NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of percutaneous tibial nerve stimulation for faecal incontinence

Treating faecal incontinence by stimulating a nerve near the ankle.

Faecal incontinence occurs when a person loses (often only partially) voluntary control of their bowel movements, resulting in leakage of faeces. The condition may relate to inadequate formation of the anus from birth. It can also relate to diseases of the nervous system (such as spina bifida, spinal cord injury, multiple sclerosis), pelvic organ prolapse, or previous pelvic surgery or radiotherapy. In women, another cause is injury to the anal canal during childbirth. This procedure involves inserting a fine needle into a nerve just above the ankle and passing a mild electric current through the needle to the nerves that control bowel function

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in October 2010.

Procedure name

- Percutaneous tibial nerve stimulation for faecal incontinence

Specialty societies

- The Association of Coloproctology of Great Britain and Ireland
- British Society of Rehabilitation Medicine.

Description

Indications and current treatment

Faecal incontinence occurs when a person loses the ability to control their anal sphincter and bowel movements resulting in leakage of faeces and/or gas.

Faecal incontinence can have a number of underlying causes affecting either the anatomy or function of the anal sphincter. The condition may relate to inadequate formation of the anus from birth. It can be also caused by neurological or spinal disease or injury (for example, spina bifida, multiple sclerosis, stroke or spinal cord injury), pelvic organ or rectal prolapse, previous pelvic organ surgery or radiotherapy. Perineal injury during vaginal delivery is a common cause in women.

Faecal incontinence is associated with a high level of physical disability and social stigma. Its true incidence may be under-reported because of the potentially embarrassing nature of the condition.

Typically, first-line treatment is conservative, including dietary management and antidiarrhoeal medication. If these are not successful, pelvic floor muscle or anal sphincter training may be used.

If conservative treatments have been unsuccessful, surgery is sometimes recommended. Options include sphincter repair, sacral nerve stimulation, stimulated graciloplasty (creation of a new sphincter from other suitable muscles), anorectal or transabdominal implantation of an artificial anal sphincter, and permanent colostomy.

What the procedure involves

Stimulation of the posterior tibial nerve delivers retrograde stimulation to the sacral nerve plexus. The posterior tibial nerve contains mixed sensory motor nerve fibres that originate from the same spinal segments as the innervations to the rectum, anal sphincter and pelvic floor. The potential benefit of percutaneous posterior tibial nerve stimulation is that it may achieve the same neuromodulatory effect as sacral nerve stimulation through a less invasive route. The exact mechanism of action of neuromodulation is unclear.

Percutaneous posterior tibial nerve stimulation (PTNS) is performed while the patient is seated or reclined in a comfortable position. A fine gauge needle or needle electrode is inserted percutaneously just above and medial to the ankle, next to the tibial nerve, and a surface electrode is placed near the arch of the foot. The needle and electrode are connected to a low-voltage stimulator. Stimulation of the posterior tibial nerve produces a typical motor (plantar flexion or fanning of the toes) and/or sensory (tingling in the ankle, foot or toes) response. The current can be adjusted as necessary during the treatment. Initial treatment usually consists of 12 outpatient sessions lasting 30 minutes each, typically once or twice a week and is sometimes adjusted, depending on the patient’s response to treatment. Treatment may be repeated if required.

Instruments to assess disease severity and measuring symptoms

Faecal incontinence disease severity instruments include:

The ‘Cleveland Clinic Florida Fecal Incontinence score’ (CCF-FI) (also referred to as the Wexner or Jorge-Wexner score) is a composite score which

combines 5 parameters: lifestyle changes; need to wear a pad; frequency of incontinence to each of gas, liquid, and solid. It is measured from a patient-completed questionnaire in which each parameter is given a score from 0 to 4 with 0 indicating its absence and 4 indicating daily presence. These values are added to give a score ranging from 0 to 20 (0 indicating perfect control, 10 to 15 indicating moderate incontinence and greater than 15 indicating severe incontinence).

The 'Fecal incontinence quality of life questionnaire' (FIQL) is a scale based on a patient-completed questionnaire with 29 questions grouped into 4 components: lifestyle, coping, depression and embarrassment. Each aspect is valued between 1 and 4 with 1 being very affected and 4 being not affected.

The Rockwood score appears to use the same parameters but lifestyle is on a scale of 0 to 45, coping on a scale of 0 to 36, depression on a scale of 0 to 20 and embarrassment on a scale of 0 to 18.

The 'Fecal Incontinence Severity Index' (FISI) is based on clinical assessment or a patient self-report outside of the clinical setting. It is calculated from a 20-cell type and frequency matrix: 4 types of leakage (gas, mucus, liquid stool, and solid stool) and 5 different frequencies (1 to 3 times per month, once per week, twice per week, once per day, twice or more per day). Higher scores indicate worse faecal incontinence.

Generic quality of life or health status instruments such as the Short Form 36 Health Survey (SF-36) are also used.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to percutaneous tibial nerve stimulation for bowel dysfunction and faecal incontinence. Searches were conducted of the following databases, covering the period from their commencement to 24 January 2011: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with bowel dysfunction or faecal incontinence.
Intervention/test	Percutaneous tibial nerve stimulation.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on about 136 patients from 1 non-randomised comparative study[1] and 6 case series[2,3,4,5,6,7].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on percutaneous tibial nerve stimulation for faecal incontinence

Abbreviations used: CCF-FI, Cleveland Clinic Florida Fecal Incontinence score; CI, confidence interval; FI, faecal incontinence; FIQL, fecal incontinence quality of life; HAS, Hospital anxiety and depression scale; IBD, inflammatory bowel disease; mA, milliamps; PTNS, percutaneous tibial nerve stimulation; SD, standard deviation; SF-36, short form (36) health survey; TENS, transcutaneous electrical nerve stimulation; VAS, visual analogue scale

Study details	Key efficacy findings	Key safety findings	Comments
Shafik A (2003)[1] **Non-randomised comparative study** Egypt Recruitment period: not reported Study population: idiopathic FI (incontinent to solid stools) refractory to alternative therapies n = **52 (32 intervention vs 20 matched controls treated with sham)** Mean age: 38.2 years Sex: 69% vs 70% women Mean duration of FI: 8.6 years Inclusion criteria: normal electromyography activity of eternal anal sphincter, puborectalis and elevator ani muscles as well as normal anorectal sensitivity, anal pressure, defaecography and anal endosonography, failure of alternative treatments such as medical therapy, pelvic floor stimulation, Kegel exercise and biofeedback. Controls were matched on age, duration of FI symptoms and investigative results. Technique: using Stoller Afferent Nerve Stimulator (UroSurge, Coralville, Iowa, USA) – stimulation every other day for 30 minutes each for a total of 4 weeks (if recurrence, twice per week for 4 weeks); the same technique was used for the control group but they did not receive stimulation. Follow-up: **up to 30 months**	Number of patients analysed: **52** ***Functional improvement (intervention group)*** **'Good' results** / **'Fair' results** / **'Poor' results** Proportion of patients: 53.1% (17/32) / 31.2% (10/32) / 15.6% (5/32) Mean score (SD) in these patients: Pre-operative: 17.4 ± 2.3 / 18.2 ± 2.6 / 18.6 ± 2.1 Post-operative: 1.7± 0.6 / 8.6 ± 1.2 / 14.8 ± 3.8 ('good', 'fair' and 'poor' were not defined in the study) (difference in pre and post-operative values were significant in those with 'good' results [$p < 0.001$] and those with 'fair' results [$p < 0.05$]) ***Functional improvement (control group)*** No improvement in these 20 patients. ***Physiological assessment*** All with 'good' results had a normal rectometrogram (all had felt the first rectal and urge sensation and this effect was maintained at 12 months. Findings were not recorded for the patients with 'poor' results. ***Recurrence*** Of those with any improvement in their score 29.7% (8/27) had a recurrence during a mean follow-up of 22.3 months (3 with 'good' results and 5 with 'fair' results). After re-treatment, 6 improved from mean 17.6 ±	***Complications*** There were no adverse effects during or after the study.	**Follow-up issues**: • No loss to follow-up reported. **Study design issues**: • All recordings were made at least twice in the same subject to ensure the results were reproducible. • It is not clear if the tool to measure FI is a validated tool. • It was not clear if measurement of treatment effect was performed by a clinician who was aware of the treatment group. • It was not clear how 'good', 'fair' and 'poor' were defined • Functional improvement was measured with a questionnaire but it was not clear if it was a validated tool. The questionnaire reported on frequency of incontinence to solid and liquid stool and flatus, frequency of pad usage and extent of social convenience. Each category had a score of 0 to 4; total scores ranged from 0 to 20 (0 being perfect continence and 20 complete incontinence). • 26 patients had uninhibited rectal contractions and 6 had uninhibited anal sphincter relaxation. Further analysis was performed but not reported here.

Abbreviations used: CCF-FI, Cleveland Clinic Florida Fecal Incontinence score; CI, confidence interval; FI, faecal incontinence; FIQL, fecal incontinence quality of life; HAS, Hospital anxiety and depression scale; IBD, inflammatory bowel disease; mA, milliamps; PTNS, percutaneous tibial nerve stimulation; SD, standard deviation; SF-36, short form (36) health survey; TENS, transcutaneous electrical nerve stimulation; VAS, visual analogue scale

Study details	Key efficacy findings	Key safety findings	Comments
Conflict of interest/source of funding: not reported	1.8 to 2.2 ±0.7. Two patients with recurrence and all patients with 'poor' results refused treatment.		

Abbreviations used: CCF-FI, Cleveland Clinic Florida Fecal Incontinence score; CI, confidence interval; FI, faecal incontinence; FIQL, fecal incontinence quality of life; HAS, Hospital anxiety and depression scale; IBD, inflammatory bowel disease; mA, milliamps; PTNS, percutaneous tibial nerve stimulation; SD, standard deviation; SF-36, short form (36) health survey; TENS, transcutaneous electrical nerve stimulation; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Boyle (2010)[2]

Case series
UK
Recruitment period: 2008–9
Study population: urge FI
n = 31
Median age: 58 years
Sex: 97% female
Aetiology: the 1 male in the study had undergone a haemorrhoidectomy 6 years previously with iatrogenic sphincter injury; of the women, obstetric injury was the cause in 77% (24/30), pelvic surgery in 6% (2/30) and unknown in 13% (4/30) (median parity in these women was 2).
Patient selection criteria: patients referred for conservative management
Exclusion criteria: pregnancy or intended pregnancy, implanted pacemaker or defibrillator, history of ischaemic heart disease, peripheral neuropathy or any medication affecting coagulation, patient with mixed symptoms (that is, concomitant passive incontinence, constipation, rectal evacuatory disorder).

Technique: PTNS using Urgent PC neuromodulation system (Uroplasty); stimulation protocol performed as outpatient procedure with 12 weekly initial 30-minute sessions followed by 2 sessions at 2-week intervals (if symptoms returned, 3 further</td>
<td>Number of patients analysed: 31

Operative success
Overall treatment response rate: 68% (21/31)
(at least 50% reduction in urge FI + patient satisfaction)
7 patients withdrew because of lack of improvement: 2 after the 6th session, 2 after the 7th and 3 after the 12th.
4 patients requested additional sessions:
- 1 had 2 blocks after 4 and 3 month periods of no symptoms
- 1 had 1 block of 3 weekly sessions after 7 months without symptoms
- 2 had 1 block after 3 and 7 months as prophylaxis
Episodes of urge FI per week
71% (22/31) had more than 50% improvement in episodes, 12 of whom were ‘continent’ after treatment (complete cessation of episodes).
Of the 9 who did not have a 50% improvement, 4 did not experience weekly episodes of incontinence (instead, 3 had an episode monthly and 1 had an episode bimonthly).
<table>
<tr><th></th><th>Baseline</th><th>Post-procedural</th><th>p value</th></tr>
<tr><td>Median episodes per week (range)</td><td>4 (0–30)</td><td>0 (0–27)</td><td>< 0.0001</td></tr>
</table>
The median reduction in episodes per week was 3 (range: +2 to −4).
CCF-FI scores
65% (20/31) of all patients had improved scores but the score deteriorated in 1 patient.</td>
<td>Complications
There was no morbidity observed during or after the procedure.</td>
<td>Follow-up issues:
• 10 patients withdrew from treatment: 2 after the 2nd session (because of pregnancy or lack of commitment to continue), 1 had apparent continence but decided to have alternative treatment (reason and time of withdrawal not given) and the rest because of lack of improvement (see efficacy column).

Study population issues:
• This is one of 2 studies in this table where patients were offered this therapy as first-line treatment rather than after other treatments had failed (this could mean that some patients were different than those in other studies who were refractory to other therapies).
• 10 had disrupted internal anal sphincter, 17 had disrupted external anal sphincter, 9 had combined external and internal sphincter defect and 13 had intact sphincter.

Other issues:
• Pre-operative and post-operative anorectal physiological measurements were not reported.</td>
</tr>
</table>

Abbreviations used: CCF-FI, Cleveland Clinic Florida Fecal Incontinence score; CI, confidence interval; FI, faecal incontinence; FIQL, fecal incontinence quality of life; HAS, Hospital anxiety and depression scale; IBD, inflammatory bowel disease; mA, milliamps; PTNS, percutaneous tibial nerve stimulation; SD, standard deviation; SF-36, short form (36) health survey; TENS, transcutaneous electrical nerve stimulation; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>weekly sessions were administered)

Median follow-up: up to 14 months

Conflict of interest/source of funding: none</td>
<td>
<table>
<tr><th></th><th>Baseline</th><th>Post-procedural</th><th>p value</th></tr>
<tr><td>Median score (range)</td><td>13 (5–20)</td><td>7 (0–20)</td><td>< 0.0001</td></tr>
</table>
The median reduction in score was 2 (range: −1 to 13)
Ability to defer defaecation
Urgency was improved in 65% (20/31) of patients.
<table>
<tr><th></th><th>Baseline</th><th>Post-procedural</th><th>p value</th></tr>
<tr><td>Median minutes able to defer (range)</td><td>1 (0–15)</td><td>5 (0–25)</td><td>< 0.0001</td></tr>
</table>
Median increase in ability to defer was 3 minutes (range: 0 to 25).
Physiological assessment
After the procedure, resting manometry pressure was attenuated in 14 patients (median 50 cmH_20), maximal squeeze increment was attenuated in 25 patients (median 40 cmH_20), and rectory sensory thresholds to balloon inflation showed 8 had relative rectal hypersensitivity (maximal tolerated volume < 90 ml). There was no correlation between improvement or deterioration in outcome measures and physiological parameters including: age, resting anal tone, squeeze increment, internal or external sphincter defects, rectal sensation thresholds (that is, desire to defaecate, maximal tolerated volume).
</td>
<td></td>
<td></td>
</tr>
</table>

Abbreviations used: CCF-FI, Cleveland Clinic Florida Fecal Incontinence score; CI, confidence interval; FI, faecal incontinence; FIQL, fecal incontinence quality of life; HAS, Hospital anxiety and depression scale; IBD, inflammatory bowel disease; mA, milliamps; PTNS, percutaneous tibial nerve stimulation; SD, standard deviation; SF-36, short form (36) health survey; TENS, transcutaneous electrical nerve stimulation; VAS, visual analogue scale

Study details	Key efficacy findings	Key safety findings	Comments
Allison M (2009)[3] **Case series** UK Recruitment period: not reported Study population: urge FI n = **30** Age: 34 to 75 years Sex: 97% female Exclusion criteria: patients with pacemakers, implanted defibrillators, history of heart problems, nerve damage or tendency to excessive bleeding, or women who are or are intending to become pregnant. Technique: PTNS using Urgent PC neuromodulation system (Uroplasty); stimulation protocol performed as outpatient procedure with 12 initial 30-minute sessions usually once or twice weekly before it is tailored to treat the patient's needs; subsequent sessions are tapered off to a maintenance regime recommended as every other week for up to 2 months Follow-up: **8 months** Conflict of interest/source of funding: none	Number of patients analysed: **21 who had completed treatment at the time of writing** ***Symptom improvement*** 71.5% (15/21) were considered to have had a successful outcome (with at least 50% reduction in episodes of FI as measured in self-completed daily bowel diary). 28.5% (6/21) were completely continent. 2 case histories describe the ability to eat out with the family.	***Side effects*** These were minimal but included discomfort or pain at the insertion site (may be throbbing in nature), redness or inflammation at or around the insertion site and toe numbness. Pain and numbness were transient. Some patients had tenderness at the insertion site if they received treatments that were a short time apart.	**Follow-up issues**: • Not reported **Study design issues**: • Patient selection: all patients with urge FI referred for nurse-led conservative management at Barts and the London NHS Trust had been offered the choice of PTNS as first-line management. **Study population issues**: • Patients included in this study were reported in Boyle 2010 study above[2] but this study was included because it reports safety data.

Abbreviations used: CCF-FI, Cleveland Clinic Florida Fecal Incontinence score; CI, confidence interval; FI, faecal incontinence; FIQL, fecal incontinence quality of life; HAS, Hospital anxiety and depression scale; IBD, inflammatory bowel disease; mA, milliamps; PTNS, percutaneous tibial nerve stimulation; SD, standard deviation; SF-36, short form (36) health survey; TENS, transcutaneous electrical nerve stimulation; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Govaert B (2009)[4]

Case series
Netherlands, Italy, Spain
Recruitment period: 2007–9
Study population: FI refractory to conservative treatments
n = 22
Mean age: 60.4 years
Sex: 73% women
Mean duration of incontinence: 7.4 years

Patient selection criteria: at least 18 years, FI with liquid or solid stool disrupting lifestyle, psychological stability and suitability for treatment (determined by investigator), willing to commit to follow-up schedule, ability to read and write, adequate motor and sensory response, intact peripheral neurosensory nervous system as determined by clinical investigation.
Exclusion criteria: major internal and/or external sphincter defect (> 120 degrees of circumference), faecal impaction, pacemaker or defibrillator, cardiopathy or bleeding disorders, pregnancy or intention to become pregnant, neurogenic or congenital disorders causing FI (multiple sclerosis, Spina Bifida), unable to travel to hospital to receive treatment.

Technique: PTNS using Urgent PC neuromodulation system (Uroplasty);</td>
<td>Number of patients analysed: 22
Completion of treatment
All completed the 6 weeks but 2 with no improvement after 6 weeks did not continue with the maintenance regime and 1 with symptom recurrence at 3 months stopped maintenance treatment.
Incontinence episode frequency
63.4% (14/22) had > 50% reduction in episodes at 6 weeks follow-up
92.9% (13/14) of these patients still had > 50% reduction at 1 year
<table>
<tr><th></th><th>Baseline</th><th>6 weeks</th><th>1 year</th></tr>
<tr><td>Mean episodes in 3 weeks (SD, 95% CI)</td><td>19.6 (21.0, 5.5–33.8)</td><td>9.9 (15.5, -1.42 – -23.8)</td><td>3.6 (4.8, 0.2–6.8)</td></tr>
</table>
p = 0.082 at 6 weeks and p = 0.029 at 1 year
CCF-FI score
<table>
<tr><th></th><th>Base-line</th><th>6 weeks</th><th>6 months</th><th>1 year</th></tr>
<tr><td>Mean score (SD, 95% CI)</td><td>11.6 (3.5,9.5 –13.6)</td><td>8.2 (2.5, 6.7– 9.7)</td><td>5.4 (4.2, 2.9– 7.8)</td><td>5.9 (3.9, 3.7– 8.2)</td></tr>
</table>
p < 0.001 at both 6 weeks and 6 months and p = 0.001 at 1 year
Quality of life (SF-36)
<table>
<tr><th></th><th>Mean baseline score</th><th>Mean score at 6 weeks</th><th>Mean score at 1 year</th></tr>
<tr><td>Physical</td><td>64</td><td>71</td><td>83</td></tr>
</table>
</td>
<td>Complications
There were 3 mild adverse events related to the procedure:
- 2 patients had gastrodynia 2–3 hours after treatment sessions and lasting for several hours.
- 1 patient reported numbness in the treated leg lasting 2 hours in the first treatment session only.
None of these events required medical intervention or hospitalisation.</td>
<td>Follow-up issues:
• Evaluation at 6 weeks, 3 months, 6 months and 1 year.
• 2 patients did not continue after 6 weeks despite good results because they found the travel to the hospital for treatment too much.

Study design issues:
• Multicentre prospective study.

Other issues:
• Study has been accepted for publication and published online but is not indexed in databases yet.</td>
</tr>
</table>

Abbreviations used: CCF-FI, Cleveland Clinic Florida Fecal Incontinence score; CI, confidence interval; FI, faecal incontinence; FIQL, fecal incontinence quality of life; HAS, Hospital anxiety and depression scale; IBD, inflammatory bowel disease; mA, milliamps; PTNS, percutaneous tibial nerve stimulation; SD, standard deviation; SF-36, short form (36) health survey; TENS, transcutaneous electrical nerve stimulation; VAS, visual analogue scale

Study details	Key efficacy findings	Key safety findings	Comments

stimulation protocol performed as outpatient procedure with 12 initial 30-minute sessions usually twice weekly; if sufficient symptom relief, maintenance therapy started (6 sessions weekly, 6 sessions every 2 weeks and 6 sessions monthly maintenance regime recommended as every other week for up to 2 months)

Follow-up: **up to 1 year**

Conflict of interest/source of funding: funded by Uroplasty BV, Geleen, the Netherlands who were also involved in study design and data collection.

functioning			
Social functioning	59	65	75
Role physical	36	43	57
Role emotional	38	60	80
Mental health	57	63	70
Vitality	54	60	57
Body pain	60	58	78
General health	50	55	60

(Scores estimated by analyst from figure in study)
At 6 weeks, this was significant improvements in domains role emotional and vitality ($p < 0.05$) and at 1 year, there was significant improvement in all domains except vitality ($p < 0.05$ for all but vitality).

FIQL scores

FIQL component	**Mean baseline score**	**Mean score at 6 weeks**	**Mean score at 1 year**
Lifestyle	2.7	2.9	3.4
Coping/ behaviour	1.9	2.4	3.0
Depression/self-perception	2.6	2.7	3.0
Embarrassment	2.1	2.7	2.8

(Scores estimated by analyst from figure in study)
This was significant for coping/behaviour and embarrassment at 6 weeks ($p < 0.05$) and for coping/behaviour and at 1 year ($p < 0.05$).

Abbreviations used: CCF-FI, Cleveland Clinic Florida Fecal Incontinence score; CI, confidence interval; FI, faecal incontinence; FIQL, fecal incontinence quality of life; HAS, Hospital anxiety and depression scale; IBD, inflammatory bowel disease; mA, milliamps; PTNS, percutaneous tibial nerve stimulation; SD, standard deviation; SF-36, short form (36) health survey; TENS, transcutaneous electrical nerve stimulation; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>De la Portilla (2009)[5]

Case series
Spain
Recruitment period: not reported
Study population: severe FI for longer than 6 months
n = 16
Mean age: 59 years
Sex: 69% female
Mean duration of FI: 24 months
Previous procedures: fistulotomy (1), fistulectomy (1), anal atresia repair (1), hysterectomy (4), low anterior resection for renal cancer (1), right colectomy for colon cancer (1), circular anopexy (1), sphincterectomy (2), haemorrhoidectomies (2), bulking agents for passive incontinence (1), endorectal repair of rectocele (1)

Patient selection criteria: 18 to 80 years of age, Wexner score of 10 or more, more than 4 faecal leaks within 28 days (recorded in defaecation diary) or incontinence for at least 6 months
Exclusion criteria: severe cardiopulmonary disease, lesion of percutaneous tibial nerve, severe distal venous insufficiency, use of cardiac pacemaker or implantable defibrillator, IBD, uncontrolled diabetes with peripheral nerve involvement, immunosuppression, active anal fissure, fistula or abscess, pregnancy, or circumferentially intact external</td>
<td>Number of patients analysed: 16
Operative success
All patients finished the first phase (first 3 months).
62.5% (10/16) of patients had ‘good results’ (at least 40% decrease in Wexner score; 5 did not continue to the 2nd phase).
During the 2nd phase (next 2 months), 43.8% (7/16) had good continence.
After 6 months without any treatment, only 31.2% (5/16) had good continence.
Wexner score
<table>
<tr><th></th><th>Baseline</th><th>After 3 months</th><th>After 8 months</th><th>6 months after treatment ended</th></tr>
<tr><td>Mean score (range)</td><td>13.2 ± 4.1</td><td>9 ± 5.2</td><td>8.1 ± 5.7</td><td>9.1 ± 5</td></tr>
<tr><td>p value from baseline</td><td>N/a</td><td>< 0.0005</td><td>0.001</td><td>0.001</td></tr>
</table>
FIQL
<table>
<tr><th>FIQL component</th><th>Mean baseline score</th><th>After 3 months</th><th>After 8 months</th><th>After 6 months without treatment</th></tr>
<tr><td>Lifestyle</td><td>2.7 ± 0.9</td><td>2.9 ± 0.7</td><td>3 ±0.8</td><td>3 ±0.7</td></tr>
<tr><td>Coping</td><td>1.7 ± 0.5</td><td>2.1 ± 0.8</td><td>2.2 ± 0.8</td><td>2.2 ± 0.9</td></tr>
<tr><td>Depression</td><td>3.1 ± 0.9</td><td>3.2 ± 0.8</td><td>3.2 ± 0.9</td><td>3.2 ± 0.9</td></tr>
<tr><td>Embarrassment</td><td>1.8 ± 0.7</td><td>2.3 ± 0.9</td><td>2.6 ± 1</td><td>2.6 ± 1</td></tr>
</table>
(p values: 0.086 for lifestyle, < 0.002 for coping, < 0.004</td>
<td>Complications
There were no cases of bleeding during or after the procedure.
(no other adverse events reported)</td>
<td>Follow-up issues:
• After 3 and 8 months and then 6 months after treatment stopped.

Study design issues:
• Quality of life was measured with VAS instead of with a validated composite score.
• Patients who did not continue with therapy (because of a lack of efficacy) were followed up in order to facilitate the intention-to-treat analysis.

Study population issues:
• 8 patients had an internal anal sphincter defect shown on endosonography</td>
</tr>
</table>

Abbreviations used: CCF-FI, Cleveland Clinic Florida Fecal Incontinence score; CI, confidence interval; FI, faecal incontinence; FIQL, fecal incontinence quality of life; HAS, Hospital anxiety and depression scale; IBD, inflammatory bowel disease; mA, milliamps; PTNS, percutaneous tibial nerve stimulation; SD, standard deviation; SF-36, short form (36) health survey; TENS, transcutaneous electrical nerve stimulation; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>anal sphincter if previous anal repair.

Technique: PTNS with Urgent PC (Uroplasty); first phase: stimulation protocol performed as outpatient procedure with initial 12 weekly 30-minute sessions; if a good response (at least 40% decreased in initial Wexner score) enter second phase: biweekly treatment for 2 months; third phase: every 3 weeks for 2 months; fourth phase: 1 session in 1 month followed by 6 months without treatment.
Follow-up: 6 months
Conflict of interest/source of funding: not reported</td>
<td>for depression, and < 0.0005 for embarrassment)
VAS for quality of life (scale 1 to 10 with 10 as best quality of life)
<table>
<tr><th></th><th>Baseline</th><th>After 3 months</th><th>After 8 months</th></tr>
<tr><td>Median score (range)</td><td>4.6 ± 1.5</td><td>7 ± 2.5</td><td>7.2 ± 2.5</td></tr>
<tr><td>p value from baseline</td><td>n/a</td><td>0.002</td><td>0.001</td></tr>
</table>
Anorectal manometry
No significant change in maximum resting pressure, first sensation (ml) and urgency (ml).
Maximum squeeze pressure significantly increased (median 44.7 to 63 mmHg, p < 0.007 at 8 months</td>
<td></td>
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</tr>
</table>

Abbreviations used: CCF-FI, Cleveland Clinic Florida Fecal Incontinence score; CI, confidence interval; FI, faecal incontinence; FIQL, fecal incontinence quality of life; HAS, Hospital anxiety and depression scale; IBD, inflammatory bowel disease; mA, milliamps; PTNS, percutaneous tibial nerve stimulation; SD, standard deviation; SF-36, short form (36) health survey; TENS, transcutaneous electrical nerve stimulation; VAS, visual analogue scale

Study details

Findlay J (2010)[6]

Case series

UK

Recruitment period: not reported

Study population: FI for at least 6 months

n = **13**

Median age: 53 years
Sex: 100% female
Aetiology: idiopathic (9), obstetric (3), previous anorectal surgery (1)

Exclusion criteria: under 18 years old, coagulopathy, neuropathy, implanted pacemaker or cardiac debrillator, pregnancy or intention to become pregnant.

Technique: PTNS with Urgent PC (Uroplasty); *first phase*: stimulation protocol performed as outpatient procedure with 12 weekly 30-minute sessions.

Follow-up: **4 months**

Conflict of interest/source of funding: not reported

Key efficacy findings

Number of patients analysed: **13**

Episodes of incontinence

Median (interquartile range)	Wind	Liquid	Solid
Baseline	6 (0–17.5)	10 (5–29.5)	18 (0–30)
p value	0.012	0.086	0.047
After 1 month	0 (0–0)	1 (0–9)	4 (1–14)
p value	0 .012	0.083	0.047
After 3 months	0 (0–0)	0 (0–4)	0 (0–0)
p value	0.018	0.012	0.012
After 4 months	0 (0–3)	0 (0–5)	1 (0–2)
p value	0.043	0.235	0.128

Rockwood score (FIQOL)

FIQL component	Mean baseline score	After 3 months	After 8 months	After 6 months without treatment
Lifestyle	2.7 ± 0.9	2.9 ± 0.7	3 ± 0.8	3 ± 0.7
Coping	1.7 ± 0.5	2.1 ± 0.8	2.2 ± 0.8	2.2 ± 0.9
Depression	3.1 ± 0.9	3.2 ± 0.8	3.2 ± 0.9	3.2 ± 0.9
Embarrassment	1.8 ± 0.7	2.3 ± 0.9	2.6 ± 1	2.6 ± 1

Key safety findings

Complications

- 1 patient withdrew after 7 weeks because of a swollen and painful leg (it was not clear if this was from the procedure).

Comments

Follow-up issues:

- 2 patients were lost to follow-up in the first month after treatment and excluded from the analysis in that month only.

Study design issues:

- Patients all presented to the authors' general colorectal clinic.
- Data collected retrospectively from medical notes and computer database.

Study population issues:

- Prior treatments more than 3 months before treatment included physiotherapy (13), sphincteroplasty (3), biofeedback (3), PTQ™ implants (injectable silicone implants, 1).
- 7 patients had subnormal anorectal physiology, 4 had damage or scarring shown on endo-anal ultrasound with no effect amenable to surgical repair.

Abbreviations used: CCF-FI, Cleveland Clinic Florida Fecal Incontinence score; CI, confidence interval; FI, faecal incontinence; FIQL, fecal incontinence quality of life; HAS, Hospital anxiety and depression scale; IBD, inflammatory bowel disease; mA, milliamps; PTNS, percutaneous tibial nerve stimulation; SD, standard deviation; SF-36, short form (36) health survey; TENS, transcutaneous electrical nerve stimulation; VAS, visual analogue scale

Study details	Key efficacy findings	Key safety findings	Comments
	International Consultation on Incontinence Questionnaire Anal Incontinence Symptoms and Quality of Life Module (ICIQ-B)		

Outcome	Mean at baseline	Mean after treatment (n = 11)	p value
Bowel pattern (1–21)	8.58	7.58	0.209
Bowel control (0–28)	19.75	15.33	0.001
Quality of life (0–26)	22.33	17.58	0.007

Emotional outcomes

Outcome	Mean at baseline	Mean after treatment (n = 11)	p value
HAD anxiety [a]	13.00	11.42	0.226
HAD depression [a]	8.17	7.50	0.510

[a] HAD has 7 anxiety items and 7 depression items, with scores greater than 7 indicating anxiety and depression, respectively.

Anal ultrasound and physiology

After the procedure, subnormal physiology was demonstrated in 7 patients. Mean resting pressure was 37.8 mmH_2O, mean squeeze pressure was 73.4 mmH_2O (pre-operative values not reported but the study stated that 'normal' values were 50–80 mmH_2O and 100–140 mmH_2O, respectively).

Abbreviations used: CCF-FI, Cleveland Clinic Florida Fecal Incontinence score; CI, confidence interval; FI, faecal incontinence; FIQL, fecal incontinence quality of life; HAS, Hospital anxiety and depression scale; IBD, inflammatory bowel disease; mA, milliamps; PTNS, percutaneous tibial nerve stimulation; SD, standard deviation; SF-36, short form (36) health survey; TENS, transcutaneous electrical nerve stimulation; VAS, visual analogue scale

Study details

Mentes BB (2007)[7]

Case series

Turkey

Recruitment period: not reported

Study population: FI (and urinary incontinence) from partial spinal cord injury

n = **2**

Patient characteristics: 51-year old woman who had lumbar disc herniation 3 years prior resulting in incontinence to solid and liquid stool, gas and urine; and 31-year old man with 10-year history of lumbar cavernous haemangioma resulting in compression to spinal cord causing incontinence to solid and liquid stool, gas and urine, and sexual dysfunction.

Technique: with Urgent PC Stimulator (Cysto Medix, Gemert, Holland); stimulation protocol was performed for 30 minutes every other day for 4 weeks and then 3 more times (every 2 months).

Follow-up: **12 weeks**

Conflict of interest/source of funding: not reported.

Key efficacy findings

Number of patients analysed: **2**

Wexner score

	Pre-operative	Post-operative
Patient 1	13	9
Patient 2	10	7

FIQL score

FIQL component	Pre-operative		Post-operative	
	Patient 1	Patient 2	Patient 1	Patient 2
Lifestyle	2.10	2.60	2.50	2.90
Coping	1.55	1.66	2.11	2.00
Depression	2.62	2.48	2.91	2.77
Embarrassment	2.33	2.33	3.00	2.66

FISI score

	Pre-operative	Post-operative
Patient 1	40	31
Patient 2	31	20

Physiologic parameters

	Pre-operative		Post-operative	
	Patient 1	Patient 2	Patient 1	Patient 2
Resting pressure (cmH_20)	23	40	34	68
Maximum squeeze pressure (cmH_20)	57	90	85	100
Sensory threshold (mA)	6.2	5.5	11.6	6.5
Pudendal nerve terminal motor latency (ms)				
Right nerve	2.4	2.3	2.3	2.2
Left nerve	2.2	2.1	2.3	2.1

Key safety findings

Not reported.

Comments

Follow-up issues:

- 1 patient who refused further treatment was lost to follow-up.

Study design issues:

- This is one of the first studies reporting on the use of this procedure for this indication.
- Patients performed pelvic floor exercises during the treatment period.
- Tests were carried out by an independent observer blinded to the treatment procedures.

Efficacy

A non-randomised comparative study of 52 patients reported that of the 32 patients treated with PTNS 53% (17/32) had 'good' results, 31% (10/32) had 'fair' results and 16% (5/32) had 'poor' results after treatment. The terms 'good', 'fair' and 'poor' were not defined, but patients in the 'good' group had a reduction in score (the scores ranged from 0 to 20 with 0 being perfect continence; not clear if tool is validated) from mean 17.4 to 1.7 ($p < 0.001$), the 'fair' group had a reduction from mean 18.2 to 8.5 ($p < 0.05$) and the 'poor' group had a reduction from mean 18.6 to 14.8 (no significance reported). There was no clinical improvement in the 20 patients treated with sham[1].

A case series of 31 patients treated with PTNS reported an overall treatment response rate of 68% (21/31) after (defined as at least 50% reduction in urge faecal incontinence and patient satisfaction)[2].

A case series of 13 patients reported a significant reduction in median episodes of wind incontinence from baseline to all periods of follow-up up to 4 months (6 to 0; $p = 0.043$), liquid incontinence was only significantly decreased after 3 months (10 to 0; $p = 0.012$) but was no longer significant at 4 months, and solid incontinence was significantly reduced at all periods up until 3 months (18 to 0; $p = 0.12$) but was no longer significant at 4 months[6].

Health status and disease severity outcomes

FIQL scores

A case series of 22 patients reported that there was a significant improvement in coping/behaviour and embarrassment from baseline to 6 weeks (1.9 to 2.4 and 2.1 to 2.7; $p < 0.05$) and at 1 year this was still significant for coping/behaviour (1.9 to 3.0; $p < 0.05$)[4].

A case series of 16 patients treated with 8 months of treatment followed by 6 months of no treatment reported a significant improvement in 3 of the 4 domains from baseline to 6 months after treatment stopped: coping (1.7 to 2.2, $p < 0.002$), depression (3.1 to 3.2, $p < 0.004$), and embarrassment (1.8 to 2.6, $p < 0.0005$)[5].

Cleveland Clinic Florida Faecal Incontinence score (CCF-FI)

The case series of 31 patients reported that 65% (20/31) of all patients had improved scores but 1 had deteriorated (median 13 at baseline to 7 after the procedure, $p < 0.0001$)[2].

The case series of 22 patients reported significantly improved scores from baseline to 1 year (11.6 to 5.9, $p = 0.001$)[4].

The case series of 16 patients reported a significant improvement in scores from 13.2 at baseline to 8.1 after 8 months ($p = 0.001$) and 9.1 in the next 6 months without treatment ($p = 0.001$)[5].

A case series of 2 patients reported improvement of score from 13 to 9 and 10 to 7 at 12-week follow-up[7].

Quality of life and emotional impact

The case series of 22 patients reported significant improvements in role–emotional (problems with work or other daily activities as a result of emotional problems) and vitality domains of the SF-36 questionnaire at 6 weeks and in all domains except vitality at 1 year (for example, mean score for physical functioning increased from 64 to 83 and social functioning increased from 59 to 75; $p < 0.05$ for all)[4].

The case series of 16 patients reported a significant increase in quality of life on a visual analogue scale (VAS) (from 1 to 10, with 10 being best quality of life) from median 4.6 at baseline to 7.2 after 8 months ($p = 0.001$)[5].

The case series of 13 patients reported no significant difference in Hospital Anxiety and Depression Scale score (0 to 14 with 14 being worst anxiety or depression) from baseline to 4 months follow-up (13.00 to 11.42 for anxiety and 8.17 to 7.50 for depression)[6].

Physiological measurements

The non-randomised study of 52 patients reported that all 53% (17/32) with ‘good’ results had a normal rectometrogram (all had felt the first rectal and urge sensation and this was maintained up to the rectometric recording in the 12th month). And all 31% (10/32) with ‘fair’ results had the first rectal sensation but the urge sensation was not recorded[1].

The case series of 16 patients reported that the only measurement that was significant from baseline to the second phase (8 months) was maximum squeeze pressure (median 44.7 to 63 mmHg, $p < 0.007$). Maximum resting pressure, first sensation (ml) and urgency (ml) were not significantly different[5].

A case series of 13 patients reported subnormal physiology was demonstrated in 7 patients after the procedure. Mean resting pressure was 37.8 mmH_2O, mean squeeze pressure was 73.4 mmH_2O (baseline values not reported)[6].

Recurrence

The non-randomised comparative study of 52 patients reported that of those with any improvement in scores after PTNS, 30% (8/27) had a recurrence during a mean follow-up of 22.3 months (3 originally considered to have ‘good’ results and 5 with ‘fair’ results). 6 had further treatment but 2 refused treatment. No patients had improvement in the sham group so recurrence was not relevant[1].

The case series of 31 patients reported that 2 patients requested additional sessions for recurrence of symptoms: 1 had recurrence after both 4 and 3 month periods of no symptoms and 1 after 7 symptom-free months. Two additional patients without recurrence of symptoms requested additional sessions as prophylaxis after 3 and 7 months[2].

Safety

Most studies reported that there were no adverse events.

The case series of 30 patients reported transient discomfort or pain at the insertion site (throbbing), redness or inflammation at or around the insertion site and transient toe numbness. Some patients had tenderness at the insertion site if their treatment sessions were a short time apart[3].

The case series of 22 patients reported 3 mild adverse events that did not require medical intervention: gastrodynia 2 – 3 hours after treatment sessions and lasting for several hours in 2 patients and leg numbness lasting 2 hours in 1 patient in the first treatment session only[4].

The case series of 13 patients reported that 1 patient withdrew after 7 weeks because of a swollen and painful leg[6].

Validity and generalisability of the studies

- There are small numbers of patients, primarily from case series, who have received this procedure for faecal incontinence in the published literature.
- There are some differences in treatment protocol in the studies. Some patients had the procedure as an outpatient procedure[2,3,4,5,6], but some studies were not clear about where the procedure was performed. There was also some variation in the time between sessions (some occurred weekly while others occurred more frequently) and the total length of treatment.
- There is some variation in the inclusion and exclusion criteria in the studies: the length of faecal incontinence symptoms prior to treatment (some stated that patients' symptoms lasted for at least 6 months prior to treatment but most did not specify how long symptoms had lasted before inclusion in the study) and whether or not the patients were refractory to other treatments (most stated that patients were refractory to other treatments but the patients treated at Barts and the London NHS Trust were treated with PTNS as first-line therapy[2,3,8]).
- Across a range of patient-reported outcome measures, some patients with a significant improvement in scores have residual moderate faecal incontinence after the procedure, so it is difficult to determine if the results are clinically significant. Considering the social stigma and adverse impact on quality of life of this condition, a small improvement in scores may be highly significant for patients.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Percutaneous posterior tibial nerve stimulation for overactive bladder syndrome. NICE interventional procedures guidance 362 (2010). Available from www.nice.org.uk/guidance/IPG362
- Transabdominal artificial bowel sphincter implantation for faecal incontinence. NICE interventional procedures guidance 276 (2008). Available from www.nice.org.uk/guidance/IPG276
- Injectable bulking agents for faecal incontinence. NICE interventional procedures guidance 210 (2007). Available from www.nice.org.uk/guidance/IPG210
- Stimulated graciloplasty for faecal incontinence. NICE interventional procedures guidance 159 (2006). Available from www.nice.org.uk/guidance/IPG159
- Artificial anal sphincter implantation. NICE interventional procedures guidance 66 (2004). Available from www.nice.org.uk/guidance/IPG66
- Sacral nerve stimulation for faecal incontinence. NICE interventional procedures guidance 99 (2004). Available from www.nice.org.uk/guidance/IPG99

Clinical guidelines

- Faecal incontinence. NICE clinical guideline 49 (2007). Available from www.nice.org.uk/guidance/CG49

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr CH Knowles, Ms Karen Nugent, Miss Carolynne Vaizey, Association of Coloproctology of Great Britain and Ireland.

- Two Advisers considered the procedure to be novel and of uncertain safety and efficacy but one adviser considered it to be established practice and not new.
- Advisers considered biofeedback therapy, acupuncture or best medical care (such as medical therapy or dietary modification) to be the comparator.

- Anecdotal adverse events or events from reports include haematoma or nerve injury.
- Additional theoretical adverse events include minor soreness at the needle site.
- Key efficacy outcomes is the sustained improvement in incontinence (even if requiring top up therapy) measured as a reduction in weekly faecal incontinence episodes and quality of life.
- One Adviser commented that there are no RCTs so the effect of placebo is unknown. The maintenance of the effect and the need for long-term top up treatments is also unknown.
- Another Adviser commented that simple acupuncture or weekly visits for 12 weeks might have a similar effect.
- Practical training within an established unit is required.

Patient Commentators' opinions

NICE's Patient and Public Involvement Programme approached 4 trusts to distribute questionnaires to patients who had the procedure (or their carers) but did not receive any response from the trusts.

Issues for consideration by IPAC

- Other trials in progress include:
  - A randomised-controlled trial (RCT) funded by North West London Hospitals NHS Trust in collaboration with Uroplasty (but funded by the trust) comparing PTNS with sham (NCT00530933; estimated enrolment 66; study is completed but results have not yet been published).
  - An RCT funded by Uroplasty in the Netherlands, Italy and France comparing PTNS with sham (NCT00974909; estimated enrolment 56; estimated primary completion date October 2011).
  - An RCT by the Ministry of Health in France comparing PTNS with placebo (NCT00977652; estimated study enrolment 144; estimated primary completion date November 2011 with estimated study completion May 2012).
  - An uncontrolled study of PTNS in Switzerland (NCT01162525; estimated enrolment 30; estimated primary completion January 2011 with estimated study completion September 2012).

References

1. Shafik A, Ahmed I, El-Sibai O et al. (2003) Percutaneous peripheral neuromodulation in the treatment of fecal incontinence. European Surgical Research 35:103–7.
2. Boyle DJ, Prosser K, Allison ME et al. (2010) Percutaneous tibial nerve stimulation for the treatment of urge fecal incontinence. Diseases of the Colon & Rectum 53:432–7.
3. Allison M, Prosser K, Martin-Lumbard K. (2009) Percutaneous tibial nerve stimulation: a new treatment for faecal incontinence. Gastrointestinal Nursing 7:19–27.
4. Govaert B, Pares D, Delgado-Aros S et al. (2010) A prospective multicentre study to investigate percutaneous tibial nerve stimulation for the treatment of faecal incontinence. Colorectal disease 12:1236–41.
5. de la Portilla F, Rada R, Vega J et al. (2009) Evaluation of the use of posterior tibial nerve stimulation for the treatment of fecal incontinence: preliminary results of a prospective study. Diseases of the Colon & Rectum 52:1427–33.
6. Findlay JM, Yeung JM, Robinson R et al. (2010) Peripheral neuromodulation via posterior tibial nerve stimulation - a potential treatment for faecal incontinence? Annals of the Royal College of Surgeons of England 92:385–90.
7. Mentes BB, Yuksel O, Aydin A et al. (2007) Posterior tibial nerve stimulation for faecal incontinence after partial spinal injury: preliminary report. Techniques in Coloproctology 11:115–9.

Appendix A: Additional papers on percutaneous tibial nerve stimulation for faecal incontinence

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Allahdin S, Oo N, Jones C. (2011) Intractable flatus incontinence treated by percutaneous tibial nerve stimulation. International Journal of Colorectal Disease	Case report n = 1	Patient with flatus incontinence had 60% improvement in her symptoms and 70% improvement on the effect on her quality of life (method of measurement not reported).	More patients included in table 2.
Allison M. (2011) Percutaneous tibial nerve stimulation for patients with faecal incontinence. Nursing Standard 25:44–8.	Case series n = 90 (which have finished treatment, an additional 24 have not completed treatment yet)	77% (69/90) had reduction of incontinent episodes by at least 50% in bowel diary and 23% (21/90) had no improvement.	Outcomes included as part of a narrative review but little detail given. Some studies included in both Boyle (2010) and Allison (2009) studies in table 2[1,2].
Mentes BB, Yuksel O, Aydin A et al. (2007) Posterior tibial nerve stimulation for faecal incontinence after partial spinal injury: preliminary report. Techniques in Coloproctology 11: 115–9.	Case series n = 2 Follow-up = 12 weeks	Both patients showed improvement in rectal sensory threshold, pudendal nerve terminal motor latency, Wexner FI scores, FISI scores, FIQL scores, quality of life scales, resting pressure and maximum squeeze pressure measurements.	Larger studies in table 2.

Appendix B: Related NICE guidance for percutaneous tibial nerve stimulation for faecal incontinence

Guidance	Recommendations
Interventional procedures	**Percutaneous posterior tibial nerve stimulation for overactive bladder syndrome. NICE interventional procedures guidance 362 (2010).** 1.1 Current evidence on percutaneous posterior tibial nerve stimulation (PTNS) for overactive bladder (OAB) syndrome shows that it is efficacious in reducing symptoms in the short and medium term. There are no major safety concerns. Therefore the procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit. **Transabdominal artificial bowel sphincter implantation for faecal incontinence. NICE interventional procedures guidance 276 (2008).** 1.1 Current evidence on the safety and efficacy of transabdominal artificial bowel sphincter implantation for faecal incontinence is based on a small number of patients and is inadequate in quantity. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake transabdominal artificial bowel sphincter implantation for faecal incontinence should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG276publicinfo). • Audit and review clinical outcomes of all patients having transabdominal artificial bowel sphincter implantation for faecal incontinence (see section 3.1). **Injectable bulking agents for faecal incontinence. NICE interventional procedures guidance 210 (2007).** 1.1 Current evidence on the safety and efficacy of injectable bulking agents for faecal incontinence does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research, which should take place in the context of a clinical trial or formal audit protocol that includes information on well-defined patient groups. 1.2 Clinicians wishing to inject bulking agents for the treatment of faecal incontinence should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy, and provide them with clear

	written information. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG210publicinfo). • Audit and review clinical outcomes of all patients receiving injectable bulking agents for faecal incontinence (see section 3.1). 1.3 The procedure should only be performed in units specialising in the assessment and treatment of faecal incontinence. The Institute may review the procedure upon publication of further evidence. **Stimulated graciloplasty for faecal incontinence. NICE interventional procedures guidance 159 (2006).** 1.1 Current evidence on the safety and efficacy of stimulated graciloplasty for faecal incontinence is limited, but appears sufficient to support the use of this procedure for carefully selected patients in whom other treatments have failed or are contraindicated, provided that the normal arrangements are in place for consent, audit and clinical governance. 1.2 This procedure should be performed only in specialist units by clinicians with specific training and experience in the assessment and treatment of faecal incontinence. **Artificial anal sphincter implantation. NICE interventional procedures guidance 66 (2004).** 1.1 Current evidence on the safety and efficacy of artificial anal sphincter implantation does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake artificial anal sphincter implantation should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's Information for the Public is recommended. • Audit and review clinical outcomes of all patients having artificial anal sphincter implantation. 1.3 Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. The Institute may review the procedure upon publication of further evidence. 1.4 It is recommended that this procedure is carried out only in units with a specialist interest in faecal incontinence. **Sacral nerve stimulation for faecal incontinence. NICE interventional procedures guidance 99 (2004).**

	1.1 Current evidence on the safety and efficacy of sacral nerve stimulation for faecal incontinence appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance. 1.2 The procedure should only be performed in specialist units by clinicians with a particular interest in the assessment and treatment of faecal incontinence.
Clinical guidelines	**Faecal incontinence: the management of faecal incontinence in adults. NICE clinical guideline 49 (2007)** 1.8.2 People with a full-length external anal sphincter defect that is 90º or greater (with or without an associated internal anal sphincter defect) and faecal incontinence that restricts quality of life should be considered for sphincter repair. They should be given a realistic expectation of what this operation can achieve and information about possible adverse events, in both the short and long terms. 1.8.3 People with internal sphincter defects, pudendal nerve neuropathy, multiple defects, external sphincter atrophy, loose stools or irritable bowel syndrome should be informed that these factors are likely to decrease the effectiveness of anal sphincter repair. 1.8.4 People undergoing anal sphincter repair should not routinely receive a temporary defunctioning stoma. 1.8.5 People undergoing anal sphincter repair should not receive constipating agents in the postoperative period and should be allowed to eat and drink as soon as they feel able to. 1.8.6 A trial of temporary sacral nerve stimulation should be considered for people with faecal incontinence in whom sphincter surgery is deemed inappropriate . These may be patients with intact anal sphincters, or those with sphincter disruption. In those with a defect, contraindications to direct repair may include atrophy, denervation, a small defect, absence of voluntary contraction, fragmentation of the sphincter or a poor-quality muscle. 1.8.7 All individuals should be informed of the potential benefits and limitations of this procedure and should undergo a trial stimulation period of at least 2 weeks to determine if they are likely to benefit. People with faecal incontinence should be offered sacral nerve stimulation on the basis of their response to percutaneous nerve evaluation during specialist assessment, which is predictive of therapy success. People being considered for sacral nerve stimulation should be assessed and managed at a specialist centre that has experience of performing this procedure. 1.8.8. If a trial of sacral nerve stimulation is unsuccessful, an individual can be considered for a neosphincter, for which the two options are a stimulated graciloplasty or an artificial anal sphincter. People should be informed of the potential benefits and limitations of both procedures. Those offered these procedures

	should be informed that they may experience evacuatory disorders and/or serious infection, either of which may necessitate removal of the device. People being considered for either procedure should be assessed and managed at a specialist centre with experience of performing these procedures. If an artificial anal sphincter is to be used, there are special arrangements that should be followed, as indicated in NICE interventional procedures guidance 66. 1.8.9 People who have an implanted sacral nerve stimulation device, stimulated graciloplasty or an artificial anal sphincter should be offered training and ongoing support at a specialist centre. These people should be monitored, have regular reviews and be given a point of contact. 1.8.10 Antegrade irrigation via appendicostomy, neo-appendicostomy or continent colonic conduit may be considered in selected people with constipation and colonic motility disorders associated with faecal incontinence. 1.8.11 A stoma should be considered for people with faecal incontinence that severely restricts lifestyle only once all appropriate non-surgical and surgical options, including those at specialist centres, have been considered. Individuals should be informed of the potential benefits, risks and long-term effects of this procedure. Individuals assessed as possible candidates for a stoma should be referred to a stoma care service.

Appendix C: Literature search for percutaneous tibial nerve stimulation for faecal incontinence

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	24/01/2011	Issue 1 of 4, Jan 2011
Database of Abstracts of Reviews of Effects – DARE (CRD website)	24/01/2011	n/a
HTA database (CRD website)	24/01/2011	n/a
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	24/01/2011	Issue 1 of 4, Jan 2011
MEDLINE (Ovid)	24/01/2011	1948 to January Week 2 2011
MEDLINE In-Process (Ovid)	24/01/2011	January 21, 2011
EMBASE (Ovid)	24/01/2011	1980 to 2011 Week 3
CINAHL (NLH Search 2.0/EBSCOhost)	24/01/2011	n/a
BLIC (Dialog DataStar)	4/10/2010	n/a
Zetoc	24/01/2011	n/a

Trial sources searched on 4/10/2010

- Current Controlled Trials *meta*Register of Controlled Trials – *m*RCT
- Clinicaltrials.gov
- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database

Websites searched on 4/10/2010

- National Institute for Health and Clinical Excellence (NICE)
- Food and Drug Administration (FDA) - MAUDE database
- French Health Authority (FHA)
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- Conference search
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	PTNS.tw.
2	neurostimulat*.tw.
3	(urgen* adj3 pc adj3 neuromodulat*).tw.
4	SANS.tw.
5	(stoller* adj3 afferent* adj3 nerv*).tw.
6	(urosurge or uroplasty).tw.
7	exp Electric Stimulation Therapy/ and exp Tibial Nerve/
8	(tibial* adj3 nerve* adj3 stimulat*).tw.
9	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
10	Fecal Incontinence/
11	((anal* or anus* or bowel*) adj3 (abnormal or impair*) adj3 function).tw.
12	((anal* or anus* or bowel*) adj3 (dysfunction or disorder*)).tw.
13	(Incontin* or leak*).tw.
14	(Faec* or Fec* or Bowel* or Anus* or Anal*).tw.
15	13 and 14
16	10 or 11 or 12 or 15
17	9 and 16
18	Animals/ not Humans/
19	17 not 18