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Comparison of the Intracorporeal Ultrasonic Lithotripsy and Intracorporeal Pneumatic Lithotripsy in Terms of Stone Removal and Postoperative Complications

Mohammad Ayub[1], Shah Jahan[2], Fiaz Ahmad Tauqeer[3], Faisal Masoud[4], Ijaz Siddiqui[5], Muhammad Nazir[6]

1 *Associate Professor, Department of Urology, PGMI / AMC / Lahore General Hospital, Lahore Pakistan*
Study Idea & design

2 *Assistant Professor, Department of Urology, FJMU / Sir Ganga Ram Hospital, Lahore Pakistan*
Statistical analysis

3 *Senior Registrar, Department of Urology, Pakistan Kidney and Liver Institute, Lahore Pakistan*
Manuscript review

4 *Senior Registrar, Department of Urology, Lahore General Hospital, Lahore Pakistan*
Data collection

5 *Senior Registrar, Department of Urology, Lahore General Hospital, Lahore Pakistan*
Data collection

6 *Professor & Head, Department of Urology, Hemodialysis & Kidney Transplantation, PGMI/AMC/ Lahore General Hospital, Lahore Pakistan*
Critical review

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CORRESPONDING AUTHOR
Dr. Mohammad Ayub
Associate Professor, Department of Urology, PGMI / AMC / Lahore General Hospital, Lahore Pakistan
Email: drmayub5@gmail.com

ABSTRACT

Background: Urolithiasis is the most common and painful urological disease. Intracorporeal lithotripsy has high success rate in management of ureteric stone. **Objective:** To do comparison of the intracorporeal ultrasonic lithotripsy and intracorporeal pneumatic lithotripsy in terms of rate of stone removal and post-operative complications. **Study Design:** Randomized Control Trial. **Settings:** Department of Urology, Lahore General Hospital, Lahore Pakistan. **Duration:** Six months from September 01, 2015 to February 29, 2016. **Methodology:** Total sixty patients were selected fulfilling the inclusion criteria into 2 groups. In group A, 30 patients were selected for intracorporeal ultrasonic lithotripsy and in group B, 30 patients were selected for intracorporeal pneumatic lithotripsy. In both groups all patients were compared in terms of rate of stone removal and postoperative complications then results were analyzed by SPSS 21. **Results:** Mean stone size in group A (Ultrasonic lithotripsy) was 1.13 ± 0.17 cm and in group B (Pneumatic lithotripsy) was 1.14 ± 0.18 cm. At first week after procedure, in group A 25(83.33%) and in group B 21(70%) of the cases had stone clearance, at 2nd week after procedure a total of 26(86.66%) in group A and 24(80%) cases in group B had stone clearance. At 3rd week after procedure there were 28(93.33%) cases in group A and 27(90%) cases in group B had stone clearance. The stone clearance in both groups at each follow up was statistically insignificant, p-value > 0.05. At 1st week, in group A 3(10%) cases and in group B 6(20%) cases had pain, at 2nd week after procedure there were 1(3.33%) cases in group A and 3(10%) in group B who reported pain and at 3rd week after procedure there were 1(3.3%) case in each group had pain. The pain at each follow up was statistically same in both groups, p-value > 0.05. According to complications, in group A and group B, 2(6.66%) and 3(10%) cases had fever, 3(10%) and 4(13.33%) had infection respectively. Only one case (3.3%) had retention of urine. All complications were statistically same in both groups, p-value > 0.05. **Conclusion:** Through the findings of this study we conclude that both intracorporeal pneumatic lithotripsy and intracorporeal ultrasonic lithotripsy are equally effective and had fewer complications. However, the ultrasonic procedure had higher rate of stone removal at each follow up (but difference was insignificant with similar morbidity compared to pneumatic devices.

Keywords: *Lithotripsy, Intracorporeal ultrasonic, Pneumatic lithotripsy, Stone clearance.*

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INTRODUCTION

Urolithiasis has been acknowledged across the world since ancient times. It is the most common and painful urological disorder. The affirmation of urolithiasis has been found in 7 Thousand years old Egyptian Mummy. Its occurrence has been increased significantly during the Twentieth Century.[1] Pakistan also located on the stone forming belt. In Pakistan the prevalence of urinary stones ranges from 4% to 20%.[2] Ureteric stones constitute a common condition that urologists experience in everyday practice and usually present with severe loin pain and hematuria. Spontaneous ureteral stone passage depends upon stone size and location. Spontaneous passage for stones less than 0.4 cm is about 80%, where only 21%

stones larger than 0.6 cm do so.[3] 26% of ureteric stones are present in upper ureter, 5.03% stones in mid ureter, 32.3% stones in lower ureter while 31.5% stones are present at vesicoureteric junction.[4] Surgical interventions are usually indicated in failure of medical management, obstructed solitary kidney, unaccommodating pain, urinary sepsis and choice of the patients as well.[5] There are various treatment options for calculi that do not pass or are unlikely to pass spontaneously.[6] (Bader MJ et al 2012) Treatment options include: MET (Medical Expulsive Therapy), ESWL (extracorporeal shock wave lithotripsy), Ureteroscopic Lithotripsy, PCNL (Percutaneous Nephrostolithotomy), Laparoscopic / Open stone removal, and/or a combination of these options. Research proved that spontaneous stone passage has been increased by medical management. Even with multiple studies demonstrating the benefits of MET, still it's underutilized as a treatment modality.[7]

Treatment options vary according to stone size, location, endourological facilities and patient choice. The most commonly performed procedure for ureteral calculi is retrograde ureteroscopy. Ureteral stones can also be dealt by Laparoscopic ureterolithotomy and antegrade ureteroscopy, preventing from the open ureterolithotomy. Due to the non-availability of endourological instruments and lack of expertise, open ureterolithotomy is still common in Pakistan. The sources of energy for intracorporeal lithotripsy are: electrohydraulic, ultrasonic, pneumatic and laser.[8]

For distal ureteric stones ureteroscopy is more effective than extracorporeal shock wave lithotripsy. Patients with stone size more than 10 mm, impaction and severe colicky pain, ureteroscopy is the best treatment option and open surgery is rarely carried out. Current indications include cases involving the anatomical ureteric abnormalities, impacted stones, and failure of the minimally invasive modalities.[9]

Obstructive uropathy due to urinary stones is a medical emergency and requires urgent diagnosis and treatment for the purpose of decompression.

Ureterorenoscopic lithotripsy has high success rates with minimal morbidity and can be performed with safety in selected subjects.[10] As ureteroscopy is a proved minimally invasive therapy for ureteric stones with significant success rates and less morbidity and current approaches broadened the indication for ureteric calculi, so we aspire to compare the ultrasonic and pneumatic lithotripsy for the lower ureteric stones treatment in terms of rate of stone removal and post-operative complications. As there is few data regarding comparison of these two aforementioned techniques in our setup, so we intend to do comparison of ultrasonic and pneumatic lithotripsy in lower ureteric stone management.

The objective of the study was to compare the intracorporeal ultrasonic lithotripsy and intracorporeal pneumatic lithotripsy in terms of rate of stone removal and post-operative complications.

METHODOLOGY

Study Design: Randomized Control Trial.

Settings: Department of Urology, Lahore General Hospital, Lahore Pakistan.

Duration: Six months from September 01, 2015 to February 29, 2016.

Sample Technique: Non-probability purposive sampling technique was used for sample selection and treatment allocation was done randomly with the help of random number table.

Sample Size: Sample size of 60 cases; 30 cases in each group is calculated with 80% power of test, 5.5% level of significance and taking expected percentage of success i.e. 95% with ultrasonic lithotripsy and 80.5% with pneumatic lithotripsy in patients with ureteral stones by following formula:

$$n = \frac{\{z_{1-\alpha}\sqrt{2D(1-D)} + z_{1-\beta}\sqrt{P_1(1-P_1)+P_2(1-P_2)}\}^2}{(P_1-P_2)^2}$$

Where

α = level of significance = 0.055, β = power of study = 0.80, p1 = proportion of sample 1 = 0.95, p2 = proportion of sample 2 = 0.805, D = difference between two proportions = P_1-P_2 = 0.95 – 0.805 = 0.145

Inclusion Criteria: Single stone up to 1.5cm, Unilateral lower ureteric stone, Stones failure to medical expulsive therapy and age above 18 years were included.

Exclusion Criteria: Patients were excluded i.e. immuno-compromised patients, Patients unfit for surgery, Pregnancy, Urosepsis and DJ placement. All patients were operated under general anesthesia.

Data Collection Procedure: Formal approval from the ethical committee and a written consent from each patient were obtained before proceeding. The patients were explained about the outcome and the complications involved, all was according to proforma designed for it. Sixty patients were admitted from OPD of Lahore General Hospital, Lahore fulfilling the inclusion criteria. Patients were randomly divided into two equal groups like, Group I: 30 patients were underwent ultrasonic lithotripsy and in Group-II 30 patients underwent pneumatic lithotripsy. All admitted patients were diagnosed on the basis of history, clinical examination, baseline investigations and some specific investigations like urine culture & sensitivity, USG KUB, plain X-rays KUB, IVU and CT KUB if needed. Informed consent was obtained before operation. Pre-operative antibiotic of Cefoperazone + Sulbactam 2gm intravenously was given after test dose 30 minutes before surgery. Post-operatively Cefoperazone + Sulbactam 2gm intravenously was repeated 6 hours after the procedure.

PROCEDURE

Intracorporeal Ultrasonic Lithotripsy: Under G/A, in lithotomy position, after all aseptic measures, with lignocaine gel application feeding tube was passed per urethra. Ureterorenoscope was introduced and then advanced towards the affected site after identifying the ureteric orifice. Guide wire was passed through the ureteric orifice. Then ureterorenoscope was advanced into the ureter. Stone was identified and ultrasonic probe was introduced through the ureterorenoscope up to stone and fragmentation of stone was done with intracorporeal ultrasonic lithotripter. After that URS was withdrawn and bladder was emptied.

Intracorporeal Pneumatic Lithotripsy: Under G/A, in lithotomy position, after all aseptic measures, with lignocaine gel application feeding tube was passed per urethra. Ureterorenoscope was introduced and then advanced towards the affected site after identifying the ureteric orifice. Guide wire was passed through the ureteric orifice. Then ureterorenoscope was advanced into the ureter. Stone was identified and pneumatic probe was introduced through the ureterorenoscope up to stone and fragmentation of stone was done with intracorporeal pneumatic lithotripter. After that URS was withdrawn and bladder was emptied.

Data Analysis Procedure: Data calculated was entered and analyzed by using SPSS 21 version. The gender would be expressed in percentages. Quantitative variable age was described by Mean ± S.D for both groups. The rate of complete removal of stone would be expressed in terms of percentages in tabulated form. Qualitative variables like complication rate and postoperative pain was described by using table of frequencies, percentages and graph.

RESULTS

The mean ages in group A and B was 34.77 ± 13.05 years and 34.37 ± 11.16 years with age range of 46 years (19 years to 65 years), p-value = 0.899. In Group–A there were 18(60%) male and 12(40%) female cases while in group-B there were 21(70%) male and 9(30%) female cases [(p-value= 0.417 (>0.05)] The mean stone size in group-A was 1.13 ± 0.17 cm and in group-B was 1.14 ± 0.18 cm with no statistical difference, p-value 0.826 (>0.05) In group –A there were 18(60%) cases who had right and 12(40%) cases had left side involvement while in group-B there were 14(46.67%) who had right and 16(53.33%) cases had left side involved. The side involvement in both groups was statistically same, i.e. p-value = 0.301 (>0.05). At first week after procedure, in group-A 25(83.33%) and in group-B 21(70%) of the cases had stone clearance, at 2nd week after procedure a total of 26(86.66%) in group A and 24(80%) in group B had stone clearance. At 3rd weeks after procedure there were 28(93.33%) cases in group A and 27(90%) cases in group B had stone clearance. The stone clearance in both groups at each follow up was statistically insignificant, p-value > 0.05. At 1st week, in group-A 3(10%) cases and in group-B 6(20%) cases had pain, at 2nd week after procedure there were 1(3.33%) cases in group-A and 3(10%) in group-B who reported pain and at 3rd week after procedure there were 1(3.3%) case in each group had pain. The pain at each follow ups was statistically same in both group, p-value > 0.05. According to complications, in group – A and group-B, 2(6.66%) and 3(10%) cases had fever, 3(10%) and 4(13.33%) had infection respectively. Only one case in Group B (3.3%) had retention of urine. All complications were statistically same on both groups, p-value > 0.05.

Table 1: Demographic characteristics of patients

	Ultrasonic lithotripsy	Pneumatic lithotripsy
N	**(n=30)**	**(n=30)**
Age (Years)	34.77±13.05	34.37±11.16
Gender (Male/Female)	18(60%)/12(40%)	21(70%)/9(30%)
Side Involved (Right/Left)	18(60%)/12(40%)	14(46.67%)/16(53.33%)
Stone Size	1.13±0.17	1.14±0.18

Table 2: Clinical characteristics of study participants

		Ultrasonic lithotripsy	Pneumatic lithotripsy	p-value*
Stone Clearance	**1st Week**	25 (83.33%)	21 (70%)	**0.22**
	2nd Week	26 (86.66%)	24 (80%)	**0.488**
	3rd Week	28 (93.33%)	27 (90%)	**0.640**
Postoperative Pain	**1st Week**	3 (10%)	6 (20%)	**0.278**
	2nd Week	1 (3.3%)	3 (10%)	**0.301**
	3rd Week	1 (3.3%)	1 (3.3%)	**-**
Complication	**Fever**	2 (6.66%)	3 (10%)	**0.640**
	Infection	3 (10%)	4 (13.33%)	**0.688**
	Urine Retention	0 (0%)	1 (3.33%)	**0.313**

*: Chi Square Test was applied to calculate the p-value

DISCUSSION

In this era, new gadgets such as laser with rigid or flexible ureteroscopes are available and so the other techniques such as ultrasonic and pneumatic lithotripsy are being replaced where laser is available. On reviewing the available literature no ample data for the evaluation of ultrasonic lithotripsy alone or in comparison with other modalities in ureteric stones is present. Perhaps, this is because of rapid development in electrohydraulic and lasers. Hence the total number of studies which report the results of ultrasonic techniques, are limited. Due to availability of this instrument in our department and due

to scarce data in literature, we present our experience in this study. Treatment modalities which are more popular for ureteric stones treatment are ESWL and intracorporeal lithotripsy. The use of ESWL was approved as a treatment modality of choice by American Urological Association.[11] But a progressive decline has been observed day by day because of its lower success rates, advancements and improvements in fibre optics and endoscopic gadgets. (intracorporeal lithotripsy).[12]

Several other intracorporeal lithotripsy alternatives includes electrohydraulic, laser and pneumatic lithotripsy.[13] Proportionately hard calculi may restrict the effectiveness of ultrasonic lithotripsy while the pneumatic probes are operational in fragmenting even hardest calculi but still there is a need of succeeding extraction of the fragments.

Time and again, ultrasonic devices used to sliver large and harder stones with aspiration of small stone specks as a result of pneumatic devices or alternatively.[14]

Zeidan in 2017 conducted a study and reported that patients with mean age of 43 years (22 to 68), underwent semirigid ureteroscopy with ultrasonic probe in a stone size of ≤1.5 cm and the stone removal rate was 95.7%.[15] In current study the mean age was 34.57 ± 12.04 years and there were 39(65%) male and 21(35%) female cases with ratio as 1.85:1. At 3rd weeks follow up, about 28(93.33%) cases in A group and 27(90%) cases in B group showed stone clearance and it was insignificant statistically with a p value of >0.05.

In a study conducted by Khan IU,[16] in pneumatic lithotripsy group the delayed stone removal rate was 98.3% for lower ureter, while in a study by Tipu SA *et al* the stone removal rate was 89.2% for pneumatic lithotripsy group.[17] Garg S *et al* reported the delayed stone free rate 84%[18] and in a study by Nutahara K *et al*, the delayed stone free rate was 97%.[19] Our results of stone free rate for ureteroscopy using pneumatic were 90% as mentioned elsewhere in this text while the efficacy of ultrasonic lithotripsy was 93.33% which is comparable to other mentioned studies and to the literature available.

Park K *et al* conducted a study regarding the incidences of acute postoperative pain which was about 14.6% collectively. Among the 21 patients with acute postoperative pain, 14 patients complained of moderate acute postoperative pain (VAS, 4 to 6), and 7 patients complained of severe acute postoperative pain (VAS, 7 to 10).[20]

Ten patients with moderate acute postoperative pain underwent placement of a ureteral stent. On the other hand, no patient with severe acute postoperative pain underwent placement of a ureteral stent (p=0.004). Four patients with severe acute postoperative pain required a stone basket intraoperatively, which was one more than in those with moderate acute postoperative pain. The pain of 11 patients with moderate acute postoperative pain was well controlled with intravenous or intramuscular injection of nonsteroidal anti-inflammatory drugs (NSAIDs), whereas 4 patients with severe acute postoperative pain did not tolerate NSAIDs and needed opioid agents. while in our study it was concluded that at 1st week, in group A 3(10%) cases and in group B 6(20%) cases had pain, at 2nd week after procedure there were 1(3.33%) cases in group A and 3(10%) in group B who reported pain and at 3rd week after procedure there was only 1(3.3%) case in each group had pain. The pain at each follow ups was statistically same in both groups, p-value > 0.05. No stents used in our study at all and pain was managed according to standard treatment strategies and varied from patient to patient.

In a study conducted by Falahatkar S *et al*,[21] fever was observed in 4% of patients only while other signs of infection like dysuria and flank pain observed in 46% and 39 % of patients respectively while in our study, in group A and group B, 2(6.66%) and 3(10%) cases had fever, 3(10%) and 4(13.33%) had infection respectively. On the other hand, in a study conducted by Park K *et al*,[20] retention of urine was observed in 2.8% of patients while in our study retention of urine was observed in group B patients 3.33 % and in case of group A patients no such complication noted.

Our study has several limitations as it was designed as a prospective study with an additional limitation of less number of patients and scarce data available. However, further research on stone size and the cutoff value of surgery time is needed from a large patient cohort. The limitation also include that it conducted on distal ureteric stones only so further work up is needed to evaluate its results on upper and mid ureteric stones. More studies are required on hard stones (high HU) and on impacted stones as well. Miniaturizing of ureteroscopes also limits the use of ultrasonic probes. One more thing is worth mentioning regarding our experience during the use of ultrasonic probe in ureteric calculi, care must be taken into account for not bending the probe which may lead to energy loss at the convexity of the bend, energy being transformed to heat, increase in fragmentation time and impending breakdown of the probe and higher suction pressures tend to draw air bubbles into the system so impeding vision.

CONCLUSION

Through the findings of this study, we concluded that both intracorporeal pneumatic lithotripsy and intracorporeal ultrasonic lithotripsy are equally effective and had fewer complications. However, in ultrasonic lithotripsy the stone free rates were higher at each follow up (but the difference was insignificant) with almost similar morbidity compared with pneumatic devices.

LIMITATIONS

This study was conducted at one center but incidence of stone disease is very high. Hence, we recommend further

extension of this study to multiple centers, to formulate guidelines regarding supremacy of one source of energy over another, in better stone clearance.

SUGGESTIONS / RECOMMENDATIONS

In order to decrease prevalence of stone disease, government should start campaign on media to educate masses about risk factors involved in stone formation.

CONFLICT OF INTEREST / DISCLOSURE

The authors have no conflict of interest in this study.

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