CODEN [USA]: IAJPBB ISSN : 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES

SJIF Impact Factor: 7.187

https://doi.org/10.5281/zenodo.5839227

Available online at: http://www.iajps.com *Research Article*

TO COMPARE THE FREQUENCY OF STONE CLEARANCE IN PATIENTS UNDERGOING ULTRASONIC LITHOTRIPSY WITH PNEUMATIC LITHOTRIPSY FOR THE TREATMENT OF LARGE RENAL CALCULI.

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Article Received: December 2021 **Accepted:** December 2021 **Published:** January 2022

Abstract:

Introduction: *Percutaneous approach to kidney was first described in 1955 by Goodwin and colleague.[1] This approach, with the insertion of nephrostomy tube, was used to provide drainage for obstructed renal unit. This example led to recognition that same access could also be used as a working channel for the percutaneous removal of the kidney stone. Thus began era of percutaneous renal surgery.[2] The indications for PCNL have gradually changed with improvement of techniques and with the introduction of extracorporeal shockwave lithotripsy (SWL) into clinical practice .[3] PCNL is generally a safe treatment option and associated with a low but specific complications rate. Many complications develop from the initial puncture with injury of surrounding organs (e.g. colon, spleen, liver, pleura, and lung). Other specific complications include postoperative bleeding and fever.[5,6]*

Objective: *To compare the frequency of stone clearance in patients undergoing ultrasonic lithotripsy with pneumatic lithotripsy for the treatment of large renal calculi.*

Study Design: *Randomized Clinical Trial.*

Setting: *The study was completed at department of Urology, Sindh Institute of Urology and Transplantation Karachi.*

Duration Of Study: *Six months after approval of synopsis. (Jan, 2018 to July 2018)*

Subject And Methods: *After approval from research evaluation unit of college of Physicians and Surgeons of Pakistan (CPSP) and ethical committee of the hospital, patients who were present in urology department of Sindh Institute of Urology and Transplantation fulfilling the inclusion criteria were included in this study until the required sample size of 128 patients is completed. An informed consent was taken from all patients before including them in this study. Patients were divided into two groups using lottery method. Group I: Patients pneumatic lithotripsy was used for the treatment of renal calculi and in Group II patient's ultrasonic lithotripsy was used. Both of these procedures were done by senior. Post-procedural X-ray KUB was done 3 days after the surgical procedure to determine the stone clearance in every patient.*

Results: *62(96.9%) patients had stone free rate in group ultrasonic lithotripsy, 51(79.7%) patients had stone free rate in group Pneumatic lithotripsy overall 113(88.3%) patients had stone free rate in both groups.*

Conclusion: *, Pneumatic and ultrasonic lithotripters were compared, and both of them were found to be effective, safe, and reliable management modalities. However, the ultrasonic lithotripter provided higher stone-free rates.*

Key Words: *Percutaneous Nephrolithotomy (PCNL), Stone free rate, large Renal Stones, pneumatic lithotripsy, ultrasonic lithotripsy.*

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Please cite this article in press Shoukat Ali et al, ***To Compare The Frequency Of Stone Clearance In Patients Undergoing Ultrasonic Lithotripsy With Pneumatic Lithotripsy For The Treatment Of Large Renal Calculi.,*** *Indo Am. J. P. Sci, 2022; 09(01).*

INTRODUCTION:

Percutaneous approach to kidney was first described in 1955 by Goodwin and colleague.[1] This approach, with the insertion of nephrostomy tube, was used to provide drainage for obstructed renal unit. This example led to recognition that same access could also be used as a working channel for the percutaneous removal of the kidney stone. Thus began era of percutaneous renal surgery.[2] The indications for PCNL have gradually changed with improvement of techniques and with the introduction of extracorporeal shockwave lithotripsy (SWL) into clinical practice .[3] The combination of these modalities have resulted in treatments which are less invasive and offer a shorter hospital stay with an earlier return to work when compared to open surgery.[4] PCNL is generally a safe treatment option and associated with a low but specific complications rate. Many complications develop from the initial puncture with injury of surrounding organs (e.g. colon, spleen, liver, pleura, and lung). Other specific complications include postoperative bleeding and fever.[5,6]

The risk of transfusion related diseases in the postoperative period remains a critical issue. It is an assumption that the open surgery for renal calculi is associated with a greater blood loss and consequently higher transfusion rate. PCNL as monotherapy, sandwich therapy or with adjuvant treatment modalities, is an accepted minimally invasive surgical treatment for renal calculi.[7] Blood loss during PCNL is assumed to be less as compared to open surgery. The procedure entails access and manipulation through the pelvicalyceal system with potentials for trauma to the segmental and interlobar renal vessels and thus results in haemorrhage.[8] The kidneys are highly vascular organs and are supplied by 20% of the cardiac output. The stones could be infected, the renal function compromised and large stone bulk could prolong the operative time and consequently blood loss. Although technological refinements and increased surgical experience have ensured the procedure's successful execution, complications including; bleeding, collecting system injuries, adjacent structure injuries, intraoperative technical complications, hypothermia, fluid overload, sepsis, stricture formation, nephrocutaneous fistula, kidney loss, and even mortality, can still occur.[9,10]

Results of my study were used for the better outcome of these patients and also it provides baseline data which werealso helpful for other healthcare professionals in future as no such study has been done previously in Karachi Pakistan.

OBJECTIVE:

The objective of my study was:
To compare the frequency of stone clearance in patients undergoing ultrasonic lithotripsy with pneumatic lithotripsy for the treatment of large renal calculi.

HYPOTHESIS:

Frequency of stone clearance is high in patients treated with ultrasonic lithotripsy as compared to the patients treated with pneumatic lithotripsy alone for the management of large renal calculi.

MATERIAL AND METHODS:

SAMPLING TECHNAQUE: Non-probability, Consecutive sampling

SAMPLE SELECTION:

Inclusion criteria:

- Patients having age 15-60 years
- Both genders male and female
- Patients with diagnosis of Large renal calculi (Calculus size >20 mm), who were planned for PCNL were selected for this study.
- Patients with any duration of kidney stone disease were included.

Exclusion criteria:

- Patients with untreated urinary tract infections (UTI) diagnosed on routine clinical examination and urine analysis report were excluded because these conditions can affect stone clearance rate after the procedure.

STUDY DESIGN: Randomized Clinical Trial.

SETTING: The study was completed at department of Urology, Sindh Institute of Urology and Transplantation Karachi.

DURATION OF STUDY: Six months after approval of synopsis. (Jan, 2018 to July 2018)

SAMPLE SIZE:
The sample size for this study is calculated by using the results of a previous study using the flowing formula;

$$n = (Z_{\alpha/2}+Z_{\beta})^2 * (p_1(1-p_1) + p_2(1-p_2)) / (p_1-p_2)^2,$$

frequency of stone clearance using ultrasonic lithotripsy (P1) : 96.9%[8]
Frequency of stone clearance using pneumatic lithotripsy (P2) : 81.9%[8]
At power of the test (β) 80.0% and level of significance (α) 5.0% the calculated sample size is 64 patients in each group. The total sample size is 128 patients.

DATA COLLECTION PROCEDURE:
After approval from research evaluation unit of college of Physicians and Surgeons of Pakistan (CPSP) and ethical committee of the hospital, patients who were present in urology department of Sindh Institute of Urology and Transplantation fulfilling the inclusion criteria were included in this study until the required sample size of 128 patients is completed. An informed consent was taken from all patients before including them in this study. Patients were divided into two groups using lottery method. I was make folded papers containing name Group I and Group II and ask the patient to pick up one paper. Patients were divided into groups depending upon the folded paper chosen by them. Group I: Patients pneumatic lithotripsy was used for the treatment of renal calculi and in Group II patient's ultrasonic lithotripsy was used.

Both of these procedures were done by senior surgeons having experience of at least 5 years after fellowship. I (the investigator) wereserve as assistant in all these procedures. Post-procedural X-ray KUB was done 3 days after the surgical procedure to determine the stone clearance in every patient. All the gathered information regarding stone clearance and other relevant information regarding patient were recorded on a pre-designed Proforma (Annexure-I).

DATA ANALYSIS PROCEDURE:
Data analysis was carried out using SPSS v20.0. Mean and standard deviations were calculated for quantitative variables like age, duration of renal stone disease, BMI and size of renal stones. Categorical variables like gender, hypertension and stone clearance rate were presented as frequency and percentage. Chi-square test was used to compare stone clearance rate between groups. P-value $\leq$0.05 were taken as significant difference. Stratification of confounder variables e.g. age, gender, BMI, hypertension, duration of renal stone disease andsize of renal stones were done. Post stratification Chi-square test were applied taking P-value $\leq$0.05 as significant difference.

RESULTS:
128 patients fulfilling selection criteria were included in the study; Patients were divided equally into two groups.

In table 1 Demographic data, stone, and operative characteristics was stated. .Mean age of the patients was 50.2±10.8, 48.5±9.8,and 48.7±8.8 in years ,in group I, group II and total respectively , Mean stone size of the patients was 28.9±3.41, 27.3±4.21,and 27.5±3.91 in mm ,in group I, group II and total respectively , Mean duration of renal stone of the patients was 25.6±9.41, 29.4±7.79,and 28.3±8.1 in years ,in group I, group II and total respectively , Mean BMI of the patients was 24.8±3.25, 25.9±4.58,and 25.8±2.9,in group I, group II and total respectively, Distribution of gender was stated, where 39(60.9%), 42(65.6%) and 81(63.3%) study subjects were male in group I, group II and total respectively, and 25(39.1%), 22(34.4%) and 47(36.7%) were female patients in group I, group II and total respectively, While 29(45.3%), 31(48.4%) and 60(46.9%) study subjects were having history of hypertension in group I, group II and total respectively.

In table 2 Distribution and comparison of stone clearance between groups, 62(96.9%) patients had stone free rate in group ultrasonic lithotripsy, 51(79.7%) patients had stone free rate in group Pneumatic lithotripsy overall 113(88.3%) patients had stone free rate in both groups.

In table 3-8 stratification for stone free rate in both of the groups was stated with respect to age, BMI, size of stone, duration, hypertension, gender. Most of the results showed significant difference with p-value≤0.05.

Table 1: Demographic data, stone, and operative characteristics.

	Group I	Group II	Total
Number of patients (%)	64(50%)	64(50%)	128(100%)
Age, years	50.2+/-10.8	48.5+/-9.8	48.7+/-8.8
Stone size mm	28.9 +/-3.41	27.3+/-4.21	27.5+/-3.91
Duration of stone, days	25.6 +/-9.41	29.4+/-7.79	28.3+/-8.1
BMI	24.8 +/-3.25	25.9+/-4.58	25.8+/-2.9
Male	39(60.9%)	42(65.6%)	81(63.3%)
Female	25(39.1%)	22(34.4%)	47(36.7%)
Hypertension	29(45.3%)	31(48.4)	60(46.9%)

Table 2: Comparison of stone clearance in both study groups (n=128)

Study Groups	Stone Clearance		Total	P-value
	Yes	No		
Ultrasonic Lithotripsy	62(96.9%)	2(3.1%)	64(100%)	0.003*
Pneumatic Lithotripsy	51(79.7%)	13(20.3%)	64(100%)	
Total	113(88.3%)	15(11.7%)	128(100%)	

Table 3: Stratification for stone clearance in both groups with respect to Age groups (n=128)

Age groups	Study Groups	Stone Clearance		P-value
		Yes	No	
</= 40 yrs.	**Ultrasonic Lithotripsy**	34(97.1%)	1(2.9%)	**0.006***
	Pneumatic Lithotripsy	22(73.3%)	8(26.7%)	
>40 yrs.	**Ultrasonic Lithotripsy**	28(96.6%)	1(3.4%)	**0.12****
	Pneumatic Lithotripsy	29(85.3%)	5(14.7%)	

Table 4: Stratification for stone clearance in both groups with respect to gender (n=128)

Gender	Study Groups	Stone Clearance		P-value
		Yes	No	
Male	**Ultrasonic Lithotripsy**	37(94.9%)	2(5.1%)	**0.02***
	Pneumatic Lithotripsy	32(76.2%)	10(23.8%)	
Female	**Ultrasonic Lithotripsy**	25(100%)	0(0%)	**0.05***
	Pneumatic Lithotripsy	19(86.4%)	3(1.6%)	

Table 5: Stratification for stone clearance in both groups with respect to duration of renal stone (n=128)

Duration	Study Groups	Stone Clearance		P-value
		Yes	No	
</= 1 month	Ultrasonic Lithotripsy	39(97.5%)	1(2.5%)	0.04*
	Pneumatic Lithotripsy	27(81.8%)	6(18.2%)	
> 1 month	Ultrasonic Lithotripsy	23(95.8%)	1(4.2%)	0.05*
	Pneumatic Lithotripsy	24(77.4%)	7(22.6%)	

Table 6: Stratification for stone clearance in both groups with respect to size of stone (n=128)

BMI	Study Groups	Stone Clearance		P-value
		Yes	No	
</= 25 mm	Ultrasonic Lithotripsy	37(100%)	0(0%)	0.019*
	Pneumatic Lithotripsy	31(86.1%)	5(13.9%)	
> 25 mm	Ultrasonic Lithotripsy	27(93.1%)	2(6.9%)	0.03*
	Pneumatic Lithotripsy	20(70.4%)	8(28.6%)	

Table 7: Stratification for stone clearance in both groups with respect to BMI (n=128)

BMI	Study Groups	Stone Clearance		P-value
		Yes	No	
</= 25 kg/m^2	Ultrasonic Lithotripsy	27(96.4%)	1(3.6%)	0.09**
	Pneumatic Lithotripsy	30(83.3%)	6(16.7%)	
> 25 kg/m^2	Ultrasonic Lithotripsy	35(97.2%)	1(2.8%)	0.008*
	Pneumatic Lithotripsy	21(75%)	7(25%)	

Table 8: Stratification for stone clearance in both groups with respect to hypertension (n=128)

Hypertension	Study Groups	Stone Clearance		P-value
		Yes	No	
Yes	Ultrasonic Lithotripsy	30(96.8%)	1(3.2%)	0.011*
	Pneumatic Lithotripsy	26(74.3%)	9(25.7%)	
No	Ultrasonic Lithotripsy	32(97%)	1(3%)	0.12**
	Pneumatic Lithotripsy	25(86.2%)	4(13.8%)	

DISCUSSION:

Kidney stones is a common disease, requiring management according to stone size and location in the pelvicalyceal system. Urologic techniques improved and stone management revolutionized proved by the excellent stone free rates and less complications [11,12]. Like other surgical techniques PCNL improved dramatically, success rates increased and associated complications and morbidities decreased. One of the advances that lead to this is the development of new lithotripter techniques that allow clearance of larger and harder kidney stones nowadays [12]. Historically , the first intracorporeal lithotripter was the electrohydraulic lithotripter invented in 1955 by Ytkin. It was used to treat urinary bladder, ureteral and kidney stones[11] [13]. Although it is a powerful lithotripter as it successfully fragments 90% of stones, it is not preferred now because it causes mucosal injuries to tissues and perforations more than other lithotripter techniques [14,15]. The pneumatic lithotripter is an old one but is still widely used to treat almost all urinary stones whether bladder, ureteral or kidney stones. It is suitable for harder stones and when applied cautiously causes minimal tissue damage.

However a disadvantage of this technique is that the stone fragments must be removed using graspers which is very time consuming [11,16]. In this study carried out in Prince Hussein Bin Abdallah the II of urology and organ transplantation they compared between the 2 major types of lithotripters we use in PCNL procedures, this is the first study from Jordan to evaluate this. All patients are admitted through the out-patient department usually one day pre-operatively and their medical , surgical history is evaluated, and lab tests are done including a CBC, KFT, and bleeding profile. The pneumatic lithotripter was the only used type until 5 years ago when the ultrasonic lithotripter was introduced to our center, and since then we were using both types in PCNL procedures. Blood loss during this procedure was much less in group B patients who underwent the procedure using the ultrasonic lithotripter and this correlates with the less tissue damage this system causes, however bleeding could be related to the tract but all of our patients didn't have clinically significant bleeding at the start of lithotripsy and after the tract was made. 2 patients developed persistent bleeding requiring embolization and this again emphasizes the fact that PCNL is a surgical procedure that might result in major complications that require recognition and treatment sometimes only in a specialized center[11,19]

Although ESWL has revolutionized the management of urinary stones, PCNL still plays an important role in the treatment of large or multiple kidney stones [20].

CONCLUSION:

Percutaneous nephrolithotomy is the procedure of choice for removing most kidney stones, because it is safe with less morbidity compared to open surgical techniques. In the present study, pneumatic and ultrasonic lithotripters were compared, and both of them were found to be effective, safe, and reliable management modalities. However, the ultrasonic lithotripter provided higher stone-free rates with similar morbidity compared with pneumatic devices. Additional studies on this topic are warranted and recommended in the future.

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