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Nonstented versus routine stented ureteroscopic holmium laser lithotripsy: a prospective randomized trial

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Abstract We conducted a prospective, randomized study to evaluate whether postoperative ureteral stenting is necessary after ureteroscopic holmium laser lithotripsy. A total of 115 consecutive patients with distal or middle ureteral calculi amenable to ureteroscopic holmium laser lithotripsy were prospectively randomized into stented group ($n = 58$) and nonstented group ($n = 57$). The stent was routinely placed in the treated ureter for 2 weeks. The outcomes were measured with postoperative patient symptoms, stone-free rates, early and late postoperative complications, and cost-effectiveness. The postoperative symptoms were measured with Ureteral Stent Symptom Questionnaire (USSQ). All patients completed a 12-week follow-up. There was no significant difference between two groups with respect to the patient age, stone size, stone location and mean operative time. According to the USSQ, the symptoms of the stented group were significantly worse compared to the nonstented group ($P = 0.0001$). In the stented group, two patients had high fever for 1 week after the operation, stent migration was found in two patients, and the stents had to be removed earlier in five patients because of severe pain or hematuria. The cost of the stented group was significantly higher than the nonstented group. The stone-free rate was 100% in both groups. No hydronephrosis or ureteral stricture was detected by intravenous pyelogram in the 12th week postoperative follow-up. In conclsion, we believe that routine stenting after ureteroscopic intracorporeal lithotripsy with the holmium laser is not necessary as long as the procedure is uncomplicated for distal or middle ureteral calculis less than 2 cm.

Keywords Ureteral calculi · Laser · Lithotripsy · Stent

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Introduction

Ureteroscopy and intracorporeal lithotripsy have become a highly effective, minimally invasive treatment for ureteric calculi, especially for distal or middle calculi. Traditionally, in order to prevent ureteral obstruction and renal colic caused by ureteral edema, surgeons placed a ureteral stent after ureteroscopic lithotripsy. It has also been thought that stenting can prevent ureteral stricture and may also aid in the passage of stone fragments [1, 2]. However, many patients complain of flank and bladder discomfort while the ureteral stent is implanted [3]. Complications that occurred have been discovered to be associated with the use of stents, including migration, infection, pyelonephritis, breakage, encrustation and stone formation [4, 5]. With the development of small caliber ureteroscopes and more effective intracorporeal lithotripsy devices, ureteroscopic stone fragmentation has become a relatively atraumatic procedure. As a result, some urologists suggest routine placement of ureteral stents after uncomplicated ureteroscopic lithotripsy is not necessary [6–9]. However, the majority of urologists still use stent as a routine practice for the common belief that problems are encountered much more frequently [10, 11]. The place of stenting in the management of patients after uncomplicated ureteroscopy remains unclear. To our knowledge, we reported a prospective, randomized trial to evaluate whether postoperative ureteral stenting is necessary after ureteroscopic holmium laser lithotripsy.

Patients and methods

Patients

From June 2005 to March 2006, a total of consecutive 118 patients with distal or middle ureteral calculi were performed ureteroscopic holmium laser lithotripsy. In our clinical practice most of the distal or middle ureteral calculi were less than 2 cm, so we selected that stones less than 2 cm were included in the study. Patients with any of the following situations were excluded from the study: stone size larger than 2 cm, previous failure in the performance of ureteroscopy for the treatment of the same stone, a history of sepsis, renal failure, solitary kidney, pregnancy, suspicion of urothelial cancer, preoperative ureteral stenting, stricture in the ureter and mucosal perforation during operation. Informed consent was obtained before operation. These patients were randomized into stented group or nonstented group at the end of the ureteroscopic procedure. Stone location and size were assessed by a plain abdominal radiograph and intravenous pyelogram. Proximal stones were considered those above the superior border of the sacroiliac joint on plain X-ray of the kidneys, ureters and bladder, distal stones were those below its inferior border and mid ureteral calculi were those within the borders of the sacroiliac joint.

Instruments and surgical techniques

All procedures were done using epidural anesthesia. Ureteroscopy was done with an 8Fr/9.8Fr Wolf semirigid ureteroscope. The ureteroscope was introduced without dilation of the ureteral orifice. Stones were fragmented with the holmium laser in all patients. Holmium laser pulse energy of 1.0–1.2 J, and pulse frequency of 10–12 Hz were used for laser lithotripsy. Stones in the ureters were completely fragmented to particles less than 2 mm and stone fragments were not attempted to remove with graspers, instead stone fragments were left in situ, following spontaneous passage.

In our study we only selected one type stent. In the stented group a double pigtail ureteral stent (Cook Ireland Ltd) was placed in the treated ureter under the zebra guide wire and the size of double pigtail ureteral stent was 4.7Fr/26 cm. Usually the ureteral stents were removed 2 weeks postoperatively using cystoscopy at the urology clinic.

Assessment

In both groups, we recorded operative time and evaluated postoperative patient symptoms, stone-free status, early and late postoperative complications. We also evaluated cost-effectiveness. All patients were administered the Ureteric Stent Symptoms Questionnaires (USSQ) as designed by Joshi et al. [12] in the 2nd week after the operation, which was investigated by the doctor who was not aware of whether the stent was used on the patient. The questionnaire evaluated the impact of stents on the domains of urinary symptoms; body pain; general health as well as any additional stent related problems faced by the patients, quality of life (QOL) were also evaluated in the 2nd week after the operation. Stone-free status was determined by plain X-ray of the kidneys, ureters and bladder at each postoperative visit until clear. Complications were measured by the questionnaire, urinalysis, plain X-ray, renal ultrasound postoperatively and incidence of stent migration. Intravenous pyelogram was performed in the 12th week postoperative follow-up to assess evidence of ureteral stricture.

Outcome analysis

All measurement data were statistically analyzed with the two-tailed Student t test and are presented as mean $\pm$ standard deviation of the mean (SD). Postoperative adverse events were compared with the two-tailed Chi-square test (exact Fisher's test).

All patients were given the same information that they may not be placed the stent as long as the procedure is uncomplicated before operation. The study was approved by our ethics committee and all patients provided an informed written consent.

Results

A total of 115 patients were randomized at the end of the ureteroscopic procedure, including 58 to the stented group and 57 to the nonstented group. Three patients were excluded from study before randomization, one due to ureteral perforation during operation and two due to ureteral stricture associated with the stone. All 115 patients were followed up for 12 weeks postoperatively. The two patient groups were comparable with respect to the baseline variables of patient age, stone location and mean stone size (Table 1). Mean operative time in the nonstented group was 29.8 ± 8.7 min compared to 32.6 ± 9.8 min in the stented group. Operative time was not significantly longer when a stent was placed.

The results of the USSQ domain score in the 2nd week. The stented group was significantly worse compared with the nonstent group ($P = 0.0001$) (Table 2).The comparison of the results for the important domains of urinary symptoms, body pain, general health and QOL show that the stented group was significantly worse compared with the nonstent group. Of the patients with the stent, 87% (51/58) voided every 2 h or less during the day and 72% (42/58) awoke twice or more at night to void. Compared with the

Table 1 Demographic data and stone parameters

	Mean ± SD		*P* value
	Stented group	Nonstented group	
No. of pts	58	57	
No. of male:female	35:23	36:21	0.85
Age	47.0 ± 10.9	45.3 ± 13.2	0.57
No. of stone location			0.52
Middle ureter	16	12	
Lower ureter	42	45	
Mean stone size (mm)	9.5 ± 2.5	9.3 ± 2.4	0.66

Table 2 Comparison of the USSQ domain scores and *P* value for two groups

	Mean ± SD		*P* value
	Stented group	Nonstented group	
Urinary symptom index	27.4 ± 5.0	17.1 ± 3.4	0.0001
Body pain index	16.8 ± 3.6	4.1 ± 5.3	0.0001
General health index	17.1 ± 3.7	10.1 ± 2.6	0.0001
QOL	4.5 ± 1.0	1.6 ± 1.1	0.0001

nonstented group, they were 40% (23/57) and 33% (19/57). The incidence of hematuria was 74% (43/58) for the stented group and 14% (8/57) for the nonstented group. The pain in kidney area at voiding in the stented group was 39% (23/58), while it was 3% (2/57) in the nonstented group. These symptoms of the stented group were more severe than the nonstent group ($P < 0.001$) (Table 3).

Complications developed in some patients of the stent group. Two patients had high fever in the 1st week after the operation because of acute pyelonephritis. They were treated with intravenous antibiotics for 1 week in the emergency room; the stents could not be removed by the cystscope in two patients because of stent proximal migration. But according to intravenous pyelogram we found the length of the two patients ureter were not different from other patients. Then the stents were removed with the ureteroscope and required hospital admission; one patient had gross hematuria with clots was treated in the emergency room. In addition, the stent had to be removed earlier in five patients because of gross hematuria and pain in kidney. Two patients in the nonstented group presented obvious flank pain and were treated satisfactorily with analgesic. These complications in the stent group were significantly more severe than the nonstent group ($P = 0.029$) (Table 3).

Table 3 Postoperative symptoms and events

	Stented group	Nonstented group	*P* value
No. of frequent micturition (%)	51 (87)	23 (40)	<0.001
No. of nocturia (%)	42 (72)	19 (33)	<0.001
No. of hematuria (%)	43 (74)	8 (14)	<0.001
No. of pain in kidney area at voiding (%)	23 (39)	2 (3)	<0.001
No. of earlier complications (%)	10 (17)	2 (3)	0.029

The cost of the stent was 518 yuan RMB (70 US dollars), and stents must be removed by the cystscope at the urology clinic with the cost of 620 yuan RMB (84 US dollars). They are all extra costs compare with the nonstented group.

The stone-free rate was 100% by plain KUB following up for 3 weeks postoperatively in both treatment groups. No hydronephrosis or ureteral strictures was detected by intravenous pyelogram in the 12-week postoperative follow-up.

Discussion

With the relatively recent development of small caliber ureteroscopes, routine balloon dilation of the ureter before introduction of the ureteroscope is seldom required [13]. Furthermore, uncomplicated ureteroscopy for treatment of distal ureteral calculi with intraoperative distal ureteral dilation can be safely performed placement of a ureteral stent [8]. In this study, ureteroscopic access was successfully achieved in all of our patients and also need not for ureteral orifice dilation. Together with the more effective intracorporeal ureteroscopy devices, ureteroscopic stone fragmentation has become a relatively atraumatic procedure [14]. Such as ureteroscopic holmium laser lithotripsy is a well-established treatment modality for ureteral calculi even as an outpatient surgery [13, 15]. For upper ureteral calculi removal ureteroscopic treatment was mainly suggested after failure of extracorporeal shock wave lithotripsy (ESWL). Meanwhile, according to our experiences, the upper ureteral calculus which was treated with ureteroscopy was easier to be pushed into pelvic and needed ESWL after ureteroscopy. Therefore, we exclude the upper calculus in our trial.

Some urologists advocate placement of stent can prevent ureteric stricture and reduce the incidence of postoperative renal colic secondary to ureteral edema [2]. But no study has proved whether stenting can actually prevent a ureteric stricture. Some urologists believe that stenting aided to hasten fragments passage. But a canine experiment showed that ureteral stent placement reduced pelvic and ureteral motility and delayed calculus transit time [16]. Clinical studies have also revealed that ureteral stenting impedes stone passage. Lennon et al. [17] reported Double J stents

are associated with ureteric dilatation, diminished peristalsis and impaired stone passage.

While with electrohydraulic or pneumatic lithotripsy with the larger fragments (at least 3–4 mm) produced may potentially cause more problems in terms of spontaneous passage and it easily caused ureteral edema leading to temporary ureteral obstruction. Some authors believe that the use of stent for these patients may be helpful. In our hospital, we used holmium laser to lithotripsy. It can break the stone into fragments smaller than 2 mm, the fragments were smaller than the other common intracorporeal lithotriptors in use today [18]. The holmium laser causes little damage to ureteral mucosa, and also it can decrease the operative time because of efficient lithotripsy. As a result, stenting is usually not necessary for relieving postoperative obstruction.

Since ureteroscopy and intracoporeal lithotripsy have become a highly effective, minimally invasive treatment for ureteral calculi, postoperative stent symptoms have now become the most morbid part of ureteroscopic stone removal in the majority of patients. Joshi et al. [12] reported 78% patients with stents had bothersome urinary symptoms that included storage, incontinence and hematuria, more than 80% of patients experienced stent related pain affecting daily activities, 32% reported sexual dysfunction and 58% reported reduced work capacity and negative economic impact. In the results with USSQ in our patients, we also found patients with stents had bothersome urinary symptoms, overall compared with the nonstented group. These significantly affected health and daily life. There were five patients in stented group required stent removal earlier than planned due to heavy hematuria and pain in our trial. In our patients without stents the risk of retreatment for flank pain after ureteroscopy was 3.5% (two patients). Even though these two patients without stents had severe postoperative flank pain, body pain index of the nonstented group was significantly lower than the stented group.

Mosli et al. [19] studied the occurrence of vesicoureteral reflux radiologically in stented patients. During the filling phase of the cystourethrogram, reflux occurred in 19 of the 30 renal units (63%); during the voiding phase of the cystourethrogram reflux was observed in 24 of 30 renal units (80%). Reflux reached only the lower ureter at low pressures during vesical filling and reaching up to the kidney at high pressures during voiding. They may lead to flank pain and pyelonephritis due to reflux because of the indwelling stent. Also, the stent itself may increase the incidence of urinary tract infection [20]. We also found flank pain occurred in 23 of the 58 stented patients (39%) during voiding, and two patients had high fever because of acute pyelonephritis postoperative 1 week. These complications occurred probably due to stent and vesicoureteral reflux.

Moreover, ureteral stents increase the expenses. The cost of stent was 520 yuan RMB.Follow-up cystoscopy for stent removal was 620 yuan RMB in our hospital. In stented group, two patients had high fever postoperative 1 week because of acute pyelonephritis. They were treated with intravenous antibiotics for 1 week in the emergency room; the stents could not be removed under the cystscope in two patients because of stent proximal migration, the stent was removed with the ureteroscope and required hospital admission; one patient had gross hematuria with clots and needed management in the emergency room. Complications developed in those patients of the stent group, they need management in the emergency room or hospital admission. Using stent added the medical expense. Furthermore, indirect cost addings in the form of patient time lost from work because of stent symptoms and return visits for stent removal would also be expected in the stented group.

Since we used holmium laser to lithotripsy, it breaks the stone into fragments smaller than 2 mm, the stone-free rate was 100% by following up for 3 weeks postoperatively in each treatment group. It has been found that ureteral perforation at the site of stone was the primary risk factor for stricture formation [21]. We believed that in this clinical situation a stent should be placed to avoid postoperative complications. In our study, we have excluded these patients with ureter and mucosal perforation during operation. Then no hydronephrosis or ureteral strictures were detected by follow-up for 12 weeks postoperatively between two groups.

Conclusion

There was no difference between the stented and nonstented group in terms of stone passage, and no radiographic evidence of obstruction or ureteral stricture in the imaging studies obtained in 12 weeks postoperatively. There were less urinary symptoms and body pain in the nonstented group. The cost was saved without a stent. It is believed that routine stenting after ureteroscopic intracorporeal lithotripsy with the holmium laser is not necessary after uncomplicated ureteroscopic lithotripsy without ureteral dilation and extraction for distal or middle ureteral calculis when stone size was less than 2 cm.

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