

A RANDOMISED CLINICAL TRIAL COMPARING OUTCOME OF STENTED VERSUS NON-STENTED URSL

Urology

Dr Soumya Mondal	Asst. Professor, Department of Urology, Institute of Postgraduate Medical Education and Research, Kolkata, West Bengal, India.
Dr Anand Abhishek	Post-Doctoral Trainee, Department of Urology, Institute of Postgraduate Medical Education and Research, Kolkata, West Bengal, India.
Dr. Murari Mohan Mondal	Asst. Professor, Department of social and preventive medicine, Institute of Postgraduate Medical Education and Research, Kolkata, West Bengal, India.
Dr Dilip Kumar Pal*	Professor and Head, Department of Urology, Institute of Postgraduate Medical Education and Research, Kolkata, West Bengal, India. *Corresponding Author

ABSTRACT

Purpose: Ureteroscopic lithotripsy (URSL) is procedure of choice for managing ureteric calculi. However placing ureteric stent after every URSL is controversial. Routine stenting exposes patient to more stent related symptoms, encrustation and complication of forgotten stent. Through this study our aim is to examine outcome of stented URSL versus non stented URSL.

Materials And Methods: This study was prospective randomised controlled trial done at tertiary care hospital of eastern India. It was hospital based interventional study. After assessing 76 patients who underwent URSL, subjects were randomised into two groups: non-stented URSL (n=38) and stented URSL (n=38). The primary outcome assessed were lower urinary tract symptoms like urgency and dysuria, flank pain, haematuria, urinary tract infection, stone free rate, need of analgesic and secondary outcome assessed were mean operative time, rehospitalisation rate and duration of hospital stay.

Results: Lower urinary tract symptoms urgency and dysuria were similar in both groups in immediate postoperative period, more in stented URSL group after post-operative day 7 and persisted till stent removal (p=0.004). Flank pain and need of analgesics were more in stented URSL group (p=0.000 for both). Stone free rates were same in both groups. No significant difference in hospital stay (p=0.563) and urinary tract infection in between two groups.

Conclusion: Ureteric stent can safely be omitted without affecting stone free rate and also patients experience less stent related symptom.

KEYWORDS

Randomized trial, Ureteroscopy lithotripsy (URSL), Ureteric stent

INTRODUCTION

Ureteroscopic lithotripsy (URSL), extracorporeal shock wave lithotripsy (ESWL), medical therapy, percutaneous nephrolithotomy and laparoscopic surgery are all the indicated for the treatment of ureteral stones.[1] Nowadays URSL and ESWL are most preferred techniques to clear stones with high degree of success [2].

Procedure of choice for treating ureteric calculi especially mid and lower ureteric calculi is ureteroscopic lithotripsy. There are specific indications for DJ stent placement after URSL such as ureteral injury, ureteral oedema with or without stone impaction, ureteral perforation, history of or present renal failure, solitary kidney or a transplant kidney.

Despite such indications for DJ stenting, stenting is being judiciously placed by urologist inspite of morbidity associated with stenting. Worldwide data shows 13% of urologists place DJ stent after every endoscopic stone surgery (URSL) [3]. This numbers would be further higher in India [4] There is still controversy regarding placing ureteral stent after every URS stone surgery. Through our study we assessed the incidence of complications after placing double j stent after uncomplicated URSL.

MATERIALS AND METHODS

Ethics:

Ethical clearance for this was taken from our institutional Ethics Committee, IPGME&R Research Oversight Committee, approval no IPGME&R/IEC/2019/520.

Study Design:

Our study was hospital based interventional randomized controlled trial (RCT) conducted at Department of Urology at tertiary care Hospital. All Adult patients coming to our outpatient department (OPD) with ureteric calculi up-to 15 mm, who were planned for URSL as treatment for ureteric calculi were assessed for inclusion. Patients with history of pyelonephritis, stone in solitary kidney, stone in transplanted kidney, concomitant stone at other place in urinary tract, intra-operative ureteric injury & ureteric stone associated with ureteric stricture were excluded from participation in study.

Enrolment started in July 2020 after approval from institutional ethical committee and CTRI Registration (Reference No.-CTRI/2020/07/026421) till December 2020 when sample size was reached. Total 85 URSL were performed during this period assessed for eligibility. Written Informed consent was taken from each participant. Study subjects were placed into two intervention groups non stented URSL group and stented URSL group with sample size 35 in each group. First study subject was placed in one study group by coin toss method (Head for Group 1 and Tail for Group 2) and then next subject allocated alternatively in each study group as per out patient department registration. Both operating surgeon and participant were not blinded about procedure however, allocation of study subject into group were blinded.

All URSL were performed under spinal anesthesia in a standard fashion with Richard Wolf® Fiber Ureterorenoscope 6/7.5 Fr under antibiotic cover according to our standard protocol which was continued for 5 days postoperatively orally. The stones were fragmented to <2mm size using Swiss LithoClast® Master pneumatic lithotripter by comparison of the gravels to the tip of probe of lithotripter. Double pigtail Bluneem® 5.5 Fr/26 cm ureteral stents were placed for the stented group and these ureteral stents was removed after 4 weeks post procedure. In non-stented group no stents were placed after URSL.

All patients were followed up at 3rd day, 1st week, 2nd week, 3rd week, one month and three months. Postoperative symptoms including flank pain and haematuria was assessed at each visit using Visual Analogue Scale (VAS) [5] and urinalysis respectively. Lower urinary tract symptom was assessed on each postoperative visit by questionnaire. We also evaluated the need of analgesics in postoperative period, rehospitalisation rate, total operating time and mean hospital stay. At least 3 months follow up done in every case for late complications.

Statistical Plan, Data was compiled in Excel spread sheet to prepare the master chart and then analysed with Statistical Package for the Social Sciences (SPSS) version 26.0. Categorical data were analysed using 'Pearson Chi-Square' test and continuous data were analysed

using Unpaired t-test. "General Linear Model" was applied for "Tests of Within Subject Effects" with a good fit to the present data (Mauchly's Test of Sphericity). Finally analysis was represented with "Profile Plots of Estimated Marginal Means" of different outcome variables. All tests of significance were calculated at 5% absolute precision with P value of <0.05.

RESULT

Eighty six patients were assessed to participate in study (Image 1) out of that four patients were excluded after considering inclusion and exclusion criteria and two patients refused to participate in the study. Remaining patients were randomized into two study groups non stented URSL (No.-41) and stented URSL (No.- 38) after obtaining informed consent. Data of 76 patients were analysed. Two

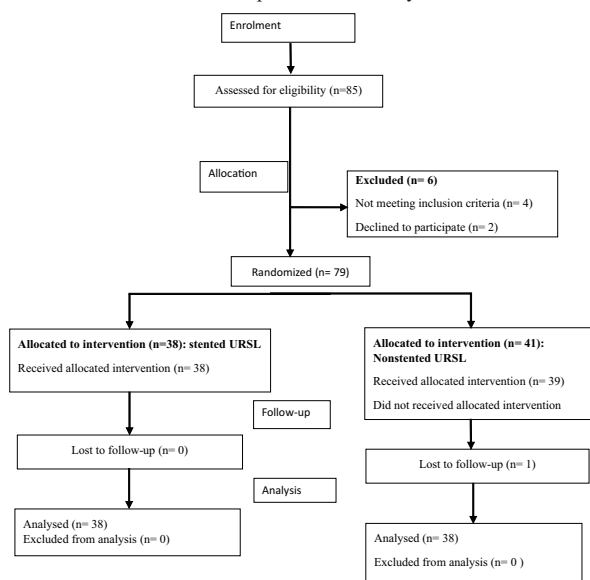


Image 1. - Flow Diagram

patients in Non stented group did not received allocated treatment due to intraoperative ureteric injury hence excluded from analysis. Data of 76 patients were analysed.

Both group were followed on post-operative day 3, 1 week, 2 week, 3 week, 4 week, and 3 months after surgery.

Both study groups were assessed regarding their demographic parameter (age, sex), size of stone and presence of hydronephrosis. Hydronephrosis was more in non-stented group however difference is not significant. (P = 0.80) (table no.- 1)

Table- 1 : Demographic Correlation Between The Two Treatment Group (URSL - ureteroscopic lithotripsy), χ^2 = value of Chi-Square test, t = value of student's t-test, p = p-value between the two group.

Parameter	Descriptive		Statistical
	Non-stented URSL	Stented URSL	
Sex	Male	24	$\chi^2 = 0.083$ $p = 0.773$
	Female	14	
Mean age (years)	39.95	42.58	t = 0.844 p = 0.401
Mean stone size (mm)	9.6474	9.4526	t = 0.402 p = 0.689
Hydronephrosis (n= no of patient)	12	10	P = 0.800

Mean operative time in non-stented group was 34.63 minute and in Stented group 36.63 min, p-value = 0.002. Hospital stay in Non stented and stented group were 2.26 and 2.34 days respectively. This difference in hospital stay was not statistically significant as p-value = 0.563 (Table-2).

Figure 2 graph A shows marginal means of pain of both groups throughout their treatment course with p value of 0.0001. Marginal means of pain were similar in two groups at postoperative day 3, but this difference became statistically significant at 1st week and it

remained statistically significant till 3rd postoperative week. At 4th postoperative week this difference became statistically insignificant. Figure 2 graph B shows marginal means of dysuria of both groups throughout their treatment course with p-value of 0.004. Marginal means of dysuria were similar in two groups at postoperative day 3, but this difference became statistically significant at 1st week and it remained statistically significant till 3rd postoperative week. At 4th week postoperative this difference became statistically insignificant.

Table- 2: Mean hospital stay and Mean operative time between the two treatment group (URSL - ureteroscopic lithotripsy), t = value of student's t-test, p = value of significance between the two group.

Parameter	Non-stented URSL	Stented URSL	Statistical
Mean hospital stay (day)	2.26	2.34	t = 0.581 p = 0.563
Mean operative time (min)	34.63	36.63	t = 2.193 p = 0.002

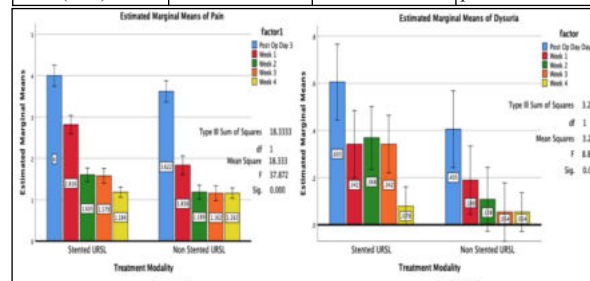


Image 2 A - Graph shows marginal means of Pain of both group. **Image B -** Graph shows marginal means of Dysuria of both group

Figure 3 graph A shows marginal means of hematuria of both groups throughout their treatment course with p-value of 0.0001. Marginal means of hematuria were similar in two groups at postoperative day 3, but this difference became statistically significant at 1st week and it remained statistically significant till 3rd week postoperative. At 4th week postoperative this difference became statistically insignificant.

Figure 3 graph B shows marginal means of need of analgesics of both groups throughout their treatment course with p-value of 0.0001.

Marginal means of need of analgesics were similar in two group at postoperative day 3, but this difference became statistically significant at 1st week when post-operative pain due to instrumentation subsides but pain related to stenting persisted in stented group and it remained statistically significant till 3rd postoperative week. At 4th week postoperative this difference became statistically insignificant after DJ stent removal.

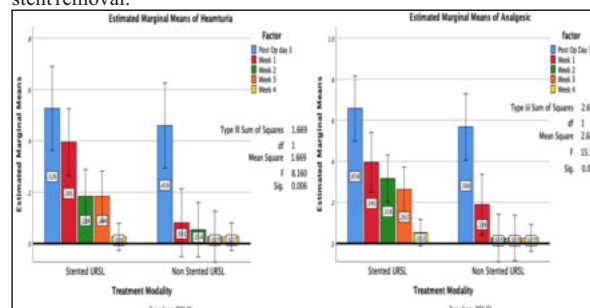


Image 3A- Graph shows marginal means of Haematuria of both group, **Image 3B -** Graph shows marginal means of need of analgesic of both group.

DISCUSSION

Double J-stents have been widely used for more than two decades, although widespread use of ureteral stents has corresponded to an increase in potential complications (stent migration, encrustation, stone formation, and fragmentation) [6].

Wang CJ [7] et al. identified ureteral stent causes significant health problem and morbidity. They found that ureteral stents are associated with significant symptoms, such as flank pain (affecting daily activities) (80%), urinary symptoms (73%), and reduced work

capacity (58%), which reduces quality of life. During the study, they also suggested stents profoundly affect psychosocial and physical health and have a negative impact on functional capacity and work performance.

Nabi et al. [8] reported the results of a meta-analysis of 9 randomized, controlled trials of stenting following uncomplicated ureteroscopy. The incidence of lower urinary tract symptoms was significantly higher in participants who had a stent inserted after ureteroscopy, which was corresponding with our study.

In our present study involving seventy eight patients, we did not find significant difference between the two groups concerning haematuria, fever, and urinary tract infection.

The same results were confirmed by Ibrahim et al. [9] and Ghoneim et al. [10] who found that patients without stents had significantly less bladder pain, urinary symptoms, and analgesic use postoperatively.

From our study we can conclude that placing ureteric stent results into increased lower urinary tract symptom in form of urgency and dysuria, flank pain and increased demand of analgesic in post-operative period. However there are no benefit to patient in terms of stone clearance also patient has to bear extra cost for additional procedure for stent removal. Main limitation of this study were non-blinded study, single institutional and small sample size. As the study was nonblinded, so patients were aware of stent placement and this may be a potential source of systemic bias.

CONCLUSION

Double J-stents can safely be omitted after uncomplicated ureterorenoscopic lithotripsy for ureteric calculi. Non-stented patients experience less stent related symptoms and analgesic need with add-on advantage of cost benefit by avoiding additional procedure for stent removal. Hence routine stenting after URSL should be avoided.

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