Evaluation of the predictive validity of the ASAS axial spondyloarthritis criteria in the DESIR cohort

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Abstract

Objective

To evaluate the predictive validity of the Assessment of SpondyloArthritis international Society (ASAS) axial spondyloarthritis (axSpA), Amor, European Spondylarthropathy Study Group (ESSG) and modified New York (mNY) classification criteria.

Methods

Patients from the DESIR cohort (inflammatory back pain suggestive of axSpA for >3 months but <3 years duration), followed for up to 5 years. Positive predictive value (PPV) of the set of criteria collected at baseline (ASAS, and its arms, Amor, ESSG and mNY: fulfilled/not fulfilled) were tested against the rheumatologist's axSpA diagnosis (fulfilled/not fulfilled) after 5 years of follow-up.

Results

In total, among the 708 patients included in the DESIR cohort at baseline, data on rheumatologist's diagnosis at 5 years was available in 411 patients; amongst them, 352 (85.6%) had an axSpA diagnosis according to the rheumatologist; 268 patients fulfilled the ASAS axial SpA (axSpA) criteria at baseline and of these, 245 were diagnosed as SpA after 5 years follow-up (PPV: 91%). The PPV of the ASAS "imaging" arm and "clinical" arm was 97% and 82%, respectively. Other criteria also showed similar PPV – Amor (91%), ESSG (90%) and mNY (99%).

Conclusion

Positive predictive validity of the ASAS criteria for axSpA (including both arms) at 5 years was excellent; it is worth noting that the performances of the other criteria were also very good in the DESIR cohort.

Key words

spondyloarthritis, classification criteria, ASAS criteria, validity, DESIR cohort

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Introduction

Axial spondyloarthritis (axSpA) encompasses both Ankylosing Spondylitis (AS) and non-radiographic SpA (nr-axSpA) (1). Classically, axSpA classification was performed based on the modified New York (mNY) criteria (2) which required the mandatory presence of structural damage of the sacroiliac joints (*i.e.* radiographic sacroiliitis). However, this lead to a significant delay, since early axSpA may present without any structural damage of the sacroiliac joints. In order to prevent this diagnostic delay, the Amor criteria (3) and the European Spondyloarthropathy Study Group (ESSG) criteria (4), were proposed.

Recently, the Assessment of Spondyloarthritis International Society (ASAS) proposed a set of criteria (5) to allow classification of patients with early axial spondyloarthritis (SpA). These criteria consists of two arms – "imaging" arm (*i.e.* patients presenting with either structural or inflammatory lesions of the sacroiliac joints, in x-rays or MRI, respectively and at least one other SpA feature) and "clinical" arm (*i.e.* patients with HLA B27 and at least two other SpA features), applicable to patients with back pain of at least 3 months duration and age at onset of <45 years.

The ASAS criteria have received broad international acceptance since then, but have also been criticised for its multi-arm construct: a concern of potential misclassification and over diagnosis of SpA due to the "clinical arm" exists; also, some health authorities (6) have risen their concerns about the non-radiographic forms of axSpA captured by the "imaging arm", despite the presence of MRI sacroiliitis.

The external validity of the ASAS criteria for axial SpA (axSpA), and its arms has been already confirmed in several SpA cohorts (7-12). Moreover ASAS criteria seem to be more sensitive in classifying patients as having SpA and perform better than the ESSG or Amor criteria with the rheumatologist's diagnosis as external standard in a clinical cohort of patients (13). However, only very few data is available regarding the predictive validity of such criteria (14-15). Recently, using the ASAS cohort, the ASAS criteria for both the axial and peripheral SpA showed an excellent positive predictive value when evaluated after more than 4 years, for both the "imaging" and "clinical" arms (15). These preliminary observations prompted us to conduct an analysis with the following two main objectives: (a) to evaluate the predictive validity of the ASAS criteria and its arms ("imaging" and "clinical") after 5 years of follow-up and (b) to evaluate the predictive validity of the other SpA sets of criteria (Amor, ESSG and mNY) in an early axSpA cohort after 5 years of follow-up.

Materials and methods

Study design and patients

The DESIR cohort (French acronym for "Outcome of recent undifferentiated spondyloarthritis") is a prospective cohort of early (*i.e.* >3 months and <3 years duration) inflammatory back pain (IBP) suggestive of axSpA according to the rheumatologist, (*i.e.* diagnosis confidence of the rheumatologist ≥5/10, where 0=not suggestive and 10=very suggestive of axSpA), which includes 708 patients. Patients were followed every 6 months during the first 2 years (months 6, 12, 18 and 24) and yearly thereafter. The follow-up is still ongoing, but these present analysis are focusing only on the first 5 years of follow-up. As per protocol, after the first 2 years of follow-up, patients could be excluded if a definitive diagnosis other than axSpA (*e.g.* mechanical back pain due to mechanical discopathies) was confirmed. All the participants at the study gave their written informed consent. This study fulfils the current Good Clinical Practice Guidelines and was performed after obtaining the approval of the appropriate ethical committee.

Data collection

Demographics (*e.g.* age, gender, date of onset and duration of the inflammatory back pain) and disease characteristics, including all items required to adequately classify a patient according to the ASAS, Amor, ESSG and mNY criteria (*i.e.* HLA B27, radiographic sacroiliitis, MRI sacroiliitis, past or present abnormal CRP, past or present peripheral arthritis, past or present enthesitis, past or present uveitis, past or present

dactylitis, past or present psoriasis, past or present IBD, family history of SpA features) were collected at baseline. At the end of each visit, the rheumatologist had to report whether the diagnosis was axSpA or other diagnosis. They also had to report their confidence in an axSpA diagnosis on an 0–10 numerical rating scale (0 = not confident to 10 = very confident). Per protocol, patients with other diagnosis than axSpA (*i.e.* non-axSpA) could be excluded after the first 2 years of follow-up up to 5 years (60 months), is included in this present analysis.

Statistical analysis

• *Calculation of the sets of criteria*

The entry criterion for ASAS axSpA is chronic back pain ≥3 months duration initiating before the age of 45 years. As previously mentioned, in DESIR the inclusion criteria was the presence of chronic and inflammatory back pain for at least 3 months. As a first step, we excluded patients initiating IBP after 45years; afterwards, all remaining patients (*i.e.* initiating IBP before 45 years) fulfilled the entry item for the ASAS axSpA criteria.

As a second step, we then calculated the number of patients fulfilling the "Imaging" arm of the ASAS criteria at baseline: patients with either a radiographic or MRI sacroiliitis (according to local reading) at baseline were classified as fulfilling the "Imaging" arm of the ASAS criteria (all patients in DESIR had IBP, no additional SpA feature [*e.g.* skin psoriasis, elevated CRP, etc.] was necessary). In case either MRI or x-ray was missing, such imagings were considered as negative.

Among patients with back pain onset <45 years and not fulfilling the "Imaging" arm, those with HLA-B27 positive and only one another additional secondary SpA feature were classified as fulfilling the "Clinical" arm of the ASAS criteria (*i.e.* here in DESIR, all patients had IBP, thus only one extra SpA feature was necessary to fulfil the "Clinical" arm).

Patients fulfilling either the "Imaging" or the "Clinical" arm were classified as fulfilling the ASAS criteria for axSpA. The Amor (3), ESSG (4), and mNY (2) were defined according to their standard accepted definitions, and in case an item was missing they were considered as negative.

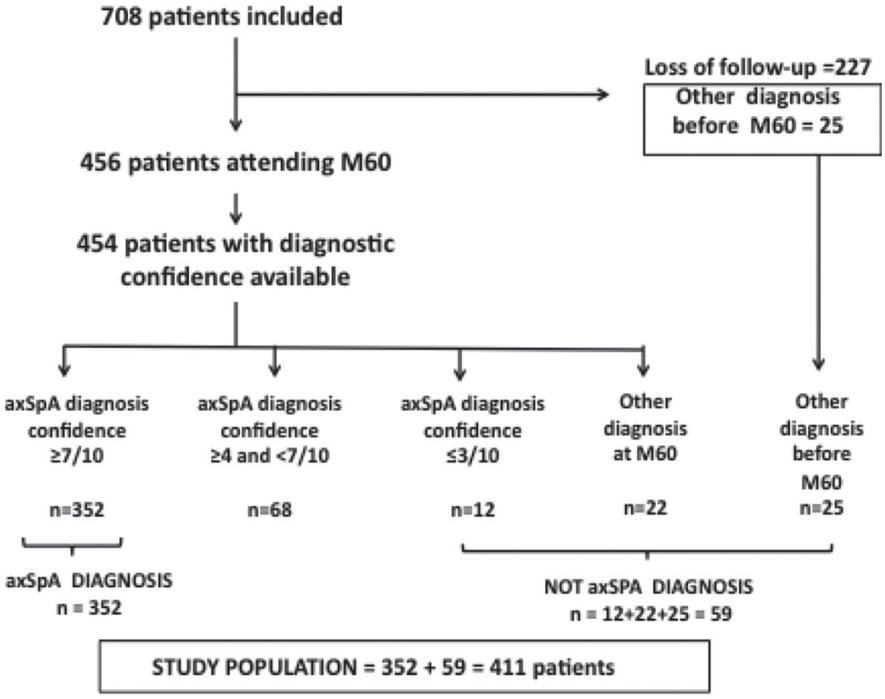

Fig. 1. Flow chart of the study.
axSpA: axial spondyloarthritis; M60: 5-year visits.

• *Definition of the Gold Standard*

The diagnosis of the rheumatologist at 5 years was the gold standard for this analysis. A patient was considered as "axSpA" if at the end of the 5-year visit the rheumatologist reported a confidence in an axSpA diagnosis of ≥7/10. Conversely, patients were considered as "Not axSpA" in case they were either excluded from the cohort, as per protocol, due to another definite diagnosis after 2 years of follow-up (see above "study design") or if at the end of the 5-year visit the rheumatologist reported a confidence in an axSpA diagnosis of ≤3/10. Patients with an axSpA diagnosis confidence of ≥4/10 and <7/10 were excluded from the analysis.

Baseline characteristics (demographics but also disease characteristics) of these two groups of patients were compared by Chi-test and T-test, for categorical and continuous variables, respectively.

• *Evaluation of the predictive validities of the sets of criteria*

All the sets of criteria collected at baseline (*i.e.* ASAS, "Imaging" and "Clinical" arms of ASAS, Amor, ESSG and mNY) were tested against the gold standard (*i.e.* the rheumatologist's diagnosis at 5 years).

Positive predictive value (PPV, *i.e.* positive predictive value = true positives/ [true positives + false positives]), and negative predictive value (NPV, *i.e.* negative predictive value = true negatives/ [true negatives + false negatives]) for all sets of criteria were calculated.

Data analysis was performed using the statistical software R 3.2.3 on a dataset locked on 16th June 2016.

Results

Baseline characteristics

Figure 1 represents the flow chart of the study. Out of the 708 patients that presented at baseline, 227 were lost to follow-up over the 5 years of follow-up and 25 patients were excluded as per protocol due to another certain diagnosis after the first 2 years of follow-up. Among the 456 patients attending the 5-year visit, rheumatologist's diagnostic confidence was available for 454 patients (Fig. 1): out of these 454 patients, 68 had a rheumatologist's diagnostic confidence of ≥4/10 and <7/10 (according to the gold standard definition) and hence were excluded from the study

Table I. Baseline characteristics of patient's with/without an axSpA diagnosis according to the rheumatologist at 5 years.

	AxSpA (n=352)*	Not axSpA** (n=59)	*p*-value***
Age (years) at baseline, mean (SD)	33.3 (8.8)	35.9 (8.7)	0.004
Duration of back pain in years, mean (SD)	1.53 (0.9) (n=351)	1.57 (0.8)	NS
Gender, male n (%)	175 (49.7%)	21 (35.6%)	0.04
Radiographic sacroiliitis+, n (%)	88 (25.3%) (n=348)	1 (1.8%) (n=57)	<0.0001
MRI sacroiliitis +, n (%)	161 (46.5%) (n=346)	5 (8.6%) (n=58)	<0.0001
HLA-B27, n (%)	226 (64.2%)	24 (40.7%)	0.006
Elevated CRP, n (%)	119 (35.2%) (n=338)	6 (10.7%) (n=56)	<0.0001
Peripheral arthritis past or present, n (%)	106 (30.2%) (n=351)	6 (10.2%)	0.001
Enthesitis past or present, n (%)	201 (57.1%)	32 (54.2%)	NS
Uveitis past or present, n (%)	33 (9.4%)	1 (1.7%)	0.06
Dactylitis past or present, n (%)	50 (14.2%)	1 (1.7%)	0.004
Psoriasis past or present, n (%)	67 (19.0%)	6 (10.2%)	NS
IBD past or present, n (%)	22 (6.3%)	2 (3.4%)	NS

*Rheumatologists' confidence in an axSpA diagnosis at 5 years ≥7 (0-10). **Rheumatologists' confidence in an axSpA diagnosis at 5 years ≤3 (0-10) or another diagnosis or no diagnosis available.
***χ^2 test for categorical variables and the independent samples *t*-test for continuous variables.
+Local reading for imaging was used.
axSpA: axial spondyloarthritis; CRP: C-reactive protein; IBD: inflammatory bowel disease; MRI: magnetic resonance imaging; NS: not significant; SD: standard deviation

Table II. Predictive validity of the different sets of classification criteria.

Criteria at baseline		AxSpA diagnosis at 5years			PPV (%) [95% CI]	NPV (%) [95% CI]
		Yes*	No**	Total		
ASAS$	ASAS	245	23	268	91 [87-94]	25 [18-33]
	Not ASAS	107	36	143		
	Total	352	59	411		
ASAS Imaging arm	Imaging	169	6	175	97 [93-99]	25 [18-33]
	Not ASAS	106	36	142		
	Total	275	42	317		
ASAS Clinical arm	Clinical	76	17	93	82 [72-89]	25 [18-33]
	Not ASAS	107	36	143		
	Total	183	53	236		
Amor	Amor	300	29	329	91 [88-94]	36 [25-48]
	Not Amor	47	26	73		
	Total	347	55	402		
ESSG	ESSG	291	33	324	90 [86-93]	30 [21-41]
	Not ESSG	61	26	87		
	Total	352	59	411		
mNY$	mNY	88	1	89	99 [94-100]	18 [14-22]
	Not mNY	260	56	316		
	Total	348	57	405		

$:for all sets of criteria, local reading was used. *Rheumatologists' confidence in an axSpA diagnosis at 5 years ≥7 (0-10). **Rheumatologists' confidence in an axSpA diagnosis at 5 years ≤3 (0-10) or another diagnosis or no diagnosis available.
ASAS: Assessment of SpondyloArthritis international Society; axSpA: axial spondyloarthritis; ESSG: European Spondylarthropathy Study Group; mNY: modified New York; NPV: negative predictive value; PPV: positive predictive value.

population. Of the remaining 386 patients, 352 patients were "axSpA" (*i.e.* axSpA confidence diagnosis ≥7/10) and 34 were "not axSpA" (*i.e.* axSpA confidence diagnosis ≤3/10). These 34 "not axSpA" patients were added to the 25 excluded patients over follow-up for other definite diagnosis, yielding a total of 59 "not axSpA"patients.

Thus, in the present analysis, the study population consisted of 411 patients (352 "axSpA" + 59 "not axSpA" patients).

Table I compares the baseline characteristics of all patients with the follow-up data available for "axSpA" and "not axSpA"patients at 5 years. Patients with axSpA were younger, more frequently males and HLA B27 positive and had more frequently objective signs of inflammation (*e.g.* MRI sacroiliitis or elevated CRP) or structural damage of the SIJ (radiographic sacroiliitis).

Predictive validity of various SpA classification criteria

Predictive validity of the different sets of classification criteria for axSpA are presented in Table II.

• *ASAS criteria for axSpA*

Among the 411 patients included in the analysis, 268 did fulfil the ASAS axSpA criteria at baseline and 143 did not. Of these 268 patients, 245 were diagnosed as "axSpA" at year 5, resulting in a PPV = 91% [95% CI = 87–94%]. Of the 143 patients not fulfilling ASAS criteria, 36 were indeed considered having as "not axSpA" at 5 years, resulting in a NPV= 25% [95% CI = 18–33%].

Among the 268 patients classified positive according to the ASAS axSpA criteria at baseline and fulfilling the rheumatologists' diagnosis, 175 (65.3%) and 93 (34.7%) fulfilled the "Imaging" and "Clinical" arms, respectively. PPV and NPV for the "Imaging" arm were 97% [95% CI=93–99%] and 25% [95% CI=18–33%]; PPV and NPV for the "Clinical" arm were 82.0% [95% CI=72–89%], and 25% [95% CI=18–33%], respectively.

• *Other sets of criteria*

PPV of Amor, ESSG and mNY criteria were 91.0% [95% CI=88–94%], 90.0% [95% CI=86–93%], and 99.0% [95%

CI=94–100%], respectively, and NPV were 36% [95% CI=25–48%], 30% [95% CI=21–41%], and 18% [95% CI=14–22%], respectively.

Discussion

This study confirms the excellent predictive validity of the ASAS criteria as a whole, but also of each of its arms, in an early axSpA setting. It is worth noting that all the other sets of criteria also performed greatly, although the ASAS (in particular the "Imaging" arm) and mNY criteria were the ones with the highest PPV.

As previously presented, and recently confirmed by a meta-analysis by Sepriano *et al*. (16), the cross-sectional validity of the ASAS criteria has been broadly demonstrated. To date, only two other studies have evaluated the predictive validity of ASAS criteria for axSpA (14-15). A recently published study by Sepriano *et al*. (15), reported an excellent predictive validity for the ASAS axSpA criteria, in a prospective, longitudinal study based on the ASAS cohort with a mean follow-up of 4.4 years. In this study, PPV of the axSpA ASAS criteria was 93.3%, slightly higher than our findings. However, in this study mean disease duration was 7.4 (9.3) years (longer than in our population) and in almost 39% cases, axSpA diagnosis was self-reported by telephone assessment, which might have increased the number of axSpA diagnosis at the end of follow-up.

The other study, by Lin *et al*., with a shorter follow-up (2 years) and including only patients with non-radiographic axSpA, showed similar performances, with a predictive validity for the ASAS criteria of 87.9% (14).

Our study has a few limitations, but also some strengths. First, despite there were already some data available with regard to the predictive validity of the ASAS criteria for axSpA, this study is, to the author's best knowledge, the first study aiming to evaluate it in an early axSpA population, including the performances of the arms of the ASAS criteria and confirming the excellent predictive validity in this setting. Secondly, a sizeable number of patients were lost to follow-up (n=227) over 5 years period. Unfortunately this is quite common in longitudinal studies, and based on other studies (*i.e*. the ASAS cohort (15)), this proportion is not greater than expected in this setting.

Further, in our study, the NPV was quite low amongst all the SpA criteria sets. However, as the disease duration increases, more SpA features might evolve overtime which might have an impact on the NPV. Hence, it is advisable to be careful when interpreting the low NPV, especially in a longitudinal cohort of early SpA like DESIR. On further exploratory analysis only 16.8% patients evolved from not satisfying the ASAS criteria at baseline to satisfy them after 5 years follow-up, which is in contrast to nearly one third of patients evolving overtime in the ASAS cohort (15).

Furthermore, another strength is that, we set a quite strict definition of "axSpA" diagnosis, by setting the threshold of diagnosis confidence as ≥7/10. This definition gives a very high probability to select only 'True axSpA patients'. To the best of our knowledge, no prior studies have reported using such high rheumatologist's conviction on diagnosis at follow-up. Most other studies have used rheumatologists' diagnosis (yes/ no) on follow-up as the external gold standard.

One particular limitation of this 5-year analysis is the number of lost-to follow-up (*i.e*. 32%); nevertheless, such numbers are unfortunately often observed in long-term cohorts, such as the ASAS cohort (15).

Furthermore, one could argue the circularity of using the physician's diagnosis as the gold standard to validate the ASAS classification criteria, since the rheumatologist will use (in his diagnosis) many features included in these criteria to perform the diagnosis. Nevertheless, this is the methodology, which has been approved and used in the validation of many sets of criteria including SpA criteria (15) but also rheumatoid arthritis criteria (17).

In conclusion, our study confirms the excellent predictive validity of the ASAS criteria and its arm, but also of all other classification criteria for axSpA in an early axSpA setting.

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