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919 Shoulder Pain

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Occupational Therapy: Management and Diagnosis of Shoulder Pain

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Learning Objectives

Upon successful completion of this course, you will be able to:

- Identify the key elements of diagnosing shoulder problems
- List and discuss the differences between the most common diagnoses
- Discuss and compare the various treatments available for shoulder problems
- Explain how to evaluate the merits of exercise vs. arthroscopic decompression

Introduction

Compromised shoulder movement due to pain, stiffness, or weakness can cause substantial disability and affect a person's ability to carry out daily activities (eating, dressing, personal hygiene) and work. Self reported prevalence of shoulder pain is estimated to be between 16% and 26%; it is the third most common cause of musculoskeletal consultation in primary care, and approximately 1% of adults consult a general practitioner with new shoulder pain annually. Occupations as diverse as construction work and hairdressing are associated with a higher risk of shoulder disorders. Physical factors such as lifting heavy loads, repetitive movements in awkward positions, and vibrations influence the level of symptoms and disability, and psychosocial factors are also important. Recent studies suggest that chronicity and recurrence are common.

Common shoulder disorders exhibit similar clinical features, and the lack of consensus on diagnostic criteria and concordance in clinical assessment complicates treatment choices. This review proposes an evidence-based approach using a simplified classification of shoulder problems, incorporating diagnostic techniques applicable to a primary care consultation and a "red flag" system to identify potentially serious disease.

Sources and selection criteria

We found six published systematic reviews of interventions for shoulder disorders and one health technology assessment systematic review of diagnostic tests for the assessment of shoulder pain.[4-10] A topic search within Clinical Evidence identified the section "Shoulder pain." We identified and critically appraised other key publications in peer-reviewed journals that were relevant to primary care or published since the latest systematic reviews.

Summary points

Mixed shoulder disorders are common, and over differentiation of diagnostic categories does not alter largely conservative management in primary care

Self help advice, including relative rest and attention to occupational, sporting, or other physical contributory factors, should be offered as well as analgesics

The evidence for common interventions such as steroids and physiotherapy is relatively weak

Physiotherapy may reduce repeat primary care consultations for rotator cuff disorders, and steroid injections have a marginal short term effect on pain

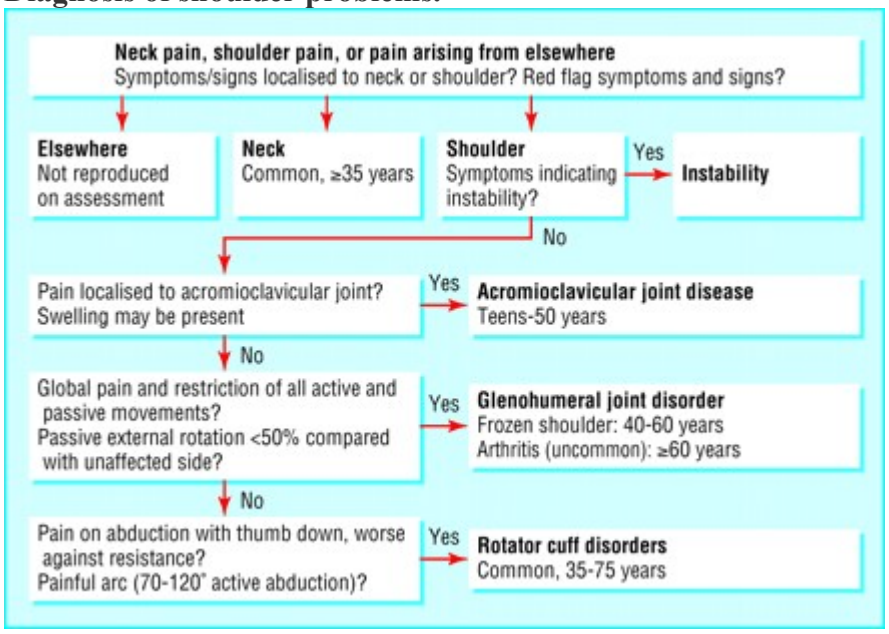
Poorer prognosis is associated with increasing age, female sex, severe or recurrent symptoms at presentation, and associated neck pain

Surgery should be considered when conservative measures fail

Diagnosis

Diagnosis should be pragmatic and based on a clinical assessment (box 1) that groups patients according to
the most common presentations in primary care (figure). An overcomplicated approach to diagnosis is unlikely to alter early conservative management in primary care.

Diagnosis of shoulder problems.



The four most common causes of shoulder pain and disability in primary care are rotator cuff disorders, glenohumeral disorders, acromioclavicular joint disease, and referred neck pain (box 2).

One primary care study that used standardized clinical tests for shoulder disorders found rotator cuff tendinopathy in 85% of patients, but in 77% of patients a clinical diagnosis of more than one shoulder problem was made—for example, tendinosis and impingement (57%); tendinosis, impingement, acromioclavicular disease, and adhesive capsulitis (6%). Blood tests and radiography are indicated only if there are "red flag" indicators such as symptoms and signs of systemic disease (weight loss, generalized joint pains, fever, lymphadenopathy, new respiratory symptoms); history of cancer; or concerning local features such as a mass lesion or bony tenderness or swelling (box 3).

Rotator cuff disorders (age 35-75)

Rotator cuff tendinopathy is the most common cause of shoulder pain. An occupational history may reveal heavy lifting or repetitive movements, especially above shoulder level. Although related to

activity, it often occurs in the non-dominant arm and in non-manual workers. Evidence suggests genetic susceptibility in some families. Wasting may be present on examination; active and resisted movements are painful and may be partially restricted, whereas passive movements are full, albeit painful. Although a painful arc is neither specific nor sensitive as a clinical sign, its presence reinforces the diagnosis of a rotator cuff disorder.

A rotator cuff tear is usually strongly indicated by the history: traumatic in young people and atraumatic in elderly people (related to attrition from bony spurs on the undersurface of the acromion or intrinsic degeneration of the cuff). Partial tears may be difficult to differentiate from rotator cuff tendinopathy on examination; weakness in resisted movement may occur in either condition. Several studies have suggested that no correlation exists between symptoms and loss of function in the presence of full thickness supraspinatus tears, that tears of the lower rotator cuff may lead to inability to rotate beyond 20°, and that partial and full thickness tears are commonly found during imaging of asymptomatic people. The "drop arm test" may be used to detect a large or complete tear (a high specificity and low sensitivity for this test was reported in a secondary care population).

Box 1: History and examination of the shoulder joint

History

- Onset, characteristics, and functional impact of shoulder pain?
- Dominant/non-dominant hand?
- Is pain at rest, on movement, or both?
- Is pain present at night?
- Does the pain affect sleeping position?
- Any neck, thoracic, or other upper limb pain?
- History of acute trauma, shoulder pain, or instability (joint dislocates or concern that might dislocate during certain movements)?
- Occupation and sporting activities?
- Other joints affected?
- Systemic symptoms of illness (fever, weight loss, rash, respiratory symptoms)?
- Significant comorbidity (diabetes; stroke; cancer; respiratory, gastrointestinal, or renal disease; ischaemic heart disease; psoriasis)?
- Current drug treatment and adverse drug reactions?

Examination

- Examine neck, axilla, and chest wall
- Assess range of movement of cervical spine
- Inspect shoulders for swelling, wasting, and deformity

- Palpate sternoclavicular, acromioclavicular, and glenohumeral joints for tenderness, swelling, warmth, and crepitus
- Compare power, stability, and range of movement (active, passive, resisted) of both shoulders
- Look for painful arc (70-120° active abduction)
- Test passive external rotation
- "Drop arm test": patient lowers abducted arm slowly to waist

Box 2: Causes of shoulder pain

Pain arising from the shoulder

- Rotator cuff disorders: rotator cuff tendinopathy, impingement, subacromial bursitis, rotator cuff tears
- Glenohumeral disorders: capsulitis ("frozen shoulder"), arthritis
- Acromioclavicular disease
- Infection (rare)
- Traumatic dislocation

Pain arising from elsewhere

- Referred pain: neck pain, myocardial ischaemia, referred diaphragmatic pain
- Polymyalgia rheumatica
- Malignancy: apical lung cancers, metastases

Box 3: Red flag indicators

- History of cancer; symptoms and signs of cancer; unexplained deformity, mass, or swelling? tumour
- Red skin, fever, systemically unwell? infection
- Trauma, epileptic fit, electric shock; loss of rotation and normal shape? unreduced dislocation

- Trauma, acute disabling pain and significant weakness, positive drop arm test? acute rotator cuff tear
- Unexplained significant sensory or motor deficit? neurological lesion

Glenohumeral disorders (adhesive capsulitis: age 40-65, median 50-55; osteoarthritis: ≥60)
Adhesive capsulitis ("frozen shoulder") and true glenohumeral arthritis are often preceded by a history of non-adhesive capsulitis symptoms, are characterized by deep joint pain, and restrict activities such as putting on a jacket (impaired external rotation). Adhesive capsulitis is more common in people with diabetes and may also occur after prolonged immobilization. On examination global pain is present, along with restriction of all movements, both active and passive.

Acromioclavicular disease (teenage to 50)
Acromioclavicular disease is usually secondary to trauma or osteoarthritis; dramatic joint dislocation can occur after injury (teenage to 30 years). Pain, tenderness, and occasionally swelling are localized to this joint, and there is restriction of passive, horizontal adduction (flexion) of the shoulder, with the elbow extended, across the body. Acromioclavicular osteoarthritis may also cause subacromial impingement.

Referred mechanical neck pain (common)

Typically there is pain and tenderness of the lower neck and suprascapular area, referred to the shoulder and upper limb area; shoulder movement may be restricted. Movement of the cervical spine and shoulder may reproduce more generalized upper back, neck, and shoulder pain. Upper limb paraesthesia may occur. Treatment is with relative rest and analgesia, and return to normal activities should be encouraged. Physiotherapy may be helpful.

Treatment

A functional holistic approach to shoulder pain, including adequate analgesia, is important to motivate patients and encourage rehabilitation. However, the evidence for common primary care interventions, including steroid injections, is relatively weak. The general practitioner should decide whether the pain is arising from the shoulder; if it is from elsewhere, the patient should be treated and referred appropriately.

If the pain is arising from the shoulder, is it due to a rotator cuff disorder or a glenohumeral joint problem? For both these shoulder disorders, analgesics should be recommended (ideally paracetamol; non-steroidal anti-inflammatory drugs should be used intermittently as second line if no contraindications exist), activity should be encouraged, and written information provided (for example, the Arthritis Research Campaign's patient leaflet).

Rotator cuff disorders (including possible minor tears)
Rotator cuff disorders should be treated initially with relative rest of the shoulder. The patient should return to normal activity or temporarily modified work as soon as possible within the limits of the disability and pain. Overall, systematic reviews and more recent studies suggest equivalent short-term benefit for physiotherapy (incorporating supervised exercise) and steroid injections in the management of shoulder disorders. In a primary care population with undifferentiated shoulder disorders,

participants allocated to a physiotherapy treatment group were less likely to re-consult with a general practitioner than were those receiving steroid injections alone.

A single recent study reported that a subacromial injection of xylocaine was as effective as steroid plus xylocaine in all disease specific outcome measures at two weeks, with follow-up of participants at six, 12, and 24 weeks. Some practitioners recommend larger volumes of injection of up to 10 ml, as a theoretical benefit of hydrodilatation of the subacromial bursa exists. However, inadequate evidence is available on evaluating outcomes with variation in volume injected. Therefore, subacromial corticosteroid injections, up to 10 ml in volume, should be considered for short-term pain relief and to facilitate rehabilitation. If the initial response is good, the injections should be repeated up to three times, at six weekly intervals.
No evidence exists to show that steroid injections are either harmful or beneficial in the presence of a rotator cuff tear, so they should be avoided if the drop arm test is positive/

Glenohumeral disorders
Traditional teaching is that the natural history of a frozen shoulder is recovery by two years; however, symptoms may persist for three years or more in some cases, particularly in patients with diabetes mellitus. Corticosteroid injections (intra-articular, anterior approach) may be of benefit in reducing pain in the early phase. No evidence exists to show that physiotherapy alone is of benefit for adhesive capsulitis; when the joint is very painful, movement is distressing and may well be counterproductive.[7] Intra-articular corticosteroid injections and physiotherapy, starting one week after the injection, may be of short-term benefit. However, in this study, intra-articular injection was done as a guided technique using fluoroscopy, limiting the generalisability of these findings to primary care.

Additional educational resources

Professional resources

- Arthritis Research Campaign. In Practice Series 4. Hazleman B. *Shoulder problems in general practice* (available by post and at www.arc.org.uk/about_arth/med_reports/series4/ip/6502/6502.htm)—one of a comprehensive series of musculoskeletal educational leaflets for general practitioners; well written and consistent with patient information
- Nuffield Orthopaedic Centre, Oxford (www.oxfordshoulderandelbowclinic.org.uk)—has a clinical algorithm for assessment linked to a management plan, physiotherapy guidelines for perioperative treatment for surgical interventions, and information for patients
- Carr AJ, Hamilton WH, eds. *Orthopaedics in primary care*. 2nd ed. Butterworth Heinemann, 2005—includes instructions for, and free downloadable video clips of, shoulder injection techniques and case study diagnosis and management; each draft chapter was reviewed and revised by the authors with a group of general practitioners
- *Frozen shoulder (adhesive capsulitis)*. BMJ Learning (www.bmjlearning.com)—an online learning module, including a short test and a certificate to include in a personal development plan

Resources for patients

- Arthritis Research Campaign. *The painful shoulder* (patient leaflet available by post and at www.arc.org.uk)—helpful for self management before going to a general practitioner; also mentions neck pain as a possible cause of shoulder pain
- NHS Direct (www.nhsdirect.nhs.uk)—most informative for "frozen shoulder;" no separate information on rotator cuff disorders or surgical interventions

Acromioclavicular disorders

Acromioclavicular disorders usually resolve with rest and simple analgesia, unless significant traumatic dislocation is present. If symptoms persist, a local steroid injection may help.

Biopsychosocial and complementary interventions

Individual psychosocial factors such as a passive coping style, fear of movement, and general psychological distress influence the risk of chronicity of symptoms in low back and neck pain. Therefore, targeted interventions to alter these and any occupational factors have also been suggested for shoulder disorders. A systematic review, however, concluded from the little evidence available that no evidence showed that multidisciplinary biopsychosocial rehabilitation is better than "usual care" in the management of shoulder problems in adults of working age.

The only complementary therapy widely reported on is acupuncture. The studies identified by systematic review were small and methodologically diverse and provided little evidence to either support or refute the use of acupuncture for shoulder disorders. The authors concluded that acupuncture may improve pain and function in the short term (two to four weeks).

Referral Criteria

The patient should be referred if:

- Pain and significant disability lasting more than six months, despite attention to occupation or sporting factors and, if indicated, physiotherapy and steroid injections
- History of instability ("Has your shoulder ever partly or completely come out of joint?" "Are you worried that your shoulder might slip on certain movements?") or acute, severe post-traumatic acromioclavicular pain
- Diagnostic uncertainty or red flag criteria summarized in box 3.

Patient's perspective

My (right) shoulder problem started about six months ago; I think it was after I had been in a

really awkward position while helping to care for my father. It became gradually more painful and was affecting my sleep; then I could not lift my arm up, nor could I put it behind my back. I could wear only clothes with front fastenings, and not if I had to use pressure, as it was painful to turn my arm inwards. When I needed to go to the toilet, I could not unfasten my trousers or pull clothes down quickly.

I am right handed, and everyday activities such as brushing my teeth or eating are still difficult and painful and take longer. When I am driving, it is painful to look over my right shoulder and to put the seat belt on. I was wary of going out if the paths were icy, because if I slipped I automatically put my right hand out, which was excruciating. Work is affected because I use computers; using the mouse becomes uncomfortable and makes my hand ache. I had had a frozen shoulder before, three years ago (the other arm); it was less painful and righted itself in about 18 months. This time I decided to go to a physiotherapist. I have been four times now; he has used acupuncture and lots of soft tissue and joint mobilizing techniques, and I have exercises to do. The pain around my shoulder has gradually lessened, and although the movement is unchanged, I am confident it will come back.

F, a 50 year old woman with shoulder pain

Future Developments and Surgical Interventions

Surgery has a place in the management of emergencies such as unreduced dislocation, infection, and traumatic acute rotator cuff tear. Its role is less clear in frozen shoulder, for which some surgeons advocate manipulation under anesthesia and arthroscopic release. A recent study found equivalent results for graduated supervised physiotherapy programmes and arthroscopic decompression for patients with rotator cuff disease. For significant persistent disability associated with impingement and rotator cuff tear, surgery may be effective at relieving pain and restoring function in patients who have failed conservative treatment. However, published studies typically involve small numbers of participants with limited long-term follow-up. Controversy exists regarding the management of mildly symptomatic small rotator cuff tears. Arguably, small tears should be repaired to relieve symptoms and to prevent progression to larger tears, which are associated with high levels of disability, but little evidence exists to support this view. For resistant acromioclavicular joint pain, an arthroscopic excision of the distal clavicle is an effective low risk procedure. Surgery remains the mainstay of management for most cases of recurrent shoulder instability; those cases that do not need surgery will need specialist physiotherapy and can be difficult and resistant problems. The management of osteoarthritis and rheumatoid arthritis has improved considerably in recent years, and joint replacement surgery, as with other joints, provides relief of pain for end stage disease.

Conclusions

Shoulder pain is a common and important musculoskeletal problem. Management should be multidisciplinary and include self-help advice, analgesics, relative rest, and access to physiotherapy. Steroid injections have a marginal short-term effect on pain.

Poorer prognosis is associated with increasing age, female sex, severe or recurrent symptoms at presentation, and associated neck pain. Mild trauma or overuse before onset of pain, early presentation, and acute onset have a more favorable prognosis. No evidence exists to show that early orthopedic intervention improves the prognosis for most rotator cuff or glenohumeral disorders. Surgery should be considered when conservative measures fail.

Two pragmatic trials of treatment for shoulder disorders in primary care: generalisability, course, and prognostic indicators

E Thomas[1], D A W M van der Windt[2], E M Hay[1], N Smidt[2], K Dziedzic[1], L M Bouter[2] and P R Croft[1]

Abstract

Objective: To investigate predictors of long-term prognosis in patients treated for shoulder pain in primary care.

Methods: Data were taken from two pragmatic randomized clinical trials investigating the effectiveness of conservative treatments for shoulder pain presenting to primary care. Shoulder pain severity, disability, and perceived recovery measured in the long term (UK, 18 months; Netherlands, 12 months) were considered as outcome measures. Prognostic indicators measured before randomization were determined by linear regression (pain severity and disability) and logistic regression (perceived recovery).

Results: 316 adults with a new episode of shoulder pain were recruited (UK, n = 207; Netherlands, n = 109). In multivariate analysis, greater shoulder disability at follow up was associated with higher baseline disability score, concomitant neck pain, and a gradual onset and longer duration of shoulder symptoms. Pain scores at follow up were higher in women and in those with longer baseline duration of symptoms and higher baseline pain or disability scores. Being female, reporting gradual onset of symptoms, and a higher baseline disability score each independently reduced the likelihood of perceived recovery.

Conclusions: The results suggest that there is no long-term difference in outcome between patients with shoulder pain treated with different clinical interventions in different clinical settings, or having different clinical diagnoses. Baseline clinical characteristics of this consulting population, rather than the randomized treatments which they received, were the most powerful predictors of outcome. Whether this highlights the need for earlier intervention or reflects different natural histories of shoulder pain is a topic for further research.

Abbreviations: NRS, numerical rating scale; RCT, randomized controlled trial; SDQ, shoulder disability questionnaire; VAS, visual analogue scale

Shoulder problems are common, with up to 47% of adults in the general population reporting such symptoms in a one-year period.[1] In terms of presentation to general practice, the annual consultation rate for new episodes of shoulder pain is approximately 1%.[2] The current evidence from both observational studies[3–5] and randomized clinical trials in primary[6–8] and secondary care[9,10] suggests that many sufferers have an unfavorable long term outcome, irrespective of treatment.

Identifying those groups of individuals with shoulder pain who have poor long-term outcome would have several advantages, including the ability to advise individual patients on their likely course.

The objectives of this analysis were threefold: first, to investigate the generalisability of the findings from two trials by determining clinical heterogeneity across the two studies in terms of participants, interventions, and outcome; second, to determine the course of shoulder complaints in the complete sample over the follow up period; and third, to investigate potential prognostic indicators for poor long term outcome, using data collected before randomization.

METHODS

This study used data from two recently completed, pragmatic randomized clinical trials investigating the effectiveness of conservative treatments for shoulder pain presenting to primary care.[6,7]

Interventions

The trial by Van der Windt *et al*[6] compared the effectiveness of a local intra-articular injection (by a posterior route) of 40 mg triamcinolone acetonide and a course of physiotherapy, in 109 participants presenting to primary care in and around Amsterdam with a new episode of painful stiff shoulder (capsular syndrome).

The trial by Hay *et al*[7] compared the effectiveness of a subacromial local corticosteroid injection of 40 mg of methylprednisolone and 4 ml 1% lignocaine (lidocaine) and a course of community based physiotherapy. This study was based in North Staffordshire and randomized a total of 207 participants attending their general practitioner (GP) with a new episode of shoulder pain. In contrast to the trial of Van der Windt *et al*, the participants in the Hay trial had a broad range of shoulder problems without focus on a particular diagnosis.

Study population

In both studies, consecutive patients consulting in primary care for shoulder pain were eligible for recruitment. The following inclusion criteria were applied in both studies: age 18 years and over, ability to complete questionnaires in the relevant languages, and able to give informed consent. Exclusion criteria in both studies included: bilateral symptoms, contraindication to the treatments being evaluated, recent treatment with either a corticosteroid or physiotherapy, and previous surgery, dislocation, or fracture in the shoulder area. However Hay *et al*[7] additionally excluded patients who had consulted their GP with shoulder pain during the preceding 12 months.

In both studies, patient characteristics and potential prognostic factors were recorded by a research nurse at an initial visit before randomization. Demographic and clinical characteristics included age, sex, duration of current shoulder complaint, and use of painkillers.

Outcome measures

Both studies assessed the following: disability associated with the shoulder pain; pain severity during the day; and participants' perception of the outcome. This information was collected at three follow up points: short term (six weeks in the UK, seven weeks in the Netherlands), mid-term (six months in both studies), and long term (18 months in the UK, 12 months in the Netherlands).

However, there were minor differences between the two studies in terms of the scaling used in these three outcome measures.

Different shoulder disability questionnaires (SDQ) were used in the two studies (SDQ-UK[11] and SDQ-NL[12]). To record the pain severity, Van der Windt *et al*[6] used a 0–100 visual analogue scale (VAS),

while Hay *et al*[7] used a 10 point numerical rating scale (NRS). To standardize these two outcome measures across both studies, measurements from the Hay study were transformed to 0–100 scales, where 100 indicates maximum pain or disability. The SDQ-UK comprises of 23 areas in which shoulder disability is assessed—for example, fastening clothing, reduced role in household jobs. To put this transformed 0–100 scale of disability into context, four points on the 0–100 scale would be approximately equal to the addition of one more area in which the participant reported difficulty on the original 23 item version of the SDQ-UK.

To rate person perceived recovery from baseline, both studies used a Likert scale, with 5 points for the Hay study and a 6-point scale for the Van der Windt study. Here, the scores from both studies were standardized by dichotomizing to two groups into (i) those who had not improved or had worsened ("unchanged", "worse", "much worse"), and (ii) those who had improved ("recovered", "improved" (UK); "recovered", "much improved", "somewhat improved" (Netherlands)).

Statistical analysis

We investigated differences between the two study populations regarding demographic and clinical characteristics collected at baseline. Summary data were calculated—proportions for categorical variables and means and standard deviations for numerical variables. For categorical data, difference in proportions and their associated 95% confidence intervals were calculated; for numerical data, mean differences and their associated 95% confidence intervals (CI) were calculated. Differences between the two study populations with regard to baseline pain and disability scores were also calculated: first, the unadjusted mean differences and 95% confidence intervals; second, the adjusted mean differences and 95% CI, allowing for any differences in the demographic or clinical characteristics between the studies (linear regression).

Comparisons of the course between the two trials, and between the two treatment groups within the trials, were made. Univariate and multivariate analyses were used to investigate the associations between potential prognostic indicators and outcome in the long term. For each of the three outcome measures examined (disability, pain, and perceived recovery) different models were built, with the model being parameterized to determine factors associated with a poor outcome—that is, a higher score for disability or pain (linear regression) and not improving or worsening (logistic regression). The variables "country" (Netherlands, UK) and "treatment" (injection, physiotherapy) were included in all models as covariates. All putative prognostic factors showing a univariate association with the outcome at issue ($p<0.10$) were put forward into a multivariate analysis (backward elimination ($p<0.10$)) to determine a group of factors that were independently associated with a poor outcome. We chose this cut off of $p<0.1$ to represent significance rather than the more conventional, but no less arbitrary, value of 0.05, the use of which has been shown to fail to identify factors known to be of importance.[13] Analyses were carried out using Stata 7.0.[14]

RESULTS

Study populations

In all, 203 patients were referred from the 60 participating GPs in the trial based in the Netherlands and 109 (53.7%) were randomized (56 to physiotherapy and 53 to corticosteroid injection). Reasons for exclusion were: diagnosis of capsular syndrome could not be confirmed (n = 73), no consent (n = 6),

not eligible (n = 10), or they had recovered (n = 5).[6] In the study by Hay *et al*,[7] 207 of 237 patients (87.3%) referred to the trial by the participating GPs were randomized (103 to physiotherapy and 104 to corticosteroid injection). Reasons for exclusion were no consent (n = 12), not eligible (n = 11), or they had improved (n = 7).

Table 1 presents the baseline demographic and clinical characteristics and measurements for both studies at baseline. The two studies were similar with respect to mean age, proportion of women, proportion with the dominant side affected, and onset of current symptoms. However, participants in the trial of Van der Windt *et al* reported a significant longer duration of current symptoms, a higher percentage of concomitant neck pain, and a lower percentage of recent use of painkillers. With respect to baseline measures of pain and disability, differences were apparent between the trials. Disability scores were significantly higher in the Dutch study, while conversely pain scores were significantly higher in the UK trial. After adjusting for demographic and clinical characteristics, the difference in pain severity between the two studies was reduced. However, the difference in disability scores persisted after this adjustment.

Table 1 **Patient characteristics at baseline in two randomized controlled trials on the treatment of shoulder disorders in primary care**

	Van der Windt *et al*[6] (n = 109)	Hay *et al*[7] (n = 207)	Difference (NL–UK) (95% CI)	Adjusted difference (95%CI)*
Demographic characteristics				
Age (years)	**58.8 (10.5)**	**57.5 (13.4)**	**1.3 (–1.6 to 4.2)**	
Women	**58 (53.2%)**	**110 (53.1%)**	**0.07% (–11.5% to 11.6%)**	
Clinical characteristics at baseline				
Duration of shoulder complaint (weeks)	**27.6 (40.4)**	**12.5 (15.5)**	**15.2 (8.9 to 21.4)**	
Dominant side affected	**43 (39.5%)**	**97 (46.9%)**	**–7.4% (–18.8% to 4.0%)**	
Concomitant neck pain	**56 (51.4%)**	**81 (39.1%)**	**12.2% (0.7% to 23.7%)**	
Painkillers in last 48 hours	**30 (27.5%)**	**146 (70.5%)**	**–43.0% (–53.4% to –32.6%)**	
Acute onset of symptoms	**24 (22.0%)**	**58 (28.0%)**	**–6.0% (–15.9% to 3.9%)**	

Baseline measures of outcome				
Pain during the day	**48.7 (22.1)**	**56.6 (24.6)**	**–7.9 (–13.4 to –2.3)**	**–4.1 (–10.3 to 2.1)**
Shoulder disability score	**69.4 (18.0)**	**47.4 (19.7)**	**22.0 (17.5 to 26.5)**	**25.6 (20.6 to 30.5)**

Values are n (%) of participants or mean (SD).

***Linear regression analysis of mean differences (95% confidence intervals) after adjustment for all demographic and clinical characteristics in the table.**

Course of shoulder symptoms

Despite a significant difference in improvement rates in the short term for the Dutch trial (difference = 17.6% (95% CI, 5.0% to 30.3%)), the pattern of improvement rates was similar over the longer term both between countries and between treatments within countries (table 2).

Table 2 **Patient perceived outcome since baseline**

	"Improvement" since baseline			
	Van der Windt *et al*[6] (n = 109)		**Hay *et al*[7] (n = 207)**	
	Injection	**Physiotherapy**	**Injection**	**Physiotherapy**
Short term follow up	**50 (96.2%)**	**44 (78.6%)**	**69 (72.6%)**	**77 (78.6%)**
Mid-term follow up	**44 (84.6%)**	**47 (87.0%)**	**80 (82.5%)**	**82 (85.4%)**
Long term follow up	**46 (93.9%)**	**46 (83.6%)**	**66 (86.6%)**	**75 (92.6%)**

Values are n (%).

Figure 1 presents the course of "severity of shoulder disability" for each intervention, separately. At the long term follow up point (12/18 months), a decrease in disability score from baseline was seen for almost all participants (90.1%), regardless of treatment or country. The course of participants who received a corticosteroid injection was slightly more favorable in the short term for the Dutch trial, but in the mid- and long term both treatment groups were similar. The course for the two treatment groups from the UK trial were almost identical. Comparing the data from the two countries, combining the

treatment groups, the average disability scores fell by 68% in the UK trial compared with 57% in the Dutch trial. Hence, despite a lower long-term disability score in the UK trial, the change from baseline was similar in both trials, as the Netherlands trial had a greater mean disability score at recruitment. A similar pattern to that observed for disability was seen for pain severity during the day (fig 2↓). Again, despite different mean scores at baseline, the UK participants having higher scores, all four treatment groups had substantially improved at long term follow up.

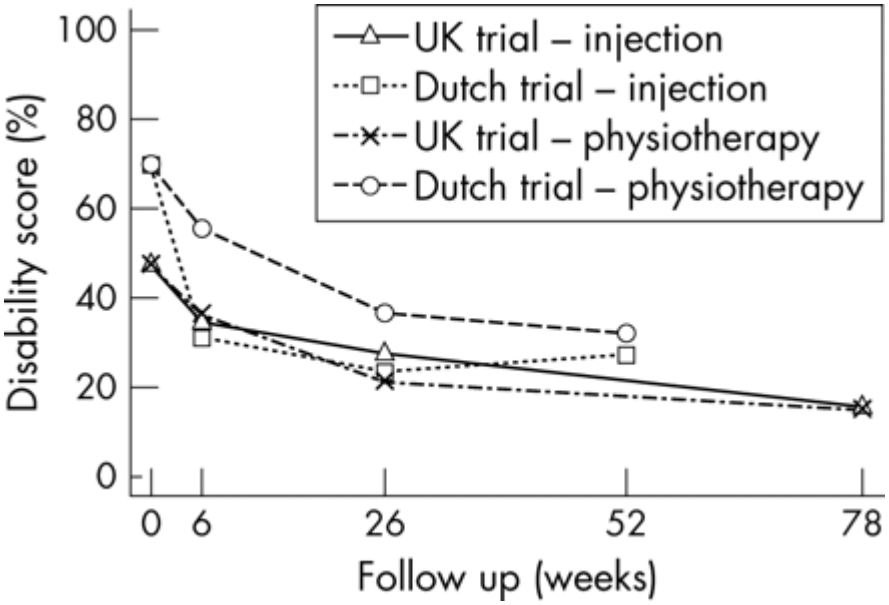


Figure 1 The severity of shoulder disability at baseline and during follow up for each intervention individually.

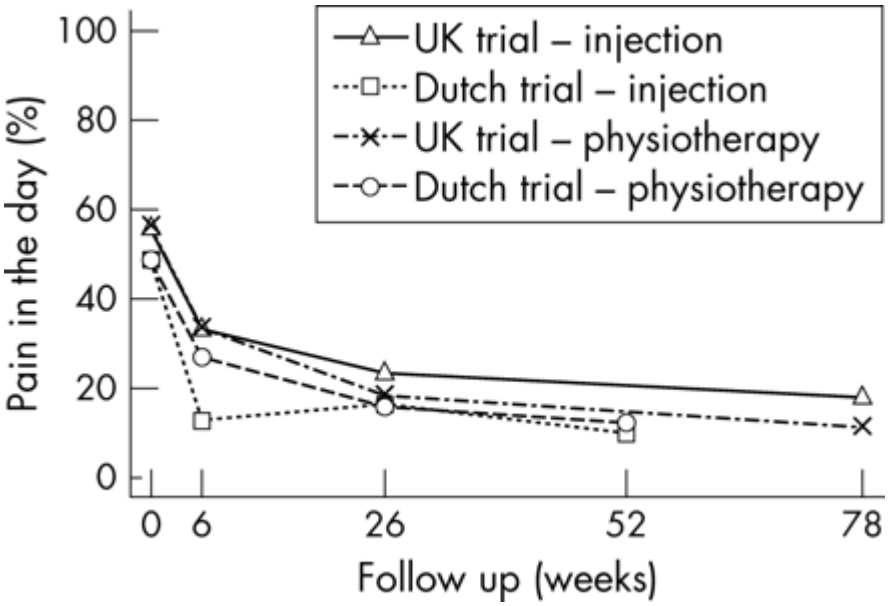


Figure 2 The severity of shoulder pain during the day at baseline and during follow up for each intervention individually.

Prognostic indicators

Disability score at long term follow up

In the univariate analysis, after adjusting for country and treatment, the following were all associated with higher disability score at long term outcome: concomitant neck pain, gradual onset of symptoms (that is, over a few weeks), longer duration of symptoms at recruitment, and higher baseline pain and disability scores (table 3↓). In the multivariate analysis, concomitant neck pain, a gradual onset of symptoms, longer duration of symptoms at recruitment, and higher baseline disability score each increased the long-term disability score (R^2 = 23.7%).

Table 3 Prognostic indicators of the severity of shoulder disability at long term follow up (n = 264): univariate and multivariate linear regression analyses

	Univariate analysis		Multivariate analysis	
Prognostic indicator*	**Mean difference**	**95% CI**	**Mean difference**	**95% CI**
Age group (years)				
20 to 50				
51 to 58	**6.78**	**–2.94 to 16.5**		
59 to 67	**3.36**	**–6.38 to 13.1**		
68 to 85	**11.06**	**1.07 to 21.0**		
Male sex	**3.90**	**–2.89 to 10.7**		
Duration of shoulder pain at baseline (per month)	**0.52**	**0.05 to 1.00**	**0.52**	**0.08 to 0.95**
Involvement of dominant side	**3.04**	**–3.85 to 9.92**		
Concomitant neck pain	**10.70**	**3.94 to**	**6.57**	**0.21 to**

		17.5		12.9
Gradual onset	6.66	–1.19 to 14.5	7.77	0.53 to 15.0
Use of painkillers in previous 48 hours	3.55	–3.74 to 10.9		
Baseline disability (per point)	0.52	0.36 to 0.67	0.52	0.36 to 0.68
Baseline pain in day (per point)	0.18	0.04 to 0.32		

*Adjusted for country and randomized treatment.

CI, confidence interval.

At baseline, the mean disability score was 55 points on a scale of 0–100. By long term follow up this had reduced to a mean of 21 points.

A substantial effect on follow up disability score was attributable to the presence of concomitant neck pain at baseline and to a gradual onset of the shoulder symptoms, with each of these factors being linked to an approximate 7 point increase in the follow up disability score among participants with these characteristics compared with those without. This is equivalent to having two additional areas of limited everyday functioning reported on the SDQ-UK. Longer duration of symptoms at baseline also increased disability score at follow up; comparing two participants, alike in all other respects, each extra month of recorded duration would increase the follow up score by 0.5 points. Not surprisingly, higher disability at baseline led to a higher score at follow up; this is equivalent to stating that for each two additional areas of limited everyday functioning recorded at baseline, one would be retained at follow up.

Pain severity during the day at long term follow up

In the univariate analysis, after adjusting for country and treatment, the following were associated with higher pain severity in the day at long term outcome: male sex, longer duration of symptoms at recruitment, and higher baseline pain and disability scores (table 4). In the multivariate analysis, being male, having a longer duration of symptoms recorded at baseline, and the severity of both baseline pain and disability scores each independently increased the long term pain scores (R^2 = 9.22%).

Table 4 Prognostic indicators of the severity of shoulder pain during the day at long term follow up (n = 264): univariate and multivariate linear regression analyses

Prognostic indicator*	Univariate analysis	Multivariate analysis

	Mean difference	95% CI	Mean difference	95% CI
Age group (years)				
20 to 50				
51 to 58	**–0.19**	**–7.67 to 7.30**		
59 to 67	**2.29**	**–5.29 to 9.87**		
68 to 85	**6.88**	**–0.81 to 14.6**		
Male sex	**6.06**	**0.83 to 11.3**	**5.77**	**0.74 to 10.8**
Duration of shoulder pain at baseline (per month)	**0.25**	**–0.13 to 0.62**	**0.30**	**–0.06 to 0.65**
Involvement of dominant side	**4.24**	**–1.08 to 9.56**		
Concomitant neck pain	**2.76**	**–2.56 to 8.08**		
Gradual onset	**3.32**	**–2.74 to 9.39**		
Use of painkillers in previous 48 hours	**3.43**	**–2.25 to 9.10**		
Baseline disability (per point)	**0.23**	**0.10 to 0.36**	**0.13**	**0.01 to 0.28**
Baseline pain in day (per point)	**0.19**	**0.08 to 0.29**	**0.15**	**0.03 to 0.26**

***Adjusted for country and randomized treatment.**

CI, confidence interval.

At baseline, the mean pain score was 54 points on a scale of 0–100. By long term follow up this had reduced to a mean of 13 points. Sex had a substantial effect on follow up pain score with men having scores 6 points higher than women. As seen for long term disability, pain severity scores at long term follow up were higher for those with longer symptom duration at baseline; each additional six months

of duration at baseline increased the pain score at follow up by approximately 2 points. Pain at long-term follow up was associated with both baseline pain and disability score.

Perceived recovery at long term

Here, as the outcome measure is dichotomous—that is, recovered or not recovered—the results are presented as odds ratios (the odds of not recovering given presence of the risk factor compared with the odds of not recovering given the absence of the risk factor). In the univariate analysis, after adjusting for country and treatment, the following were all associated with a poor outcome ("not improving") at long term follow up: male sex, gradual onset of symptoms, longer duration of symptoms at recruitment, and higher baseline pain and disability scores (table 5↓). In the multivariate analysis, being male, reporting a gradual onset of symptoms, and higher baseline disability scores were independently associated with not recovering.

Table 5 Prognostic indicators of the perceived outcome of shoulder symptoms at long term follow up (n = 264): univariate and multivariate logistic regression analyses

	Univariate analysis		Multivariate analysis	
Prognostic indicator*	**Odds ratio**	**95% CI**	**Odds ratio**	**95% CI**
Age group (years)				
20 to 50	**1.00**			
51 to 58	**0.79**	**0.24 to 2.60**		
59 to 67	**0.75**	**0.23 to 2.47**		
68 to 85	**1.50**	**0.51 to 4.45**		
Male sex	**2.35**	**1.03 to 5.31**	**2.57**	**1.10 to 5.94**
Duration of shoulder pain at baseline (per month)	**1.03**	**0.99 to 1.10**		
Involvement of dominant side	**0.90**	**0.40 to 2.00**		
Concomitant neck pain	**0.96**	**0.43 to 2.14**		
Gradual onset	**2.98**	**0.86 to 10.3**	**3.21**	**0.91 to 11.3**
Use of painkillers in previous 48 hours	**1.22**	**0.52 to**		

		2.86			
Baseline disability (per point)	**1.03**	**1.01 to 1.05**		**1.03**	**1.01 to 1.05**
Baseline pain in day (per point)	**1.02**	**1.00 to 1.03**			

***Adjusted for country and randomized treatment.**

CI, confidence interval.

Men compared with women, and those who reported a gradual compared with a sudden onset, were at a threefold increased odds of not recovering. For each additional point on the disability score at baseline, the odds of a poor outcome were increased by 3%; hence for two participants who were 10 disability points apart at baseline, the one with the higher score would be 30% more likely to have persistent symptoms at long term follow up.

DISCUSSION

Comparing data from two large recent randomized clinical trials of shoulder pain in primary care gave us the opportunity to investigate the generalisability of these findings. Our analysis confirmed that, as expected from the inclusion and exclusion criteria, there were differences between the two study population in terms of their characteristics at entry to the trial. Despite these differences, however, the long term effect of treatment appears to be similar both within each trial and across both trials.

The group of prognostic indicators associated with each of the outcome measures examined differed with only one factor (disability score at baseline) common to each model. Disability, symptom duration and baseline pain level were the only factors to reach moderate to high evidence for predicting outcome in a recent systematic review of cohort studies.[15] Prognostic models are unsuitable for making inferences on interventions to improve prognosis and so the models derived here are suitable for predicting long term outcome only—that is, they cannot imply causality.

Some of the heterogeneity seen in the clinical characteristics of the two study populations partly reflects the different exclusion criteria and definitions of "shoulder complaint" used. For example, Hay *et al*,[7] unlike Van der Windt *et al*,[6] excluded patients who had previously consulted for the same shoulder problem in the past 12 months. However, for the majority of the Dutch participants, the consultation leading them into the trial was their first in that year period. Van der Windt *et al* attempted to assemble a group of patients with a single diagnosis (capsular syndrome). This differed from the more general definition of "shoulder pain" as used by Hay *et al*. The higher level of baseline shoulder disability and higher prevalence of concomitant neck pain seen in the Dutch trial could be related to the

different diagnostic criteria used. Indeed, when a subgroup of UK participants with shoulder restriction (either in active abduction or external rotation) was compared to those without restriction, those with restriction had higher baseline disability scores. The shorter duration of symptoms at baseline in the UK participants is likely to reflect the requirement that participants should not have consulted with their affected shoulder in the previous 12 months.

It is curious that the Dutch participants had higher baseline disability but lower pain scores that the UK participants. This finding suggests that the shoulder disability questionnaires used are indeed measuring something other than pain. This is likely to be particularly so for the SDQ-UK, which includes various questions about the more general effects of shoulder pain on health status (for example, irritability and so on). By contrast, the SDQ-NL is more restricted in its content, including questions mainly focusing on the effect of pain on limitation of function. This finding has been reported previously, where a higher correlation was seen between the SDQ-UK and the EuroQol, a generic health outcome measure, than between the EuroQol and the SDQ-NL.[16]

There was no evidence from either study that local steroid injection conferred long term benefit. Local steroid injection offered some benefit in terms of improvement in short term pain and disability only in the Dutch trial. This difference between the trials might relate to different patient selection, different steroid preparations, or differences in injection techniques. For example, the majority (75%) of the Dutch participants randomized to injection received two or three injections in the treatment period compared to one in the UK trial.

Pooling data from randomized trials potentially allows for the detection of important differences in secondary outcome measures for which the original trials were not individually powered to detect. In our study such analysis was hampered by a lack of consistency in the use of outcome measures. Although we attempted to standardize the two SDQs used in the trials, there appeared to be some differences relating to the content these two tools which compromises the validity of this approach.[16] Hence the authors agree that a consensus on a core set of outcome measures for shoulder pain in needed.[16,17]

Despite the clinical heterogeneity apparent in the two study populations, the overall findings of the two trials suggest that shoulder injection and physiotherapy are similarly effective in the long term at reducing both pain and disability in patients presenting to primary care with shoulder pain. The results of this analysis suggest that there is no long term difference in outcome between patients treated with different clinical interventions in different clinical settings, or having different clinical diagnoses. Baseline characteristics of the population (gradual onset, duration and severity of symptoms) were the most powerful predictors of outcome. This has important implications for future interventions for shoulder pain; whether it highlights the need for earlier intervention or reflects different natural histories of shoulder pain is a topic for further research. However, the percentage of the variance explained in the models is quite low, which means that there are other factors not included in the model (either measured or not measured) that may explain a further amount of the variability in outcome among patients with shoulder disorders.

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Exercises versus arthroscopic decompression in patients with subacromial impingement: a randomised, controlled study in 90 cases with a one year follow up

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ABSTRACT

Objectives: To compare the effect of graded physiotherapeutic training of the rotator cuff versus arthroscopic subacromial decompression in patients with subacromial impingement.

Methods: Randomised controlled trial with 12 months' follow up in a hospital setting. Ninety consecutive patients aged 18 to 55 years were enrolled. Symptom duration was between six months and three years. All fulfilled a set of diagnostic criteria for rotator cuff disease, including a positive impingement sign. Patients were randomised either to arthroscopic subacromial decompression, or to physiotherapy with exercises aiming at strengthening the stabilisers and decompressors of the shoulder. Outcome was shoulder function as measured by the Constant score and a pain and dysfunction score. "Intention to treat" analysis was used, with comparison of means and control of confounding variables by general equation estimation analysis.

Results: Of 90 patients enrolled, 84 completed follow up (41 in the surgery group, 43 in the training group). The mean Constant score at baseline was 34.8 in the training group and 33.7 in the surgery group. After 12 months the mean scores improved to 57.0 and 52.7, respectively, the difference being non-significant. No group differences in mean pain and dysfunction score improvement were found.

Conclusions: Surgical treatment of rotator cuff syndrome with subacromial impingement was not superior to physiotherapy with training. Further studies are needed to qualify treatment choice decisions, and it is recommended that samples are stratified according to disability level.

Abbreviations: GEE, generalized estimation equations; MIREDIF, minimum relevant clinical difference; VAS, visual analogue scale

Shoulder pain is common. In a Dutch study the incidence of new cases of rotator cuff tendonitis in general practice was found to be around 3.2 to 4.2 per 1000 person–years, and the corresponding incidence of shoulder pain (all causes) was 11.2 per 1000 person–years.[1]

Rotator cuff disease with subacromial impingement has been graded in three stages: stage 1, acute inflammation, and either tendonitis or bursitis; stage 2, chronic inflammation with or without degeneration; stage 3, full rupture of the cuff.[2] The anatomical basis for impingement is a mismatch between the structures in the subacromial space. This aggravates or provokes pain.

The main idea of the treatments given is to control pain and remedy the mechanical problem in order to preserve or improve function. Improved function can be obtained through reduction of inflammatory edema, strengthening of the muscles, which act as depressors and stabilisers of the humeral head, or by removing fibrotic tissue in the subacromial bursa and a part of the acromion itself.

The condition is often treated conservatively in the primary health care sector by general practitioners or physiotherapists.[3] Studies of the effectiveness of physiotherapy versus corticosteroid injections have found inconsistent short term results. Hay *et al*, in a trial from general practice, found no difference in effectiveness at six months' follow up.[4]

Patients with resistant or longstanding shoulder pain are often referred for specialist treatment, included surgery. However, according to a Cochrane review, there is little evidence to support or refute the efficacy of common interventions for shoulder pain.[5] Also, the evidence supporting the superiority of subacromial decompression relative to physiotherapy with training has been unconvincing.[6–9]

Our objective in this study was to test the effect of graded physiotherapeutic training versus arthroscopic subacromial decompression after 12 months' follow up in patients referred to specialist treatment for shoulder pain with subacromial impingement.

METHODS

Patients and recruitment

The study was conducted between 1996 and 2001 at Herning Hospital, Ringkjoebing County, Denmark, as a collaborative project between the departments of occupational medicine, rheumatology and physical rehabilitation, orthopedic surgery, and radiology. The departments of occupational medicine and of rheumatology and physical rehabilitation receive shoulder patients referred from the primary health care sector. These referrals constituted the recruitment base. Diagnostic criteria required were: the presence of shoulder pain, pain on abduction of the shoulder with painful arch, a positive impingement sign (Hawkins sign) and a positive impingement test (relief of pain within 15 minutes after injection of local anesthetic (bupivacaine 5 ml) into the subacromial space).

A rheumatologist (SØ) assessed all patients. The eligibility criteria for participation were: fulfillment of all diagnostic criteria, report of shoulder symptoms between six months and three years (because surgery in general was not offered to cases with symptoms of shorter duration), and age between 18 and 55 years. Previous treatment with rest, non-steroidal anti-inflammatory drugs, subacromial

injection, and physiotherapy were allowed. Normal passive glenohumeral movement was a requirement. Patients were excluded for the following reasons: impaired rotation in the glenohumeral joint, a history of acute trauma, previous surgery or previous fracture in the proximity of the affected shoulder, known osteoarthritis in the acromioclavicular or glenohumeral joints, calcifications exceeding than 2 cm in the rotator cuff tendons, or signs of a rupture of the cuff or cervical root syndromes.

Study protocol
consecutively referred patients who fulfilled the inclusion criteria were informed about the project. Those interested in participation underwent a clinical reappraisal by a specialist at the rheumatology department.

The same specialist (SØ) carried out all the assessments, obtained informed consent for participation, and randomised the patients into one of two intervention groups by opening a sealed envelope containing the result of randomization, which was unknown to SØ. A computer program was used to generate a random sequence of allocation. In patients with bilateral symptoms the most affected shoulder was chosen as the primary intervention shoulder. After assessment and randomization the patient was referred to *x* ray and ultrasonography of the shoulders. The rheumatologist filled in a baseline registration card, and gave the patient a baseline questionnaire to be completed and submitted to the department of occupational medicine before the start of the intervention. Radiographic and ultrasonography findings are not presented here.

The study was approved by the hospital ethics committee.

Intervention
Intervention in both groups began four weeks after enrolment.

The physiotherapeutic treatment consisted of 19 sessions, each lasting up to 60 minutes, given by two experienced therapists (SL and EA). The treatments started with application of heat, cold packs, or soft tissue treatments. This was followed by active training of the periscapular muscles (rhomboid, serratus, trapezoid, levator scapulae, and pectoralis minor muscles) and strengthening of the stabilizing muscles of the shoulder joint (the rotator cuff). This was done within the limits of pain. During the first two weeks the patient was seen three times weekly, during the next three weeks twice weekly, and during the last seven weeks once weekly. The patients were encouraged to continue to do active exercises at home on a daily basis. After carrying out the full programme for at least 12 weeks, the patients were encouraged to continue the programme two to three times a week.

Patients treated at the surgical department underwent an investigation for stability of the shoulder joint, carried out under general anesthesia. This was followed by an arthroscopic examination of the glenohumeral joint, the rotator cuff, and the subacromial bursa. The treatment consisted of bursectomy with partial resection of the antero-inferior part of the acromion and the coracoacromial ligament. Two experienced surgeons undertook all procedures and recorded their findings on a predetermined proforma. Before discharge, the patient was instructed in performing light movements of the arm within the limits of pain. Stitches were removed by general practitioners after 10 days. At the same time, the patient was instructed by a physiotherapist to carry out increasingly active exercises, including exercises for strengthening the rotator cuff muscles. The team instructing the surgery group

was different from the group treating the control (training) group. The surgeon then saw the patients after six to eight weeks.

Outcome measures

All the patients were evaluated at baseline immediately before the intervention, and after three, six, and 12 months. Evaluation was done by two physiotherapists (SV and EH) using the Constant score,[10] which is a joint measure of four subscores: pain measured on a visual analogue scale (VAS); limitations in activities of daily living; active range of motion in four directions in the shoulder joint; and isometric shoulder strength measured in kg with a portable muscle strength analyzer (Isobex 2.1, Cursor AG, Bern, Switzerland). Each kg was allocated 2 points up to 25 points for strength of at least 12 kg.

Based on measurements of shoulder force in healthy male and female workers the force measurements among women were adjusted by multiplying the measurements by a factor of 1.94 in order to compare the values for male and female subjects.[11] The total Constant score sums up to 100 points, which indicates normal function. Physiotherapists were not blinded to the treatment given when assessing the Constant score.

After one year, patients filled in a follow up questionnaire, which repeated various questions given at baseline. In a set of four questions the patients were asked to indicate pain and dysfunction for each shoulder by using a numerical box complaint scale (Likert scale) ranging from 0 (no complaints at all) to 9 (pain as bad as could be)[12] for:

- severity of worst pain and discomfort within the past three months;
- average pain and discomfort within the past three months;
- severity of impairment of daily activities at work and at home within the past three months;
- level of average pain and discomfort within the past seven days.

The scale has been used previously in the Danish study project on research and intervention in monotonous work (PRIM).[13]

Information was collected at baseline on workplace and job title for the actual or latest jobs held (up to five appointments), employment within the past three months, sick leave, and having a labor compensation claim. Jobs were classified as either strenuous or not strenuous.[14]

Statistical analysis

The study's central hypothesis was tested by comparing change in the Constant score between the two groups for the intervention shoulder. The difference in the Constant score between treatment groups from baseline to three, six, and 12 months' follow up was tested using one way analysis of variance (ANOVA). The difference in Constant score between the two treatment groups at each measurement time was tested by GEE (generalized estimation equation) analysis. GEE corrects for the correlation and lack of independence of an individual's responses by using quasi-likelihood methods and robust variance estimators. We introduced all baseline characteristics (table 1↓) in the model. None of the variables produced changes in regression coefficients greater than 5%. In the final model we retained sex ($p = 0.54$), age ($p = 0.99$), workers' compensation claim ($p = 0.60$), and the function subscale of the Constant score at baseline ($p = 0.28$) as potential confounding variables.

Table 1 Baseline characteristics by treatment group (training *v* surgery) among 84 patients with

rotator cuff syndrome in a randomised controlled trial from Ringkjoebing County, Denmark, 1996 to 2001

Characteristics at baseline	Physiotherapy with training (n = 43)	Arthroscopic surgery (n = 41)
Demographic		
Female sex (n (%))	**29 (67.4)**	**29 (70.7)**
Age (years) (mean (SEM))	**44.5 (1.2)**	**44.3 (1.3)**
Dominant hand right (n (%))	**40 (93)**	**39 (95)**
Work		
Latest job potentially strenuous by title (n (%))	**29 (67.4)**	**30 (73.2)**
Years in employment over past 10 years (min, max)	**8.8 (2.0, 10.0)**	**9.1 (5.0, 10.0)**
Years in strenuous job over past 10 years (min, max)	**6.1 (0.0, 10.0)**	**6.9 (0.0, 10.0)**
Been at work for past three months (n (%))	**23 (53.5)**	**24 (58.5)**
Labor compensation claim filed (n (%))	**32 (74.4)**	**2 9(70.7)**
Treatments within past three years (n (%))		
Physiotherapy, passive	**29 (67.4)**	**24 (58.5)**
Physiotherapy, active	**17 (39.5)**	**14 (34.1)**
Subacromial injection	**28 (65.1)**	**20 (48.8)**
NSAID	**20 (46.5)**	**20 (48.8)**
Sick listing because of shoulder pain	**27 (62.8)**	**34 (82.9)**
Clinical		
Bilateral shoulder symptoms (n (%))	**16 (37.2)**	**14 (34.1)**
Shoulder treated, right (n (%))	**27 (62.8)**	**27 (65.9)**
Duration of symptoms <6 months* (n)	**3**	**4**
Duration of symptoms 6–12 months (n)	**10**	**3**

Duration of symptoms >1 year (n)	**29**	**34**
Constant subscores in treatment shoulder (mean (SEM))		
Pain, VAS (0 = maximum, 15 = no pain)	**4.3 (0.4)**	**4.2 (0.4)**
Function (ADL and movements) (0–20)	**7.2 (0.5)**	**6.4 (0.4)**
Range of movement (0–40)	**13.2 (1.2)**	**13.4 (1.1)**
Force (0–25)	**10.2 (0.8)**	**10.2 (0.8)**
Constant score (0–100) (higher = better condition)	**34.7 (2.2)**	**33.7 (2.3)**

***Information obtained from questionnaire after clinical reappraisal and inclusion.**

ADL, activities of daily living; NSAID, non-steroidal anti-inflammatory drug; VAS, visual analogue score.

The sample size was set at a minimum of 40 patients in each group based on an expected improvement of 30% in the physiotherapy group (mean (SD) expected baseline Constant score, 55 (14)), an α value set at 0.05 (type I error), and ß at 0.20 (type II errors), and a minimum relevant clinical difference (MIREDIF) of 50% between the two groups in favor of surgery (corresponding to 9 to 10 points). Thus, a priori, we intended to include 100 patients in expectation of a number of dropouts.

For the secondary outcome measure of pain and dysfunction the subscores of the four pain and function questions were added to a single total score ranging from 0 to 36, and this score was compared for the two intervention groups by ANOVA. Analyses were done as per intention to treat.

RESULTS

Ninety consecutive patients with subacromial impingement agreed to participate. Forty five cases were randomised to conservative treatment and 45 to surgical treatment. Among those assigned to conservative treatment, one withdrew from participation because of work problems and one failed to fill in the baseline questionnaire, leaving 43 cases in this group. In the surgery group, four cases dropped out before the start of the study (one because of work problems, one with a tumour in the humerus, one because his wife advised against participation, and one for unknown reasons), leaving 41 cases in this group. Within the conservative treatment group, a further six patients were operated on within the 12 months of the study (five because of unsatisfactory improvement during exercises and in one case because a labral lesion was suspected).

In the physiotherapy group 42 persons (93%) were followed for 12 months with the main outcome measure (Constant score). In the surgery group 40 persons (89%) had complete follow up data.

The distribution of the baseline characteristics among the 84 patients is shown in table 1 by treatment group. The two groups were very similar, though a slightly greater proportion within the surgery group had been on sick leave owing to shoulder pain within the past three years. Within the surgery group no cases with stage III impingement (complete tear of the cuff) were found.

The baseline Constant score was 34.8 in the physiotherapy group and 33.7 in the surgery group. Within the physiotherapy group the Constant score improved to 54.8, 55.5, and 57.0 after three, six, and 12 months. In the surgery group the corresponding values were 49.2, 53.8, and 52.7. Only 20 cases obtained a Constant score of 80 or more after one year (10 in each group). The mean improvement in Constant score in the physiotherapy group was 23.0 (95% confidence interval (CI), 16.9 to 29.1), and in the surgery group the improvement was 18.8 (11.5 to 26.1). Two patients in the physiotherapy group and eight in the surgery group had a reduction in the Constant score.

Table 2 shows the mean change in score with 95% confidence intervals from baseline by treatment group. Table 3 shows the GEE analysis of the difference between the two groups in Constant score at the different times of measurement. There was no difference at any point of follow up, neither did the results suggest any trends during the study period.

Table 2 **Change from baseline to three, six, and 12 months of follow up in Constant score and subscores among 84 consecutive patients with subacromial impingement**

	Change in score		
Constant's shoulder score with subscores	**Physiotherapy group**	**Surgery**	**p Value**
Pain **(VAS: 0 = max, 15 = no pain)**			
Baseline to 3 months	**3.1 (2.1 to 4.3)**	**2.8 (1.7 to 4.0)**	**0.69**
Baseline to 6 months	**3.7 (2.6 to 4.8)**	**3.8 (2.6 to 5.0)**	**0.92**
Baseline to 12 months	**3.7 (2.7 to 4.6)**	**3.6 (2.3 to 4.9)**	**0.93**
Function **(ADL and movement: 0–20)**			
Baseline to 3 months	**3.7 (2.6 to 4.8)**	**3.7 (2.1 to 5.3)**	**0.96**
Baseline to 6 months	**4.6 (3.2 to 6.1)**	**3.7 (2.0 to 5.4)**	**0.38**
Baseline to 12 months	**4.5 (3.1 to 6.0)**	**3.8 (2.1 to 5.4)**	**0.46**
Range of movement **(0–40)**			
Baseline to 3 months	**10.7 (7.7 to 13.5)**	**6.8 (3.4 to 10.3)**	**0.09**
Baseline to 6 months	**10.3 (7.1 to 13.5)**	**9.6 (6.2 to 12.9)**	**0.76**
Baseline to 12 months	**11.6 (8.3 to 14.8)**	**8.2 (4.6 to 11.8)**	**0.17**

Force **(0–25)**			
Baseline to 3 months	**2.4 (1.1 to 3.7)**	**2.1 (0.4 to 3.8)**	**0.71**
Baseline to 6 months	**2.7 (1.6 to 3.9)**	**2.9 (0.8 to 5.0)**	**0.88**
Baseline to 12 months	**3.2 (1.7 to 4.7)**	**3.3 (1.1 to 5.4)**	**0.96**
Constant score **(0–100)**			
Baseline to 3 months	**20.1 (15.0 to 25.0)**	**15.5 (9.1 to 21.9)**	**0.27**
Baseline to 6 months	**21.3 (15.4 to 27.2)**	**19.9 (12.7 to 27.1)**	**0.76**
Baseline to 12 months	**23.0 (16.9 to 29.1)**	**18.8 (11.5 to 26.1)**	**0.38**

Values are mean (95% confidence interval) by one way analysis of variance.

Constant's shoulder score = sum of pain, function, range of movements, and force.

ADL, activities of daily living; VAS, visual analogue scale.

Table 3 **Difference between groups in Constant score over time**

Constant score	ß Coefficient	95% CI	p Value
Baseline	**0.007**	**–0.005 to 0.019**	**0.27**
3 months	**–0.006**	**–0.015 to 0.003**	**0.20**
6 months	**0.005**	**–0.004 to 0.013**	**0.31**
12 months	**–0.003**	**–0.010 to 0.004**	**0.41**

GEE analysis with adjustment for sex, age, workers' compensation claim, and the function subscale of the Constant score at baseline.

CI, confidence interval; GEE, generalized estimation equations.

The secondary outcome measure of pain and discomfort is shown in table 4. No differences were found between the two treatment groups, and both groups improved during follow up.

Table 4 Comparison of mean pain and dysfunction score and sub score values (with 95% confidence intervals)* by treatment group at baseline and 12 months follow up

	Score value (mean (95% CI))		
	Physiotherapy (n = 43)	Surgery (n = 41)	p Value*
Baseline			
Worst pain and discomfort in past 3 months	**7.3 (6.9 to 7.7)**	**7.6 (7.2 to 8.1)**	**0.32**
Average pain and discomfort in past 3 months	**6.0 (5.5 to 6.5)**	**5.8 (5.3 to 6.3)**	**0.67**
Impaired activity (work and ADL)	**6.2 (5.6 to 6.7)**	**6.5 (5.7 to 7.2)**	**0.48**
Average pain and discomfort in past 7 days	**6.5 (5.9 to 7.0)**	**5.9 (5.2 to 6.6)**	**0.18**
Total PRIM score (scale 0–36)	**25.8 (24.1 to 27.5)**	**25.8 (23.9 to 28.8)**	**0.96**
12 months			
Worst pain and discomfort in past 3 months	**5.1 (4.2 to 5.9)**	**5.2 (4.3 to 6.1)**	**0.87**
Average pain and discomfort in past 3 months	**3.9 (3.2 to 4.7)**	**4.1 (3.2 to 4.9)**	**0.83**
Impaired activity (work and ADL)	**4.3 (3.4 to 5.2)**	**4.2 (3.2 to 5.2)**	**0.90**
Average pain and discomfort in past 7 days	**4.2 (3.3 to 5.1)**	**4.1 (3.0 to 5.1)**	**0.86**
Total PRIM score (scale 0–36)	**17.6 (14.2 to 20.9)**	**17.6 (14.0 to 21.2)**	**0.99**

***One way analysis of variance.**

ADL, activities of daily living; PRIM score, aggregated pain and dysfunction score used in project on research and intervention in monotonous work (PRIM).

DISCUSSION

We found similar improvements in the two treatment groups, as measured by the Constant score and the pain and dysfunction score. The greatest improvement occurred within the first three months of

treatment. The patients had lower scores, both at the beginning and at the end of the study, compared with previously reported studies of treatment for rotator cuff disease with impingement syndrome.[8,9,15]

Internal validity

The unblinded assessment of Constant scores may have introduced a bias in favor of the conservative approach, because the same physiotherapists who instructed the physiotherapy group also carried out assessment of the Constant scores. It is a weakness that the baseline constant scoring was not done before randomization and was postponed until just before the start of the treatments. The self reported pain and dysfunction score may also be biased by the patients' own preferences for a particular treatment, which have not been recorded. If this bias is present, it can be assumed to be small, because the randomization was otherwise successful and there was a low drop out rate. It is also reassuring that the results for the two different outcomes are in good agreement. Six patients in the conservative treatment group were operated on during follow up. Among these one might expect a better outcome and more improvement, but this was not so (mean constant score at 12 months was 41 (range 17 to 78). The a priori power of the study was intended to be 0.80. The actual standard deviation of the difference in the Constant score after 12 months was higher than estimated in the power calculation (21). Consequently with a power of 0.80, the MIREDIF is 13 points.

External validity

The patients differed in some ways from those in previous studies. Our cases were younger than those studied by Brox *et al* and Andersen *et al*.[9,15] A greater proportion had been sick listed (73% *v* 54–75% in the study by Brox *et al*), and more cases had filed a work compensation claim (75% *v* 25% in the study by Andersen *et al*). On the other hand, the cases in the study be Rahme *et al*[6] had the same mean age (42 years) and the same proportion were sick listed (76%). Another difference from previous studies is the very low baseline Constant score. Our patients may therefore appear to differ from those normally referred for subacromial decompression. The reason for this could be related to the setting. Medical services in a provincial hospital setting, where the study took place—with fewer resources and longer waiting times to specialized treatment compared with counties with well staffed and equipped university hospitals—may be related to lower Constant scores. This could also explain the large numbers reporting sick leave. The high number of work compensation claims may in part be explained by many cases seen at the department of occupational health. Furthermore Danish legislation requires a claim to be filed whenever an occupational disorder is suspected.

Even though the effects of surgical treatment have been unconvincing compared to physiotherapy, surgical treatment of subacromial impingement has been widely adopted in the secondary health care sector, and the predominant treatment is now arthroscopic subacromial decompression. Brox *et al*, in their study of 125 patients with a 2.5 year follow up, defined a successful outcome as the acquisition of a Neer score greater than 80, and found an odds ratio for success after surgery compared to conservative treatment of 1.5 (95% CI, 0.6 to 3.7).[9] In their study of 72 patients Peters and Kohn[8] used a modified questionnaire based Constant score and found that the surgical group had slightly higher scores after four years of follow up (mean value 84 *v* 74 points and total improvement of 30 *v* 15 points). They concluded that both treatment approaches were justified. In comparison, as mentioned above, our study found a lower score at baseline, and a lower score was also attained after treatment. This may reflect the fact that we did not exclude patients with bilateral pain and muscular tenderness, and that other studies have included patients with pain for less than three months. It has previously been mentioned that filing a work compensation claim predicts a poor prognosis.[16]

However, even though the Constant score in these patients was lower at baseline (32.6 *v* 39.5), they improved as much from baseline to the one year follow up as the other patients (mean increase 21.1 *v* 20.6). In a case-only study of 60 patients with shoulder impingement, the patients with workers' compensation claims had a lower baseline Constant score, but improvement was 24 points *v* 29 points in the group without compensation claims.[16] Thus claimants improve equally well, but to a more modest level.

Then who should be operated on?

From the results of their study, Brox *et al* recommended that patients who do not improve within six months using a supervised exercise regimen should be evaluated for surgery. The reason for this is not well documented in their own data or in other studies. Some patients may be harmed by treatment, as illustrated by our finding that some got worse in both treatment groups. This has been afforded little or no attention in the past. This risk should lead to greater caution in treatment choice decisions. In view of our findings, we are now more reluctant to recommend surgery in cases with stage II impingement. There is a need for larger scale studies with sufficient numbers of participants to allow for stratification into subgroups with different baseline levels of disability, whatever functional score one uses, before rigorous recommendations are made about who should have arthroscopic decompression and who could benefit from physiotherapy with training, maybe in combination with other medical treatments. This ought to be a prerequisite for the continually expanding industry of arthroscopic decompression operations in the shoulder.

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Select the best answer to each of the following items. Mark your responses on the Answer Form.

1. Self-reported prevalence of shoulder pain is estimated to be between _____%.

a. 5-10
b. 16-20
c. 20-30
d. 40-45

2. Occupations as diverse as construction work and hairdressing are associated with a higher risk of shoulder disorders.

a. True
b. False

3. In regard to complaints of shoulder pain, poorer prognosis is associated with _____.

a. increasing age
b. female sex
c. severe or recurrent symptoms at presentation
d. All of the above

4. Common shoulder disorders exhibit similar clinical features, and the lack of consensus on diagnostic criteria and concordance in clinical assessment complicates treatment choices.

a. True
b. False

5. One primary care study that used standardized clinical tests for shoulder disorders found rotator cuff tendinopathy in 85% of patients.

a. 23
b. 38
c. 55
d. 85

6. Rotator cuff tendinopathy is the most common cause of shoulder pain.

a. True
b. False

7. Shoulder pain is the _____ most common cause of musculoskeletal consultation in primary care

a. single
b. second
c. third
d. fifth

8. A rotator cuff tear is usually strongly indicated by the history: traumatic in young people and atraumatic in elderly people.

a. True
b. False

9. A functional holistic approach to shoulder pain, including adequate analgesia, is important to motivate patients and encourage rehabilitation. However, the evidence for common primary care interventions, including steroid injections, is relatively weak.

a. True
b. False

10. Rotator cuff disorders should be treated initially with _____the shoulder. The patient should return to normal activity or temporarily modified work as soon as possible within the limits of the disability and pain.

a. medications for
b. relative rest of
c. exercise of
d. None of the above

11. Traditional teaching is that the natural history of a frozen shoulder is recovery by_____.

a. six months
b. one year
c. two years
d. four years

12. No evidence exists to show that physiotherapy alone is of benefit for adhesive capsulitis; when the joint is very painful, movement is distressing and may well be counterproductive.

a. True
b. False

13. The authors of several studies have concluded that acupuncture may improve pain and function in the short term (_____weeks).

a. two to four
b. four to six
c. six to eight
d. 10-12

14. For significant persistent disability associated with impingement and rotator cuff tear, surgery may be effective at relieving pain and restoring function in patients who have failed conservative treatment.

a. True
b. False

15. Shoulder pain is a common and important musculoskeletal problem. Management should be multidisciplinary and include _____ and access to physiotherapy. Steroid injections have a marginal short-term effect on pain.

a. self-help advice
b. analgesics
c. relative rest
d. All of the above

16. No evidence exists to show that early orthopedic intervention improves the prognosis for most rotator cuff or glenohumeral disorders.

a. True
b. False

17. Surgery should be considered when conservative measures fail.

a. True
b. False

18. There is no long-term difference in outcome between patients with shoulder pain treated with different clinical interventions in different clinical settings, or having different clinical diagnoses.

a. True
b. False

19. Shoulder problems are common, with up to _____% of adults in the general population reporting such symptoms in a one-year period.

a. 23
b. 35
c. 47
d. 61

20. There was no evidence from studies that local steroid injection conferred long-term benefit.

a. True
b. False

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