COMPARATIVE STUDY

A Comparative Study of Trigger Point Therapy with Local Anaesthetic (0.5 % Bupivacaine) Versus Combined Trigger Point Injection Therapy and Levosulpiride in the Management of Myofascial Pain Syndrome in the Orofacial Region

Pranav Gupta¹ · Virendra Singh² · Sujata Sethi³ · Arun Kumar⁴

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Abstract

Aim To compare the efficacy of combined local anesthetic injection with 0.5 % bupivacaine and levosulpiride versus local anesthetic injection alone on outcome measures including levels of pain intensity and depression in the management of myofascial pain syndrome in orofacial region.

Patients and Methods This was a prospective, randomized, controlled and open-label comparative clinical study. Seventy-four patients diagnosed to have myofascial pain syndrome and fulfilling the inclusion criteria were enrolled for the study. Patients were randomly assigned into 2 groups. Group A received local anesthetic injection (0.5 % bupivacaine) on trigger points and Group B received combined trigger point injection therapy and 50 mg of tablet Levosulpiride orally B.I.D. They were assessed for pain intensity and depression at baseline and at follow-up of 1, 4, 6 and 12 week intervals.

Results The mean age of patients was 44.54 ± 15.977 years in group A and 39.97 ± 14.107 years in group B (P value = 0.2). Group A comprised of 25 females (67.567 %) and 12 males (32.432 %) while group B

had 27 females (75 %) and 9 males (25 %). 70.27 % were diagnosed with moderate depression in group A and 75 % in group B. 18.91 % in group A and 19.44 % in group B were diagnosed with severe depression. When the VAS score and BDI score was compared at the follow-up intervals with the baseline scores in both treatment groups, the mean difference was highly significant at all the follow-up intervals. However when the relative efficacies of two interventions were compared between the two groups, improvement in pain was significant at all the follow-up intervals except the 1st week follow-up whereas the improvement in depression was non-significant at 1st and 4th week interval while it was highly significant at 6th and 12th week intervals.

Conclusion The combined therapy with trigger point injection and levosulpiride as antidepressant significantly reduces pain and depression in the study subjects suffering from chronic myofascial pain with moderate to severe depression in the orofacial region.

Keywords Myofascial pain · Temporomandibular disorders · Masticatory muscles · Orofacial region · Depression

✉ Pranav Gupta
drgupta.pranav@gmail.com

¹ Department of Dentistry, SHKM Govt. Medical College, Mewat, Haryana, India

² Department of Oral and Maxillofacial Surgery, PGIDS, Pt. B.D. Sharma University of Health Sciences, Rohtak, Haryana 124001, India

³ Department of Psychiatry, PGIMS, Pt. B.D. Sharma University of Health Sciences, Rohtak, Haryana 124001, India

⁴ Department of Community Medicine, SHKM Govt. Medical College, Mewat, Haryana 122107, India

Introduction

Myofascial pain associated with trigger points is highly prevalent in the orofacial region. Myofascial pain syndrome (MPS) associated with masticatory muscles has been classified under group I in research diagnostic criteria for temporomandibular disorders (RDC/TMD).

These active trigger points are the key etiological factors for the pain symptoms in MPS patients along with other contributing factors that perpetuate the problem. The primary goal of treatment is to inactivate the trigger points

and loosen the taut bands. Among the various treatment modalities, trigger point (TrP) injection is one of the most effective methods in treatment of MPS. This does not, however, constitute the whole treatment of MPS and TrPs. The causes that led to the condition must be corrected, when possible. Mechanical, medical, and psychological perpetuating factors must also be eliminated or alleviated in order to reduce the chance of recurrence. Inadequate attention to these aspects of treatment often leads to failure to relieve pain and restore function [1, 2].

The biopsychosocial model of pain has pointed out the necessity of assessing psychological status of chronic pain patients; therefore anxiety, depression, and somatization should be routinely evaluated in TMD patients [3]. There is abundant work on the association of chronic pain and depression. The role of conventional tricyclic antidepressants has been mentioned in the management of MPS. However paucity of data exists about the efficacy of antidepressant in combination with conventional trigger point injection therapy in the management of patients with myofascial pain associated with masticatory muscles. Moreover, a new generation antidepressant drug, levosulpiride, a (–)-enantiomer of sulpiride, is available which has fewer side effects as compared to the conventional antidepressants.

Therefore in the present study we aim to compare the efficacy of combined trigger point injection therapy with 0.5 % bupivacaine and antidepressant therapy with levosulpiride versus trigger point injection therapy alone on outcome measures including levels of pain intensity and depression in patients of MPS associated with masticatory muscles.

Materials and Methods

Study Design

This was a prospective, randomized, controlled and open-label comparative clinical study conducted by the Department of Oral and Maxillofacial Surgery, Post Graduate Institute of Dental Sciences, Rohtak.

Keeping in view the feasibility of the study, all patients attending this department between March 2011 and June 2012 were screened for inclusion criteria to enroll them for the study.

Study was in accordance with the principles of good clinical practice (ICH-GCP) and Helsinki declaration and its amendments. An informed consent was obtained from all the patients enrolled for the study. Ethical clearance to conduct the study was sought from the concerned Post Graduate Board of Studies of the Institution.

Study Subjects

Patients of either gender diagnosed to have MPS on the basis of criteria defined by Simons et al. [4] and fulfilling the inclusion criteria were enrolled for the study. Inclusion criteria for the study were (1) Presence of at least one active trigger point, (2) Age between 19 and 65 years, (3) Symptom durations for at least 3 months and (4) patients diagnosed as group I and group II according to RDC/TMD. The following patients were excluded from the study (1) Patients with fibromyalgia; (2) patients with identifiable TMD pathology such as history of major trauma, TMJ infection and group III TMD according to RDC/TMD; (3) patients with major systemic disease; (4) patients with cervical disk lesion; (5) pregnant patients; (6) patients having undergone neck and shoulder surgery; (7) patients with drug allergy history, and abnormal laboratory results. After physical examination, all the required routine laboratory investigations were evaluated. A total of 74 study patients who met the inclusion criteria and signed the informed consent form, were enrolled for the study and were randomly assigned to the two treatment groups i.e. group A and group B using computerized random allocation software.

Group A received trigger point injection therapy with 0.5 % bupivacaine according to the technique described below and *Group B* received combined trigger point injection therapy with 0.5 % bupivacaine and 50 mg of tablet Levosulpiride orally B.I.D for an initial period of 2 weeks followed by increasing the dose to a maximum of 150 mg daily for a maximum period of 6 weeks. Injections on trigger points with 0.5 % bupivacaine were applied according to the technique described by Travell and Simons [4] and by the same doctor. The trigger point area on the muscle were determined and the skin cleaned with an appropriate antiseptic solution. A 22-gauge 1.25 inch needle was used for injection. Trigger point was ensured to be immobilized between thumb and index finger. Then, the needle was inserted perpendicularly through the skin and moved forward until the trigger point was reached. The trigger point was identified by getting local twitch response or contraction of the band with pain. The same point was inserted a few times with fan-shaped syringe movements with deposition of small amount of local anesthetic and finally the desired amount of local anesthetic was injected. Subjects were asked to maintain an analgesic diary to record the number of analgesics (Ibuprofen 400 mg), frequency and duration of relief from those medications.

The severity of pain was assessed by linear visual analog scale (VAS). The Turkish version of the beck depression inventory (BDI) [5] was administered to assess the depression. Severity of depression was interpreted from scores as: 0–9, minimal; 10–16, mild; 17–29, moderate;

and 30–63, severe [6]. BDI scoring of all the patients was also done by the same psychiatrist.

Patients were followed-up at 1, 4, 6 and 12 weeks interval to evaluate the treatment outcome in terms of pain, depression and the need of average number of analgesics per day. Telephone numbers and other contact details of study patients were recorded and efforts were made to minimize the attrition rate.

Methods for Statistical Assessment

Descriptive statistics of the study subjects were given as proportions, means and standard deviations. Initially, Kolmogorov–Smirnov test was used to test for the distribution of the characteristics of interest in the two groups in order to apply appropriate parametric or non-parametric tests. The socio-demographic factors were tested using Chi Square test, except for the age which was tested using unpaired *T* test. The baseline VAS scores of the two groups were compared with the help of Mann–Whitney U test and the baseline BDI scores by unpaired *T* test.

For determining the differences before and after treatment for both the groups, paired *T* test was used. *T* test was used to compare the efficacies of the two therapeutic modalities between the groups. A level of significance of $P < 0.05$ (two-tailed) was decided to be taken as the critical value to accept the test as significant. The analyses were performed using statistical software.

Results

Out of the enrolled cases, all the 37 cases in group A and 36 cases in the comparison group B completed the study; one patient from group B dropped-out and hence could not be followed-up (Table 1). The dropped case was not included in the data analysis. Randomization check was performed by checking statistically the differences in sociodemographic and clinical characteristics of interest i.e. VAS and BDI between the two groups (Tables 1, 2).

Sociodemographic Characteristics

The mean age of patients was 44.54 ± 15.977 years in group A and 39.97 ± 14.107 years in group B (P value = 0.2). Group A comprised of 25 females (67.567 %) and 12 males (32.432 %) while group B comprised of 27 females (75 %) and 9 males (25 %) with a predominance of females in both the groups. As regards marital status of the study subjects, 75.67 % in group A and were married and in group B, 81.08 % were married.

Baseline Clinical Characteristics

The mean duration of symptoms was 13.040 ± 12.000 months in group A and 13.222 ± 11.931 months in group B. In group A, 29.73 % patients reported bilateral pain in the orofacial region, 29.73 % reported pain on right side only and 32.43 % reported pain on left side only. In group B 19.44 % reported bilateral pain, 47.22 % reported pain on right side and 33.33 % reported pain on left side only. The total number of trigger points was 119 with a mean of 3.216 ± 1.057 in group A and 114 with a mean of 3.166 ± 1.383 in group B (Table 2). Fifty-six trigger points in group A and 50 trigger points in group B were found in masseter. Forty-six trigger points in group A and 38 trigger points in group B were found in temporalis muscle.

The mean baseline VAS score was 7.32 ± 1.203 in group A and 7.19 ± 1.091 in group B (P value 0.399). The mean baseline BDI score was 24.27 ± 7.971 in group A and 25.56 ± 7.354 in group B (P value 0.477). The study patients were stratified into mild, moderate and severe depression according to BDI score; 70.27 % in group A and 75 % in group B were diagnosed with moderate depression while 18.91 % in group A and 19.44 % in group B were diagnosed with severe depression, rest of the patients were suffering with mild depression.

Both the groups A and B were similar in baseline socio-demographic and clinical characteristics (P values given in Tables 1, 2).

Analysis of Clinical Parameters

When the VAS scores at the follow-up intervals of 1, 4, 6 and 12 weeks were compared with the baseline VAS scores, the mean differences were highly significant at all the follow-up intervals in both the groups A and B (Tables 3, 4). When the relative efficacies of the two interventions were statistically compared between the two groups in terms of reduction of VAS scores in comparison to the baseline VAS scores, mean differences at the follow-up intervals of 4, 6 and 12 weeks were found to be -1.166 , -1.456 and -1.568 with P values of 0.001, 0.002 and 0.002 respectively all of which were highly significant (Table 5; Fig. 1). However such difference in reduction of VAS scores at the 1st week follow-up interval was -0.290 (I–II) which was non-significant (P value 0.281).

Likewise, when the reduction in BDI scores at the follow-up intervals of 1, 4, 6 and 12 weeks were compared with the baseline BDI score in group A and group B, the mean differences were highly significant at all the follow-up intervals (Tables 6, 7). However when the relative

Table 1 Sociodemographic distribution of subjects in the study groups

	Group A N = 37	Group B N = 36	χ^2/T statistic	DF	P value
Mean age (in years)	44.54 $\pm$ 15.977	39.97 $\pm$ 14.107			0.2*
Gender					
Male	12	9	0.492	1	0.483**
Female	25	27			
Literacy level					
Illiterate	8	9	0.595	5	0.988**
Primary	5	5			
Middle	6	4			
Secondary	6	5			
Graduate	8	9			
Post-graduate	4	4			
Marital status					
Unmarried	4	4	1.722	3	0.632**
Married	28	30			
Widow	4	2			
Divorced	1	0			
Income group (INR)					
<1 lakh	8	3	3.430	3	0.330**
1–2 lakh	13	16			
2–4 lakh	11	14			
4–6 lakh	14	3			

DF degree of freedom

* Unpaired *T* test; ** Chi Square test**Table 2** Baseline characteristics of subjects in the study groups

Characteristics	Group A	Group B	Chi Square value/T statistic	DF	P value
No. of trigger points (mean $\pm$ SD)	3.216 $\pm$ 1.057	3.166 $\pm$ 1.383			
Duration (in months)	13.040 $\pm$ 12.000	13.222 $\pm$ 11.931			
Side affected					
Left	12	12	1.166	2	0.558*
Right	14	17			
Bilateral	11	7			
Depression level					
Mild	4	2	0.672	2	0.715*
Moderate	26	27			
Severe	7	7			
Baseline VAS score (mean)	7.32 $\pm$ 1.203	7.19 $\pm$ 1.091			0.399**
Baseline BDI score (mean)	24.27 $\pm$ 7.971	25.56 $\pm$ 7.354			0.477***

* Chi Square test; ** Mann–Whitney test; *** *T* test

efficacies of two interventions were compared between the two groups in terms of reduction of the BDI scores in comparison to the baseline BDI scores it was found that the mean differences at the 1st and 4th week follow-up intervals were -0.998 and -3.004 with *P* values of 0.304 and 0.059 respectively which were statistically non-significant. But the clinical improvement at those intervals could be

considered relevant. At the later follow-up intervals i.e. 6th and 12th week, however, the mean differences were -3.918 , -4.505 with *P* value of 0.004 and 0.004 respectively which were significant (Table 8; Fig. 2). Apart from this, a significant correlation was found between the pain and depression scores with correlation coefficient of $r = 0.471$ (*P* value <0.001).

Table 3 Efficacy of the intervention at various intervals in reduction of VAS scores in comparison to baseline scores in group A

	Mean difference	Significance	95 % Confidence interval	
			Lower bound	Upper bound
0 and 1 week	2.432 ± 1.191	0.000	2.035	2.830
0 and 4 weeks	2.973 ± 1.658	0.000	2.420	3.526
0 and 6 weeks	3.432 ± 1.659	0.000	2.879	3.986
0 and 12 weeks	3.459 ± 1.850	0.000	2.843	4.076

Table 4 Efficacy of the intervention at various intervals in reduction of VAS scores in comparison to baseline scores in group B

	Mean difference	Significance	95 % Confidence interval	
			Lower bound	Upper bound
0 and 1 week	2.722 ± 1.085	0.000	2.355	3.089
0 and 4 weeks	4.139 ± 1.334	0.000	3.687	4.590
0 and 6 weeks	4.889 ± 2.214	0.000	4.140	5.638
0 and 12 weeks	5.028 ± 2.236	0.000	4.271	5.784

Table 5 Relative efficacies of the two interventions in reduction of VAS scores in comparison to baseline scores in the two groups A and B

	Mean difference (I–II)	Std error	Significance	95 % Confidence interval	
				Lower bound	Upper bound
0 and 1 week	−0.290	0.267	0.281	−0.822	0.242
0 and 4 weeks	−1.166	0.353	0.001	−1.869	−0.462
0 and 6 weeks	−1.456	0.457	0.002	−2.368	−0.545
0 and 12 weeks	−1.568	0.480	0.002	−2.525	−0.612

Fig. 1 Relative efficacies of the two interventions in reduction of VAS scores in comparison to baseline scores in the two groups A and B**Table 6** Efficacy of the intervention at various intervals in reduction of BDI scores in comparison to baseline scores in group A

	Mean difference	Significance	95 % Confidence interval	
			Lower bound	Upper bound
0 and 1 week	3.946 ± 4.672	0.000	2.388	5.504
0 and 4 weeks	5.135 ± 5.319	0.000	3.362	6.908
0 and 6 weeks	6.054 ± 4.588	0.000	4.524	7.584
0 and 12 weeks	6.162 ± 5.520	0.000	4.322	8.003

Discussion

Myofascial pain is the most common form of musculoskeletal pain affecting the head, neck and face [7]. Though many studies have attempted to ascertain the prevalence of fibromyalgia in populations around the world, the exact prevalence of MPS in the general population is unknown. A potentially confusing aspect of epidemiologic considerations is the separation of myofascial TrPs into active and inactive or latent [4].

Rollman and Lautenbacher [8] studied the sex differences in the musculoskeletal pain and cited that both biological (sex) factors such as hormonal differences and differences in body size and muscle makeup (ratio of fast to slow twitch fibers),

Table 7 Efficacy of the intervention at various intervals in reduction of BDI scores in comparison to baseline scores in group B

	Mean difference	Significance	95 % Confidence interval	
			Lower bound	Upper bound
0 and 1 week	4.944 ± 3.455	0.000	3.775	6.114
0 and 4 weeks	8.139 ± 7.853	0.000	5.482	10.796
0 and 6 weeks	9.972 ± 6.601	0.000	7.739	12.206
0 and 12 weeks	10.667 ± 7.251	0.000	8.213	13.120

Table 8 Relative efficacies of the two interventions in reduction of BDI scores in the two groups A

	Mean difference (A–B)	Std error	Significance	95 % Confidence interval	
				Lower bound	Upper bound
0 and 1 week	−0.998	0.964	0.304	−2.921	0.924
0 and 4 weeks	−3.004	1.566	0.059	−6.126	0.119
0 and 6 weeks	−3.918	1.327	0.004	−6.565	−1.271
0 and 12 weeks	−4.505	1.506	0.004	−7.507	−1.502

Fig. 2 Relative efficacies of the two interventions in reduction of BDI scores in comparison to baseline scores in the two groups A and B

and psychosocial differences between men and women such as work demands, physical and mental stress at work and at home, social support, and other factors that are gender-based, rather than sex-based differences. In our study also, females outnumbered males in both the groups, with 67.57 % females in group A and 75 % females in group B. This finding is consistent with studies of Drangsholt and LeResche [9], Yap et al. [10] and Reiter et al. [11]. When we look at the age distribution of females in both the study groups, it was found that majority of females were of child bearing age (20–40 years). The gender and age distribution suggests a possible link between TMD and the female hormonal axis [12].

Our study samples comprised mainly of rural population with 51.34 % of patients either illiterate or literate up to the middle level. Majority of them were of low socioeconomic status. There are contributory stressors that are unique to the rural environment including: isolation; few social outlets; limited access to health services and healthcare providers; the declining farm economy; an unpredictable,

irregular income; financial and educational disadvantages; and traditional family/community caregiver responsibilities. In our study majority of females were non-working.

The mean duration of the symptoms in our study was 13.040 ± 12.00 months in group A and 13.222 ± 11.931 months in group B which suggests the chronicity of the problem. Literature suggests that myofascial pain patients have the highest levels of psychological distress [13–16]. In our study, 70.27 % patients in group A and 75 % patients in group B were suffering from moderate depression whereas 18.91 % in group A and 19.44 % patients in group B suffered severe depression. These findings are comparable with those from the study of Yap et al. [10] who found that myofascial pain and TMJ pain patients were the most compromised from a psychosocial viewpoint. A statistically significant correlation was found between the pain and depression with the correlation coefficient $r = 0.471$ (P value < 0.001). This was supported by the studies of Nifosi et al. [17], Altindag et al. [18] and Manfredini et al. [19] who studied the psychosocial profiles of painful TMD patients.

Since there is a strong correlation between pain and depression in patient of MPS, the treatment should target both the pain component as well as depression component.

The efficacy of TrP injection in terms of improvement in pain and depression has been well established in the literature [20–22]. Ay et al. [20] compared the efficacy of TrP injection with lidocaine and dry needling on the pain and depression outcome. They concluded that there was significant improvement in both pain and depression scores in both the groups at 4 and 12 week follow-up but however when the two groups were compared, there was no statistically significant difference. In our study also, Group A which was treated using TrP injections alone, there was statistically significant improvement in both pain and depression at all the follow-up intervals of 1, 4, 6, and 12 weeks.

For TMD patients who manifest appreciable psychologic disturbance, biomedical therapies aimed at alleviation of physical symptoms alone may be limited. Such a limited approach may perpetuate an unsatisfying search for dental, medical, surgical, pharmacologic, and other types of symptom management. It is therefore prudent that patients with abnormal psychologic profiles are identified at the initial visit and the psychological component should also be addressed while managing such patients.

Antidepressants have been used as an adjuvant therapy in the management of MPS. The analgesic role of antidepressants in chronic pain has been well documented in the literature [23, 24]. However to the best of our knowledge, the role of antidepressants in treatment outcome of chronic myofascial pain has not been studied in the literature [25]. In this study, in the second study group, we evaluated the efficacy of combined trigger point injection and antidepressant therapy with levosulpiride in the improvement of pain and depression. We found that there was statistically significant improvement in pain and depression scores with higher mean difference in group B, maximal at the 12th week interval.

Anticholinergic and cardiovascular side effects commonly seen with TCAs are infrequent in levosulpiride. Moreover, in a study conducted by Ferrando et al. [13] it was found that levosulpiride had rapid onset of action with equivalent long term response and fewer adverse effects. Thus levosulpiride was preferred over conventional tricyclic antidepressants in the current study.

When the two groups were compared statistically to evaluate the efficacy of the two therapies it was found that improvement in pain scores was non-significant at 1st week interval (P value 0.281). However improvement is highly significant at the follow-up of 4th week (P value 0.001), 6th week (P value 0.002) and 12th week (P value 0.002). The improvement in depression scores was non-significant at the 1st week (P value 0.304) and 4th week intervals (P value 0.059); whereas it was highly significant at the intervals of 6 weeks (P value 0.004) and 12 weeks (P value 0.004). The results from our studies can be explained by the fact that depression is closely related with intensity and duration of pain. Depression and pain often accompany each other, however, there are still arguments on which of them begins first [26, 27]. In our study we hypothesized that the treatment of depression improves the efficacy of the TrP injections in terms of pain as well as depression and our results prove the same.

Conclusion

Combined therapy with trigger point injection and levosulpiride as antidepressant is more efficacious than trigger point injection therapy alone in reducing pain and

depression in the patients of chronic myofascial pain in the orofacial region who are also suffering from moderate to severe depression.

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