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Clinical and functional outcome comparison for platelet rich plasma with steroid injection in patients with isolated subacromial impingement syndrome

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ABSTRACT

Background: To compare the 6-weeks, 3 and 6 months outcome in 80 patients who received an injection of plateletrich plasma (PRP) or steroid for sub-acromial impingement syndrome (SIS).

Methods: There were 42 males and 38 females received a single-dose injection of PRP (n=40) or steroid (n=40) for SIS that had not responded to conservative treatment for more than 6 months. Both groups were put on physiotherapy protocol followed in our institution. The use of non-steroid anti-inflammatory drugs was prohibited. Patients were evaluated before and 6 weeks, 3 and 6 months after treatment using the constant score, visual analogue scale (VAS) for pain, and range of motion (ROM) of the shoulder.

Results: No local or systemic complication occurred. Improvement in the constant score and VAS for pain at week 6, 3 and month 6 was clinically better following steroid than PRP injection. However, this difference was statistically insignificant. The 2 groups were comparable for improvement in ROM of the shoulder.

Conclusions: PRP injection was not more effective than steroid injection for treatment of SIS in terms of at the end of 6 months. However, long term studies should be indicated to substantiate the findings.

Keywords: Constant score, Platelet rich plasma, Subacromial impingement syndrome, Visual analogue scale

INTRODUCTION

Subacromial impingement syndrome (SIS) is one of the most common causes of shoulder pain in adults and is characterized by painful functional limitation of the shoulder, especially with overhead activities. There occurs soft tissue impingement between the coracoacromial arch and greater tuberosity of the humeral head, which produces subacromial bursitis, rotator cuff tendinitis, and rotator cuff tears. Subacromial impingement syndrome without a rotator cuff tear can generally be treated with conservative treatment, including medication with nonsteroidal anti-inflammatory

drugs, pain killers, physical therapy, and local corticosteroid injection. A local corticosteroid injection is used widely for relieving chronic pain in orthopedic lesions, owing to its strong anti-inflammatory and analgesic effects. Nevertheless, there is some concern regarding its side effects when used around a tendon lesion. Today, orthobiologics are commonly used in many orthopaedic applications, especially in the treatment of tendinopathies. Platelet products represent an enriched autologous source of platelets, which contain granules filled with growth factors, delivering high concentrations of growthfactors above physiological levels. There is some clinical evidence that application of autologous platelets may help to revascularize the area

of injury, to promote tendon healing and to improve pain and functional outcomes in rotator cuff pathologies.^{3,4} This study compared the 6-weeks, 3 month and 6-month outcome in 80 patients who received a single-dose injection of PRP or steroid for SIS.

METHODS

There were 83 consecutive patients seen by the author in outpatient department between 2014 and 2016 were enrolled in this study. Patients were included if they were ≥18 years. The diagnosis of sub-acromial impingement syndrome was made on the basis of a history of shoulder pain with overhead activities and clinical signs of impingement (either in internal rotation or external rotation).

Exclusion criteria were generalized inflammatory arthritis, including ankylosing spondylitis, rheumatoid arthritis or psoriatic arthritis, prior supraspinatus tendon tear, pregnancy, severe infection, known malignancy, bleeding disorder, nerve-related symptoms such as radiculopathy or osteoarthritis of the shoulder, previous extracorporeal shock wave therapy or prior injections into shoulder immunodeficiency, the anticoagulants, the use of nonsteroidal anti-inflammatory drugs in five days before and during the treatment and hemoglobin value <11 g/dl, and platelet value <150,000 mm³. Exclusions were made based on history and clinical examinations performed by the author in combination with the results of shoulder radiographs and ultrasounds performed if deemed necessary. Anteroposterior radiographic images were taken in a neutral as well as a 90 ⁰ abduction position.

All injections were performed by the author. Blind injections were performed with the patient in the same upright sitting position. A posterior approach was used, and the needle was inserted 1cm medially and inferiorly to the posterolateral corner of the acromion and directed cephalad, anteriorly, and medially toward the subacromial bursa. The first consecutive 40 patients received a cortisone injection. The injection fluid contained 1mL of 40 mg/mL methylprednisolone acetate and 5mL of 1% lidocaine hydrochloride. The PRP was prepared manually using single spin rotation.^{5,6} A total of 30cc peripheral blood was drawn from the antecubital region into tubes containing 3.2% sodium citrate. The tubes were centrifuged at 1800 rpm for 8 minutes at room temperature. From the 3.5ml PRP, 1 ml was sent to the laboratory for bacteriological testing and platelet count; the platelet count was 4 times greater than the thrombocyte count in the peripheral blood. The 2.5ml PRP was activated by 5.5% calcium chloride (50µl in 1 ml PRP), calcium chloride was added to the PRP concentrate to activate the platelets for inducing rapid formation of fibrin clot. The patients were kept in observation in lying down position for 30 minutes following injections. Both groups were instructed to perform standard rotator cuff stretching and strengthening exercises started 3 weeks after the injection but were advised to avoid sport and strenuous activities for 6 weeks. NSAIDs were not allowed for 6 months.

Clinical outcomes

After 6 weeks, 12 weeks and 6 months, patients were examined in the outpatient clinic. The main outcome measure was pain with overhead activities using a visual analog scale (VAS). A 10-cm line with "no pain" at one end and "the worst imaginable pain" at the other end was marked by the patient, and the distance from the no pain end was converted to a score out of 100 (1 mm = 1 point). This was assessed at baseline and again at 6weeks, 3 months and 6 months follow-up.

We used constant score (CS) which was among the first shoulder score systems developed and is considered the most commonly used scoring system for evaluation of various disorders of the shoulder.⁷ The CS assesses subjective and objective shoulder function with respect to: A: pain; B: activities of daily living; C: range of motion and D: strength. The CS is often used to evaluate treatment progress and to compare results of clinical trials for several specific shoulder disorders.^{8,9} The European Society for Surgery of the Shoulder and Elbow (ESSSE) and the Journal of Shoulder and Elbow Surgery recommend the CS for use in research on shoulder disorders.

The author also assessed passive shoulder range of motion in forward flexion, extension, abduction, external rotation, and internal rotation. During the course of the study, the patients were restricted from the use of any analgesic or anti-inflammatory medication or other treatments.

Patient characteristics and outcome measures in the 2 groups were compared using the Chi-square test and Student's t-test A p value of <0.05 was considered statistically significant.

RESULTS

There were 83 patients who met the inclusion criteria for the study. Three were lost to follow-up after receiving the injection. Therefore, 80 patients were alternatively allocated either the PRP group (40 shoulders) or the STR group (40 shoulders).

The final population (Table 1) comprised 42 men (PRP group= 22; STR group= 20) and 38 women (PRP group= 18; STR group= 20) with a mean age of 56.35 ± 5.68 years (PRP group= 57.65 ± 5.43 ; STR group= 55.05 ± 5.93). The mean body mass index was 25.71 ± 3.26 kg/m2 (PRP group= 26.19 ± 3.75 ; STR group= 25.24 ± 2.77). The mean duration of symptoms was 9 months (PRP= 8.65 ± 2.44 ; STR= 9.7 ± 1.47).

There were 17 injections into the right shoulder and 23 into the left shoulder were performed in the PRP group and 21 injections into the right shoulder and 19 into the left shoulder in the STR group. No infection was observed after injection in both groups. The study group had 66% (n=61) patients who had sedentary lifestyle compared to 24% (n=19) patients who were involved in heavy manual occupation. Majority of the patients were Right hand dominant (90%).

Table 1: Demographic factors of different groups.

Variables	PRP	Steroid
No. of patients	40	40
Age	57.65±5.43	55.05±5.93
Gender ratio (F/M)	18/22	20/20
BMI	26.19±3.75	25.24±2.77
Duration	8.65 ± 2.44	9.7±1.47
Dominance ratio (R/L)	40/0	32/8
Lifestyle	33/7	28/12
(sedentary/physical)		

There were no significant differences between the groups. BMI: body mass index; F: female; M: male.

Table 2: VAS and constant score outcomes of PRP and STR groups.

	PRP	STR	P value ^a		
VAS					
Pre-op	68.15±11.97	69.2±11.05	NS		
6w	40.85±10.89	39.1±7.32	NS		
3m	33.2±7.09	34.65±5.1	NS		
6m	28.5±6.34	30.6±6.61	NS		
p value b	< 0.05	< 0.05			
Constant score					
Pre-op	32.4±4.6	34.2±5.2	NS		
6w	40.6±7.2	42.3±3.4	NS		
3m	48.4 ± -8.4	52±8.2	NS		
6m	56.8±6.6	59.6±8.6	NS		
p value b	< 0.05	< 0.05			

^aSignificant difference Comparison between PRP and STR groups. ^bSignificant difference comparison between preoperative and final follow up values. VAS: Visual analogue scale; PRP: Platelet rich plasma group; STR: Steroid group; n. s: not significant

While VAS in overhead activities at the end of treatment were clinically higher in the STR group than the PRP group, however this clinically significant difference was found to be statistically insignificant (P>0.05) (Table 2).

Constant score (Table 2) showed statistically significant difference in comparison of preoperative from final follow up values (p<0.05) in both the groups, However on comparing both the groups over a period of follow up, STR group had clinically significant but statistically insignificant difference (p>0.05) from PRP group.

When we compared the PRP and STR groups (Table 3), there was no significant difference between the groups for the flexion degree of shoulder before treatment, the increase of the flexion degree at the end of the treatment and at the 6th month after the treatment were similar in both the groups (P>0.05).

Table 3: ROM score outcomes of PRP and STR groups.

	PRP	STR	P value ^a
Flexion			
Pre-Op	118±16.04	117.25±18.22	NS
6w	142.75±9.4	140.5±11.2	NS
3m	152.5±7.93	152.75±8.98	NS
6m	167±7.58	168±5.86	NS
p value b	< 0.05	< 0.05	
ABD			P value ^a
Pre-Op	95±15.44	88.75±15.43	< 0.05
6w	122±9.66	121±10.33	NS
3m	141±9.28	140±9.34	NS
6m	157.25±7.59	158.5±8.18	NS
p value b	< 0.05	< 0.05	
IR			P value ^a
Pre-Op	55.5±5.29	54.25±4.61	NS
6w	67.25±5.18	65.75±5.38	NS
3m	72.75 ± 4.38	72.25 ± 4.66	NS
6m	80±6.41	80.25±7.76	NS
	< 0.05	< 0.05	
ER			P value ^a
Pre-Op	52.75±6.3	52±7.23	NS
6w	65.5±7.66	65.5±6.58	NS
3m	70.5±5.97	74.5±4.78	< 0.05
6m	77.75±5.42	81±5.45	< 0.05
	< 0.05	< 0.05	

^a: Significant difference Comparison between PRP and STR groups. ^b: Significant difference comparison between preoperative and final follow up values. ABD: Abduction; IR: Internal Rotation; ER: External Rotation; PRP: Platelet rich plasma group; STR: Steroid group; n. s: not significant.

While before the treatment the extension degree of shoulder was significantly higher in the STR group than the PRP group, at the 6th month after the treatment the extension degree of shoulder was statistically insignificant in both the groups (P>0.05). The abduction degree of shoulder was significantly higher in the PRP group than the STR group before the treatment (P<0.05). Post injection, at all the evaluation steps, there was no significant difference between the groups for the abduction degree of shoulder (P>0.05).

After 6 months, the external rotation degree of shoulder was significantly higher in the STR group than the PRP group, while the internal rotation degrees of shoulder at all the evaluation steps were similar in both the groups (P>0.05).

DISCUSSION

Subacromial impingement syndrome was first introduced by Neer and described as 'crepitus and tenderness over the supraspinatus tendon, a good range of assisted motion but a painful arc of active elevation from 70 to 120 and pain at the anterior edge of the acromion on forced elevation'. ¹⁰

Hawkins described pain provocation upon internal rotation in forward flexion and attributed this sign to Kennedy. The manoeuvre has also been described in a more abducted position. Jobe described weakness upon resisted elevation from 90 onwards with the arm in internal rotation. The diagnosis of subacromial impingement syndrome is based upon patient history, clinical examination, and radiological finding.

The syndrome is traditionally divided into three stages: Stage I, oedema and haemorrhage; Stage II, fibrosis and tendinitis; and Stage III, tears of the rotator cuff, bicep ruptures and bone changes. The condition usually begins gradually and then over time becomes continuous.

In an early study, collagen necrosis was reported after directly injecting hydrocortisone in rabbit calcaneal tendons. Another study reported the relationship between a local corticosteroid injection and tendon rupture. A subacromial corticosteroid injection in impingement syndrome is safe; but several studies reported that repeated steroid injections may result in damage to the rotator cuff tendon.

Steroid injection is active for up to 6 months and is more efficient than NSAID but it may result in complications such as skin depigmentation, fat atrophy, or tendon ruptures.

In patients with SIS, pain and limitation in ROM is common. The subacromial bursa between the acromion and the humeral head is a source of pain, as it has mechanoreceptors and a large number of pathological nerve endings that are associated with clinical symptoms. The increased amount of substance-P and vascular endothelial growth factor (VEGF) in the subacromial bursa is associated with pain. 19,20

Numerous studies have documented the beneficial effects of individual growth factors on tendon healing shown for platelet concentrates and other orthobiologics such as autologous processed serum contain factors such as bone morphogenetic proteins, transforming growth factors, and fibroblast growth factors. Application of these agents was shown to promote tendon cell proliferation, collagen synthesis and vascularization in vitro and in vivo. A beneficial effect was also seen using PRP, platelet leukocyte membrane, platelet-rich fibrin matrix or plasma rich in growth factors in addition to rotator cuff tear surgery. A such as a su

A platelet count over 300000/µl in PRP is considered effective.⁵ A platelet concentration 2.5 times greater than the basal platelet count is reported to be most effective.²⁷ The PRP is activated by adding bovine or human thrombin or calcium chloride.²⁸ Growth factors and cytokines are revealed with the formation of platelet gel from the activated PRP. However, studies warning of hyperplasia, carcinogenesis, or tumour growth secondary to PRP injection are limited.

Hence, orthobiologics such as platelet-rich plasma (PRP), platelet-poor plasma and autologous processed serum could be an option for the treatment of this pathology. To our knowledge, the effect of PRP injections on shoulders with isolated SIS as compared to standard injection therapy with cortisone has not had many studies. Therefore, this study evaluated PRP injections versus cortisone injections into the subacromial space in patients without partial tears of the supraspinatus tendon as confirmed by clinical examination and ultrasonographic findings. The results should contribute to a better understanding of the role of PRP in treatment of symptomatic subacromial impingement syndrome. Before admission, all patients reduced their activities of daily living or suspended their sport activities due to their shoulder pain.

The most important findings of the present study were better scores and clinical improvement after injection at different follow up periods in the STR group in comparison with the PRP group. However, statistically significant differences between the two groups in terms of shoulder function and scores could not be found except for ER improvement which was more in STR group compared to PRP group (P<0.05).

Both groups showed a statistically significant better shoulder function after sub-acromial injection over time compared to pre injection values. Cortisone is widely used to treat patients with shoulder pain, and there is no doubt about the positive effect on pain especially in the short term. However, the potential complications of corticosteroid injections should also be taken into account, especially for the elderly.

After the injection, both the groups had decreased pain with overhead activities in the VAS score that was

clinically relevant as well as significant improvement in Constant scores. The decrease in pain on the VAS and increase in function on the constant score were not significantly different between groups, suggesting that there was no added clinical benefit in pain reduction or improved function of PRP injection compared to steroid injection.

The rather clear results of this study may due to the fact that the author was involved in assessing all the patients clinically and the shoulder scores, that the number of patients included in this study was reasonably high and that the clinical examinations by means of shoulder scoring systems and injection protocols were strictly standardized.

This study has several limitations. A weakness of this study is the relatively short-term follow-up of 6 months. A longer follow-up of at least 12 months may have led to differences in outcomes between groups that may not have been apparent in the short term. We did not assess the accuracy of injections using MRI, and perhaps the fact that all the injections were performed by an experienced orthopaedic surgeon well versed in injection techniques may have resulted in all injections accurately placed in the subacromial bursa, therefore diminishing the differences in the treatment of both groups, leading to the similarity of outcomes. The study is in reference to subacromial injections only, and these results cannot be extrapolated to injections in the glenohumeral joint. We tried to ensure that the study was conducted on patients with consistent homogeneous impingement with the absence of other pathological conditions; however, in some of the cases, the cause of pain changed or evolved over time.

CONCLUSION

PRP injection was not more effective than Steroid injection for treatment of SIS in terms of at the end of 6 months. However, long term studies should be indicated to substantiate the findings.

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