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A comparative analysis of pain reduction following a single intra-articular injection of platelet-rich plasma, steroid or normal saline in chronic external shoulder impingement syndrome

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ABSTRACT

Background: Shoulder impingement is a common diagnosis for patients with pain and dysfunction of shoulder joint. Due to its chronicity of clinical manifestation of the impingement syndrome, there is a need to find new therapies that collaborate to improve pain management.
Methods: A hospital based descriptive, epidemiological study was conducted with 150 patients. The patients were divided in the following three groups of 50 patients each: Platelet-rich plasma (PRP) group: 50 patients received PRP, steroid group: 50 patients received steroid injection normal saline group: 50 patients received normal saline injection. Baseline visual analogue scale (VAS) score on overhead activities were recorded. After the 4th week, 12th week, and 24th week, patients were examined in the outpatient clinic. The main outcome measure was pain with overhead activities using a VAS.
Results: The VAS score improved significantly in PRP group and Steroid group compared to normal saline group at the 4th week, 12th-week and 24th-week follow-up periods post injection, as per ANOVA test ($p<0.05$).
Conclusions: PRP and steroids, both can be considered effective methods to treat pain in chronic shoulder impingement syndrome (SIS) and less invasive compared to surgical treatment. They improve the pain and hence shoulder function in chronic impingement syndrome.

Keywords: Shoulder impingement, Shoulder pain, Platelet rich plasma, Periarthritis, Frozen shoulder, Adhesive capsulitis

INTRODUCTION

Shoulder impingement is a common diagnosis for patients with pain and dysfunction of shoulder joint. Rotator cuff disorders are considered to be among the most common causes of shoulder pain and disability encountered in both primary and secondary care, with subacromial impingement syndrome in particular being the most common disorder, resulting in functional loss and disability, of the shoulder.[1] The concept of SIS is attributed to Charles Neer following his paper published in 1972.[2] The term shoulder impingement itself however now belongs to a group of terms that essentially describes pain in the shoulder region as a result of mechanical 'impingement' of the rotator cuff as it passes under the coraco-acromial ligament. If left untreated rotator cuff impingement may proceed to partial or complete rotator cuff tendon rupture. Diagnosis of this condition remains a clinical one, and an initial careful assessment is crucial in identifying shoulder impingement as the particular cause of shoulder pain from the list of differentials. Early recognition and subsequent management are important, as this can help reduce the risk of impingement progressing and causing increased further morbidity to patients in the

form of pain, reduced activity or subsequent partial or even complete rotator cuff tears.

SIS is most commonly seen in individuals who participate in sports and activities that require repetitive overhead activities, including but not limited to handball, volleyball, swimming, carpenters, painters, and hairdressers.[4] Other extrinsic risk factors that may predispose to the development of impingement syndrome include bearing heavy loads, infection, smoking, and fluoroquinolone antibiotics.[4] The incidence of SIS rises with age, with peak incidence occurring in the sixth decade of life.[5]

Advances in imaging modalities have enabled an increased understanding of the pathological process and specific causes of shoulder impingement. Plain X-rays are useful as an initial shoulder evaluation tool in the majority of shoulder pathologies however in the case of rotator cuff disorders, including shoulder impingement, they are often normal initially and require supplementation with other imaging modalities such as ultrasound or magnetic resonance imaging (MRI) scanning.

Depending on both the stage of the condition and individual patient factors, there are a variety of treatment options available; however, a patient specific treatment plan should always be implemented. In the majority of cases an initial conservative approach may be completely adequate in leading to a resolution of symptoms, however in certain cases, various surgical options are available which look to address the cause of the impingement symptoms i.e., the acromion, rotator cuff or both.

PRP contains many growth factors such as transforming growth factor, fibroblast growth factor, vascular endothelial growth factor, insulin like growth factor, thrombocyte-derived angiogenic factor, epithelial growth factor, platelet-derived growth factor, and platelet activating factor.[6] The interest in PRP has increased due to its inclusion of growth factors.[7-9] Local corticosteroid injections have frequently been used particularly in the first and second stages of disease, and found to have no long term effect while half of the patients reported repeated symptoms.[10] In addition, corticosteroids have adverse effects such as atrophy, systemic absorption, infection, subcutaneous tendon rupture, and tendon rupture on the skin.[11]

The use of PRP as a biological solution for injuries to tendons of the rotator cuff has achieved popularity over the past several years.[12] PRP is blood plasma with a high platelet concentration that, once activated, releases various growth factors involved in the tissue repair process.[13] There is some evidence demonstrating a positive effect of PRP in tendinopathies and osteoarthritis of the knee.

Due to its chronicity of clinical manifestation of the impingement syndrome, there is a need to find new therapies that collaborate to improve pain management. PRP is very promising futuristic therapy. It is a vehicle to deliver large amount of important growth factors, which are biologically active, to the injury site. Its use has increased extensively over the last decade due to advanced technology, the availability of newer commercial PRP equipment, and the manufacturing of various PRP products in the market. It is very simple and easy to use, easily available, uses the patient's own blood (autologous), potentially cost-effective, and is considered a very safe therapy. Also, subacromial PRP injection could be considered a good alternative to corticosteroid injection, especially in patients with a contraindication to corticosteroid administration.

Hence, the present study was done at our tertiary care centre to assess the effect of subacromial injection of PRP, steroid, and normal saline on pain in SIS and compare the change in VAS score for pain in SIS.

METHODS

Study population and design

A hospital based descriptive, epidemiological study was conducted with 150 patients to assess the effect of subacromial injection of PRP, steroid and normal saline on pain in SIS. The study was done at a tertiary care centre in the department of orthopaedics on subjects attending OPD/IPD after due permission from the institutional and clinical ethics committee RGMC and Chhatrapati Shivaji Maharaj hospital, Thane (Registration Number: ECR/469/Inst/MH/2013/RR-20). Once the patients were enrolled for the study, a thorough history and physical examination was done as per proforma. An informed consent was taken in written from patients or patient's attendant. Patients were included if they were ≥40 years having chronic shoulder pain for more than 3 months and positive clinical test for SIS. The diagnosis of SIS was made based on a history of shoulder pain with overhead activities and clinical signs of impingement (either in internal rotation or external rotation). Patients with pain following history of trauma were excluded from the study. This hospital based descriptive, epidemiological study was conducted in the duration of 12 months (August 2020 to July 2021). Enrolled patients were divided into three groups of 50 patients each. First group received PRP, second group received steroid injection and third group received normal saline injection.

Study medication

Injections were performed with the patient in the same upright sitting position. A posterior approach was used, and the needle was inserted 1 cm medially and inferiorly to the posterolateral corner of the acromion and directed cephalad, anteriorly, and medially toward the subacromial bursa. The first group received PRP which was prepared manually using single spin rotation. A total of 30 cc peripheral blood was drawn from the antecubital region into tubes containing 3.2% sodium citrate. The tubes were centrifuged at 1800 rpm for 8 min at room temperature.

From the 3.5 ml PRP, 1 ml was sent to the laboratory for bacteriological testing and platelet count; the platelet count was four times greater than the thrombocyte count in the peripheral blood. The 2.5 ml PRP was activated by 5.5% calcium chloride (50 µl in 1 ml PRP), calcium chloride was added to the PRP concentrate to activate the platelets for inducing the rapid formation of the fibrin clot. The second group received a cortisone injection. The injection fluid contained 1 mL of 40 mg/mL methylprednisolone acetate and 5 mL of 1% lidocaine hydrochloride. And third group received normal saline injection. The patients were kept in observation in lying down position for 30 mins following injections.

Study assessment

The study was conducted to assess the effect of subacromial injection of PRP, steroid and normal saline on pain and to compare the change in VAS score for pain in SIS. After 4th week, 12th week, and 24th week, patients were examined in the outpatient clinic. The main outcome measure was pain with overhead activities using a VAS score. 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 of 100 (1 mm=1 point). This was assessed at baseline and again at 4th week, 12th week, and 24th week follow-up. Changes in VAS score for pain was compared among 3 groups.

Statistical analysis

Quantitative data was presented with the help of mean and standard deviation. Comparison among the study groups was done with the help of unpaired t test as per results of normality test. Qualitative data is presented with the help of frequency and percentage table. Association among the study groups is assessed with the help of Fisher test, the student 't' test and the Chi-Square test; 'p' value less than 0.05 was taken as significant. Pearson's chi-squared test where X^2=Pearson's cumulative test statistic. Oi=an observed frequency; Ei=an expected frequency, asserted by the null hypothesis; n=the number of cells in the table. Results were graphically represented where deemed necessary. Appropriate statistical software, including but not restricted to MS excel, SPSS ver. 20 was used for statistical analysis. Graphical representation was done in MS excel 2010.

RESULTS

A hospital based descriptive, epidemiological study was conducted with 150 patients to assess the effect of subacromial injection of PRP, steroid, and normal saline on pain in SIS. Respectively, the patients were divided in the following three groups of 50 patients each-first group received PRP, second group received steroid injection and third group received normal saline injection.

Distribution of patients according to mean duration of symptoms

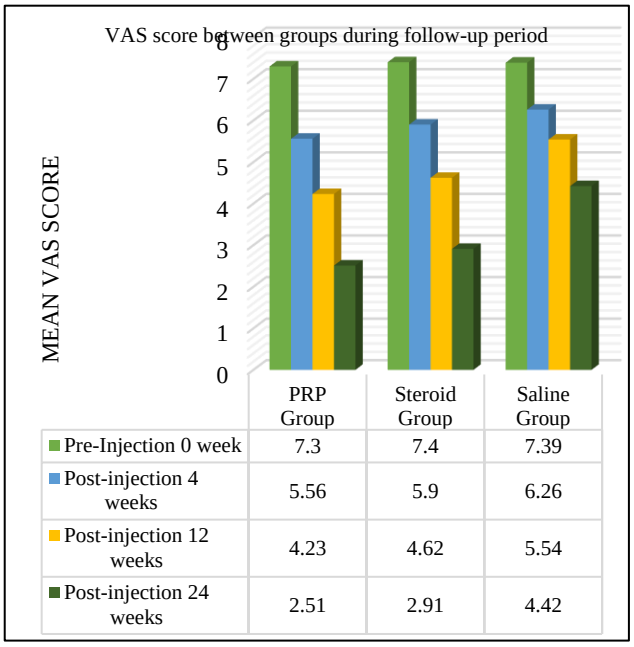
The mean duration of symptoms in PRP, steroid and normal saline groups was 5.85±1.63 months, 5.74±1.23 months and 5.52±0.96 months, respectively. There was no significant difference between the groups as per student t-test (p>0.05) (Table 1).

Table 1: Distribution of patients according to mean duration of symptoms.

Distribution of symptoms (Months)						
PRP group		**Steroid group**		**Saline group**		**P value**
Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	
5.85	1.63	5.74	1.23	5.52	0.96	>0.05

Comparison of VAS score between groups during follow-up period

The VAS score improved significantly in PRP group and steroid group compared to normal saline group at post-injection 4 weeks, post-injection 12-week period and post-injection 24-week follow-up period as per ANOVA test (p<0.05) (Figure 1).



PRP-Platelet-rich plasma; VAS-Visual analogue scale; PRP group vs saline group-p<0.05 at post injection 4, 12 and 24 weeks; steroid vs saline group-p<0.05 at post injection 4, 12 and 24 weeks.

Figure 1: Comparison of VAS score between groups during follow-up period.

DISCUSSION

In the present study, the VAS score improved significantly in PRP and Steroid groups compared to normal saline

group at post-injection 4th week, post-injection 12th week and post-injection 24th week follow-up period as per ANOVA test ($p<0.05$). Also in this study, there was no significant difference with respect to the mean duration of symptoms between PRP, Steroid and Normal saline groups as per Student t-test ($p>0.05$). Similar studies can be found in the literature. In one such study, PRP injection group (0.77±0.664 months) showed lesser mean duration of symptoms than corticosteroid injection (0.92±1.121 months) and normal saline injection (1.01±1.227 months) groups. Also, 'The shortened disabilities of the arm, shoulder and hand questionnaire' (QuickDASH) scores at week three and week eight were reported in this same study. And it was observed that PRP injection was more effective compared to corticosteroid injection and normal saline injection at week eight regarding pain, and the improvement was statistically significant.[14]Another study was conducted in two groups-PRP and steroid treated group. This study reported constant score (CS) in both the groups over a period of follow-up and showed that the steroid group had clinically significant but statistically insignificant difference. In PRP and steroid groups, there was no significant difference between the groups for the flexion degree of the shoulder before treatment, the increase of the flexion degree at the end of the treatment and at the 6th month after the treatment was similar in both the groups. Also, it was observed that, VAS score in overhead activities at the end of treatment was clinically higher in the steroid group than the PRP group, this clinically significant difference was found to be statistically insignificant.[15] One prospective single-center study assessing the efficacy of PRP therapy showed a highly statistically significant difference in VAS pain score and Shoulder pain and disability index (SPADI) score before and after PRP injection. There was highly statistically significant positive correlation between the improvement of ultrasound (US) grading score change and the improvement of VAS score change, and between it and SPADI improvement change respectively. There was a highly statistically significant difference between US grading score before and after PRP injection.[16]

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, which 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.[17] In a randomized prospective blinded study, group I, which received PRP injections showed a more improved mean VAS score as compared to group II, which received the depot corticosteroid injections.[18]

There is one meta-analysis exploring the effectiveness of PRP injection regarding functional recovery, pain relief, and range of motion of the shoulder compared with the corticosteroid injection reported in the short-term subgroup. The results indicated that the patients in the corticosteroid group had a significant reduction in shoulder pain compared with the patients in the PRP group. In the medium-term subgroup, the results revealed that PRP injection relieved the shoulder pain with a mean difference score of -0.17 compared with corticosteroid injection, but the difference was not statistically significant. In the long-term subgroup, the difference between the PRP and corticosteroid groups was also not statistically significant.[19] Another meta-analysis found that there was no difference in the short term (3 weeks) pain symptoms control between PRP and control interventions. PRP injection (s) was significantly better for medium (6 months) and long-term (12 months) pain symptom control. PRP was significantly more effective in reducing pain of up to 24 weeks. Interestingly, while PRP demonstrated a significant advantage over control for medium and long-term pain symptoms, this effect does not translate consistently with shoulder function scores.[20]

In a prospective randomized controlled study evaluating the results of subacromial injection of PRP versus corticosteroid injection therapy, both injection groups showed statistically significantly better clinical outcomes over time compared with those before injection. There was a statistically significant difference between PRP group and corticosteroid group 12 weeks after injection, in favor of the PRP group.[21]Also, another study was conducted to compare 6-week and 6-month outcome with single-dose injection of PRP or steroid for subacromial impingement syndrome. This study reported improvement in the VAS score for pain and constant score at week 6 and month 6 was significantly better following steroid than PRP injection. The difference in the constant score was greater than the mean clinically important difference of 10.4.[22]

CONCLUSION

PRP injection was more effective than corticosteroid injection and normal saline injection for SIS in the long period. PRP can be considered an effective method for treatment on pain in chronic SIS and less invasive compared to surgical treatment. It improves the pain and shoulder function. VAS score improved significantly in PRP group and Steroid group compared to normal saline group at post-injection 4 weeks, post-injection 12-week period and post-injection 24-week follow-up period.

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Ethical approval: The study was approved by the Institutional Ethics Committee by RGMC and Chhatrapati Shivaji Maharaj hospital, Thane (Registration Number: ECR/469/Inst/MH/2013/RR-20).

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