

A Randomized Comparative Study of Short Term Response to Blind Injection versus Sonographic-Guided Injection of Local Corticosteroids in Patients with Painful Shoulder

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ABSTRACT. Objective. Local corticosteroid injections, commonly accepted by rheumatologists to be effective treating painful shoulder, have shown controversial results. High frequency ultrasonography is an accurate and safe imaging modality for guiding musculoskeletal injections. We prospectively compared the short term response to randomized blind injection versus sonographic-guided injection of local corticosteroid in patients with painful shoulder.

Methods. We studied 41 consecutive patients with painful shoulder. Patients with previous trauma or chronic inflammatory arthritis were excluded. No patient had received previous physiotherapy or local steroid injection in the shoulder. Patients were randomized to receive either a blind subacromial injection of 20 mg triamcinolone (Group 1, $n = 20$) or a sonographic guided injection of 20 mg triamcinolone (Group 2, $n = 21$) by the same rheumatologist blinded to the clinical evaluation. In both groups we recorded shoulder abnormalities and the location of the steroid postinjection by ultrasound. Each patient was clinically assessed within 5 days before injection and 6 weeks after injection by another rheumatologist without knowledge of the injection technique performed. Clinical assessment included demographic and clinical data, a visual analog scale (VAS) for pain (0–100), the Shoulder Function Assessment (SFA) scale (0–70), and postinjection adverse effects. No patient received physical therapy during the followup period. Initially, demographic, clinical, and ultrasonographic findings in both groups showed no significant differences.

Results. Six weeks after injection, the VAS and the SFA score showed a significantly greater improvement in Group 2 compared with Group 1 (mean VAS score change 34.9 for Group 2 vs 7.1 for Group 1, $p < 0.001$; and mean SFA score change 15 for Group 2 vs 5.6 for Group 1, $p = 0.012$). One patient in Group 1 reported mild postinjection adverse effects.

Conclusion. We suggest that sonographic-guided corticosteroid injections should be indicated, at least, in patients with poor response to previous blind injection to ensure accurate medication placement in order to improve therapeutic effectiveness. (J Rheumatol 2004;31:308–14)

Key Indexing Terms:

ULTRASONOGRAPHY

SHOULDER

CORTICOSTEROID

SONOGRAPHIC-GUIDED INJECTION

Local injections of long-acting corticosteroids are widely performed in patients with painful shoulder, although their efficacy and effectiveness have been questioned^{1–7}. Perhaps these differences could be due to the accuracy of steroid placement⁸. High frequency ultrasonography (US) has been incorporated as an accurate bedside diagnostic technique in clinical rheumatology^{9,10}. It is a readily available, safe, and easy method for guiding musculoskeletal fluid aspiration,

infiltration, or biopsies^{11–17}. Real-time US enables correct needle placement, medication delivery, and correct postinjection steroid location.

To our knowledge, there are no studies that evaluated the effectiveness of sonographic-guided local corticosteroid injection in patients with periarticular shoulder disorders. We prospectively compared the short term response (6 weeks) to blind injection versus sonographic-guided injection of local corticosteroid in patients with painful shoulder.

MATERIALS AND METHODS

We studied 41 consecutive patients referred to our rheumatology department with a first flare of shoulder pain of periarticular etiology, at least one month of duration, without response to nonsteroidal antiinflammatory drugs (NSAID). There were 27 women and 14 men. Mean age was 52.4 years (range 24–76 yrs). Mean duration of symptoms was 10.2 months (range 1–70 mo).

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Submitted November 22, 2002; revision accepted July 15, 2003.

Periarticular disorders of the shoulder included impingement syndrome, rotator cuff lesions, subacromial-subdeltoid bursitis, and/or biceps tendon abnormalities. Patients with chronic inflammatory arthritis and previous trauma were excluded. Diagnosis of periarticular shoulder lesions was established by clinical history and examination by the same rheumatologist (FC), who performed appropriate shoulder maneuvers for evaluating periarticular and intraarticular involvement¹⁸. Plain radiographs were obtained for all patients to exclude fracture, glenohumeral osteoarthritis, characteristic findings of chronic inflammatory arthritis, bone tumors, osteonecrosis, and other bone conditions. Local injections of corticosteroid were indicated when shoulder pain had not improved after one month taking NSAID.

Patients who had received previous physiotherapy or local corticosteroid injections in the same shoulder were excluded. Patients who had been treated with local corticosteroid injections in any musculoskeletal location in 3 months prior to the study were also excluded. The study was approved by the hospital ethics committee, and informed consent was obtained from each patient.

Age, sex, duration of symptoms, shoulder involved, diurnal and nocturnal pain, and occupational demand on the shoulder were recorded initially from all patients by the same rheumatologist (FC). He evaluated active and passive range of shoulder motion (ROM) and performed a visual analog scale (VAS) for pain during the previous week, with scores ranging from 0 (no pain) to 100 mm (maximum pain), and the Shoulder Function Assessment (SFA) scale¹⁹ in each patient. Occupational demands on the shoulder were considered low if the patient rarely performed overhead activities, moderate if he or she performed frequent overhead activities, and high if vigorous overhead activities were performed. The active and passive ROM of the shoulder was subjectively assessed for flexion, abduction, and internal and external rotation. A goniometer was used for measuring active abduction. The degree of impairment of the other movements was not measured. The SFA¹⁹ is a simple, reliable, and accurate outcome measure of shoulder function. It has 2 items concerning pain on motion and at rest; 4 items for shoulder function in activities of daily living; and 3 objective ROM measures, the active abduction measure (1 point per 10° of abduction, score: 0–18) and 2 semiquantitative measures of combined movements [score: 0 (maximum pain, maximum shoulder function impairment, and maximum motion loss) to 70 points (no pain, normal shoulder function and motion)].

Patients were randomized by a random-number sequence to receive either a blind subacromial injection of 20 mg triamcinolone (Group 1, 20 patients) or a sonographic-guided injection of 20 mg triamcinolone (Group 2, 21 patients) by another independent rheumatologist experienced in US (EN), without knowledge of the clinical evaluation, within 5 days after the initial clinical evaluation. Prior to injection, all patients underwent a sonographic examination of their shoulders. Sonographic findings and postinjection steroid placement were recorded in both groups of patients.

A 21-gauge needle was used. For blind injection, a standard technique was performed. The patient's skin was sterilized with alcohol. Access to the subacromial space was achieved with a lateral approach, inserting the needle under the anterolateral aspect of the acromion process, passing it through the deltoid muscle, and directing it medially and slightly anterior to the subacromial-subdeltoid (SA-SD) bursa, with care taken to avoid injection directly into the tendons of the rotator cuff. Immediately after blind injection, an US examination was performed to search for steroid deposit as hyperechoic foci or lines, with or without acoustic shadowing.

Under US guidance, the injections were performed as follows. The transducer and the patient's skin were sterilized with alcohol. Sterile gel was applied to the probe. The transducer was held in one hand and the syringe with corticosteroid in the other hand (Figure 1). The needle was placed under the probe and its route was visualized in real-time by US, as a hyperreflective line, often with reverberation, from the skin to the target. Injection was directed into SA-SD bursa or biceps tendon sheath when increased fluid was detected. When there was effusion in both the SA-SD

bursa and the biceps tendon sheath, injection was directed into the SA-SD bursa due to its easier approach. Peri and intralesional injection was performed when rotator cuff calcifications were found. Perilesional injection directed into the SA-SD bursa was performed when tendon lesions without increased fluid were detected, avoiding direct injection into the rotator cuff tendons.

In Group 2, corticosteroid injection was sonographically guided to the SA-SD bursa in 14 patients (Figure 2), to biceps tendon sheath in 3 patients, and to rotator cuff calcification in 4 patients (Figure 3). Postinjection steroid location was confirmed by US in all patients (Figure 4).

No patient received physical therapy during the followup period. However, patients with loss of shoulder ROM were instructed to start a home physical therapy program consisting of pendulum exercises and slow shoulder abduction. No restriction was placed on the patient's ability to work or to use their shoulder as tolerated, or on NSAID intake.

Each patient was reviewed 6 weeks postinjection by the same rheumatologist who performed the initial clinical evaluation (FC), blinded to the injection technique and the sonographic findings. The assessment included presence of nocturnal pain, intake of NSAID, active and passive ROM, a VAS for pain (0–100 mm) during the previous week, the SFA scale, and any immediate or later adverse effects of the injection.

US evaluation. All patients were examined with commercial, real-time equipment (Sonoline, Prima, Siemens, Seattle, WA, USA) using a 7.5 MHz linear phased array transducer according to a standardized scanning method^{20,21}. Transverse and longitudinal planes from the biceps tendon groove, rotator cuff, and SA-SD bursa, and transverse planes from the posterior glenohumeral recess and glenoid labrum were scanned. In all patients comparable images of the opposite shoulder were obtained to compare US findings. US examination of the opposite side is routinely performed to facilitate detection of subtle abnormalities.

The normal sonographic anatomy of the shoulder and diagnostic criteria for abnormalities have been widely described²⁰. The biceps tendon groove, the subscapularis tendon, and the acromio-clavicular joint are examined with the patient seated with the arm held in neutral position, the elbow flexed 90°, and the forearm in a supinated position on the thigh. On the anterior aspect of the shoulder, the long head of biceps tendon is imaged as a fibrillar hyperechoic structure into the humeral groove, surrounded by a hypoechoic halo 1–2 mm thick of fluid within the synovial sheath. Medial to the biceps tendon, the hyperechoic subscapularis tendon is identified inserting on the lesser tuberosity with some fibers continuing across the bicipital groove to form the transverse humeral ligament. A more extensive and dynamic view of the subscapularis tendon is achieved while the shoulder is moved into external rotation. In the acromio-clavicular joint, small amounts of intraarticular fluid can be detected, and in younger patients the hyperechoic intraarticular fibrocartilage can be seen.

Next, the transducer is moved laterally to scan the rotator cuff. The supraspinatus and infraspinatus tendons are examined with the shoulder in hyperextension and internal rotation to expose the supraspinatus from underneath the acromion. This latter position allows a maximal length of tendons to be visualized²². These tendons appear as a hyperechoic homogeneous fibrillar layer, of convex shape on transverse images and curved-triangular shape on longitudinal views, deep to the deltoid muscle covering the humeral head. The SA-SD bursa is imaged as a hypoechoic line 1–2 mm thick, with a variable amount of peribursal echogenic fat, between the deltoid muscle and the supraspinatus and infraspinatus tendons. The humeral articular cartilage is seen as a thin hypoechoic layer between the supraspinatus and infraspinatus tendons and the humeral head.

After examination of the lateral rotator cuff is completed, the posterior infraspinatus and teres minor tendons are evaluated from a posterior view, with the arm in neutral position and the elbow flexed 90°. A normal small amount of fluid is seen in the glenohumeral joint. The cartilaginous posterior labrum is viewed as a hyperechoic triangle separating the infraspinatus and teres minor tendons from the glenoid.

Impingement syndrome is evaluated in dynamic examination. Dynamic view of the supraspinatus tendon is obtained by moving the arm from



Figure 1. Sonographic-guided injection approach.

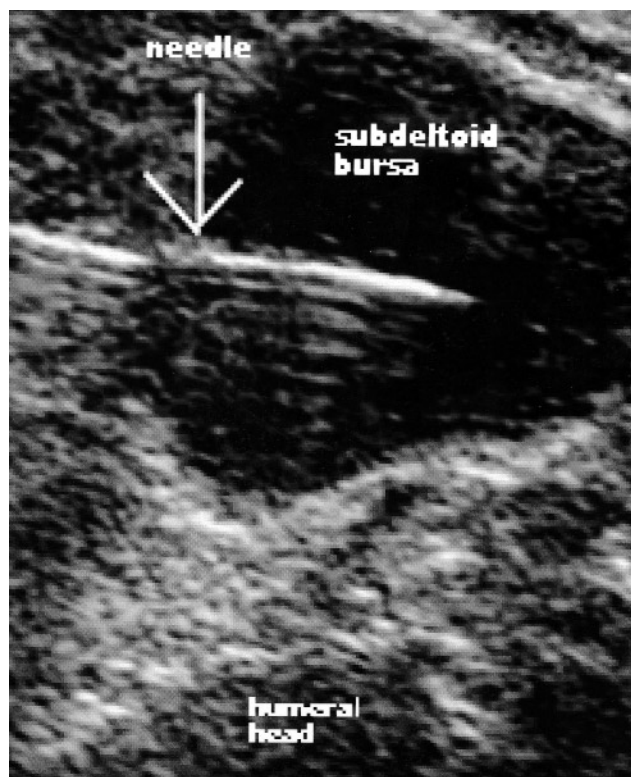


Figure 2. Sonographic-guided injection into the subacromial-subdeltoid bursa. The needle appears as a hyperreflective line (arrow).

neutral position to 90° abduction in order to detect encroachment of the acromion to the rotator cuff.

We evaluated the response to treatment by comparing the change in VAS and SFA scores from baseline to 6 weeks postinjection between the 2 groups of patients. The number of patients with a 50% improvement in VAS and SFA score was calculated for each group.

Statistical analysis. The Student-Fisher test was used for comparing independent variables and the chi-square test for quantitative variables; $p < 0.05$ was considered significant.

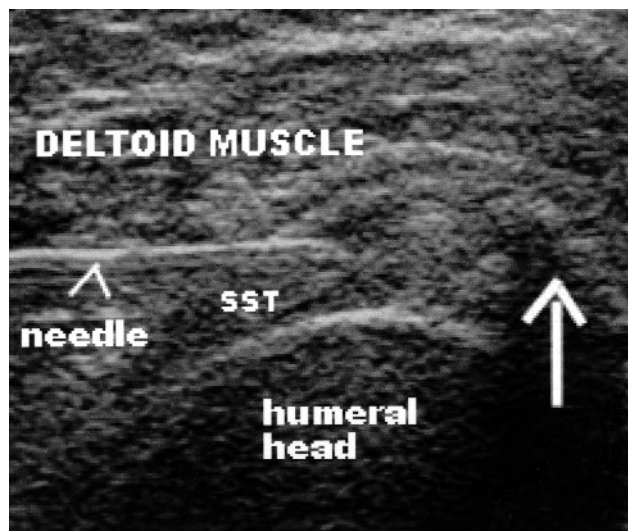


Figure 3. Sonographic-guided injection directed to a supraspinatus tendon calcification (arrow). The needle is seen as a hyperreflective line (arrow-head). SST: supraspinatus tendon.

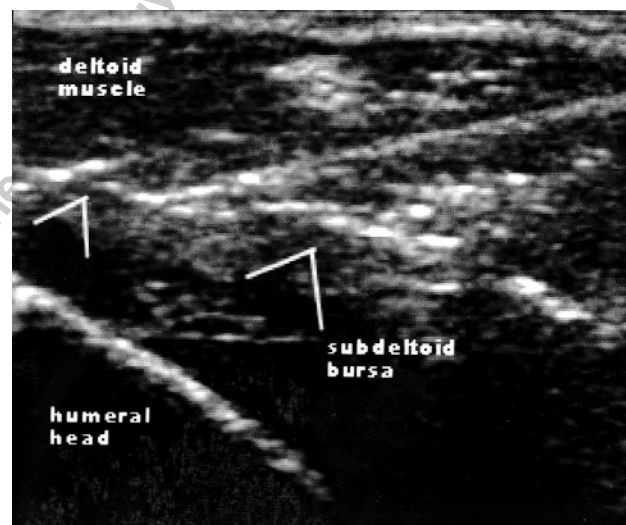


Figure 4. Corticosteroid after injection is seen as hyperreflective lines (arrowheads) in the subacromial-subdeltoid bursa.

RESULTS

There was no significant difference between the 2 groups for age, sex, mean duration of symptoms, shoulder involved, occupational demands on the shoulder, presence of nocturnal pain, active shoulder motion impairment at study entry, initial VAS and SFA scores (Table 1), and US pathologic findings (Table 2).

Six weeks after corticosteroid injection, the sonographic-guided injection group (Group 2) showed a significantly greater improvement of SFA and VAS scores compared with the blinded injection group (Group 1) (Table 3, Figure 5). Mean decrease of VAS score was 7.1 (SD 8.24) in Group 1 and 34.9 (SD 21.32) in Group 2 ($p < 0.001$). VAS score worsened in 7 patients in Group 1 (mean 9.1 points, range

Table 1. Initial clinical assessment.

	Group 1	Group 2	p
Age, yrs, mean (SD)	51.9 (13.8)	52.9 (11)	> 0.05
Sex, n (%)			
Women	12 (60)	15 (71)	> 0.05
Men	8 (40)	6 (29)	
Duration of symptoms, mo, mean (SD)	10.2 (14.7)	11.9 (14.6)	> 0.05
Shoulder involved, n (%)			
R	11 (55)	11 (52)	> 0.05
L	9 (45)	10 (48)	
Shoulder demand, n (%)			
High	6 (30)	9 (43)	> 0.05
Moderate	9 (45)	11 (52)	
Low	5 (25)	1 (5)	
Nocturnal pain, n (%)	20 (100)	20 (95)	> 0.05
Active ROM impairment, n (%)	9 (45)	8 (38)	> 0.05
VAS score, mean (SD)	63.7 (19.8)	61.2 (21.2)	> 0.05
SFA score, mean (SD)	39.3 (13.4)	42.6 (14.5)	> 0.05

ROM: range of motion; VAS: visual analog scale; SFA: Shoulder Function Assessment.

Table 2. US findings.

Findings	Group 1, n (%)	Group 2, n (%)
Increased fluid, BT sheath	5 (25)	5 (24)
BT partial tear	1 (5)	1 (5)
RC tendinosis	6 (30)	3 (14)
RC partial-thickness tear	5 (25)	3 (14)
RC full-thickness tear	6 (30)	10 (48)
RC calcification	3 (15)	4 (19)
Increased fluid, SA-SD bursa	8 (40)	9 (43)
RC impingement	16 (80)	17 (81)
Degenerative changes, acromioclavicular joint	13 (65)	16 (76)

BT: biceps tendon, RC: rotator cuff, SA-SD: subacromial-subdeltoid.

Table 3. Response to therapy. Change in VAS and SFA scores.

	Group 1	Group 2	p
Decrease of VAS score, mean (SD)	7.1 (8.2)	34.9 (21.3)	< 0.001
Increase of SFA score, mean (SD)	5.6 (7.7)	15 (13.9)	< 0.05

VAS: visual analog scale, SFA: Shoulder Function Assessment.

2–17) and in one patient in Group 2 (4 points). Mean increase of SFA score was 5.6 (SD 7.76) in Group 1 and 15 (SD 13.9) in Group 2 ($p = 0.012$). SFA score worsened in 5 patients in Group 1 (mean 7.6 points, range 2–13) and no patient in Group 2.

One patient in Group 1 and 11 in Group 2 showed a 50% decrease in VAS score ($p = 0.01$). SFA score showed a 50% increase in 2 patients in Group 1 and 5 patients in Group 2 ($p = 0.41$) (Figure 6).

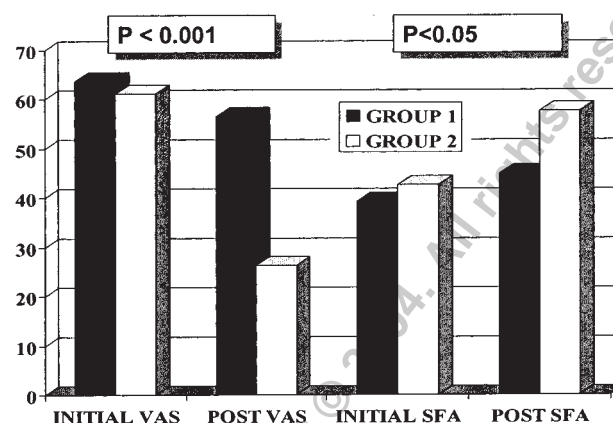


Figure 5. Response to therapy: changes in VAS for pain and Shoulder Function Assessment (SFA) scores at the start of the study and after 6 weeks of steroid injection (POST).

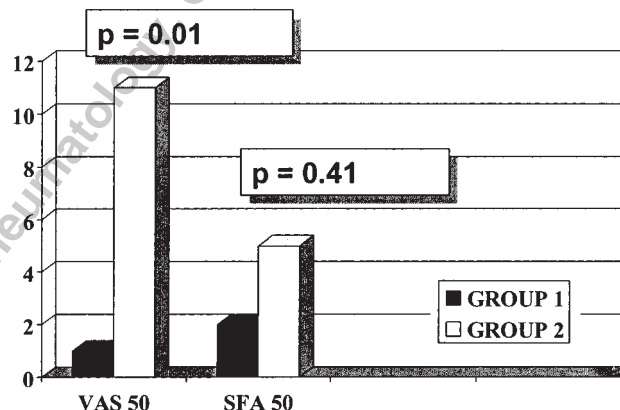


Figure 6. Number of patients with 50% decrease in VAS for pain (VAS 50) and SFA score (SFA 50).

Ten patients in Group 1 had nocturnal pain 6 weeks postinjection, whereas only 2 patients in Group 2 had nocturnal pain ($p < 0.001$). Twenty patients in Group 1 and 9 in Group 2 had active shoulder motion impairment 6 weeks postinjection ($p < 0.05$). Twelve patients in Group 1 and 12 in Group 2 had taken NSAID during the followup period.

A mild increase in pain after injection was reported in one patient in Group 1; no patient in Group 2 reported postinjection adverse effects.

In Group 1, postinjection corticosteroid was detected in the deltoid muscle just superficial to the SA-SD bursa in 7 patients, intratendon (supraspinatus and infraspinatus tendon) in 6 patients, SA-SD bursa in 3 patients, and in both deltoid muscle and SA-SD bursa in 3 patients. In one patient the steroid was not detected.

In all patients of Group 2, the needle was accurately placed in the target and correct steroid delivery was

confirmed in real-time and after injection. However, in one patient, corticosteroid was seen postinjection both in deltoid muscle and in SA-SD bursa, and in another patient it was detected in SA-SD bursa and in a supraspinatus tendon tear.

DISCUSSION

Painful shoulder is a very common complaint in clinical rheumatology. Periarticular soft tissue lesions involving the rotator cuff, the biceps tendon, and the subacromial-subdeltoid bursa are the most common pathologic findings in painful shoulder²³.

Rotator cuff chronic degeneration or tendinosis due to overuse or repetitive trauma and aging, along with primary or secondary impingement of these tendons on the antero-lateral margin of the acromion, are thought to be the main mechanisms responsible for chronic painful shoulder. Tendinosis may progress to partial and full-thickness rotator cuff tear^{23,24}.

SA-SD bursitis, biceps tendon involvement, and acromioclavicular degenerative changes frequently accompany impingement syndrome and rotator cuff lesions^{24,25}.

Since the first description in 1951 by Hollander, *et al*²⁶, local injection of long-acting corticosteroids, namely methylprednisolone, triamcinolone, and betamethasone, has been a controversial treatment for localized musculoskeletal conditions. The precise mechanism for the beneficial effects of local corticosteroid injection is not well understood. The antiinflammatory effect, production of local hyperemia, relaxation of reflex muscle spasm, generalized response from some systemic absorption of the steroid suspension, influence on local tissue metabolism, pain relief, mechanical improvement, and placebo effect have been considered as possible therapeutic effects²⁷. Nonetheless, there has been disagreement regarding the efficacy and effectiveness of this therapy in painful shoulder²⁸. Clinical experience suggests that while some patients respond dramatically well to subacromial corticosteroid injection, others respond poorly and some not at all. However, controlled trials regarding the efficacy of local injection of corticosteroid have had scarce short term studies that provided conflicting results¹⁻⁷. Most of these studies used different methodologies, making comparisons difficult. Many studies had small numbers of patients in the individual treatment groups, limiting their statistical power. In addition, most previous studies did not take into account the periarticular pathological findings because diagnosis had been established clinically. Perhaps the efficacy may relate to accurate diagnosis of the periarticular lesions.

Among most relevant prospective, double-blind, randomized controlled studies, the report by Adebajo, *et al*¹ demonstrated that subacromial injection of triamcinolone hexacetonide (80 mg) was significantly superior to placebo and oral diclofenac (150 mg daily) in decreasing pain, improving active abduction, and reducing functional limita-

tion in 50 patients with rotator cuff tendinitis, over a 4-week period. Petri, *et al*² reported that subacromial injection of triamcinolone (40 mg) was significantly more effective than oral naproxen (500 mg twice daily) during 4 weeks in 100 patients with rotator cuff tendinitis. However, the study from White, *et al*³ showed no differences between subacromial triamcinolone (40 mg) and oral indomethacin (100 mg daily) in 40 patients with rotator cuff tendinitis over a 6-week followup period. Vecchio, *et al*⁴ found no significant advantage of subacromial injection of methylprednisolone (40 mg) and lidocaine (1 ml lidocaine 1%) over lidocaine alone (1 ml lidocaine 1%) in 55 patients with early (< 12 weeks' duration) rotator cuff tendinitis, whereas Blair, *et al*⁵ demonstrated a significantly superior efficacy of subacromial triamcinolone 40 mg with lidocaine 1% versus lidocaine 1% alone in 40 patients with subacromial impingement syndrome during 28–33 weeks of followup.

Among the prospective randomized, observed-blind studies comparing local injection of steroids with physiotherapy in patients with painful shoulder, Dacre, *et al*⁶ demonstrated similar short term (6 weeks) and longterm (6 months) efficacy, whereas Van der Windt, *et al*⁷ showed a similar longterm efficacy (52 weeks), but a superior short term response (7 weeks) to local steroids, that is, a faster relief of symptoms.

A possible explanation for the contradictory responses of painful shoulder to local corticosteroid may be the variability in the accuracy of injected steroid placement. Eustace, *et al*⁸ described the accuracy of steroid placement by plain radiography and compared it with clinical outcome in patients with shoulder symptoms using a mixture of triamcinolone and radiographic contrast medium. Only 4 of the 14 subacromial injections (29%) and 10 of 24 glenohumeral injections (42%) were placed accurately. There was a significantly better response in the accurately-injected group.

The origin of pain in the painful shoulder is not well understood. A variable prevalence of periarticular shoulder abnormalities, mainly rotator cuff tears, has been reported in asymptomatic shoulders, in increasing frequency in older people, in anatomic²⁹ and imaging studies^{30,31}. It is unknown what may make some tears asymptomatic and others symptomatic. However, increased fluid within the SA-SD bursa or the biceps tendon sheath has not been described in asymptomatic shoulders^{30,31}, even in those previously symptomatic. The increased fluid in these structures accompanying rotator cuff lesions may indicate a secondary inflammatory process partially responsible for pain. Therefore, accurate placement of corticosteroid into the fluid may affect the therapeutic response due to its antiinflammatory effect.

High resolution US has proven accuracy and reliability in diagnosing a wide range of shoulder disorders compared with magnetic resonance imaging^{32,33}, arthroscopy^{34,35}, and

surgical findings^{36,37}. US has considerable advantages over other imaging techniques, e.g., dynamic examination of the musculoskeletal system can be done routinely, it is quick to perform, there is absence of secondary effects, and the cost is low. The availability of US rheumatology practice offers the possibility of establishing a more accurate diagnosis of painful shoulder.

Traditionally, musculoskeletal injections have been performed using external anatomical landmarks. Occasionally, fluoroscopy and computed tomography have been used to guide injections. US has been classically used in abdomen, breast, and thyroid examination and obstetric punctures. The accuracy, safety, and simplicity of US for guiding interventional procedures in the musculoskeletal system has been widely described¹¹⁻¹⁷. High frequency US allows careful intra or perilesional placement of the tip of the needle, even inside minimal fluid collections, into tendon sheaths¹⁶. Needle visualization relies on orienting the needle as much as possible perpendicular to the US beam. The needle is visualized as a hyperreflective line, often having a strong ring-down artefact. In a deep musculoskeletal location, when the needle cannot be directed perpendicular to the US beam, the tip of the needle is easily detected as a hyperreflective foci. The use of sterile gel guarantees an aseptic procedure. The learning time for US-guided injections is short.

Diffusion of the echoic steroid suspension can be easily detected in real-time during and after the procedure¹⁶. The suspension appears as hyperreflective foci or lines due to its crystalline structure.

Our study population represented the spectrum of patients attending a busy rheumatologic outpatient clinic, and the range of shoulder lesions were those usually seen in patients treated with local steroid injections.

We observed that the VAS and SFA scores improved significantly more in patients treated with sonographic-guided corticosteroid injections than in those treated with blind injections. Similarly to the report from Eustace, *et al*⁸, only 30% of the blind injections were placed accurately within the SA-SD bursa. Inaccurate periarticular placement may allow sufficient steroid to diffuse into the adjacent structures to yield only a partial response. Greater concentration of drug and less dispersal from the lesion would be expected from accurate placement within the target. If the antiinflammatory effect of the drug is considered, the latter might be an important factor in determining the therapeutic response.

As reported³⁸, we also found that the pain score improved more than the SFA score. Perhaps this therapy should be supplemented with early physiotherapy to obtain an optimal outcome. Nevertheless, we did find a significantly greater number of patients with active shoulder motion impairment 6 weeks postinjection in the blind steroid injection group than in those injected under sonographic guidance. Because

shoulder pain was present before the study began for a mean of 11.1 months, it seems reasonable that the clinical outcome found at Week 6 postinjection was due to the corticosteroid injection rather than to the natural progress of shoulder pain.

Some limitations of our study should be considered. A double-blind study would have been desirable to avoid bias. However, blinding of patients and the rheumatologist who performed medication injection was not technically possible.

We conclude that ultrasound guidance may be the method of choice for injecting corticosteroid in patients with painful shoulder. As well, it should be used when response to injections guided by palpation or blind injections is poor.

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