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Efficacy and Safety of NTrap® Stone Entrapment and Extraction Device for Ureteroscopic Lithotripsy

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ABSTRACT

Purpose: NTrap® stone entrapment and extraction device (NTrap®) is a device used to extract and remove stones from the urinary tract and to minimize retrograde stone migration during ureterolithotripsy (URS). This study aimed to evaluate the efficacy and safety of NTrap® in URS.

Methods: From Jan 2014 to June 2017, 148 patients underwent URS with the aid of NTrap® (Group A), and 209 patients underwent standard URS without any anti-retropulsion device (Group B). Their demographics, operation time, complications, stone migration rate, and stone-free rate (SFR) were recorded for comparison.

Results: Compared with group B, Group A had a significantly shorter operative time and lasering time (*P*=0.003, *P*=0.000, respectively). There was no significant difference between the 2 groups in overall complications, a decrease in mean hemoglobin, and length of stay (LOS) (*P* =0.426, *P* =0.097, *P* =0.058, respectively). The incidence of stone migration was significantly lower in Group A than Group B (*P*=0.035). The postoperative auxiliary procedure rate (in patients with stones retropulsion during the operation) was significantly lower in Group A compared to Group B (*P*=0.024). The SFR was considerably higher in Group A than Group B (*P*=0.009).

Conclusion: URS, with the aid of NTrap®, is an effective and safe method for treating ureteric stones. It may prevent stones from retropulsion and shorten the operative time.

INTRODUCTION

Retropulsion migration of stone fragments into the renal pelvis, calyces or both during ureterolithotripsy (URS) is a persistent problem that increases the chances of re-treatment or auxiliary procedures and subsequent cost. It is one of the challenges to deal with during ureteric stone management, especially proximal ureteric stones [1-3]. Migration of stone fragments is influenced by several factors such as the pressure of irrigation fluid, degree of proximal ureteral dilation, stone site, the degree of stone impaction, lithotripter type and experience of the surgeon [4]. An estimate of 5% to 40% of retropulsion of stone fragments occurs during intracorporeal lithotripsies [5]. However, some other studies reported that stone migration rate might reach up to 60% when patients undergo URS pneumatic lithotripsy (URS-PL) [6-8].

With the advancement in technology, several devices have been developed to prevent stone retropulsion and facilitate fragments extraction during URS [5,9-16]. These traverse from stone trap devices such as NTrap®, Stone Cone™, Accordion™ BackStop™, Escape™, and Lithocatch™ to suction devices (Lithovac™) and even balloon catheters (Passport™) [17-23]. The NTrap® is a relatively novel device designed to minimize retrograde migration of ureteral stones and enables extraction and removal urinary stone fragments plus other foreign bodies from the urinary tract during URS (laser, ultrasonic, electrohydraulic, or pneumatic lithotripsy). We performed this study to evaluate the safety and efficacy of NTrap® during holmium laser URS for the management of ureteral stones.

PATIENTS AND METHODS

Study population

From January 2014 to June 2017, patients diagnosed with ureteric stone were retrieved from the archives of Tongji Hospital of Huazhong University of Science and Technology. Patients were divided into 2 groups, Group A contained 148 patients undertaking holmium laser (Lumenis, USA) URSL and with the aid of NTrap® (Cook Urological, Bloomington, IN, USA), while Group B contained 209 patients undertaking the standard holmium laser URSL without the aid of any anti-retropulsion device. All patients were diagnosed with ureteral stones by computed tomography (CT) and intravenous urography (IVU). The demographic characters, including age, gender, BMI, stone size, stone location, stone laterality, and hydronephrosis severity were recorded. Routine blood examinations, urine analysis and culture, serum biochemistry, abdominal ultrasonography, CT, and IVU were evaluated.

The inclusion criteria were: patients with ureteric stones (as diagnosed and measured by multi-slice spiral CT and IVU) who undertook standard URS or URS with the aid of NTrap stone extractor; age ＞18 years. The Exclusion criteria: patients with ureteral stricture, ureteral stones combined with ipsilateral intrarenal stones, sepsis，age＜18 years, history of open surgery, congenital anomalies or pregnancy.

Surgical technique

NTrap® stone entrapment and extraction device consist of a 2.8-Fr flexible sheath 145-cm in length, a removable handle, and a 7 mm basket design. It is made from tightly woven nitinol wires with resilient shape memory characteristics that allow the basket to retain its shape after deployment.

All the procedures were performed in lithotomy position under general anesthesia using semirigid ureteroscopic (8F/9.8 F Wolf) combined with holmium laser (Lumenis, USA) to disintegrate the stones(24,25). In group A, the basket of NTrap® bypassed the stone to entrap stones in place for laser disintegration and prevent retropulsion migration of stone fragments into the renal pelvis. All fragments were extracted from the ureter under direct vision with the NTrap® and released into the bladder. If the stone was embedded inside the ureteric mucosa (polypoid or edema), laser polypectomy was done first to create a channel through which the NTrap® device was passed. In group B, laser lithotripsy was conducted to fragment stones into small pieces. Stone fragments were retrieved from the ureter with the help of ureteroscopic forceps. Surgery was concluded when no fragments remained in the whole ureter. Double-J stents were placed in those patients with ureteric injuries in either group.

Variables in observation were both clinical and surgical characteristics, which included lasering time, overall operative time, ureter stent insertion, intra- and post-operative complications according to Clavien–Dindo classification systems, and stone-free rates (SFR). Postoperative CT was performed after 6 weeks to evaluate the SFR. Ancillary procedures such as SWL, flexible URS were recorded. No residual stones or presence of any asymptomatic fragments ≤ 4 mm on CT at 6 weeks after the operation was considered as successful outcomes. Postoperative follow-up lasted for at least 3 to 6 months.

Statistical analysis

Statistical Package for the Social Sciences (SPSS) Version 16 was utilized for statistical analysis. Descriptive statistics were used to present the general data. The Chi-squared test and Fisher exact test were utilized to compare the differences between the 2 groups. A $P < 0.05$ was considered statistically significant.

RESULTS

Characteristics of all patients are summarized in ***Table 1***. Both groups had comparable preoperative parameters such as age, gender, BMI, stone size, stone location, stone laterality, degree of hydronephrosis, urinary tract infection (UTI) rate, and surgical history ($P > 0.05$; ***Table 1***).

Compared with group B, patients who underwent URS with the aid of NTrap (group A) had a significantly shorter operative time and lasering time (P=0.003, P=0.000, respectively) (***Table 2***). In group A, 2 patients suffered from postoperative fever and 2 from ureteric injury. In group B, 2 patients presented with hemorrhage, 3 with postoperative fever, and 4 with a ureteric injury. The overall complications in group A and group B were comparable (P =0.426; ***Table 2***). There was no significant difference between the 2 groups with regards to mean hemoglobin reduction and length of hospital stay (LOS) (P =0.097, P =0.058, respectively; ***Table 2***).

The instantaneous success rate of stone fragmentation during the operation was significantly higher in group A (only 5 patients with stone retropulsion) than in Group B (19 patients with stone migration into the pelvic or calyx). The incidence of stone migration was significantly lower in group A compared to group B (P=0.035; ***Table 2***). Regarding subsequent treatment, 1 patient in group A underwent SWL and 4 FURS while in group B, 4 patients underwent SWL and 16 FURS. The rate of requiring a postoperative auxiliary procedure was significantly lower in group A than group B (P=0.024; ***Table 2***).

No residual stones or the presence of asymptomatic fragments ≤ 4 mm on CT at 6 weeks after the operation was considered as a successful outcome. The SFR was 95.9% (142/148) and 88.0% (184/209) in group A and group B, respectively, with significant difference (P=0.009; ***Table 2***).

DISCUSSION

Both the American Urological Association (AUA) and the European Association of Urology (EAU) recommended URS as the first-choice treatment for ureteral stones > 10 mm. With the advancement of surgical technology, an increase in higher SFR and low morbidity have been achieved in URS (2,3,26,27). Lam et al. reported that URS had achieved higher SFR and lower complication rates analogous to those of SWL when managing large upper ureteric stones (2). Moreover, the miniaturization of ureteroscopy and improved intracorporeal lithotripsy technology have made it possible to successfully access and manage any stone within the ureter by relatively atraumatic fashions (28).

However, some limitations remain, including incomplete fragmentation, lack of stone extraction, and stone migration and residual fragments. Some studies reported that stone migration rate might reach as high as 60% after ureteroscopic lithotripsy (6,29,30) indicating that ureteral stone migration is one of the most significant challenges during URSL. Knispel et al. [7] reported that 40% and 5% of ureteric stone migrations occurred from the proximal and distal ureter, respectively during URS.

Stone retropulsion might increase operative time along with complication rate as a result of a change from semi-rigid to flexible ureteroscope[31]. Migrated stones might require an auxiliary procedure even after the surgical procedure [6,8,32]. Migration of stone fragments is influenced by many factors, which include pressure of irrigation fluid, stone location, degree of stone impaction, lithotripter, and experience of the surgeon [4].

Various strategies have been employed to obviate retrograde migration of stone fragments during intracorporeal lithotripsy. Fortunately, the new emerging occlusive instruments may primarily overcome this great existing dilemma. Amongst the commercially available novel devices (Accordion™, Stone Cone™, and NTrap®, etc.), Stone Cone™ has been reported to be highly effective in preventing stone retropulsion in several studies with 100% success rate during URS for proximal ureteral stones [19-22,33]. The Accordion™ device, on the other hand, is among the most recent development and now is under investigation in clinical trials [34]. There is, however, a limited number of studies concerning the effectiveness of NTrap® in endourological practice. The NTrap® stone occlusion device is also a relatively new ureteral occlusive device that prevents migration of stone fragments during URS. The NTrap® is composed of a tightly woven mesh of nitinol wires that mainly consists of the inner wire and the outer radio-opaque carrying catheter. The inner wire is a shape memory alloy that has a 7 mm sized umbrella designed basket. NTrap® device has 2.8 Fr diameter with a total length of 145 cm. Lee et al. reported the efficacy of the NTrap for managing ureteric stones with a 98.7% success rate [5]. Ouwenga et al. reported that the difference in strength for inner wire advancing was clinically insignificant between Stone Cone™ and NTrap® [35]. A meta-analysis demonstrated that NTrap® stone occlusion device was efficient in halting stone retropulsion during URSL for proximal ureteric stones [17]. Nevertheless, this meta-analysis included only included 3 studies with a small sample size. Therefore, occlusive devices represent a new generation of technology that can minimize proximal ureteric stone migration.

Our study demonstrated a significantly lower incidence of stone migration (*Table 2*) with the use of NTrap® device than without any anti-retropulsion device, especially for proximal ureteric stones. The NTrap® not only prevents stone migration but may also function as a useful tool for stone fragment extraction.

Economic efficiency can be another strong reason for choosing NTrap®, which can save time and cost by lowering the stone retropulsion rates. Stone retropulsion involves unnecessary procedures, for instance, prolonged operative time, rigid-flexible ureteroscope alteration, besides additional operations. Our study showed that patients who underwent URSL with the aid of NTrap® had a significantly shorter operative time and lasering time (***Table 2***). Furthermore, our study showed that the rate of requiring a postoperative ancillary procedure for the management of stone retropulsion was also significantly lower in NTrap group® (***Table 2***).

Although we have achieved promising results with the use of NTrap® device during URS, the limited sample size might have thwarted an ultimate conclusion in favor of NTrap® stone entrapment and extraction device. Therefore, prospective randomized control studies with larger sample sizes as well as multicenter trials are still necessary.

However, there were several limitations exist when analyzed and interpreting results in our study. The major limitation is that our study is a retrospective study, preoperative data evaluation is insufficient, selective bias and data heterogeneity may exist in our study. Secondly, the sample size in our study was relatively small that had limited impact on the outcomes. Some variables were influenced by the heterogeneities of patients' conditions, surgeon's surgical skills and the sample size of studies. Therefore, multicentre, larger sample size, randomized control studies are very necessary in the future.

CONCLUSIONS

The NTrap® Stone Entrapment and Extraction Device is an effective and safe tool for minimizing retrograde stone migration or stone retropulsion together with facilitating the extraction of stone fragments from the urinary tract during URSL.

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Ethical approval

The ethics committee approved the study, and all patients were informed about this study and a signed written consent were obtained.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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Table 1. Demographic characteristics and preoperative data

Variable	Group A (n=148)	Group B (n=209)	*P* value
Age, year	44.9±.0.8	42.5±14.2	0.084
Gender, n			0.280
Male	103	134	
Female	45	75	
BMI, kg/m^2	24.2±3.8	23.4±3.4	0.069
Stone laterality			0.188
Left	61	102	
Right	87	107	
Mean stone size, mm	16.0±3.2	16.7±3.6	0.081
Stone site			0.178
Proximal	132	176	
Distal	16	33	
Hydronephrosis			0.197
No or Mild	52	60	
Moderate or Severe	96	149	
Urinary infection	21	30	0.965
Positive urinary culture	6	11	0.597
Surgery history			
SWL	19	26	0.911
URS	12	18	0.866

Group A: URS with the aid of NTrap stone extractor; Group B: URS without any anti-retropulsion device; BMI: body mass index.
URS=

Table 2. Operative and postoperative data statistics

Variable	**Group A (n=148)**	**Group B (n=209)**	***P* value**
operative time, min	41.8±8.7	44.8±9.3	0.003
Mean lasering time, min	10.6±3.7	16.9±5.0	0.000
Mean hemoglobin reduced, g/dL	0.88±0.42	0.80±0.39	0.097
Stone migration rate (%)	5(3.4%)	19(9.1%)	0.035
Overall complications, n (%)	4	9	0.426
bleeding	0	2	
postoperative fever	2	3	
ureteric injury	2	4	
LOS	4.0±0.6	4.2±0.7	0.058
Ureter stent remove, d	30	30	
SFR at 6 weeks follow up	95.9% (142/148)	88.0% (184/209)	0.009
Auxiliary procedures	5	20	0.024
SWL	1	4	
Immediately FURS	4	16	

Group A: URS with the aid of NTrap stone extractor; Group B: URS without any anti-retropulsion device; LOS: length of hospital stay; SFR: stone-free rate; SWL: shockwave lithotripsy; FURS: flexible ureteroscope.