DIAGNOSTIC ACCURACY OF THE FEBRIDX® HOST RESPONSE POINT-OF-CARE TEST IN PATIENTS HOSPITALISED WITH SUSPECTED COVID-19

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ABSTRACT

INTRODUCTION: Management of the COVID-19 pandemic is hampered by long delays associated with centralised laboratory PCR testing. In hospitals this leads to poor patient flow and nosocomial transmission and so rapid, accurate diagnostic tests are urgently required. The FebriDx is a point-of-care test that detects an antiviral host response protein in finger prick blood within 10 minutes, but its accuracy for the identification of COVID-19 is unknown.

METHODS: We performed a real-world diagnostic accuracy study of FebriDx in hospitalised patients during the first wave of the pandemic. Measures of diagnostic accuracy were calculated based on FebriDx results compared to the reference standard of SARS-CoV-2 PCR on combined nose and throat swabs. A multivariable predictive model including FebriDx, age, sex, and clinical characteristics was developed and underwent internal validation.

RESULTS: FebriDx was performed on 251 patients and gave a valid result in 248. 118 of 248 (48%) were PCR positive for COVID-19. FebriDx results were available after 10 minutes compared with 1.7 (1.6 to 2.1) hours with point-of-care PCR testing and 23.4 (17.2 to 31.1) hours with laboratory PCR testing. Sensitivity of FebriDx for the identification of COVID-19 was 93% (110/118; 95% CI 87 to 97%) and specificity was 86% (112/130; 95%CI 79 to 92%). Positive and negative likelihood ratios were 6.73 (95%CI 4.37 to 10.37) and 0.08 (95%CI 0.04 to 0.15) respectively. In the multivariate model age, sex and other clinical features did not contribute significantly to the effect of the FebriDx result in distinguishing patients with and without COVID-19.

CONCLUSIONS: During the first wave of the pandemic, FebriDx had high accuracy for the identification of COVID-19 in hospitalised adults and could be deployed as a front door triage tool.

The management of COVID-19 patients in secondary care is negatively impacted by the long turnaround time of PCR tests which causes workflow and capacity issues, delayed diagnosis and cross infection. Alternative rapid accurate diagnostic tests are urgently needed.

FebriDx® is a low cost 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 real-world diagnostic accuracy of the FebriDx® test for the identification of COVID-19 in hospitalised patients with COVID-19.

FebriDx® was shown to be 93% (110/118) sensitive and 86% (112/130) specific for identification of COVID-19 infections compared to PCR. Several patients with FebriDx® viral positive results (negative by PCR) had classical radiological features of COVID-19, thus were likely to be true positives despite negative PCR results.

Due to the high sensitivity and negative predictive value, FebriDx® viral negative patients can be rapidly cohorted in non-COVID-19 areas allowing FebriDx® viral positive patients to be immediately isolated whilst awaiting confirmatory testing from a PCR or CT scan.

The FebriDx® test was shown to be highly accurate to rapidly identify COVID-19 infections and could be rapidly deployed as a front door triage tool in hospitals and urgent care centers to overcome current issues of delayed diagnosis from PCR testing.

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