

Combined occlusal and pharmacological therapy in the treatment of temporo-mandibular disorders

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Abstract. – Objective: Aim of the present work is to assess the effectiveness of a scientific protocol built up to relieve pain in chronic temporo-mandibular disorders (TMD) using Michigan splint together with a pharmacological therapy compared to the traditional occlusal therapy by Michigan splint alone.

Patients: 35 adult patients, with signs and symptoms of TMD lasting more than 6 months, were enrolled into this study and divided into two groups: the first receiving occlusal therapy by Michigan splint and pharmacological therapy with Delorazepam and Thiocolchicoside, while the second receiving occlusal therapy by Michigan splint and “placebo” administration. The comparisons between the two experimental groups were assessed using a 5 steps visual-analogue scale (V.A.S.).

Results and Conclusions: The outcomes from the experimental groups were statistically compared resulting significantly different with an improvement or disappearance of signs and symptoms in the treated group with respect to the placebo group at 12 and 18 months from the beginning of the experiment ($p < 0.0001$).

Key Words:

TMDs, Combined occlusal and pharmacological therapy, Michigan splint, Delorazepam, Thiocolchicoside.

(TMA). The complexity of this subject matter can be guessed by the wide range of terms used over the years to point out the alterations of the masticatory system, creating further confusion in a field characterized by an interesting and wide multiplicity of nuances^{1,2}. Nowadays, the term Temporo-Mandibular Disorder (TMD) is generally used. It includes all the alterations connected to the function of the entire masticatory system. Recently, epidemiological studies indicate that around 60% of the total population shows myoarthropathy symptoms. In particular, the prevalence of symptoms seems to be around 59%, while the prevalence of signs reaches almost the 80% of the total population. This high prevalence highlights a clear picture of their wide spread diffusion, although this is certainly due to the inclusion, in many scientific works, of signs and symptoms of little importance³⁻¹¹. The Michigan splint is a removable appliance frequently used in the treatment of patients with TMD and related diseases, such as tensive headache.

The aim of the present study is to assess the effectiveness of a new protocol built up to relieve pain with pharmacological treatment of chronic TMD, compared to the traditional occlusal therapy protocol by Michigan splint without effective pharmacological therapy.

Introduction

The term myoarthropathy of the masticatory system refers to a large number of pathologic conditions affecting the masticatory musculature and/or the Temporo-Mandibular Articulation

Materials and Methods

35 patients were enrolled in this study, 21 women (40 ± 10 years old) and 14 men (30 ± 5



Figure 1. Palpation of the masticatory muscles.

years old), who were diagnosed for TMDs; clinical criteria were palpation-related pain and clicking or limited mouth opening. The clinical diagnosis of TMDs was based on a patient symptom questionnaire including intra-oral and extra-oral muscle examination (Figure 1). All patients were examined by the same investigator in order to avoid any kind of bias. Furthermore, all subjects signed an informed consent form confirming their voluntary participation in this study. During the objective exams, all patients referred spontaneous and palpation-related pain (Figure 2).

Used Drugs

Delorazepam

Delorazepam (Chlordemethyldiazepam) is a long acting benzodiazepine with anxiolytic, hypnoinducing, myorelaxant and anticonvulsant activities. It is considered a short-acting benzodiazepine drug which exerts both therapeutic and adverse effects linking with high affinity to

GABA_A receptor sites in the central nervous system¹² enhancing the effects of GABA at the GABA_A receptor increasing the opening frequency of its chloride ion channel resulting in the therapeutic benzodiazepines actions¹³.

Thiocolchicoside

Thiocolchicoside is a muscle relaxant with anti-inflammatory and analgesic effects. It acts as a competitive GABA-A receptor antagonist and also inhibits glycine receptors with similar potency and nicotinic acetylcholine receptors to a much lesser extent. It has powerful convulsant activity and should not be used in seizure-prone individuals. It is a natural glucoside of colchicum without curare-like effects. Thiocolchicoside does not alterate voluntary motility and does not interfere with respiratory muscles. It has no valuable effects on the cardiovascular system.

Instrumental examinations were performed by panoramic X-ray (OPT) and magnetic resonance of the TMA.

A visual-analogue scale (V.A.S.)¹⁴ was used in order to evaluate the intensity pain referred by patients consequent to palpation (Table I).

The *first group* (treated group = 19 patients) received an occlusal therapy with “Michigan

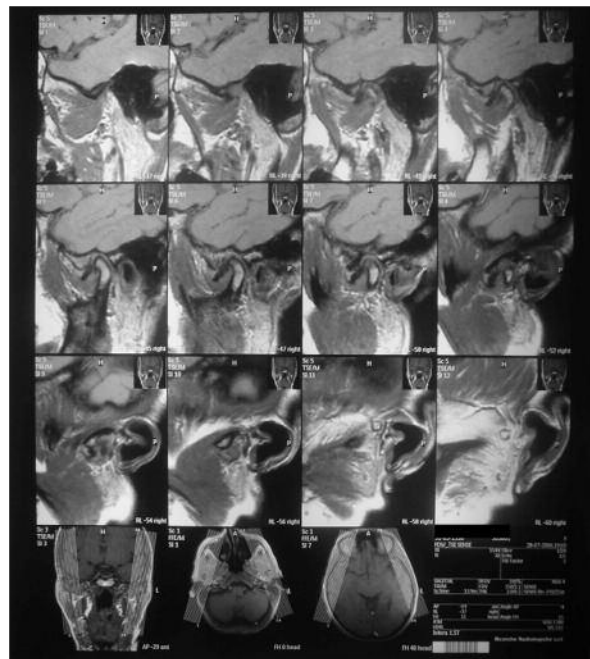













Figure 2. Magnetic Resonance of the TMA of a patient before our therapy. Anterior subdislocation of the right TMA's meniscus.

Table 1. Visual-analogue scale.

No pain		Mild pain			Troublesome pain			Intense pain		The greatest imaginable pain
0	1	2	3	4	5	6	7	8	9	10
										

splint” (Figure 3) and pharmacological therapy with “delorazepam drops” and “thiocolchicoside tablets”.

The *second group* (placebo group – 16 patients) received occlusal therapy with “Michigan splint” and “Placebo” administration: tablets and drops, prepared by a pharmacist, were similar to those used in the first group, but without the active drugs.

Patients were asked to express their pain intensity marking a point on a straight line, whose left limit was 0 (corresponding to *absence of pain*) and right limit was 10 (corresponding to the *greatest imaginable pain*). The VAS data were collected at T₀ and after 6 (T₁), 12 (T₂) and 18 months (T_{max}) from the beginning of treatment.

Data collected from the experimental group treated with “Michigan splint” and “delorazepam and thiocolchicoside” were compared with data collected from experimental group treated with occlusal therapy and “Michigan splint” alone.

Furthermore, regarding the occlusal therapy, patients were asked to wear their splint overnight along the first 12 months, positioned on superior arch.



Figure 3. Michigan splint

About the pharmacological therapy, the daily dose used were:

- *Delorazepam* drops, 1 mg/day (12 drops/day) along 12 months, decreasing 1 drop every month up to 1 drop/day during the whole 12th month;
- *Thiocolchicoside*, 1 tablet 4 mg/12 hours along 12 months.

Soon after the 12 months treatment, all patients were asked to gradually discard their splint not wearing it on Sunday in the 1st week, Sunday and Wednesday on the 2nd week, Sunday, Tuesday and Friday on the 3rd week, Sunday, Tuesday Thursday and Saturday on the 4th week and wearing it only on Sunday for the next 2 weeks. The remaining period of time (6 weeks) was considered necessary for a full wash-out from pharmacological treatment.

Statistical Analysis

V.A.S. data were statistically evaluated using Unpaired *t*-test. Analysis of variances was further performed with a nonparametric test.

Results

Comparisons between VAS values of the two experimental groups (Unpaired *t*-test) before to begin the treatment, gave not significant results ($p=0.2990$) (two-tailed $p=0.6479$, $t=0.461$; $df=33$) allowing us to proceed.

VAS values of the two experimental groups were further compared:

At 6 months from the beginning of the treatment, the comparisons between VAS values of the two experimental groups gave the following re-

sults: (two-tailed $p < 0.0088$; $t = 2.785$; $df = 33$); F test comparing variances gave *no significant results* ($F = 1.739$; $DFn = 18$; $Dfd = 15$; n.s.);

At 12 months from the beginning of the treatment, VAS data comparisons gave *significant results* (two-tailed $p < 0.0001$; $t = 7.728$; $df = 33$); F test comparing variances ($F = 3.343$; $DFn = 18$; $Dfd = 15$; $p < 0.0112$);

At 18 months from the beginning of the treatment, VAS data comparison also gave *significant results* (two-tailed $p < 0.0001$; $t = 9.041$; $df = 33$). F test comparing variances ($F = 4.754$; $DFn = 18$; $Dfd = 15$; $p < 0.0019$).

Some patients regularly using the Michigan splint (28 patients=80%) declared it comfortable. Due to the progressive dose reduction, none of the treated patients showed benzodiazepine tolerance signs. In conclusion, the effectiveness of these two types of therapies was assessed by analyzing the V.A.S. data into a statistical view: data comparison between the 2 experimental groups showed a significant improvement or disappearance of the pain only at 12 and 18 months after the beginning of the experiment ($p < 0.0001$).

Discussion

Among the large number of splints previously proposed, the “Michigan-type occlusal splints” are the most worldwide used appliances¹⁵. Michigan splints are numbered among the centric relation splints. They are characterized by a flat and smooth occlusal surface with a canine guidance on protrusion and laterotrusion. Therefore, a smooth guide surface has been built only in the canine area, in order to allow a 1mm disclusion around the posterior teeth on lateralization and on protrusion. The remaining part of the occlusal surface remained smooth and plain: this was fundamental to allow the proper mandible to place again into its physiological position.

The expected actions of this widely used occlusal appliance are: Increase of the vertical dimension; Reduction of the tone of the mandibular elevator muscles; Removal of occlusal interferences; Reduction of parafunctional movements; Unquestionable placebo effect. Thanks to these actions, the “Michigan-type occlusal splints” results to be effective in reducing asymmetry of muscle activity, muscle fatigue and all related signs and symptoms of cranio-mandibular disorders. From the results of

our study, it emerged that our non invasive management program of combined therapy is effective in treating painful muscular and related symptomatology restoring the normal parameters of the articular function (Figure 4).

Concerning the occlusal therapy and placebo, our protocol, based on the combination of occlusal (Michigan splint) and pharmacological therapy (delorazepam and thiocolchicoside) is significantly more effective (in the management of joints pain) in those patients in which a self-limiting characteristic of the TMD pathology showed a relevant problem. TMD is a clear example of clinical status commonly dubbed as multifactorial pathologies. In the past occlusal problems, they were considered the only cause of this type of disorders but a lot of recent studies have definitely proven the impossibility to find an univocal relationship between causes and effects^{12,13}. Clarity about proper etiologic factors is still a long way off. Nevertheless, there is a common understanding about the identification of some factors which could be included either among the predisposing factors, the causative factors or the perpetuating factors. It would be a mistake to draw up a list of factors and mechanically include them in each one of these categories, as

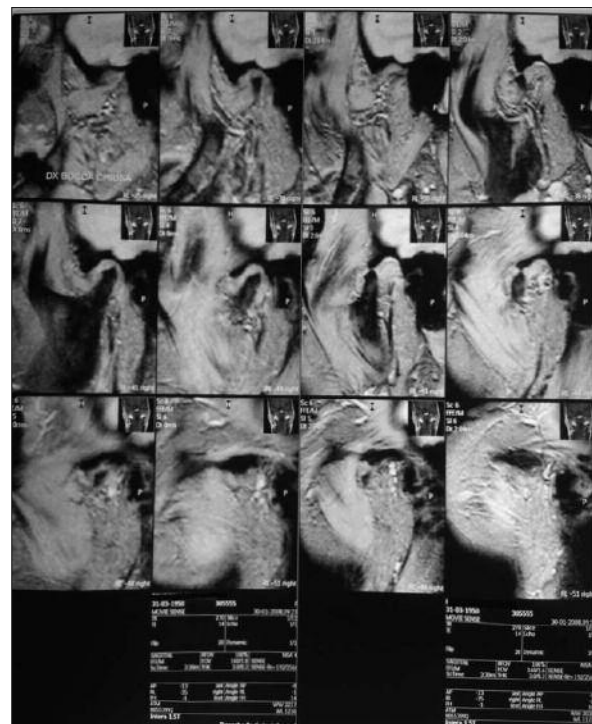


Figure 4. Magnetic Resonance of the TMA of the same patient after our therapy. Excursion of the condylus in the physiological limits.

each factor may be a causative factor in a patient, a perpetuating factor in another and neither of them in another one. Factors with a potential etiologic role are: female gender, depression and anxiety, parafunctions, occlusal disorders, emotional and physical trauma, accidents (especially whiplash injury), posture disorders, hip dysmetria, scoliosis, arthrosis, cervical lordosis¹⁶⁻²⁰. The therapeutic approach to myoarthropathies is symptomatic rather than a causal one, due to a series of distinctive characteristics of the pathologies under discussion, such as: etiologic complexity and difficulty to identify the causative factors and the intense involvement of the psychosocial sphere. TMDs are pathologies which generally end up in a good prognosis. In many cases there is a spontaneous recovery and most patients report a marked improvement of symptoms thanks to an undertaken conservative, non-invasive management. It is also important to make an accurate and well-timed diagnosis, in order to prevent a chronic developing of such a problem.

Conclusions

This latter chronic condition involves a more complex background, often leading to the necessity of a multidisciplinary approach, including: patient's assurance and information, acquirement of self-control techniques, psychiatric treatment, occlusal therapy, specialists assistance in pharmacotherapy and cognitive-behavioural therapy. The aim of these therapies is to relieve the most important and recurring symptoms, especially pain and function improvement as well as the quality of life which, in some cases, could be ruined by these annoying disorders, even in daily life activities. This pilot-study showed that the Michigan splint, combined together with our pharmacological protocol, could improve the predictability in the treatment of the TMD-related pain without a clinical relapse into the following months.

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