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TMJ Disorders

Two-needle vs. single-needle technique for TMJ arthrocentesis plus hyaluronic acid injections: a comparative trial over a six-month follow up

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Abstract. The aim of the study was to compare the effectiveness of five weekly two-needle arthrocentesis plus hyaluronic injections vs. the same protocol performed with a single-needle technique in patients with inflammatory-degenerative disorders of the temporomandibular joint (TMJ). 80 patients with TMJ osteoarthritis were randomly assigned to the two-needle or single-needle protocol and followed up for 6 months after treatment. Several outcome parameters, such as maximum pain at rest and maximum pain on chewing, subjective chewing efficiency, limitation in jaw function, jaw range of motion in mm, were recorded at baseline and multiple follow up assessments. Both treatment groups recorded significant improvement with respect to baseline levels in almost all outcome variables. The rate of improvement was not significantly different between the treatment protocols in any of the outcome variables (p-values between 0.143 and 0.970). No between-group differences emerged for the perceived subjective efficacy ($p = 0.321$) and the treatment tolerability ($p = 0.783$). The present investigation did not support the existence of significant differences in the treatment effectiveness for inflammatory-degenerative TMJ disorders of a cycle of five weekly injections of arthrocentesis plus hyaluronic acid injections performed according to the classical two-needle or the single-needle technique.

Keywords: temporomandibular joint; arthrocentesis; needle technique.

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Arthrocentesis of the temporomandibular joint (TMJ) has emerged over the years as a useful technique to manage restricted mouth opening[23]. The discovery of the importance of hyaluronic acid (HA) in joint lubrication[22] and the addition of HA injections immediately following joint lavage has allowed extending the indications to inflammatory-degenerative disorders, such as osteoarthritis[8]. The literature findings are inconclusive regarding the best treatment protocol for each specific clinical condition and further investigations are needed[20].

Protocols for symptom management in larger joints provided the adoption of a

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cycle of five weekly HA injections immediately following arthrocentesis[6], and encouraging findings also emerged from long-term case series on patients with TMJ disorders[9,18]. The classical technique to perform TMJ arthrocentesis before injecting HA uses two needles, one for saline inflow and one for outflow. Several papers refer to the most suitable technique for needle placement within the joint cavity[15]. Recently, other approaches to arthrocentesis have been proposed and reviewed[26]. A technique using a single needle for both fluid injection and ejection has been described[10] and gave interesting results over a short period[19].

The single needle approach for washing the TMJ was based on the rationale that pumping saline injection into the superior joint compartment with the patient in an open mouth position provides enough pressure to release joint adherences and to allow fluid outflow when the patient closes their mouth. The two-needle and the single-needle techniques were compared as part of a short-term investigation comparing six protocols for performing TMJ arthrocentesis with or without additional drug injections, but there was no evidence of the superiority of one technique over the other[21].

In general, there is little information on the relative efficacy of the different techniques. The present investigation aimed to provide more data over a longer follow up period, focusing on the comparison of the effectiveness of five weekly two-needle vs. single-needle arthrocentesis plus HA injections in patients with inflammatory-degenerative disorders of the TMJ.

Materials and methods

The study participants were 80 patients with Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) version 1.0[5] diagnosis of osteoarthritis (axis group IIIb) with pain lasting more than 6 months seeking treatment at the authors' clinic from 1 January to 31 December 2009. They were randomly assigned to receive either a cycle of five weekly two-needle arthrocenteses plus low-molecular weight HA injection or five weekly single-needle arthrocenteses plus low-molecular weight HA.

The two-needle techniques refers to the approach first described by Nitzan et al.[23], with a needle dedicated to the inflow of physiological saline into the upper joint compartment and a second needle for the outflow. Joint lavage was performed with at least 300 ml of saline[13]. After joint lavage, one needle was removed, and the remaining one was used to inject 1 ml low-molecular weight HA (Hyalgan®, Fidia, Abano Terme, Italy) into the joint space. The single-needle technique, introduced by Guarda-Nardini et al.[10], adopted only one needle for both fluid injection and aspiration as well as HA injection.

For each patient, a number of outcome parameters were recorded at baseline, at the end of treatment, and at 1, 3, and 6 month follow up assessments. They included maximum pain at rest and maximum pain on chewing measured on a 10-point visual analogue scale (VAS) with 0 being absence of pain and 10 being the worst pain ever. Subjective chewing efficiency was also measured on a 0–10 VAS scale (0 being the worst efficiency ever and 10 the best efficiency ever). Other factors measured were limitation in jaw function (using a five-point Likert-type scale with 0 being absence of limitation and 4 severe limitation), and jaw range of motion in mm. Treatment tolerability and perceived treatment effectiveness were measured on a five-point Likert-type scale (0 being the lowest and 4 the maximum values) and were assessed at the end of treatment and at the end of follow up, respectively. All interventions were performed by one of the two main investigators (L.G.N.; D.M.) in accordance to a random sequence of intervention, and the outcome parameters were recorded by a trained dental student blinded to the treatment protocol for all patients. The operators could not be blinded with respect to the treatment modality. The patients were as blinded as practically possible by receiving a generic explanation of the potential benefit of administering arthrocentesis as well as an explanation that the specific intervention they were undergoing was the most suitable for their disease. All patients gave informed consent.

The pain on chewing value was assumed to be the main outcome variable and power analysis was performed based on hypotheses drawn from the literature data on similar patients' samples[18]. A mean VAS value of $6/10 \pm 3/10$ in the main outcome variable was assumed. The study design was able to detect about a 30% between groups difference in mean pain on chewing VAS values with a statistical power of 5% for type I error (false positive results), and 20% for type II error (false negative results). Baseline values for patients receiving the two different treatment modalities were compared using a *t*-test for unpaired groups (continuous variables: VAS levels, values in mm) and Mann–Whitney *U*-test (ordinal variables: five-point Likert-type scales on functional limitation).

Fisher's exact test and *t*-test were performed to compare sex distribution between groups and to investigate differences in the mean age, respectively. The existence of within group differences between baseline and follow up values was assessed by means of paired *t*-tests for continuous variables and the Wilcoxon test for ordinal variables. *t*-tests for unpaired groups and the Mann–Whitney *U*-test were used to test for differences between groups as for changes over time in the continuous and ordinal variables, respectively (percentage changes were considered for the subjective variables chewing efficiency, pain levels, functional limitation, and changes in mm were considered for jaw range of motion values). Scores of subjective treatment efficacy and tolerability were compared using the Mann–Whitney *U*-test. For all comparisons statistical significance was set at $p < 0.05$.

Results

Two patients in the group undergoing the single needle protocol withdrew from the study due to time constraints that prevented them from attending the follow up assessments, so a total of 40 patients (3 males) completed the two needle (TN) and 38 (5 males) completed the single needle (SN) protocol. Sex distribution was not significantly different between groups (Fisher's exact test, $p = 0.476$).

No significant differences emerged between groups regarding the mean age of participants (TN: 56.9 ± 15.3; SN: 54.2 ± 16.2; $t = -737$, $p = 0.463$) and baseline values in the outcome variables (Table 1). During the treatment period, no side effects were reported by any patients, apart from occasional discomfort to the periorbicular muscles due to the transient anaesthesia of the TMJ area.

In both treatment groups, significant improvement with respect to baseline levels were achieved in all outcome variables, the only exception being protrusion values in the SN group (Figs. 1–8). At the end of the follow up period, the SN group reported significant improvement in chewing efficiency ($p < 0.001$), pain on chewing ($p < 0.001$), functional limitation ($p < 0.001$), mouth opening ($p = 0.001$), left ($p = 0.001$) and right laterotrusion ($p = 0.003$), and pain at rest ($p = 0.018$). The TN group reported significant improvement in all outcome variables: chewing efficiency ($p < 0.001$), pain at chewing ($p < 0.001$), pain at rest