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Impact of mupirocin and betadine-impregnated urethral catheter on the incidence rate of catheter-related bacteriuria and urinary tract infections, in comparison with conventional catheterization

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ABSTRACT

Introduction: One of the most common nosocomial infections is urinary tract infection (UTI), which more commonly seen in patients with urethral catheter. Inappropriate use of urinary catheter can lead to certain complications including infection.
Objectives: The aim of this study was to evaluate the effect of using mupirocin and betadine-impregnated urethral catheters in comparison with conventional catheterization on the incidence rate of catheter-related bacteriuria (CRB) and UTIs.
Patients and Methods: In this parallel randomized clinical trial, phase III, a total of 150 patients (male and female) ranging from 18-75 years who needed urinary catheterization were randomly assigned into three evenly distributed groups; betadine, mupirocin, and conventional (control) through permuted block randomization. Sterile urine samples were examined for bacteriuria after catheter insertion and at the time of catheter removal.
Results: The mean age of the patients was 49.81 (±15.11) years. UTI was seen most frequently in the conventional group (56%), and least frequently in the mupirocin group (24%) ($P<0.004$). A significant difference was observed in incidence of post-catheterization UTI between the conventional and mupirocin groups, as well as between the conventional and betadine groups ($P=0.001$ and $P=0.04$, respectively).
Conclusion: Using antibiotic and antiseptic-impregnated catheters (both mupirocin and betadine) could help to decrease the incidence rate of UTI in comparison to the conventional catheterization.
Trial registration: The trial was registered with the TCTR ID: TCTR20200627001 (http://www.clinicaltrials.in.th/index.php?tp=regtrials&menu=trialsearch&smenu=fulltext&task=search&task2=view1&id=6442).

Original

Implication for health policy/practice/research/medical education:
In a study on 150 patients ranging from 18-75 years who needed urinary catheterization, we found short-term use of mupirocin and betadine-impregnated catheters were more effective in reducing bacteriuria and the urinary tract infections compared to conventional catheterization.
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Introduction

Bacteriuria is the hallmark of urinary tract infection (UTI). In women, asymptomatic bacteriuria is defined as two consecutive voided midstream urine specimens with isolation of the same bacterial strain at levels of at least 105 colony-forming units (CFU) per milliliter from patients without genitourinary symptoms. In men, a single clean-catch, midstream voided urine specimen with one bacterial species at a concentration greater than 105 CFU/mL defines asymptomatic bacteriuria.

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Hospital-acquired infections (HAIs), also known as nosocomial infections, are defined as infections with an onset of more than 48 hours after admission and within 7 to 30 days after facility discharge. HAI is one of the most common causes of morbidity and mortality in hospitalized patients (1). It can lead to multiple preventable complications (2). The most common nosocomial infection is urinary tract infection, which constitutes approximately 40% of nosocomial infections. The term UTI refers to significant bacteriuria in a patient with symptoms or signs attributable to the urinary tract with no alternative diagnosis. UTI can involve any part of the urinary system and includes asymptomatic bacteriuria, urethritis, cystitis, pyelonephritis, catheter-associated UTI, prostatitis, and urosepsis. Among UTIs, acquired in the hospital, approximately 80% are associated with a urinary catheter, which is a tube inserted into the bladder through the urethra to drain urine (3,4). Fifteen to twenty five percent of patients admitted in the emergency unit have urinary tract catheter and consequently more than half of them develop bacteriuria after five days of admission (5).

The most important risk factor for developing a catheter-associated UTI (CAUTI) is prolonged use of the urinary catheter, since the chance of developing bacteriuria in hospitalized patients with urinary catheter is 1-3% per day in adults and 15% in elderly. After 1-2 weeks of admission, almost 35% of adults and 75% of elderly patients with catheter develop UTI, which one fifth of them are symptomatic (6). Several strategies are recommended to reduce the risk of CAUTIs including; educating the patients, caregivers, and the staff to wash their hands regularly, avoiding the unnecessary catheterization, using sterile techniques for catheterization, prescribing systemic antibiotics only if indicated, using closed drainage systems, frequent emptying the urine bag the use of catheter valves to prevent urinary reflex, removing the catheter as soon as possible, and using antibiotic/antiseptic-impregnated catheters (7). Several studies were conducted on different methods which were originally thought to be useful in reducing the incidence of catheter-associated UTI. Koskeroghlo et al showed that meatal disinfectants are not significantly effective in preventing CAUTIs (8). Similarly, Waitz et al showed ineffectiveness of the bladder washing solutions (acetic acid, neomycin–polymyxin or normal saline 0.9%) (9). Daily disinfecting meatus and urinary catheter with 10% povidone-iodine ointment (once a day for men and twice a day for women) were evaluated by Basami et al in hospitalized male patients in neurologic wards, which showed possible effect on reducing the CAUTIs (10).

In patients with catheter, microorganisms mainly gain access to the catheterized urinary tract by two routes; extra-luminal (the space between catheter and the urinary tract mucosa; at the time of insertion or later on by capillary action in the thin mucous film contiguous to the external catheter surface) or intra-luminal (by reflux of microorganisms gaining access to the catheter lumen from failure of closed drainage or contamination of urine in the collection bag) (11). Therefore, no definite conclusion has not been made yet on using antibacterial and antiseptic substances (chemical barriers) in preventing catheter-associated bacteriuria and UTIs.

Objectives

This study was conducted to evaluate the effectiveness of antibiotic (mupirocin) and antiseptic (betadine) substances as the extra-luminal mechanical and chemical barriers for microorganisms, in reducing the CAUTIs by comparing these methods with the conventional catheterization.

Patients and Methods

Patients

In this parallel randomized clinical trial, phase III, a total of 150 admitted patients in Hajar and Kashani hospitals (Shahrekord) enrolled in the study. Inclusion criteria were all hospitalized patients older than 18 years of age who were admitted in urology, intensive care, cardiac care, surgery, and neurology departments who required urinary catheterization. Exclusion criteria were positive urinary culture at the time of urinary catheterization, prior antibiotic consumption or history of urology operation before or during the study. Data collected by researcher-made questionnaire included demographic characteristics and background information such as the wards of hospitalization, catheterization indications, the type of catheter and the technique of catheterization. This questionnaire was developed using the relevant textbooks, articles, and the viewpoints of 10 faculty members of urology and infectious diseases departments at Shahrekord University of Medical Sciences.

All 150 selected patients in this study were randomly assigned to three groups of 50 patients through permuted block randomization (Figure 1). In the first group (mupirocin group), silicon urinary catheter was impregnated with mupirocin ointment and inserted using aseptic technique, and the urethral meatus was disinfected with mupirocin ointment, four times a day. In the second group (betadine group), the same protocol was carried out using betadine ointment, and in the third group, routine catheterization was conducted as conventional catheterization. Before collecting the urinary samples, patients were informed about the aims of this study and the informed consent was obtained

In all three groups, the urinary catheter was inserted in accordance with the physician's order by the research assistant. Simultaneously, upon acquiring patient's informed consent, urine samples were collected from the urinary catheters using 10 cc sterile syringe and sent to

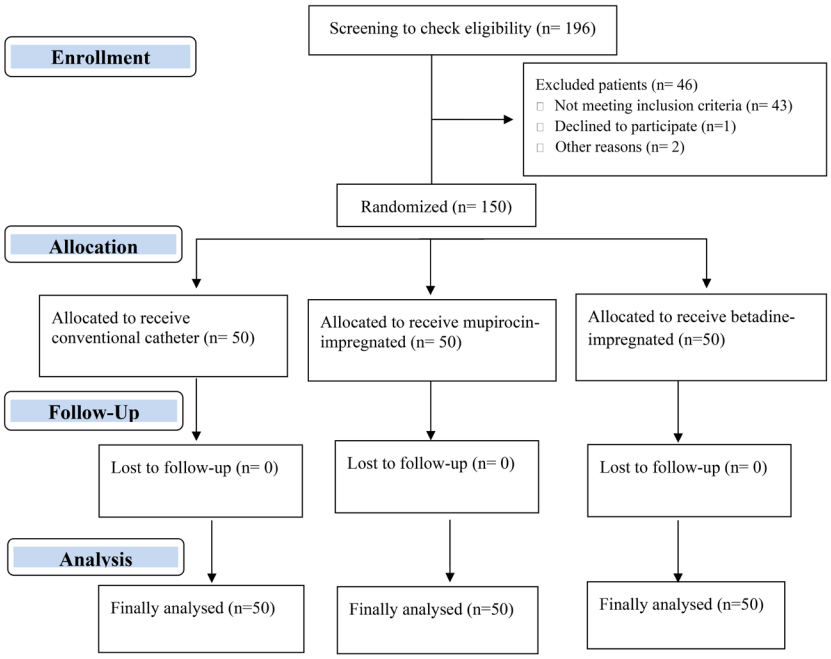

Figure 1. CONSORT flow chart showing the flow of patients through the trial.

laboratory in less than 30 minutes to check for bacteriuria. All urinary tests were conducted by a single person and in the same laboratory. To perform the tests, sterilized test tubes with cotton plugs, blood agar, McConkey agar, optical microscope, and incubator were used. Positive urine culture was defined as colony count of ≥ 1000/CFU/mL. Second urine samples were collected after two weeks of catheterization with the same technique.

Ethical issues

The research followed the tenets of the Declaration of Helsinki. This paper was extracted from the MD student thesis of Amir Qorbani, Kashani Hospital, School of Medicine, Shahrekord University of Medical Sciences. The study was approved by the ethics committee of the Shahrekord University of Medical Sciences (#739). Accordingly, informed consents were obtained from all the patients. The trial was also registered in Thai Clinical Trials Registry (TCTR20200627001; http://www.clinicaltrials.in.th/index.php?tp=regtrials&menu=trialsearch&smenu=fulltext&task=search&task2=view1&id=6442).

Statistical analysis

Descriptive statistics (frequency, relative frequency, mean, and standard deviation) and analytical statistics were used to analyze data. All the analysis was conducted using SPSS. The Kolmogorov-Smirnov statistical test demonstrated that the data do not have normal distribution. Thus, the nonparametric (Mann-Whitney U, and chi-square test) tests were used to analyze the data. $P<0.05$ was considered statistically significant.

Results

The mean age of the patients was 49.81 ± 15.11 years. The duration of catheterization was between 3-10 days. The number of patients in neurology, urology, ICU, CCU, surgery wards were 25, 26, 32, 28 and 39 patients, respectively. There were no significant differences in age, gender and the duration of catheterization among the three groups of the study ($P>0.05$).

We found, the incidence of UTIs was 56% in the control group (conventional catheterization), 36% in the betadine group (betadine-impregnated urethral catheter), and 24% in mupirocin group (mupirocin-impregnated urethral catheter). Kruskal-Wallis test showed a significant difference in the incidence rate of the UTIs among the three groups ($P=0.004$; Table 1). Mann-Whitney U test showed a statistically significant difference in the incidence rate of the UTIs between the conventional and mupirocin groups as well as between the conventional and betadine groups ($P=0.001$ and $P=0.04$, respectively), however, no significant difference was observed between the betadine and mupirocin groups ($P=0.19$).

Chi-square test did not demonstrate any significant relationship between gender and UTI incidence among the three groups ($P>0.05$; Table 2).

Most common cause of UTIs – *Escherichia coli* – was found in 55.2% of patients with positive culture. Accordingly, there was no significant difference in the

Table 1. The rate of acquiring urinary tract infections in the groups of study

Technique		Infection acquisition		*P* Value
		Yes	No	
Conventional catheter	Male	12	13	0.39
	Female	16	9	
Betadine-impregnated catheter	Male	7	18	0.37
	Female	11	14	
Mupirocin-impregnated catheter	Male	6	19	1
	Female	6	19	

Table 2. The relationship between gender and UTI in three groups

Catheterization technique	Infection acquisition	
	Yes	No
Conventional	28 (56%)	22 (44%)
Betadine-impregnated catheter	18 (36%)	32 (64%)
Mupirocin-impregnated catheter	12 (24%)	38 (76%)

causes of the UTIs among the different groups ($P > 0.05$) (Table 3).

The mean age of patients with and without the CAUTI was 55.4 (14.52) and 48.4 (14.92) years, respectively. The results of Mann–Whitney U showed significant differences between the incidence rate of the UTIs and age of subjects ($P < 0.001$), since the incidence rate of UTIs was higher in the older people. The results of Mann–Whitney U showed a significant difference in the incidence rate of the CAUTIs and the duration of different catheterization ($P < 0.001$).

The results demonstrated that dysuria was the most common manifestation in CAUTI, while the patients in the betadine-impregnated catheter complained of dysuria more than those in the other groups. Patients in the mupirocin group reported the least complaint (20%) compared to the other two groups (Table 4). Overall complications in conventional, betadine impregnated catheter, and mupirocin impregnated catheter groups were 80%, 56% and 42%, respectively.

Discussion

The mortality and morbidity rates of catheter-associated UTIs imposes a tremendous economic burden on health systems and the patients. Hence, certain strategies should be developed in order to prevent such infections. Our study was conducted to evaluate the effect of using mupirocin and betadine-impregnated urethral catheters on the incidence rate of catheter-associated bacteriuria and urinary tract infections in comparison with the conventional catheterization. Our results showed that impregnating catheters by mupirocin or betadine can reduce CAUTI incidence by acting as a chemical and mechanical barrier against the microorganisms through external route.

Even though our study shows that antimicrobial catheters could minimize CAUTI risk, however, there is a considerable uncertainty regarding their usefulness and the cost-effectiveness of these methods. Pickard et al, studied three types of antimicrobial catheters. They showed that nitrofurazone-impregnated urinary catheters were not as effective as the standard polytetrafluoroethylene (PTFE)-coated latex catheter (control) in reducing the incidence rate of the CAUTIs. In addition, silver alloy-impregnated catheters were neither effective in reducing the risk of these infections nor more economical than the PTFE coated latex catether (12). The difference between the results of our study and the study by Pickard et al may

Table 3. The causes of urinary tract infections in the studies groups

Catheterization technique	Miscellaneous	*Pseudomonas aeruginosa*	*Escherichia coli*	Mixed
Conventional catheter	2 (4%)	3 (6%)	17 (34%)	7 (14%)
Betadine-impregnated catheter	1 (2%)	2 (4%)	7 (14%)	8 (16%)
Mupirocin-impregnated catheter	1 (2%)	1 (2%)	8 (16%)	2 (4%)

Table 4. The incidence rate of different catheterization-associated side effects in different groups

Technique		Side effects							
		Fever	Flank pain	Catheter obstruction	Urinary incontinence	Dysuria	Hematuria	Wound	Obstruction tract
Conventional method	No.	5	6	3	0	18	6	1	1
	%	10	12	6	0	36	12	2	2
Betadine-impregnated catheter	No.	3	3	0	0	20	1	1	0
	%	6	6	0	0	40	2	2	0
Mupirocin-impregnated catheter	No.	3	2	2	1	10	0	2	1
	%	6	4	4	2	20	0	4	2
Total	No.	11	11	5	1	48	7	4	2
	%	15	15	10	2	96	14	8	4

due to the differences in the duration of catheterization.

In a systematic review, Schumm et al compared the effects of using silver alloy and silver oxide-impregnated catheters in a short period of time in reducing the incidence risk of catheter-associated UTIs. They showed that the silver alloy-impregnated catheters were more effective. The results demonstrated that antibacterial-impregnated catheters were effective in reducing bacteriuria in short-term catheterization, however, the results did not show statistically significant effect on long-term catheterization (13). Additionally, Saint et al demonstrated no significant difference in the prevention of the UTIs between the silver alloy and silver acid-impregnated catheters (14).

Recently, Drekonja et al showed that antibacterial catheters were effective in reducing bacteriuria and funguria, however, they did not assess the symptomatic CAUTIs (15). In our study, we found that the antiseptic and antibacterial-impregnated catheters could decrease the incidence rate of bacteriuria and the symptomatic CAUTIs, which is consistent with the study by Johnson et al (16).

In contrast, Koskeroglu et al showed that using the *meatus* disinfectant to prevent the catheter–related bacteriuria was not associated with any statistically significant reduction (17). It is worth saying that in the study by Koskeroglu et al, the matching was not conducted while it could affect their findings. Likewise, Bastable et al also reported that continuous irrigation of the bladder was not an effective way to reduce the bacteriuria (18).

The incidence rate of catheter-associated bacteriuria in our study was 26%, which is nearly similar to 10-20% reported by Haley et al (19). Edmond et al showed that 40% of nosocomial infections were urinary tract infections since among them, 80% were related to urinary catheterization (20). The duration of urinary catheterization is an important factor in catheter-related bacteriuria (21,22). A previous study showed that the incidence of bacteriuria in hospitalized adults and elderly patients with urethral catheter increased 1-3% and 15% per day, respectively. Thereby, the overall incidence rate of bacteriuria after 7 and 14 days of catheterization will increase to 35% and 75%, respectively (3). In the present study, the duration of catheterization and the chance of bacteriuria were directly correlated. Tambyan et al showed that urinary catheterization for more than six days was a modifiable and recognizable risk factor for the incidence of UTIs (13). Besides, Samimi et al reported that microbial colonization was observed in the bladder in both groups of the study after 17 days (24). Al-Hazmi showed that reducing the duration of admission and duration of urinary catheterization was effective in reducing the incidence rate of the UTIs (25).

Their findings showed, no significant relationship between gender and the incidence rate of the UTIs in the participants, however, the number of women with UTI was greater than men (33 versus 25), while it was not statistically significant by chi-square test. Using a large sample size can help to record more reliable evidence. Besides, the incidence rate of the UTI was not significantly different among the women in all three groups. In this regard, the study by Leone et al on risk factors for the catheter-associated UTIs showed, gender was effective in the incidence rate of such infections (26). Similarly, Gillen et al on 4883 people showed that the age was effective in the incidence rate of such infections (27). These differences can be due to the large sample size of the mentioned studies.

The most common cause of the acquired infections reported by Wu et al was *E. coli* (80%), *Staphylococcus saprophyticus* (10-15%), *Klebsiella pneumoniae*, Enterobacter, and Proteus, respectively (21). Similarly, in our study, the most common cause of the UTI was *E. coli* which is in line with the results of other studies (28-30).

Our data showed that dysuria was the most common manifestation in patients with CAUTI. Urinary catheter can lead to dysuria through inflammation and infection in the bladder (31). In our study, the least complaint was reported by the patients in the mupirocin group, which can be due to the antibacterial property of this substance. Meanwhile, the patients in the betadine-impregnated catheter complained more than other groups, which is due to its burning property. Therefore, we can conclude that mupirocin-impregnated catheters are mostly preferred.

Conclusion

Based on the findings of our study, short-term use of mupirocin and betadine-impregnated catheters were more effective in reducing bacteriuria and the UTIs compare to conventional catheterization. However, there was no significant difference in the incidence rate of bacteriuria and the UTIs between mupirocin and betadine impregnated catheters. Given that the least complaint was reported by the patients in the mupirocin group, it can be pointed out that mupirocin-impregnated catheters are mostly preferred in comparison with betadine-impregnated catheters.

Limitations of the study

Some limitations of the present study were the small sample size and the short time of follow-up, so we recommend that further studies conducted using a large sample size and follow- up the patients longer.

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Authors' contribution

MH conducted the research. MRI gathered the data. KN

analyzed the data. MR-I and MH prepared the primary draft. KN edited the manuscript. MH prepared the final paper. AQ contributed to writing the manuscript and review of articles. All authors read and seen the final manuscript.

Conflicts of interest

The authors declare no conflict of interest.

Ethical considerations

Ethical issues (including plagiarism, data fabrication, double publication) have been completely observed by the authors.

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