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Is magnetic stimulation effective in treating urinary incontinence?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW
In Partial Fulfillment of the Requirements For
The Degree of Master of Science
In
Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not magnetic stimulation is an effective treatment for women with urinary incontinence.

STUDY DESIGN: Review of three published, randomized controlled trials (two double-blind and one single blinded), all English language.

DATA SOURCES: The three randomized controlled trials that were used for this review were found using PubMed and EBSCOhost. Articles were selected based on relevance and that the outcomes of the studies mattered to patients.

OUTCOME(S) MEASURED: Improvement of urinary incontinence measured by pad-tests and questionnaires.

RESULTS: The results of the But study suggest that magnetic stimulation is not much more effective when compared to the control. Gilling et al. demonstrated that there was a statistically significant improvement in the active arm at 8-wks for 20-min pad test, #pads/day, PFM strength, 24-h pad test, I-QOL and KHQ scores. Although p-values suggest improvement, comparing changes in each variable from baseline between groups using ANOVA showed no statistically significant difference in any outcome measure at 8 weeks or 6 months. Wallis et al. demonstrated that there were no statistically significant differences in the outcome measures between baseline and 12 weeks for the treatment and control groups. On the subjective measure there was a statistically significant difference between the active and control groups (p=0.04).

CONCLUSIONS: The results of these three randomized controlled trials suggest that magnetic stimulation is not much more effective than a placebo in the treatment of urinary incontinence.

KEY WORDS: Urinary incontinence, magnetic stimulation
INTRODUCTION

Urinary incontinence (UI) is involuntary loss of urine. UI is a common problem in older adults and there are three types of urinary incontinence: stress, urge and overflow. Stress incontinence is most common in women and results from increased intra-abdominal pressure. This paper evaluates three randomized controlled trials (RCTs) comparing the efficacy of magnetic stimulation as a treatment for urinary incontinence.

This topic/question is relevant to patients and PA practice because it is common, costly and accounts for a significant amount of healthcare visits each year. The prevalence of urinary incontinence increases with age. The prevalence of urinary incontinence in women ranges from 25-51%. Prevalence of UI in women in nursing homes is 60-78%. 30-60% of pregnant women report UI\(^1\). $20 billion was spent on UI in 2000 and cost has nearly doubled in the past decade\(^1\). In 1998 there were 522,240 office visits with UI as primary diagnosis for female Medicare beneficiaries\(^2\).

Continence depends upon both intact micturition physiology (including lower urinary tract, pelvic, and neurologic components) and an intact functional ability to toilet oneself. Successful toileting depends upon ready access to toilet facilities, the motivation to maintain dryness, sufficient mobility and manual dexterity, and the cognitive ability to recognize and react appropriately to sensations of bladder filling. About 50% of affected women have stress incontinence, with mixed-stress and urge next common, followed by urge incontinence. Stress incontinence is caused by inadequate pelvic support and decreased estrogen. Urge incontinence is the most common form in older adults\(^1\).

The usual methods of treatment are lifestyle modifications, behavioral therapy, adjunctive treatments, pharmacologic therapy, and surgery. Lifestyle modifications include: dietary...
changes, monitoring fluid intake, avoiding caffeine and alcohol, smoking cessation, and weight loss. Behavioral therapy consists of bladder training (frequent voiding, training of CNS and pelvic mechanisms to inhibit urgency) and pelvic muscle exercises to strengthen muscular urethral closure mechanism and biofeedback. Adjunctive measures include: pads, protective garments and pessaries. Pharmacologic therapy available: Antimuscarinics, Duloxetine, OnabotulinumtoxinA.

Magnetic stimulation devices are thought to stimulate pelvic muscle contractions and/or modulate detrusor contractions, which are necessary for urinary continence. This method of treatment is being proposed because of the limited efficacy of current treatment modalities.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not magnetic stimulation is an effective treatment for women with UI.

METHODS

The studies included are three randomized controlled trials (two double-blind and one single-blinded). The population studied was women with urinary incontinence. The intervention was magnetic stimulation. Comparisons: The treatment group receiving magnetic stimulation to the experimental group who received a placebo (non-functioning magnets). Outcomes measured: improvement of urinary incontinence measured by pad-tests and questionnaires.

Key words used in the searches were “urinary incontinence” and “magnetic stimulation.” All articles were published in English and in peer-reviewed journals. This author searched articles via PubMed and EBSCOhost. The reviewed articles were selected based on relevance and that the outcomes of the studies mattered to patients (POEMs). The inclusion criteria included: women with urinary incontinence. Exclusion criteria included: implanted electronic
equipment, concurrent use of drugs to manage UI, pelvic floor surgery, and pregnancy.

Summary statistics were reported using: p values, RBI, ABI, NNT.

Table 1: Demographics and Characteristics of included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
<th># Pts</th>
<th>Age (yrs)</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
<th>W/D</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>But⁴(2003)</td>
<td>Double-blind RCT</td>
<td>55</td>
<td>&gt;18 y/o</td>
<td>Women with UI, &gt;18 y/o, not pregnant, not physically or mentally disabled.</td>
<td>Implanted electronic devices, urolithiasis, bladder infection, tumor, recent urethral/continence surgery; taking anticholinergics, BB or diuretics.</td>
<td>3</td>
<td>Magnetic stimulation</td>
</tr>
<tr>
<td>Gilling⁵(2009)</td>
<td>Double-blind RCT</td>
<td>70</td>
<td>&gt;20 y/o</td>
<td>Women &gt;20 y/o, sx's of or confirmed UI, ambulatory, live home, neurologically normal, healthy, normal UA, stable detrusor function on urodynamics</td>
<td>incontinence/pelvic floor surgery, grade 3 or 4 pelvic prolapse, pregnancy, drugs for bladder dysfunction, internal electronic medical devices, pelvic or lower limb metallic prosthesis</td>
<td>15</td>
<td>Magnetic stimulation</td>
</tr>
<tr>
<td>Wallis⁶(2012)</td>
<td>Single-blinded RCT</td>
<td>122</td>
<td>&gt;60 y/o</td>
<td>Women &gt;60 y/o, live at home, UI symptoms Q week x 6 mos.</td>
<td>implanted electronic device, symptomatic UTI, drugs for UTI last 4 weeks, scheduled for pelvic floor or GYN surgery within next 3 months</td>
<td>21</td>
<td>Magnetic stimulation</td>
</tr>
</tbody>
</table>

OUTCOMES MEASURED

But study outcomes measured were: urine frequency/loss, nocturia, and PFM contractions. The outcomes were measured by: number of pads used, pad weight, volume voided charts, power/duration of PFM contractions measured with perineometer, patient report by visual analog scale⁴.
Gilling et al. Outcomes measured were reduction of urinary leakage and quality of life which were measured by: 3-day bladder diary, 20 min. provocative pad-test with predetermined bladder volume, and 24 hour pad test, incontinence quality of life questionnaire (I-QOL) scores, Kings Health Questionnaire (KHQ) scores, CMV score, peritron perineometry score, and PFX perineometry score.

Wallis et al. Outcomes measured were cessation of incontinence, frequency and severity of symptoms, which were measured by: 24-hour pad test, BFLUTS-SF, incontinence severity index, bothersomeness visual analog scale, and 24-hour bladder diary.

RESULTS

The three studies reviewed compared magnetic stimulation to a placebo. All trials were completed in women with urinary incontinence.

The But study was a randomized, double blind, placebo controlled trial that randomized 55 subjects into an active group (30 patients) and placebo group (22 patients). Each patient in the active group was given a Pulsegen device, which produced a pulsating magnetic field, to wear day and night for 2 months. Of the 55 participants who entered the trial, 52 completed the study (5% loss to follow-up). “Worst-case” analysis was not done on participants lost to follow up. There was no statistically significant difference between the participants in the active and placebo groups as determined by the Mann-Whitney U test (P>0.05). 55.8 years was the average age of the women in the study, 40.4% had mixed incontinence, 42.3% had urge incontinence and 17.3% had stress incontinence. After 2 months of continuous magnetic stimulation with the Pulsegen device, the active group had a statistically significant decrease in daytime frequency (P=0.048), decrease in nocturia (P=0.0057), decrease in number of pads used (P=0.0031), decrease in pad weight (P=0.014), increased power of PFM (pelvic floor muscle contractions)
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(P=0.0071), and length of PFM contractions (P=0.038). The active group reported a 56.3% improvement in UI symptoms by a visual analog scale, which was statistically significant when compared to the placebo (P=0.00012). The placebo group had a statistically significant decrease in nocturia (P=0.0035). The placebo group reported a 26.3% improvement in symptoms by a visual analog scale. 79% (EER) of participants in active group and 22.7% (CER) of participants in placebo group evaluated success of magnetic stimulation as “excellent” or “good.” The placebo had a statistically significant lower success rate than the active group (P=0.0022). Table 2 shows the treatment effect of magnetic stimulation on urinary incontinence. Relative benefit increase (RBI) was calculated to be a 2.48%. Absolute benefit increase (ABI) was calculated to be 56.3%. Numbers needed to treat (NNT) was calculated as 2, indicating that 2 patients need to be treated to see one or more positive outcomes.

Table 2: Treatment effect of Pulsegen magnetic stimulation on urinary incontinence

<table>
<thead>
<tr>
<th>CER</th>
<th>EER</th>
<th>RBI</th>
<th>ABI</th>
<th>NNT</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>22.7%</td>
<td>79%</td>
<td>2.48%</td>
<td>56.3%</td>
<td>2</td>
<td>0.0022</td>
</tr>
</tbody>
</table>

The Gilling et al. was also a double blind, randomized controlled trial that randomized 35 women with urodynamically confirmed stress UI into either the active or sham groups. The women in the active group were treated with the NeoControl chair and received 3 sessions per week for 6 weeks. Of the 70 women who were enrolled in the study, only 55 completed (21.4% loss to follow-up). “Worst case” analysis was not done on participants lost to follow-up. The participants were evaluated at baseline, 8-weeks, and 6 months. The primary outcome measure was a change in the 20-minute pad test from baseline to 8-weeks. Table 3 shows the treatment effect of the NeoControl chair on SUI. In the active group there was a statistically significant
improvement at 8-weeks for the 20-minute pad test (p<0.001), number of pads used per day (p<0.01), PFM strength, 24-hour pad test (p<0.01), I-QOL (urinary incontinence quality of life scale) (p<0.001) and KHQ (kings health questionnaire) (p<0.001) scores. In the placebo group there was a statistically significant improvement at 8-weeks for the 24-hour pad test and I-QOL score. Statistical significance was defined as a 0.67 standard deviation difference in reduction between the groups. 17% (EER) of patients in the active group and 9% (CER) of patients in the placebo group did not leak on repeat urodynamics at 8-weeks. RBI was calculated to be 0.89%. ABI was calculated to be 8%. NNT was calculated as 13.5.

Table 3: Treatment effect of NeoControl chair on stress urinary incontinence

<table>
<thead>
<tr>
<th>CER</th>
<th>EER</th>
<th>RBI</th>
<th>ABI</th>
<th>NNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>9%</td>
<td>17%</td>
<td>0.89%</td>
<td>8%</td>
<td>13</td>
</tr>
</tbody>
</table>

The study by Wallis et al. was a single blinded, randomized, placebo controlled trial of static magnetic stimulation on women aged 60 and older with UI for at least 6 months. 122 subjects entered the trial and 101 completed the trial (17.2% loss to follow up). “Worst case” analysis was not done on subjects lost to follow-up. 50 participants were randomly assigned to the active group and 51 to the placebo group. The active group received an undergarment containing 15 static magnets that they were to wear at least 12 hours per day for 3 months. The primary outcome was incontinence cessation measured by 24-hour pad test (P=0.09). Frequency and severity of symptoms were the secondary outcomes, which were measured by BFLUTS-SF (Bristol Female Lower Urinary Tract Symptoms questionnaire) (P>0.05), Incontinence Severity Index (P=0.59), Bothersomeness Visual Analog scale (P=0.21) and 24-hour bladder diary (P>0.05). Data was gathered at baseline and 12 weeks later. Table 4 shows the treatment effect
of static magnetic stimulation on UI. There were no statistically significant differences between the active and placebo groups in any of the measured outcomes from baseline to 12-weeks. However, the subjects that adhered to the protocol 85% of the time, the active group had a statistically significant decrease in the Bothersomeness score at 12-weeks (P=0.02). RBI was calculated to be 0.57%. ABI was calculated to be 20.5%. NNT was calculated to be 56.

Table 4: Treatment effect of static magnetic stimulation on UI

<table>
<thead>
<tr>
<th>CER</th>
<th>EER</th>
<th>RBI</th>
<th>ABI</th>
<th>NNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>36%</td>
<td>56.5%</td>
<td>0.57%</td>
<td>20.5%</td>
<td>5</td>
</tr>
</tbody>
</table>

There appears to be few adverse events and magnetic stimulation was generally well tolerated and safe in the three articles reviewed. The But4 study reported that one patient experienced acute onset of pre-existent lumbar-ischialgia, which resolved with removal of the Pulsegen device. Two other patients in the But4 study experienced a pulsating sensation in the lower abdomen and perineum.

**DISCUSSION**

This selective evidence based medicine review investigated three randomized controlled trials to determine whether or not magnetic stimulation is an effective treatment for women with UI. None of the studies selected provided definitive evidence that magnetic stimulation is an effective treatment modality for UI.

The results of the But4 study are generalizable to female patients with UI and suggest that magnetic stimulation with the Pulsegen may be a good conservative treatment for urinary incontinence. However, the RBI of 2.48% is small and suggests that the treatment is not much more effective when compared to the placebo. ABI suggests that 56.3% of patients will have
improvement of urinary incontinence symptoms if they use magnetic stimulation instead of nothing. Some limitations of the study include: patient compliance, small sample size, unequal distribution between active and placebo groups, and inability of study to determine the rate of the placebo effect.

The results of the Gilling et al. study are generalizable to women with UI described in my clinical question. Although p-values suggest statistically significant improvement of UI with NeoControl chair, comparing changes in each variable from baseline between groups using ANOVA showed no statistically significant difference in any outcome measure at 8 weeks or 6 months. Calculated RBI of 0.89% and ABI of 8% are small values and suggest that the treatment is not more effective when compared to placebo. Some limitations of the study include: small sample size, 21.4% loss to follow-up, unforeseen effects of pelvic floor muscle training.

The results of the Wallis et al. study are generalizable to women with UI. There were no statistically significant differences in the outcome measures between baseline and 12 weeks for the treatment and control groups. On the subjective measure (when patients were asked at the end of study whether their UI had improved) there was a statistically significant difference between the active and control groups (p=0.04). However, once sensitivity analysis was done, the benefit was no longer statistically significant. The calculated RBI of 0.57% and ABI of 20.5% are small and suggest that the treatment is not more effective when compared to placebo. Some limitations of the study include: poor patient compliance because of garment issues (uncomfortable, visible under clothing), placebo effect, and difficulty blinding because the magnets attracted metal objects.

CONCLUSIONS
In theory, magnetic stimulation appears to be a promising treatment modality for UI. However, based on the results of reviewed studies, magnetic stimulation does not appear to be an effective treatment modality for UI. Statistical significance was only attained by the But⁴ study, which did not perform sensitivity analysis to rule out placebo effect. I can therefore conclude that the reviewed studies demonstrated no definitive evidence that magnetic stimulation is an effective treatment for UI. Due to the pervasiveness of UI in women, future study of non-invasive treatments such as magnetic stimulation for treatment is warranted.
References

1. DuBeau C. Epidemiology, risk factors, and pathogenesis of urinary incontinence.


