Original Research

A Randomized Controlled Trial: Double-J Stented versus Stentless Laparoscopic Ureterolithotomy

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Abstract
Introduction: Ureteric stents have been used for over five decades but recent meta-analyses reported thatstentless surgery was non-inferior to those performed with stents.Since the evidence is not clearcut and only a few randomizedcontrolledtrials are reported, hence this researchwas taken up using CONSORT guidelines at a tertiary hospital in Shillong, Meghalaya during 2020-21
Methods: The study was registered at the ICMR Clinical Trial Registry, approved by the Institution Review Board. All patients age18 years and above, with upper or mid ureteric calculus ≥ 1 cm who consented to participate in the trial were included.Pregnant Patients and those who had stone associated with ipsilateral ureteric stricture or ipsilateral renal stones were excluded.EligiblePatients were prospectively allocated to either group based ona confidential list for random allocation prepared ahead of the trial.Operating surgeons were informed of the choice prior to surgery. Patient were followed postoperatively up to 3 months.All Outcomes were assessed blindly.
Results: Both groups were similar in age, gender, size of calculi and location as well as otherclinical and radiological features.Follow-upshowed the drain quality and quantity were similar and usually became minimal by third postoperative day. Post operative complications were not statistically significant.
Conclusion:Stentless Laparoscopic ureterolithotomy is non inferior to use of DJ stent.
Key words: Laparoscopic ureterolithotomy, double-J stent, stent less.

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Introduction

Urolithiasis is the most common urological disease having a prevalence rate of 10-15% and a recurrence rate of 50%. [(1)]Ureteric calculus is a type of urolithiasis producing symptoms like loin pain, infection, hydronephrosis etc which are treated by various approaches like ESWL, endourological procedures like ureteroscopic lithotripsy and surgical methods like open or laparoscopic ureterolithotomy. The use of ureteric stents dates back to over five decades for several clinical situations[(2)]. The use of Double J (DJ) stent was first reported in 1967 and since then has become one of the most commonly used treatment modalities for internal drainage after endourological or reconstructive procedures. [(3,4)]These stents provide the path for urine drainage and improve hydronephrosis simultaneously. [(5)] However, the use of ureteral stents for the treatment of ureteral stones is still controversial. [(6)]Regardless of compelling evidence in favour of not stenting a patient after an uncomplicated ureteric procedures, stentingis still a very common practice and routinely done [(7)].Hardly any RCT has been published specifically comparing DJ stents with stentlesssurgery. [(8)]In this paper, we present a single-centre noninferiorityRCT strictly following CONSORT guidelines comparing stent less surgery with DJ-stents testing differences in benefits, complications and effective drainage control.[(9,10)]

Material and methods

CONSORT guidelineswere followed in the conduct of this study which was registered at the ICMR Clinical Trial Registry in January 2021 (CTRI/2021/01/030559). It was approved by the Institution Review Board on 17th November 2020 and carried out during for a time span of one year at a tertiary hospital in Shillong, Meghalaya.

Patientsaged 18 years or more of both genders,with upper or middle ureteric calculus of size ≥ 1 cm (measured in the greatest diameter) who consented to participate in the trial were included.Pregnant patients

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and those who had the stone associated with radiologically diagnosed ipsilateral ureteric stricture oripsilateral renal stoneswere excluded.All the participating patients were provided with patient information sheet and written informed consent for the surgical procedure as well as stent insertion was obtained from all the patients before randomisation.Aim of the study was to carry out a Randomized Controlled Study on The Outcome Of DJ-Stent as compared to Stentless Laparoscopic Ureterolithotomy to evaluate relative merits and advantages.Our objectives were to determine the operative time, nature and quantity of drain outputandearly post-operative complications between stented and stentless group, and the statistical significances of the differences.Also to formulate suitable recommendations on best clinical practices in management of ureterolithiasis in relation to stenting after laparoscopic ureterolithotomy.

Sample size calculation

Based on specific assumptions for a noninferiority trial, of 90% and 60% effectiveness in the stented and non-stented groups respectively, type 1 error of 5%, Power of 80%, each group was required to have a minimum of 35 patients.

Randomisation method: A confidential list for random allocation was prepared ahead of the trial, with blocks of 6 patients, three in each group. Patients satisfying the eligibility trial described above, were prospectively allocated randomly to either stented or stentless surgery. Operating surgeons were informed of the choice prior to surgery. There were no defaulters or dropouts or non-cooperation. Patient were kept under observation 3 months after discharge. Outcomes were assessed blind.

Surgical procedure

Laparoscopic Ureterolithotomy (LU)

Laparoscopic ureterolithotomy (LU) is reported consistently as a good alternative to open surgery when endourological means are not sufficient for stone retrieval. In this study both transperitoneal and retroperitoneal approaches were used as per the expertise of the surgeon.Once the stone is localized,aclean cut is made over the stone using a hook diathermy.[11]Das and Rangad described an easier technique for stenting after laparoscopic ureterolithotomy, unlike one of the other ways of stenting performed in lithotomy position after LU is done.[12]The stentingtechnique involving lithotomy position is cumbersome and time-consuming contributing to the increased operative time, while in the later one it is easier to insert a stent . This technique described by Das and Rangad was used for this study for the respective group of patients, details of which are described further.

In lateral decubitus kidney position while performing retroperitoneal ureterolithotomy, a Hasson port and two 5-mm working ports were placed in the subcostal area. The ureter was identified and followed up to the stone. Ureterotomy was made over the stone using the monopolar hook diathermy and the stone was removed.A simple trocar cannula also called as an antral puncture needle (used by ENT surgeons in the past), was used to pass No.5 or 6 DJ stent by puncturing through skin parallel to the camera port till the tip of the cannula was visualised. The cannula was then manipulated to reach near the ureterotomy site after which the DJ stent along with a guide wire atleast 10-15 cm longer than the stent was introduced through the cannula. Once the tip of stent was visible, stent with the guidewire was pushed down to the lower ureter and bladder through the ureterotomy site. Once the upper end of the stent was visible, the guidewire was removed. The upper end of the stent was then advanced into the upper ureter and renal pelvis with the help of atraumatic grasper and Maryland forceps. One can calculate approximately how much the stent was to be pushed up by seeing the position of the stone in the ureter in a plain X-ray kidney, ureter, and bladder (KUB).Ureterotomy was closed with one to three interrupted 3-0 polyglactin sutures.[12]While performing transperitoneal ureterolithotomy, infraumbilical camera port and 2 working ports are inserted, and the method stenting used is the same as described above. Stent location was also confirmed with Xray KUB following morning.

Data analysis

All data were entered onto Microsoft Excel sheets and analysed using SPSS software. Descriptive statistics included percentages, means with standard deviations and medians. Inferential statistics included 95% Confidential Intervals, and Normal t tests for comparing the 2 groups, and Chi-square tests of Association. Level of significance wasset atp<0.05.

Results

The Mean(SD) of age was 31.2(9.5) in Group 1(stented group) and 28.8(11.1) in Group 2(the unstented group) the difference not statistically significant(p=0.317). Majority of the study population were males ~ 68.4 % in stented and 76.3% in the stent less group. There were no statistically significant differences between the two groups (p=0.755). The Mean (SD) of calculi in Group 1 was 1.4(0.4) cm and 1.5(0.4) in Group 2, the difference not statistically significant (p>0.05).

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Table 1: location of calculus among patients in each group is shown in

Location of calculus	Stented		Not Stented	
	No	%	No	%
Left mid ureter	4	10.5	4	10.5
Left upper ureter	11	28.9	17	44.7
Right mid ureter	9	23.7	4	10.5
Right upper ureter	14	36.8	13	34.2
Total	38	100	38	100

The differences were not statistically significant.Having established the two groups are similar, the outcomes are presented.The nature of drain output is given in Table 2

Table 2: nature of drain output

Nature of drain	Stented		Not stented	
	No	%	No	%
Nil	4	10.5	5	13.2
Serous	34	89.5	33	86.8
Total	38	100.0	38	100.0

The differences were not statistically significant.The quantity of drain in the first 3 days are presented in Table 3

Table 3: drain quantity days 1-3

Drain quantity dq day 1 (ml)	Day 1				Day 2				Day 3			
	Stented		Not stented		Stented		Not stented		Stented		Not stented	
	No	%	No	%	No	%	No	%	No	%	No	%
Nil	3	7.9	1	2.6	3	7.9	2	5.3				
Min (<50)	21	55	21	55	28	74	26	68	36	95	35	92
50-150	11	29	14	37	7	19	9	24	2	5.3	1	2.6
150-300	3	7.9	2	5.3	0	0	1	2.6	0	0	2	5.3
Total	38	100	38	100	38	100	38	100	38	100	38	100

The drain quantities for each day did not show statistically significant differences.

One patient from the stented group had continuous drain output in 50-150 ml range while 5 had minimal drain output on day 4. Three patients from stent less group had high drain output i.e., 250 ml, 300 ml and 800 ml respectively. Patient-x with drain output of 800 ml underwent ureteroscopy (URS) and stenting the same day. The differences are not statistically significant (p=0.340) Only 3 patients in the stentless group were available to measure the Drain quantity on day 5 with drain 100 ml,150 ml and 75 ml(patient-x) respectively; as the rest were discharged. The one patient with 100 ml drain had spontaneous drain reduction on day 6 i.e., 50 ml, for which the drain was removed. Another patient with 150 ml drain output on day 6 as well was discharged with drain in situ on day 6, drain removed on OPD basis on follow up after 1 week. Patient-x who underwent stenting on day 4, had reduced drain output further, each day drain less than 100 ml, was discharged with stent and drain in situ on day 7 with 75 ml drain output. His drain was removed after 1 week on OPD basis.

Post-operative complications are given in table in Table 4

Table 4: post operative complication

Post op complication	Stented		Not stented	
	No	%	No	%
Lost to follow up	0	0.0	2	5.3
None	33	86.8	36	94.7
Stent induced	1	2.6	0	0.0

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Stone formation				
Urosepsis	2	5.3	0	0.0
Stent syndrome	2	5.3	0	0.0
Total	38	100.0	38	100.0

Post operative complications were mostly seen in the stented group although the differences are not statistically significant (P=0.129). Two of the patients from the stentless group were lost to follow up. They had minimal drain output for 3 consecutive post operative days and were discharged on day 3 after drain removal. In the stented group 2 patients developed urinary tract infection within three weeks managed with intravenous antibiotics. While other 2 stented patients required re-admission in the fourth week in view of urosepsis for which DJ stent was removed in the same admission with proper antibiotics and the patients improved. One of the patients had stent induced stone formation in the urinary bladder noted at the time of cystoscopic DJ stent removal in the 8th week.The mean (SD) stenting time was 187 (70.2) seconds, in minutes: 3.11 minutes. The 95% Confidence Interval is: 155.7 to 209.3 secondsMean (SD) duration of stent removal was: 6.37(0.998) weeks and the 95% CI: 5.85 to 6.69 weeks

Clinical Observations during Follow-up after discharge

Clinically no significant differences were noted between the two groups in the immediate post operative period. Stented patients who later developed UTI, required antibiotics while those with urosepsis required early stent removal. Apart from these, unlike the stentless patients, candidates in the stented group had to face additional mental, physical and financial stress of undergoing a mandatory second procedure of stent removal 6-8 weeks after stent placement to prevent stent associated complications like encrustation, stent fracture, stent migration etc.

Discussion

In clinical epidemiology and evidence-based medical practice, well-conducted randomized controlled trials have a pride of place and have proved their strengths despite some limitations [13,14].In the debate on stenting versus non-stentingsurgery for best results in management of ureterolithotomy, several excellent studies have been conducted globally, but mostly observational studies [15,16,17,18]. Although there has been an element of uncertainty as reported in systematic reviews and meta-analyses.There is no doubt that given the difficulties in organising proper RCT, well designed observational studies are a good substitute.[19,20]Nevertheless, valid proof of superiority or inferiority between 2 or more procedures can come only from RCTs.This study based on acceptable minimum sample sizes was done following strictly the CONSORT guidelines, both the original and subsequent additions. [9,10]Both the patients and the surgeons were fully cooperative and there have been no dropouts or defaulters. Random allocation need not necessarily result in comparable groups but the data show that patients undergoing DJ stents and those without stents were similar by age, gender, size and location of the calculi. The comparison of the outcomes as presented are quite valid and show that stentless surgery is not inferior to surgery with DJ stents, carried out among indigenous tribal populations of North eastern India with their unique life styles and dietary habits, this was a hospital-based study where significant numbers of patients were admitted for urolithiasis.In terms of outcomes presented in Tables 2,3 and 4, objective assessments of the drain quality and quantity over 7 days showed no statistically significant differences between the two groups, with some minor variations. Facilitation of drain output is a major reason for stenting and to assess the outcome of surgery. There could be conditions where the process of ureteric healing is in question where stents are indicated like increased age, remnant stone fragments,comorbidities, ipsilateral renal calculi, ureteric perforation, solitary kidneys, pregnancy and retroperitoneal fibrosis etc. In this study one case of remnant fragment of calculus getting lodged distal to the ureterotomy sitecausing obstruction and urine leak was seen.

Although designed and implemented well as a non-inferiority RCT, there are some limitations and weaknesses in this research. A single-centre study with defined populations in a specific geographic area cannot be generalised easily due to several extraneous factors; such as the sociodemographic and cultural factors of the population. Further, the issue of stenting cannot be considered in isolation from the type of minimal invasive surgery, the epidemiology of ureter stones in the area, the clinical and health status of the population and other characteristics that play a part not only in the size of calculi, but delays in admission to the right care, the use of traditional and alternate systems of medicine, probably complicating the presenting features of the patients. The sample sizes in this trial are reasonably large compared to many other RCTs referred to by Ordenez et al & Wang et al who have each studied over 22 trials. [21-25] Another aspect of generalisation refers to the qualifications of the operating surgeons, who were quite experienced in DJ stenting in laparoscopic ureterolithotomy in this centre as compared to surgery done elsewhere. The

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research had specific limited objectives and was not an epidemiological study. There was no separate feedback from patients such as Joshi'sUSSQ questionnaire or VAS (visual analogue scale) used, which might have given more parameters to compare between the stented and stentless group.[26] Spectacular developments have taken place in materials used for DJ-stents as well as in coating, application, and use of concomitant antibiotics, etc. as well as self-absorbing stents, which would make stenting far safer, acceptable and effective, but this research used only standard DJ stent with no additional support. A longer period of research, a longer duration of follow up, additional inputs, would make it better as a cohort study but difficult to carry out as a strict RCT.Another limitation could be the inclusion of both transperitoneal and retroperitoneal approaches in the study whereas single approach surgery for all cases would have made the study more standardised. [12,27] The use of Joshi's USSQ which includes a number of subjective factors like post operative pain would be enlightening to compare between the two groups.

Conclusions

This RCT demonstrated that the stentless LPU is non inferior to stented in terms of rate of drainage& duration of drain removal.In an uncomplicated ureterolithotomy where there is no evidence of remnant stone fragments or severe inflammation surrounding the ureter, stent can be omitted as it is safe, economical and convenient for the patient in terms of stent associated symptoms, complications and avoidance of a secondminor procedure to remove the stent.

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