ARTHRITIS & RHEUMATISM
Vol. 48, No. 3, March 2003, pp 829–838
DOI 10.1002/art.10954

Intraarticular Corticosteroids, Supervised Physiotherapy, or a Combination of the Two in the Treatment of Adhesive Capsulitis of the Shoulder

A Placebo-Controlled Trial

Simon Carette,[1] Hélène Moffet,[2] Johanne Tardif,[2] Louis Bessette,[2] Frédéric Morin,[3] Pierre Frémont,[2] Vivian Bykerk,[4] Carter Thorne,[5] Mary Bell,[6] William Bensen,[7] and Caty Blanchette[2]

Objective. **To compare the efficacy of a single intraarticular corticosteroid injection, a supervised physiotherapy program, a combination of the two, and placebo in the treatment of adhesive capsulitis of the shoulder.**

Methods. **Ninety-three subjects with adhesive capsulitis of <1 year's duration were randomized to 1 of 4 treatment groups: group 1, corticosteroid injection (triamcinolone hexacetonide 40 mg) performed under fluoroscopic guidance followed by 12 sessions of supervised physiotherapy; group 2, corticosteroid injection alone; group 3, saline injection followed by supervised physiotherapy; or group 4, saline injection alone (placebo group). All subjects were taught a simple home exercise program. Subjects were reassessed after 6 weeks, 3 months, 6 months, and 1 year. The primary outcome measure was improvement in the Shoulder Pain and Disability Index (SPADI) score.**

Results. **At 6 weeks, the total SPADI scores had improved significantly more in groups 1 and 2 compared with groups 3 and 4 ($P = 0.0004$). The total range of active and passive motion increased in all groups, with group 1 having significantly greater improvement than the other 3 groups. At 3 months, groups 1 and 2 still showed significantly greater improvement in SPADI scores than group 4. There was no difference between groups 3 and 4 at any of the followup assessments except for greater improvement in the range of shoulder flexion in group 3 at 3 months. At 12 months, all groups had improved to a similar degree with respect to all outcome measures.**

Conclusion. **A single intraarticular injection of corticosteroid administered under fluoroscopy combined with a simple home exercise program is effective in improving shoulder pain and disability in patients with adhesive capsulitis. Adding supervised physiotherapy provides faster improvement in shoulder range of motion. When used alone, supervised physiotherapy is of limited efficacy in the management of adhesive capsulitis.**

Adhesive capsulitis is a common cause of shoulder pain and disability. It is characterized by spontaneous onset of shoulder pain accompanied by progressive limitation of both active and passive glenohumeral movement (1). The pathophysiology of idiopathic adhe-

Supported by a grant from the Arthritis Society of Canada.
[1]Simon Carette, MD: University Health Network, Toronto, Ontario, Canada; [2]Hélène Moffet, PT, PhD, Johanne Tardif, PT, MSc, Louis Bessette, MD, MSc, Pierre Frémont, MD, PhD, Caty Blanchette, MSc: Laval University, Quebec City, Quebec, Canada; [3]Frédéric Morin, MD: Centre Hospitalier St-Joseph, Trois-Rivieres, Quebec, Canada; [4]Vivian Bykerk, MD: Credit Valley Hospital, Mississauga, Ontario, Canada; [5]Carter Thorne, MD: Southlake Regional Health Centre, Newmarket, Ontario, Canada; [6]Mary Bell, MD: Sunnybrook and Women's Health Sciences Centre, Toronto, Ontario, Canada; [7]William Bensen, MD: St Joseph's Hospital, Hamilton, Ontario, Canada.

Address correspondence and reprint requests to Simon Carette, MD, Toronto Western Hospital, 399 Bathurst Street, EC8-05, Toronto, Ontario M5T 2S8, Canada. E-mail: simon.carette@uhn.on.ca.

Submitted for publication June 14, 2002; accepted in revised form November 13, 2002.

sive capsulitis is poorly understood (2). Most authors have reported various degrees of inflammatory changes in the synovial membrane. Adhesions between the shoulder capsule and the humeral head have been noted by some (3), but not all (4,5), authors. The optimum management of adhesive capsulitis has been the subject of great debate, particularly since the condition tends to resolve spontaneously over months to years (6–8). Intraarticular corticosteroid injections and/or physiotherapy programs combining exercise, physical agents, and mobilization are the 2 most common treatment options used in patients with adhesive capsulitis (9–17). However, clear evidence of the efficacy of either or both of these options in improving pain and function and in changing the natural history of adhesive capsulitis is lacking (18). We conducted a controlled trial to compare the efficacy of a single intraarticular corticosteroid injection, a supervised physiotherapy program, the combination of intraarticular corticosteroid and supervised physiotherapy, and placebo in patients with adhesive capsulitis who were also taught a simple home exercise program.

PATIENTS AND METHODS

Participating centers. Patients were recruited from outpatient rheumatology clinics in 7 centers from the provinces of Quebec and Ontario, Canada. The protocol was approved by the ethics committee of each institution.

Patient selection criteria. Patients were eligible if they were age 18 years or older and had been symptomatic for <1 year. Adhesive capsulitis was defined as the presence of shoulder pain with limitation of both active and passive movements of the glenohumeral joint of ≥25% in at least 2 directions (abduction, flexion, external rotation, internal rotation), as compared with the contralateral shoulder or with normal values (19). In addition, patients had to have a total score of ≥30 on the Shoulder Pain and Disability Index (SPADI) (20).

Patients were excluded if their adhesive capsulitis was secondary to another cause, including inflammatory, degenerative, metabolic, or infectious arthritis, cerebrovascular accident, or fracture. Patients who had a known blood coagulation disorder or an allergy to radiologic contrast material were also excluded. In March 1997, due to recruitment difficulties, we decided to accept patients with diabetes mellitus.

Randomization. Randomization took place after written informed consent was obtained from the study participants and baseline information was gathered. The patients were randomized to 1 of the following 4 treatment groups: group 1, corticosteroid injection followed by supervised physiotherapy (combination group); group 2, corticosteroid injection alone (corticosteroid group); group 3, saline injection followed by supervised physiotherapy (physiotherapy group); or group 4, saline injection alone (placebo group). The assignment scheme was generated from a table of random numbers. Random assignments to the treatment groups were stratified according to study center and balanced after every 12 assignments. The opaque prenumbered envelopes containing the assignments were kept by the hospital pharmacist at each center.

Interventions. All injections were performed by trained radiologists on the day of randomization. The patient was placed in the supine position with the arm by his/her side and in internal rotation. The skin was first anesthetized with lidocaine. Under fluoroscopic guidance, a 21-gauge needle, 2½–3″ long, was then directed into the shoulder joint space. Aqueous contrast material (Omnipaque; Sanofi-Winthrop, Markham, Ontario, Canada) was injected to confirm the correct location of the needle in the joint. This was followed by injection of either 40 mg triamcinolone hexacetonide (2 ml) or isotonic saline (2 ml). The syringes containing the triamcinolone hexacetonide or saline were prepared by the hospital pharmacist and covered with aluminum foil so the radiologist administering the injections and the patient were not aware of the treatment.

Patients randomized to receive supervised physiotherapy started their program 1 week after the injection of triamcinolone hexacetonide or saline. It consisted of 12 1-hour sessions given over a 4-week period (3 sessions per week). There are no clear indications in the literature concerning the optimal treatment frequency and duration, but we hypothesized that the regimen used would be intensive and long enough to induce changes. Moreover, in the absence of scientific evidence regarding the effectiveness of multimodal physiotherapy programs, our program was developed in light of results obtained in studies of other groups with musculoskeletal disorders, in animal studies, and from expert opinions (21–24).

To reflect current clinical practice, 2 different physiotherapy strategies were used based on the stage of the capsulitis; they pursue complementary goals but differ in the nature and intensity of the modalities used. The goals of the strategy for acute capsulitis were to relieve pain, maintain or improve active and passive range of motion (ROM), and restore function. To achieve these goals, the following modalities were used: transcutaneous electrical nerve stimulation (21,25) followed by mobilization techniques (26,27), active ROM exercises (23,24), and ice application (21). Subjects were classified as having acute symptoms if they met 3 or more of the following 5 criteria: 1) pain at rest scored ≥4 cm on a 0–10-cm visual analog scale (VAS); 2) pain at rest present ≥75% of the time during the day; 3) pain on active shoulder elevation scored ≥4 cm on a 0–10-cm VAS; 4) presence of night pain; 5) spasm or empty end-feel (pain stopping passive motion before the examiner discerns any articular resistance) in at least 2 directions of passive motion.

Patients who met <3 of the above criteria for acute capsulitis were treated according to the strategy for chronic capsulitis, which aimed to improve ROM and muscle strength and to restore function. The modalities used were ultrasound (28–30) to heat the joint structures prior to mobilization techniques (26,27), active and auto-assisted ROM exercises (23), isometric strengthening exercises, and ice application (21).

The 14 physiotherapists participating in the study (2 per center) each had at least 3 years of experience in the treatment of patients with musculoskeletal disorders. Shoulder disorders were common in their daily practice. They were skilled in the application of mobilization techniques. In addition, they attended a 1-day training session prior to starting the study, in order to familiarize themselves with the 2 different treatment strategies, the criteria used to assign the patients to one strategy or the other, application of the modalities, and guidelines for treatment progression and individual adjustment. They used standardized forms to record details of all treatments provided.

Prior to randomization, all patients participating in the study were taught a simple, 10-minute exercise program to be done at home twice daily for 3 months. These exercises were taught by the physiotherapist responsible for baseline and followup assessments. They consisted essentially of active and auto-assisted ROM exercises in the planes of flexion, abduction, external rotation, and internal rotation (hand behind back). Advice about intensity, frequency, and progression of the exercises, heat and ice applications, and suitable shoulder positions was also given. Compliance with the home exercise program was recorded daily on an agenda form during the first 3 months of the study.

Other interventions. A letter was sent to the referring physician explaining the trial and the importance of limiting concurrent interventions. The patient received similar explanations. All medications used for the treatment of adhesive capsulitis, with the exception of acetaminophen, were stopped. We gave the patients a supply of acetaminophen tablets and a form to record each tablet taken. Information on acetaminophen intake and any other medication or treatment was obtained at each followup visit.

Followup and assessment of outcome. The patients were reevaluated at 6 weeks, 3 months, 6 months, and 1 year after randomization. Measures of outcome were grouped into 3 categories. First, the patient completed the SPADI, which is a self-administered instrument that measures pain and disability associated with shoulder disease (20). It consists of 13 items divided into 2 subscales: pain (5 items) and disability (8 items). The questions are asked using the preceding week as the frame of reference. Patients mark their response on a 100-mm numeric scaled line where 0 = "no pain" and 100 = "worst pain imaginable" for the 5 pain items and 0 = "no difficulty" and 100 = "so difficult it required help" for the 8 disability items. The SPADI is scored 0–100 by averaging the scores from the 2 subscales. The total SPADI and both the pain and disability scales have been shown to have high levels of internal consistency (Cronbach's α 0.86–0.95) and to correlate negatively with shoulder range of motion. They have good test–retest reliability. Finally, the instrument is sensitive to clinical changes and accurately discriminates between patients with shoulder disease who have improved, those whose condition has remained unchanged, and those who have worsened (31).

Second, general health status was measured. The Short Form 36 (SF-36) (32) was used for these assessments.

Third, physiotherapists specifically trained for the study measured active and passive ROM in the shoulder, according to a standardized and reliable method of testing (33). The universal goniometer (Conzett model; Physio ERP, Laval, Quebec, Canada) was used to measure, with the patient in the supine position, the active and passive ROM in flexion and abduction; external rotation was recorded using a hydrogoniometer (model PC5057; JA Preston of Canada, Mississauga, Ontario, Canada). The active combined functional movement of internal rotation–extension–adduction (hand behind back) was measured with the patient in the standing position. The patient first brought the hand behind the back placing the wrist on the median crest of the sacrum, and slid the hand up as far as possible. The vertical distance between the inferior angle of the scapula and the wrist (anatomic snuffbox) was measured. Each subject was assessed by the same physiotherapist throughout the trial, with a few exceptions. The physiotherapists involved in these assessments were unaware of the treatment allocation and did not normally work in the clinics where the physiotherapy was administered.

Statistical analysis. The total SPADI score at 6 weeks was used as the primary outcome measure for this trial. A previous study in patients presenting with subacute or chronic shoulder pain had shown that a decrease in the total SPADI score of $\geq$10 indicated clinically significant improvement in shoulder pain and function. Likewise, an increase in the total SPADI score of $>$10 indicated worse shoulder pain and function (1). Changes in score between $-$10 and $+$10 did not reliably distinguish between the subjects who were improved, those whose condition remained the same, and those who were worse (31). Sample size calculations were thus based on the ability to detect a difference between treatment groups of $\geq$10 points in the total SPADI scores. Using this parameter, we calculated that a sample size of 36 subjects per group would be adequate with 80% power to detect such a difference at the 5% level of significance (2-sided tests), assuming a standard deviation of the total SPADI score of $\leq$15. Unfortunately, the trial was stopped before we reached this target because of difficulty in recruiting subjects. The main limiting factor to recruitment was the requirement that subjects have limitation of *both* active and passive movements of the glenohumeral joint. Many subjects diagnosed as having capsulitis by their family physician and referred for participation in the trial had limitation of active ROM but not of passive ROM.

The primary analysis was based on an intent-to-treat principle, and all subjects were included in the analysis. In the case of subjects lost to followup, the data from the last available assessment were imputed to all subsequent evaluations. Comparisons of mean values and proportions of patients at baseline were based on the Kruskal-Wallis and Fisher exact tests (34), respectively. For continuous variables, the mean change from the baseline value was estimated for each group, and the mean changes in the 4 groups were compared with the use of contrast, by time, since the interaction by time and treatment was significant. Least-square means were estimated with the PROC MIXED program of the SAS software package (version 8.1; SAS Institute, Cary, NC) (35) to account for the correlation among repeated measures (6 weeks, 3 months, 6 months, and 12 months), by analysis of variance, in the same subject. All analyses were adjusted for sex because this was the one variable that was not evenly distributed among the 4 groups. The treatment effect was defined as the difference between the mean changes in the

Table 1. Baseline characteristics of the 93 patients with adhesive capsulitis*

Characteristic	Group 1, CS + PT (n = 21)	Group 2, CS alone (n = 23)	Group 3, PT alone (n = 26)	Group 4, placebo (n = 23)
Age, years	54.9 ± 10.5	55.4 ± 10.0	54.2 ± 8.3	56.5 ± 9.4
Education, years	10.9 ± 4.5	13.5 ± 4.0	13.5 ± 4.4	13.1 ± 3.7
% female	66.7	65.2	46.2	60.9
Employment				
% unemployed	47.4	52.4	45.8	52.4
% not working because of adhesive capsulitis	15.8	0.0	12.5	14.3
% employed	36.8	47.6	41.7	33.3
% with unilateral shoulder pain	90.5	100.0	92.3	95.6
Duration of current episode of shoulder pain, weeks	22.1 ± 14.9	21.2 ± 11.0	20.8 ± 11.2	20.3 ± 7.3
% having first episode of shoulder pain	90.5	91.3	76.9	82.6
% with diabetes	9.5	4.3	3.9	8.7
SPADI				
Total score	66.4 ± 15.5	66.6 ± 17.6	61.5 ± 16.5	67.3 ± 17.5
Pain score	69.0 ± 17.1	70.2 ± 16.4	65.4 ± 19.7	69.1 ± 18.3
Disability score	63.8 ± 16.9	63.0 ± 20.6	57.6 ± 17.3	65.5 ± 19.3
SF-36				
PCS	35.2 ± 7.8	37.5 ± 9.1	37.6 ± 7.7	36.8 ± 7.7
MCS	43.1 ± 12.9	49.4 ± 10.2	49.8 ± 11.8	49.0 ± 12.5
Active ROM, degrees†	163.0 ± 36.8	178.2 ± 22.4	180.3 ± 36.4	174.5 ± 36.8
Hand behind back, cm	34.1 ± 10.4	34.7 ± 13.1	37.2 ± 10.9	34.0 ± 11.0
Passive ROM, degrees†	180.9 ± 35.8	194.9 ± 24.8	189.9 ± 36.3	188.6 ± 38.9
Flexion	115.5 ± 19.0	123.2 ± 10.7	117.0 ± 17.5	116.5 ± 17.2
Abduction	57.5 ± 11.8	58.2 ± 10.4	57.1 ± 9.8	56.7 ± 14.4
External rotation	7.9 ± 11.6	15.1 ± 14.0	14.9 ± 14.1	17.9 ± 18.3

* Except where indicated otherwise, values are the mean ± SD. There was no significant difference between groups at baseline. CS = corticosteroid injection; PT = physiotherapy; SPADI = Shoulder Pain and Disability Index (20); SF-36 = Short Form 36 (32); PCS = physical component summary (range 15.9–62.2); MCS = mental component summary (range 12.7–68.4); ROM = range of motion.
† Sum of amplitudes of movement in flexion, abduction, and external rotation.

groups. The precision and statistical significance of this difference was indicated by the 95% confidence interval. All tests were 2-sided.

Secondary analyses were carried out using actual data on all randomized patients, without any imputation of data in the case of those lost to followup.

Table 2. Clinical and functional outcomes at 6 weeks: change from baseline and treatment effect compared with placebo*

	Mean ± SEM change from baseline				Treatment effect (95% confidence interval)			
Outcome measure	Group 1, CS + PT	Group 2, CS alone	Group 3, PT alone	Group 4, placebo	Group 1, CS + PT	Group 2, CS alone	Group 3, PT alone	*P*†
SPADI								
Total score	−46.5 ± 5.3	−36.7 ± 5.1	−22.2 ± 4.8	−18.9 ± 5.1	−27.7 (−42.1, −13.2)‡	−17.8 (−31.9, 3.7)‡	−3.4 (−17.1, 10.4)	0.0004
Pain score	−48.7 ± 5.9	−39.1 ± 5.6	−21.8 ± 5.3	−17.3 ± 5.6	−31.4 (−47.7, −15.4)‡	−21.8 (−37.4, −6.2)‡	−4.5 (−19.7, 10.8)	0.0002
Disability score	−44.3 ± 5.2	−34.2 ± 5.0	−22.7 ± 4.7	−20.4 ± 4.9	−23.9 (−38.0, −9.8)‡	−13.8 (−27.6, 0.0)§	−2.3 (−15.7, 11.2)	0.0027
SF-36								
PCS	6.4 ± 1.9	4.4 ± 1.9	1.1 ± 1.9	2.5 ± 1.9	3.9 (−1.4, 9.3)	1.9 (−3.4, 7.2)	−1.3 (−6.6, 3.9)	0.2285
MCS	5.7 ± 2.3	1.5 ± 2.2	2.0 ± 2.2	2.6 ± 2.2	3.2 (−3.0, 9.4)	−1.0 (−7.2, 5.1)	−0.6 (−6.7, 5.5)	0.5340
Active ROM, degrees	80.7 ± 9.6	49.2 ± 9.3	37.2 ± 8.8	21.6 ± 9.3	59.0 (32.7, 85.4)¶	27.6 (1.6, 53.6)§	15.5 (−9.7, 40.8)	0.0002
Hand behind back, cm	−19.8 ± 2.5	−11.3 ± 2.4	−10.5 ± 2.3	−10.8 ± 2.4	−9.0 (−15.7, −2.2)¶	−0.5 (−7.1, 6.1)	0.3 (−6.1, 6.8)	0.0203
Passive ROM, degrees	77.2 ± 9.2	48.7 ± 8.9	34.5 ± 8.4	23.7 ± 8.9	53.5 (28.3, 78.6)¶	25.0 (0.2, 49.9)§	10.8 (−13.4, 34.9)	0.0003
Flexion	29.7 ± 4.1	16.0 ± 3.9	14.2 ± 3.7	11.0 ± 3.9	18.7 (7.5, 29.9)¶	5.0 (−5.9, 16.0)	3.2 (−7.5, 13.9)	0.0071
Abduction	21.0 ± 3.0	12.9 ± 2.9	9.7 ± 2.7	5.7 ± 2.9	15.3 (7.1, 23.5)‡	7.2 (−0.9, 15.2)	4.0 (−3.9, 11.8)	0.0026
External rotation	26.5 ± 3.6	18.3 ± 3.4	9.6 ± 3.2	7.1 ± 3.4	19.4 (9.6, 29.2)‡	11.2 (1.6, 20.7)§	2.5 (−6.8, 11.8)	0.0003

* See Table 1 for explanations and definitions.
† By analysis of variance.
‡ $P < 0.05$ versus groups 3 and 4.
§ $P < 0.05$ versus group 4.
¶ $P < 0.05$ versus groups 2, 3, and 4.

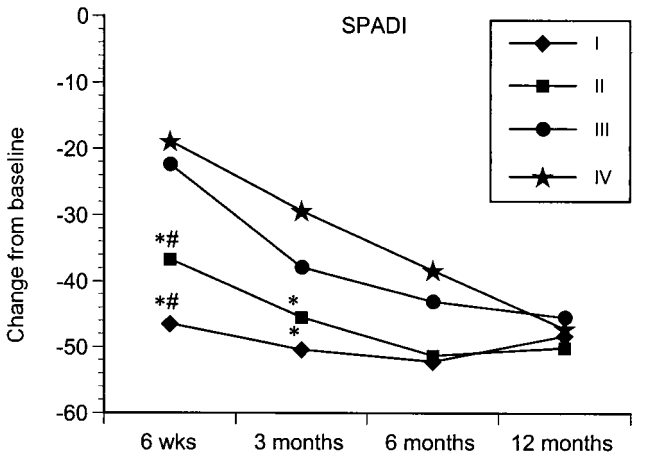

Figure 1. Mean changes from baseline in the total Shoulder Pain and Disability Index (SPADI) score. I = corticosteroid injection plus physiotherapy group; II = corticosteroid injection group; III = physiotherapy group; IV = placebo group. * = $P < 0.05$ versus placebo group; # = $P < 0.05$ versus physiotherapy group.

RESULTS

Study patients. Between November 1996 and June 2000, 97 subjects were enrolled in the study, with 22 subjects in the combination group, 25 in the corticosteroid group, 27 in the physiotherapy group, and 23 in the placebo group. Four subjects (1 in the combination group, 2 in the corticosteroid group, and 1 in the physiotherapy group) were excluded because they did not meet the entry criteria. Of the remaining 93 patients, 2 in the combination group, 9 in the corticosteroid group, 4 in the physiotherapy group, and 1 in the placebo group did not return for all visits. The baseline characteristics were similar in the 4 groups (Table 1), except that more subjects in the physiotherapy group were men.

Compliance and concurrent interventions. All patients received their assigned injection (saline or corticosteroid). Compliance with the supervised physiotherapy program was also very high. Of the 47 patients randomized to either group 1 or group 3, 38 attended the 12 planned physiotherapy sessions, 2 attended 11 and 10 sessions, respectively, and 1 patient refused to participate in the physiotherapy program. The physiotherapy reports from 6 patients were missing. Compliance with the home exercise program during the first 3 months of the trial was 73%, 81%, 74%, and 86% in the combination, corticosteroid, physiotherapy, and placebo groups, respectively ($P > 0.05$). At each of the first 2 followup visits, the patients in the placebo group reported greater use of acetaminophen than the patients in the other groups, but the difference did not reach statistical significance.

Five patients (2 in the combination group and 1 in each of the other groups) received, in addition to their assigned injection, a corticosteroid injection (triamcinolone hexacetonide, 20 mg) after randomization, and 1 patient in the saline group underwent rotator cuff repair 8 months after enrollment. All of these injections were prescribed by study investigators who were blinded to the original treatment assignment, and all were done under fluoroscopic guidance. The patient in the placebo group and the patient in the physiotherapy group each received the injection after the 6-week visit; the 3 patients in the corticosteroid and combination group received it after the 3-month or 6-month visits.

Response to treatment. Six weeks after randomization, the groups differed significantly with respect to the primary outcome measure (Table 2 and Figure 1). Compared with baseline values, total SPADI scores had improved by a mean ± SEM of 46.5 ± 5.3 in the combination group and 36.7 ± 5.1 in the corticosteroid group, which were significantly higher than the improvements of 22.2 ± 4.8 observed in the physiotherapy group and 18.9 ± 5.1 in the placebo group. Clinically important differences of ~10% in the total SPADI scores and its subscales were found between groups 1 and 2, but these differences were not statistically significant. There was no significant difference in the degree of improvement between the physiotherapy and placebo groups. In all 4 groups, the SF-36 physical and mental composite scores improved compared with baseline values, but the differences between groups were not significant. The total active and passive ROM increased in all groups compared with baseline values (Table 2 and Figure 2). The combination group had greater improvement than the other 3 groups, and the corticosteroid group had greater improvement than the placebo group.

Three months after enrollment, the groups continued to differ significantly with respect to pain, disability, and total SPADI scores, with the combination and corticosteroid groups showing greater improvement

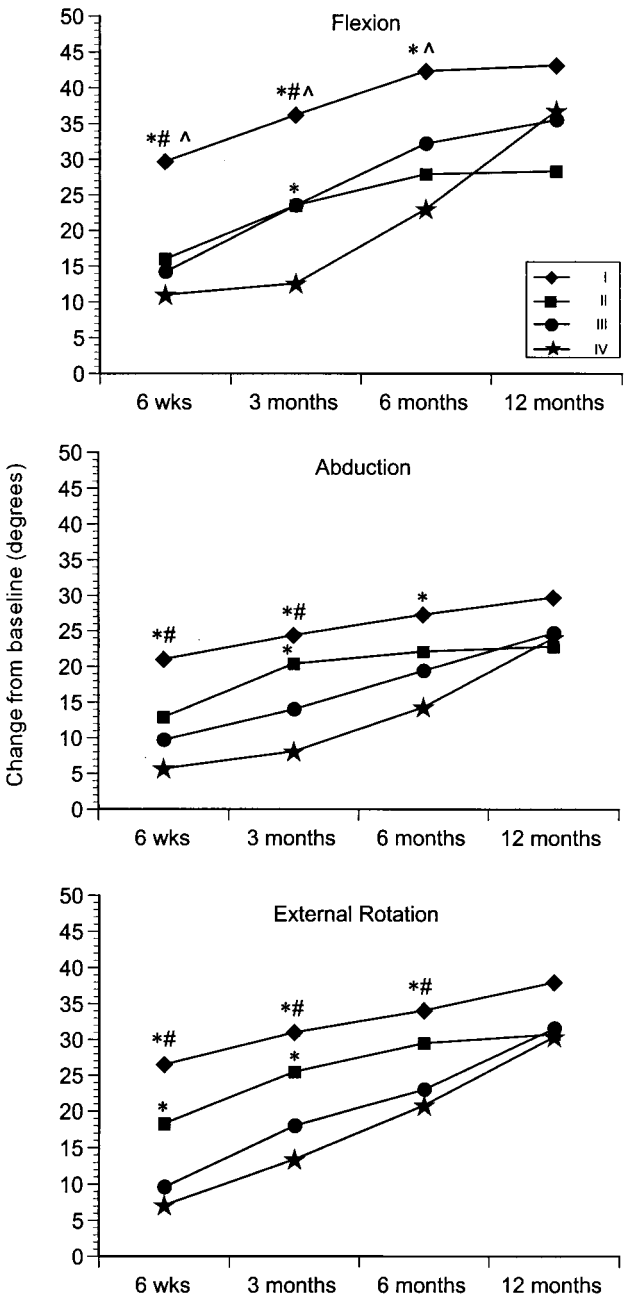

Figure 2. Mean changes from baseline in passive flexion, abduction, and external rotation. I = corticosteroid injection plus physiotherapy group; II = corticosteroid injection group; III = physiotherapy group; IV = placebo group. $* = P < 0.05$ versus placebo group; $\# = P < 0.05$ versus physiotherapy group; $\wedge = P < 0.05$ versus corticosteroid injection group.

than the placebo group (Table 3). The total active and passive ROM continued to increase in all groups, with the combination group showing the largest degree of improvement, followed by the corticosteroid group. These improvements were significantly greater in the combination group compared with the physiotherapy and placebo groups. The level of improvement in the corticosteroid group differed only from that in the placebo group.

Six months after enrollment, there was no longer any significant difference in SPADI scores between the 4 treatment groups. The combination group showed significantly greater improvement in the mental composite score of the SF-36 and higher active and passive ROM than the physiotherapy and placebo groups (Table 4). Active ROM was also significantly higher in the corticosteroid group than in the placebo group.

At 12 months, the 4 groups did not differ significantly with respect to any of the outcome measures (Table 5). As compared with baseline values, the total SPADI had improved by 48.3 ± 5.3 in the combination group, 50.1 ± 5.1 in the corticosteroid group, 45.5 ± 4.8 in the physiotherapy group, and 47.2 ± 5.1 in the placebo group. Active and passive ROM had improved by 87° and 91°, respectively, in the placebo group, compared with 113° and 111° in the combination group.

DISCUSSION

The results of this trial indicate that a single intraarticular injection of corticosteroid administered under fluoroscopic guidance, coupled with a simple home exercise program, is superior to a 12-session supervised physiotherapy program in improving shoulder pain and function at 6 weeks in patients with adhesive capsulitis of the shoulder. When given alone, supervised physiotherapy using standardized modalities, including mobilization techniques, active, passive, and auto-assisted range of motion exercises, and physical agents did not result in any significant advantage compared with placebo. Supervised physiotherapy given in conjunction with corticosteroid injection provided clinically but not statistically greater improvement in shoulder pain and function at 6 weeks compared with the corticosteroid injection alone and resulted in faster improvement in shoulder ROM.

Our results confirm those reported by van der Windt et al showing that the beneficial effects of corticosteroid injection are superior to those of a supervised physiotherapy program (17). In their pragmatic randomized trial conducted in a primary care setting with patients who had stiff and painful shoulders, they demonstrated treatment success (defined as complete recovery or much improvement) at 7 weeks in 77% of patients

Table 3. Clinical and functional outcomes at 3 months: change from baseline and treatment effect compared with placebo*

	Mean ± SEM change from baseline				Treatment effect (95% confidence interval)			
Outcome measure	Group 1, CS + PT	Group 2, CS alone	Group 3, PT alone	Group 4, placebo	Group 1, CS + PT	Group 2, CS alone	Group 3, PT alone	P†
SPADI								
Total score	−50.4 ± 5.3	−45.5 ± 5.1	−37.9 ± 4.8	−29.4 ± 5.1	−20.9 (−35.4, −6.5)‡	−16.1 (−30.2, −2.0)‡	−8.5 (−22.2, 5.3)	0.0251
Pain score	−52.1 ± 5.9	−48.1 ± 5.6	−38.1 ± 5.3	−30.1 ± 5.6	−21.9 (−37.9, −5.9)‡	−17.9 (−33.6, −2.3)‡	−8.0 (−23.2, 7.2)	0.0302
Disability score	−48.7 ± 5.2	−43.0 ± 5.0	−37.7 ± 4.7	−28.7 ± 4.9	−20.0 (−34.1, −5.9)‡	−14.2 (−28.0, −0.5)‡	−9.0 (−22.4, 4.5)	0.0386
SF-36								
PCS	8.6 ± 1.9	10.1 ± 1.9	6.4 ± 1.9	5.0 ± 1.9	3.6 (−1.8, 8.9)	5.1 (−0.2, 10.4)	1.4 (−3.9, 6.6)	0.2405
MCS	6.6 ± 2.3	2.2 ± 2.2	3.8 ± 2.2	1.2 ± 2.2	5.4 (−0.8, 11.6)	1.0 (−5.1, 7.2)	2.6 (−3.5, 8.7)	0.3418
Active ROM, degrees	93.2 ± 9.6	74.6 ± 9.3	53.3 ± 8.8	34.6 ± 9.3	58.6 (32.3, 85.0)§	40.0 (14.0, 66.0)‡	18.7 (−6.6, 43.9)	0.0001
Hand behind back, cm	−21.8 ± 2.5	−15.8 ± 2.4	−15.9 ± 2.3	−14.7 ± 2.4	−7.0 (−13.8, −0.3)¶	−1.0 (−7.6, 5.6)	−1.2 (−7.7, 5.2)	0.1690
Passive ROM, degrees	91.5 ± 9.2	71.6 ± 8.9	57.2 ± 8.4	36.2 ± 8.9	55.3 (30.2, 80.5)§	35.4 (10.6, 60.3)‡	21.0 (−3.2, 45.1)	0.0002
Flexion	36.2 ± 4.1	23.5 ± 3.9	23.5 ± 3.7	12.6 ± 3.9	23.6 (12.3, 34.8)¶	10.8 (−0.1, 21.8)	10.9 (0.2, 21.6)‡	0.0009
Abduction	24.4 ± 3.0	20.4 ± 2.9	14.0 ± 2.7	8.1 ± 2.9	16.2 (8.0, 24.4)§	12.2 (4.2, 20.3)‡	5.8 (−2.0, 13.7)	0.0006
External rotation	31.0 ± 3.6	25.5 ± 3.4	18.0 ± 3.2	13.4 ± 3.4	17.6 (7.8, 27.4)§	12.1 (2.6, 21.7)‡	4.6 (−4.7, 13.9)	0.0022

* See Table 1 for explanations and definitions.
† By analysis of variance.
‡ $P < 0.05$ versus group 4.
§ $P < 0.05$ versus groups 3 and 4.
¶ $P < 0.05$ versus groups 2, 3, and 4.

treated with corticosteroid injections (average of 2.2 injections per patient), compared with 46% of patients treated with physiotherapy (difference between groups 31% [95% confidence interval 14–48%]). However, in the absence of a placebo group, they could not comment on the efficacy of physiotherapy alone. In the current study, we did not observe any significant difference in the degree of improvement between the physiotherapy and placebo groups for any of the outcome measures at any of the 4 followup evaluations, except for the range of shoulder flexion at 3 months. However, our study had sufficient power only to detect a difference of ≥20 points on the total SPADI score. Therefore, the possibility of a smaller but still clinically significant difference favoring physiotherapy cannot be ruled out.

With time, the differences between the 2 groups that received the corticosteroid injection and the 2 groups that did not became smaller, and by 12 months

Table 4. Clinical and functional outcomes at 6 months: change from baseline and treatment effect compared with placebo*

	Mean ± SEM change from baseline				Treatment effect (95% confidence interval)			
Outcome measure	Group 1, CS + PT	Group 2, CS alone	Group 3, PT alone	Group 4, placebo	Group 1, CS + PT	Group 2, CS alone	Group 3, PT alone	P†
SPADI								
Total score	−52.5 ± 5.3	−51.3 ± 5.1	−43.1 ± 4.8	−38.4 ± 5.1	−14.1 (−28.5, 0.4)	−12.9 (−27.0, 1.2)	−4.7 (−18.4, 9.1)	0.1634
Pain score	−52.8 ± 5.9	−54.9 ± 5.6	−43.8 ± 5.3	−36.4 ± 5.6	−16.4 (−32.4, −0.4)	−18.6 (−34.2, −2.9)	−7.4 (−22.7, 7.8)	0.0779
Disability score	−52.1 ± 5.2	−47.6 ± 5.0	−42.3 ± 4.7	−40.5 ± 4.9	−11.7 (−25.8, 2.4)	−7.2 (−20.9, 6.6)	−1.9 (−15.3, 11.5)	0.3504
SF-36								
PCS	8.8 ± 1.9	10.1 ± 1.9	9.1 ± 1.9	6.8 ± 1.9	1.9 (−3.4, 7.3)	3.3 (−2.0, 8.6)	2.3 (−3.0, 7.5)	0.6684
MCS	9.2 ± 2.3	3.8 ± 2.2	1.0 ± 2.2	2.1 ± 2.2	7.1 (0.9, 13.3)‡	1.7 (−4.4, 7.8)	−1.0 (−7.1, 5.0)	0.0508
Active ROM, degrees	105.2 ± 9.6	84.2 ± 9.3	74.0 ± 8.8	57.2 ± 9.3	48.0 (21.7, 74.3)‡	27.1 (1.1, 53.1)§	16.8 (−8.5, 42.1)	0.0042
Hand behind back, cm	−22.8 ± 2.5	−17.4 ± 2.4	−18.1 ± 2.3	−16.9 ± 2.4	−5.9 (−12.7, 0.9)	−0.4 (−7.0, 6.2)	−1.1 (−7.6, 5.3)	0.3000
Passive ROM, degrees	103.8 ± 9.2	82.2 ± 8.9	76.8 ± 8.4	58.5 ± 8.9	45.3 (20.1, 70.4)‡	23.7 (−1.2, 48.6)	18.3 (−5.8, 42.5)	0.0060
Flexion	42.3 ± 4.1	27.9 ± 3.9	32.2 ± 3.7	23.0 ± 3.9	19.3 (8.1, 30.5)¶	4.9 (−6.0, 15.9)	9.1 (−1.5, 19.8)	0.0070
Abduction	27.3 ± 3.0	22.1 ± 2.9	19.4 ± 2.7	14.3 ± 2.9	13.0 (4.8, 21.2)§	7.8 (−0.3, 15.9)	5.1 (−2.7, 13.0)	0.0183
External rotation	34.1 ± 3.6	29.5 ± 3.4	23.0 ± 3.2	20.8 ± 3.4	13.4 (3.6, 23.2)‡	8.8 (−0.8, 18.3)	2.3 (−7.0, 11.6)	0.0285

* See Table 1 for explanations and definitions.
† By analysis of variance.
‡ $P < 0.05$ versus groups 3 and 4.
§ $P < 0.05$ versus group 4.
¶ $P < 0.05$ versus groups 2 and 4.

Table 5. Clinical and functional outcomes at 12 months: change from baseline and treatment effect compared with placebo*

Outcome measure	Mean ± SEM change from baseline				Treatment effect (95% confidence interval)			
	Group 1, CS + PT	Group 2, CS alone	Group 3, PT alone	Group 4, placebo	Group 1, CS + PT	Group 2, CS alone	Group 3, PT alone	P†
SPADI								
Total score	−48.3 ± 5.3	−50.1 ± 5.1	−45.5 ± 4.8	−47.2 ± 5.1	−1.1 (−15.5, 13.4)	−2.9 (−17.0, 11.2)	1.7 (−12.1, 15.4)	0.9309
Pain score	−48.4 ± 5.9	−52.6 ± 5.6	−46.1 ± 5.3	−46.0 ± 5.6	−2.4 (−18.4, 13.6)	−6.6 (−22.2, 9.1)	−0.0 (−15.3, 15.2)	0.8204
Disability score	−48.1 ± 5.2	−47.6 ± 5.0	−45.0 ± 4.7	−48.4 ± 4.9	0.2 (−13.8, 14.3)	0.8 (−13.0, 14.6)	3.4 (−10.0, 16.8)	0.9564
SF-36								
PCS	11.5 ± 1.9	11.1 ± 1.9	9.4 ± 1.9	10.1 ± 1.9	1.4 (−4.0, 6.7)	1.0 (−4.3, 6.3)	−0.7 (−5.9, 4.6)	0.8739
MCS	9.3 ± 2.3	3.5 ± 2.2	2.4 ± 2.2	3.2 ± 2.2	6.1 (−0.1, 12.3)	0.3 (−5.8, 6.4)	−0.8 (−6.9, 5.2)	0.1113
Active ROM, degrees	112.5 ± 9.6	86.8 ± 9.3	89.3 ± 8.8	86.8 ± 9.3	25.7 (−0.6, 52.1)	0.0 (−26.0, 26.0)	2.5 (−22.8, 27.8)	0.1597
Hand behind back, cm	−22.7 ± 2.5	−18.4 ± 2.4	−21.3 ± 2.3	−21.2 ± 2.4	−1.5 (−8.3, 5.3)	2.8 (−3.8, 9.5)	−0.1 (−6.6, 6.3)	0.6308
Passive ROM, degrees	110.8 ± 9.2	84.6 ± 8.9	94.7 ± 8.4	91.2 ± 8.9	19.6 (−5.6, 44.8)	−6.7 (−31.5, 18.2)	3.5 (−20.7, 27.6)	0.2112
Flexion	43.1 ± 4.1	28.3 ± 3.9	35.7 ± 3.7	36.8 ± 3.9	6.4 (−4.9, 17.6)	−8.5 (−19.4, 2.5)	−1.0 (−11.7, 9.7)	0.0786
Abduction	29.7 ± 3.0	22.8 ± 2.9	24.7 ± 2.7	24.0 ± 2.9	5.6 (−2.5, 13.8)	−1.3 (−9.4, 6.8)	0.7 (−7.2, 8.5)	0.3664
External rotation	38.0 ± 3.6	30.8 ± 3.4	31.6 ± 3.2	30.4 ± 3.4	7.6 (−2.2, 17.4)	0.5 (−9.1, 10.0)	1.2 (−8.1, 10.5)	0.3865

* See Table 1 for explanations and definitions.
† By analysis of variance.

after enrollment, all 4 groups had achieved the same degree of improvement with respect to shoulder pain and disability. This included the placebo group, in which the mean ± SD total SPADI score at 12 months was 18.5 ± 5.8, as compared with 11.2 ± 3.4 in the corticosteroid group, 12.8 ± 3.6 in the physiotherapy group, and 15.7 ± 4.7 in the combination group. The patients in the placebo group also had a significant increase in their total shoulder ROM at 12 months (mean ± SD 264 ± 11.2° for active movement and 283 ± 11.3° for passive movement). The degree of improvement in pain, function, and ROM seen in the placebo group confirms the notion that adhesive capsulitis has a favorable natural history (6–8).

Sixteen patients did not complete all followup assessments, including 9 in the corticosteroid group, 4 in the physiotherapy group, 2 in the combination group, and 1 in the placebo group. The total SPADI score at each of the visits with available data for these 16 patients is shown in Table 6. Our primary analysis, in which data obtained at the last available visit were imputed to subsequent evaluations, assumed that no further improvement occurred after that visit. The natural history of adhesive capsulitis is such that most patients improve with time (6–8). Therefore, if any bias had been introduced by data imputation, it would have favored the combination and placebo groups, which had the least missing data. The results of the secondary analysis, which was carried out only with actual data, showed a larger treatment effect for the corticosteroid group, as compared with the other groups, than was shown in the primary analysis. For example, the total SPADI scores at 6 weeks, 3 months, 6 months, and 12 months, respectively, improved by a mean ± SEM of 42.4 ± 4.9, 50.6 ± 5.0, 57.9 ± 5.3, and 54.4 ± 5.8 in the corticosteroid group, compared with 46.5 ± 4.9, 50.4 ± 4.9, 53.0 ± 5.0, and 49.3 ± 5.1 in the combination group (*P* not significant). The only remaining significant difference between these 2 groups was in the magnitude of improvement in active ROM, which was greater in the combination group (mean ± SEM 80.7 ± 9.2° and 77.2 ± 8.7°, respectively) than the corticosteroid group (54.9 ± 9.2° and 54.1 ± 8.7°, respectively).

Our study has a number of strengths, including

Table 6. Total Shoulder Pain and Disability Index scores in patients who did not complete all visits

Group*	Baseline	6 weeks	3 months	6 months	12 months
1	62.40	64.75	51.75	–	–
1	61.75	1.25	1.90	23.15	–
2	83.75	30.50	13.90	–	–
2	63.75	15.40	–	–	–
2	72.75	10.40	1.00	–	–
2	61.90	–	–	–	–
2	64.00	–	11.65	–	–
2	55.25	62.90	46.75	19.75	–
2	94.40	15.70	12.50	–	–
2	68.75	2.90	–	–	–
2	78.25	–	–	–	–
3	81.65	–	35.25	18.90	11.25
3	43.75	30.15	37.90	68.75	–
3	71.25	–	–	13.40	–
3	50.90	–	–	–	–
4	47.50	54.25	–	–	–

* Group 1 = corticosteroid injection plus physiotherapy; group 2 = corticosteroid injection; group 3 = physiotherapy; group 4 = placebo.

the use of strict selection criteria, the inclusion of a placebo arm, and the administration of the injections under fluoroscopic guidance. Recent studies indicate that injections performed blindly are inaccurate in as many as 60% of the cases and that injection accuracy is related to better clinical outcome (36,37). The favorable results observed in groups 1 and 2 might have been less pronounced had the injections been administered blindly.

We devised our physiotherapy interventions based on the best evidence available and selected physiotherapists who were experienced in the management of shoulder disorders, including mobilization techniques. While our results cannot be generalized to other types of physiotherapy interventions, they apply to patients meeting our selection criteria and for the actual interventions used in the present study.

The main limitation of our study is that it was terminated early due to difficulties in recruiting patients who met the entry criteria. We had calculated our sample size in order to detect a difference of ≥ 10 points in the total SPADI scores between treatment groups. Because the confidence intervals of the differences between physiotherapy and placebo include -10, we cannot exclude the possibility of a small but clinically significant advantage of physiotherapy as compared with placebo, particularly at the 3-month assessment.

In conclusion, a single intraarticular injection of corticosteroid administered under fluoroscopy, combined with a simple home exercise program, is effective in improving shoulder pain and disability in patients with adhesive capsulitis. Supervised physiotherapy in conjunction with the corticosteroid treatment provides faster improvement in shoulder ROM. When used alone, supervised physiotherapy is of limited efficacy in the management of adhesive capsulitis.

ACKNOWLEDGMENTS

The authors wish to thank our collaborators: study coordinators Marie Métivier, Carmen Trudel, and Vicki Lapp; physiotherapists Annette Bailey, Normand Bastrash, Julie Bellemare, Sophie Bernard, Anne Botham, Christian Brideau, Marie-Andrée Brosseau, Aleks Chafranskaia, Anne Cloutier, Amy Dehueck, Lise Dion, Martine Gastonguay, Carol Kennedy, Anne Labrecque, Nancy Landry, Hélène Laroche, Nancy Lehoux, Annie Plamondon, Jennifer Simon, Sue Thiessen, Isabelle Vézina, and Riki Yamada; blinded evaluators Nadine Bellman, Andrea Bishop, Erika Cooke, Sophie Girard, Eugenia Krpan, and Julie Rodrigue; and radiologists Hugues Archambault, Vincent Bergeron, Jacques Drolet, Rob Graham, and David Salonen.

REFERENCES

1. Grey RG. The natural history of "idiopathic" frozen shoulder. J Bone Joint Surg Am 1978;60:564.
2. Hannafin JA, Chiaia TA. Adhesive capsulitis: a treatment approach. Clin Orthop Rel Res 2000;372:95–109.
3. Neviaser JS. Adhesive capsulitis of the shoulder. J Bone Joint Surg 1945;27:211–22.
4. Lundberg BJ. The frozen shoulder. Clinical and radiographical observations. The effect of manipulation under general anesthesia. Structure and glycosaminoglycan content of the joint capsule. Local bone metabolism. Acta Orthop Scand Suppl 1969;119:1–59.
5. Wiley AM. Arthroscopic appearance of frozen shoulder. Arthroscopy 1991;7:138–43.
6. Reeves B. The natural history of the frozen shoulder syndrome. Scand J Rheumatol 1975;4:193–6.
7. Shaffer B, Tibone JE, Kerlan RK. Frozen shoulder: a long-term follow-up. J Bone Joint Surg Am 1992;74:738–46.
8. Binder AI, Bulgen DY, Hazleman BL, Roberts S. Frozen shoulder: a long-term prospective study. Ann Rheum Dis 1984;43:361–4.
9. Lee M, Haq AM, Wright V, Longton EB. Periarthritis of the shoulder: a controlled trial of physiotherapy. Physiotherapy 1973;59:312–5.
10. Lee PN, Lee M, Haq AM, Longton EB, Wright V. Periarthritis of the shoulder: trial of treatments investigated by multivariate analysis. Ann Rheum Dis 1974;33:116–9.
11. Bulgen DY, Binder AI, Hazleman BL, Dutton J, Roberts S. Frozen shoulder: prospective clinical study with an evaluation of three treatment regimens. Ann Rheum Dis 1984;43:353–60.
12. Dacre JE, Beeney N, Scott DL. Injections and physiotherapy for the painful stiff shoulder. Ann Rheum Dis 1989;48:322–5.
13. Jacobs LG, Barton MA, Wallace WA, Ferrousis J, Dunn NA, Bossingham DH. Intra-articular distension and steroids in the management of capsulitis of the shoulder. BMJ 1991;302:1498–501.
14. Rizk TE, Pinals RS, Talaiver AS. Corticosteroid injections in adhesive capsulitis: investigation of their value and site. Arch Phys Med Rehabil 1991;72:20–2.
15. Corbeil V, Dussault RG, Leduc BE, Fleury J. Capsulite rétractile de l'épaule: étude comparative de l'arthrographie avec corticothérapie intra-articulaire avec ou sans distension capsulaire. Can Assoc Radiol J 1992;43:127–30.
16. Winters JC, Sobel JS, Groenier KH, Arendzen HJ, Meyboom-de Jong B. Comparison of physiotherapy, manipulation, and corticosteroid injection for treating shoulder complaints in general practice: randomised, single blind study. BMJ 1997;314:1320–5.
17. Van der Windt DA, Koes BW, Devillé W, Boeke AJ, de Jong BA, Bouter LM. Effectiveness of corticosteroid injections versus physiotherapy for treatment of painful stiff shoulder in primary care: randomised trial. BMJ 1998;317:1292–6.
18. Green S, Buchbinder R, Glazier R, Forbes A. Systematic review of randomised controlled trials of interventions for painful shoulder: selection criteria, outcome assessment, and efficacy. BMJ 1998;316:354–60.
19. Gagey OJ, Gagey N. The hyperabduction test: an assessment of the laxity of the inferior glenohumeral ligament. J Bone Joint Surg Br 2001;83:69–74.
20. Roach KE, Budiman-Mak E, Songsiridej N, Lertratanakul Y. Development of a shoulder pain and disability index. Arthritis Care Res 1991;4:143–9.
21. Owens-Burkhart H. Management of frozen shoulder. In: Donatelli RA, editor. Clinics in physical therapy of the shoulder. New York: Churchill Livingstone; 1991. p. 91–116.
22. Grubbs N. Frozen shoulder syndrome: a review of the literature. J Orthop Sports Phys Ther 1993;18:479–87.
23. Liebesman JL, Cafarelli E. Physiology of range of motion in

human joints: a critical review. Crit Rev Phys Rehab Med 1994;6: 131–60.
24. Stam HW. Frozen shoulder: a review of current concepts. Physiotherapy 1994;80:588–98.
25. Oosterwiijk RFA, Neyler WJ, Henley EJ, Scheer SF, Tannenbaum J. Pain control with TENS and TEAM nerve stimulator: a review. Crit Rev Phys Rehab Med 1994;6:219–58.
26. Nicholson GG. The effects of passive joint mobilization on pain and hypomobility associated with adhesive capsulitis of the shoulder. J Orthop Sports Phys Ther 1985;6:238–46.
27. Maitland GD. Peripheral manipulations. 3rd ed. London: Butterworth-Heinemann; 1991.
28. Ziskin MC, McDiarmid T, Michlowitz SL. Therapeutic ultrasound. In: Michlowitz SL, editor. Thermal agents in rehabilitation. 2nd ed. Philadelphia: FA Davis; 1990. p. 134–69.
29. Hayes KW. The use of ultrasound to decrease pain and improve mobility. Crit Rev Phys Rehab Med 1992;3:271–87.
30. Draper DO, Schulthies S, Sorvisto P, Hautala NM. Temperature changes in deep muscles of humans during ice and ultrasound therapies: an in vivo study. J Orthop Sports Phys Ther 1995;21: 153–7.
31. Williams JW Jr, Holleman DR Jr, Simel DL. Measuring shoulder function with the Shoulder Pain and Disability Index. J Rheumatol 1995;22:727–32.
32. Ware JE, Sherbourne CD. The MOS-36 item short form health survey (SF-36). 1. Conceptual framework and item selection. Med Care 1992;30:473–83.
33. Moffet H, Tardif J, Ouellet D. Fidélité intra et inter-évaluateurs des mesures d'amplitude articulaire à l'épaule chez des sujets normaux et avec une capsulite rétractile. Physio Québec 1997;22: 17–8.
34. Conover WJ. Practical nonparametric statistics. 3rd ed. New York: John Wiley & Sons; 1998.
35. Littell RC, Milliken GA, Stroup WW, Wolfinger RD. SAS system for mixed models. Cary, (NC): SAS Institute; 1996.
36. Eustace JA, Brophy DP, Gibney RP, Bresnihan B, FitzGerald O. Comparison of the accuracy of steroid placement with clinical outcome in patients with shoulder symptoms. Ann Rheum Dis 1997;56:59–63.
37. Jones A, Regan M, Ledingham J, Pattrick M, Manhire A, Doherty M. Importance of placement of intra-articular steroid injections. BMJ 1993;307:1329–30.