Prospective comparison of a commercial multiplex real-time polymerase chain reaction and an enzyme immunoassay with toxigenic culture in the diagnosis of Clostridium difficile-associated infections

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Abstract

Clostridium difficile infections (CDI) is a leading cause of nosocomial infections worldwide. The changes in the epidemiology of CDI during the past years, including the appearance of new epidemic strains of C. difficile that cause CDI episodes with increased severity, have led to the development of molecular methods with improved sensitivity and specificity. This study was designed to compare the performances of one antigen assay (Vidas, bioMérieux) and one molecular assay (GeneXpert, Cepheid). Fecal specimens from hospitalized patients (n = 230) suspected of having CDI were tested by both assays. Eleven specimens were positive and 202 were negative for both methods. After discrepant analysis by C. difficile toxigenic culture with broth enrichment and neutralization assay, the total numbers of stool specimens classified as positive and negative for toxigenic C. difficile were 23 (10%) and 206 (89.6%), respectively. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value for GeneXpert were 91.7%, 99%, 91.7%, and 99%, and for Vidas were 48%, 99%, 84.6%, and 94.5%, respectively. The sensitivity and PPV of polymerase chain reactoin GeneXpert assay far exceeded those of the EIA Vidas assay. The clinical characteristics of concordant and discrepant study patients were similar with the exception of the number of previous CDI episodes, which were higher in the concordant study patients; the clinical characteristics of both groups were similar. In conclusion, due to the appearance of more virulent strains of C. difficile during the last years that have produced dramatic changes in the epidemiology of C. difficile, we recommend that toxin enzyme immunoassays be replaced with rapid molecular-based tests for toxigenic C. difficile..

Keywords

Clostridium difficil, Toxigenic culture, Real-time PCR, EIA.