McDonald Criteria Revisions Signal Shift Toward MS as a Biologically Based Disease

— Some cases of radiologically isolated syndrome will be considered multiple sclerosis

by Judy George, Deputy Managing Editor, MedPage Today
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An upcoming revised version of the McDonald diagnostic criteria for multiple sclerosis (MS) will include new MS biomarkers, a panel of experts said.

The revisions signal a shift toward looking at MS more as a biologically based disease, noted Xavier Montalban, MD, PhD, of Vall d'Hebron University Hospital in Barcelona, who presented a draft of the new criteria at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) annual meeting in Copenhagen.

The proposed changes from the Advisory Committee on Clinical Trials in Multiple Sclerosis represent the first meaningful revision to the criteria since 2017. They include changes to help MS patients get diagnosed earlier and biomarkers to help increase the specificity of an MS diagnosis.

Faster MS Diagnosis

The revised criteria will allow diagnosing MS in asymptomatic individuals -- specifically, those who previously were classified as having radiologically isolated syndrome (RIS).

People with RIS have MRI lesions suggestive of MS, but no clinical symptoms. "Some RIS, in some specific situations, will be considered multiple sclerosis," Montalban said. "This means we are moving toward a biological diagnosis, and this is happening as well in other neurodegenerative conditions such as Alzheimer's or Parkinson's disease."

Optic neuritis often is the first manifestation of disease in patients with clinically isolated syndrome, Montalban noted. Involvement of the optic nerve -- assessed by MRI, visual evoked potential, or optical coherence tomography -- now can be considered a fifth anatomical location in diagnosing MS if there's no better explanation for optic nerve

Dissemination in time will also no longer be needed to diagnose MS, though it can be helpful, and criteria for dissemination in space will be updated, he continued. Intrathecal kappa free light chain can be measured quickly; it has diagnostic properties similar to oligoclonal bands and can be used to diagnose MS.

"The biggest change is the fact that you can now make a diagnosis of multiple sclerosis in individuals who do not have symptoms [patients with RIS]," noted Daniel Ontaneda, MD, PhD, of the Mellen Center for Multiple Sclerosis at the Cleveland Clinic in Ohio. "That is a big change. It is going to open the umbrella up to who can be diagnosed with MS in a very substantial way," he told *MedPage Today*.

"Previously, to make a diagnosis of MS, you had to demonstrate dissemination in time and dissemination in space," Ontaneda added. "Now, having a second clinical attack is no longer really required. That's a philosophical change -- that dissemination in time no longer is a construct that is required for a diagnosis of MS."

Increasing Diagnostic Specificity

An MS diagnosis needs to include paraclinical evidence and should be considered only after ruling out a better explanation, Montalban said. "We don't want to make mistakes in the differential diagnosis," he emphasized. An abnormal MRI showing typical lesions is required to make a diagnosis of MS.

In certain situations, MRI could include the central vein sign or paramagnetic rim lesions (PRLs). While neither is required for diagnosis, these imaging markers can increase diagnostic specificity, Montalban pointed out. For example, in patients with typical symptoms and typical lesions in one topography, the presence of one or more PRL, plus dissemination in time or positive cerebrospinal fluid (CSF), is sufficient to diagnose MS, he noted.

Additional features should be used to confirm diagnoses in adults older than 50 years, or those with headache disorders or vascular disorders, Montalban said. These additional features could include a spinal cord lesion, positive CSF, or the central vein sign.

Myelin oligodendrocyte glycoprotein-immunoglobulin G tests are strongly recommended for children and adolescents. In patients younger than 18 years, the presence of the central vein sign in about 50% of T2 lesions strongly suggests MS.

Diagnostic criteria for relapsing MS and primary progressive MS (PPMS) will be similar, with PPMS requiring evidence of clinical progression over at least 12 months, Montalban added. "A single, unified framework should be used to diagnose relapsing and primary progressive MS," he said.

A new paper outlining the revised criteria and a diagnostic algorithm are the next steps, as is consultation with the wider MS community, Montalban said. Additional papers will discuss how to implement the criteria and both global and patient factors.

Judy George covers neurology and neuroscience news for MedPage Today, writing about brain aging, Alzheimer's, dementia, MS, rare diseases, epilepsy, autism, headache, stroke, Parkinson's, ALS, concussion, CTE, sleep, pain, and more. Follow

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Disclosures

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Montalban reported relationships through his university with AbbVie, Actelion, Alexion, Bial PD, Biogen, Bristol Myers Squibb, EMD Serono, Genzyme, Hoffmann-La Roche, Immunic Therapeutics, Janssen Pharmaceuticals, MedDay, Merck, Mylan, NervGen, Neuraxpharm, Novartis, PeerVoice, Samsung-Bioepis, Sandoz, Sanofi-Genzyme, Teva Pharmaceuticals, TG Therapeutics, Excellence in Medical Education, ECTRIMS, the MS International Federation, and the National MS Society.

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