Cost Effectiveness of Arthrocentesis Compared to Conservative Therapy for Arthralgia of the Temporomandibular Joint: A Randomized Controlled Trial

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Aims: To determine the cost effectiveness and cost utility of arthrocentesis as an initial treatment for temporomandibular joint (TMJ) arthralgia compared to usual care. **Methods:** A two-armed, parallel-design, randomized controlled trial (RCT) was conducted in the Netherlands from January 2009 to June 2012 that included patients with TMJ arthralgia. Patients were randomly allocated to arthrocentesis (n = 40) or usual care (n = 40) for initial treatment. Arthrocentesis consisted of rinsing the intra-articular space with isotonic saline, and usual care included a soft diet, physical therapy, and splint therapy. The duration of the usual care program was 6 weeks, and follow-up was conducted 3, 12, and 26 weeks after its completion. Generalized estimated equation multivariate models were assessed in order to correct for the dependency of repeated measurements in the longitudinal data analysis. An independent samples *t* test was used to compare the arthrocentesis group with the usual care group for TMJ pain after 26 weeks. Cost effectiveness (total cost from a societal view) was related to TMJ pain (as measured on a visual analog scale [0 to 100 mm]) and to cost utility (quality-adjusted life years). **Results:** TMJ pain declined more quickly in the arthrocentesis group (n = 36) than in the usual care group (n = 36) (regression coefficient β = –10.76; 95% confidence interval [CI] = –17.75 to –3.77; *P* = .003). The estimated mean total (ie, societal) cost over 26 weeks was €589 (US $795) in the arthrocentesis group and €1,680 (US $2,266) in the usual care group. Arthrocentesis was associated with a lower mean cost and better health outcomes than usual care in 98% and 95% of the bootstrap simulations, respectively. **Conclusion:** The results of this study suggest that, from an economical perspective, arthrocentesis may be superior to usual care for the initial treatment of TMJ pain, as it had better health outcomes and lower costs than usual care. *J Oral Facial Pain Headache 2018;32:198–207. doi: 10.11607/ofph.1457*

Keywords: *arthralgia, arthrocentesis, cost effectiveness, initial therapy, RCT, TMD*

Temporomandibular joint (TMJ) pain is a relatively common condition that occurs in approximately 10% of the population over 18 years of age,[1,2] primarily in young and middle-aged adults and particularly affecting young women.[1] Pain in the TMJ region has considerable impact on daily activities[3–5] and is associated with depression, anxiety, and somatization, which lead to further limitation of daily activities.[4,6,7] Patients with TMJ disorders, including patients with TMJ pain, make more use of health care services and consequently generate higher costs compared to healthy controls.[8]

Current initial therapeutic strategies for TMJ arthralgia usually focus on reducing joint load with a soft diet, mandibular movement exercises, and use of an oral appliance.[9,10] The oral appliance usually consists of a hard-acrylic occlusal splint that, like an orthopedic insole, guides the joint into a slightly different position during loading. This process is time consuming and depends on patient compliance, and the duration—as well as the outcome—are not always satisfactory. Consequently, this approach includes multiple visits to the clinic in order to monitor the clinical course and to optimize patient compliance.

If patients do not respond sufficiently to the conservative treatment and the arthralgia persists, the conservative approach is typically followed by minimally invasive techniques such as arthrocentesis. Arthrocentesis, or joint lavage, directly removes degradation products from the joint cavity and also eliminates inflammatory mediators.[11] Success rates of up to 91% have been reported for the use of arthrocentesis in patients with arthralgia due to permanent displacement of the intra-articular disc.[12] Although the evidence is not definite, arthrocentesis seems to have a beneficial effect on pain and on impairment of mandibular function[13–18] with little morbidity.[17]

Since the evidence that loading of the articular surfaces is reduced by conservative treatment is not conclusive, and since arthrocentesis is considered a highly efficient treatment modality in patients who did not respond sufficiently to conservative treatment, it may be reasonable to apply minimally invasive techniques at an earlier stage for TMJ disorders. Moreover, it is known that symptoms often disappear over time.[19,20] Therefore, the goal of the treatment should be to shorten the symptomatic period and reduce the intensity of the symptoms during this period as much as possible. Adequate reduction of TMJ pain may prevent the development of chronic pain, reduce the impact on daily activities, and reduce the need for additional health care utilization.[21] Therefore, using arthrocentesis as an initial therapy for TMJ arthralgia may reduce medical and nonmedical costs both directly and indirectly, as it seems to immediately reduce inflammatory and pain mediators and may ultimately prevent the disease from remaining symptomatic. To date, no investigations have addressed the cost effectiveness of arthrocentesis as the initial treatment compared to usual care. Therefore, the aim of this study was to determine the cost effectiveness and cost utility of arthrocentesis as an initial treatment for TMJ arthralgia compared to usual care.

Materials and Methods

This two-armed, parallel-design, randomized controlled trial (RCT) was performed at the University Medical Center Groningen (UMCG), University of Groningen, the Netherlands from January 2009 to June 2012. Approval of the ethical commission of the UMCG was obtained prior to patient recruitment, and the trial was registered within the Dutch Trial register (http://www.trialregister.nl, Dutch Cochrane Centre, Cochrane Collaboration). This article follows CONSORT reporting guidelines for two-armed, parallel-design RCTs. The clinical results of this trial have been published.[22]

Participants and Procedures

Patients with the diagnosis of arthralgia according to the revised Research Diagnostic Criteria for Temporomandibular Disorders[23] were recruited from the Department of Oral and Maxillofacial Surgery of the UMCG. The diagnosis of all patients was confirmed by one examiner (B.S.). Thereafter, patients were informed about the natural course of the disease (ie, pain reduction over time in about two-thirds of cases),[19] the interventions of both treatment groups (the procedure as well as the expected outcomes), the aim and protocols of the study, possible disadvantages, the insurance of the hospital, how confidential data were handled, that participation was voluntary, how additional information could be retrieved, and what it means to sign a written informed consent form. All patients provided written informed consent. The main objective of the therapeutic approaches investigated in the present study was to reduce symptoms, leading to the formulation of the following inclusion criteria: Age 16 years or older; pain in the pre-auricular region provoked by mandibular movement and function; persistent pain after 2 weeks of medication (eg, ibuprofen 600 mg three times daily), thus excluding acute inflammatory pain; and disappearance of pain following intra-articular injection with Ultracain forte (Aventis Pharma), thus excluding an extra-articular origin of pain.[24] The exclusion criteria were: systemic diseases such as rheumatoid arthritis; intra-articular ankylosis; a medical history of open surgery in the TMJ; use of anti-inflammatory medication, steroids, muscle relaxants, or antidepressants; pregnancy; inability to speak the English or Dutch languages; contraindication concerning medical history; and refusal to receive one of the treatment options of the trial.

Patients remaining after application of the inclusion and exclusion criteria were allocated randomly to one of the two treatment groups (1:1) according to a computer-generated sequence. One group received usual care as initial treatment, and the other group received arthrocentesis. Patient allocation was concealed (sealed envelopes) from the participants and from the treating clinician and examiner who performed all enrollment procedures. At this point, patient allocation was revealed by an independent nurse. Follow-up assessments were performed at baseline (prior to the treatment) (T_0) and at 3 (T_1), 12 (T_2), and 26 (T_3) weeks following the final treatment session (Fig 1).

Intervention Groups

Patients who were allocated to the arthrocentesis group were treated under local anesthesia. Intra-articular anesthesia (Ultracain forte) of the TMJ and anesthesia of the overlying skin were performed at the start of the arthrocentesis procedure. Afterwards,

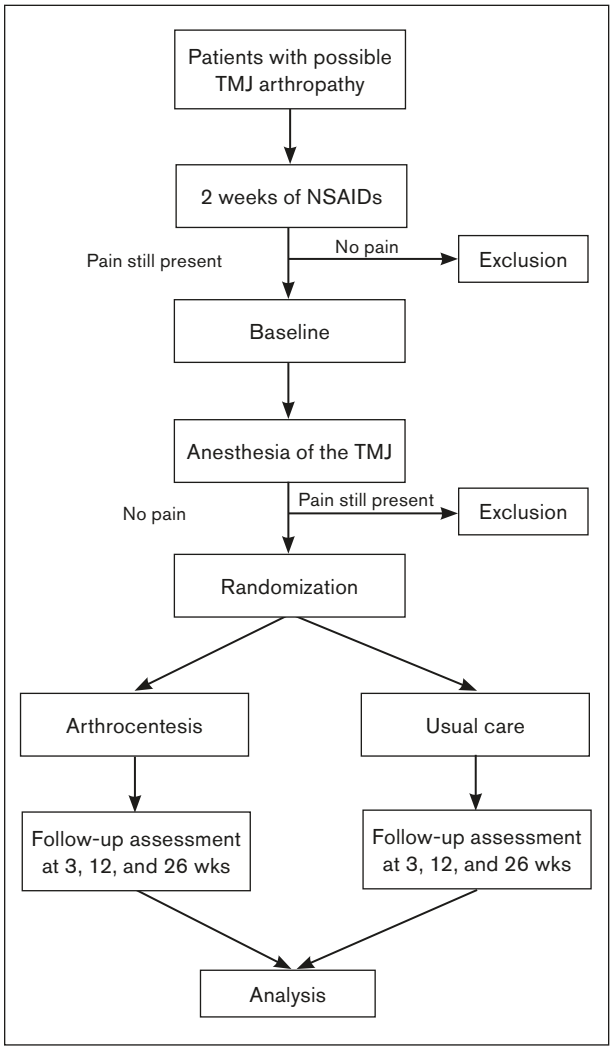

Fig 1 Flow diagram of participant selection. NSAIDs = nonsteroidal anti-inflammatory drug.

two 18-gauge needles were inserted into the upper joint space of the TMJ, and communication between the needles was established. Subsequently, the joint was rinsed with 300 mL or more of isotonic saline chloride. Application of additional substances or drugs was not performed. The duration of the procedure was approximately 30 minutes. The same clinician (B.S.) performed all arthrocentesis procedures.

The treatment procedure in the usual care group followed a strict protocol, including weekly visitation, with a total duration of 6 weeks (Fig 2). First, patients were instructed to follow a soft diet (A) for a minimum of 3 weeks. After 2 weeks, the effect of this diet was evaluated. In case the pain had decreased (at least 20-mm improvement on a 0- to 100-mm visual analog scale [VAS] during movement compared to baseline[25,26] measured by a blinded examiner [L.M.V.] using a ruler), patients continued the soft diet for another 4 weeks. If a patient complained about a restricted mandibular movement, additional physical therapy (B) was applied that involved a home exercise program, physical treatment modalities, and joint mobilization. The home exercise program consisted of hold-and-relax exercises for lateral and opening movements using tapered rubber corks of different diameters. If applicable, physical treatment was conducted once a week until the end of the 6-week period and included stretching, joint play, and dry needling in case of trigger points. If the pain had not decreased, an intraoral hard acrylic splint was made with the patient's jaw in centric relation (C), and patients were instructed to wear this oral appliance 1 or 2 hours during the day to get used to the unusual jaw position and during the night until the end of the 6-week period. The occlusion of the appliance was checked at every treatment session and adjusted if needed. Treatment modalities A and C were exclusively performed by a clinician (J.H.S.), and all physical treatments (B) were performed by two physiotherapists who were specialized in head and neck therapy. The conservative treatment program took 6 weeks in total. Participants in both groups were instructed to use pain medication (ibuprofen 600 mg) when needed, but only if it had an additional effect on pain relief.

Measures

At baseline and at each follow-up assessment, pain intensity during maximum mouth opening was measured using a 0- to 100-mm VAS, with 0 mm defined as no pain and 100 mm defined as the worst pain possible. All measurements were collected by the same examiner, who was blind to treatment allocation. There was no contact between the examiner and the participants other than during these measurements.

Prior to the treatment (T_0) and subsequently at every follow-up assessment, participants were asked to fill out two questionnaires concerning the economical aspects of treatment. Most of the information was collected with a detailed questionnaire on costs that focused on health care consumption during the previous 3, 9, and 14 weeks. Furthermore, the EuroQol-5D (EQ-5D), a standardized five-item questionnaire on health status, was used to estimate health values from a societal perspective[27]; it assesses contact with health care professionals and absence from work. A 90-item Symptom Checklist (SCL-90)[28] was used to score potential confounding psychosocial factors related to chronic pain. Patients were asked to fill out this checklist at baseline. The mandibular function impairment questionnaire (MFIQ) was used to determine functional impairment.[21] All costs were based on the price level of the euro in 2011.

At the start of the study, patients were asked to report all adverse events or reactions during the entire duration of the study. Three weeks after the last

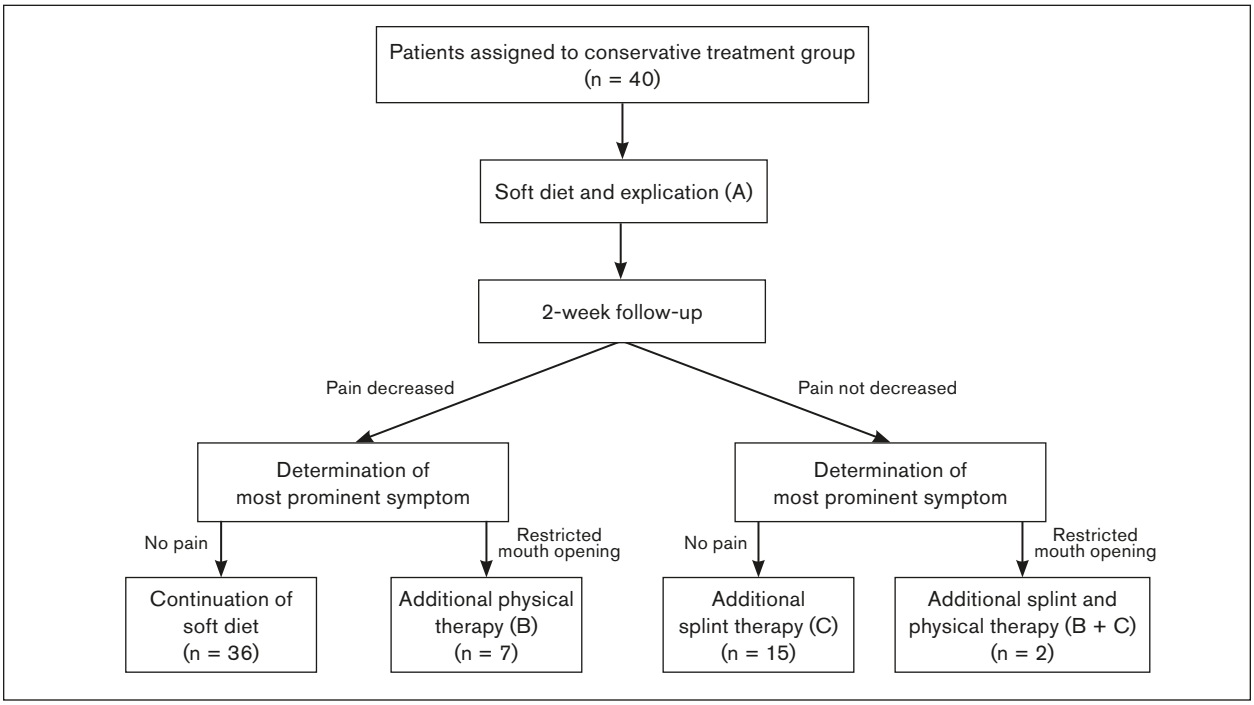

Fig 2 Flow chart of the usual care protocol. A: Explanation of the pathology was provided in order to enhance patient understanding and thereby improve compliance. B: Physical therapy was performed once a week and included joint play, stretching, and dry needling of trigger points. C: Splint therapy consisted of an intraoral hard acrylic splint, which patients were instructed to use during the night and 1 or 2 hours during the day to get used to the unusual jaw position.

treatment session (T_1), patients were specifically asked for any adverse events or reactions.

Additionally, at baseline and the 26-week follow-up (T_3), x-ray examination was performed in order to detect changes in the subchondral bone during the follow-up period. Bony changes reflected in flattening of the articular surface of the condyle, subcortical sclerosis or cysts, surface erosion, osteophytes, generalized sclerosis, and/or loose joint bodies were scored as ordinal variables by the same examiner (L.M.V.) on orthopantomographs (OPT), trans-pharyngeal radiographs (Parma), and transcranial recordings (Schüller).

Sample Size

The study was powered for a comparison of pain intensity between the two treatment groups. To test a 2-tailed hypothesis with 80% power, a 5% significance level, an estimated effect size of 0.20, and an anticipated dropout rate of 10%, a sample size of 40 patients per group was required. Treatment, gender, age, mouth opening, and duration of symptoms before inclusion were included in the model as predictors.

Statistical Analyses

The analyst (L.M.V.) was ignorant of the randomization of the patients during the analysis. In order to create an effect model for TMJ pain, univariate analyses were performed for each variable. Possible predictors were gender, age, mouth opening, and duration of symptoms before inclusion. If a predictor appeared to be significant, further development of the model was performed using the associated *P* value. For all analyses, a significance level of $\alpha = .05$ was used. Predictors with a *P* value ≤ .1 were simultaneously included in a multivariate model. The hypothesis of interest was that the pattern of progression over time of the outcome variables would be the same in both groups. In order to correct for the dependency of repeated measurements in the longitudinal data analysis, generalized estimated equation (GEE) multivariate models were assessed using Stata version 11.0 (Stata Corp). Time was based on the actual consultation dates, measured in days after the last treatment session. In all analyses, the intention-to-treat principle was used. An independent samples *t* test (using SPSS version 18.0) was used to compare TMJ pain in the arthrocentesis group to TMJ pain in the usual care group after 26 weeks.

Cost-Effectiveness Analysis

Cost analyses of arthrocentesis and usual care were conducted from a societal perspective, and direct medical, direct nonmedical, and indirect nonmedical costs were registered. The various cost categories and cost types that were included in the analyses are presented in Table 1.

Table 1 Cost Categories and Cost Types

Direct medical costs	Direct nonmedical costs	Indirect nonmedical costs
Arthrocentesis, usual care	Informal care	Productivity losses (unpaid and paid work)
Outpatient care	Out-of-pocket costs	
General health care		
Medication		

Table 2 Patient Characteristics at Baseline

Characteristics	Arthrocentesis (n = 40)	Usual care (n = 40)	*P* value
Female, n (%)	29 (72.5)	31 (77.5)	.797
	Mean (SD)	**Mean (SD)**	
Age (y)	38.3 (15.9)	36.1 (14.3)	.615
Mean VAS score (rest)	19.3 (21.5)	24.5 (27.5)	.358
Mean VAS score (MMO)	51.6 (18.9)	54.0 (25.4)	.648
MFIQ	0.5 (0.1)	0.5 (0.2)	.701
SCL-90	116.5 (28.1)	123.8 (36.1)	.992

VAS = visual analog scale; MMO = maximum mouth opening; MFIQ = mandibular function impairment questionnaire; SCL-90 = Symptom Checklist 90.

Assessment of costs included materials used per patient (eg, needles, anesthesia, and splint), personnel wages, and the duration of the procedures applied. Costs of informal care were based on the monetary valuation of the time invested by relatives or acquaintances in helping or assisting the patient (eg, household work, accompanying patients to health care professionals) by using opportunity costs (official minimum wage used to value caregiving time). Out-of-pocket costs were additional costs generated by the patients, such as the costs of cancelling holidays or other planned activities. The indirect costs of productivity losses due to disease-related absence from work were estimated using the friction-cost method,[29] and compensation mechanisms were taken into account when estimating productivity costs.[30] In addition, costs were estimated for patients who were present at work but could not function optimally due to the experienced health problems (presenteeism). The costs related to changes in the amount of voluntary (unpaid) work conducted by patients were also considered.

The price of one unit of each included cost type was primarily based on Dutch standard prices.[31] True costs of used resources were estimated when standard prices were not available. All unit prices were based on the price level of the euro in 2011. Reference prices established for previous years were adjusted to 2011 prices by applying the consumer price index.

The cost-effectiveness analysis was performed using costs (€) and pain during maximum mouth opening (measured on a 0- to 100-mm VAS).[32] A cost-utility analysis was also conducted with quality-adjusted life years (QALYs) as the primary outcome measure. Health-related preferences were determined using the algorithm according to Dolan and the raw EQ-5D scores.[33] Incremental cost-effectiveness ratios (ICERs) were calculated for each of the bootstrap iterations[34] (2,000 in the present study), and simulated values of the mean estimates for the cost and outcome differences were added to the cost-effectiveness plane.[32,35] Economical analyses were conducted using SPSS version 18.0 and R (R Foundation for Statistical Computing, 2005).

Results

A total of 80 patients were included and randomly divided into two treatment groups of 40 patients each. As the initial treatment, one group received usual care (9 men and 31 women, mean age ± standard deviation [SD] 36.1 ± 14.3 years; Table 2), and the other group received arthrocentesis (11 men and 29 women, mean ± SD age 38.3 ± 15.9 years).

Usual care started with a soft diet (A) for all patients. Additional physical therapy (A + B) was applied in 7 of these patients, additional splint therapy (A + C) was applied in 15 patients, and 2 patients received all three treatment modalities (A + B + C). Four patients dropped out of each group (arthrocentesis = 36; usual care = 36). In the usual care group, two patients dropped out during the first 2 weeks of soft diet treatment, and two other patients dropped out after 6 weeks of soft diet treatment. Furthermore, at T_1, six patients (two arthrocentesis, four usual care) did not show at follow-up. At T_2, seven patients (four arthrocentesis, three usual care) did not show (three patients were the same as at T_1) at follow-up. At T_3, a total of 15 patients (9 arthrocentesis, 6 usual care) did not show at follow-up (5 had not shown at one or both of the previous follow-up assessments).

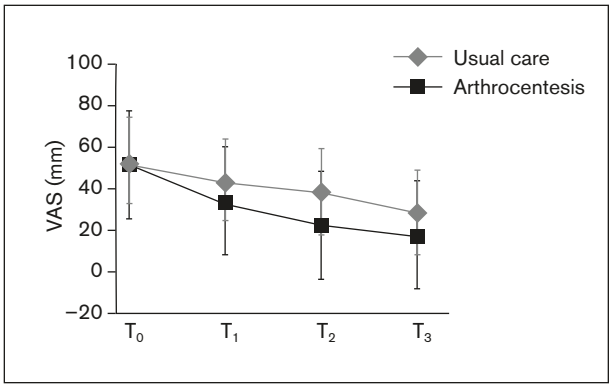

Fig 3 Progression of TMJ pain during maximum mouth opening over 26 weeks according to visual analog scale (VAS). Measurements were taken prior to treatment (T_0: arthrocentesis n = 36, usual care n = 36) and at 3 (T_1: arthrocentesis n = 34, usual care n = 32), 12 (T_2: arthrocentesis n = 32, usual care n = 33), and 26 (T_3: arthrocentesis n = 27, usual care n = 30) weeks posttreatment. Means and standard deviations (SD) are given.

Table 3 Mean Total Costs During the Study (26 weeks) in Euros (€)

	Arthrocentesis		Usual care			
Measurement period	n	Mean total cost	n	Mean total cost	Mean difference in cost	(95% CI)
T_0–T_1	28	503	25	816	–313	(–624 to –5)
T_1–T_2	27	230	21	567	–337	(–740 to 12)
T_2–T_3	16	106	17	312	–206	(–487 to 29)
T_0–T_3[a]	13	589	11	1,680	–1,091	(–1720 to –565)

[a]Estimates for T_0–T_3 were based on data from patients who were included in the cost-effectiveness analyses (bootstrap).

No changes of the subchondral bone were seen on the radiographs during the follow-up period.

Clinical Effectiveness

After 26 weeks, TMJ pain had declined in both groups (Fig 3) and did not differ significantly between them (P = .057). The GEE model of clinical effectiveness based on intention-to-treat uncovered significant differences between the use of arthrocentesis and usual care as initial treatment with regard to the pattern of progression of pain (regression coefficient β = –10.76; 95% confidence interval [CI] = –17.75 to –3.77; P = .003). The predictors gender, age, mouth opening, and duration of symptoms before inclusion did not significantly influence the outcome. There was no significant association between VAS pain during maximum mouth opening and the SCL-90 scores (P > .05). Confounders and effect modifiers could not be identified and were therefore not added to the GEE models. In the GEE model, time was defined in days posttreatment based on the actual consultation dates.

One patient in the usual care group requested additional treatment after the follow-up period of 26 weeks.

Reported Adverse Events and Reactions

No adverse events or reactions were reported in the usual care group or in the arthrocentesis group; however, some of the arthrocentesis patients reported mild and transient adverse reactions directly following the arthrocentesis: a slight increase in pain (n = 3) and mild swelling in the TMJ region (n = 1).

Cost Effectiveness

The estimated mean total (societal) cost over 26 weeks (T_0 to T_3) was €589 (US $795) in the arthrocentesis group and €1,680 (US $2,266) in the usual care group. An overview of the mean total costs generated during the various measurement periods of the study is provided in Table 3. The mean total cost in the arthrocentesis group was lower than that in the usual care group for all measurement periods.

Utilization of health care services and the percentage of patients using each cost type during the study are provided in Table 4, as are the various medical and nonmedical costs generated by both groups during the treatment and follow-up periods. Means of the different cost types were based on all patients in each group. If a patient did not make use of a specific cost type (or information was missing, which was rare on item level), costs of €0 were applied when calculating group means. The costs of the interventions had a large impact on total cost in both groups. The mean total cost of arthrocentesis was €205 (US $274) per patient, and the mean cost of usual care was €462 (US $618) per patient.

Of the costs other than intervention costs, the ones that had the most impact on total cost were visits to the outpatient clinic, informal care, and presenteeism. The differences between groups were most pronounced for the costs of the interventions and the costs of presenteeism, which were both higher for patients in the usual care group.

The mean QALY values of both groups were lower than QALY values at T_0, with better outcomes for

Table 4 Medical and Nonmedical Costs During the Study (26 weeks) in Euros (€)

	Arthrocentesis (n = 30)		Usual care (n = 31)	
Cost types	Mean cost (SD)	%	Mean cost (SD)	%
Interventions				
Personnel, materials, etc	205 (0)	100	462 (531)	81
Outpatient care				
Outpatient clinic	221 (131)	87	243 (193)	87
Emergency care	0 (–)	0	0 (–)	0
Other outpatient care	7 (41)	3	19 (107)	3
General health care				
General practitioner	2 (7)	7	5 (17)	10
Dentist	26 (69)	20	24 (93)	10
Physiotherapist	27 (100)	10	26 (121)	10
Speech therapist	1 (6)	3	0 (–)	0
Alternative health care	0 (–)	0	53 (293)	3
Other general health care	0 (–)	0	0 (–)	3
Medication				
Prescribed medication	12 (36)	60	2 (4)	26
Nonprescribed medication	2 (12)	3	4 (18)	19
Nonmedical costs				
Informal care	183 (586)	30	173 (497)	29
Out-of-pocket costs	36 (157)	17	17 (43)	26
Productivity losses				
Unpaid work	0 (–)	0	0 (–)	0
Paid work	18 (60)	10	39 (216)	3
Presenteeism	6 (27)	7	146 (452)	32

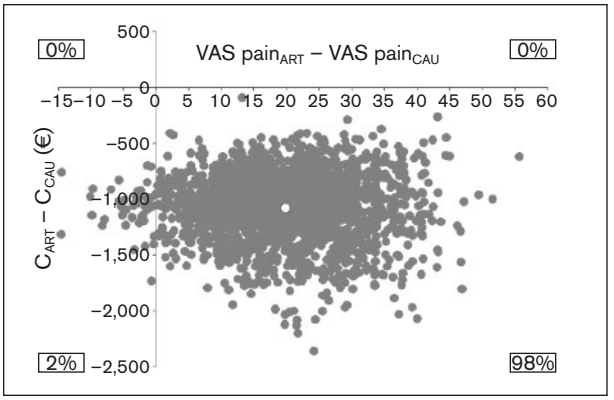

Fig 4 The cost-effectiveness analysis revealed that arthrocentesis dominated usual care in 98% of the bootstrap simulations. Incremental cost-effectiveness ratios (ICERs) were calculated for 2,000 bootstrap iterations. Simulated mean estimates of the costs (costs of arthrocentesis [€] – costs of usual care [€]) and TMJ pain differences (improvement on pain scale [VAS]*–1) are presented in the cost-effectiveness plane. C_{art} = cost of arthrocentesis; C_{cau} = cost of usual care; VAS $pain_{art}$ = TMJ pain with arthrocentesis; VAS $pain_{cau}$ = TMJ pain with usual care.

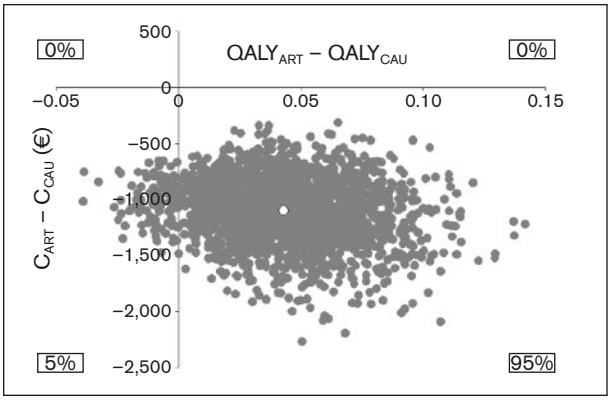

Fig 5 The cost-utility analysis indicated that arthrocentesis dominated usual care in 95% of the bootstrap simulations. Incremental cost-effectiveness ratios (ICERs) were calculated for 2,000 bootstrap iterations. Simulated mean estimates of the costs (costs of arthrocentesis [€] – costs of usual care [€]) and quality-adjusted life years (QALY) differences are presented in the cost-effectiveness plane. C_{art} = cost of arthrocentesis; C_{cau} = cost of usual care; $QALY_{art}$ = QALY with arthrocentesis; $QALY_{cau}$ = QALY with usual care.

the arthrocentesis group. The outcomes of the pain scale and the QALY (no mortality) were subsequently included in the economical analyses of cost effectiveness and cost utility.

The cost-effectiveness analysis suggested that arthrocentesis was associated with lower mean costs and better health outcomes. The point estimate of the ICERs and the results of the bootstrap analyses with regard to cost effectiveness and cost utility are presented in the cost-effectiveness plane in Figs 4 and 5, respectively. Figure 4 shows that approximately 98% of the bootstrap simulations were located in the southeast quadrant, indicating that arthrocentesis dominated over usual care in 98% of the simulations. In Fig 5, approximately 95% of the bootstrap simulations were located in the southeast quadrant, suggesting that arthrocentesis was more cost effective than usual care.

Discussion

The results of the economical evaluation in the present investigation indicate that arthrocentesis was associated with lower costs and better health outcomes than usual care. The estimated mean total (societal) cost over 26 weeks (T_0 to T_3) was €589 (US $795) in the arthrocentesis group and €1,680 (US $2,266) in the usual care group. The costs of the interventions had a substantial impact on the total costs in both groups, as did costs due to visits to the outpatient clinic and informal care. Results for the primary outcome measure (TMJ pain scored on a VAS) and for QALY were more positive for the arthrocentesis group.

The clinical findings, which are reported in more detail separately,[22] confirm currently available evidence that arthrocentesis is an effective and efficient treatment modality.[17,18] Not all studies have shown significant differences in the clinical effectiveness of arthrocentesis compared to surgical or nonsurgical treatment modalities[36,37]; however, the aim of previous studies was not to investigate arthrocentesis as initial treatment. The results of this study confirm that, over time, TMJ pain decreases with usual care.[10]

Prior to the inclusion of participants, administration of ibuprofen 600 mg three times daily for 2 weeks was used to distinguish acute inflammatory pain from pain of a more chronic nature. Ibuprofen, a prostaglandin synthetase inhibitor, is thought to influence prostaglandin E2, which is associated with acute inflammatory pain.[38] However, there are also other inflammatory mediators involved in acute inflammatory pain, and probably in arthralgia of the TMJ as well. Therefore, this part of the selection procedure was mainly concept based than experience based.

The focus of this study was to compare treatment modalities for the treatment of intra-articular pathology. Because there are challenges related to diagnostic methods and because classifications and symptoms overlap, pain intensity during maximum mouth opening is considered to be essential in the selection of patients with intra-articular pathology.[39]

The reported mild and transient adverse reactions that directly followed arthrocentesis in four of the patients receiving arthrocentesis are mentioned in other studies as well.[13,17] No severe adverse events or reactions have been reported in the literature.

In this study, the failure rate was low: Only one patient who had received usual care requested additional treatment after the follow-up period of 26 weeks. Minimizing the failure rate and thus the prevention of chronic pain may be the most important part of a cost-effective approach in the treatment of TMJ arthralgia.

Strengths and Limitations

The arthrocentesis procedure described in this study was conducted using intra-articular anesthesia and anesthesia of the overlying skin according to the standard protocol of the Department of Oral and Maxillofacial Surgery of the University Medical Center Groningen. No general anesthesia was applied. Therefore, the costs of this procedure were considerably lower than the costs of arthrocentesis performed under general anesthesia, which is still the conventional protocol in several hospitals.

Patients were included in this study if they had arthralgia of the TMJ according to the RDC/TMD, which was confirmed by disappearance of the pain after intra-articular injection of a local anesthetic. Tjakkes et al have stated that the effect of intra-articular injection of a local anesthetic is useful as a diagnostic tool in order to establish the source of the pain.[24] Because arthrocentesis aims at treatment of the TMJ itself, it is important to verify the source of the pain.

Current initial therapeutic strategies for TMJ arthralgia usually consist of prescribing a soft diet, exercises, and an oral appliance,[9,10] and the application of conservative treatment options is guided by the patient's symptoms and the duration of these symptoms. This causes an enormous variety in conservative treatment strategies. In the present study, an attempt was made to simulate the symptom-guided approach by adding treatment options when needed according to a strict protocol. However, in this research setting, the duration of the conservative treatment was limited to 6 weeks in order to avoid large differences in duration. Therefore, the costs of the usual care approach in the present study may differ from conservative treatment that exceeds 6 weeks. Furthermore, because of differences between patients in the usual care group in the persistence of the symptoms, the individual costs may differ as well. In patients who recover quickly, conservative treatment will probably be cheaper. However, these patients cannot be identified prior to the treatment. Therefore, the randomized design of this study was used to create two comparable groups.

X-ray examinations were performed at baseline and after 26 weeks 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,[40] and relatively small changes were expected since the follow-up period was only 26 weeks. Although studies often use more sophisticated imaging techniques to examine the TMJ, such as magnetic resonance imaging (MRI) and cone beam computed tomography (CBCT), CBCT may not be accurate in detecting the relatively small intra-articular bony changes since its precision is limited by the voxel size, and MRI is mainly used for the evaluation of soft tissues.[41]

The present study was conducted in the Netherlands within the Dutch health care system. Although the cost-effectiveness analysis was based on true costs, these costs may differ in other countries. Health care systems and cultural differences may influence medical costs as well as nonmedical costs. Therefore, the generalizability of the results of this study may be limited. However, despite these differences, there is a clear trend favoring the cost effectiveness of arthrocentesis as an initial treatment.

The mean total (societal) cost estimates presented in Table 3 were based on complete case analyses. Complete data on health care consumption and costs were only available for a small group of included patients. Alternative approaches to handling missing cost data applied in other economical evaluations (eg, the expectation maximization algorithm with bootstrap approach) could not be applied in the current study largely due to the relatively small number of included patients and the high percentage of incomplete data. Therefore, the mean total cost estimates during the 26 weeks of the study period and the additional economical analyses should be interpreted with caution.

Implications

Within its limitations, the results of this study show that for the initial treatment of TMJ pain, arthrocentesis is associated with better health outcomes and lower costs than usual care. It is questionable whether conventional care should still be preferred as initial therapy, since its indication is probably primarily based on its noninvasive character. The current order of treatment, in which conservative care is offered first, seems arbitrary and not based on any strong evidence. The results of this study ask for reconsideration of this order. To reduce health care costs and increase patient comfort through rapid pain control, arthrocentesis may be offered to patients with TMJ arthralgia in an earlier stage of the disease.

Conclusions

The results of this study suggest that, from an economical perspective, arthrocentesis may be superior to usual care for the initial treatment of TMJ pain, as arthrocentesis as an initial treatment seems to have better health outcomes and lower costs than the usual treatment strategy.

Acknowledgments

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