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Effect of sodium hyaluronate treatment on rotator cuff lesions without complete tears: A randomized, double-blind, placebo-controlled study

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Hypothesis: A randomized, double-blind, placebo-controlled study of sodium hyaluronate (ARTZ Dispo) treatment was performed in 51 patients with rotator cuff lesions without complete tears. We hypothesized that ARTZ Dispo would render better results than the placebo.

Materials and methods: Twenty-five patients (ARTZ Dispo group) had injections of 25 mg/wk of sodium hyaluronate into the subacromial bursa for 5 consecutive weeks. Twenty-six patients (placebo group) were given 2.5 mL of normal saline solution with the same injection protocol as the ARTZ Dispo group. No significant difference in age, height, weight, gender, vocation, involved shoulder, duration of symptoms, baseline Constant score, or visual analog scale (VAS) score existed between the 2 groups.

Results: The 2 groups did not significantly differ with regard to Constant scores, VAS scores, or global improvement assessments 1 week after injections. The ARTZ Dispo group had a better Constant score ($P = .0095$) and VAS score ($P = .0018$) than the placebo group 6 weeks after treatment. Patients in the placebo group were given 5 sodium hyaluronate injections, rather than placebo, after disclosure of the blind list, if they wished. Forty-one patients who underwent hyaluronate injection exhibited a significantly improved Constant score, from 64.0 ± 11.7 at baseline to 88.9 ± 10.4 ($P < .0001$), and a significantly improved VAS score, from 6.4 ± 1.3 to 1.5 ± 1.6 ($P < .0001$), at a mean follow-up of 33.1 months. No significant adverse effect was noted.

Conclusions: Subacromial injections of sodium hyaluronate are effective in treating rotator cuff lesions without complete tears.

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Rotator cuff pathology is a common orthopaedic disorder and major cause of shoulder pain.[1,14,24] Treatments for rotator cuff lesions without complete tears are mainly conservative.[1] Subacromial injection of anesthetics or corticosteroids is often used to treat patients with persistent symptoms after rehabilitation and use of nonsteroidal anti-inflammatory drugs (NSAIDs). Although prolonged NSAID treatment and intra-articular injections of steroids are known to alleviate inflammation and painful shoulder, serious gastrointestinal disorders after the intake of prolonged NSAID administration[20,33] and arthropathic changes and increased tendon fragility caused by prolonged use of steroid injections[12,28,34] are important concerns. Treatment with sodium hyaluronate (SH) is emerging as an alternative intra-articular regimen for osteoarthritic knee joints.[9,40] Clinical studies have reported the efficacy of hyaluronate injection in treating shoulder pain.[16,35,41] In a randomized study, SH was found to be effective for patients with rotator cuff tears.[29] Blaine et al[3] found that SH is effective and well tolerated for the treatment of osteoarthritis and persistent shoulder pain that is refractory to other standard nonoperative interventions. However, few data are available to show the efficacy and safety of SH in treating rotator cuff lesions without complete tearing. The purpose of this study was to examine the effect of subacromial injection of SH on rotator cuff lesions without complete tears using a randomized, double-blind, placebo-controlled model.

Materials and methods

This study was approved by the Institutional Review Board of Chang Gung Memorial Hospital, Kaohsiung, Taiwan (CGMH IRB No. 92-418), and all patients gave informed consent for participation. The randomized, double-blind, placebo-controlled clinical study involved 65 patients who had rotator cuff lesions without complete tearing. Of these patients, 11 did not pass the screening protocol because they chose an operation (5), refused treatment (5), or were withdrawn because of violation of the selection criteria at entry (1). The inclusion criteria were (1) patients who had pain around the shoulder, a positive impingement sign, and a positive imaging diagnosis of rotator cuff pathology without a complete tear; (2) patients who did not respond to conservative therapy or rehabilitation for at least 3 months; and (3) patients aged between 35 and 80 years, who signed the informed consent form. We excluded patients who had rheumatic diseases, glenohumeral osteoarthritis, full-thickness cuff tears, fractures, infections, or tumors; those who had hypersensitivity to hyaluronate; those who had participated in any other study within 3 months; those who had received a subacromial injection within 3 weeks; and those who were pregnant or wanted to become pregnant. The sample size was calculated under the expectation of an improvement in the Constant score of 10 points, with an SD of 12 points in each group, and a power value of 0.8. For this study design, the minimal number of patients required in each group was 23, by use of an independent-samples t test.

The intent-to-treat population of 54 patients (27 ARTZ Dispo [Seikagaku, Tokyo, Japan] and 27 placebo) was a fully randomized group of patients who had a baseline value (Constant score and VAS before treatment) and at least 1 valid post-baseline measurement. The imaging diagnosis of a rotator cuff lesion was made by a musculoskeletal radiologist[15] who had considerable experience in interpreting both magnetic resonance imaging (MRI) and sonographic results for shoulders. On the sonogram, hypoechoic thickening of the rotator cuff indicated tendinosis. Focal thinning or focal hypoechoic areas of discontinuity in the rotator cuff were suggestive of partial-thickness tearing.[39] In cases of the hypoechoic gap extending through the entire rotator cuff, tendon retraction, or the absence of a visible rotator cuff, a full-thickness tear was assumed to be present. On MRI, rotator cuff tendinosis was characterized by increased intratendinous signal intensity on T2-weighted images without tendon disruption. Partial-thickness tearing was characterized by the presence of focal hyperintense fluid or a fluid-like signal intensity that extended into the tendon on the T2-weighted images.[4] A full-thickness tear was diagnosed by the extension of hyperintense fluid or fluid-like signal intensity through the entire thickness of the interrupted rotator cuff tendon on T2-weighted images. MRI studies were performed in 15 patients, and sonography was performed in 39 patients. Of the patients, 18 were diagnosed as having articular-side tears, 5 as having bursal-side tears, and 31 as having tendinopathy of the rotator cuff. Only 1 patient did not complete the entire course of treatment, because she was unable to be absent from work 1 day weekly for consecutive 5 weeks. Two patients who completed the study were excluded from the analysis because of complex underlying diseases that might have confounded the efficacy of the study drug. One had undergone previous shoulder surgery, and one had combined osteonecrosis of the humeral head. The remaining 51 patients comprised 25 patients in the ARTZ Dispo group and 26 in the placebo group (Figure 1). Before treatment, gender, age, height, weight, vocation, affected side, and disease duration were determined. The test drug was ARTZ Dispo, 25 mg of SH (Seikagaku). The placebo was 0.9% normal saline solution, at 2.5 mL/syringe, in the same package as the test drug.

The subacromial injection was performed through a posterolateral approach, about 1.5 fingerbreadths below the posterolateral corner of the acromion, without local anesthesia. The needle was introduced along the superior border of the rotator cuff into the subacromial space. If the tip of the needle hit the undersurface of acromion, the needle was withdrawn slightly so that the material

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