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Original Research Article

Prognostic implications of double J ureteral stenting in patients with renal stones undergoing extracorporeal shockwave lithotripsy

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ABSTRACT

Background: Most patients with uncomplicated kidney stones can be successfully treated with extracorporeal shockwave lithotripsy (ESWL). Double-J ureteral stent is used to facilitate stone clearance, however double-J ureteral stents themselves may cause complications. Study conducted the study to know the exact role of double J stent in ESWL.
Methods: 80 patients undergoing ESWL were divided into two groups, group A (n=40) double J stenting and group B (n=40) without double J stenting. Both groups were compared for stone fragmentation, stone clearance, number of shockwaves required for fragmentation, time required for passing through ureter, steinstrasse, Urinary Tract Infection.
Results: Both the groups were comparable for age, sex, stone size and stone location distribution. There was no significant difference in clearance of stone and no. of shockwaves received for clearance in both the groups. The overall incidence of steinstrasse between the two groups was insignificant with a p value of 0.644. The incidence of UTI was significantly higher in stented group (p value 0.032).
Conclusions: Study recommend ESWL without double J stent in patients having solitary renal calculus of size < 2 cm. Double J stent predisposes the patient to multiple complications including urinary tract infection which increases the morbidity of the patient. Based on our study we conclude that double J stenting in patients of renal calculus of size < 2cm, prior to ESWL is not beneficial.

Keywords: Double-J ureteral stenting, ESWL, Renal calculus

INTRODUCTION

The development of minimally invasive surgical techniques for the treatment of patients suffering from urinary lithiasis has been greatly dependent on technologic advances in the fields of fiberoptics, radiographic imaging, and lithotripsy.[1] Most patients with uncomplicated kidney stones can be successfully treated with extracorporeal shockwave lithotripsy (ESWL), which has revolutionized the treatment of urinary stones.[2] Several potential mechanisms for ESWL stone breakage have been described: spall fracture, squeezing, shear stress, superfocusing, acoustic cavitation and dynamic fatigue.[3]

Double-J ureteral stent is used to prevent complications of ESWL like ureteric obstruction, especially in the cases of large stone size. However, double-J ureteral stents themselves may cause complications. Loin pain and lower urinary tract symptoms like urgency, urge incontinence, frequency and hematuria are well known complications of double-J stents. There are reports about stent causing interference with stone fragmentation and clearance through kidney and ureter. Hence there is a

need to study the precise role of double J ureteral stenting in patients undergoing ESWL.[4]

The objective of this study was to assess stone fragmentation, total shockwave required for fragmentation and passage of stones through the ureter in patients with double-J ureteral stent and to compare the same parameters in patients without the stent.

METHODS

The study was a prospective randomized control trial conducted in a Medical College at New Delhi. The Study population consisted of 80 patients of renal calculus who underwent ESWL fulfilling the inclusion criteria.

Inclusion criteria

- Solitary calculus
- Size 5 - 20mm
- Stones located in renal pelvis, upper and middle calyx.

Exclusion criteria

- Impaired kidney function tests
- Coexisting anatomical abnormality (calyceal diverticulum, renal ectopia, horseshoe kidney)
- Multiple stones
- Inferior calyceal stone
- Distal ureteral obstruction
- Coagulopathy
- Pregnancy.

All patients who joined the study were randomly allocated by computer generated random number table (http://www.randomization.com/) to one of two groups, which consisted of 40 patients each. Group A (n=40): double-J stenting was done before ESWL session. Group B (n=40): proceeded to ESWL without double-J stenting.

Written informed consent was obtained from all patients.

Preoperative work up

- Clinical history and physical examination.

All patients had the following pre-operative investigations: complete blood count, kidney function tests - blood urea, serum creatinine, serum electrolytes, urine for routine/microscopy, urine for culture/sensitivity, blood sugar-fasting, X-ray KUB, Intravenous urogram (IVU), ultrasound KUB (whenever required), non-contrast computed tomographic scan (NCCT) - (whenever required).

Intravenous urogram (IVU) - A plain radiograph KUB was obtained in a similar manner as mentioned above, following which 60ml of 75% ionic contrast (Sodium diatrizoate) was given intravenously through a previously placed intravenous cannula. Patient was observed for any adverse reactions. Sequential films were taken at 5 and 10 minutes in supine position and at 15 minutes in prone position. A full bladder film was also obtained. It was made sure that the kidney function tests were within normal limits before the study was done.

Operative technique

Double-J stenting

Patient was placed in lithotomy position and 2% Lignocaine jelly was injected per-urethra to provide local anesthesia and a waiting time of 10 minutes was given for the lignocaine to be effective. Then a 5Fr, one end open ureteral stent of 28cm length was introduced under cystoscopic guidance. Position of the stent was later confirmed under fluoroscopic guidance.

Lithotripsy

The lithotripter used was dornier compact sigma which is equipped with dornier relax+ patient Table, which is a fully motorized, four-axis table ideal for both extracorporeal shock wave lithotripsy and endourological procedures. It incorporated an exchangeable radiolucent stretcher that offered a wide range of movement as well as Trendelenburg tilting capability. The lithotripter is also equipped with fluoroscopy for stone targeting. The patients were advised to undergo proper bowel preparation with an oral stimulant purgative and charcoal on the day before the session. Patient was injected with an intramuscular injection of diclofenac sodium 50mg before the start of the procedure. The patient was then placed on the lithotripter with the loin of the affected side over the shockwave generator. The table was adjusted under fluoroscopic guidance until proper targeting of the stone was achieved. Once the stone was targeted the session was started which delivered 3000 shocks per session at 4 KV. Post procedure patient was counselled about the post ESWL symptoms and an analgesic such as diclofenac oral twice daily with a proton pump inhibitor is given for a week, Prophylactic antibiotic/antibacterial (Ciprofloxacin) twice daily was given for 5 days. Patient was also advised to take plenty of oral fluids. Repeat X-ray KUB was done after 2 weeks to see the response and sessions were planned repeat sessions depending on the residual stone load.

Failure of ESWL

No/Negligible stone fragmentation after 6 sittings was treated as failure.

Urinary tract infection (UTI)

Patients with significant pain and lower urinary tract symptoms not relieved by analgesics underwent urine routine microscopy and urine culture with a X-ray KUB. Those patients having a urinary tract infection were

treated with appropriate culture sensitive antibiotics and ESWL sessions was continued once the infection settled down.

Steinstrasse

Patients with symptoms of steinstrasse 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 smooth muscle relaxant. Those not responding to conservative treatment were considered for stone clearance with ureterorenoscopy. The next ESWL session was started once the patient's symptoms resolved and radiologically steinstrasse was cleared.

Parameters evaluated

- Stone fragmentation
- Stone clearance - Which is defined as absence of stone on X-ray KUB/NCCT or residual single stone fragment of size ≤ 4mm.
- Number of shockwaves required for fragmentation
- Time required for passing through ureter
- Steinstrasse
- Urinary tract infection.

Statistical analysis

- To see the difference between means for quantitative data, Student 't' test/ non-parametric/ Wilcoxon 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 cut off point for statistical significance.

RESULTS

A total of 80 patients with renal calculus, who underwent extracorporeal shockwave lithotripsy were included in the study. The patients were randomized in two groups "A" and "B" consisting of 40 patients in Group A and 40 in Group B. The patients in group A underwent ESWL after double J ureteral stenting, whereas patients in group B had ESWL without double J ureteral stenting. There were 24 (60%) males and 16 (40%) females in group A, while group B had 26 (65%) males and 14 (35%) females. The study contained 62.5% males and 37.5% females. Both the groups were comparable with respect to sex distribution of the patients with p value of 0.597. In Group A, the age of the patients varied from 12-60 years with mean of 35.46 years. In Group B, the age of the patients varied from 6-60 years with mean of 31.49. Analysis by chi-square test showed p value of 0.422. Thus, the two groups were comparable with respect to the age distribution of the patients. The stone size in group A was minimum of 5mm and maximum size was 20mm. The mean stone size being 12.8mm. The stone size in group B was minimum of 5mm and maximum of 20mm and mean size was 13.1mm. Stone size in both the groups was comparable with a p value of 0.910.

Table 1: Distribution of stone location.

Group	Renal pelvis	Upper calyx	Middle calyx	Total
Group A	n=31 (38.8%)	n=4 (5%)	n=5 (6.25%)	40
Group B	n=27 (33.75%)	n=5 (6.25%)	n=8 (10%)	40
Total	n=58 (72.5%)	n=9 (11.25%)	n=13 (16.25%)	80

Of the 80 patients 58 (72.5%) patients had stone in the renal pelvis, 9 (11.25%) of them had upper calyx stones and 13 (16.25%) had stones in the middle calyx. The stones in renal pelvis were distributed as 31 (38.8%) in group A and 27 (33.75%) in group B. Of the upper calyx 4 (5%) were in group A and 5 (5%) were in group B. The Middle calyceal stones were found in 5 (6.25%) and 8 (10%) of Group A and B patients respectively. On Statistical analysis by Pearson Chi-Square test the p value yielded was 0.496. The p value being insignificant both the groups were comparable with respect to the location of stone (Table 1).

Table 2: Mean, median, standard deviation of sittings received.

Group	Mean	Median	Standard deviation
Group A	2.26	2.1	1.055
Group B	2.23	2.2	1.086

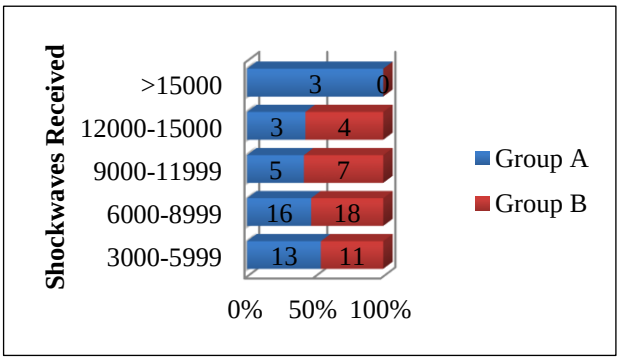

Figure 1: Shockwave distribution in both groups.

The number of shockwaves received in each group was distributed as follows, in Group A 13 (32.5%) received shocks ranging from 3000-5999, 16 (40.0%) received a range of 6000-8999, 5 (12.5%) received shocks ranging 9000-11999, 3 (7.5%) received shocks ranging 12000-15000 and 3 (7.5%) received shocks greater than 15000. The mean shockwave delivered in group A was 7700 shocks. In Group B 11 (27.5%) patients received shocks ranging from 3000-5999, 18 (45%) received a range of 6000-8999, 7 (17.5%) received shocks ranging 9000-

11999, 4 (10.0%) received shocks ranging 12000-15000 and none received shocks greater than 15000. The mean shockwave in group B was 8200 shocks. Analysis by Pearson Chi-Square test yielded a p value of 0.439. Which implied that there is no statistically significant difference in the two groups with respect to shockwaves received (Figure1).

The minimum number of sittings received in Group A was 1 with maximum being 6 and the mean was 2.26 with a standard deviation of 1.055. The minimum number of sittings received in Group B was 1 with maximum being 6 and the mean was 2.23 with a standard deviation of 1.086 (Table 2). Each sitting account to 3000 shocks. Analysis of the above values statistically using non-pair T test (Mann-Whitney test), the p value was 0.674 hence the number of sittings received in two groups was statistically insignificant.

Of the total study group 22 (27.5%) patients had stone clearance in a single sitting of which 10 (45.5%) were in group A and 12 (54.5%) in group B. The mean stone size in the patients who had clearance in single sitting was 7.1mm. Fifty-eight patients (72.5%) had to undergo re-treatment to achieve stone clearance.

Table 3: Mean, median, standard deviation of time for passage of stones.

Group	Mean (weeks)	Median (weeks)	Standard deviation
Group A	5.34	5.12	2.85
Group B	4.94	5.05	2.68

The time to passage of stones and clearance was calculated by the number of weeks required. In Group A minimum time required was 1 week and maximum 12 weeks with mean time required being 5.34weeks with a standard deviation of 2.85. In Group B minimum time required was 1 week and maximum 12 weeks with mean time required being 4.94 weeks with a standard deviation of 2.68 (Table 3). When statistically analyzed the non-pair T test (Mann-Whitney test) was used to compute the p value which was 0.495 and hence the time for passage of stones in both the groups were in-significant statistically.

The overall incidence of steinstrasse in the study was 5 (6.2%) with 3 (7.5%) in Group A and 2 (5%) in group B. On statistical analysis with Pearson Chi-Square test the p value came out to be 0.644 which makes the incidence of steinstrasse between the two groups insignificant. The mean time required for clearance of steinstrasse in group A was 8.3 weeks and group B was 9.8 weeks. Which was statistically insignificant with a p value of 0.254. When steinstrasse was co-related with the size of stones there was no steinstrasse occurrence in stones of size upto 15mm. Five patients had steinstrasse in patients with stone size >15mm the mean stone size in which steinstrasse occurred was 18.6mm and the time required for clearance of stone in patients with steinstrasse was 8.8 weeks (mean) and upto a maximum of 12 weeks. When the data was analyzed for statistical significance, it was highly significant with a Pearson's chi-square value of 0.001, which indicated strong co-relation for stone >15mm in size.

The overall incidence of UTI in the study was 18 (22.5%). The Incidence of UTI in Group A being 13 (32.5%) and in Group B was 5 (12.5%). On Statistical analysis using pearson Chi-Square test the p value was found to be 0.032 which implies that the incidence of UTI between the two groups is statistically significant, indicating much higher incidence of UTI in stented group.

The clearance was achieved in 39 of 40 patients in Group A with 1 Failure. Whereas clearance was achieved in all 40 patients of Group B. On statistical analysis with Pearson chi-square test the p value was 0.302, hence there was no statistical significance in the clearance between the two groups.

DISCUSSION

Extracorporeal shockwave lithotripsy (ESWL) has found an important place in a surgeon's armamentarium for treatment of renal stones. Renal stones of size upto 20mm can be successfully managed with in-situ shockwave therapy.[5] Controversy exists, as there are no definite guidelines on the usage of ureteral stents and with many surgeons preferring to place pre-ESWL stent routinely.[6,7] The utility of routine pre-procedural ureteral stent needs to be evaluated critically because the usage of stents has morbidity as well, as stenting is an invasive procedure increasing the chance of introducing infection into a non-infected system and the presence of stent itself leads of multitude of lower urinary tract irritative symptoms such as dysuria, frequency, hematuria, urgency.[8-10] Stents do have inherent risks of stent migration, vesicoureteral reflux and stent encrustation.

This study was done to assess the impact of double J ureteral stent on stone fragmentation, total number of sittings and shockwaves required for fragmentation and passage of stones through the ureter, so as to assess usefulness of ureteral stents in patients undergoing ESWL for renal stone.

The two groups (Group A - stented and Group B - non-stented) were comparable to each other in respect to age of the patients (p value 0.422), sex distribution (p value 0.597), mean stone size (p value 0.910) and location of stone in kidney (p value 0.496). The no of shockwaves received by the patients in the two groups varied from 3000 shocks to > 15000 shocks. Both the groups had comparable no of patients in each range of shockwaves. 3 patients received shockwaves more than 15000 in the stented group (Group A) but none of the patients needed shockwaves more than 15000 in the non-stented group

(Group B). This suggests that there might be some hindrance in fragmentation of stone by the stent placed in situ but the average no of shockwaves in both the groups (Group A - 7700 and Group B - 8200) were comparable with no statistically significant difference (p value 0.439). Similarly, the mean and standard deviation of no of sittings of shockwaves (consisting of 3000 shockwaves per sitting) in group A was 2.26±1.055 and group B was 2.23±1.086. There was no significant difference between the two group (p value 0.674) suggesting that there is no role of double J stent in preventing the fragmentation of the renal calculus according to our study. A study by Cass showed that 2,595 patients with indwelling ureteral stents required lower total power (shocks x voltage) and less radiation than the 501 patients without stents. However, the statistically significant difference was in the average radiation dose in patients with or without stents and single stones no larger than 10 mm (16 versus 18 rad).[11]

In this study 39 out of 40 patients (97.5%) in the stented group were cleared of the stones after shockwaves. 1 patient was not cleared of the stone even after 6 sittings (>15000) of shockwaves. The size of the stone in this case was 20 mm. After 6 sittings of the shockwaves treatment was declared as a failure and the patient underwent laparoscopic retroperitoneal pyelolithotomy for the removal of the stone. All patients in the non-stented group were cleared of the stone. With a p value of 0.302 our study showed no significant difference in the final clearance of stone between patients with double J stent and non-stented patients. In a study by Gupta et.al ESWL was evaluated as a montherapy for renal stones >2cm without double J stent.[12] Complete clearance (<5mm stone after 3 months) achieved in their study was 67.31%. The low rate of clearance in their study can be attributed to the size of the stone (>2cm) selected for their study. Whether insertion of double J stent could have improved the clearance rate in their patients cannot be commented as there was no comparison group in their study. Mustafa et.al in their study to assess the role of double J stent to enhance the passage of fragmented stone has report the overall clearance of 92.1%.[13] Out of the 11 stented patients 2 (81.8%) and out of 27 non-stented patients 1 (96.2%) patient did not have complete clearance. Hence their study suggested of better clearance of renal calculus in patients undergoing ESWL without double J stent, although the sample size of their study was small and the distribution of the patients was not uniform. A meta-analysis of eight randomized control trial done by Shen P et al, did not show any significant difference (p value 0.27) in the clearance of renal stone between the two groups.[14] A study done by Sofimajidpour et.al assessed the role of double J stent in children below 13 years of age and found no significant difference (p value 0.23) between the two groups.[15] Abdulla et al, further supported our results as their study too did not show any significant difference in the outcome as far as clearance is concerned.[16] Hence based on our results and studies done in the past, we may conclude that double J stent does not help or interfere in the clearance of the renal stone undergoing ESWL.

We calculated the time taken by the stone to pass down the ureter in both the groups and compared them to assess whether double J stent was accelerating or interfering in the passage of the fragmented stone particles. The mean time taken in group A for passage of stone was 5.34±2.85 weeks and in group B was 4.94±2.68 weeks. There was no statistically significant difference between the two groups (p value 0.495) suggesting that stent does not interfere or facilitate the passage of fragmented particles.

Incidence of steinstrasse in our study was 3 out of 40 (7.5%) in group A and 2 out of 40 (5%) in group B. With a p value of 0.644, our study excluded any increase in incidence of stienstrasse in the non-stented group in patients with stone size <20 mm. All 5 patients having steinstrasse in our study had stone size > 15mm suggesting the correlation of steinstrasse with increasing size of calculus. All 5 patients responded to conservative managment and cleared of their stone. The metaanalysis conduted by Shen P et.al reported steinstrasse in 5 out of 8 studies. 4 out of 5 studies showed no significant difference between the stented and non-stented group.[14] One of the studies conducted by Al-awadi et al, reported the incidence of steinstrasse in stented group as 6% and non-stented group as 13%, with a statistically significant difference (p value < 0.05). Stone size included in this study was 15-35 mm.[17] Gupta et.al reported incidence of steinstrasse as 38.94% in patients with renal stone > 2cm without double J stent. Large size calculus can be attributed to the higher incidence of steinstrasse in his study although comparison with the stented group was not there in the study.[12] Other studies done by Mustafa et.al, Bierkens AF et.al, Obaid et.al and Sofimajidpour et.al showed no significant difference between the two groups.[13,15,18,19] Suggested by majority of the studies and result of our study we may suggest that insertion of a double J stent pre ESWL may not help in prevention of steinstrasse in patients with stone size < 2cm. Double J stent may play a role in stones > 2cm but needs further evaluation to confirm it.

Overall incidence of UTI with positive urinary culture was 22.5% in our study, stented patients had a significantly high incidence of UTI with a p value of 0.032. All the patients in stented group responded to antibiotics after the removal of double J stent. All patients of non-stented group responded to antibiotics. Metaanalysis by Shen P et.al did not report any significant difference in all 8 studies included. El Assmy A et.al reported UTI in all patients with stent and a significant difference between the two groups.[20] Study by Obaid et.al and Sofimajidpour et.al also showed a significant difference in UTI between the two groups.[19] Hence UTI can be said to be one of the significant complication of placing double J stent which increases the morbidity of the patient and may cause damage to the effected renal system.[15]

Limitations of this study were small sample size, study group of stone size < 2 cm. The incidence of steinstrasse increases with the size of stone hence double J stent's role in prevention of steinstrasse needs assessment in larger stones. Only UTI among the complications were assessed in our study.

CONCLUSION

Based on our study we conclude that double J stenting in patients of renal calculus of size < 2cm, prior to ESWL is not beneficial with respect to clearance of stone, no of sittings and shockwaves received for the clearance, time of passage of stone and the incidence of steinstrasse occurrence. Double J stent predisposes the patient to multiple complications including urinary tract infection which increases the morbidity of the patient. Double J stent might have some beneficial role in stone size > 2cm, which requires further evaluation. We recommend ESWL without double J stent in patients having solitary renal calculus of size < 2 cm.

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