Patients with Subacromial Pain
Diagnosis, treatment and outcome in primary care

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Linköping 2004
To my parents, Gunnar and Tuula

To Stefan, our daughter Emma
and our unborn child

The first key to wisdom is constant and frequent questioning, for by doubting we are led to question and by questioning we arrive at the ‘truth’

Peter Abelard 1079-1142 (a French philosopher)
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ABSTRACT

The aim of the thesis was to describe the diagnostic approach and evaluate primary care management of patients with subacromial pain.

The thesis includes four different studies, a questionnaire study describing attitudes among general practitioners and physiotherapists in a Swedish county toward the diagnostic approach and management of primary care patients with subacromial pain; a combination of a systematic review and general practitioners and physiotherapists beliefs in interventions for patients with subacromial pain; a study of intra- and inter-observer reliability for the strength test in the Constant-Murley shoulder assessment; and a randomised clinical trial to evaluate and compare the efficacy of two treatment strategies for patients with subacromial pain, acupuncture combined with home exercises and continuous ultrasound combined with home exercises.

In the questionnaire study general practitioners and physiotherapists were described having a uniform diagnostic approach. The most probable choice of treatment was non-steroidal anti-inflammatory drugs and corticosteroid injection into the subacromial bursa for general practitioners and movement exercises together with ergonomics/adjustments at work for physiotherapists, but most treatments were probable choices, reflecting an uncertainty about their effectiveness.

The treatments trusted by general practitioners and physiotherapists were systematically reviewed. Forty studies were included and the level of evidence was summarised. Only corticosteroid injections into the subacromial bursa, had definitive evidence for efficacy. Acupuncture had tentative evidence for efficacy and therapeutic ultrasound was concluded as ineffective for patients with subacromial pain. The association between trusted treatments and available scientific evidence was weak.

A digital dynamometer can replace the conventional spring-balance in the standardised strength test. An almost perfect agreement was found for intra- and inter-observer reliability in young shoulder-healthy persons, regardless of whether a 'resisted-force' or a 'pull-force' was used or if calculated with mean or maximum values.

Eighty-five patients were included in the randomised clinical trial. Three shoulder scores, combined in the analysis, measure change during a 12 months follow-up together with a 'patient self-evaluation' of the experienced
result. The results favoured acupuncture combined with home exercises. Both groups improved significantly and continued to improve over time independent of treatment and most of the patients reached a satisfactory result at 12 months. At least three fourths of the patients, in each treatment group, reported large improvements or felt completely recovered. This is interpreted as a combination of treatment effect and the natural course.

This thesis has described the primary care management of patients with subacromial pain and provided scientific evidence for general practitioners to use corticosteroid injection and for physiotherapists to use acupuncture combined with home exercises, when treating these patients.

Key words: evidence based medicine, general practitioners, physiotherapy, rotator cuff, shoulder impingement syndrome
THE THESIS

In 1996, the inspiration to this thesis was triggered by the scarcity of research about both diagnosis and management of patients with subacromial pain, a condition common in patients attending primary care. The chosen aims and designs were intended to result in knowledge practicable for general practitioners and physiotherapists in primary care.

First a questionnaire study was performed to evaluate the current management of primary care patients with subacromial pain in a Swedish county. Then a randomised clinical trial was started, comparing acupuncture with continuous therapeutic ultrasound, both combined with home exercises. The choice of treatments was based on the current praxis. All were found to be used and trusted by the physiotherapists in primary care, and they seemed reasonably comparable due to their similar treatment set-up. In one of the outcome scores in the clinical trial, the Constant-Murley shoulder assessment, a digital dynamometer was used instead of the conventional spring-balance to evaluate strength. This part of the score has been discussed and criticised. A new standardised test position has recently been recommended. In order to perform the test in this position as well as to change equipment, the concurrent validity needed assessment, and methodological aspects of reliability were missing. Finally a systematic critical review was performed to report the current evidence base for treatments in primary care. To be able to facilitate implementation in clinical practice, this was performed for the treatments found to be trusted by general practitioners and/or physiotherapists.
LIST OF PAPERS

This thesis is based on the following papers, which will be referred to in the text by their Roman numerals.

**Paper I**  Johansson K, Adolfsson L, Foldevi M
Attitudes toward management of patients with subacromial pain in Swedish primary care
Family Practice 1999;16:233-237
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**Paper II**  Johansson K, Öberg B, Adolfsson L, Foldevi M
A combination of systematic review and clinicians’ beliefs in interventions for subacromial pain
British Journal of General Practice 2002;52:145-152
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**Paper III**  Johansson K, Adolfsson L
Intra- and inter-observer reliability for the force test in the Constant-Murley shoulder assessment
(Accepted for publication 2003, Journal of Shoulder and Elbow Surgery)

**Paper IV**  Johansson K, Adolfsson L, Foldevi M
Acupuncture is superior to continuous ultrasound for patients with subacromial pain: A randomised clinical trial  (Submitted 2003)
ABBREVIATIONS AND DEFINITIONS

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<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>AL score</td>
<td>Adolfsson-Lysholm shoulder score</td>
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<tr>
<td>CM score</td>
<td>Constant-Murley shoulder assessment</td>
</tr>
<tr>
<td>ES</td>
<td>Effect size</td>
</tr>
<tr>
<td>GP</td>
<td>General practitioner</td>
</tr>
<tr>
<td>ICC</td>
<td>Intraclass correlation coefficient</td>
</tr>
<tr>
<td>PT</td>
<td>Physiotherapist</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised clinical/controlled trial</td>
</tr>
<tr>
<td>UCLA</td>
<td>University of California at Los Angeles end-result scores</td>
</tr>
<tr>
<td>de qi</td>
<td>The sensation described during acupuncture treatment as numbness, heaviness and radiating paraesthesia, as an evidence for stimulation of thin myelinated nerve fibres, presumably A-delta fibres⁴</td>
</tr>
<tr>
<td>Pain</td>
<td>An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. An experience that can be neither shared nor measured objectively – defined by the International Association for the Study of Pain (IASP)⁶⁵</td>
</tr>
<tr>
<td>Subacromial pain</td>
<td>Pain thought to originate from the anatomic structures between the acromion and the humeral head. In particular pathology in the rotator cuff muscles and the subacromial bursa have been demonstrated to sometimes elicit pain during elevation of the arm when the subacromial structures are thought to be impinged between humerus and the coraco-acromial arch</td>
</tr>
</tbody>
</table>
INTRODUCTION

Many different terms are used in the literature for patients with subacromial pain and pathology: supraspinatus tendinitis, rotator cuff tendinitis, tendinopathy, subacromial bursitis, painful arc syndrome, and impingement syndrome. A controversy exists over the pathogenesis and the pain generating mechanisms. In the current thesis the term 'subacromial pain' was used, defined as pain thought to originate from the structures between acromion and the humeral head. The unknown pathology results in a diagnosis based on symptoms, in particular pain elicited from the rotator cuff and the subacromial bursa, and reproduced by manoeuvres decreasing the subacromial space impinging these subacromial structures.

Pathogenesis and aetiology of subacromial pain

The rotator cuff muscles, the subacromial bursa, and acromion as well as the ligament between processus coracoideus and acromion, seem to be involved in the pathogenesis of subacromial pain. The roof of the subacromial space is constituted of the acromion, the coraco-acromial ligament and the coracoid process, and is described as the coraco-acromial arch. (Figure 1) Other structures that could be involved in the aetiology of subacromial pain are for example the acromioclavicular joint and the biceps brachii muscle.

The subacromial pain can frequently be reproduced by manoeuvres decreasing the subacromial space. These impingement manoeuvres are reported to produce pain when the subacromial structures are compressed between the coraco-acromial ligament, the anterior edge of acromion, the under-surface of the anterior third of the acromion and the humeral head during elevation of the arm\textsuperscript{96,97,131} and thereby raising the subacromial pressure\textsuperscript{120}.

In theory, pain from the subacromial structures can occur from extrinsic mechanical wear or compression from the coraco-acromial arch, but there may also be intrinsic causes such as degenerative changes in the rotator cuff tendons. This could either be primary or secondary. The latter meaning that this occurs due to either glenohumeral or functional scapular instability.
Another possible cause is trauma, causing ruptures in the rotator cuff tendons or bleeding or scar formation in the subacromial bursa.\textsuperscript{50}

Another theory is that the rotator cuff muscles seem to be at risk of overuse due to their important role in dynamic stabilisation, always active to centre the humeral head in the glenoid fossa during arm movements\textsuperscript{17,27,89,106}.

The pain-generating mechanisms, involved in subacromial pain, have been described as ischemia, inflammation and degeneration\textsuperscript{50,71,91}. Later the occurrence of inflammation in tendons has been questioned since no inflammatory changes have been found in the tendons, rather degenerative changes are considered to cause the pain and disability\textsuperscript{3,128}. Probably this condition includes inflammatory changes in the subacromial bursa and changes like thickening, fibrosis and fibre degeneration in the rotator cuff tendons and in some cases bone changes at the under-surface of the acromion. Another possible pain mechanism, due to a neurogenic inflammation and an increase in the release of neuropeptides, has recently been suggested.\textsuperscript{61}

Neer described subacromial pain due to impingement lesions in three progressive stages and reported that it could end with tendon rupture\textsuperscript{98}. Contradictory to this, later research found a high prevalence of rotator cuff tears in non-symptomatic shoulders, increasing with age, which makes rupture a "normal" degenerative attribute\textsuperscript{129}. Frost et al. reported that supraspinatus pathology is related to age rather than clinical signs of subacromial pain\textsuperscript{49}.

![Figure 1: The anatomical structures thought to be involved in subacromial pain](image-url)
Only one report was found focusing on risk factors for subacromial pain. Frost et al. analysed the risk relative to shoulder intensive work. They reported that sustained intensive work that stresses the shoulders is a risk factor, for example working as a slaughterer, with repetitive movements loading the arm over 30° of elevation.49

The diagnostics of subacromial pain

There is no consensus on the diagnostic clinical criteria that should be used in research for identifying different patients with shoulder pain101 and this is also the case for subacromial pain38. There exists a variety of different tests, manoeuvres and procedures that could be performed in the clinical examination, all described in the literature18,31,109. A positive Neer impingement sign or test97, the Hawkins-Kennedy impingement sign58 or equivalent manoeuvres are used to diagnose patients with subacromial pain.

Neer described that the impingement occurs between the anterior edge of the acromion and the coraco-acromial ligament, rather than the lateral edge of acromion96. The Hawkins-Kennedy impingement sign was described to drive the greater tuberosity farther under the coracoacromial arch, and also impinge against the lateral acromion58. Others reported that the subacromial bursa pressure rises during impingement sign120, which reinforces the use of these manoeuvres to reproduce symptoms in patients with suspected pain from the subacromial structures.

Later research has differentiated further between the Neer impingement sign and the Hawkins-Kennedy impingement sign and where these manoeuvres stress the tissues. Valadie et al. reported that the Neer impingement sign demonstrated soft tissue contact between the medial aspect of the acromion and the supraspinatus tendon as well as between the articular surface of the rotator cuff tendons and the anterior or superior rim of the glenoid. Further they reported that the Hawkins-Kennedy impingement sign demonstrated consistent contact between the coracoacromial ligament and the rotator cuff tendons as well as between the articular surface of the rotator cuff tendons and the anterosuperior glenoid rim.131 De Wilde et al. found bony contact between tuberculum majus and the anterolateral acromion in the Hawkins-Kennedy impingement sign34. In normal shoulders, Roberts et al. found that the two impingement signs did not elicit mechanical contact between the rotator cuff and the acromion116. It is unclear whether they prevented movement in the scapulothoracic joint, and if not, this could explain their conclusion in an opposite direction to that of earlier research. The
conclusive picture seems to be that the use of these manoeuvres reproduces symptoms in patients with suspected pain from the subacromial structures.

In clinical praxis the diagnosis is often based on a combination of tests and clinical characteristics. In table 1 the most common diagnostic tests, used in clinical research, are presented. For a more detailed description, see Appendix A.

It is important to have information of the ability of a diagnostic test to recognise the condition when present, sensitivity, and when absent, specificity. Unfortunately few tests possess both high sensitivity and specificity. For clinicians in primary care, the most useful value to address is the likelihood ratio (LR). It is defined as the probability of a given level of a test result in individuals with disease divided by the probability of that same result in those without the disease.

Table 1 Diagnostic tests used in clinical research for diagnosis of patients with subacromial pain

<table>
<thead>
<tr>
<th>Diagnostic tests for Subacromial pain&lt;ref&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hawkins-Kennedy impingement sign - a manual manoeuvre to reproduce pain&lt;sup&gt;58&lt;/sup&gt;</td>
</tr>
<tr>
<td>Jobe supraspinatus test - isometric muscle activity&lt;sup&gt;109&lt;/sup&gt;</td>
</tr>
<tr>
<td>Neer impingement sign - a manual manoeuvre to reproduce pain&lt;sup&gt;97&lt;/sup&gt;</td>
</tr>
<tr>
<td>Neer impingement test - a subacromial injection of anaesthetic&lt;sup&gt;97&lt;/sup&gt;</td>
</tr>
<tr>
<td>Painful arc – in 60-120° of abduction&lt;sup&gt;75&lt;/sup&gt;</td>
</tr>
<tr>
<td>Patte manoeuvre - resisted muscle activity&lt;sup&gt;80&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Of the evaluated diagnostic tests for subacromial pain, none were found to be good enough for making a specific diagnosis and no author reported LRs. Both the Neer- and Hawkins-Kennedy impingement signs have been reported as highly sensitive, but their specificity figures are lower which lessens their discrimination ability. It is important to remember that these figures are limited by the choice of reference standard used to determine if the condition is present or not. (Table 2)
Table 2  The diagnostic value of different clinical tests for subacromial pain

<table>
<thead>
<tr>
<th>Diagnostic tests</th>
<th>Sensitivity\textsuperscript{ref}</th>
<th>Specificity\textsuperscript{ref}</th>
<th>Reference standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hawkins-Kennedy impingement sign</td>
<td>92%\textsuperscript{22}</td>
<td>25%\textsuperscript{22}</td>
<td>Neer impingement test</td>
</tr>
<tr>
<td></td>
<td>87%\textsuperscript{80}</td>
<td></td>
<td>Surgery - identifying anatomic lesions</td>
</tr>
<tr>
<td>92% bursitis</td>
<td>44% bursitis</td>
<td></td>
<td>Arthroscopy - identifying anatomic lesions</td>
</tr>
<tr>
<td>88% rotator cuff pathology\textsuperscript{85}</td>
<td>43% rotator cuff pathology\textsuperscript{85}</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Horizontal adduction</td>
<td>82%\textsuperscript{22}</td>
<td>28%\textsuperscript{22}</td>
<td>Neer impingement test</td>
</tr>
<tr>
<td>Jobe supraspinatus test</td>
<td>86%\textsuperscript{80}</td>
<td>50%\textsuperscript{80}</td>
<td>Surgery - identifying anatomic lesions</td>
</tr>
<tr>
<td>Neer impingement sign</td>
<td>89%\textsuperscript{22}</td>
<td>31%\textsuperscript{22}</td>
<td>Neer impingement test</td>
</tr>
<tr>
<td></td>
<td>89%\textsuperscript{80}</td>
<td></td>
<td>Surgery – identifying anatomic lesions</td>
</tr>
<tr>
<td>75% bursitis</td>
<td>48% bursitis</td>
<td></td>
<td>Arthroscopy – identifying anatomic lesions</td>
</tr>
<tr>
<td>83% rotator cuff pathology\textsuperscript{85}</td>
<td>51% rotator cuff pathology\textsuperscript{85}</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neer impingement test</td>
<td>70%\textsuperscript{143}</td>
<td></td>
<td>Radiographs – identifying accuracy</td>
</tr>
<tr>
<td></td>
<td>83%\textsuperscript{104}</td>
<td></td>
<td>Post-mortem dissection - identifying accuracy</td>
</tr>
<tr>
<td>Painful arc</td>
<td>33%\textsuperscript{22}</td>
<td>81%\textsuperscript{22}</td>
<td>Neer impingement test</td>
</tr>
<tr>
<td>Patte manoeuvre</td>
<td>92%\textsuperscript{80}</td>
<td>30%\textsuperscript{80}</td>
<td>Surgery - identifying anatomic lesions</td>
</tr>
</tbody>
</table>

During a positive painful arc, the acromial surface and the rotator cuff tendons were reported to be in closest proximity between 60-120°, which could explain the experienced pain\textsuperscript{46}.

The Neer impingement test is used to distinguish patients with a subacromial cause from other causes of shoulder pain\textsuperscript{97}. The targeting accuracy of subacromial injections has been questioned. The rate of injections actually reaching the subacromial bursa differs. Using an antero-inferior injection technique the rates have been reported as 70\%\textsuperscript{143} and 83\%\textsuperscript{104}, and both
reported that other structures also were infiltrated for example the rotator cuff and the gleno-humeral joint.

Another aspect of diagnostics is the intra- and inter-observer reliability. For the Hawkins-Kennedy impingement sign, the intra- and inter observer agreement has been reported as almost perfect (ICC > 0.9)\(^3\)\(^4\). Others have reported poor to moderate agreement\(^1\)\(^0\)\(^2\). Further, de Winter et al. highlights the possibility that an injection of anaesthetics and additional manoeuvres to compress the subacromial space might be helpful when establishing diagnosis and improve reproducibility\(^3\)\(^5\).

**Prevalence**

Shoulder pain is the third commonest reason, after low back- and neck pain, among patients visiting primary health care for musculoskeletal problems\(^1\)\(^1\)\(^2\). Most epidemiological research involves patients classified as shoulder pain, or as neck and shoulder pain in combination. The point prevalence for unspecified shoulder pain in the general population, has ranged from 70 to 260 per 1000 inhabitants and the prevalence increases by age\(^1\)\(^2\),\(^1\)\(^5\),\(^2\)\(^3\),\(^2\)\(^4\).

Only a limited number of studies have reported prevalence for subacromial pain. The 1-year prevalence for subacromial pain, has been reported to be 7% in a Swedish cross-sectional study\(^6\)\(^7\). In a pre-selected group of patients with upper extremity disorders, 13% were diagnosed as having subacromial pain\(^10\)\(^5\) and in Dutch general practice 48% of the patients consulting the general practitioner (GP) for shoulder problems had subacromial pain\(^13\)\(^5\). Since no consensus exists about the diagnostic clinical criteria identifying patients with subacromial pain, these prevalence figures must be interpreted cautiously.

**The natural- and clinical course of subacromial pain**

The importance of knowing the natural- and clinical course for a diagnosis is of value both in research and practice. The following definitions have been stated by Von Korff ‘studies of natural history investigate the development of a disease or illness in the absence of clinical interventions whereas studies of clinical course assess development subsequent to diagnosis and the initiation of treatment’\(^1\)\(^4\)\(^2\) (page 2041).

No studies were found describing the natural course of subacromial pain. This has only been reported for patients with unspecified shoulder pain. Ginn et al. demonstrated no improvement after 1 month in a group of patients with
shoulder pain receiving no treatment and of these 50% reported worse functional disability. In a prospective cohort studied by Macfarlane et al. 54% of the patients with shoulder complaints had shoulder pain at follow-up after three years and 90% of these reported disability.

For patients with subacromial pain, the clinical course after conservative interventions has been reported. Chard et al. reported that 39% had no significant symptoms after a mean 19 months of follow-up and 29% of the patients had residual pain. In another study the rate of recovered patients, defined as absence of complaints, was 44% after 6 months and 47% after 12 months.

Treatment in primary care

Episodes of shoulder pain presented at primary health care centres are generally persistent and associated with continuing disability for many patients. Since subacromial pain seems to be the most common shoulder complaint, it is important to find efficacious treatment in primary care.

Two systematic reviews of randomised controlled trials (RCTs) of the heterogeneous group of patients with shoulder pain, found no evidence for efficacy in any of the physiotherapist (PT) treatments. For GP treatments, Green et al. concluded that corticosteroid injections might be superior to placebo. A recent study supported this probable efficacy for patients with subacromial pain. Hay et al. reported similar effectiveness for PT treatments and local steroid injections into the subacromial space when treating a new episode of unilateral shoulder pain, but those receiving physiotherapy had fewer re-consultations with a GP for additional treatment.

The numbers of randomised controlled trials clearly describing PT interventions for patients carefully diagnosed as subacromial pain are few. The common strategy of the PT is to use a combination of interventions. In order to make the research results applicable to practice, the interventions used in any trial must be those currently used in clinical practice. The PT treatments used in paper IV, their history and theories for their efficacy, are hereby more closely described:

Acupuncture

Acupuncture has been used for at least 2000 years in the Far East. During the last 30-40 years the use of acupuncture has increased continuously in
European countries and North America\textsuperscript{37,138}. In Sweden, acupuncture was approved in 1984 by the Swedish National Board of Health and Welfare, to be used by registered medical professions when treating patients with pain. After several years of investigation, this decision was based on scientific and empirical knowledge for the efficacy of acupuncture\textsuperscript{4}.

The acupuncture mechanisms for inhibition of pain have been described as an activation of the descending pain inhibitory systems. This activation can be locally, at the stimulation site, and at spinal and central levels of the central nervous system. The needles are inserted into defined points, in for example a muscle, and the ergo-receptor is stimulated by manually twirling the needle to elicit the sensation of de qi. In theory, this activates the descending pain inhibitory systems and opioid peptides are released, especially by the midbrain periaqueductal grey, to produce the analgesia\textsuperscript{37,126}. This theory is supported by the findings that the pain relief is reversible with naloxone, which blocks the receptors from the substances from the descending endorphinergic systems\textsuperscript{84}.

There are a variety of acupuncture points described in the literature, and there are no unanimous recommendations for the choice of points or application\textsuperscript{139}. Deep acupuncture activates receptors within the muscle while superficial acupuncture activates skin receptors and when comparing the two, the former was reported to produce analgesia\textsuperscript{56}. Still it is less clear whether acupuncture has clinically important benefits for specific diagnosis\textsuperscript{138}.

For subacromial pain there are only two RCTs published. One is the trial by Kleinhenz et al. who reported acupuncture to be superior to a placebo needle at four weeks follow-up\textsuperscript{77}. A recent comparison between superficial and deep acupuncture for patients with probable subacromial pain found significantly better improvement in the deep group up to a three months follow-up\textsuperscript{26}.

Exercise therapy

Strengthening the rotator cuff, especially the supraspinatus muscle, is described as an important part in exercises for patients with subacromial pain. The impinging phenomenon is thought to be decreased due to improved ability to centre the humeral head in the glenoid fossa during arm movements\textsuperscript{17,27,89,106}.

Isotonic activation of the supraspinatus muscle has been reported to be best achieved in abduction in the plane of scapula, independent if combined with an internal or an external rotation component\textsuperscript{74,125}.
Earlier research evaluated an individualised programme consisting of stretching, strengthening and retraining for patients with non-specified shoulder pain, and reported it to be efficient in comparison with no treatment. In another study on patients with subacromial pain by Brox et al., supervised exercises were reported as equally efficient as surgery and superior to placebo laser for rotator cuff disease. They used exercises designed in 1981 and first in 1998 presented in detail by Bøhmer et al. In a recent review, including the studies described above, it was concluded that limited evidence exists to support efficacy of therapeutic exercise and orthopaedic manual therapy for patients with subacromial pain.

**Ultrasound therapy**

Ultrasound therapy has been recognised and used for treating musculoskeletal disorders for decades. Due to the lack of well conducted trials, the use of ultrasound therapy is based on empirical experience.

The following principles for therapeutic ultrasound have been recommended: the frequency depends on the depth of the tissue and varies between 0.5-5 Megahertz (MHz), and the intensity is due to the amount of energy that should cross the unit area in unit time measured in watt per square centimetre (W/cm²). The duration of treatment has been recommended to be five minutes for each area corresponding to the size of the transducer head. During ultrasound, any coupling media should be used to transmit the ultrasound energy sufficiently.

The effects of ultrasound therapy have been divided into thermal and non-thermal effects, and in a recent review these biophysical effects of ultrasound were concluded as unlikely to be beneficial.

The efficacy of therapeutic ultrasound for different shoulder conditions, including subacromial pain, has been questioned in several reviews. In recent clinical practice guidelines from the Philadelphia Panel, ultrasound is still recommended for calcified shoulder tendinitis based on the study published by Ebenbichler et al.

**Outcome measures**

In the methodological literature, several criteria are recommended to be fulfilled in an instrument to be able to measure change. One aspect is validity. There are several different types of validity; content validity, criterion validity,
and construct validity. Content validity is a dimension of validity that represents, for example, that a questionnaire really contains items valid for all types of problems involved in a disease. Criterion validity is a dimension of validity that represents concurrent validity and predictive validity. The first describes in what degree a new scale for example, agrees with a reference standard. The latter, is exemplified by a test’s ability to predict a future outcome. Construct validity, is a dimension of validity that represents the underlying factors, constructs, that are thought to explain relationships associated with, for example, a condition. Another aspect to be aware of is an instrument’s reliability. It reflects the amount of error, both random and systematically inherent in a measurement. This means that an instrument must have both stability over time, intra-observer reliability, and between different observers, inter-observer reliability.

There is no consensus about which instrument should be used when evaluating patients with subacromial pain. An instrument can be generic or more disease specific. The first measures health related quality of life, or in other words evaluates how patients perceive or react to their health status or to other non-medical aspects of their lives. A combination of a disease specific instrument and generic health measures have been recommended to evaluate patients with problems related to the shoulder, however there could be a problem to find a generic instrument that is sensitive for patients with subacromial pain. There exist many different disease specific instruments for evaluation of shoulder problems. Most scoring systems are applied to all shoulder conditions and to our knowledge, the only score developed for patients with subacromial pain is the Adolfsson-Lysholm shoulder score (AL score). ‘The European Society for Surgery of the Shoulder and Elbow’ decided in the early 1990s that the Constant-Murley shoulder assessment (CM score), should be used in all research involving patients with shoulder problems. Due to this uncertainty about which instrument to use when evaluating patients with subacromial pain, three disease specific shoulder scores were chosen in the RCT included in the current thesis.

**Predictors of outcome**

Several predictors of outcome for conservatively treated patients with subacromial pain have been reported. One study reported strain, overuse and relatively short duration as predictors for a favourable outcome after 1 month. They also reported concomitant neck pain at presentation, severity of pain during the day of the visit and precipitating trauma as predictors for persistent
symptoms at the 12-month follow-up. Batolozzi et al. reported an unfavourable outcome, after a mean follow-up of 20 months, in patients with a history of symptoms for more than a year, a significant functional impairment at the initial presentation as well as a tear of the rotator cuff during the time of follow-up. In a prospective cohort study, the significant predictors found at baseline for persistent problems at the three-year follow-up were: shoulder pain related disability and pain on the day of examination. Chard et al. described an early presentation and a history of overuse, unrelated to occupation, as positive predictors for recovery at a mean of 19 months follow-up.

**Evidence-based medicine**

The papers in this thesis, especially paper II and IV, focused on evidence for efficacy of conservative treatment of patients with subacromial pain. The use of the term 'evidence-based medicine' (EBM) has increased both in research and in clinical practice. It has been defined by Davidoff et al. in five areas: 1) the clinician’s decisions should be based on the best available evidence; 2) the clinical problem should determine the type of evidence to be sought; 3) identifying the best evidence means using epidemiological and biostatistical ways of thinking; 4) conclusions derived from identifying and critically appraising evidence are useful only if put into action in managing patients or making health care decisions; and finally 5) performance should be constantly evaluated. The Evidence-based medicine working group reported that a common misunderstanding about EBM is that it ignores clinical experience and clinical intuition.

Recommendations on how to interpret the evidence from studies of efficacy have been published by Sackett. He recommended a randomised trial with low false positive (alpha) and low false-negative (beta) errors as the best level of evidence. Later, with the increased access of systematic literature reviews and meta-analysis, this type of study has been recommended to be the highest level of evidence. Dowie highlighted the difficulties of applying evidence from RCTs and meta-analysis. He argued that 'the decision-analysis-based medical decision making' is a more suitable method since it takes into account the multiple and distinct elements of a decision. There could be several reasons for the problem with implementing research evaluating treatment efficacy in clinical practice: the lack of a consensus about diagnostic criteria or valid and reliable outcome measures, and that studied treatments are too artificial for the clinical
environment⁴. The design of the papers involved in this thesis, tried to take into account the clinical approach of the daily practice in primary care, all in order to facilitate the implementation of research results.
Aims

The general aim of this thesis was to describe the diagnostic procedure and evaluate the primary care management of patients with subacromial pain.

Specific aims

- to describe the attitudes among GPs and PTs in a Swedish county, toward the diagnostic approach and management of patients with a common shoulder disorder in primary care

- to study which treatments for patients with subacromial pain are trusted by GPs and PTs, and to compare those trusted with available evidence from a systematic critical review of the scientific literature

- to evaluate the concurrent validity between two equipments and the intra-and inter-observer reliability of the standardised strength-test in the CM score

- to evaluate and compare the efficacy of two treatment strategies for patients with subacromial pain, acupuncture combined with home exercises and continuous ultrasound combined with home exercises
MATERIALS AND METHODS

Materials

The studied patients and participants are described and summarised in table 3.

Paper I and II

A questionnaire was mailed to all GPs and PTs, totalling 188 GPs and 71 PTs, working in the county council of Östergötland, Sweden. All PTs were employed by the county council and worked at the primary health care centres or nearby. General practitioners and PTs in private practice were excluded in order to limit the size of the study.

The total response rate was 72%, for GPs 69% (129/188) and for PTs 80% (57/71). The groups were quite similar concerning their background variables. The PTs were significantly younger (p<0.001) than the GPs, but there were no differences in practice years.

Both professions were experienced. The GPs were all specialists in general practice and 95% of the PTs had some kind of postgraduate education relevant to the management of patients with musculoskeletal disorders.

A description of age and gender ratios for the non-responders and the reasons for not responding is presented in table 4. The background variables between non-responders and responders differed in one aspect, the non-responding GPs were significantly (p<0.05) older than those responding. No significant difference was seen in the same comparison between PTs. Additionally, there were no significant differences in post-graduate education between responders and non-responders.

The study population used in paper I was also used in paper II and the material is further described in Methods.
Table 3  Data for the included patients/participants in paper I-IV

<table>
<thead>
<tr>
<th></th>
<th>Paper I and II</th>
<th>Paper III</th>
<th>Paper IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients/participants</td>
<td>186</td>
<td>30</td>
<td>85</td>
</tr>
<tr>
<td></td>
<td>129 GPs</td>
<td>10 V&lt;sup&gt;a&lt;/sup&gt;</td>
<td>44 ACU&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>57 PTs</td>
<td>20 R&lt;sup&gt;b&lt;/sup&gt;</td>
<td>41 US&lt;sup&gt;d&lt;/sup&gt;</td>
</tr>
<tr>
<td>Mean age (SD)</td>
<td>46 (6) GPs</td>
<td>23 (2) V</td>
<td>49 (7) ACU</td>
</tr>
<tr>
<td></td>
<td>41 (8) PTs</td>
<td>26 (4) R</td>
<td>49 (8) US</td>
</tr>
<tr>
<td>Gender: female %</td>
<td>45 GPs</td>
<td>60 V</td>
<td>73 ACU</td>
</tr>
<tr>
<td></td>
<td>79 PTs</td>
<td>50 R</td>
<td>66 US</td>
</tr>
</tbody>
</table>

<sup>a</sup>V = validity, <sup>b</sup>R = reliability, <sup>c</sup>ACU = acupuncture, <sup>d</sup>US = ultrasound

Table 4  Description of the non-responders age and gender, and a summary of the reasons for not responding to the questionnaire

<table>
<thead>
<tr>
<th></th>
<th>General practitioners (n = 59)</th>
<th>Physiotherapists (n = 14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (SD)</td>
<td>49 (6)</td>
<td>45 (7)</td>
</tr>
<tr>
<td>Gender: female %</td>
<td>45</td>
<td>100</td>
</tr>
<tr>
<td>Reasons for not responding:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of time</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>Do not feel motivated to participate</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Refrained from answering without reason</td>
<td>44</td>
<td>4</td>
</tr>
<tr>
<td>Answered that they refrained</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Too short experience in primary care</td>
<td>-</td>
<td>1</td>
</tr>
</tbody>
</table>

Paper III

The 30 test-persons in this study were adult volunteers. They were included if they had no history of present or previous shoulder and/or upper extremity problems. None of the test-persons had performed this strength test before. In the concurrent validity part, ten test-persons (20 shoulders), four men and six
Materials and methods

25 women participated. In the intra- and inter-observer reliability part, twenty test-persons (40 shoulders) participated. Data for the participants are presented in table 3. All test-persons were students at the medical or technical faculty of Linköpings universitet.

Paper IV

The subjects were recruited from three urban primary health care centres (PHCCs) in the county of Östergötland, Sweden, from March 1997 to June 2000. Patients with shoulder pain who contacted the GPs or PTs at these PHCCs were offered an encounter with the research PT if they were between 30 and 65 years of age. The lower age limit was to decrease the number of patients with secondary impingement due to instability, and the upper age limit to decrease the number of patients with degenerative joint diseases. The GPs and PTs were instructed to recruit patients with clinical signs of subacromial pain described as pain during abduction and pain located in the proximal lateral aspect of the upper arm.

Procedure for inclusion

Potential participants went through a standardised clinical examination performed by the research PT. At the inclusion visit, background data such as age, gender, duration, occupation related to arm load, leisure activities, smoking and medical history were documented. The history included location of pain and description of symptoms, duration of current episode, occasion for onset of pain, pain in relation to rest, night sleep and activities, recurrences or a first-time problem, medication and sick-leave. The complete set of inclusion and exclusion criteria are presented in Appendix B. Patients diagnosed as having subacromial pain had a final inclusion test, an "impingement test" according to Neer, where 10 ml of a local anaesthetic (prilocaine 10mg/ml) was injected into the subacromial space by a GP. Manoeuvres to stress the subacromial structures, the Neer impingement sign and Hawkins-Kennedy impingement sign, were then re-performed after ten minutes. If the tests were not positive the manoeuvres were repeated after another 20 minutes and judged as negative if there still was no improvement. With a positive impingement test the patient experienced pronounced relief of pain. If none of the exclusion criteria were present, the patient was asked for informed consent to enter the study.
Of 173 patients, who visited the research PT, 88 were clinically diagnosed as having subacromial pain fulfilling the inclusion criteria. Three of these did not enter the study, one due to working conditions, one due to a fear of needles and one because of a fatal heart attack. Accordingly, 85 patients entered the study and were randomly assigned to two groups; 44 patients received acupuncture combined with home exercises and 41 patients received continuous ultrasound combined with home exercises. Alterations in the study sample during follow-up are presented in figure 2.

A radiological examination of the patients affected shoulder was performed to exclude malignancy, osteoarthritis of the gleno-humeral joint and skeletal abnormalities. Standard anterior-posterior and lateral projections were taken as well as a special projection of the acromio-clavicular joint.

Ethics

Written information was given to all participants in paper I-IV, complemented with verbal information in paper III-IV, before they gave their consent to participate. All was in line with the guidelines from the Ethics Committee of the Faculty of Health Sciences at Linköpings universitet. Paper IV was approved by the former.
Materials and methods

Pre-selected patients for examination by PT (n = 173)
Included (n = 85)

Acupuncture + home exercises
n = 44

Ultrasound + home exercises
n = 41

Ten treatments, twice a week for 5 weeks

Follow-up:

6 weeks
Acupuncture group
n = 44
Ultrasound group
n = 41

Adhering to study protocol
Intention-to-treat\textsuperscript{a}
Additional treatment\textsuperscript{b}
Drop-outs\textsuperscript{b}

<table>
<thead>
<tr>
<th></th>
<th>Acupuncture</th>
<th>Ultrasound</th>
<th>Acupuncture</th>
<th>Ultrasound</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 months</td>
<td>n = 43 (2 LOCF)</td>
<td>n = 34 (1 LOCF)</td>
<td>n = 2 (2 LOCF)</td>
<td>n = 7 (2 LOCF)</td>
</tr>
<tr>
<td></td>
<td>1 corticosteroid injection</td>
<td>4 corticosteroid injection</td>
<td>n = 1 decline</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>n = 38</td>
<td>n = 32 (2 LOCF)</td>
<td>n = 6 (2 LOCF)</td>
<td>n = 9 (5 LOCF)</td>
</tr>
<tr>
<td></td>
<td>4 corticosteroid injection</td>
<td>5 corticosteroid injection</td>
<td>n = 1 decline</td>
<td>n = 1 decline</td>
</tr>
<tr>
<td>12 months</td>
<td>n = 35 (2 LOCF)</td>
<td>n = 30 (4 LOCF)</td>
<td>n = 9 (3 LOCF)</td>
<td>11 (6 LOCF)</td>
</tr>
<tr>
<td></td>
<td>7 corticosteroid injection</td>
<td>6 corticosteroid injection</td>
<td>n = 1 decline</td>
<td>n = 1 decline</td>
</tr>
</tbody>
</table>

\textsuperscript{a} The number of patients becoming ITT due to not adhering to study protocol/drop-out. Last Observation Carried Forward (LOCF).

\textsuperscript{b} Description of the cumulative numbers of patients with additional treatment and drop-outs

Figure 2  Flow-chart of the study sample in paper IV
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Methods

Paper I

Two almost equal questionnaires were designed; one for GPs and one for PTs. Differences between the questionnaires existed in the part about choice of treatment since this differs between the professions.

Before the questionnaire was sent out it was pilot-tested on GPs, PTs and one lay person. The questionnaire contained one part with questions about background variables such as gender, age, educational level and years in practice and one part constructed with closed-end questions. This part contained questions about diagnosis, examination, treatment, sick leave and the use of referral to other professions. The questions were based on a written case representing a typical patient with a common shoulder disorder in primary care. The case symptoms were selected from a review of literature and from clinical cases at the PHCC, see case description. The intention was to briefly describe a patient in order to simulate the first communication with the patient.

Case description:

Eric is a 45-year-old dentist. During the past few weeks he has suffered from pain in his right shoulder. Diffuse pain, especially ventral and lateral. No pain at rest, but he experiences pain down the deltoid area during activities.

Using a five point scale, the participants were asked to mark the figure corresponding to their opinion about each item which should be rated independently. The marked alternatives in each question, were in the analysis divided into three categories; 1 or 2 called not probable, 3 neutral and 4 or 5 probable.

The questionnaire was sent out in the beginning of September 1996. Non-responders received a new questionnaire after four weeks and after another month a call to remind them or to get information about the reasons for not responding (table 4). The study was ended in December 1996.
Materials and methods

Paper II

A two-step process was used, a study of GPs’ and PTs’ trust in existing treatments followed by a systematic critical review of the efficacy of these treatments.

A study of GPs’ and PTs’ trust in existing treatments

In the questionnaire, used in paper I, an additional question was answered concerning the GPs and PTs trust in efficacy of available treatments. This question was analysed and reported first in paper II. Using a five-point scale with end points defined as no effect and good effect, the respondents were asked to mark their level of trust in different treatments for the chosen diagnosis. There was also an “I do not know”-alternative.

The treatments were defined as trusted when a majority of any profession marked three, four or five, compared to one or two on the scale. The following treatments were stated as trusted; ergonomics/adjustments at work, corticosteroid injection, non-steroidal anti-inflammatory drugs, movement exercises, acupuncture, ultrasound therapy, strengthening exercises, stretching, transcutaneous electronic nerve stimulation (TENS), superficial heat or ice therapy. The treatments where at least one profession presented trust were included in the literature search.

Systematic critical review

A search for papers was conducted in the computerised bibliographic databases MEDLINE and CINAHL using the OVID search engine, and also the EMBASE database using the Silver Platter search engine. The search was conducted for studies published between January 1984 and December 1999 (for EMBASE, January 1986 to December 1999).

The following medical subject headings and text words were used alone or in combination: shoulder, rotator cuff, subacromial, impingement syndrome, pain, therapeutics, therapy, physiotherapy, physical therapy, rehabilitation, acupuncture, ergonomic, exercise, non anti-inflammatory drugs/NSAIDs, steroids, corticosteroid injection, heat, movement, stretching, strength, transcutaneous electric nerve stimulation (TENS), ultrasonic therapy and ultrasound.

All abstracts comprising an evaluation of efficacy for any of the trusted treatments for shoulder disorders were reviewed. Studies published as full
reports in Scandinavian, English, French and German languages, and judged as dealing with symptoms originating from subacromial structures were included.

A diagnostic labelling of patients in the found studies was performed. The label subacromial pain was used when the authors described at least one of the following inclusion criteria: a positive Neer impingement sign or test\(^9\), Hawkins and Kennedy impingement sign\(^8\) or similar manoeuvres to test the subacromial structures, positive findings by ultrasonographic or radiographic examination that indicated disturbance of rotator cuff muscles and/or the subacromial bursa. Studies not fulfilling these inclusion criteria, but where the authors either stated a diagnosis of pain originating from subacromial structures or studies properly excluding adhesive capsulitis/frozen shoulder, neck-disorder, osteoarthritis or rheumatoid arthritis, were labelled non-specific. This group was judged as probably including patients with subacromial pain. Studies’ dealing with other shoulder diagnoses or single case-reports were excluded.

According to these inclusion criteria 40 studies, referred to in the original paper, were included and labelled. Their designs resulted in a level of evidence (level I-V) and grade of recommendation for each treatment according to Sackett. He defined grade A as *definitive evidence*, including at least two level I studies (a randomised trial with low false-positive and low false-negative errors), grade B as *tentative evidence*, including at least one level II study (a randomised trial with high false-positive and high false-negative errors, and grade C as *suggestive evidence*, supported only by level III-V studies (non-randomised concurrent and historical cohorts and case series).\(^1\)

In the next step, methodological quality was assessed to conclude if the grade of recommendation was supported or not. All studies were assessed using the guideline and checklist published by Fowkes et al.\(^4\) complemented by validation of statistics. The names of the authors, title, source and year of publication were blinded for the two reviewers who assessed the papers independently. The reviewers had trained beforehand in the use of the guideline and checklist. They both made an overall judgement on a five-point scale in order to state whether the methodology was good enough to support the grade of recommendation (A-C) or not. This resulted in one of three summery categories: 'yes' meaning that the grade of recommendation was methodologically supported (representing 4 or 5 on the scale), 'yes, with reservation' (representing 3 on the scale), and the final category 'no' (representing 1 or 2 on the scale), meaning that the methodology was
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insufficient to support the grade of evidence. The reviewers also stated the level of evidence for efficacy for each treatment.

Effect size was calculated for treatments where the reviewers stated some evidence for efficacy and if the following criteria were fulfilled: design of evidence level I or II, satisfactory methodology (appraised as 4 or 5) and a standard deviation was reported or could be calculated. The choice of outcomes was an over all clinical change that always included the variable pain as well as movement and/or functional limitation.

Paper III

The study was divided in two parts, one to test concurrent validity and one to test intra- and inter-observer reliability. In both parts the equipment(s) were complemented with a loose handle from a pulley-apparatus in order to standardise the grip. The test-leaders were senior physiotherapy students with experience of the testing situation and the role as a test-leader from a pilot study performed on ten test-persons (20 shoulders), not included in the present study.

Concurrent validity

The Handyscale® (Handyscale®, Bonso Electronics, Hong Kong, China) was compared with a gold/reference standard, a mechanical spring-balance (Tatsumi International Ltd., Ibarakai-city, Osaka, Japan), in order to test concurrent validity. The Handyscale, is a digital dynamometer, measuring a maximum of 15 kilograms with two decimals and an interval of 20 grams. The mechanical spring-balance measures a maximum of 20 kilograms with an interval of 2 hectograms.

The test-leaders tested five persons each. A blinded randomisation, by drawing of lots, decided which technique, which instrument and which arm to start with as well as which one of the test-leaders that would perform the test. The test situation and instructions were standardised. Before start, all test-persons performed three standardised warm-up exercises and they also practised the technique by one sub-maximal attempt.

The test-position was the one recommended by Bankes et al. with the arm in 90° of lateral elevation in the scapular plane, the shoulder internally rotated, the elbow extended and the forearm pronated⁸.
The test-leader told the test-persons that maximal effort was necessary and to continue to pull respectively hold until instructed to stop. In the pull-technique the test-persons pulled until no higher value was reached, but no longer than 6-7 seconds. The force to resist was applied slowly by the test leader until a visible break (joint movement) had occurred. The highest value obtained, in each repetition before joint movement, was noted. The equipment's, were unsecured for the technique "resisted-force" and for the "pull-force" secured in part of a pulley-apparatus which was fixed to the wall. The set-up for each technique is further described and illustrated in the paper.

Calibration of equipments was made with a weight of three kilograms before start of each test occasion.

A test-series contained three repetitions of for example "resisted-force" with the mechanical spring balance. Then the same was performed with the other arm before changing back to the first arm to perform the "pull-force". Both techniques, two test-series per arm, were then repeated with the other equipment. The test-leader counted down from three and than cheered with the word hold (three times) or pull (three times), depending on technique.

Within one test-series of three repetitions, the test-persons were instructed to rest the arm at the side between each repetition and between series until they felt ready to perform again. The time of rest, between each effort, was 10-20 seconds and there was a natural rest when changing sides as well as when changing equipment. No discomfort was reported. The test-leader recorded the result for each repetition related to the person tested and the equipment used and placed in an envelope with a code for that test-person. The data maintained concealed until analysis.

Intra- and inter-observer reliability

The test-leaders were the same as in the validity part. The test-retest was performed with exactly two weeks interval, in the same room with the same equipment and at the same time at day. The order of test-leader, which arm and what technique to start with, the “pull-force” or the “resisted-force” was randomised blindly by drawing of lots. The standardised test-situation, set-up, instructions, periods of rest as well as preparations were the same as those earlier described in the validity part and repeated at retest.

The highest value reached, in each repetition before joint movement, was recorded.

A test-series contained three repetitions of for example "resisted-force". Then this was performed with the other arm before changing back to the first
arm to perform the "pull-force". Both techniques, two test-series per arm, were then repeated with the second test-leader that waited outside the room.

The result for each repetition was recorded by the respective test-leader and placed in an envelope with a code for that test person at the first test session as well as for the retest. The data remained concealed until analysis.

Paper IV

A prospective, observer blind, randomised clinical trial was conducted. Concealed randomisation was carried out beforehand and the treatment was introduced and performed by four PTs at the same PHCC. All were experienced and had worked in primary care for an average of 13 years. The research PT was blinded throughout the study. The same clinical examination, excluding the impingement test (injection of anaesthetic), was repeated after the completed treatment period (six weeks) and at three-, six- and 12 months from the date of the initial visit. At each follow-up, current symptoms and differences in relation to baseline were documented. Three shoulder scores were used at the initial visit and at each follow-up: the AL score\(^2\), the CM score\(^30\) and the University of California at Los Angeles end-result scores (UCLA)\(^43\). The three scores were combined in the analysis of results.

The AL score is a self-reported assessment. It includes six items and in brackets, their contribution to total score is presented: pain during activity (15%), pain during rest (15%), nocturnal pain (10%), instability (20%), level of activity – work/recreational activities (20%), and activities of daily living (ADL) (20%). A total of 100 points means that the patient experiences no symptoms. The two first pain categories are measured with a 100 mm visual analogue scale (VAS), where the patient marks their mean level of pain. The rest of the score is based on fixed answer alternatives with an ordinal scale.\(^2\)

The CM score contains both subjective and objective measures with a maximum of 100 points. It includes four head items and in brackets, their contribution to total score is presented: pain (15%), ADL (20%), range of motion (40%), and strength (25%).\(^30\) The third score, UCLA, also contains both subjective and objective measures with a maximum of 35 points. It includes five items and in brackets, their contribution to total score is presented: pain (29%), function (29%), active forward flexion (14%), strength of forward flexion (14%), and satisfaction of the patient (14%).\(^43\)

One additional question, ‘the patient self-evaluation’, was also answered at each follow-up to describe the experienced result. The question was; how have your shoulder problems changed due to the treatment? It contained five response
alternatives; worse, unchanged, small improvement, large improvement, and completely recovered.

**Treatments**

A summery of the treatments is presented, for a more detailed description see paper IV.

The acupuncture group received 10 treatments with standardised needle placement, selected in accordance with clinical practice, using four local points, LI 14 (Binao), LI 15 (Jianyu), LU 1 (Zhongfu) and TE 14 (Jianliao), and one distal point, LI 4 (Hegu). All PTs have had their education and training in acupuncture in Sweden. The depths and angles of insertion used were those described in the Swedish manual. The treatment was repeated twice a week for five weeks. One treatment lasted 30 minutes. A total of three stimulation’s, twirling the needle until the sensation of “de qi” was experienced, were performed at insertion, after 15 minutes and after 30 minutes. The patients lay on a treatment table on their unaffected side.

The ultrasound group received ten treatments of continuous ultrasound twice a week for five weeks. Each treatment lasted ten minutes, and a standardised mode was used with a frequency of 1 MHz and a Spatial-Average intensity of 1 W/cm² using a gel coupling. The size of the transducer was 4 cm² and the skin area treated was twice this size covering an area of about 8-10 cm² inferior to the frontal and lateral part of the acromion. The transducer head was moved in small circles covering the area.

The patients were seated with their arm over the back of a chair, maintaining an extended and internally rotated arm in order to make the muscle insertion of supraspinatus appear beneath and frontal to the acromion. The equipment used was a Phyaction 190 (Uniphy, P.O Box 558, NL-5600 Eindhoven, the Netherlands). The same equipment was used for all patients and it was calibrated by an independent medical technician before starting the study and then once every twelve months. No alterations were reported.

Both treatments were combined with a two-step home-exercise programme see Appendix C. At the first treatment visit the patient received instructions from the PT and practiced the first part of the exercise programme and at the sixth visit the patient received instruction and practiced the second part. Pain during the exercises should not remain more than 10 to 15 minutes after the end of programme. Compliance with the exercises was registered in a ‘home-exercise compliance log’ and the use of additional drugs reported.
Data analysis

Detailed description of the statistical methods is presented in the separate papers. Statview version 5.0 (SAS Institute Inc. Berkley, California USA) was used in all papers except for paper III. A SPSS version 9.0 (SPSS Inc. Chicago, USA) was used to calculate agreement in paper III and in the between group analysis in paper IV.

Descriptive statistics were used in all four studies. An unpaired Students t-test (two-way) was used to compare continuous data (paper I). Differences in categorical data were analysed using a Chi-square analysis with Fisher’s exact test for small groups (paper I, II and IV).

Effect sizes (ESs) were calculated (paper II) by subtracting the mean change score for the placebo/control/comparison group from the mean change for the treatment group and than dividing by the standard deviation of the placebo/control/comparison group at baseline. If there were more than two groups, the figures for the placebo group were used.28 Cohen’s guidelines for the magnitude of the effect size were used interpreting an ES of 0.2 as small, one of 0.50 as moderate and one of 0.80 or greater as large.

For concurrent validity and intra- and inter-observer reliability (paper III), agreement was analysed with a repeated measure ANOVA to calculate Intraclass Correlation Coefficients (ICCs) with 95% two-sided confidence intervals. In this study an ICC value of >0.81 was considered almost perfect, 0.61-0.80 as substantial, 0.41-0.60 as moderate, 0.21-0.40 as fair and 0.0-0.20 was considered as a slight agreement.

A sample size estimation was performed in paper IV before starting the study. Forty patients in each group were required if the expected rate of improved patients was to be 30% better in one group than in the other (β = 80%, α = 0.05).

In analysis of paper IV, the three scores were combined using a mean of the three scores. The maximum of 35 points in the UCLA and 100 in the other two, was corrected by multiplying the UCLA score by 100 and then dividing by 35.

A repeated measures ANOVA was used in the between group analysis (paper IV) of the individuals change in the combined score from baseline to each follow-up. A cut-off of 80% or more of the combined score, based on earlier studies, was used to define patients thought to have a satisfactory results at 12 months. Due to changes in the sample, the mean scores at the three-, six- and 12-month visits, the proportions of those with a satisfactory result as well as the answers to ‘the patient self-evaluation’ at 12 months, were therefore analysed both for the group adhering to the study protocol and with
an "intention-to-treat" (ITT) application model for analysis of clinical trials. The latter included all patients randomised. The principle of last observation carried forward (LOCF) was used in analyses using the scores recorded just prior to the missing ones in case of missing post-treatment values during follow-up.\textsuperscript{52}

Level of significance for all testing was $p<0.05$. 
Current management of patients with subacromial pain in primary care (paper I)

The diagnosis 'rotator cuff tendinitis' was marked by 74% among GPs and 84% among the PTs as the most probable explanation of the symptoms in the case and subacromial bursitis as the second most probable. Rotator cuff rupture, osteoarthritis, neck disorder and frozen shoulder were considered less probable diagnoses. (Figure 3)

The two groups were unanimous about what examination procedures they would use, with the exception that PTs used neurological tests significantly less often (figure 4).

The two groups also agreed on what findings they expected during examination. More than 80% of the two groups marked the following findings as probable: painful arc, pain during movements in or above the height of the shoulder, tenderness and positive findings during provocation of the subacromial structures. Least probable were neurological findings. They were marked as less probable by 91%. Findings such as weakness and limited range of motion were more equally distributed over the three categories; probable, less probable and neutral.

The most frequently chosen time for sick leave was less than two weeks, which was marked by 72% of the GP’s. For the extent of the sick leave, the option ‘total sick leave’ was marked by 51%, "partial" by 18% and "no sick leave" by 31%.

Concerning referral to another profession the GPs and PTs most often referred to each other. The GPs marked this as probable in 81% and the PTs in 33%. The other options for referral were an occupational therapist (probable in 12%), orthopaedic specialist (probable in 3%) and social worker (neglected).

Non steroidal anti-inflammatory drugs (NSAIDs) were the most probable choice of treatment, marked by 73% of the GPs. Injection with corticosteroids into the subacromial space was also frequent, marked as probable by 61%. Injections into tender points or oral analgesics were less probable. (Figure 5)
Review of results

Figure 3 Pattern of diagnosing for GPs and PTs

Figure 4 Pattern of physical examinations for GPs and PTs
Review of results

For PTs, movement exercises and ergonomics were the two most probable choices of treatment, especially movement exercises, which was marked as probable by 82%. The PTs had several treatment alternatives to mark as more or less probable, but most were probable choices. (Figure 6)

![Figure 5 General practitioners choice of treatment of the case](image)

CITP = corticosteroid injection in tender points
CISB = corticosteroid injection in subacromial bursa
Efficacy for trusted treatments in primary care (paper II)

The treatments found to be trusted are presented in table 5. In the review, 40 appropriate studies were found, 17 labelled as subacromial pain and 23 as non-specific. The references of the included studies are presented in the original paper. A total of 27 studies provided evidence on level I or on level II. The results from the best available studies for each treatment are presented and conclusions from studies of lower levels are not presented when there are better studies available. Available external evidence for the trusted treatments are summarised in table 5 and their ESs in table 6.
Table 5  Reviewers’ conclusions about evidence for trusted treatments and the proposed effect in relation to grade of evidence and methodological quality

<table>
<thead>
<tr>
<th></th>
<th>Trust by GPs and PTs (%)</th>
<th>Number of studies</th>
<th>Grade of evidence&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Grade supported by methodological quality</th>
<th>Authors’ conclusion</th>
<th>Reviewers’ conclusion about evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ergonomics/adjustments at work</td>
<td>98</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>94</td>
<td>12&lt;sup&gt;b&lt;/sup&gt;</td>
<td>A</td>
<td>Yes</td>
<td>Short-term efficacy probable long-term efficacy</td>
<td>Definitive evidence for short-term efficacy, tentative for long-term efficacy</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-steroidal anti-inflammatory drugs</td>
<td>92</td>
<td>9</td>
<td>A</td>
<td>Yes</td>
<td>NSAID better than placebo or as good as corticosteroids in the acute-phase</td>
<td>Tentative evidence for short-term efficacy</td>
</tr>
<tr>
<td>Movement exercise/mobilisation</td>
<td>90</td>
<td>2</td>
<td>B</td>
<td>No</td>
<td>Decreased 24-hour pain and no effect</td>
<td>No evidence for efficacy</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>73</td>
<td>4</td>
<td>B</td>
<td>Yes</td>
<td>Acupuncture better than placebo. Acupuncture combined with Cyriax-based orthopaedic medicine results in better outcomes</td>
<td>Tentative evidence for short-term efficacy</td>
</tr>
<tr>
<td>Ultrasound therapy</td>
<td>71</td>
<td>6</td>
<td>A</td>
<td>Yes</td>
<td>No difference between true ultrasound and placebo. Probable short term efficacy</td>
<td>Tentative evidence for lack of efficacy</td>
</tr>
<tr>
<td>Strengthening exercise</td>
<td>67</td>
<td>1</td>
<td>B</td>
<td>Yes</td>
<td>Physiotherapy aimed at restoring muscle function produces better outcome than no treatment</td>
<td>Tentative evidence for short-term efficacy</td>
</tr>
<tr>
<td>Stretching</td>
<td>64</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Transcutaneous electric nerve stimulation</td>
<td>64</td>
<td>1</td>
<td>B</td>
<td>No</td>
<td>TENS &amp; Ultrasound equally effective</td>
<td>No evidence for efficacy</td>
</tr>
<tr>
<td>Superficial heat/ice therapy</td>
<td>56</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

<sup>a</sup> Grade of evidence based on design: A = at least two large randomised controlled trials, B = at least one randomised controlled trial, C = study of other designs  
<sup>b</sup> One study with two papers<sup>140,141</sup> (Four studies deal with more than one treatment, mixed treatments excluded)
Table 6  The outcome and effect size for all studies with at least evidence level II and with high methodological quality

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Authors ref</th>
<th>Outcome</th>
<th>Effect size (follow-up)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Corticosteroid injection</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Adebajo et al. 1990</td>
<td>Over all pain</td>
<td>4.74 (short term)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Limitation of function</td>
<td>0.77 (short term)</td>
</tr>
<tr>
<td></td>
<td>Itzkowitch et al. 1996</td>
<td>Clinical index</td>
<td>1.4 (short term)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(pain, active movement)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Petri et al. 1989</td>
<td>Clinical index</td>
<td>1.03&lt;sup&gt;a&lt;/sup&gt; (short term)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(pain, limitation of function)</td>
<td></td>
</tr>
<tr>
<td><strong>NSAIDs</strong></td>
<td>Adebajo et al. 1990</td>
<td>Over all pain</td>
<td>2.96 (short term)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Limitation of function</td>
<td>0.77 (short term)</td>
</tr>
<tr>
<td></td>
<td>Petri et al. 1989</td>
<td>Clinical index</td>
<td>0.81&lt;sup&gt;a&lt;/sup&gt; (short term)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(pain, limitation of function)</td>
<td></td>
</tr>
<tr>
<td><strong>Acupuncture</strong></td>
<td>Kleinhenz et al. 1999</td>
<td>Constant-Murley shoulder assessment</td>
<td>0.77 (short term)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(pain, limitation of function, active movement, strength)</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>The value is a mean of two short term effect sizes

**Concurrent validity and intra- and inter-observer reliability of the standardised strength test (paper III)**

The evaluation of the standardised strength test in the CM score concerning concurrent validity, resulted in ICCs ranging from 0.96 to 0.99. An almost perfect agreement between the Handyscale and the mechanical spring balance, independently of the technique used or if calculated with mean or maximum values.
The evaluation of intra-observer reliability resulted in ICCs ranging from 0.94 to 0.98 for test-leader A and ICCs of 0.90 to 0.96 for test-leader B. There was an almost perfect agreement independent of technique or if calculated with mean or maximum values. The inter-observer reliability was also almost perfect with ICCs ranging from 0.89 to 0.96 at the first test occasion and ICCs of 0.89 to 0.97 at retest. An almost perfect agreement independently of technique used or if ICCs were calculated with mean or maximum values.

All maximum values and the mean strength values (mean of three repetitions) measured by the Handyscale from the validity and reliability part are presented in relation to gender in table 7. The strength values from the validity part measured with the spring-balance is presented in the original paper. There were no significant differences in strength between the dominant or non-dominant arm.

Table 7  Strength measurements for the Handyscale. Each value calculated as a mean of all individuals’ maximum values and as mean of all mean values, from both test leaders

<table>
<thead>
<tr>
<th></th>
<th>Female</th>
<th></th>
<th>Male</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Handyscale</strong> (pull-force in kg(^a))</td>
<td>Validity</td>
<td>Reliability</td>
<td>Validity</td>
<td>Reliability</td>
</tr>
<tr>
<td>Max</td>
<td>5.8</td>
<td>6.5</td>
<td>10.8</td>
<td>10.6</td>
</tr>
<tr>
<td>range</td>
<td>4.4-7.2</td>
<td>4.2-9.6</td>
<td>6.0-14.1</td>
<td>5.6-14.9</td>
</tr>
<tr>
<td>Mean</td>
<td>5.5</td>
<td>6.0</td>
<td>10.2</td>
<td>10.0</td>
</tr>
<tr>
<td>range</td>
<td>4.2-6.9</td>
<td>3.9-9.2</td>
<td>5.0-13.6</td>
<td>5.1-14.9</td>
</tr>
<tr>
<td><strong>Handyscale</strong> (resisted-force in kg(^a))</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max</td>
<td>5.9</td>
<td>6.3</td>
<td>10.8</td>
<td>10.2</td>
</tr>
<tr>
<td>range</td>
<td>4.8-7.6</td>
<td>3.7-8.8</td>
<td>7.3-12.9</td>
<td>6.6-14.9</td>
</tr>
<tr>
<td>Mean</td>
<td>5.5</td>
<td>5.8</td>
<td>10.3</td>
<td>9.5</td>
</tr>
<tr>
<td>range</td>
<td>4.6-6.8</td>
<td>3.2-8.1</td>
<td>7.0-12.6</td>
<td>6.1-14.6</td>
</tr>
</tbody>
</table>

\(^a\)kg = kilogram
Efficacy of acupuncture compared to therapeutic ultrasound, both combined with home exercises (paper IV)

Before treatment there were no significant differences in the independent variables between treatment groups, except for sick-leave. Five patients in the acupuncture group were on sick-leave when they entered the study, but they did not differ from the rest of the included patients in background characteristics, scores at baseline or during follow-up. No adverse effects or side effects were reported in either group during or after the treatment period. The use of additional treatments, which is defined as not adhering to study protocol, did not differ significantly between the groups. The dropout rate was 4 out of 85. Two women underwent surgical subacromial decompression. One woman dropped out due to lack of time and one man declined further participation since he felt no improvement. The four dropouts did not significantly differ in background characteristics or in scores in comparison with the other patients.

There were no significant differences in compliance with home exercises or in use of additional pain killers between the treatment groups. In those cases where LOCF was used, there were no signs of systematically missing data for specific patient categories or unequal distribution of missing data between the groups. The scores for those where LOCF was used did not significantly differ from the rest.

The mean score at baseline and the mean score at each follow-up score as well as the change from baseline in relation to follow-ups for each treatment group are presented in table 8.

Both treatment groups improved significantly during the follow-up compared to baseline and these early improvements continued over time (figure 7).

There were no significant differences between treatment group scores at baseline (table 8). The between-group analysis of the change from baseline to each follow-up resulted in a significantly larger change (p<0.001) in the combined score for the acupuncture group, both for those adhering and for ITT.
Table 8  Outcome measures for the combined score at baseline and at each follow-up for the group adhering to study protocol and for the intention-to-treat (ITT), both with the last observation carried forward. Figures presented for respective treatment group as group mean values (SD) and the group mean changes (SD) at each follow-up related to baseline

<table>
<thead>
<tr>
<th></th>
<th>Adhering to study protocol</th>
<th>ITT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Acupuncture</td>
<td>Ultrasound</td>
</tr>
<tr>
<td>Baseline (before treatment)*</td>
<td>59 (8)</td>
<td>62 (7)</td>
</tr>
<tr>
<td>6 weeks follow-up</td>
<td>76 (12)</td>
<td>72 (12)</td>
</tr>
<tr>
<td>Change: before - 6 weeks</td>
<td>17 (11)</td>
<td>10 (10)</td>
</tr>
<tr>
<td>3 months follow-up</td>
<td>84 (9)</td>
<td>83 (10)</td>
</tr>
<tr>
<td>Change: before - 3 months</td>
<td>23 (11)</td>
<td>20 (8)</td>
</tr>
<tr>
<td>6 months follow-up</td>
<td>89 (8)</td>
<td>88 (11)</td>
</tr>
<tr>
<td>Change: before - 6 months</td>
<td>29 (10)</td>
<td>25 (10)</td>
</tr>
<tr>
<td>12 months follow-up</td>
<td>93 (5)</td>
<td>89 (9)</td>
</tr>
<tr>
<td>Change: before - 12 months</td>
<td>32 (9)</td>
<td>26 (9)</td>
</tr>
</tbody>
</table>

* The baseline mean for 3-, 6- and 12 months was altered due to sample changes for those adhering to study protocol
Figure 7  The change in the combined score from baseline to each follow-up for the treatment groups for those adhering to study protocol.

At the end-point after 12 months, the proportion of the patients with a satisfactory result and the number of patients marking each response alternative in ‘The patient self-evaluation’ are presented in table 9. There was no significant difference between these proportions when comparing the treatment groups.
Table 9  The number of patients with a satisfactory result in the combined score (≥ 80 %), and those who marked each response alternative in 'the patient self-evaluation' at 12 months. All with the last observation carried forward

<table>
<thead>
<tr>
<th></th>
<th>Adhering to study protocol</th>
<th>ITT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Acupuncture</td>
<td>Ultrasound</td>
</tr>
<tr>
<td>Satisfactory result (%)</td>
<td>34 (97)</td>
<td>26 (87)</td>
</tr>
<tr>
<td>'The patient self-evaluation' (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completely recovered</td>
<td>16 (46)</td>
<td>11 (37)</td>
</tr>
<tr>
<td>Large improvement</td>
<td>10 (29)</td>
<td>14 (47)</td>
</tr>
<tr>
<td>Small improvement</td>
<td>5 (14)</td>
<td>3 (10)</td>
</tr>
<tr>
<td>Unchanged</td>
<td>3 (8)</td>
<td>2 (6)</td>
</tr>
<tr>
<td>Worse</td>
<td>1 (3)</td>
<td>0</td>
</tr>
</tbody>
</table>
GENERAL DISCUSSION

Results

Subacromial pain was the diagnosis that GPs and PTs marked as the most probable for the case used in the questionnaire. This is in concordance with the most common shoulder diagnosis reported in Dutch primary care\textsuperscript{134}. Both professions agreed about the diagnosis and diagnostic tests to be used, contrary to the study by Liesdek C et al. who reported fair inter-observer agreement between GPs and PTs.\textsuperscript{82} This difference could be explained by the use of different methodology, a judgement case in one hand and examination of patients in clinical practice with a set of criteria on the other hand. In general when diagnosing patients with shoulder disorders, the inter-observer agreement has been reported as moderate between PTs ($k = 0.45$)\textsuperscript{36}, and fair between GPs and PTs ($k = 0.31$)\textsuperscript{82}.

The GPs choice of treatments in the questionnaire study, were the same as those recorded in Dutch primary care\textsuperscript{134}. No earlier research was found reporting PTs choice of treatments for patients with subacromial pain. The fact that most treatments were a probable choice could be explained by the uncertain pathogenesis of subacromial pain and the lack of research regarding the efficacy of many of these conservative treatments.

In the systematic review, ten treatments were trusted as efficient by the GPs and PTs. Studies evaluating any of the trusted treatments were included and their methodological quality varied. Only one treatment had definitive evidence for short-term efficacy, namely corticosteroids injected into the subacromial bursa. This was in line with the conclusion from an earlier review of treatments for shoulder disorders\textsuperscript{54}. One aspect to remember is that this efficacy could be dependent on the accuracy of the placement of the injection\textsuperscript{44}.

Among PT treatments, tentative evidence was found for acupuncture. Until recently there have been no valid studies of acupuncture for subacromial pain.

Therapeutic ultrasound was concluded to be ineffective for patients with subacromial pain and this is supported by a review with the same conclusions for shoulder disorders\textsuperscript{136}. In earlier research, the efficacy of therapeutic ultrasound for soft-tissue disorders has been questioned\textsuperscript{62,100}. Despite this, it is
commonly used by PTs in Swedish primary care for patients with subacromial pain and trusted by both GPs and PTs. The use of unspecific shoulder diagnosis decreases the clinical credibility of these earlier reviews which could explain the current use and trust. In other words, the trust in treatments had a weak association with available scientific evidence, and for many of the treatments there was a lack of or a limited number of studies.

In the validity and reliability study the standardised strength test, recently recommended by Bankes et al., could be performed with either a conventional spring balance or a digital dynamometer. Both were found to be intra- and inter-observer reliable. There has been a disagreement about which strength value to use, a mean of a number of repetitions or the maximum value. In this study, the reliability was independent of this.

Test persons without a history of upper extremity disorders were chosen since the aim was to evaluate variation due to test-leader and/or equipment. If patients with shoulder disorders had been used instead, there would have been a risk of variation due to pain. However, it is important to remember that when pain is experienced there will be no assessment of muscle strength, rather an indication of a muscle dysfunction and the level of pain experienced during this activity.

In the RCT, acupuncture was found to be superior to therapeutic ultrasound, both combined with home exercises. This supports the earlier findings by Kleinhenz et al. Perhaps can this significantly better improvement for the acupuncture group be explained by a decrease in pain due to the analgesic effect of acupuncture.

The anaesthetic injected in the impingement test cannot explain the improvements found after treatment, since it disappears after three days in muscle tissue and in the subacromial bursa.

In the systematic review, tentative evidence was reported for strengthening exercises as treatment for patients with subacromial pain. The effect of exercises can be explained by improved rotator cuff function which results in better centring of caput humeri during movements counteracting the compression of subacromial structures. It is possible that the analgesic effect of acupuncture improved the ability to perform exercises and make them more efficient contributing to the significantly better results in the acupuncture group.

Further in the RCT, both groups improved significantly during the study period. The improvement in the ultrasound group is probably an effect of home exercises in combination with the natural course, since one of the conclusions in the systematic review was that ultrasound therapy is inefficient.
Since the choice of treatments was directed towards subacromial pain, possible heterogeneity could be reflected in the results as lower improvement rates. Especially a partial rupture of the rotator cuff could be difficult to diagnose, which could explain why some patients had a less favourable outcome.

Almost all patients reached a satisfactory result independent of treatment after 12 months. Only two studies have reported the clinical course after conservative treatment for patients with subacromial pain\textsuperscript{25,135}. The proportion of patients who felt completely recovered in the RCT was almost the same as in the study by van der Wind et al. They reported that 47\% of patients with subacromial pain were recovered after 12 months.\textsuperscript{135} In another study, 39\% patients with subacromial pain had no significant symptoms after 19 months of follow-up\textsuperscript{25}. Despite the methodological problems involved in comparing results measured with different instruments and different definitions of recovery, our findings after 12 months are at least equal to earlier reported results.

The results at 12 months probably reflect the natural course of the problem, but since the acupuncture group had a significantly larger improvement already at the first follow-up, a difference maintained over time, the physical therapy strategy with a combination of acupuncture and home exercises seems more valuable for most patients with subacromial pain.

Methodological discussion and the results credibility

Study populations / participants

In this thesis, a more defined diagnosis of patients with subacromial pain than in most earlier research was used. Still there are difficulties and weaknesses of the known diagnostic tests and in the definition involvement also from the acromio-clavicular joint, the biceps brachii tendon, early phases of frozen shoulder as well as minor ruptures in the rotator cuff are possible.

The participants in the questionnaire study were from all parts of the county of Östergötland and were concluded as representative for GPs and PTs from this county. There could be a discrepancy between this county and other parts of Sweden in how they would diagnose and manage patients with subacromial pain which influence the generalizability of the results. Factors as differences in post-graduate education, current treatment trends and different
organisation of primary care could have an influence, but probably not enough to change the overall picture. However, the patients seen in Östergötland with subacromial pain, on which the GPs and PTs base their experience, are thought to be representative for Sweden. The chosen county, like the rest of Sweden, represents both large and small urban districts. The smallest urban district had 5 327 inhabitants and the two largest represents about 255 000 of the total number of 410 000 inhabitants. One is known to be dominated by blue-collar employees and the other by white collar and both have a rather large hospital where one is a university hospital.6

The non-responders differ from the responders only in age for GPs. This could be a source of bias, but no research results were found reporting that older GPs would diagnose or manage patients in a different way.

The test persons in the validity and reliability study had a rather low mean age. Earlier reported normal values for different age categories, using “resisted-force” in $90^\circ$ abduction measured with a hand-held dynamometer, resulted in no significant differences between most age categories. One exception was reported when those in 20-30-year age band were compared to those between 60-70. In other words, most of the abduction strength values found in younger ages seemed representative also for those up to 60 years of age. In contradictory to this Hughes et al. reported that isometric abduction strength decreased with age. This difference could be explained by the use of different equipment, the latter using a modified Cybex II dynamometer. 63

Out of 173 shoulder patients who visited the research PT in the RCT, 88 (51%) were diagnosed as subacromial pain. This can be compared with Dutch general practice where 48% of the patients consulting the GP for shoulder problems had subacromial pain.135

The diagnosis of subacromial pain was based on several criteria. The inclusion and exclusion used in the RCT (Appendix B) include the suggested criteria that according to a recent review interfere with successful outcome of treatment for patients with subacromial pain.38 In the systematic review as well as in the RCT, impinging manoeuvres together with the impingement test were used to label studies and to include patients. It is not known if different routes of injection, when performing the Neer impingement test, would have a different accuracy. A postero-lateral injection approach, which was used in the RCT, has been reported as helpful when entering the subacromial space.92 The reported high sensitivity of these diagnostic tests is probably valuable for identifying a group of patients having subacromial pain, but there will be some heterogeneity, since it is difficult to discriminate from the false positives.22,85. Despite this insecurity, the choice of the impingement signs and
test in this thesis were based on the importance of using the diagnostic tests available in clinical practice as well as those described in research. This might also facilitate implementation of the research results.

The Neer impingement test was compulsory in the RCT in combination with at least three other clinical findings (Appendix B). This is in accordance with the reported clinical approach where several diagnostic tests are combined during examination and perhaps the use of a combination makes the diagnosis more accurate. MacDonald et al. reported similar figures for sensitivity and specificity independent of whether the Neer impingement sign and Hawkins-Kennedy impingement sign were performed individually or combined\(^8\). However in a study by Calis et al., a combination of clinical diagnostic tests for subacromial pain increased the specificity, with a consequent decrease in sensitivity\(^2\).

Despite this insecurity about diagnostic tests and lack of existing consensus about what criteria or gold standard should be used, the chosen combination of inclusion and exclusion criteria is believed to be sufficient for identifying a group of patients having subacromial pain. Still it is difficult to state whether or not there is a partial rupture of the rotator cuff, which could explain why some patients had less improvement.

**Study designs**

The use of a written case in the questionnaire study has been reported as a good methodology when measuring attitudes, but it might differ from actual clinical practice\(^7\). More recently, it was supported for its ability to evaluate practice procedures\(^1\). The case had limited information, intended to capture the early process of pattern recognition which has been reported to dominate the diagnostic and problem-solving process in primary care\(^1\). The details in the case probably influenced the responses, and it is hard to state if this was considered in all responses about choice of treatments, but this would probably not substantially change the overall pattern of trust.

In the systematic review, the grade of evidence was a result of the used design in combination with an assessment of methodological quality. This was thought to make the conclusions from the systematic review more solid than if only the former was used.

As outlined in the review by Van der Heijden, there is no gold standard that provides a valid and reliable estimate for clinically relevant changes for
patients with shoulder disorders. The way of dealing with this in the systematic review was to calculate and report ES as well as significance’s.

The design of the validity and reliability study seemed appropriate since it dealt with the methodological aspects reported to be important to consider when evaluating validity and reliability for dynamometric measures of extremity muscles.

There were several reasons for the choice of treatments combined and compared in the RCT. When starting the study in 1997, evidence concerning the effectiveness of therapeutic ultrasound for patients with subacromial pain was not conclusive. The chosen treatments were found in the questionnaire study to be both used and trusted by the PTs in primary care, and seemed reasonable to compare due to their similar treatment set-up.

The chosen exercises in programme I were targeted to maintain or restore motion as well as to stimulate circulation in the rotator cuff using many repetitions of low intensity, without stressing involved contractile tissue. In programme II the target was to strengthen the rotator cuff muscles below the level of impingement (Appendix C). The exercises used in this study are similar to those reported as efficacious in earlier studies. Most of the exercises are supported by the research of McCann et al. They reported that forward flexion with a pulley resulted in minimal activation of rotator cuff. Further, the use of isometric exercises in all directions were reported to produce a general activation of all muscles surrounding the shoulder. The external rotation, with fixed elbows using a tube, are reported to result in the highest activation of the infraspinatus, a muscle important to strengthen in patients with subacromial pain. The fixed elbow decreases the activation in the posterior deltoid compared to when they were allowed to move. In all exercises the position of a retracted shoulder was emphasised in line with the findings of Solem-Bertoft et al. where a protracted shoulder resulted in a narrowing of the anterior aspects of the subacromial space. Some authors have reported the importance of associated movements and fixation of the scapula for patients with subacromial pain. This has not been focused on in the exercise programme used.

The difficulties with an appropriate comparison for acupuncture treatment as well for designing a double blind trial is well known. Recently, a used placebo needle has solved a part of this problem, but it was not available when the RCT started. In the RCT, the importance of selecting treatments with similar set-ups as well as the use of a standardized treatment protocol was stressed and supported by the recent published 'CONSORT statement. The conclusion in the systematic review, that ultrasound is ineffective, may imply
that the RCT has compared home exercises with and without the additional acupuncture

Outcome measures and analysis in paper IV

The knowledge and demands of psychometric properties of measurements and instrument have increased over time. During the planning of the RCT in 1996 there existed no consensus about which instrument should be used when evaluating patients with subacromial pain. This uncertainty and the decision of ‘the European Society for Surgery of the Shoulder and Elbow’ in the early 1990s that the CM score should be used in all research involving patients with shoulder problems, led to the choice of using these three disease specific shoulder scores.

Their measurement theory is incomplete, both for construct, content, and criterion validity and the knowledge about reliability is insufficient for the chosen scores. The CM score and UCLA seemed appropriate from clinical experience and they have both been frequently used in earlier research. However, the authors of the CM score described a difficulty to evaluate concurrent validity due to lack of gold standard\(^30\) and in aspects of reliability, Conboy et al. were concerned about its use for clinical follow-up\(^29\). No studies dealing with these aspects for the UCLA were found. The AL score was chosen since it was developed for patients with subacromial pain\(^2\). Further, the AL score is a self-assessment questionnaire, which has been reported to be preferable over scores with combined symptoms and clinical findings.\(^{127}\) With respect to test-retest factors, we recently evaluated intra-observer reliability for the AL score and found it to be stable over time for patients with subacromial pain (ICC = 0.91, unpublished data).

Another aspect of summary scores is that there could be a risk of loss of information\(^57\). A change can occur within and between items without changing the total score.

The RCT did not include a generic instrument. The lack of such an instrument could be a weakness, risking to conclude about efficacy, without knowing if the perceived general health of the included patients has had an influence. Other aspects of generic instruments for patients with subacromial pain and shoulder problems have been reported. Gill and Feinstein reported difficulties in finding a generic instrument that was valid for patients with subacromial pain\(^51\). Beaton et al. compared a disease specific and a generic instrument, and reported that the physical function dimension in the SF-36 was not sensitive to the disability experience by people who have problems
related to the shoulder. They highlighted the concern that the generic instruments might not be sensitive enough to patients with shoulder problems and further research is needed to determine if that is the case or if patients with shoulder problems truly are less disabled than those who have other musculoskeletal problems. Di Fabio et al. evaluated physiotherapy for patients with subacromial pain and concluded in line with this.

By combining the three scores in the analysis, the consequence of unknown possible measurement error of each score is decreased, but this can also have led to less sensitivity which underestimated the real effect. In other words, this approach is more conservative, not risking to overestimate a possible difference. To estimate the overall clinical significance of the treatments, the proportions of patients reaching a satisfactory result and their self evaluation was reported at the end-point. The difference between treatment groups in the score comparison was not seen using the satisfactory cut-off or reflected in the patient self-evaluation at 12 months.

**Implications for clinical practice**

The diagnostic procedure used in this thesis to define patients with subacromial pain, was experienced as practicable in the everyday practice. Positive clinical findings when using the manoeuvres and tests to reproduce the subacromial pain, was always followed by a positive Neer impingement test. This subacromial injection of anaesthetic is now more often used in everyday practice, outside this research, to clarify how much of a patient’s experienced problems could be attributable to subacromial structures. This has increased the collaboration between GPs and PTs.

Even if the digital dynamometer and the conventional spring-balance yielded almost the same results in aspects of validity and reliability, there were some other valuable experiences. The test-leaders expressed that the digital dynamometer was easier to use when reading the values. The use of a secured equipment, the “pull-force”, is recommended since it was easier to perform both by test-leaders and by test-persons. This could also be more suitable when used by patients where pain is involved, since the patients are more in control with the ‘pull-force’. Further, the reliability was not influenced by the use of a maximum value or a mean of three repetitions. However if the strength test is part of a summary score like the CM score where the goal is to reach as many points as possible, it seems reasonable to use the maximum value.
All the scores used in the RCT were able to evaluate a difference both within and between the groups and seem valid to measure change for patients with subacromial pain. All three could be used in clinical practice in the absence of knowledge of the existence of a better score that should be recommended.

The findings of the large number of treatments that are possible and trusted choices, even though the research is limited, makes us wonder how many of them that are unjustified to use for patients with subacromial pain. In praxis the treatments found to have some evidence for efficacy should be preferred over less supported treatments. It is important to remember, however, the difference between lack of evidence and evidence for inefficacy. Due to the findings of evidence for short-term efficacy for corticosteroids injected in the subacromial bursa and for acupuncture in combination with home-exercises, these treatments are recommended for patients with subacromial pain. Since the natural course in unknown, it is hard to state how these treatments influence the long-term changes.

The exercise programme was, according to the patients, easy to perform and no large divergences from the every day recommendation were reported. The latter could be influenced by the continuous follow-up and the awareness of being part of a research study.

Perhaps the first line management in primary care should be shifted to PTs, as suggested in a recent study where similar effectiveness for PT treatments and local steroid injections into the subacromial space were reported. Those receiving physiotherapy had fewer re-consultations with a GP for additional treatment and they suggested that local steroid injections could be used when needed for pain control\textsuperscript{59}. This implies that the PT must refer patients to the GP, which in the current management is more unusual than the other way around, as reported in the questionnaire study.

The findings in this thesis support that most of these patients could benefit from primary care management, and that fewer than 10\% of the patients in the RCT needed surgery.

**Future research of interest**

Future research is needed in the field of subacromial pain and several areas are of interest. One is the development and evaluation of more sophisticated diagnostic tests that could be used in primary care, since the process of diagnosis is the link between examination findings and interventions. A reliability study of the tests for subacromial pain is about to start.
Further knowledge and understanding of the natural course of subacromial pain is also essential to be able to compare additional effects from interventions. The main part of the treatments used by PTs needs to be explored further. A study comparing the GP treatment with definitive evidence, corticosteroids, and with acupuncture combined with exercises, are already running to contribute to the answer of who should be responsible for first-line management in primary care.

A comparison of different instruments’ ability to measure change as well as other methodological aspects are important for the future choice of outcome measures and instruments to be used when evaluating patients with subacromial pain.
CONCLUSIONS

This thesis provides further knowledge about how to diagnose and treat patients with subacromial pain in primary care and it seems likely that most of these patients benefit from primary care management.

In general, this thesis describes the primary care management of patients with subacromial pain and provides scientific evidence for GPs to use corticosteroid injection and for PTs to use acupuncture combined with home exercises, when treating these patients.

- General practitioners and PTs have a uniform diagnostic approach in Swedish primary care.

- The most probable choices of treatment for patients with subacromial pain were NSAIDs, and corticosteroids injected in the subacromial bursa for general practitioners, and movement exercises together with ergonomics for physiotherapists, but most treatments were probable choices, reflecting an uncertainty about the different treatments’ effectiveness.

- The treatments most trusted by GPs and/or PTs were corticosteroids, NSAIDs, ergonomics/adjustments at work, movement exercises/mobilisation and acupuncture.

- Only corticosteroid injections into the subacromial bursa had definitive evidence for short term efficacy.

- The number of studies evaluating PT treatments were limited and for the first time acupuncture had tentative evidence for short term efficacy.

- Therapeutic ultrasound was concluded to be ineffective for patients with subacromial pain.

- There was a weak association between trusted treatments and available scientific evidence.
Conclusions

- A digital dynamometer can replace the conventional spring-balance in the standardised strength test in the CM score.

- An almost perfect agreement was found for intra- and inter-observer reliability in young shoulder-healthy persons performing the standardised strength test in the CM score, regardless of whether a 'resisted-force' or a 'pull-force' were used or if calculated with mean or maximum values.

- Acupuncture combined with home exercises was better than therapeutic ultrasound combined with home exercises, especially in the short term, for decreasing pain and improving function for patients with subacromial pain.

- The significant larger improvements with acupuncture combined with home exercises, together with the concluded tentative evidence from the systematic review, makes the evidence for efficacy of acupuncture more definitive, especially for short-term, when treating patients with subacromial pain.

- The early improvements continued to increase independently of treatment and most of the patients reached a satisfactory result and experienced large improvement or complete recovery after 12 months. This interpreted as a combination of treatment effect and the natural course.
SUMMARY IN SWEDISH

Syftet med avhandlingen var att beskriva diagnostiken och utvärdera handläggningen i primärvård av patienter med subacromial smärta.


Distriktsläkare och distriktssjukgymnaster visade sig använda en likartad diagnostik. Det troligaste valet av behandling för distriktsläkare var anti-inflammatoriska läkemedel och kortisoninjektion i den subacromiala bursan och för distriktssjukgymnaster rörelseträning samt ergonomiska åtgärder. Dock var de flesta behandlingsalternativen troliga val, vilket tolkas som en osäkerhet om behandlingarnas effekt.


En digital dynamometer kan ersätta den konventionella fjädervägen i det standardiserade styrketestet. En nästan perfekt överensstämmelse vad gäller både intra- och interbedömarreliabilitet vid test av unga skulderfriska personer, oberoende av om en ”håll emot-” eller ”dragteknik” användes eller om medel- eller maxvärdan användes vid beräkningen av överensstämmelse.
I den randomiserade kliniska studien inkluderades 85 patienter. Tre utvärderingsinstrument, kombinerade i resultatanalysen, utvärderade förändringen under en uppföljningsperiod på 12 månader tillsammans med patienternas subjektiva skattning av resultatet.

Resultaten visade att akupunktur i kombination med hemträning är att föredra. Båda behandlingsgrupperna förbättrades signifikant och fortsatte förbättras över tid oberoende av behandling. De flesta patienter uppnådde ett tillfredsställande behandlingsresultat efter 12 månader. Åtminstone tre fjärde delar i varje behandlingsgrupp skattade sig mycket förbättrade eller helt återställda. Detta tolkas som en behandlingseffekt i kombination med naturläpplöpet.

Avhandlingen har beskrivit handläggningen i primärvård av patienter med subacromial smärta och har bidragit med vetenskapliga bevis för distriktssläkare att behandla med kortisoninjektion i subacromiala bursan och för distriktssjukgymnaster att behandla med akupunktur kombinerat med hemträning.
**DESCRIPTION OF CONTRIBUTION**

**Paper I**
- **Design**: Kajsa Johansson, Mats Foldevi
- **Data collection**: Kajsa Johansson
- **Data analysis**: Kajsa Johansson, Lars Adolfsson, Mats Foldevi
- **Manuscript writing**: Kajsa Johansson
- **Manuscript revision**: Lars Adolfsson, Mats Foldevi

**Paper II**
- **Design**: Kajsa Johansson, Lars Adolfsson, Mats Foldevi, Birgitta Öberg
- **Data collection**: Kajsa Johansson, Lars Adolfsson
- **Data analysis**: Kajsa Johansson
- **Manuscript writing**: Kajsa Johansson
- **Manuscript revision**: Lars Adolfsson, Mats Foldevi, Birgitta Öberg

**Paper III**
- **Design**: Kajsa Johansson
- **Data collection**: Helen Bergström, Åsa Johansson
- **Data analysis**: Kajsa Johansson, Lars Adolfsson
- **Manuscript writing**: Kajsa Johansson
- **Manuscript revision**: Lars Adolfsson

**Paper IV**
- **Design**: Kajsa Johansson, Lars Adolfsson, Mats Foldevi
- **Data collection**: Kajsa Johansson
- **Data analysis**: Kajsa Johansson, Mats Foldevi
- **Manuscript writing**: Kajsa Johansson
- **Manuscript revision**: Lars Adolfsson, Mats Foldevi
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Appendix A

Diagnostic tests for reproduction of subacromial pain:

**Neer impingement sign**
Passive flexion of the shoulder combined with internal rotation, and prevention of elevation of the scapula by a manual depression

**Hawkins-Kennedy impingement sign**
Passive internal rotation with the shoulder and elbow in 90° flexion, elevation of scapula is prevented by a manual depression

**Jobe supraspinatus test**
The arms in 90° elevation in the plane of scapula and the thumb pointing downwards (internal rotation). The examiner pushes downward while asking the patient to resist the pressure

**Patte manoeuvre**
The examiner supports the patient’s bent elbow with the shoulder in 90° flexion and internal rotation. Resistance against the patient’s external rotation
Appendix B

Inclusion and exclusion criteria in paper IV

Compulsory inclusion criteria:
- 30-65 years of age
- typical history; pain located in the proximal lateral aspect of the upper arm (C5 dermatome), especially during arm elevation
- a positive Neer impingement test (subacromial injection of anaesthetic)
- at least two-months duration of the current episode

Three of the following four inclusion criteria must be positive:
- Hawkins-Kennedy impingement sign
- Jobe supraspinatus test (in 90° of abduction in the scapular plane)
- Neer impingement sign
- painful arc between 60-120° during active abduction

Exclusion criteria:
- radiological findings: malignancy, osteoarthritis of the gleno-humeral joint, skeletal abnormalities decreasing the subacromial space (bony spurs, osteophytes)
- known or suspected polyarthritis, rheumatoid arthritis or diagnosed fibromyalgia
- previous fractures of any bone in the shoulder complex and/or shoulder surgery on the affected side
- dislocation of the gleno-humeral- or the clavicular joints on the affected side
- history or current clinical findings of instability in any joint of the shoulder-complex (negative apprehension sign - relocation test for exclusion of ventral instability of the gleno-humeral joint)
- suspicion of frozen shoulder: time-dependent decreased range of movements following the capsular pattern (external rotation – abduction - internal rotation) and pain during intra-articular mobilisation
- problems from the cervical spine. Shoulder symptoms reproduced with neck movements and/or a positive test for the foramina intervertebralia (pain and / or neurological symptoms during manual extension combined with manual lateral flexion and rotation toward the tested side)
• having received any of the treatment alternatives in the study earlier for the current problem
• having received a corticosteroid injection during the last two months for the current problem
• a clinical picture of ruptured rotator cuff (trauma, pronounced weakness, atrophy)
• acute subacromial bursitis, making a clinical examination impossible due to pain
• difficulty participating in data collection due to communication problems
Appendix C

Home exercises (paper IV)

Exercise programme I:

Perform the program once a day between week 1 and 5. Note each time in your home-exercise compliance log.

1. Seated under for example a hatrack, elevate the arms alternately by pulling in the sling (use a skipping-rope or similar)

   20 repetitions

2. Lay on the side, rest your upper arm along the side of the trunk. Put a small pillow in the axilla and bend your elbow to about 90°, rotate externally and then lower it slowly

   30 repetitions
Home exercises (paper IV)

Exercise programme II:

Perform the program once every two days between week 4 and 5.
Note each time in your home-exercise compliance log.

Strengthening exercises:
3. Bend your elbow to 90°. Stand in a doorpost and press your fist against it in the following directions: (use a pillow in the axilla, no movement shall occur)

10 repetitions in each direction

- Forward
- Backward
- Internal rotation
- External rotation
- To the side (abduction)

4. Standing with both elbows bent to 90°.
   External rotation with a tubing, and return slowly to starting position. Put pillows or towels in the axilla

15 repetitions x 2

Pain during these exercises should not remain more than 10 to 15 minutes after the end of program. If a longer duration is experienced decrease either the resistance or the force produced.