

# ESWL: A Safe Modality for Treatment of Renal Stones. A Clinical Study at Kidney Center, DHQ Hospital, Faisalabad

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## ABSTRACT

**Introduction:** Renal stones have been one of the most commonly encountered diagnosis in patients visiting Urology clinics and Extra-Corporeal Shock Wave Lithotripsy (ESWL) has been an effective method for management of renal stones of certain size (Up to 2.5 cm). **Objective:** To determine the complication rates in patients undergoing ESWL to look for safety level of the procedure. **Duration And Setting:** Study was conducted From December 2015-March 2016 in Kidney Center, DHQ Hospital, Faisalabad. **Methodology:** First 225 patients undergoing ESWL at Kidney Center, DHQ Hospital, Faisalabad were included in the study and they were observed for short term complications as post procedure pain, hematuria, fever and ureteric obstruction. **Results:** 225 patients included in the study. Among them 132 (58.7%) were male, 93 (41.3%) were female. Average age of patient was 38.2 years with minimum range as 5 years and maximum as 75 years. Stone size ranged from 7mm to 2.5cm with average size as 1.541cm. Fragmentation was observed in 218 (96.9 %) patients in first two sessions while no fragmentation was observed in 7 (3.1%) patients after two sessions. Out of 225, 37(16.4%) patients developed pain, 19 (8.4%) observed hematuria, 7 (3.11%) have fever and 6 (2.66%) developed ureteric obstruction. Only 3 patients developed two complications simultaneously. No statistical association was found for development of complication after ESWL in our study. **Conclusion:** Inference drawn from the statistics clearly showed that ESWL is still a very safe and effective modality for renal stone management.

**Key Words:** Renal stone, Extra Shock Wave Lithotripsy (ESWL), Hematuria, Fever.

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## INTRODUCTION

Urolithiasis is one of the most frequently encountered diagnosis in patients who present in Urology clinics. Prevalence of renal stones is increasing across the globe in last 100 years as indicated as increase in US<sup>1</sup> and Europe<sup>2-3</sup> and according to a study in US showing prevalence rate doubled in 1960s and 1970s<sup>4</sup> and life time risk of individuals for development of renal stone in US is 10-15 %<sup>5</sup>. No such study has been done in Pakistan to show any figure regarding prevalence of the disease in our region but studies done across different countries of Asia have shown increase in prevalence.<sup>6-8</sup> Renal stones are the solid structures being formed by precipitation of certain salts mostly due to change in pH being produced by bacterial activity in renal collecting system. There are many type of renal stones, among them Calcium stones are the most common type and occur in two forms:

calcium oxalate and calcium phosphate. Calcium stones are formed in high pH. Other types are Uric acid stones (form in acidic urine), Struvite stones and Cystine stones.<sup>9</sup> Renal stone management options varies from open surgery to non-invasive and minimally invasive modality. However open surgery is almost now being replaced by non-invasive (ESWL) and minimally invasive (PCNL, mini PCNL and micro PCNL) procedures. ESWL is a very effective way of treating renal stones of size up to 2-2.5 cm.<sup>10</sup> Extra corporeal Shock wave lithotripsy (ESWL) was first introduced in the 1980s for the treatment of urolithiasis.<sup>11</sup> Since then ESWL has revolutionized treatment of renal stones worldwide, and according to a study, in United States, it has been estimated that approximately 70% of kidney stones are treated using ESWL.<sup>12</sup> Mechanics for lithotripters being used to break renal

stones is that they produce acoustic shock waves which are responsible for stone fragmentation.<sup>13</sup> Lithotripters produce a powerful acoustic field that results in three types of mechanical forces on stones and surrounding tissues: (a) direct stress associated with the high amplitude shock wave (b) stresses and microjets associated with the growth<sup>14</sup> and (c) violent collapse of cavitation bubbles.<sup>15</sup> There are three types of lithotripters depending upon their source and mechanism for production of shock waves. Electrohydraulic Lithotripters use a spark source to generate a shock wave which is focused by an ellipsoidal reflector on target.<sup>16</sup> Electromagnetic lithotripters use an electrical coil which is placed in close proximity of a metal plate as an acoustic source. When this coil gets excited by a short electrical pulse, the plate observes a repulsive force which is used to generate an acoustic wave and is targeted towards the focus with help of either lens or reflector.<sup>17</sup> Piezoelectric Lithotripter utilizes piezoelectric crystals as a source to form an ultrasonic wave. When a voltage is applied to a piezoelectric crystal it deforms and creates an acoustic wave. The crystals are placed on the inside of a spherical cap and the acoustic wave are focused at the center of the curvature of the sphere.<sup>18</sup> Lithotripsy breaks stone by many mechanism<sup>19</sup> including spall fracture, cavitation, shear stress, fatigue and super-focusing.<sup>20-22</sup> ESWL breaks the renal stones whose size is too large to pass through ureter, converting them into size negotiable through the ureter. Lithotripsy shows promising results in range of size ideally up to 2.5 cm renal stone<sup>10</sup>. Size beyond this limit is poor responder for ESWL. ESWL is considered to be associated with less complications and the immediate complications are due to collateral effect of shock waves on renal parenchyma and surrounding tissue resulting into pain and hematuria, due to release of bacteria secondary to fragmentation leading to fever and complication of ureteric obstruction due to passage of fragmented particles across the ureter.<sup>23</sup>

## METHODOLOGY

**Type of Study:** Descriptive study

**Setting:** Kidney Center, DHQ Hospital, Faisalabad.

**Duration of Study:** Duration of study was 4 months (December 2015-March 2016).

**Sample Size:** In this study, first 225 patients presenting in Kidney Center, DHQ Hospital,

Faisalabad for lithotripsy of renal stones were included.

**Inclusion criteria:** Those patients were selected for lithotripsy who fulfilled the criteria of stone size < 2.5 cm, age limit between 5 years to 75 years.

**Exclusion Criteria:** Evidence of active infection or hematuria at time of session, pregnant females, element of renal compromised status, uncontrolled hypertension and patients with any evidence of distal ureteric obstruction prior to session.

**Procedure:** Patients subjected to Modulith SLK lithotripter (Electro-magnetic lithotripter variety) and patients subjected to 3000 shocks with frequency of 1 shock/sec and energy level 50-60 joules. Patient observed on outdoor basis for fragmentation, development of pain, fever, hematuria and ureteric obstruction. Pain graded on the basis of Numeric Rating Scale NRS-11 (Table-1) and patient rated from 0-11 on patient self reporting of pain as given below.

Fever monitored in terms of low grade (Temperature between 99°F to 101°F), moderate (Temperature between 101°F to 102°F) and high grade (Temperature more than 102°F). Hematuria monitored with patient subjective observation and being confirmed with the help of complete urine examination. No RBC or RBC up to 4 taken as no hematuria, RBC between 5-10 taken as moderate and RBC more than 10 taken as gross hematuria. Ureteric obstruction monitored on basis of Ultrasound KUB evident as hydronephrosis and X-ray KUB.

**Data collection and statistical analysis:** Patients observed for two sessions and data collected in terms of age, sex, stone size, laterality, fragmentation, presence or absence of pain, fever, hematuria and ureteric obstruction. Data collected and analyzed for the variables. Chi-square test applied and probability measured to look for statistical significance for development of complication after ESWL.

**Table 1: Numeric rating scale (NRS-11)**

Rating	Pain Level
0	No pain
1-3	Mild pain (nagging, annoying, interfering little with ADLs)
4-6	Moderate pain (interferes significantly with ADLs)
7-10	Severe pain (disabling; unable to perform ADLs)

## RESULTS

Total 225 patients were included in study among them 132 were male (58.7%), 93 were female (41.3%). Average age of patient was 38.2 years with minimum range as 5 years and maximum as 75 years. Stone size ranged from 7mm to 2.5cm with average size as 1.541cm. Laterality includes as right sided stone 119 cases and left sided as 106 cases. Stone fragmentation was observed in 218 patients (96.9%) after two sessions while no fragmentation observed in 7 (3.1 %) cases after two sessions.

Pain was seen in 37 patients (16.4%) among them 21 were male and 16 were female. Among 37 patients with pain 18 (48.64%) graded with mild pain, 14 (37.83%) were with moderate pain and 5 (13.51%) had severe pain. Pain resolved for all patients within 4 days of maximum, requiring low dose analgesic treatment with oral diclofenic preparation. Hematuria was seen in 19 patients (8.4%) among them 11 were male and 8 were female. Fever seen in 7 (3.1%) patients among them 3 were male and 4 were female, all with mild grade fever with maximum day span of 1 day. 6 (2.6%) patients were having distal ureteric obstruction secondary to fragmented stone obstruction which was managed conservatively among whom 2 were males and 4 were females. Three patients (2 male and 1 female) have more than 1 complication. No statistical association was found for development of complication after ESWL in our study.

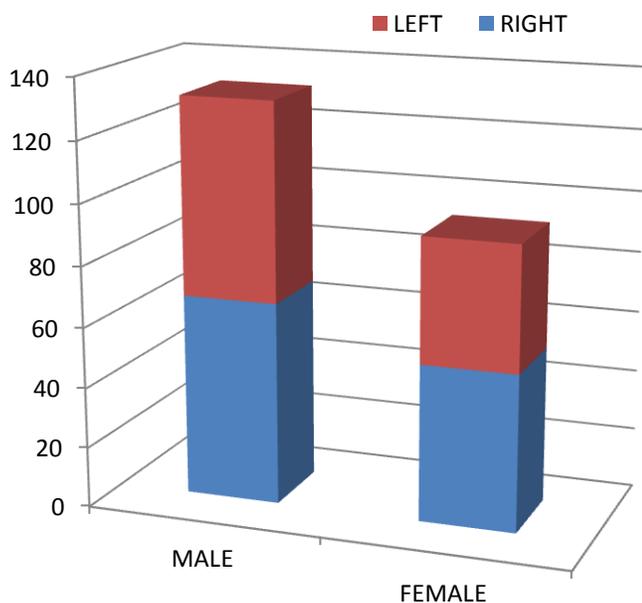


Figure 1: Gender and laterality distribution

MALE FEMALE

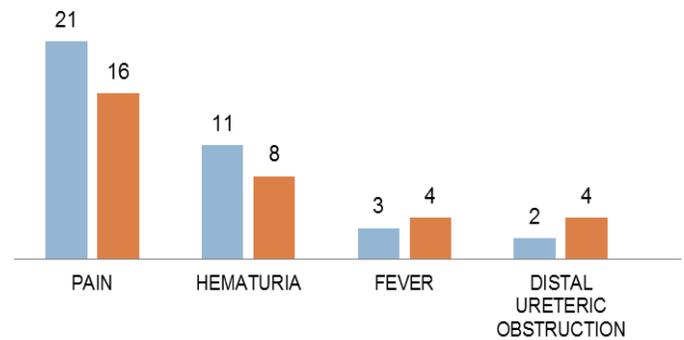


Figure 2: Complications with gender distribution

## DISCUSSION

Renal stone management comprises of medical therapy, shock wave lithotripsy, open surgery and minimally invasive endoscopic surgery. Medical management has limited role in treatment of renal stone and era of open surgery has passed away. Now treatment modalities have widely been shifted towards noninvasive or minimally invasive management. ESWL is an excellent modality for treatment of renal stone being noninvasive, easily approachable, no hospital stay, less complications and high success rate as shown by study as 60–99%.<sup>24-25</sup> Success rate of ESWL depends upon many factors including nature of stone, presence of hydronephrosis, size of stone, BMI and radiographic HFU.<sup>26</sup> Few short term complications for ESWL include pain, hematuria, fever and distal ureteric obstruction while long term complications include diabetes mellitus<sup>27</sup> and hypertension<sup>28</sup> which are very rare and require long term follow up. Patients with ESWL develops hematuria due to trauma to renal micro and macro vasculature and renal parenchyma.<sup>29</sup> Studies have shown that shock waves causes injury to the kidney vasculature<sup>30-31</sup> and veins have more tendency to get damaged and vascular damage occurs to a broad range of vessels, including vasa recta and cortical capillaries to intra-lobular and arcuate arteries and veins<sup>32</sup>. Collection of symptomatically important hematomas whether perirenal, subcapsular, or intrarenal hematomas are rare and occur in less than 1% of patients, however, if patients are investigated with CT scan or MRI, then detection of hematoma rises to 25%<sup>33</sup> because they have high sensitivity to detect such lesions. Shock wave lithotripsy can cause parenchymal injury leading to bleeding and mild to severe subcapsular hematomas.<sup>34</sup> A very few hematomas have

lasting major adverse effects.<sup>35</sup> Large hematomas are uncommon.<sup>36</sup> Hematoma rates depend on the type of lithotripter being used, as indicated by the values of less than 1% and up to 13% for different machines.<sup>36,37</sup> Increasing age acts as a risk factor for hematoma development. More is the age, more is the tendency towards development of hematuria and it has been reported that the incidence of hematomas increases about two-fold per decade.<sup>38</sup> Therefore, in elderly frequency and energy dose adjustment may be required to avoid hematoma and hematuria. During ESWL, shock waves produces cavitation effect to break stones. This effect also produces impact on renal parenchymal vasculature which can lead to micro-hemorrhagic points in renal parenchymal vasculature which not only act as source of hematuria but also act as portal for absorption of bacteria, being released from cracks of stone, in to the circulation leading to Systemic Inflammatory Response Syndrome.<sup>39</sup> Bacteriuria is present in up to 23.5% of patients<sup>40</sup> and the development of sepsis after bacteremia is relatively low, in <1% of cases.<sup>40,41</sup> Apart from some other factors, clinical urinary infection development also depends upon type of stone chemically being targeted. UTI is more frequently observed in patients with complex struvite stones.<sup>41</sup> The main goal of an ESWL is to fragment the stone to that extent that they can be spontaneously passed through the ureteric orifice and according to studies, the formation of fragments <4 mm is present in up to 59% of the cases and carries a risk of development of symptomatic distal ureteric obstruction, a surgical intervention to deal with distal ureteric obstruction after ESWL, or even both, equal to 43%.<sup>42</sup> Pain after ESWL session may be due to local tissue fatigue or due to obstructive uropathy created secondary to fragmented stone obstruction in the ureter. As far as long term complications are concerned, it has been found that renal scar formation may develop after ESWL and it was demonstrated in patients using Single Photon Emission Computed Tomography (SPECT) which showed areas of poor vascular perfusion due to scarring.<sup>43</sup> This scarring is directly proportional to the number of shocks per session.<sup>44</sup> New-onset hypertension is a potential long term complication of ESWL and is dose dependent.<sup>45</sup> Animal trials have shown that possible pathophysiology behind development of hypertension is mesangial cell proliferation.<sup>46</sup> Another important long term

complication is development of diabetes mellitus in the ESWL undergoing patients and was found to be associated with the number of shocks administered.<sup>47</sup> Other complications due to ESWL are rare including gastrointestinal lesion (1.8%)<sup>48</sup> and arrhythmias.<sup>49</sup> Considering in all, it can be concluded that ESWL complications are mostly dependent on patient dynamics, number and frequency of shock waves, number of sessions and presence of co-morbid conditions. However, ESWL is still a very safe, noninvasive and excellent modality for treatment of renal stones with high success rates.

## CONCLUSION & RECOMMENDATION

This study concludes that ESWL has got high level of effectiveness with minimal complication rate for treatment of renal stones of size up to 2.5cm. Authors strongly recommend that all the patients with such size of renal stone should be subjected should be considered for lithotripsy before deciding for invasive modality for stone management.

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