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Original Article

Transurethral Balloon Catheterization versus Percutaneous Suprapubic Cystostomy in the Perioperative Period of Laparoscopic Colon Cancer Surgery: A Randomized Controlled Comparison Study

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ABSTRACT

Introduction: Pain and abnormal sensation associated with transurethral balloon catheterization during the perioperative period of laparoscopic colectomy can cause postoperative patient distress.

Methods: We conducted a randomized prospective controlled study of 100 patients (50 patients each in the transurethral balloon catheterization and suprapubic cystostomy groups) undergoing laparoscopic colectomy to investigate the effects of suprapubic cystostomy, a nontransurethral procedure, in decreasing patient distress using the numerical rating scale. Age, sex, procedure type, intraoperative bleeding volume, intraoperative urine volume, and duration of hospital stay were compared between transurethral balloon catheterization and suprapubic cystostomy groups. Wilcoxon's signed-rank and Mann-Whitney's U tests were used for comparison of groups. This study was approved by the ethics committee at Toho University Ohashi Medical Center (approval number: H15-86).

Results: In the transurethral balloon catheterization group, the numerical rating scale score was significantly improved after catheter removal ($p < 0.001$) from a median of 5 before removal to 0 after removal. In the suprapubic cystostomy group, the comparison before (median 0, mean 0.4) and after removal (median 0, mean 0.1) revealed the near absence of abnormal sensation with or without suprapubic cystostomy. A comparison before removal (during catheter placement) of transurethral balloon catheterization and suprapubic cystostomy showed that abnormal sensation was significantly greater in the transurethral balloon catheterization group (median 5, mean 4.4) than in the suprapubic cystostomy group (median 0, mean 0.4).

Conclusions: Perioperative urinary drainage via suprapubic cystostomy appears useful for reduced pain and discomfort for patients undergoing laparoscopic colectomy.

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KEYWORDS: suprapubic cystostomy, transurethral balloon catheterization, laparoscopic colectomy

Introduction

In recent years, minimally invasive laparoscopic surgeries have increasingly been utilized. To identify pathways to providing further minimally invasive procedures, we conducted a survey on surgery-associated physical pain at our department and found that pain and abnormal sensation from transurethral balloon catheterization (TUC) were causes of postoperative distress.[1] UC is used to measure perioperative urine volume and drain urine to achieve postoperative comfort but is known to cause distress such as abnormal sensations and pain due to its transurethral properties. Recently in Japan, some surgeons have omitted TUC in laparoscopic cholecystectomy.[2] However, laparoscopic colorectal cancer surgery can take a long time and may be difficult to perform without TUC placement. As surgical procedures such as endoscopy become increasingly less invasive, specific measures will be required in TUC from the perspectives of abnormal sensation and infection control.

Suprapubic cystostomy (SPC) utilizes a nontransurethral urinary drainage route and can be performed using commercially available cystostomy kits. Cystostomy is generally performed in the urology field when patients 1. cannot undergo transurethral catheterization due to urinary retention (such as severe urethral stricture, urethral calculus incarceration, or prostatic hyperplasia);[3] 2. present with a condition that may be exacerbated by a transurethral procedure (such as urethral injury, urethral stricture, acute urethritis, or acute prostatitis); 3. present with neurogenic bladder (such as spinal cord injury, spinal cord tumor, or spina bifida); and 4. need the procedure as a palliative treatment for severe urinary incontinence.[4] Temporary cystostomy is performed in everyday clinical practice and emergency situations, and cystostomy kits are commercially available. Overseas, this procedure has been used in the gynecology and cardiovascular surgery fields as an intraoperative and postoperative method for bladder drainage.[5,6] The usefulness of this method has also been reported since 1987 in the field of general surgery[7] although it is not yet in wide use in general surgery in Japan. In the literature, several conference minutes have suggested the usefulness of the method in the gynecology field. However, no studies to date have reported experience in using SPC as an alternative method for postoperative urine drainage.

A previous study[8] demonstrated that SPC is safe, does not involve significant complications, can measure perioperative urine volume, and facilitates postoperative patient comfort.

The Enhanced Recovery After Surgery protocol recommends early removal of TUC. We also remove TUC on the morning after surgery in accordance with the clinical pathway in our department. However, the incidence of postoperative urinary retention is reported to be 5%-70%.[9] Catheterization and a repeat TUC generate burdens on both patients and the medical provider.

This randomized prospective controlled study investigated whether SPC can reduce postoperative pain with conventional TUC as primary endpoint using the numerical rating scale (NRS).

Methods

Subjects

This study investigated 100 patients who underwent a laparoscopic procedure for primary colorectal cancer between April 2016 and November 2017 in our department. Patients who would conventionally undergo removal of the urethral balloon catheter at an early postoperative stage (the next day, according to the clinical pathway) were randomly assigned to a urethral balloon catheterization group (Group TUC) or an SPC group(Group SPC) using an enveloped method (Fig. 1).

As exclusion criteria, dementia, lower rectal cancer, treatment history of a urinary organ disease including prostatic hypertrophy, and urinary tract infection.

Methods

Group TUC received TUC under general anesthesia in the operating room in accordance with conventional procedures and underwent catheter removal by a nurse the following morning. Group SPC received SPC under sterile conditions and laparoscopic view during the surgery. After laparoscopically confirming the absence of intestinal adhesion and interposition and fullness of the bladder,

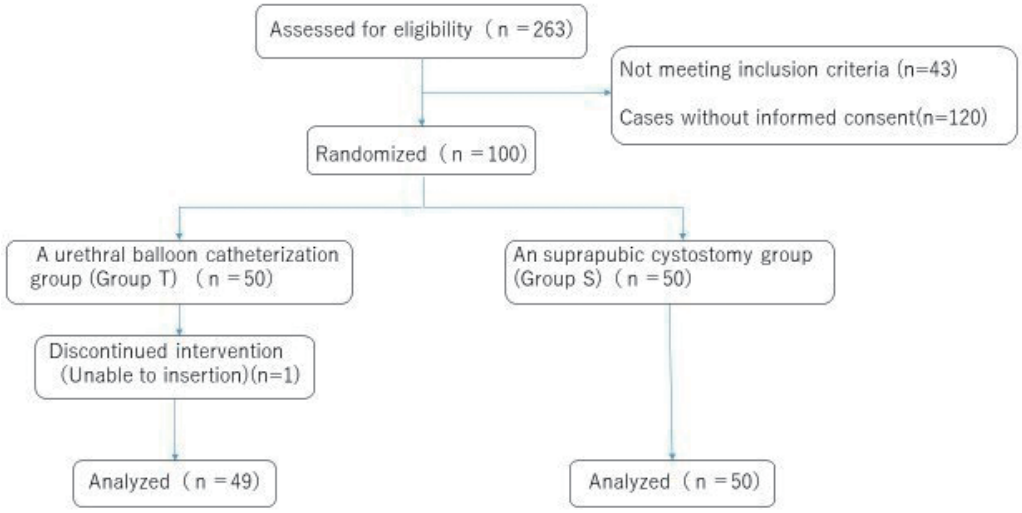

Fig. 1 Number of patients

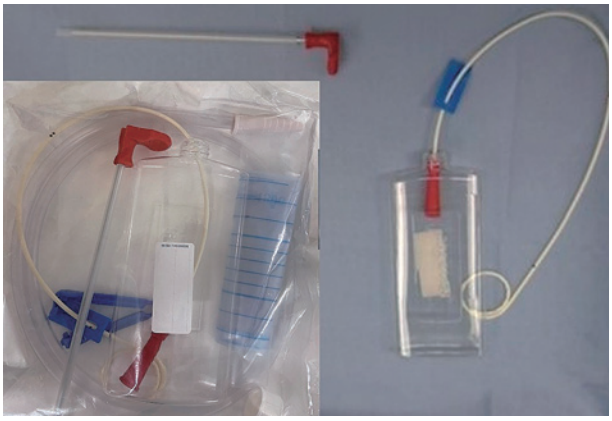

Fig. 2 Angiomed cystostomy set

Fig. 3 An insertion point of a suprapubic cystostomy

cystostomy was performed (Angiomed cystostomy set; C.R. Bard, Medicon Inc., Japan; Fig. 2). The steps for cystostomy were as follows: a pigtail drainage catheter was set up together with the puncture needle, and the bladder was transcutaneously punctured under laparoscopic view; upon confirming urine discharge, the puncture needle was retracted to the skin surface to detach the catheter from the needle. After aspirating as much urine as possible and confirming catheter placement in the bladder (Fig. 3), the catheter was fixed to the skin with a single stitch. Subsequently, a typical closed-system urine drainage tube and bag was attached under sterile conditions, and SPC was closed with a clamp at the time at which Group TUC would undergo catheter removal. The attending physician removed the catheter after confirming the ability of the patient to urinate. Using a questionnaire (Fig. 4), data mainly on the evaluation of pain after the operation were collected. All cases passed the in-hospital clinical pathway of colon cancer laparoscopic surgery. The anesthesiologist uses an epidural for all cases based on their judgment and removes it 3 days after an operation. Trans venous or oral pain killer were used for every postoperative pain by discharge. This study was approved by the ethics committee at Toho University Ohashi Medical Center (approval number: H15-86). Informed consents was obtained from all participants, and the study was approved by the ethics committee.

Statistical analyses

All data are expressed as mean±standard deviation. Wilcoxon's signed-rank and Mann-Whitney's U tests were used for comparison of groups. The significance level was set at 5%. All statistical analyses were performed using GraphPad Prism (version 9.4.1).

Results

Patient characteristics

Table 1 shows patient characteristics for these groups.

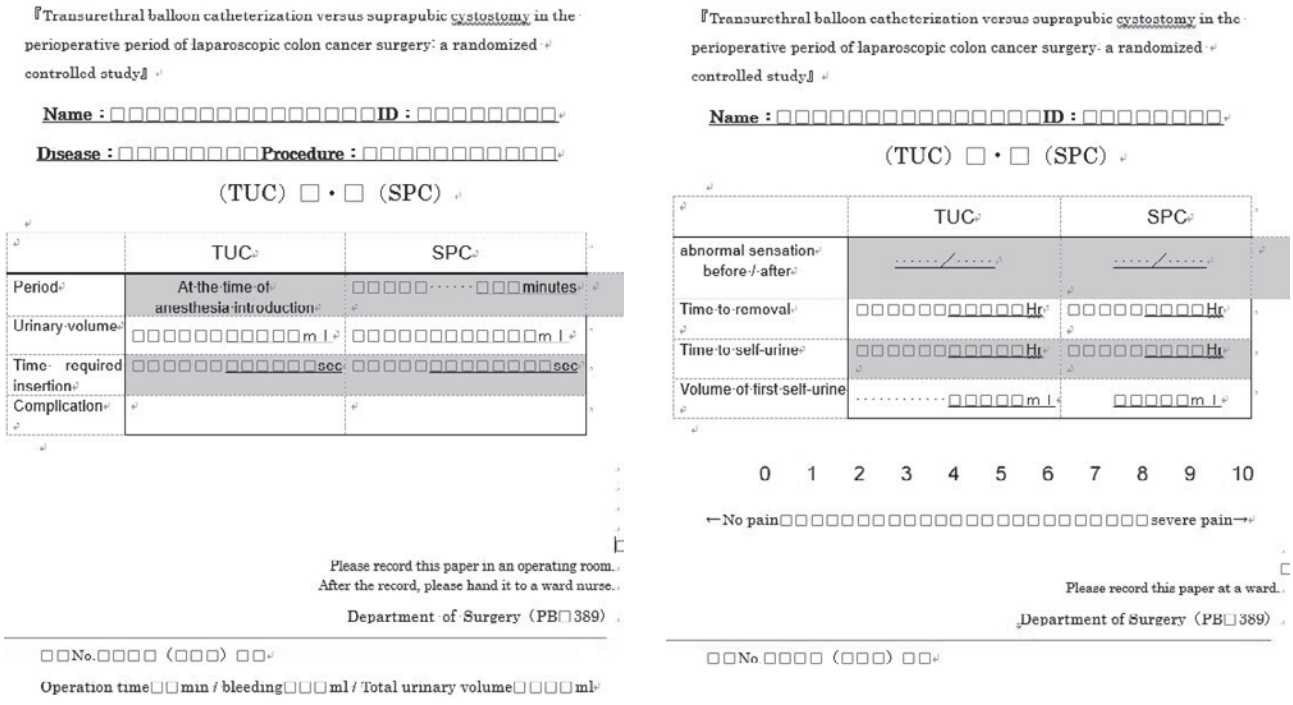

Fig. 4 Questionnaire form for patients
(Translated the Japanese questionnaire into English)

Table 1 Patient characteristics for Group TUC and Group SPC

		Group TUC	Group SPC	*p*-value
Age		69 (30–85)	66 (38–85)	0.636
Sex (Men:Female)		26:24	31:19	0.267
Procedure (case)	Cecum	2	1	
	Ascending colon	11	14	
	Transverse colon	8	4	
	Descending colon	5	2	
	Sigmoid colon	26	26	
	Rectum	3	3	0.068
Operative time (min)		186 (84–298)	230 (115–532)	＜0.001
Time required for insertion (s)		128 (69–240)	183 (60–465)	＜0.001
Time to remove (h)		Next morning	19 (10–40)	
Intraoperation blood loss (mL)		52 (0–530)	60 (0–290)	0.062
Duration of hospital stay (days)		10 (6–44)	10 (5–37)	0.409

Mann-Whitney's U test

Age, sex, procedure type, intraoperative bleeding volume, and duration of hospital stay did not differ significantly between groups. Operative time ($p < 0.001$) and time required for insertion ($p < 0.001$) were significantly longe in Group SPC.

Complications

Complications related to insertion were insertion difficulty in one patient in Group TUC and penetration into the abdominal cavity in three patients and hematuria in one patient in Group SPC. The TUC patient with insertion difficulty required cystoscopy in the Department of Urology

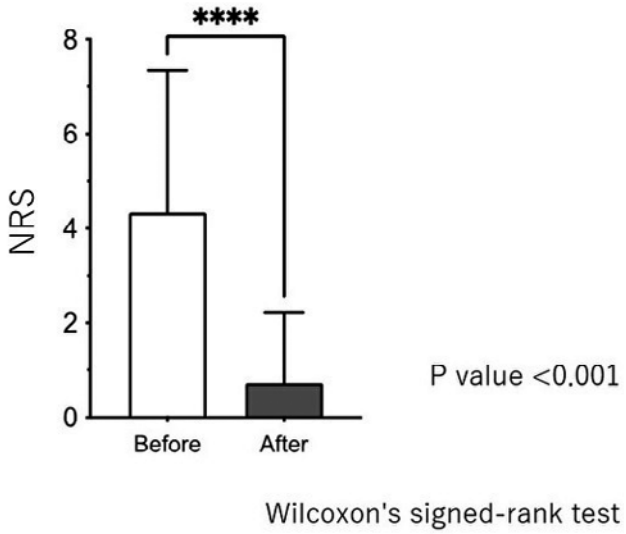

Fig. 5 Comparison before and after withdrawal in the urethral balloon catheterization group (Wilcoxon's signed-rank test). NRS: numerical rating scale

Fig. 6 Comparison before and after withdrawal in the suprapubic cystostomy group (Wilcoxon's signed-rank test). NRS: numerical rating scale

because normal catheterization could not be performed after anesthesia induction. Intraoperatively, TUC insertion was deemed problematic because of the presence of a false urethral passage from the bulbous to the membranous areas, and SPC was consequently performed. Postoperatively, residual urine was measured in the Department of Urology. SPC was removed on Day 10, and impaired urination was not observed thereafter. "Penetration into the abdominal cavity" in Group SPC indicates exposure of the puncture needle tip into the abdominal cavity under laparoscopic view. In all three patients, the needle was pulled out slightly and the tip was pointed caudally. The needle was pulled out slightly and the tip was pointed caudally, enabled catheter placement in the bladder without urine leakage into the abdominal cavity or erroneous puncture of the intestine. In the one patient with hematuria, spontaneous hemostasis occurred where the disappearance of hematuria was macroscopically confirmed during the procedure; bleeding discontinued in the postoperative period.

A comparison using the NRS

Distress was assessed using the NRS immediately before catheter removal and on the evening of the removal date in Group TUC and immediately before clamping and on the evening of the removal date in Group SPC. The NRS was used to evaluate pain. At each time point, the states in which the patient did not feel pain and felt the most pain were set to 0 and 10, respectively, and recorded. In Group TUC, the NRS score was significantly improved after catheter removal ($p < 0.001$; Fig. 5) from a median of 5 (mean, 4.4) before removal to 0 (0.7) after removal. In Group SPC, the comparison before (median 0, mean 0.4) and after removal (median 0, mean 0.1) revealed the near absence of abnormal sensation with or without SPC (Fig. 6). A comparison before catheter removal (during catheter placement) between TUC and SPC showed that abnormal sensation was significantly greater inGroup TUC (median 5, mean 4.4) than in Group SPC (median 0, mean 0.4; Fig. 7). A comparison after catheter removal showed that abnormal sensation was comparable between Group SPC (median 0, mean 0.4) and Group TUC (median 0, mean 0.7; Fig. 8).

None of the patients in either group presented with had complications at catheter removal or postoperative urinary tract infection. Two patients in Group TUC visited the Department of Urology with a chief complaint of painful urination after catheter removal. Additionally, two patients developed urinary retention after catheter removal and underwent catheterization and repeat TUC. Abnormal sensations or complications after catheter removal were not observed in Group SPC.

Discussion

TUC is convenient and is commonly used in surgical patients but can cause patient distress or infection. SPC does not involve using a transurethral procedure, and we confirmed that this can be safely performed in patients undergoing laparoscopic surgeries.

In this study, we evaluated distress using the NRS. In

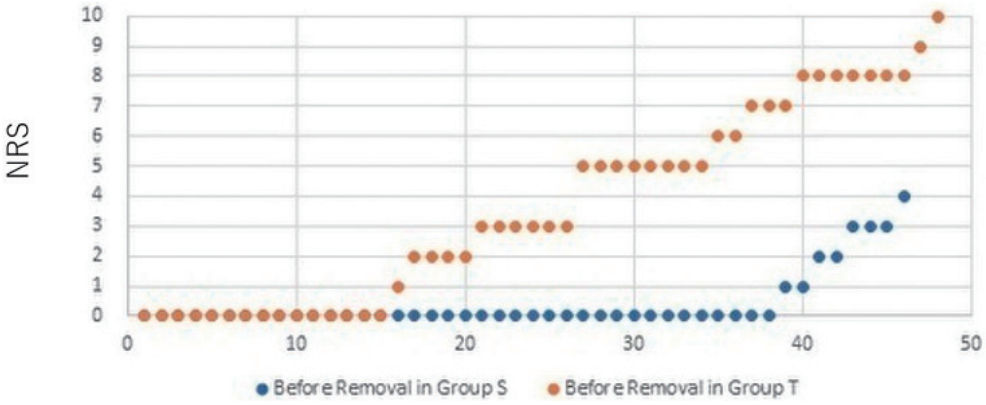

Fig. 7 Comparison before catheter removal (during placement). NRS: numerical rating scale

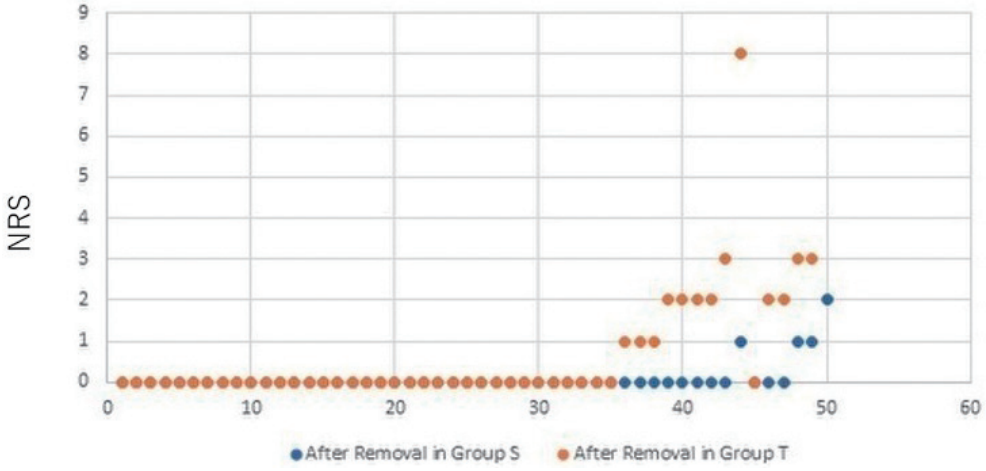

Fig. 8 Comparison after catheter removal

Group TUC, abnormal sensation significantly improved after catheter removal. Conversely, abnormal sensation was nearly absent with or without SPC in Group SPC. Group TUC had significantly greater abnormal sensation before catheter removal (during placement) compared with Group SPC. Abnormal sensation was not significantly different between the two groups after catheter removal, but all patients presenting with an abnormal sensation of NRS ≥ 3were in Group TUC.

The advantages of SPC include decreased urinary tract infections, reduced necessity of reinsertion into the ureter, avoidance of urethral stricture risks, and patient satisfaction. In our study, urinary tract infections and reinsertions were also not observed with SPC Therefore, we believe that, compared with the commonly used TUC, SPC involves minimal discomfort and greater patient satisfaction from catheter placement through to after its removal.

A catheterization and repeat TUC generate burdens on both patients and the medical provider. In this study, two patients in Group TUC developed urinary retention after catheter removal and underwent catheterization and a repeat TUC. Additionally, five patients in Group SPC did not have the urge to urinate on the day of clamping catheter, so the clamp was opened to drain the urine and closed again to wait for the urge to urinate. If these five patients had undergone TUC in a conventional manner according to the clinical pathway with catheter removal on the morning after the surgery, urinary retention may have been diagnosed and led to catheterization or reinsertion. Thus, in our study, seven patients overall presented with postoperative urinary retention. Because of the clamping step, SPC can confirm the postoperative urge to urinate without a significant burden on the patient and can be removed after confirming the ability to urinate. Moreover, because the clamp can be opened to drain the urine in the absence of an urge to urinate, SPC involves less burden on

both the patient and medical professional compared with catheterization or TUC reinsertion.

Typical complications of cystostomy include intestinal injury and hemorrhage. By laparoscopically and intraoperatively performing cystostomy, the absence of adhesion or intestinal interposition can be confirmed, thereby avoiding intestinal injuries. We did not observe intestinal injuries in this study. Most cases of puncture bleeding involve the rectus sheath, anterior cavity of the bladder, or inside the bladder, all of which are thought to stop spontaneously. Confirming the absence of abnormal coagulation test results is also important in cystostomy. In our case, this was confirmed in all patients at the preoperative examination because catheterization was performed intraoperatively. Although hematuria at puncture was observed in one patient, this condition did not extend into the postoperative period. In three patients, penetration into the abdominal cavity was laparoscopically observed, where the tip of the puncture needle penetrated the bladder wall and was exposed into the abdominal cavity. In all cases, the catheter could be successfully placed in the bladder by slightly pulling out the needle and pointing the tip caudally; urine leakage into the abdominal cavity or erroneous puncture of the intestines was not observed. Penetration is likely to occur when the puncture step is performed with a small volume of urinary retention. Using ultrasound from the operative field, as needed, may facilitate a safer puncture procedure. Moreover, hemostasis may be problematic when the prostate is damaged during the puncture. Body repositioning is common in laparoscopic colectomy; when returning the body position, the field of view often worsens and the needle puncture is frequently performed with a lateral rotation or in a Trendelenburg or reverse Trendelenburg position. Thus, it is crucial for the puncture direction to be oriented toward the median and cranial side to achieve accurate placement and avoid massive bleeding caused by prostate damage. Most complications of cystostomy can be avoided when the procedure is performed under intraoperative laparoscopic view.

In this study, SPC puncture was performed only after confirming sufficient urine retention in the bladder. Thus, we excluded patients with Ra or Rb rectal cancer, where urinary retention in the bladder may block the intraoperative field of view. At our hospital, long-term TUC or self-catheterization is currently the standard procedure in voiding dysfunction, a postoperative complication of lower rectal cancer. Further investigations on this subject are necessary because better treatment without patient distress could be provided utilizing SPC in patients presenting with postoperative voiding dysfunction.

Perioperative urinary drainage via SPC appears useful or reducing pain and discomfort in patients undergoing laparoscopic colectomy.

Although this is a prospective study, it is a single-center study with out a large number of cases. It may not have sufficient evidence due in part to the lack of statistically exact number of cases. Future prospective multiple-center studies with a large number of cases should be considered. Additionally, the SPC catheter used in this study is generally for emergency use in cases of urinary retention, and future development of the SPC catheter designed for shorter-term use is needed.

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Authors' contribution: S.Nagao, T.Enomoto, and Y.Saida designed the study; S.Nagao, T.Enomoto, N.Kakizaki, N.Futawatari, J.Maehara, performed the experiments. S.Nagao, analyzed the data. K.Asai, M.Watanabe, Y.Kotake, N.Sekido offered important advice for the experiment. Y.Saida supervised the experiments; S.Nagao wrote the manuscript.

Ethics statement: The studies involving human participants were reviewed and approved by Toho University Ohashi Medical Center (approval number: 15-86).

Conflicts of interest: None declared.

Consent for publication: Yes, I agree to publication.

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