Pilot Study of a Non-Return Catheter Valve for Reducing Catheter-Associated Urinary Tract Infections in Critically Ill Patients

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Objective: *To determine the effectiveness of a non-return catheter valve vs. the standard urine bag for prevention of catheter-associated urinary tract infections (CAUTI) in critically ill patients.*
Material and Method: *This was a pilot, randomized, stratified, open-label controlled trial (ClinicalTrials.gov, number NCT01963013). Ninety-six critically ill patients requiring indwelling urinary catheter were assigned with either a non-return catheter valve or the standard urine bag. Symptoms and signs of CAUTI before and after enrollment for all patients were recorded. If CAUTI was suspected, urine for microbiological testing was collected. The primary outcome was the incidence density rate of symptomatic CAUTI and bacteriurial presence.*
Results: *The 96 patients were randomized into two groups. Baseline patient characteristics were similar in both groups except for the sex distribution. The incidence rate ratio was 0.71 for symptomatic CAUTI in the non-return catheter valve group (95% CI 0.25-1.98, p-value = 0.51). The crude incidence rate ratio of bacteriuria in the non-return valve group was 0.66 (95% CI 0.3-1.46, p-value = 0.31). The sex-adjusted incidence rate ratio of bacteriuria in the non-return catheter valve group was 0.64 (95% CI 0.29-1.41, p-value = 0.27).*
Conclusion: *Using a non-return catheter valve might not prevent CAUTI among critically ill patients.*

Keywords: *Non-return catheter valve, Catheter-associated urinary tract infection, Critically ill patients*

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Critically ill patients have the greatest risk for developing catheter-associated urinary tract infections (CAUTI)[1], because most of them have an indwelling urinary catheter for extended periods which need to be opened frequently for accurate measurement of urine output. Clinical outcomes when CAUTI developed include increased morbidity and mortality plus higher healthcare costs. Platt et al found that acquisition of CAUTI was associated with nearly a threefold increase in mortality[2].

The 2011 review of the National Healthcare Safety Network (NHSN) reported that the incidence density rate of CAUTI among critical care units ranged between 1.2 and 4.5 cases per 1,000 urinary catheter days, depending on the type of critical care unit[3]. The 2009 report on CAUTI at the Critical Care Unit of Srinagarind Hospital, Thailand, revealed an incidence density rate of 5.5 cases per 1,000 urinary catheter days.

Varying catheter material is one of the methods for preventing CAUTI - e.g., antimicrobial/antiseptic catheters, hydrophilic catheters, closed drainage system catheters, pre-connected/sealed junction catheters and catheter valves[4]. A 2006 systematic review found no differences in bacteriuria/unspecified UTI vis-à-vis catheter values and prevention of CAUTI[5]. There are scant evidences of non-returning catheter valve for preventing CAUTI in the critically ill patients. Moreover, study about catheter valve for preventing CAUTI in the critically ill patients was conducted in mixed ICU and determined rate of bacteriuria[6]. Therefore, the present study aimed to establish whether non-return catheter valves might reduce either the incidence of symptomatic CAUTI or

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bacteriuria over the standard urine bag in medical critically ill patients.

Material and Method

Study design and participants

This was a single center, stratified, open label, randomized, controlled trial. The study was conducted at the Medical Intensive Care Unit (MICU) and the Intermediate Care Unit of the Srinagarind Hospital in Khon Kaen, Thailand, from June 2012 to December 2012. Eligible participants were adults age 18 and over who required an indwelling urinary catheter at admission to the MICU or the Intermediate Care Unit. Ineligible participants were those (a) who had a prior urinary tract infection before undergoing urethral catheterization or (b) who had a positive urine culture at baseline.

All competent patients provided written informed consents, while those with an altered mental status had consent given by their legal representative(s). This trial was approved by the Khon Kaen University Ethics Committee for Human Research (KKUEC).

Randomization and masking

Participants were allocated and stratified by simple randomization by APACHE II scores into two groups. Patients in the intervention group had a standard catheter connected to a non-return catheter valve drainage system (Unometer™ Safeti™ Plus), while those in the control group had a standard catheter connected to simple urine bag with a closed system. The allocation sequence was kept in an opaque envelope.

Procedures

The primary endpoint was the incidence density rate of symptomatic CAUTI and bacteriuria in both groups, according to the 2009 CDC definition of symptomatic CAUTI[7]. At baseline, vital signs and symptoms of urinary tract infection were obtained, including suprapubic and costovertebral angle tenderness along with urinalysis, urine Gram stain and urine culture. The studied patients were followed daily for signs and symptoms of UTI until (a) 48 hours after the catheters were removed, (b) the patient died, or (c) the patient was diagnosed with UTI. A urine sample from each patient was taken for quantitative culture when he/she was suspected of having UTI. All participants obtained a CAUTI prevention bundle, which was composed of an indwelling urinary catheter to maintain a closed drainage system keeping the collecting bag below the level of bladder. The collecting bag was emptied regularly. Hand hygiene was carried out before and after the procedure.

Statistical analysis

Data analyses were performed using R (R Development Coreteam, GNU General Public License). The incidence density of CAUTI at the hospital during 2009 was 5.5 cases per 1,000 urinary catheter days. In order to reduce the incidence by 20% with an 80% power test and a 5% one-sided type I error. Seven thousand one hundred ninety three participants were needed in each group (calculated by used two-side Type I error was 9,129 participants in each group which was impossible to do). Due to budget and equipment limitations, the pilot study was conducted with 50 recruits per group.

Descriptive statistics were used for the continuous data, including frequency, percentage, mean, median and standard deviation. Inferential statistics were used to compare the primary outcomes of each group. Simple Poisson regression was applied, then adjusted for any confounding variables using multiple Poisson regression. Variables from the bivariable simple Poisson regression were chosen with a p-value <0.25 and put into the model. All of the participants were based on the intention to treat.

Results

Between June 1, 2012, and December 31, 2012, 100 participants, 50 cases were randomized into the non-return catheter valve group, and 50 into the standard urine bag group. Two patients in each group were excluded because they had a UTI at baseline.

Baseline demographic and clinical characteristics of the patients in the study were similar in both groups except for the sex distribution (Table 1). The median catheter days were comparable, i.e.: 7 days in the non-return catheter valve group and 8 days in standard urine bag group. In more than 90% of the cases, the main indication for retained indwelling urinary catheter was monitoring urine output. Previous and concurrent antibiotic exposured, numbers of urine cultures and analysis were similar in both groups. Moreover, incidence of fever during the research period was slightly higher in non-return catheter valve group (Table 1).

Primary outcome

The respective incidence density rate of symptomatic CAUTI in the non-return catheter valve group vs. the simple urine bag group was 12.9 vs.

18.3 cases per 1,000 urinary catheter days. The incidence rate ratio of symptomatic CAUTI in the non-return catheter valve group was 0.71 (95% CI 0.25-1.98, *p*-value 0.51). After adjusting for sex and the APACHE II score, the incidence rate ratio of symptomatic CAUTI in the non-return catheter valve group was not significantly lower than the simple urine bag group (Table 2).

An analysis with respect to bacteriuria was done and found no significant differences between the two groups. The incidence density rate of bacteriuria in the non-return catheter valve group vs. the simple urine bag group was 21.5 vs. 32.5 cases per 1,000 urinary catheter days. The crude incidence rate ratio of bacteriuria in the non-return catheter valve group was 0.66 (95% CI 0.3-1.46, *p*-value 0.31). After adjusting for sex, the incidence rate ratio of bacteriuria in the non-return catheter valve group was not significantly lower than the simple urine bag group. The adjusted incidence rate ratio for bacteriuria in the non-return catheter valve group was 0.64 (95% CI 0.29-1.41, *p*-value 0.27) (Table 2). Being female was a significant risk factor for bacteriuria in critically ill patients, which had an adjusted incidence rate ratio 2.33 (95% CI 1.06-5.03, *p*-value 0.03) (Table 2).

Microbiological data

Candida spp. and *Enterococcus* spp. were the most common identified organisms causing symptomatic CAUTI 15 and 7 cases. Other organisms found subsequently were *Pseudomonas aeruginosa* and *Escherichia coli*.

Discussion

The symptomatic UTI rate in patients with indwelling urethral catheters with simple urinary drainage bags (the incidence density rate of CAUTI of 18.3 episodes per 1,000 catheter days) was higher than those reported by the National Healthcare Safety Network (NHSN) in 2011, which reported only 1.2 to

Table 1. Baseline characteristics of the 96 eligible participants

	Non-return catheter valve group (n = 48)	Simple urine bag group (n = 48)
Female, n (%)	18 (37.50)	14 (29.17)
Age (years), mean (SD)	58.33 (16.85)	58.19 (19.15)
APACHE II score (points), mean (SD)	22.31 (8.48)	21.10 (9.04)
Catheter days (days), median (IQR)	7 (4.5-12.5)	8 (4.5-13.5)
Indication for retaining catheters, n (%)		
Record urine output	47 (97.92)	45 (93.75)
Neurogenic bladder	0 (0)	2 (4.17)
Others	1 (2.08)	1 (2.08)
Prior antibiotic exposure, n (%)	8 (16.67)	8 (16.67)
Diagnoses, n (%)		
Pneumonia	12 (25.00)	12 (25.00)
GI bleeding	2 (4.17)	4 (8.33)
Solid malignancy	8 (16.67)	7 (14.58)
Hematologic malignancy	4 (8.33)	4 (8.33)
Renal failure	6 (12.5)	9 (18.75)
Septicemia	7 (14.58)	4 (8.33)
Heart failure	3 (6.25)	7 (14.58)
Cerebrovascular disease	5 (10.42)	8 (16.67)
Others	9 (18.75)	10 (20.83)
Concurrent antibiotics use, n (%)	46 (95.83)	47 (97.92)
Narrow spectrum	7 (14.58)	8 (16.67)
Broad spectrum	39 (81.25)	39 (81.25)
Fever, n (%)	31 (65.96)	27 (57.45)
Rate of urine culture per 1,000 urinary catheter days	141.63	148.07
Rate of urine analysis per 1,000 urinary catheter days	253.22	239.35

SD = standard deviation; IQR = interquartile range; GI = gastrointestinal

Table 2. Univariable and multivariable Poisson regressions for symptomatic CAUTI and positive urine cultures in the non-return catheter valve group

Factors affecting CAUTI	Symptomatic CAUTI				Positive urine culture			
	Univariable model		Multivariable model		Univariable model		Multivariable model	
	Crude rate ratio	*p*-value	Adjusted rate ratio (95% CI)	*p*-value	Crude rate ratio	*p*-value	Adjusted rate ratio (95% CI)	*p*-value
Non-return catheter valve	0.71	0.51	0.71 (0.25-1.98)	0.51	0.66	0.31	0.64 (0.29-1.41)	0.27
Female	2.24	0.12	-	-	2.29	0.04	2.33 (1.06-5.03)	0.03
Age	1.00	0.96	-	-	1.00	0.79	-	-
APACHE II score	0.96	0.21	-	-	0.99	0.67	-	-
Indication for recording urine output	0.49	0.36	-	-	0.90	0.89	-	-
Prior antibiotics exposure	1.20	0.78	-	-	0.87	0.81	-	-
Diagnoses								
Pneumonia	1.05	0.94	-	-	1.06	0.89	-	-
GI bleeding	0	0.99	-	-	0	0.99	-	-
Solid malignancy	0.46	0.45	-	-	0.53	0.39	-	-
Hematologic malignancy	0	0.99	-	-	0.84	0.81	-	-
Renal failure	0	0.99	-	-	0.85	0.80	-	-
Septicemia	0.39	0.37	-	-	0.71	0.58	-	-
Heart failure	1.60	0.54	-	-	2.48	0.07	-	-
Cerebrovascular disease	1.57	0.49	-	-	1.49	0.42	-	-
Concurrent antibiotic use	$2.27x10^6$	0.99	-	-	$3.94x10^6$	0.99	-	-
Narrow spectrum	0.57	0.59	-	-	0.66	0.58	-	-
Broad spectrum	2.02	0.50	-	-	1.73	0.46	-	-

CAUTI = catheter-associated urinary tract infection; APACHE = acute physiology and chronic health evaluation; CI = confidence interval; GI = gastrointestinal

4.5 cases per 1,000 urinary catheter days, depending on the type of critical care unit[3]. This was higher than the 2009 CAUTI report on the Critical Care Unit at Srinagarind Hospital, where the incidence density rate was 5.5 cases per 1,000 urinary catheter days. The possibility of higher UTI rate in the current study might be from daily checking for signs and symptoms of UTI. However, some critically ill patients cannot communicate symptoms of UTI, i.e.: suprapubic tenderness and costovertebral angle tenderness, for example, because of either endotracheal intubation or sedation. Fever in critical ill patients might be due to several sources of infection (i.e., pneumonia); consequently, patients who developed fever have frequent urine cultures done. The frequency of urine cultures in the current study was 140 to 148 per 1,000 urinary catheter days, which is greater than the usual rate of 105 per 1000 urinary catheter days[8]. Therefore, the rate of symptomatic CAUTI in this study might, therefore, included both of symptomatic and asymptomatic CAUTI.

In the current randomized, controlled trial of critical ill patients with an indwelling urinary catheter, patients in the non-return catheter valve group did not have significantly lower adjusted incidence rate ratio of symptomatic CAUTI and bacteriuria than those in the simple urine bag group [0.71 (95% CI 0.25-1.98, *p*-value 0.51) and 0.64 (95% CI 0.29-1.41, *p*-value 0.27).

Possible mechanisms for preventing UTI in the non-return catheter valve group might be (a) the non-return catheter valve preventing reflux of urine in the drainage system into the bladder, and (b) its being closed system. Based on the present study, neither symptomatic CAUTI nor bacteriuria was prevented by the non-return catheter. The pathogenesis of CAUTI can be via (a) the extraluminal route, (b) migration of organisms along the outside of the catheter or the intraluminal route, (c) reflux of contaminated urine in the urinary catheter or bag, or (d) secondary bacteremia. The non-return catheter valve, therefore, might prevent only intraluminal ascent. These findings were similar

to studies by German et al[9] and Wilson et al[10] who found no difference in UTI between using a catheter valve and a standard urinary bag. The results were also similar to the study on the use of an anti-reflux valve in critically ill patients by Leone et al. who found that catheter-associated bacteriuria did not differ between groups[6].

Limitations of the present study were (a) the small sample size, (b) its open label nature, and (c) non-masking of the assessors who determined the outcomes.

Conclusion

This pilot study demonstrated that the critical ill patients who received non-return catheter valve indwelling urinary catheter, the non-return catheter might not prevent the symptomatic CAUTI or bacteriuria as compared with patients receiving standard urine bag.

What is already known on this topic?

Catheter-associated urinary tract infection (CAUTI) is a major problem in patients who required indwelling urinary catheter. Guideline for prevention CAUTI in 2009 recommended several methods such as proper techniques for urinary catheter insertion and maintenance. Urinary catheter materials and collection systems are strategic prevention, but were not of sufficient quality to allow firm conclusions especially in the critically ill patients.

What this study adds?

The present study was to assess the effectiveness of a non-return catheter valve vs. the standard urine bag for prevention of CAUTI in critical ill patients. The outcomes of this study did not show the benefit of non-return catheter valve for CAUTI prevention, which confirm similar results from previous study.

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Potential conflicts of interest

None.

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การศึกษานำร่องในการใช้วาล์วป้องกันการไหลย้อนกลับของปัสสาวะเพื่อลดอัตราการเกิดการติดเชื้อในทางเดินปัสสาวะที่สัมพันธ์กับการใส่สายสวนปัสสาวะในผู้ป่วยภาวะวิกฤต

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วัตถุประสงค์: *ศึกษาประสิทธิผลของกระบอกตวงปัสสาวะที่มีวาล์วป้องกันการไหลย้อนกลับของปัสสาวะ เปรียบเทียบกับถุงเก็บปัสสาวะมาตรฐานที่ไม่มีวาล์วป้องกัน ในการป้องกันการติดเชื้อในทางเดินปัสสาวะที่สัมพันธ์กับการใส่สายสวนปัสสาวะในผู้ป่วยวิกฤต*

วัสดุและวิธีการ: *เป็นการศึกษาวิจัยนำร่องเชิงทดลองแบบสุ่มตามชั้นภูมิและมีกลุ่มควบคุม ผู้ป่วยวิกฤตที่ได้รับการใส่สายสวนปัสสาวะจำนวน 96 ราย ถูกสุ่มให้อยู่ในกลุ่มที่ใช้กระบอกตวงปัสสาวะที่มีวาล์วป้องกันการไหลย้อนกลับของปัสสาวะ หรือ กลุ่มที่ใช้ถุงเก็บปัสสาวะมาตรฐาน อาการและอาการแสดงของการติดเชื้อในทางเดินปัสสาวะที่สัมพันธ์กับการใส่สายสวนปัสสาวะจะถูกบันทึกก่อนและหลังผู้ป่วยเข้าการศึกษา ปัสสาวะจะถูกเก็บส่งตรวจทางจุลชีววิทยาในผู้ป่วยที่สงสัยว่ามีการติดเชื้อในทางเดินปัสสาวะ ผลลัพธ์ของการศึกษาหลักคือ อุบัติการณ์ของการติดเชื้อในทางเดินปัสสาวะที่สัมพันธ์กับการใส่สายสวนปัสสาวะชนิดที่มีอาการ และไม่มีอาการ*

ผลการศึกษา: *ผู้ป่วย 96 ราย ถูกสุ่มให้อยู่ใน 2 กลุ่ม ลักษณะพื้นฐานทางคลินิกของผู้ป่วยทั้งสองกลุ่มคล้ายกันยกเว้นเพศ อัตราส่วนอุบัติการณ์ของการติดเชื้อในทางเดินปัสสาวะที่สัมพันธ์กับการใส่สายสวนปัสสาวะชนิดที่มีอาการในกลุ่มที่ใช้กระบอกตวงปัสสาวะที่มีวาล์วป้องกันการไหลย้อนกลับของปัสสาวะเท่ากับ 0.71 (95% CI 0.25-1.98, p-value = 0.51) อัตราส่วนอุบัติการณ์อย่างหยาบของการติดเชื้อในทางเดินปัสสาวะที่สัมพันธ์กับการใส่สายสวนปัสสาวะชนิดที่ไม่มีอาการในกลุ่มที่ใช้กระบอกตวงปัสสาวะที่มีวาล์วป้องกันการไหลย้อนกลับของปัสสาวะเท่ากับ 0.66 (95% CI 0.3-1.46, p-value = 0.31) หลังจากปรับปัจจัยเพศอัตราส่วนอุบัติการณ์ของการติดเชื้อในทางเดินปัสสาวะที่สัมพันธ์กับการใส่สายสวนปัสสาวะชนิดที่ไม่มีอาการในกลุ่มที่ใช้กระบอกตวงปัสสาวะที่มีวาล์วป้องกันการไหลย้อนกลับของปัสสาวะเท่ากับ 0.64 (95% CI 0.29-1.41, p-value = 0.27)*

สรุป: *การใช้กระบอกตวงปัสสาวะที่มีวาล์วป้องกันการไหลย้อนกลับของปัสสาวะอาจจะไม่สามารถป้องกันการติดเชื้อในทางเดินปัสสาวะที่สัมพันธ์กับการใส่สายสวนปัสสาวะในผู้ป่วยวิกฤต*