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Editorial

Expanding the Assessment of Overall Functioning and Health Status in Patients With Spondyloarthritis

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The assessment of disease impact for rheumatological conditions is a challenging topic of relevant interest in the last years. Severity is closely related to disease impact, and related to several aspects of clinical conditions, including, among others, disease activity, physical function, and damage. All these are closely interrelated with the term "quality of life," reflecting the impact that the disease may have on the patient. The field of spondyloarthritis (SpA) has not been unaware of these concepts, and efforts have been made to develop instruments assessing domains going beyond physical function, disease activity, and pain.

Axial SpA (axSpA) is characterized by inflammation and new bone formation affecting the axial skeleton and joints.[1] These patients may have symptoms related not only to chronic back pain but also to spinal stiffness, peripheral manifestations, and extramusculoskeletal features. The disease course is characterized by functional disability and limitation in activities and social participation. The influence of the disease on health-related quality of life has been characterized and does not differ in terms of health status, disease activity, and physical function between radiographic and nonradiographic axSpA.[2]

Considering the variable evolution of axSpA, the assessment of health and functioning is now widely recognized as a relevant outcome when estimating the disease impact on patients having this condition. Recently, substantial advances have been achieved in developing instruments for the assessment of patients with axSpA focused predominantly on specific aspects of health, such as pain, disease activity, and physical function; additionally, the whole range of limitations and restrictions in activities and social participation of patients are included.

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Based on the International Classification of Functioning Disability and Health (ICF) categories of functioning, the Assessment of Spondyloarthritis international Society (ASAS) developed the ASAS Health Index (ASAS HI), which aims to measure functioning and health in patients with SpA.[3] Additionally, considering that some functional restrictions are influenced by contextual components related to personal and environmental factors (EFs), EFs are included as external elements to the individual that may influence functioning either as a barrier or as a facilitator. In this way, the EFs were developed to complement the ASAS HI and understand their interaction. The ASAS HI as a disease-specific questionnaire is intended to measure the impact of the disease in these patients. Further, the ASAS HI has been selected as a mandatory instrument for all trials in the currently updated ASAS-Outcome Measures in Rheumatology (OMERACT) core domain set for axSpA because it provides information to the domain of "overall functioning and health."[4,5]

The English version of the ASAS HI has proven to be valid, reliable, and responsive to evaluate the impact of the disease and treatment on functioning and health for use in patients with SpA.[6] Including more than one and a half thousand patients, the construct validity ranged from low (age = 0.10) to high (Bath Ankylosing Spondylitis Functional Index = 0.71) and the internal consistency was high (Cronbach α = 0.93). The reliability among more than 500 patients was good (intraclass correlation coefficient [ICC] = 0.87, 95% CI 0.84-0.89), and a moderate-large responsiveness (standardized response mean [SRM] = −0.44 for nonsteroidal antiinflammatory drugs, −0.69 for conventional synthetic disease-modifying antirheumatic drugs [csDMARDs] and −0.85 for tumor necrosis factor inhibitors) was found. Additionally, the smallest detectable change was 3.0. Values ≤ 5.0 denote good health, and values ≥ 12.0 characterize poor health status.[6] Several translations and cross-cultural adaptations of the original version of the ASAS HI have been validated and are now available to evaluate the state of health of patients with SpA in clinical practice.[7]

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As a potential endpoint for clinical trials, the ASAS HI was defined as a primary outcome in the Tight Control in Spondyloarthritis (TICOSPA)[8] treat-to-target trial, assessed after a 12-month follow-up in patients with axSpA. Although the outcome was not met (≥ 30% improvement), this study reflects the increasing relevance of health status assessment in the disease course.[8]

In the current issue of *The Journal of Rheumatology*, Kiltz and colleagues aimed to assess the psychometric properties of the ASAS HI (reliability, construct validity, discrimination, and responsiveness) in the context of 2 phase III clinical trials of ixekizumab (COAST-V and COAST-W) in patients with active radiographic axSpA. This objective was proposed having in mind that the properties of the ASAS HI had been evaluated in cross-sectional international observational studies, but not in clinical studies.[9]

Kiltz et al share the results they found. The reliability was 0.78 and 0.76 (adequate agreement) for both clinical trials with moderate-to-large correlations between ASAS HI and BASDAI (r = 0.40-0.61). Additionally, moderate-to-large correlations between changes in ASAS HI and other clinimetric tools (Bath Ankylosing Spondylitis Functional Index, Bath Ankylosing Spondylitis Disease Activity Index, Ankylosing Spondylitis Disease Activity Score [ASDAS], and patient global assessment) were observed. Additionally, patients with greater disease activity (ASDAS response groups) had higher mean ASAS HI scores in comparison to those with lower disease activity.[9]

In summary, this study shows the reliability, groups discrimination, construct validity, and responsiveness of the ASAS HI in adults with radiographic axSpA in 2 clinical trials, in addition to what has been demonstrated previously in clinical practice.[10]

However, some issues are still uncertain. First, there is little information regarding patients with peripheral SpA, and the estimation of the impact on purely peripheral manifestations needs further research. Second, the sensitivity to change of the ASAS HI and its predictive value on long-term outcomes should be confirmed by prospective longitudinal data. Third, there is a need for studies to test the usefulness of the ASAS HI as a clinimetric tool supporting therapeutic decisions and evaluating response to therapy. Further, information regarding the long-term variability and responsiveness of global functioning and health status in different populations is lacking.

This work by Kiltz et al contributes to positioning health status as an important concept and outcome that should be measured in rheumatology to assist patients in reporting how their disease and the different therapeutic options affect their daily life.

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