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Limited access to SLE lab tests in developing nations affects usefulness

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According to new research findings presented this week at the 2019 ACR/ARP Annual Meeting, supportive laboratory assays to diagnose lupus, specifically the antinuclear antibody (ANA) test, are less often offered in developing nations due to a relative lack of resources. This greatly reduced the diagnostic utility of ANA as an entry criterion for lupus classification in Ghanaian and Nigerian cohorts compared to African American cohorts in the United States. This emphasizes an urgent need for broader clinical trials and ANA testing to participants in developing countries (Abstract #705).

Systemic lupus erythematosus, referred to as SLE or lupus, is a chronic (long-term) disease that causes systemic inflammation which affects multiple organs and can be deadly. In addition to affecting the skin and joints, it can affect other organs in the body such as the kidneys, brain, the tissue lining the lungs (pleura) and/or heart (pericardium). Many patients experience fatigue, weight loss, and fever.

Diagnostic criteria for SLE are important to generate reliable epidemiologic data. Prevalence of SLE in West Africa is falsely low because of barriers to accurate diagnostic testing, including lack of resources and the labor-intensive nature of these tests. The newly developed 2019 ACR/EULAR SLE classification criteria tool may improve diagnostic sensitivity and specificity compared to the previously established ACR and SLICC criteria. This new study investigated the performance of each set of criteria in two West African lupus cohorts from Korle bu Teaching Hospital in Ghana and Lagos University

Teaching Hospital in Nigeria and compared it to an African American cohort at New York University/Langone Medical Center in New York City.

"African SLE patients throughout the diaspora are undertreated and understudied. This is in part due to the tendency for these individuals to hail from resource-limited areas of the world. In vetting diagnostic criteria, it is important to consider how more sophisticated testing may exacerbate existing disparities in diagnosis, treatment, and research," says Ashira D. Blazer, MD, MSCI, assistant professor of medicine, Division of Rheumatology, at New York University Langone Medical Center and the study's lead author. "Lack of widely available testing for ANA, the entry criterion to classify SLE using the 2019 ACR/EULAR classification criteria, throughout sub-Saharan Africa could impact SLE clinical care and slow down research", she adds. "We aimed to test the diagnostic efficiencies of each criteria in the USA compared to two low- or middle-income countries."

The researchers collected data on 355 patients with SLE for the study, including 151 African American patients in the United States, 110 patients in Ghana and 94 patients in Nigeria. All were diagnosed with lupus by expert clinicians. They gathered clinical information including demographics, SLE criteria, SLEDAI scores, SLICC damage indexes, vital signs and laboratory values that were available at the initial patient encounter. Longitudinal data was collected, at six-month intervals, over the course of at least one year during routine clinical visits. When necessary, the researchers also retrospectively reviewed clinical charts. They calculated the proportion of patients in each of the three cohorts who met each of the systems for classifying patients with lupus: (1) ACR, (2) SLICC and the (3) 2019 ACR/EULAR Classification Criteria for SLE.

The African American cohort's demographics included an average age

of 43 years, 90 percent were women, mean SLE disease duration of 14.3 years; and 96 percent met the ACR criteria, 96 percent met the SLICC criteria and 95 percent met the ACR/EULAR criteria. In the Ghanaian cohort, the average age was 32 years, all were women, the mean SLE disease duration was 2.2 years; and 85 percent met the ACR criteria, 84 percent met the SLICC criteria and 62 percent met the ACR/EULAR criteria. In the Nigerian cohort, the average age was 35, 97 percent were women, the mean SLE disease duration was 4.4 years, and 90 percent met the ACR criteria, 87 percent met the SLICC criteria and 61 percent met the ACR/EULAR criteria.

Researchers found discrepancies in the data due largely to missing laboratory data, particularly immunologic and hematologic studies. While none of the African-American cohort were missing ANA test results, 26 percent of the Ghanaian cohort and 33 percent of the Nigerian cohort were missing ANA results. Compared to both the Ghanaian and Nigerian cohorts, the African-American cohort was more likely to meet ACR, SLICC and ACR/EULAR criteria. While the ANA entry criterion greatly diminished the diagnostic utility of the ACR/EULAR classification criteria in both the Ghanaian and Nigerian cohorts, the criteria's weighted point system performed better than either the ACR or SLICC criteria, with 96 percent of the African-American, 92 percent of the Ghanaian and 95 percent of the Nigerian cohorts earning a sufficient number of diagnostic points.

"The new clinical indices provided better diagnostic efficiency in the developing world than either the ACR or SLICC criteria. These findings were enlightening, and they solidified an important concept: that SLE is a clinical diagnosis first," says Dr. Blazer. "While research partnerships across the international economic divides might provide ANA testing, it is imperative that no new barriers be created for regional investigators who might struggle to disseminate data lacking the international community's required laboratory results."

More information: Study: A Tale of Three Cohorts: SLE Criteria in Developed vs Developing Countries

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