Paper #56

Novel Immuno-Based Microbial ID Assays for Organism Detection in Synovial Fluid◊

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Introduction: New immuno-based synovial fluid Microbial I.D. (MID) assays, which directly detect microbial antigen similar to the antigen test for strep throat, have recently become commercially-available providing a result in <24 hours. The purpose of this study is to report on the diagnostic profile of this assay panel, and evaluate the utility of the test in the setting of culture-negative periprosthetic joint infection (PJI).

Methods: A panel of synovial fluid tests to detect Staphylococcus, Candida and Enterococcus spp. was evaluated prospectively for 866 synovial fluid samples using predetermined assay cutoffs. The alpha-defensin(AD) test and Culture (CX) were utilized to define synovial fluid samples as infected (AD+/CX+), not infected (AD-/CX-), and possible culture-negative PJI (AD+/CX-). Diagnostic performance of the assay was assessed.

Results: The MID panel was able to reliably confirm the synovial fluid culture results with 94.4% (95%CI: 86.4-98.5%; 68/72) sensitivity among samples that were culture-positive for Staphylococcus, Candida and Enterococcus spp. The MID panel had a very high specificity of 97.9% (95%CI: 96.4-98.9%; 557/569) with only 2.1% (12/569) false-positive results. Most interestingly, among a total of 634 culture-negative samples, the MID panel was positive among 29.2% (19/65; 95%CI: 18.6-41.8%) of samples that were AD(+), but only among 2.1% (12/569) of samples that were AD(-) (P<0.0001). This demonstrates the detection of organisms in the setting of culture-negative infection.

Conclusion: The MID assay panel, designed and validated to detect organisms in the setting of PJI, reliably confirmed synovial fluid samples that are culture-positive for Staphylococcus, Candida and Enterococcus spp. Most importantly, the MID panel detected an organism in 29.2% of apparent culture-negative PJIs, with only a 2.1% false-positive rate among aseptic samples. Considering that staphylococcal, candidal, and enterococcal organisms account for 65% of all PJIs, we believe that this new technology could have a very significant clinical impact.

◊ The FDA has not cleared the pharmaceuticals and/or medical devices listed here: Zimmer Biomet MID assay panels

Notes