Nationwide Diagnostic Performance of Synovial Fluid Microorganism Antigen Testing

Krista O'Shaughnessey Toler, Pearl Ravindra Paranjape[1], Alexander C McLaren, Brett Russell Levine[2], Alvin C Ong, Carl A Deirmengian[3]
[1]Zimmer Biomet, [2]Rush University Medical Center, [3]Lankenau Hospital

INTRODUCTION: The increasing recognition of culture-negative periprosthetic joint infection (PJI) has prompted the development of alternative methods to detect pathogens. An antigen immunoassay panel (AIP), similar to the rapid strep test for Strep throat, has become clinically available to identify staphylococcus, candida, and enterococcus in synovial fluid. Our initial experience and report on results of this assay are now augmented by a 4 -fold increase in samples, and availability of the 2018 ICM criteria for PJI. The purpose of this study was to determine 1) the sensitivity, specificity, and false positive rate for AIP, 2) The rate of AIP detection of microorganisms in the setting of culture-negative PJI, and 3) the diagnostic predictive values of AIP for ICM-defined PJI.

METHODS: 59,557 synovial fluid samples being tested for PJI, from 2,290 institutions across the USA, were analyzed in a centralized CLIA laboratory from 2017 to 2021. All samples underwent a complete set of synovial fluid tests, including CRP, alpha-defensin, WBCs, PMN%, culture, and AIP. Samples were classified as Aseptic- 43,619, Inconclusive- 4,323, or Infected- 11,615 by applying this data to the 2018 ICM definition of PJI.

RESULTS:

1) The AIP panel demonstrated a sensitivity of 93.6%, specificity of 98.7%, and false-positive rate of 1.25% in the detection of PJI caused by target organisms (staphylococcus, candida, and enterococcus). The sensitivity individually for staphylococcus, candida, or and enterococcus was 92.2%, 92.0%, and 97.7%, respectively.

2)The AIP detected microorganisms in 49.6% of 3,644 PJI samples that were culture-negative, versus 1.25% of 43,619 aseptic samples ($p<0.0001$).

3) The positive and negative predictive values of the AIP for the diagnosis of PJI were 93.8% and 92.9%.

DISCUSSION AND CONCLUSION: The synovial fluid AIP, as a method to detect the presence of a microorganism, yields good predictive value for PJI, exhibits a very low false-positive rate, and detects a microorganism in roughly half of all culture-negative PJI. With diagnostic performance comparable to other antigen tests commonly used in medicine, this synovial fluid immunoassay panel serves as an effective adjunct to traditional fluid culture, providing more timely pathogen detection (AIP: 6 hrs. vs. Culture: 7-14 days).