Validation, Usability and Acceptability of SARS-CoV-2 Loop Mediated Isothermal Amplification test in Malawi

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BACKGROUND

Real-time-reverse-transcription-Polymerase-Chain-Reaction (RT-PCR) is the gold-standard diagnostic test to confirm SARS-CoV-2 infection however RT-PCR is expensive requiring specialist laboratories. Alternatively, optimised nucleic-acid-tests such as SARS-CoV-2-reverse-transcriptase-Loop-mediated-isothermal-AMPlification (SARS-LAMP) could minimise costs and enable testing in settings without specialist laboratories

AIM

We evaluated the diagnostic test accuracy (DTA)-(sensitivity detecting cycle-threshold (CT) values <30; specificity >95%),
acceptability
and user-friendliness of SARS-LAMP test.

METHODS

- Phase 1 - Optimisation of RNA extraction free SARS--LAMP
- Phase 2 - Prospective diagnostic study using a bench top SARS-LAMP assay in Genie II instrument
- Nasopharyngeal swabs were collected and tested for SARS-COV-2 by lab technicians
- Consecutively recruited participants aged 16-80 years, n=450. attending Queen-Elizabeth-Central-Hospital (QECH) COVID-19 testing centre in Malawi.
- Study period:-September 2021-January 2022
- Usability assessed by semi – structured questionnaires, n=4.
- Acceptability assessed by semi-structured interviews (SSI), n=68.



Figure 1 : SARS –LAMP testing process

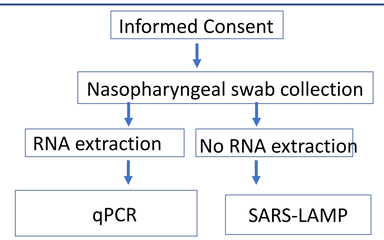

Figure 2 : Study Outline

SARS–LAMP's sensitivity is comparable to published reports.
Sensitivity = 73%
Specificity = 100%
It is acceptable to cases and contacts of COVID-19
User-friendly to lab technicians but varied responses on its adoption and implementation

METHODS - Study site







RESULTS

Table 1 Characteristics of the study participants

	Neg 261 (58%)	Cases 189 (42%)	
Age			
<40 years	137 (56.6%)	105 (43.4%)	242 (54%)
>40-55 year	79 (62.7%)	47 (37.7%)	126 (28%)
>55 year	45(54.9%)	37(45.1%)	82 (18%)
		chi^2 1.66, pr 0.44	
Sex			
Male	154 (62.0%)	94 (38.0%)	248 (55%)
female	107 (53.0%)	95 (47%)	202 (45%)
	chi^2 3.81, pr 0.05		
Vaccination			
Unvaccinated	157 (60.6%)	102 (39.4%)	259 (58%)
Vaccinated	103 (54.2%)	88 (45.8%)	191 (42%)
		chi^2 1.88, pr 0.17	
Education			
Primary	70 (53.0%)	62 (47.0%)	132 (31%)
Secondary	108 (72.5%)	41 (27.5%)	149 (35%)
Tertiary	68 (57.9%)	76 (42.1%)	144 (34%)
		chi^2 21.02, pr 0.00	

Other Demographics

- Among the 450 participants, 8 had travelled abroad
- 233/450 (52%) had comorbidities,,
- 5/192(3%) were admitted to ICU, 2 deaths occurred.

Table 2 Sensitivity and Specificity of SARS - LAMP in comparison to qPCR

PROSPECTIVE n=450	
Sensitivity	73.6%(95% CI:63.0.%-82.4%);
Specificity	100% 95% CI:98.6%-100.0%).

Acceptability to to cases and contacts of COVID-19

- 68 participants were recruited,
- median age was 37 years (IQR of (27, 50)),
- (12/68 (17.6%) were aged >55 years
- 27/68 (40.0%) were female
- SARS-LAMP was acceptable to cases and contacts of COVID-19
- 67/68 (98%) response rate by cases and contacts of COVID-19

Usability of SARS-LAMP by laboratory technicians



All 4 Laboratory technicians were recruited

- All 4 found SARS-LAMP user-friendly but collecting nasopharyngeal swabs from patients was not easy.

- All 4 stated that rapid antigen tests were easier to use but still 3/4 were in favour of SARS LAMP.

CONCLUSION

SARS -LAMP:

- Performance - highly sensitive and specific as per published studies
- Acceptable to cases and contacts of COVID-19
- Easy to use by laboratory technicians suggesting that its use is acceptable to both cases and contacts of COVID-19

➢ **These preliminary results may suggest that implementing SARS-LAMP could significantly improve diagnosis of SARS but there are other user-friendly tests , thereby decreasing its adoption by laboratory technicians and implementation**

➢ **There is need for cost-effectiveness analyses before any scale up plans of SARS LAMP**

Acknowledgements

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