

Researchers uncover potential flaws in test for Lyme Disease

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A new microscopy technique (LM-method) developed to detect Lyme disease is unable to distinguish infected patients from healthy controls, yielding false-positive results that could lead doctors to over-diagnose a patient, according to new research published in the journal Infectious Diseases.

The new research follows up on a previous study suggesting that modified microscopy techniques (LM-method) could detect active cases of Lyme disease (caused by Borrelia bacteria) and Babesia (a tick-borne malaria-like parasite) in just one to two days. Despite considerable publicity and patient demand for this test in Norway, earlier studies did not include a control group and methods were not validated and ready for use in patients.

To investigate the reliability of the new test, Dr Audun Aase, from the Norwegian Institute of Public Health, and his colleagues collected blood samples both from people who had been suffering from Lyme disease-like symptoms for several years and previously tested positive for Borrelia and/or Babesia by the LM-method (21 people), and healthy controls with no known history of tick bites (41 people). The samples were then masked and analyzed in independent laboratories using a range of diagnostic tests including the LM-method, conventional microscopy, genetic fingerprint testing (PCR), and serology.

The results indicate that the new LM-method can trigger false positives, suggesting people have Lyme disease when they really don't. Using the



LM-method, 14 (66%) patient group blood samples and 35 (85%) control group samples were judged positive for Borrelia and/or Babesia. However, only one <u>sample</u> (5%) of the patient group and eight samples (20%) of the <u>control group</u> tested positive for Borrelia DNA by PCR. None of the samples were positive for Babesia DNA, and conventional microscopy did not identify Babesia in any of the samples.

In an accompanying editorial commentary, Dr Ram B. Dessau, an expert on infectious diseases and Senior Consultant at Slagelse Hospital, Slagelse, Denmark, writes, "I hope the study serves as a warning against non-validated microscopic procedures and helps prevent mismanagement of patients with chronic complaints, who are lured to seek improper diagnosis in the future."

Lyme disease is the most common tick-borne infection in Europe and North America, with 360,000 cases reported over the last 20 years in Europe alone. While most people who contract the Lyme disease recover quickly after antibiotic treatment, up to a fifth of patients report persistent symptoms years after they have been told standard tests are negative for the <u>disease</u>. Interest in new diagnostic tests is therefore high.

More information: Audun Aase et al. Validate or falsify: Lessons learned from a microscopy method claimed to be useful for detectingandorganisms in human blood, *Infectious Diseases* (2016). DOI: 10.3109/23744235,2016.1144931

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