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Effectiveness of corticosteroid injection in adhesive capsulitis

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Objective: To assess whether intraarticular corticosteroids improve the outcome of a comprehensive home exercise programme in patients with adhesive capsulitis.
Setting: The study was undertaken in the Physical Therapy and Rehabilitation Department of a Ministry of Health hospital in Turkey.
Subjects: Eighty patients with adhesive capsulitis were enrolled in the study.
Interventions: The patients were randomly assigned to two groups: Group 1 patients were given intraarticular corticosteroid (1 mL, 40 mg methylprednisolone acetate) followed by a 12-week comprehensive home exercise programme. Group 2 patients were given intraarticular serum physiologic (1 mL solution of 0.9% sodium chloride) followed by a 12-week comprehensive home exercise programme.
Main measures: The outcome parameters were Shoulder Pain and Disability Index and University of California-Los Angeles end-result scores, night pain and shoulder passive range of motion.
Results: Mean actual changes in abduction range of motion, Shoulder Pain and Disability Index–total score and Shoulder Pain and Disability Index–pain score were statistically different between the two groups at the second week, with the better scores determined in group 1. However, there were no significant differences between the groups at the 12th week. Medians of University of California-Los Angeles scores in the second week were significantly different between the two groups ($P = 0.02$), with better scores in group 1; however, the difference in 12th week scores was insignificant.
Conclusions: Intraarticular corticosteroids have the additive effect of providing rapid pain relief, mainly in the first weeks of the exercise treatment period. In patients with adhesive capsulitis who have pain symptom predominantly, intraarticular corticosteroid therapy could be advised concomitantly with exercise.

Introduction

Adhesive capsulitis is a condition characterized by spontaneous onset of shoulder pain and gradual loss of active and passive shoulder motion. It is a common cause of shoulder pain and disability estimated to affect 2–5% of the general population.[1] The aetiology of adhesive capsulitis remains unclear; however, the factors associated with adhesive capsulitis include female, trauma, age older than 40 years, diabetes, prolonged immobility, thyroid disease, stroke, myocardial infarcts and presence of autoimmune disease.[2] The natural

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history of adhesive capsulitis goes through three phases: increasing pain and stiffness, lasting 2½–9 months, a steady-state period from 4 to 20 months, and a spontaneous recovery lasting between 5 and 26 months.[3] Some authors believe it is a self-limiting disorder,[4,5] but others suggest it is a more chronic disorder leading to longer term disability.[6–8] In the recovery stage, approximately 7–15% of patients permanently lose their full range of motion.[8,9]

Exercises, physiotherapy programmes including ultrasound, laser, transcutaneous electrical stimulation and iontophoresis, oral non-steroidal anti-inflammatory drugs and intraarticular injections to the glenohumeral joint, or their combinations are used to treat adhesive capsulitis. In resistant patients, manipulation or surgical release may be applied.[10] Van der Heijden *et al*. assessed the effectiveness of physiotherapy for patients with soft tissue shoulder disorders from randomized controlled trials and showed that ultrasound therapy seems ineffective in patients with shoulder disorders when compared with placebo or another treatment, and there was insufficient evidence to support the effectiveness of low level laser, heat, cold, electrotherapy, exercise and mobilization in such patients.[11] Green *et al*. reviewed randomized clinical trials of efficacy of non-steroidal anti-inflammatory drugs, intraarticular and subacromial corticosteroid injection, oral corticosteroid, physiotherapy, manipulation under anaesthesia, hydrodilatation and surgery in patients with shoulder pain, and reported that there was little evidence to support or refute the use of any of the common interventions.[12–14] Buchbinder *et al*. performed a systematic review of randomized and pseudo-randomized trials of corticosteroid injections for shoulder pain. Their conclusion was that intraarticular steroid injection for adhesive capsulitis may be beneficial, although its effect may be small and not well maintained.[15] A systematic review of randomized clinical trials on the effectiveness of corticosteroid injections or physiotherapy for shoulder pain showed inconsistent short-term results and limited evidence for the long-term outcome.[16]

Our objective was to assess whether intraarticular corticosteroids improve the outcome of a comprehensive home exercise programme in patients with adhesive capsulitis.

Materials and methods

This prospective study was conducted in a Ministry of Health hospital that serves individuals with social security insurance, such as blue- and white-collar workers and their relatives. This study included all newly diagnosed adhesive capsulitis patients consecutively admitted to the physical therapy and rehabilitation outpatient clinic. Adhesive capsulitis was defined as the presence of shoulder pain with limitation of both active and passive movements of the glenohumeral joint of $\geq$25% in at least two directions.[17] The inclusion criteria were as follows: age between 18 and 70, symptom duration between six weeks and six months, and no treatment other than analgesics in the last six months. The exclusion criteria were uncontrolled diabetes mellitus, contraindications of injections and previous shoulder surgery.

A total of 80 patients with adhesive capsulitis were enrolled in this study. All patients were randomized after initial evaluation by selecting a sealed unmarked envelope containing a letter that informed them of their group. Group 1 patients ($n = 40$) with 42 shoulder involvements were given intraarticular 1 mL, 40 mg methylprednisolone acetate followed by a 12-week comprehensive home exercise programme. Group 2 patients ($n = 40$) with 40 shoulder involvements were given intraarticular 1 mL serum physiologic (solution of 0.9% sodium chloride) followed by a 12-week comprehensive home exercise programme.

The injections were given intraarticularly via the posterior approach, with the patient seated, and the arm on the affected side slightly rotated internally. The index finger of the physician was placed on the coracoid process and the thumb on the angle between the spine of the scapula and the acromion. The needle was introduced 1 cm below the thumb and aimed at the coracoid process. A 1- or 2-mL syringe, fitted with a 5-cm, 21-gauge needle was used. All the injections were applied by the same physician, who was informed with regard to the injection materials, while patients were unaware of the type of injection.

All patients were assessed at initial evaluation, and 2nd and 12th weeks of treatment. Initial evaluation included the recording of demographic data, medical history, relevant comorbidities,

dominant and affected shoulder and detailed examination of the shoulder. At all three evaluations, shoulder passive range of flexion/abduction and external/internal rotation, night pain and shoulder disability were measured.

Passive range of motion of the involved shoulder was measured in all planes with a long-arm goniometer with patients in supine position. Shoulder flexion was assessed in sagittal plane with the arm at the side and hand pronated, while the shoulder abduction was measured in the frontal plane with the arm at the side and the shoulder externally rotated to obtain maximum abduction. Shoulder internal and external rotations were measured in transversal plane with the arm abducted to 90°, the elbow flexed to 90°, the hand pronated and the forearm perpendicular to the floor. When the arm could not be abducted 90°, the arc was considered to be 0°, and internal and external rotations were measured on this plane.

Night pain was measured with visual analogue scale of 0–100 mm, ranging from no pain to very severe pain.

Shoulder pain and disability index was administered to all patients to evaluate shoulder disability, and was evaluated in three forms: (a) Shoulder Pain and Disability Index–pain, (b) Shoulder Pain and Disability Index–disability and (c) Shoulder Pain and Disability Index–total. The five-item pain subscale addresses pain experienced during activities of daily living, and each item is anchored by the descriptors 'no pain' (left anchor) and 'worst pain imaginable' (right anchor). The eight disability items address the level of difficulty in performing activities of daily living. These items are anchored with descriptors 'no difficulty' (left anchor) and 'so difficult it required help' (right anchor). Each item is scored by measuring the distance from the left anchor to the mark made by the person. Subscales are scored in a three-part process. First, item scores within the subscale are summed. Second, this sum is divided by the summed distance possible across all items of the subscale to which the person responded. Third, this ratio is multiplied by 100 to obtain a percentage. Higher scores on the subscale indicate greater pain and greater disability. To obtain the Shoulder Pain and Disability Index total score, pain and disability subscales are averaged.[18,19]

University of California-Los Angeles end-result score, a 35-point scale, was used to assess the effectiveness of treatment. The items measured include pain (10 points), function (10 points), active forward flexion (5 points), strength of forward flexion (5 points) and patient satisfaction. A score of 34–35 is considered an excellent result, 29–33 a good result, and any score less than 28 a poor result.[20,21] The scale was applied at the 2nd and 12th weeks of the treatment.

All patients were given the same comprehensive home exercise programme. Initially, pendulum circumduction and passive shoulder self-stretching in forward elevation, external rotation, horizontal adduction and internal rotation were prescribed. The patient was instructed to stretch the shoulder to the point of tolerable discomfort five times a day. The goal is to stretch the capsule sufficiently to allow restoration of normal glenohumeral biomechanics. When the passive shoulder range of motions reached 90% of normal ranges, the exercise protocol was followed by isometric in all planes; theraband exercises with three different therabands (low–median–high resistances); strengthening exercises for the muscles of scapular stabilizations; and advanced muscle strengthening exercises with dumbbells, respectively. All the patients were invited biweekly to ensure compliance and to be instructed regarding the new exercise. We recommended hot pack application before and cold pack application after shoulder exercises.

Oral paracetamol (1500 mg/day) was recommended to patients when needed.

The same physician, who was blinded to the injection therapy, evaluated all patients' measurements. All patients were informed about the nature of the study procedure and provided informed consent prior to beginning the trial, which was conducted in accordance with the Helsinki Declarations of 1975.

Data analysis was performed using SPSS for Windows, version 11.5. Shapiro–Wilks' test was used to test the normality of distribution for continuous and discrete variables. Data were shown as mean ± standard deviation or median (interquartile range), where appropriate. Categorical variables were presented as percentages. Medians were compared using the Mann–Whitney *U*-test. Differences among repeated

measures were evaluated by Friedman Two-Way Analysis of Variance by Ranks. When the *P*-value from the Friedman test statistics was statistically significant, multiple comparison test was used to determine pairwise differences between groups. At the 2nd and 12th weeks, actual changes in levels according to baseline were calculated. Between-group comparisons for actual changes were evaluated by Mann–Whitney *U*-test. For categorical comparisons, chi-square or Fisher's exact test were used, where appropriate. A *P*-value less than 0.05 was considered statistically significant.

Results

The demographic characteristics of the patients according to group are shown in Table 1. Group 1 included 40 patients, two of whom had bilateral involvement; thus, a total of 42 shoulder joints were evaluated. Twenty-four patients of 40 in group 2 completed the study. Sixteen patients failed to complete the study: 10 had difficulty in attending the clinic regularly, 2 had intercurrent medical problems and 4 were lost to follow-up. A consort diagram of the patients is shown in Figure 1. There were no differences between the groups with respect to demographic data ($P > 0.05$).

Medians of night pain, all range of motions, and Shoulder Pain and Disability Index scores at each evaluation are shown in Table 2 and Figure 2. University of California-Los Angeles end-result score at each evaluation is shown in Table 2.

There were no statistical differences between the two groups in the initial measurements of night pain, Shoulder Pain and Disability Index scores and all range of motions, with the exception of external rotation ($P > 0.05$).

Range of motions, night pain, and Shoulder Pain and Disability Index scores in both groups differed significantly at the 2nd and 12th weeks with respect to baseline values (Table 2).

University of California-Los Angeles end-result score results improved significantly in both groups at the 12th week in comparison with the 2nd week score ($P < 0.05$).

Table 1 Demographic characteristics of the patients in both groups

	Group 1 ($n = 40$)	Group 2 ($n = 24$)	*P*-value
Age (year, mean, SD)	56.9 (9.56)	56.3 (8.16)	0.792
Sex (%)			
Female	25 (62.5%)	10 (58.3%)	0.105
Male	15 (37.5%)	14 (41.7%)	
Relevant comorbidities (%)	33 (82.5%)	20 (83.3%)	1.000
Dominant hand[a] (%)			
Left	4 (9.5%)	0 (0%)	0.288
Right	38 (90.5%)	24 (100%)	
Affected side[a] (%)			
Dominant	27 (64.3%)	11 (45.8%)	0.145
Non-dominant	15 (35.7%)	13 (54.2%)	

[a]Two patients had bilateral involvement in group 1; analyses were done in 42 shoulders.

The mean actual changes in night pain, range of motions, and Shoulder Pain and Disability Index scores at the 2nd and 12th weeks and differences between the two groups are shown in Tables 3 and 4. Mean actual changes in abduction range of motion, Shoulder Pain and Disability Index–total score and Shoulder Pain and Disability Index–pain score were statistically different between the two groups in the 2nd week, with the better scores determined in group 1. There was no significant difference between the two groups with respect to mean actual change in night pain, Shoulder Pain and Disability Index scores, and range of motion measurements at the 12th week.

In the 2nd week, group 1 showed 32 (76.2%) poor, 9 (21.4%) good and 1 (2.4%) excellent recovery according to University of California-Los Angeles scores. Group 2 showed 23 (95.8%) poor, 1 (4.2%) good, and 0 (0%) excellent recoveries. In the 12th week, group 1 showed 15 (35.7%) poor, 17 (40.5%) good and 10 (23.8%) excellent recovery. Group 2 showed 10 (41.7%) poor, 10 (41.7%) good, and 4 (16.7%) excellent recovery. Medians of University of California-Los Angeles scores in the 2nd week were significantly different between the two groups ($P = 0.002$), with better scores in group 1; however, difference in 12th week scores was insignificant ($P = 0.486$).

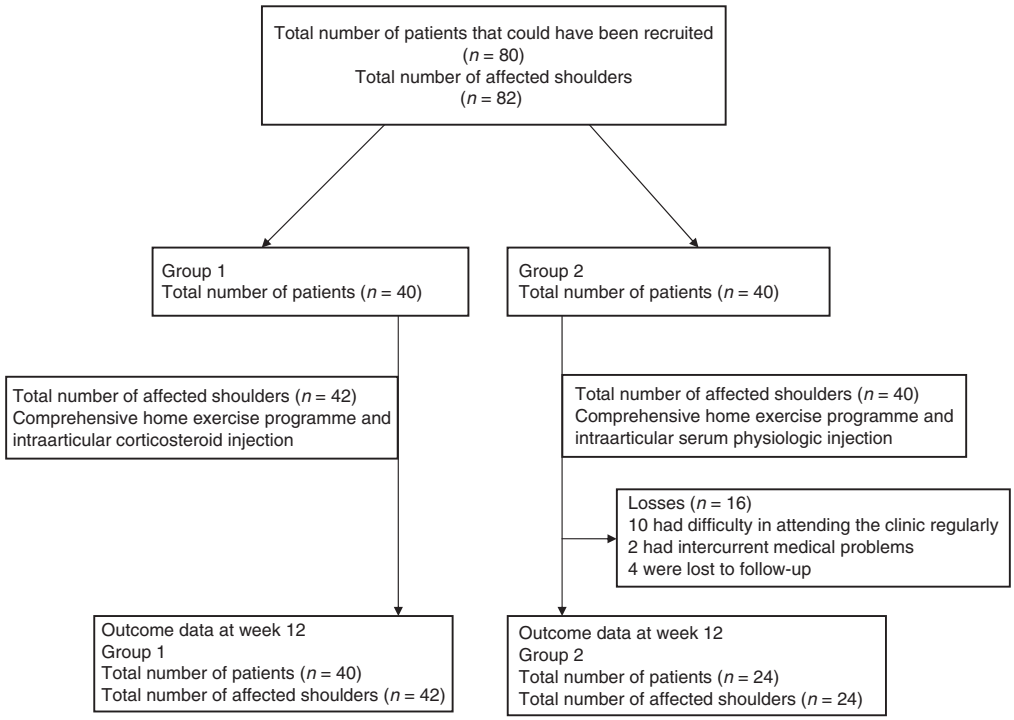

Figure 1 Consort diagram for randomized subject assignment in this study.

Table 2 Medians of night pain, all ranges of motion (ROMs), Shoulder Pain and Disability Index (SPADI) scores and University of California-Los Angeles end-result scores (UCLA) at each evaluation

	Group 1			Group 2		
	Baseline Median (IQR)	2nd week Median (IQR)	12th week Median (IQR)	Baseline Median (IQR)	2nd week Median (IQR)	12th week Median (IQR)
Night pain	77.5 (20.0)	30.0 (50.0)*	7.5 (30.0)*,†	70.0 (40.0)	50.0 (38.7)*	12.5 (50.0)*,†
Flexion	137.5 (30.0)	160.0 (38.7)*	180.0 (16.2)*,††	130.0 (27.5)	150.0 (37.5)***	165.0 (27.5)*,¶
Abduction	107.5 (41.2)	137.5 (60.0)*	180.0 (22.5)*,††	90.0 (27.5)	110.0 (46.2)***	160.0 (57.5)*,¶
Int. rotation	55.0 (25.0)	80.0 (30.0)*	90.0 (15.0)*,†	47.5 (10.0)	55.0 (18.7)	90.0 (30.0)*,††
Ext. rotation	50.0 (31.2)	75.0 (45)*	90.0 (20.0)*,†	40.0 (17.5)	50.0 (18.7)**	70.0 (37.5)*,††
UCLA		26.5 (4.5)	32.5 (6.2)††		23.0 (6.5)	31.5 (7.7)††
SPADI-t	69.4 (40.5)	29.9 (33.0)*	10.9 (23.3)*,¶	70.5 (25.6)	42.5 (38.0)**	14.5 (27.1)*,¶
SPADI-p	71.0 (39.7)	28.0 (32.0)*	12.0 (32.0)*,††	66.0 (25.0)	43.5 (48.0)**	12.5 (26.7)*,¶
SPADI-d	63.4 (38.1)	26.2 (36.0)*	10.0 (24.2)*,¶	70.5 (24.8)	44.0 (30.9)**	11.5 (31.4)*,¶

*Significant difference compared with baseline ($P<0.001$).
**Significant difference compared with baseline ($P<0.01$).
***Significant difference compared with baseline ($P<0.05$).
¶Significant difference compared with 2nd week ($P<0.001$).
†Significant difference compared with 2nd week ($P<0.01$).
††Significant difference compared with 2nd week ($P<0.05$).
IQR, interquartile range; ROM, range of motion; SPADI, Shoulder Pain and Disability Index (t–total; p–pain; d–disability); UCLA, University of California-Los Angeles end-result score.

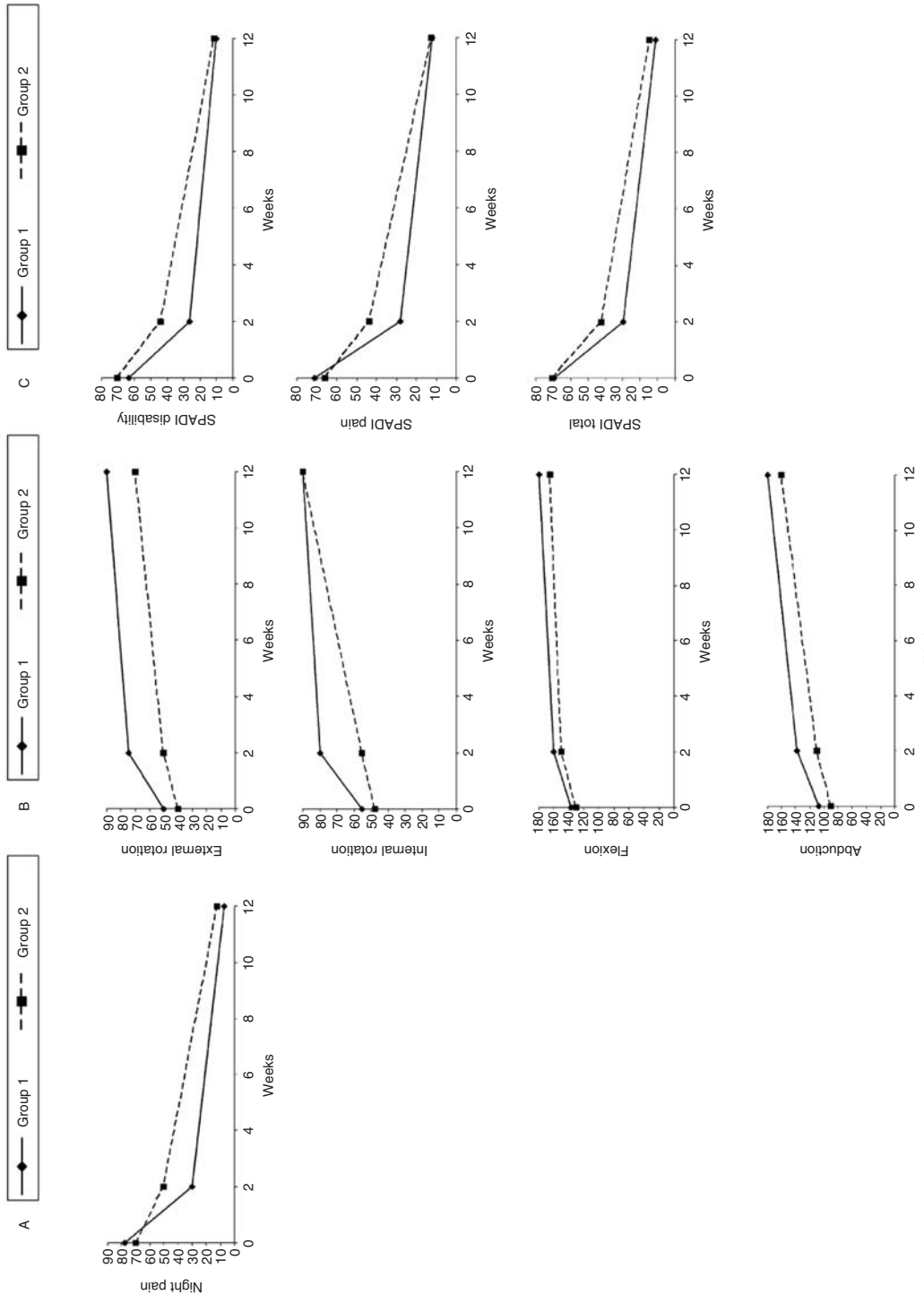

Figure 2 Medians of night pain, all ranges of motion (ROMs), and Shoulder Pain and Disability Index (SPADI) scores at each evaluation.

Table 3 Mean actual change in night pain, ranges of motion (ROMs) and Shoulder Pain and Disability Index (SPADI) scores at the 2nd week from baseline and differences between the groups

	Group 1 ($n=42$) mean actual change, SD	Group 2 ($n=24$) mean actual change, SD	*P*-value
Night pain	−36.5 (25.1)	−26.5 (25.1)	0.070
Flexion	22.4 (18.5)	13.9 (16.5)	0.075
Abduction	36.5 (27.1)	18.7 (26.8)	0.033
Internal rotation	16.5 (19.1)	9.8 (14.9)	0.088
External rotation	18.4 (16.3)	12.9 (13.4)	0.173
SPADI total	−30.9 (19.9)	−20.2 (15.0)	0.047
SPADI pain	−30.1 (22.1)	−19.0 (17.6)	0.041
SPADI disability	−28.8 (21.2)	−23.1 (17.8)	0.301

ROM, range of motion; SPADI, Shoulder Pain and Disability Index.

Table 4 Mean actual change in night pain, ranges of motion (ROMs) and Shoulder Pain and Disability Index (SPADI) scores at the 12th week from baseline and differences between the groups

	Group 1 ($n=42$) mean actual change, SD	Group 2 ($n=24$) mean actual change, SD	*P*-value
Night pain	−53.1 (27.8)	−51.7 (28.1)	0.552
Flexion	36.8 (15.9)	33.5 (16.1)	0.356
Abduction	57.8 (27.9)	54.2 (29.1)	0.639
Internal rotation	25.7 (19.1)	54.2 (29.1)	0.693
External rotation	27.4 (19.5)	31.2 (20.1)	0.421
SPADI total	−44.4 (24.0)	−48.2 (16.3)	0.407
SPADI pain	−42.4 (25.5)	−44.8 (19.4)	0.684
SPADI disability	−42.2 (26.3)	−49.8 (18.8)	0.156

ROM, range of motion; SPADI, Shoulder Pain and Disability Index.

No side-effects were noted during the drug or exercise therapy sessions.

Discussion

We aimed in this study to assess whether intraarticular corticosteroids improve the outcome of a comprehensive home exercise programme in patients with adhesive capsulitis. Our results show that intraarticular corticosteroid therapy concomitant with exercise achieves fast relief of pain and improvement in disability in the short term.

Exercise therapy is critically important in adhesive capsulitis. It is important to educate the patient regarding the improvement in range of motion. Stretching should be the focus of the treatment. It can be taken beyond the limits of the available range of motion.[2] It has been demonstrated that there is a significant deficit in shoulder muscle isometric strength and endurance.[22] Strengthening of the scapula musculature and rotator cuff muscles can be added to increase strength and endurance.[2,22] A 90% improvement can be achieved using only four directional stretching exercises.[23] In this study, we administered a comprehensive exercise programme both to the patients treated with intraarticular placebo and to those given corticosteroid. Both groups showed the same improvement at the 12th week. Comprehensive exercise therapy under close follow-up is a fundamental choice.

Steroid injection therapy has been advised in adhesive capsulitis based on the belief that inflammation plays an important role in the pathogenesis. In 1945, Neviaser introduced the term 'adhesive capsulitis' and described the inflammatory process.[24] Cytokines have been implicated recently in the inflammation and fibrosis described in adhesive capsulitis. Cytokines are involved in the initiation and termination of repair processes in multiple musculoskeletal tissues, and their sustained production has been shown to result in tissue fibrosis.[25] Early treatment with intraarticular corticosteroid may provide a chemical ablation of synovitis, thus limiting the subsequent development of fibrosis and shortening the natural history of the disease.[2]

There are contradictory findings in different studies about intraarticular corticosteroid therapy. Rizk *et al*. compared four treatments for adhesive capsulitis: (a) intraarticular methylprednisolone and lidocaine, (b) intrabursal methylprednisolone and lidocaine, (c) intraarticular lidocaine, and (d) intrabursal lidocaine. There were no significant

differences in outcome between intrabursal injection and intraarticular injection. Injection of steroid with lidocaine had the advantage of partial transient pain relief.[26] Bulgen *et al*. randomized patients to treatment with steroid, physical therapy, ice or benign neglect. The initial response to treatment was most marked in patients treated with steroid; however, no significant difference in final long-term outcome was reported when treatment groups were compared.[27] Ryans *et al*. found that patients having intraarticular corticosteroid therapy had better outcome in disability scores but not in pain and range of motion in the 6th week, but all the therapy groups had improved to a similar degree with respect to all outcome measures at 16 weeks.[28] One trial of fluoroscopically guided injection with and without physiotherapy found corticosteroid-injected patients had less disability and better range of motion outcome at six weeks compared with physical therapy alone or placebo injection.[17] Van Der Windt *et al*. compared the effectiveness of corticosteroid injection with physiotherapy for the treatment of the painful stiff shoulder. They concluded that the differences between those who received injections and those treated with physiotherapy resulted mainly from comparatively fast relief of symptoms that occurs after injections.[29] Similar to the results of our study, all these studies indicated that corticosteroid injection is more effective in the improvement of adhesive capsulitis in the early follow-up period; however, this difference disappears in the late follow-up period. Other papers evaluating the effectiveness of steroid or exercise or physical therapy found no difference in all stages in pain, disability and range of motion between the groups.[30–33] They all advised corticosteroid injection as being less costly to administer. When we assessed the systematic review of randomized clinical trials of the effectiveness of corticosteroid injections for shoulder pain, we found that intraarticular corticosteroid injection for adhesive capsulitis may be beneficial, although its effect may be small and not well-maintained; there were inconsistent short-term results and limited evidence for the long-term outcome.[15,16]

In this study, University of California-Los Angeles end-result score was used to assess the effectiveness of treatment of shoulder disorders. To our knowledge, there is no study using this score in adhesive capsulitis patients. The score included patient satisfaction, shoulder function, and range and strength of forward elevation, and our results were similar with our other findings. This score can be applied to adhesive capsulitis patients in the follow-up of the treatment.

One limitation of our study was the large number ($n = 16$) of lost patients in group 2. Two patients had intercurrent medical problems, 4 were lost during the follow-up period and 10 did not attend assessment visits regularly and thus had to be excluded from the study. This was an unexpected situation for a randomized study. We assume this may have been due to the absence of sufficient patient satisfaction, although better recovery with corticosteroid supply was observed in the short term in our results.

In conclusion, intraarticular corticosteroids have additive effects related to rapid pain relief, mainly in the first weeks of the exercise treatment period. The combination of the corticosteroid injection and therapeutic exercises was equally effective when compared with the therapeutic exercises alone at the end of 12 weeks. In patients with adhesive capsulitis who have predominant pain symptoms, intraarticular corticosteroid therapy could be advised concomitantly with exercise.

Clinical messages

- Intraarticular corticosteroids have the additive effect of providing rapid pain relief, mainly in the first weeks of the exercise treatment period.
- In patients with adhesive capsulitis who have pain symptom predominantly, intraarticular corticosteroid therapy could be advised concomitantly with exercise.

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