Randomized control trial comparing results of platelet rich plasma with steroid injection in subacromial impingement syndrome

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Abstract

Background: One of the most common causes of shoulder pain in adults is Subacromial impingement syndrome. Use of Platelet rich plasma is among the current emerging concepts in the treatment of this syndrome. This study aimed to compare the effects of subacromial injection of Platelet rich plasma (PRP) with Steroid injection in treatment of shoulder impingement syndrome. The clinical condition and functional outcome scores before and after the treatment were evaluated.

Methods: The study was conducted in the department of orthopedics of a tertiary level centre. Cases were selected from the patients attending routine OPD of orthopaedics department from January 2015 to December 2017 that had not responded to conservative treatment with NSAID and exercises for 4 weeks. A total of 100 patients were selected for the study. These were divided into two equal groups of 50 patients each. Group A (n=50) patients were treated with Single dose injection of mixture of 1 ml of steroid (Depo-Medrol containing 40mg/ml of Methylprednisolone) and 5 ml of Xylocaine. Group B (n=50) patients were treated with Single dose injection of 3 ml of autologous platelet rich plasma. The patients were followed up at 2 weeks, 6 weeks and 6 months after treatment and evaluated clinically and functionally using visual analogue scale (VAS) score for pain and the Constant–Murley score.

Results: There was an improvement in mean VAS scores and mean Constant-Murley scores in both the groups. The mean VAS score improved from 7.2 to 5.4 at 2 weeks, 2.8 at 6 weeks and 1.7 at 6 months in Group A. The mean VAS score improvement in Group B was 6.8 at 2 weeks, 5.7 at 6 weeks and 4.5 at 6 months compared to initial VAS score of 7.4 in this group. In Group A the mean Constant score increased from 37.5 at baseline to 51.6 at 2 weeks, 55.3 at 6 weeks and 63.7 at the end of 6 months after the injection; whereas it increased from 39.8 at baseline to 40.7 at 2 weeks, 42.1 at 6 weeks and 51.4 at 6 months of receiving the injection in Group B. Both the groups showed clinical improvement but the improvement in the mean Constant score and mean VAS score at 2 weeks, 6 weeks and 6 months was significantly better in Group A (Steroid) than Group B (PRP). This difference in improvement in both the groups was statistically significant (p Value <0.05).

Conclusion: In our study the results for steroid injection were better than injection of platelet rich plasma for treatment of subacromial impingement syndrome. The clinical improvements as well as improvement in VAS scores and Constant scores were significantly greater with steroid injection than with PRP injection.

Keywords: Platelet rich plasma (PRP), Steroid, Subacromial impingement syndrome, Constant-Murley Score, Visual analogue scale (VAS)

Introduction

Subacromial impingement syndrome and rotator cuff disease are among the most common causes of shoulder pain and dysfunction in adults [1, 2]. Subacromial impingement syndrome encompasses a spectrum of subacromial space pathologies including partial thickness rotator cuff tears, rotator cuff tendinosis, calcific tendinitis, adhesive capsulitis, acromioclavicular joint arthritis and subacromial bursitis [3]. The main consequences of shoulder impingement syndrome are pain and limitation of the range of motion leading to functional impairment [3]. Subacromial space is formed superiorly by the anterior edge and under surface of the anterior third of the acromion, coracoacromial ligament and the acromioclavicular joint [4]. Inferiorly it is formed by the humeral head [4]. The height of this space also known as impingement interval as seen on radiographs ranges from 1.0 to 1.5 centimeters [4]. This space is maximally narrow when the arm is abducted. Sandwiched between these two bony structures are the rotator cuff tendons, the long head of the biceps tendon and subacromial bursa [4]. Any abnormality that disturbs the relationship of these subacromial structures may lead to impingement [4]. The etiological factors include

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muscle weakness, degenerative tendinitis, shoulder overuse, thickening of the acromioclavicular ligament, acromial spurs, acromial defects and glenohumeral instability [4]. Neer classified impingement syndrome into three stages [5]. Stage I is characterized by acute bursitis accompanied by subacromial oedema and hemorrhage in patients aged ≤ 25 years [5]. Stage II is characterized by irreversible fibrosis and tendinitis of the rotator cuff in patients aged 25 to 40 years [5]. In stage III partial or complete tear of the rotator cuff is seen in patients aged > 40 years [5].

In most cases particularly stage I impingement conservative management is sufficient. It involves rest, sport and job modification and Non steroidal anti-inflammatory drugs (NSAIDS) [6, 7]. It may also involve prolonged physiotherapy in the form of muscle strengthening exercises [6, 7]. Another commonly used treatment is subacromial injection of steroid [8]. Therapeutic injection of xylocaine and steroid (Methylprednisolone) reduces subacromial inflammation and pain and enables healing of the rotator cuff and functional improvement [8]. Surgical treatment in the form of arthroscopic acromioplasty and decompression is helpful in many cases not responding to conservative management [9]. A fairly recent and evolving concept is the use of platelet rich plasma (PRP) in the treatment of subacromial impingement syndrome. Platelet-rich plasma (PRP) injection stimulates and accelerates natural healing through growth factors released from the activated platelets [10, 11]. The individual cytokines present in the platelet-granules have been shown to enhance fibroblast migration and proliferation, up-regulate vascularization, and increases collagen deposition [10, 11, 12]. It is also shown to have anti-inflammatory and antimicrobial effect [10, 11]. PRP is autogenous, easy to prepare, simple and cheap with an excellent reliability profile [11, 12]. The optimal volume, application frequency, application period, and platelet activation is still a matter of debate [13]. This study was done to compare the results of single dose steroid injection with single dose of platelet rich plasma in subacromial impingement syndrome.

**Material and Methods**

The study was conducted in the department of orthopedics of a tertiary level centre. The institute is a 1000 bedded Multispeciality hospital and Medical College situated in rural area of North India. Cases were selected from the patients attending routine OPD of orthopaedics department from January 2015 to December 2017 that had not responded to conservative treatment with NSAID and exercises for 4 weeks. The diagnosis of Subacromial impingement syndrome was based on clinical examination i.e. pain around the shoulder region with restricted shoulder movement, positive Neer impingement sign and Hawkins test. A total of 100 patients between 18 to 60 yrs of age were included in the study. The study design was single blind prospective randomized controlled trial. All patients were evaluated for age, sex, duration of symptoms, type of pain, position of limb in maximum pain, any specific aggravating factor, associated conditions, Constant–Murley Score[14] , Visual analogue scale (VAS) score [15] and any previous history of steroid injections. The inclusion and exclusion criteria for the study were as follows.

**Inclusion criteria:-**

1. Patients with complaints of shoulder pain with limitation of movement.
2. Neer’s Impingement Test – Positive.
3. Hawk’s Test – Positive.
4. Willingness and consent to participate in an Investigational Technique.
5. Willingness to forgo any other concomitant conservative treatment modality i.e. NSAIDS and orthotic devices during the study period.

**Exclusion criteria:-**

1. Adhesive Capsulitis
2. Glenohumeral Arthrosis
3. Complete Rotator cuff tear
4. Shoulder instability
5. History of fracture or surgery in the shoulder region
6. Previous history of steroid injection
7. Pregnancy and breast feeding
8. Systemic disease – Rheumatoid Arthritis, Diabetes Mellitus, local or systemic infection etc.
9. Patients with history of clotting disorder and anticoagulation therapy
10. Any malignancy
11. Low platelet count ( < 150000 / mm3)

A total of 100 patients were selected for the study. These were divided into two equal groups of 50 patients each; randomly allocated using simple number randomizing method.

**Group A (n=50) –** These patients were treated with Single dose injection of mixture of 1 ml of steroid (Depo-Medrol containing 40mg/ml of Methylprednisolone) and 5 ml of Xylocaine.

**Group B (n=50) –** These patients were treated with Single dose injection of 3 ml of autologous platelet rich plasma. The PRP was prepared manually using differential centrifugation method. A total of 30 ml patient’s own blood was drawn from the antecubital region maintaining sterile technique into tubes containing acid citrate dextrose (Anticoagulant). This was then put in Autologous Platelet Separator System (1500 RPM for 5 minutes), yielding 3.5 – 5
ml platelet rich plasma (PRP) as supernatant. The platelet count thus obtained in the supernatant was 4 times greater than the platelet count in the peripheral blood. 3 ml of the PRP was activated using 10% calcium chloride (50 μl of CaCl2 in 1 ml PRP). Injections in both the groups were given by posterior subacromial approach. The patients were monitored for 10 minutes for any adverse reactions. The patients were followed up at 2 weeks, 6 weeks and 6 months after treatment and evaluated using visual analogue scale (VAS) score for pain, the Constant–Murley score [14], and range of motion of the shoulder. The Constant–Murley score ranges from 0 to 100 points representing worst and best shoulder function respectively. Appropriate statistical tests like chi-square test, student’s t-test and u-test were applied. A p value of <0.05 was considered statistically significant. No NSAIDS or any other form of conservative treatment was given concomitantly. Both groups were put on standard shoulder physiotherapy regimen following the injection for 6 weeks. Approval of the hospital ethical committee was taken for the study.

Results
Both the groups were matched for demographic variables and were comparable in term of age, sex, Initial VAS score and Constant score (Table 1). The mean age of the patients in Group A was 43.3±6.5 years while in Group B it was 45.10±5.3 years. There were 54 males and 46 females in the study (Group A M:F Ratio was 26:24 while Group B M:F Ratio was 28:22). The duration of symptoms was about 6 month on average. Initial mean Visual analogue scale (VAS) score at the start of the study was 7.2±1.1 in Group A and 7.4±1.3 in Group B. Initial mean Constant–Murley score was 37.5±6.5 in Group A and 39.8±5.5 in Group B. There was an improvement in mean VAS scores and mean Constant-Murley scores in both the groups. The mean VAS score improved from 7.2 to 5.4 at 2 weeks, 2.8 at 6 weeks and 1.7 at 6 months in Group A. The mean VAS score improvement in Group B was 6.8 at 2 weeks, 5.7 at 6 weeks and 4.5 at 6 months compared to initial VAS score of 7.4 in this group (Table 2). In Group A the mean Constant score increased from 37.5 at baseline to 51.6 at 2 weeks, 55.3 at 6 weeks and 63.7 at the end of 6 months after the injection; whereas it increased from 39.8 at baseline to 40.7 at 2 weeks, 42.1 at 6 weeks and 51.4 at 6 months of receiving the injection in Group B (Table 3). Both the groups showed clinical improvement but the improvement in the mean Constant score and mean VAS score at 2 weeks, 6 weeks and 6 months was significantly better in Group A (Steroid) than Group B (PRP). This difference in improvement in both the groups was statistically significant (p Value <0.05).

Discussion
Subacromial impingement syndrome (SIS) is a common and painful condition seen in adults [16]. The most beneficial and appropriate management of SIS is a topic of wide debate. Both non operative and operative treatment options provide equally good outcomes [16]. The primary treatment of SIS involves NSAIDS and physiotherapy. There is currently no evidence to suggest that surgical treatment provides superior outcomes compared to non surgical treatment and hence, surgery is usually only indicated in patients with failure of conservative management [9, 16].

Neer [5] first introduced the concept of rotator cuff impingement. He stated that it resulted from mechanical impingement of the rotator cuff tendon beneath the antero-inferior portion of the acromion, especially when the shoulder is placed in the forward-flexed and internally rotated position [17]. He reported that about 90% of rotator cuff tears are a result of subacromial impingement from supraspinatus outlet narrowing.

Luime et al. estimated the prevalence of shoulder complaints
to be in the region of 7%–34% and about 14.7 new cases/1000 patients/year were seen in clinics [17]. Of these, subacromial impingement syndrome is the most common reported diagnosis accounting for up to two-thirds of all shoulder pain [18].

Corticosteroid injections into the subacromial space and physiotherapy, often in combination, form the mainstay of non operative management [16, 19]. Cummins et al. prospectively evaluated outcomes in 100 patients who had a subacromial steroid injection followed by physical therapy [19]. They found that 79% of the patients did not require surgery after 2 years, and in these patients, the average American Shoulder and Elbow Surgeons (ASES) outcome score increased from 56 to 95, with an average decrease in the visual analog score (VAS) from 4.8 to 0.6 [19].

Kang et al. also reported an improvement in University California Los Angeles (UCLA) shoulder score and VAS up to 3 months after subacromial steroid injection [20]. The use of ultrasound to perform the injection was not shown to be any superior than blind procedure using clinical landmarks [21]. The improvement in VAS and ASES scores were comparable.

Molloy et al. in their study showed that PRP may regenerate tendon or muscle function [22]. PRP applied in an un-activated form becomes activated by the collagen within connective tissue [22]. The PRP then releases its growth factors and cytokines [22]. These bioactive proteins in turn stimulate local stem cells and enhance extracellular matrix gene expression [22].

Pasin T et al. in their study on Comparison of the Effectiveness of Platelet-Rich Plasma, Corticosteroid, and Physical Therapy in Subacromial Impingement Syndrome found that PRP injection, corticosteroid injection, and physical therapy had effective roles in terms of pain, quality of life, and shoulder functions [23]. However, PRP injection was more effective compared to corticosteroid injection and physical therapy at week eight in terms of UCLA SRS, VAS during activity [23].

Shams A et al. have administered a single dose of PRP; however, in month six, they detected that PRP activity did not continue [24]. PRP injections showed earlier better results as compared to corticosteroid injections, although statistically significant better results after 6 months could not be found [24]. Therefore, subacromial RPP injection could be considered as a good alternative to corticosteroid injection, especially in patients with a contraindication to corticosteroid administration [24].

Say F et al. in their study on Platelet-rich plasma versus steroid injection for subacromial impingement syndrome concluded that steroid injection was more effective than PRP injection for treatment of SIS in terms of the Constant score and VAS for pain at 6 weeks and 6 months [25]. They used single dose injection of either steroid or PRP in their study [25].

The most important findings of the present study were better VAS scores, Constant scores and clinical improvement after steroid injection at different follow up periods of 2 weeks, 6 weeks and 6 months in comparison with PRP injection. The differences between the two groups were statistically significant in terms of shoulder function and scores (p Value <0.05).

The role of platelet rich plasma injection in treatment of subacromial impingement syndrome is still in the research phase. There are also few studies comparing results of PRP with Steroid in SIS. Although few studies have been conducted to evaluate the results but there is no common consensus about the method of preparation of PRP, its dose, frequency of administration and most importantly its efficacy.

**Conclusion**

In our study the results for steroid injection were better than injection of platelet rich plasma for treatment of subacromial impingement syndrome. The clinical improvements as well as improvement in VAS scores and Constant scores were significantly greater with steroid injection than with PRP injection. There is still a need for research on the management of subacromial impingement syndrome.

**References**


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