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Original Research Article

Is Routine Stenting Required in Uncomplicated Ureterolithotripsy For 10-20mm Lower & Middle Ureteric Stones? A Randomised Prospective Study

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Abstract

Purpose: Ureteroscopic Lithotripsy (URSL) is the standard treatment for the ureteric calculi which is a minimally invasive and very effective procedure commonly associated with placement of stent across the ureter. Stent placement is associated with increased morbidity, complications, cost and need for removal. The objective was to study the need for stenting in uncomplicated URSL in stones larger than 10mm.

Methods: A prospective randomized controlled study was conducted in the Urology department of Osmania Medical College and Hospital from October 2016- December 2019 comprising of 153 cases. All patients with ureteric calculus of size 10-20 mm (largest dimension) were included. URSL with 6 f Ureteroscope was performed and patients without any complications were randomized in the stent and no-stent groups. Patient demographics, stone characteristics and treatment parameters were recorded. Post operative symptoms and complications were recorded using a questionnaire.

Results: The patients of both groups were comparable to demographics, stone characteristics and location. SFR was 100% in both the groups, zero stricture rates. The fever, re-hospitalization rate, and the mean hospital stay were similar but operating time was higher in the stented group. Flank pain, duration of analgesic use, macroscopic hematuria, irritative and voiding symptoms were significantly higher in the stented group ($p < 0.05$). Patients without stents had a better quality of life.

Conclusion: Routine use of a ureteric stent is not necessary after an uncomplicated URSL done without ureteric dilatation even in stones larger than 10mm. Placement of stent increases morbidity, cost and harms the quality of life.

Keywords: Ureteroscopy, Ureteric Calculi, large calculi, Non-stented, stent related symptoms, quality of life

Introduction

Ureteroscopic Lithotripsy (URSL) is the standard treatment for the ureteric calculi which is minimally invasive and a very effective procedure [1]. Placement of a stent across the ureter is a very common practice after URSL in view that it will prevent ureteric obstruction and reduce the pain caused by passage of stones or due to ureteric edema [2]. Stents cause ureteric dilatation which might facilitate stone passage, help in quicker healing and prevent the development of ureteric strictures [2,3]. Despite these advantages there is considerable morbidity associated with placement of stents and around 10-85% of patients suffer from stent related complications [4,5]. Placement of stent increases the operative time and the cost of treatment [5,6]. The evolution of URSL due to miniaturization of ureteroscopes and lithotripsy devices has enabled surgeons to clear even big and impacted stones without complications [7]. Good quality of data exists to support the omission of stent in URSL involving stones less than 10 mm but data for stones of 10-20 mm are sparse. In this study we evaluated the need for routine stenting in uncomplicated URSL procedures done for ureteric stones more than 10 mm.

Materials and Methods:

A prospective randomized controlled study was conducted in the Urology department of Osmania Medical College and Hospital from October 2016-December 2019. Ethical committee approval (2016/76, 24/10/2016) was taken from Osmania Medical College before commencing the study and was conducted in accordance with Declaration of Helsinki. All patients planned for ureteroscopic lithotripsy for ureteric calculus 10-20 mm (largest dimension) were included in the study. Patients containing multiple stones were included in the

study provided their largest dimension combined was between 10-20 mm. Following patients were excluded from the study: Age <15 years and > 65 years, stones <10mm & > 20mm (largest dimension), upper ureteric stone, solitary kidney, pre-existing indwelling ureteric stent, history of sepsis or renal failure (serum creatinine >1.4), previous procedures with stent placement and those requiring opposite side stenting.

All patients were admitted and their demographics were recorded. A detailed history was noted and physical examination was done. Urine routine examination and urine culture was done and patients with positive cultures were treated with sensitive antibiotics and were included in study if there were no signs of sepsis. All patients were subjected to Non Contrast Computed Tomography (NCCT) and stone size was recorded as the maximum dimension, stone volume was calculated as V (cm^3) = (X) × (Y) × (Z) × 0.52. All patients were subjected to Intravenous Pyelography (IVP) for accessing the kidney function and ureteric obstruction. An x-ray Kidney Ureter Bladder (KUB) was done on the day of surgery. Informed consent of URSL with stenting was taken from all patients.

After spinal anesthesia, patients were placed in the lithotomy position and ureteroscopy was done with 6 French (Fr) Karl Storz semi-rigid Ureteroscope. All cases were done by the surgeons with similar experience and surgical skills in semi-rigid ureteroscopy. Cefixime 1 gm (culture sensitive antibiotic in urine culture positive patients) intravenous was given just before the start of the procedure and was continued for 2 more doses till the next day. A 0.025 inch guide wire was passed into ureter across the stone and the stones were classified as impacted if the guide wire was not able to be passed beyond the stone. Stones were fragmented with pneumatic lithotripter with 3Fr litho-probe and the fragments were removed with help of 3Fr tri-prong grasper and 3Fr basket. The whole length of the ureter was inspected after stone clearance for any residual fragments and possible ureteric injury. Intraoperative parameters were recorded including operative time, complications and outcome. Cases with gross pyuria, ureteric stricture and ureteric lesion: post ureteroscopic lesion scale (PULS) (8) grade ≥2 (any submucosal lesion or ureteric perforation) were excluded from the study and double J (DJ) stent was placed. Cases requiring dilatation of the ureteric orifice and ones having ureteric stricture hampering the easy passage of the 6 Fr Ureteroscope were excluded from the study. Patients with prolonged surgery were not excluded from the study. At the end of an uncomplicated procedure with complete stone clearance, the patients were considered suitable for recruitment into the study by the surgeon. They were then randomized into two groups by random numbers generated from computer software (Randomizer) into Stent and no-stent group. The random number was generated by a different person who was not the part of investigating team. A 3.8Fr 26 cm DJ stent (passable through the 6Fr Ureteroscope) was placed in the stent group and 14Fr Foleys catheter was placed for urinary drainage. X-ray KUB was done the next day for the confirmation of stone clearance and stent position. Patients were told that the x-ray will be handed to them on the follow up visit at the time of stent removal. Foleys was removed on day 1 in all patients. All patients were discharged on day 1 unless it was delayed for some reason. Sensitive antibiotics were continued in patients with positive urine cultures postoperatively. Analgesic paracetamol 500 mg was prescribed to be taken on demand basis. They were asked to consult if they develop fever or any pain not subsiding with the prescribed medications. All patients were explained again about the study and told to report for stent removal. Stent placement detail in the discharge sheet handed to patients was coded.

Pain was recorded by Visual Analogue Scale (VAS) separately for flank pain and suprapubic pain in all patients on a scale of 0-10 on the evening of the day of surgery and at time of discharge. Site of the pain (flank/ lower abdominal), duration of analgesic use and macroscopic hematuria were also recorded. Postoperative symptoms like urgency, dysuria, incomplete emptying and nocturia were recorded on a four point scale as used by Jeong et al (9): 0-absent, 1-mild (symptom within 3 days of operation, bearable with no medication), 2-moderate (symptoms persisting for 3–7 days, painful/troublesome enough for medication), and 3-severe (symptoms for ≥ 7 days, requiring medication). Patients were also asked to fill about the Health Related Quality of Life Parameters (HRQL) like general health, work performance and sexual performance on a four point-scale in the questionnaire: 0-unaffected, 1-mildly affected, 2-moderately affected, 3- severely affected. This questionnaire was a simple modification of the Urinary Stent Symptom Questionnaire (USSQ) by Joshi et al (10,11). All patients were handed a simple questionnaire (post operative symptoms and quality of life) and were asked to fill it in post-op day 3 and 14. All patients were reviewed on the 14th day and were asked if they were happy with the overall procedure. After submission of the questionnaire, they were told about their study group; the x-ray KUB film and decoded discharge sheet was given to them. The stent was removed under local anesthesia with cystoscope on the same day and they were asked if they would like to be stented if further procedures are done in the future.

An IVP and Ultrasonography of abdomen was done in all patients at the end of 3 months to rule out any ureteric stricture or hydronephrosis.

Sample size was calculated based on the power of the study of the Cevik et al (12) which showed benefit of not placing the stent after non-stented ureteroscopy. He had sample size of 30 patients in each group with > 90 % power to detect differences in pair wise comparison for the primary end points. Data analysis was done by XLSTAT 2018 software, independent sample t test for quantitative data and Chi-square test was done for qualitative data. A p-value <0.05 was considered statistically significant.

Results:

Out of 178 patients enrolled initially, 14 were excluded from the study (6 due to ureteric lesion PLUS ≥ 2, 5 due to gross pyuria and 3 due to stricture). 164 patients were available for randomization and were allocated into stent group (n= 82) and non-stented group (n= 82). Finally 77 patients from stent group and 76 patients from non-stented group were available for analysis (Figure 1)

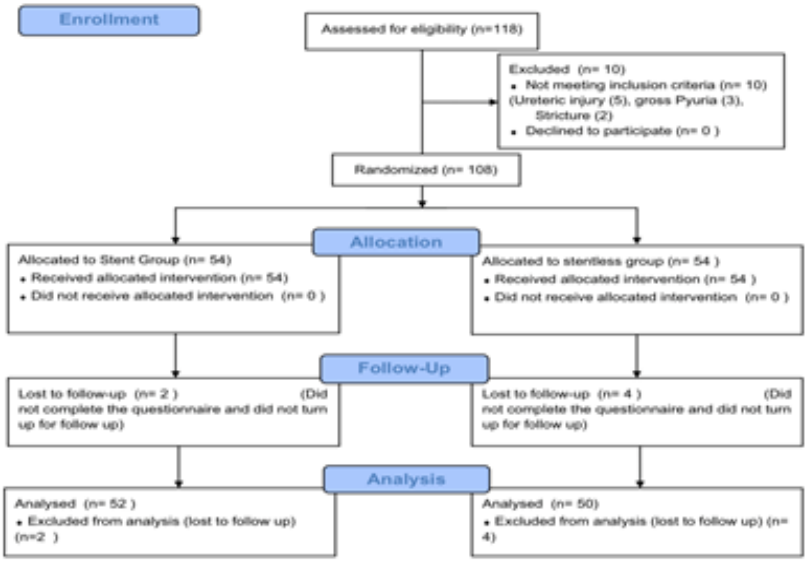

Figure 1: flowchart of patient enrollment and analysis.

The patient demographics, stone characteristics and the treatment parameters are depicted in table 1.

Table 1: patient demographics, stone characteristics and treatment parameters

Parameters	Stent (n = 77)	Non-stented (n =76)	P value
Age	41.2 ± 11.5	40.7 ± 12.1	0.541
Male	48 (62.33%)	49 (64.47%)	0.573
Female	29 (37.66%)	27 (35.52%)	0.412
Stone location (lower)	66 (85.71%)	67 (88.15%)	0.723
Stone Location (Middle)	11 (14.28%)	9 (11.84%)	0.684
Mean stone size (largest diamension) (cm)	13.4 ± 3.4	13.2 ±3.7	0.714
Mean Stone Volume (cm^3)	124.35 ± 31.21	119.24 ± 30.14	0.428
CT Hounsfield Unit	753.21±243.35	746.64±271.64	0.642
Impacted stones	15 (19.48%)	14 (18.42%)	0.854
Mean operative time	49.3 ± 13.8	45.7 ± 12.5	0.141
Mean hospital stay	1.6 ± 0.4	1.3 ± 0.3	0.438

The patients in the two groups were comparable in terms of mean age, male and female percentage, location of stone, mean stone size, mean stone volume and the percentage of impacted stones. 15 (19.48%) patients in stent group and 14 (18.42%) patients in non-stented group had impacted stones.

The stent group was associated with increase in mean operative time and hospital stay but the difference was not significant.

The post-operative pain, complications and symptoms are depicted in table 2.

Table 2: post operative pain, complications and symptoms

Parameters	Stent (n = 77)	Non-stented (n =76)	P value
VAS flank (evening)	2.13 ± 0.9	1.62 ± 0.6	**0.043**
VAS lower abdomen (evening)	1.62 ± 0.7	1.54 ± 0.6	0.942
VAS at (discharge)	1.17 ± 0.3	0.72 ± 0.2	**0.039**
VAS lower abdomen (discharge)	0.74 ± 0.2	0.69 ± 0.2	0.874
Duration of Analgesic use	3.42 ± 1.2	2.13 ± 0.9	**0.001**
Fever	6 (7.79%)	3 (3.94%)	0.126
Re-hospitalization	4 (5.19%)	1 (1.3%)	0.232
Macroscopic hematuria	21 (27.27%)	7 (9.21 %)	**0.004**
Stent migration	1 (1.29%)	0 (0%)	-
Ureteric stricture	0 (0%)	0 (0%)	-

Flank pain VAS score (both evening and at discharge) was significantly higher in the stent group. Lower abdominal pain VAS scores (both evening and at discharge) were comparable in both groups. Significantly higher rates of analgesic use were observed in the stent group. Insignificant mildly elevated rates of fever and re-hospitalization rates were noted in the stent group. 4 (5.19%) patients in the stent group were readmitted (one for stent migration and three for severe urinary tract infection) but only one in the non-stented group (urinary tract infection). 27.27% (21) of patients in stent group had significantly higher macroscopic hematuria than the observed rates of 9.21% (7) in non-stented group. No postoperative stricture was found in either group by IVP and USG done after 3 months post surgery.

The postoperative rates of patient's irritative and voiding symptoms, general health and work and sexual performance are depicted in table 3.

Table 3: postoperative rates of patient's irritative and voiding symptoms and HRQL parameters

Parameters	Stent (n = 77)	Non-stented (n =76)	P value
Urgency	1.91 ± 0.7	1.31 ± 0.6	**0.002**
Dysuria	2.19 ± 0.6	1.36 ± 0.5	**0.001**
Frequency	2.12 ± 0.7	1.38 ± 0.6	**0.001**
Incomplete emptying	1.71 ± 0.5	1.04 ± 0.5	**0.003**
Nocturia	1.02 ± 0.4	0.72 ± 0.3	**0.021**
General health	1.44 ± 0.7	1.01 ± 0.6	**0.013**
Work performance	1.64 ± 0.6	1.21 ± 0.5	**0.016**
Sexual performance	1.37 ± 0.7	0.91 ± 0.6	**0.007**

Significantly higher rates of urgency, dysuria, frequency, incomplete emptying and nocturia were observed in patients of stented group. The HRQL parameters, general health, work performance and sexual performance were significantly better in patients of non-stented group. Only 55.84% (43) of stented patients were happy compared to 84.21% (64) without stent. Only 28.57% (22) of stented patients said that they would be comfortable with stents in future procedures.

A subgroup analysis of patients having impacted stones was done. 15 (19.48%) patients in stent group and 14 (18.42%) patients in non-stented group had impacted stones. Flank pain and lower abdominal pain VAS scores were similar in the evening in both groups. But the VAS scores for flank pain at discharge were significantly higher in the stented group. Macroscopic hematuria and use of analgesics were more in the stented group but the difference didn't reach the significance level. The postoperative rates of irritative and voiding symptoms were significantly higher in the stented group. The HRQL parameters were significantly better in the non-stented group (Table 4).

Table 4: Subgroup analysis of the significant parameters in patients with impacted stones

Parameters	Stent (n = 15)	Non-stented (n =14)	P value
VAS flank (evening)	2.26 ± 0.9	2.12 ± 0.6	0.643
VAS lower abdomen (evening)	1.81 ± 0.7	1.72 ± 0.6	0.942
VAS at (discharge)	1.26 ± 0.3	0.79 ± 0.2	**0.039**
VAS lower abdomen (discharge)	0.74 ± 0.2	0.69 ± 0.2	0.874
Duration of Analgesic use	3.42 ± 1.2	2.13 ± 0.9	**0.001**
Macroscopic hematuria	5 (33.33%)	4 (28.57 %)	**0.004**

Discussion:

Stents are placed routinely after URSL to prevent the obstruction of the flow of urine in the ureter which might arise from the ureteric edema. It also minimizes the flank pain associated with the possibility of obstruction and facilitates the passage of residual ureteric stone fragments as it dilates the ureter [1,2]. The risk of ureteric stricture is also decreased with the placement of stent [2,3]. Despite the said benefits, placement of stents in the ureter is associated with a variety of complications like urinary infection, Uretero-arterial fistula, stent migration, stent knotting, stent fracture and ureteric erosion [3,4]. Stents also cause significant morbidity such as irritative and voiding symptoms, flank and suprapubic pain and hematuria which negatively impacts the quality of life [4,5]. In addition there is increased cost related with stents, the cost of stent itself and the added cost of the cystoscopic removal [5,6]. The removal of the stent under local anesthesia is related with increased patient's discomfort and increased morbidity (UTI and urethral trauma) [7]. Joshi et al reported reduced quality of life due to pain and morbidity associated with stents in 30% of patients [10,11].

The evolution in URSL has lead to miniaturization of ureteroscopes and the accessories. This has enabled clearance of even bigger and impacted stones by Ureteroscopy without any need for ureteric dilatation and as a result the complication rates have lowered and the morbidity profile has improved. But the major share of morbidity in URSL is related to the stent which is left in the ureter after the procedure [12,13]. Many animal experimental studies have also criticized the role of stents in the ureter and have observed that it causes reflux [14], increases intrarenal pressure [15], impedes ureteric motility and delays stone transit time [16].

Many randomized prospective studies have been done in pursuit of reducing the stent related complications and have compared the effects and outcomes of placement of stents after an uncomplicated URSL procedure. They have all concluded that there is no difference in stone free rates (SFR) between stented and non-stented URSL [17-21]. Recent guidelines on the management of ureteric calculi by the European Urological Association (EUA) and American Urological Association (AUA) have stated that stenting after uncomplicated URSL is optional [22]. Several meta-analyses of stented versus non-stented URSL has also failed to show any benefits of stents after uncomplicated URSL, rather they are associated with significantly higher pain scores, prolonged hematuria, more frequent voiding symptoms, increased operating time and increased overall cost [23-25]. Many medications are available for reducing the stent related complications but they lead to increased overall cost of the procedure and drug related side effects [24]. No such medications were used in our study.

Kenan et al [13] in his study reported 100 % SFR in both groups. He found significantly higher rates of irritative and voiding symptoms in the stented group and zero stricture rates. Pengfai et al [23] did a meta-analysis of 16 randomized controlled trials including 1,573 patients. He found a statistically significant difference in mean operative time between the two groups. The incidence of irritative and voiding symptoms and pain was significantly higher in the stented group. The rates of fever, urinary tract infection, unplanned readmission and late postoperative complications were similar. Our study had 100% SFR in both the groups, zero stricture rates. The patients were comparable between both groups with respect to demographics, stone characteristics and location. The mean operating time was higher in the stented group but was not statistically significant. The fever, re-hospitalization rates, and the mean hospital stay were similar. Flank pain, duration of analgesic use, macroscopic hematuria, irritative and voiding symptoms were significantly higher in the stented group.

Cevik et al [12] in his study included only impacted stones (60 patients) and reported 97% SFR in both groups and found significantly higher irritative and voiding symptoms in stented patients but no difference in other parameters. In our subgroup analysis of only impacted stones (29 patients) we also noticed significantly higher irritative and voiding symptoms in stented group.

Krambech et al [26] in his large series of 1000 ureteroscopies has reported stricture rates of only 0.2% which shows the impact of smaller size scopes in stricture rates. Our stricture rates were zero, maybe because we excluded cases with complications and the study population is smaller. The EAU and AUA guidelines [21] have also mentioned the absolute indications of placing a stent, ureteric injury, ureteric stricture, large residual stone burden, solitary kidney and renal failure. All these cases were excluded from our study to prevent bias.

We used a simplified version of the USSQ by Joshi et al (10) to study the morbidity caused by stents and studied general health, work performance and sexual performance on a four-point scale which was simpler for patients. We found significantly better performance in the patient without stent and higher rates of satisfaction when compared to the stented group. Only around quarter of stented patients said that they would choose stent again in the future. Only few studies [11] have used these HRQL parameters for studying the stent related morbidity.

Study Limitations: Our study is limited by the small sample size, single centre study, and lack of high quality data for a non-stented URSL in 10-20 mm stones. Use of only pneumatic lithotripsy devices in stone clearance in our study may limit its generalization to other newer stone fragmentation devices (like LASER). A larger multicentre randomized study should be done using different energy sources including large and impacted stones to defiantly answer the question.

Conclusion:

Routine use of ureteric stent is not necessary after an uncomplicated URSL done without ureteric dilatation for lower and middle 10-20mm ureteric stones. Placement of stent increases the morbidity and cost associated with the procedure and has a negative impact on quality of life.

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