

Topical Diclofenac Gel Application as First Line Medication for Acute Temporomandibular Joint Pain

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ABSTRACT

Introduction: Numerous patients experience acute temporomandibular (TMJ) pain. The first therapeutic action to be undertaken should be pain relief as ongoing diagnostics like Ultrasound, X-Rays and 3D Imaging need longer time to be completed. The first line medication should be able to reduce significantly the pain with minor risk of side effects and should be applicable for most of the patients. This article presents a sample of patients treated topically with 5% diclofenac gel.

Materials and methods: Visual Analog Scale (VAS) was used as measuring tool for the purpose of collection and comparing of the pain. Pain score was documented prior and after short therapy with topically applied diclofenac gel. The data collected from 18 patients with acute TMJ pain was analysed and two tailed T-test was performed.

Results: The performed two tailed t-test showed that the pain reduction was statistically significant. No side effects were reported.

Conclusion: The topical diclofenac gel therapy for TMJ pain on palpation could be used as first line medication further research should be done and higher level of evidence is necessary.

Keywords: Diclofenac gel; Temporomandibular pain; Topical application; First line medication

INTRODUCTION

Musculoskeletal pathologies and disorders in the orofacial complex can result in Temporo Mandibular Disorder (TMD) affecting the temporomandibular joint, muscles and another related anatomical structures. The main complaint reported by the patients is pain in facial and TMJ areas as well earache, limited mouth opening, locking jaw, teeth abrasion, joint clicking, muscle hyperthrophy and others [1].

Great number of patients experience acute temporomandibular (TMJ) pain [2]. This strong pain can occur and persist despite ongoing splint or oral NSAID therapy. Those patients are often referred to oral and maxillofacial surgeon for further examination and treatment.

Temporo Mandibular Disorder (TMD) is not a single diagnosis but rather a broad term that contains a number of disease entities [3]. Leading symptom in most of the cases is pain in the TMJ [4]. The first line medication should be able to reduce

significantly this pain with minor risk of side effects. It needs to be safe, effective and should be prescribed even before the suspected diagnose is confirmed through further imaging and laboratory methods. The time to diagnose the exact pathology, to start appropriate treatment and to feel the effect of this therapy can take significant time. At this time the patients shouldn't be left untreated and experiencing pain.

NSAIDs as ibuprofen and diclofenac have been proven to be effective for TMD although with possible side effects as gastrointestinal and cardiovascular complications [5-8]. Nevertheless some of the patients in our study experienced acute pain despite months of oral NSAID therapy. The clinicians need an alternative therapy to eliminate the risk of NSAID application in the general population, but have the positive effect of the oral NSAIDs. Such therapy could be the topical diclofenac gel application.

Diclofenac gel is already used for pain relief and as first line medication in the initial treatment of osteoarthritis in other

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parts of the skeletal system [9]. It has a better safety profile than orally administrated NSAIDs combined with the same positive therapy outcome [4].

The search in PubMed database showed a great number of articles but only few of them were focused on the topical use of diclofenac gel exactly for TMJ acute pain treatment.

This article presents the results from topical treatment of patients with 5% diclofenac gel.

The aim of this study was to reveal whether topically applied 5% diclofenac gel was effective as first line medication for acute tempomandibular joint pain.

MATERIALS AND METHODS

For the needs of this retrospective study the data collected from 18 patients with acute TMJ Pain treated by the first article author was analysed. In this group were included all patients with pain from extra oral palpation on the TMJ and treated topically with 5% diclofenac gel. Another TMD symptoms as clicking, muscle stiffness, irradiating pain, neck pain, migraine, limitation of closing and opening of the mouth were no excluding criteria. Patients without pain on joint palpation weren't included, because those patients weren't treated with diclofenac gel.

For the purpose of the documentation and this study the pain on joint palpation was used as repeatable measurable clinical marker. In the clinical examination the patients were asked to open and close the mouth multiple times. At the same time the joints on the both sides were palpated by the oral surgeon. After the examination the patients were asked to rank from 1 to 10 the pain maximum over the examination. VAS was used as measurement tool as it has been shown to be effective for adults [10].The patients were administered diclofenac gel 5% three times daily prescribed as first line medication. Detailed instructions were provided. If the patients were already in treatment by a general dentist with oral NSAIDs or splint, this therapy was documented but wasn't terminated. To secure the repeatability of the examinations, the examinations were performed by only one clinician. The patients were called for second checkup and the pain maximum on joint palpation was measured once again. The patients without occlusal splint at the time of the first appointment became one after the second examination of the TMJ pain. In this way the documented changes in the pain experience were caused only by the diclofenac gel therapy.

RESULTS

The mean age of the patients was 39.1 (SD17.8), male to female ratio was 7 to 11. The mean duration of the topical diclofenac therapy was 5.22 days (SD 3.12) and the mean reduction of the pain on palpation was 1.69 (SD1.26).

The performed two tailed t-test showed that the pain reduction was statistically significant with "p" value of 0.00003. Subjectively all of the patients except one reported reduction in the all-day pain and complaints connected with gain in life quality.

Nine of the patients prior to the first visit in our office were in treatment with splint. The observed pain reduction without change of the splints were 1.94 (SD 1.60). The double tailed t-test showed significant reduction with value of "p" 0.00674.

Five of the patient took regularly NSAIDs (Ibuprofen) prescribed by the general dentist before the time of the first examination. The observed pain reduction on palpation was 1.6 (SD 0.82).

The double tailed t-test showed "p" value of 0.01211, and the result wasn't statistically significant at "p" smaller than 0.01. Despite of this fact, the diclofenac gel topical therapy was beneficial for all of the patients in this group. No patient reported drugs side effect (Table 1).

Pat. Num.	FEPS	SEPS	Red	Time	Splint	NSAIDS
1	8	6	2	14		
2	7	5.5	1.5	3	Yes	
3	8	6	2	10		
4	5	2.5	2.5	7	Yes	
5	6	4.5	1.5	7	Yes	
6	5	3.5	1.5	3	Yes	
7	8	5	3	2		Yes
8	7	1	6	5	Yes	
9	4.5	3.5	1	6		Yes
10	3	2.5	0.5	3		
11	7.5	6	1.5	1		Yes
12	6	4.5	1.5	5		Yes
13	4	3	1	7		Yes
14	3.5	3	0.5	5		
15	6	4.5	1.5	5	Yes	
16	6.5	5.5	1	2	Yes	
17	5.5	5	0.5	3	Yes	
18	5	3.5	1.5	4	Yes	

Note: FEPS or first examination pain score; SEPS or second examination pain score; Red or reduction of the pain; Time or duration of the therapy in days between the first and second visit; Splint indicates the use of splint prior to the first examination of the patients; NSAIDS indicates the use of NSAIDS prior to the first examination.

Table 1: Collected data.

DISCUSSION

The temporomandibular disorder is a wide spread pathological condition. A study of 2016 reported that 5% to 12% of the USA population suffered from it. Its diagnostics and treatment have an economic impact on the healthcare system [2]. The prevalence is documented to found in people aged 20-40 years. Approximately one third of the population has at least 1 TMD complaint, and up to 7.0% of the population having TMD were seeking treatment. Typical symptoms were on first place pain combined mostly by malocclusion, jaw function impairments, jaw deviation on opening or closing, joint noises and locking limited range of motion [11].

TMD manifests itself most frequently through pain in the temporomandibular joint or in the preauricular area [4].

The term TMD can't be defined as signal diagnosis but as a term that contains a number of disease entities. Typical for the condition are pain in temporomandibular joints and masticatory muscles, headache, disturbances in jaw movements and sounds in joints while opening and closing the mouth. Numerous causes for this complex of symptoms can be found in the literature including trauma, systemic, iatrogenic, occlusal and mental health pathology [3]. Osteoarthritis has been found to be one of the most widespread joint diseases, affecting the entire joint, including articular cartilage, subchondral bone, joint capsule, synovial membrane, ligaments and even adjacent muscles [8].

The subjectiveness of the symptoms makes TMD in many cases difficult to diagnose. The patients usually search for help from other specialists as neurologist, general practitioner, otolaryngologist, and are later reoffered to oral surgeons and dentists [3].

There are three major aims of TMJ treatment: symptom relief and pain reduction, and recovery of the normal joint function [12].

Effective pharmacological agents for the treatment of TMD include analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), opioids, corticosteroids, anxiolytics, muscle relaxants, antidepressants, anticonvulsants, and benzodiazepines [11]. NSAIDs are commonly the main part of the prescriptions to treat TMD and in particular TMJ pain relief [5].

The high efficiency of ibuprofen for TMD pain relief has been shown in the literature [6,7] reported significant reduction of symptoms as joint pain, discomfort, muscle tenderness after one week treatment with diclofenac. In comparison the splint therapy led to significant reduction of the symptoms after 1 month. The effectiveness of the NSAIDs makes this group of medications suitable for first line treatment.

In particular diclofenac showed excellent potency and is associated with significant pain reduction in the placebo controlled studies. The diclofenac treated group experienced a significant decrease in tenderness to palpation of the masticatory muscles. The best response to diclofenac was observed in the patients with short duration of pain [13].

Several possible adverse effects of taking NSAIDs including Diclofenac limit their use in some group of patients. The most often reported complications were cardiovascular and gastrointestinal. Different possible negative effects were hepatic complications, impaired renal function, clotting problems, respiratory disorders. High-risk factors for NSAID-associated cardiovascular incidents include patients with history of acute coronary syndrome, percutaneous/surgical coronary revascularization, stable angina pectoris, angiographic evidence of significant coronary artery stenosis and carotid artery stenosis, patients with a history of stroke, as well as patients with congestive heart failure [14]. It is highly recommended that the lowest effective dose of NSAIDs should be used for the shortest possible time [8].

The optimal first line medication should have the high efficiency of NSAIDs and safety profile excluding the listed side effects. Many papers can be found in literature advocating the use of diclofenac gel for other musculoskeletal conditions.

Topical application of diclofenac is proven to be more effective than placebo. Regarding the treatment outcomes the diclofenac topical therapy is not less effective than orally administered diclofenac. The incidence rate of systemic side effects is shown to be lower among patients treated topically and it can be concluded that topical application eliminates the possible risk of adverse systemic effects [4,15].

The [9] found that the gel penetrated the skin locally in substantial amounts and thus reached the desired target deeper tissue. Concentrations were sufficient to exert a therapeutic effect and not dose-dependent, and the application was well tolerated by 97.4% of patients [9,16]. Plasma levels after topical and oral applications of diclofenac were proved to be comparable, as concentration levels in the muscle were higher after topical use [15,17,18].

Derry et al. showed that gastrointestinal complications in the topical NSAID group were similar to the reported in the placebo group, and were less frequent than those with oral NSAIDs. Observational studies concluded that topical NSAIDs were generally without systemic adverse events, were well tolerated and effective in the first place. Topical diclofenac is useful first line therapy, particularly for older people [15].

The observed that all patients suffer with TMJ pain who had received either 50 mg of diclofenac sodium every 12 h for 14 days administered orally or 16 mg/mL topical diclofenac (diclofenac topical solution, 10 drops 4 times a day for 14 days) reported pain relief. Moreover, the authors proved that there was no difference regarding the efficacy of both oral administration and multidose topical application of diclofenac sodium. Topical application eliminates the possible risk of adverse systemic effects, which may occur when diclofenac sodium is administered orally.

A 2020 systematic review after analyzing 646 studies initially identified through searches, concluded that there was some evidence to support the use of NSAIDs in patients with TMDs for relief of pain [10].

The results presented in this article do not focus the long time results of treatment of TMD and TMJ pain with topical Diclofenac gel, but deliver some evidence for its topical application only as first line medication.

CONCLUSION

All patients were positively affected by the therapy regarding the pain on joint palpation, and pain relief was reported in general. The therapy seemed to be well tolerated and no side effects were registered. Limiting factors as small sample size and heterogeneity of the TMJ pathology should be considered. The ongoing splint and NSAID therapy in some of the cases could have affected the outcomes from the topical treatment. Further research is necessary to follow up the long time results of the topical diclofenac gel therapy and the effect on other symptoms as clicking, muscle stiffness, irradiating pain, and neck pain, and migraine, limitation of closing and opening of the mouth. The topical diclofenac gel therapy for TMJ pain on palpation could be used as first line medication despite different previous treatments. Further research and higher level of evidence are necessary.

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