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ARTICLE

Association of acute pyelonephritis with double-J ureteral stenting: a nationwide population-based case control study

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ABSTRACT

Objective: Urinary Tract Infections (UTIs) due to ureteral catheters has been frequently seen. The risk factors of this include both timing and those of the female gender. However, the association of Acute Pyelonephritis (APN) with use of ureteral DJ stents has rarely been investigated.

Materials and Methods: This study enrolled a total of 6,459 patients who were being treated with a ureteral catheter over a 10 year period from the nationwide database of Taiwan's National Health Insurance Bureau. From these subjects, episodes of APN were found in a total of 500 patients. Additionally, 2,000 patients without APN were randomly enrolled as a control group in order to analyze the associated factors.

Results: The results indicate that the percentage of those with regards gender, age, duration of implantation, ureteral stent type, hypertension, T2DM, presence of urinary tract infection, benign prostate hyperplasia and pregnancy status were significantly statistically higher in APN patients than non-APN patients. APN did not associate with the use of antibiotics, urolithiasis, chronic kidney disease, malignancy, or uric acid stone in patients with a ureteral catheter.

Conclusion: In conclusion, patients with a ureteral catheter associated with APN should be given close attention with regards to the above risk factors. Early removal of the catheter is the best policy for the prevention of APN.

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Introduction

Ureteral catheters have been frequently used in the urological world for a variety of purposes for decades. Clinically, indications for the placement of ureteral catheters as an internal diversion include relief from ureteral obstruction, identifying the ureter(s) intraoperatively and to drain a ureteral leak or injury [1]. The timing of the removal of the catheter may depend on the purpose of placement. A study of 46 patients with ureteral catheters by Joshi et al. [2] found a 30.4% rate of bacterial colonization in double-J (DJ) stent tip culture. The risk factors involved both timing and female gender. Therefore, early removal of a catheter has been suggested in order to prevent severe infection. However, regular replacement may be required in the case of obstructions such as cancers, ureteral stricture or inflammation, until there is a definite resolution of the obstruction or surgical reconstruction is performed. The duration of each stent implant is also of importance in the above conditions.

Although urinary tract infections are frequently diagnosed, the association of a DJ stent with Acute Pyelonephritis (APN) is rarely a concern. Lin et al. [3] reported that one in 18 'forgotten' double-J stents caused acute pyelonephritis in an analysis of 479 patients who required ureteral catheterization. The definition of 'forgotten' was 2 weeks exceeding the catheter's maximal stent life. The duration of DJ stenting was 12-months and the delay in changing was 97 days. The cause of APN may be due to the long indwelling time period causing bacterial colonization. Treatment of APN was hospitalization and intravenous antibiotics.

Materials involved in DJ include rubber, polyethylene, silicon and polyurethane, along with others, however there is no ideal material to provide a better advantageous use [4–6]. Complications and consequences of DJ stenting include hematuria, irritative symptoms, urinary tract infection or pyuria, encrustation, forgotten and incontinence as well as other conditions [7]. However, more severe complications such as APN are rarely reported. This study investigated the rate and analyzed the risk factors of APN in patients with DJ indwelling.

Patients and methods

Data source

In 1995, Taiwan launched the NHI program, which is a compulsory and single-payer program that covers nearly 99% of

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Taiwan residents. In 1999, the Bureau of National Health Insurance (NHRI) released National Health Insurance Research Database (NHIRD) data to the public in an electronically encrypted form for research purposes. This database contains all medical claims from 1997 to 2013 and is maintained by the National Health Research Institutes. For the present study, we collected data from the Longitudinal Health Insurance Database (LHID 2000), which is a representative subset database that comprises one million NHI enrollees randomly selected from all the beneficiaries of the NHIRD during 1997–2013. The database included inpatient and outpatient information of disease history, operation, treatment, and drug prescription, as well as sociodemographic data. Diagnoses and disease management were defined according to the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM). The study was approved by the Research Ethics Committee of China Medical University and Hospital in Taiwan (CMUH104-REC2-115-CR-4).

Study design and study population

To explore the risk factors associated with acute pyelonephritis amongst patients with a ureteral stent, we designed a population-based case-control study. In this study, patients provided with a ureteral stent from the years 2000 to 2013 were included as our study population. The APN group involved patients with newly diagnosed acute pyelonephritis (ICD-9-CM 590.10) during the study period. The index date for each case was defined as the date of diagnosis of acute pyelonephritis. Patients who had never been diagnosed with acute pyelonephritis were randomly selected from LHID 2000 as the matched control group. The APN group and the control group were frequency matched by age (every 5-year interval), and index year in a 1:4 ratio.

Potential comorbidities

Comorbidities that were potentially related to acute pyelonephritis prior to the index date included hypertension (ICD-9-CM 401), diabetes (ICD-9-CM 250), chronic kidney disease (ICD-9-CM 585), urolithiasis (ICD-9-CM 592.0, 592.1, 592.9), benign prostate hyperplasia (ICD-9-CM 600), urinary tract infection (ICD-9-CM 590), pregnancy (ICD-9-CM V22) and malignancy (ICD-9-CM 140-208). The diagnostic accuracy of the comorbidities mentioned above based on ICD-9 codes has been discussed in previous studies.

Risk factors

The risk factors of interest in our study were gender, duration of ureteral stent implantation, type of ureteric stent and type of kidney stone surgery. We classified the duration of ureteral stent implantation into the following groups: $\leq$7 days, 8–14 days, 15–28 days, 29–60 days, 61–90 days and $>$90 days. The ureteric stent types were divided into two materials, Silicone + Polyurethane and hydroplus coating. Related kidney stone surgery included ureteral catheterization, Percutaneous Nephrolithotomy (PCNL), Ureterorenoscopic Lithotripsy (URSL), ureterolithotomy, Extracorporeal Shock-wave Lithotripsy (ESWL) and laparoscopy.

Statistical analysis

The distribution of gender, age, duration of ureteral stent implantation, type of ureteric stent, type of kidney stone surgery, comorbidities and antibiotics use between the APN group and control group were compared using the Chi-square test for categorized variables, and the *t*-test for continuous variables. Univariate and multivariate unconditional logistic regression analyses were used to calculate the Odds Ratio (OR) and the 95% Confidence Intervals (CIs) for acute pyelonephritis associated with risk factors. Multivariate analysis was performed by adjusting for the potential comorbidities. All analyses were carried out using SAS statistical software (Version 9.4 for Windows; SAS Institute, Cary, NC, USA), and a p-value <0.05 was set as the level of statistical significance.

Results

There were a total of 6,422 patients with DJ indwelling enrolled in this study (Figure 1). After excluding Acute Pyelonephritis (APN) which occurred prior to this study, there were a total of 4,529 patients with a ureteral stent who did not experience an event of APN, while there were 500 events of APN in patients with DJ indwelling (Table 1). The incidence of DJ associated with APN was 9.94% (500/5,029). Two-thousand patients without an episode of APN during the period of DJ stenting were included at a 4:1 frequency matching by age and index year. There were a total of 1,297 men and 703 women in the control group. In the APN group, the female gender number was significantly higher than the male (313 women vs 187 men, $p < 0.001$). The distribution of age in both groups was not significantly different ($p = 0.33$).

The duration of DJ implantation was significantly different between the two groups ($p < 0.001$). Most patients with a DJ implant experienced a short period within 7 days, which was 77.4% in the control group and 59.0% in the APN group (Table 1). The incidence of APN was 16.0% (295/1,843). A duration of implantation between 8–14 days was the second most common in this study, with 14.45% in the control group and 29.0% in the APN group, with an APN incidence rate of 33.41% (145/434). There were only a few patients with a long-term indwelling of DJ in both groups, with their percentage between 0.4–0.6%. For a duration of 15–28 days, the incidence of APN was 35.37% (52/147). Although there were fewer case numbers in patients with DJ over 28 days, the incidence of APN was 11.76% in total (8/68).

Nearly all patients received antibiotics treatment during the implantation of DJ in each group. The presence of a UTI was greater in the APN group than the control group (73.2% vs 47.7%). In the APN group, hypertension, diabetes mellitus, and pregnancy were significantly higher than the control group. Benign prostate hyperplasia was higher in the control

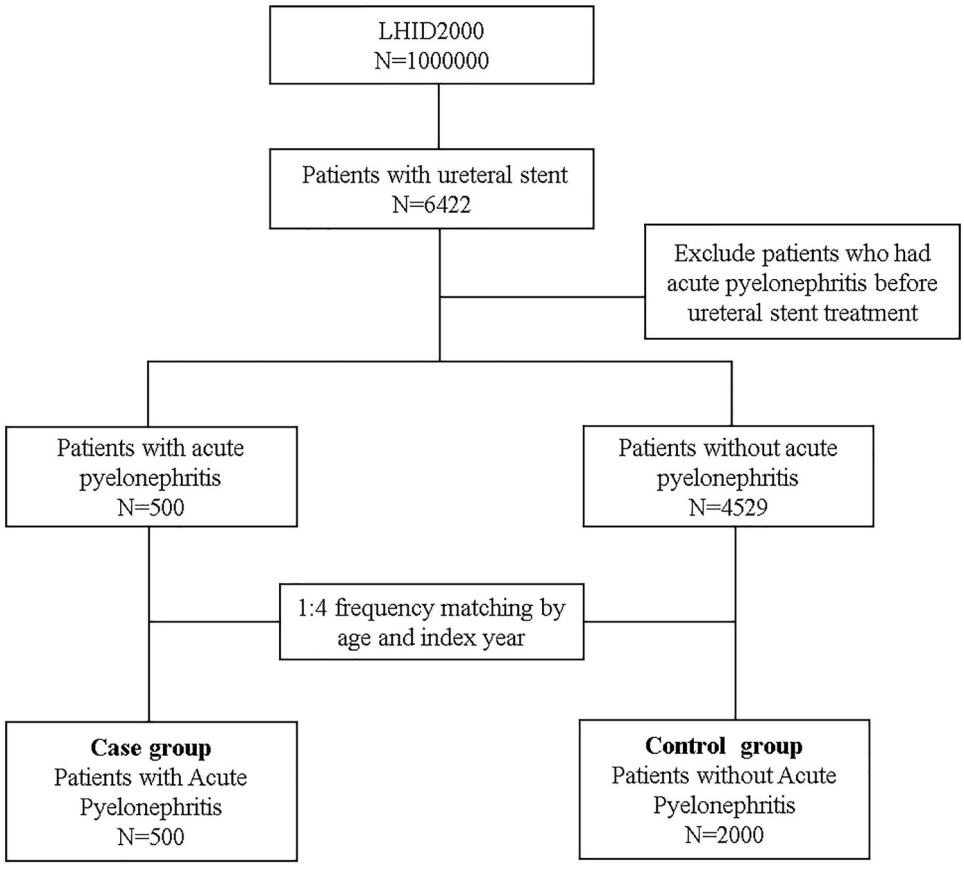

Figure 1. Flow chart of study protocol of DJ associated with acute pyelonephritis.

Table 1. Characteristics of acute pyelonephritis cases and controls.

	Acute pyelonephritis				
	No ($n = 2000$)		Yes ($n = 500$)		
Characteristics	*n*	%	*n*	%	*p*-value*
Gender					<0.0001
Male	1,297	64.85	187	37.40	
Female	703	35.15	313	62.60	
Age, years					0.33
<20	12	0.60	1	0.20	
20–39	324	16.20	71	14.20	
40–65	1,140	57.00	283	56.60	
>65	524	26.20	145	29.00	
mean ± SD	55.24 ± 15.02		56.86 ± 14.38		0.03
Duration of implantation					<0.0001
≤7 days	1,548	77.40	295	59.00	
8–14 days	289	14.45	145	29.00	
15–28 days	95	4.75	52	10.40	
29–60 days	42	2.10	3	0.60	
61–90 days	14	0.70	2	0.40	
>90 days	12	0.60	3	0.60	
Ureteric stent type					<0.0001
Hydroplus coating	681	34.05	224	44.80	
Silicone + Polyurethane	1,319	65.95	276	55.20	
Antibiotics use	1,998	99.90	500	100.00	0.48
Comorbidities					
Hypertension	1,017	50.85	306	61.20	<0.0001
Diabetes	522	26.10	166	33.20	0.002
CKD	195	9.75	41	8.20	0.28
Urolithiasis	1,782	89.10	44	88.00	0.48
BPH	323	16.15	47	9.40	<0.0001
UTI	954	47.70	366	73.20	<0.0001
Uric acid stone	19	0.95	9	1.80	0.10
Pregnancy	88	4.40	45	9.00	<0.0001
Malignancy	343	17.15	84	16.80	0.85

Data shown as *n* (%) or mean ± SD.
CKD: chronic kidney disease; BPH: benign prostate hyperplasia; UTI: urinary tract infection; Using 1:4 frequency matching.

group (16.15%) than the APN group (9.40%). Other comorbidities such as chronic kidney disease, urolithiasis, uric acid stone, and malignancy were not significantly different between the two groups.

Table 2 depicts the odds ratio and 95% confidence interval of APN associated with several variables, including comorbidities. The female gender experienced significantly higher rates than males in the developing of APN, with an adjusted odds ratio of 2.15 (95% CI = 1.67 ~ 2.77). Those with a duration of implantation between 8–14 days and 15–28 days had a significantly higher chance of developing APN than those with an implantation of less than 7 days, with an adjusted OR of 2.40 and 2.71, respectively. A hydroplus coating stent revealed a greater chance of APN than the silicon plus polyurethane stent, with a OR of 1.61 (95% CI = 1.31 ~ 1.98, $p < 0.001$). A pre-existing UTI had a high chance of APN during implantation with an OR of 1.94 (95% CI = 1.397–2.71).

Discussion

There was a high incidence of APN in patients with DJ indwelling. Significant risk factors included duration, gender, catheter type, type of surgery, comorbidities of hypertension, diabetes, BPH, UTI and pregnancy. Additionally, female gender and a pre-existing UTI displayed a higher OR than other factors. The most frequent cause of DJ indwelling was stone disease.

Table 2. Odds ratios and 95% confidence intervals of acute pyelonephritis associated with age, gender, and other covariates.

	Patients with ureteral stent			
Variables	Crude OR (95% CI)	*p*-value	Adjusted OR (95% CI)	*p*-value
Gender		<0.0001		<0.0001
Male	1.00 (reference)		1.00 (reference)	
Female	3.08 (2.52–3.78)***		2.15 (1.67–2.77)	
Age, per 1 year increased	1.01 (1.00–1.02)*	0.03	1.00 (0.99–1.02)	0.44
Duration of implantation				
≤7 days	1.00 (reference)		1.00 (reference)	
8–14 days	2.63 (2.08–3.33)***	0.0002	2.40 (1.87–3.09)***	0.0008
15–28 days	2.87 (2.00–4.11)***	0.0003	2.71 (1.82–4.04)***	0.0006
29–60 days	0.37 (0.11–1.21)	0.30	0.38 (0.11–1.27)	0.35
61–90 days	0.75 (0.17–3.31)	0.47	0.70 (0.15–3.23)	0.45
>90 days	1.31 (0.36–4.67)	0.85	1.32 (0.35–4.98)	0.80
Ureteric stent type				<0.0001
Silicone + Polyurethane	1.00 (reference)		1.00 (reference)	
Hydroplus coating	1.57 (1.28–1.91)***		1.61 (1.31–1.98)***	
Surgery				
Ureteral catheterization	0.82 (0.66–1.02)	0.07	0.79 (0.63–1.00)*	0.05
PCNL	2.04 (1.49–2.80)***	<0.0001	0.79 (1.28–2.49)	0.0006
URSL	0.75 (0.59–0.94)*	0.01	0.71 (0.56–0.90)**	0.005
Ureterolithotomy	0.81 (0.51–1.27)	0.36	0.81 (0.51–1.29)	0.38
ESWL	1.04 (0.84–1.27)	0.70	0.90 (0.72–1.12)	0.37
Laparoscopy	1.43 (0.81–2.51)	0.21	1.17 (0.65–2.11)	0.58
Comorbidities				
Hypertension	1.52 (1.24–1.86)***	<0.0001	0.69 (0.55–0.86)	0.001
Diabetes	1.40 (1.14–1.73)**	0.002	0.86 (0.68–1.09)	0.21
CKD	0.82 (0.58–1.17)	0.28	1.67 (0.15–2.43)	0.007
Urolithiasis	0.89 (0.66–1.21)	0.48	1.15 (0.81–1.62)	0.41
BPH	0.53 (0.39–0.74)***	0.0002	0.35 (0.28–0.44)	<0.0001
UTI	2.99 (2.41–3.71)***	<0.0001	1.94 (1.39–2.71)	<0.0001
Uric acid stone	1.91 (0.85–4.25)	0.11	0.48 (0.21–1.11)	0.08
Pregnancy	2.12 (1.47–3.12)	<0.0001	0.53 (0.35–0.78)**	0.002
Malignancy	0.97 (0.75–1.26)	0.85	1.22 (0.91–1.63)	0.18

*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.
Model adjusted for hypertension, diabetes, CKD: Urolithiasis, BPH, UTI, Uric acid stone, Pregnancy and Malignancy.
PCNL: percutaneous nephrolithotomy; URSL: ureterorenoscopic lithotripsy; ESWL: extracorporeal shock wave lithotripsy; CKD: chronic kidney disease; BPH: benign prostate hyperplasia; UTI: urinary tract infection.

Junuzovic et al. [8] conducted a prospective study on safety involving a total of 208 patients who underwent endourological surgeries. Postoperative bacteriuria was significantly more present in patients who had experienced a preoperative catheterization. A longer duration of catheterization resulted in a higher chance of bacteriuria. The occurrence of postoperative bacteriuria did not relate to antibiotic prophylaxis. In our study, a significantly higher chance of APN in endourological surgery was during PCNL, which was greater than in other surgeries. This may be due to PCNL treating a higher stone burden, while also indicating a high infection stone rate. Therefore, this is reasonable in terms of a high chance of APN. However, our data also indicates that nearly all patients who received antibiotic treatment did not experience a prevention in the occurrence of APN.

The duration of stent indwelling may be a significant risk factor of catheter related APN. Comparing the duration period to below 7 days, the 8–28 days of ureteral stenting period had a significantly higher chance of developing APN. Due to the limited patient number in the duration period of over 28 days, the long-term effect of an indwelling DJ stent on APN did not show any significance. However, the incidence of APN was higher in patients with a long-term DJ indwelling. The female gender revealed a greater chance of APN, which may be due to its higher incidence of developing a UTI than the male gender. Javed et al. [9] reported that a DJ indwelled over 6 weeks may be associated with high risk of infection in stone patients who underwent endourological surgeries having pre-operative sterile urine conditions. Although we could not be made aware of the patient's urine routine data in this cohort, we did discover that the duration of indwelling was a very important factor associated with APN.

UTIs are a well-known complication of DJ implantation with a reported incidence rate ranging from 25–60% [10], which varies due to the duration of the implant. Long-term urethral catheterization causing APN is also well-known, with a prevalence rate of 38% in patients in a nursing home over the age of 75 [11]. However, there is less data regarding the incidence of a ureteral catheter being associated with APN. This is the first survey of DJ being associated with APN at an incidence rate of 16–33%, due to the dependence on duration of implantation. Owing to its high incidence of APN, this issue should not be overlooked.

APN is one form of a severe urinary tract infection which may subsequently result in sepsis. In addition to lower urinary tract symptoms, fever, flank pain, or tenderness may frequently be present clinically. The annual incidence rates of APN are 0.15–0.17% within the female population, and 0.03–0.05% in the male population taken from a study of an over 525,000 enrolled population by the Group Health Cooperative maintenance organization in Washington and

Idaho states [12]. The estimated death rate of APN caused septicemia may be nearly 10% in the US [13]. Risk factors of APN include gender/age, anatomic/functional abnormality, foreign body, calculus, obstruction, pregnancy, and an immunosuppressed status, along with other concerns [14]. Indwelling of DJ in a patient's urinary tract may act as a foreign body and cause nidus of bacterial colonization. Therefore, patients implemented with a DJ for a variety reasons may serve as a risk factor for APN.

Altunal et al. [15] analyzed the risk factors of UTI in 60 patients with DJ placement and found that the duration of stent indwelling was significantly correlated, but not an indication for stenting, age or gender. Comorbidities such as diabetes mellitus and chronic kidney disease also play a role in catheter-related UTI. No malignancies, stone or hypertension were a risk factor for catheter related infection. In Altunal et al.'s study, a prolonged duration of stenting, particularly over 150 days, significantly increased the possibility of bacterial colonization and, as a result, a UTI. Our data only categorized indwelling days over 90 days and used a limited patient number which could not reveal any significance. We also found malignancy and stone disease showed no significant difference between the APN and control groups. However, comorbidity of hypertension did reveal a significant risk factor associated with APN.

In addition to the removal of the catheter within the manufacturer's recommended interval, many investigators are making an effort to reduce DJs which are coated with biofilms by improving the materials used. Biofilms are believed to be an inevitable presence in the prolonged use of catheters, and cause significant multiple resistant bacteriuria [16]. Such biofilms could potentially increase the risk of DJ associated with APN. However, the development of ideal DJ biomaterial coatings in order to prevent bacterial adhesion has until now been unsuccessful [17]. Elwood et al. [17] found that the biomaterial used in stent design did not have a preventive effect on bacterial adhesion. Instead, genitourinary cytokeratins may be implicated as playing a significant role in conditioning film formation. Lo et al. [18] reviewed coating materials on catheters for the reducing of infection, including antibiotics, antibacterial triclosan, silver, hydrogel, heparin, polyvinylpyrrolidone, hyaluronic acid, chitosan, and antimicrobial peptide, amongst others. However, few of them were shown to be fully effective. Early removal of a catheter remains the mainstay for prevention.

The DJ ureteral catheter was introduced by Finney [19] and Hepperlen et al. [20] in the year 1978. Due to several factors, a DJ may be associated with several adverse effects such as infection, encrustations, patient discomfort and a urothelial mucosal reaction, all of which will limit its long-term use for the purpose of drainage [7]. Upon analyzing our results, acute pyelonephritis may also occur. Therefore, ideal stent characters include no discomfort, no biofilm, no encrustations, no migration, radiopacity, being ultrasound detectable, requiring simple insertion & removal, and a high quality-of-life [21]. Although there is no absolute ideal ureteral stent, engineers continue to make the effort to design ideal stent technology through the analysis of coating and materials.

Our study involved a large number of patients indwelled with a DJ who had first reported a high incidence of APN. However, there were some limitations to this study. First, we didn't have certain patient laboratory data such as urine routine, bacterial cultures and biochemical profiles to be further evaluated. The database did not provide stone size and location, reasons for stent insertion and causes of delay removal. We also could not divide different DJ manufacturing material according to their maximal length of stay, due to different hospitals using various types of DJs. Instead, we categorized the duration of DJ implantation according to the records from the available database. Therefore, the risk of APN may be determined by the duration of the DJ indwelling, regardless of its material. Although antibiotic use may have a preventive effect for DJ associated with APN, we did not find the difference between APN and non-APN groups due to limited information from the database. This issue should be further studied in the future.

In conclusion, we found a high incidence of DJ to be associated with APN in this study. Risk factors of DJ associated with APN included duration of the implant, gender, catheter type, type of surgery, comorbidities of hypertension, diabetes, BPH, UTI and pregnancy. Being female and having a pre-existing UTI were the most important risk factors. Early removal of the catheter is the best policy for the prevention of APN.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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