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Is High-intensity Focused Electromagnetic Field Stimulation More Effective Than Pelvic Floor Muscle Training in Treating Stress Urinary Incontinence in Women?

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Abstract

Stress urinary incontinence (SUI), an involuntary loss of urine during physical exertion or effort, affects a disproportionately large number of women worldwide. Although pelvic floor muscle training (PFMT) is the first-line treatment for urinary incontinence, long term adherence is low, and therefore, is usually not an effective treatment. Medications may be costly and aren't always effective; surgery is invasive and often not appropriate. This condition warrants further studies to find more effective solutions. The objective of this study is to evaluate whether or not high-intensity focused electromagnetic stimulation (HIFES) is more effective than PFMT in treating stress urinary continence in women. This will be a two-arm, randomized, longitudinal, quantitative clinical trial with women who have SUI. Valid surveys will be used to analyze the severity and frequency of SUI. Two randomized groups will follow either a PFMT therapy or a HIFES therapy over the course of 6 months; analysis via surveys will be performed before therapy, at 3 months, and at the end of therapy (6 months); there will be a follow up analysis at 1 year, 3 years and 5 years after therapy was initiated. Four hundred fifty participants will be recruited from gynecologists, health clinics, and support groups within the Bay Area of Northern California for this proposed study.

Keywords: focused electromagnetic field, electromagnetic stimulation, pelvic floor muscle training, stress urinary incontinence, women

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Is High-intensity Focused Electromagnetic Field Stimulation More Effective Than Pelvic Floor Muscle Training in Treating Stress Urinary Incontinence in Women?

Urinary incontinence, an involuntary leakage of urine, affects millions of women around the world, negatively affects their quality of life, and is neither well-researched nor prioritized in women's healthcare. Loss of urinary control may be categorized as stress, urge, or mixed incontinence; incontinence results when the integrity of the structures and muscles of the pelvic region are lost or decreased.

In the United States, urinary incontinence (UI) affects approximately 5 to 7 million young adult and middle aged women, and increases to approximately 8.5 million in older women (Lewis, 2014). Stress urinary incontinence (SUI) accounts for half of the UI cases, with 60% of the cases in women under the age of 60 ("Stress Incontinence in Women", n.d.). Although we know many of the etiologies of UI and associated risk factors, few of the women affected seek healthcare due to the stigma associated with UI, the lack of knowledge about UI and the anatomy and physiology of the pelvic floor region, and the general belief that UI is part of the normal aging process.

Women of all ages may have SUI; however, the prevalence increases with childbirth and further increases with parity (Lowdermilk, Perry, Cashion, Alden, & Olshansky 2016). Other causes include menopause, obesity, and repeated heavy lifting or high impact sports. Management of SUI ranges from modification of one's lifestyle to surgical intervention, depending on the severity of the leakage and associated psychological and physical repercussions. First line therapy for stress incontinence is pelvic floor muscle training (PFMT);

however, adherence to a PFMT program has many variables with moderate success rates, and evidence of long-term benefit is lacking (Aoki, et al., 2017).

Due to the challenges of compliance with a PFMT program, side effects and risks with medical and surgical interventions, lack of evidence for long-term effectiveness of PFMT, and lack of clear evidence to support additional interventions for SUI, this study proposes a trial investigating the long-term effects of PFMT therapy and a non-invasive high-intensity focused electromagnetic stimulation (HIFES) therapy for treatment and management of stress urinary incontinence in a diverse group of women. To better understand what is currently known about these interventions, I have conducted a search for trials involving PFMT and HIFES.

Literature Review

SUI has a very high prevalence in women worldwide, and has been associated with a decreased quality of life. Defined as an involuntary leakage of urine during effort (exercise, coughing, sneezing, laughing), this condition affects women of all ages; potential causes are dysfunction of the sphincter and pelvic muscles due to aging, trauma or congenital defects (Lowdermilk et al., 2016). PFMT is usually the first line of treatment; however, adherence is low and long-term effectiveness has not been shown. HIFES is a new treatment for urinary incontinence (UI), and may be the most effective course of therapy for many women with compromised integrity of the pelvic floor structures and/or muscles. I have conducted a research of the recent literature on the effectiveness of and adherence to pelvic floor muscle training and focused electromagnetic stimulation on SUI in women. The objective of this review was to examine the most recent and relevant studies in order to assess the effectiveness of both types of

therapy in treating SUI in women of all ages. A secondary aim was to investigate if protocols or guidelines exist for optimal outcomes of HIFES.

Search Strategy

To search the research literature, I used the following databases: PubMed, Cochrane, CINAHL and Iceberg. The following search words were used together and separately: female; urinary incontinence; stress urinary incontinence; effectiveness; pelvic floor muscle training; pelvic floor therapy; long-term effectiveness; focused electromagnetic field therapy; electromagnetic field; adherence to pelvic floor therapy; and, adherence. I found over forty-five articles; however, many were not specific to the parameters of my research. I chose literature published between 2015 and 2020, and written by primary sources. Articles involving primarily urge UI and fecal incontinence were discarded, as were articles using solely men, or men and women in their samples. I also discarded articles on incontinence related to specific types of childbirth and the use of delivery assistance. Studies involving solely the effects of SUI on quality of life were not included in research, nor were studies relating urinary incontinence to depression. Literature including other modalities of UI treatment, such as surgery, medication, biofeedback, vaginal cones, pessaries and electroacupuncture were not reviewed. Finally, literature involving electromagnetic field therapy used for other areas of the body were not included in this review.

Organization of the Literature Review

For this review, I chose six articles which can be grouped into two categories: three diverse studies related to the effectiveness of and adherence to PFMT; and, three studies related to the effectiveness of HIFES on SUI. In the first category, literature focusing on the short-term

effectiveness of PFMT in the treatment of SUI is prevalent, especially in studies that combine the therapy with other modalities of treatment to increase its effectiveness. Studies of long-term outcomes of PFMT therapy are very limited; I will include in this review the only relevant and fairly recent article I found that examines therapy outcomes after five years. The second and third studies on PFMT relate to adherence to therapy, and the factors contributing to its barriers. Regarding the second category, focused electromagnetic stimulation is a fairly new intervention, thus few studies have been completed regarding its effectiveness on SUI in women. In this review, I included the only study I found that evaluated outcomes one year after treatment ended. The second and third articles evaluated the effectiveness of HIFES using a sham arm as a control, and comparing HIFES to PFMT. See Appendix A for the literature review table.

Short-term Effectiveness of PFMT and Adherence. Currently, there is a dearth of studies evaluating long-term effectiveness of PFMT in treating females with SUI. In a cross-sectional follow-up study, Beyar and Groutz (2017) sought to evaluate UI symptoms, quality of life, and rates of adherence 5 years after completing a PFMT program. Of 208 women who passed the inclusion and exclusion criteria, and completed the training program, 132 were available for analysis. Of these, 55 women (42.7%) reported some adherence to the training regimen. Five years after completion of the therapy, 97% of participants reported symptoms of UI, with 36% experiencing “frequent episodes (two or more per week) of incontinence regardless of adherence to training” (Beyar & Groutz, 2017, p. 133). Beyar and Groutz (2017) summarized that while SUI frequency and amount of leakage had improved, symptoms persisted despite a decent rate of adherence; furthermore, adherence was not correlated to better outcomes. Limitations of this study include a lack of data from participants who didn’t respond to the

follow up study; a less diverse sample due to highly motivated and educated participants; the assumption of proper exercise technique; the lack of severity in baseline UI symptoms; and, the subjective evaluations of adherence and symptoms. The authors found that previous studies are inconsistent in exercise guidelines such as frequency and duration, and concluded that more studies are needed to establish "optimal training protocols" and to evaluate the long-term effectiveness of PFMT as a treatment for SUI in women (Beyar & Groutz, 2017).

In order to study the adherence to and effectiveness of a therapy program, it is important to understand if participants find the therapy to be valuable and worth their time and energy. In a qualitative exploratory study, Grant and Currie (2020, p. 1) used focus groups to "explore perceptions and acceptability of a postnatal physical activity and PFMT intervention with postnatal women in Scotland". They found that during antenatal and postnatal care, pelvic floor rehabilitation was not prioritized with sufficient explanations and support (Grant & Currie, 2020). After collecting data from online and in-person interviews with 31 women who had given birth within the last 5 years, Grant and Currie (2020) learned that lack of time and child care were major barriers to engaging in physical activity. Specifically regarding pelvic floor muscle (PFM) exercises, Grant and Currie (2020) found that while most women in the study were told to do the exercises during an antenatal appointment, they were never taught proper technique for PFMT and didn't know if their technique was correct, which presented a definite barrier to doing PFM exercises. All of the participants agreed that a postnatal session with a therapist to teach correct technique, as well as the use of an app would be very useful (Grant & Currie, 2020). The findings also illustrated that the benefits of PFMT weren't explained adequately before, during and after pregnancy; and, there was a lack of attention to women after childbirth, especially

regarding PFMT (Grant & Currie, 2020). While there is sufficient evidence to support the effectiveness of treatments for UI, the authors found there is little research on the development of interventions, including the timeframe for rehabilitation and the perceptions of the interventions (Grant & Currie, 2020). They concluded that there is a need for further study on optimal duration of therapy, and for relative guidelines and protocols to support specific pelvic floor structure interventions (Grant & Currie, 2020).

While PFMT is effective in the short-term treatment and management of UI symptoms, effectiveness requires adherence (Sacomori et al., 2015). Finding inconsistent results regarding supervised versus non-supervised therapy interventions in the literature, Sacomori et al. (2015) assessed urinary incontinence symptoms, self-efficacy and PFM function with and without added strategies to improve both self-efficacy and adherence to PFMT. In a two-arm randomized, controlled trial, the authors found that including a testimonial video, reminder magnet, and a short-term and long-term goal-setting discussion did not increase rates of adherence (Sacomori et al., 2015). Although both the experimental and control groups received instruction in mastery of the exercises, the additional interventions did not change the participants behaviors; in both groups, adherence fell sharply between the 30 and 90-day assessments (Sacomori et al., 2015). According to Sacomori et al. (2015), positive feedback, persuasion, and mastery experience contribute to self-efficacy; factors increasing mastery of the exercises may have resulted in greater self-efficacy and therefore adherence. These factors include “enabling mastery experience through periodically supervising the exercises, giving constant feedback, and encouraging self-instructed performance” (Sacomori et al., 2015, p. 21). While there are few studies that examine the beneficial effects of strategies used to improve adherence to PFMT, an

intervention using an electronic reminder improved adherence yet did not improve symptoms of urinary incontinence (Sacomori et al., 2015). Limitations to this study were a lack of contrast in interventions between the two groups even though adherence rates were relatively high after one month, which may be due to the instruments used and. The authors concluded that supervised training with supportive therapists are effective in promoting adherence, and with the use of well-designed instruments, can be effective for urinary incontinence management and symptom improvement (Sacomori et al., 2015).

Effectiveness of HIFES Therapy. A relatively new therapy for UI is the use of non-invasive HIFES of the pelvic floor muscles. In analyzing the impact of extracorporeal magnetic innervation (ExMI) in treating SUI in women, Weber-Rajek et al. (2018) assessed UI severity in 52 women over the course of 4 weeks. In this randomized, double-blind, controlled pilot study, participants in the experimental group sat three times a week for 15 minutes on a non-invasive chair that emitted magnetic stimulation to the pelvic floor region; the intensity of the electromagnetic stimulation was gradually increased in a pulsed manner from 20% to 100% (2.0 Tesla at 50 Hz), or the highest-tolerated level, throughout the sessions (Weber-Rajek et al., 2018). Although the study cited several limitations, the Weber-Rajek et al. (2018) found a statistically significant improvement in UI using the RUIS ($P=0.001$), improvement in depressive symptoms ($P=0.006$), and decrease in myostatin concentration ($P<0.001$), a protein that increases with skeletal muscle inactivity. Besides a small sample size, the age range of the participants was narrow (61-76 years), long-term outcomes were not assessed, and the study was not truly double-blind, since participants using the chair could feel pelvic floor contractions during the intervention (Weber-Rajek et al., 2018). Weber-Rajek et al. (2018, p. 2) concluded that although

“further trials are needed to determine optimal treatment protocols for different UI types, ExMI can be an effective treatment method for SUI”.

In another study on the effectiveness of HIFES of the pelvic floor region, Samuels et al. (2019) found clinical improvement of UI, as well marked improvement in quality of life. Conducting a single-arm, open-label, multi-center prospective study, the authors enrolled 75 adult women with SUI, UUI, or MUI between the ages of 22 and 89; these women received 2 - 28 minute treatments weekly for three weeks using the BTL EMSELLA chair, a device similar to the one used in the previously reviewed study by Weber-Rajek et al. (2018). Using the ICIQ-UI SF for evaluation, Samuels et al. (2019) found that participants saw clinically significant improvement after the six treatments ($P<0.001$), and further improvement after the 3-month follow up ($P<0.001$). The authors clarified that two major advantages to HIFES therapy are the targeted stimulation of the pelvic floor region, and the production of thousands of pelvic floor muscle contractions in each session (Samuels et al., 2019). Although long-term outcomes, more objective evaluation tools, and a true control group would further validate the study, HIFES can effectively treat SUI, UUI, and MUI (Samuels et al., 2019).

Lim et al. (2017) designed a randomized, double-blind, sham controlled study evaluating outcomes one year after 120 women completed 16 sessions of pulsed magnetic stimulation (PMS) therapy using the Pelvicenter device (similar to the devices used by the other two studies reviewed here). Realizing that a study of long-term results using a true sham control arm didn’t exist in the literature, Lim et al. (2017) sought to improve the body of literature by gathering new data 12 months after the 2 month evaluation, and including a method of disguising the intervention by changing the direction of stimulation and greatly decreasing the strength of the

impulses. These are major improvements to understanding treatment guidelines for FE therapy. While the analysis revealed statistically significant improvement (P=<0.001) in the active arm at 1, 2, and 14 months, the authors found a correlation between the number of therapy sessions and degree of effectiveness in the short-term: analysis after 1 and 2 months of treatment illustrated consistently significant improvements from 4 to 8 weeks, illustrating that 4 weeks of therapy is not sufficient for optimal results (Lim et al., 2017). Conversely, after 14 months, some participants who received 32 total sessions reported lower "subjective and objective cure rates" than some who received 16 total sessions; Lim et al. (2017) speculated that this may be due to the fact that participants who received 32 sessions initially had more severe symptoms of UI, thus higher baseline scores on the ICIQ-UI SF. Lim et al. (2017, p. 6) concluded that "PMS is an attractive and promising nonsurgical alternative for patients who do not want to undergo surgery"; furthermore, they suggest additional long-term trials are necessary to further compare PMS with PFMT.

Summary of the Literature Review

Research findings of HIFES consistently support the effectiveness of electromagnetic stimulation on stress urinary incontinence in women, with consistent statistically significant improvements in clinical UI symptoms. Studies evaluating PFMT therapies did show short-term improvements; however, studies also found that adherence is low in both short-term and long-term analyses. Barriers to adherence of a PFMT program were a lack of education regarding the functions of the pelvic floor structure; a lack of time to do the therapy; a lack of motivation to do at-home exercise; incorrect exercise technique; and lack of coaching and positive reinforcement from a knowledgeable therapist. Labor and delivery, geriatric, primary care, and medical-surgical

nurses may use this information to educate their patients on the anatomy of pelvic floor structures, and the importance of pelvic floor function and strength. While this topic warrants further study regarding long-term outcomes, accessibility to treatment, and optimal guidelines and protocols for use of electromagnetic stimulation on SUI, available studies show universal effectiveness of this therapy for the improvement and/or the cure of urinary incontinence.

Research Proposal

Will high-intensity focused electromagnetic stimulation therapy demonstrate increased long-term effectiveness compared to a pelvic floor training therapy in treating stress urinary incontinence in women? Secondarily, what are efficient therapy protocols and guidelines to produce the best possible results from a high-intensity electromagnetic stimulation therapy program? SUI is a condition affecting millions of women worldwide, yet very few studies show effective long-term success. The literature review I conducted revealed a gap in trials addressing the comparison of these two interventions with a large and diverse sample size, with long-term outcomes, as well as an absence of research related to optimal protocols for use of HIFES as an effective intervention for SUI. Therefore, I propose a study of SUI in women of diverse ages and backgrounds, that compares the effects of a PFMT therapy to a HIFES therapy on long-term symptom management and/or resolution.

Theoretical Framework

Due to the physical, psychological and social implications of SUI in females, Elizabeth Lenz's Theory of Unpleasant Symptoms, a holistic, middle-range theory, helps to understand the effects of urinary incontinence as multidimensional. The Theory of Unpleasant Symptoms involves the factors influencing symptoms, such as exercise and coughing, and the consequences

of the symptoms, such as depression and embarrassment. While based on the idea that symptoms include the aspects of timing, intensity, quality, and distress, which can be measured, this theory also states that certain factors, such as when and where urinary incontinence occurs, can affect the experience of the leakage (Smith & Liehr, 2018). In other words, having urinary leakage while performing a dance on stage will result in a different experience than having urinary leakage while relaxing at home in front of the television. The theory also explains that symptom characteristics have a direct effect on symptom management or resolution: someone with severe urinary incontinence may be more inclined to choose a surgical intervention, while someone who notices improvement of their symptoms during a PFMT program may be motivated to continue therapy. The theoretical framework of this study is focused on the participants' UI symptoms and how the outcomes of the study are related to nursing practice.

Research Aims

The aim of this proposed study is to evaluate whether or not focused electromagnetic field therapy is more effective than pelvic floor muscle training in treating stress urinary continence in women. A secondary aim is to explore effective protocols and guidelines that will result in optimal long-term outcomes.

Ethical Considerations

Full informed consent will be obtained by each participant prior to the study. Respect for anonymity, privacy, and confidentiality will be observed. All information will be stored on a password-protected computer; all data will be kept in strict confidentiality. Study will be reviewed by the Dominican University review board. All data, results, methods and procedures

will be reported honestly. Study will be terminated if and when one of the interventions is obviously more effective.

Research Methods and Materials

Study Type

This study will be a two-arm, randomized, longitudinal, quantitative clinical trial.

Population

The population will be women who have been diagnosed with SUI. Inclusion criteria are women over 18 years old, women willing to participate in a 5-year study, and women who live in the Bay Area and willing to drive to San Francisco, Walnut Creek or San Rafael for treatment. Exclusion criteria include women who are pregnant, or of child-bearing age not currently using birth control; who have been diagnosed with urge urinary incontinence, overactive bladder, pelvic organ prolapse, or congenital or structural abnormalities of the pelvic floor; who have pacemakers, replaced knees or hips; with active infection of the urinary tract; with malignancy, or cardiac arrhythmias; or, women with conditions contraindicated for PFMT or HIFES. Women who become pregnant or require surgery during the trial period will be excused from the study.

Sample Size and Recruitment Strategy

A convenience sample of 450 adult women will be recruited from gynecologists and urogynecologists around the Bay Area, the support forum message board of the National Association for Continence, and message boards at health clinics around the Bay Area.

Analysis Tools

The tools to be used in this study will be the Revised Urinary Incontinence Scale (RUIS) survey, and the International Consultation on Incontinence - Female Lower Urinary Tract Symptoms Long Form (ICIQ-FLUTS LF) survey. Both of these valid scales use numerical scores, which will then be analyzed. See Appendix B and C, respectively. Data will be self-reported, with assistance from an RN if needed.

Statistical Methods

Before enrollment, volunteers will be assessed for eligibility, given details of the study and the questionnaires used for data collection, and asked to sign the informed consent. The diagnoses of SUI will be made previously by either a gynecologist or urologist. Participants will be assigned to either the PFMT group or the HIFES group using a random numerical allocation system. Before treatment begins, all participants will complete the RUIS and ICIQ-FLUTS LF surveys, with a nurse, to represent their baseline scores. The same surveys will be used for analysis at 3 and 6 months, and at 1, 3, and 5 years; a nurse will be available to the participants for survey completion assistance. The survey responses will be translated into a numerical scoring system and analyzed for statistical significance. The Student t-test will be used to evaluate the differences in the two sets of data, where the null hypothesis is that there is no difference in SUI symptoms between PFMT and HIFES therapies after treatment. A p-value <0.05 is considered statistically significant. Any adverse effects will be reported and noted.

Pelvic Floor Muscle Training Group. Before treatment begins, this group (Group A) will each have one-30 minute session with a nurse for education on the anatomy and physiology of the pelvic floor, as well as the objectives of PFMT. Furthermore, the nurse will instruct the

participants on the correct technique for pelvic floor muscle exercises, explain the program, and practice the exercises with them. The program will include three daily sets of 10 quick, complete contractions, resting between each set, and two daily sets of 10 long contractions, resting between each contraction and between each set. The total sequence of 30 quick and 20 long contractions should take approximately 5-10 minutes per day, for a total of 12 weeks; from week 12 to week 24, participants should do the exercises 3 times per week. Each participant will be given a diary to record their exercises; adherence will be assessed via the questionnaires. Participants are invited to contact a nurse at any time for assistance with proper technique and/or desired feedback.

High Intensity Focused Electromagnetic Stimulation Group. The participants in this group (Group B) will use one of three Bay Area facilities to use the BTL EMSELLA chair for two-30 minute sessions per week for three weeks. Six months after treatment initiation, the participants will have a 30 minute BTL EMSELLA follow-up session. During each session, the participant will remain clothed and will adjust herself on the center of the chair to feel the contractions in the center of her perineum, with input from the nurse. The BTL EMSELLA device (BTL Industries Inc., Boston, MA) delivers electromagnetic waves that activate motor neurons in the pelvic floor muscles, causing over 11,000 contractions during each session (“Urinary Incontinence,” n.d.). This device uses pulsed waves directed upward directly to the perineum at various time intervals throughout each session, and is powered externally from the chair. The nurse will gradually increase the intensity of stimulation, until it reaches 100% (2.5T), or as high as tolerated by the participant.

Conclusion

The global prevalence of stress urinary incontinence is high, yet effective therapies to improve or eradicate the symptoms of SUI are lacking. While some short-term studies show improvement with pelvic floor muscle therapy, the gold standard intervention for UI, studies also show that adherence to a PFMT program is low to very low, and incorrect technique often prevents success. There is a clear need for studies using alternate therapies that illustrate long-term success and validity. Focused electromagnetic stimulation has been shown to be effective in a few short-term studies; other advantages include no adverse effects, short overall treatment time, a high rate of automatic muscle contractions, and the ability to multitask during treatment.

The current available literature is lacking a definitive comparison between PFMT and HIFES in a long-term study, as HIFES is a relatively new treatment intervention for urinary incontinence. Furthermore, the literature lacks a significant study of the long-term effectiveness of HIFES and guidelines for optimal outcomes of this therapy. If this study shows statistically significant long-term SUI symptom improvement with high-intensity focused electromagnetic stimulation, healthcare professionals such as nurses, nurse practitioners, physicians, midwives, doulas and physical and occupational therapists will be able to use this information in their practices to assist and educate their patients who have stress urinary incontinence, or who expect surgical or childbirth trauma to the pelvic floor region. This study may also be used as an initial protocol for frequency of treatment for long-term effectiveness.

This proposed study takes an innovative approach to the lack of literature in this field. It has varied representation in age and background of participants; uses a large sample size from a moderately large geographical area; evaluates the effectiveness of this proposed protocol; and

assesses long-term outcomes. Limitations include the lack of a control group; subjective survey responses; lack of an objective analysis tool; nonresponse rate for one or more survey; and, a potentially high attrition rate in the long-term analyses, resulting in attrition bias.

Further studies may include the availability and costs associated with high intensity focused electromagnetic stimulation; the effect of HIFES on mixed, and urge urinary incontinence; guidelines and protocols for optimal results; and, both the short-term and long-term effects of prenatal HIFES on the strength of the pelvic floor after childbirth.

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