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N. P. Pardalidis · A. G. Papatsoris · E. V. Kosmaoglou

Prevention of retrograde calculus migration with the Stone Cone

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Abstract Retrograde calculus migration during ureteroscopic lithotripsy remains a problem in 5–40% of cases. We assessed the safety and efficacy of the Stone Cone device, in comparison with the standard flat wire basket. A total of 56 consecutive patients with ureteral calculi, suitable for ureteroscopic extraction and/or lithotripsy, where included in this prospective study. Patients were randomly allocated into two groups. In group A (30 patients), we used the Stone Cone, while in group B (26 patients) we used the standard flat wire basket. The Stone Cone was placed through a cystoscope under fluoroscopic guidance, or when necessary under direct ureteroscopic control. Whenever necessary, intracorporeal electrohydraulic lithotripsy took place in both groups. Statistical significance was assessed by the paired *t*-test. The mean operative time was 48.5 min in group A, and 42.4 min in group B. Intact calculus extraction was possible in 16.6% in group A, and in 7.6% in group B ($P < 0.01$). Retrograde stone migration was revealed in 23% in group B only ($P < 0.001$). Also, residual fragments >3 mm were recorded in 30.7% in group B only ($P < 0.001$). None of the patients in group A required auxiliary procedures, in contrary to 23% in group B ($P < 0.001$). No major complications were recorded in group A, while in group B a case of major ureteral mucosal abrasion was recorded. The Stone Cone is safe and efficient in preventing retrograde stone migration and in minimizing residual fragments during ureteroscopic lithotripsy in comparison with the flat wire basket.

N. P. Pardalidis · A. G. Papatsoris · E. V. Kosmaoglou
Department of Urology,
Hellenic Airforce and Veterans Affairs General Hospital,
Athens, Greece

N. P. Pardalidis (✉)
6 Platonos Street, Halandri,
15234, Athens, Greece
E-mail: pardalidis@internet.gr
Tel.: +30-210-6813177
Fax: +30-210-6853527

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Introduction

Ureteroscopic extraction and/or lithotripsy of ureteral stones is performed after failed shockwave lithotripsy (SWL) for calculi <1 cm, and as an alternative to (SWL) for ureteral calculi >1 cm [1]. Although ureteral access has been facilitated by using small caliber ureteroscopes (semi-rigid and flexible), and the efficacy of fragmentation has been improved by thin electrohydraulic, pneumatic, and laser lithotripsy equipment, a refractory problem is retrograde stone migration. This significant clinical entity necessitates either ureterorenoscopy or stenting, and secondary treatment by SWL; procedures that increase the overall cost and morbidity [2]. The American Urological Association (AUA) Guidelines Panel has reported an average of 1.3 procedures per patient for ureteroscopy of proximal ureteral stones [1].

Attempts to minimize retrograde stone migration by tilting the patient, controlling irrigation pressure, and by utilizing baskets or other devices to either block the ureter or place countertraction have not solved the migration problem [2, 3, 4]. Recently, the Stone Cone (Microvasive-Boston Scientific, Boston, Mass.), which is a tapered helical wire device consisting of a nitinol core with a PTFE coating, was designed with the objective of preventing proximal stone migration and facilitating safe extraction of fragments during ureteroscopic lithotripsy [5]. In the present study, we prospectively assess the efficacy and safety of the Stone Cone in comparison with the standard flat wire basket.

Patients and methods

A total of 56 consecutive patients (39 males and 17 females) with ureteral calculi suitable, according to the

AUA Guidelines Panel, for ureteroscopic extraction and/or lithotripsy, where included in this prospective randomized study, between January 2002 and December 2003. The Ethics Committee of the Hospital approved the study and all patients filled in consent forms. The mean patient age was 51.3 years (range 23–75 years), mean stone width was 10.4 mm (range 6–12 mm), and the mean calculus length was 10.6 mm (range 6–14 mm). On plain x-ray, the calculus was situated above the sacroiliac joint in 26 cases, over the joint in 12, and below the joint in 17 cases. With the help of a table of random numbers, patients were randomly allocated into two groups according to the basketry used during ureteroscopy. In group A (30 patients), we used the Stone Cone, while in group B (26 patients) we used the standard flat wire basket. The characteristics and laboratory results of the Stone Cone device were first reported by Dretler [5].

Under general anesthesia, retrograde ureteropyelograpy was performed in order to measure the width of the ureter and determine the appropriate size of the Stone Cone. In cases where opacification of the proximal ureter was prevented by stone impaction, the size of the Stone Cone was chosen according to preoperative intravenous urography and/or kidney ultrasound. In all cases, an attempt was made to introduce the Stone Cone through a cystoscope under fluoroscopic guidance. When stone impaction impeded this, placement was performed under direct ureteroscopic control. During introduction, the coiled portion of the Stone Cone was collapsed within the carrying catheter and straightened. The carrying sheath was advanced over the wire beyond the stone. Advancing the double strand of the Stone Cone beyond the tip of the carrying catheter deployed the cone. In particular, the cone was deployed when the radio-opaque marker was beyond the stone. Subsequently, the carrying sheath was removed and the cone was pulled back in order to cap the stone. In cases of small nonimpacted calculi, an attempt was made for intact extraction under fluoroscopic control, while in the remainder of cases, intracorporeal electrohydraulic lithotripsy took place. Similarly, the flat wire basket was used to trap the stone and extract it. When this was not possible, lithotripsy preceded and the basket facilitated the extraction of the stone fragments. A JJ stent was placed at the end of the procedure in both groups, after removing the coil wire and advancing a 0.038-inch wire.

The patient characteristics and the overall results are summarized in Table 1. Statistical significance was assessed by using the paired *t*-test.

Results

The Stone Cone was successfully introduced and deployed in all patients in group A; cystoscopically under fluoroscopic guidance in 25 cases (83.3%) and under direct ureteroscopic control in the remaining five (16.6%). The mean operative time was 48.5 min in group A, and 42.4 min in group B. Intact calculus extraction was possible in five cases (16.6%) in group A, and in two cases (7.6%) in group B ($P < 0.01$). Electrohydraulic lithotripsy was performed in 25 patients (83.3%) in group A, and in 24 patients (92.3%) in group B. No major complications were recorded with the use of the Stone Cone, whereas in group B a case of major ureteral mucosal abrasion was recorded (3.8%), which was treated conservatively. Minor ureteral abrasion was revealed in five patients (16.6%) in group A, and in 11 patients (42.3%) in group B ($P < 0.01$).

Retrograde stone migration to the upper third of the ureter was revealed in six patients (23%) in group B only ($P < 0.001$). On postoperative plain x-ray, residual

Table 1 Patient characteristics and overall results. NA indicates not assessed

	Stone Cone	Flat wire basket	*P*
No. patients	30	26	NA
Male/female	19/11	20/6	NA
Stone sacroiliac joint location (%)			
Above	14 (46.6)	13 (50)	NA
Over	7 (23.3)	5 (19.2)	NA
Below	9 (30)	8 (30.7)	NA
Mean stone size in mm (range)			
Width	11 (6–14)	9 (8–12)	NA
Length	10 (6–13)	11 (7–14)	NA
Mean operative time (min)	48.5	42.4	>0.01
No. passes (mean)	1	3	NA
Intact stone extraction (%)	5 (16.6)	2 (7.6)	NA
Electrohydraulic lithotripsy (%)	25 (83.3)	24 (91.3)	>0.01
No. retrograde stone migrations (%)			
Upper third of ureter	0	6 (23)	<0.001
No. residual fragments (%)			
≤ 3 mm	6 (20)	11 (42.3)	<0.01
>3 mm	0	8 (30.7)	<0.001
Major ureteral abrasion (%)	0	1 (3.8)	>0.01
Minor ureteral injury (%)	5 (16.6)	11 (42.3)	<0.01
No. auxiliary procedures (%)	0	6 (23)	<0.001
JJ stent	0	4 (15.3)	NA
Nephrostomy tube	0	2 (7.6)	NA

fragments < 3 mm were revealed in six patients (20%) in group A, and in 11 patients (43.2%) in group B ($P<0.01$). Residual fragments > 3 mm were revealed in eight patients (30.7%) in group B only ($P<0.001$). Furthermore, none of the patients in group A required auxiliary procedures, in contrast to six patients (23%) in group B ($P<0.001$), who underwent JJ stent or nephrostomy tube insertion, followed by SWL. No statistically significant differences were recorded for postoperative administration of analgesics, or for hospitalization or recovery time.

Discussion

Retrograde calculus migration during ureteroscopic procedures remains a significant problem. Clinical studies have reported an incidence of 40–50% for ureteral stone migration from the proximal ureter and 5–10% for migration from the distal ureter [6, 7]. Various devices and techniques have been proposed for preventing retrograde migration, however, each has limitations [2, 3, 4]. The Stone Cone is a novel device, designed with the aim of overcoming these limitations. Dretler compared the in vitro fragment entrapment capabilities of standard helical baskets with the Stone Cone [5]. He demonstrated that the Stone Cone was significantly more effective in collecting and extracting stone fragments than were standard baskets.

The Stone Cone has a 25 cm distal portion that substitutes for a guide wire, and its single step introduction, as a single assembly, decreases the amount of intraureteral manipulation [5]. Hence, the Stone Cone maintains continuous ureteral access and minimizes the use of disposables. It is easy to introduce, similar to the insertion of a standard guide wire. Also, it may be machined to whatever ureteral diameter is necessary, and after an appropriately sized Stone Cone is selected, there is no free space between the largest coil and the ureteral wall. Moreover, there is insufficient lateral wall tension to cause ureteral injury. It should be mentioned that as the space between two adjacent coils is < 2 mm, only fragments < 2 mm can potentially migrate proximal through the central hole [5]. A safety design characteristic of the Stone Cone is that coils may disengage from the stone or its fragments when there is an obstruction, and a excessive force of 0.127 pounds is exerted [5]. The straightened coils may be collapsed into the carrying sheath, which may again be advanced in order for the Stone Cone to be re-deployed. An additional safety component is that when traction is applied to the Stone Cone, the coils tend to rotate and separate the ureteral mucosa from the stone and unscrew it from narrow sites like the orifice [5]. At the end of the procedure, once the coil wire has been removed, a standard 0.038-inch wire may be advanced in order for a JJ stent to be easily inserted without losing ureteral access. The above mentioned advantages of the Stone Cone justify the statistically significant shorter operative time in comparison with the flat wire basket. Furthermore, these advantages might counterbalance the greater cost of the Stone Cone in terms of less analgesia, complications, auxiliary procedures, hospitalization and days off work.

The initial clinical trial of the Stone Cone was conducted by Desai et al., and to the best of our knowledge we are the first to clinically assess the safety and efficacy of the Stone Cone with electrohydraulic lithotripsy [8, 9]. In particular, Desai et al. compared the use of the Stone Cone in 23 patients with that of a flat wire basket in 20 patients; pneumatic lithotripsy was performed when necessary [8, 9]. Similarly, we compared the safety and efficacy of the Stone Cone with the flat wire basket, however, electrohydraulic lithotripsy was used. We recorded P values < 0.001 in terms of the number of proximal stone migrations, of residual fragments > 3 mm, and of the need for auxiliary procedures. In the Stone Cone group, no major complications were recorded. The contrary was true with the flat wire group. Eletrohydraulic and pneumatic lithotripsy do not damage the Stone Cone, however, the holdium laser, should not be positioned within the cone because it might melt and disrupt the wire. To date, no material has been identified that could protect the Stone Cone from the thermal effect of the holdium laser [5].

Collectively, the design of the Stone Cone, which allows working in non-dilated and dilated ureters, combined with its demonstrated fragment entrapment capability, and with the mechanism for the release of bulky fragments, along with the promising initial clinical experience, justifies its characterization as the ‘‘new generation of basketry’’ [10]. In terms of future perspectives, it would be interesting to evaluate the use of the Stone Cone with the nephroscope, with the objective of preventing stone migration from the kidney to the ureter. Recently, Smit et al. used the Stone Cone in order to prevent stone migration during percutaneous nephrolithotomy [11].

Conclusions

The Stone Cone was easily, safely, and efficiently used for preventing retrograde stone migration and for the extraction of stones and/or their fragments during ureteroscopy. It maintained continuous ureteral access and demonstrated a statistically significant advantage over the flat wire basket in terms of proximal stone migration, residual fragments > 3 mm, and the need for auxiliary procedures. Therefore, further clinical evaluation is suggested for this novel device in the armamentarium of endourology.

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