Original Article

TO COMPARE THE EFFICACY OF 70 VERSUS 100 SHOCK WAVES /MINUTE OF ESWL IN MANAGING RENAL AND URETERAL CALCULI IN TERMS OF FREQUENCY OF STONE CLEARANCE

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ABSTRACT:

OBJECTIVE: To compare the efficacy of 70 versus 100 shock waves /minute of ESWL in managing renal and ureteral calculi in terms of frequency of stone clearance.
MATERIALS AND METHODS: A Randomized Clinical Trial of Six months (12th July 2013 to 11th Jan 2014) was carried out in the Department of Urology, PIMS, Islamabad. Total 90 patients of either gender with renal or upper ureteric stones planned for shock wave lithotripsy were included. 45 patients were randomized to 70 shock waves/minute (Group I) and 45 to 100 shock waves/minute (Group II). Stone fragmentation was confirmed by fluoroscopy at the time of treatment, and with X-ray KUB/Ultrasonography at two weeks after post treatment.
RESULTS: In group I, the treatment was efficacious in 86.7% (n= 39) of patients, while in group II the percentage of such patients was 64.4% (n=29). *P* value found to be .014 (< 0.05).
CONCLUSIONS: ESWL with 70 shock waves per minute is more efficacious than 100 shock waves per minute in terms of stone free status after therapy.
KEYWORDS: Nephrolithiasis, Lithotripsy, Extracorporal shock wave therapy.

INTRODUCTION:

Extracorporeal shock waves lithotripsy is the modality which has emerged as the first-line treatment for renal calculi having size < 20mm. Its noninvasive nature and low intricacy rate settle on it a superior choice over surgery[1]. However, it does have its own complications. Shock waves impacting on the kidney can rupture blood vessels, leading to intra-parenchymal bleeding, or subcapsular hematomas. The acute renal injury resulting from extracorporeal shock waves lithotripsy expanded from the papilla to the outer cortex and in most of the patients causes a change in renal function[2]. The final result of ESWL is dependent on many factors, like size of the stone, stone site, patient selection and the rate of shock wave delivery[3]. Various regimens of the rate of shock waves have been used, such as 60, 70, 90, 100 and 120 shock waves per minute[4,5].

There is no consensus yet of the optimum shock waves rate, although some studies have shown that stones fragmentation is better when the rate of shock waves delivery is slowed[6]. On the other hand, some studies show that there is no difference between different regimens[7]. The benefits of slow rate of ESWL for stone fragmentation are more effective fragmentation, reduced renal trauma, less sub capsular hematoma and vascular damage, and cost-effectiveness[8,9]. The disadvantage of slowing the rate of delivery is that more time is required. However even with a slower shockwave administration, less number of shock waves are requisite to make the

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individual stone free. As overall stone free rate is 68.6% in slow shock wave(70sw/min) group and 27.5% in fast shock wave (100/min) group.[1]For stones less than 20mm in size, there is no need for pre-treatment double J Stinting[10,11].

Internationally, there is growing awareness about the efficacy and associated complications of the ESWL. There is growing consensus on rate of shock waves. At national level we need to evolve evidence based on our own population. This goal can be achieved if we have our own data. Our study will provide valuable information as to which of the two dose regimens (70 versus 100 shock waves per minute) is more effective in our patients. This will help improve the management outcome of our future patients.

MATERIALS AND METHODS:

A Randomized control trial was done at the Department of Urology, Pakistan Institute of Medical Sciences (PIMS) Islamabad for the duration of Six months (12th July 2013 to 11th Jan 2014). Total of 90 patients were enrolled 45 patients in each of two groups. Sample size was calculated with the help of WHO Size calculator by keeping Level of significance 5%, Power of test 95%, Anticipated populace extent 68.6%[12]. Sample was collected by Consecutive (Non-Probability) sampling technique. Patients of either gender of all ages presenting to the Department of Urology to undergo ESWL with renal or upper ureteric stones (as mentioned in operational definition) were incorporated in the study. While the patients with Stones > 20mm, patients who have previously undergone surgery for stones on the same side, patients who have previously undergone ESWL in another hospital, radiolucent stones, renal failure who are on dialysis, obstructed urinary system diagnosed on ultrasound scan were kept in exclusion.

After authorization from the Hospital Ethical Committee, the Informed written consent was taken from patients included in the study. All the participants were admitted for indoor management. Half were randomized to 70 shock waves/minute and the remainder half were randomized to the 100 shock waves/minute group by lottery method. Pre-operative investigations (Complete Blood Count, Serum Urea and Creatinine, Urinalysis, X-ray KUB and Ultrasonography KUB) were performed in all patients. Computed Tomographic Scan (CT-KUB) and Intravenous Urography (IVU) were done in cases of diagnostic uncertainty. ESWL was performed in all patients and patients were offered intravenous Ketorolac or Nalbuphine 5-10mg, with no sedation or general anesthesia. ESWL was performed on an Electromagnetic Lithotripter (Siemens Lithoskop) by the same two operators. At the end of procedure, patients were given Levofloxacin 500mg per oral for 5 days and oral diclofenac 50mg twice daily as required. Stone fragmentation was confirmed by fluoroscopy at the time of treatment, and with X-ray KUB/Ultrasonography at 2 weeks after their treatment session. A maximum of 3 treatment sessions were given to patients. Stone clearance was assessed by X-Ray/Ultrasound. Success was determined as: Asymptomatic, Stone free on X-Ray/Ultrasound or clinically insignificant (less than 3mm) stones, at two weeks after each session.

The collected data was entered on a proforma and statistical analysis of the data was done.

All the collected data was entered and analyzed using SPSS version 23.0. For continuous factors like stone size, age mean + S.D was determined and for categorical out factors like gender, site of calculus, and clearance rate was calculated. Chi square test was used for the comparison of efficacy between the two groups. P value <0.05 considered as significant. The stratification of effect modifier like age, gender, site of stone, size of stone were done.

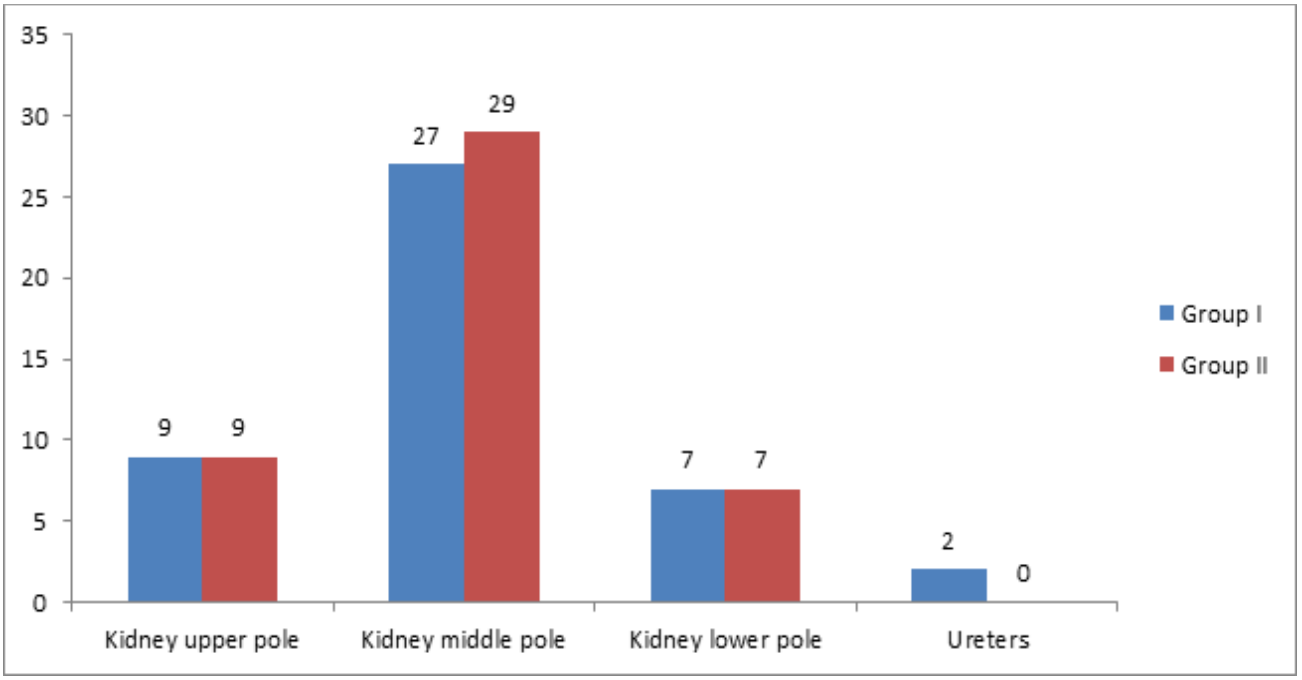
RESULTS:

Total of 90 patients were selected in this study. Sample was randomly allocated to two groups based on lottery method. Half were randomized to 70 shock waves/minute (Group I) and the remainder half were randomized to the 100 shock waves/minute group (Group II). A maximum of 3 treatment sessions were given to patients. Stone clearance was evaluated by X-Ray/Ultrasound. The detail of demographic results are described in table below.

Table 1: Statistic Profile for the Demography of investigation Population:

	Group-I (70 SW/min)	Mean Age ± SD (years)	Group-II (100 SW/min)	Mean Age ± SD (years)
Male	29 (64%)	36.38 ± 8.95	34 (76%)	37.65 ± 10.51
Females	16 (36%)	33.13 ± 6.47	11 (24%)	34.64 ± 12.49
Total	45 (100%)	35.22 ± 8.23	45 (100%)	36.91 ± 10.95

Site of Stones in both groups:
In group I (70 SW/min), 9 (20%) patients had stones at upper pole of kidney, 27 (60%) had stones at middle pole of kidney, 7 (15.6%) had stones at lower pole of kidney and 2 (4.4%) had stones in the ureters. In group II (100 SW/min), 9 (20%) patients had stones at upper pole of kidney, 29 (64.4%) had stones at middle pole of kidney and 7 (15.6%) were having stones at lower pole of kidney. Results are shown graph 1 bellow.



Graph 1: Site of stones in both groups

Size of Stones in both groups:
In group I (70 SW/min), 22 (48.9%) patients had stones with size in the range of 6-9 mm, 14 (31.1%) patients had stones with size in the assortment of 10-15 mm and 9 (20%) patients had stones with size in the range of 16-20mm. In group II (100 SW/min), 12 (26.7%) patients had stones with size in the range of 6-9 mm, 23 (51.1%) patients had stones with size in the assortment of 10-15 mm and 10 (22.2%) patients had stones with size in the range of 16-20 mm. Results are shown in table 2 bellow.

Table 2: Size of stones in both groups

Size	Group I (70 SW/min)	Group II (100 SW/min)	Total
6-9 mm	22 (48.9%)	12 (26.7%)	34 (37.8%)
10-15 mm	14 (31.1%)	23 (51.1%)	37 (41.1%)
16-20 mm	9 (20.0%)	10 (22.2%)	19 21.1%)
Total	45 (100.0%)	45 (100.0%)	90 (100.0%)

Table 3: Efficacy in both groups

Efficacy	Group I (70 SW/min)	Group II (100 SW/min)	X^2	*P*-value
Present	39 (86.7%)	29 (64.4%)		
Absent	06 (13.3%)	16 (35.6%)	6.038	0.014 (<0.05)
Total	45 (100%)	45 (100%)		

Outcome in both groups

In group I (70 SW/min), the treatment was efficacious in 39 (86.7%) patients, while 06 (13.3%) patients did not show a favorable response to treatment as per our operational definition. In group II (100 SW/min), the treatment was efficacious in 29 (64.4%) patients, while 16 (35.6%) patients did not show a favorable response to treatment. Results are shown in table 3.

The Significance of the Results:

In statistics, a result is statistically significant if it is unlikely to have occurred by chance. In our case, the data is nominal and for descriptive statistics, we made simplest kind of a 2 x 2 contingency table. We utilized Chi-square test to test the freedom between the observed proportions (variables) as our example measure was sufficiently substantial.

DISCUSSION:

Renal and ureteral stones are a typical inconvenience in essential consideration practice[13]. Patients may likewise presented with the ordinary indications of renal pain and hematuria. Others might be asymptomatic or have odd signs and indications comprising of ambiguous belly pain, intense stomach or flank pain, nausea, urinary earnestness or recurrence, inconvenience urinating, penile torment, or testicular pain. The literature reflects the perception globally that whilst the incidence of urolithiasis is increasing, the use of ESWL is not increasing at the same rate, particularly for ureteric stones, and they cite the potential factors for this. This has also been noted in the UK and a recent review[14] of Hospital Episode Statistics (HES) data even suggest the rate of ESWL has plateaued for both ureteric (3000/year) and renal (19 500/year) stones in the last 3 years[15]. There has been discussion within the UK about centralising Endourology services using the same model as for cancer, with provision of static lithotripters within those centres. This would potentially have the advantage of creating high-volume centers with quality being easier to standardize and monitor; however, this would have to be balanced against patients probably having to travel further to access ESWL. The use of Hounsfield units remains a topic of debate with conflicting data and limited clinical application[16,17]. Optimizing targeting to minimize tissue damage with maximal stone fragmentation remains a challenge and modifications tolithotripters with dual-imaging modalities, dual heads, alterations in shockwave delivery rate, control of respiratory effort and novel feedback devices have had limited success. Increasing levels of obesity within developed countries are a factor in the

utilization of ESWL, as there is a limit on focal distance. All of these factors, along with the continued improvement in the optics, miniaturisation of ureteroscopes and advent of holmium laser have contributed to a surge in the use of ureteroscopy, despite publications and guidelines showing similar success rates[18]. The other essential sorts incorporate uric corrosive, struvite (magnesium ammonium phosphate), and cystine stones.

The risk of nephrolithiasis is invigorated through urine structure, which can be influenced by positive diseases and patient propensities. For calcium oxalate stones, urinary shot components include hypercalciuria, hyperoxaluria, hypocitraturia, and healthful possibility factors comprising of a low calcium admission, extreme oxalate consumption, high creature protein consumption, high sodium admission, or low liquid admission. Expanded utilization of Vitamin C has been identified with a superior peril of stones in folks. Stone sickness is around overlap better in patients with hypertension[18]. The danger of nephrolithiasis is propelled by method for pee piece, which can be stricken by beyond any doubt ailments and influenced individual propensities. For calcium oxalate stones, urinary possibility factors comprise of hypercalciuria, hyperoxaluria, hypocitraturia, and dietary risk components comprising of a low calcium admission, high oxalate consumption, excessive animal protein consumption, excessive sodium intake, or low fluid intake. Increased intake of Vitamin C has been associated with a higher risk of stones in men. Studies have advocated that changes in way of life and weight problems have significantly increased the occurrence of stones in girls, thereby converting the preceding gender ratio of male to lady stone formation from 3:1 to at least one. 3: 1.6:1.[18]

Side effects may create when stones at first go from the renal pelvis into the ureter. Pain is the most broadly perceived appearance and contrasts from a smooth and hardly detectable exceptional Pain that it requires parenteral analgesics. The agony routinely travels every which way in reality, and makes in waves or ejections that are related to improvement of the stone in the ureter and related ureteral fit In certain patients with incessant back torment, the determination of intense colic might be troublesome without an imaging study. Nephrolithiasis may prompt diligent renal deterrent, which could cause perpetual renal damage whenever left untreated. The advancement of extracorporeal shock wave lithotripsy (SWL) is maybe the most huge advancement related to the removal of renal and ureteral stones. Many renal and ureteral stones are currently managed by this technique. However, SWL isn't the perfect methodology for the administration of extensive or complex calculi. Elective methods of stone evacuation ought to be considered for vast or hard calculi, stones situated in a calyceal diverticulum, or in patients with complex renal anatomy[19]. The study of Ohyama H et all said that Complete stone removal was achieved in 66 patients (51.6%). When the density threshold was set at 820.5 Hounsfield units, complete stone removal was achieved in 52 patients (78.8%) with lower-density stones. In multivariate analysis, single stone ($P = 0.007$) and lower-density stone ($P < 0.001$) revealed significant association with complete stone removal[20,21]. In a companion of 137 patients with renal calculi estimating 11 to 20 mm in width, single treatment achievement rates were essentially better in the individuals who experienced percutaneous stone evacuation (95%) and ureteroscopy (88%) contrasted and SWL (60percent)[22].

Our outcomes are in concordance with the outcomes officially distributed regarding the matter. Honey RJ et al;[23] in their randomized preliminary to inspect the impact of a shock wave recurrence for shock wave lithotripsy on stones situated in the proximal ureter. An aggregate of 163 participants with a formerly organic radiopaque analytics in the superior ureter estimating no less than 5 mm experienced stratified square randomization as indicated by stone volume, and stun wave lithotripsy at 60 or 120 shocks every moment. Without stone status at 3 months was affirmed with non-contrast modernized tomography or a plain abdominal x-ray and ultrasound think about. Of the 163 patients, 77 were randomized to 60 stuns every moment and 86 were randomized to 120 stuns every moment. The

gatherings were comparable for sex, age, weight list and starting stone region. They found that at 90 days the 60 shocks per minute aggregate had a privileged generally without stone rate (64.9% versus 48.8%, p = 0.039). Essentially, less shocks were managed to patients treated at 60 shocks per minute (mean 2,680 versus 2,940, p <0.001). Patients deal with 60 shocks per minute required less helper methods (29.9% versus 45.4%) (p = 0.031). They inferred that diminishing the rate of stun wave organization from 120 to 60 shocks per minute results in enhanced without stone rates. A slower treatment frequency of proximal ureteral stones lessens the requirement for extra stun wave lithotripsy or increasingly obtrusive medicines to provide patients sans stone, with no expansion in grimness, and with an adequate increment in treatment time.

Badawy AA et al; [24] assessed the safety, viability and components influencing achievement velocity and clearance of stones in youngsters deal with shock wave lithotripsy. Somewhere in the range of 2005 & 2010, a sum of five hundred kids with stones in the upper urinary tract at various areas was treated by Extracorporeal shock wave lithotripsy (ESWL). They found that the general achievement rate for renal and ureteral calculi reported 83.4 and 58.46%, separately. The retreatment rate was 4% in renal gathering and 28% for the ureteral gathering. No genuine confusions were recorded in the patients. Minor difficulties happened in 15% of patients; renal colic was accounted for in 10% of treated patients, and continued heaving was accounted for in 5% that react to antiemetics. For the renal gruop; kids with history of pervious urologic surgeries had low achievement rate of stone clearance after ESWL. In the ureteral assemble stone burden, stone area, significantly affected stone leeway result. They inferred that SWL in pediatric age gather for both renal and Ureteral stone is cost effective, safe with a worthy retreatment rate; anyway kids with large stone burden or past urologic medical procedure have low achievement rate.

CONCLUSIONS:

Extracorporeal shock waves lithotripsy with 70 shock waves per minute is more efficacious than 100 shock waves per minute in terms of stone free status after therapy.

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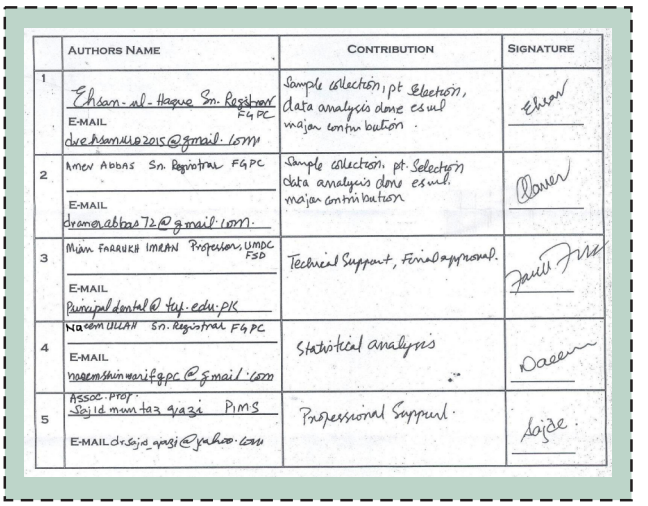

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When you have to depart from this world and have to meet death (eventually), then why wish delay (why feel nervous about death).

Hazrat Ali (Karmulha Wajhay)