

A RANDOMISED CONTROLLED TRIAL OF ANAL ELECTRICAL STIMULATION FOR FAECAL INCONTINENCE

Hypothesis / aims of study

Anal electrical stimulation was first described to treat faecal incontinence over 40 years ago, first as an implanted stimulator and later delivered via an external skin or anal electrode. It has been described as efficacious several case series and one randomised study (1), however the latter study varied other factors as well as stimulation. A Cochrane review of trials of electrical stimulation for faecal incontinence has concluded that "At present, there are insufficient data to allow reliable conclusions to be drawn on the effects of electrical stimulation in the management of faecal incontinence. There is a suggestion that electrical stimulation may have a therapeutic effect, but this is not certain" (2). No previous randomised study has addressed different stimulation parameters or the possible mechanism of any benefit.

We wished to examine whether anal electrical stimulation at 35Hz frequency, using an anal probe electrode, used on a daily basis at home for 8 weeks, in the absence of any adjunctive exercises or advice, would improve symptoms of faecal incontinence and anal sphincter pressures, when compared to the same programme of electrical stimulation at 1Hz. The study was approved by the local research ethics committee.

Study design, materials and methods

Patients referred for biofeedback for faecal incontinence in a tertiary referral hospital, and on the waiting list for this treatment, were contacted by telephone or post by a research nurse and offered the option of trying electrical stimulation while awaiting their first consultation. Ninety patients (9 men, 81 women), median age of 55 years (range 30-77 years) consented and were randomised (using random numbers generated by Excel in advance and placed in an opaque brown envelope), 47 to active anal stimulation at 35Hz and 43 to stimulation at 1Hz.

Outcome measures included a one week bowel diary, symptom questionnaire, manometry and patients' evaluation of outcome. The patient was blinded as to allocation. There was deliberately no other assessment, advice or information given to the patient. In particular, there was no instruction to perform any exercises.

The "active" stimulation involved the use of a home electrical stimulation unit (Elpha 4 Conti, Danmeter A/S, Denmark) with an "Anuform" anal plug electrode (Neen Healthcare, Dereham) for 8 weeks. "Active" stimulation was at 35Hz with a 0.5 second ramped pulse, 5-second on, 0.5 second ramp down and 5-second off duty cycle. Pulse width was 300 microseconds. The "sham" stimulator looked identical, had the same ramping duty cycle and was used to the same protocol, but with stimulation at 1Hz, a frequency which can be felt, but which does not produce any voluntary muscle contraction.

Results

Seventy patients completed the study. On an intention to treat analysis, there was no difference between the two groups on any of the outcome measures after 8 weeks. Patients rated their satisfaction with the electrical stimulation on a 0-10 scale. The median rating was 5.0 in the sham group and 5.5 in the active stimulation group, with no difference between the groups ($p = 0.46$).

Of those who completed stimulation, 44 (63%) felt the stimulation had improved their continence. Those with intact anal sphincters were not likely to rate their change more positively than those with sphincter disruption ($p = 0.71$). Median patient rating of bowel control increased from 3/10 before stimulation to 5/10 after stimulation ($p = 0.001$). There was no change in manometry results in those who underwent repeat testing. There was a significant improvement (reduction) in bowel frequency ($p < 0.001$), number of incontinent

episodes ($p=0.001$), but not in the use of pads ($p = 0.13$) as measured on the one week bowel diary in both groups.

Interpretation of results

Eight week of anal electrical stimulation was rated by patients as having improved their bowel control to a modest extent. There was no statistically significant difference detected between the groups, implying that 1Hz was as effective as 35Hz. This raises the possibility that the main effect is not sphincter contraction, but sensitisation of the patient to the anal area, or simply the effect of intervening *per se*. It is not known whether the electrical current is necessary for this effect, or if the simple insertion of an anal probe would have a similar effect. In clinical practice, electrical stimulation would normally be combined with other measures such as exercises and behavioural modification.

Concluding message

Home electrical stimulation is a relatively cheap and generally well-tolerated therapy in the conservative treatment of faecal incontinence and warrants further investigation as to mechanism of action and optimum protocol for stimulation.

References

- (1) A prospective, randomized study comparing the effect of augmented biofeedback with sensory biofeedback alone on fecal incontinence after obstetric trauma. *Dis Colon Rectum* 1999; 42(6):753-758.
- (2) Electrical stimulation for faecal incontinence in adults (Cochrane review). The Cochrane Library, John Wiley & Sons Ltd, Chichester, UK 2002; Issue 2.

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