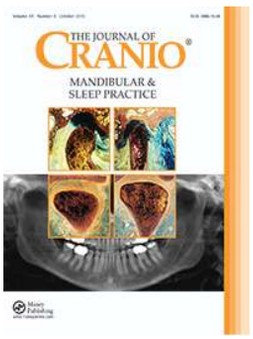

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TMJ

Therapeutic effectiveness of a combined counseling plus stabilization appliance treatment for myofascial pain of the jaw muscles: A pilot study

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Objective: This study aims to assess changes over time in pain intensity (VAS) and in pressure pain threshold (PPT) of the anterior temporalis and masseter muscles with a treatment protocol combining counseling and stabilization appliance as well as its effects on psychosocial factors.
Methods: Twenty individuals with myofascial pain of jaw muscles lasting from at least six months were selected for an uncontrolled before-after study. Counseling was performed by giving information on myofascial pain and advice on self-management. Stabilization appliances were delivered one week after the first counseling session. A number of outcome variables (i.e. visual analogue scale [VAS], pain pressure threshold [PPT] and Research Diagnostic Criteria for Temporomandibular Disorders axis II [RDC/TMD]) were assessed at different evaluation points during a six-month follow-up. ANOVA for repeated measures and Pearson's correlation test were used to evaluate changes in the outcome variables over time.
Results: Compared to baseline data, a significant positive change was found at the 1st week, 1st, 3rd, and 6th month evaluations for VAS values ($P < 0.0001$) and at the 1st week, 3rd, and 6th month evaluations for PPT values ($P < 0.05$). RDC/TMD axis II values were significantly different ($P < 0.05$) from baseline to all evaluations points.
Conclusion: The association of counseling and stabilization appliance is effective in the management of chronic myofascial pain of jaw muscles. Future controlled studies are required to get deeper into the assessment of the relative effectiveness of counseling and stabilization appliances.

Keywords: Orofascial pain, Temporomandibular joint disorders, Occlusal splints, Counseling, Masticatory muscles, Pain threshold

Introduction

Temporomandibular disorders (TMD) are a heterogeneous group of conditions[1] involving the temporomandibular joints (TMJ), jaw muscles, or both.[2] In the clinical setting, the majority of patients are diagnosed with TMJ disc displacement, even if a recent literature review found that myofascial pain is a very common diagnosis, with a prevalence of about 45% in patient populations.[3]

For years, many debates have inflamed the topics of TMD etiology and management, with arguments in favor of various treatments and strategies to control TMD pain.[4–6] However, since longitudinal studies supported the favorable course of TMD, conservative and reversible treatments are preferable to more aggressive and irreversible approaches, e.g. occlusal interventions and surgery.[7]

Oral appliances (OA) are the most widely used treatment approach,[8] especially as far as the use of stabilization appliances (SA) is concerned.[9] Their mechanism of action is not fully understood, but there is clinical evidence that they can help manage pain in the majority of patients.[10]

Psychological issues, e.g. mood disorders, anxiety, and chronic pain-related impairment, are important to determine the clinical picture in TMD patients so they are considered as a relevant target for treatment as well.[11,12] Currently, based on the so-called biopsychosocial model postulating that both biomedical factors and psychosocial

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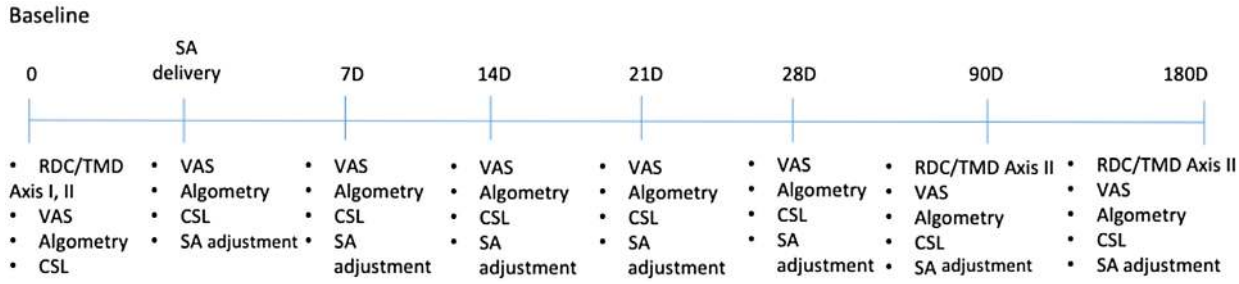

Figure 1 Evaluations chronogram.
RDC/TMD: Research Diagnostic Criteria for Temporomandibular Disorders; VAS: visual analogue scale; CSL: counseling; SA: stabilization appliance; D: day

factors are involved in the development of TMD,[13] it is suggested that treatment focuses both on the biomedical and psychosocial component of the disease. This implies the involvement of a cognitive-behavioral component in any TMD management strategies.[14]

To this aim, self-care strategies based on cognitive-behavioral therapies (CBT)[15,16] and counseling (CSL) may be useful to manage TMD pain. Those methods include, among the others, an extensive education about the disease and a reassurance of its sometimes benign course. Also, advice to try reducing parafunction, relaxing jaw muscles, and improving sleep and body posture should be part of a counseling session.[17,18] Based on these strategies, it should be interesting to assess if a counseling-based approach prior to SA treatment has positive effects on myofascial pain symptoms.

Within this premise, this study aims to evaluate the effects of a combined counseling and stabilization appliance approach on TMD pain intensity, pressure pain threshold (PPT), as well as on the psychosocial features of patients with myofascial pain of jaw muscles.

Materials and methods

The Ethics Committee in Research of Piracicaba Dental School, University of Campinas, São Paulo, Brazil (UNICAMP), approved the study protocol on April 2 2014 (protocol number 114/2013).

Participants were selected among patients seeking therapy for TMD pain at Piracicaba Dental School, University of Campinas, São Paulo, Brazil. All participants signed the informed consent form.

Twenty consecutive patients who agreed to participate in the study were selected according to the following inclusion criteria: female sex, age between 18 and 45 years, presence of jaw muscles pain in accordance to group Ia and Ib diagnoses of the Research Diagnostic Criteria for TMD (RDC/TMD)[19] for more than three months without concurrent presence of TMJ pain; presence of all teeth except third molars, self-reported pain intensity higher than 50 mm in the visual analog scale (VAS), and contraceptive use. Patients with a positive history of trauma in the face and neck area, dental pain, systemic diseases (arthritis and arthrosis), and neurological disorders were excluded from potential recruitment.

According to the experimental design, the patients were evaluated eight times during the investigation, as described in Figure 1.

The same trained clinician performed counseling (CSL) at all follow-up appointments. In brief, the CSL strategy consisted in educating the patients about the anatomy and physiology of the stomatognathic system, e.g. how the muscles work, their effects on the joints, and teaching self-care strategies to control parafunction and to manage pain. Patients were also reassured about the etiology and possible good prognosis of TMD. Information about the improvement of sleep and correct body posture, the importance of dietary habits, the execution of a home exercise program focusing on habit-reversal techniques as well as about easily available pain control techniques, e.g. thermotherapy and massage in the painful area, were also given. A leaflet with all this information was given to the patients in the attempt to help them remember all of the advice.

The stabilization appliance (SA) was a flat occlusal appliance covering all superior teeth, made of transparent heat-polymerized rigid acrylic resin and without clasps for extra retention. The appliance was delivered one week after the first counseling session, while data collection started at baseline. The patients were advised to wear the SA while sleeping, based on the following regimen: every night during the first month of treatment, three nights a week during the next two months, and one night a week during the next three months, completing six months of therapy.

Occlusal adjustment of the SA was performed, if needed, over seven sessions: on the day of SA delivery, once per week during the first month (four times), once after three months, and once after six months.

Two trained examiners performed all clinical evaluations, delivered the SA, and performed all the follow-up procedures.

The following variables were evaluated at the multiple observation points described in Figure 1, with the aim to assess changes over time:

Visual analog scale

The VAS[20] is a 100 mm horizontal line, anchored by word descriptors at each end. The left end is labeled with the words "no pain," while the right end is labeled "worst pain imaginable." The participants were instructed to mark a point on the line representing the level of their current pain.

Pressure pain threshold

The PPT[21] assessment was performed with a digital algometer (Kratos DDK-20. São Paulo, Brazil) with 1 cm^2 circular flat rod, used to press the muscles. The PPT was assessed bilaterally for the masseter and anterior temporalis muscles in a relaxed position. Pressure was applied perpendicular to the surface of the skin at a rate of 1 kg/cm^2, according to the following sequence: right anterior temporal, right masseter, left masseter, and left anterior temporal muscle; 5 min later, a second series of stimuli was applied in the following order: left anterior temporal, right anterior temporal, left masseter, and right masseter.[22] Patients were instructed to indicate the moment when the pressure became painful.

An acetate plate was fabricated for each patient in order to keep the algometer in the same position during the various recording sessions. The acetate plate was perforated at the points where the algometer was placed according to anatomic reference lines (external angle of the eye, tragus of the ear, and external angle of the mandible) to warrant reproducibility of future recordings.[23]

Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD)

The RDC/TMD are standardized diagnostic guidelines, which provide criteria for a dual-axis assessment, including both physical (axis I) and psychosocial appraisal (axis II).[19] A new version, now called DC/TMD, has been released, but it was not yet available at the time of this study.[24] Axis I gives information about the physical TMD diagnoses, i.e. muscle disorders, disc displacements, and other joint disorders, while the axis II focuses on the psychosocial symptoms. Axis II comprises an evaluation of the following: chronic pain-related impairment, based on graded chronic pain scale (GCPS) scores (0. no disability; I. low disability, low intensity; II. low disability, high intensity; III. high disability, moderately limiting; IV. high disability, severely limiting); depression levels, based on the Depression Scale (DEP) of the Symptoms-Checklist-90R (SCL-90R) (normal, moderate, severe depression); and non-specific physical symptoms (somatization) levels based on the Somatization Scale (SOM) of the SCL-90R (normal, moderate, severe somatization).

Statistical analysis

Analysis of variance (ANOVA) for repeated measures was used to test the significance of changes over time in the various outcome variables, including VAS, PPT, and Axis II scores, with significance level set at $P < 0.05$. Data were analyzed with the SAS/LAB software package (SAS. V9.0; SAS Institute, Inc, Cary, NC, USA).

Results

The mean age of the subjects was 30.4 (±6.8) years. At baseline, the mean VAS value was 6.41 (±1.89); PPT was 0.70 (±0.20) for the right, and 0.68 (±0.16) for the left masseter muscles, and 0.70 (±0.23) for the right, and 0.68 (±0.16) for left temporalis muscles.

A significant decrease ($P < 0.05$) in VAS values was shown during the first week, i.e. after the baseline CSL session. Follow-up observation points revealed that a significant reduction in VAS values with respect to baseline was present also at one, three, and six months (Table 1).

The PPT levels increased significantly ($P < 0.05$) between the baseline and the week after counseling for the left masseter (LM) and temporalis muscles (LT). Such an increase, indicating that muscles were less tender to pressure, was found for all muscles at the three-month and six-month evaluations (Table 2).

As for RDC/TMD axis II variables, the baseline prevalence of the various findings concerning the levels of depression, somatization, and chronic pain-related impairment is shown in Table 3. Most patients had low levels of pain-related impairment, i.e. GCPS grade I or II, while only 15% summed up grade III scores, and none of the

Table 1 Mean (standard deviation) of the visual analog scale (VAS) at the multiple observation points

		Phases						
Variable	Baseline	1st W (CSL)	1st W (CSL/SP)	2nd W (CSL/SP)	3rd W (CSL/SP)	1st M (CSL/SP)	3rd M (CSL/SP)	6th M (CSL/SP)
VAS SD	6.41 (±1.89) A	2.43 (±1.82) B	2.35 (±1.99)B	1.92 (±1.66)C	1.24 (±1.13) D	1.17 (±1.02) D	0.94 (±1.66) D	0.65 (±1.02) D

Notes: ANOVA for repeated measures ($P < 0.05$). Different letters represent significant difference among evaluation phases.
CSL = counseling; CSL/SP = counseling/stabilization splint; W = week; M = month; SD: standard deviation.

Table 2 Mean (standard deviation) of pressure pain threshold – PPT (kgf) studied in different phases

				Phases				
Variable	Baseline	1st W (CSL)	1st W (CSL/SP)	2nd W (CSL/SP)	3rd W (CSL/SP)	1st M (CSL/SP)	3rd M (CSL/SP)	6th M (CSL/SP)
PPT RT SD	0.70 (±0.23) A	0.79 (±0.24) A	0.71 (±0.24)A	0.64 (±0.25)A	0.64 (± 0.25)A	0.68 (±0.24) A	0.92 (±0.31) B	1.04 (±0.38) B
PPT LT SD	0.68 (± 0.16)A	0.98 (±0.12) B	0.73 (±0.21)A	0.61 (±0.21)A	0.63 (± 0.24)A	0.67 (±0.21) A	0.88 (±0.21) B	0.98 (±0.31) B
PPT RM SD	0.70 (±0.20) A	0.72 (±0.28) A	0.67 (±0.16)A	0.56 (±0.17)A	0.60 (±0.17) A	0.63 (±0.15) A	0.85 (±0.29) B	0.98 (±0.33) B
PPT LM SD	0.68 (±0.16) A	0.99 (±0.11) B	0.66 (±0.21)A	0.61 (±0.24)A	0.59 (±0.18) A	0.63 (±0.16) A	0.87 (±0.29) B	1.01 (±0.30) B

Notes: ANOVA for repeated measures ($P < 0.05$). Different letters represent significant difference among evaluation phases.
CSL: counseling; CSL/SP: counseling/stabilization splint; W: week; M: month; SD: standard deviation, RT: right temporal; LT: left temporal; RM: right masseter; LM: left masseter, kgf = kilogram force.

Table 3 Patient's distribution (%) according to RDC/TMD axis II variables in different phases of treatment

RDC/TMD axis II	Baseline (%)	1st month (%)	6th month (%)
Graded chronic pain scale (GCPS)			
0	0	0	70
I	10	60	10
II	75	30	20
III	15	10	0
IV	0	0	0
Depression scale score			
Normal	45	50	75
Moderate	25	35	25
Severe	30	15	0
Somatization scale score with pain items			
Normal	20	50	80
Moderate	35	25	20
Severe	45	25	0
Somatization scale score without pain items			
Normal	45	65	90
Moderate	20	15	10
Severe	35	20	0

subjects was graded IV. As for the other psychosocial scores, 30 and 45% of patients had severe depression and somatization, respectively.

There were significant differences ($P < 0.05$) in the GCPS, depression, and somatization with pain items Scores at the 1st and 6th month follow-up, with respect to baseline (Table 4).

Discussion

Based on the importance of biopsychosocial factors in the etiology of temporomandibular disorders,[13] a multimodal approach addressing the various biological, psychological, and social issues is recommended to manage TMD symptoms, such as chronic myofascial pain of the jaw muscles.[25] Within this biopsychosocial framework, counseling is a conservative and potentially useful treatment option for managing TMD pain, thanks to its effects on the psychological domains and reinforcement of positive behaviors.[26]

In this study, the term "counseling" was used to indicate the advice given to the patients as part of the reassurance, assistance, and information strategy. This approach influenced the patient's pain levels, as suggested by the decrease in VAS pain values during the week following the counseling session. Those findings are in accordance with previous studies on CSL[27,28] and support its potential importance as a first-step approach to myofascial pain patients. In addition, positive changes were observed as far as PPT values are concerned, i.e. increase in the left temporalis and masseter muscles PPT.

The importance of education reinforcement, behavioral changes, and the avoidance of parafunction may be key factors to explain the positive effects. In addition, CSL strategies may also affect pain modulations via their influence on the pain experience, including cognitive and emotional factors.[29] These suggestions are in line with results from studies showing that patient's education strategies and reinforcement of responsibilities may help to achieve better results.[30,31]

In the second part of the treatment protocol, a stabilization appliance (SA) was delivered to the counseled patients. Thereafter, VAS values reduction continued over the six-month follow-up span. On the other hand, the pain pressure threshold values did not significantly increase until the three-month evaluation. This finding suggests that the treatment regimen had an earlier impact on the patients' subjective perception of pain (VAS values) than on objective reaction to palpation (PPT levels). A possible explanation for such an observation may be found in the multimodal, counseling-based approach, which addressed the patients' concerns and expectations and reflected more on the subjective than objective measures.[8]

The protocol for SA wearing in this study was based on the hypothesis that the effectiveness of the SA is due

Table 4 Differences between average scores in axis II findings at the various observation points according to the phase evaluation

RDC/TMD axis II time (I)	T (J)	Difference between media (I–J)	P
Graded chronic pain scale (GCPS)			
Baseline (0)	1	0.800*	0.004
	2	1.800*	0.000
One month (1)	0	–0.800*	0.004
	2	1.000*	0.000
Six months (2)	0	–1.800*	0.000
	1	–1.000*	0.000
Depression scale score			
Baseline (0)	1	0.250	0.743
	2	0.650*	0.011
One month (1)	0	–0.250	0.743
	2	0.400	0.200
Six months (2)	0	–0.650*	0.011
	1	–0.400	0.200
Somatization scale score with pain items			
Baseline (0)	1	0.600*	0.025
	2	1.150*	0.000
One month (1)	0	–0.600*	0.025
	2	0.550*	0.045
Six months (2)	0	–1.150*	0.000
	1	–0.550*	0.045
Somatization scale score without pain items			
Baseline (0)	1	0.400	1.000
	2	0.350	1.000
One month (1)	0	–0.400	1.000
	2	–0.050	1.000
Six months (2)	0	–0.350	1.000
	1	0.050	1.000

Note: Bonferroni *post hoc* test ($P < 0.05$).
*Difference between media are significant ($P < 0.05$).

to a shift in the recruitment of muscle fibers. Thus, continuous and long-lasting wear of the SA, e.g. many hours/day for several months, is not recommended, to avoid muscle adaptation.[10]

As a result of this treatment protocol, VAS and PPT values continued to improve over time, suggesting that the reduction in the frequency of SA use did not affect symptom improvement.

In short, this study could be viewed as an "increasing effect study" and could add interesting information for the clinical application of CSL. Indeed, CSL is recommended to be part of any treatment regimen, to help reassure patients and take appraisal of habits that can perpetuate TMD symptoms. In addition, it should also be noted that, in the everyday clinical setting, it is hard to even imagine how pain management could be performed without giving patients any advice or information on their disease, performing "counseling." Based on that, a better definition and standardization of counseling strategies emerges as a compelling need for future studies.[32]

This study has several limitations related with the before-and-after design without any control groups. Therefore, it cannot be excluded that factors such as placebo effect, the natural evolution of the disease, and regression toward the mean may explain treatment outcomes.[33–35] On the other hand, it could also be hypothesized that in patients with long-lasting myofascial pain of jaw muscles, as those included in this study population, the treatment protocol actually had an active part to determine symptom improvement.[36]

This investigation also provided interesting findings as far as the assessment of axis II psychosocial aspects is concerned. At baseline, most patients had low levels of pain-related impairment, i.e. GCPS grade I or II, while only 15% showed grade III scores, and none of the subjects was graded IV. Those values were similar to reports from multicenter studies showing that subjects with the most severe GCPS ratings (grade III or IV) are about 15–20% of the TMD patient populations.[37] Thus, it can be determined that only a small portion of TMD patients developed disabling pain with negative influences on daily activities.[37] In addition, it was also hypothesized that patients with severe impairment are the worst treatment responders, while those with low impairment seem to benefit a lot from a simple cognitive-behavioral therapy regime.[35] Regarding the other axis II findings, at baseline, severe depression, and somatization were diagnosed in 30 and 45% of patients, respectively.

Interestingly, the observation points showed a time-related significant improvement in axis II scores. None of the patients had severe depression or somatization levels at the end of the treatment protocol. The levels of chronic pain-related impairment also went increasingly better over time. In contrast with other reports,[35] this study showed that patients with severe impairment (grade III) responded well to the proposed treatment protocol.

A possible explanation for this finding is the counseling-based approach, supporting the need for addressing all biomedical, psychological, and psychosocial factors involved in the development of TMD symptoms.[13]

Interestingly, regardless of the significant improvement of patients in the GCPS, Depression and Somatization scale with pain items, scores in the Somatization scale for non-pain items did not improve significantly. Therefore, it could be suggested that somatization features for non-pain items are potentially stable over time and may help researchers design studies on the personality features that influence clinical management of pain patients. Future investigations on populations of larger size and comparing treatment protocols with and without CSL are needed to get a deeper insight into the influence of these findings for the everyday TMD practice.

Conclusion

In this investigation, counseling treatment had immediate effects on myofascial pain of the jaw muscles.

Its association with the use of a stabilization appliance allowed the achievement of an effective pain reduction over a six-month period, also positively influencing the severity of psychological impairment. Controlled studies are needed to define the active role of CSL within the treatment regimen.

Source of funding for the study

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Conflict of interest

There were no conflicts of interest.

Ethical approval

The Ethics Committee in Research of Piracicaba Dental School, University of Campinas, São Paulo, Brazil (UNICAMP), on 02/04/2014 (protocol 114/2013), approved the study protocol.

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