The value of the 2011 ASAS classification criteria in patients with Spondyloarthritis and the prognosis of non-radiographic axial Spondyloarthritis: data from a large cohort of a tertiary referral hospital

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RESEARCH PROTOCOL

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ABSTRACT

Spondyloarthritisides (SpA) are a group of interrelated rheumatic disorders that includes ankylosing spondylitis (AS), psoriatic arthritis (PsA), arthritis related to inflammatory bowel disease and reactive arthritis. Since the latest classification criteria published from the ASAS (Assessment of SpondyloArthritis international Society), patients with these diagnoses can be classified either as having axial or peripheral SpA. In this study, these new criteria of ASAS will be applied to all patients with a clinical diagnosis of SpA that are followed in the Rheumatology Clinic of University Hospital of Heraklion. Furthermore, patients with non-radiographic axial SpA (nrAxSpA) will be monitored, both retrospectively and prospectively, for their long-term outcome in terms of imaging and clinical aspects (remission, disability, severe complications, eg, uveitis). This study is expected to give valuable information of the performance of these new criteria in daily clinical practice and of the prognosis of patients with non-radiographic axial SpA.

Keywords: Spondyloarthritis, classification criteria, non-radiographic, prognosis.

INTRODUCTION

Spondyloarthritisides consist of a heterogeneous group of inflammatory diseases that share common clinical, radiological and genetic features. During the last decades a tremendous progress has been achieved in the field of diagnostic approach of spondyloarthropathies by the application of magnetic resonance imaging (MRI), as well as in further understanding their pathogenesis basis (genetic background, inflammatory pathways and novel cytokines). As a result of this progress, there have been important changes in the diagnosis, classification and treatment of these diseases. In 2009 and later on in 2011, the ASAS published a new set of classification criteria for spondyloarthropathies according to clinical features and imaging that classify them in to two groups, axial and peripheral SpA. While axial SpA mainly corresponds to the “classic” term “Ankylos-
ing Spondylitis" which is the prototype of SpA, the character-
ization of peripheral SpA was a major step, since it
comprises most of the cases diagnosed in the past as
“undiifferentiated SpA”. This is considered clinically im-
portant because it allows for an earlier and more accu-
rate diagnosis of patients with clinical features of SpA.
Moreover, by applying the MRI in patients with chron-
ic low back pain and normal X rays, a new entity (the
“non-radiographic axial Spondyloarthritis” [nrAxSpA])
has well been recognized. Even today, it is not yet clear
whether the latter form represents a distinct disease or
if it represents an early stage of Ankylosing Spondylitis.4

AIM OF THE STUDY
In the present study we aim to:
1. Assess the value of the 2011 ASAS classification cri-
teria in clinical practice, focusing in patients with a
former diagnosis of undifferentiated SpA. For that aim
we will apply the new classification criteria retrospec-
tively and prospectively in a large cohort (n=600) of
patients with spondyloarthropathies.
2. To establish a registry of patients with nrAxSpA with
a detailed follow-up in order to assess the long-term
outcome regarding treatment, quality of life and the
transition rate to the radiographic form of the disease
(AS).

METHODS
The study will take place in the Rheumatology Clinic of
the University Hospital of Heraklion. All patients with
a diagnosis of SpA who are followed in our department
(including those with undifferentiated SpA, PsA, entero-
pathic and reactive arthritis) will be analyzed. All patients’
files will be reviewed, and data will be entered in the
Registry of the Clinic (Rheumatology Clinic Data Base
RCDB) in order to be analyzed. Diagnosis and time to
classification according to the latest ASAS criteria either
as Axial or as Peripheral SpA will be recorded. We will
assess:
1. The value of the new criteria to re-classify patients
with a diagnosis of undifferentiated SpA.
2. Their baseline characteristics, treatments and out-
come.
Re-classified patients as peripheral SpA will be com-
pared to those not fulfilling ASAS criteria.
Patients with nrAxSpA will be assessed for:
1. Possible transition to radiographic SpA based on
plain X-rays.
2. The use of biologic treatment compared to those pa-
tients with AS.
3. Outcome, concerning disease activity, quality of life
and functional status.
This part of the study will have a retrospective and a pro-
spective arm. All patients will have a minimum of 2 years
follow-up in order to better characterize their outcome.

Demographics, treatments, disease’s characteristics
(BASDAI, ASDAS, DAPSA) function (BASFI, HAQ) and
quality of life (EUROQUOL 5D) will be retrieved or pro-
spectively documented accordingly.
We estimate to record approximately 600 existing and
50 new SpA patients per year.

IMPORTANCE OF THE STUDY
There are not many data assessing the application in
clinical practice of the aforementioned ASAS new pro-
posed classification criteria. Moreover, there are limited
data about SpA as a group of diseases in the Hellenic
population, and generally in the Mediterranean area. A
recent study from the Hellenic Registry for Biologic Ther-
apies (HeRBT) has shown the 10-years response rate
and outcome of Tumor Necrosis Factor inhibitors (TNFi)
in patients with SpA.5 The importance of the current
study consists in assessing the usefulness in everyday
clinical practice of the new ASAS criteria to classify pa-
tients with SpA. We will aim to assess whether ASAS cri-
teria have any additional benefit compared to the earlier
criteria in classifying patients with undifferentiated SpA.
Moreover, we will assess the characteristics and the out-
come of patients classified as nrAxSpA, and we will eval-
uate whether early recognition of patients may result in
better prognosis.

CONFLICT OF INTEREST
The authors declare no conflict of interest.

STUDY APPROVAL
The Ethics Committee of the University Hospital of Irak-
lion has approved the study.

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