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Assessment of the role of platelet rich plasma (PRP) in mild to moderate osteoarthritis knee joint using VAS and WOMAC score

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Abstract
Introduction: Osteoarthritis is the most common form of arthritis afflicting mankind specially the elderly population. One of the most affected joints is the knee. Characteristic features of osteoarthritis are pain, swelling, and stiffness with the decline in physical function such as walking, climbing stairs and getting in and out of the chair. There is a large population of young and active people with early osteoarthritis who have not yet developed the classical signs of OA. But, who are strong candidates to an increased risk for accelerated development of joint degeneration. Approximately 27 million Americans over the age of 25 currently suffer from OA. This number is predicted to increase by 2030 to a staggering 67million. The number of total hip replacement and total knee replacement operations is expected to reach 572,000 and 3,480,000, respectively by 2030. At present, there are numerous, non-invasive treatment modalities like physical therapy, analgesic, non-steroid anti-inflammatory drugs, glucosamine/chondroitin supplementation, intra-articular injection of hyaluronic acid (HA), intra-articular steroid injection and Platelet Rich Plasma. In almost all published studies, PRP has been shown to have a strong positive effect on chondrocyte proliferation in vitro. Platelet rich plasma (PRP) therapy is a simple, low cost and minimally invasive method that provides a natural concentrate of autologous blood growth factors (GFs) that can be used to enhance tissue regeneration. This therapy is widely experimented in different fields of medicine to test its potential to enhance tissue regeneration.
Aims and Objectives: The aim of the study is to assess the role of PRP in active patients with symptomatic Osteoarthritis knee and to compare the clinical outcome of PRP treatment by using WOMAC and VAS scoring system at different time interval.
Materials and Methods: The study was conducted in the Department of Orthopaedics at Santosh hospital Ghaziabad over a period of 24 months (October 2013 to October 2015). Subjects were recruited randomly from patients presenting with pain in knee joint in Orthopaedics OPD, and diagnosed as a case of primary Osteoarthritis Knee after Clinical and Radiological evaluation and satisfying inclusion criteria which includes patients above 35-75 years age with Unilateral or Bilateral Osteoarthritis Knee involvements, history of chronic knee pain or swelling equal to or more than four months, radiological (X-ray) finding of articular cartilage degeneration, including Kellgren-Lawrence (KL) Grade II and III. Patients who signed written informed consent and the patients were excluded following the exclusion criteria viz. systemic disorders like Gouty Arthritis, Rheumatoid Arthritis Diabetic mellitus, any bleeding disorder, metabolic disease or cardiovascular disease, immunosuppressed patients and those receiving anticoagulation therapy, platelets values of <150,000/mmc. Pregnancy, late stages of Osteoarthritis Knee, KL Grade IV.
Results: In our study, it was observed that the age distribution of the cases ranged from 35 years to above 65 years, with a maximum number of cases i.e. 58 (53.70%) in the age group of 35-45 years. The mean age of the cases was 49.82 ± 8.62 years. In our study we observed a female preponderance, with 62 out of 108 (57.40%) cases being females. This was in accordance with the study conducted by Sandeep *et al*, which also had a female preponderance. In the present study the maximum number of patients were homemakers, being 56 (51.85%) cases, followed by labourers 15 (13.88%), maximum number of patients 75 (69.44%) cases had complaints of pain for less than a year while 33 (30.55%) cases had complaints of Pain more than 1 year. In our study 80 out of 108 cases (74.07%) had grade II disease status as per the Kellgren-Lawrence grading scale and 28 out of 108 cases i.e. 25.92% had grade III disease status. This finding differed from that of Gobbi *et al* who had approximately equal number of cases with KL Grade II and III. However the VAS score in our study showed an improvement at 24 weeks which was 4.29±2.10 and the WOMAC score showed a significant improvement at all follow ups decreasing to 44.55±20.47 at the final follow up of 24 weeks.
Conclusion: The hypothesis of this study was that PRP reduces pain and leads to a more effective and lasting functional recovery in mild to moderate osteoarthritis knee patients. Our objective was to assess the efficacy of PRP IAI for relieving pain and improving knee function in Grade 1 and 2 OA Knee using WOMAC and VAS Scoring methods. Total 108 patients diagnosed with osteoarthritis, were included in our study. All patients were given 3 intra articular injections of PRP at 0, 3 and 6 weeks and followed up at 6, 12 and 24 weeks and found better improvement in activities of daily living post PRP therapy. We demonstrated that PRP IAI is potentially safe, simple, and low-cost method to improve articular joint healing, with promising results.

Keywords: knee joint, grade 1/grade 2 osteoarthritis, platelet rich plasma, VAS, WOMAC

Introduction
Osteoarthritis is the most common form of arthritis afflicting mankind specially the elderly population. One of the most affected joints is the knee. Characteristic features of

osteoarthritis are pain, swelling, and stiffness with the decline in physical function such as walking, climbing stairs and getting in and out of the chair [1, 2]. While clinical osteoarthritis is the late stage condition for which disease modifying opportunities are limited. Osteoarthritis typically develops over decades, offering a long window of time to potentially alter its course. So, there is a large population of young and active people with early osteoarthritis who have not yet developed the classical signs of OA. Cartilage injuries are a common clinical challenge, approximately 27 million Americans over the age of 25 currently suffer from OA. This number is predicted to increase by 2030 to a staggering 67million [3, 4, 5]. The number of total hip replacement and total knee replacement operations is expected to reach 572,000 and 3,480,000, respectively by 2030. At present, there are numerous, non-invasive treatment approaches with emphasis on pain management, improvement in function and daily activities and the potential to modify the disease process and progress of cartilage degeneration [6]. Such treatment options include physical therapy, analgesic, non-steroid anti-inflammatory drugs, glucosamine/chondroitin supplementation, intra-articular injection of hyaluronic acid (HA) which is a viscos-supplementation and intra-articular steroid inj[7]. However, most of them have either shows short-term success, not addressing the biological pathology or have shown only minor benefits with significant side effects [7]. Activated platelets that may reduce inflammation, provide pain relief, improve function and stimulate possible cartilage regeneration at the site of injury, in this case the worn cartilage area of the knee [8]. Platelets play an essential part in tissue homeostasis. They contain a vast number of growth factors (PDGF, IGF, VEGF), cytokines (TGF-β, IGF) and bioactive proteins which help regulate tissue healing and restoration. Platelet rich plasma (PRP) therapy is a simple, low cost and minimally invasive method that provides a natural concentrate of autologous blood growth factors (GFs) that can be used to enhance tissue regeneration [9].

Aims and objectives

The aims and objectives of our study were:-

1. To evaluate the effects of intra-articular PRP injection in active patients with symptomatic Osteoarthritis of knee.
2. To compare the clinical outcome of PRP Treatment by using WOMAC and VAS scoring system at different time interval.
3. To find out a simple, cost effective and minimal invasive treatment of OA knee.
4. To study incidence of complication of use of PRP in management of OA knee.

Materials & methods

The study was conducted in the Department of Orthopaedics at Santosh hospital Ghaziabad over a period of 24 months (October 2013 to October 2015). Subjects were recruited randomly from patients presenting with pain in knee joint in Orthopaedics OPD, Santosh Hospital Ghaziabad and diagnosed as a case of primary Osteoarthritis Knee after Clinical and Radiological evaluation and satisfying inclusion criteria.

Inclusion criteria

1. Patients above 35-75 years age with Unilateral or Bilateral Osteoarthritis Knee involvements.
2. History of chronic knee pain or swelling equal to or more than four months.
3. Radiological (X-ray) finding of articular cartilage degeneration, including Kellgren-Lawrence (KL) Grade II and III.
4. Patients who signed written informed consent.

Exclusion criteria

1. Systemic disorders like Gouty Arthritis, Rheumatoid Arthritis Diabetic mellitus, any bleeding disorder, metabolic disease or cardiovascular disease.
2. Immunosuppressed patients and those receiving anticoagulation therapy.
3. Platelets values of <150,000/mmc.
4. Pregnancy.
5. Late stages of Osteoarthritis Knee, KL Grade IV.

Study tools

1. Radiologically: The standard radiographic evaluation including a weight bearing anteroposterior and lateral view of the knee. Kellgren-Lawrence Grading Scale was used for the assessment of the Osteoarthritis Knee. The most commonly accepted grading system for radiographic OA was proposed by Kellgren and Lawrence (KL) in their atlas of standard radiographs more than 40 years ago [10]. This scoring system is based primarily on osteophyte presence, with the more severe grades based on the progressive appearance of joint space narrowing and subchondral bone sclerosis.

Kellgren-Lawrence Grading Scale

Table 1

Grade	Classification	Feature
0	Normal	No feature of OA
1	Doubtful	Minute osteophyte, doubtful significance
2	Minimal	Definite osteophyte, unimpaired joint space
3	Moderate	Moderate diminution of joint space
4	Severe	Joint space greatly impaired with sclerosis of subchondral bone

2. Clinically

i) **Visual Analogue Score (VAS),** it consists of a 10 cm horizontal line whose extreme ends were marked as no pain on the left side and worst pain on the right side. The patients were asked to place a mark on the line which represents the level of their pain. VAS scale suggests that they are ordinal, the actual design of the VAS can be different when measuring the same construct and thus could benefit from standardization.

ii) **Western Ontario McMaster Universities Arthritis Index (WOMAC) Score** was used to measure osteoarthritis knee. The scale has three subscales, pain (5 items), stiffness (2 items) and physical functioning (17 items). Numerous studies have reported on its reliability and validity. WOMAC is a popular measure to assess impairment and activity limitation in patients with osteoarthritis [11].

Study protocol

1. Study was established after proper protocol and ethical committee clearance.
2. After the establishment of the diagnosis of primary osteoarthritis and patients fulfilling inclusion criteria were included in the study.
3. Patient was explained in detail about the treatment modality and potential adverse effect and a written informed consent was taken.
4. Baseline scoring was done using VAS & WOMAC Score and patient was subjected to the procedure which was carried out under aseptic precautions in operation theatre (O.T.).
5. Procedure: Under full aseptic precautions 3ml of PRP, prepared by 30 ml of autologous blood was injected in affected knee joint through antero-lateral approach using a 16-g needle in 5 ml syringe.
6. Post procedure protocol: At the end of the procedure the patient was observed for one hour, the patients were sent home with instructions to limit the use of the leg for at least 24 hr and to use cold therapy/ice on the affected area to subside pain and swelling if any. During this period, the use of non-steroidal anti-inflammatory medication was only advised if pain persisted.
7. Second and third dose of PRP was given after 3 weeks and 6 weeks interval respectively.
8. All results are presented as the number of knees (not the number of individuals). WOMAC and VAS Score was used in clinical evaluation.

Preparation of Platelet rich Plasma: Patients falling in the inclusion criteria were subjected to a haemogram analysis, random blood sugar and platelet count.

Procedure [12] - 30 ml autologous whole blood (WB) was obtained by venipuncture. For collection of blood acid citrate dextrose (ACD) tubes were used to prevent coagulation of blood. Care was taken so as chilling of blood was prevented at any time before or during platelet separation. Centrifugation of the blood was done using a 'soft' spin (1,800 rpm for 15 min) to separate erythrocytes. Supernatant plasma containing platelets was transferred into another sterile tube (without anticoagulant). Second Centrifugation done at a higher speed, a hard spin (at 3,500 rpm for 10 min) to obtain a platelet concentrate. The lower 1/3rd thus obtained had PRP and upper 2/3rd was platelet-poor plasma (PPP). At the bottom of the tube, platelet pellets were formed. PPP was removed and the platelet pellets were suspended in a minimum quantity of plasma (2-4 ml) by gently shaking the tube. The total number of platelets per milliliter in the PRP represented a mean increase of 600% compared with whole blood values.

Data management & statistical analysis

A database was constituted using freely available software solutions (SPSS Version 20) and electronic spreadsheets (MS Excel) to store and manage the collected data.

The data thus collected was subjected to descriptive statistical analysis by way of bar charts and/or line charts. The results were compared using student T test.

Materials used

Fig 1: Centrifugation of the blood sample

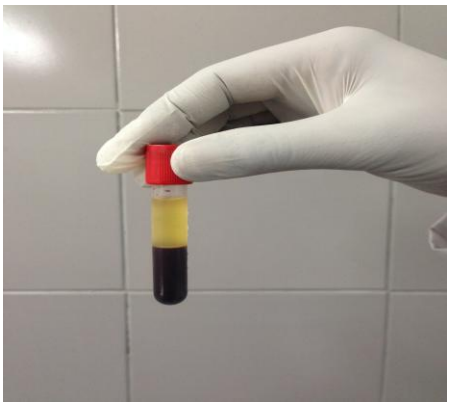

Fig 2: Platelet rich plasma after centrifugation

Fig 3: Knee intra-articular infiltration

Radiographs of Osteoarthritis Knee

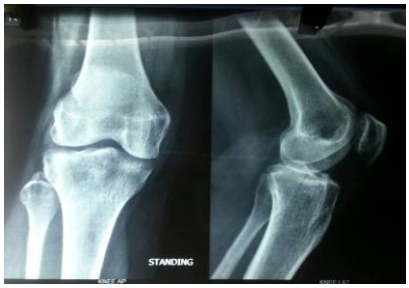

Fig 4

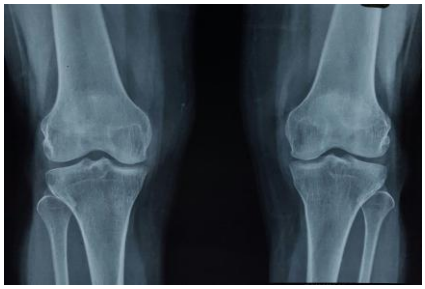

Fig 5

Results

In the present study 108 patients with Osteoarthritis Knee fulfilling inclusion criteria were included. All patients received intra-articular injections of PRP at 0, 3 and 6 weeks and followed up at 6 weeks, 12 weeks and 24 weeks. VAS and WOMAC scores were observed before giving PRP therapy and then at 6 weeks, 12 weeks and 24 weeks and evaluated. The results obtained were as follows:

1. **Age of the patients:** In our study age of the patients ranged from 35-70 years, divided in 4 groups. Maximum no. of patient were in age group 1 (35-45yr) and minimum were in age group 4 (>65yr).
   From 108 cases, 58 (53.70%) cases were in the 35-45 years age group, followed by 30 (27.70%) cases in the 46-55 years age group and 14 (12.96%) in the 56-65 age group. 6 (5.55%) cases in our study were above the age of 65 years. The mean age of the patients was 49.88±8.62 years.
2. **Sex:** In our study 62 (57.40%) cases were females, whereas 46 (42.59%) were males.
3. **Occupation:** In our study most of the cases were Housewife's i.e. 56 (51.85%), followed by labourers including hawkers, rickshaw pullers, daily wage workers i.e. 15(13.88%). 12(11.11%) of the cases were farmer, followed by shopkeeper i.e. 10(9.25%) followed by Ex-Servicemen i.e. 6(5.55%). 9 (8.33%) cases were persons with miscellaneous job profile.
4. **Duration of pain:** In our study 75 (69.44%) cases had complaint of pain for less than one year, and 33 (30.55%) had pain for more than one year.
5. **Grading:** 80(74.07%) cases, had grade II disease status and 28 (25.92%) cases had grade III disease status as per the Kellgren-Lawrence grading scale.
6. **Side of Involvement:** In our study 56(51.85%) cases were with osteoarthritis of Right knee and 44(40.74%) cases were with osteoarthritis of Left knee while 8(7.40%) cases were with bilateral involvement.
7. **Evaluation by VAS:** Table 2 shows evaluation of cases at different time intervals using VAS.

Table 2: VAS – Evaluation at different time intervals

VAS	Range	Mean± SD
Pre	4 – 9	7.12±1.33
6 wks.	2 – 9	5.54±2.04
12 wks.	1 – 9	4.96±2.13
24 wks.	1 – 9	4.29±2.10

Table 2: In this study, the pre injection VAS score was between 4-9 with a mean of 7.12±1.33. At the first follow up after (at 6 weeks), the VAS score ranged between 2-9 with a mean of 5.54±2.04. At second follow up at 12 weeks the VAS score ranged between 1-9 with a mean of 4.96 ±2.13. At 24 weeks the VAS score again ranged between 1-9, but improvement in mean score seen and was 4.29±2.10.

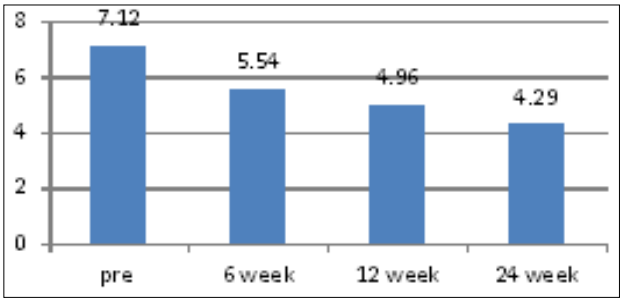

Fig 6

8. VAS – As per Kellgren-Lawrence grading: Table 3 shows evaluation of cases As per Kellgren-Lawrence grading criteria II & III at different intervals.

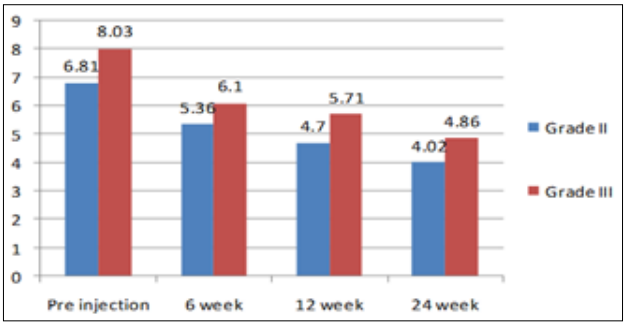

Fig 7

Table 3

Duration	Grade II (n=80)	Grade III (n=28)
Pre	6.81±1.18	8.03±0.92
6 wks.	5.36±1.79	6.10±1.86
12 wks.	4.7±2.08	5.71±2.14
24 wks.	4.02±1.97	4.86±2.31

In our study the pre-treatment mean of VAS score was 7.12+1.34, at 6 weeks it was 5.55+2.05, at 12 weeks it was 4.96+2.14 at 24 weeks the score was 4.23+2.11. The comparison between the pre-treatment VAS score and at different follow ups was done and was found to be significant.

Table 4: VAS among all scores at four different intervals

VAS pre-injection	Vas 6 week	Vas 12 week	VAS 24 week	T, DF	p value
7.12±1.34	5.55±2.05	4.96±2.14	4.23±2.11	26.25,107	<0.05(S)

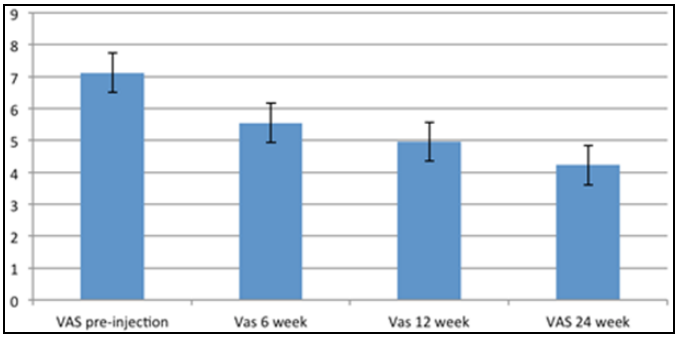

Fig 8

Table 5: WOMAC - Evaluation at different time intervals

Duration	Range	Mean± SD
Pre	35– 95	69.35±16.83
6 wks.	17 – 92	60.24±20.34
12 wks.	15 – 86	52.63±21.75
24 wks.	14 – 85	44.55±20.47

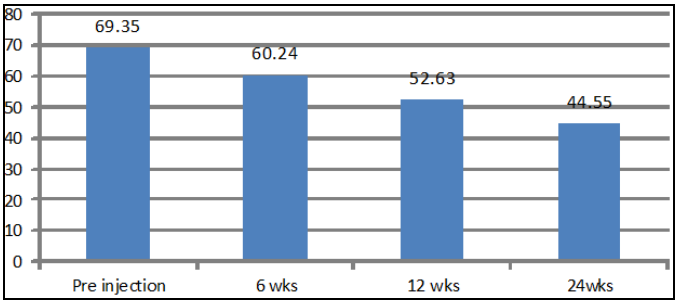

Fig 9

In this study, the pre injection WOMAC score ranged between 35-95 with a mean of 69.35±16.83. At 6 weeks the WOMAC score was between 17-92 with a mean of 60.24±20.34. At the second follow up at 12 weeks the WOMAC score ranged between 15-86 with a mean of 52.63±21.75. At third follow up at 24 weeks the WOMAC score was between 15-86, however the mean score improved and was 44.55±20.47.

Table 6: WOMAC - As per Kellgren-Lawrence grading criteria II & III at different intervals

Duration	Grade II (n=80)	Grade III (n=28)
Pre	65.63±16.46	79.99±13.69
6 wks.	55.60±19.77	73.57±14.73
12 wks.	47.99±20.54	65.93±20.63
24 wks.	41.05±17.39	54.57±20.40

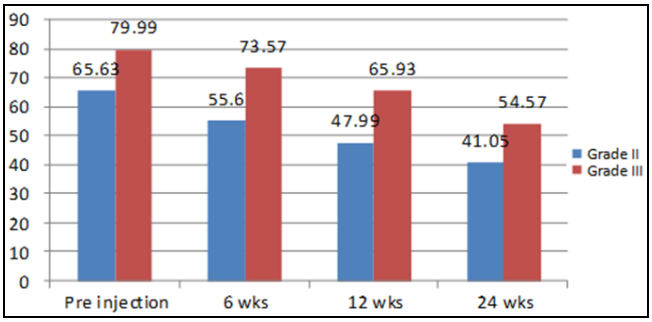

Fig 10

In this study evaluation for all 108 cases was done under KL Grading criteria including grade II & III.

Table 7: WOMAC - among all scores at four different intervals

WOMAC pre	WOMAC 6 week	WOMAC 12 week	WOMAC 24 week	T, DF	p value
69.35±16.83	60.25±20.34	52.64±21.75	44.55±20.47	45.49,107	<0.05(S)

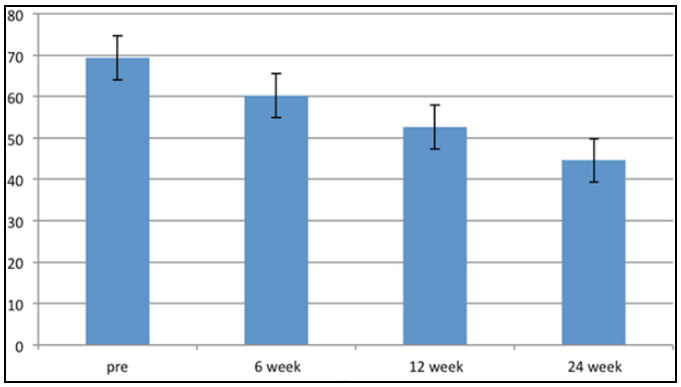

Fig 11

In the present study the mean of pre-treatment of WOMAC score was compared with the mean of WOMAC score at the subsequent follow ups at 6, 12 and 24 weeks and on comparing the score the result was found to be significant.

Discussion

One of the major illness prevalent in our country is that of the Osteoarthritis knee. It is a disease of the synovial joints that evolves with pain, loss of motion, and deformation of affected joints due to degeneration of articular cartilage and eroding of subchondral bone. Intra- articular infiltrations of autologous platelet rich plasma (PRP) have emerged in treatment of OA knee. The present study was carried out in the Department of Orthopaedics Santosh medical college and hospital, Ghaziabad, over a period of 24 months. Total 108 cases fulfilling Inclusion criteria were included in the study. These patients were followed up on regular interval. Following results were drawn in our study-

1. **Age of the Patients:** In our study, it was observed that the age distribution of the cases ranged from 35 years to above 65 years, with a maximum number of cases i.e. 58 (53.70%) in the age group of 35-45 years. The mean age of the cases was 49.82 ± 8.62 years. These findings were in accordance with the study by Giuseppe Filardo *et al*. the mean age of cases in their study groups was 53.8 ± 14.9 years and 50.3 ± 14.4 years. Our findings also coincided with the mean age of study groups included in the study conducted by Sandeep *et al*[13], which was 53.11 ± 11.55 years, 51.64 ± 9.22 years and 53.65 ± 8.17 years respectively. OA is increasing, due to increase rise in the mean age population and with the greater emphasis on physical activity in all age groups. Unfortunately, the regeneration ability of cartilage is limited, chronic overload, as well as metabolic and biological predisposition, may lead to loss of articulating tissue and homeostasis thus resulting in accelerated joint surface damage and eventually end stage arthritis, hence leading

patients of wide age range to seek medical intervention for OA Knee.

2. **Sex:** Patients were randomly selected in the study irrespective of their sex. In our study we observed a female preponderance, with 62 out of 108(57.40%) cases being females. This was in accordance with the study conducted by Sandeep *et al*. [13], which also had a female preponderance. However, our findings differed from those of Ana Wang- Saegusa *et al*. [14], who had more number of male cases i.e. 152 out of 261(58.23%) cases. Since the incidence of OA increases with age and in women hence a greater number of cases (57.40%) included in our study were females.
3. **Occupation:** In the present study the maximum number of patients were homemakers, being 56 (51.85%) cases, followed by labourers 15(13.88%). None of the study referred to took into consideration the profession of the cases included. A larger number of cases included were homemakers, owing to the sedentary life style and obesity which are both risk factors for the development and progression of OA, followed by physical workers who were involved in weight bearing activities, squatting activities, carrying loads which lead to the early wear and tear and hampered the regeneration capacity cartilage of the knee joints.
4. **Duration:** In our study maximum number of patients 75 (69.44%) cases had complaints of pain for less than a year while 33 (30.55%) cases had complaints of Pain more than 1 year. pain is the most presenting problem in OA, followed by joint stiffness and limitations of motion. These symptoms affected daily activities of the patients leading them to seek early medical intervention and treatment.
5. **Severity of the disease:** In our study 80 out of 108 cases (74.07%) had grade II disease status as per the Kellgren-Lawrence [15] grading scale and 28 out of 108 cases i.e. 25.92% had grade III disease status. This finding differed from that of Gobbi *et al*. who had approximately equal number of cases with KL Grade II and III. This finding also differed from that of Elizaveta Kon who had 33 out of 58 patients with KL Grade I to III. Our findings differ from the above mentioned studies since we have excluded KL Grade I & IV. Patients with KL Grade I of OA were relieved of pain, which is the most common complaint of patients with OA when treated with NSAIDS or non-surgical treatment options for OA. Those with KL grade IV required surgical treatment like knee replacement, hence these two groups were excluded from our study. Patients with KL grade II and III of OA were not relieved of symptoms by conventional pharmacological and non-surgical treatment options, hence were ideal candidates to benefit from PRP therapy and hence were included in our study.
6. **Evaluation of outcome by VAS Score:** In our study the pre-treatment VAS score was ranging between 4 – 9 with a mean of 7.12±1.33. Our results differed in comparison with the baseline VAS score of Ana Wang Saegusa *et al* whose pre-treatment baseline VAS score was 4.86. Our values also differed from those of the study conducted by Alberto Gobbi *et al*. [16] who had a pre-treatment VAS score of 4.1. This difference in baseline VAS score was seen because we had only included grade II and early grade III in our study whereas Ana Wang Saegusa *et al*. included all four grades in her study ranging between grade I 13.1%, grade II 30.8%, grade III 19.2% and grade IV 36.9%. However the VAS score in our study showed an improvement at 24 weeks which was 4.29±2.10. This was in accordance with the above mentioned study which also showed a similar trend of improvement in VAS score at 24 weeks follow up and subsequent intervals. This was also in accordance with the study done by Ali Soliman Hassana and Abeer Mohamed El-Shafeya [17] in (2012) which showed a significant improvement in VAS score i.e.(3.9 ± 1.1) after 6 month of PRP treatment.
7. **Evaluation of outcome by WOMAC score:** In our study the pre-treatment WOMAC score was ranging between 35–95 with a mean of 69.35±16.83. Our baseline WOMAC result was not in accordance of the group studied by Sandeep *et al*., who had a baseline score of 53.20+-16.18 and that of Ana Wang Saegusa *et al*., who had a baseline score of 30.48. In our study the WOMAC score showed a significant improvement at all follow ups decreasing to 44.55±20.47 at the final follow up of 24 weeks. In our study the pre-treatment mean of VAS score was 7.12±1.34, at 6 weeks it was 5.55±2.05, at 12 weeks it was 4.96±2.14, at 24 weeks the score was 4.23±2.11. In the present study the mean of pre-treatment of WOMAC score 69.35±16.83 was compared with the mean of WOMAC score at the subsequent follow ups at 6 weeks it was 60.24±20.34, at 12 weeks it was 52.63±21.75 and 24 weeks it was 44.55±20.47 and on comparing the score the result was found to be significant.
8. **Complication:** In our study 3 patients had mild swelling and 2 patients had erythema in knee joint after giving intraarticular PRP inj that subsided in 2-3 days with NSAIDS and ice fomentation. These complications were probably due to local inflammation which didn't warrant further investigation as they were self limiting in nature.

Limitations

We did not take into consideration the BMI of the patients. Another limitation was that we compared the total WOMAC scores and did not compare the separate scores for pain, stiffness and functional capacity.

Conclusion

The hypothesis of this study was that PRP reduces pain and leads to a more effective and lasting functional recovery in mild to moderate osteoarthritis knee patients. Our objective was to assess the efficacy of PRP IAI for relieving pain and improving knee function in Grade 1 and 2 OA Knee using WOMAC and VAS Scoring methods. Total 108 patients diagnosed with osteoarthritis, were included in our study. All patients were given 3 intra articular injections of PRP at 0, 3 and 6 weeks and followed up at 6, 12 and 24 weeks and found better improvement in activities of daily living post PRP therapy. We demonstrated that PRP IAI is potentially safe, simple, and low-cost method to improve articular joint healing, with promising results. The clinical result of our study is encouraging and suggest that this method may be

used for treatment of OA knee. We demonstrate that this is a potentially safe, simple, and low-cost method to improve articular joint healing, with promising results.

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