Rheumatology 2005;44:529–535 doi:10.1093/rheumatology/keh535
Advance Access publication 18 January 2005

A randomized controlled trial of intra-articular triamcinolone and/or physiotherapy in shoulder capsulitis

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***Objective*. To assess the effectiveness of intra-articular triamcinolone injection and physiotherapy singly or combined in the treatment of adhesive capsulitis of the shoulder.**

***Methods*. Eighty patients with adhesive capsulitis of less than 6 months duration were randomized to one of four groups: Group A, injection of triamcinolone 20 mg and eight sessions of standardized physiotherapy; Group B, injection of triamcinolone 20 mg alone; Group C, placebo injection and eight sessions of standardized physiotherapy; or Group D, placebo injection alone. All subjects were given an identical home exercise programme. Outcome measures were assessed at 6 weeks and 16 weeks. The primary outcome measure was Shoulder Disability Questionnaire (SDQ) score. Secondary outcomes were measurement of pain using a visual analogue scale (VAS), global disability using VAS and range of passive external rotation. A two-way analysis of variance was used to explore the effects of corticosteroid injection and physiotherapy.**

***Results*. At 6 weeks, the SDQ had improved significantly more in the groups receiving corticosteroid injection ($P = 0.004$). Physiotherapy improved passive external rotation at 6 weeks ($P = 0.02$) and corticosteroid injection improved self-assessment of global disability at 6 weeks ($P = 0.04$). There was no interaction effect between injection and physiotherapy. At 16 weeks, all groups had improved to a similar degree with respect to all outcome measures.**

***Conclusion*. Corticosteroid injection is effective in improving shoulder-related disability, and physiotherapy is effective in improving the range of movement in external rotation 6 weeks after treatment.**

KEY WORDS: Adhesive capsulitis, Triamcinolone, Physiotherapy, Randomized controlled trial.

Adhesive capsulitis is a common but poorly understood cause of painful shoulder. Onset is spontaneous and characterized by pain and a progressive global restriction of both active and passive range of motion at the shoulder joint [1].

The natural history of adhesive capsulitis is uncertain. Some believe it is a self-limiting disorder lasting as little as 6 months [2, 3], whilst others suggest it is a more chronic disorder leading to longer term disability [4–7].

Prognostic indicators of outcome are described [5, 8]: poor outcome is associated with previous episodes of shoulder pain, duration of symptoms greater than 1 month at presentation, passive elevation less than 101°, concomitant neck pain and severe day-time pain. A better outcome is associated with slight trauma or prior overuse.

Existing randomized controlled trials of intra-articular steroids for adhesive capsulitis have been examined in recent systematic reviews [8–10]. A search of computerized databases and citation trails found five randomized control trials of treatment in adhesive capsulitis [11–15]. Of these, three trials showed a significant benefit following intra-articular steroid treatment [11, 14, 15]. Other studies were not selective and included causes of shoulder pain other than capsulitis [16–19]. Most of these studies have been criticized for not reporting the randomization procedure, small study size, poor comparability of co-interventions and blinding procedures [9, 10]. There have been few trials of the effectiveness of physiotherapy treatments in adhesive capsulitis and evidence is weak [20–22]. One recent trial of fluoroscopically guided injection with and without physiotherapy found injection superior to physiotherapy at 6 weeks. Although there was greater improvement in those having both injection and physiotherapy compared with injection alone, this did not reach statistical significance [15].

In this study, we examined the effectiveness of intra-articular steroid treatment and physiotherapy alone and in combination in patients with adhesive capsulitis. The particular strengths of this study are the precise definition of the condition and the use of placebo injection in a randomized, controlled design.

Patients and methods

A randomized, blinded, placebo-controlled trial design was used.

Subjects for investigation

Adult subjects (aged 18 yr or above) were recruited from 20 local general practices between October 1998 and April 2002. General practitioners were contacted by letter and invited to refer patients

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Submitted 3 June 2004; revised version accepted 1 December 2004.

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for treatment and possible inclusion in the trial to a direct access shoulder assessment clinic run by a general practitioner with a special interest in rheumatology at a local district general hospital.

Inclusion criteria

The study included patients aged 18 yr or older with a painful shoulder, in the fifth cervical (C5) dermatome distribution, of more than 4 weeks and less than 6 months duration, and with limitation of active and passive range of movement greater than 25% in abduction and external rotation compared with the other shoulder.

Exclusion criteria

Patients were excluded if their pain was less than 4 weeks duration as such patients may have had spontaneous recovery in the early stages. Patients with symptoms of more than 6 months duration were not considered as patients in the chronic stages of this condition and may require a different therapeutic approach. Those who had had a previous intra-articular injection or prior physiotherapy for this episode of shoulder pain were also excluded. The presence of restriction of active and passive range of movement in both external rotation and glenohumeral abduction was taken to indicate a diagnosis of capsulitis as opposed to rotator cuff tendinopathy. Patients with limitation in only one of these planes of movement were therefore excluded. We also excluded patients with evidence of glenohumeral osteoarthritis on plain X-ray, clinical evidence of a complete rotator cuff tear (i.e. positive drop-off sign or weakness of the rotator cuff muscles), clinical evidence of significant cervical spine disease, history of significant trauma to the shoulder or a history of inflammatory joint disease or of a cerebrovascular accident affecting the study shoulder. Those with bilateral adhesive capsulitis were excluded as bilateral symptoms may suggest an underlying systemic cause, and we excluded patients with a contraindication to triamcinolone injection.

Informed consent

Patients were given a patient information leaflet and invited to ask about the implications of the trial to them. A consent form was signed by both the subject and the investigator, and a copy of both forms given to the patient. Ethical approval was gained from the medical research ethics committee for the Queen's University Belfast.

Treatment groups

Subjects were randomly allocated in premuted blocks of four using random number tables to one of four treatments. The randomization process took place in the hospital pharmacy department. Allocations were placed in sealed envelopes which were opened by the physiotherapist teaching the home exercise programme. The groups were:

- Group A: injection of triamcinolone 20 mg (1 ml) and normal saline 2 ml and physiotherapy treatment (injection and physiotherapy group).
- Group B: injection of triamcinolone 20 mg (1 ml) and normal saline 2 ml and no physiotherapy treatment (injection only group).
- Group C: injection with normal saline 3 ml and physiotherapy (physiotherapy group).
- Group D: injection of normal saline 3 ml and no physiotherapy (placebo group).

Injection technique

Injections were given by a combined approach to the shoulder: half the solution (1.5 ml) was injected by an anterior approach and half (1.5 ml) by a lateral approach. A single experienced clinician (RM) performed the procedures without imaging guidance, in keeping with normal clinical practice. The combined approach of anterior glenohumeral and lateral subacromial injection was chosen as both are used in clinical practice and there is no research evidence to indicate a preferential approach.

Physiotherapy

Physiotherapy consisted of eight sessions of standardized treatment over a period of 4 weeks by a single therapist or a nominated deputy if unavailable. The treatment programme was based on local practice and expert opinion in the absence of clear consensus in the literature. It included proprioceptive neuromuscular facilitation [23], Maitland mobilizations [3, 24, 25] which were progressed as condition improved, standardized interferential modality and active exercise therapy [3] with gym equipment.

Blinding procedures

Injections were provided in opaque syringes, and the investigator measuring outcomes (IR) was not present at the time of randomization or injection and was blinded to all study interventions. Both patients and the physiotherapist were blinded to the nature of the injection. Clearly, it was impossible to blind subjects regarding physiotherapy but subjects were asked not to reveal if they were having physiotherapy treatment.

Standardization of co-interventions

Patients who were not already taking analgesics were issued with 50×500 mg paracetamol tablets for pain relief with suggestions to take one or two tablets 4- to 6-hourly as required for pain, taking no more than a maximum of eight tablets daily. Patients recorded all analgesics and anti-inflammatory medication taken in a medication diary.

All subjects were instructed by a physiotherapist in an identical home exercise programme using a video and home exercise instruction sheet. They were asked to record, in their medication diary, when they undertook the exercise programme.

Outcome measures

The baseline record included age, gender, hand dominance, duration of symptoms, manner of onset of pain, precipitating trauma, previous management, history of diabetes and previous history of adhesive capsulitis. Short form 36 (SF-36) general health assessment [26–30] and the hospital anxiety and depression scale (HAD) [31] were administered at baseline and at 16 weeks. Active and passive range of movement in forward flexion, abduction and external rotation were measured to the nearest 2° using a Myrin^{TM} OB goniometer (LIC Rehab Vardrum, Solna, Sweden). Internal rotation was assessed by measuring the distance between the tip of the thumb and the spinous process of the seventh cervical (C7) vertebra in centimetres when reaching behind the back towards the spinous process of the C7 vertebra. Patients recorded daytime pain at rest and subject self-assessment of global function using a 100 mm visual analogue scale. Functional assessments were performed by administration of 22-point shoulder disability questionnaire (SDQ) developed and validated by Croft *et al.* [32]. This self-completed questionnaire asks the patient to evaluate their shoulder function in response to 22 questions. The maximum score

is 22, a score of zero indicates no disability, and a score of 5 and over represents significant disability and a minimal level of detectable change of three points (90% confidence) has been reported [32]. Assessments were made at 6 weeks and 16 weeks by the same observer. At 16 weeks, non-responding participants were defined as patients expressing dissatisfaction with outcome and a desire for further treatment. These patients were offered active treatment with injection and physiotherapy, and a further assessment was made at 24 weeks.

Subjects who expressed a desire to withdraw from the trial due to inability to cope with ongoing symptoms were recorded as having failed treatment and offered alternative treatment.

The primary outcome measure was change from baseline in SDQ as this gives an overall measure of the level of disability due to shoulder pain. Secondary outcome measures were improvement from baseline in pain at rest as measured by visual analogue scale, subjects' rating of global disability on visual analogue scale and range of movement as measured by passive external rotation. External rotation was chosen as the indicator range of movement as restriction in this range has been described as the most severely restricted plane of movement in shoulder capsulitis [33].

Statistical analysis

Sample size was estimated based on data from a previous study of injection therapy in shoulder pain [16]. In that study, a mean difference between placebo and injection at 4 weeks on a five-point pain scale was 1.04 with a within-group standard deviation of 1.6. For a two-way analysis of variance, we required 20 subjects in each group to achieve a power of 0.82 at a 0.05 significance level.

A two way analysis of variance was used to explore the relative contribution of the interventions to the outcome measures at 6 and 16 weeks.

A secondary analysis exploring the effect of subjects dropping out due to failure of treatment was performed using χ^2 tests and survival analysis.

SPSS v11 statistical software was used for statistical calculations.

Results

Study participants

Eighty subjects were recruited and randomly assigned to four groups. One subject was randomized twice and another failed to attend for intervention after randomization; 78 subjects were therefore available for analysis. Twenty subjects were enrolled in Group A (steroid injection and physiotherapy), 19 in Group B (steroid injection and no physiotherapy), 20 in Group C (placebo injection and physiotherapy) and 19 in Group D (placebo injection and no physiotherapy). Six subjects did not return for all follow-up visits: three in Group A, one in Group B, one in Group C and one in Group D. Fifteen subjects withdrew from the study due to failure of the study treatment. Six patients withdrew from Group B, three from Group C and six from Group D (Fig. 1).

Baseline characteristics

No disparity was found between the baseline characteristics of each group including age, duration of symptoms, mode of onset, history of minor trauma, history of diabetes or previous history of capsulitis. The non-dominant side was affected in a small majority of cases ($n = 46$; 59%) (Table 1).

Medication and home exercise diaries were returned by 35% of patients. No significant difference in analgesic usage was noted between groups (mean analgesic per day at 6 weeks: Group A, 1.1; Group B, 1.5; Group C, 0.6; Group D, 2.0). There was no significant difference in compliance with the home exercise programme between groups (mean days per week compliance at week 6: Group A, 7.0; Group B, 5.3; Group C, 5.3; Group D, 7.0).

Compliance with physiotherapy was good with 71% completing all sessions. In patients not completing all sessions, a mean of 5.7 sessions were attended.

Factorial analysis

There was a highly significant improvement ($P = 0.004$) in SDQ at 6 weeks in subjects having steroid injections. No significant improvement in SDQ was shown with physiotherapy and the interaction effect between the interventions was not significant (Tables 2 and 4).

There was a significant ($P = 0.040$) improvement in patient global assessment at 6 weeks with steroid injection, but no significant effect with physiotherapy and no significant interaction effect (Tables 2 and 4).

Physiotherapy significantly ($P = 0.020$) improved passive external rotation at 6 weeks but there was no significant effect of injection and no interaction effect (Table 4).

Analysis of improvement in the range of movement in abduction and internal rotation (thumb–C7 distance) revealed no significant association with either steroid injection or physiotherapy.

Analysis of improvement in pain at rest revealed no significant findings at 6 weeks.

Analysis at 16 weeks. There was no significant difference between interventions in all main outcome measures at 16 weeks (Table 3).

At 16 weeks, eight patients expressed dissatisfaction with the outcome of their treatment and were offered further intervention. Five patients were from Group C (placebo injection and physiotherapy) and three from group D (placebo injection and no physiotherapy). Four of these patients received injection and four received physiotherapy treatment. These subjects' mean SDQ improved from 13.1 (S.D. 4.7) at 16 weeks to 8.4 (S.D. 6.0) at 24 weeks.

Analysis with imputed missing data. Six subjects were lost to follow-up and 15 dropped out due to failure of treatment during the course of the trial. We reanalysed the data using imputed values produced by using the EM (expectation maximization) algorithm (SPSS v11.0). Analysis with imputed data revealed the same significant findings as the original analysis at week 6. At week 16, analysis with imputed data revealed a significant association between change in pain at rest at 16 weeks and steroid injection.

Analysis of subjects dropping out due to failed treatment

We also looked to see if there were significant differences in numbers dropping out in each group due to failure of treatment. Significantly more patients dropped out in Group D (placebo injection and no physiotherapy) and in Group B (steroid injection and no physiotherapy (Pearson $\chi^2 = 8.72$, $P = 0.033$). No subjects dropped out of Group A (steroid injection and physiotherapy).

Secondary analysis by survival analysis method

A further secondary analysis was performed using survival analysis. Life tables were produced using time to drop out due to failed treatment as the survival variable and comparisons made between treatment groups using the Wilcoxon (Gehan) statistic. There were significant differences in the survival experience of the groups overall ($P = 0.041$). When survival experience is compared pairwise significantly better survival is seen in Group A (steroid injection and physiotherapy) as compared with Group D (placebo

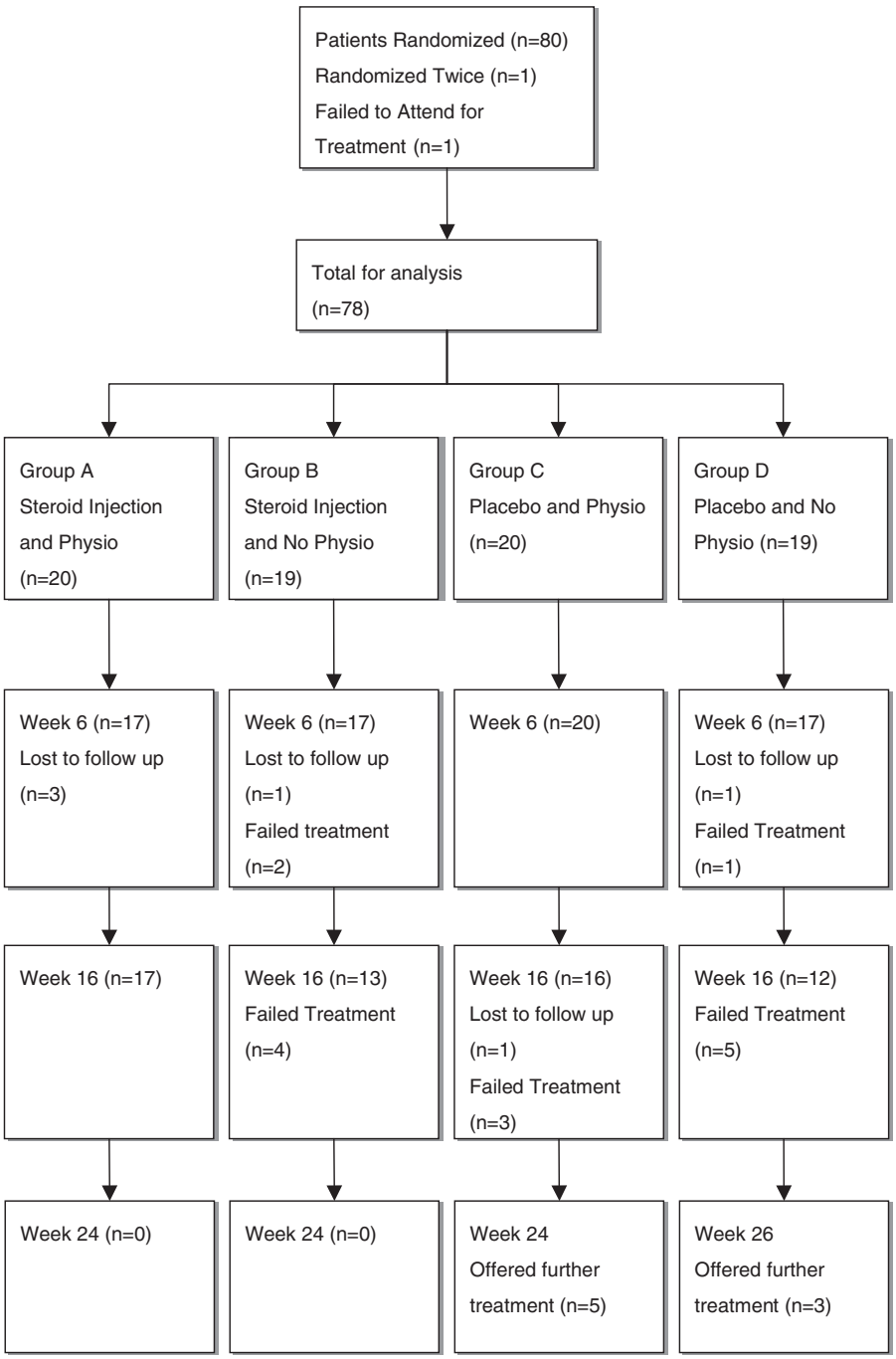

FIG. 1. Flow diagram indicating progress of subjects through the study and stage at which patients were lost to follow-up or dropped out due to failure of treatment.

injection and no physiotherapy) ($P = 0.010$) and in Group A (steroid injection and physiotherapy) compared with Group B (steroid injection and no physiotherapy) ($P = 0.010$). Other pairwise comparisons are not significant.

Discussion

Our study showed positive findings. There was an improvement in overall shoulder disability and patient global assessment at 6 weeks in subjects treated with corticosteroid injection. The range of external rotation improved at 6 weeks in those having physiotherapy treatment. These results support the findings of previous studies showing improvement in early outcome after corticosteroid injection in shoulder capsulitis [14, 15].

Previous trials have evaluated the treatment of shoulder pain with physiotherapy and corticosteroid injections both separately and together [13–15, 18, 19, 34, 35]. One recent trial of fluoroscopically guided injection of triamcinolone 40 mg with and without physiotherapy [15] found that injection was superior to physiotherapy and placebo at 6 weeks in terms of pain and function. Injections were given under radiological guidance so it may not be appropriate to generalize these findings to usual clinical practice. Three other trials were unable to show significant differences between injections and physiotherapy treatments [13, 18, 19]. In two trials in Dutch general practice, injection

TABLE 1. Baseline characteristics of patients in the four intervention groups ($n = 78$)[a]

Characteristic	Group A, $n = 20$	Group B, $n = 19$	Group C, $n = 20$	Group D, $n = 19$
Age (yr)	56.3 (6.4)	52.3 (9.3)	52.6 (7.7)	55.2 (9.4)
Duration of symptoms (weeks)	14.2 (4.4)	12.2 (5.3)	14.4 (4.4)	14.9 (3.7)
% Female	45	68	70	53
% Dominant	45	42	30	47
% Minor trauma	30	37	25	37
% First episode	80	79	85	79
% Diabetic	5	5	5	11
SDQ	13.6 (4.0)	15.8 (4.5)	14.9 (4.8)	14.1 (4.6)
Passive ROM—external rotation	31.6 (13.3)	31.7 (14.1)	28.1 (15.0)	26.7 (10.3)
VAS pain at rest	31.2 (21.0)	37.8 (19.8)	45.8 (24.7)	44.1 (33.7)
VAS global disability	57.2 (16.2)	65.0 (17.2)	63.9 (21.4)	62.7 (26.9)
SF-36 scores:				
Physical function	69 (22.0)	56.8 (23.1)	67.8 (20.4)	64.7 (30.3)
Role limitation physical	38.8 (39.3)	10.3 (26.6)	36.3 (46.9)	50.0 (42.4)
Role limitation mental	68.3 (41.2)	52.9 (47.3)	61.6 (46.3)	58.8 (43.4)
Social functioning	75.0 (22.1)	67.2 (27.8)	70.0 (25.8)	77.1 (24.7)
Mental health	73.3 (20.0)	64.9 (20.3)	62.6 (17.8)	69.4 (22.2)
Vitality	56.5 (20.5)	45.9 (20.0)	52.0 (19.6)	53.8 (21.9)
Bodily pain	42.6 (20.0)	23.4 (16.1)	29.3 (15.9)	40.4 (27.6)
Health perception	73.2 (20.0)	64.9 (21.1)	66.1 (24.3)	61.7 (19.6)
Change in health	47.5 (18.0)	45.6 (25.4)	46.1 (20.3)	38.2 (20.0)
HAD anxiety	5.1 (3.8)	7.2 (5.3)	6.4 (3.6)	5.9 (3.9)
HAD depression	3.9 (3.0)	4.9 (4.2)	4.7 (3.4)	4.3 (4.1)

[a]Values, except where indicated otherwise, are mean with S.D. in brackets.

TABLE 2. Mean values of change from baseline in main outcome measures in treatment groups and treatment effect compared with placebo group at 6 weeks after randomization

	Mean change from baseline (S.D.)				Treatment effect (95% CI)		
Outcome measure	Group A	Group B	Group C	Group D	Group A	Group B	Group C
SDQ	−7.8 (5.7)	−6.1 (6.4)	−3.5 (4.9)	−3.1 (3.4)	4.7 (1.4–7.9)**	3.1 (−0.6–6.7)	0.4 (−2.4–3.3)
VAS global	−37.8 (18.1)	−28.4 (24.1)	−26.1 (26.7)	−16.8 (22.0)	21.1 (7–35.1)*	11.6 (−5.0–28.3)	9.3 (−7.2–25.8)
VAS pain at rest	−16.3 (26.4)	−9.7 (18.5)	−17.6 (39.1)	−5.4 (27.8)	10.9 (−8.0–29.8)	4.3 (−13.0–21.5)	12.2 (−10.9–35.2)
Passive external rotation	21.0 (16.5)	14.3 (15.2)	16.7 (13.2)	6.6 (13.2)	14.4 (3.8–25.1)*	7.7 (−2.6–18.0)	10.1 (1.1–19.1)*

*$P < 0.05$ versus Group D.
**$P < 0.05$ versus Groups C and D.

TABLE 3. Mean values of change from baseline in main out come measures in treatment groups (Groups A, B, C) and treatment effect compared with placebo group (Group D) at 16 weeks after randomization

	Mean change from baseline (S.D.)				Treatment effect (95% CI)		
Outcome measure	Group A	Group B	Group C	Group D	Group A	Group B	Group C
SDQ	−7.6 (5.8)	−7.8 (5.9)	−5.6 (5.8)	−6.6 (5.4)	1.0 (−3.4–5.4)	1.3 (−3.6–6.1)	−1.0 (−3.6–6.1)
VAS global	−39.2 (25.8)	−35.6 (26.9)	−42.7 (29.4)	−40.7 (26.7)	−1.5 (−21.7–18.8)	−5.1 (−27.8–17.6)	2.0 (−27.8–17.6)
VAS pain at rest	−16.1 (24.4)	−9.8 (24.7)	−29.3 (33.7)	−24.5 (34.2)	−8.4 (−30.7–13.8)	−14.8 (−40.0–10.5)	4.8 (−21.8–31.5)
Passive external rotation	19.7 (19.7)	19.1 (19.2)	18.0 (14.0)	22.2 (18.2)	−2.5 (−17.2–12.3)	−3.1 (−30.4–27.9)	−4.2 (−18.9–12.7)

TABLE 4. Analysis of effect of steroid injection and physiotherapy on change in outcome measures between baseline and 6 weeks by two-way ANOVA. Main effect of steroid injection is significant in mean improvement in SDQ ($F = 8.7$, $P < 0.005$) and in mean improvement in Global VAS ($F = 4.5$, $P < 0.05$). Main effect of physiotherapy is significant in mean improvement in passive external rotation ($F = 5.7$, $P < 0.05$). Interaction effects are not significant[a]

	Steroid injection	No steroid Injection	Difference between means (95% CI)	P	Physio.	No physio.	Difference between means (95% CI)	P
SDQ	−6.9 (6.0)	−3.3 (4.2)	3.6 (1.2–6.1)	0.004	−5.5 (5.6)	−4.6 (5.3)	0.9 (−1.7–3.5)	0.406
Global VAS	−33.4 (21.3)	−21.8 (24.7)	11.6 (0.4–22.8)	0.040	−33.4 (21.3)	−21.8 (24.7)	9.2 (−2.1–20.6)	0.098
Passive external rotation	17.7 (16.0)	12.2 (13.0)	5.5 (−1.7–12.8)	0.092	18.7 (14.8)	10.4 (14.6)	8.3 (1.2–15.3)	0.020
Pain at rest VAS	−13.2 (22.9)	−12.0 (34.5)	1.2 (−13.1–15.5)	0.838	−17.0 (33.4)	−7.4 (23.6)	9.6 (−4.5–23.7)	0.195

[a]Values are mean (S.D.).

provided quicker relief of symptoms than physiotherapy [14, 34]. One of these studies assessed patients defined as having painful stiff shoulder [14] similar to our criteria for adhesive capsulitis. They used a higher dosage and greater number of injections (up to three) than in our study. The second Dutch study assessed patients defined as having 'synovial disorders' of the shoulder, a definition that includes patients with disorders arising from the subacromial, glenohumeral and acromioclavicular joints, a broader definition than used in the present study. Injection was better than physiotherapy or manipulation at 5 weeks. Their definition of physiotherapy excluded mobilization techniques which would not be comparable with the definition of physiotherapy used in our study or normal physiotherapy practice in the United Kingdom.

In a recent trial in the United Kingdom, primary care community physiotherapy and local corticosteroid injections were found to be similarly effective [35]. They used a broad definition of shoulder pain with no discrimination between capsulitis and other shoulder syndromes. The changes in SDQ of 2.56 with physiotherapy and 3.03 with injection were less than in our study where we recorded improvements in SDQ of 6.9 with injection and 5.6 with physiotherapy. It may be that this difference is explained by higher baseline measures of disability in the present study and our study includes only patients with capsulitis of the shoulder in contrast to the broader definition used in Hay *et al.*'s study [35]. Hay's group found no improvement in range of movement, whereas our study showed an increased range of external rotation with physiotherapy at 6 weeks although improvement in other measures of range of movement was not associated with physiotherapy.

Although the present study found improvement with injection and physiotherapy, there was no interaction detected between the two treatments in any single outcome measure. The effect of physiotherapy was detected in range of movement and injection in measures of disability and global assessment. The positive effect of these treatments may therefore be seen in different aspects of dysfunction associated with shoulder capsulitis. However, the clinical significance of improvement in range of external rotation when not associated with changes in measures of disability must be questioned.

Completion is difficult for patients in a study which involves an injection with uncertain results and an intensive physiotherapy programme. It was little surprise that failure of treatment was a significant reason for non-completion. The overall participation rates are less than another similar study [15] where completion rates were 77 out of 93 (83%) at 12 months. We recruited 80 patients of whom 57 (71%) completed the study at 16 weeks. The most common reason for dropping out was unwillingness of the subject to continue due to failure of treatment. Subjects were allowed, in keeping with ethical guidelines, to withdraw from the trial if they felt unable to cope with ongoing pain and expressed a desire for alternative treatment. Most missing data were from subjects who had failed treatment before 16 weeks. This is a potential source of bias as those subjects who felt their treatment had failed were missing from the analysis, particularly at week 16.

No benefit was shown beyond 6 weeks, but missing data due to subjects lost to follow-up and dropping out due to failure of treatment makes interpretation at 16 weeks difficult. We addressed this by secondary analysis using imputed values, analysis of failure of treatment between groups and survival analysis. Analysis using imputed values demonstrated a significant effect of steroid injection at 16 weeks on pain outcome. Our analysis of failure of treatment and survival analysis revealed that significantly fewer subjects dropped out due to failed treatment in the group having both physiotherapy and active injection. This could suggest the possibility of a more sustained treatment effect, although this should be interpreted with caution. It may be, however, that patients continued in this group for reasons other than treatment effectiveness.

Further work is necessary to assess the long-term effectiveness of these treatments, but it may be difficult for subjects to adhere to a trial protocol when allocated to a placebo group.

Injections in this study were given by a combined lateral and anterior approach at a dose of 20 mg of triamcinolone guided anatomically. Other studies have used different approaches and dosages, and practice in clinical care varies considerably. Further research is required to ascertain the most effective dose and approach to shoulder injection in this condition. Previous work has suggested that accuracy of injection is important with regard to outcome of corticosteroid injection treatment [36], and it has also been shown that injection, particularly of the shoulder joint, is often inaccurate [37]. All injections in the present study were performed by a single experienced clinician reducing potential bias from variation in injection accuracy. In this study, injections were performed without imaging guidance. Further studies could explore the effect of improving injection accuracy by the use of imaging such as ultrasonography.

The physiotherapy approach used in this study was standardized and included proprioceptive neuromuscular facilitation, Maitland mobilizations, which were progressed as condition improved, standardized interferential modality and active exercises with gym equipment. There is little evidence on which to base decisions regarding physiotherapy treatment for capsulitis of the shoulder. Little work has been done to evaluate which of the many physiotherapeutic approaches to shoulder pain is most effective and which combinations of approaches are most appropriate [20]. We are unsure which aspects of the physiotherapy treatment improved the range of movement in external rotation. Further work in this area is recommended.

The findings of the trial presented here reinforce the evidence that corticosteroid injection is effective for capsulitis of the shoulder in the short term. The clinical relevance of the finding that physiotherapy improves the range of external rotation, which was not influenced by injection, is unclear. The finding that these interventions have positive effects on different aspects of shoulder-related disability raises the possibility of benefit in combining the treatments. This is in keeping with a recent study comparing corticosteroid injection with and without physiotherapy, which suggested a clinical but not statistically significant benefit of combination treatments [15].

Strengths and weaknesses

This study has some notable strengths. We took care to define subjects using strict selection criteria; we used a placebo group and applied rigorous blinding wherever possible.

Overall, the only positive differences between treatments were at 6 weeks. This is very early in the treatment programme and the clinical relevance of treatment effects at this stage, if not maintained in the longer term, is uncertain. The lack of an overall effect at 16 weeks may be explained by the self-limiting nature of the disorder and indicate improvement independent of treatment used. It is possible, however, that our study had insufficient power to detect improvements beyond 6 weeks and the finding that patients are less likely to 'fail' treatment in the combined treatment group deserves further consideration.

Conclusions

In the treatment of adhesive capsulitis of the shoulder, corticosteroid injection is effective in improving shoulder-related disability at 6 weeks following treatment. Physiotherapy treatment is effective in improving the range of external rotation at 6 weeks after commencement of treatment.

Longer-term outcome of treatment is difficult to assess because of loss to follow-up; however, failure of treatment is less likely with a combination of physiotherapy and corticosteroid injection.

Rheumatology	Key messages
	• In the treatment of adhesive capsulitis of the shoulder, corticosteroid injection is effective in improving shoulder-related disability at 6 weeks following treatment. • Physiotherapy treatment is effective in improving range of external rotation at 6 weeks after commencement of treatment.

Acknowledgements

Professor D. MacAuley from the Department of Epidemiology at The Queen's University, Belfast contributed to the paper by assisting in the editing of the text. The study was supported by a project grant from the Arthritis Research Campaign.

The authors have declared no conflicts of interest.

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