International Journal of Life Sciences, Biotechnology and Pharma Research Vol. 13, No. 11, November 2024 Online ISSN: 2250-3137
Print ISSN: 2977-0122

DOI: 10.69605/ijlbpr_13.11.2024.19

ORIGINAL RESEARCH

A comparitive study of ultrasound guided injection at the site of tendinitis versus subacromial injection of platelet rich plasma in supraspinatus tendinitis

[1]Dr. Ramesh Krishna. K, [2]Dr. Karthik. B, [3]Dr. Preetham. N, [4]Dr. Sudheesh Kannan

[1]Professor, [2]Senior Resident, [3]Assistant Professor, Department of Orthopaedics, Bangalore Medical College and Research Institute College, Bengaluru, Karnataka, India
[4]Professor, Department of Anaesthesiology, Bangalore Medical College and Research Institute College, Bengaluru, Karnataka, India

Corresponding author
Dr. Preetham. N
Assistant Professor, Department of Orthopaedics, Bangalore Medical College and Research Institute College, Bengaluru, Karnataka, India

Received Date: 13 September, 2024 Accepted Date: 15 October, 2024

ABSTRACT

Background: To compare the efficacy of Ultrasound-guided PRP at the site of tendinitis VS subacromial injection of PRP in supraspinatus tendinitis, in terms of patient outcome and improvement in range of movements of the shoulder joint. **Materials & Methods:** Randomized single-blinded controlled trial with 2 months & 4 months follow-up using a visual analogue scale, ROM, SPADI & ASES. A total of 60 patients between the age group of 20–70 years old of both sexes were diagnosed for the first time and not treated by any other modality, fulfilling the inclusion criteria of rotator cuff tendinitis. **Results:** Descriptive and inferential statistical analysis has been carried out in the present study using a student t-test (two-tailed, dependent & independent) and Chi-square/ Fisher test. The improvement in VAS score, SPADI scores, ASES scores, [abduction], and in patients who received USG PRP injections was statistically more significant compared to patients who received blind PRP injections as inferred by P-value of <0.001, both at 2 months and 4 months follow up. **Conclusion:** Our study concludes that the efficacy of USG platelet-rich plasma to relieve the pain of rotator cuff tendinitis is better than blind PRP over a short-term follow-up period.

Key Words: Platelet Rich Plasma, Randomized Controlled Trial.

INTRODUCTION

Rotator cuff tendinopathy (RCT) is an important condition of the upper extremity, affecting 1 in 50 adults[1]. In 30% of patients with painful arc, there is a pathology in the rotator cuff, incidence increases with age, making shoulder pain a common musculoskeletal complaint in adults over age 65[2,3]. Its greatest impact is on workers with repetitive and high-load upper extremity tasks and on athletes; shoulder pain and weakness are associated with significant morbidity, affecting activities of daily living, recreation, and work life[4]. The end-stage rotator cuff disease can lead to an entity known as CUFF TEAR ARTHROPARTHY[5].

The pathophysiology of RCT is characterized by progressive, degenerative changes within the tendon as a result of overuse, altered shoulder mechanics, and a limitation of the normal tendon repair system with a fibroblastic and a vascular response known as Angio fibroblastic degeneration[6]. Reduced pain and improved function are the goals of conventional therapy, which includes relative rest, pain medication, physical therapy, corticosteroid injections, and surgery. The effectiveness of conservative compared to surgical intervention is unclear. No therapy has been shown to uniformly improve clinical, functional, and radiological outcomes across severity grades of RCT[7].

A plethora of treatment options have been recommended which include neglect, oral corticosteroids, injection of corticosteroids, injection of PRP, physical therapy exercises, rotator cuff repair.[8]PRP has emerged as a new technology that is supposed to stimulate revascularization of soft tissue and increase the concentration of growth factors to improve and accelerate tendon healing. It is defined as

DOI: 10.69605/ijlbpr_13.11.2024.19

a sample of autologous blood with concentrations of platelets above baseline values.[9]Platelet-rich plasma is a good source of many growth factors & cytokines like PDGF, TGF-beta, IGF-1, IGF-2, FGF, VEGF, EGF. Keratinocyte growth factors & connective tissue growth factors are one of the new ways of treating this painful & disabling condition. It has shown potential in many studies as compared to steroid injection & other modes of conservative treatment.[10]Various studies have concluded that PRP is more effective and durable than cortisoneinjection for the treatment of Rotator cuff tendinitis and Adhesive capsulitis.[11] Hence the present study was undertaken to evaluate the efficacy and role of autologousplatelet-rich plasma injection in rotator cuff tendinitis by comparing it with the blindPRP.

MATERIALS & METHODS

The present study was undertaken to evaluate the efficacy and role of autologousplatelet-rich plasma injection in rotator cuff tendinitis by comparing it with the blindPRP.30 patients were enrolled in each group. Inclusion criteria included patients of >18 years of age, both sex, who will give informed consent.Being diagnosed for the first time and who have failed conservative treatment in the form of NSAIDS and physiotherapy for 2 months.Patient's details were documented in appropriate proforma. Consent for the procedurewas obtained. All patients were subjected to routine blood investigation andradiographic examinations of shoulder with antero-posterior view, MRI scan understudy.Patients clinically diagnosed to have supraspinatus tendinitis and after excluding all other causes of shoulder pain were subjected to MRI. MRI findings usually are interruption of the normal cuff contour, cuff defect filled with fluid signal.The patients were randomized into two groups using the computer-generated randomisation.First group of patients were given ultrasound guided platelet rich plasma; the second group were given blind PRP. The results were recorded by visual analogue score-VAS, SPADI, ASES, ROM. The scores were recorded in the prepared proforma on the day of injection before giving the injection, then after 2 months & after 4 months. The results were studied 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.After giving injection patients were advised for home base 10 minutes of shoulder Range of Exercises for 2-3 months. To prepare platelet rich plasma, around 20 ml of patient's blood was taken by using scalp vein catheter to avoid turbulence while drawing the blood. The platelet rich plasma is prepared by differential centrifugation technique with two spins. The blood is collected in four citrate tubes having 0.9% sodium citrate as anticoagulant. The first spin was done at 1500 rpm for 15 minutes using laboratory centrifuge machine. This spin separated the RBCs from the rest of the components. The lower half of the supernatant was discarded. The upper halves of the supernatant from all the four tubes were transferred into another plain tube for second spin. The second spin was performed at 2500 rpm for 10 min. The upper half of the supernatant of second spin sample was discarded. 2 mL of lower half was taken into a syringe having 0.2mL of calcium chloride. All the results were recorded in Microsoft excel sheet and were subjected to statistical analysis using SPSS software.

RESULTS

This study included 60 patients, participants were clinically evaluated, baseline VAS scores, total pain score, total disability score, SPADI, ASES, ROM were recorded. Cases were treated with USG PRP or blind PRP after randomisation. After the procedure patients were asked to report immediately if any increase in pain was there and were asked to follow up at 2 months and 4 months intervals after the intervention.

Out of the 60 participants, 39(65%) were males and 21(35%) were females.Most of the patients i.e.36 (60%) in our study were aged between 41-50 years. Thus both the groups were comparable in terms of age distribution in each group.

Table 1: VAS Score distribution in both the groups of patients studied.

Groups	Time intervals	N	Minimum	Maximum	mean	S.D.	P value
USG	Before	30	3	6	7.70	.794	0.00*
	2 months	30	3	3	5.00	.983	
	4 months	30	3	3	4.23	.858	
BLIND	Before	30	4	9	7.17	1.53	0.00*
	2 months	30	4	8	6.10	.923	
	4 months	30	4	7	5.53	.937	

Student t test (Two tailed, independent) for between group analysis, Student t test (two tailed, dependent) with in group analysis.

The mean VAS score at the presentation in both groups was7.70+/-0.794 vs 7.17+/- 1.05; p=0.031. At 2 months these scores significantly reduced in group A (5. ±0.98) compared to group B (6.10±0.92) with (p<0.001).(Table 1)

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Table 2: SPADI-Comparison in two groups of patients at baseline, 2 months and 4 months

Groups	Time intervals	N	Minimum	Maximum	Mean	S.D.	P value
USG	Before	30	60	82	73.20	5.365	0.00*
	2 months	30	36	62	45.30	7.857	
	4 months	30	32	53	41.13	6.952	
BLIND	Before	30	53	91	71.83	6.649	0.00*
	2 months	30	52	76	65.03	6.510	
	4 months	30	4	74	59.00	12.581	

Student t test (Two tailed, independent) for between group analysis, Student t test (two tailed, dependent) with in group analysis.

The mean SPADI score at the presentation in both groups was 73.2+/-5.36 vs 71.83+/- 6.64; p=0.38. At 2 months these scores significantly reduced in group A (45.3±7.8)compared to group B (65.0±6.5) with (p<0.001). Further, at 4 months the mean SPADI scores in group A significantly reduced to (41.13±6.9) compared to group B (59.0±12.5) respectively (p<0.001). Hence the SPADI score improvement at 2 and 4 months is statistically significant in the USG PRP group compared to the blind PRP group.

Table 3: Total pain score-Comparison in two groups of patients at baseline, 2 months and 4 months

Groups	Time intervals	N	Minimum	Maximum	Mean	S.D.	P value
USG	Before	30	64	84	74.40	5.618	0.00*
	2 months	30	34	60	45.07	8.132	
	4 months	30	30	56	40.67	7.415	
BLIND	Before	30	58	92	74.80	6.697	0.00*
	2 months	30	52	83	67.80	7.332	
	4 months	30	48	80	63.47	7.628	

Student t test (Two tailed, independent) for between group analysis, Student t test (two tailed, dependent) with in group analysis.

The mean Total pain score at the presentation in both the groups was 74.4+/-5.61 vs74.80+/-6.69; p=0.8. At 2 months these scores significantly reduced in group A(45.07±8.1) compared to group B (67.8±7.3) with (p<0.001).Further, at 4 months the mean scores in group A significantly reduced to (40.6±7.4)compared to group B (63.4±7.6) respectively (p<0.001).. Hence the Total pain score improvement at 2 and 4 months is statistically significantin the USG PRP group compared to the blind PRP group.

Table 4: Total disability score-Comparison in two groups of patients at baseline, 2 months and 4 months

Groups	Time intervals	N	Minimum	Maximum	Mean	S.D.	P value
USG	Before	30	58	82	73.23	5.296	0.00*
	2 months	30	36	64	45.77	8.740	
	4 months	30	34	56	41.27	7.492	
BLIND	Before	30	50	90	74.00	7.182	0.00*
	2 months	30	50	79	66.83	7.607	
	4 months	30	49	76	62.83	7.144	

Student t test (Two tailed, independent) for between group analysis, Student t test (two tailed, dependent) with in group analysis

The mean disability score at the presentation in both the groups was 73.2+/-5.29 vs74.00+/ 7.18; p=0.64. At 2 months these scores significantly reduced in group A(45.77±8.7) compared to group B (66.8±7.6) with (p<0.001).Further, at 4 months the mean scores in group A significantly reduced to (41.27±7.4)compared to group B (62.8±7.14) respectively (p<0.001).Hence the Total pain score improvement at 2 and 4 months is statistically significantin the USG PRP group compared to the blind PRP group.

Table 5: ASES-Comparison in two groups of patients at baseline, 2 months and 4 months

Groups	Time intervals	N	Minimum	Maximum	Mean	S.D.	P value
USG	Before	30	36.0	49.0	45.23	3.2998	0.00*
	2 months	30	44.0	64.9	58.58	4.7387	
	4 months	30	46	66	61.73	4.152	
BLIND	Before	30	23.3	51.6	43.68	5.5924	0.00*
	2 months	30	40.0	68.3	50.59	6.4136	
	4 months	30	42	69	54.23	6.135	

Student t test (Two tailed, independent) for between group analysis, Student t test (two tailed, dependent) with in group analysis.

DOI: 10.69605/ijlbpr_13.11.2024.19

The mean ASES at the presentation in both the groups were 45.2+/-3.29 vs 43.68+/-5.59; p=0.19. At 2 months these scores significantly increased in group A (58.58±4.7)compared to group B (50.59±6.4) with (p<0.001).Further, at 4 months the mean scores in group A significantly increased to (61.73±4.1)compared to group B (54.23±6.13) respectively (p<0.001).Hence the ASES improvement at 2 and 4 months is statistically significant in the USGPRP group compared to the blind PRP group.

Table 6: ROM: Abduction-Comparison in two groups of patients at baseline, 2 months and 4 months

Groups	Time intervals	N	Minimum	Maximum	Mean	S.D.	P value
USG	Before	30	70	110	90.00	12.03	0.00*
	2 months	30	100	150	129.67	12.73	
	4 months	30	120	170	152.00	12.43	
BLIND	Before	30	30	150	96.33	20.92	0.00*
	2 months	30	45	170	120.17	23.80	
	4 months	30	60	170	139.67	24.14	

Student t test (Two tailed, independent) for between group analysis, Student t test (two tailed, dependent) with in group analysis.

The baseline Abduction in the USG PRP group is 90±12.03 and in the blind PRP groupis 96.33±20.92, with a P-value of 0.15 being statistically not significant and comparableto each other at baseline. At 2 months Abduction in the USG PRP group is 129.67±12.7and in the blind PRP group is 120.17±23.80 with a P-value of 0.001being statisticallysignificant.At 4 months Abduction in the USG PRP group is 152.00±12.43 and in the blind PRPgroup is 139.67±24.14 with a P-value of <0.001 which is statistically significant. Henceboth at 2 months and 4 months the improvement in Abduction is statistically significantin the USG PRP injection group compared to the blind PRP injection group with a Pvalue of <0.001.

Table 6: Complications

Complications		Groups		Total
		USG	BLIND	
Nil	Count	30	30	60
	%	100.0%	100.0%	100.0%
Total	Count	30	30	60
	%	100.0%	100.0%	100.0%

DISCUSSION

Rotator cuff pathology is a common orthopedic disorder and a major cause of shoulder pain. Treatments for rotator cuff lesions without complete tears are mainly conservative 108. Subacromial injection of anesthetics or corticosteroids is usually used to treat patients with persistent symptoms after rehabilitative therapy and the use of oral nonsteroidal anti-inflammatory drugs109. Though NSAID treatment and injections of corticosteroids are recognized to improve inflammation and shoulder pain, serious gastrointestinal side-effects after prolonged oral NSAID administration 110 as well as arthropathic changes and increased chances of tendon fragility caused by repeated corticosteroid injections are important concerns.[12]

Partial rotator cuff tears are one of the most common reasons for shoulder pain. In the Indian population, the prevalence of partial rotator cuff tendon tears is not addressed to date .[13,14,15]

Recently, research has focused on regenerative therapies with high expectations of success. The practice of autologous growth factors is believed to heal through collagen regeneration and the stimulation of well-ordered angiogenesis. These growth factors are administered in the form of autologous platelet-rich plasma (PRP). Platelets can be separated using simple cell-separating systems/Centrifuge machines. The degranulation of the α-granules in the platelets releases different growth factors that play a role in tissue regeneration processes. Platelet-derived growth factor, transforming growth factor-β, Epithelial growth factor, Vascular-derived endothelial growth factor, Hepatocyte growth factor, and insulin-like growth factor are examples of such growth factors. Injections with autologous growth factors are becoming common in clinical practice.[10]

Hence, the present study was an attempt to compare the ultrasound-guided injection at the site of tendinitis versus subacromial injection pf PRP in supraspinatus tendinitis.

Most of the patients in group A (53.3%) and group B (66.7.4%) were aged between 41 to 50 years. The mean age in group A was 46.45±7.63 years and in group B was 46.52±9.28 years suggesting all both groups were comparable with respect to age (p=0.317). Atsushi et.al. in their study observed that the mean age of all patients was 12.8 years. Vetrivel cheziansengodan et alin their study observed that the mean age of all patients was 55+/- 6.4 years.[16,17]At presentation, all the demographic and clinical variables in terms of VAS, SPADI, ASES, ROM in the abduction were comparable between both the groups.

At presentation, the mean VAS scores were comparable in both the groups (7.70±0.79 vs 7.17±1.5; P=0.031), statistically not significant. At 2

DOI: 10.69605/ijlbpr_13.11.2024.19

months the mean VAS scores were, group A (5.0±0.987) and group B (6.10±0.92) with P-value <0.001 statistically significant between the groups. At 4 months the mean VAS scores in group A significantly reduced to 4.23±0.85 compared to group B 5.53±0.93 (p<0.001) also compared to their baseline mean VAS scores, the decrease in VAS scores were statistically significant within each group at 2 months and 4 months follow up with a pvalue of <0.001

The VAS scores of both the USG PRP and blind PRP group at baseline were comparable. At both 2 and 4 months, the mean VAS score of USG PRP and blind PRP group decreased very significantly.The improvement in pain relief and decrease in VAS score in our study was comparable to a study done by Xia Chen et al[18], where The patients who received platelet-rich plasma therapy showed an improved range of movements for the short term and concluded PRP for VAS score with p<0.01.

Vetrivel cheziansengodan et al [17] did an analysis of VAS pain score in 20 patients at 8 weeks. The difference between pre-injection and post-injection VAS scores was statistically significant [p< 0.001]. The pre-injection mean VAS score was 5.4+/- 0.92 and after 8 weeks were 3.2+/- 0.94. After 3 months were 2.55+/- 0.83 with a P-value <0.001.116

At presentation, the mean SPADI scores were comparable in both groups (73.2±5.36 vs 71.83±6.64; p- 0.38). At 2 months the mean SPADI scores reduced to (45.3±7.8 vs 65.0±6.5, P<0.001) being statistically significant. At 4 months the mean SPADI scores further reduced to (41.13±6.9 vs 59.0±12.5, P-value <0.001. statistically significant. Both at 2 months and 4 months the mean SPADI scores decreased within the groups statistically being significant(P<0.001).The improvement in SPADI scores in our study was comparable to the improvement in SPADI scores in the study done by Dong wook et al. which concluded Regarding functional recovery, significant improvements were observed in SPADI-pain, SPADIdisability in all-time points when compared with baseline (p<0.05).

The mean ASES at the presentation in both the groups were 45.2+/-3.29 vs 43.68+/- 5.59; p=0.19. At 2 months mean ASES scores of group A improved to 58.58±4.7 compared to group B is 50.59±6.4, which are statistically significant (p-value<0.001). Hence the ASES score improvement at 2 months is statistically significant in the USG PRP group compared to the blind PRP group.

At 4 months ASES scores in group A is 61.73±4.1 and group B is 54.23±6.13 with p-value<0.001, hence the improvement is statistically significant in the USG PRP injection group compared to the blind PRP group. But the according to Xia Chen et al[18] study there is no significant difference between the non-PRP treated patients and PRP treated patients.

At presentation mean abduction in the USG PRP group compared to the blind group was 90±12.03vs 96.33±20.92, with a P-value of 0.15 being statistically not significant and comparable to each other comparable to each other at baseline. At months mean abduction improved to 129±12.7 vs 120±23.80 respectively with a P-value of 0.001, statistically significant.Further at 4 months, the mean abduction in the USG PRP group improved to 152.00±12.43 compared to 139.67±24.14 in the blind PRP group, P-value <0.001) which is statistically significant.

Out of 60 participants, none of the patients have complications. At six months of follow-up, both groups A and B were significantly relieved of pain with (P=<0.001).

In our study, there is significant pain relief and improvement in SPADI scores, ASES, and ROM for Abduction at 4 months in both USG platelet-rich group and blind PRP. However, at 2 and 4 months follow up there was further improvement, pain relief, and increase in ROM in the USG PRP group.

There is limited data showing a comparison between USG PRP injection and blind PRP injection in the treatment of rotator cuff tendonitis. However, the systematic reviews in terms of USG PRP and blind PRP group individually conclude better outcomes in both the groups, especially when USG guided compared to blind landmark-based injections similar to the studies by Aly et al. concluded that sonography-guided PRP injections are more effective out of subacromial space.

Saltzman et al, in 2016 had concluded that there was a significant improvement in pain and reduction in the rehabilitation period and a decrease in rehabilitation period in cases where PRP augmentation was done in Rotator cuff tear patients. PRP is used to improve rotator cuff repair, resulting in decreased retear rates, early back to daily living activities, and improvement in pain [19]

Randelli et al, study concluded that when PRP is done for augmentation of arthroscopically conducted rotator cuff repair, all the 14 patients had a decrease in pain and functional improvement and with no adverse effect as shown by improvement in the Constant score at 12 weeks after repair.[20]

The limitation of the study was the lack of comparison with other studies as there is minimal availability of similar trials comparing USG PRP vs blind PRP, and the duration of the study was only 4 months follow up. Further Randomised studies and metanalysis are necessary with long-term follow-up

CONCLUSION

The efficacy of USG guided PRP injection to relieve the pain and disabilities of supraspinatus tendinitis is better than subacromial PRPinjections, over a short-term follow-up period.

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