International Surgery Journal
Darakh PP et al. Int Surg J. 2019 May;6(5):1534-1539
http://www.ijsurgery.com
pISSN 2349-3305 | eISSN 2349-2902

DOI: http://dx.doi.org/10.18203/2349-2902.isj20191482

Original Research Article

Comparative study of different modalities of treatment for large upper ureteric calculi

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Received: 02 March 2019
Revised: 14 March 2019
Accepted: 18 March 2019

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ABSTRACT

Background: Urolithiasis is one of the most common urological diseases and has become a worldwide health problem. Minimally invasive therapies such as extracorporeal shock wave lithotripsy, ureteroscopy, percutaneous nephrolithotomy, RIRS and laparoscopic surgery have revolutionized the treatment of ureteric calculi, altering surgical treatment dramatically.
Methods: It was a prospective randomized study conducted between March 2012 to March 2017. 60 patients with large upper ureteric calculi of >15 mm in size were randomly selected for the study. Diagnosis was made using ultrasonography, plain X-ray KUB, IVU and spiral CT KUB. Patients were divided randomly into 4 groups of 15 patients each. Routine post-op X-ray KUB and USG were done for all the patients. All the data was recorded and analysed.
Results: LAP group had the highest stone clearance rate (100%) in our study. The difference in stone clearance rate was statistically significant when compared with ESWL (73.33%) and URS group (66.7%), whereas no statistical significance was found between LAP and PCNL group (93.33%). URS group in our study had highest intra-operative complications (33.33%) and laparoscopic group had least number of complications. Post-procedural complications occurred in 1 patient (6.7%) in URS group, 2 patients in ESWL group (13.3%) and 1patient each in LAP and PCNL group (6.7%).
Conclusions: Laparoscopic ureterolithotomy is a feasible and effective method of treating large (>15 mm) upper ureteric calculus. It is associated with least intra-operative complications and semirigid ureteroscopy has highest intra-operative complications.

Keywords: Urolithiasis, ESWL, RIRS, Laparoscopic ureterolithotomy

INTRODUCTION

Urolithiasis is one of the most common urological diseases and has become a worldwide health problem.[1] The life time risk of stone formation varies from 5-12% in Europe and in United States the risk is 13% and 7% in men and women respectively.[1] Over the past 2 decades the prevalence of urinary stones has increased by 37%.[2] 50% of these stone formers will have recurrence within 5 years of their first episode.[3] Men are more likely to form stones than women. The consequences of urinary stone disease are not only health related but economic as well. Total cost arising from urinary stone disease from diagnosis to treatment added with lost wages is estimated to be more than $2 billion annually in United States.[4] Minimally invasive therapies such as extracorporeal shock wave lithotripsy, ureteroscopy, percutaneous nephrolithotomy, RIRS and laparoscopic surgery have revolutionized the treatment of ureteric calculi, altering surgical treatment dramatically. Management of upper ureteric calculi especially large calculi of >15 mm still remains a challenge to the urologists. The treatment options include ureteroscopy, ESWL, PCNL and Open/LAP ureterolithotomy. There is no single best treatment available for the treatment of large upper ureteric calculi. This study aims at studying the various treatment options for upper ureteric calculi of >15 mm in size and determining the complications, stone clearance rate and post-operative morbidity of different procedures and their comparative evaluation.

Objectives

- To study the different available modalities for treatment of proximal ureteral calculus >15mm in size.
- To study the treatment outcomes following use of different modalities with reference to Complete stone clearance, Intra-operative complications and Post procedure complications.

METHODS

It was a prospective randomized study done in JSS Medical college and hospital between March 2012 to March 2017.Consent was taken from all the patients before inclusion in the study. Ethical clearance was obtained from the Ethical committee of the hospital. Patients attending the out-patient department with clinical features suggestive of ureteric colic were evaluated. Urine microscopy and serum creatinine estimation were done for all the patients. Ultrasound-KUB and Plain X-ray KUB were done for all the patients. Spiral CT KUB with contrast was done for all the patients with suspected upper ureteric calculi in USG-KUB/X-ray KUB. Hounsfield unit (HU) was calculated for these patients.

Inclusion criteria

All patients above 12 years of age diagnosed to have calculus of >15 mm in proximal ureter were included for the study.

Exclusion criteria

Include Patients with, stone size of ≤15 mm, <12 years of age, bilateral ureteral obstruction, renal insufficiency, solitary kidney with ureteric calculi, suspected pyelonephritis/pyonephrosis, associated lower/mid ureteric and renal calculi, non-functioning kidney, coagulopathy and Patients who refused to take part in the study.

Total 196 patients were diagnosed with large upper ureteric calculi, out of which 60 patients who met the inclusion criteria were selected for the study. The upper ureter was defined as the part of the ureter between the pelvi-ureteric junction proximally and upper border of the sacral ala distally.[5] The patients included in the study were divided randomly into 4 groups of 15 patients each. Group 1- Semirigid ureteroscopy (URS), Group 2- ESWL, 3-PCNL and Group 4- Lap ureterolithotomy. Stone size, location and laterality were recorded. Stone size was measured along the vertical axis as seen in the plain X-ray KUB and spiral CT- KUB. The pain score was recorded for all the patients on the basis of 10 point visual analogue scale before starting the treatment. All the patients were evaluated on out-patient basis and after getting fitness for the surgery they were admitted. All patients were admitted on the day of surgery, except those who underwent ESWL. Patients who underwent ESWL were treated on OPD basis and admitted only for the complications of the procedure, if any. Patients were again explained in detail about the procedure and consent was obtained. All the procedures were performed by a single team of four urologists. General anaesthesia was used for PCNL, Lap ureterolithotomy and ureteroscopy group. ESWL was done without any anaesthesia.

Ureteroscopy was done using semi rigid ureteroscope of 6/7.5F and 8/9.8F. Holmium laser 30W was used to fragment the stone. DJ stent was kept in all the patients.

PCNL was done in prone position using fluoroscopy. Prior ureteroscopy was done in selected patients with impacted stones, calculus dislodged and pushed into pelvicalyceal system before placing the ureteric catheter. Mid calyceal puncture done and 22 F sheath was used for all the patients. Nephrostomy tube was kept only in 3 patients indications being excessive bleeding, pelvicalyceal system perforation and residual calculi. DJ stenting was done in all the patients.

Lap ureterolithotomy was done in lateral position using 3 ports. Transperitoneal approach was used in all the patients. Colonic mobilization was done. DJ stent was deployed in all the patients. Ureterotomy incision was closed using 3-0 catgut suture by intracorporeal suturing. Drain kept in all the patients. Open ureterolithotomy was kept as an option only in failed laparoscopic cases.

ESWL was done using electromagnetic lithotripter. Ultrasound was used to localize the stone. Routine DJ stenting was done before the procedure. Stenting was done under local anaesthesia for all patients except for 2 patients who needed IV sedation due to impacted stone. It was decided to give maximum of 3 sittings of shock waves at one week interval. Around 2000 shocks were given per sitting. Patients who had no fragmentation in the first sitting were advised to undergo ancillary procedures. Patients who had residual calculi at the end of 3 sittings underwent either PCNL or ureteroscopy.

Post-operative recovery was recorded in terms of pain score, duration of hospital stay, resuming oral diet and post-operative complications. The pain score was measured on daily basis for a period of 1 week and the average was taken. Details of the drain, nephrostomy tube insertion and removal were recorded. Routine post-op X-ray KUB and USG were done for all the patients. Details of the residual calculi were recorded. Patients were reviewed one week after discharge. X-ray KUB/USG was repeated in symptomatic patients and those with residual calculi. Plain CT-KUB was done in selected patients. Patients with residual calculi were advised to undergo ancillary procedures. DJ stent was removed one month after the procedure. Complete clearance of the stone was confirmed before stent removal. All the data were recorded and analysed. Frequencies, descriptives, crosstabs (Contingency coefficient test and one way ANOVA were used for statistical analysis.

RESULTS

The mean age of patients was 37.53 years in URS group, 42.2 years in ESWL group, 36.4 years in PCNL group and 40.53 years in LAP group. In our study population, 66.6% of the patients were males and 33.3% were females with a male to female ratio of 2:1. All demographic parameters were comparable in all the groups (Table 1).

The average stone size was 19.26 mm in URS group, 19.06 mm in ESWL group, 19.06 mm in PCNL group and 18.86 mm in LAP group respectively. The overall average stone size was 19.06 mm. The smallest calculus was 16 mm in size and the largest calculi was 25 mm (Table 2).

Table 1: Demographics.

Gender	Number of patients	Percentage (%)
Male	40	66.66
Female	20	33.33

Table 2: Stone size (in mm).

Group	Min	Max	Mean size (mm)	SD
URS	16	24	19.26	2.865
ESWL	16	25	19.06	3.327
PCNL	16	24	19.06	2.219
LAP	16	24	18.86	2.475
Total	16	25	19.06	2.686

The average pain score in 10 point visual analogue scale before intervention was 6.06 in URS group, 7.0 in ESWL group, 6.06 in PCNL group and 6.53 in LAP group. The pain score after intervention (Average of 1 week) was 4.4 in URS group, 5.13 in ESWL group, 5.33 in PCNL group and 5.45 in LAP group. The average overall pain score in the study population before intervention was 6.41 and after intervention it was 5.07.

The stone clearance was considered complete when no additional procedures were needed to clear the stone. In URS group 10 (66.67%) patients had complete stone clearance. In ESWL group 11 (73.33%) patients had complete stone clearance, whereas 14 (93.33%) patients had complete clearance in PCNL group and all patients (100%) in LAP group had complete stone clearance (Table 3).

Table 3: Stone clearance rate.

Group	Number	Complete stone clearance	
		Yes (%)	No (%)
URS	15	10 (66.67)	5 (33.33)
ESWL	15	11 (73.33)	4 (26.67)
PCNL	15	14 (93.33)	1 (6.67)
LAP	15	15 (100)	0
Total	60	50 (83.33)	10 (16.67)

Table 4: Comparison of various procedures.

Parameter	ESWL	URS	PCNL	LAP
Stone clearance rate	73.33	66.67	93.33	100
Residual calculi	26.6	33.3	6.7	0
Ancillary procedures	26.6	33.3	6.7	0
DJ stenting	100	100	100	100
PCN	0	0	20	0
Drain	0	0	0	100
Procedure time (min)	165.67	48	55	75.33
Decrease in pain score	1.87	1.66	0.73	1.08
Intra-operative complications	0	33.3	20	0
Post-operative complications	13.3	6.7	6.7	6.7
Hospital stay (days)	0.733	1.266	2.13	3.27
Resumption of normal diet (hours)	1.00	4.00	12	24

In URS group 3 (20%) patients had migration of calculus and 2 (13.3%) had ureteric injury in the form of mucosal injury. In PCNL group 1 (6.7%) patient had bleeding which required blood transfusion and 2 patients had ureteric mucosal injury at the site of stone impaction which was managed by placement of antegrade stent. In LAP group there were no intra-op complications. Sepsis was seen in 2 patients (13.3%) in ESWL group when compared to 1 (6.7%) in URS group. Ileus occured in 1 patient (6.7%) in LAP group which was treated with Nasogastric tube drainage for 24 hours (Table 4).

Mean procedure time in URS, ESWL, PCNL and LAP groups were 48.00 mins, 165.67 mins, 55 mins and 75.33 mins respectively. Mean duration of hospital stay was 1.27 days in URS group, 2.13 days in PCNL group and 3.27 days in LAP group. ESWL group were treated as outpatients except those who developed sepsis who required 3 days of hospitalisation. Normal diet was started immediately in ESWL group, after 4 hours in URS group, after 12 hours in PCNL and after 24 hours in LAP group.

In our study there were residual calculi in total 10 (16.6%) patients. Out of 10 patients 5 were in URS group, 1 patient in PCNL group and 4 in ESWL group. There were no residual calculi in LAP group. In URS group 2 patients underwent PCNL whereas 3 underwent ESWL for residual calculi. In ESWL group 2 patients underwent URS and 2 patients PCNL. In PCNL group 1 patient required URS. There was no need for any additional procedure in LAP group (Table 4).

DISCUSSION

Ureteric calculi are one of the commonest problem encountered by urologists in day to day practice. With the advances in endo-urological techniques most of the ureteric calculi are treated on day care basis. The treatment of ureteric calculi becomes difficult as the distance of the stone increases from the VUJ and with increase in the size of the calculi. Large upper ureteric calculi (>15 mm in size) present unique challenges in the treatment. These patients represent special group of urolithiasis who requires individualized management considering various factors. Complete stone clearance, invasiveness, complications, cost and availability of facilities should be considered in the treatment of large upper ureteric calculi. There is no uniform consensus regarding the treatment of large upper ureteric calculi (>15 mm in size). The treatment options available for this group of patients are PCNL, ureteroscopy (semirigid/ flexible), ESWL, laparoscopic and open ureterolithotomy. RIRS is the newer addition to the armemantorium but requires multiple sitting and pre stenting in some patients. High cost involved in RIRS is the main factor prohibiting its use in rural set up. Selecting the most appropriate treatment modality out of the above options is a challenging task. Hence, we have studied the appropriateness of 4 available treatment modalities in our hospital (ESWL, PCNL, Semirigid ureteroscopy and Lap ureterolithotomy) in the treatment of large upper ureteric calculi of >15 mm size. 60 patients with >15 mm upper ureteric calculus, who met the inclusion criteria, were included in the study.

Complete stone clearance is the most important objective of any treatment modality for stone disease. The effectiveness of the procedure is estimated by the stone clearance rate. Residual calculi however small they are, is considered as treatment failure/incomplete treatment by the patients. Patients whose calculus is completely cleared are most satisfied with the treatment. Hence, the treatment modality should be chosen carefully with the aim of clearing the stone completely.

Ureteroscopy is a commonly performed procedure for ureteric stones especially mid and lower ureteric stones. Treatment of upper ureteric calculi is difficult because of difficult access and high chance of migration of stones. However with the introduction of smaller ureteroscopes, flexible ureteroscopes and holmium laser most of the stones in the upper ureter can be treated. But it is still challenging to treat larger upper ureteric stones by ureteroscopy alone. It takes longer time to fragment larger stones with the possibility of ureteric injury and residual calculi. Most of the patients require re look at the time of stent removal.[6,7] But ureteroscopy is preferred over ESWL in impacted upper ureteric calculi as stone free rate is less with ESWL alone in such cases.[8-10] According to the AUA/EAU ureteral stones guideline panel the stone free rate for ureteroscopy (URS) in the treatment of upper ureteric calculi is around 81%. Most of the cases in this study were having smaller ureteric stones. The stone free rate decreased to 79% for larger stones (>10 mm).[11] In a study by ElGanainyl et al, (2009), 267 patients with upper ureteric calculi of 9-20 mm were treated with semi-rigid ureteroscopy and pneumatic lithotripsy. The authors in this study reported a stone clearance rate of 91%.[12] In our study, stone clearance rate was 66.7% in the ureteroscopy group. Compared to the above study and AUA panel group, clearance rate was less in our study. This may be because of the large size of calculi compared to the previously mentioned studies. Hence, the success rate with ureteroscopy decreases as the stone size increases. However with the addition of flexible ureteroscopy stone clearance rate may be improved to some extent as migrated stones can be localised and treated. Availability and high cost are the prohibiting factors in using flexible ureteroscopy in all patients.

ESWL is the least invasive but effective method of treating upper ureteric calculi. With the improvement in the ureteroscopic and PCNL techniques, the use of ESWL has been decreased. In a study by Halachmi et al, (2006) 96 patients with large ureteric calculi underwent ESWL. Average stone size was 14 mm (range 10-22 mm). 66 patients had upper ureteric calculi. The overall stone free rate was 86.5%. The failure rate was 13.5%. These patients underwent ureteroscopy successfully.[13] In our study, stone clearance rate for ESWL group was 73.33%. The clearance rate was less compared to the above study. This may be because of larger size of calculi in our study. Also the previous study includes calculi in the mid and lower ureter, whereas our study included only patients with upper ureteric calculi.

PCNL is a minimally invasive and effective option for patients with large upper ureteric calculus. The stone clearance rate is highest with this approach amongst all the endo-urological procedures. In a study by Goel et al, (2005), 66 patients underwent PCNL for large upper ureteric calculi. Patients with >15 mm calculi were included in the study. The stone clearance rate was 98.5% in this study.[14] In our study, 14 (93.33%) patients had complete clearance in PCNL group. This is comparable to the above study and the difference was statistically not significant. The clearance rate with PCNL is superior to ureteroscopy and ESWL groups and the difference was statistically significant. Hence PCNL is an effective way of treating upper ureteric calculi.

Laparoscopic transperitoneal ureterolithotomy is a relatively newer method of treatment of upper ureteric stones. The drawback of laparoscopic ureterolithotomy are high learning curve, transperitoneal approach as compared to retroperitoneal approach of most of the urological procedures and hence increased morbidity. However as we gain more experience in laparoscopy the success rate increases with minimal complications. In a study by Al-Sayyad, in 2012, 12 patients with large upper ureteric calculi underwent laparoscopic transperitoneal ureterolithotomy. The stone clearance rate was 100% in this study. In our study, the mean stone size was 18.86 mm. All patients (100%) in LAP group had complete stone clearance. The results are comparable to the other studies in the literature.[15] LAP group had the highest stone clearance rate in our study. The difference in stone clearance rate was statistically significant when compared with ESWL and URS group, whereas no statistical significance was found between LAP and PCNL group.

Time required for the surgical procedure is important as the morbidity increases with the increase in operative and anaesthesia time. In our study, mean procedure time in URS, ESWL, PCNL and LAP groups were 48.00 mins, 165.6 mins, 39.6 mins and 75.3 mins respectively. In a study by Marchant et al, mean procedure time for ESWL was 55 minutes in men and 45 minutes in women. For ureteroscopy, procedure time was 80 minutes for men and 55 minutes for women[16]. In a study by Shi-Wei Huang et al 2005, the mean operative time of PCNL was 63.5 (range, 29~103) minutes.[17] The mean procedure time was more in ESWL group, as the patients required multiple sittings for stone fragmentation (average of 3 sittings). Since ESWL was done on OPD basis without any anaesthesia, patients tolerated the procedure well without any increase in the morbidity. Among the procedures which required anaesthesia, the procedure time was significantly less in URS group (48 min), as compared to PCNL (55 min) and LAP groups (75.33 mins).

Complications of a surgical procedure are a major consideration in selecting a procedure from the various options available for large upper ureteric calculi. Complications may arise in the intra-operative or post-operative period. In URS group 3 (20%) patients had migration of calculus and 2 patients (13.3%) had ureteric injury. In a study by Taie et al 8% of patients had complications, including transient hematuria (4.2%), mucosal erosion (1.4%), stone migration (1.3%), ureteral perforation (1.2%), and fever and/or sepsis (1.0%).[15]

In PCNL group 1 (6.7%) patient had bleeding which required blood transfusion and 2 patients had ureteric mucosal injury, which was treated by Antegrade stent insertion. In ESWL and LAP group there were no intra-op complications. Hence, URS group in our study had highest intra-operative complications and laparoscopic group had least number of complications. This may be because of large size of calculus and non-availability of flexible ureteroscope to treat migrated calculus in the URS group. Bleeding in PCNL patient is an expected complication, which occurred in one patient in our study. This is on par with the other studies. Laparoscopic group did not have any intra-operative complication, as the stone was removed intact and lithotripsy was not required.

Post-op complications increase the morbidity of a surgical procedure. These should be identified and treated promptly. In our study, one patient (6.7%) in the URS group had sepsis which was treated with I.V. antibiotics and supportive therapy. This patient had unexpected pyonephrosis during ureteroscopy. Hence post-operative sepsis was treated accordingly. In the ESWL group, 2 patients (13.3%) had sepsis. These patients were admitted and treated with antibiotics and supportive treatment. Sepsis occurred 24 hours after the treatment. It is an expected complication in ESWL because of infected stones which on fragmentation leads to release of organisms into the blood stream and leads to sepsis. In PCNL group, 1 patient (6.7%) had a small stone fragment which required ureteroscopy and removal of the fragment. In the LAP group, 1 patient (6.7%) had paralytic ileus in the post-operative period. It was treated with nasogastric tube drainage for 48 hours. None of the patients had life threatening complications. All the complications were treated promptly. Post-operative complications cannot be compared as they are unique to the type of the procedure used to treat the calculus. But none of the patients had mortality because of the post-operative complications.

When postoperative pain of each group was compared to all other modalities individually, it was found that the URS group had the lowest pain scores compared to all other modalities. This may be because of the minimally invasive nature of procedure with clearance of the stones in most cases and relief of obstruction due to DJ stent deployment in all cases. Though ESWL is non invasive modality, the pain score was higher than URS group probably because it required multiple sittings, residual stones and the dependency of stone clearance on washout of stone fragments from the urinary tract naturally. In our study, patients who underwent ureteroscopy had the least post-procedural pain; whereas patients who underwent lap ureterolithotomy had the highest pain score compared to other treatment modalities.

The post-operative morbidity related to stenting and drain insertion was more in LAP group due to the double drainage used in this group. In all other groups patients had minor stent related bladder irritability which required occasional analgesics. None of the patients required removal of DJ stenting for stent related complications.

Duration of hospital stay increases the cost of the treatment. With advancement in endo-urological and anaesthetic techniques, majority of the stone diseases are being treated on day care basis. But in our study it was not feasible as the stone size was >15 mm and hence all the patients were admitted except for ESWL group. ESWL group patients were treated on OPD basis. They were admitted only for the complications of the procedure, such as sepsis and residual calculi. The mean hospital stay in this group was 0.733 days. This was significantly less compared to all other groups. Mean duration of hospital stay was 1.266 day in URS group, 2.13 days in PCNL group and 3.27 days in LAP group. The hospital stay was significantly higher in the LAP group compared to other procedures as the drain was removed on 2nd post-operative day before discharging the patient. In a study by Marchant et al for ESWL, the mean hospital stay was 4.8 hours (same-day discharge for all patients) and mean hospital stay for ureteroscopy patients was 22 hours.[16] In a study by Huang et al, the mean hospital stay was 5.5 (range, 3~17) days for PCNL.[17]

CONCLUSION

Laparoscopic ureterolithotomy and PCNL are the most effective modalities in the treatment of large (>15 mm) upper ureteric calculi with acceptable morbidity. Ureteroscopy alone is the least effective method of treating large upper ureteric stones. However with the addition of ESWL and flexible ureteroscopy stone clearance rate may be improved but multiple sittings may be required for complete stone clearance. Hence we conclude that in patients who wishes for complete stone clearance in single procedure PCNL/Lap ureterolithotomy should be preferred over ESWL/ ureteroscopy in large upper ureteric calculi.

ACKNOWLEDGEMENTS

We would like to acknowledge the hospital administration, Department of Urology and entire staff for the help provided in the study. We have don't have any conflicts of interest and have not taken any funds for the above study.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Darakh PP, Ramesh RB, Doshi C. Comparative study of different modalities of treatment for large upper ureteric calculi. Int Surg J 2019;6:1534-9.