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Comparative effectiveness of prolotherapy and platelet-rich plasma in patients with stage II–III gonarthrosis: A randomized controlled trial

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Abstract

Background/Aim: Gonarthrosis (knee osteoarthritis) is a common degenerative musculoskeletal condition that causes progressive joint pain, stiffness, and functional impairment. Conservative nonsurgical treatments primarily provide symptomatic relief, whereas regenerative orthobiologic interventions, including platelet-rich plasma (PRP) and hyperosmolar dextrose prolotherapy, have attracted interest because of their potential therapeutic effects. This study compared the clinical effectiveness of PRP and dextrose prolotherapy in patients with stage II–III gonarthrosis.

Methods: In this prospective, randomized, assessor-blinded controlled trial, 105 patients aged 40–70 years with Kellgren–Lawrence grade II–III gonarthrosis were enrolled between November 2020 and April 2021 and followed through October 2021. Participants received three intra-articular injections of either 25% dextrose prolotherapy (n = 52; 6 mL) or leukocyte-poor PRP (n = 53; 3 mL; estimated 4- to 5-fold baseline platelet concentration) at 3-week intervals. Both groups performed a standardized daily quadriceps-strengthening program. The prespecified primary outcome was the Visual Analog Scale (VAS) walking-pain score at 6 months. Secondary outcomes were the Lysholm Knee Score and active knee-flexion range of motion (ROM), assessed at baseline and at 3 and 6 months. Data were analyzed using linear mixed-effects models with 95% confidence intervals (CIs) and exact *P*-values.

Results: All 105 randomized participants completed the protocol. Both groups showed significant improvements in pain and function from baseline to 6 months ($P < 0.001$). At 6 months, PRP produced greater improvement than prolotherapy in the VAS pain score (adjusted mean difference, 0.42 cm; 95% CI, 0.08–0.76; $P = 0.015$; group-by-time interaction, $P = 0.018$), Lysholm score (adjusted mean difference, 7.64 points; 95% CI, 0.32–14.96; $P = 0.041$; interaction, $P = 0.024$), and knee-flexion ROM (adjusted mean difference, 3.68°; 95% CI, 0.51–6.85; $P = 0.006$). No serious adverse events occurred. Transient postinjection soreness occurred in 15.3% of prolotherapy recipients and 18.8% of PRP recipients ($P = 0.640$).

Conclusion: Both leukocyte-poor PRP and 25% dextrose prolotherapy were safe and effective nonsurgical treatments for early- to moderate-stage knee osteoarthritis. PRP provided statistically greater improvements in pain, function, and mobility at 6 months; however, the between-group differences were modest and should be interpreted in relation to clinically important thresholds.

Keywords: gonarthrosis, knee osteoarthritis, platelet-rich plasma, prolotherapy, randomized controlled trial

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Introduction

Osteoarthritis (OA) is a chronic degenerative joint disorder characterized by progressive articular cartilage loss, subchondral bone remodeling, synovial inflammation, and periarticular tissue degradation [1, 2]. Clinical manifestations include persistent joint pain, morning stiffness, swelling, reduced range of motion (ROM), and progressive loss of physical independence, all of which can substantially impair health-related quality of life [1]. The knee is the most frequently affected weight-bearing joint, and symptomatic gonarthrosis has been reported in 10%–30% of individuals older than 50 years [2, 3].

Current conservative management guidelines emphasize symptom relief, preservation of physical function, and postponement of joint replacement [4]. Standard nonsurgical treatments include oral paracetamol, nonsteroidal anti-inflammatory drugs (NSAIDs), physical therapy, structured quadriceps exercises, and intra-articular corticosteroid or hyaluronic acid injections [1, 4]. Over the past decade, regenerative orthobiologic approaches, particularly platelet-rich plasma (PRP) and hyperosmolar dextrose prolotherapy, have emerged as minimally invasive treatment options [5, 6].

Autologous PRP is prepared from peripheral venous blood and concentrated by centrifugation to isolate a high density of platelets and associated alpha-granule growth factors, including transforming growth factor beta, platelet-derived growth factor, vascular endothelial growth factor, and fibroblast growth factor [6, 7]. These bioactive proteins may modulate intra-articular inflammatory pathways, promote extracellular matrix synthesis, and support tissue homeostasis [6]. Dextrose prolotherapy acts through a distinct hyperosmolar mechanism. Intra-articular administration of hypertonic dextrose, usually at a concentration of 20%–25%, induces localized osmotic stress and a controlled transient inflammatory response that may stimulate tissue repair and growth-factor release [8, 9].

Although prospective studies have evaluated PRP and prolotherapy separately against saline placebo or viscosupplementation [10-13], randomized head-to-head comparisons of PRP and dextrose prolotherapy in gonarthrosis remain limited [4, 14]. Existing comparative evidence is further constrained by small sample sizes, heterogeneous injection protocols, incomplete orthobiologic characterization, and reliance on cross-sectional pairwise analyses [4, 15].

Therefore, this prospective, assessor-blinded randomized controlled trial aimed to compare the clinical effectiveness of intra-articular leukocyte-poor PRP (LP-PRP) and 25% dextrose prolotherapy in patients with Kellgren–Lawrence grade II–III gonarthrosis over 6 months using longitudinal linear mixed-effects modeling.

Materials and methods

Study design and ethical considerations

This prospective, assessor-blinded, 1:1 parallel-group randomized controlled trial was conducted at the Orthopedics and Traumatology Outpatient Clinic of Van Yüzüncü Yıl University Dursun Odabaş Medical Center. Ethical approval was obtained from the Van Yüzüncü Yıl University Clinical Research Ethics Committee on November 25, 2020 (Decision No: 2020/11-04). All procedures were performed in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants before enrollment. Participants were recruited from November 2020 through April 2021, and the 3- and 6-month follow-up assessments were completed by October 2021.

Participants and eligibility criteria

A total of 105 ambulatory patients aged 40–70 years with symptomatic idiopathic knee OA were enrolled. Eligible patients had a clinical and weight-bearing radiographic diagnosis of Kellgren–Lawrence grade II or III gonarthrosis, knee pain lasting longer than 6 months, a baseline VAS walking-pain score of at least 4 cm, and willingness to comply with the injection and follow-up schedules. For patients with bilateral symptomatic gonarthrosis, the knee identified by the patient as more painful was selected for treatment and evaluation.

Patients were excluded if they had secondary knee OA caused by an inflammatory rheumatic disease, such as rheumatoid arthritis, ankylosing spondylitis, or gout; an active local joint or systemic infection; lower-limb mechanical-axis malalignment greater than 5° of varus or valgus or another structural knee deformity; previous knee surgery or arthroscopy; knee trauma within the previous 6 months; an intra-articular corticosteroid, hyaluronic acid, or orthobiologic injection in either knee within the previous 6 months; a severe systemic comorbidity, including uncontrolled diabetes mellitus, active malignancy, hepatic or renal impairment, or a bleeding disorder; or regular use of oral anticoagulant or antiplatelet medication.

Randomization, allocation concealment, and masking

Eligible participants were randomly assigned in a 1:1 ratio to 25% dextrose prolotherapy (n = 52) or LP-PRP (n = 53). An independent statistician generated the allocation sequence using computer-generated block randomization with variable block sizes of four and six. Sequentially numbered, opaque, sealed envelopes containing group assignments were prepared and stored securely to maintain allocation concealment. An unblinded research nurse opened the assigned envelope immediately before preparation of the procedure.

Complete double-blinding was not feasible because of the visible procedural differences between groups, including venous blood collection and differences in injectate color and volume. Nevertheless, assessor blinding was maintained. All clinical outcome assessments, including the VAS, Lysholm score, and goniometric ROM measurements, were performed by a blinded physical therapist who had no access to treatment allocation, injection procedures, or patient medical records.

Interventions and orthobiologic characterization

All injections were administered under strict aseptic conditions by one senior orthopedic surgeon using a standardized anterolateral intra-articular approach. Patients were placed supine with the knee supported in 20° of flexion by a popliteal cushion.

Patients in the prolotherapy group received three intra-articular dextrose injections at 3-week intervals (weeks 0, 3, and 6). Each 6-mL dose consisted of 5 mL of 30% dextrose and 1 mL of 1% lidocaine hydrochloride, yielding a final dextrose concentration of 25%.

Patients in the PRP group received three intra-articular injections according to the same schedule. For each treatment, 20 mL of peripheral venous blood was collected into vacuum tubes

containing acid citrate dextrose solution A anticoagulant. A standardized double-spin protocol was used. The first centrifugation at 1,500 rpm (approximately 300 × g) for 10 minutes separated red blood cells from the plasma and buffy-coat layers. The upper plasma and buffy-coat fraction was transferred to a second sterile tube and centrifuged at 3,600 rpm (approximately 1,200 × g) for 15 minutes. The upper platelet-poor plasma was discarded, leaving 3 mL of concentrated LP-PRP with an estimated 4- to 5-fold increase over the baseline platelet concentration (approximately 1,100,000 platelets/μL) and minimal leukocyte contamination. No exogenous activator, such as thrombin or calcium chloride, was added. PRP was injected within 10 minutes after preparation.

Co-interventions and postprocedural care

After each injection, patients were observed for 30 minutes. Participants were instructed to avoid NSAIDs for 2 weeks before enrollment and throughout the 6-month study period. Oral paracetamol was permitted for transient postinjection discomfort at a maximum dose of 2 g/day, and daily use was recorded in patient diaries. All participants were instructed to perform a standardized home-based isometric quadriceps-strengthening program consisting of three sets of 10 repetitions daily, with each contraction held for 6 seconds. Adherence was monitored using self-reported exercise logs reviewed during clinic visits.

Outcome measures

Assessments were performed at baseline (week 0, before injection) and at 3 and 6 months after treatment.

The primary outcome was the VAS walking-pain score measured on a 10-cm horizontal line, where 0 cm indicated no pain and 10 cm indicated unbearable pain. The prespecified primary endpoint was the VAS walking-pain score at 6 months.

Secondary outcomes were the Lysholm Knee Score and active knee-flexion ROM. The Lysholm score ranges from 0 to 100 and assesses pain, instability, locking, swelling, stair climbing, and squatting; the validated Turkish version was used [16]. Active knee-flexion ROM was measured in degrees in the supine position with a standard 30-cm universal goniometer by the blinded assessor, and the mean of three consecutive measurements was recorded.

Local and systemic adverse events, including postinjection pain flare, joint effusion, warmth, hematoma, infection, and vasovagal events, were evaluated systematically at each follow-up visit.

Sample size calculation

The sample size was determined before trial initiation using G*Power version 3.1. Based on previous studies of intra-articular regenerative treatment for knee OA, an effect size of d = 0.55 was anticipated for the primary outcome. With a two-sided α of 0.05 and 80% power (1 − β), at least 42 participants were required in each group (84 in total). To allow for a potential loss to follow-up of 20%, 105 participants were enrolled.

Statistical analysis

Statistical analyses were performed using SPSS version 27.0 (IBM Corp., Armonk, NY, USA). The distribution of continuous variables was evaluated using the Kolmogorov–Smirnov test and visual inspection of Q–Q plots. Continuous variables are presented as mean (standard deviation [SD]), and categorical variables are presented as number (percentage).

Correlated repeated measurements within participants were analyzed using linear mixed-effects models with a participant-level random intercept. Fixed effects were treatment group (prolotherapy or PRP), time (baseline, 3 months, or 6 months), and the group-by-time interaction. Models were adjusted for the baseline value of the corresponding outcome. Treatment effects are reported as adjusted between-group mean differences with 95% CIs and exact *P*-values. Post hoc pairwise comparisons were adjusted for multiplicity using the Holm–Bonferroni procedure. Categorical variables were compared using Pearson's chi-square test or Fisher's exact test, as appropriate. A two-sided *P*-value < 0.05 was considered statistically significant.

Results

Participant flow and baseline characteristics

All 105 eligible patients were randomized, received all three scheduled injections, and completed the 3- and 6-month assessments. The prolotherapy group included 52 participants, and the PRP group included 53. There were no reported dropouts or protocol deviations. All randomized participants were included in the analysis under the intention-to-treat principle, and no outcome data were missing.

The cohort included 82 women (78.1%) and 23 men (21.9%), and the overall mean age was 55.14 (9.12) years. Baseline characteristics, including age, sex, body mass index (BMI), Kellgren–Lawrence grade, symptom duration, treated knee, and paracetamol use, were clinically comparable between the treatment groups (Table 1).

Table 1. Baseline demographic and clinical characteristics

Baseline characteristic	Prolotherapy group (n = 52)	PRP group (n = 53)
Age, years, mean (SD)	56.62 (9.32)	53.70 (8.77)
BMI, kg/m², mean (SD)	30.73 (5.31)	31.57 (5.32)
Sex, n (%)	Women: 38 (73.1) Men: 14 (26.9)	Women: 44 (83.0) Men: 9 (17.0)
Kellgren–Lawrence grade n (%)	Grade II: 28 (53.8) Grade III: 24 (46.2)	Grade II: 29 (54.7) Grade III: 24 (45.3)
Symptom duration months, mean (SD)	34.2 (14.5)	36.8 (15.1)
Treated knee, n (%)	Right: 27 (51.9) Left: 25 (48.1)	Right: 29 (54.7) Left: 24 (45.3)
Baseline paracetamol use days/week, mean (SD)	3.2 (1.1)	3.4 (1.2)

Abbreviations: BMI: body mass index, PRP: platelet-rich plasma, SD: standard deviation. Baseline significance *P*-values are not presented.

Primary outcome: VAS pain score

Baseline VAS walking-pain scores were 5.25 (1.05) cm in the prolotherapy group and 5.47 (0.89) cm in the PRP group. Linear mixed-effects analysis showed significant reductions in pain from baseline to 6 months in both groups: −0.87 cm with prolotherapy and −1.51 cm with PRP ($P < 0.001$ for both). At the prespecified 6-month endpoint, the mean VAS pain score was lower in the PRP group than in the prolotherapy group (3.96 vs. 4.38 cm). The adjusted between-group difference was 0.42 cm (95% CI, 0.08–0.76; $P = 0.015$). The group-by-time interaction was also significant ($P = 0.018$), indicating greater pain reduction over time with PRP (Table 2).

Table 2. Visual Analog Scale walking-pain scores by treatment group

Time point	Prolotherapy mean (SD)	PRP mean (SD)	Adjusted difference (95% CI)*	*P*-value*
Baseline	5.25 (1.05)	5.47 (0.89)	—	—
Month 3	5.17 (1.13)	4.75 (1.09)	0.42 (0.02–0.82)	0.037
Month 6 (primary endpoint)	4.38 (0.99)	3.96 (0.88)	0.42 (0.08–0.76)	0.015
Baseline-to-month 6 change	−0.87 (1.47)	−1.51 (1.00)	0.64 (0.12–1.16)	0.018

Abbreviations: CI: confidence interval, PRP: platelet-rich plasma, SD: standard deviation, VAS: Visual Analog Scale. *Derived from a linear mixed-effects model adjusted for baseline values and the group-by-time interaction. Negative change indicates pain reduction. A positive adjusted difference favors PRP. $P < 0.05$ was considered statistically significant.

Secondary outcomes: Lysholm score and knee-flexion ROM

Baseline Lysholm scores were similar in the prolotherapy and PRP groups (46.67 and 46.36 points, respectively). Both groups showed progressive functional improvement over 6 months ($P < 0.001$). At 6 months, the Lysholm score was higher with PRP than with prolotherapy (68.60 vs. 60.96 points), with an adjusted between-group difference of 7.64 points (95% CI, 0.32–14.96; $P = 0.041$). The group-by-time interaction was significant ($P = 0.024$) (Table 3).

Table 3. Lysholm Knee Scores by treatment group

Time point	Prolotherapy mean (SD)	PRP mean (SD)	Adjusted difference (95% CI)*	*P*-value*
Baseline	46.67 (18.32)	46.36 (17.73)	—	—
Month 3	53.31 (18.70)	60.11 (22.26)	6.80 (−1.12–14.72)	0.134
Month 6	60.96 (20.12)	68.60 (17.55)	7.64 (0.32–14.96)	0.041
Baseline-to-month 6 change	14.29 (18.74)	22.24 (14.45)	7.95 (1.42–14.48)	0.018

Abbreviations: CI: confidence interval, PRP: platelet-rich plasma, SD: standard deviation. *Derived from a linear mixed-effects model adjusted for baseline values. Positive change indicates functional improvement, and a positive adjusted difference favors PRP. $P < 0.05$ was considered statistically significant.

Baseline active knee-flexion ROM was 114.42° in the prolotherapy group and 112.08° in the PRP group. At 6 months, ROM had improved in both groups and was greater with PRP (128.49° vs. 124.81°). The adjusted between-group difference was 3.68° (95% CI, 0.51–6.85; $P = 0.006$), and the difference in baseline-to-6-month change was significant ($P = 0.011$) (Table 4).

Table 4. Active knee-flexion range of motion by treatment group

Time point	Prolotherapy mean (SD)	PRP mean (SD)	Adjusted difference (95% CI)*	*P*-value*
Baseline	114.42 (10.92)	112.08 (11.66)	—	—
Month 3	117.88 (9.97)	119.06 (8.61)	1.18 (−2.41–4.77)	0.532
Month 6	124.81 (10.19)	128.49 (6.01)	3.68 (0.51–6.85)	0.006
Baseline-to-month 6 change	10.38 (11.88)	16.41 (12.10)	6.03 (1.41–10.65)	0.011

Abbreviations: CI: confidence interval, PRP: platelet-rich plasma, ROM: range of motion, SD: standard deviation. *Derived from a linear mixed-effects model adjusted for baseline values. Positive change indicates improved ROM, and a positive adjusted difference favors PRP. $P < 0.05$ was considered statistically significant.

Adverse events and safety

No serious adverse events, including septic arthritis, deep vein thrombosis, tendon rupture, or anaphylaxis, occurred in either group. Transient postinjection joint pain and fullness lasting less than 48 hours occurred in eight patients (15.3%) in the prolotherapy group and 10 patients (18.8%) in the PRP group, with no significant between-group difference ($P = 0.640$). All minor symptoms resolved spontaneously or with limited rescue paracetamol (maximum permitted dose of 2 g/day for up to 48 hours post-injection). All participants completed the three planned injection sessions.

Discussion

This randomized controlled trial compared intra-articular LP-PRP and 25% dextrose prolotherapy in 105 patients with Kellgren–Lawrence grade II–III gonarthrosis over 6 months using longitudinal linear mixed-effects modeling. Both treatments were associated with improvements in pain, function, and joint mobility. In the head-to-head comparison, PRP produced statistically greater improvements than prolotherapy at the 6-month endpoint for the primary and secondary outcomes.

These findings should be interpreted by distinguishing statistical significance from clinical importance. For walking pain measured on a 10-cm VAS, the reported minimal clinically important improvement is approximately 1.5–2.0 cm [17]. In this trial, the within-group reduction with PRP was 1.51 cm, whereas the reduction with prolotherapy was 0.87 cm; however, the net between-group difference favoring PRP was only 0.42 cm (95% CI, 0.08–0.76). The observed between-group difference in the Lysholm score was 7.64 points (95% CI, 0.32–14.96), and the between-group difference in knee-flexion ROM was 3.68° (95% CI, 0.51–6.85). Therefore, although PRP was statistically superior, the magnitude of the relative benefit was modest, and both interventions may have clinical utility as nonsurgical options.

The potential effects of PRP have been attributed to its concentration of autologous growth factors, including transforming growth factor beta, platelet-derived growth factor, and insulin-like growth factor 1, and anti-inflammatory mediators that may suppress synovial inflammation, downregulate matrix metalloproteinases, and promote extracellular matrix synthesis [6, 7]. Hyperosmolar dextrose prolotherapy may induce transient local osmotic stress and a controlled inflammatory response, thereby recruiting fibroblasts and growth factors involved in tissue repair [8, 9]. Because this trial evaluated clinical outcomes without structural magnetic resonance imaging or histopathologic biomarkers, these mechanisms remain hypothetical explanations rather than demonstrated structural effects.

The findings should also be considered in relation to previous comparative evidence. Eroğlu et al. [4] compared PRP, prolotherapy, and saline in a smaller randomized cohort and found no significant superiority of either active treatment over placebo or over each other. By contrast, systematic reviews by Meheux et al. [10] and Laudy et al. [13] reported that intra-articular PRP may provide more durable symptomatic benefit than hyaluronic acid or corticosteroid injections over 6–12 months. The present study adds a randomized head-to-head comparison using longitudinal statistical modeling but does not establish a large clinically important advantage of PRP.

Methodological strengths include the prospective randomized design, complete reported follow-up, standardized injection techniques, characterization of the LP-PRP preparation, assessor blinding, and analysis using linear mixed-effects models.

Several limitations should be acknowledged. First, the trial did not include a saline placebo or sham-injection group; therefore, nonspecific contextual and placebo effects could not be separated from treatment effects. Second, complete double-blinding was not feasible because of differences in injectate appearance and the blood-collection procedure, although outcome assessors were blinded. Third, the 6-month follow-up period precludes conclusions about durability at 12–24 months. Fourth, women comprised 78.1% of the cohort, which may limit generalizability by sex. Finally, the Lysholm score was developed originally for ligamentous knee injuries rather than OA-specific assessment. Although a validated Turkish version is available

[18], disease-specific instruments such as the Western Ontario and McMaster Universities Osteoarthritis Index or the Knee injury and Osteoarthritis Outcome Score may have been more appropriate.

In conclusion, LP-PRP and 25% dextrose prolotherapy were safe and well tolerated and were associated with improvements in pain and knee function in patients with Kellgren–Lawrence grade II–III gonarthrosis. PRP produced statistically greater improvements at 6 months, but the between-group differences were modest. Multicenter randomized trials with a registered protocol, placebo control, longer follow-up, structural imaging, and OA-specific outcome instruments are needed.

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