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GOOD PRACTICE STATEMENT

Safety and best practice in neuromuscular electrical stimulation for pelvic floor muscle dysfunction

Introduction

This statement is based on a synthesis of the best available current evidence and information, and the clinical knowledge of experienced healthcare professionals. It will be subject to periodic review as the evidence base evolves. It should be noted that the statement offers guidance, and should not be regarded as prescriptive; such general advice will always require to be modified in line with the needs of any individual patient and the clinician's experience.

The aim of this particular statement is to outline best practice and safety considerations for clinician-led neuromuscular electrical stimulation (NMES) for adult male and female pelvic floor muscle (PFM) dysfunction. It discusses the use of vaginal and anal electrodes, and also NMES devices that are used externally. Percutaneous posterior tibial nerve stimulation is not covered. This statement does not discuss the physiological basis of NMES effects, but it does provide short summaries of the best evidence for its use. Recommendations on how to achieve optimal results are also made, and safe practice is promoted.

Background

The International Continence Society defines urinary incontinence (UI) as the "[c]omplaint of involuntary loss of urine" (Haylen *et al.* 2010, p. 6). Faecal Incontinence (FI) is the "involuntary loss of flatus, liquid or stool that is a social or hygiene problem" that has lasted for at least 1 month (Chatoor *et al.* 2007, p. 134). Both of these symptoms of dysfunction are typically caused by weakness of or trauma to the muscular structures and fascia of the pelvic floor, which may adversely affect urethral and anal sphincter support and contraction. Pelvic floor muscle training (PFMT) has been recommended as the first-line treatment by the National Institute of Care Excellence (NICE, formerly the National Institute of Clinical Excellence) in the management of UI (NICE 2013). This form of treatment has been demonstrated to improve the strength and efficacy of PFM contractions (Jha *et al.* 2018). It has been suggested that PFMT is also suitable in the management of FI (Woodley *et al.* 2017).

Specialist physiotherapists use clinical reasoning to interpret the findings of a vaginal or rectal examination, and thereby, determine the muscle function of the pelvic floor. If an appropriate active voluntary contraction is present, then PFMT can commence. If a patient has difficulty producing a voluntary PFM contraction, or is unable to do so, NMES may be selected as an appropriate form of therapy to facilitate this. It should be noted that electrical stimulation is not routinely recommended in combination with PFMT (NICE 2013), but this form of treatment should be considered for patients who are unable to actively contract their PFMs to provide them with motivation and encourage adherence to therapy (NICE 2006).

In this statement, NMES refers to therapy that applies a high-frequency electrical current to muscles and nerves in order to stimulate an involuntary smooth tetanic contraction (Nussbaum *et al.* 2017). During a tetanic contraction, muscles can shorten or lengthen, leading to muscle tone. To normalize the contraction, a rest period is included to enable relaxation, which minimizes fatigue and facilitates muscle strengthening. Depending on an individual's dysfunction, this can be an appropriate form of exercise with or without patient participation. With regard to treating FI and the symptoms of stress urinary incontinence (SUI), it has been suggested that NMES (via the application of internal or external electrodes) contracts the PFMs directly, which strengthens the muscles and can improve collagen regeneration (Brown & Sharples 2014; Nussbaum *et al.* 2017; Jha *et al.* 2018). In overactive bladder (OAB), the mechanisms of the symptoms

of UI are unclear, but NMES is believed to inhibit the abnormal detrusor reflex (Jezernik *et al.* 2002; Abdelbary *et al.* 2015; Lucas *et al.* 2015).

The most recent European guidelines on UI (Lucas *et al.* 2015) state that NMES is as effective as PFMT in the conservative management of mixed UI and SUI. However, there is conflicting evidence about whether the addition of electrical stimulation increases the effectiveness of PFMT alone (Stewart *et al.* 2017). The modes of delivery of NMES vary considerably, and researchers often combine these with other forms of conservative therapy (e.g. PFMT and biofeedback). A recent systematic review recommended that electrical stimulation with surface electrodes (e.g. to the skin, vagina and anus) should not be offered as the sole treatment for SUI, and similarly, stated that NMES should be considered as an adjunct to behavioural therapy in the management of OAB (Stewart *et al.* 2015).

Neuromuscular electrical stimulation for incontinence

Stress urinary incontinence

Many systematic reviews have been published on the use of NMES in the treatment of SUI. However, there has been little appraisal of the appropriateness of the protocols or parameters used for specific treatment interventions. A systematic review by Stewart *et al.* (2015) assessed 56 studies evaluating the role of NMES in the treatment of SUI. These authors reported that the evidence was of low quality and inadequate, and that no firm conclusions could be about the impact of NMES on quality of life and rates of cure. Furthermore, Stewart *et al.* (2015) could not draw robust conclusions about whether NMES adds additional benefit to PFMT, but they did find that it was better than no active treatment or a sham intervention.

Overactive bladder

In the management of OAB, NMES has been shown to be better than sham interventions, PFMT, no active treatment and some drug therapies, but the reliability of this evidence was questioned in the above-mentioned Cochrane Review (Stewart *et al.* 2015). Adjunctive NMES with PFMT or drug treatment was examined, but the evidence for any benefit was inconclusive. The preferred type of NMES in OAB treatment was also not conclusively shown, nor were any long-term effects.

Faecal incontinence

It is noted that numerous trials investigating electrical stimulation in faecal incontinence use a combined therapy, most frequently biofeedback. Four trials examining the use of NMES in FI were reviewed by Hosker *et al.* (2007). This Cochrane Review determined that there was a suggestion of therapeutic benefit, but insufficient data were available to allow consistent conclusions to be drawn about the efficacy of NMES in the management of FI. A systematic review by Vonthein *et al.* (2013) identified three high-quality trials; although efficacy was not demonstrated, these did establish that low-frequency NMES can have adverse effects. Vonthein *et al.* (2013) determined that there was sufficient evidence for the efficacy and safety of combined NMES and biofeedback in the treatment of FI.

In conclusion, studies of NMES in the management of OAB, UI and FI are considered to be of low quality and poor comparability, and the variety of stimulation parameters, treatment regimens and outcome parameters employed lead to conclusions that are neither particularly robust nor clinically relevant (Lucas *et al.* 2015). The evidence does point towards some benefits that are associated with the individual assessment of deficits, good clinical reasoning and treatment prescription for a specific patient's needs. The literature suggests that the absence of a voluntary PFM contraction or a poor one [Modified Oxford Scale (MOS) grade = 0–1], or detrusor overactivity resulting in symptoms of bladder urgency, frequency or nocturia, are recognized indicators for the selection of NMES as a treatment modality.

Although no specific evidence was found for the role of electrical stimulation in the management of pelvic organ prolapse (POP), it could be argued that NMES may be beneficial if significant PFM weakness is evident in POP.

Contraindications and precautions

There is a lack of reliable evidence and poor consensus on the contraindications and precautions for the use of NMES. Adverse reactions are usually attributed to the known physiological effects.

In the absence of clear substantive evidence of efficacy and in the presence of potentially adverse effects, it is recommended that clinicians should err on the side of caution when

considering the use of NMES, and if necessary, seek the advice of the patient's medical practitioner (Table 1).

Parameters

Frequency of stimulation

Frequency refers to the number of electrical pulses produced in 1 s during stimulation, and this is measured in hertz (Hz). The frequency of stimulation influences the type of muscle contraction and the force of the motor response produced in the tissues. In order to avoid fatigue or discomfort, this should be adjusted to meet the desired treatment goals and/or to the patient's level of tolerance:

- (< 20 Hz) muscle twitches, tremors or a tapping sensation are perceived by the patient; and
- (20–50 Hz) a tetanic muscle contraction occurs that produces movement.

Physiological responses to different levels of frequency have been studied, and the consensus is that a low-frequency NMES (± 10 Hz) is effective in producing benefits for detrusor overactivity OAB, whereas a higher frequency (± 35 Hz) is required to elicit an involuntary muscle contraction in order to strengthen very weak PFMs.

Pulse duration

The time span in which a single pulse is active is known as the pulse duration. This is measured in milliseconds (ms) or microseconds (μs). There is an inverse relationship between pulse duration and stimulation intensity. The lower the pulse duration, the higher the current intensity needed to excite the muscle tissue. Many NMES units preset the pulse duration at 250 ms, but it is worth noting that reducing this slightly (perhaps trialling at 200 ms) may be beneficial; for example, if a patient finds that the intensity required to elicit a muscle contraction creates an uncomfortable sensation.

Stimulation intensity or amplitude

The current intensity, also referred to as current amplitude, is the adequate amount of current flowing over a period that is able to depolarize the cell membrane, initiating an action potential in the stimulated tissue. Stimulation intensity has an inverse relationship with pulse duration. Measured in milliamperes, this is usually set according to a patient's level of comfort. In practice, it is important to ensure that a palpable or visible PFM contraction is noted if the aim is to strengthen muscles at a higher frequency. The patient may report a sensory stimulation, but the amplitude may still be too low to elicit a muscle contraction. Continue to increase the current intensity until there is a visible and/or palpable muscle contraction, and ensure that a patient is comfortable throughout. Emphasize that more amplitude is not better; rather, the objective is to find the optimal dose.

Duty cycle (on:off ratio)

The duty cycle is the duration of time over which the stimulation is actively on and off, and this is expressed as a ratio. The strength and endurance of the muscle being stimulated should be be taken into consideration when setting the duty cycle. This is in order to minimize muscle fatigue, and maintain the quality of muscle contraction during stimulation. The minimum stimulation ratio for active muscle contraction is 1:2.

Ramp up and ramp down

Ramp up refers to the period of time taken for stimulation intensity to rise from zero to maximum amplitude. Conversely, ramp down refers to the time taken for this to fall from maximum amplitude to zero. A gradual increase (ramp up) in stimulation strength is more comfortable and tolerable for some patients.

Clinical application

It is vital that each NMES intervention is based on an individual patient's subjective symptoms, an objective assessment, and a review of the precautions and contraindications (Table 1). Thorough clinical reasoning is required for best-practice management of all patients. Many NMES devices come with preset parameters based on assumed diagnoses (e.g. SUI and urge UI). It is essential to clinically reason the optimum parameters for each individual patient in order to gain the best results.

Frequently asked questions

Can I use NMES in the presence of a Mirena coil?

With a biphasic waveform current, there is no heating effect, and therefore, NMES can be used with a Mirena (Bayer AG, Leverkusen, Germany) intrauterine device *in situ*.

Table 1. Contraindications and precautions for neuromuscular electrical stimulation (NMES)

Contraindications and precautions	Rationale
Contraindications	
No valid consent	Impaired cognitive function or unreliable decision-making
Lack of physical competence with the device	Important if the patient is to use a unit independently
Absence of sensation	NMES requires patient feedback to set intensity; if sensation is absent, intensity could be set too high and may increase the risk of an adverse event
Implanted cardiac pacemaker	May cause malfunction of an implanted medical device
Pregnancy/actively trying to conceive (i.e. may be pregnant)	May lead to unwanted uterine contractions, and potentially, to miscarriage or premature labour when applied in the first and third trimesters (the effect of electrical stimulation on foetal development is unclear; however, because the potential effects of an adverse reaction could be devastating, it is advisable not to use it)
Recent trauma or haematoma in area (e.g. immediately postpartum)	NMES promotes regional blood flow, causes the release of inflammatory mediators and vasoactive substances, and reduces platelet aggregation, which could cause bleeding
Less than 12 weeks postnatal or post-surgery in the perineal/pelvic/abdominal area	Forceful muscle contraction could disturb the incision site; increased local blood flow may provoke bleeding, increase inflammation or increase the risk of local infection
Recently radiated tissues (in previous 6 months)	May stimulate growth and promote the spread of any remaining cancer cells (recently radiated tissues may respond atypically because of the presence of radiation-induced inflammation or scar tissue, and/or the cellular or circulatory effects of radiation therapy)
Active or previous malignancy in pelvic or abdominal area	May stimulate the growth and promote the spread of cancer cells (seek advice if no longer active)
Abnormal recent smear test	There is uncertainty about the level of risk associated with NMES; therefore, delay treatment until a patient has been treated and returned to routine cervical cytology screening, and the most-recent screening result is negative
Copper intrauterine device, metal within the vagina or body piercing	Metal is very conductive, and this may cause a high current density at the point of electrode contact and possible tissue irritation/damage (remove any body piercing in the area)
Broken skin in area where electrode is to be placed (e.g. atrophic vaginitis, anal hypersensitivity, or anal fissure or fistula)	Skin damage causes uneven current flow under the electrodes, increasing the risk of tissue burns
Excessive, unexplained vaginal or anal bleeding, undiagnosed severe pain, swollen/bleeding haemorrhoids, or fistula	NMES is likely to cause an increase local blood flow, and therefore, may provoke bleeding, increase inflammation or elevate the risk of local infection (if irritation and bleeding occur following use, discontinue and seek medical advice)
Allergic reaction to electrode materials or gel	In particular, ensure that a patient has no known nickel allergy: most standard electrodes are stainless steel, which contains this metal (nickel-free electrodes do exist, and these should be sourced if required)
Precautions	
Severe pelvic organ prolapse	This condition may prevent correct positioning and retention of an electrode, which would reduce the likelihood of significant clinical change as a result of NMES
Vaginal pessary	Such devices may adversely affect the positioning of an electrode (if a patient is self-managing a pessary, ask her to remove it prior to treatment)
Scar tissue	Scars have increased electrical resistance, and therefore, the current may travel around the fibrous tissue; increased density at its edges may cause pain or sensitivity (increase the intensity slowly while gaining feedback from the patient)
Haemophilia or blood-clotting disorders	Consult with an appropriate medical practitioner
Epilepsy	Consult with an appropriate medical practitioner
Diabetes	Assess sensation, and the degree to which neurological function is or is not affected
Uncontrolled hypertension	Consult with an appropriate medical practitioner
Sexual abuse	Gain appropriate consent
Menstruation	Patient choice dictates whether to continue with the treatment session, and may depend on level of bleeding (e.g. heavy versus light spotting); ensure that valid consent to proceed is given, if applicable, or postpone the intervention if the patient is not comfortable
Within 1 m of a transmitting mobile phone or two-way radio, or 3 m of high-energy electromagnetic radiation (e.g. diathermy units or welding/cutting equipment)	Proximity may cause NMES equipment to malfunction

Can I use NMES in the presence of a metal implant such as a hip or knee replacement?
As mentioned above, the lack of a heating effect with biphasic current means that NMES is safe in the presence of local joint replacements.

Can I use NMES in the presence of a mesh implant?
There should not be any issue with the fact that a patient has undergone surgery involving mesh unless there are complications or changes to the vaginal wall. For example, if the mesh has eroded through the vagina, the stimulation current may intensify on the scar tissue, and this could be uncomfortable.

How many sessions of NMES?
This should be determined by the clinician based on an individual patient assessment. Subjective reporting of symptoms, quality of life, objective examination and clinically significant change should be considered. Clinical reasoning should suggest continuing the treatment, with relevant progression, or perhaps, adopting a different approach as required.

How long should each session be?
Patient tolerance to treatment and comfort, and the clinical reasoning for the optimal dose to achieve change should all be considered.

What position should a patient be in, ideally?
A patient should be comfortable, and able to retain the electrode in any given position. It can be helpful to adapt the position of a patient in order to improve awareness of the muscle response to the NMES. In a patient with mild or moderate POP, certain positions may allow for better positioning and retention of electrodes. A change in position may be used as a method of progressing the load in PFMT.

Can NMES be used with vaginal moisturizers, lubricants and topical oestrogen?
The use of a lubricant gel allows for the transmission of energy via NMES. It also makes electrode insertion more comfortable for the patient. The use of vaginal moisturizers, topical oestrogen or other lubricants by the patient should have no adverse effect on the treatment, and in fact, may make it more comfortable.

Conclusion

There is insufficient current evidence to recommend that NMES should be an addition to PFMT. However, anecdotal evidence suggests that it may be useful when a patient cannot perform an active PFM contraction, or only manage a poor one (MOS grade = 0–1). There is some empirical evidence to suggest that NMES alone is as useful as active PFMT. There is also some evidence that NMES may be useful in the management of OAB symptoms. It is widely accepted that the available evidence is of poor quality, and therefore, drawing definitive conclusions for clinical practice is problematic. Practitioners must consider the available evidence in conjunction with the individual patient assessment, and clinically reason the best treatment plan in each case.

Practice points

The following points should be noted:

- Complete a thorough subjective and objective assessment for each individual client. This must include a digital vaginal or anorectal examination if vaginal or rectal NMES is being considered.
- Apply clinical reasoning and identify indications for NMES.
- Screen for any contraindications, potential risks or specific considerations, as guided by clinical reasoning and good practice.
- Discuss any specific considerations with patients, and if required, ask their permission to confer with their consultant or general practitioner.
- Record consent as per usual practice.
- Clinically reason the best parameters for each individual patient and the symptoms reported, including the duration of each session and the optimal position for the patient.
- Reassess the patient at each session, and progress your clinical reasoning to ensure that your treatment planning/progression is individualized and relevant.
- Always work within your scope of practice, and adhere to any local policies.

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