Effect of electrical stimulation on stress and urge urinary incontinence: clinical outcome and practical recommendations based on randomized controlled trials

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Authors' objectives
To review the literature on randomised controlled trials (RCTs) on the effectiveness of electrical stimulation to treat urge and stress urinary incontinence.

Searching
MEDLINE was searched from 1980 (end date unclear) for full-length articles published in the English, German or Scandinavian languages. Abstracts were excluded from the review; however, any supportive or conflicting results published in abstracts were referred to in the discussion. The proceedings of the International Continence Society (1984 to 1996) were searched manually. Additional studies were also identified by examining the bibliographies of retrieved articles and other reviews.

Study selection
Study designs of evaluations included in the review
RCTs comparing electrical stimulation with placebo or control groups, or other modalities including PFM exercise. The author stated that studies with consecutive allocation and those involving other treatments in combination with electrical stimulation were excluded from the review. However, studies including combinations of treatments, e.g. electrical stimulation and PFM exercises compared with PFM exercises alone, were included.

Specific interventions included in the review
The following interventions were included in the review: electrical stimulation (various regimens including interferential therapy, long term and maximal stimulation), compared with pelvic floor muscle (PFM) exercise (various regimens), and propantheline bromide (7.5 to 45 mg, 2 to 3 times per day). Combinations of the above interventions were also included as treatment groups.

Participants included in the review
Females with stress urinary incontinence and urge incontinence were included. Studies featuring continent women and pregnant or postpartum women were excluded from the review.

Outcomes assessed in the review
The outcomes included PFM strength and function, as assessed by various devices to measure vaginal squeeze pressure, and self-reported improvement in urinary voiding.

How were decisions on the relevance of primary studies made?
The author does not state how the papers were selected for the review, or how many of the reviewers performed the selection.

Assessment of study quality
The author does not state that they assessed quality.

Data extraction
The author does not state how the data were extracted for the review, or how many of the reviewers performed the data extraction.
Methods of synthesis
How were the studies combined?
The studies were combined in a narrative according to the following: study design; sample size; electrical stimulation parameters; intervention description; self-reported and measured outcomes; duration of treatment; evaluation of PFM function; and strength improvement.

How were differences between studies investigated?
A narrative discussion of the differences between the studies was included in the results section.

Results of the review
Nine RCTs were included: 1 long-term electrical stimulation study, 2 interferential therapy studies, and 6 maximal stimulation studies. Only one study evaluated the effect on urge incontinence.

The studies varied in terms of the sample size (n=14 to n=56); the drop-out rates (0 to 27%); whether or not they reported any information on patient adherence; whether electrical intervention was compared with placebo, control or another intervention; what equipment and regimens were used; and how PFM strength was measured.

PFM strength (6 studies).

One study did not provide any data. Two studies (one interferential and one maximal stimulation study) demonstrated a significant improvement in strength when compared with placebo. Three studies failed to find any significant improvements.

Self reported outcomes (6 studies).

One study using a visual analogue assessment scale demonstrated a significant improvement after interferential stimulation when compared with placebo. Another study demonstrated a significant improvement in most of the self-reported outcome measures used, compared with a control group. Four studies failed to find any significant improvement in the self-reported variables.

Leakage or urodynamic assessment (7 studies).

Two of the 9 studies failed to measure leakage or urodynamic variables. Five studies measured leakage, of which 4 used pad testing before and after treatment. All demonstrated a significant improvement after electrical stimulation. One study measured the number of leakage episodes.

Four studies measured urodynamic variables. One study demonstrated an improvement in some urodynamic measures after electrical stimulation, whilst the remaining 3 studies failed to demonstrate any significant improvements.

Side-effects (5 studies).

Side-effects were reported in 4 out of the 9 studies. These included vaginal irritation and infection, pain, discomfort, and urinary tract infections. One study reported that no side-effects were found. In one of the larger studies, side-effects were reported in around half of the women in either group.

Authors' conclusions
The results of RCTs evaluating the effect of electrical stimulation to treat stress and urge urinary incontinence, were conflicting. There is a need for more RCTs with sufficient sample sizes, which use sensitive, reproducible and valid outcome measures, and optimal stimulation parameters. Based on the recent knowledge, PFM exercise should be the first choice of treatment for stress urinary incontinence.

CRD commentary
In general, this was a clearly presented review although the author failed to adequately describe some of the research
methods. For instance, it was unclear how the relevance of the studies was assessed, and how the data were extracted from the included studies. It would also appear that the studies were not assessed for quality, although by including only RCTs the author should be focusing the findings on the highest level of experimental evidence available.

The search used by the author appeared to be adequate, although relevant information may have been missed as a result of limiting the literature to only those articles published in the English, German or Scandinavian languages. The search terms used to retrieve the articles were not provided, making it difficult to comment further on the validity of the search or for other researchers to repeat the author's methods. Taking into consideration the heterogeneity between the studies, the use of a narrative summary of results appears to have been appropriate in this case.

Overall, from the results presented, it would appear that the conclusions and implications for further research are valid.

**Implications of the review for practice and research**

**Practice:** The author states 'electrical stimulation should be used as a first step for women not able to contract the PFM. The therapists have to assess whether the stimulators cause a correct contraction or not. When the women are able to contract voluntarily, they should continue with an intensive PFM exercise programme'.

**Research:** The author states 'there is a need for more randomised controlled studies with optimal electrical stimulation protocols'; 'studies have to be conducted with all of the different devices in use'; 'future research has to apply sensitive, reproducible and valid instruments to measure PFM strength, self report of the condition and measurement of leakage'; 'long treatment periods (6 months) and adequate sample sizes are mandatory'.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.