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

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Background

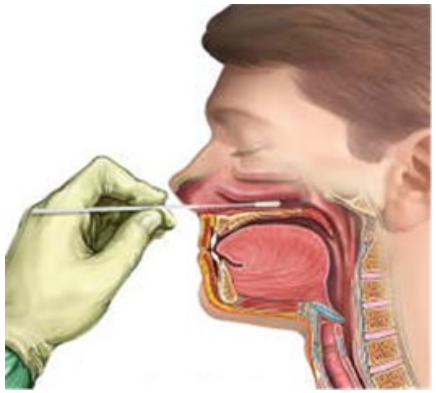
- Laboratory RT-PCR for SARS-CoV-2 takes time, often >12 hours
- With SARS-CoV-2, requirement for all admissions to be tested: patients wait together in cohort areas for results. This provides environment for transmission.
- Additionally bottle-neck causes poor patient flow and delay in study recruitment (especially in first wave, before any effective therapeutics were discovered)
- Molecular tests have been developed with equivalent accuracy to lab PCR which are simple to use and robust, therefore can potentially be deployed at the point of care
- Study hypothesis:

Molecular point-of-care testing in acute admissions may reduce turnaround time, improve patient movement around the hospital, and faster recruitment into research studies

Molecular point-of-care testing platforms

- Easy to use & no need for specialist laboratory facilities
- Results in about an hour

Methods



- Prospective, interventional, non-randomised, controlled study (CoV-19POC)
- Inclusion criteria for molecular point-of-care testing for SARS-CoV-2:
  - ≥18years
  - Has an acute respiratory illness OR otherwise suspected COVID-19
  - Recruited within 24 hours of presentation to hospital
  - In Emergency Department (ED) or Acute Medicine Unit (AMU) or other admitting area of Southampton General Hospital
  - Fully informed written consent or consultee assent
- Exclusion criteria:
  - Declining nose & throat swab
  - Included in study in last 14 days
- All enrolled patients had a nose and throat swab taken by the study team and tested at point of care using mPOCT with results immediately reported to the responsible clinical team and infection control as needed.

Methods: molecular point-of-care test

QIAstat-Dx Respiratory SARS-CoV-2 Panel (QIAGEN)

- 70 minutes turnaround time
- RT-PCR
- Syndromic panel (~ 20 pathogens, including influenza A sub-typing)
- Two gene targets for SARS-CoV-2
- We used a virus-inactivating 'molecular media' to protect operators
- Deployed into our acute medicine unit
- Sensitivity 100% vs WHO RdRp/ + E gene PCR assays (40 samples)[1]

1. Visseaux 2020 *J Clin Microbiol*

Methods

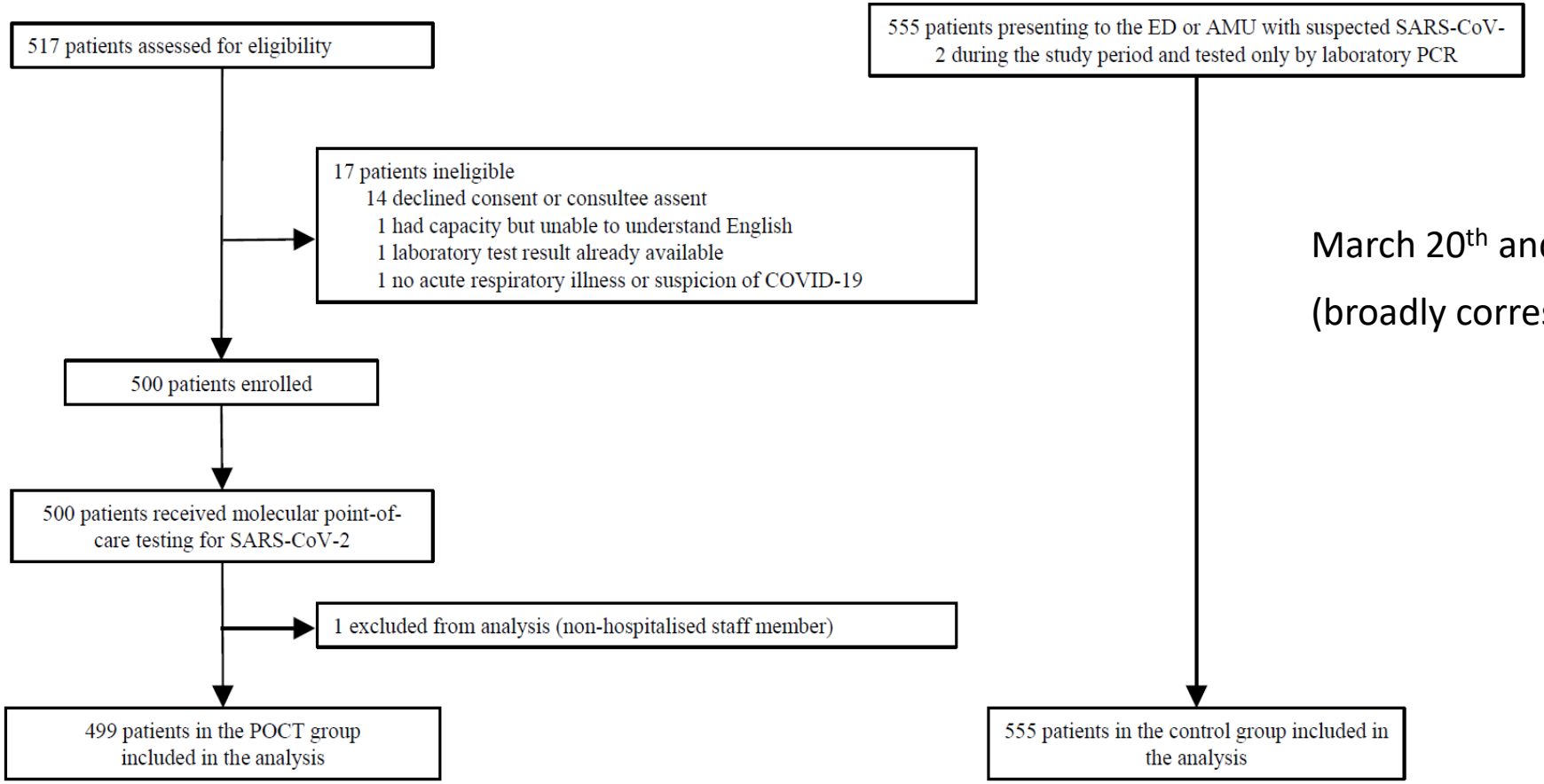
- Target 500 POCT patients (based on availability of test kits) and circa 500 control patients
- Primary outcome: time to results
  - recruitment (POCT group) or sample requested (control group) to time result available to clinical team
- Secondary outcomes included:
- Time to definitive ward, number of bed moves, duration of hospitalization, diagnostic accuracy, time to clinical trial recruitment (post hoc)

- Control group: patients in study period who did not have POCT

  (≥18years & acute respiratory illness / suspected COVID-19,

  presenting to ED or AMU) – *all had laboratory PCR*

Results: Trial Profile



March 20th and April 29th 2020

(broadly corresponds to the first wave in the UK)

Non-hospitalised staff members were permitted testing in the protocol however, only 1 inclusion, therefore excluded from analysis.

Results: baseline characteristics – groups broadly equivalent

		Point-of-care testing (n=499)	Control (n=555)	Between-group difference (95% CI)†
Characteristics				
Age, years	Median	68 (51 to 81)	70 (51 to 81)	−2 (−3 to 2)
	<50	117/499 (23%)	133/555 (24%)	−1% (−6 to 5)
	50–59	67/499 (13%)	66/555 (12%)	1% (−2 to 6)
	60–69	77/499 (15%)	78/555 (14%)	1% (−3 to 6)
	70–79	99/499 (20%)	124/555 (22%)	−2% (−7 to 2)
	≥80	139/499 (28%)	154/555 (28%)	0% (−5 to 5)
Sex	Male	262/499 (53%)	303/555 (55%)	−2% (−8 to 4)
Ethnicity	White British	406/477 (85%)	442/518 (85%)	0% (−4 to 4)
Pregnant		4/494 (1%)	5/555 (1%)	0% (−1 to 2)
Duration of symptoms, days		4 (1 to 10)	3 (1 to 7)	1 (0 to 1)
Comorbidities				
Hypertension		175/475 (37%)	247/554 (45%)	−8% (−14 to 2)
COPD		93/481 (19%)	85/554 (15%)	4% (−1 to 9)
Asthma		84/478 (18%)	95/554 (17%)	1% (−4 to 5)
Renal disease		38/473 (8%)	85/554 (15%)	−7% (−11 to 3)
Liver disease		24/476 (5%)	43/554 (8%)	−3% (−6 to 1)
Diabetes		108/478 (23%)	135/554 (24%)	−1% (−7 to 3)
Cancer		40/479 (8%)	36/554 (6%)	2% (−1 to 5)
Dementia		56/481 (12%)	57/554 (10%)	2% (−2 to 6)

		Point-of-care testing (n=499)	Control* (n=555)	Between-group difference (95% CI) †
Observations at admission				
Temperature	Median, °C	36·8 (36·4 to 37·6)	36·7 (36·4 to 37·5)	0·1 (0·0 to 0·2)
	≥38°C	92/493 (19%)	92/552 (17%)	2 (−3 to 7)
Pulse rate, beats per min		95 (82 to 109)	92 (78 to 106)	3 (0 to 5)
Respiratory rate, breaths per min		24 (20 to 28)	21 (18 to 26)	3 (0 to 2)
Oxygen saturation, %		96 (94 to 98)	96 (94 to 98)	0 (0 to 1)
Supplementary oxygen used		174/499 (35%)	128/555 (23%)	12 (6 to 17)
Systolic blood pressure, mmHg		134 (120 to 150)	133 (119 to 150)	1 (−3 to 4)
NEWS2 score		5 (3 to 6)	4 (2 to 6)	1 (0 to 1)
Laboratory and radiological parameters				
C-reactive protein concentration, mg/L		52 (12 to 125)	55 (12 to 129)	−3 (−6 to 4)
Neutrophil count, × 10^9/L		7·1 (4·6 to 11·1)	7·0 (4·8 to 10·5)	0·1 (−0·5 to 0·6)
Lymphocyte count, × 10^9/L		1·0 (0·7 to 1·6)	1·1 (0·7 to 1·7)	−0·1 (−0·1 to 0·1)
Chest x-ray done		488/498 (98%)	507/555 (91%)	7 (4 to 9)
Infiltrates or consolidation on chest x-ray		277/488 (57%)	136/507 (27%)	30 (24 to 36)

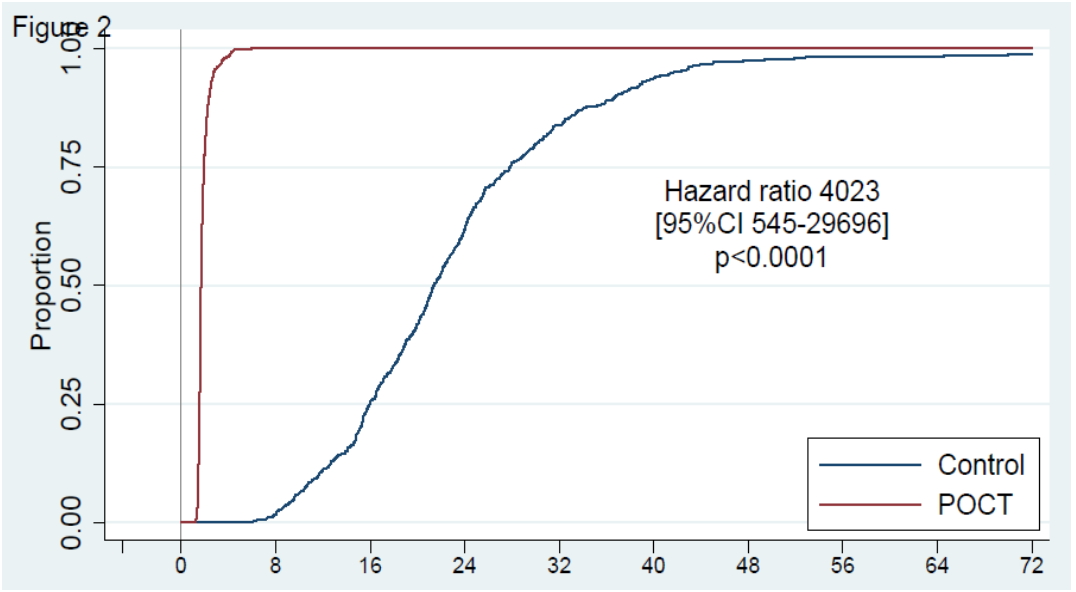
Data are n/N (%) or median (IQR). † Point-of-care testing group minus control group.
NEWS2 =National Early Warning Score 2.

Results: outcomes

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

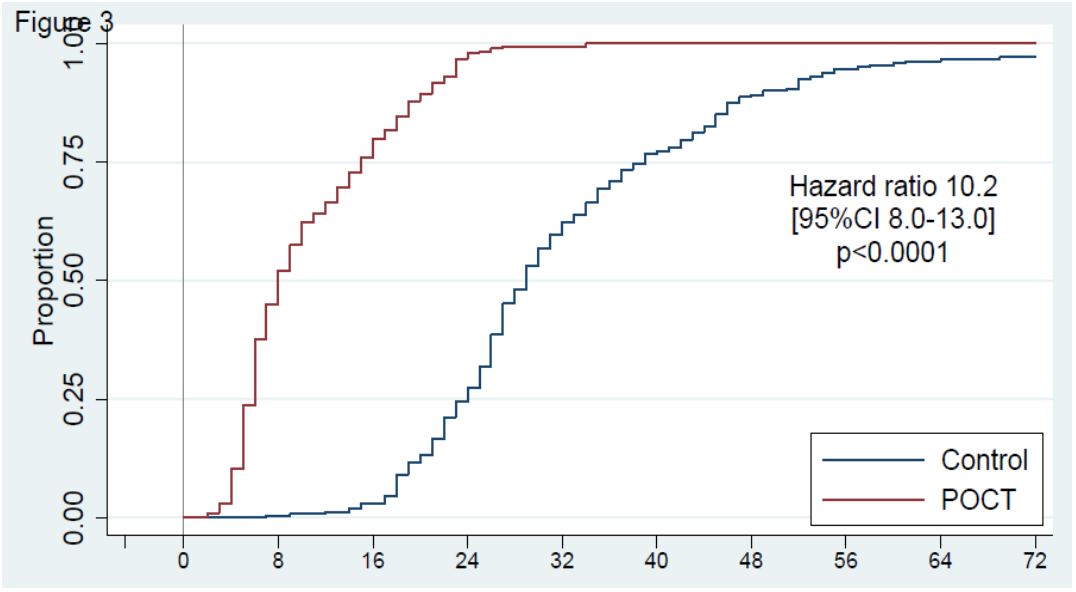
*i.e. a COVID-19 positive ward or COVID-19 negative ward
Data are n (%) or median (IQR) expect where stated otherwise.
POCT = point-of-care testing

Figure 2



Time to event: time to results POCT and control (hours)

Figure 3



Time to event: Arrival in definitive clinical area (hours) (i.e. time from admission to COVID-19 positive ward or COVID-19 negative ward)

QIAstat-Dx Respiratory SARS-CoV-2 assay diagnostic accuracy measures vs laboratory RT-PCR (including discrepant samples resolved by another laboratory using different assays)

	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 for COVID-19 in emergency admissions vs lab RT-PCR:

- Large reduction in time to results
- Fewer and more appropriate bed moves for patients
- Faster time for patients to get to COVID-19 positive or negative wards
- Faster recruitment of patients into COVID-19 clinical trials

The QIAstat-Dx Respiratory SARS-CoV-2 panel has high diagnostic accuracy.

Implementation of molecular point-of-care testing into hospital admissions pathways is now needed.

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