



**Pudendus, Tibialis oder Sakrale Nervenstimulation:
Welcher Nerv soll's denn sein?**

Prof. Dr. med. F. Hetzer
franc.hetzer@spital-linth.ch

Neurostimulation in fecal incontinence

Nervus Tibialis Stimulation (NTS)

Pudendal Nerve Stimulation (PNS)

Sacral Nerve Modulation (SNM)

Tibial Nerve Stimulation (TNS)



Percutaneous TNS (pTNS)

Transcutaneous TNS (TTNS)

Percutaneous Tibial Nerve Stimulation (pTNS)



- 34-gauge needle electrode
 - Surface electrode
 - PC Neuromodulation system
 - Puls frequency 20 Hz
 - Puls with 200 μ s
- 12 sessions (30 min) over 6-12 weeks
- «top-up» sessions

(Uroplasty, Geleen, Netherlands)
(Uroplasty Limited, Manchester, UK)

B. Govaert and C. G. Baeten. *Colorectal Dis* 2010

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

Reference	n	No. of initial weekly treatments (weeks)	Follow-up (months from start of treatment)	FI episodes/week			OCIS		
				Median (range)†	P	≥ 50% reduction (%)	≥ 50% improvement in OCIS (% of patients)	Median OCIS†	P
Shafik et al. ³¹²	32	14 (4)	22*	n.r.	n.r.	n.r.	n.r.	–	–
de la Portilla et al. ⁴³	16	12 (12)	3	n.r.	n.r.	n.r.	38	13 to 9 [–4]*	< 0.001
				8			44	13 to 6 [–5]*	0.001
				14			31	13 to 9 [–4]*	0.001
Govaert et al. ⁴⁴	22	12 (8)	1.5	7 to 3 [–4]	0.082	63	n.r.	12 to 6 [–4]*	< 0.001
Boyle et al. ⁵³	31	12 (12)	5	7 to 1 [–6]	0.029	59	n.r.	13 to 7 [–6]	< 0.001
Finlay et al. ⁴⁵	13	12 (12)	4	n.r.	n.r.	n.r.	–	–	–
Hobouras et al. ⁴⁶	88	12 (12)	3	5 to 1 [–4]	< 0.001	n.r.	n.r.	12 to 9 [–3]	< 0.001
George et al. ²⁷	11	12 (8)	1.5	8 to 2 [–6]*	n.r.	82	–	–	–
Summary (median (range))	213	12 (12–14)	5 (1.5–22)	–4 [–4 to –6]		71 (63–82)	31	13 to 6 [–4 [–3 to –6]	

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

EJ Herrocks and CH Knowles, BJS 2014

Tibial nerve stimulation - RCT

Reference	Outcome	Results
Leroi et al	FIQL Score	No sig. difference
	Anorectal manometry	No sig. difference (3 months)
George et al	St. Mark's FI Score	No sig. difference (improvement)
	FIQL Score	No sig. difference (improvement)
	SF-36	No sig. difference (vitality)
	Anorectal manometry	No sig. difference

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 Bremner, Natasha Stevens, Christine Norton, P Ronan O'Connell, Sandra Eldridge, on behalf of the CONFIDeNT study group†

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

THE LANCET



Knowles C.H. et al Lancet. 2015.

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



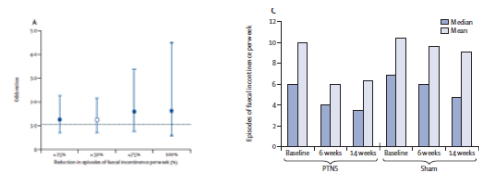
PTNS

TENS (sham)

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

Knowles C.H. et al Lancet. 2015.

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



Knowles C.H. et al Lancet. 2015.

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

	PTNS	Sham	Adjusted odds ratio (95% CI) for PTNS vs sham	p-value
≥25% reduction	53/103 (51%)	46/102 (45%)	1.364 (0.739-2.190)	0.404
≥25% reduction (primary outcome)	39/103 (38%)	32/102 (31%)	1.303 (0.774-2.181)	0.396
≥75% reduction	26/103 (25%)	17/102 (17%)	1.615 (0.779-3.388)	0.205
≥50% reduction	11/103 (11%)	7/102 (7%)	1.435 (0.552-4.514)	0.344

Data are n/N (%). We calculated adjusted odds ratios, CIs, and p values based on imputed and adjusted data. PTNS=percutaneous tibial nerve stimulation; Sham=sham electrical stimulation.

Table 2. Participants with reductions in episodes of faecal incontinence at follow-up (n=227)

Responder:

PTNS vs Sham

38 % vs 31 % (P= 0.396)



Knowles C.H. et al Lancet. 2015.

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

- PTNS is as effective as sham stimulation
- No recommendation for PTNS

Knowles C.H. et al Lancet. 2015.

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

Knowles C.H. et al Lancet. 2015.

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 Eastlake Avenue, Suite 7418
Los Angeles, CA 90033-4612

Paquette IM. et al DCR 2015.

Description
1A Strong recommendation, High-quality evidence
1B Strong recommendation, Moderate-quality evidence
1C Strong recommendation, Low- or very low-quality evidence
2A Weak recommendation, High-quality evidence
2B Weak recommendations, Moderate-quality evidence
2C Weak recommendation, Low- or very low-quality evidence

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

Percutaneous Tibial Nerve Stimulation

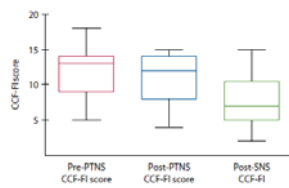
Percutaneous tibial nerve stimulation may be considered because it provides short-term improvement in episodes of fecal incontinence.

Grade of Recommendation:
Weak recommendation based on low- or very low-quality evidence, 2C.

Paquette IM. et al DCR 2015.



SNS after PTNS



N= 13
P>0.05



Hotouras A et al, DCR; 2013

Randomized clinical trial of sacral versus percutaneous tibial nerve stimulation in patients with faecal incontinence

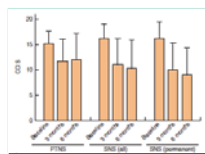
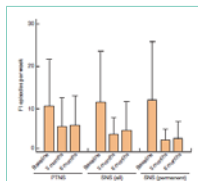
N. N. Thin, S. J. C. Taylor, S. A. Bremner, A. V. Emmanuel, N. Hounsome, N. S. Williams and C. H. Knowles

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



Thin NN et al., BJS 2015

Randomized clinical trial of sacral versus percutaneous tibial nerve stimulation in patients with faecal incontinence



Thin NN et al., BJS 2015

Randomized clinical trial of sacral versus percutaneous tibial nerve stimulation in patients with faecal incontinence

- 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

Thin NN et al., BJS 2015

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., BJS 2015

„Pudendal Nerve“

Percutaneous Pudendal Nerve Stimulation (PNS)

Sacral Lion Procedure



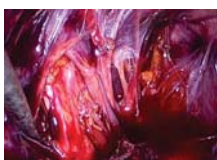
Marc Possover 2007



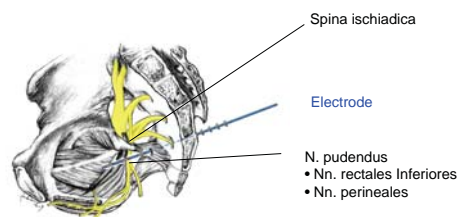
Susanne Bock 2010



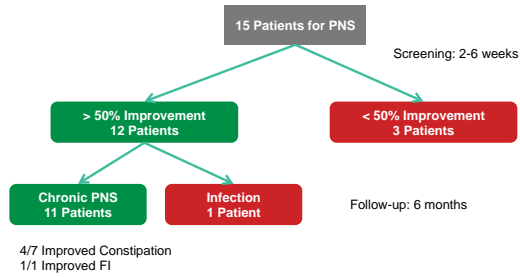
A New Technique of Laparoscopic Implantation of Stimulation Electrode to the Pudendal Nerve for Treatment of Refractory Fecal Incontinence and/or Overactive Bladder With Urinary Incontinence



Schematic drawing pudendal nerve course

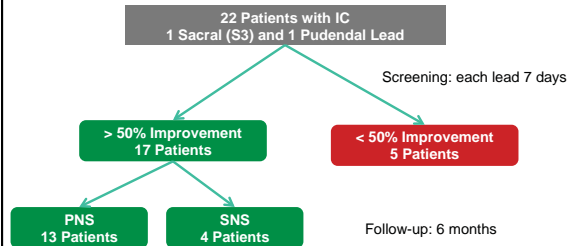


Pudendal Nerve Stimulation (PNS) in neurogenic UI



M. Spinelli, Neurology and Urodynamics 2005

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



K. M. Peters, BJU Int. 2007

First Experience: Results

Age	Reason for fecal incontinence	SNS Failure	Symptom-Reduction (%)	PNS-Permanent Implantation	Follow-up (Months)
31	Pelvic Operation (PO)	Yes	50	Yes	5.3
73	Pelvic Operation (PO)	Yes	70	Yes	6.4
35	Neurogenic (N)	No	70	Yes	5.5
50	Neurogenic (N)	Yes	60	Yes	13.3
77	Neurogenic (N)	Yes	90	Yes	10.2
71	N and PO	Yes	90	Yes	9.8
73	PO and sphincter defect	Yes	30	No	10.2
84	PO and sphincter defect	Yes	90	No	5.5

Bock S, Folie P, Wolff K, Marti L, Engeler DS, Hetzer FH. Tech Coloproctol. 2010

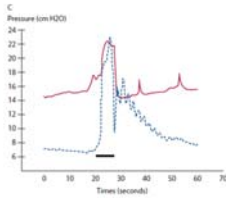
A pilot study of chronic pudendal nerve stimulation for faecal incontinence for those who have failed sacral nerve stimulation

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



Margot S. Damaser, et al, Dis Colon Rectum 2012; 55: 1284–1294

Pudendal Nerve Stimulation for Bowel Dysfunction in Complete Cauda Equina Syndrom

	Group Constipation	Group Incontinence
Patients	8	5
Improvement > 50%	5 (63%)	5 (100%)
Score	17 to 10 (CCS)	9.4 to 0.4 (FI/Week)

Thomas George et al, Annals of Surgery 2014; 259

„Sacral Nerves“

Sacral Nerve Stimulation

Tanogho et al 1982/1989



Matzel et al 1995

Tanogho, J Urol 1989; Matzel, Lancet 1995

Staged Implant

First step



Screening: 10- 21 days
1 2 weeks

Second step



Follow-up
1 3 6 12 months

Hetzer et al, Tech Coloproctol 2005

SNM – Faecal incontinence

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

Autor	Jahr	Anzahl Patienten (Baseline)	Anzahl Patienten (Follow-up)	Medianer Follow-up	Inkontinenzepisoden/Woche Median (Spannweite)		P-Wert
					Baseline	letztes Follow-up	
Follow-up ≤ 12 Monate							
Uludag et al.	2004	50	27	12 *	8 (n.a.)	1 (n.a.)	< 0.001
Melenhorst et al.	2007	100	76	12 *	10 (n.c.) §	2 (n.c.) §	< 0.001
Tjandra et al.	2008	53	53	12 *	10 (13) §	3 (10) §	< 0.001
Michelsen et al.	2010	126	49	12 *	8 (n.c.)	1 (n.c.)	< 0.001
Wexner et al.	2010	120	106	12 *	9 (7) §	2 (4) §	< 0.001
Follow-up 12-36 Monate							
Uludag et al.	2004	50	6	24 *	8 (n.a.)	1 (n.a.)	n.s.
Melenhorst et al.	2007	100	33	36 *	10 (n.c.)	2 (n.c.)	< 0.001
Dudding et al.	2008	51	48	24	6 (0-8) §	1 (0-5) §	n.a.
Hollingshead et al.	2011	86	86	33	9 (7) §	1 (2) §	< 0.001
Milgrom et al.	2011	120	77	36 *	9 (n.a.) §	2 (n.a.) §	< 0.001
Follow-up > 36 Monate							
Melenhorst et al.	2007	100	15	48 *	10 (n.c.) §	2 (n.c.) §	< 0.001
Altomare et al.	2009	60	52	74 §	4 (n.c.) §	1 (n.c.) §	0.004
Daitelm-Jakobsen et al.	2012	147	147	46	6 (n.c.)	1 (n.c.)	< 0.001
Uludag et al.	2011	50	n.a.	60	8 (n.c.)	0 (n.c.)	< 0.002
Devroede et al.	2012	120	77	48	9 (n.c.)	2 (n.c.)	< 0.001

Autor	Jahr	Anzahl Patienten (Baseline)	Anzahl Patienten (Follow-up)	Mediane Follow-up (Monate)	Mediane Score: Baseline (range)	Mediane Score: Follow-up (range)	p-Wert
Follow-up ≤ 12 months							
Tjandra et al.	2008	53	53	12 *	16 ± 1 §	1 ± 2 §	< 0.001
Brouwer et al.	2010	55	48	12 *	15 (13-18)	6 (4-8)	0.001
Gallas et al.	2011	200	130	12 *	14 (2-20)	7 (0-19)	0.001
Follow-up 12-36 months							
Brouwer et al.	2010	55	31	36 *	15 (13-18)	7 (5-8)	0.001
Hollingshead et al.	2011	86	86	33	15 ± 3	9 ± 5	< 0.001
Michelsen et al.	2010	126	126	24	16 (6-20)	10 (0-20)	< 0.001
Gallas et al.	2011	200	54	24 *	14 (2-20)	7 (0-19)	0.001
Wong et al.	2011	61	61	31	14 (n.a.)	8 (n.a.)	n.a.
Follow-up > 36 months							
Altomare et al.	2009	60	52	74 §	15 ± 4	5 ± 5	< 0.001
Brouwer et al.	2010	55	13	48 *	13 (6-19) §	6 (2-8)	0.008
Faucheron et al.	2010	87	87	45	13 (6-19) §	8 (1-17) §	n.a.
Michelsen et al.	2010	126	10	72 *	20 (12-20)	7 (2-11)	< 0.001
Lim et al.	2011	53	41	51 §	12 (9-15)	8 (5-11)	0.001

Autor	Jahr	Anzahl Patienten (Baseline)	Anzahl Patienten (Follow-up)	Medianer Follow-up (Monate)	>50% Verbesserung der Inkontinenzepisoden / Woche	Intention-to-treat 50% Verbesserung der Inkontinenzepisoden / Woche
Follow-up: ≤ 12 Monate						
Tjandra et al.	2008	53	53	12 *	71	63
Hollingshead et al.	2011	86	86	12	81	62
Wexner et al.	2010	120	106	12 *	83	66 ++
Follow-up: 12-36 Monate						
Melenhorst et al.	2007	100	100	28 §	79	59
Dudding et al.	2008	51	48	24	65	52
Govaert et al.	2009	145	145	31 §	80	56
Govaert et al.	2009	173	169	35 §	77	53
Milgrom et al.	2011	120	77	36 *	86	59 ++
Follow-up: > 36 Monate						
Altomare et al.	2009	60	52	74 §	n.a.	n.a.
Hollingshead et al.	2011	86	18	60 *	83	n.c.
Daitelm-Jakobsen et al.	2012	158	91	46	75	n.c.
Uludag et al.	2011	50	50	85	84	n.c.
Devroede et al.	2012	120	77	48 *	87	50

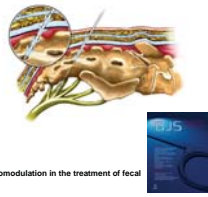
Sacral Nerve Stimulation SNS

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. Peleikis, Johannes Jongen

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



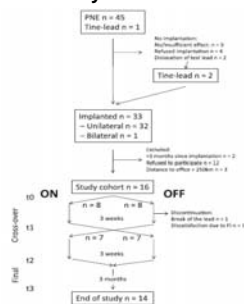
Kahlke V et al., *Dis Colon Rectum* 2015

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

Table 3. Operative data and complications of 16 patients included in the study

Unilateral stimulation	12 (93.8%)
Equipment (V)	12 (93.8%)
Mean amplitude (V)	0.9 ± 0.6
Complications (PNE, dislocation of leads)	2 (12.5%)
Complications after implantation	3 (18.8%)
-Hematomas	1 (6.3%)
-Misplacement time lead	1 (6.3%)
-Pain at stimulator site	1 (6.3%)
-Infection/Expulsion	0

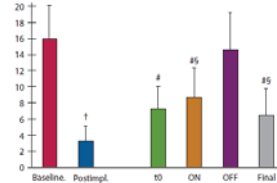
PNE = percutaneous nerve stimulation; V = volts.



Kahlke V et al., *Dis Colon Rectum* 2015

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

Cleveland Clinic Incontinence Score (CCIS)



t0 = time of randomisation
#P < 0.05 vs baseline
#§ < 0.005 vs «off»

Kahlke V et al., *Dis Colon Rectum* 2015

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



➤ High quality of study design



➤ Small number of patients

Kahlke V et al., Dis Colon Rectum 2015

**Bilateral compared with unilateral sacral nerve
stimulation for faecal incontinence; results
of a randomised, single-blinded crossover study.**

Duelund-Jakobsen J, Buntzen S, Lundby L, Sørensen M, Laurberg S

- 27 patients (55 women), mean age 63 y
- Single-center, randomized cross over study



Duelund-Jakobsen J et al., Colorectal Dis 2015

**Bilateral compared with unilateral sacral nerve
stimulation for faecal incontinence; results of a
randomised, single-blinded crossover study**

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

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

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 IM. et al DCR 2015.



Transportabler Selbstkathetierapparat aus dem 18. Jahrhundert, Medizinhistorisches Museum der Universität Zürich

