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CLINICAL PAPER

Electroacupuncture percutaneous tibial nerve stimulation for the treatment of refractory overactive bladder and urge faecal incontinence: a cost-effective option?

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Abstract
Overactive bladder (OAB) and faecal incontinence (FI) affect millions of people worldwide, and have profound economic and social implications. Physiotherapy, including assessment and treatment of pelvic floor muscle (PFM) function, bladder training, and behavioural techniques, is the first-line treatment for women with OAB. Physiotherapy, including anal sphincter and PFM exercises, and behavioural techniques, is a specialized form of management for individuals with faecal incontinence. Despite physiotherapy intervention, some adults experience refractory (persistent) symptoms. Research suggests that percutaneous tibial nerve stimulation (PTNS) is an effective second-line treatment option for OAB and urge FI (UFI). Current research also indicates that electroacupuncture (EA) is an alternative, and studies have found no significant difference between PTNS and sham electrical stimulation. Percutaneous tibial nerve stimulation is more expensive than EA. This review focuses on a local service's development of an alternative, cost-effective treatment option to standard PTNS for the management of refractory OAB and UFI using EA.

Keywords: electroacupuncture, faecal incontinence, overactive bladder, percutaneous tibial nerve stimulation.

Introduction

Overactive bladder (OAB) is defined by the International Continence Society as urinary urgency "with or without urge incontinence, usually with frequency and nocturia" (Abrams *et al.* 2003, p. 40). It is a common condition, and the prevalence in adult women in the UK is estimated to be between 11.8% and 27.2% (Coyne *et al.* 2011; Heidler *et al.* 2011). The annual progression rate with age is thought to be 1.2% (Heidler *et al.* 2011).

It is estimated that 2.5 million women in the UK have OAB, and the cost of healthcare per person per annum is around £900, equating to a yearly spend of £2.25 billion (Irwin *et al.* 2009). Reeves *et al.* (2006) predicted a 26% increase in costs per annum from 2000 to 2020 in line with an ageing population. Overactive bladder also has a significant impact on quality of life (QoL), work productivity, and levels of anxiety and depression (Coyne *et al.* 2011).

Conservative treatment is usually comprised of behavioural techniques, bladder retraining, pelvic floor re-education and pharmacotherapy (NICE 2015); however, up to 30% of patients will continue to have symptoms that are resistant to this treatment approach (Herbison *et al.* 2003). Even in individuals who respond to treatment, OAB continues to be a chronic condition that requires long-term management to maintain symptom suppression (Chapple *et al.* 2006).

The Rome III criteria define faecal incontinence (FI) as the involuntary passage of flatus or liquid/solid faeces (Drossman *et al.* 2006). The prevalence of FI in community-based adults ranges from 1.4% to 19.5% (Sharma *et al.* 2016). Faecal incontinence has a substantial impact on QoL, and is a huge economic burden (Bols *et al.* 2008).

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Physiotherapy and conservative management techniques are considered to be the first-line management approach for OAB (NICE 2015), and specialist management (following medication) for people with FI (NICE 2007). However, refractory symptoms that persist following conservative treatment may require second-line management.

Following physiotherapy management, patients with refractory symptoms of OAB and FI at the Royal Free London NHS Foundation Trust, London, UK, are sent for percutaneous tibial nerve stimulation (PTNS) outside the area (at considerable cost to the trust) or offered Botox treatment, or undergo further medical or surgical management.

Percutaneous tibial nerve stimulation is a neuromodulation technique in which an electrical stimulation system is used to stimulate peripheral nerves. This nerve stimulation causes changes in the behaviour of the lower urinary tract (Finazzi-Agrò *et al.* 2009). The posterior tibial nerve is a mixed sensory and motor nerve containing fibres that originate from L4 to S3 (lumbar spinal nerve roots L4–5 and sacral nerve roots S1–3) (Cooperberg & Stoller 2005). During PTNS, impulses from the tibial nerve travel to the sacral nerve plexus, thereby regulating signals to the bladder (Woolridge 2009). Percutaneous tibial nerve stimulation is thought to reduce detrusor overactivity by inhibiting the parasympathetic neurological pathways, which are responsible for bladder voiding, and stimulating the sympathetic neurological pathways, which are responsible for urine storage by the bladder. This is achieved by stimulating the sacral neurological complex of nerves together with Onuf's nucleus, which is located at S2–3. Stimulation of Onuf's nucleus reduces bladder activity by inhibiting the parasympathetic ganglion, and the subsequent secretion of both serotonin and norepinephrine, which support the urethra (Surwit *et al.* 2009).

Research suggests that PTNS is an effective second-line treatment for the symptoms of OAB and urge FI (UFI) (Peters *et al.* 2009, 2010; Finazzi-Agrò *et al.* 2010; Peña Ros *et al.* 2016). The results of three randomized controlled trials support the use of PTNS: Peters *et al.* (2009, 2010) and Finazzi-Agrò *et al.* (2010) reported improvements of 79.5%, 54.5% and 71%, respectively.

The Royal Free London NHS Foundation Trust physiotherapy pelvic health team initially considered setting up a PTNS service, but the costs were prohibitive. The team reviewed the literature on alternative treatment options. Current research indicates that electroacupuncture (EA) is an alternative option, and studies have demonstrated no significant difference between PTNS and sham electrical stimulation (Horrocks *et al.* 2015; Knowles *et al.* 2015). The cost per patient for 12 treatment sessions of standard PTNS with the Urgent PC Neuromodulation System (Cogentix Medical, Minnetonka, MN, USA) is £977 versus £506 for EA. Consequently, an EA PTNS service utilizing the acupuncture skills of the clinicians within the pelvic health physiotherapy team was developed.

Participants and methods

Participants

The study population was comprised of women with refractory OAB who had been referred to the Pelvic Health Physiotherapy Department at the Barnet Hospital site of the Royal Free London NHS Foundation Trust. The participants had all undergone traditional physiotherapy intervention and anticholinergic therapy, but had experienced no resolution of their symptoms. The women had no contraindications to EA PTNS. The study group was later extended to include women with symptoms of UFI who had not responded to physiotherapy intervention.

Methods

The data were collected over a 12-month period from the caseloads of three specialist pelvic health physiotherapists who were qualified to administer EA. The therapists were not blind to patient selection, and there was no control group. Each participant had completed a standard physiotherapy intervention and anticholinergic therapy without experiencing resolution of their symptoms prior to being offered EA PTNS.

Every participant completed a consent form with detailed contraindication questions prior to treatment with EA PTNS. Outcome measures were completed both before and after treatment. Patients with OAB completed the International Consultation on Incontinence Modular Questionnaire – Overactive Bladder (ICIQ-OAB), and patients with UFI completed the bowel symptom score (BSS). The ICIQ-OAB identifies changes in urinary urgency, frequency, nocturia, incontinence and QoL. The BSS shows changes in faecal and flatus urgency, incontinence, frequency of bowel movements, and QoL.

The participants were positioned on a plinth in a semi-reclined position. Acupuncture needles

(0.25 × 25 mm; Superdragon TCM UK Ltd, Leeds, UK) were sited unilaterally, based on the patient's skin condition or personal choice, at the Spleen (SP) 6 and Kidney (KI) 2 points, in line with standard PTNS points (McGuire *et al.* 1983). The needles were then attached to an EA machine (AS Super 4 digital needle stimulator, Pierenkemper GmbH, Ehringshausen, Germany) that was set at 20 Hz and 200 ms for a duration of 20 min (see Fig. 1). The women were instructed to increase the intensity in order to induce a motor and/or sensory response in the tibial nerve.

The participants attended 12 weekly sessions. On completion of the course of treatment, they were required to complete the ICIQ-OAB or BSS questionnaires, and give their perceived percentage symptom improvement.

Results and discussion

To date, 20 women have completed the treatment. Twelve presented with OAB, five with UFI, and three with both OAB and UFI. The average age of the participants was 60 years (range = 36–78 years). Fifty per cent of the women reported a perceived improvement in their symptoms of over 60%, and one patient reported a perceived improvement of 100%. All participants showed an improvement in their scores on the ICIQ-OAB and BSS. The ICIQ-OAB score reduced by an average of 22 points out of a total score of 56. Because no studies quantify the minimally important difference when using the ICIQ-OAB, the clinicians decided that a two-point reduction in QoL scores, along with a positive change of one descriptor in each category, equating to a total reduction of 12 points, would be desirable. Therefore, the present study produced positive results. The BSS reduced by an average of 13 points out of a total score of 44. A five-point reduction in the BSS was deemed desirable. A visual analogue scale score for QoL, where a reduction of three points was deemed desirable, fell by an average of five out of a total score of 10.

Sixteen participants received the full 12 sessions of EA PTNS. Four patients only underwent six sessions: three declined to continue treatment because they had a minimal response to treatment, while one experienced symptom resolution.

Of the 16 patients who completed all 12 sessions, four have continued to use a transcutaneous electrical nerve stimulation (TENS) machine periodically in order to maintain the improvement in their symptoms. They employ two surface electrodes at the same acupuncture points used in the EA PTNS, i.e. SP6 and KI2. The other 12 patients have not re-presented to physiotherapy or the hospital for bladder- or bowel-related care.

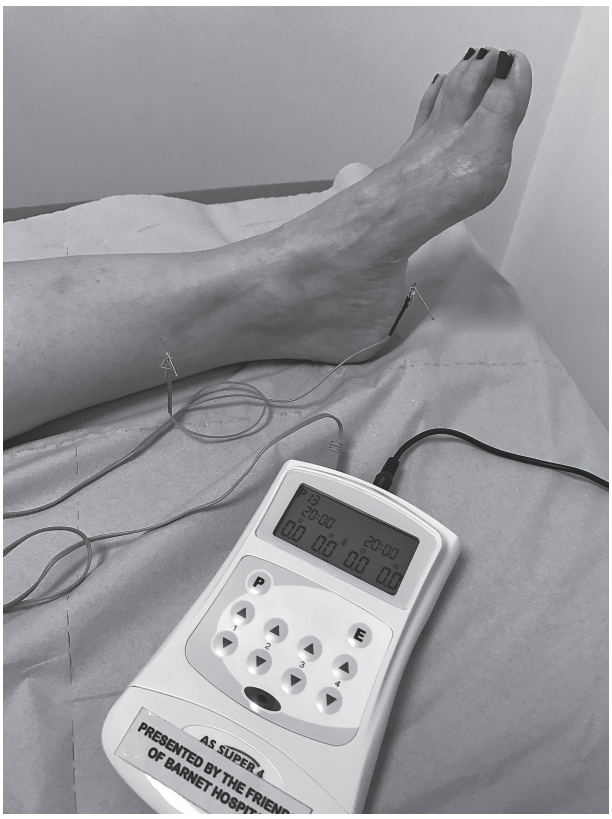

Figure 1. Percutaneous tibial nerve stimulation set-up.

Limitations

The use of EA PTNS as a treatment approach was initially piloted on a small number of patients. Limited data were recorded with regard to demographics and outcomes. When it became apparent that the patients were reporting promising outcomes, the service was expanded, and the approach to data collection was reviewed and revised.

Because the team did not originally plan the project as a study, the following limitations apply:

- Low patient numbers:
  - the number of patients agreeing to participate was low because many were not able to commit to weekly treatment sessions for up to 12 weeks; and
  - the physiotherapists had only a limited capacity to provide the additional sessions required for the treatment programme and to record data.
- No long-term follow-up data are currently available for these patients.

- The therapists were not blinded to the patient selection, and there was no control group.
- Only women were included since only female referrals for OAB and FI were accepted at the time.

Conclusions

Electroacupuncture PTNS can be effective in reducing symptoms of refractory OAB and UFI, and achieve a significant reduction in scores for both conditions. There were significant improvements in the participants' QoL and symptom reduction, and the technique is more cost-effective than standard PTNS. Future plans include implementing group sessions to further improve cost-effectiveness, and to offer male patients treatment. Ongoing investigation will assess long-term outcomes for these patients at 1 and 3 years after they have undergone EA PTNS.

The present study highlights the potential comparable effectiveness of TENS in maintaining the improvement achieved following the initial treatment with EA PTNS. This finding deserves further investigation, and the present authors plan to set up a trial to compare EA PTNS with TENS for the entire treatment procedure. Transcutaneous electrical nerve stimulation machines are considerably cheaper and can be used at home. This would substantially reduce the clinical costs incurred compared to attendance for 12 weeks of EA PTNS in the clinic. It would also lessen the impact on each clinician's caseload, thereby reducing waiting times and improving throughput of patients. Transcutaneous electrical nerve stimulation is also less invasive and has fewer contraindications. In addition, it would reduce the need for patients to return for top-up treatments of EA PTNS since they would be able to self-administer at home as often as required to maintain the improvement in their symptoms.

Implications

Electroacupuncture has the potential to provide a more cost-effective management option for refractory OAB and UFI.

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