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Validity of a mobile Phone-based application tool for COVID-19 self-screening

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Abstract

Background: The COVID-19 outbreak is proving to be a unique disaster in many countries across the globe. Screening and diagnosis are challenges in resource-limited countries, as confirmation with reverse-transcriptase polymerase chain reaction (RT-PCR) are expensive and less accessible.

Objectives: The goal of this study was to assess the validity of a newly created mobile phone application tool as a COVID-19 self-screening approach as compared with the gold standard reverse-transcriptase polymerase chain reaction test (RT-PCR).

Methods: A cross-sectional study was conducted among 1029 individuals for validity assessment of a newly developed COVID-19 screening tool by having PCR test results as a reference. Data were collected using a structured questionnaire, maintaining all the COVID-19 prevention protocols. SPSS version 25 was used to analyze the data.

Results: A total of 1005 participants were included in the study, which made the response rate close to 97.7%. The mean age of the respondents was 37(SD=±15.62) years; 574 (57.1%) were males and 366(36.4%) were in the age category of 40 years and above. The current study identified that the internal consistency of Cronbach's alpha was 0.769. The validity analysis result of the tool revealed that it has a sensitivity of 77.6% with 31.6% of positive predictive value and specificity of 46.4% with 86.5% of negative predictive value. Moderate to severe symptom was significantly associated with RT-PCR test positivity with a p-value ≤0.0001 and OR of 5.259(95% CI: 3.500, 7.900).

Conclusion: The mobile application tool is found to be a reliable tool with a good level of sensitivity and specificity for use as a primary symptom-based self-screening of COVID-19. Therefore, we recommend the use of this screening test tool. It is easily accessible and hence an effective way of reaching the population affected by the disease for early detection of symptomatic patients and taking appropriate measures.

Keywords: COVID-19, Mobile application tool, Resource-limited, Sensitivity, Specificity

Background

In late December of 2019, a cluster of cases of viral pneumonia of unknown etiology was reported in Wuhan, Hubei Province, which was later identified and referred to as Coronavirus Disease 2019 (COVID-19) by the World Health Organization (WHO). It was caused by the novel SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus-2) that was able to spread rapidly and developed into a global pandemic level within a few months (1-3). Reported symptoms include fever, cough, fatigue, pneumonia, headache, gastrointestinal (GI) upset (abdominal cramp, nausea/ vomiting or diarrhea, hemoptysis, and dyspnea which resemble respiratory illnesses caused by other viruses or bacteria (4-5). Masks, hand hygiene procedures, avoidance of public interaction, case identification, contact tracing, and quarantines have all been mentioned as possible ways to scale back transmission (6).

The COVID-19 outbreak is proving to be an exceptional disaster in the most afflicted countries, including the USA, Brazil, Italy, Iran, and China in all aspects, especially the health, social, and economic disasters (7). The current interventions on COVID-19 mainly focused on infection control and the use of effective vaccines (8-9); there is no effective specific antiviral treatment (6). Clinical diagnosis is difficult due to the coinciding symptoms, particularly during the flu season. That is why the confirmation of COVID-19 depends on the detection of SARS-CoV-2 nucleic acid by reverse-transcriptase polymerase chain reaction (RT-PCR) (10).

Infection prevention strategies and patient management depend on the accurate and timely COVID-19 test capacity. This enables or will assist the efforts which are aimed at controlling or slowing down the rapid transmission of the pandemic in the population and at the healthcare facilities (11). According to the recommendation of WHO, COVID-19 diagnosis can be made by molecular tests which detect the SARS-CoV-2 virus RNA. However, this test is difficult to perform because it necessitates a committed health system with continuous delivery of numerous reagents, expensive laboratory equipment, and trained laboratory technologist. Currently, infrastructure limitations and supply shortages are limiting the testing capacity below the growing request for COVID-19 diagnostics across the world (12).

As a result, having access to consistent rapid diagnostic tests could relieve laboratory pressure and enhance testing capacity to meet the most pressing medical and public health needs (12). Regardless of symptoms, a case of COVID-19 is considered "confirmed" when a positive laboratory test for SARS-Cov-2 virus infection is obtained. Many diagnostic tests are currently available, and more are being accepted for emergency use daily. The majority of these tests are based on four main procedures: Reverse transcription-polymerase chain reaction (RT-PCR), Loop-mediated isothermal amplification (LAMP), Lateral flow, and Enzyme-linked immune-sorbent assay (ELISA) (13). These tests are not easily accessible to low-income countries. Therefore, the need for a simple first-line screening tool is a crucial step for lowest-income countries, such as Ethiopia.

In Ethiopia, in particular, the need for proactive population screening for COVID-19 is extremely important as the general public seems to be reluctant to adhere to the preventive measures (14). Health care workers and community members alike are faced with the important challenge of quickly identifying symptoms and taking appropriate steps for laboratory investigation in line with the case definition based on surveillance or clinical characterization. Therefore, developing a quick and valid instrument or tool to capture an individual's COVID-19 like symptoms is important and timely. As a result, this study aimed to evaluate the sensitivity and specificity of a newly developed COVID-19 screening test mobile phone-based application tool to promote its widespread use.

Methods

Study setting, design, period, and population

The study site was St. Paul's Hospital Millennium Medical College. Since its establishment in 1968 by the late Emperor Haileselassie, in collaboration with the German Evangelical Church, St. Paul's hospital has been serving as a general and referral hospital for the Ethiopian people coming from all corners of the country for more than five decades. The St. Paul's Hospital Millennium Medical College (SPHMMC) was officially

launched in 2008 after it had been initiated by the Federal Ministry of Health of Ethiopia and approved by the Council of Ministers Regulation, basing the definition of Powers and Duties of the Executive Organs Proclamation No. 691/2010 and the Higher Education Proclamation No. 650/2009 of the Federal Democratic Republic of Ethiopia. The College was primarily intended to augment the national effort of mitigating the extreme shortage of medical doctors across the nation, with a special focus on making a difference in the medical workforce of the emerging regional states. Later on, it was realized that its mandate has extended to supporting neighboring countries with a severe shortage of medical doctors and specialists. With the existing actively functioning hospitals within the main campus, the number of patients that are seen daily has now increased to more than 2000, and the number of health professionals has also increased to over 3000. The college, as the governing body of the hospital, has been on a continuous streak to initiate various services that are in one or other way the nation's priority areas.

The distinct strengths of the College are thinking out of the box/out of the tradition and the vibrant academic staff in spearheading the initiatives. Through this strategic plan as well, the College is committed to keeping on striving to be innovative, research-driven, interdisciplinary, and internationally visible.

A cross-sectional analysis was designed to determine the validity of a newly developed mobile phone-based screening program. Individuals who came to the COVID-19 testing centers for various purposes were tested for COVID-19 infection symptoms using a standardized questionnaire that was included in the mobile-based screening application. The study participants were those who were suspected as a case of COVID-19 by clinicians, and isolated in the emergency unit; had contact history with COVID-19 positive individuals; had comorbid illnesses, and were required to have preadmission screening or self-interest to be tested for COVID-19. Then, their result was compared with the result of RT-PCR performed at St. Paul's Hospital Millennium Medical College. The data was collected from July 1 to September 30, 2020.

Sample size determination and data collection methods

The sample size was determined by using the Primary Avionics Software System (PASS) software. Considering this study as a screening test, the following assumptions were duly considered: Power of 80%, alpha value of 0.05, a prevalence of 5%, the desired sensitivity of 99%, and 10% of non-response rate. A total of 1029 samples were included in the study. The variables collected include a combination of demographic data such as age, sex, common symptoms of COVID-19, fever, cough, Shortness of breath, sore throat, easy fatigability, headache, anosmia/or Ageusia, GI upset (either vomiting/ nausea/or diarrheal) travel history, contact history, and the presence and absence of co-morbidities such as diabetes mellitus, cardiovascular, lung, renal and liver diseases.

The researchers have also done a reliability analysis to measure the correctness of the tool that helps to what extent does the current tool would give consistent or dependable results during multiple trials in which a total of eight variables/items were included. The variables were, cough, shortness of breathing (SOB), sore throat, fever, newly developed anosmia/Ageusia, headache, easy fatigability, and Gastrointestinal upset (vomiting or diarrhea) are the symptoms that we used to develop the COVID-19 infection screening tool. Additional analysis was done on the area under the receiver operating characteristic curve (AUROC) to show the performance of a classification model at all classification thresholds.

Data interpretations:

The result of the screening test is defined into two different categories for validation purposes and further subcategorized into two population groups for recommendation following the screening result.

Category 1: Screening results suggestive of the presence of COVID-19 in patients who exhibit COVID-19 like symptoms.

Category 2: Screening result Suggestive of the absence of COVID-19 disease, in patients who did not exhibit COVID-19 like symptoms.

Data Analysis

The currently used software automatically transfers the data to a database. Data collected were saved on the web and were checked for flaws every day during data collection; completeness was checked, cleaned, and saved in a separate file, while the raw data remained in the main database.

A total of 1029 samples were included in the study; however, the RT-PCR test result of 24 participants was not found in the registry for different reasons (inadequate sample, inconclusive result, and lost result). Therefore the responses of 1005 participants were analyzed making a response rate of 97.7%.

Sensitivity, specificity, positive and negative predictive values of the screening test were compared with the gold standard laboratory PCR test results using two by two matrix of measure of diagnostic validity (15).

Results

Sociodemographic characteristics of the respondents

As indicated above, a total of 1005 participants were included in the study which makes the response rate 97.7%. The mean age of the respondents was 37(SD=15.62) years. Among the respondents, 574 (57.1%) were males, and choric medical illness presented in 191(19%) of the participants. Only 238 (23.7%) of them had a history of contact with an individual who had confirmed COVID-19 infection (Table 1).

Table1: Description of sociodemographic and clinical factors among individuals who underwent COVID-19 test, Addis Ababa, Ethiopia, 2020.

Variables		Frequency	Percent (%)
Age	<29	389	38.7
	30-39	250	24.9
	40-49	147	14.6
	50-59	105	10.4
	>60	114	11.3
Sex	Female	431	42.9
	Male	574	57.1
Chronic medical illness	Present	191	19
	Absent	814	81
Contact History	No	767	76.3
	Yes	238	23.7
Total		1005	100

Reliability and validity of the tool

The internal consistency of Cronbach's α was 0.769. Principal components factor analysis (PCFA) was done to include items that best fit the data and a total of eight items that had values greater than one were extracted (Table 2).

Validity analysis was done by including the remaining eight items. Further, item correlation analysis was done and all of the selected items had Cronbach's alpha of above 0.70 (Table 3).

Table 2: Extraction Method by using principal components factor analysis result of the mobile phone-based application COVID-19 test tool, Addis Ababa, Ethiopia

Total Variance Explained						
Component	Initial Eigenvalues			Extraction Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	2.430	14.292	14.292	2.430	14.292	14.292
2	1.570	9.237	23.529	1.570	9.237	23.529
3	1.503	8.841	32.369	1.503	8.841	32.369
4	1.324	7.791	40.160	1.324	7.791	40.160
5	1.255	7.382	47.542	1.255	7.382	47.542
6	1.091	6.417	53.960	1.091	6.417	53.960
7	1.027	6.043	60.003	1.027	6.043	60.003
8	1.019	5.995	65.997	1.019	5.995	65.997
9	0.921	5.416	71.413			
10	0.858	5.049	76.462			
11	0.823	4.840	81.302			
12	0.754	4.433	85.735			
13	0.632	3.721	89.455			
14	0.569	3.349	92.804			
15	0.487	2.865	95.669			
16	0.437	2.572	98.242			
17	0.299	1.758	100.000			

Further correlation analysis in between the symptoms was conducted and the result shows a significant correlation among each other at 0.01 level of 2-tailed *(see Supplementary Table 1)*.

Table 3: Items correlation descriptive analysis of the mobile phone-based application of COVID-19 test tool

Item-Total Statistics					
	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
COUGH	12.65	2.806	0.541	0.396	0.722
SOB	12.61	2.784	0.594	0.439	0.711
Sore Throat	12.53	3.141	0.405	0.243	0.747
FEVER	12.58	2.849	0.577	0.393	0.715
Anosmia/Ageusia	12.47	3.149	0.535	0.358	0.730
Headache	12.61	3.038	0.398	0.215	0.750
Easy Fatigability	12.58	3.25	0.275	0.090	0.770
Gastrointestinal upset (Vomiting/ Diarrhea)	12.48	3.26	0.402	0.196	0.747

Mobile screening and RT-PCR test results of the study participants

This study revealed that 23.9% and 35.4% of the study participants showed mild and moderate to severe COVID-19 related symptoms and were classified as tested positive for the infection, based on the mobile COVID-19 screening tool. Of those who underwent the RT-PCR test, only 245 (24.4%) turned to have positive test results. The current validity analysis result revealed that the sensitivity of the tool was 77.6% with a 31.6% of positive predictive value. The specificity of the tool was 46.4% with an 86.5% negative predictive value (table 5). The Area under ROC which is 0.857(95% CI: 0.834-0.880) with a p-value <0.001 indicated that the tool is good enough in classifying the model at all classification thresholds (fig.1). On further analysis with a regression model of moderate to severe COVID-19 symptoms by the mobile application, the tool is significantly associated with RT-PCR test positivity with a p-value of ≤0.0001 and OR of 5.259(95% CI: 3.500, 7.900) (Table 5).

Table 5: symptom-based diagnosis by screening mobile application tool correlation with the Gold standard RT-PCR diagnosis

	Confirmation of Diagnosis by the gold standard method (RTPCR)		
Result of screening the by the mobile application tool	Positive	Negative	Total
Positive for COVID 19	190	407	597
Negative for COVID 19	55	353	408
Total	245	760	1005
Sensitivity	77%		
Specificity	46%		
Positive predictive value	32%		
Negative predictive value	86%		
likelihood of COVID 19 Positive test	1.44		
Likely hood of negative test	0.49		

Discussion

The new COVID-19 symptom screening test mobile phone-based application tool has a high degree of sensitivity and a strong level of specificity. It has also a better level of reliability, as demonstrated by the results, in which the questions that are included as a screening item can capture and generate significant information regarding COVID-19 infections. Further, it has also an attractive level of ability in detecting true negative and positive results from those who have total negative and positive test results. Therefore, this mobile application was found to perform well in assessing the presence and absence of COVID-19 infection in the general population and an easy to administer as an instrument.

RT-PCR assay is considered as a gold standard technique and still a fundamental method to be applied for the detection of SARS-CoV-2 to date. However, the current pandemic SARS-CoV-2 confuses the scientific and the medical community about which accurate diagnostic tool should be relied on to diagnose COVID-19 because of, the availability of few viewpoints that creates doubts as to underestimating its sensitivity and specificity (16). Therefore, due to its simplicity in utilization, the current application could be used in the screening of SARS-CoV-2. However, it might have some limitations that are usual to similar screening methods, because current studies estimating test performance characteristics have imperfect study design and statistical methods for the estimation of test performance characteristics of SARS-CoV-2 tests like rRT-PCR and NAAT (17).

Regarding the percentage of validity, the current study finding is in line with the values obtained through the meta-analysis in its sensitivity, whereas it has a lower level of specificity (18). Even though the previous tests have a high value of sensitivity and specificity in terms of detecting COVID-19 infection, it's worth noting that the difficulties and limitations described concerning pathogen detection through molecular testing (real-time RT-PCR) are for the most part just as relevant to serological detection methods (19). The current study identified high values of specificity than the previous similar attempt. Whereas, the combination of IgM and IgG antibodies, that demonstrated promising results for the parameters, sensitivity, and specificity (20).

Different studies revealed that screening for only temperature is not sensitive enough to detect the vast majority of COVID-19 (21, 22, and 23). Our study result concerning sensitivity for

COVID-19 is far better than a temperature alone screening. This improved sensitivity is the result of a combination of symptoms that led to detecting patients who don't exhibit fever or cough. The severe symptoms that become likely of turning positive are also demonstrated in this study, which strengthens our recommendation to test those with severe symptoms in countries where the test Kits shortage is pronounced.

The limitation of the study is the COVID-19 may show additional new symptoms that are not captured by the mobile applications during the study period. A continuous update is mandatory to mitigate this effect.

In conclusion, the worldwide expansion of SARS-CoV-2 infection and the emergence of new strains have led to widespread adoption of symptom and risk screening measures. This mobile phone-based application tool has a good level of sensitivity and a fair degree of specificity in the screening of COVID-19 related symptoms. Besides, the system doesn't have an additional cost on anyone and is accessible to most people at their convenient place. This screening tool is much better than only temperature screening which is found to be ineffective in most set up. An added benefit is this self-checker mobile application tool is to help patients seek medical care before they develop serious complications as the application reminds you about new symptom development each day for 14 days.

Therefore, the development of a friendly screening mobile application tool will help in halting the spread of infection and early detection of disease and look for hospital care. Further, we strongly recommended that this tool can be used by the public to detect COVID-19 symptoms prevalence in the community or detection of hot spot areas (epicenters) during the 2nd or 3rd wave. It can also be used by different institutes to guide their staff and visitors to check themselves with this self- checker before they visit the institutions rather than using temperature screening alone.

Abbreviations

COVID 19; Coronavirus disease 2019

FMOH; Federal Ministry of Health

IgG; Immunoglobulin G

IgM; Immunoglobulin M

PCR; polymerase chain reaction

SARS; Severe acute respiratory syndrome

SPHMMC; Saint Paul's Hospital Millennium Medical College

SPSS; Statistical Package for Social Sciences

WHO; World Health Organization

Declarations

Ethics approval and consent to participate

The current manuscript had got ethical approval from St. Paul's Hospital Millennium Medical College (SPHMMC) IRB. In addition, informed consent was obtained from all study participants before they enrolled in the study. They were told that their participation is voluntary, and could withdraw at any time or refuse to answer any question if they wanted to. No information concerning the individual was passed to a third party. So, in general, we carried out the current research by fulfilling all the requirements of the institutional (SPHMMC) IRB guidelines and regulations and also it fulfilled the Declaration of Helsinki guidelines and regulations.

Consent for publication

Further, informed consent for publication was also obtained from each study participant under the consent form by mentioning for all of them that the data will be published in international journals. So, this is to confirm that informed consent for publication was obtained from all the study participants. The collected data is kept confidential under the primary investigator and co-investigators.

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information.

Authors' contributions

MB and NT were involved starting from conceiving the idea, developing the proposal, the study design, reviewing the article, analysis, report writing, and drafted and write up of the manuscript; MA, AG, and TS were involved in developing the proposal, the study design, analysis, report writing, and manuscript write up and review AL, TS, and AG involved in data collection, data cleaning, analysis and review of the manuscript. YB was involved in proposal development, data analysis, manuscript writing, and editing the final manuscript. BT a software engineer involved in developing the mobile phone-based screening application tool, data cleaning and encoding, data analysis, and revision of the final manuscript.

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Competing interest

All authors read and approved the final manuscript. The authors declare that they have no competing interests.

Availability of Data and Materials

The datasets used and/or analyzed in the current study or data collection tool are available from the corresponding author on reasonable request.

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