Systemic Review

Comparative Efficacy and Safety of Mesenchymal Stem Cell Therapy and Hyaluronic Acid in Knee Osteoarthritis: A Systematic Review and Meta-Analysis

MSc Therapy and Hyaluronic Acid in Knee Osteoarthritis

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ABSTRACT

Knee osteoarthritis (OA) is the most common d disease of degenerative nature leading to the pain, reduced mobility, and diminished quality of life. Currently, treatment options are conservative approaches and advanced therapies like mesenchymal stem cell (MSC) therapy and hyaluronic acid (HA) in the injectable form Current systematic review assesses the effectiveness, safety, and comparative outcomes of MSC therapy versus HA in managing knee OA.

Methods: This systematic review and meta-analysis was conducted following PRISMA guidelines (PROSPERO registration: CRD42023473958). Literature searches across multiple databases identified randomized clinical trials (RCTs) comparing MSC therapy with HA in knee OA patients. Risk of bias was assessed using RoB 2.0, and meta-analyses employed a random-effects model to aggregate data from eligible studies.

Results: Four RCTs involving 120 patients were encompassed. Studies showed that MSC therapy, especially at higher doses, improved pain, function (WOMAC and VAS scores), and cartilage quality compared to HA. MSC-treated groups exhibited sustained benefits, including improved joint mobility and reduced inflammation, over long-term follow-ups. Meta-analysis indicated significant heterogeneity ($I^2 > 80\%$), limiting definitive conclusions on pooled results. No severe adverse events were considered for MSC therapy, underscoring its safety profile. Risk of bias ranged from low to intermediate across studies.

Conclusion: MSC therapy shows promise in improving clinical outcomes for knee OA compared to HA. However, high heterogeneity in study outcomes and intermediate risk of bias warrant caution. Further large-scale, well-designed RCTs are necessary to verify these findings and optimize therapy protocols.

Key Words: Knee osteoarthritis, mesenchymal stem cells, hyaluronic acid, systematic review, meta-analysis, regenerative medicine

Citation of Review: Alfarhan MFA. Comparative Efficacy and Safety of Mesenchymal Stem Cell Therapy and Hyaluronic Acid in Knee Osteoarthritis: A Systematic Review and Meta-Analysis. Med Forum 2025;36(12):98-103. doi:10.60110/medforum.361220.

INTRODUCTION

Knee osteoarthritis (OA) is a prevalent deteriorating joint disease primarily affecting the knee joint, constituting the most common form of arthritis [1,2]. This condition arises as the protective cartilage that cushions the ends of the bones in the knee gradually wears down over time. Cartilage degradation, essential for smooth joint movement, leads to signs and symptoms such as swelling, stiffness, pain and a diminished range of mobility in the affected knee[3].

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Received: September, 2025
Reviewed: September-October, 2025
Accepted: November, 2025

Symptoms often worsen with time, impacting daily activities like walking or climbing stairs[4]. Therapy options range from conventional modalities like lifestyle changes, physical therapy, and medications to major interventions such as surgery in severe cases[2]. Treatment of knee osteoarthritis involves a variety of medications tailored to address symptoms and enhance the overall quality of life for individuals with KA. Topical NSAIDs, such as diclofenac creams or patches, provide localized relief when applied directly to the affected joint. In cases of more severe symptoms, corticosteroid injections may be administered directly into the joint to provide temporary relief from inflammation and pain. Hyaluronic acid (HA) injections, known as visco-supplementation, aim to improve joint lubrication and reduce pain[6].

This therapy aims to stimulate local cells, encouraging their participation in the repair process. Even with ongoing research and clinical studies investigating the safety and efficacy of mesenchymal stem cell therapy for knee arthritis, there is a need of consensus on its overall efficacy and safety in comparison to HA[7]. Therefore, this review aims to appraise and summarize

existing evidence regarding the outcomes, safety, and potential benefits of MSC in comparison to hyaluronic acid, providing a comprehensive assessment of the current state of knowledge on these regenerative interventions for knee arthritis management.

METHODS

Focused question and protocol registration: Prior to commencement of the review, a focused question was constructed via the Participants, Intervention, Control, and Outcomes (PICO) principal as recommended in the Preferred Reporting Items for Systematic Reviews and Meta-analysis[8]. The focused question was: Does mesenchymal stem cell (MSC) therapy lead to higher improvement in clinical outcomes in comparison to hyaluronic acid in patients with KA?'. A protocol was registered on PROSPERO (registration number CRD42023473958).

Literature search: A comprehensive electronic search for studies published from inception to 15th November 2025 was carried out by a medical information specialist across multiple databases, including PubMed/MEDLINE, Cochrane Library, CENTRAL, EMBASE, Scopus, and ISI Web of Knowledge. The search strategy used a string of keywords and Medical Subject Headings (MeSH) related to stem cell–based therapies, hyaluronic acid, and degenerative knee osteoarthritis: [((stem cell therapy) OR (mesenchymal stem cells) OR (stem cells) OR (progenitor cells) OR (undifferentiated cells) OR (precursor cells) OR (pluripotent cells) OR (multipotent cells) OR (embryonic cells) OR (primary cells) OR (primitive cells) OR (germ cells) OR (differentiation-capable cells)) AND ((hyaluronan) OR (sodium hyaluronate) OR (hyaluronate) OR (HA) OR (glycosaminoglycan) OR (hyaluronic polymer) OR (hyaluronic gel) OR (hyaluronic fluid) OR (hyaluronic serum) OR (hyaluronic solution) OR (viscosupplementation)) AND ((knee degenerative joint disease) OR (knee osteoarthritis) OR (degenerative arthritis of the knee) OR (knee joint degeneration) OR (knee cartilage wear) OR (knee joint osteoarthrosis) OR (knee articular degeneration) OR (knee joint degenerative disorder) OR (osteoarthrosis of the knee) OR (knee OA))].

Eligible studies were randomized controlled trials (RCTs) that directly compared the clinical efficacy of mesenchymal stem cell (MSC) therapy with hyaluronic acid in patients with degenerative knee osteoarthritis. Studies were excluded if they were non-comparative cohort studies, case series, case reports, letters to the editor, or published in languages other than English or Arabic due to reviewer language constraints. Additionally, studies involving traumatic or non-degenerative forms of knee osteoarthritis were excluded.

Data extraction: Following piloting the data extraction forms two reviewers extracted the data independently. General data regarding the study author(s) and date, study groups, location details, and study setting was extracted. Furthermore, the following data was extracted associated with the patient population: ethnicity, sex, mean/median age, age, selection criteria, and duration of the disease. Mean differences in all outcomes, such as pain, quality of life, function, and other tests such as blood biomarker levels were extracted. The data was tabulated using Microsoft Excel, and any conflicts were resolved by discussion.

Risk of bias assessment: RoB assessment, utilizing RoB 2.0, covered areas like randomization, change from intended interventions, missing data, outcome measurement, and reported result selection. Criteria for bias judgment were explicitly defined. Data synthesis methods, statistical or narrative, and provisions for addressing heterogeneity and sensitivity were outlined.

Meta-analysis: The meta-analysis was performed on Review Manager (RevMan) software version 5.4, applying a random-effects model to account for any possible heterogeneity among the included studies.[9] A systematic search strategy was employed, and predefined inclusion criteria were applied to identify eligible studies. Data extraction was individually conducted by two reviewers (blinded to each other), with disagreements resolved through discussion or consultation with an additional reviewer.

RESULTS

Literature search: Initial search resulted in 1253 items. After exclusion of 1243 irrelevant articles on the basis of titles, 9 articles were selected for screening of full texts. After 5 articles were further excluded (reasons explained in Table 1), 4 randomized clinical trials that met our PICO criteria were included[10-11].

Patient characteristics of the studies

The table presents detailed information from four distinct studies focusing on osteoarthritis (OA) treatment in Spain and China. In the study by Vega et al. (2015)[10] conducted in Spain with 30 participants, the inclusion criteria involved Grade II-IV OA and chronic knee pain, with exclusion criteria such as infection and immunosuppression. The mean age was 57 years, with 17 females and 13 males. In the study by Lamo-Espinosa et al. (2016)[11], 30 patients with knee OA were randomly chosen to receive intraarticular HA alone (control) or hyaluronic acid along with either 10×10^6 or 100×10^6 cultured autologous BM-MSCs respectively, and included individuals aged 50-80 with knee OA. In their 2018 study[12], the authors then followed-up 26 of those 30 patients 4 years after the end of this study. Exclusion criteria included various conditions like polyarticular disease and recent arthroscopy. The studies compared high and low-dose mesenchymal stem cells (MSC) with hyaluronic acid (HA) treatment, reporting mean ages and gender distributions. In the Chinese study by Ho et al. (2022)

with 30 participants[13], eligibility criteria included age 50-65, primary knee OA, and a pain level ≥5 for at least 2 months. Exclusion criteria comprised conditions like alcoholism and recent steroid-based therapy. MSC and HA treatments were compared, reporting mean ages and gender distribution. These studies contribute diverse insights into OA treatment approaches, participant demographics, and outcomes.

Treatment regimens and overall outcomes

Vega et al 2015[10]: In this study, one group received intra-articular injections of allogeneic bone marrow MSCs, while the other was given intra-articular HA as a control. Over one year, the MSC-treated group showed significant enhancements in algofunctional indices (WOMAC and VAS), indicating enhanced pain relief and functional outcomes compared to the hyaluronic acid-treated control group. Quantitative magnetic resonance imaging T2 mapping revealed a notable reduction in areas of poor cartilage in the MSC-treated cohort, suggesting improvements in cartilage quality. The findings emphasize the potential efficacy of allogeneic MSC therapy, showcasing positive outcomes in pain alleviation, functional improvement, and cartilage quality enhancement for chronic knee osteoarthritis (Table 2).

Table No.1: General characteristics of the included study.

Study	Participants (N)	Country	Selected inclusion criteria	Selected exclusion criteria	Age (mean/median; years)	Sex (n)
Vega et al 2015	30	Spain	Grade II – IV osteoarthritis, chronic knee pain of mechanical origin, 18 – 75 years	Infection, co-morbidities, pregnancy, breast-feeding, neoplasia, immunosuppression	57 ± 9 years	F: 17; M: 13
Lamo-Espinosa et al 2016	30	Spain	Males and females aged 50–80, diagnosis of knee OA according to American College of Rheumatology criteria, visual analogue scale	Previous diagnosis of polyarticular disease, severe mechanical extra-articular deformation (>15° varus/15° valgus), systemic autoimmune rheumatic disease, arthroscopy	High-dose MSC: 57.8 (55.0 - 60.8) years Low-dose MSC: 65.9 (59.5 - 70.6) years HA: 60.3 (55.1 - 61.1) years	M: 19 F: 11
Lamo-Espinosa et al 2018	26	Spain	Males and females aged 50–80, diagnosis of knee OA according to American College of Rheumatology criteria, visual analogue scale	Previous diagnosis of polyarticular disease, severe mechanical extra-articular deformation (>15° varus/15° valgus), systemic autoimmune rheumatic disease, arthroscopy	High dose MSC: 65.9 (58.3 – 69.5) Low dose MSC: 57.8 (54.4 – 63.0) HA: 60.6 (58.9 - 61.1)	F: 8 M: 17
Ho et al 2022	30	China	Twenty eligible patients, aged between 50 and 65 years (58.00 4.51 years), affected by primary OA of the knee of Kellgren-Lawrence (K-L) grade 2–3 and with a pain level equal to or higher than 5 on a Visual Analogue Scale (VAS) scale of 10 for at least 2 months were recruited with informed consent.	Alcoholism or drug abuse; pregnancy and breast-feeding; serious pathologies such as carcinoma	MSC: 56.7 ± 4.83 HA: 59.1 ± 4.04	F: 12 M: 8

Lam Espinosa et al 2016[11]: In this phase I/II multicenter randomized clinical study with an active control (HA), 30 knee OA patients were randomly chosen to receive intra-articular HA alone or HA combined with either 10×10^6 or 100×10^6 cultured autologous bone marrow–derived mesenchymal stem cells (BM-MSCs). No treatment-related adverse events were reported following BM-MSC administration or throughout the follow-up period. Patients treated with BM-MSCs exhibited sustained improvements in pain and functional outcomes, as measured by the Visual Analog Scale (VAS) as well as Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Radiographic assessment revealed progressive narrowing of the knee joint space in the control group, which was not observed in the high-dose

BM-MSC group. Furthermore, magnetic resonance imaging (MRI) evaluated using the Whole-Organ Magnetic Resonance Imaging Score (WORMS) demonstrated modest reductions in joint structural damage, predominantly in the high dosage BM-MSC cohort. Overall, these findings suggest that intra-articular BM-MSC therapy, especially at higher doses, is associated with sustained improvements in pain, functional capacity, and joint integrity in patients with knee osteoarthritis (Table 2).

Lam Espinosa et al 2018[12]: This study investigated the long-term effects of mesenchymal stromal cell (MSC) treatment on knee osteoarthritis (OA) based on the evaluation of patients from the previous randomized clinical trial detailed above (Lam Espinosa et al 2016) (CMM-ART, NCT02123368). The study concludes that a single intraarticular injections of autologous BM-MSCs are a safe and viable treatment option for knee OA, resulting in long-term clinical and functional improvements for knee OA (Table 2).

Ho et al 2022 [13]

This study aimed to evaluate the effectiveness of autologous bone marrow–derived mesenchymal stem cells (BM-MSCs) in comparison to hyaluronic acid (HA) in patients with no prior surgery with knee osteoarthritis. In this single-blind, single-center randomized clinical study, 20 patients were enrolled and equally allocated to receive intra-articular injections of either cultured BM-MSCs or HA. Clinical outcomes were assessed at baseline and at 12 months, including pain intensity, functional status, and quality of life, along with radiographic and magnetic resonance imaging (MRI) evaluations to assess compositional changes in joint cartilage. Overall, the findings indicate that intra-articular administration of autologous BM-MSCs resulted in superior pain relief, functional improvement, and enhancement of quality-of-life measures compared with hyaluronic acid at one year (Table 2).

Table No.2: Summary of findings reported in the included studies.

Study	Source of MSCs	Doses and number of MSCs	Time points of outcomes assessed (months)	Study groups (n)	Duration of study	Post-treatment follow-up	Outcomes of interest reported	Serious/ severe adverse effects	Overall outcomes
Vega et al 2015	Allogenic	40 X 10^6 cells (1 dose)	BL, 3, 6, 12 months	MSC (15) HA (15)	12 months	NR	VAS, WOMAC	None	Higher improvement in MSC-treated patients.
Lamo-Espinosa et al 2016	Autologous	Low dose: 10 × 10^6 or High dose: 100 × 10^6 (1 dose)	BL, 3, 6, 12 months	Low dose MSC + HA (10) High dose MSC + HA (10) HA (10)	12 months	NR	WOMAC, VAS	None	MSC groups resulted in higher improvement up to 12 months.
Lamo-Espinosa et al 2018	Autologous	10 × 10^6 or 100 × 10^6 (1 dose)	BL, 3, 6, 12 months *	Low dose MSC + HA (8) High dose MSC + HA (8) HA (9)	5 years	4 years	WOMAC, VAS	None	MSC groups resulted in better improvements in WOMAC and VAS scores than HA alone.
Ho et al 2022	Autologous	6 X 10^6 cells (1 dose)	BL, 1, 3, 6, 9, 12 months	MSC (10) HA (10)	12 months	NR	WOMAC, VAS, SF36	None	MSC groups resulted in better improvements in WOMAC and VAS scores than HA.

* This study was a 4-year follow-up of Lamo-Espinosa et al 2016. Hence, only 4-year follow-up data is presented to avoid repetition.
BL = Base-line; WOMAC = Western Ontario and McMaster Universities Osteoarthritis index; VAS = Visual Analog Scale; SF36 = 36-Item Short Form Survey; MSC = Bone-Marrow Derived Mesenchymal Stem Cells; HA = Hyaluronic Acid; NR = Not Reported.

Table No.3. Risk of bias assessment of the included studies.

Study (author, year) (Name)	Domain					
	ROB arising from the randomization process	**ROB due to deviations from the intended outcomes**	**ROB due to missing outcome data**	**ROB in measurement of outcome**	**ROB in selection of the reported result**	**Overall ROB**
Vega et al 2015	Low	Some concerns	Low	Low	Low	**High**
Lamo-Espinosa et al. 2016, 2018	Low	Low	Low	Low	Low	**Low**
Ho et al 2022	NI	Some concerns	Low	Some concerns	Low	**Some concerns**

Results of the meta-analysis: The findings of the meta-analysis are presented in Figures 2 (WOMAC scores 12 months after administration) and 3 (VAS scores 12 months after administration). Due to the variability in the outcome measurement, only the scores at 12 months from two studies could be pooled. Dude to high heterogeneity of the outcomes (I^2 = 85% for WOMAC and 89% for VAS) it was difficult to ascertain the overall efficacy of MSC on improving both of these indices.

Risk of Bias Assessment: Table 3 summarizes the risk of bias (ROB) assessment for three studies: Vega et al. (2015)[10], Lamo-Espinosa et al. (2016, 2018)[11,12], and Ho et al. (2022) [14]. The evaluation includes different domains of potential bias. Vega et al. (2015)[10] is characterized by low ROB arising from the randomization process and missing outcome data but raises concerns in deviations from the intended outcomes, measurement of outcome, selection of the reported result, leading to an overall high ROB. In contrast, Lamo-Espinosa et al. (2016, 2018) exhibit low ROB across all domains[11,12], indicating a generally low risk of bias. Ho et al. (2022)[13] shows unclear risk in the randomization process, low risk in missing outcome data and selection of the reported result, but some concerns in deviations from the intended outcomes and measurement of outcome, resulting in an overall intermediate risk of bias.

DISCUSSION

Considering the diverse findings across these studies, several factors could contribute to the superior outcomes observed in BM-MSC-treated groups compared to HA alone. First, the regenerative properties of BM-MSCs may play a crucial role in promoting tissue repair and reducing inflammation, contributing to long-term improvements in pain and function[14]. Additionally, the ability of BM-MSCs to differentiate into various cell types, including chondrocytes, may facilitate the regeneration of damaged cartilage, a key aspect in OA management[15]. The studies also suggest that higher doses of BM-MSCs may lead to more significant and sustained improvements, as seen in Lamo-Espinosa et al. (2018) where the high-dose BM-MSC group exhibited notable decreases in WOMAC scores and joint damage over the long-term[11,12]. Assessing the impact of different medications on knee osteoarthritis involves a comprehensive evaluation of various outcomes. One crucial aspect is pain relief, measured through standardized scales like the Visual Analog Scale (VAS), as a reduction in pain intensity signifies the effectiveness of the medication[16]. The WOMAC is a questionnaire used to evaluate knee osteoarthritis severity. It assesses pain, stiffness, and physical function, with respondents rating the intensity and frequency of their symptoms. Scores range from 0 to 96, with higher scores indicating more severe symptoms and functional limitations. Healthcare providers use WOMAC scores to track changes over time and assess the effectiveness of treatments in managing knee osteoarthritis symptom Functionality and physical activity are assessed through tests or patient-reported outcomes, highlighting improvements in the ability to perform daily tasks and maintain an active lifestyle. Evaluating joint stiffness, particularly after periods of inactivity, provides insights into improved joint mobility. Radiographic assessments, such as measuring joint space width through X-rays, help gauge the medication's impact on osteoarthritis progression[17]. Quality of life is assessed using questionnaires that capture the psychological, social, and recreational aspects affected by knee OA[18].

The collective evidence from the studies described in this review supports the potential efficacy of BM-MSCs as a treatment for knee OA, showcasing improvements in pain relief, functional outcomes, and cartilage quality. The regenerative properties, differentiation capabilities, and autologous nature of BM-MSCs contribute to their promising therapeutic potential. Furthermore, no serious and severe adverse effects or failures of treatment were reported 4 years after a 12-month observation of the cohort treated by Lam Espinosa et al [17,18]. Future clinical trials required with large sample sizes and prolong follow-up durations are warranted to further validate the effectiveness and safety of BM-MSC therapy for knee OA. However, it's important to interpret the overall results of this systematic review with caution, as some aspects of the studies exhibit a risk of bias, and the meta-analysis was inconclusive in deducing the overall comparative efficacy and safety of stem-cell therapy relative to HA. Further well-designed studies with large sample sizes

and prolong follow-up durations are warranted to further validate the effectiveness and safety of BM-MSC therapy for knee OA. These studies should also aim to address potential confounding factors and biases to provide more robust evidence for the use of BM-MSCs in OA management.

CONCLUSION

In conclusion, while BM-MSC therapy holds promise as a potential treatment for knee OA, additional research is warranted to fully elucidate its therapeutic effects, optimal dosing regimens, and long-term safety profile. Nevertheless, the existing evidence suggests that BM-MSCs offer a feasible option for improving the management of knee OA and may represent a valuable addition to current treatment strategies.

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