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A Prospective Randomized Control Study Comparing the Efficacy of Intra-Articular Platelet Rich Plasma Versus Intra-Articular Steroid in Primary Osteoarthritis of Knee

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ABSTRACT

Osteoarthritis (OA) of the knee is one of the main causes of musculoskeletal disability. It is clinically heterogeneous and the processes that causes deterioration are still poorly understood. Current research efforts are focused on the identification of key biochemical pathways that can be targeted therapeutically through biological intervention and the testing of protein biotherapeutics for restoring the metabolic balance within the joint. This is a hospital based prospective randomized controlled trail. 80 patients are choosen and randomly divided into two groups of 40 each. Group 1 received intra articular injection of platelet rich plasma into the knee. Group 2 received intra articular steroid. The patients are subjected to a standardized injection protocol and are assessed on variables such as pain, stiffness and physical function using WOMAC scale and for pain, using visual analog scale at pre injection, 6 wks. post injection, 3 months and 6 months post injection. The study showed a significant decrease in global WOMAC score for group 1 patient, which was also consistent throughout the study period. Visual analog score showed a significant decrease in mean for group 1 patients, which denoted a change in patients perception of pain from intense, dreadful, horrible pain to mild annoying pain. Group 2 showed a marginal dip in VAS showing insignificant change in pain.

INTRODUCTION

Osteoarthritis (OA) of the knee is a degenerative condition that affects 38% to 47% of the population aged older than 60 years. Osteoarthritis (OA) knee is the most common degenerative joint disease worldwide. The main goals of management are directed to reduce pain, improve function, quality of life and limit disease progression. Unfortunately, there are no agents currently available that can halt the progression of knee OA. Analgesics and nonsteroidal anti inflammatory drugs (NSAIDs) have suboptimal effectiveness, surgical treatment can reduce pain and improve joint mobility and function, however, it is associated with significant cost and potential morbidity [1,2].

In the last 10 years, growth factors aroused people's interest for its properties of repair tissue lesion and maintain normal tissue structure, especially platelet-rich plasma (PRP) injection. PRP contains a high concentration of platelets, which are obtained by centrifugation of autologous blood[3]. Various growth factors and cytokines are released after the degranulation of platelets and to accelerate cartilage matrix synthesis, restrain synovial membrane inflammation and promote cartilage healing. Owing to the properties of regenerative effect and anti-inflammatory potential, PRP is widely used in musculoskeletal diseases, such as rotator cuff tear, lateral epicondylitis, patellar tendinopathy, osteoarthritis[4].

Growth factors released by platelets upon activation such as platelet derived growth factor (PDF), transforming growth factor beta (TGFß), fibroblast growth factor (FGF), hepatocyte growth factor (HGF) etc have the ability to influence and direct tissue regeneration through tissue repair, cell proliferation, differentiation and synthesis of extracellular matrix proteins[5,6].

MATERIALS AND METHODS

The proposed study is a hospital based prospective randomized controlled trail. The patients are subjected to a standardized injection protocol and are assessed on variables such as pain, stiffness and physical function using WOMAC scale and for pain, using visual analog scale at pre injection, 6 wks. post injection, 3 months and 6 months post injection.

Source of Data: The data will be collected by interviewing the 80 patients came with knee pain to orthopaedic department.

Inclusion Criteria: Patients of either sex with symptoms typical to primary osteoarthritis with clinically diagnosed as suffering from osteoarthritis knee.

Exclusion Criteria:

- Immunosupressed patients
- Patients with secondary osteoarthritis
- Patients with connective tissue disorders
- Patients who have received steroid injection within past 6 months
- Patients with haemoglobin less than 10 mg%
- Patients with tumours, metabolic disease of bone with coexisting backache
- Patients who have already undergone surgical interventions
- Any local skin pathology at injection site

Study Design: The study will be hospital based prospective randomized controlled trail. The patients are subjected to a standardized injection protocol and are assessed on variables such as pain, stiffness and physical function using WOMAC scale and for pain, using visual analog scale at pre injection, 6 wks. post injection, 3 months and 6 months post injection.

Statistical Analysis: The results were evaluated and compared using Chi Square Test.

Data Collection: After obtaining the informed, written consent from the patients, the patient will be enrolled into the study after considering the inclusion and exclusion criteria. Demographic data, history, clinical examination and details of investigation will be recorded in the study proforma. Patients will be subjected to specific investigations to rule out other conditions presenting with similar clinical features. The patients will be divided into two groups based on the treatment First group received local platelet rich plasma injection. Second group received local steroid injection. Patient don't require any surgical intervention for the study.

RESULTS AND DISCUSSIONS

The Global WOMAC showed a mean of 75.93 at pre injection period for PRP group which decreased to 60.78 at 6 weeks follow up, 62.6 at 3 months and declining to 40.95 at 6 months. The Global WOMAC showed a mean of 73.43 at pre injection period for STEROID group, which decreased to 69.88 at 6 weeks follow up, 62.6 at 3 months and 63.95 at 6 months. The Stiffness score showed a mean of 5.90 at pre injection period for PRP group which decreased to 4.70 at 6 weeks follow up, 3.85 at 3 months and declining to 2.35 at 6 months. The Stiffness score showed a mean of 4.90 at pre injection period for STEROID group, which decreased to 2.83 at 6 weeks follow up, 3.8 at 3 months and 4.70 at 6 months. The Physical Functional Score showed a mean of 51.73 at pre injection period for PRP group which decreased to 48.75 at 6 weeks

Table 1: WOMAC score

WOMAC score		Pre injection	6 weeks	3 months	6 months
Platelet Rich Plasma	N	40	40	40	40
	Mean	75.93	60.78	62.6	40.95
	SD	5.445	4.93	5.14	6.08
Intra-Article Steroid	N	40	40	40	40
	Mean	73.43	69.88	62.6	63.95
	SD	17	5.08	6.08	5.57
P-value ((unpaired t-test)		0.06,NS	<0.0001,HS	<0.0001,HS	<0.0001,HS

Table 2: Stiffness score

Stiffness Score		Pre injection	6 weeks	3 months	6 months
Platelet Rich Plasma	N	40	40	40	40
	Mean	5.90	4.70	3.85	2.35
	SD	0.87	0.94	1.25	0.53
Intra-Article Steroid	N	40	40	40	40
	Mean	4.90	2.83	3.8	4.70
	SD	1.03	0.75	0.94	1.14
P-value ((unpaired t-test)		1.000, NS	<0.0001, HS	0.001, Sig	<0.0001, NS

Table 3: Physical functional score

Physical Functional Score		Preinjection	6 weeks	3 months	6 months
Platelet Rich Plasma	N	40	40	40	40
	Mean	51.73	48.75	42.325	28.38
	SD	3.71	4.53	5.30	6.47
Intra-Article Steroid	N	40	40	40	40
	Mean	51.72	43.45	39.85	42.48
	SD	5.91	4.86	4.9	5.18
P-value (unpaired t-test)	0.4412, NS	<0.0001, HS	<0.0001, HS	<0.0001, HS	

follow up, 42.32 at 3 months and declining to 28.38 at 6 months. The Physical Functional Score showed a mean of 51.72 at pre injection period for Steroid group, which decreased to 43.45 at 6 weeks follow up, 39.85 at 3 months and 42.48 at 6 months.

The Global WOMAC showed a mean of 75.93 at pre injection period which decreased to 60.78 at 6 weeks follow up, 62.6 at 3 months and declining to 63.95 at 6 months. The study showed a significant decrease in global WOMAC score, which was also consistent throughout the study period. The Individual variables such as pain, stiffness and physical function were assessed. Mean score for pain showed a decrease from 18.3 to 16.42 at 6 weeks post injection. At the end of 6 months follow up, the mean was 10.07. Secondary variable stiffness showed significance difference at 3 months follow up and 6 months follow up. The mean of Physical function decreased from a pre injection score of 51.73 to 28.38 at 6 months follow up in Group I. Group II showed a marginal dip in mean scores from 51.72 to 43.45 and to 39.85 at 3 months. The scores leveled at 42.48 at the end of 6 months Abeer H. Ismaiel *et al*[7]. stated that "A group of 30 patients with 52 knees with advanced OA and K-L grades 3 and 4 received an IAI of PRP and the other 30 patient group with 40 knees with advanced OA and K-L grades 3 and 4 received an IAI of corticosteroids. There was no significant difference between the two groups as regards age, disease duration and all clinical and radiological parameters. VAS score decreased for both groups, with no significant differences between groups at different time points.

The differences in VAS score at 1 and 3 months compared with baseline showed no statistically significant differences between groups (P = 0.08 and 0.06); however, the difference was significant between groups at 6 months (P = 0.05). Considering that the difference tended to be greater in the PRP group" conducted on 60 patients with Kellgren Lawrence Grade 2 and 3 OA knee, who fulfilled the ACR classification criteria for knee OA. Thirty patients were given IA PRP and 30 received IA steroid. The mean change in VAS pain and total WOMAC score from baseline to 24 weeks was 32.9±12.1, 31.8±14.7 for PRP group and 12.9±5.9, 7.5±5.5 for steroid group, which was statistically significant (p< 0.0001).

Andrejs Elksninš *et al*[8]. stated that "Forty patients affected by symptomatic radiologically confirmed knee osteoarthritis (Kellgren-Lawrence grades II-III) were enrolled in this randomized study. Patients randomized in the PRP group (n = 20) received an intra-articular injection of PRP (8 mL) while patients randomized in the CS group (n = 20) received an intra-articular injection of triamcinolone acetonide (1 mL of 40 mg/mL). The pain and function of the target knee were evaluated by the Vas and WOMAC.

No serious adverse effects were observed during the follow-up period. The PRP group showed significative improvements in all scores when compared to the CS group. A single PRP INJECTION is safe. PRP demonstrated a statistically significant improvement over CS in a 1-year follow-up".

Deepak Rai *et al*[9]. showed that "A total of 98 eligible symptomatic patients received injections of standardized PRP. Clinical outcomes were evaluated using the VAS and Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire before treatment and at 6 weeks, 3 months, 6 months

and 1 year after treatment. There was a statistically significant improvement in mean VAS and WOMAC scores at 6 weeks, 3 months, 6 months and slight loss of improvement at 1 year follow-up. There was also a correlation between the degree of degeneration and improvement in the mean scores. The decrease in mean pain score is more in grades 1 and 2 (early OA) than in grade 3. The intra articular injection is safe, with no major complications. PRP is a safe and effective biological regenerative therapy for early OA Knees. It provides a significant clinical improvement in patients with some loss of improvement with time. More studies will be needed to confirm our findings[10]."

CONCLUSION

Osteoarthritis represents a failure of diarthrodial joint, characterized by degenerative changes in articular cartilage of joint. The management of Osteoarthritis has undergone a sea change during the last century. Osteoarthritis has been managed by conservative methods like lifestyle changes, physiotherapy and surgical methods like joint replacement arthroplasty, depending upon the stage of the disorder. A constant search for molecules that could aid in cartilage regeneration, thus interfering in disease process has thrown up surprises. One such ideology is, garnering the beneficial effect of growth factors in platelets to regenerate cartilage in a synovial joint. Our study relied on injecting a highly concentrated mix of platelets into joint cavity and observing the patients for reduction in symptoms of pain, stiffness and improvement in physical function. Our study has revealed a consistent reduction in pain and stiffness and a clear improvement in lifestyle of the patients. Our study has thrown up an interesting choice of treatment modality using Platelet Rich Plasma in the treatment of Knee Osteoarthritis and it has proved efficacious in the observation period of six months.

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