Randomised controlled trial of single, subacromial injection of methylprednisolone in patients with persistent, post-traumatic impingment of the shoulder

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Objective: To evaluate the impact on recovery, of single subacromial injection of methylprednisolone in patients with persistent, post-traumatic impingement of the shoulder.

Design: Randomised, controlled study.

Setting: Large accident and emergency department in Leicester, UK.

Participants: 98 patients with persistent, post-traumatic impingement of the shoulder.

Intervention: Single subacromial injection of methylprednisolone with bupivacaine (group S, n=54) or bupivacaine only (group C, n=44).

Main outcome measures: Pain using a 10 cm visual analogue scale (VAS) and active shoulder abduction.

Results: Comparison of pain scores by the 10 cm VAS between group S and group C showed no statistical difference at 3, 6, and 12 weeks. Mean patient pain scores at 12 weeks were 1.38 in both groups (p=0.09). There were 16 patients in group S (mean age 52 years) with a 10 cm VAS greater than 1 (95% CI 0.17 to 0.43), compared with 13 patients (mean age 57 years) in group C (95% CI 0.17 to 0.45). Comparison of active shoulder abduction between group S and group C showed no statistical difference at 3, 6, or 12 weeks. Mean active abduction at 12 weeks was 168.9° in group S and 170.3° in group C (p=0.8). There were 10 patients in group S (mean age 60.5) with active abduction less than 170° at 12 weeks (95% CI 0.09 to 0.31), compared with five patients (mean age 62 years) in group C (95% CI 0.04 to 0.24).

Conclusions: Single subacromial injection of methylprednisolone has no beneficial impact on reducing the pain, or the duration of immobility in patients with persistent post-traumatic impingement of the shoulder.
Sample size and study power
A power calculation undertaken three months into the study indicated that for a mean difference of 1 point in a VAS between groups, a total study size of 98 patients would give 0.80 statistical power.

Procedures for assignment and blinding
Patients who consented to participation in the trial were randomised by computer generated, random numbers obtained by telephone from a remote independent source. Patients were allocated into either a subacromial corticosteroid group (group S), or a control group (group C).

Interventions
Patients randomised to group S received (by an aseptic no touch technique) a single, subacromial injection of 40 mg methylprednisolone (Depomedrone, Upjohn) diluted with 2 ml 0.5% bupivicaine. Group C received no corticosteroid injection.

Both groups of patients were instructed in identical pendulum and wall finger climbing exercises, and asked to perform 20 repetitions of these four times a day. Patients were advised to continue with whatever drugs they were already taking and no adjustments were made.

Assessment of effectiveness
All patients were reviewed at 3, 6, and 12 weeks, with repeat pain scores measured by the 10 cm VAS, and measurements made of active and passive shoulder movements. Post-intervention assessment was blinded.

Statistical analysis
The subsequent results were analysed using the SPSS computer package. Parametric data were analysed by means of the two tailed Student t test and non-parametric data by means of the Mann-Whitney U test. Statistical significance is displayed by 95% confidence intervals (CI), and p values. All data were analysed on an intention to treat basis.

RESULTS
Recruitment and participation
Over a four year period 306 patients were reviewed in the shoulder clinic. Ninety eight patients met the inclusion criteria (61 men and 37 women, mean age 49, range 17–87 years), and were diagnosed as having persistent, post-traumatic impingement of the shoulder. Eight patients whose symptoms failed to resolve with subacromial injection of bupivicaine were diagnosed as having a complete rotator cuff tear and subsequent magnetic resonance imaging confirmed this (all exclusions listed in table 2).

Fifty four patients were randomised to group S and 44 to group C. Nine patients who were asymptomatic or improving at six weeks (group S=5, group C=4) failed to attend their subsequent appointments despite multiple recalls. Age, sex, analgesia use, baseline pain scores, and shoulder movements were comparable between group S and group C (table 3).

Primary outcomes
Comparison of pain scores by the 10 cm VAS between group S and group C showed no statistical difference at 3, 6, or 12 weeks (fig 1). Mean patient pain scores at 12 weeks were 1.38 in both groups (p=0.99). There were 16 patients in group S
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**DISCUSSION**

This study shows that a single subacromial injection of a long acting depot corticosteroid has no beneficial impact on reducing the pain, or the duration of immobility in patients with persistent post-traumatic impingement of the shoulder. These findings concur with a similar study by White et al., who compared triamcinolone with indomethacin in patients with rotator cuff tendinitis. Their study however was not powered and only followed up 22 patients through to six weeks, with the resulting possibility of a type 2 error.

Our results are at odds with a smaller study by Vecchio et al., who compared methylprednisolone with lignocaine (lidoca-

**REFERENCES**

Use of methylprednisolone for post-traumatic impingement of the shoulder


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