

Original Research Article

A randomized controlled study comparing the efficacy of ultrasound guided intra articular-triamcinolone vs platelet rich plasma in active phase (stage 1) of adhesive capsulitis (frozen shoulder)

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ABSTRACT

Background: Adhesive capsulitis is a common cause of shoulder pain and restricted movement. Various treatment options exist, ranging from analgesics and steroid injections to biologics like platelet-rich plasma (PRP). PRP offers potential healing benefits with minimal immunological risk. Given conflicting evidence for existing therapies and the growing use of PRP, comparing PRP with steroid injections is warranted.

Methods: A randomized, single-blinded controlled trial included 84 patients aged 30–70 years with adhesive capsulitis. Participants were randomized into Group A (triamcinolone 80 mg) and Group B (2 ml autologous PRP). Outcome measures included Visual Analogue Scale (VAS), range of motion (ROM), Shoulder Pain and Disability Index (SPADI), and Constant-Murley Score (CMS), assessed at baseline, 3 months, and 6 months. Statistical analysis employed Chi-square/Fisher's exact test and Student's t-tests.

Results: Patients receiving PRP showed significantly greater improvements in VAS, SPADI, CMS, and ROM compared to those receiving steroid injections at both 3- and 6-month follow-ups ($p < 0.001$). Transient side effects such as nausea, vomiting, and hypotension were more frequent in the PRP group but lacked statistical significance. Recurrence and lack of treatment response were higher in the steroid group.

Conclusion: PRP is more effective than triamcinolone in short-term pain relief and functional recovery among adhesive capsulitis patients, with minimal adverse effects. Larger multi-centric studies with longer follow-up are recommended to evaluate its long-term benefits and comparative efficacy with other treatments.

Keywords: Periarthritis, Adhesive capsulitis, Frozen shoulder, Platelet rich plasma, Randomized controlled trial, Triamcinolone, Intraarticular steroid

INTRODUCTION

Patients with adhesive capsulitis experience months to years of pain and disability due to the painful, gradual loss of both active and passive glenohumeral motion caused by progressive fibrosis and eventual contracture of the glenohumeral joint capsule.¹ Adhesive capsulitis affects 2% to 5% of the population, with females making up the majority of patients.² Patients range in age from 40 to 60

years.³ The nondominant hand is more often affected.⁴ In roughly 20% to 30% of those afflicted, the condition will develop in the opposite shoulder. Three stages are frequently utilized to characterize adhesive capsulitis. The first stage, known as "freezing," is characterized by progressively worsening pain and stiffness that can last for as long as nine months. The second stage, known as "frozen," entails a constant condition that lasts four to twenty months. The third stage, known as "thawing," is a

time of spontaneous recuperation that can last anywhere from five to twenty-six months.⁵ Clinically, this diagnosis is based on shoulder pain and limited range of motion, both passive and active. The natural history of adhesive capsulitis is unclear, despite the fact that it is usually characterized as a self-limiting illness process. Recent research has revealed that the condition can cause longer-term disability over a number of years.⁶⁻⁸ The patient's sleep is frequently disturbed by the pain, which is typically worse at night. Muscular atrophy in chronic cases (especially in the deltoid and supraspinatus muscles) or muscular spasms in early cases (especially in the pectoralis major and scapular muscles) are physical indicators of frozen shoulder syndrome. Having trouble putting on a coat, reaching into a hip pocket for a wallet, or combing one's hair are examples of common functional impairments. The inability to secure clothing behind their backs is a common complaint among women.⁹

Benign neglect, oral corticosteroids, intra-articular injections of corticosteroids, intra-articular injections of hyaluronic acid, physical therapy exercises, deep heat modalities, manipulation under anesthesia, hydro dilation, and arthroscopic release are just a few of the numerous treatment options that have been suggested; however, the most effective course of action is still up for debate.¹⁰ The physiological effects of ultrasonic therapy, such as improved blood flow, increased capillary permeability and tissue metabolism, improved tissue extensibility, increased pain threshold, and altered neuromuscular activity that results in muscle relaxation, make it a useful intervention.¹¹

Injections of intra-articular corticosteroids are one of the most used methods for treating PA shoulder. PRP has become a novel technology that is thought to improve and speed up tendon healing by increasing the concentration of growth factors and stimulating soft tissue revascularization. It is characterized as an autologous blood sample with platelet concentrations higher than normal.^{12,13} Numerous growth factors and cytokines, including PDGF, TGF-beta, IGF-1, IGF-2, FGF, VEGF, and EGF, are found in platelet-rich plasma. Connective tissue growth factors and keratinocyte growth factors are two novel treatments for this debilitating and excruciating illness. When compared to steroid injections and other conservative treatment methods, it has demonstrated promise in numerous studies.^{13,14} For the treatment of adhesive capsulitis, several studies demonstrate that PRP is more long-lasting and efficient than cortisone injection.¹⁴ In order to compare the effectiveness and role of autologous platelet-rich plasma injection with intra-articular corticosteroid injection in adhesive capsulitis, the current study was conducted.

METHODS

The study was conducted out at Victoria and Bowring & Lady Curzon Hospital from November 2017 to September 2019. For the study, 84 patients of either sex, aged 20–70

years, who were clinically exhibiting symptoms suggestive of adhesive capsulitis were enrolled. The study excluded patients who previously had any kind of treatment, including local steroid injections and other procedures. Individuals experiencing shoulder pain for other reasons, such as those with hematological problems or receiving antiplatelet or anticoagulant medication, autoimmune or inflammatory arthropathies, rheumatoid arthritis were excluded.

Authors also excluded participants with a history of surgery on the specific shoulder, infection, shoulder girdle complex fracture, neuromuscular illnesses, secondary frozen shoulder, any local skin pathology at the injection site, and those who refused to participate. Patients were subjected to ultra-sonographic examination of the shoulder. Ultrasonography findings in case of Adhesive capsulitis involves limitation of movement of the supraspinatus, thickened coracohumeral ligament (CHL), echogenic material around the long head of biceps at rotator interval, increased vascularity of long head of biceps at rotator interval. Using a computer-generated alphabetical sequence produced by randomization software, the patients were divided into two groups at random.

Patients in the first group received autologous platelet-rich plasma, whereas those in the second group received the steroid triamcinolone. Visual Analog Scores (VAS, SPADI, CMS, ROM, and Restricted ROM) were used to record the results. Before administering the injection on the day of the procedure, as well as after 12 and 24 weeks, the scores were entered into the prepared proforma. The results were analyzed using student t test for continuous variables and Chi-square test has been used to find the significance of study parameters on categorical scale between two groups, non-parametric setting for Qualitative data analysis.

RESULTS

The study included 84 patients out of which 49(58.3%) were males and 35 (41.7%) were females. In PRP group 24 were males and 18 were females. Most of the patients i.e., 61 (72.6%) in our study were aged between 50-70 years with an average age 56.49 ± 8.44 years. The mean duration of the condition in all 84 patients suffering from adhesive capsulitis was 5.90 ± 1.98 months.

The mean duration of the condition in PRP injection group was 5.89 ± 1.59 months and that in corticosteroid injection group was 6.07 ± 2.38 Months. P value= 0.663 which is not significant. Thus, both the groups were comparable in terms of duration of the condition. Males made up 25 of the corticosteroid injection group, while females made up 17, with a non-significant p value of 0.825. The majority of our study's patients i.e. 61 (72.6%), were between the ages of 50 and 70, with an average age of $56.49, 8.44$ years. Thus, both the groups were comparable in terms of age and sex distribution in each group. Similarly, both groups were

comparable in terms of affected limb dominance as well as duration of illness as the p value was non-significant. Both groups' mean VAS scores at the presentation were similar (6.17 ± 0.93 vs. 6.24 ± 0.93 ; $p=0.727$). With a p-value of 0.126, these scores decreased in groups A (5.21 ± 0.52) and B (5.00 ± 0.73) at 12 weeks in comparison to the baseline. Additionally, at six months, group A's mean VAS ratings dropped dramatically to 3.67 ± 0.65 , whereas group B's scores dropped to 5.40 ± 0.94 ($p<0.001$). At the 3-month follow-up, the VAS score dropped by 1.238 in the steroid group and by 0.952 in the PRP group. When compared to the baseline VAS at the 6-month follow-up, the PRP group's VAS score dropped by 2.500, and the steroid group's by 0.833. Both groups exhibited statistically significant declines in their VAS scores at three and six months ($p<0.001$).

There was a statistically significant reduction in the VAS score in Group A at 6 months compared to Group B done by student t test. The SPADI score's baseline P value of 0.437 indicates that it is not statistically significant. As a result, the values prior to the injection are similar. Group A's mean SPADI score at 12 weeks is 66.74 ± 6.11 , while Group B's is 63.55 ± 5.52 , both of which have statistically significant p values <0.014 . As a result, the PRP and corticosteroid injection groups' 12-week SPADI score improvements over their baseline scores are statistically significant. Group A's six-month SPADI score is 48.21 ± 4.19 , while Group B's is 64.86 ± 8.08 , both of which have statistically significant P values (<0.001). Therefore, at six months, the PRP injection group's improvement in SPADI scores is statistically significant when compared to the corticosteroid injection group. Similarly, Group A's CMS score at six months is 74.71 ± 6.32 , while Group B's is 53.97 ± 6.73 , both of which have statistically significant P values (<0.001). Therefore, at six months, the PRP injection group's CMS score improvement over the corticosteroid injection group is statistically significant.

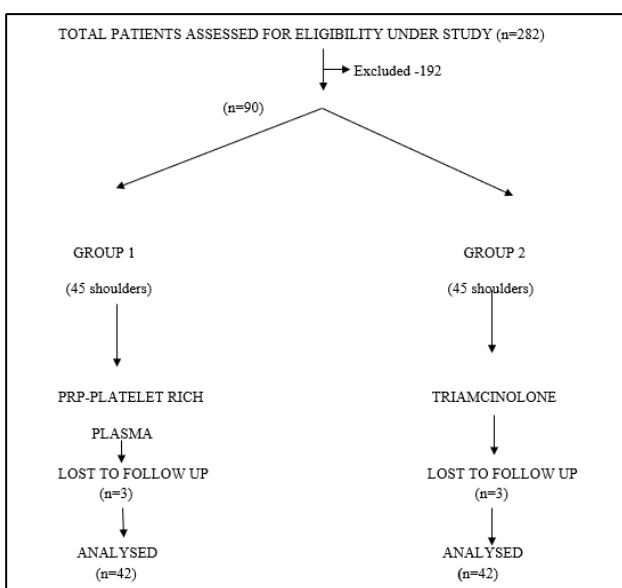


Figure 1: Study design.

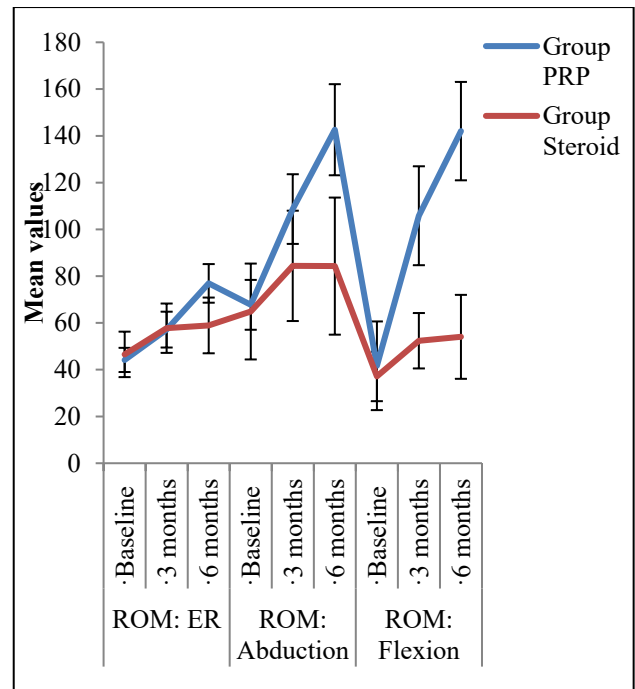


Figure 2: Cumulative rom-ER, abduction, flexion distribution.

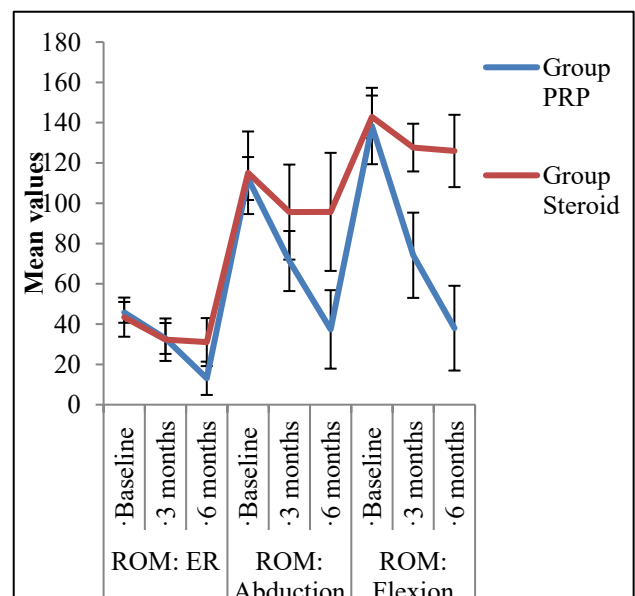


Figure 3: Cumulative restricted rom-ER, abduction, flexion distribution.

Shoulder range of motion and restricted range of motion also follows the trend of statistically significant improvement in PRP group compared to steroid group at 3 as well as 6 months as shown in the graph. Six patients (12%) out of the 84 participants had transient hypotension, nausea, vomiting, giddiness, and blackouts in the PRP group, but none of the patients in the steroid injection group experienced these side effects. Four patients (9.5%) in the steroid group experienced a recurrence of symptoms, while four patients (9.5%) in the steroid group

were not responsive to treatment. Following a steroid injection, one patient (2.4%) experienced skin rashes along their upper limb. However, none of the PRP group's

patients experienced rashes, unresponsiveness, or recurrence.

Table 1: Demographic data.

Characteristic	Group PRP (n=42)	Group steroid (n=42)	Total (n=84)	P value	Significance
Gender					
Male	24 (57.1%)	25 (59.5%)	49 (58.3%)	0.825	Not significant
Female	18 (42.9%)	17 (40.5%)	35 (41.7%)		
Age (in years)					
<40	0 (0%)	3 (7.1%)	3 (3.6%)	0.969	Not significant
40–50	11 (26.2%)	9 (21.4%)	20 (23.8%)		
51–60	17 (40.5%)	15 (35.7%)	32 (38.1%)		
61–70	14 (33.3%)	15 (35.7%)	29 (34.5%)		
Mean±SD	56.45±7.63	56.52±9.28	56.49±8.44		
Side affected					
Left	13 (31%)	18 (42.9%)	31 (36.9%)	0.258	Not significant
Right	29 (69%)	24 (57.1%)	53 (63.1%)		
Duration of condition (months)					
1–2	0 (0%)	3 (7.1%)	3 (3.6%)	0.663	Not significant
3–4	9 (21.4%)	9 (21.4%)	18 (21.4%)		
5–6	23 (54.8%)	12 (28.6%)	35 (41.7%)		
7–8	7 (16.7%)	9 (21.4%)	16 (19.0%)		
9–10	3 (7.1%)	9 (21.4%)	12 (14.3%)		
Mean±SD	5.89±1.59	6.07±2.38	5.90±1.98		

Table 2: VAS Score distribution in both the groups of patients studied.

VAS	Group PRP	Group Steroid	Total	P value
Results				
Baseline pre procedure	6.17±0.93	6.24±0.93	6.20±0.93	0.727
3 months	5.21±0.52	5.00±0.73	5.11±0.64	0.126
6 months	3.67±0.65	5.40±0.94	4.54±1.19	<0.001**
Difference from baseline				
3 months	0.952	1.238	1.095	-
6 months	2.500	0.833	1.667	-
P values from baseline				
3 months	<0.001**	<0.001**	<0.001**	-
6 months	<0.001**	<0.001**	<0.001**	-

**Statistically significant

Table 3: SPADI-Comparison in two groups of patients at baseline, 3 months and 6 months.

SPADI	Group PRP	Group Steroid	Total	P value
Results				
Baseline pre procedure	75.07±6.26	74.17±4.13	74.62±5.29	0.437
3 months	66.74±6.11	63.55±5.52	65.14±6.00	0.014*
6 months	48.21±4.19	64.86±8.08	56.54±10.54	<0.001**
Difference from pre-op				
3 months	8.333	10.619	9.476	-
6 months	26.857	9.310	18.083	-
P values from Pre-op				
3 months	<0.001**	<0.001**	<0.001**	-
6 months	<0.001**	<0.001**	<0.001**	-

**Statistically significant

Table 4: Constant score-comparison in two groups of patients at baseline, 3 months and 6 months.

Constant score	Group PRP	Group Steroid	Total	P value
Results				
Baseline pre procedure	48.50±7.15	47.24±7.30	47.87±7.21	0.426
3 months	62.24±6.80	52.90±5.98	57.57±7.91	<0.001**
6 months	74.71±6.32	53.97±6.73	64.35±12.28	<0.001**
Difference from baseline				
3 months	-13.738	-6.04	-9.893	-
6 months	-26.214	-7.11	-16.35	-
P values from baseline				
3 months	<0.001**	<0.001**	<0.001**	-
6 months	<0.001**	<0.001**	<0.001**	-

**Statistically significant

Table 5: Complications.

Complication	Group PRP (n=42)	Group steroid (n=42)	Total (n=84)
Nil	36 (85.7%)	38 (90.5%)	74 (88.1%)
Yes	6 (14.3%)	4 (9.5%)	10 (11.9%)
Hypotension, giddiness	2 (4.8%)	0 (0%)	2 (2.4%)
Recurrence	0 (0%)	4 (9.5%)	4 (4.8%)
Blackout, nausea	1 (2.4%)	0 (0%)	1 (1.2%)
Giddiness	1 (2.4%)	0 (0%)	1 (1.2%)
Nausea, transient hypotension	1 (2.4%)	0 (0%)	1 (1.2%)
Skin rashes	0 (0%)	1 (2.4%)	1 (1.2%)
Unresponsive	0 (0%)	4 (9.5%)	4 (4.8%)
Vomiting	1 (2.4%)	0 (0%)	1 (1.2%)

DISCUSSION

Primary adhesive capsulitis, or frozen shoulder, or periarthritis shoulder is a common condition encountered in the outpatient orthopedic clinic. About 2% and 5% of people get adhesive capsulitis, and majority of the patients are women.² The non-dominant hand is more frequently involved, and ages range from 40 to 60 years.⁴ The opposite shoulder will develop the disease in about 20% to 30% of those affected. Our study also reveals that the mean age ranges from 50 to 70 years but the dominant hand is more involved than the non-dominant hand (p value of 0.258), and males are more affected than females (p value of 0.825), both of which are statistically insignificant when compared to earlier studies.

According to numerous authors, periarthritis resolves on its own and lasts for two to three years on average. But, a considerable number of patients have notifying difficulties like limitation of movements for more than three years and a lesser significant number of people have residual disability.¹⁵ After three years, up to 40% of individuals still experience persistent symptoms, which mandates a treatment for adhesive capsulitis. However, a large number of randomized controlled trials offer insufficient data about the efficacy of various treatments, such as physiotherapy, corticosteroid injections, and non-steroidal anti-inflammatory medications.¹³ Therefore, more

carefully planned clinical trials are required to examine the effectiveness of periarthritis treatment. In order to improve the procedure's specificity, the current study compared local corticosteroid injections using a posterior USG-guided technique to assess the effectiveness and role of autologous platelet-rich plasma injection in adhesive capsulitis thereby influencing the result. Male to female ratios in this study were 1.33:1 in group A and 1.47:1 in group B, with a modest male preponderance in both groups (57.5% and 59.5%). Nevertheless, p=0.825 indicated that this difference was not statistically significant. According to a study by Crubbs et al 16, middle-aged women are more likely than men to have adhesive capsulitis.

At baseline, the PRP and steroid groups' VAS scores were comparable. The mean VAS score initially declined in both groups at the 3-month follow-up demonstrating a subjective improvement in the patient's symptoms. Furthermore, the mean VAS score of the PRP group dramatically dropped at 6 months, whereas the VAS scores of the steroid group increased. This suggests that the PRP group's VAS score greatly decreased in comparison to the steroid group's persistence and worsening of symptoms. In a study by Rawat et al patients who received an intra-articular steroid injection for frozen shoulder experienced statistically significant pain alleviation after 12 weeks of follow-up.¹⁷ Our study's improvement in pain relief and decrease in VAS score was comparable with a study

conducted by Jayaraman et al, who found that platelet rich plasma therapy is superior to hydro dissection for adhesive capsulitis, with $p < 0.001$ for VAS score and 0.01 for DASH score.¹⁸ The patients who received this treatment also showed improved range of motion by the end of the first month of follow-up. At the 6-month follow-up, the PRP group's SPADI scores dropped by an average of 28, while the steroid group's scores dropped by 10, demonstrating improved pain and disability alleviation in the PRP group as opposed to the steroid group. The improvement in SPADI scores in our study was similar to that in the study conducted in Turkey by Calis et al, which came to the conclusion, in terms of functional recovery, substantial improvements were shown in SPADI-pain, SPADI-disability, and SPADI-total scores compared to baseline ($p < 0.05$).¹⁹

At a 6-month follow-up, the PRP group's shoulder range of motion (ROM) improved more significantly than the steroid group's, with an average increase of 320, 740, and 1000 for ER, abduction, and flexion, and 120, 190, and 160 for the steroid group, respectively. In fact, abduction in steroid group decreased from 190 at 3 months follow up to 160 at 6 months indicating recurrence and reversal of disease pathology. Taking 900, 1800, 1800, as normal ER, abduction and flexion, at 6 months follow up restricted ER, abduction and flexion in PRP group was only 130, 370, 370 whereas ER, abduction and flexion was restricted by 310, 950, 1250 in steroid group respectively, showing residual restriction of ROM was higher in steroid group compared to PRP group. Our study's improvement in range of motion was put into perspective with a 2017 study by Kothari et al that reported that PRP treatment produced statistically significant gains in shoulder range of motion, pain (VAS), and function (Quick DASH) at 12 weeks compared to corticosteroid and ultrasonic therapy.¹⁴

Aslani et al observed that flexion improved from 70° to 150°, abduction improved from 75° to 135°, and external rotation improved from 25° to 50°. The study also found that there was a 70% increase in functional result and a 60% improvement in discomfort. Additionally, he discovered that patients with adhesive capsulitis who received PRP injections had a 70% satisfaction rating, which in terms of functional outcome in ROM, SPADI, CMS scores, and VAS ratings, is similar to our current study. At six months of follow up, significantly a greater number of patients (92.50%) patients in group A were completely relieved of pain whereas more than half (77.5%) patients in group B were not relieved of pain ($p < 0.001$) completely. A handful of studies have compared the effects of corticosteroid injection with autologous PRP injection in the management of adhesive capsulitis. Sonography-guided corticosteroid injections are more effective out of subacromial space, according to studies by Aly et al, but systematic reviews of PRP and steroid groups separately find better results in both groups, particularly when USG guided injections are used instead of blind landmark-based injections.²¹ Calis et al in 2019, in their study 'Effect of PRP on AC-an interventional case

series' concluded that there is improvement in active and passive ROMs on weeks 2, 6, and 12 when compared with baseline after treated with PRP.¹⁹ Numerous studies have shown that over a long period of time, the effects of steroids gradually diminish. Corticosteroid injections were found to be effective in the short term (six weeks) and, to a lesser extent, in the long term (one year) by Blanchard et al, who compared steroid injections and physiotherapeutic therapies for adhesive capsulitis.²² Another study by Shah et al and Lewis et al found that corticosteroid injections in adhesive capsulitis improved pain and range of motion for 6-16 weeks after the first injection.²³ Twelve randomized controlled studies on the use of corticosteroids for adhesive capsulitis were included in a systematic review, which found that while the intervention was helpful, its impact was modest and poorly sustained.²⁴ It has been proposed that the anti-inflammatory effects of corticosteroids and their suppression of the granulomatous reaction in periarthritic tissue result in clinical improvement.

However, according to a study, PRP releases a variety of growth factors that aid in tissue healing, including transforming growth factor- β , platelet-derived growth factor, and vascular and epidermal endothelial growth factor.²⁵ Additionally, PRP releases tumor necrosis factor-alpha and hepatocyte growth factor, both of which have strong anti-inflammatory properties.²⁶ The fact that PRP may have an impact on enhancing all stages of tissue repair, such as the inflammatory, proliferative, and remodeling phases of capsular healing in periarthritis, may account for the long-term benefits shown in the PRP group in this study. The reasoning above leads to the conclusion that PRP injections may have a longer-lasting effect than steroid injections, which have a shorter-lasting effect.

Limitations of the study that the study covered all periarthritis stages, more research is required to examine the effectiveness of various therapies throughout these stages. Since the majority of periarthritis research was based on single intra-articular injections, this study focused on single injections of PRP and steroids. Future research is required to examine the impact of repeated injections.

CONCLUSION

Our study concludes that, in terms of improvement in range of motion, pain relief, and patient satisfaction, a single intra-articular injection of platelet rich plasma guided by sonography is more effective than a single intra-articular triamcinolone injection over a short-term follow up period. However, multicentric randomized controlled trials are necessary to establish the efficacy of platelet rich plasma over a long-term follow-up period and to further strengthen evidence-based practice in treating adhesive capsulitis.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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