

## EFFECT OF ELECTRICAL STIMULATION OF THE DORSAL CLITORAL NERVE ON FAECAL INCONTINENCE

### Hypothesis / aims of study

The goal of this study was to investigate whether therapeutic electrical stimulation of the dorsal clitoral nerve can reduce the number of incontinence episodes in patients with idiopathic faecal incontinence.

### Study design, materials and methods

Ten female patients (median age: 60 years; range 34-68 years) with idiopathic faecal incontinence were included. The intervention comprised of 2 times 15 minutes electrical stimulation per day for a period of 3 weeks. Stimulation parameters: monophasic square current pulses, 200  $\mu$ s pulse duration, 20 Hz. The stimulation amplitude was as high as the patients could tolerate. Stimulation was conducted by the patients themselves at their own homes using a handheld battery powered stimulator (Itouch Plus, Tenscare Ltd, Epson, UK) and 2 disposable surface electrodes. One electrode (20x10 mm, Neuroline 700, Ambu, Ballerup, Denmark) was placed on the clitoris and connected as cathode. The second one (round, diameter: 32 mm, Pals Platinum, Axelgaard, Lystrup, Denmark) acted as anode and was placed 2-3 cm lateral to the right labia major. The patients were familiarized with electrode placement and control of the stimulator during a training session. During the same training session, the stimulation threshold to evoke the clitoro-anal reflex was measured.

The subjects kept a 3-week bowel habit diary prior to stimulation (baseline), during stimulation and immediately after the stimulation period. The used stimulation amplitude was also written down in the diary. The patients were contacted several months post-stimulation to investigate whether any effects of stimulation were still present.

### Results

Nine patients completed the protocol. One patient withdrew for personal reasons and data from this patient are not included in the results. All nine patients found it easy to place the electrodes and control the stimulator. They also had no difficulties to fit the stimulation sessions in their daily routine. The median threshold to evoke the clitoro-anal reflex was 9 mA (range: 8-25 mA). The median stimulation amplitude during treatment was 27 mA (range: 9-52 mA). In 4 patients (#1, 2, 3 and 7) the stimulation amplitude during treatment was above 2 times the clitoro-anal reflex threshold.

Although all 9 patients had faecal incontinence, only 8 had recorded incontinence episodes in the 3-week period prior to stimulation (Table 1). Seven of the 8 patients reported a lower number of incontinence periods during stimulation compared to prior to stimulation. In one patient the number was unchanged. Seven of the 8 patients reported a lower number of incontinence periods after the stimulation period compared to prior to stimulation. In one patient the number was unchanged. Three patients had 0 incontinence periods during stimulation while 1 patient had 0 incontinence periods in the post-stimulation period.

The average percentage reduction in incontinence episodes from baseline to during stimulation was 68%. The average percentage reduction in incontinence episodes from baseline to post-stimulation was 64%.

One patient, who did not have incontinence periods at baseline, reported 7 incontinence periods during stimulation and 2 periods post-stimulation.

When contacted several months after stimulation, all patients reported that their symptoms had recurred and that the beneficial effects from stimulation had disappeared.

### Interpretation of results

This study shows that therapeutic electrical stimulation of the dorsal clitoral nerve, using surface electrodes, reduces the number of incontinence episodes in patients with idiopathic faecal incontinence. While most patients experienced a reduction in incontinence episodes only 1 patient became fully continent. This outcome is similar to results that have been obtained with the use of posterior tibial nerve stimulation and sacral root stimulation in the treatment of faecal incontinence.

The mechanism of action for dorsal clitoral nerve stimulation on faecal incontinence is unknown. Anal resting pressure, anal squeeze pressure and rectal sensitivity were all unchanged after stimulation. It could be that it is just a placebo effect because the patient's key problem was addressed, with repeated investigations and attention from the health staff. A placebo-controlled study would be needed to investigate whether the placebo effect fully accounts for the observations.

It is unknown whether the used stimulation protocol is optimal for the treatment of faecal incontinence. However, since the onset of the effect appears to be almost instantaneous, a reduction of the number of stimulations in the treatment, e.g. from twice per day to once per day or every second day, is expected to result in a similar outcome.

The effect of stimulation lasted for at least 3 weeks but had disappeared at longer follow-up. A similar phenomenon is observed when using posterior tibial nerve stimulation for faecal incontinence. In order to maintain the effect of posterior tibial nerve stimulation, repeated maintenance treatment is offered. It is therefore possible that effects of dorsal genital nerve stimulation also could be maintained with repeated maintenance stimulation.

*Table 1: Number of incontinence episodes of 9 patients during 3 periods: Baseline (pre- stimulation), during stimulation and post-stimulation (immediately after the stimulation period). Each period lasted 3 weeks. In addition, the reduction in episodes from baseline to post-stimulation is shown.*

Patient #	Baseline	During Stimulation	Post-stimulation	Reduction in episodes from baseline to post-stimulation [%]
1	15	1	2	87
2	10	0	5	50

3	231	220	84	64
4	25	0	6	76
5	4	0	0	100
6	31	8	5	84
7	13	4	6	54
8	2	2	2	0
9	0	7	2	na

#### Concluding message

Therapeutic electrical stimulation of the dorsal clitoral nerve, using surface electrodes, reduces the number of incontinence episodes in patients with idiopathic faecal incontinence. This could be used as a low-cost, non-invasive treatment for patients with faecal incontinence. Further studies are needed to investigate how the effect of stimulation can be maintained for a longer period and whether a different stimulation protocol could result in an even larger reduction in incontinence episodes.

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<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>Yes</b>
<b><i>Specify Name of Ethics Committee</i></b>	<b>Scientific Ethical Committee of Region Midtjylland</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>