CLEAN TECHNIQUE INTERMITTENT CATHETERIZATION AS AN ALTERNATIVE TO THE INDWELLING URETHRAL CATHETER

Christine Heuston Lessels

Follow this and additional works at: https://scholarscompass.vcu.edu/etd

Part of the Nursing Commons

© The Author

Downloaded from
https://scholarscompass.vcu.edu/etd/5137
This is to certify that the thesis prepared by Christine Heuston Lessels entitled **Clean Technique Intermittent Catheterization as an Alternative to the Indwelling Urethral Catheter** has been approved by her committee as satisfactory completion of the thesis requirement for the degree of Master of Science.

Director of Thesis

Committee Member

Committee Member

Committee Member

School Director of Graduate Study

Department Chairman or Representative

School Dean

Date **12-12-80**
CLEAN TECHNIQUE INTERMITTENT CATHETERIZATION AS AN ALTERNATIVE TO THE INDWELLING URETHRAL CATHETER

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science at Virginia Commonwealth University

By

Christine Heuston Lessels
B.S.N., Medical College of Virginia,
Virginia Commonwealth University, 1973

Director: Ethelyn E. Exley, R.N., Ed.D.
Associate Professor
Medical-Surgical Nursing

Medical College of Virginia
Virginia Commonwealth University
Richmond, Virginia
December, 1980
ACKNOWLEDGEMENTS

The investigator expresses sincere thanks and appreciation to the following persons for their interest, support and expert guidance during the preparation of this thesis:

Ethelyn E. Exley, R.N., Ed.D.
Associate Professor, Medical-Surgical Nursing
School of Nursing, Medical College of Virginia
Virginia Commonwealth University

Phyllis S. Tyzenhouse, R.N., DrPH
Chairman, Department of Community Health Nursing
School of Nursing, Medical College of Virginia
Virginia Commonwealth University

M. J. Vernon Smith, M.D., Ph.D.
Professor of Urology
School of Medicine, Medical College of Virginia
Virginia Commonwealth University

C. Glen Mayhall, M.D.
Assistant Professor, Infectious Diseases
School of Medicine, Medical College of Virginia
Virginia Commonwealth University
To my mother for the gift of enthusiasm for learning

To my husband for teaching me the value of having patience and faith.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>LIST OF TABLES</th>
<th>vi</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chapter</td>
<td></td>
</tr>
<tr>
<td>1. INTRODUCTION</td>
<td>1</td>
</tr>
<tr>
<td>Purpose</td>
<td>4</td>
</tr>
<tr>
<td>Research Questions</td>
<td>4</td>
</tr>
<tr>
<td>Definition of Terms</td>
<td>5</td>
</tr>
<tr>
<td>Conceptual Framework</td>
<td>6</td>
</tr>
<tr>
<td>Assumptions</td>
<td>7</td>
</tr>
<tr>
<td>Delimitations</td>
<td>8</td>
</tr>
<tr>
<td>Limitations</td>
<td>8</td>
</tr>
<tr>
<td>2. REVIEW OF THE LITERATURE</td>
<td>9</td>
</tr>
<tr>
<td>Introduction</td>
<td>9</td>
</tr>
<tr>
<td>Incontinence</td>
<td>9</td>
</tr>
<tr>
<td>The Indwelling Urethral Catheter</td>
<td>18</td>
</tr>
<tr>
<td>Intermittent Catheterization</td>
<td>22</td>
</tr>
<tr>
<td>Summary</td>
<td>32</td>
</tr>
<tr>
<td>3. METHODOLOGY</td>
<td>34</td>
</tr>
<tr>
<td>Introduction</td>
<td>34</td>
</tr>
<tr>
<td>Subjects</td>
<td>35</td>
</tr>
<tr>
<td>Setting</td>
<td>36</td>
</tr>
<tr>
<td>Procedure</td>
<td>37</td>
</tr>
<tr>
<td>Summary</td>
<td>39</td>
</tr>
<tr>
<td>4. CASE STUDIES</td>
<td>40</td>
</tr>
<tr>
<td>Introduction</td>
<td>40</td>
</tr>
<tr>
<td>Patient Number One</td>
<td>40</td>
</tr>
<tr>
<td>Discussion</td>
<td>48</td>
</tr>
<tr>
<td>Patient Number Two</td>
<td>51</td>
</tr>
<tr>
<td>Discussion</td>
<td>57</td>
</tr>
<tr>
<td>Patient Number Three</td>
<td>59</td>
</tr>
<tr>
<td>Discussion</td>
<td>71</td>
</tr>
<tr>
<td>Chapter Summary</td>
<td>74</td>
</tr>
</tbody>
</table>
Chapter 5. SUMMARY, CONCLUSIONS, IMPLICATIONS AND RECOMMENDATIONS.

Summary .................................................. 75
Conclusions ............................................... 76
Implications for Nursing Practice .................. 77
Recommendations ......................................... 77

SELECTED BIBLIOGRAPHY .................................. 81

APPENDICES

A. Chart of Types of Neurogenic Bladder Dysfunction ..................... 89
B. Annotated Bibliography of Studies Using Sterile Technique Intermittent Catheterization ............... 92
C. Physician Order Form .................................... 98
D. Patient Consent Form .................................... 100
E. Fluid Intake and Output Record .......................... 102
F. Instructional Booklet on Clean Technique Intermittent Catheterization .................. 104
G. Protocol for Clean Technique Intermittent Catheterization .......... 107
H. Method for Urinalysis .................................. 110
I. Catheter Clamping Procedure ........................... 113
J. Approval Form .......................................... 115

VITA .............................................................. 116
LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Urinalysis and Culture Results - Patient Number Two.</td>
<td>58</td>
</tr>
<tr>
<td>2. Urinalysis and Culture Results - Patient Number Three.</td>
<td>74</td>
</tr>
</tbody>
</table>
Chapter 1

INTRODUCTION

Research has documented numerous risks and complications in the use of indwelling urethral catheters. In spite of this, indwelling catheters are still widely used for the management of incontinence.

During the past four decades, studies have shown that incontinence can be managed or resolved in many patients by using intermittent catheterization. Early investigators used elaborate sterile technique and included only patients with neurogenic bladder as a result of spinal cord injury. Later studies showed favorable results in patients with incontinence of non-traumatic etiology—even in patients previously dependent on an indwelling urethral catheter.

---


catheter. The early literature on sterile technique occasionally mentioned teaching self-catheterization to those patients capable of learning the aseptic procedure, but this was apparently uncommon.

In 1972, Lapides introduced the use of clean technique intermittent self-catheterization for the treatment of a diversity of bladder dysfunctions. The results were equivalent bacteriologically to those with sterile technique and the simplicity of the procedure made it convenient and acceptable to many patients.

During three years experience as a staff nurse in a visiting nurse association, the investigator worked with numerous patients who used indwelling urethral catheters on a permanent or semi-permanent basis and to whom nursing visits were made solely for the purpose of changing the catheter. Frequently, the catheter had been placed for

---


incontinence without urodynamic evaluation. In many cases, the individuals caring for the patient in the home were responsible and competent.

The investigator read about Lapides' research as part of graduate education and was impressed with positive results obtained even when the patient had lengthy previous dependency on an indwelling catheter.\(^7\) The investigator questioned whether there were patients with indwelling catheters living at home for whom this alternative had been overlooked and whether some of the competent care-takers could be taught the procedure in cases where the patient was not a candidate for self-catheterization.

Numerous benefits would result if a patient were freed of an indwelling urethral catheter by using intermittent catheterization: the costs of sterile equipment, personnel and transportation involved in catheter changes would be eliminated; the nurses' time would be freed for other responsibilities; medical complications and their inherent costs would be averted; and freedom from tubing and bag would permit greater mobility for the patient and simpler handling by the family.

An investigation was planned to examine the relationship between bacteria in the urine and the use of clean technique intermittent catheterization when used following

removal of an indwelling catheter. Previous research demonstrated that, in the absence of symptoms, microscopic visualization of bacteria in fresh, centrifuged urine sediment was highly predictive of growth on culture of 100,000 or more colonies per milliliter (ml.). Robins et al. suggested that the reliability of microscopy for predicting positive culture results was further enhanced by visualizing leukocytes as well as bacteria. Since the procedure of microscopic examination is inexpensive and can easily be learned by nurses, this test could be useful in monitoring bacteriuria in asymptomatic patients using clean technique intermittent catheterization.

**Purpose**

The purpose of this study was to determine whether clean technique intermittent catheterization performed by the patient or a competent care-taker was a safe alternative for adult patients with indwelling urethral catheters living at home.

**Research Questions**

The research questions addressed in this study were:

---


1. Does the substitution of clean technique intermittent catheterization for a chronic indwelling urethral catheter influence asymptomatic bacteriuria?

2. Was there a relationship between the visualization of bacteria and leukocytes on microscopic exam of fresh, centrifuged urine sediment and asymptomatic bacteriuria?

**Definition of Terms**

**Clean technique intermittent catheterization** was a protocol based on principles derived from the literature. The procedure described the insertion of a catheter into the urinary bladder to remove urine. The procedure was performed using a clean rather than sterile technique (Appendix G).

**Selected patients** referred to patients who met specific criteria related to personal circumstances and urinary tract status (see Chapter 3).

**Asymptomatic bacteriuria** was defined as urine from a patient with no clinical manifestations of urinary tract infection (fever, chills, nausea, vomiting, flank pain) which yielded results on culture of greater than or equal to 100,000 bacterial colonies per milliliter.

**Normal renal function** was assumed if normal blood urea nitrogen (6 to 22 mg/100 ml) and serum creatinine (0.4 to 1.4 mg/100 ml) values were obtained within one month.
prior to beginning the program of clean technique intermittent catheterization.

Conceptual Framework

In 1957, Kass and Shneiderman\textsuperscript{10} noted strong evidence that catheter insertion introduced bacteria into the bladder. However, urinary tract infections were much less common following single catheterization than following constant drainage by an indwelling urethral catheter. Their studies showed that bacteria applied to the periurethral epithelium of patients with indwelling catheters appeared in large numbers on urine culture within three days. They postulated that the bacteria ascended through the thin space between the catheter and the urethral mucosa which inevitably filled with greyish-green fluid within 24 hours of catheter placement and provided an ideal medium for bacterial multiplication and spread. More recent studies\textsuperscript{11} have confirmed that the periurethral space is the major pathway for bacterial entry into the urinary bladder.


Research by Cox and Hinman\textsuperscript{12} showed that the normal bladder was inherently resistant to infection. This resistance, which they called the "bladder defense mechanism" was the result of two factors: bladder emptying, and the destruction of bacteria by an antibacterial action of the bladder.

The study presented in this thesis was designed to test whether by removing the indwelling catheter and emptying the bladder at regular intervals by clean technique intermittent catheterization and/or natural voiding, the bladder defense mechanism would influence the occurrence of asymptomatic bacteriuria.

Orem stated that,

\begin{quote}
Nursing's health dimension is derived from its self-care focus. Self-care, if it is to be positively therapeutic, helps sustain life processes, maintain integrated functioning, promote normal growth and development, and prevent or control disease and disability and their effects.\textsuperscript{13}
\end{quote}

In this study, patients were taught the self-care measures involved in clean technique intermittent catheterization to prevent the complications and disability associated with an indwelling urethral catheter.

\textbf{Assumptions}

The investigator made the following assumptions in conducting this study:


1. An interim of two hours between specimen collection and culture or urinalysis would not permit a significant distortion in or among results.

2. The investigator was competent in performing microscopic exam of urine.

3. Results of urine cultures reflected accurate measurement of bacteria in the urine.

4. Blood urea nitrogen and serum creatinine levels were an adequate measurement of renal function.

**Delimitations**

The delimitations imposed on the study were:

1. The sample was delimited to patients receiving services within a three-month time period and to patients living within the metropolitan area.

2. Long-term follow-up was not done.

3. Only a small number of adult patients were accepted into the study; therefore, results could not be generalized to other populations or age groups.

**Limitations**

The study was limited by the following conditions:

1. The urodynamic status of the patients was unknown.

2. The intervention procedure was highly individualized because of inherent patient differences. The case study approach used facilitates the individualization of care but does not result in comparable data between cases.
Chapter 2

REVIEW OF THE LITERATURE

Introduction

The review of literature was divided into sections on incontinence, the indwelling urethral catheter, and intermittent catheterization. The purpose of the first section was to present a brief overview of incontinence and its causes, thereby providing a profile of the individual who is a candidate for having an indwelling urethral catheter. The second section reviewed risks and complications associated with the indwelling catheter and presented the varying views on indications for its use. The final section gave a brief history of the use of intermittent catheterization and detailed the pioneering work of Dr. Ludwig Guttmann. It concluded with a review of research by Lapides and others on the safety of using a non-sterile technique for this procedure.

Incontinence

The indwelling urinary catheter plays an essential role in modern medical care. According to Kunin,¹ it is

widely used to relieve temporary anatomic or physiologic urinary obstruction, facilitate healing following surgery involving the urethra or surrounding structures, provide a means by which urinary output can be measured accurately in seriously ill patients, and maintain a dry environment for comatose or incontinent patients. It was reasonable to assume that management of incontinence was the most likely reason for an indwelling urethral catheter to be placed in the patient living at home.

Urinary incontinence was defined as "failure of voluntary control of the vesical and urethral sphincters, with constant or frequent passage of urine."\(^2\) A very common etiology of incontinence is neurogenic bladder.\(^3\) In order to understand the basic types of neurogenic bladder, one must first understand normal micturition.

Simply stated, micturition occurs as follows: the muscular bladder wall contains stretch receptors; these nerve endings respond to the expanding volume of urine in the bladder by sending sensory impulses to the sacral bladder center at \(S_2-4\). From the sacral bladder center, motor fibers return to the bladder wall causing a contractile response during which the urine is expelled through the


urethra. This forms the spinal reflex arc which can be effective in emptying the bladder but is without voluntary control. Voluntary control of micturition comes from the cortical bladder center in the frontal cortex. Impulses reach the cortical bladder center by passing through the sacral bladder center. More specifically, the sensation of bladder filling is passed to the cortex by way of afferent fibers from the sacral bladder center. The cortex then interprets the signal in terms of whether or not the time is appropriate for voiding; if it is not, an inhibitory signal is sent to the sacral center by efferent tracts, effectively interfering with the reflex arc and postponing urination. When the time is appropriate, the cortical bladder center sends impulses to the bladder via the sacral center initiating the relaxation of the external sphincter and stimulating bladder wall contraction.4

Neurogenic bladder dysfunction was divided into the general categories of upper motor neuron lesions and lower motor neuron lesions. Each general category consists of several bladder types according to the exact site of the lesion. The types described are simplified models to aid understanding. In a clinical situation, lesions are frequently of mixed types.5 A chart in Appendix A provides a

4Ibid.
reference list of the types of neurogenic bladder and associated etiologies.

Upper motor neuron bladders are of either the uninhibited or reflex types. Both involve lesions above the sacral cord center, thus leaving the spinal reflex arc intact.

In the uninhibited neurogenic bladder, there is interruption of the inhibitory signals from the cortex. Sensations of frequency and urgency are present, but the individual lacks the ability to postpone micturition voluntarily because of the absence of reflex arc inhibition. Therefore, small volumes of urine are expelled frequently with little time lapse between perceived sensation of urgency and actual voiding. This is quite common in older individuals with cerebral arteriosclerosis or stroke.6

The reflex or "spastic" neurogenic bladder, also an upper motor neuron type, is characterized by involuntary reflex voiding without bladder sensation. In this type, the lesion lies between the sacral and cortical centers and interrupts sensory as well as inhibitory impulses. Spinal cord injury is a frequent etiology of this type.7 In some cases of upper motor neuron bladder, the external sphincter is also spastic, leading to incomplete bladder emptying.8

6 Ibid., pp. 24-25.
7 Ibid.
The patient with reflex or automatic type bladder may be able to initiate micturition prior to the period of automatic urination by stimulating so-called trigger areas. These areas may be located along the inner aspects of the thigh, or along the lower abdomen and can be triggered by manual brushing or pinching. Anal stimulation or pulling on pubic hair may also cause bladder contraction.

Lower motor neuron bladders were categorized as sensory neurogenic, autonomic or "flaccid" neurogenic, or motor paralytic types. All involve lesions directly affecting the spinal reflex arc.

In the sensory neurogenic bladder, the sensory limb of the spinal reflex arc is interrupted. Because the sensory impulse is absent, there is no input to stimulate a response in the motor limb. The individual experiences reduced or absent sensation of bladder fullness, the absence of voiding contractions, and a subsequent urinary retention with increased bladder capacity. After maximum distention is reached, dribbling occurs as an overflow incontinence. There are numerous causes, including diabetes mellitus, multiple sclerosis and pernicious anemia.9

The autonomic or "flaccid" type of neurogenic bladder involves interruption of both the sensory and motor limbs of the spinal reflex arc causing both absent bladder sensation and the inability to initiate voiding. In this

9Peterson, loc. cit.
type, the individual may be able to use Credé or Valsalva maneuvers to expel urine. Overflow incontinence is again characteristic. Cord tumor, trauma or abcess and spina bifida are among the etiologies.\textsuperscript{10}

The motor paralytic bladder is associated with a lesion involving the motor limb of the spinal reflex arc. As a result, the individual experiences painful urinary retention and overflow. Cord trauma, spina bifida and multiple sclerosis are possible causes.\textsuperscript{11}

An additional type of dysfunction which may be responsible for incontinence is the decompensated bladder. In this type, there is generally an increase in bladder capacity with inadequate emptying due to non-neurogenic obstruction of urine flow from the bladder. Sensation is intact. Etiology may include such things as bowel impaction, benign prostatic hypertrophy, or psychogenic factors such as voluntary infrequent voiding.\textsuperscript{12}

Incontinence in the young or middle aged adult usually can be explained on the basis of neurogenic bladder from illness or injury. However, incontinence in the aged

\textsuperscript{\footnotesize 10}Ibid.
\textsuperscript{\footnotesize 11}Ibid.
has additional etiological components. Mandelstam stated that one of three persons alive at age 65 will experience incontinence at some time in the remainder of their life. Lowenthal stated that, of the incontinent patients he studied in a chronic disease hospital, 85 percent were 65 years of age or older, and 80 percent had no physiologic reason for their condition.

The non-neurogenic components of incontinence in the elderly were grouped as physical, psychological, and environmental. An overview of each follows.

Physical reasons for incontinence in the elderly were numerous. Some were associated with the normal aging process. Research showed that the normal adult bladder held 500 to 600 milliliters (ml.) with about 0.5 ml. residual urine following micturition. However, normal bladder capacity diminishes with age. According to Hall, normal people between the ages of 60 and 80 years of age usually have a bladder capacity of approximately 350 ml. and a residual urine of less than 10 ml.; after age 80, bladder capacity drops to an average of 300 ml. with a residual urine

of 15 ml. The decrease in bladder capacity inherently results in increased frequency of voiding. The increase in residual urine predisposes the aging individual to bacteriuria and urinary tract infection, exacerbating frequency and urgency.17 This is often compounded by the decision on the part of the individual to reduce fluid intake in an effort to lessen the frequency, paradoxically concentrating the urine and further irritating the bladder lining.18 Two authors cited experiences in which inadequate fluid intake was the primary cause of the incontinence, noting that the incontinence resolved completely when fluid intake was increased.19 Atrophic vaginitis causes incontinence in some elderly women due to its association with a bacterial urethritis.20

It is not uncommon for stress incontinence to occur in elderly women as a result of relaxed perineal support structures. Characteristically, a small amount of urine is forced through the urethra at the time of a provocative stimulus such as coughing or straining. This may also occur

17 Hall, loc. cit.
in younger women following childbirth or for no apparent reason.

Pharmacologic factors may contribute and are often overlooked. Large numbers of elderly people are taking antihypertensive diuretics. If they are taken in the evening, frequency and incontinence can ensue during the period of peak diuresis. Indiscreet administration of sedatives can also play a part in incontinence by diminishing physical and mental responses to the sensation of bladder filling.

Several authors addressed the psychologic aspects of incontinence. Incontinence has long been accepted as a part of aging by individuals caring for the elderly; not infrequently, this attitude is adopted by the elderly person in a self-fulfilling prophecy of the label.21 Lowenthal noted that chronically ill patients who are incontinent frequently are thin and frail. He postulated that there are times when such patients fail to bring their need to urinate to the attention of their care-takers until after the fact, fearing the discomforts of bedpans and rough handling.22 Senility and psychosis may also contribute to incontinence in the older individual.23


22 Lowenthal, loc. cit.

Environmental circumstances can make a difference between independent voiding and incontinence. Correct bed height, clothing that can easily be removed, and physical proximity of toilet facilities are among many such factors.

The Indwelling Urethral Catheter

Risks and Complications

Kyle cited evidence that indwelling urethral catheters have been used in various forms for many centuries and have always been associated with the complications of trauma and infection. Trauma included damage to the urethra during insertion, long-term effects of local pressure and irritation, particularly obstruction of the glands opening into the urethra, and sensitivity reactions to the substance of the catheter, all potentially leading to stricture formation, local abscesses or fistulae. Because the indwelling urethral catheter is used in patients who are primarily in the recumbent position which fails to allow adequate drainage, bacteria multiply in the residual urine causing infection.  

In gathering data from 400 spinal cord injured patients over a period of 10 years, Hardy related the same local complications to the indwelling urethral catheter as Kyle and added the observation that calculus formation was considerably more frequent in patients with indwelling catheters.

---

catheters as compared to those using intermittent catheterization.\textsuperscript{25} Ascoli denounced the long-term use of indwelling urethral catheters, especially in those patients with high level spinal cord lesions, stating that there was a great risk of the bladder becoming small, sclerotic and uneducable. This could result further in paroxysmal hypertension if the bladder were permitted to distend.\textsuperscript{26}

The most noted risk in the use of indwelling urethral catheters was the inevitable bacteriuria with a significantly higher incidence of urinary tract infection. In 1956, Kass published a study in which he found that, using 100,000 bacteria per ml. as the dividing line between contamination and infection, 95 percent of patients with indwelling catheters and open drainage systems developed infection within 96 hours, most of them within the first 24 hours.\textsuperscript{27}

In a classic 1958 editorial, Beeson condemned the use of the catheter to obtain urine specimens or for the convenience of nurses or physicians on the basis that the resulting bacteriuria predisposed the patient to pyelonephritis.\textsuperscript{28}


It is important to realize that it was not until 1966 that sterile closed drainage systems for indwelling urethral catheters were widely used. Prior to that time, most drainage tubes led from the catheter to open urine collection bottles. In 1966, Kunin published a study of 675 patients whose initial urine was sterile which demonstrated that by using a sterile closed drainage system, the time required for 50 percent of patients to become infected was 13 and one-half days in females and 11 days in males. This was a considerable improvement when compared to Kass' figures in 1956, but the benefits were realized only in short-term use of the indwelling catheter.

Controversy Regarding Use

There has been considerable controversy over the use of the catheter since Beeson's editorial in 1958 condemning its use for the purpose of convenience or for obtaining urine specimens. Several authors supported Beeson's view. Kick expressed the view that the indwelling urethral catheter should never be used solely for the purpose of keeping the patient dry. Maney stated that it was poor judgment


30 Beeson, loc. cit.

to use a catheter for incontinence. Mandelstam took a more moderate view, stating that although the indwelling catheter should never be used without consideration of the risks involved, its use was warranted in the case of intractable incontinence. "If catheterization enables elderly patients to be discharged from the hospital, and relatives are able to cope," stated Mandelstam, "then the risks of infection must be balanced against the benefits of being able to spend their last years at home." In 1969, a group of physicians published a defense of the discriminating use of the catheter, arguing that a "catheter paranoia" had developed among physicians following Beeson's editorial 11 years earlier and that as a result, catheters were being avoided at all costs. This, they stated, oversimplified a complex issue and carried inherent risks in cases where catheters were indeed indicated.

Others also took a more positive stand toward indwelling urethral catheter use. Kunin viewed the indwelling catheter as an essential part of modern medical care, listing several indications for its use.

---


35 Kunin, op. cit., p. 1155.
stated that indwelling catheter use on a permanent or semi-permanent basis is appropriate in the management of persistent incontinence in paraplegics and elderly persons. He further stated that there were two types of incontinence in which the indwelling catheter may be used--in the atonic bladder where there is retention and overflow and in the case of reflex neurogenic, uninhibited neurogenic and some unstable bladders associated with uncontrollable bladder contractions.  

Intermittent Catheterization

Guttmann and Research on Sterile Technique

Intermittent catheterization was first widely used in the treatment of spinal cord injured patients in World War I. The catheter was passed as soon as possible after injury without regard for asepsis. Repeat catheterizations were done only as circumstances permitted while transporting the injured to hospitals. The hours which lapsed between catheterizations led frequently to overdistention of the bladder and gross infection. As a result, 80 percent of patients died of urinary sepsis, and many physicians


38Ibid., p. 219.
believed that intermittent catheterization, in and of itself, was responsible. 39

It was not until the 1940's that Dr. Ludwig Guttmann reintroduced intermittent catheterization as a desirable method of managing the initial period of shock following spinal cord injury. One major advantage of using intermittent catheterization was that it allowed the urethral tissue, vulnerable to breakdown and fistula formation during the stage of shock, to be free of continuous pressure from a foreign body. It also allowed intermittent bladder distention, thereby stimulating an earlier return of bladder function. 40 In 1946, Guttmann reported that by using a combination of intermittent catheterization and bladder irrigation with an antiseptic solution, he had rendered sterile several cases of infected urine. 41


41 L. Guttmann, September/October, 1946, p. 133.
Guttmann's method of intermittent catheterization involved an elaborate "non-touch" technique using sterile gowns, masks, gloves and forceps. It was performed only by physicians and later, in some circumstances, by patients who were able to learn the procedure. Frequency of catheterization was every eight to 12 hours. Fluid intake was adjusted so that urine volume never exceeded 600-750 ml. in adults, in order to prevent overdistention of the bladder. Abdominal expression was used just prior to catheter withdrawal to obtain residual urine and prevent stagnation. Following the period of spinal shock, fluid intake was increased to three to four liters per 24 hours. At this time, abdominal expression and attempts to trigger reflex voiding were used prior to catheterization in lower motor neuron and upper motor neuron bladders, respectively. When residual urine following these maneuvers measured less than 500 ml., catheterization frequency was reduced to twice a day; when residual was less than 250 ml., catheterization was done once a day; and when less than 100 ml., catheterization was discontinued. Thereafter, residual urine determinations were made periodically and intermittent catheterization initiated again if measurements exceeded acceptable volumes.42

---

Gradually, Guttmann refined certain aspects of his technique. In the early years, patients received routine antibiotics during the first one to two weeks of intermittent catheterization. If infection occurred, an indwelling catheter was placed immediately. In 1966, he wrote that he had discontinued the routine use of antibiotics and resorted to an indwelling catheter only if severe infection developed. In addition, he began using plastic catheters because of experiences in which allergic urethritis occurred when rubber catheters were used.\textsuperscript{43}

In 1966, Guttmann and Frankel published a study of 409 male and 67 female patients who were admitted to England's National Spinal Injuries Center within 14 days of injury (most within 48 hours). Data showed that intermittent catheterization produced favorable results in maintaining and promoting urine sterility. Eighty percent of men had sterile urine on admission and 64 percent had sterile urine on discharge. Sixty-four percent of the women had sterile urine on arrival and 49 percent had sterile urine on discharge. The overall rate of sterile urine on discharge was 62 percent.\textsuperscript{44}

Guttmann and Frankel found that complications such as hydronephrosis, vesicoureteral reflux, and renal and bladder calculi, all common to spinal cord injured patients

\textsuperscript{43}Ibid., pp. 65-66.

\textsuperscript{44}Ibid., p. 69.
using indwelling urethral catheters, occurred less frequently in such patients using intermittent catheterization. Most complications which did occur were in patients with chronic urinary tract infection.\footnote{Ibid., pp. 75-80.}

Subsequent studies modified the elaborate technique of Guttmann and demonstrated the effectiveness of the procedure in managing medical as well as traumatic lesions. These studies will not be discussed here but appear in an annotated bibliography in Appendix B.

**Lapides and Research on Clean Technique**

In 1972, Lapides introduced the use of clean rather than sterile technique in intermittent catheterization. He based his work on the belief that urinary tract infection occurred when there was a breakdown in the integrity of the bladder wall. This breakdown, he believed, developed as a result of prolonged ischemia during strong bladder contractions or overdistention which rendered the bladder wall vulnerable to bacterial invasion from hematogenous or lymphatic routes, or from bacteriuria. He postulated that when prolonged pressure or overdistention were avoided, circulation and host defenses remained adequate, preventing clinical infection even in the presence of bacteriuria. It was for these reasons that he believed sterile technique was unnecessary when performing intermittent catheterization as
long as the bladder was emptied frequently enough to avoid pressure or overdistention.\footnote{J. Lapides et al., "Clean, Intermittent Self-Catheterization in the Treatment of Urinary Tract Disease," \textit{Journal of Urology}, 107:458-61, March, 1972.} Lapides' explanation of urinary tract infection pathogenesis was later discarded\footnote{C. M. Kunin, Detection, Prevention and Management of Urinary Tract Infections (3d ed.; Philadelphia: Lea and Febiger, 1979), pp. 9-10.} but the effectiveness of non-sterile technique became widely accepted.

Fourteen patients participated in Lapides' first study of clean technique intermittent catheterization. They ranged in age from three to 65 years and had diverse underlying etiologies for their bladder dysfunction, including medical as well as traumatic lesions. All but one had problems with recurrent urinary tract infection. Eleven of the 14 suffered from incontinence.\footnote{Ibid., p. 459.}

The patients were taught clean technique intermittent catheterization by a registered nurse. They were instructed to catheterize themselves every two to three hours during the day and several times at night.\footnote{Ibid.}

Results of the study demonstrated a marked increase in the number of sterile urines and, in several patients, resolution of incontinence. Lapides concluded that a non-sterile technique was safe for use in intermittent catheterization.\footnote{Ibid.}
catheterization, and that the procedure provided a practical, highly effective way to manage numerous types of bladder dysfunction.\textsuperscript{50}

Lapides' follow-up studies of 1973,\textsuperscript{51} 1974\textsuperscript{52} and 1976\textsuperscript{53} presented cumulative data. By 1976, the number of patients totalled 128 females and 90 males. Diagnoses included neurogenic bladders of traumatic or medical etiology, atonic decompensated bladders and a few patients with normal bladder function who used self-catheterization for intermittent installation of medications. Approximately 40 percent of the patients were on indwelling urethral catheter drainage and 5 percent had a cystostomy or cutaneous vesicostomy prior to using intermittent catheterization.\textsuperscript{54}

Patients were taught clean technique intermittent catheterization with special emphasis on frequency rather than sterility. Neurogenic and antibacterial medications were prescribed as needed.\textsuperscript{55}

\begin{enumerate}
\item \textsuperscript{50} Ibid., p. 461.
\item \textsuperscript{52} J. Lapides et al., "Follow-up on Unsterile Intermittent Self-Catheterization," Journal of Urology, 111:184-87, February, 1974.
\item \textsuperscript{54} Ibid., p. 169.
\item \textsuperscript{55} Ibid.
\end{enumerate}
Complications, as in previous investigations, were very few; there were no cases in which renal function deteriorated as a result of the program. Prior to beginning the program, only 9 percent of patients had sterile urine. Following the program, the number with sterile urine increased to 48 percent, although 38 percent required antimicrobial therapy at some time.\footnote{Ibid.}

Following the introduction of clean technique intermittent catheterization by Lapides, other investigators published data on their experiences with the procedure. Herr's 1975 study of 449 patients used sterile technique for patients in the acute period following spinal cord injury. Clean technique was taught to paraplegics and patients with medical lesions. Herr defined success as a catheter-free bladder emptying to less than one third of its capacity without serious complications, and found that 317 of the 449 patients met this criteria. From observations of patient follow-up visits over a period of nine years, he concluded that sterile urine upon hospital discharge did not predict that infection would not occur even if the patient were catheter-free. Approximately 45 percent of catheter-free patients were free of infection at any one time.\footnote{H. W. Herr, "Intermittent Catheterization in Neurogenic Bladder Dysfunction," \textit{Journal of Urology}, 113: 447-49, April, 1975.}

Orikasa et al. studied 13 female and 13 male patients with bladder dysfunction of diverse etiology who
performed clean intermittent self-catheterization more than five times a day, preventing the urine volume from exceeding 300 ml. They found a low rate of complications, no deterioration of renal function, and a high incidence of sterile urine. Orikasa recommended use of this procedure in cases of bedridden patients when cooperative family were available. 58

The only nursing study on the subject was published by Champion. Seven patients who had established regimens for sterile technique intermittent catheterization were taught to adapt their procedure to clean technique. Urine specimens obtained while using clean technique were found to be equivalent bacteriologically to those obtained while using sterile technique. 59

Whitfield and Mayo used clean technique intermittent self-catheterization in 14 patients with bladder dysfunction from various causes. In seven, incontinence was the major complaint; seven complained primarily of urinary retention. After one month on the program, eight patients reported resolution of their presenting complaint, four reported improvement, and two reported no change. The investigators concluded that clean intermittent catheterization provided


great advantages over permanent indwelling catheters in such patients and suggested its use in cases of bladder dysfunction when surgery is not indicated.  

McGuire, Diddel and Wagner studied 55 patients with spinal cord injury in whom clean technique intermittent catheterization was used by the patient or family. Only six patients developed symptomatic urinary tract infection and few complications were noted. Bacteriuria was found to occur more frequently in patients who continued to use intermittent catheterization indefinitely than in those who achieved a catheter-free state. In general, female spinal cord injured patients had little success in achieving a catheter-free state.

MacGregor and Diokno published a study of 100 patients with non-neurogenic decompensated bladder in 1979. Frequent voiding and cholinergic agents had been tried unsuccessfully in all patients. Intermittent catheterization by clean technique proved highly effective in helping patients to resume normal voiding and in reducing bacteriuria and pyuria.

---


Wyndaele, Oosterlink and DeSy reported on the use of intermittent catheterization in 32 patients with neurogenic bladder of various causes. Improvement was noted in continence, sterility of urine, and in some cases, previous pathology of the upper urinary tract as shown by radiological exam. 63

Summary

An overview of incontinence and its etiology was presented including a discussion of normal micturition, the types of neurogenic bladder, and the non-neurogenic factors which may contribute to incontinence, particularly in the elderly. The purpose was to present a profile of the individual who is a candidate for an indwelling urethral catheter on the basis of urinary incontinence.

The risks and complications associated with the indwelling urethral catheter were discussed. A presentation of diverse opinions regarding appropriate use of the indwelling urethral catheter followed.

Guttmann's pioneering work to establish intermittent catheterization as appropriate medical treatment in acute spinal cord injury was reviewed. Further research on sterile technique intermittent catheterization, including patients with bladder dysfunction of non-traumatic etiology,

was presented in an appended annotated bibliography.

Lapides' research on the use of clean technique for intermittent catheterization was presented as were follow-up studies by other investigators. Results of the investigations showed that clean technique intermittent catheterization was a safe and effective method for improving sterility and continence of urine in a wide variety of bladder dysfunctions which might otherwise have been managed with an indwelling urethral catheter.
Chapter 3

METHODOLOGY

Introduction

A case study approach was used to describe the investigator's experiences teaching three patients clean technique intermittent catheterization. Case study can be seen as a descriptive survey which substitutes depth for numbers.¹ This approach to research involves detailed, intensive, factual description of individuals in their natural settings.²

The following research questions were formulated:

1. Does the substitution of clean technique intermittent catheterization for a chronic indwelling urethral catheter influence asymptomatic bacteriuria?

2. Was there a relationship between the visualization of bacteria and leukocytes on microscopic exam of fresh, centrifuged urine sediment and findings of equal to or greater than 100,000 bacterial colonies per ml. on culture?

Subjects

All adult patients with indwelling catheters receiving services between May 1, 1980 and July 31, 1980 from the agencies, clinics or private physicians contacted by the investigator for the purpose of identifying appropriate subjects comprised the population under study.

Three patients were selected on the basis of the following criteria:

1. Patient was living at home at the time of instruction. Rationale: (1) to minimize differences in settings between patients; (2) to familiarize the investigator with the circumstances under which the patient would be performing the procedure so that individual adaptations could be made.

2. Patient had an indwelling catheter at the time of instruction.

3. Patient was able to perform self-catheterization or had a reliable care-taker to learn intermittent catheterization.

4. Patient had no physical deformities making catheter placement difficult.

5. Patient's physician signed order form (Appendix C).

6. Patient and/or care-taker signed consent form (Appendix D).
7. Patient and/or care-taker understood the necessity of regular catheterization and the risks involved in allowing the bladder to overdistend.

8. Patient and/or care-taker were able to perform the tasks of monitoring body temperature and recording fluid intake and output. Rationale: to provide for early detection of infection and immediate recognition of bladder overdistention.

9. Patient had normal blood urea nitrogen and serum creatinine levels within one month prior to starting intermittent catheterization. Rationale: these values indicate the level of renal function.

10. Patient had no known obstruction or pathology of the urinary tract. Rationale: to eliminate other causes of bacteriuria which could obscure the effect of clean technique intermittent catheterization.

11. Patient had no symptoms of urinary tract infection at the start of the program.

12. Patient was taking no antimicrobial medications for one week prior to the start of the program. Rationale: to prevent distortion of urinalysis and culture results.

Setting

All patients lived in a metropolitan area of the southeast. Instruction in the technique of clean technique intermittent catheterization took place in the patients' homes. Laboratory facilities of a large medical center in
the same metropolitan area were utilized for urinalyses and cultures.

**Procedure**

Data collection proceeded as follows:

1. The investigator contacted agencies, clinics and private physicians in the metropolitan area by phone and sent to each written information describing selection criteria and methodology and requesting assistance in identifying candidates for the study.

2. The investigator contacted patient candidates by phone to determine their interest and to set up an appointment for an introductory visit.

3. Physicians of interested patients were contacted by phone to obtain verbal consent. Physicians' order forms were sent by mail with an enclosed self-addressed stamped envelope.

4. An introductory visit was made to the patient within 10 days of the starting date of the program during which intermittent catheterization was discussed using a diagram to show the procedure; patient and/or care-taker were taught to read an oral thermometer; volume measurement and the use of intake and output sheets were reviewed (Appendix E), and patient's/care-taker's interest, commitment and reliability were assessed. Consent forms were signed and an instructional booklet was given to each patient (Appendix F).
5. On day one of the program, the investigator arrived at the patient's home no later than 9 A.M. After cleaning a site on the indwelling catheter with a povidone iodine solution using a sterile gauze pad, the investigator aspirated approximately 10 ml. of urine using a sterile 20 ml. syringe with a 20 gauge needle. One ml. of urine was placed in a sterile culture container; the remaining portion of the specimen was placed in a clean urinalysis receptacle.

6. The indwelling catheter was removed and the patient given a glass (unspecified volume) of water.

7. Approximately 45 minutes after removal of the indwelling catheter, the investigator instructed the patient/care-taker in clean technique intermittent catheterization by demonstrating the procedure on the patient (Appendix G). Blood pressure and pulse were monitored by the investigator before and after the first intermittent catheterization. The patient or care-taker then performed a return demonstration of the procedure.

8. Volume measurement, care of the catheter, and appropriate restriction of fluid intake were reviewed.

9. Urine specimens were delivered or examined within two hours of the time they were obtained. Cultures were taken by the investigator to the bacteriology laboratory of a local medical center. Urinalysis was performed by the investigator using the procedure detailed in Appendix H.

10. Approximately three to four hours after the initial catheterization was performed, the investigator
returned to the patient's home and observed the patient or care-taker doing the procedure. The patient was given a phone number where the investigator could be reached in the event of questions or problems.

11. The investigator revisited the patient's home on the morning of day two and again observed the catheterization procedure.

12. Urine specimens were collected for analysis and culture by the investigator on day four, weekly for two weeks, once after a two-week interim, and once after a four-week interim (total of eight and one-half weeks). A sterile plastic catheter was used each time a specimen was collected.

13. Additional home visits were made for assessment or teaching at the discretion of the investigator. Urine specimens were not collected while patients were being treated with antimicrobial medications.

Summary

The method used in this study was summarized as follows: a case study approach was used; two research questions were formulated relating to the measurement of bacteria in the urine; subjects were selected on the basis of very specific criteria; all patients were studied in their home; and a specific procedure was used for teaching clean technique intermittent catheterization and for collecting and examining urine specimens.
Chapter 4

CASE STUDIES

Introduction

A case study method was used to describe the investigator's experiences teaching three patients clean technique intermittent catheterization. Results of urinalysis and culture were used to help determine the safety and effectiveness of the procedure. Each patient is presented in a separate section comprised of relevant history, a narrative of the investigator's experiences with the patient, and a discussion of the findings including urinalysis and culture results.

Patient Number One

History

Mrs. P., a 52 year old black woman, became paraplegic in 1962 from arachnoiditis and had total anesthesia below waist level. She was wheelchair mobile and adept at transferring into and out of the bed. Her height was 66 inches and weight approximately 200 pounds.

Mrs. P. told the investigator that she had experienced urinary leakage between voidings for many years but
had managed well using a bedpan until 1973. She reported using abdominal expression (Credé) to aid bladder emptying. Between 1973 and 1978 she had several episodes of skin breakdown requiring a temporary indwelling urethral catheter. In 1978, she was hospitalized with septicemia which originated in a large infected decubitus ulcer on her hip. From November, 1978, until the time of her participation in this study, she had an indwelling catheter which was changed as needed by the local visiting nurse association.

In the spring of 1980, Mrs. P.'s primary physician referred her to a urologist for evaluation. Urodynamic studies were recommended but Mrs. P., who admits dislike and skepticism of physicians, declined. The specific nature of her bladder dysfunction was therefore unknown.

Mrs. P. had no other known medical problems. Her medications prior to the study were methenamine hippurate and ascorbic acid, both taken by mouth twice daily for urine acidification. Her blood urea nitrogen (BUN) and serum creatinine levels on May 27, 1980, were 11.0 mg/100 ml. and 0.6 mg/100 ml. respectively, both within normal limits.

Mrs. P. lived with her husband in a small, well-kept one-story home and was independent in her self care. Her husband was employed full-time in a paper factory, frequently working the night shift and sleeping during the day. Mrs. P.'s daughter and sister assisted with housework. On a typical day, Mrs. P. dressed and transferred into the wheelchair in the early morning and remained out of bed until
evening except for returning to bed for a short nap in the early afternoon.

Experiences During the Study

May 23. Telephone contact was made with Mrs. P. to determine her interest in participating in the study. The procedure of clean technique intermittent catheterization (abbreviated CTIC) and the investigator's role as a graduate student were briefly explained. Mrs. P. expressed interest in trying the procedure but also expressed some reservations as to whether her physical limitations (obesity and paraplegia) would hinder her performance.

May 24. Mrs. P.'s urologist agreed to a trial period of CTIC but also expressed some doubts about the likelihood of success in light of the patient's physical limitations and unknown urodynamic status.

May 29. An introductory visit was made to Mrs. P.'s home. The investigator found Mrs. P. to be motivated and eager to learn CTIC in the hope that it would permit her to travel more easily by car, freeing her from years of home confinement.

Mrs. P. demonstrated the ability to read an oral thermometer and to measure and record liquid volume. She also practiced getting into the position necessary for doing self-catheterization. It was at this time that the investigator became aware of the considerable effort involved in
the patient's transferring into and out of bed. Transfer from the wheelchair to the bed involved positioning the wheelchair parallel to the side of the bed, lifting lower extremities onto the bed, removing the side of the wheelchair, and logrolling 360 degrees into a supine position. Once on the bed, Mrs. P. positioned herself for self-catheterization by placing pillows behind her head and shoulders and propping her legs in an abducted position with knees flexed, using a mirror to visualize the perineum.

Transfer from the bed to the wheelchair was accomplished by positioning the wheelchair perpendicular to the side of the bed and using a sliding board to shift the patient's weight from the bed to the chair.

The investigator's assessment of the patient on this visit was that her paraplegia and obesity presented limitations but that her high level of motivation might well compensate for them.

May 30 - Day one of the program. First visit--The investigator arrived at Mrs. P.'s home about 8:45 A.M. and obtained a urine specimen from the indwelling catheter before removing it. The investigator noticed a small open scratch on Mrs. P.'s labia minora, apparently incurred by a sharp fingernail when the patient had practiced positioning the previous evening. The patient was unaware that this had happened due to her absence of sensation. The investigator advised the patient to trim all sharp edges from her
fingernails and to use special caution when practicing positioning.

The investigator demonstrated CTIC. Blood pressure and pulse determinations before and after the procedure did not change. Urine output on catheterization was 60 ml. On return demonstration, the investigator observed that the patient had difficulty seeing the mirror well enough because of her obesity; she was able to insert the catheter into the urethra, but could not see the flow of urine. In addition, the investigator was concerned that the posterior urethral wall could be traumatized by the angle at which the catheter was being inserted. The patient attempted to find a better position for doing CTIC. However, no position was found in which visualization of the perineum was adequate.

Second visit (1 P.M.)--The investigator observed two additional scratches on the labia. The protective padding on which the patient had been sitting was quite wet and there appeared to be a slow, continuous leakage of urine. The patient performed CTIC, obtaining a catheterized volume of 150 ml. The investigator did not believe the patient's technique was adequate. The indwelling catheter was replaced to avoid constant exposure of the scratched areas to the incontinent urine. Mrs. P. expressed disappointment in the need to return to the use of an indwelling catheter and hoped that by practicing position and technique further, she could become competent in performing CTIC.
June 2. A home visit was made to check on the healing of the labial scratches; infection was not present and healing was evident. Mrs. P. stated that doing CTIC four times a day was not realistic for her because of the effort involved in transfers and because of her physical limitations. The investigator suggested an alternative of having the patient's husband or daughter do the procedure. The patient did not see this alternative as appropriate.

Mrs. P. reported that during the evening of May 30, the indwelling catheter had been expelled with the balloon inflated. Because this happened in the evening, it was the next morning before it could be replaced. During the evening, she reported experiencing nonspecific sensations of bladder fullness followed by voiding a large amount of urine in the bedpan. She felt encouraged by this and inquired about the possibility of having a voiding trial to test if she could be freed of the indwelling catheter without the need to do frequent intermittent catheterization. The investigator agreed that this might be an option and foresaw the possibility of using CTIC on an infrequent basis to rule out increasing residual urine volumes.

The investigator discussed the alternative program with Mrs. P.'s urologist, who consented. One week prior to the voiding trial, the catheter would be clamped for increasing increments of time (starting with one hour and increasing to four hours) in order to assure an adequately expanded bladder capacity. The plan was to remove the
catheter at the end of a week and check for residual urine: if the volume was greater than 100 ml., CTIC would be performed at least twice each day; if the volume was less than 100 ml. and greater than 50 ml., CTIC would be done twice a week to check for increase in residual volume.

June 17 - Day one of catheter clamping. 9 A.M. A home visit was made to instruct Mrs. P. in the catheter clamping routine (Appendix I). Mrs. P. was instructed to try to perceive any sensations associated with bladder filling to prepare for utilization of alternative signals after catheter removal.

10 P.M. The investigator received a telephone call from the patient stating that the catheter had come out with the balloon inflated. This suggested to the investigator that either the patient's sphincter tone was extremely relaxed or that the catheter was forcefully expelled by reflex bladder contraction. The patient also reported that urine had leaked around the catheter throughout the day.

June 18. The investigator made a home visit to replace the indwelling catheter. The intake and output record showed that Mrs. P. was forcing fluids in excess of that recommended in the catheter clamping protocol. Perhaps the dribbling incontinence during times when the catheter was clamped occurred as a result of distention and overflow. The patient was advised to drink her usual amount of fluids
with meals and add no more than one glass of liquid in the morning and one glass in the evening.

Mrs. P. reported that she had voided approximately 10 minutes before the investigator arrived and that the voiding occurred immediately as she sat up on the bedpan and without using Credé. The volume of urine obtained on placement of the indwelling catheter was 125 ml.

Sensation relating to bladder filling was discussed. Mrs. P. reported sensing some vague upper abdominal discomfort at times when the catheter was out and bladder filling was taking place, but felt that this occurred inconsistently and was not specific enough for her to distinguish the need for urination.

In spite of the possibility of bladder distention and overflow, which would suggest that catheter clamping was unnecessary, the investigator decided to allow the patient to complete the week's program before initiating the voiding trial.

June 24 - Day one of the voiding trial. Mrs. P.'s indwelling catheter was removed at 9 A.M. following aspiration of a urine specimen. She drank two cups of water and at 11 A.M. voided 60 ml. into the bedpan. Catheterization by the investigator immediately following the patient's voiding demonstrated no residual, although the padding underneath the patient was noted to be wet. Between 11 A.M. and 1 P.M., the patient drank one and one-half cups of
liquid and at 1 P.M. voided 180 ml., again without residual when catheterized. The padding was quite wet but since the perineal skin was intact, the trial was continued. The patient was instructed to wash and dry her perineum two or three times a day and to change the protective padding frequently.

Mrs. P. voided only small amounts of urine at 5 P.M. and 9 P.M. Paddings were saturated all day, but the bed remained dry throughout the night.

June 25 - Day two of the voiding trial. Mrs. P. reported voiding a "large amount" in the bedpan at 6 A.M. At 9 A.M., she voided 20 ml. in the bedpan using Credé; catheterization demonstrated a residual volume of 240 ml., well above the acceptable 100 ml. No explanation for the wide variation in residual volumes was apparent and the voiding trial continued.

1 P.M. The investigator arrived and found the patient sitting in the wheelchair on padding that was completely saturated and leaking to the floor. The patient readily agreed to replacement of the indwelling catheter and this was done.

Discussion

At the onset, Mrs. P. seemed to be a reasonable candidate for this study, despite the unknown urodynamic status. The reported history of bedpan use with urinary
leakage between voidings suggested distention with overflow incontinence. In spite of the physical limitations imposed by her obesity and paraplegia, it seemed possible to draw on her motivation and the use of positioning aids such as pillows to compensate.

When it became apparent that the patient would not be able to perform CTIC at the frequency recommended in the protocol, the possibility of freeing the patient from the risks and complications of long-term indwelling catheterization by an adapted program became an alternative goal.

Ultimately, the unknown urodynamic status resulted in inexplicable variations in bladder functioning. Lower motor neuron-type bladder was ruled out by the catheter expulsion (June 2, June 17) and the large residual obtained even with use of Credé during voiding (June 25). The apparent laxity of the sphincter tone was also inconsistent with the larger residual volume.

Before any further attempts to use alternatives to the indwelling catheter, a urodynamic evaluation by Mrs. P.'s urologist is essential. Several possibilities may exist depending on her urodynamic status. If, in fact, Mrs. P. has an upper motor neuron bladder, or a mixed type of neurogenic bladder with spasticity, an option would be to administer propantheline bromide, which has the antimuscarinic effect of depressing uninhibited bladder contractions
and often increasing bladder capacity.\(^1\) Mrs. P.'s inadequate sphincter tone might well be treated with imipramine hydrochloride which stimulates contractile receptors of the bladder base and proximal urethra.\(^2\) In a journal article on pharmacologic management of the neurogenic bladder, Dr. Alan Wein stated that he has had success with administering both propantheline bromide and imipramine hydrochloride and using external compression (Credé) or intermittent catheterization as needed to assist in bladder emptying.\(^3\) In Mrs. P.'s case, external compression along with use of these two agents would certainly be worth trying. Other options would exist if she lost weight and were better able to self-catheterize, or if she permitted a family member to perform the catheterization. It is possible that her bladder could be almost completely emptied by external compression and that CTIC could be used infrequently for management of residual urine. However, the use of an indwelling urethral catheter may be the only feasible solution for Mrs. P. in light of her history of extensive tissue breakdown as a result of incontinence.

Two urine specimens were collected from Mrs. P. On May 30, a specimen aspirated from the indwelling catheter


\(^2\)Ibid., pp. 31-32.

\(^3\)Ibid., p. 32.
yielded a culture with over one million Proteus morganii and Non-Hemolytic Streptococcus (enteric type) per ml. and urinalysis results of two to five leukocytes with a moderate amount of bacteria per high power field. A specimen obtained on June 24, just prior to beginning the voiding trial, showed over one million escherichia on culture and urinalysis results of six to nine leukocytes with few to moderate bacteria per high power field. This showed that a new organism became responsible for the asymptomatic bacteriuria.

Patient Number Two

History

Miss S., a 33 year old black woman, had a radical hysterectomy for cancer in August, 1978. Following surgery, a suprapubic catheter was placed to correct persistent urinary retention. It was replaced with an indwelling urethral catheter in January, 1979, following an unsuccessful voiding trial. Since then, Miss S. managed well using a leg bag for urine collection and having monthly catheter changes at the local medical center. She reported, however, experiencing recurrent urinary tract infections throughout her time of catheter dependency.

During the week prior to her participation in this study, Miss S. was evaluated by a urologist at her own request for the purpose of determining whether it was possible for the catheter to be removed on a permanent basis.
The primary motivation for seeking urological evaluation was her desire to eliminate the esthetic and physical interferences presented by the catheter during sexual activity. The urologist referred Miss S. to the investigator for instruction in CTIC. Miss S.'s BUN and serum creatinine values were within normal limits on May 23, 1980.

Miss S. had no recurrence of her tumor and no other physical problems. She did, however, have a history of psychiatric illness and had been attending a city mental health clinic monthly since 1977.

Miss S. was taking three medications at the time she was accepted into the study. Fluphenazine hydrochloride, an antipsychotic, was administered in the form of an injection at the mental health clinic every month. Bladder paralysis was listed among possible side effects.4 Procyclidine hydrochloride and nitrofurantoin were taken daily by mouth; neither drug influences bladder function.5

Miss S. was divorced and lived with two daughters, ages four and six, in a small, rented home. During the school year prior to the study, she worked as a teacher's aide.

Miss S. was an attractive, healthy-looking young woman, who took great pride in her appearance. Her

---

5. Ibid., pp. 719-20; Ibid., pp. 841-42.
boyfriend of two years visited her frequently and assisted in the care of her children.

**Experiences During the Study**

**June 6.** On the introductory visit made to the patient's home, the investigator found Miss S. to be highly motivated and capable of learning quickly. She had no difficulty with movement or positioning and was able to read an oral thermometer and measure liquid volume. Miss S. reiterated her eagerness to be free of the indwelling catheter because of its interference with her sexual activity. She stated that the presence of the catheter served as a constant reminder of her surgery, in spite of the fact that she now felt well.

**June 9 - Day one of the program.** 8:45 A.M. Specimens were obtained, the catheter was removed, and CTIC was taught as in Appendix I. Miss S. had no difficulty performing the procedure.

1 P.M. The investigator returned to the home to observe a return demonstration of the procedure and found that the patient had been able to urinate in the toilet and had remained continent. Residual urine was checked by catheterization immediately following voiding and volume was 60 ml. The investigator advised the patient to do self-catheterization every five hours as planned in addition to natural voiding.
June 10 - Day two. Miss S. reported voiding every three to four hours during the previous day. Residual volume was 30 ml. The investigator advised the patient to decrease the frequency of catheterization to once daily, immediately after voiding so that residual could be measured and recorded.

June 12 - Day four. Urine specimens were collected and the residual found to be 30 ml. The investigator advised Miss S. to further decrease the frequency of catheterization to once every other day.

Miss S. reported that the catheters were not drying adequately by room air exposure. The investigator demonstrated the use of a blow (hair) dryer in drying the lumen of the catheter and reinforced the importance of drying the catheter completely.

June 19. 9 A.M. Home visit was made to collect urine. The residual urine volume was found to be 90 ml. The patient reported catheterizing herself every other day and obtaining approximately 60 ml. residual each time. The investigator advised the patient to continue the program without change in frequency.

June 26. 9 A.M. Home visit made to collect specimens. Miss S. had just gotten out of bed and reportedly had not voided since 10 P.M. the previous evening. She was unable to initiate voiding on the toilet and, when
catheterized by the investigator, had a residual volume of 140 ml. When the investigator commented on the fact that the urine was darker and cloudier than on previous visits, Miss S. admitted that she had not catheterized herself since June 21. The investigator instructed the patient to catheterize herself twice daily and stressed the importance of following recommendations for frequency in preventing infection. On microscopic examination, the investigator noted that the specimen was loaded with bacteria but had only six to eight leukocytes per high power field. The patient admitted that prior to the catheterization for specimens, she had wiped her perineum hastily with a damp cloth rather than washing with soap and water. That admission may explain the microscopic findings.

July 3. A specimen was obtained as a follow-up of the bacteriuria noted on June 26. Residual measured 30 ml. Miss S. reported self-catheterizing twice daily. Urinalysis was omitted because the laboratory was closed for a holiday. A culture was sent.

July 10. A home visit was made for specimen collection. Miss S. reported doing catheterization twice daily using soap and water to cleanse the perineum. Residual urine measured 100 ml. The patient was advised by the investigator to continue CTIC twice daily.

July 28. The investigator contacted the patient by phone and advised her to carefully measure and record
residual urine for the next two days in order to determine any changes in volume. At this time, Miss S. expressed enjoying freedom from the indwelling catheter and reported that she was actively seeking employment.

July 30. A home visit was made to measure residual urine. Residual was 130 ml. and urine was clear with normal color. Miss S. expressed surprise at the large residual, stating that catheterization performed later in the morning usually produced 60-90 ml. The evening CTIC usually yielded less than 30 ml.

The next home visit was planned for later in the day, with the patient omitting any catheterization prior to the investigator's arrival, to determine if the residual diminished as the day progressed. The patient was advised to continue twice-daily catheterizations until that time.

August 8. Home visit was made at 2 P.M. Residual urine was 30 ml. Urine remained clear with normal color. Miss S. had voided earlier in the day but had not catheterized herself prior to the investigator's visit. This amount of residual was similar to that Miss S. had reported previously. Uncertainty as to the true volume of the residual necessitated the patient continuing this current routine of CTIC, measuring residual volumes each time for a week.

August 13. The patient reported that she had been obtaining only a few drops of residual urine with each
catheterization. This suggested that perhaps the bladder had regained normal function. To test this, the patient was instructed to omit catheterization for one week, after which a specimen would be collected to check for residual volume and infection.

**August 20.** Home visit made. Miss S. reported no problem throughout the catheterization-free week. Ten ml. of straw-colored, clear urine was measured. Urinalysis and culture results showed no infection. The patient was advised to use CTIC only if she experienced difficulty emptying her bladder or if there was a change in the color or clarity of her urine. She was advised to see her urologist if she developed frequency, urgency, dysuria or incontinence.

**September 24.** Miss S. reported feeling well and voiding clear, straw-colored urine every four hours. The symptoms of urinary tract infection were again reviewed and the patient was advised to see her urologist at the earliest sign of infection.

**Discussion**

The investigator's experiences with Miss S. demonstrated that successful bladder training can result from the use of CTIC.

Culture and urinalysis results for this patient are presented in Table 1. The bacteriuria present in the
specimen obtained from the indwelling catheter resolved by the fourth day of CTIC and new infection occurred once when the patient became delinquent in performing the procedure.

Table 1

Urinalysis and Culture Results
Patient Number Two

<table>
<thead>
<tr>
<th>Day</th>
<th>Result</th>
<th>Organism/s</th>
<th>Urinalysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>6/9*</td>
<td>+</td>
<td>Pseudomonas aeruginosa</td>
<td>numerous</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Citrobacter freundii</td>
<td></td>
</tr>
<tr>
<td>6/12</td>
<td>--</td>
<td></td>
<td>few</td>
</tr>
<tr>
<td>6/19</td>
<td>--</td>
<td></td>
<td>few</td>
</tr>
<tr>
<td>6/26</td>
<td>+</td>
<td>Escherichia</td>
<td>loaded</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Enterobacter cloacae</td>
<td></td>
</tr>
<tr>
<td>7/3</td>
<td>--</td>
<td></td>
<td>---</td>
</tr>
<tr>
<td>7/10</td>
<td>--</td>
<td></td>
<td>few</td>
</tr>
<tr>
<td>8/8</td>
<td>--</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>8/20</td>
<td>--</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

+ = >100,000 bacterial colonies per ml.
-- = <100,000 bacterial colonies per ml.
* = specimen from indwelling catheter.
History

Mrs. W., an 89 year old white woman with senile dementia, had a long history of organic heart disease and adult onset diabetes mellitus. Mrs. W. lived with her daughter and son-in-law until October, 1977, when she was hospitalized with congestive heart failure. She was discharged to a nursing home, where an indwelling catheter was placed for incontinence. She developed gangrene in her right foot and returned to the hospital for an above-knee amputation. She was again discharged to a nursing home and subsequently developed a sacral decubitus ulcer. Her daughter, believing that she could provide better care, took Mrs. W. back into her home.

Mrs. W. had an indwelling urethral catheter since October, 1977. After she came to live with her daughter, Mrs. W.'s catheter was changed as needed by the local visiting nurse association. Mrs. W.'s daughter reported that when the catheter was left out overnight due to a delay in replacing it, Mrs. W. remained continent.

Mrs. W.'s daughter was 62 years old and her son-in-law 65 years old; both were retired. The daughter had no major health problems. The son-in-law reported having a "heart condition" and was taking digoxin. Mrs. W. was largely dependent on these two people and demanded much of them. Mrs. W. was able to bathe herself partially, feed
herself, and turn from side to side in the bed. She was dependent on others for the remainder of her care.

The home in which Mrs. W. lived with her daughter and son-in-law was small and fairly well kept. She slept in a non-electric hospital bed with side rails. Her son-in-law lifted her to an adjacent bedside commode for bowel movements. When she was feeling well, she spent most of the day sitting in a wheelchair watching television.

At the time of her acceptance into this study, Mrs. W. was taking the following medications: digoxin, furosemide and potassium chloride for organic heart disease, chlorpropamide for diabetes mellitus, and low-dose trimethoprim-sulfamethoxazole for urinary tract infection prophylaxis. Dioctyl calcium sulfosuccinate and psyllium hydrophilic mucilloid were taken for constipation; neither influences bladder function. Her BUN and creatinine levels were within normal limits on May 22. A family practice physician provided her medical care.

Experiences During the Study

June 25. Mrs. W.'s daughter was contacted by telephone and agreed to participate in the program of CTIC.

June 27. Mrs. W. complained of back and abdominal pain. She was still taking the trimethoprim-sulfamethoxazole at this time.

June 28. Mrs. W.'s daughter called the family physician, who advised discontinuing the
trimethoprim-sulfamethoxazole as planned for the study. An agent combining acetaminophen and propoxyphene hydrochloride was ordered for pain relief.

**July 1.** The daughter sent a urine specimen to the family physician. She later told the investigator that the specimen was obtained about an hour after furosemide administration.

**July 4.** An introductory home visit was made. The daughter stated that Mrs. W. continued to complain of the back and abdominal pain and was eating and drinking poorly. She was also sleeping much of the time, possibly a side effect of the propoxyphene.

Physical assessment by the investigator revealed the following: oral temperature, 99 degrees Fahrenheit (acetaminophen administered 40 minutes earlier); heart rate 74, irregularly irregular; wet rales in the lower half of both lungs; pitting edema, left leg; costovertebral angle not tender; suprapubic area not tender; skin turgor diminished; urine dark and concentrated.

Mrs. W. was alert, complaining, and slightly dyspneic. The investigator elevated the head of the bed so that the patient was in a semi-seated position. In reviewing medication administration, the daughter stated that the potassium had been omitted for several weeks due to a misunderstanding of the physician's orders.
The physician was not available for consultation. However, the patient was not in acute distress. The family was advised to keep the head of the bed elevated, administer an extra furosemide tablet, begin potassium administration, and give fluids to counteract dehydration. The investigator stressed the importance of closely observing the patient's behavior and taking her to the emergency room if she became increasingly short of breath or experienced any deterioration of status. The family was also asked to take Mrs. W.'s temperature in the evening prior to giving the analgesic, and to withhold digoxin the next day.

Later in the evening, Mrs. W. reported feeling better and spent some time out of bed. Her temperature was not taken.

**July 5.** The investigator contacted the physician and relayed all findings, including the patient's reported improvement the previous evening. The physician advised administration of potassium and furosemide as originally prescribed and withholding digoxin every other day for one week before resuming daily administration.

The physician stated that the urine culture of July 1 showed no growth and speculated that the patient's abdominal and back pain were related to constipation-induced intestinal spasms. He saw no reason to delay the CTIC program.
July 8 (Day one of CTIC). Mrs. W.'s daughter, who had been instructed by the physician to administer an extra furosemide on days when marked leg edema was present, gave Mrs. W. one tablet at about 2:30 A.M. and then administered the routine dose at breakfast in the morning. Between 2:30 and 8:30 A.M., the patient's output totalled 1000 ml. and was very clear. The diuresis could distort urine test results because of dilution. 6 It was at this time that the daughter mentioned that the specimen of July 1 had also been obtained an hour after administration of furosemide.

Mrs. W. complained of left upper quadrant abdominal pain. Her heart rate was 70 beats per minute, still irregularly irregular, but skin turgor was improved and rales were confined to the lower quarter of the lung fields. Temperature was 98.6 degrees Fahrenheit, orally.

The indwelling catheter was removed at 9:30 A.M. At 10:30 A.M., Mrs. W. voided 240 ml. in the bedside commode; residual obtained by catheterization was 30 ml.

Mrs. W.'s daughter complained of tiredness because Mrs. W. had awakened her several times during the previous night. Because of the daughter's fatigue and the small volume of residual urine, the investigator postponed a second visit for return demonstration of CTIC until July 9.

---
Mrs. W. urinated in the bedside commode at 12:45 P.M., 4:30 P.M., and once in the late evening; she was continent otherwise. The daughter stated that the patient voided very shortly after reporting a sensation of urgency. This suggested an uninhibited type of neurogenic bladder dysfunction.  

July 9. At 6:30 A.M., Mrs. W. asked to be placed on the bedside commode but was unable to void.

At 8:45 A.M., a small amount was voided into the bedside commode. Mrs. W. told her daughter that she did not want to drink water because she was afraid of becoming incontinent.

The padding on which Mrs. W. had slept the previous night was damp but without strong odor.

Between 7:15 and 9:15 A.M., the patient's fluid intake was 540 ml. At 9:30 A.M. she was unable to void in the bedside commode. Catheterization by the daughter yielded 30 ml. concentrated urine. The investigator advised the patient to drink more fluids during the day until 4:00 P.M. then reduce intake until bedtime to prevent enuresis. The daughter was asked to offer the bedpan to the patient every three hours to avoid precipitous urge incontinence typical of uninhibited neurogenic bladder.  

---


8 Ibid.
Mrs. W.'s daughter felt insecure about doing CTIC alone and the investigator agreed to return in the late evening to observe the procedure a second time.

8:30 P.M. Mrs. W. remained continent throughout the day and voided in the bedpan or commode as needed. An extra furosemide tablet was administered at 2 P.M. because marked leg edema was present.

Mrs. W.'s skin turgor was diminished. She was unable to void and catheterization by the daughter yielded 60 ml. cloudy urine. The investigator felt uncertain about the significance of the residual volume because of the patient's dehydrated state.

The skin overlying Mrs. W.'s sacrum was reddened. The decision was made to do CTIC at bedtime to attempt to reduce the chance of enuresis which could lead to breakdown of the sacral tissue.

The patient's daughter stated that she had difficulty seeing adequately whether the catheter was dry using artificial light in the late evening. She was advised to rinse the catheter thoroughly in the evening and to wash it with soap and water and dry it in the morning.

**July 10.** Mrs. W.'s padding was again damp by morning.

**July 11.** Mrs. W. slept well and did not request pain medication. Her daughter withheld the furosemide until after the urine specimen was obtained. Mrs. W. voided
85 ml. straw-colored urine using the bedside commode. Her daughter performed CTIC and obtained 30 ml. concentrated, mucus-filled urine.

Mrs. W.'s heart rate was 72 beats per minute and less irregular than on previous visits. She appeared to breathe more easily.

The investigator suggested that the furosemide administration be timed so that the patient could use the bedpan during the period of peak diuresis and avoid frequent, strenuous transfers to the bedside commode.

Despite its small volume, the residual urine's heavy mucus content necessitated continued CTIC. Mrs. W.'s daughter stated that she could manage CTIC only two times a day. The investigator agreed to this frequency.

Mrs. W. ate and drank little during the remainder of the day and began complaining of back pain.

**July 14.** Mrs. W. continued to eat and drink only small amounts and complained more frequently of back and abdominal pain. Her daughter performed CTIC twice and found no residual.

Mrs. W.'s daughter gave her a laxative for constipation and she subsequently had frequent, small bowel movements requiring many transfers to the bedside commode. Mrs. W.'s oral temperature was 99.6 degrees Fahrenheit.

Mrs. W.'s urine culture result from July 8, obtained during diuresis, contained more than 200,000 bacterial
colonies per ml.; the culture on July 11, without diuresis, showed more than 300,000 colonies per ml. Urinary tract infection was suspected. The negative urine culture on July 1 may have reflected diuresis-masked bacteriuria. The primary physician agreed to treat the infection.

July 15. Mrs. W. was awake most of the night and her daughter and son-in-law were fatigued from lack of sleep.

A home visit was made. Mrs. W.'s heart rate was 70 beats per minute with occasional irregularity. There were a few scattered basilar rates bilaterally. Skin turgor was normal.

Mrs. W. was unable to void on the bedpan prior to a catheterization which yielded 120 ml. The investigator questioned whether the discomfort of sitting on the bedpan hindered the patient's initiation of voiding.

The family physician had prescribed trimethoprim-sulfamethoxazole at a maintenance dosage. This was questionable as the symptoms suggesting urinary tract infection began when the patient was taking the same agent and dose. The investigator contacted the physician requesting permission to increase the dosage to therapeutic levels for one week; if the symptoms did not resolve, a sterile specimen would be brought to the physician's office for urinalysis and culture.
July 17. Mrs. W. was awake most of the night, confused and belligerent. Her daughter stated that she was unsure how long she and her husband could continue to manage the care of Mrs. W.

The physician prescribed a sedative at the daughter's request and agreed to increasing the trimethoprim-sulfamethoxazole to therapeutic dosage.

Mrs. W.'s daughter told the investigator that Mrs. W. was especially combative in the late afternoon and evening and that performing catheterization was difficult at that time. Because of the daughter's weariness and the difficulty in performing catheterization in the evening, frequency of catheterization was reduced to once daily in the morning.

July 21 (air temperature was over 100 degrees Fahrenheit). A telephone call was made to Mrs. W.'s daughter by the investigator. The daughter stated that Mrs. W. slept well after administration of the sedative. However, Mrs. W. was reluctant to drink liquids and expressed fear of incontinence. She voided 60 to 90 ml. of urine four times daily. Her bed remained dry at night. Catheterization yielded 15 ml. residual urine. She continued to take furosemide daily.

Mrs. W. spent most of the recent days in her wheelchair and no longer complained of back or abdominal pain. This suggested a response to the therapeutic dose of trimethoprim-sulfamethoxazole.
The investigator advised Mrs. W.'s daughter to record accurately residual urine measurements over the next few days; if the volumes remained low, the frequency of CTIC would be decreased. The daughter was also encouraged to record the times at which Mrs. W. voided and, if a predictable pattern emerged, to offer the bedside commode one-half hour before the expected voiding time.

July 24. Mrs. W. began experiencing incontinence at night and occasionally while in the wheelchair. The investigator questioned whether the enuresis was related to long hours (10) in bed at night after taking a sedative. There was no change in intake or output. Residual urine by catheterization was 30 ml. Mrs. W. complained occasionally of back and abdominal pain.

Mrs. W. appeared to be feeling well. She transferred to the wheelchair without assistance, dressed herself in a favorite outfit including jewelry, and talked about her courtship days.

July 25 (Mrs. W.'s 90th birthday). A home visit was made to collect a urine specimen (furosemide withheld) and residual urine measured 60 ml. Mrs. W.'s daughter expressed interest in continuing to manage Mrs. W. without an indwelling catheter and reported less incontinence the previous night. The daughter was asked by the investigator to do CTIC at bedtime for several nights to see whether this would eliminate the enuresis. The investigator again discussed
the need to watch for voiding-time patterns and offer the bedpan or commode in advance.

**July 31.** A telephone call was made to the daughter to check on Mrs. W.'s condition. She reported that enuresis continued but that Mrs. W. remained continent during the day and was dressing in street clothes and enjoying visitors. Mrs. W.'s daughter told the investigator that she was satisfied with the current situation.

**August 1.** Mrs. W. began experiencing right posterior thoracic discomfort and showed no interest in dressing. Her urine became cloudy.

**August 4.** A home visit was made to collect a urine specimen. Mrs. W. continued to be disinterested and complain of pain. She refused most fluids, telling her daughter she was afraid of incontinence.

Mrs. W.'s daughter told the investigator that the patient was not cooperative with efforts made by the family to set up regular times for voiding. Frequently, Mrs. W.'s son-in-law would lift her from the bedside commode after she had insisted that she did not need to void, only to find that she immediately demanded being transferred back to the commode with or without subsequent urination. This was tiring and frustrating to the family. Residual urine measurements by the daughter were as large as 120 ml.

The investigator reminded Mrs. W.'s daughter of her option to discontinue the program. She decided to
continue a few more days. Because of the large residual volume, frequency of CTIC was again increased to two times a day.

**August 6.** Mrs. W.'s daughter stated that she would like to discontinue the program because of the excessive demands it placed on herself and her husband. An indwelling catheter was placed and a specimen was taken to the physician's office for culture and sensitivity.

**Discussion**

Mrs. W.'s use of clean technique intermittent catheterization was influenced by many factors. Her bladder capacity was diminished because of her age. Senility and confusion contributed to her lack of cooperation with the family's efforts to establish a timed voiding routine. The brief time lapse between her perception of urgency and actual voiding created further problems due to her need for assistance in transfers.

It is likely that Mrs. W. had symptomatic infection at the beginning of the study which was obscured by furosemide-induced diuresis. The additional diuretic therapy necessitated by congestive heart failure and the presence of dehydration influenced the frequency of voiding and may have distorted residual urine volume.

The diuresis following oral administration of furosemide begins within one hour and peaks within the first
or second hour. The duration of the diuretic effect is six to eight hours.\textsuperscript{9} Patients taking furosemide and using CTIC need to increase the frequency of voiding or doing the procedure during the hours of diuretic effect, especially the first two hours. Urine specimens should not be obtained within eight hours following furosemide administration to avoid distortion of test results.

The frequency of CTIC was limited in Mrs. W.'s case because of the many demands already placed on her daughter. It is possible that if catheterization had been done every three hours, as suggested by Lapides,\textsuperscript{10} the infection would have resolved without medication.

It is also possible that pharmacologic agents might at some time be successfully used in combination with intermittent catheterization or abdominal expression to manage incontinence in Mrs. W. or an elderly patient with similar bladder dysfunction. The administration of propantheline bromide might be able to increase the bladder capacity and eliminate the precipitous urge incontinence.\textsuperscript{11} The patient might then be less fearful of incontinence and more receptive to oral fluids. Again, as in patient number one, abdominal expression, when used with these agents, might


\textsuperscript{11}Wein, p. 30.
adequately empty the bladder so that CTIC is necessary only one or two times a day to manage the residual urine.\textsuperscript{12}

Mrs. W.'s physical and mental condition at the time of the study presented too many risks to safely administer these agents. According to the \textit{Physician's Desk Reference}, propantheline bromide should be used with caution in elderly patients and in the presence of congestive heart failure.\textsuperscript{13} Imipramine hydrochloride must also be administered with extreme caution in patients with cardiovascular disease. Imipramine hydrochloride may cause or exacerbate confusional states, especially in the elderly.\textsuperscript{14} Mrs. W. was not a candidate for a pharmacologic approach to urinary incontinence during the study due to her congestive heart failure and active senile dementia.

Mrs. W.'s urinalysis and culture results appear in Table 2. It is evident that the patient was infected with three different organisms during the course of the study. The reason for this is not apparent.

\textsuperscript{12}Ibid., p. 32.
\textsuperscript{14}Ibid., p. 889.
### Table 2

**Urinalysis and Culture Results**  
**Patient Number Three**

<table>
<thead>
<tr>
<th>Day</th>
<th>Culture Result</th>
<th>Organism</th>
<th>Bacteria</th>
<th>Leukocytes</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/8*</td>
<td>+</td>
<td>Proteus rettgeri</td>
<td>few</td>
<td>1-2</td>
</tr>
<tr>
<td>7/11</td>
<td>+</td>
<td>Providence stuasti</td>
<td>moderate</td>
<td>80-100</td>
</tr>
<tr>
<td>7/25</td>
<td>+</td>
<td>Proteus vulgaris</td>
<td>few</td>
<td>27-33</td>
</tr>
<tr>
<td>8/4</td>
<td>+</td>
<td>Proteus vulgaris</td>
<td>few</td>
<td>80-100</td>
</tr>
</tbody>
</table>

+ = \( \geq 100,000 \) bacterial colonies per ml.  
-= \(< 100,000 \) bacterial colonies per ml.  
* = Specimen from indwelling catheter.

**Chapter Summary**

Case studies were presented of three patients who participated in the program of clean technique intermittent catheterization. Each case study included a brief history of the patient, a narrative of experiences during the program, and a discussion of findings.

A total of 30 home visits were made. Fourteen urine cultures and 13 urinalyses were done.
Chapter 5

SUMMARY, CONCLUSIONS, IMPLICATIONS, AND RECOMMENDATIONS

Summary

The purpose of this study was to determine whether clean technique intermittent catheterization (CTIC) performed by the patient or care-taker was a safe alternative for adult patients with indwelling urethral catheters living at home.

Results of urine cultures were used to examine the relationship between bacteria in the urine and the use of CTIC following removal of an indwelling catheter. Microscopic examination of fresh, centrifuged urine sediment was performed to determine whether visualization of leukocytes and bacteria corresponded with positive culture results.

A case study approach was used to describe the investigator's experiences teaching CTIC to three patients selected according to specific criteria. One patient became catheter-free after nine and one-half weeks of CTIC; two patients returned to use of an indwelling catheter for reasons related to physical status or personal circumstances.
Conclusions

The following two research questions were addressed:

1. Does the substitution of clean technique intermittent catheterization for a chronic indwelling urethral catheter influence bacteriuria?

2. Is there a relationship between visualization of bacteria and leukocytes on microscopic examination of fresh, centrifuged urine sediment and findings on culture of greater than or equal to 100,000 bacterial colonies per ml.?

The program of CTIC was highly individualized because of patient differences. Two of the three patients discontinued the program and returned to use of an indwelling catheter. Therefore, it is not possible to draw any conclusions about the first research question.

Fourteen urine cultures and 13 urinalyses were performed. Of the 13 cultures for which there was a corresponding urinalysis, eight were positive, five were negative. Findings of bacteria and leukocytes on microscopic exam were highly variable in quantity and demonstrated no relationship to positive culture results. However, further research with much larger numbers of corresponding urine tests would be necessary to draw a more valid conclusion.

The results of urinalyses in patient number two suggested that this procedure may be useful in detecting poor technique. When Miss S. failed to wash properly before doing CTIC, urinalysis showed that her urine was loaded with
bacteria, which served as a warning signal. Improvement in technique averted clinical infection.

**Implications for Nursing Practice**

This study showed that it is possible for normal bladder function to return when CTIC is used following removal of a chronic indwelling urethral catheter. It demonstrated that CTIC can be taught successfully by a nurse to a patient or family member in the home environment, thereby eliminating transportation of handicapped or home-bound individuals to clinics or physicians' offices for the purpose of learning the procedure. The review of literature and the research study further pointed out the need for nurses in the community health setting to carefully evaluate patients within their charge who have indwelling catheters and actively pursue alternatives where they are indicated rather than accepting the indwelling catheter as an inevitable part of managing urinary incontinence.

**Recommendations**

The literature reviewed on intermittent catheterization gave no specific guidelines for selecting candidates for CTIC. The patient selection criteria devised for this study were intended to limit the subjects to a very specific group in which the investigator was interested. Although specifying this group yielded the information described above, it also placed severe constraints on the number of
subjects available for study. In order for the base of knowledge about the uses of CTIC as a substitute for a chronic indwelling urethral catheter to broaden, it is necessary for further research to be done with larger numbers of a wider range of patients. Eliminating the criteria requiring that the patient be living at home and be taught the procedure at home would open up clinic and nursing home populations for study. Including patients with chronic renal failure or other urinary tract pathology could also add to the volume of information as long as medical status was adequately monitored.

A number of questions were raised by this study. The first was the need to determine what minimum amount of patient contact was essential to assure adequate understanding of technique and monitor patients' physical and emotional status as related to CTIC.

A second question was whether using CTIC to eliminate risks associated with an indwelling catheter was worthwhile in elderly, senile patients such as patient number three because of the additional burden it placed on family members.

A third was whether guidelines could be developed so that nurses could determine which patients were candidates for CTIC either by history or by preliminary urodynamic evaluation.

There is an abysmal lack of nursing literature on the subject of clean technique intermittent catheterization.
It is the opinion of this investigator that the responsibility for research in this area should be actively pursued by nurses and not simply left to the medical community.
SELECTED BIBLIOGRAPHY
SELECTED BIBLIOGRAPHY

Books


Periodicals


APPENDIX A

CHART OF TYPES OF NEUROGENIC BLADDER DYSFUNCTION
### NEUROGENIC BLADDER DYSFUNCTION*

<table>
<thead>
<tr>
<th>Bladder Type</th>
<th>Lower Motor Neuron Bladder</th>
<th>Sensory Neurogenic Bladder</th>
<th>Autonomic Neurogenic Bladder</th>
<th>Motor Paralytic Bladder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site of lesion</td>
<td>Sensory limb of spinal arc</td>
<td>Both sensory &amp; motor limbs of spinal arc</td>
<td>Motor limb of spinal arc</td>
<td></td>
</tr>
<tr>
<td>Etiology</td>
<td>tabes dorsalis pernicious anemia multiple sclerosis diabetes mellitus syringomyelia progressive muscular atrophy amyloid herniated lumbar disc herpes</td>
<td>cord tumor, trauma abscess arachnoiditis--radiculitis spina bifida--myelomeningocele</td>
<td>cord tumor, trauma spina bifida--myelomeningocele polyradiculoneuronitis (Guillain-Barre) polio porphyria multiple sclerosis</td>
<td></td>
</tr>
<tr>
<td>Symptoms</td>
<td>Reduced or absent bladder sensation</td>
<td>Absent bladder sensation Inability to initiate voidance Stress incontinence Effective use of Credé-Valsalva expression of urine</td>
<td>Painful urinary retention Inability to initiate voidance</td>
<td></td>
</tr>
<tr>
<td>Bladder Type</td>
<td>Upper Motor Neuron Bladder</td>
<td>Reflex Neurogenic Bladder</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------</td>
<td>---------------------------</td>
<td>--------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Uninhibited Neurogenic Bladder</td>
<td>Sensory &amp; Regulatory Tract (above spinal arc)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site of lesion</td>
<td>Cortical Regulatory Tract</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Etiology</td>
<td>brain tumor, trauma stroke cerebral arteriosclerosis Parkinson's disease multiple sclerosis syphilis (CNS) epilepsy midline cerebellar tumor cord edema, trauma, tumor</td>
<td>extensive brain disease (occasionally) cord trauma, tumor, atrophy multiple sclerosis meningitis--arachnoiditis myelodysplasia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptoms</td>
<td>Frequency Urgency Incontinence</td>
<td>Reflex involuntary voiding Absent bladder sensation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

APPENDIX B

ANNOTATED BIBLIOGRAPHY OF STUDIES USING STERILE TECHNIQUE INTERMITTENT CATHETERIZATION
ANNOTATED BIBLIOGRAPHY OF STUDIES USING STERILE TECHNIQUE INTERMITTENT CATHETERIZATION


Thirty-six patients, two with medical lesions; urine acidifying agents used; 77 percent became catheter-free; sterile urine in 57 percent of catheter-free subjects; effects of indwelling catheter on return of bladder function discussed.


Results in 50 patients using modified sterile technique compared with those in 59 patients using Guttman's technique; results equivalent; 90 day minimum suggested for trial of intermittent catheterization; effects of indwelling catheter on return of bladder function discussed.


Forty-one patients with neurogenic bladder of diverse etiology; acidifiers used; family taught if patient incapable; sterile technique in hospital, clean after discharge; 19 patients catheter-free; 19 discharged on intermittent catheterization; 3 failures; sterility not addressed.


Sixty spinal cord injury patients; acidifiers used; sterility discussed; percentages for infection-causing organisms given; timing of infections analyzed by a regression line; prolonged use of antibiotics advocated for infection.

One hundred thirteen male, seven female patients with spinal cord injury; fluids restricted; catheterization frequency three to four times a day; results of complete versus incomplete lesions compared.


One hundred eleven spinal cord injury patients, all with indwelling catheters six months or longer; neurogenic agents used as needed; antimicrobials given routinely; 70 patients became catheter-free (residual less than 100 ml.); trial of intermittent catheterization arbitrarily cut off at 90 days; failures discussed.


Twenty-nine patients, 24 with spinal cord injury, all with previous indwelling catheters; antibiotics started prior to beginning the program in all patients with greater than 10^5 bacteria in urine; acidifiers used; intermittent catheterization not interrupted in event of infection; 16 of 23 men, five of six women became catheter-free (less than 100 ml. residual) with sterile urine; failures discussed.


Fifteen patients, 14 with spinal cord injury, all with indwelling catheters; 14 of 15 achieved return of bladder function.


Twelve patients, eight with medical etiology for incontinence; antibiotics used routinely; improvement in incontinence detailed; 10 of 12 achieved sterile urine; influence of residual urine on incontinence discussed; appropriate uses of intermittent catheterization for certain bladder dysfunctions discussed.

Thirty-five spinal cord injury patients, all with indwelling catheters; 21 of 35 catheter-free, including both spastic and flaccid patients; sterility not addressed; failures, complications discussed.


Forty-two patients with spinal cord injury; diet and agents used for urine acidification; 98 percent catheter-free; 88 percent with sterile urine.


Ninety-nine spinal cord injury patients; 74 of 75 men, 22 of 24 women catheter-free; 46 percent of men, 59 percent of women sterile without reinfection following discharge.


Two patients with spinal cord injury presented who developed hydronephrosis within two weeks of beginning intermittent catheterization without culture being positive; weekly monitoring of renal function urged when this procedure is used in the acute post-trauma period.


Eighty-nine patients, 79 with indwelling catheters; 75 percent sterility during hospitalization, 66 percent post-discharge; effects of prolonged previous catheterization discussed.


One hundred eleven patients (follow-up of 1974 study); improvement in rate of catheter-free status from 91 percent to 98 percent with use of adjunctive surgery discussed.

One hundred four male patients with spinal cord injury, all but six with indwelling catheters and established infection; analysis of patients who failed to achieve balanced bladder function presented; urodynamic evaluation in patients requiring intermittent catheterization more than eight weeks and use of adjunctive neurogenic agents and surgery advocated.


Two case studies of spinal cord injury patients presented; urodynamic evaluation recommended after three months of intermittent catheterization.


Seventy spinal cord injury patients, 39 with indwelling catheters; bladder irritant used with intermittent catheterization; urine sterility discussed in terms of incidence and causative organisms.


Nineteen male spinal cord injury patients; 100 percent catheter-free (residual less than 100 ml.) within 30 days; cholinergic agents used in 14; 37 percent infected (10^3 colonies per ml.) at time of discharge; 26 percent infected at three month follow-up.


Thirty-three spinal cord injury patients with indwelling catheters; 73 percent freed of indwelling; 56 percent completely catheter-free; failures, influence of indwelling catheter discussed.
Twenty-six spinal cord injury patients managed with indwelling catheter in acute post-injury period; follow-up revealed higher incidence of pyelocaliectasis than in patients who used intermittent catheterization.

Sixty-four patients; acidifiers used; neurogenic agents as needed; trial period of three months; 79 percent catheter-free; 35 percent of catheter-free patients had sterile urine without antimicrobials; acceptable residual volume 20 percent of bladder capacity in upper motor neuron bladders; 10 percent in lower motor neuron bladders.

One hundred seven patients, all with spinal cord injury; results presented in terms of sterility and low rate of complications; adjunctive surgical measures discussed.

One hundred spinal cord injury patients with previous indwelling catheter for average of 1.2 years, all infected; neurogenic agents used as needed; 94 patients catheter-free on discharge; failures, complications discussed.
APPENDIX C

PHYSICIAN ORDER FORM
PHYSICIAN ORDER FORM

I hereby give my consent for ____________________________, a patient under my medical care and supervision, to begin a program of clean technique intermittent catheterization according to the protocols for technique and methodology developed by Christine H. Lessels, R.N., a graduate student in nursing at VCU-MCV.

(physician's signature)
APPENDIX D

PATIENT CONSENT FORM
PATIENT CONSENT FORM

I understand the program of clean technique intermittent catheterization as described to me by Mrs. Christie Lessels, R.N., a graduate student in nursing at VCU-MCV.

I understand that information from tests done on my urine during the program will be used as a research project for graduate education by Mrs. Lessels.

I understand that the program will involve several home visits by Mrs. Lessels.

I understand that catheterization must be done regularly and that forgetting or becoming careless could cause me to become very sick.

I understand that although unlikely, the complication of urinary tract infection could occur and require treatment.

I understand that my participation in or withdrawal from the study will in no way affect my care at MCV Hospitals.

I understand that in the event of any physical or mental injury resulting from my participation in this research project, VCU will not offer compensation or medical treatment.

Date ___________________ Signed ____________________
APPENDIX E

FLUID INTAKE AND OUTPUT RECORD
INTAKE AND OUTPUT RECORD

<table>
<thead>
<tr>
<th>Date</th>
<th>Hour</th>
<th>Intake</th>
<th>Output</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

KEY: **Intake** is the amount of liquid taken in by eating or drinking. It includes hot or cold drinks, water, jello, pudding, soup or ice cream. Record the amount and what it was that you ate or drank.

**Output** is the amount of urine that is passed during or between catheterizations. Record the color, clearness and smell of your urine as well as the amount.
APPENDIX F

INSTRUCTIONAL BOOKLET ON CLEAN TECHNIQUE
INTERMITTENT CATHETERIZATION
**General Directions**

1. Do your catheterization four times a day. Do not let more than five hours pass between times that you catheterize. (Examples: 7 - 12 - 5 - 10 or 8 - 1 - 6 - 11) Measure the urine carefully every time you catheterize or if you are able pass urine on your own. If the amount of urine comes to more than 13 ounces when you catheterize, begin doing your catheterization every four hours.

2. Record all of your intake and output for the first week of intermittent catheterization. Your liquid intake should total no more than 68 ounces or eight-and-one-half cups in a day. Try to limit your intake after 5 P.M. to no more than two cups. Always record the amount of urine you pass through the catheter or on your own.

3. If at any time you begin to feel ill or feverish, or if your urine becomes cloudy or changes color, check your temperature. If it is 100 degrees or over, you will need to be examined by your doctor. Also, if this occurs, Mrs. Lessels will visit and again review the technique of intermittent catheterization with you.

4. When you are first learning intermittent catheterization, you may want to wear a pad or a diaper just in case there is a leakage of urine between times you catheterize.

---

**CARE OF YOUR CATHETER**

1. After using a catheter, wash it and rinse it carefully using soap and water. You may use pipe cleaners if needed. Allow it to dry in a clean place or use the warm air from a hairdryer as shown by Mrs. Lessels.

2. When catheter is completely dry, store it in a zip lock baggie until its next use.

3. You do not need to boil your clear plastic catheter. If it becomes cloudy and you are unable to get it clean, it is time to begin using a new catheter.
HOT TO DO INTERMITTENT CATHETERIZATION

1. Get all of your supplies together:
   - Catheter
   - Container to collect urine
   - Mirror
   - Measuring cup
   - Light
   - Chux

2. Wash the area very well from front to back using soap and water.
3. Wash your hands thoroughly.
4. Place the chux under your hips.
5. Spread your legs and place the light and mirror so that you can see the vagina and urethra.
6. Spread your labia with one hand and gently insert the catheter with the other. The catheter should enter the urethra just about two inches past where the urine begins to flow.
7. When the urine stops flowing, let go with the hand which has been spreading the labia and press gently over the bladder area. Bear down.
8. Remove the catheter slowly. If urine begins to flow again, wait until it stops before removing the catheter.
9. Measure and record the amount of urine.
APPENDIX G

PROTOCOL FOR CLEAN TECHNIQUE
INTERMITTENT CATHETERIZATION
CLEAN TECHNIQUE INTERMITTENT CATHETERIZATION

(Adapted from procedures described by Lowe & Hartman)*

Supplies: Clear plastic 14 Fr. catheters (2)  
Container to collect urine  
Measuring device to check volume of urine  
Soap and water  
Clean wash cloth and towel  
Hand mirror  
Zip lock plastic bag to store clean, dry catheters  
Chux  
Blow-type hairdryer

Procedure: Females

1. Ask patient to attempt to urinate.  
2. With patient lying supine, place chux under hips.  
3. Wash the perineal area with soap and water being especially careful to cleanse away all feces.  
4. Have patient abduct legs and place container for urine collection in the area between them.  
5. Set up an adequate light source.  
7. Spread the labia and locate both urinary meatus and vaginal orifice using the hand mirror.  
8. Gently insert the catheter about three inches (about two inches past where urine begins to flow) and allow urine to flow into container.  
9. When urine stops flowing, apply gentle manual pressure in the suprapubic area (Credé) to help assure complete emptying of the bladder. Ask patient to bear down.

10. Remove catheter and wash with soap and water. Allow it to air dry on a clean cloth or paper towel or use a blow-type hairdryer. Place clean dry catheter in zip lock plastic bag.

11. Record urine volume.

12. Monitor temperature daily.

13. Repeat catheterization every five hours except for one eight hour period at night.

14. Record all intake and output of fluid, including urine which patient is able to void. Patient to limit daily fluid intake to 2000 ml.'s (about 8 1/2 c.) with only a small portion of the total amount taken after 3 P.M.

15. If urine volume is ever greater than 400 ml., increase frequency of catheterization until it equals or is less than 400 ml.

16. If after one week of catheterizing every five hours, urine volume is consistently less than 400 ml., frequency can be slowly decreased. This is especially true of evening catheterizations, since fluid intake is restricted in the afternoons. If evening catheterizations yield less than 100 ml., they may be omitted, providing that intake restrictions are maintained.
APPENDIX H

METHOD FOR URINALYSIS
METHOD FOR URINALYSIS

Urinalysis was performed by the investigator using the facilities at the laboratory of the medical technology school associated with the local medical center. Three hours were spent doing urinalysis under supervision of faculty members in the school of medical technology to validate the investigator's competency. A faculty member was generally available for questions or confirmation of results during the time the investigator was examining specimens.

The Kova-System for standardized urinalysis was used as follows:

1. The specimen was agitated to mix the sediment and 9 ml. were poured into a Kova-tube.

2. The specimen was centrifuged at 1500 revolutions per minute for five minutes.

3. A Kova-Petter was inserted into the Kova-tube and all urine except the 1 ml. held at the base of the tube was decanted.

4. The sediment was agitated and a one or two drop specimen placed on a standard glass slide with a coverslip.

5. Ten to 12 low power fields were examined for casts and mucus, with special attention to the periphery of the cover slip.
6. High power was used to examine 12 or more fields for bacteria, white cells and red cells. Bacteria were recorded as "few, moderate, numerous or loaded." White and red cells were recorded as an average number per field. Counting was done by visualizing the field as being divided into quadrants.
APPENDIX I

CATHETER CLAMPING PROCEDURE
CATHETER CLAMPING PROCEDURE*

Directions:

1. Drink a cup of water every hour.
2. Measure and record all fluid intake and output.
3. Clamp the catheter as soon as possible in the morning.
4. For the first two days, remove the clamp for five minutes every hour.
5. Always remove the clamp at night for sleeping.
6. On the third and fourth days, remove the clamp for five minutes every two hours.
7. On the fifth and sixth days, remove the clamp for five minutes every three hours.
8. On the seventh day, remove the clamp for five minutes every four hours.
9. On the eighth day, the catheter will be removed and a voiding trial begun.

*Adapted from a Bladder Training Schedule used by the Instructive Visiting Nurse Association in Richmond, Virginia.
APPENDIX J

APPROVAL FORM
The Committee on the Conduct of Human Research of Virginia Commonwealth University met on February 27, 1980, and the above investigation was reviewed and approved.

You are cautioned to note that:

1. **Informed, written** consent is required of each human subject or his legally qualified guardian or next-of-kin, unless specifically excluded.

2. Any deviation from the above named protocol, or the identification of unanticipated problems which may involve risk to subjects, must be reported to this committee for review and approval.

3. Your study is subject to continued surveillance by this committee, and it will be reviewed periodically. The next review is scheduled for February 1981. At that time you must make available to the committee a roster of all subjects, a file of the completed permission slips and a summary of the results obtained, especially any adverse or unexpected effects.

4. All requests for information related to this investigation must include the exact title, the investigator, and the VCU Study Number as noted above.

5. This investigation has been indentified as being submitted to the Department of Health, Education and Welfare, and will be certified to H. E. W. Yes ___ NO ___ X

6. In some Instances approval is contingent upon compliance with changes designated by the committee. If such are imposed, they are listed on an attached sheet, one copy of which must be signed and returned to the committee to indicate the investigator's acceptance of the changes. Where there is no attachment, the study was accepted.

Donald L. Brummer, M.D., Chairman,
Committee On The Conduct of Human Research

(DLB /ad)

(Revised Form Dated 5/1/76)
VITA