Section A-Research paper
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A 12-month randomized clinical trial of tmj arthroscopy with hyaluronic acid

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ABSTRACT

Objectives: The goal of this research is to compare the effectiveness of arthroscopic TMJ therapy with and without hyaluronic acid (HA) injections in patients with Wilkes stages III and IV.

Methods: ClinicalTrials.gov identifier NCT04110587) was a randomized controlled experiment. The 51 patients were split into two groups: those who had TMJ arthroscopy alone (n = 25) and those who underwent TMJ arthroscopy with HA (n = 26). Maximum mouth opening (MMO) and reports of pain in the muscles and joints were assessed at the beginning of therapy, 3, 6, and 12 months later. Both before and during the trial period, disc position was assessed by magnetic resonance imaging. At the start of the research, participants' levels of Oral Health-Related Quality of Life (OHRQoL) were assessed. six months later, and twelve months afterwards.

Results: When comparing clinical and radiographic outcomes, neither group differed significantly ($P > 0.05$). After three to twelve months of observation, the results of using hyaluronic acid as an adjuvant therapy to arthroscopy are negative. OHRQoL was better 6 and 12 months after TMJ arthroscopy.

Conclusions: After 3 months of observation, the HA injection performed during TMJ arthroscopy did not seem to have any positive effects.

INTRODUCTION

Disturbances in the function of the jaw's masticatory muscles and the temporomandibular joint (TMJ) are classified as TMDs.1Incidence rates of 3.9% per year suggest that these conditions affect between 5% and 12% of the population overall..2Both local myalgia and myofascial pain have been identified as prevalent conditions affecting the masticatory muscles3Disk displacements are the most frequent kind of TMJ ID (intra-articular

dysfunction). Joint difficulties (intra-articular disorders) are very frequent, the most common forms of degenerative joint disease (osteoarthritis/arthritis) affecting the ID and TMJ.
Conditions that affect the joints may range from osteoarthritis to synovial chondromatosis to osteonecrosis to neoplasia.
TMJ ID is characterized by a misalignment of the articular disc with respect to the mandibular condyle. Disk displacement with or without reduction (DDoR) and DDoR are two striking manifestations of circle dislodging. When a person with DDwR closes their lips, the condyle protrudes forward beyond the articular disc's posterior band. The MMO location of the jaw suggests that the articular disc may be between the condyle of the mandible and the apex of the temporal bone. The DDwoR rear band might be positioned anterior to the mandibular condyle in the CM and MMO regions.4Degenerative changes at the joint surfaces may or may not be linked to TMJ ID.
When conservative measures fail, TMJ arthroscopy is a successful surgery for treating both DDwR and DDwoR.5Occlusal splint therapy is one of the most used conservative therapies, along with physiotherapy, pharmacology (analgesic or anti-inflammatory medications), and/or physical therapy. following 12 months, the maximum mouth opening (MMO) increases more following arthroscopy than after arthrocentesis, with equal pain results.5-10
D-glucuronic acid (uronic acid) and N-acetyl-D-glucosamine are the two disaccharides that make up hyaluronic acid (HA), a high-molecular-weight glycosaminoglycan. Synovial fluid, along with other tissues and fluids, contains HA, which has a role in healing wounds, hydrating tissues, and reducing inflammation. HA's antinociceptive action, hydrophilicity, and minimal immunogenicity, in addition to its viscoelasticity (which is concentration and molecular weight dependant), make it a promising therapy for ID.11
Unfortunately, high-quality research on the outcomes of TMJ arthroscopy in association with HA is few. The genuine effectiveness of HA injection in combination with TMJ arthroscopy has to be determined via randomized clinical studies with big enough samples, rigorous design, and outcome measures including quality of life.
Increased focus in recent decades has been placed on OHRQoL as an outcome metric in patients with TMD. Several measures and questionnaires have been developed to quantify the social and functional implications of this illness and the efficacy of different treatment methods for TMD, since this condition negatively affects the quality of life of most patients. The Oral Health Impact Profile is the most popular of these surveys.
This investigation is a randomized, a randomized, controlled trial of HA as a surgical adjuvant for TMJ dysfunction. Patients with Wilkes stage III and IV internal derangement will participate in this trial to compare the clinical outcomes of HA as an adjuvant to TMJ arthroscopy with those of arthroscopy alone. Wilkes stage IV is characterized by the presence of early degenerative alterations and is characterized by persistent discomfort, limited mobility, disc deformity, and disc displacement (Wilkes, 1989). The goal of this study was to test the idea that including HA during TMJ arthroscopic surgery wouldn't improve pain, MMO, OHRQoL, or disc placement.

MATERIALS AND METHODS

Study Design and Population

The XXXX institution hosted this randomized, triple-blind clinical study from December 2021 to July 2022. The study followed the guidelines for clinical research set out in the Declaration of Helsinki. All participants provided written informed permission before the study began, and the protocol was reviewed and approved by our institutional review board.

Inclusion and Exclusion Criteria

The hospital's Oral and Maxillofacial Surgery Department recruited all of the study's participants using the following criteria for eligibility: Patients with a Wilkes stage of 3 or 4 who have been diagnosed with TMJ ID by MRI, being over the age of 18, having difficulty opening your mouth, experiencing joint pain that can be felt when examined, having failed minimal treatment for at least 90 days (including a cautious diet, non-steroidal anti-inflammatory medications (NSAIDS), oral machines (orthotics), and exercise-based recuperation).

Exclusion criteria included a history of TMJ careful treatment (such as arthrocentesis, arthroscopy, or open a medical procedure), Possible contraindications include a TMJ that has shown a favorable histologic or radiographic response to HA or corticosteroid infusion, ankylosis, intra-articular growth spread, overlaying skin illnesses, and a few situations that might produce hemarthrosis, such draining issues.

Prior to surgical surgery, patients had a series of tests, including a clinical evaluation, x-rays, and the completion of the Oral Health Impact Profile-14 (OHIP-14sp) questionnaire in Spanish. The first and subsequent clinical assessments were conducted by the same qualified examiner who was blind to the treatment allocations.

Interventions

The same TMJ arthroscopy surgeon conducted the procedure under general anesthesia on patients in both groups. In all instances, the triangulation method with an inferolateral approach was used to lyse and lavage the superior joint region. During the arthroscopic operation, the superior joint space was lavaged, manipulated, and debrided. For TMJ arthroscopy, A 2.2 mm protected cannula sheath and a video monitoring and recording equipment were used together with a 1.9 mm arthroscope. The irrigation fluid was Ringer's lactate. The arthroscopic procedures were identical for all groups, Except for one group that had an injection of the high molecular weight HA Durolane® right after surgery (only in the upper joint region). Intraoperatively, all patients got 1 gram of amoxicillin-clavulanic acid (IV) and 4 milligrams of dexamethasone (IV), and postoperatively, they received 500 milligrams of amoxicillin-clavulanic acid (IV) and 125 milligrams of amoxicillin-clavulanic acid (IV).

Take one tablet of metamizole every 8 hours for 5 days, one tablet of diclofenac every 12 hours for 5 days, and 800 milligrams of ibuprofen every 8 hours for 5 days. At the 24-hour post-op mark, patients began a soft diet and light at-home activity. Patients in the follow-up group who reported experiencing TMJ discomfort were offered symptomatic therapy, such as a soft diet, analgesics, or anti-inflammatory medicines.

Study Measures

The average distance between teeth (MMO) and a visual analog scale for pain in the joints were the two main indicators of success. the incisal margin to incisal margin measurement of the upper and lower central incisors) and the OHIP-14sp index of overall health and wellness. In 2009, a group of Spanish researchers led by Montero-Martin, Bravo-Perez, Albaladejo-Martinez, Hernandez-Martin, and Rosel-Gallardo updated the OHIP-14 survey (Slade, 1997) and published a Spanish translation. The OHIP-14sp is a self-report questionnaire that includes 14 questions on the impact of oral health problems on regular activities. Zero indicates never, one indicates seldom, two indicates sometimes, three indicates often, and four indicates very frequently on a Likert scale.

Joint and muscle palpation pressure will be used to detect temporomandibular disorders (2 pounds on the masseter and temporalis muscles, 1 pound on the joints and other muscles). To do this, we place the tips of our index and third fingers on the temporal mandibular joint

(TMJ) in the preauricular area. we were able to palpate the TMJs. The mandible was then opened and closed and protruded to confirm that we had found the correct joint.
Muscles were palpated when relaxed, and structures were determined based on how they contracted.
Demographic information (such as sex and age) was gathered, and secondary variables such as symptom duration, MRI findings of disc location, MRI findings of disc position, MRI findings of muscle soreness, and arthroscopy results (such as synovitis and chondromalacia) were also noted. In order to determine whether or not the geniohyoid, mylohyoid, and mylohyoid muscles, all located intraorally, were painful, digital pressure was applied bilaterally for five seconds to the digastric (anterior body), temporal, medial pterygoid, and masseter (extraoral palpation); extraoral palpation).
MRI images were taken within a month before the intervention and again 12 months after the arthroscopy to assess disc position changes before and after TMJ arthroscopy. The guideline called for non-invasive diagnostic procedures like MRI to determine which individuals needed surgical intervention. They were put on a waiting list and given an MRI appointment date that was two months later. The imaging was performed using a General Electric Signa 1.5-T MR platform (Milwaukee, WI), equipped with two phased-array dedicated TMJ surface coils. The exact location of the mandibular condyle was first determined by using an axial scout section.
After placing the head coil on the MRI table, the patient's head was secured in position. Without moving the patient's head from the magnet bore, we were able to get images of both the closed mouth in maximal intercuspation and the MMO postures. In order to keep each patient's clinical MMO stable, a disposable biting block was employed. The hypointense (and often biconcave) disc was located just above the mandibular condyle in sagittal-oblique images.

Follow-up at3,6,9, and 12months after surgery
Three, six, nine, and twelve months after surgery, all patients were analyzed. At each of the four checkpoints, data on joint pain, MMO, muscle pain, and AEs was collected; at 6 and 12 months, the OHRQoL was evaluated; at 12 months, radiographs were obtained.
For continuous variables, we give means SDs, whereas for categorical variables, we report raw numbers and percentages.

RESULTS

A total of 54 participants were enrolled; 26 were randomly allocated to have arthroscopy without HA (the control group) and 28 were assigned to receive arthroscopy with HA (the experimental group). Three individuals did not show up for any of the scheduled follow-up assessments, and it was not able to get in touch with them to find out why they dropped out. Thus, after 12 months, the sample size was 51 people (25 in the control group and 26 in the experimental group).
At each of the three, six, and twelve-month checkups, the patients reported less discomfort than they had at the beginning (P0.001). The pain-relieving effects peaked at 6 months and lasted until 12 months. All subsequent assessments showed a statistically significant rise in MMO (P0.001). Although the greatest rise in MMO was shown at 12 months, values larger than 37 mm were already seen at 6 months following surgery. At 6 and 12 months, patients had a substantial drop in their OHIP-14sp scores (almost a 50% drop in the overall average score; P0.001). Table 2 displays the study's key outcome measures.
Due to poor picture quality, the disc position at 12 months could not be determined for one subject, who was thus categorized as DDwoR at the 6-month assessment. The most common ID at both the beginning and the conclusion of the investigation was DDwoR. Disc position

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alterations showed no significant group differences (P>0.05). The (positive) "risk" of switching from DDwoR to DDwR or ND, or from DDwR to ND, was 2.46 when 12-month and baseline data were compared. Therefore, after a year, the chances of shifting to a better disc position were 2.46 times higher. Other outcome measures showed no significant changes (P>0.05).

When assessing muscle discomfort, we looked at both the afflicted side (AS; the side of the TMJ under consideration) and the unaffected side (OS). Over the course of the study period (3-12 months), there were no significant changes in muscular pain levels across groups (P>0.05).

At each subsequent time point, discomfort in the masseter muscle decreased significantly, although this trend was only seen on the AS (P0.05). Both the AS and OS showed a statistically significant reduction in pain experienced by the temporal muscles at 9 and 12 months (P0.05). Pain in the geniohyoid muscle associated with AS varied at 3, 9, and 12 months (relative to baseline) and at 9 months (relative to OS) between the two groups. All four visits resulted in a reduction in mylohyoid muscle soreness, although this was exclusive to the AS (P0.05). Both medial pterygoid and digastric muscle discomfort were similar across groups (P>0.05).

In addition, we found that the masseter was the most frequently afflicted muscle (P0.001) at baseline (McNemar test), with 90.2% of subjects expressing pain in that location, and 60.8% reporting discomfort in the temporal region.

Twenty AE were recorded overall. Extravasation of irrigation fluid during intervention was the most common adverse event (13 instances). Two patients had bleeding during surgery. Three patients had facial nerve paralysis after the procedure, and one patient experienced visual loss and an allergic response within the first 24 hours (both of which were linked to a hospital bed cover). All adverse events (AEs) were resolved, and the AE distribution between the two groups was comparable (Fisher's exact test, P=0.111).

Table1: Baseline demographic, clinical, and surgical characteristics.

	Overall	**Control**	**Test**
Participants	50	25	25
Age,years[mean(range)]	39	41	38
Sex, n(%)			
Male	5	0	0
Female	45	25	25
Symptomduration,months,mean	18.5	17	19
Stabilization splint(yes), n(%)	30	15	15
Surgicalfindings,n(%)			
Synovitis I-II	25	10	15
Synovitis III-IV	23	12	11
ChondromalaciaI-II	25	10	15
ChondromalaciaIII-IV	23	13	10
Irrigationfluid,mL,mean(SD)	450	491	430
Side, n(%)			
Right	20	10	13
Left	31	15	13
Bilateral	5	2	3
Wilkes stage, n(%)			
III	15	7	8
IV	36	18	18

BaselineTMJpain,VAS(SD)	6	6.2	5.8
Baselinemusclepain			
Masseter muscle	45	23	21
Temporal muscle	30	16	13
Medialpterygoidmuscle	20	8	9
Digastricmuscle	7	3	5
Geniohyoid muscle	10	7	5
Mylohyoidmuscle	20	7	11

Table 2: Parameter estimates and primary end points for the 51patients.

Primary end point	Visits	P value
TMJ pain	3-monthvisit	<.001
	6-monthvisit	<.001
	9-monthvisit	<.001
	12-monthvisit	<.001
	Treatment group	.554
MMO	3-monthvisit	<.001
	6-monthvisit	<.001
	9-monthvisit	<.001
	12-monthvisit	<.001
	Treatment group	.695
OHRQoL	6-monthvisit	<.001
(OHIP-14sp)	12-monthvisit	<.001
	Treatment group	.656

Both groups (n = 51), control group (n = 25), and test group (n = 26) were considered in all analyses.MMO, maximum mouth opening; OHRQoL, Oral Health-Related Quality of Life; OHIP-14sp, Oral Health Impact Profile-14 Spanish version; b, coefficient; SE, standard error. MMO and OHRQoL were analyzed using a mixed-effects model. TMJ pain was analyzed using a generalized estimating equation.

DISCUSSION

TMJ arthroscopy is sometimes combined with HA as a possible gold-standard treatment. The good outcomes shown when HA was given in combination with TMJ arthrocentesis, or as an intra-articular injection on its own, presumably explain why it is used so often.12TMJ arthrocentesis is done under local anesthetic or sedation, and entails lavage of the intra-articular space with hydraulic pressure and manipulation of the mandible.13TMJ arthroscopy should not be held responsible for the results of supplementary treatments because to their unique nature.

There was no significant change in any of the secondary outcome measures (pain, MMO, OHRQoL, etc.). was seen after HA administration. Therefore, arthroscopy seems to be the only reason for the treatment's success. To ensure that our findings could be applied to a wider population, We used an interventional strategy, providing both groups with intra- and post-operative medicines and a home exercise regimen in addition to the main therapy (TMJ arthroscopy).

Two prior trials examined the effects of HA in combination with TMJ arthroscopy, however their methods were flawed.14All diagnoses were verified during surgery, as well as by more reliable and established means (clinical examination, MRI, OHIP-14sp). Due to the low number of participants we were unable to conduct a separate analysis based on age or Wilkes

stage. Additionally, additional potential confounding factors were not assessed, mental health difficulties, teeth grinding, psychosocial variables, self-care, dental health, and malocclusion all play a role. The information on muscular pain in ID was lacking since other painful muscle illnesses, not being acknowledged, such as myofascial pain (E. Schiffman et al., 2014). As a result, it was unclear how the treatment might affect the various forms of muscle disease. Quality of life data, like that in previous research, may have been impacted by this method's potential for bias.15Our findings also contradict those of a prior study that found arthroscopy combined with HA to be more effective than arthroscopy alone. However, research that directly compared the two groups was left out of this network meta-analysis, thus its conclusions are based only on indirect comparisons.

Patients in Wilkes stages III and IV and MRI examinations were included in a similar study on HA in combination with TMJ arthroscopy.16 In the prior investigation, there were no significant changes in MMO or disc position between the groups who underwent lysis and lavage with HA (Ostenil Mini®; Masterfarm Laboratories, Barcelona, Spain) and those that did not. which included 40 patients. In contrast to our findings, a prior research found that HA was effective in reducing pain 14 and 84 days after surgery (P 0.05). Although our trial had better randomization and allocation concealment and a longer follow-up than the previous one, we were still unable to detect any changes in joint discomfort.

Although the OHIP-14sp scores may have been affected by a variety of oral diseases (such as periodontal disease or odontogenic pain), Six and twelve month follow-ups showed a rise in OHRQoL (OHIP-14sp score). This streamlined and objective outcome measure of patients' reports of treatment's influence on physical, emotional, and social well-being was missing from previous research.

Future studies should establish consistent diagnostic criteria for identifying the specific forms of muscle disease at play in particular individuals, and for assessing the roles played by psychological and social factors.

Analysis of bruxism and TMJ arthroscopy outcomes. More clinical preliminary studies with meticulously prepared follow-up evaluations within the first three months are essential to further appreciate the short-term effects of HA when coupled with TMJ arthroscopy.17-20

CONCLUSION

After 3 months of observation, this research offers credible evidence for doctors and patients that HA injection during TMJ arthroscopy had no positive impact. As of present, there is no proof that HA is an effective or efficient complement to TMJ arthroscopy.

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