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SHORT-TERM EFFECTS OF TENS IN THE CONSERVATIVE MANAGEMENT OF UNOPERATED ROTATOR CUFF LESIONS

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ABSTRACT

Background: The purpose of the study is to assess the short-term contribution of TENS-type electrotherapy in the event of non-operated rotator cuff lesions, in terms of pain, joints and muscles in order to confirm or deny the effectiveness of the technique. The results of the study will thus contribute to the increased use of physiotherapy techniques used in the conservative treatment of this type of lesion. **Methods**: This is a double-blind, randomized controlled clinical trial carried out at the level of the P43 rheumatology department of the Ibn Rochd University Hospital in Casablanca. The study population is 30 patients suffering from unoperated rotator cuff lesions divided into two series: Series A, group in which patients benefit from the application ofTENS in addition to the physiotherapy treatment of reference and Series B, reference group; for a period of six sessions. The Constant Scapular Assessment score is the assessment tool used at the start and end of treatment. The sample size calculation was set based on Student's tests with an alpha cutoff of 0.05, a power of 0.90, a mean difference of 10, and a standard deviation of 8 for both groups. For comparison of the differences in scores between the two series, the Mann-Whitney nonparametric comparison test (One-tailed) was used. The size of the Cohen (1992) effect was also calculated for all conducted comparison results. **Results:** The study demonstrated a difference between the total measured scores using the SCM with a superiority of the TENS group (A) three times that of the reference group (B) (4.933 versus 18.933). The results of the Mann- Whitney test (Unilateral) show a statistically significant difference at the level of 1% (N Reference = 15, N TENS = 15, U = 25, Z = -4.157, P = 0.000). The magnitude of this difference is 0.724, which indicates the positive contributionof this technique on all the parameters measured.

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INTRODUCTION

The effectiveness of electrophysiological therapy has long been recognized in the fight against pain, inflammatory conditions and functional impairment (1). Whether it is the early treatment of sprains, dislocations, muscle contractures, radiculalgia or even joint, circulatory or neuromuscular damage, their action most of the time makes it possible to avoid the use of medicinal agents or less reduce the dosage.

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Hence the interest in functional rehabilitation, rheumatology, traumatology and sports medicine (2). These methods include transcutaneous electrical neurostimulation (TENS). Despite its wide use, there is little scientific evidence regarding its effectiveness, especially in the conservative management of rotator cuff lesions (3,4). The results of trials conducted in this direction are generally inconclusive due to insufficient data or methodological factors (1,9).

TENS involves applying a current to the skin to stimulate the underlying sensory nerve fibers for pain relief (5). There are three types:

- Analgesic electrostimulation by gâte control which uses low frequencies of 50 to 100 Hz for localized pain, and

that the Anglo-Saxon authors call conventional TENS(6). In 1965, Melzack and Wall proposed that TENS could stimulate low-threshold skin afferents to inhibit further transmission of nociceptive information in the central nervous system and thus relieve pain. In addition, TENS could stimulate inhibitory descending pathways or block afferent activity in peripheral neurons, thus creating a "busyline" effect (1).

- Very low frequency analgesic electrostimulation, lessthan 10 Hz, applied with small surface electrodes used in particular for the treatment of contractures and trigger points as well as for practicing electro-acupuncture, and which Anglo-Saxon authors call electro- acupuncture (EA) or AL-TENS. Nevertheless, one can wonder about the mechanisms of this analgesia and be perplexed about the release of morphine-like substances given the very short duration of the pulses, the very small surface of the electrodes and the low power of the devices (7).
- Analgic electrostimulation by release of endorphins using very low frequencies, less than 10 Hz, high intensity and large surface electrodes for the treatment of diffuse pain. It is a less well-known, less practiced modality, but remarkably effective (6). Plasma changes in endorphins produce supra-segmental sensory inhibition, i.e. at the level of the upper nervous centers. This type of stimulation is indicated for the sedation of diffuse pain: fibromyalgia and diffuse pain due to excess nociception (low back pain, back pain , neck pain, osteoarthritis, pleural sequelae, thoracic surgery sequelae, multiple site pain ...) (8).

Debate over the clinical efficacy of TENS for pain relief in adults has been present since the introduction of TENS in the early 1970s. The majority of systematic reviews published to date have been inconclusive, despite a large number of published ECRCs. This has resulted in conflicting recommendations from clinical guideline panels (9). Previous systematic trials tend to focus on pain associated with specific medical conditions, consistentwith the classic pathology-based categorization of pain as a secondary outcome of the disease. This considerably reduces the size of the pooled data samples and the statistical power of the meta-analysis (1,9). In fact, there is a plethora of systematic reviews on TENS for various conditions but most of them are inconclusive (10, 11). An overview of Cochrane reviews provides proof of principle that TENS reduces pain intensity when given as a stand-alone treatment for acute pain in adults (9). For the non-operative management of rotator cuff tears (CR), the international professional recommendations of the AAOS (12) and the HAS (13) cannot conclude on the effectiveness or ineffectiveness of TENS as it is in current knowledge. Ainsworth and Levy designed a literature review in 2007 that advocated the importance of conducting well- designed randomized clinical investigations, using validated and appropriate outcome measures, to begin to fill the considerable gaps in the knowledge base regarding the best practice to manage this common and debilitatingcondition (14). Through this work, we will evaluate the short-term contribution of analgesic electrotherapy type TENS in the conservative management of nonoperated rotator cuff lesions at the level of the rheumatology department P43 at the CHU IBN ROCHD in Casablanca, in order to contribute to the reasonable use of this method.

MATERIAL AND METHOD

Study population: The population includes n = 30 patients with rotator cuff injury divided into two groups:

- **Series A:** (n = 15) group whose patients benefit from the application of TENS for 20min in addition to the reference treatment consisting of analgesic massage (15min) and joint softening exercises (15min).
- **Series B:** (n = 15) reference group whose patients benefit from the reference treatment only.

Inclusion criteria: Patients with:

- Age:> 50
- History: Absence of notion of shoulder trauma (atraumatic lesions).
- Diagnosis: Simple tendinopathy and calcifying tendinopathy.
- Unilateral involvement

Exclusion criteria

- Rotator cuff lesions with indication for surgery
- Patients operated on for rotator cuff injury
- Patients with adhesive capsulitis, shoulderinstability or trauma
- Patients under medical treatment during rehabilitationsessions
- Patients who had already benefited from rehabilitation sessions
- Patients with pacemaker
- And epileptic patients.

Type of study: Double-blind, pivotal, randomized controlled clinical trial. Randomization was performed by a researcher not directly involved in the study. The patients assigned according to the randomization table freely signed an informed consent form with an information letter explaining the objectives and the course of the study. The aim being to assess the effectiveness or ineffectiveness of TENS in the conservative management of rotator cuff lesions, treatment would be by one of two options (with or without TENS).The control was carried out by means of a control group which benefits from the reference treatment only. Double blind: In order to have the first blinding, patients who had already benefited from rehabilitation sessions with or without TENS were excluded from the study. The second was carried out by a third-party examiner who performed the initial and final assessments without being informed of the administered treatment.

Study place: Rehabilitation unit of the rheumatology departmentP43 CHUIR of Casablanca.

Study duration: The intervention on patients using TENS-type analgesic electrotherapy is scheduled to last three weeks at the rate of two sessions per week. The overall duration of the study is 12 months.

Ethical considerations: An ethics file relating to the study was approved by theethics committee for biomedical research of the Faculty ofMedicine and Pharmacy of Casablanca under number 03/2020 on 01/27/2020.

Description of the proposed care

Equipment: TENS device: device made up of a generator with control screen and connected to 4 cables equipped with electrodes to be placed on the skin.

- Electrodes: 4 large size electrodes (≥ 150 cm2 x 2) and very long (≥ 20 cm) covered with a moistened spongy bag for a single patient then with a non-woven disposable material and placed in a way to cover as much as possible of the painful area. The cancellous tissues are essential to ensure good stimulation comfort and therefore to allow higher intensities while remaining well tolerated. The use of sponges requires that the rules of hygiene be strictly observed. Whenever possible, it is always preferable to install the electrodes in such a way as to ensure homogeneous contact over the entire surface area of the large-area electrode.
- The generator must be of sufficient power.

Method

The placement of the electrodes is an important factor that influences the effectiveness of the treatment. The analgesic benefit of very low frequency currents (4 Hz) isassociated with the use of large surface electrodes, which are absolutely essential to obtain the desired results. They are placed around the painful area of the injured muscle, on a clean, healthy and dry skin area (possibly cleaned withsoap and water or alcohol). The treatment begins with a test session to determine the stimulation modalities (type of current, frequency and intensity).

It is a question of choosing pulse widths that correspond to the chronaxies of the motor nerves of the muscles that we want to stimulate so that the pulse current offers optimum comfort. Pulse time is measured in microseconds. Chronaxy indicates the amount of time it takes for a current to act on a muscle and stimulate it to produce a muscle contraction. Not all nerves and muscles have the same chronaxy, which means that each muscle is going to need a specific pulse width to achieve a contraction. The higher the stimulation energies, the greater the percentage of motor units involved, the more significant the progress will be. Generally, a very low frequency (<10 Hz) and high intensity current is used. The frequencies that seem best suited are around 4 Hz.

The pulse width is 0.5 to 3 ms and the intensity is high in order to produce elementary shakes and stimulate the A and C fibers. Are rectangular, bidirectional and with zero mean, to allow in practice, an effective and comfortable session of a minimum duration of 20 minutes without irritation ofthe skin and without risk of chemical burns of the tissues. The rule is therefore to always seek to increase energies upto the maximum bearable.

The progression in the level of energies reached must be done throughout the session and also from session to session. The patient should feel underthe electrodes in connection with the analgesic program a sensation of very pronounced but not painful tingling. The current should be felt intensely, but not painful, over the entire surface of the electrode. The muscle contractions produced by the stimulation should be obvious and noticeable. If the stimulation area is hyperalgesic, the electrodes should be moved slightly to an area where the stimulation is better tolerated. Denervated areas do not allow current to be perceived and are contraindicated. At the end of the session, the patient should feel an impression of relaxation and tranquility. The analgesic effect should be immediate or, if necessary, appear shortlyafter the end of the session.

Procedure: The intervention will take place according to the following stages during 06 sessions at the rate of 02 sessions per week:

- Before the first session, initial assessment using the Constant scapular assessment score (CS).
- Test to determine the stimulation modalities (type of current, frequency and intensity) for the A series.
- Treatment session with analgesic current TENS for 20 min for series A
- Reference treatment session: 15min analgesic massage and 15min joint softening exercises for bothseries.
- After the 6th session, final report (CS)
- Finally, all patients will benefit from the complementof their physiotherapy treatment (reinforcement, proprioception, therapeutic education) to guarantee their right to the prescribed treatment for 09 or 14 other sessionsdepending on the prescription.

Assessment Tool: The Constant and Murley Scapular AssessmentScore (CS)**.**

Statistical analysis: The sample size is 15 patients in the reference group (series B) and 15 patients who received the TENS technique (series A) (a total of 30 patients) .The sample size calculation was fixed according to Student's tests with an alpha threshold of 0.05, a power of 0.90, a difference in means of 10 and a standard deviation of 8 for the two groups. Data were analyzed by SPSS software for Windows version 24.0. (Armonk, NY: IBM Corp). Quantitative variables have been expressed as mean and standard deviation and qualitative variables are given in proportion. The verification of the Normality hypothesis was carried out by the test of Shapiro Wilk (1965) and Smirnov Kolmogorov (1948). For the comparison of the differences in scores between the two series, the Mann-Whitney (One-tailed) nonparametric comparison test for two independent samples was conducted due to its robustness in the case ofsmall samples (less than or equal to n = 30) as well as when the normality assumption is violated for Student's parametric test. In addition to the importance of the comparison test, we present the size of the Cohen (1992) effect for all the conducted comparison results. Cohen's d is a measure of effect size representing the difference between two means test divided by the overall standard deviation. The effect sizes of 0.2, 0.5 and 0.8 are considered small, medium and large, respectively.

RESULTS

None of the patients left the study. Demographic and clinical characteristics (sex, age, affected side, stiffness, impotence, amyotrophy, tendon test, conflict maneuvers and type of tendinopathy) were assessed during the initial clinical examination (Table 1). Pain is present in 100% of cases. Ultrasound was performed systematically for all 30 patients. Supraspinatus tendinopathy was diagnosed in all 30 cases. The average age of the patients is 58.67 ± 6.354 years.The sex ratio (Female / Male) is 14. Stiffness, impotence and muscular atrophy were observed in the sample with a percentage of

36.7%. The Neer test was positive in 11 patients (36.7%), while the Hawkins test was positive in 13 (43.3%). The Yocum test is confirmed positive in (15) 50% of patients. Jobe is present in 14 patients or 46.7%. Palm up is positive in 24 (80%) of cases. For tendon tests: Patt and Lifft off are confirmed in 10 (33.3%) cases, while bugle is tested positive only in 3 (10%) patients.

Table 1. Data basic general and clinical characterization (N = 30)

Variables		N (% of 30)
Sex	Feminine	28 (93.3%)
Mean age ± SD (Years)		58.67 ± (6.354)
Affected side	Law	20 (66.7%)
Stiffness	Presence	11 (36.7%)
Impotence	Presence	11 (36.7%)
Amyotrophy	Presence	11 (36.7%)
Maneuvers	Neer	11 (36.7%)
conflicts	Hawkins	13 (43.3%)
	Yocum	15 (50.00%)
	Jobe	14 (46.7%)
	Palm up	24 (80%)
Tendon tests	Patt	10 (33.3%)
	Lifft off	10 (33.3%)
	Bugle	03 (10.00%)

Before proceeding to the test of comparison of scores in the two series, the test of normality of Kolmogorov- Smirnov and Shapiro Wilk was carried out. The results ofthese two tests are reported in Table 2.

Table 2. Normality test

Variables	Kolmogorov Smirnov			Shapiro Wilk		
	Value	dof	Sig.	Value	dof	Sig.
DIFF_DLR	, 323	30	, 000	, 830	30	, 000
DIFF_MB	, 176	30	, 018	, 898	30	, 007
DIFF_AQ	, 231	30	, 000	, 886	30	, 004
DIFF_TM	, 240	30	, 000	, 831	30	, 000
DIFF_FM	, 217	30	, 001	, 896	30	, 007
DIFF_TOT	, 152	30	, 076	, 938	30	, 080

DIFF_DLR, Pain Difference, DIFF_MB, Mobility Difference, DIFF_AQ, Daily Activities Difference, DIFF_TM, Manual Work Difference, DIFF_FM, Muscle Strength Difference, DIFF_TOT Total Score Difference

Examination of the results of the Kolmogorov Smirnov and Shapiro-Wilk normality test given in Table 2 shows that all the differences in scores do not follow a Gaussian distribution (P <5%), rejection of H0) except the Total difference in scores variable.

Table 3. Mann-Whitney Comparison Test

	Experiment (N = 30)		Mann-Whitney	Sig (Unilateral)	Hypothesis retained	Effect size
	Reference	TENS				
DIFF_DLR	0.000	0.733	53,500		H1	0.465
DIFF_MB	1,733	7.067	17,500	0.000	H1	0.698
DIFF_AQ	1,533	2.067	91,000	0.389	H0	0.161
DIFF_TM	0.467	3.067	18,500	0.000	H1	0.717
DIFF_FM	1,200	6,000	25,000	0.000	H1	0.661
DIFF_TOT	4.933	18.933	12,500	0.000	H1	0.724

DIFF_DLR, Pain Difference, DIFF_MB, Mobility Difference, DIFF_AQ, Daily Activities Difference, DIFF_TM, Manual Work Difference, DIFF_FM, Muscle Strength Difference, DIFF_TOT Total Score Difference.

Commentary on Table 3:

Pain: The difference in pain score in the reference group was 0.000, lower than that of the TENS 0.733 group.
The Mann Whitney (One-tailed) results' comparison show that the distribution of the differences in pain score between the two groups is statistically significant (NReference = 15, NTENS = 15, U = 53, 5, Z = -2.673 P = 0.013). The effect size measured by Cohena's d statistic shows a slightly weak effect of 0.465 less than 0.5.

Mobility: As for the evaluation of the mobility score in the two groups, the difference in mobility scores in the reference group is 1.733, lower than that recorded in the TENS group (7.067). - Whitney (Unilateral) shows a statistically significant difference at the 5% level (NReference = 15, NTENS = 15, U = 17, 500, Z = -4.008, P = 0.000). The effect of Cohen's TENS shows a average effect of 0.698.

Daily activity: The difference in daily activity score is 1.533 in the lower reference group than in the TENS group (2.067). This difference is statistically insignificant at the 5% level (NReference = 15, NTENS = 15, U = 91, Z = -0.927, P = 0.389). The contribution of the TENS technique is very low in terms of daily activity (d Cohen = 0.161).

Hand Work: The difference in the manual labor score in the two series is very significant at the 1% level (N reference = 15, N TENS = 15, U = 18, 5, Z = -4.116, P = 0.000). The magnitude of the difference measured by the d Cohen statistic suggests that the therapeutic effect of TENS is medium (Cohen's d = 0.717).

Muscular force: The difference in Muscle Strength score is 1,200 significantly higher than that of the TENS 6,000 group. The Mann-Whitney comparison test (Unilateral) shows a very significant distribution of the difference in score at the 1% alpha level. (N Reference = 15, NTENS = 15, U = 25,Z, -3.799, P = 0.000). The measured effect size displays anaverage magnitude of 0.661.

Difference in total score: In terms of the difference in the total score, we noticed that the difference in the total scores in the TENS group is three times that of the reference group. (4.933 versus 18.933) The results of the Mann-Whitney test (Unilateral) show a statistically significant difference at the 1% level (N Reference = 15, NTENS = 15, U = 25, Z = -4.157, P = 0.000) . The magnitude of this difference is 0.724, which indicates the positive contribution of this technique on all the parameters measured. In other words, group A which benefited from the application of TENS showed a significant superiority in the improvement of the pain score measured by means of VE and VAS of 0.733 with a slightly weak clinical effect. For mobility quantified by a goniometer, there is a greater clinical relevance (d Cohen = 0.698). The work with the hand also shows a clinical improvement after comparison of the groups (Cohen's d = 0.717) .Likewise for muscle strength, the dynamometric measurement made it possible to highlight a clinical predominance of group A, the size of the body. measured effect showing an average magnitude of 0.661. For daily activities, we notice that there is no significant difference between the two groups, which may be due to the difficulty of objectively evaluating this criterion (professional / occupational activities, leisure activities, discomfort in sleep).

All in all,the functional evaluation according to the SC shows a significant difference with a positive contribution of TENS on all the measured parameters (d Cohen = 0.724).

DISCUSSION

Shoulder pain in adults is a frequent reason for consultation, especially in general medicine, where it represents the third osteo-articular complaint (17). The HAS in 2005 (18), in its professional recommendations, indicates conservative treatment as the first-line treatment in rotator cuff lesions. Many writings deal with this subject, and are sometimes contradictory in the description of the care. However, broad lines emerge from it: First of all, drug management, with the use of analgesics, or even corticosteroid derivatives, as well as the intake of non-steroidal anti-inflammatory drugs (NSAIDs) in certain cases, account - Due to the inflammatory nature of the shoulder. Infiltrations are effective in the treatment of painful shoulders and their effectiveness is improved with the use of ultrasound when performing the latter. However, given the profile of adverse effects and drug interactions, physiotherapy is becoming more and more important in the therapeutic range of lesions of the rotator cuff. Rehabilitation can be broken down into pain management with the use of physiotherapy and joint gain techniques and muscle strengthening and sensorimotor reprogramming (19). However, recent literature reviews of exercises and treatments used for patients with CR injury have failed to identify optimal methods of treatment (20). Currently, no effective therapeutic intervention for the management of shoulder pain is universally defined (3). Among the analgesics used in the conservative treatment of CR tendinopathies, physiotherapy is an adjunct in the fight against the painful and inflammatory phenomena which constitute the main component of the vicious circle of pain - stiffness (22). It can be applied in the form of cryotherapy, analgesic current, ultrasound, excitomotors, etc. (23). According to ANAES (13), no clinical trials were found to conclude the efficacy of analgesic electrotherapy. Van der Heijdena measured the effect of electrotherapy on pain (low frequency bipolar current) by comparing the effects obtained in four groups of subjects treated differently (electrotherapy + US, US + placebo electrotherapy, US placebo + placebo electrotherapy, control group). No significant difference was found in theevolution of pain between the table groups (grade C of recommendations, since this is a case / control study). For transcutaneous neurostimulation (TENS), it has not yet been evaluated in this type of lesion (12,13, 14) although it has been shown to be effective in treating pain in other areas (24). Through this study, we were able to provide statistically significant evidence of the short-term effects of TENS on pain, mobility, muscle strength and function in the event of unoperated rotator cuff lesions. The Assessment Tool Used (SCM) is currently considered the benchmark score for shoulder assessment. In total, the functional evaluation according to this score demonstrated a significant difference with a positive contribution of TENS on all the parameters measured (d Cohen = 0.724).

CONCLUSION

The authors conclude, through this clinical trial, the significant and positive short-term contribution of TENS in the conservative management of unoperated rotator cufflesions in terms of pain, mobility, muscle strength and function.

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