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OUTCOME OF EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY FOR RENAL CALCULUS ABOVE 2 CM IN SIZE- A RETROSPECTIVE STUDY

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ABSTRACT

Introduction -The treatment of renal calculi is based on various factors such as size, location, composition of stones, and associated anatomical abnormalities. Stone burden (size and number) is perhaps the single most important factor in determining the appropriate treatment modality for a patient with kidney calculi. In the kidney, for stones up to 20mm in diameter, ESWL is the recommended treatment. For stones >20mm in diameter, percutaneous nephrolithotomy (PCNL) is the first-line treatment. This is due to the higher retreatment rates and lower likelihood of achieving stone-free state with ESWL in comparison of PCNL. Most prefer to do pre-treatment prophylactic DJ stenting while treating larger renal stones (>2 cm) with ESWL due to fear of having complications.

Aims and Objectives: To evaluate the outcome of extracorporeal shock wave lithotripsy (ESWL) as monotherapy for solitary renal stones larger than 2 cm without ureteral stenting.

Materials and Methods: This was a retrospective study conducted in our department from September 2010 to February 2012.The study population were patients with nephrolithiasis with stone size more than 2 cm treated with Dornier Compact S – lithotripter (N= 208). The Study variables were age, sex, location and size of the stones. Pre-treatment KUB plain films, etc performed in all patients. Routine investigations performed. Post-treatment follow-up USG, KUB plain films were used to monitor the fragmentation and clearance of fragments. Stone size was calculated by measuring the maximum dimensions of the stone. Complete clearance defined as having no stone fragments at 3 months radiologically. Incomplete clearance was defined as having stone fragments of 5 mm or more in size. Clinically insignificant residual fragments (CIRFs) were defined as having stone fragments of 4 mm or less. Successful outcome was defined as being stone free or having CIRF at 3 months.

Results: The mean age of the patients was 43.8 years. More than 70 percent of the patients were in the age group of 30 - 60 years. The male to female ratio was 1:1.2. One hundred nineteen patients had stones on the right kidney and eighty-nine patients had on the left kidney. 24.04% patients developed skin bruises at the site of entry of shock waves which subsided themselves over few days. Mild transient hematuria was observed in 110 patients. Two (0.96%) patients developed perirenal hematoma after the fifth session. Steinstrasse was observed in 81(38.94%) patients. The overall success rate was 67.31%. There were 8 (3.85%) cases of failure to fragmentation and 60 cases of incomplete clearance.

Conclusion: With this small population, we were able to achieve the success rates comparable to larger series. A comparison study between PNL and ESWL for larger renal stones comparing stone-free rate, retreatment rate, economics of treatment, and complications after standardization of treatment schedule is needed. But in patients who are not fit for invasive surgeries like PCNL and open surgery, ESWL can be considered as a treatment option.

INTRODUCTION

The introduction of extracorporeal shock wave lithotripsy (ESWL) for the treatment of renal stones by Chaussy et al. in 1980 has been the revolution of the century [1]. The use of shock waves has radically changed the treatment of urinary lithiasis [2]. Shock wave lithotripsy became rapidly acknowledged as a first-line, effective, non-invasive method for the majority of stones, but eventually a series of limitations were revealed. The treatment of renal calculi is based on various factors such as size, location, composition of stones, and associated anatomical abnormalities. Stone burden (size and number) is perhaps the single most important factor in determining

the appropriate treatment modality for a patient with kidney calculi [3]. In the kidney, for stones up to 20mm in diameter, ESWL is the recommended treatment, with the addition of antibiotics for infectious stones. For stones >20mm in diameter, percutaneous nephrolithotomy (PCNL) is the first-line treatment. This is due to the higher retreatment rates and lower likelihood of achieving stone-free state with ESWL in comparison of PCNL [4]. For staghorn stones (either partial or complete), the preferred treatment modality is again PCNL and the role of ESWL is secondary. The combination of PCNL and ESWL appears to be superior to that of ESWL and PCNL. ESWL is probably the least invasive, but not complication-free, procedure used to treat stone disease. There are well-known adverse effects, like those related to stone fragments (residual stone, steinstrasse, obstruction), infection (urinary tract infection, urosepsis), and effects on tissue (renal hypertension, insufficiency, haematoma) and on fertility and pregnancy, especially for kidney stones, even though in a small proportion of patients [5]. Most would prefer to do pre-treatment prophylactic DJ stenting when they prefer to treat larger renal stones (>2 cm) with ESWL due to fear of having complications. In our department, as a policy we do not follow prophylactic DJ stenting even for larger renal stones since patients are closely followed during whole treatment session. This study is aimed at to assess the efficacy of ESWL as monotherapy for larger renal stones and the safety of this therapy without prophylactic DJ stenting. We will study the outcome of ESWL monotherapy in patients with solitary renal stones greater than 2 cm who opted for it after knowing the various options of treatment.

MATERIALS AND METHODS

This study was a retrospective study conducted in the Department of Urology, Regional Institute of Medical Sciences, Imphal, from September 2010 to February 2012.The study population were patients with nephrolithiasis with stone size more than 2 cm treated. The treatment was carried out using "Dornier Compact S – lithotripter (Dornier Medtech, Germany)", a third generation electromagnetic lithotripter with an integrated fluoroscopic C-arm and Ultrasound for stone localisation and monitoring. The depth of penetration of the shock wave is 14 cm; the focal zone is 4.7x57 mm. We analyzed the hospital records of patients who underwent ESWL for solitary radio-opaque renal stones larger than 2 cm in our department during this study period. Patients with congenital anomalies of the kidney and patients who underwent ESWL following percutaneous Nephrostomy, previous surgery and previous stenting were excluded from the study. There were a total of 208 such patients who fulfilled these criteria. The Study variables were age, sex, location and size of the stones.

Pre-treatment kidney, ureter, and bladder (KUB) plain films and ultrasonography and intravenous urography were performed in all patients. Routine investigations included a complete hemogram, Bleeding Time (BT) , Coagulation Time (CT), Electrocardiogram (ECG), Urine R/E and C/S, Kidney function test (KFT), Random Blood sugar level. Post-treatment follow-up ultrasonography, tomograms, and KUB plain films were used to monitor the fragmentation and clearance of fragments at 1-week, 1-month, and 3-month-period. Stone size was calculated by measuring the maximum dimensions of the stone in KUB plain films. Patient preparation included liquid diet after bowel preparation with 2 tablets dulcolax and 4 tablets charcoal previous night after dinner and patients were given analgesic medication in the form of Diclofenac 75 mg intramuscular injection just before starting the session. All were treated in supine posture and underwent lithotripsy starting with the lowest intensity. The intensity was gradually increased to the next level after every 500 shock waves up to a maximum of 9 if the patient tolerated otherwise it was continued with the highest level the patient could tolerate. The total number of shocks per session was 3000 - 3500 given at the frequency of 60 to 90 min^{-1} and the last 500 shock were given at a rate of about 100 $min^{-1.}$

After the procedure, patients were advised with an antibiotic tablet levofloxacin 500mg once daily for five days, tablet tranexamic acid thrice daily for three days, an antispasmodic tablet and urinary alkaliser. Fragmentation of the stone during the procedure was verified by means of X-ray, ultrasound or both. All patients were advised to have fluid intake of about 2.5-3 L/day. All were instructed to report even the minor complications after treatment and were kept under a close follow-up One week after the treatment, X-ray or ultrasound was used to check the existence of haematoma or the evolution of the lithiasis. If the residual fragment size was more than 4 mm a repeat session was advised, otherwise patients were discharged from the treatment regimen. In this study, complete clearance or stone-free state was defined as having no stone fragments at 3 months radiologically. Incomplete clearance was defined as having stone fragments of 5 mm or more in size. Clinically insignificant residual fragments (CIRFs) were defined as having stone fragments of 4 mm or less in diameter in asymptomatic nonstruvite patients. Successful outcome was defined as being stone free or having CIRF at 3 months. Unsuccessful outcome was incomplete clearance or failure of fragmentation after 4500 shock waves. Any auxiliary procedure done was noted e.g. DJ stenting, PCN, URS, ureterolithotomy, Pyelolithotomy, Nephrolithotomy, Nephrectomy. All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS 15.0) for windows. All categorical data were presented using frequencies and percentage. Associations between categorical variables were assessed using Chi-square test with Yates' correction and ANOVA test. A P value less than 0.05 was considered statistically significant.

RESULTS

From September 1998 to February 2010, 1505 patients who had upper urinary tract stones underwent ESWL in the Department of Urology, Regional Institute of Medical Sciences, Imphal. Two hundred and eight patients underwent ESWL for large solitary renal stones (>2 cm). The mean age of the patients was 43.8 years. Only 3 patients were below 18 years of age. More than 70 percent of the patients were in the age group of 30 - 60 years. The male to female ratio was 1:1.2. Forty-three (20.67 %) patients had stones in the pelvicalyx, one hundred forty-nine (71.64 %) had in the renal pelvis, four (1.92 %) had in the upper calyx, two (0.96 %) had in the middle calyx and ten (4.81 %) had in the lower calyx. The stone size ranged from 21mm to 67 mm. One hundred thirty-six patients (65.39 %) had stone size between 21-30 mm, fifty-one (24.52 %) had between 31-40 mm, fifteen (7.21 %) had between 41-50 mm, five (2.40 %) had between 51-60 mm, and only one patient (0.48 %) had a stone size of 67 mm. One hundred nineteen patients had stones on the right

kidney and eighty-nine patients had on the left kidney. Table 1 below shows the patient and stone characteristics.

Table 1: Patient and stone characteristics (N= 208)

Number of Patients	208
Male: Female	1:1.2
Male	95 (45.67%)
Female	113(54.33%)
Age Group	10-80 years(Mean = 43.8 yrs)
Stone Location:	
Upper Calyx	04(1.92%)
Middle Calyx	02(0.96%)
Lower Calyx	10(4.81%)
Pelvis	149(71.64%)
Pelvicalyx	43(20.67%)
Laterality:	
Right	119(57.2%)
Left	89(42.8%)
Stone size	21-67mm

[Table 2] below shows the number of ESWL sessions in different stone sizes.

Stone Size (mm)	No. of sessions (Mean ± SD)	ANOVA p-value
21-30	3.37 ± 1.98	0.081
31-40	3.62 ± 1.94	
41-50	4.47 ± 3.07	
51-60	3.60 ± 2.97	
61-70	8.00 ± 0.00	

For a stone of 67 mm size, a total of 8 sessions were required. The difference in the number of sessions required according to stone size was not statistically significant (p-value=0.081).

Table 3 below shows the number of ESWL sessions in staghorn and non-staghorn calculi in different group of sizes.

Stone size (mm)	No. of sessions in Staghorn calculus (Mean ± SD)	No. of sessions in Non-staghorn calculus (Mean ± SD)	Unpaired T-test p-value
21-30	3.85±1.98	3.28±1.98	0.225
31-40	3.93±2.67	3.37±1.47	0.198
41-50	4.80±3.35	4.30±3.09	0.778
51-60	1.00	4.25±2.99	0.402
61-70	-	8.00	-

The difference in the number of ESWL sessions required in staghorn and non-staghorn calculi in all the size range is not clinically significant (p- value > 0.05). For stones in the size ranges of 21-30 mm, 31-40 mm, 41-50 mm, 51-60 mm and 61-70 mm, the success rates of ESWL were 85.29% (116 patients), 31.37% (16 patients), 33.33% (5 patients), 40.00% (2 patients) and 100.00% (1 patient) respectively.

Figure 1 below shows the success of ESWL in stones located in different sites.

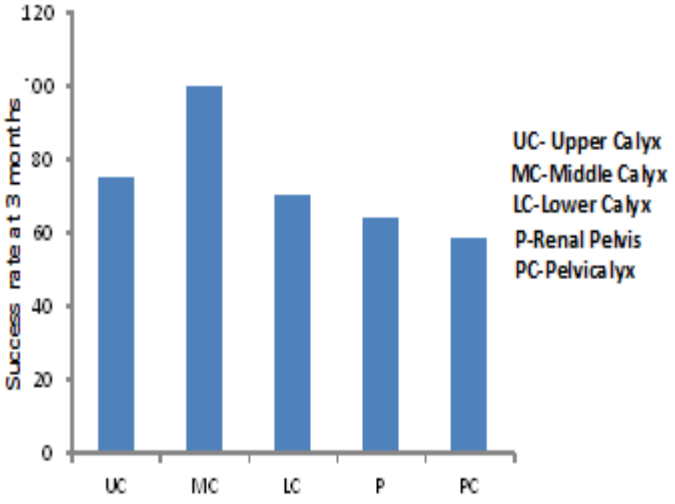
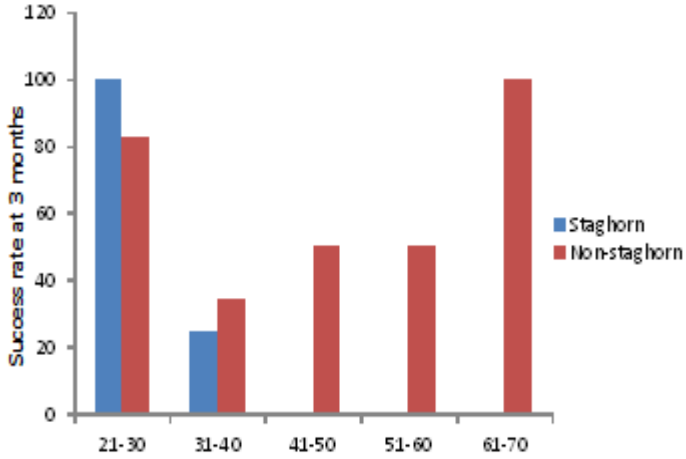


Figure 2 below shows the success of ESWL in different stone types of different sizes.



Regarding the complications of ESWL in the present study, fifty (24.04%) patients developed skin bruises at the site of entry of shock waves which subsided themselves over few days. Mild transient hematuria was observed in 110 (52.89%) patients which subsided with rest and conservative therapy. Two (0.96%) patients developed perirenal hematoma after the fifth session which subsided in a period of 3 months with conservative management. Steinstrasse was observed in 81(38.94%) patients out of whom fifty patients responded to conservative management with alpha blockers and analgesics. However, remaining patients underwent different ancillary procedures to facilitate passage of stone fragments. Different ancillary procedures had been done in 172 patients. Ten patients underwent URS + DJ stenting for steinstrasse. Eighteen patients underwent DJ stenting for steinstrasse as it failed to pass with conservative management for 6 weeks. Four patients underwent PCN insertion for Pyonephrosis. In 3 patients, ureteral meatotomy was done to hasten the passage of steinstrasse. Out of 148 failed cases, 136 patients underwent open stone surgery (Pyelolithotomy, Nephrolithotomy) but 10 patients were lost for follow-up. However, 2 patients with chronic pyonephrosis underwent nephrectomy.

DISCUSSION

ESWL has become the standard initial treatment for most renal calculi since its introduction by Chaussy et al [1]. The role of ESWL for larger renal stones is controversial. In the 1980s, ESWL monotherapy was applied for stones >2cm; however, the need for multiple treatments, the high incidence of adjunctive procedures required and the low stone-free rate prompted the recommendation that large calculi should be treated with combination therapy (PCNL+ESWL)[6]. In the 1990s and the beginning of this century, several concerning treatment of staghorn calculi with ESWL monotherapy showed a higher success rate, together with a lower rate of complications[7,8]. According to NIH consensus conferences recommendation, patients with stones larger than 2 cm, infected or not should be approached with PNL initially, followed if needed by ESWL due to high retreatment rates and the need for ancillary procedures [9]. However, many of the centers across the globe treat these patients with ESWL monotherapy with good success rates. A decade ago, the results of ESWL monotherapy for

solitary renal stones >2 cm were variable and stone-free rate was varying from 33% to 65% [10]. The advancement of technology and current expertise in ESWL has yielded much higher stone-free rates [11]. In our study, 208 patients with solitary large renal stones above 2 cm in size underwent ESWL with electromagnetic Dornier compact S Lithotripter without DJ stenting. The overall success rate was 67.31%. There were 8 (3.85%) cases of failure to fragmentation and 60 cases of incomplete clearance. Out of these 68 (32.69%) failure cases, 60 underwent open stone surgery (Pyelolithotomy, Nephrolithotomy) and 10 were lost for follow-up. In our study, when we considered the outcome of ESWL in stone size of 2-3 cm, the success rate was 85.29% which is at par with 90% success rate of PCNL [4]. Abe et al. reported 46% stone clearance and 54% residual fragments among 267 patients with renal stones with size between 20 and 30 mm in size in their series of 3024 patients treated with ESWL monotherapy. All the patients had DJ stenting prior to ESWL monotherapy. Their overall stone-free rate was 65.1%, and the success rate was 85.7% when they analyzed all the patients with stone size varying between 4 and 30 mm [12]. Their study results are better than our result as we achieved a success rate of 67.31% on stones more than 2 cm size, but without stenting. Kurien et al. have shown that equivalent stone fragmentation and clearance as adults can be achieved in children with stone size less than 20 mm at lower shock rate and lower energy level [13]. Chacko et al. had shown in their study that slower rate of shock delivery has better fragmentation than faster rate in stones with size between 1 and 2 cm[14]. In our study, we also found that with slower rate of shock delivery (70 shocks/min) has better stone fragmentation even for stone more than 2 cm. As observed in this study, success rate was not significantly different with respective of stone location. This may be because the cases are not equally distributed according to location. The number of cases seen in upper, middle and lower calyces is quite low.

ESWL is not complication-free despite its relatively non-invasive nature. The estimated rate of overall complications reported for ESWL therapy for staghorn calculi ranged from 13% to 19% [15]. In our study, fifty (24.04%) patients developed skin bruises at the site of entry of shock waves which subsided themselves over few days. Mild transient hematuria was observed in 110 (52.89%) patients which subsided with rest and conservative therapy. Two (0.96%) patients developed perirenal hematoma after the fifth session which subsided in a period of 3 months with conservative management.

The role of DJ stenting prior to ESWL for large renal stones is controversial. DJ stenting prior to ESWL monotherapy is often a prerequisite when treating renal stones of size more than 2 cm in order to get better clearance and avoiding complications. Low et al. compared 152 and 27 patients with small renal stones (<20 mm) who were treated without or with DJ stenting. There was no significant difference in stone-free rates at 1 month and 3 months (61% nonstented vs. 67% stented group) or in the retreatment rates (13.3% nonstented group vs. 14.8% stented group). Moreover, the incidence and severity of pain were similar in both the groups. They concluded that placement of DJ stents for the purpose of improving stone-free rates, alleviating pain, or preventing ureteral obstruction in conjunction with ESWL of solitary renal calculus <20 mm in diameter is unnecessary[16]. However, DJ stent has shown to increase the stone-free rates and reduce the complications due to ureteric obstruction and the need for percutaneous nephrostomy. Kumar et al. have shown that SWL monotherapy for renal stones without stenting even in solitary kidneys is safe [17]. In their series of 16 patients with solitary kidneys who underwent SWL monotherapy for renal stones between 5 and 15 mm without stenting, only one patient had complications due to obstruction of ureter. In spite of conflicting reports on pre-treatment stenting before ESWL monotherapy, our study showed that pre-treatment stenting had no significant effect on the successful outcome of ESWL. Nevertheless, closer follow-up is required in all the cases to ensure that the path is not obstructed by the fragments.

The incidence of steinstrasse is higher when SWL monotherapy is given for larger renal stones. Shouman et al. have shown that steinstrasse occurred only in four patients (16.6%) in their study [11]. Most of them have cleared the stone fragments without any problem and one underwent ureteroscopy. In our study, even though 81 (38.94%) patients had steinstrasse following ESWL, only fifty patients responded to conservative management with alpha blockers and analgesics. However, remaining patients underwent different ancillary procedures to facilitate passage of stone fragments. The higher incidence of steinstrasse noted in the study probably is due to increased frequency of follow-up X-ray KUB taken at an earlier period and probably frequent treatment sessions within a short duration. We did ESWL with real time ultrasound monitoring, so we could detect perirenal / sub capsular hematoma quite easily. Two (0.96%) patients developed perirenal hematoma after the fifth session which subsided in a period of 3 months with conservative management.

The limitations in our study were: (1) small number of patients with large stone treated with ESWL monotherapy, (2) the number of cases in different groups according to size and location were not similar for comparative study. However, with this small population, we were able to achieve the success rates comparable to larger series. A comparison study between PNL and ESWL for larger renal stones comparing stone-free rate, retreatment rate, economics of treatment, and complications after standardization of treatment schedule is needed in this part of the country to say the final verdict emphatically.

CONCLUSION

In the present retrospective study of ESWL for large solitary renal calculi above 2 cm in size, it is found that patients with large renal calculi required multiple ESWL sessions and the rate of ancillary procedures are high. Also, the success rate of ESWL in large renal calculi above 2 cm in size is low (67%). So, for both nonstaghorn and staghorn calculi with size above 2 cm, other treatment modalities like PCNL should be considered as the first treatment option. But in patients who are not fit for invasive surgeries like PCNL and open surgery, ESWL can be considered as a treatment option. For renal calculi of size 2 - 3 cm, the success rate at 3 months is 85% which is at par with that of PCNL. So, ESWL can be considered as the first treatment option for patients with renal calculi of this size. Hundred percent success rate of ESWL was achieved in calculus of 61-70 mm size seen in our present study should be interpreted with caution because only one patient had calculus in this size range and the result is of

this single patient only. Complications like hematuria, steinstrasse and pyonephrosis are increased in patients with large renal calculi above 2 cm in size.

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