2000

Outcome of Physical Therapy Treatment for Pelvic Floor Dysfunction Based on Percent Resolution and Pelvic Floor Strength

Mary E. Lundy
University of North Dakota

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Outcome of Physical Therapy Treatment for Pelvic Floor Dysfunction Based on Percent Resolution and Pelvic Floor Strength

By

Mary E. Lundy
Bachelor of Science in Physical Therapy
University of North Dakota, 1999

An Independent Study
Submitted to the Graduate Faculty of the
Department of Physical Therapy
School of Medicine
University of North Dakota
In partial fulfillment of the requirements
For the degree of
Master of Physical Therapy

Grand Forks, North Dakota
May
2000
This Independent Study, submitted by Mary E. Lundy in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Cindy Flom-Meland, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

Cindy Flom-Meland
(Faculty Preceptor)

(Graduate School Advisor)

(Chairperson, Physical Therapy)
# PERMISSION

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Date  2-13-00
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ACKNOWLEDGEMENTS

I would like to thank three people in particular: Cindy, Renee, and Megan. Without you, "this" would not have been possible. I would also like to say thank you to my wonderful friends. Without you, the person who is "I" would not be possible.
ABSTRACT

The purpose of this study is to determine the outcome of physical therapy treatment for the pelvic floor dysfunction of urinary incontinence based on percent resolution and pelvic floor strength. Percent resolution is based on the number of leakage episodes and amount, and the number and type of pads used. Pelvic floor strength is based on the length of the endurance hold, the number of repetitions, and functional use. It was found that 60% of patients had 100% resolution and 93% of patients regained functional strength following treatment. Of the remaining 40% of patients who did not have 100% resolution, 20% had less than one small leakage episode per week. The 7% of patients who did not regain functional strength were discharged as functional. These patients just did not meet the standard thirty repetitions or ten second endurance hold. This study helps prove that the pelvic floor dysfunction of urinary incontinence can be effectively treated with conservative treatment.¹
CHAPTER I
INTRODUCTION

Introduction

The pelvic floor dysfunction of Urinary incontinence is a social, psychological, and medical barrier to the health of at least ten million adult Americans. Many of these cases can be effectively treated with non-surgical, conservative treatment. With the cost of health care increasing, conservative management of urinary incontinence is becoming the wave of the future.

Problem Statement

Although there are many treatment options available, the number of patients with urinary incontinence who are not successfully treated remains high. Underreporting by the patient due to embarrassment, the misconception that urinary incontinence is just a normal part of aging, or lack of education on the health care providers part into new research are just a few examples why so many sufferers of urinary incontinence have not been treated.

Purpose

The purpose of this study is to determine the outcome of physical therapy treatment for the pelvic floor dysfunction of urinary incontinence based on percent resolution and pelvic floor strength.
Significance of Study

With the results of the study, the usefulness of physical therapy in the conservative treatment of the pelvic floor dysfunction of urinary incontinence will be demonstrated and the effectiveness of the treatment can be improved. This will directly benefit the physical therapy profession and patient care by ensuring that patients are getting the best treatment possible. The results will also be beneficial to the participating facility by providing proof of the effectiveness of their pelvic floor dysfunction treatment program for urinary incontinence.
CHAPTER II

LITERATURE REVIEW

Urinary incontinence (UI) is a social, psychological, and medical barrier to the health of at least ten million adult Americans with women affected more often than men.\textsuperscript{2-6} It is the involuntary loss of urine that can be so severe it has social and or hygienic consequences.\textsuperscript{8,12,13} Many people never seek help because of embarrassment or the misconceptions that urinary incontinence is just a normal consequence of the aging process or pregnancy.\textsuperscript{6,8,11} The changes aging and pregnancy create in the pelvic floor musculature and its supporting structures can function to predispose a person to urinary incontinence.\textsuperscript{6} The term incontinence has been interchanged with the term pelvic floor dysfunction. Pelvic floor dysfunction is defined by the International Continence Society (ICS) as a dysfunction with functional symptoms in the areas of urinary, such as incontinence, and also bowel or sexual symptoms.\textsuperscript{14} Other causes of urinary incontinence include: diseases, immobility, fecal impaction, environmental factors, medications, or acute illnesses such as bladder infections.\textsuperscript{8} If the cause is known and removed or the urinary incontinence can be improved or resolved.\textsuperscript{8,12} Thus it can be stated that urinary incontinence is not a disease it self but rather a symptom.\textsuperscript{8} In spite of this, many women remain tolerant of severe incontinence when there are management techniques that exist to alleviate or cure incontinence.\textsuperscript{15}
With regard to treatment, it has been stated that “the least dangerous and least invasive procedure that is appropriate for the patient should be the first choice”. In other words, non-surgical treatment should be attempted for the treatment of UI before surgery. It has been proven that the majority of patients with mild to severe UI show improvement with conservative management. As the cost of health care increases and because of changes in reimbursement, conservative treatment is becoming more attractive.

To better understand the pelvic floor dysfunction of UI and its treatments, a complete understanding of the pelvic floor anatomy and its role is important. The pelvic floor lies at the bottom of the abdominopelvic cavity. It not only provides the majority of support for the organs of the pelvis but also participates in the maintenance of their normal function. The pelvic floor consists of three supporting layers: the endopelvic fascia, the pelvic diaphragm and the urogenital diaphragm.

The endopelvic fascia is a continuation of the abdominal transversalis fascia, which extends over the pelvic floor. It is a fibromuscular tissue containing abundant smooth muscle fibers and functions to suspend the pelvic organs. There are distinct regions of the fascia but its connective tissue fibers interweave with those of the pelvic floor and those around vessels and nerves. The fascia is thickened in several areas to form ligaments. The cardinal ligaments join the lower uterus, cervix, and upper vagina to the pelvic walls. These ligaments, together with the uterosacral ligaments, hold the cervix and upper vagina over the levator plate. The uterosacral ligaments are more medial,
they function to stabilize the visceral structures posterior toward the sacrum. These ligaments form a curved dorsal arc from the cervix and vagina to the body of the sacrum. They assist in restricting the downward and outward movement of the uterus and upper vagina. Urethropelvic ligaments have a great functional significance for stress incontinence. They pass together with fibers of the pubococcygeus muscle and travel from the anterior aspect of the tendinous arc to the anterior vaginal wall, bladder neck, and proximal urethra. This part of the pelvic floor is the main support of the bladder neck and proximal urethra. Proper intrapelvic support requires an active component of muscular contraction during stress along with the strength of the ligament. The pubourethral ligaments join the undersurface of the pubic bone with the midurethra. Weakness in these ligaments alone allows posterior and inferior movement of the midurethra. The pubourethral ligaments do not contribute a significant amount of support, but defects in these ligaments have been implicated in urinary incontinence. In general, any tearing or stretching of the endopelvic fascia results in loss of support for the pelvic organs.¹⁸

The second layer of the pelvic floor is the pelvic diaphragm. The pelvic diaphragm is a group of striated muscles together with their fascial layers that function to close the pelvic outlet. The diaphragm is composed of the pubococcygeus, ischiococcygeus and puborectalis, collectively known as the levator ani, and the coccygeus muscles.⁶,¹⁹ The levator ani is considered to be the true muscular floor of the pelvis and provides the bulk of the supporting framework.²⁰,²¹ It acts as a single neuromuscular unit to assist with proper
support and function of the pelvic organs.\textsuperscript{1,7,18} The levator ani muscles are composed of 70% Type I and 30% Type II fibers.\textsuperscript{7,22} Type I fibers, or slow twitch fibers, are endurance fibers.\textsuperscript{7,22,23} Type II fibers, or fast twitch fibers, are rapid contraction fibers.\textsuperscript{7,22,23} The levator ani can maintain tone over an extended period, yet produce strong, quick contractions as needed.\textsuperscript{1,18} Muscles of the pelvic floor maintain constant tone by use of a spinal reflex to support the pelvic floor. The nerve supply is from two sources: the pudendal nerve L2-4 and a direct branch from the S3-4 motor roots.\textsuperscript{6,23} Also, the rectus abdominus and the pelvic floor contract simultaneously. This is demonstrated by the fact that when the abdominal muscles contract, such as with a cough or strain, the pubococcygeus also contracts. This action helps to facilitate equal pressure transmission from the abdominal cavity to the proximal urethra to maintain continence.\textsuperscript{18,24,25}

The pelvic diaphragm is divided into the anterior muscle group, also known as the pubovisceral portion, and the posterior muscle group, or the "base plate." The anterior muscle group attaches to the bladder, urethra, vagina, uterus, and rectum. It serves an active role in pelvic visceral control. The anterior pubococcygeus helps to support the visceral structures at rest, act as the support during increased intra-abdominal pressure, and serves as a backup for the endopelvic fascia. The posterior muscle group consists of the posterior levators and the coccygeus muscle. They provide a base of support for the pelvic organs and firm closure of the pelvic outlet. Both the posterior and anterior muscles are active at rest.\textsuperscript{25}
The bladder and urethra are part of the anterior muscle group. The bladder is a smooth muscle which stores from 250-300 ml of urine.\textsuperscript{15,18} It is divided into the detrusor, trigone, and bladder neck.\textsuperscript{15} The urethra is part of the bladder neck and is further divided into the proximal urethra, midurethra, and distal urethra. The bladder neck and proximal urethra together make up the initial segment. The initial segment makes up only 20% of the urethra, but it has the most influence on continence. At the proximal urethra, the pubococcygeus muscles and ligaments function to support the lateral portion of the continence mechanism to equalize the pressure of the body and bladder outlet. This contributes to this area being the most important with regard to continence. The midurethra and distal urethra are where the greatest increases in intraurethral pressure take place, thus this is another important part of the continence mechanism. The midurethra is where the extrinsic continence mechanisms, also known as the striated urogenital sphincter muscles, are found. The striated urogenital sphincter muscles are divided into three parts: the urethrovaginal sphincter, the compressor urethra, and the sphincter urethrae. They coordinate to compress, retract and elongate the urethra and to contribute to the resting urethral pressure. The first part of the striated urogenital sphincter muscle is the sphincter urethra also known as the rhabdosphinctere. It surrounds the urethra in its mid-region. The second part is the compressor urethrae, it is a continuation of the urethra sphincter. The third part is the sphincter urethrovaginalis, which blends with the compressor urethrae.\textsuperscript{6} The compressor urethrae and the
sphincter urethrovaginalis are responsible for voluntary interruption of urination.\textsuperscript{6,17,18}

Another part of the anterior muscle group is the vagina. There are three layers of the vagina: inner mucous coat, muscular layer, and outer fibrous sheath. The inner mucous coat is controlled by the autonomic system and hormones for the excretion of fluids. The muscular layer is composed of smooth muscle fibers arranged in spiral bundles. The spiral bundles allows for the distention of the vagina. The outer fibrous sheath is composed of collagen and elastic fibers that join the vagina to the surrounding endopelvic fascia.\textsuperscript{25}

The third layer of the pelvic floor is the urogenital diaphragm.\textsuperscript{6} It consists of the deep transversus peronei muscles and the intrinsic muscles of the bulbocavernosus, superficial transverse peronei, and the external and internal sphincters.\textsuperscript{6} The urogenital diaphragm adds additional support to the anterior pelvic outlet when the levator ani is deficient and is where the muscles voluntarily contract. These muscles also aid in controlling the perineum during coughing, sneezing, etc.\textsuperscript{17}

Incontinence can be caused by any pathologic, anatomic, or physiologic factor that causes intravesical pressure to exceed maximum urethral pressure.\textsuperscript{7,8} This can be an increase in intravesical pressure or a decrease in urethral pressure. Pressure can be raised by involuntary detrusor contractions, acute or chronic bladder over distension, or increases in intra-abdominal pressure.\textsuperscript{8} Decreases in urethral pressure may occur as result of uninhibited sphincter
relaxation, loss of pelvic floor support, and urethral wall defects from trauma, surgery, neurological disease or neuromuscular damage. 1,8

The most commonly encountered clinical forms of urinary incontinence are: stress, urge, overflow and mixed. 8,11 Stress incontinence is the involuntary loss of small amounts of urine. 7,24 This occurs when intra-abdominal pressure is raised above urethra resistance. 2,9,15,21,24,26 This can occur while coughing, bending, jogging or lifting heavy objects. 2,9,15,21 Stress incontinence can be caused by direct anatomic damage to the urethral sphincters or by weakening of supporting tissues surrounding the bladder outlet and urethra. 2,8,27 This is often associated with multiple births, previous pelvic surgery, or lack of estrogen in postmenopausal women. 8 Stress incontinence is the most common type of incontinence in women. 2,9,15,28 Treatment most often consists of some form of pelvic floor strengthening exercise such as Kegal exercises, vaginal weights, or electrical stimulation. 5,17,27,29

Urge incontinence occurs when patients sense the urge to void but are unable to inhibit leakage long enough to reach the bathroom. 2,8,9,15 These patients tend to void frequently and prematurely. 9 Causes of urge incontinence include: uninhibited bladder contractions, detrusor instability, local irritating factors and neurological diseases. Neurological diseases include: stroke, Parkinson's, dementia, multiple sclerosis and spinal cord diseases. 2,26 Occurrence increases with age. This is the most common form of incontinence in elderly women. 15 Treatment most often consists of behavior techniques such as bladder training or limiting caffeine, in addition to pelvic floor exercises. 5,15,17,26
Overflow incontinence occurs when the bladder cannot empty normally and becomes over distended, causing frequent and almost constant urine loss.\(^8\) Causes include neurologic abnormalities such as a hypotonic or acontractile bladder; damage to the spinal cord causing flaccid paralysis of the bladder, sphincter and pelvic muscles; and any factor that obstructs outflow such as medications, tumors, benign strictures, and prosthetic hypertrophy.\(^2,8,9\) Overflow incontinence may mimic stress or urge UI.\(^9\)

Mixed incontinence displays some aspects of more than one of the major subtypes.\(^8\) It has been found that stress and urge incontinence co-exist in 20% of patients.\(^15\)

For treatment to be successful, the proper diagnosis of the type of UI is a must.\(^8,11\) Evaluation and therapy must be tailored to the individual and take into account clinical, cognitive, functional, and residential status.\(^8\) A core evaluation is performed by a physician. A thorough history is taken, and urologic, gynecologic, neurologic assessments are performed.\(^8,28\) The duration, frequency, volume, and type of incontinence should be described and validated by a voiding diary.\(^8,22,28\) Other information obtained are associated illness, previous operations, and current medications.\(^8\) Core measurements include: urodynamic testing, urinalysis, serum creatinine or blood urea nitrogen and post void residual urine cytology.\(^8,10,11,17,28-31\)

Physical therapists will perform an exam and take a thorough history. The history can included questions regarding: severity, duration, pad usage, and a request that the patient fill out a voiding diary.\(^5,13,22,23,32,33\) They may perform a
provoked full bladder test in which a pad is weighed "dry" and reweighed after a series of exercises. They also utilize a system of muscle testing, which is a method of analyzing and assessing a patient's physiologic condition in relation to function. This is used to determine the extent and degree of muscle weakness resulting from disease, injury, and disuse.

A type of muscle testing is manual muscle testing (MMT). MMT requires comprehensive and detailed knowledge of the pelvic floor muscles functions and their origins and insertions. The therapist must also know the agonistic and antagonistic muscle actions, how they function in fixation of skeletal structures and substitution of supplemental muscle groups. The examiner will palpate the muscles and tendons, assess tone, assess normal and atrophied muscles, recognize alterations in position, and check for movement.

A digital measure for strength of muscle contraction consists of the insertion of two gloved fingers into the vagina in the anterior/posterior plane. The muscle are contracted around fingers with as much force as the patient can produce and hold for as long as possible. A rating scale of 0 to 4 is used with 0 being no muscle activity and 4 with a contraction strong enough to pull the examiners fingers in and up snugly. The length of time the maximal contraction is held can also be recorded. Patients with normal or good grades are probably incontinent due to reasons other than pelvic floor weakness (such as a medical condition).

Another measure of strength was developed by Dr. Arnold Kegel. He used a perineometer consisting of a cone shaped air-filled vaginal chamber.
records pressure from 0 to 100mm of mercury.\textsuperscript{21} This device is also used as a method of evaluating success of pelvic floor muscle exercises.\textsuperscript{6,7,19,35} During treatment, it is used for women who are unable to feel the contraction of the pelvic floor muscles or if visual feedback is desired.\textsuperscript{21} A drawback of this device is that it can also record the use of the abdominal muscles.\textsuperscript{11,36}

A subjective assessment of strength is the ability to stop urine flow.\textsuperscript{1,6,35} This is to be done only one to two times a week for testing secondary to risk of upper urinary tract infection due to urinary reflux. A rating scale from fair to zero is used with incontinent patients. A fair grade is the ability to stop urine flow in gravity resisted position but the patient’s strength is distinguished from good and normal secondary to being incontinent. A poor grade is the ability to maintain deflection of flow or a reduced stream. A trace grade is the ability to deflect or reduce stream but unable to maintain change.\textsuperscript{1} Zero is no ability to change flow.\textsuperscript{1,6}

Proper assessment of strength must be made so the appropriate level of exercise is chosen for the patient. A tenet of muscle training is that no muscle group should be exercised in gravity dependant position until a fair grade is achieved.\textsuperscript{1}

General principles of treatment is that all persons with urinary incontinence should be considered for treatment.\textsuperscript{11} Treatment decisions are based on a diagnosis, patient personality, environment, expectations, and clinical status for determinants of modalities. Patients need sufficient information and explanation to be able to make choices regarding therapy options.\textsuperscript{2,11,16} It has
been stated that "the least dangerous and least invasive procedure that is appropriate for the patient should be the first choice."  

Conservative treatment consists of implementing behavior techniques of bladder training, pelvic muscle exercises, biofeedback, vaginal cones, and electrical stimulation. 

Behavioral techniques, such as bladder training, are used most often with urge incontinence. The patient is to resist or inhibit sensation of urgency and postpone voiding. They are to urinate according to a time table rather than urge. 

The patient starts with one hour intervals or as often as 15 minute and progress to up to 3 hour waits. The patient is taught to take a deep breath, wait 10 sec, and walk to the bathroom when the urge to urinate arises. The goal is to train the bladder to hold a greater amount of urine. The patient uses a bladder diary and measures amount of urine and keeps track of fluid intake. Other behavioral techniques include: fluid regulation, change in diet, improved mobility, or environment change.

Kegal was the first to study pelvic floor muscle strengthening. He observed that only 60% of patients were able to perform exercises correctly with verbal instruction only, thus he implemented use of a periniometer. It is of great importance to use the pelvic floor muscles only during contraction and not substitute the abdominal or glutes. Pelvic muscle exercise strengthen voluntary periurethral and pelvic floor muscles. Many studies show that pelvic floor exercises to be successful in strengthening the pelvic floor in treating UI of both stress and mixed urge and stress types. Most articles
recommend about 50-100 contractions per day to make a significant difference in strength.\textsuperscript{2,13,17,19} The patient is instructed to “draw in” the pelvic floor and hold as long as possible (up to seconds), totally relax, and repeat for a set of 10. Patients are also encouraged to do both slow and “quick flicks”.\textsuperscript{1,2}

Physical therapists also find biofeedback a useful tool to reinforce pelvic floor exercises.\textsuperscript{6,8,19} It gives electromyographic or pressure information about the muscles through visual and auditory displays.\textsuperscript{2,8} The patient is given moment-to-moment information on how well they are controlling the muscles.\textsuperscript{8,11,17,19} It helps the patient learn correct responses such as to relax detrusor and abdominals and/or contract the sphincters, depending on the type of incontinence.\textsuperscript{8,11,17,27} A drawback is that biofeedback requires equipment training to enable the patient to do the exercises.\textsuperscript{8} Also, the exercises may still be performed incorrectly since biofeedback will also record abdominal contractions.\textsuperscript{11}

Weighted vaginal cones are another form of treatment. They come in a set of five weighing 20 to 60-100 grams.\textsuperscript{6,13,27} The cones are inserted into the vagina and are kept in place by the pelvic floor muscles.\textsuperscript{15} The patient is instructed to use the cones twice daily for 15 minutes.\textsuperscript{13,15,27,34} The patient must be able to retain the lightest cone prior to home use and can progress to the next cone after successful retention of a cone for two consecutive days.\textsuperscript{1,13,27} The advantages of vaginal cones are: ease of use, ease of education, inexpensive, and have been successful for both urge and stress incontinence.\textsuperscript{1,11,13,27,34}
Patients with trace to zero muscle grades are generally unable to contract or sustain isolated pelvic floor contractions.\textsuperscript{1,10} Electrical stimulation is the initial treatment of choice.\textsuperscript{1} Electrical stimulation may be used to teach isolated pelvic floor contractions in both stress and urge urinary incontinence while also resulting in muscle hypertrophy in both fast and slow twitch types.\textsuperscript{1,6,11,26,32} Once the patient is able to contract the pelvic floor muscles, they can move up to higher level exercises such as pelvic floor exercises with biofeedback or vaginal cones.

The success of physical therapy in the treatment of the pelvic floor dysfunction of urinary incontinence is encouraging as an alternative to surgery. Surgery may be tempting, but a dedicated health care worker and patient may manage incontinence non-surgically.\textsuperscript{1}
CHAPTER III
METHODOLOGY

Subjects

The subjects consist of fifteen female patients ages 31 to 83. Patients were treated by two physical therapists at Altru Health Institute for the diagnosis of the pelvic floor dysfunction of urinary incontinence. The pelvic floor dysfunctions included: pelvic floor weakness, pelvic floor support dysfunction, urge incontinence and a mixed incontinence diagnosis.

Instrumentation - Outcome Study

The outcome study consisted of routinely collected data for the treatment of the pelvic floor dysfunction of urinary incontinence. The study was based on percent resolution and pelvic floor strength. Percent resolution was measured by the decrease in number of leakage episodes, the decrease in amount of leakage, and the decrease in pad usage. Pelvic floor strength was assessed by the length of the endurance hold, the number of repetitions, and functional use. All data was obtained via chart review.

Procedure

To ensure the confidentiality of the patients, the physical therapists compiled a list of standardized information for the investigator. The investigator used pertinent information from the physical therapist's list to conduct the outcome study.
Data Analysis

The investigator will compile all data. The results will be determined by traditional descriptive and analytical statistics. This will be done with the use of the SPSS computer program at an alpha level of .05 for all tests.
CHAPTER IV

RESULTS

All outcomes were created from the combined averages of fifteen subjects. Of the fifteen subjects, three were diagnosed with pelvic floor weakness, four with pelvic floor support dysfunction, seven with urge incontinence, and one with a mixed diagnosis. Subject profile is represented on Table 1.

<table>
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<td>---</td>
</tr>
<tr>
<td>age</td>
</tr>
<tr>
<td>visits</td>
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<td>Rx length (Days)</td>
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Percent Resolution

The percent resolution was based on the comparison of the pre-treatment and post-treatment number of leakage episodes (Table 2), amount of leakage (Table 3), and type and number of pads used (Table 4).

Eight of fifteen pre-treatment subjects, or 53%, had less than or equal to two episodes of leakage per day. Zero pre-treatment subjects had no leakage.
This averages out to be 2.37 leakage episodes per day pre-treatment (Table 2). Fourteen of fifteen post treatment subjects, or 93%, had less than or equal to two episodes of leakage per day. Nine post-treatment subjects had no leakage. This averages out to be less than one leakage episodes per day post-treatment (Table 2). Both the pre-treatment and post-treatment averages were found to have .007 significance.

**Table 2.** Number of Leakage Episodes Per-day Pre and Post-treatment.

<table>
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<tr>
<th></th>
<th>N</th>
<th>Mean</th>
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<tr>
<td>Pre-Rx</td>
<td>15</td>
<td>2.37</td>
<td>2.14</td>
<td>.14</td>
<td>7</td>
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<tr>
<td>Post-Rx</td>
<td>15</td>
<td>.63</td>
<td>1.57</td>
<td>0.00</td>
<td>6</td>
<td>R Skewed and leptokurtic</td>
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</table>

All subjects had at least a small amount of leakage pre-treatment (Table 3). Nine of fifteen subjects reported no leakage post-treatment (Table 3).

**Table 3.** Amount of Leakage Pre-treatment and Post-treatment.

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The number of pads used significantly decreased from pre-treatment to post-treatment (Table 4). Also, patient who were using pads, were using less absorbent pads following treatment (Table 4). Prior to treatment, 13% or two used no pad; 33% or 5 used a panty liner; 33% or 5 used a poise; and 20% or three used a maxi pad. Following treatment, 67% or 10 used no pad and 34% or 5 used only a panty liner. Of the five subjects who used only a panty liner: two used \( \leq \) one panty liner a day, two used two per day, and one patient would use a panty liner occasionally “just in case”.

**Table 4.** Type and Number of Pads Used.

<table>
<thead>
<tr>
<th>Type of pad</th>
<th>Type of Pad Used</th>
<th>Number of Pads Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Rx</td>
<td>None</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Panty Liner</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Poise</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Maxi Pad</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>15</td>
</tr>
<tr>
<td>Post-Rx</td>
<td>None</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Panty Liner</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Poise</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Maxi Pad</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>15</td>
</tr>
</tbody>
</table>

**Strength**

Fourteen of fifteen subjects were unable to achieve a ten second functional hold pre-treatment. Post-treatment, fourteen of fifteen subjects were able to perform an endurance hold of ten seconds or greater. With regard to number of contractions, 100% of subjects were unable to achieve a thirty
repetition functional contraction pre-treatment. Post-treatment, fourteen of fifteen were able to perform a functional number of thirty contractions or greater. According to the data provided via the physical therapist's list, fifteen of fifteen subjects were non-functional prior to treatment and fifteen of fifteen were functional following treatment.
CHAPTER V
DISCUSSION

The percent resolution of urinary incontinence was based on the subjects' daily subjective reports of their number of leakage episodes, the number and type of pads used, and amount of leakage. The type of pads used was not originally part of the percent resolution, but it was found to fit in very well with regard to explaining the outcome. Amount of leakage was reported as being: zero, small, medium, and large. Subjects were instructed what constituted each amount. A small amount of leakage equaled just wetting the underwear, medium equaled wetting the outer garments, and large equaled an amount of urine that would wet the floor or a chair.\footnote{1} The percent resolution of fourteen of fifteen subjects in this outcome study was excellent. One subject continued to have six leakage episodes per day following treatment. The other fourteen had less than two leakage episodes per day following treatment. Although the leakage episodes of this individual remained at six per day, the greatest amount of leakage reported by any subject following treatment was small. Also, no subjects reported using more than two panty liners per day. Thus this subject was only having a small amount of leakage and using two panty liners at the most per day.

Comparing the number of post-treatment leakage episodes to the number and types of pads used, nine of the fifteen subjects had complete resolution of
leakage episodes but ten of the fifteen subjects used no pad. A possible explanation for this can be rationalized. Following treatment, two subjects had leakage episodes of .07 times a day or once every two weeks. Also, six of the fifteen subjects that did continue to have leakage, none had greater than a small amount. Thus, this one subject may have felt her leakage was not significant enough to warrant the need for a pad. The other subject who had leakage once every two weeks could be wearing a panty liner “just in case”.

The strength of the pelvic floor for this particular study was based on the length of the endurance hold, number of repetitions, and function. The length of the endurance hold and the number of repetitions was objectively measured by the physical therapist using biofeedback. Subjects needed to obtain a ten second hold or greater of their pelvic floor muscles and complete thirty repeated contractions of their pelvic floor muscles to be considered functional. In addition to this objective functional report of the strength of the pelvic floor, the physical therapists made a subjective statement as to whether or not they felt a subject had functional strength. The reasoning behind this is that just because a subject could not obtain the standard numbers for endurance and repetitions, does not mean that they are functional for what their individual needs are.

The strength of fourteen of fifteen subjects was found to be objectively functional following treatment when considering just the length of the endurance hold and the total number of contractions. At final testing all fifteen subjects were subjectively rated as functional by the physical therapist. This could be because of the previously stated reason that, although this one subject did not meet the
standard ten second endurance hold or the thirty repetitions of contractions, she was still functional for her needs.

It was found that subjects received these kind of results in an average of four visits. The average length of time subjects were in therapy was forty-eight days. Subject treatment ranged from two to six visits and length of time in therapy ranged from 20 days to 84 days. The reasons for this range could be due to some subjects: catching on to the exercises quicker and being more compliant with them, not having as severe as leakage or strength issues, or had more vaginal births. Also, there could have been other issues going on such as disease processes, mental health issues, environmental factors, or many more.⁶,⁸,¹¹
CHAPTER VI
CONCLUSIONS

Limitations

There are a number of limitations which may have impacted the results of this study. First, the limited number of subjects in this study may not adequately represent the statistically correct outcome of the urinary incontinent treatment population. Many subjects did not correctly fill out their bladder diary thus vital information was lacking. Secondly, the percent resolution data is based solely on the subject's subjective reports. A way to make this a more objective measure would be to have the subjects "pre-weight" and also get a "post-weight" of their protective pad. This method would not only give more accurate numbers as to the amount of leakage, but also as to whether or not the subject is using and reporting the correct pad type and number. Finally, subject strength in this study is based on function, either the subjects has it or they do not. This leaves no room for varying levels of strength. According to the physical therapist's subject list, many subjects had greater than ten contractions and greater than a thirty second endurance hold but they greater numbers were not reported. It would be interesting to know exactly what numbers subjects were achieving.

Conclusion and Clinical Implications

Although this study had a limited number of subjects, it helps to demonstrate that no matter the type of pelvic floor dysfunction with urinary incontinence a subject is diagnosed with, they do get results from conservative
treatment. With the rising costs of health care and most people taking a more proactive approach to their health, the conservative treatment of the pelvic floor dysfunction of urinary incontinence could be the wave of the future.\textsuperscript{1}
OUTCOME STUDY

An outcome study has been set up for the diagnosis of pelvic floor dysfunctions with the symptoms of stress, urge and mixed incontinence. Outcomes specific to physical therapy have been set up to be studied upon discharge from physical therapy. The studies monitored will include those individuals who have received education in the rehabilitation of the pelvic floor and bladder training. Home exercise programs may consist of pelvic floor muscle strengthening alone or augmented with vaginal weights, biofeedback or electrical stimulation.

Data compiled with the outcome studies will be kept within the Altru Health Institute as well as original copies of specific assessments/evaluations during the treatment period.

This letter is to notify those institutions, which will be assisting in helping to compile this outcome data. Individuals will be aware of their participation in the study and that confidentiality will be strictly maintained.

The two physical therapists who treat pelvic floor dysfunctions are Megan Boyd MPT, and Holly Bommersbach MPT. They can be contacted at 701-780-2315. Steve Rood MPT, Director of Physical Therapy also can be contacted at 701-780-2315.

Megan Boyd, MPT
Steve Rood, MPT
Director of Physical Therapy
Altru Health System

Holly Bommersbach, MPT

Altru Rehabilitation Center
Altru Health Institute  •  1300 South Columbia Road  •  P.O. Box 6002  •  Grand Forks, ND 58206-6002  •  701-780-2311

An Equal Opportunity Employer
This study has been designed to assess the outcome of physical therapy treatment for pelvic floor dysfunction. Urinary incontinence is the specific pelvic floor dysfunction that will be researched. There are four types of urinary incontinence: stress, urge, overflow and mixed. Two main types of treatment are surgical and non-surgical. Non-surgical treatment includes intake/output diaries, biofeedback, and pelvic floor exercises.

The purpose of this study is to determine the outcome of physical therapy treatment for pelvic floor dysfunction based on percent resolution and pelvic floor strength. Percent resolution will be measured by the decrease in the number of leakage episodes, the decrease in amount of leakage, and the decrease in pad usage. Pelvic floor strength will be assessed by the length of the endurance hold, the number of repetitions, and functional use. Data will be obtained via chart review of patients at the Altru Health Institute.
PROTOCOL: (Describe procedures to which humans will be subjected. Use additional pages if necessary.)

Subjects: The subjects will consist of patients from the Altru Health Institute that have been treated by Megan Boyd, MPT and Holly Bommersbach, MPT for pelvic floor dysfunction.

Procedures: The investigator will use patient results of percent resolution and pelvic floor strength that have been previously compiled by Megan Boyd, MPT and Holly Bommersbach, MPT of the Altru Health Institute via chart review. Percent resolution will be based on decrease in the number of leakage episodes, the decrease in amount of leakage, and the decrease in pad usage. Pelvic floor strength will be assessed by the endurance test, the number of repetitions and functional use. The names of the subjects will be kept confidential from the investigator. All subjects have volunteered for participation in this study, allowing the investigator to compile outcome data.

Data Analysis: The investigator will compile the results. The results will be determined by the use of additional descriptive and analytical statistics with use of the computer program SPSS. An alpha level of .05 will be set for all tests.

Data Reported: The results of the study will be reported to Altru Health Institute and the UND Department of Physical Therapy. The results of the study will also be available to the public.

BENEFITS: (Describe the benefits to the individual or society.)

The benefits of this study will be directed at patient care. With the results of the study, the effectiveness of the treatment of pelvic floor dysfunction can be improved. It will benefit the physical therapy profession by providing results in percent resolution and pelvic floor strength. The results will be beneficial to the Altru Health Institute by providing proof of the effectiveness of the pelvic floor dysfunction treatment program.

RISKS: (Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self-respect, as well as psychological, emotional or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to insure the confidentiality of data obtained, including plans for final disposition or destruction, debriefing procedures, etc.)

There are no risks involved with this study. Identifying data, such as names and addresses, will be kept confidential from the investigator.

CONSENT FORM: A copy of the CONSENT FORM to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no CONSENT FORM is to be used, document the procedures to be used to assure that infringement upon the subject's rights will not occur.

Describe where signed consent forms will be kept and for what period of time.

No formal consent forms will be utilized in this study. All data is collected via chart review and then given to the investigator. All subject names are kept confidential from the investigator.

For FULL IRB REVIEW forward a signed original and thirteen (13) copies of this completed form, and where applicable, thirteen (13) copies of the proposed consent form, questionnaires, etc. and any supporting documentation to:

Office of Research & Program Development
University of North Dakota
Grand Forks, North Dakota 58202-7134

In campus, mail to: Office of Research & Program Development, Box 7134, or drop it off at Room 105 Twamley Hall.

For EXEMPT or EXPEDITED REVIEW forward a signed original and a copy of the consent form, questionnaires, etc. and any supporting documentation to one of the addresses above.
The policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of Human Subjects performed by personnel conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University's policies and procedures governing the use of human subjects.

IGNATURES:

[Signatures of principal investigator, project director of student adviser, training or center grant director]

Revised 3/1996)
STUDENT RESEARCHERS: As of June 4, 1997 (based on the recommendation of UNO Legal Counsel) the University of North Dakota IRB is unable to approve your project unless the following "Student Consent to Release of Educational Record" is signed and included with your "Human Subjects Review Form."

STUDENT CONSENT TO RELEASE OF EDUCATIONAL RECORD

Pursuant to the Family Educational Rights and Privacy Act of 1974, I hereby consent to the Institutional Review Board's access to those portions of my educational record which involve research that I wish to conduct under the Board's auspices. I understand that the Board may need to review my study data based on a question from a participant or under a random audit. The study to which this release pertains is **Outcome of Physical Therapy for Pelvic Floor Dysfunction Based on Percent Resolution and Pelvic Floor Strength**.

I understand that such information concerning my educational record will not be released except on the condition that the institutional Review Board will not permit any other party to have access to such information without my written consent. I also understand that this policy will be explained to those persons requesting any educational information and that this release will be kept with the study documentation.

Date: Sept. 3, 1999

Signature of Student Researcher

1Consent required by 20 U.S.C. 1232g.
**Institutional Review Board**

**Research Project Action Report**

**Project Title:** Outcome of Physical Therapy Treatment to Pelvic Floor Dysfunction Based on Percent Resolution and Pelvic Floor Strength

The above referenced project protocol and informed consent was reviewed by the Altru Health System Institutional Review Board on September 2, 1999, and the following action was taken:

- Project approved. Next scheduled review is on September 2, 1999.
- If no date is given, then review will be required in 12 months. (See REMARKS SECTION for any special condition.)

**REMARKS:**

Any changes in protocol, adverse occurrences or deaths in the course of the research project must be reported immediately to the IRB chairperson or the IRB office (780-6161).

If the patient does not want to participate in the study, do they still get treatment for their bladder problem? It is not clear to me based on the information provided.

Signature of Chairperson or Designated IRB Member

Date 9/3/99

The proposed project is to be part of a research activity funded by a federal agency, a special assurance statement or a completed 596 Form may be required. Contact IRB office to obtain the required documents.
MEMORANDUM

To: Mary E. Lundy
    Cindy Flom-Meland
    Megan Boyd
    Holly Bommersbach
    UND Physical Therapy Department
    Box 9037
    Grand Forks, ND 58202

From: Kevin J. Tveit, MD
      Chair
      Altru Health System IRB

Date: September 9, 1999

Re: Outcome of Physical Therapy Treatment to Pelvic Floor Dysfunction Based on Percent Resolution and Pelvic Floor Strength

The above project was approved by me on September 3, 1999, and enclosed is a copy of the Research Project Action Report. Please complete the enclosed Research Project Completion/Termination Report when you have completed your project and return to:

Eleanor Tveit
Administration
Altru Clinic
P. O. Box 6003
Grand Forks, ND 58206-6003

Thank you.

KJT/ert
Enc.
Your request to conduct the above named study at an Altru Health System facility involving employees or patients as participants, and/or requiring facility resources has been reviewed. The following action has been taken:

- Permission to conduct the study is granted

- Permission to conduct the study will be granted upon completion of the following:

- Permission to conduct the study is denied for the following reason(s):

RECOMMENDATIONS/REMARKS:

Your revised application has been sent to Altru IRB.

Signature: Virginia Enloe
Title: Manager, Research
Date: 9/30/99
REFERENCES
REFERENCES


9 Savage, S. Clinical Expertise: A multidisciplinary continence clinic can offer a variety of helpful services to a community. Here are some tips on getting started. *TeamRehab Report.* 1994; 57-61.


