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Clinical evaluation of sodium hyaluronate in the treatment of patients with supraspinatus tendinosis under echographic guide: Experimental study of periarticular injections

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Abstract

Purpose: The purpose of this study was to examine the effect of periarticular injection of hyaluronate into shoulders with supraspinatus tendinosis under echographic guide.

Methods and materials: The subjects were 56 patients with clinical, echographic and magnetic resonance diagnosis of supraspinatus tendinosis. They were divided in two groups by random sampling; 28 patients were assigned in SH group (sodium hyaluronate) and 28 patients in SC group (sodium chloride).

The test drug was 20 mg sodium hyaluronate (2 ml, Hyalgan®, Fidia SpA, Abano T., P.M. 500–700.000, 20 mg/2 ml).

Results: Preliminary results showed that sodium hyaluronate presented the highest efficacy in the improvement of clinical symptoms and recovery of functional status in patients with supraspinatus tendinosis in fact the mean V.A.S. score (Visual Analogue Scale) at 1 month after the end of the infiltrative cycle was 8.0 in the SC group vs. 2.8 in SH group and these numerical data were substantially unchanged also after 3 and 4 months.

Conclusion: Hyaluronate injection under echographic guide should be use not only as a lubricant but also to prevent articular cartilage degeneration and cover and protect the articular cartilage; indeed sodium hyaluronate can decrease inflammatory joint process.

Keywords: Tendons disease; Ultrasound; Shoulder; Sodium hyaluronate; Periarticular injection

1. Introduction

Shoulder ultrasonography (US) is an accurate non-invasive method used to assess the rotator cuff tendon [1,2] and may be incorporated into the in-office physical examination of patients at risk for rotator cuff problems. The low cost, convenience, and lack of risk make US an excellent imaging tool for evaluating the supraspinatus, infraspinatus, biceps, subscapularis and teres minor tendons [1–3]. Moreover, US contributes in assessing not only the morphological aspects (ecostructure and thickness of tendons) but also the functional aspects (dynamic study). Although the plain X-ray is considered the reference technique, US is useful in measuring the subacromial space and in ascertaining the conditions of the subacromial bursa and the biceps muscle tendon. US is an indispensable guide for the performance of therapeutic procedures such as periarticular injection.

Tendinosis is considered a chronic degeneration of tendon fibers at cellular level caused by micro-tear in the connective tissue and around the tendon. In such cases corticosteroids are frequently injected locally to alleviate pain in patients with rotator cuff tears because of the good analgesic effects of this procedure. However, occurrence of local degradation of tissues has been reported as a result of repeated corticosteroid injection, as well as tendon tearing [4–6] and corticosteroid arthropathy [7,8].

Some authors [9,10] have injected corticosteroids as a conservative treatment for rotator cuff tear of the shoulder because of its excellent analgesic effect, despite the risk of complications [9–11]. Recently, hyaluronate has been injected intra-articularly to treat osteoarthritis [9,10].

It has been reported that hyaluronate serves not only as a lubricant [12] but also as a protective covering for the articular

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cartilage [13], suppressing the inflammatory process in a joint, and preventing articular cartilage degeneration [14,15].

Clinically, intra-articular injection of hyaluronate has proved to be efficient in relieving pain in patients with osteoarthritis of the knee [16–18] and in periarthritis of the shoulder [19–21].

The purpose of this study was to assess the effect of periarticular injection of hyaluronate into shoulders with supraspinatus tendinosis under echographic guidance.

2. Material and methods

This is an open-labeled prospective study. The subjects were 56 patients (30 men and 26 women, 31–71 years of age) with clinical, echographic and magnetic resonance diagnosis of supraspinatus tendinosis unresponsive to physical and medical therapy. Patients with symptoms resulting from cervical lesions and those who had undergone intra or periarticular injection of any drugs were excluded. The patients were divided into two groups by random sampling; 28 patients were assigned, for the entire length of the study, to SH group (sodium hyaluronate) and 28 patients to SC group (sodium chloride).

Before starting the study, sex, age distribution, affected side, cause of onset, occupation, disease duration, prior treatment, range of motion (R.O.M), clinical evaluation of the rotator cuff and, in particular, of the sopraspinatus were determined. Entity of pain was also evaluated with the use of the V.A.S. (Visual Analogue Scale); the degree of discomfort was assessed using a 10-point rating scale, with 1 denoting no pain at all and 10 denoting severe pain [22]. Mean pre-treatment score was 8.7 in the SH group and 8.5 in the SC group.

In the first phase morphology of the degenerated tendon was evaluated according to the echographic static scannings and subsequently in real time thanks to the execution of dynamic scannings (Fig. 1A and B). On echographic diagnosis of tendinosis all subjects underwent MR shoulder examination a few days later to confirm the diagnosis.

After determining tendon thickness and its superior limitant, the needle was introduced as far as the surface of superior limitant. Afterward at this point the solution was injected in real time and loosening of the tendon from the superior limitant was observed (Fig. 2A–C). Subsequently the needle was extracted. The same echograph (ALOKA 5500 with 7 and 10 MHz) was used for each injection.

The test drug was 20 mg sodium hyaluronate (2 ml, Hyalgan®, Fidia SpA, Abano T., P.M. 500–700.000, 20 mg/2 ml). Patients allocated to the SH group were treated with 20 mg of SH, together with 2 ml of 1% lidocaine and 2 ml of 0.9% sodium chloride solution. Patients allocated to the SC group were treated with 4 ml of 0.9% sodium chloride solution, together with 2 ml of 1% lidocaine.

Following the first injection, both groups were injected with test drugs once a week for 4 weeks for a total of five injections. During this period, Oxaprozin (Walix®, Fidia Spa, Abano T.) 600 mg × 2/d was prescribed for 3 days after each injection because of its analgesic proprieties. The same physical therapy, which included heat and cuff-strengthening exercise, was carried out on all patients. All patients underwent echographic post-treatment controls at 3, 6 and 12 months from the last injection.

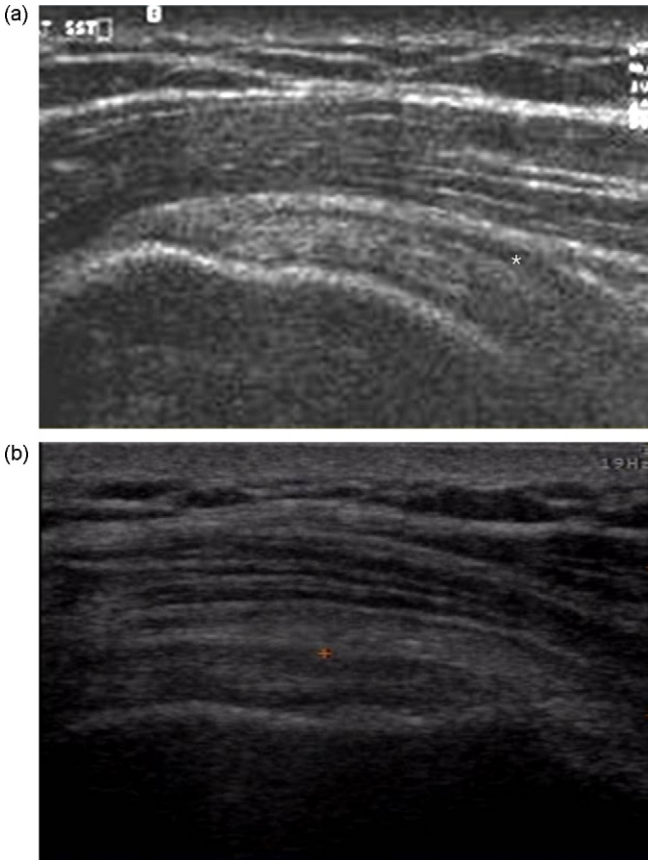

Fig. 1. Physiological tendon's morphology: tendons fibrillar aspect and its superior limitants in two different static scannings. (A) Sagittal scannings. (B) Tranverse scannings.

3. Results

Four weeks, after the final periarticular injection, patients were asked to answer questions concerning improvement of symptoms and satisfaction with treatment. Range of motion was determined. In the SH group, shoulder disability resolved in six patients after three injections of sodium hyaluronate, in 13 patients after four injections and in six patients after five injections. Only 3 out of 28 patients who were injected with sodium hyaluronate showed an insufficient improvement of symptoms.

Regarding pain, in the SH group the mean post-treatment V.A.S. score was 2.8 at 4 weeks after the infiltrative cycle and 3.1 after 12 weeks. Only three patients of SH group were dissatisfied.

In the SC group all patients were dissatisfied and none of them reported a sufficient improvement of their symptoms after five injections of lidocaine and sodium chloride solution. All patients of SC group reported a slight improvement of symptoms only for 24–36 h after each injection; mean post-treatment V.A.S. score was 8.0 at 4 weeks after the end of the infiltrative cycle and 8.1 after 12 weeks.

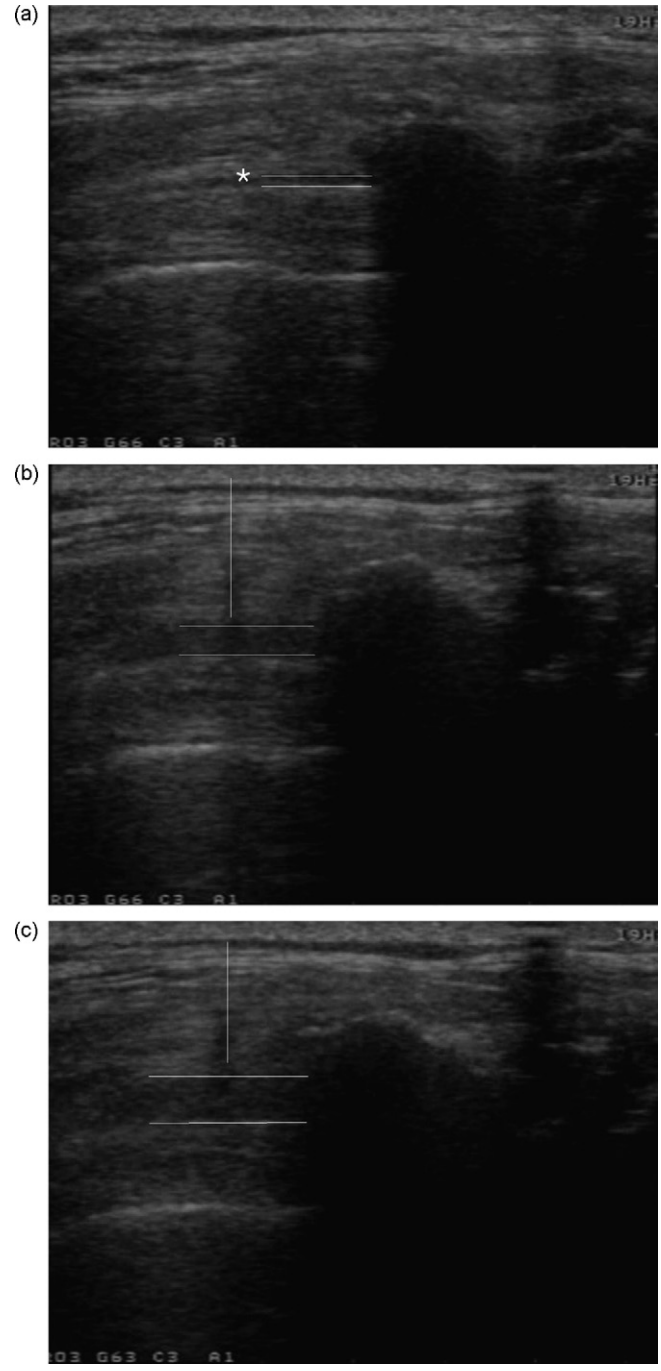

Fig. 2. Second degree tendinosis: starting disomogeneous fibrosis with disomogenity of the superior limitant. (A) Underlined tendon's thickness and its superior limitant (*) the needle (vertical line) is introduced up to reach, (B) the superior limitant (double line) that is not overcome. The solution is injected observing in real time (B and C) as the same unstick the adhesion of tendon's sliding surface (the superior limitant increase in volume).

In SH group, no statistical difference was found between satisfied and dissatisfied patients regarding age, dominant side, cause of cuff tear, disease duration and range of motion before treatment except for occupation. In fact the rate of patients who engaged in manual labour was significantly higher in the dissatisfied patients than of those satisfied; as a matter of fact three dissatisfied patients were bricklayers. SH group patients were followed up again 24 weeks and 1 year after end of treatment and 19 of them remained satisfied. The mean post-treatment V.A.S. score at 6 months was 3.8 and 5.1 after 1 year.

In SH group a significant difference was observed between the pre-treatment and post-treatment score after 4 weeks, 3, 6 months and 1 year after the end of the infiltrative cycle. Range of motion results were unchanged.

No significant difference was found in the SC group between the V.A.S. pre- and post-treatment scores. A significant difference was found between the V.A.S. post-treatment score of SH and SC group month and 3 months after end of treatments. Range of motion results were unchanged.

There were no complications such as infections and no aggravations of symptoms compared with the pre-treatment state in either group.

Regarding echographic controls at 3, 6 and 12 months from the last injection no substantial differences in aspects regarding tendon structure were found between the two groups nor between beginning and end of treatment.

4. Discussion and conclusions

Technological developments have modified the quality of echographic images, which can be superimposed without the use of dedicate spool or a particular acquisition parameter. Furthermore, ultrasound is a fast and economical methodology with which to effectuate a dynamic study.

We believe that US should be the first exam where sovraspinatus tendinosis is suspected. Our results showed that sodium hyaluronate presents a higher efficacy in the improvement of clinical symptoms and recovery of functional status in patients with supraspinatus tendinosis than the control group. In this study we observed a clear improvement of the algic syntomatology and disability after periarticular injections of sodium hyaluronte at a mean follow-up of 9 months.

The use of ultrasonography permits accurate injection of the drug at the level of the superior limitant of the sopraspinatus tendon, where it serves not only as an anti-inflammatory, but also has a lubricating mechanical effect which loosens the adhesion on the sliding surface of the tendon, which can be considered as the origin of the algic symptomatology in the degenerative processes of rotator cuff tendons. These good results should not only be correlated with the biological and physical–chemical properties of sodium hialuronate but also we can consider fundamental its mechanical effects during the drug injection at level of the superior limitant of tendon.

Despite the limited number of patients (56) and short follow-up (12 months), we obtained encouraging results which reinforce our belief that this technique is a valid tool in the conservative treatment of sopraspinatus tendinosis, resolving symptoms and disability in mild tendinosis and postponing surgical treatment in patients with medium-severe sopraspinatus tendinosis.

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