



Suprapubic versus transurethral catheterization for bladder drainage in male rectal cancer surgery (GRECCAR10), a randomized clinical trial

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Abstract

Background Bladder drainage is systematically used in rectal cancer surgery; however, the optimal type of drainage, transurethral catheterization (TUC) or suprapubic catheterization (SPC), is still controversial. The aim was to compare the rates of urinary tract infection on the fourth postoperative day (POD4) between TUC and SPC, after rectal cancer surgery regardless of the day of removal of the urinary drain.

Methods This randomized clinical trial in 19 expert colorectal surgery centers in France and Belgium was performed between October 2016 and October 2019 and included 240 men (with normal or subnormal voiding function) undergoing mesorectal excision with low anastomosis for rectal cancer. Patients were followed at postoperative days 4, 30, and 180.

Results In 208 patients (median age 66 years [IQR 58–71]) randomized to TUC ($n=99$) or SPC ($n=109$), the rate of urinary infection at POD4 was not significantly different whatever the type of drainage (11/99 (11.1%) vs. 8/109 (7.3%), 95% CI, –4.2% to 11.7%; $p=0.35$). There was significantly more pyuria in the TUC group (79/99 (79.0%) vs. (60/109 (60.9%), 95% CI, 5.7–30.0%; $p=0.004$). No difference in bacteriuria was observed between the groups. Patients in the TUC group had a shorter duration of catheterization (median 4 [2–5] vs. 4 [3–5] days; $p=0.002$). Drainage complications were more frequent in the SPC group at all followup visits.

Conclusions TUC should be preferred over SPC in male patients undergoing surgery for mid and/or lower rectal cancers, owing to the lower rate of complications and shorter duration of catheterization.

Trial registration ClinicalTrials.gov identifier NCT02922647.

Keywords Rectal cancer surgery · Bladder drainage · Transurethral catheter · Suprapubic catheter · Randomized clinical trial

Introduction

In 2020, 25,780 new cases of colorectal cancer were diagnosed in male patients in France [1], of which approximately one-third were rectal cancer. Curative treatment for rectal cancer includes anterior rectal resection with total mesorectal excision (TME). To monitor urinary output, allow safe dissection of pelvic structures by emptying the bladder to expose the surgical field, and prevent postoperative retention after rectal resection, bladder drainage is used. The reported incidence of difficulty in re-establishing micturition after low anterior resection is approximately 25% [2, 3]. Bladder

dysfunction after rectal surgery is related to autonomic nerve injury during rectal mobilization, but also to mechanical outflow obstruction due to prostatic hypertrophy, neoadjuvant radiotherapy, damage to bladder supporting structures, anesthetic drugs, and a recumbent postoperative position [4, 5].

Commonly, bladder drainage is performed by transurethral catheterization (TUC), which is associated with a high incidence of urinary infections [6]. These are expensive to treat, have significant morbidity, and are associated with a threefold increase in patient mortality [6, 7]. Other complications include pain, urethritis, periurethral abscesses, and urethral stricture formation.

Suprapubic catheterization (SPC) of the bladder is widely used after general surgery and has been reported to be

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superior to TUC in these patients, resulting in less discomfort, less frequent urinary infections, no urethritis, the ability to void spontaneously, easier nursing care, and shorter hospital stay [4]. However, SPC has its own morbidities with an increased incidence of specific complications such as migration, hematuria, obstruction, pericatheter urine leakage, and occasionally intestinal or vascular wounds.

A few randomized studies ($n=9$) have compared suprapubic and transurethral bladder drainage in general surgery [8–16]. All these studies focused on abdominal surgery, included female patients, and were published over 19 years ago. Four studies included fewer than 65 patients. A meta-analysis comparing suprapubic and transurethral catheterization for bladder drainage concluded that in general surgery, the suprapubic route is more readily accepted by patients [17]. The authors concluded that there was a need for more and better randomized controlled trials (RCT).

SPC after rectal cancer surgery has not come into widespread use. The intuitive perceived benefits of suprapubic over transurethral catheterization in rectal cancer surgery are reduced urinary tract infection, control and monitoring of return to normal voiding, reduced need to recatheterize, avoidance of risk of urethral trauma, infection, or stricture, and improved patient satisfaction.

A prospective comparison between suprapubic and transurethral catheterization has never been performed in a population of male patients with TME and low anastomosis for cancer, and the matter is still in pending.

The present multi-institutional RCT (ClinicalTrials.gov identifier NCT02922647) aimed to assess whether SPC may be superior to TUC in terms of the reduction of urinary infection, morbidity, and hospital stay in male patients (with normal or subnormal voiding function) undergoing surgery for mid or lower rectal cancer.

Methods

Design, setting, and participants

This study was a multicenter, prospective, open-label, two-parallel-group, randomized trial. Nineteen French Research Group for Rectal Cancer Surgery (GRECCAR) centers throughout France and Belgium participated between October 2016 and October 2019.

The inclusion criteria were adult males with stage T1–4 Nx Mx rectal adenocarcinoma, with or without neoadjuvant therapy, scheduled to undergo TME with low anastomosis (colorectal or coloanal, stapled or stitched) with or without loop ileostomy, by an open or minimally invasive approach, and who had signed a study-specific informed consent form.

The exclusion criteria were patients with upper third rectal cancer (partial mesorectal excision), an abdominoperineal

resection, an associated prostate and/or seminal glands and/or bladder resection (initial T4, poor responders to neoadjuvant therapy), an infected tumor, emergency surgery, received epidural analgesia, had antibiotic therapy, had a previous treated/untreated known prostate or bladder carcinoma, had symptomatic preoperative voiding disorders with an International Prostatic Symptom Score (IPSS) greater than 19 [18], a medical history of bladder catheterization for obstruction, previous urethral surgery, needed urinary output monitoring (e.g., impaired renal function), an usual contraindication for urethral catheterization or suprapubic drainage, or any known allergy to the materials comprising the medical device or sterilizing agents, or an individual deprived of liberty by judicial or administrative decision, subject to legal protection, and/or hospitalized without consent.

Exhaustive records of the characteristics of all included patients were kept by each center.

Ethical approval

The trial protocol was approved by the French Ethics Committee CPP Sud-Est V on December 17, 2015 (IRB n° 2015-A01435-44) and the French Health Authority (ANSM). Written informed consent was obtained before inclusion in the trial. In France it is against the law to collect race/ethnic data except in special circumstances and approval is difficult to obtain.

Randomization and masking

The day before the procedure, the included patients were randomly assigned, in a 1:1 ratio, to have either SPC or TUC for urinary drainage during surgery. In each center, the patient study information and informed consent form were provided by the surgeon in charge of the patient. Centralized randomization with stratification by center with blocks of random sizes was performed by the surgeon in charge of the patient through the secure electronic case report form (e-CRF) site. Neither patients nor their clinicians were blinded to the treatment assignments. The surgeon performed both the inclusion and the follow-up visits and all data collected was gathered in a patient file (source file) (entire hospitalization and follow-up). The e-CRFs were filled in by the surgeon/investigator or study clinical research assistant(s).

Study treatment

The precise procedure for TME for mid and low rectal cancer, either through median laparotomy or by a minimally invasive approach and performed by members of the GRECCAR group, has been previously described [19]. Low colorectal anastomosis (CRA) or coloanal anastomosis (CAA)

was fashioned either end-to-end, side-to-end, or with a J-pouch. The use of prophylactic diverting ileostomy was left to the discretion of the surgeon.

Antibiotic prophylaxis was provided by a single dose of cefoxitin (2 g) at the induction of anesthesia, according to the HAS (French Health Authority) April 2018 recommendations.

In the TUC group, the urethral catheter was positioned by nursing or medical staff in the operating room before the start of the procedure, following strict aseptic rules. For this study, urethral drainage was performed using a Folsil® urethral catheter (COLOPLAST straight catheter kit ref. AA6118) connected to a 1500-ml Conveen triform urine bag (COLOPLAST ref. 050630). A reference urine sample for cytobacteriological analysis (UCB) was obtained when connecting the collection bag.

For the SPC group, the suprapubic catheter was inserted by the surgeon during the operation in the operating room under strict aseptic conditions. If necessary, the placement of the suprapubic catheter was delayed until the bladder was sufficiently full. Suprapubic drainage was performed using the Cystodrain Integral-suprapubic drainage kit (COLOPLAST ref. AJ7512). The catheter was inserted very close to the pubic bone and slightly to the left, in order not to compromise a median or transversal incision for either conversion or specimen extraction. It was secured to the skin using a 2/0-gauge non-absorbable suture. The urine collection bag was connected, and a reference UCB sample was collected at that time. For this study the same uniform analgesia protocol was used in all participating GRECCAR centers with minimal use of opioids and only if absolutely necessary. The same postoperative enhanced recovery after surgery (ERAS) protocol was used in both the groups.

Assessments

Following enrolment, but before randomization, each patient underwent a baseline evaluation consisting of medical history, age, body mass index (BMI), American Society of Anesthesiology (ASA) score, physical examination, and tumor characteristics including size, site, distance from the anal sphincter and circumferential margin on MRI, metastases on CT scan, carcinoembryonic antigen (CEA) level, TNM classification, and neoadjuvant treatment. The baseline IPSS score [18], Functional Assessment of Cancer Therapy-Colorectal (FACT-C) score [20], and EQ-SD-3L quality of life score [21] were assessed.

Postoperative evaluations of general and drainage-related complications were systematically performed daily from the operation to postoperative day 4 (POD4), and then on days 30 and 180. On POD4, the IPSS, FACT-C, and EQ-SD-3L quality of life scores were again assessed, and then on days 30 and 180.

Endpoints

The primary endpoint was defined as urinary infection associated with significant bacteriuria ($\geq 10^4$ CFU/ml) and significant pyuria ($\geq 10^4$ leukocytes/ml) in the urine sample taken on POD4, regardless of the day of urinary drainage removal. A steering committee consisting of bacteriologists, infectious disease specialists, urologists, and digestive surgeons from the coordinating center generated an evidence-based consensus on the definition of urinary infection, based on the recommendations for Good Clinical Practice edited by the French Language Society of Infectious Pathology (SPILF), the French Urology Association (AFU), and the French Society for Hospital Hygiene (SF2H) [22].

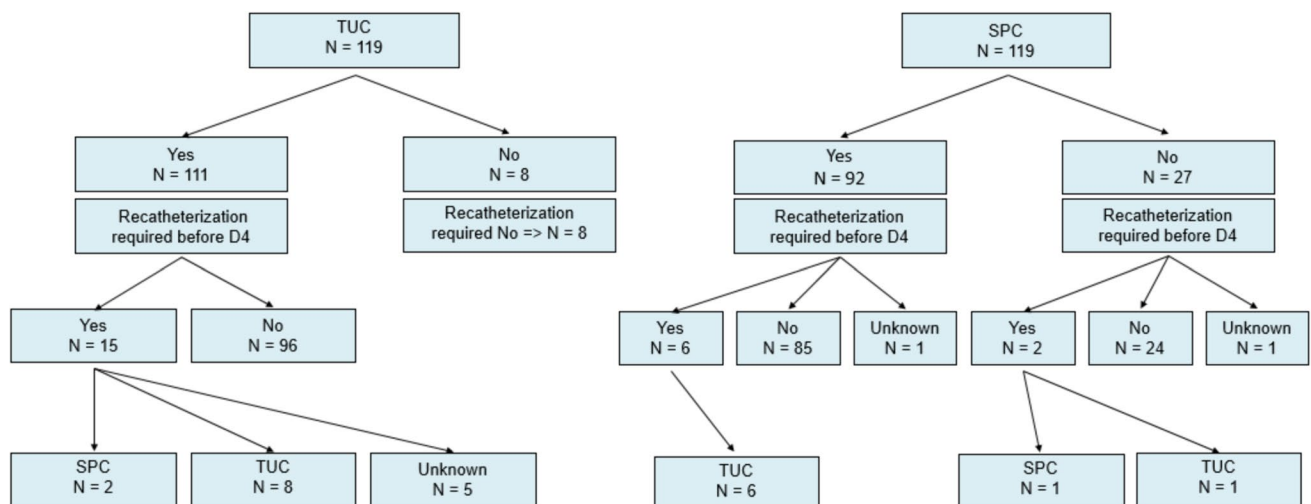
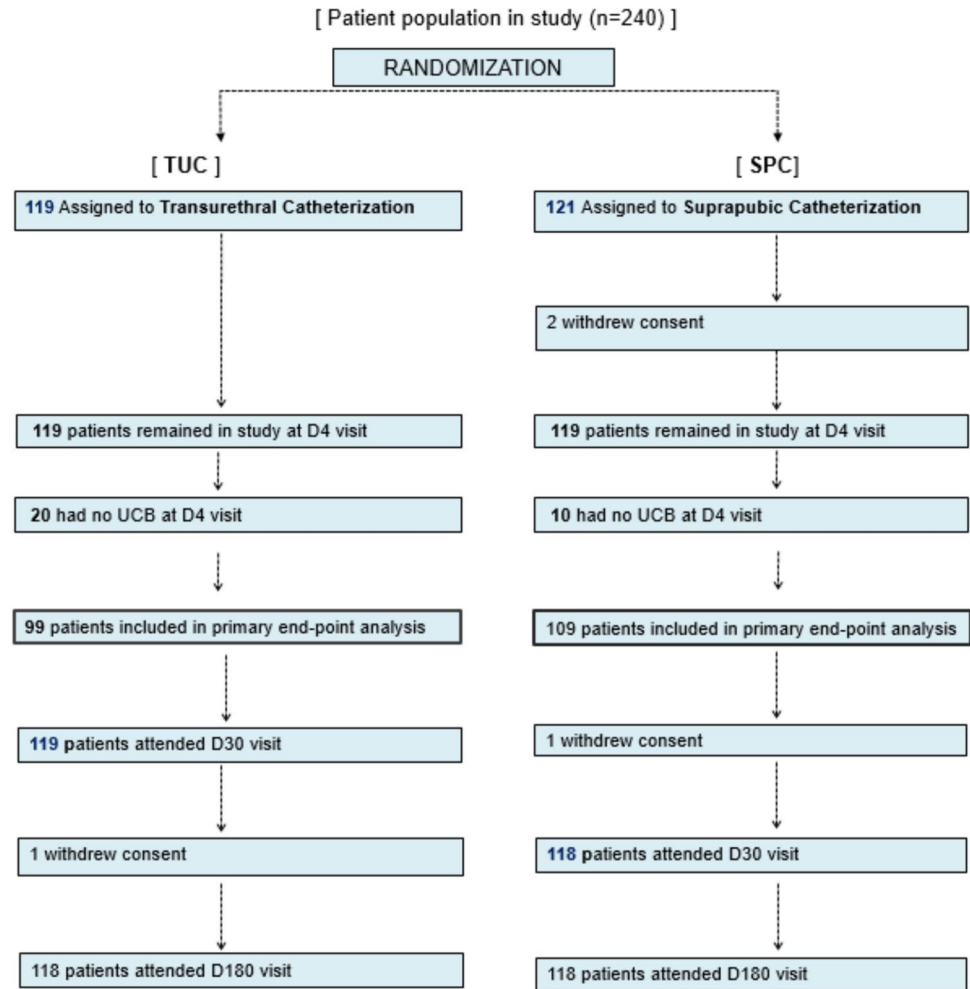
Secondary endpoints included the duration of catheterization, rate of recatheterization in the first 6 months, specific drainage-related complications up to 6 months, overall morbidity and mortality up to 6 months using the Clavien–Dindo classification [23], length of hospitalization, and number of supernumerary consultations or hospital admissions for complications or other reasons.

Sample size calculation

Assuming a urinary tract infection rate at POD4 of 10% in the group with suprapubic catheters versus 25% in the group with urethral catheters (calculated from nine randomized trials), 100 patients needed to be included per group for an alpha risk of 5% and a power of 80%. To account for patients whose primary endpoint was not evaluable, we planned to include 220 patients. Owing to missing data on the primary endpoint from one center, an amendment to increase enrolment to 240 patients was submitted to the ethics committee and approved.

Statistical analysis

All analyses were performed on the intention to treat (ITT) population (Fig. 1), with a per-protocol analysis to validate the results (Fig. 2). Descriptive analyses are presented using median values and interquartile ranges for continuous variables and the number of cases with percentages for categorical variables. Fisher tests were used to compare categorical variables between the two study arms, and *t* tests were performed for non-repeated continuous criteria if the normal distribution was graphically validated; otherwise, a Mann–Whitney test was performed. Repeated-measures analysis of variance (ANOVA) was used for repeated continuous values. For the primary endpoint, sensitivity analysis using multiple imputations (10 imputations) was performed using a logistic regression model. All *p* values were from

Fig. 1 CONSORT study flow-chart (intent to treat population)**Fig. 2** Per protocol analysis: type of catheterization and recatheterization. *UC* transurethral catheterization, *SPC* suprapubic catheterization, *CBEU* cytobacteriological examination of urine

two-sided tests, and results were declared statistically significant at p values < 0.05 . All analyses were performed using Stata 15 software (StataCorp, USA).

Results

Study patients

A total of 240 male patients for whom TME (with low CRA or CAA) for mid or lower rectal cancer was planned were enrolled and randomized to receive either TUC ($n = 119$) or SPC ($n = 121$). Two patients in the SPC group withdrew consent and were excluded from the analysis (Fig. 1). The baseline characteristics of the remaining 238 patients were well balanced between the two groups (Table 1). None of the patients had a positive UCB test on day 0. For the primary endpoint, 208 patients (86.7%) had evaluable UCB on both day 0 and POD4. A comparison between patients whose data was evaluable and those whose data was not evaluable for all criteria is shown in supplementary material Table S1.

Primary endpoint

In the ITT analysis, there was no statistical difference between the TUC and SPC groups concerning urinary infection at POD4 (11/99 (11.1%) vs. 8/109 (7.3%); difference, 3.8%; 95% CI, -4.2% to 11.7% ; $p = 0.35$). There was significantly more pyuria in the TUC group (79/99 (79.0%) vs. 60/109 (60.9%); difference, 18.1%; 95% CI, 5.7% – 30.0% ; $p = 0.004$). No significant difference in bacteriuria was observed between the groups ($p = 0.84$) (Table 2).

Secondary endpoints

The median [IQR] catheterization duration was 4 days [3–5]. Patients in the TUC group had a shorter catheterization duration than those in the SPC group (median 4 [2–5] vs. 4 [3–5]; $p = 0.002$) (supplementary material Fig. S1). There was no significant difference in the rate of recatheterization in the first 6 months (Table 3). Cumulative specific complications of drainage were more frequent in the SPC group compared with the TUC group at POD4 (29/116 (25%) vs. 10/119 (8.4%); difference, -16.6% ; 95% CI, -25.8% to -7.1% ; $p = 0.001$), day 30 (33/115 (28.7%) vs. 10/116 (8.6%); difference, -20.1% ; 95% CI, -29.6% to -10.1% ; $p < 0.001$), and day 180 visit (33/111 (29.7%) vs. 11/114 (9.6%); difference, -20.1% ; 95% CI, -30.0% to -9.7% ; $p < 0.001$). The numbers and types of specific complications are shown in Table 3. There was no statistical difference between the groups concerning overall morbidity and mortality (rated using the Clavien–Dindo grades) up to 6 months (Table 3). The median length of hospitalization was 9 days

[7–14] and was similar between the TUC and SPC groups (median 10 days [6–15] vs. 9 [7–12], respectively; $p = 0.50$) (supplementary material Table S2). Assessment of urinary function at day 30 and day 180 using the IPSS score was similar in both groups (Table 3).

There was no statistical difference in terms of quality of life as assessed by the FACT-C and EQ-5D-3L questionnaires and a visual analogue scale (Table 4).

The number of supernumerary consultations or hospital admissions for complications or other causes did not differ between the two groups (supplementary material Table S3).

Discussion

To our knowledge, the present study is the first to prospectively compare the two main types of bladder drainage in a population of male patients undergoing TME and low anastomosis for rectal cancer. This randomized clinical trial that enrolled selected male patients who had no previous severe voiding problems prior to surgery for rectal cancer showed no significant difference in the POD4 urinary infection rate between suprapubic (7.3%) and transurethral catheterization (11.1%). However, on POD4, patients in the TUC group had statistically more pyuria than those in the SPC group (79% vs. 60.9%), despite not developing more symptoms of urinary infection (9.2% vs. 6%) or higher bacteriuria (12.7% vs. 11.8%). This result is in contrast with the meta-analysis by McPhail et al. [17] that showed a relative risk of 2.02 (95% CI, 1.34–3.04, $p < 0.001$) for significant bacteriuria in the TUC group compared with the SPC group, from a selection of five trials that used $\geq 10^4$ CFU/ml in the urine sample as an endpoint [10, 12, 14–16]. In a small prospective randomized trial involving 46 patients, Vandoni et al. [24] showed that daily bacteriuria became significant in the TUC group (compared to their SPC group) on the third day of drainage. However, Botsios et al. [15] also studied pyuria and found significantly increased pyuria in the TUC group, as in our study.

The trials in the meta-analysis by McPhail et al. [17] had enrolled not only male patients with low or high rectal cancer but also general surgery patients and female patients in whom bladder catheterization is easier and does not have the same difficulties. This restricts the comparison with our trial. The significant difference in pyuria we observed in this study may come from the presence of the TUC in the bladder, which is a bigger probe than the SPC. The absence of a difference in bacteriuria may be a positive effect of the antibiotic prophylaxis.

According to a recent review of the literature, the optimal duration of urinary drainage remains unclear. However, early catheter removal seems to be superior in terms of reducing the risk of urinary infection [25–28]. Nevertheless, Lee

Table 1 Baseline characteristics of the patients at inclusion ($N=238$)

	Randomization arm		
	TUC ($n=119$)	SPC ($n=119$)	Total ($n=238$)
Age, years	63 [56–70]	66 [59–71]	65 [58–71]
Body mass index, kg/m ²	26.4 [23.7–28.4]	24.9 [22.8–28.1]	25.7 [23.5–28.4]
Antecedent	108 (88.2)	107 (89.9)	215 (89.1)
Diabetes	17 (16.2)	22 (20.6)	39 (18.4)
Immune deficiency	0 (0.0)	1 (0.9)	1 (0.5)
Hypertension	43 (40.9)	48 (44.9)	91 (42.9)
Cholesterol	18 (17.1)	17 (15.9)	35 (16.5)
Obesity	26 (24.8)	25 (23.4)	51 (24.1)
Alcoholism	8 (7.6)	11 (10.3)	19 (9.0)
Smoking	28 (26.7)	33 (30.8)	61 (28.8)
Pelvic abdominal surgery	35 (33.3)	42 (39.2)	77 (36.3)
Other	81 (77.1)	88 (82.2)	169 (79.7)
ASA score			
1	26 (23.4)	18 (16.2)	44 (19.8)
2	57 (51.4)	69 (62.2)	126 (56.8)
3	28 (25.2)	24 (21.6)	52 (23.4)
Missing	8	8	16
Tumor site, mm	60 [40–82]	60 [30–90]	60 [33–85]
Missing	19	24	43
CAE, ng/ml	3.0 [1.5–5.9]	3.0 [1.6–4.3]	3.0 [1.6–4.8]
Missing	64	64	128
Rectal MRI	106 (89.1)	110 (92.4)	216 (90.8)
Tumor size, cm	4.2 [3.0–5.6]	4.0 [3.0–5.5]	4.0 [3.0–5.6]
Missing	13	19	32
Previous metastasis	24 (22.6)	22 (20.2)	46 (21.4)
Missing	0	0	0
Circumferential margin, mm	3 [0–8]	5 [2–11]	3 [0–10]
Missing	50	51	101
Distance to sphincters, mm	40 [15–56]	44 [10–64]	42 [14–60]
Missing	29	26	55
CT scan	103 (86.5)	103 (86.5)	206 (86.5)
Metastases	10 (9.7)	7 (6.8)	17 (8.2)
Liver	8	5	13
Lung	2	1	3
Peritoneum	0	0	0
Bone	0	1	1
Brain	0	0	0
Tumor stage T			
0	1 (0.8)	4 (3.4)	5 (2.1)
1	9 (7.6)	6 (5.0)	15 (6.3)
2	18 (15.1)	20 (16.8)	38 (16.0)
3	88 (73.9)	85 (71.4)	173 (72.7)
4	3 (2.5)	4 (3.4)	7 (2.9)
Tumor stage N			
0	52 (43.7)	53 (44.5)	105 (44.1)
1	53 (44.5)	61 (51.3)	114 (47.9)
2	14 (11.8)	5 (4.2)	19 (8.0)
Tumor stage M			
0	110 (92.4)	115 (96.6)	225 (94.5)

Table 1 (continued)

	Randomization arm		
	TUC (<i>n</i> = 119)	SPC (<i>n</i> = 119)	Total (<i>n</i> = 238)
1	9 (7.6)	4 (3.4)	13 (5.5)
Radiotherapy			
No	20 (16.8)	20 (16.8)	40 (16.8)
Yes	99 (83.2)	99 (83.2)	198 (83.2)
Chemotherapy			
No	37 (31.1)	34 (28.6)	71 (29.8)
Yes	82 (68.9)	85 (71.4)	167 (70.2)

Data are presented as *n* (%), median [IQR], or number

Table 2 Urinary tract infection at day 4 visit (*n* = 208)

	ARM			
	TUC (<i>n</i> = 99)	SPC (<i>n</i> = 109)	Total (<i>n</i> = 208)	<i>p</i> value
Urinary tract infection				
No	88 (88.9)	101 (92.7)	189 (90.9)	0.35
Yes	11 (11.1)	8 (7.3)	19 (9.1)	
Bacteriuria (<i>n</i> = 212)				
No	89 (87.3)	97 (88.2)	186 (87.7)	0.84
Yes	13 (12.7)	13 (11.8)	26 (12.3)	
Pyuria (<i>n</i> = 210)				
No	21 (21.0)	43 (39.1)	64 (30.5)	0.004
Yes	79 (79.0)	67 (60.9)	146 (69.5)	

Data are presented as *n* (%)

et al. showed that urinary catheter removal on days 1 or 2 was an independent risk factor for acute urinary retention after rectal cancer surgery when compared with removal on day 5 [5]. Meillat et al. [29] recently showed that withdrawal of the urinary catheter on postoperative day 3 gives successful results after laparoscopic rectal resection and can be safely implemented in the ERAS program [29]. In this trial, the timing of catheter removal was not prespecified; the median duration of catheterization of 4 days [3–5] seems reasonable in patients undergoing surgery for mid and low rectal cancer and reflects experience in expert centers. The significantly shorter length of catheterization in the TUC group than in the SPC group may have been because no clamping for a micturition recovery study was possible for this type of drainage and the TUC removal was straightforward. Early mobilization is easier after removal of a urethral catheter to decrease urethral irritation and discomfort, as suggested by Vandoni et al. [24]. However, no difference between the two groups concerning this point was found in the present trial (data not shown). Another explanation could be that suprapubic catheters are often clamped the day before removal to check normal micturition has resumed.

Patients in the SPC group reported more cumulative complications linked to the mode of drainage than those in the

TUC group, both on POD4, and later during follow-up (days 30 and 180). This was also observed by Bouchet-Doumenq et al. [30] who reported a higher rate of complications in patients with SPC than in those with TUC (20.6% vs. 9%) in a retrospective study of 190 male patients who underwent proctectomy for cancer (including high rectal cancer and abdominoperineal excision) with SPC used in 72% of cases as a general policy.

In our trial, there were no significant differences in terms of the recatheterization rate in the first 6 months (Table 3), overall morbidity and mortality up to 6 months, length of hospitalization, urinary function at days 30 and 180, quality of life, and number of supernumerary consultations or hospital readmissions.

Strengths and limitations

The major strengths of this study were the very homogeneous patient population, that the participating centers were all expert centers, and, to our knowledge, this was the largest low rectal cancer surgery study ever performed with these endpoints, which were based on a precise definition of urinary infection, bacteriuria, and pyuria at a given time point.

The limitations included the choice of endpoint of urinary infection at day 4; this was chosen from the literature at a time (2014) when it was normal practice to leave the urinary catheter in place for at least 4 days. However, with the more recent implementation of ERAS programs, urinary catheters are nowadays removed earlier [31]. The primary endpoint was considered appropriate and in line with the recommendations of the latest Cochrane review at the time of designing the trial [32]. Morbidity and quality of life might have been more appropriate endpoints. A third limitation could be the suprapubic catheter model we chose to impose for the study, as there are other models available with different designs. This trial did not address the question of the best bladder drainage route for male patients with previous urinary dysfunction or for those undergoing abdominoperineal excision.

Table 3 Complications reported at day 4 visit (238 patients), day 30 visit (237 patients), and day 180 visit (236 patients)

	Day 0 to day 4 visit ^c				Day 0 to day 30 visit				Day 0 to day 180 visit				
	TUC	SPC	Total	p value	TUC	SPC	Total	p value	TUC	SPC	Total	p value	
	n = 119	n = 119	n = 238		n = 119	n = 118	n = 237		n = 118	n = 118	n = 236		
Complications specific to drainage	No	109 (91.6)	87 (75.0)	196 (83.4)	0.001	106 (91.4)	82 (71.3)	188 (81.4)	<0.001	103 (90.4)	78 (70.3)	181 (80.4)	<0.001
	Yes	10 (8.4)	29 (25.0)	39 (16.6)		10 (8.6)	33 (28.7)	43 (18.6)		11 (9.6)	33 (29.7)	44 (19.6)	
	Missing	0	3	3		3	3	6		4	7	11	
	n = 10	n = 29	n = 39	p value	n = 10	n = 33	n = 43	p value	n = 11	n = 33	n = 44	p value	
At insertion ^a	No	9 (90)	28 (96.5)	37 (94.9)	0.45	-	-	-	-	-	-	-	-
	Yes	1 (0)	1 (3.5)	2 (5.1)		-	-	-		-	-	-	
	No	9 (90.0)	19 (65.5)	28 (71.8)	0.23	9 (90.0)	23 (69.7)	32 (74.4)	0.41	10 (90.9)	23 (69.7)	33 (75.0)	0.24
Obstruction of the probe or catheter	Yes	1 (10.0)	10 (34.5)	11 (28.2)		1 (10.0)	10 (30.3)	11 (25.6)		1 (9.1)	10 (30.3)	11 (25.0)	
	No	7 (70.0)	18 (62.1)	25 (64.1)	0.72	7 (70.0)	22 (66.7)	29 (67.4)	>0.99	8 (72.7)	22 (66.7)	30 (68.2)	>0.99
	Yes	3 (30.0)	11 (37.9)	14 (35.9)		3 (30.0)	11 (33.3)	14 (32.6)		3 (27.3)	11 (33.3)	14 (31.8)	
Uro-peritoneum	No	9 (90.0)	29 (100.0)	38 (97.4)	0.26	-	-	-	-	-	-	-	-
	Yes	1 (10.0)	0 (0.0)	1 (2.6)		-	-	-		-	-	-	
	No	9 (90.0)	28 (96.6)	37 (94.9)	0.45	9 (90.0)	32 (97.0)	41 (95.4)	0.42	10 (90.9)	32 (97.0)	42 (95.5)	0.44
Urethral trauma	Yes	1 (10.0)	1 (3.4)	2 (5.1)		1 (10.0)	1 (3.0)	2 (32.6)		1 (9.1)	1 (3.0)	2 (4.5)	
	No	10 (100.0)	27 (93.1)	37 (94.9)	>0.99	10 (100.0)	31 (93.9)	41 (95.4)	>0.99	11 (100.0)	31 (93.9)	42 (95.5)	>0.99
	Yes	0 (0.0)	2 (6.9)	2 (5.1)		0 (0.0)	2 (6.1)	2 (4.6)		0 (0.0)	2 (6.1)	2 (4.5)	
	n = 119	n = 119	n = 238	p value	n = 119	n = 118	n = 237	p value	n = 118	n = 118	n = 236	p value	
Recatheterization	No	104 (87.4)	109 (93.2)	213 (90.3)	0.14	101 (86.3)	104 (91.2)	205 (88.7)	0.24	99 (86.1)	100 (90.1)	199 (88.1)	0.35
	Yes	15 (12.6)	8 (6.8)	23 (9.7)		16 (13.7)	10 (8.8)	26 (11.3)		16 (13.9)	11 (9.9)	27 (11.9)	
	Missing	0	2	2		2	4	6		3	7	10	
Other complications	No	2 (20.0)	17 (58.6)	19 (48.7)	0.07	2 (20.0)	16 (48.5)	18 (41.9)	0.15	2 (18.2)	16 (48.5)	18 (40.9)	0.16
	Yes	8 (80.0)	12 (41.4)	20 (51.3)		8 (80.0)	17 (51.5)	25 (58.1)		9 (81.8)	17 (51.5)	26 (59.1)	
	n = 119	n = 119	n = 238	p value	n = 119	n = 118	n = 237	p value	n = 118	n = 118	n = 236	p value	
Urinary infection (symptoms)	No	108 (90.8)	109 (94.0)	217 (92.3)	0.46	104 (88.9)	101 (88.6)	205 (88.7)	>0.99	100 (87.7)	92 (84.4)	192 (86.1)	0.56
	Yes	11 (9.2)	7 (6.0)	18 (7.7)		13 (11.1)	13 (11.4)	26 (11.3)		14 (12.3)	17 (15.6)	31 (13.9)	
	Missing	0	3	3		2	4	6		4	9	13	
	n = 11	n = 7	n = 18	p value	n = 13	n = 13	n = 26	p value	n = 118	n = 118	n = 236	p value	
Pain	No	8 (72.7)	5 (71.4)	13 (72.2)	>0.99	9 (69.2)	7 (53.9)	16 (61.5)	0.69	10 (71.4)	11 (64.7)	21 (67.7)	>0.99
	Yes	3 (27.3)	2 (28.6)	5 (27.8)		4 (30.8)	6 (46.1)	10 (38.5)		4 (28.6)	6 (35.3)	10 (32.3)	
	No	5 (45.4)	4 (57.1)	9 (50.0)	>0.99	6 (46.2)	8 (61.5)	14 (53.8)	0.70	7 (50.0)	11 (64.7)	18 (58.1)	0.48
Fever	Yes	6 (54.6)	3 (42.9)	9 (50.0)		7 (53.8)	5 (38.5)	12 (46.2)		7 (50.0)	6 (35.3)	13 (41.9)	

Table 3 (continued)

	n=11	n=7	n=18	p value	n=13	n=13	n=26	p value	n=118	n=118	n=236	p value	
Chills	No	7 (63.6)	7 (100.0)	14 (77.8)	0.12	8 (61.5)	11 (84.6)	19 (73.1)	0.38	9 (64.3)	14 (82.4)	23 (74.2)	0.41
	Yes	4 (36.4)	0 (0.0)	4 (22.2)		5 (38.5)	2 (15.4)	7 (26.9)		5 (35.7)	3 (17.6)	8 (25.8)	
Difficult urination	No	8 (72.7)	6 (85.7)	14 (77.8)	>0.99	9 (69.2)	9 (69.2)	18 (69.2)	>0.99	10 (71.4)	13 (76.5)	23 (74.2)	>0.99
	Yes	3 (27.3)	1 (14.3)	4 (22.2)		4 (30.8)	4 (30.8)	8 (30.8)		4 (28.6)	4 (23.5)	8 (25.8)	
Other signs	No	7 (63.6)	5 (71.4)	12 (66.7)	>0.99	8 (61.5)	9 (69.2)	17 (65.4)	>0.99	8 (57.1)	12 (70.6)	20 (64.5)	0.48
	Yes	4 (36.4)	2 (28.6)	6 (33.3)		5 (38.5)	4 (30.8)	9 (34.6)		6 (42.9)	5 (29.4)	11 (35.5)	
IPSS score	n=103	n=103	n=206	p value	n=89	n=90	n=179	p value	n=27	n=31	n=58	p value	
	5 [2–10]	4 [2–7]	4 [2–8]		7 [3–11]	7 [2–13]	7 [3–11]		4 [2–7]	4 [2–7]	4 [2–7]		
	n=119	n=119	n=238	p value	n=119	n=118	n=237	p value	n=118	n=118	n=236	p value	
≥1 complication	No	80 (67.2)	58 (49.6)	138 (58.5)	0.01	57 (47.9)	41 (35.7)	98 (41.9)	0.06	55 (47.0)	35 (30.4)	90 (38.8)	0.01
	Yes	39 (32.8)	59 (50.4)	98 (41.5)		62 (52.1)	74 (64.3)	136 (58.1)		62 (53.0)	80 (69.6)	142 (61.2)	
	Missing	0	2	2		0	3	3		1	3	4	
Clavien–Dindo ^b classification	I–II	28	50	78	0.15	34	52	86	0.052	29	46	75	0.27
	III–IV	13	11	24		32	23	55		36	35	71	
	V	0	0	0		2	1	3		2	1	3	

^aDay 0^bStatistical test used: Fisher test. A patient can be grade II during the day 0 to day 4 period and become grade III later. Patients cannot be moved to a lower grade^cIPSS score at inclusion visit

Table 4 Quality of life

Patients' quality of life: EQ-5D-3L	Randomization arm			<i>p</i> value
	TUC <i>n</i> = 119	SPC <i>n</i> = 119	Total <i>n</i> = 238	
Inclusion visit (day 0)				
Mobility				> 0.99
I have no problem getting around on foot	96 (92.3)	95 (91.4)	191 (91.8)	
I have problems walking	8 (7.7)	9 (8.6)	17 (8.2)	
I have to stay in bed	0 (0.0)	0 (0.0)	0 (0.0)	
Missing	15	15	30	
Autonomy				> 0.99
I have no problem taking care of myself	103 (99.0)	102 (98.1)	205 (98.6)	
I have problems bathing or dressing myself	1 (1.0)	2 (1.9)	3 (1.4)	
I am unable to bathe or dress myself	0 (0.0)	0 (0.0)	0 (0.0)	
Missing	15	15	30	
Current daily activities				0.50
I have no problem carrying out my daily activities	92 (90.2)	90 (87.4)	182 (88.8)	
I have problems carrying out my daily activities	9 (8.8)	13 (12.6)	22 (10.7)	
I am unable to carry out my usual activities	1 (1.0)	0 (0.0)	1 (0.5)	
Missing	17	16	33	
Pain/discomfort				0.30
I have no pain or discomfort	63 (60.6)	58 (56.3)	121 (58.5)	
I have moderate pain or discomfort	39 (37.5)	45 (43.7)	84 (40.6)	
I have extreme pain or discomfort	2 (1.9)	0 (0.0)	2 (0.9)	
Missing	15	16	31	
Anxiety/depression				0.21
I am neither anxious nor depressed	55 (53.4)	60 (58.3)	115 (55.8)	
I am moderately anxious or depressed	46 (44.7)	37 (35.9)	83 (40.3)	
I am extremely anxious or depressed	2 (1.9)	6 (5.8)	8 (3.9)	
Missing	16	16	32	
	<i>n</i> = 119	<i>n</i> = 118	<i>n</i> = 237	<i>p</i> value
Day 30 visit				
Mobility				0.42
I have no problem getting around on foot	84 (87.5)	79 (82.3)	163 (84.9)	
I have problems walking	12 (12.5)	16 (16.7)	28 (14.6)	
I have to stay in bed	0 (0.0)	1 (1.0)	1 (0.5)	
Missing	23	22	45	
Autonomy				0.81
I have no problem taking care of myself	88 (91.7)	86 (89.6)	174 (90.6)	
I have problems bathing or dressing myself	8 (8.3)	9 (9.4)	17 (8.9)	
I am unable to bathe or dress myself	0 (0.0)	1 (1.0)	1 (0.5)	
Missing	23	22	45	
Current daily activities				0.10
I have no problem carrying out my daily activities	58 (61.1)	57 (59.4)	115 (60.2)	
I have problems carrying out my daily activities	35 (36.8)	30 (31.3)	65 (34.0)	
I am unable to carry out my usual activities	2 (2.1)	9 (9.4)	11 (5.8)	
Missing	24	22	46	
Pain/discomfort				> 0.99
I have no pain or discomfort	38 (39.6)	37 (38.5)	75 (39.1)	
I have moderate pain or discomfort	52 (54.2)	52 (54.2)	104 (54.2)	
I have extreme pain or discomfort	6 (6.3)	7 (7.3)	13 (6.8)	
Missing	23	22	45	

Table 4 (continued)

	<i>n</i> = 119	<i>n</i> = 118	<i>n</i> = 237	<i>p</i> value
Anxiety/depression				0.43
I am neither anxious nor depressed	65 (67.7)	56 (59.0)	121 (63.4)	
I am moderately anxious or depressed	28 (29.2)	35 (36.8)	63 (33.0)	
I am extremely anxious or depressed	3 (3.1)	4 (4.2)	7 (3.7)	
Missing	23	23	46	
	<i>n</i> = 118	<i>n</i> = 118	<i>n</i> = 236	<i>p</i> value
Day 180 visit				
Mobility				0.63
I have no problem getting around on foot	77 (90.6)	74 (88.1)	151 (89.4)	
I have problems walking	8 (9.4)	10 (11.9)	18 (10.6)	
I have to stay in bed	0 (0.0)	0 (0.0)	0 (0.0)	
Missing	33	34	67	
Autonomy				> 0.99
I have no problem taking care of myself	80 (94.1)	80 (95.2)	160 (94.7)	
I have problems bathing or dressing myself	5 (5.9)	4 (4.8)	9 (5.3)	
I am unable to bathe or dress myself	0 (0.0)	0 (0.0)	0 (0.0)	
Missing	33	34	67	
Current daily activities				0.73
I have no problem carrying out my daily activities	61 (72.6)	60 (71.4)	121 (72.0)	
I have problems carrying out my daily activities	22 (26.2)	21 (25.0)	43 (25.6)	
I am unable to carry out my usual activities	1 (1.2)	3 (3.6)	4 (2.4)	
Missing	34	34	68	
Pain/discomfort				0.86
I have no pain or discomfort	43 (51.2)	39 (46.4)	82 (48.8)	
I have moderate pain or discomfort	39 (46.4)	43 (51.2)	82 (48.8)	
I have extreme pain or discomfort	2 (2.4)	2 (2.4)	4 (2.4)	
Missing	34	34	68	
Anxiety/depression				> 0.99
I am neither anxious nor depressed	56 (66.7)	55 (65.5)	111 (66.1)	
I am moderately anxious or depressed	26 (31.0)	26 (31.0)	52 (31.0)	
I am extremely anxious or depressed	2 (2.4)	3 (3.6)	5 (3.0)	
Missing	34	34	68	
VAS score from EQ-5D-3L	Randomization arm			
	TUC <i>n</i> = 118	SPC <i>n</i> = 118	Total <i>n</i> = 236	
Inclusion (day 0)				
VAS score	80 [68–90]	75 [60–90]	80 [60–90]	
Missing	19	20	39	
Day 30				
VAS score	70 [50–80]	69 [50–80]	70 [50–80]	
Missing	23	26	49	
Day 180				
VAS score	75 [60–80]	70 [60–80]	75 [60–80]	
Missing	34	36	70	
FACT-C score	Randomization arm			
	TUC <i>n</i> = 118	SPC <i>n</i> = 118	Total <i>n</i> = 236	
Inclusion (day 0)				
FACT-C score	62 [57–68]	65 [57.5–69]	63 [57–68]	

Table 4 (continued)

FACT-C score	Randomization arm		
	TUC <i>n</i> = 118	SPC <i>n</i> = 118	Total <i>n</i> = 236
Missing	27	26	53
Day 30			
FACT-C score	62 [54–69]	61 [55–67]	61.5 [55–68]
Missing	39	33	72
Day 180			
FACT-C score	62 [56–66]	61 [53.5–66.5] 42	62 [55–66]
Missing	43	42	85

Fisher test

Conclusions

TUC should be preferred over SPC for bladder drainage in male patients (with normal voiding) undergoing surgery for mid and low rectal cancer owing to the lower rate of complications and shorter duration of catheterization, without any difference in the other secondary endpoints. The results of this multicenter prospective randomized trial should be considered when revising the French [33] and international [34] guidelines concerning the type of urinary catheter to be used in male patients undergoing surgery for mid or low rectal cancer.

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Data sharing The study data will be available upon reasonable request to the corresponding author.

Declarations

Conflict of interest None of the authors has a conflict of interest with respect to this trial.

Disclaimer This study's contents are solely the responsibility of the authors.

Ethical approval The trial protocol was approved by the French Ethics Committee CPP Sud-Est V on December 17, 2015 (IRB n° 2015-A01435-44) and the French Health Authority (ANSM).

Informed consent Written informed consent was obtained before inclusion in the trial.

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