Physiotherapeutic treatment and clinical evaluation of shoulder disorders

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10 SUMMARY AND GENERAL DISCUSSION

A frozen shoulder or adhesive capsulitis[1] is a fairly common disorder of the shoulder within the age-group between 40 and 65 years. In most cases the cause remains un - clear (= primary or idiopathic). Sometimes a frozen shoulder occurs after a (minor) trauma or as a comorbid condition with diabetes, thyroid diseases or Parkinson's dis - ease (= secondary). This shoulder disorder is characterized by its protracted course in three phases. In the first phase, the pain limits active movements and (at night) lying on the affected shoulder. In the second phase of the condition, pain appears to be less pronounced but progressive decrease of active and passive shoulder movements can be observed, due to a loss of elasticity of the joint capsule. Limitations of activities of daily living and work ability are apparent. In the third phase, there is a slow increase in joint mobility, which leads to (almost) full recovery. The whole process can take 2-3 years. Physical therapy has a prominent place in the treatment of frozen shoulders, however the evidence regarding its effectiveness is scarce.

In *Chapter 1* an overview of the epidemiology, pathology, clinical presentation and diagnostics of the frozen shoulder is presented. Studies about the treatment of frozen shoulders by means of physical therapy, and mobilization techniques in particular, are discussed. These studies show the diversity of the treatment strategies employed, illus - trating the lack of consensus in the treatment of frozen shoulders. Moreover, the inter - pretation of the results of those studies is hampered by methodological shortcomings.

After this overview, the thesis is divided in two parts:
- Part I describes the results of the physiotherapeutic treatment of the frozen shoulder by means of mobilization techniques;
- Part II describes the clinical evaluation of the frozen shoulder and other shoulder disorders by various measurement instruments.

Part I Physiotherapeutic treatment of the frozen shoulder

Chapter 2 describes a multiple-subject case report concerning treatment with end-range mobilization techniques of 7 patients with a frozen shoulder. In these patients, with a mean disease duration of 8.4 months (sd 3.3), shoulder pain decreased, gleno - humeral joint mobility and joint capacity increased after 3 months of treatment with end-range mobilization techniques. Six out of seven patients reported their overall condition, after 3 months of treatment and at 9 months follow-up to be 'improved' or 'much improved'. This study also brought up the need to use validated questionnaires in measuring the impairments patients with a frozen shoulder experience in daily ac - tivities and participation.

Chapter 3 describes a randomised controlled trial comparing the effect of two treat - ment strategies: high-grade mobilization techniques (HGMT) and low-grade mobili - zation techniques (LGMT) in 100 patients with a unilateral frozen shoulder. In both groups patients suffered from a longstanding frozen shoulder with a median disease duration of 8 months. Eighty percent of the patients had formerly been treated by a

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[1] These two terms are used interchangeable in literature. In this chapter the term 'frozen shoulder' is pre - ferred.

physical therapist and sixty percent had received one or more injections in the affected shoulder, both with unsatisfactory results. The duration of both treatment strategies was 12 weeks. Outcome measures included measures of range of motion, pain, the patient's opinion about changes in shoulder disability, the Shoulder Rating Question - naire (SRQ) and the Shoulder Disability Questionnaire (SDQ) and a generic measure of quality of life (the Short Form-36). All measurements were done at baseline and after 3, 6 and 12 months.

After three months treatment, patients in both groups improved significantly be - tween baseline and all follow-up visits regardless of the outcome measures used. The largest changes were seen between baseline and three months, but after that time point patients continued to improve. In general, the improvements were greater in the HGMT-group than in the LGMT-group with significant differences for passive abduction (3 and 12 months), active external rotation (12 months), passive external rotation (total period), SRQ (total period) and SDQ (total period) in favour of the HGMT-group.

The number of patients reporting improvement in comparison to baseline was simi - lar in both groups. It was concluded that in patients with a frozen shoulder high-grade mobilization techniques were more effective than low-grade mobilization techniques in increasing joint mobility and functional ability, however, the differences were overall small.

Alongside the randomized controlled trial described in *Chapter 3*, an economic evaluation was carried out and presented in *Chapter 4*. Economic evaluations can provide useful information to support medical decisions and the allocation of health care resources, but so far, no economic evaluations of the frozen shoulder or its treat - ment have been published. The aim of this study was to compare the cost-utility of two different mobilization techniques (HGMT and LGMT) in the treatment of a frozen shoulder and to estimate the cost and health burden due to a frozen shoulder. All health care and non health care costs during the study period were estimated from the quarterly cost questionnaires. From the Short Form-36, a generic quality of life in - strument, the Short Form 6D utility index and the quality adjusted life years (QALYs) were calculated on a scale from 0 (as bad as death) to 1 (as good as full health).

Both randomization groups had similar estimated QALYs and societal costs over the total period of 12 months. In the entire sample, the average valuation of health improved from 0.597 at baseline to 0.745 after a year. The health burden due to a frozen shoulder was estimated at 0.048 QALY and the societal costs due to a frozen shoulder were estimated at € 4521 per patient. The cost-utility analysis does not allow for an evidence-based recommendation on the preferred treatment. Based on the clinical outcome measures, HGMT remains preferred over LGMT. The estimated substantial burden, both to the patient and to society, suggests that effective early treatment of adhesive capsulitis is warranted in order to attempt acceleration of recovery.

Part II Clinical evaluation of the frozen shoulder and other shoulder disorders

Measuring the movements of the shoulder is quite difficult. The large movements of the scapula under the skin make it impossible to use external markers. *Chapter 5* describes the reliability of a three-dimensional electromagnetic detection system, Flock of Birds® in measuring the movement patterns of the shoulder girdle (humerus, scapula, clavicle and thorax). With this system the position of sensors, attached to the humerus and thorax within the electromagnetic field, can be detected and registered in the computer. A third sensor, mounted on a pointer, is used to record the position and orientation of predefined bony landmarks of the shoulder girdle. A fourth sensor is attached to a scapula-locator, enabling to follow the position of the scapula during movements of the arm in steps of 10° in abduction in the frontal plane, scapular abduction and forward flexion. An assessment for one shoulder consists of 500 measurements at 1 second per measurement. With this information the local coordinate system of a bony structure can be constructed and subsequently the orientation of the different bony structures within the global coordinate system can be determined. The changes of the orientation and position of the local coordinate systems during the movements of the arm are expressed in Euler angles and computed to derive the joint angles of the separate bones. Measurements by two observers on 15 healthy subjects with a normal shoulder function showed that three-dimensional positions and movements of the shoulder girdle could be determined in a reliable way.

The study in *Chapter 5* with the Flock of Birds® laid the fundament for a clinical study. At the physical examination of patients with a shoulder disorder an abnormal rhythm can be seen and palpated during the movement of the humerus in forward flexion or abduction. However, description and measurement of this abnormal movement pattern is difficult. The aim of the study in *Chapter 6* was to get a better understanding of the kinematics of the movements of the shoulder girdle in patients with a frozen shoulder. Furthermore, the question rose whether a three-dimensional tracking system is able to differentiate between healthy and affected shoulders in 10 patients receiving treatment for a unilateral frozen shoulder. At baseline, the affected shoulders showed less glenohumeral joint mobility and faster laterorotation of the scapula than the unaffected shoulders. The end-position of the scapula of the frozen shoulders during elevation in various planes was the same as in normal shoulders, however this end-position was reached faster.

After 3 months of treatment with end-range mobilization techniques (EMT), a change in the movement patterns was seen in all three planes i.e. the glenohumeral elevation angles of the frozen shoulders increased significantly and the laterorotation of the scapula tended towards normal values. This study showed that a three-dimensional electromagnetic tracking device is able to describe and measure the movement patterns. This system is also able to differentiate between the movement patterns of a frozen shoulder and the movement patterns of the unaffected side. Moreover, the system is sufficiently sensitive to detect clinical improvements.

Many questionnaires assessing and evaluating shoulder functioning have been developed in the last decade. Most of these patient-based measures are mainly concerned

with pain, range of motion and daily activities such as self-care and household activi -
ties. The influence of shoulder disorders on the level of societal participation, such as
paid employment, leisure and sports activities is addressed less frequently, despite the
fact that these areas may be very relevant in a patient's life. The Shoulder Rating Ques -
tionnaire (SRQ, l'Insalata, 1998) is a self-administered patient-based instrument which
not only includes a global assessment, measures of pain, daily activities, areas for im -
provement and satisfaction, but also comprises two additional dimensions: recreational
and athletic activities and work. Given the comprehensiveness of the SRQ, the objec -
tive of the study described in *Chapter 7* was to translate and adapt the original English
questionnaire into a Dutch language version and evaluate its internal consistency,
reliability, validity and responsiveness to clinical change in 107 patients with various
shoulder disorders (frozen shoulder, calcifying tendinitis and rotator cuff lesions) who
underwent treatment (physical therapy, needling and acromioplasty, respectively). The
psychometric properties of the translated version regarding internal consistency, test-
retest reliability, validity and responsiveness to clinical change for well-defined clinical
shoulder problems were good and comparable with the properties of the original ver -
sion. Completing this self-administered questionnaire only takes a short time and is
therefore user-friendly.

The Shoulder Function Assessment scale (SFA, van den Ende, 1996) is a valid and
reliable instrument to assess shoulder function in patients with rheumatoid arthritis.
Chapter 8 describes a study in which the responsiveness or sensitivity to detect clinical
changes of the SFA was examined in 35 patients with rheumatoid arthritis who re -
ceived a local injection with corticosteroids in the shoulder. Four to six weeks after the
injection with steroids in the affected shoulder significant improvements in range of
motion and shoulder function as well as overall functional ability and disease activity
were seen. These improvements were in accordance with an improvement of the total
SFA score (mean change 10.9 points) as well as its subscores. Effect sizes, standardised
response mean and responsiveness ratio as measures of responsiveness were -1.16, -0.86
and 1.28, respectively. It was concluded that in this patient population the responsive -
ness of the SFA to clinical changes was found to be excellent.

Measuring muscle force is frequently used in daily physiotherapy practice, to estab -
lish abnormalities, setting therapy goals and evaluating the effect of interventions. The
aim of the study in *Chapter 9* was to compare the practical applicability and reliability
of two portable dynamometers, a hand-held dynamometer (MicroFET2 ®) and a fixed
dynamometer (Isobex2.1 ®) in measuring muscle strength of the shoulder and elbow.
In 20 healthy subjects the shoulder and elbow strength on the right-hand side were
measured with both the hand-held dynamometer and the fixed dynamometer by two
examiners. A comparison of the practical applicability and measurement properties of
two portable dynamometers, showed that both dynamometers cause some discomfort
during the testing procedure. The use of the hand-held dynamometer was the least
time-consuming. The intra- and inter-observer variation of the instruments was simi -
lar, but the absolute results of the two instruments, measured in four different move -
ment directions in the same subjects, varied. Moreover, a systematic difference between
the two testers using the same instrument was seen with both devices. The practical

applicability and reliability in both instruments are comparable but the two instru -
ments as well as the assessors should not be used interchangeably.

General discussion

In this thesis, the treatment of patients with a frozen shoulder by means of mobiliza -
tion techniques has shown good results in improving the shoulder function on differ -
ent levels of health status (body structure and function, activities and participation)
according to the ICF (International Classification of Functioning, Disabilities and
Health). The HGMT-group showed statistically significant better results than the
LGMT-group, however, the clinical differences are small. The aim of HGMT is to
influence the capsular adhesions and treat the stiffness by stretching the capsule to
the patients' tolerance, which might result in a transient increase of discomfort in the
shoulder. The burden of the treatment for the patients by means of HGMT has not
been taken into account. With respect to the small clinical differences between the
both groups, the patients' preference for one of the two treatment strategies could play
an important role in the clinical decision and is suggested to be included in further
research.

   In the absence of a control-group it is unknown to what extent the results of our
study are attributed to the natural course of the condition. In future research on the
treatment of the frozen shoulder, the use of a no-treatment group should be consid -
ered.

   In this randomised trial, it was decided to include patients with a frozen shoulder
in the second phase where the active and passive restriction of the glenohumeral joint
mobility was on the foreground. Due to the different clinical features in each phase it
might be well possible that each phase requires a specific treatment approach. For that
purpose, and to enhance the comparability among studies, a refinement of the defini -
tion of the frozen shoulder, taking into account the three phases of the condition,
would be needed. In the first (the *'freezing'*) phase shoulder pain is on the foreground
during movement, in rest and at night with restricted active range of motion due to
pain. In the second (the *'frozen'*) phase, shoulder complaints are present for at least 3
months and pain is more apparent in the end-range of the shoulder movements with
active and passive range of motion (ROM) decreased to less than 50% in abduction,
forward flexion and/or external rotation in comparison with the unaffected opposite
side. In the third (the *'thawing'*) phase an increase of active and passive shoulder mo -
bility in all shoulder movements is observed to more than 75% in abduction, forward
flexion and/or external rotation in comparison with the unaffected opposite side. The
feasibility of using these three phases in daily clinical practice as well as in future trials
has to be further established.

   With both treatment strategies a maximum of 24 treatments were prescribed. In
a future trial, regular assessments according to a fixed protocol should be performed
in order to decide whether or not the treatment can be terminated. These assessments
should not only include measures on the level of body functions and structures like

ROM, but also the attainment of patient-specific goals at the level of activities and participation.

The economic analysis revealed the substantial burden to the patient and to the society in patients suffering from a frozen shoulder, suggesting that early effective intervention is warranted to accelerate recovery. Furthermore, the treatment strategies for patients who do not respond well to conservative treatment, should be reviewed critically. An analysis of more aggressive / invasive treatments for the non-responders, e.g. manipulation under (local) anaesthesia, capsular distension and arthroscopic release, has never been executed and seems potentially useful for the decision making process in this disorder.

Regarding the clinical evaluation of the frozen shoulder and other shoulder disorders, this thesis discusses the applicability of a three-dimensional electromagnetic tracking device to obtain kinematic data of the shoulder movements. With this system, movement patterns of the frozen shoulder can be quantified and clinical changes can be determined. However, its applicability is limited to specialized movement laboratories for fundamental research where clinicians and engineers cooperate in correlating 3D data with clinical parameters, in order to improve the insight in the factors related to shoulder disorders. Subsequently, new treatment strategies can be developed and evaluated.

In the last three chapters of this thesis, three additional instruments for the assessment and evaluation of shoulder disorders are discussed. Instead of adding a new questionnaire to the list of existing shoulder specific questionnaires, it was decided to translate the English version of the SRQ into the Dutch language. In contrary to other shoulder questionnaires, the SRQ measures on different levels of health status and addresses uniquely to items that are considered to be relevant in patients' life like work, recreational activities and sports. Others reviewed the SRQ among self-report scales for the assessment of functional limitation and disability of the shoulder. None of the questionnaires demonstrated satisfactory results for all properties, but most of the shoulder scales possess adequate measurement properties, and the majority of them are easy to use. The evaluation of the quality of subjective health measurements is not standardized and clinimetric properties of a questionnaire are not fixed and may vary among different settings and populations. As no consensus has been reached which domains should constitute a joint or disease specific functional and disability scale, it depends on the researchers' preference which questionnaire to use.

The SFA is developed to be a questionnaire for patients with rheumatoid arthritis suffering from shoulder complaints. The clinimetric properties for this population appeared to be excellent, however, the substitution of the four predefined activities by a VAS for impact of shoulder function on daily activities should be considered. In this thesis, the measurement properties of the SFA also proved to be good in patients with other shoulder disorders attending institutional health care.

Within the scope of exchanging information between health care providers in different settings, the use of these shoulder questionnaires is recommendable and therefore further investigation of the applicability of the SRQ and SFA in primary health care is warranted. Moreover, their value in a core set of outcome measures for patients suffering from a frozen shoulder should be considered.

The use of portable dynamometers has been generally adopted in primary as well as in institutional health care. Using different dynamometers or different testers can bias the results of force measurements and requires large differences to reveal clinical deterioration or improvement. In the evaluation of patients suffering from shoulder complaints, where small differences are expected, it is recommended not to change devices or testers. When new devices to measure muscle strength are introduced, the interchangeability using a patient cohort should be examined as well as the tester's sat - isfaction in the practical applicability of the new devices.

Recommendations for future research

The feasibility of using a refinement of the three phases (*'freezing', 'frozen', 'thawing'*) of a frozen shoulder in daily practice has to be established.

Designing a flow chart for an evidence based decision-making process regarding treatment strategies in each of the three phases of this shoulder disorder is the next challenge.

The economic evaluation suggests more research on early interventions (in the freez - ing phase) including a no-treatment group. Given the positive results of mobilization techniques in later stages of a frozen shoulder, the value of mobilization techniques in the early stages of the disease should be established.

Subsequently, consensus should be reached about a core set of outcome measures re - garding the treatment of a frozen shoulder, with the aim of enhancing the comparabil - ity among future clinical studies. This core set should not only include questionnaires and measures on different levels of health care status, but also a clear understanding of patients' individual needs with regard to functional ability. Moreover, patients' prefer - ences regarding the various physical therapy strategies should be taken into account.