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### A study of the role of platelet rich plasma in the treatment of knee osteoarthritis

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#### Abstract

Osteoarthritis is a disorder of synovial joints characterized by focal loss of hyaline cartilage with proliferation of new bone and remodeling of joint contour, mainly due to uncoupling of balance between cartilage regeneration and degeneration. Osteoarthritis is a dynamic repair process of synovial joints that may be triggered a variety of insults we in our study had randomly chosen 100 patients with classic findings of osteoarthritis and divided them in to two groups. Both the groups were comparable on baseline characteristics of age, height, weight, BMI, pre injection womac score. Fifty of these patients were administered an intra articular injection of platelet rich plasma and other fifty received normal saline. Functional outcome was analysed and reported in this study.

**Keywords:** Role, platelet rich plasma, treatment, knee osteoarthritis

#### Introduction

Osteoarthritis is a clinically heterogenous degenerative condition characterized by destruction of articular cartilage, due to uncoupling of balance between cartilage degeneration and regeneration.

The management of osteoarthritis has varied from conventional therapy with physical education, non-steroidal anti-inflammatory drugs, intra articular glucocorticoid injection, intra articular injection of hyaluronan etc. Advanced OA in whom aggressive medical management has failed to yield desired results are managed by joint replacement arthroplasty.

Pharmacological treatment of osteoarthritis with NSAIDs is associated with an increased risk of GI disturbances along with an alarming rise in NSAID induced multisystem complications. Arthroplasty, though a definite treatment is usually reserved for advanced stages of OA. The concomitant post-operative morbidity, cost issues and the need for technical expertise and revisions has precluded arthroplasty from being a common form of treatment. PRP is postulated to modify the disease process, unlike other methods of non surgical treatment which provide symptomatic relief. PRP is a cost effective tool that could obviate the need for Total Joint Arthroplasty, or atleast reduce the number of revision surgeries

#### Aim of the Study

The Aim of this study is to evaluate the effectiveness of platelet rich Plasma<sup>17</sup> in reducing pain and improving physical function, as Platelet rich plasma provides a cocktail of growth factors directly into joint cavity.

#### Objectives

To evaluate the role of Autologous Platelet Rich Plasma in the treatment of patients presenting with primary osteoarthritis and to analyse whether it could be a cost effective disease modifying measure, bereft of major side effects and operative costs

#### Study Design

Randomized controlled trial. The patients were subjected to a standardized injection protocol and were assessed on variables such as pain, stiffness and physical function using WOMAC scale and for pain using visual analog scale at pre injection, 6 weeks post injection, 3 months post injection and 6 months post injection.

**Materials and Methods**

The patients attending the OPD of Orthopaedics Department at Stanley medical college with complaints of bilateral knee pain were screened and those diagnosed as bilateral Knee osteoarthritis were chosen for the study.

The Patients classified either grade 0 to iv on the Kellgren-Lawrence grading scale or grade 1 to 3 on the Ahlback scale were included in the study after prior well informed written consent.

Hundred Patients were chosen and randomly divided into two groups of fifty each. Group I received intra articular injection Platelet Rich Plasma in to both knees served as study group. Group II received normal saline and served as control

Randomization ensured that both the groups were comparable with respect to age, sex, height, weight, body mass index and pre injection WOMAC score

**Exclusion Criteria**

1. Immunosuppressed patients
2. Patients with secondary osteoarthritis
3. Patients with connective tissue disorders
4. Patients with inflammatory disorder of joints
5. patients who have received steroid injections within past 6 months
6. patients with haemoglobin less than 10 mg%
7. Patients with tumours, metabolic diseases of bone
8. Patients with coexisting backache

About 350 ml of venous blood was collected from the patient. The Patient was blinded from knowing the amount of blood collected. The collected blood was centrifuged in a refrigerated centrifuge and platelet rich plasma [11] was separated after removing red blood cells and buffy coat. The whole process of separating Platelet rich plasma was standardized and done under strict aseptic precautions

The process yielded Packed cells and fresh frozen plasma which was transfused back to the patient. The patients baseline platelet count and leucocyte count were determined

and platelet rich plasma was quantified as having eight to ten times the baseline value of platelets. The concentration of platelets in final product were corroborated by the Department of Transfusion medicine on a periodic basis. We in this study did not use leucocyte filter and the final Platelet Rich Plasma had contained minute traces of leucocytes About 10 ml of blood was removed from the control group and was subjected to routine laboratory testing

**Injection Protocol**

The Injection procedure was performed in Emergency operation theatre. The Patient was placed supine on the operation table. Parts painted and draped. Under sterile aseptic precautions 8 ml of platelet rich Plasma mixed with 2 ml of calcium glaciante was injected into the supra patellar pouch of knee or into the joint cavity from medial approach sterile bandaging given. The Patient is advised bed rest for 2 days. The Patient is advised to avoid NSAIDS for 2 days before and after injection. Paracetamol doses of 500mg is allowed in cases febrile illness or discomfort due to pain In the control group 8ml of normal saline is injected in to the suprapatellar pouch of the patients.

Adverse events, if any is recorded. The Patients are advised to carry on with their regular routine work from day two

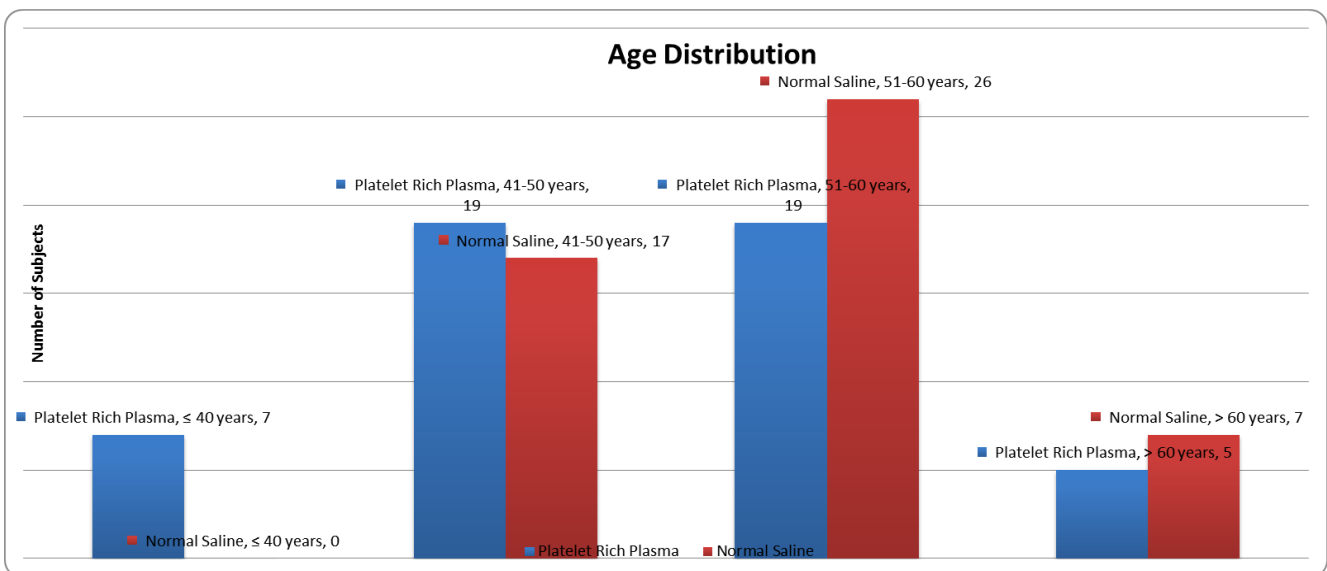
**Outcome Analysis**

The study group and the control group are advised to follow up at 6 weeks, 3 months and 6 months. outcome analysis for the efficacy was done for reduction in pain, reduction in stiffness and improvement in physical function using WOMAC scale.

The patients were also assessed for reduction in pain using Visual analog scale both at pre injection and at 6 months post injection

**Statistical Analysis**

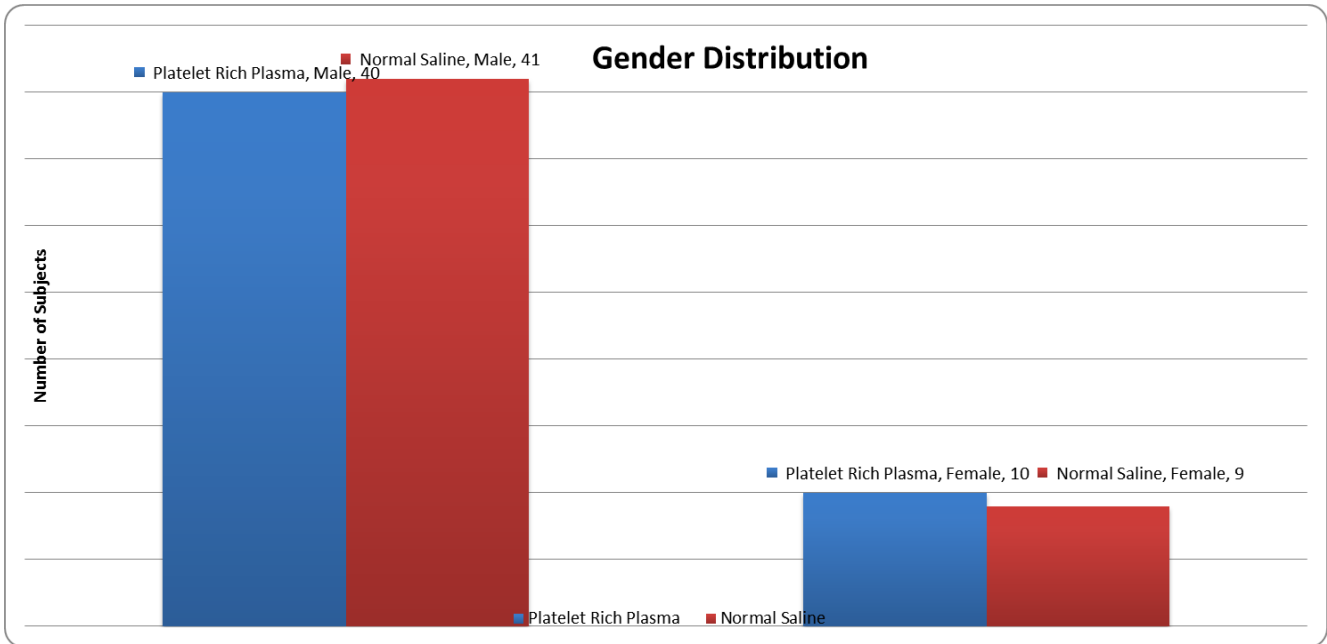
**Age Distribution**



Age Distribution	Platelet Rich Plasma	%	Normal Saline	%
≤ 40 years	7	14.00	0	0.00
41-50 years	19	38.00	17	34.00
51-60 years	19	38.00	26	52.00
> 60 years	5	10.00	7	14.00
Total	50	100	50	100

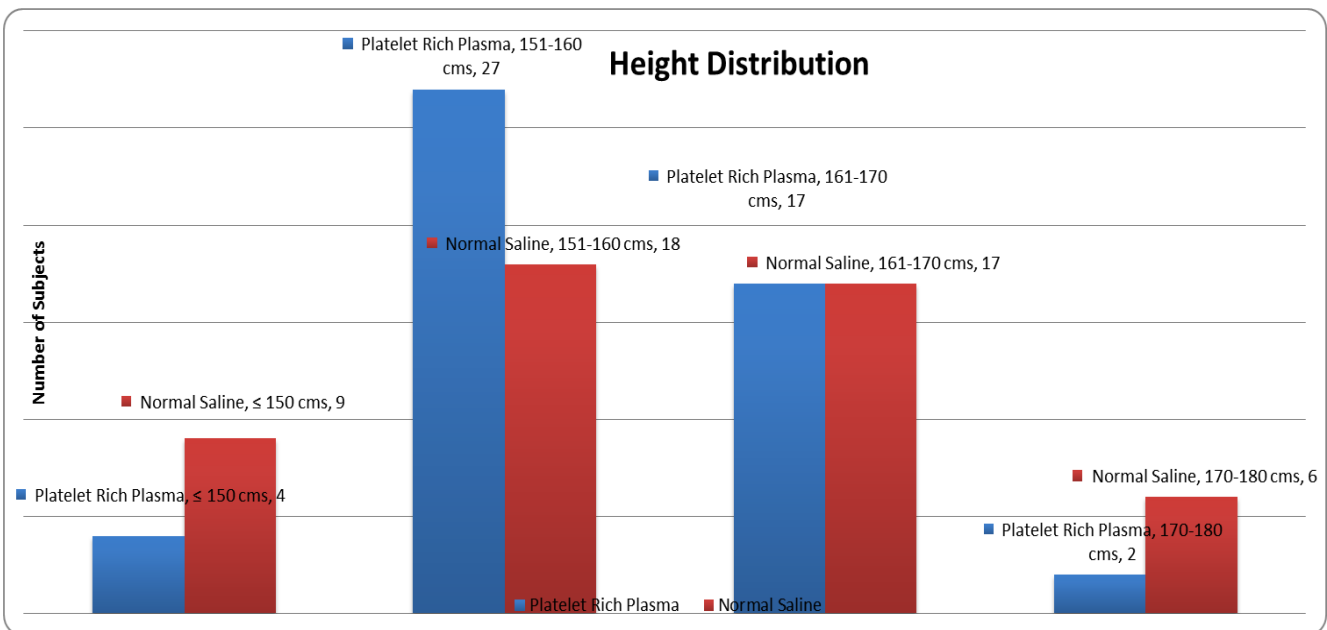
Age Distribution	Platelet Rich Plasma	Normal Saline
N	50	50
Mean	49.92	54.16
SD	7.72	5.36
P value Unpaired t Test		0.1120

### Gender Distribution



Gender Distribution	Platelet Rich Plasma	%	Normal Saline	%
Male	40	80.00	41	82.00
Female	10	20.00	9	18.00
Total	50	100	50	100
P values Chi Squared Test			0.0833	

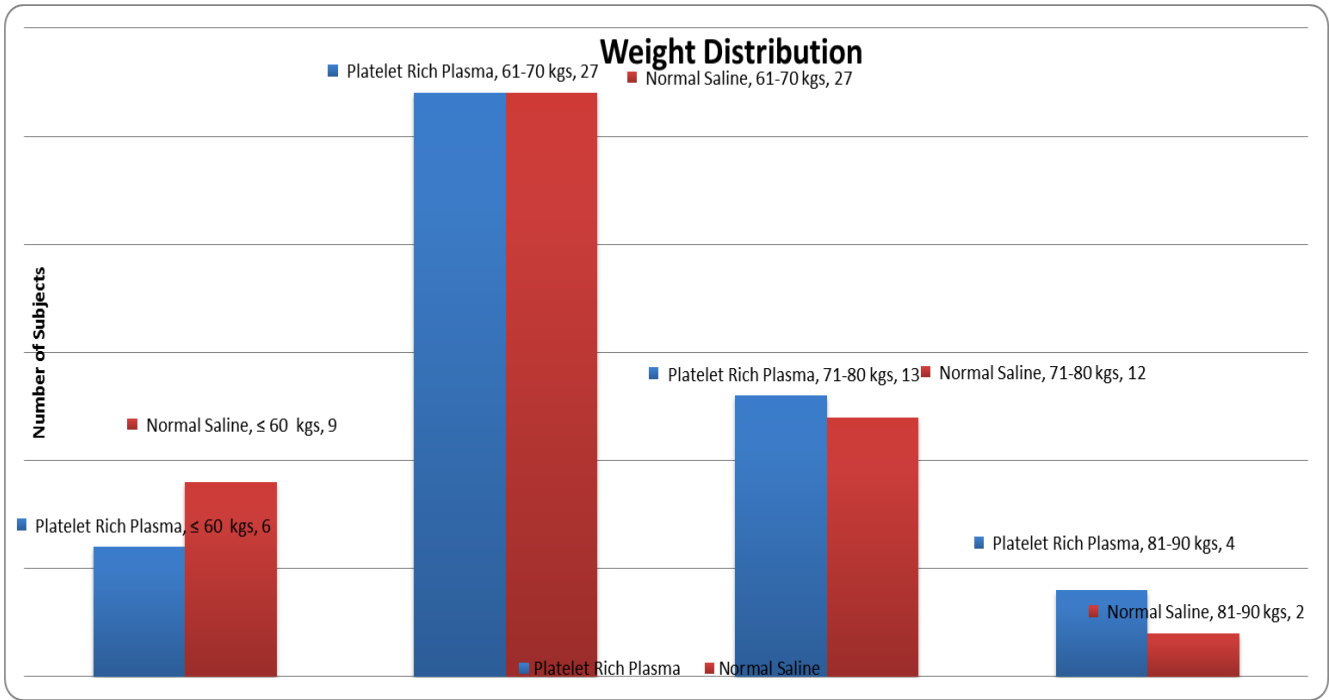
### Height Distribution



Height Distribution	Platelet Rich Plasma	%	Normal Saline	%
≤ 150 cms	4	8.00	9	18.00
151-160 cms	27	54.00	18	36.00
161-170 cms	17	34.00	17	34.00
170-180 cms	2	4.00	6	12.00
Total	50	100	50	100

Height Distribution	Platelet Rich Plasma	Normal Saline
N	50	50
Mean	159.66	159.68
SD	6.63	8.39
P value Unpaired t Test		0.9895

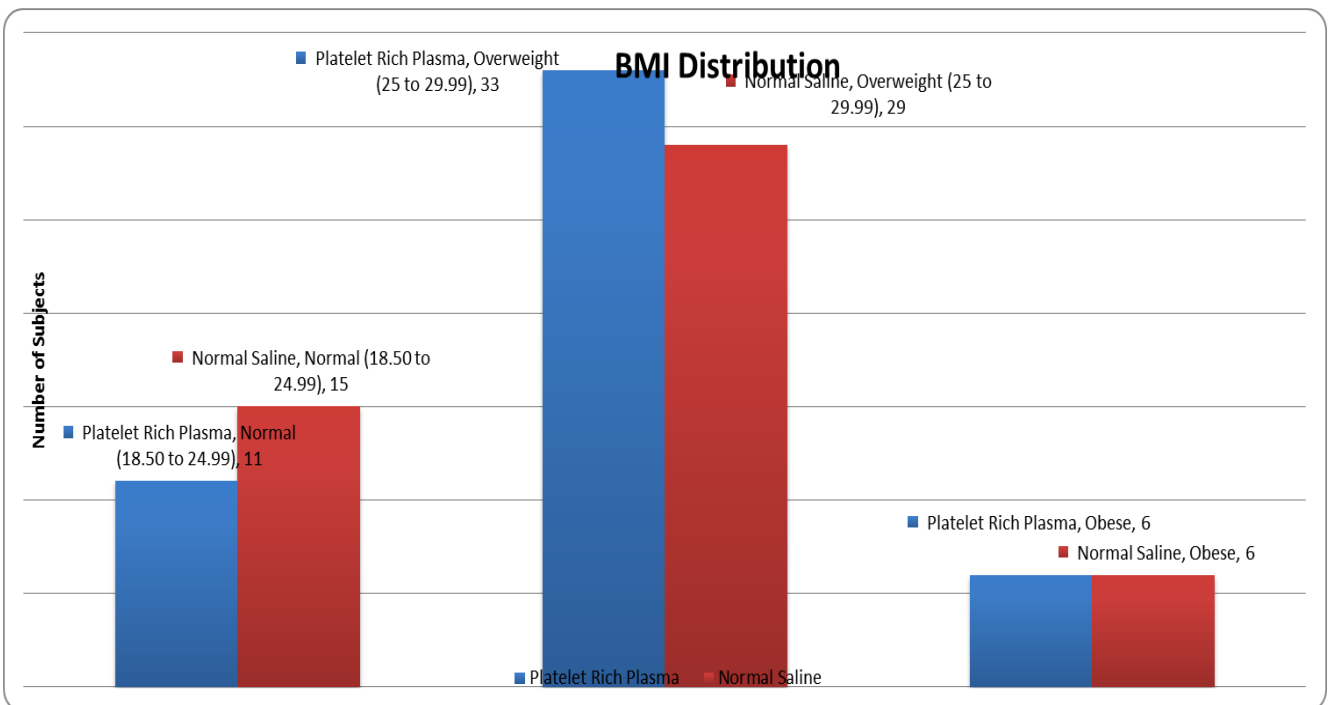
**Weight Distribution**



Weight Distribution	Platelet Rich Plasma	%	Normal Saline	%
≤ 60 kgs	6	12.00	9	18.00
61-70 kgs	27	54.00	27	54.00
71-80 kgs	13	26.00	12	24.00
81-90 kgs	4	8.00	2	4.00
Total	50	100	50	100

Weight Distribution	Platelet Rich Plasma	Normal Saline
N	50	50
Mean	68.62	67.66
SD	6.84	6.63
P value Unpaired t Test		0.4777

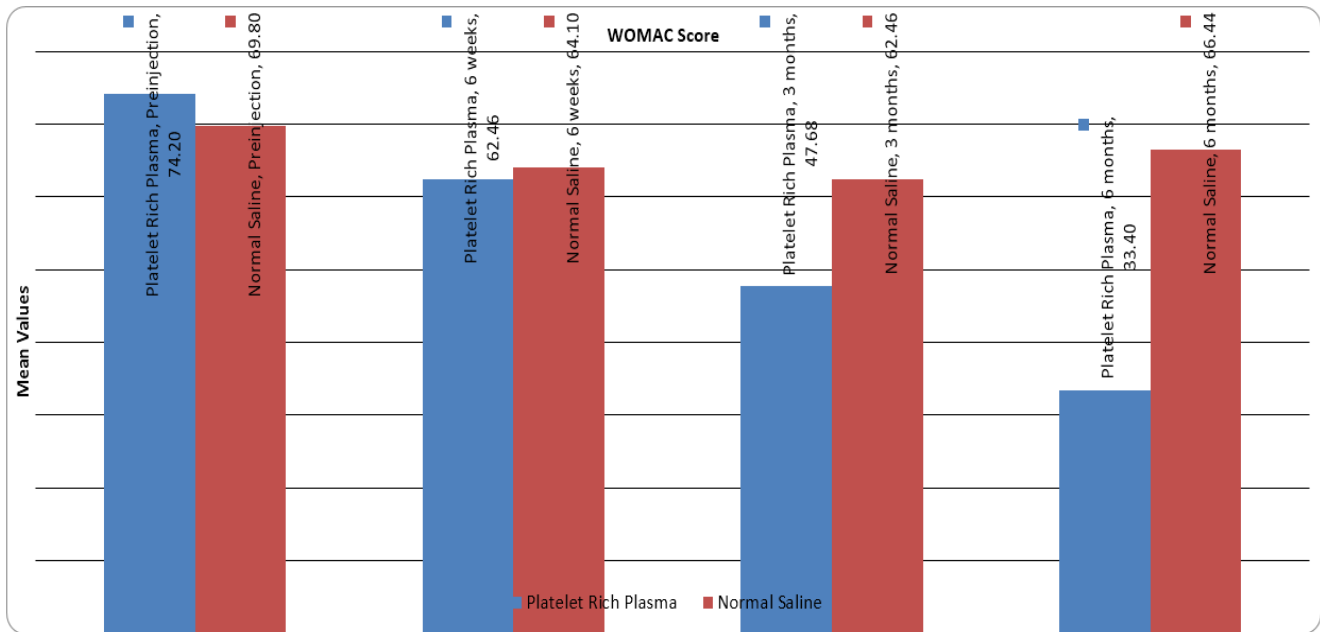
**BMI Distribution**



BMI Distribution	Platelet Rich Plasma	%	Normal Saline	%
Underweight ( $\leq 18.49$ )	0	0.00	0	0.00
Normal (18.50 to 24.99)	11	22.00	15	30.00
Overweight (25 to 29.99)	33	66.00	29	58.00
Obese	6	12.00	6	12.00
Total	50	100	50	100

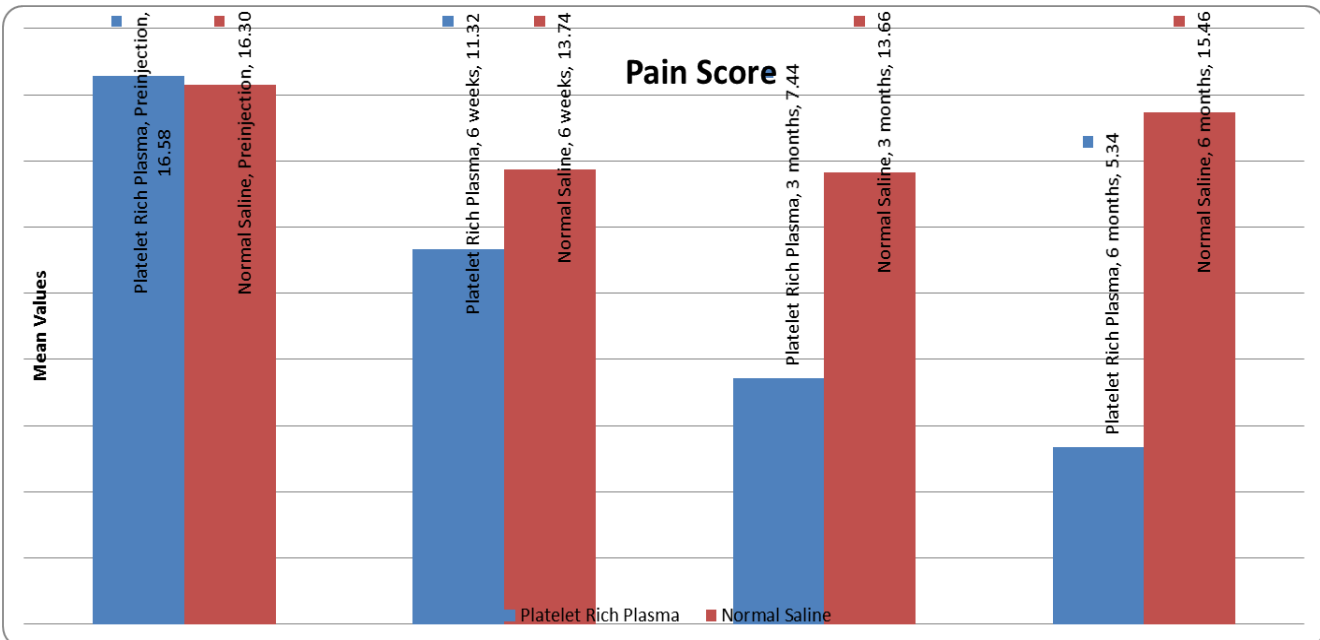
BMI Distribution	Platelet Rich Plasma	Normal Saline
N	50	50
Mean	26.97	26.64
SD	2.70	2.92
P value Unpaired t Test		0.5507

**WOMAC Score**



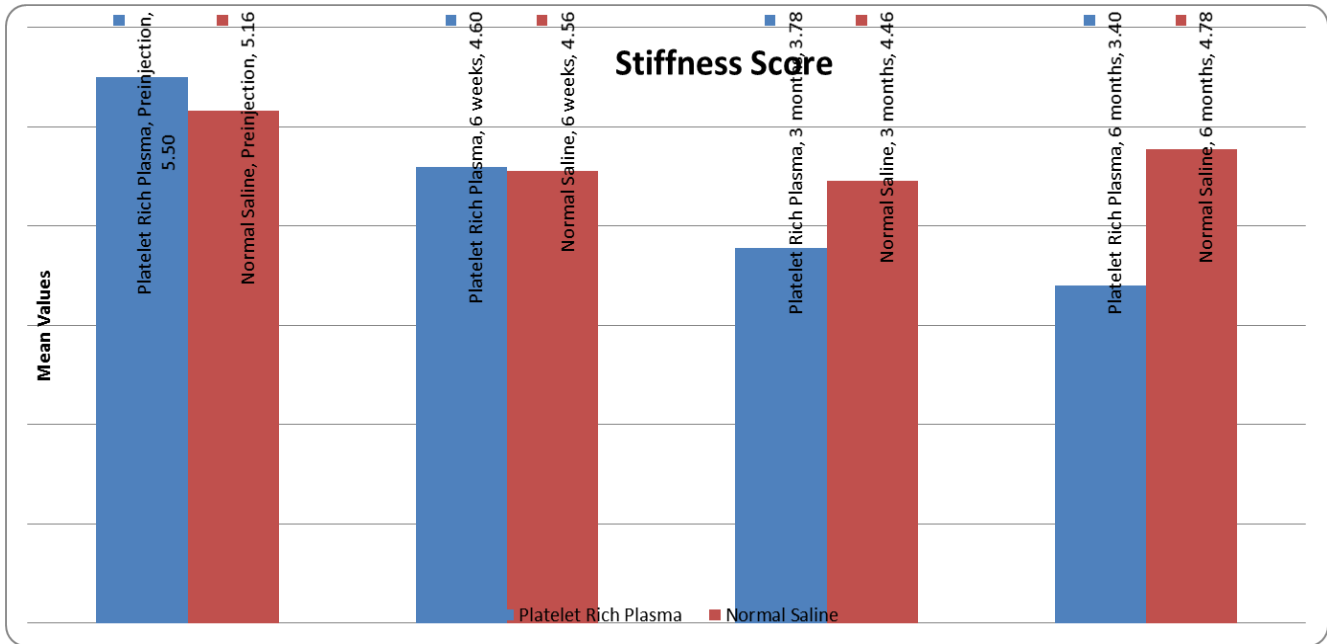
WOMAC Score		Preinjection	6 weeks	3 months	6 months
Platelet Rich Plasma	N	50	50	50	50
	Mean	74.20	62.46	47.68	33.40
	SD	4.85	6.60	8.15	7.59
Normal Saline	N	50	50	50	50
	Mean	69.80	64.10	62.46	66.44
	SD	4.68	5.50	5.44	5.01
P value Unpaired t Test		0.1804	0.0000	0.0000	0.0000

**Pain Score**



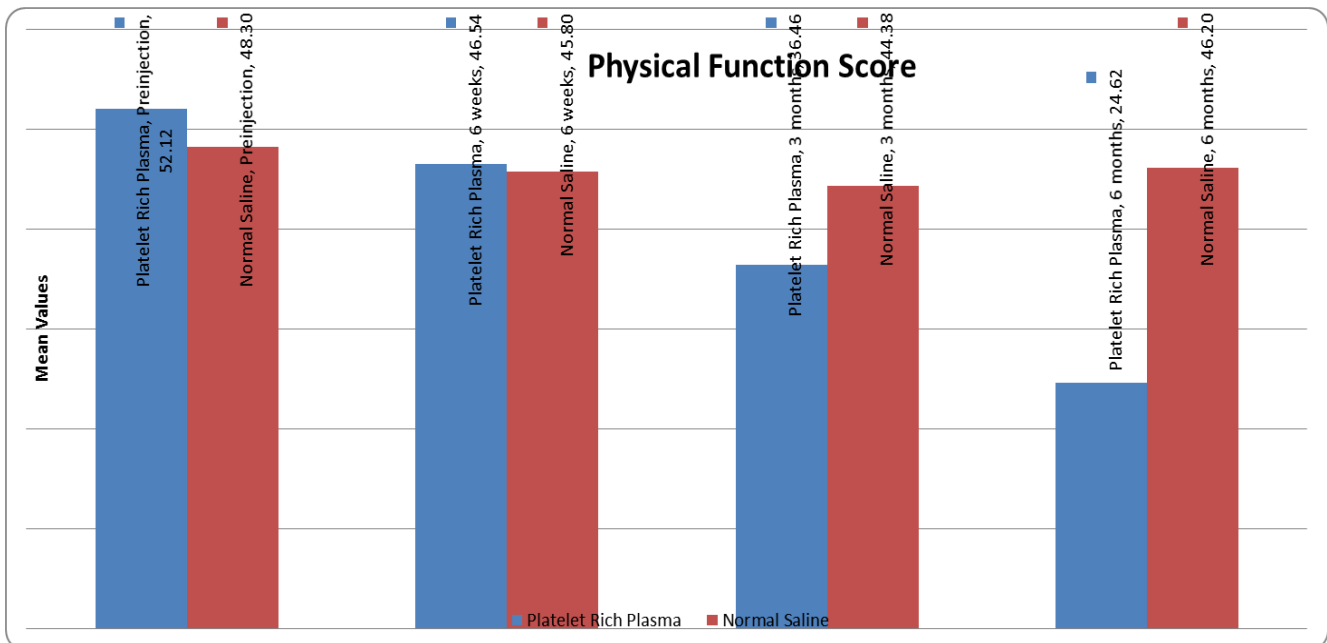
Pain Score		Preinjection	6 weeks	3 months	6 months
Platelet Rich Plasma	N	50	50	50	50
	Mean	16.58	11.32	7.44	5.34
	SD	3.08	2.76	1.93	1.42
Normal Saline	N	50	50	50	50
	Mean	16.30	13.74	13.66	15.46
	SD	2.39	2.28	2.35	1.94
P value Unpaired t Test		0.6132	0.0000	0.0000	0.0000

### Stiffness Score



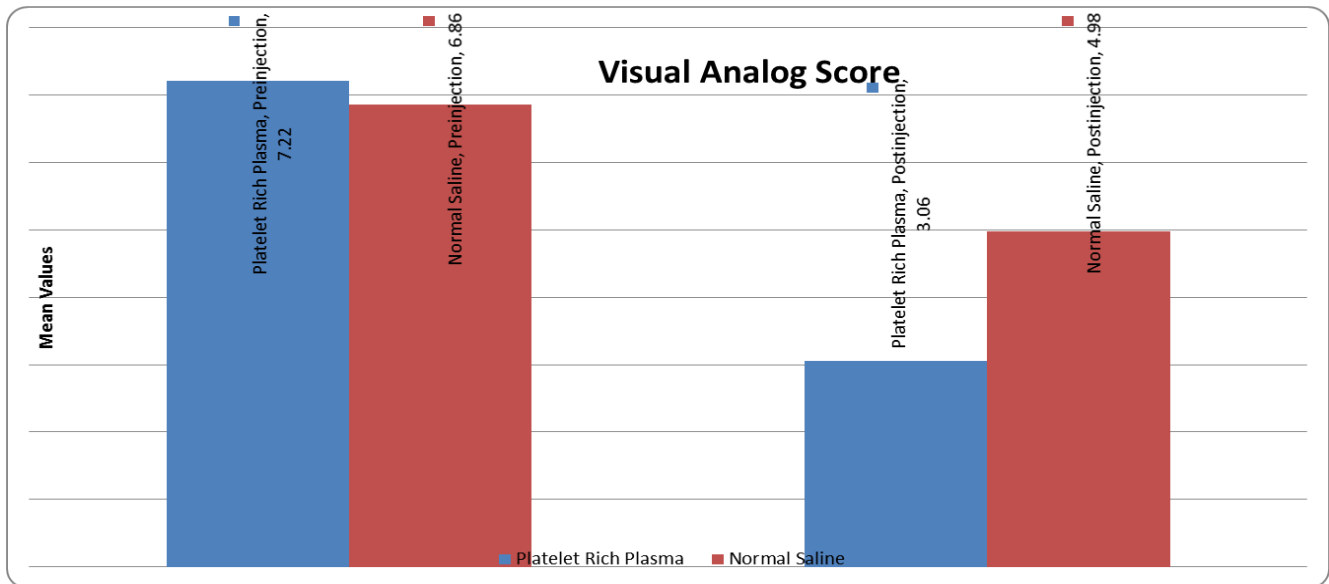
Stiffness Score		Preinjection	6 weeks	3 months	6 months
Platelet Rich Plasma	N	50	50	50	50
	Mean	5.50	4.60	3.78	3.40
	SD	1.22	1.20	1.09	1.14
Normal Saline	N	50	50	50	50
	Mean	5.16	4.56	4.46	4.78
	SD	0.93	0.81	0.73	0.84
P value Unpaired t Test		0.1204	0.8453	0.0004	0.0000

### Physical Function Score



Physical Function Score		Preinjection	6 weeks	3 months	6 months
Platelet Rich Plasma	N	50	50	50	50
	Mean	52.12	46.54	36.46	24.62
	SD	3.77	4.53	6.49	6.33
Normal Saline	N	50	50	50	50
	Mean	48.30	45.80	44.38	46.20
	SD	3.17	3.91	3.88	3.67
P value Unpaired t Test		0.3840	0.0000	0.0000	0.0000

**Visual Analog Score**



Visual Analog Score		Preinjection	Postinjection
Platelet Rich Plasma	N	50	50
	Mean	7.22	3.06
	SD	0.97	1.24
Normal Saline	N	50	50
	Mean	6.86	4.98
	SD	0.81	0.89
P value Unpaired t Test		0.0473	0.0000

**Discussion**

The efficacy of platelet rich plasma in reducing pain, stiffness and physical function were assessed and scored on WOMAC index for both study and control group. The results were analysed using unpaired t-test and chi-square test.

Age distribution revealed mean age in group I to be 49.92 and the mean age in Group II was 54.16. The p-value derived using unpaired t-test is 0.1120, rendering age factor insignificant. Gender distribution were comparable on both groups with 80 % being male 20% being female. The p-value using chi square test is 0.0833. The Gender factor was insignificant. The mean height in group I was 159.66 and the mean height in Group II was 159.68. The p-value using unpaired t test turned insignificant (0.9895). The mean weight, in group I was 68.62 and group II was 67.66 with P-value of 0.4777 (insignificant). The mean BMI was 26.97 in group I and 26.64 in Group II. The p-value is 0.5507 (insignificant). Thus the study ensured that all patients were comparable on baseline characters. The Global WOMAC showed a mean of 74.2. at pre injection period which decreased to 62.46 at 6 weeks follow up and 47.68 at 3 months and declining to 33.40 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 16.58 to 11.32 at 6 weeks post injection. At the end of 6 months follow up, mean was 5.34. The mean score for pain in group II showed a marginal decrease from 16.30 to 13.74 at 6 weeks but returned to 15.46 at 6 months follow up. The p-value using unpaired t-test showed significant improvement. 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 52.12 to 24.62 at 6 months follow up in Group I.

Group II showed a marginal dip in mean scores from 48.30 to 45.80 and to 44.38 at 3 months. the scores leveled at 46.20 at the end of 6 months follow up

Visual analog score showed a decrease in mean of 7.22 to 3.06 which denoted a change of patient’s perception of pain from intense, dreadful, horrible pain to mild annoying pain in Group I.

Group II showed a marginal dip from 6.86 to 4.98 on mean, showing insignificant change in pain

**Conclusion**

The epidemic of modernization coupled with effective health care delivery has led to an expanded lifespan of human beings. The focus of health care providers has undergone a drift towards non communicable and degenerative disorders. 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 and 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.

**Complications**

There were no major complications or incidences of infection in our study group and control group

**Limitations**

Long term follow up needed with M.R.I to assess the regeneration of cartilage.

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