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THE EFFICACY OF ELECTRICAL STIMULATION AND CONSERVATIVE PHYSICAL THERAPY IN THE TREATMENT OF FEMALE GENUINE STRESS INCONTINENCE

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THESIS

Submitted to the Department of Physical Therapy
at Grand Valley State University
Allendale. Michigan
in partial fulfillment of the requirements
for the degree of

MASTER OF SCIENCE IN PHYSICAL THERAPY

1997

ABSTRACT

THE EFFICACY OF ELECTRICAL STIMULATION AND CONSERVATIVE PHYSICAL THERAPY IN THE TREATMENT OF FEMALE GENUINE STRESS INCONTINENCE

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The purpose of this study was to determine which of three treatment strategies was most effective in the treatment of female genuine stress incontinence (GSI).

Nine females ages 41-86, diagnosed with GSI, were included in the study. Subjects were randomly assigned to one of three groups, one received electrical stimulation twice a week for 15 minutes; another received electrical stimulation three times a week for thirty minutes; and a control group receiving no electrical stimulation. All groups received identical instruction in Kegel pelvic floor muscle exercises, with the assistance of audio and visual biofeedback. Each treatment was evaluated on five criteria: a stress test, digital manual muscle test of the pelvic floor, periometry measurement of pelvic floor strength, Incontinence Impact Questionnaire score, and Urogential Distress Inventory score.

The data were analyzed using a Kruskal-Wallis 1-Way ANOVA, which computed a mean rank for each method according to the change it caused in the dependent variables, and a Pearson's Correlation Coefficient analysis, to reveal any significant relationships among the variables. Although some important relationships did emerge, none of the results of this study were shown to be statistically significant.

ACKNOWLEDGMENTS

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CHAPTER 1

INTRODUCTION

Urinary incontinence is defined as "a condition in which involuntary loss of urine is a social or hygienic problem" (AHCPR, 1992). The total cost of treating a person who suffers from incontinence, in man-power and health-related material in 1994, was 16.4 billion dollars, with community-dwelling individuals (those living outside extended care facilities) accounting for seventy percent of the cost (Hu, 1994). Fifteen to thirty percent of community-dwelling people have some form of urinary incontinence, with women twice as likely as men to be affected. (AHCPR, 1992). Of those identified as incontinent, 25-30% have episodes on a daily or weekly basis (Diokno, 1986).

One of the most common types of urinary incontinence affecting females is genuine stress incontinence (GSI). It is defined as "the involuntary loss of urine during sneezing, laughing or other physical activities that increase abdominal pressure in the absence of detrusor contraction or an over distended bladder" (AHCPR, 1996). GSI is often caused by hypermobility or displacement of the urethra and bladder neck during exertion (AHCPR, 1996). This hypermobility can be caused by any of the following: trauma to pelvic floor muscle or surrounding tissue from surgery or childbirth, damage to nerve supply of sphincter or levator ani muscle, weakness from immobility or underuse, fatigue or stretching from overuse (Polden & Mantle, 1990). Two other causes of GSI are intrinsic urethral deficiency, due to congenital sphincter weakness (AHCPR, 1996), and prolapse of the bladder and urethra, secondary to damage of their surrounding support structures (Polden & Mantle, 1990).

Incontinence is a major social issue for patients. It can be an embarrassment and lead to social isolation, depression, and self-neglect (Breakwell & Walker, 1988). As socially disabling as incontinence can be, it is often difficult to effectively treat. Many of the current techniques used to treat incontinence are controversial and have not been sufficiently tested to determine their effectiveness. One treatment being used with some success is a combination of Kegel pelvic floor muscle exercises and audio or visual biofeedback, in conjunction with electrical stimulation. This treatment has two purposes, to strengthen the pelvic floor musculature and to help patients gain concious control of these muscles. Accomplishing these two objectives improves a patient's ability to control their urination.

Due to the lack of controlled experimental research on electrical stimulation for treating urinary incontinence, specific parameters or protocols for optimal effectiveness have not been developed. The purpose of this study was to compare two different urinary stress incontinence treatment protocols using electrical stimulation therapy. The first protocol was the standard protocol developed by Empi Corporation for use with their INNOVA® pelvic floor (PFS) stimulation units. The second protocol was an experimental protocol developed by a physical therapist, specializing in the treatment of urinary incontinence. A control group, which did not receive any form of electrical stimulation, was also included in the study.

The study involved nine females diagnosed as having genuine stress incontinence (GSI), with no other forms of incontinence. Each subject was randomly assigned to one of the following treatments: 1.) Empi developed protocol; 2.) experimental protocol;

3.) control. All three treatments involved identical Kegel exercises and biofeedback regimes. The entire treatment lasted no longer than one hour. Patients were treated either two or three times per week for six weeks, depending on the group they were assigned to.

Subjects completed both a pre and post-treatment Incontinence Impact Questionnaire (IIQ) and Urogenital Distress Inventory (UDI) survey. The IIQ determines the extent to which urinary incontinence affects patients' physical activities, social relationships and emotional health. The UDI determines the severity of symptoms women are experiencing from their incontinence (Shumaker, Wyman, Uebersax, McClish, Fantl, 1994). Subjects were also evaluated with a "stress test", a mechanical periometric measurement of pelvic floor muscle strength, and manual muscle test of their pelvic floor. All three tests were performed at the initial evaluation, and again at discharge. The evaluation was conducted by a licensed physical therapist.

The results were analyzed to determine whether the experimental electrical stimulation protocol was more effective than the Empi developed protocol, for treating women with GSI, or vise versa. Additionally, the research considered whether using electrical stimulation is a necessary component of conservative treatment for GSI. The researchers hypothesized that intravaginal electrical stimulation would prove to be a necessary component in the conservative treatment of GSI. The authors further hypothesized that the experimental protocol, with its decreased duration per session and less frequent sessions of electrical stimulation, would be equally beneficial to the Empi developed protocol.

This study will be helpful to the physical therapy and medical professions, as well as the third-party payer system. The study will help determine whether electrical stimulation is an effective treatment for GSI. If electrical stimulation is deemed effective, the study will provide an initial step toward developing the optimal approach for its use in treating GSI. If standard, conservative protocols can be developed to effectively treat GSI, it will provide physicians, therapists, and patients alike with a less-expensive alternative to surgery.

CHAPTER 2

REVIEW OF LITERATURE

Stress Incontinence

Ryan and Mcfadden define urinary incontinence as "voiding involuntarily at an inconvenient time or in an inappropriate place" (1995). In addition, social or hygienic consequences may develop as secondary problems (Wyman, Harkins, Choi, Taylor & Fantl, 1987). These authors distinguish four types of incontinence: stress; urge; dribbling; and passive (1987). For the purpose of this literature review, the authors will focus on stress incontinence. Stress incontinence is the involuntary loss of urine brought on by a sudden rise in intra-abdominal pressure, occurring with physical activities such as coughing, sneezing, jogging and lifting (Burgio, Robinson, Engel & 1986). When intra-abdominal pressure exceeds the maximum pressure generated in the urethra by pelvic contraction, incontinence occurs.

Incidence and Cost

An estimated 20 million Americans have experienced involuntary loss of urine at some point in their lives (Ryan, 1996), costing this country over 16.4 billion dollars in 1994 (Hu, 1994). This is an increase of greater than sixty percent over the last estimate in 1990 (Hu, 1990). 11.2 of this 16.4 billion dollars is spent on individuals living outside of extended care facilities (ie. community dwellers) (Hu, 1994), and women are 2-3 times more likely than men to suffer from incontinence (Ryan, 1996). Therefore, community-dwelling women are the driving force behind the majority of the cost of urinary

incontinence in this country. Although urinary incontinence is usually regarded as a

condition affecting the elderly, it is common in younger populations (Bo, Maehlum,

Oseid, & Larsen, 1989). Ten to thirty percent of women aged 15-64 suffer from

incontinence (Burgio, Matthews, & Engel, 1991).

Psychosocial Considerations

The psychosocial aspect of urinary incontinence in women is an important issue.

Urinary incontinence has been defined as a "condition where involuntary loss of urine

becomes a social or hygienic problem and is objectively demonstrable." (Bates, Bradley,

& Glen, 1979). Bates et al. (1979) mention the social component of incontinence in their

definition, and numerous other authors have cited these social issues as, possibly, the

most debilitating problem associated with urinary incontinence (Wyman et al., 1987).

Despite this, a very limited number of studies directly address the psychosocial

impairments resulting from incontinence (Wyman et al., 1987). In their 1987 study

Wyman et al. (1987), asked patients to rate, using the Incontinence Impact Questionnaire,

the impact of their incontinence on specific, everyday, activities falling into three broad

categories: activities of daily living, social interactions, and self-perception. The

Incontinence Impact Questionnaire is a valid, self-administered instrument consisting of

26 items arranged into the three broad categories mentioned above. The rating scale was

divided into two categories: no or slight impact and moderate to severe impact. The

average frequency of response of moderate to severe impact was 21.9, 12.0, and 21.4%

for activities of daily living, social interactions, and self-perception respectively. The

frequency of response of no or slight impact was 78.1, 86.9, and 78.6% respectively. The

analysis of these results showed that incontinence has numerous and far-reaching effects that influence daily activities, social interactions, and self-perception. More specifically, self-perception and daily activities were affected to a greater extent. The activities being most affected were those involving unfamiliar or public places, where the availability of restrooms were unknown. This included shopping, entertainment, long-distance travel, physical recreation, and vacation. One can see how debilitating the limitations in these critical areas of a person's life can be, if allowed to escalate to a severe or even moderate level. To compound the problem, many patients are too embarrassed to report their difficulties to a doctor or other health care provider (Diokno et al., 1995). All of this evidence points to the possibility that the common associated symptoms of urgency and frequency of urination may be as significant as the incontinence itself (Wyman et al., 1987).

Anatomy and Physiology of the Female Urogenital System

To understand the goals of conservative physical therapy, a brief review of the female urogenital system is needed. Urine is stored in the bladder. The bladder is composed mainly of smooth muscle, called the detrusor muscle (Moore, 1992). At the base of the bladder there is a thickening of smooth muscle, the internal urethral sphincter, which prevents urine from leaking into the urethra (Moore, 1992). In adults, when the internal urethral sphincter contracts, it closes off the urethra, and urine remains in the bladder (Moore, 1992). The urethra is the passage way for urine to leave the body. In females, the urethra is a short muscular tube that runs from the bladder to the external urethral orifice, located in the vestibule of the vagina (Moore, 1992).

The bladder lies on top of the pelvic floor, which is made up of the coccygeus and levator ani muscles (Gosling & Dixon, 1994). The levator ani is primarily innervated by sacral nerve root S3, but receives contributions from S4 and S2, all three of which come together to form the pudendal nerve (Gosling & Dixon, 1994). When the levator ani contracts, it aids in maintaining continence, by compressing the urethra distal to the internal urethral sphincter (Gosling & Dixon, 1994). Because the levator ani muscle is made up of both types of muscle fibers, its contribution to maintaining continence is two-fold. Seventy percent of levator ani is type I aerobic oxidative muscle fibers, which are responsible for maintaining tone of the pelvic floor and providing support for the pelvic viscera, especially under conditions leading to intra-abdominal pressure increases (Critchley, Dixon, & Gosling, 1980; Koelbl, Strassegger, Riss, & Gruber, 1989). This support reduces the chances of the bladder descending into the vagina, which would displace the urethrovesical junction (Koelbl et al., 1989). Displacement of the urethrovesical junction can cause incontinence by preventing the internal urethral sphincter from properly closing the urethra (Koelbl et al., 1989). Type II anaerobic glycolytic, which constitute the remaining thirty percent of the muscle fibers, are active during events that increase intra-abdominal pressure, such as coughing (Critchley et al., 1980; Bourcier & Juras, 1995). Their activity increases urethral closure pressure, countering the increase in intra-abdominal pressure and therefore, maintains continence (Koelble et al., 1989).

The pubourethral ligaments are another anatomically important structure affecting urination. These ligaments contain smooth muscle bundles which may contract at the

same time as the detrusor, thereby maintaining the position of the urethra relative to the

pubis, at time of urination (Zacharin, 1963). Again, this proper positioning of the urethra

is crucial for the internal urethral sphincter to fully close the urethra during a contraction.

Historical Aspects of GSI Treatment

The treatment of choice for GSI for years has been surgery to repair the damaged

muscle or sphincter . Only within the last ten years have conservative treatments gained

approval as an alternative to surgery. Treating GSI with an approach combining

intravaginal electrical stimulation and Kegel exercises done with biofeedback, has very

little documentation in the literature. However, one study by Caputo, Benson and

McClellan found that 89 percent of GSI patients treated with six weekly sessions of

intravaginal electrical stimulation and Kegel exercises, combined with perineal squeeze

biofeedback, reported at least a 50 percent decrease in the number of incontinent episodes

they were experiencing, following treatment (1993). A six month follow-up showed that

88 percent of these patients had maintained their improvement (Caputo et al., 1993).

Although there is a paucity of evidence to support the use of intravaginal

electrical stimulation and Kegel exercises with biofeedback together, each is frequently

used separately for treatment. The first documented use of electricity to elicit a muscle

contraction dates back to 1744 in Germany. Since that time, electrotherapy has become a

common treatment for muscle re-education and strengthening of partially or fully

denervated muscle. Electrical stimulation was first used to treat incontinence in 1963 in

England (Caldwell, 1963). Caldwell claimed that by surgically inserting an electrical coil

in the anal sphincter and another near the left iliac spine, he was able to cure a patient

who was fecally incontinent for 23 years within four months (1963). Caldwell also

described using electrical stimulation to "cure" a women with urinary incontinence,

although he did not explain how he used the stimulation.

Electrical Stimulation

Electrical stimulation is used to treat genuine stress incontinence for two reasons;

to re-educate the patient in how to contract the pelvic floor, and to strengthen the

atrophied pelvic floor muscles. Since the levator ani is innervated by sacral nerve roots

S2-S4, all of which form the pudendal nerve, stimulation of the muscle is accomplished

by using electrical stimulation to depolarize the pudendal nerve, eliciting a passive

contraction of the pelvic floor (Fall, 1978). Muscle contraction is argued to happen either

by direct stimulation of the pudendal nerve or by reflex activation (Trontelj, Martin,

Godec, Rakovec, & Trontelj, 1974). Clinically both might take place (Vodusek, Light, &

Libby, 1983; Vodusek, Janke, & Lokar, 1983), but the greatest pelvic floor contraction

results from the reflex response (Trontelj et al., 1974). This reflex loop involves the

electrical impulse running along an afferent limb of pudendal nerve to the sacral nerve

roots and then returning via an efferent pathway back to pelvic floor muscles (Kralj,

1991). This is significant clinically because this pathway must be intact to treat GSI with

electrical stimulation. There must be at least partial innervation of the pelvic floor by the

pudendal nerve to achieve a pelvic floor contraction with electrical stimulation

(Bourcier, 1994). There are several clinical advantages of eliciting a pelvic floor

contraction by reflex activation instead of direct stimulation to the musculature. First, the

reflex pathway can activate a number of muscles from the same stimulation site, so the

position of the electrode is less critical (Plevnik, Janez, & Vodusek, 1991). Second, a

smaller electrical stimulus intensity is needed to activate the reflex, thus providing

increased patient comfort during the treatment (Vodusek & Light, 1983). Finally, the

plasticity of the nervous system is retained by the reflex pathway (Dimitrijevie, 1966).

In addition to re-educating the patient to voluntarily contract their pelvic floor and

promoting hypertrophy of the pelvic floor, electrical stimulation is used to treat GSI in

hopes of producing an inhibitory effect on the detrusor, which may be beneficial even to

patients who show no sign of detrusor instability. This is true because pelvic floor

muscle contraction normally elicits an inhibitory effect in the detrusor, therefore, if

electrical stimulation could aid the recovery of this normal function, it would be even

more valuable to the treatment of GSI. It has also been postulated that electrical

stimulation may be able to promote conversion of rapid-twitch muscle fibers to slow-

twitch fibers in the pelvic floor, promoting sphincteric competence (Plevnik, Janez, &

Vodusek, 1991; Gray, 1992; Bent, Sand, & Ostergard, 1989; Blaives, Oliver, McGuire, &

Susset, 1984; Vereecken, Shaene, VanNuland, Sansen, & Dvers, 1989). It is further

believed that electrical stimulation helps patients to achieve an increase in maximum

urethral closure pressure, therefore aiding the successful treatment of GSI (Kralj, 1991).

However, one study that treated women diagnosed with GSI, using electrical stimulation

found no significant differences in maximum urethral closure pressures registered before

and after treatment (Fall, Ahlstrom, Carlsson, Ek, Erlandson, Frankenberg, & Mattiessor,

1986).

The literature provides no specific parameters, only ranges, for using electrical

stimulation to treat GSI. Using both a square biphasic and rectangular biphasic

waveform, reported pulse widths range from .2 ms to 3 ms, although 1 ms was mentioned

by several different authors (Plevnik, et al., 1991; Sand & Wheeler, 1989; Gray, 1992;

Fall, et al., 1986). Effective frequencies of impulses used to teat GSI range from 10-100

Hz, with 20-50 Hz being mentioned most often in the literature (Erlandson, Fall, Sundin,

1978; Plevnik, 1984; Fall, 1985; Sand & Wheeler, 1989; Fall, et al., 1986). Intensity of

the stimulation ranged from 30-150 mA, but most authors noted that the intensity should

be set only as high as the patient can tolerate (Janez, Plevnik, & Vrtaenik, 1984;

Vodusek, Light, & Libby, 1986; Sand & Wheeler. 1989). Two of the studies also

delivered the stimulation with a duty cycle. Fall et al. (1986) used an on/off ratio of

10/25 seconds. while Sand and Wheeler (1989) used a 2/4 second ratio. Even though no

standard parameters have been established to optimize the effectiveness of electrical

stimulation to treat GSI, it has been shown to be a useful conservative treatment.

Subjective reports by the patients show that after being treated with electrical stimulation,

anywhere from 55-81% of them felt their condition was improved or cured. (Plevnik et

al., 1991; Sand, Wheeler, 1989). Objective evaluations have shown the following

improvements in GSI patients following electrical stimulation therapy: an improved

functional bladder capacity, an increase in pelvic floor strength, and a reduction in urine

loss during a 20 minute pad test (Fall et al., 1986); (Sand and Wheeler, 1989). These are

all important factors in improving continence in the GSI patient.

Kegel Exercises and Biofeedback

Kegel exercises and biofeedback have also been used to effectively treat GSI.

Biofeedback is not a treatment in and of itself, it is simply an adjunct to some other type

of procedure or activity. Biofeedback is defined as, "the use of electronic instrumentation

to provide objective feedback or information to a patient about a physiological function

or response, so that the patient becomes aware of his or her response" (Binder-Macleod,

1995). With this new awareness the patient attempts to alter the signal coming from the

machine. The signal is usually auditory, visual (lights), or a combination of both.

Biofeedback instrumentation allows the patient to receive immediate feedback about the

target physiological function so that he/she can modify their response in an ongoing

fashion. It eliminates the delays inherent in a strictly clinician/patient interaction.

In the case of genuine stress incontinence (GSI) biofeedback is often used in

conjunction with Kegel exercises (Burns, Pronikoff, Nochajski, Desotelle & Harwood,

1990; Burgio,Robinson & Engel, 1986; Bump, Hurt, Fantl & Wyman, 1991; Diokno &

Yuchio, 1995; Jones, 1994; Kegel, 1948). Kegel exercises are the voluntary contraction

and relaxation of the levator ani muscle (Kegel, 1948). Bump et al. (1991) cited the goal

of Kegel exercises in the treatment of urinary incontinence as being able to increase the

strength and endurance of the pelvic floor muscles (principally the pubococcygeus and

puborectalis portions of the levator ani muscle) so that urethral closure pressure is able to

overcome increased intra-abdominal pressure during certain activities. Kegel originally

intended these exercises to be done with a simple form of biofeedback, called a

perineometer. The perineometer is a pneumatic device consisting of a vaginal probe connected to a manometer. It measures pressures developed within the vaginal cavity during a Kegel effort (Kegel, 1948). Kegel advocated his method of exercise with biofeedback because he noted that many women had difficulty performing a correct Kegel contraction. Many patients will squeeze the gluteals, adductors, or abdominal muscles instead (Bump et al., 1991; Burgio et al., 1986; Kegel, 1948). Despite the availability of numerous forms of biofeedback, such as vaginal pressure measurements, electromyographic activity, and digital palpation, used in the treatment of urinary incontinence, most patients are taught Kegel exercises with only simple verbal instruction (Bump et al., 1991). Although Kegel exercises can be taught to patients by verbal instruction alone, Kegel noted that 40% of women cannot perform a correct Kegel maneuver by this method, simply because they are unaware of the muscle to be contracted. More recent research has shown similar results. Bump et al. (1991) showed that only 49% (n=23) of women in their study could produce an ideal Kegel effort -- a significant increase in the force of urethral closure without an appreciable Valsalva effort -- with verbal instruction alone. A Valsalva maneuver results in an increase in abdominal and vaginal pressure (Bump et al., 1991). These researchers also found that 26% (n=12) of women in the study had rises in vesical (vaginal) pressure greater than 15 cm H_2O, during their Kegel contractions. This level of vesical pressure increase was defined as an excessive Valsalva effort, and could potentially promote incontinence according to Bump et al. (1991). In another study, Burgio et al. compared the effectiveness of Kegel exercises with verbal feedback, to Kegel exercises with visual bladder sphincter

biofeedback, in treating stress urinary incontinence. While the verbal feedback group showed a 51% reduction in incontinent episodes, the biofeedback group showed a significantly higher improvement rate of 75.9% reduction in incontinent episodes. Additionally, the biofeedback group demonstrated an improved ability to sustain sphincter contractions and to minimize bladder pressure, while the verbal feedback group showed no improvement in this area. These are both indications of increased selective control of the pelvic floor muscles, and they allow the patient to increase urethral closure pressure, without contracting other muscles in the area, causing increased pressure on the bladder. In a six month follow-up study the women in the biofeedback group still showed a 68% reduction rate. Burns et al. also showed a slightly higher reduction rate in a biofeedback group (61%) as compared to a verbal feedback group (54%), however the difference was not statistically significant. This study also showed a negative correlation between EMG scores on quick contractions and urine loss. This means as EMG scores went up, urine loss went down. The biofeedback group showed significant improvement in EMG scores while the verbal feedback and control groups did not. These EMG findings make sense because type II fast twitch muscle fibers (quick contractors) are primarily recruited during bouts of increased intra-abdominal pressure (Brubaker & Kotarinos, 1993). Increased intra-abdominal pressure is commonly recognized as the primary inducer of bouts of genuine stress incontinence in women. This brings up a good point: Is there an association between pelvic floor muscle strength and incontinence? There is some division in the literature on this point. The above EMG findings would seem to say yes, but, in that same study the authors found no increase in any of their

subjects' resting urethral closure pressures (Burns et al., 1990). However, there is no solid evidence in the literature to demonstrate whether or not resting urethral closure pressure has any bearing on functional recovery from GSI. Resting urethral closure pressure is the minimum force needed to prevent leakage when at rest. Even though urethral closure pressures, at rest, were not improved, subjects still had decreased leakage following treatment. There must be some other factor relating to muscle retraining that accounts for these improvements.

In their 1993 review of conservative management of incontinence, Brubaker and Kotarinos state there is an association between weakened pelvic floor muscles and incontinence. In contrast, Bo and Talseth (1996), in their long term follow-up study, found no solid correlation between pelvic floor muscle strength and leakage, but they noted that women who performed Kegel exercises three times or more per week had much less leakage than those exercising less frequently. This last study may indicate that women need only to be more aware of their pelvic floor muscles to decrease incontinent episodes.

There does seem to be agreement in the literature that biofeedback is superior to verbal feedback in teaching patients the proper Kegel technique, and therefore it has a greater effect on the reduction of incontinence. Consequently, it seems odd that most patients start and finish their exercise program with only brief written or oral instruction (Bump et al., 1991). Furthermore, many Kegel exercise programs are introduced and explained to the patient at an initial session, and then the patient is asked to perform the exercises according to a daily schedule at home, with no further training sessions at the

clinic. According to Jones (1994), disadvantages of limited supervision (self-help) regimes, such as that described above, over fully supervised therapy, seem to fall into three main areas: 1. lack of understanding of initial instructions by the patient; 2. failure of monitoring equipment to deliver appropriate performance (in the case of home biofeedback units); and 3. failure of the patient to follow exercise schedules properly and conscientiously.

Lack of compliance may be the single biggest reason that women fail to improve with an independent home exercise program. In 1986, Norton demonstrated that the ability to perform regular Kegel exercises throughout the day is more likely to lead to a satisfactory cure. Similarly, it has been shown that women who perform Kegel exercises three or more times per week had less frequent leakage than those who were not (Bo & Talseth, 1996). This data indicates a need for regular therapy sessions, to supplement the home program, at which the clinician may provide feedback on exercise techniques, as well as support and encouragement to the patient.

Although good short term results have been shown with Kegel exercise programs (with and without biofeedback), very little research has been done on the long term effectiveness of these programs. This is an area of incontinence research that needs to be expanded. In a 1991 study Mouritsen, Frimodt-Moller, and Moller did 0, 3, and 12 month assessments on 76 women referred to their clinic for incontinence, following a 3 month pelvic floor exercise program conducted by an experienced physiotherapist. At the final 12 month assessment they found that 30% of their patients were cured and 17% were improved so that they did not require surgery. In a similar study, Bo and Talseth

treated patients with a six month Kegel exercise program, using verbal instruction and feedback. Bo and Talseth (1996) took "long-term" much further by re-assessing their subjects 5 years after the initial study. The home program they describe is as follows: 8-12 maximum contractions, in three series per day, for 6 months. In addition, the patients had a 45 minute session once a week with a physical therapist. The patients held each maximum contraction for 6-8 seconds and added three to four fast contractions immediately following each maximum contraction. After 5 years there was increased leakage indexes (subjective) and pad test volumes (objective), compared to immediately after treatment. However, social activity index scores and satisfaction rates remained stable.

Genuine stress incontinence is not a condition confined to nursing homes or the elderly. It is a prevalent problem in younger female patients. It has historically been a condition with primarily one treatment--surgery. Unsuccessful results and high costs have forced the medical profession to seek an alternate, less expensive treatment. The preceding review of the literature has demonstrated that the use of intra-vaginal electrical stimulation, either alone or combined with Kegel exercises and biofeedback, has shown some promise. However, as was stated previously, research has not yet determined the optimal parameters for treatment of GSI, using intravaginal electrical stimulation. The researchers feel this may explain the wide variability among the documented success rates of electrical stimulation in treating GSI. The aim of the current study is to demonstrate that electrical stimulation is an effective means of treating GSI, especially when it is supplemented with Kegel exercises and biofeedback. Furthermore, the

investigators will attempt to show that a decreased frequency of treatment with electrical

stimulation is equally as effective, as more frequent treatment.

CHAPTER 3

METHODOLOGY

Subjects

Nine volunteer female subjects ranging in age from 41 to 86 were treated by two

local, licensed physical therapists. Potential subjects were first required to complete a

medical evaluation, with either a family practitioner (MD) or doctor of osteopathic

medicine (DO).

Potential subjects diagnosed with genuine stress incontinence, and confirmed to

be free of other related diagnoses, were referred to physical therapy for conservative

treatment. Subjects eligible for the study, completed the following items at their initial

evaluation and then again prior to their discharge evaluation:

1. A subject characteristic/study exclusion form to qualify the potential subjects for the

study. Any questions about this form were explained to the patient by the treating

physical therapist (See Appendix A, "Subjective Eval").

2. An Incontinence Impact Questionnaire (short form) and an Urogenital Distress

Inventory (short form) were also completed (Ubersax, Wyman, Shumaker, McClish,

Fantl and the Continence Program for Women Research Group, 1995) (Appendix B). The

IIQ provided a subjective score indicating how patients perceived GSI to influence their

lives. The UDI provided an indication of the severity of patients' symptoms. These two

forms are approved versions of the long forms, developed by these same authors.

Appendix C provides coefficient Cronbach's alpha values for reliability of the IIQ and

UDI long form questionnaires. The Cronbach's alpha is a reliability index used for

estimating internal consistency in instruments composed of several items or questions

(Portney & Watkins, 1993). Provided in Appendix D are Pearson's correlation

coefficients for validity between the long and short form scores. The strong correlations

between these forms, establishes the short form as a valid alternative.

3. An informed consent form (Appendix E), which was required for inclusion in the

study.

Equipment

The test equipment used during this experimental study included an INCARE®

PRS 8900 biofeedback/electrical stimulation device, manufactured by Hollister Inc. A

urogenital periometer, also manufactured by Hollister Inc., was used to record objective

strength grades of the pelvic floor muscles, for each study participant. Additionally, a

standard triple beam balance was used to weigh the saturated sanitary napkins after each

patient completed a modified design stress test (Bent, Sand, Ostergard, & Brubaker,

1993). All machines were recently calibrated, or were still within manufacturers limits

for safety inspections/calibrations, to provide the safest and most effective treatments for

all of the study participants.

Procedures

Upon acceptance into the study, each subject was randomly assigned by single

blind selection to receive one of three different GSI therapy protocols. All three

protocols required the subjects to be instructed in and to perform Kegel pelvic floor

muscle exercises. The Kegel exercises required each patient to exercise their pelvic floor

muscles with a 10 second "Hold" time in a contracted state, and a 10 second "Relax"

period. This cycle was to be repeated 10 times for each session of exercise. The exercises were to be completed three times per day for a duration of six weeks, as a home exercise program (Burns, Pronikoff, Nochajski, Deostelle, & Harwood, 1990; Burgio, Robinson, & Engel, 1986). Furthermore, subjects in each of the three groups were verbally instructed on how to use the INCARE® PRS 8900 device to achieve proper muscle contraction. Written material related to Kegel exercises and the use of biofeedback to augment the Kegel response, was also provided. Proper muscle contraction was achieved via the INCARE® PRS 8900, which had a biofeedback mode and electrical stimulation mode. The biofeedback mode provided the patient with both an audio and a visual cue to indicate if she was achieving a proper contraction of her pelvic floor muscles (Burgio et al, 1986). The electrical stimulation mode was also employed, to provide stimulation of the pelvic floor muscles in to enhance the specificity of muscle contraction and decrease the possibility of substitute contraction from other muscles in the area, such as the gluteals, abdominals, etc. The main difference between the three groups was the frequency and duration of electrical stimulation therapy received. Subjects assigned to protocol #1 received a modified Empi INNOVA® electrical stimulation protocol, originally used with their INNOVA® home use pelvic floor stimulators (Sand , Richardson, Staskin, Swift, Appell, Whitmore & Ostergard, 1995). The modified protocol involved a treatment of thirty minutes of electrical stimulation, three times per week for only six weeks in duration. (See Table 3-1 "Empi Treatment Protocol"). A modified protocol was used because the original protocol developed by Empi Inc. required the patient to be treated either daily or every other day for fifteen

minutes, for a duration of twenty weeks (Richardson, Mallett, Miller, Siegal, Karram, Tuttle, Blackwood, Staskin, & Sand, 1995).

Subjects assigned to protocol #2 received an electrical stimulation protocol developed by Eileen Kishman, PT and Colleen Boyden, PT which was based on their extensive clinical experience and continuing education in this field (See Table 3-2 "Experimental Treatment Protocol"). To date there have been no studies done to validate the use of the protocol described above. Therefore, this study will provide important information regarding the efficacy of the group two's protocol. It will also provide a springboard for future studies comparing different approaches to the conservative treatment of GSI.

Subjects assigned to protocol #3 received no electrical stimulation, but they did use the INCARE® biofeedback feature to assist with proper performance of Kegel exercises. (Burns et al., 1990). These patients acted as a control, in order to determine the necessity of electrical stimulation in the conservative treatment of GSI.

Table 3-1.

Empi Treatment Protocol

1. One thirty (30) minute session, three times per week on every Monday, Wednesday & Friday for six weeks; electrical stimulation delivered by the INCARE® pelvic reeducation system PRS 8900, consisting of both an electrical stimulator & a biofeedback device in one. The INCARE® device consists of a micro processor controlled pulse generator with two stimulus output channels capable of stimulation at both 50 Hz or 12.5 Hz, and powered either by a 110-120 or 220-240 line voltage, via wall outlet.;

2. Stimulation driven by intermittent surge electrical current;

3. Stimulation parameters set at a rate of 50 Hz, a pulse width of 0.3 ms (milliseconds), a muscle stimulation to rest ratio "i.e. duty cycle" of 5 second "On" (i.e. flexing the muscle) & a 10 seconds "Off" (i.e. relaxing) period, and a current intensity of 0 to 100 mA (milliampiers), depending on the patient's tolerance.;

4. Treatment is delivered via an electrode which is a fully insertable silicone rubber probe with four carbon impregnated silicone rubber bands, manufactured by Hollister Inc. The maximum diameter of the electrode is 1.025 inches, length 2.5 inches with an electrical resistance of 85 Ohms (INCARE PRS8900 owners manual, 89).

Table 3-2.

Experimental Treatment Protocol

1. One 15 minute treatment session two times per week on every Monday & Wednesday for six weeks in duration.;

2. Stimulation driven by intermittent surged electrical current.;

3. Electrical stimulation delivered by an INCARE® PRS 8900 electrical stimulation/biofeedback unit manufactured by Hollister Inc., which has been described previously.;

4. Stimulation parameters of 50 Hz, a pulse width of 0.3 ms (milliseconds), a duty cycle of 5 seconds "On" & 10 seconds "Off", and a current of 0 to 100 mA (milliampiers), again, depending on the tolerance of the patient.;

5. A fully insertable electrode with the same dimensions and impedance levels as the first treatment protocol.

Inter-tester reliability was not addressed because all protocol treatments were conducted by the same two physical therapists. Each of them performed the initial evaluation and discharge measurements on the same set of patients. However, in order to allow the therapist's some personal time, the intermediate treatments were provided by either therapist, regardless of which one did the initial evaluation. Both therapists were instructed in the proper execution of the stress test procedure, including sanitary napkin weighing techniques. Table 3-3 describes the stress test and pad weighing procedures.

Table 3-3   **Incontinence Stress Test**

Each subject comsumed a 32 oz glass of tap water and after five minutes was asked to:

1) Walk briskly for 3 minutes in place;
2) Sit and then stand 10 times in a row;
3) Walk up and down stairs for 1 minute;
4) Pick up a 10 lb object from the floor 5 times in a row;
5) Cough 12 times;
6) Run in place for 1 minute.

A pre-weighed sanitary napkin was worn during the above mentioned tests and weighed upon completion. The weight of the sanitary napkin before testing was subtracted from the weight of the napkin after testing. This value was recorded as residual volume.

Subjects' pelvic floor muscle strengths were also graded, using a digital manual muscle exam. The grading procedure involved placing rubber gloved fingers in an anterior-posterior plane approximately 6-8 cms into the vagina. On the count of three, the woman was asked to contract the pelvic muscles around the examiners fingers with as much force and for as long as possible. The examiner checked that the woman was not using auxillary muscles in the abdomen, thighs, or gluteals (Samspelle, Brink, Wells,

1989). The grading of the contraction was similar to that described by Worth, Dougherty, & McKey, (1986)

Statistical Analysis

Data from both the initial and discharge evaluations were collected. The IIQ scores, UDI scores, residual volume measurements from the stress test, and the pelvic floor muscle grades, [both mechanical (objective) and manual (subjective)], were analyzed, using a Statistical Package for Social Sciences (S.P.S.S.). A Kruskal-Wallis One-Way ANOVA test was used to determine the significance of the difference between the three methods in the change they caused in each of the five measurement tools. A Pearson's Correlation Coefficient analysis was used to discover any significant relationships between the five measurement tools.

CHAPTER 4

RESULTS

The purposes of this study were to compare the effectiveness of two protocols for the conservative treatment of GSI , and to determine whether electrical stimulation is a necessary component of treatment. Both treatment protocols combined biofeedback, Kegel exercises, and electrical stimulation, but differed in the frequency and duration of electrical stimulation treatments. The control group received only biofeedback and Kegel exercises. The authors hypothesized that there would be no statistically significant difference between the two treatment groups. It was also hypothesized that electrical stimulation would be identified as a necessary and effective component of conservative treatment for GSI.

Nine female subjects between the ages of 41-86 years participated in the study. All subjects had a diagnosis of GSI, and all met the criteria for inclusion in the study. Each subject was randomly assigned to one of the three groups. Subjects in all three groups were evaluated according to the same five measurement tools, both initially and at discharge. The difference between the initial and discharge values for each of the measurement tools was used to determine the overall effectiveness of each treatment approach.

Due to the small number of subjects in the study, the data for each variable did not follow a normal distribution. Since the data in our study did not meet this criterion of normality, a primarily non-parametric approach was used. None of the results of this study were shown to be statistically significant. However, the raw data suggests that

method 2 may have been more effective in treating GSI because it caused greater changes in more of the dependent variables than either of the other two methods. However, there was not enough statistical power to state this unequivocally (See Table 4-1 [a-e]). The following will be a discussion of the statistical tests used in the analysis of the raw data, and the most important relationships that emerged from the analysis.

A Kruskal-Wallis 1-Way ANOVA test was used to analyze the significance of the change in each variable by method. P-values were generated for each variable to indicate the significance of the change. Table 4-1 (a-e) shows a box plot of the data. This test computes the mean rank of each method according to the change it caused in a particular variable. The ranking gave an indication of whether one of the methods of treatment was superior in causing a change in the dependent variable. Again, none of the three methods had enough statistical power to claim superiority in eliciting a change in any of the variables. However, the difference between the changes observed in residual volume with each treatment did approach statistical significance. In the analysis of residual volume, the mean rankings were 2.83, 6.88, and 4.50 for methods 1, 2, and 3 respectively. The significance (p-value) of the difference between these rankings was 0.1387. P-values for each of the dependant variables are listed in Table 4-2.

In addition a Pearson's correlation coefficient analysis was used to investigate possible relationships between each of the dependent variables. Table 4-3 shows the correlations between all of the dependent variables. The range of correlation coefficients falls between +1 and -1. Positive one (+1) represents a perfect positive correlation,

meaning that as one variable increases, the other increases proportionally. Negative one

(-1) represents a perfect negative correlation, meaning that as one variable increases the

other decreases proportionally. In the current study, two correlations were found to be

near statistical significance. The first was a +0.5491 correlation between digital manual

muscle score and residual volume, with a p-value of 0.126. This indicates that as muscle

strength increased with treatment, the change in residual volume increased as well.

Change, in this context, means that there was a greater decrease in residual volume from

initial evaluation to discharge. The second was a -0.5607 correlation between digital

manual muscle score and Incontinence Impact Questionnaire (IIQ) score, with a p-value

of 0.116. This indicates that as muscle strength increased with treatment, there was a

proportional decrease in IIQ scores. IIQ score indicated the patient's subjective

assessment of the impact they felt GSI had on their daily life. So the correlation here

would indicate that subjects who had greater muscle strength at the end of the study, also

felt that GSI had a decreased impact on their lives.

The authors expected there would be a strong positive correlation between digital

maual muscle test scores and periometry scores, since they both measure pelvic floor

muscle strength. However, the correlation was -0.1572, with a p-value of 0.686.

Although the two are not highly correlated, the negative correlation would indicate that as

manual muscle scores increased, periometry scores decreased. This would seem to raise

doubt about theses two methods as valid tools to measure pelvic floor muscle strength.

Table 4-1a. Box Plots for Data Point Distribution of Incontinence Impact Questionnaire Score Changes By Method

METHOD
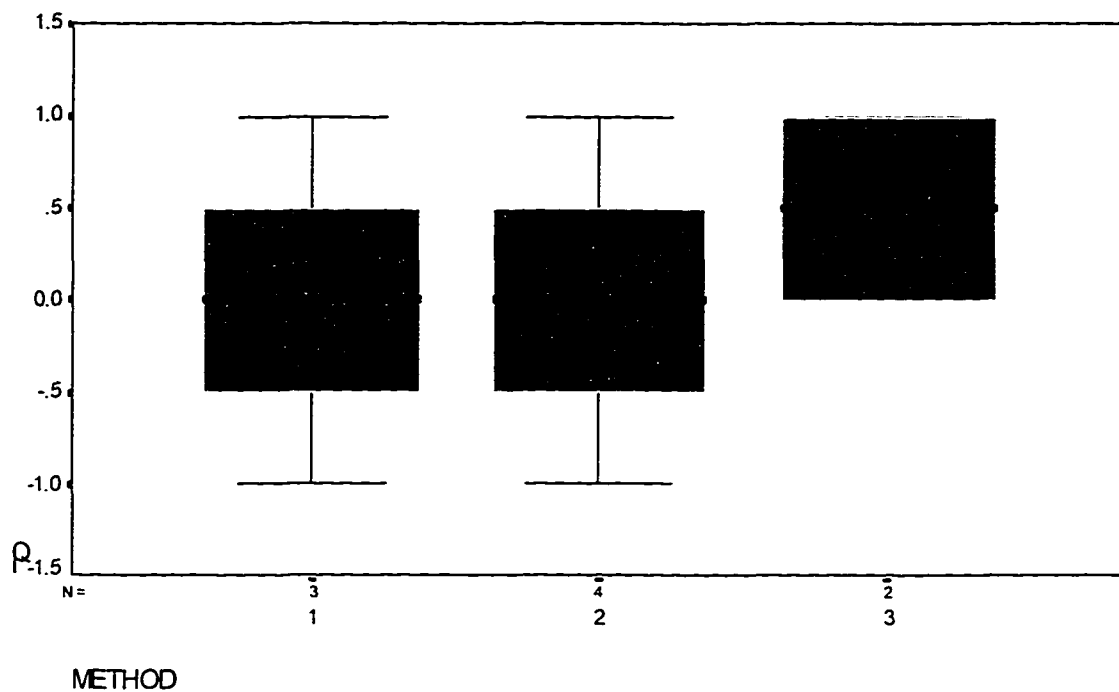
Table 4-1b. Box Plots for Data Point Distribution of Manual Muscle Test Score Changes by Method
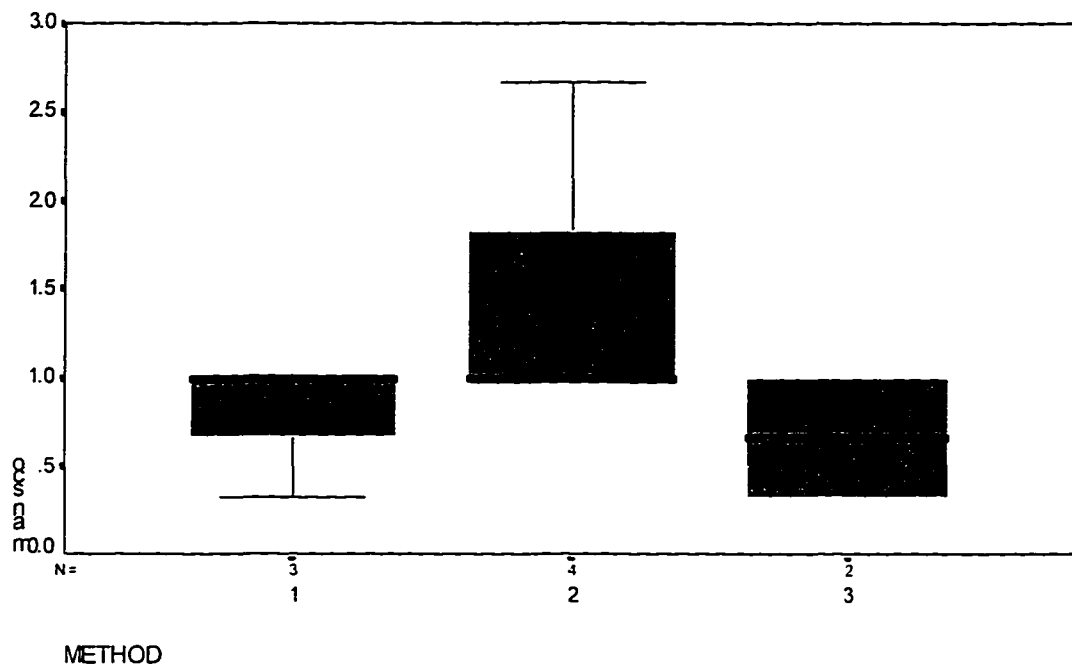
Table 4-1c. Box Plots for Data Point Distribution of Periometry Score Changes by Method
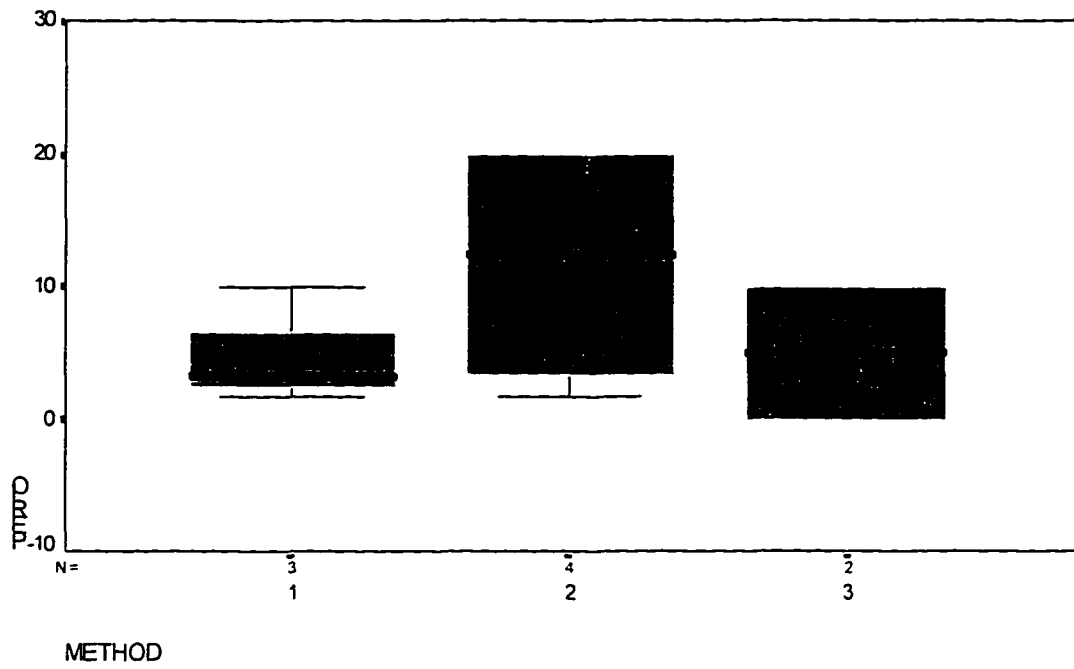
Table 4-1d. Box Plots for Data Point Distribution of Residual Volume Changes by Method
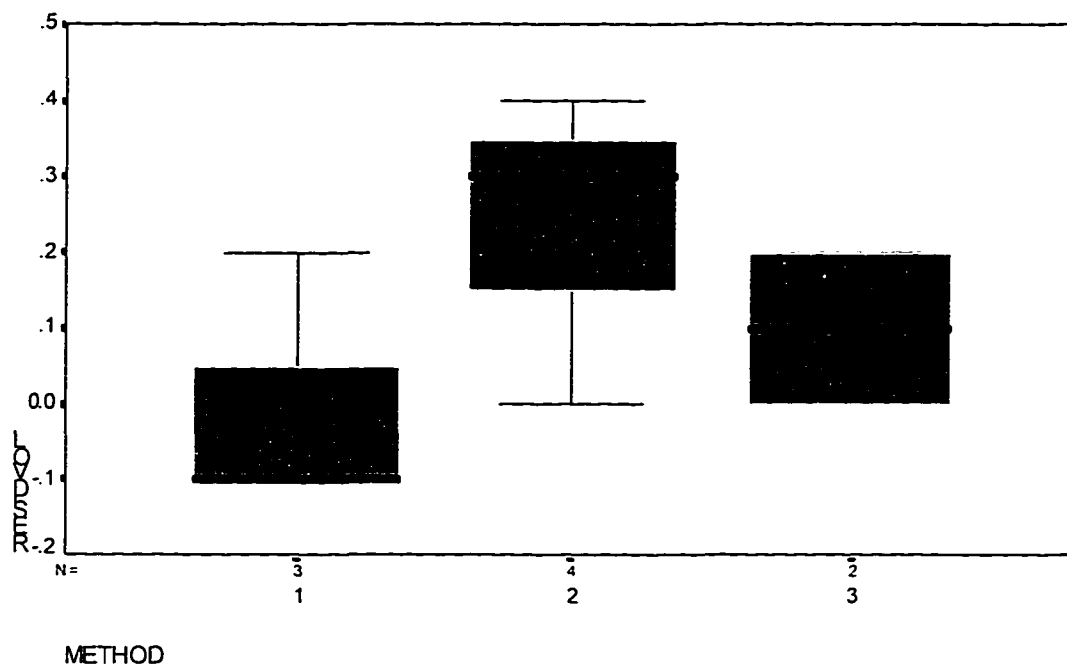
Table 4-1e. Box Plots for Data Point Distribution of Urogenital Distress Inventory Score Changes by Method
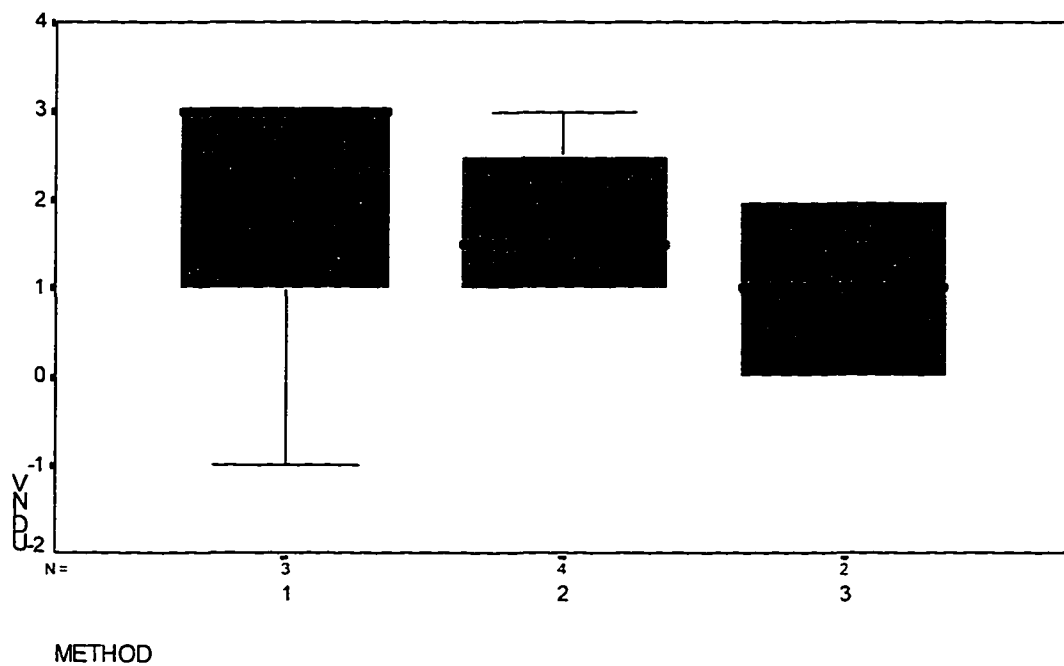
Table 4-2 Kruskal-Wallis 1-Way ANOVA P-values for Changes in Dependent Variables

Dependent Variables	P-value
IIQ Score	0.7361
Manual Muscle Test Score	0.2600
Periometry Score	0.5215
Residual Volume	0.1387
UDI Score	0.7281

Table 4-3 Dependent Variable Correlation Coefficients

	METHOD	MANSCO	RESIDVOL	IIQ SCO	UDINV	PERIO
METHOD	1.0000	.0087	.2849	.2273	-.1622	.0618
		P= .982	P= .457	P= .556	P= .677	P= .875
MAN_SCO	.0087	1.0000	.5491	-.5607	.0630	-.1572
	P= .982		P= .126	P= .116	P= .872	P= .686
RESID	.2849	.5491	1.0000	-.0285	.3910	-.2079
	P= .457	P= .126		P= .942	P= .298	P= .591
IIQSCO	.2273	-.5607	-.0285	1.0000	.0499	.1815
	P= .556	P= .116	P= .942		P= .899	P= .640
UDINV	-.1622	.0630	.3910	.0499	1.0000	-.1695
	P= .677	P= .872	P= .298	P= .899		P= .663
PERIO	.0618	-.1572	-.2079	.1815	-.1695	1.0000
	P= .875	P= .686	P= .591	P= .640	P= .663	

CHAPTER 5

DISCUSSION

Interpretation of Statistical Outcomes

The results in this pilot study were difficult to interpret. Analysis of the data did

not reveal any significant differences between the methods of treatment in their

effectiveness of treating GSI. However, there were moderate correlations shown between

the digital manual muscle test scores and residual volume ($r = 0.5491$), as well as digital

manual muscle test score and IIQ score ($r = 0.5607$). Even though neither of these

correlations was shown to be statistically significant ($p = 0.05$), the authors speculate that

a larger sample size may have increased the strength of these correlations.

The Kruskal-Wallis 1-Way ANOVA test performed on each dependent variable

computes the mean rank for each method, according to the change it caused in that

variable over the course of treatment. The higher the mean rank of the method the greater

change it caused in the variable. A p-value was calculated for each variable to show the

statistical significance of the difference between these ranks. Although none were shown

to be statistically significant ($p = 0.05$), there are some findings worth mentioning. For

two of the five dependent variables (residual volume and IIQ score) the control group

(method 3) ranked higher than at least one of the treatment groups. For residual volume,

the control group (method 3) actually ranked higher than both treatment groups. More

importantly, for three of the five dependent variables (manual muscle test score,

periometry, and residual volume), the Kishman treatment group (method 2) ranked higher

than the other two groups. The Empi treatment group (method 1) ranked only slightly

higher than the Kishman group on one of the five dependent variables (Urogenital

Distress Inventory). Although none of these results were statistically significant the

authors, again, speculate that a larger sample size may have influenced the statistical

analysis. A thorough discussion of limiting factors will be addressed in another section.

Comparison of Results to Other Studies

There are numerous studies that investigate the efficacy of Kegel exercises with

biofeedback (Bump et al., 1991; Burgio et al., 1986; Kegel, 1948), or intravaginal

electrical stimulation (Bent et al., 1989; Caputo et al., 1986; Fall et al., 1986), in

isolation. Although these studies reported some success using these treatments alone, it is

beyond the scope of this study to compare our outcomes to those of these previous

studies. This is true because previous literature has proven conservative treament

methods, in general, to be a viable way to treat GSI. The current study was not trying to

further prove the efficacy of conservative treatment. but only to compare two clinically

used conservative treatment approaches. Furthermore, clinical experince has proven to

the two treating therapists, that Kegel exercise with biofeedback, along with intravaginal

electrical stimulation, is a better treatment method than either used alone. It was the

intent of this study to prove this clinical hypothesis.

Only one previous study, by Caputo, Benson, and McCellan (1993), tested the

efficacy of intravaginal electrical stimulation combined with Kegel exercises and perineal

sqeeze biofeedback, in the treatment of GSI. They found that 89 percent of the subjects

treated with six weekly sessions reported at least a 50 percent reduction in the number of

incontinent episodes they were experiencing. Although, the present study did not ask

subjects to record their number of incontinent episodes, subjects similarily reported subjective improvements, according to Urogenital Distress Inventory scores. In addition to subjective measurements, the current study also considered the following objective measures of improvement: periometry score, manual muscle test score, and residual volume following a stress test. The authors feel that these objective measurement tools can help strengthen the case for the efficacy of conservative treatment, but due to the small sample size in the present study, there was insufficient evidence to show statistically significant improvements in subject's objective test scores.

Another difference between the present study and the one by Caputo et al. was the frequency of treatment. The present study provided treatment either 2 or 3 times a week, depending on the method the subject was assigned to, while Caputo et al. treated subjects only once per week. A concern that the authors will address in a later section is that too much intravaginal electrical stimulation can actually be detrimental to a patient's treatment. Although it appears that subjects in the Caputo et al. study reported better success with their treatment, it is difficult to compare to the present study because different subjective measurement tools were used to determine success of treatment.

Limitations

The original intent of this pilot study was to test sixty patients between two physical therapists, specializing in the treatment of female urinary incontinence. The narrow inclusion criteria of the study made it difficult to find qualified subjects. The strict inclusion criteria was necessary in order to preserve the validity of the IIQ and UDI questionnaires (Shumaker, Wyman, Uebersax, McClish, Fantl, 1994). Additionally,

method 1 required the patients to receive treatment three times per week, for six weeks, making it difficult for potential subjects to commit to the study. The authors further believe that potential subjects were deterred from participating due to the negative connotation of the phrase "scientific research".

Another inherent weakness of the study was that the therapists were testing a protocol they designed (method 2). This may have led them to inadvertently alter results of the measurement tools, for subjects assigned to method 2. Also, since every therapist's goal is to improve his/her patient's condition, there would be a natural inclination for the treating therapist to place patients in a treatment group that she feels is most effective. The authors believe that this could have potentially led to biasing of the assignment of subjects to treatment groups, as well as the alteration of treatments the therapists felt were less effective. All of this may have been avoided if the authors were able to perform the data collection, themselves. However, this was not possible because the authors were not licensed physical therapists at the time of the experiment.

The investigators believe another potential weakness of the study was the subjective nature of the digital exam. This muscle testing technique was used to provide a pelvic floor muscle strength grade for each patient at initial evaluation and again at discharge. Research literature does not provide adequate information in regard to the intertester reliability and validity of this procedure. Furthermore, the periometry apparatus used during the study to quantify pelvic floor muscle strength does not provide an actual unit of measure, such as pounds per square inch. It only provides an arbitrary numeric value relative to the strength of the subject's pelvic floor contraction.

Finally, age and estrogen were not controlled for in this study. Hypoestrogenism, which commonly occurs following menopause, has been cited as a causative factor of urinary incontinence in women (Fantl, Cardozo, & McClish, 1994). According to these authors, estrogen replacement therapy has been used for many years to treat urinary incontinence (Fantl et al., 1994). Estrogen is also frequently prescribed for a wide variety of other post-menopausal problems, from osteoperosis to hair loss. The authors of the current study failed to account for these factors, possibly skewing the results. Therefore, we suggest that future studies control for estrogen therapy in their subjects.

Suggestions For Further Study

The authors suggest that an identical study be carried out with a larger sample size, to determine whether any of the methods are statistically superior or inferior to the other two. Furthermore, the authors believe that more studies comparing the efficacy of Kegel exercises with biofeedback and electrical stimulation to both surgical interventions and no intervention at all are needed. The authors also found it interesting that subjects treated with longer bouts of electrical stimulation (method 1) did not show as large of an improvement in their manual muscle test scores as subjects in method 2. Although the sample size was not large enough to make a strong conclusion, the authors question whether too much electrical stimulation can actually hamper a patient's treatment. The authors suggest that studies testing the efficacy of different durations and frequencies of treatment be performed, to determine if too much electrical stimulation can actually be detrimental to a patient's outcome. Outcome studies of conservative treatment for GSI,

combining Kegel exercises with biofeedback and electrical stimulation are also needed to

determine if physical therapy has long-term carry-over in patients.

Conclusions and Implications For Clinical Use

Although no one treatment was statistically superior, subjects treated with

method 2 showed greater changes in residual volume, manual muscle test score, and

periometry over the course of treatment. These results indicate that method 2 may be the

most beneficial of the three methods in the treatment of GSI. Method 2 is also the more

cost effective of the two treatment groups because it requires less frequency and duration

of electrical stimulation than method 1. Keeping in mind that there were no statistically

significant differences between methods in any of the dependent variables, the authors

concluded that method 2 should be the treatment of choice based solely on cost-

effectiveness.

It may also be concluded that method 3 (the control group) could be the treatment

of choice, based on cost-effectiveness. This treatment places less burden on patients

because it requires less time commitment. This group received no electrical stimulation,

yet it was not shown to be statistically inferior to either of the treatment groups.

However, the authors believe that method 2 is preferable to method 3 because it

is likely the improvements in periometry measurements, manual muscle test score, and

residual volume of subjects treated with method 2 might have been statistically

significant with a larger sample size. Several authors have indicated that the use of

electrical stimulation, alone, is effective in the treatment of GSI (Bent et al., 1989;

Caputo et al., 1993; Fall et al., 1986). Kegel exercises, in conjunction with biofeedback,

have also been cited often in the literature as an effective conservative treatment for GSI

(Burgio et al., 1986; Burns et al., 1990; Kegel, 1948). However, no universally accepted

protocols have been established in the research literature.

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Appendix A
Outpatient information sheet

Demographic Information:

Name: _____   Date: _____

Address: _____   Phone: _____

Diagnosis: _____ with/without   Physician: _____

Marital Status: S M D W   Detrusor instibilty   Age: ___ Education level: _____
                                  symptoms

Subjective:

Primary c/o: Patient states the following _____

_____

_____

Past Medical Hx: Please list any medical problems proceedures or treatments you have been diagnosed with of treated for: _____

_____

Past Surgical Hx: Please list any surgical proceedures you have had. _____

_____

Past Gyncological Hx: (Please check all that are appropriate)

_____ Dysmenorrhea (Missing > one monthly cycle)

_____ Amenorrhea (Missing cycle for 3 months or more in a row)

_____ Dyspurunia (Pain with intercourse)

_____ Endometriosis

_____ Fibroid cysts

_____ Date of last menstration

Current Medications: _____

Birth History: Date   2nd Stage Duration   Delivery type   Weight Trama

---

Medical History Checklist: Please check any and all categories which apply currently.

___ Bladder Detrusor Instability	___ Hypermenorrhea
___ Currently Pregnant	___ Menorrhagia
___ Demand Pacemaker	___ Urinary Retention (> 100 ml)
___ Prior Pelvic Floor Stimulation	___ Pelvic Surgery in past 6 months
___ Pelvic Implanted Device	___ Atrophic Vaginitis
___ Active Vaginal Lesion or Infection	___ Genital Prolapse to Intruitis
___ Current Urinary Tract Infection (UTI)	___ Pelvic Irradiation
___ Current Pelvic Inflamatory Disease (PID)	___ Intrinsic Sphincteric Deficiency

Objective:

In General:

ROM: _____

Strength: _____

Gyncological: Before   After
                         physical therapy   physical therapy

Manual muscle test: ___ Digital ___ Periometry ___ Digital ___ Periometry

Instructions: Subtract after score line #2 from the before score line #1 and document in the residual volumn column line #3.

"PAD" Stress test:

1. Wt. of pad after test (Wet)   = ___   = ___
2. Wt. of pad before test (Dry)   = ___   = ___

3. Amount of residual Urine   = ___   = ___

Biofeedback Parameters Used: _____

_____

Kegel pelvic muscle exercise parameters used: _____

_____

Additional Information: _____

_____

Assessment:

Problem List: _____

_____

Goals: Short term (1 day to 1 wk) _____

_____

Long term (2 wks or more) _____

_____

Additional Comments: _____

_____

_____

Plan: Please circle the appropriate treatment protocol to be undertaken. Thank-You

Parameters:	#1 protocol (Empi)	#2 protocol (Kishman)	#3protocol (control)
E-stim	1* 30 min session 3* per week	1* 15 min session 2* per week	No e-stimulation
Biofeedback	1* 20 min session 3* per week	1* 20 min session 2* per week	1* 20 min session 3* per week
Kegel exer.	With biofeedback	With biofeedback	With biofeedback

Appendix B

Incontinence Impact Questionnaire

Part A

I. Has your urine leakage affected your: Please circle most appropriate answer.

(N=Not at all. S=Slightly. M=Moderately. G=Greatly)   N S M G

1. Ability to do household chores (Cooking, Housecleaning, Laundry etc)   0 1 2 3

2. Physical recreational activities (Walking, Swimming, or other exercises) 0 1 2 3

3. Entertainment Activities (Going to the Movies or Concerts etc.)   0 1 2 3

4. Ability to travel by car or bus for distances greater than 20 minutes away from home. 0 1 2 3

5. Ability to participate in social activities.   0 1 2 3

6. Your emotional health (Nervousness, Depression etc.)   0 1 2 3

II. Does Your problem cause you to experience any feelings of ...

7. Frustration?   0 1 2 3

Urogenital Distress Inventory
Part B

I. The following symptoms have been described by women who experience accidental urine loss. Please indicate which symptoms you are experiencing currently, and how bothersome they are for you. Be sure to answer all of the items, and circle the appropriate answer for each.

Legend: (First sub-question Y=Yes, scored as a #1, N=No, scored as a #0)
          (Second sub-question 0=Not at all. 1=Slightly. 2=Moderately. 3=Greatly)

A. Do you experience frequent urination episodes?   Yes No
   If Yes, How much does it bother you?   0 1 2 3

B. Do you experience urine leakage related to the feeling of urgency?   Yes No
   If Yes, How much does it bother you?   0 1 2 3

C. Do you experience urine leakage related to physical activity, coughing, Yes No
   or sneezing?
   If Yes, how much does it bother you?   0 1 2 3

D. Do you experience small amounts of leakage (That is, Drops)?   Yes No
   If Yes, how much does it bother you?   0 1 2 3

E. Do you experience difficulty emptying your bladder?   Yes No
   If Yes, how much does it bother you?   0 1 2 3

F. Do you Experience pain in the lower abdominal or genital area?   Yes No
   If Yes, how much does it bother you?   0 1 2 3

Appendix C
Cronbach's Alpha Coefficients for IIQ & UDI (long forms)

Reliabilities for the UDI subscale:

Irritative Symptoms	$\alpha = 0.70$
Obstructive Discomfort	$\alpha = 0.77$
Stress Symptoms	$\alpha = 0.48$

Reliabilities for the IIQ subscales:

Physical Activity	$\alpha = 0.87$
Travel	$\alpha = 0.87$
Social	$\alpha = 0.90$
Emotional	$\alpha = 0.90$

Appendix D
Pearson's Correlation coefficient for UDI &IIQ
(Short forms with Long forms)

Correlations or association with

Short form total Score/subscale (a)	Long form version (b)
IIQ - 7 Total	$r = 0.97$***
Physical Activity	$r = 0.91$***
Travel	$r = 0.94$***
Social/Relationships	$r = 0.88$***
Emotional health	$r = 0.92$***
UDI - 6 Total	$r = 0.93$***
Irritative Symptoms	$r = 0.86$***
Obstructive Discomfort	$r = 0.84$***
Stress Symptoms	$r = 1.00$ (d)
Sample Size	$n = 162$

(a) For short forms, informal subscale calculated by avg. items within ea. domain.
(b) Pearson correlation
(c) Same items.
***$P < .001$ (2-tailed).

Appendix E
Consent Form

PURPOSE OF RESEARCH

I have been informed that this study will test the effectiveness of three

different physical therapy approaches to treating bladder problems like mine. These

approaches are acceptable physical therapy interventions for this problem; none of

which involve hospitalization. This study will help to validate the benefits of

electrical stimulation as a component in the treatment of genuine stress incontinence.

PROCEDURE

I understand that I will be assigned by a random process to receive either a

conservative treatment consisting of biofeedback and Kegel exercises or a treatment

involving electrical stimulation combined with biofeedback and Kegel exercises. I

understand that these treatments will be administered by a licensed physical therapist

of Nova Care Inc., in Grand Rapids , MI. (Downtown Office), and will comply with

my physician's referral for such treatment. For these treatments I will be expected to

come to the clinic 2 to 3 times per week, as well as perform the specified exercises

everyday at home.

I am aware that in addition to the ordinary care received, I will be examined

and asked a series of questions by a licensed physical therapist. The physical

therapist's examination will consist of a standard incontinence evaluation and a stress

test involving completing a series of activities while wearing a sanitary napkin to

collect and measure the amount of urine lost.

I have been asked to undergo these tests at the beginning of the study, and at

the conclusion of the study. All tests will take place in the physical therapy

department at Nova Care Inc., during regularly scheduled treatment sessions. I will

not be asked to make a special trip to the clinic outside of normally scheduled hours or appointments, for these assessment.

RISKS AND DISCOMFORTS

I understand that I may experience discomfort during the examination or during treatment. This is mainly the result of my condition and the procedures of this study are not expected to exaggerate these feelings which are associated with the usual course of treatment.

BENEFITS

I understand that my participation in the study will have no direct reward to me other than the potential to reduce the frequency of incontinent episodes or improve my pelvic floor muscle strength under stress.

ALTERNATIVES

I understand that the three procedures being studied are standard ways of treating my problem. I have been referred by my physician to this clinic for a treatment program that ordinarily would be selected by a physical therapist. There are no other physical therapy alternatives offered in this clinic.

CONFIDENTIALITY

I understand that medical information produced by this study will become part my physical therapy record and will be subject to the confidentiality policies of Nova Care Inc. Information of a sensitive and personal nature will not be part of the medical record, but will be stored in the investigators research file and identified by a code number. The code key connecting name to numbers will be kept in a separate secure location.

If the data are used for publication in medical literature for teaching purposes, no names or other identifiers, will be used.

REQUEST FOR MORE INFORMATION

I understand that I may ask more question about the study at any time. Heath Jabs SPT @ 453-2851, Patrick Hadlock SPT @ 453-9423, Jason Ricci SPT @ 892-6801, Eileen Kishman PT @ (616) 451-2891, Colleen Boyden PT @ 451-2851 are all available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study which might influence my continued participation. If during the study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the Patient Care Representative or whoever we decide is best (# of person) is available to talk with me. A copy of this consent form will be given to me to keep for careful rereading.

REFUSAL OR WITHDRAWAL OF PARTICIPATION

I understand that my participation is voluntary and that I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at Nova Care Inc. I also understand that Eileen Kishman P.T., or Colleen Boyden P.T., may terminate my participation in this study at any time after they have explained the reasons for my discontinuation of care. However, further treatment will be provided if warranted, if the study concludes before my therapy in complete.

INJURY STATEMENT

I understand that in the unlikely event of injury to me resulting directly from my participation in this study, said injury will be reported promptly, and medical treatment will be available to me, but no further compensation would be provided by Nova Care Inc. I understand that my agreement to participate in this study does not waive any of my legal rights.

I have explained to _____ the purpose of the research, the procedures required, and the possible risks and benefits to the best of my ability.

_____   _____

            Investigator   Date

I confirm that Eileen Kishman P.T., or Colleen Boyden P.T. has explained to me the purpose of the research; the study procedures I will undergo and any risks or discomforts, as well as benefits of the treatment. Alternatives to my participation in the study have also been discussed. I have read and understand this consent form. I agree to participate in this research project.

_____   _____

      Participant Signature   Date

_____   _____

            Witness   Date