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Original Article

Efficacy of intra-articular injection of Steroid plus High Molecular Weight Hyaluronate in Primary Osteoarthritis of the Knee in a Tertiary Care Hospital in Eastern India.

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Abstract

Background
Knee primary osteoarthritis is a degenerative joint disease creating pain and stiffness, and disability among elderly people. Non-surgical therapies can be effective in offering partial disease-modifying and unpredictable symptomatic relief. The objective of the study was to assess the effectiveness of intra-articular steroid with high molecular weight hyaluronate in the reduction of pain and patient-reported outcomes.

Methods
The proposed interventional study was an 18-month prospective study in the Department of Physical Medicine and Rehabilitation at IPGME & R, SSKM Hospital, Kolkata, India. The inclusion and exclusion criteria were used to recruit fifty patients with primary knee osteoarthritis. A single intra-articular injection of steroid and high molecular weight hyaluronate was administered to all the patients. Pain was measured by the use of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain scale, and overall well-being was measured by the Patient Global Assessment scale. At the baseline, six weeks, and twelve weeks, the evaluations were conducted. The Tukey multiple comparison test was conducted as a statistical test.

Results
Both the WOMAC pain scores and Patient Global Assessment scores were significantly different at six weeks and twelve weeks versus the baseline. The data on the mean differences showed a clinically significant decrease in pain and better patient-reported outcomes. Nonetheless, no significant increase in the interval between six and twelve weeks was observed, indicating that most improvement in symptoms took place during the first six weeks, and beyond was not significant.

Conclusions
Intraarticular injection of steroid plus HMWH in primary OA knee is effective in terms of reduction of pain in the WOMAC scale and reduction of Patients Global Assessment scale, and negligible adverse effect occurs in this regimen.

Recommendation
Future multi-center randomized controlled trials with a larger sample and longer follow-up should verify these results.

Keywords: *Intraarticular injection, Intraarticular High Molecular Weight Hyaluronate, Intraarticular steroid, Primary Osteoarthritis knee*
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Background

Primary Osteoarthritis of the knee is a degenerative joint disease that affects elderly individuals, leading to erosion of articular cartilage. Due to an increase in life expectancy and changes in lifestyle leading to obesity[1], the prevalence of primary Osteoarthritis (OA) of the knee is on the rise and becoming a major concern[2]. Primary osteoarthritis of the knee is a degenerative disorder that leads to pain and disability in old age. Traditional non-surgical treatments offer lower disease modification. Intra-articular steroid combined with high molecular weight hyaluronate can

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increase the symptomatic relief.

Objective

To evaluate the efficacy of this combined injection in primary knee osteoarthritis.

Methods

Study design

This was a prospective interventional study aimed at determining the efficacy of intra-articular steroid combined with high molecular weight hyaluronate in primary knee osteoarthritis with the help of standardized outcome measures through predetermined follow-ups. This was a prospective, single-arm interventional design that involved pre-post evaluation, which is similar to a single-group pretest-posttest design with no control group. Outpatient services at IPGME&R, SSKM Hospital, Kolkata, consecutively recruited fifty patients of primary knee osteoarthritis during a period of 18 months (January 2023-August 2024). The baseline, 6 weeks, and 12 weeks post-injection of intra-articular steroid and high molecular weight hyaluronate were used to assess using the WOMAC pain and Patient Global Assessment scale, with analysis performed using the Tukey multiple comparison test to compare the efficacy and reduce biases by the use of a standardized procedure and independent evaluator.

Study setting

The research was done in IPGME & R, SSKM Hospital, Kolkata, India, in a period of 18 months, January 2023 to August 2024, in the Department of Physical Medicine and Rehabilitation.

Participants

Taking into account the inclusion criteria, 50 patients with a diagnosis of primary knee osteoarthritis were recruited, excluding secondary arthritis, systemic illness, and prior intra-articular therapy. Outpatient services were used to select participants consecutively.

Bias

Possible bias has been reduced with rigorous eligibility screening, standardized injection procedures, and equal evaluation instruments. Outcomes were documented by independent evaluators so as to enhance the lack of observer bias as well as because they would be constant throughout the visits of all patients.

Study size

The pragmatic approach of fifty patients was selected due to the lack of more available patients to conduct the studies within the timeframe, as it had adequate representation to perform statistical tests, and at the same time was feasible within the hospital resources.

Data collection

The major results were WOMAC pain and Patient Global Assessment scores. The baseline, six, and twelve weeks were used to collect data using validated scales that were administered by trained clinicians under standardized conditions.

Statistical methods

The Tukey multiple comparison test was used to compare the differences among the visits. The statistical approaches were used to control confounding, subgroup interaction, and to deal with incomplete data using suitable imputation techniques.

Ethical consideration

Before the start of the study, ethical approval was obtained from the Institutional Ethics Committee of IPGME & R, SSKM Hospital, Kolkata. The compliance was recorded in the approval date and clearance number.

Results

WOMAC pain

This study found that there was significant improvement of the WOMAC pain score at 6 weeks and at 12 weeks from the initial (first) visit, but improvement was not statistically significant at 12 weeks from 6 weeks.

Descriptive data

The 50 participants, mainly the older adults with primary knee osteoarthritis, showed a significant improvement in the symptoms after the intervention, but socio-demographic factors, including the mean age, gender, and BMI, were not clearly tabulated in demographic characteristics. The WOMAC pain scores were significantly higher at the end of 6 weeks (Visit 2) than at the end of 12 weeks (Visit 3; mean difference 2.905, $Q=6.092$, $p<0.05$) and 12 weeks (Visit 3; mean difference 4.095, $Q=8.589$, $p<0.05$) as compared to baseline (Visit 1). On the same note, patient global assessment scores were significantly higher between Visit 1 and Visit 2 (mean difference 2.000, $Q=7.626$, $p<0.05$) and Visit 1 and Visit 3

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(mean difference 2.333, Q=8.897, p<0.05), but no significant difference between Visits 2 and 3 (mean difference 0.333, Q=1.271, p>0.05).(Figure 1,2 & Graph 1 &2)Tukey's multiple comparison test

Table 1. Tukey multiple comparison test to compare the differences among the visits

Tukey's multiple comparison test	Mean difference	Q	Significant? p < 0.05?	Summary	95% CI of difference
V1 VS V2	2.905	6.092	YES	***	1.264 to 4.546
V1 VS V3	4.095	8.589	YES	***	2.454 to 5.736
V2 VS V3	1.190	2.497	NO	NS	-0.4506 to 2.832

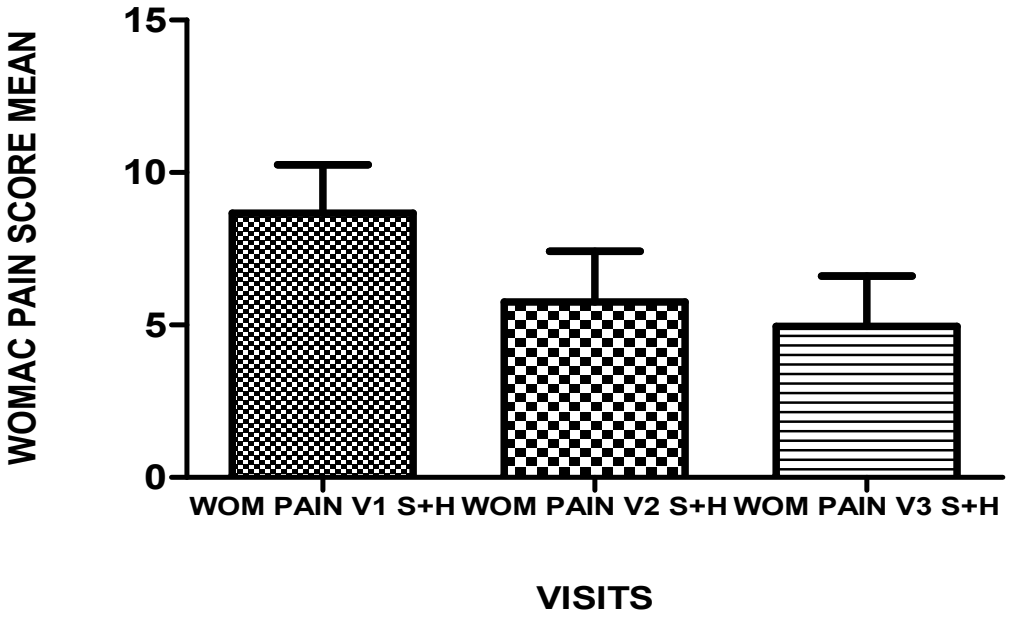

Figure 1. WOMAC Pain score

Patient's global assessment

Significant improvement occurred at 6 weeks and at 12 weeks from the initial visit, but the improvement at 12 weeks from 6 weeks was not significant.

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Table 2. Tukey multiple comparison test to compare the differences among the visits

Tukey's multiple comparison test	Mean difference	Q	Significant? p<0.05?	Summary	95% CI of difference
V1 VS V2	2.000	7.626	YES	***	1.097 to 2.903
V1 VS V3	2.333	8.897	YES	***	1.431 to 3.236
V2 VS V3	0.3333	1.271	NO	NS	-0.5694 to 1.236

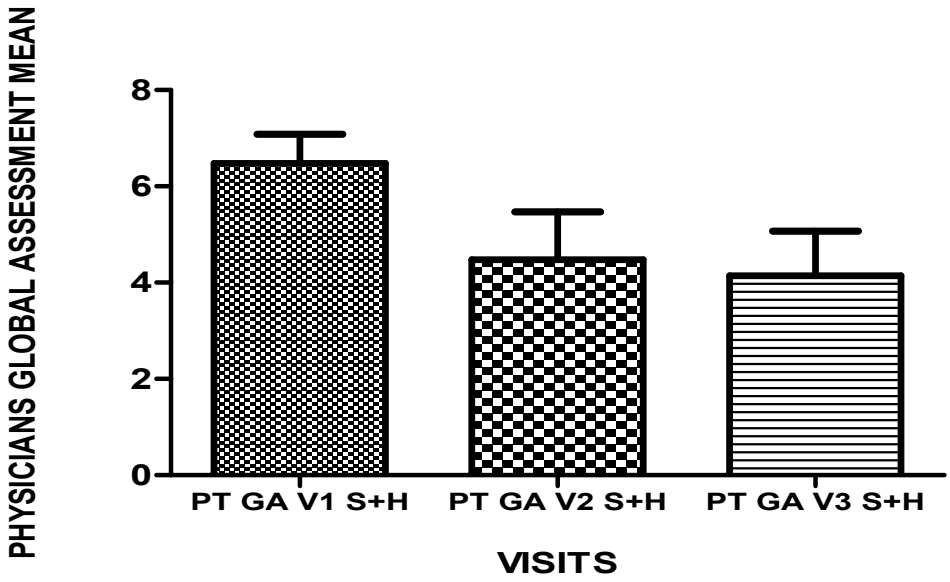

Figure 2. Patient's global assessment

Discussion

There is a deficit of studies that assessed the combined effect of intra-articular injection of Methylprednisolone plus HMWH in primary OA knee. This study showed there was statistically significant clinical improvement in outcome measures post intervention, viz. WOMAC pain and Patient Global Assessment.

In this study, its aim to evaluate intra-articular steroid and high molecular weight hyaluronate were met, where it was found that the study surpassed the baseline to 6 and 12 weeks, with significant WOMAC pain differences of 2.905 ($p<0.05$) and 4.095 ($p<0.05$), respectively, as well as parallel improvements in Patient Global Assessment, but did not improve after that time. These solitary-arm outcomes are cautiously suggestive of short-term symptomatic relief without a disease manipulation, which is in line with meta-analyses of steroids as the preferred initial therapy to manage early pain (up to 4 weeks) and hyaluronate to provide long-lasting effects (3 months), although the combination lacks strong evidence as compared to monotherapy since its impact is modest and uncontrolled. The small (n=50), single-center Eastern Indian cohort, which is based on a tertiary outpatient population, is a limitation of generalizability as it is prone to the primary OA cases and exclusion of secondary arthritis or previous injections, which restricts external validity to similar groups and requires multi-center RCTs as a measure of diversity, long-term outcomes, and blinding to prove causality.

The research tested the effectiveness of steroid and high molecular weight hyaluronate injected intra-articularly in the case of primary knee osteoarthritis and evaluated the outcomes using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain scale and

Patient Global Assessment scale. The findings showed significant statistical improvement at six and twelve weeks over baseline, but no significant change between six and twelve weeks. This trend of response offers valuable information on the dynamics of the relief of symptoms over time and the possible mechanisms of the combined intervention.

Mean difference of 2.905 and 4.095 between the baseline and six and twelve weeks, respectively, was statistically significant in the WOMAC pain scores. These results are indicative of the fact that the intervention yielded significant pain reduction in the initial six weeks, which was maintained over twelve weeks. Nonetheless, the non-significant increase in the period between six and twelve weeks shows that most of the therapeutic gain was realized in the initial stages, after which there was a plateau effect. Such a course of action is consistent with the established pharmacological profile of intra-articular steroids, which are generally effective in the short-term in reducing pain through the effects of their anti-inflammatory properties, and high molecular weight hyaluronate, which is believed to increase joint lubrication and viscoelasticity, which has a longer-term symptomatic effect. The combined injection can thus be synergistic to provide both temporary and long-term relief; however, the plateau indicates that more or more frequent intervention is needed to keep improving after three months.

The Patient Global Assessment scores reflected the WOMAC results, and significant improvement was seen in six and twelve weeks compared to baseline, but no significant difference between the six and twelve weeks. This similarity between the two outcome measures contributes to the validity of the findings and underscores the fact that patients had an actual symptomatic benefit of the intervention. The enhancement of patient-reported outcomes highlights the clinical significance of the combination injection because patient satisfaction and perceived quality of life are essential outcomes in the management of osteoarthritis.

There are also significant limitations shown in the data. The lack of a control group does not allow concluding on causality because the improvement may be partially due to placebo effects or natural variations in the symptoms of the disease. This is limited to generalizability because the size of the sample of fifty patients is small and is based on one tertiary care hospital. Moreover, the brief interval of following the programs of twelve weeks prevents the perception of the long-term effectiveness, the progression of the disease, and possible negative outcomes. Irrespective of these weaknesses, the statistically significant positive changes that were achieved give initial evidence to support the combined use of steroid and high molecular weight hyaluronate in primary knee osteoarthritis.

Clinically, the findings imply that such a regimen could be especially effective with patients who need short-term symptomatic treatment, in particular, patients with moderate levels of pain and functional impairment. The six-week plateau effect suggests that clinicians should consider the use of a combination of this therapy with the other aspects of management, i.e., lifestyle interventions, e.g., weight loss, exercise, and physiotherapy, and other alternative intra-articular therapies, e.g., platelet-rich plasma or repeated hyaluronate injections, as a long-term benefit.

In the analysis of both outcome measures, it has been seen that the improvement from visit 1 to visit 2 was much greater than from visit 2 to visit 3.

Conclusion

Intraarticular injection of steroid plus HMWH in primary OA knee is effective in terms of reduction of pain in the WOMAC scale and reduction of Patients Global Assessment scale, and negligible adverse effect occurs in this regimen.

Limitations

Initial frequent follow-up was done, so it is difficult to conclude about the immediate post injection effect, and it was a short-term study, so it is difficult to comment on the effects after 12 weeks post-injection.

Recommendations

Future multi-center RCTs should incorporate controls, long-term follow-ups beyond 12 weeks, detailed demographics, and comparisons with PRP or lifestyle interventions to validate and extend these short-term symptomatic benefits.
Multi-center randomized controlled trials with greater and more heterogeneous populations of patients should be considered in future studies. The present study had a limitation of being restricted to only one tertiary care hospital in Eastern India, which limits generalization. By going to various centers in various regions, one would have a variation in demographics, disease severity, and healthcare practices that enhance external validity. Control groups should also be included in these trials where steroids, hyaluronate, or a placebo are administered separately so that direct comparisons can be made and the relative efficacy of combination therapy can be established. There is a necessity to follow up on the long-term (more than twelve weeks) to identify whether the symptomatic benefits that the study reported continue to be present, decrease, or require another injection. Six months and one year follow-up would be very beneficial in terms of

sustaining the effects of pain relief, functional, and possibly disease-modifying. Also, there might be an opportunity to investigate the repeated dosing schedules to determine whether booster injections would increase or maintain therapeutic effects.

Future studies should also be detailed on the demographic and clinical profiling of the participants. Age, sex, body mass index, comorbidities, and baseline severity of osteoarthritis are some of the variables that might affect the response to treatment. These factors would be used to stratify analysis that could be used to identify subgroups that are likely to respond to combined intra-articular therapy. It should also be compared with other interventions like platelet-rich plasma, stem cell therapy, or lifestyle changes like structured exercise and weight reduction programs. This would explain the relative place of steroid plus hyaluronate injections in the larger therapeutic context. Lastly, the safety monitoring is to be increased to trace the potential negative outcomes, such as the risk of infection, joint stiffness, or as a result of steroids used systemically. The clinical adoption and reproducibility would be enhanced by defining a standard protocol on injection technique, dosage, and patient selection. These recommendations will help guarantee that the future evidence will be strong, clinically applicable, and have the ability to inform best practice in osteoarthritis management.

Acknowledgements

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List of abbreviations

OA: Osteoarthritis
HMWH: High Molecular Weight Hyaluronate
WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index
V1/V2/V3: Visit 1 (baseline)/Visit 2 (6 weeks)/Visit 3 (12 weeks).

Conflict of Interest

The authors declare no conflict of interest.

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Author contributions

Dr. Amalesh Basak (corresponding author) conceptualized the study, performed injections, analyzed data, and wrote the manuscript; co-authors contributed to patient recruitment, outcome assessments, and critical revisions.

Data availability

The datasets analyzed during the current study are available from the corresponding author upon reasonable request.

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