

Sacral Nerve Stimulation for faecal incontinence



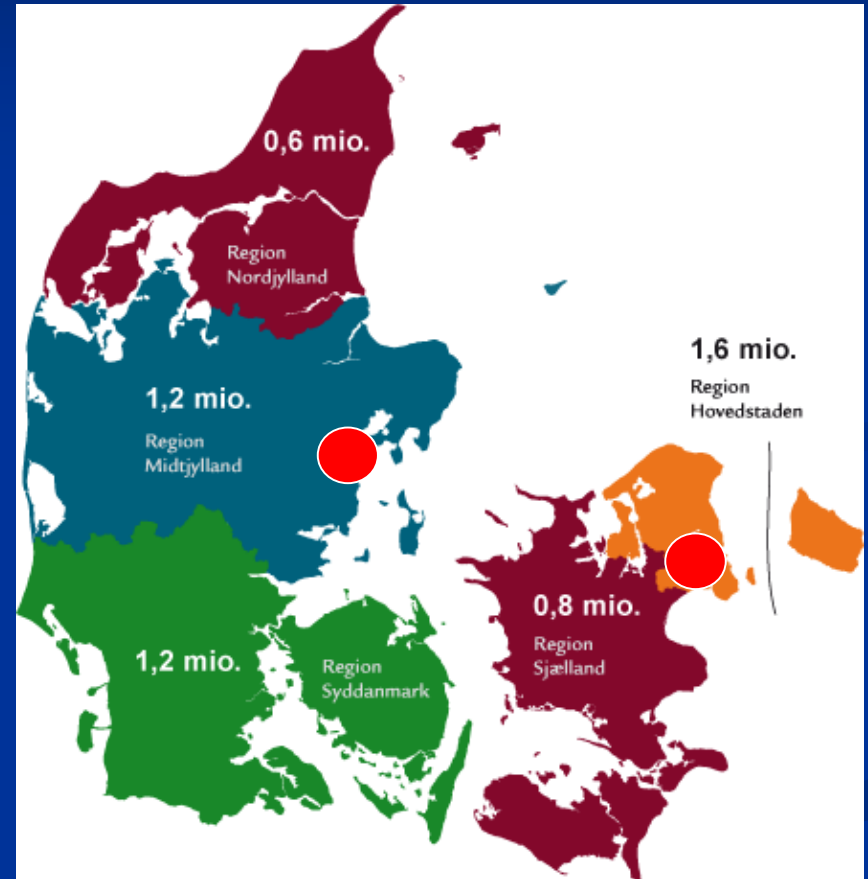
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Denmark

■ FINANCIAL DISCLOSURE

- Research support medtronic

HEALTH CARE DK

- Public-free
- Tax payed
- 5 regions
- SNS
 - Higly specialized
 - 2 sites



AARHUS 350.000

■ UNIVERSITY

- Founded 1935
- >40.000



■ HOSPITAL(new)

- New largest in scandinavia



THE PIONEER

1995 first report of SNS for faecal incontinence by
Prof. Klaus Matzel in The Lancet

Lancet 1995; **346**: 1124–27

Lancet 2004; **363**: 1270–76



SNS-MAGIC?

- CAN BE

FIRST CASE IN AARHUS

- Female patient, born in 1955
- Facio-scapulo-humeral muscular dystrophy at the age of 5
- Severe FI during the past 17 years
- January 2000
 - Wexner incontinence score 20

FIRST SNS

- June 2000
 - PNE-test
 - no episodes of FI
 - bowel movements reduced
- October 2000
 - SNS implantation
- Follow-up at 12 and 24 months
 - Wexner incontinence score 0

SACRAL NERVE STIMULATION

- Minor surgery
- Major effect
- Test operation (PNE)

Number of SNS implantations (bowel) IN DK

- 5,5 million inhabitants
- About 80 implants pr year
- corresponding to 1400 in Egypt

3 MULTICENTER TRIALS

- European (Matzel et al Lancet 2004)
- French (Leroi et al Ann. Surg. 2005)
- USA (Wexner et al Ann. Surg. 2010)

DOES IT WORK

SNS and Fecal Incontinence Results

Systematic review

Systematic review of the clinical effectiveness of neuromodulation in the treatment of faecal incontinence

N. N. Thin¹, E. J. Horrocks¹, A. Hotouras¹, S. Palit¹, M. A. Thaha¹, C. L. H. Chan¹, K. E. Matzel²
and C. H. Knowles¹

Br J Surg 2013;100:1430-1447

61 studies

Summary	Wexner (CCIS)	Incontinence episodes /week
Short term	15 → 6	8 → 1
Medium term	15 → 8	8 → 1
Long term	15 → 7	8 → 1

Fecal incontinence etiology

- Idiopathic
- Traumatic or obstetric injuries
- Anorectal surgery
- Low anterior resection syndrome
- Neurogenic
- Irradiation injuries
- Misc. (diabetic neuropathy, ileal-anal pouch..)

SNS AND FI

- SNS IS FOR **ALL** (nearly)
 - but
- SNS IS ONLY FOR A **MINORITY**

Role of SNS in the treatment of fecal incontinence

■ Options

colo- or ileostomy

Advanced surgery

Antegrade irrigation

SNS??

Sphincter reconstruction

SNS??

Transanal irrigation

Biofeedback, imodium

Diet and habits

SNS- fecal incontinence CHALLENGES

- HOW DOES IT WORK?
- DOES IT REALLY WORK ?
- PNE TEST?
- Stimulation settings?
- COST

CHALLENGES

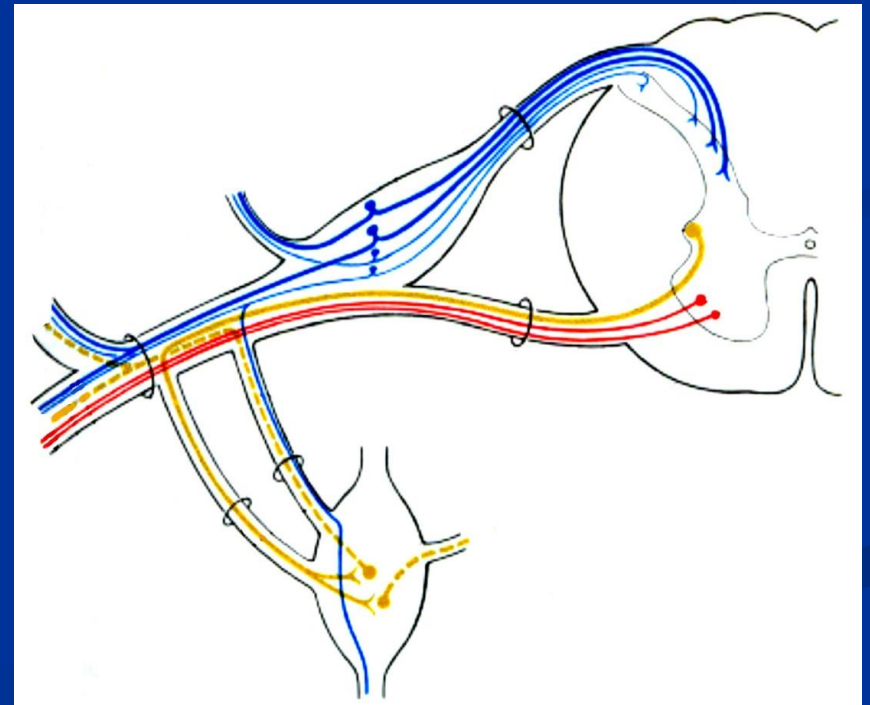
HOW DOES IT WORK ?

- The sphincters?
- The rectum ?
- The colon?
- The brain ?

How does it work?

LITTLE EFFECT ON THE SPHINCTERS

- No necessity to switch off the stimulator during defaecation
- Little or no increase in squeeze pressure
- Work with EAS defect
- No better retention artificial stool



Retention Test in Sacral Nerve Stimulation for Fecal Incontinence

Hanne B. Michelsen et al DC R 2009

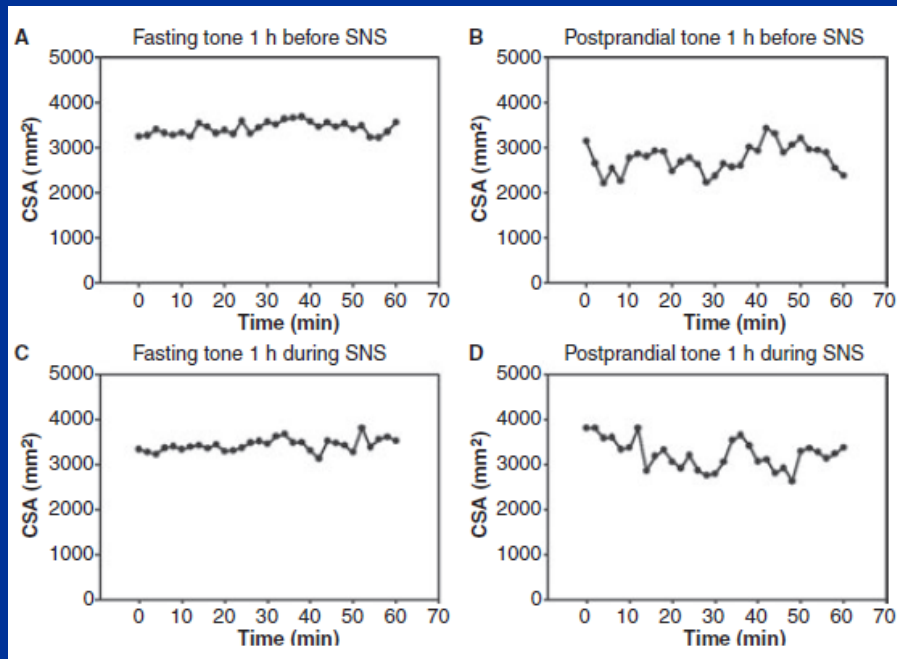
CONCLUSION: Sacral nerve stimulation does not alter patients' ability to retain rectal content. Further studies are needed to investigate the mechanism of sacral nerve stimulation.

Mechanism of action

Rectal motility after sacral nerve stimulation for faecal incontinence

H. B. MICHELSEN,^{*} J. WORSØE,^{*} K. KROGH,[†] L. LUNDBY,^{*} P. CHRISTENSEN,^{*} S. BUNTZEN^{*} & S. LAURBERG^{*}

N=25



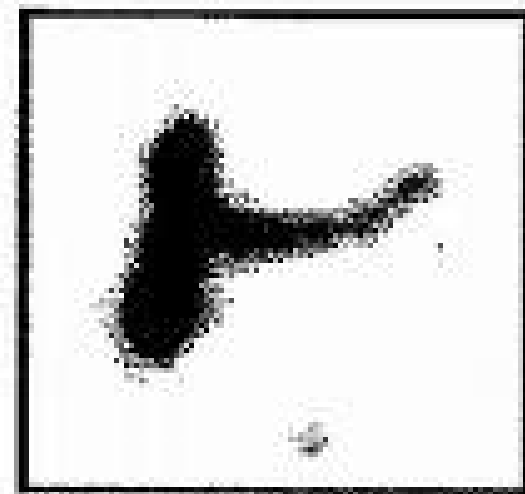
Gastrocolic response impaired

Reduction in postprandial rectal tone

Sacral nerve stimulation for faecal incontinence alters colorectal transport

H. B. Michelsen¹, P. Christensen^{1,2}, K. Krogh², M. Rosenkilde³, S. Buntzen¹, J. Theil⁴ and S. Laurberg¹

¹Surgical Research Unit, Department of Surgery P, ²Neurogastroenterology Unit, Department of Gastroenterology and Hepatology V and Department of Surgery P, ³Department of Radiology and ⁴Department of Clinical Physiology and Nuclear Medicine, Aarhus University Hospital, Aarhus, Denmark
Correspondence to: Dr H. B. Michelsen, Surgical Research Unit, Department of Surgery P, Aarhus University Hospital, Tage-Hansens Gade 2, DK - 8000 Aarhus C, Denmark (e-mail: hbn@mail.tele.dk)



N= 20 patients with faecal incontinence and a positive temporary test stimulation

The median frequency of defecation per 3 weeks decreased from 56 (range 19-136) to 26 (range 12-78).

Decrease in antegrade transport from ascending colon.
Increase in the retrograde transport from descending and transverse colon

Increase in CTT

How does it work -BRAIN?

Relief of Fecal Incontinence by Sacral Nerve

Stimulation Linked to Focal Brain Activation

Lundby et al DCR 2010

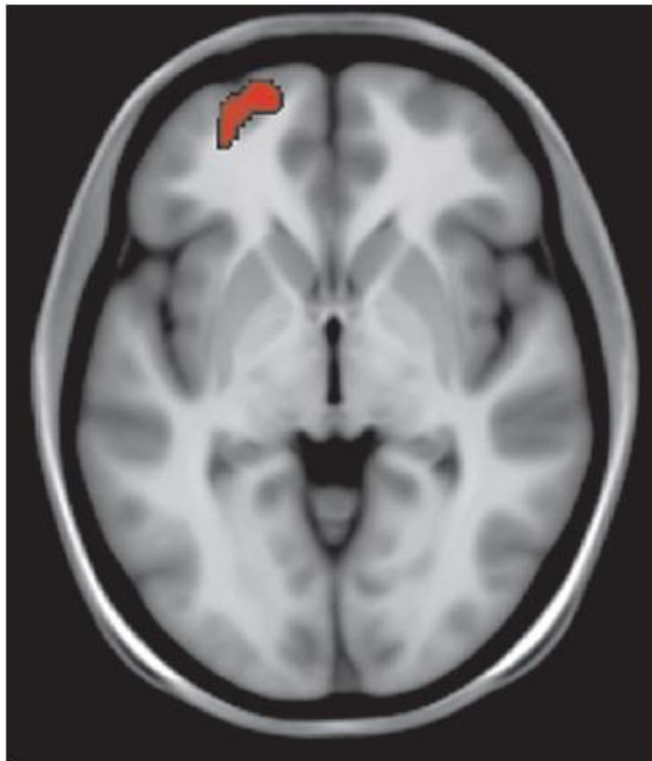


FIGURE 1. Clusters of significant changes in rCBF superimposed on an MRI atlas in Talairach space. Initial activation of the contralateral frontal cortex ($-28.2, 57.5, -12.0$ mm) 30 minutes after onset of stimulation. Statistical significance is at $P < .05$. rCBF = regional cerebral blood flow.



FIGURE 2. Changes in rCBF in ipsilateral caudate nucleus ($14.0, 8.0, 6.0$ mm) after 2 weeks of stimulation (stimulation vs 30 min without stimulation). Statistical significance is at $P < .05$. rCBF = regional cerebral blood flow.

How does it work?

Sensory afferents

- Griffin et al BJS 2011

Sacral nerve stimulation increases activation of the primary somatosensory cortex by anal canal stimulation in an experimental model

Griffin et al BJS 2011

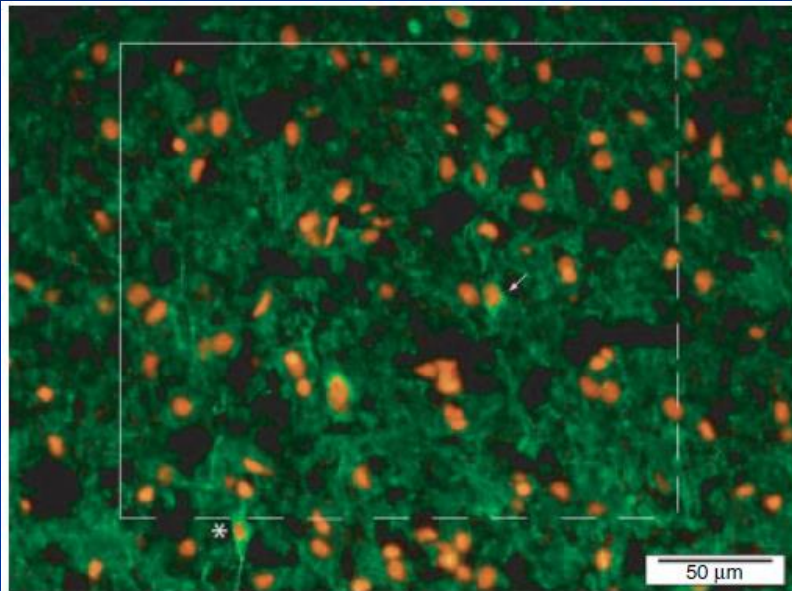


Fig. 2 Polysialylated neural cell adhesion molecule (PSA-NCAM) expression in the primary somatosensory cortex. A stereological counting frame was placed over the image. Solid and dashed lines represent inclusion and exclusion boundaries respectively. PSA-NCAM-positive cells are indicated by an arrow (propidium iodide counterstain). PSA-NCAM-positive cells excluded from the count are indicated by an asterisk

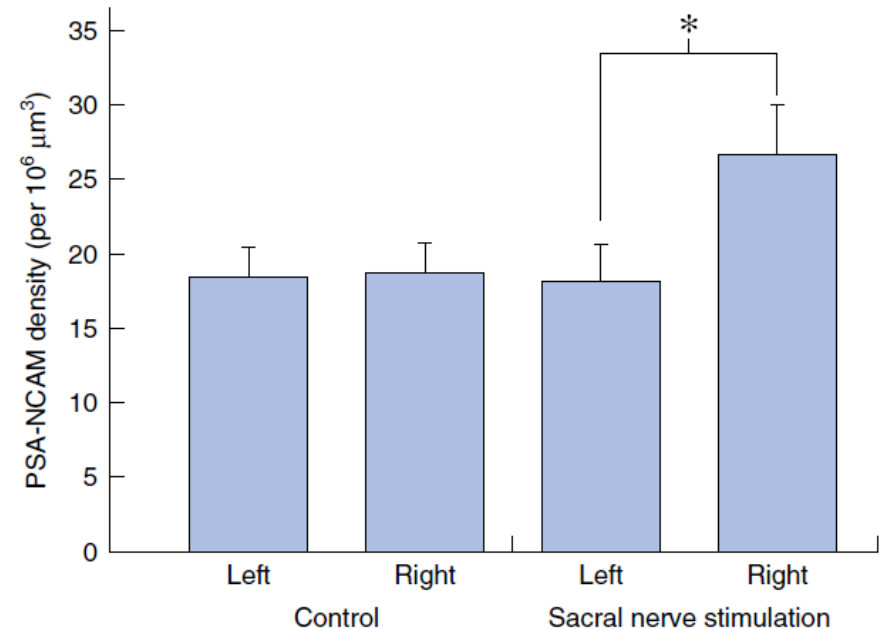


Fig. 4 Mean(s.e.m.) numerical density of polysialylated neural cell adhesion molecule (PSA-NCAM)-positive cells, calculated from the data of three blinded observers (5040 observations).
**P* = 0.032 (1-tailed paired Student's *t* test)

HOW DOES IT WORK ?

- Likely through **afferent** fibers
- Neuromodulation at spinal cord and brain of
 - Colonic motility
 - Rectum
 - ↑ sensory awareness

SNS- fecal incontinence

- HOW DOES IT WORK?
- DOES IT REALLY WORK ?
- PNE TEST?
- Stimulation settings?
- COST
- OTHER TECHNIQUES

No double blinded randomised trial

- Ongoing –multicenter- 75 pt idiopathic
- Failed conservative management
- Straight implantation
 - Placebo effect
 - Effect 50 and 90% sensory threshold
- After 12 weeks suprasensory stimulation

Design

2 to 1 group1 -2

<u>Week</u>	Group 1	Group 2
0-4	0.05 V	90% of <u>Sensory threshold</u>
5-8	50% of <u>Sensory threshold</u>	90% of <u>Sensory threshold</u>
9-12	90% of <u>Sensory threshold</u>	90% of <u>Sensory threshold</u>

CHALLENGES

SELECTION OF PATIENTS

- PNE test
 - Limitations
 - Cut off

CHALLENGES

PNE test

- Not blinded-restricted at home
- Pts wish a permanent
- No cut off point between pt s satisfaction and improvement in incontinence episodes
- 100% satisfaction with 100% reduction
- But many pts are satisfied even with more episodes since they have changed life-style

Jakobsen et al. (colorectal disease) combined data (Aarhus Maastricht)

■ Conclusions:

- A clear relation between patient **satisfaction** and **improved** continence.
- 46% of the patients with **more FI episodes** at follow-up than baseline were **satisfied**.
- functional outcome of SNS-therapy cannot be based only on bowel habit diaries and bowel scores.

CHALLENGES

stimulation parameters

Improving the efficacy of sacral nerve stimulation for faecal incontinence by alteration of stimulation parameters

T. C. Dudding, C. J. Vaizey, A. Gibbs and M. A. Kamm *British Journal of Surgery* 2009; 96: 778–784

Table 2 Faecal incontinence and soiling in 12 patients before sacral nerve stimulation, with chronic stimulation and after optimization of stimulation parameters

	Before SNS	Preoptimization baseline*	Postoptimization
Incontinence (episodes/week)	7.3(5.0)	2.3(3.1)	1.2(1.8)
Soiling (days/week)	5.4(1.4)	3.3(2.0)	1.7(1.5)

Values are mean(s.d.). *Median duration of chronic stimulation 34 (range 6–78) months. SNS, sacral nerve stimulation.

CHALLENGES

COST

- EXPENSIVE (> 13.000 euro)
- RESTRICTED LIFETIME BATTERIES

CHALLENGES COST

A Prospective, Randomized Study:
switch Off the Sacral Nerve Stimulator
During the Night? Michelsen et al DCR 2008

- Possible in many pts-but pts does not bother in DK where health care is free

Table 1. Results of Wexner incontinence score and bowel habit diary during the two three-week periods

	<i>“On” period</i>	<i>“Off” period</i>	<i>P value</i>
Wexner incontinence score	6 (2–14)	7 (3–16)	0.04
St. Mark’s score	10 (3–16)	11 (3–18)	0.03
Frequency of defecation	26 (11–71)	34 (9–70)	0.19
Episodes with urge	2 (0–16)	2 (0–34)	0.29
Episodes with incontinence for solid and liquid stool	0 (0–17)	0 (0–7)	0.53
Days with soiling	0 (0–12)	1 (0–15)	0.008

Data are medians with ranges in parentheses unless otherwise indicated.

Sacral Nerve Stimulation at Subsensory Threshold Does Not Compromise Treatment Efficacy

Results From a Randomized, Blinded Crossover Study

Jakob Duelund-Jakobsen, MD, Steen Buntzen, MD, DMSc, Lilli Lundby, MD, PhD, and Søren Laurberg, MD, DMSc

(*Ann Surg* 2013;257: 219–223)

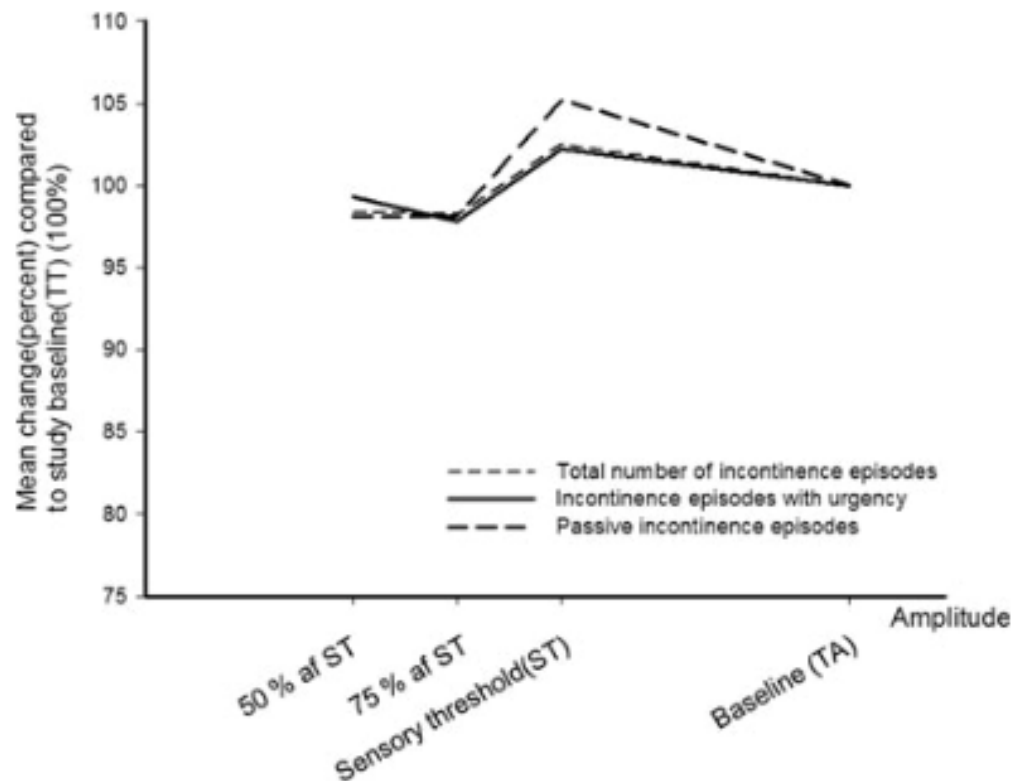


FIGURE 1. Dose–response relationship between the changes in incontinence episodes as a function of stimulation amplitude expressed in percentage, compared with pre-SNS values.

LONGTERM ????

- **Conclusions:** Sub-sensory stimulation as low as 50% of sensory threshold is as effective as stimulation at sensory threshold.

Sacral Nerve Stimulation at sub-sensory threshold does not compromise treatment efficacy in faecal incontinence patients."

- **Aim:** To explore if a 50% reduction in stimulation amplitude of ST is feasible in a **clinical setting**.
- **Conclusion :** Sub-sensory stimulation at median 39% of ST is as effective. Patients tend to increase amplitude over time.

NEUROMODULATION

- DO YOU STILL NEED IT???

FUTURE?

■ HISTORY AND SIMPLE CLINICAL EVALUATION

■ ALL

- Advice/ biofeedback /injections?

■ Still major problems

- Obvious clinical sphincter defect

- repair

- Spinal cord lesion

- TAI

- All other

- PNE

Role of SNS in the treatment of fecal incontinence

■ Conclusions:

- In a dedicated team and after thorough evaluation:

- **Be conservative**

Try woodo ,injection of bulking agents? and/or transanal irrigation

- **Be minimal invasive**

try sacral nerve stimulation before or after sphincter reconstruction

- **Advanced surgery**

In well selected and well informed patients

Role of SNS in the treatment of fecal incontinence

■ Conclusions:

- SNS minimal invasive - very low morbidity
- Use the PNE-test on wide indications
- SNS overall 70 - 80 % success rate.
- Longterm results: stable
- Expensive- and adjustments

- Thank you very much for the invitation
- Welcome to visit us
- ESCP Niece 2018