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Autologous PRP injection versus conventional analgesia in early-stage knee osteoarthritis: A comparative study

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Abstract:
One of the most disabling diseases, knee osteoarthritis (KOA), affects over 360 million people worldwide. On 100 patients with early knee osteoarthritis, this randomised controlled trial compared the clinical and functional efficacy of a single intra-articular injection of anodized platelet-rich plasma to a conventional analgesic. Both groups' baseline WOMAC and VAS scores were similar. Patients in the PRP group showed significant improvements in pain, stiffness and physical function at 6-week, 3-month and 6-month follow-ups ($p < 0.0001$). A 6 month PRP group pain score reduction was 54%, while the analgesic group showed no clinically meaningful improvement. PRP may provide long-lasting functional benefits and better structural repair than symptomatic medication due to its biological mechanisms. In early-grade DJD, PRP can preserve and restore joint function.

Keywords: Platelet-rich plasma, early knee osteoarthritis, WOMAC score

Background:
Osteoarthritis of the knee (KOA) is one of the most common joint diseases in the world. KOA affects more than 250 million people and is the 11th leading cause of disability globally **[1]**. In 2019 the global prevalence of knee OA was approximately 364.6 million cases. The age-standardized prevalence increased by 7.5% from 1990 through 2019 **[2]**. Females and those over 50 years of age are high-risk populations and higher sociodemographic index regions are growing areas of disproportionate burden **[3]**. The global burden of KOA attributable to high body mass index (BMI) has almost doubled in terms of disability-adjusted life years between 1990 and 2017 thus there is an urgent need for effective diseasemodifying interventions **[4]**. At the moment, intra-articular corticosteroids and hyaluronic acid are mostly symptomatic and do not provide any radiographic or structural improvements in the affected joint **[5]**. Long-term follow-up shows corticosteroid and hyaluronic acid injection could not show any difference in radiographic OA evolution or total knee arthroplasty **[6]**. Intra-articular corticosteroids inhibit T- and B-cell activity in the joint, resulting in inflammation reduction. Hyaluronic acid restores lubrication; however, neither modality reverses the underlying chondral pathology **[7]**. Growth factors such as TGF-β, PDGF, IGF-1, VEGF and bFGF are rich in platelet-rich plasma. Growth factors are released from platelalpha granulesupon activation of collagen or external activator in the joint **[8]**. The activated platelets release cytokines and growth factors that regulate inflammation and help to maintain and repair tissue structure. The use of intra-articular PRP injection, a valid conservative treatment that reduces pain and improves functional scores, shows proven benefits in knee OA after a mid-term follow-up at 6 months **[9]**. Comparative studies show that PRP injections produce a better reduction in pain and functional improvement than hyaluronic acid and corticosteroids in patients with mild to moderate knee OA (Kellgren-Lawrence grades I–III) **[10]**. A review of randomized controlled trials via meta-analysis shows that PRP provides clinically relevant functional improvement at 1, 3, 6 and 12 months, while treatment effect differs according to platelet concentration **[11]**. Analyses of subgroups indicate that pain relief and functional improvement were statistically significant across Kellgren-Lawrence stages 1–3, with PRP always favouring earlier disease grades **[12].** Patients who are aged 51-65 years with Kellgren-Lawrence grade 2 osteoarthritis show the best clinical outcomes after PRP treatment **[13].** This justifies the case for treatment in early osteoarthritis. In a retrospective survival analysis, Sánchez *et al.* **[14]** showed that 74.1% of KOA patients receiving PRP injections were successfully delayed from undergoing total knee arthroplasty more than 1.5 years, with an overall median delay of 5.3 years. Therefore, it is of interest to evaluate the clinical and functional efficacy of autologous platelet-rich plasma specifically in early knee osteoarthritis.

Materials and Methods:
This randomized controlled trial was carried out in the Department of Orthopaedics, Sanjay Gandhi Memorial Hospital, Shyam Shah Medical College, Rewa, Madhya Pradesh, India, from September 2022 to August 2023. The Institutional Ethics Committee approved the study protocol and all participants provided written informed consent before enrollment. To assess the criteria for eligibility, consecutive patients were screened in an outpatient department of orthopaedic for knee pain.

Participants:
Patients who were diagnosed with primary, early-stage osteoarthritis of the knee who met the inclusion criteria were enrolled in the study. The bone marrow lesions (BMLs) are likely to result in an abnormal mechanism that could increase the onset of pain by increasing the rate of cartilage deterioration. The researchers identified certain exclusion criteria in order to assure a highly selected population. This was done in order to make the study valid and credible. Any participant with any of the following characteristics was excluded from the study.

Group allocation and interventions:

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A total of one hundred eligible patients were randomly assigned in two groups each 50. The affected knee in Group I was given a single intra-articular injection of autologous platelet-rich plasma. Group II (control group) received pharmacological treatment and lifestyle modifications.

Preparation of platelet-rich plasma:
Under strict aseptic precautions the Department of Pathology prepared autologous PRP. Autologous venous blood, 15 ml was collected from each patient and centrifuged in a refrigerated centrifuge. About 6–8 mL of PRP was harvested after separation and discarding of the red blood cell layer and buffy coat. As no leukocyte filter was utilized, the final PRP preparation exhibited minimal residual leukocytes.

Injection protocol and post-procedure care:
The patient lay on his back in the emergency operating theatre for intra-articular injection. The antiseptic solution was applied to affected knee and a sterile painting was draped. With extreme aseptic measures, 6-8 mL of autologous PRP was injected into the suprapatellar pouch or the joint cavity using the medial route. A sterile compressive bandage was applied and the patient was advised bed rest for 2 days. The study allowed the use of paracetamol (500 mg) for febrile illness or pain if needed but avoided the use of NSAIDS after the injection. Patients were advised to commence regular activities starting from day 2 after the procedure.

Control group management:
Patients in the control group received 400 mg of ibuprofen orally twice a day for 5 days along with counselling about lifestyle changes.

Outcome measures and follow-up:
The Western Ontario and McMaster Universities Osteoarthritis Index and Visual Analogue Scale for pain were used to assess the severity of knee osteoarthritis. All the patients in both groups were followed up at six weeks, two months and six months post-intervention for clinical reassessment and scoring.

Table 1: Baseline demographic and anthropometric characteristics of both groups

S.No.	Variable	PRP Group (n=50)	Analgesic Group (n=50)	Statistical Test	p-Value
1	Age (years), Mean±SD	59.58 ± 7.137	61.14 ± 7.701	Unpaired t-test	0.2960
2	Gender: Male / Female, n (%)	24 (48%) / 26 (52%)	31 (62%) / 19 (38%)	Chi-square test	0.2276
3	BMI (kg/m²), Mean±SD	27.23 ± 2.445	26.00 ± 2.656	Unpaired t-test	0.0177*

Table 2: WOMACtotal score at different follow-up intervals

S.No.	Follow-up Period	PRP Group Mean±SD	Analgesic Group Mean±SD	t-Value	p-Value
1	Pre-injection	69.32 ± 9.909	67.78 ± 5.578	0.9577	0.3406
2	6 Weeks	55.86 ± 9.624	63.58 ± 5.238	4.982	<0.0001*
3	3 Months	46.28 ± 8.109	64.04 ± 4.751	13.362	<0.0001*
4	6 Months	37.88 ± 7.953	66.66 ± 5.267	21.334	<0.0001*

Table 3: WOMAC painsub score at different follow-up intervals

S.No.	Follow-up Period	PRP Group Mean±SD	Analgesic Group Mean±SD	p-Value
1	Pre-injection	16.58 ± 3.08	16.30 ± 2.39	0.6132
2	6 Weeks	11.32 ± 2.76	13.74 ± 2.28	<0.0001*
3	3 Months	7.44 ± 1.93	13.66 ± 2.35	<0.0001*
4	6 Months	5.34 ± 1.42	15.46 ± 1.94	<0.0001*

Table 4: WOMAC stiffness and physical function subscores at different follow-up intervals

S.No.	Follow-up Period	Stiffness PRP Mean±SD	Stiffness Analgesic Mean±SD	p-Value (Stiffness)	Physical Function PRP Mean±SD	Physical Function Analgesic Mean±SD	p-Value (Function)
1	Pre-injection	5.50 ± 1.22	5.16 ± 0.93	0.1204	52.12 ± 3.77	48.30 ± 3.17	0.3840
2	6 Weeks	4.60 ± 1.20	4.56 ± 0.81	0.8453	46.54 ± 4.53	45.80 ± 3.91	<0.0001*
3	3 Months	3.78 ± 1.09	4.46 ± 0.73	0.0004*	36.46 ± 6.49	44.38 ± 3.88	<0.0001*
4	6 Months	3.40 ± 1.14	4.78 ± 0.84	<0.0001*	24.62 ± 6.33	46.20 ± 3.67	<0.0001*

Table 5: Visual Analogue Scale (VAS) score – pre- and post-intervention comparison

S.No.	Assessment Point	PRP Group Mean±SD	Analgesic Group Mean±SD	t-Value	p-Value
1	Pre-injection	7.10 ± 0.86	7.06 ± 0.89	0.2281	0.2281
2	Post-injection (6 Months)	3.24 ± 0.74	6.62 ± 0.95	19.869	<0.0001*

Results and Discussion:
This study included a total of 100 patients diagnosed with early stage knee osteoarthritis. They were randomly divided into two groups of 50 patients each. Group I received intra-articular autologous platelet rich plasma (PRP) and Group II received pharmacological treatment in form of analgesics and modified lifestyle. **Table 1** shows that the two groups did not differ in age (PRP: 59.58 ± 7.137 years; analgesic: 61.14 ± 7.701 years; p = 0.2960). Gender was also similar (p = 0.2276). However, there was a statistically significant difference in BMI between the groups (27.23 ± 2.445 versus 26.00 ± 2.656 kg/m2; p = 0.0177). While a possible confounder of baseline between group BMI differences may exist, random allocation and primary outcome being within group change over time make it unlikely to influence interpretation of overall treatment. Baseline WOMAC total scores were similar at enrolment in both groups (PRP: 69.32

± 9.909; analgesic: 67.78 ± 5.578; p = 0.3406), confirming similar severity of the osteoarthritis. The results in **Table 2** showed that the total WOMAC score of PRP group was significantly decreased at 6 weeks (55.86 ± 9.624 vs 63.58 ± 5.238; p < 0.0001), 3 months (46.28 ± 8.109 vs 64.04 ± 4.751; p < 0.0001) and 6 months (37.88 ± 7.953 vs 66.66 ± 5.267; p < 0.0001). Conversely, the same scores in the analgesic group did not improve much during the follow up. The findings of the present study are consistent with a meta-analysis by Dai *et al.* **[15]** showing that intra-articular PRP provided significantly better functional improvement at 6 and 12 months' post-injection compared to hyaluronic acid and saline (effect size > MCID). In the same vein, Raeissadat *et al.* **[16]** demonstrated that the WOMAC parameters improved and were maintained at 12-month evaluation after PRP in patients with grade 1–4 knee osteoarthritis. It implies that the functional enhancement by PRP treatment is durable, which is supported by our findings. This persistent efficacy is supported by recent prospective observational studies showing very significant reductions of the WOMAC functional scores at 6 months after a single intra-articular PRP injection in early knee osteoarthritis, with good to excellent functional results in up to 80% of patients **[17, 20]**. Baseline WOMAC pain subscores were similar between the PRP group and the analgesic group (16.58 ± 3.08 and 16.30 ± 2.39, respectively; p = 0.6132) **(Table 3)**. PRP group pain decreased progressively at 6 weeks (11.32 ± 2.76 vs. 13.74 ± 2.28; p < 0.0001), 3 months (7.44 ± 1.93 vs. 13.66 ± 2.35; p < 0.0001) and 6 months (5.34 ± 1.42 vs. 15.46 ± 1.94; p < 0.0001). In contrast, the pain levels in the analgesic group remained at near baseline during the follow-up period. The amount of pain relief observed in the PRP group in our study is in agreement with the systematic review and meta-analysis of 18 randomised controlled trials by Bensa *et al.* **[11]** which showed that PRP caused statistically superior improvements in VAS and WOMAC pain scores as compared to placebo at every follow-up period and exceeded the MCID at the 3- and 6-month follow-up period. The long-term pain relief effect of PRP may be due to the release of growth factors such as PDGF and VEGF from activated platelets. This release targets nociceptive signalling and promotes subchondral healing. The baseline stiffness and physical function subscores were similar in the 2 groups (stiffness p = 0.1204; physical function p = 0.3840) **(Table 4)**. The PRP group had a significant reduction in the stiffness subscore (3 months: p = 0.0004, 6 months: 3.40 ± 1.14 vs. 4.78 ± 0.84; p < 0.0001). The PRP group was statistically significantly better than the control group in terms of physical function at 6 weeks (p < 0.0001), 3 months (p < 0.0001) and at 6 months (24.62 ± 6.33 vs 46.20 ± 3.67; p < 0.0001). The observation that stiffness outcomes were only significantly different at 3 months may indicate that the biomechanical advantage of PRP on joint mobility may require prolonged exposure to growth factors to be clinically evident. This temporal pattern is supported by Filardo *et al.* **[18]** who observed that functional improvement after PRP injection accumulates progressively between 3 and 6 months in accordance with the biological time course of cartilage matrix remodelling and resolution of synovial inflammation. The VAS scores at baseline were similar in both groups PRP 7.10 ± 0.86; analgesic 7.06 ± 0.89; p = 0.2281. The VAS score was 3.24 ± 0.74 in the PRP group and 6.62 ± 0.95 in the analgesic group at 6 months **(Table 5)**. The difference was significant (t = 19.869; p < 0.0001) The PRP had approximately 54% reduction in pain from baseline. This exceeds the threshold for clinically meaningful pain relief in the OA literature. A randomised controlled trial of PRP versus hyaluronic acid found comparable reductions in VAS in the PRP arm with superior results that persisted at 12 months (Patel *et al.* **[19]**). Limited long term affect of conventional analgesic on disease related pain is evident from little change in VAS of analgesic group over time as compared to disease modifying biological potential of PRP. Similar results have been reported in such trials with progressive reduction in mean VAS scores at 6-month intervals, confirming significant clinical improvement attributable to the regenerative nature of autologous PRP **[17]**. In the present study, a single intra-articular injection of autologous PRP resulted in clinically relevant and statistically significant improvements in pain, stiffness and physical function during a 6 months follow up in patients with early knee osteoarthritis (Kellgren-Lawrence grade 0-2 or Halfbacks grade 1-2). The progressive nature of improvement with maximal benefit seen at 6 months suggests that the biological mechanism of PRP is that of a slow-acting regeneration rather than symptom relief alone. Dai *et al.* **[15]** observed that PRP had a clinically better effect on the disease 12 months after the intervention and suggested that a longer follow-up could further increase the treatment gap found in this study. There is no meaningful improvement in the analgesic group that is worth noting. Symptomatic relief may be obtained with oral non-steroidal anti-inflammatory drugs in the short term, however, the long-term use of these agents may alter the underlying chondrodegenerative disease process. The stable WOMAC and VAS scores in the control group over the 6-month period suggest that, in the absence of a biological effect, early OA has a persistent symptomatic course. This finding supports the rationale for the use of PRP in the early stages of the disease, when the residual cartilage integrity may allow responsiveness to regeneration **[11]**. Several meta-analyses have evaluated the effect of PRP preparation characteristics on clinical outcome. The PRP preparation employed in the current study was leukocyte-rich. The leukocyte-rich PRP with residual leukocytes may be more effective for pain relief than leukocyte-poor PRP based on recent evidence. However, the difference in centrifugation speeds, platelet concentration and activation methods in the PRP preparation remains a limitation of the literature and caution is warranted in interpretation across trials **[20].** Also, recent evidence indicates that absolute platelet count and total volume injected are important determinants of clinical success. Recent randomised trials have shown that a "superdose" of 8 mL of PRP (absolute platelet count of >5 billion) results in significantly better global joint function and pain reduction compared to a conventional 4-mL dose. However, larger volumes may be associated with a higher incidence of short-term self-limiting post-injection stiffness lasting 2 to 7 days. Long-term functional benefits indicate that refinement of dose and platelet count is important to optimise therapeutic outcomes **[21]**.

Conclusion:
A single intra-articular injection of autologous platelet-rich plasma improves pain, stiffness and physical function better than conventional analgesics in early-stage knee osteoarthritis patients, statistically and clinically. These improvements, which peak six months after PRP, show that PRP preserves and regenerates the joint through biological mechanisms rather than just symptoms. This makes PRP a viable conservative intervention for functional restoration and delaying early-grade degenerative joint disease.

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