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Chapter

Diagnostic/Classification Criteria

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Abstract

Diagnostic criteria are used, as the name suggests, to make diagnosis of disease. They should encompass those characteristics that we find in every patient with the disease they are designed for. Therefore, it is extremely difficult to design such criteria. Classification criteria, on the other hand, are intended to be used only in already diagnosed patients, to classify them as having the respective disease, mainly for research purposes. Nevertheless, since classification criteria encompass those characteristics of the disease that are present in the majority of patients, it is only natural to try to use them as a helping tool in the diagnostic endeavor. This should be done appropriately, bearing in mind that the patient not fulfilling every one of them, can and may be still diagnosed as having ankylosing spondylitis, even though he/she cannot be classified as such. Classification criteria for ankylosing spondylitis (AS) have changed over time, due to the new insight obtained into the pathogenic mechanisms of the disease. Moreover, a patient fulfilling them is sometimes the initial step mandated by the paying authorities for reimbursement of therapies. All these reasons and others highlight the need to understand the different facets of the diagnostic/classification criteria and their best use.

Keywords: diagnostic criteria, classification criteria, ankylosing spondylitis, spondylarthritis, imaging, HLA B27

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1. Introduction

In order to treat patients, a doctor, regardless of his/her specialty, must establish a diagnosis. The task of establishing a correct diagnosis can sometimes be very difficult. In such a circumstance, the existence of a set of diagnostic criteria makes the task easier. On the other hand, in order to establish a set of criteria that can be called "diagnostic criteria," each used item must be present in every patient with the disease. That is what makes defining a set of items as diagnostic criteria extremely difficult. When the clinical, biological, and imagistic pictures of a disease are very variable, such is the case with ankylosing spondylitis, this process is even more complicated.

With the medical technological development characterizing the last 30–40 years, new pathogenic mechanisms have been unveiled, and it became evident that new characteristics of disease may be used as items to classify or, even, diagnose our patients.

Diagnostic/classification criteria are extremely useful in daily clinical practice, especially when the clinical picture of a certain patient is not "clear-cut." In such a circumstance, checking for the items that make a diagnosis/classification criterion might be of value in that it might help review the clinical aspects that are part of the entire clinical spectrum of a disease and establish if the patient's "fit" into the criteria. Fortunately, we have professional associations that do the entire process of establishing sets of criteria for diseases, so that we can use them for our patients.

2. Diagnostic/classification criteria: are they the same?

Diagnostic criteria, as their name implies, are used to make a diagnosis. This means they should contain those specific items that a doctor can find in ALL patients with a certain disease. So, any characteristic of that disease (should it be a clinical or laboratory or imaging one) that is NOT present in ALL patients cannot be a diagnostic criterion. As a consequence, diagnostic criteria should be infallible, unfailing to make the right diagnosis. But let us, clinicians, be realistic: for how many of the characteristics of a diseases can we say that is present in ALL our patients, to define it like a diagnostic criterion?! And this is also true for non-clinical items, as well.

This became more evident with technological progress that allowed us to get deeper into pathogenic processes and acknowledge the fact that a finding (of any nature) is seldom pathognomonic for a disease or a diagnosis. Moreover, the exponential development of clinical research (i.e., randomized control trials) made it extremely necessary to apply interventions (mainly therapeutic) to as homogeneous as possible patient populations.

Hence, the need to define criteria that would encompass disease characteristics (clinical or non-clinical) that are found in the MAJORITY of patients that we encounter in clinical daily practice and not necessarily in ALL of them. These are classification criteria. They should be used, as per their name, just to classify, not to diagnose, patients. That means that they should be applied ONLY to already diagnosed patients. So, they should NOT be used for diagnosing people with diseases, but to classify patients already diagnosed. Classifying diagnosed patients according to certain criteria is very practical when we want to compare different treatments in a population with a disease, because, as aforementioned, this is a very good way to ensure homogeneity of compared populations.

Classification criteria are, therefore, used for research purposes (comparing different interventions in already diagnosed homogeneous populations), while diagnostic criteria are used for making a diagnosis in an individual patient.

In daily clinical practice, things are not that clear-cut. Actually, the majority of rheumatologists use classification criteria established for certain rheumatological diseases, for diagnostic purposes, as well as for research purposes. And this is not wrongdoing, in the sense that, reviewing the most frequently encountered characteristics of a disease might prove very useful in trying to diagnose an individual. And there is no doubt that!

Problems arise only when a physician does not diagnose a disease in an individual only because this individual does not fulfill the classification criteria, even though there are some other characteristics that would enable a more open-minded physician to make that right diagnosis. Probably one of the best examples in this respect pertains to the 1982 American College of Rheumatology (ACR) classification criteria and the 2019 European Ligue Against Rheumatism (EULAR)/ACR classification

criteria for systemic lupus erythematosus [1, 2]: in the first set of criteria, low levels of complement had no place, even though very many patients would have such levels; so, if one was using the 1982 set of classification criteria in order to make a diagnosis of a certain patient, one would potentially be missing those patients that did not fulfill four criteria, even if they would have low complement levels. Of course, over time, as our knowledge of diseases increases, classification criteria evolve according to the need of diagnosing as many patients as possible, as early as possible, in order to treat them the most early possible, to prevent complications and disability for our patients.

3. Diagnostic/classification criteria in ankylosing spondylitis

3.1 Modified New York criteria

Ankylosing spondylitis is a more than 100-year-old disease, characterized by bone formation as a result of inflammation of entheseal sites across the body. The inflammatory nature of this disease has consequences on other systems and organs in the body, than the musculoskeletal system, leading to extra-articular manifestations of the disease. These may consistently add to the morbidity and mortality of AS. This emphasizes on the need to establish a correct diagnosis as soon as possible.

To this day, there are no specific lab tests for diagnosing AS [3]. Moreover, even if usually, in inflammatory/autoimmune disease, the patient has elevated levels of blood markers of inflammation (erythrocyte sedimentation rate [ESR] and C-reactive protein [CRP]), a lot of patients with AS may have active disease with normal levels of inflammatory markers [4]. To further complicate the matter, even the most encountered serologic marker of AS, that is, HLA-B27, is absent in up to 30% of patients [5, 6], while its prevalence in the general population is around 6–10% [5]; furthermore, only about 10% of individuals having positive HLA-B27 will ever develop AS [7]. Remember, all this information is long time known.

Now, bearing in mind all of this, it is quite conceivable that, to this day, in the absence of a set of diagnostic criteria, we still use the "modified New York classification criteria" to help us diagnose ankylosing spondylitis. These criteria are depicted in **Table 1** [modified from 8].

We very well know that the most prominent clinical feature of AS is inflammatory back pain [3]. Unfortunately, as knowledge evolved, we realized that the pathogenic process of AS starts long before the clinical diagnosis is established, so there is a consistent diagnostic gap, between the occurrence of the inflammatory back pain and the moment the patient receives the diagnosis of AS. This is, at least partially, due to the radiological criterion in the modified New York criteria. And that is because of the definitions of the different grades of sacroiliitis. They are defined in **Table 2** (modified from [3]). As one can see, looking at those definitions, it is quite difficult to make a clear-cut difference between the different grades of sacroiliitis, but especially between grade 2 and grade 1 or 3. This is mainly due to the particular spatial orientation of the sacroiliac joint, which is oblique. That "special" orientation precludes a good visualization of the entire sacroiliac joint on a standard posteroanterior radiograph of the pelvis [3]. In trying to overcome this issue, one may use the Ferguson view, which consists of the rotation of the pelvis 30 degrees, thus getting the sacroiliac joint perpendicular into the way of the X-ray beam [9].

Another way to try to overcome the problem of the sacroiliac joint spatial orientation is to perform X-ray examination on each sacroiliac joint at a time [10]. Let alone

1. Radiological criterion

   Bilateral sacroiliitis grade at least II or unilateral sacroiliitis grade III or IV

2. Clinical criteria

   a. Low back pain associated to stiffness of at least 3 months duration that is improved by exercise and is not relieved by rest

   b. Limitation of range of motion of the lumbar spine both in the sagittal and the frontal plane

   c. Limitation of chest expansion relative to values normal for age and gender

Definite AS is diagnosed if the radiological criterion plus two of the three clinical criteria are present in the patient.

Table 1.
Modified New York classification criteria for ankylosing spondylitis.

Grade	Definition
0	Normal
1	Suspiciously abnormal
2	Subchondral bone sclerosis, possible some erosions
3	Pseudo enlargement of the joint space, severe erosions
4	Complete ankylosis

Table 2.
Radiographic grading of sacroiliitis.

that there is no evidence that this kind of approach is superior to the standard pelvic X-ray approach [10], performing the standard radiograph of the pelvis may add some important clues to the diagnosis of AS: it captures the last lumbar vertebrae, allowing to search for the "vertebral squaring" sign (consequence of the vertebral osseous inflammation) [11] and it, also, captures the coxo-femural joints, allowing to visualize their frequent involvement in AS [3].

Regardless of these considerations, using the modified New York classification criteria for making a diagnosis of AS will be totally useless for early AS, since it takes a lot of time (sometimes as long as 10 years) for the aforementioned findings to become apparent on an X-ray [12, 13]. This is of great concern, because, by the time the sacroiliac joints radiograph exhibits bilateral grade II sacroiliitis, the spine (as well as other joints) of the patient may be already fused, not to mention the possible occurrence during that time, of extra-articular manifestations of the disease, a situation that makes treatment much more difficult.

This has led to the use of other imaging techniques to try to visualize more early the pathological processes involved in AS. Thus, computed tomography (CT) and magnetic resonance imaging (MRI) were tried to image AS, and it was found that CT is superior to MRI when it comes to visualize the chronic bony changes [10]. On the other hand, MRI is a technique that allows the visualization of both chronic (structural) lesions and acute (inflammatory) ones. Now we know that the way to imaging bone marrow edema (that is, osseous inflammation in its most active form), which is the most suggestive pathological imaging finding for ankylosing spondylitis, is by using MRI [14]. Moreover, MRI is capable of visualizing early changes at the level of the cartilage as well [15] and does not expose the patient to radiation Thus, the use of MRI helped defining the two subsets of axial spondylarthritis (ax SpA):

non-radiographic ax SpA (that is, the axial spondylarthritis that does not fulfill the radiographic criterion of the modified New York criteria) and radiographic ax SpA (that is, the axial spondylarthritis that does fulfill the radiographic criterion of the modified New York criteria, which is in fact AS). These two subsets are considered two stages of the same disease [15].

3.2 ASAS classification criteria

The evidence that the modified New York criteria fail to detect early AS and that MRI helps visualize early bone marrow edema led to the development of a new set of criteria: the ASAS classification criteria. They were developed and published in 2009, by the Assessment of SpondyloArthritis international Society (ASAS) group [16]. You can view those to be used for axial spondylarthritis in **Figure 1**.

Remember, this is a set of classification, not diagnostic criteria, even though both diagnosis and classification processes operate with the same set of parameters [15].

The most important first thing that one should consider when applying criteria is to know the population to which they are applicable. In this respect, the ASAS classification criteria for ax SpA should be used only in patients with back pain of at least 3 months duration, which started before the age of 45. Why is that? On the one hand, because AS is a disease that starts, in most cases, in the third or fourth decade of life [15] and, on the other hand, because 45 years of age is a good milestone to consider when considering a diagnosis of AS, in the primary care setting [17]. In most cases, the back pain will be low back pain, but some patients will have other localization of the back pain. Some characteristics of the pain will make it more susceptible to be an inflammatory pain, and this, in turn, will raise the probability of the patient having ax SpA, to around 30% based only on no other clinical feature than pain [18].

There have been multiple proposals for items that would enable a doctor to classify back pain as inflammatory back pain; historically, the oldest set of criteria (1977) is that of Calin et al. [19], who upon studying 42 patients with AS and 21 with mechanical low back pain, concluded that a patient fulfilling four of the following: age at onset lower than 40 years, duration of back pain more than 3 months,

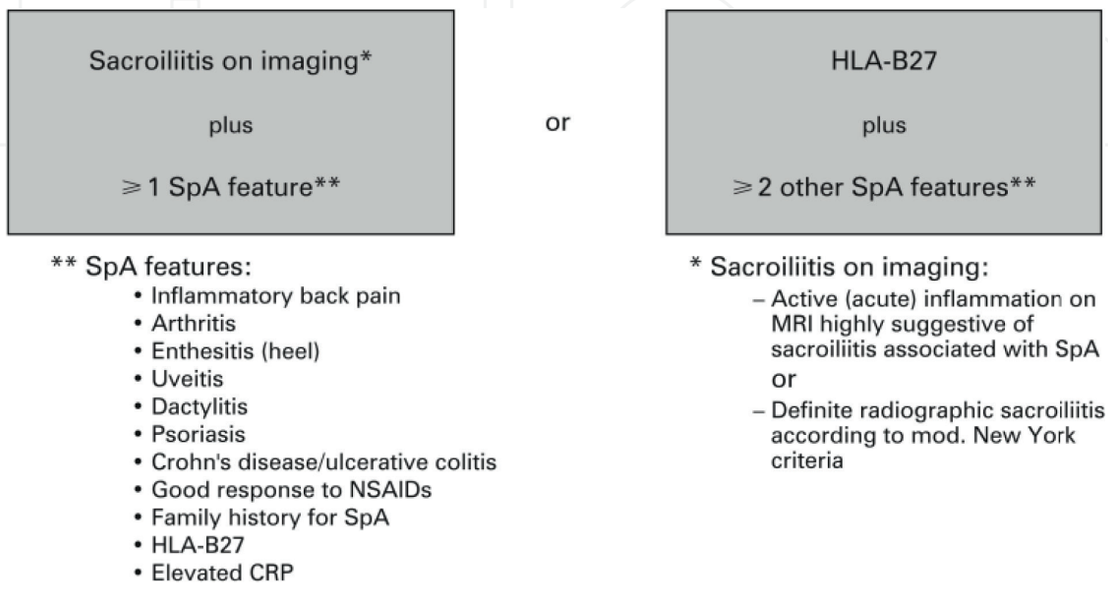

Figure 1.
ASAS classification criteria for axial spondyloarthritis [16].

insidious onset, morning stiffness and improvement with exercise can be classified as having inflammatory back pain. Then, we had the modified Berlin criteria for inflammatory back pain proposed by Rudwaleit et al. [20], who, based on the study of 101 AS patients and 112 patients with mechanical back pain, stated that inflammatory back pain may be assumed in a patient with chronic back pain with onset before the age of 45 if the patient has two of the following: morning stiffness more than 30 minute, improvement of the pain with exercise and not with rest, alternating buttock pain or awakening at second part of night because of the pain. Finally, in 2009, Sieper et al. [21] published the ASAS criteria for inflammatory back pain, which encompass the following items: age of onset of the pain less than 40 years, an insidious onset, the improvement of the pain with exercise and no improvement with rest and the existence of pain at night, with improvement upon getting up. Based on evaluating 648 patients with chronic back pain, if four out of the five aforementioned items are present, then the patient has inflammatory back pain with a sensitivity of 79.6% and a specificity of 72.4% [21]. These values might seem small, but they enable a physician to ascertain a patient as having inflammatory back pain as a first step to take on the road to establishing a correct diagnosis of radiographic ax SpA.

After properly selecting the population on which to apply the criteria, physicians have two alternative pathways to take ("arms") to classify patients as ax SpA (radiographic or non-radiographic): the "imaging arm" and the "HLA arm."

If the patient has sacroiliitis on imaging, then the doctor needs only one additional SpA feature to classify the patient. Noteworthy, it does not matter what imaging method we use; it could be either MRI showing acute active inflammation highly suggestive of sacroiliitis (in this case, we are talking about non-radiographic SpA) or an X-ray showing definite radiographic sacroiliitis according to modified New York criteria (in which case we are talking about radiographic SpA or AS) [16].

If no imaging technique is available, one can use the "HLA" arm: one should look for the presence of HLA-B27 positivity in their patient and, if so, seek for at least two more SpA features. The SpA features considered (**Table 3**) are either clinical and laboratory signs of skeletal or extra-skeletal inflammatory involvement (inflammatory back pain, arthritis, enthesitis, dactylitis, uveitis, psoriasis, Chron's colitis, good response to NSAIDs, elevated CRP) or familial history and B27 positivity [16].

It is noteworthy that peripheral involvement, extra-articular involvement, as well as response to medication, are incorporated in the axial SpA criteria, thus emphasizing on the importance of exploring all these characteristics of the disease, since they are all relevant for the diagnosis as well as for the classification of these patients. Just for example, the specificity of heel enthesitis for ax SpA is around 90% and that of dactylitis around 96% [15]. When it comes to extra-articular manifestations of SpA, the most frequent (around 20%) and potentially extremely damaging is acute anterior uveitis, followed by psoriasis (around 10%) and inflammatory bowel disease (2–7%) [15].

The ASAS classification criteria, all together, have a specificity of 84.4% and a sensitivity of 82.9% [16], which is quite good. When using the imaging criteria alone, the sensibility falls to 66.2%, but the specificity rises to 97.3% [16], which means that if the imaging criteria are negative, we might miss a few patients, but if they are positive, we are (almost) certain that we are doing the right classification for a particular patient. Moreover, this very high specificity of this set of criteria provides great confidence for the practitioner who finds them positive, even in the diagnosis making process, not only in the classification process.

Inflammatory back pain
Arthritis
Enthesitis
Dactylitis
Uveitis
Psoriasis
Crohn's disease/ulcerative colitis
Good response to NSAID's
HLA B27
Family history
Elevated CRP

Table 3.
SpA features (modified from [16]).

The development of the ASAS classification criteria for axial SpA really represented a major step forward, first because of their potential to correctly discover patients in an early stage of their disease. Since the primarily objective of any treatment for rheumatic inflammatory diseases is avoidance of structural damage, and this can be done only if we "intercept" the patient's disease as early as possible (that is, before the disease has already produced its deleterious effects), having a way to identify patients in that early stage of their disease is crucial to the successfulness of any therapy. Moreover, even if their specificity and sensibility are not 100%, the development of the ASAS classification criteria really stimulated research in the field of spondyloarthropathies, which in turn allowed medicine to better understand the pathogenesis, course, and prognosis of that group of diseases [22].

3.3 Making the diagnosis of ankylosing spondylitis

Even if, as mentioned above, the use the same set of parameters [15] and, even though this does not always happen in clinical daily practice, the diagnostic approach of ankylosing spondylitis should be different from the classification approach, because of several reasons [15].

First of all, the aim of the two processes is different: while classification aims at defining as homogeneous as possible population, for research purposes, diagnosing is establishing what is the disease that the patient presents, in daily routine practice [15].

Then, when making a diagnosis (and not only for ankylosing spondylitis), we always take into consideration a differential, which is not the case when classifying a patient [15]. The whole process of diagnosing a patient relies on many different tests that have a pre-test probability and a positive and negative likelihood ratio; their values vary depending on several factors (the test itself, background populations, etc.). This does not happen with the classification process, which uses only those tests that are part of the classification items and only with the "present" or "absent" value (since the whole classification process depends on the presence or absence of the criteria). This "yes" or "no" approach is also valuable for the outcome of the classification approach, and that is different from the outcome of the diagnostic assessment that has as outcome the probability of the presence of disease [15].

To summarize, when we make the diagnosis of ankylosing spondylitis, we should use the classification items just to remember which are the disease characteristics that we find most often in such patients and not to confirm or exclude disease. In other words, if a practitioner tries to diagnose a patient's disease, the fact that the patient does not fulfill the classification criteria for AS does not mean that the patient does not have AS. If the practitioner finds enough reasons to diagnose the patient as having AS, even if the patient cannot be classified as having AS, then, the patient has AS and the practitioner will be able to sustain his opinion to anyone. It is just like such a patient will be in the group that does have AS, but not have all of the most common characteristics of AS.

So, the two processes, the two approaches are completely different and should be used accordingly in the care of patients with AS.

4. Use of diagnostic/classification criteria in ankylosing spondylitis

In the absence of diagnostic criteria for ankylosing spondylitis, the diagnostic approach toward a patient's disease is sometimes difficult and complicated. Thus, to make their life easier, it would seem quite normal and at hand for doctors to use the classification criteria for diagnosis as well, even though, as pointed out earlier, this is not conceptually correct or appropriate. Being aware of that "psychological flaw," it is very interesting to try and find out what is the situation in the real-life setting: what is the attitude of practitioners around the world toward using the existing classification criteria (modified New York and ASAS)?!

To answer this question, Rich-Garg and coworkers [23] designed and carried out a study among rheumatologists in five countries on four continents. There were 478 rheumatologists that participated in this survey regarding multiple aspects of the modified New York criteria for AS and ASAS criteria for ax SpA and their use. The mean age of participants was around 50 so, on an average, they were quite experienced rheumatologists, and 31% were females; 90% of respondents declared spending more than 75% of their time in clinical practice [23].

The survey showed that two-thirds of the responding rheumatologists "usually or always" use the ASAS classification criteria to make the diagnosis of ax SpA [23]. This is somehow expected (because using the criteria, sometimes "makes life easier") and somehow unexpected (because one would expect that experienced rheumatologists would use the criteria just "sometimes"). Anyway, using the criteria for diagnosis, in real-life daily clinical practice, can lead to over-diagnosis [24], which in turn can lead to over-treatment, which can have potentially negative consequences. Another important finding resulting from this survey is the fact that doctors having completed rheumatology training more recently were more likely to use the classification criteria for diagnostic purposes [23]! This highlights the need for reinforcing the difference between diagnostic and classification approach to rheumatologists in training, who should be able, by the time they complete their specialty training, to use them appropriately.

Another interesting finding of the aforementioned study [23] is the perception of the specificity for diagnosing ax SpA, of the various SpA features. Inflammatory back pain, a totally subjective finding, which is the cornerstone for using the classification criteria, was thought very specific for ax SpA diagnosis by 44% of rheumatologists [23]. In contrast with this, the quite objective items such as enthesitis and peripheral inflammatory arthritis were thought very specific for ax SpA diagnosis by just 39%

and 25% of respondents, respectively [23]. Bearing in mind that the actual specificity of heel enthesitis is around 90% [15], this finding of the survey is rather surprising and might point to the fact that many rheumatologists are not aware of the real importance of enthesitis in the diagnosis of ax SpA; this may also have to do with the fact that, in the classification criteria, the various items do not differ in specific importance.

When exploring the use of imaging in the real-life diagnosing approach by rheumatologists, the survey [23] found that the majority of respondents use the X-ray of the sacroiliac joints as the initial imaging assessment modality [23]. This was to be expected since the access to radiology services is more widespread than that to other imaging modalities. On the other hand, the use of the X-ray assessment of sacroiliac joints might occasionally lose some patients, because there is a wide temporal gap between the first symptom of AS and the first abnormality found on the X-ray assessment. This might also be one of the explanations of the fact that the majority of rheumatologists rely on themselves to interpret the X-rays [23]. As was to be expected, if the radiographic examination of the sacroiliac joints is normal, most rheumatologists rather order a magnetic resonance imaging study than a computed tomography study [23], to view the potentially existing inflammatory lesions. This approach was to be expected since computed tomography, on the one hand, bears the burden of irradiation and, on the other hand, is not as sensitive for edema as magnetic resonance imaging.

5. Conclusions

Diagnostic criteria and classification criteria are not at all the same thing; they differ conceptually, even if they operate with the same set of items. Their differences make the use of ones instead of the others, totally inappropriate. Moreover, using classification criteria for diagnosing purposes could lead to over-diagnosis, which in turn may have negative consequences. On the other hand, knowing the classification criteria may help and ease the diagnostic process, since they represent the most frequently encountered characteristics of the disease. In daily clinical practice, a great number of rheumatologists use classification criteria for the diagnosis of ankylosing spondylitis and axial spondyloarthritis.

Conflict of interest

The authors declare no conflict of interest.

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