COMPARATIVE STUDY OF IN SITU ESWL VS PUSH BACK, STENTING AND ESWL FOR NON OBSTRUCTING UPPER URETERIC STONE

Ata M Mozassem1* Syed Md Muhsin2 K M Baki Billah3 Shameema Hossain Khan4 S M Nuruddin Abu Al Baki5 Mohammad Jahangir Hossain6

Abstract
Background: This is a hospital based prospective, cross sectional and interventional case control study conducted in department of urology, Chittagong Medical College, Bangladesh.

Materials and methods: Total 120 patient of upper ureteric stone were included in this study divided by Group-A (60) and Group-B (60). Group-A 60 patient under went in situ ESWL and group-B 60 patient under went push back, DJ stenting and ESWL. Number of Shock wave session, energy used (KV) stone clearance, complications of ESWL like loin pain, haematuria, fever and Lower Urinary Tract Symptom (LUTS) and cost were compared between the two groups were recorded and analyzed.

Results: In Group A total stone clearance were 96.7% (58/60) and group-B were 98.3% (59/60). But it was not statistically significant (p=0.559). Mean hospital stay of in situ group (Group A) was 1.03 ± 0.181 days compared to 2.57 ± 0.722 day in push back ESWL group (Group B). It was statistically highly significant (p=0.000). In group-A there was loin pain in 20 (33.33%). Haematuria 12(20%), fever in 06 (10%) and LUTS in 16 (26.7%) patients. In group B loin pain was in 35 (58.3%) (p=0.006). Haematuria 26(4.33%) (p=0.06), fever 14 (23.7%) (p=0.05) LUTS was 30 (50%) (p=0.009). More energy of ESWL (Kilo Volt-KV) required in group A than in group B. But it was not statistically significant (p=0.190).

Conclusion: Complications between the groups were statistically highly significant. In situ ESWL is very good option for the management of upper ureteric stone. It is non-invasive, effective, safe, cost savings, less hospital stay and usually does not need anaesthesia.

Key words
ESWL (Extra Corporeal Shock Wave Lithotripsy); Ureteric stone; DJ stenting.

Introduction
Urolithiasis is one of the common affictions of modern society though it has been described since antiquity. Several studies suggest increasing prevalence of stone diseases around the world1. Over the past three decades tremendous changes have occurred in the management of urolithiasis. Starting from watchful waiting and pharmacological manipulation to open surgery, there exists a spectrum of procedures which includes non invasive extracorporeal shock wave Lithotripsy ESWL2,3. Percutaneous Nephrolithotomy (PCNL) Uretero-Renoscopy (URS) Intracorporeal Lithotripsy (ICL) and Laparoscopic surgery. But one option can supplement the other for total stone clearance4. Urinary lithiasis can cause a greater or lesser degree of obstruction of the ureter, depending on the size of the calculus, ureteral oedema and the degree of impaction, requiring instrumental treatment, sometimes as an urgent procedure. Optimal treatment of ureteral calculi remains controversial and treatment options vary. Open surgery is rarely used. However, conservative approach is often complicated by recurrent flank pain, multiple visits to the emergency room, absence from work and an increased risk of serious complications like obstruction, infection and silent loss of renal function5.
There is a significant risk of long-term renal impairment if patients have unrelieved obstruction more than 4 weeks regardless of symptoms and stone size\(^6\). There has been a radical change in the management of urolithiasis since the introduction of ESWL in 1980. ESWL has been extensively used and recommended as first-line approach for the treatment of stones in proximal, middle, and distal parts of the ureter. It was recognized early that, the kidney stones were easily disintegrated than ureteric stone by ESWL, and fragmentation of ureteric stone required a higher shock wave energy as well as greater number of shock waves\(^6\)\(^-\)\(^9\). Push back of upper ureteric stone to kidney will facilitate easy fragmentation. But there is still debate regarding superiority of in situ ESWL and push back, stenting, and ESWL. With increased experience and technical achievements with or without low invasive auxiliary procedure it is possible in most cases to remove the stones without general or regional anaesthesia and with a low rate of complications and side effects. There is however a variable success rate reported in the literature which is related to the type of equipment, size and composition of the stone, degree of impaction and to what extent repeated shock wave sessions are accepted. The experience of the operator is also a factor of great importance\(^8\). The present study has been set to compare the success rate of treatment of upper ureteric stone by in situ ESWL and push back, stenting and ESWL and thereby to find out the superiority and cost effectiveness of one modality over the others in our perspective.

**Materials and methods**

This is a hospital-based prospective, cross-sectional and interventional case control study conducted in the Urology Department of Chittagong Medical College, Bangladesh, conducted from July 2007 to August 2009. The study was approved by the institutional Review Board and also by the Ethical Review Committee of Chittagong Medical College, Chittagong. Informed written consent were taken by the patient and guardian. All aspects of confidentiality were preserved. All patient of ureteric stone attending the outpatient Department of Urology and admitted in inpatients Department of Urology, Chittagong Medical College Hospital during the period of study were the study population. Of them 120 cases, satisfying the selection criteria were taken as sample. They were divided into two groups on simple random basis. Inclusion criteria were solitary stone in upper ureter, size of stone up to 1 cm, no obstruction distal to the stone, well excreting kidney in IVU. Exclusion criteria were size of stone > 1 cm, stone with ureteral narrowing or stricture, symptomatic urinary tract infection, pregnant women, bleeding disorder, renal failure, stone in solitary kidney and radiolucent stone, Group – A : Patient with upper ureteric stone treated by in situ ESWL. They were again classed into sub group-I stone size upto 0.6 cm and sub group –II stone size > 0.6 cm to 1 cm. Group – B : Patient with upper ureteric stone treated by push back stenting and ESWL, 60 patients. They were again sub divided by group-I stone size upto 0.6 cm and sub group-II stone size > 0.6 cm to 1 cm. Pre ESWL push back done for group B patient under spinal anaesthesia with 5Fr DJ stenting done under C-Arm guidance with 14 to 16 Fr indwelling Feley’s catheter for minimum period of 24 hrs. ESWL was performed on the same session or on the next immediate schedule. Having upper ureteric stone either stented or without stent all patients were with good bowel preparation. They were with nothing per oral and on IV fluid, IV Gentamycin 80mg injection as prophylactic antibiotics and single dose of Tramadol Hydrochloride 50mg injection IV as analgesics. All patients were advised to report after three weeks with plain X-ray KUB. If necessary a second or third session ESWL therapy were given at three weeks interval. Refractory cases were dealt with other modalities of treatment. Complaints of complications like loin pain, haematuria, fever and Lower Urinary Tract Symptoms (LUTS) were followed up routinely. Data were processed and analyzed by using computer statistical software Statistical Package for Social Sciences (SPSS) win 15. Test of significance were done by Students (t) test and Chi-square (\(\chi^2\)) test. A probability (p-value) value of < 0.05 was considered significant. The summarized data were then presented in the table, chart and graphs. Variable of interest were size of stone, shock wave, energy (KV) used, size of stone, stone clearance, hospital stay and complications like loin pain, haematuria, fever and Lower Urinary Tract Symptom (LUTS).
Results

Table I: Statistics of energy used among the study groups (With t-test significance)

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>mean ± SD</th>
<th>median</th>
<th>range</th>
<th>significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>60</td>
<td>4.90 kv</td>
<td>1.02</td>
<td>5.00 kv</td>
<td>4 - 8</td>
</tr>
<tr>
<td>Group B</td>
<td>60</td>
<td>4.67 kv</td>
<td>0.91</td>
<td>4.00 kv</td>
<td>4 - 7</td>
</tr>
<tr>
<td>Total</td>
<td>120</td>
<td>4.78 kv</td>
<td>0.97</td>
<td>4.50 kv</td>
<td>4 - 8</td>
</tr>
</tbody>
</table>

Fig 1: Required shock wave in group A and group B

Table II: Statistics of hospital stay among the study group (With t-test significance)

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>mean ± SD</th>
<th>median</th>
<th>range</th>
<th>significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>60</td>
<td>1.03</td>
<td>0.18</td>
<td>1.00</td>
<td>1 - 2</td>
</tr>
<tr>
<td>Group B</td>
<td>60</td>
<td>2.57</td>
<td>0.72</td>
<td>2.00</td>
<td>2 - 4</td>
</tr>
<tr>
<td>Total</td>
<td>120</td>
<td>1.80</td>
<td>0.93</td>
<td>2.00</td>
<td>1 - 4</td>
</tr>
</tbody>
</table>

In group A there were 60 patients and in Group B also 60 patients. For group A ESWL was done in situ and in Group B, manipulation of the stones were done to push it back to the kidney together with DJ stenting prior to ESWL.

All the patients were followed up in a regular intervals and subsequent ESWL were done if the condition demanded. The collected data were complied and analyzed. All the variables were evaluated.

Table I shows that energy used in Group A: Minimum 4 KV, maximum 8 KV, mean 4.90 ± 1.02 KV. In Group B: minimum 4 KV, maximum 7 KV, mean 4.67 ± 0.911 KV.

Fig 1 shows that mean shock wave needed according to stone size among Group-A and Group-B. It was observed that more shock wave is needed in case of large size stone and Group-A patient (without stenting) and the difference was statistically highly significant (p < 0.000).

Fig 2 shows that ESWL Session and stone clearance. It was observed that stone clearance in 1st session: In Group A: 46 (76.7%) In Group B: 48 (80%) Stone clearance after 2nd session: In Group A: 08 (13.3%) Total 46 + 08 = 54 (90%), In Group B: 10 (16.7%) Total 48 + 10 = 58 (96.7%) Stone clearance after 3rd session: In Group A: 04 (6.6%), Total 46 + 08 + 04 = 58 (96.67%), In Group B: 01 (1.7%) Total 48 + 10 + 01 = 59 (98.33%) Stone clearance is after 3 months in Group A was 58/60 (96.7%) and in group B was 59/60 (98.3%), the difference of which is not statistically significant (p = 0.494).
Fig 3 shows that serious complications like shock, septicemia, gross haematuria and bowel rupture due to ESWL in either groups were not observed. The complications observed were loin pain, haematuria, fever and Lower Urinary Tract Symptoms (LUTS). In Group A: loin pain in 20 (33.33%), pain free 40 (66.67%). In Group B loin pain in 35 (58.3%) (p =0.006) pain free : 25 (41.6%) In Group A : Haematuria in 12 (20%), no haematuria in 48 (80%), In Group B : haematuria : 26 (43.3%) (p = 0.006), no haematuria in 34 (56.7%). In Group A : Fever in 6 (10%), No fever in 54 (90%), In Group B : fever in 14 (23.3%) (p=0.05), no fever in 46 (76.7%). In Group A : LUTS 16 (26.7%), no LUTS in 44 (73.3%). In Group B : LUTS in 30 (50%) (p=0.009), no LUTS in 30 (50%). The differences between group A and group B were statistically highly significant.

Table II shows that post procedure hospital stay were in group A : Minimum 1 day, Maximum 2 days, mean 1.03 days ± 0.18 day. In group B : Minimum 2 days, Maximum 4 days, mean 2.57 days ± 0.72 day.

Discussion
ESWL is a very effective and safe procedure for the treatment of renal stones and also for the ureteric stones. The treatment option for upper ureteric stones include ESWL with or without stone manipulations, ureteroscopy with intracorporeal lithotripsy, PCNL, laparoscopy or open surgery. Nowadays ESWL is an established modality of treatment for ureteric stone, especially the proximal one. Primary ESWL is a noninvasive day care procedure which usually can be performed without anaesthesia. In present study, total patient studied were 120. In group-A : Primary ESWL 60/120 and Group B push back stenting and ESWL were 60/120. They were again classed into sub group-I stone size upto 0.6cm and sub group –II stone size > 0.6cm to 1cm. It was 22/60 and 38/60 in group-A and 20/60 and 40/60 respectively in group-B. The fragmentation of the stone depends upon the size, location, compositions shape and impaction of the stone as well as the BMI of the patient, the type of lithotripter and personal technical skill of the surgeon. Shock wave generator and the personal skill remaining constant, the stone factors may influence the fragmentation though those factors can not be quantified.

In the present study the shock wave required in Group A 2456.67 ± 944 with a minimum of 1500 to a maximum of 5500. Energy requirement was 4.90 ± 1.020 KV with minimum of 5 and a maximum of 8 KV. In group B the shock wave was 2375 ± 837.799 with a minimum of 1500 to maximum of 4500 shocks. Energy requirement was 4.78 ± 0.972 KV with a minimum of 4 to maximum 7 KV. None of the shock waves or the energy required were statistically significant between the two group. In the study by Danuser et al (1993) mentioned more shock waves and energy was necessary for the in situ ESWL group. Mean shock waves were 1844 ± 639 in primary ESWL group and 1297 ± 437 in push back group. The results are similar to the present study. The study by kumar et al (1994) recorded that 1.86 ± 1.2 sessions were required in Group A and 2.03 ± 1.2 in Group B. In the present study the comparative sessions were 1.32 + 0.62 in Group A and 1.23 ± 0.50 in Group B. The difference is not significant. In the present study the ESWL Group had 46/60 (78.3%) stone clearance in 1st session, 8/60 (13.3%) in 2nd session and 4/60 (6.7%) in 3rd session. 2/60 (3.3%) had effective fragmentation but remained unclear which needed URS as an auxiliary secondary procedure. The push back group had 48/60 (80%) stone clearance in 1st session, 10/60 (16.6%) in 2nd session and 1/60 (1.7%) in 3rd session. Remaining 1/60 (1.7%) also needed URS as an auxiliary secondary procedure. Allthough there were better stone clearance with less ESWL sessions in Group B, it was not statistically significant. The study by padhye et al (2008) recorded 91% (776/846) overall stone free rate. Clearance after 1st session ws 41% (347/846), in 2nd sitting 30.7% (260/846) and in 3rd sitting 19.9% (169/846). 8% (70) cases did not have successful outcome. The mean hospital stay in ESWL group-A was 1.03 ± 0.181 day compared to 2.57 ± 0.722 day in push back group-B with a p-value of 0.000 which is very highly statistically significant. During the study there were no serious complications of stone manipulation or ESWL procedures. Some of the patients developed some complications which needed special attention but could be treated conservatively. In group A, there were loin pain in 20 (33.33%), Haematuria in 12 (20%), Fever in 06 (10%) and LUTS in 16 (26.7%) patients. In group B loin pain was in 35...
cases (58.3%) (p=0.006) which is highly significant, Haematuria was in 26 cases (43.3%) (p= 0.006) which is highly significant, Fever in 14 (23.3%) with a (p = 0.05) which is also significant. The last but not the least complication LUTS were present in 30 (50%) cases with a (p=0.009) is also statistically significant. In this comparative study the hospital stay, post procedure complications like loin pain, fever, haematuria and LUTS are highly significantly more in Group B. Comparative study depending on the size of the stone showed that, the energy requirements, shockwaves, hospital stay, stone clearance, and complications were more in the larger stone size16. The cost of Group A was fixed amount of Tk. 5,000/- at a time. In patients of Group-B cost was more because of charges of Anaesthetic drugs, pre and post procedure medications and other related charges. Moreover considering more hospital staying Group-B (2.57 + 0.72 days) more working days are lost. With this finding it was apparently observed that in situ ESWL is cost effective than push back and ESWL. But the difference between the group was not statistically significant.

Limitations
Limitations of study was that it is only a single center hospital based study, small sample size, short follow up period, study populations are not homogenous, large and impacted stones are not included in the study.

Conclusion
ESWL is a very good option for the management of upper ureteric stone especially in situ one. It is non invasive, cost effective, safe and does not require any anaesthesia. On the other hand push back procedure is invasive and needs anaesthesia and there is more chance of complications. In fact it does not have any significant advantages over the in situ group. So after evaluating all the facts and findings it can be concluded that, for uncomplicated upper ureteric stone of < 1cm size primary ESWL is definitely a safe, effective, cost saving procedure than push back, stenting and ESWL. Further study with larger sample size with long time follow up is necessary.

Disclosure
All the authors declared no competing interest.

References
6. Campbell Walsh urology; Urinary Lithiasis (Margaret S. Pealie, Year Lotan, Saunders Elsvier, Ninth Edition. 2007; P-1363, 1452, 1453, 1454.

