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ORIGINAL ARTICLE

Clinical efficacy of hydrodistention with joint manipulation under interscalene block compared with intra-articular corticosteroid injection for frozen shoulder: a prospective randomized controlled study

Sang Won Mun, MD, Chang Hee Baek, MD*

Department of Orthopaedic Surgery, Yeosu Baek Hospital, Yeosu-si, Republic of Korea

Background: Hydrodistention is known to be an effective method of treatment for frozen shoulder. However, hydrodistention is accompanied by severe pain during the procedure. An interscalene block may relieve the severe pain associated with the procedure of hydrodistention. This study compared the clinical efficacy of hydrodistention with joint manipulation under an interscalene block with that of intra-articular corticosteroid injection.

Methods: This prospective randomized controlled study included 121 patients presenting with frozen shoulder. Patients were randomized into 2 groups; those in group A (60 patients) were treated by hydrodistention with joint manipulation under an interscalene block, and those in group B (61 patients) were managed with intra-articular corticosteroid injection. Pain intensity and patient satisfaction were assessed by the visual analog scale. Functional outcomes were assessed by the Constant score and the range of shoulder motion.

Results: Group A demonstrated better patient satisfaction and earlier restoration of range of motion than group B at 6 weeks ($P \leq .001$). At 12 weeks, the pain score was lower and the Constant score was better in group A than in group B. However, at 12 months after treatment, pain score ($P = .717$), patient satisfaction ($P = .832$), range of motion ($P > .05$), and Constant score ($P = .480$) were similar in the 2 groups.

Conclusion: Hydrodistention combined with joint manipulation under an interscalene block provided earlier pain relief and restoration of shoulder range of motion and function compared with single intra-articular corticosteroid injection in patients with primary frozen shoulder.

Level of evidence: Level II; Randomized Controlled Trial; Treatment Study

Keywords: Hydrodistention; interscalene block; manipulation; corticosteroid injection; frozen shoulder; adhesive capsulitis

This study was approved by the Public Institutional Review Board by Ministry of Health and Welfare (study number 2015-0133-002, approval number P01-201602-11-001), and all participants provided written consent before participating in the study.

*Reprint requests: Chang Hee Baek, MD, Department of Orthopaedic Surgery, Yeosu Baek Hospital, 50, Yeoseo 1-ro, Yeosu-si, Jeollanam-do, Republic of Korea.

E-mail address: Ch100c@chol.com (C.H. Baek).

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Conservative treatment methods such as oral nonsteroidal anti-inflammatory drugs (NSAIDs), physical therapy, and intra-articular corticosteroid injection are the preferred modes of treatment for frozen shoulder.[2,3,12,16,18] Among the conservative treatment methods, corticosteroid injection is widely preferred as it has better short-term outcomes compared with the other treatment options.[20,25,27]

Shin and Lee[25] reported rapid improvement in pain, better satisfaction, and earlier range of motion recovery following local corticosteroid injection compared with NSAIDs. Another study also demonstrated faster pain relief with corticosteroid injection than with physical therapy.[27] However, Bulgen et al[6] demonstrated that the effect of local corticosteroid injection was short-lasting, whereas its long-term clinical outcomes were similar to those of physical therapy. Local corticosteroid injection also did not have any effect on the natural course of frozen shoulder, and there are arguments against the effect of local corticosteroid injection alone.[13]

Andren and Lundberg[1] first described hydrodistention in 1965 to treat adherent glenohumeral joint by expansion of the joint capsule. This technique achieved joint mobility by rupturing the glenohumeral joint capsule. Early recovery of pain and range of shoulder motion was observed following hydrodistention combined with corticosteroid injection in 48 patients with frozen shoulder.[4] Hydrodistention was also associated with superior range of motion recovery than a single corticosteroid injection, as observed on short-term follow-up.[23] However, the use of hydrodistention as a primary treatment modality for frozen shoulder is restricted because of the severe pain accompanying the procedure.[4,7,11,26]

This randomized, controlled, prospective clinical study compared the clinical outcomes of hydrodistention combined with joint manipulation under interscalene block with those of intra-articular corticosteroid injection for the treatment of frozen shoulder. This study hypothesized that hydrodistention under interscalene block was superior to intra-articular corticosteroid injection for the treatment of patients with frozen shoulder.

Materials and methods

This is a prospective randomized controlled study comparing the clinical efficacy of hydrodistention with joint manipulation under interscalene block and intra-articular corticosteroid injection for frozen shoulder. A total of 140 patients diagnosed with frozen shoulder between March 2012 and December 2013 were included in this prospective randomized controlled trial.

The inclusion criteria were as follows: continuous pain in the shoulder joint not responding to medication and physical therapy; limitation of active and passive shoulder motion in at least 2 directions; forward flexion limited to 120° or less; <50% range of external rotation and internal rotation compared with the opposite shoulder; absence of abnormal findings on radiologic examination and ultrasonography; symptom duration for a minimum of 3 months; and availability for follow-up for a minimum of 1 year after treatment. Patients with abnormal findings on radiologic examination, secondary frozen shoulder, and history of surgery for rotator cuff tears, shoulder dislocations, or fractures were excluded.

Randomization

A power analysis was performed using the visual analog scale (VAS) score for pain as the primary outcome. The sample size was calculated on the basis of the results of a pilot study. With settings of 5% significance level ($\alpha = .05$), 95% test power ($\beta = .05$), and 0.25 effect size, the required number of patients was calculated as 124, in 2 groups of 62 each. Assuming a 15% dropout rate, the final sample size was set at 70 patients in each group.

Of 140 participants, 2 were excluded owing to the concomitant presence of rotator cuff tears on the affected side, and 2 refused to participate in the study. Finally, a total of 136 patients with primary frozen shoulder were included in the study. Patients were divided into 2 groups by computerized random allocation by an independent researcher. Group A (hydrodistention with shoulder manipulation under interscalene block) had 67 patients and group B (a single corticosteroid injection into the glenohumeral joint) had 69 patients. Fifteen patients were lost to follow-up. Thus, the number of patients included for analysis was 60 in group A and 61 in group B (Fig. 1).

Treatment techniques

A single interventional radiologist performed hydrodistention following ultrasound-guided interscalene block in group A. The interscalene nerve branch was identified on ultrasonography, and 20 mL of 1% lidocaine was injected by using a 23-gauge needle. After 50 minutes, the nerve block was confirmed by the patient's inability to lift the ipsilateral arm and the lack of sensation over the arm. Then, the tip of a 23-gauge needle was positioned inside the glenohumeral joint by use of an ultrasonography-guided posterior approach. After the position of the needle was confirmed, a mixture of 1 mL triamcinolone (40 mg), 10 mL 1% lidocaine, and 30 mL saline solution was injected to expand the capsule.[4,26] The outflow of injection solution to the subscapular bursa was confirmed on ultrasonography. A single orthopedic specialist performed a gentle manipulation of the range of joint motion, to the extent possible, following hydrodistention.

For intra-articular corticosteroid injection, the tip of a 23-gauge needle was positioned inside the glenohumeral joint under ultrasonographic guidance by the same orthopedic specialist. A mixture of 1 mL triamcinolone (40 mg) and 5 mL 1% lidocaine was injected.

All participants in the 2 groups were administered oral NSAIDs for 2 weeks after the procedure. Patients in group A had frozen shoulder rehabilitation exercise guided by a professional physical therapist twice a week, starting immediately after the procedure and extending for 1 month after treatment. Subsequently, patients continued the rehabilitation exercises at home, based on a self-exercise program booklet provided to them. On the other hand, patients in group B waited for 2 weeks until the pain declined before starting the same rehabilitation exercise program.[25]

Assessments

The degree of pain and function were evaluated by a physician assistant (who was not involved in this study) before treatment