

Functional improvement of bilateral frozen shoulder by unilateral intra-articular corticosteroid injection: a retrospective study

Minchul Kim, Ki-Yong Kim, Yool-Gang Huh,
Sang Hyeok Ma, Kil-Yong Jeong and
Seung-Hyun Yoon 

Abstract

Objective: Bilateral frozen shoulder (FS) is often treated with intra-articular corticosteroid injection (IACI). No studies have been performed to establish whether IACI must be administered in both shoulders or in only one shoulder to improve function. This study was therefore performed to determine whether unilateral IACI improves shoulder pain and passive range of motion (pROM) in bilateral FS.

Methods: The medical records of 165 patients with bilateral primary FS who underwent ultrasonography-guided IACI (2 mL of 10-mg/mL triamcinolone acetonide mixed with 5 mL of 1% lidocaine) in one shoulder were retrospectively reviewed. The outcome measures, namely the numeric rating scale (NRS) scores and pROM values (abduction, external rotation, flexion, hyperextension, and internal rotation), were evaluated pre- and post-injection.

Results: The patients' mean age was 54.0 ± 8.0 years. The mean symptom duration was 6.5 ± 2.8 months. The mean follow-up period after injection was 6.7 ± 0.8 weeks. The NRS scores and pROM values significantly improved in both the injected and non-injected shoulders.

Conclusions: This study showed that unilateral IACI in patients with bilateral FS improves the clinical outcome of the non-injected shoulder. We suggest that physicians observe the non-injected shoulder after unilateral injection rather than performing bilateral injections.

Department of Physical Medicine and Rehabilitation, Ajou University School of Medicine, Suwon, Korea

Corresponding author:

Seung-Hyun Yoon, Department of Physical Medicine and Rehabilitation, Ajou University School of Medicine, Worldcup-ro 164, Yeongtong-gu, Suwon 16499, Republic of Korea.

Email: yoonsh@ajou.ac.kr



Keywords

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Introduction

Frozen shoulder (FS), also known as adhesive capsulitis or painful stiff shoulder, is a common shoulder disease. FS begins with inflammation in the capsule of the glenohumeral joint and soft tissues proximal to the synovium and glenohumeral joint, resulting in global fibrosis and contracture in the glenohumeral joint.^{1,2} The treatments for FS include application of heat, flexibility exercises, nonsteroidal anti-inflammatory drugs (NSAIDs), oral corticosteroids, intra-articular corticosteroid injection (IACI), hydrodilatation, manipulation, and arthroscopic capsular release.¹⁻⁵

IACI is a conservative treatment for FS. It is effective for rapid reduction of inflammatory pain in the freezing and early frozen stages of FS.^{6,7} However, excessive doses of corticosteroids cause local and systemic complications such as tendon rupture, cartilage degeneration, disturbance of the menstrual pattern, hot flash-like symptoms, and hyperglycemia in patients with diabetes mellitus;⁸ therefore, a minimum dose of corticosteroid should be administered.¹

Although FS occurs unilaterally in most patients, it may also occur bilaterally. The prevalence of bilateral FS reportedly ranges from 20% to 50% of the total incidence of FS,^{9,10} and its risk in patients with diabetes is higher at 42% to 59%.¹¹⁻¹⁴ Although basic treatments for bilateral FS do not differ from those of unilateral FS, close attention is needed when IACI is considered as a treatment option. In principle, IACI should be performed bilaterally in

symptomatic shoulders; however, a simultaneous bilateral injection at twice the usual dose may increase the risk of systemic complications due to corticosteroid overdose. In contrast, if half the usual dose for unilateral FS is administered in each shoulder, the anti-inflammatory effect of the corticosteroid may be insufficient. Alternatively, it is possible to inject another dose into the other shoulder after a unilateral injection. If the unilateral injection sufficiently mitigates the pain in both shoulders, the second injection is unnecessary, which can alleviate the cost and inconvenience to the patient as well as the risk of complications after the injection. This study was therefore performed to investigate whether a unilateral injection for bilateral FS improves pain and passive range of motion (pROM) in both shoulders.

Materials and methods

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki. The Institutional Review Board of Ajou University Hospital reviewed the medical ethics and approved this study (IRB approval number: AJIRB-MED-MDB-19-251). The requirement for informed consent was waived because of the retrospective study design. All patients' details have been de-identified. The reporting of this study conforms to the STROBE guidelines.¹⁵

Study design and patients

This retrospective study was conducted in a university-affiliated tertiary care hospital and involved outpatients from the rehabilitation clinics. All patients underwent a standardized history taking, physical examination, and ultrasonographic evaluation by the lead author as well as active and passive range of motion testing, a painful arc and impingement test, a resistance test, muscle strength testing, and checking for tenderness and swelling of the lesion in both shoulders. Among the patients who visited the outpatient clinic with symptoms of FS from March 2011 to February 2019, patients who met the following three criteria were included in this study: (1) presence of bilateral symptomatic primary FS with normal radiographic findings in both shoulders and >30-degree restriction in pROM in two or more planes of movement;¹⁶ (2) lack of response to at least 1 month of conservative treatment, including oral NSAIDs and/or flexibility exercise; and (3) treatment by ultrasonography-guided IACI in the more painful side. The exclusion criteria were (1) secondary FS caused by inflammatory or infectious arthritis, cerebrovascular accident, tumor, or fracture; (2) partial- or full-thickness rotator cuff tear on both physical and ultrasonographic examinations; (3) referred pain from the posterior neck suggestive of cervical radiculopathy; (4) prior surgery involving either the cervical or shoulder region; and (5) diabetes with an uncontrolled blood glucose level (fasting blood glucose level of >150 mg/dL or postprandial 2-hour blood glucose level of >200 mg/dL).

Ultrasonography-guided IACI and exercise education

The patients were allowed to choose the preferred shoulder for the injection considering the degree of pain. The lead author

administered the ultrasonography-guided IACIs. The patients were instructed to maintain a sitting position with their palms on their belly. After aseptic preparation, the lead author inserted a 23-gauge, 6-cm-long needle parallel to the transducer, beginning from the posterior side of the shoulder. The needle was advanced under real-time ultrasonography (Logiq P6; GE Healthcare, Buckinghamshire, UK) using 10-MHz linear transducers until the needle tip entered the glenohumeral joint. The lead author then injected 2 mL of 10-mg/mL triamcinolone acetonide mixed with 5 mL of 1% lidocaine.

After the injection, the patients were instructed on a home exercise program to increase their pROM, including stretching forward and bending down to a desk as well as performing a wall-climbing exercise, internal and external rotation with a bar, and posterior shoulder stretching.¹⁷ We explained to the patients that no oral medications were needed because their symptoms might adequately improve with IACI. No oral medications (NSAIDs, analgesics, or opioids) were prescribed after the injection except when the patient specifically requested medications. Patients prescribed oral medications were excluded from the study.

Outcome measures

The numeric rating scale (NRS) score and pROM were compared pre- and post-injection. All outcome measures were evaluated by the lead author. The NRS score, which was the primary outcome measure, was used to assess shoulder pain. The NRS is a self-reporting scale ranging from 0 to 10 that assesses the intensity of global shoulder pain. pROM was measured in degrees using a goniometer for abduction, forward flexion, and external rotation. External rotation was measured at 90 degrees of shoulder abduction and

90 degrees of elbow flexion. Hyperextension and internal rotation were measured as the length (cm) from the spinous process of the seventh cervical vertebra to the tip of the thumb in the standing position.¹⁸ This method has high intrarater reliability¹⁹ and is relevant to activities of daily living, such as dressing, bathing, and toileting.²⁰

Subgroup analysis

A subgroup analysis was performed by dividing the patients into those with and without diabetes.

Statistical analysis

All statistical analyses were performed with R version 3.5.3 (www.r-project.org). The paired t-test was used to compare the pre- and post-injection changes in the NRS score and pROM in the injected and non-injected shoulders. The Wilcoxon signed-rank test rather than the paired t-test was conducted if the Shapiro–Wilk test result was significant. The independent t-test was used to compare the changes in outcome measures between the injected and non-injected shoulders. Statistical significance was set at $P < 0.05$.

Results

The electronic medical records of 226 patients with bilateral shoulder pain were reviewed. Six patients were excluded because of insufficient data. Another 55 patients were excluded because at least one shoulder was diagnosed with a disease other than FS (rotator cuff disorder in 24 patients, osteoarthritis in 12, myofascial pain syndrome in 9, labrum injury in 6, and rheumatic arthritis in 4). Therefore, 165 patients (69 men, 96 women) with bilateral FS were included in this study. Table 1 shows the patients' general characteristics. Their mean age was 54.0 ± 8.0 years (range, 38–77 years). The mean symptom duration

Table 1. Baseline characteristics of patients (all, N = 165; non-diabetic, n = 145; diabetic, n = 20).

Characteristic	Value
Age, years	
All	54.0 ± 8.0 (38–77)
Non-diabetic	54.2 ± 8.1 (38–77)
Diabetic	52.5 ± 6.5 (40–64)
Sex, men : women	
All	69 (41.8) : 96 (58.2)
Non-diabetic	63 (43.4) : 82 (56.6)
Diabetic	6 (30.0) : 14 (70.0)
Duration of symptom, months	
All	6.5 ± 2.8 (3–12)
Non-diabetic	6.5 ± 2.3 (3–12)
Diabetic	6.4 ± 1.8 (3–9)
Follow-up after injection, weeks	
All	6.7 ± 0.8 (6–8)
Non-diabetic	6.7 ± 0.8 (6–8)
Diabetic	6.7 ± 0.7 (6–8)

Data are presented as mean ± standard deviation (range) or n (%).

was 6.5 ± 2.8 months (range, 3–12 months). Twenty patients had diabetes and 145 did not. In our clinic's outpatient protocol, patients are asked to visit the clinic again for follow-up after 6 weeks. Only patients who returned to the clinic within 6 to 8 weeks were enrolled in the study. Therefore, mean follow-up duration after injection was 6.7 ± 0.8 weeks. No patients developed serious complications such as infection or bleeding.

Table 2 shows the changes in the outcome measures after IACI. There was a statistically significant improvement in the NRS score and pROM values, including abduction, external rotation, flexion, hyperextension, and internal rotation after IACI in the injected shoulder ($P < 0.001$ for all). Interestingly, there was also a statistically significant improvement in the NRS score and pROM values of the non-injected shoulder (flexion, $P = 0.013$; all other parameters, $P < 0.001$). The independent t-test also showed a significant improvement in the outcome measures of the

Table 2. Changes in outcome measures after intra-articular corticosteroid injection.

	Before injection	After injection	<i>P</i> *	Δ	<i>p</i> †
Numeric rating scale score					
Injected shoulder	6.3 ± 1.3	2.3 ± 1.3	<0.001	-4.0	<0.001
Non-injected shoulder	4.4 ± 0.6	2.4 ± 1.2	<0.001	-2.0	
Abduction, degrees					
Injected shoulder	78.0 ± 26.4	106.6 ± 35.0	<0.001	28.8	<0.001
Non-injected shoulder	103.1 ± 28.7	118.7 ± 30.9	<0.001	15.6	
External rotation, degrees					
Injected shoulder	27.4 ± 12.8	40.5 ± 15.2	<0.001	13.1	<0.001
Non-injected shoulder	39.8 ± 14.7	48.0 ± 16.0	<0.001	8.2	
Flexion, degrees					
Injected shoulder	129.3 ± 20.5	139.1 ± 21.7	<0.001	9.8	<0.001
Non-injected shoulder	141.0 ± 19.0	144.3 ± 21.2	0.013	3.3	
Hyperextension and internal rotation, cm					
Injected shoulder	45.3 ± 11.4	36.6 ± 11.5	<0.001	-8.7	<0.001
Non-injected shoulder	33.1 ± 9.1	30.6 ± 9.3	<0.001	-2.5	

Data are presented as mean ± standard deviation.

*Comparison of outcome measures before and after injection within the same-side shoulder.

ΔChange in outcome measures between before and after injection.

†Comparison of changes in outcome measures between the injected and non-injected shoulders.

injected shoulder ($P < 0.001$ for all). These results indicate that the improvement of all outcome measures was greater in the injected than non-injected shoulder.

A subgroup analysis was performed by dividing the patients into those without diabetes ($n = 145$) and those with diabetes ($n = 20$). According to the paired *t*-test, patients without diabetes showed improvement in all outcome measures of both the injected and non-injected shoulders after IACI ($P < 0.05$). However, in patients with diabetes, all outcome measures of the injected shoulder improved, whereas in the non-injected shoulder, improvement was seen only in the NRS score and abduction (Table 3). According to the independent *t*-test for comparison of changes in outcome measures between the injected and non-injected shoulder, there was a statistically significant difference between the injected and non-injected shoulder in all outcome measures in patients without diabetes ($P < 0.05$), meaning that the improvement of all outcome measures was greater in the

injected than non-injected shoulder. However, in patients with diabetes, there was a significant improvement in the injected shoulder only in the NRS score, hyperextension, and internal rotation.

Discussion

To the best of our knowledge, this is the first study to monitor the prognosis of bilateral FS after a unilateral injection. In this retrospective study, we administered ultrasonography-guided IACI to the shoulder with more severe pain in 165 patients with bilateral symptomatic primary FS who complained of pain and pROM limitation in both shoulders. We then investigated the changes in the NRS score and pROM values throughout an average 6.7-week follow-up. After the injection, the NRS scores and all pROM values significantly improved not only in the injected shoulder but also in the non-injected shoulder.

In one study involving 30 patients with rheumatoid arthritis and bilateral synovitis

Table 3. Subgroup analysis (non-diabetic, n = 145; diabetic, n = 20) of outcome measures after intra-articular corticosteroid injection in patients with and without diabetes.

	Before injection		After injection		P*		Δ		P†
	Injected shoulder	Non-injected shoulder	Injected shoulder	Non-injected shoulder	Injected shoulder	Non-injected shoulder	Injected shoulder	Non-injected shoulder	
Numeric rating scale score									
Non-diabetic	6.3 ± 1.3	4.4 ± 0.6	2.4 ± 1.4	2.5 ± 1.2	<0.001	<0.001	-4.0	-2.0	<0.001
Diabetic	6.4 ± 1.2	4.3 ± 0.5	1.9 ± 1.0	2.0 ± 0.7	<0.001	<0.001	-4.6	-2.3	<0.001
Abduction, degrees									
Non-diabetic	78.2 ± 25.5	104.2 ± 23.4	107.9 ± 34.8	120.4 ± 30.2	<0.001	<0.001	29.8	16.2	<0.001
Diabetic	75.3 ± 25.3	95.0 ± 23.0	97.0 ± 17.8	106.3 ± 19.5	<0.001	0.004	21.8	11.3	0.070
External rotation, degrees									
Non-diabetic	27.7 ± 13.4	39.8 ± 15.5	41.2 ± 15.3	48.6 ± 16.4	<0.001	<0.001	13.6	8.8	0.001
Diabetic	25.6 ± 11.1	39.8 ± 12.7	35.3 ± 10.9	44.0 ± 11.9	<0.001	0.062	9.7	4.2	0.054
Flexion, degrees									
Non-diabetic	130.0 ± 19.7	141.2 ± 18.6	139.9 ± 20.6	144.4 ± 20.0	<0.001	0.012	10.0	3.2	<0.001
Diabetic	124.5 ± 23.9	139.7 ± 20.9	132.9 ± 26.3	143.5 ± 21.0	0.038	0.126	8.4	3.8	0.308
Hyperextension and internal rotation, cm									
Non-diabetic	44.6 ± 11.1	32.8 ± 9.3	36.1 ± 11.3	30.1 ± 9.5	<0.001	<0.001	-8.5	-2.7	<0.001
Diabetic	50.6 ± 10.6	35.4 ± 7.5	40.0 ± 8.6	34.3 ± 7.7	<0.001	0.333	-10.6	-1.0	<0.001

Data are presented as mean ± standard deviation.

*Comparison of outcome measures before and after injection within the same-side shoulder.

Δ Changes in outcome measures between before and after injection.

†Comparison of changes in outcome measures between the injected and non-injected shoulders.

of the knees, IACI of 20 mg triamcinolone hexacetonide administered to the unilateral knee also resulted in improvement in the non-injected knee.²¹ In another study of 20 patients with rheumatoid arthritis, IACI of 4 mg dexamethasone tert-butylacetate (9 patients) or 80 mg methylprednisolone acetate (11 patients) injected into the knee joint resulted in improved hand grip in 7 patients.²² IACI has local effects in the injected joint as well as systemic effects in remote joints.²³ These studies show the possibility of a systemic effect of IACI. We speculate that the significant improvement in the NRS score and pROM in the non-injected shoulder in the present study could be attributed to the systemic action of the corticosteroid injected in one shoulder after absorption into the synovium of the glenohumeral joint, leading to inflammation reduction in the non-injected shoulder. In shoulder pathologies such as FS or rotator cuff disease, intra-articular or periarticular corticosteroid injection is a method of choice among physicians because it rapidly reduces inflammation around the lesion in comparison with oral administration of corticosteroids and particularly acts locally, resulting in less severe systemic adverse effects.^{24,25} In contrast to the expectation that a corticosteroid injection is locally acting, the corticosteroid is rapidly absorbed into the synovium after injection and thereafter induces systemic effects.^{26,27} Moreover, several studies showed no significant difference in the improvement of shoulder pain between systemic corticosteroid injection and local corticosteroid injection; this occurred because the corticosteroid exerts its effect systemically rather than locally. Valtonen²⁸ reported that single gluteal and subacromial corticosteroid (betamethasone) injections significantly and equally improved supraspinatus tendonitis compared with placebo. In a randomized double-blind study that compared subacromial injection of corticosteroids

(local group) and gluteal injection of corticosteroids (systemic group) in patients with rotator cuff disease after 6 weeks, there was no significant difference in the primary outcome measures (the Shoulder Pain and Disability Index score) between the groups.²⁹ In other words, the two studies suggested that the effect of corticosteroids on the reduction of shoulder pain should be attributed to a systemic effect rather than a local effect based on the results in the two groups. However, the findings of our study differ from those of previous studies. Specifically, we observed greater improvement in all outcome measures in the injected than non-injected shoulder. This means that the improvement of outcomes by local corticosteroid injection is greater than that produced by the systemic effect of the corticosteroid.

When IACI is considered for bilateral FS, administration of the injection in both shoulders would result in a high dose of corticosteroid, thus increasing the risk of adverse events due to the systemic effects of corticosteroid. Alternatively, a lower dose of a unilateral injection can be administered to each shoulder; however, this may result in a weaker inflammation reduction effect or a higher total injection dose compared with unilateral injection. Additionally, multiple injections may be inconvenient for patients. As mentioned earlier, simultaneous bilateral injections at twice the usual dose may increase the risk of systemic complications. In contrast, if half the usual dose for unilateral FS is administered in each shoulder, the anti-inflammatory effect of the corticosteroid may be insufficient. The dose of triamcinolone for FS treatment is diverse, ranging from 10 to 80 mg;³⁰⁻³⁵ however, a dose of 20 to 40 mg is most common.³¹ We considered an injected dose of 20 mg to be the "usual dose" and one that is sufficient to produce a favorable response to FS treatment.³¹

Although a previous study showed no difference between 20 and 40 mg of triamcinolone in the treatment of unilateral FS,³¹ there is a likely increase in the systemic effect (via an increase in absorption by the synovium) of a larger unilateral corticosteroid dose on pain reduction in the non-injected shoulder of patients with bilateral FS. Thus, further studies should focus on the difference in the effect of corticosteroid injections using a series of doses with consideration of the degree of pain in both shoulders, body weight, and presence of diabetes.

The natural history of FS can generally be divided into three stages^{4,36}: the freezing, frozen, and thawing stages. The first (freezing) stage is characterized by gradual pain and loss of motion lasting up to 9 months. During the second (frozen) stage, which lasts from 4 to 12 months, pain decreases but stiffness persists and continues to affect patients' ability to perform activities of daily living. The thawing stage is a period of recovery characterized by progressive improvement in pROM that can take 12 to 42 months. Because the purpose of IACI is to reduce pain caused by capsular inflammation, many authors assert that IACI is effective in the freezing or early frozen stages with moderate to severe pain.^{1,6} We included patients with a pain duration of up to 12 months, which is considered long enough to include patients in the freezing to frozen stages.

The result of the subgroup analysis indicated that the effect of IACI was weaker in the patients with than without diabetes. It is widely accepted that the treatment of FS is more difficult in patients with than without diabetes, and patients with diabetes show a more diminished response to treatment.^{37–}

⁴⁰ Diabetic patients commonly have more limitations of pROM than non-diabetic patients.⁴¹ High blood glucose levels cause excessive glycosylation.⁴² In diabetic FS, a structural change in the joint capsule as a

result of more rapid collagen glycosylation and cross-linking of collagen might be related to the worse prognosis, resulting in more severe shoulder pain, reduced mobility, and a poorer functional outcome.^{11,43–45} When applying our study results to diabetic patients, it should be noted that the effect of IACI on both the injected and non-injected shoulder may be less pronounced than that in non-diabetic patients.

Our study had several limitations. First, it was a retrospective study conducted in a single institution. Second, the average follow-up interval was 6.7 weeks from the application of IACI. We assumed that a follow-up of 6.7 weeks would be sufficient because the purpose of our study was to investigate the effect of IACI based on systematic reviews suggesting that corticosteroid injection has a short-term benefit for shoulder pain.^{7,46} However, previous studies, in which the prognosis of FS was monitored after one session of IACI, revealed that the improvement in pain and pROM lasted for 6 to 12 weeks and that 26 weeks of follow-up showed an extra effect of the injection.^{3,31,47} Therefore, follow-up of more than 6 weeks is required to determine the full effect of IACI. Third, although all the patients were instructed to carry out flexibility exercise programs at home, we did not check the patients' compliance individually, and exercise could cause a significant confounding effect. Fourth, shoulder-specific functional scales that reflect the gains in activities of daily living should have been investigated; however, we did not include these assessments. Fifth, we diagnosed FS in 226 patients with bilateral shoulder pain through physical examination, shoulder X-rays, and ultrasonography. However, because laboratory examinations, electromyography, and cervical and shoulder magnetic resonance imaging were not performed, potential comorbidities of autoimmune diseases (e.g., rheumatoid arthritis, polymyalgia

rheumatica), myopathy, and cervical radiculopathy could not be excluded. Moreover, in practice, it is not easy to differentiate idiopathic FS and rotator cuff stiffness without a cuff tear on ultrasonography. Although we tried to exclude patients with pain due to rotator cuff stiffness through physical examination and ultrasonographic evaluation, they may have been included in the study. Furthermore, although FS may occur in the bilateral shoulders, simultaneous onset on both sides is not common, and the duration of symptoms often differs between the two sides. We should have checked the duration of symptoms separately for each shoulder to exclude systemic diseases.

In conclusion, this retrospective study demonstrated that unilateral IACI for bilateral FS improved the outcome of the non-injected shoulder as well as the injected shoulder. Therefore, we suggest that for patients with bilateral FS, physicians should monitor the prognosis of the non-injected shoulder after a unilateral injection rather than perform simultaneous bilateral IACI to both shoulders. In future, a prospective study will be required to monitor the difference in the dosage duration effects of IACI.

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Authors' contributions

MK and SHY contributed to the design of the study. MK, KYK, YGH, and SHM performed the experiments and analyzed the data. MK drafted the manuscript and was the principal author of the paper. MK, KYK, SHM, and KYJ interpreted the results and wrote the manuscript. All authors contributed to manuscript revision and approved the final version. SHY was responsible for the conceptualization and supervision of the study.

Data availability statement

Data are available upon reasonable request.


Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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ORCID iD

Seung-Hyun Yoon  <https://orcid.org/0000-0003-1787-7282>

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