



African Journal of Biological Sciences

Journal homepage: <http://www.afjbs.com>



Research Paper

Open Access

Increased Risk of Urosepsis in Patients Undergoing DJ Stent than PCN for Obstructed Infected Kidney: A Randomized Controlled Trial

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Article History
Volume 6, Issue 7, 2024
Received: 13 Feb 2024
Accepted: 29 Mar 2024
doi: 10.33472/AFJBS.6.7.2024.65-75

Abstract

Background and Objective: With the growing clinical implications of urosepsis in obstructed infected kidneys, this study aimed to evaluate the comparative risk between patients undergoing percutaneous nephrostomy (PCN) and those receiving a double-J (DJ) stent.

Patients and Methods: A prospectively randomized comparative study was designed to compare the outcomes of patients receiving a PCN (Group A) or a DJ (Group B) for acute obstructive pyelonephritis, with our main objective the time needed to normalization of the body temperature and the incidence of urosepsis between April 2018 and August 2020 in our institution. Statistical analyses were performed utilizing SPSS 24.

Results: Of the 155 patients assessed, nine declined to participate, six had DJ procedural failure, 70 patients in Group A, and 69 in Group B because one patient lost follow-up. Group B had a significantly longer time to normalization of the body temperature post-procedure when compared to Group A (24 vs 6 hrs, $p < 0.001$), Group B was associated with higher rates of positive post-procedure urine cultures (71% vs 14.3%, $p < 0.001$) and higher C-reactive protein levels. Urosepsis incidence was significantly higher in Group B (65.2% vs. 5.7%, $p < 0.001$). Group A patients had earlier definitive treatment (median 2 vs 4 weeks, $p < 0.001$).

Conclusions: DJ stent placement for obstructed infected kidneys was associated with delayed time to normalization of the body temperature, increased risk of persistent infection, and higher rates of urosepsis when compared to PCN. The time to definitive stone treatment was shorter in the PCN group.

Keywords: Urosepsis, Percutaneous nephrostomy tube (PCN), Double-J stent, Obstructed kidney

INTRODUCTION

Urosepsis is a potentially life-threatening condition that poses a challenge when managing patients with obstructed infected kidneys [1]. The choice between using a Double J (DJ) ureteric stent or undergoing nephrostomy (PCN) is crucial in determining these patients' outcomes. Both procedures aim to relieve obstruction and promote urinary drainage, but there has been an ongoing debate among clinicians regarding their respective risks of urosepsis [2].

Risk factors for sepsis following PCN and DJ have been previously studied in the literature as Firas et al. had reported a higher incidence of septicemia 20% in the JJ stent group versus 5% in the PCN group.[3] the risk factors include preoperative urinary tract infection, preoperative increased blood glucose level, positive urine culture, and infectious stones nature [4]. Another study evaluated the efficacy of ureteral stents with different diameters to drain pus that accumulates in an obstructed kidney using an in vitro model [5]. Prior studies compared the utilization of percutaneous nephrostomy versus double J ureteral stenting in the management of infective hydronephrosis in calculi disease without any significant differences in the efficacy of relieving obstruction/symptoms [6-9]. Typically, the choice of a particular procedure depends on the site of the stone and the degree of proximal obstruction [10].

To our knowledge, there was no direct comparison between stents and PCN investigated regarding the postoperative risk of urosepsis in obstructed infected kidneys.

In the current study, our primary objective was to investigate the time needed for normalization of the body temperature and the incidence of urosepsis in patients who undergo DJ stent versus PCN for obstructed infected kidneys. By understanding the potential consequences of each intervention, we aim to equip healthcare professionals with solid grounds for making informed decisions regarding treatment options and improving patient care.

MATERIALS AND METHODS

A prospective randomized comparative study was conducted between April 2018 and June 2020. The study protocol was designed and approved by the Ethical Committee of our institution (IRB: 17200199). Registration on ClinicaTrials.gov was performed under NCT03498794. All participants provided written consent after being thoroughly informed about the study procedures in compliance with the Declaration of Helsinki's guidelines. A senior statistician validated the data and the adherence to the study protocol.

Study eligibility required adult Patients who presented with acute obstructive pyelonephritis (fever, tenderness, and increased white blood count) due to upper urinary tract stones. Patients with advanced hydronephrosis (thin renal parenchymal thickness), those with ureteric stones greater than 15 mm, or those having Steinstrasse were excluded as they are ideal candidates for PCN with no role for DJ stents. Also, patients with uncontrolled coagulopathy or those who are unfit for anesthesia were excluded from the current study.

The eligible patients were randomized to receive a PCN (Group A) or a DJ stent (Group B) using the Sequentially Numbered, Opaque, Sealed Envelope (SNOSE) technique, as outlined by Doig and Simpson, employing permuted, unstratified blocks of two distinct sizes (four and six). The personnel who were responsible for generating the envelopes did not participate further in the clinical trial and did not have any communication with the surgeons or researchers regarding the allocation process. The surgical team was made aware of the procedure at the time of surgery.

Pre-operative assessments and PCN or DJ stent insertion followed the standard of care protocols. Urine cultures were collected from the patients in the operative theater from the obstructed kidney. Fluoroscopy time recorded. Patients received Intravenous third-generation cephalosporins then a culture-specific antibiotic thereafter,

Our primary outcome was set to the post-procedural time taken for body temperature to reach normal temperature and the rate of urosepsis. Secondary outcomes included operative time, fluoroscopy time, urine culture, insertion failure, vital signs, oxygen saturation, mental status, hospital stay, urine culture clearance, time to definitive stone treatment, and complications.

Follow-up at 2 weeks included urinalysis, urine culture with antibiotic re-treatment if positive, bloodwork,

abdominal ultrasound, and a KUB.

We used the quick sequential organ failure assessment (qSOFA) criteria to identify cases of urosepsis. To meet this criteria, at least two of the following conditions needed to be met; respiratory rate of 22/min or greater, altered mentation, or systolic blood pressure of 100 mmHg or less.[11] If these criteria were met, blood cultures were taken when necessary to confirm the presence of bacteraemia and diagnose urosepsis [12]. This method allowed us to diagnose urosepsis when there was both a tract infection and signs of inflammation while ruling out infections, from other parts of the body. Patients with septic shock can be clinically identified by a vasopressor requirement to maintain a mean arterial pressure of 65 mmHg or greater and serum lactate level greater than 2 mmol/L (>18 mg/dL) in the absence of hypovolemia.[11]

Sample Size Calculation was carried out using G*Power 3 software 8. A calculated minimum sample of 140 patients was needed and randomly assigned into one of two groups (group A PCN and group B ureteral stenting to detect the effect size of 0.32 days in the Time to normal temperature with an error probability of 0.05 and 80% power. This returned a sample size of 140 patients (70 in each group).[13]

Continuous variables were expressed as means and standard deviation (SD) or medians and interquartile ranges (IQR) as appropriate. Student's T test or Mann-Whitney U test were utilized to compare continuous variables, respectively. Categorical variables were presented as numbers and percentages and were compared statistically using chi-square or Fisher's exact tests as appropriate. P values less than 0.05 were considered statistically significant. Data analysis and management were performed using SPSS version 24.0.

RESULTS

One hundred and fifty-five patients were assessed for eligibility, nine declined to participate and six were DJ procedural failures, A total of 140 patients (70 in Group A and 69 in Group B) remained for the analysis. The CONSORT flowchart of the patients is shown in (Figure 1).

Patients in group B were slightly older (Median age of 50 years old) without statistically significant difference. The distribution of gender was similar in both groups. Procedure laterality, stones' location, and stone density were almost similar in the studied two groups. However, the notable disparities between the two groups were found in terms of the stone size, length, and width. Group A had stones with a median length of 1.2 cm and a median width of 1.0 cm, whereas group B had a median length of 1.00 cm and a median width of 0.80 cm ($p=0.011$ and $p=0.012$, respectively). Patients' demographics and baseline characteristics are shown in Table 1.

Preoperative positive urine cultures were similar in both groups. Patients in group A experienced a faster return to normal body temperature with a median time of 6 hours as compared to 24 hours in group B. Also, Group A had a slightly shorter median operative time of 12.00 minutes compared to 13.00 minutes (excluding the anesthesia time) in Group B (Table 2)

Two weeks postoperatively, only 14.3% of urine cultures from group A tested positive as compared to 71% in group B ($p<0.001$). Notably, levels of C reactive protein (CRP) were significantly lower in patients from group A (median of 9) than in group B (median of 15), $p=0.004$. Of note, PCN dislodgment or blockage occurred in 12 patients in group A (17%) (Table 2).

In terms of complications, 61% of Group B patients have experienced burning micturition as compared to none of Group A patients ($p<0.001$). urosepsis and ICU admission were encountered in 65% of Group B patients and only 5.7% of Group A patients ($p=0.001$) (Table 2).

Patients in Group A had a significantly shorter time to undergo definitive treatment with a median time of 2 weeks (IQR; 2, 3) when compared to patients in Group B with a median time of 4.00 weeks (IQR; 3, 6), $p<0.001$ (Table 3). Percutaneous nephrolithotripsy (PNL) was the treatment of choice in 34.3% of Group A patients while only 14.7% of Group B patients opted for this procedure. Shock Wave Lithotripsy (SWL) was less commonly chosen in group A (8.6%) compared to group B (27.9%). Both groups predominantly opted for Ureteroscopy (URS) as a treatment option with similar percentages observed (55.7% in group A and 57.4% in the group B). Open surgery was performed in a small percentage of cases within group A (1.4%) while it was not utilized in group B.

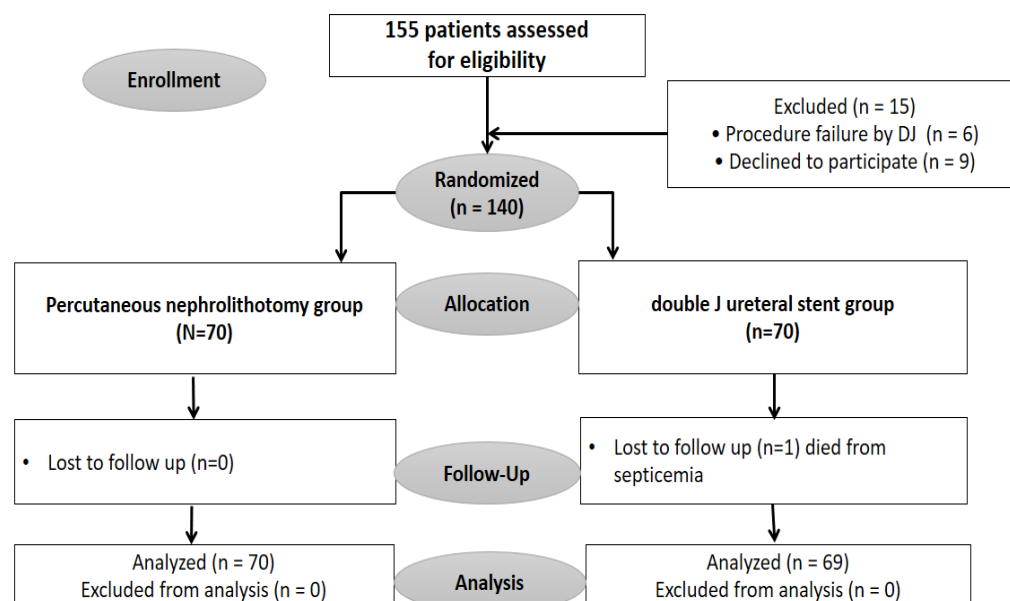


Figure (1): Flowchart showing the enrolment of patients in this study.

Table (1): Demographic and pre-procedure data in the two studied groups.

Variables	Group				<i>p value</i>	
	PCNL group (N=70)		DJ group (N=69)			
Demographic						
Age					0.419	
Median (IQR)	45.00 (35.00-60.00)		50.00 (40.00-62.00)			
Gender n (%)	male	32	45.7%	30	43.5%	0.732
	female	38	54.3%	39	56.5%	
Diabetic n (%)	12	17.1%	10	14.5%	0.642	
Pre-procedure signs						
Body temperature					0.417	
Median (IQR)	39.00 (39.00-40.00)		39.50 (39.00-40.00)			
Pre-procedure laboratory investigations						
WBCs (/mm³)					0.958	
Median (IQR)	16000 (13800-19000)		16000 (14000-18000)			
CRP (mg/L)					0.672	
Median (IQR)	155.00 (100.00-180.00)		157.00 (100.00-170.00)			
Serum creatinine (mg/dL)					0.688	
Median (IQR)	1.00 (.80-1.20)		1.00 (.80-1.60)			
Pre-procedure radiological investigations						
Stone laterality n (%)	Right	33	47.8%	44	63.8%	0.071
	Left	36	52.2%	25	36.2%	
Stone location n (%)	Upper	29	42.6%	23	33.3%	0.547
	Middle	2	2.9%	4	5.8%	
	Lower	20	29.4%	27	39.1%	
	Bilateral	1	1.5%	0	0.0%	
	Pelvic	16	23.5%	15	21.7%	
Stone density (hu)					0.958	
Median (IQR)	1132.50 (800.00-1239.00)		900.00 (622.00-1200.00)			

Stone Length (cm) Median (IQR)	1.20 (1.00-1.50)	1.00 (1.00-1.20)	0.011*
Stone Width (cm) Median (IQR)	1.00 (.70-1.00)	0.80 (.50-1.00)	0.012*

*: Statistically significant at $p \leq 0.05$

Abbreviation; CRP: C-reactive protein, DJ: Double j, IQR: Inter quartile range, PCNL: Percutaneous nephrolithotomy, WBCs: white blood cells.

Table (2): Operative and post-procedure data in the two studied groups.

Variables		Group				<i>p value</i>
		PCN group (N=70)		DJ group (N=69)		
Operative data						
Urine culture n (%)	positive	65	92.85%	61	88.40%	0.539
	negative	5	7.15%	8	11.60%	
Operative time (min.) Median (IQR)		12.00 (10.00-14.00)		13.00 (11.00-18.00)		0.008*
Fluoroscopy time (sec.) Median (IQR)		40.00 (30.00-50.00)		30.00 (30.00-50.00)		0.447
Post-procedure signs						
Time to normal temperature (hrs.) Median (IQR)		6.00 (6.00-6.00)		24.00 (12.00-24.00)		<0.001*
Post-procedure laboratory investigations						
Urine culture n (%)	positive	10	14.3%	49	71.0%	<0.001*
	negative	60	85.7%	20	29.0%	
WBCs (/mm ³) Median (IQR)		7000 (6000-8000)		7000 (6000-8000)		0.754
CRP (mg/L) Median (IQR)		9.00 (7.00-9.00)		15.00 (9.50-15.00)		0.004*
Serum creatinine (mg/dL) Median (IQR)		0.80 (0.70-1.00)		0.90 (0.80-1.00)		0.127
Post-procedure complications						
Bleeding/Hematuria n (%)	No	57	81.4%	62	89.9%	0.147
	Yes	13	18.6%	7	10.1%	
Burning micturition n (%)	No	70	100.0%	27	39.1%	<0.001*
	Yes	0	0.0%	42	60.9%	
PCN dislodgement or blockage n (%)	No	58	82.9%			
	Yes	12	17.1%			
urosepsis & ICU admission n (%)	No	66	94.3%	24	34.8%	0.001*
	Yes	4	5.7%	45	65.2%	
Hospital stay						
Length of hospital stay (days) Median (IQR)		3.50 (3.00-4.00)		2.00 (2.00-2.00)		<0.001*

*: Statistically significant at $p \leq 0.05$

Abbreviation; CRP: C-reactive protein, DJ: Double j, ICU: Intensive Care Unit, IQR: Inter quartile range, PCNL: Percutaneous nephrolithotomy, WBCs: white blood cells.

Table (3): Treatment in the two studied groups.

Items	Group				<i>p value</i>	
	PCN group (N=70)		DJ group (N=69)			
Type of treatment n (%)	PNL	24	34.3%	10	14.7%	0.001**
	SWL	6	8.6%	19	27.9%	
	URS	39	55.7%	39	57.4%	
	open	1	1.4%	0	0.0%	
Time of definitive treatment (weeks) Median (IQR)	2.00 (2.00-3.00)		4.00 (3.00-6.00)		<0.001*	

*: Statistically significant at $p \leq 0.05$

Abbreviation; DJ: Double j, IQR: Inter quartile range, PNL: Percutaneous Nephrolithotripsy, PCNL: Percutaneous nephrolithotomy, SWL: shock wave lithotripsy, WBCs: white blood cells, URS: ureteroscopy.

DISCUSSION

Our investigation aimed to compare the outcomes and complication rates of PCN and DJ stenting for managing urinary obstructions. our main findings in this study are that the PCN has a shorter operative time, low time to normalization of the body temperature, low post-procedural CRP, low incidence of urosepsis, and high length of hospital stay. To our knowledge, we found less time for definitive treatment in the PCN group.

The operation evaluation showed that group A had considerably lower operating time (min.) than group B ($p=0.008$); however, urine culture and fluoroscopy time were not statistically significant. group A had an estimated median (IQR) operative time of 12.00 (10.00-14.00) min, while group B had an estimated median (IQR) of 13.00 (11.00-18.00) min. In this study, we compared our findings to those of Elbatanouny et al. (2020) [6], the PCN group had lower operation time (10.76 ± 3.78 min vs 18.9 ± 5.58 min) ($P = 0.001$). In agreement with Wang et al. (2016) [7] that found the PCN group had a significantly shorter operative time than the emergent retrograde ureteroscopic management group (33.75 ± 5.36 min vs. 37.24 ± 6.63 min) ($P = 0.005$). Fluoroscopy resulted in a median (IQR) of 40.00 (30.00-50.00) seconds in the group A and 30.00 (30.00-50.00) seconds in the group B ($P = 0.447$). According to Elbatanouny et al. (2020) [6], fluoroscopy time was not significantly different between PCN and DJ stent groups, with fluoroscopy time being 1.78 ± 0.78 min and 1.5 ± 0.32 min respectively ($P = 0.105$).

Group B had significantly higher post-procedure symptoms and, delay to normalization of the temperature. We found that the median (IQR) time to average temperature (hrs.) was 6.00 (6.00-6.00 hrs.) in group A and 24.00 (12.00-24.00 hrs.) in group B ($P < 0.001$). Xu et al. (2021) [8] found that the PCN group returned to average body temperature in 3 h (IQR, 3-4 h) compared to the DJ group (5 h; IQR, 4-6 h) ($P < 0.001$). According to Wang et al. (2016) [7], the time to normalize body temperature (days) was similar for the PCN and DJ stent groups, with PCN taking 2.60 ± 1.35 days and DJ stent taking 2.50 ± 1.48 days ($P = 0.419$).

For more analysis of our data, the post-procedure laboratory investigations were compared between two groups. Our research findings indicate that out of the patients, in group A 85.7% had negative urine cultures while 29% of group B showed the same ($P < 0.001$). According to Elbatanouny et al. (2020) [6], post-procedure positive urine culture was significantly more frequent in the JJ stent group (58.3%) versus the PCN group (36.6%). This result was comparable to the findings of Dinic et al.[14] However, Pearle et al. reported that there was a higher number of positive urine C/S post-PCN versus post-JJ stent.[15]

About postprocedural WBC counts our study recorded a same count of 7000 (6000-8000) /mm³ for both groups. These results align, with the findings of Sucai et al. [16] who found no differences in WBC counts and the time it took for WBC levels to return to normal. Xu et al. (2021) [8] also supported these findings

by demonstrating that there were no variations in lab results, such as WBC count, hemoglobin levels, platelet count, serum creatinine levels, and preoperative CRP levels between the two groups, in their study. We observed that CRP levels were a median of 9.00 (7.00-9.00) mg/L in group A. A higher level of 15.00 (9.50-15.00) mg/L in group B. This aligns with Xu et al.'s (2021) [8] findings, which also showed a difference favoring the PCN group in terms of CRP levels. Additionally, Choi et al.'s (2019) [17] study reported differences between retrograde ureteroscopic management and percutaneous nephrostomy groups. From this data, a comparison was made between group A, and group B in post-procedure complications. Comparing group A and group B, procedural failure was 0% compared to 8.6%, bleeding/hematuria 18.6% versus 10.0%, burning micturition 0% versus 61.4%, and urosepsis 5.7% versus 65.2%. No treatment caused persistent problems in any group. Our study had 91.40% success with double J stenting, while Ahmad et al. [18] reported 94.2%. PCN insertion was used to divert urine in unsuccessful cases when stents could not be passed or ureters perforated. Our study found 100% success with PCN, compared to 96.5% and 98.0% for Ahmad et al. and Wah et al. [18, 19]. Non-dilated collecting systems, stag horn calculi, and uncooperative patients have reduced success rates. Ureteral stent complications are mechanical and related to stent material. Painful micturition was the most common consequence in our study, at 10.0%. Shao, et al. [20] and Ahmad, et al. [18] showed 12.0% and 9.0% bladder irritation, respectively, whereas Arshad [21] found 27.27%. We found that 18.6% of PCN patients had bleeding, the most common consequence. Karim et al. [22] and Shao et al. [20] found greater bleeding rates of 9.5% and 21.5%, respectively, which is similar to our findings. However, Ahmad et al., Jalbani et al., and Otaño et al. found rates of 4.0%, 5.0%, and 3.5%, respectively [18, 23]. Puncture of intercostal or parenchymal arteries can cause bleeding and extensive hematuria, which are normally self-limited and require transfusion in 2%–4% of routine nephrostomy insertions. Due to renal arterial branch injury, pseudoaneurysms, arterio-venous, and arterial calyceal fistulas cause late arterial bleeding [24]. Studies show 2-21% post-DJ stenting hematuria [25]. Of the 10.0% of patients in our trial, 5 received I.V. fluids within 24 hours, while 2 needed blood transfusion and hemostatic agents.

The most interesting finding in our data is rates of post-operative urosepsis, Our study found 65.2% of urosepsis post-DJ stenting 2.0% only developed septic shock, while Flukes et al. [25] found 7.0%. Arshad et al. [21] reported 10.2% urosepsis. Urosepsis incidence in the PCN group was 5.7%, while Jalbani et al. [23] and Elbatanouny et al. [6] reported 7.0% and 1.2%, respectively. Three patients needed DJS removal because fever and septicemia could not be treated conservatively. The investigation of urosepsis associated with PCN and RUS was conducted in other research studies. Ahmad et al. [18], Migita et al. [26], and Barton et al. [27] discovered that the prevalence of urosepsis is more frequent in patients undergoing DJ stent, whereas Monsky et al.[28] and Wong et al.[29] observed a higher incidence of urosepsis in the PCN group. However, the disparity in the urosepsis rate between the two groups did not exhibit statistical significance. In the DJ group, the prevalence of urosepsis ranges from 6% to 86%, whereas in the PCN group, it ranges from 3.5% to 35%.

Hospital stay duration was assessed to be 3.50 (3.00-4.00) days in group A and 2.00 (2.00-2.00) days in group B. The mean length of stay reported by Pearle et al. The retrograde ureteric stenting group had a mean stay of 3.2 days. Percutaneous nephrostomy patients stayed 4.5 days on average in that study, with no statistically significant difference. In contrast, Wang et al. [7] found a significant difference in hospital stay duration between percutaneous nephrostomy (10.25 ± 3.53 days) and emergent retrograde ureteroscopic management (8.24 ± 2.77 days). In contrast to our findings, Ahmed M Elbatanouny et al indicate no significant difference in hospital stay recovery time between PCN (2 ± 1 days) and JJ stent (2 ± 1.5 days; $P = 0.120$) [6]. Our finding is that the hospital stay is higher in group A may be because of the patient selection, or waiting for clearance of hematuria for these patients.

This study found significant differences between the two groups in type of definitive stone treatment and time to treatment. Treatment types for group A were: PNL 34.3%, SWL 6.8%, and URS 55.7%, Open 1.4%. For group B: PNL 14.5%, SWL 29%, URS 56.5%, Open 0%. Similar patterns were seen in past research, with a finding that pre-operative drainage technique influenced subsequent treatment selection [6]. The median time to definitive treatment was 2.00 (2.00-3.00) weeks for group A versus 4.00 (3.00-6.00) weeks for group B. This contrasts with a prior study that found no difference in time to treatment between

techniques [30]. The rapidity of the definitive treatment in group A is due to patients with a PCN who may have been more anxious to undergo treatment and rid themselves of an external tube. The results of the regression analysis indicate that high leukocytosis before surgery and longer operation times are independently associated with heightened urosepsis risk following PCN.

CONCLUSIONS

In conclusion, our research provides insights into the relative advantages of each procedure. Specifically, we found that PCN had success rates and a lower risk of complications compared to DJ stenting. These results emphasize the importance of selecting patients for these procedures and suggest that PCN may be preferred when both options are viable.

LIMITATIONS OF THE STUDY:

there is no subgroup analysis of the patients with urosepsis.

Declarations

Ethics approval and consent to participate

This study was reviewed and approved by the human ethics committee of Assiut University and informed consents were obtained from all human research subjects for participation in the study.

Competing Interests:

There is no conflict of interest.

Funding:

No funding was obtained for this study.

ACKNOWLEDGMENTS

None.

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