University of Alberta

A Comparison of Two Solutions for Cleaning Catheters Used for Clean Intermittent Catheterization: Savlon 1:30 Aqueous and Sunlight Detergent

by Katherine N. Moore

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies and Research for acceptance, a thesis entitled A COMPARISON OF TWO METHODS OF CLEANING CATHETERS USED FOR CLEAN INTERMITTENT CATHETERIZATION: SAVLON 1:30 AQUEOUS AND SUNLIGHT LIQUID DETERGENT submitted by Katherine Nancy Moore in partial fulfilment of the requirements for the degree of MASTER OF NURSING.

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DEDICATION

To the children with Spina Bifida and their parents: that their routines may be a little easier because of research such as this.

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The Alberta Foundation for Nursing Research
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ABSTRACT

Clean intermittent catheterization (CIC) is a routine non-sterile procedure for individuals with neurogenic bladder dysfunction. Some researchers believe that the chronic bacteriuria of many users of CIC is a result of unsterile catheters introducing pathogens into the bladder. The best method of cleaning the reused catheters, however, is open to question. A cross-Canada survey revealed many recommendations, none based on empirical data.

The purpose of this study was to compare the effectiveness of two solutions currently recommended for cleaning reused catheters: Savlon Aqueous 1:30 and Sunlight liquid detergent. Three research questions evolved: (1) which method is most efficient: (a) catheters soaked in Savlon, (b) washed with Sunlight, or (c) washed with Sunlight plus soaked in Savlon? The design for this question was a within-subject catheter tip study and used dependent *t*-test to measure the difference between mean organisms on catheters and Chi square to measure the difference in proportion of sterile catheters; (2) Does Savlon support Gram Negative organisms? and (3) Does the study population

have fewer incidences of bacteriuria ($\geq 10^6$ col/L) than those described in the literature? These questions were presented with descriptive data.

The non-probability convenience sample ($\underline{n}$=31) was drawn from 62 registrants of a local Spina Bifida Clinic. All specimens were collected from subjects' homes on two occasions and cultured within 30 minutes at the University laboratory.

Results showed no significant difference between the number of organisms (hand contaminants rather than pathogenic) on catheter tips cleaned by one of the three methods described. However, there were a significantly higher number of sterile Sunlight catheters (60%) compared with soap plus Savlon (47%) and Savlon soak (42%). Savlon samples were tested on several occasions: after one use, after standing at room temperature for 2 weeks after 1 use, and after daily use for $\geq$ 2 weeks. Gram negative organisms were also injected into Savlon in the laboratory. All Savlon cultures after 48 hours were sterile. Urinalyses revealed 23 of 30 subjects with bacteriuria; 20 of these were asymptomatic. These urine results are consistent with the literature.

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Chapter 1

Introduction and Statement of the Problem

Clean intermittent catheterization (CIC) has done more to control incontinence and urinary tract infection (UTI), and maintain renal and bladder health for people with neurogenic bladder dysfunction than any other urological procedure to date. The catheterization procedure is generally accepted as _clean_ rather than sterile. This is based on the belief that UTI in neurogenic bladders is caused not by the organisms introduced into the bladder on the catheter but rather from stasis of urine and incomplete emptying of the neurogenic bladder from lack of catheterization (Enrile & Crooks, 1980; Hilwa & Perlmutter, 1973; Lapides, Diokno, Lowe, & Kalish, 1974). What seems to be most important in controlling UTI in people with neurogenic bladder dysfunction is regular, complete emptying of the bladder and prevention of distention (Lapides, Diokno, Silber, & Lowe, 1972).

However, CIC is not without difficulties and some people can only partially control incontinence with CIC. Moreover, many have chronic asymptomatic bacteriuria with occasional symptomatic flare-ups including fever, malaise, flank and suprapubic pain, and incontinence. There is a group of researchers who believe that a relationship exists between the organisms on the catheter and bacteriuria and thus recommend that the intermittent catheterization procedure be sterile, rather than clean (Anderson, 1980a, 1980b; Donovan, Stolov, Clowers, & Clowers, 1978; Walhlquist, McGuire, Green, & Herlihy, 1983).

Inconclusive research results comparing bacteruria in patients using clean or sterile catheterization (Anderson, 1980a, 1980b; Comarr, 1972; Donovan, Stolov, Clowers, & Clowers, 1979; Wahlquist, McGuire, Greene, & Herlihy, 1983) and the cost of using a sterile catheter 4 to 5 times a day, leave most urologists and nurses recommending some form of home disinfection and reuse of catheters (Appendix 1). However the lack of research into the best method of cleansing catheters has left nurses and doctors giving a wide variety of suggestions to individuals using CIC. In one Canadian city, for example, staff in three institutions each recommend a different method of catheter care: boiling for 20 minutes, washing with soap and water, and soaking in Savlon Aqueous 1:30 (Savlon). None of the three surveyed had empirical data to support the choice of one method over another. Similar results were found in a cross-Canada survey (Appendix 2) which revealed little consistency in rehabilitation or paediatric hospitals across the country. The instructions to users of intermittent catheterization are based on the principles of asepsis and knowledge of infection accompanying indwelling catheters. The principle underlying CIC is much different: prevention of bladder distention by regular emptying prevents urinary tract infection. Thus it appears nurses are directing patients based on beliefs rather than scientific data which leads to ambiguous information from and among health professionals. Unclear or ambiguous information about catheter care may also lead to the poor compliance with the CIC regimen described by some authors, including: Cass, Luxenberg, Gleich, Johnson and Hagan (1984); Drago, Wellner, Sanford and Rohner (1977); Kaplan (1985); Klauber and Sant (1983). Overall, as shown by the literature and hospital survey, the most frequently recommended method for cleaning catheters is that described by Lapides, Diokno, Silber, & Lowe (1972)--liquid soap and water (Appendix 3).

The staff at the Spina Bifida Clinic of a large urban rehabilitation centre in Western Canada recommend that catheters be washed with soap and water and then soaked after each use in Savlon. To date, no studies have been done to evaluate the effectiveness of Savlon for this purpose. There is some evidence in the pharmacology research that quaternary ammonium compounds such as Savlon are not as effective as other disinfectant solutions against gram negative organisms, especially Pseudomonas aeruginosa (Favero, 1983; Martindate, 1982). Based on a review of the literature which revealed no definite research describing solutions for cleansing catheters, an evaluation of the regimen for catheter care at the above rehabilitation hospital was suggested.

The purpose of the study was to determine if Savlon was as effective a cleaning agent against organisms on reused catheters as was the more generally accepted cleanser, liquid soap and water.

The goals were: (1) to investigate the number and type of organisms on catheters soaked in Savlon and catheters washed with liquid soap and water; (2) to test the hypothesis that Savlon may support the growth of Gram negative organisms; (3) to compare the rate of bacteruria in the study population to that described in similar populations in the literature (Appendix 4).

Research Hypotheses

1. There will be no significant difference in the number of organisms cultured from catheters rinsed under running water then soaked in Savlon for 30 minutes after use and those washed with liquid detergent (Sunlight) and water.

2. Catheters washed in soap and water plus soaked in Savlon for 30 minutes will have significantly more sterile catheters than those soaked in Savlon only or washed with Sunlight only.

3. There will be no significant difference in the number of organisms in Savlon mixed <1 hour and used once; used once and left standing at room temperature for two weeks; and, used daily for two weeks.

4. Subjects reusing catheters cleansed with soap and water plus Savlon will have fewer incidences of bacteriuria than subjects using only soap and water (Appendix 5).

Operational Definitions

Intermittent catheterization: regular, complete emptying of the urinary bladder with a urethral catheter. Catheterization should be timed so that the bladder does not contain more than 150 ml (1-5 years), 240 ml (6-9 years), and 300 ml (9-12) years (Horsley, Crane, & Reynolds, 1982).

Clean Intermittent Catheterization: performed by the patient or care giver. Before use the catheter and hands are washed with soapy water and rinsed under the tap. After use, the catheter is cleaned in some way, dried and stored in a non-sterile container. Catheters are reused many times.

Sterile Intermittent Catheterization: performed by the patient or the nurse under aseptic conditions using a sterile catheter.

Detergent Soap: Sunlight liquid detergent. Sunlight was chosen for the study as it is a pure detergent soap with no additives, it is inexpensive, and easily available.

Pathogens: any organisms which could result in a urinary tract infection are considered pathogens. These included: E coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Streptococcus group D, Proteus mirabilis, Entero bacter, Providencia, Staph epidermis, Staph aureus, Acineto bacter, Citro bacter, Serratia marcescens, Candida albicans, other Gram-negative rods.

Bacteriuria: the presence of pathogens in the urine. The standard set by Kass (1956) is still followed as a guideline (>10^5 colonies/ml or 10^8 /L) although the presence of white blood cells in the urine and clinical symptoms of UTI--fever >38 C (oral), malaise, suprapubic or flank pain or incontinence--must be considered over the exact colony count (Sobel & Kaye, 1987). For purposes of this study, bacteriuria is defined as a colony count $\geq 10^6$ /L ($\geq 10^3$ /ml) as this was the lowest significant rate cited in the literature (Donovan, Stolov, Clowers, & Clowers, 1978).

Asymptomatic bacteriuria: Bacteriuria without any clinical or systemic signs of Urinary tract infection (UTI).

Symptomatic bacteriuria: Bacteriuria with the symptoms of UTI. For the study, this was determined by urine culture by standard laboratory techniques and by the subjects' responses to questions about the above clinical symptoms.

Assumptions

The study was based on the following assumptions:

1. The goal of CIC is to: (a) preserve renal function, (b) control clinically significant UTI, and (c) maintain continence, especially for social reasons (Brock, So, Harbach, & Kaplan, 1981; Crooks & Enrile, 1983).

2. Patients reuse disposable catheters for CIC and this is acceptable as a non-critical care item (Health Services Directorate, 1985).

3. After the catheter is used, it is cleaned in some way.

4. The least complicated procedure for catheter cleansing may be best accepted by patients.

5. Reducing bacteria on the catheter surfaces may reduce bacteriuria.

Chapter II

Review of the Literature

The purpose of this literature review is to explore and discuss research data concerning clean intermittent catheterization (CIC) in the care of individuals with neurogenic bladder dysfunction. For purposes of this study, the review focuses on children with spina bifida rather than the whole group of individuals who may use CIC which includes diabetics, multiple sclerosis patients, and paraplegics. The methods described to clean catheters are explored and an attempt is made to relate these methods of cleaning with the number of urinary tract infections in the study groups.

Approximately 100 relevant articles were reviewed for the period 1972-1988. The 1972 endpoint was chosen because clean intermittent catheterization was introduced in 1972 by Lapides, Diokno, Silber, and Lowe. Nursing fundamentals texts were consulted; a microbiologist and urologist at the University and the Rehabilitation Hospital were contacted about the relationship between CIC and urinary tract infection and their beliefs about the most appropriate method of catheter cleansing. The Canadian Hospital Directory was consulted for names of rehabilitation and paediatric hospitals which might teach CIC. Twenty-two hospitals were contacted about the method of catheter cleansing recommended to patients (Appendix 2).

Review of the Literature

Neurogenic bladder dysfunction results from some impairment of the neural pathways innervating the detrusor and sphincter muscles which arise from the sacral and thoraco-lumbar segments of the spinal cord (de Groat & Booth, 1980). The causes of neurogenic bladder dysfunction are many: sacral agenesis, multiple sclerosis, spinal cord injury (SCI), tumours, and in childhood, spina bifida. Untreated, the majority of children with spina bifida would have difficulty with incontinence, infection, residual urine, and upper urinary tract dilatation. The sphincter system in these cases is often overactive, and combined with a weak detrusor and /or a degree of detrusor-sphincter dysynergia results in ineffectual bladder emptying. The focus of this review is more on spina bifida than other causes of neurogenic bladder; however, treatment with intermittent catheterization may be generalized to most groups.

Management of Incontinence: A Review

Management of incontinence and urinary tract infection (UTI) is a serious problem for all children with spina bifida. Until recently, the goals of social continence, preservation of the renal tract, and independence from an external collecting device, have been impossible to attain. Historically, if the child did not succumb to the neurological complications of hydrocephalus, renal failure from chronic UTI was the next cause of death (Smith, 1972; Rose, 1962). Williams (1958) stated "the control of incontinence is the most important single factor in fitting these children for a useful existence and renal failure is the most serious threat to the life of those who have survived the early hazards of meningitis and hydrocephalus" (p. 127). Cooper (1967), reviewing charts of 415 children between 1958 and 1965, points out that "Urinary tract infection occurs in 60% of children during the first five years of life" (p. 524) and that only 50% of the study population was alive after five years. Cass, Luxenberg, Johnson, and Gleich (1985) also reviewed charts of 264 children between 1951 and 1982 and found the incidence of urinary tract infection and urinary complications of reflux, hydronephrosis, and incontinence most prevalent in the first 2 to 4 years of life.

<u>Catheter Control</u>

Many attempts have been made to control neurogenic bladder incontinence. To date, none are 100% effective. Conservative management with an indwelling (foley) catheter can be only a temporary measure as complications far outweigh any benefits. Only one study was found which described longterm indwelling catheter use as suitable for continence control when other methods fail (El Gohary, Brereton, & Lister, 1982). Overall, indwelling catheter drainage has long been associated with renal and bladder calculi, urethral lesions, epididymitis, chronic prostatitis, vesico-ureteral reflux, and/or sepsis and is not a suitable alternative for controlling incontinence or UTI in children or adults with neurogenic bladder dysfunction (McGuire & Savastano, 1986; Rolnick, 1949; Thomson-Walker, 1917; Wyndaele, DeSy, & Claessens, 1985). The indwelling catheter is also the major cause of nosocomial infection of the genito-urinary tract (Klarskov, Rischoff, Bremmelgarrd, & Hald, 1986; Meares, 1985; Platt, 1982). Thus, for children with neurogenic bladders, the foley catheter is "a useful temporary expedient, but the likelihood of trophic changes in the urethra is so great that it should not be employed permanently" (Williams, 1958). Suprapubic catheterization and condom drainage are also unsatisfactory. None of these drainage measures are socially acceptable nor is the child independent from some external collecting device (Bennett & Diokno, 1984).

Surgical Control

Surgical procedures for incontinence evolved in the 1950's. Bricker's ileal conduit procedure was considered medically and socially beneficial (Rose, 1962; Williams, 1958). Spellman and Kickham (1962) describe encouraging results in the management of incontinence, based on the following regimens: longterm administration of "suppressive doses of sulfonamides; frequent bladder expression; reduction in vesicoureteral reflux and hydronephrosis by prolonged indwelling urethral catheter drainage; and urinary diversion by ureteroileostomy in patients with intractable, severe hydronephrosis or with urinary incontinence persisting to school age"(p.244).
In the 1970's, Smith (1972) was one of many who stated with confidence that urinary diversion revolutionized

the social management of children with spina bifida. No other method thus far had provided complete continence. Credé (manual expression of the bladder by pressure above the symphysis pubis), for example, failed to keep patients dry; penile drainage led to ulceration and leakage; indwelling catheters inevitably led to infection; longterm use of sulphonamides led to renal damage. Urinary diversion such as the ileal conduit or cutaneous ureterostomy seemed the answer to improving general health and social acceptance for these children. Even in his enthusiasm, however, Smith noted that there were complications concerning a urinary stoma which must be considered: ulceration at the site, leakage of the apparatus due to poor fit because of scoliosis, and pyocystitis leading to chronic, purulent, bladder discharge. Most importantly, he considered the emotional consequences of a urinary diversion as a "most serious complication" (p. 816). The ileal conduit was popular nonetheless, and it seemed that even if reflux occurred, it happened under low pressure and therefore would not be a problem (Editorial, Lancet, 1979). As late as 1976, Cass recommended urinary diversion for the majority of cases of neurogenic bladder. He noted that with both Credé expression and foley catheter management, chronic infection and incontinence were intractable problems.

Yet by 1975, many surgeons realized the ileal conduit was responsible for the "silent deterioration of the kidneys" (Snyder, 1987, p. 1726) and children with spina bifida still died of renal failure from the freely refluxing conduit. Shapiro, Lebowitz, and Colodny (1975) were one of the first groups to describe the complications of ileal conduit--patients had a complication rate of more than 85% which included upper tract dilation, calculi, progressive renal failure, hypertension, and stoma troubles. These authors recommended the procedure only as a last resort. Cass, Luxenberg, Gleich, and Johnson (1984) conducted a restrospective study between the years 1960-1982 of 139 children who had undergone urinary diversion. The main goal of the surgery--to prevent upper tract infection and deterioration--had seemed obtainable at the time of surgery. Even five years after the surgery, most children had had satisfactory results. But over the longterm, renal complications were inevitable and over 16% of children in a ten year study had upper tract deterioration. Crooks and Enrile (1983) compared ileal conduit and intermittent catheterization in two groups of children with spina bifida. They found that up to 80% of the children originally treated with ileal conduit had at least ureteral dilation and hydronephrosis while a group treated with intermittent catheterization had no renal changes by the end of the study. Similar results were reported by Middleton and Hendren (1976). Late complications and an unacceptably high rate of renal deterioration from ileal conduit now make the procedure a last choice.

Current surgical management of urinary incontinence, especially with children, involves reimplantation of the ureters for reflux, colon conduit (rather than ileal) with non refluxing ureterocolonic anastomoses, ureterosigmoidostomy, bladder neck reconstruction, and the artificial urinary sphincter (Light, Keith, Hawila, Scott, & Brantley, 1983). Such surgical procedures are acceptable only after conservative management has completely failed. Conservative management has become a realistic possibility since the introduction of clean intermittent catheterization in 1972.

Intermittent Catheterization

Intermittent catheterization (IC) has been known for centuries. Bronze catheters were unearthed in

Pompeii and catherization technique was described by Celsus in 90 A.D. (Murphy, 1972). King (1986) claims that Kentucky Colonels carried catheters in their hat bands to relieve periodic prostatic obstruction; Connors (1934), Coulson (1881), Morton (1901), and Thompson-Walker (1917) are among many who recognized the value of intermittent rather than indwelling catheter in cases of "paralysis of the bladder" because of the associated infection and sepsis which inevitably occurred. Negley (1941) found that between 1917 and 1941, IC was chosen approximately 10% of the time in cases of bladder paralysis.

In 1944, Frankel and Guttmann began systematically studying the use of IC in the care of patients with spinal cord injuries (SCI). In 1966, they published two landmark studies based on a 10 year follow up of SCI patients which favoured IC over the use of an indwelling catheter (Frankel & Guttmann, 1965; Guttman & Frankel, 1966). They found that because the tone of the detrusor and sphincter muscles is diminished in SCI, regular intermittent catheterization mimics the normal bladder filling and emptying, making it easier for the patient to eventually resume voiding. As well, regular emptying prevents bladder distension.

They hypothesized that distension caused a thin, ischemic bladder wall while part of the defense mechanism of the bladder against infection depended on good blood supply. Thus if distension and ischemia could be prevented, so would infection. (This theory was later supported by Lapides, Diokno, Silber, & Lowe (1972)). Most significantly, Frankel and Guttmann found that complications of intermittent catheterization were few. Hydronephrosis, vesico-ureteral reflux, and bladder stones were rare. Urinary tract infections were easily treated with antibiotics. These authors firmly believed in the absolute sterility of the procedure and in fact, scrubbed and gowned with surgical technique to perform each catheterization.

<u>Sterile Intermittent Catheterization</u>

Some writers suggest that sterile catheter technique is of utmost importance when using intermittent catheterization as a bladder management procedure (Anderson, 1980a, 1980b; Comarr, 1972; Pearmann, 1971; Pearman & England, 1976). To date, these studies have focused primarily on patients with spinal cord injury rather than meningomyelocoele, and none have been conducted in the home. It is currently agreed that because of the high incidence of nosocomial infections, especially from catheterization, that the use of sterile technique in hospital is appropriate (Stover, Lloyd, Nepomuceno, & Gale (1977-78). However at home, it is not entirely practical.

Three authors have studied the incidence of bacteriuria using sterile technique and other methods. Donovan, Stolov, Clowers, and Clowers (1978) conducted a study on 60 SCI patients catheterized every 4 hours using sterile technique. The purpose of the study was to determine the number of patients free from bacteriuria (>10^3 col/ml) during intermittent catheterization. They found that 77% of patients had bacteriuria and that the onset occurred on average 31.5 days after intermittent catheterization was started. The overall ratio of bacteriuria to catheterizations was 7/1000, similar to the results of Pearman (1971) who used bladder instillation to control bacteriuria. All patients were given ascorbic acid; as well, most received methenamine mandelate. Unfortunately, the study had no control group comparing clean technique or comparing patients not taking urinary antiseptics.

Anderson (1980a) also studied SCI patients. The purpose of the study was to show the efficacy of prophylaxis to reduce bacteriuria <10^4 col/ml. He divided the sample into four groups: (1) sterile intermittent catheterization (SIC) q4 or 8 hourly; (2) SIC plus bladder instillation of neomycin/polymyxin B after each catheterization; (3) SIC and 100 mgm of nitrofurantoin po; (4) SIC, 100 mgm of nitrofurantoin po. and bladder instillation. Onset of bacteriuria ranged from 15 days to 45.5 days, respectively, and the overall rate of infection was 1/200 catheterizations. However, all patients catheterized every 8 hours had statistically higher rate of bacteriuria than those catheterized every 4 hours.This may support the belief of Lapides, Diokno, Silber and Lowe (1972) that frequent catheterization every 4 hours is crucial to controlling proliferation of bladder organisms. Only one patient had symptomatic UTI. In a second study (1980b), Anderson compared sterile intermittent catheterization to catheterization with a reused catheter which was rinsed with water, but not washed with soap and water. Two groups had oral nitrofurantoin plus bladder instillation of antibacterial solution and the third group serving as the control, used rinsed catheters only. His results were: unsterile and sterile catheterization group using bladder irrigation and prophylaxis had 8.3 and 2.8 incidents of bacteriuria per 1000 catheterizations, while the control group had 96/1000. "Significant" bacteriuria was $>10^4$ colonies/ml. Yet even in this study, only 1 patient using non-sterile technique had symptomatic pyelonephritis; all other infections were asymptomatic except for an unstated increased incidence of dysreflexia. Again, the patients catheterized every 8 hours had a significantly higher rate of bacteriuria than those catheterized every 4 hours.

These results are compared to a study by Maynard and Diokno (1984). The technique used in this study was rated as clean rather than sterile with the catheter being rinsed with benzalkonium chloride and flushed with water after each use. The purpose was to record all complications of CIC, including bacteriuria and UTI. All patients with SCI were randomly assigned to 2 groups, one receiving prophylactic antimicrobials, the other not. The groups were further divided into 2: Group 1 was treated for bacteriuria $>10^5$ col/ml; Group 2 was treated only if clinical UTI was present (temperature $\geq$100 F, urethral discharge, bacteriuria). The rate of bacteriuria was approximately 1-6/100 catheterizations compared to 1-4/100 in Anderson's study (and 9/100 in the unsterile control group).

Maynard and Diokno consider their rate of infection and that of Anderson's control group as clinically acceptable provided patients are followed carefully and treated promptly if symptoms develop. They also state that the presence of bacteriuria in the absence of symptoms or vesico ureteral reflux does not warrant treatment, a recommendation supported by many others including Cardiff-Oxford Bacteriuria Study Group (1979) Crooks and Enrile (1983), Kass, Koff, and Diokno (1981), Lewis, Carrion, Lockhart, and Politano (1984), Schroder (1985), Sobel and Kaye (1987), and Winberg (1986).

Wahlquist, McGuire, Greene, and Herlihy (1983) conducted a study similar to that of Anderson (1980a) in order to determine the efficacy of prophylactic antibiotic use. There were three groups: (1) received bladder irrigation after each catheterization; (2) received Septra BID; (3) no treatment. All three were catheterized using sterile technique. The results, similar to Anderson's study, were 1 incident of bacteriuria per 223 catheterizations. Of those patients who developed bacteriuria ($>10^4$ col/ml), one was diabetic with bladder capacities >500ml; 2 had had indwelling catheters before starting IC; and 1 had a persistently high pH of 8.0-8.5. The authors concluded that prophylaxis was not necessary for patients using IC because they run a low risk of developing UTI. Unfortunately this study was short term with some patients treated with IC for as few as four days.

Wu, Hamilton, Boyink, and Nanninga (1981) also support sterile intermittent catheterization and describe a reusable catheter which can be sterilized by soaking. This is the only study in which a number of solutions were compared for their bactericidal effects (Appendix 5). Unfortunately there is no information on the rate of bacteriuria when catheters are cleansed with the different methods nor do the authors compare Savlon to the various solutions. Broek, Daha, and Mouton (1985) recommend sterile technique and bladder irrigation with providone-iodine to prevent UTI. The control group had 28% incidence of UTI and the trial group only 4% when the bladder was irrigated with providone-iodine. The authors do not state the standard for estimating UTI nor whether the patients were symptomatic or non-symptomatic. Wolraich, Hawley, Mapel, and Henderson (1983) also suggest bladder irrigation (with silver nitrate solution) and claim an 86% success rate. Again, no standard is stated for estimating bacteriuria. Most recently, Bruschini, Denes, Mitre, & Arap (1987) state, "it is unquestionable that intermittent catheterization is preferable to indwelling catheter drainage and that aseptic technique is superior to clean technique"(p. 386). No sources are cited to support aseptic over clean technique. The authors were promoting a metal catheter with a screw-top which rests in a container of providone iodine. It is small, portable and is perhaps the most realistic of the methods suggested for home sterilization of catheters.

No studies have been documented which compare the difference in bacteriuria in patients using sterile intermittent catheterization and clean intermittent catheterization at home instead of in the hospital. It is neither realistic to expect patients to use sterile catheterization procedure at home nor reasonable to suggest bladder irrigations after every catheterization. Continued low dose antibiotic therapy does not seem to change the incidence of symptomatic bacteriuria and the value of prophylaxis is questioned in patients with neurogenic bladder. As well, the routine use of ascorbic acid does little to change the course of UTI--methanamine being an exception and requiring an acidic urine to be effective (Sobel & Kaye, 1987). By recommending sterile intermittent catheterization, the above authors are supporting the belief that urethral bacteria introduced into the bladder on a catheter cause UTI. This belief is in contrast to Lapides, Diokno, Silber, and Lowe (1972), who stressed the normative process of bacteria being drained out of the bladder immediately in the process of catheterization.

Clean Intermittent Catheterization

The urological care of children with spina bifida was revolutionized by Lapides et al (1972) when they introduced the concept of clean, self intermittent catheterization. Adoption of this nonsterile technique pointed the way for management of neuropathic bladders in children (Bellinger, 1987; Enrile & Crooks, 1980). Many call CIC the single-most important urological gain in helping children achieve regular bladder emptying. Lapides et al stated outright what Guttmann and Frankel (1966) had postulated: the most common cause of urinary tract infection for the patient with a neurogenic bladder was due to decreased blood flow to the detrusor muscle by distension and/or increased intravesical pressures. The result is ischemic tissue susceptible to Gram negative bacteria from the patient's gut. Thus, by maintaining a good blood supply to the neurogenic detrusor, the incidence of urinary tract infection should be reduced. Lapides et al further stated that "any bacteria introduced by the catheter will be neutralized by the resistance of the host" (p. 459). The conclusion is that the "Lapides clean approach" to intermittent catheterization has proved the most successful thus far.

The first sample from which Lapides et al (1972) presented their argument consisted of 14 patients (most had multiple sclerosis) with neurogenic bladder incontinence and recurrent UTI. All 14 had a great improvement over these symptoms after using intermittent catheterization. At the time, patients were encouraged to use a germicidal solution to clean the catheters after use and to keep them in a sterile container. However, on follow-up, one patient who had been plagued with UTI before starting a catheterization routine, confessed that she was only washing the catheter with soap and water even if she dropped it on the floor. The most significant point was that this woman's UTI rate was no higher than any of the other study group--all of whom had had a marked decrease in

UTI since starting self catheterization. Lapides et al concluded that UTI does not result because of urethral organisms introduced into the bladder. In fact, it was later confirmed that when the bladder is regularly catheterized and completely emptied that any bacteria which might have been introduced would be emptied out immediately, before they had a chance to multiply and cause UTI (Hinman, 1977; Lapides, Diokno, Gould, & Lowe, 1976; Tank, 1977). Thus, it seemed conclusive that clean technique was appropriate for intermittent catheterization, thereby simplifying the procedure for parents, patients, and school personnel.

And yet, clean intermittent catheterization (CIC) is not 100% effective. It is important that all patients with neurogenic incontinence are assessed with renal ultrasound, voiding cystourethrogram, urine Culture and Sensitivity (C & S) and urodynamics before commencing CIC. Patients at special risk for progressive renal changes or poorly controlled incontinence have small, high pressure, dyssynergic bladders, which are non-compliant and non-responsive to anticholinergics. In this group, continence ranges from 24-49% (Brem, Martin, Callaghan, & Maynard , 1987; Cass, Luxenberg, Gleich, Johnson, & Hagan, 1984; Drago, Wllner, Sanford, & Rohner, 1977; McGuire, Woodside, Borden, & Weiss, 1981; Plunkett & Braren, 1979; Purcell & Gregory, 1984). However, even when continence is not achieved, these authors still recommend CIC as a means of maintaining the stability of the upper urinary tract.

<u>Success of Clean Intermittent Catheterization</u>

Hilwa and Perlmutter (1973), studying 39 patients, found 88% of their study population continent using CIC and oxybutynin chloride. Lapides, Diokno, Lowe, and Kalish (1974) in a three year chart review of 100 patients with spina bifida, spinal cord injury, multiple sclerosis, diabetes, tumor, and adhesive arachnoiditis found that 65% of these patients using CIC were completely dry and had a negative urine C&S. Furthermore, the upper urinary tract was stable or improved. Lyon, Scott, and Marshall (1975) followed 15 children with spina bifida and describe CIC as effective in maintaining adequate dryness and healthy upper tracts.

McIlroy (1977) followed 10 children with spina bifida for one year after commensing CIC. Six of the children were continent with CIC; nine of the ten had improved or stable upper urinary tracts and had bacteriuria eliminated or much decreased. Enrile and Crooks (1980) followed 62 children using CIC from 6 to 42 months. The 25 subjects in Group A had normal urinary tracts and socially unacceptable urinary incontinence; the 37 in Group B had incomplete voiding and, as a result, deteriorationg upper urinary tracts. At the end of the study, none of Group A had renal deterioration; in Group B, 13 showed marked renal improvement after using CIC, 18 remained stable, and 6 had further deterioration. Continence was improved in 42 of 62 (68%) subjects. The authors do not state what criteria they used to judge "improved" incontinence. In the same study, Enrile and Crooks also surveyed 65 patients with ileal conduits. Eighty percent of the patients with conduits had decreased renal function. However, in the follow-up they did not note the state of the upper tract at the time of the diversion. Kass, McHugh, & Diokno (1979) strongly support CIC noting that success is measured by the stable or improved renal tracts, progressive renal growth, absence of clinical infection, and continence.

<u>Bacteriuria and CIC</u>

In a group of 23 children followed over a three year period, Withycombe, Whitaker, & Hunt (1978) noted that since starting CIC all subjects had bacteriuria of $>10^5$ col/ml. and pyruria $>50mm^3$, but only 4 of the 23 had constitutional symptoms of UTI. In only three cases did the upper tracts deteriorate; the remainder were unchanged or much improved. As well, only two children were not improved or completely dry after three years of CIC. Borzyskowski et al (1982) conducted a comparison study of 43 children followed for 1 1/2 to 4 years. Half were using CIC and half Credé expression. All subjects were treated with urotropics if necessary. The study group using CIC resulted in 21 of 22 children being dry or improved. The group using Credé showed only one child dry, 10 improved, and 10 unchanged. The rate of UTI's were 1 in 8 months and 1 in 11 months, respectively. It is of note that the children using Credé actually had a lower rate of infection than those using CIC while Cass (1976) found the use of Credé often led to chronic infection and upper tract dilatation. In both groups reflux and dyssynergia led to deteriorating renal function. It seems that chronic bacteriuria occurs in most patients but in the absence of reflux it does not cause pyelonephritis and frequently does not cause clinical symptoms of UTI (Appendix 4; Bennett & Diokno, 1984; Crooks & Enrile, 1983; Enrile & Crooks, 1980; Lewis, Carrion, Lockhart, & Politano, 1984; Maynard & Diokno, 1984; Schroder, 1985; Sobel & Kaye, 1987; Winberg, 1986). What is important in controlling UTI is (1) regular, complete emptying of the bladder; (2) prevention of distension; and, (3) not allowing bladder capacity to exceed 150 ml (1-5 yrs.), 240 ml (6-9 yrs.), 300ml (9-12 yrs.) and <500ml (adult) (Appendix 3, p. 1).

<u>Complications of CIC</u>

Documented complications of CIC are few. Klauber and Sant (1983) noted that mechanical problems such as obesity, hip flexure, unstable hands may contribute to unsuccessful self-catheterization. In such cases, vesicostomy, use of a larger, firmer catheter, or perineal urethrostomy may be effective for bladder drainage. The authors state trauma was rare although a false passage from repeated forceful catheterizations or urethral stricture was possible. Uehling, Smith, Meyer, and Bruskewitz (1985) report similar results from a 10 year chart review of 164 patients with spina bifida. Kaplan (1985) also notes that children with detrusor hyperreflexia and/or detrusor-sphincter dyssynergia are at risk of reflux and/or hydronephrosis. Some children still require urinary diversion if progressive hydronephrosis is not corrected by CIC, antibiotics, and anticholinergics. Maynard and Glass (1987) followed 47 spinal cord injured patients between 3 to 6 years post injury. Of these patients, 82% continued to use CIC and had a low frequency of infection. Some infrequent complications by these patients noted were strictures, false passage, epididymitis, cystolithiasis, nephrolithiasis, and 10 were hospitalized for febrile UTI.

One more serious complication of CIC in males is prostatic abscess. Steinhardt (1988) describes 5 such cases in boys using CIC for over 5 years and suggests that the atonic internal sphincter allows reflux of infected prostatic fluid into the bladder. He warns practitioners that boys with chronic bacteriuria may have developed an abscess and therefpre recommends routine evaluation of these patients should include an ultrasound. One child in the study group of this project had had chronic, symptomatic bacteriuria for 1 year. Cystoscopy revealed a catheter tip embedded in the bladder. Once removed, his infection cleared completely.

Long Term Results of CIC

The long term results of CIC use are still not known and some children do have deteriorating renal function when treated by this method. More longitudinal studies, such as that of Brem, Martin, Callaghan, and Maynard (1987) are required. These authors followed 42 patients for 5 years in an attempt to identify prospective "renal morbidity" (p. 51) in children with spina bifida and neurogenic bladder. Twenty eight children (age 11.8 years $\pm$ 0.7 yrs) were treated with CIC and 14 (21.6 $\pm$ 1.6 yrs.) had been treated with ileo loop. The CIC group had 24 of 28 stable or improved upper and/or lower tract functioning; the remaining four had increased renal scarring and hydronephrosis and were finally treated with ileo loop. The results for these four children were predictable because prior to starting CIC, each had had small, trabeculated bladders noted on voiding cystourethro-gram and were considered at risk for progressive upper tract changes. The renal deterioration occurring in children with ileo loop surgery is similar to other studies cited in this text. Bacteriuria occurred in 38% of the CIC children and 70% of the ileo loop children and 9 of 28 CIC children had reflux. Again, for the CIC group, bacteriuria and reflux did not seem to influence renal mortality. The authors point out that since the bulk of renal growth occurs between the ages of 5-7 years and that the subjects in this study were older than this, it is possible that infection and reflux would be less likely to limit renal growth and cause upper tract damage. The low infection rate would have also been affected by the prophylactic antibiotics given to all subjects during the course of the study. The authors' conclusion that "bladder character"(p. 55) is the most effective method of determining those children at risk of developing progressive upper tract changes supports the conclusions of Brem, Martin, Callaghan, and Maynard (1987), Drago, Wellner, Sanford, and Rohner (1977), Kaplan (1985), McGuire, Woodside, Borden, and Weiss (1981). These authors all support Lapides' theory that UTI is caused more by residual urine and ischemia to the bladder wall than by the introduction of bacteria through the urethra during catheterization. These authors also endorse the method of treating the catheter as clean, rather than sterile.

Conclusion

The goals in CIC are preservation of healthy upper and lower urinary tracts, social continence, and independence from an external collecting device. The literature surveyed strongly suggests these goals are obtainable with CIC. Yet in the studies cited, many rely on chart reviews and retrospective data. Those authors who support Lapides clean technique (and most do) have not questioned the method. Nurses also may have fears about using a clean rather than sterile procedure. Regardless of these fears, nurses must accept and understand the use of clean procedures it if parents are to accept it (Hendry & Geddes, 1978; Horsley, Crane, & Reynolds, 1982). It is, perhaps, because of the associated problems and the overwhelming amount of literature supporting the link between indwelling catheters and infection that some health professionals have had difficulty accepting clean catheter technique as a viable alternative for bladder drainage.

From this literature review, the majority of writers are in support of catheter care as recommended by Lapides, Diokno, Silker, and Lowe (1972). Other writers recommend sterile technique, although none suggested this for care in the home. There remains a number of health care professionals who suggest that soap and water is not a satisfactory cleansing agent for catheters used for intermittent catheterization. Their suggestion is that bacteriuria should be controlled with improved cleansing methods. It is assumed that bacteriuria will be reduced if catheters have no pathogens on them. In the studies reviewed, it was found that less bacteriuria occured with sterile catheterization rather than with clean catheterization. As yet, there is no agreement on the significance of bacteriuria when the patient is asymptomatic. However, based on the fact that a normal bladder contains sterile urine, it would seem that reducing bacteriuria should be worthwhile. Thus, health care professionals have resorted to many suggestions for cleansing catheters in an attempt to achieve sterile urine in people using intermittent cathterization. None of the suggestions are supported by research data.

<u>Summary</u>

Approximately 100 representative articles which met the criteria were reviewed. Most authors described or supported a certain method of catheter cleansing (Appendix 1). Of the nurse-authors, only one group (Wahlquist, McGuire, Greene, & Herlihy, 1983) had published an experimental study; the rest were descriptive articles and case studies. The articles written by urologists described the positive results of CIC, usually in a retrospective chart review or with a small sample size. Few studies had control groups. Three authors conducted experimental studies comparing sterile intermittent catheterization to clean intermittent catheterization but all were conducted in the hospital by medical or nursing staff. No authors compared one method of catheter cleansing, such as detergent soap and water, with another and then compared the incidence of bacteriuria in each group over several months. Nor did any studies document why a particular cleansing method was chosen. Those citing Lapides, Diokno, Silber, and Lowe (1972) accepted clean technique as a given; those offering other methods gave no research data on which to base their choice of catheter care.

Currently, several methods of catheter cleaning are recommended by health professionals. No empirical data exists which suggests that one method is necessarily better than another. The use of Savlon for cleaning catheters is expensive, time consuming, and inconvenient for children and parents. If CIC users could safely use soap and water instead of Savlon, the catheterization procedure would be simpler for all concerned. A study which compares the effectiveness of soap and water and Savlon will, at least, provide data to support the use of one of these solutions.

Chapter III

Methods

The purpose of this chapter is to describe the study methods. Each of the four hypotheses are stated and the study design to test each hypothesis is described. This is followed by a description of the setting and sample selection, data collection procedures, and ethical considerations specific to this study. The chapter concludes with a description of the data analysis.

To test the hypotheses, cultures were obtained from:

(1) catheter tips;

(2) Savlon solutions;

(3) catheter urine specimens.

Hypothesis (1): There will be no significant difference in the number of organisms cultured from catheters rinsed under running water then soaked in Savlon for 30 minutes after use and those washed with liquid detergent and water.

In order to test Hypothesis (1) a within-subject experimental design was chosen to compare the difference between means of organisms on catheters cleaned by one of the two methods. To control for internal validity, catheters were obtained from each subject on two separate occasions. Group 1 was considered to be those soaking catheters in Savlon Aqueous 1:30, and Group 2, those washing catheters with liquid soap and water. On the same day but at two separate catheterizations, each subject soaked a new Mentor catheter in Savlon or washed a catheter in soap and water, the order of washing or soaking determined randomly. Figure (1) shows the sequence which subjects followed:

New Mentor Catheter Used on Every Occasions

T (1)
(08:00)

Mix Savlon Aq. 1:30
↓
Catheterize as usual
↓
Savlon Soak x 30 mins.
Rinse, Shake, Air Dry
↓
Place Savlon in (2)
Sterile Containers

(12:00)

Catheterize as usual
↓
Sunlight Wash
Rinse, Shake, Air Dry

(16:00)

Researcher Visits
↓
Catheterize
↓
Urine Specimen
↓
Laboratory
1. Catheter Tips in
   Sterile Test Tubes
2. Savlon Sample #1
3. Urine Specimen

T (2)
(08:00)

Catheterize as usual
↓
Sunlight Wash
Rinse, Shake, Air Dry

(12:00)

Mix Savlon Aq. 1:30
Catheterize as usual
↓
Savlon Soak x 30 mins.
↓
Rinse, Shake, Air Dry

(16:00)
Researcher Visits
↓
Laboratory
1. Catheter tips
2. Savlon #2

T(1) = first visit
T(2) = second visit 2 weeks later
Order of Savlon soak/Sunlight wash was random with 1st subject; thereafter it alternated.

Figure 1: Order of Sample Collection

Hypothesis (2): Catheters washed in soap and water plus soaked in Savlon for 30 minutes will have significantly more sterile catheters than those soaked in Savlon only or washed with Sunlight only. To test Hypothesis (2) a "single group, single observation" (Smith & Glass, 1987, p. 226) was done on colony counts of catheters washed with soap and water plus soaked in Savlon. The obtained results were compared to the numbers of sterile catheters obtained in the testing of Hypothesis (1). Catheters cultured in this aspect of the study were reused Mentor catheters.

Hypothesis (3): There will be no significant difference in the number of organisms in Savlon mixed $\leq$ 1 hour and used once; used once and left standing at room temperature for 2 weeks; or used daily for two weeks.

Hypothesis (4): Subjects reusing catheters cleansed with soap and water plus Savlon soak will have fewer incidences of bacteriuria ($\geq 10^6$ col/L) than those subjects described in the literature using only soap and water.

The design of this aspect of the study was also a "single group single observation". The purpose of the design was to describe the numbers and types of organisms cultured from samples of Savlon on several different occasions. The purpose of the urinalysis was to describe the range of bacteriuria, asymptomatic and symptomatic, and the organisms in the study sample. The organisms in the urine would be correlated to those cultured on the catheter tips.

Study Setting and Sample

Setting

The setting for this study was a large Western Canadian city and participants were drawn from the Spina Bifida Clinic of a Rehabilitation Hospital. All samples were collected from the homes of the participants. It was believed that flora in the home would be the contaminents and that these could not be reproduced in the laboratory.

Equipment

The choice of Mentor catheter was based on the fact that this catheter is stocked by the local medical supply companies and is currently the least expensive plastic urethral catheter on the market. For purposes of the study, Savlon Aqueous 1:30 was fresh mixed, although in reality, many parents reused the Savlon two to four weeks.

Subject Selection

A convenience sampling procedure was used to obtain subjects. A list of all children (N=60) within a 40 km radius of the setting and using intermittent catheterization was obtained from the Spina Bifida Clinic. Inclusion criteria were: (1) CIC was an established routine for the child; (2) age range from newborn to 18 years; (3) diagnosis of Spina Bifida; (4) currently cleaning and reusing plastic urethral catheters by the method recommended at the Spina Bifida Clinic. Potential subjects were contacted by telephone by the researcher. Those who were interested in participating were taken a consent form (Appendix 6) and a description of the study (Appendix 7). Thirty three patients were originally accepted into the study but one dropped out because of being inconvenienced and one used red rubber catheters on both occasions although Mentor catheters were provided by the researcher.

Parent and Child Orientation to the Study

In the home and at school, catheterization of young children (<8 years) is usually performed by the parent or a school aide respectively. Most older children, however, catheterize themselves without difficulty. Catheterization procedure differed little between parents or children but to standardize for the study, the method recommended by the Spina Bifida Clinic was reviewed with each participant. Because the Spina Bifida Clinic recommended washing the catheters with soap and water and then soaking in Savlon, it was recognized that the researcher would not be able to determine which of the solutions was the more effective cleaning agent. In addition, there is a possibility of incompatability between soaps and quaternary ammonium compounds such as Savlon and, if mixed, anitbacterial activity may be affected (Martindale, 1982; Wolin, 1979). Thus two aspects of the "Savlon" soak developed: (1) rinse the catheter under running water, shake dry, soak in Savlon for 30 minutes; (2) wash the catheter with soap and water, rinse well, shake dry and then soak in Savlon for 30 minutes. The methods of catheter cleaning were reviewed with all participants and written instructions provided (Appendix 8).

Procedures and Data Collection

Selecting subject to begin procedure

The first subject was randomly assigned by the flip of a coin to start the study with either Savlon soak or Sunlight. Thereafter, every subject alternated starting with Savlon or Sunlight. The order of cleaning was reversed for every subject at the second sampling. The two week interval was chosen because just prior to the commencement of the study, Savlon was being reused for up to two weeks, a length of time supported by the Ayerst company, makers of Savlon. Upon reviewing the literature and in consultation with the hospital pharmacist, the Spina Bifida Clinic recommended using a mixture of Savlon only once and then discarding it.

Each subject was sampled twice, two weeks apart. On a convenient day, parents or child catheterized twice,usually in the morning and then again at lunch time. The researcher arrived at the subject's house about 16:00 when the child was due for the next catheterization. At that time, the catheters and Savlon were collected and a sterile urine specimen was obtained from the 16:00 catheterization which was immediately dipped in the "Dip and Count" container. The researcher then took all specimens to the University Microbiology Laboratory where they were plated and incubated within 30 minutes by standard laboratory procedure by a technologist blind to the study hypotheses. To maintain blindness to the study, all specimens were marked as "A" or "B" rather than Savlon or Sunlight.

Biographic data

The following information was collected on all subjects: length of time using CIC, perceived success of CIC, bowel management and success, and current medications. A requirement of the study was that all participants be familiar with the CIC regimen. It was believed by the researcher that >2 months was sufficient time for parents or child to be comfortable with the routine. Perceived success of CIC was requested in order to compare this rate with that described in the literature. Success was based on dryness, continence, and bladder and renal health. All parents were familiar with the pathological processes occuring in the urinary tract because of repeated infections and were thus able to report accurately on the stability of their child's urinary tract after starting CIC. Information on bowel routine and success was also requested because of the correlation between urinary tract infection and constipation (O'Regan & Yazbeck, 1985). If the child was severely constipated or soiling frequently, urinary pathogens could have resulted from faecal contamination rather than contamination from catheterization. Finally, questions about medications were posed. Success of CIC often depends on adjunctive treatment of detrusor-sphincter dyssynergia with Oxybutinin Chloride (Ditropan). As an anti-cholinergic agent, Ditropan itself can contribute to constipation and possibly UTI. Some children were on prophylactic antibiotics for chronic, recurrent UTI. These participants were not excluded from the study because the purpose of the project was to determine the difference between cleaning catheters with Savlon or soap and water. It was believed that organisms on the catheters would still occur and that the relative proportion would not be affected by use of oral antibiotics. A urinalysis of children using antibiotics was also done to determine how effective the prophylaxis really was in controlling urinary pathogens.

Data Collection

Catheter Tips

All catheter tips obtained from participants were cultured on blood Agar and McConkey plates using standard laboratory procedures and incubated for 48 hours. A colony count and identification were done on each specimen but not a test for sensitivity.

A further separate analysis was done in the laboratory to determine whether Sunlight was as effective as Savlon in killing coliforms on the catheters. For 7 consecutive days, to simulate reuse in the home, 7 catheters were dipped in E coli solution, 10^8 organisms/ml, washed with Sunlight soap as per the study protocol, and left to air dry for ≥4 hours. Each day, one catheter was removed and cultured so that by Day 7, #7 catheter had been dipped and washed 7 times. One catheter was wet on plating and was purposely cultured before complete drying. Three colonies of coliforms were cultured; the remaining 6 were dry when cultured and were sterile.

Savlon Samples

Several Aqueous Savlon 1:30 samples were cultured: (1) Savlon used once; (2) Savlon used once, and then left standing at room temperature for 2 weeks; (3) Savlon used daily for 2 weeks. All these samples were sterile. Therefore further attempts were made to test the hypothesis that Gram Negative pathogens may survive in Savlon. Samples of Savlon were placed in sterile test tubes and injected with 10^8 organisms/ml of Pseudomonas aeruginosa and Staph epidermidis. Specimens were plated within 30 minutes and cultured after 1 and 2 weeks incubation.

<u>Urine Specimens</u>

All urine specimens were collected in sterile containers, poured over "Dip 'N Count" culture media and incubated within 30 minutes of collection. Colony count and identification was made after 48 hours by standard laboratory procedure.

Ethical Considerations

Permission was obtained by the researcher to conduct the study through the rehabilitation hospital. Participation in the study was voluntary, without financial remuneration. The Sunlight catheter washing presented no risk to the subjects as the catheter was not used after the detergent wash. The catheters were provided to the parents through a government assistance programme and did not present a financial inconvenince to the subject. The main ethical consideration was the right of privacy. To contact subjects, names and addresses were provided to the researcher from the rehabilitation hospital On-Line Clinic Listing. The researcher then telephoned potential subjects requesting their participation in the study. This was followed by a home visit to further explain the project and the expectations requested of the participants. Two more home visits resulted if the parents and child were willing to participate. It was understood that the researcher respected the confidential nature of this information. The subjects were informed in the introductory telephone call that their names were received from the Spina Bifida Clinic and that the Clinic endorsed the project but that the researcher was a student at University of Alberta and not an employee of the Rehabilitation Hospital. The researcher stressed that parents could withdraw at any time without penalty and that refusal to participate in no way jeopardized future care in the clinic or any other facility. The subjects' names and addresses were kept in a locked drawer to which only the researcher had access. All laboratory specimens were marked with dates and initials rather than the subjects' full name. The researcher informed all participants of the results of the urinalysis as soon as the report was ready. Families were told that the results of the study would be made known to them when the project was completed. It was made clear to the parents that the researcher had no authority concerning care and that questions of this nature would be referred back to the Spina Bifida Clinic.

All subjects and families were included in the discussion of the procedure and signing of the consent. Families were invited to include a friend or relative in the information session who could act as a witness when the consent was signed. It was believed that a witness may also feel more comfortable asking questions about the study than family members. However, all families appeared very comfortable asking questions of the researcher and willingly volunteered information about their urological care. None desired or saw the need for a witness.

Data Analysis

A 2-tailed dependent *t*-test was used to compare the differences between the means of pathogens on the catheter tips washed with Sunlight and those soaked in Savlon solution, with alpha at .05 level of significance. The dependent *t*-test is based on two assumptions: that the population is normally distributed and homogeneous, and that the variability within measures between subjects will be small. While each subject in this study probably varied slightly in washing technique, it was assumed that variations would be small enough not to significantly affect results. As the sample size was over 30, the chance of a Type I or Type II error calculation was negligible (Cohen, 1977). The dependent _t_-test is appropriate for within subjects' design and gives a high correlation between experimental and control results because subjects act as their own control. To test the difference between proportions of sterile catheters soaked in Savlon, washed with Sunlight, and washed with soap and soaked in Savlon, a Chi square analysis was done with alpha ≤ 0.05. As stated previously, Hypotheses (3) and (4) were presented in descriptive form describing the numbers of organisms, mean, _SD_, and percentages of sterile catheters.

Chapter IV

Results

The characteristics of the sample are described. This is followed by the results of hypothesis testing and concludes with a description of the validity of the research design.

Sample Characteristics

A total of 33 subjects were entered into the study, 18 males and 15 females, ranging in age from 1 to 18 years. All were using CIC for $\geq$ 2 months and all had a diagnosis of neurogenic bladder and bowel due to sacral nerve involvement from Spina Bifida. Parents or school aide catheterized in 15 cases; the child catheterized at school and usually at home but did not take complete responsibility for catheter care in 11 cases, in 7 cases the child was responsible for catheterizing and cleaning catheters. For purposes of the study, all subjects used new Mentor plastic urethral catheters for each catheterization. Nine subjects took antibiotics prophylactically to control recurrent, symptomatic bacteriuria (Appendix 12). Two subjects dropped out: 1 found difficulty following the instructions; one was pressured by time committments. Replacements were not sought as the sample size was over 30.

Data for analysis were obtained by:

1. Culture of catheter tips (n=62) rinsed and soaked in Aqueous Savlon 1:30 x 30 minutes, then rinsed with running water and dried, and culture of catheter tips (n=62) washed with Sunlight soap and water, rinsed and dried (Appendix 9; 10);

2. Culture of catheter tips (n=23) washed with soap and water plus soaked in Savlon x 30 minutes, rinsed and dried (Appendix 11);

3. Culture of catheter tips (n=7) dipped in E coli (10^8 organisms/ml), washed with Sunlight, rinsed and dried;

4. Culture of urine specimens (n=30; Appendix 12);

5. Culture of Aqueous Savlon 1:30 (a) used once, (b) used once and left standing at room temperature for 2 weeks, (c) used daily for 2 weeks;

6. Culture of Savlon after injection with Pseudomonas aeruginosa and Staph epidermidis (each concentration @ 10^8 organisms/ml).

Tests of the Hypotheses

Testing of the four hypotheses was based on a final n=31 subjects. A two-tailed significance level of alpha at 0.05 was used for statistical tests of Hypothesis (1).

Hypothesis 1: Culture of Catheter Tips

There will be no significant difference in the number of organisms cultured from catheters rinsed under running water then soaked in Savlon for 30 minutes after use and those washed with liquid detergent and water.

A dependent *t*-test s used to evaluate whether or not empirically obtained results differed from the hypothesis. Use of the dependent *t*-test showed no significant difference (*t* Obtained was < *t* Critical) between mean number of organisms on the Savlon and Sunlight catheters (Table 1).

Table 1

Test Results for Sunlight and Savlon on two occasions using 2-Tailed Probability @ 0.05 level of significance.

Variable	Mean	S.D.	T-Critical	DF	T-Obtained
Total=229 Colony Count Savlon	7.516	12.807			
			2.145	30	1.610
Total=92.5 Colony Count Sunlight	2.967	7.993			

n=31
SD= Standard Deviation
DF= Degrees of Freedom

Differences in Organisms between Savlon & Sunlight Catheters

None of the organisms cultured on the catheter tips were present in high enough numbers to be considered significant. Indeed, most were hand or skin contaminants occuring on 22 of 35 Savlon catheters (62%) and 18 of 25 Sunlight catheters (72%). Total colony counts are listed in Appendices 9 and 10. Table 2 and Table 3 below summarize the contaminating organisms.

Table 2

Summary of Contaminating Organisms: Savlon Catheters

Organisms	Catheters n=62
Coagulase negative staphylococci	22
Micrococcus	9
Aerobic spore-bearing bacilli	7
Diptheroids	5
Viridens Group Streptococci	3
Non-hemolytic Streptococci	2

Table 3

Summary of Contaminating Organisms: Sunlight Catheters

Organisms	Catheters n=62
Coagulase negative staphylococci	18
Micrococcus	6
Aerobic Spore-bearing bacilli	3
Diptheroids	3
Viridens Group Streptococci	2
Non-hemolytic Streptococci	0
Yeast	1
Coliforms	1

Sunlight Catheter tips (n=7) dipped in E coli

As stated, the dependent t-test showed no significant difference between organisms on Savlon and Sunlight catheters. All organisms were similar but two cases are of note, both Sunlight catheters: Subject 17 and Subject 23 (Appendix 10). In both cases Savlon catheters had fewer organisms (Appendix 9) than the Sunlight. Subject 23 had 11 colonies of coliforms on the catheter plus symptomatic bacteriuria for which he was being treated. Unfortunately, a urinalysis was not obtained. In both cases the catheters were received by the researcher still wet from the soap and water wash--they had been put in plastic bags immediately after washing instead of air drying for 4 hours. To further investigate the possible relationship between wet Sunlight catheters and coliform counts, a trial was conducted in the laboratory. Seven catheters were dipped in E coli 10^{11} col/L, washed with Sunlight as per the study protocol, rinsed, and air dried (see page 53). Six catheters were sterile. One catheter was purposely cultured after drying <4 hours and was still damp; it supported a growth of 3 colonies of E coli. No conclusions can be drawn from this single positive culture in the laboratory. It appears, however, that catheters which are not thoroughly air dried may support the growth of pathogens.

Because the difference between organisms on catheters washed in Sunlight or soaked in Savlon was not significantly different, it was decided to use a Chi square analysis to compare differences in numbers of sterile Sunlight and Savlon catheters. The results, in this analysis, showed a significant difference between the Sunlight and Savlon sterile catheters. Table 4 shows the observed and expected calculations for Chi Square.

Table 4

Chi Square Analysis of Sterile Sunlight and Savlon catheters: observed and expected values.

Catheters	O	E	(O-E)	$(O-E)^2$	$\frac{(O-E)^2}{E}$
Savlon Sterile	26	31.5	-5.5	30.25	.960
Sunlight Sterile	37	31.5	5.5	30.25	.960
Savlon Non-" "	36	30.5	5.5	30.25	.991
Sunlight Non- "	25	30.5	-5.5	30.25	.991
					3.902

df=1

X^2 obtained (3.902) > X^2 critical (3.84)

Alpha @ 0.05

Hypothesis 2: Soap & Water Plus Savlon Soak

Catheters washed in soap and water then soaked in Savlon will have significantly more sterile catheters than those catheters soaked in Savlon only or washed with Sunlight only.

Chi square analysis was chosen to test difference between numbers of sterile and contaminated catheters washed with soap and water then soaked in Savlon for 30 minutes (Appendix 11). No significant difference was found. Further Chi square analysis was done to test the difference between numbers of sterile catheters in the three groups: (a) soap and water plus Savlon catheters (b) Savlon catheters and (c) Sunlight wash catheters. Again, the differences were not significant. The results are outlined on the following tables: in Table 5 the obtained results are described for catheters washed with both methods; in Table 6 percentages of sterile catheters cleaned by all three methods are compared; in Table 7 the observed and expected calculations for Chi square to test for significance between sterile catheters washed in the three methods are shown.

Table 5

Test Results of Colony Counts of Catheters washed with Soap and Water Plus Soaked in Savlon

n=23

Sterile catheters = 11/23 or 48%

Contaminated catheters = 12/23 or 52%

Sum of Colonies of Organisms = 264

$\bar{X}$ Colonies of organisms on each catheter = 11.47

SD=41.69

Table 6

Percentages of Sterile catheters

Savlon=42% < Soap & Water + Savlon=48% < Sunlight=60%

Table 7

Observed and Expected Values for Chi square Analysis of Sterile catheters: Sunlight, Savlon, and Sunlight plus Savlon.

Sterile Catheters	O	E	(O-E)	$(O-E)^2$	$\frac{(O-E^2}{E}$
Sunlight	37	31.5	5.79	33.52	1.074
Savlon	26	31.5	-5.21	27.14	0.869
Sun. Plus Savlon	11	11.5	-0.57	0.32	0.028
					1.971

df=2

X^2 Obtained (1.971) $<$ X^2 critical 5.991

Alpha @ 0.05

The contaminating organisms on the soap and water plus Savlon soak catheters were similar to those listed for the Savlon only and Sunlight only catheters (Table 8). It is of note that 3 of these catheters had coliform counts, compared to 1 Sunlight catheter and 0 Savlon catheters with one catheter growing >200 colonies (Appendix 11). The reason for this is not clear.

Table 8

Summary of Contaminating Organisms: Soap & Water + Savlon

Organism	Catheters $\underline{n} = 23$
Coagulase negative staphylococci	8
Micrococcus	3
Aerobic Spore-bearing bacilli	1
Diptheroids	0
Viridens Group streptococci	1
Non-hemolytic streptococci	1
Yeast	0
Coliforms	3

Hypothesis 3: Culture of Aqueous Savlon 1:30

There will be no significant difference in the number of organisms in Savlon mixed <1 hour and used once; used once and left standing at room temperature for 2 weeks; used daily for two weeks.

None of the specimens of Savlon (n=31) supported the growth of organisms. When new specimens of Savlon were injected with concentrations of 10^8 organisms/ml of Pseudomonas aeruginosa and Staphylocci epidermidis and cultured immediately, after 48 hours and after 1 week, all specimens were sterile.

Hypothesis 4: Culture of Urine Specimens (n=31)

Subjects reusing catheters cleansed with Soap & Water plus Savlon will have significantly fewer incidences of bacteriuria than those subjects described in the literature using only soap and water (Appendix 4).

Using a "Dip 'N Culture" media container, urine specimens were obtained from 30 subjects. One child (subject 23) was taking antibiotics for symptomatic bacteriuria and is not included in these results. The results obtained are descriptive in nature and no statement can be made about the relationship of catheterization to bacteriuria. The range of bacteriuria in several catheterization studies described in the literature is large, ranging from 35-100% (Appendix 4) and it could be said the subjects in this study (85% bacteriuria) fit within that range. A summary of findings is presented in the Tables below. It is noted that of the 9 children using prophylactic antibiotics, 8 are female. All were asymptomatic at the time of the study, but had been prescribed longterm antibiotics because of recurrent symptomatic bacteriuria. It appears from these urinalyses that the antibiotics were controlling symptoms of bacteriuria but not effectively controlling colony counts in 4 of the 9 children. As well, of the children who were symptomatic but not on prophylaxis, 2 of the 3 were female. This supports the literature which suggests that females of all ages are more at risk of bacteriuria than males because of the shortness of the urethra and its proximity to the perineum. Table 9 summarizes the findings of the urinalyses done on the study group.

Table 9

Summary of Urinalyses on One Occasion N=30

Female children = 14 Male Children = 16

Prophylaxis = 9/30
Sterile urine with Prophylaxis=5/9
Bacteriuria with Prophylaxis = 4/9
Asymptomatic " " = 4/9
Symptomatic " " = 0/9

Not using Prophylaxis = 21/30
Sterile Urine without Prophylaxis= 3/21
Bacteriuria without Prophylaxis = 18/21
Asymptomatic " " = 15/21
Symptomatic " " = 3/21

Total Bacteriuria 18 + 4 = 22 Of 30
Female = 9
Male = 13

(Bacteriuria = $\geq 10^6$ col/L)

A summary of the contaminating organisms in the urinalyses are listed in Tables 10, 11, 12 and 13. The organisms cultured should be considered pathogenic and in a non-neurogenic bladder would most likely cause a symptomatic urinary tract infection. The contaminants found in this study population do not differ from those cited in the literature except for the one culture of Staph simulans (Subject 30, Table 13).

Table 10

Summary of all contaminating organisms

Organisms	Number of Urinalyses Affected
E coli	14
Strept faecalis	1
Pseudomonas aeruginosa	1
Klebsiella pneumoniae	1
Staph aureus	1
Staph simulans	1

Table 11

Summary of organisms in urine treated with Prophylaxis

E coli >10^9 col/L	2
Strep faecalis 10^9 col/L	1
Strep faecalis 4.5 x 10^6 col/L	1

Table 12

Symptomatic Bacteriuria: Summary of Organisms

E coli >10^9 /L	2
Pseudomonas aeruginosa 8.8 x 10^7 col/L	1

Table 13

Asymptomatic Bacteriuria: Summary of Organisms

E coli $\geq 10^7$ col/L	2
E coli $\geq 10^9$ col/L	12
Klebsiella pneumoniae 3.4×10^7 col/L	1
Staph aureus 5.0×10^6 col/L	1
Staph simulans 10^9 col/L	1
Coag. neg. staph $<10^6$ col/L }	1
Hemophilus 2.8×10^7 col/L }	
Strept faecalis $>10^9$ col/L	1
Strept faecalis $<10^6$ col/L	1

Validity

The following discusssion outlines some of the possible threats to the internal validity of this study, specifically related to Hypothesis (1) and the use of the more powerful dependent t-test rather than Chi square. Appendix 13 includes the summary of the raw data used to calculate the dependent t-test as well as the results of the SPSS^x analysis. The discussion involves comments based on sample size as well as broader issues including the reaction between anionic surfactants (Sunlight) and cationic compounds (Savlon) and the reuse of catheters.

Sample size

A sample of 31 was chosen from a total of 60 eligible subjects. This decision was based partly on Cohen's (1977) suggestion that chances of Type I (false positive) or Type II (false negative) error would be small with a sample size larger than 30 if a dependent *t*-test of means was used as well as financial restrictions due to the high cost of culturing the samples required for the study. As Cohen points out one must estimate sample size based on resources as well as the seriousness of making a Type I or Type II error. In this study, it was deemed more important to control for Type I (false positive) than for Type II (false negative). Moreover, while a large sample size might have yielded a statistically significant result, one might question whether the result would be clinically significant.

Effect Size

The effect size (ES) of the results is small at .2 (Table 2.2.1, Cohen, 1977). Small effect size demonstrates "the degree to which the phenomenon under study is manifested (Cohen, 1988, p. 10). Thus in this study, with ES at .2, we can say the results depart from the null (.5) by only two percent.

Power of the Dependent t-test

The sample size and the use of a within-subject design rather than an independent design increased the power of the results. However, given that ES is low, using Table 2.3.5 to calculate the power of *t*-test when a_2=.05, it is discovered that the power of the obtained results equals only .12. In other words, with such low power, it is possible there would be a significant difference if the sample size was much larger. The chance of a Type II error being made (ie. stating there is no significant difference in colonies of organisms when in fact there is) is Beta of .88 (1-.12).

Power of the Chi Square Analysis

This test is not as rigid as the above dependent *t*-test because of the nature of the data being analyzed. The *t*-test measured specifically the difference between means of the colonies of organisms cultured; Chi square used proportions of sterile catheters to demonstrate significance of the overall differences. It is possible that with a larger sample size, the significant difference between numbers of sterile Sunlight (60%) and Savlon (42%) would even out. This possibility is suggested because of the lack of significant difference between colonies of organisms when measured with the dependent *t*-test.

Standard Error

Standard error (se) demonstrates the variability around the sample mean. In this case, the standard error of 2.823 is large, indicating a wide distribution and poor reliability of the obtained results. The large se probably explains the lack of a significant t in spite of the large difference in colonies of organisms between $\bar{\bar{X}}$ Savlon and $\bar{\bar{X}}$ Sunlight catheters (7.3 colonies per Savlon catheter; 2.9 colonies per Sunlight catheter, Appendix 13).

Variation in Washing Catheters between Subjects

The nature of the dependent t-test increases the validity of the results by reducing the variation with-in subjects. Clearly, however, each subject may have had variations in urinary organisms, length of time sudsing the Sunlight catheter or soaking the Savlon one. Other people in the home may have handled the catheters or one or several may have had some sort of infection. Two points are raised concerning the possibility of such variation: (1) that one can expect certain differences between subjects but that it should level out with a particular "n"; and (2) even if variation did occur, the setting of the subjects' homes was the "real world" of catheter cleaning. The intent of the project was to measure organisms and cleaning effectiveness of solutions within that setting, rather than in the more stingent conditions of the laboratory. However, to help control for washing/soaking differences, each family was given written instructions about the study protocol and observed once washing a catheter with Sunlight soap.

Random Assignment

It was not possible to randomly choose subjects from a large population. However, the first subject was randomly assigned to either starting the study procedure with Sunlight or Savlon by the flip of a coin. Heads assigned Subject (1) to starting with Soap and Water. Thereafter, subjects were alternately given instructions to begin catheter cleaning with Savlon or Sunlight.

Reaction Between Anionic and Cationic Solutions

Soaps and anionic surfactants may decrease the bactericidal activity of quaternary ammonium disinfectants such as Savlon since for maximum effect the surface must be free of soap (Favero, 1983; Martindale, 1982; Wolin, 1979). In this study, parents were also asked to wash catheters with soap, rinse, and then soak them in Savlon because this was the recommended procedure of the rehabilitation hospital. To help control for the possible interaction of soap and Savlon, parents were instructed by the researcher to thoroughly rinse catheters of soap before soaking them in Savlon. Subjects provided reused catheters and followed their usual procedure for cleaning catheters. The soap used varied from Hibitane to bath soap. The lower percentage of sterile catheters may reflect an interaction between the soap and Savlon, a change in the surface of the catheter, or less efficiency of some soaps when compared with Sunlight.

Reuse of Catheter

Catheters for intermittent catheterization are normally reused several times. It is possible that the catheter surface is affected by repeated soaking and that pathogens may cling to reused catheters but not to catheters used only once. Thus the results of the study testing Hypothesis (1) may be artificial in determining the true number of pathogens on reused catheters and should not be generalized until further research is conducted. However, all catheters washed with soap and water plus soaked in Savlon were reused $\geq$ 1 week before culturing. The lower percentage of sterile catheters in this group (11 of 23 or 48%) may reflect a change in the catheter surface which affected the bactericidal activity of the Savlon.

Antibiotics

Children taking antibiotics for any reason were not excluded from the data obtained for the first hypothesis since the efficacy of solutions for cleaning the catheter was being evaluated rather than the pathogens in the urine. Those using antibiotics for prophylaxis were also included in the urinalysis as a survey of the effectiveness of the prophylactic itself.

Instrumentation

Instrumentation and reading of culture plates were performed by one senior laboratory technologist at the University laboratory who was not informed of the study hypotheses.

Generalizing Results

Selection of subjects was based on a non-probability convenience sample. This group may be different from the whole population of people using CIC so results could not be generalized without further investigation comparing larger groups. The obtained power and effect size are lower than anticipated. However, not only is the statistical significance of the result being examined, but also the clinical significance. In this study, given that there is at least no difference between Savlon and Sunlight in destroying organisms, and that the mean difference in colonies of organisms is 4.5484 in favour of Sunlight, one should feel comfortable stating that Sunlight is as good and perhaps better at cleaning reused catheters than Savlon.

Chapter V

Discussion

Major Findings and Conclusions

In this chapter the overall findings of the study are outlined and compared to sources cited in the literature review. As well, the responses to questions asked of each family concerning the success of CIC, number of infections the child has had, and bowel management will be listed.

Purpose of the Project

The purpose of this project was to determine if Savlon was really necessary for cleaning catheters used for intermittent catheterization or if Sunlight liquid detergent was as effective. Chi square analysis of the numbers of sterile catheters in each group (Sunlight, Savlon soak, and Soap plus Savlon) suggests a significant difference between the proportion of sterile Sunlight catheters (60%) over the other two groups when Alpha was set @ 0.05. However, analysis of the data with a dependent *t*-test suggested no significant difference in the number of colonies of organisms found on each group of catheters.

Cleaning Reused Catheters

While most urology clinics and texts suggest that soap and water cleaning of catheters is adequate for home care of reused plastic catheters, no specific studies have been conducted testing this belief. Appendix 1 lists sources which specifically state that catheters should be cleaned with soap and water. All of these authors cite Lapides, Diokno, Silber and Lowe (1972) as the source of their recommendations. Yet, while Lapides et al stated that the bacteriuria rate of CIC users was only 35% (see Appendix 4) others have been unable to achieve such good results (Kass, Koff, & Diokno, 1981); Maynard & Diokno, 1984; Withycombe, Whitaker, & Hunt, 1978). In this study, the rate of bacteriuria for children not taking prophylaxis was 18 of 21 subjects (85%). Thus, it seemed reasonable to test the effectiveness of soap and water and attempt to relate the contaminated catheters to the bacteriuria rates of the users.

<u>Cultures of Catheter Tips</u>

Of note in this study, was that hand contamination rather than organisms from the urinary tract was the major contaminant of both sets of catheters. None of the colony counts on any catheters were significant enough to be pathogenic. Moreover, with the exception of four cases, there was no relationship between the types of colonies cultured on the catheter tips and those cultured in the urine. In four subjects, coliforms were colonized: once on a Sunlight catheter and three times on a soap and water plus Savlon catheter. No conclusions can be drawn from these results except to point out that the Sunlight catheter had been placed immediately in a plastic bag after being washed, rather than air drying. It is possible that the warm, moist environment of the bag allowed proliferation of coliforms. Interestingly, the Savlon catheters of this same subject did not support any coliform colonies which further suggests that, in this sample at least, the Savlon 1:30 was effective against Gram-negative organisms. On the other hand, the soap and water plus Savlon catheter had a colony count >200. Thus it is not clear whether the Savlon itself was responsible for killing coliforms on the catheters or if the surfaces of the catheters were affected by repeated soaking and use, thereby limiting the penetration of the Savlon.

Coliforms on Catheter Tips

The effectiveness of Sunlight against coliforms was checked in the laboratory: those catheters contaminated with 10^8 organisms/ ml of E coli were sterile when washed with Sunlight and then dried completely. One incompletely dried catheter supported three colonies of coliforms. It is possible that the larger proportion of sterile Sunlight catheters occurred because of a combination of the detergent action and mechanical action of actually sudsing and rubbing the catheter under running water.

Effectiveness of Savlon against Gram negative Organisms

None of the Savlon solutions supported the growth of organisms even when injected with significant concentrations in the laboratory. Several sources cited caveats that quaternary ammonium compounds are not as effective against Gram negative organisms, especially *Pseudomonas aeruginosa* and *Proteus mirabilis*, as are other solutions (*CPS*, 1986; Favero, 1983; Martindale, 1982).

Urine Cultures

The urinalyses of most subjects were contaminated with pathogenic organisms. Indeed, 23 of 30 subjects had bacteriuria (10^6 col/L, Table 9). The reasons for this are not clear. It would appear that contamination is not a result of unclean catheters because of the low correlation between urinary tract organisms and colonies cultured on the catheter. The study group was consistent with sources in the literature stating that many of these children had bacteriuria but that only a small percentage have symptoms (Appendix 4). In this group only 3 of 21 not taking prophylaxic antibiotics

had symptomatic bacteriuria. Several authors have suggested that the CIC user (host) develops resistance to the pathogens colonizing in the bladder and in fact lives in happy symbiosis with these organisms. Symptomatic bacteriuria develops when the child has decreased resistance to these organisms, most commonly from upper respiratory tract infection.
(Bennett & Diokno, 1984; Crooks & Enrile, 1983; Lapides, Sibler, Diokno, & Lowe, 1972; Lewis, Carrion, Lockhart, & Politano, 1984; Schroder, 1985; Sobel & Kaye, 1987; Winberg, 1986).

<u>Parent Responses to Questions re:</u>

(1) success of catheterizations;
(2) number of urinary tract infections (UTI) in last year;
(3) beliefs about the cause of UTI;
(4) bowel management.

<u>Success of Catheterization (n=31 subjects)</u>

Eight subjects were almost always completely dry when using CIC although all (male and female) wore a mini pad "just to be certain". These children were started on CIC because of retention and recurrent UTI rather than incontinence. Three were on prophylaxis, one had been hospitalized and placed on IV antibiotics three months before the researcher visited, two had had approximately 3 infections in the last year. All parents felt that the value in CIC was "keeping their child's kidneys and bladder healthy". CIC was found to be "part of the daily routine".

Four children were "usually dry" if they did not drink too much. Of this group, all reported no UTI in the last year. One little boy developed a symptomatic UTI the day the researcher visited; one was being treated for symptomatic UTI; and the others had positive urine cultures, but were asymptomatic.

The remaining 20 were wet "most of the time" or "usually" between catheterizations. All were wet at night. They always wore thick pads or diapers. It was of note that despite the apparent lack of success of CIC the parents continued to comply with the four-hourly regimen. Two teenage boys were in this group; both of these boys did have difficulty complying with catheterizations and both were receiving counselling from a professional concerning this. Two of the subjects with sterile urine were in this group of "wet" children.

Eleven children had had >1 UTI in the past year and had been treated with antibiotics; nine were taking prophylaxis for chronic recurrent UTI. Six stated they had not had any infections in the last year and felt well when the researcher visited, but all had significant bacteriuria when cultured for the study.

The reporting of urinary tract infection in the last year was not very reliable. It seemed that the parents who had a urine culture done every 2 months reported more infections than those who had cultures done only at annual appointments at the Spina Bifida Clinic. Certainly, many subjects reported not having UTI at the time of the researcher's visit, yet urine culture revealed significant organisms.

<u>Beliefs about the cause of UTI</u>

Two mothers suggested that UTI was related to faecal soiling; the rest said they had no idea what caused the infections although several wondered if the catheters themselves could be the cause.

<u>Bowel Management</u>

Without exception, the parents expressed concern about the child's bowels. All children had constipation and required, at least, suppositories. Bowel management was described as "the worst problem of all", "embarrassing" for the child and the parent, that "it severely limited social outings for the child". Parents were aware of the need for extra fibre in their child's diet but often stated that the child was a picky eater and just did not eat enough. Many children also had continuous soiling because of poor or absent anal reflexes.

Discussion

Several sources in the literature refer to the correlation between urinary tract infection and constipation in neurogenically normal children (Kottmeier & Clatworthy, 1965; Neumann, deDomenico, & Nogrady, 1973; O'Regan & Yazbeck, 1985; Shopfner, 1968; Yazbeck, Schick, & O'Regan, 1987). While no research was found specifically addressing this issue in children with neurogenic bowels and bladder, it would seem that the same principles should apply. It is suggested by Shopfner (1968) that constipation causes compression of the bladder and urethra, affecting efficient emptying. If the theory of Lapides, Diokno, Silber and Lowe (1972) is followed--that bacteriuria results from a distended, ischemic bladder wall--then external compression of the bladder from the constipated bowel may also result in ischemia. The children in this study were not only prone to constipation because of their neurogenic bowel, but had the problem compounded because they all took Ditropan, an anticholinergic agent which controls detrusor-sphincter dyssnergia. While Ditropan controls the bladder spasms, it also affects the innervation of the bowel (CPS, 1986), thereby slowing down further an already sluggish neurogenic bowel.

Study Limitations

Sample Size

While the sample size for the within subject design was adequate, it may not have been large enough to detect a difference in sterile catheters when washed with Soap and Water plus Savlon soak. This occurred because it was not until part way through data collection that the Spina Bifida Clinic requested this aspect of the study be conducted. The researcher had purposely omitted analyzing catheters cleaned with the two solutions because of the possible interaction of Savlon and Sunlight (Favero, 1983; Martindale, 1982). Catheters washed in soap and water plus Savlon soak were collected only once from 23 subjects, rather than on two separate occasions.

Urinalyses

The results of the urinalyses of subjects can only be considered descriptive as they were collected only once. All but two subjects had problems with bowel management and frequent soiling of diapers. It is possible that urine contamination resulted more from faecal soiling around the urethral meatus than from the catheterization procedure itself. On the other hand, if organisms were residing in and around the urethral meatus, the catheter may indeed have introduced the organisms into the bladder.

Further Research

This study has laid a foundation for some further research in the area of bacteriuria and neurogenic bladder. Bacteriuria and constipation appear to be correlated. A project needs to be designed to follow a group of children, such as the subjects of this study, presently having difficulty with faecal soiling and constipation. After establishing adequate bowel routines in this group, it is expected urinalyses would reveal significantly less bacteriuria if constipation and bacteriuria are related as suggested by the literature.

It would also be important to know if the use of sterile, rather than clean, catheters affects the incidences of bacteriuria. A study comparing the results of bacteriuria in two groups of children, one using clean, reused catheters, the other using clean technique and sterile catheters, should be conducted.

It is possible that the mechanical action of rubbing and sudsing the Sunlight on the catheter effectively removed most of the organisms. Since Savlon also contains a surfactant (Wolin, 1979) it would be of interest to test the effectiveness of

Savlon by using it as a detergent (although the CPS, 1986, does not suggest using Savlon this way to increase its disinfectant qualities).

Implications of the Study

The purpose of the project was to compare two solutions for cleaning reused catheters used for CIC. The results suggest there is at least no difference between Savlon and Sunlight for this purpose and that Sunlight washing rather than Savlon soak may result in more sterile catheters. If health professionals are comfortable suggesting soap and water for catheter cleaning, the whole procedure then becomes simpler and more convenient for parents, school aides, and children. It is possible that adolescent children who have previously had difficulty complying with the regimen of soaking their catheters in Savlon after every use may be more willing to follow the soap and water procedure, just as they wash their hands after using the toilet.

If health professionals do suggest soap and water instead of Savlon soak for resued catheters, it must be clear in the directions to parents that catheters are to be exposed to the air and left to dry completely. Most catheters in the study had low colony counts; those which were wet, including the single catheter in the laboratory cultured wet, did grow coliforms after 48 hours incubation.

Use of Sunlight rather than Savlon will also save some government money since a financial support programme for the disabled currently covers the cost of Savlon. Each family spends approximately $90.00 a year on Savlon.

On a broader scope, the study has provided empirical data for choosing one solution over another. It is possible that other Clinics may be encouraged to evaluate their own recommendations in light of this project. If this occurred, Spina Bifida Clinics across the country would be providing parents with consistent information based on research rather than beliefs.

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Appendix 1

A Summary of Cleansing Techniques for Catheters used for CIC: Methods described in the literature

1. Use the catheter, rinse under cool water to remove organic debris, wash and suds well with liquid detergent, rinse to remove all soap, shake dry, and store in a clean dry place which allows evaporation of moisture (Lapides' method developed at University of Michigan, Ann Arbor (Appendix 3))

(Altshuler, Meyer, J. & Butz, 1977; Lynch, & Jackson, 1986; Borzyskowski, Mundy, & Neville, 1982; Brem, Martin, Callaghan, & Maynard, 1987; Cass, Luxenberg, Johnson, & Gleich, 1985; Clarkson, 1982; Fay, 1978; Gillenwater, Grayhack, Howards, & Duckett, 1987; Hinman, 77; Hendry, Crane, & Reynolds, 1982; Horsley, Crane, & Reynolds, 1982; Howards, & Duckett, 1987; Joiner, & Lindan, 1982; Kass, McHugh, & Diokno, 1979; Lowe, & Diokno, 1982; McIlroy, 1977; Slade, & Gillespie, 1985; Sorenson, & Luckman, 1986; Stauffer, 1984; Tank, 1977; Tortorelli, Church, & Garis, 1984; Whitfield, 1977).

2. Wash catheters after use and either boil or keep in sodium hypochlorite solution (Hunt, Whitaker, & Doyle, 1984).

3. Soak catheters 1/2 hour in Alconox, 1 TBSP to 1 Gallon water (Champion, 1976).

4. Boil catheter (metal, glass or red rubber) 15 minute in a covered pot
(Birdsell, 1985; Hartman, 1978; Lyon, Scott, & Marshall, 1975; Withycombe, Whitaker, & Hunt, 1978)

Appendix 1

A Summary of the Literature

5. Immerse the catheters in Milton antiseptic solution overnight
(Scott, 1978).

6. Soak the catheter in Savlon Solution 1:2000 (Boles, Marawu, & Porteous, 1978-79).

Sources: Appendix 1(b)

Appendix 1(b)

Catheter Cleaning Techniques described in the Literature: Sources

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Appendix 2

A Survey of Some Canadian Hospital Procedures for Cleaning Catheters Used for CIC

N=22 Institutions surveyed by letter or telephone
Response=20

1. Wash catheter with soap and water after use. Rinse well.
Store in a clean, dry place. Boil catheter and container once a week for two minutes. If using a plastic catheter, do not boil. Store and carry catheter in a container with Zephiran Chloride (Children's Rehabilitation Centre, St. John's, Nfld.).

2. As above but boil the catheter for 5 minutes and store in a clean, dry container (G.F. Strong Rehabilitation Centre, Vancouver).

3. Wash catheter with soap and water after use; rinse well. Store in a clean dry place. Boil red rubber or metal catheters once a day for 5 minutes. Discard plastic catheters at the end of each day (B.C. Childrens' Hospital, Vancouver; Ontario Crippled Children's Centre, Toronto).

4. Rinse metal catheters after use and at end of day wash well with soap and water; rubber catheters are used once and boiled 10 minutes at the end of the day, and stored in a clean dry towel or jar (Nova Scotia Rehabilitation Centre, Halifax).

5. Wash catheters after each use with soap and water and store in zip lock bag (IWK Hospital for Children, Halifax).

6. Use each catheter only once and at end of day, place in pan and boil for 20 minutes; store in clean towel or clean container
(Royal Alexandra Hospital, Edmonton; Shaughnessy Hospital, Vancouver; Victoria Order of Nurses Health Care Manual, 1987).

Appendix 2

A Survey of Canadian Hospitals

7. Use plastic catheters only once; wash red rubber catheters with soap and water, rinsing well under running water. Store in a Clean dry place. U of A Hospital, Edmonton.

8. Use catheter only once, rinse under tap and wash with soap and water. Soak in Savlon Aq. 1:30 solution for 1/2 hour. Change Savlon daily (Glenrose Rehabilitation Hospital, Edmonton).

9. Wash well in soap and water then soak 20 minutes in Javel solution (1 Cup Javel to 1 Gallon of water); rinse, dry, and store in clean place such as a Zip lock bag (The Montreal Children's Hospital, Montreal).

10. Use catheter only once and soak after use or at the end of the day in H2O2 (Ottawa Rehabilitation Centre, Ottawa)

11. Boil red rubber catheters once or twice a week for 2 minutes; reusable plastic catheters soak in Savlon 1:30 for 20 minutes once or twice a week; use disposable catheters only once. (Shaughnessy Hospital, Vancouver, B.C.)

Appendix 3

University of Michigan

Ann Arbor, Michigan 48109

Department of Surgery
Section of Urology

INTERMITTENT CATHETERIZATION FOR MYELODYSPLASTIC CHILDREN

Intermittent catheterization is a safe and effective method for completely emptying the bladder when one is unable to do so otherwise. The goal is to improve or eliminate urinary incontinence as well as to control bladder and kidney infection. It is expected that the child will learn to self-catheterize when able to do so.

A. CARDINAL RULE: EMPTY THE BLADDER COMPLETELY, REGULARLY AND HAVE MORE THAN THE BELOW LISTED AMOUNT OF URINE IN THE BLADDER

AT ANY TIME. ALL ELSE IS SECONDARY TO THIS RULE.

1-5 YEARS	5 OUNCES (150 CC)
6-9 YEARS	8 OUNCES (240 CC)
9 YEARS AND UP	10 OUNCES (300 CC)

B. Materials needed:

1. catheter size ____ Fr.
2. Catheter carrying containers can be as follows:

    1. Plastic bag (Baggie)
    2. Paper towel
    3. Cigarette case - cosmetic case
    4. Anything easy to carry

3. Catheter extension (Bardic urinary drainage tube #017517 For children in wheelchairs).

4. Clear plastic liquid detergent container with a hanger if needed (For children in wheelchairs).

5. Water soluble lubricant - large tube and packets for males.

DO NOT USE VASELINE OR PETROLEUM BASED LUBRICANT

Appendix 3

Catheterization Procedure

Preparation and Procedure:

For Females:

1. Wash your hands if you wish, however, this is not necessary.

2. Place the child on her back with the knees apart.

3. Spread the labia apart with one hand.

4. Hold the catheter one inch from the tip and insert it into the urethra until the urine flows.

5. Hold the catheter in place until the urine stops draining, then push the catheter in another inch or so to be sure the bladder is completely emptied.

For Males:

1. Wash your hands if you wish, however, this is not necessary.

2. Hold the penis up and outward from the body. Grasp on the sides of the penis rather than pinching the top and bottom.

3. Lubricate the tip of the catheter for about two inches.

4. Insert the catheter until urine flows. If you find it hard to push the catheter after you have inserted it a few inches and no urine flows, this is due to the sphincter muscle that controls the opening of the bladder. Use <u>gentle</u> but <u>firm</u> pressure on the catheter until the muscle relaxes and the catheter becomes easier to advance.

5. Insert the catheter until urine flows, let go of the penis and wait until the urine stops draining.

Appendix 3

Catheterization Procedure

For Both Males and Females:

6. Remove the catheter slowly, stopping anytime urine flows so as to empty the bladder completely. When the catheter tip is ready to come out, hold the catheter tip up so that the urine will drain down from the tip of the catheter and not on you.

7. After removing the catheter, coil the catheter and wash it using any soap between your soapy hands. (Do not rub the catheter on the bar of soap, as this may be hard to remove.) Rinse the catheter with tap water, inside and out, then dry and store. This is done to keep odor under control - if for any reason you are unable to wash the catheter, put it away until it is time to use again - if you can wash it then, do so, if not, be sure to catheterize.

8. Keep a catheter in any of the suggested containers in the following places as needed for convenience:

1. purse, wallet, pocket
2. bathroom
3. bedroom
4. at school
5. car (glove compartment)

9. Catheterize every 3-4 hours during the day, just before sleep and upon awakening in the morning so that there is never more than ____oz. of urine in the bladder at any time. If the child goes to bed early it may be necessary to catheterize the child before you retire. To help establish an individual routine, keep a daily record of the time of catheterization, the amount of urine obtained, and if the child is wet, damp, or dry. This is extremely important. When a satisfactory routine has been established it will no longer be necessry to measure the urine. This may take several months. It is suggested that the volume of urine then be measured once or twice a week to be sure it is not more than the _____oz. limit.

At no time should you permit the bladder to hold more than _____ounces of urine. Catheterize regularly. Do not skip a catheterization for any reason.

Do not force fluids.

Appendix 3

Catheterization Procedure

It is not harmful to catheterize every hour.

DO NOT CREDE THE BLADDER (Hard pressure on the bladder). The bladder will empty by gravity. Hard pressure on the bladder may push urine back into the kidneys.

Additional Information:

You will be washing and using the catheters repeatedly. You may wish to cleanse your catheter occasionally with vinegar, Miracle White or a Denture cleanser (rinse well).

Be sure that both parents as well as babysitters are taught to catheterize the child.

Discuss this program with the school teacher so that she knows why this is being done, what is happening and can therefore assist in reminding the child to catheterize if this is appropriate. If necessary, the physician will write a letter to the school about this procedure. Parent may need to perform catheterization at school.

Children mature at different ages so that it is difficult to predict when self-catheterization can be taught.

Many children have difficulty with hand-eye coordination. It is important to work with the child to practice activities to assist them to direct the catheter into the urethra.

When the young female has her menstrual period, it is not harmful if blood gets on the catheter.

If by chance the catheter is dropped and it cannot be washed, it may be wiped off to remove any possible grit and then used to cathterize.

If lubricant is not available, the child's own saliva may be used.

When the child is unable to pull the clothing down for catheterization, you may need to adapt it by sewing zippers or Velcro into the side seams, or

Appendix 3

Catheterization Procedure

inserting Velcro in the crotch of slacks.

To be as independent as possible, the child should learn to catheterize while sitting (wheelchair, car, etc) as well as in bed and on the toilet. It the urine is not longer being measured, one may catheterize directly into the toilet.

Medications which the child may be given to be used with the self-catheterization program are:

1. Ditropan--This helps control bladder spasms so that the bladder muscles relax. This medication may make the mouth dry and the skin flushed.

2. Tr. of Belladonna--This may be given instead of Ditropan. This may cause the pupils of the eyes to be dilated, the skin to be flushed and make the mouth dry.

3. Ephedrine--This increases the ability of the urethral sphincter to contract to keep the chld dry. Possible side effects are restlessness and sleeplessness.

If these side effects are troublesome to you, contact the urologist.

The above medications are an important part of the whole program and when ordered must be taken as prescribed.

<u>DO NOT RUN OUT OF MEDICATION</u>

Make a return visit to the Pediatric Urology Clinic in one month and approximately every six months thereafter. In case of any problems, contact our Pediatric Urologist. Please bring your daily record with you at your return visit.

Developed by Mrs. Bette S. Lowe, RN
Nurse Clinician
Room C-5104, Box 03
Phone 313-763-4018

Appendix 4

Bacteriuria in patients using CIC: Review of the Literature
Clean Catheters Only: No antibiotics/bladder irrigation

Reference	N=	Overall Bacteriuria	Asympt. Bacteriuria	Symptom. Bacteriuria	Sterile Urine
Borzyskowski et al (1982) (2 year study)	22			12%	45%
Hilwa & Perlmutter (1973)	39	35%			65%
Kass, Koff & Diokno (1981)	255	56%	45%	11%	
Lapides et al (1974) (3 year study)	100	35%			65%
Maynard & Diokno (1984) (2 year study)	50	88%	68%	22%	12%
McGuire & Savastona (1986) (2-12 year follow up)	22	32%		32%	
Tank (1977)	50	30%	15%	15%	70%
Withycombe et al (1978)	23	100%	83%	17%	
Present Study (1988)	**30** (21/30)	**85%** (18/21)	**71%** (15/21)	**14%** (3/21)	**14%** (3/21)

Overall= Overall incidence of bacteriuria during the study (Average 1 year)
Asymp.=Percentage of asymptomatic bacteriuria
Sympto.=Percentage of symptomatic " "
Bacteriuria in above studies = $\geq 10^5$ col/ml
Bacteriuria in Present Study = $\geq 10^3$ col/ml or $\geq 10^6$ col/L.
Bacteriuria in Present Study: only subjects <u>not</u> on Prophylaxis
Blank spaces indicate no figures given in article
Sources: see Appendix 4(b)

Appendix 4(b)

Clean Intermittent Catheterization and Bacteriuria: Sources

Borzyskowski, M., Mundy, A.R., Neville, B.G.R., Park, L., Kinder, C.H., Joyce, M.R.L., Chantler, C., & Haycock, G.B. (1982). The conservative management of vesico-ureteral dysfunction in children: A trial comparing clean intermittent catheterization with manual expression combined with drug treatment. British Journal of Urology, 54, 641-644.

Hilwa, N. & Permutter, A.D. (1973). The role of adjunctive drug therapy for intermittent catheterization and self-catheterization. Journal of Urology, 119, 551-554.

Kass, E.J., Koff, S.A., & Diokno, A. (1981). The significance of bacilluria in children on long term intermittent catheterization. Journal of Urology, 126, 223-225.

Lapides, J., Diokno, A., Lowe, B.S., & Kalish, M.D. (1974). Follow up on unsterile intermittent self-catheterization. Journal of Urology, 111, 184-187.

Maynard, F.M. & Diokno, A. (1984) Urinary infection and complications during clean intermittent catheterization following spinal cord injury. Journal of Urology, 132, 943-946.

McGuire, E.J. & Savastano, J. (1986). Comparative urological outcome in women with spinal cord injury. Journal of Urology, 135, 730-731.

Tank, E.S. (1977). Clean intermittent self-catheterization in children with bladder emptying dysfunction. Birth Defects, 13 (5), 117-119.

Withycombe, J., Whitaker, R., & Hunt, G. (1978). Intermittent catheterization in the management of children with neuropathic bladder. Lancet, 2, 981-983.

Appendix 5

Comparison of Solutions for Cleaning Catheters

Method	Time	E Coli	Proteus (Vulg./Retro)		Pseudo	Klebs	Entero	Serra	Staph
			Vulg.	Retro					
None		+	+	+	+	+	+	+	+
Betadine	5"3'4hr24hr	-	-	-	-	-	-	-	-
H202	" "	-	-	-	-	-	-	-	-
Acetic Acid	12hr	-	+	+	+	-	+	+	+
Alcohol 75%	12hr	+	+	+	+	-	+	+	-
Chlorox 5ml/1L	12hr	+	+	+	+	+	+	+	+
Boiling	5'	-	-	+	+	+	+	+	+
(not	10'	-	-	+	+	+	-	+	-
under	30'	-	-	-	+	+	+	-	-
pressure)	35'	-	-	-	+	-	-	-	-

Colony counts were not included. The presence of any bacteriuria is shown as a + on this table.
"=seconds
'=minutes
+bacteria present
-bacteria not present

Source: Wu, Y., Hamilton, B.B., Boynick, M., & Nanninga, J.B. (1981). Reusable catheter for long-term sterile intermittent catheterization. Archives of Physical Medicine and Rehabilitation, 62, 39-41.

Appendix 6

Consent to Participate in the Study

<u>Project: A comparison of the amount of bacteria on catheters used for clean intermittent catheterization when cleansed with Savlon and when cleansed with Sunlight Soap and water.</u>

Investigator: Katherine Moore, RN, Graduate Student at the Faculty of Nursing, University of Alberta.

Supervisor: Rene Day, PhD, Faculty of Nursing, University of Alberta.

The nature of this research project and my rights as a subject have been explained to me. I understand the purpose of the project is to compare the amount of bacteria on catheters used for clean intermittent catheterization when cleansed with Savlon and when cleansed with Sunlight soap. I will be required to use new catheters and cleanse them after use with these two solutions. The nurse-researcher will come to our home twice, two weeks apart, to test the catheters and the Savlon and to obtain a urine specimen from our child. There will be no harm to our child as the catheter washed with soap and water is not being reused, but tested by the researcher.

I expect to be informed of all the results when the study is completed in six months.

It has been made clear to me that I may withdraw at any time without affecting the care my child receives from the Glenrose Hospital or any other facility.

I hereby give my consent to participate in this study with the understanding that my identity and my family's identity will be safeguarded. The researcher will keep all personal information in a locked desk to which only she has access.

Appendix 6

Consent to Participate

I have received a copy of the consent and a description of the procedure I will follow, Sunlight soap which I may keep, and the researcher's phone numbers (home 433-0195 and work 432-6685).

Signed: Date: Witness:

Appendix 7

Introductory Letter to Potential Subjects

Faculty of Nursing
3-120 Clinical Sciences Building
University of Alberta
T6G 2G3

Dear Parents and child:

I am a graduate student in nursing at the University of Alberta. I am particularly interested in children with Spina Bifida who use clean intermittent catheterization and the number of bladder infections they have. I would like to find the most convenient method to clean catheters which also gives your child the most chance of not having bacteria in his or her urine.

At present, you are most likely using Savlon to soak your catheters. This is a satisfactory method to clean catheters. There are other solutions which may be as effective and not require long soaking--one of these is liquid soap and water (such as Sunlight detergent).

I ask your help in finding the best solution by washing a catheter in soap and water after you have used it, and saving it for me. I will take it to the laboratory for bacteria testing. I don't want you to reuse the catheter, just to wash it and save it for me. I will come to your home to obtain the catheter. I would also like a catheter urine specimen from your child to see if he or she has any bacteria in the urine.

When the study is completed, you will be informed of the results. At all times, your name and address will remain confidential information.

I would certainly appreciate it if you participate in this study. The Sunlight soap for the project will be provided for you at no cost. The cost of the four

Appendix 7

Introductory Letter

catheters will be covered by AADL. I will telephone you in 10 days to see if you are interested in being part of this project. If you are we can set a time to meet at your home and discuss the exact method of the study.

If you are not interested, you do not jeopardize your child's care in any way. You are welcome to telephone me to discuss the project before you decide to participate.

Sincerely,

Katherine Moore
Home 433-0195
Message 432-6685

Appendix 8

Explanation of the Procedure

On a convenient day, the family will follow the steps listed below:

1. Mix a new batch of Savlon.

2. Using a new (unbroken package) Mentor catheter, catheterize your child in the usual way.

3. Rinse the catheter and soak it in the Savlon for 30 minutes.

4. Remove the catheter from the Savlon, rinse it and store it in a clean dry place away from the other catheters you normally use

5. Note the time on the attached sheet.

6. Pour Savlon into the two containers provided.

7. At the next catheterization, again use a new Mentor catheter;

8. Catheterize your child as you normally do.

9. Rinse this catheter after use under the tap, sudsing for 30 seconds with the Sunlight detergent provided; rinse under the tap, shake dry, and store in a clean dry place away from all other catheters. Note the time on the sheet.

10. Researcher will come to your home approximately three hours after the second catheterization--she will have arranged this with you. If there is a problem please call her at 433-0195.

11. Researcher will cut the tips off the two catheters and place them on culture plates to take to the laboratory. She will also ask you to collect a catheter urine specimen from your child.

12. Two weeks later, the procedure will be repeated.

Appendix 8

Explanation of the Procedure

This time, you will wash the first catheter in soap and water (Step 9) and the second catheter in Savlon (Step 3 and 4). This is being done to see if the length of time catheters are sitting after being washed makes a difference to the bacteria on them.

13. The researcher will visit your home, again after arranging the time with you and will take the catheter specimens and a Savlon specimen. She will not require a urine specimen.

14. When the project is completed, you will be informed of the results.

Time Sheet

Name:
Date:
First Step of Study

Catheterized at ______Time?
Catheter soaked in Savlon and left to dry at______Time?
Next catheterization at ______Time?
Catheter washed with Sunlight and water at ______Time?

Second Step of Study two weeks later
Date:

Catheterized at _____Time?
Catheter washed with Sunlight and water at ______Time?
Next catheterization at _____Time?
Catheter soaked in Savlon and left to dry at _____Time?

Researcher's phone number: 433-0195
Message can be left at :432-6685

Appendix 9

Raw Data Summary of Savlon soaked Catheters Tested on two Occasions, 2 Weeks apart

N	Savlon (1)	Total	Savlon (2)	Total	$\bar{X}$ Savlon
(1)	19 micrococcus 4 Coag. Neg. Staphyloccus	23	1 acinetobacter	1	12.0
(2)	1 diptheroid 5 micrococcus 1 aerobic spore-bearing bacillus	7	0 no growth	7	3.5
(3)	2 coag.neg.staph. 15 diptheroids 1 yeast	18	2 micrococcus	2	10.0
(4)	2 coag.neg.staph 15 viridans gr.strep.	17	0	0	8.5
(5)	2 coag.neg.staph. 1 viridens gr.strep.	3	1 coag.neg.staph.	1	2.0
(6)	2 micrococcus	2	1 micrococcus	1	1.5
(7)	0	0	0	0	0
(8)	3 coag.neg.staph. 2 micrococcus 1 viridens gr. strep.	6	0	0	3.0
(9)	2 micrococcus 1 diptheroids	3	2 micrococcus 7 coag.neg.staph.	9	6.0
(10)	0	0	0	0	0
(11)	2 aerobic spore-bearing bacilli 5 coag.neg.staph.	7	3 coag.neg.staph.	3	5.0
(12)	0	0	0	0	0

Appendix 9

N	Savlon (1)	Total	Savlon (2)	Total	X̄ Savlon
(13)	0	0	0	0	0
(14)	0	0	0	0	0
(15)	1 coag.neg.staph	1	0	0	0.5
(16)	1 aerobic spore-bearing bacilli	1	1 coag.neg.staph.	1	1.0
(17)	0	0	1 coag.neg.staph.	1	0.5
(18)	11 coag.neg.staph.	11	0	0	5.5
(19)	29 coag.neg.staph. 4 aerobic spore-bearing bacilli	33	1 coag.neg.staph.	1	17.0
(20)	dropped from study				
(21)	2 coag.neg.staph. 2 diptheroids 4 micrococcus	8	0	0	4.0
(22)	18 coag.neg.staph. 1 aerobic spore-bearing bacilli	19	0	0	9.5
(23)	1 aerobic spore-bearing bacilli	1	1 diptheroids	1	1.0
(24)	0	0	1 aerobic spore-bearing bacilli	1	0.5
(25)	41 coag.neg.staph. 1 micrococcus	42	4 non-hemolytic streptococci	4	23.0
(26)	1 non-hemolytic streptococci	1	22 coag.neg.staph.	22	12
(27)	0	0	0	0	0
(28)	0	0	0	0	0

Appendix 9

N	Savlon (1)	Total	Savlon (2)	Total	X̄ Savlon
(29)	>100 coag.neg.staph.	>100	2 coag.neg.staph.	2	51.0
(30)	0	0	2 micrococcus	2	1.0
(31)	>100 coag.neg.staph.	>100	1 coag.neg.staph.	1	51.0
(32)	0	0	0	0	0

Total = 31 x 2= 62 catheters tips cultured

X̄ Colonies of Organisms on each Savlon Catheter = 7.5161
Total Colonies of organisms on Savlon catheters = 229.00
SD=12.807
Subject (20) dropped from study

Appendix 10

Raw Data Summary of Sunlight Wash Catheters Tested on Two Occasions, 2 weeks apart

N	Sunlight (1)	Total	Sunlight (2)	Total	X̄ Sunlight
(1)	2 coag.neg.staph. 2 micrococcus	4	0	0	2.0
(2)	1 diptheroids 1 yeast	2	0	0	3.5
(3)	3 coag.neg.staph. 10 diptheroids	13	0	0	6.5
(4)	0	0	0	0	0
(5)	0	0	1 coag.neg.staph.	1	0.5
(6)	1 coag.neg.staph.	1	0	0	0.5
(7)	0	0	0	0	0
(8)	0	0	0	0	0
(9)	0	0	0	0	0
(10)	0	0	0	0	0
(11)	0	0	1 coag.neg.staph.	1	0.5
(12)	0	0	2 coag.neg.staph.	2	1.0
(13)	9 coag.neg.staph.	9	1 micrococcus	1	5.0
(14)	1 micrococcus	1	0	0	0.5
(15)	0	0	0	0	0
(16)	0	0	3 coag.neg.staph.	3	1.5
(17)	0	0	75 diptheroids 12 coag.neg.staph.	87	43.5
(18)	0	0	0	0	0

Appendix 10
Raw Data: Sunlight Wash

N	Sunlight (1)	Total	Sunlight (2)	Total	X̄ Sunlight
(19)	0	0	0	0	0
(20)	dropped from study				
(21)	1 coag.neg.staph.	1	0	0	0.5
(22)	1 aerobic spore-bearing bacilli	1	4 coag.neg.staph.	4	2.5
(23)	3 coag.neg.staph. 1 micrococcus	4	11 coliforms	11	7.5
(24)	0	0	0	0	0
(25)	0	0	1 coag.neg.staph.	1	0.5
(26)	0	0	3 coag.neg.staph.	3	1.5
(27)	2 aerobic spore-bearing bacilli 3 viridens gr.strep. 1 coag.neg.staph.	6	0	0	3.0
(28)	12 coag.neg.staph. 11 viridens gr.strep. 1 aerobic spore-bearing bacilli	24	0	0	12.0
(29)	0	0	1 coag.neg.staph.	1	0.5
(30)	0	0	1 micrococcus	1	0.5
(31)	0	0	0	0	0
(32)	2 coag.neg.staph.	2	1 micrococcus	1	1.5

Subject (20) dropped from catheter tip study.
Total 31 x 2 catheter tips cultured.
X̄ Colonies of organisms on each Sunlight catheter = 2.9677
Total Colonies of organisms on all Sunlight catheters = 92.50
SD = 7.986

Appendix 11

Raw Data Summary of Soap & Water wash Plus Savlon Soak

(Recommendation of the SB Clinic at the time of the Study)
Total Colonies of each Organism

N (Total=23, tested on one occasion)

(1) 0 No growth

(2) 7 micrococcus
1 coag.neg.staph.

(4) 0

(5) 0

(7) 1 non-hemolytic strept.

(8 0

(9) 0

(12) 0

(13) 0

(16) 1 coag.neg.staph.

(17) 0

(18) 1 coag.neg.staph.

(20) 2 coliforms
5 viridens group strep.
3 coag.neg.staph.

(21) 2 coag.neg.staph.

(22) 3 aerobic spore-bearing bacilli
4 micrococcus
26 coag. neg. staph.

(23) 2 coag. neg. staph.

(25) 1 micrococcus

Appendix 11

Raw Data Summary of Soap & Water + Savlon Soak

(26) 0

(28) 4 coag. neg. staph.

(29) 0

(30) >200 coliforms

(31) 0

(32) 1 coliform

N=23
Sterile catheters = 11/23
Contaminated catheters = 12/23
Percentage Sterile = 47%
Percentage contaminated = 52%
Total Organisms on all catheters= 264
$\bar{X}$ organisms on each soap + Savlon catheter = 11.48
SD = 41.70

Appendix 12

Raw Data Obtained from Urinalysis On One Occasion (n=30)

N	Sex	Colonies/L	Symptomatic	Treatment
(1)	F	10^8 E coli	yes	Prophylaxis Bactrim BID
(2)	M	2.8×10^7 Hemophilus (not influenzae) $<10^6$ coag. neg. staph	yes	No antibiotics
(3)	F	>10 E coli	No	No antibiotics
(4)	M	8.8×10^7 Pseudomonas aeruginosa	No	No Antibiotics
(5)	F	10^9 Strep faecalis	No	Prophylaxis Septra BID
(6)	M	10^9 E coli	No	No Antibiotics
(7)	F	no growth	No	Prophylaxis Nitrofurantoin
(8)	M	4.5×10^6 Strep faecalis	No	Prophylaxis Bactrim BID
(9)	F	no growth	No	Prophylaxis Septra BID
(10)	F	no growth	No	Prophylaxis Bactrim BID
(11)	M	no growth	No	No Antibiotics
(12)	F	no growth	No	Prophylaxis Microdantin
(13)	M	$>10^9$ Strept faecalis	No	No Antibiotics
(14)	F	3.4×10^7 Klebsiella pneumoniae	No	No Antibiotics

Appendix 12

Raw Data From Urinalyses

N	Sex	Colonies/L	Symptomatic	Treatment
(15)	M	no growth	No	No Antibiotics
(16)	F	10^8 E coli	No	No Antibiotics
(17)	F	10^9 E coli	No	Prophylaxis Septra BID
(18)	F	no growth	No	Prophylaxis Bactrim BID
(19)	M	10^9 E coli	No	No Antibiotics
(20)	M	10^9 E coli	No	No Antibiotics
(21)	F	$<10^6$ Strept faecalis	No	Asymptomatic
(22)	F	10^9 E coli	Yes	No Antibiotics
(23)	M	no specimen collected		
(24)	M	6.2×10^7 E coli	No	No Antibiotics
(25)	M	no specimen collected		
(26)	M	5.0×10^6 Staph aureus	No	No Antibiotics
(27)	M	10^7 E coli	No	No Antibiotics
(28)	M	10^9 E coli	Yes	No Antibiotics
(29)	M	no growth	No	No Antibiotics
(30)	F	10^9 Staph simulans	No	No Antibiotics
(31)	M	10^9 E coli	No	No Antibiotics
(32)	M	10^9 E coli	No	No Antibiotics

Total urine specimens = 30
Subject (20) was dropped from the catheter tip study (Appendix 9 and 10)
Subject (23) was being treated for symptomatic bacteriuria
Subject (25) was unable to produce a specimen.

Appendix 13

Summary of X Savlon and X Sunlight Colony Counts on Catheter Tips
Calculation for Dependent t-Test @ Alpha = 0.05_2

Subject	$\frac{T(1)+T(2)}{2}$ ($\bar{X}$ Savlon -	$\frac{T(1) + T(2)}{2}$ $\bar{X}$ Sunlight) =	D
(1)	12.0	2.0	10.0
(2)	3.5	1.0	2.5
(3)	10.0	6.5	3.5
(4)	8.5	0	8.5
(5)	2.0	0.5	1.5
(6)	1.5	0.5	1.0
(7)	0	0	0
(8)	3.0	0	3.0
(9)	6.0	0	6.0
(10)	0	0	0
(11)	5.0	0.5	4.5
(12)	0	1.0	-1.0
(13)	0	5.0	-5.0
(14)	0	0.5	-0.5
(15)	0.5	0	0.5
(16)	1.0	1.5	-0.5
(17)	0.5	43.5	-43.5
(18)	5.5	0	5.5
(19)	17.0	0	17.0
(21)	4.0	0.5	3.5
(22)	9.5	2.5	7.0
(23)	1.0	7.5	-6.5
(24)	0.5	0	0.5
(25)	23.0	0.5	22.5
(26)	12.0	1.5	10.5
(27)	0	3.0	-3.0
(28)	0	12.0	-12.0
(29)	51.0	0.5	50.5
(30)	1.0	0.5	0.5
(31)	51.0	0	51.0
(32)	0	1.5	-1.5

N=31	$\bar{X}$ Savlon 7.387	$\bar{X}$ Sunlight 2.983	$\bar{D}$ 4.548
	Σ 229.000	Σ 92.500	136.500
	SD 12.807	SD " " 7.993	15.719
			SE of D 2.823

Correlation = -0.094
2-Tailed Probability 0.616
Critical Value of T = 2.042
T-Obtained = 1.610