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**Original Research Article**

# Comparative study on the efficacy of intra-articular steroid injection through glenohumeral versus subacromial approach in the treatment of adhesive capsulitis

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## ABSTRACT

**Background:** Objective of the study was to compare the efficacy between gleno-humeral and sub-acromial approach of intra-articular steroid injection in the management of adhesive capsulitis.
**Methods:** This study was a randomized parallel group, open label, interventional study conducted during the period of May 2018 to October 2019. Patients with stage1 or stage2 adhesive capsulitis of shoulder (n=56) were selected and after computer generated randomization they were allocated into two groups (gleno-humeral and sub-acromial) consisting of 28 patients in each group. Gleno-humeral and sub-acromial group received intra-articular injection of 40 mg (1ml) depot methylprednisolone acetate with 2 ml of 2% lignocaine through gleno-humeral and sub-acromial approach respectively along with physical therapy. Primary outcome measure was improvement of range of motion of intervened shoulder joint from the baseline to 3rd and 6th weeks post injection. Secondary outcome measures were VAS, physician and patient's global assessment of pain and functional status.
**Results:** At baseline and 3rd post-injection none of the outcome parameters showed statistically significant difference between those two groups. At 6th post-injection sub-acromial group showed statistically significant improvement in active flexion (p value=0.040), passive flexion (p value=0.024), passive abduction (p value=0.044) and physician's global assessment score (p value=0.017).
**Conclusions:** Sub-acromial approach of injection is better than gleno-humeral approach in terms of improvement in flexion, passive abduction and physician's global assessment score at 6th post-injection in patients with stage1 or stage2 adhesive capsulitis.

**Keywords:** Adhesive capsulitis, Gleno-humeral and sub-acromial approach, Steroid

## INTRODUCTION

The terms 'adhesive capsulitis' and 'frozen shoulder' have been used interchangeably to describe multiple etiologies of shoulder stiffness that include primary or idiopathic adhesive capsulitis, secondary adhesive capsulitis resulting from a known intrinsic or extrinsic cause, and shoulder stiffness secondary to surgical intervention.[1,2] Adhesive capsulitis is 2 to 4 times more common in female than male and is most commonly affects individuals between 40 to 60 years of age group.[3]

Primary or idiopathic adhesive capsulitis of shoulder has an insidious onset, gradually progressive, painful

restriction of active and passive range of motion. It usually has a self-limiting course over a period of 1 to 2 years.[4] It is more common in non-dominant shoulder and in 34% cases bilateral shoulder may be involved.[5] Patients usually present with gradual onset, progressive pain in shoulder which is worse nocturnally and exacerbated by overhead activity and decreased range of motion leading to loss of external rotation followed by abduction and internal rotation.[4,6]

Normal shoulder joint allows flexion (0 - 180 degrees), extension (0 - 60 degrees), abduction (0 - 180 degrees), internal rotation (0 - 90 degrees), external rotation (0 – 90 degrees).[7] Apart from those motions shoulder joint also have adduction, circumduction, horizontal adduction and horizontal abduction.

Adhesive capsulitis can be divided into four stages.[3,8] Diagnosis of adhesive capsulitis is essentially clinical with presence of restriction of both active and passive range of motion of shoulder. Though there are no universally accepted criteria for the diagnosis of adhesive capsulitis, patients having external rotation of less than 50% of normal and less than 90 degrees of abduction can be classified as suffering from adhesive capsulitis.[9] As it can be difficult to differentiate scapulothoracic movement from pure gleno-humeral abduction, it is preferable to use restriction of external rotation for making the diagnosis clinically. Plain radiographs are inconclusive and not sufficient to make the diagnosis.[10] Ultrasound examination may reveal several nonspecific findings in adhesive capsulitis. But in most of the patients, ultrasound may be completely normal.[11] However presence of hypoechoic area with raised vascularity in the rotator interval provides early and accurate diagnosis.[12]

Non-surgical intervention appears to be the initial treatment of choice for adhesive capsulitis.[13] Treatment is mainly conservative using local ice compression, application of moist heat, gentle stretching, activity modification, shoulder mobilization exercises, NSAIDs, physical modalities(UST, TENS, Iontophoresis) etc.[14,15] NSAIDs are often used for short-term pain relief particularly in the inflammatory stage of the disease but they do not appear to improve pain or function as compared to placebo.[12]

Combined use of physical therapy and intra-articular corticosteroid injection provide relief of symptoms, limit the development of fibrosis and shorten the natural history of the disease.[8,16,17] In stage- 1 and stage-2 of adhesive capsulitis up to three intra-articular corticosteroid injection can be used.[18]

Different literatures showed the effectiveness of gleno-humeral as well as sub-acromial route of steroid injection in adhesive capsulitis.[19-22] This project was intended to find out which approach of intra-articular steroid injection (gleno-humeral or sub-acromial) is more efficacious in adhesive capsulitis.

## METHODS

For the purpose of sample size calculation, the range of motion of individual movement of shoulder joint was taken as primary outcome measure. Earlier studies suggest that a difference of 5 degree of range of motion may be detected and the standard deviation for this parameter were in the range of 3 to 7 degree.[23] We estimated that 22 subjects would be required in each group in order to detect 5 degrees difference in range of motion with 90% power and 5% probability of type 1 error, assuming standard deviation to be 5 degree. Assuming 20% drop out rate this translates a recruitment target of 28 patients/group. Since there were two groups, our overall recruitment target was 56 subjects (n=56). Randomization was done with subjects stratified by injection site.

Before starting the study approval was taken from institutional ethics committee. Informed written consent was taken from each patient before including them in this study. Every patient was explained about the course and prognosis of the disease, its present available management, the outcome and complications in a language that was understandable to them. All participants were given free choice to withdraw themselves from the study whenever they want.

### *Inclusion criteria*

Patients of age between 18 years to 65 years with unilateral stage-1 and stage-2 adhesive capsulitis were included the study.

### *Exclusion criteria*

Patients with rotator cuff tear, diabetes, hypothyroidism, rheumatoid arthritis, spondyloarthritis or other inflammatory arthritis and gout, adhesive capsulitis secondary to post myocardial infarction, post pacemaker placement, post stroke, post mastectomy, prolonged immobilization, overlying soft tissue infection or significant skin breakdown at the proposed injection site, infection in and around the joint, systemic infection, uncontrolled bleeding diathesis, presence of a joint prosthesis, patients who got intra-articular injection in shoulder within last one year, adhesive capsulitis secondary to brachial plexopathy or other peripheral nerve injury, adhesive capsulitis with recent bony injury or malignancy in and around that shoulder joint, pregnancy and exclusive breast feeding mothers were excluded from the study.

In this study patients suffering from adhesive capsulitis were selected for intervention according to the inclusion and exclusion criteria. Detailed history was taken and clinical examination was done. Routine blood, sugar and thyroid profile were checked. X-ray & USG of affected shoulder were done prior to giving injection. Every patient was given intra-articular steroid injection of 1ml

of depot methylprednisolone acetate (40mg) and 2 ml of 2% lignocaine under strict aseptic condition. One group was given through gleno-humeral approach and second group was given through sub-acromial approach in the shoulder joint.

Injection technique by Gleno-humeral and Sub-acromial approach: In gleno-humeral approach of injection patient was sitted comfortably on a stool, antiseptic dressing was done then the coracoid process was palpated with sterile gloved hand, then the needle was introduced 1 cm below and lateral to the coracoid process. Direction of needle was horizontal and just lateral to avoid injury to axillary nerve. Before injection aspiration was done to check for any vessel puncture. In sub-acromial approach of injection acromian angle was palpated then needle was introduced 1 cm below that point maintaining strict asepsis. Direction of needle was horizontal and just medial. The rest of the procedure was same.

Both the groups received education regarding life style modification, shoulder mobilization exercises (codman's exercise, rope and pulley exercise, wall walking exercise, cross body reach, overhead stretching etc.) for two sittings daily with 10 times of repetitions in each sitting. After injection a 5 days course of Aceclofenac (100mg) twice daily, Pantoprazole (40mg) once daily and Cefixime (200mg) twice daily were given per orally to every patient. No patient had any contraindication for any of those drugs. The following parameters were studied at baseline (on the day of injection or Visit-1), 3rd post-injection (Visit-2) and again at 6th post-injection (Visit-3).

Range of Motion of affected shoulder by goniometry: active and passive, flexion, abduction, external and internal rotation, pain on Visual Analogue Scale(VAS) in 0 to 10 cm scale, patient's global assessment (PTGA) in 0 to 10 cm scale, global assessment (PHGA) in 0 to 10 cm scale.

Using those parameters, the results were analyzed according to the standard statistical methods to fulfill the aims and objectives of the study.

## RESULTS

Data had been summarized by descriptive statistics, that is mean and standard deviation for numerical variables, counts and percentages for categorical variables. Numerical variables had been compared between groups by student's independent sample t-test where normally distributed and by Mann-Whitney U test where not normally distributed followed by Dunn's test. Chi-square test/Fisher's exact test had been employed for comparison of independent proportion. All analysis was 2-tailed and $p<0.05$ had been considered as statistically significant.

**Table 1: Demographic characteristics of the patient population.**

| Variables | Gleno-humeral (n=25) | Subacromial (n=26) | P value |
|---|---|---|---|
| **Age (Mean±SD) in years** | 47.2±8.59 | 48.4±7.87 | 0.598 |
| **Sex (Male:Female** | 13:12 | 10:16 | 0.404 |
| **Side (Left:Right)** | 15:10 | 15:11 | 1.000 |
| **Stage (1:2)** | 12:13 | 13:13 | 1.000 |
| **Weight (Mean±SD) in kg** | 49.9±5.53 | 50.0±6.04 | 0.961 |

**Table 2: Comparison of parameters between groups at Visit-1.**

| Variables (ROM in degrees and VAS, PTGA, PHGA in 0 to 10cm scale) | Glenohumeral (Mean±SD) | Subacromial (Mean±SD) | P value |
|---|---|---|---|
| **Active flexion** | 87.4±28.14 | 97.5±21.87 | 0.158 |
| **Passive flexion** | 93.8±28.81 | 101.0±19.24 | 0.297 |
| **Active abduction** | 78.0±27.46 | 87.5±23.59 | 0.191 |
| **Passive abduction** | 82.6±26.07 | 92.3±25.39 | 0.184 |
| **Active ER** | 14.6±6.11 | 16.5±7.59 | 0.321 |
| **Passive ER** | 16.6±6.88 | 19.8±8.77 | 0.154 |
| **Active IR** | 22.6±9.03 | 27.3±7.90 | 0.053 |
| **Passive IR** | 28.4±8.17 | 30.8±8.77 | 0.161 |
| **Pain VAS** | 8.8±1.02 | 8.7±1.03 | 0.693 |
| **PTGA** | 9.0±1.06 | 9.4±0.81 | 0.203 |
| **PHGA** | 8.4±1.00 | 9.0±0.82 | 0.060 |

In this study, 5 out of 56 patients dropped out following the baseline visit (Visit-1). In gleno-humeral (GH) group 25 patients and in sub-acromial (SA) group 26 patients completed follow up (Visit-2 and Visit-3).

In total study population, 45.10% were male and 54.90% were female, 41.18% had right shoulder and 58.82% patients had left shoulder involvement, 49.02% patients were in stage-1 and 50.98% were in stage-2 adhesive capsulitis. There was no statistically significant difference regarding age, sex, side, stage of adhesive capsulitis and body weight between those two groups (Table 1).

***Comparison of parameters between groups***

In this study all the injections were given by one person. Evaluation was done by two separate persons at all visits. Evaluators were blinded regarding the injection approach. Inter-reader and intra-reader reliability were done for all outcome measures.

**Table 3: Comparison of parameters between groups at visit-2**

| Variables (ROM in degrees and VAS,PTGA,PHGA in 0 to 10cm scale) | Glenohumeral (Mean±SD) | Subacromial (Mean±SD) | P value |
|---|---|---|---|
| **Active flexion** | 129.4±32.70 | 137.1±16.44 | 0.290 |
| **Passive flexion** | 135.6±32.22 | 142.9±17.39 | 0.317 |
| **Active abduction** | 120.4±34.67 | 126.2±20.41 | 0.471 |
| **Passive abduction** | 126.0±34.61 | 131.3±21.29 | 0.508 |
| **Active ER** | 38.4±19.19 | 30.4±6.92 | 0.051 |
| **Passive ER** | 42.0±20.36 | 34.2±7.58 | 0.075 |
| **Active IR** | 48.2±15.20 | 44.6±8.11 | 0.296 |
| **Passive IR** | 52.4±15.95 | 49.2±9.45 | 0.390 |
| **Pain VAS** | 4.5±1.56 | 4.6±1.13 | 0.445 |
| **PTGA** | 4.9±1.36 | 4.7±1.22 | 0.692 |
| **PHGA** | 4.8±1.34 | 4.5±1.07 | 0.283 |

**Table 4: Comparison of parameters between groups at Visit-3.**

| Variables (ROM in degrees and VAS,PTGA, PHGA in 0 to 10cm scale) | Glenohumeral (Mean±SD) | Subacromial (Mean±SD) | P value |
|---|---|---|---|
| **Active flexion** | 147.6±27.43 | 159.6±9.58 | 0.040 |
| **Passive flexion** | 154.6±26.45 | 167.3±8.74 | 0.024 |
| **Active abduction** | 139.8±31.01 | 150.2±16.82 | 0.140 |
| **Passive abduction** | 145.2±29.06 | 158.5±14.61 | 0.044 |
| **Active ER** | 50.4±18.02 | 49.2±8.68 | 0.768 |
| **Passive ER** | 54.0±19.31 | 53.3±11.04 | 0.868 |
| **Active IR** | 64.6±13.76 | 63.7±12.93 | 0.801 |
| **Passive IR** | 69.0±13.84 | 70.2±13.00 | 0.752 |
| **Pain VAS** | 3.5±1.50 | 2.8±1.14 | 0.142 |
| **PTGA** | 3.5±1.42 | 2.9±1.24 | 0.129 |
| **PHGA** | 3.4±1.42 | 2.5±1.03 | 0.017 |

At visit-1 (on the day of injection) there was no statistically significant difference between those two groups in any parameters (Table 2). At visit-2 (3 weeks post-injection) both the groups showed improvement in all parameters but there was no statistically significant difference in terms of improvement in any parameter between the two groups (Table 3). At visit-3 (6 weeks post-injection) there was statistically significant improvement in active and passive flexion, passive abduction and physician's global assessment score in sub-acromial group as compared to the gleno-humeral group (Table 4).

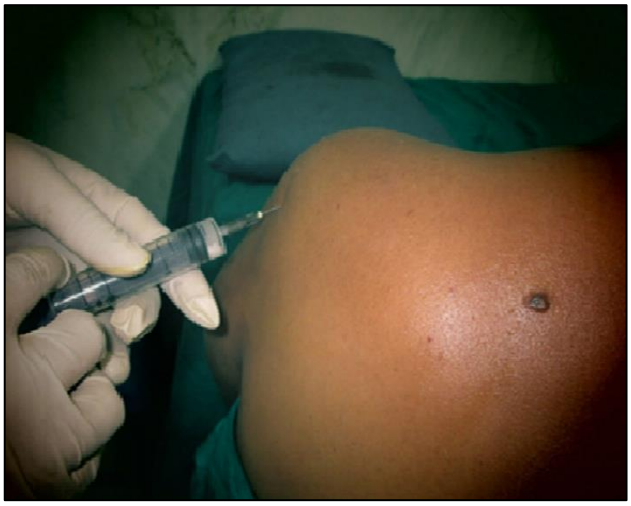

**Figure 1: Corticosteroid injection through sub-acromial approach.**

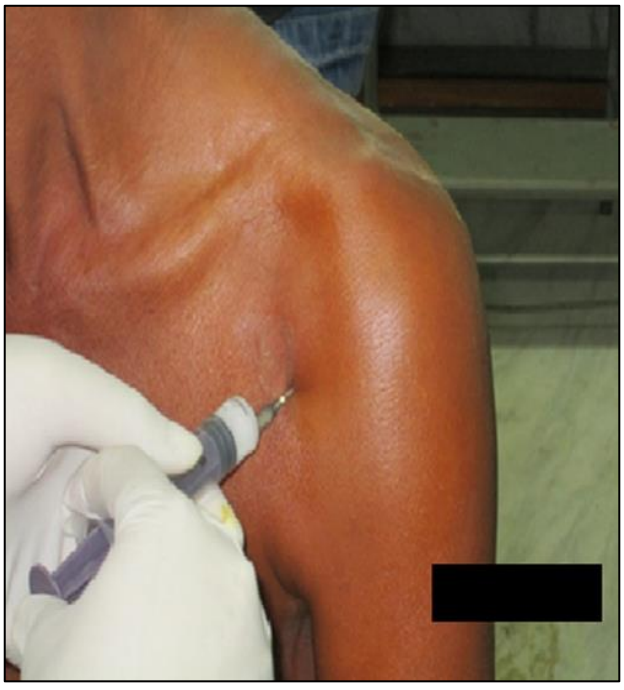

**Figure 2: Corticosteroid injection through gleno-humeral approach.**

## DISCUSSION

The effectiveness of intra-articular injection of steroid in adhesive capsulitis has been claimed in many literatures. Injection can be given through different approach.[24]This study showed that age is an important risk factor for the occurrence of adhesive capsulitis as majority of the patients (44 out of total 51 patients) in this total study population were between the age group of 40 to 60 years. As per several literatures incidence of adhesive capsulitis is highest between 40 to 60 years of age group.[3,25,26] Adhesive capsulitis is more common in women.[17,26,27] In our study 54.9% of the total study population were female and 45.1% were male. All the patients in our study were right handed. 58.82% patients of the total study population had left shoulder involvement and 41.18% had right shoulder involvement. This finding is also supported by some literatures as saying that non-dominant shoulder involvement is more common in adhesive capsulitis.[5] 50.98% patients of the total study population were in stage 2 and 49.02% patients were in stage 1 of adhesive capsulitis. Patients in stage 3 and stage 4 adhesive capsulitis were not included in the study, as these are not inflammatory stage.[28]

For flexion, between gleno-humeral versus sub-acromial group at visit-1 (baseline) and visit-2 (3 weeks post-injection) there were no significant difference, but at visit-3 (6 weeks post-injection) Sub-acromial group showed better improvement in active as well as passive flexion than Gleno-humeral group. For abduction, there was no significant difference between gleno-humeral versus sub-acromial group at visit-1 and visit-2, but at visit-3 passive abduction was better in Sub-acromial as compared to gleno-humeral group. No significant difference was found in external rotation or internal rotation between those groups in any visit.

In a study done by SJ et al. did not found efficacy of a single corticosteroid injection to be related to the site of injection.[24] In a prospective, randomized short-term comparison study JH et al. did not observed any statistically significant difference in improvement of shoulder range of motion between gleno-humeral and sub-acromial group in any follow up visit. In that study gleno-humeral group showed lower pain VAS at 3 week post-injection.[29]

But in our study there was no statistical difference in pain VAS between those groups in any visit. Patient's global assessment also did not show any significant difference in any visit between those groups.

Though difference in physician's global assessment score was not significant at visit-1 and visit-2 between the two groups, in visit-3 sub-acromial group showed statistically significant improvement as compared to gleno-humeral group.

It is important to mention that not a single patient in any group enjoyed pain reduction to zero on VAS scale. In all of the cases pain intensity reduced, but never came to zero. So, none of the treatment option was able to reduce the pain completely. Onset of improvement of various parameters could not be determined, as while asking the patients at follow up visits about the onset of improvement of various parameters, most of the patients could not remember the exact time of onset of improvement. From the result of our study it is assumed that the timing of improvement could be between 4 to 5 weeks. The duration of the improvement also could not be determined as the final follow up period was at 6 weeks. So, better designed and better planned studies could be done to find out those in future. Total 5 patients failed to follow up (drop out 8.93%) after visit-1. Only one patient complained of mild local pain during administration of steroid in the shoulder joint and that was transient. No other adverse reaction occurred in any patient, which suggests that all the treatment options are safe if not otherwise contraindicated.

### *Limitations*

This study was a short term study. The effects of intervention were not studied beyond 6 weeks after intervention, the sample size was small, and there was no control group.

## CONCLUSION

Sub-acromial approach of injection is better than gleno-humeral approach in terms of improvement in flexion, passive abduction and physician's global assessment score at 6th post-injection in patients with stage1 or stage2 adhesive capsulitis.

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