Passive mobilisation of shoulder region joints plus advice and exercise does not reduce pain and disability more than advice and exercise alone: a randomised trial

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Question: Is the addition of passive mobilisation of shoulder region joints to advice and exercise for patients with shoulder pain and stiffness more effective than advice and exercise alone? Design: Randomised trial with concealed allocation, assessor blinding, and intention-to-treat analysis. Participants: 90 people who had shoulder pain and stiffness for more than one month. Intervention: All participants received advice and exercise. The experimental group also received passive joint mobilisation of shoulder region joints. Outcome measures: Primary outcome measures included pain and disability measured with the 13-point Shoulder Pain and Disability Index. Secondary outcome measures were self-perceived global improvement measured on a 6-point scale and active ranges of motion. Subjects received a maximum of 10 sessions of therapy. Results: The experimental group had 3% (95% CI –5 to 11) less pain and disability than the control group at one month and 1% (95% CI –13 to 16) less pain at six months, which are statistically non-significant. Their global perceived effect was 0.1 out of 5 (95% CI –0.2 to 0.4) worse than the control group at one month and 0.1 (95% CI –0.5 to 0.7) better at 6 months, which are also statistically non-significant. Differences between groups in all range of motion measures were small and statistically non-significant. Conclusion: The addition of passive joint mobilisation of shoulder region joints is not more effective than advice and exercise alone for shoulder pain and stiffness. Trial registration: ACTRN 12605000080628. [Chen JF, Ginn KA, Herbert RD (2009) Passive mobilisation of shoulder region joints plus advice and exercise does not reduce pain and disability more than advice and exercise alone: a randomised trial. Australian Journal of Physiotherapy 55: 17–23]

Key words: Shoulder joint, Shoulder pain, Randomised controlled trial, Exercise, Physiotherapy

Introduction

Shoulder pain and stiffness is common in the general community, with the prevalence up to 33% (Luime et al 2004, McBeth and Jones 2007, van der Heijden 1999, van der Windt et al 1995). The shoulder is the most frequent site of musculoskeletal pain after the back and neck (Urwin et al 1998), with an incidence of 15 new episodes per 1000 patients seen in the primary care setting (van der Windt et al 1995). Significant disability such as inability to sleep, limitations in activities of daily living, and a resulting loss of quality of life have been reported, especially in the elderly (Ostör et al 2005, Smith et al 2000, Vecchio et al 1995).

Physiotherapy intervention is often the first line of management for shoulder problems, with 53% to 79% of general practitioners referring to physiotherapists (Glazier et al 1998, van der Windt et al 1995). In Australia, shoulder pain accounts for up to 10% of all referrals to physiotherapists (Peters et al 1994). Passive joint mobilisation and exercise therapy are commonly employed by physiotherapists for shoulder problems (Green et al 2003). Systematic reviews have found some evidence in support of manual techniques. However, these reviews included studies which investigated passive joint mobilisation directed at both shoulder region joints and vertebral column joints (Desmeules et al 2003, Green et al 2003, Michener et al 2004). Only two small, controlled clinical trials have specifically investigated the efficacy of passive joint mobilisation applied at the shoulder region joints in painful, stiff shoulders (Conroy and Hayes 1998, Nicholson 1985). Both trials reported no improvement in activity or range of shoulder motion in the group receiving joint mobilisations compared with the control group. However, both of these studies lacked the statistical power to detect small but clinically-meaningful effects of passive joint mobilisation applied to shoulder region joints.

Whilst there is growing evidence to support the efficacy of exercise for shoulder pain (Ainsworth and Lewis 2007, Ginn et al 1997, Ginn and Cohen 2005, Grant et al 2004, Trampas and Kitsios 2006) evidence for the efficacy of passive mobilisation of shoulder region joints to reduce pain and disability is lacking. Therefore, the research questions for this study were:

1. Is the addition of passive mobilisation of shoulder region joints to advice and exercise for patients with shoulder pain and stiffness more effective in reducing pain and disability than advice and exercise alone?
2. Are any gains retained at 6 months?

Method

Design

The study was a single-blinded randomised trial. After baseline measurements of pain, disability, and range of motion were taken, participants were randomly allocated into either the experimental or control group based on an assignment schedule that was stored in consecutively numbered, sealed opaque envelopes to ensure concealment. The assignment schedule was generated by an investigator.
who was not associated with recruitment, intervention, or assessment. Disability and range of motion measures were obtained at baseline, four weeks, and six months after randomisation by a measurer blinded to group allocation. Global self-perceived improvement was assessed four weeks and six months after randomisation. To maintain assessor blinding, participants were specifically requested not to discuss any aspects of their intervention with the assessor at any stage of re-assessment.

Participants

All patients 18 years and above, presenting at a large metropolitan public hospital for physiotherapy intervention for shoulder pain and stiffness of more than one month’s duration were invited to participate if they understood spoken English. Patients were eligible to enrol in the study if the shoulder pain was unilateral, over the glenohumeral joint or in the proximal upper limb, and reproduced during shoulder movements. In addition they needed to have less than 140 degrees of active shoulder flexion and abduction range of motion or a greater than 10 cm hand-behind-back deficit compared to the unaffected side. In order to justify the need for passive joint mobilisation, they also had to have pain and/or stiffness during accessory movements of the shoulder region joints. They were excluded if they had trauma within the last month, inflammatory joint disease, local neoplastic disorder, a feeling of instability at the glenohumeral joint, contraindications to passive joint mobilisations at the glenohumeral, acromioclavicular, or sternoclavicular joints, or shoulder pain referred from the vertebral column structures. Referred pain was defined as pain reproduced by active neck movements or by palpation of the vertebral column, or if paraesthesia was present in the affected limb. Patients with bilateral shoulder pain were excluded as one outcome measurement relied on comparison with the unaffected side.

Intervention

The experimental group received passive joint mobilisations in the form of graded, passive, accessory movements directed either at the glenohumeral, acromioclavicular and/or sternoclavicular joint in addition to advice and exercise. Passive joint mobilisations were performed either as a passive oscillatory movement or a sustained stretch with or without tiny amplitude oscillations at the limit of the range. Only low-velocity mobilisations were used; manipulations involving high-velocity, low-amplitude thrusts were not employed. The movements were aimed at restoring structures within the target joints to their normal or pain-free positions so as to recover full-range, painless movement (Maitland 1991). Progression of these techniques was determined by the treating therapist based on the participant’s clinical signs and symptoms as per routine clinical practice, since the aim of this pragmatic study was to investigate the effectiveness of a commonly-used physiotherapeutic technique. In addition, participants were advised to avoid painful activities involving the shoulder and were also advised how to use pain-free methods to perform everyday activities such as dressing. They also received exercises aimed at restoring neuromuscular control of the shoulder muscles in order to restore the dynamic stability and muscle force couple co-ordination of the shoulder region (Ginn et al 1997, Ginn and Cohen 2005). Exercises were conducted in a pain-free manner so as to maximise normal muscle function and movement pattern (Ginn and Cohen 2005). Exercises were progressed using motor learning principles designed to improve shoulder function by gradually increasing the complexity of the exercises (Stevans and Hall 1998). Exercises which involved a single shoulder muscle force couple (such as rotation with the humerus supported into abduction range) were progressed to exercises which required multiple muscle force couples (such as range of motion). Exercises were tailored for the individual patient by the therapist and upgraded as muscle function improved. Participants were directed to perform the exercises at least twice daily.

The control group received advice and exercise only.

Intervention consisted of up to ten 30-minute individual sessions delivered within an 8-week period. Participants attended up to twice weekly initially, and then once a week. Experimental participants were required to receive a minimum of six sessions of passive joint mobilisation in the course of therapy. Participants were asked not to seek other therapy during the trial. Intervention was administered by a single experienced physiotherapist who met with one of the authors to confirm the intervention protocol and to clarify protocol issues as required. A data sheet was kept by the treating therapist to record the type of intervention given to each participant. The total number of interventions received by the participants in both groups, and the exact number of sessions of passive joint mobilisation performed in the experimental group were recorded.

Outcome measures

The primary outcome measure was the Shoulder Pain and Disability Index (SPADI) (Roach et al 1991) which is a self-administered questionnaire designed to measure the effect of pathology of the shoulder on pain and disability. This was chosen for its overall validity and patient acceptability (Paul et al 2004). It is responsive to change (Bot et al 2004, Heald et al 1997, Paul et al 2004), quick to complete (Paul et al 2004), and has no floor or ceiling effects (Bot et al 2004). The SPADI consists of 13 items divided into two subcategories addressing pain (five items) and disability (eight items). All items were rated with a visual analogue scale anchored at ‘No pain’ and ‘Worst pain imaginable’ for pain, and ‘No difficulty’ or ‘So difficult it required help’ for disability. A numeric value was obtained by dividing the scale into 10 segments from 0 to 10 for each item. The questionnaire required only 5–10 minutes to complete.

Secondary outcomes included global perceived effect and active shoulder range of motion. Global perceived effect was measured using a 6-point Likert scale with categories ‘Significantly deteriorated’, ‘Slightly deteriorated’, ‘No change’, ‘Slightly improved’, ‘Significantly improved’ and ‘Completely recovered’ (Likert 1932). In this study, active range of movement in flexion and abduction was measured using still photography as described by Ginn et al (1997). This method was chosen over goniometry as it was less likely to exacerbate shoulder symptoms due to the shorter time required to complete measurements. Hand-behind-back range of movement was measured using a tape measure (Ginn and Cohen 2005). Participants were instructed to ‘take the arm to as far as they could go’ and the distance between T1 and the styloid process was measured. The difference between the affected and non-affected side was reported so that the larger the negative value the worse the range of motion. The intra-tester reliability of active range of movement measurements taken by the assessor involved in the study was determined prior to the commencement of
the clinical trial. Intra-class correlation coefficients (ICC\(_{1,1}\)) demonstrated excellent intra-rater reliability (0.92 to 0.98) for these measures (Shrout and Fleiss 1979).

### Data analysis

The sample size for this study was based on a predetermined 15-point difference between groups in the reduction on the SPADI score. Power calculations indicated that a sample of 90 participants (45 per group) would provide an 80% probability of detecting a 15-point difference on SPADI assuming a standard deviation of 24 points, with an alpha of 0.05, and an estimated loss to follow-up of 10%. A reduction of 13 points on SPADI has been recommended as the minimum clinically-worthwhile improvement (Roach et al 1991).

Analyses were conducted on an intention-to-treat principle, using all available data from all randomised participants. To estimate the effects of intervention, between-group differences of primary outcome measures (SPADI) and secondary outcomes (patient’s global self-perceived improvement scale and range of motion) at one month and six months were examined with analysis of covariance using a regression approach. Baseline values were included as covariates in the regression models to increase the precision of estimates.

### Results

#### Flow of participants, therapists and centres through the trial

Between November 2004 and May 2007, 224 patients were screened for eligibility in this study. Of these, 97 (43%) met the inclusion criteria and were invited to participate. Ninety patients accepted the invitation and were randomised. The reasons for exclusion and flow of participants through the trial are illustrated in Figure 1. Three participants allocated to the control group withdrew after randomisation and did not commence intervention and no data were collected from these participants after baseline measurement. Six participants were unable to physically attend for range of motion measurements at six months but their pain and disability as well as the global perceived effect were obtained over the phone. Williams et al (1995) demonstrated that the SPADI was suitable for telephone administration should this be necessary. Therefore, at one month, 87% of participants were measured, and at six months 89% of the participants were measured for the primary outcome.

Characteristics of participants who completed the study and those lost to follow-up are shown in Table 1. Both groups were comparable except that there were more participants in the experimental group with concomitant neck pain. Participants lost to follow-up did not differ significantly from those who completed all measures, except that participants in the control group lost to follow-up at one month had a longer duration of complaint than the other participants.

A single senior physiotherapist with 13 years experience provided the intervention to both the experimental and control groups throughout the study. Although this therapist has not been involved in research before, her normal workload included over 40% of patients with shoulder problems.

This study was carried out at the Physiotherapy Musculoskeletal Outpatient Department in a major metropolitan public teaching hospital with a throughput of 440 patients per year. Referrals for intervention to the shoulder represent 51% of the throughput of this department per year.

#### Compliance with trial method

Eighty-seven participants attended for intervention. Participants in the experimental group received a mean of 8 (range 1–10) sessions of intervention and those in the control group also received a mean of 8 (range 0–19) sessions. One participant in the control group was hospitalised due to a medical condition and subsequently developed a frozen shoulder, and hence attended a large number (19) of intervention sessions. In the experimental group, participants received a mean of 8 (range 1–10) sessions of mobilisation intervention to the shoulder joints, which was more than the minimum requirement of 6 sessions. Fourteen participants (16%), seven from each group, terminated intervention

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**Table 1. Characteristics of participants.**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Randomised (n = 90)</th>
<th>Lost to Month 1 follow-up (n = 12)</th>
<th>Lost to Month 6 follow-up (n = 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exp (n = 45)</td>
<td>Con (n = 45)</td>
<td>Exp (n = 6)</td>
</tr>
<tr>
<td>Gender, n female (%)</td>
<td>35 (78)</td>
<td>29 (64)</td>
<td>4 (66)</td>
</tr>
<tr>
<td>Age (yr), mean (SD)</td>
<td>64.7 (12.5)</td>
<td>65.5 (12.7)</td>
<td>61 (16.6)</td>
</tr>
<tr>
<td>Side of pain, n right (%)</td>
<td>30 (67)</td>
<td>28 (62)</td>
<td>5 (83)</td>
</tr>
<tr>
<td>Hand dominance, n right (%)</td>
<td>44 (98)</td>
<td>42 (93)</td>
<td>6 (100)</td>
</tr>
<tr>
<td>Duration of complaint (mth), mean (SD)</td>
<td>9.3 (11.1)</td>
<td>11.1 (13.6)</td>
<td>9.8 (12.9)</td>
</tr>
<tr>
<td>Previous history of shoulder problem, n yes (%)</td>
<td>20 (44)</td>
<td>20 (44)</td>
<td>2 (33)</td>
</tr>
<tr>
<td>Concomitant neck pain, n yes (%)</td>
<td>31 (69)</td>
<td>19 (42)</td>
<td>4 (67)</td>
</tr>
</tbody>
</table>

Exp = Experimental Group, Con = Control Group
Research

Patients with shoulder problems screened by telephone (n = 224)

Excluded (n = 113)
• Poor English (n = 49)
• No active restriction (n = 22)
• Bilateral pain (n = 23)
• Declined (n = 7)
• No contact (n = 7)
• Other reason (n = 5)

Screened physically (n = 111)

Excluded (n = 21)
• Cervical involvement (n = 6)
• No active restriction (n = 8)
• No passive restriction (n = 7)

Lost to Month 1 follow-up
• increased pain (n = 1)
• medical reasons (n = 3)
• did not attend (n = 2)

Experimental Group
– passive joint mobilisation
– advice
– exercise
– > 6 and < 10 x 30-min sessions in 2 mth

Control Group
– advice
– exercise
– < 10 x 30-min sessions in 2 mth

Lost to Month 1 follow-up
• withdrew after allocation (n = 3)
• medical reasons (n = 1)
• did not attend (n = 2)

Month 0

Measured pain and disability, range of motion, global perceived effect
(n = 45) (n = 45)

Randomised (n = 90)

Experimental Group
– passive joint mobilisation
– advice
– exercise
– > 6 and < 10 x 30-min sessions in 2 mth

Control Group
– advice
– exercise
– < 10 x 30-min sessions in 2 mth

Lost to Month 1 follow-up
• withdrew after allocation (n = 3)
• medical reasons (n = 1)
• did not attend (n = 2)

Month 1

Measured pain and disability, range of motion, global perceived effect
(n = 39)

Randomised (n = 90)

Experimental Group
– passive joint mobilisation
– advice
– exercise
– > 6 and < 10 x 30-min sessions in 2 mth

Control Group
– advice
– exercise
– < 10 x 30-min sessions in 2 mth

Lost to Month 1 follow-up
• withdrew after allocation (n = 3)
• medical reasons (n = 1)
• did not attend (n = 2)

Month 6

Measured pain and disability, range of motion, global perceived effect
(n = 41)
(n = 39)

Experimental Group
D/C < 2 mth

Control Group
D/C < 2 mth

Lost to Month 6 follow-up
• withdrew after allocation (n = 3)
• medical reasons (n = 1)
• did not attend (n = 2)

Figure 1. Design and flow of participants through the trial.

against the treating physiotherapist’s advice (Figure 1). No participants reported having had other intervention during the study period.

Of the participants who received passive joint mobilisation, 70% had mobilisation directed to the glenohumeral joint, 10% to the acromioclavicular joint, and 20% to a combination of these two joints. No passive mobilisation was directed to the sternoclavicular joint as this was not found to be symptomatic in this cohort. Anteroposterior glides at the end of available range of abduction were the most commonly-used technique for the glenohumeral joint, and anteroposterior and posteroanterior glides were equally
commonly applied at the acromioclavicular joint. Only Grade II and Grade III movements were used.

Effect of intervention

Group data for all outcomes at baseline, one month and six months for control and experimental groups are presented in Table 2 while individual data are presented in Table 3 (see eAddenda for Table 3). One month after randomisation, participants in both the experimental and control groups had improved in all outcome measures. Further improvements were seen at six months.

The experimental group had 3% (95% CI –5 to 11) less pain and disability than the control group at one month, and 1% (95% CI –13 to 16) less at six months which are both statistically non-significant. Their global perceived effect was 0.1 out of 5 (95% CI –0.2 to 0.4) worse than the control group at one month, and 0.1 (95% CI –0.5 to 0.7) better at six months which are also both statistically non-significant. Likewise, differences between groups in all range of motion measures were small and statistically non-significant.

No adverse effects of intervention were reported.

Discussion

This is the first well-powered, randomised trial of passive joint mobilisation of the shoulder region joints of painful and stiff shoulders. The results of this study demonstrate conclusively that the addition of this commonly-used technique to advice and exercise is no more effective than advice and exercise alone. Pain and disability, global self-perceived effect, and range of motion were similar in outcome for both groups.

While there exists variable evidence for the efficacy of passive joint mobilisation in the intervention of other musculoskeletal problems (Green et al 2001, Hoeksma et al 2004), our randomised trial demonstrated that passive mobilisation of shoulder region joints conferred no added benefit to advice and exercise in the management of shoulder pain and stiffness. Several authors (Johnson et al 2007, Vermeulen 2006) have demonstrated improvements in shoulder joint range with mobilisation in participants with shoulder problems; however, these were not randomised controlled trials and hence do not provide high level evidence.

Our results confirm those of previous small studies where passive mobilisation of shoulder region joints was not found to be effective in the management of shoulder pain and restriction. Nicholson (1985) carried out a clinical trial to determine the effects of passive mobilisation and active exercise in patients with painful restricted shoulders. Twenty patients with painful glenohumeral restrictions were randomly allocated to receive mobilisation and active exercise for four weeks. The mean reduction in pain for the experimental group was –5.1 out of 10 (SD 4.6) compared with –2.9 (SD 4.4) for the control group which resulted in a non-significant difference of –2.2 (95% CI –6.4 to 2.0). Only passive abduction range of motion increased significantly more in the mobilisation group than in the control group.

Conroy and Hayes (1998) examined the effect of shoulder region joint mobilisation as a component of comprehensive intervention for primary shoulder impingement syndrome. Fourteen participants with superolateral shoulder pain,
decreased active humeral elevation, and limited overhead movement were randomly assigned to receive joint mobilisation and comprehensive intervention (consisting of hot packs, active range of motion, stretching, muscle strengthening, soft tissue mobilisation and patient education), or comprehensive intervention alone. Blinded assessors evaluated 24-hour pain, pain with the subacromial compression test, active range of motion and activity limitations, before and after nine sessions of interventions performed within three weeks. The group receiving passive joint mobilisations had less 24-hour pain and pain with the subacromial compression test than the control group but, as in Nicholson’s study, there were no difference in range of motion or activity limitations when compared with the control group.

Both of these studies demonstrated little or no benefit of passive joint mobilisation for painful, restricted shoulders. However both studies were small and lacked the power to detect clinically-important differences between groups. Furthermore, there were no long-term measures collected in either study. Our present study was designed to have adequate power to detect important intervention effects if they had been present, both in the short and medium term.

Michener et al (2004) concluded in their systematic review that the addition of shoulder region joint mobilisation in combination with exercise should be favoured over exercise alone for shoulder pain and restriction in subacromial impingement syndrome. This was based on one study by Bang and Deyle (2000) where passive joint mobilisation was applied to joints and soft tissues of the cervical and thoracic spine as well as to shoulder region joints. In our opinion, the evidence does not support this recommendation.

The strength of this randomised trial is that it incorporated features to minimise bias, thus enhancing the internal validity of the study. Participants were assigned to experimental and control groups using a concealed random allocation procedure. All measurements were performed by the same person who was blinded to group allocation. The inclusion criteria were general enough to reflect the variety of patients commonly presenting to public hospital physiotherapy outpatient departments with shoulder pain and stiffness. The size of the cohort yielded adequate statistical power. The control group received exercise therapy with proven efficacy (Ginn et al 1997, Ginn and Cohen 2005). Both experimental and control groups received the same average number of interventions, and contact time between therapist and participant was similar in both groups. Data analysis was by intention-to-treat. The analysis was blinded. A limitation of the study is that, due to the nature of the interventions, it was not possible to blind the participants and the treating therapist.

The shoulder region joint mobilisation intervention was pragmatic rather than prescriptive. In the trial, as in clinical practice, the type of mobilisation was tailored to the participant’s specific presentation. For example, the different grades and directions of passive joint mobilisation and joints treated were determined by the treating therapist in response to the presenting signs and symptoms in individual participants. This means that the findings of the trial can directly inform clinical practice.

The participants in this study represent the cross-section of patients referred to hospital physiotherapy departments in Australia. More than 50% of participants were referred to the physiotherapy department by general practitioners for ‘painful, restricted shoulders’. The lack of consensus of current diagnostic classification of shoulder problems and the lack of accuracy of clinical tests for shoulder conditions were the reasons that diagnostic labels were not used to select participants in this study (Bamji et al 1996, de Winter et al 1999, Kuhn et al 2007, Liesdek et al 1997, Norregaard et al 2002, Park et al 2005, Hughes et al 2008). The presence of pain and loss of range were also the criteria used in previous shoulder studies (Ginn et al 1997; Ginn and Cohen 2005).

This assessor-blinded randomised trial has shown that the addition of passive joint mobilisation to shoulder region joints to advice and exercise in patients with shoulder pain and stiffness is not more effective than advice and exercise alone. Individually-tailored exercises aimed at restoring neuromuscular control of the shoulder and advice on how to avoid shoulder pain alone are as effective in the short and medium term. The present study included participants with both shoulder pain and loss of range so it is not known whether our results apply to patients who have shoulder pain but no loss of range; future studies will be needed to address this issue. ■

eAddenda: Table 3 available at AJP.physiotherapy.asn.au

Ethics: The South East Sydney Area Health Service Human Research Ethics Committee – Eastern Section, and The University of Sydney Human Research Ethics Committee approved this study. Informed consent was obtained from all participants before data collection began.

Competing interests: None declared.

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