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CLINICAL OPINION

How to report electrotherapy parameters and procedures for pelvic floor dysfunction

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Abstract

Electrical stimulation is widely used for pelvic floor muscle dysfunctions (PFMDs), but studies are not always clear about the parameters used, jeopardizing their reproduction. As such, this study aimed to be a reference for researchers and clinicians when using electrical stimulation for PFMD. This report was designed by experts on electrophysical agents and PFMD who determined all basic parameters that should be described. The terms were selected from the Medical Subject Headings database of controlled vocabulary. An extensive process of systematic searching of databases was performed, after which experts met and discussed on the main findings, and a consensus was achieved. Electrical stimulation parameters were described, including the physiological meaning and clinical relevance of each parameter. Also, a description of patient and electrode positioning was added. A consensus-based guideline on how to report electrical stimulation parameters for PFMD treatment was developed to help both clinicians and researchers.

Keywords Consensus · Electric stimulation therapy · Electrodes · Parameters · Pelvic floor disorders

Introduction

Pelvic floor muscle dysfunction (PFMD) is a term applied to a wide variety of clinical conditions, including urinary incontinence, anal incontinence, pelvic organ prolapse, sensory and emptying abnormalities of the lower urinary tract, defecatory dysfunction, sexual dysfunction and chronic pain syndromes related to the pelvic organs [1]. The prevalence of PFMD is high in women and men and increases with age [2, 3]. These dysfunctions undermine quality of life [4] and cause problems involving significant healthcare costs [5, 6].

Physical therapy interventions have been considered the first-line treatment for stress urinary incontinence [7, 8]. It can be also effective for the treatment of the intestinal constipation [9] and fecal incontinence [9, 10], urgency urinary incontinence [11], sexual dysfunction symptoms [12, 13] and pelvic pain [14]. Among physical therapy modalities, electrical stimulation can be used as an adjuvant treatment with several purposes, such as muscle inhibition [15], muscle activation [16–18] and analgesia [14]; electrical stimulation has been used to treat almost all kinds of PFMD, with different levels of evidence [19]. Nonetheless, scientific evidence is still not strong enough to determine the best parameters for each application. This difficulty may be related to differences in the reported parameters and the lack of others.

Several studies on electrical stimulation as a therapy for pelvic floor dysfunction have been published in recent years [13, 17, 20–24], but most do not thoroughly describe the electrical stimulation parameters, such as the current and electrode type, pulse width, frequency, patient positioning, duration and number of sessions, and inclusion of other resources other

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than electrical stimulation. This may generate a bias especially for systematic reviews as it may be difficult to synthesize and summarize results without complete information on parameters. Hence, standardization of how to report these parameters can make it easier to reproduce and interpret data from future studies. This kind of report has been published and extensively used for other electrophysical agents, such as low-level laser therapy [25], and in a recent report on pelvic floor dysfunction [26]. Having confirmed the need for accurate and complete reports on a wide range of technical and electrotherapeutic parameters, the objective of this article was to prepare a report to standardize the presentation of this information and to be a reference guide for recommendations for academics, clinicians and researchers to report the parameters and physical procedures of electrotherapy used in patients with PFMD.

Methods

This literature review was performed to identify studies that have been published on the subject, detecting what kind of information was missing from those studies. Thus, the authors formed a working group to elaborate guidelines so that future studies will have more complete descriptions, allowing better study reproduction in clinical settings as well as research facilities. All working group members who hold expertise in the areas of pelvic floor dysfunction (AMPB and PD) and electrotherapy (NAP, CRP, REL and MAA), participated in several meetings for brainstorming during which the design of this report was planned. During the meetings, all the authors provided terms and expressions normally used in the literature on their area. Then, the terms were grouped according to the order in which all items should be reported, as follows: patient, equipment, surface electrode, vaginal/anal electrode, treatment, electrical pulse parameters, electrical burst parameters and medium-frequency current parameters.

Authors searched several databases (Embase, PubMed, Bireme, Scopus, Web of Science, Science Direct and Cochrane) from April to December 2017. Also, several books used in undergraduate physical therapy courses to teach about electrophysical agents were consulted [27–34]. The terms related to the reporting of electrotherapy for PFMD were selected from the MeSH (Medical Subject Headings) database of controlled vocabulary. Each electronic database was searched from the earliest year available to identify relevant studies. Additional searching for omitted terms in existing terminology papers was performed. Existing definitions of established terms concerning pelvic floor dysfunction [26, 35–38] and electrotherapy [27–29, 31–34, 39–42] were used when available, and agreement on definitions and clinical relevance was reached by a consensus. Next, the terms and definitions were assessed by experts (two in pelvic floor dysfunction and two in electrotherapy), and all suggestions were brought to the last meeting and discussed among all authors. The final version of each definition was unanimously determined.

The next step consisted of summing up the information gathered during the literature review; the group chose to put information on two different tables to allow everyone working with electrotherapy for PFMD (from the undergraduate student to the professor and clinician) to have important information at hand during treatment planning. The authors decided on two tables, one focused on the electrotherapy parameters and the other describing everything that should be reported/ performed for the application of electrotherapy in PFMD.

Results

The authors developed two tables (Tables 1 and 2) based on the consensus reached during discussions. Table 1 shows the definitions of the parameters for electrotherapy with the clinical relevance for each parameter. Table 2 presents the results on how the use of electrical stimulation and its parameters should be described in studies involving patients with PFMD.

Discussion

Some of the most important aspects of the subject are discussed. The first and most important point is to determine whether the patient is eligible for electrotherapy treatment. Researchers and clinicians must make sure that all exclusion criteria for electrical stimulation use have been assessed, for example, pacemaker use or peripheral vascular diseases [27]. Another point is the conditions of the skin or mucosa to receive the electrical stimulation. If, for example, the electrical stimulus will be delivered directly to the vaginal mucosa, counterindications to the use of a vaginal probe must be evaluated. The main counterindications in this case are inflammatory processes, genitourinary infection or sexually transmitted diseases. Also, the clinician/researcher should be alert to the skin/mucosal integrity and obtain the patient's consent before starting an intervention. A proper and accurate assessment of the pelvic floor muscles is mandatory to determine the most appropriate kind of treatment (and of electrical stimulation) or clinical trial design. This kind of assessment must be performed by specially trained healthcare professional (for example, physical therapists, nurses, physicians, etc.) to provide consistency and accuracy. Clinical conditions of each patient or participant should be respected, and, once again, the therapist or researcher must consider the indications and counterindications for electrical stimulation use.

The benefit of the application of electrical stimulation under some circumstances remains unclear and needs special

Table 1 Definitions and clinical relevance of each electrotherapy parameter as agreed upon by the authors

Parameter	Description	Clinical relevance
Type of current (direct, alternating or pulsed)	Direct current is at the most basic level continuous and flows in only one direction; alternating is a current that passes in one direction and then another. Pulsed current is the current (direct or alternating) in which there is a gap between successive pulses [33]	The direct current can be thought as of an "infinite pulse duration;" clinically, it is used for iontophoresis. The alternating current is used mainly for innervated muscle contraction and sensory stimulation, and the pulses are joined and continuous; however, from the point of view of nerve excitation, the alternating current/direct current distinction is irrelevant. The pulsed current is distinguished from the alternating current because pulses are separated. This means less energy may be delivered to the tissue when using this type of current [33]
Current amplitude (in A, mA or μA [34]; alternatively, in V, mV or μV [32])	Magnitude of current with reference to the zero-current baseline at any one moment It can be referred to as the intensity of stimulation, which explains why controls on clinical generators that regulate the amplitude of induced current are often labeled "intensity" [32]	Increasing current amplitude will increase the amount of energy one delivers to the tissues under the electrode. It contributes the sensory or motor response the electrical current produces. The current amplitude is one of the determinants of torque production when using neuromuscular electrical stimulation. Increasing the current amplitude increases the percentage of muscle activated; increasing the current amplitude results in a proportional increase in the torque produced and the size of the activated cross-sectional area of the stimulated muscle [43]
Current polarity	Monophasic pulse: the charged particles move in only one direction [30], known as polar current Biphasic pulse: charged particles move in one direction and then in the opposite direction [30], known as nonpolar current	If the current is polar, physiological effects will include alterations in the cell membrane permeability, causing different responses under positive (anode) and negative (cathode) electrodes [33]. For example, a marked hyperemia is usually expected under the cathode and a decreased nerve excitability is expected under the anode [33]
Pulse duration (in μs or ms, [34])	The elapsed time between the beginning and end of all phases in a single pulse; on clinical stimulators, the pulse duration is often incorrectly labeled "pulse width" [30, 32]	The greater the pulse duration, the greater the skin impedance and the greater the patient's discomfort. Increasing pulse duration has been shown to increase the charge of the pulse and motor unit recruitment [44]. Altering the pulse duration is dependent on the patient's comfort and desired therapeutic effect; however, pulses with too short duration are inefficient
Pulse frequency (in Hz or pulses per second, pps)	The number of pulse cycles generated per unit of time for pulsed current [30, 32, 34]	Frequency of the pulses has been studied extensively because of its important role in determining the torque development and controlling muscle fatigue. Increasing the frequency results in a sigmoidal increase in torque production but concurrently accelerates muscle fatigue [43, 44]
Waveform shape (rectangular, square, triangular, sawtooth or spike [32]).	Geometric shape of the pulse as it appears on the graph of current (or voltage) versus time	Little clinical research has examined the clinical effect of using different pulse shapes; previous study showed that there were individual differences in preferences for three different waveforms of sinusoidal, sawtooth and square symmetric biphasic waveforms and no particular waveform that was either the least or most comfortable to the patient during neuromuscular electrical stimulation [45]
Stimulation mode (when using more than one channel)	Reciprocal, asynchronous or sequential	Channels operate in a simultaneous or alternating fashion, per set duty cycle. In sequential stimulation, multiple stimulation channels are used (usually, to separately activate multiple synergistic muscles), thereby allowing motor units to rest when the corresponding stimulation channel is not active [46]. Asynchronous stimulation also uses multiple stimulation channels; however, the stimulus pulses are delivered in an interleaved manner so that lower stimulation frequencies are achieved at each stimulation channel while retaining a high composite stimulation frequency [46]

Table 1 (continued)

Parameter	Description	Clinical relevance
Medium-frequency alternating current parameters		
Carrier frequency (in Hz or kHz)	Frequency of underlying alternating current waveform in the burst	Medium frequencies are used to diminish the impedance offered by the skin and subcutaneous tissues, turning the current more comfortable to the patient. Thus, by diminishing skin impedance, the discomfort normally incurred by traditional low-frequency currents is reduced [33, 47]
Burst	The generation of 2 or more consecutive pulses or cycles separated (by burst interval) from the next series of consecutive pulses or cycles	The burst duration has a role in torque production, discomfort, and fatigue [48, 49]
Burst frequency or modulation	Frequency at which bursts are generated	This parameter focuses on the fatigue possibilities of muscles if the frequency is high (> 50 or 60 Hz). In low frequencies we have good recruitment of nervous fibers (between 20 and 50 Hz), and in very low frequencies (2–10 Hz) the nervous fibers relax the muscle fibers)
Burst duty cycle	Burst duty cycle of medium-frequency alternating current, expressed as a percentage, can be defined as the ratio of the burst duration to the total time of the cycle (burst length and interburst interval) [48]	Burst duty cycle, similarly to burst duration, has an impact on torque production, discomfort, and fatigue [48, 49]

attention. For example, no studies were found on the effects of transcutaneous electrical stimulation on ovarian hormones or on users of intrauterine hormone devices. The use of electrical stimulation during pregnancy is still controversial; while the recommendation is to avoid neuromuscular electrical stimulation over the lower back, pelvis and abdomen [53], because it can increase uterine contractility in nonpregnant women [54], other studies have shown positive effects of TENS for low back pain during pregnancy with no harm to fetal formation [55, 56]. The use of electrical stimulation during labor and delivery is well established [57–60], while the form of application (transcutaneous versus vaginal stimulation) remains unclear. Several studies have been found on the effects of electrical stimulation in the postpartum period, but most of them are experimental and related to direct brain/nerve stimulation. Two studies have reported good results for electrical stimulation in the postpartum period after vaginal delivery [61, 62] and cesarean section [61]. They used current delivered through the skin [61] or intravaginally [62], and both reported pain reduction. No reports on pelvic floor nerve damage affecting electrical stimulation were found. Nonetheless, it is not common to apply electrical stimulation when sensitive nerves have been damaged as this may interfere with the current amplitude delivered to the tissue.

Users of electrotherapy for PFMD should be alert to the correct nomenclature for the electrical stimulation modality to be used. Transcutaneous electrical stimulation (TES) can be divided into several forms of use. Transcutaneous electrical nerve stimulation (TENS) involves a generic application of electrical currents across the intact surface of the skin to stimulate the peripheral nerves to produce various physiological effects [63]. Neuromuscular electrical stimulation (NMES) is defined as the application of an electric current using electrodes placed on skeletal muscles with the main objective to produce muscle contraction by activating intramuscular nerve branches for the purpose of restoring a degree of control over an abnormal or absent muscle function [64, 65]; when an electrically induced contraction is performed to produce a functional movement, this is called functional electrical stimulation (FES). Usually, TENS and NMES are the most used modalities for treating PFMD.

Recommendations on safe handling of devices and for patients must be followed to minimize the risk of patient injury [27]. Also, each country has specific guidelines for maintenance and inspection that should be respected. In most countries, the required maintenance is annual to avoid injuries or discomfort to patients and device failures. Operation manuals, models and serial numbers as well as the inspection certificates need to be updated. Regarding patient safety, metal parts (present in the connectors) must not be in contact with the patient's skin to avoid local irritation or burns [28]. Hence, checking the integrity of the connectors is important for safe therapy.

Electrode configuration needs special attention. Electrode placement should be determined by the target tissue. For example, if the target is muscle tissue, both electrodes must be placed over the same muscle belly; if the target tissue is a nerve, the electrodes should be placed along its path or at least one electrode placed where the nerve is more superficial (nerve motor point) and another electrode over the target muscle. Another topic is the interelectrode distance as the greater the distance the deeper the electrical current penetration in the tissue [29]. Usually, the distance should not be less than the surface area of the smallest electrode used [30]. Therapists

Table 2 Description of each parameter that needs to be reported in studies using electrotherapy

Item	Parameter	Description
Patient	Positioning: describe in which position patient received the electrical stimulation	Lithotomy, modified lithotomy, prone or supine, seated or standing position, or other
		Use of support to patient's accommodation
		Furniture/device in which patient is positioned (chair, ball, litter)
	Skin/mucosa preparation: describe how skin or mucosa was prepared to receive the electrodes	Skin hygiene
		Trichotomy
Pelvic floor muscle assessment	Complete description on the method of assessment of pelvic floor muscles (if more than one method was used, describe all). Describe as suggested by [26, 36]	Vaginal inspection, vaginal palpation (describe the scale used: Modified Oxford Grading Scale [50], PERFECT Scheme [50], Brink's Scale [51], Ortiz's Scale [52], etc.), manometry, dynamometry, electromyography, ultrasonography
Device	Complete device description	Commercial name, brand and model
		Manufacturer's country
		Periodic calibration (if performed)
Surface electrode	Electrode model	Brand
		Manufacturer's country
	Electrode placement	Electrode location
		Orientation over muscle or fiber direction, anatomical references used to place the electrodes
	Distance between electrodes	Distance from the center of one electrode to the other
	Material	Metal, carbon, self-adhesive
	Interface material (between skin and electrodes): describe if any kind of interface material was used	Liquid, gel or sticky gel type
	Size and format	In cm, diameter or width × length
		Format: square, rectangular, circular
	Number of channels used for stimulation	Describe number of channels (number of pairs of electrodes). If two or more, describe how each channel was located in relation to the other(s)
Anal or vaginal electrode	Electrode model	Brand
		Manufacturer's country
	Probe dimensions and format	Total length
		Circumference
		Format: cylindrical, plane, conical
	Format and placement of conductive plates	Number of conductive rings
		Distance between conductive rings
		Format: horizontal, vertical, relation to the probe
	Anatomical placement	Depth of probe insertion into the vagina
		Anatomical reference to place probe
Treatment	Electrical stimulation duration (in each session)	Time (in minutes) or number of contractions
	Therapy duration	Number of sessions in which electrical stimulation was applied
	Interval between sessions	Number of hours or days held between sessions
	Pelvic floor muscle status: whether the patient performed voluntary contraction along with electrical stimulation must be described	If contraction was performed simultaneously to the electrical stimulation, describe: protocol (sustained contraction time, rest time, duration of whole treatment) and presence of verbal encouragement
	Patient physical activity status	Describe if patient was resting or performing other physical activity while receiving the electrical stimulation (for example, on a stationary bicycle)
	Patient's discomfort report	Discomfort assessment during treatment
		Instrument used to assess discomfort (self-report, visual analog scale, etc.)
	Presence of reported/observed collateral effects	Any reported or observed collateral effects during physical therapy treatment need to be described: major discomfort after treatment session end, skin burn or rash, etc.

Table 2 (continued)

Item	Parameter	Description
	Patient's adherence to treatment	Percentage of adherence to treatment (number of effective sessions/number of planned sessions)
	Combined treatment: describe any kind of combined therapy performed simultaneously to the electrical stimulation	Home exercises, exercise sessions (without electrical stimulation), medications, education sessions or any other kind of therapy used—describe each therapy thoroughly
	Patient education: describe all educational sources and devices used to educate the patient about the pelvic floor muscles and dysfunctions and about treatments proposed. Patient's education level also needs to be described	Verbal explanation
		Anatomical models
		Drawings and pictures
		Performance corrections
		Telephone follow-up
		Motivational interviewing
		Physical therapist involvement with the patient (PT reminds patient about home exercises, etc.)
	Outcome: describe which variable is the primary outcome and the methods used to evaluate the outcome	For scientific studies:
		Pelvic floor muscle function
		Urinary loss
		Cure
		Quality of life
		For clinical practice:
		Clearly state the main physical therapy objective
Electrical pulse parameters	Current type	Continuous, alternating or pulsed
	Amplitude	Electrical current amplitude (mA or V). Describe if stimulation was performed on sensory or motor levels
	Pulse duration	Pulse duration in μs or ms
	Current frequency	Frequency; describe in Hz or pps
	Waveform	Describe waveform: rectangular (square), sinusoidal, triangular, etc.
	Polarity (biphasic or monophasic)	If the current is pulsed, specify if monophasic or biphasic
Burst parameters	T ON/T OFF	For stimulation on the motor level, describe contraction and relaxation times (in s) for each contraction
	Rise and decay	Describe if rise and decay times (in s) were used
	Modes	Stimulation mode: reciprocal, synchronic or sequential
	Modulation: describe if any kind of modulation was applied to the current	Variation of amplitude, pulse duration or frequency during the stimulation time
Medium-frequency currents	Commercial current name	Russian
		Interferential
		Aussie, etc.
	Carrier frequency	Describe carrier frequency (in Hz or kHz)
	Modulation frequency	Describe modulation frequency or burst frequency (in Hz)
	Burst duty cycle	Describe burst duration and interburst interval (in ms) or duty cycle (in percentage)

should be aware of the size of electrodes. When too small, they might not be effective since the large current spreads within the fat layer and the current does not easily reach the deeper lying motor nerves [42]. Another effect of small electrodes is the generation of high current densities, which may be uncomfortable or even painful [40]. It is important to describe the number of pairs of electrodes to inform the number of different structures treated during the same application.

We currently find a wide variety of electric generators used for clinical purposes. The choice of electrical generator depends on the therapist experience [31] as well as how much the therapist can change the parameters to achieve the ideal current for the desired effect, in accordance with evidence-based practice. To have the minimum conditions to properly program an electrical stimulation treatment, the therapist should be able to select and modulate the frequency, pulse

duration and amplitude. The device needs to provide information about the wave form, treatment time, T-on/T-off, rise and decay times when applicable [28, 32]. The clinician or researcher needs practice and knowledge of parameter controls so that he/she can ensure that they are applied to achieve the proposed goals. Also, clinical studies on electrical stimulation for PFMD should describe the parameters and procedures used in detail to enable the reproducibility of the work and comparison between different studies.

Conclusions

From the results of this article, we can conclude that it was possible to successfully elaborate the reporting of electrotherapy parameters and procedures for pelvic floor dysfunction. We recommend recognition of these standards in written publications related to the use of electrotherapy in pelvic floor dysfunctions and the results of this report. We hope that use of the present report will assist researchers and professionals who work toward rehabilitation of pelvic floor dysfunctions, allowing the parameters to be adequately and completely described, thus facilitating better reproducibility of the methods used, a critical analysis of the results obtained with the method used and advancement of the knowledge in this area.

Compliance with ethical standards

Conflicts of interest None.

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