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Efficacy of standardised manual therapy and home exercise programme for chronic rotator cuff disease: randomised placebo controlled trial

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ABSTRACT

Objective To investigate the efficacy of a programme of manual therapy and exercise treatment compared with placebo treatment delivered by physiotherapists for people with chronic rotator cuff disease.

Design Randomised, participant and single assessor blinded, placebo controlled trial.

Setting Metropolitan region of Melbourne, Victoria, Australia.

Participants 120 participants with chronic (>3 months) rotator cuff disease recruited through medical practitioners and from the community.

Interventions The active treatment comprised a manual therapy and home exercise programme; the placebo treatment comprised inactive ultrasound therapy and application of an inert gel. Participants in both groups received 10 sessions of individual standardised treatment over 10 weeks. For the following 12 weeks, the active group continued the home exercise programme and the placebo group received no treatment.

Main outcome measures The primary outcomes were pain and function measured by the shoulder pain and disability index, average pain on movement measured on an 11 point numerical rating scale, and participants' perceived global rating of overall change.

Results 112 (93%) participants completed the 22 week trial. At 11 weeks no difference was found between groups for change in shoulder pain and disability index (3.6, 95% confidence interval −2.1 to 9.4) or change in pain (0.7, −0.1 to 1.5); both groups showed significant improvements. More participants in the active group reported a successful outcome (defined as "much better"), although the difference was not statistically significant: 42% (24/57) of active participants and 30% (18/61) of placebo participants (relative risk 1.43, 0.87 to 2.34). The active group showed a significantly greater improvement in shoulder pain and disability index than did the placebo group at 22 weeks (between group difference 7.1, 0.3 to 13.9), although no significant difference existed between groups for change in pain (0.9, −0.03 to 1.7) or for the percentage of participants reporting a successful treatment outcome (relative risk 1.39, 0.94 to 2.03). Several secondary outcomes favoured the active group, including shoulder pain and disability index function score, muscle strength, interference with activity, and quality of life.

Conclusion A standardised programme of manual therapy and home exercise did not confer additional immediate benefits for pain and function compared with a realistic placebo treatment that controlled for therapists' contact in middle aged to older adults with chronic rotator cuff disease. However, greater improvements were apparent at follow-up, particularly in shoulder function and strength, suggesting that benefits with active treatment take longer to manifest.

Trial registration Clinical trials NCT00415441.

INTRODUCTION

Shoulder disorders are a common cause of persistent musculoskeletal morbidity,[1 2] particularly in the middle to older age groups.[3] Pain and compromised shoulder function have a substantial impact on tasks essential to daily living, as well as on sleep.[4] Shoulder disorders are a common reason for seeking medical care and may require surgical intervention in up to 28% of cases.[5-7] Shoulder disorders can thus lead to considerable disability, reduced health related quality of life, absenteeism from work, and use of healthcare resources.[4 8 9]

Although definitions of different diagnostic categories of shoulder pain are controversial, a large proportion of shoulder problems can be classified as "rotator cuff disease," the most common cause of shoulder pain in primary care.[10] The term, or its variants such as impingement syndrome, may include a spectrum of pathologies of rotator cuff disease (such as subacromial bursitis, partial rotator cuff tears, and bicipital tendinosis), but they are characterised clinically by pain with abduction (painful arc) and signs of impingement.[11] Although standard criteria have not been established for use in clinical trials, most trials that have assessed interventions for rotator cuff disease have used variations of these features to select their study populations.[12-14] Rotator cuff disease differs

from other major diagnostic categories of shoulder pain such as adhesive capsulitis, osteoarthritis, and calcific tendinitis, which are known to have different presentations, underlying causes, prognoses, and responses to treatment.

A combination of modalities of physiotherapy, such as manual therapy and exercise, is often used in the management of rotator cuff disease.[15] These aim to correct modifiable physical impairments thought to contribute to pain and dysfunction rather than to treat the specific pathology. These impairments include rotator cuff and scapular muscle weakness and dysfunction, tightness of the posterior capsule and other soft tissues, and postural abnormalities.[16] Little conclusive evidence supports or refutes the efficacy of different physiotherapy programmes given the variable methodological quality of the trials, including a lack of placebo control and the fact that many tested a single modality despite multimodality treatment being the most common way in which physiotherapists treat shoulder disorders.[13 17-20] The conclusions and recommendations of recent systematic reviews support the need for further clinical trials.[21-23] The primary aim of this trial was, therefore, to determine whether a 10 week programme of standardised manual therapy and home exercise delivered by a physiotherapist improves shoulder pain and function more than placebo treatment does in people with chronic rotator cuff disease.

METHODS

Participants

Between March 2004 and November 2007, we recruited people with chronic rotator cuff disease through medical practitioners and from the community through print and radio media. We required all participants to have a plain radiograph of the shoulder to check for exclusions (see below), and we required potential participants recruited directly from the community to have the diagnosis of rotator cuff disease confirmed by a medical practitioner. After an initial screen by telephone, an experienced physiotherapist (EW or SC) did a physical examination. Inclusion criteria were age over 18 years, shoulder pain for more than three months, severity of pain on movement rated greater than 3/10 on an 0-10 numerical rating scale, pain on active abduction or external rotation, and a positive quick test for shoulder impingement.[24] Exclusion criteria were resting severity of shoulder pain greater than 7/10; reason to suspect a complete rotator cuff tear (for example, substantial shoulder weakness, a positive drop-arm sign, or a high riding humerus on plain radiograph); previous shoulder surgery; radiological evidence of shoulder osteoarthritis, calcification, or previous fracture; systemic pathology including inflammatory joint disease or neoplastic disorders; more than 50% restriction of passive range of motion in two or more planes; shoulder pain referred from vertebral structures diagnosed by spinal clearing tests[25]; symptoms of complex regional pain syndrome; active intervention in the previous three months,

including corticosteroid injection, arthrographic distension of the glenohumeral joint with corticosteroid and saline (hydrodilatation), or physiotherapy; anti-inflammatory drugs in the previous two weeks; and inability to understand written and spoken English.

Procedures

We did a randomised, participant and assessor blinded, controlled trial. Participants had a baseline assessment and were randomised in permuted blocks of six and eight, stratified by treating physiotherapist, to receive either active manual therapy and home exercise treatment or placebo treatment according to a computer generated table of random numbers created by the study biostatistician (AF). Allocations were sealed in opaque and consecutively numbered envelopes kept in a central locked location. An independent administrator opened the envelopes in sequence and then revealed the group allocation to the relevant physiotherapist by facsimile just before the participant presented for treatment.

Interventions

Details about the interventions have been published previously.[26] Fourteen musculoskeletal physiotherapists (all with more than four years of relevant clinical experience) from 12 centres (two public hospital physiotherapy departments and 10 private physiotherapy clinics) were trained to provide both interventions. Therapists attended initial training sessions and were given a detailed treatment manual. We could not blind the therapists to treatment group. Both interventions were standardised and comprised individual sessions twice weekly for the first fortnight, once a week for the next four weeks, then once a fortnight in the last four weeks (10 visits, 30-45 minutes each). To minimise the risk of participants meeting, appointments were scheduled at different times. We assessed therapists' adherence to the protocol by completion of a treatment log. Simple analgesia was permitted, but participants were asked to refrain from seeking other forms of treatment during the trial. Treatment in both groups was provided at no cost to the participant.

We based the active intervention on the literature and on the results of a formal written survey of 16 Australian musculoskeletal physiotherapists with expertise in treating shoulder conditions.[27] The intervention was directed at improving dynamic scapular control, strengthening scapular stabiliser and rotator cuff muscles, improving shoulder and thoracic posture, and increasing range of motion of thoracic extension. The intervention had five components comprising soft tissue massage, passive mobilisation of the glenohumeral joint, scapular retraining and postural taping, spinal mobilisation (to assist in improving shoulder girdle posture and spinal range of motion), and home exercises (table 1).[26] We incorporated behavioural strategies, including education, goal setting, motivation, and positive reinforcement. Home exercises were done daily, except during the first week of treatment when exercises were completed twice daily (web appendix).

Table 1 | Components of active physiotherapy intervention

Treatment component	Description	Dosage
Soft tissue massage	Anterior and posterior shoulder tissues, in supine and side-lying positions respectively	6 minutes each position
Glenohumeral joint mobilisation	Anteroposterior and inferior joint glides in supine position with shoulder at 45° and 90° abduction respectively	4×30 seconds each position
Thoracic spine mobilisation (T1-8)	In prone position, using central posteroanterior technique	Grade IV on each level: 4 minutes in total
Cervical spine mobilisation (C5-7)	In prone position using unilateral posteroanterior technique on both sides	Grade IV on each level: 4 minutes in total
Scapular retraining	In side-lying position, therapist passively moves shoulder through range from elevation/protraction to retraction/depression, then assisted by participant, then independently by participant; isometric holds in retraction/depression	Weeks 1 and 2 only; 15 repetitions × 5 repetitions with 10 second holds
Postural taping	Taping of shoulders and scapula to encourage scapular retraction and depression and thoracic extension	Continuous (day and night) for two weeks; re-applied after one week by therapist
Home exercises	Supervised and done as home programme	Home programme: twice daily in first two weeks; once a day thereafter

After the 10 week programme, participants in the active group were instructed to maintain their daily home exercise programme for 12 weeks.

Participants in the placebo group attended the same number of treatments as did those in the active treatment group but received sham ultrasound therapy and light application of a non-therapeutic gel to the shoulder region for 10 minutes each. They received no instruction in exercise techniques and no manual therapy. We have successfully used this same placebo protocol in previous studies.[28-30] During the 12 week follow-up period, placebo participants did not receive any intervention and were not instructed to do any home exercises.

Outcome measures

The same blinded assessor (EW) evaluated all participants at baseline, at 11 weeks (at the conclusion of the supervised active or placebo intervention), and at 22 weeks after randomisation. Baseline demographic information was collected, and participants rated their expectation of a beneficial effect of active physiotherapy treatment on an ordinal scale from 1 to 5, with higher scores indicating higher expectations.

The primary outcomes were the shoulder pain and disability index (SPADI), average pain on movement assessed by a numerical rating scale, and participants' perceived global rating of change overall. The shoulder pain and disability index is a self administered, shoulder specific index consisting of 13 items divided into two subscales—pain (five items) and function (eight items)—with responses to each item recorded on a 10 point scale.[31-33] We calculated a total shoulder pain and disability index score by summing the subscales and then averaging for a score out of 100 (higher scores indicate more pain/dysfunction).

We measured participants' overall assessment of average pain on movement and pain at rest in the previous week by separate 11 point numerical rating scales (0 to 10) numbered in 1 cm intervals.[34] The minimal clinically important difference for shoulder pain on movement measured on this scale is 1.1 units.[34] The amount of weakness, stiffness, and interference with activities of daily living over the previous week were similarly measured.

Participants' perceived global rating of change overall and in pain, strength, and stiffness (from baseline) were recorded on separate five point Likert-type scales (1=much worse, 2=slightly worse, 3=no change, 4=slightly better, 5=much better).[35] We defined a successful outcome for each a priori as "much better" on the rating scale.

We measured generic health related quality of life with the Medical Outcomes Study 36-item short form (SF-36) (eight subscales scaled from 0-100, in which a higher score represents better health, summarised into physical function and mental health scales) and the assessment of quality of life (AQoL) instrument.[36 37] The latter instrument comprises 15 items covering five dimensions (illness, independent living, social relationships, physical senses, and psychological wellbeing).[38 39] Item responses are all ordinal scales with four levels per item. Scores are scaled from −0.04 (worse than death) to 1.00 (perfect health).

We measured isometric shoulder strength of the symptomatic limb for shoulder abduction and internal and external rotation with the Nicholas Manual Muscle tester (Lafayette, USA). For abduction, participants were in supine position with the shoulder in 90° of abduction and the dynamometer positioned on the lateral surface of the distal humerus. Measurements of external and internal rotation were made in sitting position with the arm by the side against a folded towel with the elbow flexed to 90° and the dynamometer positioned on the distal forearm. After a demonstration and one warm-up trial, participants were asked to push as hard as they possibly could against the dynamometer for four seconds while the tester provided consistent loud verbal encouragement. The mean reading of three maximal contractions was taken. Reliability is excellent in our laboratory (12 people with rotator cuff disease tested by two examiners twice two to four days apart: intraclass correlation coefficient (2,3) values ≥0.89 for intra-rater reliability of each examiner and ≤0.90 for inter-rater reliability[27]).

We measured participants' adherence to treatment by recording the number of physiotherapy sessions attended (out of a maximum of 10). Participants in the active group also completed a daily log book to record the number of home exercise sessions

completed. Adverse events and the use of co-interventions in both groups were recorded in a log book. To measure the success of blinding, we asked participants to indicate which treatment they believed they had received at the 22 week assessment.

Sample size

We calculated sample size on the basis of ability to detect a 10 point difference in improvement in total shoulder pain and disability index score, previously reported to indicate a clinically important improvement (or worsening) of shoulder function.[32] Applying power calculations appropriate for analysis of covariance (adjusting for baseline shoulder pain and disability index score), to detect a difference in 11 week shoulder pain and disability index score of 10 units assuming a common between participant standard deviation of 27 and a baseline to 11 week correlation of 0.45 (from our pilot study[27]), we calculated that we needed 91 participants per group to achieve 80% power at a two sided 5% significance level.

As recruitment was much slower than anticipated, an independent statistician not previously associated with the trial did a blinded assessment of the between participant standard deviation and baseline to 11 week correlation after 46 patients had completed follow-up. These were more favourable than initially planned (SD=21, r=0.60), and we revised the total trial sample size downwards to 60 participants per arm to maintain 80% power to detect a difference of 10 units with these revised parameters.

Data analysis

We did analyses on an intention to treat principle, using all randomised participants. We replaced missing data by the last score carried forward. For outcomes measured using an essentially continuous scale, we compared differences in mean change from baseline to each time point between groups by using linear regression modelling with adjustment for baseline levels of the outcome measure. We checked model assumptions by standard diagnostic plots.

We dichotomised participants' measures of perceived global change after active or placebo treatments into successful (much better) or unsuccessful (slightly better, no change, slightly worse, and much worse) outcome. We compared the percentage of successful outcomes between groups by calculating relative risks and their 95% confidence intervals at each time point with log binomial regression.[40]

We calculated an index to assess the success of blinding after treatment.[41] This index takes the value one for complete blinding and zero for complete lack of blinding.

RESULTS

We recruited 120 participants (59 active, 61 placebo), and 112 (54 active, 58 placebo; 93%) completed the 22 week trial. Figure 1 shows the flow of participants through the trial. Two participants, both from the active group, withdrew before completing the 10 week intervention. A further six participants (three active, three placebo) withdrew before the 22 week follow-up. Demographic and clinical characteristics of the eight participants who withdrew from the study did not differ from those of the 112 who remained (data not shown).

The groups were similar at baseline for demographic and clinical characteristics, although the median duration of symptoms seemed to be longer in the active group (table 2). The participants' expectation of treatment outcomes for active physiotherapy was similar in the two groups (P=0.79); 95/105 (90%) participants who provided this information expected a moderate or large beneficial effect.

Efficacy analysis

Immediately after treatment (11 weeks)

Both groups showed significant improvements immediately after treatment (11 weeks). However, we found
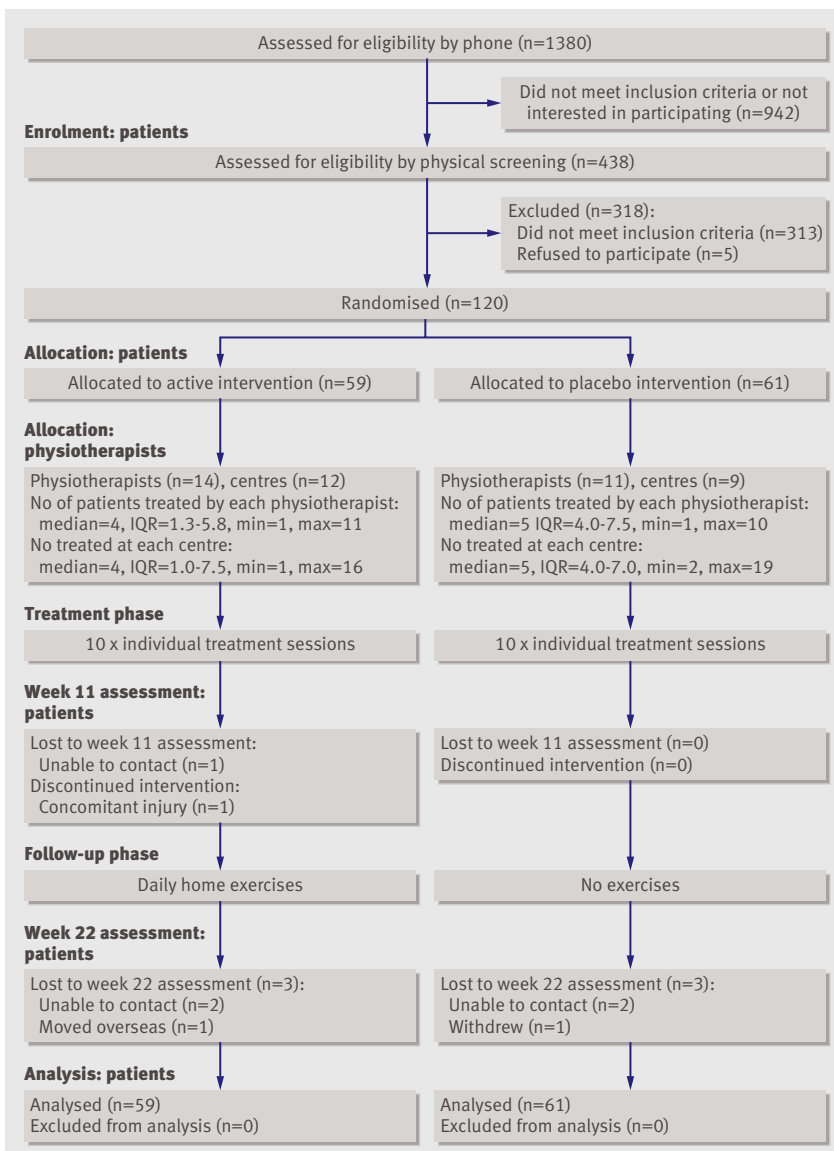

Fig 1| Flow of participants through study. IQR=interquartile range

Table 2 | Demographic and clinical characteristics of active and placebo groups. Values are numbers (percentages) unless stated otherwise

Characteristic	Active n=59	Placebo n=61
Mean (SD) age (years)	59.3 (10.1)	60.8 (12.4)
Median (interquartile range) duration of symptoms (months)	24 (6-54)	14 (6-24)
Mean (SD) height (cm)	169.0 (9.1)	167.5 (10.8)
Mean (SD) body mass (kg)	79.5 (13.5)	78.9 (15.9)
Mean (SD) body mass index (kg/m²)	27.8 (4.4)	27.9 (4.8)
Male sex	34 (58)	30 (49)
Affected shoulder (right:left)	35:24	38:23
Dominant side affected	38 (64)	42 (69)
Previous treatment:	29 (49)	35 (57)
Physiotherapy	20 (34)	26 (43)
Corticosteroid injection	10 (17)	15 (25)
Massage	2 (3)	1 (2)
Acupuncture	5 (8)	4 (7)
Chiropractic/osteopathy	6 (10)	6 (10)

no significant between group differences for the primary outcomes of changes in shoulder pain and disability index total score (3.6, 95% confidence interval −2.1 to 9.4) and pain on movement (0.7, −0.1 to 1.5) (table 3, fig 2). More participants in the active group reported an overall successful outcome (defined as "much better"), although the difference was not statistically significant: 42% of active participants and 30% of placebo participants (relative risk 1.43, 95% confidence interval 0.87 to 2.34) (table 4).

With regards to the secondary outcomes, the active group showed significantly greater improvements in both self reported and objective measures of strength (tables 3 and 4). We found no significant differences between treatment groups for other outcomes, including changes in health related quality of life.

Twenty-two week follow-up
The active group showed a significantly greater improvement in shoulder pain and disability index total score at 22 weeks than did the placebo group (mean between group difference 7.1, 0.3 to 13.9) (table 3, fig 2). However, this was not accompanied by significant differences between the active and placebo groups for change in pain on movement (table 3, fig 2) or for the percentage of participants reporting an overall successful treatment outcome (table 4). Within group changes in the primary outcomes remained significant at the 22 week follow-up (all P<0.001).

Several secondary outcomes also showed benefits in favour of the active group. We saw greater improvements in shoulder pain and disability index function score, muscle strength, interference with activity, and health related quality of life as measured by the assessment of quality of life instrument (tables 3 and 4).

Other analyses
The results immediately after treatment and at follow-up were essentially unaltered when reanalysed comparing the active group participants who reported more than 50% adherence to the home exercise programme (n=35) with the placebo participants; as a completers' analysis without replacing the missing values; controlling for duration of symptoms by adding a term in the regression analysis; and using generalised estimating equations to fit population averaged models (data not shown).

Adherence, adverse events, and co-interventions
Fifty-two (91%) of 57 participants in the active group and 57/61 (93%) of those in the placebo group attended all 10 physiotherapy treatment sessions. The number of sessions attended by the remainder ranged from three to nine with a mean of 4.8 (SD 2.7) in the active group and from one to seven with a mean of 6.0 (3.5) in the placebo group. Of the active group participants who completed the exercise diaries (52/57 during the intervention period and 39/55 in the follow-up period), the mean self reported completion of home exercise sessions was 57.2 (SD 15.7, 82%) during the intervention period and 49.0 (20.3, 70%) during the follow-up period.

During the intervention period, 17/55 (31%) participants in the active group reported adverse events. These comprised increased short term pain during or after the treatment session (n=3), increased short term pain with the home exercises (12), and mild irritation to the tape used for postural taping (2). In the placebo group, 5/61 (8%) reported adverse events comprising increased short term pain during or after the treatment session. During the follow-up period, adverse events were reported only by the active group (7/49, 14%) and comprised increased short term pain with the home exercises.

Use of analgesics and non-steroidal anti-inflammatory drugs was similar in the active and placebo groups over both the intervention period (analgesics: 11/55 (20%) active v 14/61 (23%) placebo; non-steroidal anti-inflammatories: 12/55 (22%) v 13/61 (21%); both P>0.05) and the follow-up period (analgesics: 8/49 (16%) v 8/55 (15%); non-steroidal anti-inflammatories 6/49 (12%) v 8/55 (15%); both P>0.05).

During the intervention period, one (2%) placebo participant received a cortisone injection into the shoulder. During the follow-up period, two (4%) participants in the active group received a cortisone injection into the shoulder and one (2%) participant in the placebo group received acupuncture treatment.

Success of blinding
In the active group, 32/55 (58%) participants correctly identified their treatment group at 11 weeks compared with 21/61 (34%) participants in the placebo group; 15 (27%) participants in the active group were uncertain which treatment they had received compared with 27 (44%) participants in the placebo group; and 8 (15%) participants in the active group incorrectly identified their treatment group compared with 13 (21%) participants in the placebo group. The blinding index was 0.70 (bootstrap 95% confidence interval 0.58 to 0.82),

Table 3 | Mean (SD) of groups, mean (SD) difference within groups, and mean (95% CI) difference between groups adjusted for baseline scores for outcomes with interval data

Outcome	Groups						Difference within groups*				Difference between groups†	
	Week 0		Week 11		Week 22		Week 0 to week 11		Week 0 to week 22		Week 0 to week 11	Week 0 to week 22
	Active (n=59)	Placebo (n=61)	Active (n=59)	Placebo (n=61)	Active (n=59)	Placebo (n=61)	Active	Placebo	Active	Placebo		
SPADI total (0-100)	43.3 (18.9)	43.9 (17.5)	27.2 (18.9)	31.2 (21.0)	20.9 (18.6)	28.3 (24.5)	16.1 (17.7)	12.7 (16.3)	22.4 (22.0)	15.6 (17.8)	3.6 (−2.1 to 9.4)	7.1 (0.3 to 13.9)
Pain on movement (0-10)	4.9 (2.2)	4.9 (1.8)	2.9 (2.3)	3.6 (2.3)	2.4 (2.4)	3.3 (2.7)	2.1 (2.6)	1.3 (2.2)	2.6 (2.9)	1.6 (2.4)	0.7 (−0.1 to 1.5)	0.9 (−0.03 to 1.7)
SPADI pain (0-100)	47.8 (20.1)	48.4 (17.5)	29.8 (20.8)	33.9 (22.7)	23.0 (21.0)	31.0 (26.0)	18.0 (18.8)	14.4 (18.5)	24.8 (23.7)	17.3 (19.6)	3.2 (−3.2 to 9.6)	6.8 (−0.7 to 14.3)
SPADI function (0-100)	33.6 (20.0)	33.8 (20.2)	20.0 (16.3)	25.1 (19.3)	14.1 (14.6)	22.2 (22.8)	13.6 (17.3)	8.7 (13.9)	19.6 (20.7)	11.6 (16.6)	4.7 (−0.1 to 9.5)	7.6 (1.8 to 13.4)
Pain at rest (0-10)	2.3 (1.9)	2.1 (1.8)	1.4 (1.9)	1.7 (1.9)	1.0 (2.0)	1.6 (2.1)	1.0 (2.2)	0.4 (2.0)	1.3 (2.5)	0.4 (2.5)	0.4 (−0.2 to 1.1)	0.7 (−0.1 to 1.4)
Weakness on movement (0-10)	4.6 (2.4)	4.1 (2.3)	2.6 (2.3)	3.2 (2.4)	2.1 (2.3)	2.9 (2.6)	2.0 (2.6)	0.9 (2.0)	2.5 (3.0)	1.1 (2.7)	0.8 (0.05 to 1.5)	0.9 (0.1 to 1.8)
Stiffness on movement (0-10)	3.3 (2.6)	3.4 (2.4)	2.1 (2.1)	2.6 (2.2)	1.9 (2.3)	2.6 (2.4)	1.2 (2.2)	0.8 (2.2)	1.4 (2.7)	0.8 (2.7)	0.4 (−0.2 to 1)	0.7 (−0.1 to 1.5)
Interference with activity (0-10)	3.9 (2.5)	3.8 (2.3)	2.0 (1.9)	2.6 (2.1)	1.5 (1.9)	2.5 (2.6)	1.9 (2.3)	1.2 (1.9)	2.4 (2.7)	1.3 (2.4)	0.6 (−0.04 to 1.2)	0.9 (0.1 to 1.7)
SF-36 physical (0-100)	49.3 (23.4)	48.9 (25.0)	61.0 (28.1)	55.0 (27.5)	60.0 (27.2)	53.5 (29.1)	11.7 (26.5)	6.1 (17.4)	10.8 (25.0)	4.7 (22.3)	5.7 (−2.1 to 13.6)	6.3 (−2.0 to 14.5)
SF-36 mental (0-100)	70.2 (23.4)	61.5 (21.4)	69.7 (22.1)	61.9 (20.7)	69.3 (20.4)	63.3 (21.0)	−0.6 (19.3)	0.4 (16.0)	−1.0 (19.7)	1.8 (15.8)	2.1 (−3.8 to 8)	0.6 (−5.2 to 6.4)
AQoL (−0.4–1.0)	0.7 (0.1)	0.7 (0.2)	0.7 (0.2)	0.7 (0.2)	0.7 (0.2)	0.7 (0.2)	0.0 (0.1)	0.0 (0.1)	0.0 (0.2)	0.0 (0.1)	0.0 (−0.04 to 0.03)	0.0 (0.04 to 0.1)
Abduction strength (kg)	7.2 (5.4)	6.2 (3.4)	8.4 (4.7)	6.7 (3.8)	8.3 (3.8)	6.5 (3.9)	1.2 (3.9)	0.5 (2.2)	1.1 (4.4)	0.4 (2.5)	1.0 (−0.1 to 2)	1.2 (0.1 to 2.3)
External rotation strength (kg)	8.1 (4.5)	7.1 (2.6)	8.3 (3.9)	7.2 (3.0)	8.4 (3.6)	7.0 (3.0)	0.2 (3.8)	0.1 (1.4)	0.3 (4.3)	−0.1 (1.9)	0.5 (−0.4 to 1.4)	0.9 (−0.1 to 1.9)
Internal rotation strength (kg)	10.9 (5.5)	10.2 (4.5)	11.7 (5.2)	10.1 (4.3)	12.2 (5.3)	10.2 (4.6)	0.9 (3.1)	−0.1 (2.7)	1.3 (3.4)	0.0 (2.7)	1.1 (0.1 to 2.1)	1.5 (0.4 to 2.5)

AQoL=assessment of quality of life; SF-36=Medical Outcomes Study 36-item short form; SPADI=shoulder pain and disability index.
*Positive change equals improvement, and positive values favour active group.
†Results from regression analyses adjusted for baseline scores.

interpreted as a moderate to high degree of blindedness and representing a statistically significant amount of blinding beyond that expected by chance (the value of the blinded index is 0.5 for random guessing).

DISCUSSION

This randomised, participant and single assessor blinded, placebo controlled trial evaluated the efficacy of a 10 week manual therapy and home exercise programme delivered by physiotherapists for the treatment of chronic rotator cuff disease in middle aged to older adults. Immediately after the intervention (11 weeks), the standardised active treatment generally produced similar beneficial effects on shoulder pain and function, the primary endpoints of the trial, compared with a realistic placebo treatment that controlled for therapists' contact time and the therapeutic environment. Both groups improved by amounts deemed to be clinically important,[42] and more than a third of participants reported a successful treatment outcome. However, we found significant differences favouring the active group for objective and subjective measures of muscle strength. At follow-up (22 weeks), we saw greater improvements with active treatment for several outcome measures. Changes in overall pain and function measured by the shoulder pain and disability index favoured the active group, although the mean between group difference of 7.1 was slightly below the 8 to 13.2 points reported in the literature as being the minimal clinically important difference.[42] Several secondary outcomes also favoured the active group, including shoulder pain and disability index function score, muscle strength, interference with activity, and quality of life.

Explanation of results

The significant improvements seen in both groups over the 22 weeks may reflect natural recovery of the rotator cuff disease. Although we did not include a third "no treatment" study arm to ascertain this, natural recovery is unlikely to explain the whole effect given the long duration of symptoms, particularly in the active group, and the moderate baseline disability of the cohort—factors that have been associated with a poorer prognosis.[43 44] Furthermore, other clinical trials in patients with chronic rotator cuff disease found minimal changes in pain or function over similar timeframes in control groups receiving no treatment.[14 19]

Table 4 | Number (percentage) of participants reporting a successful outcome ("much better") compared with those reporting an unsuccessful outcome ("slightly better," "no change," "slightly worse," or "much worse") in both groups, with relative risks

	11 weeks			22 weeks		
Outcome	Active (n=57)	Placebo (n=61)	Relative risk (95% CI)	Active (n=54)	Placebo (n=58)	Relative risk (95% CI)
Global change overall	24 (42)	18 (30)	1.43 (0.87 to 2.34)	31 (57)	24 (41)	1.39 (0.94 to 2.03)
Global change in pain	22 (39)	20 (33)	1.18 (0.72 to 1.91)	31 (57)	25 (43)	1.33 (0.92 to 1.94)
Global change in strength	19 (33)	7 (11)	2.90 (1.32 to 6.39)	22 (41)	14 (24)	1.69 (0.97 to 2.95)
Global change in stiffness	20 (35)	13 (21)	1.65 (0.91 to 2.99)	25 (46)	18 (31)	1.49 (0.92 to 2.41)

Improvement in our cohort may also have arisen from the statistical phenomenon of regression to the mean.[45] This refers to the tendency for extreme symptoms at baseline to return to a more typical state at final assessment. Symptoms associated with chronic rotator cuff disease fluctuate over time, and patients often seek medical care or enrol in research when the symptoms are at their worst. Furthermore, we included patients only if their pain was worse than a specific threshold level. The next change in symptoms is thus more likely to be an improvement.[46] However, we accounted for regression to the mean in our statistical analyses by adjusting for the baseline value of each variable.[47]

In addition to spontaneous improvement, another factor contributing to the total treatment effect is the placebo effect.[48] A recent meta-analysis showed that for active treatment of chronic pain conditions (not specifically of the shoulder), spontaneous recovery contributes around 10% and placebo effects around 30%.[46] Placebo effects have also been found to be greatest for non-drug interventions and for patient reported outcomes, particularly pain.[49] Other factors contributing to the placebo effect in our trial include blinding of participants, a treatment protocol involving considerable interaction with the therapist (10 individual sessions), and the fact that most (90%) participants expected to gain a moderate to large benefit from active treatment (given that positive expectations are known to be associated with improved outcomes[50]). Interestingly, the 33% reduction in pain reported by the placebo group is consistent with the 38% reduction found in the placebo group of our previous study in patients with osteoarthritis of the knee, in which we used an identical placebo treatment and pain measure.[28]

Our primary outcome measures included an assessment of pain but did not include an assessment of function in isolation. The results of both the primary and secondary outcomes suggest that active treatment did not substantially affect pain compared with placebo. However, evidence from the secondary outcome of shoulder pain and disability index function score suggests that shoulder function was improved to a significantly greater extent with active treatment. Given that our primary outcome of shoulder pain and disability index total score includes both the pain and function subscales, the benefits of active treatment on function could have been masked at the 11 week time point and attenuated at the 22 week time point, when a significant treatment group effect was found for shoulder pain and

disability index total score. Although the mean between group difference at the latter time point (7.1 units) was slightly below the minimal clinically important difference we used when designing the study, the 95% confidence interval includes the 10 unit threshold. This, together with the fact that the active treatment also led to significantly greater improvements in many secondary outcomes, indicates that manual therapy and home exercise may be beneficial particularly over time.

Aspects of active and placebo interventions

Some debate exists in the literature about whether the use of a placebo treatment as a comparator for complex interventions such as physiotherapy is appropriate.[48] The direct and indirect (placebo) effects of the therapy have been argued to be unlikely to be distinct and divisible, and elements that may be categorised as indirect effects in drug trials may in fact be integral to many non-drug interventions. Hence, using a placebo controlled trial design to test an intervention such as physiotherapy can mean that the differences between the groups substantially underestimate the total effects
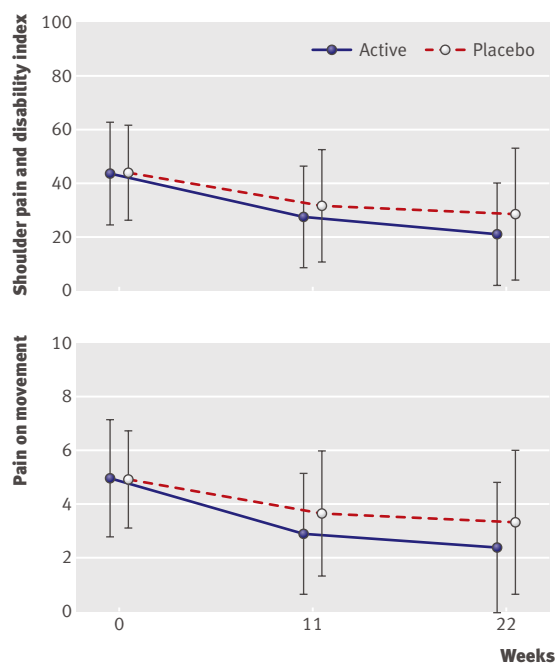
Fig 2 | Mean (SD) shoulder pain and disability index (SPADI) and pain on movement for active and placebo groups at baseline, 11 weeks, and 22 weeks

of treatment. This can lead to false negative results and erroneous conclusions about efficacy. We would have found significant beneficial effects of treatment if we had compared the active treatment with a no treatment control group as other studies in this area have done.[21-23]

Several aspects of the active intervention warrant consideration. Firstly, our standardised programme could be argued to have failed to adequately treat the specific physical impairments that patients presented with and that relate to shoulder pain and dysfunction. We noted significant improvements in isometric strength of 12-15% for the shoulder abductor and internal rotator muscles, as well as self reported strength gains, suggesting some effect. Whether the active treatment also successfully tackled other physical factors such as dynamic scapular control and thoracic posture is unknown, as these were not measured. Limited research shows that manual therapy techniques and exercises similar to those used in our study can alter shoulder and trunk biomechanics.[51]

Secondly, several participants failed to complete more than half of the prescribed home exercises, particularly during the unsupervised follow-up period. Problems with adherence to exercise programmes are common and reinforce the need to better incorporate strategies to enhance adherence, particularly when formal supervision by therapists ceases. However, our results were unaltered when we reanalysed the data excluding participants who failed to complete more than 50% of the home exercises, suggesting that levels of adherence in this study did not unduly influence the outcome.

Thirdly, to ensure a consistent approach and allow replication, we chose to evaluate a standardised treatment programme based on common elements identified from our survey and from the literature. It does not reflect the practice of every clinician involved in the conservative management of rotator cuff disease, and our results cannot necessarily be generalised to other manual therapy and exercise programmes given differences in type and dosage. Furthermore, as our treatment was standardised it may have been ineffective or even inappropriate for some patients, thus worsening symptoms and attenuating the treatment effects in the active group. However, a similar proportion of participants in both groups reported that they were worse after treatment (9/57 (16%) in the active group; 7/61 (12%) in the placebo group), suggesting that this was not the case. Further research is needed to evaluate the efficacy of other physiotherapy protocols for chronic rotator cuff disease and to assess treatment that is tailored to individual patients, as occurs in clinical practice.[52]

Like most other trials of rotator cuff disease to date, we chose to include participants on the basis of clinical features alone. Rotator cuff disease is known to most commonly affect the supraspinatus tendon,[10] but we cannot exclude the possibility that differences existed in the underlying structural abnormalities within our study population, although these were likely to be equally distributed between the treatment groups. Imaging techniques such as magnetic resonance imaging or ultrasonography may further improve diagnostic accuracy,[53] but these still lack sensitivity for certain pathological features,[54 55] are costly, and are generally not used in the primary care setting. Furthermore, physiotherapy treatment is not directed at the specific pathology but at the movement dysfunction and potential underlying mechanisms such as altered muscle function, tight structures, and poor scapular and spinal posture that have been reported in patients with rotator cuff disease.[51] Whether better outcomes with physiotherapy could be gained if subgroups of rotator cuff disease could be defined and specifically treated is not known.

Comparison with previous studies

A limited number of randomised controlled trials of physiotherapy modalities for chronic rotator cuff disease have been done, and none has tested a combined intervention of manual therapy and exercise against a placebo control to allow a direct comparison with our results. The only study to use a placebo control treatment (detuned laser twice weekly for six weeks) evaluated a three to six month exercise programme supervised by physiotherapists.[56] This trial found that exercise resulted in a significant 66% reduction in pain (measured on the Neer score), which is slightly higher than the 43% reduction in pain with our active treatment. However, unlike our study, the researchers noted little improvement in their placebo group, rendering their between group differences significant. Whether blinding of participants was successfully achieved was not stated. Other studies have compared exercise with arthroscopic surgery and shown similar beneficial outcomes in patients with rotator cuff disease.[56-58] The limited studies evaluating exercise combined with manual therapy have used an exercise only group as the comparator.[59-61] These have found that the effects of exercise on both pain and function are augmented with manual therapy, providing a rationale for evaluating a combined intervention.

Strengths and weaknesses

The strengths of our study include the rigorous study design, adequate statistical power, excellent retention of participants, inclusion of a placebo control, and the use of several therapists and a variety of recruitment sources to increase the external validity of the results. Our study has some limitations. Therapists were not blinded to treatment group, which is unavoidable in a trial of this nature. However, their interaction with patients was standardised and any bias due to non-blinding of therapists would probably favour the active group, which was not particularly evident in the outcomes. Participants were blinded, but given the difficulty in designing a credible placebo for physiotherapy interventions, blinding may not have been as complete as can be achieved in a drug trial in which an identical placebo pill can be administered. However, formal testing of the success of blinding indicated that we achieved a moderate to high degree of blindedness, representing a statistically significant amount of

WHAT IS ALREADY KNOWN ON THIS TOPIC

Rotator cuff disease is a common shoulder condition causing pain and loss of function

Manual therapy techniques and exercise programmes are often used in the management of rotator cuff disease, yet little conclusive evidence supports or refutes their efficacy

WHAT THIS STUDY ADDS

Immediate beneficial effects of a standardised manual therapy and home exercise programme were comparable to those of a realistic placebo treatment in middle aged to older adults with chronic rotator cuff disease

Benefits of manual therapy and exercise may accrue over time and may be of more value for improving shoulder function than pain

blinding beyond that expected by chance. Our sample size was reduced after a blinded interim analysis but gave sufficient power (80%) to detect clinically meaningful differences in the primary outcome. We replaced missing values by using the last observation carried forward method that was commonly used at the time the study was being planned but has fallen out of favour more recently.[62] This method is unlikely to have influenced the results, given the small dropout rate (8/120 participants, 7%) and the fact that we found similar outcomes when we used generalised estimating equations to fit population averaged models to the known scores.

Conclusions and practice implications

Our study showed that the particular manual therapy and home exercise programme tested conferred no additional benefit immediately after treatment compared with a realistic placebo in middle aged to older adults with chronic rotator cuff disease. However, given evidence of significantly greater improvements with active treatment at follow-up in one of the primary outcomes and in several secondary outcomes, the benefits of manual therapy and exercise may accrue over time. Physiotherapy interventions may also be of more value for improving shoulder function than pain per se in this population. Clinicians should thus establish whether the patient's primary presenting problem is pain, impaired function, or both. If pain is a major factor, then other treatments that reduce pain, such as corticosteroid injections, may be more appropriate. If both pain and loss of function are factors, then drugs or other pain relieving treatments may be needed in combination with manual therapy and exercise to adequately treat all facets. To facilitate adherence, clinicians should advise patients that the effects of manual therapy and exercise are not necessarily immediate but may take several months before they are evident. Further research is needed to evaluate the effectiveness of different physiotherapy treatment regimens and whether the combination of drug treatment with physiotherapy leads to greater benefits in people with mild to moderate chronic rotator cuff disease.

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Subacromial Impingement Syndrome: A Systematic Review of Existing Treatment Modalities to Newer Proprioceptive-Based Strategies

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Abstract

Musculoskeletal pain is a common reason for primary care visits, with many visits for shoulder pain due to subacromial impingement syndrome (SIS). Current treatments lack evidence for effective management, showing only temporary outcomes. This systematic review evaluates existing modalities in comparison to the use of more permanent proprioceptive-based strategies. Specifically, this meta-analysis compared the use of kinesiology tape, myofascial trigger point release (MPTR), scapular stabilization exercises (SSE), and resistance training. PubMed, BioMedCentral, and ScienceDirect databases were queried for studies evaluating proprioceptive-based exercises in the last nine years. In total, 48 studies met the inclusion and exclusion criteria. After removing duplicates, a total of 14 level 1 studies were left. Kinesiology tape use demonstrated a statistically significant reduction in pain-free range of motion. MPTR improved in all pain scores and the disability scores index. SSE also reduced pain; however, mixed results were seen for range of motion. Finally, resistance training not only reduced pain but improved proprioception and joint position sense. Even though all techniques showed some promise in treating SIS, further large-scale studies exploring related outcomes are needed.

Introduction And Background

Musculoskeletal pain is the second most common reason for visits to a primary care physician. The American Academy of Orthopaedic Surgeons (AAOS) estimates that a quarter of Americans have a musculoskeletal condition, which costs the United States over $850 billion dollars per year [1]. The prevalence of these conditions has led to a doubling of skeletal muscle relaxant prescriptions from 2005 to 2016 [2]. Of all musculoskeletal pain disorders, shoulder pain is the third most common reason for chronic pain visits [3]. The anatomy of the thoracic spine plays a crucial role in these pathologies as it is linked to different orientations of the scapula. In patients with subacromial impingement syndrome (SIS), particularly secondary SIS caused by muscular imbalance, the scapula can be found to be more protracted and the thoracic spine more flexed [4]. These alignment impairments may interfere with shoulder kinematics, leading to poor posture with chronic loss of range of motion and increased muscle relaxant prescriptions as patients attempt to deal with the pain [5].

It is estimated that 44-65% of all visits for shoulder pain are due to SIS [6]. Primary impingement syndrome is caused by structural changes that cause the narrowing of the subacromial space. Secondary impingement syndrome refers to an incorrect centering of the humeral head often due to muscular imbalance causing soft-tissue impingement when the shoulder joint is moved [3]. SIS does not describe one specific disorder but rather a spectrum of possible pathological processes, including partial thickness tears, rotator cuff tears, rotator cuff tendinosis, calcific tendinitis, and subacromial bursitis. Its prevalence is high in a wide range of repetitive overhead sports, such as swimming, volleyball, and handball, as well as in manual jobs requiring prolonged overhead positioning of the arm such as builders, electricians, and hairdressers.

The main consequences of SIS are functional loss, pain, and disability. Treatment strategies include a combination of exercise therapies, steroid injections, and, for refractory or severe patients, surgery [7]. There is growing evidence to support the use of resistance training, improved joint position sense, and proprioceptive shoulder exercises over movement-based exercise therapies alone. Current research, however, not only lacks evidence for the outcome of these management modalities but, specifically, there is a limitation as to which exercise therapies are most clinically effective [8].

There remains a need for high-quality clinical research on the treatment of SIS. This systematic review will focus on evaluating several existing functional rehabilitation strategies in comparison to the use of specific

proprioceptive-based strategies. It also reviews scapular kinematic deficits that should also be addressed with specific exercises in the rehabilitation of SIS.

Review

Methodology

Databases Queried

Following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, a systematic review of the literature for proprioceptive-based exercise therapies was conducted by searching PubMed, BioMedCentral, and ScienceDirect. Articles published in the past nine years (January 1, 2011, to December 31, 2020) were identified using various keyword combinations. The following string was utilized for the search: (("Subacromial impingement syndrome" OR "SIS" OR "Chronic Shoulder pain") AND ("Kinesiology tape" OR "KT" OR "Scapular stabilization exercises" OR "SSE" OR "Resistance training" OR "Myofascial Trigger point release" OR "MTPR")).

Inclusion and Exclusion Criteria

Publications were eligible for inclusion if they: (1) included patients with existing chronic shoulder pain and/or SIS; (2) included a comparison of both pre and posttreatment results; (3) the level of evidence was level 2 or higher based on the American Society of Plastic Surgeons; and (4) the study was performed in the United States, Canada, United Kingdom, or Australia. Studies were excluded if they: (1) were published beyond 2011; (2) included surgical intervention as a treatment modality; (3) were written or published in a language other than English; (4) the full text was not available; and (5) were systematic reviews, meta-analyses, case reports, case studies, feasibility or pilot studies, letters to the editor, or surveys.

Eligible Studies

The primary search of the PubMed database generated 23,374 results, of which 25 met the inclusion and exclusion criteria. The original search of the BioMed database resulted in 222 entries. Of these, seven met the inclusion and exclusion criteria. The initial search of the ScienceDirect database returned 7,601 results, of which 16 met our inclusion and exclusion criteria. After removing duplicates and further assessing for relevance, we were left with a total of 14 studies, all reporting level 1 evidence (Figure *1*).
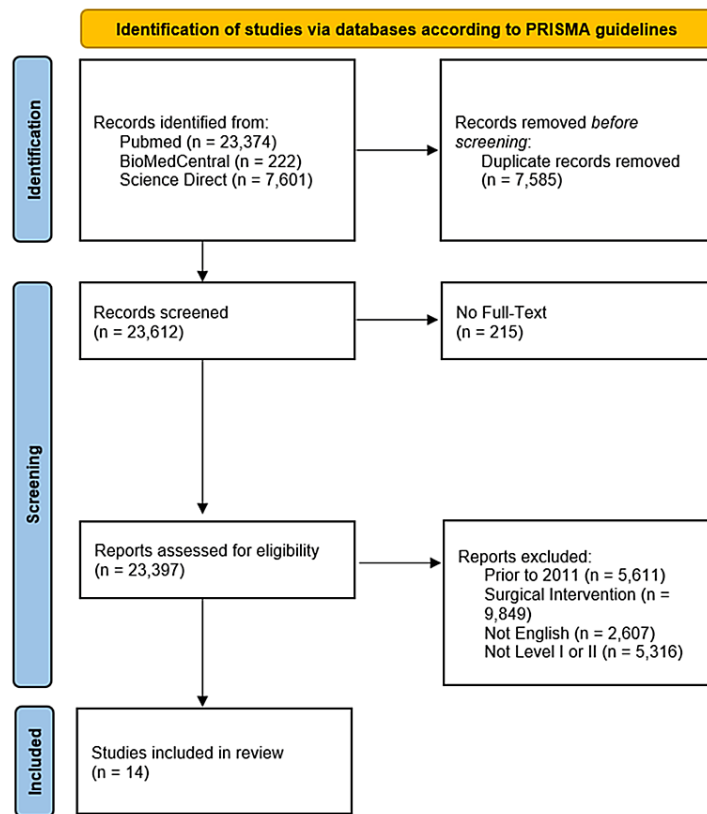
FIGURE 1: PRISMA flowchart.

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Study Data/Extracted Data

The 14 studies included in this systematic review were assessed, and the data extracted included the type of study, diagnosis, type of treatments utilized, exercise therapy strategies, rehabilitation intervention, control and intervention group characteristics, time to follow-up, and outcome measures.

Treatment Modalities

The first treatment considered was kinesiology tape (KT). KT works by extending from a muscle's origin to insertion using different degrees of stretch at either side of the tape to achieve a desired effect depending on the specific muscle ailment that it is being used for.

The second treatment, myofascial trigger point release (MTPR), involves the use of the therapist's hands to palpate and identify points of resistance in the muscle tissue. Once found, the therapist applies specific pressure to the point until there is a release of tension or decline in pain.

Scapular stabilization exercises (SSE) refer to several exercises designed to strengthen the muscles that anchor the scapula to the thoracic cage. The serratus anterior, serratus posterior, trapezius, rhomboids, teres major, levator scapulae, and the latissimus dorsi are all crucial to allow for scapular stability which directly impacts the ability of the shoulder joint to correctly function.

Resistance training consists of specific movements and exercises that target progressive stretching/strengthening designed to reverse specific shoulder complications. This treatment modality utilizes resistance/weight training and focuses on the strengthening of muscles surrounding the shoulder joint with the intention of facilitating greater joint stabilization.

Results

Treatment One: Elastic Kinesiology Tape

When a muscle is acutely overstressed, the goal of therapy is to inhibit the muscle to decrease the load, and

thereby the pain that patients feel. Elastic KT can achieve this effect by tensing the KT to 15-25% stretch starting from the painful area at the muscle insertion and ending at the origin of the muscle. In a weakened muscle, the aim is to stimulate the muscle by applying 15-25% tension to the KT and attaching it to the origin of the muscle, with the other end of the KT attached to the insertion. With these two methods, KT decreases pain and increases range of motion (ROM) [9]. Elastic KT is a useful technique that is designed to prevent and treat many musculoskeletal injuries, as well as increase sports performance [9]. Three level 1 studies evaluating the use of KT are included in this review.

Shakeri et al. [10] evaluated 30 patients with SIS. The experimental group received KT taping on/around their shoulder girdle on day one and were assessed using outcome measures, such as the Visual Analog Scale (VAS) and pain-free ROM for abduction, flexion, and scapular plane elevation. Patients kept the KT on for three days and underwent the first evaluation on day four after the KT was removed. The application of the tape was repeated, kept on for three days, and following KT removal, patients were again evaluated. A control group received taping at the same intervals but placebo taping techniques were used in place of KT. When compared with pretreatment scores, the experimental group saw a significant decrease of 2-3 points in VAS for pain intensity during movement (p = 0.000). There was a significant decrease of 3-4 points in VAS for nocturnal pain (p = 0.000). Significant differences in pain-free ROM compared to pretreatment were reported for all three shoulder ROMs (10-19 degrees) (p = 0.000). After placebo taping, the control group showed no significant differences in VAS for pain intensity during movement nor in shoulder flexion ROM when compared to pretreatment scores. A significant difference in VAS for nocturnal pain was found immediately after taping (1-point difference) and a week after taping (2-point difference). A significant difference was found in pain-free shoulder abduction ROM (9 degrees) and scapular elevation ROM (8 degrees) after one week of placebo when compared to pretreatment values (control group).

The study by Kul and Ugur [11] divided 40 patients with SIS into two groups based on the treatment modality they were to receive. The first group, KT group (KTG), received KT as well as a home exercise program (HEP). The second group, physiotherapy (PT) modalities group (PTG), received 15 sessions of physical therapy with HEP. Patients were followed up with two calls at five-day intervals for a total of six calls. Patients who had received corticosteroid injections in the last three months were not included in this study. Outcome measurements in this study included the VAS for rest, nocturnal and activity pain, as well as ROM values for active flexion, abduction, and internal rotation. Patients were assessed pretreatment (time 1; T1), after treatment (T2), and one month after treatment ended (T3). All values at T2 in the KTG showed significant changes when compared to baseline (all p < 0.001). At T3, significant improvements were seen in VAS rest pain (p < 0.01), VAS nocturnal pain (p < 0.01), and VAS activity pain (p < 0.05). The PTG showed significant improvements for all variables at T2 (p < 0.01). At T3, significant improvements were seen in shoulder abduction ROM (p < 0.05) and VAS nocturnal pain (p < 0.05). PT was more effective than KT in VAS activity pain (p < 0.05) and VAS nocturnal pain (p < 0.01) at T2 compared to T1. PTG improvements continued to be statistically significantly different from KTG until T3 for rest pain (p < 0.05).

A study by Goksu et al. [12] compared the therapeutic effects of KT versus subacromial corticosteroid injections (SCI) in patients with SIS. In total, 61 patients were separated into two groups. The KTG received taping three times in three-day intervals. The corticosteroid injection group (CIG) received a corticosteroid as well as a local anesthetic (bupivacaine). Both groups were prescribed the same home exercise regimen to follow for seven sessions with 24 hours between each session. The outcome measurements for this study evaluated flexion/abduction ROM values, and the VAS was used to quantify shoulder pain at rest/during movement. Shoulder functional status was detected by the Shoulder Pain and Disability Index (SPADI). Evaluations were done at baseline (T1), one week after therapy (T2), and four weeks after therapy (T3). Both groups were found to have significant improvements in ROM, VAS scores, and SPADI scores at the end of T2 and T3. When comparing the two groups at T2, the CIG had statistically significant improvement in VAS scores at rest (p < 0.025), abduction ROM (p < 0.028), and SPADI scores (p < 0.043). At T3, the CIG again had statistically significant changes when compared to the KTG for VAS scores at rest (p < 0.01), abduction ROM (p < 0.043), and SPADI scores (p < 0.031). Both groups had similar score improvements in VAS pain scores in motion, as well as ROM for flexion and abduction. All parameters improved after both treatment modalities at a statistically significant level.

Summary: Elastic KT has been shown to be effective in the treatment of shoulder pain, and more specifically in SIS. The VAS was an outcome measure common to all three studies assessed. KT was found to decrease VAS scores at rest, during movement, and at night. This effect lasted for at least one month after treatment ceased. Shakeri et al. found that KT increased the pain-free ROM for abduction, flexion, and scapular plane elevation. Kul and Uger found significant increases in ROM for all movements; however, this was only found immediately after treatment and not at one-month post treatment. Goksu et al., however, showed statistically significant lasting effects (four weeks post treatment) of KT on flexion and abduction ROM as well as on SPADI scores. Elastic KT appears to be an effective treatment modality for chronic shoulder pain due to SIS.

Treatment Two: Myofascial Trigger Point Release

Myofascial trigger points (MTPs) are tender points in tight bands of muscle that cause pain, known as myofascial pain. In MTPR, a therapist applies pressure on a patient's muscle until they find an area of

increase in tissue resistance, the MTP. On palpation of the MTP, the patient often experiences pain/discomfort. The pressure is maintained until the patient feels a release of tension/decline in pain or until the therapist feels a release of tension underneath their palpating finger. With this manual therapy, the practitioner searches for MTPs and attempts to provide relief at these points. Three studies reporting level 1 evidence were included to evaluate MTPR.

Bron et al. [13] investigated the effect of MTPR in patients with chronic shoulder pain. In total, 72 patients were included in the study and placed into one of two groups. The intervention group (IG) consisted of 37 patients who received MTPR treatment once weekly for a maximum of 12 weeks. Patients in the control group were instructed to continue their current treatment interventions, whether medicine or stretching. At six and 12 weeks of treatment, both groups reported results. The primary outcome measurement was the Disabilities of Arm, Shoulder and Hand (DASH) questionnaire score. Another outcome measure was the VAS for Pain (VAS-P). This is a general pain score and rates pain at that moment (VAS-P1), pain in the last seven days (VAS-P2), and the most severe pain in the last seven days (VAS-P3). Lastly, the number of muscles with MTP between the two groups was assessed and compared at six and 12 weeks. There was a significant improvement in the IG when compared to the control group at 12 weeks (all p < 0.05). Differences were detected on the DASH (mean difference = 7.7), the VAS-P1 (mean difference = 13.8), the VAS-P2 (mean difference = 10.2), and the VAS-P3 (mean difference = 13.8). The IG had a mean difference of 2.7 fewer muscles with MTPs when compared to the control group. After 12 weeks of study, 55% of IG patients reported improvement in shoulder pain, whereas this number was only 14% in the control group.

Myofascial pain syndrome (MPS) is a musculoskeletal disorder that features many MTPs, as well as increasing muscle stiffness. A study by Kisilewicz et al. [14] studied the effects of MTPR on trapezius muscle stiffness and the resultant presence of MPS. The study considered 12 professional Polish basketball players with unilateral neck or shoulder pain on the dominant side. Once MTPs were localized, they were treated with MTPR. The main outcome measure of this study was dynamic stiffness. Dynamic stiffness is the resistance of soft tissue to an external or internal force. The more dynamic stiffness, the more resistance, resulting in greater pain. Dynamic stiffness was measured immediately before and after MTPR with a device called the MyotonPRO. The results of the trial produced mixed results. There was a significant decrease in muscle stiffness of the upper trapezius by 11.8% (p < 0.01). Comparatively, no significant changes were detected in the middle or lower trapezius. Furthermore, no significant change was seen in the dynamic stiffness in the whole contralateral trapezius muscle (p > 0.05).

A study by Gordon et al. [15] examined the effects of MTPR on 23 patients with shoulder pain. All patients received four 10-minute sessions of therapy exclusively on the painful shoulder over a span of two weeks. Outcomes were assessed before treatment (T1), after two weeks (T2), and after six weeks (T3). The MyotonPRO was utilized in this study to assess changes in muscle stiffness. Muscle stiffness scores showed significant improvements for the treatment when comparing pre and posttreatment values (p = 0.012). The non-treated side did not show these same significant improvements in muscle stiffness (p = 0.241). Pain scores were assessed using the Brief Pain Index (BPI). The BPI scores showed that MTPR brought forth statistically significant changes in BPI scores (p < 0.0001). Pain scores also remained stable at the four-week follow-up appointment and continued to be stable at the 13-month follow-up appointment. The Wilcoxon test was utilized to determine three different parameters indicating the effect of MTPR on quality of life. Levels of stress (p = 0.024), average suffering (p < 0.0001), and reduction of quality of life scores (p < 0.0001) significantly improved, indicating that MTPR was effective in decreasing patient stress, decreasing patient suffering, and improving the quality of life.

Summary: MTPR was found to be an effective therapy for reducing pain, decreasing muscle stiffness, as well as improving patient quality of life and disability. Bron et al. reported that the IG that received treatment improved significantly in all pain scores when compared to the control group. Furthermore, disability scores were also seen to improve. Kisilwecz et al. identified that MTPR was not as effective in the treatment of the middle or lower trapezius regarding changes in muscle stiffness. However, the upper trapezius was responsive to MTPR, and dynamic muscle stiffness was found to decrease in post versus pretreatment scores. Gordon et al. found that all outcomes assessed showed statistically significant improvement in comparison to pretreatment scores. As exemplified above, MTPR appears to be an effective treatment for chronic shoulder pain from SIS or by other causes.

Treatment Three: Scapular Stabilization Exercises

Forward head posture and round shoulder posture are two of the most common postural disorders, often seen together. It increases the gravitational force exerted on the head, which can lead to degenerative changes in the cervical spine. This is known to be from a dysfunction of the flexion-relaxation phenomenon (FRP). The FRP is a normal and physiologic pattern that refers to the reduction or silence of myoelectric activity of the lumbar erector spinae (ES) muscle during full-trunk flexion [16]. In patients with shoulder injuries, postural correction can be seen to improve pain. Several investigations have shown that pain can be reduced through SSE. These SSEs include chin-tuck, overhead press, horizontal pull apart, chest press, serratus anterior punches, retraction plus external rotation, and scapular protraction. Some studies reported increased ROM using these exercises, which occurs from improved joint position sense and proprioception [16]. Four level 1 studies evaluating the use of SSE were included in this systematic review.

Shiravi et al. [17] assessed 132 consecutive patients who presented with secondary SIS due to forward head and round shoulder postures. All participants were submitted to the evaluation of the joint position sense (JPS) at 30, 60, 90, 120, and 150 degrees of shoulder forward flexion during the sitting position. Study group 1 consisted of 45 patients who used SSE and the control group included 45 patients who underwent no intervention. The SSEs were performed 30 minutes each day for six weeks (three sessions per week). The study found that group one had significant decreases in pain (-3.8 ± 0.48, $p = 0.021$) and proprioception (-2.5 ± 0.2, $p = 0.033$) after six weeks. The addition of SSE for the cervical spine led to greater improvements in pain, posture, FRP, and strength (start of the concentric contraction, $p = 0.009$, and end of the concentric contraction, $p = 0.044$). No significant changes were seen in pain and proprioception in the control group.

Hotta et al. [18] assessed 50 patients with SIS, of whom 25 were in the control group and 25 were in the treatment group. The treatment group underwent eight weeks of SSE with periscapular strengthening. Scapular kinematics, shoulder pain, and shoulder disability index were the outcome measures used. The orientation and position of the thorax, scapula, and humerus of the patients were assessed using the three-dimensional motion capture system 3 SPACE Liberty. Electromagnetic sensors were used, which were attached to the body segments to be analyzed and to digitize the anatomical points. There was a significant improvement in shoulder pain and disability index ($p < 0.01$), shoulder kinematics for upward rotation ($p < 0.01$), anterior tilt ($p < 0.01$), and internal rotation ($p < 0.01$) of the scapula. Muscular strength increased in the treated group after carrying out the protocol. In the treatment group, a significant reduction in pain was seen with a mean difference of 32.4 points ($p < 0.01$), indicating improved shoulder function in the treatment group.

Moezy et al. [19] conducted a randomized controlled trial (RCT) to compare the effectiveness of SSE with conventional PT in 68 patients with SIS. The flexibility exercises included the sleeper stretch, crossed arm stretch, and corner stretch. The outcomes measured included improved ROM and joint position sense. Scapular clock exercises using a ball were used to help with joint kinesthesia. The PT protocol included pendulum and ROM exercises. The improvement of shoulder abduction ($p = 0.024$), external rotation ranges ($p = 0.001$), postural parameters such as forward shoulder translation ($p < 0.0001$), forward head posture ($p = 0.001$), mid-thoracic curve ($p = 0.001$), and pectoralis minor length in the SSE group were significantly greater than that the PT group. After six weeks, the SSE group also demonstrated significant improvement in shoulder flexibility ($p < 0.0001$) and protraction of the shoulder ($p = 0.001$). In the PT group, there were also significant differences in scapular rotation and pectoralis minor length; however, no improvement in scapular symmetry and no reduction in pain were seen ($p = 0.576$).

Struyf et al. [20] conducted an RCT among 22 patients with SIS. The scapular-focused treatment group included stretching and scapular motor control training which included upward and downward rotation, external and internal rotation, and posterior and anterior tilting of the scapula. The control therapy group included stretching and rotator cuff training with an elastic band. The forward posture head was measured vertically with a sliding caliper. One gravity-referenced inclinometer was used to measure humeral elevation, and a second inclinometer was used to reliably measure the upward rotation of the scapula. Clinically significant improvement was seen in scapular motor control training using self-reported disability (Cohen's $p = 0.93$, $p = 0.025$), and improvement in pain during the Neer test, Hawkins test, and empty can test ($p = 0.076$, 0.014, and 0.092, respectively). The experimental group demonstrated a moderate improvement in self-experienced pain at rest, whereas the control group showed no improvement. However, no significant difference was seen in the scapular upward rotation and the shoulder disability questionnaire.

Summary: The use of SSE in patients with SIS has demonstrated improvements in various outcomes of measures. With the studies evaluated for this treatment, some contradicting results were found. A key finding that was common to all the RCTs studied here was an improvement in scapular rotation and ROM. This increase in ROM can be attributed to reduced pain which was also seen in all studies. The study by Struyf et al. was unique in that no significant difference was found in scapular upward rotation; however, motor control training including external/internal rotation and posterior/anterior tilting of the scapula demonstrated improvement. In addition, all the above studies showed a reduction in pain using scapular exercises alone except the study by Moezy et al., which showed an equal reduction in pain using both SSE and PT.

Treatment Four: Resistance Training Exercises

Several studies measure the effect of active exercises and strength training for shoulder injuries and pain that cause the weakening of the surrounding muscles. Shoulder movement is a modifiable factor that can contribute to shoulder pain and disability. Because people with SIS, rotator cuff injuries, or even diabetes demonstrate decreased shoulder motion and strength, specific movement and exercise strategies targeting progressive stretching and strengthening will help to reverse these shoulder complications. Two main aspects should be taken into account during strength training: specific muscle-force level and the force balance among muscles that act on the same joint [7]. Proprioception, the ability to recognize and locate the body in relation to its position and orientation in space, is essential for motor control and joint stability during daily activities and sports practice [7]. Several studies have described its effects on muscle strengthening which directly affects the functional capacity. Therefore, it is important to understand the effects of resistance training on proprioception so that we can improve the strength-training protocols to

increase joint stability. The strength-training program exercises reviewed in these studies included a sling suspension system, bench press, lat pull-down, shoulder press, seated row, inferior glide, isometric low row, dynamic knee push-up, wall press, and wall slide with weights. Four level 1 studies were included in this exercise.

Jung et al. [21] assessed 36 patients who received active shoulder exercise with a sling suspension system and 18 patients in the control group who received bilateral arm training for 40 minutes five days a week for four weeks. The outcome measures before and after the intervention included measurement of shoulder subluxation distance, shoulder proprioception, the Fugl-Meyer assessment (FMA) scale, and the manual function test (MFT). A sling suspension-based exercise method can compensate for gravity by hanging part of the body on a string. It can induce selective active muscle contraction by adjusting the gravity, designed to strengthen muscles around the shoulder joint. The control group underwent shoulder flexion-extension exercise, elbow joint flexion-extension exercise, and a forward-reaching exercise. The shoulder subluxation distance was evaluated using an L-shaped thermoplastic rod (or jig). The assessment of shoulder proprioception was performed using a repositioning test of shoulder flexion position sense using five specified angles. The FMA tool was used for quantitative assessment of the functional recovery. The change in distance measured in shoulder subluxation (p = 0.008), the degree of shoulder proprioception (p = 0.006), and the upper extremity manual function (p = 0.002) demonstrated significantly greater results in the study group than in the control group.

Shiravi et al. [17] assessed 132 consecutive patients who presented with secondary SIS due to forward head and round shoulder postures. Study group one consisted of 45 patients who used abdominal control feedback (ACF) exercises and the control group included 45 patients who underwent no intervention. All participants were submitted to the evaluation of the JPS at 30, 60, 90, 120, and 150 degrees of shoulder forward flexion during the sitting position. Shoulder proprioception was measured by a goniometer. Electromyography data were normalized for maximum voluntary contraction. The maximal isometric strength of scapular upward rotators was measured using a handheld dynamometer. The addition of ACF to a conservative program for a shoulder injury led to greater improvements in neck pain, posture, FRP, and strength. The study found that group one had significant decreases in pain (p = 0.036) and proprioception error (p = 0.034) after six weeks. No significant changes were seen in pain and proprioception in the control group.

Salles et al. [22] assessed a total of 90 male undergraduates. They were randomly distributed into three groups: group one with 24 subjects performed four exercises at the same high intensity, group two with 27 subjects performed exercises at different intensities, and the control group with 30 subjects performed no upper body exercise. The ACF exercises including bench press, lat pulldown, shoulder press, and seated row were performed 30 minutes each day for six weeks (three sessions per week). They determined the ROM for shoulder rotation by measuring the amplitude between the maximum internal and external rotation. The JPS absolute error (AE) was assessed by applying the joint-position reproduction test, with a target position at 50% of ROM. At pretraining, there was no difference in JPS AE among groups, yet at post-training, group one demonstrated less AE than both group two and the control group with the best performance. JPS improved in group one compared to group two and the AE in group two was also less compared with the control group. Meanwhile, the control group maintained the same AE and did not improve proprioceptive acuity. The results demonstrate that AE depends on training intensity; strength training improved healthy participants' ability to reproduce joint position and thus improved proprioception.

Mueller et al. [23], conducted an RCT for three months on 52 participants with shoulder pain or limited motion and were randomized to a group receiving progressive shoulder movement intervention (ShoMo group) and a control group receiving wellness activities. The ShoMo intervention group included exercises to improve shoulder ROM. Participants started with passive stretching of end-range shoulder flexion and rotation (internal, external) that progressed to active, followed by resisted shoulder motions tailored to their ability level. Participants were then instructed to perform three assigned stretching motions for a minimum of two sets of 10 repetitions every day. Participants were also instructed in active shoulder movement that could be incorporated into daily activities with a dose based on the participant's measured activity count at baseline using accelerometers. The intent of the wellness program was to control interactions with physical therapists (participants seen four times over three months) and to provide useful information for disease management, but not provide intervention that directly targeted shoulder joint motion. The outcome measures involved ROM and SPADI. The ShoMo group had a 7.2-degree increase in active shoulder flexion compared to the wellness group after three months of intervention (p < 0.05). However, the difference did not persist for more than three months. The ShoMo group showed a 12.7-point improvement in the total SPADI score compared to the wellness group following three months of intervention. The significant difference between groups persisted over 12 months.

Summary: The use of resistance for strengthening and active weight-bearing exercises has been shown to significantly reduce pain and improve proprioception in those who have shoulder injuries. In each of the studies reviewed, strengthening exercises improved joint position sense and shoulder kinesthesia. The simultaneous reduction in pain parallels the improved ROM also seen in the literature. In the study by Mueller et al., the results did not persist over the long term because there was no follow-up after the therapeutic intervention was completed. It becomes important to continue to note any confounding factors that may have caused the results. Therefore, the results of the present study should be verified by additional

studies with larger sample sizes. Furthermore, although all the studies demonstrated improved ROM, only the study by Jung et al. actually measured the improved manual function test.

Discussion

Chronic shoulder pain is an extremely prevalent problem that plagues Americans. It is the third most common reason for physician visits, of which secondary muscular SIS pathologies make up approximately half. To assess the usefulness of specific proprioceptive-based treatment modalities compared to more traditional and existing rehabilitation exercises, this review looked at the use of KT, MTPR, SSE, as well as resistance training. KT was seen to effectively reduce pain and improve functional limitation, especially in combination with exercise therapy [11]. However, it was also seen that proper posture and scapular stabilizer exercises appear to be more effective than general exercise therapy. Furthermore, when conventional treatment modalities fail, surgical methods are considered. Yet, several RCTs have reported no difference in pain outcomes between conservative compared to surgically treated patients [24]. Aside from these options, however, this review reviewed more unconventional therapies. KT appears to be an effective treatment modality for chronic shoulder pain and improvement in functional ROM for up to four weeks posttreatment. MTPR was universally found to be an effective therapy for reducing pain, decreasing muscle stiffness, as well as improving patient quality of life. SSE-based treatment has some contradicting results where pain and ROM were improved in all studies except one. Finally, resistance training improved joint position sense and shoulder kinesthesia in each of the studies reviewed; however, the pain was less studied. All techniques reviewed showed promise in effectively treating SIS, but further studies are needed to make definitive conclusions.

There are some limitations to this review. One limitation of this review includes inconsistent patient follow-up. Most literature studies measured outcomes up to three months to a maximum of one year. To determine promising long-term results, it is vital to maintain continuity. However, the fact that not many papers have focused on this aspect of the research is the reason why this review is important. Despite the positive results seen in this paper, physicians limit SIS treatment to the more commonly used methods such as non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroids because there is a need for continuity. Another limitation is the limited number of studies available for each technique. There is limited research conducted on proprioceptive-based modalities specifically, which is the basis of this paper. Improving joint position sense is what allows for an increase in ROM. Limited ROM is the root cause of pain and functional disability. More studies are needed to help assess whether treatment modalities such as KT and resistance training increase the degree of joint position sense. The ideal goal is that once more research is conducted and shows promising results, management of SIS can shift primarily to these treatments instead of NSAIDs or just physiotherapy. Finally, the scoring systems for each outcome measured can be hard to quantify because a wide range of scoring techniques have been used. For example, studies used a varying range of exercise sets and repetitions for the resistance training group. It is important to assess the numerical threshold after which improvement was seen. This can help us determine whether continuing treatment in those that did not see improvement might have proved beneficial. Regardless of this, the reports reviewed showed promising results and allow us to potentially standardize scoring systems in the future.

Previous literature studies have shown a range of improvements with KT treatment. Yam et al. [25] compared RCTs measuring lower limb muscle strength and performance in patients with muscle fatigue, chronic musculoskeletal disease, those without disabilities, and those with postoperative orthopedic conditions. This was done by conducting distance in a single leg hop and vertical jump height. From each study, the greatest improvement seen favoring KT was in those with chronic musculoskeletal diseases [25]. Similarly, Wilson et al. [26] saw improvements in stability for lateral ankle sprains with a reduction in recurrence seen using KT. They measured proprioception using the dynamic balance test and endurance using the heel raise test. It was seen that KT may increase afferent input and improve proprioception on ankle stability. It was also seen that KT increased plantar flexor endurance and vertical jump height. Finally, improvements in postural control were also found [26]. These results are similar to those reviewed in this study.

Literature supports MTPR treatment of head and neck muscles in tension-type headaches and migraine-type headaches. Dry needling is a type of treatment using a thin filiform needle to penetrate the skin that stimulates MTPR. In a review by Navarro-Santana et al. [27], it was seen to improve pain-related disability compared to no treatment. Similarly, Falsiroli Maistrello et al. [28] have shown the effectiveness of manual MTPR regarding frequency, intensity, and duration of attacks in both tension-type and migraine headaches. Those with either of these have a greater number of trigger points compared to healthy subjects, and a higher number correlates with the severity and the duration of attacks. The treatment used ischemic compression, myofascial release, muscle energy, soft-tissue treatment, and positional release. The results showed a greater reduction in pain, intensity, and duration scales of headaches [28].

Studies have shown that targeted SSE can lead to improvement in posture and pain. An RCT by Kang et al. [29] used 14 exercises, including press-ups in a chain, push-up plus, supine deep breathing, supine shoulder at 90 degrees of flexion with scapular protraction/retraction, arm raise in the quadruped position, lateral arm raises with 2 kg dumbbells, posture education, prone I, prone Y, prone T, prone W, and lateral pulldown. Significant improvements were seen using the pain scale and neck function using the neck

disability index. An RCT was also conducted by Beurskens et al. [30] to measure the effectiveness of physiotherapy following breast cancer and axillary node dissection. Treatments included postural correction, upper extremity coordination exercise, strengthening and conditioning exercise, and exercise for lymphedema. The program took place in nine sessions over three months. The main outcome was the VAS, which showed that shoulder/arm pain was significantly improved [30].

Previous studies have shown that intensity resistance training exercises improve pain and functional mobility. The scientific evidence behind this is due to muscle hypertrophy which contributes to muscle growth that stems from an increase in neural adaptations from exercising [31]. An RCT by Jones et al. [32] was conducted to compare resistance training versus general exercises versus no treatment in women with fibromyalgia. The regime consisted of resistance training using hand weights up to 3 lb and elastic tubing. The outcomes showed improvements of 26% in multidimensional function, 15.9% in self-reported physical function, 44.6% in pain, 12.6% in tenderness, and 25% in muscle strength in the resistance groups. Similarly, a meta-analysis of 667 articles by Papa et al. [33] showed that resistance training can decrease age-related regression in functional mobility. The training focused on the large muscle groups in the lower extremities, the effects of full-body resistance training, as well as resistance training for the muscles in the core of the body, including abdominals and spine stabilizers. Improvements in the functional mobility, gait, speed, and balance of older adults were seen. The most common outcomes included the Timed Up and Go test (TUG) and the Functional Reach test (FR). There is a 15% decrease in muscle strength every 10 years after the age of 50. However, this paper shows that resistance training can slow the loss of muscle mass and muscle strength if performed two to three days per week. These findings are in line with the ones discussed here and may provide promising results in the future.

Conclusions

Musculoskeletal disorders, and specifically SIS, are common reasons for primary care visits, and more permanent therapeutic modalities in this area need a focus of care. Most current treatment options are temporary or only have short-term outcomes. The need for improvements in care has shed light on newer therapies for treating SIS. This meta-analysis compared the use of KT, MTPR, SSE, and resistance training. All techniques reviewed showed some promise in effectively treating SIS, but further information is needed to make definitive conclusions. Future studies should explore the use of resistance, improved joint position sense, and proprioceptive shoulder exercises, and focus on providing further information and insights on the fascial mobilization used in these techniques that contribute to the outcome measures.

Additional Information

Disclosures

Conflicts of interest: In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any organization for the submitted work. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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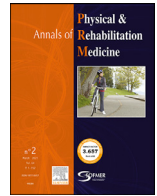
Original article

Effectiveness of scapular mobilization in people with subacromial impingement syndrome: A randomized controlled trial

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ABSTRACT

Background: Scapular mobilization is a manual therapy technique widely used in the management of musculoskeletal disorders of the shoulder.
Objective: To determine the effects of scapular mobilization in addition to an exercise program in people with subacromial impingement syndrome (SIS).
Methods: Seventy-two adults with SIS were randomly allocated to 1 of 2 groups. The control group (n=36) participated in a 6-week exercise program, and the intervention group (n = 36) participated in the same exercise program plus passive manual scapular mobilization. Both groups were assessed at baseline and 6 weeks (end of treatment). The primary outcome measure was upper limb function assessed using the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire. Secondary outcome measures were the Constant-Murley questionnaire, pain (visual analog scale [VAS]), and scapular upward rotation.
Results: All participants completed the trial. The between-group difference in DASH was -1.1 points (Cohen d = 0.05; p = 0.911), Constant-Murley 2.1 points (Cohen d = 0.08; p = 0.841), VAS rating of pain at rest -0.1 cm (Cohen d = 0.05; p = 0.684), and VAS rating of pain during movement -0.2 cm (Cohen d = 0.09; p = 0.764); scapular upward rotation at rest (arm by the side) was 0.6° (Cohen d = 0.09; p = 0.237), at 45° shoulder abduction was 0.8° (Cohen d = 0.13; p = 0.096), at 90° was 0.1° (Cohen d = 0.04; p = 0.783), and at 135° was 0.1° (Cohen d = 0.07; p = 0.886). Most differences were in favor of the intervention group; however, the effect sizes were weak and not statistically significant.
Conclusions: In the short-term, the addition of scapular mobilization did not provide significant clinical benefits in terms of function, pain or scapular motion in participants with SIS.
Trial registration: Brazilian registry of clinical trials UTN number U1111-1226-2081. Registered February 25, 2019.

Introduction

Subacromial Impingement Syndrome (SIS) is the most common cause of shoulder pain [1]. Currently, it is considered a multifactorial condition caused by intrinsic and extrinsic mechanisms relating to rotator cuff pathology [2,3]. The most important biomechanical factors that contribute to SIS are kinematic alterations in the glenohumeral and/or scapulothoracic joints [2–4].

The contribution of the scapula has long been considered essential for normal shoulder function [5,6]. Scapular position and motion are closely integrated with arm motion to accomplish most shoulder functions [5,7]. The normal movement of the scapula involves 3 rotations: upward/downward rotation around a horizontal axis perpendicular to the plane of the scapula, internal/external rotation around a vertical axis through the plane of the scapula, and anterior/posterior tilt around a horizontal axis in the plane of the scapula; in addition, linear displacements occur in association with the rotations [6–8].

The association between altered scapular kinematics and SIS has been previously established [2,4,9–11]. SIS is characterized by a reduction in upward scapular rotation in the first phases of glenohumeral motion [9–11]. Several authors have proposed that this decrease in scapular motion could be a key mechanism behind the symptoms associated with SIS [4,6,9–11]. Therefore, it is important

to include the scapula in the development of treatment strategies. In recent decades, physiotherapists have used manual therapy with or without therapeutic exercise to recover shoulder function and glenohumeral and scapular motion in people with SIS [12−15]. Scapular mobilization is a widely used manual therapy technique for the management of musculoskeletal disorders of the shoulder; it involves the manual application of a sustained mobilization (in 4 directions) to the scapulothoracic joint [16]. However, to our knowledge, only 1 clinical trial has reported the effects of scapular mobilization in people with SIS [17].

A network meta-analysis showed that physiotherapy treatment that included exercises and manual therapy techniques tended toward greater clinical effects than exercise alone in the early stage of SIS [18]. Despite this, the biomechanical and/or neurophysiological rationale for improving active shoulder or upper limb function using a passive joint mobilization technique remains unclear.

The main aim of this study was to determine the short-term effects of scapular mobilization in combination with an exercise program for upper limb function in people with SIS. We hypothesized that the addition of scapular mobilization to a 6-week exercise program would improve upper limb and shoulder function, scapular motion and pain when compared with the exercise program alone. Therefore, the study question for this randomized controlled trial was: Does scapular mobilization in addition to an exercise program improve upper limb and shoulder function, scapular motion and pain in people with SIS?

Materials and methods

Design

A single-blinded, randomized controlled trial with two parallel groups was conducted. This research was prospectively registered in the Brazilian Registry of Clinical Trials (number U1111-1226-2081). Ethical approval was obtained from the Ethics Committee on 4 January 2019 (#048975). Recruitment was conducted between February 2019 and February 2021. All participants signed an informed consent form approved by the ethics committee. The study is reported according to the Consolidated Standards of Reporting Trials (CONSORT) Statement for Randomized Trials of Nonpharmacologic Treatments [19].

Participants

Participants were recruited from the Physical Therapy Department. They were eligible for enrollment if they were ≥18 years and presented with SIS diagnosed by an orthopedic surgeon according to the following clinical criteria: (i) pain located on the anterolateral side of the shoulder for at least 3 months; and (ii) 3 or more positive clinical signs of SIS, such as the Neer or Hawkins-Kennedy test, a painful arc, pain on resisted external rotation, or the empty can test. The sensitivity and specificity values for these signs are >74% for the diagnosis of SIS [20]. Scapular upward rotation during shoulder abduction was measured using an inclinometer. This method has been reported to have good to excellent concurrent validity compared with a 3-dimensional magnetic tracking device, and very good intrarater reliability (ICC range 0.81−0.94) [21,22]. All participants were prescribed 500mg oral naproxen twice daily for 2 weeks after which they were referred to the Physical Therapy Department. People were excluded if they met any of the following criteria: (i) diagnosis of osteoarthritis in the acromioclavicular or glenohumeral joint, calcific tendinitis, adhesive capsulitis, glenohumeral instability, or a partial- or full-thickness rotator cuff tear. To confirm the exclusion of these shoulder pathologies, the clinical diagnosis was complemented with radiographs and magnetic resonance imaging [23]. (ii) A clinical history of acute trauma, previous surgery, or previous fracture in the affected shoulder; (iii) corticosteroid injection in the affected shoulder in the last 12 months; and (iv) intolerance to oral anti-inflammatories.

Randomization and blinding

The participants were randomly allocated to the intervention and control groups via a sequence of numbers generated by a computer program before the selection process. The group to which each participant was assigned was kept in a sealed envelope to conceal the assignment. Given the nature of the therapeutic interventions studied, blinding of the physiotherapists and participants was not possible; however, the evaluator and statistician were blinded to group allocation.

Interventions

The control group received a standardized exercise program based on stretching and strengthening of the rotator cuff and scapular muscles [24]. The stretching exercises targeted the upper trapezius, pectoralis minor, and posterior region of the shoulder. The dose was 3 repetitions of 30 s, with 30 s between repetitions [24]. Following the stretching exercises, 3 strengthening exercises were performed using elastic resistance bands, including external shoulder rotation, shoulder extension targeting lower trapezius strengthening, and shoulder protraction targeting serratus anterior strengthening. Electromyography has been used to investigate impairments in the intensity and timing of muscle activation of the shoulder complex in people with SIS [25]. Although there is no consensus in the electromyographic studies, at the scapulohumeral level the most significant findings were a reduction in the activity of the serratus anterior and the lower trapezius, associated with a delay in their activation [25,26]. Based on these findings, the exercise program included selective strengthening of weak muscles, avoiding activation of overactive muscles. The dose was 3 sets of 10 repetitions for each exercise, with 1 min of rest between sets. The program consisted of 12 sessions, performed twice a week for 6 weeks [24].

The intervention group received the same exercise program as the control group, plus passive manual scapular mobilization, which consisted of applying superior and inferior glides, rotations and distraction to the scapula of the affected shoulder [16,17,27]. All interventions were applied in a side-lying position with the involved extremity accessible to the physiotherapist. The physiotherapist grasped the superior and inferior angle of the scapula and moved it superiorly and inferiorly for superior and inferior glide, respectively, and then rotated it upward and downward for scapular rotation. Second, the physiotherapist grasped the inferior angle and medial border of the scapula and, with both hands, tilted and distracted the scapula away from the thoracic wall (Fig. 1). Three sets of 10 repetitions were performed at a rate of one cycle per 6 s, with a 30 s interval between sets [17].

Both interventions were delivered by 2 physiotherapists, each with a master's degree in manual therapy and more than 15 years of experience in musculoskeletal physiotherapy. The interventions were standardized and taught to the physiotherapists through a seminar and videos before the study. Participants in both groups also received advice on their clinical condition and self-care, and an exercise program to perform at home, which consisted of 4 exercises for the neck and shoulder without any external load. Participants were instructed to perform active shoulder elevation, shoulder retraction, shoulder abduction in the scapular plane, and neck retraction to the pain threshold. Each exercise was repeated 10 times, twice daily at home and adherence was monitored using a phone call once a week by a physiotherapist who recorded it in the data collection notebook of each participant.

Application of superior and inferior glide mobilization

Application of scapular upward and downward rotation

Position for the distraction

Application of scapular distraction

Fig. 1. Photographs of the scapular mobilization techniques.

Outcome measures

Two blinded evaluators performed outcome assessments at baseline and the end of the 6-week intervention. Both blinded physiotherapists evaluated the same proportion of participants in each group. The primary outcome measure was upper limb function assessed with the Spanish version of the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire [28]. Scores range from 0 to 100 points, with higher scores indicating a worse condition [29]. The minimal clinically important difference is 11 points [30].

The secondary outcome measure was shoulder function assessed using the Constant-Murley questionnaire [31,32]. Scores range from 0 to 100 points, with lower scores indicating a worse condition. The minimal clinically important difference is an increase of 17 points [33]. Additionally, pain intensity at rest and during movement was assessed using a visual analog scale (VAS), the scores of which range from 0 ("no pain") to 10 ("the worst imaginable pain") [34]. The minimal clinically important difference in people with rotator cuff disease is 1.4 cm [35]. Finally, scapular upward rotation was assessed according to a standardized protocol using an inclinometer at rest (ie with the arm by the side), and at 45°, 90° and 135° of shoulder abduction on the affected side [36]. The dual inclinometer is reliable for the assessment of scapular upward rotation in all ranges of shoulder abduction in people with shoulder pathologies [22].

Statistical analysis

The sample size calculation was based on the minimum clinically important difference of 11 points in the DASH questionnaire [30]. The assumed mean for the calculation was 11.7, with a standard deviation of 9.5 points, based on the results of a previous randomized controlled trial [24]. To detect this difference between the 2 treatments with an α-level of 0.05 and a statistical power of 95%, a minimum of 31 participants per group was needed. This minimum sample size estimate was increased by 20% after considering potential dropouts, and finally a total of 36 participants was included in each group.

Descriptive statistics were used for baseline data in both groups. Continuous variables are presented as mean and standard deviation (SD) and categorical variables as number and percentage. To determine the statistical tests to use in the data analysis, we first evaluated the normality of the data distribution using the Shapiro-Wilk test.

To compare data between groups, we used the t test or Mann-Whitney test for 2 independent samples; in both cases, a significance level of 0.05 with 95% confidence intervals (95% CI) was used. Additionally, we calculated Cohen d for the effect of scapular mobilization in addition to the exercise program, considering the effect to be trivial (<0.2), small ($0.2-0.5$), medium ($0.5-0.8$), or large (>0.8) [37]. Before conducting the study, we decided to conduct an intention-to-
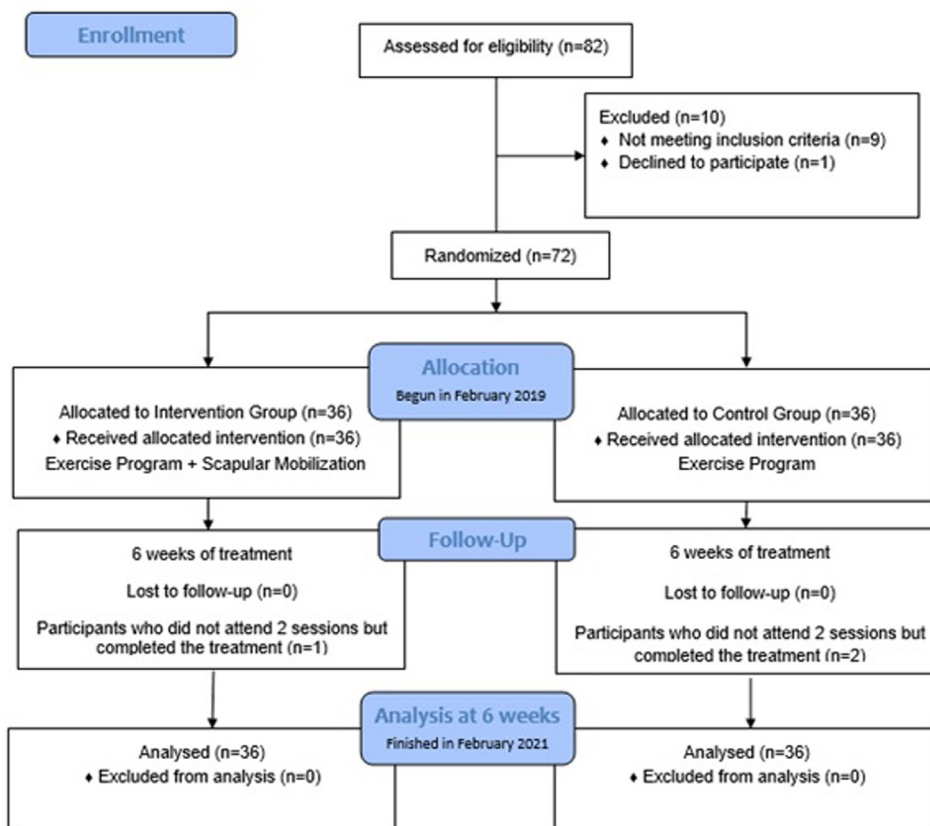
Fig. 2. Flowchart of participants (CONSORT).

treat statistical analysis if data were lost or participants discontinued their treatment. Statistical analyses were performed using Stata SE software, version 14 (Stata Corp, College Station, Texas, USA).

Results

Seventy-two participants, 36 in the control group and 36 in the intervention group, were recruited (Fig. 2). The baseline characteristics of each group are presented in Table 1. All participants received treatment according to their group allocation, and no dropouts were registered. Regarding treatment adherence, in the control group, 2 participants (6%) did not attend 2 sessions, and in the intervention group, 1 participant (3%) did not attend 2 sessions. All absences were because of health problems not directly related to SIS. Despite this, all participants completed the assigned treatment schedule. Regarding complications associated with both treatments, 2 participants (6%) in the intervention group reported increased pain at the end of the sessions during the first 2 weeks of treatment. In the control group, only 1 participant (3%) reported increased pain at the end of the second week of treatment.

The comparisons of the within- and between-groups analyses at the end of the 6-week period are presented in Table 2. The primary outcome, upper limb function, improved in both groups ($p < 0.05$). At 6 weeks, the mean between-group difference was -1.1 points for the DASH questionnaire (95% CI -9.9 to 8.6; Cohen d = 0.05; p = 0.911). For the secondary outcomes, except for scapular upward rotation at 90° and 135° of shoulder abduction, the intra-group differences were statistically significant ($p < 0.05$). The between-group differences were in favor of the intervention group; however, the effect size was weak (Cohen $d < 0.2$). Additionally, when comparing the results with the minimum clinically important differences, the differences obtained were not clinically important, and the confidence intervals largely excluded effects that could be considered clinically relevant.

Table 1
Baseline characteristics of participants with SIS in both groups.

Characteristics	Intervention group (n = 36)	Control group (n = 36)
Sex male, number (%)	30 (83)	31 (86)
Age in years, mean (SD)	45.2 (6.8)	44.5 (7.9)
Duration of symptoms in months mean (SD)	3.5 (1.1)	3.8 (1.2)
Dominant shoulder affected, number (%)	32 (89)	31 (86)
Education level, number (%)		
Primary	1 (3)	1 (3)
Middle	15 (42)	17 (47)
University	20 (55)	18 (50)
Height (m), mean (SD)	1.67 (0.74)	1.66 (0.73)
Weight (kg), mean (SD)	76.46 (7.01)	75.85 (7.69)
Body mass index (kg/m²), mean (SD)	27.38 (2.33)	27.48 (2.38)

SD: Standard Deviation SIS: Subacromial Impingement Syndrome.

Discussion

This study showed that the addition of passive manual scapular mobilization to an exercise program did not further improve shoulder function, scapular motion, or pain after 6-weeks of intervention in participants with SIS. However, improvements tended to be greater in the intervention than the control group for most of the outcome measures assessed. Despite this, caution should be taken when interpreting these results because the effect size was weak, and the wide confidence intervals indicated that participants may or may not benefit from adding scapular mobilization to an exercise program.

Physiotherapists usually use joint mobilization in association with other physiotherapy interventions to recover shoulder and scapular function [6,12,13,15]. However, manual therapy techniques have primarily focused on mobilization of the glenohumeral joint in people with SIS [38,39], and only a few clinical trials have examined the

Table 2
Within-group and between-group differences at the end of 6 weeks of treatment in participants with SIS.

Outcome	Groups										
	Pre intervention		6 weeks		Difference within groups			Difference between groups			
	CG	IG	CG	IG	CG	IG	p-value	Mean Difference	95% CI	Cohen d	p-value
DASH	52.6 (10.5)	50.7 (9.4)	25.8 (10.8)	22.8 (10.1)	-26.8 (10.2)	-27.9 (11.3)	0.001	-1.1	-9.9–8.6	0.05	0.911 [†]
CM	44.2 (12.5)	42.7 (13.1)	68.3 (10.3)	68.9 (10.4)	24.1 (14.6)	26.2 (11.7)	0.001	2.1	-11.3–14.1	0.08	0.841 [†]
VAS at rest	2.6 (2.1)	2,8 (1.7)	1.4 (0.7)	1.5 (0.6)	-1.2 (0.9)	-1.3 (0.8)	0.002	-0.1	-0.9–0.7	0.05	0.684 [‡]
VAS during movement	5.2 (1.5)	5.6 (1.1)	2.2 (1.6)	2.4 (1.2)	-3 (1.5)	-3.2 (1.3)	0.001	-0.2	-1.1–0.8	0.09	0.764 [‡]
Scapular UR at rest	2.9 (4.8)	2.8 (5.1)	6.2 (3.1)	5.5 (3.4)	3.3 (3.2)	2.7 (2.6)	0.003	0.6	-2.2–3.8	0.09	0.237 [‡]
Scapular UR at 45°	10.5 (7.6)	10.9 (8.1)	13.4 (5.1)	13 (5.5)	2.9 (2.5)	2.1 (2.3)	0.002	0.8	-1.6–3.2	0.13	0.096 [‡]
Scapular UR at 90°	25 (6.4)	25.2 (5.8)	25.8 (6.1)	25.9 (5.4)	0.8 (0.4)	0.7 (0.3)	0.341	0.1	-0.2–0.4	0.04	0.783 [†]
Scapular UR at 135°	42.4 (8.1)	42.6 (7.6)	42.8 (5.9)	43.1 (6.2)	0.4 (0.3)	0.5 (0.3)	0.629	0.1	-0.3–0.5	0.07	0.886 [†]

Data are mean (SD).
CG: Control Group, CM: Constant-Murley, DASH: Disabilities of the Arm, Shoulder and Hand, IG: Intervention Group, SD: Standard Deviation, SIS: Subacromial Impingement Syndrome, UR: Upward Rotation, VAS: Visual Analog Scale, 95% CI: 95% Confidence Intervals.
  [†] p-value: obtained with Student's T-test for independent samples.
  [‡] p-value: obtained with the Mann-Whitney test for independents samples.

effectiveness of scapular mobilization in shoulder pathologies [16,17,27]. Usually, the effects of scapular mobilization in some shoulder pathologies can be explained by two mechanisms: (i) scapular mobilization may increase scapular motion and reduce upper limb disability, and ii) the scapular mobilization technique may decrease adhesion of the muscles around the scapula [16]. As a result, scapular mobilization may improve the motion and function of the structures adjacent to the scapulothoracic joint [40].

Despite the variability of the inclusion criteria, 2 systematic reviews provided cautious support for the use of scapular-focused interventions (including scapular mobilization) for people with SIS, although they both drew unclear conclusions [41,42]. More positively, however, a third systematic review suggested that scapular-focused interventions are a beneficial adjunct to usual interventions that do not address scapular components to improve pain, shoulder function, and abduction range of motion within the same group of participants [43]. Finally, it should be noted that the scapular-focused interventions varied across the studies included in these systematic reviews, and only 1 of the included studies analyzed the effects of scapular mobilization in people with SIS [17].

Our results support the findings of a previous study that reported no clinically significant effects of scapular mobilization on shoulder function, pain, range of motion, and satisfaction when compared with a sham or supervised exercise program in people with SIS [17]. A possible explanation for this is that kinematic scapular alterations are associated with an increase in upper trapezius activity; and a reduction in the level of activity and a delay in the activation time of the serratus anterior and lower trapezius muscles in these individuals [6,25,26]. Therefore, we believe that the implementation of a specific exercise program focused on the reduction of muscle impairments is sufficient to improve shoulder function, scapular motion, and pain relief in these people with SIS.

People with SIS usually complain of pain at night or on movement that is exacerbated by lying on the affected shoulder or sleeping with the arm over the head [44]. In accordance with this, the participants in our study had low pain ratings on the VAS (0 to 10 cm) at rest at baseline (mean 2.6 cm in the control group, and 2.8 cm in the intervention group). Few studies have analyzed the predictive capacity of baseline pain intensity for perceived function or the perpetuation of symptoms in persons with shoulder pain. One study showed that higher levels of pain intensity and catastrophizing at baseline were associated with the perpetuation of chronic shoulder pain at 6 months [45]. Another study showed that a duration of symptoms >3 months, high levels of pain intensity at rest, and reduced shoulder flexion significantly contributed to low levels of shoulder function [46]. Accordingly, we believe that low levels of pain at rest at baseline could be a predictor of better functional outcomes in the participants of our study.

Compared with electromagnetic tracking systems used to measure 3-dimensional motion, the inclinometer is a unidimensional, low cost, and easily used tool to assess scapular upward rotation in clinical settings [22]. Despite the limited clinical generalizability of our results, at baseline the low values of scapular upward rotation at rest and during the first phase of glenohumeral abduction demonstrated the lack of scapular motion in these individuals [9,11]. Additionally, at the end of treatment, within-group differences were only statistically significant for scapular upward rotation at rest and at 45° of glenohumeral abduction in both groups. This could be explained by the fact that all participants received a standardized exercise program targeting the activation of the scapular stabilizers (serratus anterior and lower trapezius), thereby explaining the increases in upward rotation in both groups. According to this, as the addition of scapular mobilization is not required for all persons to achieve these clinical benefits, we suggest including scapular mobilization only when there is a lack of improvement with exercise alone or if shoulder stiffness is associated with SIS.

This study has several limitations. First, the biomechanical mechanism for how a passive joint mobilization technique could improve active shoulder or upper limb function remains unclear. Second, the inclinometer is not the gold standard tool for the assessment of 3-dimensional scapular kinematics. Third, it is important to emphasize that only scapular upward rotation was assessed. This is a significant limitation, but unfortunately the inclinometer we used cannot measure other scapular motions such scapular tilt. Fourth, only the affected side was assessed in our study. Five, the absence of follow-up once both treatments were finished did not allow us to establish their long-term effectiveness. Six, blinding of the physiotherapists and participants was not possible due to the nature of the studied interventions. These limitations should be considered when attempting to extrapolate our findings to the treatment of people with SIS.

Conclusion

The addition of passive manual scapular mobilization to an exercise program did not provide significant clinical benefits in terms of function, pain or scapular motion in participants with SIS. These results have important clinical implications: they demonstrate that an exercise-based program should be the primary intervention for this clinical condition and that the addition of scapular mobilization should only be considered if there is a lack of improvement with exercise alone. Our results are only generalizable to people with SIS. Further studies are needed to identify subgroups of individuals who respond well to scapular mobilization and to assess the medium- or long-term effects in those groups.

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Data availability

The data that has been used is confidential.

Declaration of Competing Interest

None.

CRediT authorship contribution statement

Héctor Gutiérrez-Espinoza: Visualization, Data curation, Writing – original draft, Writing – review & editing. **Sebastián Pinto-Concha:** Visualization, Data curation, Writing – original draft, Writing – review & editing. **Oscar Sepúlveda-Osses:** Visualization, Data curation, Writing – original draft, Writing – review & editing. **Felipe Araya-Quintanilla:** Visualization, Data curation, Writing – original draft, Writing – review & editing.

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Guideline for diagnosis and treatment of subacromial pain syndrome

A multidisciplinary review by the Dutch Orthopaedic Association

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Treatment of "subacromial impingement syndrome" of the shoulder has changed drastically in the past decade. The anatomical explanation as "impingement" of the rotator cuff is not sufficient to cover the pathology. "Subacromial pain syndrome", SAPS, describes the condition better. A working group formed from a number of Dutch specialist societies, joined by the Dutch Orthopedic Association, has produced a guideline based on the available scientific evidence. This resulted in a new outlook for the treatment of subacromial pain syndrome. The important conclusions and advice from this work are as follows:

(1) The diagnosis SAPS can only be made using a combination of clinical tests. (2) SAPS should preferably be treated non-operatively. (3) Acute pain should be treated with analgetics if necessary. (4) Subacromial injection with corticosteroids is indicated for persistent or recurrent symptoms. (5) Diagnostic imaging is useful after 6 weeks of symptoms. Ultrasound examination is the recommended imaging, to exclude a rotator cuff rupture. (6) Occupational interventions are useful when complaints persist for longer than 6 weeks. (7) Exercise therapy should be specific and should be of low intensity and high frequency, combining eccentric training, attention to relaxation and posture, and treatment of myofascial trigger points (including stretching of the muscles) may be considered. (8) Strict immobilization and mobilization techniques are not recommended. (9) Tendinosis calcarea can be treated by shockwave (ESWT) or needling under ultrasound guidance (barbotage). (10) Rehabilitation in a specialized unit can be considered in chronic, treatment resistant SAPS, with pain perpetuating behavior. (11) There is no convincing evidence that surgical treatment for SAPS is more effective than conservature management. (12) There is no indication for the surgical treatment of asymptomatic rotator cuff tears.

Shoulder problems are common. Between 7% and 34% of adults have shoulder pain at times (Reilingh et al. 2008). The incidence of shoulder pain in primary care in the Netherlands is estimated to be 19 per 1,000 person-years—highest in women over 45 years and lower in young adults (Greving et al. 2012). In the Netherlands, the orthopedic diagnosis of "supraspinatus tendinitis" is made 50,000–60,000 times a year (source Prismant). The course, independent of the chosen therapy, appears to be unfavorable in terms of resumption of previous work, and after 1 year, a third of the patients still have some kind of restriction and/or pain (Reilingh et al. 2008, Greving et al. 2012). Neer (1983) developed the concept of "impingement syndrome". This can be caused or aggravated by contact between the acromion and the rotator cuff while lifting the arm. However, this hypothesis cannot be substantiated with improved imaging and arthroscopic techniques. More value is placed nowadays on the role of degeneration of the rotator cuff tendons, eventually giving rise to the development of tears (Papadonikolakis et al. 2011). A direct relationship between the anatomical substrate, functional load and pain is not always explicitly present. Naming this condition "subacromial pain syndrome", abbreviated to SAPS, describes the condition better.

SAPS is defined as all non-traumatic, usually unilateral, shoulder problems that cause pain, localized around the acromion, often worsening during or subsequent to lifting of the arm. The different clinical and/or radiological names, such as bursitis, tendinosis calcarea, supraspinatus tendinopathy, partial tear of the rotator cuff, biceps tendinitis, or tendon cuff degeneration are all part of SAPS.

As patients come into contact with various healthcare providers, it was deemed necessary—following the Dutch General practitioners guideline for shoulder complaints (Winters

Table 1. GRADE evidence levels of intervention studies

Evidence level of intervention study (examples)	
High	RCTs without severe limitations.
	Observational studies with very large effects and without severe limitations.
Moderate	RCTs with severe limitations.
	Observational studies with large effects and without severe limitations.
Low	RCTs with extremely severe limitations.
	Observational studies without severe limitations.
Very low	RCTs with extremely severe limitations and inconsistent results.
	Observational studies with severe limitations.
	Non-systematic clinical observations (e.g. case series and case reports).

Table 2. EBRO evidence levels of diagnostic accuracy research or research into etiology and prognosis

Evidence level	Diagnostic accuracy research	Etiology, prognosis
A1	Meta-analysis of at least 2 independently conducted studies at the A2 level	
A2	Research compared to a reference test (gold standard) with previously defined cutoff values and independent evaluation of results, with a sufficiently large series of consecutive patients who have only had the index and reference test.	Prospective cohort study with sufficient size and follow-up and with adequate controlling for "confounding", and where selective follow-up has been sufficiently ruled out.
B	Research compared to a reference test, but not with all the features listed under A2.	Prospective cohort study but not with all the features listed under A2, retrospective cohort study, or patient-controlled study.
C	Non-comparative study.	

et al. 2008), and to supplement the Dutch Physical Therapists Guideline for aspecific complaints of arm, neck and shoulder (KNGF 2012) and the KNGF Evidence Statement for subacromial shoulder pain (Jansen et al. 2011)—to create a guideline for the treatment of SAPS.

Methods

A working group was formed by the Netherlands Orthopedic Society (NOV), consisting of representatives from the Orthopedic Society, the Netherlands Association of Physical Therapy, the Netherlands Association of General Practitioners, the Netherlands Society of Rehabilitation Medicine, the Netherlands Association of Occupational Medicine, and the Netherlands Society of Radiology, who all have interest and expertise in clinical shoulder problems. This group formulated 8 clinical questions relevant to SAPS:

1. What is known about the prognosis of SAPS?
2. What measures are effective in preventing SAPS?
3. Which physical diagnostic tests are most accurate, sensitive, and specific for SAPS?
4. What is the added value of imaging for diagnosis of SAPS?
5. Which instruments are most suitable for measurement of outcomes in SAPS?
6. Which conservative treatment is the most effective for patients with SAPS?
7. When is surgical treatment for SAPS indicated, and which technique is preferred?
8. What advice can be given to patients with SAPS, argued from the patient's point of view?

Literature search
The group conducted an exploratory search for existing international guidelines in Medline (OVID), the databases of the Guidelines International Network (GIN), the Quality Dome and Artsennet, and systematic reviews in Medline (OVID) and the Cochrane Library. Next, for each clinical question based on specific search terms, a search was conducted for published scientific studies in electronic databases. The searches were limited to literature in English, Dutch, French, and German. Additional studies were searched for on the basis of the reference lists of the articles selected. Search filters were used based on the filters used by the Scottish Intercollegiate Guideline Network (SIGN) to identify possible systematic reviews and randomized clinical trials.

Grading of study quality
The working group members selected articles based on criteria established in advance (Tables 1 and 2). From these data, the level of the recommendations was defined (Table 3). In general, the studies showed great heterogeneity in study populations, factors examined, duration of follow-up, and outcome measures. There were also confounders due to the definition

Table 3. Level-of-evidence strength of the conclusion, based on the literature underlying the conclusion

Level	Conclusion based on
1	For therapeutic intervention studies: high-quality studies. For diagnostic accuracy research or prognosis, etiology or side effects: A1-level study or at least 2 independently conducted A-2 level studies.
2	For therapeutic intervention studies: moderate-quality studies. For diagnostic accuracy research or prognosis, etiology or side effects: one A2-level study or at least 2 independently conducted B-level studies.
3	For therapeutic intervention studies: low-quality studies. For diagnostic accuracy research or prognosis, etiology or side effects: one B-level study or at least 2 independently conducted C-level studies.
4	For therapeutic intervention studies: very low-quality studies. For diagnostic accuracy research or prognosis, etiology or side effects: one C-level study.

of shoulder complaints, as the difference between subacromial complaints and general pain in the shoulder and/or neck was not always clear. The working group formulated recommendations on each of the questions following the highest level of evidence. When a scientific basis was not possible, consensus of the working group was obtained on the recommendation.

Results

Clinical Question 1: What is known about the prognosis of SAPS?

Scientific evidence level 1: There is an association between a longer duration of shoulder pain (> 3 months) and poorer outcome (Kuijpers et al. 2004, Bot et al. 2005, Thomas et al. 2005, Reilingh et al. 2008). There is an association between being middle-aged (45–54 years) and worse outcome (Kuijpers et al. 2004).

Level 2: Psychosocial factors appear to have a greater association with the course and prognosis of chronic shoulder pain (> 3 months) than with that of shorter-term shoulder pain (< 6 weeks) (Reilingh et al. 2008).

Level 3: There are indications that a worse outcome is associated with a worse score at the start, longer duration of symptoms, and type II or III acromion morphology (Taheriazam et al. 2005).

Considerations

There is consistent evidence that a longer duration of symptoms (> 3 months) is a poor prognostic factor. There is evidence that psychosocial factors play a role in chronic complaints.

Recommendation

The working group recommends being aware of the effect of symptom duration on prognosis (> 3 months) and distinguishing between acute symptoms and chronic symptoms when deciding on interventions for SAPS.

Clinical Question 2: What measures are effective in preventing SAPS?

Scientific evidence level 1: There are associations between the occurrence of SAPS and (1) repetitive movements of the shoulder or hand/wrist during work, (2) work that requires much or prolonged strength of the upper arms, (3) hand-arm vibration (high vibration and/or prolonged exposure) at work, (4) working with a poor ergonomic shoulder posture, and (5) a high psychosocial workload. Psychosocial factors associated with prolonged shoulder complaints are high psychological demands, low control, low social support, low job satisfaction, and high pressure to perform (van Rijn et al. 2010).

Level 2: There is evidence that regular sporting activities (> 3 h per week for at least 10 months a year) have a preventive effect on the risk of neck and shoulder complaints and (long-term) illness (van den Heuvel et al. 2005).

Considerations

There were fewer modifiable factors found in studies on psychosocial risks than in studies on physical factors. In one study (Kennedy et al. 2009), influencing the entire kinematic chain is mentioned as the starting point for prevention and treatment of sports-related shoulder pain. However, there have been no studies on the effects of these interventions.

Recommendations

The working group recommends early intervention to modify repetitive movements of the shoulder or hand/wrist during work, work that demands much or prolonged power of the upper arms, hand-arm vibration (high vibration and/or prolonged exposure) during work, and work in a non-ergonomic shoulder position. An approach based on the "biopsychosocial model", focusing on early return to work, has the best chance of success (Shanahan and Sladek 2011).

Clinical Question 3: Which physical diagnostic tests are most accurate, sensitive and specific for subacromial pain syndrome of the shoulder?

Scientific evidence level 1: No single test is sufficiently accurate to diagnose SAPS (Hegedus et al. 2008, Hughes et al. 2008). The inter-rater reliability of the most common tests varies greatly. Inter-rater reliability of active abduction and abduction trajectory pain is moderate (May et al. 2010).

Level 2: The combination of a number of tests increases the post-test probability of the diagnosis of SAPS. (Murrell and Walton 2001, Park et al. 2005, Michener et al. 2009).

Considerations

As one physical sign cannot sufficiently differentiate between the various shoulder disorders, or give a clear distinction regarding the status of the rotator cuff, a combination of multiple tests increases post-test probability of a diagnosis of SAPS.

Recommendations

To determine SAPS, a combination of the Hawkins-Kennedy test, the painful arc test, and the infraspinatus muscle strength test should be used; and for a rotator cuff tear, the drop-arm test and the infraspinatus and supraspinatus muscle strength tests should be used.

Clinical Question 4: What is the added value of imaging tests for diagnosis of SAPS?

Scientific evidence level 1: The sensitivity and specificity of ultrasound and conventional MRI are not significantly different in the detection of partial- or full-thickness rotator cuff tears (Dinnes et al. 2003). MR arthrography is an accurate method to rule out partial rotator cuff injuries (de Jesus et al. 2009, Ottenheijm et al. 2010).

Level 2: It is likely that ultrasound is an accurate method for the detection or exclusion of rotator cuff tendinopathy, subacromial bursitis, biceps tendon rupture, and tendinosis calcarea (Ottenheijm et al. 2010). The interobserver variability of ultrasound with respect to detection of rotator cuff injuries is low, as the results are very similar (Rutten et al. 2010, Sipola et al. 2010).

Level 3: There is evidence that ultrasound is not sufficiently reliable to differentiate between an intact rotator cuff and partial lesions (Sipola et al. 2010).

Considerations

Ultrasound of the shoulder is a sensitive and specific method. The diagnostic accuracy is good and comparable to that of conventional MRI for identification and quantification of complete (full-thickness) rotator cuff injuries. There are conflicting results about the value of ultrasonography in partial rotator cuff tears and tendinopathies. For optimal sonographic analysis of the shoulder, standardized examination and expertise as well as high-quality equipment (7.5- to 20-MHz linear trans-

ducers) should be available. When repair of a rotator cuff tear is intended, MRI provides useful information on size, retraction, and matching atrophy and fatty infiltration. For the detection of partial articular side cuff injuries (PASTA lesions), MR arthrography may be considered because of its high sensitivity and specificity. It is preferable to perform a series in abduction/external rotation position (ABER). Although a correlation has been described between the shape of the acromion (type III, angled) and the presence of rotator cuff injuries (Toivonen et al. 1995), this association is not significant in patients over 50 (Gill et al. 2002, Oh et al. 2010).

Recommendations

Ultrasound is advised as the most valuable and cost-effective diagnostic imaging if a first period of non-operative treatment fails. This can be combined with conventional radiography of the shoulder to determine osteoarthritis, osseous abnormalities, and presence/absence of calcium deposits. MRI of the shoulder is indicated when reliable ultrasound is not at hand or inconclusive, and should be used in patients who are eligible for surgical repair of a cuff tear to assess the degree of retraction and atrophied fatty infiltration. An MRI study with intra-articular contrast can be considered if any intra-articular abnormality or a partial rotator cuff injury have to be ruled out. It is preferable for a study in abduction and external rotation (ABER) to be part of an MR arthrography protocol.

Clinical Question 5: Which instruments are most suitable for measuring the outcome of treatment of SAPS?

Scientific evidence level 2: Measurements of ROM using instruments (in goniometry and inclinometry) are more reliable than those based on visual assessment (van de Pol et al. 2010). The Dutch Shoulder Disability Questionnaire seems to be responsive (van der Windt et al. 1998, van der Heijden et al. 2000).

Levels 2/3: The internal consistency and test-retest reliability of the Dutch Simple Shoulder Test seem high and the construct validity moderate to good (van Kampen et al. 2012).

Level 3: There is insufficient inter-rater reliability of visual estimation of ROM (Terwee et al. 2011). There are indications that the inter-rater reliability of ROM measured using a digital inclinometer for individual patients is poor, with differences in ROM of less than 20–25 degrees being indistinguishable from measurement error (de Winter et al. 2004). The DASH-DLV has excellent internal consistency, reasonable test-retest reliability, and reasonable criterion validity (Veehof et al. 2002). The English Oxford Shoulder Score has a high test-retest reliability, high internal consistency, and a weak-to-moderate criterion validity (Berendes et al. 2010). The Dutch Shoulder Rating Questionnaire has high internal consistency, high test-retest reliability, moderate-to-good criterion validity, and is an appropriate instrument to demonstrate clinical differences (Vermeulen et al. 2005).

Level 4: It is possible that isokinetic muscle strength measurements using a dynamometer have good reliability at group level and poor reliability at individual level (Meeteren et al. 2002).

Considerations

Visual assessment of the ROM is appropriate only for distinguishing between the affected and the contralateral side. Even when using a goniometer, which can increase the reliability of the measurements, the measurement error remains high. In selecting an outcome instrument, it is important for the instrument to have been validated in the Dutch language. The Simple Shoulder Test and the Oxford Shoulder Score are instruments with relatively few questions and are easy to use. The Dutch Shoulder Disability Questionnaire with 16 questions is a medium-length questionnaire and is also easy to use. The Shoulder Rating Questionnaire is more detailed, has a more complex calculation of the sum score, and for certain items it misses answers quite often.

Recommendations

Visual estimates of the range of motion can only serve to distinguish between the affected and the contralateral shoulder. Instruments to assess the effects of treatment of SAPS, validated in the Dutch language, are: Disabilities of the Arm, Shoulder and Hand (DASH), English Oxford Shoulder Score (DOSS), Dutch Simple Shoulder Test (DSST), and Shoulder Disability Questionnaire (SDQ-NL).

Clinical Question 6: Which non-operative treatment is most effective for patients with SAPS?

- *Corticosteroid injections*
  Scientific evidence level 1: In the first 8 weeks, corticosteroid injections are more effective than placebo injections, physiotherapy, or no treatment in reducing pain and improving shoulder function. Corticosteroid injections in the short term are no more effective than NSAIDs in reducing pain. The effect of corticosteroids in the long term (≥ 3 months) is unclear (Buchbinder et al. 2003, Arroll and Goodyear-Smith 2005, Gaujoux-Viala et al. 2009).
- *Extracorporeal shockwave therapy (ESWT)*
  Level 1: High-energy extracorporeal shockwave therapy (ESWT) is more effective than low-energy ESWT or placebo in reducing pain and improving shoulder function in patients with tendinosis calcarea. ESWT (all forms) is no more effective than placebo or other treatments in reducing pain or in improving shoulder function of patients without calcium deposition in the tendons (Huisstede et al. 2011).
- *Exercise therapy*
  Levels 1–2: Exercise therapy is more effective than no treatment in reducing pain and improving function of the shoulder (Dickens and Williams 2005, Lombardi et al. 2008). There appears to be no difference in effectiveness between exercise therapy and home exercises (Werner et al. 2002,

Walther et al. 2004). Exercises specifically focused on rotator cuff and scapular stabilizers appear to be more effective than general exercise therapy (Holmgren et al. 2012). Manual joint mobilizations have no added benefit to a program of active exercises in reducing pain and improving shoulder function (Brudvig et al. 2011).
  Level 2: Massage (myofascial trigger points in the shoulder muscles, or soft tissue) appears to be more effective than placebo or no treatment in reducing pain and improving shoulder function in patients with shoulder pain (van den Dolder and Roberts 2003, Hains et al. 2010, Bron et al. 2011, Yang et al. 2012)
- *Other interventions*
  Level 3: Oral NSAIDs appear to be more effective than placebo in reducing pain in the first 1–2 weeks (Mena et al. 1986, Petri et al. 2004). Laser treatment (of all types) appears to be more effective than placebo or ultrasound treatment in reducing pain after 2–4 weeks (England et al. 1989, Taverna et al. 1990, Saunders 1995, Vecchio et al. 1993, Santamato et al. 2009). Ultrasound treatment is no more effective than placebo, no treatment, physiotherapy, or exercise therapy (Berry et al. 1980, Ebenbichler et al. 1999, Gam et al. 1998, Kurtais Gursel et al. 2004, Nykanen 1995). Electrical stimulation has not been shown to be more effective than placebo (Binder et al. 1984, Dal Conte et al. 1990, Aktas et al. 2007). Acupuncture treatment appears to be no more effective than placebo and exercise therapy (Green et al. 2005).

Considerations

Much research has been done on the effect of non-operative therapies for various subacromial and shoulder pain syndromes. There is a great diversity of interventions and methods, and many studies use the terms shoulder pain and SAPS interchangeably. Also, any co-interventions and complications often remain unnamed. There is no literature on the effectiveness of behavioral counseling, but it is unlikely that therapy is given without behavioral counseling. The effectiveness of such advice (ranging from absolute rest to passive mobilization beyond the pain threshold) is unclear.

Recommendations

A non-operative treatment algorithm for SAPS starts with a recommendation of relative rest in the acute phase, if necessary combined with a prescription of NSAIDs for 1 or 2 weeks. This should be followed by gradually expanding activities. Corticosteroid injections may be used for severe pain, if possible under ultrasound guidance, in the first 8 weeks. The use of corticosteroid injections as single long-term therapy is not recommended. Use of high-energy ESWT can be considered for proven subacromial calcium deposits. ESWT is not recommended in the acute phase. Movement within the pain threshold is desirable. Neither strict immobilization nor passive joint mobilization in SAPS is recommended. Exercise

should preferably be performed at low intensity and high frequency, within the pain threshold, and focusing on eccentric training. Scapular stabilization training and relaxation with proper posture should be part of the regime. Treatment of myofascial trigger points (including stretching of the muscles) may be considered. Rehabilitation can be considered for chronic, treatment-resistant SAPS, where pain-perpetuating behavior plays a role.

Clinical Question 7: When is surgical treatment for SAPS indicated, and which technique is preferred?

- *Interventions with an intact rotator cuff*
  Scientific evidence level 2: It has not been shown that surgical treatment of SAPS is more effective than non-operative management to improve shoulder function or reduce pain (Coghlan et al. 2008, Dorrestijn et al. 2009, Gebremariam et al. 2011). No difference in outcome (shoulder function, complications) has been shown between an arthroscopic approach and an open approach. A bursectomy is likely to give the same clinical outcome as a bursectomy with acromioplasty (Faber et al. 2006, Barfield and Kuhn 2007, Coghlan et al. 2008, Davis et al. 2010, Donigan and Wolf 2011).

     Level 3: An open decompression may lead to longer hospital stay and a delayed return to work compared to arthroscopic surgery for SAPS (Davis et al. 2010).
- *Interventions to repair a torn rotator cuff*
  Level 3: There are indications that there is no difference between single-row and double-row fixation technique in terms of the final clinical outcome (shoulder function, re-ruptures) in surgical treatment of rotator cuff tears (Nho et al. 2009b). There are indications that there is a greater chance of anatomical recovery (tendon adhesion to the footprint) in the double-row fixation technique than in the single-row fixation technique (Saridakis and Jones 2010). There are indications that the chance of re-ruptures is smaller in the double-row fixation technique in tears larger than 1 cm (Duquin et al. 2010). There are indications that there is no difference between an open, mini-open, or arthroscopic approach with regard to final clinical outcome in the surgical treatment of rotator cuff tears (Morse et al. 2008, Seida et al. 2010). There are indications of worse outcome after arthroscopic rotator cuff repair measured after 1–2 years of follow-up associated with simultaneous procedures on the biceps, simultaneous procedures on the acromioclavicular joint, preoperative fatty degeneration of the m. supraspinatus, sex (women have worse outcomes than men), and age (the risk of poorer outcome increases with age) (Nho et al. 2009a, Oh et al. 2009, Grasso et al. 2009, Park et al. 2010).
- *Biceps tendon tenotomy or tenodesis*
  Level 3: A biceps tenotomy leaves more cosmetic defects; a biceps tenodesis gives more pain (Hsu et al. 2011).

Considerations

There is no convincing evidence that surgical treatment is more effective than non-operative treatment. No clear preference for surgical technique can be indicated either. There is no indication for surgical treatment of asymptomatic rotator cuff tears (AAOS. 2010). If rotator cuff repair is indicated, performing an open, a mini-open, or an arthroscopic approach makes no difference in end-results. There is moderate evidence for fewer re-ruptures in tears larger than 1 cm (measured backward) with a double-row fixation, but any effect on clinical outcome has not been demonstrated. Comparison between ESWT, barbotage (needling of the calcium deposit guided by fluoroscopy or ultrasound), and surgical removal shows no obvious preference for one of these interventions (Diehl et al. 2011) in the treatment of tendinosis calcarea. The only difference between a biceps tendon tenotomy and biceps tenodesis is cosmetic (Hsu et al. 2011).

Recommendations

SAPS should preferably be treated non-operatively. If the patient does not respond to exhaustive non-operative treatment and does not qualify for a rehabilitation treatment, bursectomy can be considered. A mini, mini-open, or arthroscopic approach is associated with shorter hospital stay and faster return to work. When surgical repair of symptomatic rotator cuff tears is indicated, the condition of the muscles as well as age and activity level of the patient play a role in the decision. Surgical treatment of tendinosis calcarea is not recommended, given the availability of equivalent alternatives.

Clinical Question 8: What advice can be given to patients with SAPS, argued from the patient's point of view?

Considerations

There is little research on the patient's point of view. From the few existing studies, it can be tentatively concluded that dissatisfaction with the outcome of treatment is more common in women than in men. There are indications that after a course of treatment, two-thirds of patients are still looking for one or more subsequent treatments, either in the medical sector or in alternative sectors.

Conclusion

Patients with shoulder pain who are often part of the working population come into contact with various healthcare providers. The collected recommendations from all disciplines in this guideline provide treatment advice based on the best-available evidence.

   The "do's" in this treatment algorithm are:
1 A diagnosis of SAPS can only be made after a combination of tests; the Hawkins-Kennedy test, the painful arc test, and the infraspinatus muscle strength test are advisable.
2. It is preferable to treat SAPS non-operatively.

3. Treat acute pain with advice, explanation, and possibly analgesics (NSAIDs) for a maximum of 2 weeks.

4. If symptoms persist longer than 6 weeks, take steps in the workplace to prevent development of a chronic syndrome.

5. Prescribe therapy or home exercises of low intensity and high frequency, combining eccentric training with stabilization training of the scapula and focusing on relaxation and proper posture.

6. Treatment of myofascial trigger points (including stretching of the muscles) can support exercise therapy.

7. For persistent symptoms, subacromial injection with corticosteroids is an effective treatment.

8. If symptoms persist longer than 6 weeks, ultrasound can be performed to rule out cuff rupture—if indicated, supplemented by conventional radiographic examination.

9. MRI is indicated when ultrasound examination is inconclusive, or to measure the size of the tear and the condition of the muscles when rotator cuff repair is being considered.

10. For tendinosis calcarea, ESWT or barbotage can be used.

11. Rehabilitation in a specialized center can be considered for chronic, treatment-resistant SAPS, in which pain-perpetuating behavior plays a role.

12. The indication for surgical repair of a symptomatic rotator cuff tear depends on the size of the tear, the condition of the muscles, and the age and activity level of the patient.

The "don'ts" in this algorithm are:

1. Strict immobilization.

2. No active intervention to prevent overload in work or sports and to address psychosocial factors.

3. Limiting imaging to conventional radiographic examination.

4. Ultrasound examination with suboptimal technique and experience.

5. ESWT in the acute phase, and in absence of tendinosis or bursitis calcarea.

6. Surgical treatment without exhaustive non-operative treatment.

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