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# Title: Clinical and Functional outcome of Ultrasound guided versus Landmark guided Corticosteroid injections in adults with Frozen shoulder - A Randomised Control Trial

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## Abstract

**Introduction**: Frozen shoulder presents with painful and progressive loss of both active and passive ROM of shoulder joint which can be very debilitating for the patient. Intra-articular corticosteroid injections are an established treatment method in the early stages of frozen shoulder, as it reduces synovitis, limits the development of capsular fibrosis and alters the natural history of the disease.It can be given either by landmark guided or using ultrasonography guidance. Current literature has not confirmed the superiority of one technique over the other. This study was undertaken to compare the functional and clinical outcome of these two techniques of corticosteroid injection in the management of frozen shoulder.

**Materials and Methods:**This study included patients attending the Orthopaedics out patients clinic who were clinically diagnosed to have primary frozen shoulder- Stage I&II and Patients were divided into two groups using block randomization, one group received landmark guided steroid injection and the other group received ultrasound guided steroid injection.The patients were reviewed at 2nd week, 1 month, 3 months and 6 months postintraarticular injection and at each follow up they were evaluated using VAS score and the Constant and Murley(CM) score to assess pain and functional outcome respectively.

**Results**: 40 patients were included in the study, 20 in each group. CM score at 4 weeks was 89.9±7.74 and 95.6±2.72 in the landmark guidedand ultra sound guided group respectively and

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this difference was significant (p = 0.004).VAS score at 4 weeks was 2.1±1.08 and 1.2±0.41 in the landmark guided andultra sound guided group respectively which was significant (p< 0.001). 6 months post procedure mean VAS was 1.4±2.62 and 0.8±1.79 landmark and USG group which was not significant. Likewise the mean CM score in landmark and USG groups at 6 months was 93.2±14.13 and 95.6±10.65 respectively which was not significant.

**Conclusion**:Quicker pain relief and functional improvement was found in US-guided technique in the initial stage post-injection, with no significant difference between the two groups in the long term.

**Keywords**: Frozen shoulder, ultrasound guidance, landmark guidance

## Introduction

Active and passive range of motion of the glenohumeral joint slowly decreases in Frozen shoulder(FS).It affects about 2% of the general population with a female predilection.Females have a four times higher incidence compared to males. [1, 2, 3] Frozen shoulder is usually self-limiting. The two most common types of FS are primary and secondary. [4] In the primary type there is no underlying etiological factor whereas the secondary type results because of underlying disorders. These underlying disorders maybe intrinsic(rotator cuff tears), extrinsic(cervical radiculopathy) or systemic(diabetes, hypothyroidism).(4)

Patients with FS benefit from a variety of treatment options, including conservative and surgical approaches. Injections of corticosteroid are a well-known treatment for frozen shoulder. [5–8] Numerous studies have shown that corticosteroid injections improve shoulder mobility and pain relief in the short term. (8),(9). It works by reducing inflammation in the synovial and GH joints, as well as the number of fibroblasts, vascular hyperplasia, and fibromatosis, and thereby modifies disease course by reducing pathologic changes in the capsular tissue. [9, 10] Intra-articular injections are often carried out with the aid of landmarks or ultrasound (US).Previous literature has not been able to establish the superiority of one injection technique over the other. In a randomised control trial, the authors found that in the US group the accuracy was higher 90% vs 76.19 but the difference was not found to be statistically significant. The improvements in pain and rom were more prominent in the US group but the difference was not found to be statistically significant.[11] Injections under US guidance are attempted to enhance the accuracy. However, since there is no strong agreement on which technique is best, we decided to compare the clinical and functional outcomes of US-guided versus landmark-guided intra-articular corticosteroid injection for FS.

## Materials and Methods

All patients presenting to the Department of Orthopaedics, with shoulder pain and clinically diagnosed with primary frozen shoulder-stage I and II between January 2019 and May 2020 were included after the institutional review board approved the study. Patients that suffer from a

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secondary frozen shoulder, septic arthritis, patients with aprevious history of intra-articular steroid injection in the ipsilateral shoulder were excluded. Detailed clinical history was taken, and an examination of the shoulder was done. After applying inclusion and exclusion criteria and a written informed consent taken, cases were segregated into two groups based upon block randomization. In all cases,pre-injection movements were recorded, and the VAS score was assessed for pain and CM score for function. For Group 1, in the GH joint of the affected shoulder, a blind or landmark direct corticosteroid was injected. Cases in Group 2 received a corticosteroid injection under the supervision of US doctors. The recovery procedure was the same for all participants in the study.

**Technique**

**Landmark guided intraarticular corticosteroid injection**

In the sitting position, the affected shoulder was draped and made sterile. Palpation of the posterolateral corner of the acromion determined injection site (GH joint).The injection site is marked 2 cm beneath and medial to the acromion process's posterolateral corner. The soft spot was palpated, needle (21 Gauge) tip was inserted at this site directing towards the coracoid process.(Figure 1) Once the needle was inside the joint, corticosteroid injection (consisting of a mixture of 1 mL of 40 mg/mL Triamcinolone Acetonide and 2 mL of 2% lignocaine) was injected. Triamcinolone was selected because it was the least water-soluble corticosteroid preparation with minimum systemic spillover and the longest effective length.[12]

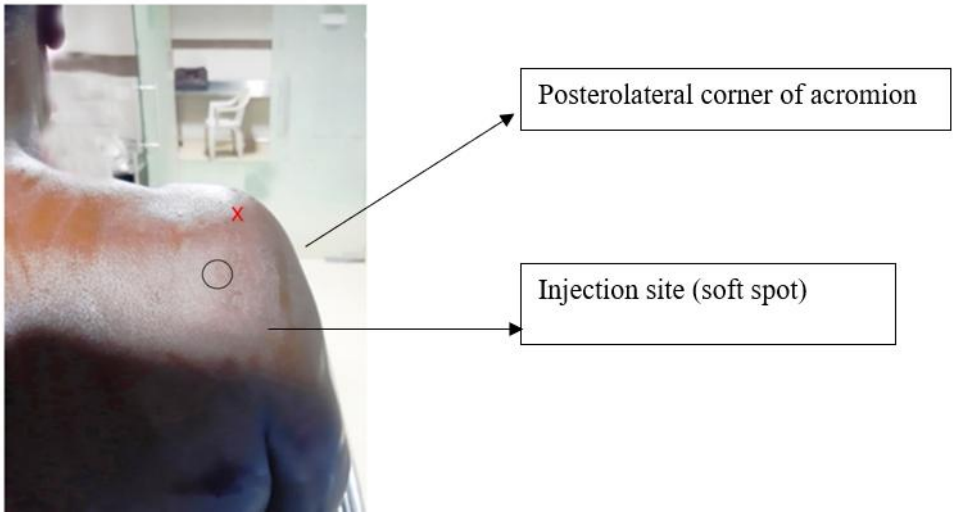


**Figure 1: Anatomical landmark for GH injections**

**Ultrasound-guided GH injection**

A high-frequency ultrasound machine (GE LOGIQ S7 expert) with a linear probe of frequency 9 megahertz was used, which touched the acromion sideways on the lower part (Figure 2).The

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needle tip (22G spinal needle) was advanced into the cavity of the glenohumeral joint using the posterior method, and its position inside the glenohumeral joint was verified by USG. A drug mixture containing 1mL of 40 mg/mL Triamcinolone Acetonide, 2mL of 2%lignocaine was administered. It was mobilized immediately and sequentially through a forwarding flexion, extension, internal rotation, abduction, and external rotation.

**Figure 2: Inserting the needle tip under US guidance**

Patients were observed for any adverse reactions to the injection. All patients were given analgesics for 5 days, were explained of steroid flare, and advised to take tablet diclofenac in case of pain increased. Additionally,they were told to proceed with a home-based exercise program including a range of shoulder motion and strengthening program, emphasizing the Rotator cuff and periscapular area (trapezius and serratus anterior). In a home-based exercise program, wall climbing stretch exercises, pendulum exercises, and gentle ROM exercises were included.

Patients were reviewed at the 2nd week, 1 month, 3 months, and 6 months post intra-articular injection. On each follow-up, functional outcome was evaluated using Constant-Murley Scoring, and analysis of pain was done using VAS score.[13] The patient's ROM of the shoulder was also assessed, and complications, if any, were noted. All the details were recorded in master charts, and statistical analysis was done.

**Statistical Analysis**

Statistical Package for Social Sciences (SPSS) for Windows 26.0 was used to analyze the results. (SPSS, Inc. Chicago, Illinois). 95% confidence intervals were used, and values of $p<0.05$ were considered statistically significant. Descriptive statistics were used to calculate numbers, percentages, mean and standard deviations. Fisher's Exact test was applied for demographics and clinical characteristics such as sex, diabetes. An unpairedt-test was used for comparing mean age in both groups. It was also used to compare Constant Murley Scoring (CMS) and Visual Analog

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Scale (VAS) at presentation, 2 weeks, 4 weeks, 3 months, and 6 months between both the groups. Unpaired t-test was applied to compare diabetes and non-diabetes for Constant Murley Scoring (CMS) and Visual Analog Scale (VAS) at presentation, 2 weeks, 4 weeks, 3 months, and 6 months between both groups.

**Results**

About 40 patients with frozen shoulder who attended the outpatient department of Orthopedics, were selected based on pre-defined inclusion criteria and recruited for the study after obtaining informed consent. There was no loss to follow-up of patients.57.83±9.1 was the mean of the patients. 70% of patients were between 46-65 age group. (Table 1) out of which 22 were males (55%), and 18 were females (45%). 70% of patients in the Landmark guided and 55% in the USG guided groups had diabetes, but this difference was statistically insignificant. (Table 2)

**Table 1: Age Distribution**

| Age (In Years) | Number | Percentage (%) | Mean ± Std. Deviation |
|---|---|---|---|
| 36 - 45 | 3 | 7.5 | 57.83± 9.1 |
| 46 – 55 | 16 | 40 | |
| 56 - 65 | 12 | 30 | |
| 66 - 75 | 9 | 22.5 | |
| Total | 40 | 100.0 | |

**Table 2: Diabetes Distribution in both groups**

| | | Landmark Guided | USG Guided | p-value |
|---|---|---|---|---|
| **Diabetes** | Absent | 6 (30%) | 9 (45%) | 0.5 (NS) |
| | Present | 14 (70%) | 11 (55%) | |

The VAS for the LMG group at presentation was 7.8 ± 0.6. It gradually decreased to 3.4 ± 0.94 and 2.1 ± 1.08 at 2 and 4 weeks post-procedure, respectively, both of which were statistically significant. At 3 months and 6 months, the mean VAS was 1.7 ± 2.2 and 1.4 ± 2.6, respectively. (Table 3) Similarly, the VAS for the USG group at presentation was 8.0 ± 0.6. It gradually decreased to 2.4 ± 0.54 and 1.2 ± 0.41 at 2 and 4 weeks post-procedure, respectively, which was

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statistically significant. At 3 months and 6 months, mean scores were 1.3 ± 1.18 and 0.8 ± 1.79, respectively. The VAS score at 4 weeks was better in the USG compared to the LMG group,the difference being statistically significant. However, the difference in these scores at 3 and 6 months was not significant in both groups. (Table 3)

**Table 3: Comparison of VAS scores in both the Groups**

| VAS scores | Landmark Guided | | USG Guided | | p-value | Significant |
|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | | |
| Presentation | 7.8 | 0.6 | 8.0 | 0.64 | 0.4 | NS |
| 2 weeks | 3.4 | 0.94 | 2.4 | 0.59 | 0.0001 | S |
| 4 weeks | 2.1 | 1.08 | 1.2 | 0.41 | 0.001 | S |
| 3 months | 1.7 | 2.22 | 1.3 | 1.18 | 0.4 | NS |
| 6 months | 1.4 | 2.62 | 0.8 | 1.79 | 0.4 | NS |

The CM score for the LMG group at presentation was 66.2 ± 3.6, and for the US group was 63.3 ± 5.9. It increased to 89.9 ± 7.74 and 95.6 ± 2.72 at 4 weeks in the LMG and US groups, and this difference was statistically significant, $p< 0.04$. At 3 months, 6 months followups, the mean scores were 92.8 ± 11.95 and 93.2 ± 14.13 in the LMG group and 95.9 ± 6.06 and 95.6 ± 10.65 in the US group, showing no statistically significant difference. (Table 4)

**Table 4: Comparison of mean values of Constant Murley Scoring in both the Groups**

| Constant Murley Scoring | Landmark Guided | | USG Guided | | p-value | Significant |
|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | | |
| Presentation | 66.2 | 3.6 | 63.3 | 5.9 | 0.07 | NS |
| 2 weeks | 87.2 | 5.0 | 89.8 | 3.66 | 0.05 | S |
| 4 weeks | 89.9 | 7.74 | 95.6 | 2.72 | 0.04 | S |
| 3 months | 92.8 | 11.95 | 95.9 | 6.06 | 0.3 | NS |

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|---|---|---|---|---|---|---|
| 6 months | 93.2 | 14.13 | 95.6 | 10.65 | 0.5 | NS |

Statistically significant improvement was seen in terms of VAS for pain and CM score for functional improvement in both the groups) up to 4 weeks post-procedure. ($p<0.05$)VAS scoreshowed slightly higher in patients with diabetes compared to non-diabetic patients at presentation (8.12 and 7.60 respectively) and each follow-up (1.24 and 0.87 at 6 months respectively), but this difference wasn't statistically significant (Table 5). The average CM score was slightly higher in non-diabetic patients than diabetic patients at presentation (64.93 and 64.68 respectively) and each follow-up (95.07 and 94.00) but was statistically insignificant. (Table 6)

**Table 5: VAS Scores of patients with DM and No DM**

| VAS Scores | Diabetes | N | Mean | Std. Deviation | p-value |
|---|---|---|---|---|---|
| PRESENTATION | Yes | 25 | 8.12 | 4.534 | 0.09 (NS) |
| | No | 15 | 7.60 | 5.994 | |
| 2 WEEKS | Yes | 25 | 3.00 | 4.865 | 0.5 (NS) |
| | No | 15 | 2.80 | 3.904 | |
| 4 WEEKS | Yes | 25 | 1.76 | 7.609 | 0.2 (NS) |
| | No | 15 | 1.53 | 3.159 | |
| 3 MONTHS | Yes | 25 | 1.72 | 10.806 | 0.5 (NS) |
| | No | 15 | 1.27 | 6.997 | |
| 6 MONTHS | Yes | 25 | 1.24 | 12.754 | 0.7 (NS) |
| | No | 15 | .87 | 12.233 | |

**Table 6: CM Scores of patients with DM and No DM**

| CMS | Diabetes | N | Mean | Std. Deviation | p-value |
|---|---|---|---|---|---|
| PRESENTATION | Yes | 25 | 64.68 | 4.534 | 0.889 (NS) |
| | No | 15 | 64.93 | 5.994 | |

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| | | | | | |
|---|---|---|---|---|---|
| 2 WEEKS | Yes | 25 | 88.00 | 4.865 | 0.348 (NS) |
| | No | 15 | 89.33 | 3.904 | |
| 4 WEEKS | Yes | 25 | 91.68 | 7.609 | 0.107 (NS) |
| | No | 15 | 94.53 | 3.159 | |
| 3MONTHS | Yes | 25 | 93.76 | 10.806 | 0.580 (NS) |
| | No | 15 | 95.33 | 6.997 | |
| 6MONTHS | Yes | 25 | 94.00 | 12.754 | 0.795 (NS) |
| | No | 15 | 95.07 | 12.233 | |

## Discussion

This prospective, randomized control trial compared two intra-articular injection techniques - LMG and US-guided – in 40 patients with frozen shoulder (Stage I and II). We observed that both groups had significant improvement with respect to pain, functional outcome, and ROM, which was not significant between the groups, except for early follow-ups at the 2nd and 4th week. The USG group had a significantly better outcome in terms of CM score.

The mean VAS score at presentation for both the groups was within a comparable range with a mean of 8.0 ± 0.6 in the USG guided group and 7.8 ± 0.6 in the landmark guided group. Different studies have reported similar scores at 1st presentation ranging from 5.4-8.0 and 6.0-7.9 for USG guided and landmark guided groups, respectively.[8,9,11,14,15]These studies have reported that the mean VAS score after treatment ranges from 1.2-4.45 in USG guided group and from 1.8-4.32 in the landmark guided group.[1,8,9,11,14]Some studies have reported a statistically significant difference in pain outcomes favoringthe USG method over the landmark guided method except for Raessidata et al. and Moore et al.,who found a similar result in both groups. Despite the fact that there was no statistically significant difference between the two groups, the LMG group's mean VAS score post-treatment was higher. Raessidata et al. concluded that USG is more reliable and offers better relief based on shoulder function and range of motion.[11] Moore et al. found no distinction between the two classes as well. Still, they found that the USG guided injections could decrease by extending the time between injections, the need for repeated injections reduced.[15]

The mean CM score- at the presentation- for both the groups was within a comparable range with a mean of 63.3±5.9 in the USG guided group and 66.2±3.6 in the LMG group. Similar scores at presentation were reported by Ucuncu et al. with a mean of 56.7± 21.6 and 70± 16.4 in USG and LMG groups, respectively. (Table 7)[9] After treatment in our study, the mean CM score was 89 ± 13.1 in USG guided group and 82.2± 16.5 in the LMG group, with a statistically significant

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difference at 4 weeks post-procedure. Other studies have also reported a statistically significant difference between shoulder function, ROM outcomes in favor of USG methods compared to landmark guided method.[8,11,16]

**Table 7: Shows the comparative results of VAS scoring in both groups between our study and other literature**

| Study | Total sample size(USG+LMG) | Mean VAS in USG group (pre-treatment) | Mean VAS in USG group (post-treatment) 1* | Mean VAS in LMG group (pre-treatment) | Mean VAS in LMG group (post-treatment) 2* | P values (between 1* and 2*) |
|---|---|---|---|---|---|---|
| Present study | 40(20+20) | 8.0 ± 0.6 | 4 weeks-1.2±0.41<br>3months-1.3±1.18<br>6 months-0.8±1.79 | 7.8 ± 0.6 | 4 weeks-2.1 ± 1.08<br>3 months-1.7±2.22<br>6months-1.4±2.62 | 0.001 |
| Naredo et al[114] | 41(21+20) | 6.12 | 4 weeks-2.16 | 6.37 | 4 weeks-4.32 | <0.001 |
| Lee HJ et al[13] | 40(20+20) | 5.4±0.5 | 4 weeks-1.5±0.4<br>3 months-0.9±0.3 | 6.0±0.4 | 4 weeks-1.8±0.3<br>3 months-0.9±0.3 | |
| Ucuncu et al[15], 2009 | 60(30+30) | 6.3± 1.8 | 4 weeks-2.27± 1.94 | 6.0± 1.4 | 4 weeks-3.77± 1.65 | <0.05 |
| Raeissadata et al[17] | 41(20+21) | 7.6 ± 1.5694 | 4 weeks-4.45 ±2.187 | 6.66± 2.35 | 4 weeks-3.8± 1.93 | 0.32 |
| Moore et al[18] | 30(15+15) | 8.0±1.8 | 4 weeks-2.2±2.4<br>6 months-5.8±2.8 | 7.9±1.3 | 4 weeks-1.8±2.7<br>6 months-6.4±2.9 | 0.66 |

Our study found that although the VAS score and CM score were slightly better in the non-diabetic group, no statistically significant difference was found in VAS and CM score when comparing diabetic and non-diabetic frozen shoulders. Barbosa F et al., in their study, reported high failure rates with conservative management (steroid injection + physiotherapy) for diabetic patients with frozen shoulder (70%) when compared to non-diabetic frozen shoulder cases (44%).[17] Furthermore, they found a high failure rate of surgical outcome (arthroscopic capsular release and mobilization under anesthesia) among diabetic FS cases (25%) when compared with non-diabetic frozen shoulder cases (10%). Chul-Hyun Cho et al. did a comparative analysis of treatment outcome between Followingone US-guided intra-articular corticosteroid injection, idiopathic frozen shoulder, and diabetic FS were treated. They discovered that it resulted in substantial changes in all outcome tests, including VAS, shoulder function ratings, and passive ROMs, in both groups at 3 weeks post-injection. (0.0027 p-value) Even so, at 6 and 12 weeks, all of the idiopathic FS group's parameters improved slightly more than those of the diabetic FS group. As a result, although a single intra-articular steroid injection can be utilized to treat diabetic FS, the long-term effect is less in diabetic FS than in idiopathic FS.[18] In the present study, no statistically significant difference was found between the two groups due to exclusion of patients who underwent arthroscopic capsular release/MUA, whereas other studies have included patients with operative intervention. Soh et al. demonstrated that corticosteroids associated complications such as steroid flare, depigmentation, and extreme pain at the injection site, which was more common in the landmark community, were recorded. In our analysis, no such complications were found in either group.[16]

**Limitations**

Blinding of the research participants for group allocation was not done, which could have led to bias with favorable results for the ultrasound-guided group. Our study had a small sample size, so larger sample size may be useful. We used only a single dose of steroid in both groups. Studies have reported 2 serial injections, but the superiority of multiple doses has not been established. Correlation about the severity of diabetes and FS was not established as in subsequent follow-ups, diabetic parameters were not evaluated. Also, our study had a short-termfollow-up of 6 months; a long-termfollow-up may be done.

**Conclusion**

Quicker pain relief and functional improvement were found in US-guided technique at initial stages post-injection, with no significant difference between the two groups in the longer term.

**Conflict of Interest:** None

**Funding:** None

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