Patient-Reported Outcomes in Axial Spondyloarthritis

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KEYWORDS

• Axial spondyloarthritis • Ankylosing spondylitis • Patient outcome assessment

KEY POINTS

- More than 20 separate studies in more than 12,000 patients have validated patient-reported outcome measures in axial spondyloarthritis over the past 30 years.
- Of the available patient-reported outcome measures available for axial spondyloarthritis, only 3 to 4 are currently used routinely.
- About half of North American rheumatologists with expertise in axial spondyloarthritis use formal patient-reported outcome measures in their practice.

Axial spondyloarthritis (axSpA) is a complex, debilitating inflammatory condition characterized by involvement of the joint of the spine and the sacroiliac joints. Ankylosing spondylitis (AS)—a severe and prototypic form of axial spondyloarthritis—includes fibrous or bony bridging of joints in the spine, frequently involving multiple intervertebral discs. Although the history of AS, as the most obvious presentation of axSpA, extends back several centuries, its cause and pathophysiology have yet to be fully defined. The delineation of patient-reported outcomes (PROs) in axSpA and AS has been a longstanding challenge, due to the lack of data from longitudinal epidemiologic studies and the nonspecific nature of inflammatory laboratory markers to monitor disease activity. At least since the execution of therapeutic trials in the 1960s,[1] PROs have been increasingly used to better define this disorder. PRO measures provide a quantifiable and reproducible method of capturing data in the context of medical practice, allowing for efficient measures of quality of life and disease activity. An overview of current patient-reported measures and their validation are provided herein.

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HISTORY OF AXIAL SPONDYLOARTHRITIS AND ANKYLOSING SPONDYLITIS

The diagnosis of AS traces back to Galen's initial differentiation from rheumatoid arthritis in 200 AD, but it was not until 1559 that the first historical description of AS appeared in the literature. In that year, Realdo Colombo described 2 skeletons with AS-like characteristics in his book, *De Re Anatomica*. Other clinical descriptions have been scattered since then, and AS has historically been synonymous with terms such as Bechterew's disease and Marie-Strumpell disease.[2,3] As radiographic and clinical reports began to more precisely depict the features of AS, umbrella terms—"spondyloarthropathy" and "spondyloarthritis"—were then introduced in the 1970s, to distinguish this family of related disorders from rheumatoid arthritis.[4] This group of conditions included AS, psoriatic arthritis, reactive arthritis, inflammatory bowel disease–associated arthritis, and undifferentiated spondyloarthritis.

In his 1977 landmark paper, rheumatologist Andrei Calin and colleagues[5] described modern diagnostic criteria for inflammatory back pain (IBP), which was a hallmark of AS, and later, axSpA. Their criteria included: (a) age at onset less than 40 years; (b) back pain greater than 3 months; (c) insidious onset; (d) morning stiffness; and (e) improvement with exercise.[5] A few years later, a simplified version of the concept of IBP was codified in the modified New York criteria, which gained rapid acceptance.[6] Although adequate for identifying the well-established disease represented by AS, these criteria did not capture more subtle and earlier forms of axSpA. Thus, 2 additional classification criteria were constructed in the 1990s that identified a broader disease concept, including early-stage disease and peripheral spondyloarthritis without axial involvement.[7,8] Finally, in 2009, the Assessment of SpondyloArthritis international Society (ASAS) Criteria were developed using more rigorous methodology to allow for the identification of axSpA by integrating clinical, laboratory, and imaging data.[9]

DIFFERENT PATIENT-REPORTED OUTCOME MEASURES

The emergence of each of these classification criteria has often ushered in a complementary set of PRO measures. As a result, outcome measures for describing spondyloarthritides have exploded within the last 15 to 20 years, with significant progress in documentation of PROs, clinical and physical assessments, and characterization of disease stages for treatment protocols.[10] The characterization of disease activity in axSpA, on the other hand, has been somewhat delayed by comparison.

The following discusses the current uses, critiques, and evidence of validation for the currently published series of axSpA measures. Basic information regarding the content, format, method of calculation, and both respondent burden and time to score is provided in **Table 1**.

Quality of Life

The Ankylosing Spondylitis Quality of Life (ASQoL) questionnaire was originally developed using a needs-based model of health from 3 hospitals in northern England and 3 hospitals in southern Netherlands to monitor the impact of AS on a patient's ability to satisfy their needs of sleep, motivation, activities of daily living, relationships, and social life. The investigators established a goal of using the information to provide practitioners with a tool to guide clinical decision-making and improve patient outcomes. Since its publication, the ASQoL has been the most frequently used disease-specific measure of health quality of life in AS studies, including the assessment of tumor necrosis factor inhibitor (TNFi) therapy among AS patients.[11]

The ASQoL questionnaire was originally derived from interview transcripts in the field and ultimately condensed to an 18-item measure that uses dichotomous format