Effect of a Single-Use Sterile Catheter for Each Void on the Frequency of Bacteriuria in Children With Neurogenic Bladder on Intermittent Catheterization for Bladder Emptying

Theresa A. Schlager, MD*‡; Maureen Clark, MT*; and Susan Anderson, MD*

ABSTRACT. Objective. The frequency of bacteriuria is high in children with neurogenic bladder on intermittent catheterization for bladder emptying. In an effort to decrease bacteriuria, we examined whether the method of catheter care was responsible for the high rate of bacteriuria. For this, the frequency of bacteriuria was examined in the same patient on single-use sterile catheters and on reused clean catheters.

Methods. A prospective, randomized, crossover trial was conducted with 10 patients who were randomized to 4 months of a new, sterile catheter for intermittent catheterization and 4 months of reuse of a clean catheter for intermittent catheterization. Each week, a urine sample was collected and symptoms of infection and medication use were recorded.

Results. A total of 158 urine samples were collected during 164 patient-weeks on the new catheter method for each void; 115 (73%) were positive for a pathogen. Of the 161 samples collected during 169 patient-weeks on the standard, reuse method for voiding, 123 (76%) were positive (115 [73%] of 158 vs 123 [76%] of 161). Escherichia coli was the most common pathogen detected during both method periods.


ABBREVIATIONS. IC, intermittent catheterization; UTI, urinary tract infection.

The majority of children with neurogenic bladder have loss of control over voiding; urinary retention and bladder distention usually occur in the absence of intervention. Obstruction caused by urinary retention may lead to deterioration of the urinary tract. In addition, urinary retention may result in reflux into the upper urinary tract and subsequent renal damage. Several strategies for complete emptying of the bladder on a regular basis have been tried. Intermittent catheterization (IC) of the bladder several times daily is the preferred method of bladder emptying in patients with neurogenic bladder. A disadvantage of IC is the inoculation of bacteria into bladder urine during the course of repeated catheterization. As a result, bacteriuria is frequent in urine samples collected from patients who are on IC. In an effort to decrease bacteriuria and subsequent urinary tract infection (UTI) in this population, investigators compared sterile IC with clean IC. They found no significant difference in the number of positive urine cultures in the group on IC and sterile technique compared with a second group on IC and clean technique.

For the next step in an effort to decrease bacteriuria in patients who are on IC, we compared the effect of sterile, single-use catheters with reused, clean catheters in patients who are on IC. Our study was the first prospective, randomized, crossover trial of single, sterile versus reused, clean catheters in outpatients with neurogenic bladder attributable to myelomeningocele.

METHODS

Patients

Patients who had neurogenic bladder and were on IC 4 times per day were enrolled if they lived at home and had a normal renal ultrasound and no reflux on voiding cystourethrogram. The frequency of bacteriuria in our study group is 75%. All patients continued to receive medical care from their primary physician; no therapies were withheld or altered. The urine cultures obtained for the study did not influence the patient’s care, because the results were kept on file by a research technologist and were not available to either the patient’s physician or the investigator. The protocol was approved by the University of Virginia Human Investigation Committee.

Ten patients enrolled and completed study. Two families declined enrollment because they preferred use of a new catheter for each void. Six of the 10 participants were female; 6 participants were 10 to 16 years of age, and 4 were 18 to 20 years of age. All participants had myelomeningocele (level of lesion: 1 thoracic, 5 lumbar, 4 sacral). All attended school or worked outside the home.

Design

This was a prospective, randomized, crossover trial. Patients were enrolled according to geographical location from March to November 1999. Patients were studied for 8 months; for 4 months, a patient used 1 catheter method followed by 4 months of the alternate catheter method. The same catheter and IC were used during the entire 8-month study period; the only change during the study was whether the patient used a new, sterile catheter for each void or reused the same catheter.

IC was performed 4 times a day according to the following procedure. After hand-washing, the parent or patient rinsed the perineum with soap and water before inserting a soft, plastic catheter into the bladder by way of the urethra. After urine flow stopped, the patients performed a Valsalva maneuver (or the
parent applied gentle pressure over the suprapubic area) to express the remaining urine before removal of the catheter. For the “new method,” after the perineum was rinsed with soap and water, a new, sterile, plastic catheter (Mentor Corporation, Santa Barbara, CA) was removed from the package, inserted into the urethra, removed after urine flow stopped, and discarded. During the “new method period,” a new sterile catheter was used for each void. For the “standard method,” after the perineum was rinsed with soap and water, a sterile, plastic catheter (Mentor Corporation) was removed from the package, inserted into the urethra, and removed after urine flow stopped. The catheter was then rinsed with tap water, air dried, and stored in a plastic bag. At the end of the day, catheters were removed from the plastic bag, boiled in water for 3 minutes, air dried again, and stored in a new plastic bag. During the “standard method period,” a catheter was reused 5 times for bladder emptying and cleaned as described before each use. After the fifth void, the catheter was discarded; a new, sterile catheter was obtained; and the “standard method” was repeated. The initial catheter schedule (new or standard) was assigned randomly by the research pharmacist.

Each patient was visited weekly at home for 8 months by the investigator or the study nurse. At each visit, a catheter count was made to assess compliance, and symptoms or signs of a UTI and all medications were recorded.

A sample of bladder urine collected during routine IC on the day of the visit was refrigerated immediately and plated within 10 hours. Organisms were identified by standard technique.

Definitions

The appropriate definitions of bacteriuria and UTI are unclear in this population. For this study, “bacteriuria” was defined as ≥ 10⁴ colony-forming units or more of a pathogen per milliliter of urine obtained by bladder catheterization. “UTI” was defined as bacteriuria with fever, abdominal pain, change in continence pattern, or change in color or odor of urine. This definition of UTI is in accordance with the guidelines originated at the Round Table Discussion of Symptoms of UTI in Neurogenic Bladder at the October 1990 meeting of the American Academy for Cerebral Palsy and Developmental Medicine. The distinction between urinary tract pathogens and nonpathogens in a patient with neurogenic bladder also has not been established. For this study, the Enterobacteriaceae, Enterococcus species, Staphylococcus saprophyticus, and group B streptococci were designated as “usual pathogens.” Coagulase-negative staphylococci (excluding S saprophyticus), α-hemolytic streptococci or nonhemolytic streptococci, and Corynebacterium species were designated as “commensal” organisms.

RESULTS

Five patients performed the “new method” first, and 5 patients performed the “standard method” first during the 8-month study period (Table 1). The frequency of bacteriuria in an individual patient was similar during both periods whether the new or standard method was performed first. In addition, there was no evidence of a carryover effect of the “new method” period into the “standard method” period in the 5 patients who performed the “new method” first. Two symptomatic infections occurred in 2 patients (1 UTI per patient) who were using the new method, and 2 symptomatic infections occurred in 2 patients (1 UTI per patient) who were using the standard method. Patients with UTI were seen by the investigator or the study nurse. At each visit, a catheter count was made to assess compliance, and symptoms or signs of a UTI and all medications were recorded. A sample of bladder urine collected during routine IC on the day of the visit was refrigerated immediately and plated within 10 hours. Organisms were identified by standard technique.

Bacteriuria is common in patients who have chronic neurogenic bladder and are undergoing IC for bladder emptying. Efforts to decrease bacteriuria and prevent UTIs have included oral antimicrobial suppressants, perineal or intravesical antiseptics, and alternative methods of catheterization. Anderson examined clean IC in hospitalized adult males with acute spinal cord injury. Patients on clean IC were placed on antimicrobial prophylaxis, and control subjects on sterile IC were not on prophylaxis. Bacteriuria was found in 83% of patients on clean IC, compared with 96% of control patients on sterile IC. Anderson concluded that clean IC had an unacceptably high infection rate in the hospital environment. King et al examined the incidence of UTI in hospitalized patients with spinal cord injury using sterile IC and clean IC. For sterile IC, an aseptic technique was followed and the external meatus was cleansed with providone iodine before catheteriza-

**TABLE 1.** Frequency of Bacteriuria During 8-Month Study Period With 5 Patients Performing New Method First (Group 1) and 5 Patients Performing Standard Method First (Group 2)

<table>
<thead>
<tr>
<th>Patient Number</th>
<th>New Method Month 1–4 (Number Positive/Total)</th>
<th>Standard Method Month 5–8 (Number Positive/Total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>7/17</td>
<td>15/15</td>
</tr>
<tr>
<td>2</td>
<td>6/18</td>
<td>7/16</td>
</tr>
<tr>
<td>3</td>
<td>15/16</td>
<td>15/15</td>
</tr>
<tr>
<td>4</td>
<td>15/15</td>
<td>18/18</td>
</tr>
<tr>
<td>5</td>
<td>14/14</td>
<td>17/17</td>
</tr>
<tr>
<td>Total</td>
<td>57/80</td>
<td>72/81</td>
</tr>
<tr>
<td>Group 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>5/15</td>
<td>8/13</td>
</tr>
<tr>
<td>7</td>
<td>15/16</td>
<td>16/16</td>
</tr>
<tr>
<td>8</td>
<td>9/17</td>
<td>2/15</td>
</tr>
<tr>
<td>9</td>
<td>17/18</td>
<td>16/16</td>
</tr>
<tr>
<td>10</td>
<td>14/14</td>
<td>16/18</td>
</tr>
<tr>
<td>Total</td>
<td>51/80</td>
<td>58/78</td>
</tr>
</tbody>
</table>

The frequency of individual species was similar during the new and standard method periods (Fig 1). *Escherichia coli* was the most common pathogen detected during both method periods followed by Klebsiella species, Proteus species, and Citrobacter species. Of the 158 samples from patients on the new method, 53 (34%) were positive for *E coli* compared with 50 of 161 samples (31%) from patients on the standard method (53 [34%] of 158 vs 50 [31%] of 161; *P* = .72, χ² with Yates correction).

In summary, 158 urine samples were collected during 164 patient-weeks on the new method, and 115 (73%) were positive for a pathogen (Table 2). Of the 161 samples collected during 169 patient-weeks on the standard method, 123 (76%) were positive (115 [73%] of 158 vs 123 [76%] of 161; *P* = .54, χ² with Yates corrections). The number of UTIs was too small to compare between groups.

**DISCUSSION**

Bacteriuria is common in patients who have chronic neurogenic bladder and are undergoing IC for bladder emptying. Efforts to decrease bacteriuria and prevent UTIs have included oral antimicrobial suppressants, perineal or intravesical antiseptics, and alternative methods of catheterization. Anderson examined clean IC in hospitalized adult males with acute spinal cord injury. Patients on clean IC were placed on antimicrobial prophylaxis, and control subjects on sterile IC were not on prophylaxis. Bacteriuria was found in 83% of patients on clean IC, compared with 96% of control patients on sterile IC. Anderson concluded that clean IC had an unacceptably high infection rate in the hospital environment. King et al examined the incidence of UTI in hospitalized patients with spinal cord injury using sterile IC and clean IC. For sterile IC, an aseptic technique was followed and the external meatus was cleansed with providone iodine before catheteriza-
tion. For the clean technique, staff wore nonsterile gloves and the external meatus was cleansed with soap and water. Thirteen of 23 patients (56%) in the sterile group and 15 of 23 patients (65%) in the clean IC group developed infection \( (P = .55) \). The mean number of days until infection occurred was 8.8 for the sterile IC group and 7.9 for the clean IC group \( (P = .75) \). In contrast to Anderson, these investigators concluded that clean IC is safe to use in hospitalized patients with spinal cord injury with careful monitoring of technique and infection.

The frequency of bacteriuria in our group of outpatients on IC is 75%,\(^2\) similar to the bacteriuria rate found in hospitalized patients.\(^3,4\) One reason for the high frequency of bacteriuria may be care of the catheter after voiding. Lavallee et al\(^9\) examined the effect of cleaning catheters contaminated with \( 10^7 \) \( E. coli \), rinsing and drying. After voiding, catheters were removed and the catheter tip was placed in a test tube with a neutral solution. After sonication, dilutions of the eluate were plated and then incubated for 24 hours; bacterial counts were performed. The investigators demonstrated that rinsing followed by drying a catheter achieved a lower bacterial count to 0. Cleaning agents (detergents, water, vinegar, peroxide) had similar log reductions when used after rinsing and drying.

Many outpatients on IC work outside the home or attend school, making it difficult to comply with a catheter cleaning regimen. To examine whether the method of catheter care was responsible for the high rates of bacteriuria in outpatients on IC, we compared the frequency of bacteriuria in the same patient on single-use, sterile catheters with reused, clean catheters. We found that a new, sterile catheter for each void did not decrease the frequency of bacteriuria in patients who had neurogenic bladder and were using IC.

In previous work,\(^9\) we demonstrated that bacterial pathogens are carried in high titer on the periurethral mucosa of children with neurogenic bladder. During IC performed several times a day, periurethral bacteria are inoculated into the bladder urine. We found that when \( E. coli \) was detected in the urine, the identical clone was on the periurethra. These findings suggest that the origin of \( E. coli \) isolated from the urine of patients with neurogenic bladder on IC is the periurethra. Catheterization techniques that reduce inoculation of periurethral bacteria into bladder urine deserve investigation.

**ACKNOWLEDGMENT**

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**REFERENCES**


**TABLE 2.** Frequency of Bacteriuria in 10 Patients With Neurogenic Bladder on Standard, Reuse Catheter Method or New Catheter Method During Intermittent Catheterization

<table>
<thead>
<tr>
<th></th>
<th>Standard Method (n = 161 Urine Cultures)</th>
<th>New Catheter Method (n = 158 Urine Cultures)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteriuria</td>
<td></td>
<td></td>
</tr>
<tr>
<td>( E. coli ) isolated</td>
<td>123 (76%)</td>
<td>115 (73%)</td>
</tr>
<tr>
<td>( E. coli )</td>
<td>50 (31%)</td>
<td>53 (34%)</td>
</tr>
</tbody>
</table>
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