Electrical Stimulation for Urinary Incontinence in Women: A Systematic Review

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ABSTRACT

Background: Electrical stimulation is commonly recommended to treat urinary incontinence in women. It includes several techniques that can be used to improve stress, urge, and mixed symptoms. However, the magnitude of the alleged benefits is not completely established.

Objectives: To determine the effects of electrical stimulation in women with symptoms or urodynamic diagnoses of stress, urge, and mixed incontinence.

Search Strategy: Our review included articles published between January 1980 and January 2012. We used the search terms “urinary incontinence”, “electrical stimulation”, “intravaginal”, “tibial nerve” and “neuromodulation” for studies including female patients.

Selection Criteria: We evaluated randomized trials that included electrical stimulation in at least one arm of the trial, to treat women with urinary incontinence.

Data Collection and Analysis: Two reviewers independently assessed the data from the trials, for inclusion or exclusion, and methodological analysis.

Main Results: A total of 30 randomized clinical trials were included. Most of the trials involved intravaginal electrical stimulation. Intravaginal electrical stimulation showed effectiveness in treating urge urinary incontinence, but reported contradictory data regarding stress and mixed incontinence. Tibial-nerve stimulation showed promising results in randomized trials with a short follow-up period. Sacral-nerve stimulation yielded interesting results in refractory patients.

Conclusions: Tibial-nerve and intravaginal stimulation have shown effectiveness in treating urge urinary incontinence. Sacral-nerve stimulation provided benefits in refractory cases. Presently available data provide no support for the use of intravaginal electrical stimulation to treat stress urinary incontinence in women. Further randomized trials are necessary to determine the magnitude of benefits, with long-term follow-up, and the effectiveness of other electrical-stimulation therapies.

INTRODUCTION

Urinary incontinence is a common health problem in the female population. It results in limitations to daily activity and quality of life (1,2). About 25% of women between 15 and 64 years old and more than 50% of those attended in geriatric clinics are incontinent (3).
and mixed (urinary) incontinence (MUI) is the complaint of involuntary loss of urine associated with urgency and also with effort or physical exertion, or upon sneezing or coughing (4).

Current guidelines recommend conservative management, defined as interventions that do not involve treatment with drugs or surgery targeted to the type of incontinence, as a first-line therapy in urinary incontinence (5,6).

Electrical stimulation (ES) is a therapeutic option for patients with UI. It includes the suprapubic, transvaginal, sacral and tibial nerves (5,7).

Functional ES of the muscles of the pelvic floor was originally proposed by Caldwell in 1963 to address faecal and urinary incontinence. Since then, clinical trials have reported some efficacy in treating SUI, UUI and MUI (7,8). The electrodes can be implantable or not, and the electrical stimulation can be of long or short duration (9).

The exact mechanism involved in improvement of urinary symptoms through electrical stimulation is not completely understood. Reorganization of spinal reflex and regulation of cortical activity are suggested as important outcomes of electrical stimulation, which would be related to the mechanism of action of this therapy (10). The mechanism of action of ES was initially investigated in animal models, where it caused bladder relaxation by inhibiting the parasympathetic motor neurons. Other studies showed that transvaginal ES causes contractions of the pelvic floor, increasing the number of muscle fibers with rapid contraction, which are responsible for continence in situations of stress (9).

Sacral-nerve stimulation consists of implantation of a wire electrode in one of the sacral foramina, usually S3, which is then connected to a stimulator device. Usually it is used for refractory urinary incontinence and idiopathic urinary retention (9,11).

Tibial nerve electrical stimulation is a peripheral non-implantable method that can be applied percutaneously with a needle or transcutaneously with a stick-on electrocardiograph-type electrode (9). It was described by Mc-Guire in 1983 (12). Tibial-nerve stimulation delivers neuromodulation to the pelvic floor through the S2-S4 junction of the sacral nerve plexus via the less invasive route of the posterior tibial nerve. This anatomical area has projections to the sacral nerve plexus, creating a feed-back loop that modulates bladder innervations (13-15).

Suprapubic electrical stimulation aims for a direct stimulation of S3 nerve roots, in order to inhibit the detrusor activity, similarly to the sacral electrical stimulation, but less invasive (16).

This systematic review assessed published randomized trials on electrical stimulation, used to treat urinary incontinence in women.

**MATERIALS AND METHODS**

We performed an extensive electronic systematic review, searching through the Pubmed, Embase and Lilacs databases. We used a combination of the following terms: “urinary incontinence”, “electrical stimulation”, “intravaginal”, “tibial nerve”, and “neuromodulation” in trials including female patients. This search was performed according to the PRISMA Statement (17).

Two reviewers independently assessed data from trials, for inclusion or exclusion and methodological analysis. The inclusion criteria were: randomized trials, published between January 1980 and January 2012, and patients with symptoms or urodynamic diagnosis of SUI, UUI, and MUI. Electrical stimulation was used in at least one arm of the trial, and with clearly described methodology. We excluded trials with patients with neurological disease, a language other than English, Spanish or Portuguese, or no outcomes related to urinary incontinence (scale validation, for example). We subdivided the articles into groups according to each specific electrical stimulation therapy: intravaginal, tibial, sacral, or suprapubic. When applicable, we presented the results according incontinence types (stress, urge or mixed).

We analyzed results of each group (median and range of mean values), comparing available baseline and outcome clinical data (women’s observation, quantification, clinician’s observation, and quality of life). In addition we compared the control or the other study group with each electrical stimulation subgroup.

**RESULTS**

We initially identified 763 articles through the electronic search. We evaluated the full text of 63 publications, and selected 30 randomized trials for inclusion (Figure-1).

The studies were divided into subgroups, according to the therapy studied: 21 investigated intravaginal electrical stimulation, 6 tibial nerve, 2 sacral stimulation, and 1 suprapubic.

**Intravaginal Electrical Stimulation**

Twenty-one randomized trials included intravaginal electrical stimulation treatment for incontinent women. Ten of them analyzed women...
with stress urinary incontinence, nine included urge urinary incontinence, and four focused on women with mixed incontinence. Two of 21 articles analyzed included stress and urge incontinence in the same paper, but we analyzed separately each complaint on the same paper.

We described the results of intravaginal therapy according to the type of incontinence.

**Stress Urinary Incontinence**

Ten trials to treat stress urinary incontinence were included with a total of 765 patients (18-27). Most patients in all trials were close to 50 years of age. The most important outcomes of each paper are described in Table-1.

The articles described different frequencies and durations of therapies, from twice daily to once per week in frequency, and from 6 weeks to 6 months in duration, with a wide variability in the designs.

Most articles (8/10) used 50 Hz as stimulation frequency, and intensities up to 100 mA (7/10).

The most frequent outcome measure used was subjective satisfaction, used in all papers; bladder diary was used in eight; pad test in six; and quality-of-life questionnaires in six, in a total of 10 papers.

Goode et al. published the trial with the largest sample analyzing 200 patients comparing IVES, behavioral training and self help booklet. Significant improvement related to baseline was established in all groups, with no difference between groups. (18).

IVES, PFMT, Vaginal Cones and no treatment were compared in 2 trials (21,23). While Castro et al. observed a statistically significant reduction in the pad test, in subjects who used pelvic floor exercises, electrical stimulation, and vaginal cones compared to the control group; Bo et al. found that reduction in leakage on pad test was greater in the exercise group than in the others.

**Figure 1 - Flow of articles through different phases of the systematic review.**

763 articles identified through database searching

511 articles included for title-abstract evaluation after duplicates removed

448 articles excluded based on inclusion criteria

33 full-text articles excluded
2 Full text in a language other than English, Spanish, Portuguese (1 Icelandic, 1 Chinese)
5 Neurological diseases
6 Electromagnetic stimulation
13 No evaluated outcomes related to urinary incontinence
4 Not randomized
3 No urinary incontinence

30 randomized trials included
<table>
<thead>
<tr>
<th>First Author/ Year</th>
<th>N</th>
<th>Comparison (s) group (s)</th>
<th>Outcome measures</th>
<th>Clinical outcomes</th>
<th>Significance between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alves 2011 (19)</td>
<td>20</td>
<td>IVES medium x low frequency</td>
<td>Pad Test</td>
<td>Significant improvement related to baseline in both groups. No difference between groups.</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td>Santos 2009 (20)</td>
<td>45</td>
<td>IVES x vaginal cones</td>
<td>Pad Test, QoL, Bladder Diary</td>
<td>Significant improvement related to baseline in both groups. No difference between groups.</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td>Castro 2008 (21)</td>
<td>101</td>
<td>IVES x PFMT x Vaginal Cones x No treatment</td>
<td>Pad Test, QoL-IQOL, Bladder Diary</td>
<td>Significant improvement related to baseline and no treatment in both groups. No difference between treatment groups.</td>
<td>Treatment x No treatment: p &lt; 0.001 (QoL), p = 0.003 (pad test), p &lt; 0.001 (bladder diary)</td>
</tr>
<tr>
<td>Seo 2004 (22)</td>
<td>120</td>
<td>IVES x Vaginal cones</td>
<td>Pad Test, Subjective</td>
<td>Significant improvement related to baseline in both groups. No difference between groups</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td>Goode 2003 (18)</td>
<td>200</td>
<td>IVES x Behavioral training x Self help booklet</td>
<td>QoL-IIQ, SF-36, Bladder Diary</td>
<td>Significant improvement related to baseline in both groups. No difference between groups</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td>Bo 1999 (23)</td>
<td>107</td>
<td>IVES x PFMT x Vaginal Cones x No treatment</td>
<td>Pad Test, Bladder Diary</td>
<td>Significant improvement PFMT related to IVES, Vaginal cones and No treatment.</td>
<td>p = 0.01 (bladder diary), p = 0.038 (pad test), p &lt; 0.001 (subjective)</td>
</tr>
<tr>
<td>Luber 1997 (24)</td>
<td>44</td>
<td>IVES x Sham therapy</td>
<td>Bladder Diary, Subjective, Urodynamics</td>
<td>No difference between groups</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td>Brubaker 1997 (25)</td>
<td>60</td>
<td>IVES x Sham therapy</td>
<td>Bladder Diary, QoL, Urodynamics, Subjective</td>
<td>No difference between groups</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td>Smith 1996 (26)</td>
<td>18</td>
<td>IVES x PFMT</td>
<td>Bladder Diary, Subjective</td>
<td>Significant improvement related to baseline in both groups. No difference between groups.</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td>Sand 1995 (27)</td>
<td>52</td>
<td>IVES x Sham therapy</td>
<td>Pad Test, QoL-IQOL, Bladder Diary</td>
<td>Significant improvement IVES related to sham. No difference in QoL.</td>
<td>p &gt; 0.05 (QoL), p = 0.01 (pad test), p = 0.02 (bladder diary)</td>
</tr>
</tbody>
</table>

**IVES** = Intravaginal Electrical Stimulation / **QoL** = Quality of Life Questionnaire / **PFMT** = Pelvic Floor Muscle Training / **IQoL** = Incontinence Quality of Life Questionnaire / **IIQ** = Incontinence Impact Questionnaire / **SF-36** = Short Form 36 Health Survey
IVES versus sham therapy was evaluated in 3 trials (24,25,27). Although Sand et al. found significant improvement in the active pelvic floor stimulator comparing to sham device in pad test, bladder diary and subjective self report of leakage, no difference was demonstrated in QoL.

Urge Urinary Incontinence

Nine trials to treat urge urinary incontinence were included with total of 534 patients (25,26,28-34). Most patients in the trials were close to 55 years of age. The most important outcomes of each paper are described in Table-2.

Five articles (total of nine) described a frequency of twice-weekly therapy and sessions of 20 minutes. Twelve weeks was the most common duration of therapy (3/9), ranging from 4 to 16 weeks. All the studies applied an intensity of stimulation below 100 mA, and four of them (4/9) used 10 Hz as the frequency.

The most frequent outcome measure was bladder diary, used in all papers; subjective satisfaction was used in 8; and quality-of-life questionnaires in 6, from a total of 9 papers.

Wang et al. described the largest sample with 103 patients, comparing IVES, PFMT and BAPFMT (28). IVES had the greatest subjective improvement and was the most effective of the three treatments. BAPFMT was more effective than PFMT.

Five trials compared IVES and anticholinergic drugs (26,29-32). All reported significant improvement related to baseline in both groups; however, Wang et al. found significant improvement in IVES related to Oxybutinin and placebo.

Mixed Urinary Incontinence

Four trials to treat mixed urinary incontinence were included with a total of 143 patients (35-38). Most patients in the trials were close to 50 years of age. The most important outcomes of each paper are described in Table-3.

The frequency of sessions was between twice daily and 3 times a week; the duration of therapies ranged between 7 and 12 weeks. All papers applied an intensity of stimulation below 100 mA, and a range of 4 to 50 Hz as the frequency.

The most frequent outcome measures were subjective satisfaction (2/4), bladder diary (2/4), and pad test (2/4). Quality-of-life questionnaire was applied in 1 paper.

Amaro et al. had the largest sample, that included 40 patients, comparing IVES and sham therapy (35). In the 60-min pad test and in the subjective satisfaction level, there was a significant reduction in both groups, with no significant difference between them.

Tibial Nerve Electrical Stimulation

Six randomized trials provided data on the use of tibial nerve stimulation for treatment of urge urinary incontinence (39-44). These trials included a total of 426 women, Peters et al. had the largest sample analyzing 174 women (39). Mean ages in the trials ranged from 40.3 to 68.9 years of age. The most important outcomes of each paper are described in Table-4.

The frequency of sessions was weekly in all papers, with a duration of 30 minutes for 12 weeks in most of them (4/6). Five papers applied an intensity of stimulation below 10 mA, 20 Hz as the frequency and use percutaneous technique (Urgent PC device).

The most frequent outcome measures were bladder diary (6/6), quality of life (5/6), and subjective satisfaction (4/6).

Peters et al. had the largest sample analyzing 174 women, comparing PTNS and sham therapy (39). They reported significant improvement related to baseline in both groups although significant improvement was seen in the PTNS group related to sham therapy.

Three trials compared IVES and anticholinergic drugs (41-43). All reported significant improvement related to baseline in both groups, nevertheless, two of them found significant improvement PTNS group related to medication.

Sacral Stimulation

Based on our criteria, we identified only two randomized trials evaluating sacral-nerve stimulation in urge urinary incontinence. One hundred twenty-seven women were evaluated in these papers. Both trials were done using the Interstim Device, and included patients who were refractory to previous treatments. The mean age in the papers was close to 40 years of age.

Schmidt et al. demonstrated significant improvement in urge urinary incontinence in a one-day bladder diary in the sacral-nerve group, compared to the control group (p < 0.001) and this benefit was sustained after 18 months (45).

Hassouni et al. demonstrated significant (p < 0.05) sacral stimulation benefits in quality of life (SF-36), voiding parameters, and refractory urgency frequency symptoms, compared to a standard medical treatment group (46).
<table>
<thead>
<tr>
<th>First Author/ Year</th>
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<th>Comparison (s) group (s)</th>
<th>Outcome measures</th>
<th>Clinical outcomes</th>
<th>Significance between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Franzén 2010 (29)</td>
<td>61</td>
<td>IVES x Tolterodine 4mg once daily</td>
<td>Bladder Diary QoL- KHQ Subjective</td>
<td>Significant improvement related to baseline in both groups. No difference between groups.</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td>Ozdedeli 2008 (30)</td>
<td>31</td>
<td>IVES x Trospium 45mg/ day</td>
<td>Bladder Diary QoL-IIQ Subjective</td>
<td>Significant improvement related to baseline in both groups. No difference between groups.</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td>Arruda 2007 (31)</td>
<td>64</td>
<td>IVES x Oxybutinin 10mg/ day x PFMT</td>
<td>Bladder Diary Subjective</td>
<td>Significant improvement related to baseline in both groups. No difference between groups.</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td>Wang 2006 (32)</td>
<td>68</td>
<td>IVES x Oxybutinin 7.5 mg/ day x Placebo</td>
<td>Pad Count QoL- KHQ</td>
<td>Significant improvement in IVES related to Oxybutinin and placebo. Significant improvement related to baseline in IVES and Oxybutinin.</td>
<td>Pad count/24h p = 0.018 (x Oxy) p = 0.012 (x plac) QoL - KHQ total p &lt; 0.001 (x Oxy) p = 0.006 (x plac)</td>
</tr>
<tr>
<td>Wang 2004 (28)</td>
<td>103</td>
<td>IVES x PFMT x BAPFMT</td>
<td>QoL Subjective</td>
<td>Significant improvement in IVES and BAPFMT related to PFMT. No subjective differences between groups.</td>
<td>QoL - KHQ total p = 0.952 (x BAPFMT) p = 0.004 (x PFMT) Subjective p = 0.567.</td>
</tr>
<tr>
<td>Berghans 2002 (33)</td>
<td>68</td>
<td>IVES x PFMT x IVES+PFMT x No treatment</td>
<td>DAI</td>
<td>Significant improvement IVES related to no treatment.</td>
<td>Treatment x no treatment) DAI p = 0.032</td>
</tr>
<tr>
<td>Yamanishi 2000 (34)</td>
<td>68</td>
<td>IVES x Sham therapy</td>
<td>Bladder Diary QoL Subjective</td>
<td>Significant improvement IVES related to sham therapy.</td>
<td>Bladder diary p = 0.006 Quality of life p = 0.045</td>
</tr>
<tr>
<td>Brubaker 1997 (25)</td>
<td>33</td>
<td>IVES x Sham therapy</td>
<td>Subjective Urodynamic</td>
<td>Significant improvement IVES related to sham therapy.</td>
<td>Subjective P = 0.027 Urodynamic p = 0.004</td>
</tr>
<tr>
<td>Smith 1996 (26)</td>
<td>38</td>
<td>IVES x Propantheline bromide</td>
<td>Bladder Diary Subjective</td>
<td>Significant improvement related to baseline in both groups. No difference between groups.</td>
<td>p &gt; 0.05</td>
</tr>
</tbody>
</table>

**IVES** = Intravaginal Electrical Stimulation  /  **QoL** = Quality of Life Questionnaire  /  **KHQ** = Kings Health Questionnaire  /  **IIQ** = Incontinence Impact Questionnaire  /  **PFMT** = Pelvic Floor Muscle Training  /  **Oxy** = Oxybutinin  /  **Plac** = Placebo  /  **BAPFMT** = Biofeedback-Assisted Pelvic Floor Muscle Training  /  **DAI** = Detrusor Activity Index
Table 3 - Outcome parameters of intravaginal stimulation in mixed urinary incontinence.

<table>
<thead>
<tr>
<th>First Author/ Year</th>
<th>N</th>
<th>Comparison (s) group (s)</th>
<th>Outcome Measures</th>
<th>Clinical outcomes</th>
<th>Significance between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schmidt 2009 (36)</td>
<td>32</td>
<td>IVES x Biofeedback x PFMT</td>
<td>Bladder Diary</td>
<td>Significant improvement related to baseline in both groups. No difference between groups.</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>QoL-KHQ</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amaro 2006 (35)</td>
<td>40</td>
<td>IVES x Sham therapy</td>
<td>Pad test</td>
<td>Significant improvement related to baseline in both groups. No difference between groups.</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Subjective</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barroso 2004 (37)</td>
<td>36</td>
<td>IVES x Placebo</td>
<td>Bladder Diary</td>
<td>Significant improvement in IVES related to baseline and placebo.</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Spruijt 2003 (38)</td>
<td>35</td>
<td>IVES x PFMT</td>
<td>Pad test</td>
<td>No significant improvement related to baseline in both groups. No difference between groups.</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Subjective</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IVES = Intravaginal Electrical Stimulation / PFMT = Pelvic Floor Muscle Training / QoL = Quality of Life Questionnaire

KHQ = Kings Health Questionnaire

Suprapubic Stimulation

We found only one randomized trial that used suprapubic stimulation in urinary incontinence. This trial compared three groups: suprapubic stimulation associated with pelvic floor muscle training and bladder training, suprapubic stimulation associated with pelvic-floor muscle training, and bladder training combined with trospium and trospium alone. Forty six patients were included. The stimulation group, combined or not with trospium was superior to trospium alone in quality of life (p = 0.017) and amount of urine leakage (p = 0.079) (47).

DISCUSSION

We included 30 randomized trials in this systematic review. Most of these studies used a variety of techniques for stimulation, several comparison groups, and measurements of outcomes. Therefore, it was not possible to conduct a meta-analysis.

There was no consistency between the trials in terms of types and parameters of intravaginal electrical-stimulation (IVES). It seems that no standard protocol or “best” methodology of IVES for the treatment of women with urinary incontinence exists. IVES offers a seemingly infinite combination of current-type waveforms, frequencies, and intensities. Some clinical trials suggest using 50 Hz for stress urinary incontinence, and 10 - 20 Hz for urge urinary incontinence; and that mixed symptoms should be treated according to the predominant symptom (35,37).

Intravaginal electrical stimulation is a conservative treatment option described over 40 years ago. Its adverse events reported during the studies (vaginal irritation, occasional pain, vaginal infection, urinary tract infection) were not severe, and were reversible (18–20).

An argument in favour of IVES is that more than 30% of the women with stress urinary incontinence cannot manage to voluntarily contract the pelvic muscles adequately (37). Given the systemic side effects of current pharmacotherapy, IVES should be a good option for treatment in urge urinary incontinence (28).
<table>
<thead>
<tr>
<th>First Author/ Year</th>
<th>N</th>
<th>Comparison (s) group (s)</th>
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<th>Significance between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schreiner 2010 (40)</td>
<td>51</td>
<td>TTNS + PFMT + BR x PFMT + BR</td>
<td>QoL- KHQ, Bladder Diary, Subjective</td>
<td>Significant improvement related to baseline in both groups. Significant improvement TTNS group related to PFMT + BR</td>
<td>Bladder diary p &lt; 0.001 Subjective p = 0.0017 QoL p &lt; 0.05</td>
</tr>
<tr>
<td>Sancaktar 2010 (41)</td>
<td>38</td>
<td>PTNS + Tolterodine x Tolterodine</td>
<td>QoL- IIQ, Bladder Diary</td>
<td>Significant improvement related to baseline in both groups. Significant improvement PTNS group related to Tolterodine.</td>
<td>Bladder diary p &lt; 0.001 QoL p &lt; 0.05</td>
</tr>
<tr>
<td>Peters 2010 (39)</td>
<td>174</td>
<td>PTNS x Sham therapy</td>
<td>QoL- OAB-q, SF-36, Bladder Diary, Subjective</td>
<td>Significant improvement related to baseline in both groups. Significant improvement PTNS group related to Sham.</td>
<td>Bladder diary p &lt; 0.001 Subjective p &lt; 0.001 QoL p &lt; 0.05</td>
</tr>
<tr>
<td>Peters 2009 (42)</td>
<td>97</td>
<td>PTNS x Tolterodine</td>
<td>QoL- OAB-q, SF-36, Subjective</td>
<td>Significant improvement related to baseline in both groups. Significant improvement PTNS group related to Tolterodine. No differences in QoL between groups.</td>
<td>Bladder diary p = 0.006 Subjective p = 0.01 QoL p &gt; 0.05</td>
</tr>
<tr>
<td>Karademir 2005 (43)</td>
<td>38</td>
<td>PTNS x PTNS + Oxibutynin</td>
<td>Bladder Diary, Subjective</td>
<td>Significant improvement related to baseline in both groups. No difference between groups</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td>Finazzi Agró 2005 (44)</td>
<td>28</td>
<td>PTNS once weekly x PTNS 3 times per week</td>
<td>Bladder Diary, QoL- I-QoL, SF-36, Urodynamics, Subjective</td>
<td>Significant improvement related to baseline in both groups. No difference between groups</td>
<td>p &gt; 0.05</td>
</tr>
</tbody>
</table>

TTNS = Transcutaneous Tibial Nerve Stimulation / PFMT = Pelvic Floor Muscle Training / BR = Bladder Retraining / QoL = Quality of Life Questionnaire / KHQ = Kings Health Questionnaire / PTNS = Percutaneous Tibial Nerve Stimulation / IIQ = Incontinence Impact Questionnaire / OAB-q = Overactive Bladder Questionnaire / IQOL = Incontinence Quality of Life Questionnaire / SF-36 = Short Form 36 Health Survey

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Randomized trials evaluating intravaginal stimulation for stress urinary incontinence showed beneficial results with respect to the baseline symptoms. Only three papers compared sham vs. active therapy; two of them described no significant superiority of stimulation, which is explainable by a pelvic-floor-muscle-training effect of the sham vaginal probe in those patients, or a placebo effect in both groups.

Two studies on stress urinary incontinence showed a significant improvement when comparing stimulation with no treatment. However, in other trials, any of the treatment groups (vaginal cones, pelvic floor muscle training, behavioural training and self-help booklet) had the same or better effectiveness than intravaginal electrical stimulation in stress urinary incontinence.

Although intravaginal electrical stimulation is used worldwide, with few adverse effects, low cost, and easily available, there are not sufficient data in comparative randomized trials to characterize intravaginal electrical stimulation as an effective therapy for stress urinary incontinence. When compared with other therapies, even those that are less invasive such as pelvic-floor muscle training, it appears to provide inferior results. Therefore, the available data do not support the use of this technique in this group of patients.

In respect to intravaginal electrical stimulation to treat urge urinary incontinence, two trials compared active to sham therapy, and both showed superiority of the active therapy as evaluated by bladder diary, quality of life, urodynamics and subjective parameters. IVES showed no significant difference in effectiveness when compared with pharmacotherapy in 4 of 5 trials and it was superior in one of them (pad count an quality of life and pad count).

If we consider the relatively few adverse effects, low cost, and similar effectiveness when compared to pharmacotherapy, intravaginal electrical stimulation, according to available data, appears to be a good alternative treatment for urge urinary incontinence. Most of papers used a twice-weekly therapy, sessions of 20 minutes during twelve weeks with a 10 Hz frequency.

All trials (four) about intravaginal stimulation in mixed incontinence had small samples, which is a limitation for an adequate analysis of this type of incontinence. One of the trials used a sham group for comparison, and reported no significant benefit related to the baseline, or between groups. We found contradictory results about mixed incontinence. Little information was available about the predominant symptoms (urge or stress) in this subgroup of patients, and this factor may determine the results of therapy.

Among the tibial nerve stimulation trials, a large randomized study compared the technique with sham therapy, showing significant improvement in quality of life, bladder diary, and subjective outcomes. Other trials compared stimulation with pharmacotherapy (three trials), pelvic-floor muscle training plus bladder retraining (one trial) and confirmed the superiority of tibial-nerve therapy.

Tibial-nerve stimulation has shown promising initial results in large trials of urinary incontinence. However, a long follow-up period is needed to establish whether this benefit is sustained over time. We found no trials that compared the difference between percutaneous and transcutaneous techniques.

Sacral-nerve stimulation was evaluated in two randomized trials in patients with refractory urinary incontinence. This group was characterized by severe incontinence, and even so they showed significant improvement. Because this is an invasive and expensive therapy, some restrictions must be placed on its evaluation in a non-refractory group of patients. A comparison with other therapies that have been used in refractory patients (botulin toxin, for example) is necessary to determine the best option for use with refractory patients.

Very few data from randomized trials were available about suprapubic stimulation. The only paper included pelvic floor muscle training and biofeedback in both groups of suprapubic stimulation, therefore we can’t attribute the improvement to electrical stimulation itself. Further studies need to be done, in order to evaluate the true value of this therapy.

Reports about electrical stimulation generally lack information on its cost-effectiveness. This is an important point, especially because in therapies with similar benefits, cost may be one of the factors to indicate the most appropriate treatment.

Any of papers reported significant complications related to the therapies, which is a point to be considered when choose the therapy to each patient.

CONCLUSIONS

Electrical stimulation is increasingly indicated in urinary incontinent patients worldwide, especially with tibial-nerve and sacral stimulation. However, few randomized trials have focused on the true benefits of this group of therapies.
Intravaginal stimulation has proved to provide some benefit in urge urinary incontinence, but shows contradictory results in the treatment of stress and mixed incontinence. Evaluation of efficacy remains inconclusive because of the variations in stimulation parameters, and presently available data provide no support for the use of IVES to treat SUI patients.

 Tibial nerve stimulation showed promising results in recent papers with few adverse effects and contraindications. However, a long follow-up period is necessary to determine whether these results persist over time. Sacral-nerve stimulation has shown interesting results in refractory patients, although comparative trials with other therapies used to treat refractory cases are needed.

### ABBREVIATIONS

ICS = International Continence Society  
UI = Urinary Incontinence  
SUI = Stress Urinary Incontinence  
UUI = Urge Urinary Incontinence  
MUI = Mixed Urinary Incontinence  
ES = Electrical Stimulation  
IVES = Intravaginal Electrical Stimulation.

### CONFLICT OF INTEREST

None declared.

### REFERENCES


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