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A COMPARISON OF TWO INTERMITTENT CATHETERIZATION SYSTEMS: THE CLOSED O'NEIL SYSTEM AND THE TRADITIONAL OPEN SYSTEM

BY

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ABSTRACT

While it is acknowledged that the risk for infection is reduced with the use of intermittent catheterization, urinary tract infections continue to be attributed to the intermittent catheterization method. The closed O'Neil system (experimental group) and the traditional Open system (control group) were compared using the criteria of number and types of organisms introduced into bladder urine during intermittent catheterization procedures. Convenience sampling was used within acute care neurosurgical areas in two Western Canadian hospitals to obtain subjects who were randomly assigned to the two groups. A total of 33 urine specimens and 11 urethral meatal swab were collected. Data were analyzed using the Fisher Exact Test and the *t*-test for comparison of means. While a statistical level of significance was not achieved with the small sample size, the overall results supported the expectation that urine specimens obtained with the O'Neil system would yield little or no growth.

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CHAPTER 1

INTRODUCTION

Historically, urinary tract infections (UTIs) in hospitalized patients have been associated with invasive procedures such as urinary catheterization (Beeson, 1958; Gruneberg & Wilson, 1994; Guttmann & Frankel, 1966; Langer, Pifferi, & Peta, 1994; Murray, 1990; Widmer, 1994). In spite of improvements in procedural technique (Stamm, 1975; Wong, 1983), in continuous drainage equipment (Kunin & McCormack, 1966), and methods of catheterization (Guttman & Frankel; Lapides, Diokno, Silber, & Lowe, 1972), prevalence of UTIs remains high (Johnson, 1991).

It is still generally believed that most UTIs arise by the ascending route, via the urethra to the bladder after entry of bacteria through the urethral meatus (Kunin, 1987). Kunin adds that it is the most common route for women and, in association with instrumentation, in both sexes. Catheterization, as a method of instrumentation, is partially responsible for development of UTIs (Langer et al., 1994) by introducing organisms into the bladder (Barnes, Timoney, Moulas, Shaw, & Sanderson, 1992) where they may multiply and cause infection. Many UTIs are believed to be related to the indwelling catheter (Kunin) with the catheter itself as an important site for bacterial adherence and persistence. In addition, the bladder wall becomes traumatized through contact with the catheter and thus becomes susceptible to invasion by microbes introduced via the catheter (Garibaldi, 1993). While it is acknowledged by some that infection risk is reduced with intermittent catheterization

(Bennett, Young, & Darrington, 1995; National Institute on Disability & Rehabilitation Research Consensus Statement, 1992). UTIs continue to be attributed to this catheterization method (Barnes et al.).

In this project, two intermittent catheterization systems were compared to determine if one system of intermittent catheterization introduced fewer organisms to the bladder than the other. An effective intermittent catheterization system may reduce the number and type of organisms entering the bladder thereby minimizing the risk of acquiring a UTI for the hospitalized patient. Fewer UTIs benefit the patient, the institution and the health care system in general.

Statement of the Problem

Hospital-acquired infections are a major health problem and consume a large portion of health care resources (Dixon, 1978; Gruneberg & Wilson, 1994; Murray, 1992; Stamm, Long, & Belcher, 1993; Stamm, Martin, & Bennett, 1977; Widmer, 1994). Up to 42% of all hospital-acquired infections are estimated to be urinary tract infections (Haley, Culver, White, Morgan, & Emori, 1985; Stamm et al., 1977; Turck & Stamm, 1981). Costs associated with UTIs affect the patient, the institution, and third party payers (Wakefield, 1993). Costs to the patient include morbidity, pain and suffering, delayed return to work, decreased functional status, and perhaps premature death. Also of concern is that the development of the first infection may set the stage for more to follow (Garibaldi, 1993; Kunin, Polyak, & Postel, 1980). The institution bears the cost of increased laboratory and radiological tests,

medications, infection control procedures, and increased length of stay of the patient. Third party payers have increased costs for payments to hospitals as well as outpatient, home care, and physician services.

As technology changes, so do the possibilities of changing the infection outcomes related to catheterization procedures. A straight urinary catheter now exists that may reduce the risk to the patient of exposure to the number and types of microbes existing in the distal urethra. O'Neil, Jenkins, and Wells (1982) adapted a straight catheter system from a sealed introducer which was developed by O'Neil (1981) for the purpose of collecting urethral swabs. Swabs collected through the introducer from proximal urethras in women yielded contamination results of only 10%. The O'Neil Urinary Catheter (O'Neil et al.) was designed to extend a sterile field into the female urethra to provide sterile passage for a straight catheter through the colonized distal portion of the urethra. Theoretically, the catheter reaches the relatively sterile proximal urethra uncontaminated, thereby breaking the link between colonized organisms in the distal urethral and periurethral areas, and the bladder urine.

While the catheter was introduced in Australia as a method for catheterizing women, it has been used since in the United States and Canada with both men and women. Charbonneau-Smith (1993) conducted a study in a long-term care facility using the O'Neil catheter for intermittent catheterization. She demonstrated that only 44.4% of patients in the experimental group had more than one UTI per admission to the facility compared with 79.3% of patients in the control group. A lower

incidence of UTI was also demonstrated by Pang-Wright and Dasalla (1990) but because of the small sample size, they could not establish a statistically significant difference. Young, Bennett, and Darrington (1992) described a 30% reduction in the infection rate in hospitalized patients over a three year period using the O'Neil system (0.61%) compared with an alternate closed system without an introducer tip (0.91%). In 1995, Bennett et al. again studied hospitalized men and women. A total of 75 infections in 10,945 catheterizations was identified for an overall low infection rate of 0.68%. All catheterizations were performed with the O'Neil system.

While use of the O'Neil catheter has been documented in studies pertaining to long term management of urinary retention, there is little evidence in the literature that the effectiveness of the O'Neil Urinary Catheter has been studied in acute care settings for short term management of patients with acute urinary retention. More studies are needed to determine the impact of this technology compared with the traditional technology on the risk of and/or development of UTIs related to short-term urinary retention management in acute care facilities. Since nursing staff perform or oversee urinary catheterizations, the catheterization system used is a clinical nursing concern.

Purpose of the Study

The purpose of this study was to compare the traditional open intermittent catheterization system which is believed to expose a patient's sterile bladder to the microbes from the distal urethra via a contaminated catheter, with the O'Neil system

which theoretically provides a sterile passage for the catheter. The systems were compared in relation to two factors: number of microorganisms (size of inoculum) and the types (genus, or genus and species) of microorganisms recovered from bladder urine and the urethral meatus. This approach permits a closer examination of the impact of the etiological agent in the infection equation (etiologic agent plus host defenses equals the presence or absence of UTI) in contrast to other studies which examine the rates of UTI.

Research Hypotheses

The hypotheses in this study were:

1. There will be a significant difference in the number of bacteria found in the urine of the subjects using the O'Neil system compared with the subjects using the Open system.
2. There will be a significant variation in types of bacteria in the urine of subjects using the Open system compared with those using the O'Neil system.
3. The relationship between the bacteria found at the urethral meatus and in the urine is stronger for the Open system than for the O'Neil system.

Operational Definitions

O'Neil Intermittent Catheterization System (O'Neil system)

The O'Neil system is a completely self-contained sterile field consisting of an introducer, a straight catheter, water soluble lubricant and a graduated collection bag. The sterile field is closed to the environment during the procedure. Sterile gloves and povidone-iodine (precatheterization skin cleanser) are used in combination with the O'Neil system. Urine drains into the closed collection bag. A sterile specimen is obtained by pouring urine from a sterile port on the bag into a sterile specimen container. The port becomes accessible once the contaminated catheter and introducer are removed from the collection bag. Precatheterization preparation of the equipment is not required prior to performing the procedure except for opening the packages of povidone-iodine swabs for cleansing and removing the cap from the tip of the catheter. Aseptic technique is used.

Open Intermittent Catheterization System (Open system)

The open system consists of a sterile straight catheter, and a sterile tray that includes a collecting receptacle, drapes, cotton swabs, povidone-iodine cleanser, water soluble lubricant, disposable forceps, and sterile gloves. The sterile field is prepared prior to the procedure by opening the sterile catheterization tray, opening the cleanser package and expelling the contents onto the cotton swabs, opening the lubricant package and expelling the contents into the collection receptacle, and adding other sterile items such as the straight catheter. The sterile field is exposed

(open) to the environment during precatheterization equipment preparation and the actual catheterization procedure. Urine drains into the open collecting receptacle. A sterile specimen is obtained by pouring urine from the receptacle into a sterile specimen bottle. Aseptic technique is used.

Aseptic Technique

Aseptic technique (Crow, 1989) involves washing the hands thoroughly prior to preparing the sterile field, and using sterile equipment, technique and supplies. Povidone-iodine is used for urethral meatal cleansing. Sterile gloves are worn by the nurse. The gloved hand that contacts the periurethral area does not contact the sterile catheter or any other part of the sterile field.

Assumptions

The study is based on the following assumptions:

1. The ascending route is a common route of urinary tract infection.
2. Colonization of the urethra with microbes may contribute to the development of UTIs.
3. Microbes colonized in the distal urethra will likely be similar to those present at the urethral meatus.
4. Host defenses and agent characteristics interact in the development of UTIs.
5. Host defenses influence the ability of microbes to invade bladder tissue depending on the number and type of microbes presented.

6. If fewer microbes are introduced into the bladder, the patient will be at less risk for the development of a UTI.
7. Catheterization supplies exposed to the environment are more susceptible to contamination than those enclosed in a sterile environment.
8. Nursing staff follow the designated procedures by using aseptic technique when performing intermittent catheterization, and by using correct catheterization and sterile specimen collection techniques.

Summary

An introduction to the study including the statement of the problem, the purpose of the study, the research hypotheses, operational definitions, and assumptions are presented in Chapter 1. A review of the literature is presented in Chapter 2. In Chapter 3 the research design and methods, including the data analysis, are explained. The results are presented in Chapter 4. In the final chapter, the major findings of the study and the implications of this study for nursing staff are discussed.

CHAPTER 2

REVIEW OF THE LITERATURE

The background and theoretical foundation for this study is provided in this literature review. It comprises four main sections; agent-host-environment interaction, host defenses including the urethra and the bladder, bacterial causes of UTIs in hospitals, and intermittent catheterization. In particular, the literature is explored from the perspective of the potential infective agent of UTIs and the relationship with intermittent catheterization.

Agent-Host-Environment Interaction

Relationships are known to exist between infectious agents, the human host, and the environment (Lilienfeld & Lilienfeld, 1980) (see Figure 1). Infectious diseases are usually classified by agent on the basis of biological features (categories of metozoa, protozoa, bacteria, fungi, rickettsia, viruses). The agent enters the human host through portals such as the respiratory tract, the gastrointestinal tract, the genitourinary tract, conjunctiva, or skin and tissue (percutaneous entry).

The interval between the time of agent contact with the host and the onset of disease (incubation period) is generally thought to be the time required for the multiplication of the agent within the host to a threshold point where the agent population is large enough to produce symptoms in a host. The incubation period is largely dependent upon the rate of growth of the agent in the host (Benenson, 1990).

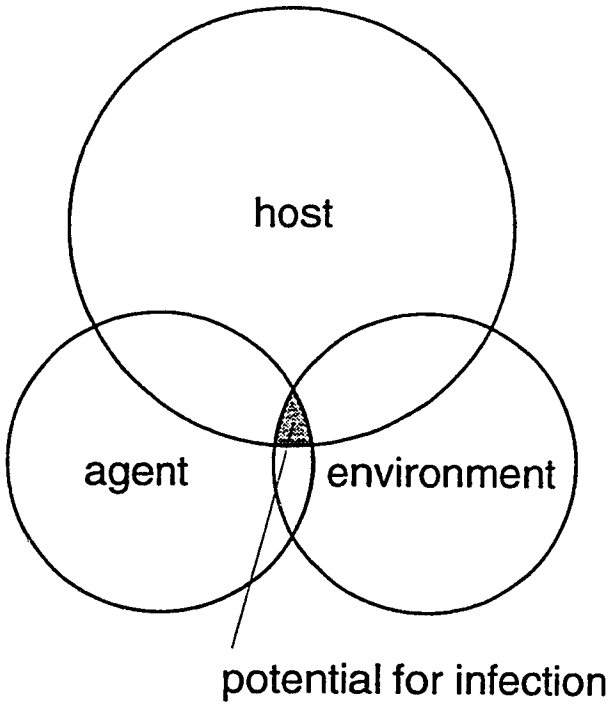

Figure 1. Agent-Host-Environment Interaction as it relates to the potential for infection. An etiological agent such as bacteria may be carried on the tip of a catheter from the environment into the bladder of the host during catheterization. Host defenses rally to minimize the ability of the agent to cause disease.

Patterns of infectious diseases depend upon factors that enhance the probability of contact between an infectious agent and a susceptible host (Lilienfeld & Lilienfeld, 1980). Such enhancing factors include diminished host defenses in the urethra, urine, and bladder (internal environment), virulence features of infectious bacteria (agent), and the use of instruments such as urinary catheters (external environment) in the provision of health care.

Host Defenses

The human host has natural defenses against diseases such as UTIs (Sobel, 1991). Host defenses may minimize the impact of intruding infectious agents on body functions.

The Urethra

The female urethra is a small tube approximately three to four centimeters in length, located behind the symphysis pubis and anterior to the vagina (Dittmar, 1989). It serves only the urinary tract, and connects the bladder to the perineum, allowing for the passage of urine. Periurethral mucous secreting glands surround the distal two-thirds of the urethra (Moore & Hira, 1965). Mucus that lines the urethra traps bacteria attempting to ascend the urethra, and may delay or prevent them from reaching the fourth centimeter of the urethra that is contiguous with the bladder (Hutch, 1970).

The male urethra extends through the prostate gland, fibrous sheath and penis and serves both the urinary and reproductive tract (Spence & Mason, 1983). The male urethra is approximately 20 cm in length and is divisible into three parts. The prostatic urethra passes through the prostate gland and receives secretions from ejaculatory ducts of the reproductive system. The membranous urethra passes through the urogenital diaphragm (pelvic floor). The cavernous urethra is the longest portion extending from below the urogenital diaphragm to the external urethral orifice. The cavernous urethra receives secretions from the bulbourethral reproductive glands near its proximal end.

Both male and female urethras (see Figure 2) have internal and external sphincters. The internal urethral sphincter is located at the junction of the bladder and the urethra and functions to keep the urethra closed between voluntary voiding. As the urethra passes through the urogenital diaphragm, it is surrounded by skeletal muscles that form the external urethral sphincter. When contracted, this sphincter holds the urethra closed against strong bladder contractions and when relaxed, it permits the passage of urine (Spence & Mason, 1983).

High Pressure Zone. Tanagho and Miller (1973) demonstrated that the external striated sphincters in the male (within the membranous urethra) and in the female (approximately 1.5 cm from the meatus) create high pressure zones (see Figure 2) which constitute relative barriers to bacterial ascent (Mayo & Hinman, 1973) from the distal urethra to the bladder. Urethral contents distal to the high

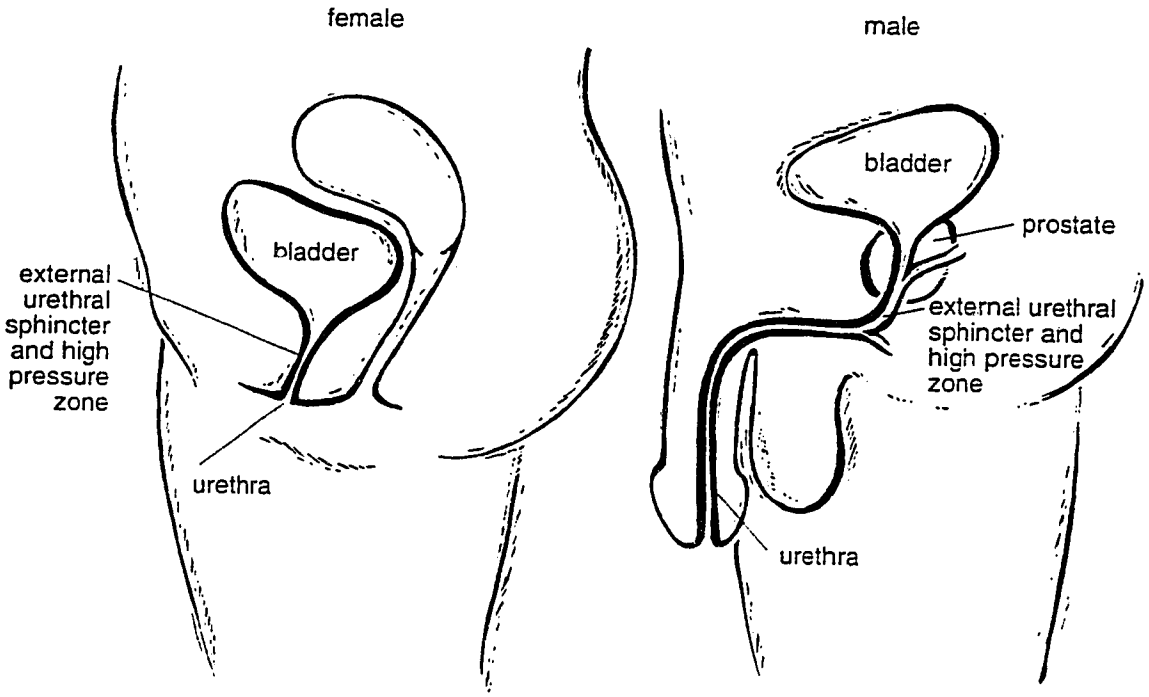

Figure 2. External urethral sphincters and high pressure zones in relation to the female and male urethras

pressure zone are milked toward the urethral meatus while contents proximal to the high pressure zone are milked toward the bladder.

An association between the urethral high pressure zone and distribution of colonized microbes within the urethra is believed to exist. The urethral high pressure zone may partially determine, as a relative barrier, whether or not colonized microbes, without the aid of a catheter, ascend from the distal urethra or periurethral area to the bladder to cause UTIs. During urethral catheterization, the catheter passes through the distal urethra and penetrates the natural barrier. The catheter carries microbes of particular types which are inoculated into the bladder at the time of entry of the catheter into the bladder.

Colonization. The number and location of urethral microorganisms vary among individuals as shown in Table 1. Helmholz (1950) found that few male subjects displayed bacteria as far as the fifth and sixth urethral segments. The most frequently colonized segment was the first one. Cox (1966) and Cox, Lacy, and Hinman (1968) showed that the majority of female subjects were colonized along the entire urethra and that all were colonized in the first centimetre. O'Neil (1981), in contrast to Cox et al., showed that while 90% of female subjects were colonized in the first centimetre, only 10% were colonized in the second, third and fourth centimetres. The measuring instruments were markedly different in design which partially explains the variation in results of O'Neil and Cox et al.

Table 1

Percentage Of Subjects Colonized Per Urethral Segment

Urethral Segment	Men - Symptoms[1]	Women - No Symptoms[2]	Women - Symptoms[3]	Women - No Symptoms[4]
1st (1 cm)	95%	100%	100%	90%
2nd (1 cm)	68%	88.5%	97.2%	10%
3rd (1 cm)	54%	81%	88.6%	↓
4th (1 cm)	34%	54%	77.2%	↓
5th (1 cm)	17%	-	-	-
6th (1 cm)	7%	-	-	-

Note. [1]Helmholz, 1950; [2]Cox, 1966; [3]Cox et al., 1968; [4]O'Neil, 1981

Hemholz (1950) showed the male urethra to be colonized with gram negative bacteria and gram positive cocci (most likely *Streptococcus faecalis*) in gradually decreasing amounts from the first to the fourth segments. The fifth segment continued to harbor gram negative bacteria but not *Streptococcus faecalis*. He suggested that the presence of gram negative bacteria in the fifth segment may be a significant factor in development of UTIs in men.

Crow (1989) suggested that the urethras of both men and women are colonized with microbes which vary with the stage of sexual development. Maskell, Pead & Hallett (1975) indicated that in prepubertal boys and men over 60 years of age, the most frequent urinary infecting microbe was *Proteus* species which resided in the prostatic ducts and urethra rather than on the perineum. The authors speculated that these infections related more to the characteristics of the prostatic secretion than to periurethral colonization. UTIs in older boys and young men occur

but are infrequent unless they were subjected to urinary instrumentation (Kunin, 1987) or have functional or anatomical abnormalities of the genitourinary tract (Lipsky, 1989). In these cases, *Escherichia coli (E. coli)* has been the most frequent uropathogen. Bennett et al. (1995) demonstrated that not only was *E. coli* a prevalent cause of UTIs but that *E. coli* infections were significantly greater in female subjects compared with male subjects in a recently injured group of spinal cord patients. In healthy young women (age 18 to 20 years), anaerobic bacteria such as *Bacteroides melaninogenicus* and aerobic bacteria such as lactobacilli, *Staphylococcus epidermidis*, Corynebacteriaceae, and alpha-hemolytic *Streptococcus* species are common occupants of the urethra (Marrie, Harding, & Ronald, 1978). Crow (1989) agrees that enterococci and alpha-hemolytic *Streptococcus* species are commonly found in the anterior urethra of women and adds *Candida albicans* to the list of microbes. Lactobacilli and *Bacteroide* species, among others, are also common to the vagina. The external genitalia of women (Crow) and young girls (Schlager, Hendley, Lohr, & Whittam, 1993) may be colonized with gram negative bacteria.

The Bladder

The bladder serves as a reservoir and can store 350 to 450 ml of urine (Dittmar, 1989). When empty, it lies behind the symphysis pubis. Smooth muscle lines the bladder and is continuous with and lines the urethra, allowing the bladder and urethra to function as a unit.

Micturition or emptying of the bladder occurs with voluntary relaxation and contraction of the external sphincter and pelvic floor musculature. A relatively constant intravesicular pressure is maintained by the detrusor muscle, which lines the bladder, despite varying urine volumes. The sensation of bladder filling is usually felt when the bladder contains 100 ml of urine. At about 400 ml, the desire to void is felt. Over-distention of the bladder disrupts tissue integrity by decreasing blood supply to the bladder wall (Lapides, 1979) making the bladder susceptible to bacteria via the hematogenous route (Lapides, Costello, Zierdt, & Stone, 1968). Bladder defenses represent host responses to the number and type of microbes persisting in the bladder.

Bladder Wall. The size of the bacterial inoculum in the urine influences the ability of the bladder to defend itself. Hand, Smith, and Sanford (1971) and Norden, Green, and Kass (1968) demonstrated rapid killing of bacteria in contact with the bladder wall. Norden et al. showed that a small number of bacteria was killed more effectively than a large number of bacteria, and that some kinds of bacteria were killed more rapidly (e.g. *Proteus mirabilis*) than others (e.g. *Staphylococcus aureus*). Hand et al. (with rabbits) and Norden et al. (with rats and guinea pigs) also showed that while organisms are multiplying in urine (e.g. *E. coli*), the bladder wall continues to exert a bactericidal effect on organisms attached to the bladder surface. Parsons, Greenspan, Moore and Mulholland (1977) demonstrated that attachment of bacteria to the bladder wall epithelium is normally inhibited by mucopolysaccharides in a mucous layer covering the epithelium.

Bladder Urine. Multiplication of bacteria in the bladder urine occurs in four phases: lag phase, logarithmic phase, maximum stationary phase, and phase of decline (Asscher, Sussman, & Weiser, 1968) as shown in Figure 3. The lag phase is a high energy phase in which the bacteria are adapting to the new environment rather than increasing in cell mass or in number. The logarithmic phase begins once bacteria have adapted and accounts for growth at a constant energetic rate until the condition of the urine changes enough to inhibit growth (e.g. reduced nutrients, increased toxic waste). Bacteria vary in the size of cell mass required before the parent cell can split to create two identical daughter cells (Morris, 1990) and they vary in growth rates (Nierlich, 1978). The time it takes viable *E. coli*, for example, to double in number (generation time) can be as short as 12.5 minutes (Roberts, Clayton, & Bean, 1968) while for other organisms the generation time may be hours (e.g. *Mycobacterium tuberculosis*). Eventually the maximum stationary phase may be reached while at the same time resources in the urine decline. Due to lack of nutrients and build up of toxic waste, the phase of decline sets in and bacteria begin to die (Asscher et al.).

Kaye (1968) provided evidence that bladder urine is generally bacteriostatic for small inocula ($< 10^2$ organisms/ml) under optimal conditions (e.g. low pH). Properties of urine such as pH, osmolity, glucose and amino acid content, organic acids and urea can promote or inhibit the growth of bacteria (Asscher et al., 1968; Kaye; Roberts et al., 1968).

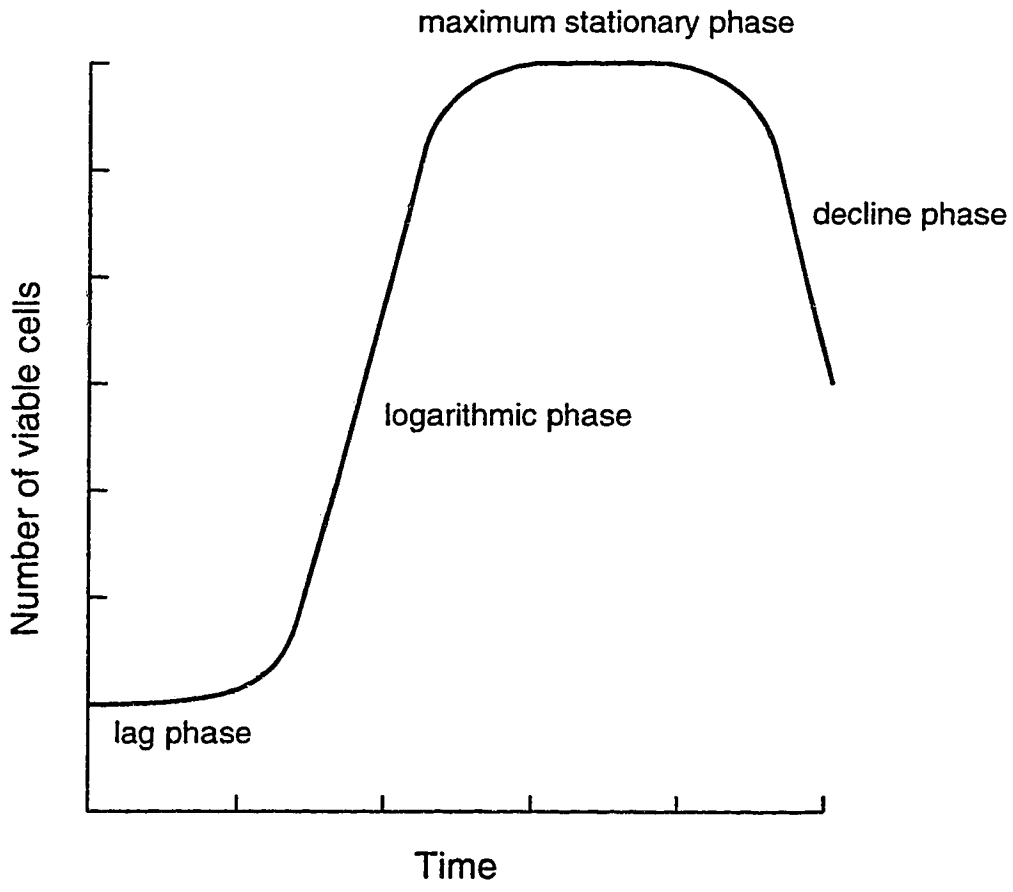

Figure 3. Growth phases of bacteria

The frequency of bladder emptying, high urinary flow, and the amount of residual urine are factors that contribute to the presence or absence of bacteria in the urine (O'Grady & Cattell, 1966). Catheterization may eliminate many bacteria by draining the colonized urine. However, bacteria in varying numbers may be retained in residual urine and represent the beginning inocula for the next round of bacterial growth (Cox & Hinman, 1961). Dilute urine (influenced by high urinary flow and intake of fluids) reduces the rate of multiplication and climax concentration. Increased frequency of bladder emptying minimizes the multiplication and concentration of organisms. This makes reaching a maximum concentration unlikely.

Antibiotics are most effective against a small number of bacteria in the urine (O'Grady & Cattell, 1966). As the concentration of organisms increases, the effect of antibiotics decrease. If the rate of excretion of the drug is constant, maximum drug effect is achieved when there is frequent bladder emptying and high urine flow which decreases concentration of organisms. If the antibiotic is characterized by a peak excretion rate, administration of antibiotics should be timed so that peak excretion of the drug occurs just after emptying the bladder when residual urine and therefore residual bacterial inoculum are minimal.

Bacterial Causes of UTIs in Hospitals

Once in the bladder urine, bacteria may be eliminated by the bladder defense mechanisms; or they may colonize, invade the bladder wall, multiply, and cause an infection (Sobel, 1987). Bladder infections may persist and contribute to kidney

infections or bacteremia (Garibaldi, 1993). The ability of bacteria to grow in number (Kunin, 1987; Roberts et al., 1968) and to cause infection is partially determined by the characteristics of the bacteria inoculated (Sobel, 1991) and the adequacy of host defenses.

It is generally accepted that the types of bacteria predominant in hospital differ from those in the community (Murray, 1992; Stamm et al., 1993). In addition, many bacterial strains in hospital are increasingly resistant to antibiotics (Boyce & Edwards, 1960; Gruneberg & Wilson, 1994; Murray; Stamm et al., 1993), making infections with these organisms difficult and expensive to treat (Murray, 1991). The common infectious organisms in intensive care areas are bacteria (Gruneberg & Wilson; Massanari, 1989) such as *Escherichia coli*, *Pseudomonas* species, *Staphylococcus epidermidis*, *Staphylococcus aureus* and *Enterococcus* species.

Under normal circumstances, many bacteria are commensal (symbiotic, normal) with humans and the environment. *Staphylococcus epidermidis*, as an example, is commonly found in the environment and on the skin, and usually does not cause disease in healthy individuals. Infections emerge because commensal bacteria become opportunistic pathogens, that is they take advantage of diminished host defenses and maximize their capacity to cause disease. *Staphylococcus epidermidis* demonstrates this capacity in intensive care units as it frequently causes bacteremias associated with intravascular devices (Gruneberg & Wilson, 1994). Gram negative bacteria such as *Escherichia, Enterobacter, Klebsiella, Proteus*, and *Serratia* species as well as *Pseudomonas* species (Bryan & Reynolds, 1984; Stamm

et al., 1977; Turck & Stamm, 1981) are commonly found (commensal) in the intestine but not in the urinary tract. These bacteria are frequently reported as causes of hospital UTIs.

Patients with spinal cord injury are susceptible to *Pseudomonas* species colonization especially if wearing external urinary catheters (Montgomerie & Morrow, 1978). Fawcett, Chawla, Quoraishi, and Stickler (1986) suggest that patients with spinal cord injury who have indwelling catheters or who are being intermittently catheterized begin to colonize with gram negative bacteria such as *Klebsiella pneumonia* and *Pseudomonas* species within two to three days of admission to hospital.

Widmer (1994) suggests that trends in the type of pathogens, and their antibiotic susceptibility patterns, change with each decade that passes. In the 1960s and 1970s gram negative bacteria, such as *E. coli* and coliforms were predominantly responsible for UTIs, while worldwide in the 1990s gram positive bacteria including enterococci are becoming more prevalent.

Escherichia coli

E. coli is a member of the bacteria family Enterobacteriaceae. It is a commensal intestinal inhabitant, and usually lives in humans in peaceful harmony. *E. coli* is not commensal to the urinary tract and is the most common cause of UTIs in hospitalized patients (Murray, Baron, Pfaller, Tenover & Yolken, 1995). It has the most rapid growth rate of any known bacteria (Roberts et al., 1968).

Coliforms

Coliforms are generally considered to be gram negative enteric (commensal to the intestinal tract) rods (bacilli). Coliforms include the Enterobacteriaceae family members of *E. coli* and species of *Klebsiella, Enterobacter*, and *Citrobacter* which ferment lactose (Miller & Keane, 1987), and other family fermentative members such as *Serratia* and *Providencia* species. Coliforms are a common cause of UTIs in hospitalized patients.

Enterococci

Enterococci constitute a subgroup of gram positive *Streptococcus* Group D species. This subgroup includes *Enterococcus faecalis* and *Enterococcus faecium* (previously known as *Streptococcus faecalis* and *Streptococcus faecium*). Of the two, *Enterococcus faecalis* is more commonly involved in UTIs and the incidence is increasing steadily (Widmer, 1994). Both species are developing significant resistance to antibiotics (Murray, 1992; Murray et al., 1995). Enterococci commonly cause UTIs in hospitalized patients.

Intermittent Catheterization

Intermittent catheterization is highly effective for emptying the bladder while minimizing the risk of urinary tract infection (Kunin, 1987). The general indications for use are short term urological management of patients with acute urinary retention or with patients being monitored in intensive care units, long term urological

management of the patient with spinal cord injury, and management of children and adults with neurogenic bladders. Intermittent catheterization mimics normal emptying of the bladder, eliminates the indwelling catheter as a persistent foreign body, prevents incontinence due to overflow, improves self esteem of the patient, and enhances the effectiveness of antimicrobial therapy.

Guttmann and Frankel (1966) pioneered the use of intermittent catheterization in the urological management of patients with spinal cord injury. The authors demonstrated that it was possible to maintain the urine in a sterile state by using meticulous sterile technique. Lapides et al. (1972) modified the procedure using clean technique believing that the key to preventing UTIs is maintaining good blood supply to the bladder thereby protecting the integrity of the bladder wall. Kunin (1987) stresses that the method (sterile or clean) of preventing infection while on intermittent catheterization is secondary to emptying the bladder as completely as possible at each catheterization.

Maynard and Diokno (1984) specify that the frequency of catheterization is dependent on urine volumes. Optimally, catheterizations should be performed as needed to keep the volume of urine in the bladder below 400 ml. This is the average volume at which the desire to void usually occurs (Dittmar, 1989).

Whether to use sterile or clean intermittent catheterization technique in hospitalized patients with short term catheterization needs or in home care patients with long term catheterization needs remains controversial. Nurses have yet to standardize practice in the performance of this common procedure (Rainville, 1994).

In many community applications, intermittent catheterization is accepted as a clean rather than sterile procedure (Moore, Kelm, Sinclair, & Cadrain, 1993). In hospital settings, debate between advocates of sterile and clean technique continues.

Even though the bladder is emptied with less risk using a straight rather than an indwelling catheter, urethral catheterization itself remains an invasive procedure. The patient is at risk for developing bacteriuria and possibly a UTI (Bakke & Vollset, 1993).

Summary

Relationships are known to exist between the human host, infectious agent, and the environment. In the human host, the urethra connects the bladder to the perineum. A high pressure zone exists within the urethra at a point where the urethra passes through the urogenital diaphragm. This zone creates a natural barrier to ascent of organisms colonized in the distal urethra. The bladder stores urine and has natural defenses against invading organisms.

The interaction of host defenses with bacteria (infectious agent) determines whether or not the bacteria persist. A small number of bacteria and some types of bacteria are controlled more effectively by natural bladder defense mechanisms and frequent bladder emptying than a large number of bacteria. *E. coli*, coliforms and enterococci are considered common bacterial causes of UTIs. Intermittent catheterization is an effective way of relieving the bladder of urine but as an invasive procedure it remains a risk factor in the development of a UTI.

CHAPTER 3

METHODS

The purpose of this chapter is to describe the study methods. The study design is described, followed by a description of the setting, subject selection, supplies, procedures and data collection, and ethical considerations specific to this study. The chapter concludes with a description of the data analysis.

Design of the Study

The study design was experimental as shown in Table 2. Group 1 was the experimental group and Group 2 was the control group. All urine specimens, except those for the control group at Time 1, were obtained using the O'Neil system to standardize urine collection procedures until the time of intervention. The intervention consisted of the use of the O'Neil system for the collection of urine specimens from the experimental group (Group 1) and the use of the Open system for the collection of urine specimens from the control group (Group 2).

Table 2

Two Groups of Subjects

	Discard Urine	Time 0 Baseline	Time 1 Intervention	Time 2 Follow-up
Group 1 - Experimental	O'Neil*	O'Neil	O'Neil Meatal Swab	O'Neil
Group 2 - Control	O'Neil	O'Neil	Open** Meatal Swab	O'Neil

Note. * - O'Neil system; ** - Open system

Cultures from urine and swab specimens were analyzed for organisms known to commonly cause UTI, such as *E. coli*, coliforms, and enterococci. Limiting the organisms reported from cultures partially controlled laboratory costs.

Urine was obtained from each subject immediately prior to beginning the study. This urine was obtained by intermittent catheterization with the O'Neil system within 10 hours of Foley catheter removal. Because urine may become colonized with bacteria as a result of the presence of an indwelling catheter, this urine was discarded in an attempt to clear bacteria that remained in the bladder once the Foley catheter was removed. The next three urine specimens (Times 0, 1, and 2) and the urethral meatal swab taken at Time 1 were cultured. Time 0 results were considered baseline data, Time 1 results the intervention data and Time 2 results the follow-up data. The specimens were collected between three and six hours apart to minimize the concentration of organisms subject to logarithmic multiplication between collections (S. Henwick, May, 1994, personal communication). Residual urines (urine collected via catheter immediately following partial bladder emptying) were acceptable as specimens at Times 0, 1, or 2.

Setting

The study was conducted in two large urban acute care teaching hospitals in Western Canada. An intensive care unit and a nursing unit at Site A, and a nursing unit at Site B provided the population for study. Both male and female patients were admitted to these nursing units and had central nervous system trauma or disease

(such as closed head injury, traumatic brain/head injury, spinal cord injury, aneurysms, brain tumours or hemorrhages), or back injuries which gave rise to neurological concerns. Patients were either admitted to the intensive care unit and transferred to the general care area, or directly to the care area without first going to the intensive care unit.

Most patients in these care areas had a Foley catheter inserted into their bladder because their ability to void was impaired. Usually, once the patient's physical condition was stabilized, the Foley catheter was removed. If there was a delay in regaining spontaneous voiding, intermittent catheterization was performed as necessary. It was acceptable practice to use either the Open or O'Neil systems at Site A while only the Open system was used at Site B.

Variations in the catheterization schedule occurred between the intensive care unit and the general care areas. In the intensive care unit, most nurses catheterized every four hours if the urine volume was greater than 400 ml and every six hours if the volume was less than 400 ml. The staff on the nursing unit of Site A planned for catheterization every four to six hours; but periodically the time extended to every eight or ten hours depending on staffing. The staff at Site B converted, during the patient's hospital stay, from catheterizing every 4 to 6 hours over 24 hours to four times a day (0800, 1400, 1800, and 2200 hours) or as needed once the patient's fluid intake and output were balanced. This schedule was implemented as part of a bladder training program for patients with spinal cord injury who had neurogenic bladders.

Nursing staff in the intensive care area were registered nurses (RNs) who work only in the intensive care unit. On the nursing units there were RNs, licensed practical nurses (LPNs), and nursing attendants who worked only in these areas. All regular staff (RNs and LPNs) performed intermittent catheterizations in their respective care areas.

Subject Selection

A patient was eligible for inclusion as a subject if over 18 years of age, and at least 48 hours post therapy if antibiotics had been administered. A potential subject was excluded if less than 18 years old, had a known UTI, had known pathology of the urinary tract including obstruction, renal disease, calculi, or was on antibiotics. A subject would be withdrawn from the study if transferred from the study care area, discharged from the hospital, chose to withdraw, started on antibiotics, began to void spontaneously, or died.

All patients admitted to three care areas, who were considered as potentially eligible, were screened by the investigator through a review of the patient charts and/or cardex. The investigator consulted with nursing staff about those patients who fit the eligibility criteria regarding an anticipated need for intermittent catheterization following Foley catheter removal. A note was placed on the front of the chart in the intensive care unit, or given to the unit clerks on either of the two nursing units, requesting that the investigator be notified when a physician's order was received to discontinue the Foley catheter. Consent was then obtained from the patient willing to

participate in the study and competent to give consent, or the family and two physicians if the patient was unconscious, or incompetent, and unable to provide an informed consent. At this point the patient was considered a subject for the study.

The first subject at each site was randomly assigned to Group 1 or Group 2. A nurse who was unaware of the system of categorization of the groups pointed with a sharp object while blindfolded and chose a number on a random number table. The first subject was then assigned to the group indicated by the random choice (even number - O'Neil system; odd number - Open system). Thereafter, the next eligible and consenting subject was assigned the alternative system by the investigator. However, in order to balance the male-female ratio, if a male subject was assigned to Group 1, so was the next female subject. Since data were collected at two sites for three of the nine months of data collection time, two subject assignment lists were maintained. Consecutive numbers beginning with the number one were used to order the list at Site A while consecutive letters beginning with the letter A were used at Site B.

Demographic Data

Demographic information collected on all subjects included gender, age, and diagnosis. Age and gender were considered important because of anatomical differences and hormonal influences in men and women. Diagnosis was also recorded. As well, the time of discard of the first urine removed from the bladder in relation to the time the Foley catheter was removed (less than or more than 10 hours

post Foley catheter) was recorded. Documentation of the system used for collection of the discard urine and whether or not the subject had used intermittent catheterization prior to the study was also done. Hospital site, nursing care area, and staff (RN or LPN) performing the procedure were also recorded.

Supplies

The supplies were prepackaged to minimize organization and collection time for the nursing staff, and to maintain consistency in supplies for each catheterization. As subjects entered the study, prepackaged supplies were labelled with the subject's name and taken to the bedside. Inside a large plastic ziplock package, four smaller ziplock plastic bags contained the required supplies for each part of the process. Each bag and each piece of supplies inside were identified with either a green (O'Neil system) or yellow (Open system) fluorescent dot corresponding to the intermittent catheterization system to be used.

Open System Supplies

An Open system package included four bags. Three bags each contained an O'Neil catheter, three povidone-iodine swabs, a sterile urine specimen container, and sterile gloves, and were used to obtain the discard urine and the urine specimens for culture at Time 0 and Time 2. The other bag contained a catheterization tray, a straight catheter, a povidone-iodine packet and swab for cleansing, a sterile urine specimen container, sterile gloves, and a sterile swab for use at Time 1.

O'Neil System Supplies

Inside the O'Neil system package, there were four bags each of which contained an O'Neil catheter, three povidone-iodine swabs, a sterile urine specimen container (in three bags only), and sterile gloves to collect urine at discard time, and specimens at Time 0, Time 1, and Time 2. The Time 1 bag also contained a sterile swab.

O'Neil Urinary Catheter

As shown in Figure 4, the introducer was made of a soft silicone product and had a tip with a self-opening cruciate (star shaped) seal. A flange separated the introducer from the collection bag and limited entry into the urethra beyond approximately 1.5 cm. The head of the introducer was preloaded with non-drying water soluble non-allergenic lubricant. It had a removable cap to protect the tip until the catheter was used. The system included a straight catheter of designated size (#14 Fr. in this study) inside the introducer with the tip contacting the water soluble lubricant. The body of the catheter extended out from the introducer. A collection bag was attached to the introducer distal to the flange enclosing the distal end of the introducer and the body of the catheter. The entire unit, beginning with the introducer, extended the sterile field within the distal urethra for approximately 1.5 cm (see Figure 5). Functionally this permitted the catheter to bypass the reservoir of organisms in the distal urethra anterior to the high pressure zone (Mayo & Hinman,

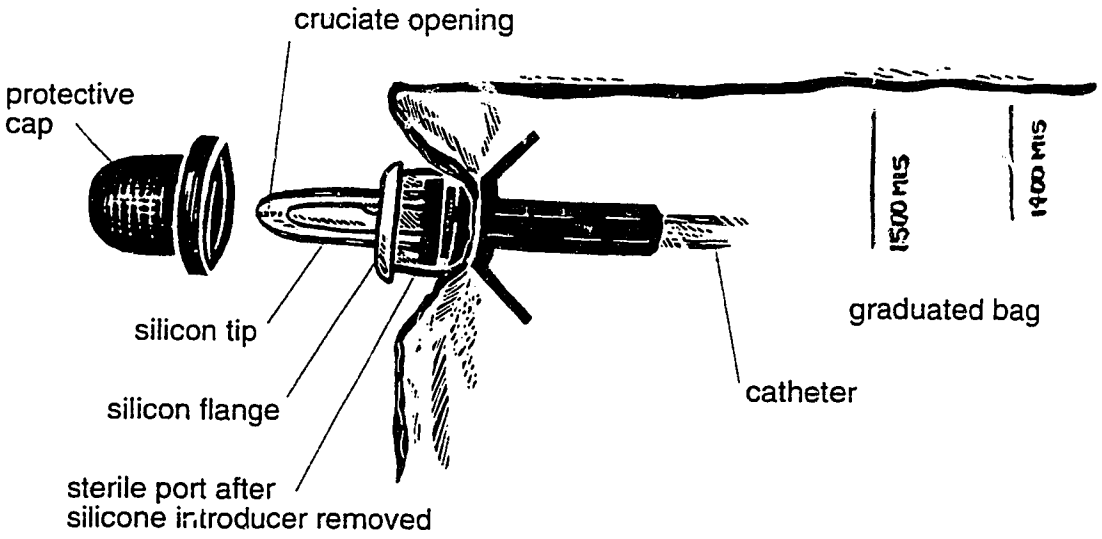

Figure 4. The O'Neil Urinary Catheter with straight catheter enclosed in a sterile silicone introducer and sterile graduated bag

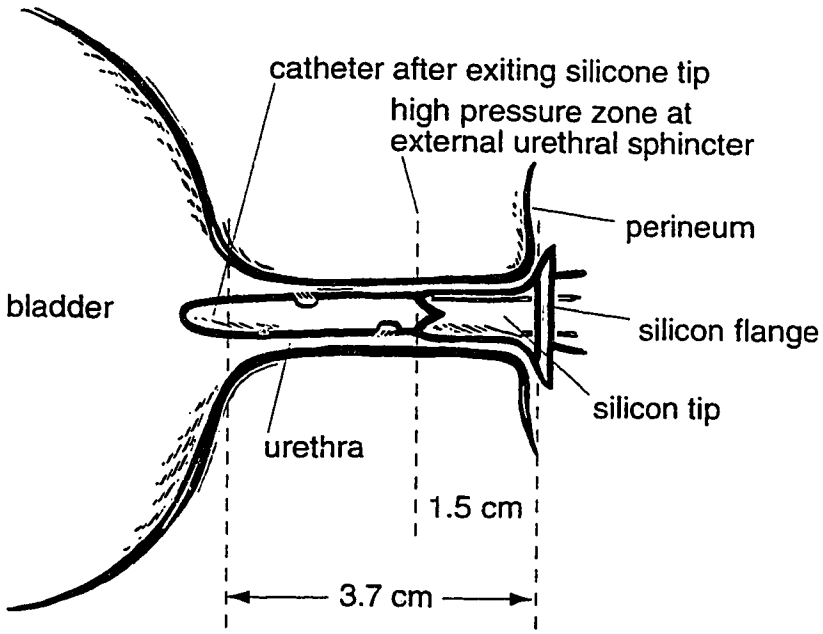

Figure 5. High pressure zone at external urethral sphincter in female urethra in relation to inserted O'Neil Urinary Catheter

1973; O'Neil, 1981; Tanagho & Miller, 1973) in both men and women. There was minimal opportunity for contamination because of the self-contained design.

Procedures and Data Collection

The investigator oriented the nursing staff to the study, assessed eligibility of patients for the study, obtained the informed consent (with staff assistance if physician proxy consent was required), and randomly assigned subjects. The investigator retrieved and transported specimens to the laboratory, and plated samples for incubation. Questions posed by the staff or subjects and family regarding the study process were answered.

The staff orientation was conducted for all regular staff to facilitate understanding of project activities and to foster staff support for the study. Information was provided about the clinical problem addressed, the purpose of the study, the research hypotheses, eligibility criteria, informed consent procedures, subject assignment, and collection and preparation of specimens for transport. As well, emphasis was placed on using correct aseptic technique with the Open or O'Neil systems. Non-regular float staff and/or casual staff received instruction from regular staff who attended training sessions.

Nurse managers in the care areas agreed to participate in the study but requested that staff related tasks be minimized. Nursing staff notified the investigator of potential subjects, assisted with obtaining physician proxy consents when required, assisted with random assignment of the first subject at each site, used prepackaged

supplies, and collected meatal swab and urine specimens according to the study protocol indicated on the chart or cardex.

Data collection occurred over a period of nine months. Site B was brought on stream six months after Site A when it became apparent that appropriate subjects at Site A were not readily available.

Urine Specimen Collection

When the subject was admitted to the study, a color coded flowsheet (see Appendix A) was attached to the subject's chart and a notation made on the cardex to alert staff to catheterization system assignment. Catheterizations were performed by nursing staff assigned to care for the subjects. Staff followed the guidelines on the study system flowsheet and documented collection times. The investigator was contacted and advised when specimens were collected.

Four catheterizations (1 for urine to be discarded and 3 for urine to be cultured) were performed on each subject. The urine specimens were collected between three and six hours apart and were obtained using the O'Neil catheters except at Time 1 for Group 2 subjects when the Open system was used.

Urethral Meatal Swab Collection

Urethral meatal swabs were collected from both Group 1 and Group 2 subjects just prior to the precatheterization cleansing procedures at Time 1 and were placed directly into clear transport mediums.

Specimen Processing

The investigator was trained by the laboratory research technician at Site A in the preparation of urine and swab cultures for incubation. The investigator retrieved all urine and swab specimens from the care areas, transported them to the laboratory within one hour of collection, and plated the samples. Standard plating procedures were used to process the specimens. The plates were incubated at 37° C for 48 hours. All processing was logged on a Laboratory Record Sheet (see Appendix B). Specimens obtained at Site B were plated and incubated by the investigator in the laboratory at Site B. Following incubation, they were transported without delay in ambient temperatures to Site A for reading.

Differential agar plates were used to plate all urine and swab specimens. For each urine specimen, samples of 10 microliters (ul) and 100 ul were obtained with an Eppendorf micropipettor. Each volume and each swab was plated on sheep blood agar and MacConkey agar. Samples were spread on plates with sterile glass spreaders.

All agar plates were read and interpreted by the same laboratory research technician at Site A. Bacterial counts in the urine were expressed as colony forming units per millilitre (cfu/ml) and identified to a genus level with some exceptions, for example, coliforms and yeast. The coded laboratory results, compiled by the laboratory research technician, were delivered to the Medical Microbiologist who retained the results until data collection was complete. Calculations were performed by the investigator.

If a UTI as indicated by clinical symptoms was suspected, the symptoms were documented in a journal by the investigator for consideration at the time of data analysis. Subjects clinically suspected of having a UTI were evaluated by the attending physicians according to standard hospital protocol.

Ethical Considerations

Ethical guidelines of the University of Alberta and those of the two institutions were followed. Subsequent to ethical approval from the Faculty of Nursing, University of Alberta (see Appendix C) and the two institutions, and prior to the commencement of the study, the investigator explained the study and its relevance to the nursing staff on the nursing units, and responded to any questions or concerns regarding the protocol.

The investigator met with each patient (or family member) and explained the nature of the project. If there was agreement to participate, a signed and witnessed consent was obtained (see Appendix D). If the patient was sedated, unconscious, or moderately or severely cognitively impaired, verbal assent was obtained from a close family member or spokesperson and documented on the consent form. In addition proxy consents were obtained from two physicians. If nursing staff obtained the consent, the investigator followed up with the patient or the family member who gave assent to ensure that the consent was understood and that all questions were answered. If there were any 'no' answers as responses to questions asked on the consent forms, the investigator provided more information and explanations to the

family member until either the family member could answer 'yes' to the question or decide not to participate in the study. It was made clear that participation was voluntary and the patient could withdraw at any time without penalty. Confidentiality and anonymity were maintained. Identity of the patients in relation to the data collected is known only to the investigator.

In no situation was the study protocol allowed to interfere with delivery of subject care. There was no harm done to subjects if they participated nor did they benefit directly. Subjects in this study were at no greater risk for infection than others outside the study who had catheters inserted into their bladders. The use of either the O'Neil system or Open system was acceptable protocol.

Data Analysis

The first hypothesis was tested for significance using Fisher's Exact Test (two-tailed). The second and third hypotheses were analyzed using a *t*-test to compare means. The tests were performed for *E. coli*, coliforms and enterococci.

Summary

The study, conducted in two large urban acute care teaching hospitals in Western Canada, was designed to compare the number and types of organisms cultured from urine specimens obtained by two intermittent catheterization systems, the closed O'Neil system and the traditional Open system. Men and women with neurological conditions who met the admission criteria were enrolled in the study and randomly assigned to Group 1 (Experimental Group) or Group 2 (Control Group). Three urine and one urethral meatal swab specimens were collected, with prepackaged supplies, from each subject. The specimens were transported to the laboratory, plated on sheep blood and MacConkey agar plates, and incubated. Fisher's Exact Test (two-tailed) and the *t*-test comparing means were used for statistical analysis.

CHAPTER 4

RESULTS

The purpose of this chapter is to present the results of the study. The characteristics of the sample are described, followed by the results of hypotheses testing. Culture results (number and types) for all urine and swab specimens for male and female subjects are presented. Time 1 results are presented first because only these were used for statistical analysis.

Sample Characteristics

There were 19 subjects on two sites (15 and 4 respectively) initially selected for the study (see Table 3). Nine were from the intensive care unit on the first site, six from one nursing unit on the same site, and four from the nursing unit on the second site. Seven male and two female subjects were assigned to Group 1 (O'Neil system) and seven male and three female subjects to Group 2 (Open system).

The subjects ranged in age from 21 to 78 years. All diagnoses were neurological in origin: Spinal Cord Injury (SCI) - 8 subjects; Closed Head Injury (CHI) - 4 subjects; Traumatic Brain Injury (TBI) - 1 subject; Intracranial Hemorrhage (ICH) - 5 subjects; and Lower Back Injury (LBI) - 1 subject. Sixteen subjects had Foley catheters in place for a period of time. Two subjects did not have Foley catheters: one had problems voiding following a low back injury and one had been on intermittent catheterization since suffering a spinal cord injury years ago.

Table 3

Characteristics of the Original 19 Subjects

Subject	System	Gender	Age	Diagnosis	Location	Hours	IC	Discard urine using O'Neil catheter
#1	O'Neil	M	52	TBI	A-ICU	< 10	N	Yes/RN
#2	O'Neil	F	21	CHI	A-ICU	< 10	N	Yes/RN
#3	Open	M	53	ICH	A-ICU	< 10	N	Yes/RN
#4	Open	F	51	ICH	A-unit	< 10	N	Yes/RN
#5	Open	M	78	ICH	A-ICU	< 10	N	Yes/RN
#6	O'Neil	M	21	CHI	A-ICU	< 10	N	**/RN
#7	Open	M	71	LBI	A-unit	N/A	Y	Yes (not O'Neil)/RN
#8	O'Neil	F	49	ICH	A-ICU	> 10	Y	Yes/**
#9	Open	F	40	SCI	A-unit	N/A	Y	**/**
#10	Open	M	64	SCI	A-unit	> 10	Y	Yes/RN
#11	O'Neil	M	62	CHI	A-ICU	< 10	N	Yes/RN
#12	Open	M	20	SCI	A-ICU	> 10	Y	Yes/**
#13	O'Neil	M	59	SCI	A-unit	> 10	N	Yes/RN
#14	Open	F	41	SCI	A-ICU	> 10	Y	Yes/RN
#15	O'Neil	M	68	ICH	A-unit	< 10	N	Yes/LPN
#A	O'Neil	M	24	SCI	B-unit	**	**	**/**
#B	Open	M	21	SCI	B-unit	< 10	N	Yes (not O'Neil)/**
#C	O'Neil	M	30	SCI	B-unit	> 10	Y	Yes/**
#D	Open	M	32	CHI	B-unit	> 10	Y	Yes/RN

Note. Location: A - first hospital site; B - second hospital site; Hours: Time between removal of Foley catheter and collection of discard urine; IC: Intermittent catheterization performed between time of Foley catheter removal and time discard urine collected (Yes or No); Discard urine: Includes category of staff performing intermittent catheterization; **: Missing data; Shaded lines: Subjects excluded from study after Time 0 (4) and after initial data analysis (4)

Information on the presence or absence of a Foley catheter was missing for one subject.

Ten subjects were not catheterized intermittently between the removal of the Foley catheter and entrance to the study but eight were catheterized while waiting for completion of antibiotic therapy. For one subject this information was missing.

Of the 16 discard urines obtained, 14 were obtained with the O'Neil system and 2 with the Open system. For 3 of 19 subjects, discard urine information was missing. The two Open system discard urines were from subjects who were being catheterized while waiting completion of antibiotic therapy and catheterization volumes were greater than 500 ml. At least 12 subjects were catheterized by RNs and 1 by an LPN.

All 19 subjects remained in the study until after the collection of urine specimens at Time 0 (baseline specimen). At this time four subjects were withdrawn for various reasons. One subject started voiding spontaneously. The second subject stated she forgot about being on the study and let her husband catheterize her twice (long time spinal cord injury who often was catheterized by her husband at home). One specimen collection for the third subject was missed by staff during the night and one specimen collection exceeded the "every three to six hour" time parameter by four hours. In retrospect, perhaps this specimen should have been collected, documented and analyzed with the collection delay in mind.

During the initial data analysis phase, four more subjects were excluded from the study because of consistently high bacterial counts present from the onset of the

study (bacteriuria or UTI) but unknown to the investigator until data collection was complete. Analysis was conducted on data pertaining to the remaining 11 subjects. Group 1 was comprised of six subjects (four male, two female) and Group 2 of five subjects (four male, one female).

Data for analysis

Data from subjects (N=11) for analysis were obtained by:

1. Culture of urine specimens taken at Times 0, 1, and 2. Quantitative counts were reported by the laboratory.
2. Culture of urethral meatal swab specimens at Time 1. Semi-quantitative results were reported.

A total of 33 urine specimens were collected for 11 subjects across Times 0, 1, and 2, and a total of 11 urethral meatal swabs were collected at Time 1. Culture results for all urine specimens and urethral meatal swabs are shown in Table 4.

Tests of Hypotheses

Testing of three hypotheses was based on 11 subjects. The statistical analyses were done on specimens containing coliforms and enterococci only at Time 1. *E. coli* was not identified on any culture.

Table 4

Culture Results of Urine Specimens and Urethral Meatal Swabs from 11 Subjects

		Urine						Meatal Swab	
		Time 0		Time 1		Time 2		Time 1	
	System	Type	Count	Type	Count	Type	Count	Type	Count
1-M	O'Neil		NG		NG	VGS NPN	>[illegible] [illegible]	CNS	++
2-F	O'Neil	Yeast CNS BHS	$1x10^1$ $1.1x10^2$ $1x10^1$		NG		NG	Yeast Lactobacilli	+++ +++
3-M	Open	Coliforms	$>1x10^3$	Coliforms	$>1x10^3$		NG	Coliforms	++
4-F	Open		NG		NG	CNS	$1x10^1$	CNS	+
7-M	Open	Enterococci	$2.6x10^2$		NG		NG	VGS Enterococci	++ +
8-F	O'Neil	CNS	$1x10^1$		NG		NG	CNS Enterococci Coliforms	++++ ++ +
11-M	O'Neil	Enterococci Diphtheroids	$1x10^1$ $1.1x10^2$		NG	Enterococci	$8.2x10^2$	Coliforms Enterococci Diphtheroids	++ ++ +
15-M	O'Neil		NG		NG		NG	CNS Diphtheroids	++ ++
B-M	Open		NG		NG		NG		NG
C-M	O'Neil		NG		NG		NG	CNS Diphtheroids	+ +
D-M	Open		NG	Pseudomonas Enterococci Yeast	$1.2x10^2$ $8x10^1$ $3x10^1$		NG	Pseudomonas Enterococci Yeast	++ ++ +

Note.
NG - No growth;
Time 0, 1, and 2 results are reported in colony forming units/millilitre (cfu/ml) per agar plate;
Meatal Swab results are semi-quantitative
+ - scant growth;
++ - few colonies;
+++ - moderate growth;
++++ - many colonies;
VGS - Viridans group *Streptococcus* species
NPN - Non-pathogenic *Neisseria* species
CNS - *Staphylococcus* species coagulase negative
BHS - Beta-hemolytic *Streptococcus* species

Testing for Hypothesis 1

There will be a significant difference in the number of bacteria found in the urine of the subjects using the O'Neil system compared with the subjects using the Open system at Time 1.

Number of Organisms. There were 11 specimens cultured. Six of the six O'Neil system specimens did not support any growth compared with two of the five Open system specimens which did support growth. The two specimens supporting growth (see Table 4) were Open system specimens: one at $> 1x10^3$ cfu/ml and one at $1.2x10^2$ cfu/ml. One half of the O'Neil system no-growth specimens (three of six) followed Time 0 specimens that supported growth at a small number of $\leq 1.1x10^2$ cfu/ml. The other three of six followed no-growths at Time 0. Only one of three of the Open system no-growth specimens followed Time 0 specimens that supported growth at a small number of $\leq 2.6x10^2$ cfu/ml. The other two of three followed no-growths at Time 0. None of the specimens collected from female subjects supported growth.

Table 5

Results of Fisher's Exact Test

	System				
	O'Neil		Open		
Organisms	No growth	Growth	No growth	Growth	*p*
Coliforms	6	0	4	1	Not significant
Enterococci	6	0	4	1	Not significant
Total organisms	6	0	3	2	Not significant

Fisher's Exact Test was used to evaluate whether or not the obtained results differed from the hypothesis (see Table 5). For the three tests conducted, the results were not significant at $p < .05$ on the number of organisms cultured from the urine specimens collected from the sample of 11 subjects at Time 1.

Testing for Hypothesis 2

There will be a significant variation in types of bacteria in the urine of subjects using the Open system compared with those using the O'Neil system at Time 1.

Types of Organisms. There were four different organisms appearing in two urine specimens culturing positive (see Table 4). Coliforms were present in one specimen, and pseudomonas, enterococci, and yeast were present in the second specimen.

The independent *t*-test for comparison of means was used to determine if the obtained results differed from expected results specified by the hypothesis. A level of statistical significance at $p < .05$ was not achieved.

Testing for Hypothesis 3

The relationship between the bacteria found at the urethral meatus and in the urine at Time 1 is stronger for the Open system than for the O'Neil system.

Types of Organisms. There were four types of organisms represented in specimens culturing positive at Time 1 for two subjects. Coliforms appeared in the

urine and at the meatus in one subject while pseudomonas, enterococci, and yeast were present in both urine and swab specimens in the second subject (see Table 4).

The independent *t*-test was used to determine if the obtained results differed from expected results (organisms in urine and at the meatus are the same) specified by the hypothesis. While the organisms at the meatus and in the urine were the same for subjects culturing positive at Time 1, a level of statistical significance at $p < .05$ was not achieved.

Urine Specimens at Time 0 and Time 2

While these specimens were not used for statistical analysis, culture results were examined and reported (see Table 4). Of the 11 specimens cultured at Time 0 (all obtained with O'Neil catheters), 5 specimens showed growth. Quantitative counts were $\leq 2.6 \times 10^2$ cfu/ml from four agar plates (yeast, *Staphylococcus* species coagulase negative, beta-hemolytic *Streptococcus* species, enterococci, diphtheroids) and $> 1 \times 10^3$ cfu/ml on one plate (coliforms).

All of the specimens at Time 2 were obtained with the O'Neil system. Two of six of the O'Neil system no-growth results at Time 1 converted to supporting growth at Time 2. One specimen supported a high number ($> 1 \times 10^3$ cfu/ml) and one a moderate number (8.2×10^2 cfu/ml). Four of six specimens remained no-growth. Only one of the five results of Open system specimens taken at Time 2 converted to support any growth. Two of five converted to no-growth at Time 2 and two of two remained no-growth.

Other Observations Regarding Types of Organisms

There was a total of nine different organisms identified in the urine specimens from Times 0, 1, and 2 of 11 subjects (see Table 4). Those that appeared more than once were enterococci (4), *Staphylococcus* species coagulase negative (3), coliforms (2), and yeast (2). Others that appeared once were viridans group *Streptococcus* species, non-pathogenic *Neisseria* species, pseudomonas, diphtheroids, and beta-hemolytic *Streptococcus* species.

Table 6

Frequency of Appearance of Organisms in Urine and in Urethral Swabs for Men and Women

	Men (n = 8)				Women (n = 3)			
	Urine at Times			Urethra	Urine at Times			Urethra
Organisms	0	1	2	Time 1	0	1	2	Time 1
VGS			1*	1*				
NPN			1					
Enterococci	2	1	1	3				1
Diphtheroids	1			3				
Coliforms	1	1		2				1
CNS				3	2		1	2
Pseudomonas		1		1				
Yeast		1		1	1			1
BHS					1			
Lactobacilli								1

Note. VGS: Viridans group *Streptococcus* species; NPN: Non-pathogenic *Neisseria* species; CNS: *Staphylococcus* species coagulase negative; BHS: beta-hemolytic *Streptococcus* species. * - not same subject.

As shown in Table 6, the urine specimens from female subjects cultured *Staphylococcus* species coagulase negative, yeast, and beta-hemolytic *Streptococcus* species. The urine specimens from male subjects cultured enterococci, coliforms, viridans group *Streptococcus* species, non-pathogenic *Neisseria* species, diphtheroids, pseudomonas, and yeast. Urethral swab cultures from men revealed multiple meatal growth more frequently than those from women. One swab from a male subject did not culture any organisms.

Table 7

Organisms Cultured from Urines and Urethra Meatal Swabs

	Same Organisms - Same Subject	Different Organisms - Same Subject	
Subject	Urine and Swab	Urine	Swab
1		VGS, NPN	CNS
2	Yeast	CNS, BHS	Lactobacilli
3	Coliforms		
4	CNS		
7	Enterococci		VGS
8	CNS		Enterococci, coliforms
11	Enterococci, diphtheroids		Coliforms
15			CNS, Diphtheroids
B			
C			CNS, Diphtheroids
D	Pseudomonas, enterococci, yeast		

Note. CNS: *Staphylococcus* species coagulase negative; VGS: Viridans group *Streptococcus* species; NPN: non-pathogenic *Neisseria* species; BHS: beta-hemolytic *Streptococcus* species

In 7 of 11 subjects (see Table 7), some of the organisms at the urethral meatus (Time 1) were the same as in the urine at Times 0, 1, or 2 of the same subjects. The organisms were enterococci (3), *Staphylococcus* species coagulase negative (2), yeast (2), coliforms (1), diphtheroids (1), and pseudomonas (1). However, in 2 of 11 subjects, some organisms cultured in urine were different from those at the urethral meatus at the time of collection.

Summary

A total of 33 urine specimens were collected for 11 subjects across Times 0, 1, and 2 and a total of 11 urethral meatal swabs were collected at Time 1. Fisher's Exact Test was used to statistically analyze results pertaining to Hypothesis 1. The independent *t*-test was used to analyze for Hypotheses 2 and 3. Testing lacked power due to the small sample size and statistical significance was not achieved for any of the hypotheses.

At Time 1 when the two catheterizations were compared, none of the six O'Neil system specimens supported growth while two of five Open system specimens indicated growth. Four different organisms grew on plates from two urine specimens. All swab specimens except one yielded growth. In 7 of 11 subjects, the same organisms were identified from urine and swab cultures.

CHAPTER 5

DISCUSSION

The overall findings of the study are discussed in this chapter. The purpose of the study was to compare two intermittent catheterization systems to determine if one system introduced a fewer number and fewer types of organisms into the bladder than the other system.

Major Findings

Number of Organisms

It was expected that urine specimens from subjects in Group 1 at Time 1 would yield fewer organisms than those from subjects in Group 2. While not statistically significant, the observed results from a small number (n = 11) of urine samples at Time 1 supports the expected result. Of the six Group 1 specimens, none supported growth compared with two of five Group 2 specimens that supported growth. Upon examination of the total number of urine specimens at Times 0, 1, and 2 (O'Neil, n = 28; Open, n = 5), the percentage of O'Neil specimens culturing positive was 29% (8/28) compared with 40% for the Open specimens (2/5). This observation that use of the O'Neil system yields fewer positive cultures than the Open system in a small number of specimens, has clinical significance.

Expected Pattern. One of the two urine specimens with growth at Time 1 (Subject D) fit the expected pattern of activity for the Open system intervention. The expected pattern is that the Time 0 and 2 urine cultures do not support growth

(following intermittent catheterization with the O'Neil system). but the Time 1 urine culture supports growth with the Open system. Not only did this positive growth specimen (Group 2) follow a "no growth" result at Time 0 but it was followed by another "no growth" culture result at Time 2. An alternate explanation is that the culture may represent contamination of the specimen at the time of collection after it was obtained from the subject. Documentation by the investigator at the time of collection indicated a possibility that environmental contamination occurred.

Types of Organisms

It was expected that the types of organisms in bladder urine would be more similar to those at the urinary meatus for subjects using the Open system compared with the O'Neil system. At Time 1, although not statistically significant, two of two specimens culturing positive revealed the same (although not serologically verified) bacteria in the urine and at the urethral meatus. The urine specimen of subject D (Open system) cultured pseudomonas, enterococci, and yeast which were present at the urethral meatus at the time of catheterization. The other urine specimen (Open system) cultured the same bacteria (coliforms) as did the swab of the urethral meatus. These two specimen results (the only two supporting growth at Time 1) support the clinical expectation that organisms in the urine would also likely appear at the urinary meatus in subjects catheterized with the Open system.

Most Prevalent Organisms in Urine Specimens. It was expected that the most common types of bacteria found in the urine and at the urethral meatus would be *E.*

Coli, coliforms, and enterococci based on literature concerning past trends (Widmer, 1994). All of these bacteria may infect men and women. In this study the most commonly occurring bacteria in urine were enterococci in three male subjects (see Table 6). Coliforms appeared in one male subject. *E. coli* did not appear in any of the cultures. In this study, data on these three organisms were collected for statistical analysis. The presence of other organisms, identified by the laboratory, was examined and reported (e.g. *Staphylococcus* species coagulase negative, yeast).

The appearance of enterococci as the most common bacteria in this study is in keeping with a current trend identified in the literature (Gruneberg & Wilson, 1994; Morrison & Wenzel, 1986; Murray, 1990, 1992; Spera & Farber, 1992; Widmer, 1994). A heavy reliance on antibiotic therapy in the recent past may have created a selective pressure on this bacteria primarily in hospital settings. Many bacteria have some intrinsic ability to resist antibiotic effect and they can acquire resistance through a variety of genetic mechanisms. Enterococci, particularly *Enterococcus faecalis* and *Enterococcus faecium*, have managed to overcome virtually every therapy of established value (Murray, 1992) and are implicated frequently in intensive care unit infections related to invasive monitoring (Gruneberg & Wilson). Because resistant organisms are difficult to treat they become more prevalent.

Coliforms are still of a prime concern in hospitals because of the increasing capacity of gram negative bacteria to develop antibiotic resistance. *E. coli*, *Klebsiella pneumonia* are not readily resistant but may become resistant (induced to produce

hydrolysing enzymes) under certain conditions (e.g. exposure to beta-lactamase antibiotics). *Enterobacter, Serratia*, and *Citrobacter* species are intrinsically resistant (Murray, 1992). In addition *Pseudomonas* species, also gram negative, are intrinsically resistant to a majority of antimicrobials.

Other Observations

Other organisms were present in the urine cultures as well. *Staphylococcus* species coagulase negative, known to be prevalent on the skin of healthy humans (usually *Staphylococcus epidermidis*), was cultured three times in female subjects. Unusual organisms cultured were viridans group *Streptococcus* species, non-pathogenic *Neisseria* species, and beta-hemolytic *Streptococcus* species. None of these bacteria were present in the corresponding meatal swabs. The source of viridans group *Streptococcus* species or non-pathogenic *Neisseria* species cultured in one male may be the prostate or reproductive glands. The source of beta-hemolytic *Streptococcus* species in a female subject may be the periurethral glands thought by some to be analogous to the male prostate (Moore & Hira, 1965).

Presence of Investigator

The investigator was present at all urine and swab collections at Site B and assisted or guided the nurses as they performed the catheterization procedures. The presence of the investigator during catheterizations probably enhanced the maintenance of aseptic technique, thereby influencing the consistently culture negative results (89%) at Site B. Comparatively, at Site A where the researcher was

seldom present when specimens were collected, only 15 of 24 specimens (62%) were culture negative. The concern is whether or not correct aseptic and catheterization techniques were used consistently during the procedures at Site A where specimens cultured positive, particularly at Time 0. These results support the efforts to standardize procedures which promotes more consistent performance in carrying out procedures.

Bladder Washout and Bladder Wall Effect

Of the 11 specimens taken at Time 0, all with the O'Neil system, six were culture negative and five were culture positive. All subjects were catheterized intermittently prior to collection of baseline data in attempts to clear the bladder of bacteria remaining following removal of Foley catheters. None of this urine was cultured. The positive cultures at Time 0, with the exception of one ($\leq 2.6 \times 10^2$ cfu/ml) had small counts ($< 1 \times 10^1$ cfu/ml). Further, four of the five culture positive specimens at Time 0 were culture negative at Time 1. It is probable that intermittently catheterizing up to and including baseline specimen collection (Time 0) following Foley catheter removal almost completely cleared the bladder of residual organisms. This clearance may represent the washout effect for each subject. The washout effect minimizes the residual inoculum of bacteria at each catheterization by removing as much contaminated urine as possible on a regular basis (less than six hours apart). Contact with the bladder wall for any remaining small residual

inoculum during the period between Time 0 and Time 1 may have facilitated bacterial destruction before Time 1 testing.

Time 2 Urine Specimens

Two out of six O'Neil system specimens and one out of five Open system specimens at Time 2 supported growth. These results were unexpected. The O'Neil system was used to collect all specimens at Time 2. It was expected that the specimens that were negative at Time 1 would remain negative and the specimens culturing positive with low bacterial counts at Time 1 would also be negative. There are three possible explanations for the results.

The first explanation concerns the culture positive specimen from one case only. Bacteria cultured in the urine were not present at the urethral meatus, which may indicate an alternate source of bacteria such as the prostate or reproductive glands. If these glands were harbouring bacteria, contamination of the proximal urethra would occur prior to catheterization. This may explain the presence of bacteria in the urethra that are different from the urethral meatus. It is unlikely that the source of organisms was the distal urethra since the O'Neil catheter is thought to provide sterile passage through this area. For such a case in which the source of organisms may be the prostate, either the Open or O'Neil catheter system could contaminate the urine yielding the same positive culture result. Secondly, the staff collecting the specimen may not have been instructed as to how to retrieve a sterile specimen from the collection bag. If the correct way is not known, the only option is

to tear the plastic bag along a perforated line and pour from the opening. If the opening is harbouring any bacteria transmitted from the hands of the worker while tearing the bag, these environmental bacteria could contaminate the specimen during the action of pouring urine into a specimen bottle. Lastly, each specimen may represent bacterial content of the bladder urine at the time of catheterization following introduction of bacteria sometime earlier.

Progression from Meatus to Bladder Urine

In some subjects, organisms appear at the meatus but not in urine (see Table 7). This observation supports the notion that mere presence of organisms in periurethral areas is not itself a risk factor (Schlager et al., 1993). However, presence of pathogens in combination with cellular defect may be a risk factor. Fowler and Stamey (1977) suggest that in women under normal circumstances, coliforms must compete with commensal flora which adhere avidly to vaginal cells. A defect in vaginal cell structure may permit pathogens to adhere more easily and commensal flora less easily. Perhaps a cellular deficit in uroepithelial cells, rather than mere presence of organisms, more critically determines whether or not pathogens present at the urinary meatus will progress from the meatus to bladder urine thereby increasing the risk of UTI.

Limitations

There are three major limitations to this study; study design, sample size, and staff participation.

Study Design

The closed O'Neil system was used both as a strategy to provide internal control (by reducing the number of organisms in bladder urine of both control and experimental participants prior to the time when the intermittent catheterization systems were compared) and as a system to be experimentally tested at Time 1. This action may have contributed to minimizing the difference between the Open and O'Neil system results.

Variables impacted the study. Subject variables such as restlessness during the Open system catheterization procedure were difficult to control and may have contributed to environmental contamination of specimens on collection. In addition, variables such as infections in physiological systems other than the urinary system that required antibiotic treatment, interfered with the eligibility of participants which ultimately affected the total number of subjects obtained. Variables such as age, gender and neurogenic or non-neurogenic bladder status were not matched. Matching may have provided more insight into how these variables related to host defenses. Other variables may also limit the study results. As an example, the povidone-iodine preparation, used in cleansing procedures for both systems, may have been bactericidal to flora in the distal urethra, or to bacteria carried by the catheter toward

the bladder. If fewer bacteria reach the bladder, this result could be attributed to the povidone-iodine and not the catheterization system.

Identification of bacteria on culture was restricted. Only those considered most common (*E. coli*, coliforms, enterococci) were identified fully in order to control laboratory costs. Data recorded for organisms not identified fully could not be used for statistical analysis or for comprehensive clinical reporting. Consequently it was not possible to create a comprehensive profile of organisms present.

While the investigator performed all functions relating to specimen preparation in the laboratory to maintain consistency in procedures, she was not able to be present at all catheterizations to provide guidance to staff in order to ensure consistency in performance of the catheterization procedure. Inconsistent collection technique may decrease the quality of specimens obtained and subsequently cultured. The investigator was not employed at either site so performing any study function meant a special trip to the study site at various times of day. Processing specimens during the night, for example, was particularly disruptive to sleep patterns. Any special trip was time consuming (averaged 30 minutes one way from home or 15 minutes from place of employment) and costly (automobile gasoline and parking).

Sample Size

The sample was too small to detect a statistically significant difference between the number or types of bacteria in the urine of subjects using the O'Neil or Open systems. It was intended that at least 40 subjects, 20 in each group with male

and female subjects equally represented, be enrolled in the study but for various reasons, only 11 subjects were eventually studied. There were more male than female subjects in the study which may minimize the apparent impact of intermittent catheterization on the bladder urine of women. Attrition of subjects, because of return of spontaneous voiding or staffing workloads in relation to missed specimens, contributed to the small sample size. The decision to withdraw subjects, with apparent bacteriurias at the beginning of the study, after data collection was complete further lowered the sample size.

Of those patients who were anticipated to need intermittent catheterization, many were excluded before getting to the consent stage. Three uncontrolled diabetic patients were not included because of the three fold increased risk of UTI (Stamm et al., 1977). However, in retrospect they should have been included because they met the eligibility criteria. Two other potential subjects did not wish to participate, and at least 32 potential subjects were transferred over the nine month period from the intensive care unit to non-study care areas before subject selection was complete.

Staff Participation

Staff unfamiliar with the O'Neil system (e.g. float staff) may have been asked by other staff to perform catheterizations with very little instruction. Of particular concern here is the lack of knowledge about how to obtain a sterile specimen from the system. Consistency in specimen collection technique may have been

compromised because many different people collected specimens during the catheterizations.

Breaks in aseptic technique during catheterization procedures may have occurred threatening the quality of specimens collected. For example, opening the povidone-iodine swab packages for use in cleansing procedures with the O'Neil system proved to be awkward and messy so the swabs may not have been used properly or in a consistent manner during precatheterization cleansing. Another example is contaminating the specimen during collection by pouring from an unsterile port.

Conclusions

Two conclusions are drawn relating to the number and types of organisms.

Number of Organisms

While not statistically significant, observations made on a small subject sample during this study suggest that bladder urine remains free of organisms following intermittent catheterization with the closed O'Neil system more often than following intermittent catheterization with the traditional Open system. Organisms were absent in urine after use of the O'Neil system at Time 1 while organisms were present in two urine specimens after use of the Open system. Control is exercised over the number of bacteria introduced to the bladder urine at any one time if a protected-catheter system is used. Emptying the bladder at regular three to four hour

intervals (especially during the day) through intermittent catheterization, leaving minimal residual urine contributes to this control.

Types of Organisms

While not statistically significant, observations made from meatal cultures from a small sample support the notion that bacteria present at the meatus may be the same as those found in bladder urine following intermittent catheterization with the Open system. Organisms at the meatus may be representative of those in the distal urethra. None of the O'Neil system urine specimens supported growth which supports the view that if using a closed system, the presence of any organisms in the distal urethra or at the meatus is of minimal consequence.

Recommendation

It is recommended that a closed or self-contained intermittent catheterization system such as the closed O'Neil system be used as the standard for intermittent catheterization in acute care hospitals (exceptions to be made based on individual needs of the patients). The results of this study suggest that, clinically, the risk of causing a UTI related to intermittent catheterization using the O'Neil system is no worse than, and may be much less than using the Open system. The O'Neil system is also cost effective. At the time of the study the direct cost to use the O'Neil system was $0.90 less than to use the Open system (Open - $3.52; O'Neil - $2.62).

Implications for Practice

The practice of Nursing is a changing practice accommodating insights gained from both planned inquiry and serendipitous events. The anticipated results of this study support the view that use of the O'Neil system yields fewer positive cultures than the Open traditional system thereby reducing the risk of UTI. It is conceivable that, if the O'Neil system is the standard system used for intermittent catheterization and correct technique is consistently performed by users, the risk and ultimately the rate of UTIs in hospitalized patients may be reduced even further benefiting the patient, the health care system, and third party payers. Minimizing the risk of infection also reduces the risk of escalating the emergence of antibiotic resistant organisms.

The unanticipated insights gained stem from the literature search and observations not directly related to the research questions. For example, it was observed that specimens collected in the presence of the investigator cultured fewer organisms. This observation supports the view that the immediate presence of resource people that can readily provide staff with information and reinforce correct technique has a direct impact on the outcome of patient care. An observation possibly relating the low bacterial counts at Time 0 to the bladder wall and bladder washout effect brings forward once again the importance of three notions. The first is the scheduling of intermittent catheterizations based on physiological need rather than convenience in care planning. The second is the importance of minimizing the number of organisms in the bladder urine by deliberately balancing a planned intake

of fluids (high urinary flow) with a toileting or intermittent catheterization schedule that reduces bacterial concentrations at any one time. The third is to regularly empty the bladder, avoiding distention which interferes with blood supply to the bladder wall, threatening its integrity.

The notion that cell structure defect in the presence of pathogens may permit and facilitate adherence of pathogens to vaginal cells and perhaps also uroepithelial cells, reinforces to nurses that while mere presence of organisms at the meatus is not in itself a high risk factor, reducing the number of pathogens present at any one time remains desirable. Thorough handwashing, sound hygienic practice in patient and personal care, and protection of the immediate environment are fundamental in minimizing exposure of compromised patients to threatening organisms in the external environment.

Through documentation by the investigator of an incident at a collection time of an Open system specimen, it was indicated that environmental contamination may have occurred. The observation of this incident supports the view that catheterization supplies exposed or open to the external environment (external space surrounding subject including bedclothes and hands of the nurse) are susceptible to inadvertent environmental contamination. Specimens obtained with these supplies may yield false positive culture results. In such a case, the threat of contamination is not direct but indirect for the patient. A false positive culture result may lead to unnecessary antibiotic treatment. This treatment contributes to the escalating presence of antibiotic resistant organisms.

Further Research

Three issues arising from observations during the study should be considered for further investigation.

Environmental Contamination

Specimen contamination during collection should be averted. Sterile supplies exposed to the open external environment are more susceptible to contamination. If coupled with unintentional delays in sending urine specimens (urine in a container) to the laboratory for processing, contamination may result in false positive bacterial growth. False positive growth may contribute to unnecessary administration of antibiotics which contributes to the growing problem of antibiotic resistance. A similar nursing study but with a larger sample may provide evidence that self enclosed sterile catheters which tend to be more user friendly, particularly for short term application in acute care settings, may afford protection against false positive growth in urine specimens. Avoiding false positive growths would benefit the patient (fewer antibiotics administered), the laboratory (improved quality of specimens collected and decreased laboratory costs), and the health care system (e.g. shorter length of patient stay).

Balance between Bladder and Urine Activity

Balance among fluid intake and output, dynamics of urinary flow, integrity and antibacterial activity of the bladder wall, and chemical composition of the urine is important to nursing practice. The benefits of avoiding distension and minimizing the size of a residual inoculum warrants further examination in relation to planning nursing interventions. A nursing study should be conducted comparing conventional practices (balancing fluid intake and output with urinary elimination) with a planned modified practice to maintain high urinary flow, systematic urinary washout, and minimal residual volumes or residual inoculum in relation to the risk of UTI. A study like this would enhance the development of nursing strategies (including intermittent catheterization) designed to protect against urinary tract infection and to support optimal biophysical urinary tract function.

Minimizing UTIs with Pathogens that are Difficult to Treat

Another study, similar to the present one which examines the infecting agent aspect of the infection equation, may reveal that recurrent UTIs caused by pathogens known to colonize in patients with previous infections (e.g. *Proteus* species, *Pseudomonas* species) and known to be difficult to treat could be averted or minimized through the use of shielded catheters. This study may contribute to standardizing nursing practice in the use of sterile catheterization procedures when in hospital or institutional environments. Morbidity and perhaps mortality would

decrease in specific populations, for example, people suffering from spinal cord injury.

Summary

The O'Neil system is likely more effective at restricting bacterial inoculations into the urine to a small number, or preventing any inoculation, than the Open system. This information enriches the theoretical and practical nursing knowledge base that contributes to the positive clinical client outcome of preventing or reducing risk of UTI in short term management of urinary retention in acutely ill patients.

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NURSING RESEARCH PROJECT - COMPARISON OF TWO INTERMITTENT CATHETERIZATION SYSTEMS
RESEARCHER: MARILYN ALBERS, PAGER 445-5952
RESEARCH ASSISTANT: MARCY ALBERS, PAGER 445-3736

FLOW SHEET FOR OPEN (TRADITIONAL) SYSTEM

NOTE: (1) Page Marilyn (445-5952) or Marcy (445-3736) just prior to collecting specimens. One of them will come in to process the specimen in the lab.
(2) Prepackaged study supplies found at bedside or in Clean Utility Room.

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
Foley out	First I/O cath following foley removal - Use O'Neil cath and discard urine (clears bacteria post foley)	TIME 0 Next I/O cath (3-6 hrs post last I/O cath and may be residual urine) - Use O'Neil cath and save sterile urine specimen - Label specimen with . subject name . Time 0 (baseline) . time taken . indicate if residual urine - Put urine specimen in biohazard bag for transport to lab by researcher	TIME 1 Next (consecutive) I/O cath (3-6 hrs post last I/O cath and may be residual urine) 1. Collect swab specimen prior to precath cleansing (twirl swab directly over meatal opening) 2. Cleanse 3. Use cath tray and straight cath; save sterile urine specimen - Label with . subject name . Time 1 . time taken . indicate if residual urine - Put urine and swab specimens in biohazard bag for transport to lab by researcher	TIME 2 Next (consecutive) I/O cath (3-6 hrs post last I/O cath and may be residual urine) - Use O'Neil cath and save sterile urine specimen - Label with . subject name . Time 2 . exact time taken . indicate on label if residual urine - Put urine specimen in biohazard bag for transport by researcher
Date _____, Time _____, & Initial _____	Date _____, Time _____, & Initial _____	Date _____, Time _____, & Initial _____	Date _____, Time _____, & Initial _____	Date _____, Time _____, & Initial _____

/jpio
Albers.001/L
26 Jun 95

NURSING RESEARCH PROJECT - COMPARISON OF TWO INTERMITTENT CATHETERIZATION SYSTEMS
RESEARCHER: MARILYN ALBERS, PAGER 445-5952
RESEARCH ASSISTANT: MARCY ALBERS, PAGER 445-3736

FLOW SHEET FOR CLOSED (O'NEIL) SYSTEM

NOTE: (1) Page Marilyn (445-5952) or Marcy (445-3736) just prior to collecting specimens. One of them will come in to process the specimen in the lab.
(2) Prepackaged study supplies found at bedside or in Clean Utility Room.

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
Foley out	First I/O cath following foley removal - Use O'Neil cath and discard urine (clears bacteria post foley)	TIME 0 Next I/O cath (3-6 hrs post last I/O cath and may be residual urine) - Use O'Neil cath and save sterile urine specimen - Label specimen with . subject name . Time 0 (baseline) . time taken . indicate if residual urine - Put urine specimen in . biohazard bag for transport to lab by researcher	TIME 1 Next (consecutive) I/O cath (3-6 hrs post last I/O cath and may be residual urine) 1. Collect swab specimen prior to precath cleansing (twirl swab directly over meatal opening) 2. Cleanse 3. Use O'Neil cath and save sterile urine specimen - Label with . subject name . Time 1 . time taken . indicate if residual urine - Put urine and swab specimens in biohazard bag for transport to lab by researcher	TIME 2 Next (consecutive) I/O cath (3-6 hrs post last I/O cath and may be residual urine) - Use O'Neil cath and save sterile urine specimen - Label with . subject name . Time 2 . exact time taken . indicate on label if residual urine - Put urine specimen in biohazard bag for transport by researcher
Date _____, Time _____, & Initial _____	Date _____, Time _____, & Initial _____	Date _____, Time _____, & Initial _____	Date _____, Time _____, & Initial _____	Date _____, Time _____, & Initial _____

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26 Jun 95

NURSING RESEARCH PROJECT - COMPARISON OF TWO INTERMITTENT CATHETERIZATION SYSTEMS
RESEARCHER: MARILYN ALBERS, BEEPER 445-5952

LABORATORY RESULTS

SUBJECT NUMBER _____

SPECIMEN	COLLECTION			READING DATE	RESULTS Record quantitative counts		
		DATE	TIME		10 UL	100 UL	ORGANISM(S)
Urine	0						
Urine	1						
Urine	2						

SPECIMEN	COLLECTION			READING DATE	RESULTS	
		DATE	TIME		COUNT	ORGANISM(S)
Swab	1					

/jpio
Albers.001\L
12 Dec 94

Appendix C

ETHICS APPROVAL

University of Alberta
Edmonton

Faculty of Nursing

Canada T6G 2G3

3rd Floor Clinical Sciences Building

Certification of Ethical Acceptability for Research Involving Human Subjects

---

NAME OF APPLICANT(S): Marilyn Albers, MN Candidate

TITLE OF PROJECT: "A Comparison of Two Intermittent Catheterization Systems: Closed O'Neil System and the Traditional Open System"

The members of the review committee, having examined the application for the above-named project, consider the procedures, as outlined by the applicant, to be acceptable on ethical grounds for research involving human subjects.

Sept. 6, 1994
Date

Greta Olinyk, RN, MEd
Acting Chair
Ethics Review Committee

The Ethics Review Committee is a Joint Committee of
The Faculty of Nursing, University of Alberta
and
The Nursing Division, University of Alberta Hospitals

Appendix D

CONSENT FORM
Study Information Sheet For the Research Subject
A Comparison of Two Catheter Systems:
The Traditional Open System and the O'Neil Closed System

Purpose: Presently your bladder is emptied through a catheter every 4-6 hours or as needed. You are being asked to participate in a research study that compares two catheters. Both catheters are presently being used by staff. We want to find out if there is less risk of infection to the patient when using one catheter compared with using another catheter.

Procedure: If you participate, you have an equal chance of being assigned to either of the two ways to collect urine from your bladder. You will not be able to choose the way to collect the urine. Staff will save three urine samples for testing. Staff will also save three samples taken with cotton swabs from the skin surface near where the catheters are inserted. These procedures for collecting samples are not painful. The samples will be collected over a two day period (48 hours).

Participation: There will be no harm to you if you participate in this study nor will you benefit directly. Results from the study will help nurses determine which catheter is safer for use with patients in the future. Participation is voluntary. Your continuing medical care will not be affected in any way if you decide not to participate. You are free to withdraw from the study at any time by telling the researcher. If you develop an infection, your doctor will decide how to treat the infection.

Confidentiality: All information recorded about you or the samples collected will be kept confidential. No information will be released that identifies you. Data may be used in the future, if the researcher receives approval from the appropriate ethical review committee. The findings of this study may be published or presented but your name will not be used. All records will be kept in a locked cupboard separate from consent forms. Consent forms will be destroyed in five years (or a full calendar year after completion of the study). The records will be destroyed seven years after the study is complete.

We would be pleased to answer any questions you have about the study. Please contact either of the persons named below if you have any questions or concern:

Marilyn Albers, Co-Investigator (RN, MN Candidate, Faculty of Nursing)
Pager (24 hours) 445 5952 Telephone 459 6380

Marcy Albers, Res. Assistant (BScN) Pager (24 hours) 445 3736

Rene Day, Principal Investigator (RN, PhD, Faculty of Nursing-U of A)
Telephone 492 6481

CONSENT FORM
(TO BE COMPLETED BY THE RESEARCH SUBJECT)

Title of Project: **A COMPARISON OF TWO INTERMITTENT CATHETERIZATION SYSTEMS: CLOSED O'NEIL SYSTEM AND THE TRADITIONAL OPEN SYSTEM**

	Yes	No
Do you understand that you have been asked to be in a research study?	/___/	/___/
Have you read and received a copy of the attached Information Sheet?	/___/	/___/
Do you understand the benefits and risks involved in taking part in this research study?	/___/	/___/
Have you had a chance to ask questions and discuss this study?	/___/	/___/
Do you understand that you are free to withdraw from the study at any time without having to give a reason and without affecting your future medical care?	/___/	/___/
Has the issue of confidentiality been explained to you, and do you understand who will have access to your study information?	/___/	/___/

Who explained this study to you? _____

I agree to take part is this study: Yes /___/ No /___/

Signature of Research Subject _____

(Printed Name) _____

Date _____

Signature of Witness _____

Signature of Researcher or Designee _____

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH SUBJECT

PROXY CONSENT FORM
(TO BE SIGNED BY TWO PHYSICIANS)

Title of Research Project: **A COMPARISON OF TWO INTERMITTENT CATHETERIZATION SYSTEMS: CLOSED O'NEIL SYSTEM AND THE TRADITIONAL OPEN SYSTEM**

Principal Researcher: Dr. Rene Day, Bscn, PhD
Faculty of Nursing, University of Alberta
Telephone 492 6785

Co-Investigator: Marilyn Albers, RN, MN Candidate
Faculty of Nursing
PAGER 445 5952 Telephone 459 6380

We acknowledge that this patient _____ qualifies for participation in the above study. We acknowledge that we know the patient's clinical status and that there are no medical contraindications or exclusion criteria* to enrolling the patient.

_____ _____
Print Name of Physician No. 1 Signature

_____ _____
Print Name of Physician No. 2 Signature

Date: _____

Was a close family member or other appropriate individual able to be informed of the patient's enrollment in this study?
Yes /____/ No /____/

If yes, name of member is

UNIVERSITY OF ALBERTA

A COMPARISON OF TWO INTERMITTENT CATHETERIZATION SYSTEMS: THE CLOSED O'NEIL SYSTEM AND THE TRADITIONAL OPEN SYSTEM

BY

MARILYN KAYE ALBERS

A THESIS SUBMITTED TO THE FACULTY OF GRADUATE STUDIES AND RESEARCH IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF NURSING

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Degree: Master of Nursing

Year this Degree Granted: 1996

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Date Oct 3/96

University of Alberta

Faculty of Graduate Studies and Research

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 Intermittent Catheterization Systems: The Closed O'Neil System and the Traditional Open System* submitted by Marilyn Kaye Albers in partial fulfilment of requirements for the degree of Master of Nursing.

Dr. R. Day

Dr. M. Allen

Dr. K. Kowalewska-Grochowska

Date Oct 3/96

ABSTRACT

While it is acknowledged that the risk for infection is reduced with the use of intermittent catheterization, urinary tract infections continue to be attributed to the intermittent catheterization method. The closed O'Neil system (experimental group) and the traditional Open system (control group) were compared using the criteria of number and types of organisms introduced into bladder urine during intermittent catheterization procedures. Convenience sampling was used within acute care neurosurgical areas in two Western Canadian hospitals to obtain subjects who were randomly assigned to the two groups. A total of 33 urine specimens and 11 urethral meatal swab were collected. Data were analyzed using the Fisher Exact Test and the *t*-test for comparison of means. While a statistical level of significance was not achieved with the small sample size, the overall results supported the expectation that urine specimens obtained with the O'Neil system would yield little or no growth.

ACKNOWLEDGEMENTS

I wish to express my appreciation to Dr. Rene Day, Dr. Marion Allen, and Dr. Kinga Kowalewska-Grochowska for their conscientious guidance during the conduct of this research project.

Appreciation is also extended to Marcy Albers for assisting with data collection, and to Elnora Hibbert for assisting with the editing of this manuscript. Gratitude is extended to all nurses at two hospital sites who participated in the collection of specimens for this study.

I wish to thank MMG Canada for donating the MMG/O'Neil sterile catheters used in the study.

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CHAPTER 1

INTRODUCTION

Historically, urinary tract infections (UTIs) in hospitalized patients have been associated with invasive procedures such as urinary catheterization (Beeson, 1958; Gruneberg & Wilson, 1994; Guttmann & Frankel, 1966; Langer, Pifferi, & Peta, 1994; Murray, 1990; Widmer, 1994). In spite of improvements in procedural technique (Stamm, 1975; Wong, 1983), in continuous drainage equipment (Kunin & McCormack, 1966), and methods of catheterization (Guttman & Frankel; Lapides, Diokno, Silber, & Lowe, 1972), prevalence of UTIs remains high (Johnson, 1991).

It is still generally believed that most UTIs arise by the ascending route, via the urethra to the bladder after entry of bacteria through the urethral meatus (Kunin, 1987). Kunin adds that it is the most common route for women and, in association with instrumentation, in both sexes. Catheterization, as a method of instrumentation, is partially responsible for development of UTIs (Langer et al., 1994) by introducing organisms into the bladder (Barnes, Timoney, Moulas, Shaw, & Sanderson, 1992) where they may multiply and cause infection. Many UTIs are believed to be related to the indwelling catheter (Kunin) with the catheter itself as an important site for bacterial adherence and persistence. In addition, the bladder wall becomes traumatized through contact with the catheter and thus becomes susceptible to invasion by microbes introduced via the catheter (Garibaldi, 1993). While it is acknowledged by some that infection risk is reduced with intermittent catheterization

(Bennett, Young, & Darrington, 1995; National Institute on Disability & Rehabilitation Research Consensus Statement, 1992), UTIs continue to be attributed to this catheterization method (Barnes et al.).

In this project, two intermittent catheterization systems were compared to determine if one system of intermittent catheterization introduced fewer organisms to the bladder than the other. An effective intermittent catheterization system may reduce the number and type of organisms entering the bladder thereby minimizing the risk of acquiring a UTI for the hospitalized patient. Fewer UTIs benefit the patient, the institution and the health care system in general.

Statement of the Problem

Hospital-acquired infections are a major health problem and consume a large portion of health care resources (Dixon, 1978; Gruneberg & Wilson, 1994; Murray, 1992; Stamm, Long, & Belcher, 1993; Stamm, Martin, & Bennett, 1977; Widmer, 1994). Up to 42% of all hospital-acquired infections are estimated to be urinary tract infections (Haley, Culver, White, Morgan, & Emori, 1985; Stamm et al., 1977; Turck & Stamm, 1981). Costs associated with UTIs affect the patient, the institution, and third party payers (Wakefield, 1993). Costs to the patient include morbidity, pain and suffering, delayed return to work, decreased functional status, and perhaps premature death. Also of concern is that the development of the first infection may set the stage for more to follow (Garibaldi, 1993; Kunin, Polyak, & Postel, 1980). The institution bears the cost of increased laboratory and radiological tests,

medications, infection control procedures, and increased length of stay of the patient. Third party payers have increased costs for payments to hospitals as well as outpatient, home care, and physician services.

As technology changes, so do the possibilities of changing the infection outcomes related to catheterization procedures. A straight urinary catheter now exists that may reduce the risk to the patient of exposure to the number and types of microbes existing in the distal urethra. O'Neil, Jenkins, and Wells (1982) adapted a straight catheter system from a sealed introducer which was developed by O'Neil (1981) for the purpose of collecting urethral swabs. Swabs collected through the introducer from proximal urethras in women yielded contamination results of only 10%. The O'Neil Urinary Catheter (O'Neil et al.) was designed to extend a sterile field into the female urethra to provide sterile passage for a straight catheter through the colonized distal portion of the urethra. Theoretically, the catheter reaches the relatively sterile proximal urethra uncontaminated, thereby breaking the link between colonized organisms in the distal urethral and periurethral areas, and the bladder urine.

While the catheter was introduced in Australia as a method for catheterizing women, it has been used since in the United States and Canada with both men and women. Charbonneau-Smith (1993) conducted a study in a long-term care facility using the O'Neil catheter for intermittent catheterization. She demonstrated that only 44.4% of patients in the experimental group had more than one UTI per admission to the facility compared with 79.3% of patients in the control group. A lower

incidence of UTI was also demonstrated by Pang-Wright and Dasalla (1990) but because of the small sample size, they could not establish a statistically significant difference. Young, Bennett, and Darrington (1992) described a 30% reduction in the infection rate in hospitalized patients over a three year period using the O'Neil system (0.61%) compared with an alternate closed system without an introducer tip (0.91%). In 1995, Bennett et al. again studied hospitalized men and women. A total of 75 infections in 10,945 catheterizations was identified for an overall low infection rate of 0.68%. All catheterizations were performed with the O'Neil system.

While use of the O'Neil catheter has been documented in studies pertaining to long term management of urinary retention, there is little evidence in the literature that the effectiveness of the O'Neil Urinary Catheter has been studied in acute care settings for short term management of patients with acute urinary retention. More studies are needed to determine the impact of this technology compared with the traditional technology on the risk of and/or development of UTIs related to short-term urinary retention management in acute care facilities. Since nursing staff perform or oversee urinary catheterizations, the catheterization system used is a clinical nursing concern.

Purpose of the Study

The purpose of this study was to compare the traditional open intermittent catheterization system which is believed to expose a patient's sterile bladder to the microbes from the distal urethra via a contaminated catheter, with the O'Neil system

which theoretically provides a sterile passage for the catheter. The systems were compared in relation to two factors: number of microorganisms (size of inoculum) and the types (genus, or genus and species) of microorganisms recovered from bladder urine and the urethral meatus. This approach permits a closer examination of the impact of the etiological agent in the infection equation (etiologic agent plus host defenses equals the presence or absence of UTI) in contrast to other studies which examine the rates of UTI.

Research Hypotheses

The hypotheses in this study were:

1. There will be a significant difference in the number of bacteria found in the urine of the subjects using the O'Neil system compared with the subjects using the Open system.
2. There will be a significant variation in types of bacteria in the urine of subjects using the Open system compared with those using the O'Neil system.
3. The relationship between the bacteria found at the urethral meatus and in the urine is stronger for the Open system than for the O'Neil system.

Operational Definitions

O'Neil Intermittent Catheterization System (O'Neil system)

The O'Neil system is a completely self-contained sterile field consisting of an introducer, a straight catheter, water soluble lubricant and a graduated collection bag. The sterile field is closed to the environment during the procedure. Sterile gloves and povidone-iodine (precatheterization skin cleanser) are used in combination with the O'Neil system. Urine drains into the closed collection bag. A sterile specimen is obtained by pouring urine from a sterile port on the bag into a sterile specimen container. The port becomes accessible once the contaminated catheter and introducer are removed from the collection bag. Precatheterization preparation of the equipment is not required prior to performing the procedure except for opening the packages of povidone-iodine swabs for cleansing and removing the cap from the tip of the catheter. Aseptic technique is used.

Open Intermittent Catheterization System (Open system)

The open system consists of a sterile straight catheter, and a sterile tray that includes a collecting receptacle, drapes, cotton swabs, povidone-iodine cleanser, water soluble lubricant, disposable forceps, and sterile gloves. The sterile field is prepared prior to the procedure by opening the sterile catheterization tray, opening the cleanser package and expelling the contents onto the cotton swabs, opening the lubricant package and expelling the contents into the collection receptacle, and adding other sterile items such as the straight catheter. The sterile field is exposed

(open) to the environment during precatheterization equipment preparation and the actual catheterization procedure. Urine drains into the open collecting receptacle. A sterile specimen is obtained by pouring urine from the receptacle into a sterile specimen bottle. Aseptic technique is used.

Aseptic Technique

Aseptic technique (Crow, 1989) involves washing the hands thoroughly prior to preparing the sterile field, and using sterile equipment, technique and supplies. Povidone-iodine is used for urethral meatal cleansing. Sterile gloves are worn by the nurse. The gloved hand that contacts the periurethral area does not contact the sterile catheter or any other part of the sterile field.

Assumptions

The study is based on the following assumptions:

1. The ascending route is a common route of urinary tract infection.
2. Colonization of the urethra with microbes may contribute to the development of UTIs.
3. Microbes colonized in the distal urethra will likely be similar to those present at the urethral meatus.
4. Host defenses and agent characteristics interact in the development of UTIs.
5. Host defenses influence the ability of microbes to invade bladder tissue depending on the number and type of microbes presented.

6. If fewer microbes are introduced into the bladder, the patient will be at less risk for the development of a UTI.
7. Catheterization supplies exposed to the environment are more susceptible to contamination than those enclosed in a sterile environment.
8. Nursing staff follow the designated procedures by using aseptic technique when performing intermittent catheterization, and by using correct catheterization and sterile specimen collection techniques.

Summary

An introduction to the study including the statement of the problem, the purpose of the study, the research hypotheses, operational definitions, and assumptions are presented in Chapter 1. A review of the literature is presented in Chapter 2. In Chapter 3 the research design and methods, including the data analysis, are explained. The results are presented in Chapter 4. In the final chapter, the major findings of the study and the implications of this study for nursing staff are discussed.

CHAPTER 2

REVIEW OF THE LITERATURE

The background and theoretical foundation for this study is provided in this literature review. It comprises four main sections; agent-host-environment interaction, host defenses including the urethra and the bladder, bacterial causes of UTIs in hospitals, and intermittent catheterization. In particular, the literature is explored from the perspective of the potential infective agent of UTIs and the relationship with intermittent catheterization.

Agent-Host-Environment Interaction

Relationships are known to exist between infectious agents, the human host, and the environment (Lilienfeld & Lilienfeld, 1980) (see Figure 1). Infectious diseases are usually classified by agent on the basis of biological features (categories of metozoa, protozoa, bacteria, fungi, rickettsia, viruses). The agent enters the human host through portals such as the respiratory tract, the gastrointestinal tract, the genitourinary tract, conjunctiva, or skin and tissue (percutaneous entry).

The interval between the time of agent contact with the host and the onset of disease (incubation period) is generally thought to be the time required for the multiplication of the agent within the host to a threshold point where the agent population is large enough to produce symptoms in a host. The incubation period is largely dependent upon the rate of growth of the agent in the host (Benenson, 1990).

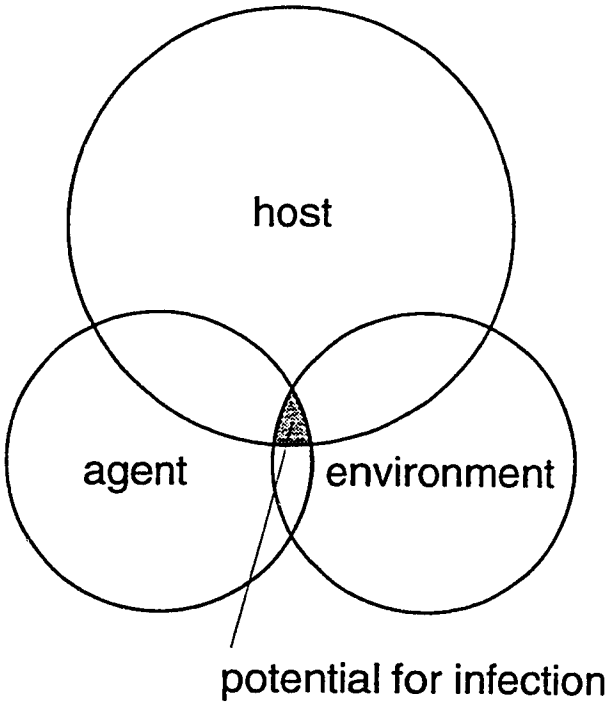

Figure 1. Agent-Host-Environment Interaction as it relates to the potential for infection. An etiological agent such as bacteria may be carried on the tip of a catheter from the environment into the bladder of the host during catheterization. Host defenses rally to minimize the ability of the agent to cause disease.

Patterns of infectious diseases depend upon factors that enhance the probability of contact between an infectious agent and a susceptible host (Lilienfeld & Lilienfeld, 1980). Such enhancing factors include diminished host defenses in the urethra, urine, and bladder (internal environment), virulence features of infectious bacteria (agent), and the use of instruments such as urinary catheters (external environment) in the provision of health care.

Host Defenses

The human host has natural defenses against diseases such as UTIs (Sobel, 1991). Host defenses may minimize the impact of intruding infectious agents on body functions.

The Urethra

The female urethra is a small tube approximately three to four centimeters in length, located behind the symphysis pubis and anterior to the vagina (Dittmar, 1989). It serves only the urinary tract, and connects the bladder to the perineum, allowing for the passage of urine. Periurethral mucous secreting glands surround the distal two-thirds of the urethra (Moore & Hira, 1965). Mucus that lines the urethra traps bacteria attempting to ascend the urethra, and may delay or prevent them from reaching the fourth centimeter of the urethra that is contiguous with the bladder (Hutch, 1970).

The male urethra extends through the prostate gland, fibrous sheath and penis and serves both the urinary and reproductive tract (Spence & Mason, 1983). The male urethra is approximately 20 cm in length and is divisible into three parts. The prostatic urethra passes through the prostate gland and receives secretions from ejaculatory ducts of the reproductive system. The membranous urethra passes through the urogenital diaphragm (pelvic floor). The cavernous urethra is the longest portion extending from below the urogenital diaphragm to the external urethral orifice. The cavernous urethra receives secretions from the bulbourethral reproductive glands near its proximal end.

Both male and female urethras (see Figure 2) have internal and external sphincters. The internal urethral sphincter is located at the junction of the bladder and the urethra and functions to keep the urethra closed between voluntary voiding. As the urethra passes through the urogenital diaphragm, it is surrounded by skeletal muscles that form the external urethral sphincter. When contracted, this sphincter holds the urethra closed against strong bladder contractions and when relaxed, it permits the passage of urine (Spence & Mason, 1983).

High Pressure Zone. Tanagho and Miller (1973) demonstrated that the external striated sphincters in the male (within the membranous urethra) and in the female (approximately 1.5 cm from the meatus) create high pressure zones (see Figure 2) which constitute relative barriers to bacterial ascent (Mayo & Hinman, 1973) from the distal urethra to the bladder. Urethral contents distal to the high

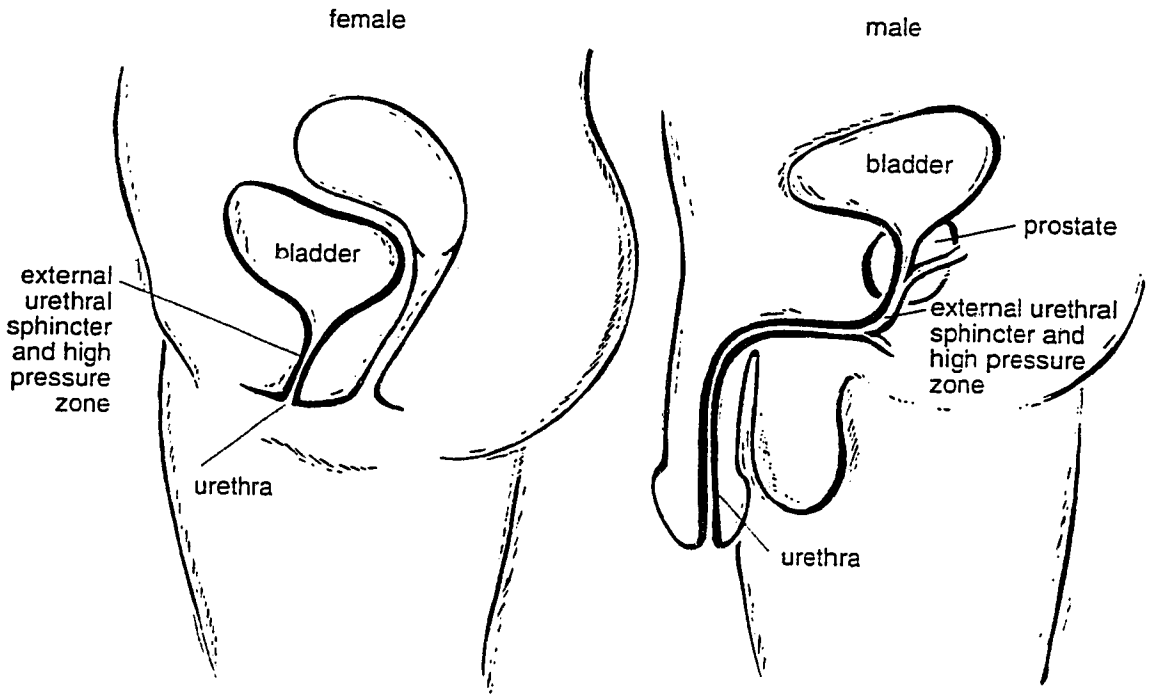

Figure 2. External urethral sphincters and high pressure zones in relation to the female and male urethras

pressure zone are milked toward the urethral meatus while contents proximal to the high pressure zone are milked toward the bladder.

An association between the urethral high pressure zone and distribution of colonized microbes within the urethra is believed to exist. The urethral high pressure zone may partially determine, as a relative barrier, whether or not colonized microbes, without the aid of a catheter, ascend from the distal urethra or periurethral area to the bladder to cause UTIs. During urethral catheterization, the catheter passes through the distal urethra and penetrates the natural barrier. The catheter carries microbes of particular types which are inoculated into the bladder at the time of entry of the catheter into the bladder.

Colonization. The number and location of urethral microorganisms vary among individuals as shown in Table 1. Helmholz (1950) found that few male subjects displayed bacteria as far as the fifth and sixth urethral segments. The most frequently colonized segment was the first one. Cox (1966) and Cox, Lacy, and Hinman (1968) showed that the majority of female subjects were colonized along the entire urethra and that all were colonized in the first centimetre. O'Neil (1981), in contrast to Cox et al., showed that while 90% of female subjects were colonized in the first centimetre, only 10% were colonized in the second, third and fourth centimetres. The measuring instruments were markedly different in design which partially explains the variation in results of O'Neil and Cox et al.

Table 1

Percentage Of Subjects Colonized Per Urethral Segment

Urethral Segment	Men - Symptoms[1]	Women - No Symptoms[2]	Women - Symptoms[3]	Women - No Symptoms[4]
1st (1 cm)	95%	100%	100%	90%
2nd (1 cm)	68%	88.5%	97.2%	10%
3rd (1 cm)	54%	81%	88.6%	↓
4th (1 cm)	34%	54%	77.2%	↓
5th (1 cm)	17%	-	-	-
6th (1 cm)	7%	-	-	-

Note. [1]Helmholz, 1950; [2]Cox, 1966; [3]Cox et al., 1968; [4]O'Neil, 1981

Hemholz (1950) showed the male urethra to be colonized with gram negative bacteria and gram positive cocci (most likely *Streptococcus faecalis*) in gradually decreasing amounts from the first to the fourth segments. The fifth segment continued to harbor gram negative bacteria but not *Streptococcus faecalis*. He suggested that the presence of gram negative bacteria in the fifth segment may be a significant factor in development of UTIs in men.

Crow (1989) suggested that the urethras of both men and women are colonized with microbes which vary with the stage of sexual development. Maskell, Pead & Hallett (1975) indicated that in prepubertal boys and men over 60 years of age, the most frequent urinary infecting microbe was *Proteus* species which resided in the prostatic ducts and urethra rather than on the perineum. The authors speculated that these infections related more to the characteristics of the prostatic secretion than to periurethral colonization. UTIs in older boys and young men occur

but are infrequent unless they were subjected to urinary instrumentation (Kunin, 1987) or have functional or anatomical abnormalities of the genitourinary tract (Lipsky, 1989). In these cases, *Escherichia coli (E. coli)* has been the most frequent uropathogen. Bennett et al. (1995) demonstrated that not only was *E. coli* a prevalent cause of UTIs but that *E. coli* infections were significantly greater in female subjects compared with male subjects in a recently injured group of spinal cord patients. In healthy young women (age 18 to 20 years), anaerobic bacteria such as *Bacteroides melaninogenicus* and aerobic bacteria such as lactobacilli, *Staphylococcus epidermidis*, Corynebacteriaceae, and alpha-hemolytic *Streptococcus* species are common occupants of the urethra (Marrie, Harding, & Ronald, 1978). Crow (1989) agrees that enterococci and alpha-hemolytic *Streptococcus* species are commonly found in the anterior urethra of women and adds *Candida albicans* to the list of microbes. Lactobacilli and *Bacteroide* species, among others, are also common to the vagina. The external genitalia of women (Crow) and young girls (Schlager, Hendley, Lohr, & Whittam, 1993) may be colonized with gram negative bacteria.

The Bladder

The bladder serves as a reservoir and can store 350 to 450 ml of urine (Dittmar, 1989). When empty, it lies behind the symphysis pubis. Smooth muscle lines the bladder and is continuous with and lines the urethra, allowing the bladder and urethra to function as a unit.

Micturition or emptying of the bladder occurs with voluntary relaxation and contraction of the external sphincter and pelvic floor musculature. A relatively constant intravesicular pressure is maintained by the detrusor muscle, which lines the bladder, despite varying urine volumes. The sensation of bladder filling is usually felt when the bladder contains 100 ml of urine. At about 400 ml, the desire to void is felt. Over-distention of the bladder disrupts tissue integrity by decreasing blood supply to the bladder wall (Lapides, 1979) making the bladder susceptible to bacteria via the hematogenous route (Lapides, Costello, Zierdt, & Stone, 1968). Bladder defenses represent host responses to the number and type of microbes persisting in the bladder.

Bladder Wall. The size of the bacterial inoculum in the urine influences the ability of the bladder to defend itself. Hand, Smith, and Sanford (1971) and Norden, Green, and Kass (1968) demonstrated rapid killing of bacteria in contact with the bladder wall. Norden et al. showed that a small number of bacteria was killed more effectively than a large number of bacteria, and that some kinds of bacteria were killed more rapidly (e.g. *Proteus mirabilis*) than others (e.g. *Staphylococcus aureus*). Hand et al. (with rabbits) and Norden et al. (with rats and guinea pigs) also showed that while organisms are multiplying in urine (e.g. *E. coli*), the bladder wall continues to exert a bactericidal effect on organisms attached to the bladder surface. Parsons, Greenspan, Moore and Mulholland (1977) demonstrated that attachment of bacteria to the bladder wall epithelium is normally inhibited by mucopolysaccharides in a mucous layer covering the epithelium.

Bladder Urine. Multiplication of bacteria in the bladder urine occurs in four phases: lag phase, logarithmic phase, maximum stationary phase, and phase of decline (Asscher, Sussman, & Weiser, 1968) as shown in Figure 3. The lag phase is a high energy phase in which the bacteria are adapting to the new environment rather than increasing in cell mass or in number. The logarithmic phase begins once bacteria have adapted and accounts for growth at a constant energetic rate until the condition of the urine changes enough to inhibit growth (e.g. reduced nutrients, increased toxic waste). Bacteria vary in the size of cell mass required before the parent cell can split to create two identical daughter cells (Morris, 1990) and they vary in growth rates (Nierlich, 1978). The time it takes viable *E. coli*, for example, to double in number (generation time) can be as short as 12.5 minutes (Roberts, Clayton, & Bean, 1968) while for other organisms the generation time may be hours (e.g. *Mycobacterium tuberculosis*). Eventually the maximum stationary phase may be reached while at the same time resources in the urine decline. Due to lack of nutrients and build up of toxic waste, the phase of decline sets in and bacteria begin to die (Asscher et al.).

Kaye (1968) provided evidence that bladder urine is generally bacteriostatic for small inocula ($< 10^2$ organisms/ml) under optimal conditions (e.g. low pH). Properties of urine such as pH, osmolity, glucose and amino acid content, organic acids and urea can promote or inhibit the growth of bacteria (Asscher et al., 1968; Kaye; Roberts et al., 1968).

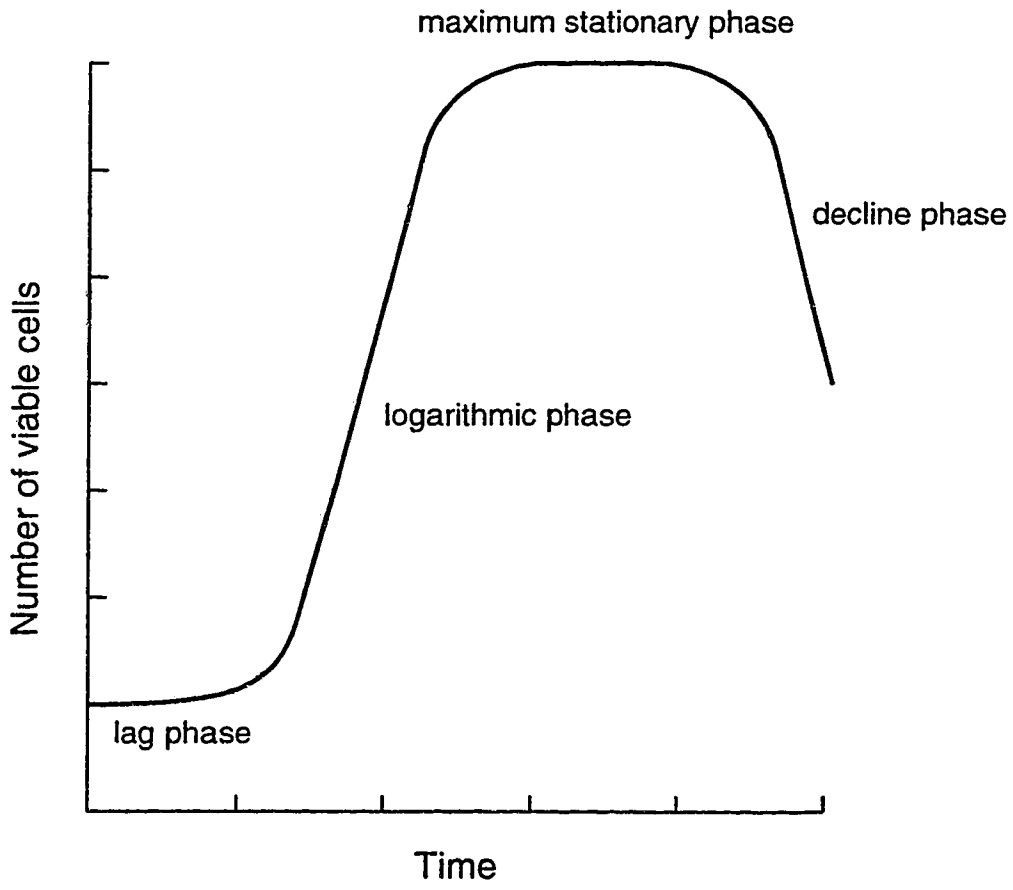

Figure 3. Growth phases of bacteria

The frequency of bladder emptying, high urinary flow, and the amount of residual urine are factors that contribute to the presence or absence of bacteria in the urine (O'Grady & Cattell, 1966). Catheterization may eliminate many bacteria by draining the colonized urine. However, bacteria in varying numbers may be retained in residual urine and represent the beginning inocula for the next round of bacterial growth (Cox & Hinman, 1961). Dilute urine (influenced by high urinary flow and intake of fluids) reduces the rate of multiplication and climax concentration. Increased frequency of bladder emptying minimizes the multiplication and concentration of organisms. This makes reaching a maximum concentration unlikely.

Antibiotics are most effective against a small number of bacteria in the urine (O'Grady & Cattell, 1966). As the concentration of organisms increases, the effect of antibiotics decrease. If the rate of excretion of the drug is constant, maximum drug effect is achieved when there is frequent bladder emptying and high urine flow which decreases concentration of organisms. If the antibiotic is characterized by a peak excretion rate, administration of antibiotics should be timed so that peak excretion of the drug occurs just after emptying the bladder when residual urine and therefore residual bacterial inoculum are minimal.

Bacterial Causes of UTIs in Hospitals

Once in the bladder urine, bacteria may be eliminated by the bladder defense mechanisms; or they may colonize, invade the bladder wall, multiply, and cause an infection (Sobel, 1987). Bladder infections may persist and contribute to kidney

infections or bacteremia (Garibaldi, 1993). The ability of bacteria to grow in number (Kunin, 1987; Roberts et al., 1968) and to cause infection is partially determined by the characteristics of the bacteria inoculated (Sobel, 1991) and the adequacy of host defenses.

It is generally accepted that the types of bacteria predominant in hospital differ from those in the community (Murray, 1992; Stamm et al., 1993). In addition, many bacterial strains in hospital are increasingly resistant to antibiotics (Boyce & Edwards, 1960; Gruneberg & Wilson, 1994; Murray; Stamm et al., 1993), making infections with these organisms difficult and expensive to treat (Murray, 1991). The common infectious organisms in intensive care areas are bacteria (Gruneberg & Wilson; Massanari, 1989) such as *Escherichia coli*, *Pseudomonas* species, *Staphylococcus epidermidis*, *Staphylococcus aureus* and *Enterococcus* species.

Under normal circumstances, many bacteria are commensal (symbiotic, normal) with humans and the environment. *Staphylococcus epidermidis*, as an example, is commonly found in the environment and on the skin, and usually does not cause disease in healthy individuals. Infections emerge because commensal bacteria become opportunistic pathogens, that is they take advantage of diminished host defenses and maximize their capacity to cause disease. *Staphylococcus epidermidis* demonstrates this capacity in intensive care units as it frequently causes bacteremias associated with intravascular devices (Gruneberg & Wilson, 1994). Gram negative bacteria such as *Escherichia, Enterobacter, Klebsiella, Proteus*, and *Serratia* species as well as *Pseudomonas* species (Bryan & Reynolds, 1984; Stamm

et al., 1977; Turck & Stamm, 1981) are commonly found (commensal) in the intestine but not in the urinary tract. These bacteria are frequently reported as causes of hospital UTIs.

Patients with spinal cord injury are susceptible to *Pseudomonas* species colonization especially if wearing external urinary catheters (Montgomerie & Morrow, 1978). Fawcett, Chawla, Quoraishi, and Stickler (1986) suggest that patients with spinal cord injury who have indwelling catheters or who are being intermittently catheterized begin to colonize with gram negative bacteria such as *Klebsiella pneumonia* and *Pseudomonas* species within two to three days of admission to hospital.

Widmer (1994) suggests that trends in the type of pathogens, and their antibiotic susceptibility patterns, change with each decade that passes. In the 1960s and 1970s gram negative bacteria, such as *E. coli* and coliforms were predominantly responsible for UTIs, while worldwide in the 1990s gram positive bacteria including enterococci are becoming more prevalent.

Escherichia coli

E. coli is a member of the bacteria family Enterobacteriaceae. It is a commensal intestinal inhabitant, and usually lives in humans in peaceful harmony. *E. coli* is not commensal to the urinary tract and is the most common cause of UTIs in hospitalized patients (Murray, Baron, Pfaller, Tenover & Yolken, 1995). It has the most rapid growth rate of any known bacteria (Roberts et al., 1968).

Coliforms

Coliforms are generally considered to be gram negative enteric (commensal to the intestinal tract) rods (bacilli). Coliforms include the Enterobacteriaceae family members of *E. coli* and species of *Klebsiella, Enterobacter*, and *Citrobacter* which ferment lactose (Miller & Keane, 1987), and other family fermentative members such as *Serratia* and *Providencia* species. Coliforms are a common cause of UTIs in hospitalized patients.

Enterococci

Enterococci constitute a subgroup of gram positive *Streptococcus* Group D species. This subgroup includes *Enterococcus faecalis* and *Enterococcus faecium* (previously known as *Streptococcus faecalis* and *Streptococcus faecium*). Of the two, *Enterococcus faecalis* is more commonly involved in UTIs and the incidence is increasing steadily (Widmer, 1994). Both species are developing significant resistance to antibiotics (Murray, 1992; Murray et al., 1995). Enterococci commonly cause UTIs in hospitalized patients.

Intermittent Catheterization

Intermittent catheterization is highly effective for emptying the bladder while minimizing the risk of urinary tract infection (Kunin, 1987). The general indications for use are short term urological management of patients with acute urinary retention or with patients being monitored in intensive care units, long term urological

management of the patient with spinal cord injury, and management of children and adults with neurogenic bladders. Intermittent catheterization mimics normal emptying of the bladder, eliminates the indwelling catheter as a persistent foreign body, prevents incontinence due to overflow, improves self esteem of the patient, and enhances the effectiveness of antimicrobial therapy.

Guttmann and Frankel (1966) pioneered the use of intermittent catheterization in the urological management of patients with spinal cord injury. The authors demonstrated that it was possible to maintain the urine in a sterile state by using meticulous sterile technique. Lapides et al. (1972) modified the procedure using clean technique believing that the key to preventing UTIs is maintaining good blood supply to the bladder thereby protecting the integrity of the bladder wall. Kunin (1987) stresses that the method (sterile or clean) of preventing infection while on intermittent catheterization is secondary to emptying the bladder as completely as possible at each catheterization.

Maynard and Diokno (1984) specify that the frequency of catheterization is dependent on urine volumes. Optimally, catheterizations should be performed as needed to keep the volume of urine in the bladder below 400 ml. This is the average volume at which the desire to void usually occurs (Dittmar, 1989).

Whether to use sterile or clean intermittent catheterization technique in hospitalized patients with short term catheterization needs or in home care patients with long term catheterization needs remains controversial. Nurses have yet to standardize practice in the performance of this common procedure (Rainville, 1994).

In many community applications, intermittent catheterization is accepted as a clean rather than sterile procedure (Moore, Kelm, Sinclair, & Cadrain, 1993). In hospital settings, debate between advocates of sterile and clean technique continues.

Even though the bladder is emptied with less risk using a straight rather than an indwelling catheter, urethral catheterization itself remains an invasive procedure. The patient is at risk for developing bacteriuria and possibly a UTI (Bakke & Vollset, 1993).

Summary

Relationships are known to exist between the human host, infectious agent, and the environment. In the human host, the urethra connects the bladder to the perineum. A high pressure zone exists within the urethra at a point where the urethra passes through the urogenital diaphragm. This zone creates a natural barrier to ascent of organisms colonized in the distal urethra. The bladder stores urine and has natural defenses against invading organisms.

The interaction of host defenses with bacteria (infectious agent) determines whether or not the bacteria persist. A small number of bacteria and some types of bacteria are controlled more effectively by natural bladder defense mechanisms and frequent bladder emptying than a large number of bacteria. *E. coli*, coliforms and enterococci are considered common bacterial causes of UTIs. Intermittent catheterization is an effective way of relieving the bladder of urine but as an invasive procedure it remains a risk factor in the development of a UTI.

CHAPTER 3

METHODS

The purpose of this chapter is to describe the study methods. The study design is described, followed by a description of the setting, subject selection, supplies, procedures and data collection, and ethical considerations specific to this study. The chapter concludes with a description of the data analysis.

Design of the Study

The study design was experimental as shown in Table 2. Group 1 was the experimental group and Group 2 was the control group. All urine specimens, except those for the control group at Time 1, were obtained using the O'Neil system to standardize urine collection procedures until the time of intervention. The intervention consisted of the use of the O'Neil system for the collection of urine specimens from the experimental group (Group 1) and the use of the Open system for the collection of urine specimens from the control group (Group 2).

Table 2

Two Groups of Subjects

	Discard Urine	Time 0 Baseline	Time 1 Intervention	Time 2 Follow-up
Group 1 - Experimental	O'Neil*	O'Neil	O'Neil Meatal Swab	O'Neil
Group 2 - Control	O'Neil	O'Neil	Open** Meatal Swab	O'Neil

Note. * - O'Neil system; ** - Open system

Cultures from urine and swab specimens were analyzed for organisms known to commonly cause UTI, such as *E. coli*, coliforms, and enterococci. Limiting the organisms reported from cultures partially controlled laboratory costs.

Urine was obtained from each subject immediately prior to beginning the study. This urine was obtained by intermittent catheterization with the O'Neil system within 10 hours of Foley catheter removal. Because urine may become colonized with bacteria as a result of the presence of an indwelling catheter, this urine was discarded in an attempt to clear bacteria that remained in the bladder once the Foley catheter was removed. The next three urine specimens (Times 0, 1, and 2) and the urethral meatal swab taken at Time 1 were cultured. Time 0 results were considered baseline data, Time 1 results the intervention data and Time 2 results the follow-up data. The specimens were collected between three and six hours apart to minimize the concentration of organisms subject to logarithmic multiplication between collections (S. Henwick, May, 1994, personal communication). Residual urines (urine collected via catheter immediately following partial bladder emptying) were acceptable as specimens at Times 0, 1, or 2.

Setting

The study was conducted in two large urban acute care teaching hospitals in Western Canada. An intensive care unit and a nursing unit at Site A, and a nursing unit at Site B provided the population for study. Both male and female patients were admitted to these nursing units and had central nervous system trauma or disease

(such as closed head injury, traumatic brain/head injury, spinal cord injury, aneurysms, brain tumours or hemorrhages), or back injuries which gave rise to neurological concerns. Patients were either admitted to the intensive care unit and transferred to the general care area, or directly to the care area without first going to the intensive care unit.

Most patients in these care areas had a Foley catheter inserted into their bladder because their ability to void was impaired. Usually, once the patient's physical condition was stabilized, the Foley catheter was removed. If there was a delay in regaining spontaneous voiding, intermittent catheterization was performed as necessary. It was acceptable practice to use either the Open or O'Neil systems at Site A while only the Open system was used at Site B.

Variations in the catheterization schedule occurred between the intensive care unit and the general care areas. In the intensive care unit, most nurses catheterized every four hours if the urine volume was greater than 400 ml and every six hours if the volume was less than 400 ml. The staff on the nursing unit of Site A planned for catheterization every four to six hours; but periodically the time extended to every eight or ten hours depending on staffing. The staff at Site B converted, during the patient's hospital stay, from catheterizing every 4 to 6 hours over 24 hours to four times a day (0800, 1400, 1800, and 2200 hours) or as needed once the patient's fluid intake and output were balanced. This schedule was implemented as part of a bladder training program for patients with spinal cord injury who had neurogenic bladders.

Nursing staff in the intensive care area were registered nurses (RNs) who work only in the intensive care unit. On the nursing units there were RNs, licensed practical nurses (LPNs), and nursing attendants who worked only in these areas. All regular staff (RNs and LPNs) performed intermittent catheterizations in their respective care areas.

Subject Selection

A patient was eligible for inclusion as a subject if over 18 years of age, and at least 48 hours post therapy if antibiotics had been administered. A potential subject was excluded if less than 18 years old, had a known UTI, had known pathology of the urinary tract including obstruction, renal disease, calculi, or was on antibiotics. A subject would be withdrawn from the study if transferred from the study care area, discharged from the hospital, chose to withdraw, started on antibiotics, began to void spontaneously, or died.

All patients admitted to three care areas, who were considered as potentially eligible, were screened by the investigator through a review of the patient charts and/or cardex. The investigator consulted with nursing staff about those patients who fit the eligibility criteria regarding an anticipated need for intermittent catheterization following Foley catheter removal. A note was placed on the front of the chart in the intensive care unit, or given to the unit clerks on either of the two nursing units, requesting that the investigator be notified when a physician's order was received to discontinue the Foley catheter. Consent was then obtained from the patient willing to

participate in the study and competent to give consent, or the family and two physicians if the patient was unconscious, or incompetent, and unable to provide an informed consent. At this point the patient was considered a subject for the study.

The first subject at each site was randomly assigned to Group 1 or Group 2. A nurse who was unaware of the system of categorization of the groups pointed with a sharp object while blindfolded and chose a number on a random number table. The first subject was then assigned to the group indicated by the random choice (even number - O'Neil system; odd number - Open system). Thereafter, the next eligible and consenting subject was assigned the alternative system by the investigator. However, in order to balance the male-female ratio, if a male subject was assigned to Group 1, so was the next female subject. Since data were collected at two sites for three of the nine months of data collection time, two subject assignment lists were maintained. Consecutive numbers beginning with the number one were used to order the list at Site A while consecutive letters beginning with the letter A were used at Site B.

Demographic Data

Demographic information collected on all subjects included gender, age, and diagnosis. Age and gender were considered important because of anatomical differences and hormonal influences in men and women. Diagnosis was also recorded. As well, the time of discard of the first urine removed from the bladder in relation to the time the Foley catheter was removed (less than or more than 10 hours

post Foley catheter) was recorded. Documentation of the system used for collection of the discard urine and whether or not the subject had used intermittent catheterization prior to the study was also done. Hospital site, nursing care area, and staff (RN or LPN) performing the procedure were also recorded.

Supplies

The supplies were prepackaged to minimize organization and collection time for the nursing staff, and to maintain consistency in supplies for each catheterization. As subjects entered the study, prepackaged supplies were labelled with the subject's name and taken to the bedside. Inside a large plastic ziplock package, four smaller ziplock plastic bags contained the required supplies for each part of the process. Each bag and each piece of supplies inside were identified with either a green (O'Neil system) or yellow (Open system) fluorescent dot corresponding to the intermittent catheterization system to be used.

Open System Supplies

An Open system package included four bags. Three bags each contained an O'Neil catheter, three povidone-iodine swabs, a sterile urine specimen container, and sterile gloves, and were used to obtain the discard urine and the urine specimens for culture at Time 0 and Time 2. The other bag contained a catheterization tray, a straight catheter, a povidone-iodine packet and swab for cleansing, a sterile urine specimen container, sterile gloves, and a sterile swab for use at Time 1.

O'Neil System Supplies

Inside the O'Neil system package, there were four bags each of which contained an O'Neil catheter, three povidone-iodine swabs, a sterile urine specimen container (in three bags only), and sterile gloves to collect urine at discard time, and specimens at Time 0, Time 1, and Time 2. The Time 1 bag also contained a sterile swab.

O'Neil Urinary Catheter

As shown in Figure 4, the introducer was made of a soft silicone product and had a tip with a self-opening cruciate (star shaped) seal. A flange separated the introducer from the collection bag and limited entry into the urethra beyond approximately 1.5 cm. The head of the introducer was preloaded with non-drying water soluble non-allergenic lubricant. It had a removable cap to protect the tip until the catheter was used. The system included a straight catheter of designated size (#14 Fr. in this study) inside the introducer with the tip contacting the water soluble lubricant. The body of the catheter extended out from the introducer. A collection bag was attached to the introducer distal to the flange enclosing the distal end of the introducer and the body of the catheter. The entire unit, beginning with the introducer, extended the sterile field within the distal urethra for approximately 1.5 cm (see Figure 5). Functionally this permitted the catheter to bypass the reservoir of organisms in the distal urethra anterior to the high pressure zone (Mayo & Hinman,

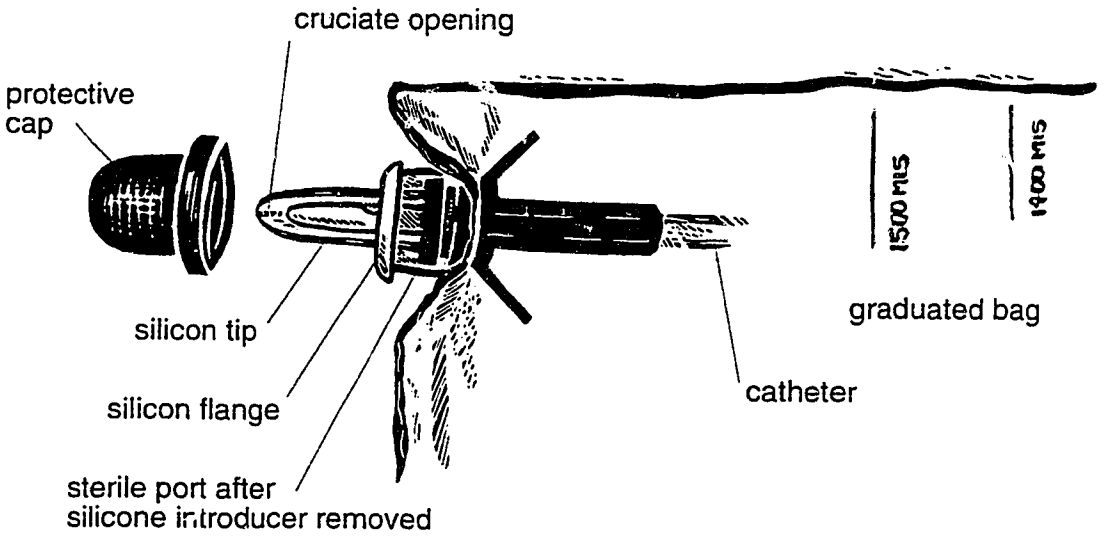

Figure 4. The O'Neil Urinary Catheter with straight catheter enclosed in a sterile silicone introducer and sterile graduated bag

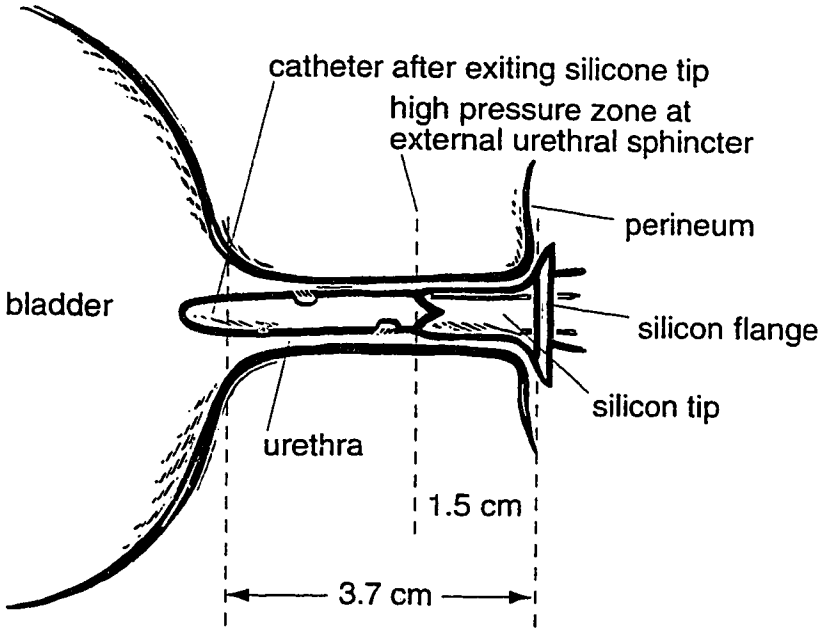

Figure 5. High pressure zone at external urethral sphincter in female urethra in relation to inserted O'Neil Urinary Catheter

1973; O'Neil, 1981; Tanagho & Miller, 1973) in both men and women. There was minimal opportunity for contamination because of the self-contained design.

Procedures and Data Collection

The investigator oriented the nursing staff to the study, assessed eligibility of patients for the study, obtained the informed consent (with staff assistance if physician proxy consent was required), and randomly assigned subjects. The investigator retrieved and transported specimens to the laboratory, and plated samples for incubation. Questions posed by the staff or subjects and family regarding the study process were answered.

The staff orientation was conducted for all regular staff to facilitate understanding of project activities and to foster staff support for the study. Information was provided about the clinical problem addressed, the purpose of the study, the research hypotheses, eligibility criteria, informed consent procedures, subject assignment, and collection and preparation of specimens for transport. As well, emphasis was placed on using correct aseptic technique with the Open or O'Neil systems. Non-regular float staff and/or casual staff received instruction from regular staff who attended training sessions.

Nurse managers in the care areas agreed to participate in the study but requested that staff related tasks be minimized. Nursing staff notified the investigator of potential subjects, assisted with obtaining physician proxy consents when required, assisted with random assignment of the first subject at each site, used prepackaged

supplies, and collected meatal swab and urine specimens according to the study protocol indicated on the chart or cardex.

Data collection occurred over a period of nine months. Site B was brought on stream six months after Site A when it became apparent that appropriate subjects at Site A were not readily available.

Urine Specimen Collection

When the subject was admitted to the study, a color coded flowsheet (see Appendix A) was attached to the subject's chart and a notation made on the cardex to alert staff to catheterization system assignment. Catheterizations were performed by nursing staff assigned to care for the subjects. Staff followed the guidelines on the study system flowsheet and documented collection times. The investigator was contacted and advised when specimens were collected.

Four catheterizations (1 for urine to be discarded and 3 for urine to be cultured) were performed on each subject. The urine specimens were collected between three and six hours apart and were obtained using the O'Neil catheters except at Time 1 for Group 2 subjects when the Open system was used.

Urethral Meatal Swab Collection

Urethral meatal swabs were collected from both Group 1 and Group 2 subjects just prior to the precatheterization cleansing procedures at Time 1 and were placed directly into clear transport mediums.

Specimen Processing

The investigator was trained by the laboratory research technician at Site A in the preparation of urine and swab cultures for incubation. The investigator retrieved all urine and swab specimens from the care areas, transported them to the laboratory within one hour of collection, and plated the samples. Standard plating procedures were used to process the specimens. The plates were incubated at 37° C for 48 hours. All processing was logged on a Laboratory Record Sheet (see Appendix B). Specimens obtained at Site B were plated and incubated by the investigator in the laboratory at Site B. Following incubation, they were transported without delay in ambient temperatures to Site A for reading.

Differential agar plates were used to plate all urine and swab specimens. For each urine specimen, samples of 10 microliters (ul) and 100 ul were obtained with an Eppendorf micropipettor. Each volume and each swab was plated on sheep blood agar and MacConkey agar. Samples were spread on plates with sterile glass spreaders.

All agar plates were read and interpreted by the same laboratory research technician at Site A. Bacterial counts in the urine were expressed as colony forming units per millilitre (cfu/ml) and identified to a genus level with some exceptions, for example, coliforms and yeast. The coded laboratory results, compiled by the laboratory research technician, were delivered to the Medical Microbiologist who retained the results until data collection was complete. Calculations were performed by the investigator.

If a UTI as indicated by clinical symptoms was suspected, the symptoms were documented in a journal by the investigator for consideration at the time of data analysis. Subjects clinically suspected of having a UTI were evaluated by the attending physicians according to standard hospital protocol.

Ethical Considerations

Ethical guidelines of the University of Alberta and those of the two institutions were followed. Subsequent to ethical approval from the Faculty of Nursing, University of Alberta (see Appendix C) and the two institutions, and prior to the commencement of the study, the investigator explained the study and its relevance to the nursing staff on the nursing units, and responded to any questions or concerns regarding the protocol.

The investigator met with each patient (or family member) and explained the nature of the project. If there was agreement to participate, a signed and witnessed consent was obtained (see Appendix D). If the patient was sedated, unconscious, or moderately or severely cognitively impaired, verbal assent was obtained from a close family member or spokesperson and documented on the consent form. In addition proxy consents were obtained from two physicians. If nursing staff obtained the consent, the investigator followed up with the patient or the family member who gave assent to ensure that the consent was understood and that all questions were answered. If there were any 'no' answers as responses to questions asked on the consent forms, the investigator provided more information and explanations to the

family member until either the family member could answer 'yes' to the question or decide not to participate in the study. It was made clear that participation was voluntary and the patient could withdraw at any time without penalty. Confidentiality and anonymity were maintained. Identity of the patients in relation to the data collected is known only to the investigator.

In no situation was the study protocol allowed to interfere with delivery of subject care. There was no harm done to subjects if they participated nor did they benefit directly. Subjects in this study were at no greater risk for infection than others outside the study who had catheters inserted into their bladders. The use of either the O'Neil system or Open system was acceptable protocol.

Data Analysis

The first hypothesis was tested for significance using Fisher's Exact Test (two-tailed). The second and third hypotheses were analyzed using a *t*-test to compare means. The tests were performed for *E. coli*, coliforms and enterococci.

Summary

The study, conducted in two large urban acute care teaching hospitals in Western Canada, was designed to compare the number and types of organisms cultured from urine specimens obtained by two intermittent catheterization systems, the closed O'Neil system and the traditional Open system. Men and women with neurological conditions who met the admission criteria were enrolled in the study and randomly assigned to Group 1 (Experimental Group) or Group 2 (Control Group). Three urine and one urethral meatal swab specimens were collected, with prepackaged supplies, from each subject. The specimens were transported to the laboratory, plated on sheep blood and MacConkey agar plates, and incubated. Fisher's Exact Test (two-tailed) and the *t*-test comparing means were used for statistical analysis.

CHAPTER 4

RESULTS

The purpose of this chapter is to present the results of the study. The characteristics of the sample are described, followed by the results of hypotheses testing. Culture results (number and types) for all urine and swab specimens for male and female subjects are presented. Time 1 results are presented first because only these were used for statistical analysis.

Sample Characteristics

There were 19 subjects on two sites (15 and 4 respectively) initially selected for the study (see Table 3). Nine were from the intensive care unit on the first site, six from one nursing unit on the same site, and four from the nursing unit on the second site. Seven male and two female subjects were assigned to Group 1 (O'Neil system) and seven male and three female subjects to Group 2 (Open system).

The subjects ranged in age from 21 to 78 years. All diagnoses were neurological in origin: Spinal Cord Injury (SCI) - 8 subjects; Closed Head Injury (CHI) - 4 subjects; Traumatic Brain Injury (TBI) - 1 subject; Intracranial Hemorrhage (ICH) - 5 subjects; and Lower Back Injury (LBI) - 1 subject. Sixteen subjects had Foley catheters in place for a period of time. Two subjects did not have Foley catheters: one had problems voiding following a low back injury and one had been on intermittent catheterization since suffering a spinal cord injury years ago.

Table 3

Characteristics of the Original 19 Subjects

Subject	System	Gender	Age	Diagnosis	Location	Hours	IC	Discard urine using O'Neil catheter
#1	O'Neil	M	52	TBI	A-ICU	< 10	N	Yes/RN
#2	O'Neil	F	21	CHI	A-ICU	< 10	N	Yes/RN
#3	Open	M	53	ICH	A-ICU	< 10	N	Yes/RN
#4	Open	F	51	ICH	A-unit	< 10	N	Yes/RN
#5	Open	M	78	ICH	A-ICU	< 10	N	Yes/RN
#6	O'Neil	M	21	CHI	A-ICU	< 10	N	**/RN
#7	Open	M	71	LBI	A-unit	N/A	Y	Yes (not O'Neil)/RN
#8	O'Neil	F	49	ICH	A-ICU	> 10	Y	Yes/**
#9	Open	F	40	SCI	A-unit	N/A	Y	**/**
#10	Open	M	64	SCI	A-unit	> 10	Y	Yes/RN
#11	O'Neil	M	62	CHI	A-ICU	< 10	N	Yes/RN
#12	Open	M	20	SCI	A-ICU	> 10	Y	Yes/**
#13	O'Neil	M	59	SCI	A-unit	> 10	N	Yes/RN
#14	Open	F	41	SCI	A-ICU	> 10	Y	Yes/RN
#15	O'Neil	M	68	ICH	A-unit	< 10	N	Yes/LPN
#A	O'Neil	M	24	SCI	B-unit	**	**	**/**
#B	Open	M	21	SCI	B-unit	< 10	N	Yes (not O'Neil)/**
#C	O'Neil	M	30	SCI	B-unit	> 10	Y	Yes/**
#D	Open	M	32	CHI	B-unit	> 10	Y	Yes/RN

Note. Location: A - first hospital site; B - second hospital site; Hours: Time between removal of Foley catheter and collection of discard urine; IC: Intermittent catheterization performed between time of Foley catheter removal and time discard urine collected (Yes or No); Discard urine: Includes category of staff performing intermittent catheterization; **: Missing data; Shaded lines: Subjects excluded from study after Time 0 (4) and after initial data analysis (4)

Information on the presence or absence of a Foley catheter was missing for one subject.

Ten subjects were not catheterized intermittently between the removal of the Foley catheter and entrance to the study but eight were catheterized while waiting for completion of antibiotic therapy. For one subject this information was missing.

Of the 16 discard urines obtained, 14 were obtained with the O'Neil system and 2 with the Open system. For 3 of 19 subjects, discard urine information was missing. The two Open system discard urines were from subjects who were being catheterized while waiting completion of antibiotic therapy and catheterization volumes were greater than 500 ml. At least 12 subjects were catheterized by RNs and 1 by an LPN.

All 19 subjects remained in the study until after the collection of urine specimens at Time 0 (baseline specimen). At this time four subjects were withdrawn for various reasons. One subject started voiding spontaneously. The second subject stated she forgot about being on the study and let her husband catheterize her twice (long time spinal cord injury who often was catheterized by her husband at home). One specimen collection for the third subject was missed by staff during the night and one specimen collection exceeded the "every three to six hour" time parameter by four hours. In retrospect, perhaps this specimen should have been collected, documented and analyzed with the collection delay in mind.

During the initial data analysis phase, four more subjects were excluded from the study because of consistently high bacterial counts present from the onset of the

study (bacteriuria or UTI) but unknown to the investigator until data collection was complete. Analysis was conducted on data pertaining to the remaining 11 subjects. Group 1 was comprised of six subjects (four male, two female) and Group 2 of five subjects (four male, one female).

Data for analysis

Data from subjects (N=11) for analysis were obtained by:

1. Culture of urine specimens taken at Times 0, 1, and 2. Quantitative counts were reported by the laboratory.
2. Culture of urethral meatal swab specimens at Time 1. Semi-quantitative results were reported.

A total of 33 urine specimens were collected for 11 subjects across Times 0, 1, and 2, and a total of 11 urethral meatal swabs were collected at Time 1. Culture results for all urine specimens and urethral meatal swabs are shown in Table 4.

Tests of Hypotheses

Testing of three hypotheses was based on 11 subjects. The statistical analyses were done on specimens containing coliforms and enterococci only at Time 1. *E. coli* was not identified on any culture.

Table 4

Culture Results of Urine Specimens and Urethral Meatal Swabs from 11 Subjects

		Urine						Meatal Swab	
		Time 0		Time 1		Time 2		Time 1	
	System	Type	Count	Type	Count	Type	Count	Type	Count
1-M	O'Neil		NG		NG	VGS NPN	>[illegible]	CNS	++
2-F	O'Neil	Yeast CNS BHS	$1x10^1$ $1.1x10^2$ $1x10^1$		NG		NG	Yeast Lactobacilli	+++ +++
3-M	Open	Coliforms	$>1x10^3$	Coliforms	$>1x10^3$		NG	Coliforms	++
4-F	Open		NG		NG	CNS	$1x10^1$	CNS	+
7-M	Open	Enterococci	$2.6x10^2$		NG		NG	VGS Enterococci	++ +
8-F	O'Neil	CNS	$1x10^1$		NG		NG	CNS Enterococci Coliforms	++++ ++ +
11-M	O'Neil	Enterococci Diphtheroids	$1x10^1$ $1.1x10^2$		NG	Enterococci	$8.2x10^2$	Coliforms Enterococci Diphtheroids	++ ++ +
15-M	O'Neil		NG		NG		NG	CNS Diphtheroids	++ ++
B-M	Open		NG		NG		NG		NG
C-M	O'Neil		NG		NG		NG	CNS Diphtheroids	+ +
D-M	Open		NG	Pseudomonas Enterococci Yeast	$1.2x10^2$ $8x10^1$ $3x10^1$		NG	Pseudomonas Enterococci Yeast	++ ++ +

Note.
NG - No growth;
Time 0, 1, and 2 results are reported in colony forming units/millilitre (cfu/ml) per agar plate;
Meatal Swab results are semi-quantitative
+ - scant growth;
++ - few colonies;
+++ - moderate growth;
++++ - many colonies;
VGS - Viridans group *Streptococcus* species
NPN - Non-pathogenic *Neisseria* species
CNS - *Staphylococcus* species coagulase negative
BHS - Beta-hemolytic *Streptococcus* species

Testing for Hypothesis 1

There will be a significant difference in the number of bacteria found in the urine of the subjects using the O'Neil system compared with the subjects using the Open system at Time 1.

Number of Organisms. There were 11 specimens cultured. Six of the six O'Neil system specimens did not support any growth compared with two of the five Open system specimens which did support growth. The two specimens supporting growth (see Table 4) were Open system specimens: one at $> 1x10^3$ cfu/ml and one at $1.2x10^2$ cfu/ml. One half of the O'Neil system no-growth specimens (three of six) followed Time 0 specimens that supported growth at a small number of $\leq 1.1x10^2$ cfu/ml. The other three of six followed no-growths at Time 0. Only one of three of the Open system no-growth specimens followed Time 0 specimens that supported growth at a small number of $\leq 2.6x10^2$ cfu/ml. The other two of three followed no-growths at Time 0. None of the specimens collected from female subjects supported growth.

Table 5

Results of Fisher's Exact Test

	System				
	O'Neil		Open		
Organisms	No growth	Growth	No growth	Growth	*p*
Coliforms	6	0	4	1	Not significant
Enterococci	6	0	4	1	Not significant
Total organisms	6	0	3	2	Not significant

Fisher's Exact Test was used to evaluate whether or not the obtained results differed from the hypothesis (see Table 5). For the three tests conducted, the results were not significant at $p < .05$ on the number of organisms cultured from the urine specimens collected from the sample of 11 subjects at Time 1.

Testing for Hypothesis 2

There will be a significant variation in types of bacteria in the urine of subjects using the Open system compared with those using the O'Neil system at Time 1.

Types of Organisms. There were four different organisms appearing in two urine specimens culturing positive (see Table 4). Coliforms were present in one specimen, and pseudomonas, enterococci, and yeast were present in the second specimen.

The independent *t*-test for comparison of means was used to determine if the obtained results differed from expected results specified by the hypothesis. A level of statistical significance at $p < .05$ was not achieved.

Testing for Hypothesis 3

The relationship between the bacteria found at the urethral meatus and in the urine at Time 1 is stronger for the Open system than for the O'Neil system.

Types of Organisms. There were four types of organisms represented in specimens culturing positive at Time 1 for two subjects. Coliforms appeared in the

urine and at the meatus in one subject while pseudomonas, enterococci, and yeast were present in both urine and swab specimens in the second subject (see Table 4).

The independent *t*-test was used to determine if the obtained results differed from expected results (organisms in urine and at the meatus are the same) specified by the hypothesis. While the organisms at the meatus and in the urine were the same for subjects culturing positive at Time 1, a level of statistical significance at $p < .05$ was not achieved.

Urine Specimens at Time 0 and Time 2

While these specimens were not used for statistical analysis, culture results were examined and reported (see Table 4). Of the 11 specimens cultured at Time 0 (all obtained with O'Neil catheters), 5 specimens showed growth. Quantitative counts were $\leq 2.6 \times 10^2$ cfu/ml from four agar plates (yeast, *Staphylococcus* species coagulase negative, beta-hemolytic *Streptococcus* species, enterococci, diphtheroids) and $> 1 \times 10^3$ cfu/ml on one plate (coliforms).

All of the specimens at Time 2 were obtained with the O'Neil system. Two of six of the O'Neil system no-growth results at Time 1 converted to supporting growth at Time 2. One specimen supported a high number ($> 1 \times 10^3$ cfu/ml) and one a moderate number (8.2×10^2 cfu/ml). Four of six specimens remained no-growth. Only one of the five results of Open system specimens taken at Time 2 converted to support any growth. Two of five converted to no-growth at Time 2 and two of two remained no-growth.

Other Observations Regarding Types of Organisms

There was a total of nine different organisms identified in the urine specimens from Times 0, 1, and 2 of 11 subjects (see Table 4). Those that appeared more than once were enterococci (4), *Staphylococcus* species coagulase negative (3), coliforms (2), and yeast (2). Others that appeared once were viridans group *Streptococcus* species, non-pathogenic *Neisseria* species, pseudomonas, diphtheroids, and beta-hemolytic *Streptococcus* species.

Table 6

Frequency of Appearance of Organisms in Urine and in Urethral Swabs for Men and Women

	Men (n = 8)				Women (n = 3)			
	Urine at Times			Urethra	Urine at Times			Urethra
Organisms	0	1	2	Time 1	0	1	2	Time 1
VGS			1*	1*				
NPN			1					
Enterococci	2	1	1	3				1
Diphtheroids	1			3				
Coliforms	1	1		2				1
CNS				3	2		1	2
Pseudomonas		1		1				
Yeast		1		1	1			1
BHS					1			
Lactobacilli								1

Note. VGS: Viridans group *Streptococcus* species; NPN: Non-pathogenic *Neisseria* species; CNS: *Staphylococcus* species coagulase negative; BHS: beta-hemolytic *Streptococcus* species. * - not same subject.

As shown in Table 6, the urine specimens from female subjects cultured *Staphylococcus* species coagulase negative, yeast, and beta-hemolytic *Streptococcus* species. The urine specimens from male subjects cultured enterococci, coliforms, viridans group *Streptococcus* species, non-pathogenic *Neisseria* species, diphtheroids, pseudomonas, and yeast. Urethral swab cultures from men revealed multiple meatal growth more frequently than those from women. One swab from a male subject did not culture any organisms.

Table 7

Organisms Cultured from Urines and Urethra Meatal Swabs

	Same Organisms - Same Subject	Different Organisms - Same Subject	
Subject	Urine and Swab	Urine	Swab
1		VGS, NPN	CNS
2	Yeast	CNS, BHS	Lactobacilli
3	Coliforms		
4	CNS		
7	Enterococci		VGS
8	CNS		Enterococci, coliforms
11	Enterococci, diphtheroids		Coliforms
15			CNS, Diphtheroids
B			
C			CNS, Diphtheroids
D	Pseudomonas, enterococci, yeast		

Note. CNS: *Staphylococcus* species coagulase negative; VGS: Viridans group *Streptococcus* species; NPN: non-pathogenic *Neisseria* species; BHS: beta-hemolytic *Streptococcus* species

In 7 of 11 subjects (see Table 7), some of the organisms at the urethral meatus (Time 1) were the same as in the urine at Times 0, 1, or 2 of the same subjects. The organisms were enterococci (3), *Staphylococcus* species coagulase negative (2), yeast (2), coliforms (1), diphtheroids (1), and pseudomonas (1). However, in 2 of 11 subjects, some organisms cultured in urine were different from those at the urethral meatus at the time of collection.

Summary

A total of 33 urine specimens were collected for 11 subjects across Times 0, 1, and 2 and a total of 11 urethral meatal swabs were collected at Time 1. Fisher's Exact Test was used to statistically analyze results pertaining to Hypothesis 1. The independent *t*-test was used to analyze for Hypotheses 2 and 3. Testing lacked power due to the small sample size and statistical significance was not achieved for any of the hypotheses.

At Time 1 when the two catheterizations were compared, none of the six O'Neil system specimens supported growth while two of five Open system specimens indicated growth. Four different organisms grew on plates from two urine specimens. All swab specimens except one yielded growth. In 7 of 11 subjects, the same organisms were identified from urine and swab cultures.

CHAPTER 5

DISCUSSION

The overall findings of the study are discussed in this chapter. The purpose of the study was to compare two intermittent catheterization systems to determine if one system introduced a fewer number and fewer types of organisms into the bladder than the other system.

Major Findings

Number of Organisms

It was expected that urine specimens from subjects in Group 1 at Time 1 would yield fewer organisms than those from subjects in Group 2. While not statistically significant, the observed results from a small number (n = 11) of urine samples at Time 1 supports the expected result. Of the six Group 1 specimens, none supported growth compared with two of five Group 2 specimens that supported growth. Upon examination of the total number of urine specimens at Times 0, 1, and 2 (O'Neil, n = 28; Open, n = 5), the percentage of O'Neil specimens culturing positive was 29% (8/28) compared with 40% for the Open specimens (2/5). This observation that use of the O'Neil system yields fewer positive cultures than the Open system in a small number of specimens, has clinical significance.

Expected Pattern. One of the two urine specimens with growth at Time 1 (Subject D) fit the expected pattern of activity for the Open system intervention. The expected pattern is that the Time 0 and 2 urine cultures do not support growth

(following intermittent catheterization with the O'Neil system). but the Time 1 urine culture supports growth with the Open system. Not only did this positive growth specimen (Group 2) follow a "no growth" result at Time 0 but it was followed by another "no growth" culture result at Time 2. An alternate explanation is that the culture may represent contamination of the specimen at the time of collection after it was obtained from the subject. Documentation by the investigator at the time of collection indicated a possibility that environmental contamination occurred.

Types of Organisms

It was expected that the types of organisms in bladder urine would be more similar to those at the urinary meatus for subjects using the Open system compared with the O'Neil system. At Time 1, although not statistically significant, two of two specimens culturing positive revealed the same (although not serologically verified) bacteria in the urine and at the urethral meatus. The urine specimen of subject D (Open system) cultured pseudomonas, enterococci, and yeast which were present at the urethral meatus at the time of catheterization. The other urine specimen (Open system) cultured the same bacteria (coliforms) as did the swab of the urethral meatus. These two specimen results (the only two supporting growth at Time 1) support the clinical expectation that organisms in the urine would also likely appear at the urinary meatus in subjects catheterized with the Open system.

Most Prevalent Organisms in Urine Specimens. It was expected that the most common types of bacteria found in the urine and at the urethral meatus would be *E.*

Coli, coliforms, and enterococci based on literature concerning past trends (Widmer, 1994). All of these bacteria may infect men and women. In this study the most commonly occurring bacteria in urine were enterococci in three male subjects (see Table 6). Coliforms appeared in one male subject. *E. coli* did not appear in any of the cultures. In this study, data on these three organisms were collected for statistical analysis. The presence of other organisms, identified by the laboratory, was examined and reported (e.g. *Staphylococcus* species coagulase negative, yeast).

The appearance of enterococci as the most common bacteria in this study is in keeping with a current trend identified in the literature (Gruneberg & Wilson, 1994; Morrison & Wenzel, 1986; Murray, 1990, 1992; Spera & Farber, 1992; Widmer, 1994). A heavy reliance on antibiotic therapy in the recent past may have created a selective pressure on this bacteria primarily in hospital settings. Many bacteria have some intrinsic ability to resist antibiotic effect and they can acquire resistance through a variety of genetic mechanisms. Enterococci, particularly *Enterococcus faecalis* and *Enterococcus faecium*, have managed to overcome virtually every therapy of established value (Murray, 1992) and are implicated frequently in intensive care unit infections related to invasive monitoring (Gruneberg & Wilson). Because resistant organisms are difficult to treat they become more prevalent.

Coliforms are still of a prime concern in hospitals because of the increasing capacity of gram negative bacteria to develop antibiotic resistance. *E. coli*, *Klebsiella pneumonia* are not readily resistant but may become resistant (induced to produce

hydrolysing enzymes) under certain conditions (e.g. exposure to beta-lactamase antibiotics). *Enterobacter, Serratia*, and *Citrobacter* species are intrinsically resistant (Murray, 1992). In addition *Pseudomonas* species, also gram negative, are intrinsically resistant to a majority of antimicrobials.

Other Observations

Other organisms were present in the urine cultures as well. *Staphylococcus* species coagulase negative, known to be prevalent on the skin of healthy humans (usually *Staphylococcus epidermidis*), was cultured three times in female subjects. Unusual organisms cultured were viridans group *Streptococcus* species, non-pathogenic *Neisseria* species, and beta-hemolytic *Streptococcus* species. None of these bacteria were present in the corresponding meatal swabs. The source of viridans group *Streptococcus* species or non-pathogenic *Neisseria* species cultured in one male may be the prostate or reproductive glands. The source of beta-hemolytic *Streptococcus* species in a female subject may be the periurethral glands thought by some to be analogous to the male prostate (Moore & Hira, 1965).

Presence of Investigator

The investigator was present at all urine and swab collections at Site B and assisted or guided the nurses as they performed the catheterization procedures. The presence of the investigator during catheterizations probably enhanced the maintenance of aseptic technique, thereby influencing the consistently culture negative results (89%) at Site B. Comparatively, at Site A where the researcher was

seldom present when specimens were collected, only 15 of 24 specimens (62%) were culture negative. The concern is whether or not correct aseptic and catheterization techniques were used consistently during the procedures at Site A where specimens cultured positive, particularly at Time 0. These results support the efforts to standardize procedures which promotes more consistent performance in carrying out procedures.

Bladder Washout and Bladder Wall Effect

Of the 11 specimens taken at Time 0, all with the O'Neil system, six were culture negative and five were culture positive. All subjects were catheterized intermittently prior to collection of baseline data in attempts to clear the bladder of bacteria remaining following removal of Foley catheters. None of this urine was cultured. The positive cultures at Time 0, with the exception of one ($\leq 2.6 \times 10^2$ cfu/ml) had small counts ($< 1 \times 10^1$ cfu/ml). Further, four of the five culture positive specimens at Time 0 were culture negative at Time 1. It is probable that intermittently catheterizing up to and including baseline specimen collection (Time 0) following Foley catheter removal almost completely cleared the bladder of residual organisms. This clearance may represent the washout effect for each subject. The washout effect minimizes the residual inoculum of bacteria at each catheterization by removing as much contaminated urine as possible on a regular basis (less than six hours apart). Contact with the bladder wall for any remaining small residual

inoculum during the period between Time 0 and Time 1 may have facilitated bacterial destruction before Time 1 testing.

Time 2 Urine Specimens

Two out of six O'Neil system specimens and one out of five Open system specimens at Time 2 supported growth. These results were unexpected. The O'Neil system was used to collect all specimens at Time 2. It was expected that the specimens that were negative at Time 1 would remain negative and the specimens culturing positive with low bacterial counts at Time 1 would also be negative. There are three possible explanations for the results.

The first explanation concerns the culture positive specimen from one case only. Bacteria cultured in the urine were not present at the urethral meatus, which may indicate an alternate source of bacteria such as the prostate or reproductive glands. If these glands were harbouring bacteria, contamination of the proximal urethra would occur prior to catheterization. This may explain the presence of bacteria in the urethra that are different from the urethral meatus. It is unlikely that the source of organisms was the distal urethra since the O'Neil catheter is thought to provide sterile passage through this area. For such a case in which the source of organisms may be the prostate, either the Open or O'Neil catheter system could contaminate the urine yielding the same positive culture result. Secondly, the staff collecting the specimen may not have been instructed as to how to retrieve a sterile specimen from the collection bag. If the correct way is not known, the only option is

to tear the plastic bag along a perforated line and pour from the opening. If the opening is harbouring any bacteria transmitted from the hands of the worker while tearing the bag, these environmental bacteria could contaminate the specimen during the action of pouring urine into a specimen bottle. Lastly, each specimen may represent bacterial content of the bladder urine at the time of catheterization following introduction of bacteria sometime earlier.

Progression from Meatus to Bladder Urine

In some subjects, organisms appear at the meatus but not in urine (see Table 7). This observation supports the notion that mere presence of organisms in periurethral areas is not itself a risk factor (Schlager et al., 1993). However, presence of pathogens in combination with cellular defect may be a risk factor. Fowler and Stamey (1977) suggest that in women under normal circumstances, coliforms must compete with commensal flora which adhere avidly to vaginal cells. A defect in vaginal cell structure may permit pathogens to adhere more easily and commensal flora less easily. Perhaps a cellular deficit in uroepithelial cells, rather than mere presence of organisms, more critically determines whether or not pathogens present at the urinary meatus will progress from the meatus to bladder urine thereby increasing the risk of UTI.

Limitations

There are three major limitations to this study; study design, sample size, and staff participation.

Study Design

The closed O'Neil system was used both as a strategy to provide internal control (by reducing the number of organisms in bladder urine of both control and experimental participants prior to the time when the intermittent catheterization systems were compared) and as a system to be experimentally tested at Time 1. This action may have contributed to minimizing the difference between the Open and O'Neil system results.

Variables impacted the study. Subject variables such as restlessness during the Open system catheterization procedure were difficult to control and may have contributed to environmental contamination of specimens on collection. In addition, variables such as infections in physiological systems other than the urinary system that required antibiotic treatment, interfered with the eligibility of participants which ultimately affected the total number of subjects obtained. Variables such as age, gender and neurogenic or non-neurogenic bladder status were not matched. Matching may have provided more insight into how these variables related to host defenses. Other variables may also limit the study results. As an example, the povidone-iodine preparation, used in cleansing procedures for both systems, may have been bactericidal to flora in the distal urethra, or to bacteria carried by the catheter toward

the bladder. If fewer bacteria reach the bladder, this result could be attributed to the povidone-iodine and not the catheterization system.

Identification of bacteria on culture was restricted. Only those considered most common (*E. coli*, coliforms, enterococci) were identified fully in order to control laboratory costs. Data recorded for organisms not identified fully could not be used for statistical analysis or for comprehensive clinical reporting. Consequently it was not possible to create a comprehensive profile of organisms present.

While the investigator performed all functions relating to specimen preparation in the laboratory to maintain consistency in procedures, she was not able to be present at all catheterizations to provide guidance to staff in order to ensure consistency in performance of the catheterization procedure. Inconsistent collection technique may decrease the quality of specimens obtained and subsequently cultured. The investigator was not employed at either site so performing any study function meant a special trip to the study site at various times of day. Processing specimens during the night, for example, was particularly disruptive to sleep patterns. Any special trip was time consuming (averaged 30 minutes one way from home or 15 minutes from place of employment) and costly (automobile gasoline and parking).

Sample Size

The sample was too small to detect a statistically significant difference between the number or types of bacteria in the urine of subjects using the O'Neil or Open systems. It was intended that at least 40 subjects, 20 in each group with male

and female subjects equally represented, be enrolled in the study but for various reasons, only 11 subjects were eventually studied. There were more male than female subjects in the study which may minimize the apparent impact of intermittent catheterization on the bladder urine of women. Attrition of subjects, because of return of spontaneous voiding or staffing workloads in relation to missed specimens, contributed to the small sample size. The decision to withdraw subjects, with apparent bacteriurias at the beginning of the study, after data collection was complete further lowered the sample size.

Of those patients who were anticipated to need intermittent catheterization, many were excluded before getting to the consent stage. Three uncontrolled diabetic patients were not included because of the three fold increased risk of UTI (Stamm et al., 1977). However, in retrospect they should have been included because they met the eligibility criteria. Two other potential subjects did not wish to participate, and at least 32 potential subjects were transferred over the nine month period from the intensive care unit to non-study care areas before subject selection was complete.

Staff Participation

Staff unfamiliar with the O'Neil system (e.g. float staff) may have been asked by other staff to perform catheterizations with very little instruction. Of particular concern here is the lack of knowledge about how to obtain a sterile specimen from the system. Consistency in specimen collection technique may have been

compromised because many different people collected specimens during the catheterizations.

Breaks in aseptic technique during catheterization procedures may have occurred threatening the quality of specimens collected. For example, opening the povidone-iodine swab packages for use in cleansing procedures with the O'Neil system proved to be awkward and messy so the swabs may not have been used properly or in a consistent manner during precatheterization cleansing. Another example is contaminating the specimen during collection by pouring from an unsterile port.

Conclusions

Two conclusions are drawn relating to the number and types of organisms.

Number of Organisms

While not statistically significant, observations made on a small subject sample during this study suggest that bladder urine remains free of organisms following intermittent catheterization with the closed O'Neil system more often than following intermittent catheterization with the traditional Open system. Organisms were absent in urine after use of the O'Neil system at Time 1 while organisms were present in two urine specimens after use of the Open system. Control is exercised over the number of bacteria introduced to the bladder urine at any one time if a protected-catheter system is used. Emptying the bladder at regular three to four hour

intervals (especially during the day) through intermittent catheterization, leaving minimal residual urine contributes to this control.

Types of Organisms

While not statistically significant, observations made from meatal cultures from a small sample support the notion that bacteria present at the meatus may be the same as those found in bladder urine following intermittent catheterization with the Open system. Organisms at the meatus may be representative of those in the distal urethra. None of the O'Neil system urine specimens supported growth which supports the view that if using a closed system, the presence of any organisms in the distal urethra or at the meatus is of minimal consequence.

Recommendation

It is recommended that a closed or self-contained intermittent catheterization system such as the closed O'Neil system be used as the standard for intermittent catheterization in acute care hospitals (exceptions to be made based on individual needs of the patients). The results of this study suggest that, clinically, the risk of causing a UTI related to intermittent catheterization using the O'Neil system is no worse than, and may be much less than using the Open system. The O'Neil system is also cost effective. At the time of the study the direct cost to use the O'Neil system was $0.90 less than to use the Open system (Open - $3.52; O'Neil - $2.62).

Implications for Practice

The practice of Nursing is a changing practice accommodating insights gained from both planned inquiry and serendipitous events. The anticipated results of this study support the view that use of the O'Neil system yields fewer positive cultures than the Open traditional system thereby reducing the risk of UTI. It is conceivable that, if the O'Neil system is the standard system used for intermittent catheterization and correct technique is consistently performed by users, the risk and ultimately the rate of UTIs in hospitalized patients may be reduced even further benefiting the patient, the health care system, and third party payers. Minimizing the risk of infection also reduces the risk of escalating the emergence of antibiotic resistant organisms.

The unanticipated insights gained stem from the literature search and observations not directly related to the research questions. For example, it was observed that specimens collected in the presence of the investigator cultured fewer organisms. This observation supports the view that the immediate presence of resource people that can readily provide staff with information and reinforce correct technique has a direct impact on the outcome of patient care. An observation possibly relating the low bacterial counts at Time 0 to the bladder wall and bladder washout effect brings forward once again the importance of three notions. The first is the scheduling of intermittent catheterizations based on physiological need rather than convenience in care planning. The second is the importance of minimizing the number of organisms in the bladder urine by deliberately balancing a planned intake

of fluids (high urinary flow) with a toileting or intermittent catheterization schedule that reduces bacterial concentrations at any one time. The third is to regularly empty the bladder, avoiding distention which interferes with blood supply to the bladder wall, threatening its integrity.

The notion that cell structure defect in the presence of pathogens may permit and facilitate adherence of pathogens to vaginal cells and perhaps also uroepithelial cells, reinforces to nurses that while mere presence of organisms at the meatus is not in itself a high risk factor, reducing the number of pathogens present at any one time remains desirable. Thorough handwashing, sound hygienic practice in patient and personal care, and protection of the immediate environment are fundamental in minimizing exposure of compromised patients to threatening organisms in the external environment.

Through documentation by the investigator of an incident at a collection time of an Open system specimen, it was indicated that environmental contamination may have occurred. The observation of this incident supports the view that catheterization supplies exposed or open to the external environment (external space surrounding subject including bedclothes and hands of the nurse) are susceptible to inadvertent environmental contamination. Specimens obtained with these supplies may yield false positive culture results. In such a case, the threat of contamination is not direct but indirect for the patient. A false positive culture result may lead to unnecessary antibiotic treatment. This treatment contributes to the escalating presence of antibiotic resistant organisms.

Further Research

Three issues arising from observations during the study should be considered for further investigation.

Environmental Contamination

Specimen contamination during collection should be averted. Sterile supplies exposed to the open external environment are more susceptible to contamination. If coupled with unintentional delays in sending urine specimens (urine in a container) to the laboratory for processing, contamination may result in false positive bacterial growth. False positive growth may contribute to unnecessary administration of antibiotics which contributes to the growing problem of antibiotic resistance. A similar nursing study but with a larger sample may provide evidence that self enclosed sterile catheters which tend to be more user friendly, particularly for short term application in acute care settings, may afford protection against false positive growth in urine specimens. Avoiding false positive growths would benefit the patient (fewer antibiotics administered), the laboratory (improved quality of specimens collected and decreased laboratory costs), and the health care system (e.g. shorter length of patient stay).

Balance between Bladder and Urine Activity

Balance among fluid intake and output, dynamics of urinary flow, integrity and antibacterial activity of the bladder wall, and chemical composition of the urine is important to nursing practice. The benefits of avoiding distension and minimizing the size of a residual inoculum warrants further examination in relation to planning nursing interventions. A nursing study should be conducted comparing conventional practices (balancing fluid intake and output with urinary elimination) with a planned modified practice to maintain high urinary flow, systematic urinary washout, and minimal residual volumes or residual inoculum in relation to the risk of UTI. A study like this would enhance the development of nursing strategies (including intermittent catheterization) designed to protect against urinary tract infection and to support optimal biophysical urinary tract function.

Minimizing UTIs with Pathogens that are Difficult to Treat

Another study, similar to the present one which examines the infecting agent aspect of the infection equation, may reveal that recurrent UTIs caused by pathogens known to colonize in patients with previous infections (e.g. *Proteus* species, *Pseudomonas* species) and known to be difficult to treat could be averted or minimized through the use of shielded catheters. This study may contribute to standardizing nursing practice in the use of sterile catheterization procedures when in hospital or institutional environments. Morbidity and perhaps mortality would

decrease in specific populations, for example, people suffering from spinal cord injury.

Summary

The O'Neil system is likely more effective at restricting bacterial inoculations into the urine to a small number, or preventing any inoculation, than the Open system. This information enriches the theoretical and practical nursing knowledge base that contributes to the positive clinical client outcome of preventing or reducing risk of UTI in short term management of urinary retention in acutely ill patients.

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NURSING RESEARCH PROJECT - COMPARISON OF TWO INTERMITTENT CATHETERIZATION SYSTEMS
RESEARCHER: MARILYN ALBERS, PAGER 445-5952
RESEARCH ASSISTANT: MARCY ALBERS, PAGER 445-3736

FLOW SHEET FOR OPEN (TRADITIONAL) SYSTEM

NOTE: (1) Page Marilyn (445-5952) or Marcy (445-3736) just prior to collecting specimens. One of them will come in to process the specimen in the lab.
(2) Prepackaged study supplies found at bedside or in Clean Utility Room.

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
Foley out	First I/O cath following foley removal - Use O'Neil cath and discard urine (clears bacteria post foley)	TIME 0 Next I/O cath (3-6 hrs post last I/O cath and may be residual urine) - Use O'Neil cath and save sterile urine specimen - Label specimen with . subject name . Time 0 (baseline) . time taken . indicate if residual urine - Put urine specimen in biohazard bag for transport to lab by researcher	TIME 1 Next (consecutive) I/O cath (3-6 hrs post last I/O cath and may be residual urine) 1. Collect swab specimen prior to precath cleansing (twirl swab directly over meatal opening) 2. Cleanse 3. Use cath tray and straight cath; save sterile urine specimen - Label with . subject name . Time 1 . time taken . indicate if residual urine - Put urine and swab specimens in biohazard bag for transport to lab by researcher	TIME 2 Next (consecutive) I/O cath (3-6 hrs post last I/O cath and may be residual urine) - Use O'Neil cath and save sterile urine specimen - Label with . subject name . Time 2 . exact time taken . indicate on label if residual urine - Put urine specimen in biohazard bag for transport by researcher
Date _____, Time _____, & Initial _____	Date _____, Time _____, & Initial _____	Date _____, Time _____, & Initial _____	Date _____, Time _____, & Initial _____	Date _____, Time _____, & Initial _____

/jpio
Albers.001/L
26 Jun 95

NURSING RESEARCH PROJECT - COMPARISON OF TWO INTERMITTENT CATHETERIZATION SYSTEMS
RESEARCHER: MARILYN ALBERS, PAGER 445-5952
RESEARCH ASSISTANT: MARCY ALBERS, PAGER 445-3736

FLOW SHEET FOR CLOSED (O'NEIL) SYSTEM

NOTE: (1) Page Marilyn (445-5952) or Marcy (445-3736) just prior to collecting specimens. One of them will come in to process the specimen in the lab.
(2) Prepackaged study supplies found at bedside or in Clean Utility Room.

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
Foley out	First I/O cath following foley remov - Use O'Neil cath and discard urine (clears bacteria post foley)	TIME 0 Next I/O cath (3-6 hrs post last I/O cath and may be residual urine) - Use O'Neil cath and save sterile urine specimen - Label specimen with . subject name . Time 0 (baseline) . time taken . indicate if residual urine - Put urine specimen in . biohazard bag for transport to lab by researcher	TIME 1 Next (consecutive) I/O cath (3-6 hrs post last I/O cath and may be residual urine) 1. Collect swab specimen prior to precath cleansing (twirl swab directly over meatal opening) 2. Cleanse 3. Use O'Neil cath and save sterile urine specimen - Label with . subject name . Time 1 . time taken . indicate if residual urine - Put urine and swab specimens in biohazard bag for transport to lab by researcher	TIME 2 Next (consecutive) I/O cath (3-6 hrs post last I/O cath and may be residual urine) - Use O'Neil cath and save sterile urine specimen - Label with . subject name . Time 2 . exact time taken . indicate on label if residual urine - Put urine specimen in biohazard bag for transport by researcher
Date _____, Time _____, & Initial _____	Date _____, Time _____, & Initial _____	Date _____, Time _____, & Initial _____	Date _____, Time _____, & Initial _____	Date _____, Time _____, & Initial _____

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26 Jun 95

NURSING RESEARCH PROJECT - COMPARISON OF TWO INTERMITTENT CATHETERIZATION SYSTEMS
RESEARCHER: MARILYN ALBERS, BEEPER 445-5952

LABORATORY RESULTS

SUBJECT NUMBER _____

SPECIMEN	COLLECTION			READING DATE	RESULTS Record quantitative counts		
		DATE	TIME		10 UL	100 UL	ORGANISM(S)
Urine	0						
Urine	1						
Urine	2						

SPECIMEN	COLLECTION			READING DATE	RESULTS	
		DATE	TIME		COUNT	ORGANISM(S)
Swab	1					

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12 Dec 94

Appendix B

LABORATORY RECORD SHEET

Appendix C

ETHICS APPROVAL

University of Alberta
Edmonton
Canada T6G 2G3

Faculty of Nursing
3rd Floor Clinical Sciences Building

Certification of Ethical Acceptability for Research Involving Human Subjects

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NAME OF APPLICANT(S): Marilyn Albers, MN Candidate

TITLE OF PROJECT: "A Comparison of Two Intermittent Catheterization Systems: Closed O'Neil System and the Traditional Open System"

The members of the review committee, having examined the application for the above-named project, consider the procedures, as outlined by the applicant, to be acceptable on ethical grounds for research involving human subjects.

Sept. 6, 1994
Date

Greta Olinyk, RN, MEd
Acting Chair
Ethics Review Committee

The Ethics Review Committee is a Joint Committee of
The Faculty of Nursing, University of Alberta
and
The Nursing Division, University of Alberta Hospitals

Appendix D

CONSENT FORM
Study Information Sheet For the Research Subject
A Comparison of Two Catheter Systems:
The Traditional Open System and the O'Neil Closed System

Purpose: Presently your bladder is emptied through a catheter every 4-6 hours or as needed. You are being asked to participate in a research study that compares two catheters. Both catheters are presently being used by staff. We want to find out if there is less risk of infection to the patient when using one catheter compared with using another catheter.

Procedure: If you participate, you have an equal chance of being assigned to either of the two ways to collect urine from your bladder. You will not be able to choose the way to collect the urine. Staff will save three urine samples for testing. Staff will also save three samples taken with cotton swabs from the skin surface near where the catheters are inserted. These procedures for collecting samples are not painful. The samples will be collected over a two day period (48 hours).

Participation: There will be no harm to you if you participate in this study nor will you benefit directly. Results from the study will help nurses determine which catheter is safer for use with patients in the future. Participation is voluntary. Your continuing medical care will not be affected in any way if you decide not to participate. You are free to withdraw from the study at any time by telling the researcher. If you develop an infection, your doctor will decide how to treat the infection.

Confidentiality: All information recorded about you or the samples collected will be kept confidential. No information will be released that identifies you. Data may be used in the future, if the researcher receives approval from the appropriate ethical review committee. The findings of this study may be published or presented but your name will not be used. All records will be kept in a locked cupboard separate from consent forms. Consent forms will be destroyed in five years (or a full calendar year after completion of the study). The records will be destroyed seven years after the study is complete.

We would be pleased to answer any questions you have about the study. Please contact either of the persons named below if you have any questions or concern:

Marilyn Albers, Co-Investigator (RN, MN Candidate, Faculty of Nursing)
Pager (24 hours) 445 5952 Telephone 459 6380

Marcy Albers, Res. Assistant (BScN) Pager (24 hours) 445 3736

Rene Day, Principal Investigator (RN, PhD, Faculty of Nursing-U of A)
Telephone 492 6481

CONSENT FORM
(TO BE COMPLETED BY THE RESEARCH SUBJECT)

Title of Project: **A COMPARISON OF TWO INTERMITTENT CATHETERIZATION SYSTEMS: CLOSED O'NEIL SYSTEM AND THE TRADITIONAL OPEN SYSTEM**

	Yes	No
Do you understand that you have been asked to be in a research study?	/___/	/___/
Have you read and received a copy of the attached Information Sheet?	/___/	/___/
Do you understand the benefits and risks involved in taking part in this research study?	/___/	/___/
Have you had a chance to ask questions and discuss this study?	/___/	/___/
Do you understand that you are free to withdraw from the study at any time without having to give a reason and without affecting your future medical care?	/___/	/___/
Has the issue of confidentiality been explained to you, and do you understand who will have access to your study information?	/___/	/___/

Who explained this study to you? _____

I agree to take part is this study: Yes /___/ No /___/

Signature of Research Subject _____

(Printed Name) _____

Date _____

Signature of Witness _____

Signature of Researcher or Designee _____

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH SUBJECT

PROXY CONSENT FORM
(TO BE SIGNED BY TWO PHYSICIANS)

Title of Research Project: **A COMPARISON OF TWO INTERMITTENT CATHETERIZATION SYSTEMS: CLOSED O'NEIL SYSTEM AND THE TRADITIONAL OPEN SYSTEM**

Principal Researcher: Dr. Rene Day, Bscn, PhD
Faculty of Nursing, University of Alberta
Telephone 492 6785

Co-Investigator: Marilyn Albers, RN, MN Candidate
Faculty of Nursing
PAGER 445 5952 Telephone 459 6380

We acknowledge that this patient _____ qualifies for participation in the above study. We acknowledge that we know the patient's clinical status and that there are no medical contraindications or exclusion criteria* to enrolling the patient.

_____ _____
Print Name of Physician No. 1 Signature

_____ _____
Print Name of Physician No. 2 Signature

Date: _____

Was a close family member or other appropriate individual able to be informed of the patient's enrollment in this study?
Yes /____/ No /____/

If yes, name of member is