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PHONOPHORESIS VERSUS ULTRASOUD THERAPY IN MYOFASCIAL PAIN DYSFUNCTION SYNDROME

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ABSTRACT

Purpose: Myofascial pain dysfunction syndrome (MPDs) coupled by trigger points (TPs) has been conversed medically and dentally for over a century. Phonophoresis (PH) is a non-invasive transdermal drug delivery system that use ultrasound (US) to enhance the distribution of topically applied drugs which provide less chance of an overdose and permit both local and systemic treatment effects.

The aim: of this study was to assess the outcome of phonophoresis with Extrauma and ultrasound therapies in the treatment of myofascial pain dysfunction syndrome.

Patients and method: twenty cases with MPDs of TPs in the masseter muscle were selected and divided into two groups; study group (PH): comprised ten female patients that were treated with phonophoresis (PH) using Extrauma gel for 10 sessions over three weeks. Control group (US): comprised ten female patients that were treated with ultrasound (US) for 10 sessions over three weeks. Postoperative clinical assessment including visual analogue scale (VAS) and maximum mouth opening (MMO) were assessed.

Results: Comparison of VAS between the two groups at immediate post-operative period showed that PH group recorded decrease and significant values and at six months post-operative period the two groups showed non-significant decrease in VAS. MMO showed non-significant increase values in both groups along the follow up periods.

Conclusion: Extrauma phonophoresis in the masseter muscle trigger points considered an effective treatment option for myofascial pain dysfunction syndrome.

Keywords: Myofascial pain dysfunction syndrome, ultrasound, phonophoresis, Extrauma gel.

INTRODUCTION

Myofascial pain dysfunction syndrome (MPDs) is a known painful musculoskeletal condition that has been studied over many years. However, its physiopathology, clinical manifestations and treatment still unclear**.** Painful areas are caused by the hypersensitive spots within the muscle, known as myofascial trigger points (MFTPs) in skeletal

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muscle that are associated with a palpable localized nodule within a taut band of muscle fibers, that when compressed produce referred pain.[1-2]

Simons[3] presented the hypothesis for myofascial trigger points as the continuous contraction of the affected muscle will lead to shift to nonkrebs cycle and extra release of acetylcholine accompanied by increased muscle fiber tension which develops the taut band in a myofascial trigger point that constrict the blood flow with local hypoxia which disturbs mitochondrial energy metabolism leads to local energy crisis in the form of tissue distress and the release of sensitizing substances with activation of nociceptors (pain receptors).[3-5]

There are several therapies to treat myofascial trigger points including massage, stretching, dry needling/injections, electrical stimulation, cold laser treatment, and ultrasound. Ultrasound is one of the physical therapy modalities generally used for many musculoskeletal disorders. Ultrasound converts electrical energy to an acoustic waveform that is converted to heat as it passes through tissues with different resistance compositions. The objective is to warm tendons, muscle and other tissues to improve blood flow, eliminating inflammatory mediators and accelerate healing.[6]

Ultrasound waves are sound waves that are above the audible limit (>20 kHz). The properties of the US are described by the amplitude and the frequency of the longitudinal waves. Similar to audible sound, US waves undergo reflection, refraction, or absorption when they encounter another medium with dissimilar properties. [7-12] If the properties of the encountered medium are different from those of the transmitting medium, the acoustic energy of the transmitted US beam is attenuated. The attenuation of US in tissue limits its depth of penetration. This principle would apply both for US administered with conductive gel alone or for US administered with a gel that includes an active drug agent. Typically, using a conductive, water-soluble gel, US at 3 MHz has been reported to penetrate 1 to 2 cm, whereas US at 1 MHz has been reported to penetrate 2 to 4 Cms. [7-12]

Phonophoresis which is a non-invasive local transdermal drug delivery system through the stratum corneum that use ultrasound (US) to enhance the distribution of topically applied drugs; which avoid the risks of intravenous therapy, avoid affection of the liver in terms of elimination, provide less chance of an overdose and permit both local and systemic treatment effects. The beneficial action of topically applied drugs will depend on a variety of factors; including the rate, the quantity, and the depth to which the drugs infiltrate the skin and the potential toxicological hazards of the drugs on the tissues.[6-12]

Compounds are thought to transfer through the skin by a predictable system of passive diffusion, which is defined by Fick's Law and the rate of permeation.[8-9] Diffusion for the lowest molecular weight substances occur uniformly through the stratum corneum over a large fraction of its area by rupturing the lipids present in stratum corneum, which allows the medicament to permeate via biological barrier.[11]

In summary, the diffusion rate of topically applied drugs will vary because of both internal (physiological) and external (environmental) features. The skin of the patient needs to be cautiously assessed the natural internal barriers to transcutaneous drug distribution as, dehydrated skin, dense skin, and poor circulation and to maximize the natural enhancers as, ensuring the patient is well hydrated, warm, and well perfused with increased kinetic energy as well as by covering the area with a dressing after the drug application to maintain moisture and activate the reservoir capacity of the skin.[13-14]

Phonophoresis topical drugs that being used; anesthetics as lidocaine which block pain receptors by creating numbness, counterirritants as menthol

that cause skin inflammation for relieving pain from stimulation rather than depression of sensory receptors, and anti-inflammatories as steroidal medications like hydrocortisone or nonsteroidal medications like salicylates. [5] Physical appearance of the thermal and nonthermal characteristics of high frequency sound waves can develop the diffusion of topically applied drugs via the mechanical effects which simplify drug diffusion through diminishing membrane potential, shifting the lipid structure, increasing cell permeability, increasing ion conductance, or disrupting the cell membrane.[13-14]

The initial world-wide topical form of synthetic recombinant r-Hirudin is Extrauma® with double effect as anti-thrombotic and anti-inflammatory outcome, which formed through the innovative Hansenula polymorpha technology. Hirudin the most potent natural inhibitor of thrombin, alternative anticoagulant for heparin, direct thrombin inhibitor and does not require endogenous cofactors and has no effect on other enzymes of the coagulation or fibrinolytic systems and the only effect observed is inhibition of thrombin.[15-17]

Methodology:

Twenty female patients complaining of myofascial pain dysfunction syndrome were selected from the outpatient clinic of the oral and maxillofacial Surgery department, faculty of dentistry, Cairo university. The age of patients ranged from 18 to 43 years with a mean of 30.5 years. Ethical approval for this study was obtained from the ethical committee and informed written consent was performed from all patients before they were included in this study. The clinical examination of the patients was done according to Helkimo index [18].

Inclusion criteria: Tenderness in masseter muscles, Exclusion criteria: Pregnant and lactating women, neuromuscular disorders, myopathy, intra-articular temporomandibular disorders (internal derangement), trigger points injections, also trauma. The patients were assigned into 2 equal groups: study group (PH) comprised ten female patients that were treated with phonophoresis for 10 sessions over three weeks using Extrauma gel (Recombinant Hirudin 420 IU. Minapharm 10th of Ramadan-Egypt) over the affected area**, (figure1)** and control group (US) comprised ten female patients that were treated with ultrasound for 10 sessions over three weeks using media gel. For both groups the US machine turned on for 5 minutes in a dose of 1.5 watt/cm^2 pulsed pattern. **(figure2)** The hand-held transducer was applied with coupling gel and moved in a circular motion over painful area of the masseter muscle. The drug was left on the skin with an occlusive dressing after treatment and the patients were instructed to avoid exposure to air after the session not to collapse. The patients were instructed not to take any analgesics during the treatment and the follow up periods. Patients were recalled one month immediate post-operatively, three months and six months, Pain was estimated subjectively by asking the patient to rate the experience on a Visual Analogue Scale (VAS) of 0-10 preoperatively where '0' was marked as 'No Pain' and '10' as 'Most Severe Pain' at the end of the sessions and at 6 months postoperatively. Maximal interincisal opening in centimeters was recorded using digital caliper preoperatively, at the end of sessions and at 6 months postoperatively.

Statistical analysis, quantitative data were presented as mean, standard deviation. Data were explored for normality by checking the data distribution, calculating the mean using Kolmogorov-Smirnov and Shapiro Wilk tests. Statistical analysis was performed using a commercially available software program (SPSS 19; SPSS, Chicago, IL, USA. 2016) to compare the mean of MMO recorded at the start of the study and in the different observation times. As data was parametric, significance of the difference was evaluated using one-way analysis of variance (ANOVA test). For the nonparametric data, Mann-Whitney U test was used

Fig. (1) Photograph showing the Extrauma gel.

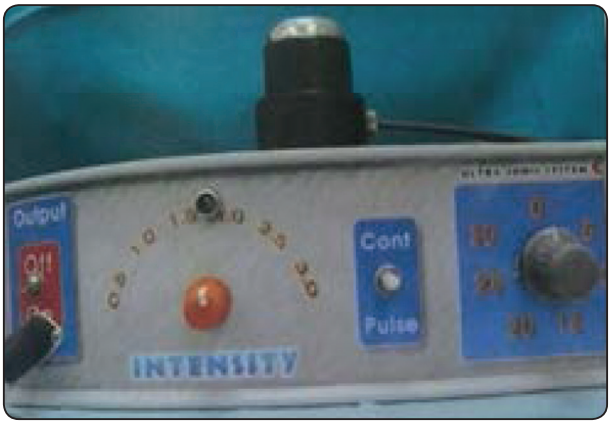

Fig. (2) Photograph showing the ultrasound device.

to compare between the two groups. Friedman's test was used to study changes in each group by time. Wilcoxon signed-rank test was used for pairwise comparisons when Friedman's test is significant. The level of significance was set at $P < 0.05$.

RESULTS

For pain, Visual Analogue Scale (VAS) in PH group using Mann-Whitney U test showed lower mean values compared with US group and there was statistical significance difference between studied groups immediately postoperative and there was no significance difference six months postoperatively. **Table (1) (Figure 3)** For maximum mouth opening, through all periods, there was no significance difference between studied groups. **Table (2) (Figure 4)**

TABLE (1): Descriptive statistics and results of Mann-Whitney U test for the comparison of pain (VAS scores) in the two groups:

VAS	Preoperative		Immediate post-operative		6 months		*P*-value*:* *preop-immediate post* 0.006* *Preop-6months* *0.651*
	Mean	SD	Mean	SD	Mean	SD	
Group I (PH)	7.4	1.02	2.3	1.1	2.1	2.5	
Group II (US)	7.1	1.04	3.6	1.2	2.0	2.1	

Significance level p<0.05, * significant

TABLE (2): MMO (cm) pre-and post-operatively and significance of the difference using t-test for the comparison in the two groups:

MMO	Preoperative		Immediate post-operative		6 months		*P*-value*:* *preop-immediate post* 0.730 *Preop-6months* *0.147*
	Mean	SD	Mean	SD	Mean	SD	
Group I (PH)	3.3	4.2	3.7	2.2	3.9	1.7	
Group II (US)	3.1	4.8	3.5	2.8	3.8	2.3	

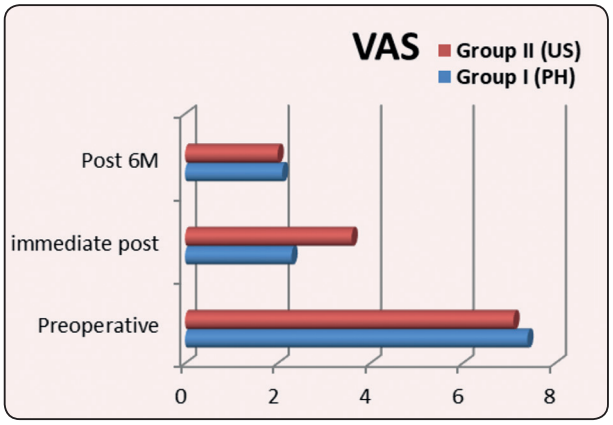

Fig. (3) Bar chart representing mean pain scores (VAS) in the two groups

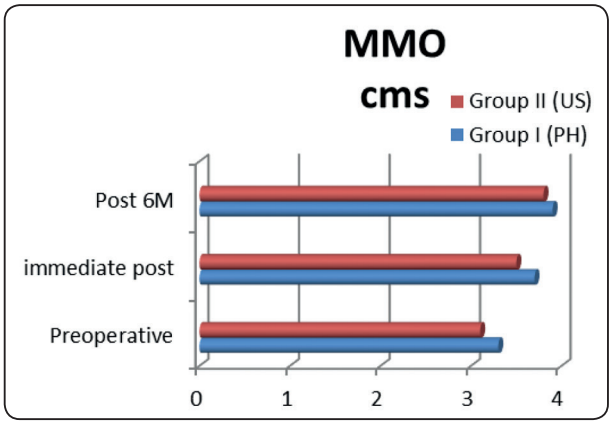

Fig. (4) Bar chart representing mean maximum mouth opening (MMO) in the two groups

DISCUSSION

Sustained contractile activity of the affected muscle in MPDs leads to increased metabolic stress, alternation to non-Krebs cycle and local ischemia with secondary changes that contribute to clot formation and the persistence of the trigger points, and increased release of cytokines, inflammatory mediators and neurotransmitters that maintain these trigger points and pain. [14] Pain relief and reestablishment of normal function are the main purposes of the treatment of patients with myofascial pain dysfunction syndrome. Therefore, it was the purpose of the present study to evaluate the effectiveness of phonophoresis using Extrauma gel for the treatment of patients with MTrPs in masseter muscle.

The patients selected for the present study complained from pain and tenderness in facial muscles mainly the masseter with no tenderness or pain in the TMJ. The age of patients in this study was ranged between 18-43 years as this was the most common age for this disorder which was found in agreement with many authors. [19-21]

Among the masticatory muscles, the Masseter muscle frequently harbors trigger points**.** In the present study, masseter was the most frequent muscle involved**,** this finding was supported by Laskin, and Butler et al studies. [22-23] They reported that the superficial portion of the masseter was the most commonly involved part in the form of pain and tenderness of the muscle. [22-23] Twenty female patients were included in the current study, suffering from trigger points in the masseter muscle mainly, as women's face almost three times the risk of developing chronic masticatory myofascial pain than men patients. This was in general agreement with Velly et al and Koidis and Zarifi .[24-25]

In the present study, VAS showed improvement in Phonophoresis group at the fourth cession for the patients while in ultrasound group was at the sixth cession; and statistically significant difference immediately postoperative due to Extrauma gel is a synthetic recombinant form of r-Hirudin anticoagulant which binds to and inhibits the activated thrombin, as it has a thrombolytic activity with a specific activity on fibrinogen, therefore, hirudin prevents or dissolves the formation of clots and thrombi. Also Extrauma is an anti-inflammatory so decrease inflammatory cytokines, with decreased pain, tenderness and the trigger points and this leads to increase in motion.[15-17,26] At the end period of follow up, no significant difference was observed between PH and US group, but PH was effective in reducing the symptoms of MPDS at the early stage of treatment.

Improvement in MMO in this study due to the use of ultrasound (US) which allows the drug to penetrate the deeper layer beyond the skin in the subdermal tissues with increase in blood flow through vasodilatation of blood vessels by the thermal effects which increase the collagen elasticity.

CONCLUSION

Extrauma phonophoresis in the masseter muscle trigger points considered a successful treatment option for myofascial pain dysfunction syndrome and effective than ultrasound in controlling pain. It is necessary to mention that the frequency and intensity of US device, age, thickness, hydration, lipid structure, and vasculature of skin of the patients affect the efficacy of PH.

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