A comparison of Stone Cone *versus* lidocaine jelly in the prevention of ureteral stone migration during ureteroscopic lithotripsy

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Abstract:

Background: Intracorporeal lithotripsy modalities and stone removal devices have been created to facilitate endoscopic management of ureteral stones. These devices, along with improved techniques, have resulted in stone-free rates greater than 95% with low morbidity. However, problems remain that preclude consistent 100% stone-free rates with endoscopic treatment of ureteral calculi. Retrograde migration during ureteroscopic procedures remains a significant problem.

Objectives: The aim of this study was to compare the Stone Cone device and instillation of lubricating lidocaine jelly as two methods to prevent retrograde stone migration during ureteroscopic lithotripsy.

Patients and methods: This study included patients suffering from ureteral stones that were treated with intracorporeal lithotripsy using the pneumatic Lithoclast. These patients were divided into two groups. In group I, the Stone Cone device was used, while in group II, lidocaine jelly 2% concentration was used.

Results: This study included 40 patients with a mean age of 38.6 ± 9.3 years (20 patients in each group). There was no significant difference between the groups with regards to stone site, size or state of the upper urinary tract by excretory urography. The pneumatic Lithoclast allowed successful fragmentation of all calculi into small fragments. Upward stone migration did not occur in patients in the Stone Cone group, while in the lidocaine jelly group it occurred in three patients (15%). The operative time in the Stone Cone group ranged between 30 and 55 minutes (mean, 41.8 ± 5.3), while in the lidocaine jelly group it ranged between 40 and 71 minutes (mean, 51.4 ± 3.4), and this difference was statistically significant ($p < 0.05$).

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 over the lidocaine jelly in terms of proximal stone migration, operative time, and the need for auxiliary procedures.

Keywords: Stone Cone, lidocaine Jelly, ureteroscopy and lithotripsy

Introduction

The management of ureteral calculi has changed considerably over the past decade with the advent of progressively smaller ureteroscopes and more efficient lithotripsy modalities. These changes have allowed urologists to remove ureteral calculi more safely and with a higher rate of success [Lam *et al.* 2002].

Proximal fragment migration during ureteroscopic lithotripsy is a common problem as

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 [Chow *et al.* 2001; Delvecchio and Preminger, 2000]. In addition, residual stone fragments may serve as a source of recurrent stone growth, persistent infection, and renal colic [Delvecchio *et al.* 2000].

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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 [Dretler, 2000]. Different stone-trapping devices have been created specifically to prevent retrograde stone migration and assist with fragment extraction [Durano and Hanosh, 1988].

The Dretler 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, the Dretler Stone Cone can be a substitute for a ureteral guide wire, thus maintaining continuous ureteral access [Dretler, 2001].

Lubricating lidocaine jelly instillation proximal to the ureteral calculi before applying the kinetic energy has been proven to be an effective method to prevent retrograde stone displacement during intracorporeal lithotripsy [Mohseni *et al.* 2006]. The aim of this study was to compare between the Stone Cone device and instillation of lubricating lidocaine jelly as methods to prevent retrograde stone migration during ureteroscopic lithotripsy.

Patients and methods

This prospective, randomized study was performed in the Urology Department, Tanta University Hospital, during the period between January 2010 and October 2010. A total of 40 patients suffering from ureteral stone disease were included in this study. The patients included in this study were adult patients ≥ 18 years old with radiological evidence of ureteral stone (6–20 mm) on plain X-ray film of the kidneys, ureter, and bladder (KUB) or spiral CT scan.

These patients were randomly divided into two groups, each group containing 20 patients. In the first group the Stone Cone device was used while in the second group, lidocaine jelly was used to prevent proximal stone migration during ureteroscopic lithotripsy. The randomization list was concealed from the investigators during this study to avoid selection bias as subjects were enrolled.

The rate of retrograde stone migration during ureteroscopic lithotripsy procedures and the

stone-free rate using the Stone Cone device *versus* instillation of lubricating lidocaine jelly were the primary and the secondary study outcome, respectively.

Patients with the presence of any degree of ureteral stricture distal to the stone, stone impaction, clinical evidence of sepsis, coexistence of a kidney stone on KUB or ultrasound or with occurrence of ureteral perforation during the procedure were excluded from the study.

All patients in this study were radiologically examined with KUB, excretory urography (IVU) and spiral CT scan when indicated.

All patients in this study had solitary ureteral stone. The site of the stone was in the proximal ureter in six patients (15%), midureter in four patients (10%), and in the distal ureter in 30 patients (75%) as shown in Table 1.

The ureteroscope used in this study was semi-rigid ureteroscope 'Karl Storz' 9.5 Fr with a 5 Fr working channel using pressure bag irrigation. Stone Cone (Boston Scientific Corp, Natick, MA) with 7 mm diameter, lidocaine jelly 2% concentration (water soluble) and Pneumatic Swiss Lithoclast were used during this study.

Technique

Group 1 (Stone Cone group). After placing a safety guide wire and once the stone was visually identified in the ureter, the collapsed Stone Cone was passed through the working channel until the black lines proximal to the cone were behind the calculus. The cone was then released and brought caudally to rest against the stone. The device was used only as a backstop, not to extract the fragments. The ureteroscope was reintroduced again into the ureter beside the Stone Cone and advanced to the level of the stone. Now, the probe of the Swiss Lithoclast was advanced through the working channel of the semirigid ureteroscope and applied over the stone under direct vision where it was fired and the process was continued until the stone was too fragmented. After complete fragmentation of the stone into small particles (approximately 2–3 mm particles), the probe of the pneumatic Lithoclast was removed from the working channel, and a double J stent was advanced into the ureter over the guide wire after removal of the collapsed Stone Cone from the ureter.

Table 1. Preoperative criteria in both groups.

	Stone Cone group	Lidocaine jelly group	Total
• Site of stone:			
- Proximal ureter	2 (10%)	4 (20%)	6 (15%)
- Midureter	2 (10%)	2 (10%)	4 (10%)
- Distal ureter	16 (80%)	14 (70%)	30 (75%)
• Stone size:			
- Proximal ureter	Range: 8–20 Mean $\pm$ SD 14.0 $\pm$ 0.1	Range: 9–18 Mean $\pm$ SD 13.5 $\pm$ 0.5	
- Midureter	Range: 9–16 Mean $\pm$ SD 12.1 $\pm$ 0.3	Range: 7–18 Mean $\pm$ SD 12.6 $\pm$ 0.7	
- Distal ureter	Range: 6–14 Mean $\pm$ SD 10.8 $\pm$ 0.9	Range: 7–16 Mean $\pm$ SD 11.9 $\pm$ 0.8	
• State of kidney			
- No hydronephrosis	5 (25%)	3 (15%)	8 (20%)
- Mild hydronephrosis	10 (50%)	12 (60%)	22 (55%)
- Moderate hydronephrosis	5 (25%)	5 (25%)	10 (25%)

-75% of stones were in the lower ureter. There was no significant difference between the two groups as regard the stone location.

-The stone size ranged from 6 to 20 mm in the Stone Cone group and from 7 to 18 mm in the lidocaine jelly group. There was no significant difference between the two groups with regards to stone size, $p > 0.05$.

-There was no significant difference between both groups with regards to the state of the upper urinary tract by excretory urography.

Group II (lidocaine jelly group). After placing a guide wire and reaching the stone with the semi-rigid ureteroscope, an open end ureteral catheter (5 Fr) was advanced through the working channel, until it reached beyond the stone, and 2 ml of 2% lidocaine jelly was instilled in the ureteral lumen proximal to the stone using a 5 ml syringe. After instillation of the lidocaine jelly, the ureteral catheter was withdrawn, and the probe of the pneumatic Lithoclast was advanced through the working channel to start the process of stone fragmentation.

After the stone had been fragmented to the same particle size as the Stone Cone group, the stone fragments were left in place and the remaining amount of lidocaine jelly was washed out with saline irrigation. A double J stent was inserted over the guide wire.

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.

Stone migration was defined as proximal or upward stone migration to the kidney as determined by postoperative KUB or spiral CT scan. KUB was used as the imaging standardized test except in only four cases with radiolucent stones (three cases in the Stone Cone group and one case in the lidocaine jelly group) where spiral CT was used (its limited use was due to its high cost). Migration was determined from the day 1 KUB, and the stone-free rate from KUB or spiral CT scan at 1 month postoperatively. All cases of migration were treated with adjunctive extracorporeal shock wave lithotripsy (ESWL).

Statistical analysis

Statistical analysis of data was performed with the SPSS (Statistical Package for the Social Sciences, Inc., Chicago, IL) for Windows, version 11.0 by using Student's *t*-test and chi-square test. Type I error was set at $\alpha = 0.05$ and $p < 0.05$ was considered statistically significant.

Results

This study included 40 adult patients, suffering from ureteral stone disease at different sites of the ureter, documented by radiological studies.

There were 28 males (70%) and 12 females (30%) with ages ranging from 21 to 68 years (mean, 38.6 ± 9.3).

The size of stones was ranged from 6 to 20 mm, with a mean stone size of 12.6 ± 0.8 mm. In proximal ureter, the stone size was ranged from 8 to 20 mm (mean, 13.9 ± 0.4). In the midureter, the stone size was ranged from 7 to 18 mm (mean, 12.6 ± 0.8) while in the distal ureter the stone size was ranged from 6 to 16 mm (mean, 11.9 ± 0.7), as shown in Table 1.

The state of the renal dilatation showed normal pelvicalyceal system in 8 patients (20%), mild hydronephrosis in 22 patients (55%) and moderate hydronephrosis in 10 patients (25%). No patient in this study had severe hydronephrosis, as shown in Table 1.

The pneumatic Lithoclast allowed successful fragmentation of all calculi into small fragments. Upward stone migration did not occur in any patient of the stone cone group, while in the lidocaine jelly group it occurred in three patients (15%). Two of these patients had proximal ureteral stones with moderate hydronephrosis, while the third patient had midureteral stone with mild hydronephrosis, as shown in Table 2.

The operative time in the Stone Cone group ranged from 30 to 55 minutes (mean, 41.8 ± 5.3), while in the lidocaine jelly group it was ranged from 40 to 71 minutes (mean, 51.4 ± 3), and this difference was statistically significant ($p < 0.05$) as shown in Table 3.

Follow up after 1 month by KUB or spiral CT scan showed complete clearance of the stone in 19 patients in the Stone Cone group, one patient had a clinically insignificant stone fragment (≤ 3 mm). In the lidocaine jelly group, complete clearance of the stone occurred in 16 patients while one patient had a clinically insignificant residual fragment, and no patient had clinically significant residual fragment in both groups, as shown in Table 2.

In the Stone Cone group, hospital stay was ranged from 1 to 4 days (mean, 1.7 ± 0.3) and the patients returned to normal daily activities after 2–6 days (mean, 3.3 ± 0.7). In the lidocaine jelly group, hospital stay was ranged from 1 to 5 days (mean, 1.9 ± 0.1) and the patients returned

to normal daily activities after 2–5 days (mean, 3.1 ± 0.4), as shown in Table 3.

Mild bleeding occurred during or after fragmentation of the stone in 12 patients (30%). Postoperative complications included mild hematuria in 24 patients (13 in the Stone Cone group and 11 in the lidocaine jelly group) which lasted for 24–48 hours postoperatively and resolved conservatively with high fluid intake and diuretics. Renal pain or colic occurred in 28 patients (15 in the stone cone group and 13 in the lidocaine jelly group), which could be attributed to transient obstruction from blood clot or edema.

Discussion

Intracorporeal lithotripsy modalities and stone removal devices have been created to facilitate the endoscopic management of ureteral stones. These devices, along with improved technique, have resulted in stone-free rates often greater than 95% with low morbidity. However, problems remain that preclude consistent 100% stone-free rates with endoscopic treatment of ureteral calculi [Lam *et al.* 2002].

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 [Knispel *et al.* 1998].

The risk of proximal fragment migration is influenced by the pressure of the irrigant fluid, type of energy source used for intracorporeal lithotripsy, site and degree of calculus impaction, and degree of proximal ureteral dilatation [Hendlin *et al.* 2008; Lee *et al.* 2003].

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 [Delvecchio *et al.* 2000].

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

Table 2. Upward stone or fragment migration and stone clearance in both groups.

	Stone Cone group	Lidocaine jelly group
• Number of stone migrations	0.0	3/20 (15%)
• Stone clearance		
- Complete stone clearance	19 (95%)	16 (80%)
- Clinically insignificant residual fragments (≤ 3 mm)	1 (5%)	1 (5%)
- Total	20 (100%)	17 (85%)
There was significant difference between both groups as regards proximal stone migration. ($p < 0.05$).		

Table 3. Hospital stay and convalescence in both groups.

	Stone Cone group	Lidocaine jelly group	<i>p</i> -value
● Operative time (min):			
- Range	30 – 55	40–71	Significant
- Mean ± SD	41.8 ± 5.3	51.4 ± 3.8	
● Hospital stay			
- Range	1–4	1–5	Not significant
- Mean ± SD	1.7 ± 0.3	1.9 ± 0.1	
● Return to activity			
- Range	2–6	2–5	Not significant
- Mean ± SD	3.3 ± 0.7	3.1 ± 0.4	
There was significant difference between the groups with regards to the operative time.			

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 [Mirabile *et al.* 2008; Knispel *et al.* 1998; Robert *et al.* 1994].

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 [Rane *et al.* 2010a].

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 [Pardalidis *et al.* 2005].

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.

On the other hand, Mohseni and colleagues used 9.8 Fr ureteroscope with lidocaine jelly (2 ml of 2% concentration) instilled through a 5 Fr ureteral catheter through the ureteroscope working channel with a cut tip proximal to the stone to prevent retrograde stone displacement during pneumatic lithotripsy [Mohseni *et al.* 2006]. This modification by using the 5 Fr catheter enabled them to place the catheter under direct vision. They used lidocaine jelly in 16 patients and upward stone or fragment migration to the kidney occurred in two patients giving a success rate of 87.5%. However, its effect on the stone-free rate was not significant in that study.

They suggested that lubricating jelly instillation proximal to the ureteral stone during lithotripsy is

an effective method of preventing retrograde stone displacement.

Similarly, in the lidocaine jelly group in our study, we used a 8 Fr ureteroscope and a 5 Fr open-ended ureteral catheter instead of 6 Fr catheter to instill the jelly under direct vision through the working channel of the ureteroscope that has a single 5 Fr working channel, and so obviating the need of fluoroscopic guidance with its difficulty for radiolucent stones.

Proximal stone migration was prevented in 17 of 20 patients, giving 85% success rate. The procedure was terminated in three patients by insertion of a DJ stent, and they were treated later on by ESWL.

In contrast, Zehri and colleagues instilled 2 ml of 2% concentration jelly through a 6 Fr ureteral catheter in the ureteral lumen proximal to the stone [Zehri *et al.* 2008]. They used this method in 25 patients and retrograde stone migration to the kidney occurred in one patient (4%) compared with (28%) in the control group giving a success rate of 96%.

Previous studies on using lidocaine jelly for prevention of proximal calculus migration did not report a longer operative time as they used a 6 Fr ureteral catheter for instillation of the jelly [Maislos *et al.* 2004]. In our study the semirigid ureteroscope used throughout the whole study had a single 5 Fr working channel, so we were obliged to instill the jelly through a 5 Fr ureteral catheter to perform the procedure under direct vision which resulted in a longer operative time. Also, washing out the remaining jelly with saline irrigation after completion of the procedure adds to the operative time.

Instillation of the jelly has the potential to impair visibility during ureteroscopy [Zehri *et al.* 2008; Ali *et al.* 2004]. However, we did not experience this problem in our study.

In our study, we compared two methods for prevention of proximal stone migration during ureteroscopic lithotripsy, the Stone Cone device and the lidocaine jelly injected proximal to the stone. The two therapeutic groups were comparable with regard to most of the preoperative parameters, with no significant difference. Proximal stone migration was prevented in 17 of 20 patients in the lidocaine jelly group giving 85%

success rate *versus* 100% success rate in Stone Cone group with a statistically significant difference ($p < 0.05$).

Similarly, the stone-free rate in the Stone Cone group was 100% (20/20) *versus* 85% (17/20) in the lidocaine jelly group.

The mean operative time was longer in the lidocaine jelly group compared with the Stone Cone group (51.4 ± 3.8 *versus* 41.8 ± 5.3) and this difference was statistically significant ($p < 0.05$). This is due to the additional time taken during instillation of the viscous lidocaine jelly through a 5 Fr ureteral catheter using a narrow needle that needs time and force to propel the jelly along the catheter. The time taken for instillation of lidocaine jelly above the stone was about 10 minutes on average.

However, the use of lidocaine jelly to prevent proximal stone migration does not add to the cost of the procedure in contrast to the use of the Stone Cone device.

The differences between the groups were in stone migration rate, stone-free rate, and the operative time. This difference was in favor of the Stone Cone group which showed no proximal stone migration, higher stone-free rate, shorter operative time, 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 over the lidocaine jelly in terms of proximal stone migration, stone-free rate, operative time, and the need for auxiliary procedures.

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Conflict of interest statement

The authors declare that there was no conflicts of interest in preparing this article.

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