

Effectiveness Of Double J Stent With Extracorporeal Shockwave Lithotripsy: An Analysis Of Stone-Free Rates

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Abstract: Introduction: Preservation of renal function and integrity is of profound importance and therefore renders stent-related symptoms a secondary concern. The usage of DJ stent is known for decades to support stone removal, this study aims to assess the effect of DJ stent after extracorporeal shock wave lithotripsy for stone removal and DJ stent-related complications in adult patients. **Methods:** This is a prospective, comparative study, Patients were selected after being diagnosed with established radiological evidence of a single radio-opaque stone ≤ 2 cm. The presence of the visible radio-opaque shadow post-procedure indicated residual stones and negative results. Primary follow-up was recommended after 2 weeks post-procedure and participants were inquired about all the anticipated complications, data was entered on SPSS version 23.0 for analysis. The chi-square test was applied to assess the significance and a p-value ≤ 0.05 was deemed significant for our results. **Results:** The sample size of the study was 150, sorted equally into two separated groups categorized by presence and absence of DJ stent after ESWL, stone size was almost similar to avoid any confounding factor with the mean value of 1.24 ± 0.2 in group A and 1.6 ± 0.1 in group B, with a p-value of 0.05. Hematuria was categorized within mild 6(4%) & 7(4.6%), moderate 6(4%) & 5(3.3%) while gross hematuria was reported in 1(0.6%) & 2(1.3%) in group A and B respectively. **Conclusion:** This study concluded that using a DJ stent with ESWL does not help in the stone passage or improve stone-free rates of stone removal after breaking the calculi with shockwave lithotripsy.

Keywords: Extracorporeal Shockwave lithotripsy, Double J stent, Renal Stone

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Introduction

Nephrolithiasis is a very common disease implying stone formation in the kidneys. These stones when formed in the kidney can obstruct the urinary flow there or the stones can travel into the ureter, where they can again block the urinary flow towards the bladder [1]. They are often passed through the urethra if they are small (less than 5 mm) [2]. The incidence of nephrolithiasis is 50 % in urological patients as Pakistan is a part of the “stone belt” [3]. Because of delayed intervention in Pakistan 8-10% of CKD patients are at high risk of reversible cause of kidney injury [4]. There are various types of stones, and these are classified according to size, composition, radiological appearance, or cause [5]. The stones can be broadly divided into less than 5mm, 5 to 20 mm, and



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more than 20 mm, although differences are present in classification according to sizes. Furthermore, stones can be hard or soft, radiolucent, faintly radio-opaque, or radio-opaque. The stones can also be classified as familial, infective, or drug stones⁶ Stones are dealt with by different means. The management depends upon both stone and patient factors. Stones of smaller size and in the distal ureter can be managed conservatively and allowed to pass through expulsion therapy [7]. Larger stones of Hounsfield Units < 800 can be dealt with extracorporeal shockwave lithotripsy. Harder stones of bigger sizes are dealt with endoscopic or percutaneous approaches combined with intracorporeal lithotripsy or lithoclast [8]. A DJ stent or Double J stent is a prosthetic tube used as a diversion to keep unobstructed urine flow from the kidney to the bladder [9]. The stents are used in routine clinical practice in pre or post-phases of stone clearance.¹⁰ Some urologists prefer pre-stenting in some procedures while others prefer to proceed without it. Similarly, a complicated ureterorenoscopy or percutaneous nephrolithotomy (PCNL) requires DJ stenting to prevent any post-operative complications. The DJ stents are generally kept in place for 4 to 6 weeks, although the specific duration of DJ stent placement is still under discussion. These stents are known to be safe and are tolerated well by most patients, but they have some well-known complications. Preservation of renal function and integrity is of profound importance and therefore renders stent-related symptoms a secondary concern. A few studies have highlighted the side effects of DJ stent on quality of life, sexual life, pain, and other aspects of daily activities due to these complications [11] Symptoms related to DJ stent placement can be strangury, hematuria, flank pain, and dysuria. These can be controlled with medicines and adequate hydration [12, 13]. A stent can also be obstructed or migrated, and that case needs urgent intervention. Extracorporeal shockwave lithotripsy is meant to give shock waves targeted to the stone from outside the body and these fragments are then expelled per urethra. These fragments however can obstruct the urinary flow or can cause hematuria, arteriovenous malformation, or hypertension in the long run¹⁴. Pakistan shares a large weight of renal stone disease in the Eastern world, previous decade innovative approaches to eliminate stones with negligible incisions have been familiarizing, however, ESWL is still the method of choice for many patients. This study aims to assess the effects of DJ stent on stone-free rates after extracorporeal shockwave lithotripsy in adult patients with renal stones.

Materials and Methodology

This is a prospective, comparative, randomized study, Patients were selected based on a filter questionnaire indicating the age group of 16-35 years diagnosed with established radiological evidence of single radio-opaque stone ≤ 2 cm were included. Basal Metabolic Index (BMI) was calculated with the help of the classified formula: "BMI= weight (kg)/Height (m²)" These classifications for BMI have been adopted by the NIH and WHO for White, Hispanic, and Black individuals. Because these cutoffs underestimate risk in the Asian population, the WHO and NIH guidelines for Asian individuals define overweight as a BMI between 23 and 24.9 kg/m² and obesity as a BMI >25 kg/m². Some investigators employ four classes of obesity such that class 3 is defined as BMI 40 to 49.9 kg/m² and super obesity is defined as BMI ≥ 50 kg/m². Patients with deranged renal functions, chronic kidney disease, staghorn calculi, severe hydronephrosis, bilateral or multiple stones, or any anatomical anomalies were excluded from the study. 171 patients were considered eligible and 150 accepted the study. The researcher ensured unbiased randomization via computerized randomization software and sorted into two groups, No sorting of patients or any variation in the list was allowed after grouping. 75 patients were added to group A while the other 75 were placed in group B. This convenient sample size ensured the timely completion of data collection. The site of the study was Liaquat University of Medical Health Sciences, Jamshoro, Hyderabad, Emergency and OPD of Urology. After getting written and informed consent from the participants, they were asked for the demographic data, and Height and Weight were recorded. A list of comorbidities was obtained. Groups were allocated on



randomization and patients who were to have a Dj stent placed after ESWL were put in Group A and patients without stent were placed in Group B in a ratio of 1:1. Patients in Group A were given General Anesthesia and underwent ESWL with DJ stenting while Group B underwent ESWL under local anesthesia. The frequency of shockwaves was kept at 1 to 1.5 Hz with an energy level of up to 9 Joules. The immediate post-procedural success was recorded using radiological imaging. The presence of the visible radio-opaque shadow indicated residual stones and negative results. Primary follow-up was recommended after 2 weeks post-procedure and participants were inquired about all the anticipated complications. The answers were recorded on a pre-structured Performa and data was entered on SPSS version 23.0 for analysis. The chi-square test was applied to assess the significance and a p-value less than ≤ 0.05 was deemed significant for our results.

Results

The sample size of the study was 150, sorted equally into two separated groups categorized by presence and absence of DJ stent after ESWL, Group A had patients who underwent ESWL and DJ stent was administered, while Group B participants had no DJ stent placement after ESWL. The demographic details of all participants indicated mean age of 27.2 ± 5.2 years, while the stone size was measured as 1.2 ± 0.2 . Male gender was dominant with 82 (54.6%) as compared to females, maximum participants were normal weight on BMI scale 124(82.7%), only 20(13.3%) were overweight. 96(64%) participants needed three sessions of ESWL for complete stone clearance, Pain was the most commonly reported complication after the procedure indicating 88(58.7%) frequency while hematuria was reported with mild 29(19.3%), moderate 15(10%) and gross 7(4.7%) categories. Table 1

Table 1: Demographic and stone characteristic details of all study participants

Variables		Results
Age (Mean \pm St.Dev)		27.2 \pm 5.2
Stone size (Mean \pm St.Dev)		1.2 \pm 0.2
Hounsfield units (Mean \pm St.Dev)		1061.3 \pm 37.6
Shockwave (Mean \pm St. Deviation)		5065.2 \pm 1895.6
Gender	Male	82 (54.6%)
	Female	68 (45.3%)
BMI	Underweight	6 (4%)
	Normal weight	124 (82.7%)
	Over weight	20 (13.3%)
Stone location	Pelvis	97 (64.7%)
	Mid calyx	23 (15.3%)
	Lower calyx	30 (20%)
ESWL Sessions	2 sessions	54 (36%)
	3 sessions	96 (64%)
Clearance	Partial	21 (14%)
	Complete	129 (86%)
Complications	Mild Hematuria	29 (19.3%)
	Mod hematuria	15 (10%)
	Gross Hematuria	7 (4.7%)
	Pain	88 (58.7%)
	Anuria	6 (4%)
	Stainstasse	5 (3.3%)



Satisfaction	Not satisfied	48 (32%)
	Satisfied	102 (68%)

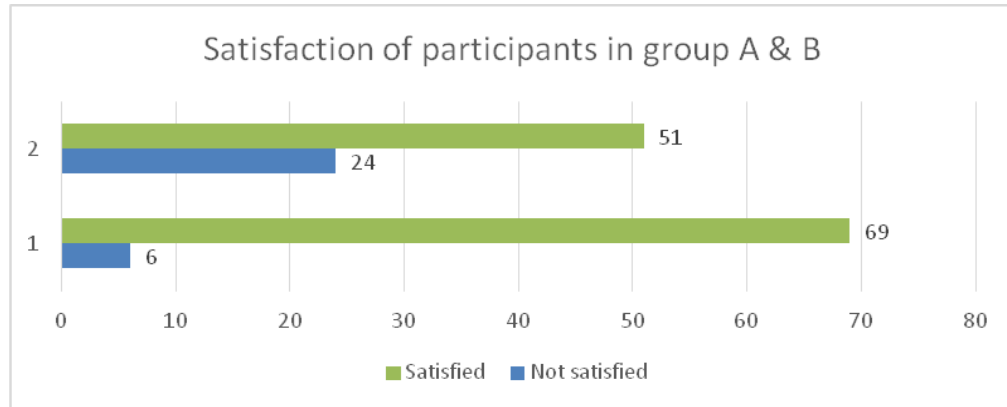
Upon categorization of participants within group A (DJ stent group) and group B (Non-DJ stent group), data indicated mean age of 27.9 ± 4.9 & 26.4 ± 5.5 in group A & B respectively with a p-value of > 0.05 , stone size was almost similar to avoid any confounding factor with a mean value of 1.24 ± 0.2 in group A and 1.6 ± 0.1 in group B, with a p-value of 0.05. The endpoint of this study was to assess the effect of DJ stent on stone-free rates after ESWL, the results of our study showed no significant difference in stone clearance within both groups, 11 (7.3%) participants of group A had particle clearance while 10(6.6%) of group B participants showed partial clearance. Table 2.

Table 2: Demographic, stone and ESWL details sorted in Group A and Group B.

Variables		Group A	Group B	P-Value
Age (Mean \pm St.Dev)		27.9 ± 4.9	26.4 ± 5.5	0.01
Weight (Mean \pm St.Dev)		59.7 ± 8.9	59.7 ± 8.5	0.04
Stone size (Mean \pm St.Dev)		1.24 ± 0.2	1.6 ± 0.1	0.05
Hounsfield units (Mean \pm St.Dev)		1067.5 ± 37.5	1055.3 ± 37.0	0.03
Sessions of ESWL (Mean \pm St.Dev)		2.7 ± 0.4	2.5 ± 0.5	0.02
Shockwave (Mean \pm St. Deviation)		5388.3 ± 1956.3	4750.7 ± 1791.8	0.07
Gender	Male	39 (26%)	43 (28.6%)	< 0.05
	Female	36 (24%)	32 (21.3%)	
BMI	Underweight	0	6 (4%)	0.31
	Normal weight	64 (42.6%)	60 (40%)	
	Over weight	11 (7.3%)	9 (6%)	
Stone location	Pelvis	55 (36.6%)	42 (28%)	0.36
	Mid calyx	8 (5.3%)	15 (10%)	
	Lower calyx	12 (8%)	18 (12%)	
ESWL Sessions	2 sessions	28 (18.6%)	16 (10.6%)	0.01
	3 sessions	35 (23.3%)	58 (38.6%)	
Clearance	Partial	11 (7.3%)	10 (6.6%)	0.9
	Complete	64 (42.6%)	65 (43.3%)	

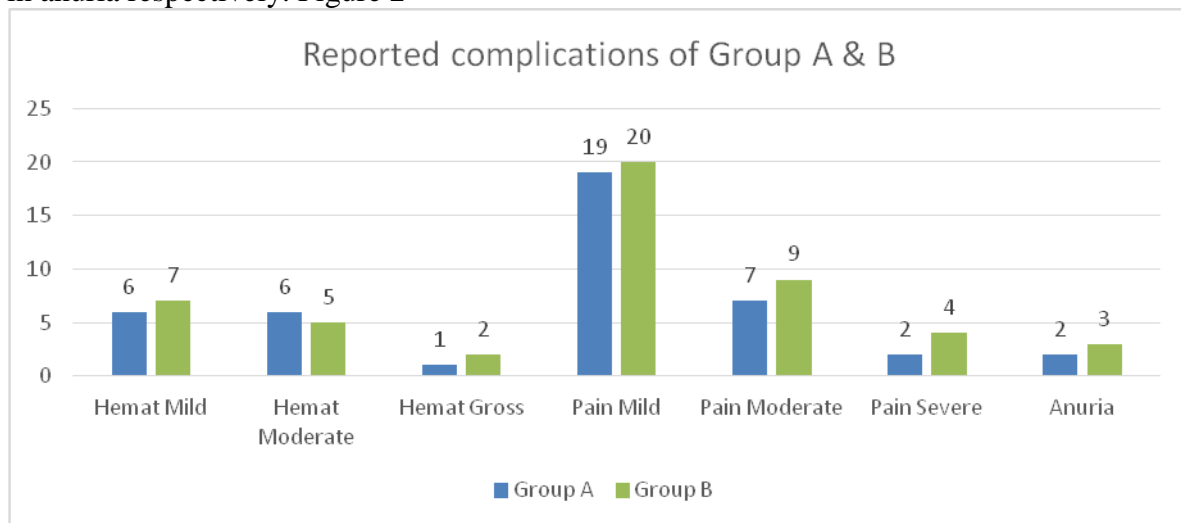
Participants of both groups were asked if they were satisfied with the treatment they received, Group A participants were mostly satisfied with 69 (46%) while only 6(4%) indicated that they were not satisfied with the treatment. Group B participants showed different results and 51(34%) indicated satisfaction with treatment and 24(16%) were not satisfied with treatment. Figure 1





To explore the reason for different satisfaction results between both groups post-procedure complications were evaluated and results indicated higher complications in group B(non-DJ group) as compared to group A (DJ group)

Hematuria was categorized within mild 6(4%) & 7(4.6%), moderate 6(4%) & 5(3.3%) while gross hematuria was reported in 1(0.6%) & 2(1.3%) in group A and B respectively. Post-operative pain was also categorized in VAS pain score within mild moderate and severe categories, results were slightly elevated in group B participants with mild, moderate, and severe post-operative pain in 20(13.3%), 9(6%) and 4 (2.6%) as compared to group A participants with 19(12.6%), 7(4.6%) and 2(1.3%) respectively. Anuria was mentioned by 2(1.3%) in Group A and 3(2%) in Group B respectively. The significance of data was measured as 0.04 in hematuria, 0.05 in pain, and 0.01 in anuria respectively. Figure 2



Discussion:

Our sample size consists of 150 subjects divided into two subgroups with or without Double J stent placement, all the participants were subjected to extracorporeal shockwave lithotripsy for their single renal radio-opaque stone less than 2 cm in size. ESWL is an old and well-known non-invasive management option for renal and ureteric stones. The use of advanced lithotripters with better preoperative evaluation and complimentary testing is allowing better stone-free rates in fewer sessions. The use of stents has always been debatable when it comes to ESWL. The main purpose is to prevent any obstructive complications that may occur due to passing fragments and in the long run can also cause strictures and need for secondary sessions or operative intervention [17]. There are limited studies when it comes to the method of DJ stenting after shockwave lithotripsy. The majority of studies focus on stenting before the treatment. R study the stenting is done in the same setting as lithotripsy [18]. A study by Abdullah Ahmed focused on pre-stenting before ESWL and concluded that the use of Double J stent before ESWL is not beneficial in any



way. There was not a much-documented difference in the stented vs non-stented group in terms of the stone-free rate as well (88 vs 91%) [19].

In another study by Mudassir et al, they considered stones in the proximal ureter for ESWL. They compared two groups of stented and non-stented patients and came to the significant conclusion that stone clearance after three months was higher in non-stented patients [18]. In a meta-analysis, eight Randomized control trials were compared and the conclusion was against stenting in terms of not preventing stricture formation as well as the stent predisposing the patient to bothersome lower tract symptoms [19]. The study was specific to proximal ureteric calculi. Ahmed al Asmmy in 2006, reported about obstructing renal calculi. The participants had moderate to severe obstructive uropathy secondary to stone and hence were given ESWL with and without stenting. The stented participants did not have any beneficial effect over the non-stented ones in terms of stone clearance [20]. A meta-analysis compared 22 Randomized Control Trials. The conclusion again resulted against stenting in terms of stone-free rates but provided evidence that stenting reduced post-operative emergency hospitalizations [21]. Ghoneim IA also concluded no additional benefit of stenting over not stenting in patients receiving ESWL for solitary upper ureteric stones less than 2cm. although, again, significant patient discomfort and morbidity were associated with an indwelling ureteral stent [22]. One of the randomized trials in 1990, did compare the efficacy of pre-stenting for renal stones targeted by ESWL. It was done by Alexander F. Bierkens et al and their target stone burden was more than 2 cm. The stent placed was of 6 Ch size. The results were in favor of treating these patients with in situ ESWL without pre-stenting [23]. The effects and morbidity associated with indwelling stents are also influenced by the size and composition of the stent [24]. The stent however not only causes discomfort but has significant effects on a patient's quality of life. The stent alters daily activities, sexual life, and miscellaneous parts of life. These are better quantified and assessed by a standard ureteral stent symptom questionnaire and are therefore a routine concern for urologists. Dj stents have been used routinely for over 20 years in urology practice. They are made of either polyurethane or Silicon and are available in different sizes and lengths. They also are manufactured in medicated forms for long-term insertions.

These medicated stents prevent the formation of bacterial biofilms over the stent thereby continuing the urinary flow with reduced risk of septic complications. The stent is still a foreign body with the upper coil in the renal pelvis and the lower coil in the bladder. It, therefore, can cause significant adverse effects. The stent can cause pain, hematuria, and strangury due to direct physical irritation to the ureteral or vesical mucosa[23]. Also, the contracting bladder during voiding can cause severe strangury when the bladder walls touch the distal coil. Dehydration and constipation can augment the Dj-related symptoms but are easily preventable. The stent can also migrate upwards with a distal coil landing in the ureter or it can be dislodged into the bladder. Upward migration makes it difficult to remove it transurethrally and sometimes needs percutaneous evacuation or reinsertion of a new stent. In quick stone formers, or with forgotten stents, the stents can get encrusted and requires lithoclast to get cleared of stone fragments before it is removed [19]. The stent is a potential source of infection, and a blocked stent can further cause more disturbance in a patient's management. Many patients present with culture-positive urinary tract infections which are difficult to eradicate as the bacteria reside on the stent and therefore require prompt stent removal to completely cure the infection. In rare instances, the stent can also get fragmented during removal or in long-term stenting and may require combined endoscopic and percutaneous approaches to completely remove the pieces [25]. Another patient-related complication or complication arising from lack of counseling is a forgotten stent. Forgotten stents have landed in emergencies and outpatient departments with disastrous effects and have also included emphysematous pyelonephritis as one of the main presentations [26]. Moreover, bothersome lower urinary tract symptoms are most encountered and are managed with alpha-blockers, anti-cholinergic, or their combination [27]. Keeping such complications in mind



and the need for a stone-free rate in minimal sessions, the decision of stenting with ESWL is difficult. The majority of the studies did not support stenting but this may contradict the clinical practices of countries with huge stone burden and fewer resources, where multiple re-admissions or quick access to the hospitals are not easy[28].

Conclusion

This study concluded that using a DJ stent with ESWL does not help in the stone passage or improve stone-free rates of stone removal after breaking the calculi with shockwave lithotripsy.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

ERC approval was taken from IRC LUMHS.

HUMAN AND ANIMAL RIGHTS

No animals were used in this study. The study on humans was conducted in accordance with the ethical rules of the Helsinki Declaration and Good Clinical Practice.

CONSENT FOR PUBLICATION

Informed consent was signed by patients.

AVAILABILITY OF DATA AND MATERIALS

None.

FUNDING

None.

CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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