Ureteral Stenting after Flexible Ureterorenoscopy with Ureteral Access Sheath; Is It Really Needed?: A Prospective Randomized Study

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Objective: *The aim of this study was to compare perioperative outcomes of patients who underwent uncomplicated flexible ureterorenoscopy with ureteral access sheath, with and without postoperative ureteral stenting.*
Material and Method: *Between April to December 2014, 50 consecutive patients underwent flexible ureterorenoscopy were enrolled in the study. The patients who had indications for postoperative ureteral stent or those who had ureteric complications during procedure that needed postoperative ureteral stenting were excluded. Thirty-eight eligible patients were randomized into a ureteral stent or non-ureteral stent group following flexible ureterorenoscopy with ureteral access sheath. Patient demographic data, operative data and perioperative outcomes were evaluated. Irritative voiding symptom score was calculated by using irritative domains of International Prostate Symptom Score (IPSS).*
Results: *Baseline characteristics were well balanced between both groups. There was no significant difference in postoperative pain, analgesic requirement, postoperative fever, urinary tract infection, irritative voiding symptom scores and length of hospital stay between the two groups. Three patients in stent group had unplanned hospital visits. Operative time was significantly shorter in non-stent group: 52±22 vs. 71±29 min (p = 0.02).*
Conclusion: *Non-ureteral stenting is safe and feasible in uncomplicated cases after flexible ureterorenoscopy with ureteral access sheath compared to stenting.*

Keywords: *Ureteral access sheath, Ureteral stenting, Flexible ureterorenoscopy, Safety*

J Med Assoc Thai 2017; 100 (Suppl. 3): S174-S178
Full text. e-Journal: *http://www.jmatonline.com*

In 1970s, to assist access to ureters with for ureteroscopy in difficult cases, the ureteral access sheath was developed[1]. Nowadays, ureteral access sheaths are commonly used for flexible ureterorenoscopy. By using access sheath, we can insert flexible ureteroscope directly upward into it. The advantages of ureteral access sheath are better flow of irrigation, improve renal drainage, decrease intrarenal pressure and facilitate the rapid entry and re-entry of flexible ureteroscope into the collecting system[2]. However, ureteral access sheaths could cause acute ureteral injury and increase the potential of stricture formation[3,4].

Several randomized prospective trials have found that routine ureteral stenting after uncomplicated semirigid ureterorenoscopy is not necessary[5]. But there are limited data on the necessary of ureteral stenting in flexible ureterorenoscopy with ureteral access sheath. In this study, we compared the perioperative outcomes of patients who underwent uncomplicated flexible ureterorenoscopy with ureteral access sheath, with and without postoperative ureteral stenting.

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Material and Method

This is a prospective, randomized, single center cohort study. From April to December 2014, 50 consecutive patients underwent flexible ureterorenoscopy with ureteral access sheath were enrolled in the study. The indications for flexible ureteroscopy were to do retrograde intrarenal stone surgery (RIRS), to do ureterolithotripsy in upper ureter (URSL), and to manage upper urinary tract tumor. Of these, patients who had indications for postoperative

ureteral stent or patient who required pre-stent were excluded. Therefore the eligible 38 patients were randomized into two groups, with and without ureteral stent postoperatively. All patients in the protocol were 18 years or older. Informed consent was obtained from all individual participants included in the study. The study was approved by Siriraj Institutional Ethical Review Board.

The procedure was performed under general anesthesia. Ureteral access sheath (12/14 Fr) was utilized. Access sheath length was 35 cm for women and 45 cm for men. Holmium: YAG laser was used for laser lithotripsy. Stone fragments were removed with stone basket. The fragments less than 2 mm were left in situ to pass spontaneously. At the end of the procedure, ureter was visualized to evaluate degree of ureteric injury.

Patient demographic data included age, gender, body mass index, comorbidity (diabetes, hypertension, chronic kidney disease, and cardiovascular disease), and history of recent anticoagulant/antiplatelet usage were recorded. All participants were requested to answer questionnaires which to evaluate irritative voiding symptom scores before underwent the surgery. This was calculated by using irritative domains of International Prostate Symptom Score (IPSS). Perioperative outcomes included postoperative flank pain (visual analogue scale), analgesic usage, perioperative complications, duration of indwelled urethral catheter, and length of hospital stay (defined as day of operation to day of discharge) was analyzed. Ureteral stent was scheduled to be removed at day 14 post surgery and irritative bladder symptom scores were reevaluated before stent removal. Unplanned hospital visit was recorded to compare between 2 groups.

SPSS version 15 was used to analyze the collected data. The outcomes between the two groups were compared with Chi-square or Fisher's exact test. The categorical variable and independent t-test or Mann Whitney U test were used for continuous variable. Significance was set as *p*-value less than 0.05.

Results

A total of 38 patients were randomized; 19 patients underwent flexible ureterorenoscopy with ureteral access sheath and ureteral stent indwelling after the procedure, whereas 19 patients did not have the stent postoperatively. Patient demographic data was well balanced between two groups as shown in Table 1. The mean age was 48.5 and 50.1 years in stent and non-stent group, respectively. Mean BMI was slightly lower in stent group; 27.3 kg/m^2 vs. 28.3 kg/m^2. The number of patients with comorbidities and anticoagulant/antiplatelet usage were comparable between both groups.

Flexible ureterorenoscopy was performed for therapeutic purposes in all patients in stent group. In non-stent group, the procedures carried out for therapeutic purpose in 16 patients (84%), while 3 patients had diagnostic aims (Table 2).

Perioperative outcomes were shown in Table 3. Pre-operative ureteral stent for passive dilation was placed for three patients (stent group 1, non-stent group 2). Operative time was significantly shorter in the non-stent group (52$\pm$22 vs. 17$\pm$29 min, *p*-value = 0.02). There was no significant difference in postoperative pain scores and analgesic usage between the two groups. Moreover, incidences of postoperative fever/pyelonephritis, duration of indwelled urethral catheter and length of hospital stay were not statistically different. There was a trend toward higher irritative voiding symptom scores post-operative in stent group but did not reach statistical levels. Among patients in stent group, 3 of 19 patients (15%) had unplanned hospital visit. Two patients were treated in the outpatient department, one had gross hematuria which improved after conservative treatment and another had flank pain that was better after analgesia given. One patient had acute pyelonephritis that needed readmission in hospital for intravenous antibiotic. On the other hand, no patient in non-stent group had

Table 1. Patient demographic data

Demographic data	Stent group (19)	Non-stent (19)	*p*-value
Male/female	15/4	13/6	0.50
Age (year)	48.5+12.2	50.1+10.3	0.66
BMI (kg/m^2)	27.3+5.3	28.3+4.6	0.57
Anticoagulant/antiplatelet usage (%)	1 (5%)	4 (21%)	0.34
Comorbidity (%)	11 (58%)	10 (53%)	0.74

unplanned hospital visit. However, there were no statistical differences between the two groups (15% vs. 0%: *p*-value = 0.23).

Discussion

Flexible ureteroscopy has become a popular procedure in this decade especially for kidney stone treatment. Using of ureteral access sheath is to facilitate the insertion of the scope and to prevent high intrarenal pressure. After the procedure, there was no conclusion on which situation required the ureteral stent postoperatively. Therefore, we studied the uncomplicated flexible ureterorenoscopy with the ureteral access sheath to compare with and without ureteral stent after the surgery. The study composed of diagnostic and therapeutic procedures. The majority of cases were kidney stone diseases, while others were the upper urinary tract tumor. Regardless of the disease, we only considered the necessity of ureteral stent after using the ureteral access sheath. The purpose of this study was to compare the differences in complications after the procedure; therefore, the smallest sample size that can have the power of analysis was required.

In this study, there was no difference of perioperative outcomes between patients who underwent flexible ureterorenoscopy with ureteral access sheath with and without ureteral stent. The incidence of postoperative urinary tract infection, postoperative pain, requirement of postoperative analgesia, length of hospital stay, and unplanned hospital visit were similar in both groups. The finding was consistent with previous studies with semirigid ureteroscopy. In a systematic review of 16 randomized controlled trials in 1,573 patients, Pengfei et al reported

Table 2. Operative procedure

Procedures	Stent group (19)	Non-stent group (19)
Therapeutic procedure		
RIRS	16 (84%)	15 (79%)
Flexible URSL	2 (11%)	-
Flexible URS + tumor laser ablation	1 (5%)	1 (5%)
Diagnostic procedure		
Flexible URS	-	3 (16%)

Table 3. Overall perioperative outcome

Parameters	Stented group (19)	Non-stent group (19)	*p*-value
Operative time (min)	71±29	52±22	0.02
Side (Right/Left)	10/9	13/6	0.31
Preoperative stent (%)	1 (5%)	2 (10%)	1.0
Pain score			
Post op day 0	2.6±2.6	2.4±2.7	0.85
Post op day 1	0.8±1.5	1.1±1/7	0.81
Post op day 2	1.4±1.3	1.2±1/0	0.75
Morphine usage (mg)	0.7±1.3	1.5±1.4	0.08
Paracetamol 500 mg usage (tab)	5.6±6.2	6.2±4.6	0.47
Postoperative fever (%)	3 (16%)	4 (21%)	1.0
Urethral catheter (day)	1.0±1.3	1.7±1.8	0.76
Length of hospital stay (days)	2.0±2.2	2.5±2.4	0.88
Irritative bladder symptom score			
Preoperation	5.6±3.0	8.3±6.0	0.09
Post op day 14	8.1±5.2	8.0±8.1	0.97
Unplanned hospital visit			
Gross hematuria (%)	1 (5%)	-	0.23
Flank pain (%)	1 (5%)	-	-
Pyelonephritis (%)	1 (5%)	-	-

that semirigid ureterorenoscopy without a postoperative stent was feasible and safe. Fever, urinary tract infection, length of hospital stay and unplanned hospital visits were similar between stent and non-stent groups[6].

Patients who have ureteral stent experienced more irritative symptoms. This was evaluated by higher irritative bladder symptom scores. Likewise, meta-analysis from Liang Tang et al revealed similar results with significantly higher rate of urinary frequency and urgency rate in patients of stent group[7].

Contrary to prior retrospective studies of selective ureteral stenting after flexible ureteroscopy with a ureteral access sheath, our study was not consistent with better postoperative outcomes for unplanned hospital visits or post-operative pain[8,9]. In our study, non-stented group had shorter operative time than stented group because there were three patients (16%) in the non-stented underwent diagnostic procedure while the other underwent all therapeutic procedures.

Conclusion

This study is a randomized trial to demonstrate that non-ureteral stenting after flexible ureteroscopy with ureteral access sheath is safe and feasible and should be considered in an uncomplicated case.

What is already known on this topic?

Many arguments about to use or not to use ureteral stents after flexible ureteroscopy with the access sheath still exists. Observation studies depend on individual experience and did not provide enough information; thus, RCT is required to ascertain strong evidence for this issue.

What this study adds?

According to our RCT study, ureteral stent is recommended in complicated cases after flexible ureteroscopy with ureteral access sheath, while routine use of a stent is unnecessary.

Potential conflicts of interest

None.

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การใส่สายระบายท่อไตหลังการส่องกล้องแบบโค้งงอได้ในท่อไตหรือไตโดยการใช้ปลอกหุ้มภายในท่อไตมีความจำเป็นหรือไม่

วิเชียร ศิริธนะพล, ศิรส จิตประไพ, ธวัชชัย ทวีมั่นคงทรัพย์, ไชยยงค์ นวลยง, เอกรินทร์ โชติกวาณิชย์

วัตถุประสงค์: เปรียบเทียบผลลัพธ์ของการใส่สายระบายท่อไตและไม่ใส่สายระบายท่อไตในผู้ป่วยที่ได้รับการรักษาด้วยการส่องกล้องแบบโค้งงอได้ในท่อไตหรือไตโดยการใช้ปลอกหุ้มภายในท่อไตที่ไม่มีภาวะแทรกซ้อน

วัสดุและวิธีการ: ระหว่างเดือนเมษายน ถึง เดือนธันวาคม พ.ศ. 2557 มีผู้ป่วยที่ได้รับการรักษาด้วยการส่องกล้อง แบบโค้งงอได้ในท่อไตหรือไตทั้งหมด 50 ราย โดยผู้ป่วยที่มีข้อบ่งชี้ในการใส่สายระบายท่อไตหลังการส่องกล้องหรือผู้ป่วยที่ได้รับบาดเจ็บที่ท่อไต ซึ่งต้องได้รับการใส่สายระบายท่อไตนั้นถูกคัดออกจากการศึกษาเหลือผู้ป่วย 38 ราย ที่ได้รับการสุ่มออกเป็น 2 กลุ่ม คือ กลุ่มที่ได้รับการใส่สายระบายท่อไตและกลุ่มที่ไม่ได้รับการใส่สายระบายท่อไตโดยศึกษาข้อมูลทั่วไปของผู้ป่วย ข้อมูลเกี่ยวกับการผ่าตัดและผลลัพธ์ของการผ่าตัด อาการระคายเคืองกระเพาะปัสสาวะประเมินจากแบบสอบถามของ International Prostate Symptom Score (IPSS) ในหัวข้อที่เกี่ยวกับอาการระคายเคือง

ผลการศึกษา: ข้อมูลทั่วไปของผู้ป่วยพบว่ามีความใกล้เคียงกันระหว่าง 2 กลุ่ม ไม่มีความแตกต่างกันในเรื่องระดับความเจ็บปวดหลังการส่องกล้อง การใช้ยาแก้ปวด การเกิดไข้หลังการส่องกล้อง การติดเชื้อทางเดินปัสสาวะเรื่องอาการระคายเคืองกระเพาะปัสสาวะ และเรื่องระยะเวลาการนอนโรงพยาบาล มีผู้ป่วย 3 รายในกลุ่ม ที่ใส่สายระบายท่อไตที่มาโรงพยาบาลก่อนการนัดหมาย ส่วนระยะเวลาของการผ่าตัดพบว่ากลุ่มที่ไม่ใส่สายระบายท่อไตนั้นสั้นกว่ากลุ่มที่ใส่สายระบาย 52±22 vs. 71±29 นาที ($p = 0.02$)

สรุป: การไม่ใส่สายระบายท่อไตหลังการส่องกล้องแบบโค้งงอได้ในท่อไตหรือไตโดยการใช้ปลอกหุ้มภายในท่อไตในคนไข้ที่ไม่มีภาวะแทรกซ้อนนั้นสามารถทำได้และมีความปลอดภัยเมื่อเปรียบเทียบกับกลุ่มที่ใส่สายระบายท่อไต