Effectiveness of corticosteroid injections versus physiotherapy for treatment of painful stiff shoulder in primary care: randomised trial

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D A W M van der Windt, B W Koes, W Devillé, A J P Boeke, B A de Jong, L M Bouter

Abstract

Objective To compare the effectiveness of corticosteroid injections with physiotherapy for the treatment of painful stiff shoulder.

Design Randomised trial.

Setting 40 general practices.

Subjects 109 patients consulting general practitioners for shoulder pain were enrolled in the trial.

Interventions Patients were randomly allocated to 6 weeks of treatment either with corticosteroid injections (53) or physiotherapy (56).

Main outcome measures Outcome assessments were carried out 3, 7, 13, 26, and 52 weeks after randomisation; some of the assessments were done by an observer blind to treatment allocation. Primary outcome measures were the success of treatment as measured by scores on scales measuring improvement in the main complaint and pain, and improvement in scores on a scale measuring shoulder disability.

Results At 7 weeks 40 (77%) out of 52 patients treated with injections were considered to be treatment successes compared with 26 (46%) out of 56 treated with physiotherapy (difference between groups 31%, 95% confidence interval 14% to 48%). The difference in improvement favoured those treated with corticosteroids in nearly all outcome measures; these differences were statistically significant. At 26 and 52 weeks differences between the groups were comparatively small. Adverse reactions were generally mild. However, among women receiving treatment with corticosteroids adverse reactions were more troublesome: facial flushing was reported by 9 women and irregular menstrual bleeding by 6, 2 of whom were postmenopausal.

Conclusions The beneficial effects of corticosteroid injections administered by general practitioners for treatment of painful stiff shoulder are superior to those of physiotherapy. The differences between the intervention groups were mainly the result of the comparatively faster relief of symptoms that occurred in patients treated with injections. Adverse reactions were generally mild but doctors should be aware of the potential side effects of injections of triamcinolone, particularly in women.

Introduction

Shoulder pain is a common complaint in primary care; estimates of the annual incidence in general practice vary from 6.6 to 25 cases per 1000 patients.1–3 Shoulder conditions that are characterised by a painful restriction of the passive range of motion, particularly of lateral rotation and abduction, are usually referred to as painful stiff shoulder or capsular syndrome.3,4 Despite the fact that in many cases symptoms persist, few patients are referred to a specialist.5–7 In primary care, diagnosis is usually based only on history and physical examination.

Treatment often consists of physiotherapy or local infiltration of a corticosteroid.1 Systematic reviews have shown that the effectiveness of these interventions remains questionable.1,8–9 Our objective was to compare the effectiveness of corticosteroid injections with physiotherapy on the treatment of painful stiff shoulder in a primary care setting.

Subjects and methods

Subjects

Consecutive patients who consulted one of 60 participating general practitioners were considered for participation. The main inclusion criteria were that patients had a painful restriction of glenohumeral mobility, were age 18 years or older, and gave informed consent. Patients were excluded if they had bilateral symptoms; if they had had treatment with corticosteroid injections or physiotherapy during the preceding six months; if they had contraindications to treatment; if they had had surgery, dislocation, or fractures in the shoulder area; if they had insulin-dependent diabetes mellitus, systemic disorders of the musculoskeletal system, or neurological disorders. Patients who met the selection criteria were referred to the research centre by their general practitioner. The study protocol was approved by the Ethics Committee of the University Hospital of the Vrije Universiteit Amsterdam.

At the research centre an independent observer, who was a trained physiotherapist, confirmed that all selection criteria had been met. The diagnosis of painful stiff shoulder (capsular syndrome) was made using the diagnostic guidelines for shoulder complaints issued by the Dutch College of General Practice.

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Department of Rehabilitation Medicine, Academic Medical Centre, University of Amsterdam, Melberghof 9, 105 AZ Amsterdam

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Practitioners—that is, passive glenohumeral mobility must be painful and limited, lateral rotation must be relatively more restricted than abduction and medial rotation, and there must be no clear signs (painful arc, positive resistance tests, loss of power) that the shoulder pain was caused by another condition. After enrollment prognostic indicators and baseline values of outcome measures were assessed.

**Randomisation**
Patients were randomly allocated six weeks of either treatment with injections or physiotherapy (figure). The use of permuted blocks of four patients guaranteed nearly equal distribution of patients between the interventions. The random sequence of the blocks was generated using random number tables. Numbered, opaque, sealed envelopes containing the treatment allocation were prepared before the trial. After selection and baseline assessment an administrative assistant opened the next envelope in the appropriate stratum.

**Interventions**
Intra-articular injections of 40 mg triamcinolone acetonide were given by the general practitioners using the posterior route. Nearly all of the general practitioners had attended training in this technique before the study; although most had had previous experience with the technique. No more than three injections were given during the six weeks.

Physiotherapy consisted of 12 sessions of 30 minutes during which all patients received passive joint mobilisation and exercise treatment. Ice, hot packs, or electrotherapy could be used to reduce pain. Acupuncture and high velocity thrust manipulations were not allowed under the protocol. Ultrasound treatment was not used because it was not considered to be effective for this disorder. Treatment could be adjusted according to the severity of symptoms. Physiotherapists and general practitioners recorded details of treatment on standardised forms which included spaces for documenting deviations from protocol and adverse reactions. Adverse reactions were also recorded by patients on their own forms.

Patients were allowed to continue taking drugs for pain if they had started before enrollment; drugs could also be prescribed if pain was severe. All other interventions were to be avoided during the study.

**Outcome assessment**
The outcome of the intervention was assessed at 3 and 7 weeks. Additional follow-up assessments were scheduled for 13, 26, and 52 weeks. The assessments at 13 and 52 weeks were by postal questionnaire only but contained all primary outcome measures.

**Primary outcome measures**
Patients were asked to score their improvement on a six point Likert scale. For the analysis of success rates for each treatment patients who rated themselves as having made a complete recovery or as having much improvement were counted as successes. Patients were asked to score the pain associated with their main complaint and the severity of their pain during the day and at night on a 100 mm visual analog scale; the score of 100 indicates very severe pain. Functional disability was evaluated with the shoulder disability questionnaire, a 16 item scale consisting of common situations that might cause shoulder pain. Scores on the questionnaire range from 0 to 100; 100 indicates severe disability.

**Secondary outcome measures**
After a standardised physical examination the independent observer scored the overall clinical severity of the disorder on a visual analog scale. Using the healthy shoulder as a reference, the observer measured the restriction of mobility during passive lateral rotation and glenohumeral abduction with a digital inclinometer (EDI-320, Cybex, Ronkonkoma, New York). The independent observer did not know to which intervention the patient had been assigned. To optimise blinding the patient was instructed by the administrative assistant not to reveal any information about their treatment. In all patients the actual or potential injection site was covered with gauze. Immediately after each examination the observer was asked to guess to which intervention the patient had been assigned.
Results

Patient flow and follow up
A total of 109 out of 203 patients referred by their general practitioners were enrolled in the trial. Most of the exclusions (73/94) were made because the independent observer could not confirm capsular syndrome as the main cause of shoulder pain. Other probable causes of pain were diagnosed as rotator cuff tendinitis, subacromial bursitis, and dysfunction of the cervical spine. Twenty one patients were excluded for other reasons (figure).

One patient withdrew from the study immediately after randomisation, refusing to have any injections. A total of six patients (5.5%) withdrew from the study, four of whom reported complete recovery before withdrawal. All patients who withdrew from the study were included in the statistical analysis until withdrawal.

Characteristics of patients
Fifty three patients were allocated to treatment with injections and 56 patients to physiotherapy. Despite randomisation there were some differences between the intervention groups in regard to sex, the onset of pain, involvement of the dominant side, concomitant neck pain, previous episodes of shoulder pain, baseline severity of the main complaint, and rating of the pain at night (table 1).

Interventions
Twenty five patients (48%) allocated to receive injections had three injections. The mean number of injections was 2.2 (SD 0.8). All patients allocated to physiotherapy received passive joint mobilisation and exercise treatment. Additional electrotherapy was used in 41 patients and ice or hot packs in 33.

At baseline, the use of pain medication was evenly distributed between the two groups; 15 patients in each group used paracetamol (acetaminophen) or non-steroidal anti-inflammatory drugs. The number of patients needing additional treatment after six weeks and the types of treatment received are shown in table 2. Additional treatment was given more often to patients allocated to physiotherapy (47% vs 42%).

The observer correctly guessed the allocated treatment for 65 (60%) out of 108 patients after 7 weeks and for 51 (48%) out of 105 after 26 weeks. The frequency of correct guesses was similar in both groups (30/52 (58%) for patients having injections and 35/56 (63%) for those having physiotherapy at 7 weeks).

Outcome
The mean improvement in outcome measures at each point of follow up is shown in table 3. Using the intention to treat analysis we found a statistically significant improvement between the groups over time was done with a multivariate analysis of variance (repeated measurements design); this analysis included the results of outcome assessments at each follow up (at baseline, 3, 7, 13, 26, and 52 weeks).

Calculations of sample size were based on the ability to detect a clinically important difference in success rate of 25% between the two groups. We assumed a success rate of 40% in the group having the least successful treatment and thus estimated the target sample size at 60 patients in each group (two tailed, α = 0.05, β = 0.20).

Table 2 Number (percentage) of patients with painful stiff shoulder needing treatment for residual pain or disability at seven week follow up (treatment no longer restricted to interventions as described by protocol)

<table>
<thead>
<tr>
<th>Additional treatment</th>
<th>All (n=108)*</th>
<th>Treated with corticosteroid injection (n=52)*</th>
<th>Treated with physiotherapy (n=56)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>44 (41)</td>
<td>30 (58)</td>
<td>14 (25)</td>
</tr>
<tr>
<td>Paracetamol or non-steroidal anti-inflammatory drugs</td>
<td>6 (5)</td>
<td>2 (4)</td>
<td>4 (7)</td>
</tr>
<tr>
<td>Corticosteroid injection</td>
<td>16 (15)</td>
<td>6 (11)</td>
<td>10 (18)</td>
</tr>
<tr>
<td>Physiotherapy</td>
<td>27 (25)</td>
<td>8 (15)</td>
<td>19 (34)</td>
</tr>
<tr>
<td>Corticosteroid injections and physiotherapy</td>
<td>13 (12)</td>
<td>5 (10)</td>
<td>8 (14)</td>
</tr>
<tr>
<td>Arthroscopic surgery</td>
<td>2 (2)</td>
<td>1 (2)</td>
<td>1 (2)</td>
</tr>
</tbody>
</table>

*One patient withdrew from the study after three weeks so no information on additional treatment was available.

Statistical analysis
The changes in scores of symptoms over time were calculated for each patient by subtracting the results at baseline from those at follow up. The differences in the changes in symptom scores between the two groups were computed with 95% confidence intervals. The principal analysis was performed on an intention to treat basis. In an alternative analysis all patients who had not been treated according to protocol during the intervention period were excluded; these were cases of non-compliance with treatment and violation of protocols. Statistical analysis of the differences in improvement between the groups over time was done using a multivariate analysis of variance (repeated measurements design); this analysis included the results of outcome assessments at each follow up (at baseline, 3, 7, 13, 26, and 52 weeks).

Results

Patient flow and follow up
A total of 109 out of 203 patients referred by their general practitioners were enrolled in the trial. Most of the exclusions (73/94) were made because the independent observer could not confirm capsular syndrome as the main cause of shoulder pain. Other probable causes of pain were diagnosed as rotator cuff tendinitis, subacromial bursitis, and dysfunction of the cervical spine. Twenty one patients were excluded for other reasons (figure).

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At baseline, the use of pain medication was evenly distributed between the two groups; 15 patients in each group used paracetamol (acetaminophen) or non-steroidal anti-inflammatory drugs. The number of patients needing additional treatment after six weeks and the types of treatment received are shown in table 2. Additional treatment was given more often to patients allocated to physiotherapy (47% vs 42%).

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difference between the groups which favoured treatment with corticosteroid injections. In a multivariate analysis differences in prognosis at baseline had little influence on the outcome of the study (data not shown). At 7 weeks 40 (77%) out of 52 patients treated with injections were considered to be treatment successes compared with 26 (46%) out of 56 treated with physiotherapy (difference between groups 31%, 95% confidence interval 14% to 48%). The difference in improvement was in the same direction for all outcome measures; these differences were statistically significant (multivariate analysis of variance) for most outcome measures but not for restriction of abduction and severity of the main complaint. The change in scores for the main complaint had a non-gaussian distribution. Non-parametric testing (Mann-Whitney U test) indicated that there was a significantly greater improvement in the main complaint among those treated with corticosteroids at 3, 7, 14, and 52 weeks. Table 3 shows that the differences between the groups were mainly due to the comparatively fast relief of symptoms occurring among those receiving corticosteroids. At assessment 26 and 52 weeks there were comparatively small differences between the groups.

An alternative analysis was conducted which excluded 12 patients who were not treated according to protocol. For all outcome measures the results were similar to those in the intention to treat analysis. At 7 weeks treatment was considered to be successful in 39 (77%) out of 51 patients receiving injections and in 22 (48%) out of 46 for those treated with physiotherapy.

Adverse reactions
Mild adverse reactions, mainly increased pain after treatment, were reported by more than 50% (62/128) of all patients (table 4). Few adverse reactions occurred after physiotherapy. Adverse reactions to corticosteroids were particularly frequent in women; facial flushing was reported by nine and irregular menstrual bleeding by six women, two of whom were postmenopausal.

Discussion
This paper describes a randomised trial in a primary care setting that compared two common interventions, corticosteroid injections and physiotherapy, for treatment of painful stiff shoulder. The analysis done on an intention to treat basis and an alternative analysis that excluded patients whose treatment deviated from the protocol showed that corticosteroid injections were superior to physiotherapy in terms of the success of treatment; improvement in degree of lateral rotation; improvement in clinical severity; and in relief of the main complaint. The change in scores for the main complaint had a non-gaussian distribution. Non-parametric testing results in statistically significant differences at 3, 7, 14, and 52 weeks.

Table 3 Mean (SD) improvement in outcome measures in patients with painful stiff shoulder and differences between groups by treatment at different points in follow up

<table>
<thead>
<tr>
<th>Patients treated with corticosteroid injection*</th>
<th>Patients treated with physiotherapy*</th>
<th>Mean (95% CI) difference between groups</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement in rating of severity†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Associated with main complaint:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 weeks</td>
<td>32 (26)</td>
<td>17 (21)</td>
<td>15 (6 to 24)</td>
</tr>
<tr>
<td>7 weeks</td>
<td>58 (28)</td>
<td>32 (29)</td>
<td>26 (15 to 37)</td>
</tr>
<tr>
<td>13 weeks</td>
<td>66 (29)</td>
<td>47 (33)</td>
<td>19 (7 to 31)</td>
</tr>
<tr>
<td>26 weeks</td>
<td>63 (31)</td>
<td>54 (33)</td>
<td>9 (3 to 22)</td>
</tr>
<tr>
<td>52 weeks</td>
<td>70 (24)</td>
<td>59 (30)</td>
<td>11 (1 to 23)</td>
</tr>
<tr>
<td>Of pain during the day:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 weeks</td>
<td>22 (20)</td>
<td>10 (15)</td>
<td>12 (5 to 18)</td>
</tr>
<tr>
<td>7 weeks</td>
<td>35 (20)</td>
<td>23 (24)</td>
<td>12 (4 to 21)</td>
</tr>
<tr>
<td>13 weeks</td>
<td>36 (26)</td>
<td>27 (31)</td>
<td>9 (-3 to 28)</td>
</tr>
<tr>
<td>26 weeks</td>
<td>32 (25)</td>
<td>32 (28)</td>
<td>0 (-10 to 10)</td>
</tr>
<tr>
<td>52 weeks</td>
<td>38 (23)</td>
<td>35 (26)</td>
<td>3 (-7 to 13)</td>
</tr>
<tr>
<td>Of pain at night:</td>
<td></td>
<td></td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>3 weeks</td>
<td>13 (17)</td>
<td>0 (18)</td>
<td>13 (6 to 20)</td>
</tr>
<tr>
<td>7 weeks</td>
<td>24 (20)</td>
<td>9 (20)</td>
<td>15 (7 to 22)</td>
</tr>
<tr>
<td>26 weeks</td>
<td>29 (24)</td>
<td>27 (27)</td>
<td>2 (-9 to 11)</td>
</tr>
<tr>
<td>Improvement in rating of shoulder disability§</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>External rotation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 weeks</td>
<td>6 (14)</td>
<td>-3 (12)</td>
<td>9 (3 to 14)</td>
</tr>
<tr>
<td>7 weeks</td>
<td>13 (16)</td>
<td>-2 (14)</td>
<td>15 (7 to 20)</td>
</tr>
<tr>
<td>26 weeks</td>
<td>16 (18)</td>
<td>7 (21)</td>
<td>9 (1 to 16)</td>
</tr>
<tr>
<td>Abduction:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 weeks</td>
<td>2 (12)</td>
<td>-3 (13)</td>
<td>5 (3 to 8)</td>
</tr>
<tr>
<td>7 weeks</td>
<td>4 (11)</td>
<td>-1 (14)</td>
<td>5 (2 to 10)</td>
</tr>
<tr>
<td>26 weeks</td>
<td>9 (12)</td>
<td>7 (17)</td>
<td>2 (-3 to 8)</td>
</tr>
<tr>
<td>Improvement in degree of restriction of range of motion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>External rotation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 weeks</td>
<td>6 (14)</td>
<td>-3 (12)</td>
<td>9 (3 to 14)</td>
</tr>
<tr>
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<td>13 (16)</td>
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</tr>
<tr>
<td>Abduction:</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>3 weeks</td>
<td>2 (12)</td>
<td>-3 (13)</td>
<td>5 (3 to 8)</td>
</tr>
<tr>
<td>7 weeks</td>
<td>4 (11)</td>
<td>-1 (14)</td>
<td>5 (2 to 10)</td>
</tr>
<tr>
<td>26 weeks</td>
<td>9 (12)</td>
<td>7 (17)</td>
<td>2 (-3 to 8)</td>
</tr>
</tbody>
</table>

*Includes 52 patients treated according to protocol and 5 patients treated with both interventions. $Includes 56 patients treated according to protocol and one patient treated with both interventions.

Table 4 Frequency of adverse reactions to treatment for painful stiff shoulder. Values are number of occurrences unless indicated otherwise

<table>
<thead>
<tr>
<th>Adverse reactions</th>
<th>Patients treated with injection (n=57)*</th>
<th>Patients treated with physiotherapy (n=57)†</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of patients having any adverse reaction</td>
<td>30 (53%)</td>
<td>32 (56%)</td>
</tr>
<tr>
<td>Pain after treatment:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lasting &lt;1 day</td>
<td>9</td>
<td>17</td>
</tr>
<tr>
<td>Lasting ≥2 days</td>
<td>16</td>
<td>13</td>
</tr>
<tr>
<td>Facial flushing</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>Irregular menstrual bleeding</td>
<td>5§</td>
<td>0</td>
</tr>
<tr>
<td>Fever reported by patient</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Skin irritation</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Other reaction</td>
<td>6§</td>
<td>4§</td>
</tr>
</tbody>
</table>

*Includes 52 patients treated according to protocol and 5 patients treated with both interventions. $Includes 56 patients treated according to protocol and one patient treated with both interventions.

Reactions included sweating, fatigue, dry mouth, dizziness, and headache.
Contributors: DAWMW contributed to the design of the study, planned and coordinated data collection, analysed the data, and wrote the paper. All other authors contributed important suggestions to the writing of the paper. BKW contributed to designing the study and supervised the planning, coordination, and collection of data. WOL provided statistical advice, and assisted with the analysis and interpretation of the data. APJB contributed to designing the study, provided advice on planning and coordination, and participated in data collection. BAJ had the original idea for the study, contributed to designing the study, and participated in planning and organising the study. LMB contributed to designing the study, discussed core ideas, and chaired the trial supervising committee.


Conflict of interest: None.

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(Accepted 14 August 1998)