Int. J. Oral Maxillofac. Surg. 2016; 45: 813–819
http://dx.doi.org/10.1016/j.ijom.2016.01.006, available online at http://www.sciencedirect.com

International Journal of Oral & Maxillofacial Surgery

Clinical Paper
TMJ Disorders

Is dextrose prolotherapy superior to placebo for the treatment of temporomandibular joint hypermobility? A randomized clinical trial

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S. Cömert Kiliç, M. Güngörmüş: Is dextrose prolotherapy superior to placebo for the treatment of temporomandibular joint hypermobility? A randomized clinical trial. Int. J. Oral Maxillofac. Surg. 2016; 45: 813–819.

Abstract. A randomized clinical trial involving adult patients with bilateral temporomandibular joint (TMJ) hypermobility referred for treatment was implemented. The sample comprised 30 consecutive patients, who were divided randomly into two groups. The TMJ hypermobility was treated with either saline (placebo group) or dextrose injections (study group). The solution was injected into five different TMJ areas in three sessions at monthly intervals. The predictor variable was the treatment technique. The outcome variables were visual analogue scale (VAS) evaluations and maximum inter-incisal opening (MIO). Outcome variables were recorded preoperatively and at 12 months postoperatively. Descriptive and bivariate statistics were computed, and significance was set at a *P*-value of <0.05. The follow-up sample comprised 26 subjects: 12 in the placebo group and 14 in the study group. Masticatory efficiency increased and general pain complaints and joint sounds decreased significantly in both groups. MIO decreased significantly only in the study group. Insignificant changes in the other parameters were found for both groups. After estimating differences between follow-up and baseline outcomes, the mean change in primary outcome variables showed no statistically significant difference between the two groups. These findings suggest that dextrose prolotherapy is no more effective than placebo treatment for any of the outcome variables of TMJ hypermobility assessed.

Key words: TMJ hypermobility; dextrose prolotherapy; saline injection; clinical symptoms.

Accepted for publication 13 January 2016
Available online 2 February 2016

0901-5027/070813 + 07

Temporomandibular joint (TMJ) dislocation or hypermobility is defined as excessive abnormal displacement of the condyle, where the condylar head moves anterior to the articular eminence during wide mandibular opening, such as yawning and laughing, while the jaw can be closed without any assistance. Dislocation is generally categorized as acute or chronic. Different definitions such as habitual dislocation, subluxation, recurrent dislocation, protracted dislocation, and long-standing dislocation have been used for the definition of subgroups of the dislocation.[1–4]

Acute dislocation, with the sudden displacement of the condyle anterior to the eminence, cannot be corrected by the patient, and pain due to muscular spasm and intra-articular effusion occur during this 'open-locking' situation. The management of this condition involves moving the condyle backwards into the glenoid fossa by manipulation, with or without local anaesthesia or sedation.[5] Chronic forms of this condition require no manipulation, and the head of the condyle can return into the glenoid fossa easily.[6]

The aetiology of TMJ dislocation is generally associated with the morphology of the condyle – glenoid fossa – articular eminence, generalized joint laxity, excessive activity of the lateral pterygoid muscle, the intake of certain drugs, trauma, and prolonged anaesthetic and endoscopic procedures.[7]

Surgical and non-surgical methods have been advocated for the treatment of TMJ hypermobility. Non-surgical methods include physiotherapy, the use of occlusal splints, intermaxillary fixation, avoiding wide opening during daily activities, and injections of autologous blood, botulinum toxin, and sclerotic agents (intra-articular and/or extracapsular alcohol or hypertonic glucose). Surgical methods include the reduction or augmentation of the articular eminence, condylectomy, lateral pterygoid myotomy, temporalis tendon scarification, the use of miniplates, and capsular plication.[1,4,6,8–12]

Prolotherapy is an injection therapy consisting of repeated injections of an irritant solution at or near the site of connective tissue dysfunction over the course of several months. This therapeutic approach has been used in clinical practice for more than 100 years to treat various chronic conditions under different terms, such as sclerotherapy, proliferative injection therapy, proliferant injection, regenerative injection therapy, and growth factor stimulation injection therapy. This injection technique was first introduced in 1937 by Louis Schultz as an effective treatment for painful subluxation of the TMJ.[13] Prolotherapy has also been advocated for the treatment of osteoarthritis and laxity of other joints,[14] lower back pain,[15] and headaches.[16] However, the clinical outcome of TMJ dislocation treated with dextrose prolotherapy has been evaluated in only a limited number of studies.[10,17,18]

Zhou et al. used the injection of lignocaine and 50% dextrose at a single site in the posterior peri-articular tissues for the treatment of recurrent TMJ dislocation, and reported significant improvements in the number of episodes of dislocation (91%) and clicking after injection.[17] Ungor et al. reported the total recovery of TMJ locking, significant decreases in pain scores, and increased quality of life in 10 patients treated with dextrose prolotherapy.[18] However, they reported statistically insignificant changes in MIO measurement and clicking sounds after this treatment. In a recent randomized clinical trial conducted on 12 patients, Refai et al. assessed the efficacy of dextrose prolotherapy for the treatment of TMJ hypermobility, and found that prolotherapy with 10% dextrose was promising for the treatment of symptomatic TMJ hypermobility. This was evidenced by the therapeutic benefits, simplicity, safety, patient acceptance of the injection technique, and the lack of significant side effects.[10]

The studies mentioned above have important drawbacks: Refai et al.[10] and Ungor et al.[18] reported the results of short-term evaluation in small-sized populations. Zhou et al.[17] and Ungor et al.[18] conducted studies involving only a dextrose prolotherapy group, without a placebo control group. Thus, the interpretation of the results of these latter two studies is restricted due to the potential to draw misleading conclusions. Furthermore, data reported in the literature suggest that the profound improvements observed after saline or dextrose injections do not result from the injections themselves, but from needle trauma and micro-bleeding. It has been well documented by some authors that cell membrane disruption caused by a needle will stimulate the release of proinflammatory lipids from cell membranes, which can produce growth factors.[15,19]

Thus, long-term clinical outcome comparisons between prolotherapy and placebo groups in large-sized populations are lacking in the literature. The purpose of this study was to compare the treatment outcomes of TMJ hypermobility treated with injections of dextrose or saline solution. The specific aims of the present study were to measure and compare pre- and post-treatment visual analogue scale (VAS) parameters, maximum inter-incisal opening (MIO), and lateral and protrusive mandibular motions in patients treated with dextrose prolotherapy or placebo.

Materials and methods

To address the research purpose, the investigators designed and implemented a prospective randomized clinical trial involving patients with TMJ hypermobility who underwent one of the two TMJ hypermobility treatment protocols at Ataturk University Faculty of Dentistry in Erzurum, Turkey. This study was approved by the local ethics committee, and all participants signed an informed consent agreement.

The study population comprised all patients presenting for the evaluation and management of TMJ hypermobility between January 2013 and March 2014. To be included in the study sample, patients had to meet the following criteria: (1) hypermobility (diagnosed with clinical and cone beam computed tomography (CBCT) evaluations), (2) complaints of joint sounds, open-locking, and facial pain, (3) age >16 years, (4) completion of one of the two treatment protocols for TMJ hypermobility, and (5) adequate existing clinical and CBCT data at baseline and for the post-operation time interval (follow-up).

Patients were excluded from the study if they had a haematological or neurological disorder, inflammatory or connective tissue disease, malignant disease in the head and neck region, degenerative TMJ, previous TMJ treatment or craniofacial surgery, existing parafunctional habits, or inadequate existing data at baseline or for the post-operation time interval (follow-up).

The sample size was calculated based on a significance level of 0.05 and a power of 80% to detect a clinically meaningful difference of 4 mm in inter-incisal opening. The power analysis showed that 11 patients were required in each group. To increase the power of the study and to compensate for possible dropouts during the planned study period, more patients were included in the two groups (15 subjects in each group).

Thirty patients were assigned randomly to one of the two treatment groups, in equal numbers. Participants in the placebo group (group 1) received 1-ml injections of placebo solution in each of the five injection areas at three sessions, each a month apart; this solution consisted of