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ORIGINAL ARTICLE

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Percutaneous nephrostomy tube versus double J ureteric stent for the management of non-septic calcular anuria in adults: Prospective randomized study

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ABSTRACT

Objective: To compare the use of JJ and PCN tubes as initial urinary drainage methods in patients with obstructive calcular anuria.

Methods: Between January 2021 and January 2024, 239 eligible patients with obstructive calcular anuria were randomly classified into two groups. Group A (JJ group) included 121 patients and group B (PCN group) included 118 patients. Laboratory data, stone characteristics, and intraoperative and postoperative data were also collected. The time needed to normalize the serum creatinine levels, postoperative complications, and quality of life scores were assessed.

Results: The procedures had comparable success rates (86.8% vs. 90.7%; $p = 0.9$). The PCN group had a shorter operative time ($p < 0.001$). No significant differences were observed in the time required for serum creatinine to return to normal between the two groups ($p = 0.669$). Fever, haematuria, and LUTS were more evident in the JJ stent group. In the JJ group, the presence of upper ureteral stones and stone burden were risk factors for procedure failure, whereas the presence of upper ureteral stones and preoperative serum creatinine were risk factors for ureteral perforation. Mild hydronephrosis was a risk factor for procedural failure in the PCN group. Spontaneous stone passage was more common in the PCN group ($p = 0.028$). The Overall quality of life and general health scores were significantly better in the PCN group ($p < 0.001$).

Conclusions: Both PCN and JJ stents had comparable success rates. PCN was associated with a lower incidence of LUTS, higher incidence of spontaneous stone passage, and better quality of life scores than the JJ stent.

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Percutaneous nephrostomy; JJ ureteric stent; calcular anuria; calcular acute kidney injury

Introduction

Egypt is part of the stone-forming belt region [1]. There is a high incidence of calcular anuria in Egypt owing to the elevated prevalence of stones [2–4]. Anuria is defined as a urine excretion of less than 100 ml in 24 h, either due to bilateral upper urinary tract obstruction or unilateral obstruction in a solitary functioning kidney. Such conditions necessitate early diagnosis and urgent management to avoid serious sequelae [5]. Acute kidney injury (AKI) is a serious problem associated with increased morbidity and mortality, particularly in developing nations [6].

Urgent urinary drainage is mandatory in patients with calcular obstructive anuria. This was performed with either a percutaneous nephrostomy tube (PCN) or retrograde ureteric stenting. This has led to a controversy about which PCN or JJ stents are better for upper urinary tract drainage. Multiple studies have focused on situations where infection was the primary reason for drainage; others were designed to select patients for either a PCN or a JJ stent, with few studies being randomized [7].

The best technique for draining the upper urinary tract remains a controversial issue, and few randomized studies have been carried out on this subject, but high-quality data are still lacking, and no definite guidelines regarding the proper procedure for drainage have been established [8,9]. The efficiency, morbidity, and complications of both procedures have been studied in multiple studies on the management of obstructive uropathy. PCN and JJ stents have advantages and disadvantages regarding cost, QOL, complications, and further management, and both are recommended by the European Association of Urology (EAU) guidelines for proper decompression [10,11].

The current randomized study was designed to compare the PCN tube with the JJ ureteric stent as an initial urinary drainage technique in patients with obstructive calcular anuria, and to evaluate the safety and the possible complications of both procedures.

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Patients and methods

This prospective randomized study was conducted on patients who visited our clinics with obstructive calcular anuria and fulfilled the inclusion criteria between January 2021 and January 2024. This study was approved by the institutional ethics committee (approval code: SVU-MED-URO0016-4-23-3-594). Written informed consent was obtained from each participant.

Inclusion criteria

The study included adult patients (≥18 years) with acute calcular anuria due to ureteral or renal stones, with a serum creatinine (sCr) level higher than 2 mg/dL, and a negative urine culture at the time of drainage.

Exclusion criteria

Patients with age <18 years, active urinary tract infection with fever (>38°C), leukocytosis, pyonephrosis, positive urine culture at the time of initial drainage, coagulopathy, urinary diversion, urinary tract malignancies, incomplete recovery (postoperative serum creatinine persisted more than 1.5 mg/dl), unstable patients who were candidates for dialysis, and pregnant females were excluded.

Intervention

All patients underwent complete medical history taking, clinical assessment, CBC, coagulation profile, serum creatinine, sodium, and potassium; abdominal ultrasound to assess the kidneys and the extent of obstruction (according to methodology employed by the Society for Foetal Urology) and non-contrast enhanced CT to evaluate the positions, volumes using an ellipsoid formula (stone volume = length × width × depth × π × 0.167), and densities of the stones. Under spinal anaesthesia, a rigid 22-Fr cystoscope (Karl Storz, Germany) was used to insert a polyurethane 6-Fr JJ stent in the lithotomy position in group A patients (JJ group). A 10-Fr PCN tube was inserted in the prone position under local anaesthesia (1% lidocaine) in group B (the PCN group), both procedures were guided by fluoroscopy. A urine sample was obtained for culturing at the time of drainage. Ceftriaxone (1 gm) was administered to all the patients before the intervention. The site of the better kidney (according to renal parenchymal thickness, echogenicity, and the degree of obstruction) was chosen for intervention.

Intraoperative data, including the operative time, fluoroscopy time, procedure failure, conversion to other procedures, stone migration, and occurrence of any intraoperative complications, were recorded.

Postoperative assessment, including daily measurement of serum creatinine until it became normal (<1.5 mg/dL) and the time needed for its normalization, calculation of urine output until the time of discharge, assessment of the postoperative complications such as fever, septicemia (hypotension, palpitation, etc.), significant haematuria (defined as haematuria necessitating blood transfusion or associated with haemodynamic instability or persisting for more than 48 hours), PCN slippage or JJ migration, loin or suprapubic pain (using a visual analog scale), LUTS (as increased frequency [>8/day], dysuria, urgency, etc.), and recording spontaneous stone passage were carried out.

Quality of life was evaluated for all patients using the overall QOL and general health domains of the WHO quality of life scale by asking the patients how they rated their quality of life and how satisfied they were with their health, and each question had a score of 1 (very dissatisfied), 2 (dissatisfied), 3 (neither satisfied nor dissatisfied), 4 (satisfied), and 5 (very satisfied) [12]. Abdominal US was repeated to ensure renal decompression, and another urine sample was collected for culture before definitive stone management (DSM).

The definitive management of renal stones was extracorporeal shock wave lithotripsy (ESWL) for stones ≤2 cm and percutaneous nephrolithotomy (PNL) for stones >2 cm (using laser or pneumatic disintegration). Proximal ureteral stones were treated by ureteroscopy (with laser disintegration) or ESWL for stones <1 cm, and by PNL or ureteroscopy (with laser disintegration) for stones >1 cm (depending on the position of the stones in the upper ureter). All middle- and lower-third ureteral stones were treated using ureteroscopy (with laser or pneumatic disintegration). Simultaneous bilateral interventions were performed in cases of bilateral ureteroscopy or ureteroscopy for one side with contralateral PNL.

Outcomes

The outcomes of the current study were classified into primary outcomes, including the time needed for normalization of serum creatinine, secondary outcomes, including both operative and fluoroscopy data, and tertiary outcomes, including safety and complications of both procedures, with analysis of the factors predicting procedure failure and the complications of both techniques.

Sample size

Sample size calculation was performed using G*Power 3.1.9.2 (Universitat Kiel, Germany), and the time needed for normalization of serum creatinine (the primary outcome) to detect variation between the two

groups (based on the previous studies) [7,13–16]. A standard deviation of 1.5 days was used for sample size calculation. The Cohen's d effect size was estimated to be approximately 0.4. Therefore, with an alpha of 0.05, using the ANOVA test, the enrollment of a total of 105 patients in each group will provide 90% power. The sample size was increased to compensate for any attrition bias.

Randomization

Random allocation of the cases into two groups was performed using a block randomization method in Stata, version 13.1, Stata Corp, for Microsoft Windows): group A (JJ group) and group B (PCN group).

Statistical analysis

Statistical analysis was performed using SPSS version 25 (IBM Corp., Armonk, NY, USA). Frequencies and percentages (n [%]) were used to convey qualitative data. Shapiro-Kolmogorov tests were used to examine the data for normality, and the median and interquartile range (IQR) were used to represent quantitative data. Qualitative data were compared using the Chi-squared (x^2) test, and quantitative data were compared using the Mann-Whitney U test (as the data were not normally distributed). Multivariate logistic regression analysis was used to determine the variables that influenced the outcomes in both groups. p values were considered statistically significant at $p < 0.05$.

Results

In this study, 301 patients were evaluated for eligibility. After exclusions, 239 patients were included. They were allocated into two groups: group A (JJ group) included 121 patients (50.6%), and group B (PCN group) included 118 patients (49.4%). (Figure 1)

The demographic data of the patients were evaluated and revealed no statistically significant differences between the groups regarding the baseline data (Table 1).

Group A included 36 patients (29.8%), and group B included 37 patients (31.4%) who had a solitary functioning kidney ($p = 0.79$). No statistically significant differences were observed between the two groups in the degree of hydronephrosis ($p = 0.63$). No statistically significant differences were observed between the two groups regarding the site, volume, or density of the stones at the site of intervention, (Table 2).

Regarding the postoperative serum creatinine and the postoperative urine output at 24, 48, 72, and 96 h follow up, we did not observe any statistically significant differences between the two groups, similar to

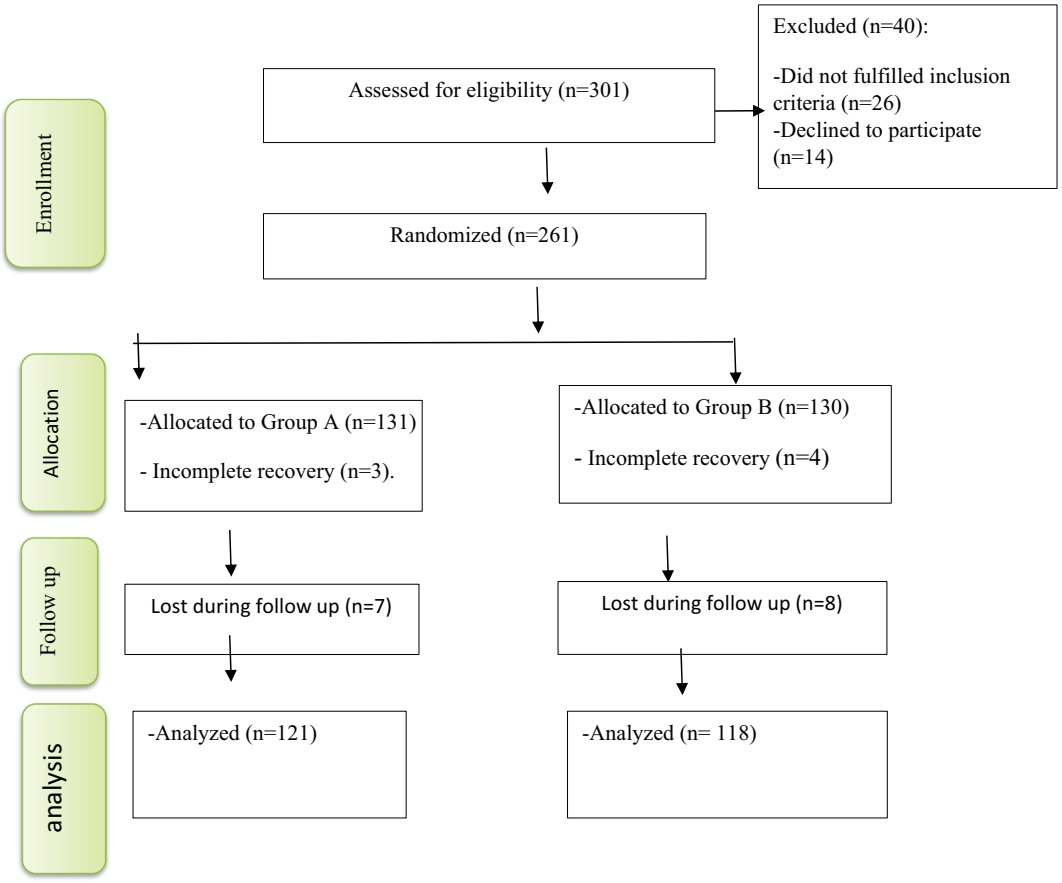

Figure 1. Consolidated standard of reporting trials (CONSORT) diagram for patients flow throughout the study.

Table 1. Comparisons between JJ and PCN groups regarding demographic and laboratory data.

Demographic data		JJ group (n = 121)		PCN group (n = 118)		P-value
Gender	Males	66	54.5%	70	59.3%	0.4
	Females	55	45.5%	48	40.7%	
Age (years)		48 (43 – 55)		52 (46 – 55)		0.05
BMI (kg/m^2)		26 (25 – 27)		25 (25 – 26)		0.07
	Diabetes	23	19%	18	15.3%	0.4
	Hypertension	18	14.9%	27	23.1%	0.1
Duration of anuria (days)		1.5 (1.5 – 2)		1.5 (1.5 – 2)		0.9
HB		12.2 (11.2 – 13.8)		12.3 (11.2 – 14.2)		0.3
Platelets		207 (190 – 224)		206 (198 – 230)		0.4
WBCs		8.4 (8 – 8.8)		8.4 (8 – 8.7)		0.8
Prothrombin Conc. (%)		90 (87 – 92)		90 (87 – 94)		0.4
RBS		107 (100 – 120)		109 (100 – 119)		0.9
Creatinine		6.1 (5.2 – 6.7)		6 (5.2 – 6.6)		0.8
K		4.7 (4.4 – 5)		4.7 (4.3 – 4.9)		0.4
Na		137 (136 – 138)		137 (136 – 138)		0.9

Table 2. Comparisons between JJ and PCN groups regarding the imaging data.

		JJ group (*n* = 121)		PCN group (*n* = 118)		P-value
Solitary Kidney		36	29.8%	37	31.4%	0.7
Grade of HN	Grade II	96	79.3%	92	78%	0.6
	Grade III	25	20.7%	26	22%	
Site of stone	Pelvis	22	18.1%	25	12.1%	
	Ureteropelvic junction	24	19.8%	27	22.9%	
	Upper ureter	20	17.3%	19	15.2%	0.9
	Middle ureter	26	21.4%	22	18.6%	
	Lower ureter	29	23.9%	25	21.1%	
Stone volume in intervention site (mm^3.)		1334 (946 – 1660)		1326 (938 – 1639)		0.9
Stone density in intervention site (HU)		880 (680 – 1030)		893 (720 – 1000)		0.8

-Chi-squared test (X^2) was used to compare the qualitative variables and Mann-Whitney U test to compare the quantitative parameters.
-HN: hydronephrosis.
-HU: Hounsenfield unit.

that observed with regard to the time needed for normalization of the serum creatinine [3 (2–3) days in the JJ group vs. 3 (2–3) days in the PCN group, $p = 0.669$] (Table 3).

Operative time was prolonged in the JJ group [37 (35–39 min.) vs. 23 (20–25 min.) in the PCN group, $p = < 0.001$], which could be explained by the additional time required for anaesthesia in the JJ group. Fluoroscopy time was longer in the PCN group [60 (56–66 s) vs. 39 (36–42 s) in JJ group $p < 0.001$]. Failure of the procedure with conversion to the other was encountered in 16 (13.2%) patients in JJ group and 11 (9.3%) cases in PCN group, without statistically significant differences between the groups ($p = 0.98$). Ureteral perforation occurred in nine (7%) patients in JJ group, and renal pelvis perforation occurred in four (3.4%) in PCN group (Table 4).

Overall quality of life scores and general health scores were significantly better in the PCN group [4 (3–4) vs. 3 (3–3), $p < 0.001$] and [4 (3–4) vs. 3 (3–3), $p < 0.001$], respectively. Statistically significant differences were observed between both groups regarding the occurrence of postoperative fever [47 (38.8%) in JJ group vs. 15 (12.7%) in PCN group, p <0.001], significant postoperative haematuria [39 (32.3%) in JJ group vs. 22 (18.6%) in PCN group, p = 0.016], LUTS [102 (84.3%) in JJ group vs. 9 (7.6%) in PCN group, p < 0.001], loin pain [87 (71.9%) in JJ groupvs. 37 (31.4%)

Table 3. Comparisons between JJ and PCN groups regarding post-operative creatinine and urine output.

	JJ group (*n* = 121)	PCN group (*n* = 118)	P-value
24 hours creatinine	3.2 (2.5 –3.8)	3.1 (2.5 –3.8)	0.7
48 hours creatinine	1.8 (1.4 –2.2)	1.8 (1.4 –2.1)	0.8
72 hours creatinine	1.4 (1.2 –1.5)	1.4 (1.3 –1.4)	0.9
96 hours creatinine	1.3 (1.2 –1.4)	1.3 (1.2 –1.4)	0.8
Time for creatinine normalization (days)	3 (2 –3)	3 (2 –3)	0.6
24 hours urine output (ml)	5200 (4500 –5650)	4950 (4450 –5463)	0.3
48 hours urine output (ml)	8400 (7875 –9150)	8400 (7838 –9000)	0.8
72 hours urine output (ml)	11550 (11200 12,400)	11600 (11150 12,313)	0.7
96 hours urine output (ml)	15000 (14450 15,675)	15150 (14488 15,500)	0.8

Mann Whitney U test was used to compare the variables.

Table 4. Comparisons between JJ and PCN groups regarding the intraoperative data, post-operative complications and spontaneous stone passage.

	JJ group (n= 121)		PCN group (n= 118)		P-value
Operative time (min.)	37 (35 – 39)		23 (20 – 25)		< 0.001*
Fluoroscopy time (sec.)	39 (36 – 42)		60 (56 – 66)		< 0.001*
Procedure failure	16	13.2%	11	9.3%	0.09
Conversion to the other procedure	16	13.2%	11	9.3%	0.09
Ureteral perforation (JJ group)	9	7%			
Renal pelvis perforation (PCN group)			4	3.4%	
Postoperative fever	47	38.8%	15	12.7%	< 0.001*
Postoperative hematuria	39	32.3%	22	18.6%	0.016*
LUTS	102	84.3%	9	7.6%	< 0.001*
Loin pain	87	71.9%	37	31.4%	< 0.001*
Suprapubic pain	16	13.2%	2	1.7%	0.001*
Septicemia	3	2.5%	0	0.0%	0.08
Spontaneous stone passage	2	1.7%	9	7.6%	0.028*

in PCN group, p < 0.001], and suprapubic pain [16 (13.2% in JJ group vs. 2 (1.7%) in PCN group, p < 0.001]. Postoperative septicemia occurred in three patients (2.5%) in the JJ group but it was not encountered in PCN group. Spontaneous stone passage occurred in two cases (1.7%) in JJ group and nine (7.6%) patients in PCN group, with statistically significant differences (p = 0.028) (Table 4). PCN slippage was encountered in 8 patients and was reinserted again, while JJ slippage or migration was not encountered in this study. Multivariate logistic regression analysis revealed that in JJ group, the presence of upper ureteric stones (OR = 22.431, p < 0.001; 95% CI = 5.766-87.2) and stone burden (OR = 1.151, p = 0.011; 95% CI = 1.033-1.283) were the risk factors for procedure failure, while the preoperative serum creatinine (OR = 2.19, p = 0.032; 95% CI = 1.070- 4.476) and the presence of upper ureteric stones(OR = 60, p < 0.001; 95% CI = 7.33- 491) were the risk factors for ureteral perforation. In PCN 7 group, it was found that the grade of hydronephrosis was the risk factor for procedure failure (OR = 3.197, p = 0.023; 95% CI = 1.171- 8.734). No statistically significant differences were observed between the two groups regarding the method used for definitive stone management. Positive urine cultures at the time of DSM were more evident in JJ group (33.8% vs. 16.9%, p= 0.003) (Table 5).

Discussion

Obstructive Anuria is a urological emergency, and if not properly managed, it may be a fatal condition. Urgent renal decompression is crucial to avoid serious sequelae before definitive stone management [10]. Double- J ureteral stent and PCN tube insertion are the most commonly applied approaches for urinary drainage; both are accompanied by diverse success rates, complications, and QOL issues. Clear guidelines concerning the proper method for urinary diversion have not been established, and the decision regarding the method of urinary diversion is usually individualized [17]. A significant difference existed between the European and the American schools regarding this issue, as the European school recommends PCN for urgent decompression in septic patients with renal obstruction, while the American school found that PCN showed higher rates of sepsis, prolonged length of hospital stay, higher cost, and higher rates of mortality than retrograde ureteral stenting [18,19].

Regarding the comparison between the JJ stent and PCN as the primary drainage procedures in adults, few prospective randomized trials exist, and most of them were carried out on a small number of cases and focused mainly on drainage of infected hydronephrosis [13,14,17,20].

Operative time was significantly increased in the JJ group. This was explained by the additional time

		JJ group (n = 121)		PCN group (n = 118)		P-value
URS (single intervention)		25	20.6%	20	16.9%	0.4
Bil. URS (same session)		42	34.7%	32	27.1%	0.2
URS+ PNL (Same session)		26	21.4%	33	27.9%	0.2
URS + PNL (Two interventions)		1	0.8%	0	0.0%	0.3
URS and ESWL (two interventions)		2	1.6%	0	0.0%	0.1
PNL (single intervention)		15	12.3%	17	14.4%	0.6
BIL PNL (Two interventions)		9	7.4%	12	10.1%	0.4
PNL and ESWL (two interventions)		1	0.8%	1	0.7%	0.9
Nothing (stone passed)		0	0.0%	3	2.5%	0.07
Urine culture at the time of DSM	Positive	41	33.8%	20	16.9%	0.003*
	Negative	80	66.2%	98	83.1%	

required for spinal anaesthesia in this group, which is in accordance with Elbatamony et al. [14]. Fluoroscopy time showed a significant increase in the PCN group, which was in accordance with the findings of Pearle et al. [20]. In contrast, Mokhmalji et al. noticed that the fluoroscopy time was longer in the JJ group [13].

Double J insertion was successful in 105/121 patients (86.8%), whereas PCN insertion was successful in 107/118 patients (90.7%), with no statistically significant difference ($p = 0.098$). Ureteral perforation occurred in 9 (7%) patients. Multivariate logistic regression analysis revealed that the presence of upper ureteric stones and stone burden were risk factors for procedure failure, whereas preoperative serum creatinine level and the presence of upper ureteric stones were risk factors for ureteral perforation. This is in accordance with the results of Yossepow-itch et al. Varda et al. Savic et al. and Rajadoss et al. [21–24].

In PCN group, failed PCN insertion occurred in 11 (9.3%) patients, renal pelvis perforation in 4 (3.4%) patients. Multivariate logistic regression analysis revealed that the grade of hydronephrosis was a risk factor for procedure failure. This is in accordance with the findings of Mokhmalji et al. and Sommer et al. [13,25].

No statistically significant difference was observed in the time needed for the normalization of sCr [3 (2–3) vs 3 (2–3) days, $p = 0.669$]. Weltings et al. Mokhmalji et al. Mittal et al. and Harraz et al. reported similar results [7,13,15,16].

Postoperative fever, LUTS, loin pain, and suprapubic pain were more obvious in the JJ group than in the PCN group. In general, PCN was more tolerated than JJ in the early postoperative period. This is in accordance with the findings of Elbatamony et al. and Morais et al. [14,26]. Fever was of low grade in most cases and was managed with the usual antipyretics. In the JJ group, significant haematuria was detected in 32.3% of cases, whereas in the PCN group, it was observed in 18.6% of cases with statistically significant difference ($p = 0.016$). It was treated with fluids and haemostatic medications without the need for blood transfusions, and all patients presented with significant haematuria were haemodynamically stable, and which was consistent with the findings of Firas et al. who reported that 37% of the JJ stent group and 11% of the PCN group had haematuria. Elbatamony et al. found that compared to 14% in the PCN group, 25% of patients in the JJ stent group had haematuria [14,27].

Septicaemia occurred in three patients (2.5%) in JJ group but not encountered in PCN group. These patients were admitted to the ICU and managed through the usual measures without long-term sequelae. Firas et al. demonstrated an elevated rate of sepsis in the JJ stent cohort compared with PCN group (20% vs. 5%) [27]. In contrast, Harraz et al. reported that the occurrence of septicaemia was more frequent in the PCN cases (11.5% vs. 7.5%) [16].

In the PCN group, spontaneous stone passage occurred more frequently (7.6% vs. 1.7%, $p = 0.028$). This was consistent with the findings of Elbatamony et al. who found that spontaneous stone passing occurred in 4 cases (5.6%) in the PCN group and in 1 case (1.4%) in the JJ group [14]. Furthermore, Morais et al. found that when PCN and JJ stents were adjusted based on the size and location of the stone, there was a higher incidence of spontaneous stone passage with PCN [26].

No statistically significant differences were observed between the two groups regarding the method used for definitive stone management, but the presence of JJ facilitated subsequent URS due to ureteral dilation, and the presence of PCN facilitated subsequent PNL as the track of the PCN was utilized for PNL. This was in accordance with the findings of Bozkurt et al. and Wang et al. [28,29].

We found that post-procedure positive urine culture was more frequent in the JJ stent group (33.8%) compared to the PCN cases (16.9%), with statistically significant differences ($p = 0.003$). This finding is comparable to those of Dinic et al. and Elbatamony et al. [14,30]. In contrast, Pearle et al. documented an increased number of positive urine cultures after PCN compared with following-JJ stents [20].

The QOL scores were better in the PCN group with a statistically significant difference between the two groups with regard to the overall QOL and general health domains of the WHO quality of life scale [4 (3–4) vs. 3 (3–3), $p = < 0.001$ and 4 (3–4) vs. 3 (3–3), $p = < 0.001$]. This was in accordance with Morais et al. who found a significant reduction in pre- and post intervention QOL in cases with JJ ($p < 0.001$), but not in cases with PCN ($p = 0.206$) [31]. Mokhmalgi et al. assessed the QOL of patients subjected to diversion and concluded that the JJ stent may negatively affect the QOL in comparison with PCN [13].

The current study had several limitations, including the exclusion of patients with active infection, lack of assessment of the cost of both procedures, and the fact that we did not use the ultrasonic- guided technique for PCN insertion.

Conclusions

Both PCN and JJ have nearly similar success rates in cases with obstructive urolithiasis, and in general, the complications of both procedures rarely occur. PCN has a shorter operative time in addition to a reduced incidence of post-operative urinary tract infection with better QOL scores. Conversely, patients with JJ stents had worse quality of life (QOL) scores and more LUTS.

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Ahmed Mahmoud Hasan: Concept, protocol, data collection, manuscript writing

Ahmed Mamdouh Abdelhamid: data collection, manuscript editing

Mostafa Abdelrazek: data collection

Ahmed Mahmoud Reyad: data collection, data analysis

Informed consent statement

Informed consent was obtained from all the participants involved in the study.

Institutional review board statement

Institutional ethics committee approval: SVU-MED-URO0016-4-23-3-594

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