Cross-sectional Study

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Risk factors for bacterial stent colonization in patients with a double J ureteral stent: a prospective study

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Background: The increasing use of double J ureteral stents (DJS) has increased the risk of early intolerance and long-term complications. Studies have reported stent colonization rates ranging from 19 to 90% with various bacterial profiles in the colonization of stents.

Objectives: To identify the risk factors associated with bacterial colonization of DJS and report the common micro-organisms isolated and drug susceptibility pattern.

Methods: This study is a prospective study of patients who underwent DJS. A total of 48 patients from our institution were studied between March 2022 and August 2023. After the removal of DJS with a sterile technique, the tips of both ends (renal end and bladder end) of the stent were cut and processed in the microbiology lab.

Results: Bacterial colonies were detected in 56.25% (27 out of 48) of the stents. Among the pathogens identified, *Enterococcus* species, *Pseudomonas aeruginosa* and *E. coli* were the most frequently isolated. The colonization rate increased with the duration of stent placement and albuminuria.

Conclusions: The study indicated that prolonged indwelling time and albuminuria are a risk factor for bacterial colonization on the stent therefore, it is advisable to use double J ureteral stent only when absolutely necessary and to remove them promptly.

Keywords: colonization, double J stent, risk factors, urinary tract infection

Introduction

The double J ureteral catheter has been used to prevent upper urinary tract obstructions or strictures and to facilitate stone clearance after procedures such as percutaneous nephrolithotomy (PCNL), retrograde intrarenal surgery (RIRS), and ureteroscopic lithotripsy (URSL)[1–3]. However, with growing experience, there have been reports of early intolerance and long-term complications associated with double J ureteral stent (DJS). The overall complication rate due to double J ureteral stent ranges from 70 to 79.2%[4]. The study by Damiano *et al.*[5] identified early side effects such as lower abdominal pain, irritative bladder symptoms (18.8%), fever (12.3%), urinary frequency, nocturia, and hematuria (18.1%) in patients with double J ureteral stents. Major late complications for those with indwelling ureteral stents include stent migration (9.5%), stent fragmentation (3–10%), worsening hydronephrosis accompanied by flank pain (25.3%) and urinary tract infection (UTI) (12.3%)[3–5]. Urinary symptoms and pain from double J ureteral stents affect daily activities and reduce the quality of life in 60% of patients[3]. Forgotten double J stents require procedures such as ureteroscopic lithotripsy (URSL) or open surgery for removal, which significantly increases morbidity, mortality, financial burden, and reduces work ability and quality of life[6].

Ureteral stents provide an ideal surface for microbial colonization and biofilm formation, leading to stent obstruction, dysfunction, and infections[7,8]. Studies have shown rapid

HIGHLIGHTS

- The study found a 56.25% bacterial colonization rate in double J ureteral stents, with *Enterococcus*, *Pseudomonas aeruginosa*, and *E. coli* being the most common pathogens.
- Prolonged indwelling time and albuminuria were significant risk factors for increased colonization.
- Tazobactam/Piperacillin and Vancomycin were identified as the most effective antibiotics against the primary pathogens.
- The findings emphasize the need for timely stent removal and targeted antibiotic therapy to minimize complications.

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All the authors declare that the information provided here is accurate to the best of our knowledge.

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biofilm formation uropathogens like *E. coli*, *Proteus mirabilis*, *Staphylococcus epidermidis*, and Enterococcus faecalis on ureteral stents within 24 h, often undetected by urinary culture due to low sensitivity of 40%[8,9]. Co-morbidities like chronic renal fail ure, diabetes, pregnancy and prolonged indwelling time often elevate the risk of lower urinary tract infections in these patients[10,11]. Stent-associated infections can lead to severe com plications like fever, pyelonephritis, bacteremia, reflux, renal failure, and mortality, necessitating early stent replacement, antibiotics, and hospitalization[7,8].

There is limited research on the bacterial colonization pattern and drug sensitivity in patients with double J ureteral stent in our setting, which has a crucial role in guiding the prophylactic antibiotics to prevent urinary tract infection and sepsis. This study aims to identify the risk factor associated with bacterial colonization of Double J ureteral stent and identify the associated micro-organisms and drug susceptibility pattern.

Materials and methods

Study design

This was a quantitative prospective observational study. The study protocol conforms to the ethical guidelines of the Declaration of Helsinki 2013 and has been reported in line with the STROCSS criteria[9].

Setting and population

This study was conducted at the Department of Urology and Kidney Transplant Surgery, Tribhuvan University Teaching Hospital (TUTH), Maharajgunj, Kathmandu, Nepal.

Sample size

Sample size of 48 was calculated using formula

$$n = z^2pq/d^2$$

with $q = 100\text{-}19 = 81$, Z at 95% C.I. = 1.96, prevalence of 19%, $d = 10\%$

obtained from a previous study which reported a prevalence of 19% published by Shaker *et al.*[11]. A Convenient non-probability sampling method was utilized to select the required sample.

Inclusion and exclusion criteria

Patients from all sexes, backgrounds, and locations undergoing double J ureteral stent regardless of indication were included. We excluded patients with positive urine culture before stenting, taking antibiotics during double J ureteral stent removal, presence of yeasts in urine culture, and individuals declining informed consent.

Methodology

Data collection spanned from March 2022 to August 2023, with approval from the Institutional Review Committee of the IOM (IRC Reference no: 510[6–11]). Prior informed consent was obtained from all participants. All patients coming to TUTH Out-Patient department (OPD) and Emergency Department (ER) for urological surgery were assessed for the placement of a Double J ureteral stent (polyurethane). Patients fulfilling inclusion criteria were admitted and underwent Double J ureteral stent placement after their respective procedures. All patients received prophylactic antibiotic therapy with levofloxacin for 2–3 days at the time of double J ureteral stent insertion. The double J ureteral stent was in situ until the duration allocated according to the procedure. The double J ureteral stent was removed postoperatively based on patients' conditions with aseptic precaution under local anesthesia (2% lignocaine jelly) with the help of a 30° Karl Storze scope with cystoscope sheath 19/21 and alligator forceps following the standard technique. The equipment was sterilized with a 2.45% Cidex solution for 12 minutes prior to all double J ureteral stent removal. Then the patient was positioned in the lithotomy position, with proper cleaning of the external genitalia with povidone-iodine 10%, complete separation of the labia in the female, and proper cleaning of the prepuce and glans in the male. Then sterile xylocaine jelly 2% was instilled in the urethra, a cystoscope was inserted into the bladder, alligator forceps were inserted, and a double J ureteral stent was removed. After removal of the double J ureteral stent with sterile technique, the tips of both ends (renal end and bladder end) of the stent were cut with surgical blade number 10 and collected in a plastic screw-capped container, and sent for bacterial evaluation. The report of the culture and sensitivity pattern were collected and treated according to the sensitivity pattern with appropriate antibiotics correlating with the symptoms. Colonization was defined as the growth of micro-organisms ($>100\ 000$ Colony forming units) in the tip culture of either end or both ends of double J ureteral stent. All the demographic data with other study variables were recorded in proforma. Any amount of preoperative urine albumin from trace amounts and above (+,++, etc.) was considered in this study.

Outcomes

The primary objective of this study was to study the risk factors associated with bacterial colonization in patients with Double J ureteral stent.

Data collection

Data were collected and entered into a predesigned proforma. The surgery resident recorded all data in a patient proforma, which was subsequently compiled into a Microsoft Excel sheet (Microsoft Corporation). Continuous and categorical variables were assessed, including age, sex, BMI, diabetes mellitus, hypertension, duration of indwelling stents, preoperative urine albumin levels, presence of malignancy, chronic renal diseases, patients on immunosuppressants, renal transplant patients, and the type of bacteria involved.

Data analysis

The collected data was edited and then entered into Microsoft Excel 2010 and converted into SPSS version 26 for statistical analysis. Descriptive statistics, including frequency, percentage, mean, and median, were used to present the data. Results were expressed as mean ± standard deviation, median and range wherever applicable. χ^2 test was applied for categorical variables. The confidence interval of 95% was taken and a p value less than 0.05 was considered statistically significant.

Ethical consideration

The study protocol was performed in accordance with the principles of the Declaration of Helsinki and approved by the Institutional

Review Committee and Protocol Committee of our institution. Prior to enrollment, patients provided informed consent. To maintain confidentiality, patient information was safeguarded.

Results

Demographic and clinical characteristics

Forty-eight patients with double J ureteral stent after operative procedures meeting the inclusion criteria were included in the study. The mean age was 38.45 ± 15.10 years. The female/male ratio was 26/22 (45.8%). The mean BMI of the patient was 22.70 ± 3.02 kg/m^2. Most patients 26 (54.2%) had no comorbidity, while 9 (18.8%), 10 (20.8%), and 9 (18.8%) suffered from diabetes mellitus, hypertension, and chronic kidney diseases, respectively (Table 1). Twenty-three (47.9%) of patients had positive preoperative urine albumin (10 patients have + and 13 patients have trace urine albumin level).

Stent indwelling duration and procedures

The mean duration of stent indwelling duration was 23 ± 10.47 days (Range 12–50). The most common indications placement of double J ureteral stent were post-surgical procedures for urinary stones; ureteroscopic lithotripsy (URSL) 14 (29.2%) followed by retrograde intrarenal surgery (RIRS) 10 (20.8%) and percutaneous nephrolithotomy (PCNL) 9 (18.8%).

Bacterial isolates from culture

Twenty-seven (56.25%) patients had bacterial colonization; 19 (70.3%) patients had overlap that is colonization at both ends, 7 (25.9%) had colonization only at the bladder end and 1 (3.7%) patient had colonization only at the renal end. Twenty (41.7%) of the renal end and 26 (54.2%) of the bladder end of stents were culture-positive (Table 2).

Pseudomonas aeruginosa (14.6%) and Enterococcus faecalis (14.6%) were the most prevalent bacteria at the renal end. Enterococcus faecalis (18.8%) was the most prevalent in the bladder end followed by Pseudomonas aeruginosa (16.7%) (Table 2).

Table 1

Demographic distribution of patients.

Variables	Frequency, *n* (%)
Age, years	
Mean ± SD	38.45 ± 15.10
Range	2.5–67
Sex	
Male	22 (45.8)
Female	26 (54.2)
Female:male ratio	1.18:1
BMI	
Mean ± SD	22.70 ± 3.02
Range	16–28
Co-morbidities	
HTN	10 (20.8)
DM	9 (18.8)
CKD	9 (18.8)
Renal transplants	9 (18.8)
Malignancy	1 (2.1)
Patients on immunosuppressive drugs	10 (20.8)

CKD, chronic kidney disease; DM, diabetes mellitus; HTN, hypertension.

Table 2

Bacterial isolates from culture distribution.

Micro-organisms	Renal end Frequency, n (%)	Bladder end Frequency, n (%)
Sterile	28 (58.3)	22 (45.8)
Pseudomonas Aeruginosa	7 (14.6)	8 (16.7)
E. coli	5 (10.4)	5 (10.4)
Enterococcus Faecalis	7 (14.6)	9 (18.8)
Citrobacter	1 (2.1)	0
Others	0	4 (8.3)
Total	48 (100)	48 (100)

Antibiotic sensitivity pattern of isolated organisms

At the renal end, Tazobactam/Piperacillin was the most sensitive drug (85.7%) to *Pseudomonas aeruginosa*. Teicoplanin, Tigecycline, and Vancomycin were the most sensitive (100%) to Enterococcus faecalis. Nitrofurantoin (80%) was the most sensitive to *E. coli* (Table 3).

At the bladder end, Tazobactam/Piperacillin was the most sensitive drug (85.7%) to Pseudomonas aeruginosa. Vancomycin was the most sensitive (100%) to *Enterococcus faecalis*. Tazobactam/Piperacillin (80%) was the most sensitive to E. coli (Table 3).

Factors associated with stent colonization

The mean duration of indwelling stent in patients with colonization was significantly longer than those without colonization (26.33 ± 11.73 vs. 19.71 ± 7.29 d, p 0.02). A higher proportion of patients with bacterial colonization had positive urine albumin compared to those without (66.67% vs. 18.5%, p 0.004) (Table 4).

Stent-related sepsis

Two patients following stenting developed fever and features of urinary tract infection. Enterococcus faecalis was isolated in both patients and treated according to sensitivity pattern.

- The first patient was a 48-year-old female who underwent a Boari flap with double J ureteral stent for radiation-induced ureteric stricture for carcinoma cervix. Thus, double J ureteral stent exchange was done on 30th day post-stenting.
- The second patient was a 2.5-year-old male child who had left ureterocystoneostomy and developed fever. Thus, double J ureteral stent was removed in 21 days.

Discussion

The increasing use of double J ureteral stent has increased the risk of complications such as infections, which can be as high as 28%[12]. Biofilm formation after bacterial adhesion and colonization on the surface of stents plays a major role in infection, which can lead to bacteremia and sepsis if not treated[13]. These ureteral stents, made from synthetic biomaterials, provide sur faces conducive to bacterial colonization and the formation of polysaccharide biofilms. Within these biofilms, bacteria pro liferate and form numerous microcolonies[1].

Out of 48 patients, 20 (41.7%) and 26 (54.2%) had bacterial colonization in the renal and bladder end of Double J ureteral stent. This finding is similar to a previous study, which reported a colonization rate of 44%[7]. However, previous studies have

Table 3

Sensitivity pattern of DJS.

	Renal end, *n* (%)				Bladder end, *n* (%)		
Micro-organisms	**Pseudomonas aeruginosa**	**Enterococcus faecalis**	**E. coli**	**Citrobacter**	**Pseudomonas aeruginosa**	**Enterococcus faecalis**	**E. coli**
Tazobactam/Piperacillin	6 (85.7)	2 (28.5)	3 (60)	1 (100)	7 (87.5)	2 (22.2)	4 (80)
Gentamicin	5 (71.4)	3 (42.8)	3 (60)		6 (75)	5 (55.5)	2 (40)
Amikacin	4 (57.1)		1 (20)	1 (100)	6 (75)		2 (40)
Levofloxacin	2 (28.5)		1 (20)	1 (100)	4 (50)		2 (40)
Nitrofurantoin		3 (42.8)	4 (80)			4 (44.4)	3 (60)
Teicoplanin		7 (100)				8 (88.8)	
Tigecycline		7 (100)		1 (100)		8 (88.8)	1 (20)
Vancomycin		7 (100)				9 (100)	
Amoxicillin/clavulanate		1 (14.2)	1 (20)			1 (11.1)	1 (20)
Doxycycline		2 (28.5)				1 (11.1)	
Imipenem			1 (20)	1 (100)	1 (12.5)		2 (40)
Polymyxin			1 (20)	1 (100)	1 (12.5)		2 (40)
Ciprofloxacin	2 (28.5)				2 (25)		
Meropenem			2 (40)		1 (12.5)		2 (40)
Cefixime			3 (60)				3 (60)
Ceftriaxone			2 (40)				2 (40)
Ampicillin/Sulbactam			2 (40)				2 (40)

reported varying stent colonization rates ranging from 19 to 90%[11,14]. These discrepancies in the stent colonization rate may be attributed to the characteristics of the stent, different indwel ling times, different patient populations and technique of sample processing[11]. Studies with higher colonization rates identified Staphylococcus epidermidis and Gram-positive cocci as the pri mary organisms, likely due to urethral contamination[12].

Several studies have demonstrated different bacterial profiles in stent colonization. In the current study, the main organisms isolated were *Enterococcus* species, *Pseudomonas aeruginosa*, and *E. coli*, consistent with findings from previous studies[7,11,15]. Isolations of *Pseudomonas aeruginosa* are notably more common compared to *E. coli* in patients with long-term indwelling urethral catheters who receive prophylactic antimicrobials compared to those who do not[15].

Table 4

Association of demographic variables and clinical characteristics with stent colonization.

Variables	**With colonization (*n* = 27)**	**Without colonization (*n* = 21)**	***P***
Age (years)	37.38 ± 16.86	39.81 ± 12.76	0.57
Sex, *n* (%)			
Male	10 (37)	12 (57.1)	0.165
Female	17 (63)	9 (42.9)	
BMI (Kg/m^2)	22.73 ± 3.007	22.66 ± 3.11	0.94
Co-morbidities, *n* (%)			
DM	5 (18.5)	4 (19)	0.96
HTN	7 (25.9)	3 (14.3)	0.478
CKD	3 (11.1)	6 (28.6)	0.153
Malignancy	1 (3.7)	0	0.37
Patient on Immunosuppressive drugs	4 (14.8)	6 (28.6)	0.297
Urine albumin	18 (66.67)	5 (18.5)	0.004*
Stent indwelling days	26.33 ± 11.73	19.71 ± 7.29	0.02*

CKD, chronic kidney disease; DM, diabetes mellitus; HTN, hypertension.
*P value significant (χ^2 test).

Consistent with the findings of previous studies, our study observed a significant increase in bacterial colonization rates with longer indwelling times[7,16]. Notably in our study, the bacterial colonization was significantly higher after 3 weeks of stenting. As the indwelling time increases, there will be more chances for different bacterial strains to adhere and colonize the stent, which eventually forms a biofilm[17]. This has important clinical impli cations; for instance, routine prophylactic antibiotic use for peri ods shorter than three weeks might be unnecessary. This could help avoid adverse drug reactions, the selection of resistant organisms, and increased costs.

Similar to the findings of the prior studies, our study showed no significant association between bacterial colonization and the age of patients[9,18]. A higher proportion of female patients in our study had bacterial colonization compared to male (65.3% vs. 45.4%) but the difference was not statistically significant prob-ably due to the small sample size. A study by Bonkat *et al.*[19] reported female gender as a risk factor for stent colonization explaining the shorter urethra and proximity of the urethral opening to the vagina and anus in females might be risk factors for urinary tract infection and bacterial colonization.

Unlike previous studies linking co-morbidities such as diabetes mellitus (DM) and chronic kidney disease (CKD) with increased stent colonization rates[10,20], our study found no significant association between diabetes mellitus, chronic kidney disease, and stent colonization. However, we observed a significant association between preoperative urine albumin and bacterial colonization. The association of albuminuria and the coloniza-tion of stents has not been discussed in the medical literature till date. Albuminuria, often considered a marker of early kidney damage, could reflect underlying renal dysfunction, even in patients without clinically diagnosed chronic kidney disease. Additionally, it may also indicate subclinical inflammation or an undetected urinary tract infection, as some patients can harbor infections below the conventional clinical threshold of 100 000 CFU/ml. The presence of albumin in urine is thought to be a result of increased glomerular permeability, which may

provide a favorable environment for bacterial adhesion and colonization on foreign bodies such as stents. We hypothesize that albuminuria might serve as an indicator of poor systemic control of conditions like diabetes mellitus and hypertension, rather than diabetes mellitus itself being the direct cause of colonization. The tight control of such chronic conditions, as reflected by albumin levels, could influence the body's immune response to the presence of a foreign object such as a Double J ureteral stent. Additionally, the presence of protein in the urine could facilitate bacterial growth, further contributing to colonization. Our findings suggest that albuminuria may be an early marker for assessing the risk of bacterial colonization in patients with indwelling stents. While the exact mechanism remains unclear, this association highlights the importance of monitoring urine protein levels preoperatively in patients undergoing stent placement. More research is needed to investigate the pathophysiological mechanisms underlying this relationship and to explore whether albuminuria can be used as a predictive marker for stent-related infections, especially in high-risk populations.

Strengths of study

The prospective study design allows for the collection of real-time data, reducing recall bias. Additionally, the use of sterile techniques and rigorous methodology ensures the reliability and accuracy of bacterial culture results, providing valuable insights into the colonization patterns and antibiotic sensitivities.

Limitations of study

The sample size is relatively small, which may limit the generalizability of the findings. Moreover, the study's single-center setting could introduce biases related to specific local practices or patient demographics, potentially affecting the broader applicability of the results.

Conclusion

Prolonged indwelling time and albuminuria are significant risk factors for bacterial colonization on double J ureteral stents (DJS).Therefore, it is advisable to use Double J ureteral stent only when absolutely necessary and to remove them promptly. When choosing antibiotics, it is crucial to prioritize coverage against *Enterococcus* species and *Pseudomonas aeruginosa*, given their significance as primary pathogens in stent-related infections. Further research is needed to explore the role of albuminuria in stent colonization and its potential use as a predictive marker for stent-related complications.

Ethical approval

Ethical clearance and permission letters were obtained from the Institutional Ethical Committee of our institution, with IRC Reference no: 510[6–11]. Prior to enrollment, patients provided informed consent. To maintain confidentiality, patient information was safeguarded. The study protocol conforms to the ethical guidelines of the Declaration of Helsinki 2013.

Consent

Written consent obtained from all patients for publication and any accompanying images, copy of which is available for review by the Editor-in Chief of this journal on request.

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Author contribution

P.M.: concepts, design, literature search, data acquisition, data analysis, statistical analysis, manuscript preparation. P.L.: concepts, literature search, data analysis, statistical analysis, manuscript preparation, manuscript editing. S.P.: concepts, literature search, data analysis, statistical analysis, manuscript preparation, manuscript editing. I.T.: concepts, literature search, data analysis, statistical analysis, manuscript preparation, manuscript editing. U.K.S.: concepts, manuscript preparation. S.C.: concepts, design, data acquisition, manuscript preparation. P.G.: data acquisition, manuscript review. B.R.L.: data acquisition, manuscript review. P.R.C.: data acquisition, manuscript review.

Conflicts of interest disclosure

There were no conflicts of interest among all authors.

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Guarantor

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Data availability statement

The datasets used during this study will be available from the corresponding author upon reasonable request.

Provenance and peer review

Not commissioned, externally peer-reviewed.

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