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Intra-articular injection, subacromial injection, and hydrodilatation for primary frozen shoulder: a randomized clinical trial

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Background: The aim of this prospective randomized study was to compare the efficacy of 3 injection methods, intra-articular injection, subacromial injection, and hydrodilatation (HD), in the treatment of primary frozen shoulder.
Methods: Patients with primary frozen shoulder were randomized to undergo intra-articular injection (n = 29), subacromial injection (n = 29), or HD (n = 28). Evaluations using a visual analog scale for pain, Simple Shoulder Test, Constant score, and passive range of shoulder motion were completed before treatment and 1 month, 3 months, and 6 months after treatment.
Results: Among the 3 injection methods for primary frozen shoulder, HD resulted in a greater range of motion in forward flexion and external rotation, a lower visual analog scale score for pain after 1 month, and better outcomes for all functional scores after 1 month and 3 months of follow-up. However, there were no significant differences in any clinical outcomes among the 3 groups in the final follow-up at 6 months.
Conclusions: Although HD yielded more rapid improvement, the 3 injection methods for primary frozen shoulder resulted in similar clinical improvement in the final follow-up at 6 months.
Level of evidence: Level I; Randomized Controlled Trial; Treatment Study

Keywords: Primary frozen shoulder; stiff shoulder; injection method; intra-articular injection; subacromial injection; hydrodilatation

Frozen shoulder (adhesive capsulitis) is a common disease that restricts passive and active range of motion (ROM) in the glenohumeral (GH) joint. The concept was initially developed by Codman and Neviaser.[12] Frozen shoulder accounts for approximately 2% to 5% of all cases of shoulder pain.[3,6,28] Frozen shoulder consists of 3 sequential phases or stages: inflammatory, freezing, and thawing. The condition may persist for 1 to 3 years, and it can be self-limited.[17] Unfortunately,

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most patients with frozen shoulder reportedly do not regain full ROM irrespective of the treatment modality employed.[10,27] Moreover, despite the availability of various treatments for frozen shoulder, an optimal treatment has not yet been established.[21] The primary treatment methods for frozen shoulder include medication[5] and physical rehabilitation.[18,20] However, if these fail, several injection methods, such as intra-articular injection (IAI), subacromial injection (SAI), or injection with hydrodilatation (HD), may be employed effectively[1,4,7,13,26,33] before consideration of more aggressive treatments, such as manipulation under anesthesia[11,14] or surgical release.[2,15]

IAI can decrease pain and thereby help improve ROM of the GH joint in patients with frozen shoulder, but it is technically more difficult to perform than SAI.[7] SAI is relatively easy to perform, and it does not require radiologic guidance. HD, or arthrographic distention of the shoulder joint, induces capsular rupture by introducing a fluid into the GH joint, resulting in increased shoulder joint motion. It was introduced as an injection treatment modality for frozen shoulder by Andren and Lundberg.[1] It is known to be relatively safe and cost-effective, and it can elicit a rapid and satisfactory outcome.[13] However, the evidence is insufficient to conclude which injection method is superior among IAI, SAI, and HD for the treatment of frozen shoulder.

Thus, we designed a prospective, randomized study to compare treatment outcomes using IAI, SAI, and HD in patients with primary frozen shoulder. The aim of this study was to identify which treatment modality is superior in terms of the visual analog scale (VAS) score for pain as well as functional outcomes, including ROM. We hypothesized that HD would provide superior clinical improvement compared with IAI and SAI.

Methods

Sample size calculation and patient allocation

This was a randomized, prospective, controlled study. We conducted this study in accordance with the principles of the Declaration of Helsinki. The reporting of data from this trial complies with the Consolidated Standards of Reporting Trials (CONSORT) statement.

Sample sizes were calculated to detect a 20% difference among the groups in the VAS score for pain on the basis of the pilot study and previous literature.[30] A sample size of 30 patients in each group was required for a power of 90% at a type I error level of .05, with an expected dropout rate of 20%.

A total of 164 consecutive patients with primary frozen shoulder were prospectively enrolled between June 2012 and September 2013. Patients were diagnosed with frozen shoulder if they had limitations of both active and passive shoulder motion and more severe pain at night than during the day and if findings on radiography of their shoulders were normal.[24] Patients were eligible for the study if their shoulder symptoms (pain or discomfort) were present for 6 months to 1 year, if they had a VAS score of <7 of 10 for pain[4] (thus probably in the freezing stage rather than in the inflammatory stage[10]), and if they remained unresponsive to conservative treatment consisting of medication or physical therapy for at least 6 months. All patients had limited active and passive ROM in at least 2 directions (abduction and forward flexion <100°, external rotation <20°, or internal rotation <L3).[31] All patients underwent simple radiography and sonography. Patients with secondary causes of frozen shoulder such as rotator cuff tear (n = 32) or calcific tendinitis (n = 9), those with GH arthritis (n = 4), those with a history of surgery on the same shoulder (n = 1), those who received a steroid injection within 6 months before enrollment (n = 23), and those who refused to participate in the study (n = 5) were excluded. No patient had a history of previous shoulder trauma, manipulation under anesthesia, or suprascapular nerve injection, and none had a worker's compensation status. The remaining 90 patients were randomly allocated into the IAI, SAI, or HD group (30 patients in each group). Patients were randomized using a computer-generated block randomization sequence (www.randomizer.org) by an independent researcher, and the group assignment was disclosed to the physician at the time of intended treatment.

Among these 90 patients, 4 (1 from the IAI group, 1 from the SAI group, and 2 from the HD group) were lost to follow-up. Accordingly, 86 patients (26 men, 60 women; mean age, 54.5 years [standard deviation, 8.3]) with primary frozen shoulder (idiopathic adhesive capsulitis) were ultimately enrolled in this study (Fig. 1). The demographic and clinical data did not differ among the groups (all $P < .05$), and these data are summarized in Table I. During the study period, all patients underwent conventional conservative treatment, including medication and a home-based physical therapy exercise program. The medication included a nonsteroidal anti-inflammatory drug and muscle relaxant, which were administered for approximately 4 weeks. For physical therapy, active assisted ROM exercise, including stick exercise, was performed for approximately 10 weeks, depending on the recovery of ROM. We employed a 4-quadrant stretching program (passive flexion, horizontal adduction, internal rotation behind the back with the unaffected arm, and external rotation at the side using a stick) to stretch the entire capsule at least 3 times a day (10-15 minutes per session). When ROM had recovered, muscle-strengthening exercise was performed on the scapular stabilizers (such as the lower trapezius and serratus anterior muscles) and rotator cuff using a resistance band at least 3 times a day (10-15 minutes per session).

Clinical variables

All data were prospectively collected by a clinical researcher (A.-S.C.) who was blinded to the study design. The patients' demographic data and other characteristics, including age, sex, symptom duration, dominant shoulder, underlying