Outcome of extracorporeal shock wave lithotripsy for renal and upper ureteric stone clearance

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Abstract

Introduction: Extracorporeal shockwave lithotripsy (ESWL) is a daycare, less invasive procedure not requiring anesthesia for the treatment of renal and ureteric stones.

Method: This was a cross-sectional study of retrospectively collected data on ESWL from May 2018 to January 2020 at the department of Urology, Bir Hospital, National Academy of Medical Sciences (NAMS), Nepal. The data on ESWL for renal and upper ureteric stones up to 20 mm were included. Stone clearance was defined as stone fragment <4 mm on kidney ureter bladder (KUB) X-ray or ultrasonography (USG) during follow-up at 1 - 3 mo. Ethical approval was obtained from NAMS ethical committee. Microsoft Excel was used for descriptive analysis of age, gender, stone size, density, location, hydronephrosis, and clearance. A Chi-square test was used for the association, and a p-value <0.05 was considered statistically significant.

Result: Out of 79 cases, overall stone clearance was 48(60.8%), 100% for <10 mm (14/14) and density <500 HU (5/5), and 80% for upper ureteric stone (4/5) and 74.1% for those without hydronephrosis (20/27). Patients in the age group of 20-39 y accounted for 48(60.8%), males 52(65.8%), 52(65%) had 10-15 mm stones, 48(60.8%) density of 751-1000 HU, and mild hydronephrosis present in 44(55.7%).

Conclusion: Stone clearance was highest (100%) for small stones <10 mm in size and low density <500 HU. The stone clearance rate decreased as the size, density, and hydronephrosis increased.

Keywords: extracorporeal shock lithotripsy, hydronephrosis, renal and upper ureteric stone, stone clearance, stone size, and density
Introduction

The renal stone disease occurs in 8-46% and varies according to age, gender, race, and geography.1,2 More stones are detected with increased use of imaging technology like ultrasonography (USG) and computed tomography (CT) scan.1,2 Less invasive treatment modalities like ureterorenoscopy (URS), percutaneous nephrolithotomy (PCNL), and extracorporeal shockwave lithotripsy (ESWL) are preferred over open surgery.3,4

The ESWL is indicated for renal stone up to 20 mm in the pelvis, upper pole, or mid-pole, and ureteric stone >10 mm.3 It is a daycare less invasive procedure without anesthesia and has comparable stone clearance.5-8 Success of ESWL for stone clearance depends on age, gender, stone size and density, location, state of hydronephrosis, skin-to-stone distance and power delivered per stone volume unit during the ESWL, and use of adjunctive measures.3,9,10 Most resistant stones for shock lithotripsy are cysteine, brushite, and calcium oxalate monohydrate.8

The ESWL service started in Nepal in 1987 at Shree Birendra Hospital- Nepal Army Institute of Health Sciences and reported a stone clearance of 73.52% (522/710) during a 10 y period from 2002 to 2012.11 Other centers have reported a clearance of 79.3% (341/430) increasing to 96.3% (414/430) after multiple sessions,12 and yet another study13 found clinically significant residual fragments in 1/3rd of 34 cases of ESWL after 3 mo.

This study aimed to analyze the outcome of ESWL for stone clearance following the start of service in 2018 at the Bir hospital, Nepal. The findings of the effectiveness of lithotripsy will help to optimize the service delivery.

Method

This was a cross-sectional study of retrospectively collected data from the ESWL service unit from May 2018 to January 2020 at the department of Urology, Bir Hospital, National Academy of Medical Sciences (NAMS), Nepal. Inclusion criteria were stone size <20 mm for renal and upper ureter, the stone density of <1000 HU, absence of urinary tract infection based on urine culture and sensitivity, normal creatinine level of <1.5 mg/dl, and no abnormalities of the stone-bearing kidney. Ethical approval was obtained from NAMS institutional review board (Ref. No. 1368/2078/79).

As per hospital protocol, patients had pre-operative routine laboratory tests for urine routine and culture sensitivity, white blood cell count (WBC), hemoglobin (Hb), platelets, coagulation profile (bleeding time, clotting time, and prothrombin time), renal function test (RFT) including urea, creatinine, sodium, and potassium. The radiology investigation included USG of the abdomen and pelvis, kidney ureter bladder (KUB) X-ray, and CT intravenous urography (IVU). The CT-IVU was done in a patient with thinned-out parenchyma, moderate hydronephrosis, or suspected anatomical abnormalities. The ESWLs were performed on a daycare basis using Allenger Urolith + electro-hydraulic machine (SN 2K17100011-DL) to deliver shockwaves after focusing stone on the C-arm (SN 2K1710094-DC) image. Analgesic ketorolac 30 mg was given intramuscularly before the procedure. The ESWL session was terminated on the complaint of severe pain, radiolucency on the C-arm, or reaching 4000 shocks for kidney stones and 3500 for upper ureteric stones. Tamsulosin 0.4 mg once a day was prescribed for one month. In case of urgent need (severe pain, fever, hematuria) patients were advised to attend the emergency.

Success for stone clearance after ESWL was based on follow-up at 1 mo showing the absence of radiopaque shadow on X-ray KUB and stones of <4 mm on USG abdomen and pelvis. Patients who did not clear the stones at 1 mo had repeat X-ray KUB and USG at 3 mo.

Microsoft Excel was used for descriptive data analysis for age, gender, stone characteristic
(size, density, location, hydronephrosis), and stone clearance. The Association of stone characteristics and stone clearance was analyzed by \(X^2\) test. A \(p<0.05\) was considered statistically significant.

**Result**

There was a total of 79 cases of ESWL data available for analysis during two years study period. Out of 79 cases, 48(60.8%) had stone clearance at 3 mo follow-up. The males were 52(65.8%) and females 27(34.2%), M:F ratio of 1.9:1. There were 48(60.8%) patients in the age group 20-39 y, Table 1

Stone size of 10-15 mm was present in 52(65%), 46(58.2%) in the pelvis, 48(60.8%) stones had a density of 751-1000 HU, and mild hydronephrosis was present in 44(55.7%), Table 2.

**Table 1. Demographic characteristics and stone clearance after extracorporeal shock wave lithotripsy in renal and upper ureteric stones (N=79)**

<table>
<thead>
<tr>
<th>Gender</th>
<th>N</th>
<th>%</th>
<th>(X^2) value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>52</td>
<td>65.8</td>
<td>7.9</td>
<td>0.0049</td>
</tr>
<tr>
<td>Female</td>
<td>27</td>
<td>34.2</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Age (y)</th>
<th>N</th>
<th>%</th>
<th>(X^2) value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;20</td>
<td>5</td>
<td>6.3</td>
<td>61.0</td>
<td>0.0000</td>
</tr>
<tr>
<td>20-39</td>
<td>48</td>
<td>60.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥60</td>
<td>6</td>
<td>7.6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Discussion**

We found that an overall stone clearance of renal and upper ureteric stones after ESWL was 60.8%(48/79). This finding is consistent with the other reported studies in the literature on stone clearance rate of 56-96%\(^{11-14}\). The stone clearance depends on size, density, location, sessions of ESWL, types of lithotripters, dedicated services setups, use of adjunctive measures like PID (percussion, inversion, and diuresis), and radiological confirmation during and after the treatment.

In the present study, we found that the clearance for small size stones of <10 mm was 100% (14/14) compared to 61% (32/52) for 10-15 mm and only 15% (2/13) for a larger stone of 15-20 mm, which showed there was a statistically significant difference (\(X^2\) value of 37.5, \(p<0.0000\)) for the clearance of stones after ESWL, and decrease in stone clearance rate as the size of the stone increased.
Various studies have reported a higher clearance rate for smaller stones after ESWL, and it decreases gradually with the increase in size and density.10,15-17

Studies have shown that stone disintegration occurs better when the focal diameter of the shock-wave generator is larger than the stone size. This is because the mechanism of stone fragmentation depends on various factors like squeezing or circumferential quasistatic compression, the Hopkinson effect, shear force, and cavitation.18,19 The larger and harder stone requires more shock waves.20 As shown in our study, there was a poor outcome after ESWL for larger (>15 mm) and harder (>750 HU) stones. The shock generator used in this study has a focal length of 12 x 4 mm size. This shows that patient selection greatly improves ESWL effectiveness and its role as a noninvasive treatment for a better outcome with higher stone clearance.21

In the present study, the clearance rate was 100% (5/5) for low-density stones. The CT scan measurements of substance density in Hounsfield units (HU) are the standard criteria to predict stone density and stone clearance after the lithotripsy. Various studies in the published literature have reported the rate of stone clearance as high as 70-100% for density <500 HU, which decreases to 66-93% for 500-1000 HU and further decreases to 33-51% for >1000 HU.13,14,22,23 In this study we also analyzed the sub-group of patients with a stone density of 500-750 HU and 751-1000 HU which showed a success rate of 88.5% (23/26) and 41.7% (20/48) respectively. The difference in stone clearance was significant (X2 value =14.1, p=0.0008) in a present study showing a stone clearance decreasing from 100% for <500 HU to 88.5% for >500-750 HU, and further decreased to 41.7% for >751 HU for the renal and upper ureteric stones.

In the present study occurrence of steinstrasse was not recorded in the data we analyzed from the ESWL department; possibly, there was no such case. Spontaneous steinstrasse without shock wave occurs rarely and was reported in 1 of 9 cases requiring prompt management after ESWL to preserve the renal function.24 The management includes repeat sessions of ESWL, DJ stenting, medical management, or simply observation depending on the functional status of the kidney, the number and size of fragments, and the use of endourological interventions like ureterorenoscopy (URS), percutaneous nephrostomy (PCN) or nephrolithotomy (PCNL). Bilateral steinstrasse is even rarer.

In the present study, the maximum number of shock wave delivered were 4000 for renal stones and 3500 for upper ureteric stones. The Shockwave session was terminated if radiolucency was noted on C-arm which was checked after every 1000 shocks. Ramping-up protocol was followed after 200-300 initial shocks. The energy ramp-up (14-22 kVa) was maintained depending upon the pain tolerance.

In the present study, the clearance rate was highest for upper pole stones (4/5 i.e. 80%). However, other studies have shown better clearance in the renal pelvis and upper ureter.13,17,25 The difference could be due to stone characteristics and the presence of hydronephrosis. Another possible explanation for low overall clearance in the present study (48/79, i.e. 60.8%) may be because of the initial set-up of ESWL services without provision for repeat sessions and no routine adjunctive measures of PID.

The present study shows statistically significant (p=<0.0000) success after ESWL with or without hydronephrosis. The clearance rate was 74% (20/27) for no hydronephrosis compared to 54.5% (24/44) for mild, and 50% (4/8) for moderate hydronephrosis. We had no case of severe hydronephrosis. The presence of hydronephrosis and stone clearance is controversial. Some studies have shown no significant differences26,27 and others show a higher stone clearance17,28 in the absence of hydronephrosis. The mechanism of high clearance rate in absence of hydronephrosis is because of the impedance of shockwave in...
presence of water, and mechanical movement of stone after shock wave; and, also the functional status of the kidney to clear the stone is affected by hydronephrosis.\textsuperscript{18,19}

Placement of double-J (DJ) stent is not routinely practiced and is unnecessary because it does not improve the stone-free rate and causes irritative symptoms.\textsuperscript{29,30} Recent comparative studies on the placement of DJ stents found that stenting did not improve stone-free rate, neither it benefited the passage of the stone fragments following ESWL; thus, the study concluded that stenting is unnecessary, especially for smaller stones, for example, renal stones with a diameter of less than 2.5 cm.\textsuperscript{30} In the present study we did not use a DJ stent during or after the ESWL sessions for renal and upper ureteric stones.

Medical expulsion therapy (MET) is an important adjunct in ESWL treatment for passage of fragmented stones, and reduces expulsion time as well as requirement for analgesics. A recent systematic review and meta-analysis found that tamsulosin is an effective MET in patients who require multiple sessions of ESWL for specific stone sizes or locations.\textsuperscript{31} In the present study all patients had tamsulosin 0.4 mg once a day as adjunctive MET for one month after the ESWL sessions. Tamsulosin is known to inhibit basal tone, peristalsis, and ureteral contractions, and also is effective in dilatation of the ureter which further increases the fluid bolus volume of the ureter and helps in expulsion of stone distally, resulting in better stone clearance.

There is a lack of well-designed randomized control trials using CT to assess residual stone fragments after lithotripsy for renal and upper ureteric stones.\textsuperscript{31} The limited use of CT overestimates the stone-free rate (based on residual fragments ≤3 mm).\textsuperscript{32} There is no protocol for routine CT follow-up after ESWL at Bir hospital, possibly due to cost and also considering the significance of finding clinically insignificant stone fragments of a very small size of fewer than four millimeters. Some of the limitations of the present study could be a single-center study, the retrospective data in which we could not analyze details of complications, the use of adjunctive therapy, and the role of additional endourological interventions. However, this is the first documentation of the outcome of ESWL service at Bir hospital since the start of this service in May 2018. This data may provide the basis for the extension of studies on shock wave therapy for renal and ureteric stones locally.

Conclusion

We observed a higher clearance rate for the upper urinary tract stones less than 10 mm in size, and a density of less than 500 house field units. The stone clearance rate decreased as the size and density of the stone increased. The stone clearance was high in the absence of hydronephrosis.

Conflict of Interest
None

Funding
None

Author Contribution
Concept, design, planning: PR, BA, AC, CS, RB, JNS; Literature review: PR, JNS; Data collection: PR; Data analysis: PR, BA, AC, CS, RB, JNS; Draft manuscript: PR, RB, JNS; Revision of draft: PR, BA, AC, CS, RB, JNS; Final manuscript: PR, RB, JNS; Accountability of the work: PR, BA, AC, CS, RB, JNS.

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