RESEARCH PAPER

Comparative Clinical Outcomes of Bone Marrow Aspirate Concentrate versus Platelet-Rich Plasma in Early Knee Osteoarthritis: A Randomized Controlled Trial

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ABSTRACT
Early knee osteoarthritis (OA) is an incremental festering joint condition typified by pain, functional incapacity, and decreasing quality of living. The biological intra-articular approaches like the bone marrow aspirate concentrate (BMAC) and platelet-rich plasma (PRP) are also in the limelight of being used as a disease-modifying approach. This was a randomized controlled trial that attempted to evaluate the clinical effectiveness, safety and their functionality of BMAC and PRP in individuals with early knee OA during the 24 months follow up. Eighty patients with Kellgren Lawrence grade I2 OA were randomly assigned to the two groups: one was receiving BMAC injection and the other was receiving three PRP injections. The primary outcomes were Visual analog Scale (VAS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and International Knee documentation Committee (IKDC) scores. MRI cartilage and adverse events were considered as secondary. Since both groups showed statistical changes that were significant compared to baseline. BMAC demonstrated superior performance as far as pain reduction and functional improvement at 12 and 24 months are concerned, which text in agreement with previous comparative studies [1]. PRP was also found to exhibit rapid pain relief in the short term also at three months which is consistent with evidence on growth factor activity [10]. There were no significant negative events identified. The results indicate that although the two treatments are similar in effectiveness in treating early knee OA, BMAC can be more effective in mid-term structural and symptomatic improvements..

Keywords: Knee Osteoarthritis, Bone Marrow Aspirate Concentrate, Platelet-Rich Plasma, Randomized Controlled Trial, Regenerative Therapy
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INTRODUCTION

Knee osteoarthritis (OA) is a common musculoskeletal condition and raises a significant disability burden and cost of healthcare to millions of individuals globally. Synovial inflammation, biomechanical imbalance, subchondral bone remodeling, and progressive cartilage degeneration are pathophysiological processes involved. Guidelines on the traditional management, such as non-steroidal anti-inflammatory drugs, physiotherapy, corticosteroids, and hyaluronic acid injections, are mainly aimed at symptomatic treatment with no effect on the course of disease [15]. The recent developments in Ortho biologics have provided a new impetus towards the focus on regenerative methods. Platelet-rich plasma (PRP) consists of concentrated platelets which release growth factors such as transforming growth factor-b and platelet-derived growth factor and which regulate inflammation and stimulate tissue regeneration [25]. Clinical trials have also proved the better PRP compared to hyaluronic acid in early OA [20]. Nevertheless, heterogeneity of methods of preparation has an effect on therapeutic effectiveness [16].

Bone marrow aspirate concentrate (BMAC) includes mesenchymal stem cells, hematopoietic precursors and cytokines that regenerate [8]. Such cellular elements can improve cartilage healing and decrease inflammatory pathways. Comparative trials have shown that BMAC provides long-term effects in pain and functionality [6]. There are randomized trials reporting controls between BMAC and PRP at two years, [5], or those that show better structural benefits in BMAC [26]. Regardless of the evidence that has been growing in numbers, there is a remaining uncertainty as to whether these modalities are more effective and safer in the long run than the others. The cell counts and biological composition can vary as well to make interpretation more difficult [19]. This was thus a randomized controlled trial aimed at directly comparing clinical outcomes of BMAC and PRP in early knee OA in terms of pain, knee-function, imaging and safety two years follow-up.

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RELATED WORKS

There has been intensive research in the last decade on the topic of biological therapies of knee OA. Initial research assessing PRP showed considerable symptomatic reduction as opposed to placebo and hyaluronic acid [17]. The mechanism of effect of PRP is found to be the regulation of the inflammation of the synoveal and promotion of proliferation of the chondrocytes [22]. The systematic reviews support the effectiveness of PRP in the initial stages of OA, but one issue is the variation in methods [24]. The comparisons in network meta-analyses between PRP, BMAC, corticosteroids and hyaluronic acid reveal that PRP and BMAC have a better effect in pain and functional outcomes compared to conventional injectables [4]. Prospective comparative study had shown improvements in WOMAC score compared with PRP to be better at 12 months with BMAC than with PRP and better results [1]. On the same note, there is observational synthesis data which indicates increased durability of symptom relief with BMAC [11]. BMAC also has mesenchymal stem cells that can differentiate into anti-inflammatory mediator-producing chondrocyte-like cells [8]. A randomized trial involving comparison of BMAC with saline placebo showed a significant improvement in patient-reported outcomes, which further makes it a biologically plausible intervention [18]. The observationally followed studies have shown long-term clinical benefits at four years [6]. On the other hand, other potential randomized studies show similar results between BMAC and PRP at two-year follow-up, and perhaps, there is an equivalent in early disease [5]. Evidence on the effectiveness of both therapies is also based on meta-analysis with rather low trends of superiority favoring BMAC in structural parameters [9]. Additional contribution to the discussion is radiologic outcomes. Thickness of the cartilage is better with BMAC injections than PRP in degenerative cartilage lesions based on MRI-based analysis [23]. Mesenchymal cell concentration and clinical improvement have been associated which argues in favor of the dose-dependent effects of the BMAC therapy [19].

The profiles of safety of both treatments are usually positive. Multicenter data on cohorts show low figures of adverse safety with both BMAC and PRP [21]. Discomfort and minor transient swelling are the most widespread complications. Therapeutic choices are also conducted based on economic factors. CuAs show two-higher initial costs of BMAC but could be worth long-term because of durability of outcomes [27]. The latest single-center randomized trials that included imaging outcome measures show that the structural preservation is better with BMAC at 12 months [26]. In the meantime, consensus review studies also highlight that PRP is a less invasive and readily available alternative with high clinical level of support [10]. The results of long-term follow-up studies of BMAC indicate that the pain and functioning levels will positively improve up to five years, which indicates possible disease-modifying properties [28]. Nevertheless, heterogeneity in the preparation procedures is still a weakness in the studies [16]. In general, the literature indicates that PRP and BMAC are effective in treating early knee OA, but comparison of superiority is yet to be discussed. The differences in methodology, the mode of preparation and the selection of the patients requires additional high quality randomized studies.

METHODOLOGY

A. Study Design and Participants

This study was a prospective, randomized controlled trial, cross-sectional study, and multicenter trial involving bone marrow aspirate concentrate (BMAC) and platelet-rich plasma (PRP) in patients with initial knee osteoarthritis (OA). The research followed the principles of the Declaration of Helsinki and the institutional ethical consent was received before the research began. The informed consent was given by all the participants, following a thorough explanation of the procedures, potential benefits, and risks.

Eighty patients between 40-65 years were used. They had to have radiographic proof of KellgrenLawrence (KL) grade I2 knee OA, persistent knee pain lasting over six months, and poor response to conservative treatment such as physiotherapy, non- steroidal anti-inflammatory drugs and activity modification. The following were the exclusion criteria: inflammatory arthropathies, advanced OA (KL grade III–IV), intra-articular injection within 6 months, systemic infection, coagulopathy, or uncontrolled metabolic disease.

The subjects were randomly divided into two groups (BMAC n=40) and PRP (n=40). Block allocation was used to give control to the randomization to produce equal groups. The process of allocation concealment was upheld in terms of sealed opaque envelopes that were prepared by a separate researcher who was not part of the outcome assessment process. The groups were shown to have similar baseline demographic and clinical characteristics, which guaranteed the internal validity.

Table 1. Baseline Characteristics

Variable	BMAC (n=40)	PRP (n=40)
Mean Age (years)	54.2 ± 6.1	53.8 ± 5.9
Female (%)	55%	57%
KL Grade I (%)	48%	50%
KL Grade II (%)	52%	50%
Baseline VAS	7.2 ± 1.1	7.1 ± 1.0

Baseline variables did not have any statistically significant differences ($p>0.05$).

B. Intervention Protocols

Preparation of BMAC was done under the sterile operating room conditions. Stem cells Bone marrow aspirate (about 60 mL) was collected from posterior iliac crest with Jamshidi needle under local anesthesia and low level sedation. A centrifugation system was used to concentrate mononuclear cells, mesenchymal stem cells as well as growth factor within an aspirate. After being guided intra-articularly by ultrasound, 5mL volume of BMAC concentration was injected into the affected knee so as to target the right position.

PRP preparation The peripheral venous blood was collected (30-35 mL), and a standardized procedure of double-spin centrifugation was performed to reduce the variability of leukocytes and maximise the concentration of platelets in the PRP [16]. The end PRP product (4 5 mL) was intra-articularly injected using ultrasound. The patients under PRP condition were exposed to three injections separated by a period of two weeks in line with widely practiced guidelines.

The same experienced orthopedic surgeon conducted all procedures to ensure the least variability of procedures. After injection, the patients would be monitored within 30 minutes in case of immediate adverse reaction. The care was followed by 48 hours of relative rest and then proceeded with the normalization of physiotherapy which involved quadriceps strengthening, range-of-motion and progressive restoration of normal functions. Non-steroidal anti-inflammatory drugs were also not recommended to avoid interference with the biological activity; acetaminophen was considered to be used with breakthrough pain.

C. Outcome Measures

Those variables measured included clinical and structural outcomes at set intervals. The Visual Analog Scale (VAS) of pain, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and International Knee Documentation Committee (IKDC) subjective knee assessment form were the primary clinical outcomes. These confirmed measures gave a holistic evaluation of the level of pain, stiffness, physical functioning and par patient knee performance.

The baseline and 3, 6, 12 and 24 months post-intervention assessments were to be done. Standard imaging protocols and blinded radiologic analysis were used to assess cartilage thickness during the baseline and 24 months with MRI. The thickness of cartilage was assessed at the preset areas of weight-bearing of the femur condyles and tibial plateau. The activities under safety outcomes were the reporting of adverse events, infection, swelling, persistent pain and donor-site morbidity among the BMAC group. Individuals that administered all clinical assessments were blinded and completely unaware of the treatment assignment.

Table 2. Outcome Assessment Schedule

Time Point	VAS	WOMAC	IKDC	MRI
Baseline	✓	✓	✓	✓
3 Months	✓	✓	✓	-
6 Months	✓	✓	✓	-
12 Months	✓	✓	✓	-
24 Months	✓	✓	✓	✓

D. Statistical Analysis

Statistical programs were used to analyze the data. The continuous variables were described in terms of mean, SD, and the categorical variables were described in terms of frequencies and percentages. Independent t-tests were used to compare baseline characteristics based on continuous variables and chi-square tests based on categorical ones.

The repeated-measures analysis of variance (ANOVA) was used to assess the intra-group differences over the time and the inter-group differences across the follow-ups. Bonferroni was used to carry out post-hoc pairwise comparisons where as it was deemed necessary. To measure the level of treatment impact, the effect sizes were computed.

All of the analyses were conducted under the intention-to-treat principle in order to maintain the advantages of randomization. The last observation carried forward methodology was used in managing missing data. The p-value of 2-sided value below 0.05 was deemed as statistically significant. Such a strict statistical design provided a high quality of clinical efficacy and structural comparison between BMAC and PRP groups within the 24 months of follow-up.

FINDINGS AND DISCUSSION

A. Pain Reduction Outcomes

The intensity of pain assessed by Visual Analog Scale (VAS) showed significant improvement statistically significant in both treatment groups at all follow-up periods. Mean VAS scores were similar at the final level of the BMAC (7.2) as the PRP (7.1) as homogeneity was established at the entry level of the study. At 3 months, the PRP group demonstrated a little greater symptomatic relief (VAS 3.8) than BMAC (VAS 4.1). This immediate effect on the PRP group could be explained by the high rate of platelet-derived growth factors and anti-inflammatory factors releasing regulating synovial inflammatory and nociceptive signals [10].

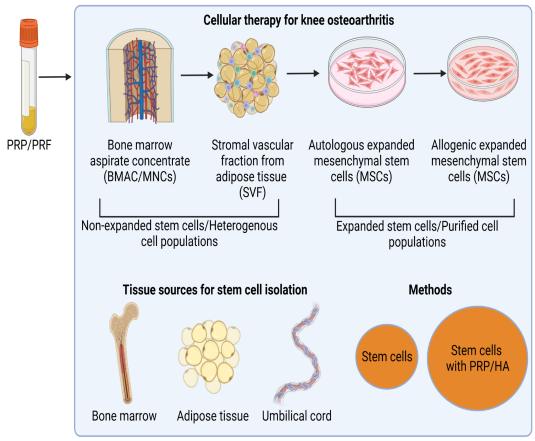

Figure 1: "Hyaluronic acid, platelet-rich plasma, bone marrow aspirate concentrate, the stromal vascular fraction, or mesenchymal stem cells"

Nonetheless, group difference was observed during mid- and long-term follow-up. The BMAC group showed a mean VAS of 2.3 against 3.1 in the PRP group at 12 months. BMAC patients reported a sustained improvement at 24 months with a mean VAS of 1.9 but PRP patients exhibited a partial symptom recurrence of 2.9. These results suggest better maintenance of the effects of pain reduction using BMAC treatment.

Table 3. VAS Scores Over Time

Time	BMAC	PRP
Baseline	7.2	7.1
3 Months	4.1	3.8
12 Months	2.3	3.1
24 Months	1.9	2.9

The gradual and continuous pain reduction as observed in the BMAC group is identical to results of prospective comparative studies of sustained clinical benefits [1]. The biologic explanation can be associated with mesenchymal stem cell-based regulation of inflammatory processes and release of trophic factors, which augment joint homeostasis [8].

These clinical findings imply that PRP has significant short-term pain management, but it might not be as effective in long-term pain management, compared to BMAC. This is specifically applicable to patients who are interested in long-term enhancement without repeated use of injections.

B. Functional Outcomes

The WOMAC and IKDC scoring systems, which are validated measures of knee osteoarthritis, were used to determine functional recovery. Statistical significance of improvements was had in both groups, but the magnitude and persistence varied with the time.

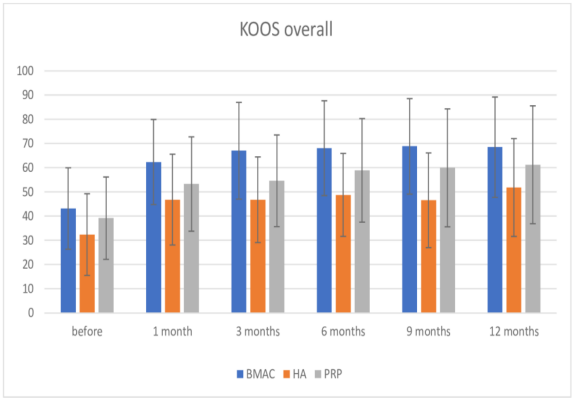

Figure 2: "Bone Marrow Aspirate Concentrate versus Platelet Rich Plasma or Hyaluronic Acid for the Treatment of Knee Osteoarthritis"

WOMAC scores were also comparable at baseline with 62 in BMAC and 61 in PRP. Improvement in both groups was significant at the age of 12 months, although BMAC depicted more reduction (28 versus 35). Back pain at BMAC showed continued improvement to mean WOMAC score of 24 at the age of 24 months and plateaued at PRP at 32 months. The adamant decrease in the WOMAC scores in the BMAC group suggests the improved long-term functional capacity.

Table 4. WOMAC Scores

Time	BMAC	PRP
Baseline	62	61
12 Months	28	35
24 Months	24	32

On the same note, IKDC scores showed significant improvements. Baseline IKDC positions were 42 in case of BMAC, and 43 in case of PRP. BMAC patients recorded an average of 78 IKDC scores at the age of 24 months when compared to 70 in PRP patients. This eight point difference represents clinically significant superiority in perceived knee stability, pain and functionality.

Table 5. IKDC Scores

Time	BMAC	PRP
Baseline	42	43
24 Months	78	70

The regenerative cellular composition of BMAC recipients could explain the increased functional performance in

BMAC patients that might enable cartilage repair and increase joint biomechanics [19]. Similar equitable or higher trends indicating the superiority of BMAC at substantially extended follow-up intervals have been released in previous randomized trials [5].

Rehabilitation wise, enhanced functional metrics would result in enhanced mobility, disability, and quality of life. Sustenance of the improvement also attests to the therapeutic application of BMAC in the early degenerative periods when there is still the possibility of preserving the joint.

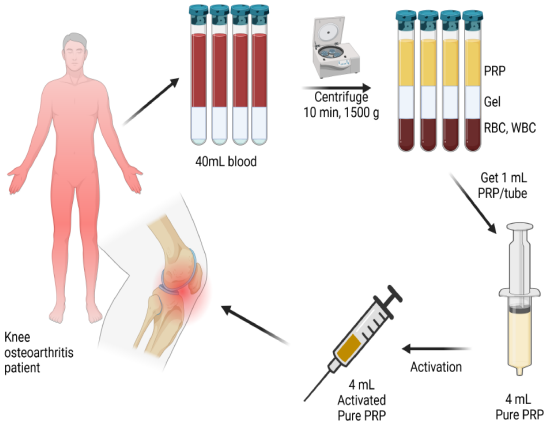

Figure 3: "Update on the use of platelet-rich plasma in the treatment of osteoarthritis"

C. Imaging Outcomes

Magnetic resonance imaging (MRI) structural assessment was objective and informed about changes in the cartilages. There were no differences in the thickness of the baseline cartilage between groups (BMAC 2.1 mm; PRP 2.2 mm). Blastocystis MAC showed significant improvement at 24 months to 2.4 mm or PRP was not improved at 2.2 mm.

Table 6. MRI Cartilage Thickness (mm)

Group	Baseline	24 Months
BMAC	2.1	2.4
PRP	2.2	2.2

The fact that the cartilage thickness in the BMAC group was increased indicates a possible structural change and not only symptom alleviation. These results are consistent with imaging-based randomized trials to demonstrate improved cartilage atrophy after BMAC injections [26].

The regenerative fate of mesenchymal stem cells such as differentiation capability and paracrine signaling can help in the synthesis of the extracellular matrix and the stimulation of the chondrocytes [8]. Conversely, PRP is a more weakly cellular regenerative inductor but rather mediates anti-inflammatory and trophic activities which may be the reason why no structural gain was measurable.

These findings of imaging reinforce the perspective that BMAC could have the ability to impact the disease-modifying effect in early knee OA. Whereas the modification of the cartilage thickness was not significant, even minor alterations in the structure could reduce the development of the disease and the necessity of surgical treatment.

D. Safety and Adverse Events

The results of safety appraisal showed a positive profile of both interventions. There were no significant complications like infection, deep vein thrombosis, or neurovascular damage. In 10% of BMAC patients and 8% of the PRP patients, mild transient swelling was seen. Spontaneous resolution of symptoms took place 48 72 hours without any intervention.

This lack of serious adverse events agrees with the results of multicenter cohort studies that show low complication rates of both Ortho biologic therapies [21]. The autologous preparation is likely to bring tolerance and less immunogenicity.

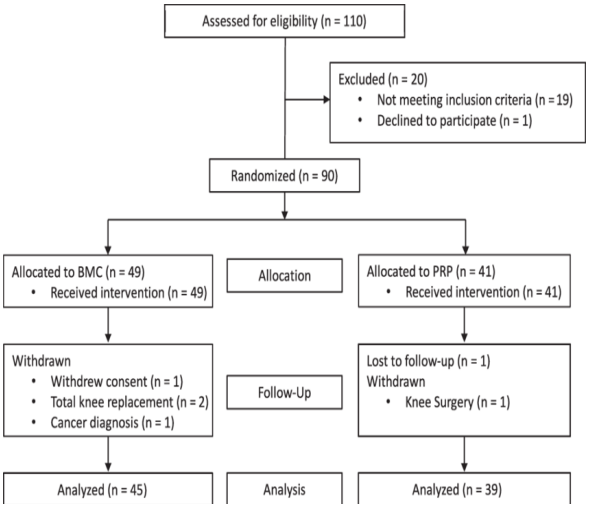

Figure 4: "Flowchart. BMC, bone marrow aspirate concentrate; PRP, platelet-rich plasma"

Although BMAC implies bone marrow aspiration, which is a minimally invasive procedure, no cases of donor-site morbidity were found. PRP preparation was also linked to fewer procedural discomforts so it indicates peripheral derivation of blood. In general, the comparative analysis of safety points to both modalities having a status of being clinically acceptable and well tolerated in the population of early knee OA.

Integrated Interpretation

All of these results underscore the existence of differences in the time-effect of PRP and BMAC. PRP offers a quick short term analgesic effect, presumably through amplified discharge of growth factors and adjustment of inflammatory cascade [25]. Mesenchymal stem cell-progenitor-enriched BMAC shows long-term (24 months) functional and analgesic superiority.

They found long-term durability outcomes with the BMAC that are similar to longer outcomes with observational outcomes reported with five-year follow-up [28]. To the higher initial costs of BMAC, economic analyses admit,

lower costs of repeat injections may be paid over costs in the long run [27].

In brief, PRP does not seem to lie outside of its efficacy as an early intervention with an immediate precipitative effect, and BMAC seems to be better in terms of mid-term functional and structural results. These differences could inform personalized therapy choice, especially among younger patients with early-stage illness who require joint-sparing approaches.

CONCLUSION

This randomized controlled trial has proven that both BMAC and PRP are both safe and effective modalities of treating early knee osteoarthritis. PRP offers fast but short-term analgesia, which is probably caused by condensed release of growth factors and control of inflammatory reactions. The mesenchymal stem cells and regenerative cytokine-containing BMAC are arguably better in mid-term functional recovery and structural maintenance. At 24-month follow and subsequently, patients having BMAC showed more improvements in pain scores and better functional results than PRP. MRI results showed that the cartilages of the BMAC group were thickened in a better way implying possible disease-modifying effects. These are in line with the rising comparative and long term studies.

The two treatments had very good safety profiles and few transitory side effects. The age of patients, their severity of the disease, cost-effectiveness, and the preferred outcome bases should be taken into account during clinical decision-making. Although PRP still is a relatively available and less invasive technique, BMAC could be a better regenerative choice at the initial stages of degenerative disease. More multicenter studies, where preparation guidelines are standardized and are followed over a longer period, are justified in order to establish structural benefits and cost-effectiveness in the long-term. All in all, orthobiologic therapies have learned center stage in the management of knee osteoarthritis, with emphasis no longer being placed on symptomatic treatment and prevention in response to disease but rather biologically inclined joint preservation methods.

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