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ORIGINAL ARTICLES

Role of corticosteroid Injections versus Physiotherapy for the Treatment of Painful Stiff Shoulder: A Randomised Control Trial

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Abstract

Study Question: among local corticosteroid injections and physiotherapy, which is the more effective treatment for painful stiff shoulder?

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

Design: *Randomised trial.*

Setting: *Physical Medicine Outpatient Department (OPD) of BSMMU and NITOR*

Subjects: Total 119 patients reported to the Outpatient Department (OPD) of NITOR and BSMMU with pain and stiffness in shoulder were enrolled in the trial.

Interventions: *Patients were randomly allocated to 6 weeks of treatment either with corticosteroid injections (62) or physiotherapy(57).*

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 47 (76%) out of 62 patients treated with injections were considered to be treatment successes compared with 26 (45%) out of 57 treated with physiotherapy (difference between groups were 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.*

Conclusions: *The beneficial effects of corticosteroid injections administered by the physicians 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 of injections were generally mild.*

Introduction

Painful shoulder is a very common condition encountered in the tertiary care hospitals of Bangladesh like BSMMU and NITOR. It

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is also fairly common in primary medical care settings. According to the western statistics annual incidence in general practice vary from 6.6 to 25 cases per 1000 patients[1-3]. Shoulder conditions that are characterized 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]. In our country there is no convincing study that denotes the incidence of the condition at primary care level. But number of patients report to the tertiary hospitals like NITOR and BSMMU every year is very high.

Treatment often consists of physiotherapy or local infiltration of a corticosteroid[3]. Systematic reviews have shown that the effectiveness of these interventions remains questionable[7-9]. Our objective was to compare the effectiveness of corticosteroid injections with physiotherapy on the treatment of painful stiff shoulder in the out-patient setting.

Materials and methods

Subjects

Patients were included from Physical Medicine OPD of BSMMU and NITOR

Inclusion criteria:

- patients who had a painful restriction of gleno-humeral mobility.
- age 18 years or older.
- gave informed consent.

Exclusion criteria:

Patients

- had bilateral symptoms.
- had treatment with corticosteroid injections or physiotherapy during the preceding six months.
- if they had contraindications to treatment.
- had surgery, dislocation, or fractures in the shoulder area.
- had insulin-dependent diabetes mellitus, systemic disorders of the musculoskeletal system, or neurological disorders.

Study Period : January 2004 to July 2006

Diagnostic Criteria:

The diagnosis of painful stiff shoulder (capsular syndrome) was made using the standard diagnostic guidelines for shoulder complaints[3,4], 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 random sequence of the blocks was generated using random number tables.

Interventions

Intra-articular injections of 40 mg triamcinolone acetonide were given by the physiatrists in BSMMU and NITOR using the posterior route[10]. All of these physicians was expert in this technique as they had been practicing it for long time 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. No significant adverse reaction was noted.

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[11]. Functional disability was evaluated with the shoulder disability questionnaire, a 16 item scale consisting of common situations that might cause shoulder pain [12, 13]. 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 goneometer[14].

Blinding

The independent observer did not know to which intervention a patient had been allocated. 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.

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)[15]. 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).

Results

Patient flow and follow up

Total 119 patients out of 197 reported to the Outpatient Department (OPD) of NITOR and BSMMU with pain and stiffness in shoulder were enrolled in the trial. Most of the exclusions 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 tendonitis, subacromial bursitis, and dysfunction of the cervical spine. Nineteen patients were excluded for other reasons.

Characteristics of patients

Sixty two patients were allocated to treatment with injections and fifty six 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.

Interventions

Thirty patients (48.3 %) allocated to receive injections had three injections. The mean number of injections was 2.2 ($\pm$SD 0.8). All patients allocated to physiotherapy received passive joint mobilisation and exercise treatment. Additional electrotherapy was used in 44 patients and ice or hot packs in 36.

At baseline, the use of pain medication was evenly distributed between the two groups; 18 patients in each group used paracetamol (acetaminophen) or non-steroidal anti-inflammatory drugs.

Outcome

The mean improvement in outcome measures at each point of follow up is shown in table III. Using the intention to treat analysis we found a statistically significant 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, 13, and 52 weeks.

Table III shows that the differences between the groups were mainly due to the comparatively fast relief of symptoms occurring among those receiving corticosteroids. At assessment at 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% (62/108) of all patients (table IV). 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 tertiary 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 pain, and disability. We decided against performing an analysis of the long term results by treatment actually received as this would have produced a biased outcome. The reasons for concluding or modifying treatment were, after all, strongly related to the results of the allocated intervention[16] .

Four earlier trials compared the effectiveness of corticosteroid injections with physiotherapy for shoulder pain[17-20]. Three trials with relatively small study populations (fewer than 25 patients per intervention group) were unable to show significant differences between the treatments. These studies used a single injection[17,19] or a different type of corticosteroid[18,19]. Only one trial was conducted in a primary care setting and this trial reported significant differences between the treatments[20]. In that study treatment was considered successful after five weeks for 35 (75%) out of 47 patients treated with injections and for seven (20%) out of 35 treated with physiotherapy. Corticosteroid treatment consisted of multiple injections. Passive mobilisation was not permitted for patients allocated to physiotherapy, a practice that is not compatible with everyday practice. To enhance the external validity of our trial and to facilitate implementation of the findings in clinical practice we tried to ensure that the interventions used resembled those carried out in primary care.

In that study injections were administered by general practitioners. Inaccurate placement of intra-articular injections is reported to occur often, even among trained rheumatologists[21 22]. Recent studies report a better response to treatment after

accurately placed injections[22,23]. Despite the inevitable uncertainty about placement in our study, many of our patients had a good response to the corticosteroid injections administered by their general practitioner.

Adverse reactions were generally mild but were sometimes troublesome, particularly in women receiving corticosteroid injections. Surprisingly, published reports of irregular menstrual bleeding after corticosteroid injection are scarce. One letter that we identified described this side effect as a frequent occurrence, especially in women not taking oral contraceptive[24]. These observations should be investigated further. Doctors and patients should be aware of the possibility of irregular menstrual bleeding after corticosteroid injection so that women are not needlessly made anxious or subjected to diagnostic procedures; however, women and their doctors should be aware that postmenopausal bleeding may be a sign of cancer of the endometrium or cervix.

This randomised trial showed that corticosteroid injections administered by general practitioners for treatment of painful stiff shoulder are superior to physiotherapy. Differences between the intervention groups were mainly due to the comparatively quick relief of symptoms occurring in patients treated with injections. Injections may be preferable to physiotherapy in the initial treatment of painful stiff shoulder.

Conclusion:

- Few studies of the effectiveness of treatments for shoulder pain have been done in a primary care setting even though most patients with shoulder pain are treated there.
- This randomised trial shows that patients treated with corticosteroid injections are significantly more likely to improve on measures of pain and disability than patients treated with physiotherapy.
- The differences between those who received injections and those treated with physiotherapy result mainly from comparatively fast relief of symptoms that occurs after injections.
- Doctors and patients should be aware of mild, but sometimes troublesome, adverse reactions to corticosteroids that may occur.

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