Microcurrents in the treatment of chronic pain: biological, symptomatological and life quality effects

G. Barassi[1]*, A. Younes[1], P.A. Di Felice[1], A. Di Iulio[2], S. Guerri[1], L. Prosperi[1], A. Stamile[3] and A. Di Iorio[4]

[1]Physiotherapy Rehabilitation and Re-education Centre (Ce.Fi.R.R.) venue 'G. d'Annunzio University \ Chieti-Pescara, Italy; [2]UOC Thoracic Surgery 'Santo Spirito 'Hospital Pescara – ASL Pescara, Italy; [3]University Hospital Polyclinic 'G. Martino', University of Messina, Messina, Italy; [4]Department of Aging Sciences, CG. Annunzio ' University Chieti-Pescara, Chieti, Italy

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To the Editor,

Chronic Pain (CP) is a condition, with or without a specific organic cause, that persists longer than a usual three to six months of organic recovery. A functional somatic syndrome (FSS) is characterized by a persistent pattern of bodily symptoms that cannot be sufficiently pathologically explained after adequate physical examination (1). CP and FSS include fibromyalgia (FM) and often involve psychological or social problems. Comorbid mental disorders have been found in 35% of patients with CP. In addition, economic costs of sick leave and early retirement exceed the total amount of medical expenditures associated with both CP and FM (2). Many different approaches have been proposed in the past for the management of CP and FM (3). Recognition of the role of bioelectricity in tissue healing provides a rationale for the therapeutic application of electrical stimulation. Microcurrent therapy (MCT) is one example (4, 5). HD2000+ (Luxxamed GmbH, Kassel, Germany) is a therapeutic machine based on the principle of cellular bioregulation (BCR). It is a type of MCT which is able to analyze the patient's cellular metabolism through an internal impedance meter, detects a measurement and modulate the micro-current in intensity, polarity, frequency and damping in a completely automatic way. During the treatment, the modulation of the current changes with the variation of the tissue resistance in response to the metabolic modification of the cells. The aim of this is to stimulate a homeostasis status in the treated tissue through the application of microcurrents characterized by low intensities (variable between 1pA and 999pA) and modulated frequencies (variable between 0.1Hz and 10kHz). The purpose of this study is to evaluate the effects on CP in patients with FM associated with FSS evaluated through Visual Analogue Scale (VAS), the European Quality of Life-5D (EQ-5D), Fibromyalgia Sympotms Severity Scale (FSSc) and Bioelectrical Impedance Analysis (BIA) (6).

MATERIALS AND METHODS

Patients were recruited at the Physiotherapy Rehabilitation and Re-education Center (CeFiRR) venue at Gabriele d'Annunzio University, Chieti-Pescara, to allow interested parties to assess their suitability. All patients selected from March to October 2019 with CP with a diagnosis of FM associated with FSS were chosen for this study. The exclusion criteria were: cancer, antihypertensives, antidepressants, anxiolytics drugs, pregnant women and pacemacker

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Corresponding Author:
Dr Giovanni Barassi,
Physiotherapy Rehabilitation
and Re-education Centre (Ce.Fi.R.R.) venue
Gabriele d'Annunzio University" Chieti-Pescara,
Viale Abruzzo, 322 Chieti Scalo 66100, Italy
e-mail: coordftgb@unich.it

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carriers. A total of 24 Caucasian subjects affected by CP were enrolled in the study (4 males and 20 females, aged 26 to 60 years with an average age of 41.9±8.2). Patients gave informed consent to the experimental procedure, which was in accordance with the latest revision of the Helsinki Declaration for human research and with the procedures relating to the protection of privacy of the subjects participating in biomedical research, as defined by ISO 9001- 2015 for research and experimentation (7).

Patients received a total of 10 MCT treatments, 2 times a week for 5 weeks. Each session consisted of the administration of microcurrents through the BCR system. The hypothesis is based on the principle that MCT are similar to the MCT produced by the body during tissue healing and can therefore be particularly useful where endogenous healing has failed. This means that tissue organs, such as skin, tendons and muscles, which are in a pathological metabolic state, are treated until an impedance shift in the desired direction occurs. In the therapeutic context, this can be observed through relaxation of the muscles (rebalancing of the tone), better elasticity of the fascia, and reduction of pain in the patient. All patients underwent a treatment of 24 minutes per session with the "Inflammation" program. The "Inflammation program is divided into 6 steps (4 minutes each) shown in Table I.

The microcurrents provided by the device work in the range of 0.1Hz-10kHz (in 0.1Hz steps) and 1pA-999pA (in 1pA steps) and can be administered through 4 channels, each one able to transmit microcurrents through 2 electrodes. All the 4 channels were used, and the electrodes were placed as shown in Table II. Patients were evaluated at TO (before treatment) and T1 (after five weeks of treatment) and the results were measured using VAS which is a well-known scale used for the evaluation of perceived subjective pain, indicated as values in a defined numerical scale normally between 0 and 10. The EQ-5D defines the health status and it is measured in terms of five dimensions (5D) such as mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. FSSc is a diagnostic and evaluative instrument for FM. It is composed by 2 subscales: Widespread Pain Index (WPI) and the Symptoms Severity scale (SS). BIA measures body composition by sending a low and safe electric current through the body. The parameters considered for this study were the basal metabolic rate (BMR), the percentage of lean mass and fat mass (% LEAN and% FAT) and the total body water in liters (water). Each patient needed four hours fasting with no physical exercise for at least 12 hours.

RESULTS

Statistical analysis was performed using the NCSS 11 software (Kaysville, Utah, United States of America), using the non-parametric Wilcoxon Signed-Rank Test The level for significance was set at $p < 0.05$.

Statistical analysis of outcome measures showed that there was a statistically significant improvement on VAS scale. There was a decrement in the level of perceived pain of a better feeling that promotes the recovery and reduces the discomfort. A statistically significant improvement should be noted also in the EQ-5D measure of health-related quality of life (Table III). The results confirmed that this approach

Table I. Steps of the "Inflammation" program

- Step 1: current = 150 {jA, frequency = 40 Hz, rising time = 0.8 seconds, polarity = + (plus)
- Step 2: current = 150 pA, frequency = 81 Hz, rising time = 0.8 seconds, polarity = + (plus)
- Step 3: current = 150 pA, frequency = 284 Hz, rising time = 0.8 seconds, polarity = + (plus)
- Step 4: current = 150 pA, frequency = 396 Hz, rising time = 0.8 seconds, polarity = + (plus)
- Step 5: current = 150 pA, frequency = 91 Hz, rising time = 0.8 seconds, polarity = +/- (bi-polar)
- Step 6: current = 150 pA, frequency = 9 Hz, rising time = 0.8 seconds, polarity = +/- (bi-polar)

Table II. Electrode positioning

- Channel A: from right plantar fascia to the right lumbar area (approximately at the level of L1)
- Channel B: from left plantar fascia to the left lumbar area (approximately at the level of L1)
- Channel C: from the right to the left paravertebral area (approximately at the level of T5)
- Channel D: from the right to the left-hand palm

Table III. Comparison of the significance of changes in health status and pain variables from TO to T1

Variables	Mean ± SD	if*
(TO) EQ-5D index	0.47±0.27	
(T1) EQ-5D index	0.81±0.17	0.00003
(TO) VAS	6.9±2.4	
(T1) VAS	4.41Ü.8	0.001

EQ-5D index: European Quality of Life-5D indexM; VAS: Visual Analogue Scale for pain; p value is referred to the difference between T0-T1 of variables (Wilcoxon matched-pairs signed rank test)

Table IV. Comparison of the significance of changes in Body Impedence Analysis variables from TO to T!

Variables	Mean ± SD	P*
(TO) BMR	1510.8±49.4	
(T1) BMR	1578.4±37.3	n.s.
(TO) %FAT	34.7Ü0.5	
(T1) %FAT	31.6±11.1	n.s.
(TO) %LEAN	63.7Ü3.78	
(T1) %LEAN	68.19i 1.2	n.s.
(TO) Water	35.125 5.23	
(T1) Water	36.2■6.31	n.s.

BMR: Basal Metabolic Rate (Kcal); %FAT: Fat Mass Percentage; %LEAN: Lean Mass Percentage; Water: Total Body Water (Liters); p value is referred to the difference between T0-T1 of variables (Wilcoxon matched-pairs signed rank test)

Table V. Comparison of the significance of changes in FSSc variables from TO to T1

Variables	Mean ■ SD	EE*
(TO) FSSc	21.45■3.97	
(T1) FSSc	16.83■3.46	0.00002

FSSc: Fibromyalgia Symptom Severity Scale; p value is referred to the difference between T0-T1 of variables (Wilcoxon matched-pairs signed rank test)

is not detrimental to the wellbeing of patients in terms of autonomy and perception of themselves. Moreover, BIA measures showed that there was an increment of lean mass and total body water and a decrement of fat mass, even if none of these variations resulted statistically significant (Table IV). Finally, a statistically significant reduction in the score of the FSSc was detected, indicating an improvement of the symptomatology in terms of number of painful areas and of severity of symptoms (Table V).

DISCUSSION

MCT is an innovative treatment for different CP disorders and this can also be confirmed with positive results observed in patients with FM associated to FSS (8). Furthermore, precise frequencies seem to interact through resonance with biological tissues and biochemical regulators in such a way as to reduce inflammatory conditions, and address specific tissues, possibly by changing membrane configuration (9). Considering the mentioned positive effects of MCT, we can attribute the positive results obtained in this study on fibromyalgic patients to a multitude of possible explanations. MCT proved to be effective in the management of CP, with mechanisms involving the reduction of central pain sensitization mediated by the increase of inflammatory factors (10). Other possible explanations for the antalgic effects of MCT can depend on the ability of low frequency electrical impulses to influence nervous activity, especially at the level B and C fibers (11, 12). In this study, pain, disability and quality of life improved statistically significantly after therapeutic intervention of MCT, as demonstrated by changes in VAS, FSSc and EQ-5D. Although not statistically significant, MCT showed changes in patients' body composition, by increasing their lean body mass and general hydration status. Luxxamed BCR system would seem an effective therapy to reduce the pain and improve the quality of life of individuals affected by a complex FSS as in FM. In response to our hypothesis, the biochemical regulation of tissues, which come from MCT, can stimulate the body to change its altered state. This is relevant for those individuals who endure this chronic condition, and it is therefore important to make it public. It is hoped that this will provide impetus for further studies to provide more solid evidence of the influence of microcurrent therapy on the signs and symptoms of FM associated with FSS. Further randomized controlled trials with a larger sample should confirm these findings and include patient evaluation and follow-up to establish the large-scale efficacy of this therapeutic approach.

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