Scleroderma dramatically under-diagnosed with commercial screening method

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New research from Georgetown University Medical Center (GUMC) suggests that up to 40 percent of scleroderma patients will not be correctly diagnosed with the disorder using a new automated commercial screening test. The findings of the study will be presented Wednesday, November 10th at the Annual Scientific Meeting of the American College of Rheumatology in Atlanta, Georgia.

The American College of Rheumatology recommends immunofluorescence antinuclear antibody (IF-ANA) testing to help detect the presence of scleroderma specific antinuclear antibodies. Finding the antibodies is a helpful predictor of disease manifestations, clinical course and outcome in scleroderma. However, many commercial labs have recently adopted a newer, automated method that use non-immunofluorescence antinuclear antibody testing. This test is known as NEW ANA.

To test the accuracy of the commercial method for detecting scleroderma antibodies, GUMC researchers evaluated the all test results performed through commercial laboratories of more than 200 scleroderma patients treated in the Georgetown scleroderma clinic between June 2008 and June 2009.

Test results using NEW ANA were available in 58 scleroderma patients. Twenty-eight patients (48 percent) tested negative. Of these 28 patients, 22 had either positive results using IF-ANA or one of the scleroderma specific antibodies. "The NEW ANA testing, that is the ANA test

without immunofluorescence, failed to identify patients with a particular subset of scleroderma specific antinuclear antibodies and other patterns that are picked up with IF ANA testing. This finding was significant," says Victoria K Shanmugam, MBBS, MRCP, assistant professor in the Division of Rheumatology, Immunology and Allergy who presented the findings.

NEW ANA test results were not available for the remaining 183 scleroderma patients. IF ANA testing was conducted in these patients and the positive antibody results were divided by subtypes.

"Given what we know about the subsets that are not detected by the NEW ANA testing, it appears that as many as 40 percent of the scleroderma patients would have tested negative using the new commercial testing method," Shanmugam says. "If a clinician has clinical suspicion for scleroderma, they should order the immunofluorescent ANA."

Provided by Georgetown University Medical Center