

Indications of stented uncomplicated ureteroscopic lithotripsy: a prospective randomized controlled study

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Abstract The purpose of our trial was to evaluate whether stents could be eliminated after uncomplicated ureteroscopic lithotripsy for ureteral stones and the indications of ureteral stent placement. A total of 228 patients underwent uncomplicated ureteroscopic intracorporeal lithotripsy. After the procedures, patients without marked ureteral edema, polypoid change or stent placement were treated as a control group. The other patients were randomized to two groups. Patients were followed on the first postoperative day, 6 and 12 weeks, postoperatively. In stented cases the stent was removed after 1 week. Outcome measures included visual analog scale assessment, postoperative analgesic requirements, complications and the stone-free rate. On the first postoperative day the symptoms of flank pain, dysuria and frequency were significantly greater in the stented group ($P < 0.0001$). The overall perioperative complication rate, including fever, pyuria, flank and loin pain, was 3.3% (3/90) in group 1, 16.9% (12/71) in group 2, and 41.8% (28/67) in group 3. We believe that in selected patients undergoing ureteroscopy for ureteral stone, stents can be safely omitted. Patients without stents have significantly less stent-related symptoms and are not at higher risk of complications with smooth ureteral mucosa. When there is ureteral edema or polypoid change with pyuria, ureteral stents should be indwelled to avoid severe postoperative complications.

Keywords Ureteroscopic lithotripsy · Double-J stent

Introduction

Ureteroscopy is one of the treatment options for ureteral calculi [1–3]. Improvements in ureteroscope design, including flexibility and downsizing, and advancement in intracorporeal lithotripsy have made ureteroscopy an outpatient procedure with high success rates and minimum morbidity. Following ureteroscopy for stone extraction, insertion of a double-J stent is recommended [1, 4, 5]. The advantage of routine stenting is that it minimizes postoperative ureteral obstruction and renal colic that may result from ureteral edema caused by balloon dilatation or stone manipulation [6]. Routine stenting has also been thought to promote healing and reduces the incidence of ureteral stricture [1]. However, stents are associated with significant flank pain and suprapubic discomfort, frequency, and dysuria, which adversely affect the patient's quality of life [7–9].

Recently, investigators have reported that routine insertion of stents after ureteroscopy for ureteral stones can be safely omitted without affecting the outcome [10–13]. We conducted a randomized controlled trial wherein patients undergoing ureteroscopy for ureteral stones were stented or not stented according to the ureteroscopic findings. The three groups were also followed to determine the risk of postoperative complications. Herein, we report the results of this trial.

Materials and methods

Our Institutional Review Board approved the study, and all patients signed an informed consent form before participating. The study was designed as a randomized controlled trial and carried out from January 2004 to December 2007. Adult patients were included if they were scheduled for

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ureteroscopy for ureteral stones. Patients were excluded from the study if the stone diameter was greater than 15 mm, there was a history of sepsis or renal failure, there were bilateral ureteral stones or if the patient had a solitary kidney.

A total of 228 consecutive patients underwent ureteroscopy for ureteral stones on an outpatient basis. A 7.0F Wolf semirigid ureteroscope (Knittlingen, Germany) was used for all the procedures without ureteral dilatation, under direct vision and intravenous general anesthesia. The stones were fragmented with pneumatic lithotripsy (EMS, Switzerland), if required or extracted under vision with the help of a basket. Intraoperative data included intraoperative findings (urine catheterization, mucosal edema, or polyps formation), operative time (from insertion of the ureteroscope to the end of the procedure), and outcome. Successful ureteroscopy was defined as the complete removal or radiographic absence of calculi at followup. At the end of the procedure, those patients with marked edema or polyps formation (complicated ureteroscopy) were randomized to the stented or non-stented group (using random numbers table). The patients, neither marked ureteral edema or polypoid change nor stent placement, were treated as control group (uncomplicated ureteroscopy). In the stented group, a double-J stent (7F) was placed by body height under cystoscopy.

All patients were followed up at first postoperative day, 6 weeks and 12 weeks later, to assess for pain on a 10 cm linear visual analog scale, stent-related symptoms (frequency, urgency, nocturia, dysuria, flank pain with voiding) (5 points score of International Prostate Symptom Scale), fever, need for analgesics and any postoperative complications. Meanwhile a plain radiograph (KUB film) was obtained on the day after surgery to document the stone status. Patients in the stented group underwent stent removal 1 week later in the Urology Clinic under intravenous anesthesia. All patients were prescribed Pipemic acid trihydrate 250 mg twice per day for 2 weeks to minimize urinary tract infections, and allowed to use sublingual buprenorphine 0.2 mg on demand. Overall dosage was documented and compared.

Statistical analysis was performed using commercially available software. The chi-square test, ANOVA test, non-parametric Wilcoxon two-sample *t* test and independent sample Student's *t* test was used as appropriate. A *P* value lower than 0.0001 was considered significant.

Results

A total of 228 patients undergoing ureteroscopy for ureteral stones completed the study protocol, 90 patients in the control group 1 (without marked edema or polyp formation)

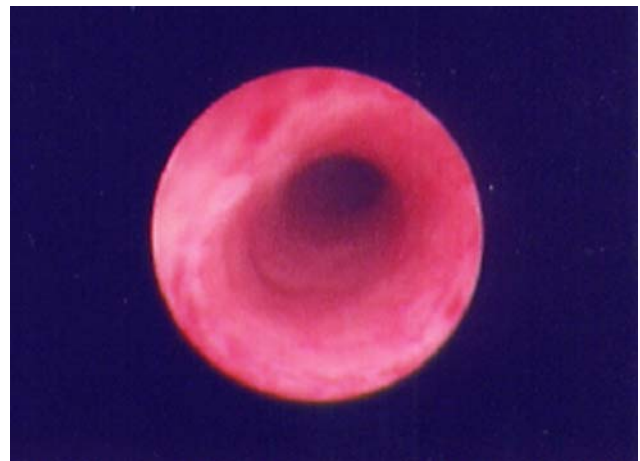


Fig. 1 Smooth mucosa of ureter after lithotripsy



Fig. 2 Polypoid formation of ureteral mucosa

(Fig. 1), 71 patients in stented group 2 and 67 in the non-stented group 3 (Fig. 2). No significant statistical difference was observed in patient age, gender distribution, body height, stone sizes, operative times and stone locations (Table 1). A successful outcome was achieved in 100% of the cases without ureteral orifice dilatation in all groups.

Concerning perioperative complications, pyuria was noted before the procedures, 13.3% (12/90) in group 1, 25.4% (18/71) in group 2 and 23.9% (16/67) in group 3, respectively. Intraoperative ureteral catheterization revealed pyuria in 15.6% (14/90) in group 1, 29.6% (21/71) in group 2 and 34.3% (23/67) in group 3, respectively. No ureteral perforation was encountered during the procedures. Besides, no unstented patients require stent or nephrostomy tube placement postoperatively or have to be admitted due to flank pain. The overall perioperative complication rate, including fever, pyuria, flank and loin pain, was 3.3% (3/90) in group 1, 16.9% (12/71) in group 2, and 41.8% (28/67) in group 3, which was significantly different (logistic regression

Table 1 Baseline patients characteristics ($n = 107$)

Characteristic	Control (1)	Stented (2)	Non-stented (3)	<i>P</i> value
Patients (<i>n</i>)	90	71	67	
Age (year)				1 versus 2:0.02 ^c 1 versus 3:0.02 ^c 2 versus 3:0.84 ^c
Mean	59.7	54.3	54.6	
Range	29–91	33–83	31–85	
Gender (<i>n</i>)				0.86 ^b
Male	75	55	57	
Female	15	16	10	
Body height (cm)	162.4	162.8	163.5	0.81 ^a
Male	164.7	166.3	165.4	0.71 ^a
Female	157.4	156.4	158.6	0.77 ^a
Stone sizes (mm)	10.1	10.1	9.9	0.13 ^d
Operative times (min)	25.7	23.6	24.9	1 versus 2:0.86 ^a 1 versus 3:0.55 ^a 2 versus 3:0.49 ^a
Locations				0.883 ^e
Upper	8	9	6	
Middle	30	26	22	
Lower	52	36	39	

NA not applicable

^a Non-parametric wilcoxon 2-sample test^b Chi-square test^c *t* test^d Anova test^e logistic regression analysis

analysis, $P = 0.0013$). Five patients in group 3 required hospitalization for intravenous antibiotics as a result of genitourinary sepsis, while one patient in group 2 did. Mean sublingual buprenorphine consumption was 0.01 ± 0.05 mg in group 1, 0.09 ± 0.15 mg in group 2, and 0.16 ± 0.18 mg in group 3.

As shown in Table 2, at the first postoperative day the mean VAS for pain was 2.22 in group 1, 3.30 in group 2, and 2.10 in group 3. The mean score for voiding flank pain was 3.4 in group 1, 5.17 in group 2, and 3.31 in group 3. The mean score of frequency in IPSS was 1.6 in group 1, 4.39 in group 2, and 1.60 in group 3.

The mean score of urgency in IPSS was 3.11 in group 1, 3.82 in group 2, and 3.21 in group 3. The mean score of nocturia in IPSS was 1.88 in group 1, 2.89 in group 2, and 1.99 in group 3. The mean score of dysuria in IPSS was 1.3 in group 1, 5.28 in group 2, and 1.22 in group 3. At the 6th week follow-up visit, the mean VAS for pain was 1.31 in group 2, greater than 0.53 in group 1, and 0.49 in group 3. The mean score of frequency in IPSS was 1.37 in group 2, greater than 1.10 in group 1, and 1.07 in group 3. At the 12th week follow-up, only the mean VAS for pain scores had changed, and the other scores at the 12th week were the same as from the 6th week. Intravenous urography and renal ultrasonography follow-up tests were available for all patients at the 12th week visit. None of the patients had evidence of ureteral stricture or residual stone fragments. In the analysis of different time periods, when comparing the

6th week and the 12th week evaluations with that of the first postoperative day, all groups showed significant improvement of urinary symptoms and body pain (all P value <0.0001).

Discussion

Placement of a ureteral stent after ureteroscopy has been a standard practice. The reported advantages are that it may reduce colic caused by ureteral obstruction secondary to edema [6] and prevent stricture formation [1]. On the other hand, indwelling ureteral stents may be associated with significant symptoms and signs such as pain, urgency, dysuria, and hematuria and may lead to complications such as stent migration and urosepsis [7–9]. With the relatively recent development of small caliber ureteroscopes and more effective intracorporeal lithotripsy devices, it is now possible to perform ureteroscopy in most patients without ureteral dilation [14]. We believed that because of these technological advances, postoperative stent symptoms have now become the most morbid part of ureteroscopic stone removal in the majority of patients. In the study by Wollin et al. [13], 28 patients undergoing ureteroscopy for distal ureteral stones were randomized into a stented and nonstented group. Patients without stents had lesser bladder irritative symptoms than those with stents. Although it should be noted that none of the patients underwent intraoperative dilatation

Table 2 Randomization study results

Variable	Control (1)	Stented (2)	Non-stented (3)	<i>P</i> value
Pain(VAS) 1st day	2.22 ± 1.03	3.30 ± 1.06	2.10 ± 1.05	1 versus 2: <0.0001 2 versus 3: <0.0001
W6	0.53 ± 0.60	1.31 ± 0.75	0.50 ± 0.59	1 versus 2: <0.0001 2 versus 3: <0.0001
W12	0.2 ± 0.43	0.59 ± 0.52	0.18 ± 0.39	1 versus 2: <0.0001 2 versus 3: <0.0001
Voiding flank pain(VAS) 1st day	3.4 ± 1.07	5.17 ± 1.08	3.31 ± 1.08	1 versus 2: <0.0001 2 versus 3: <0.0001
W6	0.09 ± 0.29	0.11 ± 0.32	0.10 ± 0.31	
W12	0.03 ± 0.18	0.07 ± 0.26	0.05 ± 0.21	
Frequency 1st day	1.6 ± 0.91	4.40 ± 1.26	1.60 ± 0.87	1 versus 2: <0.0001 2 versus 3: <0.0001
W6	1.1 ± 0.30	1.37 ± 0.68	1.07 ± 0.26	1 versus 2: <0.0001 2 versus 3: 0.0008
W12	0.72 ± 0.45	0.78 ± 0.45	0.73 ± 0.45	
Urgency 1st day	3.11 ± 1.02	3.82 ± 0.95	3.82 ± 0.95	1 versus 2: <0.0001 2 versus 3: 0.0005
W6	1.28 ± 0.78	1.20 ± 0.73	3.20 ± 1.08	
W12	0.82 ± 0.53	0.8 ± 0.5	1.22 ± 0.73	
Nocturia 1st day	1.88 ± 1.03	2.60 ± 1.18	1.99 ± 1.02	1 versus 2: <0.0001 2 versus 3: 0.0017
W6	0.28 ± 0.45	0.27 ± 0.45	0.25 ± 0.44	
W12	0.1 ± 0.4	0.17 ± 0.38	0.15 ± 0.36	
Dysuria 1st day	1.3 ± 0.8	5.28 ± 1.42	1.22 ± 0.74	1 versus 2: <0.0001 2 versus 3: <0.0001
W6	0.23 ± 0.43	0.23 ± 0.42	0.24 ± 0.43	
W12	0.09 ± 0.29	0.14 ± 0.35	0.07 ± 0.26	
Buprenorphine dosage	0.01 ± 0.05	0.09 ± 0.15	0.16 ± 0.18	0.0002

Non-parametric wilcoxon
2-sample *t* test

of the ureteral orifice, the study demonstrated that leaving patients without stents is both safe and well tolerated. Srivastava et al. [15] reported that in select patients undergoing ureteroscopy for distal ureteral stones, stents can be safely omitted. A recent study by Ibrahim et al. [16] also stated that uncomplicated ureteroscopy for treatment of distal ureteral stones is safe without stent placement. Patients without stents have significantly fewer irritative bladder symptoms and are not at risk of increased complications.

Our prospective controlled study objectively demonstrates that ureteral stenting after uncomplicated ureteroscopic stone fragmentation is no longer absolutely necessary in selected cases. Patients in whom a stent was not placed had an improved early postoperative course with respect to the usual irritable voiding symptoms and flank pain compared to the stented group. This difference was statistically significant. Ureteral stents negatively impact quality of life and can cause significant morbidity. Recently Haleblan et al. [17] made a systematic review and concluded that patients with stents seem to have significantly

more bladder and lower urinary tract symptoms than those in whom stents are not placed.

The primary objective of ureteroscopic treatment (achieving a stone-free result) was also not compromised by eliminating a stent. To date many ureteroscopic procedures can be classified as uncomplicated, defined as procedures with minimal or no ureteral trauma, minimal or no ureteral dilation and minimal or no residual stone burden. Smaller ureteroscopes can now provide stone fragmentation with minimal trauma and no ureteral dilation. A number of randomized, prospective trials in patients undergoing ureteroscopic stone removal investigated the effects of placing a stent at the termination of the procedure and concluded that the complication rates in patients were no different in the nonstented cohort than in the stented cohort without impacting stone-free rates [12, 18–20]. Haleblan et al. [17] also concluded that there is a subgroup of patients that possibly benefits from stenting following a procedure because of the increased risk of complications. Most importantly, in select cases especially when marked

edema or polyps combined with infected catheterized urine existed, ureteral stent indwelling can prevent the perioperative complications. Under such circumstances, the indication for ureteral stent placement is ureteral edema or polypoid formation with infected urine. The complication rates were significantly different between stented (16.9%) and non-stented group (3.3%, 41.8%). In fact, only one patient in the stented group developed urinary sepsis, with urine culture showing growth of *Pseudomonas* sp., necessitating treatment with intravenous antibiotics and requiring a hospital stay. Five patients in group 3 required hospitalization for intravenous antibiotics as a result of genitourinary sepsis. The results were comparable to that reported by Rodrigues Netto et al. [19]. They reported that the overall perioperative complication rate was 4.9%. On the other hand, there was a marked difference in the lower urinary tract symptoms in the two groups. Patients in the non-stented group had a significantly lower incidence of overall pain and, in particular, flank pain with voiding, urgency, and dysuria. The mean pain score at the time of stent insertion was 3.30 in the stented group, and 2.10 in the non-stented group. Also, an interval visit for stent removal is avoided. A prospective randomized study by Borboroglu et al. [18] followed 107 patients after ureteroscopic treatment of distal ureteral calculi with or without the use of ureteral stents. They also found that those without stents not only had significantly less bladder pain, urinary symptoms and narcotic use postoperatively, but also had less flank and overall pain as compared to the stented group.

The major complication that is of concern after ureteroscopy is the development of ureteral stricture. Boddy et al. [6] studied the effects of distal ureteral dilatation in the minipig model. They demonstrated that dilatation to 2.5 times its original size caused upper urinary tract dilation and obstructive uropathy for 96 h. At 4 weeks, some of the ureters were still dilated. However, there was no evidence of ischemic necrosis or ureteral stricture formation. Clinical studies show the incidence of stricture to be 0.5–24%. Roberts et al. [21] reported that stone impaction for 2 months is associated with a higher risk of stricture and that ureteral perforation at the site of stone impaction was the primary risk factor for the development of postoperative ureteral stricture. These findings suggest perhaps we can predict which patients may have problems without stent placement. In our study, postoperative imaging was available in all the patients, and no evidence of ureteral stricture was seen. Similarly, Hosking et al. [10], found no evidence of stricture in 93 patients undergoing nonstented ureteroscopy for distal ureteral stone. Borboroglu et al. [18], in their multi-institutional study, also did not report any ureteral stricture in 91 patients (85%) for whom a postoperative radiographic study was available.

There are certain shortcomings in the present study. Ureteroscopy was not performed by a single urologist, which may theoretically have influenced the outcome. Similarly, identification of marked edema by different urologists may not be uniform. Finally, the randomization schedule was known to the operating surgeon, which could have introduced bias. However, there was no difference in the operative variables, success rates, or intraoperative or postoperative complications.

Conclusions

We believe that in select patients undergoing ureteroscopy for ureteral stone, stents can be safely omitted. Patients without stents have significantly less pain, frequency, urgency and dysuria and are not at higher risk of complications. When there is ureteral edema or polypoid change with pyuria, ureteral stents should be indwelled to avoid severe postoperative complications.

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