Section: Orthopedics

Original Research Article

CLINICAL OUTCOMES OF INTRA ARTICULAR INJECTION OF PLATELET RICH PLASMA IN GRADE I AND II OSTEOARTHRITIS OF KNEE

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Abstract

Background: Osteoarthritis (OA) is a common degenerative disease manifesting as a clinical syndrome of joint pain characterized by gradual loss of articular cartilage, ostephyte formation, subchondral bone remodeling and joint inflammation. The present study was carried out to compare the outcomes of OA knee between Platelet Rich Plasm (PRP) therapy and conservative management as a single institution experience. **Materials and Methods:** This randomized controlled trial was carried out among 100 participants with grade I and II OA knee with 50 participants randomized into intervention (autologous PRP) and control group (conservative management). Wester Ontario McMaster Universities Osteoarthritis Index (WOMAC) score was used to evaluate the functional outcomes before and after the intervention at 1st, 3rd, 6th, 12th weeks and 6th month of follow up. **Result:** The present study demonstrated a statistically significant difference in the WOMAC grading between the two groups at 1st week of follow up ($p=0.005$), at 6th week of follow up ($p=0.002$), and then on at 12th week ($p<0.05$) and at 6th month of follow ups ($p=0.008$). **Conclusion:** The results of the present study support intra articular injection of platelet rich plasma, which is safe, cost-effective method of delaying the features of Osteoarthritis knee in grade 1 and grade 2.

INTRODUCTION

Osteoarthritis (OA) is a common degenerative disease manifesting as a clinical syndrome of joint pain characterized by gradual loss of articular cartilage, ostephyte formation, subchondral bone remodeling and joint inflammation.[1] OA has been considered as a major public health problem, ranking among the top 10 causes of disability across the world. The prevalence of OA knee has been rising globally, and in India, studies have reported a prevalence ranging from 22% to 39%.[2] The disease majorly affects women more than men, especially above 65 years of age where 45% of the women present with symptoms of OA and above 70 years, 70% of the women show radiological signs of OA knee.[3]

The characteristic symptom of OA knee is pain, accompanied by swelling and stiffness of the joint resulting in a progressive decline in physical function. As a result, disability ensues, compromising the quality of life. The presence of various structures in the synovial joint including bone, cartilage, synovial fluid, ligaments and muscle can undergo derangement, triggering these symptoms.[4] As far as the management of OA knee goes, several clinical guidelines recommend conservative, non-pharmacological management and pharmacotherapies which are administered either orally or intra-articular. Each of these therapeutic options have their own benefits and risks, ranging from ineffective pain relief to septic arthritis.

The main objective in conservative management is to improve the quality of life by providing symptomatic relief and limiting the disease progression. An optimal method of management is by providing a combination of pharmacological and non-pharmacological treatment customized to individual patient needs. One of the newer advances in conservative management is based on the principle of regenerative medicine, essentially through platelet rich plasma (PRP). PRP has been extensively used in Europe and United states and has demonstrated potential benefits among OA knee patients.[5] Platelets actively participate in the healing process by delivering broad spectrum of growth factors and other active molecules, which, together enable chondrogenesis, bone remodeling and also exhibit anti-inflammatory relief.[6-8] A wide range of applications have been derived for the use of PRP in therapeutics and in India, specific therapeutic benefits of PRP on OA knee have been seldom documented. With this background, the present study was carried out to compare the outcomes of OA knee

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between PRP therapy and conservative management as a single institution experience.

MATERIALS AND METHODS

Study Setting and Participants

The present study was carried out as a randomized controlled trial in the Department of Orthopedics of our tertiary teaching institution for a period of --- months/years. All the patients above 40 years of age who were diagnosed with OA knee were selected for the study. Patients with history of substantial trauma/ systemic illness and surgically treated OA knee were excluded. In addition, immunocompromised patients and those receiving anti coagulation therapy were also excluded.

Randomization

The study was carried out among 100 participants with 50 participants in each group, randomized using computer generated random numbers.

Group I– consisted of experimental group, where the participants were treated with injection of autologous platelet rich plasma as intra articular injection in knee and conservative management.

Group II – consisted of control group, where the participants were treated with standard conservative management.

Ethical Approval and Informed Consent

Approval was obtained from the Institutional Ethics Committee prior to the commencement of the study. Each participant was explained in detail about the study and informed consent was obtained prior to the data collection.

Preparation of PRP

PRP was prepared using standard technique on the day of application from the participant's own blood. A 100 mil of patient's blood was drawn form the antecubital vein into a bag containing 14 mil citrate phosphate dextrose adenine (CPDA) and was given a low spin of 1750 rpm. The contents of the bag were separated into plasma and packed cell. The supernatant platelet poor plasma was shifted to sterile transfer bag through trans-connecting devise which was attached to the mother bag. Further, both the bags were given a heavy spin of 2600 rpm and supernatant platelet poor plasma was shifted to the mother bag and residual platelet rich plasm was kept in the transfer bag with platelet count of approximately five times greater than the peripheral blood.

Intervention

For the intervention group (Group I), the participant was placed in supine position with knee in flexion of 15 degrees and 6-8ml of PRP was injected intra-articular under aseptic precautions. For the control group (Group II) and intervention group (Group I), standard conservative therapy including health education and lifestyle modifications were provided.

Data Collection

A structured proforma was used to obtain clinical details regarding the demographic particulars and clinical symptomatology. The clinical diagnosis and grading of OA knee was carried out using Western Ontario and McMaster Universities Osteoasthritis index (WOMAC) scale. The WOMAC score was assessed after 1st, 3rd, 6th, 12th week and after 6th month of intervention.

Data Analysis

Data was entered and analyzed using SPSS ver.20 software. The outcome of interventions was expressed as mean scores. Comparison between the two groups was carried out using Independent sample t test. A p value <0.05 was considered statistically significant.

RESULTS

In this study, majority of the participants belonged to the age group of 51-55 years (36%) in Group I while in group II, majority of the participants belonged to the age group of 46-50 years (30%). In both the groups, majority of the participants were females (66%) and right sided lesions were predominant (53%). Majority of the participants were overweight (49%) and obese (25%). Diabetes mellitus was the most common comorbidity in both the groups (24%). [Table 1].

Based on WOMAC grading, majority of the participants in group I (72%) and group II (64%) belonged to grade II of WOMAC. [Figure 1] The present study demonstrated a statistically significant difference in the WOMAC grading between the two groups at 1st week of follow up (p=0.005), at 6th week of follow up (p=0.002), and then on at 12th week (p<0.05) and at 6th month of follow ups (p=0.008). [Table 2]

The daily requirement of analgesics in both the groups were compared during the follow up periods. It was observed that although 100% of the participants in both the groups required analgesics in the first week of follow up, subsequently, the number of participants requiring daily analgesics considerably reduced in group I to 46 in the 3rd week and 23 in the 6th month of follow up. [Figure 2]

Table 1: Background particulars of the study participants

S. NO	Particulars	GROUP I	GROUP II
		N(%)	N(%)
1	Age (in years)		
	40-45	14(28)	11(22)
	46-50	14(28)	15(30)
	51-55	18(36)	13(26)
	>55	4(8)	11(22)
2	Sex		
	Males	16(32)	18(36)

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	Females	34(68)	32(64)
3	Laterality		
	Right	26(52)	27(54)
	Left	19(38)	20(40)
	Bilateral	5(10)	3(6)
4	Body mass index		
	Underweight	0(0)	0(0)
	Normal	14(28)	12(24)
	Overweight	23(46)	26(52)
	Obese	13(26)	12(24)
5	Co-morbidities		
	Diabetes mellitus	11(22)	13(26)
	Hypertension	4(8)	3(6)
	Diabetes mellitus and hypertension	3(6)	4(8)
	hypothyroid	3(6)	4(8)
	None	29(58)	26(52)

Table 2: Comparison of WOMAC scores among the study groups

Pain scores (WOMAC)	Group I (PRP) Mean±SD	Group II (Conservative) Mean±SD	Tvalue	p value
Before treatment	88.1±3.2	87.8±3	1151.00	0.492
At 1stweek	78.6±2.6	79.9±2.1	844.00	0.005*
At 3rdweek	71.6 ±1.7	72.2±1.7	1060.50	0.180
At 6thweek	64.7±2.8	66.2±1.8	798.00	0.002*
At 12thweek	57.9±2.4	59.1±1.9	951.50	0.036*
At6months	49.4±3.6	51.5±3.2	866.00	0.008*

*statistically significant

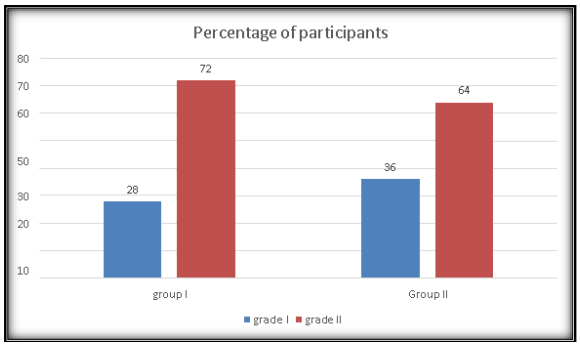

Figure 1: Diagnostic grading of OA knee using WOMAC

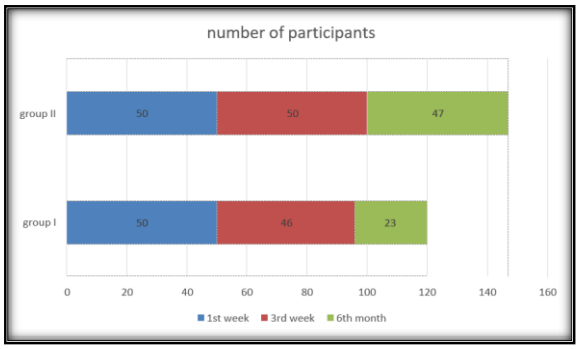

Figure 2: Daily requirement of analgesics in both the groups

DISCUSSION

In the present study, the mean age of the participants was 49.7 years, similar to a study by Spakova et al where the mean age of the study participants was 52.8 years.[9] and ALI soliman et al,[10] where the mean age of the study population was 50.4 years. In this study, 66% of affected participants were females, similar to studies by Spakova et al (64%) and Ali Soliman et al(70%).[9,11] Based on the WOMAC grading, 68% of the participants belonged to grade 2 osteoarthritis. In contrast to the study findings, a study done by Sandeep pate L,[12] showed that only 22% of the participants had grade 2 osteoarthritis. This difference could have arisen due to inherent differences in the population characteristics.

During the 1st week of follow up after intervention, there was a mild increase in functional activity in both group 1 and in group 2 which was statistically significant. However, in second follow up at 3rd week after starting treatment, there was moderate increase in daily functional activity in both groups, which was not statistically significant. During 3rd follow up at 6th week there was significant improvement in daily functional activity in both group, but improvement in functional daily activity in group 1 was significantly more than that in group 2 which was calculated by improvement in stiffness score, pain score, and functional activity of WOMAC score in both the group (p=0.002). Furthermore statistically significant difference in the functional activity was observed at 12th week and 6th month of follow up, with Group I showing better improvements compared to group II (p<0.01). Sampson et al,[10] and colleagues evaluated the effect of three monthly doses of PRP and observed a linear improvement of VAS score and knee injury OA outcome score in 60% of patient at follow up. In this study PRP showed a better performance compared with conservative treatment. According to WOMAC score 22% patient had excellent clinical out come and 49% patient had good clinical out come and 12% had fair clinical out come and 19% had poor clinical outcome.

In this study, none of the participants developed any allergic reaction or anaphylactic reaction after intra articular injection of PRP. None of the participants developed any local inflammatory reaction at

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injection site after receiving PRP injection, except three participants who developed acute exacerbation of knee joint pain at an average of 6 to 8 hours after injection; however, they recovered shortly within 24 to 48 hours by treatment with short analgesics and ice packing.

Studies done by Ali Soliman et al,[13] have proven that administration of PRP in early grades (grade I and II) is very safe as no complication such as infection or fever developed among study groups. As it is well documented in literature that PRP helps in cartilage regeneration specifically when OA is at low grade that is grade 1 and grade 2, it is emphasized that one can delay worsening of OA with physical and medical therapy but with PRP very good results can be expected.

CONCLUSION

The results of the present study support intra articular injection of platelet rich plasma, which is safe, cost-effective method of delaying the features of Osteoarthritis knee in grade 1 and grade 2.

Group 1 who received conservative treatment and intra articular injection of autologous platelet rich plasma showed better clinical outcome compared to group two who received only conservative management.

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