

New classification criteria released for research on Sjogren's Syndrome

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An international team of researchers released new classification criteria for the common autoimmune condition Sjogren's syndrome. Classification criteria are the consensus opinion of a group of experts that researchers use in clinical studies to confirm a previous diagnosis and/or subclassify patients who have the same type of a given condition. The new guidelines appear in the April issue of the journal *Arthritis Care & Research*.

The classification criteria are the first for Sjogren's syndrome to be based solely on objective clinical tests. Other criteria historically have permitted various testing subjectivity to enable the classification of this notoriously complex syndrome that affects multiple parts of the body, typically the eyes, salivary glands, and joints. The subjectivity has made standardization of clinical trial enrollment something of a moving target, limiting comparability of research data across studies and impeding the needed robust clinical evaluation of possible new treatments.

The new criteria come from the Sjogren's International Collaborative Clinical Alliance, or SICCA. The work was supported by the National Institute of Dental and Craniofacial Research (NIDCR), with support from the National Eye Institute and the Office for Research on Women's Health. All are part of the National Institutes of Health.

Importantly, the American College of Rheumatology (ACR) voted to accept the SICCA criteria. This marks the first time that ACR has approved classification criteria for Sjogren's syndrome and, in doing so, recognized the need for rheumatologists, ophthalmologists, and oral medicine practitioners to collaborate in research studies to diagnose the condition.

"The next step will be to present our criteria to representatives of the European League Against Rheumatism, EULAR, the European equivalent of

ACR, with a goal of achieving a single international standard," said Caroline Shiboski, D.D.S, Ph.D., a professor at the University of California at San Francisco (UCSF) School of Dentistry and Medicine and a co-lead author on the study.

Founded in 2003, the SICCA alliance is an integrated research network that spans seven countries (Argentina, China, Denmark, India, Japan, United Kingdom, and United States). By sharing their scientific resources, the researchers assembled the first large international Sjogren's syndrome patient registry, a major step forward in studying this condition. The SICCA alliance was launched by Troy Daniels, D.D.S., and John Greenspan, Ph.D., and is now co-directed by Caroline Shiboski and Lindsey Criswell, M.D., M.P.H. All are affiliated with the UCSF School of Dentistry and Medicine.

In the SICCA study, an international expert panel of ophthalmologists, rheumatologists, and oral medicine/pathology specialists began by compiling a consensus list of existing diagnostic tests to assess the various components of Sjogren's syndrome (oral, ocular, and systemic). Using the various tests, the researchers performed comprehensive clinical evaluations on nearly 1,400 participants enrolled in the SICCA Registry. All had possible signs and/or symptoms of Sjogren's syndrome that are typical of those of patients seen in a clinical practice, and were drawn from ethnically diverse patient populations worldwide.

Combining the expert consensus and data collected from study participants, the SICCA scientists developed a set of preliminary classification criteria for Sjogren's syndrome. These criteria were then validated using novel statistical methods and comparisons with existing classification approaches, most notably the American-European Consensus Group (AECG) criteria. Published in 2002, the AECG criteria are currently the most frequently cited in Sjogren's

syndrome studies.

Based on this intensive process, the new SICCA classification criteria emerged. They stipulate that to be classified with Sjogren's syndrome, research participants must be positive for at least two of three objective diagnostic tests:

-- Anti-SS-A/B blood test: There are two scenarios:

1) Positive serum levels of either the SSA and/or SSB antibody and/or 2) positive serum levels of the rheumatoid factor antibody (RA) and elevated antinuclear antibody (ANA) titers. All are associated with the syndrome.

-- Ocular surface staining: Measures the dissipation rate of a specialized dye that is applied to the tear film that bathes the surface of the eye. A score of three or more is considered to be positive.

-- Salivary gland biopsy: A pathologist examines the biopsy for sites of inflammation. One or more sites of inflammation per four millimeters squared area is considered positive.

"Uniform classification criteria based on objective tests are important to help ensure that participants in clinical studies and treatment trials on Sjogren's syndrome are correctly classified as having the disease," said Caroline Shiboski. "This is especially important with respect to treatment trials to avoid exposing individuals to new investigational drugs and any potential toxicity if they don't have Sjogren's syndrome."

The SICCA analyses also reinforced that the subjective may not always be as informative as it at first seems. "Dry mouth and eyes long have been associated with Sjogren's syndrome," said Dr. Troy Daniels, a senior author on the paper. "But our data showed that although patients may complain of dry mouth and eyes, these symptoms lack a statistically significant association with positive antibodies, ocular staining, and/or salivary biopsy. This shows the tremendous complexity of Sjogren's syndrome and the true value of assembling more objective classification criteria moving forward."

Stephen Shiboski, Ph.D., the first author on the classification paper, and a professor of biostatistics

at the UCSF School of Medicine, noted that the comparisons of the SICCA and AECG criteria were particularly interesting. "When the AECG criteria are employed in their strictest form, they agree quite closely with the new ACR criteria," he said. "However, because the AECG criteria can be applied in multiple ways, their application is more subjective and may result in a higher risk of misclassification."

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