

# Outcome measures and treatment of shoulder capsulitis (frozen shoulder) by corticosteroid injections

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Thesis for the Degree of Philosophiae Doctor (PhD)  
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(frozen shoulder) by corticosteroid injections**

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## Scientific environment

This thesis has been accomplished within the framework of the PhD programme at the Faculty of Medicine, Department of Global Public Health and Primary Care, University of Bergen. The clinical part of the project was executed at Rolland legesenter, a primary care centre with four general practitioners.

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# 1. Acknowledgements

Musculoskeletal disorders has always been my field of interest since I graduated from physiotherapy school back in 1976. This interest continued to grow after medical school and while working as a general practitioner. I had great privilege of having Professor Alice Kvåle to be my local supervisor for the MSc Orthopaedic medicine (now musculoskeletal medicine) from Middlesex University, London in 2004-2006. I learned a lot from Prof. Kvåle during this MSc period. She has been a compassionate and understanding guide. She encouraged me to continue the process since I had already done much work on frozen shoulder. That is how I silently entered into the PhD schooling. At that time I did not have the faintest idea what a randomised controlled trial meant, doing it alone, in terms of time and energy.

Friends have often asked me what use I have of doing a PhD at this stage (read age). I have never thought in those terms. It was too late for any academic carrier anyway. I started out because I realised that I had strong presumptions about results of my work regarding musculoskeletal patients. This did not fit-in the general picture painted by the literature that the musculoskeletal patients are difficult to diagnose and treat. I needed to understand more and felt therefore a strong need for critical appraisal of what I was doing and what others were claiming to achieve. There have been many ups and downs during this journey. Very slow recruitment of participants was a huge trial of patience. It took four years to recruit 106 patients for this project. However, gradually things became easier and I could see the light at the end of the tunnel. I have never looked back since then and feel satisfied of having taken this journey. It has been a very interesting and learning process and it has made me more humble and self-critical regarding my knowledge, competency and certainties in clinical decisions regarding this group of patients.

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and my children Shruti and Shaurya. This project would have never been fulfilled without their continuous support.

## **Abstract**

### **1.1 English Summary**

#### **Background**

Shoulder adhesive capsulitis, also called frozen shoulder, is a painful chronic condition causing reduced movement at the gleno-humeral joint in several planes affecting shoulder function. Shoulder adhesive capsulitis can be a challenge in both diagnosis and management. As range of motion is an important criterion in follow-up of these patients, high intertester reliability for measurement of range of motion is essential in an environment where a fellow colleague may follow the patient further. There is a need for an evidence-based easy and pragmatic treatment approach for this condition in general practice. Intraarticular corticosteroid injections by posterior approach using landmarks is an important treatment modality for this condition in primary care that needs to be explored further. Awareness of that comorbidity may affect outcome in musculoskeletal conditions is important to keep in mind.

#### **Objectives**

1. To examine intertester reliability of measuring passive range of motion (PROM) bilaterally using plurimeter in patients with adhesive shoulder capsulitis over an 8-weeks period and examine whether the measurement error remained the same.
2. Investigate the effect, if any, of multiple corticosteroid injections with distension as compared to corticosteroid injections alone and to treatment-as-usual.
3. Determine whether treatment outcome can be predicted by subjective health complaints and neuroticism in patients with frozen shoulder as measured by Shoulder Pain and Disability Index (SPADI) and change in SPADI.



**Design/method**

The first study is a prospective intertester reliability study for measurement of PROM in the shoulder of 50 patients with frozen shoulder. Two testers measured PROM with a pluri-meter several times during an 8-week period. The second study is a randomised controlled single blinded three-armed trial comparing effect of two different interventions with treatment-as-usual in 106 patients. Treatment-as-usual in this scenario means any other conservative treatment like non-steroid anti-inflammatory drugs, painkillers, physiotherapy and acupuncture but no steroids to be used orally or as injection. The intervention consisted of four intraarticular steroid injections with or without distension. SPADI was the primary outcome measure, Numerical Pain Rating Scale (NPRS) secondary, and PROM, the tertiary outcome measure. The third study is observational where we investigated whether comorbid factors measured with the questionnaires Subjective Health Complaints (SHC) and Neuroticism can predict outcome of the given treatment in 105 patients. We collected data from patients answering the questionnaires at baseline and at the end of 8-week clinical follow up.

**Results**

**Study I:** Intertester agreements varied from very good to excellent for PROM for all three time-points for the affected arm. Very reliable to excellent values were achieved for intraclass correlation coefficient (ICC 2.1). The measurement error remained the same throughout.

**Study II:** At short-term (4 and 8 weeks) statistically significant differences ( $p < 0.01$ ) in change scores for SPADI, NPRS and PROM were observed when comparing those receiving corticosteroid injections, with or without distension, to treatment-as-usual. At long-term (12 months) there was no difference between the three groups for SPADI ( $p > 0.05$ ). A large effect size (ES) was observed between both injection groups and treatment-as-usual (ES 1.2) at short term. The effect size between the injection groups and treatment-as-usual was reduced to low (ES 0.3 and 0.4) at 12 months. The difference between the two injection groups at short-term (4-and 8

weeks) or long-term (12 months) was not statistically significant. All participants recovered.

**Study III:** Little comorbidity was observed in the 105 patients included in the study, as measured with the questionnaire Subjective Health Complaints (SHC). Significant predictive power ( $p < 0.001$ ) was exhibited by the Pseudoneurology subscale in SHC for outcome at 8 weeks. All included patients scored within normal range on Neuroticism.

### **Conclusion**

**Study I:** Intertester reliability between the two testers over a time-period of 8 weeks measuring PROM in patients with adhesive shoulder capsulitis with a plurimeter was very good. This method can reliably determine passive range of motion in this patient population and be a reliable outcome measure.

**Study II:** This randomised controlled trial indicated that four serial injections with corticosteroid with or without distension during 8 weeks were better than treatment-as-usual in treatment of patients with adhesive shoulder capsulitis. However, no difference was found between any of the groups at 12 months, indicating that natural healing takes place independent of treatment.

**Study III:** Comorbidity as measured by the Pseudoneurology subscale in the SHC questionnaire did predict the treatment outcome in frozen shoulder as measured by SPADI at 8 weeks, whereas when measured by change in SPADI from baseline to 8 weeks, it did not. Comorbidity may affect symptoms but do not predict the rate of recovery.

## 1.2 Norwegian summary – norsk sammendrag

### **Bakgrunn**

Skulder kapsulitt, også kalt frossen skulder, er en smertefull tilstand som forårsaker redusert bevegelighet i flere plan og påvirker skulder-funksjon. Skulder kapsulitt kan være en utfordring både diagnostisk og behandlingsmessig. Korrekt måling av passive bevegelser er derfor viktig i oppfølging av pasienter der terapeuter ofte må følge opp andres pasienter med frossen skulder. Det er behov for evidensbaserte pragmatiske løsninger for behandling av frossen skulder i allmennpraksis. Intraartikulære steroid injeksjoner etter landemerker med bakre tilgang er en pragmatisk konservativ behandlingsmetode for frossen skulder i allmennpraksis. En bør ta i betraktning at komorbiditet kan påvirke utfallet av behandling i muskelskjelettlidelser.

### **Formål**

1. Undersøke intertester reliabilitet for måling av passive bevegelsesutslag (PROM) bilateralt med plurimeter hos pasienter med frossen skulder over en 8 ukers periode, samt undersøke om målefeil forblir uendret.
2. Undersøke om en serie med fire steroid-injeksjoner med eller uten distensjon påvirker forløp av frossen skulder sammenlignet med vanlig brukt konservativ behandling uten steroid.
3. Utforske om subjektive helseplager og nevrotisisme kan forutsi utfall av behandling målt med Shoulder Pain and Disability Index (SPADI) og endring i SPADI.

### **Design/metode**

Første studie er en prospektiv intertester reliabilitetsstudie for måling av PROM på skulder hos 50 pasienter med frossen skulder. To testere målte PROM med plurimeter flere ganger i løpet av 8 uker. I den andre studien som er en randomisert kontrollert studie med 106 deltakere, har vi sammenlignet to former for injeksjoner, steroid

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injeksjoner uten distensjon og med distensjon, mot vanlig brukt konservativ behandling (kontrollgruppen) som for eksempel ikke-steroid betennelsesdempende midler, smertestillende, fysioterapi og akupunktur. Deltakerne i intervensjonsgruppene fikk fire intraartikulær steroid injeksjoner med og uten distensjon over en 8 ukers periode. SPADI ble brukt som primært utfallsmål, numerisk smerteskala (Numerical Pain Rating Scale (NPRS) sekundært og PROM som tertiært utfallsmål.

Den tredje studien er en observasjonsstudiet av 105 deltakere der vi undersøkte om subjektive helseplager og nevrotisisme kan forutsi utfall av gitt behandling.

Pasientene besvarte spørreskjemaene ved start og etter 8 uker.

## **Resultater**

**Studie I:** Samsvar ved måling av PROM i affisert skulder ved test-tidspunktene var enten veldig god eller utmerket. Fra veldig pålitelig til utmerkete verdier ble registrert for intraklasse korrelasjonskoeffisient (ICC 2.1) og målefeilen var den samme i testperioden.

**Studie II:** På kort sikt (4 og 8 uker) ble det påvist statistisk signifikant forskjell ( $p < 0.01$ ) for endring i SPADI, for NPRS og PROM når steroid injeksjoner uten eller med distensjon ble sammenlignet med vanlig konservativ behandling (kontrollgruppen). Det var ingen forskjell mellom de tre gruppene på lang sikt (12 måneder) for SPADI ( $p > 0.05$ ).

Det ble registrert stor effekt-størrelse (ES) på kort sikt mellom injeksjonsgruppene og gruppen som fikk vanlig konservativ behandling (kontrollgruppen). Denne effekt-størrelsen mellom injeksjonsgruppene og kontrollgruppen ble lav (ES 0,3 og 0,4) på lang sikt (12 måneder). Det var ingen statistisk signifikant forskjell mellom injeksjonsgruppene hverken på kort sikt (4 og 8 uker) eller på lang sikt (12 måneder). Alle ble like bra til slutt.

**Studie III:** Det ble funnet lite komorbiditet hos de 105 pasientene i denne studien, målt med spørreskjema vedrørende Subjektive helseplager (SHC). Signifikant prediktiv verdi ( $p < 0.001$ ) ble demonstrert kun ved Pseudonevrologi subskalaen i SHC for utfall ved 8 uker. Deltakerne viste lite forekomst av Nevrotisisme.

**Konklusjon**

**Studie I:** Svært god intertester reliabilitet mellom de to testerne over en periode på 8 uker ble registrert ved måling av passive bevegelsesutslag med plurimeter hos pasienter med frossen skulder. Denne målemetoden kan brukes som et pålitelig utfallsmål av passive bevegelsesutslag.

**Studie II:** Denne randomiserte kontrollerte studien på pasienter med frossen skulder indikerer at fire intraartikulære steroid injeksjoner i serie med eller uten distensjon var bedre enn vanlig konservativ behandling i en periode på 8 uker. Ingen forskjell ble funnet mellom gruppene ved 12 måneder, noe som tyder på naturlig tilheling, uavhengig av gitt behandling.

**Studie III:** Komorbiditet målt med subskalaen Pseudonevrologi i spørreskjemaet SHC predikerte behandlingsutfall i frossen skulder målt med SPADI ved 8 uker, men ikke når målt i forhold til endring i SPADI fra utgangspunktet til 8 uker. Komorbiditet kan påvirke symptomer men ikke hvor fort de ble bedre.

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## List of publications

- I Sharma SP, Baerheim A, Kvale A. Passive range of motion in patients with adhesive shoulder capsulitis, an intertester reliability study over eight weeks. *BMC Musculoskelet Disord.* 2015;16:37.
  
- II Sharma SP, Baerheim A, Moe-Nilssen R, Kvale A. Adhesive capsulitis of the shoulder, treatment with corticosteroid, corticosteroid with distension or treatment-as-usual; a randomised controlled trial in primary care. *BMC Musculoskelet Disord.* 2016;17(1):232.
  
- III Sharma SP, Moe-Nilssen R, Kvåle A, Baerheim A. Predicting outcome in frozen shoulder (shoulder capsulitis) in presence of comorbidity as measured with subjective health complaints and neuroticism. *BMC Musculoskelet Disord.* 2017;18(380):7.

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## Abbreviations

ANCOVA	Analysis of covariance
EPQ_R	Eysenck Personality Questionnaire- Revised short form
ES	Effect size
ICC	Intraclass correlation coefficient
ITT	Intention to treat
MRI	Magnetic resonance imaging
MUA	Manipulation under anaesthesia
NPRS	Numerical Pain Rating Scale
NSAID	Non-steroid anti-inflammatory drug
PROM	Passive range of motion
RCT	Randomised controlled trial
ROM	Range of motion
SF-36	Short Form Survey-36
SHC	Subjective Health Complaints
SPADI	Shoulder Pain and Disability Index
VAS	Visual Analogue Scale
VRS	Visual Rating Scale

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## 2. Introduction - background

Shoulder adhesive capsulitis, also called frozen shoulder, is a painful chronic condition causing reduced movement at the gleno-humeral joint in several planes. Apparently, restricted active movements have been confused with characteristically painful restricted active and passive movements in frozen shoulder, leading to over diagnosis. A need for standardisation of diagnostic definition has been emphasised (1, 2). The condition was first described by Dupley in 1896, later termed as “frozen shoulder” by Codman in 1934 and described as “difficult to define, difficult to treat and difficult to explain” (3) and as “adhesive capsulitis” by Neviaser in 1945 (4). Some authors suggest abandoning the term adhesive capsulitis as adhesions are not seen on arthroscopy in patients with frozen shoulder, but instead synovitis, thickening and contracture of the gleno-humeral joint capsule can be seen (5-8). “The surgical findings showed a consistent alteration in the rotator interval and coracohumeral ligament. The rotator interval was obliterated, and the coracohumeral ligament was transformed into a tough contracted band” (9). Bunker suggested the term contracture of the shoulder (10), which was further modified to be called frozen shoulder contracture syndrome (11). In this thesis, the terms ‘frozen shoulder’, ‘shoulder capsulitis’ and ‘adhesive shoulder capsulitis’ will be used interchangeably.

Frozen shoulder may be primary or secondary, a term introduced by Lundberg (12). Primary refers to cases without any apparent cause, while secondary is often associated with trauma or other systemic conditions such as diabetes, thyroid disease, cardiovascular disease and hemiparesis, among which diabetes is the largest group with a severe and protracted disease course (6, 13-15). Others have suggested further division of secondary frozen shoulder into three subcategories: intrinsic, extrinsic and systemic types (2). Intrinsic type occurs in association with rotator cuff disorders (tendonitis and partial or full thickness tears), biceps tendonitis or calcific tendonitis with calcific deposits within the subacromial space/rotator cuff tendons). In extrinsic type, there is an association with an abnormality remote to the shoulder itself, such as

previous ipsilateral breast surgery, cervical radiculopathy, chest wall tumor, previous cerebrovascular accident or more local extrinsic disorders such as previous humeral shaft fractures, acromioclavicular arthritis or clavicle fractures. The systemic types occur in association with systemic disorders such as diabetes mellitus, hypo- and hyperthyroidism and heart disease, but the association may not be definite.

## 2.1 Epidemiology

Frozen shoulder affects 2-5% of the general population (15-17) and about 11-14% of diabetic patients (16, 18). Frozen shoulder affects mostly middle-aged persons (6, 19, 20) and women in their fifties are commonly affected (16, 17). Both shoulders may be affected simultaneously or one of the shoulders may be affected later (16, 17, 21-23). Genetic factors may play a role in the aetiology of frozen shoulder (24). A strong association between shoulder capsulitis and Dupuytren's disease attributed to genetic factors has been shown by earlier studies (6, 7, 25, 26). Frozen shoulder may affect activities of daily living causing dysfunction in the aged population and may lead to increased sick leave in the working population (27).

## 2.2 Pathoanatomy, pathophysiology and histopathology

The pathogenesis of frozen shoulder is not well understood and various theories have been put forward. Most commonly, there is synovitis and contracture of capsule leading to restriction of movements in primary frozen shoulders. Contracture of the antero-superior capsule, antero-inferior capsule and postero-superior capsule leads to most restriction of lateral rotation in adduction, lateral rotation in abduction and medial rotation respectively (1). Structures commonly involved are gleno-humeral ligament, coraco-humeral ligament and joint capsule in the rotator interval, also confirmed by magnetic resonance imaging (MRI) and cadaver dissection (28-30).

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Synovial tissue between the long head of biceps and the rotator interval has shown vascular proliferation with fibrin and fibrous tissue in frozen shoulders (31). Histologically there is presence of both chronic inflammatory cell infiltrate and fibrosis in biopsies during capsulotomy (32). These findings are similar in Dupuytren's contracture with a mature type III collagen containing fibroblasts and myofibroblasts (7). It is suggested that cytokines and growth factors induce production of fibroblasts, which leads to production of type III collagen. Cytokines may also stimulate angiogenesis giving the new blood vessel appearance on the capsular surface on arthroscopy. Capsular tissue has been found to contain increased mRNA for metalloproteinases, which can degrade the connective tissue matrix, and metalloproteinase inhibitor (33). Biopsies of capsules from adhesive capsulitis shoulders have revealed cytokines. These are transforming growth factor- $\beta$  and platelet-derived growth factor that may be involved in the inflammatory and fibrotic processes in adhesive capsulitis. Matrix-bound transforming growth factor- $\beta$  may act as a persistent stimulus, resulting in capsular fibrosis (34). Reduction of bone mineral density in primary frozen shoulder and similarity to Sudeck's syndrome has led to the assumption that it is an algoneurodystrophic process (35). The pain may be neurogenic and since the suprascapular nerve contains high proportion of sympathetic fibres supplying the joint, suprascapular nerve block can be used (36).

## 2.3 Natural course

Clinically, frozen shoulder may be divided into three phases (23): I) Painful phase lasting 2-9 months, pain predominant phase with increasing stiffness, II) Stiffening, freezing or predominant stiffening phase, lasting 4-12 months, where there is gradual reduction of pain but considerable restriction in range of motion (ROM), and III) Resolution or thawing phase, lasting 12-42 months with gradual improvement in ROM. Others have divided frozen shoulder into four stages relating to the results of arthroscopy and physical examination (37). The stiffness stage is usually related to the duration of the recovery stage. The total duration is longer than is generally

supposed (an average total of 30 months, in contrast to about 18 months as often postulated). Generally, a longer stiffness stage leads to a longer recovery stage (23). Despite the fact that frozen shoulder has been recognised for over 100 years there still remains a lack of reliable evidence on the natural and variable history of the condition (14). Codman and others have stated that frozen shoulder is a benign condition recovering within two years (3, 23, 38, 39), but this may not be true. In a long-term follow up study, 50% of patients still had pain after seven years while 60% had persistent stiffness (21). Nearly 50% will have a normal shoulder in the long term, while 35% will have persistent mild pain and some stiffness in the long term and only 6% will have severe symptoms (17). Another study estimated 7% to 15% of the patients to have some degree of ROM loss which patients were not aware of, while a few had functional disability (40). A Finnish study with 2-27 years follow-up showed that 94% of the idiopathic shoulders recovered to normal levels of function without treatment (41). The outcome differences may be a result of heterogeneous outcome measures.

## 2.4 Diagnosis

Frozen shoulder is essentially a clinical diagnosis based on the findings of passive range of motion (8, 42). ROM is often used as an outcome measure to demonstrate effect of the interventions in frozen shoulder (43-45). To ascertain the diagnosis, reliable ROM measurement, irrespective of the measuring instrument, is important. However, no consensus exists as to degree of restriction required in range of motion to diagnose frozen shoulder, leading to confusion in clinical diagnosis. Frozen shoulder remains mainly a clinical diagnosis for lack of other formal diagnostic criteria (46). Other authors include in diagnostic criteria exclusion of other pathologies like osteoarthritis of the gleno-humeral joint, dislocation and sarcomas and a normal radiograph (1, 11). Radiographs in frozen shoulder may depict significant loss of bone mineral density, but has good prognosis in the long term (47). Clinically there is a general painful restriction of active and passive movements.

Generally, there is a marked loss of external rotation with the arm in both neutral and abduction, which may not reach 90 degrees (1). Cyriax used the term “capsular pattern” to emphasize that in frozen shoulder passive external rotation is most limited and passive internal rotation least, while reduction of passive abduction is somewhere in between (48) (page 33). This is generally true, but there may be exceptions, as in some patients, passive internal rotation may be more restricted than external rotation.

MRI can show synovial and capsular thickening in frozen shoulder (49). Thickening of coracohumeral ligament and capsule in rotator interval is a characteristic finding in MRI arthrography in frozen shoulder (29). MRI is not imperative for diagnosis and may result in false negatives.

Considering differential diagnosis, associated conditions like calcified tendinopathies, fractures of greater tuberosity and tears of rotator cuff and early osteoarthritis of the glenohumeral joint can be present with frozen shoulder. Red flags are rare, but one should bear in mind osteosarcoma and possibility of metastases. Plane radiograph or ultrasound examination is sufficient to exclude these pathologies (1, 11).

## 2.5 Management

Treatment of frozen shoulder aims to relieve pain and regain function by increasing range of motion. There are many types of treatment used to manage the frozen shoulder, but there is lack of consensus on best management of this painful condition (50). Several conservative treatment strategies are used such as non-steroid anti-inflammatory drugs, physiotherapy in its various forms, acupuncture, per oral prednisolone, intraarticular corticosteroid injection with or without distension, and hyaluronic acid injections. Manipulation under anaesthesia and capsulotomy is used for refractory cases (51, 52).

### **2.5.1 Non-steroid anti-inflammatory drugs (NSAIDs)**

Use of NSAIDs may relieve pain in frozen shoulder. Three trials in a systematic review demonstrated superior short-term efficacy of NSAIDs in comparison with placebo intervention for shoulder pain. Fourteen trials comparing two types of NSAIDs showed no conclusive evidence in favour of any particular NSAID with respect to efficacy or tolerability (43).

### **2.5.2 Physiotherapy**

Physiotherapy is commonly prescribed in frozen shoulder and passive mobilisation and stretching is commonly used. This however, may have negative effects in the inflammatory painful phase when analgesic treatment and modified activity in pain-free range is best suited (1). Efficacy of physiotherapy in frozen shoulder, particularly in the painful phase, is debated. According to a Cochrane review: "Based on 25 clinically heterogeneous trials, we are uncertain of the effect of manual therapy or exercise when not delivered together, as most reported differences between groups were not clinically or statistically significant, and the evidence is mostly of low quality" (53). Another study did not find any difference in outcome regardless of the technique of mobilization used (54). In a prospective study of 77 patients with idiopathic frozen shoulder syndrome, effect of intensive physical rehabilitation treatment, including passive stretching and manual mobilization (stretching group), were compared with supportive therapy and exercises within the pain limits (watchful waiting group). Watchful waiting yielded better outcomes than intensive physical therapy and passive stretching in patients with frozen shoulder (55).

In a retrospective study, Jewell et al. demonstrated positive effect of mobilization and exercise for patients with adhesive capsulitis while ultrasound, massage, iontophoresis, and phonophoresis reduced the likelihood of a favourable outcome (56). Short wave diathermy combined with stretching and laser therapy combined

with home exercise, may be beneficial in management of frozen shoulder (57, 58). In a prospective outcome study for conservative treatment including physiotherapy and passive stretching, positive results were seen in 90% of the patients (59). Better results were registered in a 3.8 years follow-up of 110 shoulders by moderate mobilization than mobilization under anaesthesia (60). Another study found equivalent effect of physiotherapy and corticosteroid injection with cautious interpretation of results due to heterogeneity of studies included in the review (61). In a review, Struyf et al. have discussed the role of physiotherapy in frozen shoulder and state that although some physiotherapeutic interventions show evidence regarding reducing pain or increasing mobility, there is little evidence to suggest that the disease prognosis is affected. A change in physiotherapy approach to these patients is therefore suggested (62).

### **2.5.3 Oral corticosteroids**

Oral corticosteroids can be helpful in reducing pain in the painful phase of frozen shoulder. In a study by Binder et al. 10mg of daily prednisolone improved pain at night and patients had a rapid initial recovery, but no difference was registered after 5 months compared to the control group (63). This finding is supported in a prospective double-blind randomised placebo-controlled trial in 50 patients administering 30 mg prednisolone for three weeks. Significant reduction in pain and better function was revealed in the steroid group at 3 and 6 weeks, but effects were not maintained after 6 weeks (64). In a systematic Cochrane review, there is evidence of significant short-term benefits in pain, range of motion and function in adhesive capsulitis, but the effect may not be maintained beyond 6 weeks (65).

### **2.5.4 Intraarticular corticosteroid injection**

Many studies have demonstrated short-term benefit of intraarticular corticosteroid injection in reducing pain and improving function in frozen shoulder (45, 66-70). A



meta-analysis concluded, “Intraarticular injection for adhesive capsulitis may be beneficial although their effect may be small and not well-maintained” (71). Therapists very often combine physiotherapy with intraarticular corticosteroid to enhance the treatment effect (66, 69).

It is claimed that injection technique regarding anterior or posterior approach and accuracy of placement of needle may play a role while others have a different opinion (72). By accuracy of placement we mean that the opening of the needle is between cartilage and shoulder capsule. In practice, it means that the physician has to touch the bone (humeral head) before starting to inject the solution to be certain that the needle end is intraarticular. In anterior approach, patient can be sitting or in half-lying. The needle, 4 to 5 cm long 21 gauge, is inserted 1-2 cm lateral to the coracoid process at 45 degrees (73, 74). The posterior approach by landmarks in this thesis is described under Intervention in section 3.6 (72, 74). In a cadaver study, 80% accuracy rate was achieved by anterior approach as compared to 50% by posterior approach (75). White et al. found better results with anterior approach than posterior approach (76). Anatomically correctly placed injection gave better results in two studies (77, 78). Corticosteroid injection in rotator interval gave clinical important improvement in function measured by Shoulder Pain and Disability Index (SPADI) after 12 weeks (79). In another study, no difference was found between intraarticular and rotator interval ultrasound guided corticosteroid injection (80). Some suggest that ultrasound guided intraarticular corticosteroid injections give better outcome than injections given by landmarks (81). In another study, the difference between ultrasound-guided intraarticular corticosteroid injection and intraarticular injection by landmarks did not last beyond 3 weeks (82). A Cochrane review did not find any added benefit by ultrasound-guided corticosteroid injections in shoulder pain (83).

Intraarticular steroid dose has also been compared to assess difference between low and high dose. De Jong et al. found better outcome with higher dose comparing 10 mg to 40 mg Triamcinolone acetonide (84), while another study did not find any difference between 20 mg and 40 mg dose (85). Most of the studies on intraarticular

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corticosteroid injections have been on single intraarticular injection and there is a debate whether multiple injections are more beneficial than single intraarticular injection (26). There are a few studies on multiple intraarticular injections in frozen shoulder, but of varying quality and done around 20-30 years ago (17, 67, 84, 86-91). A review on multiple intraarticular corticosteroid injections favours multiple injections in shoulder capsulitis (26).

### **2.5.5 Intraarticular corticosteroid injection with distension (hydrodilatation)**

Distension by intraarticular normal saline injection without corticosteroid was first tried to stretch the capsule. Sixty-four stiff shoulders were treated by injecting 20 ml of saline water with contrast in a case series study in 1965 (92). Vad et al. reported good results in 19 patients treated by distension and capsular rupture in a non-randomised controlled trial study (93). In a case series, Betamethasone along with 40 ml of saline water intraarticular injection by anterior approach to rupture capsule as an office procedure was used (94). Good results were reported by hydrodilatation in two other studies (95, 96). Since these are case series without randomisation, there is a room for bias. Jacobs et al. compared intraarticular steroid injection against capsular distension with liquid and air combined and intraarticular steroids and liquid and air distension. The difference between the groups was insignificant (87). The volume of injected air was small as compared with dilatation with saline of much larger volume in other earlier mentioned studies. The distending capacity of the injected air, being small in volume, is therefore questionable. In a small randomised controlled trial (RCT) comparing intraarticular steroid injection with steroid and distension with posterior approach, Gam et al. (90) found larger increase in range of motion as compared to intraarticular steroid only. One RCT found better improvement in function, pain and range of motion by intraarticular corticosteroid and distension than placebo (97). Corbeil et al. did not find any significant difference between distension with corticosteroids and corticosteroid alone in a double-blind prospective study of

45 patients with shoulder capsulitis (98). Multiple distensions with saline and steroids were beneficial up to two distensions, with no added benefit with the third distension (99). A Cochrane review found evidence that arthrographic distension with saline and steroids provided short-term benefit in pain, range of motion and function (100). Another study did not find any significant treatment difference resulting from distension with steroids than with intraarticular steroid alone (101). A meta-analysis found intraarticular steroid injection as effective as distension in improvement of shoulder function and reduction of pain (102). A recent review has concluded that the effectiveness of gleno-humeral joint distension was similar to intraarticular corticosteroid injection (103)

### **2.5.6 Manipulation under anaesthesia**

In manipulation under anaesthesia (MUA) a general anaesthetic is administered and the shoulder joint capsule is gently stretched by moving the humerus into flexion, abduction and then (optionally) moving the adducted shoulder into external rotation (104). Good results have been reported for MUA by some studies (105-108). However, an RCT did not show any difference between MUA and home exercises and the control group who did home exercises in 12 months (109). In another study, MUA did not enhance the benefit conferred by home exercises and there is therefore need for high-quality research studies (110). Combining corticosteroid injection with MUA did not yield any additional benefit (111). Complications can arise under MUA and in a post-manipulation arthroscopic study intraarticular lesions as hemarthrosis, iatrogenic superior labrum anterior posterior lesions, partial subscapularis tendon tears, anterior labral detachments and tears of the middle glenohumeral ligament were found (112).

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### 2.5.7 Arthroscopic capsular release

Arthroscopic capsular release consists of resecting the contractures in rotator interval, releasing coracohumeral ligament, anterior capsule, superior and middle glenohumeral ligaments and the subscapular bursa (1). Several studies have reported arthroscopic release as an effective and safe treatment for resistant frozen shoulder (113-117). It is also considered a cost effective procedure, restoring normal function and health related quality of life in most patients with frozen shoulder within 6 months (118). Arthroscopic capsular release compared with MUA in a systematic review concluded, that available evidence had low quality and that little benefit of capsular release was demonstrated instead of or in addition to MUA (119).

## 2.6 Frozen shoulder, quality of life and comorbidity

Adhesive capsulitis causes considerable pain and dysfunction, as measured with the disease-specific questionnaire SPADI, and quality of life measured with Short Form Survey-36 (SF-36) (120). Patients' own ranking regarding their general health in presence of shoulder pain is as high as in some of the medical conditions as heart failure, high blood pressure, acute heart infarction, diabetes and depression (121, 122). The duration and degree of symptoms were found to be prognostic factors for recovery from arm, neck and shoulder complaints in a systematic review (123). Another review found that longer duration and high degree of shoulder pain level partly, contributing to high SPADI scores (124) resulting in chronic shoulder pain (125), similar to other findings regarding severity of pain and longer duration causing chronification of shoulder pain (126). In patients with full thickness rotator cuff tears, patients' mental health may play an influential role on patient-reported pain and function (127). Patients with frozen shoulder experienced worsening of pain and dysfunction with comorbidity (15). Improvement in shoulder capsulitis leading to less pain and dysfunction may lead to betterment of general health. Most patients with

frozen shoulder experienced improved general health as measured by SF-36 after arthroscopic capsular release (128, 129).

Health complaints in chronic conditions can be measured by several questionnaires (130). The validated questionnaire Subjective Health Complaints (SHC), with 29 items covering severity and duration of physical and psychological health complaints for previous 30 days, is widely used in the Nordic countries. It reliably measures health status and comorbidity (131). Subjective health complaints may also cover “functional somatic syndromes” and “medically unexplained symptoms” (132). Complaints are common in the general population regarding musculoskeletal pains, digestive system, dizziness, sleep disorders, tiredness and other unspecific symptoms (133, 134). Ihlebaek et al. have registered high prevalence of SHC in the Norwegian population. Eighty percent reported pain from the muscular system, covering pain in all the regions of musculoskeletal origin like extremities, neck, back and shoulders. Sixty-five percent reported complaints that are characterised as “pseudo-neurological” and consists of complaints as sleep problems, anxiety, headaches, menopausal symptoms as hot flushes, extra systoles and depression (134). However, general health complaints have not been measured earlier by SHC in patients with shoulder capsulitis.

Outcome prediction of neck and shoulder disorders can be affected by psychological comorbidity besides other clinical findings (135). Some authors have suggested models explaining a relationship between psychosocial factors and development of musculoskeletal complaints and its chronification in association with work environment (136, 137). Patients with widespread pain more frequently have psychological problems and a worse prognosis regarding working capacity compared with patients with more localized problems (138). In patients with chronic pain, pain-related beliefs are often associated with physical and psychosocial dysfunction (139). It is postulated that fear-avoidance is an essential feature of pain chronification in some patients (140).

Experiencing outer environment as hostile, stressful or difficult is a characteristic of neuroticism. Strong associations have been found between generalized anxiety disorders, depression and neuroticism, which can be a significant predictor of subjective health complaints (141). Whether treatment outcome in frozen shoulder may be influenced by health complaints and neurotic symptoms has not been investigated earlier.

### 3. Aim and research questions

The main aim of this thesis was to contribute to better management by the preferred treatment regime for patients with frozen shoulder (adhesive shoulder capsulitis) among general practitioners in primary care. This aim was to be fulfilled by suggesting an evidence based, pragmatic treatment and reliable follow-up of patients with frozen shoulder.

#### **The three studies had the following specific aims:**

- I** To determine the reliability between two testers in examination of shoulder passive range of motion (PROM) bilaterally in participants with adhesive capsulitis using a validated measuring instrument, the plurimeter, over an 8-week period.  
To determine if the measurement error remained the same during the 8-week period, measured three times 4 weeks apart.
- II** To elucidate the effect, if any, of multiple corticosteroid injections with distension, as compared to multiple corticosteroid injections alone and to treatment-as-usual.
- III** To investigate whether subjective health complaints and neuroticism would predict treatment outcome at 8 weeks in patients diagnosed with frozen shoulder as measured by the Shoulder Pain and Disability Index (SPADI) and change in SPADI.

## 4. Design, material and methods

We have conducted three studies with varying research methods. The first study is a longitudinal reliability study between two testers in which we registered passive range of motion at the gleno-humeral joint and investigated intertester reliability of measurements at three different time points. The second and main study is a randomised single blinded controlled trial in which we compared the effectiveness of intraarticular corticosteroid injection with and without distension to treatment-as-usual. The third study is an observational study where we have investigated whether subjective health complaints and neuroticism could predict treatment outcome in frozen shoulder in terms of pain and function.

### 4.1 Setting

The study was conducted at a primary care clinic in Bergen, a coastal Norwegian city, with a population of about 250,000. Patients were referred by general practitioners in the city of Bergen and surrounding districts. The recruitment of the participants, follow-up and collection of data took place between September 2009 and December 2013. Collection of data after one year of participation and until December 2014 was by postal communication.

### 4.2 Participants

During the patient's first visit, it was confirmed whether the inclusion criteria were fulfilled and that there were no exclusion criteria. Before entering the study, every patient was given verbal and written information about the study. Patients were asked to consider their participation in the study and reply by returning a pre-stamped



addressed envelope with their consent form duly signed within 14 days after the first visit or they could reply by SMS or e-mail. Patients had their second visit 14 days after the initial consultation, referred to as day one of the study.

### 4.3 Inclusion and exclusions criteria

To be included in the study patients had to be 18 years or older. They should have verbal and written knowledge of Norwegian, and there should be no contraindications for use of corticosteroids. Female patients in the fertile age group were asked about prevention and to take a pregnancy test if necessary. Passive range of motion had to be reduced with pain in external rotation, abduction and internal rotation. The reduction of motion had to be by more than 30% in two out of three shoulder movements and none of the three movements could be normal. All patients were having both pain and stiffness, and evaluated to be in phase II of frozen shoulder (59, 142) (ref 142: page 306-307). Patients were excluded if they had diabetes, asthma, were pregnant or were breast-feeding mothers. The patient could not have other coexisting disorders in the arm or have a painful neck that could disturb pain and functional assessment of the shoulder.

### 4.4 Material

#### **Study I**

The first 50 patients who fulfilled the inclusion criteria and accepted to participate in the RCT were included in the reliability study.

#### **Study II**

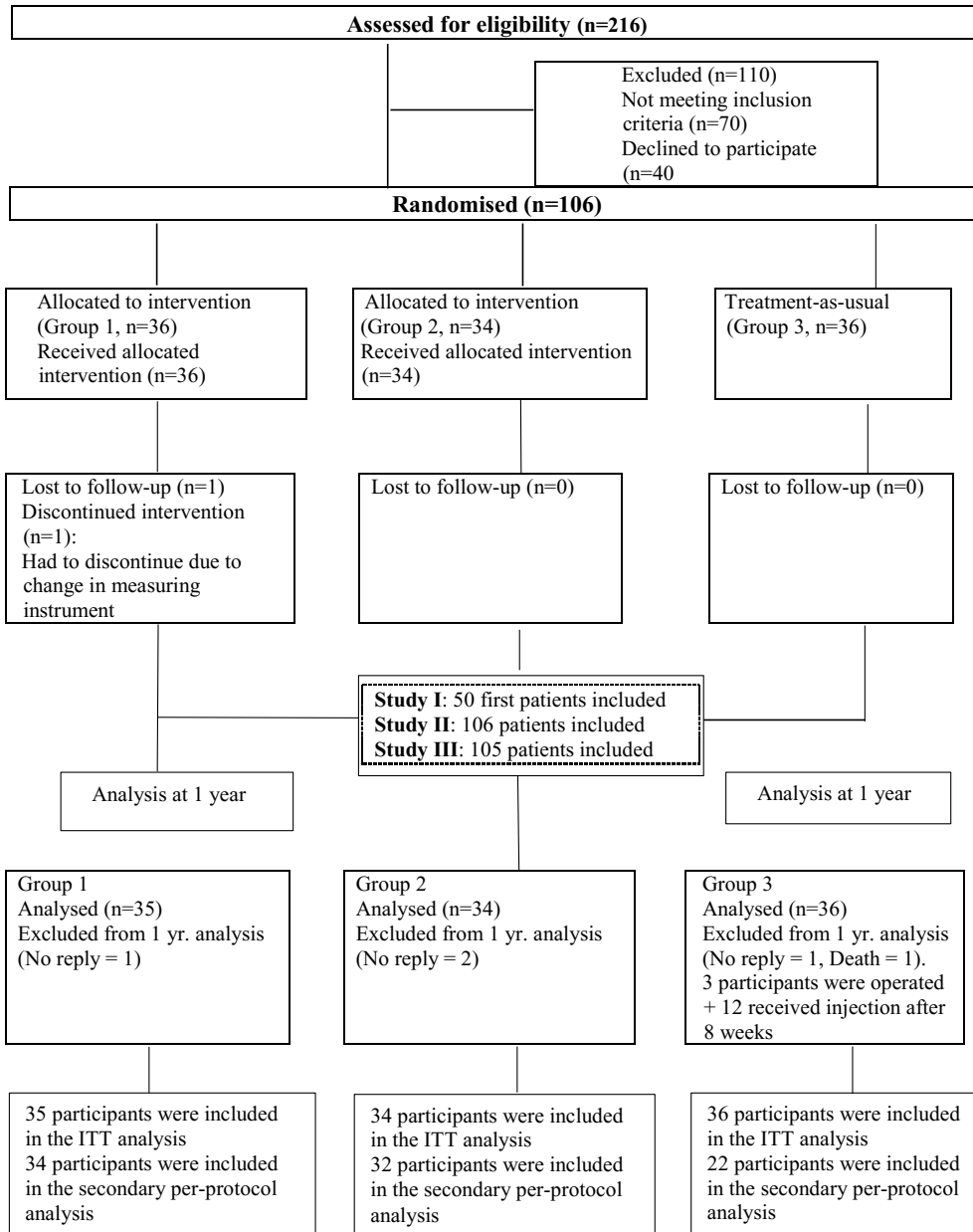
We assessed 216 patients for eligibility for the effect project. Seventy patients did not meet the inclusion criteria and 40 patients declined to participate, as they feared to end

up in the treatment-as-usual group and would need to wait for 8 weeks in case they wanted to receive treatment by steroid injections. Altogether 106 patients were included for randomisation.

In the RCT 36 patients (35 analysed) were included in the steroid-only group (Group 1), 34 patients (34 analysed) in the steroid group with distension (Group 2), and 36 patients (36 analysed) were included in the treatment-as-usual group or control group (Group 3). One patient had to be excluded from the RCT due to change in measuring instrument from manual goniometer to pluriometer, a gravity inclinometer. At the 1-year analysis for study II, one patient was excluded from steroid-only group (Group 1) for lack of postal reply. In steroid with distension (Group 2), 34 patients were analysed at 8 weeks and 32 patients at 1 year. Two patients dropped out (“no-reply”) from treatment-as-usual (Group 3) at the 1-year analysis (Figure 1).

### **Study III**

In the third study, 105 patients were included. Both injection groups were merged into a single group (69 patients), and this intervention group was compared with treatment-as-usual (36 patients). Both groups were followed for 8 weeks.



**Figure 1.** Flow diagram for randomisation and follow-up

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## 4.5 Study I

PROM was used in examination of intertester reliability in study I and as outcome measure in study II. Plurimeter -V, a validated gravity inclinometer (Plurimeter-V inclinometer; Dr. Rippstein, Zurich, Switzerland) was utilised as the measuring instrument for measurement of PROM. Abduction was measured with the patient in standing while external rotation and internal rotation was measured in supine lying position with arm in about 30 degrees of abduction. A plurimeter measures relative angle between two surfaces and is a light hand-held instrument. In the gravity referenced inclinometer, the starting position for the measurement is fixed, which is either 0° or 180°. We used 0 degree as the starting position to minimize placement error. Studies by Green et al. and Watson et al. have confirmed the validity and reliability of plurimeter for measuring PROM for shoulder (143, 144). The assessors measured the PROM motion in sideways passive elevation, passive medial rotation (by “hand behind back” method) and passive lateral rotation in degrees. Studies have pointed out that “hand behind back” method does not actually measure true medial rotation (145, 146). Passive medial rotation (hand behind back) was measured in standing by measuring the distance of the patient’s radial tuberosity from posterior inferior iliac spine in centimetres. One assessor was blinded for the treatment received by the patient. This assessor received thorough information regarding the study and had been instructed in the procedure by the treating investigator. Only in the reliability study, PROM was also measured on the normal side on all visits. The end point was when the arm could not be moved more or the pain became unbearable. To avoid discrepancies in measurements due to affection of movements of thumb joints, we measured the distance in “Hand behind back” in centimetres between the styloid process of the radius to the posterior inferior iliac spine. This procedure with measuring PROM on the normal side with two testers was followed for the first 50 patients. For the remaining participants PROM was measured only on the affected side.

## 4.6 Study II

### 4.6.1 Randomisation

The main study (study II) was an effect study, and all the included participants were randomised to one of three groups, the steroid injection only group (Group 1), steroid with distension (Group 2) and treatment-as-usual (Group 3). We allocated patients to the study groups by computerised block-randomisation with three permutations per block. One of the supervisors accomplished the randomisation without involving the investigator. Information on assigned grouping was put in envelopes with the patient code by the supervisor to be opened after each patient's inclusion. It was therefore complete block randomisation.

### 4.6.2 Intervention

Intervention in this RCT project was applicable to study II only. In the steroid alone group, patients received 4 ml of total solution by intraarticular injection with Triamcinolone acetonide, 20 mg, 1 ml and Lidocaine 10 mg/ml, 3 ml. Patients in the steroid group with distension received 4 ml of Lidocaine and Triamcinolone intraarticularly and in addition 8 ml to 20 ml of physiological Natrium chloride 9 mg/ml. The posterior approach by landmarks for intraarticular steroid injection was used. The following procedure was followed during the injections: The patient was in sitting position and the physician stood behind the patient slightly to the affected side. The left thumb was placed on the posterior corner of the acromion with index finger on the coracoid process. The needle was inserted 1-2 cm below the bony corner pointing towards lower edge of the coracoid process. The needle was pushed until it hit the bone. Injection was given slowly while keeping the needle in position. If there was a problem in emptying the syringe, the syringe was rotated while maintaining the pressure on the syringe, until it gave way. If there still was a problem in emptying the syringe, the needle was retracted 1-2 cm and then reinserted in a slightly different

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direction. The above procedure was then repeated (72, 74). The limiting factor for injecting amount of volume was pain and difficulty in injection. The treatment-as-usual group served as comparison or control group and patients in this group could receive any other treatment other than corticosteroid injections or per oral corticosteroid medication. The control group remained without treatment with corticosteroids, in injection or tablet form, until 61 days, which was also the last day for outcome measurements. The time interval between the 1<sup>st</sup> and 2<sup>nd</sup> treatment was 7 days, between the 2<sup>nd</sup> and 3<sup>rd</sup> treatment 10 days, and between the 3<sup>rd</sup> and 4<sup>th</sup> treatment 14 days. Those receiving intraarticular injections were offered further continued treatment if desired after 8 weeks and if the patient himself/herself wished so due to residual pain. In case patients opted for different treatment e.g. physiotherapy, a referral was provided. After 8 weeks, similar facilities for corticosteroid injection or physiotherapy were made available to the control group as well.

#### **4.6.3 Outcome measures**

The primary outcome measure for the effect study was Shoulder Pain and Disability Index (SPADI), the secondary outcome measure was Numerical Pain Rating Scale (NPRS) and PROM the third outcome measure. The SPADI consists of 13 items and measures two aspects: pain and disability. A 5-item subscale measures pain and an 8-item subscale measures disability. Each item has a score from 0 to 10. For pain, 0 meant no pain and 10 unbearable pain. The total possible score is calculated in percentage and is 100. Higher score indicates increased pain and disability (124, 147). We chose to use the newer version of SPADI using Numerical Pain Rating Scale, instead of the earlier version with Visual Analog Scale. SPADI has earlier been used in a variety of medical conditions in primary care (148, 149), in rotator cuff disease and shoulder capsulitis (150-153). High reliability has been reported in a systematic review with ICCs  $\geq 0.89$  (154) and Cronbach alpha above 0.90 proving high internal consistency (154, 155). SPADI has proved good construct validity, correlation with other shoulder questionnaires, as well as responsiveness

discriminating change in the condition without large floor or ceiling effect (124, 148, 154, 156, 157). The minimal detectable change important to the patient is considered to be 8 points (156), but with repeated use of SPADI it is 18 points (158, 159). Any change less than this can be due to measurement error (147). For SPADI, being the primary outcome measure, we considered an outcome of 20% better or worse to be clinically significant. To be clinically significant, we accepted a change in outcome of 20%, SPADI being the primary outcome measure. A SPADI score of 70 would mean a change of 14 in total SPADI score. A difference in score of  $\geq 10$  has been accepted as clinically significant by other authors (66, 124). Buchbinder et al. had a variance at 19.8 in SPADI as primary outcome measure (97).

The 10-point Numerical Pain Rating Scale (NPRS) was used as secondary outcome measure to evaluate pain intensity, on an average of previous 7 days. Validated pain rating scales commonly used in clinical situations and clinical trials for measuring pain intensity are Visual Analogue Scale (VAS), Numerical Pain Rating Scale (NPRS) and Verbal Rating Scale (VRS). However, none of them has proved to be superior to the other (160, 161). The NPRS is, however, easier to use and has proved better compliance, better responsiveness and good applicability relative to VAS and VRS (162). Comparing VAS, VRS and NPRS in acute post-operative oral pain Breivik et al. found VAS to be better than VRS, but equal sensitivity was found between VAS and NPRS (163). In comparison between NPRS and VRS for episodic pain exacerbations in cancer patients, NPRS demonstrated higher reproducibility than VRS (164).

The tertiary outcome measure was passive range of motion (PROM): PROM in abduction in standing, internal rotation by a pragmatic “hand behind back” method (143) and internal and external rotation in supine lying.

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## 4.7 Study III

For the third study, we used Subjective Health Complaints (SHC) and the Neuroticism component of the Eysenck Personality Questionnaire- Revised short form (EPQ-R. Degree of each complaint is rated on a 4-point scale in the SHC questionnaire (0= none, 1= some, 2= much, 3= severe. Total SHC sum scores for 29 items and differentiated SHC scores for five subscales were calculated. The subscales are: Musculoskeletal (consists of headache, neck pain, back pain, pain in arms, shoulders, migraine and pain in feet on exertion); Pseudoneurology (comprising sleep problems, tiredness, anxiety, depression, dizziness, hot flushes and extra systoles); Gastrointestinal (consists of stomach discomfort, heartburn, ulcer/non-ulcer dyspepsia, stomach pain, flatulence, diarrhoea and obstipation), Flu (consists of flu, bad cold, cough/bronchitis) and Allergy (consists of asthma, chest pain, breathing difficulty, eczema and allergy) (131).

The EPQ-R has four scales but we used only the Neuroticism component of the four scales. The four scales are: E (Extraversion vs. Introversion), N (Neuroticism or Emotionality), P (Psychoticism or Tough Mindedness) and L (Lie scale). In the short form questionnaire, Neuroticism (N) consists of 12 questions in yes and no format (165).

## 4.8 Data collection

### 4.8.1 Study I, The intertester reliability study

Earlier intertester reliability studies have usually measured only affected (166-168) or only non-affected shoulders (169, 170). Participant numbers have usually been below 35 (143, 167, 170-174), although as many as 50 patients has recently been recommended to be included in reliability studies (175, 176) (177). Fifty participants



were recruited in the intertester reliability study with age span from 38 to 75 years (mean age 52 years). Demographic data including side affected, duration of condition and previous treatments was collected before examination of PROM. Patients filled in schemas for NPRS and SPADI before PROM measurements. In patients having bilateral affection, the most affected side was chosen as the “affected” side and the less affected side as the non-affected side. Both testers had experience in measuring PROM on shoulder from an earlier pilot study and were experienced general practitioners. In addition, both had trained on use of plurimeter for measurement of shoulder motion before the commencement of the study. The measurement procedures were standardised beforehand. Tester B (investigator) always tested first and tester A afterwards. They kept their measurement records confidential and unavailable to each other during the study until all data for the reliability study had been collected.

#### **4.8.2 Study II - The randomised controlled trial**

The outcome measures data for this RCT was SPADI, NPRS and PROM, and was collected for all the 106 patients. The patients completed the SPADI and NPRS questionnaires on the first visit, at 4 weeks and 8 weeks, before they underwent clinical examination. At 12 months, the SPADI questionnaire was sent by post to the participants. On the first 50 participants, both testers measured the PROM on the affected and non-affected side at the first visit, at 4 weeks and at 8 weeks. From patient 51 and onwards the PROM was measured only on the affected side by both testers. Data for PROM was collected only for these three time points. By 8 weeks, we excluded one patient as participant in Group 1 due to change in measuring instrument at the start of the study.

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### 4.8.3 Study III - The predictive observational study

For the purpose of this study, the two injection groups were merged into one group as no significant differences were found between them in Study II, hereafter called the intervention group (n=69). At inclusion, at 4 and 8 weeks, subjective health complaints were measured with the SHC questionnaire, neuroticism was measured with the Neuroticism (N) component of the Norwegian version of Eysenck Personality Questionnaire- Revised short form (EPQ-R) (165, 178, 179), and pain and function was measured with SPADI. Patients answered the questionnaires before examination at each visit.

## 4.9 Analyses

### 4.9.1 Study I

We calculated intertester reliability that accounts for both relative agreement between testers and absolute measurement error between the measurements. For this purpose we used the Intraclass correlation coefficients (ICC model 2.1) for calculation of reliability, as this takes into consideration both systematic and random error (175) (page 103). ICCs ranges between 0 and 1, but there are no fixed values for ICC to be considered as acceptable. Eliasziw and co-workers have however defined ICC values from moderate to excellent; ICC values  $>0.90$  are considered excellent,  $\geq 0.80$  to  $0.90$  as very reliable and  $\geq 0.60$  to  $0.79$  as moderately reliable (180). However, coefficients are dependent upon spread in data, as low spread in scores may give low ICCs despite little measurement error. A good spread in scores is required to demonstrate high agreement. Low values of ICC do therefore not necessarily indicate poor agreement, they can also be a consequence of restricted range of scores, and therefore agreement cannot be based on ICC alone(181, page 239-240). We calculated the size of

measurement error by absolute agreement, which is the actual difference in measurements and is expressed in degrees and centimetres.

#### **4.9.2 Study II**

Change in SPADI of  $\geq 10$  indicates clinically important change, improvement or worsening of shoulder pain and function (124). We calculated that a sample size of 31 would have an 80% power to detect a difference in mean SPADI of  $\geq 10$  if standard deviation was  $\leq 15$ . We used repeated measures analyses of covariance (ANCOVA) and regression-based ANCOVA to analyze differences in outcome between the groups. We have analysed 4- and 8-weeks data as multiple follow up observations since these were not independent data. We have also differentiated between short-term (4 and 8 weeks) and long-term follow up (12 months). To extract the main effect of treatment between groups, we used repeated measure ANCOVA with 4 and 8 weeks observations as repeated measure, adjusting baseline differences between subjects using pretest as covariate (182) (p.197). Using 12 months observation as dependent variable, group as a categorical independent variable and pretest as covariate, we used another ANCOVA model with regression procedure to analyze the long-term follow-up data. To control for confounding factors, we added other independent variables to both ANCOVA models in an additional/secondary analysis.

By subtracting the post-test scores (8 weeks and 12 months) from the baseline scores in the two groups and dividing it by standard deviation of the change scores, effect size (ES) for mean change in SPADI was deduced. An ES of 0.2 is small without any clinical importance, while an ES of 0.8 is considered large and of crucial practical and clinical importance (182).

Keeping patients in their original allocations on randomisation in accordance with intention-to-treat (ITT) principles (183), imputing the missing data ITT analysis was

performed (184). There was very little missing data at short-term follow-up; for two patients at 4 weeks and one patient at 8 weeks. At long-term, data was lacking for six patients for 1-year follow-up.

### **4.9.3 Study III**

We examined comorbidity and Neuroticism variables and had a close look at correlations between SPADI at 8 weeks and baseline SHC total and subscale scores as well as Neuroticism score. We chose appropriate baseline scores as predictors of outcome as measured by SPADI at 8 weeks by correlational analysis. The same analyses were repeated with change in SPADI from baseline to 8 weeks as outcome parameter because regression analyses can be affected by subtle baseline differences. Controlling for age, gender, intervention and duration of shoulder pain, we performed the multiple regression analysis with the items that correlated significantly with SPADI as predictors. We removed the insignificant predictors one by one by using backward elimination method for the multiple regression analysis. Both the initial and final models are presented.

Software package IBM SPSS Statistics 22 for Windows was used for all statistical analyses.

### **4.9.4 Missing values**

In the first study, we chose to include consecutively patients between 2 and 51. The first patient was excluded from further participation in steroid-alone group (Group 1) because of change in the measuring instrument, which was a crucial part in enhancing the quality of measurements. In the second study, all 106 patients were analysed on intention-to-treat principle. Missing data were imputed following ITT principles; see section 3.9.2.

## 4.10 Ethics

Declaration of Helsinki is followed during this study and has been approved by the Regional Ethical Committee (REK nord), UiT The Arctic University of Norway, Postbox Langnes, 9037 Tromsø, Norway; [rek-nord@asp.uit.no](mailto:rek-nord@asp.uit.no). Project EUDRACT-NR 2008-004385-49; reference 200804384-7/KST017/400 and reference for change in protocol (2012) 2012/717/REK Nord. Consent for the project was received from The Norwegian Social Science Data Services (reference: 19675/2/SM) for handling of data regarding personal information of patients. Consent was also received from The Norwegian Medicine Agency regarding use of Triamcinolone acetonide in this study, reference 08/18009 ([post@legemiddelverket.no](mailto:post@legemiddelverket.no)). Protocol for the study is available from ClinicalTrials.gov identifier: NCT01570985 where the study is also registered. Signed informed consent was obtained from all patients on inclusion in the study.

## 5. Results

### 5.1.1 Study I

The reliability study with two testers that measured passive range of motion (PROM) three times (at inclusion, after 4 and 8 weeks) in 50 patients with adhesive capsulitis in stage II, demonstrated from very good to excellent intertester reliability. We achieved excellent intertester reliability on the affected side at all three time-points. No change was observed on the unaffected side while the affected side showed change in measurements probably caused by either general improvement or treatment or a combination of both. The variation in measurement errors was small, between  $\sim 5^{\circ}$ - $7^{\circ}$  at all three time-points while measuring passive abduction, passive external and internal rotation on the affected shoulder. Small measurement error was registered during measurement of passive abduction in the normal arm ( $\sim 1.5^{\circ}$ - $2^{\circ}$ ) and hand behind back ( $\sim 1$  cm - $2$  cm) at all three time-points in both arms.

The ICCs values (ICCs  $\geq 0.83$  -  $0.96$ ) were highly reliable for the affected side at all three time-points. The normal side showed slightly lower ICC values than the affected side at the third visit only.

The absolute measurement error found in our study was small and stable throughout the test period. The smallest detectable changes from pre-test to 8 weeks were statistically significant for the affected arm.

### 5.1.2 Study II

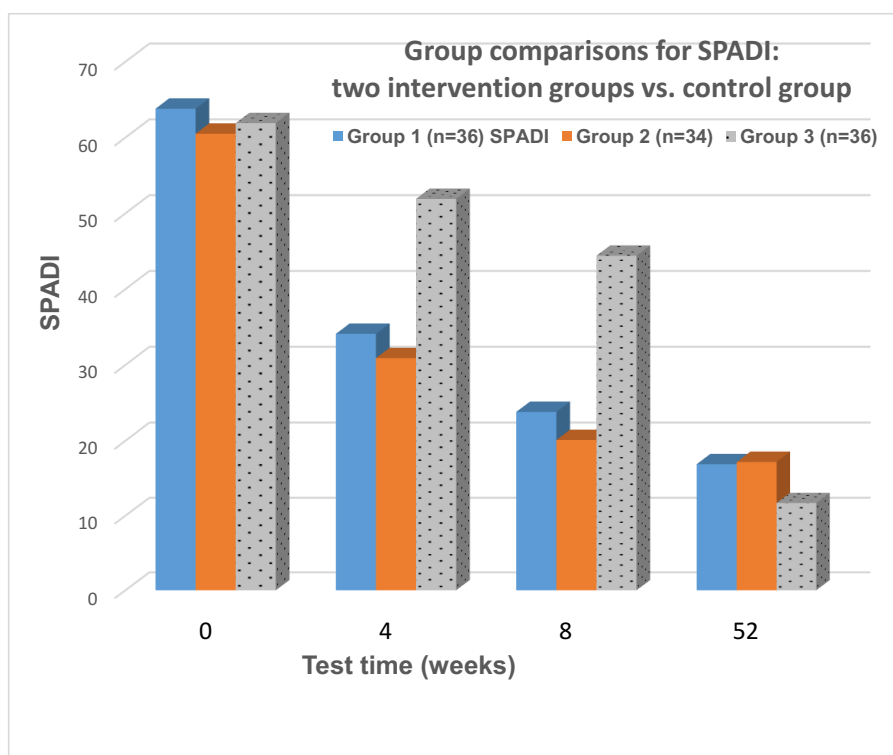
We randomised 106 patients for participation in the RCT. The group who received injection with corticosteroid alone (Group 1) had 36 patients, the corticosteroid and distension with saline group (Group 2) had 34 patients, and the treatment-as-usual (Group 3) had 36 patients after randomisation.

**Table 1.** Baseline characteristics of patients\*

<b>Characteristics</b>	<b>Steroid injection alone (Group 1) Number and % n=36</b>	<b>Steroid injection and saline (Group 2) Number and % n=34</b>	<b>Treatment-as-usual (Group 3) Number and % n=36</b>
Mean age in years (SD)	52 (8.3)	53 (9.2)	54 (6.9)
Female	21 (58%)	21 (62%)	19 (53%)
Duration in months Median (range)	7.5 (2.0 – 18.0)	7.0 (3.0 – 37.0)	6.0 (3.0 – 24.0)
Concurrent neck pain	16 (44%)	15 (44%)	16 (44%)
Trauma to shoulder	2 (6%)	11 (32%)	3 (8%)
Previous shoulder treatment	15 (42%)	22 (65%)	13 (36%)
Analgesics	19 (53%)	14 (41%)	11 (31%)
Participants on sick leave	17 (50%)	16 (47%)	15 (42%)
SPADI	64	61	62

\*Source: article 2, (modified).

Except for one patient in Group 1, there was no dropout and all patients completed the specified intervention until 8 weeks (Figure 1). Altogether 100 patients (95%) answered the SPADI questionnaire at 1-year follow-up. We did not perform interim analysis during the study. The baseline characteristics of the three groups were comparable concerning age, gender, mean duration of shoulder pain, concurrent neck pain, previous frozen shoulder, number of affected right side and dominant side and sick leaves (Table 1).



**Figure 2.** Group comparison for SPADI at baseline, 4 weeks, 8 weeks and 12 months



Thirty-five patients in Group 1 and 34 patients in Group 2 received four injections each within a period of 8 weeks. All three groups showed clinically significant change in SPADI from baseline to 8 weeks (>14 points improvement). Both intervention groups improved significantly more as compared to Group 3. After 12 months, there was no difference between the three groups (Figure 2). Similarly, there was a significant improvement in NPRS at 8 weeks for both intervention groups, but less in Group 3. Change in PROM for abduction from pre-test to 8 weeks was slightly better between the intervention groups (in Group 1: 54° increased to 69° i.e. 15° increase; in Group 2: 51° increased to 72°, a 21° increase) than in Group 3 (51° increased to 57°; i.e. 6° increase). Similarly, external rotation for Group 1 increased by 18°, for Group 2 by 18°, and 7° for Group 3. The increase in PROM for internal rotation for Group 1 was 18°, for Group 2 19° and for Group 3 it was 7°.

There was no difference between the two intervention groups for effect size (ES) regarding SPADI at 8 weeks (ES 1.2) and at 12 months (ES 0.3 and 0.4). However, at 12 months, all three groups were equivalent, the change was equally large in all groups and no statistically significant difference was found between the three groups.

### **5.1.3 Study III**

The baseline characteristics of patients, including baseline SPADI, was the same for the intervention group and the control group. Contrary to our expectation, low prevalence of subjective health complaints existed when descriptive scores for SHC and for Neuroticism at baseline and 8 weeks were analysed. We were interested in finding out whether prediction of outcome in frozen shoulder was possible in presence of comorbidity as measured by SHC and Neuroticism. Using relevant variables, possible correlation was analysed and the most appropriate variables were then used in the regression analysis. Statistically significant Pearson's correlation coefficients for SHC total score at baseline versus SPADI at 8 weeks was demonstrated by the variables group allocation ( $p < 0.001$ ) and the Pseudoneurology

subscale in SHC at baseline ( $p=0.009$ ). SPADI at baseline and female gender also had a significant correlation. The total SHC score became insignificant after removing the Pseudoneurology subscale from the baseline total SHC score, proving that significance was due to the Pseudoneurology subscale. Neuroticism did not show any correlation with outcome measure at 8 weeks, while statistically significant correlation was shown with change in SPADI from baseline to 8 weeks by female gender and group allocation. None of the other SHC subscales at baseline returned significant correlation coefficients with SPADI. We chose therefore to keep only the Pseudoneurology subscale as predictor and not the total SHC baseline score in the multiple regressions analysis. We did not find any correlation between baseline Neuroticism and SPADI or change in SPADI after 8 weeks.

Multiple regression analysis with SPADI at 8 weeks as the dependent variable, controlling for age and gender, revealed a statistically significant predictive value for Pseudoneurology in SHC at baseline ( $p<0.001$ ) and group allocation ( $p<0.001$ ). Shoulder pain duration did not show any statistically significant predictive value.

Group allocation exhibited statistically significant predictive value for change in SPADI from baseline to 8 weeks ( $p<0.001$ ). No significant predictive value at 8 weeks for change in SPADI was exhibited by baseline SHC scores, while statistically significant predictive value for change in SPADI from baseline to 8 weeks ( $p<0.01$ ) was revealed by shoulder pain duration.

## 6. Discussion

### 6.1 Methodological considerations

#### 6.1.1 Design

This thesis is based on three studies involving examination and treatment of patients diagnosed with frozen shoulder. The first study is a prospective intertester reliability study where the participants were followed over time and outcome of interest registered by two testers. The second study is an RCT comparing outcome after intervention with a control group, and the third study is a prospective observational study exploring prediction of outcome in frozen shoulder in presence of comorbidity.

#### Study I

Correct measurement of passive range of motion is important for both diagnosis and in follow up of patients with painful and stiff shoulders as an outcome measure to consider effectiveness of given treatment (42-45). We examined PROM of the first 50 patients recruited in the main RCT, regardless of group allocation to avoid channelling bias, which occurs when patient prognostic factors decide the group placement of the cohorts (185). All recruited patients had confirmed diagnosis of shoulder adhesive capsulitis/frozen shoulder, and were mainly in phase II with both pain and reduced shoulder movement. We used standardised diagnostic criteria as described in the literature, as it is essentially a clinical diagnosis (8, 186, 187). Two testers measured PROM in both the affected and non-affected shoulder at three time-points. To reduce bias, we had standardised the measurement procedure and the testers had undergone training in measurement of PROM to reduce intertester variability (143). However, there were some limitations regarding data collection. The investigator himself (tester B) was one of the data-collectors and carried out measurements. This might have introduced interviewer bias (188) in data collection as tester B might have remembered group allocation of a patient at the time of

inclusion, which may reduce internal validity (189). To avoid this, only the patient's identity number was written on the data registration sheet and the page was removed right after the measurement was finished. The two testers measured PROM in the same pattern, i.e. tester A always measured after tester B, possibly inducing systematic error.

## **Study II**

A selection bias in the material by excluding patients with diabetes and asthma might have been unknowingly introduced, although this factor would have been equally distributed in all three groups in the RCT. We were concerned during the decision making process about inclusion and exclusion criteria, that asthma patients might drop out of the study due to need for treatment with steroids during an exacerbation of asthma, as use of steroids in any form except for intervention would have led to exclusion from the study. Diabetes was also an exclusion criterion in this study. Some diabetes patients get larger fluctuation in their blood sugar level due to corticosteroid injection, making it difficult to regulate, and this could have caused dropout. It is known that diabetes patients are about five times more prone to develop frozen shoulder than the normal population (190-192). Patients with diabetes are generally more resistant to interventions (6, 20, 59, 193). Yet another criterion was to exclude patients who could not express themselves in Norwegian. To include these patients would have required much more administrative work for arranging translators and arranging the consultations at different timings for the blinded assessor. This would have caused considerable economic burden on the project, which was out of reach for this study. The included patients had to have more than 30% reduced PROM and none of the three passive shoulder movements for abduction, external rotation and internal rotation should be normal. We thereby excluded patients with milder frozen shoulder and most patients included in the study were therefore in stage II with SPADI above 60. This increased the recruiting time substantially and it took a total of 4 years to recruit 106 patients. Of the eligible participants, 40 patients declined to participate for fear of ending up in the control group, further delaying their treatment process by 8 weeks. Most of the patients were referred from other general

practitioners and the patients had probably an expectation of receiving treatment straight away. Being asked to participate in a trial became something unexpected and induced hesitation to participate. On one hand, it delayed the recruiting process; while on the other hand, it introduced bias in choice of population as fair representatives of this condition. It is possible that some of the patients who declined participation in the study had a lot of pain and did not want to wait for treatment. However, most patients with frozen shoulder contact health services in phase II and we thus consider our study population as representative of the general population with this condition. The study investigator was involved in carrying out the injections and that may have introduced bias. While giving injection, patients were placed in a way that they were unable to see the injection syringe, almost 1/3 of the patients guessed wrong group when asked about group belongingness after the intervention period. We consider this successful blinding of the patients in the intervention group regarding given treatment. The patients themselves filled out the questionnaires regarding degree of pain and disability without the presence of study personnel, and hopefully with little or no Hawthorne effect. Hawthorne effect refers to the phenomenon that being participant in the study has a positive effect on participant's behaviour and thereby results.

We divided the participants in three groups, two intervention groups and one treatment-as-usual-group who served as control group with usual conservative treatment, except for steroids in any form. We did not have a placebo group, which we think would have increased the internal validity of the study. We considered it unethical to have a placebo group when we planned the protocol, as some patients experience very strong shoulder pain and expect to be offered pain relieving treatment (104). One of the general problems in effect studies is to ensure that the control group remains without exposure or only to the specified exposure, which we were able to monitor in our study with the treatment-as-usual group. This was controlled on visits at 4 weeks and 8 weeks and none of the patients were exposed to corticosteroids in direct or indirect form.

An important aspect of this study is that it is a pragmatic randomised controlled trial, well suited to and in accordance with current practice of treatment for frozen shoulder in general practice and we have tried to reduce the pitfalls (189, 194). The pragmatic part in this RCT was having one of the investigator as also the one who gave injections and who was one of the assessors. This may introduce bias (interviewer bias), but may also be positive in some respects. The practical hurdles in having someone from outside the clinic to do injections included a need for different locations to carry out the procedures and more importantly unavailability of qualified person to do the procedures. We did not have any dropout for the first 8 weeks of the trial. The one dropout was due to change in measurement instrument and non-compliance was not the reason. At 1-year follow up, 100 (95%) patients answered the questionnaire, which is very good and maintained the strength of study.

Although accuracy of intraarticular steroid injections is debated (75-78, 81, 83, 195), the degree of difference between ultrasound guided and injection by anatomical landmarks is very unclear (196). Most of the studies involving distension are performed in secondary care using imaging techniques. We chose to give injections by anatomical landmarks using a common intraarticular injection technique as it is practiced in primary care in Norway, i.e. by posterior approach. Most patients with frozen shoulder are treated in primary care and it was therefore natural to use the same treatment procedure that is in common use in general practice. Similarly, we used 20 mg Triamcinolone dose, which is common to use in treatment of frozen shoulder in general practice. Morale is to use the minimum effective dose. Former studies did not find any difference in effect between low and high dose (197, 198). Furthermore, multiple injections were used in this study, in accordance with the common practice in general practice in treatment of frozen shoulder. A review has favoured multiple injections in the treatment of frozen shoulder (26). Intraarticular injections were given with increasing time gap from 1 week, 1 ½ week and 2 weeks. Previous studies using multiple injection have used injections from once a week to once in 2 weeks and once in 4 weeks, with assessment of outcome measures varying from 6 weeks to 52 weeks (84, 87, 90, 91, 199). We followed the current practice in

Norwegian primary care. In summary, the combination of using injection techniques by anatomical landmarks, low dose of 20 mg Triamcinolone acetonide and use of multiple injections is the same as currently practised in primary care.

### **Study III**

The patients included in this study are the same as mentioned in study II. The intervention group constitutes both the steroid intervention groups from the RCT, combined to one group. In the SHC questionnaire we omitted the scoring of frequency of complaints the last 30 days as it was difficult for the patients to remember this reliably. This has probably avoided recall bias. Scoring for neuroticism in EPQ-N questionnaire is dichotomised to yes/no answer and not graded in degree of symptoms. This might have affected the results as patients with slight anxiety or slight symptoms might have answered no. On the other hand, slight symptoms might not in any way have affected the outcome.

### **Validity**

Validity refers to being genuine or valid. The Oxford dictionary defines it as “the quality of being logically or factually sound; soundness or cogency.” In this thesis, validity also refers to originality and trustworthiness of our collected data. The internal and external validity will be discussed here, as it is applicable to the studies included in this thesis.

### **Internal validity**

Internal validity refers to how well the collected data corresponds to results. It may also refer to the reverse i.e. how well the results fit the original data. In other words it may reveal that a causal relationship exists between the independent (for example given treatment) and dependent variable (181) (page 75). It also addresses the issues of the study being free from bias or systematic errors, how well confounding is avoided and the results are based on its bias free data. Randomisation is a good tool to reduce bias and confounding. Confounding refers to a variable, which changes with an independent variable. Controlling as many as possible confounding variables

will increase internal validity. Randomisation with blinding of both assessor and patients at inclusion minimises bias and increases internal validity (181) (page 75-77).

In study I, the investigator was one of the data collectors and remembering group allocation at the time of inclusion might induce interviewer bias if the investigator had a presumption towards a particular result. To avoid this, only the identity number was written on the PROM registration sheet and was removed after measurements. Having a big enough sample size and large number of measurements producing an overall good result contributes to increased internal validity. A systematic error might have been introduced while performing measurements as tester A always measured after tester B. Pain provocation after tester B had taken measurements might have affected measurements by tester A since the criteria for PROM were pain and stiffness. Using another tester or in other words having the study as double blind would have solved this problem. This would have of course change the actual study in many ways. Practically and economically, it was not feasible to do so. On the other hand, having an experienced investigator who is well versed with measuring PROM and treating this group of patients has been a great advantage. The dropout rate in the first 8 weeks has been under one percent and has maintained sample size and strength of the study. As assessor B was also the investigator in the study that, generates trust and might have led to reduced dropout rate. One can also trust the performed procedures, which increases internal validity of the study.

### **External validity**

External validity is about certainty of applicability of results from this study to patients with frozen shoulder in other studies or in general, or in other words, generalisation of the results. One can generalize to groups, settings or times or across groups if multiple subgroups of population, settings or times are studied (181) (page 87). Patients with asthma may require corticosteroid during an exacerbation and use of corticosteroid in patients with diabetes may make blood sugar levels very unstable leading to drop out from the study. We excluded patients diagnosed with asthma and



diabetes from the study, for fear of dropout since use of corticosteroid in any form was contraindicated. The exclusion of these patients affects external validity of this study. Excluding patients who could not speak or understand Norwegian may also affect the generalisability of the study. However, by chance, all patients eligible for participation could speak and understand Norwegian, and external validity for this reason was therefore not affected. In study I, the standard error of measurement was small and reliability was from very good to excellent which increases generalisation of the study due to its applicability in measuring PROM for follow-ups and research. We did not continue registration of the SHC and EPQ-N questionnaire past 8 weeks, which limits the generalisation of the results because frozen shoulder is a chronic condition and often needs long follow up. This may affect the external validity of the study. Using injection techniques by anatomical landmarks, low dose of 20 mg Triamcinolone acetonide and use of multiple injections is the same as currently practised in primary care ensuring the usefulness of results in general practice.

## 6.2 Discussion of results

The three studies in this project form a continuum of the research project on shoulder capsulitis from using range of motion as a reliable follow up tool (study I), to management of the condition by intraarticular injections with or without distension (study II), taking into consideration possible impact of comorbidity on interventional outcome of treatment for frozen shoulder (study III).

The baseline characteristics were similar in the intervention groups and the treatment-as-usual group, and one of the testers did not know the patients' group belonging.

The first study focused on the reliability of measurement of passive range of motion in patients with frozen shoulder. We performed a large number of measurements in this reliability study with 50 participants, measuring PROM on both affected and

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unaffected side at three different time points. Based on several factors described below, the results in study I are comparable with or better than other reliability studies measuring shoulder ROM (143, 166, 173, 200). This might be due to large number of measurements measuring also on the normal side and beforehand training in measurements of assessors. The standard error of measurement was small and reliability between the two testers was very good to excellent. The standard error of measurement is a measure of how much measured test scores are spread around a “true” score. The standard error of measurement is especially meaningful to a test taker because it applies to a single score and it uses the same units as the test (168).

The variation in measurement errors in our study was small, between  $\sim 5^{\circ}$ - $7^{\circ}$  on all three time-points while measuring passive abduction, passive external and internal rotation on the affected shoulder, and in measurement of external and internal rotation on both sides. The ICCs values (ICCs  $\geq 0.83$  - 0.96) were highly reliable for the affected side on all three time-points in spite of the fact that the participants at baseline had quite high pain intensity (scored between 5 and 9 on NPRS). This increases the generalisability of the study and results from the study provides support for that PROM measured with a plurimeter can reliably be applied in clinical practice as well as be used as an outcome measure in research. It indicates that measuring PROM reliably is important in diagnosis and in follow up of patients with frozen shoulder, especially in an outpatient setting when a patient is examined and followed-up by different therapists. However, we did not perform an intratester reliability study. That would have increased the applicability in single practices as well. Furthermore, active movements were not measured either. Active movements involve trick movements unconsciously to overcome pain and stiffness. Some patients stop long before pain is uncomfortable for fear of pain provocation as it is very common to have “after- pain” after activity in frozen shoulder. Factors like fear for pain and trick movements would make interpretation of true ROM very difficult and probably unreliable and therefore it was decided not to include active movements in the ROM measurement protocol, even though some studies have shown active range of motion to be more reliable than PROM (201).

The participants in our study are representative for patients with frozen shoulder, having a mean age of 53-54 years, and the majority being female as they usually are more affected than men. The use of analgesics in the treatment-as-usual group was 16% less than the intervention group. We believe that this had little or no impact on the results, as most pain reduction happened in the first 8 weeks in the intervention group. Twice as many participants in the treatment-as-usual group were on sick leaves. This could have affected the economic outcome. Unfortunately, we did not calculate any economic impact of intervention in this study so far, even though it would have been interesting to do so. There are probably large potentials in savings for patients on sick leaves if this condition can receive early treatment. The high costs for society associated with sick leave and disability due to adhesive capsulitis indicate that there is a clear need to determine the most cost-effective interventions for this disorder (202).

The included patients in the study represent a patient population in phase II of frozen shoulder, being in the painful phase with reduced function and with a SPADI score at circa 62. There was only one drop out at short-term i.e. at 8 weeks and 95% answered the questionnaire at one year. We had expected a dropout at 10%, but in our study, it was far less. The study has therefore maintained good strength throughout.

A review regarding effect of intraarticular steroid injection concludes: "Intra-articular steroid injection is effective and safe for frozen shoulder and relieves pain, improves functional performance, and increases range of motion" (203). Former studies have claimed good results with distension (97). The difference in outcome in terms of SPADI and NPRS at 4 and 8 weeks between the two intervention groups was not statistically significant. It has been argued that since former distension studies did not observe any difference in outcome, the major effect seemed due to corticosteroid (98, 101). The study by Buchbinder et al. using 21-80 ml of saline (median 43 ml), argued that the distension must be large enough to have an effect (97). Tveitå et al. who observed that capsular rupture had occurred at even 10 ml of dilatation in some cases

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(101 177) contradicted the statement by Buchbinder et al. They questioned further injecting of saline, as it would leak out of the joint anyway.

Our study did not find any difference in outcome between using distension and not, making it possible to recommend use of multiple injections with moderate dose of steroids without distension. A systematic review and meta-analysis did not find any superior effect of dilatation at long-term. Aspects of approaches, imaging guiding techniques and doses of distension were not found to modify treatment effectiveness. In conclusion, distension of the gleno-humeral joint provides a similar long-term efficacy to all reference treatments (103). Another systematic review and network meta-analysis comparing efficacy of intraarticular steroid injection and distension in patients with frozen shoulder conclude that intraarticular steroid injection is as effective as distension in shoulder-function improvement and reduction of pain (102). This is in accordance with our conclusion. Results of intervention with or without distension may be equivalent to guided injections. It is important to follow the correct injection technique, i.e. to have bone contact while injecting to have a successful outcome by giving intraarticular injection by anatomical landmarks (142, 204).

We used anatomical landmarks for intraarticular injections both for patients without distension and with distension. We could not be sure whether the medication had been delivered intraarticular or extra articular. It was not certain whether capsular rupture had taken place, even if the intention was a non-capsular rupture dilatation. Results in our study by landmarks are still comparable with studies using fluoroscopy or ultrasound (101), even though others maintain to have better results with guided injections (81). A two weeks superiority of ultrasound-guided intraarticular injection as compared to injection by landmark guidance (195) is too little considering the extra resources employed in using guided injections.

Three patients were operated and 12 patients chose to receive intraarticular corticosteroid injections in the time interval between 8 weeks and 1 year. We did not find any significant difference between any of the groups regarding change in

SPADI, and a secondary per-protocol analysis performed excluding the 15 patients that did not follow the initial treatment-as-usual protocol after the 8-week period. This means that the results of the trial are still valid though the sample size of the Group 3 was reduced.

Frozen shoulder has been considered to be a self-limiting disease (12, 23, 38). The condition lasts for about 2 to 3 years, and 40% of patients may still have residual disability and pain several years afterwards (21, 40, 67). The research community tend to focus on the long-term results that might lead to passive attitude towards early management of this condition. This has probably led to long standing wait and see attitude. Shoulder pain and stiffness is accompanied by severe disability often resulting in absenteeism from work, inability to perform leisure activities, and utilization of health care resources (202). Patients find it difficult to sleep, to perform activities of daily life or to take care of personal hygiene, finding this disorder most disturbing, all due to pain and stiffness. While under treatment, patients express their extreme satisfaction for being able to sleep without being awakened by pain. Most patients have considerable relief from both pain and stiffness during the first 8 weeks of treatment. Even if patients are interested in long-term relief as well, they value this early relief very much. Thus, from patients' perspective, a short-term relief is extremely valuable which takes them back to their somewhat normal daily routine.

Literature describing economic burden of frozen shoulder is scanty. According to data from 2013 for Global Burden of Disease Project and the Norwegian Directorate of Health, musculoskeletal disorders caused the highest production cost mainly due to sick leaves (205). Putting suffering due to pain and disability aside in frozen shoulder disorders, the major economic impact is from sick leave. This is an extra burden particularly for self-employed single person businesses. Literature regarding economic evaluation in frozen shoulder is mainly related to economic burden for given conservative treatment. Van den Hout et al. found that the burden due to adhesive capsulitis was estimated at 0.048 quality adjusted life years and €4,521 per patient. About half of these costs were due to absenteeism (206). Another trial

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calculated the cost difference between the intervention and the placebo group. Difference in monthly non-health care cost favoured the physiotherapy group (\$14.6 AUD), largely due to work absence costs that outweighed the travel and time costs to visit the physiotherapist (202). A review could not conclude regarding the most economical intervention since the cost of interventions varied widely depending upon the setting, i. e. primary care versus secondary care; type of intervention and whether a specialist or a physiotherapist performed the intervention. In UK, cost of intraarticular steroid injection by anatomical landmarks varied from £36 to £139 and for guided injection from £99 to £476. With addition of physiotherapy, these costs varied from £121 to £607 (69). To my knowledge, in Norway, the cost for intraarticular steroid injection in shoulder varies from NOK 350 to NOK 500 with physicians and specialists under National Health Scheme, and up to NOK 1500 for privately practicing physiotherapists or physicians.

Neuroticism did not show any correlation with the outcome measure at 8 weeks, while statistically significant correlation was exhibited with change in SPADI from baseline to 8 weeks by female gender and group allocation. Pseudoneurology in SHC at baseline ( $p < 0.001$ ) and group allocation ( $p < 0.001$ ) demonstrated statistically significant predictive value using SPADI at 8 weeks as dependent variable in a multiple regression analysis. We had expected that the Musculoskeletal subscale would reveal predictive value with SPADI as outcome since it has components of pain, which we expected to matter in this scenario. Very often pain and stiffness go hand in hand in frozen shoulder, although this may not always be the case. The possible explanations may be that psychological distress seems to matter more than stiffness in frozen shoulder as demonstrated by Bagheri et al. (207). Frozen shoulder and psychological conditions seem to have a correlation, as there is more self-reported pain and disability among patients having both conditions simultaneously (208). Engebretsen et al. (209) found education as the most consistent predictor of outcome as measured by SPADI, along with work status at 1-year follow up in subacromial shoulder pain. Other parameters that predicted outcome were baseline SPADI score and self-reported health status. We might have observed some

correlation, had we gathered data on SHC and Neuroticism before patients received their diagnosis and explanation of the condition. However, this would have been a tedious job to achieve in around 200 possible participants before inclusion. Anxiety about the condition seems to disappear after the patients received the final diagnosis and explanation about natural course of the condition. There is also a possibility that SHC and Neuroticism are not able to measure psychometric parameters unless they are highly accentuated, as was also revealed by Ursin et al. (210). Absence of correlation of Neuroticism with outcome measure is in accordance with other studies (211). Literature does seem to reveal that psychological parameters can affect the outcome (15, 135-137), but our study could not demonstrate it.

Every pharmacological treatment can have side effects. Corticosteroids in injection form can give side effects that generally are transient (212). Most common of these are flushing with redness and feeling of swelling on face, discolouration of skin commonly seen at places where there is little subcutaneous tissue, and sometimes women in productive age can get disturbances in menstruation cycle. Simultaneous intake of anticoagulating agents can cause bleeding under skin and give bluish discolouration. Intraarticular or periarticular infection are most feared but are seldom, varying from 1 in 14000 - 50000 injections with aseptic technique (213, 214). In this trial 29% of patients in the intervention group experienced flushing and after-pain. No other side effects were reported. This is an acceptable degree of side effects. This practice of using multiple steroid injections for frozen shoulder in primary care can therefore be considered safe.

## 7. Conclusions

This thesis has contributed to more insight into importance of correctly measuring passive range of motion, treating optimally and pragmatically by simple conservative means and follow-up of patients with frozen shoulder. It has shed light on what comorbidity might mean for outcome and rate of recovery from frozen shoulder.

- Measuring passive range of motion in patients with frozen shoulder using a plurimeter has demonstrated very good intertester reliability.
- Examining passive range of motion by this method can be used as a reliable outcome measure clinically as well as in research.
- Multiple corticosteroid injections with or without distension in series, with increasing intervals during an 8-week period had better outcome than treatment-as-usual (control group) in our intention to treat RCT.
- The long-term outcome at 12 months did not differ between intervention and control groups, highlighting the natural course of the condition
- Treatment outcome, as measured by SPADI at 8 weeks in frozen shoulder, was predicted by the Pseudoneurology subscale in Subjective Health Complaints, but not by change in SPADI from baseline to 8 weeks.
- Psychological factors do not predict rate of recovery as reflected by change in SPADI as measured by Subjective Health Complaints and Neuroticism. However, psychological factors may accentuate burden of symptoms in frozen shoulder.



## **8. Implications and recommendations for future research**

### **8.1 Clinical implications**

This thesis has contributed in understanding successful management of frozen shoulder in primary care using simple conservative means by a pragmatic approach.

- Passive range of motion can be measured accurately by pluriometer for both diagnostics and follow up of patients with frozen shoulder, and is easy to implement in clinical practice and research.
- It is not necessary to use distension in treatment of frozen shoulder with intraarticular corticosteroid injection, saving patients from the discomfort of adding saline.
- Even if the long-term results are the same, it is the early painful months which often mean most to the patients suffering from frozen shoulder. Patients can therefore be spared from unnecessary pain and markedly reduced function and quality of life. They should be offered this alternative of treatment by intraarticular steroid injections in the painful phase.
- Comorbidity as measured by Subjective Health Complaints and Neuroticism may not necessarily affect outcome negatively if patients receive thorough information at an early stage of the condition.

## 8.2 Future research

- High quality research with multi-armed preferably multi-centred adequately powered randomised controlled trials that may lead to diagnostic consensus and consensus regarding best conservative management strategy for frozen shoulder.
- To compare outcomes with multiple intraarticular corticosteroid injections: anatomical landmark versus ultrasound or fluoroscopically guided with and without distension with added physiotherapy comparing group treatment, individual based treatment and self-treatment (exercises) after instructions including patients with primary (idiopathic) and secondary frozen shoulder.
- Furthermore, management of primary and secondary frozen shoulder in painful phase can also be compared.
- Assess the role of high quality patient information/education regarding frozen shoulder and self-management at an early stage.
- Outcomes should measure pain, function, sleep and quality of life with standardised validated questionnaires.
- Future research should examine the impact multiple corticosteroid injections have on sick-leave and economic burden as compared to other conservative treatment approaches.

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# PAPERS



RESEARCH ARTICLE

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# Passive range of motion in patients with adhesive shoulder capsulitis, an intertester reliability study over eight weeks

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## Abstract

**Background:** Measuring range of motion (ROM) in the shoulder joint is important for the diagnosis and monitoring of change over time. To what degree passive ROM can be trusted as a reliable outcome measure was examined as part of an on-going randomized controlled trial for patients with shoulder capsulitis. The aim of this study was to examine intertester reliability of passive ROM in the shoulder joint over a period of eight weeks in patients with adhesive capsulitis stage II.

**Methods:** Fifty patients with a clinical diagnosis of adhesive shoulder capsulitis were examined by two independent testers. A predefined protocol was used for measuring passive range of motion with an inclinometer, a pluri-meter, in both affected and non-affected shoulders three times; at the start of the study and after 4 and 8 weeks.

**Results:** Very good to excellent intertester agreements were found for most parameters for the affected arm at all three test points. The intraclass correlation coefficient (ICC 2.1) values ranged from 0.76 to 0.98, i.e. from very reliable to excellent. The measurement error was in general small for the affected arm (5°–7°). ICCs were slightly lower for the non-affected arm at 8 weeks, but with acceptable measurement errors.

**Conclusions:** Intertester reliability between two testers was very good at three visits over a time period of eight weeks using a pluri-meter to measure passive range of motion in patients with adhesive shoulder capsulitis. This method can reliably determine passive range of motion in this patient population and be a reliable outcome measure.

**Keywords:** Adhesive capsulitis, Reliability, Passive range of motion, Pluri-meter

## Background

Range of motion (ROM) in the shoulder joint is among the commonly used clinical criteria for diagnostic purposes and to monitor effectiveness of given treatment [1]. ROM is often used as an outcome measure in studies observing effect of intervention in stiff joints and in shoulder pain [2-4]. Therefore it is important that the movement measured is reproducible without much variation, independent of instrument being used.

Shoulder capsulitis is a painful condition affecting between 2 - 5% of the adult population [5-7]. There is a global reduction of active and passive movement, generally in a capsular pattern characterized by most reduction of

external rotation, less of abduction and least of internal rotation. Reliable measurement of ROM is therefore essential for the correct diagnosis of adhesive capsulitis of the shoulder, as this is mainly a clinical diagnosis. Measurement variations in patients with shoulder capsulitis are bound to occur due to pain, fear of pain, stiffness, fatigue and measurement error at any one given time point [1]. To our knowledge no intertester reliability study has been conducted in this patient group. Reliability of measurements is therefore essential on both the affected and the non-affected side for diagnostic purposes and over time to monitor progression. Earlier intertester reliability studies have usually measured only affected [8-10] or only non-affected shoulders [11,12] and with participant numbers below 35, and ROM has only been measured at one visit or with an insignificant time difference between measurements [8,10-15]. Most former studies have only reported

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correlation coefficients and have not reported standard error of measurement ( $s_e$ ) [8,14,16,17]. Although as many as 50 patients have recently been recommended to be included in reliability studies (p. 126 in de Vet et al., [18]), only a few studies have examined this many participants [8,17,19,20]. See Table 1 for an overview of former studies.

To what degree ROM can be trusted as a reliable outcome measure was examined as part of an on-going randomized controlled trial for patients with adhesive capsulitis of the shoulder. The aims of the study were:

- To determine the reliability of shoulder passive ROM (PROM) bilaterally between two testers in a large number of participants with adhesive capsulitis using a validated measuring instrument, the plurimeter [16,25], over an eight week period.
- To determine if the measurement error remained the same during the eight week period, measured three times four weeks apart.

The intertester reliability was evaluated for PROM in abduction, external rotation, internal rotation and “hand behind back” in patients with shoulder capsulitis.

## Methods

PROM in the shoulder joint is defined as to the extent an investigator can move the arm until pain or stiffness limits the movement. We measured PROM on both the affected side and the non-affected side. There are no set rules regarding measurement intervals or the number of times measurement should take place. To avoid too much pain provocation we decided to measure each movement only once for each tester. Therefore a total of eight measurements for PROM were carried out for each of the two testers on each patient. No standardized time interval was set between tester 1 and 2, and usually only a few minutes elapsed between the two measurement sessions.

## Participants

Patients potentially eligible for inclusion in the randomized controlled trial for treatment of shoulder capsulitis were referred to a primary care clinic by physicians and physiotherapists in the period 2010–2012. The study was approved by the Regional Ethical Committee REK NORD, reference 148/2008, in compliance with the Helsinki Declaration. Informed consent was obtained from all participants, and from the tester appearing in the photographs.

The measurement took place on the second consultation and is hereafter referred to as visit 1 in the study. The PROM testing took place on visit 1, four weeks later (visit 2) and then at eight weeks (visit 3).

To be included in the study patients had to be above 18 years of age, should be able to understand and speak Norwegian, and there should be no contraindications for use of corticosteroids. Participants should have reduced range of motion in a capsular pattern with a reduction of more than 30% of two out of three shoulder movements and none of the three movements (Abduction = ABD, External rotation = ER and Internal rotation = IR) should be normal. All patients were having both pain and stiffness, and can be referred to as being in stage 1 and/or stage 2 [25,26]. Patients with diabetes, asthma, pregnant women and breast feeding mothers were excluded from the study.

The first 50 participants recruited in the main study were included in the intertester reliability study, comprising 22 men and 28 women, age ranging from 38 years to 75 years (mean age 52 years; SD 9.3). Along with other demographic data, information regarding the affected shoulder, such as the side affected, how long the condition had lasted and details of any previous treatment, was collected before taking the PROM measurements. Mean pain intensity measured with Numerical Pain rating Scale (NPRS) was 6.8 (SD 1.7) and Shoulder Pain and Disability Index (SPADI) was 63.0 (SD 19.3). Four of the included participants had bilateral capsulitis. In these patients we chose the more affected side as the “affected” and the other side as the “non-affected” side.

## Testers

Both testers were experienced general practitioners and had experience with measurements of shoulder movements with goniometer from a former pilot study. They had also trained with plurimeter on each other and on patients with shoulder capsulitis before the start of the study. Tester 2 (SS), who is also a physiotherapist, had experience in measurements of ROM. The testers planned beforehand how the measurements were to be carried out and standardised the procedures. The two testers performed ROM-testing in the same order; tester 2 always tested first and tester 1 last. The two testers kept their measurements records confidential and inaccessible to each other throughout the duration of the study until all the data was collected.

## Measurements

The Plurimeter-V gravity inclinometer (Plurimeter-V inclinometer; Dr. Rippstein, Zurich, Switzerland) was used in this study to measure PROM for abduction, external rotation and internal rotation. A plurimeter is a hand-held instrument for measuring relative angles between surfaces. In the gravity referenced inclinometer the starting position for the measurement is fixed, which is either 0° or 180°. The reliability of this instrument for measuring shoulder and scapular passive range of motion

**Table 1 Summary of intra- and intertester reliability studies for range of motion on both the affected and the non-affected shoulders using different measuring modalities**

Authors	Study sample & Size (N)	Movement	Side measured affected/ non-affected	Measuring instrument	Point estimates or over time	Study type	ICC	Sw
Pandya et al. [19]	Muscular dystrophy N = 150	PROM: ABD	Affected	Goniometer	Point estimates	Inter-tester & intra-tester	0.67	No
Riddle et al.[8]	Shoulder pain N = 100, two groups of 50 each	PROM: ABD PROM: ER PROM: IR	Affected	Goniometer	Point estimates	Inter-tester & intra-tester	0.87 0.88 0.55	No
Croft et al. [21]	Shoulder complaints N = 6	PROM: EL PROM: ER	Affected	Protractor	Point estimates	Inter-tester	0.95 0.43	No
Green et al.[16]	Shoulder pain & stiffness N = 6	AROM: FLEX, ABD, ER, IR, HBB	Affected	Plurimeter	Point estimates	Inter-tester & intra-tester	0.62–0.95	No
Sabari et al. [14]	Rehab.patients N = 11 Normal N = 19	AROM: FLEX, ABD PROM: FLEX, ABD	Mixed	Goniometer	Point estimates	Intra-tester	0.73–0.78 0.78–0.81	No
MacDermid et al. [9]	Shoulder pathology N = 34	PROM: ER	Affected	Goniometer	Point estimates	Inter-tester & intra-tester	0.85 & 0.80	Yes
Hayes et al. [10]	Shoulder pathology N = 8	AROM: ABD AROM:ER AROM: HBB	Affected	Goniometer, visual est., photography Goniometer Measuring tape	Point estimates	Inter-tester & intra-tester	ICC(Rho) 0.69 0.64 0.39	Yes
Hoving et al. [22]	Shoulder pain & stiffness N = 6	AROM: ABD ER in neutral ER in abd IR in abd HBB	Affected	Plurimeter	Point estimates	Inter-tester & intra-tester	0.51 0.29 0.11 0.06 0.80	No
Awan et al. [23]	Normal (athletes) N = 56	ER without scapular stabilization IR standard technique IR with scap. stab. IR without scap. stab	Unaffected, right & left side	Digital inclinometer	Point estimates	Inter-tester/ intra-tester	0.41–0.51 0.50–0.66	No
de Winter et al. [17]	Shoulder complaints N = 155	PROM: ABD PROM: ER	Affected/ non-affected	Digital inclinometer	Point estimates	Inter-tester	0.83/0.28 0.90/0.56	No
Terwee et al. [20]	Shoulder complaints N = 201	PROM: ABD AROM: EL PROM: ER	Affected/ non-affected	Visual estimation	Point estimates	Inter-tester	0.67/0.15 0.88/0.76 0.73/0.34	Yes
Nadeau et al. [12]	Normal N = 30		Non-affected	Goniometer & tape measure	Point estimates	Inter-tester &	0.78–0.46	No

**Table 1 Summary of intra- and intertester reliability studies for range of motion on both the affected and the non-affected shoulders using different measuring modalities (Continued)**

						intra- tester	0.75–0.32	
Tveitå et al. [15]	Shoulder adhesive capsulitis N = 32	AROM: ELEV, PROTR, RETRAC PROM: ABD Affected/non- affected FLEX IR ER		Digital inclinometer	Point estimates	Intra- tester	0.72/0.89 0.76/0.61 0.81/0.88 0.91/0.86	Yes
Mullaney et al. [13]	Shoulder pain N = 20	AROM: FLEX ER IR	Affected/non- affected	Goniometer/ digital level	Point estimates	Inter- tester & intra- tester	0.93/0.74, 0.92/0.79, 0.82/0.62	Yes
Kolber et al. [11]	Normal N = 30	AROM: ABD AROM: ER AROM: IR	Non-affected Non-affected	Inclinometer	Point estimates	Inter- tester & intra- tester	0.95 0.88 0.93	Yes
De Jong et al. [24]	Hemiplegic shoulder N = 43	PROM: ABD PROM: ER	Affected Affected	Hydro- goniometer	Over time 4, 8 & 20 weeks	Inter- tester	0.97 0.94	Yes

ABD = abduction, ER = external rotation, IR = internal rotation, HBB = hand behind back, EL = elevation, PROM = Passive range of motion, AROM = Active range of motion, Sw = standard error of measurement, scap. stab = scapular stabilization. With few exceptions only the inter-tester ICC values are written in the table.

(PROM) has been examined in previous studies [16,27]. The exact technique of measurement was standardised considering the position of the patient, position of the arm in relation to the body, and position of the pluri-meter in relation to the arm (Figure 1 a-d). The starting

position of the plurimeter was from 0 for every measurement with the instrument on the arm prior to the start of the shoulder movement. This minimizes placement error. To determine the end point of range, the arm was passively moved up to the tolerance level of pain or



**Figure 1 Measurement of passive range of motion in shoulder. a) Abduction. b) External rotation. c) Internal rotation. d) Hand behind back.**

when it was not possible to move it further due to stiffness.

The following individual passive movements were measured:

*In standing*

**Passive gleno-humeral abduction (ABD)** The patient was in standing position and the tester stood partly behind and partly to the side of the patient to be measured. The scapula was stabilized by the tester holding the inferior angle of the scapula between thumb and index finger of one hand and holding the patients arm just proximal to the patient’s elbow while at the same time holding the plurimeter between 2nd and 3rd finger on the dorsal aspect of the upper arm. Care was taken to hold the plurimeter base in a straight line on the upper arm. The arm was then passively abducted. The end point was reached either when the pain was reported as unbearable by the patient or the scapula began to rotate and the examiner could not hold the scapula in place. The reading on the plurimeter was then registered.

**Hand behind back (HBB)** HBB was measured in centimetres. The patient was in standing position and the distance was measured in centimetres (cm) by placing the patient’s hand behind the back as far as it could reach within pain limits with the ventral side of palm facing outwards. The end point was considered to be the highest landmark reached with the upper end of the radius proximal to the wrist. We chose the distal end of radius as the highest landmark to avoid measurement errors involving movement of wrist and thumb. The starting point (0 point) was taken from the posterior inferior iliac spine (PIIS). If the hand did not reach PIIS, the distance to PIIS was denoted in minus centimeters (-cm). In case the hand did not reach medially enough, parallel lines were drawn from the 0 point and the distance between them was measured horizontally. Though a complex movement, this is a pragmatic way of measuring internal rotation of the shoulder joint and is commonly used in clinical situations [16]. Studies have however demonstrated that HBB does not measure the exact range of internal rotation [28,29].

*In supine lying*

**Passive external rotation (ER) in 45° of abduction** The patient was lying supine with about 45° of gleno-humeral abduction and the elbow was kept at 90° of flexion and the forearm was kept in mid position. The plurimeter was placed between the shaft of radius and ulna in a straight line. The arm was rotated in external rotation. If the arm did not reach 0°, the ROM was noted in minus degrees.

**Passive internal rotation (IR) in 45° of abduction** The position of the patient was the same as for measuring ER. The arm was then rotated in internal rotation. The reading on plurimeter was registered at the end point of movement i.e. when the pain was unbearable or the arm could not be moved further.

**Statistics**

Descriptive statistics with mean measurement including standard deviation (SD) for each movement is presented. Reliability refers to relative agreement as well as absolute measurement error. For calculation of reliability the Intraclass correlation coefficients (ICC model 2.1) was used, as this accounts for both systematic and random error. ICC is a reliability parameter and ranges between 0 and 1, and there are no fixed standards regarding what can be considered as acceptable. According to Eliasziw and co-workers [30], ICC values from 0.60 to 0.79 indicate moderate reliability, values ≥0.80 to 0.90 as very reliable, and >0.90 as excellent. For absolute agreement, which is the actual difference in measurements (i.e. absolute measurement error in degrees and centimeters), the size of measurement error was calculated. Bland and Altman [31] have suggested estimating within-subject standard deviation (s<sub>w</sub>), i.e. the common SD of repeated measurements, derived from one-way analysis of variance. Statistical analysis was carried out using the IBM SPSS Statistics version 19, software program.

**Results**

Mean raw data for measurement of abduction, external and internal rotation and hand behind back are listed for both the affected and the non-affected arm in Tables 2, 3, 4 and 5.

**Table 2 Mean range and standard deviation (SD) for two testers for abduction (ABD) in 50 patients with shoulder capsulitis**

Visit	Tests	ROM tester 1 ROM° (SD)	ROM tester 2 ROM° (SD)	ICC 2,1	s <sub>w</sub> °
1.	ABD non-affected	87.3 (7.7)	88.4 (6.6)	0.91	2.1
	ABD affected	53.2 (17.0)	54.1 (15.1)	0.83	6.7
2.	ABD non-affected	88.3 (6.8)	89.0 (4.7)	0.88	2.0
	ABD affected	60.6 (17.9)	61.7 (18.7)	0.90	5.9
3.	ABD non-affected	89.7 (2.9)	89.7 (1.6)	0.64	1.4
	ABD affected	65.4 (19.5)	68.3 (19.5)	0.86	7.2

Relative agreement is reported with intraclass correlation coefficient, ICC (2,1), and absolute measurement error is reported with within-subject standard deviation, s<sub>w</sub>, between the two testers. ROM = Range of motion.

**Table 3 Mean range and standard deviation (SD) for two testers for external rotation (ER) in 50 patients with shoulder capsulitis**

Visit	Tests	ROM Tester 1	ROM Tester 2	ICC	s <sub>w</sub> °
		ROM° (SD)	ROM° (SD)	2,1	
1.	ER non-affected	70.8 (16.0)	75.0 (17.9)	0.83	6.5
	ER affected	18.6 (16.2)	22.1 (16.1)	0.90	4.5
2.	ER non-affected	71.8 (14.1)	76.4 (15.7)	0.80	6.0
	ER affected	25.0 (19.2)	28.6 (17.6)	0.89	5.8
3.	ER non-affected	72.0 (13.2)	78.5 (11.3)	0.69	5.7
	ER affected	34.0 (22.6)	35.3 (19.2)	0.91	6.2

**Abduction (ABD)**

Very good to excellent reliability calculated with ICC 2.1 was found during all three visits, except for the 3rd visit for the normal side (Table 2).

The measurement error (s<sub>w</sub>) for the affected arm ranged from 6.7° at first visit, 5.9° at the 2nd and 7.2° at the last visit, whereas s<sub>w</sub> for the non-affected arm was between 1.4 and 2.1°.

**External rotation (ER)**

Very good to excellent reliability was found at all three visits, except for a moderate reliability shown for the non-affected arm on the third visit (Table 3).

The measurement error (s<sub>w</sub>) for the affected arm ranged between 4.5°, 5.8° and 6.2°. The s<sub>w</sub> was almost the same for the healthy arm: 6.5° on the first visit and 5.7° on the last.

**Internal rotation (IR)**

Good reliability calculated with ICCs was found on both the normal and affected side for all three visits, except for moderate reliability (ICC 0.63) shown in the last visit for the normal arm. Measurement error for IR ranged from 5.6° to 7.0° on the affected side and from 5.1° to 6.2 on the healthy side (Table 4).

**Table 4 Mean range and standard deviation (SD) for two testers for internal rotation (IR) and hand behind back (HBB) in 50 patients with shoulder capsulitis**

Visit	Tests	ROM Tester 1	ROM Tester 2	ICC	s <sub>w</sub> °
		ROM° (SD)	ROM° (SD)	2,1	
1.	IR non-affected	73.0 (14.3)	77.9 (13.9)	0.76	6.2
	IR affected	40.7 (14.9)	42.4 (14.1)	0.85	7
2.	IR non-affected	72.9 (13.0)	78.0 (13.4)	0.78	5.4
	IR affected	44.3 (16.9)	47.3 (17.8)	0.85	6.4
3.	IR non-affected	73.8 (10.8)	80.3 (9.9)	0.63	5.1
	IR affected	51.0 (18.3)	54.1 (18.0)	0.89	5.6

**Hand behind back (HBB)**

Excellent reliability was found on both the normal and the affected side when measuring HBB. The measurement error ranged from 1.6 cm to 1.9 cm on the affected side, and from 1.1 cm to 2.1 cm on the normal side (Table 5).

Graphic scatter plots showed that there were a few outliers (see Figure 2a and b) where the two testers had measured a difference in range of 15° - 20° in a couple of patients.

**Discussion**

This large cohort study demonstrated very good to excellent intertester reliability when examining PROM in patients with shoulder adhesive capsulitis stage II. The results in our study are comparable or better than other reliability studies measuring shoulder ROM in normal individuals or in other shoulder populations (Table 1) [8,13,16,17,20,22,24]. To our knowledge this is the first reliability study that has measured passive ROM in patients with adhesive shoulder capsulitis using a pluri-meter, whereas most former studies have used a variety of measuring instruments and techniques. The intertester reliability remained excellent at all three visits for examination of the affected side. The unaffected arm had stable measurements over time, while the affected arm changed over time, possibly due to treatment and/or general improvement. The measurement errors were found to vary between ~5°- 7° on all three visits when examining the affected shoulder for passive abduction, and bilaterally when examining external and internal rotation. The measurement error was relatively small when examining abduction (ABD) (~1.5°- 2°) in the normal arm and for measuring hand behind back (HBB) in both arms (~1 cm -2 cm) on all three visits. Some of the good results found in our study may be attributed to training of the testers who practiced the procedures on each other and on patients before the start of the study. Better results have been observed due to increased practice earlier [16].

The ICCs values for the affected side were very reliable on all three visits (ICCs ≥ 0.83 - 0.96). The measurements on the non-affected side had slightly lower ICC values than the affected side, but only at the third visit. De Winter et al. [17] had an ICC of 0.28 on the non-affected side and 0.83 on the affected side for ABD, and 0.56 for the non-affected side and 0.90 for the affected side for ER in patients with painful shoulder. Possibly a combination of low spread in scores and low variance has resulted in a low ICC, albeit with a low measurement error as demonstrated in Figure 2 b.

The absolute measurement error found in our study is generally better than the few studies where ROM in the shoulder has been measured. However, no values



**Table 5 Mean range and standard deviation (SD) for two testers for hand behind back (HBB) in 50 patients with shoulder capsulitis**

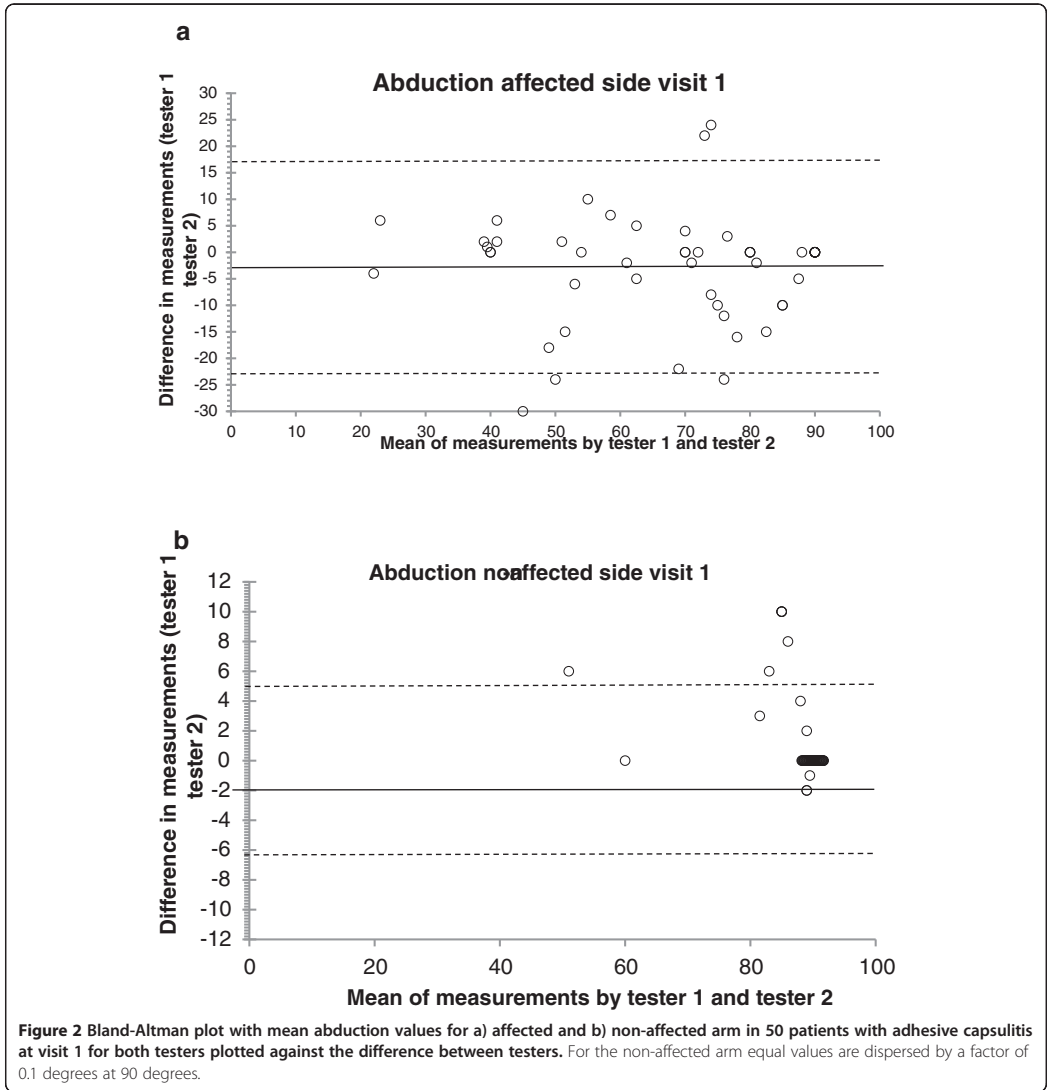
Visit	Tests	ROM Tester 1	ROM Tester 2	ICC 2,1	s <sub>w</sub> cm
		ROM (SD)	ROM (SD)		
1.	HBB non-affected (cm)	18.3 (5.7)	18.4 (5.8)	0.97	2.1
	HBB affected (cm)	0.2 (6.9)	1.5 (7.0)	0.91	1.9
2.	HBB non-affected (cm)	19.0 (5.8)	19.0 (5.5)	0.98	0.9
	HBB affected (cm)	4.9 (7.3)	4.3 (7.9)	0.94	1.8
3.	HBB non-affected (cm)	19.1 (5.0)	19.4 (5.3)	0.96	1.1
	HBB affected (cm)	7.9 (8.6)	8.7 (7.9)	0.96	1.6

have formerly been reported on patients with capsulitis. Hayes et al. [10] found standard error of measurement (i.e.  $s_w$ ) to range from 14° - 25° for flexion, ABD and IR. Kolber et al. [11] reported small  $s_w$  ranging from approximately 2° - 4° in ABD, ER and IR among 30 normal participants. In the study by de Winter et al. [17], 155 participants with shoulder pain were examined, and  $s_w$  ranged from 14° - 20° for ABD and ER. Muir et al. [1] studied a mixed participant group of 17, and the  $s_w$  ranged from 6° - 9° in flexion, ABD, ER and IR in supine lying. The measurement error indicates that some variation must be expected when using ROM as an outcome measure. In our study the affected arm had about 1/3 to 1/2 of the ROM as compared to the non-affected arm at the first visit. Smallest detectable change SDD ( $\sqrt{2} \times 1.96 = 2.77 s_w$ ) is often used to indicate statistical significant change [32]. An  $s_w$  of ~5°-7° for ER, IR and ABD and an  $s_w$  of ~2 cm for HBB for the affected side would indicate that statistical change larger than the measurement error in the effect study would have to be 14°- 19°, and ~5.5 cm. In our study, the SDD values for the affected arm were close to statistical significant change above measurement error from the first to the third visit. Range of motion is an important and reliable outcome measure, and a change of  $\geq 15^\circ$  is necessary to represent a clinically significant change in patients with adhesive capsulitis. Patients with shoulder capsulitis in stage II generally have a large movement reduction and a change of  $>15^\circ$  has a positive impact on functionality in activities of daily living. Clinically important change should be defined within a context, and may sometimes be smaller than the SDD [33].

A sample size of 50 participants and measurement of ROM on both the affected and non-affected side constitutes a large sample size for examination of reliability [18]. Inclusion of 50 patients was based on the recommendations made in "Measurement in medicine" [32]. However, since two testers tested both sides three times, a lower sample size would have been sufficient.

Our sample is representative concerning gender (56% female) and age (mean 52 years) for patients with shoulder adhesive capsulitis in stage II [15]. At inclusion, participants in our study were patients with moderate to severe capsulitis. The numerical pain rating scale (NPRS) ranged from 5 to 9, which characterizes moderate to severe pain and may pose problems in measuring ROM. However, the very good to excellent reliability proves otherwise, i.e. measurements were still reliable in patients with moderate to severe painful stiff shoulders corresponding to stage II. The pre-treatment value for pain and function indicated moderate to severe problems (SPADI values varied from 42 to 98, on average 63). The recruited patients had restricted shoulder movement with more than 30% reduction in two of three PROM values and none of the three movements were normal. We chose to only examine passive ABD, ER, IR and HBB as these are the standard movements for diagnosis of shoulder capsulitis and may also be used over time to monitor progression [34,35]. Since pain and stiffness pose particular problems while measuring PROM, for example in finding out the exact end point of movement, measurement of AROM could have been a good supplement. Studies have shown that AROM is more reliable than PROM, probably because the extra pressure from the examiner while measuring PROM may affect the ROM [36,37].

The strength of this study lies in its good power, representativeness of the condition studied and good to excellent results, as well as being the first study that measures intertester reliability in patients with shoulder adhesive capsulitis with plurimeter. Among limitations it may be mentioned that non-randomization of testers may have induced systematic measurement error, as tester 2 may have provoked pain and thus affected the PROM for tester 1. The testers had two criteria, pain and stiffness, for judging the end of movement and this may also have constituted some source of measurement variation, although small. Despite the non-randomised test-procedure our results are very good.



Although tester 2, who always tested before tester 1, had a tendency to measure a larger range for external and internal rotation, and mostly for the non-affected arm, findings in our study show an overall very good to excellent reliability for measuring PROM in patients with this condition. This is an important finding because measuring PROM is the diagnostic test for adhesive shoulder capsulitis. Little difference in intertester reliability occurred for the duration of the study (eight weeks). Although an intra-

tester reliability study with short time intervals was not performed, our results indicate that we can trust the measurements from one tester at different visits also in an effect study.

**Conclusion**

Intertester reliability between two testers was very good at three visits over a time period of eight weeks using a pluri-meter to measure passive range of motion in

patients with adhesive shoulder capsulitis. This method can reliably determine passive range of motion in this patient population and be a reliable outcome measure.

#### Competing interests

The authors declare that they have no competing interests.

#### Authors' contributions

All authors contributed to the design of the study. SS recruited the patients, measured range of motion and drafted the manuscript, performed statistical analysis with help from AK. AK and AB helped in drafting the manuscript. All authors have read and approved the final manuscript.

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RESEARCH ARTICLE

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# Adhesive capsulitis of the shoulder, treatment with corticosteroid, corticosteroid with distension or treatment-as-usual; a randomised controlled trial in primary care

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## Abstract

**Background:** Optimal management for adhesive shoulder capsulitis (frozen shoulder) is currently unclear. We intended to explore whether treatment by intra-articular injections with corticosteroid and distension is more effective than treating with corticosteroids alone or treatment-as-usual in a primary care setting in Norway.

**Methods:** In this prospective randomised intention to treat parallel study, 106 patients were block randomised to three groups; 36 (analysed 35) receiving steroid injection and Lidocaine (IS), 34 receiving steroid and additional saline as distension (ISD) and 36 had treatment-as-usual (TAU). Intervention groups received four injections within 8 weeks, assessed on 1st visit, at the 4th and 8th week. Outcomes were Shoulder Pain and Disability Index (SPADI), Numerical pain rating scale (NPRS) and passive range of motion (PROM). Postal assessment was repeated after 1 year for SPADI. Patients in the IS and ISD groups were "blinded" for intervention received and the assessor was "blinded" to group allocation.

**Results:** At baseline there were no differences between groups in outcome measures. There were no statistical significant differences between the intervention groups in SPADI, NPRS and PROM at baseline, at short-term (4-and 8 weeks) or long-term (12 months). There were statistically significant differences ( $p < 0.01$ ) in change scores at short-term for SPADI when comparing the IS and TAU groups (-20.8; CI-28.9 to -12.7), and the ISD and TAU groups (-21.7; CI-29.4 to -14.0), respectively for NPRS (-2.0; CI-2.8 to -1.1 and -2.2; CI-3.0 to -1.4), and for PROM, but not at long-term for SPADI ( $p > 0.05$ ).

Effect size (ES) at 8 weeks was large between both injection groups and TAU (ES 1.2). At 12 months ES was reduced to 0.3 and 0.4 respectively. Transitory side effects as flushing and after-pain were reported by 14 % in intervention groups.

**Conclusion:** This intention to treat RCT in primary care indicates that four injections with corticosteroid with or without distension, given with increasing intervals during 8 weeks, were better than treatment-as-usual in treatment of adhesive shoulder capsulitis. However, in the long run no difference was found between any of the groups, indicating that natural healing takes place independent of treatment or not.

**Trial registration:** ClinicalTrials.gov, <https://clinicaltrials.gov/> identifier: NCT01570985

**Keywords:** Adhesive capsulitis, Corticosteroid, Distension, Frozen shoulder

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## Background

Adhesive capsulitis of the shoulder, also called frozen shoulder, has a prevalence of 2 to 5 % of the general population, but among diabetic patients the prevalence ranged from 11 to 30 % [1, 2]. There is a strong correlation between adhesive capsulitis and other medical conditions such as diabetes, rheumatic disease, heart disease, hyperthyreosis [3]. Adhesive capsulitis occurs mostly in middle age [4–6] and women between 50 and 60 years are most commonly affected [7]. Both shoulders can be affected simultaneously and/or the other side can be affected a few years later [7, 8]. Shoulder stiffness and pain interferes considerably with activities of daily living, and may be associated with increased sick leave in people of working age and incapacity in the elderly.

Adhesive capsulitis is a long-lasting disorder with spontaneous onset of pain and progressive stiffness [9]. It generally involves reduced movement of the gleno-humeral joint in several planes, with most restriction of external rotation, some restriction of abduction and least affection of internal rotation carried out passively, also called the capsular pattern [5, 6]. Adhesive capsulitis is primarily a clinical diagnosis and radiography can be complementary in the diagnosis [10, 11]. Pathophysiologically, thickening and contracture of the inferior capsule [12], contracture of the rotator interval, coraco-humeral ligament and anterior capsule with a combination of synovial inflammation and capsular fibrosis, has been described [10]. Bunker et al. found the histo-pathological picture comparable to Dupuytren's disease of the hand with no inflammation and no synovial involvement [13]. The natural history remains controversial. Earlier studies considered the condition as self-limiting, lasting for 2 to 3 years, reporting that the majority of patients would get almost complete recovery or full recovery [14, 15]. Other authors report long-term pain and stiffness for several years [16–18]. For convenience, the condition is divided into three phases; the painful phase lasting from 3 to 9 months, followed by a freezing phase with progressive stiffness lasting from 4 to 12 months and finally, the recovery phase with gradual return of movement, lasting 5–26 months [19, 20]. Some have divided the condition into four stages, based on the correlation of findings on physical examination and arthroscopic examination [21].

Commonly used conservative therapies for adhesive capsulitis include non-steroidal anti-inflammatory drugs, intra-articular glucocorticosteroid injections, oral glucocorticosteroid medication, physical therapy, manipulation under anaesthesia and hydrodilatation [22]. However, despite the amount of research in the topic, results still appear to be inconclusive regarding effectiveness of the different treatment modalities [23, 24]. In hydrodilatation or arthrographic distension procedures, an intra-articular injection is performed under fluoroscopy with local

anaesthetics, normal saline and often with contrast medium. Most of the interventional studies with corticosteroid injections, with or without hydrodilatation (distension), have been done with single corticosteroid injection under fluoroscopy or ultrasound guided, either sub-acromial or intra-articular or both. Van der Windt et al. [25] used up to a maximum of three intra-articular injections over 6 weeks. According to Cyriax's treatment method [1], adhesive capsulitis is often treated with between three to six corticosteroid intra-articular injections with increasing interval between injections, which is also supported by others [4–6, 26]. A short term efficacy of arthrographic distension with normal saline and corticosteroid versus placebo was demonstrated in a randomised controlled trial (RCT) in patients with painful stiff shoulder [27]. A systematic Cochrane review regarding efficacy of hydrodilatation concludes: "there is "silver" level evidence that arthrographic distension with saline and steroid provides short-term benefits in pain, range of movement and function in adhesive capsulitis. It is uncertain whether this is better than alternative interventions" [28]. Hydrodilatation studies [29–31] did not demonstrate any statistically significant differences in functional outcome compared to steroid injection [32].

The present study has followed the existing practice of treating patients with adhesive capsulitis in primary care in Norway. In a pilot trial, there was no clinically significant difference in overall results between corticosteroid alone and corticosteroid with distension [33]. The aim of this study was to elucidate the effect, if any, of multiple corticosteroid injections with distension as compared to multiple corticosteroid injections alone, to treatment-as-usual.

## Methods

This RCT comprises two parallel intervention groups and a control group allocating equal number of patients. The intervention period lasted 8 weeks, with a postal follow-up after 1 year. The patients were recruited from the city of Bergen and neighboring municipalities by referral from primary care (PC) practitioners from January 2010 to October 2013.

Included patients had to be above 18 years of age, should be able to understand and speak Norwegian, and have no contraindication for use of corticosteroids. Patients should have reduced passive range of motion (PROM) with a reduction of more than 30 % of two of three shoulder movements and none of the three movements (Abduction = ABD, External rotation = ER and Internal rotation = IR) should be normal. Patients with diabetes, asthma, pregnant women and breast feeding mothers were excluded from the study. Female patients in fertile age were asked about prevention.

Eligible patients were invited to participate in the study were randomly assigned to one of three groups according to serial no. on the closed envelope by one of authors (SPS). The block randomisation, using a block size of three, was carried out by one of the supervisors (AB). Possible permutations were strung together using a random cipher table. The resulting information on treatment was printed out and put in a closed envelope with the patient serial number outside. The envelope was to be opened after the inclusion of the patient. Treatment allocation was thereby “blinded” for both researcher and patient at the point of inclusion. The patients in the active intervention groups were not informed which treatment option (with or without distension) was carried out.

### Intervention

Intra-articular injections were administered by landmarks using posterior approach thus preventing the patients from seeing the size of syringe used. This was to avoid possible bias as the patients might consider treatment with distension and corticosteroid to be superior to corticosteroid alone. The injections were administered by one of the authors (SPS) who is both a general practitioner and a physiotherapist at a primary care center in municipality of Bergen and has several years of experience in treating adhesive capsulitis by intra-articular injections both by landmarks and ultrasound guided.

Patients in the steroid alone group (IS) received Triamcinolone 20 mg injection, with Lidocaine 10 mg/ml 3 ml and a total of 4 ml solution. Those in the distension group (ISD) also received steroid and Lidocaine (Triamcinolone 20 mg, 3 ml Lidocaine), but with additional physiological Sodium chloride 9 mg/ml, comprising a total volume from 8 ml and upwards to 20 ml. Limiting factors for injected volume were difficulty in further injection and/or increasing pain during injection. Injection to IS and ISD groups were given after inclusion on day 1, after 7, 17, and 31 days from the start. Adherence to planned intervention was assessed continuously by one of the authors (SPS). Patients receiving treatment-as-usual (TAU) were informed about the possibilities of optional conservative treatment, such as physiotherapy or pain medication other than corticosteroid injections or per oral corticosteroid medication until 61 days after inclusion.

### Outcome measures

The primary outcome was the Shoulder pain and disability index (SPADI), which measures a combination of pain and functional disability on a score from 0 to 100, a high score indicating more pain and disability [34]. The second outcome measure was pain intensity on average for the previous 7 days, measured on a 10-point

Numerical pain rating scale (NPRS), where 0 meant no pain and 10 meant unbearable pain. PROM was measured in sideways elevation (abduction), internal rotation (by “Hand behind back” method) and external rotation. A pluri-meter, found to be a reliable gravity inclinometer, was used as the measuring instrument for PROM [35–37]. PROM was measured, also on the normal side, on all visits. PROM was measured in supine lying position for external and internal rotation, and for abduction in standing. The endpoint was when the arm could not be moved more or the pain became unbearable. To avoid discrepancies in measurements due to affection of movements of thumb joints, the distance in Hand-behind-back was measured in centimeters between the styloid process of the radius to the posterior inferior iliac spine. PROM was measured by a research collaborator (a GP) being unaware which group the patients were randomised to. The assessor who took PROM had experience in use of the pluri-meter, and had shown acceptable inter-tester reliability [37]. The assessor made entries of the PROM on a separate paper so that confidentiality was maintained from the treating doctor throughout the study.

The time intervals between the consecutive treatments were 1, 1½ and 2 weeks. The control group remained without treatment with corticosteroids in injection or tablet form until 61 days, but could use NSAIDs, Paracetamol or Codeine as needed. SPADI and NPRS were registered on the first visit, after 4 and 8 weeks. The 1 year follow-up for SPADI was only by postal communication.

### Sample size

For SPADI, being the primary outcome measure, we considered an outcome of 20 % better or worse to be clinically significant. This represents a difference in score of 14 at the level of SPADI = 70. Others have considered a difference in score of  $\geq 10$  to represent clinically important change [34, 38]. In a previous study where SPADI was a primary outcome measure, the variance in SPADI was 19.8 [27]. Given  $\alpha = 0.05$ , we calculated the sample size to be 31 in each group to have an 80 % power to detect a difference in mean SPADI score of  $\geq 14$ . With a 10 % drop out the number of patients required for the study to have the above mentioned power were calculated to be 34 in each group.

### Statistical analysis

Differences in outcome between the groups were analyzed using repeated measure ANCOVA and regression based ANCOVA. In our analysis we have distinguished between short-term follow-up (4 and 8 weeks) and long-term follow-up (12 months). Since the 4 and 8 weeks data were not independent, we chose to analyze these data as multiple follow-up observations. This was done in a repeated measures ANCOVA model with 4 and 8 weeks

observations as repeated measures to capture the main effect of treatment between groups [39] (p.197), and with pretest as a covariate to adjust for baseline differences between subjects. Similarly, we analyzed the long-term follow-up data in another ANCOVA model using a regression procedure with the 12 months observations as dependent variable, group as a categorical independent variable and pretest as a covariate. In an additional/secondary analysis we added other independent variables (specified) to both ANCOVA models to control for possible confounding.

Effect size (ES) for mean change in SPADI was also calculated by subtracting post-test score (8 weeks and 12 months) from baseline in two groups, dividing it by the standard deviation (SD) of the change score:

$$\text{Effect size} = \frac{[\text{Mean of intervention group}] - [\text{Mean of treatment-as-usual group}]}{\text{Standard Deviation}}$$

An ES of 0.8 is considered large and of crucial practical or clinical importance, while an ES of 0.2 is considered to be small and without any practical or clinical importance [39].

We performed intention to treat (ITT) analysis [40], keeping patients in their original allocations on randomisation in accordance with ITT principles [41]. We had intervention data for all patients until 8 weeks except for missing data for two patients for 4 weeks and one patient for 8 weeks. One year follow-up data was lacking for six patients. Missing data were imputed following ITT principles.

Software package IBM SPSS Statistics 22 for Windows, was used for all statistical analyses.

We have followed the CONSORT (Consolidated Standards of Reporting Trials) 2010 guidelines for reporting of parallel group randomised trials. Figure 1 included in the manuscript has followed 2010 CONSORT Flow Diagram template. CONSORT 2010 Checklists for Randomised Trials, CONSORT extension for Abstracts Checklist and TIDieR (Template for Intervention Description and Replication) checklist files.

## Results

Of the 216 patients referred for the study, 146 met the inclusion criteria, whereof 40 patients declined to participate for fear of coming in the TAU group and not receiving treatment immediately. Seventy patients were excluded as they were less affected than the specified criteria for reduced ROM or had diabetes. One hundred and six patients were randomised for participation. Thirty-six patients were allocated to the IS group, 34 patients to the ISD group, and 36 patients to TAU (Fig. 1). All completed the specified intervention until 8 weeks, and there were no dropouts, except for one in the IS group. After 1 year 100 patients (95 %) answered the

postal questionnaire. One year follow up ended in December 2014. No interim analysis was carried out during the trial.

## Patient characteristics

Baseline characteristics of all the included patients are displayed in Table 1. The three groups were comparable in their baseline regarding age, gender, mean duration of shoulder pain, concurrent neck pain, previously frozen shoulder, number of affected right side and dominant side and sick leaves. There were no statistically significant differences between the three groups regarding side affected, operated shoulder prior to adhesive capsulitis, trauma to shoulder (traumatic adhesive capsulitis), previous shoulder treatment, and smoking. There was a statistically significant difference in use of analgesics at baseline between the two intervention groups ( $p < 0.05$ ), but not between the injection groups and TAU. Furthermore, 11 patients in the distension group had "trauma to shoulder" whereas the IS group had two and the TAU had three patients with previous trauma.

## Intervention

Thirty-five patients in the IS group and 34 patients in the ISD group received four injections each within the time frame of 8 weeks. After the intervention period of 8 weeks, 12 patients (33 %) in the TAU group received additional treatment with intra-articular injections with corticosteroid and Lidocaine, same as in the IS group, for pain relief, and three were operated. During the 8 weeks after recruitment, 11 patients in the TAU group had received NSAIDs and/or pain killers as needed, and three patients had received acupuncture for pain relief.

All three groups showed clinically significant change in SPADI from baseline to 8 weeks (>14 points improvement), although both intervention groups had improved significantly more as compared to the TAU group at 8 weeks. Similarly, there was a significant improvement in NPRS at 8 weeks for both intervention groups, but less in the TAU group. Change in PROM for abduction was slightly better between the distension group (54° increased to 69°; i.e. 15° increase) and the TAU group (51° increased to 57°; i.e. 6° increase) at 8 weeks (Table 2).

Both intervention groups had equivalent ES concerning SPADI at 8 weeks (ES 1.2) and 12 months (ES 0.3 and 0.4) (Table 3). At 12 months, however, the change in the TAU group was as large as the change in the two intervention groups and no statistical significant difference was found in SPADI between the three groups, illustrated in Fig. 2.

Repeated measure ANCOVA for short-term and regression based ANCOVA for long-term revealed no statistically significant difference between the two intervention groups in SPADI, NPRS and PROM, neither at



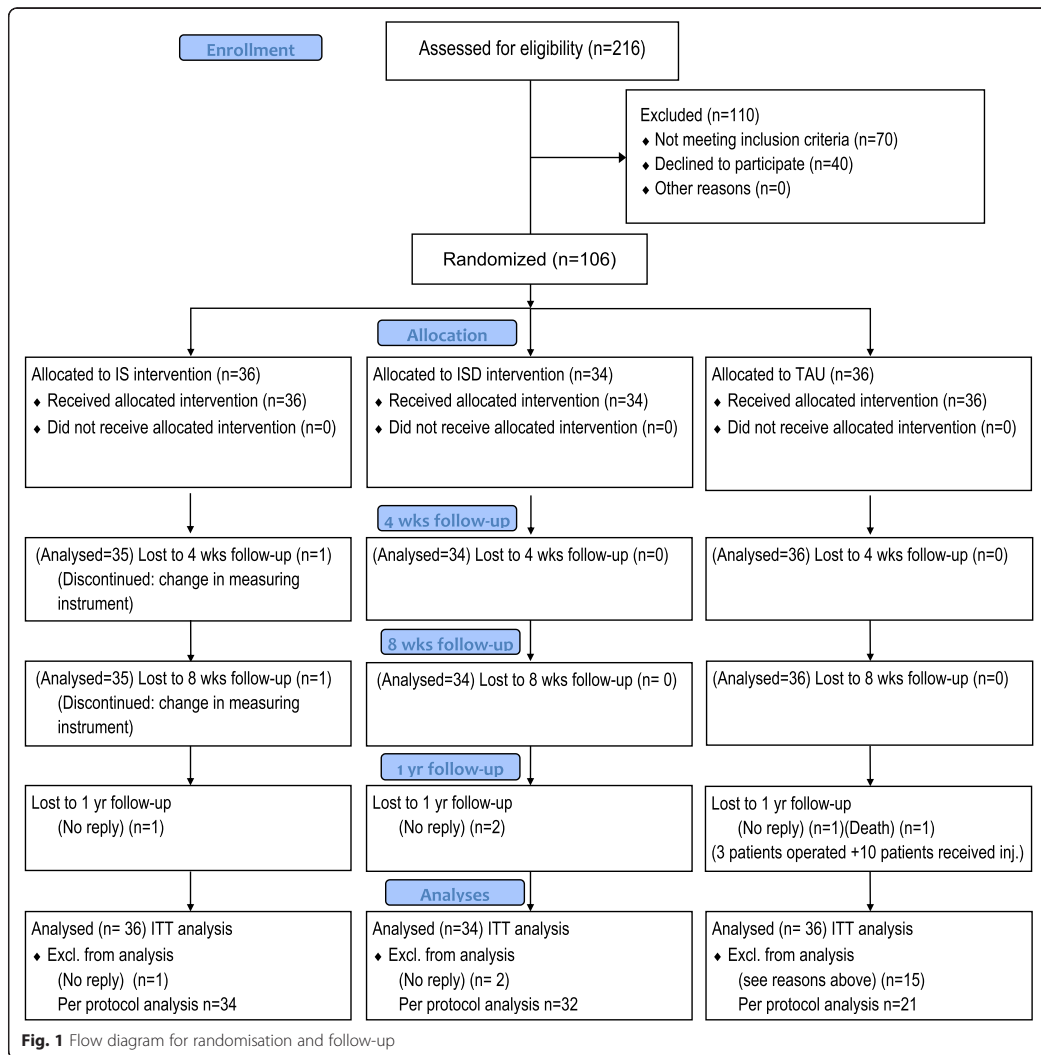


Fig. 1 Flow diagram for randomisation and follow-up

baseline, nor at short-term, or in SPADI at long-term. A statistically significant change ( $p < 0.001$ ) was found for both intervention groups when compared to the TAU group at short-term for SPADI and NPRS. There was a statistically significant difference ( $p < 0.01$ ) at short-term for all PROMs between the two injection groups and TAU (Table 4).

In the TAU group, three patients were operated after 8 weeks, and 12 patients chose to receive intra-articular corticosteroid injections without distension. In the intention-to-treat analysis at 12 months, including all patients in the groups to which they were allocated,

there were no significant differences between any of the groups regarding change in SPADI (Table 4).

In our study there was only one drop out up to 8 weeks and we did not expect this to affect the results substantially. A secondary per-protocol analysis was performed excluding the 15 patients that did not follow the initial TAU protocol after the 8 week period. This did not affect the results. However, we do acknowledge the fact that exclusion of these patients lowers the sample power for the TAU group.

Five patients (14 %) in the IS group, eight patients (24 %) in ISD group and six patients (14 %) in the TAU group were still on sick leave after 1 year. Eight patients

**Table 1** Baseline characteristics of patients

Characteristics	Injection group Steroid alone (IS)	Injection group Steroid and saline (ISD)	Treatment-as-usual (TAU) group
	Number and % within group n = 36	Number and % within group n = 34	Number and % within group n = 36
Mean age (years)	52 (8.3)	53 (9.2)	54 (6.9)
Female	21 (58 %)	21 (62 %)	19 (53 %)
Duration in months Median (range)	7.5 (2.0–18.0)	7.0 (3.0–37.0)	6.0 (3.0–24.0)
Affected right shoulder	18 (50 %)	12 (35 %)	15 (42 %)
Previous frozen shoulder	6 (17 %)	4 (11 %)	4 (11 %)
Concurrent neck pain	16 (44 %)	15 (44 %)	16 (44 %)
Trauma to shoulder	2 (6 %)	11 (32 %)	3 (8 %)
Previous operation on shoulder	3 (8 %)	3 (9 %)	1 (3 %)
Dominant right side	34 (94 %)	30 (88 %)	34 (94 %)
Previous shoulder treatment	15 (42 %)	22 (65 %)	13 (36 %)
Analgesics	19 (53 %)	14 (41 %)	11 (31 %)
Participants on sick leave	17 (50 %)	16 (47 %)	15 (42 %)
Smokers	8 (22 %)	6 (18 %)	12 (33 %)

(22 %) in the IS group, nine patients (26 %) in the ISD group and three patients (8 %) in the TAU group were still on medication for shoulder pain at 12 months follow-up.

Six patients (17 %) in the IS group and four (12 %) patients in the ISD group experienced minor transitory side-effects such as flushing and after-pain. No incidences of other side effects were reported. Patients in the two injection groups were asked to guess to which group they belonged to after the last injection. Twenty-six patients (38 %) guessed the wrong group.

## Discussion

Repeated intra-articular steroid injections given with increasing intervals in the gleno-humeral joint gives short-term (8 weeks) benefit. Added capsular distension did not significantly affect the outcome measures for SPADI, NPRS and PROM. However, at long-term follow-up, those who had received no intervention did equally well.

Earlier studies combining distension (10 ml) and corticosteroid versus distension alone and corticosteroid alone, have reported better results for distension [42]. While in studies by Corbeil et al. & Tveitå et al. [30, 31] no significant differences between distension and non-distension arthrography with corticosteroids were found, the main effect might therefore be attributed to corticosteroid alone. Comparing our results between ISD group and TAU group with Tveitå et al. [31], our study has demonstrated larger improvement; for SPADI 24 versus 6, for ABD 15.4 versus 2, for ER 18.7 versus 2 and for IR 12.3 versus 3 respectively. A systematic review concluded with “silver level” evidence for short-term efficacy in pain, ROM, and function of shoulder by arthrographic saline distension

and corticosteroid in patients with adhesive capsulitis [28]. Studies with distension and corticosteroid causing capsular rupture performed in hospital settings have also shown significant results [27, 29, 42]. These and other case series studies in primary care with distension and capsular rupture [43, 44] are, however, not comparable to the present study, as capsular rupture was not the intended intervention. We cannot however rule out that capsular rupture might have occurred in some patients. Tveitå et al. [31] have observed capsular rupture at a volume as low as 10 ml.

A dose of 20 mg Triamcinolone was a tradeoff dose between effect and side effects in both intervention groups and is the generally accepted and practiced treatment dose for adhesive capsulitis in primary care. A study by de Jong [45] has shown better effect with a dose of 40 mg Triamcinolone than with 10 mg, whereas another study by Yoon et al. [46] found no significant difference in outcome between a dose of 20 and 40 mg Triamcinolone. In this study we used a series of injections, a total of four over a period of 8 weeks. Many studies with distension have only used a single corticosteroid injection, which makes comparison difficult. Only a few studies have used multiple injections and even fewer have used multiple injections with dilatation [25, 29, 31, 42, 47]. A review has concluded that multiple injections improve pain and ROM in short term from 6 to 16 weeks from the first injection. There is evidence that up to three injections can be beneficial and limited evidence that up to six injections is beneficial [4].

This study has followed the actual practice of treating these patients in primary care with intra-articular injections by landmarks, without fluoroscopic guidance. Some studies with ultrasound guided intra-articular steroid

**Table 2** SPADI, NPRS and PROM and comparison in outcomes between three groups

	Injection group Steroid alone (IS) Mean (SD)	Injection group Steroid and saline (ISD) Mean (SD)	Treatment-as-usual (TAU) Mean (SD)
Primary outcome variable			
SPADI			
At inclusion	63.8 (16.0)	60.5 (16.8)	61.9 (19.0)
4 weeks	34.1 (21.4)	30.9 (21.0)	51.9 (22.2)
8 weeks	23.8 (22.0)	20.1 (18.4)	44.4 (23.6)
12 months	16.9 (18.9)	17.2 (19.8)	11.7 (20.3)
Secondary outcome variable			
NPRS			
At inclusion	6.9 (1.4)	7.2 (1.6)	6.6 (2.1)
4 weeks	3.8 (2.2)	3.5 (1.7)	5.6 (2.5)
8 weeks	3.0 (2.3)	2.9 (1.6)	4.7 (2.0)
Tertiary outcome variables			
Abduction (ABD)			
At inclusion	53.7 (13.4)	51.0 (17.8)	50.5 (19.0)
4 weeks	62.7 (15.6)	64.7 (17.2)	53.9 (19.4)
8 weeks	68.9 (15.3)	71.9 (17.0)	56.5 (20.9)
External rotation (ER)			
At inclusion	19.6 (14.7)	25.2 (17.7)	17.3 (13.5)
4 weeks	30.1 (16.3)	35.6 (15.8)	18.8 (14.8)
8 weeks	38.2 (17.6)	42.7 (17.9)	24.0 (18.1)
Internal rotation (IR)			
At inclusion	38.8 (15.5)	41.1 (14.1)	40.2 (15.4)
4 weeks	49.5 (17.4)	52.7 (17.3)	43.7 (16.6)
8 weeks	57.2 (15.7)	59.6 (16.1)	47.3 (18.2)
Hand behind back (HBB)			
At inclusion	0.4 (6.2)	2.2 (7.8)	-0.5 (6.0)
4 weeks	5.9 (7.2)	7.5 (7.8)	1.0 (6.1)
8 weeks	10.1 (6.3)	11.2 (7.2)	4.3 (6.5)

SPADI shoulder pain and disability index, NPRS numeric pain rating scale, PROM passive range of motion  
IS injection steroid alone, ISD injection steroid plus saline, TAU treatment-as-usual

**Table 3** Effect size (ES) for SPADI from baseline to 8 weeks and 12 months follow-up for the three groups

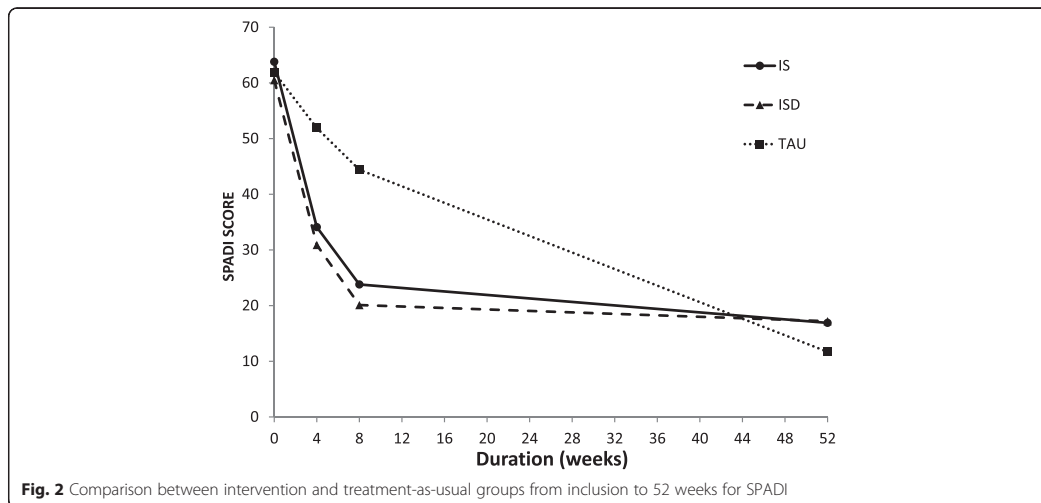
SPADI	IS	ISD	TAU	IS & ISD	IS & TAU	ISD & TAU
8 weeks						
Mean change	-40.3	-40.4	-17.4	0.2	22.8	23.0
SD	19.0	19.1	19.8	19.1	19.4	19.4
ES				0.0	1.2	1.2
12 months						
Mean change	-43.0	-39.8	-48.1	3.1	5.1	8.2
SD	19.6	24.7	20.4	22.3	20.0	21.4
ES				0.1	0.3	0.4

SPADI shoulder pain and disability index  
IS injection steroid alone, ISD injection steroid plus saline, TAU treatment-as-usual

injections claim a short time superiority in pain reduction of about 2 weeks, compared to injections by landmarks [48], which we consider is little as compared to the extra resources required in terms of time and costs.

On 1 year follow-up all three groups had similar outcome, which reflects the natural history of the condition [14, 16, 18, 20, 49]. But the major difference in pain relief (NPRS) and pain and function (SPADI) were recorded in the first 8 weeks in the intervention groups as compared to the control group. From the patient's perspective, pain relief leading to undisturbed sleep is of great importance [50], which is not so often accredited in studies measuring outcome over time.

One of the strengths of this study is that it is conducted in line with the actual practice in treatment of



adhesive shoulder capsulitis in primary care in Norway, i.e. intra-articular steroid injection in gleno-humeral joint by landmarks. There are very few studies that are close to actual practice in treatment of shoulder adhesive capsulitis in primary care [25, 51]. The procedure is safe and simple and easy to learn and cost

effective. Only 15 % of patients reported transient side effects and the procedure was not experienced as particularly painful. The limitations of the study are lack of visual verification of delivery of medication in the joint. The injected volume varied from 8 to 20 ml and we cannot assert with certainty that the observed

**Table 4** SPADI, NPRS and PROM: Differences in change scores between the two injection groups (Intervention steroid alone (IS); Intervention steroid plus saline (ISD)) and the treatment-as-usual group (TAU)

	Between groups differences in change, mean (95 % CI)		
	IS vs ISD	IS vs TAU	ISD vs TAU
Primary outcome variable			
SPADI			
Short-term (4 and 8 weeks) <sup>a</sup>	1.2 (-7.1 to 9.6)	-20.8 (-28.9 to -12.7)***	-21.7 (-29.4 to -14.0)***
Long-term (12 months) <sup>b</sup>	0.1 (-10.4 to 10.7)	-7.0 (-16.4 to 2.5)	-7.0 (-16.8 to 2.8)
Secondary outcome variable			
NPRS			
Short-term (4 and 8 weeks) <sup>a</sup>	0.3 (0.6 to 1.2)	-2.0 (-2.8 to -1.1)***	-2.2 (-3.0 to -1.4)***
Tertiary outcome variables			
Abduction			
Short term (4 and 8 weeks) <sup>a</sup>	-4.5 (-9.7 to 0.8)	8.3 (2.3 to 14.3)**	12.7 (6.6 to 18.9)***
External rotation			
Short term (4 and 8 weeks) <sup>a</sup>	-0.9 (-5.8 to 4.1)	10.8 (5.8 to 15.9)***	11.9 (6.8 to 17)***
Internal rotation			
Short term (4 and 8 weeks) <sup>a</sup>	-1.1 (-6.6 to 4.5)	8.8 (3.1 to 14.6)**	9.9 (4.7 to 15.1)***
Hand behind back			
Short term (4 and 8 weeks) <sup>a</sup>	-0.7 (-2.4 to 2.2)	5.0 (2.8 to 7.2)***	5.1 (2.9 to 7.2)***

SPADI shoulder pain and disability index, NPRS numeric pain rating scale, PROM passive range of motion

\*\*\*p < 0.001, \*\*p < 0.01, \*p < 0.05

<sup>a</sup>Repeated measures ANCOVA with baseline value as covariate. Differences and CIs from estimated marginal means

<sup>b</sup>Regression based ANCOVA with baseline value as covariate

effect was due to distension and not to capsular rupture. Longer time taken in injecting the fluid in the joint might have introduced bias as patients might assume that he or she was in the distension group, which might have been considered the superior method by the patients.

## Conclusion

This intention to treat RCT in primary care indicates that four injections with corticosteroid with or without distension, given with increasing intervals during 8 weeks, were better than treatment-as-usual in adhesive capsulitis of the shoulder. However, in the long run no difference was found between any of the groups, indicating that natural healing takes place independent of treatment.

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## Authors' contributions

All authors read and approved the final manuscript. SPS, AK and AB contributed to design of the study. SPS recruited patients, collected data and drafted the manuscript and performed statistical analyses with help from RMN, AK and AB. RMN helped in statistical analyses. AK and AB helped in drafting the manuscript. SPS, AK and AB have read and approved the final manuscript.

## Availability of data and materials

The clinical raw data file is available at: <https://osf.io/4xvru/>.

## Competing interests

The authors declare that they have no competing interests.

## Ethics and consent

The study is performed in accordance with the Declaration of Helsinki and is approved by the Regional Ethical Committee (REK nord), UiT Norges Arktiske Universitet, Postboks Langnes, 9037 Tromsø, Norway; rek-nord@asp.uit.no. Project EUDRACT-NR 2008-004385-49; reference 200804384-7/KST017/400 and reference for change in protocol (2012) 2012/717/REK nord. The Norwegian Social Science Data Services (reference: 19675/2/SM) has accepted handling of data regarding personal information of patients and given its consent for the project. The Norwegian Medicine Agency has given its consent regarding use of Triamcinolone acetonide in this study, reference 08/18009 (post@legemiddelverket.no). The study is registered with ClinicalTrials.gov (<https://clinicaltrials.gov/>) identifier: NCT01570985 where the protocol is also available. Signed informed consent is obtained from all patients on inclusion in the study.

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RESEARCH ARTICLE

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# Predicting outcome in frozen shoulder (shoulder capsulitis) in presence of comorbidity as measured with subjective health complaints and neuroticism

Satya Pal Sharma<sup>1\*</sup>, Rolf Moe-Nilssen<sup>2</sup>, Alice Kvåle<sup>2,3</sup> and Anders Bærheim<sup>1</sup>

## Abstract

**Background:** There is a substantive lack of knowledge about comorbidity in patients with frozen shoulder. The aim of this study was to investigate whether subjective health complaints and Neuroticism would predict treatment outcome in patients diagnosed with frozen shoulder as measured by the Shoulder Pain and Disability Index (SPADI) and change in SPADI.

**Methods:** A total of 105 patients with frozen shoulder were recruited for a randomised controlled trial, where 69 were in the intervention group and received intraarticular corticosteroid injections and 36 patients served as control group. The SPADI was used as the outcome measure after 8 weeks, and change in SPADI from baseline to 8 weeks as a measure of rate of recovery. To examine comorbidities, all participants completed the Subjective Health Complaints (SHC) questionnaire with its five subscales, and the Neuroticism (N) component of the Eysenck Personality Questionnaire Revised. Multiple regression analysis was performed with the baseline comorbidity variables that correlated significantly with SPADI after 8 weeks, and with change in SPADI from baseline to 8 weeks, controlling for the variables intervention, age, gender and duration of pain.

**Results:** In this study, patients with frozen shoulder had little comorbidity as measured with SHC and scored normally with respect to Neuroticism. Only the Pseudoneurology subscale in SHC correlated significantly with SPADI and had significant predictive power ( $p < 0.001$ ) for the outcome at 8 weeks. The intervention group exhibited significant statistical predictive power ( $p < 0.001$ ) for the treatment outcome as measured by a change in SPADI from baseline to 8 weeks. Being female also had some predictive significance for change in SPADI ( $p < 0.005$ ).

**Conclusion:** Psychometric parameters as measured by the Pseudoneurology subscale in SHC questionnaire did predict the treatment outcome in frozen shoulder as measured by SPADI at 8 weeks, but not by change in SPADI from baseline to 8 weeks. One may conclude that psychometric parameters may affect symptoms, but do not predict the rate of recovery in frozen shoulder.

**Trial registration:** ClinicalTrials.gov, identifier: NCT01570985.

**Keywords:** Frozen shoulder, Shoulder capsulitis, Shoulder pain and disability index, SPADI, Subjective health complaints, SHC, Neuroticism

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## Background

Frozen shoulder or capsulitis of the shoulder has a prevalence of 2–5% in the general population and occurs mostly in middle age between 40 and 60 years. Women are more commonly affected than men [1–4]. Both shoulders can be affected simultaneously or one side becomes affected first and then the other side a few years later in 6–17% of patients [5–7]. One has observed a significantly adverse impact on pain, function and quality of life in patients with shoulder adhesive capsulitis as measured with Shoulder Pain and Disability Index (SPADI) and the Short Form survey-36 (SF-36) [8]. The burden of shoulder conditions, in terms of affecting a patient's perception of his or her general health, has been ranked as highly as the burden of having any of hypertension, congestive heart failure, acute myocardial infarction, diabetes mellitus and/or depression [9, 10]. In a systematic review of prognostic factors for arm, neck and shoulder complaints, the duration and degree of symptoms and resulting limitation of shoulder function were prognostic for recovery [11]. Another systematic review found that a high SPADI score [12], in addition to greater severity and longer duration of shoulder pain were associated with becoming the shoulder pain chronic [13]. Kuijpers et al. had similar findings regarding the duration and severity of pain at the time of presentation and its association with chronic shoulder pain [14]. Comorbid factors had a significant effect on pain and dysfunction, as measured on shoulder-specific and general health instruments, experienced by patients with adhesive shoulder capsulitis [15]. General health may also be seen to improve after reduction in shoulder pain and dysfunction. Functional outcome as measured by SF-36 after arthroscopic release in refractory adhesive shoulder capsulitis, improved clinical and general health status for most of the patients [16, 17].

Several questionnaires are available to measure complaints among patients with chronic conditions [18]. In Nordic countries, a validated questionnaire consisting of 29 parameters have been used to measure severity and duration of subjective somatic and psychological complaints during the previous 30 days. The SHC questionnaire is a systematic, easy and reliable way to measure subjective health status and comorbidity [19]. It is also argued, that what may be termed as “medically unexplained symptoms” or functional somatic syndromes [20], are better covered under “subjective health complaints” [21]. Subjective health complaints concerning musculoskeletal disorders, the digestive system, tiredness, dizziness, sleep and unspecific pain etc. are common in the general population [22, 23]. Prevalence of reported SHC was found high in general Norwegian population, where 80% reported diverse musculoskeletal complaints e.g. headache, neck pain, back pain, pain in the arms, shoulder pain, migraine and or pain in the feet on exertion. Whereas 65%

reported “pseudoneurological” complaints, including sleep problems, tiredness, anxiety, depression, dizziness, hot flushes and/or extra systoles, among others [23]. The SHC questionnaire has not been used earlier for measuring health status in patients with frozen shoulder.

Apart from the clinical characteristics, psychological factors also play a role in predicting outcome of neck and shoulder symptoms [24]. The relationship between psychosocial factors particularly related to work environment and development of musculoskeletal complaints and the transition to a chronic state has been hypothesized by some authors and explanatory models are suggested [25, 26]. Further, the physical and psycho-social disability in patients with chronic pain has been shown to be associated with patients' pain-related beliefs [27]. Pain related fear and avoidance is postulated to be an essential feature of chronification of pain for at least some patients [28].

Neuroticism is a broad personality trait that reflects the extent to which a person experiences the world as stressful, threatening, and problematic. “Neuroticism has been linked to a wide array of clinical syndromes, with particularly strong associations to distress-based disorders such as major depression and generalized anxiety disorder. The trait has also been found to be a significant predictor of Subjective Health Complaints” [29]. The aspect that whether patients with frozen shoulder have comorbidity and have neurotic symptoms that may influence response to treatment has previously not been studied.

## Aim

The aim of this study was to investigate whether Subjective Health Complaints and Neuroticism would predict treatment outcome in patients diagnosed with frozen shoulder as measured by SPADI and change in SPADI.

## Hypothesis

Comorbidity as measured with SHC and Neuroticism at baseline can predict outcome in frozen shoulder as measured by SPADI at 8 weeks and change in SPADI from baseline to 8 weeks.

## Methods

Patients in this study were participants in a randomised controlled trial (RCT), where 69 were in the intervention group and received intraarticular corticosteroid injections during a period of 8 weeks and 36 patients were in the control group [30]. Most of the patients were in stage II of frozen shoulder with SPADI score around 60. The SPADI was used as the outcome measure. We measured SPADI at 8 weeks and change in SPADI from baseline to 8 weeks. We interpret change in SPADI as a measure of rate of recovery. There were statistically significant differences between those receiving intervention and the control group after 8 weeks in the primary outcome measure. At inclusion

and after 8 weeks, comorbidity was measured with the SHC questionnaire and Neuroticism was measured with the Neuroticism (N) component of the Norwegian version of the Eysenck Personality Questionnaire- Revised short form (EPQ-R) [31–33].

SPADI measures a combination of pain and functional disability on a score ranging from 0 to 100, a high total score indicating more pain and disability [12]. In the SHC questionnaire, severity of each complaint is rated on a 4-point scale (0 = none, 1 = some, 2 = much, 3 = severe). In this study, we calculated the total SHC scores for 29 items and differentiated SHC scores in five subscales. These are: Musculoskeletal (comprising headache, neck pain, back pain, pain in arms, shoulder pain, migraine and pain in feet on exertion); Pseudoneurology (sleep problems, tiredness, anxiety, depression, dizziness, hot flushes and extra systoles); Gastrointestinal (stomach discomfort, heartburn, ulcer/non-ulcer dyspepsia, stomach pain, flatulence, diarrhea and obstipation), Cold/Flu (flu, bad cold, cough/bronchitis) and Allergy (asthma, chest pain, breathing difficulty, eczema and allergy) [19]. The EPQ-R questionnaire has four scales: E (Extraversion vs. Introversion), N (Neuroticism or Emotionality), P (Psychoticism or Tough Mindedness) and L (Lie scale). The short form Neuroticism (N) questionnaire has 12 questions to be answered with yes or no options and only this part was used in this study [31].

### Statistics

Baseline variables of comorbidity and Neuroticism were explored. To have an overview of the burden of symptoms, we performed descriptive analysis of SHC with its subscales and Neuroticism. To select appropriate baseline scores as predictors of outcome, we explored correlations between SPADI at 8 weeks and change in SPADI from baseline to 8 weeks with baseline SHC total and subscale scores, and with the Neuroticism sum score. Multiple regression analysis was performed with the items that correlated significantly with SPADI at 8 weeks and change in SPADI from baseline to 8 weeks as predictors, controlling for intervention, age, gender and duration of shoulder pain. We chose a backward elimination method for multiple regression analysis, and removed non-significant predictors one by one. Both initial and final models are reported.

### Results

Baseline characteristics of patients and SPADI are displayed in Tables 1 and 2. There were no noteworthy differences in the demography between the intervention and control groups at baseline except for a higher percentage of patients with trauma in the intervention group. The baseline SPADI was similar in the two groups (Table 2). Descriptive scores for SHC and for Neuroticism at baseline and 8 weeks presented in Table 3, show relatively low prevalence of health complaints. The preliminary correlation analysis returned

**Table 1** Baseline characteristics of patients diagnosed with frozen shoulder

Characteristics	Intervention group Number and % within group <i>n</i> = 69	Control group Number and % within group <i>n</i> = 36
Mean age (years)	53 (8.7)	54 (6.9)
Female	42 (60%)	19 (53%)
Duration in months: Median (range)	7.2 (2.0–37.0)	6.0 (3.0–24.0)
Affected right shoulder	30 (43%)	15 (42%)
Previous frozen shoulder	10 (14%)	4 (11%)
Concurrent neck pain	31 (44%)	16 (44%)
Trauma to shoulder	13 (19%)	3 (8%)
Previous operation on shoulder	6 (9%)	1 (3%)
Dominant right side	64 (91%)	34 (94%)
Previous shoulder treatment	37 (53%)	13 (36%)
Analgesics	33 (47%)	11 (31%)
Participants on sick leave	14 (20%)	15 (42%)
Smokers	6 (18%)	12 (33%)

significant Pearson's correlation coefficients for SPADI at 8 weeks versus total SHC score at baseline, the Pseudoneurology subscale in SHC at baseline ( $p = 0.009$ ), as well as group allocation ( $p < 0.001$ ) (Table 4). None of the other SHC subscales at baseline returned significant correlation coefficients. There was a significant correlation between female gender and SPADI at baseline. When we removed the Pseudoneurology subscale from the total SHC score at baseline, the remaining total SHC score became insignificant. This showed that the significant correlation coefficient related to the total SHC baseline score was due to inclusion of the Pseudoneurology subscale. Therefore, only the Pseudoneurology subscale and not the total SHC baseline score was kept as predictor in the multiple regression analysis. No correlation was found between baseline Neuroticism and the outcome measure after 8 weeks. Correlation analysis with change in SPADI from baseline to 8 weeks showed statistically significant correlation to group allocation and female gender (Table 4).

**Table 2** SPADI at baseline and 8 weeks, and change in SPADI from baseline to 8 weeks for the intervention and control groups

SPADI	Intervention group Mean, (Std. deviation)	Control group Mean, (Std. deviation)
Baseline	62.3 (16.4)	61.4 (19.07)
8 weeks	22.2 (20.3)	43.5 (23.8)
Change from baseline to 8 weeks	40.2 (19.0)	17.8 (15.0)

**Table 3** Subjective Health Complaints (SHC) and Neuroticism in the intervention and the control group at baseline and 8 weeks

	Intervention group Mean, (Std. deviation)		Control group Mean, (Std. deviation)	
	Baseline	8 weeks	Baseline	8 weeks
SHC - Total score 29 items (score 0–87)	15.34 (8.16)	11.33 (8.04)	12.22 (6.66)	11.08 (7.98)
Musculoskeletal (8 items) (score 0–24)	8.11 (4.06)	5.62 (3.87)	7.44 (3.45)	6.50 (3.57)
Pseudoneurology (7 items) (score 0–21)	4.17 (3.03)	3.23 (2.98)	3.11 (2.67)	2.86 (3.07)
Gastrointestinal (7 items) (score 0–21)	1.70 (2.30)	1.35 (1.92)	0.92 (1.44)	0.94 (1.66)
Flu (2 items) (score 0–9)	0.57 (1.11)	0.67 (1.07)	0.56 (1.27)	0.53 (1.08)
Allergy (5 items) (score 0–15)	0.76 (1.36)	0.48 (0.95)	0.25 (0.55)	0.36 (1.05)
Neuroticism (score 0–12)	2.42 (2.14)	1.57 (2.05)	2.06 (2.28)	1.50 (1.80)

Multiple regression analysis with SPADI at 8 weeks as the dependent variable, controlling for age and gender, revealed a statistically significant predictive value for Pseudoneurology in SHC at baseline ( $p < 0.001$ ) and group allocation ( $p < 0.001$ ) (Table 5). Shoulder pain duration was also registered but did not show any statistically significant predictive value.

Being allocated to the intervention or control group exhibited statistical significant predictive value. This was also the case for change in SPADI from baseline to 8 weeks ( $p < 0.001$ ). Baseline SHC scores did not have significant predictive value at 8 weeks for a change in SPADI. Shoulder pain duration showed a statistically significant predictive value for change in SPADI from baseline to 8 weeks ( $p < 0.01$ ).

## Discussion

In this study, we found that patients with frozen shoulder had little comorbidity as measured with SHC and they scored normally on the Neuroticism questionnaire. We found that both the SHC Pseudoneurology subscale and group allocation predicted pain and function as measured by SPADI at 8 weeks. However, when looking at factors

predicting change in SPADI from baseline to 8 weeks, shoulder pain duration and group allocation predicted better outcome, while SHC as a whole and each subscale lost its predictive power.

Most of the participants were in stage II of frozen shoulder [30] with relatively high baseline SPADI score (Table 2). The mean duration of frozen shoulder at the time of inclusion in the study was 6 months (Table 1). Some patients go through a very painful phase and delayed diagnosis resulting in frustration, anxiety and depression. Jones et al. observed in their study that lack of diagnosis or misdiagnosis led to diverse consequences among the participants; for example, anxiety, denial and delays in definitive diagnosis and referral [34]. In patients with cervical radiculopathy, variables regarding present neck pain intensity, fear avoidance and anxiety were most significant in dimensions underlying pain and disability, personal factors and health status [35]. One of the major complaints in frozen shoulder in late stage I and stage II is pain which in some cases can be very severe [36], resulting in very disturbed sleep and tiredness. Perceived disability in patients with chronic shoulder pain has been found to be strongly influenced by

**Table 4** Pearson's correlations<sup>a</sup> between independent variables and SPADI at 8 weeks and change in SPADI from baseline to 8 weeks

Correlated independent variables	SPADI at 8 weeks		Change in SPADI (baseline to 8 weeks)	
	Pearson's r	p-value	Pearson's r	p-value
SHC Pseudoneurology baseline	0.26*	0.009	0.11	0.287
Gender (male = 0; female = 1)	0.08	0.429	0.26*	0.007
Group allocation (control = 0; intervention = 1)	-0.45*	< 0.001	-0.43*	< 0.001
Shoulder pain duration	-0.16	0.108	0.28*	0.004

\* $p < 0.05$

<sup>a</sup>Only variables with significant correlations are listed in the table

**Table 5** Multiple regression models with backward elimination for participants ( $n = 105$ , control and intervention groups) with the Shoulder Pain and Disability Index (SPADI) at 8 weeks and change in SPADI from baseline to 8 weeks as dependent variables

	Initial model			Final model		
	B	p-value	R <sup>2</sup>	B	p-value	R <sup>2</sup>
SPADI at 8 weeks			0.30			0.29
SHC Pseudoneurology baseline	2.4	0.001		2.6	< 0.001	
Gender (male = 0; female = 1)	0.78	0.85				
Age	-0.36	0.15				
Group allocation (control = 0; intervention = 1)	-25.1	< 0.001		-24.8	< 0.001	
Change in SPADI from baseline to 8 weeks			0.36			0.36
SHC Pseudoneurology baseline	0.19	0.77				
Gender (male = 0; female = 1)	11.78	0.002		11.99	0.002	
Age	0.48	0.04		0.47	0.04	
Group allocation (control = 0; intervention = 1)	19.50	< 0.001		19.73	< 0.001	
Shoulder pain duration	0.93			0.91	0.013	

depressive symptoms [37]. In our study, 44% of patients in both groups also had neck pain, which may have contributed to elevated self-experience of pain or disability (Table 1). It is possible, that after receiving information at the time of inclusion in the study regarding frozen shoulder and its natural course patient's anxiety and depressive symptoms were reduced. The Pseudoneurology subscale was no longer significantly predictive with regard to change in SPADI from baseline to 8 weeks.

In this study, the follow up was limited to 8 weeks and this may affect external validity. A further follow up at 6 or 12 months would have been appropriate to predict long-term outcome. This is a limitation of this study.

Since we lack reference values for SHC and Neuroticism, we cannot compare our findings with the general population. This is also a limitation of the study.

In our study, Neuroticism did not have any significance in predicting the outcome of frozen shoulder. Others have found that personality factors may modulate presentation of pain and symptoms and influence a broad range of health outcomes and mechanisms [20, 38]. Rozencwaig et al. have demonstrated that the number of medical conditions has a quantitative effect on shoulder function. The parameters for general health perception and vitality in the SF-36 questionnaire has previously been found to have a strong negative correlation with the increasing comorbidity in patients with gleno-humeral degenerative joint disease [39].

Belonging to the intervention group had significant predictive value ( $p < 0.001$ ) for both SPADI at 8 weeks and change in SPADI from baseline to 8 weeks. Contrary to what we had expected, SHC total score, SHC subscales and Neuroticism had no predictive value for change in SPADI from baseline to 8 weeks. We expected the Musculoskeletal subscale to have a predictive power because this subscale contains parameters regarding neck pain, back pain, pain in arms,

shoulder pain and pain in feet, which are relevant to this study. We do not have any good explanation for this lack of predictive influence. Absence of predictive power for Neuroticism is in accordance with findings in other studies. Ring et al. found that self-reported upper extremity-specific health status correlated with the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire, but not with Neuroticism, as measured by the EPQ-R [40]. Factorial analysis of subjectively felt health complaints by Ursin et al. revealed that factors involving neck, back, arm and shoulder pain and migraine, did not relate to anxiety and depression [41]. Psychological factors explained only a moderate amount of variance of muscle pain, when the population was looked at as a whole, in their study [41]. This is similar to our findings, i.e. the Musculoskeletal subscale did not show predictive power for SPADI. In general, psychological comorbidity has been found to enhance self-experience of suffering due to pain and dysfunction. Bagheri et al. reported more suffering due to depression and anxiety than that from a reduced range of motion in patients with frozen shoulder [42]. Further, physical and psychosocial disability in patients with chronic pain have been shown to be associated with patients' pain-related beliefs [27]. Patients with psychological disorders have been found to have more self-reported pain and functional disability in activities of daily life, indicating correlation with frozen shoulder and psychological conditions [43]. However, the Musculoskeletal subscale did not predict the outcome in our study even though it has components of pain parameters. There is a possibility that the SHC and Neuroticism questionnaires are not able to measure psychometric parameters when these are not sufficiently accentuated or are dominating the clinical picture. However,

frozen shoulder may be a very distinct physical and clinical entity, without associated psychological aspects. When patients are informed of the diagnosis, its natural history and possible outcome after intervention, the condition is no longer dramatic and they cope well with it. According to available literature, psychometric parameters can in some way affect the outcome [15, 24–26], but it was not obvious or consistent in our study.

## Conclusion

Psychometric parameters as measured by the Pseudo-neurology subscale in SHC questionnaire did predict the treatment outcome in frozen shoulder as measured by SPADI at 8 weeks, but not by change in SPADI from baseline to 8 weeks. One may conclude that psychometric parameters may affect symptoms, but do not predict the rate of recovery in frozen shoulder.

## Abbreviations

EPQ-R: Eysenck personality questionnaire- revised; SF-36: Short form survey-36; SHC: Subjective health complaints; SPADI: Shoulder pain and disability index

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## Availability of data and materials

Link for anonymized data <https://osf.io/a4ba9/files/>.

## Authors' contributions

SPS, AK and AB contributed to design of the study. SPS drafted the manuscript with the help from AK, AB and RMN. RMN helped in statistical analyses. Statistical analyses were discussed with AK and AB. All authors have read and approved the final manuscript.

## Ethics approval and consent to participate

The study is performed in accordance with the Declaration of Helsinki and is approved by the Regional Ethical Committee (REK nord), UiT Norges Arktiske Universitet, Postboks Langnes, 9037 Tromsø, Norway; rek-nord@sp.uit.no. Project EUDRACT-NR 2008-004385-49; reference 200804384-7/KST017/400 and reference for change in protocol (2012) 2012/717/REK nord. The Norwegian Social Science Data Services (reference: 19675/2/SM) has accepted handling of data regarding personal information of patients and given its consent for the project. The Norwegian Medicine Agency has given its consent regarding use of Triamcinolone acetonide in this study, reference 08/18009 (post@legemiddelverket.no). The study is registered with ClinicalTrials.gov (<https://clinicaltrials.gov/>) identifier: NCT01570985 where the protocol is also available. Signed informed consent was obtained from all patients on inclusion in the study.

## Consent for publication

Not applicable.

## Competing interests

The authors declare that they have no competing interests.

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