



TITLE: Magnetic Stimulation for the Treatment of Urinary Incontinence in Women

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MAGNETIC STIMULATION FOR THE TREATMENT OF URINARY INCONTINENCE IN WOMEN

INTRODUCTION

The California Technology Assessment Forum has been asked to review the scientific literature on the use of magnetic stimulation as a treatment for urinary incontinence in women.

BACKGROUND

Urinary incontinence is the involuntary loss of urine from the urethra that is sufficient to be a social or hygienic problem (Fantl *et al.*, 1996). It is a multifactorial syndrome involving the intersection of neurourinary pathology, age-related factors and co-morbid conditions. The prevalence varies with the definition used and the age and sex of the population. Overall, urinary incontinence affects about 15% of the ambulatory adult population or approximately 13 million adults in the U.S. (Resnick and Griffiths, 2003). Risk factors for the development of urinary incontinence in women include childbirth, hysterectomy, recurrent urinary tract infections, smoking, medications such as diuretics and sedative-hypnotics and alpha blockers, the presence of two or more co-morbid diseases such as CHF and COPD, advancing age, higher levels of educational attainment and increased body mass index (Holroyd-Leduc and Strauss, 2004). Dementia is also associated with urinary incontinence. Alzheimer's and multi-infarct disease damage cortical and subcortical inhibitory centers, leading to uninhibited bladder contractions and urinary incontinence. Severely demented individuals remain continent if they have preserved mobility (Brandeis *et al.*, 1997).

Most persons with urinary incontinence are women. Up to 35% of women over the age of 60 in the U.S. are bothered by urinary incontinence, and at least half of all nursing home residents are affected (Berghmans *et al.*, 1998). Urinary incontinence brings significant costs to the individual and to society. For the individual, it is associated with social isolation, increased depression, lower self-rated health and impaired quality of life and psychological distress (Holroyd-Leduc and Strauss, 2004; Burgio *et al.*, 2001). Urinary incontinence-related costs in the U.S. are estimated at \$12.4 billion for women (in 1995 dollars) though all cost estimates likely underestimate the impact of the problem, as many patients remain undiagnosed. Fewer than half of individuals with urinary incontinence living in the community consult health care providers about the problem (Fantl *et al.*, 1996). The majority of the costs associated with urinary incontinence reflect management (e.g., protective garments) rather than curative treatment (Resnick and Griffiths, 2003).

There are several different types of urinary incontinence in women including urge incontinence (UI), stress incontinence (SI), mixed incontinence and overflow incontinence. UI is defined as the uncontrolled loss of urine that is preceded by a strong, unexpected urge to void. It is unrelated to position or activity (Stoller *et al.*, 2004). UI is generally due to detrusor overactivity. SI is associated with activities that cause an increase in intra-abdominal pressure (e.g. sneezing, coughing, and lifting). Laxity of the pelvic floor musculature, secondary to childbirth or surgery, is thought to result in diminished sphincter function. Mixed incontinence is a result of a combination of SI and UI. Overflow incontinence, an uncommon type of incontinence, results from over-distention of the bladder usually from obstruction in men, or a neurological impairment such as a spinal cord injury.

Treatment of urinary incontinence can be divided into non-pharmacologic, pharmacologic and surgical. Non-pharmacologic therapies consist of behavioral interventions such as pelvic floor muscle training (PFMT), biofeedback, vaginal weights, bladder training and pelvic stimulation. Of these, PFMT and exercises are strongly supported on the basis of multiple randomized trials (Borello-France and Burgio, 2004) and were found to be an effective treatment for adult women with stress or mixed incontinence by a Cochrane review (Hay-Smith *et al.*, 2001). Behavioral treatment for urge urinary incontinence is based upon two general principles: frequent voluntary voiding to keep the bladder volume low and training of central nervous system and pelvic mechanisms to inhibit/ablate detrusor contractions. Behavioral therapy for stress urinary incontinence (SUI) begins with pelvic muscle exercises. Pelvic muscle exercises (Kegel exercises) strengthen the muscular components of the urethral closure mechanism. It is based on the rationale that a strong and fast pelvic floor muscle contraction will clamp the urethra, create increased intraurethral pressure and prevent leakage of urine when the intra-abdominal pressure rises abruptly (Hay-Smith *et al.*, 2001).

Pharmacologic treatments mainly include anticholinergic drugs to inhibit involuntary detrusor contractions in UI and alpha-adrenoreceptor agonists for SI. A variety of surgical techniques have been evaluated including open retropubic colposuspension, bladder neck needle suspension, anterior vaginal repair, suburethral sling procedures and periurethral injections. Surgery is associated with a high cure rate, but is invasive and can be associated with significant morbidity. There is insufficient evidence to compare surgery with other interventions and most experts recommend that patients undergo non-surgical options first (Holroyd-Leduc and Strauss, 2004).

Pelvic floor electrical stimulation (PFES) has been proposed as a treatment for patients who do not benefit from or cannot utilize behavioral or drug therapy, or, as an adjunct to these therapies. Electrical stimulation was first proposed in 1963 to address urinary and fecal incontinence. Electrical stimulation is believed to work through three different mechanisms: by direct stimulation of motor nerves supplying the pelvic floor and external urethral sphincter that results in muscle contraction thereby strengthening the muscles; by exhausting afferent sensory nerves from the bladder thereby suppressing overactive bladder contractions; and by blocking irritative bladder symptoms via the

gate control theory (Klausner and Steers, 2004). PFES can be performed in a clinical setting or with intravaginal devices designed for home use (Borello-France and Burgio, 2004).

Magnetic stimulation

As with functional electrical stimulation (FES), the intent of magnetic stimulation is to stimulate both autonomic and somatic nerve pathways so as to improve urinary continence. Similar to FES, the mechanism of action of magnetic stimulation upon the continence mechanism is not clearly understood.

Magnetic impulses have been shown to stimulate central and peripheral nerve pathways in the pelvis (Goldberg and Sand, 2000). It has been used in the treatment of overactive bladder (detrusor instability), for SI and to promote micturition in an areflexic bladder (Goldberg and Sand, 2003). At the tissue level, magnetic stimulation is thought to induce a flow of ions, establishing electrical eddy currents due to differences in voltage between two spatial points. This phenomenon can lead to membrane depolarization. Although this contrasts with electrical stimulation, which is thought to directly stimulate the nerve, the end result for both is nerve depolarization and the propagation of an action potential along the axon (Goldberg and Sand, 2003).

In contrast to electrical current, the conduction of magnetic energy is unaffected by tissue impedance. As a result, to establish any given current at the nerve root level, magnetic stimulation requires relatively little current to be generated at the body surface. Electrical stimulation requires relatively high voltages at the skin; transvaginal and transrectal probes are used for more direct application to the pelvic floor nerves (Fujishiro *et al.*, 2002).

Extracorporeal magnetic stimulation is performed with the patient fully clothed and involves no probes, skin preparation, physical or electrical contact with the skin. The patient sits fully clothed on a chair containing an electromagnet controlled by an external power source. High frequency or continuous magnetic stimulation of up to 20 pulses per second produce stimulation to the pelvic floor musculature. Optimal coil position can be verified by visual confirmation of muscle contractions, or from surface EMG recordings (Goldberg and Sand, 2003). The methods of magnetic stimulation differ in frequency of magnetic wave forms, stimulating pulse width, maximum output, length of time of each session and overall time period for device use (Goldberg and Sand, 2000). Magnetic stimulation appears to be safe, with no significant adverse affects reported in the literature to date. Minimal sensation and heat reportedly is generated at the tissue level.

This review considers the benefits and risks of magnetic stimulation for urinary incontinence in women. The main types of incontinence addressed in this review are SI, UI and mixed incontinence.

TA Criterion 1: The technology must have the appropriate regulatory approval.

On August 29, 2000, the FDA approved the NeoControl® Pelvic Floor Therapy System (Neotonus, Inc., Marietta, GA) through the 510k process as substantially equivalent to the InCare Pelvic Floor Therapy System. Previously, the FDA had given 510k clearance to the Neotonus Model 1000 Muscle Stimulator System.

TA criterion 1 is met

TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.

There have been three randomized trials and six pre/post-test trials of magnetic stimulation for treatment of urinary incontinence in women published in peer-reviewed journals. Most of these trials included patients with different types of incontinence and some of the trials included men.

The most commonly used measure of urinary incontinence treatment efficacy is a reduction in urinary incontinence episodes, variably measured as the reduction in the mean number of daily episodes, percent reduction from baseline or reduction in leakage volume. Cure is usually defined as complete absence of urinary incontinence. Other outcome measures frequently used are total number of daytime and nighttime continent voids, bladder capacity (or mean voided volume) and post void residual volume. However, these measures may not reflect the patient's perception of improvement. Patient-based outcomes may be better assessed using general satisfaction questions, relief of most bothersome aspects of urinary incontinence or urinary incontinence-specific quality of life measures. General health-related quality of life measures (such as the Medical Outcomes Study Short Form-36) largely have proved insensitive to changes in urinary incontinence after treatment (Burgio *et al.*, 2001). Most of the trials follow patients for no more than 6 months, limiting our ability to conclude if the intervention had a long-term impact on continence.

It is difficult to draw conclusions from the few randomized clinical trials of magnetic stimulation because of the small number of patients studied in these trials, the limited follow-up, variability in the treatment protocols, the equipment used and their outcome measurements.

TA criterion 2 is not met

Levels of Evidence: 2 and 5.

TA Criterion 3: The technology must improve the net health outcomes.

Randomized Trials:

Magnetic Stimulation vs. Placebo/Sham

There are two published randomized trials that examined the safety and efficacy of magnetic stimulation vs. placebo in the treatment of female urinary incontinence. Fujishiro *et al.* (2000) report on a placebo controlled trial to evaluate the efficacy and safety of magnetic stimulation of the sacral roots for the treatment of urinary frequency and UI.

Thirty-seven women, from 43 to 75 years of age, were recruited from an outpatient clinic in Japan and randomized to active treatment (n=22) and placebo/sham (n=15). Magnetic stimulation was performed with the patient prone (rather than seated) and proper positioning of the magnetic coil was confirmed with a pelvic x-ray. They used 15 Hz repetitive magnetic stimulation, at 50% maximum intensity, for five seconds per minute, for 30 minutes. Patients received treatment at one session only. They recorded urethral closure pressure during stimulation. Patients completed a three-day voiding diary and quality of life questions before and one week after stimulation. Other outcomes included mean number of voids daily, mean urine volume per void and number of UI episodes. They report that patients who received active stimulation experienced "strong" muscle contractions in the buttocks and lower extremities and a tingling sensation in the toes bilaterally. Sham patients reported only slight warmth. The mean number of voids daily decreased significantly from 10.2 \pm 2.2 to 9.3 \pm 2.3 after treatment in the active group ($p=0.03$). However, no statistically significant inter-group differences were found between sham and active patients. Significant intergroup differences were found in the mean number of leaks per three days. In the active group, the mean number of leaks per three days decreased from 5.3 \pm 6.7 to 1.6 \pm 3.2 while it declined from 2.0 \pm 1/2 to 1.6 \pm 1.2 ($p=0.04$) in the sham group. The authors conclude that only one session of magnetic stimulation induced satisfactory improvement of symptoms in one week compared with sham stimulation. No patients complained of discomfort or pain and they report no adverse effects of the treatment. The authors correctly point out, however, that several concerns about magnetic stimulation must be resolved before it can be recommended for widespread clinical use. These concerns include: 1) what are the optimal stimulation parameters (intensity, frequency, duration) of magnetic stimulation; and 2) what is the best positioning of the magnetic coil and how many sessions should be applied? The authors conclude that "further studies are needed to confirm long term efficacy".

The most recent study (But, 2003) was a randomized, placebo (sham) controlled trial of 55 women with urinary incontinence recruited by a single uro-gynecologist practicing in Slovenia. This trial used a portable device called the Pulsegen that is powered by a 3-volt battery and designed to be placed in specially designed underwear and worn continuously. The control patients received an identical appearing sham device. The Pulsegen generates pulsating, low frequency, electromagnetic fields day and night for two months. This device is not yet FDA approved.

Magnetic Stimulation vs. Electrical Stimulation

Yamanishi *et al.* (2000) report on a randomized trial investigating the urodynamic effects of functional magnetic stimulation (FMS) and FES on the inhibition of detrusor overactivity. Thirty-two patients with urinary incontinence due to detrusor overactivity (15 men, 17 women) were randomly assigned to either FMS or FES. Stimulation was applied continuously at 10Hz in both groups. For FMS, the magnetic coil was positioned in a chair and patients were instructed to sit on the seat so that the perineum was positioned at the center of the coil. For FES, patients used an intravaginal device and stimulation was given up to the highest tolerable level. Cystometry was performed before and during stimulation. Other clinical outcomes were not tracked. They found that both treatments increased the bladder

capacity at the first desire to void and the maximum cystometric capacity. The amount of increase in bladder capacity was significantly greater in the FMS group. It is not possible to conclude from this study if FMS is a useful treatment for women with urinary incontinence.

Non-randomized Prospective Cohort Trials

There have been six, pre/post- cohort studies published in the peer reviewed literature that have examined the effect of magnetic stimulation on urodynamic measures, continence and quality of life in women. These trials will be reviewed briefly as it is difficult to draw firm conclusions from non-randomized studies.

Almeida *et al.* (2004) report on a prospective study of 91 Brazilian women with urinary incontinence. Treatment consisted of 16 sessions, over eight weeks, of 20 minutes each; ten minutes of intermittent low frequency stimulation (five seconds at 5Hz and five seconds off) and ten minutes of intermittent high frequency stimulation (50 Hz) using a specially designed chair (Neocontrol™, Neotonus, Inc., Marietta, Georgia). Patients were evaluated at baseline and after treatment. Initially, they found a 35% increase in quality of life scores, 54% decrease in the mean number of leakage episodes daily and 40% decrease in mean daily pad use. However, the authors report that over time the initial benefits of magnetic stimulation were lost. For example, by one year, 94% of the patients who had become dry after the magnetic stimulation had recurrence of incontinence. The authors conclude that 16 sessions of magnetic stimulation are “not effective definitive treatment” for urinary incontinence.

Chandi *et al.* (2004) studied 24 patients in the Netherlands with urge and mixed incontinence treated with the Neocontrol chair, twice weekly for eight weeks. They used a slightly different frequency protocol than did Almeida *et al.* (2004). In the pad test, they found an improvement at eight weeks in the patients with UI only (n=12); there was no significant improvement seen in half of the cohort. Data is not reported after eight weeks.

Unsal *et al.* (2003) evaluated the efficacy of magnetic stimulation for 35 patients with SI and 17 with UI followed in Ankara, Turkey. Patients were treated with the Neocontrol chair for 20 minutes (10 minutes at 5 Hz and 10 minutes at 50 Hz), twice weekly for eight weeks. Forty-four total patients completed one-year of follow-up. They found that at one year, 11 patients (38%) with SI and six patients (40%) with UI were “cured” (i.e. completely dry) and there was improvement in another 19 patients, for an overall success rate of 79%. However, patients who dropped out were not included in the analysis. No adverse effects were noted.

Galloway *et al.* (1999, 2000) report on a prospective, multicenter U.S. study of magnetic “innervation” therapy for SUI. In the latter study, they report on a six-month follow-up for 111 women who had been treated for 20 minutes, twice per week for six weeks with the Neocontrol chair. At six months, 47 women had completed follow-up. Of these, 13 patients were completely dry and pad use was significantly reduced in 33 patients. Patients who failed to attend all treatments were excluded from the analysis. It is difficult to draw conclusions from this study because, as with other

cohort trials, there is no comparison control group and in this paper, the authors report results on less than half of their cohort.

Yamanishi *et al.* (2000) report on a small study of 12 female patients with stress and urge urinary incontinence. Cystometry was performed before and during 15-minute stimulation at 10 Hz. They found that maximum intraurethral pressure increased significantly in the six patients with SI and maximum cystometric capacity increased in the six patients with UI. In addition, at five weeks, they found a statistically significant reduction in leak episodes per day in SI patients (from 4.9 +/- 3.6 to 3.6 +/- 4.0). Most UI patients had an underlying brain or spinal disorder. A significant reduction in leak episodes per day was reported. The small sample size and short follow-up make it difficult to draw firm conclusions from this study.

Systematic Reviews

Berghmans *et al.* (1998) published a systematic review of randomized clinical trials of conservative treatment of SUI in women. There was no discussion of magnetic stimulation in this review.

The Cochrane library (Hay-Smith *et al.*, 2001) reviewed the literature on PFMT for urinary incontinence in women. In this review, they concluded that PFMT is better than no treatment or placebo treatment, for women with SI and/or mixed incontinence. The Cochrane library has not published a review of magnetic stimulation.

Pending Trials

There are no known randomized clinical trials of magnetic stimulation in process.

Patient Risks

Adverse events associated with magnetic stimulation have not been reported. Potential adverse outcomes include patient discomfort, inconvenience or anxiety. There are no known long-term adverse consequences associated with magnetic stimulation.

TA criterion 3 is not met

TA Criterion 4: The technology must be as beneficial as any established alternatives.

Other strategies that have been used to treat urinary incontinence in women include behavioral interventions such as PFMT, biofeedback, vaginal weights and bladder training; pharmacological interventions and surgery. PFMT was first introduced in 1948 by Arnold Kegel to treat women with urinary incontinence. In the management of SUI, it is based on the rationale that pelvic floor contraction will clamp the urethra and thereby increase intraurethral pressure, thus preventing leakage of urine during abrupt increases in intra-abdominal pressure. The rationale for PFMT is less clear in UI, though one theory holds that PFMT may lead to reflex inhibition of detrusor contractions (Borello-France and Burgio, 2004). Results from several randomized trials strongly support the use of PFMT as a safe and effective

treatment in the management of stress, urge and mixed incontinence in women. A recent Cochrane review concluded that PFMT is superior to placebo treatment for women with stress and/or mixed incontinence (Hay-Smith *et al.*, 2001). The frequency and intensity of PFMT needed for sustained response is less clear.

For PFMT to be effective, the patient must learn to contract the appropriate muscles without straining, which can lead to increases in intra-abdominal pressure. Biofeedback assisted PFMT has been used as an adjunct to teach patients proper pelvic muscle contraction. Results from randomized trials, however, do not confirm that biofeedback improves outcomes over PFMT alone (Hay-Smith *et al.*, 2001; Berghmans *et al.*, 1998). Vaginal cones also have been used to promote strengthening of the pelvic floor musculature, particularly in the treatment of SI. Results from randomized trials do not support their use over PFMT (Holroyd-Leduc and Strauss, 2004).

A variety of pharmacological therapies have been used in the treatment of urinary incontinence in women. For UI, anti-cholinergic medications have been found to be superior to placebo in subjective improvement or cure. Tricyclic antidepressants have also been shown to be of benefit (Holroyd-Leduc and Strauss, 2004). For SI, the role of pharmacotherapy has been more limited. Research has focused recently on alpha-1 A selective adrenoceptor agonists, with the theory that these agents might effectively increase the bladder outlet resistance and therefore, limit symptoms in women with SUI. Clinical trials are still ongoing (Klausner and Steers, 2004). Other treatments, such as botulinum toxin for UI, are far on the horizon.

Surgery is an option for women with SUI who have failed more conservative treatment approaches. A variety of surgical techniques have been evaluated. The goals of surgical treatment are to stabilize the bladder neck to prevent descent with increased intra-abdominal pressure and to create a stable fascial layer for urethral compression. A recent Cochrane review concluded that open retropubic colposuspension (Burch procedure) was the most effective treatment modality for SUI, with 85 to 90 % of patients content after one year and 70 % after five years (Lapitan *et al.*, 2003). Comparing the different surgical procedures is difficult due to variations in patient selection, experience of the surgeon, diagnostic methods, techniques, outcome criteria and length of follow-up. Potential complications of surgery include urinary retention (generally short term), detrusor overactivity, injury to the bladder or ureter, infection, hemorrhage and enterocele.

In sum, effective treatments are currently available for the treatment of urinary incontinence that has demonstrated to be more beneficial than magnetic stimulation. These include PFMT alone for stress and mixed incontinence and anti-cholinergic medication for UI. Surgery has shown to be effective for women who have failed conservative measures. There is insufficient evidence from randomized clinical trials to conclude that magnetic stimulation is as beneficial as these alternative therapies. In addition, it has not been shown to improve management of urinary incontinence in women when used as an adjunct to PFMT.

To date, magnetic stimulation has not been shown to be as effective as behavioral or pharmacological therapy in the treatment of stress, urge and mixed incontinence in women.

TA criterion 4 is not met.

TA Criterion 5: The improvement must be attainable outside the investigational settings.

Magnetic stimulation has not been shown to improve outcomes in clinical trials, so improvement is not attainable outside of investigational settings.

TA criterion 5 is not met.

ABBREVIATIONS USED IN THIS ASSESSMENT:

PFMT – pelvic floor muscle training

PFES – pelvic floor electrical stimulation

SUI – stress urinary incontinence

SI – stress incontinence

UI – urge incontinence

FES – functional electrical stimulation

FMS – functional magnetic stimulation

RECOMMENDATIONS OF OTHERS

Blue Cross Blue Shield Association (BCBSA)

The BCBSA TEC Medical Advisory Panel reviewed the use of magnetic stimulation in the treatment of urinary incontinence in adults in June 2000 and determined that this technology did not meet TEC criteria.

Centers for Medicare and Medicaid Services (CMS)

CMS does not have a national policy specific to the use of magnetic stimulation for the treatment of urinary incontinence. Other therapies such as biofeedback and PFES are considered appropriate for the treatment of stress and/or UI when pelvic muscle exercise has not worked.

Two regional CMS carriers do have policy specific to extracorporeal magnetic stimulation as a treatment of urinary incontinence. In 2003, Cahaba Government Benefit Administrators with jurisdiction for Georgia determined that studies have shown that this therapy can be of benefit for selected female patients with urinary incontinence. Also in 2003, HGS Administrators with jurisdiction for Pennsylvania (Region III) noted that current medical literature does not support the clinical efficacy of this procedure in the Medicare population.

California Urological Association (CUA)

The CUA was represented at the CTAF meeting and provided testimony in support of the recommendation.

American College of Obstetricians and Gynecologists (ACOG), District IX (California)

The California chapter of ACOG was represented at the CTAF meeting and provided testimony in support of the recommendation.

CONCLUSION

Urinary incontinence, defined as involuntary leakage of urine, affects over 13 million Americans and disproportionately impacts women and the elderly. It imposes a significant psychological impact on patients, their families and caregivers; and it is a major cause of institutionalization of the elderly (Fantl *et al.*, 1996). Urinary incontinence is underreported by patients and families, often going undiagnosed and under-treated. Current treatment options for urinary incontinence include pharmacologic options; non-pharmacologic approaches such as PFMT, vaginal cones and electrical stimulation; and surgery. Of these, only PFMT has been shown, in randomized trials, to be an effective first line therapy for women suffering from urinary incontinence.

Magnetic stimulation is thought to stimulate peripheral nerves in a similar manner to electrical stimulation. As with electrical stimulation, the exact mechanism of action is unknown. Similarly, it has been asserted that as with electrical stimulation, magnetic stimulation may be particularly useful for the sub-group of women who are initially unable to voluntarily contract their pelvic floor muscles. Magnetic stimulation may help these women achieve continence by training them in this technique, and once active contraction becomes possible, pelvic floor exercises alone can be practiced. Its proponents point out, however, that it has several potential advantages over electrical stimulation: no probes are required—the patient can remain fully clothed during treatment; lower voltages are required since the conduction of magnetic energy is unaffected by tissue impedance; patient discomfort is minimized and therefore compliance may be enhanced. To date, these benefits have not yet been demonstrated in clinical trials and as with electrical stimulation, the long term clinical efficacy of magnetic stimulation for treatment of urinary incontinence in women is unclear.

There is a paucity of well-done randomized trials that examine the effect of magnetic stimulation on urinary incontinence in women. There are two published randomized trials that examined the safety and efficacy of magnetic stimulation vs. placebo in the treatment of female urinary incontinence (Fujishiro *et al.*, 2002; But, 2003) and one randomized trial that compared urodynamic outcomes between magnetic stimulation and electrical stimulation (Yamanishi *et al.*, 2000). One of these trials, But (2003), used a technology that is not FDA approved and is not considered in this review. In the Fujishiro study, they did not find a significant difference in most important clinical outcomes between the active and sham group. In addition, the study is limited by small numbers and short-term follow-up, leading the authors themselves to conclude: “further studies are needed to confirm long term efficacy”. Yamanishi *et al.* (2000) report on a randomized trial investigating the urodynamic effects of FMS (FMS) and FES on the inhibition of detrussor overactivity. They found that both treatments were effective in increasing maximum cystometric capacity. While intriguing, these urodynamic outcomes may not translate into long-term clinical benefits for patients.

Results from pre/post- cohort trials have demonstrated mixed results. Outcomes from these trials must be interpreted with caution, given the potential for bias in trials conducted without concurrent controls.

In sum, magnetic stimulation is still emerging as a potential treatment of urinary incontinence in women. Issues that will need to be addressed in future studies include: 1) what are the optimal stimulation parameters (intensity, frequency, duration) of magnetic stimulation; 2) what is the best positioning of the magnetic coil; and 3) how many sessions should be applied? In addition, studies will need to be designed with long term follow-up to address the concern that the effect of magnetic stimulation, if any, is relatively short lived.

A potential confounder in all of the trials of magnetic stimulation is the fact that it is difficult to adequately blind patients to the intervention. Since magnetic stimulation causes warmth and sensation in the target tissue, some patients in the active arm will realize that they are receiving the intended treatment. Some researchers attempt to correct this potential bias by informing patients that active treatment may not cause a sensation. Few trials, if any, asked women if they could identify into which arm they were randomized.

Effective treatments are currently available for the treatment of urinary incontinence. These include PFMT alone and anti-cholinergic medication for UI. There is insufficient evidence from randomized clinical trials to conclude that pelvic floor magnetic stimulation is as beneficial as these alternative therapies.

RECOMMENDATION

It is recommended that magnetic stimulation does not meet CTAF criteria 2-5 for the treatment of urinary incontinence in women.

The California Technology Assessment Forum approved the recommendation as stated.

October 20, 2004

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