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Physical functioning in Ankylosing Spondylitis patients

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Summary

Ankylosing Spondylitis (AS), also known as Bechterew's disease, is a chronic inflammatory rheumatic disease that primarily affects the axial skeleton and belongs to a group of diseases called (axial) Spondyloarthritis (SpA). The disease affects young people <40 years. It is characterised by back pain, stiffness and reduced spinal mobility due to inflammation and structural damage of the spine. As a consequence patients experience limitations in physical functioning. Therefore, physical functioning is considered a prominent outcome domain in the evaluation of the disease's course and of the effectiveness of (non-)pharmacological therapy. Both in research and clinical practice, physical functioning is assessed with self-reported outcome measures using a questionnaire, generally the Bath AS Functional Index (BASFI). However, self-report questionnaires can give an under- or overestimation of the actual level of functioning. Therefore, assessment of physical functioning requires a valid outcome measure that is not influenced by patient perceptions to measure the effectiveness of AS treatment on physical functioning to supplement the currently used self-report BASFI questionnaire.

Chapter 1 describes the disease characteristics of AS and the currently used treatment and outcome measures. The thesis' objectives are (i) to develop performance-based tests of physical functioning for patients with AS (**Chapters 2-5**) and (ii) to gain more insight into the course and predictors of physical functioning of AS patients treated with TNF-inhibitors in clinical practice (**Chapter 6**).

Chapter 2 describes eight performance-based tests of physical functioning based on the 10-item BASFI questionnaire. They are: 'climbing stairs', 'bending', 'reaching', 'putting on socks', 'rising up and sitting down on a chair', 'getting up from the floor', 'looking over the shoulder' and the 'shuttle-walk test'. The remaining 2 BASFI items do not lend themselves to clinical observation. Each performance test received three scores: the time to complete a task in seconds and a score for pain and exertion associated with executing the test. Using data from 65 AS patients, the intrarater test-retest reliability of the performance tests was found to be adequate to excellent for all tests. The levels of reliability were satisfactory for group assessment in a research context (i.e., ICC >0.70). In clinical treatment of individual patients, repeated measurements are recommended.

Chapter 3 analyses the interrelatedness among the eight performance tests using data from 126 AS patients. All eight tests were shown to measure the same construct, except for the test 'looking over the shoulder'. Subsequent analyses were therefore performed separately for this test and the combination of the remaining seven tests.

Chapters 2 and 3 examine the association between the performance-based tests and the BASFI questionnaire. The associations were moderate to weak, both on item level (e.g. the test for 'reaching' and the corresponding BASFI item for 'reaching') and total score (the combined score of all performance tests vs. the total BASFI score). This result shows that

different aspects of physical functioning were measured by the performance tests and the BASFI questionnaire. Multivariable analysis showed pain and exertion to be the dominant predictors of the BASFI score, not time. The association between the BASFI questionnaire and time alone was lower than between the BASFI and a composite performance score based on time, pain, and exertion. Moreover, time contributed only little to the explained variance in the multivariable analyses. This suggests that AS patients determine the level of physical functioning on the BASFI questionnaire not by the time it takes to complete a task but more by the pain and exertion it requires. This questions the validity of the BASFI questionnaire as an outcome measure for the assessment of functioning alone.

In addition, performance-based tests seemed to be more influenced by impairment in spinal and hip mobility as measured by the Bath AS Metrology Index (BASMI) than by disease activity as measured by the Bath AS Disease Activity Index (BASDAI).

Chapter 4 assesses the responsiveness of the performance-based tests. Patients eligible for tumor necrosis factor inhibitors (TNFi) treatment ($n=82$) were examined before and after 3 months of TNFi therapy. The majority of patients (63%) showed a significant improvement of $\geq 20\%$ in the performance tests after treatment. A substantial portion of patients improved on performance-based physical functioning, but was not defined as responder according to the ASAS20 improvement criteria or BASFI questionnaire (i.e., 16% and 21%, respectively). These results suggest that self-reported questionnaires and performance-based tests measure different aspects of physical function. Both outcome methods are complementary to each other and both add to the understanding of physical functioning in AS patients.

Numerous (AS-specific) factors may contribute to the limited relationship between both assessment methods. For future research it would be interesting to examine the role of structural damage and hip involvement, fatigue, psychological factors and physical activity in relation to performance-based physical functioning. In addition, it should be analysed in larger patient groups what specific patient characteristics are predictors of improvement performance-based physical functioning.

Chapter 5 investigates the possibility of selecting a limited number of tests in order to prevent and eliminate redundant testing; this would improve the feasibility of the performance tests in clinical practice. All tests were well tolerated by the patients, who had varying limitations in physical functioning. Based on adequate reliability and highest standardized response means, the tests for 'bending', 'putting on socks', and 'getting up from the floor' were selected. After 3 months of TNFi therapy, these three performance tests yielded equivalent information on improvement in physical functioning compared to the full set of tests. The three tests are easy to administer in a clinical setting. Limiting the performance-based tests to these three prevents unnecessary test burden on patient when measuring treatment effectiveness.

Evaluation of physical functioning might be improved by adding these tests to other AS outcome measures. The next step will be to replicate these results in larger, placebo-controlled trials with a longer follow-up duration. Furthermore, reliability, responsiveness

and feasibility of the tests should be assessed in a physiotherapy setting and in a broader range of SpA diagnoses (i.e., non-radiographic-axial SpA).

Chapter 6 describes the 3-year outcome and course of physical functioning and spinal mobility impairments in patients routinely treated with TNFi. In AS patients receiving treatment with non-steroidal anti-inflammatory drugs (NSAIDs), limitations in physical functioning on average increase over time, while the course of physical functioning is highly variable. A marked and sustained improvement of physical functioning after TNFi treatment was shown in randomised clinical trials (RCTs). However, thus far only limited information is available on the course and risk factors of limitations in physical functioning in AS patients receiving TNFi in daily clinical practice. In this study spinal mobility showed a stable course over time. After a gradual improvement during the first 6 months of TNFi treatment, the level of physical function stabilised. This result suggests that the optimal time-point for the evaluation of treatment effects should be at 6 months instead of the currently used 3 months.

Predictors of a more favourable outcome and course of physical functioning after 3 years of TNFi treatment included lower baseline BASFI and BASMI scores, absence of comorbidity, younger age, and lower body mass index (BMI). In clinical practice it is of paramount importance to prevent (further) functional decline. Up-to-date knowledge of risk factors for functional decline is therefore needed. Despite the fact that it remains difficult to predict the course and outcome of the disease, the identification of these risk factors can be helpful to stimulate patients to adopt a healthy lifestyle including regular physical activity and weight reduction aiming at the prevention of further decline.

Chapter 7 summarizes and discusses the main results of the studies in this thesis. Suggestions for further research and implications for clinical practice are given.