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TO COMPARE THE OPERATIVE OUTCOMES IN PATIENTS TREATED WITH COMBINED PNEUMATIC LITHOTRIPSY PLUS ULTRASONIC LITHOTRIPSY VERSUS PNEUMATIC LITHOTRIPSY ALONE FOR THE MANAGEMENT OF STAGHORN RENAL CALCULI.

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Abstract:

Introduction: *Current guideline recommends percutaneous nephrolithotomy as a procedure of choice having stone size larger than 2 cm, infected stones, lower calyceal stones and in patients in whom shock wave lithotripsy has failed. The pneumatic and ultrasonic lithotripsy devices can be used alone or in combination (pneumatic + ultrasonic). These two systems work through different mechanisms but possess different advantages and disadvantages in practice.* ***Objective:*** *To compare the operative outcomes (e.g. operation time, stone clearance rate and hospital stay) in patients treated with combined pneumatic lithotripsy plus ultrasonic lithotripsy versus pneumatic lithotripsy alone for the management of staghorn renal calculi.* ***Study Design:*** *Randomized Clinical Trial.* ***Setting:*** *The study was completed at Sindh Institute of Urology and Transplantation Karachi, Pakistan.* ***Duration of Study:*** *8th, Feb 2017 to 7th, Aug 2017.****Patients and Methods:*** *A total number of 66 patients with diagnosis of staghorn calculi, who were plan for PCNL, were included in this study. Patients were divided into two equal groups. Group I: Patients underwent combined use of pneumatic plus ultrasonic lithotripsy for the treatment of renal stones and Group II patients underwent pneumatic lithotripsy alone. Operation time, hospital stay and stone clearance was noted in all patients. Data analysis was carried out using SPSS v20.0. Chi-square test was used to compare outcome result between groups. Independent sample t-test was used for comparison of operation time and hospital stay time between the groups.* ***Results:*** *The mean age of the patients was 49.83±9.06 years. There were 42 (63.6%) males and 24 (36.4%) females. There were 50 (75.8%) patients who presented with partial staghorn stones and 16 (24.2%) patients were presented with complete staghorn stones. Stone clearance rate was 87.9% in group I and 81.8% in group II patients with a p-value of 0.49. The mean operation time was 190.72+17.15 minutes in group I and 225.09+18.49 in group II (p-value <0.001). The hospital stay time was 3.48±1.00 days in group I and 4.45±1.37 days in group II (p-value 0.002).* ***Conclusion:*** *The combination of ultrasonic lithotripter and pneumatic lithotripter is more effective than pneumatic lithotripter alone because it significantly decreases operative time hospital stay and increases stone clearance rate.*

Keywords: *Staghorn stones, pneumatic lithotripsy, ultrasonic lithotripsy*

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INTRODUCTION:

Technology advancement has made endourology much more feasible and accessible. A wide range of lithotripters is now available, out of these pneumatic lithoclast and ultrasonic lithotripters are most commonly used.[1,2] These two systems work through different mechanisms but possess different advantages and disadvantages in practice.[3] However, the superiority of the combined lithotripsy device has been demonstrated in various studies regarding stone clearance rate.[3]

Zengin et al found higher rate of stone clearance of 85.5% in patients treated with combined pneumatic lithoclast plus ultrasonic lithoclast as compared to 67.7% in patients treated with pneumatic lithoclast alone.[4] In their study, mean operation time was less 181±50 minutes in combined pneumatic lithoclast plus ultrasonic lithoclast as compared to 221±65 minutes in with pneumatic lithoclast alone. They also found less hospital stay time in patients treated with combined pneumatic lithoclast plus ultrasonic lithoclast 11.6±3.8 days versus 14.2±4.4 days in patients treated with pneumatic lithoclast only.[4] Very few data is available in literature regarding efficacy of combined use of pneumatic and ultrasonic lithoclast and little has been published about the use of ultrasonic lithotripters in Pakistan. To determine the superiority of combined use of pneumatic lithotripsy plus ultrasonic lithotripsy regarding operation time, stone clearance rate and hospital stay time as compared to pneumatic lithotripsy we conduct this study. Combination use of lithotripters may prolong the procedural time and hence patient's morbidity.

Stone that occupies pelvis and at least one calyx (partial) and stone that occupies pelvis and 2/3 of all calyces are known as staghorn stones. Diagnosis of

staghorn stones was made using Ultrasound report of the patient. Classification of staghorn calculi was done using computed tomography. Radio-opaque stone that occupied the pelvis and 2/3 of all calyces are known as Complete Staghorn Calculus. Radio-opaque stone that occupied the pelvis and at least one calyx is known as Partial Staghorn Calculus.

METHODS:

Taking power of the test 80% and level of significance 5.0%, the sample size for this study was 33 patients in each group. So 66 patients were selected for this study. With Inclusion criteria of Patients having age 15-70 years, both genders male and female, Patients with diagnosis of staghorn calculi, who were plan for PCNL, were selected for this study. On other side the exclusion criteria was, Patients with stones associated with congenital anomalies of kidney and ureter (diagnosed on ultrasound studies before surgery, morbidly obese patients e.g. patients with BMI >35 kg/m^2, Untreated coagulation abnormalities e.g. hemophilia diagnosed on pre-procedural lab investigations, as these can cause bleeding problem resulting in increased in operation and hospital stay time.

Approval taken from the ethical committee of the hospital, patients who presented in stone clinic of Sindh Institute of Urology and Transplantation (SIUT) with diagnosis of renal stones fulfilling the inclusion criteria were included in this study until the required sample size of 66 patients was completed. An informed consent was take from all patients before including him/her in this study. Then patients were divided into two groups using lottery method. Patients were divided into two equal groups depending upon the folded paper chosen by them. Group I: Patients underwent combined use of pneumatic plus ultrasonic lithotripsy for the treatment of renal stones and Group II patients underwent pneumatic lithotripsy alone.

Both of these procedures were carried out by consultant urologists having at least five years of post-fellowship experience. For the group II patients, PCNL was done by the use of pneumatic lithotripsy only and lithotripsy was continued until the stone will be fragmented into pieces small enough to be removed directly by a two- or three-pronged grasper. For group I patients: PCNL was done by combined use of pneumatic and ultrasonic lithoclast, pneumatic lithotripsy was initiated at first with a few bursts of the Lithoclast, after which the ultrasonic lithotripter was used. At the end of the operation, a nephrostomy tube (a 20 Fr self-retaining balloon catheter) was placed and maintained until the hematuria disappeared. Total operation time was noted at the end of the surgical procedure in every patient. After 1 week of primary procedure X-ray KUB was done in every patient to evaluate residual stone fragments. Hospital stay time was noted at the time of discharge of patient from the hospital (all outcomes were measured according to the operational definitions). Patient were followed until discharge from the hospital. All the information was recorded on a pre-designed Proforma (Annexure-I).

Data analysis were carry out using SPSS v20.0. Mean and standard deviations were calculate for quantitative variables like age, height, weight, BMI, duration of renal stone disease, operation time and hospital stay time. Categorical variables like gender, type of renal stone, and stone clearance rate were presented as frequency and percentage. Chi-square test was used to compare stone clearance rate between groups. Independent sample t-test was used for comparison of operation time and hospital stay time between the groups. Stratification of confounder variables e.g. age, gender, BMI, duration of renal stone disease, type of renal stones was done. Post stratification Chi-square test or independent sample t-test (where appropriate) were applied taking P-value ≤ 0.05 as significant difference.

RESULTS:

In this study, we included 66 patients. There were 33 patients in each group. The mean age of the patients was 49.83 ± 9.06 years. Minimum age was 18 and maximum was 60 years. There were 42 (63.6%) males and only 24 (36.4%) females in this study.

Mean body mass index (BMI) of the study patients was $25.84+4.19$ kg/m^2. Minimum BMI was 15.97 and maximum BMI was 35.00 kg/m^2.

Mean duration of renal stone disease was 8.33 ± 4.44 months. Duration of disease was calculated on the basis of first time of presentation of patient due to kidney pain to time of operation. The minimum duration of disease was 1 months and maximum duration was 23 months (Table 1).

Mean operation time of study patients was 207.90 (24.75 standard deviation) minutes, with a minimum time of 160 minutes (Table 2).

Mean hospital Stay was 3.96 ± 1.28 days. Minimum stay of a patient in hospital after surgery was only 2 days and maximum stay was 7 days (Table 3).

Regarding type of renal stones, most of the patients were presented with partial staghorn stones. There

were 50 (75.8%) patients who presented with partial staghorn stones and only 16 (24.2%) patients were presented with complete staghorn stones.

Stone clearance was achieved in 56 (84.8%) patients. while PCNL was unsuccessful in remaining 10 (15.2%) patients. There was no statistically significant difference in stone clearance rate in group I and group II. Stone clearance rate was 87.9% in group I and 81.8% in group II patients with a p-value of 0.49 (Table 4).

Regarding comparison of mean operation time between the groups, the mean operation time was 190.72±17.15 minutes in group I and 225.09±18.49 in group II. Mean operation time was significantly high in group II patients with a p-value of <0.001.

Regarding comparison of hospital stay between the groups. The hospital stay time was 3.48±1.00 days in group I and 4.45±1.37 days in group II. Hospital stay time was significantly high in group II patients with a p-value of 0.002.

Stratification was done on the basis of age to determine either there is any effect of age of patients on the outcomes of the study e.g. operation time, hospital stay and stone clearance rate. There was no significant effect of patients on the outcomes of study and results were same in all age groups (Table 5, 6, and 7).

Stratification was done on the basis of gender to determine either there is any effect of gender of patients on the outcomes of the study e.g. operation time, hospital stay and stone clearance rate. There was no significant effect of gender of patients on the outcomes of study and results were same in all age groups (Table 8, 9 and 10).

Stratification of patients was also done on the basis of BMI and patients were divided into normal weight and overweight to obese groups. There was no significant effect of BMI of the patients and outcomes of the study were same in normal weight and overweight to obese patients (Table 11, 12 and 13).

Stratification was done on the basis of duration of disease to determine either there is any effect of duration of disease of patients on the outcomes of the study e.g. operation time, hospital stay and stone clearance rate. For this, the patients were further subdivided into two groups, i. patients with duration of disease ≤ 1 years and ii. Patients with duration of disease >1 years. There was no significant effect of duration of disease of patients on the outcomes of study and results were same in all age groups (Table 14, 15, and 16).

Stratification was done on the basis of type of renal stones to determine either there is any effect of type of renal stones on the outcomes of the study e.g. operation time, hospital stay and stone clearance rate. There was no significant effect of type of renal stones on the outcomes of study and results were same in all age groups (Table 17, 18 and 19).

Table 1. Descriptive Statistic of Duration of Disease.

Duration of Disease (Months)	Value
Mean	8.33
S.D.	4.44
Minimum	01
Maximum	23

Table 2. Descriptive Statistics of Mean Operation Time

Operation Time (Minutes)	Value
Mean	207.90
S.D.	24.75
Minimum	160
Maximum	264

Table 3. Descriptive Statistics of Hospital Stay

Hospital Stay (Days)	Value
Mean	3.96
S.D.	1.28
Minimum	2
Maximum	7

Table 4. Comparison of Stone Clearance Rate between the Groups.

Stone Clearance	Group I	Group II	P-value
Yes	29 (87.9%)	27 (81.8%)	0.49
No	4 (12.1%)	6 (18.2%)	

Table 5. Stratification of Age to Determine the Effect of age on mean Operation Time.

A. Age Group 15-49 Years

Operation Time (mins)	Group I	Group II	P-value
Mean	187.26	224.0	<0.001
Standard Deviation	18.95	19.2	

B. Age Group 50-70 Years.

Operation Time (mins)	Group I	Group II	P-value
Mean	193.6	226.00	<0.001
Standard Deviation	15.44	18.42	

Table 6. Stratification of Age to Determine the Effect of age on mean Hospital Stay.

A. Age Group 15-49 Years

Hospital Stay (days)	Group I	Group II	P-value
Mean	3.40	4.46	0.02
Standard Deviation	0.98	1.30	

B. Age Group 50-70 Years.

Hospital Stay (days)	Group I	Group II	P-value
Mean	3.55	4.44	0.04
Standard Deviation	1.04	1.46	

Table 7. Stratification of Age to Determine the Effect of age on Stone clearance Rate.

A. Age Group 15-49 Years

Stone Clearance	Group I	Group II	P-value
Yes	12	11	0.81
No	4	3	

B. Age Group 50-70 Years.

Stone Clearance	Group I	Group II	P-value
Yes	17	16	0.08
No	0	3	

Table 8. Stratification of Gender to determine the effect of Gender on Mean Operation Time.

A. Male Gender

Operation Time (mins)	Group I	Group II	P-value
Mean	186.26	222.63	<0.001
Standard Deviation	15.13	16.74	

B. Female Gender

Operation Time (mins)	Group I	Group II	P-value
Mean	201.00	228.42	0.003
Standard Deviation	17.83	20.80	

Table 9. Stratification of Gender to determine the effect of Gender on Mean Hospital Stay.

A. Male Gender

Hospital Stay (days)	Group I	Group II	P-value
Mean	3.56	4.31	<0.001
Standard Deviation	1.12	1.26	

B. Female Gender

Hospital Stay (days)	Group I	Group II	P-value
Mean	3.30	4.64	0.01
Standard Deviation	0.67	1.49	

Table 10. Stratification of Gender to determine the effect of Gender on Stone Clearance Rate.

A. Male Gender

Stone Clearance	Group I	Group II	P-value
Yes	21	16	0.48
No	2	3	

B. Female Gender

Stone Clearance	Group I	Group II	P-value
Yes	8	11	0.93
No	2	3	

Table 11. Stratification of BMI to determine the effect of BMI on Mean Operation Time.

A. Normal Weight (BMI: ≤24.9 kg/m^2)

Operation Time (mins)	Group I	Group II	P-value
Mean	188.78	228.14	<0.001
Standard Deviation	14.19	16.67	

B. Overweight to Obese (BMI: ≥25.0 kg/m^2)

Operation Time (mins)	Group I	Group II	P-value
Mean	192.15	222.84	<0.001
Standard Deviation	19.29	19.86	

Table 12. Stratification of BMI to determine the effect of BMI on Mean Hospital Stay.

A. Normal Weight (BMI: ≤24.9 kg/m^2)

Hospital Stay (days)	Group I	Group II	P-value
Mean	3.52	4.00	<0.001
Standard Deviation	1.07	1.56	

B. Overweight to Obese (BMI: ≥25.0 kg/m^2)

Hospital Stay (days)	Group I	Group II	P-value
Mean	3.15	4.78	<0.001
Standard Deviation	0.83	1.13	

Table 13. Stratification of BMI to determine the effect of BMI on Stone Clearance Rate.

A. Normal Weight (BMI: ≤24.9 kg/m^2)

Stone Clearance	Group I	Group II	P-value
Yes	12	10	0.35
No	2	4	

B. Overweight to Obese (BMI: ≥25.0 kg/m^2)

Stone Clearance	Group I	Group II	P-value
Yes	17	2	1.0
No	2	17	

Table 14. Stratification of patients on the basis of Duration of Disease to determine the Effect of Duration of Disease on Mean Operation Time.

A. Duration of disease ≤1 years.

Operation Time (mins)	Group I	Group II	P-value
Mean	190.00	227.14	<0.001
Standard Deviation	17.05	18.09	

B. Duration of Disease > 1 years.

Operation Time (mins)	Group I	Group II	P-value
Mean	194.80	213.60	<0.001
Standard Deviation	12.04	18.20	

Table 15. Stratification of patients on the basis of Duration of Disease to determine the Effect of Duration of Disease on Mean Hospital Stay.

A. Duration of disease ≤1 years.

Hospital Stay (days)	Group I	Group II	P-value
Mean	3.53	4.50	<0.001
Standard Deviation	1.07	1.40	

B. Duration of Disease > 1 years.

Hospital Stay (days)	Group I	Group II	P-value
Mean	3.20	4.20	<0.001
Standard Deviation	0.44	1.30	

Table 16. Stratification of patients on the basis of Duration of Disease to determine the Effect of Duration of Disease on Stone Clearance Rate.

A. Duration of disease ≤1 years.

Stone Clearance	Group I	Group II	P-value
Yes	24	24	0.95
No	3	4	

B. Duration of Disease > 1 years.

Stone Clearance	Group I	Group II	P-value
Yes	5	3	0.13
No	1	2	

Table 17. Stratification of patients on the basis of Type of Renal Stones to Determine the Effect of Type of Renal Stone on Mean Operation Time.

A. Partial Staghorn Stones.

Operation Time (mins)	Group I	Group II	P-value
Mean	190.07	225.12	<0.001
Standard Deviation	15.23	20.05	

B. Complete Staghorn Stones

Operation Time (mins)	Group I	Group II	P-value
Mean	193.14	225.00	0.006
Standard Deviation	24.34	14.55	

Table 18. Stratification of patients on the basis of Type of Renal Stones to Determine the Effect of Type of Renal Stone on Mean Hospital Stay.

A. Partial Staghorn Stones.

Hospital Stay (days)	Group I	Group II	P-value
Mean	3.50	4.33	0.02
Standard Deviation	1.06	1.43	

B. Complete Staghorn Stones

Hospital Stay (days)	Group I	Group II	P-value
Mean	3.42	4.77	0.02
Standard Deviation	0.78	1.20	

Table 19. Stratification of patients on the basis of Type of Renal Stones to Determine the Effect of Type of Renal Stone on Stone Clearance Rate.

A. Partial Staghorn Stones.

Stone Clearance	Group I	Group II	P-value
Yes	22	20	0.90
No	4	4	

B. Complete Staghorn Stones

Stone Clearance	Group I	Group II	P-value
Yes	7	7	0.18
No	0	2	

DISCUSSION:

Although ESWL has revolutionized the management of urinary stones, PCNL still plays an important role in the treatment of large or multiple kidney stones.[5] With regard to the stone fragmentation, a number of lithotripsy approaches have been developed. The first is electrohydraulic lithotripsy (EHL), which is based on spark-gap technology and was first introduced by Yutkin (1955). Raney and Handler have reported the use of EHL for open nephrolithotomy.[6] EHL is cheaper than the other lithotripsy devices. However, despite the technical improvements and extensive clinical experience with EHL, it remains the least safe of all lithotripsy devices. In fact, Hofbauer et al showed that EHL is associated with a higher rate of perforation than is the use of a pneumatic lithotripter (17.6% vs. 2.6%, respectively).[7]

Another lithotripter is the holmium yttrium aluminum garnet (Ho: YAG) laser, which is a high-energy pulse solid-state laser. The efficacy of the Ho: YAG laser is correlated with the pulse energy output. It has been reported to be a safe and effective treatment modality for large renal stones, even at high power settings.[8] The upsides of the Ho: YAG laser are that it adequately pieces a wide range of renal calculi, and the strands are sufficiently little to be gone through adaptable endoscopes.[9] However, one inconvenience of the Ho-YAG laser is that the subsequent stone parts must be separated by getting a handle on every one independently. The unintentional introduction of the urothelium to the laser shaft may prompt puncturing or seeping from stun wave presentation and warming. In addition, the cost of this laser framework is high.[10] Pneumatic lithotripters use compressed air to accelerate a projectile to the metal probe. This mechanical energy is dissipated through the metal wire and acts as a chisel on the surface of the stone; therefore, direct contact with the stone surface is required, and heat is not generated throughout this action. An overall fragmentation rate of 84–100 per cent and stone-free rate of 70–98.6 per cent have been reported.[11] There are different test sizes accessible, however they can't be utilized with adaptable instruments, which is viewed as a hindrance. The powerlessness to at the same time separate stones amid fracture, and retropulsion of the stone because of the vitality discharged after contact with the stone, are different hindrances.

Ultrasonic lithotripters use ultrasonic waves generated by piezoceramic elements. The ultrasonic wave energy is transmitted along a probe and converted to vibration at the tip, which results in the drilling action. Direct contact between the probe and the stone is required. The fragments are aspirated through the hollow probe.[12] Being safe, causing minimal tissue effects and aspirating fragments through the hollow probe are the known advantages. The inability to be used with flexible instruments due to the thick probes, and overheating, are disadvantages. In order to avoid this, it should not be used for prolonged periods without a suction probe. A fragmentation rate of 97–100 per cent and stone-free rate of 94 per cent have been reported.[13] The ultrasound and pneumatic lithotripsy technologies have recently been combined to produce a single device. Compared with an ultrasonic device, the combined pneumatic and ultrasonic device is associated with significantly increased lithotripsy efficacy (stone disintegration) and efficiency (stone fragmentation and clearance).[14] The main advantage of using an ultrasonic lithotripter in combination with a pneumatic lithotripter is that the fragmented stones can be cleared by active negative pressure suction. No other instruments are needed for the whole stone fragmenting and clearing process. Thus, there is no need to wash the nephroscope, which requires that it be repeatedly withdrawn from and then reinserted into the body. This reduces the intra- and postoperative complication rates, increases the stone-free rate, and shortens the operation time. Because negative pressure suction maintains the renal collection system at a low pressure, this also reduces the risk of bacterial infection. When considering the stone fragmentation efficacy of combined Lithoclast® and ultrasonic lithotripsy, Lithoclast® is more powerful for treating hard stones, whereas small fragments, granulation tissue-wrapped stones, impacted stones, and stones with a soft matrix (e.g., phosphate-containing calculi) are particularly suitable for aspiration through the ultrasound probe. Stone fragments can either be cleared out by forceps after crude fragmentation with the Lithoclast® or be flushed out through the hollow probe of the ultrasound lithotripter. In our study, the combination technique had a valuable synergistic effect.[15]

In our study, we found significant higher benefits of the use of combined pneumatic and ultrasonic lithotripters as compared to the pneumatic lithotripters alone. In our study, mean operation time and hospital stay period was significantly less in combined group as compared to the pneumatic group alone. The mean operation time was 190.72±17.15 minutes in group I and 225.09±18.49 in group II. The hospital stay time was 3.48±1.00 days in group I and 4.45±1.37 days in group II. Hofmann *et al*. compared the combined device with both the ultrasonic and the pneumatic lithotripsy devices *in vitro*. They found that the

disintegrated stone mass was 1.5–4 times larger, and the 50 per cent disintegration time was 30–50 per cent shorter after 1 min with the combined system.[16] Ague *et al*. conducted a similar study. The complete calculus removal time was found to be significantly shorter with the combined device.[17] Pietrow *et al*. compared the combined device and the pneumatic device clinically, and the mean complete stone clearance time was found to be significantly shorter with the combined system.[18] Lehman *et al*. compared the combined device and the pneumatic device and obtained similar values for fragmentation time and operative time. However, regarding the composition of the calculi, they reported that the combined device was more effective for hard calculi.[19] Cho *et al*. compared the combined device and the pneumatic device and found significantly lower values for operative time, number of hospital days and average hemoglobin loss with the combined device.[15] In their patients treated with the combined system, Hofmann *et al*. reported a complete stone-free rate of 66 per cent following the first PNL, without significant complications, and as 76 per cent when a second PNL was required.[16]

Combined ultrasonic/pneumatic probe disintegrates stones faster and this shortens total operative time and higher stone clearance rate. Even though no statistically significant success rate difference between groups was detected regarding stone clearance rate, best results were achieved in combine ultrasonic and pneumatic lithotripsy groups.

CONCLUSION:

The combination of ultrasonic lithotripter and pneumatic lithotripter is more effective than pneumatic lithotripter alone because it significantly decreases operative time hospital stay and increases stone clearance rate.

Ethical Approval
IRB Number: 260
Approval No: SIUT-IRB-260

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