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Original Article

Comparing the results of knee osteoarthritis treatment with intra-articular injection of steroid (methylprednisolone) and hyaluronic acid

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Abstract

Background: Treatments for osteoarthritis, including steroids and nonsteroidal anti-inflammatory drugs, are not very satisfactory. Therefore, we decided to compare the therapeutic results of intra-articular injection of hyaluronic acid and methylprednisolone.

Methods: In this single-blind clinical trial, 132 patients with osteoarthritis of the knee were randomly assigned to two treatment groups; hyaluronic acid and methylprednisolone. Treatment results were measured based on the standard McMaster Universities Arthritis Index (WOMAC) questionnaire.

Results: Although the desired level of satisfaction was higher in the short-term in the methylprednisolone group and in the long-term in the hyaluronic acid group, however, these differences were not significant.

Conclusion: The recovery of patients is better with methylprednisolone injection in the short term and hyaluronic acid in the long term. However, since methylprednisolone has complications, it is recommended to consider hyaluronic acid as a suitable drug in the treatment process.

Keywords: Knee osteoarthritis, Hyaluronic acid, Methylprednisolone.

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Osteoarthritis is a destructive disease of the joints in which joint surfaces are eroded and corroded, and due to this, smooth movements of the joint are disturbed (1). More than 13% of people aged 55-64 years and more than 17% of people aged 65-74 years suffer from pain and movement restrictions due to osteoarthritis (2, 3). In older people, osteoarthritis of the knee causes more movement problems than any other disease (4, 5). Usually, in osteoarthritis of the knee joint, the internal compartment undergoes metamorphic changes, and the amount of this involvement is 10 times higher than the external compartment (6, 7). Osteoarthritis causes significant morbidity in patients due to disability caused by clinical symptoms of pain and limitation of joint movement (8, 9).On the other hand, due to the lack of vascularity of articular cartilage tissue and the low capacity of cell replication, the process of spontaneous repair of articular cartilage cells occurs less often (10). In general, due to the resulting disabilities caused by this disease and the significant reduction in the quality of life of patients, effective treatment measures are considered a necessity (11, 12). Although surgery relieves the pain caused by osteoarthritis and returns the patient to previous activities, not all patients are suitable candidates for surgery (13, 14). On the other hand, a large number of patients want to postpone the time of surgery, so alternative treatments have become important (15, 16). These treatments include lifestyle changes, taking drugs systemically (such as anti-inflammatory drugs) or locally such as intra-articular injections of corticosteroids or hyaluronic acid (17-19).

Intra-articular injection of hyaluronic acid and corticosteroids is one of the most popular treatment methods for osteoarthritis, especially in patients who have failed other treatment methods due to toxicity or ineffectiveness (20). In many studies, the beneficial effects of intra-articular injection of hyaluronic acid in controlling the pain and activity of patients have been shown. Intra-articular injection of corticosteroids has been reported to be effective and well tolerated but should be limited to 3-4 injections per year (21, 22). Because it may cause a decrease in the functions of sensory receptors, the progressive destruction of articular cartilage, and the development of the Charcot joint (17, 23). For this reason, the use of drugs with fewer side effects, such as hyaluronic acid, has been suggested (24). In this regard and considering the existence of reports on the effectiveness of hyaluronic acid, this study was planned with the aim of comparing the results of knee osteoarthritis treatment using an intra-articular injection of steroid (methylprednisolone) and hyaluronic acid in patients referred to the clinic of Razi Hospital in Qaemshahr.

Methods

Trial design: This study was a single-blinded, randomized clinical trial design.

Randomization and blinding: Patients were divided into two study groups using a random sequence of computerized blocks with 66 samples. Allocation was concealed using opaque sealed envelopes. Recruitment, outcome measurement, and statistical analysis were performed by investigators who were unaware of assigned treatment.

Participants: Participants in this study were selected from Patients with knee osteoarthritis referring to the orthopedic clinic of Razi Qaimshahr Hospital in 2020 (academic centers of the Islamic Azad Mazandaran University of Medical Sciences).

Selection criteria: Patients willing to participate in the study at the age range of 50 to 60 years, Patients with a history of infection or primary inflammatory disease of the knee joint, arthritis caused by crystals, intra-articular tumors, ligamentous instability of the knee joint, previous intra-articular fracture, Knee joint surgery (arthroscopic, etc.) in the last 12 months. Exclusion criteria included; Reluctance to participate in the study, Diabetes mellitus, Coagulation disorders, Terrestrial neuropathy, History of allergy to injectable solutions (corticosteroid-hyaluronic acid), History of corticosteroid or hyaluronic acid use in the past 6 months.

Intervention: In this double-blind clinical trial, 132 patients with knee osteoarthritis referred to Razi Qaemshahr hospital who were willing to participate in the study were examined. All the selected subjects had moderate primary osteoarthritis (grade 3 based on the Kellgren-Lawrence classification). People were randomly placed in two treatment groups, hyaluronic acid (HA), and methylprednisolone (MP). Then, to increase the accuracy of the results, the two groups were matched in terms of demographic characteristics (age, sex, severity of symptoms, and severity of osteoarthritis). Injections were performed in the knee joint by one person with the same method, observing local disinfection. Sodium hyaluronate in the amount of 20 mg was injected twice with an interval of 2 weeks, and methylprednisolone 40 mg was injected only once. The results of the treatment were measured based on the standard WOMAC questionnaire before and after the treatment at intervals of 1 and 6 months after the treatment

Outcomes: McMaster Universities Arthritis Index (WOMAC), WOMAC is an index for evaluation of function with three parts: pain with five items, joint stiffness with 2 items, and physical function with 17 items (total WOMAC score was 24 items). Each item includes 5 scales from 0 to 4 (none: 0, mild: 1, moderate: 2, severe: 3, and extreme: 4). The total WOMAC score is defined between 0 as the best function and 96 as the worst function (25). The level of satisfaction of patients with their treatment results was measured based on the reduction of pain intensity, reduction of joint stiffness, and better performance of daily activities, and the question of whether they would recommend this treatment method to others was evaluated. Finally, the collected data were entered into SPSS software Version 21 and analyzed based on the type of data and their distribution with the help of appropriate statistical tests at a significance level of 0.05 alpha.

Sample size: According to the previous sources and based on the following formula, considering alpha. study (Beta 0.05) the second error of the study (P 0.2) the frequency of cases of improvement in Frequency of cases among people under treatment with methylprednisolone after 6 months (P 0.77 and 2) Improvement among people treated with hyaluronic acid after 6 months (132, 0.8 people in two groups of 66 people are included in the study.

$N=[P1\ (1-P1)] + [P2\ (1-P2)] \times (Z\ 1-\alpha/2+ Z\ 1-\beta)^2 \setminus N= (0.2 \times 0.8) + (0.23 \times 0.77) \times 7.8\ (P1-P2)^2\ (0.2)\ N= 66$

Ethical considerations: We explained both methods and side effects to each patient before participating in the study. All patients gave their informed consent form. They could withdraw from the study whenever they wanted. This study was approved by the Medical Ethics Committee of Sari University of Medical Sciences with the ethics number: IR.IUA.SARI.SARI.REC.1398.131.

Results

Thirty-six (54.5%) people in the methylprednisolone group and thirty-four (51.5%) people in the hyaluronic acid group were women. The chi-square test showed that the two groups did not differ significantly in terms of gender ($p > 0.05$). The average age of patients in MP and HA groups were reported as 55.1±3.24 and 55.36±3.2 years, respectively. The Mann-Whitney test showed that the observed differences are not significant and the two groups have a similar age distribution (P = 0.70). The average score obtained from the WOMAC questionnaire before the start of therapeutic intervention in the MP and HA groups were 35.71±7.7 and 37.11±7.35, respectively. Mann-Whitney test shows that these differences are not significant and the condition of patients before the start of treatment was not significantly different from each other (P = 0.18). Before the beginning of therapeutic interventions, the two groups did not have a significant difference in terms of pain (8.68±2.40 for MP, 8.71±2.33 for HA, P = 0.72). Although the average swelling score of patients in the MP group was higher than the HA group before the start of the intervention, these differences were considered insignificant at the significance level of 0.05 and the two groups did not differ from each other in terms of knee swelling before the intervention (1.72±0.86 for MP, 1.46±0.82 for HA, P = 0.11). The score of knee stiffness of the patients in the examined groups before the intervention did not show any significant difference from each other (4.72±1.66 for MP, 4.39±1.32 for HA, P = 0.09). The physical performance of the patients in the two groups were not different before the beginning of the therapeutic intervention (20.72±7.01 for MP, 22.48±7.03 for HA, P = 0.14).

Table 1. Descriptive results*

Variable	HA group (N = 66)	MP group (N = 66)	P-value
Gender (female)	34 (51.5)	36 (54.5)	0.43
Age (year)	55.36±3.2	55.1±3.24	0.7
WOMAC score before intervention	37.11±7.39	35.71±7.70	0.18
Swelling score	1.46±0.82	1.72±0.86	0.11
Knee stiffness score	4.39±1.32	4.72±1.66	0.09
Pain score	8.71±2.33	8.68±2.40	0.72
Physical performance score	22.48±7.03	20.72±7.01	0.14

* For qualitative variable; N (%) and for quantitative variable; mean±SD

Table 2. The average scores obtained from the WOMAC questionnaire in the studied groups at intervals of 1 and 6 months

Group	WOMAC – before	WOMAC – 1 month	WOMAC – 6 months
Methylprednisolone (mean±SD)	35.88±7.58	29.55±8.16	26.67±6.43
Hyaluronic acid (mean±SD)	37.11±7.39	31.94±7.85	23.85±8.15

One month after re-evaluation, the average scores obtained from the WOMAC questionnaire in the MP and HA groups were reported as 29.55±8.16 and 31.94±7.85, respectively. The Mann-Whitney test showed that these differences are significant and the effectiveness of MP is greater than HA in short-term evaluation (P=0.03). but in the long-term study, people in the HA group had lower average scores compared to the other group; In this way, the average WOMAC was reported in MP group 26.67±6.43 and in HA group 23.85±8.15 (P=0.01). The average recovery score (changes in the score obtained from the WOMAC questionnaire before and after the intervention) was also different in the time intervals of one and six months. Thus, the recovery score one month after the intervention in the MP and HA groups was reported as 9.95±6.69 and 6.88±5.10, respectively. This figure was measured six months after the intervention as 8.59±7.76 and 13.97±6.02 respectively. Therefore, it can be concluded that the effectiveness of methylprednisolone is better than hyaluronic acid in the short term, while the effectiveness of

hyaluronic acid is better in a 6-month evaluation. The pain score of patients in the hyaluronic acid group decreased from 8.71±2.33 to 6.89±2.45 and 6.77±2.93 at intervals of one and six months after the intervention.

The pain score of methylprednisolone group patients one and six months after the intervention was 6.41±2.75 and 6.97±2.80, respectively. The pain score in this group of patients before treatment intervention was reported as 8.68±2.40. The average knee stiffness score of patients treated with hyaluronic acid before the treatment study was reported to be 4.39±1.32. This score was reduced to 4.03±1.22 and 3.15±1.41, one and six months after the intervention. The average knee stiffness score of patients treated with methylprednisolone before the treatment study was reported to be 4.72±1.66. This score was reduced to 3.85±1.65 and 3.12±1.10, one and six months after the intervention. The average knee swelling score of hyaluronic acid group patients was 1.46±1.37 before the intervention, and it reached 1.4 ±0.75 and 1.37±0.80 one and six months after the intervention, respectively.

The average knee swelling score of methylprednisolone group patients was 1.72±0.86 before the intervention, and it reached 1.55±0.68 and 1.63±0.75 one and six months after the intervention, respectively. The score obtained by the patients in the hyaluronic acid group for physical performance before the intervention and one and six months after the intervention was reported as 22.48±7.03, 17.61±7.21 and 15.15±6.88, respectively. The score obtained by the patients in the methylprednisolone group for physical performance before the intervention and one and six months after the intervention was reported as 20.72±7.01, 15.91±7.14 and 13.70±4.82, respectively. One month after the therapeutic intervention on the patients, 75.2% of the methylprednisolone group and 62.1% of the hyaluronic acid group rated their level of satisfaction as good and excellent. Meanwhile, the level of good and excellent satisfaction six months after the intervention reached 60.6% in the methylprednisolone group and 73.3% in the hyaluronic acid group. However, the chi-square test showed that there is no significant difference in the level of patient satisfaction in the two groups in any of the investigated time intervals ($p>0.05$). 81.8% of the methylprednisolone group and 75.8% of the hyaluronic acid group admitted that they would recommend the treatment approach adapted for themselves to others.

Discussion

The findings obtained from our study showed that despite the higher effectiveness of MP in controlling symptoms and improving patients with osteoarthritis, the effectiveness of HAs is better in the long term. The level of patients' satisfaction with the treatment approach adopted for them was not significantly different between the two groups. In general, considering the long-term effects of HA, it seems that this treatment approach can be a suitable and safe alternative to treatment through corticosteroids.

In the present study showed that the effectiveness of methylprednisolone is higher than hyaluronic acid in the short term, while the effectiveness of hyaluronic acid was better in the 6-month evaluation. This finding is consistent with the results obtained from the previous studies (26-28). In the study of Liu et al. in 2018, it was found that people treated with hyaluronic acid showed a better improvement in the WOMAC questionnaire score in the long term. In addition, people who were treated with corticosteroids also showed a higher pain score than other people in the long term, but they had good effectiveness in the short term (29). The low long-term effectiveness of corticosteroids was also proven in the studies of Raynauld et al. in 2003 and Bellamy et al. in 2006 (30-32).

In the review study by Bannuru et al. in 2009, it was also found that the effectiveness of corticosteroid injection is significantly higher than that of hyaluronic acid during the first 4 weeks after treatment. In the 8th week, the two methods were equally effective, and after 8 weeks, hyaluronic acid showed a higher effectiveness than corticosteroids (33). Maheu et al. in 2016 investigated the effectiveness and safety of hyaluronic acid in the treatment of knee osteoarthritis and in the end reported this method as a safe and effective method in the treatment of knee osteoarthritis (34). In the study of Tasciotaoglu et al. in 2003, 60 women with knee osteoarthritis were examined in two groups. One group was injected with 30 mg of sodium hyaluronate and the other group was injected with 40 mg of methylprednisolone, and the results showed that sodium hyaluronate had more benefits in the treatment of osteoarthritis in the long term (35).

In 2014, Fakoor et al. examined fifty-three patients with knee osteoarthritis and matched them in two treatment groups: sodium hyaluronate (20 mg) and methylprednisolone (40 mg) according to age and gender. The findings of this research showed that hyaluronic acid and methylprednisolone have similar short-term therapeutic effects, but in the long term (after more than 6 months), hyaluronic acid will have a higher effectiveness (36). In 2001, ARYAL et al. showed that the analgesic effects of hyaluronic acid and methylprednisolone are similar. However, the palliative effects of methylprednisolone start earlier and end earlier. Hyaluronic acid is also a safer drug;

as intra-articular corticosteroids increase joint surface lesions in animal studies. Therefore, it is recommended not to use it more than 3-4 times a year (37). In the study of Frizziero et al. in 2002, ninety patients with osteoarthritis of the knee were examined in two groups treated with hyaluronic acid and methylprednisolone. At the beginning of the intervention, it was found that methylprednisolone has better therapeutic effects compared to hyaluronic acid. But after 180 days, it was found that the therapeutic effects of hyaluronic acid are better than methylprednisolone in the long term (38). Esmaili Jah et al. showed in 2006 that the analgesic effects and recovery of patients were better in the case of methylprednisolone injection. But this drug has reports of the possibility of causing joint destruction; Meanwhile, hyaluronic acid injection has analgesic and healing effects similar to methylprednisolone, and no destructive effects have been reported (39).

In 2018, Ran and his colleagues compared the effectiveness of hyaluronic acid and methylprednisolone in the pain management of patients with knee osteoarthritis. For this purpose, 5 clinical trials including one-thousand and four patients were examined in this meta-analysis. The findings of this study showed that the 2 groups did not differ from each other in terms of WOMAC pain score and physical performance during time intervals of 4, 12, and 26 weeks. The rate of pain complications in both groups was low and did not show a significant difference (40). This finding was consistent with the results obtained from patients in the methylprednisolone group of the present study. One month after therapeutic intervention on the patients, 75.2% of the methylprednisolone group and 62.1% of the hyaluronic acid group rated their level of satisfaction as good and excellent.

Meanwhile, the level of good and excellent satisfaction six months after the intervention reached 60.6% in the methylprednisolone group and 73.3% in the hyaluronic acid group. However, the chi-square test showed that there is no significant difference in the level of satisfaction of patients in the two groups in any of the investigated time intervals ($p > 0.05$). 81.8% of people in the methylprednisolone group and 75.8% of the people in the hyaluronic acid group admitted that they would recommend the treatment approach adopted for themselves to others. In the study of Esmaili Jah et al. in 2006, 28 patients (70%) in the hyaluronic acid injection group and 16 patients (100%) in the corticosteroid injection group were satisfied with the treatment results (39). Considering that repeated injections of corticosteroids can ultimately cause joint destruction and exacerbation of osteoarthritis and decrease the patient's performance, and also considering the response of patients to treatment in terms of reducing pain intensity and fewer side effects to hyaluronic acid treatment than methylprednisolone and not having complications such as joint destruction, it is recommended to use more hyaluronic acid than methylprednisolone.

Hyaluronic acid forms a viscoelastic solution in water, which as a lubricant in the joint plays an important role in modulating the interaction between the surfaces of adjacent joints. This drug cannot affect the progression of the disease, but it can improve pain and function due to its physical and chemical properties through several mechanisms. This drug improves the reduced viscoelasticity of synovial fluid. Methylprednisolone exerts its anti-inflammatory effects by preventing the accumulation of inflammatory cells in the area of inflammation, inhibiting phagocytosis and the release of enzymes responsible for inflammation, and inhibiting the production and release of chemical mediators of inflammation, which is why the effect of prednisolone is shorter. And it is faster, and hyaluronic acid has a slower effect and its effect remains longer.

This study was conducted in a small sample size and in a single center. Therefore, it is recommended that this study be conducted in a larger sample size and multicenter conduct. This study was conducted in a one-sided blind way, and for better generalization of the findings, it seems that conducting three-sided blind studies with a larger sample size and in a multi-center manner is necessary to generalize the results. It is suggested that future studies be implemented and implemented on a large scale in other medical centers. Examining the complications observed in patients and comparing them between the studied groups is another issue that can be considered by researchers in future research. Also, the comparison of other steroids with hyaluronic acid can be considered a study aim for researchers.

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Data availability: The data used to support the findings of this study are available from the corresponding author upon request.

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