

Leading Clinical Paper
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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L. Guarda-Nardini, G. Ferronato, D. Manfredini: Two-needle vs. single-needle technique for TMJ arthrocentesis plus hyaluronic acid injections: a comparative trial over a six-month follow up. Int. J. Oral Maxillofac. Surg. 2012; 41: 506–513. © 2011 International Association of Oral and Maxillofacial Surgeons. Published by Elsevier Ltd. All rights reserved.

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.

Accepted for publication 8 November 2011
Available online 16 December 2011

Arthrocentesis of the temporomandibular joint (TMJ) has emerged over the years as a useful technique to manage restricted mouth opening²³. The discovery of the importance of hyaluronic acid (HA) in joint

lubrication²² and the addition of HA injections immediately following joint lavage has allowed extending the indications to inflammatory-degenerative disorders, such as osteoarthritis⁸. The literature findings are

inconclusive regarding the best treatment protocol for each specific clinical condition and further investigations are needed²⁰.

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

cycle of five weekly HA injections immediately following arthrocentesis⁶, 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 cavity¹⁵. Recently, other approaches to arthrocentesis have been proposed and reviewed²⁶. A technique using a single needle for both fluid injection and ejection has been described¹⁰ and gave interesting results over a short period¹⁹.

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 adhesences 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 other²¹.

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 1.0⁵ 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 saline¹³. 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' samples¹⁸. A mean VAS value of 6/10 ± 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

Table 1. Baseline values for the outcome variables. Comparison between patients undergoing the two-needle (TN) and single-needle (SN) protocols.

Outcome parameters	TN protocol (N = 40)	SN protocol (N = 38)	Significance
Chewing efficiency (0–10)	6.1 ± 1.7	6.4 ± 1.6	0.406
Maximum pain at chewing (0–10)	6.4 ± 2.5	5.9 ± 2.2	0.326
Maximum pain at rest (0–10)	3.8 ± 3.3	2.9 ± 2.6	0.681
Functional limitation (0–4)	2.2 ± 0.7	1.9 ± 0.6	0.093
Mouth opening (mm)	37.0 ± 8.4	40.2 ± 7.8	0.086
Right laterotrusion (mm)	6.8 ± 2.4	7.8 ± 2.2	0.070
Left laterotrusion (mm)	7.4 ± 2.8	7.8 ± 3.1	0.526
Protrusion (mm)	6.4 ± 2.3	7.4 ± 2.4	0.094

($p < 0.001$), functional limitation ($p < 0.001$), mouth opening ($p < 0.001$), right ($p < 0.001$) and left laterotrusion ($p < 0.001$), and protrusion ($p = 0.008$).

The rate of improvement was not significantly different between the two treatment protocols in any of the outcome variables (p -values ranged between

0.143 and 0.970) (Tables 2 and 3). No between-group differences emerged regarding the perceived subjective efficacy at the end of the follow up period ($Z = -0.991$, $p = 0.321$) and the treatment tolerability assessed at the end of the treatment cycle ($Z = -0.276$, $p = 0.783$).

Discussion

In patients with internal derangements and inflammatory-degenerative disorders of the TMJ, arthrocentesis has been proposed as an effective approach to manage the symptoms, and several techniques have been described in an attempt to minimize tissue trauma and to implement treatment effect^{1,10,23,25}. The injection of HA after joint washing was claimed to add potential benefit by restoring smooth jaw function². No definitive data are available to support any specific suggestion for the adoption of one particular technique, the literature seems to be inconclusive concerning the indications and success rate of arthrocentesis alone and with HA injections^{12,20}.

Clinical trials comparing the different arthrocentesis strategies are needed. In particular, regarding the effectiveness of

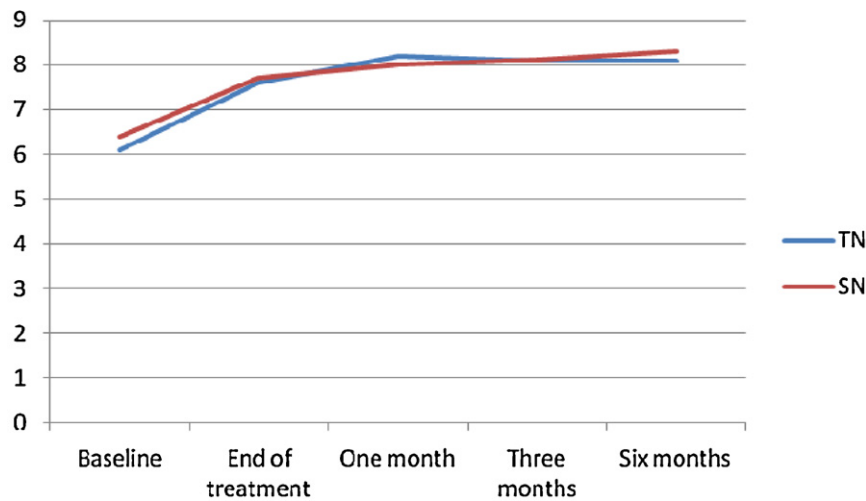


Fig. 1. Chewing efficiency values (0–10 VAS scale). Changes over time in the two treatment groups.

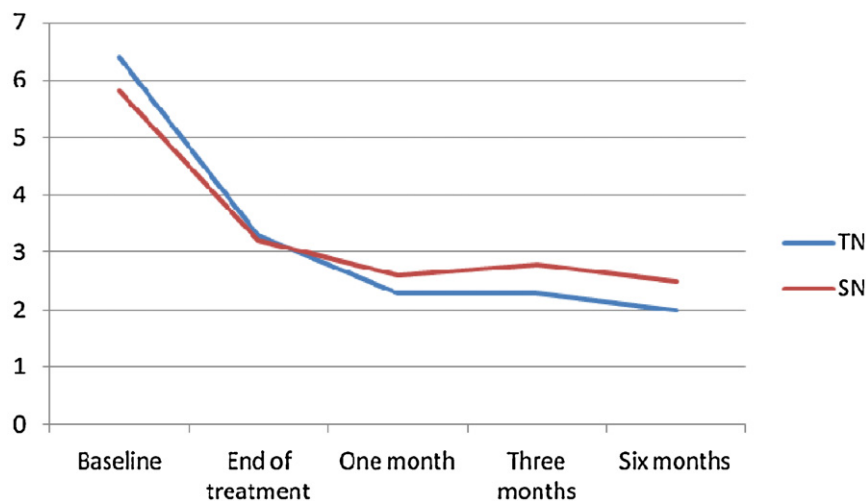


Fig. 2. Pain at chewing levels (0–10 VAS scale). Changes over time in the two treatment groups.

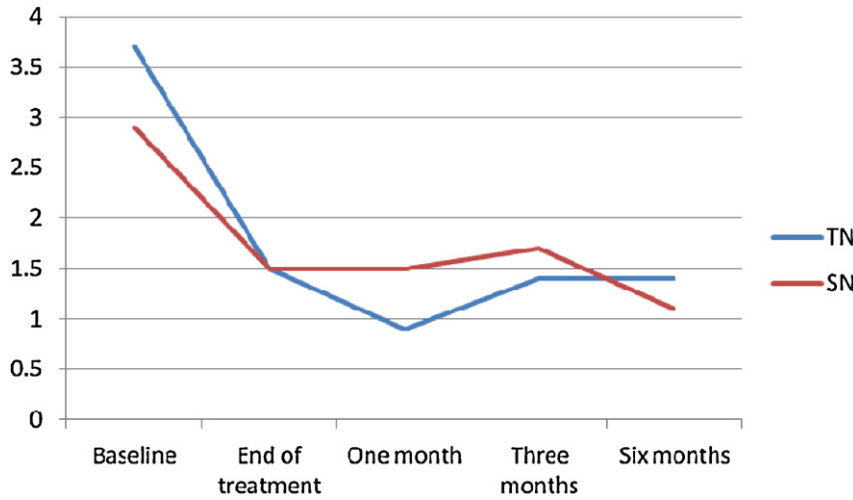


Fig. 3. Pain at rest levels (0–10 VAS scale). Changes over time in the two treatment groups.

TMJ arthrocentesis and injections in the management of inflammatory-degenerative disease the available data only gave preliminary suggestions. For example, the effects of a cycle of five HA injections immediately following arthrocentesis was found similar to those of occlusal splints and superior to no treatment at 6 months⁸, no significantly different treatment effects at 6 months were detected between two HA and corticosteroid injections performed 2 weeks apart⁴, and a single HA injection proved to be superior to oral anti-inflammatory drugs over a 3 month follow up²⁴. A recent clinical trial comparing six different treatment protocols (different combinations of single/multi-session arthrocentesis with or without drug injection) reported that no statistically significant differences existed between the treatment groups²¹.

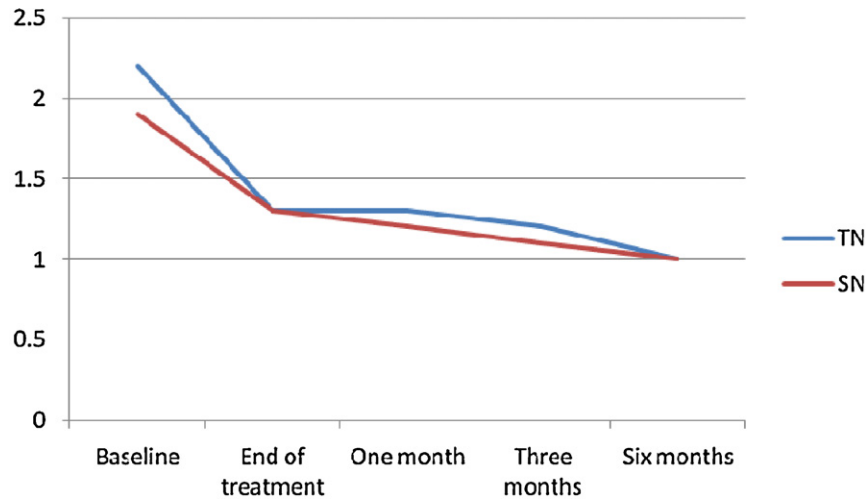


Fig. 4. Functional limitation levels (0–4 Likert-type scale). Changes over time in the two treatment groups.

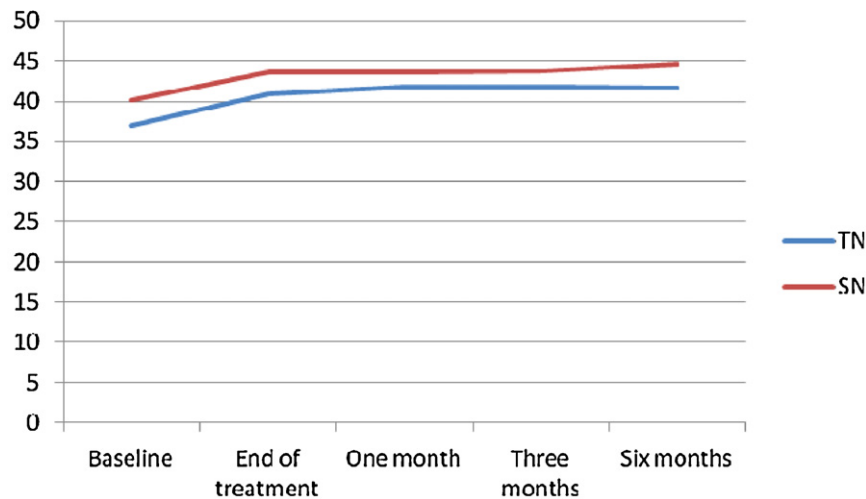


Fig. 5. Mouth opening values (in mm). Changes over time in the two treatment groups.

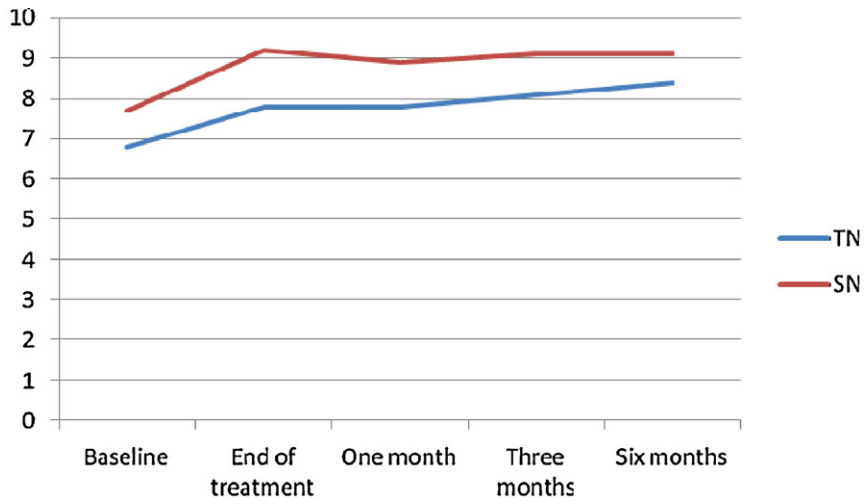


Fig. 6. Right laterotrusion values (in mm). Changes over time in the two treatment groups.

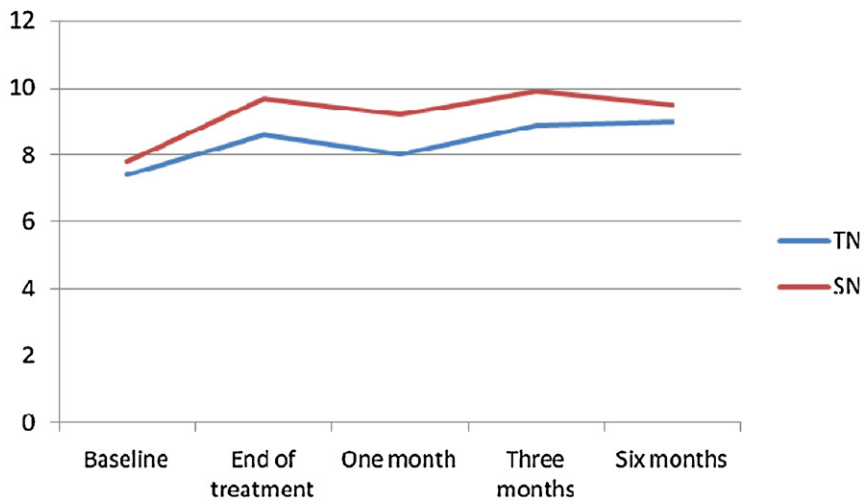


Fig. 7. Left laterotrusion values (in mm). Changes over time in the two treatment groups.

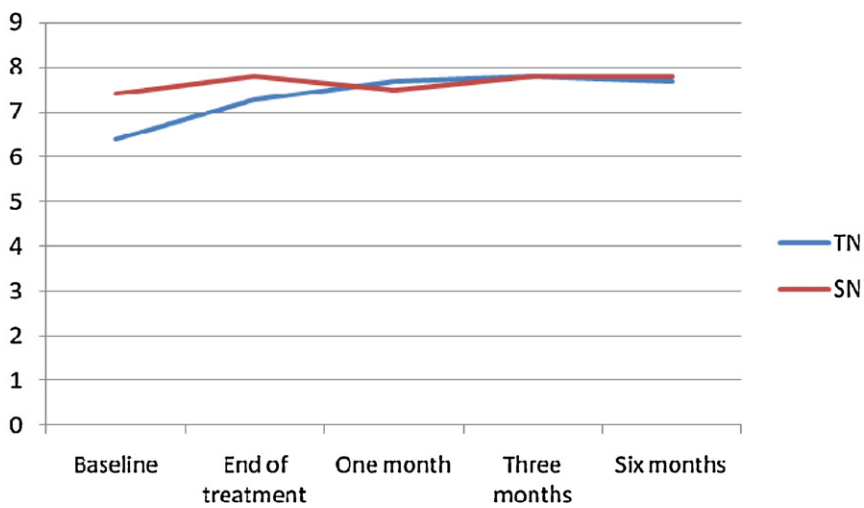


Fig. 8. Protrusion values (in mm). Changes over time in the two treatment groups.

Table 2. Percentage changes at the end of the follow up period with respect to baseline values for the subjective variables (chewing efficiency, pain levels, functional limitation). Comparison between patients undergoing the two-needle (TN) and single-needle (SN) protocols. The expected sign for improvement is given in parentheses.

Outcome parameters	TN protocol (N = 40)	SN protocol (N = 38)	Significance
Chewing efficiency (+)	41.6 ± 72.1	33.5 ± 37.0	0.539
Maximum pain at chewing (-)	-63.6 ± 43.9	-56.2 ± 45.8	0.471
Maximum pain at rest (-)	-39.1 ± 62.4	-40.7 ± 59.8	0.909
Functional limitation (-)	-51.6 ± 43.3	-43.4 ± 46.7	0.423

Table 3. Changes at the end of the follow up period with respect to baseline values for the jaw range of motion (values in mm). Comparison between patients undergoing the two-needle (TN) and single-needle (SN) protocols. The expected sign for improvement is given in parentheses.

Outcome parameters	TN protocol (N = 40)	SN protocol (N = 38)	Significance
Mouth opening (+)	4.0 ± 5.6	4.0 ± 6.7	0.970
Right laterotrusion (+)	1.6 ± 2.6	1.3 ± 2.2	0.553
Left laterotrusion (+)	1.5 ± 3.2	1.7 ± 2.9	0.847
Protrusion (+)	1.3 ± 2.5	0.4 ± 2.4	0.142

Notwithstanding that, a protocol providing five weekly low-molecular weight HA injections immediately following a classical two-needle arthrocentesis was slightly superior to all the other treatments to reduce pain-related symptoms in patients with inflammatory-degenerative TMJ disease over a 3 month period.

In the present investigation, that protocol was adopted to compare the effectiveness and tolerability of the two-needle approach to the TMJ with that of a single-needle entry. The latter approach adopted one needle for both the saline injection and ejection thanks to a pumping effect. It was suggested to achieve higher intra-articular pressure during saline inflow, to help break adhesions, and to be less traumatic than the two-needle entry, due to the insertion of a single needle within the superior joint compartment¹⁰. A short-term trial gave encouraging findings concerning the clinical effectiveness of the single-needle approach¹⁹, but comparison with the classical technique is fundamental to retrieve indications for use in daily practice.

At 6 months, the effectiveness of the two-needle and single-needle protocols was similar, both resulting in significant improvement with respect to baseline levels of pain, chewing efficiency, and jaw range of motion. Both protocols recorded marked significant improvements at the end of treatment that were maintained during the follow up. The subjective perceived efficacy and treatment tolerability were not different between the two protocols.

These findings are open to several interpretations. First, it can be suggested that the purported differences between a two-needle and a single-needle approach to TMJ arthrocentesis are much less important than thought, since neither of the two techniques have specific advantages over the other. In particular, the single-needle technique was shown to be equally effective as the classical two-needle technique, but it gave no advantages in terms of tolerability. This may be explained by the fact that the reduced trauma due to the positioning of one needle instead of two counteracts the higher, potentially discomforting, intra-articular pressure exerted by the single needle technique with respect to the inflow-outflow circuit created with two needles.

Second, the two protocols have similar effects. The literature reports many positive treatment outcomes achieved with different conservative therapeutic modalities¹⁶, suggesting that, at least to some extent, the successful management of TMD patients may be due to mechanisms not specifically related to TMD pathophysiology, such as the placebo effect, the natural fluctuation and self-remission of symptoms, and the regression to the mean effect^{7,17}. Prognostic factors for treatment effectiveness are hard to find amongst the physical findings and seem to be mainly related to the psychosocial sphere, as suggested by investigations on the effectiveness of multimodal therapy for TMD symptoms²⁷. In particular, a recent paper underlined that baseline physical findings and the type of intervention (two-needle

vs. single-needle approach) were not predictors for treatment effectiveness in patients with TMJ inflammatory-degenerative disease¹¹. Further studies need to be designed to understand specific treatment effects by comparing different treatment modalities with the natural course of the disease.

Third, no information was reported on the potential additional benefit of HA injections immediately following arthrocentesis because the investigation was not designed to assess that issue. The literature on HA injections has been inconclusive, with a few papers supporting its additional benefit with respect to arthrocentesis alone² in contrast with early reports not supporting its superiority¹⁴. In general, the quality of the literature was low²⁰, and a recent short-term trial did not support the existence of statistically significant difference between protocols including arthrocentesis with or without drug injection (HA or corticosteroids)²¹. The same trial showed that, even if they were not significantly higher than those achieved with the other treatment modalities at the 3 month follow up, the percentage changes with respect to baseline values achieved with the five weekly arthrocentesis plus HA injection were more marked. Such protocol might be assumed as a reference for comparison to assess the effectiveness of protocols that are less invasive in terms of number of sessions and trauma to the joints. It should be noted that the absence of differences between the two-needle and single-needle arthrocentesis described in this investigation is a first step towards the identification of the most effective approach to perform arthrocentesis in terms of risk-to-benefit ratio.

Fourth, limitations of the present investigation should be taken into account. From a strictly methodological viewpoint, it should be remembered that the quality of any clinical investigations should be assessed according to the recommended guidelines for reporting clinical trials, such as the CONSORT statement³. The peculiar nature of the treatments under investigation prevented the authors from achieving a full double-blind design. The operators were blind with respect to the patients' outcome parameters but they could not be blind to the technique they were performing. The expertise of the investigators performing the interventions and the single-examiner recording of the patients' outcome parameters seem to be key factors in the validity of the results and should be taken into account in future studies. The drop-out rate (2 of 80 participants, 3%) is not a matter of concern.

Regarding statistical power, the size of the study sample, which was suitable to detect about 30% between-group differences in the main outcome variable, is likely to be enough, because differences lower than 30% are likely to be non relevant in the clinical setting. Enlargement of the study sample in future studies might be not recommended because of the risk for type I error, detecting statistical, non clinical, significances.

As a recommendation for the future, longer follow up periods would be useful to monitor treatment outcomes over time and to compare the treatment effect with the natural course of the disease. In particular, a multidimensional assessment of pain measures and daily pain diaries seem to be promising strategies to increase the internal validity of the research and to control for the fluctuation of symptoms over time.

Regarding the clinical implications of these findings, the absence of differences in treatment effects at the group level does not mean that differences do not exist at the individual level. From a technical viewpoint, some joints are hard to access with two needles due to adhesions that prevent good entry points into the joint cavity, suggesting that the single-needle approach should be preferred in those selected cases. The volume of fluid that can be injected/ejected with a single needle is much smaller than that with the two-needle technique, which might therefore be preferred in cases in which thorough joint washing has to be achieved. Logistic regression models attempting to identify predictors of treatment outcome and taking into account the technical aspects of the intervention could be useful to gather data for application at the individual level.

In conclusion, findings from the present investigation did not show significant differences in the treatment effectiveness for inflammatory-degenerative TMJ disorders of a cycle of five weekly injections of arthrocentesis plus HA injections performed according to the classical two-needle technique or the single-needle technique. The two approaches were both effective over a 6 month follow up and similarly tolerated. The two techniques may be equally used in further studies and compared with other protocols to detect the most suitable approach at the individual level.

Funding

None.

Competing interests

None declared.

Ethical approval

Not required.

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