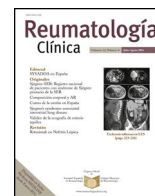




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## Brief Report

### Development of a Checklist for Patients With Axial Spondyloarthritis and Psoriatic Arthritis in Daily Practice: ONLY TOOLS Project<sup>☆</sup>



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## ABSTRACT

**Objective:** To standardize clinical evaluation of patients with axial spondyloarthritis (SpA) and psoriatic arthritis (PsA) using a checklist.

**Methods:** Qualitative study that included: (1) nominal group (18 experts); (2) literature reviews of measures used in the assessment of patients with axial SpA or PsA; and (3) focus groups, one with rheumatologists and another with patients, organized to become familiar with their opinion on medical assistance. Taking this into account, the experts selected the measures to be included in the checklist based on their relevance, feasibility, and the outcome type.

**Results:** The checklist includes measures for the evaluation of personal history, physical examination, activity and function, laboratory tests, imaging studies and treatments. It also defines risk factors of radiographic progression, predictors of the response to biological therapies, and comprises measures of excellence.

**Conclusions:** This checklist for patients with axial SpA and PsA could help standardize daily clinical practice and improve clinical management and patient prognosis.

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<sup>1</sup> The names of the components of the ONLY TOOLS working group are available in [Appendix A](#).

## Desarrollo de un cuadro de actuación para la evaluación de pacientes con espondiloartritis axial y artritis psoriásica en la práctica diaria: proyecto ONLY TOOLS

### R E S U M E N

#### Palabras clave:

Espondiloartritis axial  
Artritis psoriásica  
Cuadro de actuación

**Objetivo:** Estandarizar la evaluación clínica de pacientes con espondiloartritis (EspA) axial y artritis psoriásica (APs).

**Métodos:** Estudio cualitativo que incluyó: 1) grupo nominal (18 expertos); 2) revisión de la literatura sobre variables empleadas en la evaluación de los pacientes con EspA axial o APs, y 3) grupo focal con reumatólogos y otro con pacientes con EspA axial o APs para analizar la evaluación de las EspA en las consultas de reumatología. Los expertos seleccionaron las variables a incluir en el cuadro de actuación con base en su relevancia, factibilidad en consulta y método/s de medición.

**Resultados:** El cuadro de actuación incluye las variables para valorar antecedentes personales, exploración física, actividad y función, pruebas complementarias y tratamientos. Detalla factores de riesgo de progresión radiográfica, factores predictores de respuesta a terapia biológica, e incluye variables de excelencia.

**Conclusiones:** Este cuadro de actuación para pacientes con EspA axial y APs podrá ayudar a homogeneizar la práctica clínica diaria y a mejorar el manejo y el pronóstico de estos pacientes.

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## Introduction

In routine clinical practice, it is recommended that patients with spondyloarthritis (SpA) be evaluated according to clinical signs, symptoms and acute-phase reactants,<sup>1,2</sup> for example the Bath Ankylosing Spondylitis Disease Activity Index, C-reactive protein or the Ankylosing Spondylitis Disease Activity Score, which combines the 2 aspects (both subjective assessment of the patient and the acute-phase reactants).<sup>3</sup> The same occurs with psoriatic arthritis (PsA).<sup>2</sup>

However, despite the availability of a number of Spanish and international guidelines for the evaluation of SpA including PsA, the EmAR II study, conducted in Spain,<sup>4</sup> demonstrated that, in the assessment of SpA patients, approximately 60% of their medical records do not include an assessment of possible joint involvement or overall evaluation of the patient. In 87%, no joint score is recorded and, in 84%, there is no mention of a functional score. Distinct factors may contribute to this situation. At the present time, there is great pressure on health professionals that does not favor the evaluation and systematic collection of data. Moreover, there is a great variability in the assessment variables recorded for these patients (number, characteristics, feasibility, validation, etc.). This means that the outpatient follow-up of these individuals may not be optimal.<sup>5</sup>

These facts justify the need to design realistic strategies that contribute to improving the quality of clinical practice in order that these patients receive integrated care.<sup>4</sup> On the basis of the above aspects, the purpose of this project was to draw up a normalization tool (a framework for action, in the form of a checklist of items to be considered in visits to the rheumatologist, for an adequate assessment of the patient) to enhance the evaluation in routine practice of patients with axial SpA and PsA, for the aim of standardizing and achieving a stricter control of the disease, favoring the identification of high-risk factors and responses, as well as control of comorbidities.

## Material and Methods

### Study Design

We designed a qualitative study based on the methodology of the nominal group and a review of the literature promoted by

the Work Group for the Study of Spondyloarthritis of the Spanish Society of Rheumatology, which comprises 2 projects: *APROXIMA* (“Approximate”) and *PERSONALIZA* (“Personalize”).

### Participant Selection

We selected a group of 18 experts (with interest and demonstrated experience in the subject of the project) from all the regions of Spain.

### Drafting the Checklist

We performed a literature review that included PubMed, as well as Spanish and international guidelines and consensus documents. For this, we selected all of the variables employed for the evaluation of axial SpA and PsA patients (sociodemographic, clinical and treatment-related). We then organized 2 focus groups, 1 with rheumatologists (to explore the barriers and facilitators in the management of patients with axial SpA and PsA, as well as the most relevant aspects of their routine evaluation in the rheumatology department) and another with patients (to assess the needs that they detected in their visits to their physician, so that they subsequently be evaluated by the experts). The list of variables and the results of the focus groups were presented and discussed in a nominal group of experts, which prepared a provisional list of variables, both for the first visit and for successive appointments. The experts assessed each of these variables in terms of their: (1) relevance (impact on the patient, decision making, prognostic factor, etc.) from 1 (little relevant) to 10 (very relevant); (2) feasibility in the outpatient office from 1 (difficult to implement) to 10 (very feasible); (3) periodicity of the evaluation; and 4) method/s of measurement (direct question, questionnaire, scale, etc.). Once all the variables had been evaluated, the experts selected them for inclusion in the first visit and for successive appointments (together with their periodicity) those that had achieved the best scores and that they considered important for the evaluation of these patients. Next, they defined: (1) measures of excellence (those that, by taking into account the characteristics of routine clinical practice, may be more complicated to measure); variables considered prognostic factors, on the basis of the literature; (3) variables that predict the response to biological therapies, according to published reports;

and 94) common variables and those specific for axial SpA and PsA. These specifications were included in the checklist.

Finally, this checklist and its specifications were presented and analyzed in local meetings throughout Spain by an extensive and representative group of rheumatologists (see ONLY TOOLS work group in [Appendix A](#)). All of the recommendations proposed in these local meetings were conveyed to the experts, who drafted the definitive checklist and specifications. This entire process was done with the aid of methodological advice, that helped both in the organization of the focus groups and in the subsequent discussion of the elements to be included in the checklist.

### Statistical Analysis

This analysis was based on a descriptive study.

### Results

We drafted a checklist to evaluate SpA patients, with differentiated markers for patients with axial SpA and PsA, and their periodicity, as well as other specifications ([Fig. 1](#)). It includes sociodemographic variables, like the date of birth and sex (risk factor for the risk of radiographic progression and a determinant of a good response to biological therapy).

Concerning personal history, we documented, among other data, allergies, profession/employment status and use of tobacco (another risk factor affecting radiographic progression). Likewise, we recorded the date of symptom onset, the date of the diagnosis, related family history, enthesitis, dactylitis, extra-articular manifestations and the presence of inflammatory lower back pain. In the group of PsA patients, we included peripheral involvement, cutaneous symptoms and nail involvement.

With respect to comorbidities, we considered only those that had been diagnosed, such as hypertension, gastric ulcers and osteoporosis. As biomarkers, we included human leukocyte antigen (HLA) B27 and, specifically, in PsA, rheumatoid factor and anti-cyclic citrullinated peptide antibodies.

For patients with PsA, the physical examination included a study of synovitis in an upper and a lower limb and dactylitis, as well as a study of the skin and nails. Those with axial SpA underwent examinations of hip mobility, modified Schöber test, chest expansion and cervical rotation.

On the other hand, patient weight, height, body mass index, abdominal circumference and arterial blood pressure should be determined yearly in PsA patients and, as a measure of “excellence”, in the case of those with SpA.

With respect to clinical control, for axial SpA, the checklist includes the physician global assessment, the Bath Ankylosing Spondylitis Functional Index and the Disease Activity Score in 28 joints in the case of polyarticular involvement, aside from the Ankylosing Spondylitis Disease Activity Score and the Bath Ankylosing Spondylitis Disease Activity Index as determinants of a good response to biological therapy, and the former, moreover, as a risk factor of radiographic progression. In the case of PsA, the patient global assessment and morning joint stiffness are also evaluated.

Ancillary tests that should be performed in the control of axial SpA are complete blood count, erythrocyte sedimentation rate, routine laboratory tests, urinalysis and C-reactive protein (a determining factor of a good response to biological therapy and of radiographic progression). As a measure of excellence, it was decided to include 25-OH vitamin D and bone densitometry. In PsA patients, urinary uric acid should also be determined and, as a measure of excellence, the lipid profile, as well. With regard to imaging studies, plain radiography of the pelvis, spine and sacroiliac joints (and peripheral joints in patients with PsA) helps to monitor risk

factors for radiographic progression. A radiograph of the pelvis enables a proper assessment of the sacroiliac joints and the hips, making it unnecessary to X-ray these structures. Magnetic resonance of the sacroiliac joints serves as a marker of radiographic progression, and is also related to the response to biological therapy. Thus, the decision was made to include it.

Finally, this checklist incorporates a section on treatments.

### Discussion

The work group for the study of SpA of the Spanish Society of Rheumatology has developed a practical and simple checklist, achieved by consensus. It is adapted to the characteristics of Spanish outpatient clinics, and is based on a review of the literature and the opinion of experts for the assessment of patients with axial SpA and PsA in routine clinical practice.

A number of studies have shown that adherence to the recommendations for the evaluation of patients with SpA and PsA is highly variable, either because of a lack of time, motivation or knowledge, or because of the considerable number of the variables and their characteristics.<sup>2,5–8</sup>

In addition to standardizing routine clinical practice, the drafting of this checklist was to facilitate the identification of different risk profiles in patients (response to biological therapies,<sup>9</sup> radiographic progression,<sup>10,11</sup>, etc.) and aid in improving our approach to their comorbidities.<sup>12</sup> With these “warning signs” the effort is made to stress the need for greater awareness and control in these patients. It includes all the variables recommended in the Spanish and international guidelines and is presented in a simple form so that its use is feasible, either printed out or incorporated into the electronic medical record.<sup>1,2</sup> Thus, although these items are familiar to rheumatologists, providing them in an orderly and accessible way that is easy to employ should be an incentive for its implementation. This should contribute to a better control, adaptation of the resources utilized and facilitation of an integrated management of complex patients and serve as a tool to resolve the detected needs.<sup>5</sup>

The project has several limitations. For example, a possible limitation could be derived from the representativeness of the panelists, making it difficult to generalize and compare the suggested ideas. To avoid these limitations, we contacted rheumatologists from different centers in Spain to ensure demographic representativeness. Another limitation could be derived from the election of the items included in the checklist; although the failure to mention a relevant variable does not appear to be probable, new ones can be defined during every patient visit. We have not performed a real implementation of the checklist to determine whether or not its use is truly feasible and whether it enhances the care of patients with axial SpA, but this will be the object of future projects.

The design of a checklist as a tool for standardization might improve normalization and evaluation in the outpatient clinic. It could lead to a stricter control of the disease, identification of risk profiles and the control of comorbidities in routine clinical practice. At the present time, a project is underway for the introduction and assessment of the use of this checklist.

### Ethical Disclosures

**Protection of human and animal subjects.** The authors declare that no experiments were performed on humans or animals for this study.

**Confidentiality of data.** The authors declare that no patient data appear in this article.

Date of birth	___/___/___
<b>i</b> Sex	<input type="checkbox"/> Man <input type="checkbox"/> Woman

**Personal history**

Allergies	
Profession / employment status	
Physical activity	___ hours / week
<b>i</b> Smoking	<input type="checkbox"/>
Alcohol	<input type="checkbox"/>
<b>⊕</b> Date of onset of psoriasis	___/___/___
<b>⊕</b> Date of onset of joint symptoms	___/___/___
Low back pain	___/___/___
Lower back pain	<input type="checkbox"/> Inflammatory (nocturnal pain, morning stiffness, insidious onset, improvement with exercise and NSAID, and/or alternating buttock pain) <input type="checkbox"/> Mechanical
Family history	<input type="checkbox"/> IBD <input type="checkbox"/> Psoriasis <input type="checkbox"/> Reactive a. <input type="checkbox"/> Uveitis <input type="checkbox"/> SpA
Peripheral involvement	<input type="checkbox"/>
Skin symptoms (psoriasis)	<input type="checkbox"/>
Nail involvement	<input type="checkbox"/>
Enthesitis	<input type="checkbox"/>
Dactylitis	<input type="checkbox"/>
Extra-articular manifestations	<input type="checkbox"/> Diarrhea/ IBD <input type="checkbox"/> Psoriasis <input type="checkbox"/> Urethritis/ cervicitis <input type="checkbox"/> Uveitis

**Comorbidities**  
(Check only if diagnosed)

<input type="checkbox"/> Hypertension
<input type="checkbox"/> Diabetes mellitus
<input type="checkbox"/> Dyslipidemia
<input type="checkbox"/> Cardiovascular event
<input type="checkbox"/> Gastric ulcer
<input type="checkbox"/> Depression
<input checked="" type="checkbox"/> Obesity
<input checked="" type="checkbox"/> Gout / hyperuricemia
<input type="checkbox"/> Renal insufficiency
<input type="checkbox"/> Osteoporosis
<input type="checkbox"/> Others (Indicate other conditions that can interfere with treatment or evaluation)

**Biomarkers**  
(Check only those in which the result was positive. A single determination would be sufficient)

<b>⊕</b> <input checked="" type="checkbox"/> HLA B27
<input checked="" type="checkbox"/> Rheumatoid factor
<input checked="" type="checkbox"/> Anti-CCP antibodies

**i** Notice: Risk factor for radiographic progression.

**⊕** Determining factor of a good response to biological therapy.

**★** Measure of excellence.

  Specific for psoriatic arthritis.

  Specific for axial spondyloarthritis.

**Treatment**  
(Check treatments being taken at each visit)

<input type="checkbox"/> NSAID
<input checked="" type="checkbox"/> Corticosteroids
<input checked="" type="checkbox"/> DMARD
<input type="checkbox"/> Biological therapy
<input type="checkbox"/> Health-related lifestyle (smoking, exercise, alcohol, diet)

Physical examination (DMR: according to data from the medical record; AM: annual minimum; 6 m: every 6 months; RF: periodicity according to risk factors)		___	___	___	___	___	___	___	___	___	___	___	___	___	___	___	___	___	___
Upper limb synovitis	DMR																		
Lower limb synovitis	DMR																		
Enthesitis (if painful)	DMR																		
<b>i</b> Dactylitis	DMR																		
Skin/nails	AM																		
Examination of hips	AM																		
Modified Schöber	AM																		
Chest expansion	AM																		
Cervical rotation	AM																		
<b>★</b> Weight/Height/BMI*	AM																		
<b>★</b> Abdominal circumference*	AM																		
<b>★</b> Arterial blood pressure*	AM																		
<b>Clinical control</b>																			
Physician global assessment (0-10)	DMR																		
Patient global assessment (0-10)	DMR																		
Morning joint stiffness (min)	DMR																		
<b>i</b> <b>⊕</b> ASDAS	DMR																		
<b>⊕</b> BASDAI	DMR																		
BASFI	DMR																		
DAS28 (in the case of polyarticular involvement)	DMR																		
<b>Ancillary tests</b>																			
Complete blood count																			
ESR																			
<b>i</b> <b>⊕</b> CRP																			
Routine laboratory tests																			
<b>★</b> Lipid profile	6 m																		
<b>★</b> Uric acid	6 m																		
<b>★</b> 25-OH vitamin D																			
Urinalysis																			
<b>i</b> Simple radiography of pelvis and spine																			
<b>i</b> Radiography of sacroiliac joints																			
<b>i</b> Peripheral radiography																			
<b>i</b> <b>⊕</b> Radiography of sacroiliac joints <sup>11</sup>																			
<b>★</b> Bone densitometry	RF																		

\* Measure of excellence only in axial SpA.

Fig. 1. Checklist for the evaluation of patients with axial spondyloarthritis and psoriatic arthritis.

**Right to privacy and informed consent.** The authors declare that no patient data appear in this article.

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### Conflict of Interest

EL has received funding for research projects from AbbVie, Roche, MSD, Pfizer, Gebro, UCB, Grünenthal, Sobi, Celgene and Eisai. The remaining authors declare they have no conflicts of interest.

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### Appendix A. ONLY TOOLS Work Group

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