A PROSPECTIVE, MULTICENTER CLINICAL EVALUATION OF A RAPID DIAGNOSTIC TEST TO DETECT CLINICALLY SIGNIFICANT IMMUNE RESPONSES TO VIRAL AND BACTERIAL ACUTE RESPIRATORY INFECTIONS

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OBJECTIVE

To evaluate the performance of FebriDx, a point-of-care (POC) test with rapid measurement of myxovirus resistance protein A (MxA) and C-reactive protein (CRP) for the differentiation of viral and bacterial infection in patients with acute respiratory infections.

METHODS

A prospective, multicenter, blinded, observational clinical trial was conducted at 11 clinical emergency department and urgent care centers, both private and academic, across the United States from December 2013 through October 2014 to determine the clinical accuracy of a 15-minute, POC MxA and CRP immunoassay (FebriDx; RPS Diagnostics; Sarasota, FL).

The study enrolled 205 patients with acute febrile upper respiratory symptoms and 165 controls without symptoms of respiratory tract infection. FebriDx test results were compared to a final diagnosis derived from a panel of microbiologic and laboratory tests obtained as part of the study or during clinical care. Participants provided fingerstick blood for the FebriDx immunoassay testing. Participants also provided both oropharyngeal and nasopharyngeal samples for viral and atypical bacteria polymerase chain reaction (PCR) testing as well as routine bacterial cell culture. Additionally, a venous blood sample measured procalcitonin and white blood cell counts.

FINDINGS

Thirty eight percent (78/205) of febrile patients had a confirmed infection, 26% (53/205) viral and 12% (25/205) bacterial, while 62% (127/205) had a microbiologically unconfirmed respiratory illness (MURI). For detecting bacterial infection, the FebriDx test demonstrated 80% sensitivity and 94% specificity, with a positive predictive value (PPV) of 65% and negative predictive value (NPV) of 97%. For detecting viral infection, the FebriDx test demonstrated 87% sensitivity and 83% specificity, with a 64% PPV and 95% NPV.

CONCLUSIONS

Independently, neither MxA nor CRP alone is sensitive or specific at identifying both viral and bacterial infection but in combination, these biomarkers can aid in the diagnosis of acute respiratory infection. Global use of POC testing to rapidly distinguish between immune response to viral and bacterial infection may reduce antibiotic overuse, reduce antibiotic resistance, and lower healthcare costs.

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