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REVIEW

Non-invasive transcutaneous electrical stimulation in the treatment of overactive bladder

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Abstract We reviewed the literature on transcutaneous electrical nerve stimulation (TENS) used as a therapy for overactive bladder (OAB) symptoms, with a particular focus on: stimulation site, stimuli parameters, neural structures thought to be targeted, and the clinical and urodynamic outcomes achieved. The majority of studies used sacral or tibial nerve stimulation. The literature suggests that, whilst TENS therapy may have neuromodulation effects, patient are unlikely to benefit to a significant extent from a single application of TENS and indeed clear benefits from acute studies have not been reported. In long-term studies there were differences in the descriptions of stimulation intensity, strategy of the therapy, and positioning of the electrodes, as well as in the various symptoms and pathology of the patients. Additionally, most studies were uncontrolled and hence did not evaluate the placebo effect. Little is known about the underlying mechanism by which these therapies work and therefore exactly which structures need to be stimulated, and with what parameters. There is promising evidence for the efficacy of a transcutaneous stimulation approach, but adequate standardisation of stimulation criteria and outcome measures will be necessary to define the best way to administer this therapy and document its efficacy.

1. Introduction

Overactive bladder (OAB) symptoms syndrome is a well-recognised set of symptoms which patient experience during the storage phase of the micturition cycle. It is characterised by urgency (a sudden compelling desire to pass urine which is difficult to defer) which, in almost all patients, is accompanied by increased frequency and

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nocturia and, particularly in female patients, by urgency incontinence [1]. Around one third of female patients are severely bothered by urinary incontinence [2].

Electrical stimulation has been used over several decades in the treatment of various lower urinary tract dysfunctions. The well-established Finetech-Bridley sacral anterior root stimulator [3], an implanted electrical sacral roots (S_2—S_4) stimulator to aid emptying the bladder, formed a precursor to today's widely used sacral neuromodulation techniques [4,5]. The S_2—S_4 nerve roots provide the principle motor supply to the bladder. Specifically the S_3 root mainly innervates the detrusor muscle and is the main target of sacral neuromodulation.

Another important and well-established stimulation site is that of the posterior tibial nerve (PTN). The PTN is a mixed nerve containing L_5—S_3 fibres, originating again from the same spinal segments as the parasympathetic innervations to the bladder (S_2—S_4). The Stoller afferent nerve stimulator (SANS) was introduced, to stimulate PTN using a 34-gauge needle electrode inserted into the same place as used in electro acupuncture (the so-called SP6 point), with a surface electrode placed behind the medial malleolus [6]. Currently a commercial device (Urgent-PC, Uroplasty, Inc., Minnetonka, USA) uses this technique. Usually 12 sessions of the percutaneous posterior tibial nerve stimulation (PTNS), at weekly intervals, are used and a large randomized placebo controlled trial showed significant improvement in overall OAB symptoms (60/110) compare to sham (23/110) [7]. It was shown that PTNS responders can continue to benefit from the therapy over 12 months [8]. The exact mechanism of PTNS remains unclear and further multidisciplinary studies are needed to clarify this.

For the purpose of this review we are going to consider only non-invasive techniques, defined as "a procedure which does not involve introduction of an instrument into the body". Further, we also define transcutaneous electrical nerve stimulation (TENS) as a technique where the electrical stimuli are passed through the intact skin.

The primary reason to focus on this modality is that it has a number of practical advantages in its delivery. The method is completely non-invasive, with surface electrodes connected to a battery operated low cost stimulator and applied to an appropriate site of the body. The stimulators are simple to operate with non-expensive, usually hydrogel based, electrodes and batteries being the only on-going treatment cost. TENS treatment itself should not require regular patient visits at clinics and usually is self-administered at home, which is convenient for the patient. In general there are minimal or no side effects from TENS, although sometimes redness or skin irritation may occur around the electrodes which resolves once the stimulation session is finished. TENS has also been used for several decades for pain control. The use of TENS in the treatment of OAB and lower urinary tract diseases is less well-established.

Other minimally invasive electrical stimulation techniques such as: anal, vaginal stimulation plugs [9,10]; percutaneous stimulation (needle is inserted near a targeted nerve); or implanted stimulation devices are beyond the scope of this review [4,5]. In particular plugs are often rejected by the patient because of embarrassment and a sense of unclean liness [11].

The dorsal genital nerve has been used as another site of stimulation [10] using surface electrodes to deliver the stimuli. However, as this review is focused on techniques that are convenient for patients we have not reviewed in detail these studies.

2. Methods

We searched the electronic database PubMed from inception until December 2013. Search terms used were "urge incontinence", "urgency", "overactive bladder", "urinary incontinence" or "detrusor instability" in combination with "electrical stimulation", "TENS", "transcutaneous electrical nerve stimulation", "nerve stimulation", "surface neuromodulation", "non-invasive stimulation", "trial" or "study". In addition, we followed citations from the primary references to relevant articles which the database could not locate. Exclusion criteria were: studies which were not in English; studies of faecal incontinence treatment; those involving children, those studying animal models; those involving percutaneous electrical stimulation, anal stimulation, vaginal/penile stimulation or implanted devices or those not primarily focused on storage symptoms. A flow diagram of the selection process is shown in Fig. 1.

3. Results

The primary search identified 410 articles. Using the defined exclusion criteria we reviewed in detail 16 articles. We have not specifically reviewed studies with a primary focus on interstitial cystitis or voiding dysfunction although these are mentioned where relevant.

3.1. Sacral stimulation

In 1996 Hasan et al. [12] compared S_3 neuromodulation using implanted devices with TENS applied over the perianal region (S_2—S_3 dermatomes). Improvement in more than 50% of idiopathic detrusor overactivity patients suggested the potential of using TENS at a sacral site.

In a study by Walsh et al. [13] 1 week of continuous stimulation for 12 h per day at S_3 dermatomes significantly improved both frequency and nocturia. However only 3/32 patients continued with the therapy, and only on an intermittent basis, during up to 6 months of follow-up. The authors did not evaluate whether the patients found using TENS for 12 h a day was inconvenient and potentially may lead for discontinuing the therapy.

Following this study, an urodynamically assessed group of 33 patients with detrusor overactivity and symptoms of OAB reported similar effects for self-administered stimulation over the sacral site twice a day when compared to oxybutynin in a 14-weeks crossover trial (6 w stimulation +2 w washout +6 w stimulation) [14]. The stimulation group also reported far fewer side effects in a comparison to oxybutynin. The authors non-specifically documented some degree of difficulty in applying the stimulation in 30% of patients. This might reflect the inconvenience of placing electrodes over S_2—S_3 dermatomes or the length of the daily treatment session (up to 6 h).