Neurostimulation in fecal incontinence

Nervus Tibialis Stimulation (NTS)

Pudendal Nerve Stimulation (PNS)

Sacral Nerve Modulation (SNM)

Tibial Nerve Stimulation (TNS)

Percutaneous Tibial Nerve Stimulation (pTNS)

- 34-gauge needle electrode
- Surface electrode
- PC Neuromodulation system
  - Puls frequency 20 Hz
  - Puls with 200 µs

- 12 sessions (30 min) over 6-12 weeks
- "top-up" sessions

B. Govaert and C. G. Baeten. Colorectal Dis 2010 (Uroplasty, Geleen, Netherlands) (Uroplasty Limited, Manchester, UK)
Tibial nerve stimulation (TNS)

- 2 RCT, TTNS vs Sham, pTNS vs TTNS vs Sham
- 7 case series for pTNS
- 6 case series for TTNS

EJ Herrocks and CH Knowles, BJS 2014

Percutaneous TNS – Case Series

<table>
<thead>
<tr>
<th>Reference</th>
<th>No. of patients</th>
<th>Follow-up (months)</th>
<th>Score</th>
<th>LSP (%) Improvement</th>
<th>Median (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leroi et al</td>
<td>27</td>
<td>7.5</td>
<td>0.005</td>
<td>71</td>
<td>12 (2-60)</td>
</tr>
<tr>
<td>George et al</td>
<td>31</td>
<td>12 (0-21)</td>
<td>0.005</td>
<td>71</td>
<td>12 (2-60)</td>
</tr>
<tr>
<td>Allot et al</td>
<td>12</td>
<td>12 (0-21)</td>
<td>0.005</td>
<td>71</td>
<td>12 (2-60)</td>
</tr>
<tr>
<td>Summary median</td>
<td>21.8</td>
<td>12 (0-21)</td>
<td>0.005</td>
<td>71</td>
<td>12 (2-60)</td>
</tr>
</tbody>
</table>

NICE Quality Assessment score: median 4 (range 3-6)

EJ Herrocks and CH Knowles, BJS 2014

Tibial nerve stimulation - RCT

<table>
<thead>
<tr>
<th>Reference</th>
<th>Outcome</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>LeRoie et al</td>
<td>FIQL Score</td>
<td>No sig. difference</td>
</tr>
<tr>
<td>George et al</td>
<td>St. Mark’s FI Score</td>
<td>No sig. difference (improvement)</td>
</tr>
<tr>
<td>SF-36</td>
<td>No sig. difference (vitality)</td>
<td>Anorectal manometry</td>
</tr>
</tbody>
</table>

EJ Herrocks and CH Knowles, BJS 2014

Percutaneous tibial nerve stimulation versus sham electrical-stimulation for the treatment of faecal incontinence in adults (CONFIDeNT): a double-blind, multicentre, pragmatic, parallel-group, randomised controlled trial

Charles H Knowles, Emma J Horrocks, Stephen A Bremer, Natasha Stevens, Christine Norton, P Ronan O’Connell, Sandra Eldridge, on behalf of the CONFIDeNT study group

- 227 patients, PTNS vs sham electrical stimulation for FI
- Double-blind, multicenter, RCT
- Aim: Efficacy of PTNS

Percutaneous tibial nerve stimulation versus sham electrical-stimulation for the treatment of faecal incontinence in adults (CONFIDeNT): a double-blind, multicentre, pragmatic, parallel-group, randomised controlled trial

- 12 outpatient stimulations
- Lasting 30 minutes
- Once a week
- Response < 50% of FI episodes/week

Responder:

PTNS vs Sham
38% vs 31% (P=0.396)

PTNS is as effective as sham stimulation
No recommendation for PTNS
Percutaneous tibial nerve stimulation versus sham electrical-stimulation for the treatment of faecal incontinence in adults (CONFIDeNT): a double-blind, multicentre, pragmatic, parallel-group, randomised controlled trial

- High quality of study design
- Sham group with TTNS

The American Society of Colon and Rectal Surgeons’ Clinical Practice Guideline for the Treatment of Fecal Incontinence

Ian M. Paquette, Madhulika G. Varma, Andreas M. Kaiser, Scott R. Steele, Janice F. Rafferty

The scope of this updated practice parameter (last version 2007) is to address the evaluation and management of patients with fecal incontinence based on a thorough review of the published evidence.

Paquette IM. et al DCR 2015.

The American Society of Colon and Rectal Surgeons’ Clinical Practice Guideline for the Treatment of Fecal Incontinence

Prof. Andreas Kaiser
Department of Surgery / Division of Colorectal Surgery
USC Norris Cancer Center and Hospital
1441 ElCamino Avenue, Suite 7418
Los Angeles, CA 90025-4012

Paquette IM. et al DCR 2015.

Percutaneous Tibial Nerve Stimulation

Percutaneous tibial nerve stimulation may be considered because it provides short-term improvement in episodes of fecal incontinence.

Grade of Recommendation: Weak recommendation based on low- or very low-quality evidence, 2C.
Randomized clinical trial of sacral versus percutaneous tibial nerve stimulation in patients with faecal incontinence


- 40 patients (39 women), mean age 59 y
- Investor-blinded randomized pilot trial

Both treatments provide some short-term benefit
Nearly all outcomes were favourable for SNS than for PTNS
SNS effects increased at 6 months
PTNS effects are declining at 6 months
Randomized clinical trial of sacral versus percutaneous tibial nerve stimulation in patients with faecal incontinence

- First study
- Small number of patients
- Short follow up

Thin NN et al., BJU 2015

“Pudendal Nerve“

Percutaneous Pudendal Nerve Stimulation (PNS)
Sacral Lion Procedure

Marc Pozzorov 2007
Susanne Bock 2010

A New Technique of Laparoscopic Implantation of Stimulation Electrode to the Pudendal Nerve for Treatment of Refractory Fecal Incontinence and/or Overactive Bladder With Urinary Incontinence

Schematic drawing pudendal nerve course

Spina ischiadica
Electrode
N. pudendus
• Nn. rectales inferiores
• Nn. perineales
Pudendal Nerve Stimulation (PNS) in neurogenic UI

- 15 Patients for PNS
  - > 50% Improvement: 12 Patients
  - < 50% Improvement: 3 Patients
- Chronic PNS: 11 Patients
- Infusion: 1 Patient

Follow-up: 6 months

M. Spinelli, Neurourology and Urodynamics 2005

4/7 Improved Constipation
1/1 Improved FI

Pudendal Nerve Stimulation (PNS) vs Sacral Nerve Stimulation (SNS) in Interstitial Cystitis (IC)
(Prospective, single-blinded, randomized crossover trial)

- 22 Patients with IC
- 1 Sacral (S3) and 1 Pudendal Lead

Screening: 2-6 weeks

- > 50% Improvement: 17 Patients
- < 50% Improvement: 5 Patients

Follow-up: 6 months

K. M. Peters, BJU Int. 2007

First Experience: Results

<table>
<thead>
<tr>
<th>Age</th>
<th>Reason for faecal incontinence</th>
<th>Initial Failure</th>
<th>Symptom Reduction (%)</th>
<th>PNS Permanent Implantation</th>
<th>Follow-up (Months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>31</td>
<td>Pelvic Operation (PO)</td>
<td>Yes</td>
<td>Yes 50</td>
<td>Yes</td>
<td>5.3</td>
</tr>
<tr>
<td>70</td>
<td>Pelvic Operation (PO)</td>
<td>Yes</td>
<td>Yes 70</td>
<td>Yes 90</td>
<td>6.4</td>
</tr>
<tr>
<td>90</td>
<td>Neurogenic (N)</td>
<td>No</td>
<td>No</td>
<td>No 60</td>
<td>9.3</td>
</tr>
<tr>
<td>77</td>
<td>Neurogenic (N)</td>
<td>Yes</td>
<td>Yes 90</td>
<td>Yes 10 10.2</td>
<td></td>
</tr>
<tr>
<td>71</td>
<td>N and PO</td>
<td>Yes</td>
<td>Yes 90</td>
<td>Yes 90 9 10 10.2</td>
<td></td>
</tr>
<tr>
<td>72</td>
<td>PO and sphincter defect</td>
<td>Yes</td>
<td>No 36</td>
<td>No 10 10.2</td>
<td></td>
</tr>
<tr>
<td>84</td>
<td>PO and sphincter defect</td>
<td>Yes</td>
<td>No 90</td>
<td>No 6 5.9</td>
<td></td>
</tr>
</tbody>
</table>


A pilot study of chronic pudendal nerve stimulation for faecal incontinence for those who have failed sacral nerve stimulation

- N=10
- Improvement > 50%: 5 (50%)
- Follow-up: 4 (40%)

Thomas George et al, Tech Coloproctol 2014;18
Electrical Stimulation of Anal Sphincter or Pudendal Nerve Improves Anal Sphincter Pressure

Ten virgin female Sprague Dawley rats

Electrical stimulation caused an increase in anal pressures.


Pudendal Nerve Stimulation for Bowel Dysfunction in Complete Cauda Equina Syndrom

<table>
<thead>
<tr>
<th></th>
<th>Group Conspiration</th>
<th>Group Incontinence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>Improvement &gt; 50%</td>
<td>5 (63%)</td>
<td>5 (100%)</td>
</tr>
<tr>
<td>Score</td>
<td>17 to 10 (CCS)</td>
<td>9.4 to 0.4 (FI/Week)</td>
</tr>
</tbody>
</table>

Thomas George et al. Annals of Surgery 2014; 259

„Sacral Nerves“

Sacral Nerve Stimulation

Tanagho et al 1982/1989

Matzel et al 1995

Tangoho, J Urol 1989; Matzel, Lancet 1995

Staged Implant

First step

Screening: 10–21 days

1 week

Second step

Follow-up

1 week

6 months

Hetzer et al. Tech Coloproctol 2005
Follow-up > 36 months

Follow-up 12-36 months

Tjandra et al.

Muscular dystrophy (Buntzen, Dis Colon Rectum 2004)

Effekt der chronischen SNS: Cleveland Clinic Jahr 2009

SNM – Faecal incontinence

Low anterior resection and RCT (Ratto, Dis Colon Rectum 2005)

Rectosigmoidectomy (Jarrett, Int J Colorectal Dis 2005)

Partial spinal injury (incl. disc prolapse) (Jarrett, Br J Surg 2005)

Rectal Prolapse repair (Jarrett, Dis Colon Rectum 2005)

External Sphincter Disruption (Conaghan, Dis Colon Rectum 2005)

Muscular dystrophy (Buntzen, Dis Colon Rectum 2004)

<table>
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<tr>
<th>Autor</th>
<th>Jahr</th>
<th>Geschlecht</th>
<th>Patienten (Baseline)</th>
<th>Patienten (Follow-up)</th>
<th>Medianer Median (Spannweite)</th>
<th>Faktor</th>
<th>p-Wert</th>
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<tr>
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<td>2013</td>
<td>54</td>
<td>24</td>
<td>24 (19-29)</td>
<td>24 (19-29)</td>
<td>0.001</td>
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<td>56</td>
<td>24</td>
<td>24 (19-29)</td>
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<td>2013</td>
<td>58</td>
<td>26</td>
<td>26 (21-31)</td>
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<td>0.001</td>
<td></td>
</tr>
</tbody>
</table>

Follow-up ≤ 12 Monate

Follow-up > 36 Monate

SNM – Faecal incontinence

Follow-up 12-36 months

Tjandra et al.

Muscular dystrophy (Buntzen, Dis Colon Rectum 2004)

Effekt der chronischen SNS: Cleveland Clinic Jahr 2009

SNM – Faecal incontinence

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External Sphincter Disruption (Conaghan, Dis Colon Rectum 2005)

Muscular dystrophy (Buntzen, Dis Colon Rectum 2004)
Sacral Nerve Stimulation SNS

The most established neuromodulation up-to-date
...but also the most invasive one!

Newest data show success rates in median:
- Short-term: 69%
- Mid-term: 58%
- Long-term: 54%

Thin NN, Knowles CH et al; Systematic review of the clinical effectiveness of neuromodulation in the treatment of fecal incontinence. BJS 2013; 100: 1430-1447

Sacral Nerve Modulation for Fecal Incontinence: Results of a Prospective Single-Center Randomized Crossover Study

Volker Kahlke, Heidi Topic, Hans G. Pelakis, Johannes Jongen

- 31 women, mean age 56 y
- Single-center, prospective study, RCT
- Aim: Efficacy of permanent SNS

Kahlke V et al., Dis Colon Rectum 2015

Sacral Nerve Modulation for Fecal Incontinence: Results of a Prospective Single-Center Randomized Crossover Study

Kahlke V et al., Dis Colon Rectum 2015

Sacral Nerve Modulation for Fecal Incontinence: Results of a Prospective Single-Center Randomized Crossover Study

Kahlke V et al., Dis Colon Rectum 2015

\( t_0 \): time of randomisation
\#P < 0.05 vs baseline
\#§ < 0.005 vs <off>
<table>
<thead>
<tr>
<th>Sacral Nerve Modulation for Fecal Incontinence: Results of a Prospective Single-Center Randomized Crossover Study</th>
</tr>
</thead>
</table>
| ➢ High quality of study design  
➢ Small number of patients |

Kahlke V et al., Dis Colon Rectum 2015

<table>
<thead>
<tr>
<th>Bilateral compared with unilateral sacral nerve stimulation for faecal incontinence; results of a randomised, single-blinded crossover study.</th>
</tr>
</thead>
</table>
| • 27 patients (55 women), mean age 63 y  
• Single-center, randomized cross over study |

Duelund-Jakobsen J et al., Colorectal Dis 2015

<table>
<thead>
<tr>
<th>Bilateral compared with unilateral sacral nerve stimulation for faecal incontinence; results of a randomised, single-blinded crossover study</th>
</tr>
</thead>
</table>
| Bilateral SNS-therapy for faecal incontinence is not superior to standard unilateral stimulation in the short term.  
Equal functional results can be obtained regardless the side of implantation. |

Duelund-Jakobsen J et al., Colorectal Dis 2015

<table>
<thead>
<tr>
<th>The American Society of Colon and Rectal Surgeons’ Clinical Practice Guideline for the Treatment of Fecal Incontinence</th>
</tr>
</thead>
</table>
| Sacral Neuromodulation  
Sacral neuromodulation may be considered as a firstline surgical option for incontinent patients with and without sphincter defects.  
Grade of Recommendation: Strong recommendation based on moderate-quality evidence, 1B. |

Paquette M et al. DCR 2015.
Transportabler Selbstklistierapparat aus dem 18. Jahrhundert, Medizinhistorisches Museum der Universität Zürich