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STENTLESS AND STENTED URETEROSCOPIC LITHOTRIPSY IN MANAGEMENT OF URETERIC CALCULUS–A CROSS-SECTIONAL OBSERVATIONAL STUDY.

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Abstract

Background

Ureterolithiasis is a common urological condition managed with ureteroscopic lithotripsy. While stents prevent strictures, they cause discomfort. This study compares postoperative pain and urinary symptoms in stented versus stentless patients to determine the optimal management approach.

Materials and Methods

This prospective observational study, approved by the Institutional Ethics Committee (MGMCRI/Res/01/2020/124/IHEC/190), included patients with ureteral calculi ≤10 mm. Exclusions were prior procedures, contraindications, or sepsis. Patients were divided into stented and stentless groups, assessing post-operative loin pain, frequency, urgency, and dysuria.

Results

The sociodemographic analysis revealed no significant differences between the stented and stentless groups in terms of age, gender distribution, or renal parameters ($p>0.05$). The mean age was 38.28±12.36 years in the stented group and 42.75±9.84 years in the stentless group, with a male predominance in the stented group (71.9%). On univariate analysis, there was no difference in age, renal parameters, size, and site of calculus in the stented and stentless groups. The study found that post-operative loin pain was significantly higher in the stented group ($p=0.001$), with greater symptoms of frequency ($p=0.03$), urgency ($p=0.05$), and dysuria ($p=0.02$). These findings suggest that stentless ureteroscopy may be preferable for reducing post-operative discomfort.

Conclusion

Stentless ureteroscopic lithotripsy reduces post-operative loin pain and urinary symptoms, improving patient quality of life. Stented patients experienced significantly more pain and symptoms from day 1 to day 14 post-surgery.

Recommendation

Stentless ureteroscopic lithotripsy is recommended for uncomplicated cases to minimize post-operative pain and urinary symptoms, improving patient recovery and quality of life.

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Introduction

Urolithiasis is the most common urological ailment, with a prevalence rate of 10-15% and a recurrence rate of 50%. Urinary blockage, renal colic, nausea, infection, and hydronephrosis are some common ailments that are frequently caused by urinary stones [1].

One of the methods most frequently used to effectively get rid of ureteral stones is ureteroscopic lithotripsy (URSL) [2]. Insertion of a DJ stent is recommended after URSL for stone passage [3]. The DJ stent was first described in 1978 by Finney. It has a proximal and distal curl that sits in the pelvis and bladder, respectively, to keep the stent in place [4]. Regular ureteral stent implantation lowers the risk of renal colic and ureteral blockage [5]. A stent reduces hydronephrosis by enhancing the flow of urine from the kidney to the bladder. It also helps repair tiny ureteral perforations and severe mucosal injuries, which lowers the risk of late problems such as ureteral stricture [6]. Colitis is a result of ureteral edema due to stone manipulation, instrumentation, and balloon dilatation. Small stone pieces

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can flow through the tract more easily when a stent is placed because it passively dilates the tube [7].

Placement of a stent is also associated with the need for secondary cystoscopy and additional cost of stent removal [8,9]. The literature lists recognized stent-related problems, including a 10-85% incidence of stent-related symptoms and/or morbidity [10].

To date, the need for post-operative stenting is controversial [9, 11, 12]. The American Urological Association's current guidelines state that in cases of simple URSL, ureter stent implantation is not necessary for the surgical treatment of ureteral stones [13]. Urinary tract trauma, ureteral dilatation, and residual stone load are all considered mild or absent in uncomplicated URSL [14]. Moreover, ureteroscopy is now performed with smaller scopes and lithotripters without the need for ureteral dilatation, making the procedure less traumatic, which causes less edema. As a result, routine stent placement for uncomplicated cases is questionable.

Although URSL with stenting has been routinely performed in Mahatma Gandhi Medical College and Research Institute, Pondicherry, given the change in current guidelines, in this study, URSL without stenting will be carried out to conclude after observation which method is better for the management of ureteric calculus. Thus, this study aimed to compare post-operative outcomes, including pain and urinary symptoms, between stented and stentless ureteroscopic lithotripsy patients to determine the optimal approach for ureterolithiasis management.

Materials and Methods

Study Design

It was a prospective, cross-sectional observational study. A total of 60 patients were enrolled in the study.

Study Duration

The study has been conducted for one year, i.e., from September 2020 to August 2021. The study was conducted in the Department of Urology at Mahatma Gandhi Medical College and Research Institute, Pondicherry, India, a tertiary care center specializing in advanced urological treatments and surgical interventions.

Study Population

The study population included patients who were diagnosed with ureteric calculus and planned for ureteroscopic lithotripsy. A total of 60 patients were enrolled in this study, with 32 in the stented group and 28 in the stentless group. The sample size was determined based on prior studies evaluating post-ureteroscopic lithotripsy outcomes, ensuring adequate statistical power to detect significant differences in postoperative pain and urinary symptoms between groups. Additionally, feasibility constraints and patient availability within the study duration influenced the final sample size selection. The criteria for participation were all patients who were more than 18 years of age and diagnosed with ureteric calculus with a size of up to 10 mm. The exclusion criteria were patients who were in sepsis, had a history of previous intervention like DJ stenting or PCN, or failed attempt of ureteroscopy on the same side, other than general contraindications for surgical procedures.

Study procedure

The patients were admitted and consent forms were signed, demographic information was obtained, and other clinical findings were recorded. Preoperatively, routine laboratory tests, ultrasound, and plain X-ray KUB (kidney, ureter, bladder) were reviewed. Computed Tomography of the kidney, ureter, and bladder was performed wherever required. After pre-operative anesthetist clearance, patients were posted for surgery. Interventions were carried out under Spinal Anesthesia or General Anesthesia, as per the anesthetist's or patient's preference. Further, the patients were divided into two groups:

Group I: Patients undergoing stentless URSL (n=28).
Group II: Patients undergoing stented URSL (n=32).

Patients were placed in a Lithotomy position and underwent Ureteroscopic lithotripsy with a semi-rigid single channel Richard Wolf 6/7.5 Ch. ureteroscope with a 4 Fr working channel width, a 5° lens, and a length of 430 mm. A ballistic (pneumatic) generator, Lithomed, ARK, was used to break the stone. Stone retrieval was done by use of a Dormia Basket, irrigation, or forceps.

For patients in group II, a 5 Fr Double J polyurethane stent was placed over a guide wire under C-ARM guidance on the same side as the URSL was done. Stent removal was done 2 weeks postoperatively after reviewing X-ray KUB.

After completion of the procedure in both groups, a Foley catheter was placed and retained till the morning of postoperative day 1. All patients in whom complete stone clearance was not possible or there was intraoperative evidence of any other pathology, like stricture, growth, iatrogenic injury, or presence of pus, were excluded from the study.

In both groups, patients were given Inj. Paracetamol 1 GM IV 12 hourly postoperatively, starting 4 hours after surgery till the time of discharge. Tablet Paracetamol 650 MG BD was given after discharge to be continued for three days. Post-procedure loin pain was monitored 6 hours after surgery, on postoperative day 1, and at discharge by the Numeric Pain Rating Scale. Postoperative symptoms of dysuria, urgency, and frequency were monitored after catheter removal on postoperative day 1.

After discharge, patients were followed up on postoperative Days 2, 3, 4, and 6 telephonically for loin pain based on the Numeric Pain Rating Scale and for symptoms of urgency, frequency, and dysuria. Patients were asked to follow up in the hospital on day 7, on which pain and symptoms of dysuria, urgency, and frequency were noted and recorded. Patients were followed up on postoperative day 14 in the

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hospital, and symptoms of dysuria, urgency and frequency, pain score, and stone-free status were noted and recorded. Stented patients underwent stent removal after 2 weeks under local anesthesia after reviewing plain x-ray KUB. If patients had a pain score of more than 6 during the period of follow-up, they were asked to take a Tablet of Diclofenac 50 mg per oral maximum of three times a day as rescue analgesia, in case of severe pain that does not subside or is intolerable, the patient was asked to visit the hospital and undergo evaluation also including urine culture and thereafter treated accordingly. Figure 1 represents the flow diagram of the study procedure.

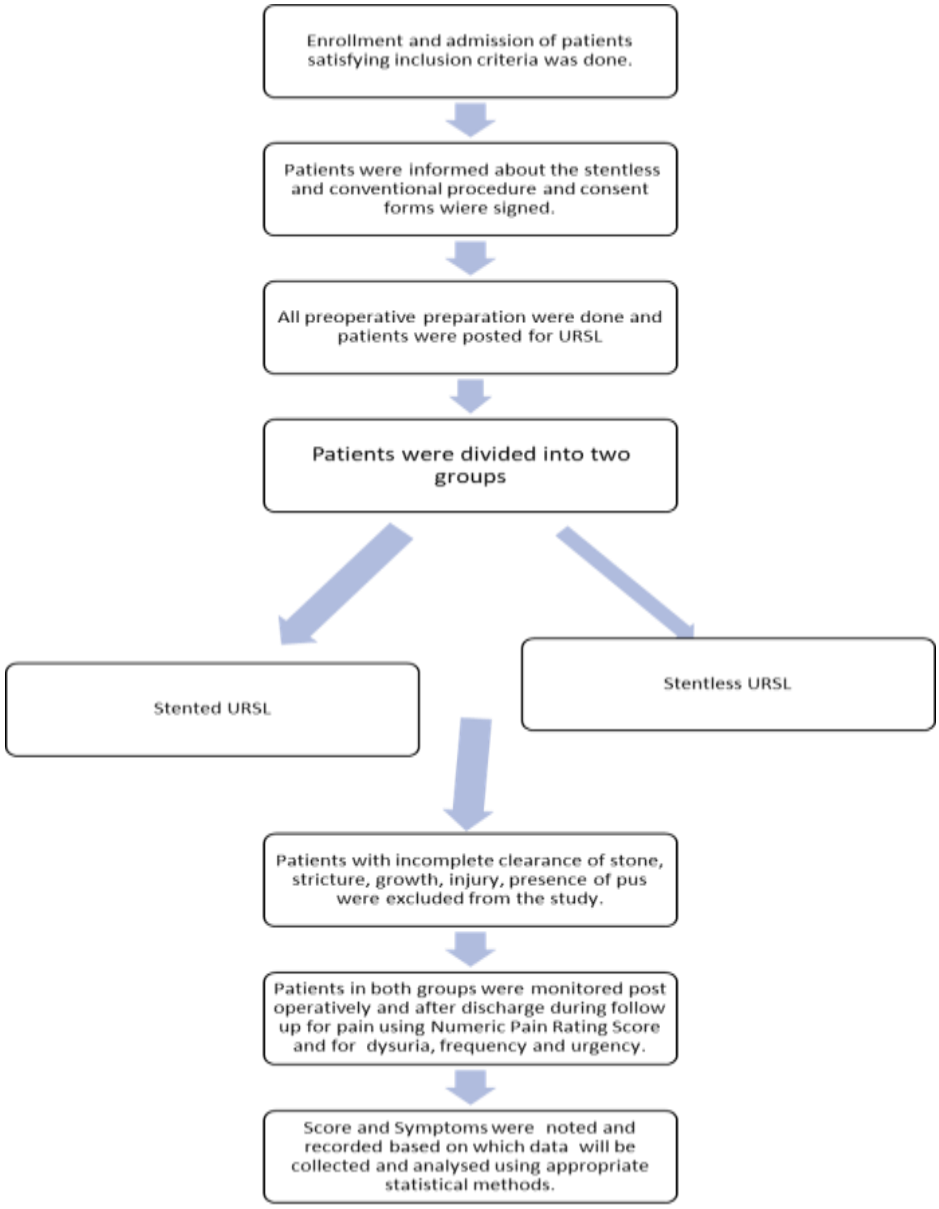

Figure 1. Flow diagram of study procedure

Standard Numeric Pain Rating Scale (NPRS-numeric version of VAS), which includes a pain rating from 0-10 based on severity, where 0 indicates no pain and 10 indicates worst pain imaginable, was used to monitor the pain post-operatively. The patients were asked verbally about the number that they feel represents their current state. In addition to demographic details and stone-related parameters, various clinical findings were documented. Preoperative symptoms included flank pain, hematuria, dysuria, fever, and a history of previous urinary tract

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infections (UTIs). Stone characteristics such as size, location, and number of calculi were also recorded. Intraoperative findings encompassed ureteric mucosal injury, stone impaction, the presence of pus, and the requirement for additional procedures. Postoperative parameters were assessed, including pain scores at different time points (6 hours post-surgery, postoperative day 1, and at discharge), urinary symptoms such as frequency, urgency, and dysuria, duration of hospital stay, and the need for additional analgesia or interventions.

Bias and Efforts to Mitigate It

To minimize selection bias, consecutive eligible patients meeting the inclusion criteria were enrolled. Random allocation to the stented and stentless groups was not possible due to ethical and clinical considerations, but group assignment was guided by surgeon discretion based on intraoperative factors. Observer bias was reduced by using standardized pain and symptom assessment tools, such as the Numeric Pain Rating Scale (NPRS) for pain evaluation and predefined criteria for urinary symptoms.

Statistical Analysis

Statistical analysis was done by recording, categorization, and computation with the help of Microsoft Excel. Quantitative variables were expressed as mean ± standard deviation (SD) or n (%) or n. An independent t-test was used to obtain significant results in demographics. Statistical homogeneity was evaluated by Pearson's chi-square tests of homogeneity. An ANOVA test was performed to analyze the variance within the groups. Statistical tests used in analysis had a two-sided *p*-value<0.05, which was considered the level of significance. All statistical analyses were performed using IBM SPSS (version 26.0, IBM Corporation, Armonk, NY, USA) software.

Ethical Approval

Ethical clearance for the conduct of the study has been provided by the Institutional Research Committee and Human Ethics Committee (MGMCRI/Res/01/2020/124/IHEC/190) at Mahatma Gandhi Medical college and research institute, Puducherry.

Results

In this prospective observational study, patients were divided into stented and stentless groups after ureteroscopic lithotripsy. It was observed that among the patients who were stented, 9 were female and 23 were male. In the stentless group, male and female patients were equal, with 14 in each group. In the stented group, 14 (43.8%) patients had calculus in the lower ureter, 9 (28.1%) patients had it in the mid ureter and upper ureter each, and in a stentless group of patients, 17 (60.7%) patients had calculus in the lower ureter, 4 (14.3%) patients had calculus in the mid ureter and location of the stone in 7 (25%) patients were upper ureter. The mean age of patients in the stented group was 38.28±12.36 years, and that of those in the stentless group was 42.75±9.84. The mean size of calculus in stented patients was 7.83±0.8mm, and that in a stentless group of patients was 8.11±0.8mm. However, there was no statistical difference concerning gender, site of calculus, age, renal parameters, and size of calculus in patients in the stented and stentless groups. Table 1 compares the various demographics, while Table 2 compares the renal parameters in both stented and stentless groups of patients.

Table 1: Comparison of age and gender in stented and stentless patients.

Variables	Stented URSL (n=32)	Stentless URSL (n=28)	p-value
Male	23 (71.9%)	14 (50%)	-
Female	09 (28.1%)	14 (50%)	-
Age	38.28±12.36	42.75±9.84	0.13

Table 2: Comparison of the size of calculus and renal parameters in stented and stentless patients

Variables	Stented URSL (n=32)	Stentless URSL (n=28)	p-value
Urea	24.63±9.77	24.96±8.54	0.88
Creatinine	1.18± 0.38	1.16±0.32	0.78
Size of Calculus	7.83±0.80	8.11±0.86	0.19
Site of calculus			
Lower Ureter	14 (43.8%)	17 (60.7%)	-
Mid Ureter	9 (28.1%)	4 (14.3%)	-
Upper ureter	9 (28.1%)	7 (25.0%)	-

Data is presented as n (%) or mean±SD

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p-value is significant at <0.05

An Independent t-test was used to obtain a p-value.

In this study, the mean loin pain score, which was measured 6 hours after ureteroscopic lithotripsy, was 0.63±0.833 in stented patients and 0.21±0.4 in stentless patients. Further, the main loin pain scores were measured on postoperative days 1, 2, 3, 4, 6, 7, and 14 in both groups, respectively. The mean difference in pain scores measured in stented and stentless groups in the postoperative period was significant (P = 0.001). Table 3 shows a comparison of loin pain scores after ureteroscopic lithotripsy among both stented and stentless groups.

Table 3: Comparison of mean loin pain scores in the postoperative period

Pain score	Stented URSL (n=32)	Stentless URSL (n=28)
6 Hours	0.63±0.8	0.21±0.4
POD1	0.38±0.6	0.14±0.3
POD2	0.53±0.6	0.36±0.4
POD3	0.19±0.3	0.11±0.4
POD4	3.03±1.09	1.32±0.8
POD6	2.34±0.8	0.75±0.6
POD7	1.88±0.7	0.29±0.5
POD14	0.97±0.8	0.21±0.4
p-value	**0.001**	**0.001**

Data is presented as mean±SD
The p-value is significant at <0.05

The ANOVA (analysis of variance) test was used to obtain a p-value.

Out of 32 stented patients, 12 patients experienced urgency postoperatively, 18 patients experienced increased frequency of micturition, and 12 patients complained of dysuria. While in another group of 28 patients that belonged to the stentless group, 4 patients complained of urgency, 8 patients had increased frequency of micturition, and 3 patients experienced dysuria in the post-operative period, followed up till day 14. The statistical difference in both groups concerning symptoms of urgency, frequency, and dysuria was significant. Table 4 represents lower urinary tract symptoms in the postoperative period in both stented and stentless patient groups.

Table 4: Comparison of lower urinary tract symptoms in the postoperative period in stented and stentless patients

Complications	Stented (n=32)	Stentless (n=28)	p-value
Urgency	12 (37.5%)	04 (14.28%)	**0.05**
Frequency of Micturition	18 (56.25%)	08 (28.57%)	**0.03**
Dysuria	12 (37.5%)	03 (10.71%)	**0.02**

Data is presented as mean±SD
The p-value is significant at <0.05
The chi-square test was used to obtain a p-value

Discussion

Due to the acute nature of the symptoms, the patient may require hospitalization and prompt treatment of symptoms and stones. Ureteroscopic lithotripsy followed by stenting is a common surgical procedure done for the management of ureteric calculi with high success rates. Insertion of a stent keeps the tract dilated and prevents obstruction and stricture formation [3, 14], but it comes along with an added morbidity due to pain and symptoms caused by the presence of the stent, and stent-related complications like migration, breakage, and encrustation [10].

The study was conducted to evaluate the pain and lower urinary tract symptoms of frequency, urgency, and dysuria in the presence and absence of a stent and draw conclusions regarding the necessity and morbidity related to the procedure of stenting after ureteroscopy.

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This study involved 61.7% of male patients, and 38.3% of patients were female. Male predominance was seen in the study concerning the occurrence of ureteric calculus, suggesting a higher susceptibility in men, possibly due to lifestyle, dietary factors, or metabolic differences. In a similar study by Shao et al, of 115 patients, 71 (61.7 %) patients were male and 44 (38.3%) patients were female [15]. In a study by Isen et al, among a total of 43 patients who took part in the study, 24 (55.81%) were males, and 19 (44.19%) were female, showing male predominance, which is consistent with this study [16].

The mean age of patients in whom a stent was placed in this study was 38.2±12.3 years, and in those without a stent was 42.75±9.8 years. Which is consistent with a study conducted by Bryne et al that recorded the mean age of patients with stent to be 41±14 years and 47±16 years in stentless group [11].

Among the total of 60 patients, the position of calculus in 31(51.7%) patients was in the lower ureter, 13 (21.7%) patients at the mid ureter, and 16 (26.6%) patients were found in the upper ureter. This trend aligns with the natural course of stone migration, as most ureteric calculi originate in the kidneys and move downward. The higher prevalence of lower ureteric stones may be due to their tendency to become lodged at the ureterovesical junction, where the ureter narrows. This finding is clinically relevant as stone location influences treatment decisions and post-operative outcomes. Netto et al. performed a study with 295 patients; 237 (80.3%) patients had stones located in the lower ureter, 40 (13.5%) patients had mid-ureteric calculus, and 18 (6.1%) patients had proximal ureteric calculus [14]. A study by Chen et al. included 48 (80%) patients who had lower ureteric calculi, and 6(10%) patients had mid-ureteric and lower ureteric calculi each [17].

The mean creatinine levels in stented patients were 1.18±0.38, and that in stentless patients was 1.16±0.3, indicating no significant difference in renal function between the two groups preoperatively. This was consistent with the study published by Başeskioğlu et al. in which the mean creatinine value in stented patients was 1.16±0.5 and in stentless patients was 1.06±0.3 [18].

The mean size of calculus in this study in stented patients was 7.831±0.8 mm, and that in stentless patients was 8.1±0.86 mm. In a similar study conducted by Srivastava et al mean stone size in stented patients was 7.58±1.9 mm and the mean stone size of 7.82±1.5 mm in stentless patients [19]. In another study by Cevik et al 2010, the mean stone size in stented patients was 9.1±4.5 mm and in stentless patients was 7.5±2.1 mm [20].

In this study, the stented group of patients experienced more loin pain overall, but the difference was not significant till post-operative day 3. From postoperative day 4, the pain measured via visual analog scale was statistically higher in the stented group of patients, indicating increased post-operative discomfort associated with stent placement. A recent meta-analysis done by Ordonez et al comprising 23 studies and 2275 patients confirms similar findings [21]. A study by Borboroglu et al also recorded more post-operative pain measured 48 hours, 1 week, and 4 weeks after the procedure in a stented group of patients, thus consistent with the present findings [22]. A study by Byrne et al reported that the post-operative pain was higher in the stented group of patients on postoperative days 0, 1, and 6 [11]. In a systematic review by Shen et al that constituted 20 randomized control trials and 1573 patients, 8 studies reported pain scores by using VAS and found that symptoms of pain were higher in the stented group than in the stentless group, and the difference was statistically significant [23].

The presence of symptoms of frequency and urgency, referred to as irritative bladder symptoms and dysuria, was significantly more frequent in stented patients as compared to stentless patients. According to a recent meta-analysis by Chen et al [23], and in various studies by Damaino et al, Hussein et al, Jeong et al, Shao et al, Srivastava et al and Xu et al [24, 25, 26, 15, 19, 27] respectively, have all been consistent with these findings of significantly worse lower urinary tract symptoms in stented patients. A study by Byrne et al also confirmed the findings of a significantly higher occurrence of dysuria and irritative bladder in a stented cohort of patients [11]. All these studies are consistent with the findings of this study.

Conclusion

The study concluded that post-ureteroscopic lithotripsy in both groups of stented and stentless patients revealed no statistically significant differences in terms of renal parameters, age, gender, calculus location, and size. The mean post-operative loin pain measured using a visual analog scale was significantly higher in the stented group of patients. Post-operative urgency frequency and dysuria were also observed more in the stented group of patients comparatively.

Generalizability

The findings of this study apply primarily to patients undergoing ureteroscopic lithotripsy for ureteric calculi up to 10 mm in size in similar tertiary care settings. However, variations in patient demographics, surgical expertise, and institutional protocols may limit broader applicability. Further multicentric studies with larger sample sizes are needed to confirm these results.

Recommendation

Stent placement may be avoided in uncomplicated ureteroscopic lithotripsy to reduce post-operative loin pain and urinary symptoms, thereby improving patient comfort and quality of life. However, careful patient selection is essential to prevent complications.

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List of Abbreviations
URSL - Ureteroscopic Lithotripsy
KUB – Kidney, Ureter, and Bladder
NPRS - Numeric Pain Rating Scale
UTI - Urinary Tract Infections
SD – Standard Deviation

Conflict of Interest
The authors declare no conflicts of interest related to this study.

Source of Funding
This study did not receive any external funding. It was conducted as part of institutional research efforts without financial sponsorship.

Author Contributions
All authors contributed significantly to the study.

Data Availability
The data supporting this study's findings are available from the corresponding author upon reasonable request.

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