OBJECTIVES: To compare the safety and cost of clean versus sterile intermittent bladder catheterization in male nursing home residents. To provide evidence to support the hypothesis that intermittent catheterization is a valid, alternative method of bladder management in male residents of long-term care in whom urinary retention is a documented problem.

DESIGN: Randomized clinical trial.

SETTING: Three long-term care sites having predominantly male populations.

PARTICIPANTS: Eighty male veterans, residents of three long-term care facilities, ranging in age from 36 to 96 years with a mean age of 72.

INTERVENTIONS: Standardized procedures for clean and sterile intermittent catheterization (IC) were implemented by staff nurses at each site. Patients were randomized into clean and sterile IC groups. Nursing time and catheterization equipment usage were recorded using bar code readers. Clinical data were collected from the medical chart. Treatment of urinary tract infection was prescribed by the medical personnel responsible for each individual resident.

MEASUREMENTS: We compared the number of treatment episodes for symptomatic bacteriuria between groups randomized to receive either clean or sterile intermittent catheterization. Laboratory analysis of blood and urine was done on predetermined days. Control variables were research site and patient history of urinary tract infection within the last 6 months. A cost comparison of nursing time and equipment usage for the two catheterization techniques was also performed.

RESULTS: No significant differences were found between clean and sterile groups with regard to number of treatment episodes, time to first infection, type of organism cultured, or cost of antibiotic treatment. The cost of sterile technique was considerably higher both in terms of nursing time and supplies.

CONCLUSIONS: Findings from this study demonstrate that clean technique intermittent catheterization is a safe and cost-effective bladder management technique with male, nursing home residents, despite the frailty of this high risk population. An annual savings of approximately $1,460 per patient in nursing time and catheterization supplies could be anticipated if a patient were catheterized an average of four times per day substituting clean IC technique for sterile IC technique. J Am Geriatr Soc 43:865–870, 1995.

Sterile intermittent catheterization (IC) for bladder rehabilitation of paraplegic and quadriplegic patients was introduced in England after World War II by Sir Ludwig Guttmann. Clean technique IC is the result of the research of Jack Lapides at the University of Michigan in the 1960s and 1970s. Since the introduction of IC, the therapeutic indications for its use have expanded to include patients for whom bladder training is not the goal. Examples of long-term care patients who might be considered appropriate for IC include those with bladder outlet obstruction secondary to prostatic hypertrophy, atomic bladders caused by neurological disease, increased residual urine resulting from medication side effects, and those who are currently managed with an indwelling catheter.

The safety and efficacy of clean IC of the urinary bladder has been established through controlled laboratory and clinical trials in home care and rehabilitation centers. Early literature recommended that strict sterile technique be used for intermittent catheterization in order to avoid the risk of infection thought to be associated with bacteria entering the bladder via the catheter. Use of sterile technique has limited IC because it is both cumbersome and expensive in nursing time and equipment required. Other research has suggested the most common cause for increased susceptibility to bacterial invasion of the bladder is decreased blood flow to the tissue. Lapides and colleagues research with laboratory mice led him to the conclusion that "a distended bladder causes reduced blood flow, thus making the tissues less resistant to invading Gram-negative organisms from the patient's own gut via the hematogenous or lymphogenous route." These findings support the use of clean IC technique in long-term care settings where urinary retention is a documented problem.
researchers attributed urinary tract infection to overdistention and high intrabadder pressure rather than to the presence of residual urine or bacteria. This theory is consistent with the findings of other clinical studies of patients using clean intermittent catheterization.9,10

Urinary tract infection and urinary incontinence have been identified as major problems for the institutionalized geriatric patient.7,11,12 Urinary retention places the already “high risk” individual in danger of reflux, upper tract deterioration, urinary tract infection, and overflow incontinence. Traditional management techniques include indwelling catheters, condom catheters, toileting, and diapering. The prevalence of urethral catheters in long-term care has been reported to range from 2% to 12%. Prospective studies reported by Warren indicate that patients maintained with long-term indwelling urethral catheters develop a new episode of bacteriuria at least every 2 weeks. Warren suggests that infections associated with long-term urethral catheters are the most common of all infections occurring in American health care facilities.13 Clean intermittent catheterization is becoming an accepted alternative treatment for persons of all ages with urinary retention and incontinence attributable to unrelieved bladder outlet obstruction.14,15

Although clean IC has been used with other populations for many years, there has been reluctance to use this procedure in long-term care. Clean IC was considered to increase risk of urinary tract infection in frail older patients. There is no literature to support this stance. Previous literature argues against the possibility of increased risk; yet, in surveys of institutionalized older patients, IC is rarely reported.16–18

It is suggested that “treatment of asymptomatic bacteriuria in older disabled, institutionalized men is of uncertain value.” This rationale is based on the premise that there is a difference between bacteriuria and cystitis, and that not all bacteriuria deserves treatment.19

The purpose of this study was two-fold. First, we sought to determine whether there would be an increased incidence of symptomatic bacteriuria associated with clean versus sterile IC in a long-term care (LTC) population. Second, we compared the total cost of the two treatments. Such information could provide clinical data useful for decision-making with regard to bladder management programs representing large budget expenditures in the LTC setting.

METHODS

The study was a randomized, controlled, clinical trial, lasting up to 125 days, designed to compare the rate of urinary tract infection (treated bacteriuria) between groups of patients receiving either sterile intermittent catheterization or clean intermittent catheterization in a LTC setting.

After obtaining written informed consent, subjects were randomly assigned to a clean intermittent catheterization (CIC) group or a sterile intermittent catheterization (SIC) group. Randomization was controlled for research site and presence or absence of urinary tract infection (UTI) history (defined as two or more symptomatic episodes of UTI within the past 6 months). History of UTI is considered to be an important prognostic factor, and imbalances between groups on this factor might have significantly biased the data.

Sample and Selection

The study population included 80 male subjects recruited from three long-term care sites: the St. Cloud VA Medical Center Nursing Home Care Units, St. Cloud MN (n = 21), the Minnesota State Veterans Home, Minneapolis MN (n = 40), and the Minneapolis VA Medical Center Extended Care (n = 19). The study protocol was approved by the Committees for the Protection of Human Subjects at each participating site.

Patients were included in the study if they had indwelling catheters for relief of residual urine, were currently managed by intermittent catheterization, or had significant residual urine and had an anticipated length of stay of at least 110 days. Exclusion criteria included a medical diagnosis of urethral stricture, which would put the patient at high risk for complication, or the presence of combativeness or other behavioral problems, which would make a program of intermittent catheterization impossible for staff to carry out. (Combativeness was defined as striking out or kicking at the nurse caregiver. Behavior problems included verbal resistance, resistance to undressing for catheterization, unwillingness to maintain a position making it possible to catheterization to be carried out).

A total of 203 possible subjects were screened, and 82 were entered in the study. Reasons for not entering subjects into the study included: individual was not expected to remain in facility for 110 days; long-term indwelling Foley catheters were removed in preparation for the study and patients voided adequately with minimal residual urine; consent could not be obtained because of cognitive dysfunction and absence of family or the patient refused consent. Presence of urethral stricture was also identified. Additional reasons included suprapubic catheters in place that patients were unwilling to give up for purposes of the trial and, finally, one patient died during the period of assessment.

Demographic Data

Baseline data collected on all subjects included age, primary diagnosis, presence/absence of cognitive disorder noted on chart history, ability to transfer or ambulate (assessed by observation), reason for retention of urine, usual volume of residual urine for patients who could void, UTI history, urologic history, medication profile, and antibiotic history.

DESIGN

Technique of Catheterization

Standardized procedures for both sterile and clean catheterization were used at all sites. Consistency was insured by preliminary and bimonthly staff inservice programs plus reliability checks on the nursing care units. Sterile procedure required all sterile equipment for each catheterization, setting up of a sterile field with drapes, and cleansing of the urinary meatus with Betadine before catheterization.

Clean technique catheterization does not require a sterile field and can be done in bed or chair as the patient desires. No cleaning of the meatus was done if normal daily hygiene (daily cleansing with soap and water) appeared sufficient and there was no obvious contamination with stool or other drainage. All catheterization equipment was supplied by the pharmacy in a sterile condition. However, after the first use and for each catheterization done during a one week period, the catheter was simply washed with mild soap and running water, dried on a clean, lint free towel and stored at the patient’s bedside in a clean, dry container. Clean catheters were replaced each week.
Frequency of Catheterization

Frequency of catheterization varied between subjects, based on their postvoid residual urine measurements. For those who did not void, catheterization intervals were determined by the individual's pattern of fluid intake and total bladder volumes. Total bladder volumes were closely monitored in all subjects to ensure accumulation of amounts no greater than 350cc to 400cc of urine. Volumes were obtained by adding the amount of urine voided to the amount of urine obtained by catheterization within 10 minutes of voiding time. For patients who did not void, catheterized urine volumes equaled total bladder volume.

Symptomatic Bacteriuria

For purposes of this study the diagnosis of urinary tract infection (UTI) was made according to one of three criteria:
1. The presence of greater than 100,000 colonies/mL of a single organism coupled with the presence of one or more signs or symptoms of UTI.
2. Bacteriuria of a lesser colony count coupled with one or more symptoms or signs of UTI.
3. The presence of one or more signs or symptoms of UTI coupled with greater than 10 WBCs/hpf on urinalysis.

Signs and Symptoms

Signs and symptoms included fever, dysuria, urgency, frequency, costovertebral angle tenderness, altered mental status, change in activity level, abrupt onset of incontinence, hematuria, or cloudy, foul smelling urine containing mucus.

Laboratory Data

Routine blood and urine specimens were collected on all study patients on days 0, 2, 4, 6, 10, 15, 60, and 90. All specimens were tested at the St. Cloud and Minneapolis VA Medical center laboratories. Blood and urine samples were sent on other than specified days if the medical or nursing staff felt it was clinically indicated.

The number of days to occurrence of the first infection and number of infections on Day 15 were chosen to compare episodes of UTI between groups. The analysis of time to the first episode of symptomatic bacteriuria has higher statistical power than the analysis of the nominal variable (presence/absence of at least 1 episode), because of the increased information available from this interval level variable.

Scheduled, routine, non-blinded laboratory examination of blood and urine was obtained from each subject. All urine samples sent for culture and sensitivity were collected using sterile technique and sterile equipment, regardless of the study group to which a subject was assigned. Daily clinical data on each subject, including possible signs and/or symptoms of UTI, were recorded by the research nurse coordinator for each site.

Cost Analysis

Cost data included both nursing time and supplies required for each catheterization. This information was collected by the nurse at the bedside using a bar code scanner. Use of this technology insured accurate time recordings based on an internal clock, which stamps each data entry with the date and time of collection. The nurse scanned a bar code at the start of the procedure and another bar code at the end of the procedure. Total time spent during the catheterization procedure included initial hand washing, positioning the patient, actual catheterization, repositioning the patient, disposal of the urine obtained and of soiled supplies during sterile IC, washing and storing of the catheter for clean IC, and final hand washing. Supply use was recorded at the bedside in a similar manner, by scanning the appropriate bar codes to indicate any and all new equipment used. Reusable equipment was scanned only when it was initially put into service. The barcodes for each subject were on a waterproofed sheet kept at the bedside or nursing station. Pocket sized barcode scanners were available to the nurses on each station.

RESULTS

Analysis of data is based on a total of 4967 bar code scans for subjects assigned to sterile technique and 4128 scans for subjects assigned to clean technique. This represents the data for 80 patients over the total study period of 2.5 years. Subjects were entered at intervals throughout that period and remained in the study from 15 to 107 days. Average number of days in the study for the sterile groups was 63.6 and for the clean groups 63.8. Reasons for dropping out of the study before the end of the 90-day protocol were: death unrelated to the study, clean 1, sterile 1, (C1, S1), request for discontinuation of study (C1, S1), hospitalization of the patient for >21 days for an unrelated problem (C3, S2), subject discharged from facility (C3, S6), communicative (C0, S1), reduction in volume of residual urine so that patient no longer required catheterization (C9, S11), and end of study funding period (C1, S1). A total of 20 from the clean group and 19 from the sterile group completed the entire 90 day protocol. Total number of days in the study for all patients equaled 2452 for the clean group and 2672 for the sterile group. Table 1A describes the distribution of risk factors for UTI, Table 1B addresses the total scores for mean and standard deviations for dependent and independent variables. All subjects had a full data set for Day 15 of the study, making it an appropriate time to compare groups on IC frequency and residual urine volumes. None of the variables in Tables 1A and 1B were significantly different across the two groups. Table 2 lists diagnoses of residents and causes of residual urine. No significant differences were found between the IC groups in the proportion of residents exhibiting specific primary diagnoses ($x^2=0.712$) or the proportion of individuals with specified causes of residual urine ($x^2=0.878$).

History of urinary tract infection (UTI) as a significant predictor for future symptomatic bacteriuria was revealed by using Day 15 data in a 2x2x3 ANOVA (IC technique * UTI history * study site, with number of bacterial colonies >100,000 reported on urine cultures for each subject as the dependent variable. Subjects with a history of UTI were more likely to become infected than subjects without, $F_{1,78} = 5.58$, $P < .05$).

Intermittent catheterization did not affect the occurrence of UTI between clean and sterile groups ($F_{1,78} = 1.03$), and no differences were found to exist among the research sites ($F_{2,74} = 1.03$). Survival analysis, based on the time to first treatment episode, was also used to compare clean and sterile groups. There was no significant difference in the number of days to onset of symptomatic bacteriuria (UTI) between the two groups. Total number of days at risk for the sterile group was 2672, with 35 treatment episodes occurring during that
Table 1. Key Characteristics of Clean and Sterile Groups

<table>
<thead>
<tr>
<th>Risk factors for UTI</th>
<th>Clean (n = 38)</th>
<th>Sterile (n = 42)</th>
<th>$\chi^2$</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive impairment</td>
<td>22</td>
<td>17</td>
<td>2.423</td>
<td>0.120</td>
</tr>
<tr>
<td>Transfer assistance</td>
<td>27</td>
<td>26</td>
<td>0.747</td>
<td>0.388</td>
</tr>
<tr>
<td>Ambulation impairment</td>
<td>29</td>
<td>28</td>
<td>0.907</td>
<td>0.341</td>
</tr>
<tr>
<td>Prophylactic antibiotic</td>
<td>15</td>
<td>3</td>
<td>0.802</td>
<td>0.370</td>
</tr>
<tr>
<td>History of urinary tract infection</td>
<td>20</td>
<td>22</td>
<td>0.001</td>
<td>0.982</td>
</tr>
<tr>
<td>Primary diagnosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurologic disease</td>
<td>23</td>
<td>22</td>
<td>0.538</td>
<td>0.463</td>
</tr>
<tr>
<td>Medical</td>
<td>2</td>
<td>3</td>
<td>0.120</td>
<td>0.729</td>
</tr>
<tr>
<td>Psychiatric</td>
<td>6</td>
<td>7</td>
<td>0.011</td>
<td>0.915</td>
</tr>
<tr>
<td>Urological</td>
<td>3</td>
<td>5</td>
<td>0.356</td>
<td>0.550</td>
</tr>
<tr>
<td>Orthopedic</td>
<td>4</td>
<td>5</td>
<td>0.038</td>
<td>0.846</td>
</tr>
<tr>
<td>Cause of residual urine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underactive detrusor</td>
<td>18</td>
<td>20</td>
<td>0.001</td>
<td>0.982</td>
</tr>
<tr>
<td>Infravesical obstruction</td>
<td>15</td>
<td>19</td>
<td>0.271</td>
<td>0.602</td>
</tr>
<tr>
<td>Idiopathic</td>
<td>5</td>
<td>3</td>
<td>0.802</td>
<td>0.370</td>
</tr>
</tbody>
</table>

Table 2. Total Scores for Dependent and Independent Variables

<table>
<thead>
<tr>
<th></th>
<th>Clean Mean ± SD</th>
<th>Sterile Mean ± SD</th>
<th>t</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>70.9 ± 12.1</td>
<td>72.6 ± 10.8</td>
<td>0.632</td>
<td>0.529</td>
</tr>
<tr>
<td>IC frequency (day 15)</td>
<td>3.0 ± 1.1</td>
<td>2.8 ± 1.1</td>
<td>0.752</td>
<td>0.455</td>
</tr>
<tr>
<td>Residual urine (cc day 15)</td>
<td>332.3 ± 188.9</td>
<td>269.5 ± 171.9</td>
<td>1.546</td>
<td>0.126</td>
</tr>
<tr>
<td>Days to first treatment</td>
<td>24.4 ± 21.2</td>
<td>21.8 ± 21.9</td>
<td>0.400</td>
<td>0.688</td>
</tr>
<tr>
<td>Days in study</td>
<td>63.8 ± 32.9</td>
<td>63.7 ± 31.3</td>
<td>0.027</td>
<td>0.978</td>
</tr>
</tbody>
</table>

A series of analyses were performed to compare the costs of the clean versus sterile IC per catheterization. A 2x2x3 ANOVA (technique x UTI history x site), with nursing time as the dependent variable, revealed a significant difference in total cost of sterile versus clean technique catheterization. A total of 9095 complete scans of procedure time were collected for the 80 patients over the course of the study. Mean nursing time for sterile technique catheterization was 9 minutes, exactly 60 seconds more than for clean technique ($F_{1,78} = 8.79, P < .005$). However, there was no significant difference in procedure time between RNs and LPNs assigned to study subjects for either technique. Clean technique ($t_{36} = 1.23$, ns), Sterile technique ($t_{40} = 0.95$, ns).

Average cost per catheterization, based on RN salary ($25.00/h), LPN salary ($13.00/h), and supply costs, was significantly higher for sterile catheterization ($$6.25) than for
clean catheterization ($4.00) \( (t_{78} = 12.58, P < .0001) \). (Figures based on 1993 Minneapolis VA Pharmacy costs and average salaries for RN and LPN staff nurses.)

Clean and sterile groups were compared for the occurrence of Gram-negative versus Gram-positive organisms on culture (Day 15). There were no significant differences between the groups \( (x^2 = 2.35) \). The cost of antibiotic treatment for the first treatment episode was not different for clean and sterile groups \( (t_{43} = 0.67) \). *Escherichia coli* and *Klebsiella pneumonia* were the most commonly found Gram-negative organisms, reported with equal frequency for each group. Gram-positive organisms in the clean and sterile groups were predominantly *Enterococcus*. Urosepsis developed in one subject during rehabilitation for total hip arthroplasty. This subject was in the sterile group and the organism cultured was *K. pneumonia*.

**DISCUSSION**

Every effort was made to design a trial that would approximate usual care. On site nursing staff performed the catheterizations. Although all three study sites treat veterans, they had important differences. The Minnesota State Veterans Home and St. Cloud VA Medical Center nursing home care units both serve very long stay residents, whereas the extended care units of the Minneapolis VA Medical Center serve residents who stay for shorter periods. In addition, the St. Cloud VA Medical Center has a very high proportion of patients who have chronic psychiatric diagnoses. The fact that there appears to be no difference in the frequency of urinary tract infections between clean and sterile IC regardless of site or number of staff involved suggests that clean intermittent catheterization may offer a safe and cost-effective alternative to sterile intermittent catheterization for select male residents in long-term care settings.

In this study, the use of clean IC resulted in a cost savings of $2.00 per catheterization. Using 1993 Minneapolis VA pharmacy costs, we estimated that an annual savings of approximately $1460.00 per patient could be anticipated if catheterization was done an average of four times per day using a clean rather than a sterile technique.

Even though clean IC appears to be as safe and effective as sterile IC, and promises substantial savings, it is of little significance if IC continues to be perceived by the medical community as appropriate for only a small number of LTC residents. This view is attributable partly to the fact that the majority of residents are older women whose incontinence is usually diagnosed as stress and/or urge. However, female LTC residents are appropriate potential candidates for IC, as was demonstrated in a 1984 study conducted by Bennett and Diokno of clean IC in older patients. There were comparable numbers of female and male subjects. In female subjects, the most common indication for IC was “non-neurogenic, atonic, or decompensated bladder.”

The literature suggests that when intermittent catheterization is substituted as an alternative to indwelling catheters for bladder management, rates of both bacteriuria and symptomatic infection decrease. In addition, IC users are not put at risk of other complications often seen with chronic catheterization. However, concerns about frail older people have resulted in the continued use of the indwelling Foley catheter or IC using sterile procedures in long-term care settings. The debate about clean versus sterile IC continues. Data on the incidence of infection is confounded by the routine use of prophylactic systemic antibiotics. In spite of this, it appears that a high percentage of patients will eventually develop bacteriuria using either technique, but morbidity and mortality associated with IC may be substantially less than that found in patients on indwelling catheters.

Frequency of catheterization is key to the success of the program as a means of avoiding over distention and to reducing bacterial growth.

The literature includes very little data on the use of intermittent catheterization in a long term care population. Most well controlled studies have been done in rehabilitation settings, frequently with spinal cord-injured or other neurologically compromised individuals. Two longitudinal studies of catheter-related infections in long-term care are described in the literature. In a survey of the complications caused by chronic indwelling urinary catheters among male residents in 90 Veterans Administration nursing homes, Ouslander and colleagues found that 41% of patients were identified as continent and 22% of these were managed by indwelling catheters. Of the 90 patients with catheters included in this study, 54 (60%) were catheterized for retention of urine. Research with female residents of long-term care managed with indwelling catheters found that three of the 47 participants had a diagnosis of retention of urine. One participant had a catheter placed to facilitate output measurements, one other for unknown reasons, and the rest were catheterized for urinary incontinence. Warren and colleagues presented a prevalence study of 1,315,800 nursing home residents across the United States. Urethral catheterization use ranged from 9.2% to 10.1% in women and from 6.1% to 6.7% for men. Of the total population of men in the survey (972), 6.4% had urethral catheters, 5.9% used condom catheters, 2.3% had suprapubic catheters, and only 0.2% were on intermittent catheterization.

In this age of health care reform, findings of this study will contribute to knowledge regarding cost-effective bladder management for patients with urinary retention and incontinence. The average cost of continence care for long-term care patients is $4 to $8 per day. *Hu* et al. report total health care costs related to UI in the Nursing Home may be as much as $4104 annually for each incontinent resident. This includes care of skin rashes, decubitus ulcers, treatment of urinary tract infections, and injury from falls. Cost of care of the incontinent patient represented more than 10% of the total national costs for Nursing Home care in 1987 dollars.

The medical community will not use IC in long-term care unless they become convinced that it offers a safe, comfortable, and economical means of treating incontinence. Veterans Administration facilities may realize the greatest financial benefit from such a policy change because they care primarily for male residents. Nevertheless, the benefits of IC should not be overlooked for other patients when quality of life may be an issue. Based on this study, and others, it is clear that clean intermittent catheterization should be considered an alternative treatment for urinary incontinence in the older, institutionalized male.

Further comparison of indwelling versus clean intermittent catheterization must include females and must assess cost, quality of life, and acceptance by patients.
ACKNOWLEDGMENTS

We are indebted to the three study sites and their nurses and physicians, without whose cooperation this work would not have been possible. We thank A. Ami Sidi, MD, for urologic consultation, Jodeen Pasell, LPN, for data collection in St. Cloud, Laura Walton-Bell, MS, and Mary Wright, MA, data coding management, Bruce Bakke, PhD, Patricia Brugge-Wiger, PhD, Mary Erdman, RN, and William Korchik, MD, for guidance and expertise on clinical and research issues and Melitta Maddox, MSN, RNC for editorial assistance.

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