Clinical efficacy of ultrasound-guided hyaluronic acid injections in patients with supraspinatus tendon tear

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Abstract

Objective

To evaluate the clinical efficacy of ultrasound (US)-guided soft tissue adapted biocompatible hyaluronic acid (STABHA) injections in the subacromial-subdeltoid bursa of patients with supraspinatus tendon tear.

Methods

In this prospective study, patients with a symptomatic partial-thickness or small full-thickness supraspinatus tendon tear, diagnosed by US, were consecutively enrolled. Patients received one injection at baseline visit and one after 2 weeks and performed rehabilitation therapy. Clinical assessment was performed with visual analogue scale (VAS) for pain, Constant-Murley Scale (CMS), and patient reported efficacy on a 0–4 Likert scale. Patients were examined at baseline, at week 2 and at week 12.

Results

Thirty patients were enrolled. Sixteen (53.3%) and 19 (63.3%) patients reported significant improvement at week 12 in pain and function, respectively. Reduction in VAS pain was statistically significant both at week 2 and at week 12 in comparison with baseline visit (mean-difference -27.2 and -36.8, respectively, $p<0.01$). The same trend was observed with CMS (mean-difference 17.7 and 19.8, respectively, $p<0.01$). At week 12, 18 patients (60.0%) reported a subjective improvement. At week 12, in non-responders (n=14) US detected inflammatory changes and/or progression of tendon tear in 7 (50.0%) patients and no relevant changes in 7 (50.0%).

Conclusion

US-guided STABHA injections followed by rehabilitation therapy were found effective in improving both pain and shoulder function at the 12-week follow-up. In half of the non-responders, US allowed the detection of US findings responsible for treatment failure.

Key words

hyaluronic acid, ultrasonography, interventional ultrasonography, supraspinatus tendon tear

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Introduction

Rotator cuff pathology is the most common cause of shoulder pain and disability, and tendon tears account for more than half of the cases (1). Conservative approach is the first-line treatment of partial-thickness or small full-thickness tendon tears (2). Although partial-thickness tendon tears have been shown to frequently enlarge over time and often progress to full-thickness tears without treatment (3, 4), significant improvements in functional outcomes have been reported with non-surgical therapy having a successful rate ranging between 40% and 60% (2).

Several studies have documented that hyaluronic acid (HA) may be useful in the treatment of tendon pathology (5, 6). Moreover, there is *in-vitro* and *in-vivo* evidence that a shorter healing time is needed for tendon tears when treated with HA rather than with placebo (5). However, only few studies investigated the effect of ultrasound (US)-guided HA injection in patients with rotator cuff tears (6). The main aims of the present study were: to evaluate the clinical efficacy of US-guided Soft Tissue Adapted Biocompatible HA (STABHA™) injections at shoulder level in patients with supraspinatus tendon tear and to investigate the ability of US to identify the pathological findings responsible for treatment failure.

Material and methods

Study design

This was a prospective, non-randomised and non-controlled study involving consecutive patients with a symptomatic partial-thickness or small full-thickness supraspinatus tendon tear (maximum diameter <1 cm) diagnosed by US. Patients were enrolled in the outpatient clinic of the Rheumatology Unit "Carlo Urbani" Hospital, Polytechnic University of Marche (Jesi, Ancona, Italy).

Patients were considered eligible for US-guided HA injections if they were 18 years old or older, had persistent shoulder pain for at least 1 month and had US diagnosis of supraspinatus tendon tear. Exclusion criteria were: presence of other relevant pathological changes of the shoulder detected by US [*i.e.* rotator cuff tears other than supraspinatus tendon, rotator cuff calcific tendinopathy, moderate/severe biceps tenosynovitis, moderate/severe gleno-humeral synovitis and moderate/severe subacromial-subdeltoid (SAD) bursitis], previous surgery or relevant trauma at shoulder level, known hypersensitivity to HA, and a known diagnosis of the following rheumatic diseases: crystal-related arthropathies, inflammatory arthritis, fibromyalgia or symptomatic cervical spine disease. A 0–3 semiquantitative scoring system for synovial inflammation at shoulder level was adopted (0: no effusion, 1: mild effusion, 2: moderate effusion, 3: severe effusion) (7).

Patients with US inflammatory signs at shoulder level were not definitively excluded from the study. In patients with US inflammatory findings (*i.e.* moderate/severe tenosynovitis and/or moderate/severe gleno-humeral synovitis and/or moderate/severe SAD bursitis) and coexisting supraspinatus tendon tear, an US-guided steroid injection (methyl-prednisolone 20–40 mg) was performed. In the presence of inflammatory signs at two or more sites, the US-guided steroid injection was performed at the site considered most responsible for the reported painful symptoms. Eight weeks after the steroid injection, the patients were re-evaluated by US to check the fulfilment of inclusion and exclusion criteria.

The only rescue medication allowed during the study was oral paracetamol at a maximum dosage of 3 g/day, and the amount taken by each patient was recorded at the follow-up visits.

Patients were evaluated three times: before the first injection of HA (baseline visit, t0), 2 weeks after baseline visit (first follow-up visit, t1) and 12 weeks after baseline visit (second follow-up visit, t2).

During each visit, the following clinical data were recorded: visual analogue scale (VAS) for pain, Constant-Murley Scale (CMS) (8) and patient reported efficacy of HA injections on a 0–4 Likert scale. Clinical data were recorded by a rheumatologist (E.C.), not involved in the US examinations and US-guided injections.

The study was conducted in accordance with the Helsinki Declaration.

All the patients gave informed consent prior to enrolment.

Ultrasound examination

Patients were examined with a MyLab Class C US system (Esaote SpA, Genoa, Italy) using a 8-13 MHz linear transducer according to a standardised scanning protocol (9, 10). All the US examinations were carried out by an expert rheumatologist (E.F.) to detect US findings reported in the inclusion and exclusion criteria. US assessment was aimed at confirming the presence of a supraspinatus tendon tear and excluding the presence of other relevant pathological changes of the shoulder (*i.e.* rotator cuff tears other than supraspinatus tendon, moderate or severe biceps tenosynovitis, moderate or severe gleno-humeral synovitis and moderate or severe SAD bursitis). Supraspinatus tendon tear was defined as a hypoechoic or anechoic tendon defect with or without ancillary signs such as "cartilage interface" sign, "sagging peribursal fat" sign, cortical irregularity of the greater tuberosity and/or mild synovial inflammatory signs (SAD bursitis and/or biceps tenosynovitis and/or gleno-humeral joint effusion) (11, 12) (Fig. 1A-B). Particular attention was paid to avoid anisotropy-dependent artefacts in the diagnosis of tendon tears (12). Supraspinatus tendon defect can involve the entire thickness of the tendon (full-thickness tear) or it can be incomplete (partial-thickness tear) (12). Only small full-thickness tears (maximum diameter <1 cm) were included in the study. During follow-up visits US examination was carried out to identify any changes of supraspinatus tendon tear and to detect any inflammatory findings at long head of the biceps tendon, gleno-humeral joint and SAD bursa.

Ultrasound-guided injection

All the patients underwent two US-guided HA injections: at baseline visit and at first follow-up visit. US-guided injections were performed using a standardised protocol (13). Patient was seated with the arm held in neutral position, the elbow flexed at 90 degrees, and the forearm in a supinated position on the homolateral thigh. A rheumatologist (E.F.) with 22 years of experience injected all the shoulders using a free-hand and direct US-guided anterolateral in-plane approach (real-time visualisation of the needle tip during its progression from the skin to the target). A specific high molecular weight (1 million Daltons) HA preparation (12 mg/1.2 ml) (Tendovis™, MDT Int'l SA, Geneva, Switzerland) was injected into the SAD bursa. A 21-Gauge needle was used and its placement at target level together with HA spreading within the SAD bursa were confirmed by real-time US monitoring in all the procedures (Fig. 1C-D).

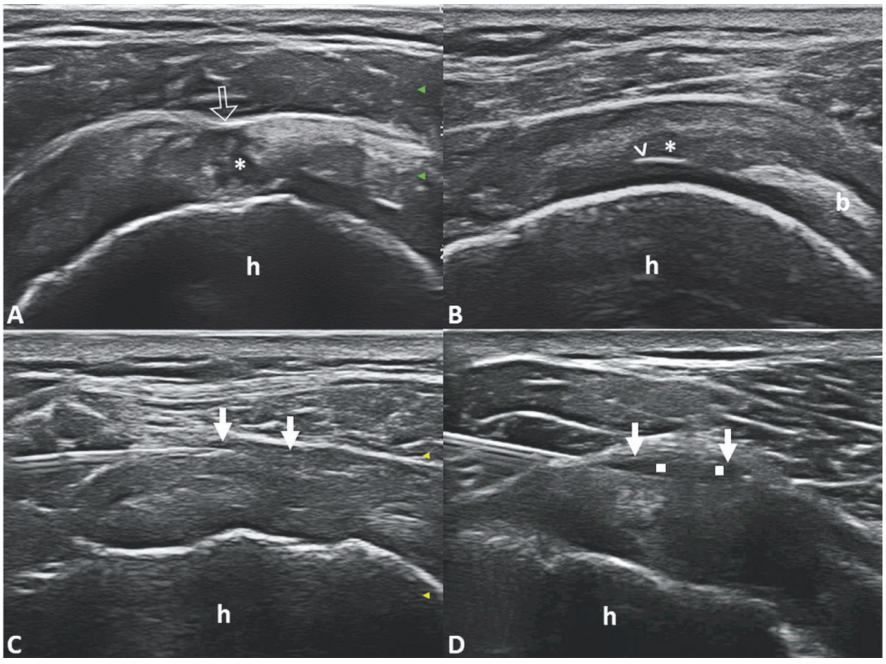

Fig. 1. A: Short-axis scan of the supraspinatus tendon revealing a small full-thickness tear (asterisk) extending from the bursal margin to the articular one. Note the presence of the "sagging of the peribursal fat" sign (empty arrow).
B: Short-axis scan of the supraspinatus tendon showing a partial-thickness tear (asterisk). Note the presence of the "cartilage interface" sign (arrowhead).
C-D: In-plane approach displaying the correct placement of the needle tip into the SAD bursa (C) and the spreading of the hyaluronic acid within the SAD bursa (D).
arrows: SAD bursa, **asterisks**: tendon tear, **b**: long head of the biceps tendon, **h**: humeral head, **squares**: hyaluronic acid.

Rehabilitation protocol

All the patients were instructed to maintain shoulder at rest after each HA injection for seven days without weight-bearing activities. Thereafter, a specific and progressive rehabilitation protocol was adopted (14): Codman's pendulum exercises and closed chain isometric strengthening exercises (alternative arm isometric wall push-up). Training was performed every other day with a progressive increase of the repetitions starting with 10 and reaching the maximum number of 30. Patients were informed to perform exercises without pain and to avoid increasing the number of repetitions in case of pain.

Outcome measurements

Primary outcome measure was the VAS pain. Secondary outcomes measures were CMS, patient reported efficacy on a 0–4 Likert scale, and the safety of STABHA. CMS is a 100-points scale divided into four subscales: pain (15 points), activities of daily living (20 points), strength (25 points) and range of motion: forward elevation, external rotation, abduction and internal rotation of the shoulder (40 points). The higher the score, the higher the quality of the function. The minimal important change in the CMS in patients with rotator cuff tears was an improvement of at least 15 points (15).

Clinical efficacy of HA injection was defined as an improvement in the VAS pain of at least 50% of the baseline value, in the CMS of at least 15 points and

as a value 3 or 4 in the 0–4 Likert scale. Of note, US findings were not used as outcome measures to assess STABHA injection therapy efficacy. US was performed to identify patients to be included in the study, to guide injections and to detect shoulder pathological conditions responsible for treatment failure.

Statistical analysis

Qualitative variables were expressed as absolute frequency and/or corresponding percentage, whereas quantitative variables as mean±standard deviation. Chi-Square test was used to compare qualitative variables and Mann-Whitney U-test to compare quantitative variables. Two tailed *p*-values less than 0.05 were considered significant. Statistical analysis was performed using SPSS (Statistical Package for the Social Sciences) software (v. 25.0 for Windows, Chicago, Illinois, USA).

Results

Thirty-two patients were enrolled in this study. Thirty (93.7%) completed the second follow-up visit. Two patients (6.3%) were excluded from the analysis of the results due to the use of non-steroidal anti-inflammatory drugs. In 8 patients (26.7%), a moderate/severe SAD bursitis was detected by US and, therefore, a US-guided steroid injection was performed prior to the inclusion. The main demographic and clinical data at the baseline visit were reported in Table I.

No significant difference of the daily dose of oral paracetamol was found between responders (1.5±0.7 g) and no responders (2.0±1.2 g) at baseline (p=0.43). Among responders, a non-significant reduction in the daily dose of oral paracetamol (1.5±0.7 g *vs*. 0.5±0.9 g) was observed between baseline and second follow-up visits (p=0.08).

The US examination revealed a partial-thickness tear in 25 patients (83.3%) and a small full-thickness tear in 5 (16.7%). US confirmed the correct placement of HA into the SAD bursa in all the procedures.

With reference to the primary objective of the study, a significant improvement in VAS pain was observed at both t1 (in 13 patients, 43.3%, p<0.01) and

Table I. Main demographic and clinical data of the patients.

Age (years, mean ± SD)	67.3 ± 13.1
Sex (female/male)	2/1
BMI (kg/m^2, mean ± SD)	25.9 ± 4.4
Tear in the dominant side (n)	21 (70.0%)
Pain duration (months, mean ± SD)	3.9 ± 4.5
Tear in subjects with chronic inflammatory arthritis (n)	13 (43.3%)
Tear in subjects without chronic inflammatory arthritis (n)	17 (56.7%)

BMI: body mass index, SD: standard deviation.

Table II. Pain and functional status at baseline and during follow-up visits.

	VAS pain	CMS
Baseline visit (t0)	62.4 ± 15.0	52.9 ± 15.2
First follow-up visit (t1)	35.1 ± 21.0	70.6 ± 14.7
Second follow-up visit (t2)	25.5 ± 20.3	72.6 ± 20.6
p-value (t0-t1)	<0.01	<0.01
p-value (t0-t2)	<0.01	<0.01
p-value (t1-t2)	0.65	1.0

CMS: Constant-Murley Scale, VAS: visual analogue scale.

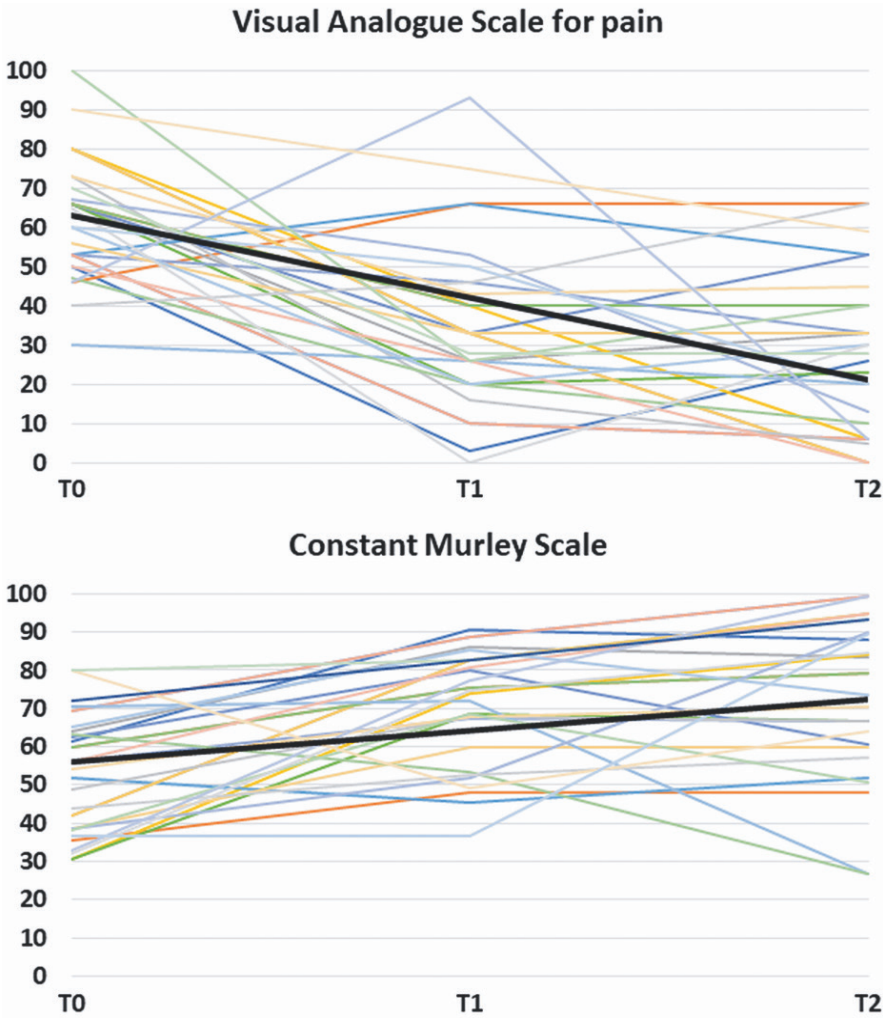

Fig. 2. Longitudinal changes of pain and functional status by subjects over the study period. Each line represents a patient, while the black solid line indicates the median value.

t2 (in 16 patients, 53.3%, $p<0.01$). In addition, a significant improvement of shoulder function measured with the CMS was found at both t1 (in 17 patients, 56.7%, $p<0.01$) and t2 (in 19 patients, 63.3%, $p<0.01$). Even if a further improvement was noted between t1 and t2, no significant difference was recorded for VAS pain or for CMS values.

According to patient reported efficacy, HA injection was effective in 16 (53.3%) patients at first follow-up visit and in 18 (60.0%) at second follow-up visit.

Table II and Figure 2 report the VAS pain and the CMS values at baseline and follow-up visits.

Despite the absence of statistical significance, according to patient reported efficacy on the VAS pain, the CMS and the Likert scale, the effectiveness of US-guided HA injections was higher in patients with partial-thickness tear (56.0%, 68.0% and 76.0%, respectively) than in patients with small full-thickness tear (40.0%, 40.0% and 40.0%, respectively).

Among the 14 patients without significant improvement in the VAS pain at the second follow-up visit, US examination showed inflammatory changes and/or progression of tendon tear in 7 patients (50.0%) [isolated moderate/severe SAD bursitis in 4 (28.6%), progression of tendon tear together with inflammatory findings (*i.e.* moderate/severe SAD bursitis) in 3 (21.4%)] and no relevant changes in 7 (50.0%). In 2 patients (14.3%) a small full-thickness tear progressed to complete tendon tear and in 1 patient (7.1%) a partial-thickness tear progressed to small-full thickness tear.

In the remaining 16 responders, no relevant US changes were observed at second follow-up visit.

Although not statistically significant, a positive correlation between the persistence of pain at second follow-up visit and the US progression of tendon tear (Phi=0.36, $p=0.09$) was found.

Finally, US-guided HA injection at shoulder level was well-tolerated and, with the exception of the three patients in whom a progression of tendon tear was observed, no adverse events were reported.

Discussion

HA injection has been shown to be an effective therapeutic option in the management of both acute and chronic tendinopathies, such as rotator cuff pathology, ankle sprains and elbow epicondylitis (14, 16, 17).

However, only very few studies investigated the efficacy of HA injection into the SAD bursa in the management of partial-thickness or small full-thickness rotator cuff tears (18-21).

Due to the exploratory nature of this study, we decided to not include randomisation and a placebo-control group. In fact, despite the protocol (two injections of STABHA two weeks apart) was already found effective in rotator cuff tendinopathy (14), it was never tested in rotator cuff tears.

Our study provides new insights in the management of rotator cuff tears. First, STABHA, a highly purified HA bioadapted for soft-tissue injection together with physical therapy were effective in both reducing pain and improving shoulder function at short (2 weeks) and medium (12 weeks) term. Second, this study provides limited but interesting evidence in favour of the US ability to identify the causes of treatment failure (22-26). In fact, during follow-up visits, US revealed inflammatory or structural abnormalities that could explain the treatment failure. Finally, although it was not an aim of the study, we noted a higher but not significant efficacy of this protocol in patients with partial-thickness tendon tears rather than in those with small full-thickness tendon tears.

In the 8 patients who received a steroid injection because of the coexistence of supraspinatus tendon tear and US inflammatory findings, and who were enrolled in the study 8 weeks after the steroid treatment because fulfilled inclusion and exclusion criteria, a possible bias could be related to the fact that the clinical data, especially the shoulder pain at baseline and first follow-up visits, could have been skewed by the resolution of the inflammation. However, no significant difference was found in terms of shoulder pain, shoulder function, patient's reported outcome and US inflammatory findings at the second follow-up visit (all p-values were >0.05) between the patients who received the steroid injection and those who did not receive it.

The results of the present study should be read taking into account that US examination influenced the patient selection and provided an imaging evidence of correct placement of HA into the SAD bursa. In fact, the use of US-guidance potentially offers significantly benefits over blind (landmark-guided) injections in adults with shoulder pain (27-29) and, recently, US-guided procedures around the shoulder have been strongly recommended by the European Society of Musculoskeletal Radiology (30).

The monocentric design, the absence of placebo-control group and of randomisation, the lack of a correlation between US and magnetic resonance imaging findings at both baseline and follow-up visits, the short observational period and the relatively low sample size are the main limitations of this pilot study.

In conclusion, two STABHA injections followed by physical therapy were found effective in improving both pain and shoulder function at 12 weeks follow-up visit. In a significant proportion of patients, clinical improvement was observed at first follow-up visit, 2 weeks after the first US-guided HA injection.

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