ARD Online First, published on January 3, 2014 as 10.1136/annrheumdis-2013-204262

EXTENDED REPORT

Evaluation of the validity of the different arms of the ASAS set of criteria for axial spondyloarthritis and description of the different imaging abnormalities suggestive of spondyloarthritis: data from the DESIR cohort

Anna Moltó,[1,2] Simon Paternotte,[1] Désirée van der Heijde,[3] Pascal Claudepierre,[4,5] Martin Rudwaleit,[6] Maxime Dougados[1]

Handling editor Tore K Kvien

[1]Paris Descartes University, Department of Rheumatology, Hôpital Cochin – Assistance Publique- Hôpitaux de Paris, INSERM (U1153): Clinical epidemiology and biostatistics, PRES Sorbonne Paris-Cité, France
[2]Departament de Medicina, Universitat Autònoma de Barcelona, Barcelona, Spain
[3]Leiden University Medical Center, Leiden, The Netherlands
[4]Laboratoire d'Investigation Clinique (LIC) EA4393, Université Paris Est Créteil, Créteil, France
[5]Service de Rhumatologie, AP-HP, Hôpital Henri-Mondor, Créteil, France
[6]Endokrinologikum Berlin, Berlin, Germany

Correspondence to
Dr Anna Moltó, Rheumatology B Department, Hopital Cochin, 27 rue du Faubourg Saint Jacques, Paris 75014, France; anna.molto@cch.aphp.fr

Received 10 July 2013
Revised 18 November 2013
Accepted 10 December 2013

To cite: Moltó A, Paternotte S, van der Heijde D, *et al*. *Ann Rheum Dis* Published Online First: [*please include* Day Month Year] doi:10.1136/annrheumdis-2013-204262

ABSTRACT

Background The Assessment of Spondyloarthritis International Society (ASAS) criteria for axial spondyloarthritis (SpA) allows classification of patients with ('imaging' arm) and without ('clinical' arm) imaging abnormalities of the sacroiliac joints.

Objective To compare the phenotype of early axial SpA with regard to the two arms of the ASAS axial SpA criteria.

Methods Demographics, clinical and biological features of SpA, disease activity, severity parameters, and imaging abnormalities at the sacroiliac and spine levels were compared, in the two arms of the ASAS axial SpA criteria, in the patients of the French cohort of early SpA.

Results Of the 615 patients analysed, 435 (70.7%) met the ASAS criteria (262 (60.2%) and 173 (39.8%) in the imaging and clinical arms, respectively). There were no major differences in the characteristics of the two groups except that those in the imaging arm were more likely to be younger, male and have higher concentrations of C-reactive protein. Imaging abnormalities other than those meeting the ASAS criteria for the imaging arm (ie, x-ray-determined structural damage or MRI-revealed inflammatory changes in the sacroiliac joint (SIJ)) were observed (MRI–SIJ structural damage (55.0% vs 3.5%), MRI–spine inflammatory changes (35.1% vs 12.9%), MRI–spine structural damage (10.3% vs 5.3%) and x-ray–syndesmophytes (11.8% vs 5.3%)) in the imaging versus clinical arm, respectively.

Conclusions Our study confirms the external validity of the clinical arm of the ASAS criteria. It is notable that many patients in the clinical arm showed other imaging changes in SIJs and spine.

The Assessment of Spondyloarthritis International Society (ASAS) has proposed a set of criteria[1] for recognising patients with early axial spondyloarthritis (SpA). These criteria can be summarised in two main arms, which can both be applied to patients with chronic back pain starting before the age of 45 years:

- The 'imaging' arm, in which a patient meets the criteria if an objective sign of inflammation (MRI)[2] or structural damage (conventional pelvic x-ray analysis) is demonstrated in the sacroiliac joints (SIJs), together with a history or current symptoms of at least one feature suggestive of SpA (eg, inflammatory back pain (IBP), psoriasis, enthesitis, etc.)
- The 'clinical' arm, in which a patient meets the criteria despite the lack of demonstration of an objective sign of inflammation on MRI or structural damage in the SIJs. In this case, the patient has to be HLAB27 positive and have a history or current symptoms of at least two features suggestive of SpA (eg, IBP, psoriasis, enthesitis, etc.)

The validity of these criteria is still under debate both in terms of validity of the clinical arm and with regard to the imaging abnormalities that allow classification of a patient as meeting the criteria of the imaging arm.

The ASAS criteria for axial SpA (ax-SpA), especially the clinical arm, have been externally validated in different SpA populations and clinical trials[3–6] (eg, by evaluating the clinical presentation, the level of activity and/or severity of the disease, the treatment effect of drugs usually effective in radiographic spondyloarthritis), and also in terms of face validity (eg, by evaluating the percentage of patients with histological features suggestive of sacroiliitis despite the lack of imaging (either x-ray analysis or MRI) evidence of such sacroiliitis).[7] However, the clinical arm is not well recognised by the different national and international healthcare systems; for example, in many countries, patients with active, severe ax-SpA that is refractory to non-steroidal anti-inflammatory drugs are not eligible for treatment with tumour necrosis factor (TNF) blockers if imaging investigations do not show any sign of sacroiliitis. Moreover, increased C-reactive protein (CRP) is sometimes required.

Another aspect of the ASAS criteria that is currently under debate is the definition of imaging abnormalities. According to the published criteria, and in order to meet the criteria of the imaging arm, patients must have either obvious structural SIJ damage on pelvic x-ray analysis (eg, bilateral grade 2–4 or unilateral grade 3–4 of the modified New York criteria[8]) or active (acute) inflammatory lesions of the SIJs observed on pelvic MRI according to the ASAS/OMERACT definition.[9]

However, there is increasing evidence that other imaging abnormalities might also be of clinical relevance for classifying a patient as having SpA. For example, structural SIJ damage might be more easily detected by either CT scan[10] or MRI,[11 12] but, because of the potential long-term risk of radiation exposure,[13] MRI is the preferred technique. Another example is that, when these changes (eg, acute inflammation or structural damage) are observed at the spinal level, they might also be of relevance in the classification of a patient with symptoms suggestive of SpA, in particular when using MRI technology.[14 15]

These preliminary observations prompted us to conduct an analysis of the data collected in patients with early IBP suggestive of SpA and participating in the ongoing French multicentre DESIR (acronym which stands in French for outcome of early undifferentiated spondyloarthritis) study with the following two main objectives: (a) to compare patient characteristics with regard to the arm (imaging vs clinical) of the ASAS criteria they meet; (b) to describe the prevalence of the different imaging abnormalities in the two arms of the ASAS criteria.

PATIENTS AND METHODS

Study design

DESIR is a French prospective, multicentre, longitudinal study of patients with early IBP suggestive of SpA (clinicaltrials.gov NCT01648907).[16]

This study followed the current Good Clinical Practice guidelines and was approved by the appropriate ethics committees. Participants gave their written informed consent. The website contains the detailed description of the centres, organisation of the cohort, and the full detailed protocol and case report form.[17]

A total of 708 patients with early IBP were included (inclusion period October 2007–April 2010). Consecutive patients aged >18 years and <50 years with IBP involving the thoracic or lumbar spine or buttock area for >3 months but <3 years and symptoms suggestive of a diagnosis of SpA (score ≥5 on a numerical rating scale of 0–10 where 0=not suggestive and 10=very suggestive of SpA) were included in the DESIR cohort. Patients had to meet the IBP criteria of Calin *et al*[18] or the Berlin criteria.[19] Patients with a definite diagnosis of non-SpA back pain, conditions that might interfere with the validity of informed consent and/or prevent optimal compliance (eg, alcoholism, psychiatric disorders), or a history of treatment with TNF blockers were excluded. For this study, analysis included the whole of the DESIR cohort, and used the dataset locked on 12 December 2011.

Data collected

The data collected comprised both patient demographics and clinical presentation of the disease. Demographics included age, gender and body mass index. All items required to adequately classify a patient according to the ASAS criteria were collected. The activity of the disease was evaluated using BASDAI (Bath Ankylosing Spondylitis Disease Activity Index)[20] and ASDAS-CRP (Ankylosing Spondylitis Disease Activity Score–CRP).[21] The severity of the disease was assessed using BASFI (Bath Ankylosing Spondylitis Functional Index)[22] and BASMI (Back Ankylosing Spondylitis Metrology Index).[23] Finally, quality of life was evaluated according to the Short Form 36 Health Survey Questionnaire (SF36).[24]

To ensure the quality and standardisation of the images collected, a specific written procedure was given to each participating centre. Conventional x-ray analysis of the cervical spine, lumbar spine and pelvis was performed. Radiologists or rheumatologists at each study centre scored each SIJ as follows: 0=normal; 1=doubtful; 2=obviously abnormal; 3=fused. For the present analysis, SIJs were considered abnormal if at least one was scored 2 or 3. This scoring method, used by local investigators in DESIR, is derived from the modified New York criteria for radiographic sacroiliitis changes[8] with one modification: grades 2 and 3 of the New York criteria were pooled to make one combined grade.

The modified Stoke Ankylosing Spondylitis Spine Score (mSASSS)[25] was calculated from conventional x-rays of the cervical and lumbar spine. Definite radiographic damage was defined as an mSASSS score of ≥2 at at least one vertebral edge of each patient, representing the appearance of at least one syndesmophyte in that patient.

MRI scans of the SIJs, upper spine (C2 to T10) and lower spine (T8 to S1) were performed using short-tau inversion recovery and T1 fast spin echo acquisitions. A contrast product was not used.

The presence of inflammatory and structural damage at the SIJs and spine was assessed by radiologists or rheumatologists at each study centre. Inflammatory changes in the SIJs were defined as the presence of bone oedema. Structural SIJ damage was defined as the presence of clear characteristic lesions such as sclerosis, erosions, bone bridges or ankylosis. The spine was evaluated at three different levels (cervical/thoracic/lumbar), and the presence of either inflammatory (defined as the presence of bone oedema/with contrast enhancement at the entheseal site at vertebral corners or the whole vertebrae, with/without disc involvement) or structural (defined as the presence of sclerosis, erosions or vertebral syndesmophytes) damage was separately assessed at each of these three levels. For each MRI evaluation, radiologists or rheumatologists at each study centre recorded scores as follows: 0=normal; 1=doubtful; 2=abnormal. For this analysis, the MRI finding was considered abnormal only if scored as 'abnormal' by a rheumatologist or radiologist.

DESIR definitions for MRI involvement are similar to, but not identical to, the ASAS/OMERACT definitions for MRI sacroiliitis/MRI spinal involvement in SpA,[9 26] because the DESIR study was designed before the publication of the ASAS/OMERACT definitions.

Statistical analysis

The first step consisted of classifying each patient according to the ASAS criteria for ax-SpA, resulting in the following three categories: patients meeting, or not, the ASAS criteria, and, for those who did not meet the criteria, whether the abnormal image findings permitted classification of the patient in the imaging arm. If they did not, patients were classified in the clinical arm if HLAB27 was positive and two features suggestive of SpA were present.[1] For this purpose, we excluded patients who had data missing, preventing us from adequately categorising them into a specific arm of the ASAS criteria for ax-SpA.

The second step consisted of comparing the patient characteristics according to the arm of the criteria that they met (eg, imaging vs clinical). Categorical variables were compared using the χ^2 test (or Fisher exact test as applicable), while continuous variables were compared using the Student T test (the non-parametric Wilcoxon test as applicable).

Because different scenarios can be observed according to the imaging modalities in the imaging arm and according to the CRP status in the clinical arm, we performed a descriptive analysis in five different subgroups: (1) x-ray-determined definite SIJ damage and MRI inflammatory changes in the SIJ; (2) x-ray-determined definite SIJ damage and normal SIJ on MRI;

(3) SIJ normal on x-ray analysis and MRI inflammatory changes in the SIJ; (4) SIJ normal on x-ray analysis and MRI, and CRP abnormal; (5) SIJ normal on x-ray analysis and MRI, and CRP normal (where abnormal CRP was defined as >6 mg/L).

The third step consisted of evaluating other (not included in the ASAS criteria for ax-SpA) imaging findings suggestive of SpA (eg, MRI-determined structural damage of the SIJ, MRI-determined inflammatory and structural damage at the spine level, and the presence of at least one syndesmophyte at the cervical or lumbar level) observed in the different arms of the ASAS ax-SpA criteria. We then estimated the concordance of the abnormal imaging findings observed with the x-ray and MRI modalities using a κ coefficient of concordance (eg, at the SIJ level between the pelvic x-ray grades 0–1 (normal or doubtful)/2–3 (abnormal or partially fused) vs MRI grades 0–1 (normal or doubtful)/2 (abnormal) of structural damage; at the spine level between spine x-ray (mSASSS ≥2 at at least one vertebral edge, yes/no (cervical or lumbar)) vs spine MRI grades 0–1 (normal or doubtful)/2 (abnormal) of structural damage at at least one of the three levels (cervical/thoracic/lumbar)).

RESULTS

Classification of patients according to the ASAS criteria and relating to the two arms of the ASAS criteria

Figure 1 summarises the flowchart of the recruited patients. Because of missing data, the fulfilment (or not) of the ASAS criteria was assessed in 615 of the 708 patients in the DESIR cohort. Of these 615 patients, 435 met the ASAS criteria: 262 and 173 met the criteria for the imaging and clinical arms, respectively. Within the imaging arm, 126, 47 and 89 patients belonged to the 'x-ray definite SIJ damage/MRI inflammatory changes in the SIJ', 'x-ray definite SIJ damage/MRI SIJ normal' and 'x-ray SIJ normal/MRI inflammatory changes in the SIJ' subgroups, respectively. Thus, of the patients in the imaging arm, 66.0% could be classified as having radiographic ax-SpA, and 34.0% as having non-radiographic ax-SpA. In the clinical arm (eg, 'x-ray SIJ normal/MRI SIJ normal'), 32 (18.5%) had abnormal CRP levels, and 138 (79.8%) had normal CRP levels. For three patients, the available data allowed them to be classified in the clinical arm despite the absence of CRP data; however, because of the missing data, they were excluded from the subgroup analysis.

Imaging versus clinical arm

Table 1 summarises the comparison of the patient (age, gender, B27 positivity) and disease (clinical presentation, disease activity and severity) characteristics fulfilling the two arms of the ASAS criteria for ax-SpA. No differences were found between the groups except that those in the imaging arm were younger, more likely to be male and had higher CRP concentrations.

Comparison of the five subgroups according to imaging and/or CRP abnormalities

A descriptive analysis was performed (summarised in table 2) in the five different subgroups according to imaging and/or CRP abnormality. Patients in the 'x-ray definite SIJ damage/MRI inflammatory changes in the SIJ' subgroup were younger (mean±SD 29.3±6.7 years) than those in the other subgroups. Interestingly, BASDAI was strikingly higher in the 'abnormal CRP' subgroup of the clinical arm (57.3±17.2) than in any of the other

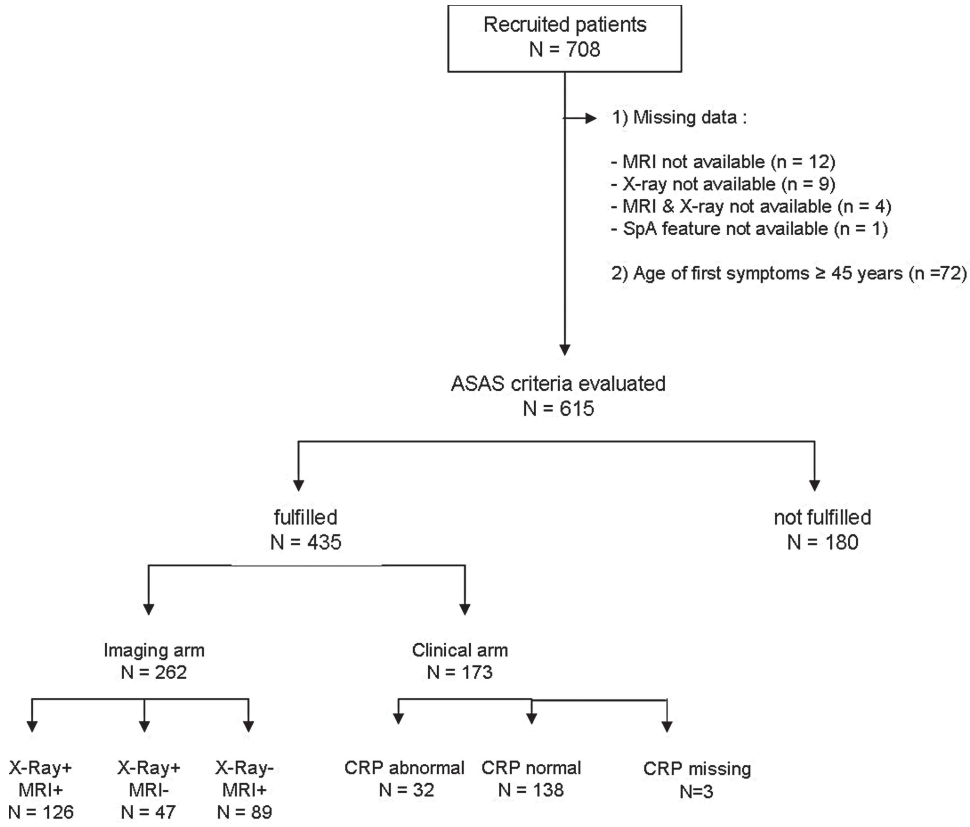

Figure 1 Distribution of the 708 patients recruited in the DESIR cohort according to the axial Assessment of Spondyloarthritis International Society (ASAS) criteria.

Table 1 Comparison of patient and disease characteristics of early axial spondyloarthritis according to the arm (imaging vs clinical) of the ASAS criteria they met

Characteristic	ASAS criteria		p Value†
	Imaging* (N=262)	Clinical (N=173)	
Age (years), mean±SD	30.6±7.2	32.6±7.3	0.005
Female gender, n (%)	107 (40.8)	101 (58.4)	0.0003
Disease duration (months), mean±SD	18.6±10.5	19.2±11.2	0.683
History or current symptoms of: n (%)			
Enthesitis	112 (42.8)	86 (49.7)	0.154
Peripheral arthritis	56 (41.2)	34 (35.1)	0.344
Dactylitis	36 (13.7)	20 (11.6)	0.506
Uveitis	27 (10.3)	12 (6.9)	0.229
Psoriasis	42 (16.0)	28 (16.2)	0.966
Inflammatory bowel disease	14 (5.3)	5 (2.9)	0.221
HLAB27 positivity, n (%)	192 (73.6)	173 (100.0)	<0.0001
Family history of SpA, n (%)	110 (44.4)	84 (50.0)	0.257
BASDAI, mean±SD	41.3±20.4	44.0±20.2	0.169
CRP (mg/L), mean±SD	11.6±15.7	5.2±9.3	<0.0001
Raised CRP‡, n (%) (N=459)	111 (44.4)	32 (18.8)	<0.0001
ASDAS-CRP, mean±SD	2.6±1.1	2.3±1.0	0.006
BASFI, mean±SD (N=4730)	28.7±22.2	29.3±22.5	0.840
BASMI, mean±SD (N=463)	2.4±1.0	2.1±0.9	0.020
Mental SF36, mean±SD	41.3±11.5	40.5±10.8	0.420
Physical SF36, mean±SD	40.9±9.0	39.8±9.6	0.191
Radiological sacroiliitis, n (%)	173 (66.3)	0 (0.0)	<0.0001
MRI acute inflammation of the SIJ, n (%)	215 (83.7)	0 (0.0)	<0.0001

*Either definite SIJ damage on pelvic x-ray examination according to the modified New York criteria[8] or inflammatory lesion of the SIJs on MRI as defined in the Methods section.
†Statistical significance defined by p<0.05. Categorical variables were compared using the χ^2 test (or Fisher exact test when the χ^2 test was not applicable), while continuous variables were compared using the Student t test (or the non-parametric Wilcoxon test when the Student t test was not applicable).
‡Raised CRP defined as CRP >6 mg/L.
ASAS, Assessment of Spondyloarthritis International Society; ASDAS, Ankylosing Spondylitis Disease Activity Score; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BASFI, Bath Ankylosing Spondylitis Function Index; BASMI, Bath Ankylosing Spondylitis Metrology Index; CRP, C-reactive protein; SF36, Short Form 36 Health Survey Questionnaire; SIJ, sacroiliac joint; SpA, spondyloarthritis.

subgroups. CRP levels were higher in the 'abnormal CRP' subgroup than in any of the subgroups of the imaging arm.

Concerning the structural damage (presence of structural damage, yes/no) of the SIJs and spine, the concordance between MRI and x-ray findings was very low at both the SIJ (κ 0.55 (0.49–0.61)) and spine (0.18 (0.06–0.31)) level (tables 3 and 4).

Other imaging abnormalities

Table 5 summarises the other imaging findings observed in the five subgroups as previously described. MRI structural damage of the SIJs was, as expected, more common in the subgroup of patients with x-ray-determined damage (65.3%), but, more interestingly, also in 3.5% patients of the clinical arm. MRI-determined inflammatory changes in the spine were more common in the presence of other markers of inflammation (eg, local MRI inflammatory changes in the SIJs (38.6%) or abnormal CRP (21.9%)). Furthermore, in the subgroups without x-ray-determined damage of the SIJs, there was evidence of x-ray-determined damage of the spine in 6.7% of the subgroup 'x-ray SIJ normal/MRI inflammatory changes in the SIJ' and 9.4% of the subgroup 'x-ray SIJ normal/MRI SIJ normal/CRP abnormal'.

DISCUSSION

This analysis of the DESIR cohort allowed us to evaluate potential differences in the clinical presentation of SpA with regard to the different arms of the ASAS criteria they met, in a population of patients with IBP suggestive of SpA. Patients in the DESIR cohort did not have to meet any particular set of criteria, other than to present with IBP for >3 months and <3 years, before the age of 50, and to have a confident physician diagnosis of SpA (above 50%, ie >5 on a 0–10 scale, where 0=no SpA and 10=definite diagnosis of SpA). Only after inclusion in the study were the different sets of criteria applied on the basis of data collected during the first visit.

Comparison of the patients in the imaging and clinical arms showed that the clinical features (eg, peripheral arthritis, dactylitis, uveitis, psoriasis) and most parameters evaluating the activity (eg, BASDAI), severity (eg, BASFI, BASMI) and impact of the disease in terms of quality of life (eg, SF36) were identical in the two groups.

Furthermore, this study confirms the presence of structural damage both at the spine and SIJ level and inflammatory lesions of the spine in a small proportion of patients in the clinical arm of the ASAS criteria.

This study has some weaknesses but also some strengths. First, because of missing data, we were unable to evaluate whether ASAS criteria were met in 26 patients (eg, 3.7%). This raises the question of how to handle the missing items of the ASAS criteria, in particular concerning the B27 antigen and the imaging modalities. In some epidemiological studies, such missing items have been considered as negatives in the evaluation of the ASAS criteria.[4 27] Because of the main objective of our study, we excluded patients with missing items that would not allow us to classify the patient according to the different arms of the ASAS criteria.

Second, the technique for evaluating the imaging modalities (eg, by each local participating investigator and not by a central reader) might be seen as a weakness, but this methodology could also be seen as a strength because it reflects daily practice. In any case, in the DESIR study, imaging modalities were standardised in terms of both image collection (eg, standardised written protocols) and evaluation (a specific case report form with a reminder of the definition of the abnormalities suggestive of SpA was provided), since the readers (either a rheumatologist or radiologist) had to complete a case report form as described in the Methods section.

Another limitation is that the specificity of either arm of the ASAS criteria cannot be evaluated because of the lack of a control group; even though a group of patients in the DESIR cohort did not fulfil the ASAS criteria, they could not be used as a control population, as all patients in the DESIR cohort had to have a confident physician diagnosis of SpA as described above. Another limitation is the cross-sectional design of our study, with no gold standard for the diagnosis of SpA.

However, our multicentre study also has some strengths. First, our analyses were performed on a large number of patients with IBP suggestive of SpA (N=682), ensuring a good representation of early SpA from a western European country.

As previously reported, the similarity of the clinical disease manifestations between the patients with regard to the arm of the ASAS criteria they met is a strong argument in favour of the

Table 2 Comparison of patient and disease characteristics of early axial spondyloarthritis according to the ASAS criteria arms (imaging vs clinical) and subarms (x-rays vs CRP) they were fulfilling

	ASAS criteria				
	Imaging*			Clinical†	
Characteristic	X-ray+/MRI+‡	X-ray+/MRI−§	X-ray−/MRI+¶	X-ray−/MRI−/abnormal CRP**	X-ray−/MRI−/normal CRP
Number	126	47	89	32	138
Age (years), mean±SD	29.3±6.7	31.1±8.4	32.3±6.8	31.4±6.1	32.8±7.6
Female gender, n (%)	46 (36.5)	22 (46.8)	39 (43.8)	21 (65.6)	78 (56.5)
Disease duration (months), mean±SD	19.1±9.9	19.3±11.2	17.7±11.0	17.1±10.0	19.2±10.4
History or current symptoms of: n (%)					
Enthesitis	45 (35.7)	25 (53.2)	42 (47.2)	21 (65.6)	63 (45.7)
Peripheral arthritis	22 (36.7)	14 (46.7)	20 (43.5)	13 (61.9)	20 (27.0)
Dactylitis	15 (11.9)	8 (17.0)	13 (14.6)	6 (18.8)	14 (10.1)
Uveitis	15 (11.9)	3 (6.4)	9 (10.1)	5 (15.6)	6 (4.4)
Psoriasis	16 (12.7)	9 (19.2)	17 (19.1)	5 (15.6)	23 (16.7)
Inflammatory bowel disease	9 (7.1)	3 (6.4)	2 (2.3)	1 (3.1)	3 (2.2)
Family history of SpA, n (%)	56 (45.9)	18 (40.0)	36 (44.4)	16 (50.0)	66 (49.6)
HLAB27 positivity, n (%)	101 (80.2)	29 (61.7)	62 (70.5)	32 (100.0)	138 (100.0)
BASDAI, mean±SD	40.2±19.9	40.7±24.0	43.2±19.1	57.3±17.2	41.5±19.5
CRP (mg/L), mean±SD	10.9±13.4	15.9±20.8	10.5±15.7	15.9±17.6	2.7±1.7
ASDAS-CRP, mean±SD	2.6±1.0	2.6±1.3	2.6±1.1	3.5±0.9	2.0±0.8
BASFI, mean±SD	27.4±22.5	31.5±23.2	29.0±21.3	45.0±22.8	26.1±21.0
BASMI, mean±SD	2.5±1.0	2.5±1.0	2.2±0.8	2.4±1.2	2.1±0.8
Mental SF36, mean±SD	41.2±11.5	42.5±12.3	40.7±11.0	39.8±11.3	40.5±10.7
Physical SF36, mean±SD	41.9±8.4	40.0±10.4	39.9±8.9	33.5±8.3	41.1±9.3

*Either definite SIJ damage on pelvic x-ray examination according to the modified New York criteria[8] or inflammatory lesion on MRI as defined in the Methods section.
†Presence of HLA-B27 plus two clinical features of SpA.
‡Presence of both structural damage of the SIJs on pelvic x-ray analysis and MRI inflammatory changes in the SIJs.
§Presence of structural damage of the SIJs on pelvic x-ray analysis without MRI inflammatory changes.
¶Presence of MRI inflammatory changes in the SIJs without structural damage on pelvic x-ray analysis.
**Abnormal CRP defined as >6 mg/L.
ASAS, Assessment of Spondyloarthritis International Society; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BASFI, Bath Ankylosing Spondylitis Function Index; BASMI, Bath Ankylosing Spondylitis Metrology Index; CRP, C-reactive protein; SF36, Short Form 36 Health Survey Questionnaire; SIJ, sacroiliac joint; SpA, spondyloarthritis.

validity of such criteria. Yet, there were also differences between the two arms with respect to age, gender and elevated CRP, which may be have relevance for disease progression, for example.

Our findings on the prevalence of other imaging abnormalities in the clinical arm of the ASAS criteria raises the question of the potential need to revisit these criteria when conducting clinical epidemiological studies/trials, and also the question of MRI and radiographic investigation of patients presenting with symptoms suggestive of SpA in daily practice. However, these results have to be carefully interpreted, and will need further validation, as the prevalence of these abnormalities in patients without SpA or in a normal population has not been reported so far. Long-term longitudinal evaluation of the patients enrolled in the DESIR study and/or other ongoing studies should permit us to confirm, or not, our findings.

Table 3 Concordance between MRI and x-ray findings on the structural damage of sacroiliac joints (SIJs)

		Structural damage of SIJs on conventional pelvic x-rays*	
		Yes	No
Structural damage of SIJs on pelvic MRI†	Yes	179	75
	No	89	515

*Structural damage of SIJs on conventional pelvic x-rays defined as grades 2–3 (grades of sacroiliitis in the DESIR cohort are defined as: 0=normal; 1=doubtful; 2=obviously abnormal; 3=fused): this scoring method used by local investigators in DESIR is derived from the modified New York criteria for radiographic sacroiliitic changes with one modification: grades 2 and 3 of the New York criteria were pooled to make a single grade.
†Structural damage of the SIJs on pelvic MRI. Structural damage was defined as the definite presence of characteristic lesions such as sclerosis, erosions, bone bridges and ankylosis. Changes were scored as: 0=normal; 1=doubtful; 2=abnormal. For this analysis, structural damage of SIJs, yes=grade 2.

Table 4 Concordance between MRI and x-ray findings on the structural damage of the spine

		Structural damage of the spine on conventional x-rays*	
		Yes	No
Structural damage of the spine on MRI†	Yes	11	33
	No	35	532

*Defined as an mSASSS score of ≥2 (presence of at least one syndesmophyte) at at least one vertebral edge of each individual patient.
†Defined as presence of sclerosis, erosions or syndesmophytes on the vertebrae by scoring of the MRI scans as normal (grade 0), doubtful (grade 1) or abnormal (grade 2). For this analysis, structural damage of the spine on MRI yes=grade 2.
mSASSS, modified Stoke Ankylosing Spondylitis Spine Score.

Table 5 MRI and x-ray findings on spine and sacroiliac joints (apart from those included in the ASAS criteria) in patients with early axial spondyloarthritis

	ASAS criteria				
	Imaging*			Clinical†	
	X-ray+/MRI+‡	X-ray+/MRI−§	X-ray−/MRI+¶	X-ray−/MRI−/abnormal CRP**	X-ray−/MRI−/normal CRP
Number	126	47	89	32	138
MRI: SIJ structural damage††	92 (73.0)	21 (50.0)	31 (34.8)	3 (9.4)	3 (2.2)
MRI: spine inflammatory lesions‡‡	53 (42.7)	9 (21.4)	30 (34.1)	7 (21.9)	15 (10.9)
MRI: spine structural damage§§	18 (14.5)	3 (7.1)	6 (6.9)	2 (6.3)	7 (5.1)
X-ray: spine¶¶	14 (11.1)	11 (23.4)	6 (6.7)	3 (9.4)	6 (4.4)

Values are number (%).
*Either definite damage of SIJs on pelvic x-ray analysis according to the modified New York criteria[8] or inflammatory lesion of SIJs at MRI as defined in the Methods section.
†Presence of HLA-B27 plus two clinical features of SpA.
‡Presence of both structural damage on pelvic x-ray analysis and MRI-determined inflammatory changes in SIJs.
§Presence of structural damage of SIJs on pelvic x-ray analysis without MRI-determined inflammatory changes.
¶Presence of MRI-determined inflammatory changes in SIJs without structural damage on pelvic x-ray analysis.
**Abnormal CRP defined as >6 mg/L.
††Structural damage of SIJs on MRI defined as clear characteristic lesions such as sclerosis, erosions, bone bridges or ankylosis.
‡‡Inflammatory changes in the spine defined as bone oedema in or adjacent to the entheses at the margin of the vertebrae or whole vertebrae (with or without disc involvement), compatible with lesions observed in cases of ankylosing spondylitis.
§§Structural damage of the spine defined as clear characteristic lesions such as sclerosis, erosions or syndesmophytes on the vertebrae.
¶¶X-ray-revealed spine abnormalities defined as an mSASSS of 2 with at least one syndesmophyte at at least one vertebral edge.[25]
ASAS, Assessment of Spondyloarthritis International Society; CRP, C-reactive protein; mSASSS, modified Stoke Ankylosing Spondylitis Spine Score; SIJ, sacroiliac joint.

Contributors All authors collaborated in the conception and design of the study, or analysis and interpretation of data, revising the manuscript critically for important intellectual content, and gave final approval of the version to be published. AM drafted the article.

Funding DESIR is financially supported by unrestricted grants from both the French Society of Rheumatology and Pfizer Ltd France.
This study financially supported by a Pfizer grant. The funders had no role in the study design, data collection, analysis, decision to publish or preparation of the manuscript.

Competing interests None.

Ethics approval Local ethics committee.

Patient consent Obtained.

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES

1 Rudwaleit M, van der Heijde D, Landewé R, *et al*. The development of Assessment of SpondyloArthritis international Society classification criteria for axial spondyloarthritis (part II): validation and final selection. *Ann Rheum Dis* 2009;68:777–83.
2 Sieper J, Rudwaleit M, Baraliakos X, *et al*. The Assessment of Spondyloarthritis international Society (ASAS) handbook: a guide to assess spondyloarthritis. *Ann Rheum Dis* 2009;68:ii1–44.
3 Aydin SZ, Maksymowych WP, Bennett AN, *et al*. Validation of the ASAS criteria and definition of a positive MRI of the sacroiliac joint in an inception cohort of axial spondyloarthritis followed up for 8 years. *Ann Rheum Dis* 2012;71:56–60.
4 Rudwaleit M, Haibel H, Baraliakos X, *et al*. The early disease stage in axial spondylarthritis: results from the German Spondyloarthritis Inception Cohort. *Arthritis Rheum* 2009;60:717–27.
5 Haibel H, Rudwaleit M, Listing J, *et al*. Efficacy of adalimumab in the treatment of axial spondylarthritis without radiographically defined sacroiliitis: results of a twelve-week randomized, double-blind, placebo-controlled trial followed by an open-label extension up to week fifty-two. *Arthritis Rheum* 2008;58:1981–91.
6 Sieper J, van der Heijde D, Dougados M, *et al*. Efficacy and safety of adalimumab in patients with non-radiographic axial spondyloarthritis: results of a randomised placebo-controlled trial (ABILITY-1). *Ann Rheum Dis* 2013;62:815–22.
7 Gong Y, Zheng N, Chen SB, *et al*. Ten years' experience with needle biopsy in the early diagnosis of sacroiliitis. *Arthritis Rheum* 2012;64:1399–406.
8 van der Linden S, Valkenburg HA, Cats A. Evaluation of diagnostic criteria for ankylosing spondylitis. A proposal for modification of the New York criteria. *Arthritis Rheum* 1984;27:361–8.
9 Rudwaleit M, Jurik A-G, Hermann K-GA,, *et al* Defining active sacroiliitis on magnetic resonance imaging (MRI) for classification of axial spondyloarthritis—a consensual approach by the ASAS/OMERACT MRI Group. *Ann Rheum Dis* 2009;68:1520–7.
10 Devauchelle-Pensec V, D'Agostino MA, Marion J, *et al*. Computed tomography scanning facilitates the diagnosis of sacroiliitis in patients with suspected spondylarthritis: results of a prospective multicenter French cohort study. *Arthritis Rheum* 2012;64:1412–19.
11 Weber U, Maksymowych WP. Sensitivity and specificity of magnetic resonance imaging for axial spondyloarthritis. *Am J Med Sci* 2011;341:272–7.
12 Weber U, Lambert RG, Pedersen SJ, *et al*. Assessment of structural lesions in sacroiliac joints enhances diagnostic utility of magnetic resonance imaging in early spondyloarthritis. *Arthritis Care Res (Hoboken)* 2010;62:1763–71.
13 Smith-Bindman R, Lipson J, Marcus R, *et al*. Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. *Arch Intern Med* 2009;169:2078–86.
14 Hermann KG, Althoff CE, Schneider U, *et al*. Magnetic resonance imaging of spinal changes in patients with spondyloarthritis and correlation with conventional radiography. *RadioGraphics* 2005;25:559–70.
15 Bollow M, Enzweiler C, Taupitz M, *et al*. Use of contrast enhanced magnetic resonance imaging to detect spinal inflammation in patients with spondyloarthritides. *Clin Exp Rheumatol* 2002;20(6 Suppl 28):S167–74.
16 Dougados M, d'Agostino MA, Benessiano J, *et al*. The DESIR cohort: a 10-year follow-up of early inflammatory back pain in France: study design and baseline characteristics of the 708 recruited patients. *Joint Bone Spine* 2011;78:598–603.
17 http://www.lacohortedesir.fr
18 Calin A, Porta J, Fries JF, *et al*. Clinical history as a screening test for ankylosing spondylitis. *JAMA* 1977;237:2613–14.
19 Rudwaleit M, Metter A, Listing J, *et al*. Inflammatory back pain in ankylosing spondylitis: a reassessment of the clinical history for application as classification and diagnostic criteria. *Arthritis Rheum* 2006;54:569–78.
20 Garrett S, Jenkinson T, Kennedy LG, *et al*. A new approach to defining disease status in ankylosing spondylitis: the Bath Ankylosing Spondylitis Disease Activity Index. *J Rheumatol* 1994;21:2286–91.
21 van der Heijde D, Lie E, Kvien TK, *et al*. ASDAS, a highly discriminatory ASAS-endorsed disease activity score in patients with ankylosing spondylitis. *Ann Rheum Dis* 2009;68:1811–18.
22 Calin A, Garrett S, Whitelock H, *et al*. A new approach to defining functional ability in ankylosing spondylitis: the development of the Bath Ankylosing Spondylitis Functional Index. *J Rheumatol* 1994;21:2281–5.
23 Jenkinson TR, Mallorie PA, Whitelock HC, *et al*. Defining spinal mobility in ankylosing spondylitis (AS). The Bath AS Metrology Index. *J Rheumatol* 1994;21:1694–8.
24 Jenkinson C, Coulter A, Wright L. Short form 36 (SF36) health survey questionnaire: normative data for adults of working age. *BMJ* 1993;306:1437–40.
25 Creemers MC, Franssen MJ, van't Hof MA, *et al*. Assessment of outcome in ankylosing spondylitis: an extended radiographic scoring system. *Ann Rheum Dis* 2005;64:127–9.
26 Hermann KG, Baraliakos X, van der Heijde DM, *et al*. Descriptions of spinal MRI lesions and definition of a positive MRI of the spine in axial spondyloarthritis: a consensual approach by the ASAS/OMERACT MRI study group. *Ann Rheum Dis* 2012;71:1278–88.
27 Moltó A, Paternotte S, Comet D, *et al*. Performances of the Assessment of SpondyloArthritis International Society axial spondyloarthritis criteria for diagnostic and classification purposes in patients visiting a rheumatologist because of chronic back pain: results from a multicenter, cross-sectional study. *Arthritis Care Res (Hoboken)*. 2013;65:1472–81.

Evaluation of the validity of the different arms of the ASAS set of criteria for axial spondyloarthritis and description of the different imaging abnormalities suggestive of spondyloarthritis: data from the DESIR cohort

Anna Moltó, Simon Paternotte, Désirée van der Heijde, et al.

Ann Rheum Dis published online January 3, 2014
doi: 10.1136/annrheumdis-2013-204262