kaplan-Meier curve of disease-free survival after transanal total mesorectal excision.



No. at risk (% survival)	Baseline	Year 1	Year 2	Year 3
Stage 0	12 (100)	11 (100)	7 (100)	5 (100)
Stage 1	25 (100)	23 (100)	17 (100)	8 (90.0)
Stage 2	12 (100)	9 (83.3)	5 (83.3)	4 (66.7)
Stage 3	22 (100)	19 (100)	12 (100)	8 (90.0)
Stage 4	8 (100)	6 (75.0)	5 (75.0)	2 (75.0)

FIGURE 3. Kaplan-Meier curve of overall survival after transanal total mesorectal excision, stage-specific.



	Baseline	Year 1	Year 2	Year 3
Stage 0	12 (100)	11 (100)	7 (100)	5 (100)
Stage 1	25 (100)	23 (100)	17 (100)	8 (100)
Stage 2	12 (100)	9 (91.7)	5 (91.7)	4 (91.7)
Stage 3	22 (100)	18 (90.9)	11 (85.2)	6 (59.0)
Stage 4	7 (100)	4 (71.4)	1 (17.9)	0

FIGURE 4. Kaplan-Meier curve of disease-free survival after transanal total mesorectal excision, stage-specific.

similar to those of the ALaCaRT trial: overall (this cohort 94.7% vs ALaCaRT 94%) and disease-free (91.2% vs 80%). Our rate of 13.5% distant recurrence/metastasis at nearly 2½ years was comparable to the Surveillance, Epidemiology, and End Results Program rate of 24% at 3 years and the 13.8% reported by Hol et al[13] in a recent study, despite a relatively high proportion of patients with node-positive disease (70.9% vs 46% in their cohort). Although a single-center study cannot be used in isolation to demonstrate the safety of a technique, our 2-year rates are similar to what has been reported in the wider literature. With a low overall complication rate and short postoperative length of stay (median, 4 days), 73% of patients were able to receive their adjuvant chemotherapy, limiting the impact postoperative complications have on the administration of adjuvant chemotherapy and potential impact on long-term survival.[27]

Transanal TME is a technical advance that can aid in dissection by providing in-line visualization of the deep pelvis in the most challenging cases, specifically obese men with mid to low rectal tumors following radiotherapy.[9,28] One of the greatest strengths of our series is the high rate of obese (32%), male (64%), irradiated patients (85%) in our cohort. Despite these real-world challenges, our conversion rate was only 1.2% and the sphincter preservation rate was 94%. Consistent with our findings, Ma et al[29] demonstrated that laparoscopic TME had a 4 times higher likelihood of conversion than TaTME, whereas the International TaTME registry reported low conversion rates (4.3%).[30] The high-definition visualization and direct access to the low pelvis provided by the TaTME approach contribute to the technical success of the operation, with no reported adjacent organ injuries, no positive distal resection margins, and low positive CRMs, despite including consecutive patients with locally advanced tumors, including T4, and threatened CRM on MRI.

Our series additionally demonstrates a low rate of anastomotic complications that are a substantial cause of early and long-term morbidity and may also adversely impact cancer outcomes. Historically, anastomotic complications are known to occur in approximately 20% of patients following low anterior resection in the setting of preoperative radiotherapy.[31] Mirnezami et al[32] revealed a significant association between colorectal anastomotic leak and local recurrence, reducing long-term cancer-specific survival. Despite the administration of neoadjuvant chemoradiotherapy in 87% of patients and all patients receiving low coloanal anastomoses, the rate of anastomotic leak in this study is notably low at 3.8%. Our default

anastomotic technique is the double-pursestring, single-stapled method, which has been demonstrated to have low rates of leak with open and laparoscopic approaches.[33] This anastomosis is accessible through the transanal platform and can be inspected and suture reinforced to close any staple line defects. Our low anastomotic leak rate may reflect a benefit of TaTME when performing a coloanal anastomosis, which has been shown to have the highest leak rate of any colorectal anastomosis at 5% to 19%.[33,34]

There are important limitations to this study. First, our data set is only mature enough to report on 29-month follow-up; the standard 5-year oncologic outcomes for this cohort of patients are pending. Considering the pressing international concerns over oncologic outcomes following TaTME, we felt it was imperative to provide our experience to date, because our series represents the largest experiences in the United States and, by virtue of introducing the technique in 2014, our center is one of the few US centers able to analyze and present these data. Although our follow-up is limited to 29 months, the majority of local recurrences occur within 2 years of resection, as shown by the COLOR II trial and the Dutch TME trial.[3,35] In addition, our 29-month median follow-up period exceeds the 19.5-month median follow-up period reported in the updated Norwegian study.[36] Second, although this study may be limited by selection bias, it is important to note that patients with mid to low rectal tumors were included consecutively, and all patients with low rectal cancer at our center underwent TaTME exclusively. Third, this study may not be widely generalizable, because it includes data from a single academic institution where the perineal portion of the TaTME is performed by 2 highly experienced surgeons.[37]

CONCLUSION

The international discourse related to oncologic outcomes of minimally invasive surgical approaches for rectal cancer has expanded to include the TaTME procedure. Although several prospective, randomized trials are ongoing, results from an early-adopting institution like ours provide key data for tracking outcomes to optimize patient care and define the utility of this innovative and valuable surgical technique. As the largest series with the longest follow-up in the United States, we have reported low local recurrence rates and favorable oncologic outcomes at a median follow-up of 29 months. These results support the continued use and advantageous role of TaTME in the management of cancers of the mid to low rectum at centers with appropriate expertise and regular monitoring of outcomes.

ACKNOWLEDGMENTS

The authors would like to thank Theodore McDade, M.D., M.P.H., and Allison Crawford, M.S., for their contributions.

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