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Original Research Article

A randomised, prospective, parallel and open label study to compare efficacy and safety of single dose versus double dose intra-articular platelet rich plasma in patients of osteoarthritis knee

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ABSTRACT

Background: Knee osteoarthritis (OA) is a leading cause of chronic pain, disability and impaired quality of life worldwide, with a rapidly increasing burden in the aging population. Conventional therapies primarily provide symptomatic relief and fail to alter disease progression. Platelet-rich plasma (PRP), an autologous biologic has emerged as a promising regenerative therapy. However, the optimal dosing strategy particularly the comparative efficacy of single versus multiple injections remains uncertain.

Methods: This randomized, prospective, parallel, open-label study evaluated 70 patients with Kellgren–Lawrence grade I–III knee OA at a tertiary care center in North India. Participants were randomized into two groups: Group A received a single intra-articular PRP injection (10 ml) while Group B received two PRP injections (10 ml each) administered three weeks apart. Patients were followed up at 21, 60 and 90 days. Clinical outcomes were assessed using the Visual Analog Scale (VAS) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Safety was monitored through adverse event reporting.

Results: Both groups demonstrated statistically significant improvements in VAS and WOMAC scores over the 90-day follow-up period ($p < 0.001$). Double-dose PRP group showed greater reductions in VAS scores and superior improvement in WOMAC parameters compared to the single-dose group ($p < 0.001$). PRP therapy was well tolerated with only minor and self-limiting adverse events.

Conclusion: Intra-articular PRP is a safe and effective treatment modality for knee OA. A double-dose regimen offers superior outcomes compared to a single-dose approach. These findings highlight the importance of dosing strategy in optimizing PRP therapy and support the use of repeated injections for improved patient outcomes.

Keywords: Knee osteoarthritis, Platelet-rich plasma, Western Ontario and McMaster Universities osteoarthritis index, Visual analogue scale

INTRODUCTION

Osteoarthritis (OA) is the most common chronic degenerative disorder affecting synovial joints and is a major cause of pain, physical disability and impaired quality of life worldwide. Knee is the most frequently

affected large joint and is characterized by progressive degeneration of articular cartilage, subchondral bone remodelling, osteophyte formation, synovial inflammation and varying degrees of joint dysfunction.¹ Worldwide about 10–15% of all adults aged over 60 years have some degree of OA. It affects women more than men and its

prevalence increases with age. While the global prevalence of knee OA was 3.8%, the BJD (Bone and joint decade) India COPCORD (community-oriented program for control of rheumatic diseases) study showed a prevalence of any form of OA as 4.39%. In India, knee OA represents one of the leading causes of chronic musculoskeletal disability among middle-aged and elderly individuals imposing a substantial socioeconomic burden.²

Conservative treatment includes lifestyle modification, weight reduction, physiotherapy and exercise while pharmacological therapy consists mainly of non-steroidal anti-inflammatory drugs (NSAIDs), Intra-articular corticosteroid and hyaluronic acid injections. Although these interventions provide symptomatic relief, none has demonstrated consistent disease-modifying effects. Furthermore, prolonged NSAID therapy is associated with gastrointestinal, renal and cardiovascular adverse effects whereas repeated corticosteroid injections may accelerate cartilage degeneration. These limitations have encouraged the development of biological therapies capable of modulating the disease process rather than merely relieving symptoms.^{3,4}

Platelet-rich plasma (PRP) is an autologous biological product prepared by centrifugation of whole blood to obtain plasma containing platelets at concentrations higher than baseline physiological levels. Activated platelets release numerous bioactive molecules including platelet-derived growth factor (PDGF), transforming growth factor- β (TGF- β), vascular endothelial growth factor (VEGF), insulin-like growth factor-1 (IGF-1), epidermal growth factor (EGF) and fibroblast growth factor (FGF). These growth factors promote chondrocyte proliferation, extracellular matrix synthesis, angiogenesis and tissue repair while simultaneously suppressing pro-inflammatory cytokines such as interleukin-1 β and tumour necrosis factor- α . Consequently, PRP has emerged as a promising regenerative therapy for patients with mild-to-moderate knee OA.^{5,6}

Several randomized controlled trials and systematic reviews have demonstrated that intra-articular PRP provides superior pain relief and functional improvement compared with hyaluronic acid, corticosteroids or placebo particularly in early-stage knee OA. Nevertheless, substantial heterogeneity exists regarding PRP preparation methods, platelet concentration, leukocyte content, injection volume and the number of injections administered. Among these variables, the optimal number and dose of PRP injections remain one of the most debated issues. Evidence regarding the superiority of single versus multiple-injection PRP regimens remains inconsistent. Tavassoli et al. conducted a single-blinded, RCT to compare the clinical effectiveness of intra-articular PRP versus HA in patients with bilateral knee OA (Ahlback grade I–II). Ninety-five patients were allocated into three groups: a single PRP injection, two PRP injections given 3 weeks apart and three weekly injections of HA. Clinical outcomes were assessed prospectively at baseline and at 4,

8 and 12 weeks using the WOMAC and the VAS for pain. At 12 weeks, the proportion of patients experiencing at least a 30% reduction in the WOMAC pain subscale was 86% in the PRP-1 group, 100% in the PRP-2 group and 0% in the HA group ($p < 0.001$), indicating significantly better pain relief with PRP, particularly with multiple injections. No major adverse effects were reported and the authors concluded that PRP is a safe and more effective therapeutic option than HA for knee OA with evidence that efficacy increases with multiple injections.⁷

Moretti et al. conducted a prospective clinical study to assess the efficacy and safety of autologous PRP injections in patients with knee OA (KL grades I–III). A total of 153 patients (mean age 59.06 ± 8.78 years) received three consecutive intra-articular PRP injections and were evaluated at baseline (T0), one month (T1), three months (T2) and six months (T3) using the VAS scale for pain, the WOMAC scale and the Knee Society Score (KSS). The results demonstrated a statistically significant reduction in pain and improvements in functional scores across all follow-up time points compared with baseline ($p < 0.05$), indicating that PRP injections significantly reduced symptoms and improved knee function up to six months after treatment.

The study concluded that intra-articular PRP represents a valid conservative treatment for reducing pain and improving QOL and functional outcomes in knee OA patients at follow-up.⁵ Despite the widespread use of platelet-rich plasma (PRP) in knee OA, the optimal dosing regimen remains uncertain. This randomized, prospective, open-label study compares the efficacy and safety of single-dose versus double-dose (10 ml each) intra-articular PRP. The findings may help standardize PRP therapy and guide evidence-based clinical practice.

The primary objectives of the study were to evaluate the efficacy of intra-articular platelet-rich plasma (PRP) in patients with knee osteoarthritis in the North Indian population and to compare the efficacy of single-dose versus double-dose intra-articular PRP in patients receiving treatment. The secondary objectives were to assess the safety of the treatments administered and to evaluate the quality-of-life parameters in patients receiving treatment.

METHODS

Study design

Randomized, prospective, parallel-group, open-label comparative study.

Study place

Department of Pharmacology, Department of Orthopaedics and Department of Blood Bank, Government Medical College, Amritsar, Punjab, India.

Study duration

Study was conducted for a period of 1 year.

Study population

Patients with symptomatic knee OA of any age group and sex who fulfil American college of Rheumatology criterion for the diagnosis of OA were enrolled.

Inclusion criteria

Patients with symptomatic OA of any age group and sex who fulfill American college of Rheumatology criterion for the diagnosis of OA were enrolled. Chronic history (for at least 4 months) of knee joint pain. Radio graphically documented knee OA of grades 1 to 3 (Kellgren-Lawrence [K-L] radiographic classification scale).⁸

Exclusion criteria

OA flare up with significant effusion. Patient with active cardiac lesion or uncontrolled hypertensive patient. Pregnant females or those who are planning their pregnancy during the study. Radiographically severe knee OA of grade 4 (K-L radiographic classification scale). Previous femur and tibia fractures. Previously operated knee. (e.g., arthroscopy). Hyaluronic acid infiltration within the previous six months. Haemoglobin levels < 10 g/dL. History of oncohematological disease, infections or immunosuppression.

Preparation of platelet-rich plasma

Autologous platelet-rich plasma was prepared under strict aseptic precautions at Blood Bank, GND Hospital,

Amritsar using the patient's own venous blood. Blood was processed according to the institutional standard operating protocol to obtain leukocyte-rich platelet-rich plasma (LR-PRP).

Each injection consisted of 10 ml of PRP concentrate which was administered immediately after preparation to preserve platelet viability and biological activity. The entire preparation and administration procedure was carried out under sterile conditions by trained personnel.

Ethical approval

Before starting the study, approval of Institutional Ethics Committee (No. 40802/D-26/2023) and Thesis Committee was taken. 70 diagnosed cases of knee OA of any age group and sex who fulfill American college of Rheumatology criterion for the diagnosis of OA were enrolled.

A written informed consent was taken from all the patients prior to enrolment and after explaining the study particulars in easily understandable vernacular language.

Sample size calculation

The size of the sample was $n=70$ (35 in each group). The sample size was calculated to be a minimum of 64 participants, keeping a 95% confidence level, study power of 80% and effect size of 1 with standard deviations of 1.12 and 1.18 as reported in a similar previous study. Patients were randomly divided by using a computer software (Random Allocation Software) into 2 groups of equal distribution Group A and Group B, consisting of 35 patients each.⁶

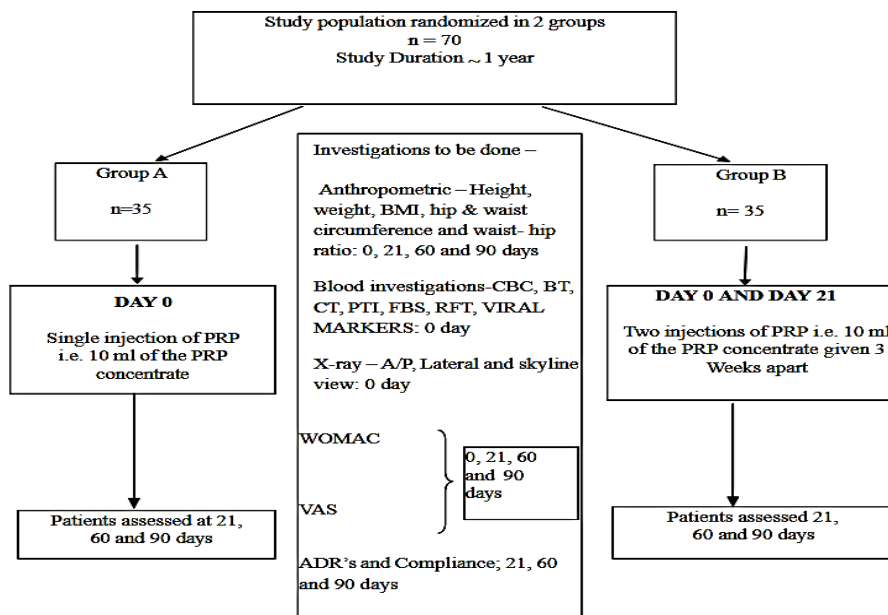


Figure 1: Study design.⁹⁻¹¹

Statistical analysis

Data were entered into SPSS software version 26.0 using appropriate statistical software. Continuous variables were expressed as mean $\pm$ standard deviation (SD) while categorical variables were expressed as frequencies and percentages. Comparisons within treatment groups over time were performed using the paired Student's t-test whereas comparisons between the two treatment groups were carried out using the unpaired Student's t-test. A $p < 0.05$ was considered statistically significant whereas $p < 0.001$ was considered highly statistically significant.

RESULTS

Both treatment groups were comparable with respect to demographic and baseline clinical characteristics. The mean age was 59.03 ± 10.42 years in Group A and 60.00 ± 9.45 years in Group B. Females (65.7%) constituted the majority of participants in both groups. Obesity was common with a prevalence of 74.3% in Group A and 82.9% in Group B. KL Grade III OA was the predominant radiographic grade accounting for 60% of the study population. No statistically significant differences were observed between the two groups at baseline ($p > 0.05$) indicating successful randomization (Table 1).

Table 1: Comparison of 'baseline parameters' between group 'A' and group 'B'.

Baseline parameters	Group A (n=35)	Group B (n=35)	Total (n=70)
Age (in years) (Mean $\pm$ SD)	59.03 $\pm$ 10.42	60.00 $\pm$ 9.45	0.724 (p value)
Female	22 (62.9%)	24 (68.6%)	46 (65.7%)
Male	13 (37.1%)	11 (31.4%)	24 (34.3%)
>30.00 BMI (Obese)	26 (74.3%)	29 (82.9%)	55 (78.6%)
OA K-L Grade 3	20 (57.2%)	22 (62.8%)	42 (60.0%)

$p > 0.05$: Not significant * $p < 0.05$: Significant; ** $p < 0.001$: Highly significant [p value: Unpaired t-test]

WOMAC pain score

Both groups showed a statistically significant reduction in WOMAC pain scores throughout the follow-up period ($p < 0.001$). By Day 90, the mean WOMAC pain score had decreased from 15.17 ± 1.01 to 9.00 ± 1.73 in Group A and from 15.40 ± 0.95 to 5.77 ± 1.44 in Group B. The difference in pain reduction between the two groups at Day 90 was highly statistically significant ($p < 0.001$) (Figure 2).

WOMAC function score

Functional ability improved steadily in both groups over the course of the study. However, patients treated with the two-injection PRP regimen exhibited significantly greater improvement in functional outcomes compared to those receiving a single injection. By Day 90, the mean WOMAC function score decreased from 52.11 ± 3.55 to 35.91 ± 6.29 in Group A and from 52.46 ± 4.31 to 28.89 ± 6.14 in Group B. The difference in functional improvement between the two groups was highly statistically significant, favouring the two-injection regimen ($p < 0.001$) (Figure 2).

WOMAC stiffness score

Both treatment groups showed significant improvement in joint stiffness during follow-up. WOMAC stiffness scores declined steadily from baseline to Day 90, with greater improvement observed among patients receiving two PRP injections. At Day 90, the mean WOMAC stiffness score was 3.17 ± 0.95 in Group A and 2.23 ± 0.60 in Group B. The difference between the groups is statistically significant ($p < 0.001$) (Figure 2).

Total WOMAC score

A progressive reduction in total WOMAC score was observed in both treatment groups indicating improvement. At baseline, the mean total WOMAC score was 73.20 ± 4.44 in Group A and 73.97 ± 4.84 in Group B ($p > 0.05$) demonstrating comparable symptom severity before treatment. During follow-up, total WOMAC scores decreased significantly in both groups. However, the reduction was significantly greater in patients receiving the two-injection PRP regimen. At Day 90, the mean total WOMAC score declined to 48.09 ± 8.55 in Group A and 36.83 ± 7.66 in Group B ($p < 0.001$) indicating superior overall clinical improvement in Group B (Figure 2).

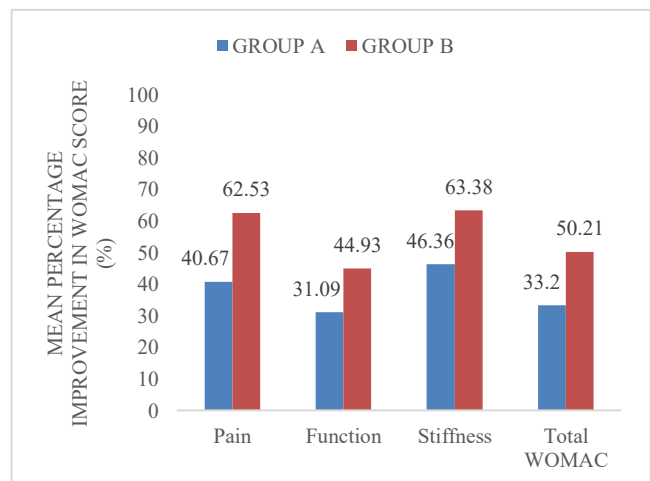


Figure 2: Inter group comparison of WOMAC scale between group 'A' and group 'B' over 90 days of treatment

Visual analogue scale (VAS)

Pain intensity assessed using the Visual Analogue Scale improved significantly in both treatment groups during follow-up. Baseline VAS scores were comparable between the groups (7.74 ± 0.74 vs 7.86 ± 0.77 ; $p=0.444$). Progressive reduction in pain was observed over time, with significantly greater improvement among patients receiving two PRP injections. At Day 90, the mean VAS score decreased to 5.06 ± 0.87 in Group A compared with 3.43 ± 1.29 in Group B. The intergroup difference was highly statistically significant ($p<0.001$) demonstrating superior pain relief following the two-injection regimen (Figure 3).

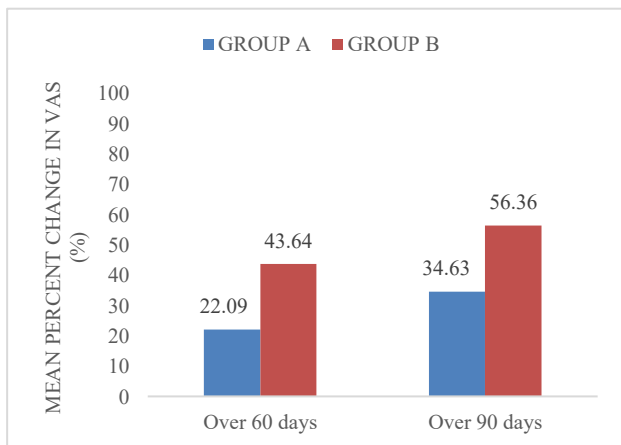


Figure 3: Inter group comparison of vas score between group 'A' and group 'B' over 60 and 90 days of treatment.

Quality of life (QOL)

QOL improved significantly in both treatment groups as statistically significant improvement from baseline ($p<0.001$) is observed. However, patients receiving the

two-injection PRP regimen achieved greater percentage improvement in WOMAC as well as VAS scores. The mean percentage reduction in pain, stiffness, function, total WOMAC score and VAS score was consistently higher in Group B than in Group A, indicating superior overall clinical outcomes with the two-injection regimen (Figure 4).

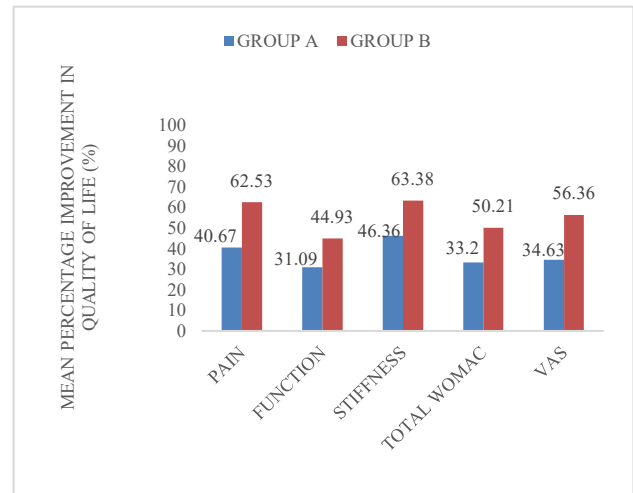


Figure 4: Inter group comparison of quality of life between group 'A' and 'B' over 90 days of treatment according to WOMAC and VAS scales.

Safety analysis

During the 90-day follow-up period, seven adverse drug reactions were reported among the 70 enrolled participants representing an overall incidence of 10%. According to the WHO-UMC causality assessment scale, all adverse events were classified as possible while severity assessment using the Modified Hartwig and Siegel scale categorized all reactions as Level 1 (mild). None of the adverse events required hospitalization or resulted in discontinuation of treatment. Overall, intra-articular LR-PRP was found to be safe and well tolerated in both treatment groups (Table 2).

Table 2: Adverse effect profile of patients in group 'A' and 'B' over 90 days of treatment along with causality and severity assessment.

Adverse Effect	Number of Adverse Effects (%)	Causality assessment	Severity assessment
Allergy	2 (2.86)	Possible	Level 1 (Mild)
Skin discoloration	4 (5.71)	Possible	Level 1 (Mild)
Infection	1 (1.42)	Possible	Level 1 (Mild)
Bleeding	0 (0)	-	-
Tissue damage	0 (0)	-	-
Nerve injuries	0 (0)	-	-
Total no. of ADRs	7 (10)		

(Causality assessment: WHO-UMC Scale and Severity assessment: Modified Hartwig and Siegel's Severity Assessment Scale)

Total number of patients with ADRs from PRP were 10% over 90 days of treatment with possible causality assessment in all and Level 1 (Mild) severity assessment for all ADRs. None of the ADRs required hospitalization.

DISCUSSION

The prevalence of OA knee increased with the increasing age (2.9% in age ≤ 40 years, 20% in age 41-50 years, 28.6%

in age 51-60 years, 35.7% in age 61-70 years and 12.9% in age > 70 years). Present study is in accordance with a RCT conducted by Bansal et al where 150 patients with knee OA were enrolled to evaluate the efficacy of PRP therapy. The mean age of the study population was 56.3 ± 8.9 years, indicating that most patients were above 50 years of age, reflecting the increased prevalence of the disease with advancing age.¹²

Females constituted the majority in both groups, accounting for 62.9% in Group A and 68.6% in Group B, comprising 65.7% of the total sample. The present study which is in accordance with a study conducted by Raeissadat et al which included 200 patients with knee OA, in which female patients constituted the majority of the study population (approximately 69%).¹³

The majority of participants in both groups were obese ($\text{BMI} > 30.0 \text{ kg/m}^2$) comprising 78.6% ($n=55$) of the total study population. Obesity was observed in 74.3% ($n=26$) of Group A and 82.9% ($n=29$) of Group B. This is in accordance with a randomized clinical trial conducted by Bansal et al 150 patients with knee osteoarthritis were included to evaluate the efficacy of PRP therapy. The study population had a mean body mass index (BMI) of $29.8 \pm 4.3 \text{ kg/m}^2$, indicating that most participants were overweight or obese.¹²

The distribution of study participants based on OA grade according to KL system showed that OA Grade 3 was the most prevalent, observed in 60.0% ($n=42$) of participants, followed by OA Grade 2 in 24.3% ($n=17$) and OA Grade 1 in 15.7% ($n=11$). However present study is in opposition with Felson et al. which reported that early radiographic osteoarthritis (KL I–II) was more prevalent in community-based populations.¹⁴

Efficacy parameters

WOMAC pain score

Over 90 days, the mean score decreased from 15.17 ± 1.01 to 9.00 ± 1.73 in Group A and 15.40 ± 0.95 to 5.77 ± 1.44 in Group B with $p < 0.001$ indicating a highly significant difference, suggesting that Group B experienced greater improvement in pain compared to Group A. Zhao et al conducted a study in China including 120 patients with knee OA, comparing sequential versus single intra-articular PRP injections. The study reported that the sequential PRP group (3 injections at weekly intervals) showed significantly greater improvement in WOMAC pain scores compared with the single-injection group at 3 months ($p < 0.05$) and at 6 months ($p < 0.001$) indicating that repeated PRP administration may provide better pain relief.¹⁵

WOMAC function score

Over 90 days, the mean function score decreased from 52.11 ± 3.55 to 35.91 ± 6.29 in Group A and from 52.46 ± 4.31

to 28.89 ± 6.14 in Group B with $p < 0.001$ indicating a highly significant difference favouring Group B. Kavadar et al conducted a randomized prospective clinical study in Turkey including 75 patients with knee OA, comparing single (4 ml) and triple (4ml each) intra-articular PRP injections. The study demonstrated that patients receiving multiple PRP injections showed significantly greater improvement in WOMAC functional scores compared with the single-injection group at 3 and 6 months ($p < 0.001$) follow up period.¹⁶

WOMAC stiffness score

Over 90 days, the mean stiffness score reduced from 5.91 ± 0.82 to 3.17 ± 0.95 in Group A and from 6.09 ± 0.56 to 2.23 ± 0.60 in Group B with $p < 0.001$ indicating a highly significant difference, with Group B showing greater improvement in stiffness. Tavassoli et al conducted a RCT in Iran involving 90 patients with knee OA, comparing single-dose (5 ml) and double-dose (5 ml each given 2 weeks apart) PRP with HA injections. The study demonstrated significant improvement in WOMAC stiffness scores with both single and double PRP injections ($p < 0.05$). Double-dose PRP administered at a 2-week interval showing superior outcomes at 6 and 12 months ($p < 0.05$).⁷

Total WOMAC score

Over 90 days, the mean score decreased from 73.20 ± 4.44 to 48.09 ± 8.55 in Group A and from 73.97 ± 4.84 to 36.83 ± 7.66 in Group B with $p < 0.001$ demonstrating a highly significant difference favouring Group B. Patel et al conducted a prospective, triple-blind randomized clinical trial in India including 192 patients with knee OA comparing conventional-dose PRP with super-dose PRP. The study reported significant improvement in total WOMAC scores in both groups with greater improvement observed in the super-dose PRP group at 6 month follow up ($p < 0.001$).⁶

VAS score

Over 90 days, the mean VAS score decreased from 7.74 ± 0.74 to 5.06 ± 0.87 in Group A and from 7.86 ± 0.77 to 3.43 ± 1.29 in Group B with $p < 0.001$, indicating a highly significant difference, with Group B showing greater pain relief. Zhao et al conducted a study in China comparing sequential and single intra-articular PRP injections. The study demonstrated significant reduction in VAS pain scores in both groups with greater improvement in the sequential PRP group compared with the single-injection group at 6 month ($p < 0.001$) follow up.¹⁵

Quality of life

Improvement in QOL in the present study was reflected by significant reductions in VAS pain scores and improvement in WOMAC scores which assess pain, stiffness and functional limitation in patients with knee

OA. Group B receiving two PRP injections demonstrated greater improvement compared to Group A receiving single-injection indicating better overall patient outcomes. Similar findings have been reported in previous studies where multiple PRP injections resulted in greater improvement in VAS and WOMAC parameters, suggesting enhanced clinical benefit with repeated PRP administration.¹⁷⁻¹⁹

Safety parameter

During the study period, a total of 7 adverse drug reactions were reported among 70 participants accounting for 10% of the study population. All the reported adverse reactions were categorized as possible according to the WHO-UMC causality assessment scale. In terms of severity, all adverse events were classified as Level 1 (mild) according to the Modified Hartwig and Siegel's Severity Assessment Scale, indicating that the reactions were mild and did not require significant medical intervention. Wang and Yao conducted a systematic review and meta-analysis of RCTs evaluating the efficacy and safety of PRP injections for knee OA. The analysis reported that PRP treatment was generally safe with only mild and transient adverse events such as injection-site pain or swelling reported in approximately 8–12% of patients and no significant increase in serious adverse reactions compared with control treatments ($p > 0.05$).²⁰

Limitations

The study had a relatively small population ($n=70$) which may limit the statistical power and generalizability of the results. Duration of follow-up was short (3 months) which restricts assessment of long-term efficacy and safety of PRP therapy. Study was conducted at a single center, limiting the applicability of findings to a wider population. Heterogeneity in existing literature regarding PRP protocols makes direct comparison with other studies difficult.

CONCLUSION

From the observations of the present study, it can be concluded that both Group A (single dose PRP) and Group B (double dose PRP) showed statistically significant improvement in pain, stiffness and functional outcomes as assessed by WOMAC and VAS scores. However, Group B demonstrated significantly greater improvement in comparison to Group A indicating superior efficacy of double dose PRP in the management of OA knee. Both groups were found to be safe with minimal adverse effects observed. The severity and causality assessment revealed that most adverse events were mild and self-limiting with no serious complications reported during the study period. Overall, intra-articular PRP is an effective and safe treatment option for OA knee and 2 injections (10 ml each) given at an interval of 3 weeks of PRP appears to provide better clinical outcomes compared to single injection PRP.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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