LITERATURE REVIEW

Does neuromuscular electrical stimulation increase pelvic floor muscle strength in women with urinary incontinence with an ineffective pelvic floor contraction?

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Abstract

Women's health physiotherapists employ various techniques to treat urinary incontinence (UI) in patients who are attempting to restore function by improving the strength, stamina and coordination of their pelvic floor muscles (PFMs). Urinary incontinence can be subdivided into stress UI (SUI), urge UI (UUI) or mixed UI (MUI). Both the Chartered Society of Physiotherapy, and the National Institute for Health and Care Excellence advocate neuromuscular electrical stimulation (NMES) in patients whose PFM contractions register as grade 0 or l on the Modified Oxford Scale (MOS). A literature search was conducted to review the evidence supporting the use of NMES in this population. Twenty-two controlled trials were found, 10 of which used PFM strength as an outcome measure. Follow-up times ranged from 5 to 24 weeks. Five of the six studies of NMES in SUI found a statistically significant improvement in PFM strength following stimulation (mean increase = 6.17–21.60 cmH_2O, or +0.9 on the MOS), and the remaining paper reported a statistically insignificant improvement. Four of these studies described improvements in symptoms. Two of the three studies examining NMES in MUI elicited improved PFM strength, and two achieved statistical significance (mean increase = 14.2–17.7 cmH_2O, $P<0.05$). All three studies showed improvements in symptoms. There were inadequate data to allow conclusions to be drawn about the role of NMES in UUI. The clinical evidence supports the use of NMES, and the methodological irregularities in the literature are unlikely to obviate the study conclusions. However, the lack of subgroup analysis for baseline demographics or PFM strength preclude identifying the groups most likely to benefit from NMES, and call the guidelines' limitation to a low MOS grade into question. Future research requires a multicentre randomized controlled trial of NMES in patients with UI, and subgroup analysis of PFM strength.

Keywords: contraction, neuromuscular electrical stimulation, pelvic floor muscles, strength, urinary incontinence.

Introduction

Urinary incontinence (UI) is defined as an involuntary loss of urine. The condition may be subdivided into stress UI (SUI) and urge UI (UUI), which were characterized by Haylen *et al.* (2010, p. 5) as the "[c]omplaint of involuntary loss of urine on effort or physical exertion [. . .], or on sneezing or coughing" and the "[c]omplaint of involuntary loss of urine associated with urgency", respectively. There are multiple

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techniques available to treat these conditions, all of which are intended to restore function to the pelvic floor muscles (PFMs) (Berghmans *et al.* 1998).

Neuromuscular electrical stimulation (NMES) is one of the clinical modalities used to treat both types of UI (Brubaker *et al.* 1997). Eriksen & Mjølnerød (1987) defined NMES as the activation of the pudendal nerve afferents, which results in turn in the activation of pudendal and hypogastric nerve afferents, causing contraction of the smooth and striated periurethral muscles and PFMs. The aims of NMES include strengthening the PFMs (Sand *et al.* 2005), modifying the vascularity of the tissues (Fall & Lindström 1991, 1994), and inhibiting reflex bladder contractions (Plevnik *et al.* 1991). The treatment is administered with a patient-controlled, handheld device, and can be used in clinical or home settings. Various treatment parameters may be adjusted by the therapist, including frequency, amplitude, pulse widths, duty cycle and number of treatments. At present, there are no clinical guidelines to help with parameter choice. The present paper does not aim to explore this. Studies investigating the physiological theory of NMES are limited, but will be discussed to improve understanding of the effect of this form of stimulation.

The indications for NMES use have been outlined by the Chartered Society of Physiotherapy (CSP) (Laycock *et al.* 2001, p. 38): ''Patients with pelvic floor muscle contractions registering a grade 0 or l on the modified Oxford scale are unlikely to be able to undertake a course of pelvic floor muscle exercises; they may therefore benefit from a course of neuromuscular electrical stimulation'' (Grade III evidence).

Similarly, the National Institute for Health and Care Excellence (NICE) guidelines (NCCWCH 2013, p. 5) state: ''Electrical stimulation [. . .] should be considered in women who cannot actively contract pelvic floor muscles in order to aid motivation and adherence to therapy.''

The Modified Oxford Scale (MOS) (Laycock 1991) provides a six-point grading system to assess PFM strength that ranges from 0 to 5. Grade 0 represents ''no contraction'', and grade 1 ''a flicker''. For the purposes of the present paper, MOS grades 0 and 1 can be taken to correspond to an inability to actively contract the PFMs.

In clinical practice, women's health physiotherapists regularly encounter patients with UI whose PFM strength is graded 0–1 on the MOS. The aim of the present study is to review the evidence supporting the selective use of NMES in women with UI to improve strength and reduce symptoms. The papers were assessed using the Physiotherapy Evidence Database (PEDro) quality score for randomized controlled trials (RCTs). An explanation and validation of the PEDro score can be found elsewhere (Maher *et al.* 2003; de Morton 2009).

Materials and methods

The Cumulative Index to Nursing and Allied Health Literature (CINAHL), the Allied and Complementary Medicine Database (AMED), and the Medical Literature Analysis and Retrieval System Online (MEDLINE) were searched. No year restrictions were applied. Studies were limited to adult female populations, non-drug-related research and articles in English. The search terms ''electrical stimulation'' and ''urinary incontinence'' were used with Medical Subject Headings (MeSH) terms. Only RCTs were included because these studies provide the strongest single-study evidence (Greenhalgh 2001). Tibial and sacral neuromodulation trials were excluded because these have different therapeutic targets (i.e. S2–4 nerve roots) and assessment methods (e.g. detrusor activity, sphincter control and micturition reflexes) (Peters *et al.* 2009; Van Kerrebroeck & Marcelissen 2012). Single-disease caseloads were excluded to increase the generalizability of the review. A hand search of reference lists and citation searches was employed to supplement the results.

Results

The literature search yielded 42 papers. Twenty-two were considered eligible on the basis of the titles. Articles were excluded if measurement of PFM strength was not an outcome measure. Figure 1 summarizes the studies that were included in the present review.

The 10 papers selected were all RCTs and investigated a mixture of types of incontinence: six studies examined SUI, one assessed UUI and three dealt with mixed UI (MUI) (Table 1).

Five of the six studies of women with SUI found a statistically significant increase in PFM strength following NMES (Sand *et al.* 1995; Jeyaseelan *et al.* 2000; Seo *et al.* 2004; Castro *et al.* 2008; Demirtürk *et al.* 2008). The results ranged from 6.17 to 21.6 cmH_2O, as measured

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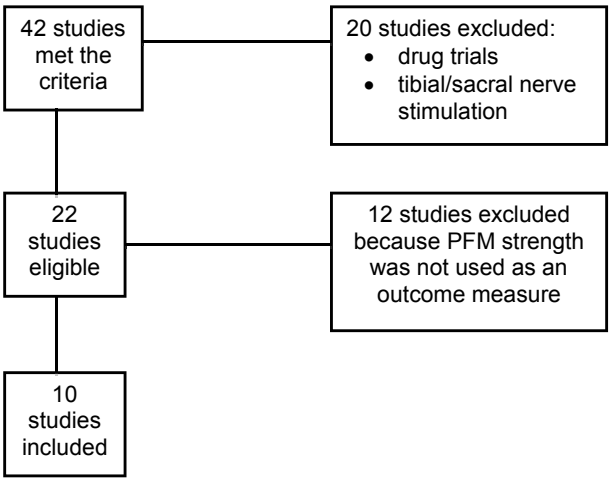

Figure 1. Summary of the studies included in the literature review: (PFM) pelvic floor muscle.

by a perineometer, or a score of 0.9 on the MOS ($P<0.05$). Four of these RCTs found a statistically significant improvement in symptoms ($P<0.05$) (Sand *et al.* 1995; Seo *et al.* 2004; Castro *et al.* 2008; Demirtürk *et al.* 2008).

Neuromuscular electrical stimulation significantly increased PFM strength in two of the three studies of women with MUI (Amaro *et al.* 2005; Schmidt *et al.* 2009). The results ranged from 14.2 to 17.7 cmH_2O ($P<0.05$). All three RCTs investigating MUI found statistically significant improvements in symptoms ($P<0.05$) (Spruijt *et al.* 2003; Amaro *et al.* 2005; Schmidt *et al.* 2009).

The study by Wang *et al.* (2004) was the only RCT that solely addressed UUI. Although final PFM strength was apparently measured, these results were not disclosed, and the authors did not report a statistically significant improvement in symptoms ($P=0.567$).

Spruijt *et al.* (2003) were the only authors to assess a single age group. They reported that NMES treatment was ineffective in women over 65 years of age.

No studies subdivided subjects according to baseline PFM strength.

Table 2 shows the overall quality of the papers according to the PEDro scale. The highest-rated studies were Jeyaseelan *et al.* (2000) and Bø *et al.* (1999), which both scored between 8 and 9. Only Seo *et al.* (2004) lacked clear eligibility criteria. Beyond stating that women with SUI were included, the above authors provided no inclusion or exclusion criteria, such as the omission of research into prolapses or neurodegenerative conditions. In the absence of subgroup analysis, this may call the generalizability of their conclusions into question.

Demirtürk *et al.* (2008) and Seo *et al.* (2004) did not specify their randomization methods. With regard to the other RCTs: Wang *et al.* (2004) employed concealed envelope allocation; Schmidt *et al.* (2009) and Amaro *et al.* (2005) used, but did not give details of, random allocation; and the remainder used a computer-generated table of numbers (Sand *et al.* 1995; Bø *et al.* 1999; Jeyaseelan *et al.* 2000; Spruijt *et al.* 2003; Castro *et al.* 2008).

Statistically significant differences in baseline demographics between treatment groups were noted in Wang *et al.* (2004), Castro *et al.* (2008) and Schmidt *et al.* (2009). Appropriate adjustments were made for these during statistical analysis (Pocock *et al.* 2002). However, although Sand *et al.* (1995) stated that the participants in their control group were older by 6.3 years ($P=0.04$), no adjustment was made for this. They believed that this did not bias their results, citing a lack of objective differences in urodynamic parameters being shown during PFM stimulation in older women with SUI compared to younger women. However, multiple studies confirm that PFM contractility is inversely proportional to age (Perucchini *et al.* 2002; Ashton-Miller & DeLancey 2007), and therefore, this baseline difference may in fact confound the improvement in the treatment group.

Amaro *et al.* (2005), Jeyaseelan *et al.* (2000) and Sand *et al.* (1995) were able to blind participants to the treatment that they received because the control group utilized a sham device. The authors of the latter two studies commented that the sham device actually administered an amount of current to the patient, which raises the question of whether this was a true control group. Both Jeyaseelan *et al.* (2000) and Sand *et al.* (1995) stated that the sham device had no effect on skeletal muscle. Because physiotherapy is a physical modality, it is difficult to provide a sham or placebo effect, and therefore, analyst blinding is important in these types of studies (Greenhalgh 2001). Sand *et al.* (1995), Bø *et al.* (1999) and Jeyaseelan *et al.* (2000) blinded therapists and assessors. Wang *et al.* (2004), Amaro *et al.* (2005) and Castro *et al.* (2008) blinded either the therapist or the assessors. The greater the extent and quality of blinding, the lesser the effect of reporter and investigator bias (Greenhalgh 2001).

Sand *et al.* (1995), Spruijt *et al.* (2003), Wang *et al.* (2004) and Seo *et al.* (2004) reported on outcomes in less than 85% of subjects. This was because the total number of dropouts exceeded

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Table 1. Studies included in the literature review: (NMES) neuromuscular electrical stimulation, measured using cmH_2O (range ± standard deviation), the modified Oxford scale (MOS), or a non-validated 1–15 scale; (SUI) stress urinary incontinence; (MUI) mixed urinary incontinence; (PFMEs) pelvic floor muscle exercises; (N/A) not applicable; and (VAS) visual analogue scale

				Strength					
Study	Incontinence (number of participants)	Control group intervention	Measure of strength	Before NMES	After NMES	Change	*P*-value	Measure of symptom improvement	*P*-value
Bø *et al.* (1999)	SUI ($n=107$)	PFMEs, cones or no treatment	Perineometer	14.8 (10.9–18.7) cmH_2O	18.6 (13.3–23.9) cmH_2O	3.8 cmH_2O	0.90	Pad test	>0.05
Demirtürk *et al.* (2008)	SUI ($n=40$)	Biofeedback	Perineometer	25 (17–33) cmH_2O	32 (23–42) cmH_2O	7.0 cmH_2O	<0.05*	Pad test	<0.05*
Seo *et al.* (2004)	SUI ($n=120$)	Cones	Perineometer	24.17 (± 14.90) cmH_2O	45.73 (± 22.73) cmH_2O	21.6 cmH_2O	0.001*	Pad test	0.049*
Castro *et al.* (2008)	SUI ($n=118$)	PFMEs, cones or no treatment	Digital palpation	2.0 (± 0.8) (MOS)	2.9 (± 1.00) (MOS)	0.9 (MOS)	0.002*	Pad test, subjective response, voiding diaries	0.003*, not documented, 0.001*
Jeyaseelan *et al.* (2000)	SUI ($n=27$)	Sham stimulation	Perineometer	20.09 (± 16.11) cmH_2O	24.00 (± 12.5) cmH_2O	3.91 cmH_2O	0.86	Pad test	>0.05
			Digital palpation	8 (1–12) (1–15 scale)	9 (−1 to +5) (1–15 scale)	1 (1–15 scale)	0.01*		
Sand *et al.* (1995)	SUI ($n=52$)	Sham stimulation	Perineometer	14.49 (± 2.65) cmH_2O	20.66 (± 3.05) cmH_2O	6.17 cmH_2O	0.003*	Pad test, subjective response, VAS	0.005*, 0.002*, 0.007* (SUI)/0.02* (UUI)
Amaro *et al.* (2005)	MUI ($n=40$)	Sham stimulation	Perineometer	39.6 (± 16.2) cmH_2O	53.8 (± 18.6) cmH_2O	14.2 cmH_2O	0.05*	Number of micturitions	<0.05*
Spruijt *et al.* (2003)	MUI ($n=35$)	PFMEs	Perineometer	14.62 (1.01–47.58) cmH_2O	20.90 (2.37–54.38) cmH_2O	6.3 cmH_2O	0.245	Pad test, subjective response	0.081*, 0.893
Schmidt *et al.* (2009)	MUI ($n=32$)	PFMEs or biofeedback	Perineometer	29.98 (± 24) cmH_2O	47.67 (± 25.26) cmH_2O	17.7 cmH_2O	0.05*	Subjective response	<0.05*
Wang *et al.* (2004)	Overactive bladder ($n=103$)	PFMEs or biofeedback	Digital palpation and perineometer	Not documented	Not documented	N/A	N/A	Subjective response	0.567

*Statistically significant result.

Table 2. Studies included in the literature review rated with the PEDro scale of randomized controlled trials (Maher *et al.* 2003): (1) criterion is satisfied; and (0) criterion is not satisfied. The total score is calculated by adding up the criteria that have been satisfied (the "Eligibility criteria specified" component is not included in the total)

	Study									
Criterion	Spruijt *et al.* (2003)	Bø *et al.* (1999)	Schmidt *et al.* (2009)	Demirtürk *et al.* (2008)	Wang *et al.* (2004)	Seo *et al.* (2004)	Castro *et al.* (2008)	Jeyaseelan *et al.* (2000)	Sand *et al* (1995)	Amaro *et al.* (2005)
Eligibility criteria specified	1	1	1	1	1	0	1	1	1	1
Subjects randomly allocated	1	1	1	0	1	0	1	1	1	1
Allocation concealed	0	1	0	0	1	0	1	1	1	0
Groups similar at baseline	1	1	0	1	0	1	0	1	0	1
Subjects blinded	0	0	0	0	0	0	0	1	1	1
Therapist blinded	0	1	0	0	1	0	0	1	1	1
Assessors blinded	0	1	0	0	0	0	1	1	1	0
Measure of key outcomes administered in 85% of subjects	0	1	1	1	0	0	1	1	0	1
Data analysed by intention to treat	0	0	1	0	0	0	0	0	0	0
Comparison between groups conducted	1	1	1	1	1	1	1	1	1	1
Point measures and measures of variability provided	1	1	1	1	1	1	1	1	1	1
Total score	4	8	5	4	5	3	6	9	7	7

15% of the total number of participants. This potentiates observational bias because the total number left in the study does not give a true representation of all the results of a treatment. The participants' reasons for dropping out may involve adverse treatment effects or no effect at all, and therefore, outcomes from all subjects should be reported. Only Schmidt *et al.* (2009) used intention-to-treat (ITT) analysis, and they did not report any dropouts. This process evaluates data from all participants included in a study (Lachin 2000). Without this, authors are unable to comment on the overall clinical effectiveness of a treatment.

Discussion

These studies show that NMES produces a statistically significant increase in PFM strength and an improvement in symptoms in women with SUI and MUI. The lack of subdivision of participants according to baseline PFM strength precludes drawing conclusions about which group benefits most.

The majority of the papers measured PFM strength using a perineometer. In clinical practice, the MOS is used, and guidelines from the CSP (Laycock *et al.* 2001) and the NCCWCH (2013) also use this scale. Bø & Finckenhagen (2001) demonstrated reliability and reproducibility between trained professionals using the MOS. Therefore, studies that used a perineometer to measure strength may have less direct clinical relevance, but it remains a method that is standardized and reproducible.

Sand *et al.* (1995) and Castro *et al.* (2008) both excluded patients with a urethral pressure below 20 cmH_2O. Patients with a low urethral closing pressure may also have weak PFMs (Dietz & Clarke 2001), and excluding them could mean excluding individuals with a low MOS score, i.e. the group that the guidelines recommend for NMES.

Although the RCTs reviewed in the present paper did not support the guidance that NMES should only be used for patients with a MOS score of 0–1, current clinical practice and the physiological changes induced by this form of stimulation support this hypothesis. Salmons (2009) documented the fact that muscle properties change during NMES. There is a physiological difference between using NMES to contract the PFMs and stimulating these muscles via the central nervous system: NMES activates all the muscle fibres in the pelvic floor simultaneously;

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in contrast, exercise-induced muscle contraction is milder and intermittent (Salmons 2009).

Pette & Vrbová (1999) stated that a slow-twitch fibre can be transformed into a fast-twitch fibre if its physiological tonic activity is manipulated, i.e. denervation. Thus, a patient who has a weak pelvic floor as a result of a denervation injury (e.g. after childbirth) could gain more fast-twitch fibres from NMES. It has not been documented whether these new fast-twitch fibres return to being slow-twitch fibres once NMES is stopped.

Limitations

These studies used a variety of different treatment parameters for NMES, and currently, there is no guidance on the best way to provide this kind of stimulation. The changes in strength improvement reviewed in the present paper may be a reflection of choosing the correct treatment parameters rather than the baseline levels of strength of the patients. Until parameters in NMES are clearly researched, this will remain a variable in most NMES studies.

The present review has not discussed asymptomatic patients with a low MOS score because none of the RCTs included asymptomatic patients. Therefore, no conclusions can be drawn for this subgroup.

Castro *et al.* (2008) used the MOS to measure the improvement in strength of the PFMs, and this was the only study to employ the MOS. It is difficult to compare these results with those from the RCTs that used a perineometer. Jeyaseelan *et al.* (2000) used a non-validated scale of 1–15 as a measurement of strength. The above authors only found a statistically significant improvement in the subjective measure in strength and not in the objective measure using a perineometer, and therefore, it is difficult to compare their results with the findings of other studies.

Future research

A well-designed double-blind RCT should be conducted in order to investigate the effects of NMES on patients with varying levels of strength according to the MOS. This should include participants with UI and asymptomatic individuals because there is a lack of research into both these patient groups. Such research should enable clinicians to make informed decisions when choosing specific treatments for patients with a low MOS score. It could also influence guidelines from the CSP (Laycock *et al.* 2001) and NICE (NCCWCH 2013) since current management is based largely on expert opinion.

There have been no studies of best practice in the management of patients with a low MOS. Other techniques have not been investigated in an RCT, and research in these areas may prove useful to clinicians. These approaches include recruiting the abdominal muscles to initiate a PFM contraction (Savage 2005), and contraction and relaxation of the lips (Liebergall-Wischnitzer *et al.* 2005).

Conclusions

The evidence from the studies reviewed in the present paper supports the use of NMES in SUI and MUI. The methodological irregularities are unlikely to obviate the study conclusions. However, the lack of subgroup analysis for baseline demographics or PFM strength precludes identifying the groups most likely to benefit from NMES and calls the guidelines' limitation to a low MOS grade into question. Future research requires a multicentre RCT of NMES in patients with UI that includes subgroup analysis of PFM strength.

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