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New MS Diagnostic Criteria Will Allow Earlier Diagnosis

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PARIS — New proposed revisions to the McDonald diagnostic criteria for multiple sclerosis (MS) should enable the disease to be diagnosed earlier in many patients, the authors say.

The updated criteria include the presence of oligoclonal bands in the cerebrospinal fluid (CSF) in patients with a first symptom, as an alternative to waiting for additional symptoms or lesions to present, and the allowance of symptomatic as well as asymptomatic lesions to be considered for the diagnosis of MS.

The McDonald diagnostic criteria were last updated in 2010. The new update was formulated by a 30-member expert panel that reviewed the latest data, was organized under the auspices of the International Advisory Committee on Clinical Trials in MS, and was funded by the US National MS Society and ECTRIMS.

Presenting the update at this week's 7th Joint European Committee for Treatment and Research in Multiple Sclerosis-Americas Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS-ACTRIMS) 2017, co-chair of the expert panel, Dr Jeffrey Cohen, Cleveland Clinic, Ohio, outlined the major changes as follows:

1. In a patient with a typical clinical isolated syndrome (CIS) and fulfilment of clinical or MRI criteria for "dissemination in space" and no better explanation for the clinical presentation, demonstration of CSF-specific oligoclonal bands allows an MS diagnosis to be made without the previously required "dissemination in time."

Dr Cohen explained that previously, a diagnosis of MS relied on symptoms or lesions being "disseminated in space and time" — meaning they need to be seen in different locations and at different times. With the new criteria, if patients have symptoms or lesions in more than one location that fulfill the dissemination-in-space requirement, they can be diagnosed with MS without waiting if they test positive for CSF oligoclonal bands. "CSF oligoclonal bands can now be viewed as substitution for the dissemination-in-time requirement," Dr Cohen said.

2. Both symptomatic and asymptomatic MRI lesions can be used for fulfilling MRI criteria for dissemination in space or dissemination in time.

This is a change from the 2010 criteria, under which the symptomatic lesion in a patient presenting with a brainstem or spinal cord CIS could not be included as MRI evidence of dissemination in space or time.

3. In addition to juxtacortical lesions, cortical lesions can also be used to demonstrate dissemination in space requirements.

This is also change to the 2010 criteria, which stipulated that cortical lesions could not be used to fulfill dissemination-in-space requirements. "This recognizes that our ability to detect cortical lesion is relatively limited," Dr Cohen said.

4. The requirements for the diagnosis of primary progressive MS have not changed, apart from the removal of the distinction between symptomatic and asymptomatic lesions and

that cortical lesions can be used.

5. At the time of diagnosis, a provisional disease course should be determined and periodically be re-evaluated on the basis of accumulating evidence.

Dr Cohen commented to *Medscape Medical News* that the new updated criteria may lead to an increase in MS cases being diagnosed, "but more importantly they will enable earlier diagnosis. Our goal was to accomplish that while reducing misdiagnosis."

"We want to stress, however, that neurologists should not robotically apply the criteria but rather rigorously synthesize all the clinical, imaging, and laboratory data," he said.

Jeremy Chataway, MA, PhD, FRCP, consultant neurologist, National Hospital for Neurology and Neurosurgery, London, United Kingdom, presented several examples of cases where the new criteria would have enabled earlier diagnosis of MS and the likely earlier initiation of treatment.

These included a 28-year-old man with one clinical attack and lesions in two different areas on MRI fulfilling the dissemination-in-space requirement. But the diagnosis of MS took another 2 years until new symptoms appeared. "Now, under the updated criteria this patient could be diagnosed with definite MS at the time of first presentation as there were positive CSF oligoclonal bands. This would have advanced the diagnosis by 2 years," Dr Chataway said.

Another case involved a patient with a progressive spinal cord situation over 18 months, with imaging showing a cranial lesion and two areas in the spinal cord. No CSF was available. Under the 2010 criteria, an MS diagnosis would not have been made as the spinal cord lesions would have been considered symptomatic. But with the updated 2017 criteria, the diagnosis could be made as the spinal cord lesions can be included whether symptomatic or asymptomatic, Dr Chataway explained, adding that "sometimes it's obvious but sometimes it hard to know if a lesion is symptomatic."

Dr Cohen reported that the new update was motivated by new data on MRI and CSF markers and other paraclinical tests; the relationship with other diseases with overlapping features, such as neuromyelitis optica spectrum disorder (NMOSD); challenges in making the diagnosis in patients with nonclinical presentations (ie, radiologic isolated syndrome); and the frequency and consequences of misdiagnosis.

"The main aims of the update were not to make major changes but to simply clarify components of the 2010 criteria, facilitating earlier diagnosis when MS is likely and reducing misdiagnosis."

Distinguishing MS From NMOSD

Dr Cohen noted that substantial new data on NMOSD have been published since 2010 and that the 2015 International Panel for NMO diagnostic criteria largely distinguish MS and NMOSD, although uncertain cases still occur.

The new criteria state that NMOSD should be considered in all cases being evaluated for MS and that serologic testing for *aquaporin - 4 (*a highly specific marker for NMO) and when available myelin oligodendrocyte glycoprotein (MOG) should be performed in all patients with features suggesting NMOSD and considered in groups at high risk for NMOSD. However, Dr Cohen added that the diagnostic utility of MOG antibodies still is uncertain.

He stressed that it was important to remember that the McDonald criteria were developed to identify a high likelihood of MS in patients with typical CIS, not to differentiate MS from other conditions. "Integration of the history, imaging, and laboratory evidence by a clinician with MS-related expertise remains fundamental in making a reliable diagnosis of MS or an alternative condition."

He added: "Besides merely confirming dissemination in space and dissemination in time, diagnostic rigor in the interpretation of clinical data and test results is necessary in the absence of a clear-cut typical CIS. Considerations that may help avoid misdiagnosis of MS include caution on accepting historical events lacking objective corroboration, confirmation of the diagnosis with additional clinical and radiological follow-up, and possible postponement of the diagnosis or institution of therapy to accumulate additional evidence."

The update also notes that there should be a low threshold for spinal cord MRI and/or CSF examination if there is insufficient clinical and brain MRI evidence supporting MS, a nonclassical presentation (including progression from onset), or atypical features, as well as in populations where MS is uncommon.

Dr Cohen said the 2017 update document "was in the final stages of revision and has been submitted for publication."

Dr Cohen has received personal compensation for consulting for Adamas and Celgene and as a coeditor of Multiple Sclerosis Journal — Experimental, Translational and Clinical.

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