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HOW EFFECTIVE IS ELECTRICAL STIMULATION WITH NON-IMPLANTED DEVICES IN TREATING OVERACTIVE BLADDER? A COCHRANE SYSTEMATIC REVIEW AND META-ANALYSIS

Hypothesis / aims of study

To determine the effectiveness of i) electrical stimulation (ES) with non-implanted electrodes compared to placebo or any other active treatment for overactive bladder; ii) ES added to another intervention compared to the other intervention alone; and iii) different methods of ES compared to each other.

Study design, materials and methods

We searched the Cochrane Incontinence Group Specialised Register, which contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE In-Process, EMBASE, LILACS, ClinicalTrials.gov, WHO ICTRP and hand-searching of journals and conference proceedings (searched 10 December 2014). Reference lists of relevant articles were checked and specialists in the field were contacted. We imposed no language restrictions.

We included randomised or quasi-randomised controlled trials of ES with non-implanted devices compared to any other treatment for overactive bladder in adults. Eligible trials included adults with overactive bladder with or without urgency urinary incontinence. Trials whose participants had stress urinary incontinence were excluded. Risk of bias was assessed with the Cochrane Collaboration's Risk of Bias tool. The GRADE approach was used to assess the quality of the body of evidence.

Results

We identified 51 eligible trials (3443 randomised participants). Thirty-three trials did not report the primary outcome of subjective change in overactive bladder symptoms. The majority of trials were deemed to be at low or unclear risk of selection and attrition bias and unclear risk of performance and detection bias. Lack of clarity with regard to risk of bias was largely due to inadequate reporting.

Twenty-three trials (1654 participants) compared ES with no active treatment, placebo or sham treatment. Moderate quality evidence indicated that overactive bladder symptoms were more likely to improve in people receiving ES than with no active treatment, placebo or sham treatment (relative risk [RR] for no improvement 0.54, 95% confidence interval [CI] 0.47 to 0.63) (figure 1). Moderate quality evidence indicated that similar numbers of people receiving ES and no active treatment, placebo or sham treatment experienced adverse effects (38/227 versus 31/223), which included skin irritation, urinary tract infection, vaginal pain, discomfort and tingling.

Eight trials (542 participants) compared ES with conservative treatment. Very low guality evidence suggested no evidence of a difference between ES and conservative treatment in overactive bladder symptoms. With regard to adverse effects, low quality evidence indicated no evidence of a difference between ES and conservative treatment, based on only one trial which reported that no participants in either group experienced adverse effects.

Sixteen trials (894 participants) compared ES to drug treatment (oxybutynin, solifenacin succinate, tolterodine, trospium chloride, propantheline bromide). Moderate quality evidence indicated that overactive bladder symptoms were more likely to improve with ES than drug treatment (RR for no improvement 0.66, 95% CI 0.48 to 0.90). Low quality evidence suggested a greater risk of adverse effects with oxybutynin (RR 1.26, 95% CI 1.07 to 1.49) and with tolterodine (RR 1.51, 95% CI 1.21 to 1.89) than with ES. There was insufficient evidence of a difference between ES and trospium hydrochloride in terms of adverse effects (RR 0.73, 95% CI 0.43 to 1.25).

Eight trials (252 participants) compared ES combined with another treatment to the other treatment alone, two trials (48 participants) compared ES plus conservative treatment to no active treatment, placebo or sham treatment and six trials (361 participants) compared different types of ES. None of these comparisons had sufficient evidence to indicate any differences between the treatment groups in terms of overactive bladder symptoms or adverse effects.

Moderate quality evidence suggested that ES improved overactive bladder-related quality of life more than no active treatment, placebo or sham treatment. There was insufficient evidence of any difference between ES and any other treatment with regard to quality of life.

There was insufficient evidence to determine if the benefits of ES persisted after the active treatment period stopped.

Interpretation of results

ES appears to be more effective than both no treatment and drug treatment for overactive bladder. There is insufficient evidence to determine if ES is more effective than conservative treatment or which type of ES was more effective.

Concluding message

This review confirms that ES is an effective treatment for overactive bladder but it also highlights an evidence gap whereby welldesigned, adequately powered trials, measuring subjective outcomes and adverse effects, are required to compare ES to conservative treatment, and to compare different parameters of ES compared to each other.

Figure 1: ES versus no treatment/placebo/sham: numbers of people with no improvement in OAB symptoms							
0	favours	ES	Control			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% Cl
1.2.1 ES versus no active treatment							
Monteiro 2014	0	12	9	12	4.1%	0.05 [0.00, 0.81]	<
Oldham 2013	13	50	25	47	11.2%	0.49 [0.29, 0.84]	
Subtotal (95% CI)		62		59	15.4%	0.37 [0.22, 0.63]	
Total events	13		34				
Heterogeneity: Chi ² = 2.95, df = 1 (P = 0.09); i ² = 66%							
Test for overall effect:	Z = 3.66 (I	P = 0.0	003)				
1.2.2 ES versus plac	ebo						
Wang 2006	10	24	19	21	8.8%	0.46 (0.28, 0.75)	
Wang 2009	9	26	20	23	9.2%	0.40 [0.23, 0.69]	
Subtotal (95% CI)		50		44	18.1%	0.43 [0.30, 0.62]	◆
Total events	19		39				
Heterogeneity: Chi ² = 0.15, df = 1 (P = 0.70); l ² = 0%							
Test for overall effect:	Z = 4.50 (i	P < 0.0	0001)				
1.2.3 ES versus sham treatment							
Booth 2013	4	15	9	13	4.2%	0.39 [0.15, 0.96]	
Kennelly 2011	37	80	46	83	19.7%	0.83 [0.62, 1.13]	
Peters 2010	50	110	87	110	37.9%	0.57 [0.46, 0.72]	
Vohra 2002	2	11	10	10	4.8%	0.22 [0.07, 0.66]	
Subtotal (95% CI)		216		216	66.6%	0.61 [0.51, 0.73]	•
Total events	93		152				
Heterogeneity: Chi ² = 8.55, df = 3 (P = 0.04); l ² = 65%							
Test for overall effect:	Z = 5.44 (i	P < 0.0	0001)				
Total (95% CI)		328		319	100.0%	0.54 [0.47, 0.63]	◆
Total events	125		225				
Heterogeneity: Chi ² = 15.58, df = 7 (P = 0.03); l ² = 55%							
Test for overall effect: Z = 7.80 (P < 0.00001)							
Test for subgroup differences: Chi ² = 5.36, df = 2 (P = 0.07), l ² = 62.7%							

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