General Discussion

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Primary aims of this thesis were a) to describe the current management in relation to diagnostic work-up (including the use of diagnostic ultrasound) and treatment strategies of physiotherapy care for patients with shoulder pain and b) to identify prognostic factors (including the use of diagnostic ultrasound and working alliance) of recovery for patients with shoulder pain. Firstly, we will discuss the study design, main findings and methodological considerations for current management and diagnostic ultrasound for patients with shoulder pain in physiotherapy care (chapters 2-5). Secondly, we will discuss the development of the prognostic model and the adjusted measurement instrument for the working alliance (chapter 6 and 7). Lastly, we will address implications for practice and recommendations for future research.

Study design

A considerable part of this thesis is based on a prospective cohort study performed in physiotherapy practice with a follow-up of 26 weeks in patients with shoulder pain. The study was conducted in the Southwest region of the Netherlands, between November 2011 and November 2012. We aimed to include as many physiotherapists (PTs) as possible to insure a successful patient recruitment. After sending out several emails to the physiotherapist network of the Avans University of Applied Sciences and organizing several recruitment meetings, 125 physiotherapists participated in the study. Although all 125 PTs did consent to participate, not all PTs did recruit patients for the study. Ultimately all participants were enrolled by 43% of the PTs with an average enrollment of 7 patients per PT. There was a wide variety in the characteristics of PTs participating in the study making selection bias unlikely. However, due to the study sub-question, related to diagnostic ultrasound, bias towards an increased selection of PTs using diagnostic US cannot be disregarded.

The participating PTs received a laminated card to quickly check patients' eligibility during the first consultation and 10 freepost envelopes with the information letter and informed consent. This made it fairly easy for the PTs to select and include the patients for this cohort.

During the recruitment period we continuously checked the number of patients who were recruited, as it is known that only 50% of the Dutch primary care studies succeed in recruiting their target number of patients [1]. An estimated 400 patients were needed based on a 40% recovery rate, 15 prognostic factors in the prognostic model and adjustments for 20% missing values. Eventually, our recruitment was successful as 412 patients were enrolled in the study. In total 389 patients provided us their informed consent. We took great care of designing the enrollment procedures as it is known that researchers are usually overly optimistic regarding recruitment [2]. To reach our target

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we carried out several activities/interventions to stimulate patient recruitment. Firstly, participating PTs were regularly reminded of the study by sending out monthly newsletters about the number of patients that were a recruited, the average recruitment rate and how many patients the PT recruited themselves (mirror information). These newsletters also contained some new relevant scientific facts on shoulder pain or interesting conferences. Nevertheless, the number of patients that were enrolled throughout the year decreased and appropriate actions were taken to address these. Secondly, we organized a conference, where PTs that recruited >3 patients were offered to register for free and lastly, we aimed to increase the recruitment rate by offering the PTs accreditation points for their membership to the Dutch central quality register for PTs. An increase of the enrollment rate was observed after each stimulating intervention.

We tried to minimize selection bias through adequate participant selection and therefore designed recruitment methods that resulted in the most representative samples of clinicians and patients. This resulted in a cohort of patients with similar baseline characteristics compared to other studies conducted in primary care.

Another issue in a prospective cohort study can be the loss to follow-up rate. Loss to follow-up was minimized by sending out reminders to patients and PTs by email and telephone. A general rule of thumb requires that the loss to follow-up rate not surpasses 20% [3]. The loss to follow-up rate varied on the several follow-up moments between 31% and 28%; at 12-weeks the amount of missing data was highest (31%). Loss to follow-up mainly becomes a problem when there is a selective loss to follow-up. Fortunately, in our cohort we did not find any indication of selective loss to follow-up. The missing value analysis showed the data was missing (completely) at random and the necessary steps were taken to account for these missing data.

Current management: main findings

Diagnosis. The PTs rated most patients to suffer from a suspected subacromial impingement as primary hypothesis after history taking. This hypothesis commonly coexisted with the assumption of pathology of the glenohumeral joint or the cervico-thoracic spine. Nearly all PTs formulated multiple initial diagnostic hypotheses for each patient, reflecting that the diagnostic process in patients with shoulder pain is complex. After physical examination only a small number of PTs changed the primary initial hypothesis (which was based on history taking alone), indicating that additional physical examination did not provide additional information for the PT to change the initial hypothesis.

Diagnostic ultrasound (US) was performed in 31% of patients and was mostly done before the physical examination and in a substantial number of patients (38%) diagnostic US was performed instead of the physical examination. The PTs believed using diagnostic US would lead to a more specific clinical diagnosis or a more appropriate intervention compared to using physical examination. Semi-structured interviews with GPs showed

that general practitioners (GPs) believe that diagnostic US can lead to more accurate diagnoses as well [52]. Based on the systematic review of the literature no conclusions can be made for the different imaging procedures for shoulder pain patients on the efficacy and influence on patient recovery. Unfortunately only experimental studies were found that included patients with low back pain and knee pain and these studies show that a more specific clinical diagnosis did not lead to better patient reported outcome measures.

Tendinopathy of the rotator cuff was the most occurring pathology assessed by diagnostic US followed by calcification. A full thickness tear based on diagnostic US was found in 5% of patients. The initial hypothesis changed in 31% of the patients after receiving diagnostic US and usually changed to hypotheses such as sprain (trauma) or strain, suggesting that the pathology (tear or tendinopathy) found on diagnostic US determined the final clinical diagnosis. Of patients that had a diagnostic US, 16% were referred back to their GP compared to 8% in those without a diagnostic US. In most of the referred patients the diagnosis was calcific tendinitis or tendinopathy.

The high number of diagnostic US seems to reflect that PTs prefer to use a patho-anatomical diagnosis in the management of shoulder pain. However, previous research has shown that treatment based on a patho-anatomical diagnosis is not more effective than treatment based on signs and symptoms [5]. Results from our study indicate that diagnostic ultrasound does not need to be a standard diagnostic procedure in primary care physiotherapy. The changes in clinical diagnosis observed in our study (to the specific pathologies tendinopathy or calcification) do not increase the need of immediate care from a medical specialist. It might be appropriate in patients where a full thickness tear is suspected, as these cases might need surgical repair. Moreover, assessment of a full thickness tear by a PT shows adequate agreement compared to assessment by radiologists [6]. Furthermore, necessary actions should be taken to improve accuracy of operators and ultrasound findings should always be considered in the clinical context, as asymptomatic findings may be frequently found.

Diagnostic management for the physical examination and diagnostic US was not standardized as it aimed to reflect usual care. PTs that used diagnostic US were only trained in a standardized scanning protocol to ensure that all PTs reviewed the same anatomical structures. Standardizing the diagnostic process would bias the results of an observational study, but on the other hand it might lack validity of the hypotheses and pathologies found on diagnostic ultrasound.

We aimed to observe usual care, but at the same time one of our study questions concerned the use of diagnostic US. Consequently, there might have been more PTs that regularly use diagnostic US that participated in our study because of their specific interest. This could have resulted in an overestimation of the proportions of patients receiving diagnostic US in this study. PTs were considered to be experienced ultrasonographers,

but the criteria for determining the pathology on the diagnostic US are not yet fully developed and might differ between therapists and may have negatively influenced the diagnostic labels from diagnostic US.

Treatment. When studying usual care we can describe the variability between practitioners and assess consistency with recommendations from evidence based practice guidelines. The descriptive goal required measurements of a wide array of potential treatment processes as opposed to narrowly specified measurements. Specific features on treatment intensity (i.e. the specific exercise regimen or specificities of other interventions) were not measured because of feasibility. We also hypothesized that the choice of treatment was primarily based on the clinical diagnoses. However, the patient preferences, contextual factors or insurance policies may have been important factors which have influenced treatment choices, but these were not measured.

Interventions that were most frequently used for patients with a suspected subacromial impingement were advice and exercise therapy. For patients with a suspected cervical/thoracic dysfunction or frozen shoulder, advice and manual mobilization/manipulation of the spine were the most provided interventions. Using several interventions is common practice for PTs. The evidence statement for the management of subacromial complaints from the Royal Dutch Society of Physiotherapists (KNGF) also recommends a combination of advice and exercise therapy in the treatment of a suspected subacromial impingement [7]. Furthermore, the evidence statement suggests that extracorporeal shock wave therapy (ESWT) might be used in patients with a suspected calcification. When PTs suspected a patient to suffer from a calcification, based on diagnostic US findings, 32% (n=15) of patients indeed received ESWT. Overall, less than 10% of all patients were treated with a passive approach (massage, trigger point therapy or electrotherapy); these interventions are not recommended in the evidence statement.

Moreover, the evidence statement recommends 6-12 weeks of PT treatment. After 3 weeks 12% had ended treatment, 29% after 6 weeks and 59% after 12 weeks. A high number of patients still received treatment after 12 weeks (41%).

The evidence statement considers a referral to the GP when patients do not improve after 6 to 12 weeks. The high number of patients without improvement at 12 weeks (41%), as observed in this study, would have increased the number of referrals to the GP or medical specialist enormously. Although we do not know exactly how many patients were referred back after twelve weeks, we can assume that 41% would be an extremely high percentage that would be referred back when following the recommendations from the evidence statement. Furthermore, the higher referral rate (16%) in the diagnostic US group (compared to 8% in the non-US group), might also reflect an unjustified extra number of visits to medical experts or GPs.

Data collection. To collect relevant data of the diagnostic- and therapeutic process of the PTs regarding their management of patients with shoulder pain we used several

questionnaires, for patients and PTs. The questionnaire used by patients was developed using validated questionnaires. We developed a questionnaire for the data collection of the PTs in close collaboration with PTs. Even though the questionnaire was developed through several consensus steps and extensive piloting, the PTs might have misclassified some of the variables of diagnostic criteria or treatment modalities.

Patient therapist relationship (working alliance). The interaction between the patient and PT is considered to be a crucial part of the therapeutic process. In order to measure the working alliance, we used a Belgian-Dutch (Flemish) version of the working alliance inventory (WAV-12). Unfortunately, we found a high number of missing responses for specific items (especially on the bonding scale), probably due to the linguistic character-istics of these items. Therefore, we subsequently made changes in terms of adjustments in language and the context of physiotherapy in the WAV-12 using a Delphi consensus study involving patients, researchers and practitioners. This new version of the WAI-12; the Dutch Physio Alliance Scale (D-PAS), however, needs further validation.

Prognosis and recovery: main findings

Recovery. After 6 months 60% of patients were completely recovered according to the GPE (global perceived effect) scores. In the working population the recovery rate was slightly higher: 65%. The recovery rates found in our study were slightly higher than other studies in general practice [56, 57, 58]. It might be questioned whether this difference is due to the therapeutic interventions, the measurement instrument or because there might be a different population in PT practice compared to general practice. We excluded patients that had surgery in the past 6 months and all patients that received previous physio-therapy treatment for the same complaint, which is an important difference compared to other studies. An observational study in the Netherlands found that patient who were not referred to the PT by their GP are younger, more often have recurrent complaints and the complaints are more often related to sports or leisure activities [11]. On the other hand, our population did not seem to differ concerning baseline characteristics from other observational studies done in primary care.

Prognosis/prediction. We found the following prognostic factors for recovery after 6 months; a short duration of complaints; not having feelings of depression or anxiety; having a paid job; a better working alliance with their PT and a low disability score. Duration of complaints and disability were also predictors of recovery in the working population. Having a paid job and not having feelings of depression or anxiety were the strongest predictors. The predictors age, sex, repetitive movements and comorbidities, that were reported as predictors in the literature [12, 13, 14, 15], did not remain in our final prognostic model. This might be due to differences in measurement. We defined only upper limb co-morbidity, while other studies take into account all comorbidities or also measure concomitant low back- and neck pain. Because the prognostic model only

showed moderate performance it will be necessary in the future to include additional factors like psychosocial and emotional factors to improve the performance and discrimination of the model. Due to the lack of evidence of these factors in shoulder pain patients at the time we designed this study we did not include these variables in our project.

There are different ways to develop prognostic models, statistically and methodologically, all of which could lead to differences in the final prognostic models [16]. We selected prognostic factors based on the literature and presented all important performance statistics [13, 12, 17, 18, 19]. We added diagnostic US as a possible prognostic factor because imaging procedures might influence recovery [20] and we assumed that US would lead to a more specific diagnosis, a subsequent more specific treatment and thus to better patient outcomes. This variable was dichotomized however, the performance of diagnostic US might differ for different subgroups. The low number of patients with an ultrasound diagnosis limited our ability to perform any additional analysis for subgroups (e.g. rotator cuff tears)

Likewise, we added working alliance to the model because it showed significant associations in other musculoskeletal populations [21]. Working alliance remained in the final prognostic model, meaning that the relationship between the physiotherapist and the patient is an important factor for the treatment process.

Implications for practice

We suggest that the 12 week time frame for referral is not helpful in clinical practice, since surgical management and conservative management show similar results and the time needed for conservative management (mostly exercise therapy) to work might be longer than 12 weeks in patients with high levels of pain or disability [22, 23, 24]. For the patients that progress into chronic complaints, other factors (like psychosocial-emotional factors or central nervous system in pain behavior) should be taken into account [14].

Several studies showed that pathologies are found in asymptomatic shoulders and therefore the pathology seen on the US might not be the cause of the symptoms experienced. However, in case of full thickness tears (early) surgical repair is sometimes required and therefore it is necessary to identify these tears early in primary care [25, 26].

The use of prognostic models links to a shift towards stratified care, where the individual's profile and the presence of prognostic factors help guide individual treatment decisions. Although the prediction model is not yet valid for use in clinical practice, prognostic factors like duration of complaints, level of disability, having a paid job, working alliance and feelings of depression/anxiety should be addressed or taken into account when making a treatment decision in patients with shoulder pain.

Implications for future research

Almost all PTs in our study used exercise in all treatment sessions. However, it is not clear what specific type or dose of exercise can be recommended and future studies should investigate these or whether exercise therapy might be more effective for a specific subgroup of patients.

In our study, the use (yes/no) of diagnostic US (and not the outcome) was dichotomized to predict recovery. The effect of receiving a diagnostic ultrasound on recovery and reassurance might differ for different subgroups of patients and should be studied in a large controlled trial. The working alliance between PT and patient predicted recovery but further research is needed to explore the concept and impact of working alliance in physiotherapy care.

The explained variance of the prognostic model for recovery in this study was still only moderate, meaning that we cannot yet validate a useful prognostic tool to select patients that are at risk for chronicity. More factors should be taken into account to improve the explained variance in future prognostic models. Some of the prognostic factors are modifiable and future research should investigate whether changes in these factors can contribute to patient recovery.

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