UTILITY OF FEBRIDX® IN EARLY INDENTIFICATION OF POSSIBLE COVID-19 INFECTION

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ABSTRACT

BACKGROUND: Reliable differentiation between uncomplicated and self-limiting acute respiratory tract infections (ARIs) and more severe bacterial respiratory tract infections remains challenging, due to the non-specific clinical manifestations in both systemic bacterial or viral infections. The current COVID-19 pandemic is putting extraordinary strain on healthcare resources. To date, molecular testing is available but has a long turnaround time and therefore cannot provide results at the point of care, leading to a delay in results thereby exposing patients to cross-infection and delay in diagnosis.

METHODS: We prospectively evaluated the utility of FebriDx®, a point-of-care (POC) fingerstick blood test that can differentiate viral from bacterial ARIs through simultaneous detection of both myxovirus-resistance protein A (MxA) and C-reactive protein (CRP), in rapidly determining viral cases requiring immediate isolation and confirmatory molecular testing, from non-infectious patients or bacterial infections that require antibacterial therapy.

RESULTS: 75 consecutive patients were assessed and 48 eligible cases were tested with FebriDx®. Overall, 35 patients had FebriDx® test viral positive. All 35 patients had either positive rt-PCR (n=30) for COVID-19 or clinical picture highly suggestive of COVID-19 infection (PPV of 100% in a pandemic situation). In the 13 cases it was viral negative, rRT-PCR was also negative in all cases. In one case of LRTI, it was not possible to determine the exact cause of infection and a viral infection couldn't be excluded. Including this patient, the NPV was 12/13 (92%), exceeding the NPV of rRt-PCR at 71% (12/17). Sensitivity was conservatively calculated at 97% (35/36) compared to 85.7% (30/35) for rRt-PCR. Similarly, the specificity of both FebriDx® and rRt-PCR was 100% (12/12).

CONCLUSION: In the current COVID-19 pandemic, FebriDx® shows potential as a reliable POC test and a proxy marker of COVID-19 infection amongst inpatients in a secondary care setting.

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 identifying COVID-19 infections compared to 82.9% 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 be successfully deployed as a reliable triage test amongst hospital or emergency department patients suspected of having COVID-19.

FebriDx® is not currently available in the United States.

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