



# Fibro-adhesive Bursitis: A Novel Sonographic Finding in Adhesive Capsulitis Patients and a Proposal of Management

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## ABSTRACT

**Introduction:** Adhesive capsulitis, also known as “frozen shoulder,” is a debilitating shoulder condition increasingly linked to fibroadhesive bursitis, particularly after COVID-19 and related vaccinations. There is no definitive gold standard for its treatment, the primary therapeutic objectives of which are the reduction of pain

and the restoration of shoulder range of motion. The aim of our study was to analyze treatment outcomes based on quantitative measures of shoulder function and symptom relief.

**Method:** Conducted between January 2022 and April 2023, the research involved 45 patients initially diagnosed with adhesive capsulitis and associated fibroadhesive bursitis. After excluding nine patients for other concomitant pathologies

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(five for calcific tendinopathy and four for rotator cuff injury), 36 patients were randomized into two groups: one group was treated with glenohumeral hydrodistension, the other with glenohumeral hydrodistension combined with bursal injection. Assessments were conducted at baseline and then 2, 4, and 6 months after treatment, focusing on changes in pain levels, functional scores, and range of motion in all planes. Each group followed a home-based rehabilitation protocol.

**Results:** Significant improvements were observed in both treatment groups, with the combined hydrodistension and bursal injection group showing notably superior outcomes. Specifically, the range of motion in flexion improved from an initial median of 80° to 155° in the combined treatment group, compared to an increase from 75.5° to 129° in the group treated with hydrodistension alone. This enhancement was statistically significant ( $p < 0.001$ ).

Regarding pain reduction, the combined treatment group demonstrated a dramatic decrease in visual analogue scale (VAS) scores, from a baseline median of 7 to 1 at the 6-month follow-up. In contrast, the hydrodistension-only group showed a reduction from 7 to 3, with these differences also proving statistically significant ( $p < 0.001$ ).

**Conclusions:** Ultrasound-guided hydrodistension of the glenohumeral joint, if combined with bursal injection and specific exercises, effectively reduces pain, decreases disability, and improves range of motion in patients with second-stage adhesive capsulitis. This study highlights the importance of a combined approach in the management of this complex condition, especially after the histological changes that occurred after COVID-19 and related vaccinations.

**Trial Registration:** ClinicalTrials.gov identifier NCT06062654.

**Keywords:** Shoulder pain; Adhesive capsulitis; Frozen shoulder; Ultrasonography; Intra-articular injection

### Key Summary Points

Adhesive capsulitis, also known as “frozen shoulder,” is a debilitating shoulder condition increasingly linked to fibroadhesive bursitis.

There is no definitive gold standard treatment for adhesive capsulitis, with the aim to reduce pain and shoulder range of motion restoration.

Ultrasound-guided hydrodistension of the glenohumeral joint, coupled with bursal injection and specific exercises, demonstrated effectiveness in patients with second-stage adhesive capsulitis.

A combined approach in the management of fibroadhesive bursitis associated with adhesive capsulitis is warranted.

## INTRODUCTION

Adhesive capsulitis, commonly known as “frozen shoulder,” is a debilitating condition characterized by pain and progressive stiffness in the shoulder, initially described by Codman in 1934 and further detailed by Neviasser in 1945 [1]. It affects 2–5% of the general population, with prevalence rates significantly higher, ranging from 10% to 36%, among individuals with diabetes mellitus [2, 3]. This condition predominantly affects women, typically manifesting in those aged between the fifth and seventh decade of life. While adhesive capsulitis can be idiopathic, it is sometimes secondary to surgical interventions, local trauma, myocardial infarction, diabetes mellitus [2], hypothyroidism [4], Parkinson’s disease [5], or barbiturate use. Genetic predisposition, such as a positive family history and expression of the HLA-B27 antigen, is also influential [6]. Recent research highlighted that adhesive capsulitis involves inflammatory and fibrotic processes within the joint capsule, leading to a reduction in capsular volume and the formation of adhesions that significantly impair motility [7, 8]. Histologically,

the condition is marked by a fibrotic pattern with fibroblasts surrounded by a matrix rich in type I and III collagen. Myofibroblasts present in the samples suggest their role in the development of capsular contractures. Disruption in collagen metabolism, indicated by abnormal expression of metalloproteinases and their inhibitors, further complicates the scenario [9–11]. The presence of inflammatory cytokines, neoangiogenesis, and neoinnervation supports the underlying inflammatory processes. Elevated levels of intercellular adhesion molecule-1 (ICAM-1) have been observed in both patients with adhesive capsulitis and those with diabetes, elucidating the frequent co-occurrence of these two conditions [10–12]. The clinical progression of adhesive capsulitis traditionally unfolds through stages that include initial diffuse shoulder pain that worsens at night, followed by increasing stiffness and pain, severe joint restriction, and ultimately, a gradual resolution of stiffness and pain accompanied by mature collagen deposition and reduced inflammation [13–16]. The importance of early diagnosis and timely intervention is emphasized to alleviate symptoms and hasten recovery. Advances in imaging technology, particularly magnetic resonance imaging (MRI) and ultrasound, have become primary tools for diagnosis due to their ability to directly visualize the pathological changes. Ultrasound is especially valuable for its diagnostic efficiency, cost-effectiveness, and ability to guide therapeutic interventions like hydrodistension and drug injection [17–22]. Specific signs of adhesive capsulitis on ultrasound evaluation include effusion of the bicipital recess, thickening/hyperemia of the axillary recess of the capsule, thickening/hyperemia of the pulley at the rotator, the articular effusion of the subscapular recess (subcoracoid space), and typical folding of the infraspinatus tendon during posterior assessment of passive external rotation during maneuvers [21–23].

An increased frequency of adhesive capsulitis has been observed during the COVID-19 pandemic and fibroadhesive bursitis due to an increase in cytokines and growth factors, in particular interleukin (IL)-1, IL-6 and tumor necrosis factor (TNF)- $\alpha$ ; fibroadhesive bursitis following COVID-19 vaccination is considered a

rare occurrence and is generally associated with incorrect vaccine administration techniques [24, 25]. This condition is part of a broader category known as shoulder injury related to vaccine administration (SIRVA), which encompasses various shoulder injuries caused by improper injection methods. Although specific cases of fibroadhesive bursitis have been reported, they are not widespread and are typically linked to individual instances of vaccination errors rather than the vaccines themselves [26].

With this as background, this study was designed to evaluate the effectiveness of ultrasound-guided procedures, specifically glenohumeral joint capsule hydrodistension and subacromial-subdeltoid bursa injections, in the management of adhesive capsulitis in association with fibroadhesive bursitis.

## METHODS

This study employed a prospective cohort design to evaluate the efficacy of ultrasound-guided treatments in adult patients diagnosed with adhesive capsulitis and concomitant fibroadhesive bursitis based on the typical signs on shoulder ultrasound [22]. Recruitment was conducted from January 2022 through April 2023; after applying exclusion criteria, - i.e., other comorbidities, calcific tendinopathy, rotator cuff injury, glenohumeral osteoarthritis, pregnancy, allergy to anesthetics, and inability to provide informed consent -, a cohort of 36 patients was finalized. In the study, participants were randomly allocated to two groups using a double-blind, 1:1 ratio method facilitated by the statistical software R (The R Foundation for Statistical Computing). Group 1, consisting of 18 patients, received both hydrodistension and bursal injection, while group 2, also comprising 18 patients, received only hydrodistension (Fig. 1). The allocation sequence was generated using the R package ‘blockrand’ to ensure unbiased and random assignment. Both the researchers and participants were blinded to group assignments to maintain the study’s integrity and minimize

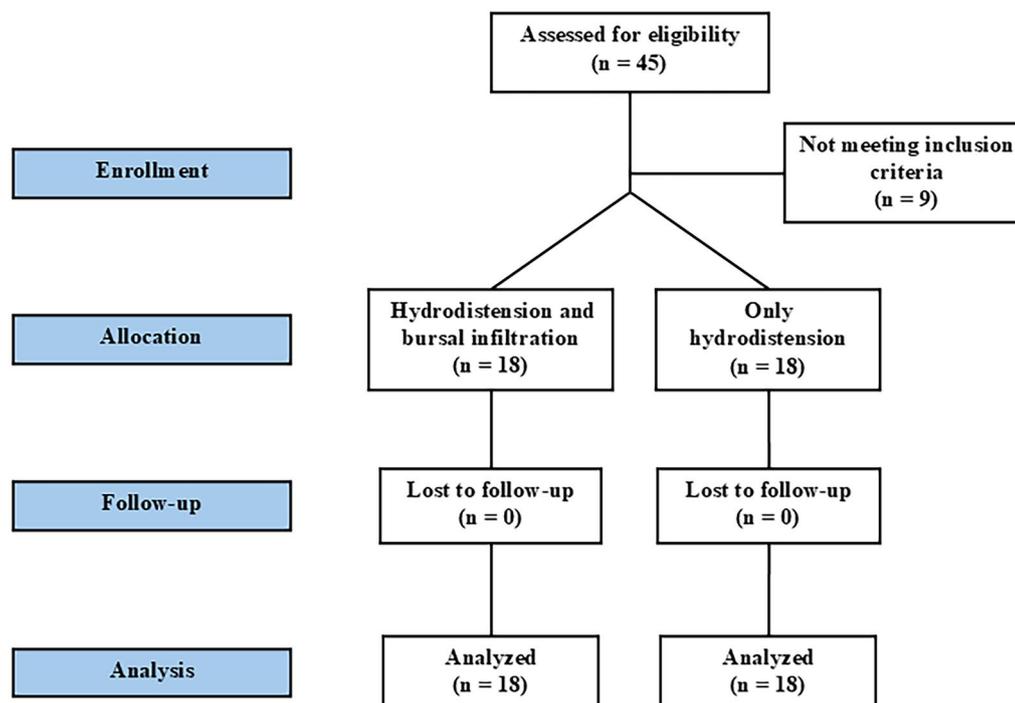


Fig. 1 Flow chart of the study design

potential biases, thereby enhancing the reliability of the trial results.

Pain was assessed as previously described [27] by means of the visual analogue scale (VAS), a measure used to quantify pain intensity, by which patients rate their pain on a scale typically ranging from 0 (no pain) to 10 (worst possible pain), whereas shoulder function was investigated via tools such as disabilities of the arm, shoulder, and hand (DASH), a standardized form used to measure physical function and symptoms in people with musculoskeletal disorders of the upper limb, with a score ranging from 0 (no disability) to 100 (most severe disability); the shoulder pain and disability index (SPADI), a tool that assesses pain and disability specifically related to shoulder conditions, with scores divided into two components: pain and disability, each contributing to a total score where higher values represent greater impairment; and the American shoulder and elbow surgeons standardized shoulder assessment form (ASES), a combined patient- and clinician-reported questionnaire that assesses the functional status of the shoulder, covering various aspects of

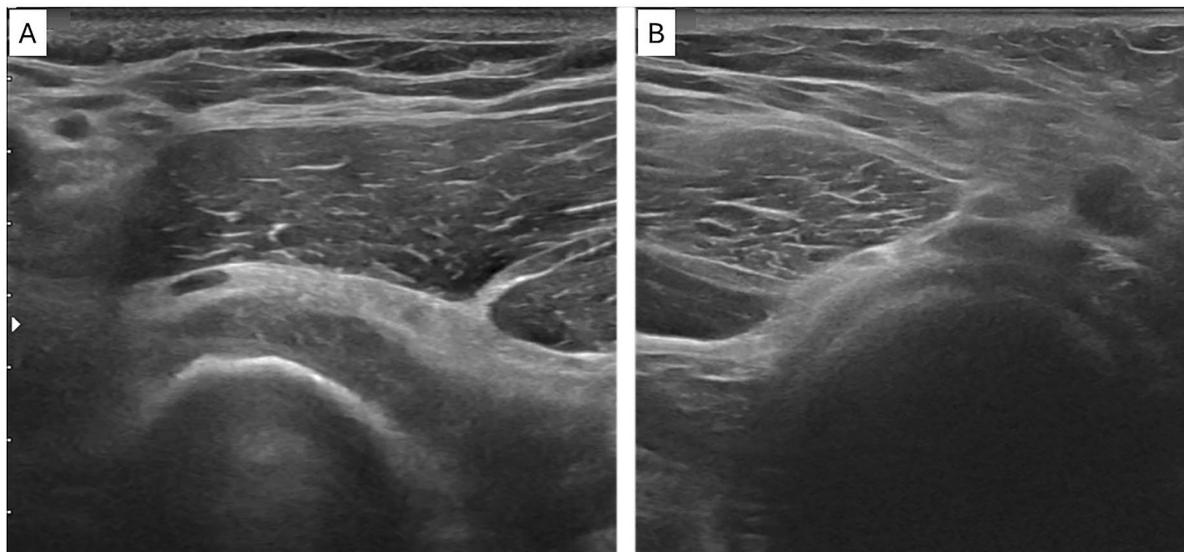
shoulder function, with scores ranging from 0 (severe disability) to 100 (no disability).

### Ethical Considerations

The study protocol was rigorously reviewed and approved by the local Ethics Committee (379/2022/Sper/IOR) of IRCCS Istituto Ortopedico Rizzoli, Bologna, Italy, ensuring compliance with the ethical standards stipulated in the Declaration of Helsinki. The present study was registered on ClinicalTrial.gov (NCT06062654). Comprehensive informed consent was obtained from all participants, which covered all aspects of the intervention, potential risks, benefits, and the use of photographic or video documentation for research purposes.

### Sample Size Calculation

To ensure robust statistical power for detecting meaningful clinical differences, we calculated the required sample size based on a medium



**Fig. 2** Thickening of the axillary pouch (A) compared to the contralateral unaffected shoulder (B)

effect size, with an alpha level of 0.05 and a power of 80%. Anticipating a minimal dropout rate of 5%, we aimed for a final sample size of 34 participants. This necessitated an initial recruitment of 36 participants to account for potential attrition.

## Ultrasound Examination

### *Ultrasound Assessment of Adhesive Capsulitis*

The shoulder ultrasound examinations were performed using a Samsung HS 50 with a 5–17-MHz linear transducer with musculoskeletal preset and we evaluated the following:

- Axillary recess thickening in the anterior/axillary regions: patients were examined in a recumbent position with the shoulder abducted as permitted. A cut-off value of 4 mm for the thickness of the axillary sac demonstrates a sensitivity of 93.8% and a specificity of 98% in the diagnosis of adhesive capsulitis. Furthermore, a 60% difference between affected and unaffected sides can help identify this condition, particularly in patients presenting with suggestive symp-

toms but with axillary recess thickness less than 4 mm (Fig. 2) [22];

- Thickening of the coracohumeral ligament (CHL): patients were scanned in a sitting position, with the shoulder in a neutral position and the hand resting on the thigh, placing the transducer on the lateral edge of the coracoid process in an oblique axial plane, we managed to obtain a longitudinal image of the CHL, the average measurement of the thickness of the CHL in both the short and long axes is 3 mm in shoulders affected by adhesive capsulitis [22]. Articular effusion of the subscapular recess (subcoracoid space). Indeed, the latter is a synovial recess of the glenohumeral joint without a capsular coat that frequently distends and collects the articular effusion in the early phase of the adhesive capsulitis (Fig. 3) [21].
- Thickening of the rotator interval (RI) and hypervascularization: the patient is evaluated sitting, upper limb supine, elbow flexed at 90°, it is evaluated on the plane of the oblique axis, the RI is formed superiorly by the anterior part of the supraspinatus tendon and inferiorly by the superior surface of the subscapularis tendon, and the medial border is formed by the lateral border of the coracoid process; RI thickness was measured

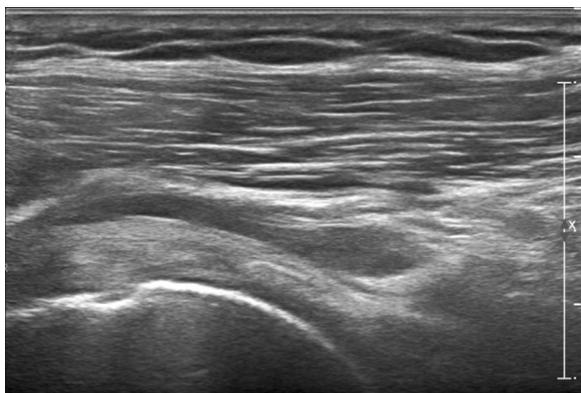


Fig. 3 Evidence of effusion in the subscapular recess

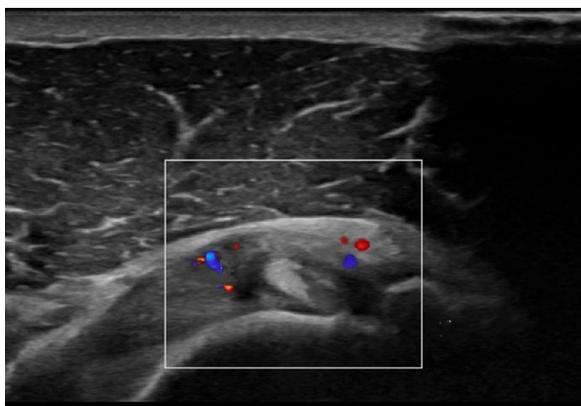


Fig. 4 Thickening and hypervascularization in the rotator interval

as the shortest distance between the long head of the biceps tendon and the peribursal fat, including the CHL, the superior glenohumeral ligament. For the diagnosis of adhesive capsulitis, soft tissue hypervascularity within the rotator interval has demonstrated high sensitivity (97%) and specificity (100%) (Fig. 4) [3].

- Effusion of the long head of the biceps tendon (LHBT) sheath: the patient is assessed sitting, upper limb supine, elbow flexed at 90°, the synovial sheath surrounding the LHBT typically connects with the glenohumeral joint cavity and normally has a small amount of fluid around the biceps that tends to an eccentric position. Patients with adhesive capsulitis showed a higher preva-

lence of effusion in the tendon sheath of the long head of the biceps [28].

- Dynamic visualization of the infraspinatus tendon: the patient is evaluated sitting, upper limb supine, elbow flexed at 90° during a passive external rotation (PER), with a posterior dynamic study, the internal folding of the tendon towards the joint capsule occurs, and can vary from minimal movement to more pronounced movement [22, 29, 30].

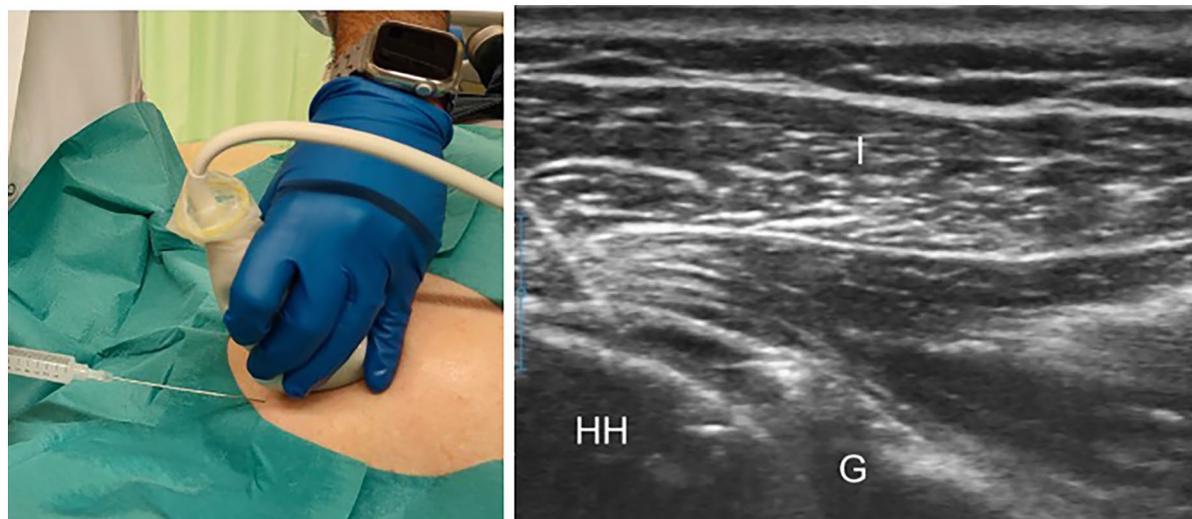
### **Ultrasound Presentation of Fibroadhesive Subacromial Bursitis**

The fibroadhesive type of subacromial-subdeltoid bursitis (SASDB) typically presents identifiable ultrasound features including:

- The bursal thickness, measured from the superficial limit of the upper wall to the deep limit of the lower wall, is typically greater than 1.5 mm;
- Varying degrees of increased echogenicity, although it may sometimes appear hypoechoic. In instances of hypoechoic appearance, the bursal content, composed of minimal fibrinous exudate, tends to be hypoechoic, non-homogeneous, and partially organized into connective septa;
- Occasionally, a wavy aspect of the bursa may be observed, sometimes resembling a rosary crown pattern;
- In cases where bursal thickness leads to impingement, the “step sign” may be evident. This sign refers to the imprint and depression of the coracoacromial ligament on the thickened subacromial-subdeltoid bursa in the axial ultrasound section of the ligament [22, 29, 30].

### **Ultrasound-Guided Procedures**

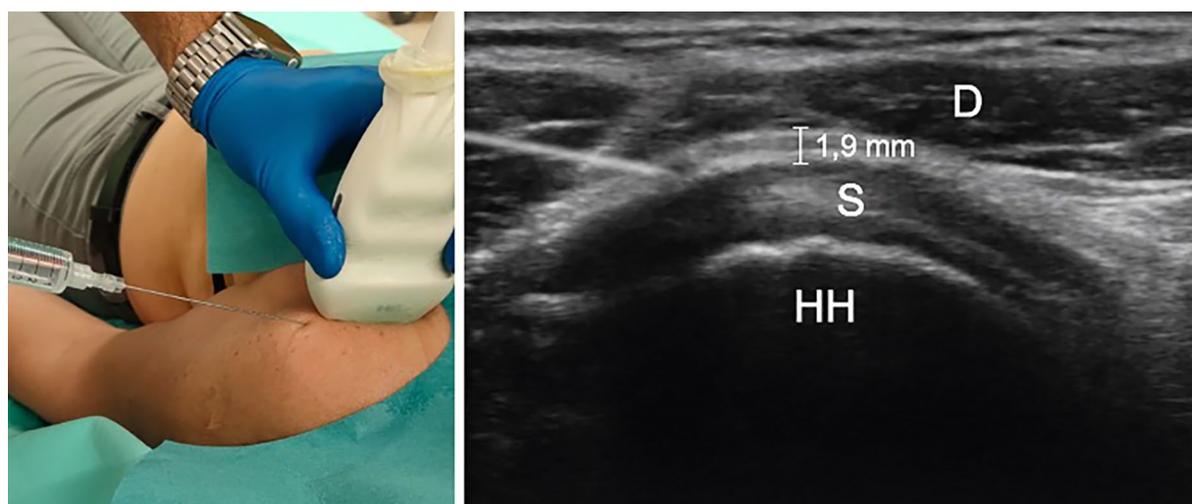
Treatment procedures were meticulously performed under ultrasound guidance to ensure precision and safety. For the hydrodistension of the glenohumeral joint, a mixture of 1 ml of corticosteroid (methylprednisolone depot 40 mg), 10 ml of 2% lidocaine hydrochloride, and 10 ml of saline was injected into the joint capsule



**Fig. 5** Clinical image and ultrasound-guided hydrodistention with posterior lateral approach in a patient with adhesive capsulitis

using a 20 G, 90 mm needle through a posterior and lateral-to-medial access to the shoulder joint. The technique emphasized a posterior lateral approach to optimize distribution of the injectate within the joint space (Fig. 5). For patients with adhesive capsulitis, hydrodilata-tion is typically performed using corticosteroids with ultrasound guidance via the posterior glenohumeral recess. Recently, a new intervention technique via the rotator cuff interval has been

described [31]. In cases of fibroadhesive bursitis, the ultrasound-guided approach is an in-plane technique with an anterior and lateral-to-medial approach that facilitates the precise identification and separation of the adhered bursal layers. The intervention involved the injection of a mixture of 1 ml cortisone (betamethasone 4 mg), 3 ml of 2% lidocaine hydrochloride, and 3 ml of saline to distend the bursa, reduce inflammation, and alleviate pain [19, 26] (Fig. 6).



**Fig. 6** Clinical image and ultrasound-guided injection with anterolateral approach in a patient with fibroadhesive bursitis

**Table 1** Baseline characteristics of study participants' age and pain

Description	Group 1	Group 2	<i>p</i> value
Age (median years, SD)	42.5 (5.2)	48.6 (4.9)	0.05
Sex	12 females, 6 males	10 females, 8 males	0.45
Work	10 manual workers, 8 sedentary workers	6 manual workers, 12 sedentary workers	0.10
Sports	6 padel/tennis, 5 swimmers, 4 no sport, 3 runners	7 runners, 4 padel/tennis, 3 other sports, 2 no sport, 2 swimmers	0.25
Pain (median VAS, SD)	22.6 (3.1)	19.7 (2.8)	0.15

*SD* standard deviation, *VAS* Visual Analogue Scale

Following the medical intervention, participants in each group were tasked with performing rehabilitation exercises from the comfort of their homes. These exercises were part of a specifically designed protocol tailored to support recovery and enhance the effectiveness of the treatment. Each participant received a personalized set of exercises aimed at restoring function and reducing recovery time. Details of these exercises and their intended benefits are described in a recently published paper [27].

### Statistical Analysis

Data were analyzed using SPSS version 15.0 (SPSS Inc. in Chicago, IL, USA). Continuous variables, including range of motion, pain, and functional scores, were expressed as mean  $\pm$  standard deviation (SD). Categorical variables were summarized as frequencies and percentages. The primary statistical tests employed were independent and paired Student's *t* tests to compare outcomes between and within groups, respectively. Significance levels were predetermined at  $p < 0.001$ . This analytical approach was designed to robustly quantify the improvements in shoulder function and pain, thereby providing a scientifically valid basis to evaluate the treatment efficacy.

## RESULTS

Between January 1, 2022, and April 28, 2023, the study involved 36 participants who were randomly distributed across two groups. This randomization was conducted using a computer-generated sequence, ensuring that each participant had an equal chance of being assigned to either group; group 1 underwent glenohumeral hydrodistension and bursal injection while group 2 received glenohumeral hydrodistension. The initial demographic analysis (Table 1) shows that group 1 had a younger mean age of 42.5 years compared to 48.6 years in group 2. The distribution of participants in terms of sex and work activity revealed notable differences between the two groups. Notably, group 1 had a higher percentage of manual workers. Manual labor is often associated with increased physical stress on the shoulder, possibly predisposing individuals to different baseline levels of shoulder pathology compared to non-manual workers. Such differences could affect both the initial condition of the participants and their response to the treatments under investigation. In terms of treatment efficacy, longitudinal evaluation of ROM revealed superior improvement in group 1 in all movements measured, including flexion, extension, abduction, and rotational movements, as detailed in Table 2. For example, flexion in group 1 increased from an initial median level of 80° to 155° at 6-month follow-up, while group 2 started at 75.5°, achieving a smaller improvement to 129° over the same period.

**Table 2** Range of motion and number of infiltrations over time in the study population

Measurement	Timepoint	Group 1 median (SD)	Group 2 median (SD)	<i>t</i> test <i>p</i> value
Flexion	Baseline	80 (8.0)	75.5 (7.5)	< 0.001
	2 months	133 (10.0)	104 (9.0)	< 0.001
	4 months	155 (12.0)	123 (11.5)	< 0.001
	6 months	155 (11.0)	129 (10.0)	< 0.001
Extension	Baseline	17 (2.0)	15 (2.5)	< 0.001
	2 months	35 (3.0)	29 (3.5)	< 0.001
	4 months	40 (2.5)	33 (3.0)	< 0.001
	6 months	45 (2.0)	38 (2.5)	< 0.001
Abduction	Baseline	55 (5.0)	60 (6.0)	< 0.001
	2 months	120 (10.0)	77 (8.0)	< 0.001
	4 months	155 (12.0)	91 (9.5)	< 0.001
	6 months	158 (11.5)	120 (10.0)	< 0.001
Internal rotation in abduction	Baseline	10 (1.5)	10 (1.5)	< 0.001
	2 months	40 (4.0)	22 (3.5)	< 0.001
	4 months	65 (5.0)	41 (4.5)	< 0.001
	6 months	81 (6.0)	63 (5.5)	< 0.001
External rotation in abduction	Baseline	13 (1.0)	16 (1.5)	< 0.001
	2 months	34 (3.5)	40 (4.0)	< 0.001
	4 months	48 (5.0)	55 (5.5)	< 0.001
	6 months	70 (6.5)	76 (7.0)	< 0.001
Number of infiltrations	Baseline	18 (0)	18 (0)	
	2 months	6 (1.0)	10 (1.5)	
	4 months	2 (0.5)	5 (0.75)	
	6 months	0 (0)	2 (0.25)	

*SD* standard deviation

This enhanced recovery pattern in group 1 persisted across other movements such as extension and abduction, suggesting a more robust response to the combined treatment modality. Pain assessment using VAS and functional scores via tools such as the DASH, SPADI, and ASES demonstrated dramatic reduction in pain and improvement in shoulder function, particularly

in group 1, as reported in Table 3. Both groups started from similar baseline scores; however, pain reduction and improvement in function were more pronounced in group 1, reaching a VAS score of 1 at 6-month follow-up from an initial median score of 7. These significant changes, with *p* values < 0.001, emphasize the therapeutic benefit and clinical improvement

**Table 3** Pain and functional scores of the recruited patients over time

Assessment	Timepoint	Group 1 median (SD)	Group 2 median (SD)	<i>t</i> test <i>p</i> value
Pain VAS	Baseline	7 (1.2)	6 (1.1)	< 0.001
	2 months	2 (0.8)	4 (1.0)	< 0.001
	4 months	1 (0.5)	1 (0.7)	< 0.001
	6 months	1 (0.3)	1 (0.4)	< 0.001
DASH	Baseline	43 (6.0)	46 (5.5)	< 0.001
	2 months	27 (3.8)	29 (4.2)	< 0.001
	4 months	18 (2.5)	22 (2.8)	< 0.001
	6 months	10 (2.1)	8 (2.0)	< 0.001
SPADI	Baseline	50 (7.5)	48 (7.0)	< 0.001
	2 months	39 (6.0)	33 (5.5)	< 0.001
	4 months	19 (3.1)	20 (3.5)	< 0.001
	6 months	6 (1.2)	10 (1.5)	< 0.001
ASES	Baseline	43 (5.2)	42 (5.0)	< 0.001
	2 months	31 (4.0)	29 (3.5)	< 0.001
	4 months	17 (2.6)	21 (2.9)	< 0.001
	6 months	11 (1.8)	13 (2.0)	< 0.001

*ASES* American Shoulder and Elbow Surgeons standardized shoulder assessment form, *DASH* disabilities of the arm, shoulder and hand, *SD* standard deviation, *SPADI* Shoulder Pain and Disability Index, *VAS* Visual Analogue Scale

derived from the intervention. The frequency of injections, a direct measure of the intensity of treatment required to maintain or improve shoulder mobility and reduce pain, decreased during the study period (Table 2). Initially, each group required a total of 18 injections, with one injection administered to each subject; however, at the 6-month evaluation, no further injections were necessary for group 1, indicating sustained improvement and possibly a longer-lasting effect of the treatment regimen employed.

## DISCUSSION

Adhesive capsulitis, or frozen shoulder, represents a formidable challenge in the clinical setting due to the severe pain and limited range of motion it imposes on patients [1, 26].

The results of this investigation demonstrate notable improvements in shoulder range of motion and significant reductions in pain, underscoring the potential of these interventions to mitigate symptoms associated with this condition. Significant improvements were observed in all movements measured, except extension. Movements such as flexion, abduction, and internal and external rotations have shown substantial improvement. The sustained improvement in these parameters during the 6-month follow-up period suggests a lasting effect of ultrasound-guided procedures on restoration and maintenance of shoulder motility. This observation indicates not only immediate relief but also long-term benefits in joint function, which are crucial for patient recovery and quality of life.

Pain assessment, conducted using the pain VAS and SPADI, revealed a substantial reduction

in pain levels after treatment. The marked decrease in VAS and SPADI scores at each follow-up point provides robust evidence of the effectiveness of the interventions in relieving the pain and discomfort associated with adhesive capsulitis. Significant functional improvement was observed quantitatively using the ASES scale. The continuous improvement observed throughout the study period reinforces the overall benefits of the treatment regimen in improving overall shoulder health and functional outcomes. Furthermore, the high adherence to the therapeutic regimen, highlighted by the need for repeated injections during the follow-up period, emphasizes the necessity of ongoing management to sustain the therapeutic gains. The absence of adverse events reported during interventions or throughout the entire follow-up period further attests to the safety and tolerability of ultrasound-guided procedures [27, 32–34].

Every study, including those of treatments for conditions such as adhesive capsulitis with concomitant subacromial-subdeltoid fibroadhesive bursitis, faces inherent limitations that affect the interpretation and generalization of findings. A common limitation is the absence of a control group, which makes it difficult to attribute the observed improvements exclusively to the tested interventions, as these could alternatively result from natural progression of the disease, placebo effects or regression to the mean. While it is necessary to consider potential placebo effects or regression to the mean in our analysis, it is also important to recognize that the natural course of untreated adhesive capsulitis typically involves worsening of symptoms in the majority of cases [14, 15, 22]. Adhesive capsulitis is characterized by a gradual increase in pain and stiffness, often peaking before eventually resolving, which can take several years. This progression underscores the need for effective therapeutic interventions to manage and potentially expedite recovery, as the condition's natural trajectory often leads to significant discomfort and reduced quality of life, so treating a group of patients with only a placebo would not have been ethically acceptable.

Our data clearly demonstrate that the group receiving the combined treatment of

hydrodistension and bursa injection showed more significant improvement in shoulder motility, pain reduction and function compared to the group treated with hydrodistension alone and the statistical significance of these results reinforces the reliability of the findings and supports their relevance in clinical practice for managing complex shoulder conditions [32, 33]. Indeed, the single-center design of this study may have introduced biases related to specific patient selection or treatment application, further limiting the ability to apply the results universally. However, the effectiveness of the double combined treatment was also confirmed by the study of Wang et al., where at the 3-month follow-up, the dual-target injection group had a sustained effect of symptom relief, while the standard injection group tended to exhibit rebounding pain [34]. Furthermore, the short 6-month follow-up duration, while sufficient to observe immediate results, may not adequately capture the long-term effects and potential for recurrence, which are critical for assessing the durability of treatment benefits.

Our findings not only validate the efficacy of the combined therapeutic approach but also suggest its potential for a broader application in similar musculoskeletal conditions.

## CONCLUSIONS

In conclusion, this study substantiates the effectiveness of glenohumeral hydrodistension combined with intrabursal injection for treating adhesive capsulitis with fibroadhesive bursitis, demonstrating significant improvements in shoulder motility, pain, and functionality after 6 months. However, the study's limitations—including lack of a control group, and brief follow-up period—necessitate caution in generalizing these results. Future research should aim to validate these findings through larger, controlled, long-term studies to fully establish the treatment's efficacy and sustainability. Despite these limitations, our results suggest that this therapeutic approach could be an integral part of a comprehensive management strategy for

patients with adhesive capsulitis and fibroadhesive bursitis.

**Author Contributions.** Fabio Vita, Roberto Tedeschi, Marco Cavallo, and Danilo Donati researched the literature and conceived the study. Fabio Vita, Roberta Gualtierotti, Flavio Origlio and Enrico Guerra wrote the first draft of the manuscript and made subsequent corrections to the article. Salvatore Massimo Stella, Cesare Faldini, Marco Miceli, Stefano Galletti, and Roberta Gualtierotti reviewed, edited, and approved the final version of the manuscript. All authors have read and agreed to the published version of the manuscript.

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**Data Availability.** The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

### Declarations

**Conflict of Interest.** Roberta Gualtierotti is advisory board of Bayer, Roche, Sanofi, SOBI, Novo Nordisk; and speaker bureau/educational meetings Pfizer, SOBI, Takeda, Novo Nordisk. Fabio Vita, Marco Miceli, Roberto Tedeschi, Flavio Origlio, Marco Cavallo, Stefano Galletti, Salvatore Massimo Stella, Enrico Guerra, Danilo Donati and Cesare Faldini have nothing to disclose.

**Ethical Approval.** The study protocol was rigorously reviewed and approved by the local Ethics Committee (379/2022/Sper/IOR) of IRCCS Istituto Ortopedico Rizzoli, Bologna, Italy, ensuring compliance with the ethical standards stipulated in the Declaration of Helsinki. Comprehensive informed consent was obtained from all participants, which covered all aspects of the intervention, potential risks, benefits, and the use of photographic or video documentation for research purposes.

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## REFERENCES

1. Neviasser AS, Neviasser RJ. Adhesive capsulitis of the shoulder. *J Am Acad Orthop Surg.* 2011;19(9):536–42.
2. Tighe CB, Oakley WS Jr. The prevalence of a diabetic condition and adhesive capsulitis of the shoulder. *South Med J.* 2008;101(6):591–5.
3. Le HV, Lee SJ, Nazarian A, Rodriguez EK. Adhesive capsulitis of the shoulder: review of pathophysiology and current clinical treatments. *Shoulder Elbow.* 2017;9(2):75–84.
4. Kelley MJ, Shaffer MA, Kuhn JE, Michener LA, Seitz AL, Uhl TL, Godges JJ, McClure PW. Shoulder pain and mobility deficits: adhesive capsulitis. *J Orthop Sports Phys Ther.* 2013;43(5):A1-31.
5. Chang YT, Chang WN, Tsai NW, Cheng KY, Huang CC, Kung CT, Su YJ, Lin WC, Cheng BC, Su CM, Chiang YF, Lu CH. Clinical features associated with frozen shoulder syndrome in Parkinson's disease. *Parkinsons Dis.* 2015;2015: 232958.
6. Prodromidis AD, Charalambous CP. Is there a genetic predisposition to frozen shoulder?: A systematic review and meta-analysis. *JBJS Rev.* 2016;4(2): e4.
7. Merolla G, Bhat MG, Paladini P, Porcellini G. Complications of calcific tendinitis of the

- shoulder: a concise review. *J Orthop Traumatol.* 2015;16(3):175–83.
8. Spinnato P, Masuzzo O, Tuè G, Tucci F, Bevere A, Vita F, Cavallo M, Marinelli A, Miceli M. A novel ultrasound-guided interventional procedure for the combined treatment of rotator cuff calcific tendinopathy complicated with adhesive capsulitis: the “Rizzoli” technique. *Acad Radiol.* 2023;30(10):2437–8.
  9. Lubis AM, Lubis VK. Matrix metalloproteinase, tissue inhibitor of metalloproteinase and transforming growth factor-beta 1 in frozen shoulder, and their changes as response to intensive stretching and supervised neglect exercise. *J Orthop Sci.* 2013;18(4):519–27.
  10. Bunker TD, Reilly J, Baird KS, Hamblen DL. Expression of growth factors, cytokines and matrix metalloproteinases in frozen shoulder. *J Bone Joint Surg Br.* 2000;82(5):768–73.
  11. Ling Y, Peng C, Liu C, Zhang N, Yue S. Gene polymorphism of IL-6 and MMP-3 decreases passive range of motion after rotator cuff repair. *Int J Clin Exp Pathol.* 2015;8(5):5709–14.
  12. Kim YS, Kim JM, Lee YG, Hong OK, Kwon HS, Ji JH. Intercellular adhesion molecule-1 (ICAM-1, CD54) is increased in adhesive capsulitis. *J Bone Joint Surg Am.* 2013;95(4):e181–8.
  13. Date A, Rahman L. Frozen shoulder: overview of clinical presentation and review of the current evidence base for management strategies. *Future Sci OA.* 2020;6(10):FSO647.
  14. Wong CK, Levine WN, Deo K, Kesting RS, Mercer EA, Schram GA, Strang BL. Natural history of frozen shoulder: fact or fiction? A systematic review. *Physiotherapy.* 2017;103(1):40–7.
  15. Hand C, Clipsham K, Rees JL, Carr AJ. Long-term outcome of frozen shoulder. *J Shoulder Elbow Surg.* 2008;17(2):231–6.
  16. Rangan A, Brealey SD, Keding A, Corbacho B, Northgraves M, Kottam L, Goodchild L, Srikesavan C, Rex S, Charalambous CP, Hanchard N, Armstrong A, Brooksbank A, Carr A, Cooper C, Dias JJ, Donnelly I, Hewitt C, Lamb SE, McDaid C, Richardson G, Rodgers S, Sharp E, Spencer S, Torgerson D, Toye F, UK FROST Study Group. Management of adults with primary frozen shoulder in secondary care (UK FROST): a multicentre, pragmatic, three-arm, superiority randomised clinical trial. *Lancet.* 2020;396(10256):977–89.
  17. Al Khayyat SG, Falsetti P, Conticini E, Frediani B, Galletti S, Stella SM. Adhesive capsulitis and ultrasound diagnosis, an inseparable pair: a novel review. *J Ultrasound.* 2023;26(2):369–84.
  18. Fodor D, Rodriguez-Garcia SC, Cantisani V, Hammer HB, Hartung W, Klauser A, Martinoli C, Terslev L, Alfageme F, Bong D, Bueno A, Collado P, D’Agostino MA, de la Fuente J, Iohom G, Kessler J, Lenghel M, Malattia C, Mandl P, Mendoza-Cembranos D, Micu M, Möller I, Najm A, Özçakar L, Picasso R, Plagou A, Sala-Blanch X, Sconfienza LM, Serban O, Simoni P, Sudoł-Szopińska I, Tesch C, Todorov P, Uson J, Vlad V, Zaottini F, Bilous D, Gutiu R, Pelea M, Marian A, Naredo E. The EFSUMB guidelines and recommendations for musculoskeletal ultrasound - part I: extraarticular pathologies. *Ultraschall Med.* 2022;43(1):34–57.
  19. Papalexis N, Ponti F, Rinaldi R, Peta G, Bruno R, Miceli M, Battaglia M, Marinelli A, Spinnato P. Ultrasound-guided treatments for the painful shoulder. *Curr Med Imaging.* 2022;18(7):693–700.
  20. Momma D, Nimura A, Muro S, Fujishiro H, Miyamoto T, Funakoshi T, Mochizuki T, Iwasaki N, Akita K. Anatomic analysis of the whole articular capsule of the shoulder joint, with reference to the capsular attachment and thickness. *J Exp Orthop.* 2018;5(1):16.
  21. Ricci V, Mezzan K, Naňka O, Özçakar L. Assessing/imaging the subcoracoid space: from anatomy to dynamic sonography. *J Ultrasound Med.* 2022;41(9):2149–55.
  22. Stella SM, Gualtierotti R, Ciampi B, Trentanni C, Sconfienza LM, Del Chiaro A, Pacini P, Miccoli M, Galletti S. Ultrasound features of adhesive capsulitis. *Rheumatol Ther.* 2022;9(2):481–95.
  23. Izumi T, Aoki M, Tanaka Y, Uchiyama E, Suzuki D, Miyamoto S, Fujimiya M. Stretching positions for the coracohumeral ligament: strain measurement during passive motion using fresh/frozen cadaver shoulders. *Sports Med Arthrosc Rehabil Ther Technol.* 2011;3(1):2.
  24. Al Khayyat SG, Stella SM, Trentanni C, Falsetti P, Frediani B, Del Chiaro A, Galletti S. Ultrasound definition of subacromial chronic “fibro-adhesive” bursitis and its treatment via ultrasound guided hydrodilatation: a prospective pilot study. *J Ultrasound.* 2024. <https://doi.org/10.1007/s40477-024-00894-9>.
  25. Castro ADAE, Prado RMA, Carrera EDF, Yokoo P, Santos DDCB, Rosemberg LA, Taneja AK. Incidence of adhesive capsulitis of the shoulder during the beginning of the COVID-19 pandemic. *Einstein (Sao Paulo).* 2022. [https://doi.org/10.31744/einstein\\_journal/2022AE0163](https://doi.org/10.31744/einstein_journal/2022AE0163).

26. Donati D, Vita F, Tedeschi R, Galletti S, Biglia A, Gistri T, Arcuri P, Origlio F, Castagnini F, Faldini C, Pederiva D, Benedetti MG. Ultrasound-guided infiltrative treatment associated with early rehabilitation in adhesive capsulitis developed in post-COVID-19 syndrome. *Medicina (Kaunas)*. 2023;59(7):1211.
27. Vita F, Pederiva D, Tedeschi R, Spinnato P, Origlio F, Faldini C, Miceli M, Stella SM, Stefano Galletti S, Cavallo M, Pilla F, Donati D. Adhesive capsulitis: the importance of early diagnosis and treatment. *J Ultrasound*. 2024. <https://doi.org/10.1007/s40477-024-00891-y>.
28. Park I, Lee HJ, Kim SE, Bae SH, Lee KY, Park KS, Kim YS. Evaluation of the effusion within biceps long head tendon sheath using ultrasonography. *Clin Orthop Surg*. 2015;7(3):351–8.
29. Ricci V, Özçakar L. Looking into the joint when it is frozen: a report on dynamic shoulder ultrasound. *J Back Musculoskelet Rehabil*. 2019;32(4):663–5.
30. Ricci V, Chang K, Güvener O, Mezian K, Kara M, Leblebicioğlu G, Stecco C, Pirri C, Merve Ata A, Dughbaj M, Jain NB, Özçakar L. Euro-musculus/USPRM dynamic ultrasound protocols for shoulder. *Am J Phys Med Rehabil*. 2022;101(3):e29–36.
31. Wang JC, Tsai PY, Hsu PC, Huang JR, Wang KA, Chou CL, Chang KV. Ultrasound-guided hydrodilatation with triamcinolone acetonide for adhesive capsulitis: a randomized controlled trial comparing the posterior glenohumeral recess and the rotator cuff interval approaches. *Front Pharmacol*. 2021;7(12): 686139.
32. Ricci V, Galletti S, Chang KV, Özçakar L. Ultrasound imaging and guidance in the management of adhesive bursopathy of the shoulder: a video demonstration. *J Ultrasound Med*. 2020;39(3):633–5.
33. Donati D, Tedeschi R, Spinnato P, Pederiva D, Pilla F, Faldini C, Benedetti MG, Guerra E, Cavallo M, Miceli M, Galletti S, Vita F. Ultrasound hydrodistention in adhesive capsulitis: hospital versus home-based rehabilitation. *Egypt Rheumatol*. 2024;46(4):166–70.
34. Wang JC, Chang KV, Wu WT, Han DS, Özçakar L. Ultrasound-guided standard vs dual-target subacromial corticosteroid injections for shoulder impingement syndrome: a randomized controlled trial. *Arch Phys Med Rehabil*. 2019;100(11):2119–28. <https://doi.org/10.1016/j.apmr.2019.04.016>.