The present study aimed to compare the effects of various catheter fix sites on catheter-associated lower urinary tract symptoms (CALUTS) in 450 patients who underwent surgical removal of upper urinary calculi 24 h earlier. All patients had 16 French Foley catheters inserted and the balloons were filled. In group A, the catheters were fixed on the top one-third of the thigh. In group B, the catheters were fixed on the abdominal wall. Patients in whom the catheters were neither fixed on the thigh nor abdominal wall were designated as controls. There were 150 patients in each group. CALUTS, such as frequency, urgency, burning during micturition, odynuria, bladder pain and other symptoms, including urethral discharge, a red and swollen external urethral orifice, catheter traction or blockage and catheter-associated discomfort were recorded. Patients in group A compared with the control group had a significantly lower incidence of frequency, urgency, odynuria, urethral discharge, catheter traction and catheter-associated discomfort (P<0.05). Patients in group B were observed to have a significantly lower incidence of urgency, urethral discharge, catheter traction and catheter-associated discomfort compared with the control group (P<0.05), but a higher incidence of odynuria, urethral pain, urethral discharge and a red and swollen external urethral orifice compared with group A (P<0.05). An additional catheter fixation site for bedridden patients was necessary and an additional fix site on the thigh was preferred to the abdominal wall, which may further reduce catheter-associated lower urinary tract symptoms.

Introduction

Indwelling urethral catheters are a mainstay in the care of hospitalized patients. An estimated 30 million indwelling urethral (Foley) catheters are used annually in the United States (1) and ~20% of hospitalized patients have a urethral catheter at any given time (2,3). Catheter-associated lower urinary tract symptoms (CALUTS) refer to a range of symptoms, including frequency, urgency, burning during micturition, odynuria and suprapubic pain (3). These symptoms may be caused by involuntary detrusor contractions induced by activation of muscarinic type III receptors, also known as M₃mAChR, and the increased release of acetylcholine, which are caused by reactions of the mucosa in the trigone and urethra after insertion of a catheter (1-8). An indwelling catheter enables the continuous drainage of urine, which maintains an empty bladder, enhances the stimulatory effects of the catheter on the bladder walls and causes an increased incidence of CALUTS (6). In addition, server CALUTS may also be associated with higher the volume of the balloon and the weight of the catheter and/or urine bag (9). Previous studies have reported that CALUTS may aggravate post-operative pain, increase the occurrence of post-operative complications, including burning during micturition, odynuria and suprapubic pain or even prolong the length of hospital stay (7,10,11). Previous studies in CALUTS prevention have focused on the use of post-operative medications, including anticholinergic drugs, α receptor blockers (2-4,12-14). However, the side effects, such as nausea, vomiting, dizziness and conscious state changes may have adverse effects on patient recovery (11).

The present study aimed to compare the effects of various fixed catheter sites on preventing CALUTS in patients who underwent surgical removal of upper urinary calculi 24 h after surgery.

Materials and methods

Study design and subjects. A total of 450 patients who underwent surgical removal of upper urinary calculi at The Affiliated Hospital of Southwest Medical University (Luzhou, China) between January 2018 and September 2018 were included in this study. A total of 450 patients were selected in the present study, however, later 4 patients were excluded due to breakage of their catheter balloons. A final of 446 patients were included in the present study, which were control group (n=148) and groups A and B (n=149/group). A 16 French double-cava Foley urethral catheter (Bardex) was inserted.
into the bladders of each patient following surgery (Fig. 1). Patients >18 years of age with normal cognitive ability and renal function (serum creatinine ≤44.00 μmol/l, urea nitrogen ≤1.70 mmol/l) met the inclusion criteria for participation in the present study. Patients who were diagnosed with benign prostatic hyperplasia or urethrostenothesis, had a history of bladder dysfunction (overactive bladder, nocturia >3, or micturition >8 for 24 h before the surgery (7) neurogenic bladder, bladder inflammation, incontinence, lower urinary tract infection, urinary tuberculosis or cognitive disorders were excluded. One hundred and fifty patients were included in each group. The present study was approved by the Ethics Committee of the Affiliated Hospital of Southwest University (Luzhou, China; approval no. K2019002-R). Informed written consent was obtained from all the patients.

All patients were randomly and evenly divided into 3 groups (control, group A and group B), 150 patients in each group. The present study was not double blinded as the fixed site for the catheter on patients was visible. Patients with renal calculi who underwent percutaneous nephrolithotomy were treated with 100 ml of 0.9% normal saline (NS) + 50 mg of flurbiprofen axetil (Beijing Forte Meditec Co., Ltd.) in an intravenous drip twice on the day of surgery and the first day after surgery, while patients with ureteral calculi were not treated with post-operative analgesics. Ureteral stents (double J tube; C.R. Bard, Inc.) were retained for one month in all patients post-operatively.

A highly trained nurse was responsible for catheter fixation and all patients were followed-up for 24 h after catheter insertion. Catheters were inserted into the bladders of all patients and the balloons were filled. The catheter was pulled back after filling the balloon and stopped when the balloon was in contact with the bladder neck. In group A, the catheters were fixed on the top one-third of the thigh at the same level as the external urethral orifice. In doing so the extra-urethral part of the catheter was U-shaped (Fig. 2A). In group B, the catheters were fixed to the lower abdominal wall adjacent to the groin (Fig. 2B). The patients in whom the catheters were neither fixed on the thigh nor the abdominal wall were designated as controls (Fig. 2C).

Observation indices were recorded 24 h following catheter insertion, including the incidence of various CALUTS, such as frequency, urgency, odynuria, pain in the urethra or bladder, an increase in urethral discharge, a red and swollen external urethral orifice and other discomfort associated with the indwelling catheter or catheter obstruction.

Pain in the urethra and bladder were evaluated according to a previous study as follows: 0, no pain; 1-3, mild pain; 4-6, moderate pain; and 7-10, severe pain (15). The catheter-associated level of discomfort was quantified as follows: 0, no discomfort; 1, mild discomfort; 2, moderate discomfort, but able to tolerate the indwelling catheter; and 3, severe discomfort requiring removal of the catheter (6).

Statistical analysis. The data were analyzed using the SPSS 18.0 (SPSS, Inc.). The normality of data distribution of the continuous variables was assessed using the Shapiro-Wilk test. Continuous variables with normal distribution are presented as the mean ± standard deviation (SD). The means of normally distributed continuous variables were compared using Tukey’s test and one-way ANOVA (Respectively, if the results of ANOVA was significant, Tukey’s test was used to compare the differences between the two means.). Tukey's test was used to compare between groups. P<0.05 was considered to indicate a statistically significant difference.

Results

Basic characteristics. No significant differences were observed in indices, such as age, sex, education level, types of surgery, including percutaneous nephroscopy (PCNL) and ureteroscopy (URL) and the length of the operation between the control group and groups A and B (P>0.05; Table I).

Comparison of urinary catheter related LUTS. Patients in group A had significantly lower incidences of frequency, urgency and odynuria compared with patients in the control group (P<0.05). The proportion of patients who complained of bladder pain in groups A or B was significantly lower compared with patients in the control group (P<0.05) (Table II), while the number of patients with mild bladder pain in group A was significantly higher compared with group B (P<0.05) (Table II). The incidence of dysuria and total urethral pain scores of group A was significantly lower than group B (P<0.05). In addition, patients in group B had a significantly lower incidence of urgency when compared with the control group (P<0.05) (Table II). Significantly lower incidences of urethral discharge and catheter traction were observed in patients in group A compared with patients in the group B (P<0.05; Table III). In group B, a significantly higher incidence of urethral discharge was observed compared with group A and the control group, and a significantly higher incidence of red and swollen external urethral orifices in group B compared with group A was observed (P<0.05; Table III). The incidence of urethrorrhea in the control group was significantly higher than group A and B (10 vs. 1 and 4, respectively), while there were only two cases with catheter blockage in group A.

Comparison of catheter associated discomfort. There were 51 cases with mild of catheter-associated discomfort in control group, while it was 40 and 41 cases in group A and group B,
respectively. The total cases with catheter associated discom-
fort was 63 in control group, while it was 42 and 46 in group A
and group B, respectively. Patients in groups A and B had a
lower incidence of mild discomfort when compared with the
control group (Table IV).

Discussion

In the present study the effects of various fixed sites of
catheters on preventing CALUTS in patients who underwent
surgical removal of upper urinary calculi were assessed, and
it was demonstrated that catheters fixed by filling the balloon
then fixing the catheter to the top one-third of the thigh were
most beneficial for patients.

In the present study, patients in group A complained of
significantly less frequency and urgency, odynuria and bladder
pain compared with the control group, which may be due to
the additional fixed site of the catheter. The additional fixed
site on the thigh changed the pressure of the catheter and
urine bag weight on the additional fixed position. Hence, this
fixation site could decrease the pull force of the catheter and
urine bag on the neck of the bladder and urethra. In the control
group, the pull force of the catheter and urine bag may directly
press on the neck of the bladder and urethra, especially when
the patients were in bed. The aforementioned reason may
explain the complaints of majority of the patients in the control
group who reported more serious CALUTS when in bed, and
may also be responsible for the significantly higher incidence
of frequency, urgency and odynuria in the control group
compared with group A and B.

In the present study, patients in group B also had an
additional fixed site of the catheter on the abdominal wall;
however, they had a significantly lower incidence of frequency
and a significantly decreased composition ratio of bladder pain
when compared with the control group (P<0.05). Patients in
group B had a significantly increased incidence of odynuria,
urethral pain and proportion of severe bladder pain compared
with group A (P<0.05). The findings of the present study were
consistent with those of Zhang and Zhang (16) who reported
that the additional fixation of the catheter on the inside of the
thigh may lower the incidence of external urethral orifice pain,
ulcers and necrosis in patients with neurosurgical crises. The
present study hypothesized that the difference of CALUTS
between groups A and B in the present study may be due to the
different fixed position of urethral catheter resulting in different
changes in normal physiological structure of the urethra.

Although, in the present study the additional fixation of the
catheter on the abdominal wall decreased the pull forces from
the catheter and urine bag on the urethra, the additional fixa-
tion site was still at a higher level compared with the external
urethral orifice, which caused a reverse angle to be formed
between the extra-urethral part of the catheter and the urethra
(the size of the angle depends on the fat thickness beneath the
abdominal wall). This reverse angle causes the catheter to pull
and press on the urethra and therefore increases the incidence
rate of odynuria. In addition, the additional fixation on the
abdominal wall affects the physio anatomy of the urethra and
causes the disappearance of the urethral ante curvature (6,17).
The urethral ante curvature was therefore passive straightened
in the present study which increased the urethral pain. In
Table I. Parameters of patients (n=446) with different catheter fixation sites who underwent surgical removal of upper urinary calculi.

| Patients        | Age, years $\bar{X} \pm S$ | Length of the operation, min $\bar{X} \pm S$ | Sex, n (%) | Education level, n (%) | Type of surgery, n (%) |
|-----------------|-----------------------------|---------------------------------------------|-------------|------------------------|------------------------|
| Control (n=148) | 54.14±18.97                 | 45.53±17.89                                 | Male 91 (61.49) | 57 (38.51) | Illiterate 20 (13.51) Primary 53 (35.81) Junior 45 (30.41) High 20 (13.51) University 10 (6.76) PCNL 64 (43.24) URL 84 (56.76) |
| Group A (n=149) | 54.27±18.54                 | 45.79±17.58                                 | Male 95 (63.76) | 54 (36.24) | Illiterate 21 (14.09) Primary 50 (33.56) Junior 47 (31.54) High 22 (14.77) University 9 (6.04) PCNL 67 (44.97) URL 82 (55.03) |
| Group B (n=149) | 53.99±19.12                 | 46.01±17.64                                 | Male 93 (62.42) | 56 (37.58) | Illiterate 20 (13.42) Primary 51 (34.23) Junior 48 (32.21) High 23 (15.44) University 7 (4.70) PCNL 65 (43.62) URL 84 (56.38) |

$\chi^2$ value$^a$  0.06  0.13  0.164  0.3  0.085  0.765$^e$

$P$-value$^a$ >0.05 >0.05 0.686 0.99$^d$ 0.004

$\chi^2$ value$^b$ t=0.07 0.23 0.027 0.871 0.044$^e$

$P$-value$^b$ t=0.05 >0.05 0.869 0.929$^d$ 0.947$^e$

$\chi^2$ value$^c$ t=0.13 0.11 0.058 0.317 0.054

$P$-value$^c$ t=0.05 >0.05 0.810 0.989 0.816$^e$

$^a$Represents the comparison between group A and control group; $^b$represents comparison between group B and control group; and $^c$represents comparison between group A and group B. PCNL, percutaneous nephrolithotripsy; URL, transurethral ureteroscopic lithotripsy; $^d$comparison of constituent ratio of different education levels; $^e$comparison of different surgical types.

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Table II. Comparison of catheter-associated lower urinary tract symptoms between the 3 groups of patients.

| Patients        | Frequency n (%) | Urgency | Odyuria | Urethral pain scores (15) n (%) | Bladder pain scores n (%) |
|-----------------|-----------------|---------|---------|---------------------------------|--------------------------|
|                 |                 |         |         | 1-3    | 4-6  | 7-10 | Total | 1-3 | 4-6 | 7-10 | Total |
| Control (n=148) | 86 (58.11)      | 36 (24.32) | 18 (12.16) | 54 (36.49) | 3 (2.03) | 2 (1.35) | 59 (39.87) | 23 | 7 | 47 | 37 | 25.00 |
| Group A (n=149) | 68 (45.64)      | 16 (10.74) | 13 (8.72) | 33 (22.15) | 0 | 2 (1.34) | 35 (23.49) | 23 | 1 | 24 | 16 | 11.11 |
| Group B (n=149) | 73 (48.99)      | 18 (12.08) | 26 (17.45) | 55 (36.91) | 2 (1.34) | 2 (1.34) | 59 (39.59) | 20 | 0 | 5 | 5 | 3.36 |

$\chi^2$ value$^a$  4.635  9.489  0.938  3.082  9.203  11.974  0.003$^d$ 0.058

$P$-value$^a$ 0.032 0.002 0.333 0.214$^e$ 0.002 3.911 0.019$^d$ 0.081

$\chi^2$ value$^b$ 2.480 7.482 1.645 0.211 0.002

$P$-value$^b$ 0.115 0.006 0.200 0.900$^d$ 0.962

$\chi^2$ value$^c$ 0.337 0.133 4.986 2.135 8.951 4.073 0.044$^d$ 0.876

$P$-value$^c$ 0.562 0.716 0.026 0.344$^e$ 0.003

$^a$Represents the comparison between group A and control group; $^b$represents comparison between group B and control group; $^c$represents comparison between group A and group B; $^d$represents the comparison constituent ratio of urethra pain; and $^e$represents the comparison of bladder pain with different severity.
In the present study, patients in groups A and B were observed to have a significantly lower incidence of catheter traction compared with the control group (P<0.05); however, no significant difference in the incidence of catheter traction or blockage was observed between groups A and B (P>0.05). The findings of the present study were not consistent with those of Zheng and Li (18), which considered that catheter traction was more likely to occur in the thigh fixation than in the abdominal wall fixation. The present study hypothesized that the different additional fixation sites and methodology utilized may be responsible for this inconsistency. In the present study, in patients from group A the pull force of the catheter and urine bag on the urethra and bladder neck could be released when the patients abducted their thigh, bend their knees and rolled over in bed. Patients in groups A or B demonstrated no significant difference in incidence of a red and swollen external urethral orifice compared with the control group (P>0.05), while a significantly lower incidence was found in group A when compared with group B (P<0.05). The aforementioned findings were consistent with the results obtained by Zhang and Zhang (16). The present study hypothesized that the additional fixation on the abdominal wall may increase the pull force of the catheter on the urethra, form the reverse angle and cause the passive straight urethral antecurvature. In addition, the significant increase in urethral discharge in group B compared with group A and the control group may also be responsible for the difference observed between the groups (P<0.05).

In the present study, the incidence of catheter-associated discomfort and the proportion of severe catheter-associated discomfort in groups A and B was significantly lower compared with the control group. In groups A and B, the majority of patients complained of mild catheter-associated discomfort, while in the control group, the majority of patients complained of moderate and severe discomfort. The different incidence rates of pull force by the catheter may be responsible for this finding. The pull force from the catheter may have a crucial effect on CALUTS; however, in the present study the incidence of odynuria, urethral and bladder pain in group A was significantly lower compared with group B, while no significant difference was observed in the incidence of catheter-associated discomfort and the proportion of severe catheter-associated discomfort between groups A and B. The present study hypothesized that catheter-associated discomfort may involve the incidence of CALUTS and the pull force of the catheter, and might also depend on the tolerance of the patient. This may explain inconsistent results between the present study and those of Sun and Wang (19) who compared the different comfort levels between various catheter fixation sites and concluded that there was no significant difference of the comfort of female patients between the abdominal wall fixation and thigh fixation.

The present study had some limitations. First, whether fixation of the catheter could be applied to urological surgery of the lower urinary tract was not evaluated. Further studies with clinical efficacy were needed. Secondly, the observation

| Patients | Urethral discharge n (%) | Urethrorrhea n (%) | Catheter traction, n (%) | Red and swollen urethra, n (%) | Catheter blockage n (%) |
|----------|--------------------------|-------------------|--------------------------|-------------------------------|--------------------------|
| Control (n=148) | 77 (52.03) | 10 (6.76) | 71 (47.97) | 12 (8.11) | 0 (0.00) |
| Group A (n=149) | 94 (63.09) | 1 (0.67) | 14 (9.40) | 7 (4.70) | 2 (1.34) |
| Group B (n=149) | 111 (74.50) | 4 (2.68) | 13 (8.72) | 20 (13.42) | 0 (0.00) |
| χ² value² | 3.718 | 7.710 | 54.089 | 1.442 | 0.497 |
| P-value² | 0.054 | 0.005 | 0.000 | 0.230 | 0.481 |
| χ² value³ | 16.137 | 2.741 | 56.388 | 2.182 | - |
| P-value³ | 0.000 | 0.098 | 0.000 | 0.140 | - |
| χ² value⁴ | 4.517 | 0.814 | 0.041 | 6.883 | 0.503 |
| P-value⁴ | 0.034 | 0.367 | 0.840 | 0.009 | 0.478 |

³represents the comparison between group A and control group; ²represents comparison between group B and control group; and ⁴represents comparison between group A and group B.

Table IV. Comparison of catheter associated discomfort between the 3 groups of patients (6).

| Patients | Level 1 (mild) n (%) | Level 2 (moderate) n (%) | Level 3 (severe) n (%) | Total n (%) |
|----------|----------------------|--------------------------|------------------------|-------------|
| Control (n=148) | 51 (34.46) | 8 (5.41) | 4 (2.70) | 63 (42.57) |
| Group A (n=149) | 40 (26.85) | 0 (0.00) | 2 (1.34) | 42 (28.19) |
| Group B (n=149) | 41 (27.52) | 0 (0.00) | 5 (3.36) | 46 (30.88) |
time was only 24 h. With the extension of catheter indwelling time, whether different fixation methods have different effects on the occurrence of CALUTS and other accompanying symptoms needs further observation and confirmation.

The present study demonstrated that additional fixation of the catheter for bedridden patients was necessary and decreased the incidence of CALUTS and other concomitant symptoms, such as catheter traction and urethral discharge. An additional fixation site on the thigh is recommended based on the results of the present study.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

The authors declare that all the listed authors have participated actively in the study and met the requirements of the authorship. LZ and RJ conducted study design and experimental supervision. LZ wrote the first draft of the manuscript, RJ edited the manuscript and reviewed it, XW conducted secondary fixation and data collection of urinary catheters in all patients, LP and QD were responsible for intraoperative dexamethasone and prednisolone on postoperative catheter-related bladder discomfort. A prospective, randomized, placebo-controlled, double-blind study. Brit J Anaesth 96: 377-380, 2006.

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The authors declare that they have no competing interests.