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Evaluation of Clinical Results of Three Different Treatment Groups in the Patients with Moderate (Stage 2-3) Osteoarthritis

Ilımlı Diz Osteoartriti Olan Hastalarda (Evre 2 ve 3) Üç Farklı Tedavi Grubunun Klinik Sonuçlarının Değerlendirilmesi

¹⁰ Güzelali Özdemir,¹ ¹⁰ Barış Yılmaz,² ¹⁰ Kenan Bayrakçı,³ ¹⁰ Erman Ceyhan,¹ ¹⁰ Uğur Günel⁴

ABSTRACT

Objectives: The aim of this study is to analyze the effectiveness of intraarticular hyaluronic acid injection and arthroscopic debridement for stage 2 and 3 osteoarthritides of the knee based on the Kellgren-Lawrence system.

Methods: One hundred and thirteen patients with knee pain complaints diagnosed as osteoarthritis were divided randomly into three groups. The first group was treated with intraarticular hyaluronic acid injection the second group was treated with arthroscopic debridement operation and for the last group, both procedures were performed. The patients were evaluated with Lysholm Knee Score and Visual Analogue Scale just before and 3 months after the treatment. The evaluation has continued every 3 months for the rest of the year.

Results: About 82.3% (n=93) of the patients were female. There was no significant statistical difference between the groups according to age and Body Mass Index. All the three groups had significant improvement in the Visual Analog Scale (VAS) and Lysholm Scale compared with the starting values. This improvement especially occurred in the first 3 months, then stopped and entered a plateau phase between the 3 and 6 months. After the 6 month a decline phase starts although the values are still positive compared to starting ones. According to sex, the Lysholm scale values of male patients were statistically significantly higher at the 3, 6, 9, and 12 month. During the treatment period, no complications were observed among the patients. The existence of torn meniscus, plica, or injured or intact ACL did not influence the VAS and Lysholm values. The only significant score change was observed in patients with synovial hypertrophy.

Conclusion: We observed that arthroscopy alone or with additional hyaluronic acid injection after the operation is an effective treatment for knee osteoarthritis. For our selected patient group the first treatment option is intraarticular hyaluronic acid injection. If there is no significant improvement at the 3 and 6 months follow-up period an arthroscopic debridement procedure should be performed. If any cartilage injury is obtained during arthroscopic intervention we think that postoperative intraarticular hyaluronic acid improves functional scores.

Keywords: Arthroscopic debridement; hyaluronic acid injection; intraarticular injection; lysholm scale score.

ÖZET

Amaç: Kellgren-Lawrence sistemine göre evre 2 ve 3 diz osteoartrit olan olgular için intraartiküler hyaluronik asit enjeksiyonu ve artroskopik debridman uygulanmasının güvenilirliği ve etkinliğini göstermek amaçlandı.

Yöntem: Diz ağrısı ile başvuran osteoartritli 113 olgu, rastgele üç gruba ayrıldı. İlk gruba intraartiküler hyaluronik asit enjeksiyonu, ikinci gruba artroskopik debridman ve üçüncü gruba her ikisi birden uygulandı. Olgular tedaviden hemen önce ve tedavi sonrası ilk üç ay aylık, daha sonra üç ayda bir Lysholm Diz Skorlama Skalası ve Vizüel Analog Skala ile değerlendirildiler.

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Surgery and Traumatology, Ankara City Hospital, Ankara, Turkey ²Department of Orthopedic Surgery and Traumatology, Fatih Sultan Mehmet Training and Research Hospital, Istanbul, Turkey ³Department of Orthopedic Surgery and Traumatology, Spitali American Hospital, Istanbul, Turkey ⁴Department of Orthopedic Surgery and Traumatology, Ankara Magnet Hospital, Ankara, Turkey

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Correspondence:

Dr. Güzelali Ozdemir. Ankara Şehir Hastanesi, Ortopedi ve Travmatoloji Kliniği, İstanbul, Turkey

> Phone: +90 532 584 36 11 e-mail:

drguzelali@yahoo.c



Bulgular: Olguların %82,3'ü (n=93) kadındı. Gruplar arasında BMİ ve yaş açısından istatistiksel olarak anlamlı fark bulunmadı. Tüm tedavi gruplarında başlangıç değerlerine göre takipler boyunca VAS ve Lysholm skalası puanlarında anlamlı düzelme saptandı. Bu durum ilk üç ayda daha hızlı gerçekleşmekte, 3. ve 6. aylar arasında gelişme durarak bir plato çizmekte ve sonrasında başlangıca göre değerler pozitif olmasına rağmen azalma eğilimi göstermektedir. Cinsiyete göre Lysholm skalası puanlarına bakıldığında tedavi sonrası 3, 6, 9, 12. aylarda erkeklerde Lysholm skalası puanları istatistiksel olarak anlamlı şekilde daha fazla bulundu. Olgularımızda tedavi süreleri boyunca herhangi bir komplikasyon gözlenmedi. Menisküs yırtığı durumu, plika varlığı ve ACL'nin sağlam veya yırtık olması ile VAS ve Lysholm skala puanları arasında bir ilişki saptanmadı. Tek anlamlı bulgu synoviyal hipertrofisi olanlarda saptandı.

Sonuç: Artroskopik debridmanın tek veya intraartiküler hyaluronik asit enjeksiyonu ile birlikte uygulanmasının etkili bir tedavi olduğu sonucuna vardık. Bu olgu grubu için intraartiküler hyaluronik asit eklem içi enjeksiyonunun tercih edilmesi gerektiğini, sonraki takiplerinde 3-6. aya kadar anlamlı düzelme görülmez ise artroskopik debridman uygulamasının planlanması gerektiği kanaatindeyiz. Yine aynı olgu grubu için artroskopik debridman uygulaması tercih edilebilecek bir diğer tedavi seçeneğidir. Artroskopik girişim sırasında eklem kıkırdaği hasarı saptanır ise, postoperatif dönemde hyaluronik asit enjeksiyonu yapılmasının fonksiyonel skorları daha da iyiye götüreceğini düşünmekteyiz.

Anahtar sözcükler: Intraartiküler enjeksiyon; Artroskopik debridman; hyaluronic asit enjeksiyon; Lysholm skala skor.

K nee osteoarthritis (OA) is a disease that can affect the quality of life of the patient markedly by causing severe muscle strength, stability, proprioception, and gait disorders in addition to disability and movement disorders. Clinical picture beginning with just pain at first can make the patient handicapped and disabled with limitation in daily life activities and by disturbing the harmony between work and home life.^[1]

Any treatment modality that could reverse the clinical course of OA could not be shown yet. However, the patients can be relieved with appropriate treatment methods substantially and their quality of life can be improved. In the treatment of knee OA, patient education, exercises, lifestyle modification, paracetamol, nonsteroidal anti-inflammatory drugs (NSAIDs), topical agents, intra-articular injections, arthroscopic surgery, osteotomies, and arthroplasty techniques can be used. There is little information about the efficacy of the intra-articular hyaluronic acid (HA) injection and arthroscopic debridement alone or in combination in the mild-to-moderate knee OA.

The aim of this study is to investigate the efficacy of administration of intra-articular HA injection and arthroscopic debridement alone or in combination in the patients with stage 2 and 3 OA according to the Kellgren-Lawrence system for whom there is no definite data out of early and advanced cases.

Methods

The patients who were stage 2 and 3 OA according to Kellgren-Lawrence radiological knee OA staging^[2] and unresponsive to NSAID, activity modification, and physical therapy methods for at least 6 months were included in this prospectively designed study. The ethics committee approval was obtained from local committee and informed consent forms were obtained from the patients included in the study. All researchers contributed to the study signed the Helsinki's declaration.

Stage 1 and 4 patients, undergoing surgical therapy, intraarticular injection treatment, fractures around the knee, and inflammatory arthritis diagnosis previously were excluded from the study.

One hundred and thirteen patients meeting these criteria were randomly assigned into three groups. The randomization was done with sealed envelop method. Intra-articular HA injection was administered alone in the first group (group 1, n=46), arthroscopic debridement was performed alone in the second group (group 2, n=32) and intra-articular HA injection and arthroscopic debridement were administered in combination in the third group (group 3, n=35). (Table 1).

Characteristics	Number	Percentage
Interventions		
Arthroscopy	32	28.3
Intra-articular inject.	46	40.7
Arth+I.A	35	31.0
Total	113	100.0
Degeneration		
2 nd degree	35	33.7
3 rd degree	69	66.3
Total	104	100.0

Two mL of HA injection was administered 3 times in total to the patients in Group 1 at 1st, 2nd, and 3rd weeks. Infrapatellar medial or lateral portals of the knee were used for intra-articular injection. Arthroscopic debridement was performed to the patients in Group 2. The knee joint space was entered through infrapatellar medial and lateral portals while the patient was in supine position under general anesthesia after application of pneumatic tourniquet. During arthroscopic procedure, unstable ruptured meniscal fragments, hypertrophic synovial tissue, pathologic plica, free cartilage fragments, and unstable cartilage flaps were excised. The knee joint was continuously irrigated with Ringer's lactate solution during arthroscopy. Entrance portals were closed and surgical procedure was terminated with application of pressure dressing. Arthroscopic findings were noted down. Intra-articular HA injection was performed to the patients in Group 3 with the same protocol of the patients in Group 1 two weeks after application of arthroscopic debridement as it was in Group 2.

Synovium was systematically observed in all areas during arthroscopy and diagnosis of synovial hypertrophy was made by evaluating three parameters (hypertrophy, vascularity, and synovitis) according to the macroscopic scoring system.^[3]

Articular cartilage injury or degeneration observed during arthroscopy was classified according to the Outerbridge system.^[4] Each patient was mobilized early with weightbearing as far as tolerable. Knee rehabilitation program that would be applied at home was initiated in all cases. Full range of motion, quadriceps, and hamstring strengthening exercises were given. All cases with high body mass index were recommended to lose weight. Analgesic and anti-inflammatory drug use of the cases was not restricted. At the beginning of the study and during the follow-ups, pain status was recorded for each case using Lysholm Knee Scoring Scale^[5] and Visual Analog Scale (VAS). The patients were followed up monthly for the first 3 months and then once every 3 months. An independent physician performed all injections and made all clinical assessments at the present study.

One Way ANOVA and Tukey HSD tests were used for the determination of difference between treatment groups. Paired Samples t-test was used to determine the difference between months and periods and independent samples t-test was used to determine the statistical correlation between the different groups. P values of <0.05 level were considered to be statistically significant. Statistical analysis was performed by using the SPSS 11.5 statistical software package (SPSS, Inc., Chicago, IL, USA).

Results

Eighty-two point three percent of the patients (n=93) were females, mean age was 57.9 ± 11.1 (min=36, max=85) years and mean body mass index was 30.2 ± 5.0 (min=20.0, max=42.2). No statistically significant difference was found regarding body mass index and age between the groups.

No statistically significant difference was found regarding VAS pain scores between the groups (p>0.05). A statistically significant decrease was determined in VAS pain scores at 1st and 2nd months in Group 1 and at 2nd and 3rd months in Group 2 and Group 3 (p<0.01). While the increase in VAS pain values in all groups during follow-up compared to baseline was relatively small, a statistically significant increase was determined in VAS pain values from 6th to 15nd months (Fig. 1).

There was no statistically significant difference in VAS pain scores between Group 1 and Group 2 in the first two months regarding baseline values (p>0.05). In Group 3, VAS pain scores were statistically significantly lower compared to these groups (p<0.01). In the subsequent follow-ups, VAS pain scores were statistically significantly higher in Group 1 and Group 2 compared to Group 3 (p<0.01).

There was no significant correlation between gender and VAS pain score (p>0.05). A positive significant correlation was determined between VAS pain scores at the 2^{nd} , 3^{rd} , and 6^{th} months after treatment and age (p<0.05).

VAS pain scores were statistically significantly higher in the patients with 3^{rd} degree degeneration on the radiograms until 12 months compared to baseline (p<0.05). VAS pain scores decreased until 2 months in the patients with 2nd degree degeneration on the radiograms and within the first 3

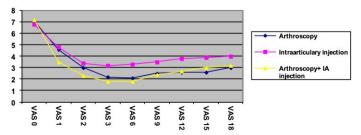


Figure 1. Distribution of VAS scores over time according to the treatment modality. VAS: Visual analog scale.

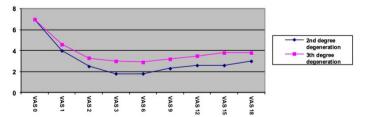
months in the patients with 3rd degree degeneration on the radiograms (p<0.01) (Fig. 2).

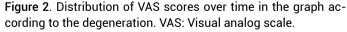
A statistically significant increase was observed in Lysholm scale scores within the first 3 months (p<0.01). While no difference was observed between 3 and 6 months; a decrease occurred between 6 months to 15 months, but this decrease was not statistically significant (p>0.05) (Fig. 3).

No statistically significant difference was observed between Group 1 and Group 2 regarding Lysholm scale scores after treatment (p>0.05). Lysholm scale scores were significantly higher in Group 3 compared to Group 2 within the first 2 months (p<0.01). This condition was not observed after 2 months (p>0.05). Lysholm scale scores were observed to be higher in Group 3 compared to Group 1 until 6 months after treatment (p<0.01). This feature appeared also at the 12 months after treatment (Fig. 4).

Lysholm scale scores were found to be statistically significantly higher in the males (p<0.05). Lysholm scale scores were found to be statistically significantly higher in the patients with 2^{nd} degree degeneration compared to the patients with 3^{rd} degree degeneration after treatment until 2^{nd} to 6^{th} months (p<0.01) (Fig. 5).

VAS pain scores were statistically significantly higher in the patients with degenerated tibial condyle within the first 3 months after treatment. While the difference continued until 15 months, statistical significance disappeared in the subsequent months (p>0.05). There was no statistically





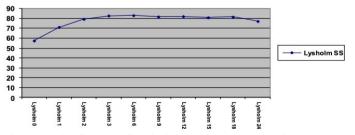


Figure 3. Distribution of Lysholm scale scores over time.

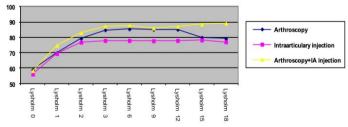
significant difference between the status of the presence of degeneration in the other areas of the joint and VAS pain scores (p>0.05).

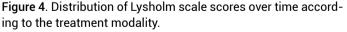
There was no statistically significant difference in all of the months after treatment between the status of presence of degeneration in the other areas of the joint and Lysholm scale scores (p>0.05). While there was no difference before treatment, Lysholm scale scores were statistically significantly lower in the patients with medial tibial condyle degeneration until 9 months after treatment (p<0.05). The statistical significance disappeared in the other months (p>0.05).

Lysholm scale scores were statistically higher in the patients without synovial hypertrophy between 2 and 9 months after treatment. No correlation was determined between duration of complaint, duration of surgery, body mass index, age, meniscal tear, presence of plica, intact or ruptured anterior cruciate ligament and Lysholm scale scores and VAS pain scores (p>0.05).

Discussion

Efficacy and safety of intra-articular HA injection in the treatment of knee OA were confirmed using meta-analysis study.^[6-8] HA therapy takes place at the previous step of the surgical treatment of the algorithm for the management of OA of the knee.^[9-11] In consequence of placebo-controlled clinical studies performed, after HA therapy, it was stated that less joint space narrowing in the medial compartment





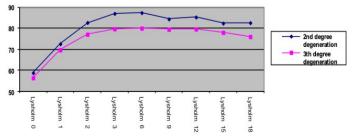


Figure 5. Distribution of Lysholm scale scores over time in the graph according to the degeneration.

was observed in the patients who were radiologically moderate at the beginning,^[12] it was superior to placebo,^[13,14] it had beneficial impacts on general scores^[15] and administration of HA in addition to the appropriate treatment methods provided benefit for patients with OA of the knee.^[16] There are also studies showing no significant difference between placebo and HA regarding pain reduction.^[17,18] Also in our study, a significant improvement was determined in Group 1 patients administered HA alone regarding VAS pain and Lysholm scale scores.

Total knee arthroplasty (TKA) was performed in none of the patients administered intra-articular injection during our study period. This result seems to be consistent with the result of the studies showing that administration of intra-articular HA delays the need for TKA applications and reduces treatment costs.^[19-21]

It has been suggested in various studies that as the degree of OA increased radiographically the response to HA application also reduced.^[6,22,23] In our study, VAS pain scores of the patients with 3rd degree degeneration on the radiograms were significantly higher compared to VAS pain scores of the patients with 2nd degree degeneration on the radiograms and this condition was consistent with the literature.

With arthroscopy in OA of the knee, cartilage degradation products are removed from the joint with increased concentration of cartilage degrading enzymes, and transmission of pain stimuli caused by chloride ions in the lavage fluids to unmyelinated C-fibers are prevented.^[24] Free cartilage flap, synovial hypertrophy, and meniscal tears can be treated with arthroscopic surgery. Short-term complaints, presence of mechanical symptoms, and positive test for meniscus show that the patient can benefit from the arthroscopic surgery.^[25] In our study, there is no correlation between duration of complaint, duration of surgery, body mass index, age, and VAS pain scores and Lysholm scale scores of the patients who performed arthroscopic surgery. We think that better interpretations can be made on this subject with studies that will be conducted with large case series.

Advanced staged cases with mechanical axis disorder which is candidate for poor outcome^[25-29] were not included in the study. In addition, the cases in which conservative treatment methods were successful were not included in the study either. The patients with stage 2 and 3 OA for whom definite data were lacking in the literature were not included in the study. Arthroscopic surgery proved itself to be an advisable treatment option giving successful results in this patient group.

In addition to the study indicating that success rate which is 80% in the arthroscopic lavage at the beginning regressing to 45% by the end of 2 years,^[30] there are studies suggesting that the results of lavage even in the early period are not good enough.^[31] In another study, while success rate was reported to be 86% by the end of 1 year and 81% by the end of 2 years, it was suggested that additional HA injection did not change this rate.^[32] However, when this study is investigated, knee scores of the patients included in the study seem to be higher also before the surgery.

It has been suggested that the outcomes of the patients with positive tests for meniscus at the physical examination and unstable meniscal tear observed during arthroscopy were better.^[33] Again it was suggested that need for prosthesis has gone away in 67% of the patients with osteotomy or TKA indication but performed arthroscopic debridement.^[34]

Moseley et al.^[35] advocated that there was no difference between the outcomes of the patients in the group performed arthroscopic debridement or lavage and the outcomes of the patients in the placebo group performed surgical incision. However, this study was criticized a lot for methodology, randomization, and ethical issues.^[36-38]

It has been shown that administration of intra-articular HA injection after arthroscopic meniscectomy reduced the pain.^[39] Better outcomes were observed in the patients with OA and a symptomatic meniscus tear after performing arthroscopic surgery plus HA injections compared to after performing arthroscopy alone.^[40] It has been shown that arthroscopic debridement combined with HA injections was an effective treatment option for selected patients with knee OA.^[41] It has been shown that arthroscopic debridement provided benefit in pain and functional outcomes and the postarthroscopic instillation of a HA-based synovial fluid substitute into the joint was a suitable way of achieving long-term stabilization of the treatment outcomes.^[42] Our study has yielded similar results with these studies. Comparison of treatments as three separate groups can be considered as the superiority of our study. Not standardization of treatment modalities such as NSAID and physical therapy and rehabilitation can be considered as limitation of our study.

When the study results are evaluated, administration of arthroscopic debridement alone or in combination with intra-articular HA injection seems to be an effective treatment in the patients with stage 2 and 3 knee OA according to Kellgren-Lawrence system. In case of determination of articular cartilage injury during arthroscopic debridement, we think that administration of intra-articular HA injection in the postoperative period will improve the functional scorings.

Disclosures

Ethics Committee Approval: Before beginning present study approval was given by the institutional review board at Ankara Numune Research and Training Hospital in 2003 as a postgraduate thesis of Guzelali Ozdemir. Then, the thesis was approced by the jury and other authorities in 2005.

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

Authorship Contributions: Concept – G.O., K.B., U.G.; Design – G.O., K.B., U.G.; Materials – G.O., E.C.; Data collection and processing – G.O., E.C.; Analysis and interpretation – G.O.; Literature search – G.O., K.B., B.Y.; Writing – G.O., K.B., B.Y.; Critical review – G.O., K.B.

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