INTRODUCTION Lifetime risk of developing renal stones is estimated to be

Address for Correspondence:

Mobile: +91-8860227087. E-mail: vaishali.shirale@gmail.com

To evaluate the role of double J stent versus

calculus undergoing extracorporeal shock

no stent in patients of renal and upper ureteric

Vaishali Shirale¹, Sudhir Kumar Jain², Rohit Kaushik³

¹Associate Professor, Department of Surgery, ESI-PGIMSR, Basaidarapur, New Delhi, India, ²Professor and Head of the Unit, Department of Surgery, ESIC Medical College and Hospital, Faridabad, Haryana, (Formerly Director Professor, Department of Surgery MAMC and Lok Nayak Hospital New Delhi, India), 3Senior Resident, Department of Surgery, All India Institute of Medical Science, Rishikesh, Uttarakhand, India

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ABSTRACT

Background: Extracorporeal shock wave lithotripsy (ESWL) was first introduced by Chaussy in 1980 for the treatment of urolithiasis, which has revolutionized the treatment of urinary stones. Renal colic, urinary tract obstruction, uremia, and renal failure can occur because of the stone fragments obstructing the ureter during the post-ESWL period. The role of double-J (DJ) stents in ESWL is controversial. Aims and Objectives: The aim of the study was to evaluate the role of DJ stent in patients with renal and upper ureteric calculus undergoing extracorporeal shockwave lithotripsy. Materials and Methods: Two hundred patients with solitary calculus 5 mm-2 cm in size, amenable to ESWL, located in renal pelvis, upper or middle calyx, upper ureter visiting Lok Nayak Hospital, New Delhi from December 2015 to April 2019 were studied and randomized into two groups: Test group (non-stented, 100 patients) and control group (Stented, 100 patients). Both groups underwent ESWL and subsequently compared for the following parameters: Stone clearance, post lithotripsy pain and analgesic dose requirement, number of ESWL sittings and shockwaves required, steinstrasse, urinary tract infection (UTI), and hematuria. Patients were followed up for 3 months after stone clearance to look for any recurrence. Results: There was a significant difference (P<0.05) in the two groups with smaller number of ESWL sittings and number of shockwaves required, low frequency of colicky pain episodes and mean pain score, less analgesic dose requirement, lower incidence of hematuria, and UTI in non-DJ stent group. The overall stone clearance was higher in the non-DJ stent group (96.4%) as compared to the DJ stent group (89.3%). The incidence of steinstrasse was higher in the DJ stent group (10.7%) as compared to none in the non-DJ stent group. Conclusions: There is no additional benefit of DJ stent on stone clearance, rather stenting further increases the morbidity due to associated complications. DJ stenting should not be performed in patients undergoing ESWL for renal and upper ureteric calculus up to 2 cm size.

Key words: Double-J stent; Extracorporeal shock wave lithotripsy; Pain; Renal and upper ureteric calculus; Stone clearance

Dr. Vaishali Shirale (Saxena), Associate Professor, Department of Surgery, ESI-PGIMSR, Basaidarapur, New Delhi, India.

1-5% in Asian countries.^{1,2} The incidence of renal stones is increasing off late, mainly due to changes in lifestyle and diet combined with environmental factors, with urolithiasis being more prevalent in warm regions.³

Before the development of endourologic techniques, open surgery was the treatment of choice for renal stones.⁴

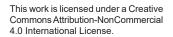
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Endourologic techniques for the treatment of urolithiasis were introduced around 40 years ago, and since their advent, they have become an important modality for the treatment of renal and ureteric stones, largely because of higher stone free rates combined with lower complication rate.³

Extracorporeal shock wave lithotripsy (ESWL) was first introduced by Chaussy et al., in 1980 for the treatment of urolithiasis, which has revolutionized the treatment of urinary stones.⁵ ESWL is one of the commonly used modalities of the treatment and is considered as the first line treatment for renal and upper ureteric calculus up to 2 cm.6 Renal colic, urinary tract obstruction, uremia, and renal failure can occur because of the stone fragments obstructing the ureter during the post-ESWL period.7 Steinstrasse or stone street refers to the formation of column of stones in the ureter following ESWL. It is a well-known complication reported in 2-20% of cases within the first 48 h following ESWL.8 Steinstrasse is a morbid complication of ESWL and can be associated with irreversible loss of renal function and urethral stricture.9 Other common complication post-ESWL is urinary tract infection (UTI).10,11

The role of double-J (DJ) stents in ESWL is controversial. It is thought to aid in prevention of steinstrasse and prevention of renal colic by facilitating passage of stones distally as is reported by some studies²⁻¹⁴ whereas other studies have reported increased incidence of lower urinary tract symptoms (LUTS), UTI, hematuria, and a lower stone free rate.¹⁵⁻¹⁷ The present study was designed to evaluate the role of DJ stenting in patients with renal and upper ureteric calculus undergoing ESWL and aims to provide a snapshot of the treatment findings in a tertiary care hospital setting in India.

Aims and objectives

The aim of the study was to evaluate the role of DJ stent in patients with renal and upper ureteric calculus undergoing extracorporeal shockwave lithotripsy.

MATERIALS AND METHODS

The present study was conducted in the Department of Surgery, Maulana Azad Medical College and Lok Nayak Hospital, New Delhi-110002. The study population consisted of 200 patients who presented with renal and upper ureteric calculus and subsequently underwent ESWL after fulfilling the inclusion criteria. It was a prospective and randomized control study and was preapproved by the Institutional Ethics Committee for the final permission.

Inclusion criteria

Solitary calculus located in renal pelvis, upper and middle calyx, and upper ureter measuring between 5 mm and 2 cm as visualized on computed tomography (CT) urography

Exclusion criteria

The following criteria were excluded from the study:

- Inferior calyx stones, multiple stones, or staghorn calculus
- Proximate calcified abdominal aortic aneurysm or renal artery aneurysm
- Distal ureteric obstruction
- Pregnancy
- Untreated UTIs
- Decompensated Coagulopathy
- Uncontrolled arrhythmia.

Sampling method

Informed written consent was obtained from all patients who were included in the study. Sample of convenience was taken on the basis of patient load as per previous records in the hospital. Patients were given the option to opt out of the study without compromising their right of the treatment. Patients were randomized into two groups, either test or control group, each consisting of 100 patients based on computer generated random numbers which were kept in a sealed envelope. The sealed envelope was opened by a nurse who was not involved in the study.

Group A (n=100) – Control Group: ESWL done after inserting a 5Fr, one end open, and DJ stent. Group B (n=100) – Test Group: ESWL done without any DJ stenting.

Pre-procedure work up

- Clinical history and physical examination
- All patients underwent the following pre-operative investigations:
- Complete blood count
- Kidney function tests, that is, blood urea and serum creatinine
- Serum electrolytes
- Urine for routine microscopy
- Urine for culture/sensitivity
- Blood sugar fasting
- X-ray abdomen kidney ureter bladder region
- CT urography
- Non-contrast CT (NCCT) in patients with known allergy to contrast media or impaired renal function.

ESWL technique

The lithotripter used was Dornier Compact Sigma. Patients were injected with an intramuscular injection of Diclofenac sodium 50mg before the start of the procedure. The session was started with Level 1 which delivered maximum pressure of 6–7 MPa and gradually increased to Level 5 delivering maximum pressure of 52 MPa depending on patient tolerance and stone density as measured on CT urography. Triggering was kept at a constant rate of 90–100 shock waves/min, to avoid complications of ESWL, for example, perirenal hematoma.

Post-procedure, patients were counseled about the post-ESWL symptoms. Patients were followed with NCCT 2 weeks after every session and depending on the residual stone load, further ESWL sessions were planned, with an interval of 2 weeks between subsequent sessions. Patients were also evaluated for pain and analgesic requirement using the visual analog scale immediately after the procedure and then at 24 h, 48 h, and 72 h telephonically. Stone analysis was not performed, as no facilities were available for the same at the institute. Patients were followed up for a period of 3 months after stone clearance. Patients were given oral Diclofenac 50 mg on sos basis for flank pain, while those who developed ureteric colic after ESWL were given intramuscular Diclofenac injection 50 mg.

Failure of ESWL

No/Negligible stone fragmentation after 3 sittings was treated as failure of ESWL.

UTIs

Patients with significant pain and LUTS not relieved by analgesics underwent urine routine microscopy and urine culture with an X-ray KUB. Patients having a UTI were treated with appropriate culture sensitivity antibiotics before ESWL sessions.

Steinstrasse

Patients with symptoms of persistent pain underwent X-ray KUB for confirmation of steinstrasse. Once confirmed, ESWL sessions were withheld and patients were treated conservatively with a period of observation, hydration, and Tamsulosin hydrochloride 0.4 mg daily. For patients who developed steinstrasse in the DJ stent group, the stent was removed and patients were kept on daily Tamsulosin therapy for 6 weeks.

Parameters evaluated

- Stone Clearance Which is defined as absence of stone on X-ray KUB/NCCT or residual single stone fragment of size ≤i mm
- Steinstrasse
- UTI
- Post-lithotripsy colicky pain or flank pain and analgesic requirement
- Any stent related complication, for example, hematuria and stent migration
- Recurrence with/without DJ stent.

Statistical analysis

To see the difference between means for quantitative data, Student "t" test/non-parametric/Wilcoxan Mann–Whitney rank sum test was used. To see the difference between means for qualitative data, Chi-square/Fischer's exact test was used. P<0.05 was the cutoff point for statistical significance.

RESULTS

Patient demographics, stone size, and stone location are summarized in Table 1. There was no statistically significant difference between the two groups. Objective and subjective data were obtained from 200 patients.

The overall stone clearance rate was 93% (186 out of 200 patients) with individual clearance of 89% in the DJ stent group and 97% in the non-stent group. The difference was statistically significant. The mean number of sittings and number of shockwaves required for stone clearance was significantly lower in non-stent group. Patients in the DJ stent group experienced more frequent pain episodes and the mean visual analog scale score was higher as compared to non-stent group Figure 1.

The overall analgesic requirement for post-lithotripsy colicky pain and flank pain was significantly lower in nonstent group. Three patients experienced steinstrasse, all belonging to DJ stent group, contradicting the role of DJ stent. The incidence of UTI and hematuria was higher in the DJ stent group. The different parameters evaluated and their statistical significance are recorded in Table 2.

DISCUSSION

Controversy exists on the use of ureteral stents before ESWL. Although routine placement of ureteral stents was preferred previously, recent studies have advocated against the routine usage of ureteral stents as they offer no added advantage in stone clearance and prevention of

Table 1: Patient demographic and stone details			
Parameter	DJ Stent	Non-DJ stent	
Mean age	34.5	36.79	
Sex distribution (%)			
Males	16 (57.1)	17 (60.7)	
Females	12 (42.9)	11 (39.3)	
Stone size	11	12.07	
Stone location			
Renal Pelvis	9	11	
Upper Calyx	4	5	
Middel Calys	9	6	
Upper Ureter	6	6	
P-value- (DJ~Non DJ stunt)=0.26	is insignificant		

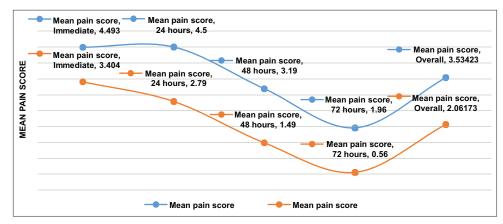


Figure 1: Comparing mean pain scores at different time intervals post lithotripsy

between the two groups				
Parameter	DJ Stent	Non-DJ Stent	P-value	
Total number of sittings	5.00	3.43	<0.001	
Total number of shockwaves received	14900	10000	<0.001	
Stone clearance Percentage (n)	89.3% (25)	96.4% (27)	0.611	
Frequency of Colicky Pain episodes	6.72	3.14	<0.001	
Mean pain score	3.53	2.06	<0.001	
Mean analgesic Requirement (mg) (%)	1283.93	837.50	<0.001	
Steinstrasse percentage (n)	10.7 (3)	0	0.236	
UTI	75 (21)	3.6 (1)	<0.001	
Hematuria	42.9 (12)	14.3 (4)	0.037	
UTI: Urinary tract infection, DJ: Double-J				

steinstrasse.^{6,12,18} The European Association of Urology recommends pre-ESWL stenting for renal stones with a diameter >20 mm and patients with solitary kidney wherein a DJ stent is inserted to reduce obstructive and infective complications after the use of ESWL.^{12,19}

The utility of pre-procedure ureteric stenting needs to be evaluated as stenting is an invasive procedure, associated with increased chances of introducing infection into a non-infected system. In addition, the presence of stent itself poses a multitude of problems such as hematuria, UTIs, and LUTS such as dysuria, nocturia, frequency, and pain.¹²

Number of ESWL sittings

The minimum number of sittings required in Group A was 2 and maximum 6 with a mean of 5.0 sittings. The minimum number of sittings required in Group B was 2, with maximum being 7 and a mean of 3.54 sittings, which showed a significant difference between the two groups. ESWL sessions were conducted every 2–3 weeks. Similar

findings of more number of ESWL sittings in stent group were observed by Ghoneim et al.,¹⁴ (mean number of sittings 1.97 in the non-stent group, whereas it was 2.0 sessions in DJ stent group) and Mohayuddin et al.,²⁰ (mean ESWL sittings of 1.55 in non-stent group and 1.63 in stent group).

Number of shockwaves required

The range of shockwaves received in Group A varied from 6000 to 19000 with a mean of 14900 shockwaves. The range of shockwaves required in Group B was 6000-16000 with a mean of 10000 shockwaves. In comparison to the literature, Ghoneim et al.,¹⁴ reported similar findings (average number of shock waves required for stent group -7425, while in non-stent group – 6511.67). The difference was, however, not statistically significant. Sharma et al.,¹⁵ in their study divided patients into three groups, one without DI stent, second with DI stent and third group, which had DJ stent for a brief period of time. The results showed that average shockwave requirement was 3859 in patients without DJ stent, in contrast to patients who harbored a DJ stent whose mean shockwave requirement was 3872 and 3155 for Groups 2 and 3, respectively; whereas other studies do not show any significant difference between the shockwave requirement of the two groups stent versus no stent. There was a significant difference in our study. Increased number of shockwaves in DJ stent group are associated with enhanced incidence of local complications, for example, perirenal hematoma. Although studies with a large sample size would be needed to ascertain this fact. Patients without DJ stent required less number of sittings and less number of shockwaves in comparison to patients with DJ stent, which has two aspects:

- Less number of sittings imply smaller number of ESWL related complications. (Medically efficient)
- Less number of sittings help in better utilization of machine and more number of patients can be treated. (Economically efficient).

Stone clearance

Stone clearance was calculated by regular follow-up of patients with NCCT. The overall clearance achieved in our study was 92.86% with residual stones in four patients. Out of the four patients, three were in DJ stent group and one was in non-DJ stent group. While comparing individual groups, stone clearance in DJ stent group was 89.3% while in non-DJ stent group, it was 96.4%. Although this difference was not statistically significant, it depicts higher rates of stone clearance in non-DJ stent group, implying the fact that DJ stent offers no additional benefit with respect to stone clearance.

Our findings are in confirmation with those reported by Sfoungaristos et al.,¹⁷ (stone clearance of 68.6% in DJ stent group as compared to 83.7% in non-stent group), Mustafa et al.,¹³ (overall stone clearance rate of 92.1%, 81.8% in DJ stent group versus 96.3% in non-stent group) and Chandhoke et al.,²¹ (overall stone clearance rate of 80%, 84% in non-stent group while 80% and 77% for DJ stent groups) implying the fact that DJ stent offers no advantage in stone clearance.

Pain score

The frequency of patients experiencing colicky pain in our study was 57.1% (32/56), of which 25 (89.3%) were in DJ stent group and 7 (25%) were in non-DJ stent group. The frequency of colicky pain episodes experienced in each group was 6.72 in DJ stent group, compared to 3.14 in the non-stent group. This difference was statistically significant, implying that more number of patients with DJ stent experienced colicky pains at an increased frequency.

This was further supported by Wang et al.,²² who reported a higher incidence of flank pain among DJ stent group patients (Odds ratio 2.45) in their meta-analysis, the difference being statistically significant. The increased incidence of colicky pain in the DJ stent group may be due to lumen compromise of ureter by the DJ stent, and hence, less space is available for passage of stones.

Analgesic requirement

The mean analgesic requirement in our study was 1283.93 mg in DJ stent group as compared to 837.50 mg in the non-stent group. The difference between the two groups was statistically significant, implying higher dose of analgesic requirement in the DJ stent group. Sharma et al.,¹⁵ reported the total duration of analgesic requirement in their study to be 1.9 days in non-stent group compared to 3.2 days and 1.7 days in DJ stent groups. Musa²³ had reported the need for analgesic requirement to be 23.3% (28 patients out of 120) in his study, of which 12 (20%) were in the stent group and 16 (26.7%) in non-stent group.

Patients without DJ stent had lower frequency of colicky pain and mean pain score and less analgesic requirement than DJ stent group, implying that ESWL without DJ stent is a much more patient friendly experience.

Steinstrasse

Sfoungaristos et al.,¹⁷ had reported the incidence of steinstrasse to be 6.4% (10 patients out of 156). Mustafa et al.,¹³ reported two cases of steinstrasse (5.26%), one each in DJ stent group and non-stent group. Chandhoke et al.,²¹ found out the incidence of steinstrasse to be 4 in 31 (13%) in non-stent group as compared to 1 in 60 (2%) in DJ stent group.

El-Assmy et al.,¹⁶ reported the incidence of steinstrasse to be two times more frequent in DJ stent group (4 of 93, 4.3%) as compared to non-stent group (2 of 93, 2.1%). Conventionally, DJ stents were used to prevent the risk of steinstrasse as they were thought to enhance stone clearance; however, no convincing data exist supporting this fact. Although published data show a slightly reduced risk of steinstrasse in patients with DJ stent, the results are not statistically significant.

The overall incidence of steinstrasse in our study was 3 (5.35%). All the three patients belonged to the DJ stent group (10.7%). This difference was, however, not statistically significant. On correlating steinstrasse with stone size, it was observed that two patients with stone size 10–15 mm developed steinstrasse while one patient with stone size more than 15 mm developed steinstrasse. The higher incidence of steinstrasse in the DJ stent group was associated with severe UTI, for which the stent was removed, though stenting overall neither prevented steinstrasse formation nor resulted in enhanced clearance.

Our findings are contrary to the reported literature. This can be explained by the fact that, due to presence of DJ stent, there is luminal compromise of the ureter and ureteric peristalsis is reduced, and hence, stone fragments are not propelled distally.

UTI

The overall incidence of UTI was 22 (39.3%) with 21 in 28 patients (75%) in DJ stent group and 1 in 28 patients (3.6%) in non-stent group. The difference was highly significant, implying stenting increased the risk of developing UTI. These findings are further supported by El-Assmy et al.,¹⁶ who reported UTI in 30 patients out of 93 (32.2%) in stented group versus 6 patients (6.5%) in the non-stented group. Ghoneim et al.,¹⁴ recorded the incidence of UTI with DJ stent as 26.7%, compared to 10% without stent, the difference being statistically significant. Musa²³ also reported similar findings (incidence with stent-5%)

compared to non-stent, 1.67%). Higher incidence of UTI in the DJ stent group can be explained by the fact that DJ stent acts as a foreign body and promotes colonization of bacteria over it.

Hematuria

The overall incidence of hematuria in our study was 28.6% (16 out of 56 patients). Out of these 16 patients, 12 were from DJ stent group (42.9%) and four were from non-DJ stent group (14.3%). This difference came out to be statistically significant. Mohayuddin et al.,²⁰ reported the overall incidence of hematuria to be 80% (64 of 80 patients) with 67.5% (27) in non-stent group and 92.5% (37) in stent group. El-Assmy et al.,¹⁶ reported 5.4% incidence of hematuria (10 patients out of 186) of which one belonged to non-stent group (1.1%) and the remaining 9 (9.6%) belonging to the stent group. This difference was statistically significant as is confirmed in our study too. The increased incidence of hematuria in the DJ stent group can be multifactorial, namely, due to increased incidence of UTI, steinstrasse, and colicky pain.

Limitations of the study

Multicentric trial is required to gather more insight into the subject. In view of conflicting reports in the published literature regarding the use of DJ stents in ESWL, there is a need for further studies with large sample size to delineate the precise role of DJ stents. The utility of pre-procedure ureteric stenting needs to be evaluated as stenting is an invasive procedure, associated with increased chances of introducing infection into a noninfected system. We are also contemplating meta-analysis to get final answers.

CONCLUSIONS

In view of the results of this study, we would like to conclude that patients with renal and upper ureteric calculus of size 5mm–20mm should undergo ESWL without DJ stenting.

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Authors' Contributions:

VS – Prepared the draft of manuscript, statistical analysis, and interpretation; SKJ – Concept and design of the study and reviewed the literature; and RK- Coordination and patient study.

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Maulana Azad Medical College and Lok Nayak Hospital, New Delhi, India.

Orcid ID:

Dr. Vaishali Shirale - o https://orcid.org/0000-0002-7311-4338 Dr. Sudhir Kumar Jain - o https://orcid.org/0000-0003-0879-6878

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