18

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HOW EFFECTIVE IS ELECTRICAL STIMULATION WITH NON-IMPLANTED DEVICES IN THE MANAGEMENT OF STRESS URINARY INCONTINENCE IN WOMEN? A COCHRANE REVIEW OF RANDOMISED CONTROLLED TRIALS.

Hypothesis / aims of study
To determine the effectiveness of electrical stimulation (ES) with non-implanted devices for stress urinary incontinence (SUI) in women compared to other treatments or no active treatment.

Study design, materials and methods
Trials have been identified through the Cochrane Incontinence Group Specialised Register, bibliographic databases, clinical trials registries and reference lists of relevant articles (searched November 2015). Trials including women with mixed urinary incontinence (non stress-predominant) or women with urgency incontinence were excluded, unless data were presented separately for women with SUI. Risk of bias was assessed using the Cochrane Collaboration's risk of bias tool and the GRADE approach was used to assess the quality of evidence. The primary outcomes were subjective cure or improvement, and quality of life (QoL) due to SUI. An important secondary outcome was the risk of adverse effects.

Results
Fifty-five eligible trials were identified (3792 women), several of which were three- or four-arm trials. Twenty-two trials compared ES to sham or no treatment, 33 to conservative treatment, two to drug therapy (oestrogen), 16 compared ES plus another treatment versus the other treatment alone and four compared different types of ES to each other. The risk of bias was generally unclear in most domains.

Low quality evidence suggested that ES was more effective than no treatment or sham ES in terms of subjective cure or improvement (relative risk [RR] 2.48, 95%CI 1.31 to 4.71) (figure 1). Adding ES to pelvic floor muscle training (PFMT) was slightly more effective than PFMT alone for subjective cure or improvement (RR 1.16, 95%CI 1.00 to 1.35; 6 trials, n = 323); again, this was based on low quality evidence and heterogeneity between the trials was high.

Regarding subjective cure or improvement, low or very low quality evidence indicated that there was no evidence of a difference when ES was compared to PFMT (RR 0.89, 95%CI 0.62 to 1.29; 6 trials, n = 191) or vaginal cones (RR 1.08, 95%CI 0.98 to 1.19; 4 trials, n = 280)

One small trial (n = 39) compared ES to PFMT plus vaginal cones and another (n = 50) compared ES to oestrogen. Neither showed any evidence of a difference in terms of subjective cure or improvement (RR 1.39, 95% CI 0.73 to 2.65 and RR 13.89, 95%CI 0.84 to 230.82, respectively; very low quality evidence). Based on a further single trial (n = 120), there was no evidence of a difference between ES plus surgery and surgery alone for subjective cure or improvement (RR 1.07, 95%CI 0.99 to 1.17) (very low quality evidence).

ES was more effective than no treatment or sham ES in improving Incontinence Quality of Life questionnaire scores (mean difference (MD) 28.87, 95%CI 22.17 to 35.56; 2 trials, n = 144). A similar effect was shown for QoL measured with other instruments (standardised mean difference (SMD) -0.81, 95%CI -1.07 to -0.55; 4 trials, n = 275) (low quality evidence).

Low quality evidence indicated that there was no evidence of a difference in QoL when ES was compared to PFMT or vaginal cones or when comparing ES plus PFMT to PFMT alone.

Adverse effects were reported by ten trials (18%) and included discomfort, vaginal irritation and bleeding. Low or very low quality evidence indicated that there was no evidence of a difference in adverse effects when ES was compared to:

- Sham ES (RR 2.01 95%CI 0.52 to 7.67; 4 trials, n = 233)
- PFMT (RR 5.00, 95%CI 0.25 to 99.16; 3 trials, n = 121)

A single small trial (n = 52) comparing ES to vaginal cones found no evidence of a difference in adverse effects (RR 0.54, 95%CI 0.11 to 2.70; very low quality evidence).

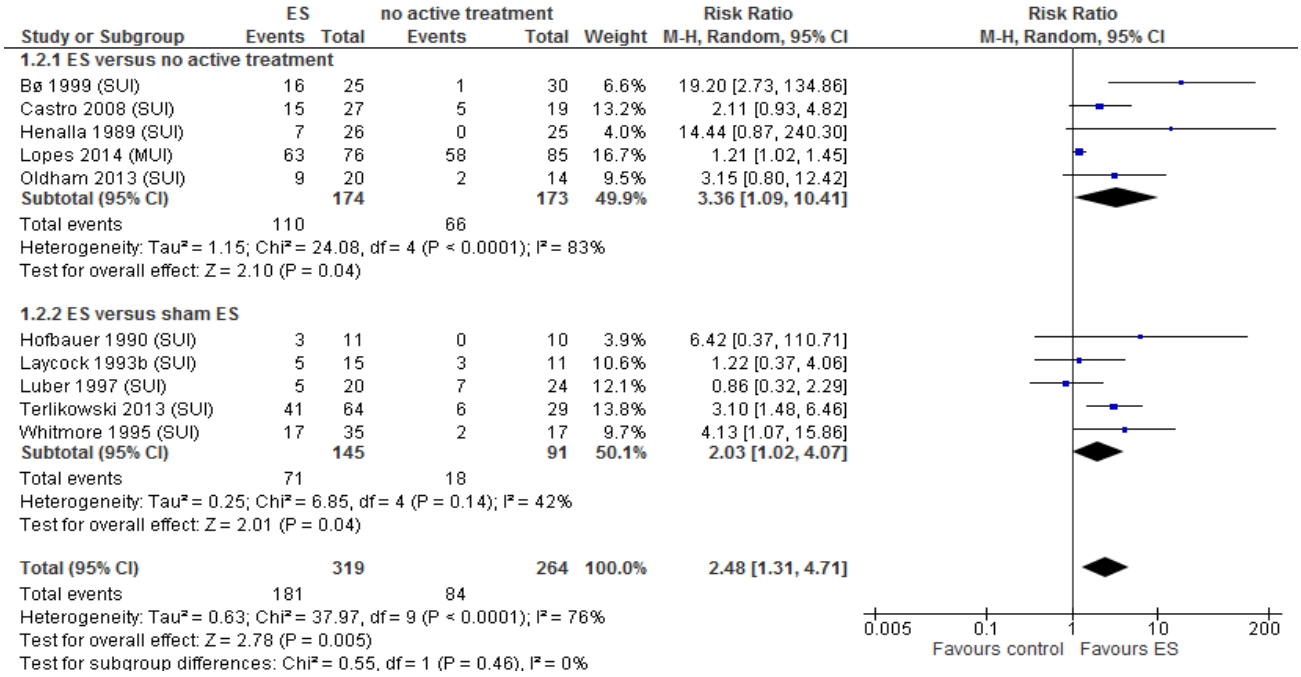
There was insufficient evidence to compare one type of electrical stimulation to another.

Interpretation of results
ES appears to be more effective than no treatment but may not be more effective than other conservative treatments. Some limited evidence suggests that ES may enhance the effects of PFMT and it may also increase incontinence-related quality of life. Inconclusive evidence from single small trials means it is unclear if ES is more effective than oestrogen or if it can enhance the effects of surgery in terms of subjective cure or improvement. It is also unclear if there is a greater risk of adverse effects with ES than with other treatments.

Concluding message

In the context of the low quality of evidence identified, it is important to exercise caution when interpreting these results. To provide a more robust evidence base, adequately powered trials with long-term follow-up should be conducted comparing ES to other conservative treatments, surgery and drug therapy. Future trials should also include head-to-head comparisons of different types of ES and should measure adverse effects.

Figure 1: ES versus no treatment or sham ES: subjective cure or improvement



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