

## SACRAL NERVE STIMULATION INCREASES RECTAL SENSITIVITY IN PATIENTS WITH FAECAL INCONTINENCE: RESULTS OF A RANDOMIZED DOUBLE-BLINDED CROSSOVER STUDY

### Hypothesis / aims of study

Sacral Nerve Stimulation is successful in the treatment of faecal incontinence with a decrease in number of incontinence episodes (1). The mode of action is unclear; direct stimulation of the pelvic floor muscles is only partly responsible. SNS increases anal resting and squeeze pressure as well as rectal volume tolerability, however not to an extent that fully explains the results of SNS (2).

The aim of the study was to evaluate anorectal motility in patients with faecal incontinence successfully implanted with SNS for more than 12 months.

### Study design, materials and methods

7 patients, 6 females and 1 man, age 67 years (60 - 87 years) were included. All patients were treated with SNS for more than 12 months (range 25 – 60 months) and all with good result. The study period was 2 weeks, one week with the stimulator turned on and one week with the stimulator turned off. The design of the study was double-blinded and crossover, neither the patients nor the examiners knew the status of stimulation. The patients were randomised to either the stimulator turned on or off the first week. An independent observer was used for the setting of the stimulator. The threshold of the stimulus was found and the stimulator was set at 80% of the threshold, where stimulation cannot be felt by the patient and a clinical response is still present (3) and the stimulator was turned on or off according to randomisation. After one week the patient returned and the stimulator was turned off if it was turned on the first week and turned on if it was turned off the first week. The patients recorded faecal incontinence diaries both weeks. At the end of each week anorectal physiology testing was performed. Anal resting pressure and squeeze pressure as well as rectal volume tolerability was recorded.

### Results

The results from the faecal incontinence diaries are summarised in table 1.

**Table 1**

	SNS ON Mean (95% CI for mean)	SNS OFF Mean (95% CI for mean)	P-Value (one sample t-test)
Defecations/week	8,86 (6,21-11,5)	12,1 (6,32-17,9)	0,11
Urge episodes/week	2,43 (-0,23 – 5,1)	4,14 (-0,16 - 8,44)	0,21
Incontinence episodes/week	0	0	1
Passive leakage/week	0	0,43 (-0,41 - 1,27)	0,36
Soiling/week	0,71 (-0,69 - 2,11)	1,86 (0,29 - 3,43)	0,12

The results from anorectal physiology testing are summarised in table 2

**Table 2**

	SNS ON Mean (95% CI for mean)	SNS OFF Mean (95% CI for mean)	P-Value (one sample t-test)
Resting pressure (mmHg)	61,9 (51,5-72,3)	78,1 (52,3-104)	0,22
Squeeze pressure (mmHg)	164 (117-211)	164 (113-215)	0,85
First sensation (ml)	27,1 (17,8-36,4)	50,0 (34,6-65,4)	0,03
Desire to defecate (ml)	60 (48,7-71,3)	82,9 (64,8-101)	0,07
Maximum tolerable volume (ml)	124 (82,4-165,6)	124 (106-142)	1

#### Interpretation of results

Sacral nerve stimulation in patients with faecal incontinence decreases the number of defecations, urge episodes, soiling and passive leakage. This decrease was not significant. Also the patients had no incontinence episodes while the stimulator was turned off. The reason for this finding is likely to be a result of prolonged effect of the stimulation, because the period with the stimulator turned off was probably too short.

Surprisingly anal resting pressure was increased with the stimulator turned off whereas anal squeeze pressure was unaltered. In other studies a small increase in both anal resting pressure and squeeze pressure is found. First sensation of content in rectum was significantly lower with the stimulator turned on, which may indicate an important action of sacral nerve stimulation, since the patient will be more aware of content in the rectum.

#### Concluding message

In this randomised double-blinded crossover study a significant increase of rectal sensitivity was found, indicating an important effect of sacral nerve stimulation.

#### References

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<b><i>Is this a clinical trial?</i></b>	<b>Yes</b>
<b><i>Is this study registered in a public clinical trials registry?</i></b>	<b>No</b>
<b><i>Is this a Randomised Controlled Trial (RCT)?</i></b>	<b>Yes</b>
<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>De Videnskabsetisk Komiteer for Region Hovedstaden</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>