# Water versus antiseptic periurethral cleansing before catheterization among home care patients: A randomized controlled trial

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***Background:*** There is a lack of research studies on periurethral cleansing before catheterization among home care patients. The purpose of this study was to compare the risk of acquiring symptomatic urinary tract infections through the conventional practice of using 0.05% chlorhexidine gluconate (CHG) versus sterile water for periurethral cleansing before insertion of an indwelling urinary catheter.
***Methods:*** A randomized controlled trial was used, and subjects were randomly allocated to either the sterile water group or the 0.05% CHG group. Urine specimens for culture were collected 4 times for each subject within 2 weeks.
***Results:*** Seventy-four urine samples were collected in 20 subjects (sterile water group, 8; 0.05% CHG group, 12). There was no significant difference in colonization count between the 2 groups. In addition, none of the subjects in the 2 groups developed symptomatic bacteriuria.
***Conclusion:*** Using sterile water to clean the periurethral area before catheterization among home care patients will not increase the risk for urinary tract infections. (Am J Infect Control 2008;36:375-80.)

Generally, urinary catheterization can be categorized into 2 types: intermittent and indwelling.[1] Intermittent catheterization is usually performed at home, at which home care patients are required to perform self-catheterization at least 4 times a day.[1] A series of comparative studies have recommended that intermittent catheterization using clean procedure would not increase the risk for urinary tract infections (UTIs).[1-9] These studies demonstrated that soap and water periurethral cleansing did not introduce bacteria into the bladder via the urethra. It can be argued that one of the contributing factors for these results is the relatively clean environment at home.

Unlike intermittent catheterization, health care professionals recommend strict sterile techniques with antiseptic periurethral cleansing for the indwelling catheterization procedure.[1] This could be due to the fact that, conventionally, most indwelling catheterizations are performed in the hospital. In addition, catheter-associated UTIs remain the most common nosocomial infection.[10,11] Hence, the practice of the indwelling catheterization procedure in the community also follows the hospital procedure. However, there is no direct evidence to show that this conventional practice reduces bacterial colonization.[12] Currently, some researchers have challenged this conventional practice. Updated research findings from hospital settings have indicated that the use of clean solutions such as tap water[9,12] made no difference on bacterial colony counts as compared with antiseptic solutions. However, in these studies, the catheters were only placed in situ for 1 or 3 days. It is questionable whether bacteria could be cultured within this short period of time. In addition, indwelling catheters are usually placed in situ for months or years for long-term use, especially for home care patients.

However, no study related to periurethral cleansing before catheterization has been performed among home care patients. Moreover, worldwide, over the past 10 years, the demand for home care services has increased dramatically because populations are aging and hospital stays are shorter. More patients are discharged from the hospital requiring catheterization care. Nursing care traditionally performed in hospitals has shifted to the community. Because the home

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environment is relatively cleaner than that of the hospitals, the research team believes that antiseptic periurethral cleansing can be replaced by other less costly solutions such as sterile water for indwelling catheterization among home care patients. It is estimated that 3 Hong Kong dollars would be saved per patient if sterile water were used. The results of this study will add knowledge of catheterization care among home care patients and might change conventional practice to cost-effective, evidence-based practice. In addition, the results will serve as a baseline study for future research using other more cost-effective solutions such as boiled water and soap.

The purpose of this study is to compare the risk of acquiring symptomatic UTIs through the conventional practice of using 0.05% chlorhexidine gluconate (CHG) versus sterile water for periurethral cleansing before insertion of a urinary catheter. The specific aims of the study are to test the following hypothesis: there is no difference in acquiring symptomatic UTIs among home care patients when the periurethral area is cleaned with either sterile water or 0.05% CHG before the insertion of an indwelling urinary catheter.

Most catheterized home care patients are elderly. Antibiotic therapy criteria for UTIs differ for younger and elderly adults. UTIs in adults are defined as the presence of significant numbers of a single microorganism in a urine specimen.[13] Although there is a lack of consensus on the definition of UTIs in the elderly population,[13] most of the literature agrees that antibiotics should be used only for elderly individuals with symptomatic bacteriuria.[13-15] In Hong Kong, the common parameter for bacteriuria is $>10^5$ colony-forming units (cfu) per milliliter (mL).[14] Symptoms of UTI include fever, pyuria, frequency, dysuria, urgency, hematuria, and/or low back pain.[14] Therefore, symptomatic bacteriuria is both the definition of a UTI and the dependent variable of this study.

## METHODS

### Subjects

This was a randomized controlled trial. Subjects were recruited from one community nursing service (CNS) center in Hong Kong. Nurses in the CNS provide services to patients who live at home or in a nursing home. The inclusion criteria for the study were (1) aged 18 years or older, (2) receiving community nursing services, (3) requiring long-term indwelling latex urinary catheter, and (4) already under community nursing service requiring long-term catheter care for at least 1 month. However, subjects with a symptomatic UTI on the day of baseline urine collection were excluded from the study. Ethical clearance was obtained from the Human Subjects Committee of The Hong Kong Polytechnic University and the Clinical Research Ethics Committee of the Hong Kong Hospital Authority.

Eligible home care patients who were willing to participate in the study were recruited on voluntary basis. After listening to the explanation given by the nurses and reading the information sheet, subjects signed the consent form. The simple randomization method suggested by Simon[16] was used to allocate subjects to either the sterile water group or the conventional 0.05% CHG group.

### Sampling procedure

The protocol suggesting the frequency for changing a latex indwelling catheter in home care is once every 2 weeks. Therefore, urine specimens for culture were collected 4 times for each subject: (1) baseline (first day), before removing the old urinary catheter; (2) T1 (first day), after inserting the new urinary catheter; (3) T2 (7 days), 1 week after catheter change; and (4) T3 (2 weeks), 2 weeks later and before catheter change.

Nurses working in the community nursing service center followed the standard protocol for urinary catheterization. Latex catheters were used in this study.

In the CHG group, nurses washed hands with a detergent before catheter insertion, wearing a surgical mask and apron and using sterile gloves. A sterile catheterization set and nontouch technique were used for catheterization. The nurse lubricated the catheter with single-use K-Y jelly, and the genitalia area was cleaned with 0.05% CHG. Sterile water was used to inflate the balloon, and the urethral catheter would be secured in position, which would be connected to a closed urinary drainage system. In the sterile water group, the nurses also followed the standard protocol, but they used sterile water to clean the genital area.

Nurses also followed the standard protocol for urine collection: all urine specimens were collected through a sterile syringe into a sterile bottle to avoid contamination, and the specimens were kept in a cooler and sent to the laboratory within 2 hours.

### Internurse reliability

To ensure trust, the procedures of urinary catheterization and urine specimen collection were performed by the nurse who provided primary care to the patient. To ensure consistency, a nursing manager reviewed the nurses' performance against the standard protocol for urinary catheterization and urine collection. The result of the internurses reliability was 100% compliance rate.

### Variables under study

**Dependent variables.** Symptomatic bacteriuria reported by the clients or caregivers and the colonization counts from urine culture collected were the

**Table 1.** Demographic characteristics and baseline data of the subjects in each group

| | Sterile water group (n = 8) | | 0.05% CHG group (n = 12) | | Significance |
|---|---|---|---|---|---|
| | n | % | n | % | By $\chi^2$ test |
| Sex (female) | 4 | 50.0 | 10 | 83.3 | .11 |
| Accommodation (nursing home) | 3 | 37.5 | 8 | 66.7 | .20 |
| Activity level (bed-chair bound) | 5 | 62.5 | 7 | 58.3 | .85 |
| Level of care (totally dependent) | 5 | 62.5 | 5 | 41.7 | .36 |
| Personal hygiene (good) | 7 | 87.5 | 11 | 91.7 | .76 |
| Physique (normal) | 7 | 87.5 | 9 | 75.0 | .49 |
| Mental status (normal) | 6 | 75.0 | 8 | 66.7 | .69 |
| Oral intake (no difficulty) | 8 | 100.0 | 8 | 66.7 | .07 |
| Signs of dehydration (no) | 8 | 100.0 | 12 | 100.0 | |
| Colonization count in baseline ($\leq 10^5$ cfu/mL) | 6 | 75.0 | 12 | 100.0 | .07 |
| | Mean ± SD | | Mean ± SD | | By *t* test |
| Age | 74.8 ± 15.6 | | 80.8 ± 8.8 | | .3 |
| History of UTI | 0.8 ± 1.2 | | 0.5 ± 0.9 | | .6 |
| No. of diagnoses | 2.3 ± 1.3 | | 3.2 ± 1.7 | | .2 |
| Barthel index | 25.4 ± 30.1 | | 26.8 ± 28.6 | | .9 |
| Duration of catheter used (days) | 1989.4 ± 3699.5 | | 518.4 ± 468.5 | | .2 |
| Daily perineal care frequency | 2.3 ± 1.0 | | 2.3 ± 1.4 | | .9 |

dependent variables of the study. Symptomatic bacteriuria was recorded as yes or no, and colonization counts were dichotomized into ''high'' ($>10^5$ cfu/mL) and ''low'' ($\leq 10^5$ cfu/mL).

**Independent variables.** Independent variables collected were either nominal or continuous data. Some of the data were obtained by asking the clients or their caregivers. They were age, accommodation (categorized as nursing home and home), difficulty in oral intake (categorized as yes and no), history of UTI, and daily perineal care frequency (recorded as continuous data). The other data were collected based on health assessment performed by the nurse. Those data included level of care (categorized as totally independent, partially dependent, and totally dependent), personal hygiene (categorized as good, smelly, and neglected), activity level (categorized as fully mobility, walk with assistance/aids, and bed-chair bound), physique (categorized as normal, obese, thin, and emaciate), mental status (categorized as normal, disoriented, confused, and stuporous), and signs of dehydration (categorized as no and yes). In addition, the Barthel index[17] for evaluation of client's functional abilities such as feeding, bathing, mobility, dressing, and elimination was used. The lower the score represents the higher the dependency.

## Microbiologic investigation of urine samples

Each of the urine samples was mixed gently, and 1 μL urine was sampled by dipping a sterile calibrated loop vertically into the urine. The drop of urine was streaked onto a cysteine lactose electrolyte-deficient agar plate (Oxoid, Basingstoke, United Kingdom). The agar plate was then incubated at 37°C aerobically for 24 hours. After incubation, the agar plate was examined, and the number of colonies for each type of microorganism was counted. The bacterial count (cfu/mL) was estimated by the following formula: number of colonies on cysteine lactose electrolyte-deficient agar plate × 1000.

A single colony of each type of microorganism was selected using a sterile straight wire; the chosen colony was identified using conventional biochemical tests.[18] If the colony was too small or mixed with other microorganisms, the colony was subcultured onto a blood agar plate (Columbia agar base [Oxoid] supplemented with 5% defibrinated horse blood) and incubated at 37°C aerobically for 24 hours. A single colony was selected and subjected to identification.

## Statistical analysis

The data analysis was conducted using the Statistical Package for the Social Science (SPSS) version 12 (SPSS, Inc, Chicago, IL). Descriptive statistics were examined for all variables under study. Variables under study were used to compare the 2 groups (ie, sterile water vs antiseptic) with a parametric test such as the *t* test for continuous data such as age, history of UTI, number of diagnoses, duration of catheter used, and frequency of perineal care. In addition, a nonparametric test such as the $\chi^2$ test would be used for nominal data such as gender, accommodation, activity level, and colonization count.

# RESULTS

Twenty-six subjects were recruited. Four subjects refused to participate in the study on the day of the

**Table 2.** Comparison of colonization count between sterile water group and 0.05% CHG group

| | Colonization count ($>10^5$ cfu/mL) | | | | |
|---|---|---|---|---|---|
| | Sterile water group | | 0.05% CHG group | | Significance |
| | No. | % | No. | % | By $\chi^2$ |
| Baseline | (n = 8) 2 | 25.0 | (n = 12) 0 | 0 | .07 |
| T1 | (n = 8) 0 | 0 | (n = 12) 0 | 0 | |
| T2 | (n = 8) 6 | 75.0 | (n = 10) 6 | 60.0 | .50 |
| T3 | (n = 7) 7 | 100.0 | (n = 9) 8 | 88.9 | .36 |

N = 20.
In T2, 2 subjects dropped out from the 0.05% CHG group because of urinary catheter removal as prescribed by physician and were admitted to the hospital for respiratory problem. In T3, 1 subject dropped out from the sterile water group because of urinary catheter removal as prescribed by physician. In T3, 1 subject dropped out from the 0.05% CHG group because of being admitted to the hospital for general condition deterioration.

**Table 3.** Combination of microorganisms found in the urine specimens at various times during the study

| | Number of subjects | Combination of microorganisms found (number of subjects) |
|---|---|---|
| Baseline | 10 | *Klebsiella pneumoniae* + *Staphylococcus aureus* (2) |
| | | *Staphylococcus aureus* + *Escherichia coli* (3) |
| | | *Staphylococcus aureus* + *Proteus* (1) |
| | | *Klebsiella pneumoniae* + *E coli* (3) |
| | | *E coli* + *Proteus* + *Diphtheroid* (1) |
| T1 | 6 | *Klebsiella pneumoniae* + *E coli* (2) |
| | | *Klebsiella pneumoniae* + *Staphylococcus aureus* (1) |
| | | *E coli* + *Proteus* (1) |
| | | *Staphylococcus aureus* + *E coli* (1) |
| | | *E coli* + *Proteus* + *Diphtheroid* (1) |
| T2 | 10 | *Klebsiella pneumoniae* + *Staphylococcus aureus* (2) |
| | | *Proteus* + *Strep group D* (1) |
| | | *Staphylococcus aureus* + *Proteus* (1) |
| | | *Klebsiella pneumoniae* + *E. coli* (2) |
| | | *E coli* + *Proteus* (1) |
| | | *E coli* + *Psudomonas* (1) |
| | | *Staphylococcus aureus* + *Psudomonas* (1) |
| | | *Klebsiella pneumoniae* + *Staphylococcus aureus* + *E coli* (1) |
| T3 | 8 | *Klebsiella pneumoniae* + *E coli* (2) |
| | | *Proteus* + *Acinetobacter* (1) |
| | | *Staphylococcus aureus* + *E coli* (2) |
| | | *Klebsiella pneumoniae* + *Pseudomonas* (1) |
| | | *Staphylococcus aureus* + *Proteus* (1) |
| | | *Klebsiella pneumoniae* + *E coli* + *Strep group D* (1) |

catheter change. Two subjects were excluded from data analysis because one had a UTI diagnosis and the other was on antibiotic treatment for fever. Therefore, 20 subjects (14 females and 6 males) and 74 observations were used for analysis. Eight subjects were in the sterile water group, and 12 subjects were in the 0.05% CHG group.

The average age of the subjects was 78.4 (SD, 11.8) years, and 55% (n = 11) of the subjects lived in a nursing home. One subject (5.0%) had 7 medical diagnoses, and only 4 subjects (20.0%) had one diagnosis. Eight subjects (40.0%) had suffered cerebrovascular accidents, and 8 subjects (40.0%) had diabetes mellitus. None of subjects had signs of dehydration. Overall, subjects were evenly matched in sterile water and 0.05% CHG groups in terms of age, gender, accommodation, history of UTI, and others (See Table 1 for details).

None of the subjects developed symptomatic bacteriuria in this study. In addition, rates of bacteriuria at baseline ($\chi^2$ = 3.33, $P$ = .07), T1 (no difference), T2 ($\chi^2$ = 0.45, $P$ = .50), and T3 ($\chi^2$ = 0.83, $P$ = .36) were similar in each group (see Table 2 for details). These results support the hypothesis.

Of the 74 observations, the most common microorganism isolated in the urine specimens was *Escherichia coli* (58.2%; n = 43), followed by *Klebsiella pneumoniae* (29.7%; n = 22) and *Staphylococcus aureus* (20.0%; n = 20). Moreover, there was no difference in the type of microorganism found in either group. In addition, more than one microorganism was found in the baseline urine culture of 10 subjects (50.0%), 6 subjects (30.0%) at T1, 10 subjects (50.0%) at T2, and 8 subjects (40.0%) at T3 (see Table 3 for details).

## DISCUSSION

The results of the study suggest acceptance of the null hypothesis, ie, there is no difference in acquiring symptomatic UTIs between home care patients whose periurethral area is cleaned with sterile water or 0.05% CHG before the insertion of an indwelling urinary catheter. Also, the results of this study of home care patients support the findings of studies conducted with hospital patients.[9,12] The target populations were different in the studies of Carapeti et al[12] and Webster et al.[9] Carapeti et al[12] focused on general surgical patients who needed to be catheterized before surgery, whereas Webster et al[9] focused on pregnant women admitted for delivery and for whom an indwelling catheter was a required part of routine management. Although the details of patient diagnoses were not discussed in their papers, it is expected that the target populations in these 2 studies might have been relatively healthy, and their need for catheterization was temporary; the urinary catheters would, most likely, have been removed 1 to 3 days after surgery or delivery. Unlike these 2 studies, the home patients in the present study were elderly, had multiple diagnoses of medical conditions, and their catheters were placed in situ for longer periods of time (from 1.5 months to 30 years). In addition, the solutions used in these studies were different: Carapeti et al[12] tested periurethral cleansing with tap water against 0.05% chlorhexidine gluconate (Medlock Medical, Oldham, United Kingdom) and

sterile water (B. Braun Medical Industries, Penang, Malaysia); Webster et al[9] tested tap water against 0.1% CHG, and the present study tested sterile water against 0.05% CHG. In addition, it is expected that the sterile technique would have been used in the urinary catheterization technique. Carapeti et al[12] took the testing even further by using the clean technique rather than the sterile technique in the treatment group. Even though the target populations, solutions used, and catheter insertion techniques were different in these 3 studies, the results of the studies were congruent. Hence, the results of these 3 studies strongly suggest that the solution used for periurethral cleansing before catheter insertion might not affect the incidence of UTI. In other words, it might not be necessary to use an antiseptic to clean the periurethral area. Owing to the lack of research in this area, more studies are required to see whether the current practice of using antiseptic solution should be reviewed based on evidence-based practice. Other factors such as the type of catheter used[12] might affect colonization counts. Latex catheters were used in the present study, but the types of catheter used for the other 2 studies were not provided. Hence, studies using different types of catheter such as silicon catheters should be conducted. In addition, although there is no difference in the accommodation between the sterile water and 0.05% CHG groups in the present study, it would be valuable to conduct a similar study for clients living at home and those in nursing homes to see whether the result will be congruent. Furthermore, because the home environment is relatively cleaner than the hospitals, studies should be conducted to test the use of sterile technique versus the clean technique in indwelling catheterization, such as the technique used for intermittent catheterization.

In addition to the technique of urinary catheterization, the results of this study also add knowledge to the microbiologic aspect of the urinary tract with an indwelling catheter. The common microorganisms isolated from the urine samples in the present study were similar to those found in the other studies. *E coli*, *K pneumoniae*, and *S aureus* were 3 most common types. In addition, the findings support that asymptomatic bacteriuria in the elderly population was polymicrobic.[15,19] In the present study, 39% (n = 29) of urine samples had significant bacteriuria, but subjects were asymptomatic. This finding is similar to the result discussed in a Hong Kong Guideline on Antimicrobial Use in Primary Health Care Clinics, which stated that ''up to 40% of elderly may have asymptomatic bacteriuria''.[14(p39)] In addition, 40.5% (n = 30) of urine samples had 2 bacteria, and 5.4% (n = 4) of urine samples had 3 bacteria. Furthermore, there was a trend that the longer the catheter stayed in the bladder, the greater the colonization counts. None of the urine samples had colonization counts $>10^5$ cfu/mL after insertion of the new catheter at T1. However, the percentage of urine samples that had colonization counts $>10^5$ cfu/mL increased dramatically at T2 and T3 (see Table 2 for details). Hence, latex catheters should be changed weekly or biweekly to reduce bacterial colonization, which might induce UTIs. This finding further supports the study of different types of catheters, which could provide recommendations on the frequency of catheter change for indwelling catheter patients.

Although the results of the present study are congruent with other studies[9,12] and the Hong Kong Department of Health guideline,[14] cautions should be taken in interpreting the data. The limitation of the study is its relatively small sample size. The total number of observations in the present study was 74. With 80% power at $\alpha = .05$, the effect size would be 0.45.[20] Based on the results of previous studies,[9,12] the recommended effect size might be from 0.2 to 0.3. Further research with a larger sample is required to elucidate further the effect of the solution used for periurethral cleansing before catheterization among home care patients. However, this present study is the first of its kind on the area, and it provides the foundation for future study of home care patients.

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