Comparison of the Efficacy of Different Treatment Modalities in Massateric Myofascial Pain: Masseteric Nerve Block, Local Anesthetic Injection and Dry-needling

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This document contains study design and statistical analysis plan of the study entitled "Comparison of the Efficacy of Different Treatment Modalities in Masseteric Myofascial Pain: Masseteric Nerve Block, Local Anesthetic Injection and Dry-needling".

Study Design:

This is a 3-armed randomized, parallel, controlled, interventional clinical study enrolling 45 patients with myofascial pain originated from masseter muscle.

Eligibility

- Inclusion Criteria: Definite diagnosis of myofascial pain with a referral, based on the DC/ TMD criteria, presence of the myofascial pain for at least six months; the presence of one or more trigger point in the unilateral or bilateral masseter muscle, no history of any invasive procedures in the related masseter muscle in last two years;
- Exclusion criteria: Factors that can cause pain in the orofacial region other than MTPs (decayed tooth, TMJ internal disorder, etc.), presence of any muscle disorders or neuropathy (e.g. fibromyalgia), patients with a history of hypersensitivity to local anesthetics.

Patients were grouped according to the treatment they received: Masseteric nerve block (MNB), TrP injections with local anesthetic (LA) and dry-needling (DN). Localization of the MTPs was based on the clinician′s sense and patients′ expressions of pain. Local twitch response was not observable in all cases. This procedure was completed by using digital palpation. Clinical examiner′s palpation was calibrated using a pressure algometer (1.5 Kg).

Sample size

The sample size was calculated using IBM SPSS 22 (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.). Based on a power of 0.80 and an alpha value of 0.05, the sample size was calculated to be a total of 45 subjects with 15 in each group.

Outcome measures

The Rate of Pain on Function (PoF) assessed by Numerical pain Scale (NRS): Patients rated their pain on function (pain during chewing or speaking etc.) on a Numeric Rating Scale (NRS) (0−10 where 0 is no pain and 10 is the worst pain imaginable)

The Rate of Pain Intensity on Palpation (PoP): Patients rated their pain intensity on massater muscle by a 4-point Likert-type scale (0 = no pain, 3 = as worst pain imaginable) while a calibrated examiner palpating their masseter muscle.

The measurement of pain-free maximum mouth opening (MMO) in milimeters.: Pain-free MMO was measured as the distance between the incisal edges of the upper and lower incisors while patient′s mouth is open as possible without any assistance and without pain in massater muscle. Three measurements were performed, and their average is recorded.

The patients were assessed before the injections (T0), and at one week (T1), 4 weeks (T2), and 12 weeks (T3) after the injections. Patient′s pain on palpation, pain on function and maximum mouth opening values were reexamined and recorded on follow-up appointments. Treatment protocol and the outcome measures were recorded in the patient′s form.

Statistical Analysis Plan: Descriptive statistics of variables were presented as mean ± standard deviation for continuous variables and n (%) for categorical variables in statistical analysis. IBM SPSS 22 was used to analyze the data (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.). Pearson chi-square test was used in the analysis of categorical variables. One-way ANOVA was used in the analysis of discontinuous variables (such as % difference Baseline-T1). Bonferroni test was used as post hoc test after ANOVA. Repeated Measures ANOVA test was used when testing group differences for repeated measurements. Bonferroni correction was used in multiple comparisons when determining the differences between the groups at each time point. The statistical significance level was accepted as $p < 0.05$.