Arthrocentesis and viscosupplementation as treatment modalities for arthralgia of the temporomandibular joint
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Chapter 4

Arthrocentesis as initial treatment for temporomandibular joint arthropathy: a randomized controlled trial

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Abstract

Objective To determine the effectiveness of arthrocentesis compared to conservative treatment as initial treatment with regard to temporomandibular joint pain and mandibular movement.

Methods In this randomized controlled trial, 80 patients with arthralgia of the TMJ (classified according to the Research Diagnostic Criteria for Temporomandibular Disorders) were randomly assigned to one of the two treatment groups. One group received arthrocentesis as initial treatment (n=40), the other group received conventional treatment including soft diet, physical treatment and occlusal splint therapy (n=40). Follow-up was after three, 12 and 26 weeks post treatment. Prior to treatment, and at every follow-up assessment, pain intensity was measured (VAS 0-100mm at rest, and VAS 0-100mm during movement) and maximum mouth opening (MMO) (mm interincisor distance). Furthermore patients were asked to fill out several surveys concerning the impact of mandibular impairment on their daily life, and psychosocial aspects.

Results After 26 weeks, the TMJ pain (mm VAS at rest, and mm VAS during movement) had comparably declined in both groups (arthrocentesis n=36; conservative treatment n=36) and MMO (mm interincisor distance) had slightly improved. GEE models showed significant differences between arthrocentesis as initial treatment and conservative treatment, indicating that the arthrocentesis group improved more rapidly with regard to TMJ pain (VAS at rest p=0.008; regression coefficient $\beta=-8.90$ (95% confidence interval -15.50, -2.31), VAS during movement p=0.003; regression coefficient $\beta=-10.76$ (95% confidence interval -17.75, -3.77)) and MMO (p=0.045; regression coefficient $\beta=-2.70$ (95% confidence interval -5.35, -0.06)) compared to conservative treatment.

Conclusions Arthrocentesis as initial treatment reduces pain and functional impairment more rapidly compared to conservative treatment. However, after 26 weeks, both treatment modalities achieved comparable outcomes.

Trial registration number www.trialregister.nl: NTR1505
Introduction

Arthralgia of the temporomandibular joint (TMJ) is often a chronic degenerative process, leading to destruction of essential molecules of the lubricating system, the articular surface lining of fibrocartilage and the subchondral bone. Due to secondary inflammatory components, the most prominent symptoms are pain in and around the joint, and restricted mandibular movement. Furthermore, joint sounds like clicking and crepitation, as well as internal derangements frequently occur.

The synovial fluid of inflamed TMJs often contains elevated levels of degradation products, proinflammatory interleukins, matrix degrading enzymes, and reactive cytokines. Treatment of TMJ arthropathies usually focuses on reduction of the joint loading by prescribing a soft diet, physical exercises, and oral appliances. Recuperation of the joint initiated by this pursued force reduction starts with phagocytosis of degeneration products. This process takes time, is dependent on patient compliance, and its outcome and duration are clinically unpredictable. By contrast, arthrocentesis or lavage of the joint directly removes not only most of the degradation products, but inflammatory mediators as well. Success rates up to 91% have been reported for the use of arthrocentesis in anterior disc displacement without reduction. Although evidence is not conclusive, it seems that arthrocentesis has indeed a beneficial effect on pain and impairment of mandibular motion. Al-Belasy and Dolwick even concluded that arthrocentesis is a highly efficient procedure with low morbidity.

Contemporary therapeutic strategy consists of initially conservative treatment including soft diet, physical treatment and occlusal splint therapy, which is followed by minimally invasive techniques like arthrocentesis when patients are non-responsive to this approach and the arthropathy appears to be persistent. However, since there is no definite evidence that loading of the articular surfaces is indeed reduced by conservative therapy, and arthrocentesis seems to be highly efficient in patients that did not benefit sufficiently from conservative treatment, minimally invasive techniques could be applied in an earlier stage. We reported promising results using arthrocentesis as initial therapy. However, that study was not designed to investigate the effectiveness of arthrocentesis as initial treatment. Therefore, the objective of this randomized controlled trial was to determine the effectiveness of arthrocentesis as initial treatment with regard to TMJ pain intensity and mandibular movement compared to conservative treatment.

Material and methods

Study design
This randomized effectiveness study was conducted at the University Medical Center Groningen (UMCG) from January 2009 to June 2012. Approval of the ethical committee of the UMCG was obtained prior to patient recruitment (METc 2008/197). All patients signed a written informed consent. Patients were recruited from the department of Oral and Maxillofacial Surgery of the UMCG. Because the main target of the investigated
therapeutic approaches is reduction of symptoms, the inclusion criteria were formulated likewise.

Inclusion criteria were:
- Minimum of 16 years of age
- Pain in the TMJ region, aggravated by protrusion, maximal mouth opening and/or lateral excursions of the mandible and function
- Pain still present after two weeks of ibuprofen 600mg three times daily (exclusion of acute inflammatory pain)
- Pain disappears after intra articular injection (Ultracain forte, Aventis Pharma, Hoevelaken, The Netherlands) (exclusion of myogenic pain) 17 (figure 1).

Exclusion criteria were:
- Systemic rheumatic disease
- Bony ankylosis of the TMJ
- Incompetence to speak the Dutch or English language
- Pregnancy
- Concurrent use of anti-inflammatory medication, steroids, muscle relaxants or antidepressants
- Medical contraindication
- Unwillingness to receive one of the study treatments
- Prior open TMJ surgery

Sample size calculation
A sample size calculation was performed for the main outcome measure. In order to obtain a power of 0.80, 72 patients were required (estimated effect size = 0.20, 5 predictors), which resulted in 36 patients per group. To account for loss of information from dropouts, a 10% increase in sample size resulted in two groups of 40 patients each. Predictors included in the model were treatment, age, gender, duration of symptoms before inclusion and mouth opening.

Participants
80 patients who obeyed the inclusion criteria were included and randomly allocated to one of the two treatment groups (table 1). One group received arthrocentesis as initial treatment (11 man and 29 woman, mean age 38.3, SD 15.9) and the other group was treated as usual (9 man and 31 woman, mean age 36.1, SD 14.3). A random sequence was generated by an independent co-worker using a randomization software package (Statsdirect version 2.7.7, StatsDirect Ltd., Cheshire, United Kingdom). Treatment allocation was concealed from participants, treating clinician and researchers in sealed envelopes until the enrolment procedure was completed. At this point an independent nurse revealed the group allocation. Follow-up assessments were three (T1), 12 (T2) and 26 (T3) weeks after the last treatment session. Prior to the treatment (T0) and at every follow-up
assessment, pain intensity was measured at rest and during maximum mouth opening (MMO) using a visual analogue scale (VAS, 0-100 mm). MMO (interincisor distance in mm) was measured as well. These measurements were performed by one examiner who was ignorant of the treatment allocation. The examiner had no contact with the participants other than during the measurement procedures. Furthermore, at baseline and every follow-up assessment, patients were asked to fill out several questionnaires concerning the impact of function impairment on their quality of life. This is described in more detail below. Additionally, at baseline a psychosocial profile was assessed. X-ray examination was performed at baseline and after 26 weeks follow-up (T3) in order to detect any bony changes during follow-up period using orthopantomography (OPT), transpharyngeal recordings according to Parma, and transcranial radiographs according to Schüller.
Table 1. Patients’ baseline characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Arthrocentesis (n=40)</th>
<th>Care as usual (n=40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (female), n (%)</td>
<td>29 (72.5)</td>
<td>31 (77.5)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, years</td>
<td>38.3 (15.9)</td>
<td>36.1 (14.3)</td>
</tr>
<tr>
<td>VAS rest</td>
<td>19.3 (21.5)</td>
<td>24.5 (27.5)</td>
</tr>
<tr>
<td>VAS movement</td>
<td>51.6 (18.9)</td>
<td>54.0 (25.4)</td>
</tr>
<tr>
<td>MMO</td>
<td>34.7 (8.2)</td>
<td>38.6 (8.8)</td>
</tr>
<tr>
<td>MFIQ</td>
<td>0.5 (0.1)</td>
<td>0.5 (0.2)</td>
</tr>
<tr>
<td>SCL-90</td>
<td>116.5 (28.1)</td>
<td>123.8 (36.1)</td>
</tr>
<tr>
<td>OHIP-49</td>
<td>26.6 (21.0)</td>
<td>35.7 (28.4)</td>
</tr>
<tr>
<td>RAND-36</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical functioning</td>
<td>27.2 (5.7)</td>
<td>26.2 (6.3)</td>
</tr>
<tr>
<td>Social functioning</td>
<td>8.9 (1.7)</td>
<td>8.3 (1.9)</td>
</tr>
<tr>
<td>Role limitations (physical problem)</td>
<td>1.0 (2.1)</td>
<td>2.8 (3.2)</td>
</tr>
<tr>
<td>Role limitations (emotional problem)</td>
<td>0.7 (1.6)</td>
<td>2.1 (2.5)</td>
</tr>
<tr>
<td>Mental health</td>
<td>23.4 (4.6)</td>
<td>23.5 (4.8)</td>
</tr>
<tr>
<td>Vitality</td>
<td>15.9 (3.7)</td>
<td>16.5 (3.6)</td>
</tr>
<tr>
<td>Pain</td>
<td>43.5 (9.5)</td>
<td>41.4 (11.1)</td>
</tr>
<tr>
<td>General health perception</td>
<td>18.1 (3.2)</td>
<td>18.6 (4.5)</td>
</tr>
<tr>
<td>Health change</td>
<td>3.2 (1.0)</td>
<td>3.2 (0.8)</td>
</tr>
</tbody>
</table>

SD = standard deviation

Treatment procedures

Participants were randomly allocated to the arthrocentesis group, where arthrocentesis was performed as initial treatment, or to the conservative treatment group (figure 1). At the start of the arthrocentesis procedure, anaesthesia of the TMJ was achieved using intra-articular anaesthesia and anaesthesia of the overlying skin (Ultracain forte, Aventis Pharma, Hoevelaken, The Netherlands). Thereafter, two 18 gauge needles were inserted in the upper joint space, and communication between the needles was established. The joint was then lavaged with at least 300 ml isotonic saline chloride. No additional substances or drugs were applied. All arthrocentesis procedures were performed by the same clinician (BS). Participants who were assigned to the conservative treatment group were treated following a strict protocol (figure 2). First they were instructed to use a soft diet (A) for at least three weeks. After two weeks the effect of the soft diet was evaluated. If the symptoms had improved (improvement of at least 20 mm on the VAS during movement, compared to baseline \(^{18,19}\)), the soft diet was continued for another four weeks. If the patient complained about a restricted mouth opening, additional physical therapy (B) was offered which involved a home exercise program, joint mobilisation, and physical treatment modalities. The physical treatment was performed once a week and included ‘joint play’, stretching and dry needling of trigger points. If the pain had not improved, an intra-oral hard acrylic splint (C) was made, and patients were instructed to use this
oral appliance during the night, and one or two hours during the day to get used to the unusual jaw position. Treatments A and C were performed by the same clinician (JHS), and all physical treatments (B) were performed by two physiotherapist who were specialized in head and neck therapy. The duration of the conservative treatment program was six weeks in total. The participants of both groups were instructed to use pain medication (Ibuprofen 600mg) when needed.

**Figure 2. Flow chart of the conservative treatment protocol**

**Outcomes**
Primary outcome variables were pain in the TMJ, at rest and during movement, and the mandibular range of motion. Pain was scored using a continuous scale (0-100mm VAS), and mandibular range of motion was determined using the maximum active mouth opening (MMO, interincisor distance in mm). Secondary outcome measurements were: mandibular function impairment (assessed with the Mandibular Function Impairment Questionnaire; MFIQ), oral health related quality of life (assessed using the Oral Health Impact Profile; OHIP-49), and quality of life in general (assessed with the RAND-36 health survey). Patients were asked to fill out these questionnaires at baseline and at every follow-up evaluation. Any bony changes were scored as ordinal variable on OPT, Parma and Schüller recordings at baseline and after 26 weeks. Potential confounding psychosocial factors
related with chronic pain were scored using the 90-item Symptom Checklist (SCL-90) which patients were asked to fill out at baseline. All questionnaires were checked on missing values when collected to make sure that they were filled out completely.

**Statistical Procedures**

During data analysis, the analyst (LMV) was ignorant of which patients had received arthrocentesis and which patients had received conservative treatment. For all analyses a significance level of alpha = 0.05 was used. In order to create effect models, univariate analyses were performed for each variable. If variables were found to be significant, the P-value was used in further development of the model. Predictors with a P-value less than or equal to 0.1 were simultaneously entered into a multivariate model. To correct for the dependency of repeated measurements in the longitudinal data analysis, generalized estimated equations (GEE) multivariate models were used. All procedures were performed in Stata version 11.0 (Stata Corp., College Station, Texas, USA). Analyses were executed using the intention-to-treat principle. GEE models were designed for MMO, VAS at rest, and VAS during movement (figure 3). Time was defined in days after the last treatment session, based on the actual consultation dates. For all analyses, treatment group (i.e. arthrocentesis vs. conservative treatment) was the first predictor variable to be entered into the model. The hypothesis of interest was whether the pattern of progression of the outcome variables over time differed between the two treatment groups.

**Results**

A total of 80 patients were included and randomly allocated to one of the two treatment groups, which consisted of 40 patients each. In both groups, four patients dropped out. Furthermore, at T1 six patients (arthrocentesis n=2, conservative treatment n=4) did not show at follow-up, at T2 seven patients (arthrocentesis n=4, conservative treatment n=3), of which three were the same as at T1, and at T3 a total of 15 patients (arthrocentesis n=9, conservative treatment n=6) did not show at follow-up, of which 5 had not showed at one or both of the previous assessments as well. Four patients reported mild transient swelling of the TMJ immediately after arthrocentesis.

In the conservative treatment group all patients received a soft diet (A). Seven patients received additional physical therapy (A+B), 15 patients received additional splint therapy (A+C), and two patients received all three treatment modalities (A+B+C).

After 26 weeks, the TMJ pain (mm VAS at rest, and mm VAS during movement) had comparably declined in both groups and MMO (mm interincisor distance) had slightly improved. GEE models showed significant differences between arthrocentesis as initial treatment and conservative treatment, indicating that the arthrocentesis group improved more rapidly with regard to TMJ pain and MMO compared to care as usual.

VAS score at rest was associated significantly with MFIQ¬, and SCL-90 scores. Furthermore, RAND-36 (Social functioning) was added as a confounder. No effect modifiers were added to the model. VAS during movement was associated with MFIQ¬ scores, which were added as predictors. No confounders or effect modifiers were added. A significant association of MMO was found with MFIQ scores, therefore MFIQ scores
were added to the model. No confounders or effect modifiers were identified. Estimated regression coefficients and P-values for the different GEE models are displayed in table 2. No significant bony changes were seen on the X-rays during the follow-up period.
### Table 2. Regression Coefficients and P-values as derived from GEE Analysis

<table>
<thead>
<tr>
<th>Model</th>
<th>Variable</th>
<th>Primary multivariate model</th>
<th>Adjusted for confounding</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>β (95% CI)</td>
<td>P-value</td>
</tr>
<tr>
<td>MMO</td>
<td>Treatment</td>
<td>-2.70 (-5.35, -0.06)</td>
<td>0.045</td>
</tr>
<tr>
<td></td>
<td>MFIQ</td>
<td>-11.42 (-16.34, -6.50)</td>
<td>0.000</td>
</tr>
<tr>
<td>VAS score rest</td>
<td>Treatment</td>
<td>-9.83 (-16.41, -3.25)</td>
<td>0.003</td>
</tr>
<tr>
<td></td>
<td>MFIQ</td>
<td>36.90 (23.74, 50.05)</td>
<td>0.000</td>
</tr>
<tr>
<td></td>
<td>SCL90</td>
<td>0.17 (0.07, 0.28)</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>RAND-36 (Social functioning)</td>
<td>-1.54 (-3.63, 0.55)</td>
<td>0.149</td>
</tr>
<tr>
<td></td>
<td>Treatment</td>
<td>-10.76 (-17.75, -3.77)</td>
<td>0.003</td>
</tr>
<tr>
<td></td>
<td>MFIQ</td>
<td>78.23 (64.19, 92.26)</td>
<td>0.000</td>
</tr>
</tbody>
</table>

\(\beta\) = regression coefficient  
CI = confidence interval

### Discussion

The results of this study indicate that progression in TMJ pain reduction and improvements of the mandibular range of motion differ between arthrocentesis as initial treatment, and conservative treatment. Improvement of the primary outcome variables seems to be most explicit relatively short after arthrocentesis as initial treatment, whereas progression after conservative treatment seems to occur more gradually. However, over time, both treatment modalities appear to achieve comparable outcomes.

These findings are consistent with currently available evidence that arthrocentesis is an efficient and effective treatment modality, although these studies did not investigate arthrocentesis as initial treatment.\(^{14,15}\) With regard to the effectiveness of the conservative treatment approach, the results of this study confirm that in particular TMJ pain improves over time.\(^{6}\) However, conservative treatment, and in particular splint therapy, may be more effective when combined with arthrocentesis.\(^{7}\)

The relatively rapid improvement after arthrocentesis compared to conservative treatment may be explained by the immediate removal of pro-inflammatory cytokins, matrix degrading enzymes, reactive cytokines and degeneration products. Hereby, the joint is given a head start in the recuperation process. However, favourable substances like hyaluronic acid and lubricin may be removed from the joint space as well by the lavage therapy.\(^{8}\) Furthermore, arthrocentesis is less dependent on patient compliance compared to conservative treatment since the treatment consists of a one-time lavage of the joint that is performed by the treating clinician. Possibly, this may have contributed to the rapid improvement after arthrocentesis as well.
Strengths of this study were the randomized allocation to the different treatment groups, the blinded follow-up observations and analyses, a sufficient sample size, and the extended psychosocial patient profiling by means of several validated questionnaires. The main weaknesses of this study were the generalizability, and the relatively large number of patients lost to follow-up.

The generalizability of this trial may be limited due to the inclusion procedure. Patients were selected using intra-articular anaesthesia, which excluded patients with mainly myogenous symptoms. Therefore, the results of this study may be representative for a select group of TMD patients, since TMD patients usually present mixed, arthrogenous and myogenous, symptoms.  

In this trial, the number of patients lost to follow-up was equally distributed among the two treatment groups. Therefore, association of patient compliance and treatment group is unlikely. However data about reasons for lost to follow-up were not collected. Since the number of patients lost to follow-up increases with time and in both groups symptoms tend to decrease over time, possibly compliance is associated more with the severity of the symptoms.

At baseline and at 26 weeks, X-ray examinations were performed in order to detect any bony changes. Differences between the two treatment groups were not likely to occur, since treatment modality seems to have no significant influence on subchondral bone modulations. Furthermore, changes that may occur during 26 weeks follow-up, as in the present study, are relatively small. Often more sophisticated imaging techniques are used for TMJ evaluation, such as Magnetic Resonance Imaging (MRI) and Cone-Beam Computed Tomography (CBCT). However, in order to detect the relatively small intra-articular bony changes, CBCT may not be accurate since its precision is limited by the voxel size. Furthermore, MRI is mainly used for evaluation of the soft tissues.

Contemporary therapeutic strategy consists of initially conservative treatment, which is followed by minimally invasive techniques like arthrocentesis, when patients are non-responsive to this approach and the arthropathy appears to be persistent. However, in this study arthrocentesis was used as initial therapy. Since the results of this study indicate that arthrocentesis as initial treatment reduces pain and functional impairment more rapidly than non-invasive therapy with low morbidity, the statement that non-invasive treatment should be used as initial treatment because it would be less harmful, is at least doubtful.

Conclusion

Arthrocentesis as initial treatment reduces pain and functional impairment more rapidly compared to conventional initial therapy. Progression of the reduction of TMJ pain and functional impairment seems to be most explicit relatively short after arthrocentesis as initial treatment, whereas progression after conservative treatment seems to develop more gradually. However, over time, both treatment modalities appear to be equally effective.
References


