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Comparison of the Analgesic Effect of Intra Articular Platelet Rich Plasma and Triamcinolone in Patient of Osteoarthritis Knee-Randomized Control Trial

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Abstract
Osteoarthritis (OA) is a degenerative joint disorder that causes joint pain and stiffness. Knee osteoarthritis is a chronic progressive disease affecting more than 20% of people older than 45 years. Platelet-rich plasma (PRP) is considered a recent line of management of OA. PRP helps in repair of the tissue and decreases disease progression hence decreases health care burden and patient financial burden by reducing surgical intervention. To compare analgesic effect of intra articular Platelet rich plasma and Triamcinolone in patient of osteoarthritis knee. Total of 62 patients with Grade 1, 2 and 3 osteoarthritis of knee according to American college of Rheumatology coming to Pain clinic in Sir T. hospital, Bhavnagar from 1st July 2021-31st December 2022. The study included two groups and subjects were assigned the group by randomized sampling. Patients of Group P were given PRP injection and Group S were given Injection Triamcinolone. Both the groups are evaluated by Visual analogue score (VAS) for pain and KOOS score for functional improvement at day 0, at 6 weeks interval and at 3 months interval. Statistical analysis was done by applying t-test and calculating the p-value. There was no significant statistical difference between both the groups regarding VAS score and KOOS score in pain of osteoarthritis of knee. Intra articular PRP and Triamcinolone were effective in reducing pain of osteoarthritis of knee, both of them showing almost equal results.

INTRODUCTION

Osteoarthritis (OA) is a chronic, progressive, degenerative disorder affecting synovial-lined joints, with a prevalence exceeding 20% among individuals over 45 years old[1]. Knee osteoarthritis is recognized as a leading cause of chronic disability and due to increased lifespan and obesity rates, its prevalence is rising within the Indian population[2]. This condition arises from an imbalance between normal cartilage destruction and repair mechanisms, leading to net cartilage loss, bone hypertrophy and the formation of osteophytes, resulting in knee pain, stiffness and impaired mobility.

The treatment of OA knee is aimed at pain reduction, enhancement of function and mobility, prevention and correction of deformities and notably, the deceleration of disease progression. Individualized self-management strategies, including exercise, weight management, appropriate footwear utilization, bracing, walking aids, pacing, thermotherapy, electro therapy (TENS) and physiotherapy (comprising exercises, manipulation and stretching), are recommended for all patients[3-5].

Additional nonsurgical and surgical treatment options for osteoarthritis of the knee include pharmacological and interventional approaches. Pharmacological management involves the use of nonsteroidal anti-inflammatory drugs (NSAIDs) and intra articular injections. Topical NSAIDs and/or paracetamol are favored over oral NSAIDs, COX-2 inhibitors, or opioids, administered at the lowest effective dose and for the shortest duration to mitigate serious side effects such as gastritis, peptic ulcers, ulcer rupture and chronic renal failure associated with prolonged use.

Interventional management includes intra articular injections of various substances aimed at delivering localized treatment with fewer systemic adverse effects and enhanced direct joint effects. Corticosteroid injections, for instance, exert immunosuppressive and anti-inflammatory effects by directly acting on nuclear receptors, thereby interrupting the inflammatory cascade at multiple levels. This action leads to decreased production and action of inflammatory substances such as IL-1, leukotrienes, prostaglandins and metalloproteinases[6-8].

To date, intra-articular corticosteroid injections have been widely regarded as the gold standard and most commonly utilized treatment modality for managing knee osteoarthritis-related pain. However, the utilization of intra-articular corticosteroids in the treatment of osteoarthritis has engendered controversy for several reasons:

- These injections afford short-term alleviation of pain
- They predominantly exert symptomatic relief by mitigating pain without addressing the underlying etiology
- They manifest deleterious effects on musculoskeletal tissues, including diminished collagen synthesis, suppressed cell proliferation, induction of oxidative stress and perturbation of cell viability

In light of the aforementioned disadvantages associated with intra-articular corticosteroid administration, recent years have witnessed the emergence of novel therapeutic approaches and products aimed at targeting factors beyond inflammation to impede disease progression. Among these modalities is the intra-articular injection of Platelet Rich Plasma (PRP).

PRP is characterized by its content of growth factors released from platelets and an endogenous fibrin scaffold[7,9-11]. These growth factors play pivotal roles in chemotaxis, differentiation of mesenchymal stem cells, proliferation of chondrocyte, synthetic activity of osseous and cartilaginous cells and exert significant influence on the healing and remodeling of cartilage tissue[7-14].

Arthroplasty, a definitive treatment for advanced stages of osteoarthritis (OA), is often reserved for cases where conservative measures have proven inadequate. However, its utilization is limited due to associated post-operative morbidity, cost considerations, technical demands and the potential need for revisions. Experimental approaches such as autologous chondrocyte transplantation and cartilage repair utilizing mesenchymal stem cells and autologous osteochondral plugs are currently under investigation.

The field of pain management originated in the 1960s[12]. Pain specialists focus on enhancing patients' functional abilities and overall quality of life. In cases of chronic or complex pain, primary care physicians may refer patients to pain management specialists, who develop comprehensive treatment strategies to alleviate pain and facilitate the resumption of daily activities, minimizing the reliance on surgery or heavy medication.

Given their expertise in pain management, anaesthesiologists, who have significant experience in operating theatres, are proficient in administering both peripheral and central neuraxial blocks for pain relief. Patients with knee osteoarthritis are typically managed by orthopaedic specialists. However, if pain persists despite medication, referral to a pain clinic for further interventional management may be warranted.

Hence, this study was undertaken to compare analgesic effect of intra articular platelet rich plasma (PRP) and triamcinolone In patients of osteoarthritis knee.

MATERIALS AND METHODS

The study employed a randomized controlled trial design over a period of one year at the Operation Theatre of the Sir T. General Hospital, Govt. Medical College, Bhavnagar, Gujarat, India. The sample consisted of all pre-diagnosed patients with grades I, II, and III osteoarthritis of the knee, who were attendees of the pain clinic and were enrolled for a duration of six months. These participants were followed up for three months during the course of the study. The intervention of the study involved the administration of intra-articular corticosteroid (triamcinolone) in one group, while intra-articular platelet-rich plasma was administered in another group.

Following approval from the institutional review board, the study commenced with the recruitment of patients diagnosed with grades I, II and III knee osteoarthritis (OA) as per the criteria established by the American College of Rheumatology (ACR)[13]. These patients were referred to the pain clinic by the orthopedic department. The inclusion criteria comprised patients aged between 35-70 years, with a history of chronic pain lasting more than three months, accompanied by knee swelling persisting for over four months and confirmed by X-ray diagnosis indicating Kallgren Lawrence grades 1 and 2. Exclusion criteria were set to exclude patients with knee joint deformities, acute infections, a history of knee surgery, diabetes mellitus, rheumatoid arthritis, gout, severe cardiovascular, haematological, or renal disorders, immunodeficiency, those taking anticoagulants, with haemoglobin levels <10 g/dl and platelet counts below 150,000/mm3, a history of vasovagal shock, pregnant or lactating females and those who had consumed corticosteroids within the preceding three months.

The study commenced with the provision of detailed procedural explanations to patients, following which informed written consent was obtained in the local language. Subsequently, patients underwent comprehensive pre-anesthetic evaluations, including detailed medical histories, general and systemic examinations. Laboratory investigations, including complete blood counts (CBC) and knee radiography, were conducted. Vital signs, including pulse rate, non-invasive blood pressure (NI BP) and oxygen saturation (SpO2), were recorded. Pre-injection assessments were performed utilizing visual analogue scores (VAS) and Knee Injury and Osteoarthritis Outcome Scores (KOOS). Patients were then randomly allocated into two groups, designated as Group P and Group S, utilizing simple random sampling via the odd/even number method. Group P received intra-articular injections of 5 ml of platelet-rich plasma (PRP), while Group S received intra-articular injections of 40 mg triamcinolone plus 4 ml normal saline. The injection procedure was conducted in the operation theater under sterile conditions. Patients were placed in the supine position and aseptic precautions were observed. PRP and corticosteroid injections were administered into the joint cavity via the anteromedial approach using a 22-gauge hypodermic needle. Respective syringes were covered with white tape and prepared by team members not involved in patient assessment. Patients were subsequently assessed at 6 weeks, 3 months and 6 months post-injection. Evaluations included clinical assessments of knee pain using VAS scores and KOOS, functional assessments of the knee using KOOS and radiological assessments employing the Kellgren and Lawrence classification of knee osteoarthritis. Patients were queried regarding the frequency of analgesic requirements during the study period, with a decrease in analgesic requirements defined as a reduction from thrice-daily intake to twice-daily intake for three or fewer days per week.

Statistical Analysis: Data was collected, compiled and tabulated in excel sheet. Quantitative data were represented as mean with standard deviation. Un-Paired t test was used for pre-injection and post-injection comparison data analysis. Multiple follow-up data pattern was analyzed with the help of repeated measured ANOVA. Statistical analysis was done by SPSS 26.0 version software (IBM, SPSS, Inc.). <0.05 value considered as a statistically significant.

RESULTS AND DISCUSSIONS

Patient's characteristics in terms of age, weight and height were comparable among both the groups (Table 1).

The reduction in pain assessed using the Visual Analog Scale (VAS) from pre-injection to 6 weeks, 3 months and 6 months after injection was found to be highly statistically significant ($p<0.05$) in both Group P and Group S. However, there was no significant difference in pain assessment based on VAS scores between the two groups at 6 weeks, 3 months and 6 months post-injection ($p>0.05$). In Group P, the mean baseline VAS score was 6.06, while in Group S, it was 6.35. After six months, these scores decreased to 2.19 and 2.26, respectively, with no statistically significant difference observed between the groups ($p = 0.68$) (Table 2, Fig. 1).

The functional improvement assessed via the Knee Injury and Osteoarthritis Outcome Score (KOOS) from

pre-injection to 6 weeks, 3 months and 6 months after injection demonstrated a highly statistically significant increase ($p<0.05$) in both Group P and Group S. However, there was no significant difference observed in functional assessment based on KOOS scores between the two groups at 6 weeks, 3 months and 6 months post-injection ($p>0.05$). In Group P, the mean baseline KOOS score was 49.44, while in Group S, it was 51.46. After six months, these scores increased to 69.49 and 66.88, respectively, with no statistically significant difference observed between the groups ($p = 0.15$) (Table 3, Fig. 2).

The need for analgesics decreased in both groups following intra-articular injection compared to baseline. Furthermore, there was a notable reduction in analgesic requirement (>50%) observed earlier in the Platelet Rich Plasma (PRP) group compared to the steroid group. Throughout the treatment and follow-up period, no significant complications related to the injections were observed.

Osteoarthritis is a chronic degenerative musculoskel *et al* disorder affecting the knee joint, characterized by the breakdown of cartilage, leading to bone-on-bone contact and resultant knee pain, stiffness and impaired mobility. This pain can significantly impact an individual's activity level and overall quality of life. The primary objective of pain physicians is to alleviate pain and restore normal functionality. A variety of treatment modalities are available for knee osteoarthritis. Over the past decade, researchers have increasingly recognized the efficacy of Platelet-Rich Plasma (PRP) in treating musculoskeletal ailments such as rotator cuff tears, osteoarthritis, lateral epicondylitis, patellar tendinopathy and Achilles tendon repair[14]. Given PRP's regenerative and anti-inflammatory properties, numerous studies have investigated its therapeutic potential via intra-articular injection for patients with knee osteoarthritis[15-21].

The present study aimed to assess the effectiveness of intra-articular injections of PRP and corticosteroids based on Visual Analog Scale (VAS) and Knee Injury and Osteoarthritis Outcome Score (KOOS). The findings indicated that both intra-articular corticosteroid and PRP injections exhibited beneficial effects in reducing pain, as evidenced by improvements in VAS and KOOS scores in both groups. Pain levels decreased over the six-month study period in both treatment groups, with significant reductions observed compared to baseline. Importantly, no statistically significant differences were detected between the two treatment modalities, suggesting comparable effectiveness in symptom management for patients with knee osteoarthritis.

The present study demonstrated a sustained increase in Knee Injury and Osteoarthritis Outcome Score (KOOS) until the six-month follow-up period. Significant improvements in KOOS were observed in both treatment groups compared to baseline ($p<0.0001$). However, no statistically significant differences were detected when comparing the effectiveness of both treatment modalities, indicating comparable symptom control outcomes for patients with knee osteoarthritis.

A previous study conducted by Joshi Jubert et al. in 2013[22] investigated the efficacy of single leukocyte-reduced Platelet-Rich Plasma (PRP) or corticosteroid intra-articular injections in patients with knee osteoarthritis. Visual Analog Scale (VAS) assessments were conducted at 1, 3 and 6 months post-treatment, revealing improvements in VAS scores in both groups over the six-month period. Secondary outcomes included KOOS assessments at the same intervals, with significant increases observed in quality-of-life differences between values at 3 and 6 months compared to baseline in the PRP group ($p = 0.05$ and 0.03, respectively). KOOS scores improved in both groups up to 6 months, with no statistical differences between the groups, consistent with the findings of the current study.

However, several previous studies[23,7,24] have reported reductions in VAS scores and increases in KOOS scores in both treatment groups, with the PRP.

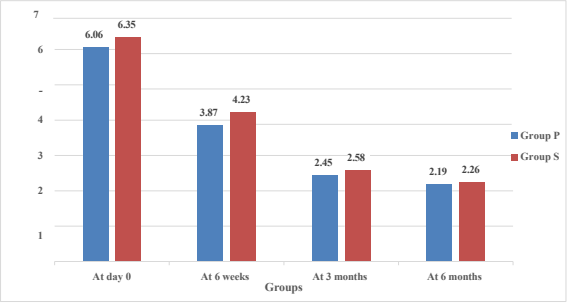

Fig. 1: Objective assessment of pain using VAS in both groups in various interval

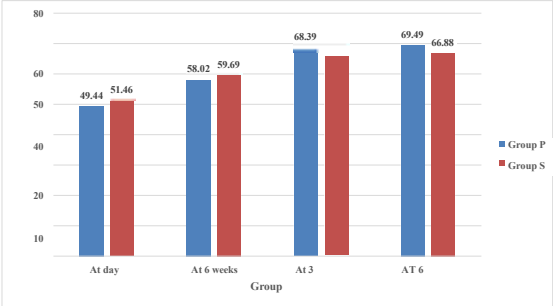

Fig. 2: Functional assessment of knee using KOOS in both groups at various interval

Table :1 patient's characteristic

Variables	Group-P	Group-S	p-value
Age (year)	51.48±9.06	52.26±9.38	0.078
Gender Male / Female	18/14	20/12	0.054
BMI (Body mass index) Kg/m^2	27.78±3.29	28.4±2.78	0.041

Table 2. Objective assessment of pain using VAS in both groups

Duration	Mean VAS in Group P	Mean VAS in Group S	p-value
At day 0	6.06	6.35	0.07
At 6 weeks	3.87	4.23	0.08
At 3 months	2.45	2.58	0.25
At 6 months	1.67	2.25	0.68
Intra group p-value	< .00001	< .00001	

Table 3. Functional assessment of knee using KOOS in both groups

Duration	Mean KOOS in Group P	Mean KOOS in Group S	p-value
At day 0	49.44	51.46	0.20
At 6 weeks	58.02	59.69	0.22
At 3 months	68.39	65.43	0.05
AT 6 months	69.49	66.88	0.15

Table 4. Comparison of decrease analgesic requirements in both groups

Duration	No. of patients in Group P	No. of patients in Group S
0 weeks	0 (0%)	0 (0%)
6 weeks	9 (29.03%)	6 (19.35%)
3 months	16(51.61%)	15 (48.38%)
6 months	27 (87.09%)	25 (80.64%)

group showing significantly greater improvements compared to the corticosteroid group.

In a study conducted in 2018 by Kilincoglu *et al*.[23] the authors compared the effects of intra-articular platelet-rich plasma (PRP) and corticosteroid injections on pain in patients with knee osteoarthritis. Similar to the current study, reductions in pain assessed by the Visual Analog Scale (VAS) and improvements in functionality measured by the Knee Injury and Osteoarthritis Outcome Score (KOOS) were observed up to six months in both treatment groups. However, statistically significant improvements in VAS and KOOS scores were specifically noted in the PRP group. Discrepancies between these findings and those of the current study may be attributed to differences in several factors, including the injection intervals, centrifugation methods, use of ultrasound guidance during intra-articular injections and variations in participant selection criteria. Notably, Kilincoglu *et al*. administered injections once a month for three consecutive months, whereas the current study adhered to the gold standard protocol of administering injections once a month as per institute guidelines. Additionally, variations in centrifugation techniques and the use of ultrasound guidance during injections may have influenced treatment outcomes. Furthermore, the study by Kilincoglu *et al*. included participants with lower grades of osteoarthritis (grades I-II), whereas the current study included patients with grades I, II and III osteoarthritis[23].

In another randomized controlled trial conducted by Pratibha Matche *et al.*[7] in 2018, intra-articular injections of PRP were compared with local anesthetic combined with steroid injections for the treatment of knee osteoarthritis. Sixty-four patients meeting inclusion criteria received two intra-articular injections at 4-week intervals. Similar to the current study, improvements were observed in both treatment groups at the 3-month follow-up assessment. However, at the 6-month follow-up, significantly lower mean VAS scores, International Knee Documentation Committee (ISK) scores, Modified Western Ontario and McMaster Universities Arthritis Index (MWI) scores, and range of motion (ROM) were reported in the PRP group compared to the corticosteroid group ($p<0.0001$, $p<0.0001$, $p = 0.003$, $p = 0.001$).

The potential factors contributing to the observed differences include variations in injection frequency, with the previous study administering two injections spaced four weeks apart, while the current study followed a protocol of single monthly injections in alignment with the gold standard protocol of our institute. Additionally, the addition of a local anesthetic adjuvant and the utilization of ultrasound guidance during intra-articular injections may have influenced treatment outcomes. In a study conducted in 2018 by Bahram Naderi Nabi *et al*.[24], the authors compared the effects of intra-articular platelet-rich plasma (PRP) and corticosteroid injections on pain in patients with knee osteoarthritis. Similar to the current study, reductions in Visual Analog Scale (VAS) scores and improvements in Knee Injury and Osteoarthritis Outcome Score (KOOS) were observed up to six months in both treatment groups. However, statistically significant improvements in VAS and KOOS scores were specifically noted in the PRP group. The differences observed may be attributed to variations in injection intervals, as the previous study administered injections once a month for three consecutive months, compared to the single monthly injection protocol

followed in the current study, consistent with the gold standard protocol of our institute. Additionally, the use of ultrasound-guided techniques during intra-articular injections may have influenced treatment outcomes.

Limitation of the study: Study limitations include the observation that PRP injections administered at one-month intervals demonstrated superior improvement in VAS and KOOS scores, suggesting potential for enhanced outcomes with increased injection frequency. Although ultrasound guidance can improve injection precision, its unavailability in our setting precluded its utilization. While radiological assessment at six months evaluated cartilage regeneration, more objective measures such as knee MRI or ultrasonographic cartilage thickness assessment could offer greater accuracy in evaluating patient outcomes, yet financial constraints hindered the implementation of follow-up MRI scans for all patients. Additionally, our study's six-month follow-up period limits the evaluation of platelet-rich plasma's long-term regenerative effects, emphasizing the need for extended follow-up to fully assess treatment outcomes.

CONCLUSION

In conclusion, both single platelet-rich plasma (PRP) and triamcinolone intra-articular injections are deemed safe and non-invasive modalities, exhibiting efficacy in ameliorating knee pain, enhancing functional capacity, improving mobility and enhancing the overall generic health status of patients afflicted with symptomatic knee osteoarthritis of grades I, II, and III.

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