Clean and Sterile Intermittent Catheterization Methods in Hospitalized Patients With Spinal Cord Injury

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The purpose of this study was to compare the incidence of urinary infection using clean intermittent catheterization with the incidence of infection using sterile intermittent catheterization in patients hospitalized with spinal cord injury who were not receiving prophylactic antibiotics. Forty-six patients were assigned randomly to a clean (n = 23) or sterile (n = 23) study group. Catheterizations were done at least every six hours. Infection was defined as bacteriuria >100,000 organisms/mL or ≥10,000 organisms per mL with fever of 100°F or greater. Results of urinary dipslides were recorded daily. Twenty-eight subjects (60.9%) converted to ≥100,000 organisms per mL. Method of catheterization was neither associated significantly with development of ≥100,000 organisms per mL. (X^2[1,46] = .36, p = .55) nor with symptomatic infections (X^2[1,46] = .15, p = .70). Data support the use of clean intermittent catheterization under the conditions used in this study, including the use of a sterile catheter each day and careful monitoring of infection and technique. Before using this method with other diagnostic groups or in different clinical settings, further investigation is needed.

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KEY WORDS: Catheterization; Intermittent; Spinal cord injury; Urinary infection

Reports on the use of sterile intermittent catheterization have provided evidence for the effectiveness of the procedure in early management of neurogenic bladder after spinal cord injury (SCI).1,2 Lipides and colleagues3 subsequently described the use of nonsterile (clean) intermittent catheterization in long-term management of the dysfunctional bladder. Numerous reports have supported the effectiveness of clean technique among outpatients with a variety of conditions.4,7 Clean intermittent catheterization for hospitalized patients has the potential to decrease costs associated with the use of sterile technique and to decrease time spent in performing catheterizations and in teaching self-catheterization. However, the question of whether it is necessary to follow strict aseptic technique when catheterizing hospitalized patients has not been adequately addressed by research.

Three studies of clean intermittent catheterization in hospitalized patients were found in the literature. Anderson6 examined the effect of antibiotic prophylaxis on the infection rate of 25 patients using nonsterile intermittent catheterization. A significantly lower rate of infection was reported for a control group using sterile technique and receiving antibiotic prophylaxis.

Maynard and Diokno11 studied 50 patients with SCI who were using clean intermittent catheterization during initial rehabilitation hospitalization. Patients were assigned randomly to groups that either did or did not receive prophylactic antibacterial medications. These groups were divided further into subgroups that varied in the way bacteriuria and clinical infections were treated. Results showed that antibacterial prophylaxis reduced the probability of laboratory infections, but not the probability of clinical infections.

Wyndaele and DeTaeye6 compared nonsterile intermittent catheterization in 25 SCI patients with sterile intermittent catheterization in 48 patients. No significant difference in rate of infection at discharge was reported between groups. Variables such as presence of infection at entry to the study and use of antibiotics were not controlled.

Although these studies provided important data on incidence of infection or effectiveness of prophylactic medication with clean intermittent catheterization, they did not compare the risk of infection between clean and sterile techniques in the absence of prophylactic antibiotic medication. A study was needed to identify the relative risk of using clean intermittent catheterization vs. sterile catheterization without the use of prophylaxis. Antimicrobial prophylaxis has been shown to have no significant advantage with clean or sterile intermittent catheterization. The purposes of this study were to compare the incidence of urinary infections using clean intermittent catheterization...
with the incidence of infection using sterile intermittent catheterization and to determine the incidence of resistant infections using the two catheterization techniques.

METHODS

Subjects

The sample consisted of patients with SCI, admitted to an inpatient rehabilitation program at any time postinjury, who were placed on intermittent catheterization either before or during their hospitalization. They were eligible to participate in the study if the following criteria were met: (1) catheterizations performed at least every six hours; (2) normal serum creatinine, BUN, and urinalysis; (3) no prophylactic antibiotics; (4) absence of drug-resistant organism on urine culture; and (5) bacteriuria less than 10,000 colonies per mL. “Drug-resistant organism” was defined as any organism found on urine culture and sensitivity testing that was sensitive to two or less drugs.

After randomly assigning patients to either clean or sterile technique, a written order for participation in the study was obtained from the attending physician. Patients were then approached to obtain informed consent. Participation in the study continued for 28 days or until an infection occurred. Patients were discontinued from the study before 28 days if catheterizations were ordered less frequently than every six hours or if they were discharged.

Procedures

Catheterization procedures. Patients with sufficient hand function and willingness to learn were taught self-catheterization. Others were catheterized by nursing staff in the hospital or by a family member during home visits. In both clean and sterile catheterization procedures, the first step was hand washing.

In the clean intermittent catheterization procedure patients did not wear gloves; staff and family caregivers donned nonsterile gloves to do clean catheterization. A sterile catheter was used at the beginning of each 24-hour period. The catheter was lubricated, and the urinary meatal area was cleansed with a castile soap wipe. The catheter was then inserted. Urine was drained into a urinal or other receptacle, and the volume was measured. After each use, the catheter was washed with bar soap, rinsed with tap water, dried, and stored in a plastic bag for reuse. Catheters were discarded after 24 hours’ usage.

Sterile intermittent catheterization was carried out using a sterile catheterization kit for each procedure and following principles of asepsis such that care was taken to avoid contaminating the catheter. The external meatus was cleansed with povidone iodine before sterile catheterization.

Patients in both groups were instructed in the importance of catheterizing frequently enough to avoid bladder overdistention.

Monitoring infection. Bacteriuria, temperature, and catheterization intervals were monitored daily. Urine specimens for bacteriuria were obtained at 4 AM using a sterile catheter and the assigned technique. Bacteriuria was assessed using the dipslide method.12 The reliability and validity of the dipslide method have been reported by Guttman and Naylor.13 who compared it to the pour-place method. In a series of 385 specimens, there were no false-negative results, and an insignificant number of false-positive results were reported. Interrater reliability in the present study was evaluated at two intervals and was 100% among three nurse raters who interpreted dipslide results.

Urinary infection was defined as ≥100,000 colonies per mL with or without clinical symptoms, or ≥1,000 colonies per mL with a temperature of 100°F or more, or ≥10,000 colonies per mL with costavertbral or suprapubic tenderness. Dipslides were incubated for 18 to 24 hours at 35°C to 40°C and were interpreted by nurse raters. Urine for culture and sensitivity testing was obtained when (1) a fever developed; (2) a dipslide indicated ≥10,000 colonies per mL with symptoms, or (3) a dipslide indicated ≥100,000 colonies per mL without symptoms for two days. Day of infection was recorded as the first day that urine converted to ≥100,000 colonies per mL or to ≥10,000 colonies per mL with symptoms.

Statistical Analysis

The SPSS/PC+ was used in analysis of data. Descriptive statistics were computed for all variables. Depending on level and distribution of data, χ2 or t test for independent samples was used to assess similarity of groups on demographic and illness-related variables. χ2 was used to test independence between methods and urinary infection. The t test for independent samples was used to compare risk days for infection in the clean and sterile groups. A p value of less than .05 was considered statistically significant.

RESULTS

Subjects

Fifty-eight patients met the inclusion criteria. Twelve individuals (20.7%) did not wish to participate in the study; 11 of those who refused had been assigned to the clean group. Four patients gave no reason for not participating, and eight patients either expressed concern about infections or preferred not to change from their current intermittent catheterization method (ie, sterile).

Demographic and disability-related characteristics of the resulting sample of 46 patients, 23 in the clean group and 23 in the sterile group, are shown in table 1. No significant differences between groups were found. Only four patients, three in the clean group and one in the sterile group, were on intermittent catheterization less than two weeks upon entry to the study. Because 14 (61%) of those assigned to the clean group and 17 (74%) of the subjects assigned to the sterile group started intermittent catheterization in the acute setting, it was not possible to estimate accurately the length of time on such programs before participation in the study.
Table 1: Demographic and Illness Characteristics of Clean and Sterile Groups

<table>
<thead>
<tr>
<th>Variables</th>
<th>Clean (n = 23)</th>
<th>Sterile (n = 23)</th>
<th>Total (n = 46)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of SC1 (days)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>18-179</td>
<td>16-100</td>
<td>16-179</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>69 ± 39</td>
<td>51 ± 25</td>
<td>60 ± 33</td>
</tr>
<tr>
<td>Median</td>
<td>65</td>
<td>48</td>
<td>53</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>18</td>
<td>22</td>
<td>40</td>
</tr>
<tr>
<td>Female</td>
<td>5</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>15-53</td>
<td>16-56</td>
<td>15-56</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>27.9 ± 10.3</td>
<td>32.8 ± 13.7</td>
<td>29.9 ± 12.4</td>
</tr>
<tr>
<td>Median</td>
<td>24</td>
<td>27</td>
<td>25.5</td>
</tr>
<tr>
<td>Level of injury</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quadriplegia</td>
<td>11</td>
<td>8</td>
<td>19</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>12</td>
<td>15</td>
<td>27</td>
</tr>
<tr>
<td>Self-catheterization</td>
<td>Yes</td>
<td>15</td>
<td>34</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>4</td>
<td>8</td>
</tr>
</tbody>
</table>

The number of days in the study ranged from one to 28. Eleven subjects (23.9%) were terminated early from the study (X = 11.5 days) due to discharge home or a change in catheterization program. Six of these subjects were in the sterile group and five were in the clean group. Number of days in the study, categorized into five-day intervals for clean and sterile groups, is shown in Table 2.

Four of the six women in the study developed urinary infections; one was symptomatic. No woman had sterile urine (absence of bacterial growth on dip slide) at completion of the study, whereas the urine of 13 of 40 men (32.5%) was sterile at the end of the study. Because of the small representation of women, it was not possible to determine the statistical significance of the relationship of gender to infection.

Comparison of Catheterization Methods

Twenty-eight of 46 patients (60.9%) developed urinary infections. Twenty of the infections were asymptomatic (≥100,000 colonies per mL with no symptoms) and eight were symptomatic (≥10,000 colonies per mL and temperature ≥100°F). Fifteen patients in the clean group (65.2%) developed infections, compared to 13 (56.5%) in the sterile group (fig). No significant association was found between incidence of infection and catheterization technique (X²[1.46] = .36, p = .55). Five of the 23 patients (21.7%) using clean intermittent catheterization and three of the patients (13%) using sterile intermittent catheterization developed symptomatic infections (fig). X² analysis with Yates correction showed no significant relationship between symptomatic infection (X²[1.46] = .15, p = .70) and method of catheterization. All patients with clinical infections were treated effectively with antibiotics. There were no episodes of sepsis or drug-resistant infection in either group.

Table 2: Number of Days on the Study for Clean and Sterile Groups

<table>
<thead>
<tr>
<th>Number of Days</th>
<th>Clean</th>
<th>Sterile</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-5</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>6-10</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>11-15</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>16-20</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>21-25</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>26-28</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>23</td>
<td>23</td>
</tr>
</tbody>
</table>
311 catheterizations were done in the sterile group: 1,497 ($X = 65, SD = 53$) catheterizations were done in the clean group. Patients assigned to sterile technique had 311 days at risk ($X = 13.5, SD = 9.5$), whereas those in the clean group had 256 risk days ($X = 11.1, SD = 8.5$).

The rate of infection was .74%, or 7.4 infections per 1,000 catheterizations for the sterile method. The infection rate in the clean group was 1.0%, or 10.0 infections per 1,000 clean catheterizations. Similarly, the rate of symptomatic infections was higher for the clean group than for the sterile group. Table 3 provides a comparison of symptomatic and asymptomatic infections for sterile intermittent catheterization and clean intermittent catheterization groups using several units of measurement.

Comparison of catheterization intervals in clean and sterile groups. Thirty-five patients were catheterized every four hours or more frequently. Ten of the remaining patients were catheterized every six hours; one patient was catheterized every four hours during the day and every six hours at night. To examine differences in frequency of catheterizations between the two methods, the interval between catheterizations was dichotomized into three to four hours for group 1 and more than four hours for group 2. No significant association was found between catheterization interval and clean or sterile method ($X^2 = .48[1.46], p = .49$).

DISCUSSION

The purpose of this study was to compare the incidence of urinary infections in patients using clean intermittent catheterization with those using sterile intermittent catheterization. Results indicated similar outcomes for the two methods, using the number of patients with infection and number of days until infection occurred as the units of measurement.

Incidence of infection also was analyzed by number of catheterizations and daily probability of infection to provide a basis for comparison with the Maynard and Diokno study. Five patients (21.7%) in the clean group did not develop bacteriuria compared to 12% of patients reported by Maynard and Diokno. The average number of days for that study was 50 compared to 11 days for patients on clean catheterization in this study. The daily probability of .059 for infection, or approximately six infections for every 100 days of intermittent catheterization, was greater than the daily probability of .042 for sterile intermittent catheterization and was similar to the value of .065 reported by Maynard and Diokno.

Considering the benefits to be obtained, we agree with the suggestion of Maynard and Diokno that the slightly greater risk of infection associated with clean technique may be acceptable if careful monitoring of patients and prompt treatment of symptomatic infections are provided. Comparisons of findings of this study with those of other studies using clean intermittent catheterization are not meaningful because the definitions of urinary infection differ or only discharge data are provided.

Limitations

Sterile intermittent catheterization is the routine protocol used in the clinical setting where the investigation took place. When subjects were asked to participate in the study, those in the clean group were asked to agree to a change from the standard practice. Although the samples were not significantly different on duration and level of injury, age, and gender, the fact that more patients assigned to the clean catheterization method refused to participate may have introduced bias. The investigators knew which group each patient was assigned to at the time of requesting consent; thus, potential existed to influence participation. Despite these potential sources of bias, the attrition rates of the two groups were similar and there were no statistically significant differences on other variables with potential to influence outcome (catheterization interval, self-catheterization).

An additional limitation of the study was attrition of 11 subjects (23.9% of the sample) before the 28-day trial period due to discharge or to changes in catheterization protocol such that patients no longer met the study criteria. Also, data on duration of intermittent catheterization, including time before this study, were not available for analysis; total time on intermittent catheterization may be an important variable.

The validity of findings is dependent on the accuracy of following catheterization procedures and the reliability and validity of measurement of infection. Despite instruction and investigators' weekly review of catheterization procedures, the fact that multiple caregivers and patients participated in the study and catheterizations were done multiple times allows the possibility for error in following prescribed procedures.

Replication using a larger sample, a longer duration of study, assessment of duration on intermittent catheterization, and group assignment after informed consent is obtained are recommended to evaluate the long-term consequences of using clean intermittent catheterization in the hospital. Further study of other diagnostic groups is suggested. Although the SCI patients in this study had neurogenic bladder, they were otherwise healthy.
CONCLUSION

The findings suggest that clean intermittent catheterization using a new sterile catheter daily can be used safely in hospitalized SCI patients, with catheterization intervals no more than every six hours and frequent monitoring of catheterization technique and infection. Clinical protocols for intermittent catheterization should be developed based on research, with careful consideration of risks and benefits. Because cross-contamination is a serious risk in hospitals and until further research supports the safety of catheter reuse, we recommend that a sterile catheter be used for each catheterization when a clean method of catheterization is adopted. Patients on any intermittent catheterization program should be monitored closely for urinary complications.

Clean intermittent catheterization has important implications for financial costs, time expenditure, and functional independence. Further research is needed to determine the risks and benefits of the clean method of intermittent catheterization for patients with SCI and other conditions.

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References