A prospective randomized trial comparing non-stented versus routine stented ureteroscopic holmium laser lithotripsy

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ABSTRACT

الأهداف: تم إجراء تجربة استطلاعية عشوائية ذات شواهد لتحديد فيما إذا كانت دعامة الحالب بعد العملية ضرورية بعد تفتيت الحصى عن طريق منظار المسالك البولية لعلاج حصى الحالب المتوسطة والحادة.

الطريقة: تم إجراء التجربة فسم المسالك البولية – مستشفى الصين الغربية – جامعة سيشوان – تشنجدو – الصين خلال الفترة من مايو 2005 إلى مايو 2006. خضع 110 مريض لتفتيت الحصى عن طريق منظار المسالك البولية والغير مصحوب بمضاعفات. تم تقسيم المرضى بعد العملية عشوائياً إلى مجموعة استخدمت الدعامة (n=55) ومجموعة لم تستخدم الدعامة (n=55). تم تركيب الدعامة لمدة 3 أسابيع. شملت المؤشرات الناتجة: وقت العملية، ومقدار المعطيات البصري، والمسكنات اللازمة بعد العملية، والمضاعفات، ومعدل إزالة الحصى.

النتائج: كانت الإصابة بالبيلة الدموية في مجموعة الدعامة أعلى من المجموعة التي لم تستخدم الدعامة. كانت آلام الخاصرة، ألم البطن، أعلى في مجموعة الدعامة في 48 ساعة. لم يكن هناك أي اختلافات بين المجموعتين فيما يتعلق بوقت العملية، الأعراض التهيجية، استخدام المسكنات، و المضاعفات. بلغ معدل إزالة الحصى 100% لكلا المجموعتين.

خاتمة: أن تفتيت الحصى عن طريق منظار المسالك البولية والغير مصحوب بمضاعفات قد يجرى بطريقة آمنة بدون إزالة دعامة الحالب. المرضى الذين لم يستخدموا الدعامة أقل ألم وبيلة دموية.

Objectives: To determine whether post-operative ureteral stenting is necessary after ureteroscopic lithotripsy for the treatment of middle and distal ureteral calculi.

Methods: The trial was carried out in the Department of Urology of West China Hospital, Sichuan University, Chengdu, China, between May 2005 and May 2006. A total of 110 patients underwent uncomplicated ureteroscopic lithotripsy. After the procedure, patients were randomized to a non-stented (n=55), or stented (n=55) group. The stent was routinely placed for 3 weeks. Outcome measures included operative time, visual analog scale, post-operative analgesic requirements, complications, and the stone-free rate.

Results: The incidence of hematuria was higher and the operative time was longer in the stented group compared to the non-stented group. At 48 hours post-operatively, the symptoms of flank pain and abdominal pain were significantly greater in the stented group. There was no statistical difference in the 2 groups, in terms of irritative symptom, analgesic use, and complications. The stone-free rate was almost 100% in both groups.

Conclusion: Uncomplicated ureteroscopic lithotripsy can be safely performed without the placement of a ureteral stent. Patients without stents had less operative time, pain and hematuria.

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Ureteroscopic stone fragmentation and removal has been recognized as a highly effective, minimally invasive procedure for treating ureteral calculi, especially the middle and distal ones.[1] Traditionally, ureteral stents are frequently placed after ureteroscopy. It has been reported that the placement of a ureteral stent reduces the risk of post-operative ureteral obstruction, and possibly aids in the passage of small fragments.

However, numerous recent studies have shown that routine stenting after an uncomplicated ureteroscopic lithotripsy may be unnecessary.[2-4] It is well-documented that ureteral stenting is associated with irritative voiding symptoms and pain that can affect quality of life temporarily. Furthermore, there are complications associated with ureteral stenting, including migration, urinary tract infection, breakage, encrustation, and stone formation.[5-7] With the introduction of small caliber endoscopes and lithotripsy devices, the procedure of ureteroscopic lithotripsy become more atraumatic. However, most urologists still use stenting as a routine practice after ureteroscopic procedure. Whether the stent may be eliminated after uncomplicated ureteroscopy for middle and distal stone remains unclear. Recently, we performed this study in our institute to assess the need for routine ureteral stenting after uncomplicated ureteroscopic lithotripsy for distal and middle ureteral stones.

Methods. The investigative review board and committee for the protection of human subjects approved the protocol at our institution. This study was designed as a prospective randomized controlled trial, which was carried out in the Department of Urology of West China Hospital, Sichuan University, Chengdu, China, between May 2005 and May 2006. Adults, 18 years or older were considered eligible for the study if they were scheduled for ureteroscopy for distal and middle ureteral calculi. Holmium laser lithotripsy was performed in 120 patients who had impacted ureteral stones. Patients were excluded from the study when they had a stone size was larger than 2 cm, a history of sepsis, renal failure, solitary kidney, multiple ureteral stones, pregnancy, or previous ureteroscopic lithotripsy in the same position. Patient's who were detected intra-operatively with severe mucosal injury, and ureteral perforation were also considered not eligible. Distal and middle ureteral stone diagnosis was carried out when the stone was localized below the superior border of the sacroiliac joint. Stone location and size were assessed by a plain abdominal radiography and intravenous pyelogram, or retrograde pyelography if needed. Patients were enrolled after informed consent was obtained, and were hospitalized the prior day of the operation. The patients were randomized into stented and non-stented groups at the end of the ureteroscopic procedure. A 7 Fr Wolf semi-rigid ureteroscope (Yong Xu, Chengdu, China) was used in all patients under general anesthesia. Laser lithotripsy was delivered using a pulsed 100-watt holmium laser. A 365-μm laser fiber was used. The laser energy was generally applied at a setting of 1.0-1.2 Joules, and the pulse frequency was used at a setting of 10-12 Hertz. All the stones were completely fragmented to particles less than 2 mm. No attempt was made to remove stone fragments with baskets, or graspers. Instead, stone fragments were left *in situ*, allowing spontaneous passage. If the stone cannot be fragmented to bits less than 2 mm, additional forceps application should be used to remove the bits. In the stented group, a double-J stent (4.8 Fr/26 cm) was placed through the working channel. Usually the double-J stents was cystoscopically removed at the third post-operative week. Patients with slight pain received oral diclofenac (75 mg), and with severe pain, received intramuscular dolantin (50 mg). The outcomes measured were operative time, stone-free rate, post-operative flank, and lower abdominal pain, irritative voiding symptoms, post-operative analgesic requirements, and early and late post-operative complications. Post-operative pain was measured using a 10 cm visual analog scale (VAS), in which 0 represented no pain, and 10 represented extreme pain. A symptom and event questionnaire was completed at 48 hours, one, and 4 weeks post-operatively. The questionnaire was with regard to flank and lower abdominal pain, dysuria, irritative voiding symptoms, fever >37°C, and urinary tract infection. Complications were measured by the questionnaire, urinalysis, plain x-ray of the kidney, ureters, and bladder (KUB), renal ultrasound post-operatively, and incidence of stent migration. Stone-free status was determined by KUB at each post-operative visit until clear. Intravenous pyelogram was performed 3 months post-operatively to assess evidence of ureteral stricture.

Statistical analysis was performed using the Statistical Package for Social Sciences software version 16 (SPSS Inc., Chicago, IL, USA). All continuous variables were expressed as mean ± standard deviation. Two-tailed independent t test was used for comparison of continuous variables when appropriate. Categorical variables were compared with the Chi-square test (exact Fisher's test), and 95% confidence interval (CI) for independent variables were calculated. A $p \leq 0.05$ was considered statistically significant.

Results. Of the 120 patients, 10 patients were removed from the study as they did not meet the secondary intra-operative eligibility criteria of the study, necessitating ureteral stent placement at the conclusion of the procedure. A total of 110 patients were randomized at the end of the ureteroscopic procedure, including 55 patients to the stented group, and 55 patients to the non-stented group. The characteristics of the patients and operative time in the 2 groups are shown in **Table 1**.There was no statistical difference with respect to patient gender, age, stone location, mean stone size. The operative time was longer in the stented group compared to the non-stented group.

A successful outcome was achieved in 100% of the cases without ureteral orifice dilatation in all groups. **Table 2** shows the mean VAS at 48 hours, one, and 4 weeks post-operatively. At 48 hours, the mean VAS in the stented group was much higher than in the non-stented group. This result was statistically significant. At one, and 4 weeks the mean VAS were not statistically different between the 2 groups. The irritative voiding symptoms, complications, and analgesic use are summarized in **Table 3**. The incidence of hematuria (more than 3 red blood cells per high-powered field in a urinalysis) in the stented group was higher than in the non-stented group (23 versus 11, p=0.013). There was no difference between the 2 groups with respect to the analgesic use. Dysuria and frequency/urgency were more prevalent in the stented group, although without statistically significant difference. The stent had to be removed earlier in 6 patients due to gross hematuria and flank pain. One patient in the non-stented group had high fever at the third day post-operatively, because of ipsilateral acute pyelonephritis. The patient had to be treated with intravenous antibiotics for one week. No stent migration occurred in the stented group. The stone-free rate in the non-stented group was 100% by KUB, followed up for 3 weeks post-operatively. The stone-free rate in the stented group was 98.2% at 3 weeks post-operatively. One patient had a 2 mm residual distal ureteral stone noted on the third week follow up KUB, with subsequent 4-week plain film revealing no evidence of residual stone burden. No stricture was detected by intravenous pyelogram in the 6-month post-operative follow-up.

Table 1 - Characteristics of patients in the 2 groups.

Characteristics	Stented n=55	Non-stented n=55	*P*-value
Age, mean ± SD	38.69 ± 6.00	40.04 ± 5.15	0.21
Ratio, male:female	34:21	36:19	0.69
Stone ureteral location			
Distal	46	44	0.62
Middle	9	11	
Stone size, mean ± SD (mm)	11.19 ± 2.11	11.46 ± 2.24	0.52
Operative time, mean ± SD (mm)	43.07 ± 6.00	39.07 ± 6.21	0.001

Table 2 - Mean visual analog score 48 hours, one, and 4 weeks post-operatively.

Characteristics	Stented mean ± SD	Non-stented mean ± SD	*P*-value
At 48 hours			
Flank pain	4.57 ± 1.76	3.62 ± 1.57	0.004
Abdominal pain	3.12 ± 1.53	2.28 ± 1.29	0.002
At one week			
Flank pain	2.12 ± 1.71	1.62 ± 1.41	0.095
Abdominal pain	1.23 ± 1.05	0.89 ± 1.00	0.083
At 4 weeks			
Flank pain	0.45 ± 0.46	0.38 ± 0.46	0.44
Abdominal pain	0.31 ± 0.41	0.24 ± 0.35	0.322

Table 3 - Postoperative symptoms, complications, and analgesic use.

Characteristics	Stented	Non-stented	*P*-value
	n (%)		
Dysuria	26 (47.3)	18 (32.7)	0.119
Hematuria	23 (41.8)	11 (20)	0.013
Frequency/urgency	29 (52.7)	20 (36.4)	0.084
Fever	5 (9.1)	7 (12.7)	0.541
Stent migration	-	-	
Ureteral stricture	-	-	
Narcotic analgesic use	6 (10.9)	4 (7.3)	0.507
Non-narcotic analgesic use	20 (36.4)	17 (30.9)	0.545

Discussion. The routine use of ureteral stent after ureteroscopic lithotripsy is currently under debate. Some urologists advocate that placement of a stent can prevent ureteral stricture, and decrease the risk of flank pain secondary to ureteric edema, and facilitate the passage of stone fragments.[8,9] Djaladat et al[10] revealed that short-term ureteral stenting had a considerable role in reducing post-operative morbidity like renal colic, peritonism, and analgesic usage. However, the traditional prevailing method has been questioned by more urologists. A number of studies have shown that the placement of a ureteral stent may be associated with significant morbidity such as dysuria, urinary frequency, urgency, flank pain, and hematuria.[2-4] Although recently some urologists have reported that alpha-1 blockers may relieve ureteral stent discomfort,[11] the morbidity related to the stent is still difficult to be avoided completely. Furthermore, patients with stents are exposed to numerous potential risks that stents have shown to be associated with: migration, infection, pyelonephritis, breakage, encrustation, and stone formation.

Animal experiments and clinical studies have demonstrated that a ureteral stent impedes stone passage.[12,13] Chen et al[14] reported that ureteral stenting neither hastened stone passage, nor facilitated restoration of renal function. Moreover, the potential benefits to non-stented patients after ureteroscopy include cost savings, reduced operative time, and avoidance of follow-up cystoscopy for removal. Hosking et al[15] reported 87% of patients who underwent rigid ureteroscopy for distal ureteral stones, without ureteral stents required either no analgesia, or oral medications alone post-operatively, and none required repeated instrumentation. Recently, various kinds of biodegradable ureteral stents were

used in animal experiment and clinical trials. These new devices may result in less ureteral dilatation, fewer positive urine cultures, and better biocompatibility.[16,17] This experience indirectly confirms that the current ureteral stent indeed, has some problems. An ideal stent does not exist. Ongoing research is essential to optimize biocompatibility, and decrease stent-related complications. Interest has been great in this field of research, marked by the introduction of new biomaterials, coatings, and stent designs.

With the development of caliber ureteroscopes and more effective intracorporal lithotripsy devices, it is now possible to perform ureteroscopy in most patients without ureteral dilation. As a result, ureteroscopic stone fragmentation has become a relatively atraumatic procedure, and most of the calculi can be fragmented successfully. Current low intra-operative complication rates are likely due to the advent of smaller-diameter rigid ureteroscopes, and more liberal use of flexible devices. A surgeon's experience may not be as important a predictive factor as once indicated. This finding was demonstrated by Schuster et al,[18] who reported surgeon experience had no impact on the likelihood of intra-operative ureteral injury when comparing 5 surgeons with a range of ureteroscopic experience. In our study, due to the use of 7 Fr semi-rigid ureteroscope, no patient required dilation of the ureteral orifice. The results were comparable to that reported by Wang et al.[19] The stones can be fragmented to a particle size of 2 mm by holmium laser. Therefore, there was no difference between the 2 groups for the stone-free rate by following up for 4 weeks post-operatively. Furthermore, the non-stented patients had improved early post-operative course, with respect to the pain and hematuria compared to those in the stented group. Nevertheless, with the recovery of ureteral mucosal injury, the difference was not statistically significant (at one week post-operatively).

It is our belief that intra-operative ureteral mucosal injury may play a key role in the emergence of complications, associated with stenting for short periods after ureteroscopy. In our opinion, patients that underwent slight ureteral mucosal trauma will not benefit from stenting. In contrast, the stent may delay the recovery of trauma, and aggravate early complications. Certainly, severe mucosal injury is exceptional, which will result in severe ureteral obstruction. No hydronephrosis, or ureteral stricture was detected by follow-up for 6 months post-operatively in both treatment groups. The mechanism of stricture formation has not yet been completely elucidated, and it is likely to be multi-factorial. Roberts et al[20] argued that stone impaction for 2 months was associated with a higher risk of stricture, and primary risk factor of ureteral stricture was ureteral perforation at the stone site. There are different attitudes with respect to vesico-ureteral reflux. Mosli et al[21] indicated that in most patients with double pigtail ureteral stents, vesico-ureteral reflux occurred at a low grade during vesical filling, and at a high grade during voiding. Also, the stents adversely affected the ureteral peristaltic activities.[21] However, Yossepowitch et al[22] reported that vesico-ureteral reflux was not a guaranteed consequence of double-J stent placement. According to their opinion, there was correlation between vesico-ureteral reflux and intravesical volume.[22]

A limitation in our study is that there was no validated instrument to measure stent morbidity. Stent morbidity was characterized as flank pain, abdomen pain, or a variety of irritative symptoms. Post-operative pain was quantified by 10-point VAS, which was completed by patients, and lacked an objective criteria. Another limitation is that the randomization schedule was known to the operating surgeon, which could have introduced bias.

In conclusion, uncomplicated ureteroscopic lithotripsy for middle and distal ureteral calculi can be safely performed without the placement of a ureteral stent. Patients without stents have significantly less flank and abdominal pain, hematuria, and operative time compared to those with stents. Irritative voiding symptoms were more prevalent in the stented group, although without statistically significant difference. There was no difference in the 2 groups in terms of analgesic use, ureteral stricture, and stone-free status.

The small number of randomized patients and stent-related morbidity cannot be quantified by valid instruments. Future studies will most likely require a larger, randomized sample, and more validated instruments to demonstrate this issue.

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Related topics

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