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Evaluating the Efficacy of Ureteroscopic Management of Proximal Ureteric Calculi using Stone Cone Entrapment Device

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ABSTRACT

Background: The patient has higher morbidity and financial burden due to the migration of stone particles during lithotripsy. These pieces may need to be recovered using a number of extra steps. These include ureteric stenting, further fragmentation, the necessity for specialized retrieval equipment, flexible ureterorenoscopy, and, in certain situations, extracorporeal shock wave lithotripsy (SWL).
Objectives: To compare the stone clearance rate of ureterorenoscopic (URS) pneumatic lithotripsy with and without stone cone in proximal ureteric stone.
Materials and Methods: There were 94 patients, aged 20 to 60, of both genders, who were having URS lithotripsy and had a single 7–15 mm proximal ureteric stone. Individuals with a single kidney, urinary tract congenital abnormalities, pyonephrosis, and sepsis were not included. The patients were split into two groups at random using the lottery method. Group A underwent URS lithotripsy using a stone cone, whereas Group B underwent URS lithotripsy without a stone cone. A lone surgeon carried out every operation. For 48 hours, the patients were monitored and stone clearance (stone free status as shown on ultrasound scan and X-Ray KUB at 48 hours after the procedure) was recorded.
Results: Patients in groups A and B had mean ages of 36.72 ± 9.64 and 36.89 ± 9.93 years, respectively. The majority of the 65 patients (69.15%) ranged in age from 40 to 120. Of these 94 patients, the ratio was 1.8:1, with 57 (60.64%) being male and 37 (39.36%) being female. 33 (70.21%) patients in group B (URS without stone cone device) and 44 (93.62%) patients in group A (URS with stone cone device) had a stone clearance rate with a p-value of 0.003.
Conclusion: This study concluded that stone clearance rate is significantly higher using stone cone device.
Keywords: Lithotripsy, Proximal, Stone cone device, Ureterorenoscopy, Ureteric stone.

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INTRODUCTION

Urological problems involving the calculus urinaricum are frequent. Information on ureteric stone cases that have been identified or treated is lacking. The best course of action for treating ureteral calculi is a contentious matter.[1] The conservative ways of handling ureteric stones have been superseded by endoscopic removal, laparoscopic surgery, open surgery, minimally invasive surgery, and extracorporeal shock wave lithotripsy.[2,3]

When studying unusual imaging findings, evaluating blockage or unilateral essential hematuria, or identifying the cause of positive urine cytology results, ureteroscopy is utilised as a diagnostic technique. Ureterotomy has expanded its therapeutic applications to encompass a range of less invasive treatments. Modern ureteroscopic procedures enable the following current treatments: stricture incisions, ureteropelvic junction blockage repair, therapy of upper urinary tract urothelial cancers, and endoscopic lithotripsy (treating stones).[4]

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The success rates and safety of invasive ureteric operations have significantly risen with the invention of semi-rigid and flexible ureteroscopy. Many equipment for intracorporeal lithotripter have been developed to increase the efficiency of stone fragmentation.[2] The appropriate course of treatment for ureteral stones—especially large proximal stones—remains up for dispute despite these developments. The 2007 AUA/EAU guidelines for the treatment of ureteral calculi state that patients should be informed that ureteroscopic stone removal (URS) is associated with a greater likelihood of being stone-free following a single procedure.[3]

When lithotripsy is performed, the patient's morbidity and financial burden are raised due to the migration of stone particles.[4] These pieces may need to be recovered using a number of extra steps. These include ureteric stenting, further fragmentation, the necessity for specialised retrieval equipment, flexible ureterorenoscopy, andextracorporeal shock wave lithotripsy (SWL) under specific circumstances.[5] In addition, these fragments may induce colic or act as a nidus for infection or growth. Several devices have been developed to aid in the extraction of ureteric calculi and to halt their retrograde migration during lithotripsy.

These gadgets are not flawless, though; each has a unique set of limitations and success rates.[6,7] During

ureteroscopic lithotripsy, the Stone Cone is a tool designed to safely extract tiny calculi and stop proximal calculus migration.[7]

Apart from these applications, the Stone Cone can serve as an alternative to a ureteral guide wire, ensuring uninterrupted ureteral access.[8] In one research, the post-operative clearance rate following pneumatic lithotripsy without a stone cone was 70.0%, but the clearance rate following pneumatic lithotripsy with a stone cone was 95.0%, with a statistically significant p-value of less than 0.05.[9] Pneumatic lithotripsy without a stone cone had a 72.0% post-operative clearance percentage in another research, but pneumatic lithotripsy with a stone cone had a 100.0% clearance rate.[10]

Higher percentages of stone-free outcomes and decreased rates of morbidity have resulted from improved endoscopic techniques for treating ureteral stones. However, problems persist that prevent endoscopic treatment from yielding a 100% stone-free rate. One such problem is the retrograde migration of the proximal ureteric calculus after ureteroscopic lithotripsy.
The purpose of this study is to evaluate the efficacy of ureterorenoscopic (URS) pneumatic lithotripsy in the treatment of stone cone-free and stone-containing proximal ureteric stones.

There is paucity of data on the use of stone cone device in the management of proximal ureteric stones in Pakistan. Therefore further research is needed on this topic to determine it's efficacy in our population. The rationale of this study is to compare the stone clearance rate of ureterorenoscopic (URS) pneumatic lithotripsy with and without stone cone in proximal ureteric stone. As routinely stone cone is not used which results in proximal migration of stone and results in infection or further growth or may lead to colic. So on the basis of results of my study, the morbidity and expenditures of the patients with ureteric stone can be minimized by avoiding upward migration of stone.

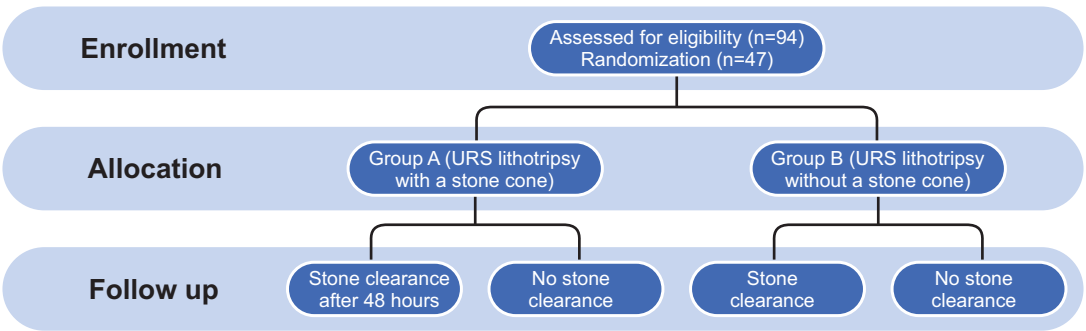
MATERIALS AND METHODS

This randomized controlled trial (No: 7724/23) was done on 94 patients (47 in each group) who presented to the Urology departments of Shahida Islam Teaching Hospital, Lodhran, and Bahawal Vitoria Hospital, Bahawalpur, from June 2023 to January 2024. Patients of age >20 years who had a single proximal ureteric stone (presence of all these i.e. URS lithotripsy patients with a single, proximal ureter stone (defined by bright echogenic foci with posterior acoustic shadowing) and radiopaque shadow on plain x-ray KUB, measuring 7–15 mm (as determined by USG), were selected by non-probability consecutive sampling technique. Randomization was done by using lottery method. Using the WHO calculator for two proportions, the sample size was calculated to be 94, or 47 in each group, with 90% study power and a 5% level of significance and taking post-operative clearance rate following pneumatic lithotripsy without a stone cone as 70.0% and with stone cone as 95.0%.[9] (As 23 sample in one group is less, so in order to make results more authentic, we have included larger sample size).

Nine patients were eliminated due to congenital defects in the urinary system, single kidney, pregnant females, and sepsis and pyonephrosis (as determined by USG and fever >101F^0).

Every patient gave their informed permission (Institutional ERC No. SIMC/H.R./7724/23 dated 2-01-2023). The patients were informed about the process and the goal of the research. Using a lottery, we split the patients into two groups at random. URS lithotripsy with a stone cone was performed on group A, whereas URS lithotripsy without a stone cone was performed on group B. A single surgeon with at least three years of post-fellowship experience carried out every surgery. Following a 48-hour period, patients' stone clearance was recorded.

Statistical analysis was performed using SPSS version 25. Shapiro wilk test was used to check the normality of data. Age, height, weight, BMI, size of stone and operative time were presented as mean, median and SD or median (IQR). Gender and stone clearance (yes/no) were presented as frequency and percentage. The stone clearance of the two study groups was compared by Chi Square/fisher exact test and p value ≤0.05 was considered as significant.

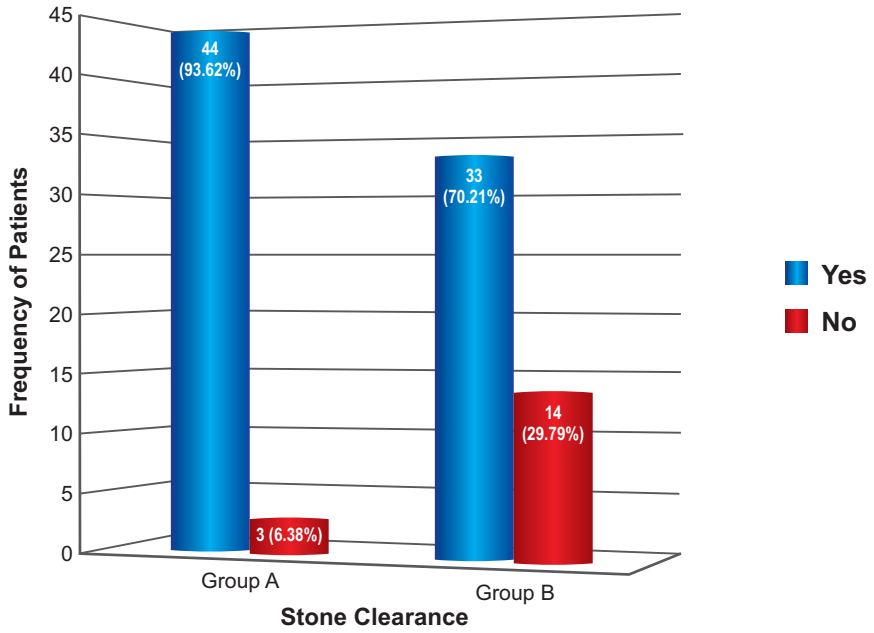


Consort Flow Chart (n=94)

RESULTS

The study's age range was 20 to 60 years old, with a mean age of 36.78 ± 9.69 years. Patients in groups A and B had mean ages of 36.72 ± 9.64 and 36.89 ± 9.93 years, respectively. The majority of the 65 patients (69.15%) ranged in age from 20 to 40. Of these 94 patients, the ratio was 1.8:1, with 57 (60.64%) being male and 37 (39.36%) being female. The illness lasted 3.24 ± 1.39 months on average. 26.07 ± 3.72 kg/m2 was the mean BMI. The stone's average size was 11.81 ± 1.94 mm. The average operation lasted 28.57 ± 4.92 minutes.

Figure I illustrates the stone clearance rate (chi square = 8.689, p-value = 0.003) for 44 (93.62%) patients in group A (URS with stone cone device) and 33 (70.21%) patients in group B (URS without stone cone device).



- Chi square value = 8.689
- P-value = 0.0032 which is statistically significant.

Figure 01. Comparison of stone clearance rate of ureterorenoscopic (URS) pneumatic lithotripsy with and without stone cone in proximal ureteric stone.

DISCUSSION

This study compares the stone clearance rate of proximal ureteric stones treated with ureterorenoscopic (URS) pneumatic lithotripsy with and without a stone cone. The age at presentation in our study varied from 20 years to 60 years with mean age of 36.78 ± 9.69 years. Patients in groups A and B had mean ages of 36.72 ± 9.64 and 36.89 ± 9.93 years, respectively. The majority of the 65 patients (69.15%) ranged in age from 20 to 40. Khan MS et al[11] has also shown almost similar mean age i.e. 38 years as observed in our study. Bangash M et al[12] and Mustafa G et al[13] have shown higher age i.e. 41 & 42 years respectively as compared to our study. Moreover, in our study 60.64% patients were male and 39.36% were female with ratio of 1.8:1 which is very much comparable to studies of Khan MS et al,[11] Durmus E et al[14] and Godse S et al[15] who had also found higher incidence of male than female patients.

In our study, 34 (93.62%) patients in group A (URS with stone cone device) and 33 (70.21%) patients in group B (URS without stone cone device) in my study had a stone clearance rate with a p-value of 0.003. In one research, the post-operative clearance rate following pneumatic lithotripsy without a stone cone was 70.0%, but the clearance rate following pneumatic lithotripsy with a stone cone was 95.0%, with a statistically significant p-value of less than 0.05.[9] Pneumatic lithotripsy without a stone cone had a 72.0% post-operative clearance percentage in another research, but pneumatic lithotripsy with a stone cone had a 100.0% clearance rate.[10] Our results are comparable to this study. Although the previous described study has already shown stone cone better option for proximal ureteric stone clearance but recent study is required in this aspect that's why we have conducted this study.

Similarly to our study, Desai and colleagues employed the Stone Cone in 50 consecutive instances of upper and lower ureteral calculi and has shown stone cone as effective method for complete stone clearance.[16] Raphael JE et al has shown that the stone cone is a safe device and is useful during ureteroscopy and lithotripsy for mid-and proximal ureteric stone in preventing retropulsion and improving stone

clearance.[17] In a prospective, paired trial including 56 patients, Paradalidis et al. found that the Stone Cone was both safe and effective, and that it dramatically increased the percentage of patients who were free of stones when compared to a flat wire basket.[18]

Eighty individuals suffering from proximal ureteric calculus participated in a prospective randomised control study.[19] Two groups of forty patients each were randomly assigned to the patient population. Group 1 underwent ureteroscopic pneumatic lithotripsy of the proximal ureteric calculus using a stone cone, while Group 2 underwent lithotripsy without the use of a stone cone. The two groups' rates of stone clearance were compared, and the findings were examined. In the immediate postoperative phase, 95% of patients (38 out of 40) had full stone removal. In two cases, residual particles as large as 4 mm were found. Group 2 consisted of forty patients who did not get a stone cone during routine ureteroscopic pneumatic lithotripsy. In the first postoperative phase, 28 out of 40 patients in this group had a 70% stone removal rate. Four patients had remaining pieces larger than 4 mm, and eight patients experienced stone migration into the renal pelvis. All 40 patients in the Stone Cone group had full stone clearance at the one-month follow-up, as determined by a KUB or spiral CT scan.[19] 37 individuals in group 2 had the stone completely removed. In the stone cone group, all patients had a 100% success rate in preventing proximal stone migration, while the non-stone cone group had an 80% success rate (8 patients had stone migration into the kidney). The Stone Cone group outperformed the other in terms of success rate in avoiding stone migration, with a statistically significant difference ($p<0.05$). In the one-month follow-up period, the Stone Cone group's stone-free rate was 100% (40/40) as opposed to 87.5% (35/40) in the other group.[19]

In another study,[20] the Stone Cone instrument and proximal lidocaine jelly injections were compared for their ability to stop proximal stone migration during ureteroscopic lithotripsy. The preoperative measures did not show a significant difference between the two therapy groups for the most part. The success rates of the lidocaine jelly group (85%) and the Stone Cone group (100%), with 17 out of 20 patients managing to prevent proximal stone migration, were found to vary statistically significantly ($p < 0.05$). In contrast, the Stone Cone group had a stone-free rate of 100% (20/20) whereas the lidocaine jelly group had an 85% (17/20) rate.[20]

In our study we compared stone cone group with the control group and the difference was significant in favour of stone cone group and the main reason behind this was that the coils of stone cone prevents the upward migration of the stone gravels. Utilizing a stone cone during ureteroscopic lithotripsy is a secure and ecient method for treating ureteric stones. It may aid in minimizing the duration of surgery, enhancing the rate at which stones are removed, and reducing the length of hospitalization. The main limitation of our study was that it did not take into account the level of patient satisfaction with the procedures used. However, our sample size was similar to, or relatively better than the very few studies available in the literature. Multicenter prospective study has not been done yet and needs to be done to elaborate the differences between the two aforementioned modalities.

CONCLUSION

According to the study's findings, utilising a stone cone device considerably increases the rate of stone clearing. In order to reduce the morbidity associated with leftover stone pieces, we advise using the stone cone device in ureteroscopic therapy of renal calculi. This will lead to greater stone clearance rates.

Ethical consideration

This study was approved by Institutional Review Board of Shahida Islam Teaching Hospital, Lodhran, (SIMC/HR/7724/23), Pakistan.

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Conflict of Interest

Authors declared no conflict of interest.

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DATA SHARING STATEMENT: The data that support the findings of this study are available on request from the corresponding author. The data is not publicly available due to privacy or ethical restrictions.

AUTHORS' CONTRIBUTION

The following authors fulfill authorship criteria as per ICMJE guidelines;

Pansota MS, Saleem MS: Substantial contribution to conception and design, drafting the manuscript, final approval, agreed to be accountable for all the work.

Barkat B: Substantial contribution to conception and design, data acquisition, drafting the manuscript, final approval, agreed to be accountable for all the work.

Aleem A: Analysis and interpretation of data, drafting the manuscript, final approval, agreed to be accountable for all the work.

Rasool M: Analysis and interpretation of data, critical revision, final approval, agreed to be accountable for all the work.

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