

# Antibiotic Prophylaxis Prior to Urodynamic Study in Patients with Neurogenic Bladder and Asymptomatic Bacteriuria: A Randomized Controlled Trial

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**Background:** Symptomatic urinary tract infection (UTI) is a common complication after urodynamic study (UDS). While the role of antibiotic prophylaxis before UDS is controversial.

**Objective:** To compare the incidence rate of symptomatic UTI after UDS in patients with and without antibiotic prophylaxis.

**Materials and Methods:** We conducted a randomized, open-label, noninferiority controlled trial in adults with asymptomatic bacteriuria who were undergoing UDS. The participants were randomly assigned (1:1) to receive either gentamicin 5 mg/kg plus ampicillin 1-gram intravenous (IV) infusion 1 hour before UDS or no prophylaxis. The primary outcome was an incidence rate of symptomatic UTI within 48 hours after UDS. Secondary outcomes were adverse effects and microbiological clearance of urine at 48 hours after UDS. The study was terminated early after the first interim analysis due to safety concerns.

**Results:** 26 patients were enrolled, median age was 52 years (range, 25 to 75 years), 69.2% were male, and all had a neurogenic bladder as indication for UDS. Of these, 13 patients each were allocated to the antibiotic prophylaxis group and the non-antibiotic prophylaxis group. In the antibiotic prophylaxis group, 12/13 (92.3%) received gentamicin plus ampicillin and one received ceftriaxone. The incidence rate of symptomatic UTI after UDS was significantly higher in patients with no antibiotic prophylaxis (5/13; 38.5%) than those who received antibiotic prophylaxis (0%) ( $p=0.04$ ). No adverse drug events were observed. The microbiological clearance in urine at 48 hours after UDS was significantly higher in patients who received antibiotic prophylaxis (8/11; 72.7%) compared to those without antibiotic prophylaxis (0/13; 0%) ( $p<0.001$ ).

**Conclusion:** Antibiotic prophylaxis reduced the incidence of symptomatic UTI in patients with neurogenic bladder and asymptomatic bacteriuria who were undergoing UDS. A single-dose of antibiotics within an hour prior to UDS seems to be a proper option.

**Keywords:** Antibiotic prophylaxis; Asymptomatic bacteriuria; Urodynamic study

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Urodynamic study (UDS) is a part of an evaluation in patients with lower urinary tract dysfunction such as urinary incontinence, voiding dysfunction, and a neurogenic bladder. The test provides the accuracy of diagnosis and facilitates the target treatment<sup>(1)</sup>. However, undergoing UDS may be complicated with symptomatic urinary tract infection (UTI) or bacteriuria<sup>(2,3)</sup>. The incidence of UTI after UDS has been reported in 3.2 to 15.8%<sup>(4-6)</sup>. Risk factors for developing UTI following UDS include the following:

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undergoing invasive urologic procedures, known neurogenic lower urinary tract dysfunction, elevated postvoid residual, asymptomatic bacteriuria, immunosuppression, advanced age, and patients with indwelling catheter or performing intermittent catheterization<sup>(7)</sup>.

Prior to UDS, symptomatic UTI should be evaluated and treated before undergoing UDS. However, there has been limited a high-level evidence to support the recommendation for antimicrobial treatment or prophylaxis before UDS in patients with UTI risk factors but having asymptomatic bacteriuria as noted in the Best Practice Policy Statement<sup>(7)</sup>. Some studies have demonstrated the benefit of antibiotic prophylaxis for prevention of UTI after UDS but other studies do not support routine prophylaxis due to the lack of efficacy for preventing UTI after UDS<sup>(8-10)</sup>. Besides the efficacy issue, using antibiotics treatment or prophylaxis can cause adverse effects and may lead to the emergence of resistant microbes<sup>(11,12)</sup>. We therefore conducted a prospective, randomized controlled trial to determine the efficacy and safety of a single-dose antibiotic prophylaxis prior to undergoing UDS for prevention of symptomatic UTI in patients with asymptomatic

bacteriuria.

## Materials and Methods

A randomized, open-label, non-inferiority trial study was conducted at Srinagarind Hospital-a tertiary, university hospital in northeastern Thailand, between June 2020 and February 2021. The patients were eligible for the study if they met all of the following criteria: 1) aged over 18 years, 2) were admitted for urodynamic examination (cystometry and/or a voiding vesicourethrogram [VCUG]) in the Rehabilitation unit of the hospital, 3) had no signs and symptoms of UTI, defined according to at least one of the following; fever (temperature  $\geq 37.8^{\circ}\text{C}$ ) with no other apparent causes, the onset of dysuria, urgency, frequency, suprapubic or flank pain, increased spasticity, autonomic dysreflexia, and malaise, lethargy or sense of unease, 4) evidence of pyuria; urine WBC  $\geq 10$  cells/high power field (HPF) or positive urine leukocyte esterase, 5) evidence of significant bacteriuria; bacteria count from urine culture  $\geq 10^5$  colony-forming units (CFU)/mL from non-catheter specimens or  $\geq 10^2$  CFU/mL from catheter specimens or positive urine nitrite, and 6) written informed consent. Exclusion criteria were as follows: 1) pregnancy or breastfeeding, 2) received any antibiotics 7 days prior to enrollment, 3) known allergy or contraindicated for penicillin, ceftriaxone or gentamicin, 4) immunocompromised state defined as received immunosuppressive agents, prednisolone  $\geq 15$  mg/day or equivalent dose, chemotherapy session in the past 1 month, neutropenia (WBC  $< 1,000$  cells/mm<sup>3</sup>), 5) liver cirrhosis child B or C, 6) a history of urinary stones or bladder outlet obstruction, and 7) a history of urosepsis post UDS.

## Study procedure

Eligible patients were randomized 1: 1 to an antibiotic prophylaxis group or a non-antibiotic prophylaxis group via a computer-generated random sequence in blocks of 4 and the code was kept in the sealed opaque envelop. Patients and staff responsible for randomization were unblinded to treatment assignments but staff involved in clinical assessment remained blinded. Patients that were assigned to the antibiotic prophylaxis group received a 30-minute intravenous (IV) infusion of gentamicin 5 mg/kg and a 1-gram IV infusion of ampicillin within 1 hour before UDS if their creatinine clearance was  $> 60$  mL/min (calculated by Cockcroft-Gault Equation). Patients with a creatinine clearance  $\leq 60$  mL/min received a 2-gram IV infusion of ceftriaxone instead of ampicillin plus gentamicin. Patients who were assigned to the non-antibiotic prophylaxis group did not receive antibiotics before UDS. After completing UDS, all patients were monitored for clinical signs and symptoms of symptomatic UTI and adverse effects from antibiotics for 48 hours. If the patients did not develop clinical symptomatic UTI, they were discharged from the hospital with a urinalysis and urine culture performed before being discharged. Patients who developed symptomatic UTI within 48 hours after UDS, urinalysis and urine culture were

performed at the time of symptomatic UTI presented. Empiric antibiotics for treatment of symptomatic UTI were administered based on baseline urine culture and susceptibility testing results. Patients were followed-up until recovery. One week after being discharged from the hospital, all patients were assessed for clinical symptomatic UTI by a telephone call from the investigators.

Data was collected for each participant including age, gender, body weight, comorbidities, indications for UDS, bladder emptying management, type of UDS, previous UDS, previous antibiotics use, baseline urinalysis and urine culture, clinical symptoms after UDS, antibiotics treatment, and adverse events. The study protocol was reviewed and approved by the institutional review board of Khon Kaen University (Reference No. 4.2.02: 12/2020, HE631104).

The urine cultures were performed by the Calibrated loop/Surface Streak Method, the urine was inoculated on sheep's blood and MacConkey agar plates by calibrated loop taking 1  $\mu\text{L}$  of urine, which was incubated aerobically at  $35^{\circ}\text{C}$  for 24 hours. The minimum level of detection for standard culture was  $10^3$  CFU/mL, represented by 1 colony from growth on either plate. VITEX<sup>®</sup>2 automated microbiology system (BioMerieux, France) was used to determine the genus/species of the implicated bacterium. Antimicrobial susceptibility testing was performed using a Sensititre ARIS 2X (Thermo Scientific, Lenexa, KS) and determined following the recommendation of the Clinical Laboratory Standards Institute (CLSI), 2020<sup>(13)</sup>.

## Statistical analysis

The primary outcome was the proportion of patients with symptomatic UTI within 48 hours after UDS. Diagnostic criteria for symptomatic UTI was defined as the presence of 1) at least 1 acute clinical sign or symptom suggestive of UTI: fever (temperature  $\geq 37.8^{\circ}\text{C}$ ) with no other apparent causes, dysuria, urinary incontinence, suprapubic or flank pain, increased spasticity, autonomic dysreflexia, malaise, lethargy, or sense of unease, in combination with 2) evidence of pyuria, defined as a presence of urine WBC  $\geq 10$  cells/HPF or positive urine leukocyte esterase, and 3) evidence of significant bacteriuria, defined as a bacteria count  $\geq 10^5$  CFU/mL from non-catheter specimens or  $\geq 10^2$  CFU/mL from catheter specimens or positive urine nitrite<sup>(14)</sup>. Asymptomatic bacteriuria was defined as the current evidence of significant bacteriuria without any clinical symptoms and signs suggestive of UTI<sup>(15,16)</sup>. The secondary outcomes were adverse effects of antibiotic prophylaxis and the proportion of microbiological clearance of urine at 48 hours after UDS.

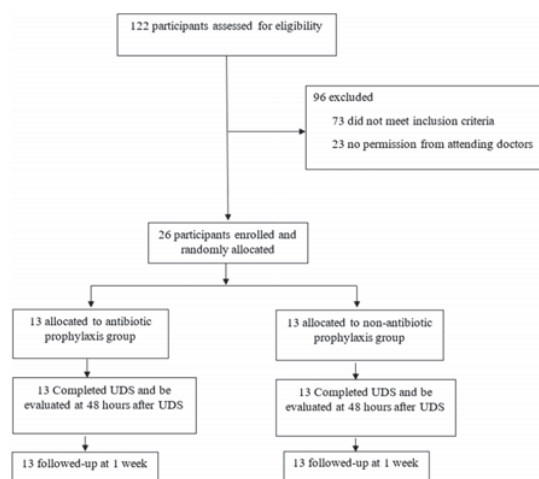
The study was designed to determine the noninferiority of non-antibiotic prophylaxis when compared to antibiotic prophylaxis strategy for the incidence rate of symptomatic UTI within 48 hours after UDS. Using a 10% noninferiority margin and assuming the incidence of symptomatic UTI was 3.4 and 2.5 in the non-antibiotic prophylaxis and antibiotic prophylaxis groups, respectively, we estimated that a sample size of 54 participants in each group would provide 80% power to demonstrate

noninferiority at a one-sided alpha of 2.5%. Interim analysis was planned to be performed after 25% and 50% of participants had completed 1-week of follow-up. O'Brien Fleming with a 2-sided significant test and a type I error rate of 5% were used for planned interim analyses. However, this trial was terminated early due to safety concerns after the first interim analysis (n=26) because of a higher incidence rate of symptomatic UTI observed in the non-antibiotic prophylaxis group.

Continuous variables were presented as medians and ranges, and as frequencies and percentages for categorical variables. Comparisons of categorical variables between the two study groups were performed using the Fisher's exact test, while the Kruskal-Wallis test was used for continuous variables. A p-value of less than 0.05 was considered statistically significant. Statistical analysis was performed using IBM SPSS Statistics for Windows, version 19.0 (IBM Corp., Armonk, NY, USA).

## Results

Between June 2020 and February 2021, 26 patients were enrolled and randomly assigned to the antibiotic prophylaxis group (n=13) and the non-antibiotic prophylaxis group (n=13) (Figure 1). Among the patients in the antibiotic prophylaxis group, 12/13 (92.3%) received ampicillin plus gentamicin and one case received ceftriaxone. Demographic and baseline characteristics of the patients were similar between the two study groups (Table 1). The median age of all patients was 52 years (range, 25 to 75 years) and approximately two-thirds (69.2%) were male. Most patients (80.8%) had previous UDS. None had a history of antibiotics exposure within 3 months prior to this UDS. Nineteen (5/26 cases) percent of the patients had underlying diabetes mellitus. The indication for UDS was neurogenic bladder in all cases.



UDS = urodynamic study

**Figure 1.** Study flow diagram.

Using urinary catheterization, either indwelling or intermittent urinary catheterization, as a recent voiding management, was not significantly different between the antibiotic prophylaxis and non-antibiotic prophylaxis groups (69.2% vs. 53.8%,  $p=0.42$ ).

Overall urinalysis findings at baseline showed 73.1% of patients had evidence of significant pyuria (WBC  $\geq 10$  cells/mL) plus positive leukocyte esterase tests. The proportion of patients who had significant pyuria was similar between the two study groups (76.9%), which a range of 10 to 30 and 30 to 50 cells/mL WBC in the urine was 61.5% and 15.4%, respectively (Table 1). Urine cultures demonstrated significant bacteriuria in all cases, but 38.5% of these were positive for urine nitrite. About two-third (57.7%) of the urine cultures grew a single pathogen. The common uropathogens found in both groups were *Escherichia coli*, 61.5% in the antibiotic prophylaxis group, and 84.6% in the non-antibiotic prophylaxis group, followed by *Proteus mirabilis* (23.1%) and *Enterobacter* species (15.4%) in the antibiotic prophylaxis group, and *Klebsiella* species (15.4%) and *Morganella morganii* (7.7%) in the non-antibiotic prophylaxis group, respectively (Figure 2A).

Among 29 isolates of Enterobacteriaceae pathogens from urine at baseline, there were 10.3% resistant to gentamicin, 84.6% resistant to ampicillin, and 27.6% resistant to ceftriaxone. In addition, 24.1%, 34.5%, and 20.7% of these isolates were resistant to trimethoprim-sulfamethoxazole (TMP-SMX), ciprofloxacin, and amoxicillin-clavulanate, respectively (Figure 2B). Overall, extended-spectrum beta-lactamase (ESBL) producing and multidrug-resistant Enterobacteriaceae were reported in 24.1% and 6.9%, respectively. Urine cultures at 48 hours after UDS was performed in 24/26 cases (92.3%). 2 patients in antibiotic prophylaxis group had missing urine culture specimens. Of these, 72.7% of the patients in the antibiotic prophylaxis group had microbiological clearance, while all patients in the non-antibiotic prophylaxis group had significant bacteriuria ( $p<0.001$ ). The type of uropathogens and antimicrobial resistance of Enterobacteriaceae isolates at 48 hours after UDS are presented in Figure 2C and 2D.

The incidence rate of symptomatic UTI after UDS was significantly higher among patients who did not receive an antibiotic prophylaxis than those given an antibiotic prophylaxis (5/13, 38.5% vs. 0%,  $p=0.04$ ) (Table 2). Twenty-three percent (3/13) of the patients that received an antibiotic prophylaxis had uropathogens at baseline resistant to prophylactic drug but none developed symptomatic UTI after UDS. No adverse drug events were observed. All symptomatic UTI cases developed within 48 hours after UDS. Clinical presentations of UTI were autonomic dysreflexia (2 cases), flank/suprapubic pain (2 cases), increased spasticity, and dysuria in one case each.

All symptomatic UTI cases were treated with antibiotics: 2 cases with oral TMP-SMX, one case each with oral ciprofloxacin, intravenous ceftriaxone, and amikacin. The duration of antibiotic treatment ranged from 7 to 10 days. All patients recovered and survived by the end of follow-up.

**Table 1.** Demographic data of patients underwent urodynamic study

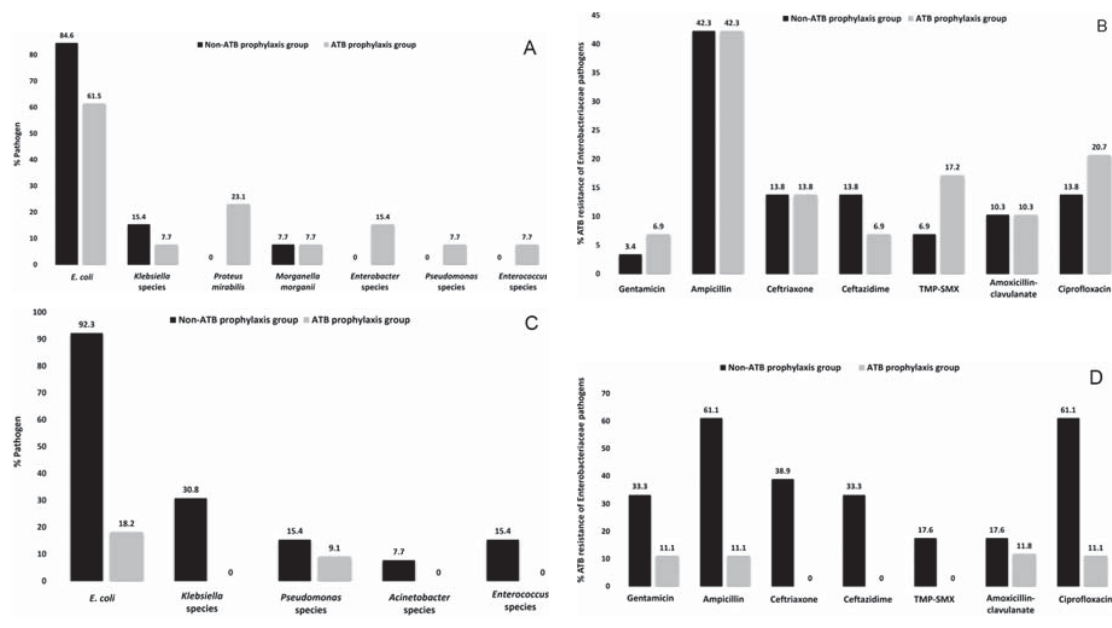
Characters	Number of patients (%)		p-value
	Non-antibiotic prophylaxis group n=13	Antibiotic prophylaxis group n=13	
Male	9 (69.2)	9 (69.2)	1.00
Median age; years (range)	46 (27 to 75)	53 (25 to 75)	0.80
Comorbid diseases	5 (38.5)	5 (38.5)	1.00
Diabetes mellitus	3 (23.1)	2 (15.4)	1.00
Hypertension	3 (23.1)	2 (15.4)	1.00
Others*	1 (7.69)	4 (30.8)	0.32
Voiding management			
Voluntary urination	6 (46.2)	4 (30.8)	0.69
Intermittent urinary catheterization	3 (23.1)	2 (15.4)	1.00
Indwelling urinary catheterization	4 (30.8)	7 (53.8)	0.43
Prior urodynamic study			
None	1 (7.7)	4 (30.8)	0.32
1 to 3 times	7 (53.8)	5 (38.5)	0.70
>3 times	5 (38.5)	4 (30.8)	1.00
Inflammatory markers in urine			0.59
WBC >10 cells/mL only	0 (0)	1 (7.7)	
Positive leucocyte esterase test only	3 (23.1)	3 (23.1)	
WBC >10 cells/mL plus positive leucocyte esterase test	10 (76.9)	9 (69.2)	
Pyuria			1.00
WBC <10 cells/mL	3 (23.1)	3 (23.1)	
WBC 10 to 30 cells/mL	8 (61.5)	8 (61.5)	
WBC 30 to 50 cells/mL	2 (15.4)	2 (15.4)	
Bacteriuria			0.69
By culture criteria	9 (69.2)	7 (53.8)	
By culture criteria plus positive nitrite	4 (30.8)	6 (46.2)	
Urine microbiology			
Number of pathogens			0.64
Single pathogen	8 (61.5)	7 (53.8)	
Two pathogens	3 (23.1)	5 (38.5)	
Mixed pathogens	2 (15.4)	1 (7.7)	

\*Others: Cancer (1), tuberculous spondylitis (2), deep vein thrombosis (1), transverse myelitis (1)

## Discussion

In this randomized, controlled trial, we demonstrated the effectiveness of antibiotic prophylaxis before UDS to reduce the incidence of symptomatic UTI, particularly in patients with a neurogenic bladder who have asymptomatic bacteriuria. The necessity of antibiotic prophylaxis for UDS is still an ongoing debate because of inconsistent study results regarding the benefits of antibiotic prophylaxis and the risks (adverse drug effects and emergence bacterial resistance). These conflicting data on the

effectiveness of antibiotic prophylaxis are partly due to limited well designed studies and the difference in study population, definition of UTI, and antibiotic prophylaxis intervention. Based on a Best practice policy statement on urodynamic antibiotic prophylaxis in patients with UTI risk factors, it is recommended antibiotic prophylaxis for UDS in the high-risk patients, which includes patients with relevant neurogenic lower urinary tract dysfunction, bladder outlet obstruction, and/or elevated post-void residual, age over 70 years, asymptomatic bacteriuria,



**Figure 2.** Microbiological and antimicrobial resistance profiles of urine culture at baseline and 48 hours after urodynamic study. A) Uropathogen at baseline urine culture; B) Antimicrobial resistance profiles of Enterobacteriaceae pathogens at baseline urine culture; C) Uropathogen of urine culture at 48 hours after urodynamic study; D) Antimicrobial resistance of Enterobacteriaceae pathogens of urine culture at 48 hours after urodynamic study.

**Table 2.** Primary and secondary outcomes

Outcomes	Number of patients (%)		p-value
	Non-antibiotic prophylaxis group n=13	Antibiotic prophylaxis group n=13	
Primary outcome			
Symptomatic UTI after UDS	5 (38.5)	0 (0)	0.04
Secondary outcome			
Microbiological clearance in urine <sup>a</sup>	0 (0)	8/11 (72.7)	<0.001

UTI = urinary tract infection; UDS = urodynamic study; CI = confidence interval

<sup>a</sup> Microbiological clearance in urine was defined as a proportion of negative urine cultures at 48 hours after UDS in each group.

immunosuppression, and chronic catheter. However, there is not a high-level of evidence supporting this recommendation ('Level of evidence IV'; limited evidence and expert opinion)<sup>(8)</sup>.

A retrospective cohort study with 661 spinal cord injury patients from three units of the same hospital network adopted different protocols regarding the preparation of patients for UDS. In summary, there were 3 protocols: A) given a single-dose antibiotic prophylaxis, 1-hour before UDS in patients with or without bacteriuria; B) not given antibiotic prophylaxis; and C) given a single-dose antibiotic prophylaxis,

2-hour before UDS in patients with bacteriuria but none in those without bacteriuria. The overall UTI rate observed after UDS was 3.2%, without distinction between the protocols A (2.5%), B (3.4%), and C (3.7%). This study concluded that the use of antibiotics does not prevent UTI after UDS<sup>(4)</sup>. In contrast, a small, randomized prospective study that included 40 patients with spinal cord injury to received either a 3-day oral course of ciprofloxacin or placebo, beginning 2 days prior to UDS, demonstrated trend toward protective efficacy of antibiotic prophylaxis for preventing



symptomatic UTI after UDS (14% vs. 0% in ciprofloxacin and placebo, respectively;  $p=0.24$ )<sup>(16)</sup>.

The results from our study could add important data supporting the benefit of antibiotic prophylaxis before UDS for preventing symptomatic UTI among these high-risk groups. Despite the early termination of the study due to safety concerns, the efficacy of antibiotic prophylaxis before UDS was still significantly demonstrated. Patients with a neurogenic bladder commonly colonized with bacteria in the bladder and frequently develop symptomatic UTI which is a common cause of morbidity and mortality in these patients. In general, there are not recommended to screen and treat asymptomatic bacteriuria in these patients because the lack of benefits for preventing symptomatic UTI, and the increase in reinfecting strains with antimicrobial resistance. However, when these patients undergo an invasive urological procedure, they are at risk for complication with symptomatic UTI. The incidence rate of symptomatic UTI after UDS in the present study was higher (38.5%) than previous reports (3.2% to 15.8%)<sup>(4,6)</sup>. This was probably due to difference in study populations, which we focused on patients with asymptomatic bacteriuria and that almost had a neurogenic bladder. In addition, we specifically selected the populations with pyuria to study because the presence of pyuria raises a great concern among physicians and results in unnecessarily prolonged course of antibiotics for the clearance of pyuria prior to proceeding with a UDS. This practice leads to an emergence of antimicrobial resistance, risks for adverse drug events, increased cost of treatment, and prolonged hospitalization. The present study supports a single-dose antibiotic prophylaxis before UDS for prevention of symptomatic UTI in high-risk populations.

A single-dose of TMP-SMX within an hour prior to UDS is recommended as a first choice for prophylaxis<sup>(7)</sup>. However, the growing problem of antimicrobial resistance particularly in Enterobacteriaceae is our concern for the proper choice of antibiotic use for prophylaxis. In our hospital, we have used these study drugs for prophylaxis before UDS since 2004. The majority of uropathogens were still in the Enterobacteriaceae pathogens, which the most common was *Escherichia coli* similar to the previous study<sup>(2)</sup>. In the present study, reported ESBL- and MDR-strains of Enterobacteriaceae pathogens were 24.1% and 6.9%, respectively. Gentamicin resistance among these pathogens was up 10.3%. Twenty-three percent of patients had colonization with bacteria in their urine which was resistant to prophylactic antibiotics but none developed symptomatic UTI. This may be explained by the high concentration of gentamicin in the urine that might overcome the resistant uropathogen. However, in the current situation of global emerging bacterial resistance, using local antibiogram or screening the urine culture before UDS could guide for selecting the appropriate drug for prophylaxis.

The present study has some limitations. The open-label design, which could have caused bias in both participants and study investigators. However, we had a blinded investigator for assessing the clinical outcomes. The present

study was conducted in one center and limited in patients with neurogenic bladder who undergoing UDS which consisted of VCUG and bedside cystometry, therefore the results may not be generalizable outside the study setting. A small sample size limits strong conclusion of the study results due to the by chance effect, false-positive results, and effect of the confounder. However, the continuation of the randomization with the possibility of harms from the non-antibiotic prophylaxis would have not been ethical. Finally, we could not evaluate the effect of antibiotic prophylaxis before UDS to the emergence of antimicrobial resistance due to the short period of follow-up.

## Conclusion

Antibiotic prophylaxis reduced the incidence of symptomatic UTI in patients with neurogenic bladders with asymptomatic bacteriuria who undergoing UDS. A single-dose of antibiotic within an hour prior to UDS seems to be a proper option. Concern of the emerging problem of antimicrobial resistance particularly in Enterobacteriaceae pathogens, using local antibiogram or screening urine cultures before UDS could help for appropriate selection of prophylactic antibiotics.

## What is already known in this topic?

Asymptomatic bacteriuria may not require treatment, but some studies suggest that it has increased risk for UTI after UDS in spinal cord injury patients with neurogenic bladder. The incidence rate of UTI after UDS varies. The role of antibiotic prophylaxis before and immediately after UDS is controversial. Some studies suggest considering antibiotic prophylaxis for UDS in high-risk patients.

## What this study adds?

Prophylactic antibiotics before UDS have protective efficacy to prevent symptomatic UTI after UDS in asymptomatic bacteriuria patients, especially with neurogenic bladders. A single-dose of antibiotic within an hour prior to UDS seems to be a proper option.

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## Potential conflicts of interest

The authors declare no conflict of interest.

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