

Comparison of the effects of intra-articular injection of Hyaluronic Acid Versus Methyl Prednisolone Acetate in a Group of Iraqi Patients with Knee Osteoarthritis: A Double-Blind Controlled Study

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Abstract

Background: Osteoarthritis is a prevalent chronic joint condition that occurs when the cartilage, which acts as a low-friction surface between the joints, deteriorates, resulting in pain, stiffness, and swelling. There has been controversy regarding the effectiveness and tolerability of corticosteroids and hyaluronic acid, as well as the superiority of one over the other in treating osteoarthritis.

Objective: To compare the efficacy and safety of hyaluronic acid and methylprednisolone in the treatment of knee osteoarthritis.

Methods: One hundred and four patients with knee osteoarthritis were randomized to receive intra-articular injections of either hyaluronic acid (HA) or methylprednisolone (MP), and followed for three months. The study was conducted in a private clinic in Baghdad, Iraq in June 2024. Each patient from each group received a single injection at the time of enrollment. The participants and the evaluator were blinded to the nature of the injected material. The primary outcomes were to measure the change from baseline in Western Ontario McMaster University Osteoarthritis (WOMAC) index and visual analogue pain scale (VAS), and to record any treatment-related adverse events.

Results: There was 49 females and 3 males in the hyaluronic acid group (mean age 59 ± 15.5 years and 46 females and 6 males in the MP group (mean age 63 ± 15.5 years). No significant differences between the two groups were detected at baseline. Both groups demonstrated improvements in WOMAC and VAS scores throughout the follow-up period. The effect size for WOMAC and VAS scores favored HA over MP from month 2 to month 3. Both interventions were relatively safe, and no serious adverse events were reported.

Conclusion: It appears that both HA and MP were effective in improving pain and function in osteoarthritic knees, with no significant difference between the two interventions in the short term. However, HA seems to be superior to MP at the long term. Both medications seem to be safe, with minimal adverse events.

Keywords: Double blind; Hyaluronic acid; Intra-articular; Methylprednisolone; Osteoarthritis.

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Introduction

Osteoarthritis, which is the most common type of arthritis, impacts around 500 million individuals globally (1,2). Osteoarthritis of the knee is particularly more prevalent than other types of osteoarthritis, with an estimated prevalence rate of 16% in individuals aged 15 and over and 22.9% in individuals aged 40 and over (3). Aging, obesity, knee injury and female gender increase the incidence of knee osteoarthritis (4).

Intra-articular (IA) injection of corticosteroids and hyaluronic acid are used for the treatment of knee osteoarthritis (1). Hyaluronic acid is an inherent glycosaminoglycan found within the synovial fluid, functioning to provide lubrication and absorb shocks elastically during joint motion. In osteoarthritic joints, both the amount and size of hyaluronic acid molecules

decline (5). There is a debate regarding the efficacy and safety of IA corticosteroids and hyaluronic acid. The American College of Rheumatology and the European Alliance of Associations for Rheumatology (EULAR) recommend the use of IA corticosteroids over IA hyaluronic acid (1,6). Results from several studies showed that IA hyaluronic acid is more effective and safer than IA corticosteroids for knee osteoarthritis (7,8). However, other studies found that IA corticosteroid and hyaluronic acid are comparable in efficacy and safety (9–11). The results of the studies are conflicting, and more studies are needed to reach a consensus about the safety and efficacy of IA hyaluronic acid compared to IA corticosteroids. Since there are no studies done on Arabic or Iraqi patients, the aim of current study was to compare the efficacy and safety of IA hyaluronic acid and corticosteroids in Iraqi patients with knee osteoarthritis. The primary

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objectives of the study were to measure the changes in the Western Ontario and MacMaster Universities Arthritis (WOMAC) index score and Visual Analogue Scale (VAS) score for pain at baseline and after treatment with IA hyaluronic acid in comparison to methylprednisolone in a group of Iraqi patients with knee osteoarthritis. In addition, to record treatment related adverse events in both groups. The secondary objectives were to measure the changes in the Physician Global Assessment and Patient Global Assessment at baseline and after treatment with IA hyaluronic acid compared to methylprednisolone in a group of Iraqi patients with knee osteoarthritis.

Subjects and Methods:

Study design: This was a three-month randomized, double blind study with parallel groups. The study was done in a private clinic in Baghdad, Iraq in June 2024.

Patients selection: One hundred and four patients with OA were randomly selected to participate in this study. Patients recruited in current study were those able to provide an informed consent, aged ≥ 40 years and have a diagnosis of knee osteoarthritis according to the American College of Rheumatology criteria. However, pregnant women and those; with previous knee injury, had injections in the same joint during the last three months, taking oral or parenteral corticosteroids within 30 days, have contraindications to hyaluronic acid or methylprednisolone as well as those have history of rheumatic diseases were excluded from the study.

The patients were randomised to receive by intra-articular injection with either 60 mg (in 6 ml) of hyaluronic acid (HA, Suplasyn, Mylan, Galway, Ireland) or 80 mg (in 2 ml) of methylprednisolone (MP, Depo-Medrol, Pfizer, Puurs, Belgium). Randomization was done by a random sequence generated using a computer. A physician was responsible for the allocation of the patients and the administration of the injections. Both the researcher in charge of the evaluation of the patients at baseline and in the follow-up (at months 1, 2, 3), and the patients were blinded to the nature of the injected material.

Ethical approval: Ethical Approval was obtained from the Scientific Research Ethics Committees at the Department of Pharmacology, College of Medicine, University of Baghdad.

Clinical evaluation of patients

Western Ontario McMaster University Osteoarthritis (WOMAC) index: The assessment of the knee pain, stiffness and physical function was done using an Arabic version of WOMAC index (12). Pain (5 items, score range 0–20), stiffness (2 items, score range 0–8), and physical function (17 items, score range 0–68) are the three subscales that make up the 24-item self-administered questionnaire that makes up the index. The normalized WOMAC-total score was calculated by adding the three normalized subscale values. The patients answered the WOMAC questionnaire at the time of inclusion and at months 1, 2 and 3 of the study.

Visual analogue scale: Pain intensity was measured using a VAS ranging from 0 – 100 mm. In the present study, the researcher asked the patients: “Based on VAS, how much pain are you in/ experiencing?”. In the follow-up, based on VAS, the researcher asked the patients about their pain again. The patient's global assessment (PGA) of disease activity was measured using a VAS with a range of 0 to 10 mm (Figure 2.2). "How active is your knee osteoarthritis based on VAS?" the researcher asked the participants.

Investigator global assessment (IGA): Likert scale was used to measure investigator's global assessment (IGA) of disease activity.

Adverse events: Treatment-emergent adverse events were recorded in all visits.

Statistical analysis:

Data of categorical variables such as gender, smoking status and IGA were summarized as frequencies and percentages. Data of quantitative variables such as age, weight, VAS score for pain and PGA were summarized as median and interquartile range (IQR). Data of WOMAC score were summarized as mean and standard deviation (SD), Shapiro-Wilk test was used to test normality. The Chi-square test was used to determine if there is a statistically significant associations of variables in the study groups. For WOMAC score the student's t-test was used to identify statistically significant differences between the study groups. As for age, weight, VAS score for pain, and PGA, the Mann-Whitney U test was used to find statistically significant differences between the study groups. A P value < 0.05 was considered statistically significant.

Results: There were no statistically significant differences between the two groups at baseline in terms of demographic and clinical characteristics. Three patients were lost from the follow-up for unknown reasons, but their available information was included in the analysis using the last observation carried forward approach (Table 1).

Table 1: Demographic and clinical characteristics of the study groups at baseline

| Variable | | HA group (N=52) | MP group (N=52) | P value |
|---------------------------------|-------------|-----------------|-----------------|---------|
| Gender No. (%) | Female | 49 (94.2%) | 46 (88.5%) | 0.295 |
| | Male | 3 (5.8%) | 6 (11.5%) | |
| Age (year) median±IQR | | 59±15.5 | 63±15.5 | 0.069** |
| Weight (Kg) median±IQR | | 90±21.0 | 82.5±22.5 | 0.082** |
| Smoking status No. (%) | Smokers | 4 (7.7%) | 6 (11.5%) | 0.506 |
| | Non-smokers | 48 (92.3%) | 46 (88.5%) | |
| WOMAC score (0-96) mean±SD | | 54±16.1 | 53.5±16.6 | 0.967* |
| VAS for pain (0-100) median±IQR | | 75±28.8 | 72.5±25.0 | 0.678** |
| IGA by Likert scale No. (%) | Mild | 1 (1.9%) | 2 (3.8%) | 0.697 |
| | Moderate | 17 (32.7%) | 17 (32.7%) | |
| | Severe | 30 (57.7%) | 26 (50%) | |
| | Very severe | 4 (7.7%) | 7 (13.5%) | |
| PGA by VAS (0-10) median±IQR | | 8±3.6 | 8±2.2 | 0.945** |

HA: Hyaluronic acid; MP: Methylprednisolone; N: number of cases; WOMAC: Western Ontario McMaster University Osteoarthritis index; VAS: Visual Analogue Scale; IGA: Investigator Global Assessment; PGA: patient global assessment; P ≤ 0.05 is considered statistically significant.

* Student's t-test was used to obtain the P-value

** Mann-Whitney U test was used to obtain the P value

Western Ontario McMaster University Osteoarthritis (WOMAC) index

Although there was a difference in mean WOMAC score between the two groups at the end of the first month, the difference was not statistically significant (P = 0.084). At the end of the second month the HA group had a WOMAC score of 26 ±19.1 compared to 34 ±23.3 in the MP group (P=0.043), and at the end of the third

month WOMAC score for HA group was 25 ±18.8 compared to 34 ±23.5 in the MP group (P=0.038). WOMAC score was significantly different between the two groups at the end of the second and third months, Table 2.

Table 2: Comparison of mean±SD WOMAC scores between the two study groups

| WOMAC score (0-96) | HA group (n=52) | MP group (n=52) | P value* |
|--------------------|-----------------|-----------------|----------|
| Baseline | 54±16.1 | 54±16.6 | 0.967 |
| Month 1 | 34±18.0 | 41±21.1 | 0.084 |
| Month 2 | 26±19.1 | 34±23.3 | 0.043 |
| Month 3 | 25±18.8 | 34±23.7 | 0.032 |

*Student's T test was used to obtain the P value

Pain intensity: Improvement in VAS scores for pain were similar between the two study groups at baseline and at the end of month 1 (P=0.678 and P=0.109, respectively). At the end of month 2 and month 3, the

HA group showed a significantly greater improvement compared to the MP group (P=0.05 and P=0.011, respectively), Table 3.

Table 3: Comparison of median±IQR VAS score between the two study groups

| VAS score (0-100) | HA group (n=52) | MP group (n=52) | P value* |
|-------------------|-----------------|-----------------|----------|
| Baseline | 75±28.8 | 72.5±25 | 0.678 |
| Month 1 | 40±40 | 50±41.3 | 0.109 |
| Month 2 | 30±30 | 40±50 | 0.05 |
| Month 3 | 20±30 | 35±50 | 0.011 |

*Mann-whitney U test was used to obtain the p value

Investigator global assessment (IGA): As shown in Table 4, there was no statistically significant associations between the Likert scale levels and the type of drug used for IA injection two study groups at the end of month 1 (P=0.466) and month 2 (P=0.312) regarding the IGA. However, there was a significant association at the end of month 3 (P=0.49) with more mild cases in the HA group, and more moderate – very severe cases in the MP group.

Table 4: Comparison of investigator global assessment between the two study groups

| IGA by Likert scale | | HA group (n=52) | MP group (n=52) | P value |
|---------------------|-----------------|-----------------|-----------------|---------|
| Baseline | Mild | 1 (1.9%) | 2 (3.8%) | 0.697 |
| | Moderate Severe | 17 (32.7%) | 17 (32.7%) | |
| | Very severe | 30 (57.7%) | 26 (50%) | |
| | | 4 (7.7%) | 7 (13.5%) | |
| Month 1 | Mild | 11 (21.2%) | 9 (17.3%) | 0.466 |
| | Moderate Severe | 26 (50%) | 21 (40.4%) | |
| | Very severe | 13 (25%) | 17 (32.7%) | |
| | | 2 (3.8%) | 5 (9.6%) | |
| Month 2 | Mild | 25 (48.1%) | 17 (32.7%) | 0.312 |
| | Moderate Severe | 16 (30.8%) | 17 (32.7%) | |
| | Very severe | 9 (17.3%) | 13 (25%) | |
| | | 2 (3.8%) | 5 (9.6%) | |
| Month 3 | Mild | 32 (61.5%) | 18 (34.6%) | 0.049 |
| | Moderate Severe | 10 (19.2%) | 15 (28.8%) | |
| | Very severe | 8 (15.4%) | 14 (26.9%) | |
| | | 2 (3.8%) | 5 (9.6%) | |

Patient global assessment (PGA): The improvement in PGA from baseline was not significant in both groups at the end of month 1 and month 2. Although at the end

of month 3 there was a statistically significant difference in the HA group compared to the MP group (P = 0.027; Table 5).

Table 5: Comparison of median±IQR patient global assessment scores between the two study groups

| Patient global assessment (0-10) | HA group (n=52) | MP group (n=52) | P value* |
|----------------------------------|-----------------|-----------------|----------|
| Baseline | 8 (3.63) | 8 (2.25) | 0.905 |
| Month 1 | 5 (4.13) | 5 (4.13) | 0.074 |
| Month 2 | 2 (4.25) | 4 (7) | 0.059 |
| Month 3 | 2 (4) | 3.5 (7) | 0.027 |

*Mann-whitney U test was used to obtain the p value

Adverse events: One patient from the MP group reported elevated blood pressure. Two patients from each group reported pain at the injection site which persisted for three days.

Discussion

WOMAC score index The finding of the current study that WOMAC score at month 3 was significantly different from baseline in both the study groups and also being significantly higher in the HA than MP group is in line with the results reported by Bisicchia *et al.* (13) in a one-year follow up study, which used a lower dose of HA (48 mg). These results are further supported by the findings of a meta-analysis by Singh *et al.* (14). This meta-analysis included studies that used different IA corticosteroids than MP, and shown no significant differences between the different corticosteroids in terms of efficacy and safety in osteoarthritis. On the other hand, a six-month study by Housman *et al.* found that there was no statistically significant difference between HA and steroids at month 2 and beyond (15), which were different from the current results, despite using a higher dose of HA (80 mg). This difference in the results may be due to that the authors used a different IA HA formulation (Jonexa Hyalastan SGL-80), which is a modified, cross-linked HA. It was made with the intention to increase the half-life and its viscoelastic properties. However, it was found that it reduced the viability of synoviocytes by 40%. In the

current study, a linear non-modified HA was used, which was found to preserve the viability of synoviocytes (16). Although great emphasis was placed on ensuring the correct injection technique in both studies, this may not always be followed in practice potentially leading to extraarticular injection and a shortened duration of effect (15).

Visual analogue scale (VAS) for pain similar results to the findings of the current study was reported by a study with a one-year follow up Bisicchia *et al.* (13). These results had shown that VAS score for pain was significantly different from baseline in both groups. Between the two groups, no statistically significant difference was found at month 1, but statistically significant difference was found in favor of HA at the end of months 2 and 3. A meta-analysis showed results that were in agreement with our results Singh *et al.* (14). These findings indicated that HA relieves knee pain due to OA for a longer duration compared to steroids. A three-month study by Askari *et al.* showed no statistically significant difference in VAS score for pain between the two interventions at months 1, 2 and 3 (17). This can be explained by the authors using a HA with a low molecular weight in a dose of 20 mg. In the current study, we used a HA with a high molecular weight and a higher dose (60 mg). It was found that in humans, it is crucial to use formulations with medium to high molecular weights to replicate the conditions and biological properties of the HA naturally produced in

the body (5). Moreover, administering low molecular weight HA results in weak binding and consequently weak HA biosynthesis (5). In contrast, medium and high molecular weight HA exhibit stronger binding, stimulating more HA receptors, boosting endogenous HA production (5).

HA has various mechanisms of action. It acts by increasing the viscosity and elasticity of the joints, serving as a shock absorber and lubricant during joint movements, also it forms a cover around nociceptors that decreases pain signaling (5,7). Moreover, it has been suggested that HA has an anti-inflammatory effect, it binds to CD-44 receptors located on synoviocytes, preventing IL-1 release, enhancing collagen type-2 synthesis and decreasing matrix metalloproteinases (MMP) secretion by chondrocytes and synoviocytes (11). Furthermore, it has been found that exogenous HA stimulates the biosynthesis of endogenous HA and proteoglycans. Ultimately, these effects culminate in preventing chondrocyte apoptosis (5,11). This explains the long duration of effect of IA HA, lasting between 4-26 weeks (10). HA has an affinity to bind to opioid receptors, which further enhances its analgesic effect. It was explained that this affinity is due to the similarity in conformational structures of HA with morphine.

On the other hand, corticosteroids act through a complex mechanism of action, interacting directly with nuclear steroidal receptors, interrupting the inflammatory and immune cascade at several levels (18). They inhibit the production of inflammatory mediators such as prostaglandins and leukotrienes, reducing pain. Additionally, corticosteroids interfere with the release of pro-inflammatory cytokines including IL-1 and TNF- α , which aids in halting the progression of OA (18). However, a study where the patients received a corticosteroid injection every three months for a total of four injections demonstrated that corticosteroids accelerate the progression of OA, leading to increased cartilage and bone damage. This may explain the shorter duration of effect of corticosteroids compared to HA (18,20).

The most common adverse event reported in the present study was injection site pain, with a similar and low occurrence rate in both HA and MP groups. This suggests that both HA and MP are relatively safe and tolerable. These results were in accordance with previously published data (13,14).

Conclusion

It appears that both HA and MP are effective in improving the pain and function of osteoarthritic knees with no significant difference between the two interventions at the short term. However, HA seems to be superior to MP at the long term. Both medications seem to be safe, with minimal adverse events.

Recommendations:

- Future studies should focus on increasing the follow up period to assess the full extent of the prolonged pain-relieving effect of HA.
- Adding another group using different products of HA to compare its efficacy to the type of HA used in the current study.

Authors' declaration:

We hereby confirm that all the Figures and Tables in the manuscript are ours. Besides, the Figures and images, which are not ours, have been given permission for republication attached with the manuscript. Ethical Clearance: The project was approved by the local ethical committee in (Department of Pharmacology, College of Medicine, University of Baghdad.) according to the Reference number 1578 on (01.06.2024)

Conflicts of Interest: None

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Data availability: Upon reasonable request, the corresponding author will make the data sets generated and/or analyzed during the current work available.

Authors' contribution

Dr. Mohammed AHJ Al-Zobaidy is an Editor in the journal, but did not participate in the peer review process other than in his role as an author.

Study conception & design: Sami Salman and Mohammed AHJ AL-Zobaidy. **Literature search & Manuscript preparation:** Mohammed AH AL-Zobaidy and Mohammed Jiyar Ibrahim. **Data acquisition, Data analysis & interpretation;** Sami Salman and Mohammed Jiyar Ibrahim. **Manuscript editing & review:** Sami Salman and Mohammed AH AL-Zobaidy

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مقارنة آثار حمض الهيالورونيك داخل المفصل مقابل خلات ميثيل برينديزولون في مجموعة من المرضى العراقيين الذين يعانون من الفصال العظمي: دراسة مزدوجة التعمية المسيطر عليها

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الخلاصة

الخلفية: الفصال العظمي هي حالة مزمنة شائعة تصيب المفاصل وتحدث عندما يتدهور الغضروف، الذي يعمل كسطح منخفض الاحتكاك بين المفاصل، مما يؤدي إلى الألم والتصلب والتورم. كان هناك جدل حول فعالية وتحمل الكورتيكو ستيرويدات وحمض الهيالورونيك، وحول تفوق أحدهما على الآخر في علاج الفصال العظمي.

الهدف: مقارنة فعالية وأمان حمض الهيالورونيك والميثيل برينديزولون في علاج الفصال العظمي.

المنهجية: تم توزيع مائة وأربعة مرضى مصابين بالفصال العظمي بشكل عشوائي لتلقي حقنة داخل المفصل من حمض الهيالورونيك أو ميثيل برينديزولون، وتمت متابعتهم لمدة 3 أشهر. تم إجراء الدراسة في عيادة خاصة في بغداد، العراق في حزيران 2024. تلقى كل مريض من كل مجموعة حقنة واحدة في وقت التسجيل. لم يكن المشاركون والمقيم على علم بطبيعة المادة المحقونة. كانت النتائج الأولية هي قياس التغيير من خط الأساس في مؤشر الفصال العظمي بجامعة ماكماستر في غرب أونتاريو (WOMAC) ومقياس الألم التناظري البصري (VAS)، وتسجيل أية آثار جانبية مرتبطة بالعلاج.

النتائج: كان هناك 49 أنثى و3 ذكور في مجموعة حمض الهيالورونيك (متوسط العمر 59 ± 15.5) و46 أنثى و6 ذكور في مجموعة الميثيل برينديزولون (متوسط العمر 63 ± 15.5). أظهرت كلتا المجموعتين تحسناً في درجات مؤشر الفصال العظمي بجامعة ماكماستر في غرب أونتاريو (WOMAC) ومقياس الألم التناظري البصري (VAS) طوال فترة المتابعة. كان حجم التأثير لصالح حمض الهيالورونيك على الميثيل برينديزولون من الشهر الثاني إلى الشهر الثالث. وكان كلا التدخلين آمنين نسبياً، ولم يتم الإبلاغ عن أي أحداث سلبية خطيرة.

الاستنتاج: يبدو أن كلا من حمض الهيالورونيك وخلات ميثيل برينديزولون فعالان في تحسين ألم ووظيفة الركبة المصابة بالفصال العظمي، دون أي فرق يذكر بينهما على المدى القصير. ومع ذلك، يبدو أن حمض الهيالورونيك يتفوق على خلات ميثيل برينديزولون على المدى الطويل. ويبدو أن كلا الدواءين آمنان، مع آثار جانبية ضئيلة.

الكلمات المفتاحية: مزدوج التعمية، حمض الهيالورونيك، داخل المفصل، ميثيل برينديزولون، الفصال العظمي