RESEARCH ARTICLE

VALIDATION OF THE COVID-19 SCREENING TOOL AND CLINICAL-EPIDEMIOLOGICAL CHARACTERISTICS OF CONFIRMED COVID-19 PATIENTS AT FAUJI FOUNDATION HOSPITAL RAWALPINDI

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ABSTRACT

Objectives: *To assess clinical and epidemiological features of COVID-19 patients at Fauji Foundation Hospital and to validate COVID-19 case definition devised by WHO.*

Study design: *Cross Sectional Validation.*

Study Place: *Fauji Foundation Hospital Rawalpindi.*

Study Duration: *June 2020 to January 2021.*

Sample Technique & Size: *Purposive sampling of 836 COVID-19 suspected cases as per definition.*

Methodology: *Clinical and epidemiological features of COVID-19 positive patients were assessed along with validation of case definition of COVID -19.*

Results: *Four hundred and ninety-two (58.9%) of study population were females, 507(60.7%) were non health care workers. Hypertension and diabetes were a comorbidity in 184(22%) and 507(60.7%) of patients respectively. The WHO questionnaire validation revealed 63.6% sensitivity and specificity of 56.6%. After screening , positive predictive value of 75.7% and negative predictive value of 42.2% was attributed to the screening tool.*

Conclusion: *Keeping in view the high prevalence as well as variety of clinical symptoms of COVID 19 and its unpredictable fatality behaviour in Pakistani population; the WHO tool left much to be changed in case definition to improve the sensitivity and specificity besides predictive value of its recommended current screening tool.*

Keywords: *Case Definition, COVID-19 Screening, Validation*

INTRODUCTION

A century after the Spanish flu caused mayhem by fatally affecting one third of the world's population, infecting five hundred million people in four sequential waves,[1] the world is once again under the rampage of another global pandemic. COVID-19, originating from Wuhan, China in December 2019 spread far and wide via infected respiratory droplets; the viral disease was considered initially to have been transferred to humans from the horseshoe bat.[2]

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Worldwide, the number of cases surged, having touched the 680,206,721 mark in February 2023; with over 653,025,677 recoveries and more than 6,801,721 deaths.[3] The recorded number of patients of COVID-19 in USA were more than 190,340,817 with people dying due to disease being over 1,012,461.[4] Till date there are 44,686,879 cases of COVID-19 reported from India with 530,772 deaths.[5]

Pakistan is a developing country of 224,206,949 population with minimal resources. The burden of COVID-19 cases has been over 922,824, with nearly 20,850 deaths till 12th June 2022.[3]

Clinical criteria for diagnosis of this novel virus is set to be typical presentation of flu like symptoms with fever, cough, sore throat, breathlessness, generalized body

aches and fatigue, while atypical symptoms being diarrhea and fever. Common neurological symptoms include loss of taste and smell. According to CDC Clinical Criteria for COVID-19 is sudden onset of fever and cough. Epidemiological criteria includes those living / working in high risk areas, especially health care settings, closed office spaces like banks with high public interactions and temporary domiciliary settings like camps and those who are in contact with cases within incubation time.[4,5]

Many asymptomatic cases fall short of epidemiological criteria. People who are contacts without any symptoms having positive SARS-CoV-2 Antigen-RDT are considered as cases/carriers.[6,7]

Due to unavailability of definitive treatment, the most potent way to control this pandemic is accepted to be early detection of COVID-19 disease and speedy isolation of cases.[8] The reverse transcription polymerase chain reaction (RT-PCR) or gene sequencing from blood and nasal or pharyngeal secretions are the diagnostic methods recommended by the Chinese government for the confirmation of COVID-19 infection. The entire positive RT-PCR rate of these throat swab samples is approximately 30% to 60% legitimate while there are shortcomings in sample collection, transportation, and kit performance.[9] Low sensitivity of RT-PCR is leading to under diagnosis of COVID-19 patients, who may not receive proper management in time. Diagnosed patients are tip of iceberg and these subclinical patients contribute a huge risk for infecting more people. Under scarce resources, physicians have a large burden to treat this heavy number of patients for COVID-19 screening. For early diagnosis and prompt treatment, screening test should be cost-effective.[10]

Due to the shortage of testing kits, trained personnel, and Personal Protective Equipment (PPE), it is difficult to test every approaching person having flu-like symptoms for COVID-19.[11] The procedure of selecting suspected cases for investigating COVID-19 can be simple to prevent a financial catastrophe at health centers.[12] To reach this goal, the screening process is continuously being revised and is diverse in different countries.

Only testing people with respiratory symptoms such a fever, dry cough, shortness of breath, or a history of virus exposure was advised by the Centre for Disease Control and Prevention (CDC). Based on statistics of community transmissions, the CDC modified its recommendations on March 4, 2020, allowing anyone with respiratory symptoms to get tested with a doctor's approval.[12]

According to the World Health Organisation (WHO), a patient with severe acute respiratory illness (fever and at least one sign/ symptom of respiratory disease, such as cough, shortness of breath requires hospitalization. Travel history to an area with a high number of COVID-19 patients, asymptomatic patients with history of contact are all risk factors for COVID-19.[13, 14]

The aim of this study was to validate the COVID-19 assessment forms used by hospitals in Pakistan to filter COVID-19 patients. This is ultimately expected to lead to confirming the utility and reliability of case definitions used for suspected cases while reducing need for resource intensive lab tests for Preliminary diagnosis of COVID-19.

This would also help explore clinical and epidemiological features of confirmed COVID-19 patients reporting to tertiary care hospital in Rawalpindi to assess the local clinical profile of confirmed COVID-19 cases in Pakistan.

METHODOLOGY

Purposive sampling was used to conduct a validation study on suspected COVID-19 patients who visited the Fauji Foundation Hospital between June 2020 and January 2021.

A sample size of 836 was estimated using a screening tool's sensitivity of 76%, specificity of 68%, and local COVID-19 prevalence of 6%. Based on the case definition published by the Government of Pakistan on March 27, 2020, a questionnaire was created to screen out patients who may have COVID-19 infection.

Seventeen nasopharyngeal swabs from patients who were suspected of having COVID-19 were sent for PCR analysis, and the results were then followed up. Patients were divided into asymptomatic, mild, moderate, severe, or critical cases on a clinical basis, and the choice to admit them was made in accordance with this clinical categorization.

Epidemiological characteristics of COVID-19 PCR positive patients were also studied.

Clinical feature included presence of fever, cough, chest pain, shortness of breath, diarrhea, smell taste loss, sore throat, flu and pneumonia.

Data analysis was done in SPSS 26. Sensitivity, specificity, positive and negative predictive values of case definition were calculated and ROC curve was drawn to assess validity.

RESULTS

Data of 836 COVID-19 PCR positive patients were included in final analysis. Epidemiological features of these patients are given in Table I:

Table I: Epidemiological features of COVID-19 patients

EPIDEMIOLOGICAL FEATURES	N (%)
Age (Mean +/- SD	43.42 ± 17.58
Gender	
Male	344(41.1%)
Female	492(58.9%)
Job description	
Health care worker	329(39.3%)
Non Health care worker	507(60.7%)
Contact history with known patients	
Hospital	184(22%)
Home	162(19.4%)
Workplace	129(15.4%)
No history	361(43.2%)
Co morbids	
Hypertension	184(22%)
Diabetes	178(21.3%)
Ischemic heart disease	108(12.9%)
Cancer	84(10%)
Kidney disease	62(7.5%)
Asthma/COPD	64(7.7%)
Tuberculosis	60(7.2%)

1. Four hundred ninety nine (59.7%) patients were found to be positive on screening test. Cases were classified according to severity into asymptomatic, mild, moderate and severe COVID-19 as given in Table II. Among COVID-19 positive patients majority, 614(73.4%) were sent for home isolation.

Table II: Frequency of COVID 19 clinical Severity in total PCR positive patients

CLINICAL SEVERITY CLASSIFICATION	N (%)
Asymptomatic	481(57.5%)
Mild COVID-19	266(31.8%)
Moderate COVID-19	78(9.3%)
Severe COVID-19	10(1.2%)
Severe COVID-19 with complications	1(0.2%)

Clinical features of patients considered for evaluation as falling on the COVID-19 case definition spectrum were varied . These are given in table III.

Table III: Clinical features of COVID-19 positive patients

Clinical features	N (%)
Fever	
Afebrile	403(48.2%)
Low grade	388(46.4%)
High grade	45(5.4%)
Cough	
Present	472(56.5%)
Flu	
Present	391(46.8%)
Sore throat	
Present	379(45.3%)
Myalgia	
Absent	348(41.6%)
Mild	473(56.6%)
Severe	15(1.8%)
Diarrhea	
Present	252(30.1%)
Pneumonia	
Mild	86(8.3%)
Severe	10(1.2%)
Headache	
Present	183(21.8)
Chest pain	
Present	379(45.3%)
Shortness of breath	
Absent	614(73.5%)
Mild	201(24%)
Moderate	15(1.8%)
Severe	6(0.7%)
Vomiting	
Present	444(53.1%)
Loss of taste	
Present	427(51.1%)
Loss of smell	
Present	409(48.9%)

2. Case fatality rate was found to be 9.5%. Among 80 deaths 51.2% (41) were males. Case fatality rate was found to be highest in age group 65-75 years (32.5%) followed by 30% in 55-65 years of age range.

3. For validation of the clinical criteira used as primary screening tool vs PCR test used as gold standard, sensitivity of screening questionnaire was 63.6% and specificity being 56.6%. It came with a positive predictive value of 75.7% and negative predictive value

of 42.2%.

When plotted on ROC, area under the curve was 0.399(0.35-0.44) pointing at poor screening capability of clinical questionnaire for COVID-19. This validity is especially important to be raised for cost effective and safe screening tool of a rapidly progressive and fatal disease especially in filter clinics.

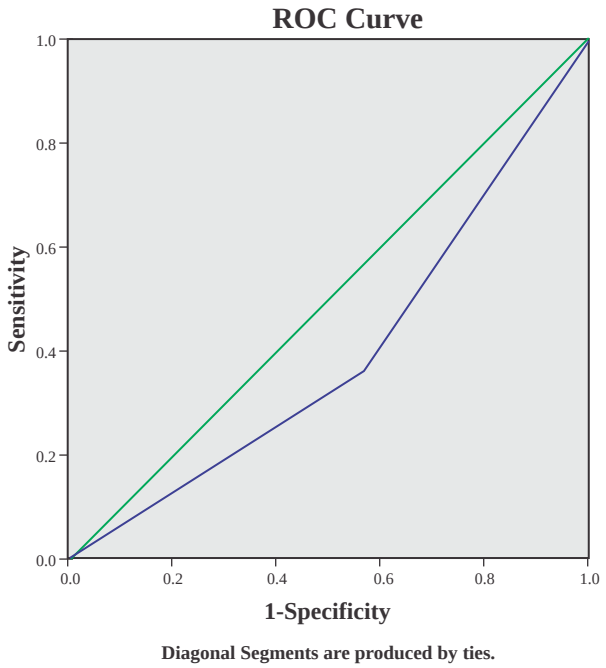

Fig 1: ROC curve for the clinical criteria based screening tool for COVID-19

DISCUSSION:

COVID-19 affected Pakistani population rapidly. The disease quickly spread to multiple countries in the world causing serious illness, and constant human-to-human transmission made it a worldwide Public Health Emergency of International Concern.[19]

Globally COVID-19 caused tremendous burden on the healthcare system. For timely implementation of effective public health response measures and surveillance , natural history of disease must be studied completely.[20]

Our study primarily focuses on clinical and epidemiological features of COVID-19 and validation of screening questionnaire in Pakistani context. Demographic profile of study population showed females to have been affected more than males(58.9% Vs 41.1%). This is almost reverse of findings of a research from Wuhan, China, which found that 56% of COVID-19 patients were men.[21] and another study by Tahir in East Karachi showing 64.6% males were affected.[22] This gender differential was more obvious in a study done by Ahmed M et al on multicenter retrospective data showed male predominance (80.9%).[23] Another study done by Farrukh G in Rahim Yar Khan showed 58% males are affected by COVID-19.[24] Males are naturally assumed to be at risk for severe disease and deaths due to COVID-19 owing to their exposure outside home.[25]

Out of 836 cases, approximately 614(73.4%) were sent for home isolation as compared to study by Tahir[22] in East Karachi, were 58% were sent for home isolation. That might be due to more asymptomatic patients in our study population which were 57% of total sample while there were only 9.0% (n=37) asymptomatic patients in the study at Karachi.

The clinical signs of COVID-19 range from asymptomatic or mild symptoms to severe illness and/or death. Most common presentation were myalgia 58%, cough 56.5%, vomiting 53%, fever 51.8%, loss of taste 51%. In contrast with study by Huang et al and Zheng Y et al in which most common presentation was fever (96%, 86%).[26,27] Pakistani population responded to infection through a wider range of clinical symptoms.

Approximately half of study population 361(43.2%) gave no history of contact and 184(22%) reported hospitals as contact history while in study by Tahir[23] about 89.3% of patients in study had positive history of exposure to cases and study by Zheng Y et al showed 49% gave history of contact with COVID-19 positive patient.[27]

Comorbidities such as diabetes, heart disease, hypertension, or other chronic conditions might make the patient's presentation and sequelae more problematic[23] most common co morbid condition reported in this study were hypertension 22% and diabetes 21%. Tan S C in China[20] found 51% patients were hypertensive and 21% were diabetic among those screened for COVID-19. Diagnosis of false positive in COVID-19 can cause useless self-isolation and can lead to mental and financial issues. Diagnosis of false negative in COVID-19 can result in spread of virus. The reference standards for evaluating the accuracy of screening strategies may include viral detection tests, such as standard RT PCR and clustered regularly interspaced short palindromic repeat.[28]

In present study, definition of suspected case initially given by WHO and then adopted by Government of Pakistan was validated as screening tool for filtering of

patients. This comprises of clinical features of COVID-19 including fever, chest pain, shortness of breath, cough etc. with history of travel. This approach is similar to Epidemiological and clinical factors being used by EPICOVID study in Italy; to test COVD-19. The two-phase EPICOVID19 study, which began in April 2020, involved a convenience sample of 201,121 Italian individuals. With the help of 38 questions, the Phase I questionnaire looked into six different domains, including socio-demographic factors, clinical evaluation, personal characteristics, and health status. It also asked about housing conditions, lifestyle, and behaviours after the lockdown.[15]

For adults aged 18-84 years, the cutoff score was 2.56 (sensitivity:76.56%; specificity:68.24%) for Nasopharayngeal swab positive subjects as compared to our study in which sensitivity was 63.6%, specificity of 56.6%.[15] Sensitivity of current study was much less than previous study that might be due to increased influx of asymptomatic patients out of fear only.

Conclusion:

COVID-19 clinical case definition poorly screened all COVID-19 positive patients due to the multiple and varied clinical features in our study population. Clinical agreement needs to be sought to adapt the case definition locally for cost effective screening.

Limitations:

Small sample size and limited scope ,due to single centre study so results can not be generalized.

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