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Safety and efficacy of using the stone cone and an entrapment and extraction device in ureteroscopic lithotripsy for ureteric stones

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Stone cone;
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ABBREVIATIONS

URS, ureteroscopy;
MSL, maximum stone length

Abstract ***Objective:*** To assess the safety and efficacy of using a stone cone and an entrapment and extraction device (N-Trap®, Cook Urological, Bloomington, IN, USA) to avoid stone retropulsion during ureteroscopic lithotripsy for ureteric stones.

Patients and methods: This retrospective comparative study included 436 patients treated with ureteroscopic lithotripsy for a single ureteric stone from February 2011 to January 2014. The diagnosis of a stone was confirmed by plain spiral computed tomography in all cases. Patients were divided according to the ureteric occlusion device applied to avoid stone retropulsion during pneumatic lithotripsy into three groups; group 1 (156) had no instruments used, group 2 (140) in whom the stone cone was applied, and group 3 (140) in whom the N-Trap was used. Patient demographics, stone criteria, operative duration and complications, and success rates (complete stone disintegration with no upward migration) were reported and analysed statistically.

Results: The stone was in the lower ureter in > 55% of patients in all groups. The mean (SD) of maximum stone length was 9.8 (2.5), 10.4 (2.8) and 9.7 (2.9) in groups 1–3, respectively. The use of the stone cone or N-Trap did not significantly increase

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the operative duration ($P = 0.13$) or complication rates ($P = 0.67$). There was a statistically significant difference ($P < 0.001$) favouring groups 2 and 3 for retropulsion and success rates, being 83.3% in group 1, 97.1% in group 2 and 95.7% in group 3.

Conclusion: The stone cone and N-Trap gave high success rates in preventing stone retropulsion during ureteric pneumatic lithotripsy. Both devices caused no increase in operative duration or complications when used cautiously.

Introduction

Ureteroscopy (URS) remains a less-invasive approach with high patient tolerance, even with repeated procedures, and has fewer adverse effects than other methods of treating ureteric calculi. Retrograde URS is considered the first choice of procedure for treating ureteric calculi, as it has a success rate of >90%. Many technical advances in the ureteroscope manufacture and stone-retrieval instruments have led to a widespread acceptance and prevalence of endoscopic management for ureteric calculi [1]. The high success rate of ureteroscopic stone retrieval is attributed to the development of effective semi-rigid and flexible ureteroscopes, new grasping devices as well as pneumatic and laser lithotriptors [2]. There are some minor issues limiting the success of ureteroscopic stone manipulation, such as the possible upward migration or retropulsion of the stone, because of propulsion effect of the irrigant or, more frequently, due to application of kinetic energy used for stone disintegration. The reported retropulsion rate is 2–60% [1,3], and this wide variation in migration rate is mainly related to the site of the stone, because proximal ureteric stones have a higher retropulsion rate than those located distally in the ureter. As a solution to this retropulsion, instruments such as the stone cone (Boston Scientific, Natick, USA), and N-Trap® (Cook Urological, Bloomington, IN, USA) have been developed. The stone cone and N-Trap are ureteric occlusion devices designed to hinder the retropulsion of ureteric calculi and enable the safe extraction of stone fragments. In addition, the stone cone can substitute for the ureteric guidewire, thus maintaining continuous ureteric access and minimising the use of excess disposables [4,5]. Despite the low proximal migration rate with laser lithotripsy, its limited availability in developing countries led to our evaluation of these occlusive devices. Here we present our experience with the use of the stone cone and the N-Trap during the pneumatic lithotripsy of ureteric stones, and assess their safety and efficacy.

Patients and methods

We retrospectively reviewed our database for patients who underwent ureteroscopic stone removal from February 2011 to January 2014. In all, 521 patients had ureteroscopic removal of ureteric calculi. In 34 patients there were multiple ureteric stones and hence they were excluded from the study, whilst the stones of 51 patients were totally extracted by either forceps or a Dormia basket without using the lithotripsy machine, and these patients were also excluded from the study. Intracorporeal lithotripsy was required in the remaining 436 patients and pneumatic lithotripsy was used in all cases. According to the device which was used to prevent stone upward migration or retropulsion during lithotripsy, these patients were categorised into three groups; group 1 (156) had no additional instruments used for preventing stone retropulsion, in group 2 (140) the stone cone was used, and in group 3 (140) the N-Trap was applied. Non-contrast spiral CT was used to confirm the diagnosis and determine the exact location and size of the stone. Routine laboratory testing, urine analysis, culture and sensitivity of urine were assessed before surgery and an appropriate antibiotic was given when needed. All patients had received an intravenous prophylactic antibiotic 2 h before surgery. Under fluoroscopic control, the retrograde ureteroscopic approach was used in all cases, with a semi-rigid ureteroscope. The Swiss pneumatic lithoclast was used to disintegrate the stone. A ureteric stent was placed at the end of the procedure when indicated. Retropulsion was considered when the stone or fragments of $\geqslant 5$ mm migrated upwards and could not be reached by ureteroscopy. Success was defined as a safely completed procedure with no residual fragments or retropulsion, and no additional procedures, e.g., ESWL, being required. Residual stones or fragments were assessed 'on-table' by fluoroscopy and after surgery by a follow-up plain X-ray and noncontrast CT in all patients. Patient demographics, stone criteria, operative duration, perioperative complications and the success rate were reported and analysed statistically.

Data were checked, entered, and analysed using appropriate software. Data are expressed as the mean (SD) for quantitative variables, and number and/or percentage for qualitative variables. The chi-squared and anova tests were used when appropriate. In all tests, $P < 0.05$ was considered to indicate statistical significance.

Results

In all, 436 patients were included in the study (> 57% male), and the stone was in the lower ureter in > 55% of patients in all groups. The range of maximum stone length (MSL) was 6.7–13.1 mm, 6.8–13.5 mm and 6.4–13.3 mm in groups 1–3, respectively. There was a mild degree of hydro-ureteronephrosis in > 72% of the patients. Table 1 shows that there were no significant differences among the three groups in patient demographics and stone criteria. The mean (SD) operative duration in groups 1–3 was 58.6 (4.1), 57.9 (5.1) and 59.1 (4.8) min, respectively, with no statistically significant differences ($P = 0.13$). There was retropulsion of stone fragments of $\geqslant 5$ mm in 24 patients in group 1 and one patient in each of the other two groups, whilst the stone migrated back to the kidney during insertion of the ureteric occlusion device in two and three patients in groups 2 and 3, respectively ($P < 0.001$). There was a ureteric injury in 12 (7.7%), 13 (9.3%) and 15 (10.5%) patients in groups 1–3, respectively, which was not statistically significant ($P = 0.67$), most of which were mucosal lacerations, with ureteric perforation in two patients in each group. There was a statistically significant difference in the success rate ($P < 0.001$) favouring groups 2 and 3, being 83.3% in group 1, 96.7% in group 2 and 95.8% in group 3. A JJ stent was placed in 37.8%, 38.6% and 37.1% of groups 1–3, respectively. Table 1 also shows the operative duration, complication and success rates.

Discussion

URS and ESWL are the most common procedures used for treating ureteric stones, with better results for URS in cases of impacted stones [6]. URS is a minimally invasive intervention with high patient tolerance, even with repeated procedures, and has fewer adverse effects. Proximal or upward stone migration (retropulsion) during URS is a significant problem, especially during pneumatic lithotripsy, which has a back-pressure effect that frequently pushes the stones back into the kidney [7]. In a study using the Swiss lithoclast for fragmentation in 362 patients with ureteric calculi, Tunc et al. [3] reported a stone-free rate of 90% and the retropulsion rate was 5.5%. Similarly, in 500 patients, Sözen et al. [8] reported stone-free and migration rates of 95% and 2%, respectively. In the present study the retropulsion rate was 15.4% in the control group. The other two groups (stone cone and N-Trap) had significantly ($P < 0.001$) lower migration rates of 2.1% and 2.9%, respectively.

More than half of the retropulsed stones (16 of 31) were located in the upper ureter before surgery. Knispel et al. [9] stated that the retropulsion rate is related to the stone location, as proximal ureteric calculi migrate upwards more than distally located ones. They reported a 40% ureteric stone retropulsion rate from the upper ureter, vs. only 5% from the lower ureter. Robert et al. [10] reported a 48% upward migration rate from the proximal ureter when pneumatic intracorporeal lithotripsy was used. Laser lithotripsy is thought to cause a lower incidence of retropulsion. In a study on 208 cases of ureteric stones, with 55 of them in the proximal ureter, Gupta [11] reported only a 3.3% failure rate due to retropulsion during holmium laser lithotripsy.

Several reports recommended many different materials and devices for preventing retrograde stone displacement during ureteric lithotripsy, including lidocaine

Table 1 Patient demographics, stone criteria, operative duration, complications and success rates.

Mean (SD) or *n* (%) variable	Group (*n*)			*P*
	1 (156)	2 (140)	3 (140)	
Age (years)	34.5 (5.1)	36.0 (5.2)	35.2 (8.2)	0.11
Male	90 (57.7)	85 (60.7)	84 (60.0)	0.86
Female	66 (42.3)	55 (39.3)	56 (40.0)	
Right	73 (46.8)	71 (50.7)	75 (53.6)	0.50
Left	83 (53.2)	69 (49.3)	65 (46.4)	
Location:				0.93
Upper ureter	19 (12.2)	21 (15.0)	20 (14.3)	
Middle ureter	43 (27.6)	35 (25.0)	42 (30.0)	
Lower ureter	94 (60. 2)	84 (60.0)	78 (55.7)	
Degree of hydronephrosis:				0.86
Mild	115 (73.7)	101 (72.1)	105 (75.0)	
More than mild	41 (26.3)	39 (27.9)	35 (25.0)	
MSL (mm)	9.8 (2.5)	10.4 (2.8)	9.7 (2.9)	0.11
Operative duration (min)	58.6 (4.1)	57.9 (5.1)	59.1 (4.8)	0.13
Retropulsion	24 (15.4)	3 (2.1)	4 (2.9)	< 0.001
Ureteric injury	12 (7.7)	13 (9.3)	15 (10.7)	0.67
Ureteric perforation	2 (1.3)	2 (1.4)	2 (1.4)	0.99
Successful procedure	130 (83.3)	135 (97.1)	134 (95.7)	< 0.001

jelly, ureteric baskets, the stone cone and recently, thermophilic polymers [4,5,12–19]. The reported operative duration of ureteroscopy is 18–93 min [20]. The application of the stone cone or N-Trap did not significantly increase the operative duration in the present study ($P = 0.13$) as reported elsewhere [14,15,17].

Minor lesions of the ureter are the most frequent during ureteroscopy, with reported rates of 0–15.4% [21]. Most ureteric injuries in the present study were mucosal lacerations, with ureteric perforation in two patients in each group. Overall, there were ureteric injuries in 12 (7.7%), 13 (9.3%) and 15 (10.7%) patients in groups 1–3, respectively, with no statistically significant difference ($P = 0.67$) as reported by many studies examining the stone cone or N-Trap [5,14,16,17]. A JJ stent was placed if there were moderate or marked degrees of preoperative hydronephrosis, intraoperative ureteric injury or perforation, to ensure non-strictured healing of the ureter, and if there was retropulsion, until ESWL was used to complete the treatment of these patients.

Some authors reported that application of the stone cone and N-Trap was associated with a significantly shorter operation and a lower incidence of ureteric injury, as well as the need for stenting, than in a control group [19].

The definition of clinically significant residual fragments and stone-free status is reported differently in published articles, and this might lead to confusion in the interpretation of the results [22]. Desai et al. [15] compared the efficacy of the Dretler stone cone with that of a flat wire basket. In the stone cone group, 12% of 50 patients had residual fragments of > 3 mm, but none required any auxiliary procedures. In the flat wire basket group, there were residual stones of > 3 mm in 30% of 20 patients ($P < 0.001$) and auxiliary intervention was required in four of them ($P < 0.01$). Farahat et al. [19] compared the efficacy of the stone cone vs. the N-Trap and stated that patients in the stone cone group had a significantly lower incidence of stone retropulsion and subsequently success than those in the N-Trap and control groups. In the present study, we considered stones or fragments of $\geqslant 5$ mm as a failure if they migrated into the kidney or were left *in situ* (in case of ureteric perforation).

There was a significant difference ($P < 0.001$) in success rates among the three groups, favouring both the stone cone (97.1%) and N-Trap (95.7%) over the control (83.3%). The retrospective nature of this work and the absence of randomisation are considered as study limitations.

In conclusion, the stone cone and N-Trap gave high success rates in preventing stone retropulsion during ureteric pneumatic lithotripsy, especially for proximal ureteric stones. Both devices did not significantly increase the operative duration or complication rates when used cautiously.

Conflict of interest

None declared.

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None.

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