

Clinical Outcomes of Retrograde Double J Stenting of the Ureter in Benign Obstructed Etiology Under Local Anesthesia - a Prospective Observational Study

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Abstract

Background : To study the clinical outcome of retrograde double J stent insertion of the ureter in benign etiologies, using rigid cystoscope under LA along with factors leading to failure and its complications. **Material and Methods:** A prospective observational study was conducted from December 2015 to June 2017 and a total of 140 patients were studied after institute ethics committee approval. Retrograde DJ stent insertion is done under LA with fluoroscopic guidance. The demographic data and other parameters were studied to find out the success of the DJ stent along with factors for failure of the procedure and its complications. **Results:** Calculous diseases were the most common cause followed by diabetic papillary necrosis. The success of stenting was 90.3% of patients. The cooperation of patients tolerating the procedure under LA was related to the success of the procedure and showed a significant association ($p = 0.026$). Failure of contrast going up on retrograde pyelography was the main reason for the failed procedure and is significant ($p=0.000$). UWT on NCCT didn't have any relation with the failed procedure. ($p=1$) **Conclusion:** The DJ stenting of the ureter with a rigid cystoscope under LA (spongiosal block in males) is safe and feasible with a high success rate. The ureteral parameters especially the UWT do not predict the success or failure of the procedure pre-operatively. The failure of contrast going up on RGP is significant ($p=0.000$) with failure of DJ stent.

Key Words

Double J stent , Kidney, Ureteral Obstruction, Local Anesthesia, Urolithiasis

Introduction

Urolithiasis is a common disease in the modern world and its incidence and prevalence is increasing all over the world in recent decades regardless of risk factors. ^[1] Acute infected and obstructed renal system is a urological emergency and requires decompression in the form of Double J stenting (DJ) or percutaneous nephrostomy (PCN) insertion under general anesthesia (GA) or local anesthesia (LA). ^[2] DJ stenting of the ureter is a commonly performed procedure in urology for diversion of the upper urinary tract for obstructive uropathy caused by various conditions. Emergency indications for diversion of the kidney(s) are

bilateral obstruction, unilateral obstruction with contralateral contracted or small kidney, single kidney with obstruction and urinary tract infection or urosepsis, and intractable renal colic not controlled by analgesia. ^[3] The use of DJ stents has increased worldwide in urological practice, which has resulted in improved patient care and outcomes of endourological surgery. ^[3,4] 1967, Zimskind first described the cystoscopic placement of indwelling ureteral stents for obstructive uropathy. ^[5] The modern cystoscopic DJ stent insertion was performed in

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1978 and traditionally performed under GA.^[6] In the majority of western countries, retrograde DJ stent insertion is performed using flexible cystoscope as an office-based procedure. Multiple studies have reported the safety and efficacy of DJ stenting of ureter obstruction using a flexible cystoscope under LA.^[7-11] In centers where cost and resources are no problems, endourological procedures such as DJ stent insertion can be done under GA. But in developing and underdeveloped countries where resources and cost are deciding factors for these endourological procedures on an emergency basis, whether these can be done under LA, paucity of literature is noted.

In our hospital, retrograde DJ stenting of the ureter is usually performed with rigid cystoscope under LA or intravenous morphine due to long delay in getting operation room slot under GA and due to the high cost and limited durability of the flexible cystoscope. This study aims to document the outcome of DJ stent insertion using a rigid cystoscope under LA. The factors leading to failure and complications if any will also be analyzed, so that it will be helpful in the future in deciding which patient can be taken for PCN directly without attempting DJ stenting.

Materials and Methods

This was a prospective observational study conducted from December 2015 to June 2017 in the Department of Urology, of our institution. The study was approved by the Institute Ethics Committee and included all consenting patients who were above 18 years of age for whom DJ stenting was indicated. Those with pregnancy, uncorrected coagulopathy, and urethral stricture disease were excluded.

The demographic data such as age, gender, body mass index(BMI), comorbidities along with lab parameters complete blood counts, serum creatinine, blood urea, urine culture pre and post-operative were recorded. The patients were evaluated with ultrasound of the kidney, ureter, and bladder(KUB) region, and non-contrast computer tomography (NCCT) scans of KUB were performed.

Technique: All consented patients received a single prophylactic dose of oral antibiotic one hour before the procedure. All procedures are done in lithotomy position with rigid cystoscope 30 degrees and 20 F sheath after instilling local xylocaine jelly intraurethral along with spongiosal block(male patients only) of 1% plain

xylocaine. After locating the desired ureteral orifice retrograde pyelography was performed to see the level of obstruction. Then a DJ stent of size 5F/26cm was placed under fluoroscopic guidance. The co-operation of the patient during the intervention was recorded by the operating surgeon on an ordinal scale as co-operative, very cooperative, and non-cooperative. The pain perception of the patient was recorded after one hour using the visual analogue score by the operating surgeon. The data such as stone size, location, ureter wall thickness(UWT), proximal ureter diameter, renal parenchymal thickness, transverse renal pelvis diameter(TPD) recorded from axial NCCT KUB. The intraoperative parameters such as retrograde pyelography findings, failure of contrast to go beyond the obstruction, patient's cooperation, and success of procedure were recorded. The clinical parameters such as fever, hemodialysis done or not recorded and NCCT-KUB-parameter correlated for stenting failure. The postoperative parameters were recorded such as, success rate, fever escalation, WBC count, need of antibiotics change, ICU admission (inotropic support, ventilatory support, hemodialysis), and change of serum creatinine. Statistical analysis

The Sample size was estimated using the statistical formula for estimating a single proportion with 5% level of significance and 5% absolute precision. The minimum expected proportion of failure rate was 0.10 and the estimated sample size calculated is 140. The distribution of data on categorical variables such as gender, BMI, comorbidity status, stone position, clinical outcomes, complications, etc. was expressed as frequency and percentage. The continuous data such as age, stone size, ureter parameters, etc. were be expressed as mean with standard deviation(S.D) or median with range. The association of the clinical outcomes with other categorical variables mentioned above was carried out by using chi-square or Fisher exact test. The comparison of continuous data in relation to clinical outcomes (success or failure) was carried out using the independent students't test or Mann-Whitney U-test. The independent clinical factors associated with the clinical outcome were expressed using multiple logistic regression analysis. All statistical analyses were carried out using the software SPSS Version 19 and a p-value ≤ 0.05 was considered significant.

Results

A total of 140 patients were screened for eligibility to

Table 1 Showing Outcome Related Parameters of the Patients

		Mean \pm SD/Frequency (%) / median (IQR)		
Success of the procedure (DJS)	Yes	127(90.7%)		
	No	13(9.03%)		
Admission to ICU	Yes	6(4.3%)		
	No	134(97.7%)		
	Calculous disease	110(78.6%)		
	PUJO	3(2.1%)		
	Papillary necrosis	20(14.3%)		
	GUTB	3(2.1%)		
	Post Procedure	3(2.1%)		
Indications	EPN	1(.7%)		
	Fever	Absent	101(72.1%)	
	Fever preoperative	Present	39(27.9%)	
	Fever post-operative	Absent	130(92.9%)	
		Present	10(7.1%)	
		Pre-operative	10,600 (8000-14397)	
		Post-operative	9020 (7875-12070)	
	WBC (per/microlitre)	Pre-operative	3.6 (1.5-6.98)	
		Post-operative	1.85 (1.140-4.2)	
	Serum creatinine(mg/dl)			
	Need for haemodialysis pre-operatively		26(18.6%)	
	Need for haemodialysis post-operatively		1(0.7%)	
	Requiring change in antibiotics post operatively		24(17.1%)	
	Urine culture	Positive	4(2.97%)	
	Preoperative	Sterile	136(97.1%)	
Urine culture post-operative	Sterile	106(75.7%)		
	Positive	34(24.3%)		
Clinical parameters	Requiring ICU admission	No	134(95.7%)	
		Yes	6(4.3%)	
	If requiring ICU admission	Inotrope	No	134(95.7%)
		Support	Yes	6(4.3%)
	Need for		No	139(99.3%)
		Haemodialysis		
			Yes	1(0.7%)
		Mechanical	No	Nil
		Ventilator	Yes	Nil

participate in the study during the period from December 2015 to June 2017. There were 107 male and 33 female patients. The patient's age ranged from 20 years to 75 years, the mean age was 46.31 ± 13.75 years. The (BMI) of patients ranged from 13.7 to 31.2 and the majority of patients didn't have any comorbidities (69.3%) with diabetes most commonly accounted for (17.1%). The most common indication for the DJ stenting procedure was calculous disease 110(78.6%) followed by diabetic papillary necrosis 20(14.3%), PUJO 3(2.1%), GUTB 3(2.1%), and post procedure related 3(2.1%) 1 patient has emphysematous pyelonephritis. (Table 1) The median stone size was 5(10-18) mm and the median UWT (in

mm) was 2.45(1.52-3.375). (Fig. 1) The median renal parenchymal thickness, proximal ureter diameter, and TPD were 2.26(1.5-2.8) cm, 8.9 (5.025-11.975) mm, and 1.7 (1.1-2.4) cm. The study showed no significant association between the success of DJ stenting and UWT, TPD, proximal ureter, renal parenchymal thickness. The failure of contrast to go above the level of obstruction was seen in 12(8.6%). The patient's co-operation measured in Likert's scale as co-operative, very co-operative, and non-co-operative were 129(92.1%), 10(7.1%), and 1(0.7%) respectively. (Table 2) The Visual Analog Score measured 1 hour after the procedure by the operating surgeon was documented as mild, moderate,

Table 2 Association of Ureteral wall Thickness, TPD, Proximal Ureter, and Parenchymal Thickness, Co-operation of Patients and Contrast to go Beyond the level of Obstruction During RGP with Success of DJ Stenting

Variable	Success of Procedure	Failure of Procedure	p value
Ureteral wall thickness (mm)	2.4 (IQR 1.6-3.6)	2.5 (IQR1.5-3.05)	1.00
Transverse Pelvic Diameter(cm)	1.7 (IQR 1.1-2.4)	1.9 (IQR 1.05-2.68)	1.00
Proximal Ureter diameter(mm)	8.8 (IQR 5-11.8)	10.00 (IQR 3.24-13.45)	0.244
Parenchymal thickness(cm)	2.3 (IQR 1.5-2.8)	2.16 (IQR 1.67-2.59)	0.564
Co-operative	119(92.2%)	10(7.8%)	0.026
Very cooperative	8(80.0%)	2(20.0%)	0.026
Non co operative	0(00.0%)	1(100.0%)	0.026
Contrast going beyond Obstruction	127(99.2%)	1(0.8%)	0.000
Contrast not going beyond Obstruction	0(0.0%)	12(100.0%)	0.000

Fig 1. Axial image of NCCT Kub of Right Ureter (horizontal arrow) Ureter Wall Thickness with Calculus in Situ



and severe in 16 (11.4%), 118(84.3%), and 6(4.3%) of the patients respectively.

The ureter was successfully stented in 127 (90.7%) patients and failure was seen in 13 (9.03%) patients. (Table 1) Among the failure, 11 were male and 2 were female. In the case of calculous disease, the failure rate was in 10 patients (9%). The study could not find any significant association between the two (P = 0.715).

Out of the 140 patients taken for stenting, 6 (4.3%) developed complications in the form of urosepsis and required intensive ICU care with inotropic support. Fever was present in 39(27.9%) patients pre-operatively but

decreased to 10(7.1%) after the procedure. The median WBC/microlitre and serum creatinine(mg/dl) preoperatively were 10,600 (8000-14397) and 3.6 (1.5-6.98) respectively. The corresponding post-operative values were 9020 (7875-12070) and 1.85(1.140-4.2) respectively. 26 (18.6%) patients needed hemodialysis pre-operatively for optimization whereas only 1(0.7%) patients required hemodialysis postoperatively. The Pre-operatively urine culture was positive in 4 patients, post-operatively it was positive in 34 patients. The reason may be urine samples collected pre-operatively may not be representative in view of complete obstruction of the ureter.

Table 2 shows the outcome of the patient's co-operation with the success of the procedure. In co-operative patients, the failure rate was only 7.8% whereas in non-cooperative patients the failure rate was 100%. This study shows a significant association (p = 0.026). The outcome of DJ stenting success with VAS score, there is a significant association between the two (p=0.009).

Discussion

Renal colic with features of obstruction, fever or intractable pain may need urinary diversion such as ureteral DJ stent or nephrostomy insertion. There are no established guidelines though and the procedure of DJ stenting can be undertaken either in local, regional, or GA. [11] In most urological centers in the developed world, these procedures are done under GA with a rigid cystoscope or flexible cystoscope under LA with

fluoroscopic guidance. But doing the procedure under these circumstances the cost and burden on the healthcare system increases which puts strain on the underdeveloped or developing health care system.

In our prospective observational study, the procedures were done under LA (with spongiosal block in case of males) in 140 patients. The overall success rate for DJ stenting under LA was 127 (90.7%). The patient's characteristics were heterogeneous in our study. The calculous disease was the most common followed by papillary necrosis.

In our study, failure of the procedure was seen in 13 (9.03%) patients. In 12(8.6%) patients, the contrast could not go beyond the level of obstruction ($P=0.000$) whereas in one patient the failure was due to non-co-operation ($P=0.026$) which was statistically significant in both cases. None of our procedures failed due to the non-visualization of the ureteric orifice.

This is contrary to the findings by Adeyoju AB *et al.* who studied the feasibility of DJ stenting with flexible cystoscopy under LA and found the main reason for failure (3 failures out of 20 cases) in their series was due to non-visualization of the ureteric orifice. In their series, 82.3% of patients didn't have any pain or discomfort after the procedure. [7]

Ahmad I *et al.* compared patients with obstructive uropathy with DJ stent or PCN insertion and reported a success rate of 96.00% with rigid cystoscopy under LA in the DJ stent group, and the most common indication for DJ stenting in their study was calculous disease. The most common reason reported for the failure of the procedure was malignancies of bladder and prostatic carcinoma where the ureteric orifices were involved by the tumor. The most common complication reported was painful trigone irritation in 12% of patients followed by bleeding and hematuria in 10%. [12]

Flukes S *et al.* did a study by inserting a DJ stent in obstructive uropathy under GA in 52 patients and the success of the procedure was 98%, 9 patients (17%) required ICU care out of which 6 were preintervention in ICU care. All 9 patients were on inotropes support, 5 require ventilator support, and 4 needed hemodialysis. In all, 35 of the 52 patients had positive culture results (67%), of which the highest yield was from pre-intervention urine cultures (64%). In our study, urosepsis was seen in 6(4.3%) of the patients and required ICU care with

inotropic support. The pre-operative fever was present in 39(27.9%) but the number decreased to 10(7.1%) post-operatively which is explained by diversion of the obstructed system. [2]

Paz A *et al.* in their retrospective study of 100 DJ stent insertions that initially 13 patients presented as febrile compared to 22 patients who developed a fever after the procedure in initially 87 afebrile patients. But these febrile complications was opposite to our finding and the main reason that they studied multifactorial such as urine stasis or breakdown of urothelial defence mechanism during instrumentation or pyrogenic reaction to stent material

The pre-operative urine culture in our study was 4(2.97%) but post-operatively it increased to 34(24.3%). In our study 26 (18.6%) patients needed hemodialysis pre-operatively for optimization whereas only 1(0.7%) patient required hemodialysis. 24(17.1%) patients required a change in antibiotics after the procedure(3). We have observed a significant association of failure of the procedure with the co-operation of the patient($P=0.026$), failure of the contrast to go beyond the level of obstruction on RGP($P=0.00$), and VAS score ($P=0.009$) on univariate analysis. We could not find any significant association of procedure failure with variables like age, sex, side of the procedure, location of the stone in the ureter, stone size, ureteral wall thickness, and transverse pelvic diameter. There was a significant association of ICU admission requiring inotropic support with pre-operative urine culture ($p=0.009$), post-operative urine culture ($p=0.031$), and BMI ($p=0.007$) on univariate analysis but on multiple regression analysis, it was not found to be statistically significant. In our study, the VAS score measured on a Likert scale of 1-10 (where 10 is the worst pain the patient can tolerate) and subdivided into 1-3 (mild pain), 4-6 (moderate pain) & 7-10 (severe pain) were 16 (11.4%), 118(84.3%) & 6(4.3%) respectively.

Hussein NS *et al.* studied the feasibility and safety of DJ stenting under LA and assessed the impact of self-watching of procedure on pain while inserting DJ stent under LA with rigid cystoscopy in 80 patients. The participants were divided into two groups of self observer and non-observer. The pain score was categorized using VAS into mild, moderate, and severe pain. The mean pain score was 3.91 ± 3.12 , 14 patients experienced no pain, 22 patients experienced mild pain, 3 experienced moderate pain and

1 experienced severe pain in the self-observed group. They concluded that the patient who viewed the procedure had experienced less pain compared to those who did not view the procedure. ^[13] The mean UWT was 2.45(1.52-3.375) mm, however, no association could be found between the UWT and the success of the procedure.

The major strength of our present study is the prospective nature of the study, the other strength being the introduction of spongiosal block in males and inclusion of UWT as a predictor of outcome. There are various limitations of our study such as the indications were heterogeneous, study population includes both male and female whereas the spongiosal block was given only in the male patients and the procedure was done by different surgeons who had a different level of experience.

Conclusions

The analysis of this study suggests that DJ stenting of the ureter with a rigid cystoscope under local anesthesia (spongiosal block in males) is safe and feasible with a high success rate. The ureteral parameters especially the UWT do not predict the success or failure of the procedure pre-operatively. The patient's co-operation and failure of contrast to above the level of obstruction are important factors in the success of the procedure. Post-procedure urosepsis is a serious complication and requires ICU admission with inotrope support, appropriate antibiotics, and close observation.

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Conflicts of Interest

There are no conflicts of interest.

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