

Effects of Hydrodilatation versus Corticosteroids in Primary Idiopathic Frozen ShoulderJaykumar Maheshbhai Patel¹, Angel Nareshbhai Patel², Swati Kapadiya³, Drashti Mukeshkumar Patel⁴^{1,2,3}Assistant Professor, Department of Orthopedics, Nootan Medical College and Research Centre Visnagar, Mehsana, Gujarat, India⁴Senior Resident, Department of Radiology, GCS medical college, Hospital & Research Centre, Ahmedabad, Gujarat, India

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Conflict of interest: Nil

Abstract:**Background and Aim:** No optimal treatment has been found yet for freezing-phase frozen shoulder to quickly alleviate pain and enhance joint mobility. This study aims to compare the outcomes of Hydrodilatation technique with intra-articular corticosteroid injections on range of motion and pain at 1 month and 1 year.**Material and Methods:** The study involved 50 patients who were randomly assigned to be evenly distributed among the two study groups. Normal saline, Iohexol dye, a 22 G spinal needle, and a 10 ml syringe were utilized for the hydrodilatation procedure. During the procedure, 2 ml of Triamcortolone acetate (80 mg), 2 ml of 2% lignocaine, and a 22 G spinal needle were utilised. The patient undergoes assessment following a thorough history, examination, and investigation to determine the appropriate procedure, such as hydrodilatation or corticosteroid injection. The SPADI and ASES Score have been computed.**Results:** The majority of patients fall within the 40-50 age bracket. 31 individuals are male, making up 62% of the group, while 19 individuals are female, accounting for 38%. Within the Corticosteroids group, the initial mean abduction was just 21%, but increased to 61%. Similarly, external rotation in a neutral position started at 18% and rose to 89%, while external rotation in abduction began at 20% and improved to 83% after 1 year. After hydrodilatation, the SPADI score improved from 113 to 36 at 1-year follow-up, whereas in the corticosteroid group, the SPADI score improved from 112 to 34 at 1-year follow-up. After 1 year, the ASES score was 86 in the hydrodilatation group and 87 in the corticosteroid group.**Conclusion:** The shoulder of the dominant hand (right side) is frequently affected. There was no notable variation in the results when evaluated with SPADI and ASES between the two groups after 1 month, 6 months, and 1 year of follow-up.**Keywords:** Capsular Ligament, Corticosteroids, Hydrodilatation technique, Frozen Shoulder.This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.**Introduction**

Having a frozen shoulder can lead to shoulder pain and limited mobility. This condition involves sudden shoulder joint pain and restricted movement. This blend of pain and restricted movement can lead to discomfort and hinder daily activities for the patient.

In 1945, it was stated that the main issue with the condition is a thickening and contraction of the capsule, leading to reduced joint mobility in affected patients. [1] No issues were detected within the joint during the arthroscopy procedure. Recent arthroscopic studies on patients with frozen shoulder have found no clear intraarticular adhesions of this nature, leaving uncertainty about the role of such adhesions. [2,3] Research indicates that contractions of the joint capsule are evident,

with studies showing a significant decrease in joint volume caused by collagenous tissue contraction around the joint. [4]

During the freezing phase, individuals may experience increasing shoulder pain and a gradual reduction in shoulder mobility. [5] At this stage, patients are most eager for treatment options, typically leaning towards conservative methods such as oral non-steroidal anti-inflammatory drugs, physiotherapy, corticosteroid injections, hydrodilatation, and other local treatments. Hydrodilatation with corticosteroids is often seen as a highly effective conservative treatment for frozen shoulder, providing rapid pain relief by decreasing inflammation. [5,6] Yet, a thickened and contracted joint capsule does not easily soften,

making the process of improving ROM quite gradual. [7] Arthroscopic contracture release is a valuable method for enhancing range of motion and typically used for frozen-phase or stubborn frozen shoulder cases. For individuals experiencing freezing-phase frozen shoulder, addressing the severe on going inflammation may not be fully effective, leading to a high risk of recurrence. [8-10]

So far, there hasn't been a perfect solution for freezing-phase frozen shoulder to quickly alleviate pain and enhance joint mobility. This study aims to compare the outcomes of Hydrodilatation technique with intra-articular corticosteroid injections on range of motion and pain at 1 month and 1 year.

Material and Methods

The study was conducted in the orthopaedics department at Nootan Medical College and Research Centre Visnagar, Mehsana, Gujarat, India for the duration of 2 years. Patients experiencing shoulder pain and stiffness in one or both shoulders for at least 3 months, along with limited external rotation and abduction, were enrolled in the study following informed consent and approval from the institutional ethical committee.

This study involved 50 patients who were randomly allocated equally to both study groups. During the hydrodilatation procedure, normal saline, Iohexol dye, a 22 G spinal needle, and a 10 ml syringe were utilized. During the procedure, 2 ml of Triamcelone acetate (80 mg), 2 ml of 2% lignocaine, and a 22 G spinal needle were utilized.

Inclusion Criteria

1. Primary Adhesive Capsulitis
2. Limitation of passive movement in the glenohumeral joint, external rotation in neutral position less than 30 degrees, forward flexion less than 90 degrees and abduction less than 60 degrees.
3. Pain is predominantly symptom lasting for more than 3 months, less than 1 year.

Exclusion Criteria

1. Gross restricted range of motion.
2. Age fewer than 30 or over 80.
3. Various contraindications to injections: allergy to injection material, allergy to radio opaque dye (Iohexol Dye).
4. Patients having rheumatoid arthritis.
5. Local site infection.
6. Patient in whom surgical intervention is planned.

The patient's initial evaluation focuses on the history of shoulder pain, considering any past injuries, infections, or involvement of multiple joints. Following a detailed review of the patient's medical

background, the shoulder joint is examined.

Examination of shoulder includes following:

1. Examination of local site by inspection and palpation to see for wasting, redness.
2. Tenderness
3. Active and passive range of motion mainly abduction and external rotation.
4. Special Tests
 - a. External Rotation Lag Sign (Test for rotator cuff)
 - b. Drop Arm Test (Test for rotator cuff)
 - c. Belly Press Test (Test for rotator cuff)
 - d. Empty Can Test (Test for rotator cuff)
 - e. O'Brien's Test (Test for acromioclavicular joint)

After history and examination, patients are investigated with:

- Xray of Respective Shoulder joint (AP View).
- USG of the shoulder was done to rule out Rotator Cuff Tear in these Patients.
- Routine blood investigation like Complete blood count, Random blood sugar done to rule out Infection and Other pathologies.

After a thorough evaluation of the patient's history, physical examination, and diagnostic tests, the appropriate procedure is determined, such as hydrodilatation or corticosteroid injection. We have assigned the patients randomly to receive either hydrodilatation or corticosteroid injection. The patient is being escorted to the operating room for the procedure. Both procedures are performed while lying down under local anaesthesia. After the procedure, the patient is monitored for 2 hours. Once the procedure is completed, the patient can go home the same day. The patient has been recommended physiotherapy by a physiotherapist to perform range of motion exercises for the shoulder joint. Initial check-in completed after one month. The patient underwent an examination to evaluate shoulder joint movements, pain levels, and SPADI & ASES scores. The patient should undergo physiotherapy at home and have follow-up appointments scheduled for 6 months and 1 year.

SPADI and ASES scores are calculated at the 6-month follow-up. Final follow-up occurs at the conclusion of one year.

Procedures

Corticosteroid injection Procedure

Using Fluoroscopy guidance, a 22 G spinal needle was inserted into the Shoulder Joint through the rotator interval at the lateral aspect from the coracoid process into the joint capsule. Then, 2 ml of triamcinolone acetonide (80 mg) and 2 ml of 2% Lignocaine local anaesthetic were administered

slowly, followed by keeping a Spirit swab for 2 minutes.

Hydrodilatation Procedure

Arthrograms were conducted following the Kaye-Schneider technique. Patients were positioned lying on a table with an X-ray tube above and a pillow supporting the opposite shoulder. During image-intensified fluoroscopy, a marker was positioned over the glenohumeral joint space near the middle to lower third junction. Next, the spot was indicated on the skin using a pen. The skin was thoroughly cleansed using an antiseptic solution. A needle with a gauge of 22 punctured the joint, and its position was monitored regularly using fluoroscopy throughout the procedure.

During the injections, the syringe contained 4 ml of contrast medium, 4 ml of local anesthetic lignocaine 2%, and 20 ml of saline. All patients receiving the dilatation treatment were administered a total of 28 ml through injection. The liquid was administered at a gradual pace into the joint. When faced with resistance, the injection was paused briefly before being resumed. While administering the injection, the joint expanded slowly, this improved the visibility of the axillary and subscapular recesses. Typically, the capsule ruptures in the wall of the subscapular recess, or occasionally in the wall of the bicipital or axillary recesses. It was noted as a loss of resistance and contrast leakage was identified by fluoroscopy with a popping sound, followed by the resistance giving away.

SPADI and ASES Score

1. SPADI score

The SPADI tool is a self-assessment questionnaire designed to evaluate both pain and disability related to shoulder conditions. There are five pain and eight disability items, each measured on a visual analogue scale. The pain and disability

subscales are determined by averaging the related items on a scale of 0-130, with a higher score indicating more severe pain and disability. The overall score is determined by averaging the pain and disability subscales. The pain scale consists of 50 points, while the disability scale comprises 80 points. The rating system utilized in our research was a visual analogue scale SPADI has been utilized in prior randomized trials studying treatment effects in populations with frozen shoulder. As the score increases, so does the level of disability. A notable distinction is indicated when there is a 10-point variance between two procedures.

2. American Shoulder Elbow Society Score (ASES)

The ASES scale was utilized to assess the patient's functional disability upon initial evaluation and to track improvements at 1 month, 6 months, and 12 months follow-up. The results of both methods were then compared. A 10-point difference in SPADI and ASES Scores between two treatment groups is deemed significant. When calculating abduction of 160 degrees, the normal reference values are external rotation in neutral position of 90 degrees and external rotation in abduction of 120 degrees.

Statistical analysis

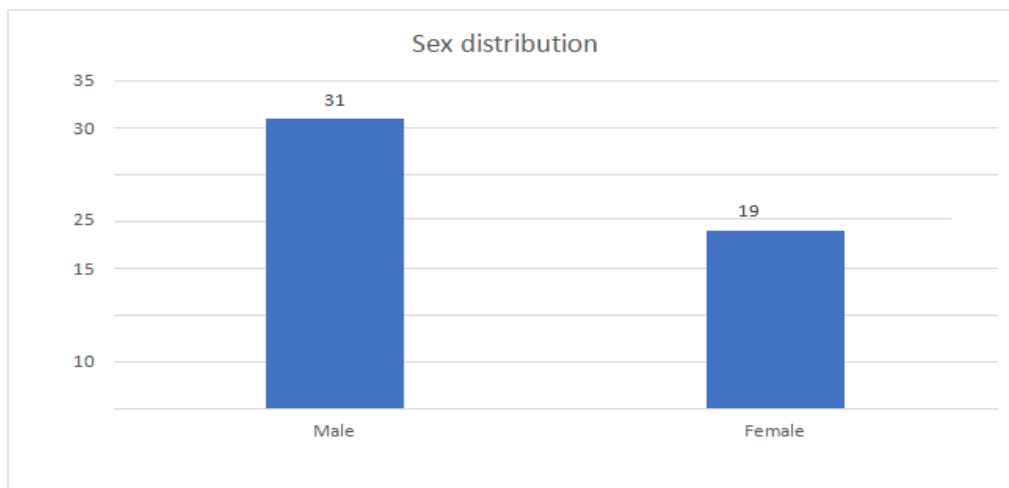
The data was gathered, organized in Microsoft Excel 2007, and then transferred to the data editor in SPSS version 15 (SPSS Inc., Chicago, Illinois, USA). Quantitative variables were typically presented as means and standard deviations or median and interquartile range depending on their distribution. Numerical data was displayed as counts and percentages. Confidence level and level of significance were both set at 95% and 5% for all tests conducted.

Results

Table 1: Age Distribution among study participants

Age (Years)	Number of patients	Percentage (%)
40-50	20	40
50-60	19	38
60-70	9	18
70-80	2	4

The age group with the highest number of patients is 40-50 years, with 20 patients (40%), followed by the 50-60-year age group with 19 patients (38%).



Graph 1: Gender Distribution among study participants

In our study, there are 31 males (62%) and 19 females (38%). The right side is more frequently affected in 33 patients (66%), while the left side is involved in 17 patients (34%).

Table 2: Comparison of pre procedure and final follow up (1 year) movements in shoulder joint treated with corticosteroids.

Range of Motion (in degrees)	Mean Range of motion at Presentation in Percentage (Mean)	Mean Range of motion at 1 year follow up in Percentage (Mean)
Abduction	21% (35)	61% (97)
External Rotation in neutral position	18% (17)	89% (80)
External rotation in abduction	20% (28)	83% (100)

Within the Corticosteroids group, the mean abduction at presentation was only 21% but improved to 61%. Similarly, external rotation in neutral position started at 18% and increased to 89%, while external rotation in abduction began at 20% and rose to 83%.

Table 3: Comparison of pre procedure and final follow up (1 year) movements in shoulder joint treated with Hydrodilatation

Range of Motion (in degrees)	Mean Range of motion at Presentation in Percentage (Mean range of motion)	Mean Range of motion at 1 year follow up in Percentage (Mean range of motion)
Abduction	20% (32)	60% (96)
External Rotation in neutral position	18% (17)	86% (78)
External rotation in abduction	22% (27)	82% (98)

Within the Hydrodilatation group, the mean abduction at Presentation was only 20% but improved to 60%. The external rotation in neutral position was initially 18% and increased to 86%, while the external rotation in abduction was 22% and improved to 82%.

Table 4: Average Change in SPADI Score at Presentation, 1 year follow up

Procedure	At Presentation	1 Year Follow up
Hydrodilatation	113	36
Corticosteroids	112	34

At the 1-year follow-up, the SPADI Score for Hydrodilatation is 36, while for Corticosteroids it is 34. This indicates that there is no significant difference between the two methods at the 1-year mark.

Table 5: Average Change in ASES Score at Presentation, one year follow up

Procedure	At Presentation	1 Year Follow up
Hydrodilatation	6	86
Corticosteroids	7	87

The ASES Score at the 1-year follow-up is 86 for hydrodilatation and 87 for corticosteroids, showing almost identical results, indicating no significant difference between the two treatments at the 1-year follow-up.

Discussion

Acute synovitis and progressive capsular contracture characterize frozen shoulder. [11] In the initial phases of this condition, inflammation is commonly observed, followed by the eventual development of fibrosis due to collagen and matrix production. [12] In the initial phase, there is a development of synovial hyperplasia and increased vascularity, leading to fibrosis of capsular synovium and sub synovial tissue, known as the freezing stage. When looking at control subjects, patients with frozen shoulders show significantly elevated levels of various inflammatory factors in their joint capsules and subacromial bursae. [13] The primary goals of the treatment involve alleviating pain and enhancing range of motion and functionality. A corticosteroid injection is a common treatment for frozen shoulder that has been shown to be effective in reducing pain and inflammation by disrupting inflammatory mediators and synovitis. Regrettably, this method is not as effective in resolving capsular and rotator interval contractures. [14,15] According to the study, there was no improvement in pAB, pFL, and pIR in group B after 1 week, with group A consistently showing better passive ROM than group B over the first 24 weeks. One-time corticosteroid injections are not sufficient for chronic frozen shoulders. Receiving a series of three to six injections could be beneficial. [16]

Researchers have utilized different volumes of fluid ranging from 10 ml to 43 ml in hydrodilatation procedures. In their study, Buchbinder et al. used ml, while we utilized 28 ml of normal saline for our research. We believe that this volume will expand the capsule without causing it to rupture and lead to deposition outside the joint. Our study found that the highest number of patients fall within the 40-50-year age group, with 20 patients (40%). This is followed by the 50-60-year age group, with 19 patients (38%). In total, 39 patients (78%) were in the 40-60-year age group, which is the most common age range for patients with frozen shoulder. In our study, there are 31 males (62%) and 19 females (38%). Other studies often have more female patients than male patients.

Hydrodilatation is believed to have positive effects by enhancing glenohumeral mobility through stretching or rupturing of the joint capsule. In their study, Gam et al [17] found a notable enhancement in different ROM measures in the group that received distension plus steroid in comparison to the group that only received steroid. Although we utilized a single injection for both procedures, re-

searchers have employed varying numbers of injections ranging from 1 to 6. Most of them administered a single injection, whereas Gam & Colleagues utilized 6 injections. Despite being significantly underpowered, Gam's study indicates that dilatation might be more effective than simple injection in enhancing range of motion. In the group treated with corticosteroids, a single dose of Triamcelone acetate (80 mg) was administered. During the hydrodilatation procedure, a total of 28 ml was administered, consisting of 20 ml normal saline, 4 ml iohexol dye, and 4 ml lignocaine 2%. It remains uncertain whether the effects of hydrodilatation accumulate with repeated injections. Perhaps the effects of hydrodilatation could have been more easily pinpointed if only a single injection had been administered.

Corticosteroids work by decreasing inflammation, which in turn helps to alleviate pain. Within the Corticosteroids group, the initial mean abduction was just 21% but increased to 61%. Similarly, the initial external rotation in a neutral position was only 18% but improved to 89%. External rotation in abduction started at 20% and improved to 83% after 1 year. There has been a notable enhancement in the range of motion (ROM).

The hydrodilatation procedure is believed to have a positive impact by enhancing glenohumeral mobility through capsule stretching. Within the Hydrodilatation group, the initial mean abduction was just 20% but increased to 60%. Similarly, external rotation in a neutral position started at 18% and improved to 86%, while external rotation in abduction began at 22% and increased to 82% at the 1-year follow-up.

Our research involved the utilization of SPADI and ASES scores. After hydrodilatation, the SPADI score improved from 113 to 36 at the 1-year follow-up, whereas in the corticosteroid group, the SPADI score improved from 112 to 34 at the same follow-up point. After 1 year, the ASES score was 86 in the hydrodilatation group and 87 in the corticosteroid group. These findings indicate a comparable enhancement in the outcomes of both groups. In their study, Gam et al [17] found a notable enhancement in different range of motion measures in the distension-treated group compared to the group that received only steroids. In this study, the ranges of motion measures were nearly identical in both groups during the follow-up, which aligns well with the results of Corbeil et al [18] study.

Conclusion

Exploring treatment outcomes in individuals with adhesive capsulitis who received either intra-articular corticosteroid injections or hydrodilatation. The shoulder on the dominant hand side (right side) is typically more affected. There was no notable variation in the results when evaluated using

SPADI and ASES between the two groups at 1 month, 6 months, and 1 year follow-up. Both groups experienced a notable enhancement in range of motion and pain relief.

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