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ORIGINAL RESEARCH

Intrarticular Autologous Platelet-Rich Plasma Versus Methyl Prednisolone Acetate In Adhesive Capsulitis Of Shoulder: A Comparative Study

[1]Dr. Basant Rai, [2]Dr. Vipan Kumar, [3]Dr. Dixit Bansal

[1]Associate Professor, [2,3]Senior Resident, Department of Orthopedics, Guru Nanak Hospital, Amritsar, Punjab, India

Corresponding Author
Dr. Vipan Kumar
Senior Resident, Department of Orthopedics, Guru Nanak Hospital, Amritsar, Punjab, India

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ABSTRACT

Aim: To compare intrarticular autologous platelet-rich plasma with methyl prednisolone acetate in management of adhesive capsulitis of shoulder. **Materials and Methods**: This prospective randomized study was conducted in the Department of Orthopaedics among 60 subjects more than 18 years of age were included in the study and divided into Group A-receiving PRP and Group B receiving methylprednisolone. Clinical assessment was made before injection 1 month and 3 months following injection and consisted of pain and function assessment on Shoulder Pain and Disability Index (SPADI) and Visual Analogue Scale (VAS). All the data thus obtained was arranged in a tabulated form and analyzed using SPSS software. **Results**: There was a significant decrease in VAS score at 1 and 6 months among both the group, however VAS was decreased more in PRP group. The SPADI scores decreased significantly in both PRP and steroid group. However in intergroup comparisons, the improvement was more significant statistically in the PRP group at 3 months. **Conclusion**: Both PRP & Steroid showed improvement in treating frozen shoulder. However, PRP resulted in significant pain relief and greater functional improvement in shoulder motion compared with steroid injection. This study highlights the growing importance of PRP in chronic musculoskeletal conditions such as AC, especially in clinical scenarios where CS is contraindicated or refused by the patient.

Keywords: Platelet-Rich Plasma, Methyl Prednisolone Acetate, Adhesive Capsulitis, Shoulder, VAS

INTRODUCTION

Adhesive capsulitis is defined as a thickened, contracted glenohumeral joint capsule with scarcity of synovial fluid and chronic inflammatory changes in capsule[1]. Adhesive capsulitis is the condition which is characterised by painful and restriction of active & passive glenohumeral range of motion more than 20% in at least two directions[2]. Adhesive capsulitis (AC) is one of the common causes of shoulder pain and disability in the upper extremity. It affects the functions of glenohumeral (GH) joint, limiting both active and passive movements of the shoulder. Limitation of passive range of movements (ROMs) of the shoulder, particularly external rotation, has remained pivotal to the clinical diagnosis of AC. In the general community, the incidence of adhesive capsulitis in the general population is estimated to be 3-5%, while the prevalence in patients with diabetes is 10-24%[3].

It usually develops between 40-70 years of age. The underlying pathology is soft tissue fibrosis and inflammation of rotator interval, capsules and ligament. The symptoms are generally self-limiting over one to three years and condition more common in females than males and the greatest incidence occurs in the 5th and 6th decades. The X-ray appearances may show either nothing abnormal or calcific deposits in the capsule or periarticular tissue[2].

The goals of treatment of AC are to relieve pain, restore movement, and ultimately regain shoulder function. Various treatment options like intra-articular injection of corticosteroid, hyaluronic acid, deep heat modalities, manipulation under anesthesia, hydro dilation, arthroscopic release has been tried but none of them proved to superior in managing the condition successfully[1].

Intra-articular corticosteroid (IA-CS) injection still remains one of the most common procedures for

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treating AC because of its cost-effectiveness and acceptance among patients. Studies have shown that CS into the shoulder joint provides symptomatic relief and limits the development of capsular fibrosis. However, corticosteroid injection has been linked to hyperglycemia, articular cartilage damage, an increased risk of tendon rupture, local skin depigmentation & subcutaneous tissue atrophy. Given the potential negative effects of steroid injections, physicians and patients must understand how to design the best treatment strategy for patients with adhesive capsulitis who are contraindicated to or unwilling to receive corticosteroid injection[4].

Another practice of modern medicine is to inject methylprednisolone to prescribe anti-inflammatory medications. Platelet-rich plasma (PRP) is an orthobiologic that has recently gained popularity as an adjuvant treatment for musculoskeletal injuries. The platelets contain alpha granules that are rich in several growth factors, such as platelet derived growth factor, transforming growth factor-ß, insulin-like growth factor, vascular endothelial growth factor and epidermal growth factor, which play key roles in tissue repair mechanisms. The PRP injection therapy can have a beneficial effect in the management of frozen shoulder[5,6].

Evidences from previous studies have shown that PRP has anti-inflammatory and regenerative qualities and is quite safe alternative to corticosteroids. Based on this background of limited evidence of effectiveness of intra-articular PRP in adhesive capsulitis, it is not used as much as intra-articular corticosteroid injection. Given the background of inconclusive evidence for treatment modalities & recent introduction of PRP as a biological agent promoting healing, there is a need to examine the role of PRP & compare its efficacy with steroid injection.

MATERIAL AND METHODS

The present prospective comparative study was conducted in the Department of Orthopedics after getting clearance from Ethical Committee (IEC) among 60 patients with Adhesive Capsulitis Of Shoulder who fulfilled the inclusion and exclusion criteria were enrolled for study.

Inclusion criteria

- All Adult Patients with Adhesive Capsulitis of Shoulder after informed and written consent.
- All patients diagnosed clinically with Adhesive Capsulitis of shoulder that are between Stage 1-4 (not relieved with physiotherapy and analgesic trial at 3 months of onset.)
- All Patients who developed Adhesive capsulitis of shoulder due to any cause.

Exclusion criteria

- Patients with previous history of Intra-articular steriod injection in affected shoulder.
- Patients with Persistent symptoms after single intra-articular injection, was excluded from the study and were treated with different mode of treatment.
- Any bony injury in the ipsilateral shoulder joint.
- Rotator cuff tear on the affected side.
- Overlying skin lesion, skin abrasion, superficial infection.

Methodology

a. Patient with shoulder pain and restricted movement who come in department of orthopaedics was undertaken for study after informed and written consent.
b. Patients were divided into 2 groups (PRP and MethlyPrednisolne Acetate) by simple randomisation using chit and box method.
c. Under all aseptic conditions either MethlyPrednisolne Acetate or Platelet Rich Plasma injection was given in affected shoulder as per respective groups allotted post injection care was done according to the protocol.
d. SPADI[7] and VAS[8] was assessed before injection and at 1week, 1 month, 3 months and 6 month of follow up period.

Platelet Rich Plasma was made by PRP METHOD. This freshly prepared PRP (5ml) was injected in the affected shoulder within 2 hour of preparation. No local anaesthesia was used before injection. Under full aseptic precautions PRP/MethlyPrednisolne Acetate was injected in affected shoulder with a 22G needle using standard approaches. Accordingly, Patients in PRP group received 5ml PRP solution and those in MethlyPrednisolne Acetate group was given 80mg Methylprednisolone acetate in Sitting Position.

Post Procedure protocol

- After the injection patient was told to actively do ROM of shoulder for few times daily.
- Patient was sent home after 15-20 minutes of rest.
- Patient was advised to use cold packs 3-4 times a day for 10 minutes till 72 hours.
- Patients were encouraged to perform Shoulder strengthening exercises.
- Patient was prescribed: *Tablet – Tramadol 50 mg SOS
- Follow up were advised after a period of 1week, 1, 3, and 6 months.

Statistical analysis

Data so collected was tabulated in an excel sheet, under the guidance of statistician. The means and standard deviations of the measurements per group were used for statistical analysis (SPSS 22.00 for windows; SPSS inc, Chicago, USA). For each assessment point, data were statistically analyzed using one way ANOVA along with Tukey HSD Post Hoc test. Difference between two groups was

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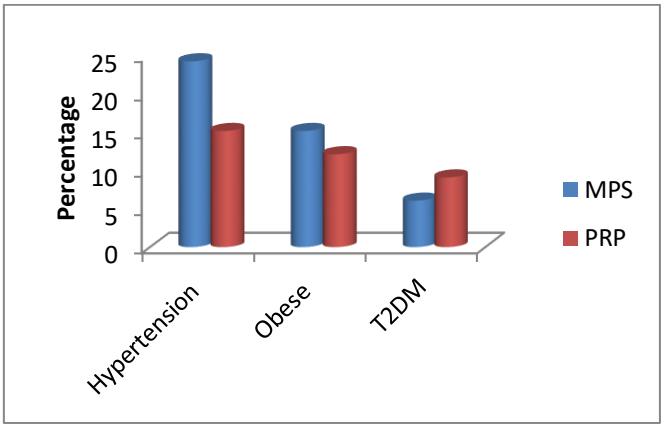
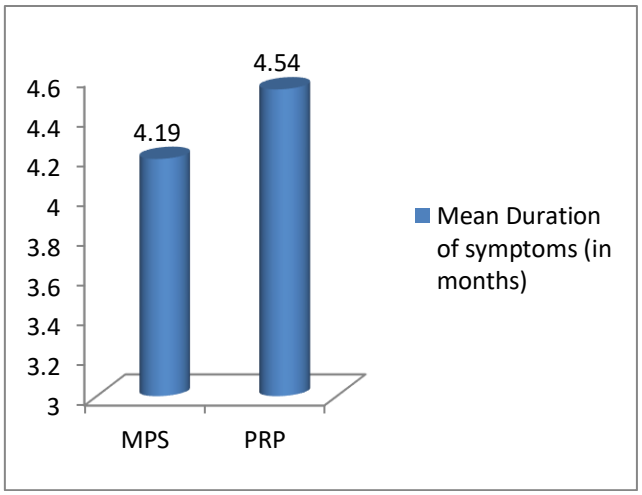
determined using t test as well as chi square test and the level of significance was set at $p < 0.05$.

RESULTS

Female and male comprised of 42%, 58% of the subjects in MPS and 54%, 46% in PRP group. Mean age of the study subjects in MPS was 46.94±11.98 and in PRP was 48.83±9.60 years. Co-morbidities viz. hypertension, obese and T2DM was revealed 24%, 15%, 6% in MPS and 15%, 12%, 9% of the subjects in PRP group. (graph 1).



Graph 1: Co-morbidities On an average, subjects were suffering from symptoms related to adhesive capsulitis since 4 months (graph 2).



Graph 2: Duration of Symptoms

Table 1 shows the comparison of VAS score among the study groups at different intervals. VAS score was found to be similar among the study groups before first injection. After first week and month of injection, VAS score decreased significantly in both the groups ($p<0.05$), however the decrease was slightly more in PRP group. After 3 month of injection, mean VAS score decreased by 4.66in MPS and 6.49 in PRP group. Mean VAS score decreased in PRP while it increased after 3 months to final followup in MPS group with statistically significant difference as $p<0.05$.

Table 1: Comparison of VAS score among the study groups at different intervals

Interval	MPS		PRP		p value
	Mean	SD	Mean	SD	
Before 1st Injection	8.78	0.73	8.84	0.85	0.87
1 Week After Injection	6.26	1.15	6.07	1.3	0.54
1 Month After Injection	4.87	1.12	4.63	1.03	0.43
3 Month After Injection	4.08	1.1	2.35	1.02	<0.01*
6 Month After Injection	5.76	1.19	2.07	0.78	<0.01*
p value	0.047*		0.036*		

*: statistically significant

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SPADI score was found to be similar among the study groups before first injection. After first week and month of injection, SPADI score decreased significantly in both the groups as p<0.05, however the decrease was slightly more in PRP group. After 3 month of injection, mean SPADI score decreased by 23.76 in MPS and by 48.55 in PRP group. Mean SPADI score decreased in PRP while it increased after 6 months to final followup in MPS group with statistically significant difference (p<0.05) as shown in table 2.

Table 2: Comparison of SPADI (%) among the study groups at different intervals

Interval	MPS		PRP		p value
	Mean	SD	Mean	SD	
Before 1st Injection	76.94	9.27	78.58	7.82	0.47
1 Week After Injection	71.73	14.72	70.27	11.5	0.79
1 Month After Injection	54.82	12.13	57.12	12.04	0.42
3 Month After Injection	53.18	10.61	29.73	14.26	<0.01*
6 Month After Injection	52.67	11.48	27.97	9.11	<0.01*
p value	0.005*		<0.01*		

*: statistically significant

DISCUSSION

Recently, new evidence has emerged on the effectiveness of platelet-rich plasma (PRP) injection in the treatment of chronic tendon and muscle injuries, tendinopathies, osteoarthritis etc. In PRP therapy, autologous "platelets," obtained by whole-blood centrifugation, are concentrated and then reinjected into the affected joint. Studies have suggested that injection with PRP is safe and it has antinociceptive, anti-inflammatory, and regenerative properties. Platelet-rich plasma could stimulate the healing process of tissues with chronic injuries and relieve pain and stiffness of the joints. However, its evidence of effectiveness in patients with AC is limited[6]. Hence this study was conducted to compare the clinical outcomes of intra-articular injections of Platelet rich plasma versus MethylPrednisolone acetate in patients of adhesive capsulitis of shoulder.

In this study; no difference was reported with respect to baseline characteristics among the study groups. In a study by Sanjeev Kumar et al[9], majority of patients were seen in the age group of 40- 58 years. The right side was affected more in both PRP group (n=17) and steroid (n=19). Apurba Barman et al[10] in their study too revealed that No disparity was found between the baselines characteristics of both groups including age, body mass index, duration of symptoms, initial pain score, active and passive movements of shoulder, and SPADI scores. The dominant side was affected in most cases in both groups. This is in correspondence to the present study. Somisetty T et al[11] too reported similar demographic characteristics among the study groups.

In the present study; VAS score was found to be similar among the study groups before first injection. After first week and 1 month of injection, VAS score decreased significantly in both the groups as p<0.05, but on comparing both the groups (MPS and PRP) with each other after first week (p value - 0.58) and 1 month of injection (p value – 0.47), there was no significant difference, however the decrease was slightly more in PRP group. After 3 month of injection, mean VAS score decreased from 8.82+/- 0.77 to 4.12+/- 1.14 i.e. 4.66 in MPS and from 8.88+/- 0.89 to 2.39+/- 1.06 i.e. 6.49 in PRP group. Mean VAS score kept on decreasing in MPS group till 3rd month after injection after which VAS increased in 6th while in PRP group VAS decreased till 6th month follow up (1.42), with statistically significant difference (p<0.05).

The recent study by Aslani J et al[12] shows that on treatment with PRP, VAS scores significantly improved from pre-injection level on subsequent follow up. In a study by Sanjeev Kumar et al[9] too, there was significant improvement in the pain score after PRP injection from 8.53±0.51 to 1.07±1.36 at final follow up. A similar trend was also observed by Kothari et al[13] in their study, IA-PRP group patients showed significant improvements in terms of pain compared with IA-CS group, but this study was complicated by lack of standardized PRP preparation technique. Scarpone et al[14] also showed improvements in pain after a single injection of PRP in patients with rotator cuff tendinopathy. A case study, reported by Aslani et al[12] in 2016, also showed good results with PRP in frozen shoulder[1].

However, Kesikburun et al[15] failed to show significant improvements with PRP injection, compared with placebo injection in patients with rotator cuff tendinopathy. However, most of these studies were done on patients with rotator cuff tendinopathy and injections were given extra-articularly, in the subacromial bursa, and they did not compare effects of IA-PRP injection with IA-CS injection.

Similarly Apurba Barman et al[10] in their study showed that intra-articular platelet-rich plasma injection provided better pain relief compared with IA-CS injection at 12 wks. Immediately after interventions in the first 3 weeks, both groups showed a significant decrease in pain scores. More than 50% pain improvements, as measured by VAS pain scores, were observed in both groups at 3 weeks. At 3 weeks, no statistically significant differences were obtained

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among the two groups, but later at the end of 12 weeks, IA-PRP group showed significant improvement in pain score.

SPADI score was found to be similar among the study groups before first injection. After first week and month of injection, SPADI score decreased significantly in both the groups as $p<0.05$, however the decrease was slightly more in PRP group. After 3 month of injection, mean SPADI score decreased from 76.91 to 53.15 (i.e. 23.76) in MPS and from 78.55 to 29.07 (i.e. 48.55) in PRP group. Mean SPADI score decreased in PRP on 6 month (27.94) till final follow up (12.35), while it increased after 6 months (52.64) to final follow-up (65.54) in MPS group with statistically significant difference as $p<0.05$ in this study. On comparing SPADI score in MPS group on 1month with 3 month (0.742) and 3 month with 6 month the score worsened (0.79), whereas in PRP group SPADI score shows significant difference till final follow up with statistically significant difference (<0.01).

According to Somisetty T et al[11], the mean difference in SPADI between the study groups at pre-injection, post-injection, two weeks, and four weeks was not statistically significant ($P>0.05$). However, a significant difference was discovered in SPADI at eight weeks, 12 weeks, and 24 weeks. Apurba Barman et al[10] in their study too reported that intra-articular platelet-rich plasma injection provided better pain relief and greater functional improvement compared with IA-CS injection at 12 weeks.

A similar trend was also observed by Kothari et al[13] in their study, IA-PRP group patients showed significant improvements in terms of shoulder motion compared with IA-CS group. Scarpone et al[14] and Tahririan et al[16] in their studies also showed improvements in function after a single injection of PRP in patients with rotator cuff tendinopathy. The present study proves the efficacy of steroid at short term as suggested by other authors like Saedian SR et al[17] and Kothari SY et al[13] with improvement in active and passive movement.

LIMITATIONS

a. We did not explore the cost-benefit analysis of treatments. Compliance with the home rehabilitation program was not measured.
b. We did not use any special technique advocating the activation of platelets in the PRP after preparation. We did not estimate the growth factor levels in our PRP product, because many studies have shown that the dose-response curves of growth factors are not linear and may be inhibitory at higher concentrations.
c. We administered a single injection when few studies had shown that multiple injections at interval can provide better improvement than a single injection. We believed that subsequent rehabilitation exercises after single injection would be influential for long-term functional improvement.

CONCLUSION

Both PRP (Platelet Rich Plasma) &MPS showed good efficacy in treating Adhesive Capsulitisof shoulder, however the effect of PPRP is gradual in onset with better outcome on follow up till 6 months. Platelet-rich plasma showed better long-term outcomes than MPS, suggesting that PRP can be used as a treatment modality in managing Adhesive Capsulitis for better results. We emphasize the emerging importance of PRP in treating chronic musculoskeletal disorders like AC, particularly in situations where the patient refuses or is contraindicated for MPS treatment.

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