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Efficiency of adding pulsed electromagnetic field therapy to mobilization and exercises in patients with TMJ dysfunction after facial penetrating injury: A randomized single-blinded study

Skuteczność wprowadzenia pulsacyjnej terapii polem elektromagnetycznym do mobilizacji i ćwiczeń u pacjentów z dysfunkcją stawu skroniowo-żuchwowego po urazie penetrującym twarzy: randomizowane badanie z pojedynczą ślepą próbą

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Abstract

Background. Facial penetrating wound can affect TMJ function, even if it didn't cause a facial bone fracture. Pulsed Electromagnetic Field Therapy (PEMFT) is a common physical therapy modality that used to speed up musculoskeletal injuries' recovery. No previous studies described the effect of adding PEMFT to traditional TMJ mobilization for the treatment of such cases. Aim. is to investigate the effect of in combination with traditional physical therapy on the pain and mouth opening, after facial penetrating wound injury with no facial fractures, that treated conservatively. Materials and Methods. Thirty-three patients were complaining from TMJ pain and mouth opening limitation after 1 month of facial penetrating wound injury and met the selection criteria were randomized to either study or control group. Control group received TMJ manual physical therapy program (mobilization and gentle isometric exercises). Study group patients received PEMFT in addition to the manual physical therapy program. Treatment was administrated for 12 sessions 3 times per week for both groups. Patients' pain was assessed using visual analogue scale while mouth opening was measured using digital Vernier caliper, before and after one month of treatment. Results. all 33 patient results were analyzed. After treatment values showed a statistically significant reduction in pain and increase in mouth opening in comparison to pretreatment values at both groups with (P-value < 0.001). Post-treatment between groups comparison showed a significant difference in pain and mouth opening variables (p-value = 0.0001 and 0002 respectively), in favour of group B (Study group). Conclusion. adding PEMFT to TMJ manual physical therapy program, in treatment of patients with TMJ dysfunction (pain and limitation of mouth opening) after facial penetrating wound injury, has a superior effect in comparison to using of manual physical therapy treatment program only.

Key words:

Magnetic, facial wound, facial gunshot, TMJ dysfunction

Streszczenie

Informacje wprowadzające. Rana penetrująca twarzy może wpływać na funkcję stawu skroniowo-żuchwowego, nawet jeśli nie spowodowała złamania kości twarzy. Pulsacyjna terapia polem elektromagnetycznym (PEMFT) jest powszechną metodą fizjoterapeutyczną, która służy do przyspieszenia powrotu do zdrowia po urazach układu mięśniowo-szkieletowego. Żadne wcześniejsze badania nie opisywały wpływu wprowadzenia PEMFT do tradycyjnej mobilizacji stawu skroniowo-żuchwowego w leczeniu takich przypadków. Cel. Zbadanie wpływu PEMFT w połączeniu z tradycyjną fizykoterapią na ból i otwieranie ust po urazie penetrującym twarzy bez złamania, leczonym zachowawczo. Materiały i metody. Trzydziestu trzech pacjentów, którzy skarżyli się na ból stawu skroniowo-żuchwowego i ograniczenie otwierania ust po 1 miesiącu od urazu penetrującego twarzy i spełnili kryteria selekcji, zostało losowo przydzielonych do grupy badanej lub kontrolnej. Grupa kontrolna była poddawana programowi fizjoterapii manualnej stawu skroniowo-żuchwowego (mobilizacja i łagodne ćwiczenia izometryczne). Pacjenci z grupy badanej byli poddawani PEMFT w połączeniu z programem fizjoterapii manualnej. W obu grupach przeprowadzono 12 sesji 3 razy w tygodniu. Ból pacjentów oceniano za pomocą wizualnej skali analogowej, a otwarcie ust mierzono suwmiarką cyfrową, przed i po miesiącu leczenia. Wyniki. Przeanalizowano wyniki wszystkich 33 pacjentów. Wartości po leczeniu wykazały statystycznie istotne zmniejszenie bólu i zwiększenie otwierania ust w porównaniu z wartościami przed leczeniem w obu grupach (wartość $p < 0,001$). Porównanie po zastosowanym leczeniu wykazało istotną różnicę w zmiennych dotyczących bólu i otwierania ust (odpowiednio wartość $p = 0,0001$ i 0002) na korzyść grupy B (grupa badana). Wniosek. Wprowadzenie PEMFT do programu fizjoterapii manualnej stawu skroniowo-żuchwowego w leczeniu pacjentów z dysfunkcją stawu skroniowo-żuchwowego (ból i ograniczenie otwierania ust) po urazie penetrującym twarzy, daje lepsze efekty niż zastosowanie samego programu fizjoterapii manualnej.

Słowa kluczowe

Pole magnetyczne, rana twarzy, postrzał twarzy, dysfunkcja stawu skroniowo-żuchwowego

Introduction

Temporomandibular joint dysfunction (TMD/TMJ) is a major public health problem with prevalence between 5% and 12% [1]. TMD is not life-threatening, but when symptoms become difficult to manage and being chronic, it greatly impacts patients' daily living activities and quality of life [2].

A facial penetrating injury can lead to TMJ dysfunction symptoms as pain the periauricular area or in the muscles of mastication, limited mouth opening, headaches ankylosis of TMJ, clicking in temporomandibular joints during movement, headaches, and cervical pain [3].

Face penetrating injury by a foreign object is relatively common, especially injuries that affect the oral and maxillofacial region [4]. The types of soft-tissue injuries could be simple or complex. Common causes of severe facial injuries are road traffic accidents, domestic violence [5], foreign bodies, homicidal trauma, burn [thermal, chemical and electrical], bites or knife penetrating injury [6, 7]. Other causes may include compact sports which a source of a high percentage of facial injuries affecting young adults [8, 9]. One of the most severe reasons for facial injuries is gunshot wounds and other explosive or incendiary devices [10, 11] which are associated with higher morbidity and mortality rates [12, 13].

Signs and symptoms of penetrating facial injury may be ecchymosis, oedema, sub-conjunctival haemorrhage, crepitus, hyperaesthesia, evidence of facial nerve palsy, inadequate excursion of the muscles of expression and mastication, wound with or without exposed vital structures and fractures [6]. Physical therapy one of the common 10 treatment used in the management of TMJ Dysfunction [14]. Physical therapy TMD treatment is aiming to reduce pain, allow muscles to relax, decreased muscle hyperactivity, and regain normal muscle function and joint mobility [15].

Pulsed Electromagnetic Field Therapy [PEMFT] is a safe non-invasive effective electrotherapeutic modality utilized in various musculoskeletal disorders to speed up patient's recovery and reduce the time of rehabilitation [16]. This type of treatment works through alteration of electrochemical balance in the cell membrane which interacts with the biologic transduction mechanisms [17]. It helps to stabilize the metabolism, contributing to a better balance between the cell and the intercellular spaces [18].

Up to our knowledge, there was few studies have been conducted to test the effectiveness of PEMFT in treatment of TMD [19], with no other study examined the added effect of PEMFT to the physical therapy mobilization and exercises in solving such a problem. To fill the gap of knowledge, our study was conducted to investigate the effect of magnetic therapy in combination with traditional physical therapy on the pain and mouth opening, after facial penetrating wound injury with no facial fractures, that treated conservatively.

Materials and methods

Study design

The design is a randomized single-blinded parallel study with active control and treatment groups. Clinical examiner and patient were blinded to treatment. Before its initiation, the study was approved by the ethical committee of faculty of Physi-

cal Therapy, Cairo University, Egypt. The study protocol is registered at ClinicalTrials.org with registration NO. NCT04561037. The study was conducted following the declaration of Helsinki ethical principles for medical research involving human subjects.

Participants

A study sample of 37 male patients was included in the study. The sample size is calculated after power analysis. Participants recruited for the study were patients referred to Physical Therapy Clinic at Faculty of Physical Therapy, Deraaya University, Minya, Egypt between Oct 2019 and Sept 2020. They complained from TMJ pain and mouth opening limitation after 1 month of facial penetrating wound injury as the wound is fully healed. The age of the patients was ranged from 22 to 40 years (mean age 29.879 ± 4.948 years). To be included in the study, patients had to have TMJ pain (in 1 or both joints) after facial penetrating wound injury with no bone future or TMJ dislocation. All participants had been diagnosed with TMD with Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) axis I which consists of rest spontaneous pain evoked on palpation of the TMJ, TMJ limitation in mouth opening (the maximum self-opening distance between upper and lower middle incisors was less than 35 mm), reciprocal clicking, or joint noise with mandibular movement examination [20, 21]. Patients excluded from the study if they had, TMJ fracture, previous TMJ surgeries, dental diseases, infectious or systemic diseases, malignancy, a pacemaker or metal implants and systemic diseases that affect joint function such as rheumatoid arthritis.

Randomization and Interventions

After explaining the nature, purpose, and benefits of the study, informing patients of their right to refuse or withdraw from the study at any time, and about the confidentiality of any information collected, each patient signed a written informed consent form. Anonymity was assured through coding of all data.

After the clinical assessment and the establishment of diagnosis, random allocation of patients to the study groups was carried out through block randomization. Blocks of six were carried out by statistician not involved in data collection or analysis. Blinded, independent research assistant, opened sealed randomization block envelopes, randomized patients to either control group or study group, and he scheduled patient to treatment sessions. Patients are blinded about which group they are allocated to, control or study.

Control group patients received traditional physical therapy treatment. The traditional physical therapy treatment program consisted of TMJ mobilization techniques include distraction, anterior glide, anterior glide with pre-positioned mouth opening, medial/lateral glides, caudal-anterior-medial (CAM) glide, and CAM glide with pre-positioned mouth opening [22] and isometric exercises against resistance for muscles of mastication [23].

Study group patients received PEMFT, using EMG 8400 PEMF device (made in Italy, by EME) in addition to the physical therapy treatment program. PEMFT device was installed in a separate room in the Physical Therapy Clinic at the Faculty

of Physical Therapy, Deraya University. One patient only treated at a time. The patient was placed in a comfortable relaxed seated position. The appliance was connected to electrical mains supplying 220v. Pair of applicators sized 16x10x3 cm was adjust to be over TMJ, on both sides of the face; the appliance was adjusted to the frequency of 50 HZ and intensity of 90 Gauss. Twelve PEMF treatment sessions of 30 min duration were provided 3 times per week [19, 24].

Both groups received 12 sessions of treatment, three times per week for four weeks.

Outcome measures

Qualified examiner, who is blinded to treatment allocation, evaluated all for the selected treatment outcome measures. The evaluation was carried out pre-study and after one month of treatment. He also, recorded and reviewed all medical history of patients.

The mandibular function was evaluated by measuring the maximum opening of the mouth in millimetre (mm). Every participant was asked to open his or her mouth as wide as possible after that the examiner used a digital Vernier caliper to measure the maximum vertical distance from the incisal edge of the upper central incisors to the incisal edge of the lower central incisors at the midline [25, 26].

Visual Analogue Scale (VAS) was used to evaluate pain intensity. VAS is a subjective pain measurement method consisting of a straight line of 100 mm on which patients scored their pain intensity where 0 corresponds to no pain and 10 corresponds to the worst maximum pain [27].

Sample size

A pilot power analysis with β value = 0.1 (type II error) and α value = 0.05 (type I error) was carried out to avoid type II error. The calculated effect size was 0.827 after a pilot study on 6 participants using the mouth opening as the primary variable. Our power analysis estimated 14 participants for each group as a sample size. The power analysis was carried out by G*Power 3.1.9.2 software, using test family as t-test and statistical test as Mean difference between two independent groups.

Data analysis

All examination data were coded, and computer-assisted evaluation was performed using SPSS for Windows, version 25 (SPSS, Inc., Chicago, IL) statistical software. The current test involved two dependent variables (Pain and mouth opening). Prior to final analysis, data were screened for normality assumption. Parametric teste (paired sample testes and independent sample t-tests, for within-group and between groups comparison, respectively) was used for inferential analysis. Intestinal alpha level was 0.05 for all tests.

Results

The primary analysis was conducted using an intent-to-treat approach and therefore included all randomized patients. Thirty-seven participants were eligible for inclusion. Only 33 were randomized for study intervention (Figure 1), 16 in the control and 17 in the study group. The groups were similar at baseline regarding demographic data (age, weight, and height) (Table 1). Also, the distribution of patient with different caused in both groups was similar between groups.

Table 1. Baseline characteristics of participant according to treatment group

Characteristic	Study Group (n = 17) mean ± SD	Control Group (n = 16) mean±SD	P-value
Age	29.88 ± 5.098	29.88 ± 4.951	0.997
Height	171.18 ± 5.876	173.66 ± 5.924	0.237
Weight	82.64 ± 9.397	85.03 ± 7.915	0.437
gunshot patients*	8	7	0.849 ^χ
facial wound patients*	9	9	

Data expressed as Mean and SD (stander deviation)

* Data expressed as frequencies

^χChi-square test

Statistical analysis showed no statistically significant differences ($P > 0.05$) between subjects in both groups concerning outcome variables at baseline (pre-intervention) regarding Pain and mouth opening variables (Table 2). Moreover, post-test comparison between both groups showed significant statistical difference ($p < 0.05$) regarding the Pain (95%CI = -31.014 and -13.619),

and mouth opening variable (95%CI = 1.263 and 9.16). The within-group comparison showed significant improvement (decrease) in Pain, with a percentage of improvement (68% and 36%), and mouth opening with a percentage of increase (38% and 25%) in study and control groups, respectively, after treatment in comparison to the pre-treatment values.

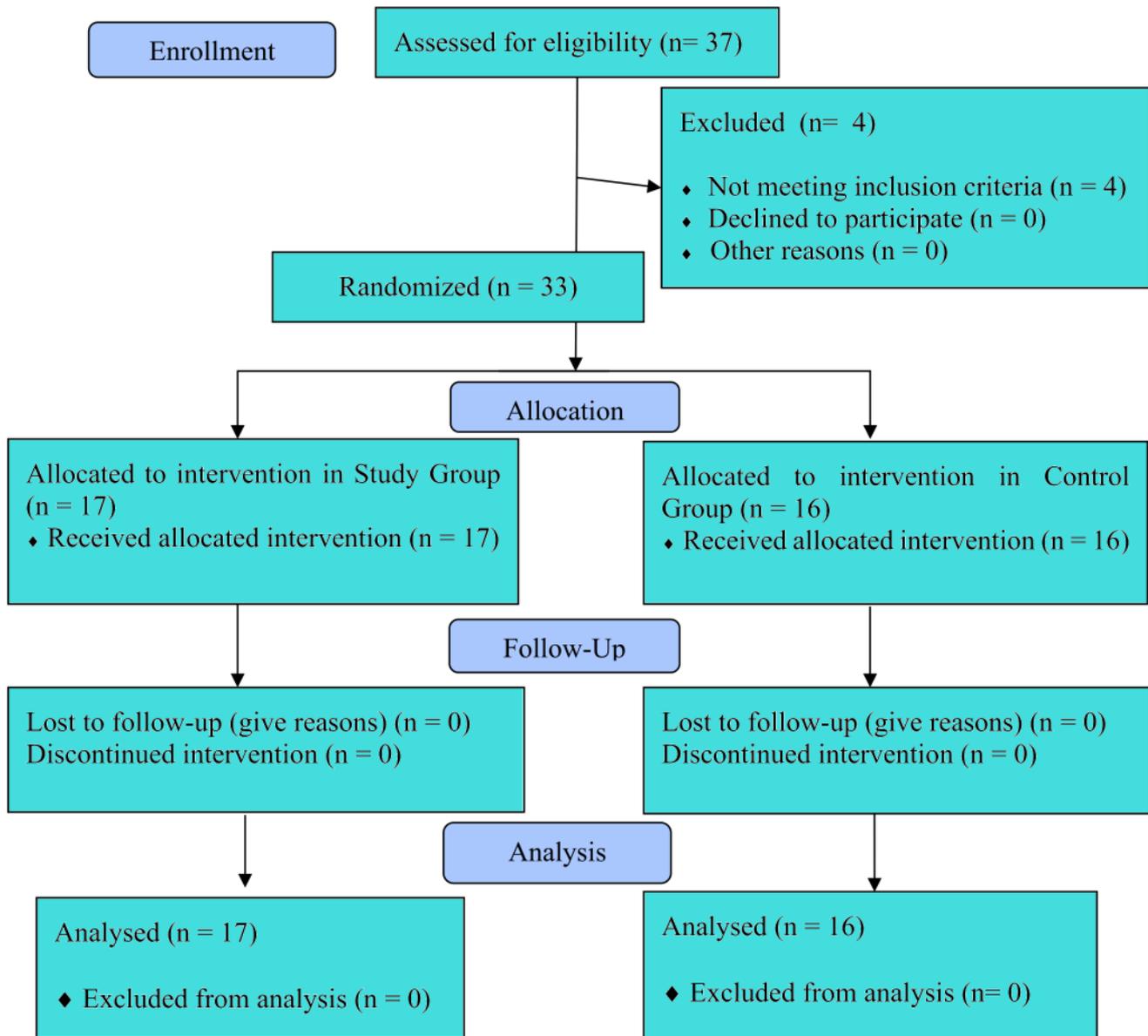


Figure 1. Study flow chart

Table 2. Pain and mouth opening pre and post-treatment Mean ± SD, within and between groups comparison

Variable	Group	Pre Mean±SD	P-value*	Post Mean±SD	P-value**	P-value***
Pain	Study Group	67.33 ± 12.938	0.836	21.67 ± 13.584	< 0.001	< 0.001
	Control Group	68.33 ± 13.318		43.67 ± 13.947		< 0.001
Mouth opening	Study Group	28.31 ± 5.977	0.558	39 ± 5.574	0.011	< 0.001
	Control Group	27.09 ± 5.268		33.74 ± 5.142		< 0.001

Data expressed in mean±SD

*Between groups difference before treatment

** Between groups comparison after treatment

*** Comparison between pre and post-treatment values in each group

Discussion

The temporomandibular joint disorder has many causes, including injury, occlusal change, stress, malocclusion, muscular imbalance, impaired functions, TMJ dysfunction, and postural alterations [28-30]. Pain and limited jaw range of motion is an important clinical sign of trauma inflicted by a facial penetrating injury, usually due to secondary inflammation following injury [31]. The treatment goal of TMDs is to increase mouth opening range of motion and reduction of local and radiating pain to enable the return to normal temporomandibular joint function [32]. One of the effective non-invasive treatment of TMDs is physical therapy modalities including manual therapy [33, 34], low-level laser therapy [35], therapeutic ultrasound and electrical stimulation [32].

The lack of researches regarding the added effect of PEMF to TMJ mobilization and exercises in the treatment of TMD, emphasizes the necessity of conducting this study.

Findings of our study indicated that patients suffering from a limitation of mouth opening and pain after facial penetrating wound injury with no bone fracture improved significantly using manual physical therapy. Statistical analysis showed [68% and 36%] improvement in the control group and [38% and 25%] improvement in the study group regarding maximum mouth opening and pain, respectively. Between groups comparison showed a statistically significant difference between study and control groups regarding mouth opening [P-value = 0.011] and pain [P-value = 0.000] measures after treatment in favour to study group. Many studies demonstrate the effectiveness of physical therapy programs in the treatment of TMJ dysfunctions. One form of physical therapy interventions is the mobilization of TMJ. It was shown to be effective in reducing pain and increase mouth opening and range of motion [33, 34].

Another study suggests that rehabilitation could be the primary treatment for individuals with TMJ closed lock that could replace unnecessary surgical procedures [36]. Many systematic reviews have been conducted around the physical therapy treatment role in orofacial pain. These studies concentrated on the role of manual therapy and exercise interventions for TMD. Manual therapy has been used to regain ROM, improve local circulation, stimulate proprioception, breakdown fibrous adhesions, stimulate the production of joints' synovial fluid, and decreased pain. [14, 37, 38]. The main mechanisms by which mobilization improve joint function are decreasing the level of pain, increasing of ROM, and muscle spasm inhibition [39]. Other mechanisms include; spinal excitability inhibition of nociceptive pathways, which induced central pain inhibition [40].

In a recent study, the efficacy of mandibular manipulation TMD patients with mouth opening limitation was tested through measure limitation in the mouth-opening, orofacial pain, and TMJ sounds at baseline and after 18 weeks. Results founded a significant improvement after treatment in the first session of manipulation in mouth opening limitation with no long-term effect or improvement observed in other parameters[41]. This came in partial agreement with our results. The difference in results may

be due to the different manual therapy technic used, as we used mobilization and isometric exercise rather than manipulation. Another cause is the different cause of mouth opening limitation. In our study limitation was caused by post penetrating wound immobilization and adhesions while in Nagata, Hori [41] study mouth opening limitation was caused by myalgia or arthralgia or both that elicited by mouth opening or palpation.

Effectiveness of masticatory muscle exercises was confirmed by other studies to increase the mobility of the mandible, decreased the myofascial pain [42] and improve patients' clinical measures [43]. Further studies showed the efficacy of physical therapy exercises in improving myofascial pain, cervical spine dysfunction and clicking, in patients with TMJ problems [23, 44-46].

The use of PEMF in our study showed added improvement in pain and mouth opening over the mobilization only group. This may be explained by results of other studies on orthopaedic disorders which showed that PEMF is effective in the treatment of orthopaedic problems such as knee stiffness is OA knee patients [47, 48]. Further explanation is that local application of a specific PEMF waveform can elicit significant arteriolar vasodilation [49]. Farther more, PEMF increase in NO activity which improves blood perfusion and pressure which in turn improve nerve functions and pain [50].

On the other hand, Peroz, Chun [19] examined the efficacy of PEMF in treatment of 42 patients with TMJ disorder and found that no difference in pain intensity, frequency and active mouth opening at PEMF group in comparison to placebo control. In other words, PEMF had no specific treatment effects [19]. The difference in results between our study and Peroz, Chun [19] study could be due to the difference in treatment parameters and type of electrodes used in treatment. Also, the diagnosis of patient mostly disk displacement with and without reduction and osteoarthritis or arthritis of TMJ or fracture, which is different from the diagnosis of patients selected in our study.

Limitations of this study predominantly include male-only participant as they are more suspected for these types of injuries by more than 3.5-time in comparison to females [51]. Future studies should include a larger sample size, including both sexes, and use other treatment parameters of PEMF.

Conclusions

Within the limitations of this study, we can conclude that, adding PEMF to manual physical therapy program increase the treatment effect and lead to an improvement in pain and mouth opening in patients with TMJ dysfunctions after facial penetrating wound injury. Also, the effect of this treatment combination is better than manual physical therapy only in the treatment of those patients.

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