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CLINICAL IMPACT OF MAGNESIUM SULFATE INJECTION VERSUS LOCAL ANESTHETIC INJECTION ON PAIN MANAGEMENT IN PATIENTS WITH MYOFASCIAL PAIN DYSFUNCTION SYNDROME: A RANDOMIZED CLINICAL STUDY

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ABSTRACT

Background & aim: Management of Temporomandibular joint disorders are challenging that necessitates continuous research of efficient treatment options. This study aimed at evaluating the clinical efficacy of magnesium sulfate injection in the treatment of myofascial pain in patients with parafunctional habits versus local anesthetic injection.

Methodology: Forty patients with myofascial pain disorder as a result of parafunctional habits are randomly assigned equally into two groups; the study group (group I) undergone injection with magnesium sulfate (MgSO4), 0.5ml for each trigger point, while the control group (group II) undergone injection with plain local anesthesia (3% Mepivacaine), 0.5ml for each trigger point. Repeated injections were performed within one week interval for one month. Each patient was assessed in terms of pain intensity, maximum mouth opening and lateral jaw motions pre-operatively, immediately pre-operatively and six months post-operatively.

Results: The results indicated a significant time improving effect with no significant difference due to group effect (either injection of our studied materials) and obviously no significant effect due to interaction between time and group (nearly same therapeutic effects). The effect size due to time was high regarding pain scores, MMO and was intermediate regarding both lateral movements; *p value* < *.05*.

Conclusion: Injections of magnesium sulfate and local anesthesia are both useful in treating myofascial pain brought on by parafunctional habits.

KEYWORDS: Magnesium sulfate, MgSO4, TMD, trigger points, parafunctional habits & myofascial pain disorder.

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INTRODUCTION

Temporomandibular joint disorders (TMD) are one of challenging conditions in the maxillofacial area that involve muscles of mastication and the associated joint structures with various contributing etiological factors including; (1) occlusal abnormalities, (2) parafunctional habits, (3) macro-trauma, (4) micro-trauma & (5) psychological factors. Parafunctional habits are among commonly seen etiological factors in TMD which are abnormal behaviors in oral structures and the associated muscles. Bruxism, clenching, lip biting and other behaviors are among these abnormal habits which adversely affect structural components of temporomandibular joint (TMJ) with resultant pain which is the most common chief complaint in patients with TMD. [1–3]

The muscle component in TMD is a common clinical finding. Myofascial pain disorder is a commonly seen muscle disorder that affects both muscles of mastication and fascia with resultant localized areas of muscle spasm which known as trigger points. These points are locally tender, stiff, hypersensitive and painful on palpation leading to referred pain. These localized areas of muscle spasm are poorly vascularized and are characterized by presence of inflammatory & pain mediators. [2,4–6]

Regarding treatment modalities of myofascial pain disorder; trigger points injection with various injecting materials can be successfully performed and these injecting materials include: (1) physiological saline, (2) local anesthesia, (3) botulinum toxins, (4) corticosteroids and (5) others. Local anesthetic injection is aimed at increasing blood flow at these trigger points with resultant elimination of pain and inflammatory mediators. Moreover, local anesthesia temporarily blocks sensory signals at these points with resultant pain relief. Lidocaine, bupivacaine and other local anesthetic agents can be used safely. [2][5]

Myofascial pain disorder is a condition that presents in a large scale and consequently necessitating continuous research for various treatment modalities of this challenging clinical condition. Among recent injecting materials is magnesium sulfate (MgSO4) which is known with its muscle relaxing and vasodilator properties and consequently used in a large scale in musculoskeletal disorders with promising results. Furthermore, it has a low molecular weight (120.36 g/ mol.) with subsequent ability to penetrate deeper in comparison to local anesthesia & other injectable materials with resultant promising outcomes in management of myofascial pain disorder. The efficacy of this material is based upon its analgesic effect and pre-synaptic acetylcholine blockage with evidence of its efficacy in management of neuritis & myalgia. [2,7,8]

Previous studies have explored that there is a limited research on the effectiveness of injecting MgSO4 directly into myofascial trigger points; accordingly, this study was conducted to evaluate the clinical efficacy of magnesium sulfate injection in the treatment of myofascial pain in patients with parafunctional habits versus local anesthetic injection.

MATERIAL AND METHODS

Study Design

This randomized study included 40 patients with myofascial pain as a result of parafunctional habits since (June 2023 to August 2024); Patients were selected from Out Patient Clinic of Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Cairo University). This study was approved by the research ethics committee of Faculty of Dentistry, Cairo University with the reference number: 51723.

Sample size calculation

The study main outcome measure was pain relief; measured from data collected through the use of a scale (0 to 10). A sample size calculation performed with STATA V16.0, based on data from a previous

study, indicated that 40 patients would be required based on projected effect size, study power, and the desired significance level.; to achieve a study power of 80% with an alpha level of 0.05. Despite the smaller sample size, efforts were made to ensure the study's findings were as robust as possible within these limitations.

Randomization and allocation:

The study employed a randomized approach to ensure participants were allocated without bias. Forty patients with myofascial pain caused by parafunctional habits were randomly divided into two groups, with 20 patients in each. The first group received magnesium sulfate injections, while the second group was treated with local anesthetic injections. A computer-generated sequence was used to randomize the participants, and allocation was concealed from both the patients and the clinicians administering the treatments, ensuring blinding was preserved throughout the study.

The study included two groups of patients who equally distributed into the following groups; the study group (group I) underwent injection with magnesium sulfate (MgSO4); while the control group (group II) will be injected with plain local anesthesia and patients were randomly assigned to one of the two previously mentioned groups. Patients were recruited according to the following inclusion criteria: (1) patients with an age range from 18 to 50 years, (2) patients diagnosed with myofascial pain (3) One or more palpable taut bands in a skeletal muscle, (4) patients with parafunctional habits & (5) highly cooperative patients. While the exclusion criteria includes (1) patients with any gross anatomical deformity in relation to the TMJ, (2) patients with any systematic joint or muscle disorder, (3) patients with serious systemic disease & (4) patients undergone TMJ surgeries.

Intervention

The procedure was conducted under sterile conditions and included the following steps: (1) Identifying the area with the greatest tenderness within the muscle, (2) Pinpointing trigger points using the thumb and index finger, (3) Inserting a 30-gauge ¾-inch needle into the trigger point through the skin, (4) Performing negative aspiration, and (5) Administering magnesium sulfate (MgSO4, sterile ampoule 10%, Memphis for Pharmaceuticals & Chemical Industries, Cairo, Egypt), 0.5ml for each trigger point to Group I, while the other group received 3% Mepivacaine local anesthesia (Mepecaine, Alexandria Pharmaceuticals, Egypt), 0.5ml for each trigger point with one week interval between each injection for both groups. [2]

Outcome measures:

Pain intensity, maximum mouth opening (MMO), and lateral jaw movements were measured at three intervals: preoperative, immediately postoperative, and six months postoperatively. Pain intensity was recorded using the Visual Analogue Scale (VAS), which consists of a 10-cm line with endpoints marked as 0 ('no pain') and 10 ('worst pain imaginable'). Patients marked their current pain level on this line. MMO was determined by measuring the distance between the upper and lower central incisors with the mouth opened, while the lateral jaw movements (the distance from the upper centrals to the mandibular midline) were measured when the jaw was fully shifted to either side.

RESULTS

The study involved 40 participants who randomly assigned equally into two groups: group I receiving magnesium sulfate (n=20, with 4 males and 16 females), while the other receiving local anesthesia (n=20, comprising 7 males and 13 females). **Figure** (1) The average age in the magnesium sulfate group was 25.91±7.62 years, while that of the local anesthesia group was 28.53±8.51 years.

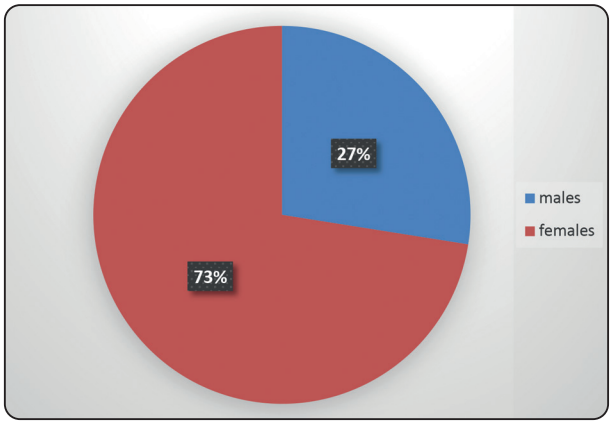

Fig. (1) Percent distribution of sex among the participants n= (40)

Both groups experienced minor side effects, such as redness and slight discomfort at the injection site which resolved spontaneously.

Mixed design ANOVA (one-way, repeated measures) was conducted to evaluate the null hypothesis that there is no difference between the two groups; magnesium sulfate (Mg So4) and local anesthesia (LA) at each time point 1(baseline preoperatively), 2 (immediately after injection), & 3(after six months) and across these time points regarding pain score and MMO and lateral movement (right &left). The results indicated a significant time effect with no significant difference due to group effect (either injection of our studied materials) and obviously no significant effect due to interaction between time and group (nearly same therapeutic effects). The effect size due to time was high regarding pain scores, MMO and was intermediate regarding both lateral movements. **Table (1 & 2), Figure (2 &3)**

Follow up comparisons revealed that for the pain score only; there was a significant difference between the means between immediate and after six months' time points. Moreover, there was significant difference of the means of each of the 3 time scores MMO, and lateral movements between baseline & each of immediate and after six months' time points. **Table (3 & 4), figures (2&3)**

TABLE (1) Design ANOVA (one-way, repeated measures) of time points for Pain score

Time	LA		MG		ANOVA			
	M	SD	M	SD	Effect	F ratio	df	η^2
Pain score								
Baseline	9.5	0.6	9.0	0.6	T	179.4*	1.1	.825
Immediate	0.8	0.6	1.4	0.9	G	0.002	1	0.00
After 6 months	2.9	3.3	2.7	3.4	T×G	0.8	1.1	0.02

N = 40. ANOVA = analysis of variance. G = group, T = time. *p<.05

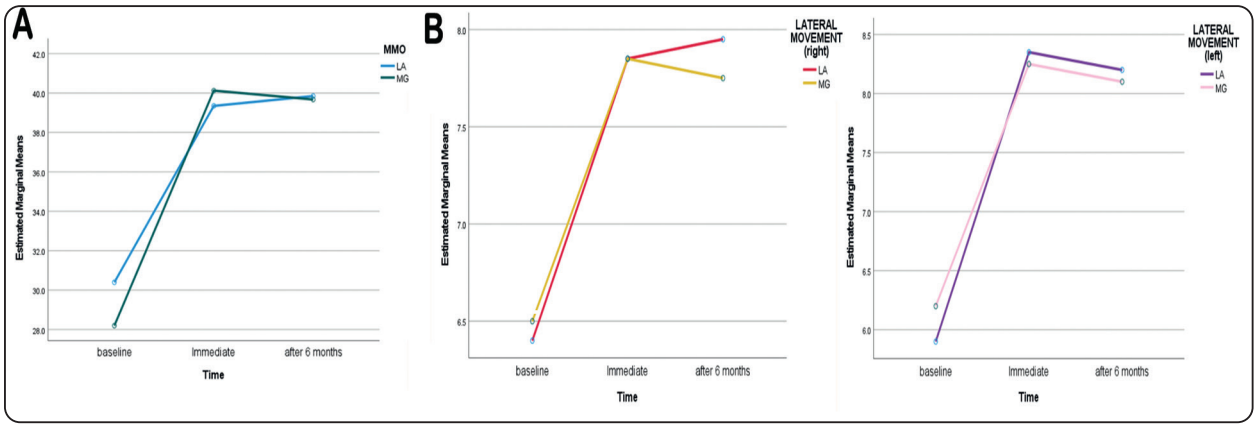

Fig. (2) Estimated marginal means of MMO (A), Pain score, Lateral movement (B) (right) & Lateral movement (left) by group and time

TABLE (2) Mixed design ANOVA (one-way, repeated measures) of time points for (MAXIMAL MOUTH OPENING) MMO, and, Lateral movement (Right & Left)

Time	LA		Mg So4		ANOVA			
	Mean	SD	Mean	SD	Effect	F ratio	df	η^2
MMO								
Baseline	30.4	3.4	28.2	4.1	T	170.9*	2	.818
Immediate	39.4	4.4	40.1	1.6	G	.789	1	.020
After 6 months	39.9	1.6	39.7	1.9	T×G	2.7	2	.067
Lateral movement (Right)								
Baseline	6.4	2.3	6.5	2.6	T	17.6*	1.3	.31
Immediate	7.8	1.0	7.8	1.2	G	0.006	1	.000
After 6 months	7.9	0.9	7.8	0.9	T×G	0.2	1.3	.004
Lateral movement (Left)								
Baseline	5.9	1.7	6.2	1.9	T	49.3*	1.6	0.6
Immediate	8.4	0.9	8.3	0.9	G	0.01	1	0.00
After 6 months	8.2	0.8	8.1	0.9	T×G	0.4	1.6	0.01

N = 40. *ANOVA =* ***analysis of variance. G = group, T = time.*** **p < .05*

TABLE (3) Pairwise comparisons between different time points regarding pain scores.

(I) time	(J) time	Mean Difference (I-J)	*P*	95% Confidence Interval for Difference	
				Lower Bound	Upper Bound
Pain score					
1	2	8.2*	<.001	7.8	8.5
	3	6.4*	<.001	5.1	7.7
2	3	-1.8*	<.001	-3.2	-0.3

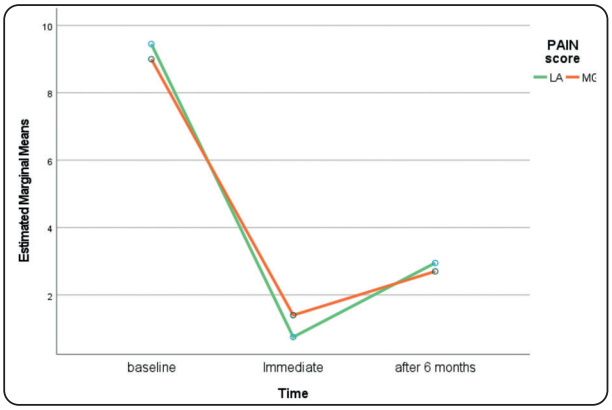

Fig. (3) Estimated marginal means of Pain scores by group and time

TABLE (4) Pairwise comparisons between different time points regarding MMO and lateral movements.

(I) time	(J) time	Mean Difference (I-J)	*P*	95% Confidence Interval for Difference	
				Lower Bound	Upper Bound
MMO					
1	2	-10.4*	<.001	-12.2	-8.7
	3	-10.5*	<.001	-12.1	-8.8
2	3	-.03	1.000	-1.5	1.5
Lateral movement (Right)					
1	2	-1.4*	<.001	-2.0	-0.8
	3	-1.4*	<.001	-2.3	-0.5
2	3	.000	1.0	-0.4	0.4
Lateral movement (Left)					
1	2	-2.3*	<.001	-2.9	-1.6
	3	-2.1*	<.001	-2.9	-1.3
2	3	0.2	1.0	-0.3	0.5

Adjusted for multiple comparisons Bonferroni. P is significant at <.05

DISCUSSION

Temporomandibular joint disorders (TMD) are one of challenging conditions in oral and maxillofacial area that involve muscles of mastication and the associated joint structures which are attributed to various etiological factors. When it comes to etiological factors, parafunctional habits are among commonly seen factors. The muscle component in TMD represents a common clinical finding with corresponding trigger points which are the hallmark of this clinical condition. When it comes to management of myofascial pain disorder; there are different treatment modalities that are currently adopted including trigger point injection with different injecting materials like local anesthesia, botulinum toxin, physiological saline and others. Currently, magnesium sulfate is used in a large scale for treating musculoskeletal disorders based on its muscle relaxing and vasodilating effects. [2,4,9–11]

The present study aimed at clinical assessment of injecting magnesium sulfate versus local anesthesia in pain management in patients with parafunctional habits. Magnesium sulfate is well known with its muscle relaxing and vasodilating effects. Moreover, one of its unique criteria is; it's low molecular weight material with subsequent great potential to penetrate deeper in comparison to local anesthesia & other injectable materials. [2,7,8]

In a study performed by Peng Y-N et al. to assess the clinical impact of magnesium sulfate on post-operative pain, they concluded that magnesium sulfate diminished post-operative pain significantly in orthopedic surgery. [12] Regarding its muscle relaxing effect, Wang H. et al. came to the conclusion that magnesium sulfate had a positive impact as muscle relaxant as a result of inhibition of acetylcholine receptors. [13]

In this study, a detailed patient history and clinical examination (intra-oral & extra-oral) was obtained for accurate diagnosis and management of each patient. The patients were randomly assigned into either receiving injection with magnesium sulfate (group I) or injection with plain local anesthesia (3% Mepivacaine) (group II) with one week interval between each injection for both groups. Assessment of Outcomes (pain intensity, MMO and lateral movements) were performed as following; pre-operatively, immediate post-operatively and six months post-operatively.

In present study, the majority of both groups were female patients (72.5%) which were consistent with the studies performed by Wahlund K, Wieckiewicz M. et al., Yadav U. et al. and Alrizqi AH. et al. who concluded that TMD is commonly seen in female than male patients as a consequence of various contributing factors including; (1) anxiety and depression, (2) bruxism and (3) hormonal changes. [14–17]

With regard to age prevalence in the current study, the average age was 25.91±7.62 years in the group I and 28.53±8.51 years in the group II. This finding was in agreement with studies performed by da Silva CG. et al. and Valesan LF. et al. who concluded that TMD is a common clinical condition that is commonly encountered in adult patients. [18,19]

Regarding the clinical results obtained in the present study, both magnesium sulfate and plain local anesthetic injections achieved significant decrease in pain intensity with no significant statistical difference between both groups and this was possibly related to the muscle relaxing and vasodilating effects of magnesium sulfate & vasodilating effects and temporarily sensory signal blockage of local anesthesia with subsequent positive impact on reducing pain intensity when injected in trigger points in patients with myofascial pain disorder. This finding was consistent with the studies accomplished by Ibrahim NA. et al. and Refahee SM. et al. who concluded that magnesium sulfate resulted in significant pain intensity reduction as an injectable material in trigger point injections

as a result of its previously mentioned properties.[2,8] Similar findings were retrieved by Lee C. et al. and Sane S. et al. [20,21]

Moreover, Yilmaz O. et al., Albagieh H. et al. and Hasuo H. et al. emphasized the efficacy of using local anesthetic injection in patients with myofascial pain disorder with resultant great reduction in pain intensity with trigger point injections. [5,22,23]

Additionally, in this study, both maximum mouth opening and lateral jaw movements are significantly improved in group I and group II patients with no significant difference between both groups and that improvement was a consequence of pain intensity reduction encountered with both injecting materials and muscle relaxing benefit of magnesium sulfate. This clinical finding was aligned with the study carried out by Refahee SM. et al. who investigated the efficacy of magnesium sulfate injection versus saline injection with a more favorable outcomes regarding pain intensity reduction, MMO, lateral jaw movements and patient's quality of life score were obvious with magnesium sulfate injection. They highlighted the important role of magnesium sulfate as a muscle relaxing material. [2]

Furthermore, Tantanatip A. et al. and Korkmaz N. et al. concluded that local anesthetic trigger point injections resulted in significant improvements regarding pain intensity and functional movements. [24,25]

This study highlighted the efficacy of both magnesium sulfate and local anesthetic trigger point injections in pain intensity reduction and functional improvements. However, there were few limitations regarding patient compliance.

CONCLUSION

Injections of magnesium sulfate and local anesthetic are both useful in treating myofascial pain brought on by parafunctional habits. Clinical concerns and the unique characteristics of each patient should be taken into consideration for selecting the appropriate treatment modality.

Recommendations for Future Research

More research work with larger number of patients is required for accurate assessment of the outcomes. Additionally, analyzing how demographic characteristics affect treatment outcomes may assist in customizing interventions to meet the needs of particular patients.

Competing interests

No conflict of interest

Ethical approval

The Ethics and research committee, Faculty of Dentistry, Cairo University approved the study and patients' consent was obtained.

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