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Retrospective Observational Study

NEEDLE-FREE INFILTRATION OF KEY MYOFASCIAL TRIGGER POINTS IN THE TREATMENT OF POSTURAL DYSFUNCTION ASSOCIATED WITH CHRONIC MYOFASCIAL PAIN SYNDROME

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ABSTRACT

Myofascial Pain Syndrome (MPS) is a pathology characterized by pain and biomechanical-postural alterations in the presence of myofascial trigger points (MTrPs). Among the treatment techniques for MPS, MTrPs infiltrations with dry needling or with the injection of pharmacological substances is often used, which however, can present criticalities in terms of safety and tolerability. However, recent technological developments allow to obtain deeply focused active ingredient delivery effects through dedicated electromedical devices. This pilot retrospective analytical observational study aims to evaluate the efficacy of a cycle of 5 sessions of needle-free infiltration (N-Fi) with the delivery of a gel based on hyaluronic acid, ozone and vitamin C in reducing pain, measured with the Numeric Pain Rating Scale (NPRS), and postural dysfunction, measured with the computerized calculation of the Postural Biometric Index (PBI). Data from 30 patients (mean age 56±13 years) affected by MPS were considered. At the end of the study, a significant reduction in the NPRS score (-41.9%) and PBI (-31.1%) values was observed. Therefore, our observations confirm that MPS patients treated with N-Fi show a significant improvement in pain and biomechanical-postural dysfunction associated with their pathology. Further in-depth studies on the topic are recommended to confirm the preliminary results of our research.

KEYWORDS: *Rehabilitation, physical therapy, trigger point, myofascial pain syndrome, injection*

INTRODUCTION

Myofascial pain syndrome (MPS) is a pathology characterized by alterations in the morphology and functionality of the muscular and fascial tissue of one or more areas of the human body; these qualities determine the appearance of pain and reduced musculoskeletal function, often accompanied by anxious and depressive states (1,2). It is estimated that the prevalence of MPS can reach rates of 85% (3), with a fair amount of variability between sexes and between the types of pathological population considered (3,4).

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The main detectable alteration that occurs in the myofascial tissue of subjects affected by MPS is the establishment of myofascial trigger points (MTrPs), which are typically described as hyperirritable spots in the skeletal muscle that are associated with hypersensitive palpable nodules in a taut muscular band. The spot is painful on manual compression and can give rise to characteristic referred pain, referred tenderness, motor dysfunction, and autonomic phenomena (5). At the diagnostic level, a MTrP is usually identified when at least two of the three typical features recur during the evaluation: the presence of a taut band in the muscle, the presence of a hypersensitive spot, and a referred pain pattern evoked by stimulation of the point examined (6). It follows that the diagnosis of MPS in the presence of MTrPs is predominantly clinical, by virtue of the good reliability of palpatory evaluation in this pathological context (7); however, even instrumental examination with imaging techniques such as ultrasound or with impedenziometric assessment devices would seem to have its relevance in the observation of this complex and insidious syndrome (8,9).

Given the complexity of MPS, numerous therapeutic solutions have been proposed over time, with efficacy that is often unclear and debated (3). The management of MPS can in fact be based on treatments that range from less invasive manual, physiotherapy-instrumental and physical exercise methods, to more severe approaches such as pharmacological and infiltrative treatments (3,10,11).

The infiltrative therapy of MTrPs represents one of the most frequently applied techniques in the clinical field for the management of MPS (12). In most cases, these techniques are based on the infiltration of substances such as anesthetics, corticosteroids, NSAIDs and Botulinum into the MTrP (13,14). In other cases, the stimulation technique is based on the use of so-called dry needling (15). Despite their mixed efficacy, these techniques are not free from side effects and risks of various kinds such as infections, potential lesions caused to non-muscular tissues, systemic allergic reactions to the absorption of the injected substances, cellulite and inflammation phenomena at the injection site, pneumothorax in the torso and inapplicability of the technique in the presence of trypanophobia (14,16,17). Hence, it could be useful in the clinical field to investigate new methods of chemical stimulation of MTrPs through delivery techniques mediated by physical means such as electricity, sound waves and light, as occurs, for example, in the case of iontophoresis and phonophoresis (18,19).

Therefore, given the previously exposed considerations, we aimed to conduct an observational pilot study on the efficacy in the treatment of MPS of a needle-free infiltration (N-Fi) therapy, applied through a device that integrates athermic diathermy (AD) and low-level laser therapy (LLLT) for the delivery of a compound based on hyaluronic acid, ozone and vitamin C.

MATERIALS AND METHODS

This research is a pilot retrospective analytical observational study carried out at the Center for Physiotherapy, Rehabilitation and Re-Education (Ce.Fi.R.R.), a venue of the “Gabriele d’Annunzio” University of Chieti-Pescara (Chieti, Italy), from January to September 2023.

All the procedures applied comply with the national safety regulations regarding health services. The protocol is accessible to anyone who does not highlight specific contraindications during the initial clinical evaluation necessary for all patients who access the study venue. The protocol is not an experimental application, since it uses the same procedures applied at the study facility for all patients who do not present the above-mentioned contraindications. This study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Written informed consent was obtained at enrolment from participants who were willing and able. Furthermore, the Ce.Fi.R.R., as the institution in charge for performing the study, owns the ISO 9001:2015 certification for the realization of "Clinical observational studies in the rehabilitation field" (Certificate from the Italian Accreditation Body "Accredia" n. IT15/0304). Due to these considerations and the lack of incontrovertible national legislation regarding the need for the submission of retrospective and/or non-pharmacological observational studies to an ethics committee (20), normal ethics committee clearance was not required (21).

Data were collected from 30 patients (9 males and 21 females, Caucasian ethnicity, mean age 56±13 years) confluent in the study site, affected by MPS, who underwent N-Fi treatments.

Physiatrists in charge of the initial clinical evaluation of each patient diagnosed the presence of chronic MPS associated with MTrPs, with the presence of frequent muscle pain associated with the presence of knotty and painful muscle areas upon palpation for at least 6 months (22).

Inclusion criteria were an age between 30 and 80 years and the diagnosis of chronic MPS.

Exclusion criteria were all the typical contraindications for treatment with electrotherapies (cancer, pregnancy, electronic implants, epilepsy, infections, tuberculosis, serious vascular and cardiac diseases), eventual severe neurological impairments and primary or secondary sensory alterations.

At the initial clinical evaluation (T0, before the treatments were performed) and at the final clinical reevaluation (T1, after the treatments were performed), the observed patients were assessed using the following methods:

(a) *The Numeric Pain Rating Scale (NPRS):* it is one of the most widespread tools in clinical practice for assessing the pain subjectively perceived by patients. It is a derivate of the Visual-Analogue Scale (VAS) divided into ten levels, usually distributed equidistant on a 10 cm long strip, which correspond to the level of pain perceived by the patient at the time of the evaluation, where 0 is the total absence of pain and 10 is the maximum level of pain imaginable and/or ever experienced by the patient (23). This scale is reliable, effective and easy to apply even in the presence of dysfunctions of the musculoskeletal system such as MPS (23). In the present study, patients were asked to express a value from 0 to 10 corresponding to the maximum level of pain perceived at the muscular levels which resulted the most insidious points for them.

(b) *Postural Biometric Index (PBI):* this is an index calculated by the software of the Milletrix 3.0 platform (Diasu Health Technologies, Rome, Italy) on the basis of a stabilometric evaluation carried out using the same device (24). This index takes into account the parameters of Center of Pressure, Symmetry of Bipodalic Load, Symmetry of Retro-Forefoot Load, Angle of Centers of Pressure, Podalic Angle, Location of Maximum Pressure Point, Symmetry of Support Surface and Center of Gravity Deviation - Center of Pressure (24). These parameters are then calculated to obtain an index that quantifies the patient's postural state, which can often be altered in the presence of MPS (24). The PBI value is considered healthy from 0 to 10 and dysfunctional if >10.

Patients in the studied population underwent a total of 5 treatment sessions, performed every 48 hours, of N-Fi therapy applied through a device called Sinapsi 2.0 (Winform Medical Engineering S.r.l., San Donà di Piave, Italy). The N-Fi handpiece combines a multi-wavelength LLLT emission (450nm, 650nm, 1064nm) with an endogenous stimulating athermal radiofrequency designed to deliver specific phytocompounds and integrative substances for joints and the musculotendinous system. Through the N-Fi system, the special compound called TriJALUX Gel (Winform Medical Engineering S.r.l., San Donà di Piave, Italy), based on a combination of 5% triple molecular weight hyaluronic acid, 10% ozone, and 2% vitamin C, is conveyed deep into the treated area.

In the observed patients, the N-Fi was performed on multiple body areas in which palpable MTrPs were located. Following the principles of the Bio-Physico-Metric approach (25,26), the presence of MTrPs was checked by the therapist before each treatment session, through a palpatory examination of the patient's body aimed at identifying the most painful and irradiating MTrPs, also defined as key MTrPs. When a potential key MTrP was manually detected, the therapist performed a functional evaluation of the range of motion of the location area; if the range of motion of the suspect area appeared to be reduced in comparison to the contralateral one, the palpated MTrP was considered in need of treatment. The N-Fi was applied on each of the identified key MTrPs for the time necessary for a quantity equal to 1ml of TriJALUX Gel to be absorbed into the area (on average 5 minutes for each spot).

Once all the data consistent with the observation criteria of the study have been catalogued, statistical analysis was carried out on collected data using the Wilcoxon Signed Rank test for dependent samples, performed through the Statistics Kingdom online calculator (https://www.statskingdom.com, Melbourne, Australia).

RESULTS

At the end of the study (T1), a significant reduction in the NPRS score value was observed ($p < 0.001$) which went from 6.2 ± 1.1 to 3.6 ± 1.1, for an overall reduction of 41.9% (Fig.1).

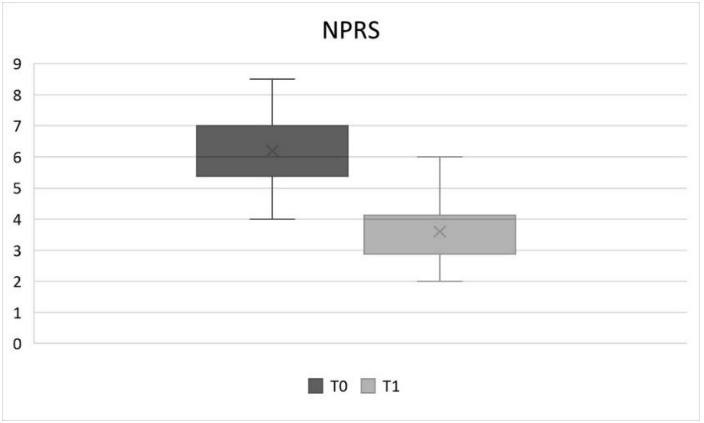

Fig. 1. *Change in NPRS values between T0 and T1.*

Similarly, at time T1, a significant reduction in the PBI value was observed ($p < 0.001$) which went from 15.5 ± 4.4 to 10.7 ± 1.9, for an overall reduction of 31.1% (Fig.2).

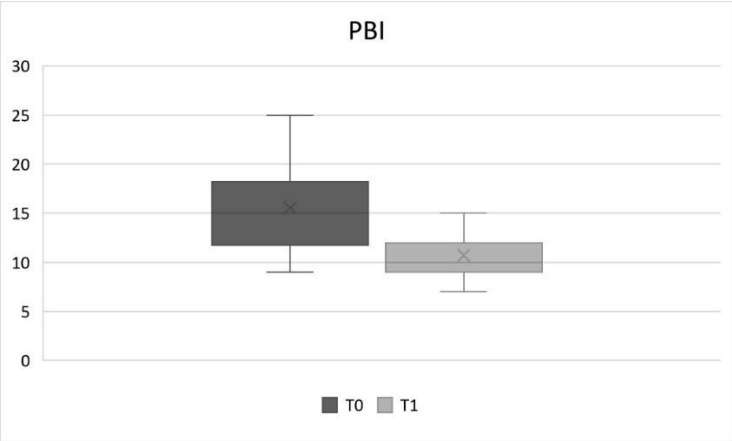

Fig. 2. *Change in PBI values between T0 and T1.*

DISCUSSION

The observation of the data collected highlights how, in patients with MPS subjected to treatment with N-Fi of key MTrPs, there is a significant reduction in NPRS pain values and postural dysfunction measured through the PBI.

We have previously reported that the chemical-physical stimulation of MTrPs through physical and infiltrative therapies appears to be one of the typical management strategies of MPS (3,10-15). The N-Fi treatment strategy adopted for the patients observed in this study conceptually falls into the same therapeutic category reported above. The chemical compound vehiculated through the N-Fi technique is in fact composed of a combination of substances whose role has already been analyzed in literature in the context of MPS and the management of MTrPs.

Several studies have highlighted a very important influence of hyaluronic acid in the genesis and perpetuation of MPS and MTrPs (27,28). It is believed that a variation in the densification of the hyaluronic acid present in the muscle fascia can in fact determine a worsening of the mechanical sliding of the tissues involved in MPS, producing phenomena of functional limitation and pain (27,28). In fact, one of the most interesting options in the management of MTrPs and MPS is represented by the use of hyaluronidase (alone or in addition to other substances) through localized infiltration in the painful areas (29,30), with the aim of dissolving any connective thickening from degeneration of hyaluronic acid *in situ*. In our case, the delivery of chemically stable and non-pathologically altered hyaluronic acid to the MTrPs sites could have contributed to restoring optimal viscosity of the soft tissues of the dysfunctional areas.

Furthermore, the use of ozone (alone or in combination with other molecules, such as oxygen or corticosteroids) would also appear to possess excellent healing properties when applied directly to the muscles, probably due to its anti-inflammatory properties and its ability to control tissue oxidation (31,32).

Similarly, vitamin C also appears to possess important healing properties, especially of an antioxidant nature, even for myofascial tissues, especially in the presence of pathologies such as pain and functional limitation as in the case of MPS (33-35).

We can therefore consider that the metabolic and mechanical rebalancing properties attributable to TriJALUX Gel delivered with N-Fi in the MTrPs site may have contributed, in the observed patients, to improve the monitored symptoms. In fact, the pathogenesis of MPS appears to be extremely complex, involving aspects of a mechanical nature connected to the thickening of the fascial components of the areas involved (36,37), as well as chemical-metabolic aspects due to oxidative and inflammatory phenomena of the affected tissues (38,39). From the point of view of pain, the improvement of the NPRS score, which went from a medium-light pain equal to 6.2 points to an almost absent pain equal to 3.6 points, can be attributed to the anti-inflammatory, antioxidant and elasticizing activity of the delivered product. Similarly, the same modulation properties of the chemical-physical quality of the treated soft tissues due to the vehiculation of the TriJALUX Gel through the N-Fi device may have induced an improvement of the PBI score, which went from a totally dysfunctional value of 15.5 points to one close to the normal cutoff equal to 10.7 points, probably by virtue of better mechanical resilience of the stimulated areas.

Despite the results obtained are positive and encouraging, it is necessary to specify some weaknesses of the present study. First of all, the sample might be relatively small in comparison to the general spreading of MPS. Moreover, in

relation to the sample characteristics, it must be highlighted a certain variability in the age of the patients enrolled (ranging from 30 to 71 years from the youngest to the oldest patients observed) and in the sex distribution, which was not evenly spread between males and females. Additionally, it must be considered that the study, due to its observational nature, was carried out without a control group (either no-treatment or sham) and in the absence of follow-up. To overcome these weaknesses, it would be useful to conduct new in-depth studies on the topic, which should take into consideration a randomized and controlled experimental setting with follow-up, perhaps also integrating more specific evaluation methods dedicated to the histochemical analysis of the treated areas to observe their response to the administration of TriJALUX Gel through N-Fi.

Despite the critical issues mentioned, overall, the results of this study are positive and encouraging, supporting the idea that treatment with TriJALUX Gel delivered with the N-Fi system at the level of MTrPs is able to effectively reduce pain and biomechanical-postural dysfunction in patients affected by MPS. Finally, it should be emphasized that the observed treatment, together with the intrinsic characteristics of speed and ease of application, has shown a very high tolerability; in fact, no local or systemic side effects were reported during the entire data collection process, consistently with the safe and non-invasive nature of the observed treatment.

CONCLUSIONS

The treatment of MPS through the delivery of TriJALUX Gel with the N-Fi system to the MTrPs is effective in reducing pain and improving the dysfunctional biomechanical-postural setting characteristic of the pathology. Since the method is easy to apply and reproducible in the absence of all the side effects potentially related to the classic infiltrative stimulation with needle of the MTrPs, our observations lay the foundations for investigating deeper a method that would allow to expand the group of subjects affected by MPS who could receive a valid treatment for their condition.

Conflict of interest

The authors declare that they have no conflict of interest.

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