

The feasibility and advantages of immediate removal of urinary catheter after lobectomy: A prospective randomized trial

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Abstract

Aim: This study aims to evaluate the feasibility and advantages of immediate urinary catheter removal compared with prolonged indwelling catheterization in lung cancer lobectomy.

Design: This study was designed as a prospective, single-centre, randomized and open-label clinical study.

Methods: People with lung cancer undergoing lobectomy/pneumonectomy were recruited and randomly allocated to two groups. One group had their urinary catheter removed immediately while the other group had it removed 48 hr after surgery.

Results: No significant difference in the incidence of postoperative urinary retention (POUR) was observed between the two groups. However, the incidence of postoperative catheter-associated urinary tract infection (CAUTI) in the immediate removal group (6.7%) was lower than the control group (17.2%) ($p = .030$). Furthermore, the incidence of catheter-associated emergence agitation (CAEA) in the control group (25.3%) was higher than the immediate removal group (8.9%) ($p = .007$). The average length of hospital stay of the immediate removal group [6.51(4–11) days] was shorter than the control group [7.20(5–12) days] ($p = .002$). Immediate removal of urinary catheter appeared to have fewer complications and shorter hospital stay than delayed removal.

KEYWORDS

lobectomy, removal, urinary catheter, urinary retention, urinary tract infection

1 | INTRODUCTION

The removal of an entire lung lobe is called a lobectomy, and video-assisted thoracoscopic surgery (VATS) lobectomy has become a minimally invasive surgical procedure for lung cancer resection (Guido-Guerrero et al., 2018; Nachira et al., 2018; Buitrago and Restrepo, 2019; Raveglia et al., 2019). It becomes a routine preparatory step that an indwelling urinary catheter is used to prevent

intraoperative urinary retention (Van Backer et al., 2019) in VATS lobectomy. The urinary catheter is conventionally left after surgery to prevent postoperative urinary retention (POUR); however, catheter removal 48 hr after surgery may increase the risk of catheter-associated urinary tract infections (CAUTI, mainly include cystitis and pyelonephritis) and prolong the length of hospital stay. Due to urinary tract irritation, the patient is in pain and unwilling to leave bed for activity, which is not conducive to postoperative rehabilitation.

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The Centers for Medicare and The Joint Commission initiated The Surgical Care Improvement Project (SCIP), aiming that reducing the surgical complications. SCIP 9, one of the adopted requirements, mandates the removal of urinary catheters within 48 hr after surgery to reduce the risk of CAUTI (Centers for Medicare & Medicaid Services, 2017). Enhanced recovery after surgery (ERAS) is also recommended by the guidelines in cardiac and pulmonary surgery (Engelman et al., 2019) and immediate removal of the urinary catheter after surgery has shown advantages in clinical practice (Van Backer et al., 2019; Meillat et al., 2021; Okrainec et al., 2017; Wang et al., 2020). In perioperative management of lung cancer removal surgery, the advantages may include the reduction in adverse urethra irritation, risk of urinary tract infections, use of antibiotics and enhancement of early postoperative movement, which may facilitate rapid postoperative recovery and shorten the length of hospital stay. Injecting warm normal saline into the bladder before removing the catheter has been shown to be an effective method to urge patients to urinate spontaneously after extubation (Chao and Mansuria, 2019; Mills et al., 2020; Wormer et al., 2017). Urethral catheterization has to be re-established if urinary retention happens. However, the appropriate time for the indwelling urethral catheter removal after surgery is still controversial.

Some prospective clinical studies suggested that early removal of urinary catheter within 24–48 hr after surgery is safe (Hu et al., 2014; Parks et al., 2018). However, no studies have reported whether immediate removal of an indwelling urinary catheter after lobectomy would reduce complications and lead to a significant increase in the need for catheter reinsertion compared with catheter removal within 48 hr after surgery. Here, we designed and implemented a randomized trial to determine whether immediate catheter removal after lobectomy would influence the incidence of CAUTI and catheter reinsertion.

2 | METHODS AND MATERIALS

2.1 | Study design and population

This study was designed as a prospective, single-centre, randomized and open-label clinical study aiming to compare the incidence of complications and catheter reinsertion between immediate (0 hr) catheter removal after surgery and standard catheter resection (48 hr) in patients underwent VATS lobectomy. The study was conducted at the Department of Thoracic Surgery, the Fourth Affiliated Hospital of China Medical University in accordance with the ethical guidelines based on the Declaration of Helsinki and was approved by the Fourth Hospital Affiliated to China Medical University Ethical Committee (approval number: EC-2018-KS-032) (registered on ClinicalTrials.gov (NCT03621514)). Informed written consent was obtained from all recruited participants.

From July 2018–June 2019, 206 patients were recruited. The inclusion criteria include people with lung cancer older than 18 years old with stage I–II lung cancer and the tumour maximal diameter

1. What is already known about this topic?

The urinary catheter is conventionally left after lung cancer lobectomy surgery to prevent POUR. The current guidelines mandate the removal of urinary catheters within 48 hr after surgery to reduce the risk of CAUTI. Early removal of urethral catheter has also been recommended. However, the appropriate time for the indwelling urethral catheter removal after surgery is still controversial.

2. What this paper adds?

Here, we designed and implemented a randomized trial to determine if immediate catheter removal after lobectomy would influence the incidence of CAUTI and catheter reinsertion. We found that immediate removal of urinary catheter appeared to have less complications (including CAUTI and CAEA) and shorter hospital stay than delayed removal.

3. The implications of this paper?

Immediate catheter removal after lobectomy can be safely implemented for people with lung cancer.

≤3 cm, and no mediastinum and hilar lymph node metastases were identified. Patients with the following conditions were excluded: (1) a history of benign prostatic hyperplasia, (2) known history of previous urinary tract malignancy, (3) long-term urinary tract infections (UTIs), (4) prior lower urinary tract surgery, neurogenic bladder, greater than stage 2 long-term kidney disease, or long-term indwelling urethral catheter, and (5) patients with complicated procedure during the lobectomy so that an indwelling catheter had to be kept postoperatively on the surgeon's decision, or reoperation within 72 hr.

2.2 | Study interventions and randomization

Indwelling urinary catheters (16F Foley catheter) were placed by the operating room nurse using standard aseptic procedure after general anaesthesia. Catheters have been kept connected with continuous bladder drainage during surgery. The amount of intraoperative intravenous fluid was determined by the patient weight and intraoperative status. The surgical nurse called the study coordinator immediately after surgery to conduct eligibility screening and to generate and assign a unique number to each eligible subject using a computerized random number generator. After the inclusion criteria were confirmed, the patient number was reported to the nursing team and recorded by the statistician. All patients were then randomly assigned to early or late catheter removal group by the operating room nurse, who was not involved in data collection and statistics. Doctors and statisticians were not aware of how the allocation was handled. Participants in early removal

group had their urinary catheter removed immediately after surgery while the catheter was removed 48 hr after operation in the control group. Intravenous injection of flurbiprofen 100 mg every 12 hr for 3 consecutive days was used as the analgesic regimen after surgery. The postoperative antibiotic use was similar for both groups. The amount of postoperative fluid intake (orally and transvenously) was based on the patient's weight.

2.3 | Study outcomes and evaluations

Primary outcome of this study was incidence of POUR and CAUTI. Postoperative urinary retention was defined as inability to empty the bladder voluntarily for over eight hours after catheter removal or difficulty in voiding with postvoid residual (PVR)>300 ml measured by ultrasound examination (Serlin et al., 2018; Stoffel et al., 2017). After urinary catheter removal, patients were allowed to empty their bladders freely. Postvoid residual volume measured by ultrasound examination was performed if patients had not voided for six hours after urinary catheter removal or complained on urinary fullness or pain. An indwelling catheter was reinserted if there was a clinical or ultrasound evidence of urinary retention. The diagnosis of CAUTI was based on the following criteria: urine culture exhibited more than 10⁵ colony-forming units per ml, and (or) have at least one of the symptoms, including frequency, urgency, burning sensation at micturition, haematuria, or dysuria (Choe et al., 2018; Korbel et al., 2017). All patients had a midstream urine sample collected for culture analysis on the next day after catheter removal, and the test result was compared with the preoperative one. The catheter-associated emergence agitation (CAEA), time of ambulation after operation and length of postoperative hospital stay were assessed as the secondary outcomes.

2.4 | Sample size and statistical analysis

The equation $n = (U_{\alpha} + U_{\beta})^2 P(1-P) / (P_1 - P_0)^2$ was used for sample size estimation, in which n is the required sample size for each group, and U_{α} and U_{β} are the corresponding U values for α and β . When 0.05 was chosen for α and 0.1 was chosen for β , U_{α} (0.05)=1.65 and U_{β} (0.1)=1.28 were obtained from the quantile table of normal distribution. P_0 and P_1 represent the incidence the expected incidence in this study and the incidence from previous literatures, respectively. In this study, the estimated POUR rate was 13% and the CAUTI rate was 17%. The POUR incidence was selected for sample size estimation because it required larger sample size. If $P_1=13\%$ and $P_0=33.3\%$, $P=(P_1+P_0)/2 \times 100\%=(33.3 + 13)/2 \times 100\%=23.2\%$, the sample size $n=(1.65 + 1.28)^2 \times 0.232 \times (1-0.232) / (0.333-0.13)^2 = 75.35$. Therefore, 75 cases were required for each group. Considering the dropout rate of 20% in our clinical studies, the final estimated sample size should be 90 cases for each group and totally 180 cases. The statistical calculations were conducted using SPSS 17.0. Qualitative data were expressed as a percentage (%), while quantitative data

that meet the normal distribution were reported as mean \pm SD, and quantitative data that do not satisfy the normal distribution of variance is reported as the median with quartile. The chi-square and Fisher's exact tests were used to test the significance for qualitative variables while two-sample t tests and nonparametric rank sum test (Mann-Whitney U test) were used to test the significance of difference for quantitative variables. $p < .05$ was defined as a statistically significant value in this study.

3 | RESULTS

3.1 | Study population and patient characteristics

Two hundred and six patients were enrolled into this study between July 2018 and June 2019 (Figure 1). Twenty-nine patients were excluded due to history of benign prostatic hyperplasia ($n = 10$), history of previous urinary tract malignancy ($n = 2$), prior lower urinary tract surgery ($n = 3$), neurogenic bladder ($n = 1$), long-term indwelling urethral catheter ($n = 1$), necessitating extended urine output monitoring after 48 hr ($n = 3$), inadvertent catheter removal ($n = 5$), patients requested early removal of the catheter ($n = 2$) and reoperation ($n = 2$). As a result, the final study cohort included 177 patients, including 90 patients with early catheter removal and 87 patients with standard catheter removal. This included 107 (60.5%) men and 70 (39.5%) women with median age at 68 years (range: 33 to 80 years) in which 43 patients were over 65 years old. No differences between the two groups were found in sex, body mass index, patient history or the surgical factors (the surgical field, surgical approach, operation time and intraoperative blood loss volume) (Table 1).

3.2 | Primary outcome and secondary outcomes

No difference was found in the incidence of urinary retention between the early removal group (12.2%) and the control group (10.3%) ($p = .693$). However, the incidence of urinary tract infection was significantly lower in the early removal group (6.7%) than in the control group (17.2%) ($p = .030$, Table 2). The rate of CAEA after anaesthesia in the control group (25.3%) was higher than that of the early removal group (8.9%) ($p = .007$). The time of ambulation in the control group was significantly shorter compared with the early removal group [1.43 (1–3) d versus 1.76 (1–5) d, $p = .001$]. The length of postoperative hospital stay in the early removal group was shorter than that in the control group [6.51 (4–11) d versus 7.20 (5–12) d, $p = .002$, Table 2]. Meanwhile, most patients from the control group had painful urination after the removal of catheter 48 hr postoperatively, which could be the result of urethral mucosa damage caused by the long-time indwelling catheterization. In addition, the incidence of urinary retention was not lower than those with early catheter removal, which could be due to the relaxation of urinary detrusor muscle in long-time catheter indwelling.

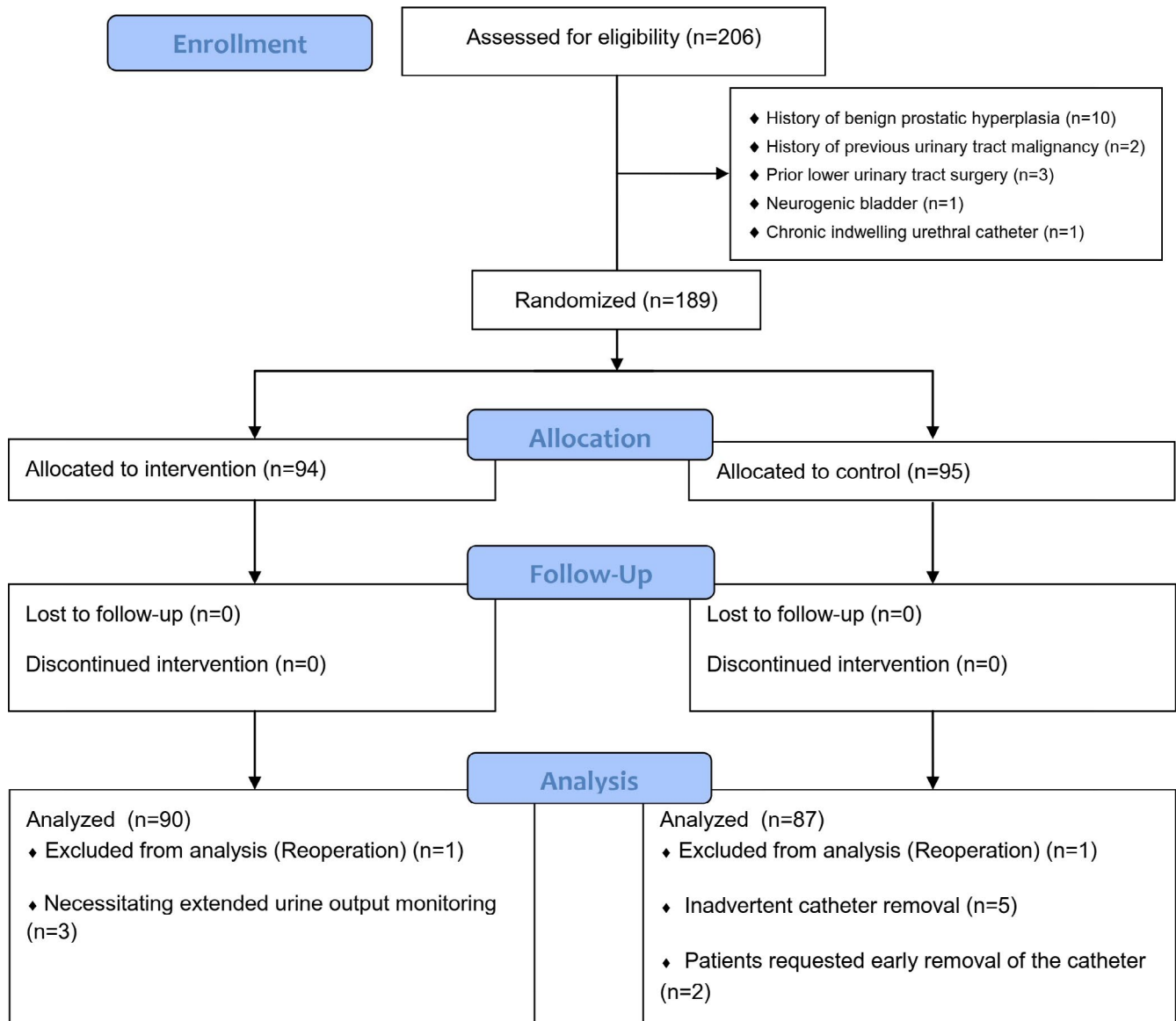


FIGURE 1 The flow chart for patient inclusion and exclusion in this study

4 | DISCUSSION

In this study, we found that early removal of urinary catheter after VATS lobectomy was associated with lower risks of POUR and CAUTI, lower rate of EA, earlier patient mobility and shorter hospital stay. Conventionally, indwelling urinary catheters are used after most thoracic surgery to assess urine output and to prevent postoperative urinary retention (Young et al., 2018; Zaouter et al., 2012). However, the time for postoperative urinary catheter removal remains controversial (Allen et al., 2016; Hayami et al., 2019), and indwelling urinary catheters have been shown to increase the incidence of urinary tract infections (Centers for Medicare & Medicaid Services, 2017; Young et al., 2018) and prolong hospital stays (Allen et al., 2016; Batchelor et al., 2019).

Our study showed no increased rate of recatheterization due to postoperative urinary retention from the observation with early

catheter removal compared with the control group. In consistence with our results, Patel DN et al. (Patel et al., 2018) found lower risks of urinary retention in cases of immediate removal of catheter after surgery. However, observation from a recent study by Ghuman A (Ghuman et al., 2018) was contrary to our findings. Ghuman's study indicated that early postoperative catheter removal was associated with an increased risk of urinary retention. The surgical procedure in Ghuman's study was different from ours, in which the radical resection of rectal cancer was performed. Since rectum is adjacent to bladder, intraoperative operation could irritate or even damage the bladder, which may cause urinary retention. Therefore, they made the conclusion that early removal of the catheter after abdominal surgery was not appropriate.

In this study, we found a lower incidence of urinary tract infections in patients with early catheter removal compared with the control group. There are some risks for long-term indwelling urethral

catheterization. As a foreign body from invasive procedure, urethral catheterization may damage urethral mucosa, weaken the barrier of urethral mucosa and cause infection. Indwelling the urinary tube also leads to direct contact of external environment by the urinary system, increasing the risk for bacteria invasion and subsequent infection. Early removal of the catheter can therefore reduce these risks. It was reported that urinary catheterization is a major cause of CAUTI (Baenas et al., 2018; Wilde et al., 2017). Meanwhile, similar to our findings, many studies have shown that prolonged postoperative catheterization is considered to be a major factor in CAUTI (Doganay et al., 2017; Leihof et al., 2019). It was also found that the ambulation

time and length of stay were correlated with the timing of urinary catheter removal, as early catheter removal had a shorter time of ambulation and hospital stay compared with the control. Early ambulation may be interfered by indwelling urinary catheters as a result of pain and anxiety. The prolonged length of stay was attributed to the CAUTI which required long-term in-patient antibiotic treatment.

There were several limitations to this study. First, although prospective, randomized data from a wide variety of patients undergoing lobectomy for lung cancer were included in this study, patients and surgeons were not blinded, and only the statisticians were blinded. Secondly, the study was performed in a single-centre study with a relatively small sample size. Thirdly, although the venous fluid intake was similar for each patient after surgery, some patients may have larger amount of oral fluid intake, thereby increasing the amount of urine, which may increase the patient's urine retention rate. In order to eliminate this bias, we prescribed oral fluid intake for each patient according to patient's weight. Finally, we did not include patients with complicated thoracic surgery, and it remains unknown if the study results would be translational for this group of patients. Fifth, we excluded all patients with benign prostatic hyperplasia, and our findings could not be applied to such patients.

Immediately urinary catheter removal after surgery did not increase the risk of postoperative urinary retention but exhibited a lower incidence in urinary tract infection, earlier ambulation and shorter hospital stay. In contrast, late catheter removal was associated with higher incidence of urinary tract infection and longer hospital stay. Thus, early removal of the catheter appeared to have more advantageous than delayed urinary catheter removal. The fact that early removal of the catheter shortened the length of hospital stay can be explained by the following points. First, patients were willing to leave bed early and were able to recover quickly after catheter removal. Secondly, the reduced risk of urinary tract infection shortened hospital stay. Thirdly, there was no increased risk of urinary retention and no indication for prolonged hospital stay. Meanwhile, due to reduced urinary tract infection rate and shorter hospitalization days, the perioperative costs will be reduced, saving medical insurance expenses. Therefore, our study supported the recommendation of early removal of the catheter after VATS lobectomy as it

TABLE 1 Patient demographics and clinical data

Characteristics	Early Removal (n = 90)	Control Group (n = 87)	p Value
Demographic			
Age, y	57.5(33–80)	61.0(38–80)	0.1738
Male	57(63.33)	50(57.47)	0.5198
Female	33(36.67)	37(42.53)	
Diabetes mellitus	16(17.78)	19(21.84)	0.6245
No diabetes mellitus	74(82.22)	68(78.16)	
BMI \geq 30	25(27.78)	23(26.43)	0.9748
BMI<30	65(72.22)	64(73.56)	
Abdominoperineal resection	25(27.78)	23(26.44)	0.9748
No abdominoperineal resection	65(72.22)	64(73.56)	
Open approach	10(11.1)	10(10.3)	1
VATS	80(88.9)	77(89.7)	
EBL \geq 600 ml	8(8.9)	10(11.5)	0.566
EBL<600 ml	82(91.1)	77(88.5)	
Operative time \geq 3 hr	16(17.8)	17(19.5)	0.763
Operative time<3 hr	74(82.2)	70(80.5)	
IVF,L	1,500(1000–5000)	1,500(1000–4500)	0.874

Abbreviations: BMI, Body mass index; EBL, Estimated blood loss; IVF, Intravenous fluid; VATS, Video-assisted thoracic surgery.

Variables	Early Removal Group (n = 90)	Control Group (n = 87)	p Value
POUR	16(17.78)	9(10.34)	0.2287
No POUR	74(82.22)	78(89.66)	
CAUTI	7(7.78)	18(20.69)	0.0245
No CAUTI	83(92.22)	69(79.31)	
Time of ambulation(days)	1.43(1–3)	1.76(1–5)	0.0014
LOS(days)	6.51(4–11)	7.20(5–12)	0.0017
CAEA	8(8.89)	22(25.29)	0.0068
No CAEA	82(91.11)	65(74.71)	

Abbreviations: CAEA, Catheter-associated emergence agitation; CAUTI, catheter-associated urinary tract infection; LOS, Length of postoperative stay; POUR, postoperative urinary retention.

TABLE 2 Summary of primary and secondary outcomes

was associated with lower risks of urinary tract infection and earlier patient mobility.

CONFLICT OF INTEREST

The authors claim no conflict of interest in this study.

AUTHOR CONTRIBUTIONS

Lei Zhang and Xueying. Yang: Study design. Lei Zhang, Ye Tian, Qian Yu, Yang Xu, Di Zhou, Zhuo Wu and Xitong Zhao: Recruitment of patients and clinical data collection. Lei Zhang: Statistics and tables and figures. Lei Zhang: Manuscript writing. Xueying Yang: Manuscript proofreading. Xueying Yang: Manuscript submission.

ETHICAL APPROVAL

The study was conducted at the Department of Thoracic Surgery, the Fourth Affiliated Hospital of China Medical University in accordance with the ethical guidelines based on the Declaration of Helsinki and was approved by the Fourth Hospital Affiliated to China Medical University Ethical Committee (approval number: EC-2018-KS-032) (registered on ClinicalTrials.gov (NCT03621514)). Informed written consent was obtained from all recruited participants.

DATA AVAILABILITY STATEMENT

All data for this study are included in this article. The data that support the findings of this study are available from the corresponding author upon reasonable request.

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