

A PILOT TRIAL OF TRANSCUTANEOUS POSTERIOR TIBIAL NERVE STIMULATION FOR BLADDER AND BOWEL DYSFUNCTION IN ELDERLY ADULTS IN RESIDENTIAL CARE

Hypothesis / aims of study

Bladder and bowel dysfunction are highly prevalent among older people in institutional care¹. Current continence management relies heavily on containment through use of absorbent pads¹, which are undignified, expensive and do not treat the bladder or bowel dysfunction. Older people are as likely to respond to conservative treatment of bladder and bowel symptoms as other groups and arguably have a greater need for non-pharmacological, non-invasive interventions, given the propensity for adverse effects associated with increasing age². Transcutaneous posterior tibial nerve stimulation (TPTNS) is a technique of non-invasive peripheral electrical neuromodulation used for the treatment of lower urinary tract symptoms (LUTS), urinary incontinence (UI) and faecal incontinence (FI)³. Research to date has focused on the use of TPTNS to treat overactive bladder in women with no trials or observational studies including frail older people. Thus the potential for TPTNS as a first line treatment option for bladder and bowel dysfunction in later life has yet to be established. This pilot study aimed to assess the feasibility of a full-scale randomised trial of effectiveness of transcutaneous posterior tibial nerve stimulation (TPTNS) on bladder and bowel dysfunction in frail older adults in residential care.

Study design, materials and methods

A six week pilot randomised controlled trial of TPTNS versus sham therapy was undertaken. Thirty older adults with self-reported bladder and/or bowel dysfunction were randomised, via remote computer-generated allocation, to twelve sessions of TPTNS (2 per week for 6 weeks) or sham therapy. TPTNS comprised 30 minute stimulation sessions delivered via two surface electrodes; the negative electrode was placed behind the medial malleolus and the positive electrode 10cm proximal to it. Correct positioning was determined by noting a halux reaction or the participant's description of tingling, pulsing or movement in the great toe. The stimulation protocol was delivered at fixed frequency of 10 Hz and pulse width 200ms in continuous mode. The intensity level of the stimulation current (range 0-50 mA) was determined once correct positioning had been established, according to the comfort level of the participant. The sham group underwent the same procedure however the stimulation current was reduced to 2mA. Bladder and bowel symptoms were self-reported prior to treatment and on completion of the 6 week treatment programme using the International Prostate Symptom Score (IPSS), International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-SF) and Bowel Short Form (early version of the ICIQ-Bowel). Treatment acceptability was assessed at each treatment session by asking the resident and care staff. Protocol fidelity was recorded. Changes in bladder and bowel symptoms (overall scores and individual symptoms) were compared between the groups.

Results

The TPTNS was reported to be an acceptable intervention by the participants and the care staff with no adverse effects identified. Fidelity to the protocol was high and 28 of the 30 participants completed the full 12 session course, with two discontinued at session five because they developed infections (urinary tract and skin). Urinary symptoms reduced in the TPTNS group by a median of 7 points on the IPSS (IQR -3 to -8) and increased in the sham treatment group by a median of 1 point (IQR -1 to 3); this was a statistically significant difference between the groups (Mann-Whitney U=16.500, z= -3.742, p< 0.001). A trend towards greater reduction in urinary incontinence in the TPTNS group was found: ICIQ-SF score reduced by a median of 2 points (IQR 0 to -6) in the TPTNS group, compared to 0 points (IQR -3 to 3) in the sham group (Mann Whitney U=65.000 z=1.508, p=0.132).

Change in individual bladder and bowel symptoms was categorised as better, unchanged or worse and additional analysis of differences between trial groups undertaken (table 1). A trend towards greater improvement in both bladder and bowel dysfunction in the TPTNS group was observed; the difference between groups reached statistical significance for incomplete bladder emptying ($X^2= 8.086$, df=2, p=0.018) and weak urinary stream ($X^2=8.299$, df=2, p=0.016). The exception to this trend was for constipation which worsened in the treatment group.

Type of dysfunction	Percentage of older people reporting changes in dysfunction symptoms					
	Better (%)		Same (%)		Worse (%)	
	TPTNS (n=15)	Sham (n=13)	TPTNS (n=15)	Sham (n=13)	TPTNS (n=15)	Sham (n=13)
**Incomplete bladder emptying *	8 (53%)	1 (8%)	6 (40%)	7 (54%)	1 (7%)	5 (39%)
**Frequency	11 (74%)	5 (42%)	3 (20%)	5 (42%)	1 (7%)	2 (17%)
**Urgency	11 (74%)	4 (31%)	3 (20%)	5 (39%)	1 (7%)	4 (31%)
**Nocturia	7 (47%)	3 (23%)	7 (47%)	8 (62%)	1 (7%)	2 (15%)
**Weak urinary stream *	9 (60%)	1 (8%)	4 (27%)	8 (62%)	2 (13%)	4 (31%)

**Intermittency	5 (33%)	2 (15%)	8 (53%)	6 (46%)	2 (13%)	5 (39%)
**Straining	6 (40%)	1 (8%)	6 (40%)	8 (62%)	3 (20%)	4 (31%)
***Constipation	2 (13%)	7 (54%)	9 (60%)	4 (31%)	4 (27%)	2 (15%)
***Bowel urgency	4 (27%)	1 (8%)	9 (60%)	8 (62%)	2 (13%)	4 (31%)
***Faecal leakage	7 (47%)	3 (23%)	6 (40%)	10 (77%)	2 (13%)	0

*=significant at 5%

** = Symptom assessed by IPSS

*** Symptom assessed by Bowel Short Form

Table 1 – Change in bladder and bowel dysfunction symptom status at 6 weeks

Interpretation of results

This study indicates that in this group of older care home residents with self-reported bladder and/or bowel dysfunction, TPTNS was an acceptable intervention. The study provided preliminary evidence of effect in reducing the residents' bladder symptoms of incomplete emptying and weak stream and bowel symptoms of faecal leakage and urgency. Trends towards positive impact on other bladder symptoms including frequency, urgency and nocturia were found.

Concluding message

TPTNS is safe and acceptable with evidence suggestive of potential clinical effect for both bladder and bowel dysfunction in older people resident in care homes. The data support the feasibility of a substantive trial of TPTNS in this population.

References

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3. Amarenco G, Sheikh Ismael S, Even-Schneider A, Raibaut P, Demaille-Wlodyka S, Parratte B, Kerdraon J 2003. Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder The Journal of Urology 169, 2210-2215

Disclosures

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