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TO COMPARE THE STONE FREE RATE AT ONE WEEK OF IN SITU EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (ESWL) AND URETERORENOSCOPIC (URS) MANIPULATION IN THE TREATMENT OF PROXIMAL URETERIC STONE.

[1]Dr.Mohsin Mustafa Memon, [2]Dr.Farag Mohsen Saleh Abo Ali, [3]Naveed Mahar, [4]Dr.Sunil Kumar, [5]Prof.Murli Lal

[1]Senior Lecturer in Urology SIUT Karachi, E-mail: mmemon82@hotmail.com,
[2]Senior Lecturer in Urology SIUT Karachi, E-mail: farag_ye@hotmail.com,
[3]Assistant Professor in Urology SIUT) E-mail: navidmahardowite@gmail.com
[4]Assistant Professor in Urology JMC Khuzdar Balochistan) E-mail: sunilpanjwani28@yahoo.com,
[5]Professor of Urology SIUT Karachi, E-mail: chhabriam@yahoo.com

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Abstract:

Objective: *To compare the stone free rate at one week of in situ Extracorporeal shock wave lithotripsy (ESWL) and ureterorenoscopic (URS) manipulation in the treatment of proximal ureteric stone.*

Study Dsesign: *Comparative cross-sectional.*

Setting*: Department of Urology & Nephrology Peoples University of Medical and Health Sciences (PUMHS), Nawabshah, Sindh.*

Duration*: Fourteen months from January 15, 2014 to March 15, 2015.*

Material and methods: *Study was conducted on a total number of 100 patients i.e. 50 patients in group A (dealt with extracorporeal shock wave lithotripsy) & 50 patients in group B (dealt with ureterorenoscopic manipulation). Extracorporeal shock wave lithotripsy (ESWL) was done under intravenous sedation as an outpatient procedure in supine position, and the electromagnetic lithotripter was used. Whereas, ureterorenoscopic (URS) manipulation was done under general anaesthesia, and an 8.0 Fr or 8.5 Fr semi rigid ureteroscope was used. A pneumatic (Swiss lithoclast) was used for intracorporeal lithotripsy. The stone free rate were compared between the two groups by taking a look into clinical factor such as the size of stone at one week after the procedures.*

Complication rate, success rate, re-treatment rate and auxiliary procedures were compared in each group.

Results: *A total of 100 patients were treated for upper ureteric calculi,* ***the stone free rate*** *for in situ extracorporeal shock wave lithotripsy (ESWL) was 52% (26 of 50) patients, and for Ureterorenoscopic (URS) was 60% (30 of 50) patients (P=0.008). Whereas, the retreatment rate was significantly greater in ESWL group then in URS group (ESWL % v/s URS %). No major complications were encountered in both groups.*

Conclusion: *Despite the fact that extracorporeal shock wave lithotripsy (ESWL) is considered by many urologist as the 1st line treatment for the proximal ureteric calculi, our study demonstrates that ureterorenoscopic manipulation (URS) with intracorporeal lithotripsy is a viable modality, and a safe alternative with an advantage of obtaining an early stone free status.*

Keywords: *Extracorporeal shock wave lithotripsy (ESWL), Ureterorenoscopic (URS), proximal ureteric stone.*

Corresponding author:
Dr. Mohsin Mustafa Memon,
Senior Lecturer in Urology SIUT Karachi,
E-mail: mmemon82@hotmail.com

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INTRODUCTION:

Urolithiasis is the worldwide health problem.[1] Pakistan falls into Afro-Asian stone Belt (Stretching from Egypt, Iran, India, and Thailand to Indonesia and the Philippines) falling within the tropical and sub-tropical region have consistently reported a high incidence of urolithiasis. Countries in the region show a wide variation in prevalence and the site of stone disease.[2] Approximately 12% of the population suffers from urinary stone disease in their life time and recurrence rate approaches 50 %.[3] In Pakistan stone diseases is the major work load in adult and paediatric papulations.[4] Stone in the ureter occur following passage of renal calculi, stone may pass or lodge in the ureter. For the purpose of study to determine the site of impacted stone, ureter is divided into different sections. This sectional anatomy of the ureter was initially proposed in 1994. According to this, Section 1, from UPJ (uretero-pelvic junction) to the lower border of kidney; Section 2, up to 2.5 cm below the lower border of kidney, Section 3 up to the upper border of sacroiliac joint; section 4, parallel to the sacroiliac joint; Section 5 up to the ischial spine; Section 6 up to the vesico-ureteric junction[5] (section 1, 2 & 3 constitute proximal ureter, section 4 constitute middle and section 5 & 6 lower ureter). In the context of stone passage, a meta-analysis of five groups of patients (224 patients) yielded an estimate that 68% stone of about 5mm size would pass spontaneously (97%, CL 46% - 85%). Another analysis of three groups (104 patients) yielded an estimate that 47 % stone of > 5mm and < 10mm size would pass spontaneously (95% CL 36% -59%)[6] and stones of > 10mm size need intervention. A variety of treatment options are available for ureteric calculi but there is increasing trend towards minimally invasive procedures. Advances in the equipment and the design of shock wave lithotripters, both for extracorporeal and intracorporeal shock wave lithotripters (SWL), the development of endourological equipments and improving skills with these modalities have greatly diminished the role of open surgery in managing ureteric calculus.[7] The concept of using shock waves to fragment stone was first noticed in 1950 in Russia.[8] The introduction of extracorporeal shock wave lithotripsy (ESWL) by Chaussy and his co-workers in 1980 revolutionized the management of urinary calculus.[9] It is the treatment of choice for renal and ureteric calculi. The technology is easy to use, non-invasive and effective, while patient recovery time remains short.[10] All shock waves despite their source are capable of fragmenting stones when focused. The most popular management for proximal ureteric stone is the extracorporeal shock wave lithotripsy (ESWL), as it is non-invasive therapy with low morbidity and acceptable efficacy.[11] A review by SEGURA et al in 1997 suggested extracorporeal shock wave lithotripsy (ESWL) as the first line treatment of most proximal ureteric stone. The high success rate 85% to 93% of extracorporeal shock wave lithotripsy (ESWL) has been previously reported. In context of ureteric calcui a combination of ureterorenooscopy and intracorporeal lithotripsy has proven to be a viable alternative to extracorporeal shock wave lithotripsy (ESWL). The introduction of small caliber semi rigid ureteroscope, as well as development of intracorporeal lithotripsy method has substantially improved the ureterorenoscopic manipulated stone free rate (71% - 78%) and significantly decreased the complication rate.[12] The Swiss lithoclast (ICL) was developed in Switzerland in 1989, and clinical result of its use in fragmenting urinary stone was published in early 1990. Salman et al has achieved an over al stone clearance rate of 82% at four week time by using this modality.[13] In a series by Youssef RF et al, the overall success rate for ureterorenoscopy (URS) was greater than extracorporeal shock wave lithotripsy (ESWL), but the difference was not significant (P= 0.8). Considering the stone clearance rate with the stone size of 10 mm, is the size where there is no difference in clearance rate with either modality, while with stone size more than 10 mm, a better stone clearance rate is achieved with ureterorenoscopic manipulation. However literature shows insignificant effect.[14] Extracorporeal shock wave lithotripsy (ESWL)

remains the primary modality of treatment for proximal ureteric calculi in many centers. However, some urologists have recommended ureterorenoscopic manipulation as the first line treatment. Despite the prescribed guide lines of EUA & AUA (European & American Urologic Association) for proximal ureteric stone.[15] The debate still continues whether Extracorporeal shock wave lithotripsy (ESWL) or ureterorenoscopic manipulation should be the first line treatment for proximal ureteric stone.

OBJECTIVE OF STUDY

To compare the stone free rate at one week of in situ extracorporeal shockwave lithotripsy (ESWL) and ureterorenoscopic (URS) manipulation in the treatment of proximal ureteric stone (10-15 mm size).

ALTERNATIVE HYPOTHESIS

Ureterorenoscopic (URS) manipulation have better stone clearance rate than extracorporeal shock wave lithotripsy (ESWL).

MATERIAL AND METHOD:

SETTING: Department of Urology & Nephrology Peoples University of Medical and Health Sciences (PUMHS), Nawabshah, Sindh, Pakistan. So many patients of proximal ureteric stone are visiting in our stone clinic and undergoing extracorporeal shock wave lithotripsy (ESWL) / Ureterorenoscopic (URS) manipulation every month.

DURATION OF STUDY: Fourteen months from 15, 2014 to March 15, 2015.

SAMPLING TECHNIQUE: Non probability consecutive sampling.

STUDY DESIGN: Comparative cross-sectional.

SAMPLE SIZE: Ureterorenoscopic (URS) manipulation achieved a success rate greater than that for extracorporeal shock wave lithotripsy (ESWL) (i.e. 90% vs. 80%) for stones above 10 mm. So p1 = 0.90 and p2= 0.80, with respect to these proportion, group sample sizes of 50 in group A and 50 in group B achieve 80% power to detect a difference of 0.10 using a two-sided Chi-square test without continuity correction and with a significance level of 0.05.

SELECTION CRITERIA

INCLUSION CRITERIA

- Over 16 years of age
- Either Gender
- Patients with proximal ureteric stone of 10-15 mm size.
- Solitary stone.
- Normal renal function (serum creatinine 0.7-1.5 mg/dl).

EXCLUSION CRITERIA

- Patients with renal failure.
- Pregnancy.
- Sepsis.
- Patient with Co morbid (Cardiac or respiratory diseases).
- Coagulation disorder (INR 1-1.4)
- Sever hydronephrosis (renal pelvis > 6 mm diameter and cortex <1cm on ultrasound KUB.
- Multiple ureteric stones.

DATA COLLECTION PROCEDURE

Catchment's area for these patient populations was stone clinic at the Department of Urology and Nephrology, PUMHS, Nawabshah. Diagnosis was based on detailed history, clinical examinations, plain X-ray KUB / Ultrasound Kidney ureter and bladder. Those who fulfilled the selection criteria were included in the study. An informed written consent was taken after full explanation of the study. Haematological investigation like total leukocyte count (TLC), haemoglobin, and coagulation profile, biochemical investigation (e.g. serum urea / creatinine), urine routine examination, culture and sensitivity were performed. Proximal ureteric stone was assessed at the time of admission, and the selected patients were randomized into two groups. Group A, patients were treated by extracorporeal shock wave lithotripsy (ESWL) and patients in group B were treated by ureterorenoscopic (URS) manipulation.

ESWL was performed by using the electromagnetic generator as an energy source. Stone was targeted with the help of Fluoroscopy, and 3000 shock waves were given with the rate of 60-90 shock waves per minute. The level of shock wave energy was progressively stepped up till satisfactory stone fragmentation with in the comfort of patients. All patients were previously well hydrated to improve the efficacy of ESWL. Fluoroscopy was used time to time during the procedure to see the cleavage of stone and re-targeting, where required. The procedure was done as the day care procedure. All patients were treated in supine position and had received analgesia according to their body weight. All patients were advised oral analgesic drug and 1-alpha blocker drug on discharge to improve stone clearance.

Ureterorenoscopic (URS) manipulation was performed in the operating theater under full general anaesthesia in the modified lithotomy position.

Ipsilateral leg was kept somewhat straight to facilitate easy handling of semi rigid ureteroscope with continuous irrigation, 8 or 8.5 Fr semi rigid ureteroscope (Olumpus) was used. Intracorporeal lithotripsy was performed by using pneumatic (Swiss) lithoclast. Fluoroscopy was used wherever needed to see the slippage of fragmented stones and also remaining stone. A 4.8 Fr double J stent was placed to prevent ureteric obstruction where required and in last folleys' catheter was placed. Patients in this group were treated as day care procedure, unless admission was required.

Follow ups were done after one week of each procedure in stone clinic. The stones were assessed postoperatively using plain X-ray KUB (Kidneys, ureter, bladder). Treatment outcome was assessed by the post procedure stone size. Stone free rate at one week of in situ extracorporeal shock wave lithotripsy (ESWL) and ureterorenoscopic (URS) manipulation in the treatment of proximal ureteric stone clearance (stone free) was noted in Proforma.

Re-treatment performed where inadequate stone fragmentation was observed on plain X-ray KUB after extracorporeal shock wave lithotripsy (ESWL). Cases in which there was no disintegration of stone after two sessions of ESWL was observed were considered as ESWL failure, and patients were then treated with ureterorenoscopic (URS) manipulation / open ureterolithotomy. For residual stone after ureterorenoscopic manipulation we did ancillary procedures including ESWL / double J stenting.

DATA ANALYSIS PROCEDURE

Data was entered and analyzed in social science software, version 16 (SPSS-16). Frequency and percentage were computed for categorical variables like age groups, gender, socioeconomic status, presenting complaints, past history, co-morbid and stone free status. Mean, standard deviation and 95% confidence interval were computed for quantitative measurement like age and stone size. Chi-square test was applied to compare proportion of gender, socioeconomic status and stone free rate between groups. Independent sample test was applied to compare mean difference between groups for age and stone size. $P<0.05$ was considered level of significant. Stratification was done with regard to age, gender and stone size to observe the effect on outcomes.

RESULTS:

A total of 100 patients with proximal ureteric stone of 10 to 15 mm were included in this study. Patients were equally divided into two groups. Group A patients were treated by extracorporeal shock wave lithotripsy (ESWL), and patients in group B were treated by ureterorenoscopic (URS) manipulation. Most of the patients were between 31 to 60 years of age as presented in figure 1. The average age of the patients was 42.54±14.07 years (95% Cl: 41.14 to 46.53). Similarly average stone size was 12.45±3.45 mm (95% Cl: 11.24 to 13.65) as presented in table 1.

Out of 100 patients, 72 (72%) were male and 28 (28%) were female as shown in table 2. Significant difference was not observed between groups in gender (p=0.73). Average age and stone size were also not significant between groups as presented in table 3.

Regarding socioeconomic status of the patients, most of the patients were in poor and middle class (table 4). The commonest presenting complaint was renal colic i.e. 80%, followed by vomiting and nausea 50%, haematuria 19%, burning 10% and fever 22.6% and these were also presented with respect to groups in table 5.

The overall stone free status at 1 week of the treatments is presented in table 6. Success rate of ureterorenoscopy (URS) remained high than extracorporeal shock wave lithotripsy (ESWL), but the statistically significant difference was not observed between groups (49% vs. 57%; p=0.088). Stone free status at 1 week was 49% in ESWL group. In total, 40% patients required 2nd session of ESWL for disintegration, out of these 22% patients required ancillary treatment like URS. Regarding the complication, steinstrasse was observed in 7%, UTI was 5% and haematuria was found in 5%. While in URS group, stone free status was 57.8% and 11% patients required repeated ureteroscopy. Ancillary treatments like ESWL / Ureteric stenting / Double J stent were done in 18%. Proximal ureteric stone migration was observed in 10%, UTI 5% and fever was observed in 20%.

When we stratified the cases according to gender, age and stone size, stone free rate was greater in group B than group A in gender and different age groups but significant difference was also not observed between groups as presented in table 7 and 8 respectively. While Stone free rate was significantly higher in URS group than ESWL group (p=0.020) for stone size >12mm as presented in table 9.

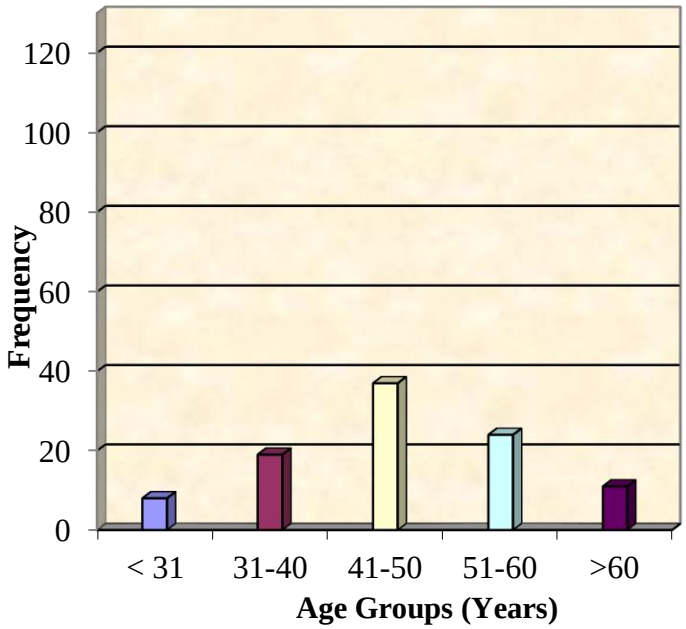

Figure 1: AGE DISTRIBUTION OF THE PATIENTS
n= 100

Table 1: DESCRIPTIVE STATISTICS OF STUDY VARIABLES
n= 100

Variables	Mean ± SD	95%Cl	Median(IQR)	Max-Min
Age (years)	42.54±14.07	41.14 to 46.53	46(12)	60 -19
Stone Size (mm)	12.45±3.45	11.24 to 13.65	12(5)	15-15

Table 2: GENDER DISTRIBUTION

Gender	Group A (ESWL) n=50	Group B (URS) n=50	Total n=100
Male	35(70%)	37(74%)	72(72%)
Female	15(30%)	13(26%)	28(28%)

Chi-Sqaure =0.114 p=0.73

Table 3: DESCRIPTIVE STATISTICS OF STUDY VARIABLES

Variables	Group A (ESWL) n=50	Group B (URS) n=50	P-Values
Age (years)	44.32±10.07	45.41± 13.21	0.68
Stone Size (mm)	10.84±4.25	11.32±3.74	0.54

Table 4: COMPARISON OF SOCIOECONOMIC STATUS BETWEEN GROUPS

Socioeconomic Status	Group A (ESWL) n=50	Group B (URS) n=50	Total n=100
Poor	26(52%)	28(56%)	54(54%)
Middle	15(30%)	14(28%)	29(29%)
High	9(18%)	8(16%)	17(17%)

Chi-square= 1.26 p= 0.53

Table 5: PRESENTING COMPLAINTS

Presenting Complaints	Total
Colic	80(80%)
Vomiting	50(50%)
Fever	5(5%)
Burning	10(10%)
Nausea	50(50%)
Haematuria	19(19%)

Table 6: COMPARISON OF FREQUENCY OF STONE CLEARENCE BETWEEN THE TWO GROUPS AT ONE WEEK

Stone Status at 1 week	Group A (ESWL) n=50	Group B (URS) n=50	Total n=100
Free	24.5(49%)	28.5(57%)	53(53%)
Not Free	25.5(51%)	21.5(43%)	47(47%)

Chi-square= 2.919 p=0.088

Table 7: COMPARISON OF FREQUENCY OF STONE CLEARENCE BETWEEN THE TWO GROUPS AT ONE WEEK WITH RESPECT TO THE GENDER

Gender	Stone Status at 1 week	Group A (ESWL) n=50	Group B (URS) n=50	P-Values
Male (n=72)	Free Not free	18 17	22 15	0.09
Female (n=28)	Free Not free	6 9	7 6	0.63

Table8: COMPARISON OF FREQUENCY OF STONE CLEARENCE BETWEEN GROUPS AT ONE WEEK WITH RESPECT TO AGE GROUPS

Age Groups	Stone Status at 1 week	Group A (ESWL) n=50	Group B (URS) n=50	P-Values
19 to 40 (n=33)	Free Not free	11 4	14 4	0.56
41 to 50 (n=30)	Free Not free	7 11	8 4	0.58
>50 (n=37)	Free Not free	6 11	7 13	0.175

Table 9: COMPARISON OF FREQUENCY OF STONE CLEARENCE BETWEEN GROUPS AT ONE WEEK WITH RESPECT TO SIZE OF STONE

Stone Size	Stone Status at 1 week	Group A (ESWL) n=50	Group B (URS) n=50	P-Values
≤ 12 mm (n= 44)	Free Not free	10 12	10 12	0.97
>12 mm (n= 56)	Free Not free	14 14	19 9	0.020

DISCUSSION:

With the development of advanced instruments and techniques, minimally invasive surgical procedures have gradually replaced open surgery for treating proximal ureteric stones.[16] To choose between active stone removal and conservative treatment, it is important to take into account all individual circumstances that may affect treatment decisions.[17] Stone removal is indicated in the presence of persistent obstruction, failure of stone progression, or in the presence of increasing or unremitting colic.[18] For proximal ureteric calculi, the chance of spontaneous passage is lower than that of mid and distal ureteric calculi. According to guidelines of urolithiasis 2010, the Panel performed a meta-analysis of studies in which spontaneous ureteral stone passage was assessed. The median probability of stone passage was 68% for stones <5 mm (n=224) and 47% for those >5 and <10mm (n=104) in size. The Panel recognized that these studies had certain limitations including non-standardisation of the stone size measurement methods and lack of analysis of stone position, stone-passage history, and time to stone passage in some. Although patients with ureteral stones >10 mm could be observed or treated with medical expulsive therapy (MET), in most cases such stones will require surgical treatment. No recommendation can be made for spontaneous passage (with or without medical therapy) for patients with large stones.[19] Extracorporeal shock wave lithotripsy (ESWL) and ureterorenoscopy (URS) are the most common modalities for treatment of ureteral stones, but the first choice of treatment between the two modalities is still the bone of contention.

The main problem is that stone in the ureter are often more difficult to locate and, therefore more difficult to target with the shock wave. However several studies have demonstrated stone-free rate close to 100% for the treatment of proximal ureteral stone with the extracorporeal shockwave lithotripsy (ESWL). However, stone free rate appear to decline to 70% for mid ureteral stone for many lithotripters.[20] The number of previous randomized trials of URS v/s ESWL for proximal ureteric stone is very limited. Most of the previous studies addressing this issue were retrospective in design.[21] these retrospective reviews have been the only evidence base for advocating the merits of 1 treatment over the other. Kijvikai K et al suggested that URS achieved excellent result and should be considered first-line therapy for proximal ureteric stones greater than 1cm.[22] Zanetti et al experienced an overall stone free rate of 50% in ESWL and 80% in URS.[23] Radulovic S et al found that 83.6% of patients with proximal ureteric stone became stone free after one session of ESWL.[24] Wu CF et al achieved an overall stone free

rate of 83.3% but with high re-treatment rate about 60% after ESWL.[25] In our study stone free rate at 1 week is 49% in ESWL and 57% in URS. We also did the follow up of patients up to 1 month and performed re-treatment / Secondary treatment to make them stone free if required. In group A (patients treated with ESWL) we did 2nd session in 40 % of patients and out of them 22% underwent URS / JJ stenting. Double j stent is used to prevent complication after ESWL like ureteric obstruction, especially in cases of large stone burden. However, DJ stents themselves can cause complications. After all efforts we achieved the stone free rate of 59 % after ESWL and 68% after URS in 1 month follow up.

Ziaee SA et al treated patients by URS with stone size <15mm, they reached an initial stone free rate of 70%. While shock wave application is contraindicated during pregnancy[26.] Semins MJ et al. successfully treated 10 pregnant women by ureteroscopy and intracorporeal lithotripsy and did not note obstetric or urological complication[27].

In group B (patients treated with URS) re-treatment was required in 11 % of the patients and ancillary treatment like double J stent/ ESWL / ureteric stenting in 18% of patients. Stone migration was observed in 10 % of patients, while Kawano AM et al[28] experienced 8 % rate of stone migration.

Tamsulosin (selective alpha-1 D adrenergic inhibitor) used as an adjunct to extracorporeal shockwave lithotripsy (ESWL) for renal and ureteric stone improves stone clearance rate, and reduce the symptom of ureteric colic and analgesic requirement[29].

Finally each treatment modality has its own advantages and disadvantages, and several factors will influence the choice of treatment. Studies have reported overall complication rate after ureteroscopy of 10-20% [30.]

CONCLUSION:

Although ESWL is regarded by many urologists as the preferred choice of treatment for proximal ureteric stone, our results suggest that ureterorenoscopic manipulation (URS) with intracorporeal lithotripsy is a viable and safe alternative, with an advantage of obtaining an earlier or immediate stone-free status. Laparoscopic approaches are reasonable alternatives in rare cases, where ESWL and URS have failed.

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