Original Article

Bio Electro Magnetic Energy Regulation (BEMER) therapy in myofascial pain dysfunction syndrome: A preliminary study

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ABSTRACT

Background: Myofascial pain dysfunction syndrome (MPDS) is of the commonest form of orofacial pain encountered in the clinics. Though, many therapies have been suggested in the recent past, still the management of this condition remains a therapeutic problem. The search for newer, relatively safe and effective long term approach lead to the use of magnetic stimulation in pain modulation. Bio Electro Magnetic Energy Regulation is one such modality that has been studied in the musculoskeletal disorders. However, no studies in this regard have been explored in orofacial region.

Objectives: The objective of the present study was to evaluate the efficacy of BEMER therapy as an adjuvant to relieve pain in myofascial pain dysfunction syndrome.

Materials and methods: The present randomized comparative study was on 40 patients who were diagnosed with Myofascial pain dysfunction syndrome (MPDS). They were grouped into two groups of 20 each. Group 1 patients were administered analgesic + muscle relaxants & Group 2 was receiving both analgesic + muscle relaxants with BEMER therapy. All the patients were evaluated for pain relief on visual analog scale (VAS) and the mouth opening (MO) was measured using digital vernier callipers.

Results: The group 2 showed a significant improvement in the symptoms even after 2 months follow up. In group 2 the mean mouth opening was 45.60 ± 3.648 ($P < 0.05$) and 45.50 ± 3.663 ($P < 0.05$); the Mean VAS Score was 3.10 ± 0.912 and 2.90 ± 0.968 ($P < 0.05$) after one month and after two months respectively. The independent *t*-test, was used for inferential statistics.

Conclusion: It can be concluded from this study that Combined therapy proved to be more effective in providing long term symptomatic relief compared to conventional pharmacological therapy. BEMER as an adjuvant therapeutic modality proved to be beneficial in the management of MPDS.

1. Introduction

Temporomandibular joint disorders can be grouped into disorder of myogenous origin and true articular disease. The myofascial pain dysfunction syndrome is a disorder causing pain involving the muscles of head and neck. Pain is the primary reason for which patient seeks medical treatment.

Several therapeutic approaches with varying success rates to treat Myofascial pain dysfunction syndrome (MPDS). These include pharmacological therapies like systemic (muscle relaxants, non steroidal anti-inflammatory drugs, benzodiazepine) and physiotherapy treatments (transcutaneous electrical nerve stimulation magnetic therapies, ultrasound, biofeedback).¹ These therapeutics seem to be effective in temporary pain reduction. However, they are also accompanied by

adverse effects on long term usage. Often, management of pain in these patients is challenging after all the therapeutic treatments fail.

Among the above mentioned approaches, transcutaneous electrical nerve stimulation (TENS) is the most frequently employed treatment modality reported to alleviate pain in the immediate post-treatment period.² BEMER (Bio-Electro-Magnetic-Energy-Regulation) therapy is a novel treatment approach using magnetic stimulation with promising outcome in musculoskeletal pain management.^{3–7} The advantage of BEMER over conventional electrical stimulation is that it is non invasive and causes activation of the deeper anatomical structures with minimal or no local discomfort.³

BEMER (Bio-Electro-Magnetic-Energy-Regulation) devices uses “weak” magnetic field and a pulsed signal (BEMER signal), that enhances microcirculation. Microcirculation enables tissue oxygen

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perfusion in a microcirculatory area.^{3–8} Fatigue reduction through microcirculation are the clinical applications that have been confirmed in previous studies on knee osteoarthritis, low back pain and other chronic musculoskeletal pains.^{6,7} With this background, the current study attempted to explore the effectiveness of BEMER as an adjuvant therapy in the management of pain in MPDS.

2. Aims and objectives

To determine effectiveness of BEMER therapy in the management of Myofascial pain dysfunction syndrome, to determine the efficacy of Combined use of pharmacological and BEMER therapy in myofascial pain dysfunction syndrome. The objectives were to evaluate the improvement in VAS score (visual analogue scale), to evaluate the changes in the mouth opening in pre & post treatment cases to signify the therapeutic effects.

3. Materials and Methods

Patients attending the Department of Oral medicine and Radiology in a private dental college. clinically diagnosed with MPDS following Laskin's criteria were included in the study. This study was approved by the Institutional Ethical Committee. Prior to the start of the study written and informed consent was obtained from all the patients.

4. Sample selection

A total of 40 patients were divided into two groups of 20 each (Group1,2). The sampling method was simple randomised sampling. A detailed case history of patients, with a thorough clinical examination extra orally (mouth opening, deviation/deflection, muscle tenderness) and intraorally (occlusion, wear facets) on a standard proforma. Laskin's criteria was used to diagnose the cases. Orthopantomogram (OPG) and limitation views of TMJ were made to rule out any temporomandibular joint (TMJ) disorders.

4.1. Inclusion criteria

1. Patients diagnosed with MPDS based on Laskin's criteria, complaining of persistent pain with no previous treatment were included in this study.

4.2. Exclusion criteria

1. Patients not willing to participate in the study were excluded
2. Patients with diagnosed Psychological disorders
3. Patient with a known history of drug allergies
4. Patient with a known history of GIT, Renal disorders
5. Pregnant women
6. Patients with cardiac pacemakers

The Severity of pain was assessed using visual analog scale (VAS) with a score ranging from 0 to 10, where 0 means no pain and 10 means extreme pain subjectively perceived by the patient. The mouth opening (MO) between upper and lower incisal edges was recorded using a digital Vernier callipers. The patients were followed up for 2 months after the initiation of the treatment. Both the parameters were assessed on day 0, by the end of 1 month and 2 months respectively for each group.

5. BEMER device

BEMER (Bio-Electro-Magnetic-Energy-Regulation) therapy uses a low-frequency pulsed magnetic field. The detailed physical properties of this device are reviewed in the following patents: EP 0995463 A1, WO 2011023634 A1; WO 2008025731 A1.^{8–11} The device has control unit Box with 10 different levels of magnetic field intensity (from 0 μ T

Fig. 1. BEMER device and B spot unit.

to 35 μ T) with a pulse-frequency of 30 Hz and pulse-duration of 30 ms electric field will be generated. A B spot unit (Fig. 1) is used for small body parts to deliver the magnetic energy. (BEMER International AG, Triesen, Liechtenstein). The B spot unit has a handle to hold the device in place and a flat surface that is kept in contact with the surface at the affected area (Fig. 2). Treatment time in previous medical studies in pain of musculoskeletal system suggested application for 20 min a day for 2–4 weeks depending on the diagnosis for therapeutic benefits.²

6. Treatment

After detailed case history, clinical examination and investigation the diagnosed MPDS patients were randomly divided in two groups. Twenty patients were included in Group 1 to study the efficacy of well established pharmacological modality of muscle relaxants and

Fig. 2. Placement of B spot unit at the affected site.

Fig. 3. a) mouth opening at day 0 b) mouth opening after 1 month c) mouth opening after 2 month.

analgesics. They were advised Muscle Relaxants & Analgesics thrice daily (Ibuprofen 400 mg + Paracetamol 325 mg + Chlorzoxazone 250 mg) for 5 days.

Similarly group 2 Comprised of twenty patients treated with combination of BEMER therapy along with, pharmacological drugs (Ibuprofen 400mg + Paracetamol 325 mg + Chlorzoxazone 250mg). BEAMER was administered for a period of 20 min with a stimulation and is gradually adjusted as tolerated by the patient over the tender muscles with a maximum magnetic induction of 35 μ T. Each session included 2 cycles per day with an interval gap of 3 h for 8 weeks. Along with this the patients were advised to take Muscle Relaxants & Analgesics thrice daily (Ibuprofen 400 mg + Paracetamol 325 mg + Chlorzoxazone 250 mg) for 5 days.

In all the patients 2 parameters i.e. Pain by VAS, Interincisal distance in mm were recorded before and after the treatment. These findings were recorded on the day of starting the treatment, and thereafter the parameters were regularly reassessed after 1 month, 2 months respectively (Fig. 3). The obtained data were subjected to statistical analysis using SPSS 16 software. Independent t-test was used to analyze the improvement with the respective treatment modalities. Analysis of variance test was used to compare the change in the mean mouth opening and mean VAS scores among the two groups. The P value of ≤ 0.05 was considered to be statistically significant.

7. Results

Out of total 40 patients, 62.5% (24) were females and 37.5% (16) were males. In group 1 the mean mouth opening at base line was found to be 40.40 with a standard deviation of 5.345 and after 1 month the mean mouth opening was 41.80 with a standard deviation of 4.731 and after 2 month the mean mouth opening was 40.95 with a standard deviation of 4.979 (Table 1). It can be inferred that the mouth opening was gradually increasing and showed a maximum response by 1 month and the P value was found to be significant. However the after 2 months there was no significant improvement.

Similarly In group 2 the mean mouth opening at base line was found to be 40.80 with a standard deviation of 4.764 and after 1 month the mean mouth opening was 45.60 with a standard deviation of 3.648 and after 2 month the mean mouth opening was 45.50 with a standard deviation of 3.663 (Table 1). It can be inferred that the mouth opening

was gradually increasing and showed a significant response by 1, 2 months and the P value was found to be significant.

In group 1 the mean VAS score at base line was found to be 5.25 with a standard deviation of 1.773 and after 1 month the mean was score was 3.90 with a standard deviation of 1.586 and after 2 month the mean VAS score was 4.15 with a standard deviation of 1.226 (Table 2). In group 2 the mean VAS score at base line was found to be 5.15 with a standard deviation of 1.565 and after 1 month the mean was score was 3.10 with a standard deviation of 0.912 and after 2 month the mean was score was 2.90 with a standard deviation of 0.968 (Table 2). The P value was found to be significant at both 1, 2 months compared to the base line.

On comparison using the Independent t-test. The over all mean mouth opening of group 2 was found to be significant at both 1, 2 months (Graph 1). The over all mean VAS score of group 2 was found to be significant at 2 months (Graph 2). This result could be attributed to the fact that the treatment given in the control group was effective, but only for a short duration after which the pain may have reappeared at a lower intensity. But in the study group due to the synergistic action of medications with the underlying mechanism of BEMER therapy the treatment outcome was effective for longer duration with lesser chances of relapse.

8. Discussion

Myofascial pain dysfunction syndrome (MPDS) is the most common form of temporomandibular disorder. It is characterised by pain that originates from myofascial trigger points in skeletal muscle.¹ Musculotendinous pain is the primary symptom in this condition. It has always been a diagnostic enigma, to the oral physician since the etiology is multifactorial and often the management aims at pain relief.

Myofascial pain dysfunction syndrome was defined as “an entity characterized by regional pain originating from hyperirritable taut bands of skeletal muscle, known as myofascial trigger points.”¹ These areas when compressed may lead to localized or radiating pain on the orofacial region.

It is more commonly seen in females and the results of the current study, also suggested females predominance 24/40 (62.5%) compared to males 16/40 (37.5%). The definitive treatment of MPDS depends on the symptoms of the patient. Some patients require relief of symptoms

Table 1

Mean mouth opening in mm score in both the groups.

Mean mouth opening in mm score in both the groups					
Group	N	Baseline	After 1 month Mean mouth opening $\pm$ Standard deviation	After 2 months Mean mouth opening $\pm$ Standard deviation	
Group 1	20	40.40 $\pm$ 5.345	41.80 $\pm$ 4.731	40.95 $\pm$ 4.979	
Group 2	20	40.80 $\pm$ 4.764	45.60 $\pm$ 3.648	45.50 $\pm$ 3.663	
Independent samples t-test		p = 0.804	p = 0.007 *	p = 0.002 *	

Table 2
Mean VAS Score in both the groups.

Mean VAS Score in both the groups				
Group	N	Baseline	After 1 month Mean VAS score $\pm$ Standard deviation	After 2 months Mean VAS score $\pm$ Standard deviation
Group 1	20	5.25 $\pm$ 1.773	3.90 $\pm$ 1.586	4.15 $\pm$ 1.226
Group 2	20	5.15 $\pm$ 1.565	3.10 $\pm$ 0.912	2.90 $\pm$ 0.968
Independent samples <i>t</i> -test		<i>p</i> = 0.851	<i>p</i> = 0.058	<i>p</i> = 0.001 *

Graph 1. Mean mouth opening in both the groups.

Graph 2. Mean VAS scores in both the groups.

while in some patient the treatment of underlying causative factor like occlusal discrepancies is mandatory.

Nonsteroidal anti-inflammatory drugs (NSAIDs) are the most commonly used drugs for MPDS as they are readily available and have a relatively mild adverse effects. Their main mechanism of action is by producing analgesic and anti-inflammatory properties. Despite their widespread use, there are not many studies conducted specifically to evaluate the role of oral NSAIDs in the management of MPDS. Considering the evidence that have been established already, It would be reasonable to consider NSAIDs as an initial appropriate treatment for pain relief in myogenous disorders of the orofacial region. Long-term use should be with caution due to the antiplatelet, gastrointestinal and renal side effects.¹

Chlorzoxazone is a centrally acting alpha-2-adrenergic agonist, which decreases muscle spasticity. Numerous studies evaluated centrally acting skeletal muscle relaxants in conditions associated with muscular pain.¹ Since MPDS is a disorder of myogenous origin it can be also be used for the therapeutic relief. However, hepatotoxicity has been reported as an adverse effect. Further more, due to the sedating effects of muscle relaxants they are not to be prescribed for long term usage. Considering the adverse effects of the pharmacological drugs, novel therapeutics have been under research in the recent past.

Bio Electro Magnetic Energy Regulation is one such treatment modality that is being investigated for musculoskeletal pain.^{3–7} Till date very few studies have been published and the exact therapeutic mechanism of action is to be elucidated.

In previous studies on knee osteoarthritis and chronic pain disorders BEMER therapy was reported to show pain-relieving and fatigue-reducing effects due to increased vasomotion and microcirculation by the BEMER signal. Microcirculation facilitates functional blood flow, tissue oxygen perfusion and removal of metabolites.^{3–7}

In this study, we used BEMER therapy as an adjuvant in combination with pharmacological drugs. Many studies with pulse electromagnetic field in patients with locomotor diseases have been published.¹² BEMER system, also uses a low-frequency, pulsed magnetic field (max. 35 μ T) with a series of half-wave shaped sinusoidal intensity variations shown as BEMER signal.³ At molecular levels this vasomotion regulates blood flow to the tissue and the local tissue responds to factors released from the micro vessels in response to the magnetic stimulus. Bernat SI et al. in 2013 evaluated the beneficial effects of BEMER therapy in thirty patients with lower limb obliterative vascular disease. The patients were administered 8 sessions of BEMER therapy, along with i.v. pentoxifylline. They suggested that the Combined therapy showed a significant improvement of symptoms.⁴

According to a study by Piatkowski J et al. in thirty seven patients with multiple sclerosis, evaluated fatigue relief with BEMER therapy applied twice daily for a duration of 8 min for 12 weeks. The results suggested significant fatigue relief.⁵ Subsequently, a 3-year open-label trial by the same group confirmed similar long-term therapeutic effects of BEMER therapy.⁶

A study by Gyulai F et al. evaluated the effect of adjuvant BEMER therapy in 50 patients with knee arthrosis and chronic low back pain. They inferred that BEMER therapy reduced pain and fatigue for short term in patients with chronic low back pain and while long-term therapy proved to be beneficial in patients with knee osteoarthritis.³

The randomized controlled double-blind pilot study was conducted by Benedetti MG et al. to evaluate the efficacy of Bio-Electro-Magnetic-Energy-Regulation (BEMER) magneto-therapy on pain and functional outcome in 30 complex regional pain syndrome patients. They demonstrated that the group treated with combination of BEMER as an adjuvant showed significant pain relief.⁷ The results of our study are in accordance with these previous studies.

In this study, BEMER was used as adjuvant physiotherapy and not as monotherapy. Therefore, in group 2 the long term effects could be because of the deeper drug penetration due to tissue perfusion (however, this is only a hypothesis and needs further research). Furthermore, in our research we noted that no subjects in the study group reported any significant side effects from use of BEMER therapy and the Compliance with this treatment was good as there were no dropouts in the study.

9. Conclusion

The role of BEMER therapy, in the management of chronic pain disorders is promising and the results of our study also proved it to be a useful adjuvant in pain management in orofacial region. It is a non-invasive technique found to be simple and relatively effective means of pain modulation. Though it has shown potential therapeutic benefit; more evidence is required before advising it as an efficacious main line treatment strategy. We recognize that the nature of this study is preliminary and the method may need to be further explored with larger sample size and evaluation of this therapy for other pain disorders in

orofacial region.

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