UTILITY OF THE FEBRIDX® POINT-OF-CARE TEST FOR RAPID TRIAGE AND IDENTIFICATION OF POSSIBLE CORONAVIRUS DISEASE 2019 (COVID-19)

Karim N, et al.

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ABSTRACT

OBJECTIVES: The Coronavirus disease 2019 (COVID-19) pandemic is straining healthcare resources. Molecular testing turnaround time precludes having results at the point-of-care (POC) thereby exposing COVID-19/non-COVID-19 patients while awaiting diagnosis. We evaluated the utility of a triage strategy including FebriDx®, a 10-minute POC finger-stick blood test that differentiates viral from bacterial acute respiratory infection through detection of Myxovirus-resistance protein A (MxA) and C-reactive protein (CRP), to rapidly isolate viral cases requiring confirmatory testing.

METHODS: This observational, prospective, single-center study enrolled patients presenting to/within an acute care hospital in England with suspected COVID-19 between March and April 2020. Immunocompetent patients ≥ 16 years requiring hospitalisation with pneumonia or acute respiratory distress syndrome or influenza-like illness (fever and ≥ 1 respiratory symptom within 7 days of enrolment, or inpatients with new respiratory symptoms, fever of unknown cause or pre-existing respiratory condition worsening). The primary endpoint was diagnostic performance of FebriDx® to identify COVID-19 as a viral infection; secondary endpoint was SARS-CoV-2 molecular test diagnostic performance compared with the reference standard COVID-19 case definition (molecular or antibody detection of SARS-CoV-2).

RESULTS: Valid results were available for 47 patients. By reference standard, 35 had viral infections (34/35 COVID-19; 1/35 non-COVID-19; overall FebriDx® viral sensitivity 97.1% [95%CI 83.3-99.9]). Of the COVID-19 cases, 34/34 were FebriDx® viral positive (sensitivity 100%; 95%CI 87.4-100); 29/34 had an initial SARS-CoV-2 positive molecular test (sensitivity 85.3%; 95%CI 68.2-94.5). FebriDx® was viral negative when the diagnosis was not COVID-19 and SARS-Cov-2 molecular test was negative (negative predictive value [NPV] 100% [13/13; 95%CI 71.7-100]) exceeding initial SARS-CoV-2 molecular test NPV 72.2% (13/19; 95%CI 46.4-89.3). The diagnostic specificity of FebriDx® and initial SARS-CoV-2 molecular test was 100% (13/13; 95%CI 70-100 and 13/13; 95%CI 85.4-100, respectively).

CONCLUSIONS: FebriDx® could be deployed as part of a reliable triage strategy for identifying symptomatic cases as possible COVID-19 in the pandemic.

The COVID-19 pandemic is placing a significant strain on healthcare resources. Molecular testing is available, but the long turnaround time and false negative results have led to delays in diagnosis which in turn, hampers isolation procedures and places patients at risk of cross-infection.

FebriDx® is a 10-minute POC test from fingerstick blood to differentiate viral from bacterial acute respiratory infection through simultaneous detection of Myxovirus resistance protein A (MxA); a specific viral biomarker and C-reactive protein (CRP).

The study prospectively evaluated the utility of FebriDx® to rapidly identify viral cases requiring immediate isolation and confirmatory molecular testing from non-infectious patients or bacterial infections requiring antibiotics.

FebriDx® was shown to be 100% sensitive for detecting COVID-19 infections compared to 85.3% for RT-PCR (initial test). The specificity of both FebriDx® and RT-PCR was 100%. FebriDx® also correctly identified 8/8 bacterial infections (100% sensitive and 92.5% specificity).

Single biomarker CRP was unable to differentiate viral from bacterial infections due to the considerable overlap in values. This was also the case for procalcitonin and leukocyte counts.

The use of FebriDx® as an initial triage test may have prevented COVID-19 negative patients being exposed to COVID-19 positive patients caused by the delay in molecular test results. FebriDx® can improve time to initial triage and isolation when compared with rRT-PCR.

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