Original Article

The Efficacy of Ultrasound-Guided Capsule-Preserving Hydrodilatation with Corticosteroid Versus Conventional Corticosteroid Injection in Shoulder Adhesive Capsulitis: A Randomized, Double-Blinded, Controlled Trial

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ABSTRACT

Objectives: To compare the outcomes of treating subacute adhesive capsulitis (AC) using capsule-preserving hydrodilatation with corticosteroid (CPHC) versus intra-articular corticosteroid injection (IACI)

Study design: A randomized, double-blinded, controlled trial

Setting: Chaophrayayommarat Hospital, Suphanburi, Thailand

Subjects: Fifty-two participants with AC and shoulder pain who had a numeric rating scale (NRS) of at least four after having received physical therapy for at least one month.

Methods: Eligible patients were randomly allocated either to the study group treated with CPHC or to the control group treated with IACI. The CPHC group (n=26) received a mixture of 4 mL of triamcinolone (10 mg/mL), 6 mL of 1% lidocaine, and 10 mL of normal saline, whereas the IACI group (n=26) received a mixture of 4 mL of triamcinolone (10 mg/mL) and 1 mL of 1% lidocaine. Following that, all participants underwent physical therapy at the hospital and a participated in a home exercise program. The primary outcome was shoulder passive range of motion (PROM). Secondary outcomes were subjective numeric rating scale (NRS), the Shoulder Pain and Disability Index (SPADI), and the Oxford Shoulder Score (OSS). Assessments were conducted at baseline and at 1- and 6-weeks post-treatment.

Results: At one week post-treatment, all outcomes were significantly different from baseline in both groups. The SPADI-disability and SPADI-total scores were significantly different between groups. At six weeks, all outcomes showed a strongly significant improvement in both groups and significant differences between groups except the internal rotation.

Conclusions: Capsule-preserving hydrodilatation with corticosteroid combined with physical therapy and a home exercise program demonstrated superior efficacy to intra-articular corticosteroid injection combined with the same physical therapy and a home exercise program for treating subacute adhesive capsulitis, resulting in improved ROM, reduced pain, and restored shoulder function

Keywords: adhesive capsulitis, capsule-preserving hydrodilatation, corticosteroid, ultrasound-guided, range of motion

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Introduction

Adhesive capsulitis (AC), also known as frozen shoulder, is a disorder presenting with a spontaneous onset of pain along with restricted active and passive shoulder movement. It is caused by inflammatory glenohumeral and subacromial synovium, coracohumeral ligament hypertrophy, and progressive fibrosis of the glenohumeral capsule.[1,2] The shoulder stiffness and pain usually significantly limit activities of daily living and lower quality of life.

Conservative therapy for adhesive capsulitis includes oral analgesic medication and physical therapy followed by an intra-articular corticosteroid injection (IACI), capsular hydrodilatation, arthrographic capsulotomy, and manipulation under anesthesia (MUA). Despite the amount of research on this topic, results appear inconclusive regarding the effectiveness of such treatment modalities.[3]

Hydrodilatation, which involves injection of fluid and corticosteroid into the shoulder capsule, also known as arthrographic distension, is aimed at stretching the contracted capsule and reducing inflammation.[4] To avoid discomfort and maximize the effectiveness of the treatment, it is necessary that the needle is inserted properly into the shoulder capsule. Two randomized controlled trials have reported that ultrasound-guided capsular hydrodilatation has similar effects as fluoroscopy for the treatment of AC but with less radiation exposure and greater cost-effectiveness.[5,6] However, hydrodilatation has several disadvantages, e.g., complaints of excruciating pain, time-consuming procedures, and complex preparations.[4] Hydrodilatation can distend the joint capsule until it ruptures, however, most rupture sites are located at the subscapularis bursa or the biceps sheath, not at the

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thickened capsule where the actual pathology is located.[4] Therefore, hydrodilatation with maximum volume and preservation of the capsule has a superior effect compared with the rupturing method.[4] Hydrodilatation has been demonstrated to be more effective than physiotherapy and to be as effective as MUA.[7] In review articles, physical therapy following hydrodilatation or IACI provided improvement of ROM and reduction of pain.[8,9] However, several studies have shown that without physical therapy the effectiveness of IACI is similar to hydrodilatation.[3,4,10] For that reason, determining the impact of concomitant physical therapy on the efficacy of hydrodilatation was problematic.

In a Cochrane review by Buchbinder et al. (2008), hydrodilatation with corticosteroid and saline provided short-term benefits in pain relief when compared with a placebo.[11] According to one 2018 systematic review, hydrodilatation was as effective as IACI in shoulder function improvement and pain reduction and yielded better external rotation improvement in the medium term (4-24 weeks),[12] while Saltychev et al. reviewed the efficacy of hydrodilatation based on 12 trials and concluded that hydrodilatation has only a small, clinically insignificant effect when treating AC.[13] However, there were differences in the methods utilized to expand the glenohumeral capsule in each of the research studies e.g., whether the capsule was preserved or ruptured, differences in injectate volumes and consistencies, approaches and guiding methods, the number of repeated injections, the duration and severity of the diseases, whether the study included physical therapy and/or a home exercise program or not, and the varied amounts of volume in the comparison groups, such as participants who received intra-articular injections of 10 mL, most likely had some dilatation.

According to a retrospective review of treating AC, hydrodilatation with an injected volume of 20 mL followed by physical therapy and home-based exercise provides significantly increased shoulder ROM and reduced pain.[14] However, there have been no studies of randomized trials reporting on the most effective therapy for AC patients. The present study aimed to compare the effect of CPHC versus IACI when combined with physical therapy and a home exercise program using the objective indices of shoulder functioning as well as improvement in self-reported outcomes.

Methods

Study design

The hospital ethics committee approved this randomized controlled trial with both the patient and assessor blinded. The trail was registered with the Thai Clinical Trials Registry [Registry number TCTR20210217005]. It was conducted from December 2020 to December 2023 at the rehabilitation outpatient clinic, Chaophrayayommarat Hospital. All enrolled subjects provided written informed consent prior to participation.

Participants

Study participants were adults (age ≥ 18 years) with a diagnosis of primary unilateral AC, limited shoulder PROM (more than 30 degrees restriction) in at least two directions[3] including external rotation, duration of symptoms less than 12 months (to minimize the possibility of interference with the natural recovery of shoulder ROM), subjective numeric rating scale (NRS) of shoulder pain scores of at least 4 out of 10, and no improvement after receiving at least one month of physical therapy.[14] Exclusion criteria were (1) a history of steroid injection or shoulder surgery at the affected shoulder prior to enrollment, (2) partial or full-thickness tear of the rotator cuff and/or other significant shoulder pathologies such as labral tears, significant osteoarthritis, or shoulder instability on ultrasonography or magnetic resonance imaging (MRI), (3) secondary AC (secondary to other causes including fracture, inflammatory, infectious arthritis or hemiplegia), (4) bleeding disorder, and (5) allergy to corticosteroid or lidocaine.

The sample size calculation was based on a study by Park et al. that showed capsular distension was more effective in passive external rotation improvement than IACI[15], in which the primary outcome was determined using the external rotation of the shoulder passive ROM at six weeks after the IACI with a mean (SD) of 44.5 (7.7) in the control group. The estimated clinical improvement increased by 15% in the CPHC group. Results were calculated for the sample size to compare two independent means. For an alpha level of 0.05, a power of 80% (β = 0.2), and an estimated drop-out rate of 10%, the target sample size was 52 participants (26 participants per group).

sample size formula: $$n = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 \left[\sigma_1^2 + \frac{\sigma_2^2}{r}\right]}{\Delta^2}$$

$$r = \frac{n2}{n1}, \Delta = \mu 1 - \mu 2$$

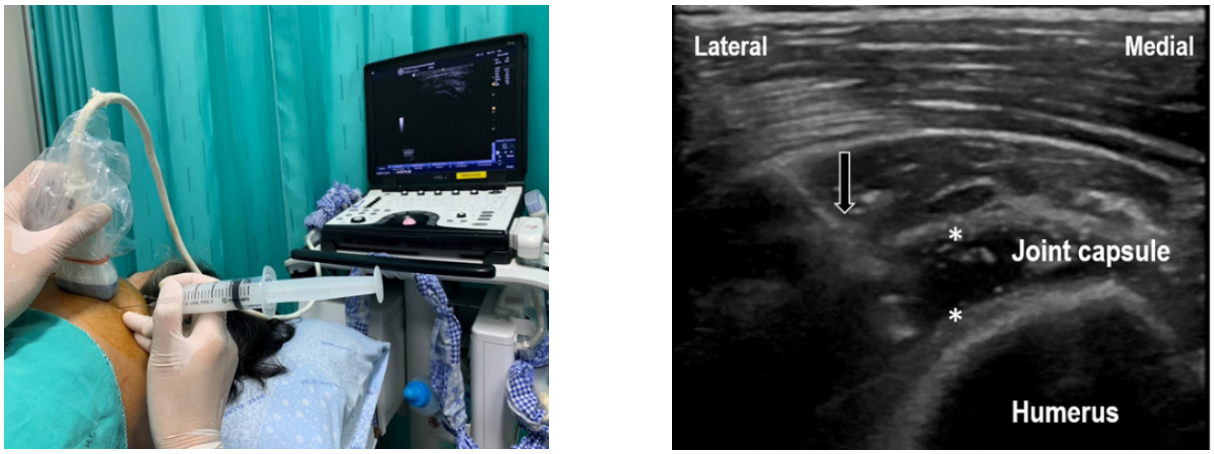
Randomization

Participants were randomly assigned to either the CPHC or IACI group using computer-generated block randomizations (block size 2). All assignments were concealed in sequentially numbered. Both the patients and the assessors were blinded to the treatment allocation.

Intervention

The investigator performed a musculoskeletal ultrasound to screen for partial or full-thickness tears of the rotator cuff to exclude participants with shoulder pathologies. After the inclusion and exclusion screening, written informed consent was obtained from the participants. The shoulder PROM was assessed and recorded.

All injections were performed under ultrasound guidance by a single certified physiatrist with more than five years of experience in ultrasound-guided injections using a 4 to 13 MHz linear array transducer. An aseptic technique was used following skin cleansing (Figure 1).



A B

Figure 1. Ultrasound-guided capsule-preserving hydrodilatation with corticosteroid. (A) approach and aseptic technique, (B) sonographic view of capsular distension during the injection (black arrows: needles; white asterisks: capsular distension).

All patients were in a lateral decubitus position with the shoulder and elbow semi-flexed, resting on a pillow for comfort, and the procedure was administered to the glenohumeral joint via the posterior approach, which is often used because it allows good needle and target visualization[16] and prevents the patient from seeing the size of syringe used.[3] Local anesthesia at the site of the injection was performed with 2 mL of 1% lidocaine. Then a 22-gauge, 1.5-inch-long needle was inserted parallel to the ultrasound probe until the needle tip entered the glenohumeral joint.[17] For the IACI group, a mixture of 4 mL of 10 mg/mL triamcinolone and 1 mL of 1% lidocaine was slowly introduced into the shoulder joint.[17] For the CPHC group, a 20 mL fluid mixture was injected composed of 4 mL of 10 mg/mL triamcinolone, 6 mL of 1% lidocaine, and 10 mL of normal saline. The capsular distension was monitored in real-time as a hypoechoic volume within the glenohumeral joint.

The participants were scheduled to return to the outpatient clinic for the first follow-up assessment one week after the injection and the start of an intensive rehabilitation program, including physical therapy at the hospital and a home exercise program. All participants received hospital-based physical therapy 2-3 times per week, consisting of shortwave diathermy for 15 minutes[18] and hot packs for 20 minutes, followed by manual shoulder mobilization for 10 minutes, therapeutic shoulder exercises for 15 minutes, and a cold pack for 15 minutes. The physiotherapist could end the therapy when the participant had a numeric rating scale (NRS) for pain of less than two and ROM was nearly average.

All participants received picture leaflets describing the home exercise program, which included active ROM, table-lean passive stretching, and cane-stretch exercises. They were advised to perform the exercises at least 10 minutes per session for a minimum of two sessions per day.

Whenever the participants attended a physical therapy program at the hospital, they were reminded and encouraged to continue their workouts at home. In addition, they were allowed to take the prescribed acetaminophen (500 mg) 1-2 tablets every 8 hours with a maximum of 6 tablets per day to control pain. No other analgesic drugs or pain therapy was permitted. The participants were allowed to contact the physiatrist who performed the injection if they thought that their symptoms had become worse.

Participants recorded their exercise sessions, medication use, physical therapy sessions, and any adverse effects or complications in a logbook every day.

At 6 weeks after injection, the assessors re-assessed all participants' shoulder PROM and subjective pain NRS, and their diaries were reviewed.

At the end of the trial, patients who had no significant improvement (NRS remaining at least four and shoulder passive ROM restricted by more than 30 degrees in at least two directions) were re-assessed by the physiatrist and continuation of physical therapy and performing an intervention such as CPHC was considered. Capsule-preserving hydrodilatation with corticosteroids could be considered when after continuing physical therapy for at least a month, if the NRS remained at least four and the shoulder passive ROM continued to be restricted by more than 30 degrees in at least two directions.

Outcome measurements

Passive shoulder ROM was the primary outcome measure. It was determined using a goniometer by one of the two well-trained physiotherapists who had high interrater reliability (Prior to this study, their intraclass correlation coefficient in all directions was more than 0.98). They were blinded to the patient's treatment. Flexion and abduction ROM were measured in a supine position, whereas external and internal rotation ROM was recorded in 90-degree abduction of the shoulder and 90-degree flexion of the elbow. If the observed abduction was less than 90 degrees, the maximum possible abduction was determined before measuring the external and internal rotation. To avoid bias, the assessor reported ROM values on separate sheets each time.

Shoulder pain and limited function or disability were assessed using two self-reported questionnaires, the shoulder pain and disability index (SPADI) and the Oxford shoulder score (OSS). Both were translated into Thai; the Thai SPADI has been reported to have excellent internal consistency and moderate to high construct validity[19], and the OSS-TH has demonstrated acceptable validity and reliability.[20]

The Thai SPADI questionnaire consisted of 13 items: 5 items for the pain domain and 8 items for the disability domain.[19] Each item is rated using NRS (0 for no pain or no difficulty to 10 for the worst pain/difficulty imaginable). The means of the pain and the disability domains are averaged to produce a total score ranging from 0 (best) to 100 (worst). The minimal clinically significant difference (MCID) for the SPADI total is between 8 and 13.[21]

The OSS-TH questionnaire consists of 12 questions to assess pain and daily function difficulty using a five-point Likert scale. A higher OSS score indicates more severe pain or greater movement difficulty.[20] The MCID for OSS has been reported to be between 5 and 6.[22,23]

In terms of NRS, patients were asked to rate the severity of their average degree of pain in the affected shoulder during motion in the last week on a scale ranging from 0 (no pain) to 10 (worst pain imaginable). Because AC is characterized by mobility restriction, pain during motion is a more sensitive measure for determining the disease's progression.[24]

At each follow-up visit, the physiatrist reviewed the participant's logbook to assess home exercise compliance, adverse effects, and complications.

Statistical methods

The data were processed using Stata Statistical Software version 14 (Stata Corp LLC, College Station, Texas, USA). The demographic data for both groups are shown as mean and standard deviation (SD) or median (25^{th}, 75^{th} percentiles) for continuous data and a percentage (%) for categorical data. The Kolmogorov-Smirnov test was used to determine data normality. When the data were normally distributed, the unpaired t-test was performed to compare the mean values of the two groups. For data lacking a normal distribution, the Mann-Whitney U-test was employed. The Chi-square test or Fisher's exact test were used to compare categorical variables between the two groups. Mixed models were used to compare the effect of treatment over time on quantitative outcomes using the mean difference from baseline. Model selection was based on the Bayesian Information Criterion. Residual plots were used to comprehensively test assumptions for mixed models, e.g., error term normality. A comparison of the predicted outcomes between the two treatments at each time point was also performed. The intention-to-treat concept was followed. In the case of missing data due to a loss of follow-up, the last observation carried forward approach was used. For individuals lost to follow-up, the last observations were defined as the last observations prior to dropout. *P*-values < 0.05 were considered statistically significant.

Results

Sixty-eight patients were evaluated for eligibility, with 52 accepted into the trial. Twenty-six patients were randomly allocated to the CPHC group and 26 to the IACI (control) group. A schematic flow chart of the participants, reasons for exclusion, and follow-up throughout the study is shown in Figure 2. Six participants did not complete the intervention: three in the CPHC group and three in the IACI group. The reasons for the loss of follow-up were unrelated to post-therapy effects: there were two COVID-19 infections and one trans-

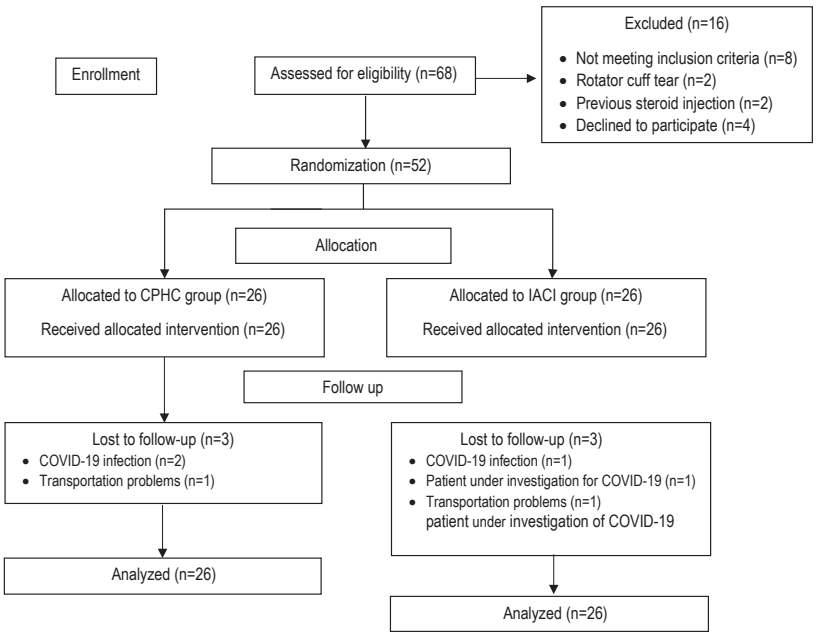


Figure 2. Consort diagram shows the progression of participants through the study's phases
CPHC, capsule-preserving hydrodilatation with corticosteroid; IACI, intra-articular corticosteroid injection

portation problem in the CPHC group, one COVID-19 infection, one patient under investigation for COVID-19, and one transportation problem in the IACI group.

There were no significant between-group differences in demographic data, pre-treatment or baseline variables. However, there were significant differences in the SPADI and NRS at baseline (Table 1).

Table 2 shows that both capsule-preserving hydrodilatation with corticosteroid (CPHC) and intra-articular corticosteroid injection (IACI) increased shoulder passive ROM in all directions at both one week and six weeks after intervention with statistically significant differences from baseline. In the comparison between groups, there was a statistically significant difference between the groups in increased ROM in all directions with the exception of internal rotation at six weeks but not at one week post-intervention. The CPHC group demonstrated a statistically significant mean difference from baseline between at 1 and 6 weeks in all directions, whereas the IACI group showed a statistically significant difference in all directions at 1 and 6 weeks except internal rotation.

Table 3 shows the pain and functional outcomes for the shoulder. According to NRS and SPADI-pain, the CPHC group had higher baseline scores than the IACI group. The pain scores declined significantly from baseline at both one week and at six weeks in both groups, while there was a statistically significant difference between groups only at six weeks. Regarding daily function difficulty, the SPADI-disability score at one week and six weeks decreased significantly from baseline in both groups, but there was a significant difference between groups only at six weeks after intervention. The OSS scores also decreased significantly in both groups, but only reached statistical significance between groups six weeks after intervention. These findings suggest that both interventions effectively reduced pain and improved shoulder function, with differences in outcomes becoming more pronounced over time.

Throughout this study, there was no significant difference in the number of acetaminophen tablets used between the two groups at any time. The median (25^{th} and 75^{th} percentiles) of sessions of the hospital-based physical therapy program was 12.0 (10.0-14.0) in the CPHC group and 13.0 (10.0-15.0) in the IACI group, which was not a statistically significant difference. Only one patient in each group discontinued the physical therapy because their NRS was less than two and their ROM was nearly normal. According to the patients' logbooks, all participants completed at least two sessions of the home exercise program each day. Both interventions were tolerated and did not result in adverse events such as vasovagal reaction, infection, hematoma, permanent neurogenic symptoms, steroid-induced arthritis, or skin discoloration.

Table 1. Baseline demographics and clinical characteristics prior to injection of capsule-preserving hydrodilatation with corticosteroid (CPHC) and intra-articular corticosteroid injection (IACI) groups.

	CPHC (n = 26)	IACI (n = 26)	*p*-value
Age (years)[1]	57.6 (9.0)	57.4 (8.1)	0.941[a]
Female[2]	6 (23)	5 (19)	0.733[b]
BMI (kg/m^2)[1]	23.5 (3.5)	25.3 (5.3)	0.141[a]
Duration of symptoms (weeks)[3]	20.0 (12.0-28.0)	20.0 (12.0-24.0)	0.520[c]
Affected side, right[2]	12 (46)	12 (46)	1.002[b]
Dominant side, right[2]	22 (85)	23 (88)	1.004[b]
Diabetes mellitus[2]	7 (27)	9 (35)	0.550[b]
Prior injection:			
Physical therapy (sessions)[3]	8.5 (6.0-12.0)	10.0 (8.0-14.0)	0.242[c]
Acetaminophen[2]	12 (46)	9 (35)	0.404[b]
Oral NSAIDs[2]	17 (65)	14 (54)	0.401[b]
Oral opioid[2]	5 (19)	4 (15)	1.003[b]
Oral muscle relaxant[2]	13 (50)	17 (65)	0.262[b]
Flexion[1]	133.9 (15.9)	131.7 (17.9)	0.640[a]
Abduction[1]	95.8 (24.0)	97.1 (18.2)	0.831[a]
Internal rotation[1]	53.3 (20.3)	55.1 (21.4)	0.760[a]
External rotation[1]	37.4 (15.5)	39.0 (14.4)	0.702[a]
NRS[1]	8.1 (1.2)	7.2 (1.4)	0.015[a]
SPADI- pain[1]	67.3 (13..8)	54.6 (13.9)	0.002[a]
SPADI- disability[1]	56.9 (15.9)	47.9 (15.5)	0.044[a]
SPADI- total[1]	60.9 (14.0)	50.5 (13.7)	0.009[a]
OSS[1]	33.8 (4.7)	31.8 (5.7)	0.182[a]

[1]Mean (SD), [2]number (%), [3]median (25^{th}, 75^{th} percentiles); [a]Unpaired T test, [b]Chi-square test or Fisher's exact test, [c]Mann-Whitney U-test; $p < 0.05$ indicates statistical significance

NSAIDs, non-steroidal anti-inflammatory drugs; NRS, numeric rating scale; SPADI, shoulder pain and disability index; OSS, Oxford Shoulder Score

Table 2. Comparison of outcome data of range of motion (ROM) at baseline, 1 and 6 weeks after injection between the capsule-preserving hydrodilatation with corticosteroid (CPHC) and the intra-articular corticosteroid injection (IACI) groups.

Outcomes	CPHC (n = 26)		IACI (n = 26)		Margin coef.[2] between groups (95%CI)	*p*-value
	Mean (SD)	Mean difference from baseline (SD)	Mean (SD)	Mean difference from baseline (SD)		
Flexion						
Baseline	133.9 (15.9)		131.7 (17.9)			
1 week	145.5 (16.6)	11.6 (11.4)[a]	136.6 (16.4)	5.2 (12.3) a	6.5 (-0.2, 13.1)	0.058
6 weeks	161.3 (15.4)	27.2 (11.0)[b]	146.7 (18.4)	16.1 (14.4) b	10.7 (3.7, 17.7)	0.003*
Margin coef.[1] (95%CI)		15.1 (10.0, 20.2)		10.9 (5.7,16.1)		
p-value		<0.001*		<0.001*		
Abduction						
Baseline	95.8 (24.0)		97.1 (18.2)			
1 week	110.2 (26.7)	14.4 (11.2)[a]	107.4 (21.7)	10.3 (11.3)[a]	4.1 (-2.0, 10.2)	0.186
6 weeks	150.1 (31.4)	52.8 (29.2)[b]	123.8 (28.4)	26.7 (20.2)[b]	26.1 (11.7, 40.5)	<0.001*
Margin coef.[1] (95%CI)		38.4 (27.7, 49.0)		16.4 (5.5, 27.3)		
p-value		<0.001*		0.003*		
Internal rotation						
Baseline	53.3 (20.3)		55.1 (21.4)			
1 week	60.6 (20.6)	7.3 (17.4)[a]	62.8 (21.7)	7.7 (16.8)[a]	-0.4 (-10.8, 10.0)	0.942
6 weeks	74.3 (15.6)	19.9 (23.3)[b]	66.2 (23.0)	13.6 (18.7)[b]	6.9 (-3.9, 17.7)	0.209
Margin coef.[1] (95%CI)		13.1 (5.8, 20.4)		5.8 (-1.6, 13.2)		
p-value		<0.001*		0.123		
External rotation						
Baseline	37.4 (15.5)		39.0 (14.4)			
1 week	46.7 (15.6)	9.3 (7.1)[a]	45.4 (16.1)	6.4 (12.1)[a]	2.9 (-5.0, 10.7)	0.476
6 weeks	65.3 (19.0)	27.8 (16.9)[b]	54.9 (19.4)	15.1 (19.4)[b]	12.3 (4.1, 20.5)	0.003*
Margin coef.[1] (95%CI)		18.3 (11.4, 25.1)		9.4 (2.4, 16.4)		
p-value		<0.001*		0.009*		

There were interaction effects between time and group for all outcomes. Positive change scores (95%CI) of ROM indicates improvement.

Margin coef.[1], margin coefficients comparing mean differences from baseline between 1 week and 6 weeks in marginal effect for mixed models.

Margin coef.[2], margin coefficients for comparing mean differences from baseline between the two groups in marginal effect for mixed models. CI, confident interval; *$p < 0.05$ indicates statistical significance.

[a]Statisitically significant difference between the baseline and 1st week in the same group ($p < 0.05$).

[b]Statisitically significant difference between the baseline and 6th weeks in the same group ($p < 0.05$).

At the end of the study, the investigator decided to perform CPHC on seven participants in the IACI group due to less than expected improvement, but none in the CPHC group. In addition, all participants were asked to guess which intervention they had received. Fifty percent of the participants in the CPHC group and 23.1% in the IACI group gave a correct guess, showing that they had not assumed they had a successful outcome because they were in the trial group.

Discussion

The results of this study demonstrate that both CPHC and IACI followed by hospital-based physical therapy and a home-based exercise program can increase shoulder ROM, reduce pain intensity and improve daily function as early as one week and both can continue to improve at six weeks after the interventions. The difference between the two groups was a statistically significant: CPHC was more effective than IACI in all measured outcomes except internal rotation. The CPHC group had improved internal rotation to a greater extent than the IACI group. The CPHC group also showed a statistically significant mean difference in internal rotation from baseline between 1 and 6 weeks, whereas the IACI group was not statistically significant. Additionally, the data suggest "most likely" improvements in range of motion in all directions, consistent with the previous studies.[25,26]

Many studies have reported no statistically significant difference in ROM, pain, or functional recovery with hydrodilatation combined with corticosteroid compared to corticosteroid alone.[3,4,10] It is believed that hydrodilatation facilitates hydraulic pressure and expands the constricted joint cavity.[24] In the present study, the injections were done using an ultrasound-guided technique to ensure that the joint capsule was distended but was still preserved to allow the injected corticosteroid to remain within the joint capsule and enhance the excellent anti-inflammatory effect.[27,28] This study chose capsular preservation as it has been reported to provide faster improvement than using an aggressive hydrodilatation technique which results in rupture of the joint capsule,[4] a rupture

Table 3. Comparison of outcome data of numeric rating scale (NRS), shoulder pain and disability index (SPADI) and Oxford Shoulder Score (OSS) at baseline, 1 and 6 weeks after injection between capsule-preserving hydrodilatation with corticosteroid (CPHC) and intra-articular corticosteroid injection (IACI) groups

Outcomes	CPHC (n=26)		IACI (n=26)		Margin coef.[2] between groups (95%CI)	*p*-value
	Mean (SD)	Mean difference from baseline (SD)	Mean (SD)	Mean difference from baseline (SD)		
NRS						
Baseline	8.1 (1.2)		7.2 (1.4)			
1 week	5.2 (1.8)	-3.0 (1.6)[a]	4.8 (2.2)	-2.4 (1.8)[a]	-0.6 (-1.6, 0.5)	0.272
6 weeks	2.0 (1.7)	-6.0 (2.0)[b]	3.35 (1.9)	-3.8 (2.2)[b]	-2.3 (-3.3, -1.2)	<0.001*
Margin coef.[1] (95%CI)		-3.1 (-3.8, -2.3)		-1.4 (-2.1, -0.6)		
p-value		<0.001*		<0.001*		
SPADI- pain						
Baseline	67.3 (13.8)		54.6 (13.9)			
1 week	42.7 (14.8)	-24.6 (13.7)[a]	34.3 (15.2)	-20.3 (13.7)[a]	-4.3 (-12.4, 3.8)	0.296
6 weeks	14.1 (15.2)	-53.2 (15.4)[b]	24.6 (14.6)	-29.9 (17.0)[b]	-23.5 (-31.9,-15.1)	<0.001*
Margin coef.[1] (95%CI)		-28.4 (-33.9, -22.9)		-9.2 (-14.8, -3.7)		
p-value		<0.001*		0.001*		
SPADI-disability						
Baseline	56.9 (15.9)		47.9 (15.5)			
1 week	36.0 (14.2)	-20.9 (15.1)[a]	36.2 (17.3)	-11.7 (11.5)[a]	-9.1 (-16.7, -1.6)	0.018*
6 weeks	12.34 (10.8)	-44.8 (14.6)[b]	19.2 (14.8)	-29.0 (14.9)[b]	-16.3 (-24.1, -8.4)	<0.001*
Margin coef.[1] (95%CI)		-24.0 (-29.2, -18.8)		-16.9 (-22.1, -11.6)		
p-value		<0.001*		<0.001*		
SPADI-total						
Baseline	60.9(14.0)		50.5 (13.7)			
1 week	38.6(13.9)	-22.3 (13.0)[a]	35.4 (15.8)	-15.0 (11.1)[a]	-7.3 (-14.3, -0.3)	0.041*
6 weeks	13.0(11.9)	-48.0 (13.0)[b]	21.3 (14.2)	-29.6 (14.2)[b]	-19.0 (-26.3,-11.8)	<0.001*
Margin coef.[1] (95%CI)		-25.7 (-30.5, -20.8)		-13.9 (-18.9, -9.0)		
p-value		<0.001*		<0.001*		
OSS						
Baseline	33.8 (4.7)		31.8 (5.7)			
1 week	25.5 (4.8)	-8.2 (5.7)[a]	25.4 (5.4)	-6.4 (4.1)[a]	-1.8 (-4.5, 0.9)	0.182
6 weeks	18.0 (4.0)	-15.6 (5.1)[b]	20.5 (4.5)	-11.2 (4.6)[b]	-4.2 (-6.9, -1.5)	0.003*
Margin coef.1 (95%CI)		-7.3 (-8.8, -5.7)		-4.9 (-6.5, -3.3)		
p-value		<0.001*		<0.001*		

There were interaction effects between time and group for all outcomes.

Negative change scores (95%CI) of NRS, SPADI and OSS indicates improvement.

Margin coef.[1], margins coefficient comparing mean difference from baseline between 1 week and 6 weeks in marginal effect for Mixed models.

Margin coef.[2], margins coefficient comparing mean difference from baseline between 2 groups in marginal effect for Mixed models.

CI, confident interval; *$p < 0.05$ indicates statistical significance.

[a]Statisitically significant difference between the baseline and 1st week in the same group ($p < 0.05$).

[b]Statisitically significant difference between the baseline and 6th weeks in the same group ($p < 0.05$).

which mainly occurs at the subscapularis recess or the long biceps sheath,[29,30] not at the thickened capsule where the actual pathologies of AC are found.[31] It is possible that the mechanical effect of hydrodilatation allows more motion during therapy and exercise than IACI. This explanation suggests that capsular distension shares a mechanism similar to manipulation under anesthesia.[11]

Both interventions in this study were done under ultrasound-guidance, but used different total injected volumes: 5 mL in IACI.[15,17] In contrast, the higher volume of 20 mL used in CPHC[4],[14,15,32] makes more capsular distension and ruptures. Why did shoulder ROM improve more in patients treated with CPHC? One possible factor is the difference in injected volume between the two interventions in this study: more lidocaine was used in CPHC than in IACI (6 mL vs. 1 mL, respectively). Additionally, local anesthetics are commonly combined with corticosteroids to assist in control of the pain that occurs after an injection. The CPHC group received 6 mL of 1% lidocaine in an attempt at pain alleviation following hydrodilatation, while the IACI group received only 1 mL of 1% lidocaine following conventional therapy to minimize the volume in order to avoid excessive capsular distension. Lidocaine hydrochloride is a fast but short-acting local anesthetic agent,[33] so it would be expected that a greater amount of lidocaine would not increase pain control at one week or at six weeks after the intervention. On the contrary,

a previous systematic review concluded that local anesthetic agents have dose-dependent and duration-dependent chondrogenic effects.[34] Grishko et al. found evidence that a 1% lidocaine-based dose does not significantly decrease cell viability at 24 hours, while 2% lidocaine remains chondrogenic at 24 hours.[35] The effect of a local anesthetic injection into a peripheral joint in vivo, however, is unclear.[34] Based on that information the principal investigator of this study decided to use a smaller amount of 1% lidocaine to avoid possible chondrotoxic effects.

It is believed that corticosteroid inhibits the inflammatory process in the inflamed joint capsule after being distended as well as in the inflamed tendons around the shoulder joint following physical therapy and exercise.[36] The duration of the effect of triamcinolone after intra-articular injection is 2-3 weeks.[37] The appropriate dose of corticosteroids for IACI or hydrodilatation has not yet been determined. Many studies have utilized 40 mg triamcinolone[4,12,38] with both methods. In this study, the injected solution in both interventions contained the same dose of 40 mg of triamcinolone (10 mg/mL). For individuals with diabetes mellitus or those who need to monitor their blood sugar levels, hyaluronate or NSAID injection may be an alternative option.

In this study, ROM between group comparisons revealed statistically significant increases in all directions with the exception of internal rotation. The rotator cuff interval has been defined as the critical structure in the pathogenesis of AC. The coracohumeral ligament (CHL) is often the first component to be compromised. A thickened CHL that covers the rotator interval has been shown to limit shoulder joint external rotation.[24] According to Koide et al.[39], arthroscopic resection of the thickened CHL from the coracoid base to the superomedial capsule is responsible for the restriction of internal rotation.

Recently, a new injection procedure using the anterior approach via the rotator interval and guided by ultrasound has been described. It is anticipated that injection via the anterior approach would raise the local corticosteroid concentration at the pathological site. In 2020, Elnady et al.[40] randomly assigned participants to hydrodilatation with 1 ml of methyl-prednisolone acetate (40 mg), 1 mL of 2% lidocaine, and 15 mL of saline via either the posterior or anterior rotator interval approach. The anterior approach showed a statistically significantly higher level of improvement in flexion, abduction, and external rotation, but internal rotation was not different between the two approaches. Furthermore, in 2021, Wang et al.[24] reported that ultrasound-guided hydrodilatation with triamcinolone achieved better pain relief during motion with injection via the anterior rotator cuff interval than with the posterior approach. However, there was no significant difference in SPADI or ROM recovery. Burkhart et al.[41] demonstrated that in individuals who had restricted internal rotation, the posteroinferior recess and the capsule are constricted and thickened. The limitation of internal rotation may be due to posterior capsular stiffness. In this study, injection into the glenohumeral joint was performed via the posterior approach, and the results showed improved internal rotation with a significant difference from baseline in both groups. The CPHC group also showed a statistically significant mean difference from baseline between 1 and 6 weeks. Why significant improvement was seen in the CPHC group but not in the IACI group is not clear.

The posterior approach using ultrasound guidance provides easy visualization of the joint capsule for needle advancement. The anterior approach needle is carefully inserted between the CHL and the biceps tendon, and needle movement during the procedure should be kept at a minimum to minimize injury to the biceps pulley and supraspinatus muscle. However, this approach through the posterior glenohumeral recess would be more challenging for obese patients. Obesity was not an issue in the present study. In clinical practice, improvements in flexion, abduction, and external rotation as well as internal rotation are the last to appear and may not be regained. Further research, e.g., anatomical, biomechanical, and clinical studies are needed.

Combining intraarticular corticosteroid injection and physiotherapy improved SPADI and disability scores more than physiotherapy alone.[8,42] Buchbinder et al.[9] followed 156 individuals after hydrodilatation. Participants were randomly assigned to either physical therapy (manual therapy and directed exercise) or a placebo (sham ultrasound) and were assessed at baseline, 6, 12, and 26 weeks. Physical therapy following hydrodilatation provided no additional benefits in terms of pain, function, or quality of life. However, it did result in sustained greater active ROM and participant-perceived improvement for up to 6 months. Other previous studies[3,4,10] have demonstrated that hydrodilatation with corticosteroids is as effective as corticosteroid injection alone in patients who received only a home exercise program. Assessing the influence of concurrent physical therapy on the effects of hydrodilatation is challenging. Nonetheless, following hydrodilatation to expand the constricted joint cavity, the synergistic effect of physical therapy and therapeutic exercise may have helped optimize glenohumeral joint ROM by stretching soft tissue near the joint, restoring proprioception, and establishing normal shoulder and trunk biomechanics.[9] Another belief is that the patient's pain would subside following the injection, allowing them to participate in physical therapy.

As with ROM and pain, in this study the SPADI and OSS scores were significantly reduced in both groups with a statistically significant difference between the groups. There was also a clinically significant change from baseline at both the one-week and six-week time points. Clinically, an effective treatment should result in a significant change. The MCID for the SPADI has been reported to be an 8-13-point change.[21] The MCID at six weeks from baseline for the SPADI-total change was 48.0 and 29.6 in the CPHC and IACI groups

respectively. Similarly, the MCID for the OSS has been reported to provide a 5-6-point change.[22,23] The MCID for the OSS is reported to be a 15.6- and 11.2-point change in the CPHC and IACI groups, respectively.

In the present study, the mean differences between groups after six weeks were -19.0 (95% CI [-26.3, -11.8]) for the SPADI-total and -4.2 (95% CI [-6.9, -1.5]) for the OSS. These results surpassed the recommended level of change and the patients showed more clinical improvement and less difficulty in daily function as seen in the CPHC group. These findings are the result of less pain and more ROM in the shoulder.

It has been reported that AC is correlated with diabetes, which impairs collagen cross-linking mediated by hyperglycemia and, consequently, loss of tissue compliance and limitation of joint mobility.[43] It has been reported that diabetic patients with AC have worse functional outcomes compared with non-diabetic persons.[43] In the present study, 27% of the patients in the CPHC group and 35% in the IACI group had diabetes, but there were no statistically significant differences between the two groups. Thus it is unlikely that the lower level of improvement seen in the IACI group was due to diabetes.

To the best of our knowledge, this is the first study to investigate the effects of ultrasound-guided capsule-preserving hydrodilatation with a corticosteroid compared with conventional corticosteroid injection alone, and to combine both approaches with physical therapy and home exercise programs to improve outcomes for AC patients who do not improve with medication and physical therapy alone. In clinical practice, when patients do not respond to medication even after prolonged physical therapy, the physiatrist needs to evaluate pain and ROM. Previous studies have suggested that corticosteroid injection alone is more beneficial in the early stages of AC, which is primarily a continuous inflammatory process. Hydrodilatation was more effective in the later stages.[12,38] The frozen phase lasts for 4 to 12 months, which is consistent with the outcomes of this study that found a duration of about five months. However, hydrodilatation is both more painful and more time-consuming than IACI alone.[4] The procedure should be customized to the stage of the disease. For example, if the pain is severe but there is only a mild limitation of ROM, IACI may be sufficient. However, in cases of pain and severe limitations, CPHC might be of considerable benefit. To provide the most effective therapy for AC patients, physical therapy in the hospital and home exercise programs should be used to improve symptoms and shorten the length of the treatment program.

CPHC and IACI have some advantages. They can be performed as a day-case operation, are cost-saving, and place no additional strain on surgery waiting periods. CPHC may also reduce the probability of the injection being repeated. In this study, seven participants in the IACI group received repeated injections with CPHC. The injector needs to be trained and have experience using an ultrasound-guided approach to enhance the effectiveness of the treatment.

In this study, bias was minimized. The investigator chose the posterior approach for injection into the glenohumeral joint to prevent the patients from seeing the size of the syringe used and thus guessing which intervention they received. As stated in the information provided for informed consent, the hypothesis of the study was that CPHC provides better outcomes than IACI. In addition, both the assessors and the participants were blinded to the intervention.

Limitations

The current study had several limitations. First, the injector was not blinded. Second, the follow-up time periods were limited to short-term (4 weeks) and medium-term (4 to 24 weeks)[8] with no long-term follow-up. Third, capsule-preserved hydrodilatation was attempted; however, without real-time intra-articular pressure monitoring, inadequate distension or capsular rupture might have occurred. Finally, this study was conducted over an extended period due to the limited number of patients who failed physical therapy in the hospital and the outbreak of COVID-19.

Conclusions

The results of this study suggest that capsule-preserving hydrodilatation with corticosteroid combined with physical therapy and a home exercise program provides superior efficacy over intra-articular corticosteroid injection combined with physical therapy and an a home exercise program for treating subacute adhesive capsulitis, improving ROM, reducing pain, and restoring shoulder functions.

Disclosure

The authors declare no conflicts of interest.

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