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Rapid test shows 'solid performance' for diagnosing infection around joint implants

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The recently FDA-authorized alpha-defensin lateral flow test is a highly accurate, ten-minute test for diagnosis of periprosthetic joint infection (PJI)—a serious and costly complication of total joint replacement,

reports a study in *The Journal of Bone & Joint Surgery*.

The study shows "solid diagnostic performance" of the alpha-defensin lateral flow test, according to the report by Carl Deirmengian, MD, of The Rothman Orthopedic Institute, Wynnewood, Pa., and colleagues. The data led to US Food and Drug Administration authorization of the new test: The first rapid test for specifically designed and validated to aid in the diagnosis of PJI. The alpha-defensin test also represents the first diagnostic test specifically designed for use in orthopedics.

Lateral flow test enables faster, simpler diagnosis of PJI

Periprosthetic joint infection is a devastating complication of failed total hip or knee replacement, and one that can be challenging for orthopedic surgeons to diagnose. Accounting for 25 percent of total knee replacement failures and 16 percent of total hip replacement failures, PJI has a major impact on patients' lives and health-care costs.

Alpha defensins are peptides produced by the immune system specifically in response to an infection. The new test measures alpha-defensin levels in samples of synovial fluid from the joint. The new alpha-defensin lateral flow test is a simple test kit that provides results in 10 to 20 minutes. An alpha-defensin enzyme-linked immunosorbent assay (ELISA) is also available. With the ELISA, the sample must be sent to a laboratory, providing results in 24 to 48 hours.

Dr. Deirmengian and colleagues designed a formal study to evaluate the performance of the alpha-defensin lateral flow test in diagnosing PJI. The study included synovial fluid samples from 305 patients with knee (203 patients) or hip (102 patients) arthroplasties. Of these, 57 patients had PJI, based on expert review.

The alpha-defensin lateral flow test was highly accurate in distinguishing between patients with and without PJI. The sensitivity and specificity of the alpha-defensin lateral flow test was 94.3 percent and 94.5 percent, respectively, when excluding rare poor-quality synovial fluid samples that were composed of substantial blood (greater than 1M RBCs/μL). Including even the poor-quality samples, the test had a sensitivity of 89.5 percent and specificity of 94.8 percent.

Another important finding was that the diagnostic performance of the rapid lateral flow assay matched the accuracy of the laboratory-based test for alpha-defensin. Both tests demonstrated a diagnostic performance that closely matched the standard approach to PJI diagnosis, based on a combination of clinical findings and laboratory tests (Musculoskeletal Infection Society criteria).

"Our study enhances the literature by extending the evaluation of alpha defensin to a formal diagnostic trial, thus confirming the solid diagnostic performance demonstrated by previous studies using other methods," Dr. Deirmengian and co-authors write. They emphasize the need for further studies to compare different approaches to diagnosis in patients with suspected PJI.

More information: Carl Deirmengian, MD et al, Validation of the Alpha Defensin Lateral Flow Test for Periprosthetic Joint Infection, *The Journal of Bone and Joint Surgery*
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