



Hyaluronic Acid and Platelet-Rich Plasma Mixture Versus Hyaluronic Acid and Corticosteroid in the Treatment of Temporomandibular Joint Internal Derangement: A Comparative Randomized Study

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Abstract

Objectives This study aimed to compare the effects of different intra-articular injections using a mixture of hyaluronic acid (HA) and platelet-rich plasma (PRP) versus hyaluronic acid and corticosteroid in the management of TMJ internal derangement with reduction.

Materials and Methods Sixty patients were randomly divided into two equal groups. Group I was injected with hyaluronic acid and PRP, while group II was injected with hyaluronic acid and corticosteroid. Pain intensity according to the visual analogue scale, maximum inter-incisal opening (MIO), lateral movement, and joint sound were measured pre-operatively and at 1 week, 1 month, and 6 months post-operatively.

Results MIO and lateral movements were improved in both groups, with a reduction in the number of patients suffering from clicking sounds along the follow-up periods with no significant difference between the studied groups. However, regarding pain, the group injected with HA and PRP achieved the best results after 6 months, while patients treated with HA and corticosteroids obtained the best results at the end of the 1st week.

Conclusion Hyaluronic acid and platelet-rich plasma mixture performed better than hyaluronic acid and corticosteroid in the treatment of TMJ internal derangement with reduction at the long-term follow-up regarding pain intensity.

Keywords PRP · Hyaluronic acid · Intra-articular injection · TMJ internal derangement · Corticosteroids

Introduction

TMJ is a complex joint that permits a range of movements of the associated structures. The presence of pathology within the joint cavity, changes involving the capsule, disc, and the activating muscles of the joint can cause limitations of free movement of the joint. Internal derangement of the joint is considered the most prevalent TMJ disorder (TMJD) and represents almost 80% of adult patients complaining of TMJ symptoms [1–3].

An abnormal relationship between the disc, the mandibular condyle, and the articular eminence is called “temporomandibular joint internal derangement” (TMJID) or “articular disc displacement” which results from stretching or tearing of the attachment of the disc to the condyle and glenoid fossa that leads to pain during mandibular movement, abnormal joint sounds (clicking), and limitation in the range of mandibular movement [4].

The primary goal in TMJD treatment is to alleviate pain and restore mandibular functions (mastication and speech) initially using conservative measures, which will resolve symptoms in over 80% of the patients. However, for the patients that show no response, surgical intervention is advocated for managing these patients [5–9], arthrocentesis and lavage of the TMJ, arthroscopy, intra-articular injection of medications, ranging from steroids to HA were injected successfully into several joints of the body to offer relief for joint chronic pain [10], and finally open joint surgery all serve as potential treatment options [5–9, 11, 12].

HA is a high-molecular-weight (high-MW) glycosaminoglycan natural synovial fluid and shares in joint lubrication.

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HA injections have been widely used in the management of TMJDs, and several studies showed promising results in the improvement of MIO and pain reduction [13].

The viscosupplementation concept describes the physical mechanism of action primarily achieved by high-MW HAs and by-products based on modifications of HA molecules to achieve greater elasto-viscosity [14]. Whereas viscoinduction explains the chief mechanism of action achieved by HA of low MW to induce clinical benefits following intra-articular application [15]. So significant differences can occur between the HA-based formulations suggested for the intra-articular therapy of TMJD.

Corticosteroids intra-articular injection is commonly used to treat TMJ osteoarthritis with confirmed benefits in reducing pain and associated symptoms [16].

PRP injections presented many advantages over the use of corticosteroids in the management of TMJD and inflammatory conditions, the most notable being the absence of serious and/or permanent side effects. PRP increases glycosaminoglycan chondrocyte synthesis, affords a scaffold for stem cells migration, stimulates cell proliferation and the production of cartilage matrix by chondrocytes and bone marrow-derived mesenchymal stromal cells, and increases the production of hyaluronic acid [11, 17]. PRP intra-articular injection has recently gained popularity in treating TMJ osteoarthritis due to its palliative and anti-inflammatory effects [8, 11, 12, 18, 19].

Intra-articular injection of HA and corticosteroids have proven efficacious in relieving TMJ pain [10, 20, 21]. HA and PRP mixture were used in many studies treating TMJ or other joints osteoarthritis [11, 22, 23].

Because of the paucity of researchs on intra-articular injection (with HA and PRP mixture) in the management of patients with TMJ internal derangement and the potentialities of each substance separate, the present study aimed to assess and compare the efficacy of this mixture with a mixture of HA and corticosteroid in the management of patients with TMJ internal derangement with reduction.

Patients and Methods

Patient Selection and Study Design

This prospective randomized study included 60 adult patients suffering from internal derangement as confirmed by clinical and MRI examination. They were selected from patients attending the Oral and Maxillofacial Surgery Department clinic, Faculty of Dentistry. Patients were diagnosed according to the original version of the research diagnostic criteria for temporomandibular disorders (RDC/TMDs) [24]. All included patients had a chief complaint of TMJ pain, clicking sound, with or without limited mouth

opening (early/intermediate stage according to Wilkes classification) [25, 26], and patients unresponsive to conservative treatment modalities such as soft diet, moist heat application, analgesics, anti-inflammatory drugs, and splint therapy for TMJ dysfunction. Patients with a history of TMJ surgery, polyarthritis or other rheumatic diseases, neurologic disorders, and patients with medical devices claustrophobia were excluded. Treatment for each patient was assigned by a randomization list automatically created preceding the beginning of the study, in which the method of treatment was determined. The study followed the principles of the Declaration of Helsinki on medical studies and was approved by the Institutional Review Board (No. M12010222). All patients signed informed written consent.

Pre-Operative Patients' Assessment

Patients' personal data and detailed medical and dental histories were recorded. A comprehensive clinical examination was carried out to evaluate the following variables:

- Pain intensity was measured by VAS score. Zero score for no pain and 10 score for worst pain experienced [27].
- Clicking sound was assessed as to its presence = 1 or absence = 0.
- The maximal unassisted, pain-free mouth opening was measured in millimetres (mm) using a Vernier caliper.
- Lateral movements were measured in mm as the horizontal distance extending from maxillary midline to mandibular midline using Vernier caliper.

All the measurements were recorded and considered a baseline to be used in comparison with post-operative measurements.

Magnetic Resonance Imaging

Magnetic resonance imaging (MRI) (open and closed) was used to diagnose internal derangement with reduction for all patients pre-operatively. The MRI protocol included bilateral sagittal oblique proton-density images of the right and left sides in both the closed-mouth (maximum intercuspatation) and maximum mouth opening positions. The examination also included bilateral coronal proton-density images of the right and left sides at the closed-mouth position.

Operative Phase

The patients were positioned at a 45° angle on the dental chair with the head rotated towards the unaffected side. The surgical field was painted with an alcohol swap, and a line was drawn between the lateral canthus of the eye and the tragus of the ear. About 1 ml of Mepeccaine-L (Mepivacaine

Hcl 2% with Levonordefrin 1:20,000, Alexandria Co. for pharmaceuticals, Alexandria, Egypt) was infiltrated into the areas of joint penetration. The injection point was marked 10 mm in front of the middle of the tragus and 2 mm below the traced line [28]. Patients were instructed to open their mouths widely and maintain the mandible in protruded position.

Patients were randomly divided into two groups each included 30 patients

Group I ($n=30$): a mixture of 1-ml HA (Hyalubrix[®] hyaluronic acid sodium salt 30 MG/2 ML, manufactured by Fidia SPA, Padova, Italy, stored at temperature $>25^{\circ}\text{C}$) and 1-ml PRP mixture was slowly injected intra-articular at the point of entry. The injection was preceded by collecting 10 ml of the patient's blood from the ulnar vein into a glass tube containing sodium citrate as an anticoagulant. After mixing the blood with the citrate, using rotating movements, the tubes were centrifuged at 1500 rpm for 6 min. Patients were informed about the possibility of feeling temporary fullness or compression in the joint regions after injection [29].

Group II ($n=30$): a mixture of 1-ml HA and 1-ml corticosteroid (Kenacort A-40: each ml contains triamcinolone acetonide 40 mg. with sodium chloride manufactured by SmithKline Beecham, Egypt. An affiliated Co. to GlaxoS-mithKline) was slowly injected.

Each patient received a single injection, once the injection was completed and needles were removed, the patient's mandible was lightly manipulated in the vertical, protrusive, and lateral excursions to facilitate breaking down the adhesions and help additional freeing up the disc.

Post-Operative Phase

Patient's Instructions

Patients were instructed to apply the ice bag extra orally for 10 min/half an hour for the first 24-h post-operative. Then apply hot fomentation after 24 h, for 2 weeks. Maintain a soft diet; avoid eating hard food and gum chewing for 2 weeks post-operatively. Gradually transform to a normal diet within the 3rd post-operative week.

Medications

Augmentin 1-g tablets (equivalent to Amoxicillin 875 mg and clavulanic acid 125 mg, Glaxo SmithKline Pharmaceuticals Ltd., USA) twice daily for 6 days to prevent any chance of TMJ infection.

TMJ Splint Therapy

Occlusal stabilization splint was used for all the patients for 6 months [30]. Maxillary full-arch hard stabilization splints fabricated with fluid resin. The occlusal splint has indentations on its occlusal surface to guide and hold the mandible in centric relation. It has vertical thickness of 2 mm. the occlusal readjustment visits took place with the following periodicity: 1 week and 1 month after the beginning of treatment, and thereafter, every month. Patients were instructed to wear the splint 8 h in the day and during sleeping time.

Post-Operative Follow-Up

Follow-up was done at 1 week, 1 month, and 6 months to assess pain level, joint clicking, MIO, and lateral movements.

Statistical Analysis

Data were analyzed using IBM-SPSS software (IBM Corp. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp.) Shapiro–Wilk test was used to test the normality of distribution. Quantitative data were presented in median and range (minimum–maximum). Mann–Whitney *U*-test was used to compare two different groups of non-parametric data while Friedman's test was used to compare more than two related groups of non-parametric data. *P*-value less than 0.05 was considered statistically significant.

Results

The current study included 60 patients suffering from TMJ internal derangement with reduction. The mean age of the patients in group I was 24.61 ± 3.21 , of which 19 were females and 11 were males. In group II, patients were with mean age (26.12 ± 6.74) of which 17 were females and 13 were males (Table 1). Patients in the studied groups endured the procedures without major complications.

Table 1 Demographic data of the study groups

	Group I ($n=30$)	Group II ($n=30$)
<i>Age</i>		
Mean \pm SD	24.61 ± 3.21	26.12 ± 6.74
<i>Gender</i>		
Female	19 (63%)	17 (56.6%)
Male	11 (36.6%)	13 (43.3%)

SD: standard deviation

Table 2 Comparison of VAS scores between the studied groups and within the follow-up periods

Pain	Group I (n = 30)	Group II (n = 30)	<i>P</i> ^a (Between groups I and II)
Baseline	8 (4–10) ^A	8 (4–10) ^A	0.42
After 1 week	7 (0–9) ^B	5 (1–8) ^B	0.001*
After 3 months	2 (0–4) ^C	3 (0–5) ^C	0.003*
After 6 months	0 (0–2) ^D	2 (0–4) ^C	<0.001*
<i>P</i> ^b	<0.001*	<0.001*	

Data expressed as median and range

P: probability

*: significance < 0.05

P^a: Test used Mann–Whitney

P^b: Test used Friedman's (different capital letters indicate a difference in significance)

Table 3 Comparison of clicking scores between the studied groups and within follow-up periods

Clicking	Group I (n = 30)	Group II (n = 30)	<i>P</i> ^a (Between groups I and II)
Baseline	1 (1–1) ^A	1 (1–1) ^A	1.00
After 1 week	1 (0–1) ^A	1 (0–1) ^B	0.78
After 3 months	0 (0–1) ^B	0 (0–1) ^C	0.77
After 6 months	0 (0–1) ^B	0 (0–1) ^C	0.09
<i>P</i> ^b	<0.001*	<0.001*	

Data expressed as median and range

P: probability

*: significance < 0.05

P^a: Test used Mann–Whitney

P^b: Test used Friedman's (different capital letters indicate a difference in significance)

VAS score was used to measure pain pre-operatively and at 1 week, 1 month, and 6 months after treatment. The results showed that there was a statistically significant difference between the studied groups during the follow-up intervals ($P < 0.05$). However, we found that after 1 week of injection therapy, there was a highly significant pain reduction in group II more than in group I ($P = 0.001$), and the reduction was more in group I after 6 months ($P < 0.001$) (Table 2).

Table 3 represents clicking scores between the two groups during the follow-up intervals, no statistically significant difference ($P > 0.05$) was observed. However, there was a statistically significant difference between clicking scores at the baseline when compared to the follow-up intervals within each group ($P < 0.05$); except for group I baseline scores and 1 week post-operatively, there was no significant difference between the two intervals.

A gradual increase in MIO was observed between baseline measurements and during follow-up intervals regardless of the type of treatment used. As there was a statistically significant difference, between baseline MIO and the follow-up intervals in each group ($P < 0.001$), and no significant difference between the two groups at any time interval ($P > 0.05$) (Table 4).

Regarding lateral movements, there was no significant difference between the studied groups ($P > 0.05$). While there was a statistically significant difference between baseline lateral movements (right and left) when compared to movements during the follow-up intervals in each group ($P < 0.001$) (Table 4).

Discussion

TMJID is one of the most prevalent intra-articular disorders. It has always been considered a therapeutic challenge for oral and maxillofacial surgeons. The prominent findings have been related to this disorder are pain, joint sounds, irregular jaw function, and limitation in jaw opening [31].

Intra-articular injection therapy is a modality that is used especially in patients who cannot get favourable results with other conservative methods [32]. Steroids [33], hyaluronic acid [10, 33], and NSAIDs [13] were injected into the joint either separately or in combination [10, 33], and did not reverse or end the deterioration cycle of the internal derangement [34].

In the present study, TMJ disc displacement with reduction was managed by intra-articular injection of either HA and PRP mixture or HA and corticosteroid mixture to compare the effectiveness of each treatment regarding pain, clicking, MIO, and lateral movements. About 60% of our patients were females; this high incidence of TMJID in females was like the results of Nardini et al. [35]

Improvement was noted in the severity of pain between both groups, with a statistically significant difference between baseline and all the follow-up intervals, which was marked at the 1st post-operative week in the HA + corticosteroid group and the 6 months in the HA + PRP group. This finding can be explained by the ability of PRP on healing, which requires time and persists after injection due to their molecular effects on the joint structure. In addition, the potent anti-inflammatory effect of corticosteroids on the synovial tissue decreases effusion and pain, and increases the range of the motion of the joints [36, 37]. This result was in accordance with Saturveithan et al. [23], who reported pain reduction in the long-term follow-up when used HA and PRP combination in knee osteoarthritis. Also, in agreement with Girardi et al. [37].

There was no statistically significant difference between both groups along the follow-up periods regarding clicking.

Table 4 Compare MIO and lateral movement measurements between two studied groups and within follow-up periods

	Group I (n = 30)	Group II (n = 30)	P ^a (Between groups I and II)
<i>MIO</i>			
Baseline	36.00 (26.00–52.00) ^A	36.50 (28.00–52.00) ^A	0.88
After 1 week	41.50 (32.00–54.00) ^B	43.00 (32.00–55.00) ^B	0.34
After 3 months	47.00 (40.00–56.00) ^C	49.00 (41.00–56.00) ^C	0.63
After 6 months	53.00 (44.00–56.00) ^D	51.00 (44.00–59.00) ^D	0.26
P ^b	<0.001*	<0.001*	
<i>Rt. lateral movements</i>			
Baseline	7.00 (2.00–13.00) ^A	7.00 (2.00–11.00) ^A	0.74
After 1 week	10.50 (9.00–11.00) ^B	10.00 (6.00–12.00) ^B	0.18
After 3 months	11.50 (11.00–12.00) ^C	11.00 (8.00–14.00) ^C	0.056
After 6 months	13.00 (10.00–15.00) ^D	12.00 (7.00–15.00) ^D	0.1
P ^b	<0.001*	<0.001*	
<i>Lt. lateral movements</i>			
Baseline	9.50 (3.00–12.00) ^A	8.00 (2.00–13.00) ^A	0.42
After 1 week	11.00 (7.00–16.00) ^B	11.00 (6.00–14.00) ^B	0.33
After 3 months	12.00 (6.00–15.00) ^B	12.00 (5.00–14.00) ^{BC}	0.26
After 6 months	13.00 (8.00–15.00) ^C	13.00 (8.00–15.00) ^C	0.06
P ^b	<0.001*	<0.001*	

MIO: maximum inter-incisal opening, *Rt*: right, *Lt*: left

Data expressed as median and range

P: probability

*: significance < 0.05

P^a: Test used Mann–Whitney

P^b: Test used Friedman’s (different capital letters indicate a difference in significance)

However, there was a statistically significant decrease in the number of patients with clicking sounds between baseline and 6 months in each group. This finding was comparable to Al-Delayme et al. [38] and dissimilar to Hassan et al. [39] who used PRP and revealed that there was no difference in joint sounds all over the follow-up period. As well Moon et al. [40] stated that PRP was effective only in TMJ pain and limited mouth opening management, but not in clicking.

Improvement in the TMJ clicking was recorded in both groups by managing the patients with intra-articular injections alone without performing arthrocentesis before the injection. This result was in agreement with Hegab et al. [11] who performed intra-articular injections of PRP and HA in the treatment of osteoarthritis without arthrocentesis, so avoid arthrocentesis complications.

This study showed a significant increase in MIO and lateral movement measurements throughout the follow-up intervals within each group. Parallel results were achieved by Giraddi et al. [31], Sousa et al. [36], Ferrnandez-Ferro et al. [41], Delayme et al. [38], and Yang et al. [42] who applied PRP with a positive effect on the functioning of the TMJID. The same finding was in contrast with the result obtained by Yeung et al. [43] who used 2-ml hyaluronic acid, twice intra-articular injections, and documented that there

was no difference in the mean lateral movements and MIO for 1-year follow-up.

Occlusal stabilization splint was used for all patients in both groups to decrease forces directed at the TMJ along with the intra-articular pressure to prevent the negative effect of continuous stress in the disc and retrodiscal tissue during clenching and bruxism on the prognosis of the intra-articular injections [44].

Although the results of this randomized clinical study are encouraging, the study is not without limitations. It was carried out through a small population because of the COVID-19 pandemic and social distancing protocols in Egypt, recruiting a larger number of patients and incorporating a longer follow-up period did not seem possible. Positives in this study were the simplicity of intra-articular injection which makes it the treatment of choice instead of using arthrocentesis. Also, TMJ intra-articular injection is less invasive, less painful, less time-consuming than arthrocentesis or open surgery. The present study revealed no acute local reaction in any patient. Future studies are better to be conducted with a multicentre larger population and longer follow-up periods.

In conclusion, hyaluronic acid and platelet-rich plasma mixture performed better than hyaluronic acid and

corticosteroid in the treatment of TMJ internal derangement with reduction at the long-term follow-up regarding pain intensity.

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Authors' Contributions AAMMA helped in conceptualization, methodology, resources, and writing the original draft. SSA contributed to methodology, resources, and writing, reviewing, and editing the original draft. All authors have read and approved the final version of the manuscript.

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Declarations

Conflict of interest The authors have no competing interests to declare that are relevant to the content of this article.

Ethics Approval The study followed the principles of the Declaration of Helsinki on medical studies and was approved by the Institutional Review Board (No. M12010222). All patients signed informed written consent.

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