International Journal of Current Advanced Research
ISSN: O: 2319-6475, ISSN: P: 2319-6505, Impact Factor: 6.614
Available Online at www.journalijcar.org
Volume 7; Issue 9(D); September 2018; Page No. 15525-15528
DOI: http://dx.doi.org/10.24327/ijcar.2018.15528.2837

Research Article

EFFICACY OF URETEROSCOPIC MANAGEMENT OF PROXIMAL URETERIC CALCULUS USING STONE CONE ENTRAPMENT DEVICE – A PROSPECTIVE RANDOMIZED CONTROL STUDY

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A R T I C L E I N F O

Article History:

Received 13th June, 2018
Received in revised form 11th July, 2018
Accepted 8th August, 2018
Published online 28th September, 2018

Key words:

Proximal ureteric calculi, Stone Cone, Ureteroscopy, Retropulsion device, Lithotripsy

A B S T R A C T

Background: Endoscopic management of proximal ureteral calculus with new improved techniques have resulted in greater stone-free rates with low morbidity. However, problems remain preventing to achieve a 100% stone free rate with endoscopic management. One such problem is retrograde migration of proximal ureteric calculus during ureteroscopic lithotripsy. There are many retro-pulsion devices and maneuvers available and practiced nowadays. In this study we aim to assess the efficacy of stone cone in the ureteroscopic management of proximal ureteric calculus.

Methods: This is a prospective randomized control study conducted in the Department of Urology in Goverment K.A.P.viswanatham Medical College Hospital, Trichy during the period August 2016 - January 2018. 80 patients with proximal ureteric calculus who presented to our department were included in this study. Our patients were randomized into 2 groups with 40 patients in each group. In group 1, Ureteroscopic pneumatic lithotripsy of proximal ureteric calculus with the help of stone cone was done and in group 2, lithotripsy done without stone cone. Stone clearance rates were compared between the two groups and results were analysed.

Results: 80 patients with proximal ureteric calculus were randomly distributed into 2 groups. Group 1 included 40 patients who underwent ureteroscopic pneumatic lithotripsy with Stone Cone. The success rate in terms of complete stone clearance is 95% (38 out of 40) patients in the immediate postoperative period. Residual fragments up to 4 mm was noted in 2 cases. In Group 2 with 40 patients who underwent standard ureteroscopic pneumatic lithotripsy without stone cone were included. The stone clearance rate in this group is 70% (28 out of 40 patients) in the immediate postoperative period. 8 patients had stone migration into renal pelvis and 4 patients had residual fragments more than 4mm. Follow up after 1 month by KUB or spiral CT scan showed complete clearance of the stone in all 40 patients in the Stone Cone group. In group2, complete clearance of the stone occurred in 37 patients. Proximal stone migration was prevented in all patients in the stone cone group with 100% success rate versus without stone cone group (8 patients had stone migration into the kidney) with success rate of 80%. Success rate in terms of preventing stone migration showed Stone Cone group superior with a statistically significant difference ($p < 0.05$). Similarly, the stone-free rate in the Stone Cone group was 100% (40/40) *versus* 87.5% (35/40) in the other group in the one month follow up period.

Conclusion: Our study demonstrated superior proximal stone clearance rates when ureteroscopic lithotripsy was done with stone cone. It is also safe and efficient in preventing proximal stone migration. Hence it can be considered in managing upper ureteric calculus as an effective retropulsion device.

INTRODUCTION

Proximal fragment migration during ureteroscopic lithotripsy is a most common problem occurring in 5 to 40% of cases. The migrating stone fragments may necessitate additional procedures involving ureterorenoscopy with further fragmentation or extraction with retrieval devices, ureteral stenting, or secondary procedures such as shock wave lithotripsy and ureteroscopy. In addition, residual stone fragments may serve as a source of recurrent stone growth, persistent infection, and renal colic.The risk of upward migration is influenced by the pressure of the irrigant fluid, type of energy source used for intracorporeal lithotripsy, the site and degree of calculus impaction, and the degree of proximal ureteral dilation. Smaller stones and greater proximal

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ureteral dilation or hydroureteronephrosis increase the rate of stone migration.

Various strategies have been employed to prevent retrograde migration of stone fragments during ureterolithotripsy. Procedural modifications, such as placing the patient in the reverse Trendelenburg position and decreasing the irrigant pressure and flow rate, have been tried. Different stone-trapping devices have been created specifically to prevent retrograde stone migration and assist with fragment extraction. The Stone Cone is a device that aims to prevent proximal calculus migration and enable safe extraction of small calculi during ureteroscopic lithotripsy. In addition to these uses, it can be a substitute for a ureteral guide wire, thus maintaining continuous ureteral access.In this study we evaluated the efficacy of stone cone device during intracorporeal lithotripsy of upper ureteral calculi.

Aim of the Study

To assess the efficacy of Stone Cone device in preventing retrograde calculus migration and stone clearance in the ureteroscopic management of proximal ureteric calculus.

MATERIALS AND METHODS

This is aprospective randomized control study conducted in the Department of Urology in GoverntmentKilpauk Medical College Hospital, Kilpauk and Government Royapettah Hospital, Chennai during the period February 2017- January 2018. 80 patients with proximal ureteric calculus who presented to our department were included in this study. Sample size was calculated according to our convenience. Our patients were randomized into 2 groups with 40 patients in each group using computer generated random numbers table. In group 1,Ureteroscopic pneumatic lithotripsy of proximal ureteric calculus with the help of stone cone was done and in group 2, lithotripsy was done without stone cone. Stone clearance rates were compared between the two groups and results were analysed.

Patients between 20 to 50 years of age, with a single proximal ureteric calculus ranging between 8 to 20mm, who have consented for the study were included in this study. Patients with bleeding disorders, significant medical comorbidities precluding surgery or anesthesia, pregnancy, previous history of calculus disease on same side, ipsilateral endoscopic or open ureteric surgeries, any degree of ureteral stricture distal to the stone, stone impaction, clinical evidence of sepsis, coexistence of a renal calculus were excluded from the study were excluded from this study. All patients were preoperatively thoroughly evaluated and the location of the stone was confirmed by non-contrast computed urography (CT). All patients underwent ureteroscopy under general or regional anaesthesia using 8.5 Fr semi-rigid (Storz) ureteroscope.

In group 1, Stone Cone, using 3 Fr with a coil size of 10 mm, was inserted cystoscopically under fluoroscopic guidance for ureteral occlusion to bypass the stone. After the tip of the carrying catheter was passed above the stone into the proximal ureter, the device was then activated and pulled back to fit over the stone.The device was used only as a backstop, not to extract the fragments. Then URS and fragmentation of the stone using pneumatic lithotripsy were performed. When the stone was fragmented, the device was pulled under vision to extract the fragments. A double J stent was inserted over the guide wire.

The rate of retrograde stone migration during ureteroscopic lithotripsy procedures and the stone-free rate using the Stone Cone device *versus* without stone cone device were the primary and the secondary study outcome, respectively. The procedure was considered successful in either group if no proximal stone migration occurred, if the stone was fragmented completely (approximately 2–3 mm particles), and if the calculus subsequently was seen to be cleared on follow-up radiographs. Postoperative KUB was performed on the next morning (24 hours the procedure). Patients were discharged and returned back after 1 month from the procedure for follow-up KUB or spiral CT scan, and for removal of the double J stent.

Follow-up of the patients was performed with X-ray film of the urinary tract (KUB) after 24 hours to exclude stone migration and assess the clearance of stones. Another was performed after 1 week.All cases of migration were treated with adjunctive extracorporeal shock wave lithotripsy (ESWL). The main outcome we analysed in this study is the stone clearance rate in either groups.

Results on categorical measurements are presented in percentage. Chi-square test has been used to find the significance of study parameters on categorical scale between two groups. Student ‘t’ test has been used to determine the significance between two group means. All analyses were two tailed and $p < 0.05$ was considered significant. SPSS version 16.0 was used for data analysis.

RESULTS & ANALYSIS

80 patients with proximal ureteric stones were randomly distributed into 2 groups. Group 1 included 40 patients who underwentureteroscopic pneumatic lithotripsy with Stone Cone. The success rate in terms of complete stone clearance is 95% (38 out of 40) patients in the immediate postoperative period. There were no cases of stone migration. Residual fragments up to 5 mm was noted in 2 cases and medical expulsion therapy was given for these patients. No significant complications were noted in this study group. Operative time was 30 to 55 minutes (mean, 41.8 ± 5.3). All patients were discharged on POD 2 without any complications.

In Group 2 with 40 patients who underwent standard ureteroscopic pneumatic lithotripsy without stone conewere included. The stone clearance rate in this group is 70% (28 out of 40 patients) in the immediate postoperative period. 8 patients had stone migration into renal pelvis and 4 patients had residual fragments more than 5mm. Hematuria occurred in 4 cases, which cleared few days postoperatively. Other than that no significant complications were noted in this group too. The operative time was 30 to 40 minutes with average of 35 minutes. The average hospital stay was 36 hours in this group.

Table 1

Immediate Postoperative Period	Stone Cone Group	Non-Stone Cone Group
Number of Stone Migrations	0	8
Complete Stone Clearance	38 (95%)	28 (70%)
Significant Residual Fragments	0	2
Clinically Insignificant Residual Fragments	2	2

Follow up after 1 month by KUB or spiral CT scan showed complete clearance of the stone in all 40 patients in the Stone Cone group. In group2, complete clearance of the stone occurred in 37 patients. 8 patients with stone migration were subjected for ESWL and 7 achieved stone clearance and one patient had clinically significant residual fragment. Whereas out of the 4 patients with residual fragments 2 patients had a clinically significant residual fragment requiring intervention and 2 patients had clinically insignificant residual fragments.

Table 2

Follow Up After 1 Month	Stone Cone Group	Non-stone cone group
Complete Stone Clearance	40 (100%)	35 (87.5%)
Significant Residual Fragments	0	3
Clinically Insignificant Residual Fragments	2	2

DISCUSSION

URS of ureteral stones has become more common in the last 10 to 15 years. It has become more practical and tolerable, and with higher success results. URS has become the standard procedure in the management of ureteral stones, especially with a combination of auxiliary procedures. Advances in endoscopic equipment has increased the indications of URS, so that proximally ureteric stones can be managed successfully, in addition to distal and mid-ureteric stones.Some studies have shown that pneumatic lithotripsy is well-tolerated and cost effective, and it has a stone clearance rate of up to 85%.

The use of Stone Cone with URS in our study increased the success rate up to 95% and prevents stone migration with no significant complications. Our results were comparable to previous studies. Stone Cone is an instrument used during ureteroscopic lithotripsy for proximal ureteric calculi. It can be considered a very effective instrument that blocks the upward movement of ureteric stones and aids in safe stone removal.
Pneumatic and electrohydraulic lithotrites cause more retrograde propulsion of the ureteral stones than holmium:YAG laser and ultrasonic lithotrites. Proximal stone migration is more likely with smaller stones, and greater proximal ureteral dilation or hydronephrosis.Retrograde stone migration results in a longer operating time, more invasive endoscopy, and an increase in residual stones and the need for secondary procedures, leading to higher morbidity, and greater expense. To prevent stone migration, surgeons have traditionally used a number of maneuvers, including reverse Trendelenburg position, to optimize the effects of gravity and decreased irrigation pressure and flow rate. These techniques, however, compromise surgeon comfort and visibility and can therefore also prolong procedures.

In centers such as ours that primarily use pneumatic lithotriptors and have limited access to flexible ureteroscopes, antiretropulsion devices are critical to the success of the operation.Numerous devices have been employed to reduce the incidence of proximal stone migration during ureteroscopy including the use of ureteral baskets, Lithocatch, Lithovac, passport balloon, parachute, entrapment net (N Trap), Accordion, BackStop and the Stone Cone.

The entrapment net (N Trap) is a relatively new ureteral occlusion device that is considered to be a reliable efficient mean for prevention of stone migration. It has a safety release to help prevent larger stones from being trapped within the basket. An *in vitro* report suggested equal efficacy with both Accordion and the Stone Cone but there are no sufficient reports discussing its safety and efficacy [Ahmed *et al.* 2009; Holley *et al.* 2005].

The Escape nitinol retrieval basket is a 1.9 Fr, zero-tip, four-wire stone retrieval basket. The benefit of the Escape basket over the Stone Cone and N Trap is the use of the device through the working channel of the ureteroscope [Vejdani *et al.* 2009].

BackStop is a water-soluble biocompatible polymer with reverse thermosensitive properties. It exists as a liquid at temperatures below 16°C and as a soft but injectable gel at room temperature, and then transitions to a viscous gel at body temperature. BackStop is dispensed above the stone, and forms a gel plug that conforms to the ureter and prevents the stone(s) from migrating up the ureter and potentially into the kidney. On completion of stone fragmentation and extraction BackStop is dissolved by conventional saline irrigation [Rane *et al.* 2010b].

The Stone Cone showed ease of placement, safety and efficacy for preventing retrograde stone migration without apparent ureteral damage. In our study, the Stone Cone device prevented proximal stone migration in all patients, giving a 100% success rate. The Stone Cone was easily deployed, and all stones were fragmented into small particles without proximal migration.

Similarly, Desai and colleagues used the Stone Cone in 50 consecutive cases of upper and lower ureteral calculi with 100% success, and no need for auxiliary procedures [Desai *et al*. 2009]. Also, Maislos and colleagues used the device with 100% success in 19 consecutive patients with upper ureteral stones, and concluded that it reduced morbidity and saved time and money [Maislos *et al*. 2004].

In a prospective, comparative study of 56 patients, Paradalidis and colleagues achieved a significantly higher stone-free rate using the Stone Cone compared with a flat wire basket, they also concluded that the Stone Cone was safe and effective [Paradalidis *et al*. 2005].

Ali and colleagues proposed a new method to prevent retrograde displacement of ureteral stones during lithotripsy using lidocaine jelly [Ali *et al*. 2004]. They passed a 6 Fr ureteral stent beyond the stone through an 8 Fr ureteroscope and instilled 1 to 2 ml of lubricating jelly before applying kinetic energy. They treated seven patients with this method. In all seven patients, stone displacement was prevented and fragmentation was satisfactorily performed.They suggested that lubricating jelly instillation proximal to the ureteral stone during lithotripsy is an effective method of preventing retrograde stone displacement.

In our study, we compared the success rate of treating proximal ureteric calculi with and without stone cone device. The two groups of patients were comparable with regard to most of the preoperative parameters, with no significant difference. Proximal stone migration was prevented in all patients in the stone cone group with 100% success rate versus without stone group (8 patients had stone migration into the kidney) with success rate of 80%. Success rate in terms ofpreventing stone migration showed Stone Cone group superior with a statistically significant difference

($p < 0.05$).Similarly, the stone-free rate in the Stone Cone group was 100% (40/40) *versus* 87.5% (35/40) in the other group in the one month follow up period.

The differences between the groups were in stone migration rate and stone-free rate. This difference was in favor of the Stone Cone group which showed no proximal stone migration and higher stone-free rate and these differences were significant. This gives a privilege to the Stone Cone which is preferred as an efficient device for prevention of stone migration.

CONCLUSION

The Stone Cone is safe and efficient in preventing proximal stone migration during ureteroscopic pneumatic lithotripsy. It maintained continuous ureteral access and demonstrated a statistically significant advantage terms of proximal stone migration and stone-free rate and the need for auxiliary procedures.We recommend the ureteroscopic management of proximal ureteric calculi using Stone Cone and pneumatic lithotripsy.

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