

A comparison of the effectiveness of therapies for frozen shoulder (FS): mobilization with continuous interscalene block (CISB) and mobilization with intra-articular steroid injection (IASI)

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Abstract

Background: Frozen shoulder (FS) can cause significant discomfort and limited range of motion for the affected individual. Early and painless mobilization of the shoulder has been shown to yield positive results in treating the condition.

Objectives: The aim of this study was to evaluate and compare the effectiveness of two therapies for frozen shoulder (FS): mobilization with continuous interscalene block (CISB) and mobilization with intra-articular steroid injection (IASI). Specifically, we aim to determine the effectiveness of both interventions in improving clinical and functional outcomes and to evaluate the impact of adding IASI to mobilization with CISB.

Methods: We conducted a prospective comparative study. The participants were divided into three groups of 20 patients each. The distribution was performed by simple randomization. The primary outcomes of pain and patient satisfaction were assessed using VAS scores. Outcome measures such as pain, patient satisfaction, range of motion, and UCLA scores within groups were assessed.

Results: The majority of patients were women. There was a significant improvement in early pain relief and range of motion in patients treated with mobilization in the CISB setting. Late functional outcomes were similar in all groups, regardless of treatment modality. IASI did not have a significant impact on the early or late outcomes of CISB mobilization.

Conclusion: Mobilization under CISB provides early pain relief, improvement in range of movements, and good long-term functional results for frozen shoulders. IASI has no effect on early pain relief or improving range of motion.

Keywords: Frozen shoulder, Bursitis, Periarthritis, Shoulder, Interscalene block, Intraarticular injection.

Introduction

Frozen shoulder, or adhesive capsulitis, is a prevalent condition characterized by pain and stiffness in the shoulder joint with an unknown etiology.¹ Primary FS is typically benign and self-limiting, with complete recovery often achieved within 18 months.² In some cases, patients may experience persistent symptoms and a limited range of motion, which can lead to long-lasting disability and discomfort.³ The primary goal of treatment for FS is to shorten the duration of the disease process, minimize

symptoms, and improve function.

Standard treatments for frozen shoulders include nonsteroidal anti-inflammatory drugs (NSAIDs) and shoulder physiotherapy.^{4,5} Other treatment approaches, such as manipulation under anesthesia, prolotherapy using saline, and arthroscopic arthrolysis, have also been found useful in decreasing pain and improving mobility.^{6,7} Intraarticular steroid injection and mobilization are effective in providing early pain relief with long-term results comparable to those achieved through

physiotherapy,^{5,8} while interscalene block (ISB) followed by mobilization is another effective treatment for FS.⁹

Numerous studies have explored the comparative efficacy of different treatment modalities for frozen shoulders. Intraarticular steroid injection (IASI) has been found to be more effective than nonsteroidal anti-inflammatory drugs (NSAIDs) and physiotherapy.^{5,10-15} Controversies exist regarding the role of IASI alone versus in combination with hydrodistension. Mobilization under continuous analgesia (MUA) is another treatment approach for frozen shoulder, which can be utilized alone or in conjunction with IASI.¹¹ However, the efficacy of one treatment approach over the other is not yet conclusively proven and remains a subject of controversy among experts in the field.

To ensure the success of mobilization under anesthesia (MUA), it is crucial to provide appropriate analgesia. This can be achieved through the use of regional blocks and nonsteroidal anti-inflammatory drugs (NSAIDs).^{16,17} When combined with hydrodistension, MUA has been shown to yield good functional outcomes with the addition of an interscalene block.¹² While continuous interscalene block (CISB) is commonly used for postoperative analgesia,¹⁸ its potential efficacy in providing sufficient pain relief during MUA for frozen shoulder patients has yet to be thoroughly investigated.

Objectives

The aim of this study was to compare the clinical and functional effects of mobilization with continuous interscalene block (CISB) versus mobilization with intra-articular steroid injection (IASI) in people with frozen shoulder (FS), both at baseline and at the end of the therapeutic process. The objective is to study the impact of adding IASI to mobilization and CISB on patient outcomes, with particular attention to clinical and functional measures.

Methods

We conducted a prospective comparative study at a single center in a tertiary care teaching hospital, specifically the Government Medical College Kozhikkode. The study focused on adult patients who presented at our

outpatient clinic between January 2014 and October 2018 with shoulder pain and stiffness. To be included in the study, patients had to be between the ages of 40 and 60 years old and diagnosed with frozen shoulder (FS), with no improvement observed after at least 2 months of conservative treatments. Patients with posttraumatic stiffness, radiographic abnormalities, infectious foci in the shoulder region, severe osteoporosis, past shoulder surgeries, allergies to medicines or local anesthetics, contraindications to steroids, and subsequent adhesive capsulitis were excluded from the study. Additionally, we excluded patients with uncontrolled HbA1C levels over 7% (HbA1C>7) and those who were unable to attend follow-up visits until the study's conclusion.

The study defines a case of FS as a person who has experienced shoulder pain for over three months and has a progressive restriction of shoulder movements in at least two directions. This involves a $\geq 30\%$ restriction in passive external rotation and a $\geq 30\%$ restriction in the second plane when compared to the opposite side, with no radiological or ultrasonographic anomalies. The study's major outcome measure is pain and patient satisfaction, which are quantified using VAS values ranging from 0 to 10. Here, zero indicates the absence of pain or satisfaction, while a score of 10 represents the highest level of pain or full satisfaction. By using the VAS scores, the study aims to assess the severity of pain and determine the level of patient satisfaction for better treatment outcomes.

In addition to pain and patient satisfaction, the study also measured functional outcomes using the UCLA shoulder score and the change in range of motion, both active and passive. A UCLA shoulder score greater than 27 was considered a good or very good result, while a score less than 27 was considered poor. A goniometer was used to measure a patient's range of motion in five directions: forward flexion, extension, abduction, external rotation, and internal rotation. To measure internal rotation, the thumb position was correlated with the vertebral level on the back, and the mean of three values was used for analysis. These parameters were used to provide a more comprehensive assessment of the patient's shoulder function and were considered secondary outcomes in the study.

The study calculated a sample size of 45 by taking into consideration the prevalence of FS at 5.3%, a confidence interval of 90%, and a power of 80% with OpenEpi version 3 software. Assuming a dropout rate of 15 to 20%, the total sample size was estimated to be 54. A total of 77 patients with shoulder pain and limited movement visited the clinic during the study period, out of which eight were excluded due to the diagnosis of a rotator cuff tear by ultrasonography (2). In addition, patients with radiological anomalies (2), drug allergies (4), hydradenitis suppurativa (1), neuropathic joints (1), and caries sicca (1) were excluded. The remaining 60 patients were selected for the study and were randomly divided into three groups, each containing 20 patients, using simple randomization through randomization.com. Figure 1 provides an overview of the patient selection process for the study. The study divided the 60 selected patients into three groups, each receiving a specific treatment. The first group was treated with manipulation under CISB and mobilization (group A), while the second group received an IASI and mobilization (group B). The third group received a combination of IASI and CISB with mobilization (group C).

Prior to the interventions, the study recorded the demographic details, medical history, and symptom duration of the selected patients. The patients were then assigned to one of the three treatment groups. The study evaluated and recorded the pain levels, functional scores, and patient satisfaction levels at various points in time, including before the intervention, at the end of the exercise program after one month, and at 3, 9, and 12 months by an independent, blinded investigator. Patients who did not show improvement after the exercise program were further assessed to rule out other potential causes.

Mobilization under continuous interscalene block

The same surgeon administered the interscalene block with the same technique in all cases. The study administered one gram of prophylactic cefotaxime and a 2 mg midazolam intravenous injection as a sedative 30 minutes before the procedure. The patient was positioned supine with marks made at the posterior edge of the sternomastoid muscle, scalene triangle, and cricoid cartilage. The entry point for the needle was determined by

drawing a horizontal line from the cricoid cartilage to the interscalene groove after turning the head towards the opposite side. The needle entry point was determined as the point of intersection between the line and the posterior edge of the sternomastoid muscle. At this level, the AB Braun Contiplex needle was introduced, which included an 18 G insulated Tuohy needle, a hemostasis valve with a side port, a 20 G polyamide-nylon catheter with a closed tip, and a catheter connector. The needle was carefully advanced in a direction that was both caudal, medial, and posterior to elicit shoulder muscle contraction with a stimulation intensity of 2 mA. As soon as muscle contraction was evident, the stimulation intensity was carefully reduced by 0.5 mA. Following needle withdrawal, a 30 mL total volume of local anesthetics (10 mL 0.25% Bupivacaine, 10 mL 2% Lidocaine, and 10 mL distilled water) was carefully delivered to offer pain relief. A 20G catheter was then inserted through the needle and threaded into place before being secured with adhesive plaster after subcutaneous tunneling [Figure 2]. The detection of motor and sensory blockages in the upper limb indicated the efficiency of the ISB treatment. Finally, under ultrasound guidance, patients received an intra-articular injection of 40 mg of methylprednisolone via a 23G needle positioned in the glenohumeral joint.

Following the confirmation of complete motor and sensory block in the ipsilateral upper extremity, patients were positioned in a semi-reclined posture. A single orthopedist gently manipulated the glenohumeral and scapulothoracic joints, using little effort to avoid fractures or injuries. During the maneuver, a noticeable audible or palpable rupture of the capsule or intra-articular adhesions could be observed. The application of flexion and extension forces was carried out as close to the shoulder joint as possible to minimize torque rupture of the inferior capsule. For abduction of the glenohumeral joint, scapular stabilization was employed, with a downward thrust on the scapula employed to rupture the inferior capsule. Finally, external rotation of the shoulder joint at 90 degrees of abduction was carried out with the utmost care to gently rupture the anterior and inferior capsules. For abduction of the glenohumeral joint, scapular stabilization was employed, with downward thrust on the scapula

completing the rupture of the inferior capsule. External rotation of the shoulder joint at a 90-degree angle of abduction was delicately performed, rupturing the anterior and inferior capsules. The superior glenohumeral ligament and anterior capsule were ruptured during adduction and external rotation. Rupture of the posterior capsule was facilitated through a combination of cross-body adduction and internal rotation. Finally, the full range of movement in all directions was achieved in the operating room without unnecessary force. Postoperative mobilization commenced 4-6 hours after surgery on the same day and was maintained under continuous interscalene analgesia. The analgesic effect was accomplished by continuously administering 0.125% isobaric bupivacaine solution through the catheter using an easy pump at a rate of 5 mL per hour throughout the day. The catheter's placement was verified on the second postoperative day before advising the patient to continue the exercise program at home. A follow-up visit was scheduled one week after surgery for catheter removal. Thereafter, the patient was advised to resume regular activities, along with continuing the exercise program, which lasted for a month.

Intra-articular corticosteroid injection

Before mobilization, patients in Group B had an intra-articular injection of 40 mg of methylprednisolone through a 23G needle put under ultrasound guidance in the glenohumeral joint. On the other hand, group C underwent mobilization under continuous interscalene block along with intra-articular steroid injection.

Statistical analysis

All statistical analyses were performed with SPSS (version 19.0, SPSS Inc, Chicago, IL, USA). P<0.05 was considered significant. Continuous variables; pain, patient satisfaction, range of motion, and UCLA scores were expressed as the mean and were analyzed using ANOVA. Categorical variables are expressed as proportions and were analyzed using the Kruskal-Wallis test.

Ethical considerations

We conducted this study after obtaining institutional research committee approval, and we obtained informed consent from all the participants. The study was conducted in accordance with the Declaration of Helsinki. The

present study did not interfere with the process of diagnosis and treatment of patients.

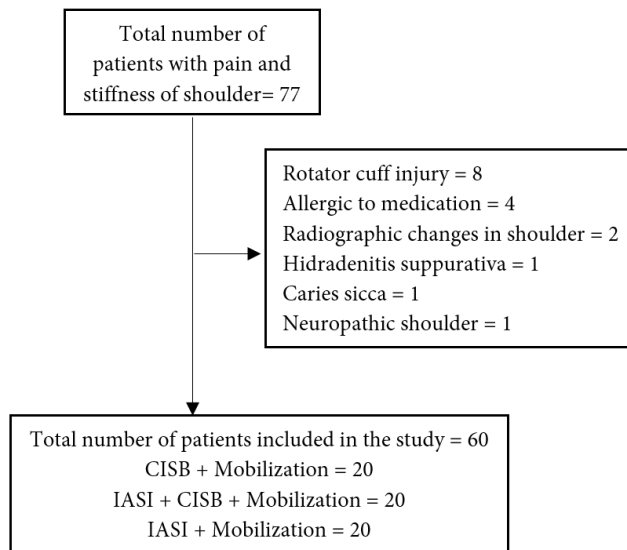


Figure 1. Patients included in the study

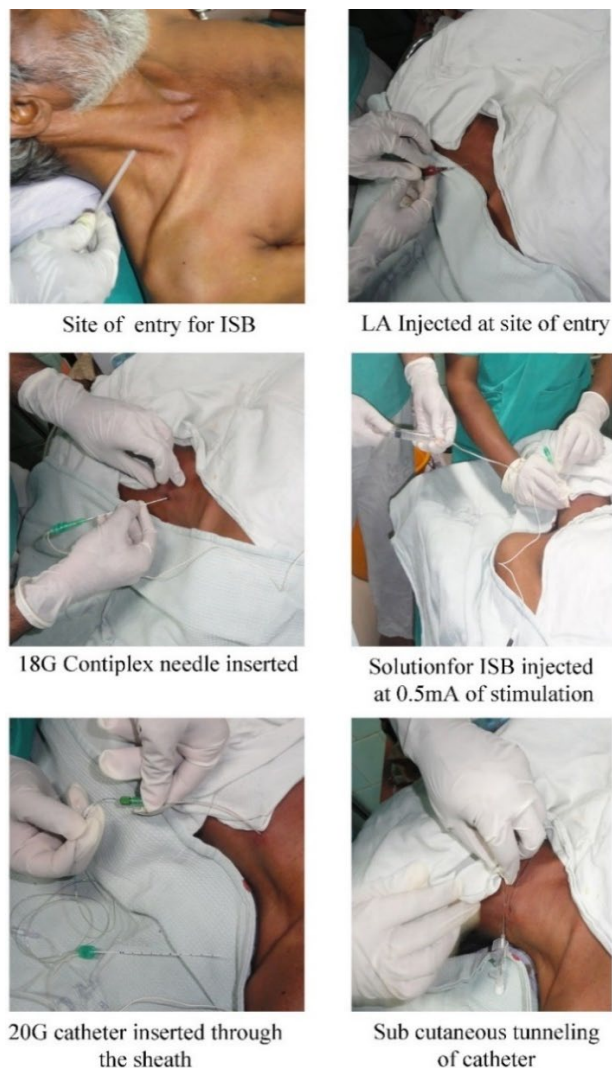


Figure 2. Photograph showing the different steps in the procedure of giving interscalene block and mobilization

Results

The three groups were similar in terms of various demographic and clinical parameters [Table 1].

Primary outcomes

All three groups showed significant improvement in the VAS pain score at the one-year follow-up. After four weeks, groups A and C displayed a significantly greater decrease in VAS scores compared to group B. This pattern of improvement continued until the 12-week follow-up. At nine months and one year of follow-up, there was no significant difference in the pain score between the three groups, as shown in Figure 3.

At the one-year follow-up, all three groups showed a significant increase in VAS scores for patient satisfaction compared to baseline ($p < 0.01$). The CISB group had a significantly higher difference in VAS score compared to the IASI group (7.3 ± 1.2 vs. 4.2 ± 1.2 ; $p < 0.001$), and this difference remained significant until the 12-week follow-up. With the exception of two patients in the IASI group who had persistent scores of 8–9 at one year, all included patients showed improvement in VAS scores. Notably, both of these patients did not experience improvement in VAS pain scores.

Secondary outcomes

The shoulder's range of motion (ROM) improved in all groups over time. All groups showed significant improvement in forward flexion at 4 weeks (group A $p = 0.0002$, group B $p = 0.03$, and group C $p = 0.002$). Between 4 and 12 weeks, group A (137 ± 8.23 to 151.5 ± 5.9 ; $p = 0.04$) and group C (139 ± 10.23 to 154.5 ± 7.9 ; $p = 0.002$) had a statistically significant increase in forward flexion, whereas there was no significant improvement in group B patients ($105^\circ \pm 18.7$ to $114^\circ \pm 12.24$; $p = 0.96$) during this period. At 4 weeks, groups A and C had a significantly higher range of flexion compared to group B ($p = 0.0008$), which remained consistent until 12 weeks. With the exception of two patients in group B, flexion ranges were similar across

groups at the 9-month and 1-year follow-ups.

At 4 weeks, patients in all three groups demonstrated significant improvement in extension (group A: $p = 0.0003$, group B: $p = 0.0008$, group C: $p = 0.0004$). The improvement in extension from 4 weeks to 1 year did not show any significant differences in any of the groups. The range of extension was similar among the groups at 4, 12, and 48 weeks of follow-up ($p = 0.62$, $p = 0.96$, and $p = 0.83$, respectively).

All three groups showed a significant improvement in abduction at the 1-year follow-up. Group A and group C patients had significant improvement in abduction as early as 4 weeks, while group B showed significant improvement by 12 weeks. However, after 12 weeks, the difference in the improvement of abduction among the three groups was not significant [Figure 4].

Group A and group C patients had significantly earlier restoration of external rotation than group B patients at 4 weeks ($p = 0.003$), and this difference remained significant until 12 weeks ($p = 0.008$). Internal rotation showed an improving trend over time in all groups, but the difference among groups was not significant. However, Group A and Group C had earlier restoration of internal rotation compared to Group B at 12 weeks ($p = 0.003$) [Figure 5].

Improvement in shoulder function based on the UCLA score was significant within all three groups at 1 year (group A $p = 0.002$, group B $p = 0.02$, and group C $p = 0.003$). Although there was an increasing trend in function over time for all groups, there was no significant difference among the groups at 4, 12, and 36 weeks. However, the difference in UCLA score between groups A and C versus group B was significant at 4 and 12 weeks [Table 2].

During the exercise program, two patients experienced CISB catheter pull-out, which required reinsertion. No complications such as Horner syndrome, hoarseness of voice, paralysis of the hemidiaphragm, rotator cuff tear, septic arthritis, or any other complication related to CISB or IASI were observed.

Table 1. Demographic characteristics of patients included in the study

Parameter	Group A (20)	Group B (20)	Group C (20)	P-value
Mean age +/- SD	54.7±9.05	55.2±8.23	54.8±10.23	0.324
Gender (M/F)	4/16	2/18	3/17	0.375
Duration of symptoms (months)	7±2.1	7±1.8	7±2.3	0.723
Dominant/nondominant side (R/L)	5/15	6/14	5/15	0.465

SD = Standard deviation, M = males, F = females, R = right, L = left

Table 2. Comparison of mean UCLA score with time in the groups

Duration of follow up	Before intervention	4 weeks	12 weeks	36 weeks	48 weeks
Group A	13.65±6.9	27.5 ±7.2	29.2±5.8	30.1± 6.5	33.1± 2.3
Group B	13.54±7.2	19.3±6.8	21.4±6.2	25.3±4.3	31.2±3.2
Group C	13.58±8.1	26.4±5.2	31.2±3.8	28.4±5.2	34.5± 2.1
Difference between groups	P=0.092	P=0.045	P=0.032	P=0.065	P=0.841

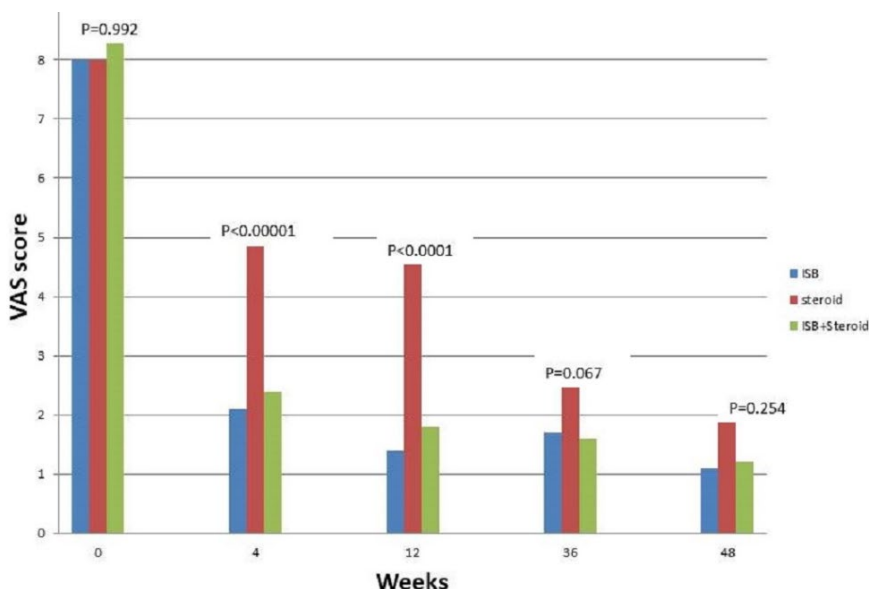


Figure 3. Diagrammatic representation of a comparison of VAS scores for pain between the three groups over time

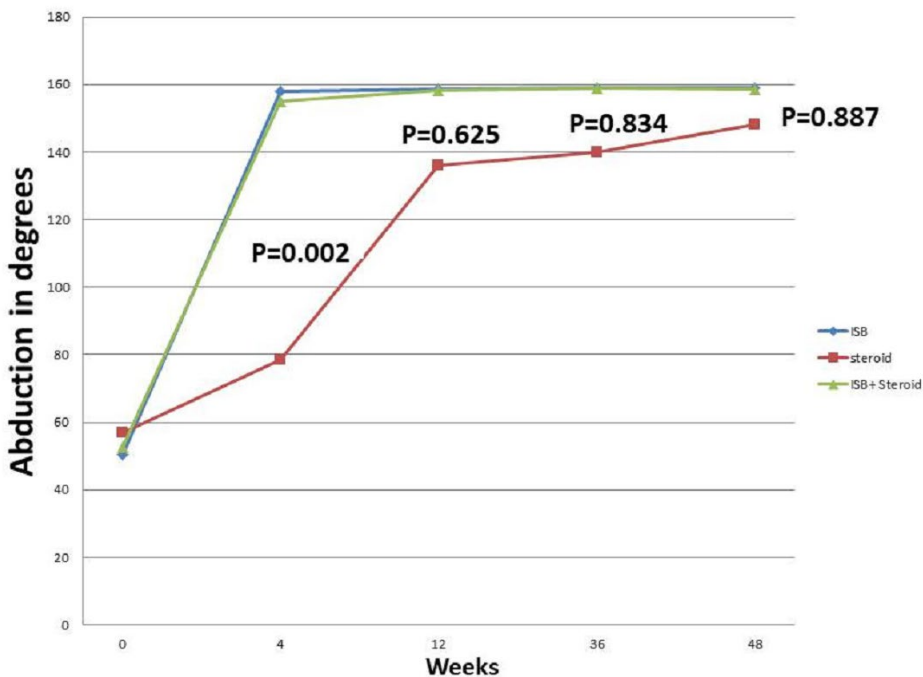


Figure 4. Diagram showing a comparison of abduction between the three groups with time. Between the groups, the difference in the degree of abduction was significantly higher in group A and group C at 4 weeks; however, there was no difference noted from 12 weeks onward.

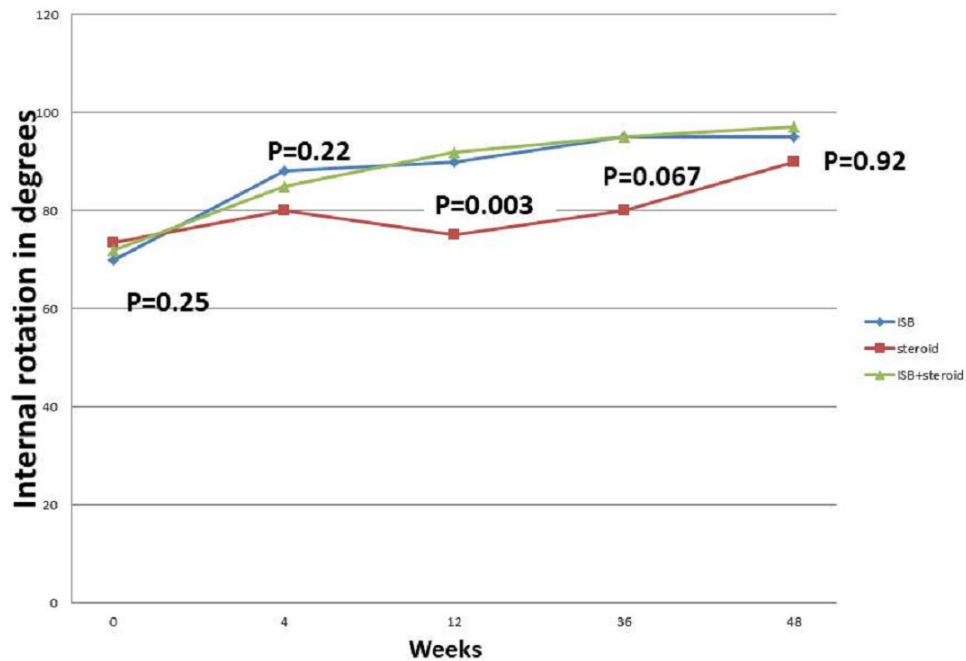


Figure 5. Diagram showing a comparison of internal rotation between the three groups over time

Discussion

Our study shows that mobilization under analgesia, combined with IASI or CISB, effectively reduces pain and improves range of motion and function in adults with frozen shoulders (FS). IASI and mobilization, however, lagged behind the others in achieving pain reduction and range of motion improvement in the first 3 months. All groups showed a steady improvement in function. Patients who received MUA and CISB exhibited early functional improvements, regardless of IASI. CISB provided continuous analgesia during the initial mobilization days, enabling early exercise.

Effective treatment of FS involves attaining permanent recovery and alleviating pain while the physiotherapy shows success. In cases of severe shoulder pain and limited motion range, exercise programs prove ineffective. Analgesia during mobilization is, therefore, crucial for successful treatment. A manipulation under general anesthesia, without surgery, cannot sustain movement range throughout the rehabilitation period due to severe pain. Interscalene brachial plexus block, used for anesthesia and postoperative analgesia in shoulder surgery, is a useful technique.¹⁹⁻²¹

Studies evaluating the effectiveness of CISB for analgesia in the treatment of FS are limited. Treatment-resistant FS improved significantly in abduction and external rotation

after mobilization under anesthesia with intermittent interscalene block.¹⁰ Manipulation under brachial plexus block followed by exercise therapy showed patient satisfaction of 100% with no need for additional analgesia.¹⁶ Glenohumeral gliding manipulation under an interscalene brachial plexus block also resulted in improved pain and range of motion.²¹ Intraarticular steroid injections are a commonly used treatment for frozen shoulders. A comparative study of glenohumeral joint injection with corticosteroids and physical therapy demonstrated significant improvement in pain, disability, and range of motion in the steroid injection group at 3 and 7 weeks.²² The success of treatment with intraarticular corticosteroids is dependent on the duration of symptoms.¹⁴ A systematic review of randomized controlled studies on IASI concluded that multiple injections were beneficial until 16 weeks from the date of the first injection.²³

Interscalene brachial plexus block is generally considered a safe procedure, though complications such as infection, catheter displacement, cardiac arrest, cervical and thoracic epidural block, and pneumothorax can occur. We encountered two cases of catheter displacement, but this was successfully managed through proper care and placement techniques, including suturing the catheter to the skin and securing it with sterile adhesive tape. In two

cases, however, we did not observe significant improvement after treatment, and MRI scans revealed full-thickness rotator cuff tears in both patients. While a study by Ramirez et al. reported that 17% of patients who received subacromial injections for shoulder pain experienced such tears,²⁴ another study found no correlation between rotator cuff tears and such injections.³ We cannot determine with certainty whether the ruptures in our cases were due to the injections or to the manipulations performed.

Our study shows that CISB and mobilization are a safe and minimally invasive technique for treating FS, with results comparable to other treatments such as arthroscopic release, surgical release, and manipulation under anesthesia. The procedure has a short learning curve, requires less hospital stay, and allows patients to practice mobilization at home. Improvements in range of motion and function can be monitored during the entire treatment period. However, our study had limitations, including a small sample size and the lack of a placebo group without interventions. Further studies with a larger population are needed for external validation of our results.

Conclusions

It may be concluded that mobilization with continuous interscalene block is an effective and minimally invasive approach for treating frozen shoulders, offering early pain alleviation, range of motion improvement, and favorable long-term functional outcomes. On the other hand, intraarticular steroid injection alone or in combination with interscalene block does not appear to have a significant impact on early pain relief or range of motion improvement. Further research with larger sample sizes is needed to validate these findings.

Acknowledgment

None.

Competing interests

The authors declare that they have no competing interests.

Abbreviations

Frozen shoulder: FS; Continuous interscalene block: CISB;

Intraarticular steroid injection: IASI; Interscalene block: ISB; Nonsteroidal anti-inflammatory drugs: NSAIDs; Mobilization under continuous analgesia: MUA.

Authors' contributions

Corresponding author - conceptualized the idea, helped in collecting data, analyzing, statistics, writing, and editing the manuscript.

Coauthor 1 and 3 - collecting data, analysis, statistics, writing, and editing the manuscript.

Coauthor 2 - collecting data, analysis, statistics, writing the manuscript.

All authors read and approved the final manuscript. All authors take responsibility for the integrity of the data and the accuracy of the data analysis.

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Availability of data and materials

The data used in this study are available from the corresponding author on request.

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki. Institutional Review Board approval was obtained. The present study did not interfere with the process of diagnosis and treatment of patients and all participants signed an informed consent form.

Consent for publication

By submitting this document, the authors declare their consent for the final accepted version of the manuscript to be considered for publication.

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