CLINICAL OUTCOME OF RENAL CALCULI PATIENTS UNDERGOING EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY WITH AND WITHOUT DJ STENT

Manu M. K.¹, Darsan S.², Vasantharaja R.³, Sunil R.⁴, Aravind S. Ganapathi⁵, Naveen Kanakara⁶, Josef B. Pachikara⁷, Premjith Chandran⁸

¹Additional Professor, Department of Urology, Medical College, Thiruvananthapuram, Kerala.
²Senior Resident, Department of Urology, Medical College, Thiruvananthapuram, Kerala.
³Senior Resident, Department of Urology, Medical College, Thiruvananthapuram, Kerala.
⁴Senior Resident, Department of Urology, Medical College, Thiruvananthapuram, Kerala.
⁵Senior Resident, Department of Urology, Medical College, Thiruvananthapuram, Kerala.
⁶Senior Resident, Department of Urology, Medical College, Thiruvananthapuram, Kerala.
⁷Senior Resident, Department of Urology, Medical College, Thiruvananthapuram, Kerala.
⁸Senior Resident, Department of Urology, Medical College, Thiruvananthapuram, Kerala.

ABSTRACT

BACKGROUND
ESWL is suitable for stones smaller than 2 cm situated in upper and middle calyx. The routine insertion of DJ stents during ESWL of renal calculi is controversial. Some studies support the role of DJ stents in facilitating stone passage and preventing renal colic whereas other reports claim that stent causes significant lower urinary tract symptoms, hematuria, urinary tract infection and can even lower the stone-free rate.

METHODS
This is a prospective study conducted among 81 patients each in stented and non stented group who underwent ESWL for renal calculus. The primary outcome measured was stone fragmentation. The secondary outcomes measured were renal colic, urinary tract infection, steinstrasse and stent related LUTS.

RESULTS
Stone fragmentation rates in stented and non-stented groups were 91.4% and 86.4% respectively (p-value > 0.05). Ureteric colic in the stented group was only 14.8% but 45.7% in the non-stented group (p-value <0.05). Lower urinary tract symptoms were significantly higher in the stented group (44.4%) when compared to the non-stented group (13.6%) and the p-value was < 0.05. The occurrence of steinstrasse and urinary tract infection were similar in both groups.

CONCLUSIONS
Double J stents neither improve the stone fragmentation nor lead to enhanced passage of stone fragments in patients undergoing ESWL. DJ stent effectively prevents ureteric colic which occurs due to the passage of fragments down the ureter. Patients with DJ stent have statistically significant lower urinary tract symptoms. The occurrence of UTI and Steinstrasse was seen in both groups and was unrelated to the presence of DJ stent.

KEYWORDS
Renal Calculi, Extracorporeal Shockwave Lithotripsy, Double J Stent, Stone Fragmentation, Lower Urinary Tract Symptoms, Ureteric Colic, Steinstrasse


BACKGROUND
The history of urinary stones parallels with the history of civilization. In 1901, the English archaeologist Smith found a bladder stone from a 4500-5000-year-old mummy in El Amrah, Egypt. Treatments for stones were mentioned in ancient Egyptian medical writings from 1500 BC.¹

The lifetime prevalence of nephrolithiasis is estimated to be between 5% and 12% and varies according to age, gender, race, and geographical location. Men more commonly affected than women, with a male to female ratio of 2:1 or 3:1. The incidence of nephrolithiasis peaks in the fourth to sixth decades of life.

Current modalities for the management of the renal calculi are extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL), laparoscopic and open surgery. The introduction of shock wave lithotripsy (SWL) for the treatment of renal stones by Chaussy et al. in 1980 has been the revolution of the century. ESWL is
suitable for stones smaller than 2 cm situated in upper and middle calyx. The routine insertion of DJ stents during ESWL of renal calculi is controversial. The old rationale was that the use of ureteral stents reduces complications after extracorporeal shock wave lithotripsy and contributes to successful stone passage. However, there are reports of complications that are attributed to indwelling ureteral stents. Studies also state that ureteral stents do not reduce post-SWL complications and do not improve stone passage markedly. In this study, the overall clinical outcome of patients with or without DJ stent is compared in patients undergoing ESWL for renal calculi less than 2 cm.

METHODS

Study Design
Prospective observational study.

Study Setting
Department of Urology, Government Medical College Hospital, Thiruvananthapuram.

Study Population
Patients who are diagnosed to have Renal calculi and underwent Extra corporeal shock wave lithotripsy in urology OPD of Govt. Medical College Thiruvananthapuram.

Inclusion Criteria
1. All patients diagnosed to have renal stones less than 2 cms and who underwent ESWL
2. Patients with normal renal function
3. Patients without major renal abnormalities
4. Patients without symptomatic urinary tract infection
5. Patients willing for further follow up.

Exclusion Criteria
1. Contraindications to ESWL-pregnancy, coagulopathy, aortic aneurysms, distal obstruction, skeletal malformations
2. Factors negatively affecting ESWL success rate-stone attenuation >1000 HU, skin to stone distance more than 10 cm, stones in lower pole
3. Patients who lost follow up

Study Period
One year from 1 April 2017 to 31 March 2018.

Sample Size
81 patients in stented group and 81 patients in non-stented group.

Sampling Technique
Consecutive patients of renal calculi, both stented and non-stented, who underwent ESWL were followed up for the specified period till the sample size was reached.

Methods of Data Collection
Data was collected from hospital records and from patients using a semi structured Questionnaire based interview.

Stone size was measured at end of 3 weeks by plain X-ray KUB and Ultrasonography and refragmented if residual stone of adequate size was remaining. If the stone size after initial fragmentation was less than 50% of actual size patient was followed up with. X-ray /ultrasound at 6 weeks, 8 weeks.

Patients were given alpha blocker (Tamsulosin) during this period. Stone size was recorded during each visit, presence or absence of renal colic was also checked for and recorded. Steinstrasse and stent related symptoms (LUTS) were also noted. NSAIDS and anti-spasmodic were given to patients who complained of colic. Patients who were suspected of having UTI were managed with urine culture sensitivity and appropriate antibiotics.

At the end of 3 months plain X-ray KUB and Ultrasonography was taken and checked for stone clearance. Stent is usually removed at the end of 3 months. If the stone is not visible or stone size was less than 4 mm in an asymptomatic patient at end of 3 months treatment was considered successful.

Outcome Measurement
Primary Outcome- If a stone was not fragmented or if there was residual fragments 4 mms or larger after ESWL, this was considered as failure and another treatment option was sought. The “success group” comprised patients who had successful stone fragmentation (less than or equal to 4 mm and asymptomatic) and who had complete stone clearance. The “failure group” comprised patients who failed to clear the stone because fragmentation either did not occur at all or did occur partially, but, with significant residual fragments (larger than 4 mm).

Secondary Outcome- Complications related to ESWL and DJ stenting like Renal Colic (subjective), Urinary tract infection (positive urine culture) Steinstrasse (stone street on follow up radiography) and stent related LUTS were recorded.

Data Analysis
All quantitative variables were expressed as mean (SD) and all categorical variables as proportions. Chi square test was used for testing significance between groups. A p value less than 0.05 was considered as statistically significant. Data analysis is entered in MS Excel. Appropriate statistical software (SPSS version 16) was used for analysis of data

RESULTS
In this study 81 patients each, in stented and non-stented group, with renal calculus of less than 2 cm were subjected to ESWL. 64 females were included in the study (34 in stented and 30 in non-stented groups). The total numbers of males in the study were 98, of which 47 were in stented group and 51 in non-stented group. Patients were followed up for a period of 3 months with history, physical examination and radiological tests. The parameters recorded were stone fragmentation, clinically insignificant stone fragments, complete stone clearance, ureteric colic, lower urinary tract symptoms, steinstrasse, urinary tract infection.
Stone fragmentation is defined as radiological evidence of stone fragment after extracorporeal shock wave lithotripsy. Regarding stone fragmentation in stented group, 74 patients had stone fragmentation from total number of 81 patients which account for 91.4% while in stented group 70 patients had stone fragmentation from total number of 81 patients, which accounts for 86.4%. There is no significant difference in the stone fragmentation in both groups and it does not depend on the present or absence of the double j stent, P value was 0.317 (> 0.05).

<table>
<thead>
<tr>
<th>Stone Fragmented</th>
<th>Stented</th>
<th>Non-Stented</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Yes</td>
<td>74</td>
<td>91.4</td>
</tr>
<tr>
<td>No</td>
<td>7</td>
<td>8.6</td>
</tr>
<tr>
<td>Total</td>
<td>81</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 1. Stone Fragmentation

χ²=1.000 df=1 p=0.317

Clinically insignificant stone fragments (CIRF) is defined as radiological evidence of stone after shock wave lithotripsy of less than 4 mm in an asymptomatic patient. It had been evaluated in both groups radiologically by ultrasound and KUB. In stented group, 24 patients from total number of patients (81), had clinically insignificant stone fragments which account for 29.6%. In stent less group also 24 patients from total number of patients (81), had clinically insignificant stone fragments during follow up period after shock wave lithotripsy which accounts for 29.6%. P value = 1, which is >0.05.

<table>
<thead>
<tr>
<th>CIRF</th>
<th>Stented</th>
<th>Non-Stented</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Yes</td>
<td>24</td>
<td>29.6</td>
</tr>
<tr>
<td>No</td>
<td>57</td>
<td>70.4</td>
</tr>
<tr>
<td>Total</td>
<td>81</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 2. CIRF

χ²=0.000 df=1 p=1.000

Stone free state is defined as no radiological evidence of stone after sessions of shock wave lithotripsy during follow up period by radiological investigations. In stented group 50 out of 81 patients had complete stone clearance (61.7%) whereas in non-stented group 46 out of 81 patients had stone free state (56.8%). P value was 0.522, which means that complete stone clearance is not statistically significant with the presence or absence of DJ stent.

<table>
<thead>
<tr>
<th>Stone Free</th>
<th>Stented</th>
<th>Non-Stented</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Yes</td>
<td>50</td>
<td>61.7</td>
</tr>
<tr>
<td>No</td>
<td>31</td>
<td>38.3</td>
</tr>
<tr>
<td>Total</td>
<td>81</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 3. Stone Free State

χ²=0.409 df=1 p=0.532

Ureteric colic develops after sessions of shock wave lithotripsy. It is assessed during period of follow up by history and physical examination. It is due to the fragmented stone particles migrating downwards along the ureter. 37 out of 81 patients developed ureteric colic in stent less group which accounts for 45.7%. But in stented group only 12 patients developed colic, which accounts for only 14.8%. P value was <0.001 and the decreased incidence of colic in stented patients is statistically significant.

<table>
<thead>
<tr>
<th>LUTS</th>
<th>Stented</th>
<th>Non-Stented</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Yes</td>
<td>36</td>
<td>44.4</td>
</tr>
<tr>
<td>No</td>
<td>45</td>
<td>55.6</td>
</tr>
<tr>
<td>Total</td>
<td>81</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 5. LUTS

χ²=18.733 df=1 p<0.001

UTI-urinary tract infection is defined as the inflammatory response of urothelium to microbial invasion and is mostly associated with pyuria and bacteriuria. It is confirmed by urine microscopy followed by culture in symptomatic patients during follow up. In stented group 6 patients and in stent less group 3 patients were confirmed to have urinary tract infection. Incidence of UTI in stented group is 7.4% and in non-stented group is 3.7%. There is no statistical difference in the incidence of UTI in both these groups. (p value 0.303)

<table>
<thead>
<tr>
<th>UTI</th>
<th>Stented</th>
<th>Non-Stented</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Yes</td>
<td>6</td>
<td>7.4</td>
</tr>
<tr>
<td>No</td>
<td>75</td>
<td>92.6</td>
</tr>
<tr>
<td>Total</td>
<td>81</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 6. UTI

χ²=1.059 df=1 p=0.303

In stented group 21 out of 81 patients underwent second sitting ESWL and 23 out of 81 patients in non-stented group underwent second sitting ESWL. It accounts for 25.9% and 28.4% in stented and non-stented groups respectively. The need for second sitting ESWL in both these groups were statistically not significant and is not related to the presence or absence of DJ stent.

<table>
<thead>
<tr>
<th>Second Sitting ESWL</th>
<th>Stented</th>
<th>Non-Stented</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Yes</td>
<td>21</td>
<td>25.9</td>
</tr>
<tr>
<td>No</td>
<td>59</td>
<td>74.1</td>
</tr>
<tr>
<td>Total</td>
<td>80</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 7. Second Sitting ESWL

χ²=0.125 df=1 p=0.724

In this study 1 patient in the stented group had stent migration on follow up X-ray. The distal end of the stent had migrated upwards. It was removed with semi rigid ureterorenoscopy.

Steinstrasse is defined as street of stones accumulated in the ureter. The stone fragments after shock wave lithotripsy pass down through the ureter into the bladder, sometimes their passage may be blocked leading to accumulation of these stone fragments in the ureter. It is diagnosed by radiological examination of patients during follow up. In the stented group 13 out of 81 patients developed Steinstrasse i.e. 16%. In non-stented group 9 out of 81 i.e 11.1% developed Steinstrasse. The occurrence of Steinstrasse was not statistically significant, p value was 0.359 (>0.05)

**DISCUSSION**

The first extra corporeal shockwave lithotripsy (ESWL) treatment of a human was performed on February 07, 1980 by Christian Chaussy, Dieter Jocham and Bernd Forssmann using a prototype Dornier HM1 (Dornier Human Model 1) lithotripter. The first serial Dornier HM3 (Dornier Human Model 3) was installed in 1983 at the Katharinen Hospital in Stuttgart. With the introduction of less expensive second and third generation lithotripters the practice of ESWL became available in smaller centers also. This rapid propagation of extracorporeal shockwave lithotripsy even in smaller centers inevitably resulted in dilution of experience and poorer results with ESWL. As the newer lithotripters also proved easier to operate than the Dornier HM3, they were considered “plug and play” and proper training in ESWL was neglected leading to a further deterioration in results. Since the introduction of double-J stent and the single-pigtail stent by Finney and Hepperlen in 1978, ureteral stent usage has become a routine practice for every urologist.

The ideal ureteral stent has not yet been designed. The perfect ureteral stent should demonstrate optimal flow characteristics and should be well tolerated by patient. Resistance to infection, corrosion and encrustation, visibility on ultrasound, ease of insertion and removal are also important features that are crucial for long-term ureteral patency.

Double J stent is used to prevent complications after ESWL like ureteric obstruction which may lead to urosepsis. On one hand, some studies support the role of DJ stents in facilitating stone passage, preventing renal colic and steinstrasse, whereas other reports claim that stent presence causes significant lower urinary tract symptoms, hematuria, urinary tract infection, and can even lower the stone-free rate.

In this study, the overall clinical outcome of patients with or without DJ stent is compared in patients undergoing ESWL for renal calculi less than 2 cm. Regarding stone fragmentation, in stented group 91.4% and in non-stented group 86.4% had stone fragmentation. So there is no significant difference in the stone fragmentation in both groups and it does not depend on the present or absence of the double j stent, P value >0.05. In a randomized trial by Chandhoke et al the stone free rate was 84% in the group without DJ stent an 80% in the group with a DJ stent.

In another prospective randomized study by Musa et al stone free rate was 91% in the unstented group vs 88% in the in the stented group. Both these studies have similar results which are consistent with our study also. Stone free state is defined as the complete clearance of all stone fragments in radiological investigations. In our study stented group showed complete stone clearance in 61.7% whereas in non-stented group 56.8% showed complete stone clearance. The p value was >0.05, which means that stone clearance is not affected by the presence of DJ stent.

Bierkens et al study stated that pre-lithotripsy will affect the clearance of stone fragments. But in our study the presence of DJ stent had no influence in the clearance of stone fragments. Our study agrees with study done by Low et al who found that stone free rate is not superior in the stented group to that in the stent less group.

Ureteric colic occurring after sessions of shock wave lithotripsy is due to the fragmented stone particles migrating downwards along the ureter. In our study 45.7% developed colic in non-stented group whereas only 14.8% in stented group had colic. Patients who had colic underwent treatment with NSAIDS and Antispasmodics. p value was <0.05 which confirms that stented patients has less incidence of colic when compared to stent less patients. Our observations are similar to Chandhoke et al study where pain scores were high in the group without DJ stent as compared to those who had a DJ stent placed before ESWL. But Musa et al reported no statistical difference in pain in both the stented or unstented groups. In a study by Taku Abi et al evaluating outcome of ESWL for upper urinary tract stones found that pain occurred as a minor complication in 35.3% of patients and stated that pain is a subjective symptom and is different in different populations.

The lower urinary tract symptoms e.g. urinary frequency, nocturia, urgency, dysuria and hematuria were quite high in the stented group (44.4%) as compared to stent less group (13.6%). Stent related LUTS were due to the fragmented stone particles migrating downwards along the ureter. In our study stented group 56.8% showed complete stone clearance in 61.7% whereas only 14.8% in stented group whereas only 14.8% in stented group had colic. Patients who had colic underwent treatment with NSAIDS and Antispasmodics. p value was <0.05 which confirms that stented patients has less incidence of colic when compared to stent less patients. Our observations are similar to Chandhoke et al study where pain scores were high in the group without DJ stent as compared to those who had a DJ stent placed before ESWL. But Musa et al reported no statistical difference in pain in both the stented or unstented groups. In a study by Taku Abi et al evaluating outcome of ESWL for upper urinary tract stones found that pain occurred as a minor complication in 35.3% of patients and stated that pain is a subjective symptom and is different in different populations.

The lower urinary tract symptoms e.g. urinary frequency, nocturia, urgency, dysuria and hematuria were quite high in the stented group (44.4%) as compared to stent less group (13.6%). Stent related LUTS were due to the presence of foreign body in the urinary bladder irritating the trigone and the bladder neck. Most of the patients with LUTS responded to tamsulosin and bladder relaxants. This is similar to the findings of Perminger et al study who found a higher incidence of LUTS in patients with DJ stents (43%). Same findings were reported by Musa147 who also found a
much higher frequency of lower urinary tract symptoms (85%) in the stented group as compared to the non-stented group. None of the patients in our study underwent stent removal because most of them had symptomatic relief with tamsulosin.

In this study Steinstrasse developed in 16% patients in stented group and in 11.1% patients in non-stented group (P value of 0.359). A study by Al Awadi et al showed that the incidence of Steinstrasse depends on stone size and is irrespective of whether DJ stent is present or not. Our result is consistent with observations of Beirkens et al who also did not find any difference in the occurrence rate of Steinstrasse in both groups. Most of the steinstrasse responded to conservative management with analgesics and alpha blocker. Majority of asymptomatic patients with steinstrasse cleared their fragments spontaneously over 2-3 weeks. Three patients underwent ureteroscopic manipulation under anaesthesia and was re-stented intraoperatively for mucosal oedema and minor mucosal injuries.

Urinary tract infection developed in 6 patients (7.4%) in stented group and 3 patients (3.7%) in non-stented group (p value of 0.303). All of them had fever with varying degrees of dysuria and hematuria. In Musa et al study there was slightly higher incidence of fever in stented patients. This could be explained by the fact that patients with DJ stent had two additional procedures performed and a foreign body was placed in a normally sterile system.

Incidence of fever in our study was much less comparable to Pansota MS et al study (20%). All patients underwent treatment with culture sensitive antibiotics and antipyretics and responded well. In 2 patients DJ stent was removed due to persisting low grade fever even though the culture became sterile.

In this study 1 patient in the stented group had stent migration on follow up X-ray (1.2%). The distal end of the stent had migrated upwards. It was removed with semi rigid ureterorenoscopy. Upward migration is primarily due to placement of a short stent. Incidence of stent migration reported in Nawaz et al study was 3.5%. The low incidence in our study population is possibly due to correct positioning and proper size selection.

CONCLUSIONS
Double J stents neither improve the stone fragmentation nor lead to enhanced passage of stone fragments in patients undergoing ESWL. The passage of fragments is not hindered by the presence of DJ stent as recorded in previous studies. DJ stent effectively prevents ureteric colic which occurs due to the passage of fragments down the ureter. Ureteric colic is one of the most common complications seen after ESWL. Patients usually require parenteral analgesics for ureteric colic which is avoided with the usage of DJ stent. Patients with DJ stent has statistically significant lower urinary tract symptoms (LUTS), but most of them responded to alpha blockers and bladder relaxants. None of the patients were subjected to stent removal due to refractory LUTS. The occurrence of steinstrasse was also seen in both groups and was not related to DJ stent. Steinstrasse incidence is directly related to stone size in earlier recorded studies. But in our study as the stone size was less than 2 cm the relation between stone size and steinstrasse was not obvious. Most of the studies which recorded higher incidence of steinstrasse has stone size of more than 2 cms and reaching up to 3 cm. Though the presence of stent can trigger an infection, in our study, the incidence of symptomatic culture positive UTI was seen in both groups and was unrelated to the presence of DJ stent. The duration of antibiotic therapy was also same for both stented and non-stented groups. In 2 patients stent had to be removed due to persisting low grade fever in spite of a sterile urine culture.

REFERENCES