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*Original Research Article*

# Ultrasound guided platelet rich plasma versus corticosteroid injection in the treatment of rotator cuff disease: A randomized controlled trial

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## Abstract

**Introduction:** More than 50% of all shoulder pains are attributed to Rotator cuff diseases. Platelet rich plasma (PRP) is a preparation of concentrated autologous platelets containing growth factors and bio active substances essential for musculoskeletal healing. The purpose of this study is to compare the effectiveness of platelet-rich plasma injection versus corticosteroid injection with respect to pain relief and functional recovery.

**Methods:** Sixty five patients with rotator cuff disease have been randomized into 2 groups. One group received PRP and another group received corticosteroid injection. The primary outcome pain is assessed by visual analogue scale. Secondary functional outcome is assessed by passive range of movements and WORC score.

**Results:** VAS score, ROM and WORC score have significantly improved up to 12 months when compared to pre-interventional scores in both the groups. The mean VAS score was significantly lower in CS group compared to PRP group at 3 weeks follow-up ($p<0.05$).

The mean WORC score was comparable between both the study groups at 3 weeks follow-u p. ($p>0.05$). There were no significant differences in the WORC, ROM, or VAS scores between the two groups at 3 months, 6 months, and 12 months follow-up.

**Conclusion:** Corticosteroid injection produced superior pain relief and improved ROM but same functional recovery compared with PRP injection for rotator cuff diseases at short term follow-up (3weeks). However, there was no statistically significant difference between the 2 groups in pain relief and functional outcomes at the mid-term (3-6 months) or long-term (12 months) follow-up suggesting both are equally effective.

**Keywords:** PRP, corticosteroids, visual analogue scale, WORC score

## Introduction

An estimated 0.9% to 2.5% of the population reports shoulder area pain, and the prevalence increases rapidly with age, reaching as high as 6.7% to 66.7% over a lifetime [1].

Shoulder area pain is often complex and multifaceted and may be accompanied by several changes in the shoulder structures [2]. Rotator cuff disease (RCD) is a leading cause of shoulder pain and a significant source of disability and loss of work. It is a common disorder, and its prevalence increases with age and with occupations involving overhead activities[11]. Rotator cuff disease is the degeneration of the four RC muscle tendons, and calcific deposits of tendon can be concurrent [2].

Management of RCD without full-thickness tear is mainly conservative in addition to non-steroidal anti-inflammatory drugs (NSAIDs), physiotherapy, manipulation, and injection

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therapies and ultrasound guided needling (barbotage) [16], which show a high rate of recurrence and persistent pain due to the limited ability of rotator cuff tendon to regenerate leading to chronic tendon disease [11].

Injection therapy options include corticosteroids (CSs), platelet-rich plasma (PRP), and hyaluronic acid. A meta-analysis suggests that CS may yield short-term symptom alleviation; however, PRP may be better in the long term [6]. PRP injection therapies have shown great potential in RC-related problems as well as in other tendon and joint related disorders [5].

Only few studies directly compared subacromial injections of PRP with CS, and further comparisons to the widely used CS injections are still warranted. Most previous studies were conducted using a very small number of patients and/or had a short follow-up [16].

The aim of this study was to compare the clinical and functional outcomes of sub-acromial PRP and CS injections in Rotator cuff diseases.

## Objectives

1. To compare the effectiveness of platelet-rich plasma (PRP) injection versus corticosteroid injection in, pain relief, in patients with Rotator cuff diseases treated non-operatively.
2. To compare the effectiveness of platelet-rich plasma (PRP) injection versus corticosteroid injection in functional recovery of shoulder in patients with rotator cuff diseases treated non-operatively.

## Materials and Methods

### Source of data

Patients presenting to orthopedic OPD who are meeting the inclusion criteria at Basaveshwara Medical College and Hospital, Chitradurga during the study period, will be considered.

**Study design:** Randomized control trial
**Study period:** 12 Months (July 2021 to June2022)
**Place of study:** Orthopedic department at Basaveshwara Medical College Hospital. Chitradurga.
**Sample size:** All patients meeting the inclusion criteria during the study period

### Inclusion criteria

1. Patients aged between 35 years to 75 years of either sex.
2. Patients with Rotator cuff tendinitis.
3. Patients with partial rotator cuff tear diagnosed by musculoskeletal USG.
4. Patient willing to give consent for the study.
5. Shoulder pain duration more than 3 weeks.

### Exclusion criteria

1. Patients with full thickness rotator cuff tear.
2. Patients with prior steroid injection into the same shoulder joint.
3. Patient with prior surgical intervention to the same shoulder joint.
4. Patients with shoulder joint infection.
5. Systemic diseases like bleeding disorder, Rheumatoid Arthritis and Diabetes.

### Methodology

This study is an open-label randomized clinical trial, The study is conducted after obtaining institutional ethical committee approval.

Patients who meet the eligibility criteria will be included in this study after explaining the purpose of the study and obtaining written and informed consent. A thorough history will be taken and clinical examination will be done.

The enrolled patients are randomized into two groups

1. PRP group

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2. Corticosteroid group

Randomization is performed using a Computer-generated Random number table.
The random number table is generated prior to the initiation of enrolment for the study USG of the affected shoulder joint is done to Diagnose Rotator cuff diseases and to rule out complete Rotator cuff tear.

**Patient Selection**
A total of 65 patients (PRP, n=30; CS, n=30) were included in the final analysis after inclusion and exclusion criteria were applied.
A two-sided p-value of ≤0.05 was set as statistically significant. For comparisons between the study groups, we used Student t-test for continuous variables and Fisher exact test for discrete variables, according to the data type.
We evaluated the pre-intervention parameters and identified differences in the WORC emotions sub-score.

**Procedure**
Patients are randomized into PRP and Corticosteriods group by computer generated randomization table. Patients received either single injection of 1mL (40 mg/ml) of triamcinolone or 4-5 mL injections of autologous PRP single injection in the subacromial space. The injection was performed by an experienced orthopaedic surgeon using anatomical landmarks with ultrasound guidance.
The PRP preparation protocol was as follows: 20 ml of venous blood was drawn from the patient. The blood was centrifuged at 1,500 revolutions per minute (rpm) for 5 minutes, the RBCs were discarded, and a second centrifugation was performed for 10 minutes at 3,500 rpm. White blood cells were not separated from the PRP. The final product contained approximately 4-5 ml of PRP with four to eight time's higher platelet concentration than the normal physiological level.

**Intervention**
PRP is injected into the center of the lesion in Rotator cuff tendon under real time USG guidance through subacromial approach.
Corticosteroid group Inj. Triamcinolone 40 mg is injected into the subacromial space similar to PRP injection under USG guidance.
After the injection Home based isotonic strengthening and stretching exercise are advised for 6 weeks.

**Follow up and criteria for evaluation**
The patients will be followed up clinically at 3weeks and 3 months, 6 months and 12 months, At every follow up clinical examination will be done to assess status of the, pain, tenderness, range of motion and function of shoulder joint.

**Primary outcome:** Pain assessed with I- Visual analogue score
**Secondary outcome:** Shoulder function assessed with passive range of movements
1. Flexion
2. Extension
3. Abduction
4. Adduction
5. External rotation
6. Internal rotation

2) Western Ontario Rotator Cuff Index (WORC) score is used to evaluate the functional outcomes

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**Method of Use**

The WORC Index is a self-administering health questionnaire – (PROM) patient reported outcome measures.

It has 21 items, exploring 5 different domains:

1. Physical symptoms
2. Sports and recreation
3. Work
4. Social function
5. Emotions

Each question uses a visual analogue scale (VAS) - which is a straight line, representing a 100-point scale, ranging from 0-100.

The maximum score is 2100 (worst possible symptoms). Zero (0) represents no symptoms at all.

1. The score can be reported as a percentage by subtracting the total from 2100, dividing by 2100, and multiplying by 100. This will give you an overall percentage. Total final WORC scores can, therefore, range from 0% (lowest functional status level) to 100% (the highest functional status)

$$\text{WORC score percentage} = \frac{2100 - \text{Total WORC score x } 100}{2100}$$

**Statistical analysis**

The data will be presented as Mean, +/- SD, percentages. Data will be analyzed using appropriate statistical tests. The normality of distribution of variables will be assessed by appropriate variables. Appropriate statistical tests were applied to assess the significance of association among the study variables. Data will be compiled in MS Excel spread sheet and analyzed using SPSS version 20, and p value 0.05 is considered as significant

**Result**

A total of 60 patients treated for Rotator cuff diseases between July 2021 to June2022 were included in the final analysis. Of them, 30 patients (50%) received PRP injections while 30 (50%) received a CS injection. (Fig.1).

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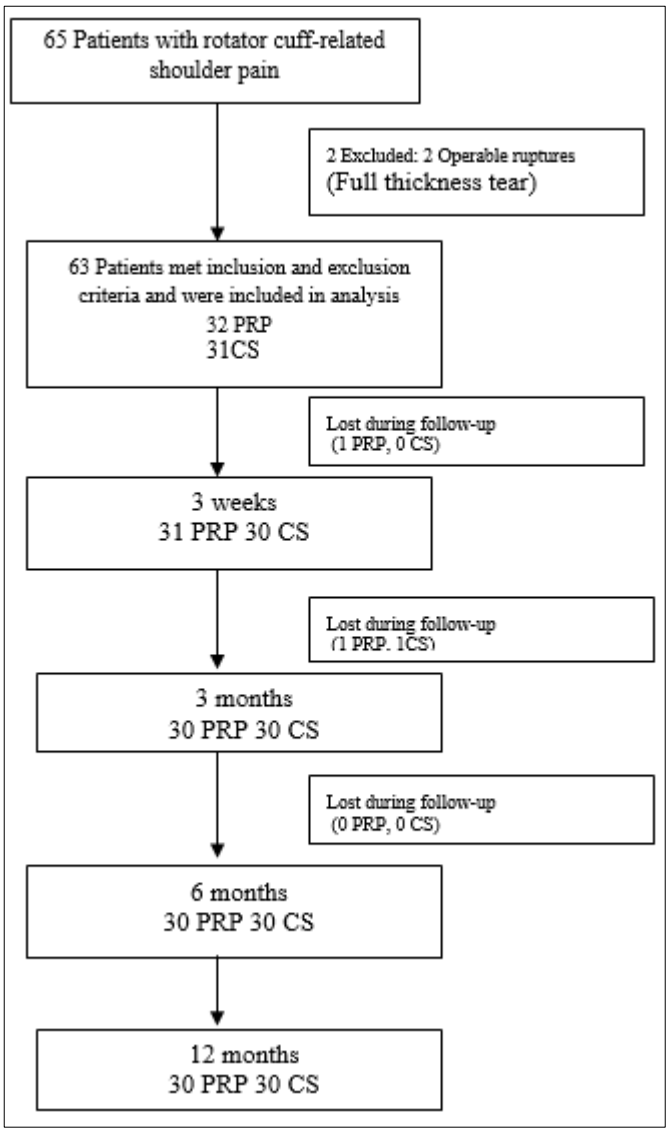


**Fig 1:** Flow chart

Demographic data are outlined in Table 1 the parameters showed no significant difference in age, gender, BMI and co-morbidities, in two study groups before intervention.

**Table 1:** Demographic charecterstics of patient

| Variables | PRP Group | Corticosteriod Group | P value |
|---|---|---|---|
| Age | 54.5±5.2 | 55.2±4.8 | 0.667 |
| Male | 18 | 13 | 0.2 |
| Female | 12 | 17 | |
| Mean (bmi)kg/$m^2$ | 27.8±2.1 | 28.8±2.5 | 0.17 |
| Diebetes | 4 | 2 | 0.54 |
| Hypertension | 4 | 5 | 0.62 |
| Cardiac diseases | 5 | 4 | 0.73 |
| Lipid diseases | 5 | 4 | 0.73 |

Table 2 shows the Comparison of pre interventional parameters pain, Range of movements and functional score in the two groups of patients. Both the study groups were comparable in term of VAS, WORC, Flexion, Extension, Abduction, Adduction Internal Rotation, External Rotation before intervention ($p>0.05$). There is no significance difference between the 2 groups in VAS,ROM shoulder and WORC scores before intervention.

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**Table 2:** Comparison of pre interventional parameter pain score, range of moments, in the two groups of patients

| S. No | Variables | PRP group (20) | CS group (20) | p-value |
|---|---|---|---|---|
| 1 | **VAS (1-10 scale)** | 6.7 ± 1.8 | 6.1±1.6 | 0.27 |
| 2 | **Range of movements** | | | |
| | Flexion | 114.90 ± 35.58 | 132.42 ± 33.70 | 0.11 |
| | Extension | 34.15 ± 10.72 | 35.40 ± 10.80 | 0.7 |
| | Abduction | 100.80 ± 34.07 | 116.42 ± 40.42 | 0.19 |
| | Adduction | 20.50 ± 8.23 | 21.20 ± 7.0 | 0.7 |
| | Internal rotation | 62.24 ± 18.06 | 60.20 ± 18.38 | 0.72 |
| | External rotation | 58.64 ± 22.80 | 56.12 ± 22.66 | 0.72 |
| 3 | WORC Score | 30.85 ± 18.43 | 32.56 ± 15.97 | 0.94 |

Table 3 shows the Comparison of study parameters of pain and function after intervention at 3 weeks follow-up. The mean VAS score was significantly lower in CS group compared to PRP group when independent sample t-test was applied at 3 weeks follow-up ($p<0.05$).We found that the corticosteroid group had better extension, flexion and adduction which was significantly higher compared to PRP group ($p<0.05$). We found that the mean abduction was also higher in CS group compared to PRP group, however, this difference was not statistically significant ($p>0.05$).

The mean WORC score was comparable between both the study groups at 3 weeks follow-up. ($p>0.05$).

**Table 3:** Comparison of study parameters of pain and shoulder function at 3 weeks follow-up

| S. No | Variables | PRP | CS | P-value |
|---|---|---|---|---|
| 1 | VAS score | 4.30 ± 1.62 | 2.56 ± 1.89 | 0.003 |
| 2 | **Range of movements** | | | |
| | Flexion | 114.42 ± 38.03 | 142.40 ± 32.78 | 0.018 |
| | Extension | 36.52 ± 10.36 | 45.59 ± 11.39 | 0.012 |
| | Abduction | 106.39 ± 32.18 | 126.63 ± 40.10 | 0.086 |
| | Adduction | 22.16 ± 7.37 | 27.53 ± 5.29 | 0.014 |
| | Internal rotation | 69.52 ± 16.10 | 65.81 ± 20.52 | 0.52 |
| | External rotation | 67.82 ± 22.15 | 65.18 ± 24.83 | 0.72 |
| 3 | WORC score | 42.66 ±16.72 | 46.87 ± 19.49 | 0.46 |

Table 4 shows The post interventional data showed no significant differences in the WORC, ROM, or VAS scores between the two groups at 3 months,

**Table 4:** Comparison of study parameters of pain and shoulder function at 3 months follow-up

| S. No. | Variables | PRP | CS | P- Value |
|---|---|---|---|---|
| | 3 Months follow up | | | |
| 1 | VAS score | 3.75 ± 2.15 | 3.84 ± 2.07 | 0.8 |
| 2 | **Range of movements** | | | |
| | Flexion | 132.73 ± 39.06 | 140.09 ± 36.98 | 0.54 |
| | Extension | 46.16 ± 11.19 | 50.76 ± 9.02 | 0.16 |
| | Abduction | 115.66 ± 36.75 | 127.50 ± 43.68 | 0.35 |
| | Adduction | 26.50 ± 4.57 | 27.69 ± 4.73 | 0.43 |
| | Internal rotation | 78.50 ± 13.3 | 77.50 ± 15.18 | 0.82 |
| | External rotation | 74.83 ± 20.36 | 64.03 ± 26.42 | 0.15 |
| 3 | WORC score | 49.93 ± 22.36 | 48.46 ± 20.60 | 0.83 |

Table 5. The post interventional data showed no significant differences in the WORC, ROM, or VAS scores between the two groups at 6 months.

No adverse events were detected during the follow-up because of the injection procedures.

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**Table 5:** Comparison of study parameters of pain and shoulder function at 6 months follow-up

| S. No. | Variables | PRP | CS | P-value |
|---|---|---|---|---|
| | 6 Months follow-up | | | |
| 1 | VAS score | 3.10 ± 1.9 | 3.8 ± 2.0 | 0.2 |
| 2 | **Range of movements** | | | |
| | Flexion | 140.50 ± 32.4 | 142.62 ± 32.4 | 0.49 |
| | Extension | 54.24 ± 10.18 | 53.58 ± 7.15 | 0.81 |
| | Abduction | 143.82 ± 32.04 | 139.24 ± 39.24 | 0.68 |
| | Adduction | 32.5 ± 2.64 | 30.44 ± 5.18 | 0.12 |
| | Internal rotation | 84.16 ± 9.38 | 80.62 ± 12.54 | 0.31 |
| | External rotation | 78.58± 16.30 | 74.45 ± 24.29 | 0.53 |
| 3 | WORC score | 56.90 ± 22.46 | 53.44 ± 20.45 | 0.61 |

Table 6. The post interventional data showed no significant differences in the WORC, ROM, or VAS scores between the two groups at 12 months follow-up.
No adverse events were detected during the follow-up because of the injection procedures.

**Table 6:** Comparison of study parameters pain and function at 12 months follow-up

| S. No. | Variables | PRP | CS | P-Value |
|---|---|---|---|---|
| | 12 Months follow-up | | | |
| 1. | VAS score | 5.2 ± 1.8 | 5.6 ± 2.2 | 0.2 |
| 2. | **Range of movements** | | | |
| | Flexion | 138.50 ± 32.4 | 130.62 ± 32.4 | 0.49 |
| | Extension | 52.24 ± 12.18 | 49.58 ± 8.15 | 0.81 |
| | Abduction | 138.82 ± 31.06 | 130.24 ± 30.22 | 0.68 |
| | Adduction | 28.52 ± 1.64 | 26.44 ± 6.18 | 0.12 |
| | Internal rotation | 78.16 ± 10.38 | 70.60 ± 15.52 | 0.31 |
| | External rotation | 78.58± 16.30 | 74.45 ± 24.29 | 0.53 |
| 3. | WORC score | 52.88± 22.46 | 46.44 ± 22.46 | 0.61 |

The VAS score before intervention has significantly decreased (better pain relief) in subsequent follow-up period at 3 weeks, 3 months, 6 months and 12 months in both PRP and CS group
Functional outcome using WORC score as significantly improved in both the groups during the follow-up at 3 weeks, 3 months, 6 months and 12 months when compared to pre-intervention WORC score. There was a significant improvement in VAS score and ROM shoulder (flexion, extension, adduction) in the CS group compared to PRP group at 3weeks.
Otherwise there is no significant difference between the 2 groups with respect to VAS score, ROM shoulder, shoulder function at any follow up - at 3 months, 6 months and 12 months.

## Discussion

In this study, functional recovery and pain alleviation in patients with rotator cuff diseases (Tendinitis and Partial thickness tear) treated non-operatively are compared between platelet-rich plasma (PRP) injection and corticosteroid injection.
It appears that the healing rate has not been improved to date due to the biologic characteristics of the aged tendon. Recently, focus has shifted to the biology of tendon repair as a way to enhance how these injuries heal. The use of growth factors in biologic treatment methods for rotator cuff injuries may be advantageous. Stimulation of growth factor concentrates may lead to an increase in tenocyte proliferation, maturation.
PRP injection versus corticosteroid injection has been evaluated in recent years for the treatment of a number of musculoskeletal conditions, including plantar fasciitis, elbow epicondylitis, knee osteoarthritis, patellar and achillis tendinitis and rotator cuff lesions. However, it is still unclear if PRP injection is more effective than corticosteroid injection as a conservative treatment for rotator cuff diseases. Since its introduction in 1950 [22],

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corticosteroid injection has been used often for tendinous lesions [23].

There isn't enough solid information to say if corticosteroid injections for the treatment of rotator cuff injuries have any long-term impact, according to a number of clinical trials [29, 30]. Recent systematic evaluations have demonstrated that corticosteroid injection is more effective than PRP injection in the short term for treating hip osteoarthritis [32] and elbow epicondylitis [26]. PRP and corticosteroid injection efficacy in patients with rotator cuff injuries has been compared in certain recent emerging RCTs [24, 27, 28], although the findings are debatable.

Corticosteroid injection produced statistically better short-term functional recovery and pain relief than PRP injection for rotator cuff injuries. A corticosteroid injection, on the other hand, may result in negative side effects include subcutaneous atrophy, recurrence, effusion, infection, systemic absorption, skin depigmentation and subcutaneous tendon rupture [25, 33, 34]. Alternative therapies were needed to progress the status of treatment due to the short-term efficacy and potential negative effects.

The aetiology of rotator cuff tendinopathy has been largely explained by the notion of overuse damage throughout the last few decades [35]. Tendons have a finite capacity for regeneration [36]. It has been proposed that a lack of healing capability, rather than inflammation, is the primary cause of chronic tendinopathy [35]. Therefore, treating this condition may be possible using novel biological therapeutics like PRP. Growth factors, bioactive cytokines, and other chemokines found in PRP are thought to encourage tissue repair and trigger tissue regeneration by enhancing cellular proliferation, enhancing cellular migration, speeding up angiogenesis, and boosting matrix deposition [37, 38].

Shams *et al*. demonstrated that the PRP group had better results in early stages of follow-up (3 months), but they detected no statistical differences in the long-term (6 months) results. Their study was randomized, including MRI for confirmed partial RC ruptures with persistent (over 3 months) shoulder pain [43]. In our study we compared Platelet-rich plasma injection and corticosteroid injection for conservative treatment of rotator cuff disease, revealed short-term (3 weeks) efficacy of corticosteroid injection and no significant medium- to long-term difference between corticosteroid and PRP injection in the treatment of rotator cuff diseases.

In a study by Scarpone *et al*. evaluating the effects of PRP among patient with RC tendinopathy resistant to physical rehabilitation, they found that after injection of Lignocaine (1%) and 3.5ml of PRP within the lesion, during a 52-week follow-up, functional scores showed a significant improvement (at weeks 8 and 12 of follow-up) [44]. Our study also showed significant improvement on medium and long term (3months, six months), following PRP injection. When compared to pre-interventional parameters (pain and function)

In a double-blind randomized controlled trial conducted by Kwong CA, Woodmass JM, *et al*. where they compared PRP and corticosteroid injection in patients with partial-thickness rotator cuff tears [10]. PRP obtained superior improvement in pain and function at short-term follow-up (3 months). There was no sustained benefit of PRP over CS at longer-term follow-up (12 months). In our study corticosteroidsteroid group has better pain relief at 3 weeks but no significant difference between these two group at 3 months, 6 months and 12 months.

Sabaah, Hala M. Abd Elsabour; Nassif, Mary A. conducted a RCT, where they compared the efficacy of deep prolotherapy, platelet-rich plasma, and betamethasone corticosteroid for treatment of Rotator cuff diseases to find the most effective one based on clinical, functional, and radiological assessment[11]. They found out that Prolotherapy injections improve shoulder ROM, VAS, WORC index, and rotator cuff tendon healing while PRP injections improve WORC index and tendon healing but steroid injection has no effect on healing. Whereas in our study where we compared PRP with corticosteroids, corticosteroid group had good outcome in short term, and there was no significant difference in long term outcome between 2 groups.

In a study conducted by Wang C, Zhang Z, Ma Y *et al*. where they compared Platelet-rich plasma injection and corticosteroid injection for conservative treatment of rotator cuff lesions[14], revealed short-term efficacy of corticosteroid injection and no significant medium-to long-term difference between corticosteroid and PRP injection in the treatment of rotator

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cuff lesions. Similar results were obtained in our study too.

In A randomized clinical trial study conducted by Dadgostar H, Fahimipour F *et al*. Where they compared Corticosteroids with PRP injections for rotator cuff Partial thickness [15], showed that PRP renders similar results to that of corticosteroids in most clinical aspects, in our study similar results are obtained except corticosteroids showed better short term results compared to PRP.

In a comparative study by Annaniemi JA, Pere J, Giordano S. where they compared Platelet-rich plasma versus corticosteroid injections for rotator cuff Partial thickness Rotator cuff tear [16] showed no significant differences were detected between the two groups in any of the primary (WORC) or secondary outcomes over 6, 12, and 18 months. Similarly in our study too, there was no significant long term change in outcomes between 2 study groups at 3, 6 and 12 months.

## Conclusion

Our research showed that the CS group outperformed the PRP group in terms of results at the 3-week follow-up. In comparison to the PRP group, the mean VAS score was considerably lower in the CS group at 3 week. In terms of ROM, we discovered that the corticosteroid group had much better extension, flexion, and adduction than the PRP group 3week. At the 3-week follow-up, the mean WORC scores for the two study groups were comparable.

However, after a lengthy follow-up of three and six months, neither group's WORC, ROM, or VAS ratings revealed any discernible differences. The same outcomes were discovered during a 12-month follow-up. WORC, ROM, and VAS ratings did not significantly differ between the two study groups. Nevertheless the mean VAS score and functional outcomes improved significantly in both CS and PRP group at 3 weeks, 3 months, 6 months and 12 months when compared with pre-interventional parameters.

Thus, we draw the conclusion that this study demonstrated that, follow-up period, corticosteroid injection produced statistically significant superior functional recovery and pain reduction compared with PRP injection for rotator cuff injuries at short term follow-up only (3weeks). However, there was no statistically significant difference between the 2 groups at the medium-term (3-6 months) or long-term (beyond 12 months) follow-up.

Both CS and PRP are equally effective in relieving shoulder pain and improving functional outcomes. Thus we recommend PRP injections for conservative treatment of rotator cuff diseases over corticosteroids as we can avoid negative side effects of corticosteroid group.

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