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Assessment of clinical outcome of platelet rich plasma (PRP) injection in progression of mild to moderate osteoarthritis patients, a retrospective study

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Abstract

Background and Objectives: Global reports (2020) state that an annual 86.7 million people (age >20 years) are diagnosed with incident knee Osteoarthritis. Various therapies and medications have been given to treat this condition and one such upcoming therapy is the use of Platelet-rich plasma. In spite of the promising outcomes, some experts in the field are yet skeptical about the use of Platelet-rich plasma therapy to treat osteoarthritis. In this study, the investigators attempt to measure the clinical outcome of platelet-rich plasma therapy in patients with progression of mild to moderate osteoarthritis.

Methods: Analysis of 102 patient records was carried out from the years 2016-2020 to assess the clinical outcome of the intra-articular Platelet Rich Plasma (PRP) injection in the progression of mild to moderate osteoarthritis patients from the period of pre-injection to 12 months post-injection. Assessment tools such as the VAS and the WOMAC score were used. IBM SPSS software version 1.0 was used for the statistical data analysis.

Results: Medical records analyzed of the patients showed a gradual decrease in pain, observed over a period of 12 months post-injection (as assessed by the VAS and WOMAC score). Significant reduction in swelling (Friedman test: Chi-square = 199.68, $P < 0.0001$) and tenderness (Friedman test: Chi-square = 199.14, $P < 0.0001$) was also observed.

Conclusion: A significant reduction in pain, swelling, tenderness and improvement in function was observed post 12 months of the injection given. The results are encouraging when compared to pre-injection pain and symptoms, suggesting a positive clinical use of PRP injections for mild to moderate osteoarthritic patients.

Keywords: Osteoarthritis, platelet-rich plasma, WOMAC score, VAS, joint inflammation, arthritis

Introduction

An osteoarthritis is a form of arthritis that is also known as a degenerative joint disease; it is the inflammation of the joint that results from cartilage degeneration. Aging, injury from trauma, heredity or disease could be possible risk factors contributing to Osteoarthritis (OA). In India, Osteoarthritis is the 2nd most typical rheumatologic complication and it's the foremost frequent joint illness with a prevalence of 22% to 39%. A global statistical report published in 2021 suggested that the economic burden of osteoarthritis has increased three times or even higher in patients with total knee replacement/total hip replacement. Additionally, OA is more common in females than males; however the prevalence increases dramatically with age [1]. In early OA, the treatment remains conservative therapy for pain reduction because currently, there are no-available pharmacologic agents, possessing the capacity to halt OA progression or reverse the existing damage.

Treatment procedures for OA range from the use of Medications such as Acetaminophen, Non-steroidal anti-inflammatory drugs (NSAIDs), Duloxetine (Cymbalta), Surgical techniques such as Cortisone injections, Lubrication injections, Realigning bones, Joint replacement to Therapies such as Transcutaneous electrical nerve stimulation (TENS), Physical therapy and occupational therapy. One of the recent procedures being used to treat OA is platelet-rich plasma (PRP) therapy. The concept of platelet-rich plasma (PRP) rose in the 1970s in the field of hematology.

In the 1980s and 1990s, PRP gained importance as it was used in surgical procedures because it has many properties that help reduce inflammation, close wounds and promotes the growth of new cells [2]. PRP therapy uses the patient's own concentration of platelet injections to expedite the healing of damaged tendons, joints, ligaments and muscles. Therefore, PRP injection uses the patient's healing system to improve the musculoskeletal system. High blood platelet plasma levels have been found to significantly enhance the healing process; and the use of PRP injections to treat shoulder pain caused by Achilles tendon rupture, rotator cuff rupture, and other soft tissue injuries is becoming more frequent. PRP has also been shown to improve function and relieve pain in patients with tendinitis or chronic tendinitis (such as tennis elbow or golfer's arm). It is a form of regenerative medicine. The duration of the effect of PRP is expected to remain for 8.8 months [3]. Some of the main benefits of plate-rich plasma injections are that they can reduce the need for anti-inflammatory drugs or more powerful drugs such as Opioids. In addition to this, the side effects of plate-rich plasma injections are very limited because the injections are made with one's own blood, so one's body will not reject them or react negatively to them [4].

In spite of some promising outcomes of PRP therapy in OA patients (including data from early clinical trials), some experts still do not recommend the use of PRP therapy to treat Osteoarthritis. Lack of concrete evidence and conflicting results could be some of the reasons for the same [5]. Hence through this study, the Investigators have tried to explore this novel biologic approach for the treatment of degenerative articular disease of the knee and to assess its clinical effects concerning pain, quality of life and return to activity of daily routine.

Materials and Methods

Post-approval from the Institutional Ethics Committee, the Investigators retrieved the patient record files from Jan 2016-Dec 2020; in whom intra-articular PRP injections were given. For analysis, only those patients' data were taken into consideration that fulfilled the eligibility criteria. The eligibility criteria are as follows:

Inclusion criteria

1. Patients, both males and females with symptomatic OA of the knees (Kellgren-Lawrence Grade: 1-3 on radiographs) between the ages of 40 and 80 years, who were given intra-articular PRP injection.
2. Patients who showed normal complete blood count and coagulation control.
3. Patients presented with severe pain and were under anti-inflammatory treatment without improvement for more than 3 months.
4. Patients with normal tibio-femoral alignment, stable knees or patella-femoral tracking
5. Patients in whom 3 months, 6 months, 12 months follow up data is available (in the hospital's orthopedic department records).

Exclusion Criteria

1. Patients having clinical signs of inflammation or infection, sepsis, blood related diseases, immunodeficiency, hepatitis B/C, significant joint swelling or HIV – positive.
2. Patients with poly-articular or rheumatoid arthritis, symptomatic hip osteoarthritis, advanced and tri-

compartmental osteoarthritis, or symptomatic contralateral knee osteoarthritis, varus-valgus malalignment above 5°, total or subtotal meniscectomy more than 2/3 excised.

3. Patients in who require data is not available.

The following parameters of the patients that were recorded were to be analyzed: Pain, swelling, tenderness, restriction of activities and range of motion at 3 months, 6 months and 12 months.

Assessment tools

Two assessment tools-VAS and a WOMAC score were used; for analyzing the clinical outcome of the therapy used. VAS- The visual analog scale (VAS) is a validated scale that is used to measure the intensity of pain that an individual experiences. It ranges from 'no pain' to 'worst pain'. WOMAC score- Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a proprietary, standardized questionnaire, widely used by healthcare providers and clinicians to assess patients with hip and knee osteoarthritis, including stiffness, joint pain, and physical functioning of the joints. Cumulatively, for graphical representation, the average pain observed in patients (by utilizing the assessment tools), pre-injection and post the PRP injection was taken into consideration and is documented below.

Statistical tools

IBM SPSS software version 1.0 was used for the statistical data analysis. To compare and analyze the results obtained from the assessment tools (VAS and WOMAC score); Mann-Whitney U-test was performed. And to compare and analyze the results of the assessment of swelling and tenderness of the patients' joint area, the Friedman test: Chi-square was performed.

Results

The use of PRP therapy in patients with progression of mild to moderate osteoarthritis does show a positive clinical outcome. From the assessment tools used, the WOMAC score indicates a better clinical outcome, whereas the visual analog scale shows a slight variation for the same. 12 months post-injection follow-up results reveal a high effective rate of PRP therapy for Osteoarthritis patients from both the assessment tools. Assessment of swelling and tenderness of the patients from the time of pre-injection to 12 months post-injection was performed. A significant reduction (at $P < 0.0001$) in swelling and tenderness was observed post 3 months of the injection given.

Discussion

7% of the world's population is affected by Osteoarthritis. This condition is not included in the global strategic plan for non-communicable diseases, but OA is often associated with diabetes, heart disease and mental health issues and can exacerbate the morbidity and mortality associated with all the mentioned health conditions [6]. Hence it is imperative to devise and validate upcoming treatment options for the aforementioned medical condition. The discussion part is categorized into 4 different parts:

1. Patient demographics

102 patients were considered for this study, from which 69.6% were female patients were and 30.3% were male patients. The average age of all the patients was found to be

between 41 years to 78 years.

2. Assessment using Visual Analog Scale

Pain assessment of the patient using a visual analog scale showed a gradual decrease from the time of pre-injection to 3 months post-injection period, then a slight surge in pain was

observed from 3 to 6 months post-injection; followed by a decrease in pain from 6 to 12 months post-injection. The average pain measured is shown in Figure 1. The overall graph drawn represents a zig-zag line. Also, the gender-wise comparison using the pain score was performed, whose results are documented in Table 1.

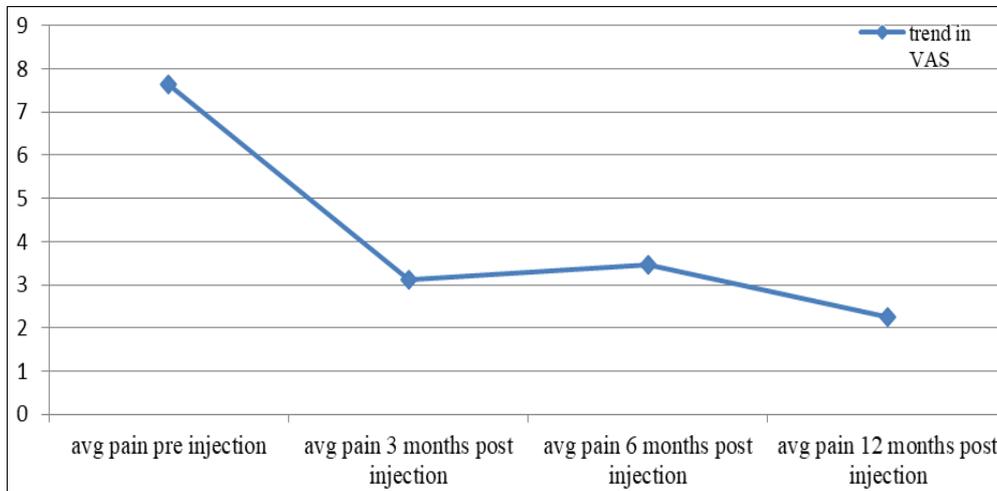


Fig 1: Graph for VAS Assessment

Table 1: Comparison of pain score-VAS according to gender in the study group

VAS score	Male (N=31)		Female (N=71)		MW test Z Value	P-Value
	Mean	SD	Mean	SD		
Pre injection	7.74	.773	7.61	.870	0.76	0.45
At 3 months	3.13	.718	3.13	.809	0.07	0.95
At 6 months	3.58	.672	3.42	.768	0.93	0.35
At 12 months	2.35	.877	2.20	1.050	0.50	0.62

3. Assessment using WOMAC score

The patient’s pain assessment using the WOMAC score showed a gradual decrease in pain from the time of pre-injection to the one-year follow-up period. The average pain

measured is shown in Figure 2. The results of the gender-wise comparison using the WOMAC score is documented in Table 2.

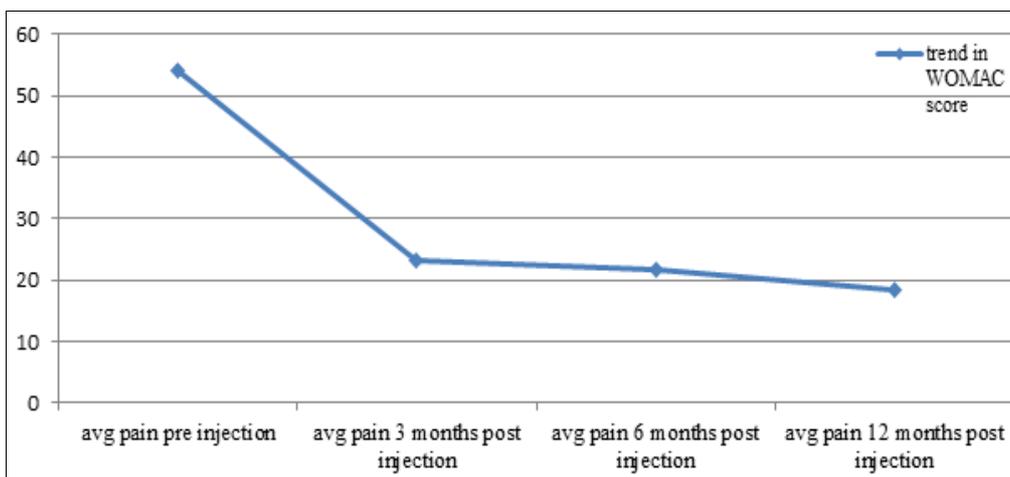


Fig 2: Graph for WOMAC Score Assessment

Table 2: Comparison of WOMAC pain score according to gender in the study group

WOMAC pain score	Male (N=31)		Female (N=71)		MW test Z Value	P-Value
	Mean	SD	Mean	SD		
Pre injection	55.29	7.091	53.76	4.318	0.99	0.32
At 3 months	23.29	3.227	23.04	3.635	0.22	0.83
At 6 months	22.00	1.983	21.58	2.266	0.93	0.35
At 12 months	18.16	2.697	18.38	2.949	0.40	0.69

4. Assessment of swelling and tenderness in patients from pre to post-injection period (up to 12 months)

Osteoarthritis being a degenerative disease worsens over time resulting in pain, swelling and tenderness of the joint and its surrounding area as the cartilage erodes. In such a case, assessing the tenderness and swelling of the joint area becomes essential to analyze the effect of PRP therapy. In this study, the investigators compared the tenderness and swelling nature of the joint area of the patient at pre-injection period, 3

months, 6 months and 12 months post-injection; results for the same are documented in Table 3 and 4. The results obtained are statistically significant.

Table 3: Comparison of swelling between pre-injection with post-injection at 3, 6 and 12 months in the study group

Swelling	Pre-injection	Post injection		
		At 3 months	At 6 months	At 12 months
Mild	53	33	10	6
Moderate	39	14	5	4
Severe	2	1	1	1
No	10	69	102	102

Friedman test: Chi-square = 199.68, $P < 0.0001$

Table 4: Comparison of tenderness between pre-injection with post-injection at 3, 6 and 12 months in the study group

Tenderness	Pre-injection	Post injection		
		At 3 months	At 6 months	At 12 months
Mild	32	20	14	8
Moderate	51	14	9	4
Severe	19	10	4	2
No	0	68	102	102

Friedman test: Chi-square = 199.14, $P < 0.0001$

In this study, it was observed that, patients experienced pain, swelling and tenderness only up to 3 months post-injection. At the 6th and 12th month follow-up, patients seemed to show no swelling or tenderness of the joint area.

Study Limitations

Larger sample size, longer periods of follow-up (more than 12 months post injection) of patients might help gaining a better insight into the utility of PRP therapy for mild to moderate osteoarthritis patients. Also, the study does not involve patients suffering from severe osteoarthritis; hence studying the effect of PRP therapy on patients having severe osteoarthritis could validate the use of the therapy.

Conclusion

PRP is an evolving and reliable treatment option in musculoskeletal medicine. PRP is an autologous plasma preparation whose platelet concentration is higher than the normal concentration in whole blood. The basic principle of the use and therapeutic potential of high-concentration platelets is based on their ability to provide super physiological amounts of vital growth factors to provide regenerative stimulation and promote tissue repair with low healing potential [7]. Results from many randomized clinical trials have shown that in the short to medium term (6-12 months), PRP is preferred over other intra-articular therapies to improve pain scores, but the overall evidence is low. Therefore, the clinical effectiveness of PRP in the treatment of knee osteoarthritis remains controversial [8]. Hence through this study, the investigators aimed to confirm the positive use of PRP therapy for patients having mild to moderate osteoarthritis.

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