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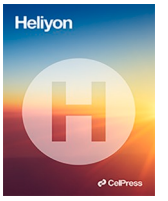

Research article

Postoperative urinary retention following transanal versus laparoscopic total mesorectal excision for rectal cancer: A randomized trial report from an experienced center☆

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ABSTRACT

Background: Transanal total mesorectal excision has emerged as a potential solution to certain limitations associated with laparoscopic total mesorectal excision in rectal cancer patients. Differences in surgical approaches have raised questions regarding their impact on the risk of postoperative urinary retention, with limited data available from large scale randomized clinical study.

Objective: To report incidence of postoperative urinary retention and evaluate the associated risk factors for transanal total mesorectal excision.

Design: In this randomized controlled trial (ClinicalTrials. gov NCT06147492), we retrieved 524 patients who received total mesorectal excision (TME) for stage I–III rectal cancer between June 2019 and April 2022, and the patients were randomly assigned in a 1:1 ratio to undergo either taTME or laTME.

Patients: We enrolled 524 patients who underwent total mesorectal excision for stage I–III rectal cancer between June 2019 and April 2022.

Main outcome measures: The incidence of postoperative urinary retention.

Results: Among the 524 enrolled patients, 261 were randomized to the laTME group, while 263 were were randomized the taTME group. The median age was 58 years, and 340 participants (64.8 %) were male. Notably, 37 individuals (7.0 %) experienced postoperative urinary retention during the follow-up period, with no significant disparity was observed between the taTME and

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laTME groups (6.8 % and 7.2 %, respectively, $P = 0.98$). Risk factors associated with PUR in patients following taTME encompassed early removal of the urinary catheter ($P = 0.006$), net infusion rate >4.09 ml $kg^{-1}.h^{-1}$ ($P = 0.006$), and an age surpassing 65 years ($P = 0.0321$).
Limitations: The generalizability of the findings outside specialist rectal cancer centers may be limited.
Conclusions: Transanal total mesorectal excision was not found to heighten the risk of postoperative urinary retention. Nonetheless, it is advisable removing postoperative catheter beyond the initial day and exercising caution in the administration of intravenous fluids in clinical practice for taTME procedures.

1. Introduction

The global incidence of colorectal cancer continues to rise [1], and total mesorectal excision (TME) has maintained its status as a promising therapeutic approach since its inception [2]. While laparoscopic TME (laTME) is widely recognized as a viable modality for rectal cancer treatment [3], it may occasionally fall short in achieving complete radical resection for rectal tumors located in challenging anatomical regions within the pelvis. In contrast, transanal TME (taTME), employing a "bottom-to-up" surgical approach, demonstrates increased feasibility in constrained pelvic spaces and offers enhanced assurance of achieving adequate distal resection margins [4]. Consequently, taTME has emerged as a promising strategy for achieving curative resection, particularly in cases involving low- and mid-rectal tumors. Nevertheless, the safety profile of taTME has remained a subject of ongoing debate [5,6], primarily due to the close anatomical proximity between the rectum and the urinary tract, rendering transanal surgery susceptible to urinary dysfunction [7].

Postoperative urinary retention (PUR) is a well-documented complication indicative of urinary dysfunction following colorectal surgery, with reported incidences ranging from approximately 5.5 %–16.0 % [8]. PUR, defined as insufficient spontaneous urination following catheter removal [9], has been associated with urinary dysfunction, urinary tract infections, and the imposition of additional financial burden [10]. Previous research has established that alterations in surgical techniques can influence the risk of PUR following colorectal cancer surgery [11]. Given its "inside to outside" approach, taTME carries a technical predisposition to induce PUR by potentially damaging the anal sphincter complex and pelvic floor muscles. Furthermore, the occurrence of anal pain resulting from surgical trauma further heightens the susceptibility of taTME to PUR. Notably, the reported rates of urinary retention necessitating additional management following transanal surgery have ranged from 11 % to 21 % [12,13], which is relatively higher than those observed after transabdominal procedures. However, the precise incidence and underlying risk factors for PUR subsequent to taTME have received limited investigative attention.

The primary objective of this study is to investigate the impact of Transanal vs. Laparoscopic TME on the occurrence of PUR, while also encompassing other urological complications, including urinary tract infections (UTIs). Additionally, this study seeks to evaluate the contributing risk factors associated with PUR in patients undergoing taTME.

2. Methods

2.1. Patients and clinical indexes

A cohort of patients who underwent either taTME or laTME for non-metastatic rectal cancer within the time frame of 2019–2022 were identified. Ethical approval was obtained from our center's Ethics Committee, and all patients received comprehensive written information about the study's objectives. Prior to their inclusion in the study, each patient provided informed consent through the signing of written consent forms. Inclusion criteria encompassed patients falling within the age range of 18–65 years, diagnosed with rectal cancer at clinical stages I or III. Furthermore, patients were required to have a palpable tumor as determined by digital rectal examination or accessible through proctoscopy, with the distal border situated within 12 cm from the anal verge. Eligible patients were those for whom curative resection of the tumor was deemed feasible, and who exhibited no hepatic, renal, or other conditions that would contraindicate the study treatment or follow-up. Additionally, patients were expected to possess an Eastern Cooperative Oncology Group (ECOG) performance status of 0–1, and to demonstrate essentially normal erectile function and urinary function, as indicated by a five-item International Index of IPSS (International Prostate Symptom Score) of $\leq$12.

The exclusion criteria in this research is to exclude patients presenting clear indications of pelvic side wall involvement as revealed by imaging, those with evidence of distant metastasis, or individuals suffering from uncontrolled hypertension or cardiovascular disease that could impede their participation in the study or follow-up. Patients with synchronous colon cancer, those who were pregnant, nursing, or fertile and not employing effective contraception methods, individuals with a history of other malignancies within the past 5 years, or those affected by psychiatric or addictive disorders or any other conditions precluding their participation in the study were also excluded.

2.2. Sample size and study design

We analyzed data obtained from the Gastrointestinal Tumor Database of the Sixth Affiliated Hospital of Sun Yat-sen University and

confirmed that the rate of PUR in patients in the laTME or taTME groups was 1.5 % and 6.5 %, respectively. We powered the study to detect a 5 percent reduction in PUR rates for the laTME group compared to the taTME group. At 80 % power, it takes 476 (238 in hand) to get the type I error of 5 %. Calculating a 10 % attrition rate at 30-day follow-ups, the sample size was 524, 262 patients per arm. Patients were randomly assigned to the laTME or taTME groups according to the surgical method taken (Fig. 1). In the taTME group, a transanal bottom-up approach was employed for the TME procedure, rendering it essentially identical to the laTME group. In both treatment cohorts, the surgical procedures strictly adhered to the principles of TME, with the surgeon having the discretion to perform either a hand-sewn or stapled anastomosis, depending on their preference.

All surgical interventions were carried out by designated surgeons in the same hospital environment. Furthermore, independent investigators, unaware of the group assignments, were responsible for conducting the post-procedural follow-up assessments. This trial is registered with ClinicalTrials.gov NCT06147492.

2.3. Data collection

Each patient received a phone call to provide a comprehensive overview of the study's background, objectives, and key

Fig. 1. Flowchart illustrating the screening process for the inclusion of eligible patients in the study.

characteristics during the follow-up period. Pertinent patient information, including age, gender, weight, height, and relevant clinical data, was meticulously collected and entered into the hospital information system. This data encompassed the duration of post-operative indwelling urinary catheter use and the length of hospital stay. Furthermore, we employed the IPSS questionnaire, consisting of seven items that assess various aspects of urinary function, namely, emptying, frequency, intermittency, urgency, weak stream, hesitancy, and nocturia. Each item was rated on a scale of 1–5, resulting in a total possible score of 35 points, where higher scores indicated more pronounced urinary dysfunction. Patients were tasked with completing these two questionnaires both prior to surgery and at the one-month postoperative mark. The gathered data were systematically recorded within a dedicated database and subjected to rigorous statistical analysis.

2.4. Outcome assessment

The principal focus of our study centered on the occurrence of postoperative urinary retention after discharge from the hospital up to 30 days, defined as failure to void urine requiring catheterization after removal of the urinary catheter, or when the residual urine volume exceeded 300 mL, as determined through bladder scan measurements (Fig. 2). Secondary outcomes included assessment of bladder-related complications, urinary tract issues, and UTIs during the surgical procedure and in the postoperative period.

2.5. Statistical analysis

Data analyses were carried out utilizing IBM SPSS Statistics 26.0 and R studio. The primary method employed for classification criteria determination was the chi-squared test, with corresponding counts and percentages duly recorded. For the assessment of continuous variables, the Mann-Whitney *U* test or Student's t-test was utilized, accompanied by the description of medians with interquartile ranges (IQR) or means with standard deviations (SDs). To investigate patients with PUR, a chi-square test and multivariate logistic regression analysis were conducted to pinpoint independent predictors. Furthermore, a post hoc exploratory analysis was performed based on the surgical methods to ascertain the urinary retention rates among high-risk patients. Statistical significance was established when the two-tailed *P* value was less than 0.05. In our pursuit to construct a prediction model based on ROI-free analysis, we incorporated the net infusion rate (calculated as the total infusion rate minus the output infusion rate) and the net fluid amount (determined by subtracting the output fluid amount from the input fluid amount). Subsequently, their predictive

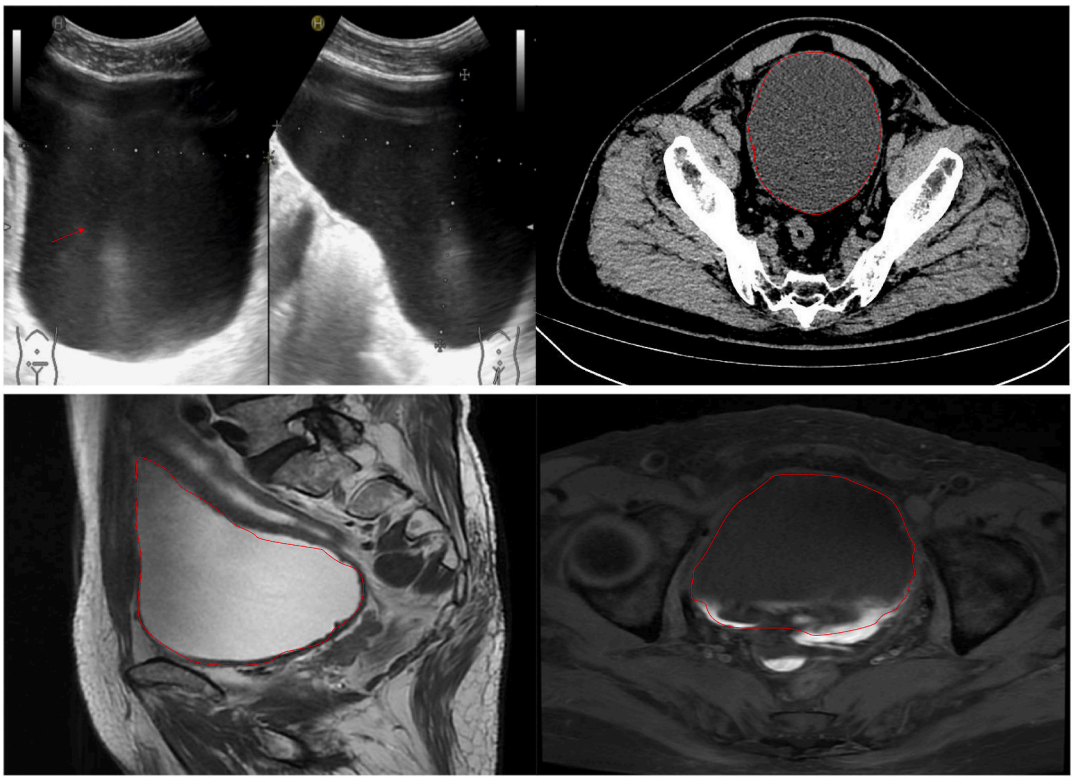

Fig. 2. Representative image demonstrating urine retention: (Top left) B-scan ultrasonography of a 45-year-old woman developing PUR two weeks after taTME (Top right) Computed Tomography of a 51-year-old male developing PUR three weeks after taTME (Bottom left) (Bottom right) Magnetic Resonance Imaging of a 65-year-old male who was detected chronic urinary retention in preoperative examination and excluded in the research.

performance was compared in terms of the area under the curve (AUC) value, as depicted in Fig. 3.

The reporting of our study adheres to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement [14], ensuring comprehensive and transparent reporting of observational research.

3. Results

Of the 533 patients enrolled, two were lost to follow-up, one in the catheter group, and one in the no-catheter group. Of the 524 patients randomized, 263 received taTME and 261 received laTME (Fig. 1). The baseline characteristics of the patients are shown in Table 1. The median age, presented with IQR, was 58 years (49–65), and 340 of the participants (64.8 %) were male. The median body mass index (BMI), also with IQR, stood at 22.65 (20.7–24.843), and merely three patients (0.5 %) had a history of benign prostatic hyperplasia (BPH). The clinical staging, as determined through preoperative imaging, exhibited a well-balanced distribution between the two groups. The median distance, noted with IQR, from the inferior margin of the tumor to the anal verge was 5 (3.9–6.2) cm.

3.1. The effect of taTME vs laTME on PUR and other urological complications

During the follow-up period, 37 patients (7.0 %) experienced PUR. Notably, there was no discernible difference in the incidence of PUR between the taTME and laTME groups, with 18 patients (6.8 %) in the former and 19 patients (7.2 %) in the latter ($P = 0.98$). PUR diagnoses were predominantly made after patients had been discharged from the hospital, with 34 patients (91.89 %) falling into this category. The most common treatment approach for PUR involved the use of straight and indwelling catheters, accounting for 18 patients (48.65 %) as detailed in Table 1. Furthermore, there were no significant disparities observed in the timing of PUR diagnosis and subsequent treatment between the two groups. Urethral trauma was identified in four patients, with three cases occurring in the laTME group and one in the taTME group. Ten cases of hematuria were reported, four of which were associated with the taTME group. Additionally, one intraoperative bladder injury and two cases of rectovaginal fistulae were noted in the taTME group. Furthermore, three patients developed UTIs: one in the taTME group and two in the laTME group.

3.2. The risk factors of PUR

To investigate factors associated with the development of PUR in patients who experienced it, we conducted chi-square tests. The examined factors included male sex, surgical complications, nCRT, obesity, ASA degree of 2 or 3, low rectal cancer (defined as distance from the anal verge <5 cm), age over 65 years, uncontrolled hypertension. Subsequently, we performed a multivariate logistic regression analysis (Table 2) to ascertain the significance of these factors. The analysis revealed that several factors were associated with the development of PUR, including surgical complications ($P < 0.01$), obesity ($P < 0.01$), ASA degree of 2 and 3 ($P = 0.01$), low rectal cancer ($P = 0.01$), and age over 65 years ($P < 0.01$). To further explore these associations, we conducted a post hoc analysis in

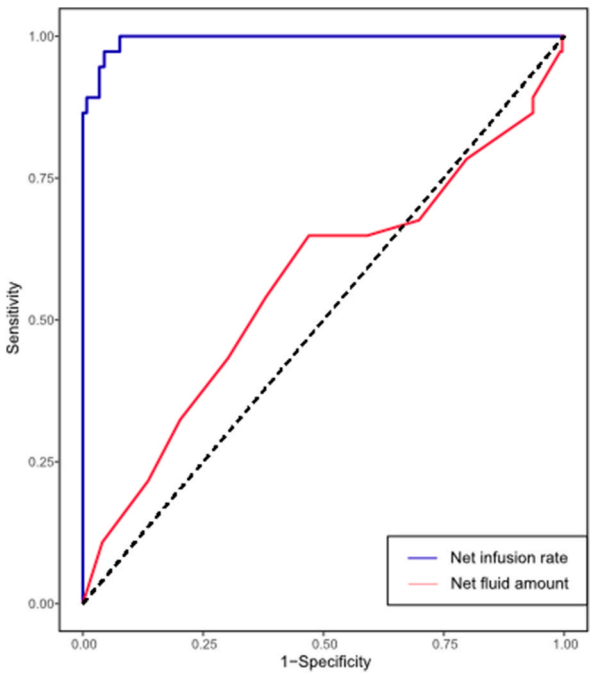

Fig. 3. The ROC curves for net fluid amount and Net infusion rate. The AUC values were calculated using the R software: Net fluid amount AUC, 0.561 (0.451–0.671), $P = 0.279$; Net infusion rate, AUC: 0.995 (0.989–1), $P < 0.001$, and optimal Cutoff value: 4.09.

Table 1
Patient demographic and operative outcome.

Variables/Outcome	Total (n = 524)	laTME (n = 261)	taTME (n = 263)	*P* value
Age (years)				
median [IQR]	58 [49, 66]	59 [51, 66]	57 [48, 65]	0.1317
BMI (kg/m^2)				
median [IQR]	22.650 [20.700,24.843]	22.680 [20.930, 24.500]	22.500 [20.565, 25.280]	0.6535
Female (%)	184 (35.11)	90 (34.48)	94 (35.74)	0.8334
Diabetes (%)	28 (5.34)	11 (4.21)	17 (6.46)	0.3419
Uncontrolled hypertension (%)	19 (3.63)	8 (3.07)	11 (4.18)	0.6524
BPH (%)	3 (0.57)	1 (0.38)	2 (0.76)	1
nCT (%)	204 (38.93)	102 (39.08)	102 (38.78)	1
nCRT (%)	55 (10.50)	25 (9.58)	30 (11.41)	0.5891
Clinical stage (%)				
I	77 (14.69)	29 (11.11)	48 (18.25)	0.0571
II	253 (48.28)	128 (49.04)	125 (47.53)	
III	194 (37.02)	104 (39.85)	90 (34.22)	
Distance from the inferior margin of the tumor to the anal verge (cm)				
median [IQR]	5.000 [3.900, 6.200]	5.000 [4.000, 6.500]	5.000 [3.800, 6.000]	0.173
ASA degree (%)				
I	230 (43.89)	115 (44.06)	115 (43.73)	0.8983
II	276 (52.67)	138 (52.87)	138 (52.47)	
III	18 (3.44)	8 (3.07)	10 (3.80)	
Operative time (minutes)				
median [IQR]	192.5 [155.0,242.0]	195.0 [158.0, 248.0]	190.0 [155.0, 236.5]	0.188
Surgical procedure				
One team	348 (66.41)	261 (100)	87 (33.08)	<0.01
Two teams	176 (33.59)		176 (66.92)	
Anastomotic technique, No. (%)				
Handsewn	105 (20.04)	26 (9.96)	79 (30.04)	<0.01
Stapled	419 (79.96)	235 (90.04)	184 (69.96)	
Anastomosis method, No. (%)				
straight	328 (62.60)	160 (61.30)	168 (63.88)	0.785
side to end	116 (22.14)	61 (23.37)	55 (20.91)	
colon pouch	80 (15.27)	40 (15.33)	40 (15.21)	
Enterostomy, No. (%)	283 (54.01)	138 (52.87)	145 (55.13)	0.604
Blood loss (ml) median [IQR]	50 [50,100]	50 [50, 100]	50 [50, 50]	0.1146
Surgical complication (%)	18 (3.44)	10 (3.83)	8 (3.04)	0.7977
Bladder injury	1 (0.19)	0	1 (0.38)	
Urethral trauma	4 (0.76)	3 (1.53)	1 (0.38)	
Hematuria	10 (1.91)	6 (2.30)	4 (1.52)	
Rectovaginal fistula	2 (0.38)	0	2 (0.76)	
Spleen Injury	1 (0.19)	0	1 (0.38)	
Pathological stage (%)				
0	27 (5.15)	13 (5.00)	14 (5.32)	0.949
I	164 (31.30)	79 (30.27)	85 (32.32)	
II	173 (33.02)	87 (33.33)	86 (32.70)	
III	160 (30.53)	82 (31.42)	78 (29.66)	
Tumor regression grade (%)				
0-1	31 (15.20)	15 (14.71)	16 (15.69)	0.845
2-3	173 (84.80)	87 (85.29)	86 (84.31)	
PUR (%)	37 (7.06)	19 (7.28)	18 (6.84)	0.9808
Timing of urinary retention diagnosis (%)				0.157
before discharge	3 (8.11)	2 (5.41)	1 (2.70)	
after discharge	34 (91.89)	17 (45.95)	17 (45.95)	
Treatment of urinary retention (%)				0.199
Straight catheterization and Indwelling catheter	18 (48.65)	11 (29.73)	7 (18.92)	
Indwelling catheter and discharge	3 (8.11)	2 (5.41)	1 (2.70)	
Straight catheterization and admitted	16 (43.24)	6 (16.22)	10 (27.03)	
UTI (%)	3 (0.57)	2 (0.77)	1 (0.38)	0.9947
Excessive intravenous fluid				
volume (%)	75 (14.31)	37 (14.18)	38 (14.45)	1
Early removal of UC (%)	187 (35.69)	93 (35.63)	94 (35.74)	1
The usage of diuretics (%)	27 (5.15)	9 (3.45)	18 (6.84)	0.1186
Renal failure (%)	1 (96.55)	1 (3.45)	0 (6.84)	0.1186
Postoperative hospital stays (hours)				
median [IQR]	192.5 [155.0,242.0]	195.0 [158.0, 248.0]	190.0 [155.0, 236.5]	0.188

Abbreviations: BMI, body mass index; nCT, neoadjuvant chemotherapy (chemotherapy alone and chemotherapy plus radiation); nCRT, neoadjuvant chemoradiotherapy; ASA, American Society of Anesthesiologists; BPH, benign prostatic hyperplasia; UC, urinary catheter.

Table 2
Chi-square test and multivariate logistic regression with patients who developed urinary retention.

	Chi-square test	Multivariate analysis	
Parameter	*P* value	Odds ratio (95 % CI)	*P* value
taTME	0.9808		
Male gender	0.0497	1.96 (0.85–5.11)	0.14
Early removal of UC	0.0594		
Excessive intravenous fluid volume	0.5576		
Surgical complications	0.0001	7.81 (2.23–25.49)	0.00
nCT	0.7517		
nCRT	0.0442	2.42 (0.88–6.10)	0.07
Obesity	0.0015	6.99 (1.91–23.34)	0.00
ASA degree = III	0.0084	2.39 (1.24–4.71)	0.01
Operative time > 4 h	0.0611		
Low rectal cancer	0.0084	2.50 (1.21–5.23)	0.01
Age >65	0.0357	3.01 (1.39–6.54)	0.00
Diabetes	0.0557		
Uncontrolled hypertension	0.049	2.76 (0.68–9.25)	0.12
BPH	0.5148		
The usage of diuretics	1		
Clinical stage = III	0.9502		
cT4	0.624		
pT4	0.931		
Trg = 2-3	0.769		

Abbreviations: BMI, body mass index; nCT, neoadjuvant chemotherapy; nCRT, neoadjuvant chemoradiotherapy; ASA, American Society of Anesthesiologists; BPH, benign prostatic hyperplasia; UC, urinary catheter; Trg, tumor regression grade.

patients with surgical complications, obesity, ASA degree of 2 and 3, low rectal cancer, and age over 65 years (eTable in the Supplement). Notably, taTME was not found to be associated with an increased risk of PUR in these specific groups.

Additionally, to gain deeper insights into the differences between taTME and laTME regarding PUR, we conducted chi-square tests and subsequently performed multivariate logistic regression analyses for each subgroup. In the taTME group (Table 3), early removal of the urinary catheter (defined as catheter removal on the first postoperative day, $P = 0.0061$), excessive intravenous fluid volume (Net infusion rate >4.09 ml.kg−1.h−1,cut-off value determined by ROC curve, $P = 0.0058$, and intraoperative fluid volume make no difference [15]), and age over 65 years ($P = 0.0321$) were identified as contributing factors to PUR. Conversely, in the laTME group (Table 4), PUR was associated with obesity ($P = 0.04$), ASA degree of 2 and 3 ($P = 0.01$), low rectal cancer ($P = 0.001$), diabetes ($P = 0.02$), and uncontrolled hypertension ($P = 0.04$).

Table 3
Chi-square test and multivariate logistic regression with patients who developed urinary retention in the taTME group.

	Chi-square test	Multivariate analysis	
Parameter	*P* value	Odds ratio (95 % CI)	*P* value
During the early period of the learning curve	0.9808		
Male gender	0.6343		
Early removal of UC	0.0098	4.54 (1.60–14.450	0.0061
Excessive intravenous fluid volume	0.044	5.10 (1.54–16.31)	0.0058
Surgical complications	0.1756		
nCT	0.4465		
nCRT	0.7314		
Obesity	0.0935		
ASA degree = III	0.3764		
Operative time > 4 h	0.1344		
Low rectal cancer	0.3797		
Age >65	0.0319	3.06 (1.09–8.66)	0.0321
Diabetes	0.7382		
Uncontrolled hypertension	1		
BPH	1		
The usage of diuretics	1		
Clinical stage = III	0.9003		
cT4	0.923		
pT4	0.834		
Trg = 2-3	0.451		

Abbreviations: BMI, body mass index; nCT, neoadjuvant chemotherapy; nCRT, neoadjuvant chemoradiotherapy; ASA, American Society of Anesthesiologists; BPH, benign prostatic hyperplasia; UC, urinary catheter.

Table 4
Chi-square test and multivariate logistic regression with patients who developed urinary retention in the laTME group.

	Chi-square test	Multivariate analysis	
Parameter	*P* value	Odds ratio (95 % CI)	*P* value
Male gender	0.0423	3.33 (0.79–23.32)	0.14
Early removal of UC	1		
Excessive intravenous fluid volume	0.415		
Surgical complications	0.0006	3.91 (0.74–18.59)	0.09
nCT	0.1532		
nCRT	0.03	3.37 (0.75–13.63)	0.09
Obesity	0.0042	14.99 (1.19–367.05)	0.04
ASA degree = III	<0.001	4.49 (1.64–13.87)	0.01
Operative time > 4 h	0.3761		
Low rectal cancer	0.0092	7.27 (2.26–27.66)	0.001
Age >65	0.5563		
Diabetes	0.0439	7.19 (1.17–38.76)	0.02
Uncontrolled hypertension	0.008	7.42 (1.02–46.64)	0.04
BPH	0.0995		
The usage of diuretics	1		
Clinical stage = III	0.9481		
cT4	0.571		
pT4	0.77		
Trg = 2-3	0.75		

Abbreviations: BMI, body mass index; nCT, neoadjuvant chemotherapy; nCRT, neoadjuvant chemoradiotherapy; ASA, American Society of Anesthesiologists; BPH, benign prostatic hyperplasia; UC, urinary catheter.

4. Discussion

This research aimed to assess the impact of taTME versus laTME on PUR in rectal cancer patients. Our findings indicate that taTME did not exhibit a discernible effect on PUR or other urological complications when compared to laTME. Additionally, we identified specific risk factors associated with PUR in patients following taTME, including early urinary catheter (UC) removal, excessive intravenous fluid volume, and age over 65 years.

A recent meta-analysis [16] has demonstrated an association between the type of surgical procedure and PUR. This connection may be attributed to nerve palsy resulting from the traction exerted by laparoscopic instruments [11] and reduced urine output due to elevated pneumoperitoneum pressure [17]. TaTME, which introduces additional instruments and elevates pneumoperitoneum pressure compared to laTME, carries a potential risk of PUR. Furthermore, the technical aspects of taTME, particularly its potential impact on the anal sphincter complex and pelvic floor muscles [18], along with reported cases of urethral injury in men [19], specific surgical complications, and potential PUR, have raised concerns. However, it's worth noting that existing literature has suggested that the transanal technique is superior in preserving urinary function [20]. Consequently, a comprehensive investigation into the association between taTME vs. laTME and PUR is urgently needed. Based on our study results, no significant impact of taTME versus laTME on PUR was observed.

LaTME allows surgeons to uphold oncological resection principles for total mesorectal excision while offering less invasiveness compared to open surgery [21]. This has established laTME as a recognized modality for treating resectable rectal cancer. Nonetheless, this technique may not be suitable for all rectal cancer patients, especially those with challenging anatomical characteristics such as a narrow pelvis, the possibility of conversion to open surgery, or potential difficulties in achieving complete TME or preserving adequate resection margins. In such cases, taTME emerges as an optimal approach for rectal cancer surgery. By incorporating a single port as a transanal approach [22], taTME offers unique technical advantages and improved visualization within confined pelvic spaces. Hence, taTME becomes an indispensable component of the quest for less invasive surgical techniques in the management of resectable rectal cancers.

PUR is a relatively common and detrimental complication occurring in colorectal surgery patients, affecting approximately 5.5–16.0 % of cases [23]. This concern is exacerbated by the rising incidence of rectal cancer, potentially leading to decreased patient satisfaction with medical treatment [24]. Consequently, it is imperative to identify the risk factors for PUR following. A meta-analysis has previously highlighted several risk factors for PUR after colorectal surgery, including male sex, advanced age, diabetes, low rectal cancer, early urinary catheter removal, and excessive fluid volume. Our exploratory multivariate analysis identified surgical complications, obesity, ASA degrees of 2 and 3, low rectal cancer, and age over 65 years as significant risk factors for developing PUR. However, a post hoc analysis involving these high-risk patient groups failed to reveal any association between transanal versus laparoscopic TME and PUR.

Furthermore, to elucidate the risk factors for PUR specifically in patients who underwent taTME, we conducted an exploratory multivariate analysis among patients who experienced PUR. The results indicated that early UC removal, excessive fluid volume, and age over 65 years were contributing factors to the development of PUR. In conventional colorectal surgery, it is standard practice to remove the catheter on the third postoperative day [25]. Multiple studies have underscored that earlier UC removal increases the risk of PUR [15,26,27]. A prospective, randomized, non-inferiority trial has demonstrated the feasibility of early UC removal following pelvic surgery [28], and ERAS guidelines [29] recommend early UC removal in elective colorectal surgery. However, these guidelines

do not encompass taTME as a novel approach, warranting specific recommendations. Our research indicates that early removal of the postoperative urinary catheter, within one day, elevates the risk of PUR in taTME patients. Therefore, clinical practice should adhere to the standard protocol of postoperative catheter removal beyond the first day. Furthermore, excessive intravenous fluid volume has been linked to PUR, advocating for judicious fluid management with lower volumes of infused fluids. Notably, two patients suffered from rectovaginal fistulas underwent taTME in the early stages of the team's taTME learning curve, it is worth exploring whether rectovaginal fistulas are more likely to occur in the early stages of the taTME learning curve. Several ongoing taTME trials would provide sufficient evidence to further explore this question.

Several limitations should be acknowledged in our study. Firstly, the study population was drawn from a single center; however, we perform taTME with a high volume of procedures in this the largest colorectal disease center in Asia. Secondly, our primary focus was on PUR in rectal cancer patients, and the long-term impact of taTME on urinary function remains unexplored. We plan to establish a more extended follow-up period to investigate the long-term effects. Thirdly, assessing erectile function is essential for gauging the safety of taTME, and a forthcoming study will address this aspect. Finally, as the follow-up of several multi-center clinical trial remains incomplete, data pertaining to 3- or 5-year overall survival, disease-free survival, and local recurrence rates between the laTME and taTME groups remain unavailable. Consequently, questions regarding the efficiency and safety of taTME cannot yet be definitively answered. Nevertheless, our current findings allow us to conclude that taTME versus laTME had no apparent impact on the occurrence of PUR.

5. Conclusion

In the present study, it was observed that taTME did not pose an elevated risk of PUR. However, specific risk factors associated with PUR following taTME were identified, including early removal of the UC, excessive intravenous fluid volume, and an age exceeding 65 years. Consequently, we recommend adhering to the standard protocol of postoperative catheter removal beyond the initial day and exercising prudence in the administration of intravenous fluids in clinical practice for taTME procedures.

Ethics approval and consent to participate

The experimental protocol was established, according to the ethical guidelines of the Helsinki Declaration and was approved by by the Ethics Committee of The Sixth Affiliated Hospital of Sun Yat-sen University ethics committee (E2019052). Written informed consent was obtained from individual or guardian participants. This trial is registered with ClinicalTrials.gov NCT06147492.

Consent for publication

Not applicable.

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Presentation

None.

Data available statement

Authors agree to make data and materials supporting the results or analyses presented in their paper available upon reasonable request. A website is being built to make the data accessible, which can be used by anyone with a simple registration. Further information is available upon request toward corresponding author.

CRediT authorship contribution statement

Fujin Ye: Writing – original draft, Validation, Supervision, Resources, Investigation, Funding acquisition. **Lei Ruan:** Writing – review & editing, Writing – original draft, Validation, Resources. **Zhanzhen Liu:** Visualization, Software, Methodology, Formal analysis, Conceptualization. **Hao Xie:** Software. **Taixuan Wan:** Validation, Software, Methodology. **Wenliang Zhu:** Software, Project administration, Formal analysis, Conceptualization. **Ze Li:** Methodology, Investigation. **Wei Xiao:** Funding acquisition, Conceptualization. **Haoqi Zheng:** Validation, Resources, Conceptualization. **Dongxu Lei:** Resources, Investigation. **Yebohao Zhou:** Methodology, Funding acquisition. **Xiaobin Zheng:** Investigation, Data curation. **Zhenxing Liang:** Visualization, Resources. **Huashan Liu:** Formal analysis. **Pinzhu Huang:** Software, Resources, Methodology. **Liang Kang:** Visualization, Resources, Methodology, Investigation, Conceptualization. **Liang Huang:** Writing – review & editing, Project administration, Funding acquisition, Formal analysis.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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