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ACCEPTANCE

This dissertation, CLINICAL OUTCOMES INVOLVING THE USE OF EXTRACORPOREAL MAGNETIC INNERVATION IN THE TREATMENT OF URINARY INCONTINENCE by Kathy E. Davis was prepared under the direction of the candidate's dissertation committee. It is accepted by the committee members in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Nursing in the Byrdine F. Lewis School of Nursing in the College of Health and Human Sciences, Georgia State University.

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ABSTRACT

CLINICAL OUTCOMES INVOLVING

THE USE OF EXTRACORPOREAL MAGNETIC INNERVATION

IN THE TREATMENT OF URINARY INCONTINENCE

by

KATHY E. DAVIS

Urinary incontinence affects approximately 25 million Americans, significantly diminishing their function and quality of life. It is estimated that 50% of all women will experience some form of urinary incontinence in their lifetime. Although women are disproportionately affected by urinary incontinence, 69% of men who have undergone prostatectomy also report post-surgical incontinence.

Extracorporeal Magnetic Innervation (ExMI) is a novel conservative approach to the treatment of urinary incontinence. As a patient sits fully clothed on a chair, an electromagnet delivers a timed magnetic field that penetrates the pelvic floor, inducing a nerve impulse that prompts contractions of the muscles of the pelvic floor. When the magnet is switched off, the muscles relax. This forced, passive exercise of the pelvic floor muscles serves to build endurance and strengthen the muscles supporting the bladder during times of physical stress such as coughing, laughing or running.

This study is a descriptive, retrospective analysis of data collected from a specialty continence center within a major Atlanta metropolitan outpatient facility. The records for all patients who received ExMI from 2000 to 2012 were reviewed. Of the 43 patients who had received ExMI, 35 met study inclusion criteria. Eight patients were eliminated from the study. Four of these patients experienced ExMI benefits for

conditions unrelated to urinary incontinence and are discussed. Data were analyzed using descriptive and inferential statistics. .

The majority of the patients were women (n=26, 74%); most patients had stress urinary incontinence (n=16, 46%) or mixed urinary incontinence (n=12, 34%). The patient outcome was determined by comparing the pad usage before treatment and at the end of treatment (16 weeks). The average number of pads used daily was significantly reduced to 1.6 3 $\pm$ 0.94 ($p<.0001$). Treatment with ExMI for urinary incontinence was briefly popular in the United States shortly after it was introduced. Although ExMI is used extensively across Europe and Asia, very few studies on the efficacy of ExMI appear in the literature. These results will add to this body of knowledge.

CLINICAL OUTCOMES INVOLVING

THE USE OF EXTRACORPOREAL MAGNETIC INNERVATION

IN THE TREATMENT OF URINARY INCONTINENCE

by

KATHY E. DAVIS

A DISSERTATION

Presented in Partial Fulfillment of Requirements for the
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2014

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LIST OF ABBREVIATIONS

ALSWH	Australian Longitudinal Study on Women's Health
CNS	Central Nervous System
COPD	Chronic Obstructive Pulmonary Disease
EMG	Electromyography
EQ-5D	Standardized instrument for measuring health outcomes
ExMI	Extracorporeal Magnetic Innervation
HZ	Hertz
IAD	Incontinence Associated Dermatitis
IC	Interstitial Cystitis
IRB	Institutional Review Board
MRI	Magnetic Resonance Imaging
NAFC	National Association for Continence
NOBLE	National Overactive Bladder Evaluation
OAB	Overactive Bladder
PFME	Pelvic Floor Muscle Exercises
QOL	Quality of Life
WOMAC	Western Ontario and McMasters Universities Osteoarthritis Index

CHAPTER I

INTRODUCTION

Urinary incontinence is defined as the involuntary loss of urine from the bladder (Craven & Hirnle, 2003). According to Sakamoto, Sharma, and Wheeler (2007) this is a problem that affects approximately 25 million Americans. Anatomical differences, trauma that can occur during childbirth and hormonal changes brought about by menopause predispose women to be disproportionately affected by urinary incontinence more than men (Katz, 2009). It is estimated that 50% of all women will experience some form of urinary incontinence in their lifetime (Melville, Katon, Delaney, & Newton, 2005; Huang et al., 2006). The overall prevalence of urinary incontinence in ambulatory men is reported at around 30% (Smoger, Felice, & Kloecker, 2000). Of men who have undergone radical prostatectomy, up to 69% have reported some post-surgical incontinence (Hollenbeck et al., 2002). It is of interest that men report more social limitation and more frustration and shame from urinary incontinence than women (Lagro-Janssen, Hilkens, Klaasen, & Teunissen, 2008).

It is difficult to predict the financial cost of urinary incontinence with any precision since most projections fail to take into consideration inflation and increases in the cost of medical care and supplies, however, the yearly expense of incontinence care is estimated at over $27 billion. This expense is attributed to catheters, containment devices, laundry services, medical care for infections, injuries sustained in falls, prolonged hospital stays, and the indirect costs of lost time from work for patients or

caregivers (Kerr, 2005; Landefeld, et al., 2008). In addition to the high financial cost of urinary incontinence, there is personal degradation from the negative physical, social, and emotional impact of this dysfunction.

Urinary incontinence is categorized according to etiology and is commonly referred to as stress, urge, mixed, reflex, overflow, or functional incontinence. Stress and mixed urinary incontinence (symptoms of both stress and urge) predominate (Diokno et al., 2003; Kristensen, Eldoma, Williamson, Wood, & Mainprize, 2010). Treatment is based on the type of incontinence the patient is experiencing and includes self-management strategies, behavioral therapies, pelvic floor rehabilitation, medications and surgery.

Problem Statement

Although therapies exist, many people continue to live with the physical and psychological distress of urinary incontinence. Control over urination is learned in early childhood, so loss of this control in adulthood is a demoralizing condition that has been described as “a disfigurement of self” (Nahon, Dorey, Waddington, & Adams, 2009). The reasons for living with urinary incontinence are varied. Hagglund & Wadensten (2007) suggest that living with the shame of incontinence and fear of humiliation prevent some patients from seeking care for incontinence. Too embarrassed to discuss this problem with their nurse or doctor, they try to manage the incontinence on their own. Some patients think that being incontinent is to be expected with aging, and not viewed as abnormal (Newman, 1998) while others do not think that there is any effective treatment (MacKay & Hemmett, 2001). According to Newman (1998) most women will

wait approximately three years before seeking medical care for urinary incontinence, whereas men will seek help within six months.

Urinary incontinence has a negative impact on emotional health and self-esteem (Fultz & Herzog, 2001; MacKay & Hemmett, 2001) and significantly diminishes function and quality of life (Melville, Katon, Delaney, & Newton, 2005). Patients have reported sleep disturbances related to eneuretic episodes. Complaints of interrupted sleep resulting in next day exhaustion, or no longer sleeping with their partner so that their partner's sleep is not disturbed are commonly expressed (Palmer, Fogarty, Somerfield, & Powel, 2003). These patients experience a higher incidence of depression and lower self-esteem that they believe negatively affects their work performance and social activities (Yeung et al., 2003).

Incontinence is frequently cited as being a barrier to physical activity. Brown & Miller (2001) examined results from the Australian Longitudinal Study on Women's Health Survey (ALSWH) to ascertain both the prevalence of urinary incontinence and whether women perceived the incontinence to be a barrier to physical activity. The ALSWH has been collecting information on physical, psychological and social aspects of women's health since 1996. At that time over 40,000 women were included in the baseline study. Data was collected from young (18-23), middle age (45-50), and older women (79-75) with regard to their experience of urinary incontinence. All age groups reported episodes of urinary incontinence. In 1999 a follow up survey to examine the relationship between incontinence and physical activity was sent to 1500 women who had participated in the baseline survey. Over 1000 women participated in the follow-up survey. Overall, 89% of respondents reported leaking urine when coughing or laughing,

and more than 40% reported leaking when engaged in physical exercise. These women described a variety of management strategies to avoid or minimize incontinence while participating in any sort of physical exercise. More than one third of middle aged women and one quarter of older women completely avoided physical activity due to their incontinence. Similar self-imposed modifications and restrictions to recreation and physical functions such as walking, running, lifting, and carrying have also been reported in the literature (Brocklehurst, 1993; Hagglund, Walker-Engstrom, Larsson, & Leppert, 2004; St. John, Wallis, Griffiths, & McKenzie, 2010).

Living with incontinence on a daily basis, wearing sanitary pads or diapers, choosing clothing that can conceal a leak, and frequent washing to prevent odors can all negatively affect a person's self-image and sexuality. Incontinence has been shown to cause a loss of libido and sexual dysfunction that can result in barriers to healthy relationships (Katz, 2009). All the work that goes into daily management of urinary incontinence as well as the involuntary loss of urine during sexual intercourse have been cited as having a major negative impact on sexual relations (O'Connell, Baker, & Munro, 2007). In a study of 166 men who had undergone prostatectomy, 114 (69%) reported problems with urinary incontinence, management of urinary incontinence and coping. Patients found the social limitations of urinary incontinence to be the most difficult. These men voiced their reluctance to become sexually involved in the future for fear that their incontinence would be discovered (Palmer, Fogarty, Somerfield, & Powel, 2003).

Compounding the financial costs and psychological toll, there are other risks associated with urinary incontinence. Incontinence-associated dermatitis (IAD) of the perineum has been reported in up to 50% of persons who suffer with incontinence.

Inflammation of the skin with erythema, edema and erosion of superficial layers of skin is characteristic of IAD. In reviewing the existing literature, several factors were found to contribute to the development of IAD including the patient's age, general health, nutrition, friction/shear, volume and frequency of incontinence (Gray et al, 2007; Langemo, Hanson, Hunter, Thompson, & Oh, 2011). These skin injuries add to the physical misery as well as the economic burden.

Falls and resultant injuries are serious concerns for persons with urinary incontinence. They threaten independence and are the leading cause of death in persons over the age of 65 (Brady & Lamb, 2008). Byles, Millar, Sibbritt, & Chiarelli (2009) examined ALSWH data and found a positive correlation between the incidence of falls in older women with incontinence. Hasegawa, Masafumi, & Iguchi (2009) conducted a study with over one thousand participants, both men and women. Their study also indicated that recurrent and injurious falls have been associated with urinary incontinence and are prevalent in long-term care facilities among the elderly who are frail and who have comorbid conditions including diabetes, cancer, hypertension, osteoporosis and dementia.

Clearly urinary incontinence is a major healthcare problem that negatively affects millions of people. The physical discomfort and potential risk of injury related to incontinence is compounded by the personal and social burden that accompanies it. Urinary incontinence also poses a challenge to healthcare professionals and drains available resources. First line treatment for urinary incontinence includes the use of pads, behavioral modification and conservative, self-management strategies such as fluid, diet, and bowel management. Patients may also be taught how to perform Kegel exercises to

strengthen the pelvic floor. If these techniques fail to provide the desired continence, more aggressive therapies, including pessaries, biofeedback, electrical stimulation, medications, the injection of bulking agents or surgery may be the next step. There is another treatment modality that uses pulsed electromagnetic fields to force pelvic muscle contraction. Extracorporeal magnetic innervation (ExMI), the use of pulsed electromagnetic fields in the treatment of urinary incontinence, is a non-invasive, conservative treatment that has been available for more than a decade, but there is little in the literature regarding the effectiveness of this treatment. This study will add to the body of knowledge of the effectiveness of ExMI.

Purpose of the Study

The purpose of this study is to describe clinical outcomes for patients who were treated with ExMI for stress, urge and mixed urinary incontinence. Clinical outcomes are the end results of treatment effectiveness, length of time this effectiveness lasts, and any benefits unrelated to urinary incontinence. The literature has shown that electromagnetic pulse therapy can have other beneficial effects. Although ExMI is intended for the treatment of urinary incontinence, end results unrelated to urinary incontinence will be included in clinical outcomes.

Specific objectives of the study

1. Examine the differences in selected demographics (age in years, gender, race, weight in pounds) and relationship among health behaviors (dietary/fluid management, bowel management, Kegel exercises), medications (diuretics, central nervous system [CNS] depressants, hormones, anticholinergics, antihistamines, others as appropriate to bladder function), substance use

(tobacco, caffeine, alcohol), physical findings (cystocele, rectocele, uterine prolapse, vaginal/rectal tone/grip), medical history (length of incontinence, pelvic surgery, cardiovascular disease, hypertension, diabetes, neurologic disorders, stroke, COPD/asthma, bladder/kidney infections, pelvic/abdominal/back pain, pregnancies, methods of delivery, number of wetting episodes and number of pads used per day prior to treatment), between patients with stress urge, and mixed urinary incontinence.

2. Explore the relationship of selected demographics (age in years, gender, race, weight in pounds) and health behaviors (dietary/fluid management, bowel management, Kegel exercises), medications (diuretics, central nervous system [CNS] depressants, hormones, anticholinergics, antihistamines, others as appropriate to bladder function), substance use (tobacco, caffeine, alcohol), physical findings (cystocele, rectocele, uterine prolapse, vaginal/rectal tone/grip), medical history (length of incontinence, pelvic surgery, cardiovascular disease, hypertension, diabetes, neurologic disorders, stroke, COPD/asthma, bladder/kidney infections, pelvic/abdominal/back pain, pregnancies, methods of delivery, number of wetting episodes and number of pads used per day prior to treatment), and post-treatment wetting episodes following ExMI treatment for urinary incontinence.
3. Explore the relationship of selected demographics (age in years, gender, race, weight in pounds) and health behaviors (dietary/fluid management, bowel management, Kegel exercises), medications (diuretics, central nervous system [CNS] depressants, hormones, anticholinergics, antihistamines, others as

appropriate to bladder function), substance use (tobacco, caffeine, alcohol), physical findings (cystocele, rectocele, uterine prolapse, vaginal/rectal tone/grip), medical history (length of incontinence, pelvic surgery, cardiovascular disease, hypertension, diabetes, neurologic disorders, stroke, COPD/asthma, bladder/kidney infections, pelvic/abdominal/back pain, pregnancies, methods of delivery, number of wetting episodes and number of pads used per day prior to treatment), and post-treatment pad usage following ExMI treatment for urinary incontinence.

4. Describe the patients who experienced relapse in urinary incontinence after treatment with ExMI and any benefits received unrelated to reduction of urinary incontinence.
5. Examine the differences in selected demographics (age in years, gender, race, weight in pounds) and health behaviors (dietary/fluid management, bowel management, Kegel exercises), medications (diuretics, central nervous system [CNS] depressants, hormones, anticholinergics, antihistamines, others as appropriate to bladder function), substance use (tobacco, caffeine, alcohol), physical findings (cystocele, rectocele, uterine prolapse, vaginal/rectal tone/grip), medical history (length of incontinence, pelvic surgery, cardiovascular disease, hypertension, diabetes, neurologic disorders, stroke, COPD/asthma, bladder/kidney infections, pelvic/abdominal/back pain, pregnancies, methods of delivery, number of wetting episodes and number of pads used per day prior to treatment), wetting episodes, and pad usage

between patients who do not relapse following ExMI treatment and those who do.

Research objectives were modified due to sample size limitations and available information that was documented in the archived records. The revised research objectives are as follows and will be referred to in the following chapters.

1. Examine the differences in selected demographics (age in years, gender, weight in pounds) and relationship among health behaviors (dietary/fluid management, bowel management), medications (diuretics, central nervous system [CNS] depressants, hormones, anticholinergics, antihistamines, others as appropriate to bladder function), physical findings (cystocele, rectocele, uterine prolapse, vaginal/rectal tone/grip), medical history (length of incontinence, pelvic surgery, cardiovascular disease, hypertension, diabetes, neurologic disorders, stroke, COPD/asthma, bladder/kidney infections, pelvic/abdominal/back pain, pregnancies, methods of delivery, and number of pads used per day prior to treatment), between patients with stress, urge, and mixed urinary incontinence.
2. Explore the relationship of selected demographics (age in years, gender, weight in pounds) and health behaviors (dietary/fluid management, bowel management), medications (diuretics, central nervous system [CNS] depressants, hormones, anticholinergics, antihistamines, others as appropriate to bladder function), physical findings (cystocele, rectocele, uterine prolapse, vaginal/rectal tone/grip), medical history (length of incontinence, pelvic surgery, cardiovascular disease, hypertension, diabetes, neurologic disorders,

stroke, COPD/asthma, bladder/kidney infections, pelvic/abdominal/back pain, pregnancies, methods of delivery, and number of pads used per day prior to treatment), and post-treatment pad usage following ExMI treatment for urinary incontinence.

3. Describe the patients who returned for additional ExMI treatments.
4. Describe any benefits received unrelated to reduction of urinary incontinence.

Conceptual Framework

The framework for this study is based on scientific concepts including the physiology of micturition and the physics of pulsed electromagnetic fields.

Physiology of Micturition

Normal micturition is a highly synchronized act involving both involuntary and voluntary mechanisms. There are storage and evacuation phases that must be coordinated between the bladder and urinary sphincters so that continence is maintained. During the storage phase, sympathetic stimulation keeps the detrusor muscle of the bladder relaxed, and the internal urethral sphincter contracted. As the bladder fills with urine and the volume reaches about 200 mL, stretch receptors in the bladder stimulate the spinal cord at the level of S2-S4. This information is relayed to the pontine micturition center in the brain which becomes activated resulting in the urge to void. Voiding occurs when parasympathetic stimulation relaxes the internal urethra, and causes the detrusor muscle to contract. Sympathetic nervous system stimulation closes the internal urethral sphincter and at the same time allows for conscious control over voiding through voluntary contraction of the external urethral sphincter. When the time and place are

appropriate, conscious voluntary relaxation of the external sphincter is allowed so that the bladder can empty (Athwal et al., 2001; Blok, Sturms, & Holstege, 1998; Porth, 2011).

Types of Urinary Incontinence

Stress Incontinence. Pelvic floor muscle support is critical to the maintenance of continence. The levator ani is the largest and most important muscle of the pelvic floor. It forms a sling that supports and holds the pelvic organs in place as well as helps to maintain voluntary control over urination in coordination with the parasympathetic and sympathetic nervous systems, bladder, and urethral sphincters (Moore & Dalley, 1999). Overstretched and ruptured connective tissue, muscle, and nerve fibers result in loss of muscle tone and result in poor support of the bladder and urinary sphincter (Baessler & Schuessler, 2003). Neuromuscular and connective tissue damage from overstretching has been associated with vaginal delivery. A sudden increase in intra-abdominal pressure such as in coughing or sneezing, or physical activity such as lifting or running can result in the involuntary loss of urine known as stress incontinence (Keyock & Newman, 2011).

Vaginal and periurethral tissues are sensitive to the effects of circulating estrogen. It is believed that estrogen increases urethral closure pressure which helps to maintain continence (Robinson & Cardozo, 2003). Low estrogen levels just prior to menstruation and after menopause have been linked to lowered urethral closure pressure and weakened sphincter muscles (Palmieri et al., 2007). When urethral pressure is lowered, the chance of leakage with a sudden rise in intra-abdominal pressure increases. Post menopause, as the urethral lining thins, the structural support for the bladder is reduced, again, increasing the chance for stress incontinence to occur.

In patients who smoke, research suggests there may be a link between incontinence and the synthesis of collagen (Bottomley, 2000; Bump & McClish, 1992). Collagen in connective tissue is essential for providing pelvic floor support and lack of adequate pelvic floor support may be in part due to abnormal collagen synthesis (Wong, Harmanli, Agar, Dandolu, & Grody, 2003). The periurethral tissues are comprised mainly of type I and type III collagens. Smoking has been shown to decrease biosynthesis of these collagens (Knuutinen et al., 2002). Compounding this problem, the inflammation of the respiratory passages from smoking results in a chronic cough. The pairing of poor pelvic floor support and sudden increase in intra-abdominal pressure from coughing increases the risk of urinary incontinence.

Although associated with damage incurred during childbirth or lack of estrogen, stress incontinence is not strictly a woman's disorder. Approximately half of all men who undergo radical prostatectomy experience urinary incontinence due to damage to the urethral sphincter, presenting with urine loss associated with coughing, sneezing or increased physical activity (Abrams, 2003; Yokoyama et al., 2004). Radical prostatectomy patients also experience urine leakage resulting from bladder dysfunction in the form of overactive bladder and urge incontinence or a combination of bladder dysfunction and sphincter damage.

Urge Incontinence. Patients who experience involuntary loss of urine accompanying the sensation of a need to void have urge incontinence. Typically, this is the result of inappropriate bladder spasms caused by abnormal nerve stimulation (de Groat, 1997).

Overactive bladder (OAB) is a syndrome which is characterized by urgency, frequency and nocturia, and can occur with or without urinary incontinence. The National Overactive Bladder Evaluation (NOBLE) program surveyed over 5,000 adults across the United States by age, gender and geographic region to determine the prevalence and risk factors for OAB. Data from the NOBLE program show that about one third of all patients with OAB experience urinary incontinence. While both men and women are equally affected by OAB, overactive bladder with incontinence is more common among women than men, and the prevalence of both forms increases with age (Stewart et al., 2003).

Theories related to the pathophysiology of OAB can be described as either neurogenic or myogenic. Damage along nerve pathways can cause bladder over activity from uncontrolled voiding reflexes. Stroke or other neurological diseases such as multiple sclerosis or Parkinson's disease are often implicated in overactive bladder of neurogenic origin (Porth, 2011). With myogenic etiology, patients often have bladder outlet obstruction with an increase in intravesical pressure. Rather than a normal contraction that can empty the bladder, mini-contractions of the detrusor muscle occur resulting in overactive bladder symptoms (Wein & Rackley, 2006).

Certain foods, dyes, chemicals, caffeine in any substance, alcohol and tobacco products have all been implicated as irritants to the bladder wall and are associated with increased urinary incontinence (Bottomley, 2000).

Mixed Incontinence. Mixed urinary incontinence is a common finding where patients present with urinary leakage associated with both urgency and physical exertion (Chu & Domochowski, 2006). Rates of urge and mixed incontinence increase with age,

while stress incontinence is not significantly associated with age. This may be due, in part, to age-related diseases that can alter normal urinary function (Wallner et al., 2009).

Other Types of Incontinence. Other common forms of urinary incontinence include overflow and functional incontinence. Overflow incontinence occurs when the bladder fails to empty completely, allowing constant dribbling of urine. This can be the result of a physical obstruction like a urinary stone or enlarged prostate. Overflow incontinence can also stem from a neurologic abnormality such as a birth defect or spinal injury or tumor. Functional incontinence is most commonly seen in older adults who have comorbid or debilitating conditions that may predispose them to urinary incontinence by limiting their ability to move quickly enough, or to mentally process their need to urinate or communicate that need to caregivers.

Failure of any aspect of the neuromuscular coordination of micturition can result in urinary incontinence. The causes of overflow and functional incontinence are very specific and require management that targets the specific cause. However, pelvic floor weakness, poor vesicourethral support, and detrusor instability are of great interest with regard to the application of ExMI because of the potential for this technology to strengthen the pelvic floor musculature and reduce detrusor contractility.

Treatment for Urinary Incontinence

Treatment regimens for urinary incontinence vary according to etiology. First, a determination of the kind of urinary incontinence is made by obtaining a thorough history including food and fluid intake and voiding diaries, as well as physical examination to assess for pelvic floor abnormalities. Urodynamic studies may also be performed at this time to help determine bladder and urethral function. Once the underlying cause and the

severity and type of urinary incontinence is determined, management techniques and treatments can begin.

Patients are first taught behavioral techniques such as fluid, diet, and bowel management, Kegel exercises, and in some cases, scheduled voiding or double voiding. Kegel exercises, sometimes referred to as pelvic floor muscle training, helps to strengthen and tone the muscles of the pelvic floor and support the urethra so that when there is an increase in intraabdominal pressure, as with a cough or sneeze, or the patient experiences an involuntary detrusor contraction, he or she can contract the pelvic muscles so that urine leakage is prevented (Huebner et al., 2011; Ramundo & Davis, 2002). This training must be consistently practiced every day and may take months before any benefit is discernible.

Food/fluid intake diaries and voiding diaries provide valuable information that is helpful in assessing voiding patterns and leakage. Many foods can irritate the lining of the bladder resulting in pain, bladder spasms, and urinary incontinence. The volume of fluid is as important as the types of fluids that patients drink. Drinking excessively as well as drinking too little can provoke bladder spasms and leakage. These diaries are simple to use and can give the patient, as well as the practitioner, insight into triggers that may be causing incontinence. Once the patient has become aware of the relationship between intake and incontinence, they can modify their diet to help reduce wetting episodes.

Bladder innervation and function is very similar to rectal innervation and function. Research has shown that there is a positive correlation between constipation and bladder dysfunction (Kim, Lee, Jung, & Lee, 2011). Patients who present with

urinary incontinence frequently have chronic constipation (Bannister, Lawrence, Smith, Thomas, & Read, 1988) therefore; bowel management is a critical first step in conservative treatment of urinary incontinence. Patients are taught how to prevent constipation and improve bowel function. Many find that it does help to reduce incontinent episodes.

Kegel exercises and dietary, fluid and bowel management plans require motivation and daily adherence, but can be very effective for some patients. If these behavioral management therapies are inadequate, however, more invasive treatment regimens may be required and are often used in combination with behavioral techniques. The use of a pessary, an intravaginal device that supports the bladder neck, when fitted properly can be helpful in preventing stress urinary incontinence in some patients (Keyock & Newman, 2011).

Electrical stimulation has been used successfully for many years to force contractions in an effort to strengthen or relax pelvic floor muscles and is often combined with biofeedback. However, electrical stimulation of the pelvic floor requires the insertion of probes in the vagina or rectum, and it is not well accepted by patients because it is invasive and uncomfortable. Adjusting the frequency (Hertz or Hz) of the electrical stimulation allows the practitioner to force contractions that will either strengthen and build up muscle or relax muscle. The ability to relax muscle is helpful in patients who experience detrusor instability of OAB where the bladder contracts without provocation. Relaxing the bladder helps to lessen leaking episodes in patients who have incontinence associated with overactive bladder. Electromagnetic stimulation through the use of ExMI offers the same results without pain, without probes or embarrassment, making it an

attractive alternative. Studies have extrapolated treatment parameters from traditional electrical stimulation treatments of the pelvic floor. Frequencies of 5 to 20 Hz have been reported to inhibit detrusor contractility (Bradshaw, Barker, Radley, & Chapple, 2003); whereas frequencies of 20 to 50 Hz have been reported to increase intraurethral pressure which is effective in preventing stress incontinence (Fujishiro et al., 2000; Yamanishi, Yasuda, Suda, & Ishikawa, 1999).

Magnetic Field Therapy. The use of magnets for the treatment of various disorders is not a new idea. They are discussed in ancient Chinese and Egyptian writings from as early as 2000 B.C. Fifteenth century Swiss alchemist, Paracelsus investigated the use of magnets to heal illness (Macklis, 1993) by restoring the body's natural energy (Philpott & Kalita, 2000). Eighteenth century physician and astrologer, Franz Mesmer believed in an energy that flowed through the body that he called animal magnetism (Macklis, 1993). Both Paracelsus and Mesmer treated individuals by passing magnetized stones called lodestones over the bodies of those seeking to be healed (Philpott & Kalita, 2000). For centuries, magnets were widely used to treat illness and restore health, but as medicine became more grounded in scientific evidence and therapeutic regimens included effective medications, the use of magnet therapy began to wane. For most of the twentieth century, magnets were viewed with skepticism and associated with quackery (Philpott & Kalita, 2000).

While there have been anecdotal reports that static magnets have been helpful in treating various medical conditions, there is little clinical or experimental data to support these claims. On the other hand, the use of magnetic energy is readily accepted by both the medical community and general public for diagnostic imaging with MRI (Lalande et

al., 2004). Pulsed electromagnetic field therapy has been reported to help a wide variety of medical conditions including bone healing (Garland, Adkins, Matsuno, & Stewart, 1999; Kumar et al., 2005; MacKenzie & Veninga, 2004; Massari, Fini, Cadossi, Setti, & Traina, 2006), and soft tissue healing (Kenkre, Hobbs, Carter, Holder, & Holmes, 1996; Strauch et al., 2006; Yamaguchi, Ogiue-Ikeda, Sekino, & Ueno, 2006). This technology has also been shown to affect neural tissue (Goodwin, 2003; Mert, Gunay, Gocmen, Kaya, & Polat, 2006), ease pain (Lyskov et al., 2005; Pipitone & Scott, 2001; Shupak et al., 2006; Weintraub & Cole, 2004, relieve mental depression (Baeken et al., 2009; Fitzgerald, Hoy, Daskalakis, & Kulkarni, 2009; Vanderhasselt, DeRaedt, Leyman, & Baeken, 2009) and help individuals with urinary and fecal incontinence (Galloway et al., 1999; Thornton, Kennedy, & Lubowski, 2005; Yokoyama et al., 2004; Yokoyama et al., 2005).

Pulsed Electromagnetic Fields. The application of a pulsed electromagnetic field is a non-traditional, non-invasive form of energy medicine that is gaining popularity in healthcare today. The application of a magnetic field is thought to be beneficial by positively affecting physiological processes. Magnetic therapies can be further divided based on whether a static magnet or pulsing electromagnet is used. A static magnet is one that creates a field that moves in a steady flow. An electromagnet can reverse direction generating a pulsed electromagnetic field when turned off and on rapidly.

The therapeutic application of pulsed electromagnetic fields is based on Faraday's Law of Magnetic Induction which asserts that a changing magnetic field will produce electrical current in adjacent tissues (Walker, 2004). When the changing magnetic field is generated near living tissue, electrical currents induced within the tissues cause

depolarization in motor nerves. The ensuing nerve impulse stimulates the release of acetylcholine, depolarization of muscle fibers and muscle contraction (Galloway, El-Galley, Sand, Appel, Russell, & Carlan, 1998; Hoscan, et al., 2008; Voorham-Van der Zalm, Pelger, Stiggelbout, Elzevier, & Lycklama A Nijeholt, 2006). No electric current actually enters the body. The magnetic field is indifferent to tissue impedance. With no opposition, the magnetic field encounters no obstruction from clothing or human tissue. Patients who receive pulsed electromagnetic field therapy targeting the pelvic floor muscles do not need to undress. There is no need for probes or insertion of internal devices. They sit, fully clothed, on a chair with the electromagnet imbedded within the seat. When the electromagnet is engaged, the pulsing magnetic field painlessly induces contractions of the pelvic floor and sphincter muscles (Chandi, Groenendijk, & Venema, 2003; Doganay, Kilic, & Yilmaz, 2010). Termed extracorporeal magnetic innervation (ExMI), this forced exercise of the pelvic floor serves to build endurance and strengthen the muscles supporting the bladder during times of physical stress such as coughing, sneezing or increased physical activity. Another advantage of this treatment is based on the fact that magnetic stimulation of sacral nerve roots is insufficient to induce bladder contractions. Studies have demonstrated that when magnetic stimulation is applied, bladder contractions are inhibited, suppressing detrusor instability in patients with urge incontinence (Bradshaw, Barker, Radley, & Chapple, 2003; Bycroft, Craggs, Sheriff, Knight, & Shah, 2004; Voorham-VanDerZalm, Pelger, Stiggelbout, Elzevier, & Lycklama A Nijeholt, 2006).

Summary

The purpose of this study was to evaluate the clinical outcomes involving the use of pulsed electromagnetic fields in the treatment of urinary incontinence. This study is based on scientific concepts including the physiology of micturition and the science of pulsed electromagnetic fields. The use of pulsed electromagnetic fields in the treatment of urinary incontinence is relatively new and there is little in the literature with regard to this therapy's efficacy and long-term effects. This study will add to that body of knowledge related to the effectiveness of ExMI.

CHAPTER II

REVIEW OF THE LITERATURE

The application of pulsed electromagnetic fields has been used for treating a number of disorders that range from bone and tissue healing to the treatment of incontinence. This chapter presents an overview of literature related to the effects of pulsed electromagnetic fields on biological tissues, and includes information on how this technology has been studied as a modality to treat a variety of conditions including urinary incontinence.

Stress Urinary Incontinence

Galloway, El-Galley, Sand, Appell, Russell, and Carlan (1999) reported using pulsed electromagnetic field stimulation to treat stress urinary incontinence in women. Participants completed 3-day bladder diaries in which they recorded their voided volumes, the number of leaks they experienced each day, and the number of pads they used in a day. They also had a standardized pad weight test and urodynamic study to assess the severity of their leakage. Additionally, all women completed a quality of life survey. A total of 83 females with stress urinary incontinence were exposed to the pulsed field by sitting on a chair that had been fitted with an electromagnet under the seat. This particular piece of equipment is called the Neocontrol System by Neotonus, and has been FDA approved for the treatment of stress urinary incontinence in women (Galloway et

al., 1999). The therapy has been named ExMI for extracorporeal magnetic innervation. The women were completely clothed and seated on the chair so that the perineum was centered and the pelvic floor muscles were in the direct line of the magnetic field. Treatments were given twice a week for six weeks. They included ten minutes of pulsed stimulation at 5 Hz, a 1 to 5 minute rest period, and then ten minutes of pulsed stimulation at 50 Hz. Every two weeks the patients kept a three-day bladder diary. Two weeks after the end of the study, all women repeated all baseline studies. At week 12, the bladder diary and quality of life survey only were repeated. There were 50 women at follow-up in 3 months. The reduction in pad use was significant ($p=0.001$) from baseline to completion of treatment, as was the reduction in frequency of leaking episodes ($p=0.001$). Mean bladder capacity was unchanged. Detrusor instability had been demonstrated in five patients during urodynamic examination at baseline, but only in one patient after treatment. This is of interest because detrusor instability is associated with involuntary bladder contraction either spontaneously or on provocation (Chapple & Christmas, 1992) which results in urge incontinence.

A study by Hoscan et al. (2008) evaluated the long-term efficacy of electromagnetic stimulation for stress incontinence. Thirty subjects completed bladder diaries, pad weight tests, urodynamics and quality of life surveys prior to receiving treatment sessions lasting 20 minutes, twice a week, for six weeks. They received the same protocol as previously discussed studies with frequencies of 5 and 50 Hz intermittently for 10 minutes. Follow-up was performed at 3, 12, and 24 months after treatment. At 3 months, the cumulative success rate was 77.8% with only six subjects not showing any improvement in symptoms. After one year, researchers report the effect of

electromagnetic stimulation gradually decreased until subjects' symptoms were near baseline at the 24 month follow-up. They concluded that while this therapy offers an effective modality for urinary incontinence that is painless and non-invasive, more studies need to be done to determine how long benefits would last and when retreatment would provide the best outcome.

Bakar, Ozdemir, Ozengin, & Duran (2010) explored the efficacy of ExMI for older women who were diagnosed with stress urinary incontinence. Thirteen patients between the ages of 61 and 69 (mean 65.23 $\pm$ 2.8 years) participated in this study. Urinary symptoms, pelvic floor electromyographic activity (EMG), pad testing and Quality of Life (QOL) were evaluated at baseline and at six weeks. Pad test results showed significant reduction in urine loss ($p=0.016$), significant improvement in EMG values ($p=0.005$) and in QOL scores ($p=0.002$). This study suggests that ExMI could be a viable treatment alternative for older women who do not wish to have definitive surgical intervention or who might not be good surgical candidates.

Ismail, Forward, Bastin, Wareham, Emery, & Lucas (2009) conducted a prospective, non-controlled study specifically to assess efficacy, side effects, and dropout rates for women treated with ExMI for stress urinary incontinence. Forty-eight patients were recruited and outcome measures of pad weight test, daily pad use, daily leaking episodes and quality of life were evaluated. Thirty-one patients completed eight weeks of twice weekly treatments. Twenty-seven patients returned at the three month re-evaluation. This study revealed no significant differences in outcomes for pad weight, pad use, leaking episodes or quality of life from beginning to end of treatment or at the three month reassessment. When asked about side effects the majority of patients

(62.7%) cited various types of pain. Eight percent of patients who dropped out of the study cited various types of pain, and 15% of dropouts gave no reason. This study is unique in that it looks at side effects and dropout rates, something that has not been found in other studies.

Detrusor Instability with Incontinence (Urge)

Choe, Choo, & Lee (2007) studied forty eight women with detrusor instability using the Neocontrol chair and the same protocol as in previous studies. They reevaluated these subjects at 2, 12, and 24 weeks post treatment and found that subjects' perception of treatment benefit and overall satisfaction was 68.8% and 66.7% at week 2, 58.3% and 54.2% at week 12, and 54.2% and 52.1% at week 24. Their study demonstrated that electromagnetic stimulation therapy has a beneficial effect that can be sustained for an extended period of time in persons with detrusor instability.

Mixed Urinary Incontinence

Yamanishi et al. (2000) conducted a pilot research study and a therapeutic study to evaluate efficacy of pulsed electromagnetic stimulation on urethral closure and bladder inhibition. The pilot study consisted of 11 subjects with stress incontinence and 11 subjects with urge incontinence. The urethral pressure differences between on and off phases of electromagnetic stimulation showed that maximum urethral closure pressure significantly increased ($p=0.0409$) after stimulation for subjects with stress incontinence. Also, there was a statistically significant increase in bladder capacity at first desire to void ($p=0.0164$) and maximum desire to void ($p=0.0208$) during stimulation for subjects with urge incontinence.

In the therapeutic arm, 15 subjects, seven with stress incontinence and eight with urge incontinence were studied. Urodynamic testing was performed on each subject before and after a five week treatment regimen with the electromagnetic stimulation. These subjects recorded frequencies of voiding, leaking, degrees of urgency, pad changes as well as their perceptions of the therapy and their quality of life scores. At the end of the study, six of the subjects with stress incontinence and six of the subjects with urge incontinence indicated that they were either cured or had significant improvement in their symptoms. Quality of life scores were significantly improved after the treatment regimen ($p=0.0033$) with most respondents reporting that they were delighted or mostly satisfied with their overall quality of life.

These researchers assert that although the outcomes of electromagnetic stimulation are similar to those of electrical stimulation of the pelvic floor, electromagnetic stimulation is superior due to the fact that it does not cause pain and it is noninvasive.

Unsal, Saglam, and Cimentepe (2003) looked at one year follow-up for patients who had received ExMI for both stress and urge incontinence. The researchers evaluated clinical outcomes by voiding diary documentation of leaking episodes and pad weight as well as increase in mean valsalva leak point pressure in patients who had stress incontinence. At the one year follow-up, patients who reported no leaking episodes and less than 1 gram urine in pad weight test were documented as cured. Patients who reported greater than 50% in reduction of leaking episodes and pad weight tests were documented as improvement. They began with a total of 57 female patients. Of these patients, 35 were diagnosed with stress and 17 with urge incontinence. Forty-four

patients completed treatments and returned for follow up in one year. Of the 44 patients, 11 (38%) with stress and 6 (41%) with urge were deemed cured. In addition, there was an improvement in symptoms in 12 patients (41%) in the stress group and 7 (47%) in the urge group. Pad weight was reduced from 15.4 to 5.8 g in the stress group and from 12.4 to 4.7 g in the urge group ($p = 0.000$ and 0.001, respectively). Mean Valsalva leak point pressure was increased from 87.3 $\pm$ 15.9 to 118.0 $\pm$ 11.0 cmH2O in the stress group ($p = 0.000$).

Yokoyama et al. (2004) conducted an almost identical study as the one by Galloway et al. (1999) however; they were interested in exploring whether this therapy would be effective in treating urge incontinence. These researchers used the same Neocontrol System chair in their study. Twenty patients with urge incontinence and seventeen patients with stress urinary incontinence were recruited for this study and although the results were not as dramatic as for stress incontinence alone, episodes of leaking were reduced from 5.6 times per day before treatment to 1.9 times per day at 8 weeks ($p<0.05$) and the mean pad weight was reduced from 7.9 g at baseline to 1.9 g at 8 weeks ($p<0.05$). Twenty-four weeks after the last treatment, eight patients with urge incontinence and three with stress incontinence experienced recurrence.

Almeida, Bruschini, and Srougi (2004) studied 91 women using the Neocontrol chair. These subjects were treated for 20 minutes twice a week for eight weeks. The treatment protocol consisted of 10 minutes of intermittent low frequency stimulation for 5 seconds at 5 Hz and 5 seconds off, then 10 minutes of intermittent high frequency stimulation for 5 seconds at 50 Hz and 5 seconds off. The researchers note that subjects experienced significant improvement midway through the study. By the end of the study,

they report 34 of the 91 were totally dry with no leaking episodes. These subjects were followed by interview at 3, 6, and 12 months after the study. The recurrence rate was high at 47%, 61.7%, and 94% respectively. These researchers conclude that the 16 sessions are not adequate for long-term success since the benefits were temporary with high and early recurrence rates.

Doganay, Kilic, & Yilmaz (2009) evaluated the long term efficacy of ExMI over three years. They followed a similar protocol as Unsal, Saglam, & Cimentepe in 2003, but they added number of pads used daily and Quality of Life (QOL) score as part of their evaluation of clinical outcomes. In the stress incontinence group, there was a significant reduction in pad use between the baseline (3.2 ± 1.6) to first (2.4 ± 1.2), second (2.9 ± 1.17), and third (3.0 ± 1.1) year follow-ups ($P < 0.001$, $P > 0.05$, $P>0.05$, respectively). There was no difference in pad use between the second and third year follow-ups. In the urge incontinence group where baseline daily pad use was 3.7 ± 1.9, the numbers at first, second, and third years were 2.4 ± 1.3, 3.1 ± 1.8, and 3.3 ± 2.4, respectively. Quality of Life scores for patients with stress incontinence improved from baseline 62.5 to 88.7 at eight weeks which was significant (p=0.001). Quality of Life scores for patients with urge incontinence saw a similar improvement from baseline at 60.8 to 86.3 at eight weeks (p=0.001). Patients were evaluated at 12, 24, and 36 month intervals. The effects of ExMI and QOL scores gradually decreased and were close to baseline at the 3rd year mark. This suggests that ExMI can provide temporary relief from urinary incontinence and short-term improvement in quality of life and patient satisfaction. More understanding of how to extend the benefits of this treatment is needed.

Lo, Tseng, Lin, Liang, Lu, and Pue (2013) conducted a retrospective review of 93 patients with stress urinary incontinence and overactive bladder (OAB) who were treated with ExMI. Results revealed that 72 patients (77%) completed a 9 week protocol of 10 Hz followed by 50 Hz. Thirty-two of 34 patients (94%) experienced improvement for OAB and 33 of 38 patients (86.8%) experienced improvement of for stress urinary incontinence. Urogenital Distress scores and Quality of Life scores improved for both groups. Researchers cite cost of treatment and geographic location as reasons for the high dropout rate among patients.

Post Prostatectomy Incontinence

A study to compare the effect of pulsed electromagnetic stimulation and electrical stimulation on urinary incontinence in patients who had retropubic radical prostatectomy (Yokoyama et al., 2004) showed rapid improvement in symptoms with both methods. Subjects were randomly assigned to receive electrical stimulation, electromagnetic stimulation, or be in the control group. The electromagnetic stimulation protocol was the same as used in previous studies employing the Neocontrol system. The electrical stimulation protocol used an anal electrode that delivered stimulation at parameters consistent with electrical stimulation standards for urinary incontinence therapy (Barroso, Ramos, Martins-Costa, Sanches, & Muller, 2005; Moore, Griffiths, & Hughton, 1999; Nakagawa et al., 2010). The control group only performed pelvic floor muscle exercises. After one month, the control group showed slight improvement over electromagnetic or electrical stimulation groups, but by the second month there was a statistically significant decrease in incontinence volume in both treatment groups. The researchers consider both

methods to be viable, recommendable options for patients who seek improvement of urinary incontinence after radical prostatectomy.

Yokoyama et al. (2005) investigated the effects of pulsed electromagnetic field stimulation on urinary incontinence after retro-pubic radical prostatectomy. Ten men who had suffered from urinary incontinence for at least 12 months post radical prostatectomy were enrolled into the study. Urodynamic studies were performed at baseline and again at the completion of treatment. The researchers used the same Neocontrol System as in previous studies to induce the pulsed electromagnetic field. Patients received treatments for 20 minutes, twice a week for two months. The pulsed field was set at 10 Hz for 10 minutes, then at 50 Hz for 10 minutes. Bladder diaries, pad weight testing and quality of life surveys were obtained at one, two, three, and six months after the start of treatment. Results showed that three patients became dry (30%), three patients showed improvement (30%), and 4 patients showed no change (40%). Mean pad weight decreased from 25 g to 10.3 g, and the quality of life scores improved from 70.5 to 84.9. The frequency of leak episodes in a day was reduced from five times prior to the treatment to 1.9 times after the treatment. Three of six patients who showed improvement, however, did return to baseline values within a year of treatment, and requested to be allowed to continue the treatment.

Terzoni, Montanari, Mora, Ricci, and Destrebecq (2012) compared pelvic floor muscle exercises (PFME) and ExMI for the management of post-prostatectomy urinary incontinence. Eighty seven patients were treated with PFME, 23 patients were treated with ExMI, and 22 patients refused intervention and served as the control group. Both interventions improved scores on the International Prostate Symptom survey and ExMI

demonstrated faster reduction in symptoms than PFME. Most of these researchers were rehabilitation nurses and they proposed that ExMI could be an effective treatment administered and managed by nurses. They suggest that ExMI could be used to quickly increase pelvic floor muscle strength and that PFME could be used to help patients maintain that level.

Fecal Incontinence

Thornton, Kennedy, & Lubowski (2005) conducted a study to determine the effect of pulsed electromagnetic stimulation on anorectal function and physiology. They studied ten subjects with fecal incontinence, and compared those findings with five subjects who were continent. Subjects received pulsed electromagnetic stimulation by sitting in the Neocontrol Chair as discussed in previous studies. The protocol of 10 Hz for 10 minutes followed by 50 Hz for 10 minutes was followed for this study. The results revealed that stimulated anal pressures were significantly increased when compared to resting pressures ($p=0.005$). After six weeks of treatment, there was a statistically significant increase in resting pressures ($p=0.007$), in squeeze anal pressures ($p=0.008$), and a decrease in continence scores ($p=0.017$). Although statistically significant, there was only a small increase in the subjects' perceived improvement after six weeks of treatment.

Studies examining pulsed electromagnetic fields effects on pelvic muscles for urinary and fecal incontinence suggest that this technology can be beneficial to patients who have voiding and anorectal dysfunction. More research is needed to determine who will benefit the most from this therapy, as well as optimal settings and timing duration of treatment.

Bone and Tissue Healing

Garland, Adkins, Matsuno, and Stewart (1999) examined the effects of pulsed electromagnetic fields on osteoporotic bone at the knees of six males with spinal cord injury. Bone density of both knees was assessed at baseline, 3, 6, and 12 months. One knee was stimulated with a pulsed electromagnetic field while the other knee served as the control. Electromagnetic stimulation was conducted for a period of six months. At three months, during the middle of the treatment period, bone density increased in the knees that received the stimulation by 5.1%, but declined in the knees that served as control by 6.6% (significant at $p<.05$ and $p<.02$, respectively). At six months, bone density had returned to near baseline and at 12 months both knees had lost bone density with the stimulated knees being 2.4 % below baseline, and the control knees being 3.6% below baseline. This would suggest that pulsed electromagnetic field therapy could be helpful in slowing down the progression of osteoporosis, but raises questions about the length of time needed to obtain therapeutic effects and how long positive effects can be sustained once treatment has ended.

In a study by Massari, Fini, Cadossi, Setti, and Traina (2006) 66 patients (a total of 76 hips) with early to late osteonecrosis of the femoral head were treated with pulsed electromagnetic field stimulation for eight hours a day over a period of five months. Although the researchers considered whether or not the patients were able to avoid hip replacement surgery to be the ultimate goal of this study, they also compared diagnostic images taken of the hips at the beginning of the study and at the time of follow-up. While fifteen hips did require total hip replacement, the number of patients not requiring hip replacement was significant. All patients were experiencing pain when they entered

the study, but by the sixtieth day of treatment, thirty-five patients declared that they were pain free. Another seventeen patients admitted that pain was only of moderate intensity. The researchers concluded that pulsed electromagnetic field stimulation may help to protect the cartilage and bone by reducing inflammation and edema. They hypothesized that long-term use might actually stimulate bone growth where it is necrotic, thereby preventing fracture and bone collapse. However, this hypothesis has yet to be tested in humans.

MacKenzie and Veniga (2004) report in a case study how pulsed electromagnetic field stimulation was successfully used to reverse delayed union of an anterior cervical fusion. Their patient was a 43 year old female who presented with complaints of a clicking noise when turning her head, difficulty swallowing and a feeling of choking at times. She also complained of shooting pains from her neck to her lower back and numbness in her upper arms and hands. An MRI revealed severe disc degeneration from C5 through C7. They performed surgery by removing the diseased disks and placed allograft bone dowels in the C5-C6 and C6-C7 interspaces secured with an anterior fixation plate. This patient reportedly had an uneventful recovery and was asymptomatic for about six months. At her one year postoperative visit she complained of an ache in her neck that had been getting worse over the past 6 months. X-rays were obtained and revealed that while bone had formed around the C5-C6 level, the bone graft had failed at the C6-C7 level. Rather than return to surgery, the patient chose to wear a pulsed electromagnetic field stimulator for three hours every day for ten months. After three months, the neck pain had completely resolved, and X-rays taken after fifteen weeks of stimulation revealed that fusion of the bone graft at the C6-C7 level was beginning to

take place. At the end of treatment, diagnostic imaging showed solid bone formation at the C6-C7 level. MacKenzie and Veninga also reported that at the time of their published case study, which was thirteen months post-treatment, the patient was still asymptomatic and pain free.

Kenkre, Hobbs, Carter, Holder, and Holmes (1996) studied electromagnetic therapy as an adjunct to conventional compression dressings in venous leg ulcers. Their study was a randomized, double blind clinical trial with nineteen patients who had been diagnosed with venous leg ulcers. They looked at several outcomes including the rate and scale of wound healing, quality of life, reported pain levels, and degree of mobility. Patients were randomly assigned to either the active treatment or placebo groups. Active treatment groups received pulsed electromagnetic stimulation at either 600Hz or 800Hz. A machine that was indistinguishable from the actual stimulator was used for placebo treatment. Patients received 30 minute treatments for 30 days. Upon completion, they were observed and received the standard compression dressing changes only for the next four weeks. They were assessed on treatment days 1, 5, 20, and 30 and a final assessment was performed on day 50. The researchers found that the majority of patients (68%) reported improvement in the size of their ulcers, with 21% of the patients experiencing complete healing. Relief of pain during the trial was significant ($p<0.05$). Patients who received treatment at 800Hz experienced significant healing ($p<0.05$) when compared to either the placebo group or the active group that received treatment at 600Hz.

Perception of Pain

Lyskov et al. (2005) conducted a study on the effect of pulsed electromagnetic fields on reported pain level, heart rate, and blood pressure in 24 healthy volunteers. This was a double blind, crossover design study where the subjects served as their own controls. Twelve males and 12 females each received infusions of 5% hypotonic saline solution into the erector spinae muscle to induce muscle pain. This experiment was performed twice, at least two days apart. One time the subject was exposed to the pulsed field, and one time to a sham field. Results revealed that blood pressure elevation due to pain occurred during both active and sham exposures, and there was no statistical difference for heart rate. The study did, however, demonstrate gender differences as exposure to the pulsed field increased the subjective pain levels in females, but not in males. This has implications for future investigations into the use of pulsed electromagnetic fields for the treatment of chronic pain especially with regard to gender differences in the perception of pain.

Pipitone and Scott (2001) performed a randomized, placebo-controlled, double-blind study on the effect of pulsed electromagnetic field therapy with 75 patients with osteoarthritis of the knee. Patients completed the WOMAC Osteoarthritis Index and the EuroQoL (EQ-5D) at baseline and again after treatment to assess pain, joint stiffness, disability, and quality of life. There were significant improvements in the actively treated group on the WOMAC global score ($p=0.018$), WOMAC pain score ($p=0.065$), WOMAC disability score ($p=0.019$), and EQ-5D quality of life score ($p=0.001$). These results suggest that pulsed electromagnetic field therapy could be beneficial in improving

quality of life by reducing pain and disability for patients who suffer with osteoarthritis of the knee.

Weintraub and Cole (2004) used a one-group experimental design study to examine the effect of pulsed electromagnetic fields on refractory neuropathic foot pain in 24 patients who had been diagnosed with peripheral neuropathy. Among these patients, the one with the most symptomatic foot received nine daily 1-hour treatments with exposure to the pulsed electromagnetic field at 30Hz. All 24 patients (24 feet) completed the 9 day study and 15 of the 24 completed follow-up. Mean pain scores decreased 21% from baseline to end of treatment ($p=0.19$), but there was a 49% reduction in pain from baseline to follow-up which was significant ($p<0.01$). This study suggests that pulsed electromagnetic field therapy could be useful in providing pain relief for persons suffering with neuropathic pain.

Shupak, McKay, Nielson, Rollman, Prato, and Thomas (2006) investigated the use of pulsed electromagnetic fields on pain and anxiety in patients with fibromyalgia and rheumatoid arthritis. The researchers used a double blind, randomized, placebo-controlled design. Eighteen patients had fibromyalgia, and 13 patients had rheumatoid arthritis. They received either the pulsed electromagnetic field therapy or sham exposure. The results revealed that there was no significant reduction in anxiety ratings for either group. However, there was significant ($p<0.05$) reduction in pain for the patients who had rheumatoid arthritis, and significant ($p<0.01$) reduction in pain for patients who had fibromyalgia when they were exposed to the active therapy.

Mental Depression

Pulsed electromagnetic fields have most recently been investigated for treatment of resistant mental depression. Baeken et al. (2009) studied a small group of subjects who had been diagnosed with treatment-resistant depression. All subjects were free of antidepressant and psychotropic medication prior to and during the study. A psychiatrist rated the subjects' depression symptoms and depression severity before and after application of transcranial magnetic stimulation. Forty-three percent of the subjects experienced a reduction of at least 50% of their depression scores.

A study by Fitzgerald, Hoy, Daskalakis, and Kulkarni (2009) examined the differences between the application of high frequency transcranial magnetic stimulation and low frequency transcranial magnetic stimulation. They determined that both treatment groups showed significant improvements in their depression and there were no significant differences between the use of high or low frequencies. This is an important study because there have been very few investigations that compare the efficacy of the two methods.

Vanderhasselt, DeRaedt, Leyman, and Baeken (2009) discovered similar effects when depressive symptoms improved in more than half of their therapy-resistant subjects after receiving transcranial magnetic stimulation.

There is much conjecture as to how transcranial application of pulsed electromagnetic fields improves mental depression. It has been suggested that it works by triggering action potentials which cause the neurotransmitters dopamine and serotonin to be released. Researchers have theorized that the magnetic stimulation alters cerebral blood flow as well as improves mood by altering brain waves (Baeken et al., 2009;

Huerta & Volpe, 2009). Results of preliminary studies are promising, but more research is needed.

Summary

Pulsed electromagnetic field therapy is a painless, non-traditional, non-invasive modality that holds incredible promise for patients who have not responded to traditional treatment methods or who may not be good candidates for surgery or other medical procedures. Currently FDA approved for the treatment of stress urinary incontinence and muscle rehabilitation, studies suggest that this technology can stimulate cell growth, improve peripheral perfusion and reduce pain. Because this is a relatively new area of medicine, there is not a large body of information available. Reported results are varied and there is little data on the long term effects of pulsed electromagnetic field therapies. More research is needed to add to the knowledge base of electromagnetic stimulation as a treatment modality.

CHAPTER III

METHODOLOGY

This chapter describes the methodology that was used in this study. Purpose, objectives, design, sample, data collection, and data analysis are discussed.

Study Design

This study is a descriptive, retrospective analysis of data collected from a specialty continence center within a major Atlanta metropolitan outpatient facility. All patients who were treated with extracorporeal magnetic innervation (ExMI) from 2000 through 2012 were included. Sample size was projected to include 75 to 100 patients; however the sample size was much smaller with a total of 43 patients who received ExMI. The purpose of this study is to examine the demographic, clinical and behavioral factors that support the effectiveness of ExMI treatment for patients with urinary incontinence. The following objectives are explored:

1. Examine the differences in selected demographics (age in years, gender, weight in pounds) and relationship among health behaviors (dietary/fluid management, bowel management), medications (diuretics, central nervous system [CNS] depressants, hormones, anticholinergics, antihistamines, others as appropriate to bladder function), physical findings (cystocele, rectocele, uterine prolapse, vaginal/rectal tone/grip), medical history (length of incontinence, pelvic surgery, cardiovascular disease, hypertension, diabetes,

neurologic disorders, stroke, COPD/asthma, bladder/kidney infections, pelvic/abdominal/back pain, pregnancies, methods of delivery, and number of pads used per day prior to treatment), between patients with stress, urge, and mixed urinary incontinence.

2. Explore the relationship of selected demographics (age in years, gender, weight in pounds) and health behaviors (dietary/fluid management, bowel management), medications (diuretics, central nervous system [CNS] depressants, hormones, anticholinergics, antihistamines, others as appropriate to bladder function), physical findings (cystocele, rectocele, uterine prolapse, vaginal/rectal tone/grip), medical history (length of incontinence, pelvic surgery, cardiovascular disease, hypertension, diabetes, neurologic disorders, stroke, COPD/asthma, bladder/kidney infections, pelvic/abdominal/back pain, pregnancies, methods of delivery, and number of pads used per day prior to treatment), and post-treatment pad usage following ExMI treatment for urinary incontinence.
3. Describe the patients who returned for additional ExMI treatments.
4. Describe any benefits received unrelated to reduction of urinary incontinence.

Sample

Data was collected on all patients who received treatment with ExMI at this center from 2000 through 2012 totaling 43 patients. These patients were diagnosed with stress, urge, or mixed urinary incontinence as well as fecal incontinence, pelvic pain and urinary frequency and urgency. Data from both female and male patients who received ExMI was collected, however, the number of females was higher than males. This was

expected since, statistically, urinary incontinence is more prevalent among middle aged and older adult females than among males (Huang et al., 2006; Melville, Katon, Delaney, & Newton, 2005). Exclusion criteria for this treatment included pregnancy, diagnosis of pelvic cancers, and having a cardiac pacemaker or other implanted metal device. Due to the overall small number, manual medical record chart review was performed in order to capture all patients who had completed this treatment.

An online power analysis (Soper, 2012) using a maximum of eleven variables, a medium effect size, alpha of <0.05 and power of 0.80 determined that a minimum sample size of 122 patients will be needed. As previously stated, this is a fixed sample size predetermined by the number of patients at this site who were treated with ExMI. Not all independent variables are expected to have a significant relationship to the dependent variable, and so it is anticipated that the number of variables actually entered into the analysis model will be less. A statistical consultation and adjustment will be made as necessary to support the power of the findings.

Site

Study data was obtained from patient records of a specialty continence center within a major Atlanta metropolitan outpatient facility. This center manages about 2000 patients a year who are diagnosed with incontinence. There are differing data in the literature regarding the prevalence of urinary incontinence among the general population. According to the National Association for Continence (NAFC), women comprise approximately 75%-80% of the population who suffer with urinary incontinence (NAFC facts and statistics) while Melville, Katon, Delaney, and Newton (2005) report that 45% of the population who have some form of urinary incontinence are women.

Approximately 75% of the patients treated for urinary incontinence within this center are women and approximately 25% are men.

IRB Approval

Dr. Niall Galloway, MD, is the medical provider for these patients and primary prescriber of ExMI treatment. He has been involved with original research related to the use of ExMI for urinary incontinence and has granted permission for the use of the data (Galloway et al., 1999). Letters of support from the medical center's Institutional Review Board (IRB) and Dr. Niall Galloway granting permission to access records and perform research at the center pending IRB approval can be found in Appendices A and B respectively. The study received approval from Georgia State University's IRB. The IRB at the medical center where data was obtained deemed that IRB approval was not required since the study did not meet the definition of research with "human subjects" (Appendix C).

ExMI Treatment Protocol

Patients sit fully clothed on a chair designed with a magnetic field generator imbedded in the seat. This generator is connected to an external power control panel that controls the pulse current that the patient receives. The practitioner who administers the treatment can either manually adjust the amplitude and strength of the magnetic field, or as in most cases, insert a "smart card" into the control panel. The control panel reads the prescription imbedded in the "smart card" and automatically administers the treatment to the patient. The standard treatment protocol prescription administers 10 minutes of intermittent low-frequency stimulation (15 Hz), followed by rest (no stimulation) for 2 minutes, and ends with 10 minutes of intermittent high-frequency stimulation (40 Hz).

These treatments are administered twice a week for 8 weeks (Galloway et al., 1999; Hoscan et al., 2008).

There is little in the literature related specifically to ExMI therapy, but among these studies, there is varied information regarding side effects. Some studies have reported that patients complained of pain, tingling, abdominal cramping and muscle fatigue after receiving stimulation (Groenendijk et al., 2008; Ismail et al., 2009) while other studies report no complaints of discomfort (Galloway et al., 1999; Hoscan et al., 2006; Yamanishi et al., 2000). Only one study cited reasons for dropping out. These reasons included pain, urinary tract infection, no improvement and inability to keep appointments (Ismail et al., 2009). Given the fact that the treatment is administered twice a week for eight weeks, the time commitment and ability to travel to the clinical site could certainly have an impact on the dropout rate.

Measures

The following variables were obtained from the medical records and used to explore the relationship between demographics, medical history, health behaviors, physical findings, and clinical outcomes. The information was transferred to a data collection sheet designed for this purpose (Appendix D). This investigator collected the data while at the center and under the supervision of Dr. Galloway. No patient identifiers were on the data collection sheets.

Demographics. The following are categorized as demographics: age in years, gender, and weight in pounds. These characteristics are important because the literature points to a relationship between age, gender, and weight and the prevalence of urinary incontinence. Women are more likely to suffer from urinary incontinence than men

(Keyock & Newman, 2011). Excess weight strains the muscles of the pelvic floor (Smith, 2004). In longitudinal, population based studies, obesity has been associated with increased incidence of urinary incontinence (Subak, Richter, & Hunskaar, 2009).

Medical History. The health information relevant to a medical history for patients with urinary incontinence include the following: length of incontinence, incontinence diagnosis (stress, urge, mixed), number of pads used per day, number of pregnancies, method of delivery (vaginal, C-section, both), presence of pelvic/abdominal/back pain (yes/no), presence of pelvic organ prolapse (yes/no), history of pelvic surgery (yes/no), history of diabetes (yes/no), cardiovascular disease (yes/no) hypertension (yes/no) and stroke (yes/no), COPD/asthma (yes/no), bladder/kidney infections (yes/no) , neurologic disorders (yes/no), and specific medications. Classifications of medications that are of primary interest include diuretics, central nervous system depressants, hormones, anticholinergics, and antihistamines. Other medications that can affect bladder function will also be noted.

Urinary incontinence and pregnancy, process of childbirth and method of delivery have been strongly associated and documented in the literature (Foldspang, Mommsen, & Djurhuus, 1999; Rortveit, Hannestad, Daoltweit, & Hunskaar, 2001; Wesnes, Hunskaar, & Rortveit, 2009). Research suggests that prolonged stages of labor and delivery have more of an impact on post-natal urinary incontinence than method of delivery; however data for post-natal urinary incontinence after C-section are inconclusive. In this study the number of pregnancies and methods of delivery will be noted as vaginal, C-section, or both.

Muscles and ligaments cradle and support the pelvic floor structures of the bladder, urethra, vagina and uterus. Excessive stress on these muscles and ligaments from overweight, birth trauma, prolonged heavy lifting, and chronic coughing cause weakness that can result in pelvic organ prolapse. Patients who have had a hysterectomy are also at risk for prolapse as the uterus acts as a support structure for the pelvic floor. When the uterus is removed, an important support is also removed so there is an association between pelvic organ prolapse and urinary incontinence (Luft, 2006; Serati et al., 2011; Smith, 2004).

The literature suggests that urinary incontinence is prevalent among individuals with chronic medical illnesses such as cardiovascular disease and diabetes (Boyd et al., 2011; Lee, Cigolle, & Blaum, 2009; Lifford, Curhan, Hu, Barbieri, & Grodstein, 2005; Phelan et al., 2009; Rosso et al., 2011). Neurologic bladder control with successful urine storage and emptying is the result of coordination between the parasympathetic and sympathetic nervous systems. Patients with neuropathology, whether congenital or acquired, are at risk for urinary incontinence. Patients who have urinary tract infections can experience urinary incontinence when the irritated bladder causes urgency and frequency. Illnesses, infection and neuropathic disorders will be noted and summed.

Some medications like diuretics, central nervous system depressants, hormones, anticholinergics and antihistamines have shown the potential to impact bladder function and may result in urinary incontinence (Keister & Creason, 1989). This researcher is interested in whether or not a patient takes medication (yes/no) from any of the selected drug classifications. However, the dosing regimens are not of interest in this study. The

number of the classifications of medications (from 0 being none to the number they are using) that patients are taking will be summed for the medication variable.

Health Behaviors. Conservative therapies that help to manage urinary incontinence will be included as health behaviors; these include diet and fluid management, bowel management and Kegel exercises. Use of conservative therapies will be reported as yes (1) or no (0). The types of therapies the patients participate in will then be summed with scores ranging from 0 (none) to 3. Data regarding the use of conservative therapies will be reported, before ExMI treatment and during ExMI treatment. For patients who repeat ExMI treatment, use of conservative therapies post ExMI will also be noted.

Physical Findings. Several physical findings may be associated with urinary incontinence. These include cystocele, rectocele, and uterine prolapse, vaginal/rectal tone and grip. Cystocele and rectocele are herniations of the bladder and rectum in to the vagina. This occurs when there is weakening of the pelvic floor muscles. Uterine prolapse is the dropping of the uterus into the vagina which results when the ligaments that support the uterus are overstretched. Vaginal and rectal tone and grip are indicators of pelvic floor muscle strength. These physical findings are discovered during the medical examination and are noted in the patients' records on the Continence Center Intake Form. Cystocele, rectocele, and uterine prolapse are described as no (0) or yes (1) and if yes, its station with respect to the introitus: slight (1), to introitus (2), beyond introitus (3). Vaginal/rectal tone is described as normal (1) or abnormal (0) and grip is described as sustained (1) or not sustained (0).

Pressure and pain in the pelvis, lower abdomen and lower back are common complaints for patients with pelvic organ prolapse; (Lau, Weinstein, Wakamatsu, Macklin, & Pulliam, 2013; Reddy, Barber, Walters, Paraiso, & Jelovsek, 2011). The literature suggests that ExMI may have an ameliorating effect on pain. Pain is assessed prior to beginning ExMI treatment and will be recorded as no (0) or yes (1).

Clinical Outcomes

Urinary incontinence was measured by the dependent variable, number of pads used per day, as reported by the patient. The number of pads used in a day was noted at the beginning and end of treatment and. For patients who returned to repeat the protocol, the number of patients as well as how long (how many weeks) between treatment protocols was included in clinical outcomes. The number of pads used in a day are compared from beginning to end of treatment and are markers that are frequently used to determine if a treatment for urinary incontinence has been successful. There is very limited literature related to the effect of ExMI on pad usage or wetting episodes, but one multicenter study of ExMI for stress incontinence revealed that pad usage was reduced from 2.5 to 1.3 per day ($p=0.001$) and the number of wetting episodes was reduced from 3.3 to 1.7 ($p=0.001$) per day (Galloway et al., 1999).

Any reports of benefits unrelated to reduction in incontinence are also included in clinical outcomes. The literature indicates that the application of pulsed electromagnetic fields has therapeutic benefits including pain relief, increased blood flow, and tissue healing. For this reason, any patient-reported benefits unrelated to improvement in incontinence are included and described.

Procedure

Once institutional review board (IRB) approval was obtained from Georgia State University and the healthcare system where data was collected, a list of all patients who received ExMI treatment was provided through the offices of clinical research for the urology department and health information management. Because electronic records were not available for these patients, archived records were reviewed.

A data collection sheet (Appendix D) was created to hold all data abstracted from the medical records. Each record was assigned a study number that was used instead of patient names. A key code sheet with information that could link the study number with the patient was stored separately from the data to protect privacy. All study information is stored in a locked file cabinet owned by this researcher. Names or other facts that could identify the patients will not appear when the study is presented or when results are published.

Design and Data Analysis

A descriptive, retrospective, secondary analysis of medical records was performed. Frequencies and percentages were calculated for gender, diagnosis (stress, urge, mixed), health behaviors (dietary/fluid management, bowel management), medications (diuretics, central nervous system depressants, hormones, anticholinergics and antihistamines), physical findings (cystocele, rectocele, uterine prolapse, vaginal/rectal tone/grip), medical history (length of incontinence, pelvic surgery, cardiovascular disease, hypertension, diabetes, neurological disorders, stroke, COPD/asthma, bladder/kidney infections, pain (pelvic, abdominal, back), pregnancies, number and methods of delivery, number of patients who repeated the treatment protocol,

number of pads used per day before treatments and number of pads used per day after the treatments. Means, standard deviations and ranges were calculated for age, weight and number of pregnancies. T-tests were performed to examine the differences in improvement (reduction in pad usage) with respect to age, weight, gender, pain, pelvic surgery, number of deliveries, and daily pad usage at the beginning of treatment and at the end of treatment. Analyses of correlation were performed to examine the association between age, weight, number of pregnancies, number of deliveries and improvement (reduction in pad usage).

Summary

This chapter has described the purpose, objectives, design, sample, data collection and data analysis that were used in this study.

CHAPTER IV

RESULTS

The results of a retrospective review of all patients who were treated for urinary incontinence with ExMI, a description of the sample and a discussion of the research objectives are presented in this chapter. Research objectives were modified due to sample size limitations and available information that was documented in the archived records.

All medical records for patients who received ExMI from 2000 through 2012 were examined. Data was collected on a total of 43 patients. Of those 43 patients, thirty-five were treated for urinary incontinence. Each of the 35 patients received the same treatment protocol of 15 Hz for 10 minutes, a two-minute rest period, and 40 Hz for 10 minutes. Each patient received two treatments a week for eight weeks. Eight patients were excluded for various reasons ranging from receiving ExMI for a condition other than urinary incontinence to being lost to follow-up. Those patients who were excluded will be discussed separately.

Sample Characteristics

The mean age of the patients in this study (n=35) was 63.4 years (*SD*=12.38). There were 26 (74%) females and nine (26%) males. Of the 26 females, 11 had stress incontinence, six had urge incontinence, and nine had mixed incontinence. Of the nine males, five had stress, one had urge and three had mixed incontinence. Eight males were

treated post- prostatectomy and they had either stress or mixed incontinence. The one male with urge incontinence had not undergone prostatectomy. See Table 1.

Weight was calculated separately for males and females. One female was an extreme outlier weighing 416 pounds; her weight was removed from this calculation to give a more accurate description of this sample. The mean weight for the nine males was 177.6 (*SD*=26.33) pounds and the mean weight for the remaining 25 females was 140.9 (*SD*=24.86) pounds. See Table 2.

Table 1

Type of Urinary Incontinence by Gender N=35

Gender	Stress	Urge	Mixed	N
Female	11	6	9	26
Male	5	1	3	9

Table 2

Weight by Gender *N=34

Gender	N	Range	M	SD
Female	25	112-222	140.9	24.87
Male	9	125-215	177.6	26.33

*One female was an extreme outlier at 416 pounds and was removed from this calculation

Research Objective 1: Examine the differences in selected demographics (age in years, gender, weight in pounds) and relationship among health behaviors (dietary/fluid management, bowel management), medications (diuretics, central nervous system [CNS] depressants, hormones, anticholinergics, antihistamines, others as appropriate to bladder function), physical findings (cystocele, rectocele, uterine prolapsed, vaginal/rectal tone/grip), medical history (length of incontinence, pelvic surgery, cardiovascular disease, hypertension, diabetes, neurologic disorders, stroke, COPD/asthma, bladder/kidney infections, pelvic/abdominal/back pain, pregnancies, methods of delivery, and number of pads used per day prior to treatment), between patients with stress, urge, and mixed urinary incontinence.

All 35 patients were given instruction for a dietary/fluid management and bowel management program prior to beginning ExMI. Only one patient admitted to not following the program while receiving treatment. No statistical calculation was made for these variables since all patients were placed on this routine.

Patients who were treated with ExMI completed an intake record at their initial visit to the medical center. In this record patients disclosed medical history, previous surgeries and listed any medications that they were taking. Forty percent of all patients were on hormone therapy and approximately 49% of patients were taking anticholinergics and antihistamines. Medications that could impact bladder function were recorded and are summarized in Table 3.

Table 3

Patient Medications

N=35

Medications	Frequency	Percentage
Diuretics	5	14.29
Hormones	14	40.00
Anticholinergics	7	20.00
Antihistamines	10	28.57
CNS Depressants	8	22.86

Part of the medical history included acute or chronic illnesses that could impact continence, pelvic surgeries, and pain were of interest. Fourteen women had hypertension, eight had cardiovascular disease and one woman was a diabetic. Of the men, two had hypertension, two had cardiovascular disease and one was a diabetic. Neurologic disorders included one patient with Parkinson's, one patient with cerebral palsy and hemiplegia, and three patients who had experienced neurological deficits that required spinal fusion surgeries. Patients who had pelvic surgery included eight men who had prostatectomies, eleven women who had hysterectomies, one woman who had bladder suspension and one woman who documented "many pelvic surgeries". Of the eight patients who experienced pain, five complained of pelvic pain and three complained of back pain. Table 4 summarizes medical history with regard to acute and chronic illness, pelvic surgery and pain.

Table 4

Medical History: Acute and Chronic Illness, Pelvic Surgeries & Pain

N=35

Condition	Frequency	Percentage
CVD	10	28.57
HTN	16	45.71
Diabetes	2	5.71
Neurologic Disorder	5	14.29
Bladder/Kidney Infection	4	11.43
Pain	8	22.86
Pelvic Surgery	21	60.00

Medical history also included pregnancies and methods of delivery. Most women had 2 or 3 pregnancies (57%) and delivered vaginally (85%). Two women had both vaginal and C-section deliveries (10%). Pregnancies and methods of delivery are presented in Table 5.

Table 5

Number of Pregnancies and Methods of Delivery

N=26

Number of Pregnancies	Frequency	Percent
0	5	19.23
1	2	7.69
2	10	38.46
3	5	19.23
4	1	3.85
5	2	7.69
6	1	3.85
Methods of Delivery		
Vaginal	17	85.00
C-Section	1	5.00
Both	2	10.00

Most patients had experienced urinary incontinence between 1 to 5 years (69%). When separated by gender, five of nine men (56%) were incontinent for two years or less, whereas only eight of 26 women (31%) were incontinent for two years or less. Eighteen women (69%) were incontinent for three or more years. Length of time of incontinence is presented in Table 6.

Table 6

Length of Time of Incontinence

N=35

Incontinence	Frequency	Percent
< 1 year	10	28.57
1-2 years	16	45.71
3-5 years	2	5.71
6-10 years	5	14.29
> 10 years	4	11.43

Physical examination findings included 12 patients with cystocele (44.44%), and 11 with rectocele (42.31%). Uterine prolapse was not documented for any of the patients. Vaginal tone was abnormal in 16 patients (61.54%) with grip not sustained in 23 patients (88.46%). Rectal tone was abnormal in 10 female and 7 male patients (48.57%) with rectal grip not sustained in 19 female and 8 male patients (77.14%).

Research Objective 2: Explore the relationship of selected demographics (age in years, gender, weight in pounds), health behaviors (dietary/fluid management, bowel management), medications (diuretics, central nervous system [CNS] depressants, hormones, anticholinergics, antihistamines, others as appropriate to bladder function), physical findings (cystocele, rectocele, uterine prolapse, vaginal/rectal tone/grip), medical history (length of incontinence, pelvic surgery, cardiovascular disease, hypertension, diabetes, neurologic disorders, stroke, COPD/asthma, bladder/kidney infections,

pelvic/abdominal/back pain, pregnancies, methods of delivery, and number of pads used per day prior to treatment), and post-treatment pad usage following ExMI treatment for urinary incontinence.

Patients documented the number of pads they used daily at the beginning of treatment and again at the end of treatment. Before treatment, 37% of patients used one to two pads daily, but 63% of patients used three to five pads daily. After treatment, 31% of patients were no longer using pads, 54% had reduced daily pad usage to one or two and only 14% were using three or four pads daily. Daily pad usage at the start of treatment and at the end of treatment is summarized in Table 7.

Table 7

Pad Usage

Pad Usage Before Treatment	Frequency	Percentage	Cumulative Percentage
1	4	11.43	11.43
2	9	25.71	37.14
3	13	37.14	74.29
4	7	20.00	94.29
5	2	5.71	100.00

(Table 7 Continues)

(Table 7 Continued)

Pad Usage After Treatment	Frequency	Percentage	Cumulative Percentage
0	11	31.43	31.43
1	14	40.00	71.43
2	5	14.29	85.71
3	2	5.71	91.43
4	3	8.57	100.00

Patient outcome was measured by comparing the pad usage before treatment and at the end of treatment (16 weeks). A paired t-test was performed to examine the difference between daily pad usage in the beginning and at the end of treatment. Results in this study were significant ($t(34)=10.23$, $p<.0001$) with the average number of pads used daily being reduced to 1.63 ± 0.94. All but six patients saw improvement in urinary incontinence with the reduction of daily pad use (83%). No patients experienced an increase in urinary incontinence or an increase in pad usage. The improvement in the number of pads per patient is shown in Table 8.

Table 8

Improvement by Number of Pads

Number of Pads	Patients	Percent
0	10	28.57
1	16	45.71
2	2	5.71
3	5	14.29

To examine the difference in age and weight between those who had improvement (reduction in pad usage) and those who did not, an independent t-test was performed (Table 9). There was no evidence that the average age for those who improved was any different than for those who did not improve ($t(33)=0.31$, $p=0.7606$); also no evidence that the average weight for those patients who improved was any different than for those who did not improve ($t(33)=1.62$, $p=0.1154$).

Table 9

Improvement with Regard to Age and Weight

Variable	Improvement	N	Mean	SD
Age	No	6	64.83	8.93
	Yes	29	63.10	13.09
Weight	No	6	189.7	115.7
	Yes	29	151.7	29.02

With regard to gender (Table 10) using the independent t-test, no statistical difference in improvement (reduction in the number of pads used daily) was noted between males or females ($t(33)= -0.67$, $p=0.5045$) .

Table 10

Average Improvement (reduction in number of pads) for Males and Females

Gender	N	Mean	SD
Male	9	1.44	1.01
Female	26	1.69	0.93

There was no significant difference in improvement for patients who experienced pain ($M=1.25$, $SD=1.17$) and those who did not experience pain ($M=1.74$, $SD=0.86$; $t(33)=1.31$, $p=0.2000$). Patients who had undergone pelvic surgery ($M=1.76$, $SD=0.10$) and those patients who had not undergone pelvic surgery ($M=1.43$, $SD=0.85$; $t(33)=-1.03$, $p=0.312$) did not differ in improvement.

When looking at frequencies for improvement by diagnosis, 16 patients (100%) with stress incontinence, 5 patients (71%) with urge incontinence, and 8 patients (67%) with mixed incontinence reported improvement (reduction in pad usage). Because the sample was small, a Fisher's Exact Test was performed. While patients with stress incontinence experienced overall greater reduction in pad usage than patients with urge or mixed incontinence, the results were not statistically significant ($p=0.2328$).

Frequencies for improvement by length of time of incontinence revealed that 29 patients (83%) experienced improvement by reduction in pad usage by 1 to 3 pads a day.

Nineteen of these patients (54%) had been incontinent for three or more years. Although clinically interesting, the overall improvement by length of time of incontinence was not statistically significant (p=0.8743).

Frequencies for improvement by patients who had previous pelvic surgery indicated that 29 patients (83%) experienced improvement by 1 to 3 pads a day. However, six patients who also had previous pelvic surgery had no reduction in pad usage. Overall these results were not significant (p=1.000) indicating that having pelvic surgery did not result in a significant reduction in pad usage.

Pearson product moment correlations were performed to assess the relationships between improvement and the variables of age, weight, number of pregnancies, and number of deliveries. One patient's weight was in excess of 400 pounds. This outlier's data was removed from the analysis. No correlations were found between improvement and age (r=0.038, n=35, p=0.827), improvement and weight (r=-0.0188, n=34, p=0.288), improvement and number of pregnancies (r=0.203, n=26, p=0.320), or improvement and number of deliveries (r=0.01, n=23, p=0.9666).

Research Objective 3: Describe the patients who returned for additional ExMI treatments.

Four patients repeated the treatment protocol. These returning patients were all females with a mean age of 64 (*SD*=12.19) and mean weight of 133 pounds (*SD*=13.14). Two of the women had mixed incontinence, one had stress and one had urge incontinence. All four of the women had been pregnant (a total of 15 pregnancies) and three had delivered vaginally; only one had delivered by Cesarean. All were instructed to follow the same fluid/dietary management and bowel management program that they had

used during the first treatment protocol. It is not known if these patients had continued the fluid and bowel program after they completed the first treatment protocol to the time of their return or if they had stopped using those conservative techniques. The length of time between protocols varied significantly. One patient returned after nine months, one returned after two years, one after three years and one after six years. Two of the patients were using two pads daily when they began the second protocol and after the eight weeks treatment had reduced to zero pads. The other two patients began with three pads a day and reduced to one pad a day. All returnees had good results and none of the returnees came back for a third treatment protocol.

Eight patients were excluded for various reasons. Of the eight patients who were omitted, five were males and three were females. Of the eight patients who were excluded from the study, one was a female who had severe paravaginal defects and who, after four weeks of treatment, discontinued care to have surgery. One was a female who had a rectovaginal fistula as a result of birth trauma. She received eight weeks of treatment, but did not have improvement in fecal incontinence and had surgical repair of the fistula. The other two patients attended for two weeks receiving a total of four treatments, but failed to keep any additional appointments and were lost to follow-up.

Research Objective 4: Describe any benefits received unrelated to reduction of urinary incontinence

Four patients benefited from ExMI unrelated to urinary incontinence. All four of the patients were males with a mean age of 58.5 (*SD*=8.39) and mean weight of 180.75 (*SD*=26.03). One patient had undergone colon cancer surgery and radiation which resulted in rectal and pelvic floor spasms with occasional fecal leakage. This patient

received a treatment prescription of 50 Hz for 10 minutes followed by a two minute rest period and an additional 50 Hz for 10 minutes twice a week for eight weeks. With a high frequency setting at 50 Hz the muscles of the pelvic floor are unable to contract and relax, and instead there is a tetanic contraction. This setting is most commonly used in electrical stimulation devices for alleviation of pain. At the completion of 16 weeks, this patient reported that the pain had become less constant and more manageable.

The second patient who had pain and fecal incontinence had undergone cystoprostatectomy and creation of an orthotopic neobladder. He presented with fecal incontinence, pelvic pain, erectile dysfunction and urinary incontinence from the orthotopic neobladder for which he wore condom catheters. This patient also received a prescription of 50 Hz for 10 minutes followed by a two minute rest period and an additional 50 Hz for 10 minutes twice a week for eight weeks. By the end of his treatments this patient reported "significant improvement" in his pain as well as in the fecal incontinence. There was no appreciable improvement in the urinary leakage, however, and the patient continued to wear condom catheters.

The third patient presented with scrotal and rectal pain, and irritative symptoms of urinary frequency and nocturia, but no urinary incontinence. This patient's medical history was significant for cervical spine defects with radiculopathy and cervical spondylosis, left hip neuropathy and sleep apnea. He had been managing his pain with gabapentin and amitriptyline. His prescription was the standard 15 Hz for 10 minutes, a two minute rest period, and 40 Hz for 10 minutes. This patient completed the eight week regimen of treatments and reported that he had received relief from pain and urinary frequency within the first few visits.

Diagnosed with interstitial cystitis (IC), the final patient received treatment for pain, urgency, frequency and nocturia. There were no surgeries documented for this patient and his only history beside IC was atrial fibrillation and hypertension. His medications included Atenolol and Elmiron which he had taken for IC for two years. After the standard prescription for eight weeks this patient reported pain, urgency, frequency and nocturia had improved.

Summary

The characteristics of the study sample and the results of data analysis related to the research objectives were presented in this chapter. While there was a total of 43 patients who received this treatment, 35 patients were treated solely for urinary incontinence. Most of the patients were women (n=26, 74%) and most patients had stress urinary incontinence (n=16, 46%) or mixed urinary incontinence (n=12, 34%). Patient outcome was measured by comparing the pad usage before treatment and at the end of treatment (16 weeks). The average number of pads used daily was significantly reduced from 2.82 $\pm$ 1.15 to 1.6 3 $\pm$ 0.94 ($p<.0001$). Testing to evaluate comparisons and correlations for other variables within the research objectives did not demonstrate statistical significance.

Excluded from the central study, two patients with pelvic pain and fecal incontinence and two patients with pelvic pain alone received treatment for their respective conditions with ExMI. All four patients reported improvement in their symptoms. Although rating scales are commonly used in reporting pain levels, only subjective reports of symptom relief were available for these patients. When considering

quality of life, even a small improvement in pain or reduction in episodes of fecal incontinence could be considered clinically significant by that patient.

CHAPTER V

DISCUSSION

In this study, clinical outcomes for patients who received Extracorporeal Magnetic Innervation therapy for urinary incontinence were examined. This chapter presents a discussion of study findings as well as limitations and implications for nursing practice.

The goal of ExMI treatment is to strengthen the pelvic floor muscles to the extent that when the patient laughs, coughs or sneezes, they can engage those muscles and prevent urine leakage. The clinical outcomes of a retrospective study of patients receiving ExMI treatment are presented below.

Sample

A total of 43 patients received ExMI from 2000 through 2012. Of those 43 patients, 35 were treated for urinary incontinence and were included in this study. The eight remaining patients were treated for conditions other than urinary incontinence or were lost to follow-up; those cases are discussed separately.

Of the 35 patients, 26 were females and nine were males. That women were disproportionately represented in the sample is supported by the literature that maintains more women than men experience urinary incontinence (Katz, 2009; Moore & Gray, 2004; Riss & Kargl, 2011). This is an expected finding since previous studies that

explored ExMI for urinary incontinence also recruited more women than men participants unless the study was specific to male incontinence post-prostatectomy.

Most of the patients would be considered to fall within the older adult category. Although the age range of the sample was 21 to 91 years, the mean age was 63.4 years (median=64 years). This is an expected finding and is supported by the literature (Bakar, Ozdemir, Ozengin, & Duran, 2010; Moore & Gray, 2004). In aging adults, normal physiological changes such as loss of tissue elasticity or general weakening of pelvic tone can result in urinary incontinence. Prostate enlargement is a common cause of voiding problems in older men and atrophic changes in the vagina and urethra as a result of decreased estrogen levels is a common problem in older women.

Prior to, throughout, and following ExMI treatment, all patients were instructed to follow a fluid/dietary management plan instructing them to avoid bladder irritants such as caffeine, highly acidic foods and juices, carbonated drinks and artificial sweeteners. Patients were also instructed to drink adequate fluids (six to eight 8-ounces) daily. While some patients might overindulge in liquids, most patients who have experienced incontinent episodes will reduce their daily fluid intake to prevent incontinent episodes. Concentrated urine alone can cause irritating symptoms which can increase urgency, frequency and leakage. By avoiding bladder irritants the patient may be able to remove the stimulant that contributes to urinary frequency, urgency and leakage. In addition, all patients were instructed to begin a bowel program using a fiber supplement and, if necessary, a stool softener to effectively empty their bowel and keep it empty. The bowel and bladder communicate through neural pathways that allow for normal function. If the

bowel is sluggish and the patient becomes constipated, the bladder also receives the message, resulting in urinary dysfunction. Patients who present with urinary incontinence are often troubled with chronic constipation. While this is not an indication of major neurologic disease, it demonstrates the neurologic link between bowel and bladder function. Although compliance with this fluid/dietary/bowel management plan is important to the success of ExMI treatment, statistical testing was not performed on this variable since all patients were placed on these routines and reported adherence to the regimen.

Many of the patients in this study were on medications for various medical conditions which could have an effect on bladder function. Diuretics are known to increase urgency, frequency and urinary output. Commonly prescribed for patients who have cardiovascular problems or hypertension, five patients were taking diuretics. The CNS depressants, anticholinergics, and antihistamines can all cause urinary retention by either relaxing the bladder or increasing bladder outlet resistance. Eight patients were taking CNS depressants, seven patients were taking anticholinergics, and 10 patients were taking antihistamines. It was not documented as to whether the patients were taking these medications to help them manage their incontinence or if they were on the medications for some other reason. Fourteen patients were taking hormones. Used to improve the condition of vaginal and urethral tissues, hormonal replacement, either oral or topical can be very helpful in the treatment of urinary incontinence. Most of the patients in this study were older women, so it was a reasonable finding that 40% of the patients were on hormone replacement. There were no changes in medications documented from pre to post treatment.

In reviewing past medical history among the patients in this study, it was not surprising to find that cardiovascular disease and hypertension were very prevalent since these conditions are prevalent among the general aging population. The risk of cardiovascular disease increases for women past menopause due to the loss of estrogen. Indirectly, the medications for these conditions, such as diuretics, may be implicated in incontinence. Previous pelvic surgery which included hysterectomy and prostatectomy were also prevalent among these patients. For females, the removal of the uterus alters pelvic floor support and can predispose the patient to leakage of urine. In men, the prostate gland offers some mechanical protection from incontinence. Prostatectomy removes that barrier.

Five of the eight patients in this study who complained of pain experienced pelvic pain. Pelvic pain is a common complaint, but the origin of the pain may not be obvious making assessment and treatment difficult. Pelvic floor laxity with subsequent prolapse of the bladder or rectum, damage to the pudendal nerve related to birth trauma (Hompes, Jones, Cunningham, & Lindsey, 2010) and pelvic floor spasm related to prolonged sitting, pelvic surgery or traumatic vaginal delivery (Swisher, Rich, & Weiss, 2012) have all been implicated.

Physical examination findings revealed that most women in the study had some degree of pelvic floor dysfunction which includes cystocele and rectocele. Abnormal vaginal or rectal tone and non-sustained grip were common findings in the sample as well. Although these conditions are implicated in urinary incontinence, the sample was too small to show a relationship between these variables and the outcome. Detailed physical examination findings were not documented for the final (post treatment) visit.

Approximately 69% of all patients in this study had experienced urinary incontinence between one and five years and nearly 29% had been living with incontinence ranging from six to over ten years. Based on the information that was available, this researcher could not determine if these patients had tried and failed in their efforts to resolve their urinary incontinence prior to coming to this center. It is difficult to predict when someone will seek care for incontinence. Lack of knowledge about the disorder and what can be done for it rank high among reasons that patients cite for delaying medical care. Patients may feel that incontinence is just a normal part of aging that must be tolerated or they may fear treatment or medication that might be prescribed for them and the side effects they may cause. Because incontinence is not a life threatening disorder, patients tend to ignore the symptoms until they are no longer tolerable and negatively impact other aspects of their lives. Primary care providers or specialists who care for these patients and help them manage other medical problems usually do not ask their patients if they experience urinary incontinence. Initiating the conversation about incontinence with their patients might be helpful in removing the stigma associated with it and encourage more patients to seek help earlier.

Pregnancy and childbirth subject the muscles and ligaments of the pelvic floor to stretch and overload. The gravid uterus takes up space and adds pressure to the surrounding structures. Pregnancy has been likened to "being in a constant state of increased weight bearing" (Smith, 2004, p. 132). When the delivery takes place, stretching and tearing of the pelvic floor tissues occur. Episiotomies are performed to limit tearing, but cutting through the perineum and posterior vaginal wall to assist in delivery still traumatizes the pelvic floor. According to the CDC, Cesarean births

reached an all-time high in the United States in 2009, but have leveled off since that time (Osterman & Martin, 2013). Cesarean deliveries are performed for various, complex reasons that may be medically necessary or may be controversial and performed for convenience or to limit liability. The patients who were included in this study were pregnant and delivered prior to the time period when Caesarian sections were on the rise. Most of the women in this study who were pregnant had either two or three pregnancies and the majority (85%) of all pregnancies ended in vaginal delivery. While there is a train of thought that Cesarean delivery can help to protect the structure and stability of the pelvic floor, maintaining continence in later years, this has not been definitively validated in the literature. Only one patient in this study had a single Cesarean delivery and two patients had both vaginal and Cesarean deliveries. It is this researcher's opinion that this finding reflects obstetrical practices at the time of their deliveries and does not suggest that women who have Cesarean births experience less incontinence than women who have vaginal births.

In looking at the diagnoses of stress, urge or mixed incontinence, most of the patients experienced either stress or mixed incontinence. Stress incontinence is urinary leakage resulting from an increase in intra-abdominal pressure as would occur when coughing, laughing or with increased activity like lifting or running. Urge incontinence is the result of an overactive bladder that prompts a strong, sudden need to urinate. Urge incontinence is generally the result of neurological dysfunction or irritative symptoms. Mixed incontinence is a combination of both stress and urge. In the general population, the prevalence of both stress and mixed incontinence is greater than the prevalence of

urge incontinence alone (Nitti, 2001) and the findings in this sample are consistent with Nitti's research.

While there are several ways to measure treatment efficacy, comparing daily pad counts before a treatment regimen and after a treatment regimen is frequently used as an outcome marker to define the effectiveness of that treatment and is the method used in this study. The results in this study were significant ($p<.0001$) with the average number of pads used daily being reduced to 1.63 ± 0.94. Improvement by reduction in daily pad usage is consistent with the literature on ExMI (Almeida, Bruschini, & Srougi, 2001; Bakar, Ozdemir, Ozengin, & Duran, 2010; Doganay, Kilic, & Yilmaz, 2009; Galloway et al., 1999; Hoscan et al., 2008; Lo et al., 2013; Terzoni, Montanari, Mora, Ricci, & Destrebecq, 2012; Unsal, Saglam, & Cimentepe, 2003; Yamanishi et al., 2000; Yokoyama et al., 2004). When looking at improvement and gender, there was no difference in improvement as measured in reduction of daily pads between males or females. Theoretically, pelvic floor muscle exercises (PFME) strengthen the muscles to improve urethral sphincter closure whenever there is an increase in intra-abdominal pressure. These exercises have long been prescribed for male patients post-prostatectomy to help them regain continence, however, most of the literature on the efficacy of PFME focuses on women and not men, and this knowledge may not apply to the complex issues of incontinence in men. In this study it does appear that the male patients did respond to ExMI as well as the female patients, suggesting that ExMI is equally effective in the management of urinary incontinence in men and women.

Age, weight, medical history, pelvic surgeries, pain, medications, length of incontinence, physical exam findings, pregnancies, deliveries and type of incontinence

were not significantly associated with the reduction of daily pad usage (outcome) in this study. Pearson product moment correlation testing did not demonstrate any relationships between age, weight, number of pregnancies or number of deliveries. Other studies exploring the efficacy of ExMI have had similar results with regard to influence of study variables on outcomes. Almeida, Bruschini, & Srougi (2004) explored duration of incontinence, history of hysterectomy, duration of menopause, BMI, patient age and type of incontinence and found that these variables had no influence on outcome in spite of improvement in the reduction of pad usage and improved quality of life for participants in that study. ExMI studies by Ismail et al. (2009) and Voorham-Van der Zalm, Pelger, Stiggelbout, Elzevier, and Nijeholt (2006) both cite no significance related to the study variables and outcomes in their respective studies. A small sample size is the consistent feature of these ExMI studies and this must be considered as a possible reason why the variables do not appear to influence outcomes.

In this study there were four patients who repeated the treatment protocol. All four participants received good results with the first protocol, but urinary symptoms returned with increased incontinent episodes and pad usage prompting them to return for an additional series of treatments. With any exercise program, if the exercise stops, the muscle tone is eventually lost, and this appears to hold true with ExMI. Researchers have noted that improvement in urinary incontinence peaks during the treatment period, lasts up to a year, but then degrades. Doganay, Kilic, & Yilmaz (2009) noted how the majority of patients experienced good results for up to a year after treatment, but then returned to baseline within three years of completion.

Patients tend to delay seeking medical care for urinary incontinence until it becomes a problem that negatively affects other aspects of their lives. It is unclear from the data if the patients who returned came back for more treatment soon after symptoms returned or if they waited until the symptoms could no longer be ignored. Knowing this information could help providers educate their patients about the possibility of needing additional treatments. The literature has shown that symptoms return a year or more after treatment ends. What was unique about those patients who did not return? Did they have sustained symptom relief, or did they choose not to return because the location for treatment was inconvenient, the treatment was too costly, or some other issue prevented them from returning? Would "booster" treatments at specific intervals help patients maintain continence?

Of the eight patients who were excluded from the study, one was a female who had severe paravaginal defects and who after four weeks of treatment, discontinued care to have surgery. One was a female who had a rectovaginal fistula as a result of birth trauma. She received eight weeks of treatment, but did not have improvement in fecal incontinence and had surgical repair of the fistula. The other two patients attended for two weeks receiving a total of four treatments, but failed to keep any additional appointments and were lost to follow-up. There were four patients who received benefit from ExMI unrelated to urinary incontinence. Two had pelvic pain and two had fecal incontinence and pelvic pain. All four patients reported improvement in their symptoms. Previous ExMI studies in which individuals were treated for pain (Lyskov et al., 2005; Pipitone & Scott, 2001; Weintraub & Cole, 2004; Shupak et al., 2006) and fecal incontinence (Thornton, Kennedy, & Lubowski, 2005) had shown promise for patients

with these conditions. While these four patients were not included in the main study, their response to treatment in light of the literature suggests that ExMI could be considered as a viable treatment option for patients with pelvic pain and fecal incontinence.

Study Limitations

The most compelling limitation of this study was the small sample size. Although the outcome of improvement by reduction of pad usage was significant, the study did not yield any significant relationships between other selected variables and the outcome. This could be a result of the very small size of the sample. Because this was a retrospective chart review, the small size was unfortunate, but unavoidable.

When performing a retrospective record review the researcher must accept the data that is available and design a study with questions and variables that would be appropriate to the existing data. Because the data was retrieved from existing patient records, the details and notes found were not bound by strict guidelines that would be established when designing a scientific inquiry and may not have included variables that would be of interest to the researcher. The latter was an issue in this retrospective study.

While the findings may not have been statistically significant with regard to a number of variables and outcome, it is possible that the patients who received even modest improvement would consider their outcome to be clinically significant. There was no way to explore the patients' perceptions of treatment effectiveness.

Implications for Nursing Practice

Providing conservative therapies for continence care have traditionally fallen within the realm of nursing. Nurses can provide the education patients need about their

condition. They can teach patients the conservative measures such as pelvic floor muscle exercises, fluid management and bowel management that can help them attain some relief and control over their symptoms, and they can work with the patient's provider to manage care and provide treatments as prescribed.

With regard to ExMI, this therapy holds great promise for patients with different diagnoses and pelvic floor dysfunctions. With the aging of our population, it is reasonable to expect to see more patients needing continence care who might not desire or meet the criteria for surgical intervention. Patients today are savvy healthcare consumers and are open to alternative therapies that can offer improvement without serious side effects. Patient safety is of prime importance and throughout the literature, the absence of adverse effects related to the use of ExMI is repeatedly discussed (Culligan, Blackwell, Murphy, Ziegler, & Heit, 2005; Hoscan et al., 2008; Yamanishi et al., 2000).

At the present time this therapy is readily available and used extensively in over 80 countries across the globe. Nurses in Italy who care for incontinent patients have the autonomy to decide if ExMI is right for their patients and to independently provide this treatment (Terzoni, Montanari, Mora, Ricci, & Destrebecq, 2012). ExMI is prescribed less often in the United States than it was when it was first introduced, but this has less to do with treatment efficacy and more to do with availability of the technology, the problem patients had with getting to and from clinics that had the chair, cost of treatments and reimbursement issues. The good news is that engineers are looking at a new design that could address some of those problems and could renew interest in using ExMI in the United States (personal communication with Dr. N. Galloway).

Summary

This study has explored the relationships between specific variables and clinical outcomes involving the use of ExMI in the treatment of urinary incontinence. Results revealed that patients who received ExMI for incontinence experienced improvement as evidenced by reduction in daily pad usage that was statistically significant. Age, weight, medical history, pelvic surgeries, pain, medications, length of incontinence, physical exam findings, pregnancies, deliveries and type of incontinence were not significant with regard to the outcome. Charts on all patients who received ExMI from 2000 to 2012 were reviewed. Eight patients who did not meet the criteria for inclusion in this study, however four of these patients did experience benefits from ExMI treatment for other clinical conditions than a reduction in urinary incontinence; these cases were also discussed.

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Appendices

Appendix A

Letter from Emory IRB

EMORY UNIVERSITY | Institutional Review Board

September 20, 2011

Institutional Review Board
Georgia State University

RE: Human Subjects Research by Ms. Kathy Davis at Emory

Dear Colleague,

This letter is to confirm that the Emory IRB is fully aware and supportive of the proposed research Ms. Davis plans to conduct at Emory University as part of her doctoral thesis. Ms. Davis will be performing a retrospective review of Emory Healthcare medical records with Emory faculty support provided by Dr. Niall Galloway, Associate Professor of Urology and Director of the Emory Continence Center. Following approval by our respective review boards, the Emory IRB has no objection to Ms. Davis conducting this research at Emory.

Sincerely,

Sean Kiskel
Research Protocol Analyst
Institutional Review Board
Emory University
This letter has been digitally signed

Appendix B

Letter from Dr. Niall Galloway

Feb. 26. 2013 12:45PM No. 4537 P. 2

EMORY HEALTHCARE

THE EMORY CLINIC, INC.

Emory Clinic
Department of Urology
1365 Clifton Road, NE
B1400
Atlanta, Georgia 30322
Phone 404-778-4898
http://urology.emoryhealthcare.org

Chad W. M. Ritenour, MD
Interim Chairman

Daniel J. Canter, MD
K. Jeff Carney, MD
Hark C. Chang, MD
Niall T. M. Galloway, MD, FRCS
Wayland Hsiao, MD
Viraj A. Master, MD, PhD
Peter T. Nieh, MD
Kenneth Ogan, MD
John G. Pattaras, MD
Hadley Wyre, MD

February 19, 2013

To whom it may concern:

Kathy Davis plans to conduct a retrospective record review of patients who received ExMI treatment for urinary incontinence as part of her doctoral dissertation. Following approval by Georgia State University and Emory IRB, I have no objection to Ms. Davis conducting this research.

Niall T. M. Galloway, MD, FRCS

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Appendix C

Emory IRB Determination

EMORY UNIVERSITY | Institutional Review Board

August 6, 2013

RE: **Determination: No IRB Review Required**
eIRB#: 56479
Title: Clinical Outcomes Involving the Use of Pulsed Electromagnetic Fields in the Treatment of Urinary Incontinence
PI: Kathy Davis

Dear Kathy Davis :

Thank you for requesting a determination from our office about the above-referenced project. Based on our review of the materials you provided, we have determined that it does not require IRB review because it does not meet the definition(s) of research with "human subjects" as set forth in Emory policies and procedures and federal rules, if applicable. Specifically, in this project, you will not access to any identifiers when reviewing clinical outcomes involving the use of pulsed electromagnetic fields in the treatment of urinary incontinence.

Please note that this determination does not mean that you cannot publish the results. If you have questions about this issue, please contact me.

This determination could be affected by substantive changes in the study design, subject populations, or identifiability of data. If the project changes in any substantive way, please contact our office for clarification.

Thank you for consulting the IRB.

Sincerely,

Olga Dashevskaya, JD
Research Protocol Analyst

Emory University
1599 Clifton Road, 5th Floor - Atlanta, Georgia 30322
Tel: 404.712.0720 - Fax: 404.727.1358 - Email: irb@emory.edu - Web: http://www.irb.emory.edu
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Appendix D

Data Collection Sheet

Subject ID number _____ _____ _____

Demographics

Age (in years) _____

Gender _____
1. Male
2. Female

Weight (in pounds) _____

Race/Ethnicity
1. African American
2. Asian/Pacific
3. Caucasian
4. Hispanic
5. Native American

Medical History

Length of time of incontinence _____
1. < 1 year How many months? _____
2. 1-2 years
3. 3-5 years
4. 6-10 years
5. > 10 years

Diagnosis _____
1. Stress Incontinence
2. Urge Incontinence
3. Mixed Incontinence

Number of Pregnancies _____

Methods of Delivery _____
1. Vaginal
2. C-Section
3. Both

Number of Deliveries

1. Vaginal _____
2. C-Section _____
3. Both _____

Pain
No (0)
Yes (1) **_____**
Location **_____**

1. Pelvic
2. Abdominal Scale 0-10 _____
3. Back

Disorders

_____Cardiovascular
_____Hypertension
_____Diabetes
_____Neurologic
_____Stroke
_____COPD/asthma
_____Bladder/kidney infections

Pelvic Surgery **_____**

1. Yes
   Type of surgery: _____
2. No

Health Behaviors

Conservative therapies	**Pre**	**During**	**Post**
Yes (1) Total Number _____			
No (0)			
_____Fluid/dietary management	____	____	____
_____Bowel management	____	____	____
_____Kegel exercises	____	____	____

Medications
Yes (1)
No (0)
_____Diuretics
_____CNS depressants
_____Hormones
_____Anticholinergics

_____Antihistamines
_____Other _____

Substance Use
Yes (1)
No (0)

_____Tobacco_____Never smoked
_____Currently smoking
_____Cigarettes per day
_____Cigars per day
_____Pipes per day
_____Smokeless tobacco per day
_____Smoked in the past _____time since cessation

_____Caffeinated beverages
Type_____

_____ number per day

_____Alcohol
Type_____

_____number per day

Physical Findings

No (0)
Yes (1)

Station with respect to introitus
(1) Slight
(2) To introitus
(3) Beyond introitus

_____Cystocele _____

_____Rectocele _____

_____Uterine prolapse ____

Abnormal (0) **Not Sustained (0)**
Normal (1) **Sustained (1)**

_____Vaginal tone _____ grip

_____Rectal tone _____grip

Urodynamics results _____

Treatment Protocol

Number of Treatments _____tx week X _____weeks

Prescription _____Hz_____Min.
_____Min. rest
_____Hz_____Min.

Outcome Measures

	First Evaluation	Midpoint	Final Evaluation
Number of Daily Wetting Episodes			
Number of Daily Pad Use			

Repeated Protocol _____

1. Yes
   How long between protocols_____

   Number of Treatments _____tx week X_____weeks

   Prescription _____Hz_____Min.
   _____Min. rest
   _____Hz_____Min.
2. No

Repeated Protocol

	First Evaluation	Midpoint	Final Evaluation
Number of Daily Wetting Episodes			
Number of Daily Pad Use			