ACRM
AMERICAN CONGRESS OF REHABILITATION MEDICINE

Archives of Physical Medicine and Rehabilitation

journal homepage: www.archives-pmr.org

Archives of Physical Medicine and Rehabilitation 2013;94:264-70

ORIGINAL ARTICLE

Treatment Effects of Ultrasound-Guided Capsular Distension With Hyaluronic Acid in Adhesive Capsulitis of the Shoulder

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Abstract

Objective: To investigate the efficacy of ultrasound-guided intra-articular (IA) hyaluronic acid injection with capsular distension compared with steroid injection alone in patients with adhesive capsulitis of the shoulder by assessing pain relief, functional improvements, and range of motion at 2 and 6 weeks after final injections.

Design: Prospective randomized controlled trial.

Setting: University hospital.

Participants: Patients (N = 100) with adhesive capsulitis of shoulder.

Interventions: Subjects were randomly assigned to 2 groups: 45 patients in group A were treated with 0.5% lidocaine plus triamcinolone 40mg IA injection and 45 patients in group B were treated with 0.5% lidocaine plus hyaluronic acid 20mg and capsular distension. All injections were performed every 2 weeks for a total of 3 times.

Main Outcome Measures: Treatment effects were assessed using the Shoulder Pain and Disability Index (SPADI), Verbal Numeric Scale (VNS), and passive range of motion (ROM) of the shoulder (flexion, abduction, external rotation) before injections and at 2 and 6 weeks after the last injections.

Results: SPADI, VNS, and passive ROM were improved at 2 and 6 weeks in both groups. The statistical differences were not observed in SPADI and VNS between groups ($P<.05$), and shoulder passive external rotation was more improved in group B than in group A ($P<.05$).

Conclusions: Capsular distension with IA hyaluronic acid injection was shown to be a treatment method as effective as the steroid injection alone in pain relief and functional improvement; additionally, it was more effective in passive external rotation improvement than steroid injection alone.

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Adhesive capsulitis is one of the most common afflictions of the shoulder joint, with as much as 2% of the general population suffering from the affliction.[1,2] It is characterized by spontaneous onset of pain and progressive stiffness of the glenohumeral joint, accompanied by significant disability.[3,4] Ombregt[5] reported that it is possible to recover to normative function using home-based therapies, moist heat, simple analgesics, and reassurance, whereas others have emphasized the importance of continuous treatment to prevent persistent pain, limitations of shoulder joint motion, and adverse effect on the activities of daily living, including sleep disturbance. In patients with severe pain or limitations in range of motion (ROM), physiotherapy, exercise, and oral medication are recommended. These can include intra-articular (IA) injections, capsular distension, manipulation after anesthesia, and surgery.[5-7] However, manipulation after anesthesia and surgery are limited by poor accessibility; thus, the IA injections of drugs, such as corticosteroids, and capsular distension after IA injection are more commonly used. On the other hand, IA injection of corticosteroid may cause complications, such as fat atrophy, skin color changes, and weakness of ligaments or tendons caused by leakage of drugs into surrounding soft tissues.[8]

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0003-9993/13/$36 - see front matter © 2013 by the American Congress of Rehabilitation Medicine
http://dx.doi.org/10.1016/j.apmr.2012.10.002

It has recently been accepted that sodium hyaluronate injections are a safe and effective treatment method, especially for knee osteoarthritis.[8] A 1-week interval is regarded as an ideal injection period, and the therapeutic effect generally begins after the second week injection.[9-11]

There are a few clinical studies of hyaluronic acid's positive effect for the treatment of shoulder disease, including adhesive capsulitis.[12-14] Arthrographic distension of the glenohumeral joint capsule leading to capsular rupture was first described as a potential treatment for painful stiff shoulder by Andren and Lundberg.[15] Gam et al[16] reported a significant improvement in ROM and analgesic use in the group treated with distension and steroids compared with steroids alone, but they reported no difference in pain.

It is important that injections be made correctly, because incorrect placement can cause discomfort and significantly reduce treatment efficacy.[8] The requirement for correct placement of a needle into IA space for capsular distension also enhances the importance of injection precision.[15] Shoulder IA injection is usually performed with a fluoroscopy-guided anterior approach. However, deployment of ionizing radiation is a disadvantage. Interventions guided with an ultrasound (US) are found to be valuable, because the needle can be followed real-time during the procedure and no radiation is involved.[17]

Although IA injection of sodium hyaluronate is a treatment option in the management of adhesive capsulitis of the shoulder, its effect remains controversial. We hypothesized that a more accurate injection using US guidance and IA injection concurrent with capsular distension would result in positive effects in passive shoulder ROM and general clinical outcome measures and pain scales. To our knowledge, no study has yet compared the treatment efficacies of US-guided capsular distension with hyaluronic acid to steroid IA injections. The purpose of this study was to compare the treatment efficacies of IA steroid injection and capsular distension plus IA hyaluronic acid injection using US guidance in patients with adhesive capsulitis of the shoulder.

Methods

After obtaining approval from the institutional review board and registering for a clinical trial, 100 patients complaining of shoulder pain and shoulder ROM limitations were enrolled into this prospective, randomized, blinded study. The study took place from June 1, 2010 to May 31, 2011.

Diagnoses of adhesive capsulitis were performed by 2 physiatrists based on the patients' medical history, physical examination, radiologic evaluation, and musculoskeletal ultrasonographic findings. Patients were assessed for eligibility according to the following criteria: a disease duration of 3 to 9 months and a reduction in passive ROM in at least 2 of the following: forward flexion, abduction, or external rotation (ER) of the affected shoulder of $>30^\circ$ compared with the contralateral side.[18]

The exclusion criteria applied were a US finding of a full thickness tear, massive tear of the rotator cuff, hospitalization over the previous 6 months because of a shoulder joint-related incident, severe psychiatric problem, aged under 19 or over 70 years, shoulder joint plain radiographic finding of significant glenohumeral joint arthritis, systematic rheumatic disease, neurologic disorder, such as cervical radiculopathy or stroke, bleeding tendency, the taking of anticoagulants, diabetes mellitus (associated with steroid side effects), history of side effects to local anesthetics, presence or suspicion of infection, or the taking of any drug (other than acetaminophen) during treatment or follow-up that might affect outcome results.[9,18,19]

List of abbreviations:

ER	external rotation
IA	intra-articular
ROM	range of motion
SPADI	Shoulder Pain and Disability Index
US	ultrasound
VNS	Verbal Numeric Scale

Randomization of participants

After documenting general patient characteristics, participants were randomly assigned into 1 of 2 groups using a computer-generated randomization table. Patients in group A were administered a mixture of 0.5% lidocaine (4mL) plus triamcinolone (40mg/mL; 1mL); group B was administered 0.5% lidocaine (18mL) for capsular distension with high molecular weight sodium hyaluronate (10mg/mL; 2mL). All patients received 3 US-guided IA injections every 2 weeks (a total of 3 injections), and they were blinded to injection methods.

US-guided IA injection techniques

All US-guided IA injections were performed by 2 physiatrists with over 7 years of relevant experience using an Accuvix XQ[a] and a linear 6-12MHz probe. Patients were asked to sit on a chair without a backrest and lower the unaffected arm. The elbow joint was then flexed at approximately 90° and the forearm pronated (fig 1). The US probe was placed just below the spine of the scapular at the level of the glenohumeral joint. We used US-guided IA injections using the needle (23G, 7.5cm) by the posterior approach method (see fig 1).[20]

All injections were made after ensuring that the needle tip was properly located in the IA space by the US. The accuracy of injection into the IA space was checked during the procedure, and joint capsule distension was checked in appropriate cases. The patients were asked to limit shoulder motion for at least 10 minutes postinjection to allow localization of injected drugs in the articular capsule.

Participants in both groups received a simple exercise program comprising a pendulum exercise and scapular setting (isometric scapular retraction). Additionally, acetaminophen with no anti-inflammatory effect or ice massage was permitted if the patients complained of pain at the injection site.

Assessments of treatment effects

The same blinded outcome assessor evaluated all patients at baseline and at 2 and 6 weeks after the final injections. Data collected at baseline included both personal and clinical characteristics, including duration, symptom severity, and previous treatment.

Primary

The primary outcome was the Shoulder Pain and Disability Index (SPADI), a self-administered assessment tool that measures pain and disability related to shoulder disease.[21] It consists of 5 pain and 8 disability items that are measured on a visual analog scale. Pain and disability subscales were calculated as the mean of the corresponding items on a 0 to 100 scale; the highest score