Clinical impact of molecular point-of-care testing for suspected COVID-19 in hospital: A prospective, interventional, non-randomised, controlled study (COV-19POC)

Nathan J Brendish[1,2], Stephen Poole[1,2,3], Vasanth V Naidu[2], Christopher T Mansbridge[2], Nicholas J Norton[2], Helen Wheeler[3], Laura Presland[3], Stephen Kidd[4], Nicholas J Cortes[4], Florina Borca[3], Hang TT Phan[3], Gavin Babbage[5], Benoit Visseaux[6], Sean Ewings[7], and Tristan W Clark[1,2,3,8]

1. School of Clinical and Experimental Sciences, Faculty of Medicine, University of Southampton, Southampton, UK
2. Department of Infection, University Hospital Southampton NHS Foundation Trust, Southampton, UK
3. NIHR Southampton Biomedical Research Centre, University Hospital Southampton NHS Foundation Trust, Southampton, UK
4. Department of Microbiology, Hampshire Hospitals NHS Foundation Trust, Basingstoke, UK
5. NIHR Southampton Clinical Research Facility, University Hospital Southampton NHS Foundation Trust, Southampton, UK
6. Université de Paris, Assistance Publique – Hôpitaux de Paris, Laboratoire de Virologie, Hôpital Bichat, Paris, France
7. Southampton Clinical Trials Unit, University of Southampton, UK
8. NIHR Post Doctoral Fellowship Programme, UK

Introduction

The management of the COVID-19 pandemic is hampered by long delays associated with centralised laboratory PCR testing. In hospitals, these delays lead to poor patient flow and nosocomial transmission. Rapid, accurate tests are therefore urgently needed in preparation for the next wave of the pandemic.

Methods

We did a prospective, interventional, non-randomised, controlled study of molecular point-of-care testing (POCT) in patients aged 18 years or older presenting with suspected COVID-19 to the emergency department or other acute areas of Southampton General Hospital during the first wave of the pandemic in the UK. Nose and throat swab samples taken at admission from patients in the point-of-care testing group were tested with the QIAstat-Dx Respiratory SARS-CoV-2 Panel. Samples taken from patients in a contemporaneous control group were tested by laboratory PCR. The primary outcome was time to results and secondary outcome measures included infection control outcomes and measures of diagnostic accuracy. Study registered: ISRCTN14966673; Regional Ethics Committee approved (20/SC/0138). Written informed consent or consultee assent required for POCT group enrolment. Funded by University Hospitals Southampton NHS Foundation Trust.

Results

Between 20th March and 29th April 2020, 517 patients were assessed for eligibility of which 499 patients were tested by POCT, and 555 controls who were tested with laboratory PCR, were identified.

Table 1: Primary and secondary outcome measures

Outcome Measures	POCT n=499	Control (lab PCR) n=555	Difference (95%CI)	p value
Time to results (hours)	1.7 (1.6 to 1.9)	21.3 (16.0 to 27.9)	-19.6 (-19.0 to -20.3)	<0.0001
Transferred from assessment area to definitive ward*	313/428 (73%)	241/421 (57%)	15.7% (9.1 to 22.0)	<0.0001
Time from admission to definitive ward arrival (hours)	8.0 (6 to 15)	28.8 (24 to 39)	-20.8 (-18.4 to -21.2)	<0.0001
Number of bed moves once admitted (mean, SD)	0.9 (0.5)	1.4 (0.7)	-0.5 (-0.4 to -0.6)	<0.0001
COVID-19 positive patients enrolled into other COVID-19 trials	124/197 (62.9%)	104/155 (67.1%)	-4.2% (-14.0 to 5.9)	0.42
Time from admission to enrolment into other COVID-19 trials (days)	1.0 (1.0 to 3.0)	3.0 (2.0 to 4.5)	-2.0 (1.0 to 2.0)	<0.0001

Data are n/N (%) or median (IQR), unless otherwise specified. *(i.e. COVID-19 positive or negative ward)

Figure 1: Time-to-event curve for time to results

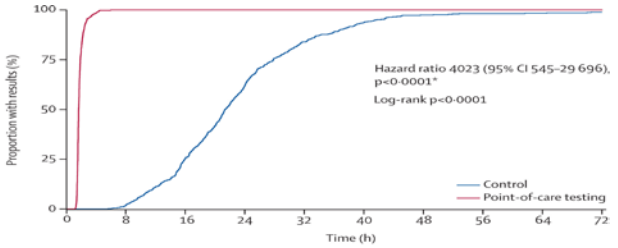
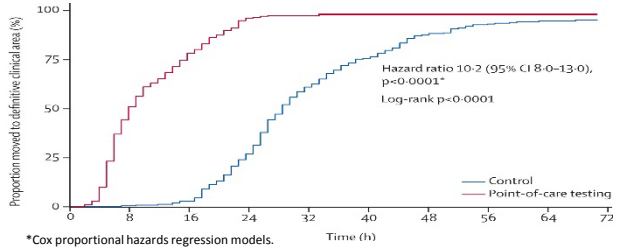


Figure 2: Time-to-event curve for time to arrival in a definitive clinical area (COVID-19-positive or COVID-19 negative area)



*Cox proportional hazards regression models.

Table 2: QIAstat-Dx Respiratory SARS-CoV-2 assay diagnostic accuracy vs lab PCR (including discrepant samples tested by third lab)

	n/n	% (95%CI)
Sensitivity	176/177	99·4% (96·9 to 100)
Specificity	288/292	98·6% (96·5 to 99·6)

Conclusions

Molecular point-of-care testing is associated with large reductions in time to results and could lead to improvements in infection control measures and patient flow compared with centralised laboratory PCR testing. In addition, patients were recruited onto other clinical trials more rapidly with POCT. The QIAstat-Dx SARS-CoV-2 panel had high diagnostic accuracy for the detection of COVID-19 compared to laboratory PCR. Resources should be urgently made available to support the widespread implementation of molecular POCT in hospitals, in preparation for the second wave.

@nathanbrendish

Presented at IDweek 2020.