Original Article

View Score: An early warning score to detect possible complications among COVID-19 patients

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Abstract

Introduction: Understanding pulmonary function at various phases after coronavirus disease 2019 (COVID-19) infection is critical for determining the exact pathophysiological mechanism of COVID-19. **Research Question:** What is the correlation between spirometry indices and clinical indicators in COVID-19 patients over a 6-week follow-up? **Objectives:** 1) To assess deterioration or improvement in spirometry parameters including forced vital capacity (FVC), forced expiratory volume in one second (FEV_1), and ratio FEV_1/FVC in COVID-19 patients. 2) To study the correlation between FVC, FEV_1, and FEV_1/FVC with oxygen saturation and clinical findings. **Materials and Methods:** A prospective observational study was conducted for a 6-week period among 25, COVID-19 patients who were either asymptomatic or mildly symptomatic. Each patient received a home-use-connected spirometer—SpiroPRO®, a pulse oximeter, and a thermometer from Briota Technologies Pvt Ltd. (BRIOTA). Patients and healthcare professionals were given training for performing spirometry twice a day as well as access to mobile apps was provided. Spirometry indices, patient symptoms, and vital statistics were used to calculate the VIEW™ score using machine learning algorithms. **Result:** The Bland–Altman plots showed that FEV_1 reduced slightly up to 21–28 days and comes back to normal around 42 days. VIEW™ score increased up to *day 21* and then decreased toward *day 42*. An increase in VIEW™ score increases the risk of COVID-19 complications. VIEW™ score and FEV_1 showed a significant correlation. **Conclusion:** Home-based spirometry acts as an effective tool for COVID-19 patients to predict lung complications and also promote self-monitoring thereby reducing the burden on the health system.

Keywords: COVID-19, daily spirometry, VIEW™ score

Introduction

Coronavirus disease 2019 (COVID-19) is a new and extremely invasive respiratory disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus, which poses a threat of transmission from person to person.[1] The World Health Organization (WHO) designated COVID-19 a pandemic on March 11, 2020, with around 20% of infected individuals requiring hospitalization and 6% requiring critical care and invasive ventilatory assistance.[2] Early epidemiological reports revealed that 8.2% of all cases had rapid and increasing respiratory failure, which was similar to acute respiratory

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distress syndrome (ARDS).[3] Concerns have been raised about the assessment of lung injury in discharged patients due to the widely documented lung injuries associated with COVID-19.[4] According to a recent study, COVID-19 pneumonia patients who have been discharged still had persistent abnormalities in their chest, with ground-glass opacity being the most common pattern.[5] The severe damage to alveolar epithelial and endothelial cells, as well as subsequent fibroproliferation, is a hallmark of COVID-19, implying the possibility of persistent vascular and alveolar remodeling resulting in lung fibrosis and/or pulmonary hypertension.[6,7] It has been reported from a retrospective study, that many patients when discharged, had imaging abnormalities. Lung function damage among patients with COVID-19 in the early convalescence phase needs immediate attention to prevent further complications and mortality.[8]

Spirometry Pulmonary function test (PFT) is the basic lung function test that is useful for detecting early change and disease progression. Once training is given it is easy to perform and can be performed anywhere by the trainee itself. Training from a reputable center or qualified person should be undertaken to ensure that the measures are understood as well as how to get the best results from the patient.[9] To have a more comprehensive understanding of the possible clinical outcomes of COVID-19 and the link between spirometry parameters and lung function deterioration, a prospective study was conducted among COVID-19-positive patients.

Methods

This was a prospective observational study conducted among patients with COVID-19 disease, for 6 weeks to understand pulmonary function. A total of 25 patients (asymptomatic or mildly symptomatic) comfortable in the use of an android phone and willing to follow instructions and given written consent were enrolled. Patients who had a previous history of heart surgery, eye surgery, abdominal surgery, pregnant females, and those who had recent myocardial infarction were excluded from the study. Patients who were discharged earlier than 14 days were asked to isolate themselves at home to reduce the risk of aerosol spread. Home-quarantined patients were advised to conduct spirometry in an atmosphere where there will not be any risk to other healthy members of the family. Patients who were in the hospital were told to perform spirometry in a private room or closed environment to prevent the spread of infection to other hospital personnel.

Briota Technologies Pvt Ltd. (BRIOTA) provided a personal VIEW™ kit, which contained a SpiroPRO® spirometer, a SpO_2 device, a digital thermometer, a digital glucometer, and a digital blood pressure meter to each patient. BRIOTA also provided safety supplies and consumables like filters, safety shields, covers, disposable mouthpieces, and sanitizers. VIEW™ Readings (Spirometry, Temperature, SpO_2, Blood Pressure, Sugar, etc.) and medical history was recorded by every patient every day from *day 1* to *day 42 (*6 weeks) along with symptoms if any. BRIOTA's professional respiratory technicians had given training to participants on how to take "self-readings" using SpiroPRO® to perform spirometry. SpiroPRO® was used to record forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1), SpO_2 device to check oxygen saturation level, and a digital thermometer to record body temperature. Readings were taken via video call by respiratory technician and patient. In accordance with the COVID-19 safety policy, hospital staff assisted patients who were hospitalized by taking blood pressure in hypertensive patients and random sugar levels for diabetic patients at least once a day. Patients who had previously been discharged from hospitals and were in home quarantine were educated remotely via video call by BRIOTA technicians.

Step-Wise Guidelines for Measuring Vital Parameters:

1. Digital Thermometer
   Wash hands with soap and warm water. Use a clean thermometer that has been washed in cold water, cleaned with rubbing alcohol, and then rinsed with water to remove the alcohol.
   Not to eat or drink anything for at least 5 min before taking the temperature because the temperature of the food or beverage could make the reading inaccurate. keep the mouth closed till placing the thermometer tip under the tongue and hold the thermometer in the same spot for about 40 s. Readings will continue to increase and the F (or C) symbol will flash during measurement. Usually, the thermometer will make a beeping noise when the final reading is done (usually about 30 s). If you are keeping track, record the temperature and the time. Rinse the thermometer in cold water, clean it with alcohol, and rinse again.
2. SpO_2 Meter
   This is a clip-like device to be placed on the finger, earlobe, or toe. Keep the probe on for as long as needed to monitor pulse and oxygen saturation. Once the test is over, the clip or probe should be removed. Prob should be cleaned with dry tissue to avoid any contamination.
2. Digital Glucose Monitor
   Wash hands to prevent infection. Turn on the glucometer and place a test strip in the machine when the machine is ready. Watch the indicator for placing the blood on the strip. Make sure your hand is dry and wipe the area you have selected with an alcohol prep pad and wait until the alcohol evaporates. Pierce your fingertip on the side of your finger, between the bottom of your fingernail to the tip of your nail. Place the drop of blood on or at the side of the strip. The glucometer will take a few moments to calculate the blood sugar reading. Follow your doctor's orders for whatever blood sugar reading you get.
4. SpiroPRO®
   Wash hands to prevent infection. Use a new disposable filter and safety shield for every reading. Make sure your hand is dry and wipe the spirometer with a clean cloth. Connect the SpiroPRO® device to the mobile app installed over Bluetooth. Start the spirometer device by pressing the red ON button. The spirometer device has a beep alarm to help

you get the correct position. Take a deep breath and then do forceful exhalation in the mouthpiece. You should try to exhale till you get all the three LED lights (1 s, 3 s, and 6 s) turned ON. Once exhale is complete, breathe in forcefully till you hear another beep, which is an indication of test completion. The mobile application will detect any errors during the test and if required may suggest repeating the test for a quality outcome.

From every patient data like clinical history, symptoms, COVID-19 test result, complete blood count (CBC), chest X-ray, random blood sugar, electrocardiogram (ECG), spirometry readings, temperature, respiratory rate, blood pressure (optional), SpO_2, clinical assessment, observations and recommendations of doctors, number of days patient hospitalization, number of days patient required hospital visit/doctor visit postdischarge, discharge summary, any incident of intensive care unit (ICU) admission, ventilator administration, or any other critical incident including death was recorded.

BRIOTA's software assigned each patient to one of the initial clinical evaluation zones A, B, C, D, and E based on the various data points collected in the system. Post software assessment and initial classification, doctors examined data collected in the VIEW™ system, and the zones (A, B, C, D, and E) were confirmed or adjusted. Upon which each patient's "Own Final Daily Judgement" of VIEW™ zone had been recorded. At this point of time, the doctors also looked at the spirometry data to understand any risk conditions [Table 1a and b].

Table 1a: Score range as per view score zone

VIEW™ Zone Marking	Score Range (Indicative)	
	Min	Max
Zone E	161 and above	
Zone D	121	160
Zone C	80	120
Zone B	40	79
Zone A	0	39

Table 1b: Depending on zone, action for investigator/ medical doctor

Zone E	Inform the responsible medical doctor of the patient's zone E classification at earliest possible opportunity—Briota sent an automated SMS for each such incidence to the investigator
Zone D	Patient needs close monitoring—if in hospital inform the responsible medical doctor, if at home—inform the patient to visit hospital as soon as possible—Briota sent an automated SMS for each such incidence to the investigator
Zone C	Request patient and family to take all precautions and inform any govt medical helpline if they need any help—Briota sent an automated SMS for each such incidence to the investigator and patient
Zone B	Request patient and family to take all precautions and inform medical helpline if they see any symptoms—Briota sent an automated SMS for each such incidence to the investigator and patient
Zone A	Green Zone: No specific action required—Briota sent an automated SMS to encourage patients to continue taking good care of their health and inform any government medical helpline if they need any help.

VIEW™ Score Based Patient Stratification:

Example of a machine learning algorithm for calculation of system VIEW™ score using linear regression analysis:

VIEW™ Score = a × (Temperature) + b × (SpO_2 concentration) + c × (Symptoms) + d × (Medical condition) + e × (COVID-19 status) + f

i.e. a, b, c, d, e, and f are coefficients and constants derived using a training dataset of participants.

Ethics statement

The study was reviewed and approved by the Institutional Ethics Committee of Symbiosis International (Deemed University) Pune, Maharashtra, India.

Data management

All the filled forms were entered into a software database. Critical fields in the tool were identified to check the completeness and accuracy of the form. All the critical fields and a few noncritical fields were monitored. Discrepancies up to 0.1% for the critical data and up to 1% for the noncritical data were considered acceptable. For the discrepancies related to data entry, the alternate forms were physically cross-checked. Statisticians cleaned and analyzed the data by excluding the missing data.

Data analysis

Data were analyzed by using the Statistical Package for the Social Sciences (SPSS) (IBMSPSS Chicago USA version 25). Descriptive statistics (mean and SD) were calculated for the continuous variables and the frequencies and percentages were calculated to summarize the qualitative variables. The multivariate logistic regression analysis was carried out to identify the determinants of Acute respiratory tract infection (ARI). $P < 0.05$ was considered statistically significant

Results

A total of 25 patients who were diagnosed with COVID-19 positive as asymptomatic or mildly symptomatic were included in the study. To achieve a high percentage of acceptable spirometry maneuvres, the technicians made a great effort to train each participant adequately. Reference data were collected to study the correlation between FVC, FEV_1, and FEV_1/FVC with SpO_2 data. This study presents the results of individual measurements of the main spirometric parameters in a population of home quarantine and hospitalized entities. In this study, data on potentially acceptable spirometric values, temperature, SpO_2, blood pressure, and sugar readings

Table 2: Demographic and spirometric characteristics of study participants

Parameters	Male (7)			Female (18)			*t*	df	*P*
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
Age (years)	34.14	8.552	3.232	25.39	4.654	1.097	3.318	23	0.003
FVC	106.57	29.585	11.182	89.72	33.129	7.808	1.173	23	0.253
FEV_1	88.57	12.608	4.765	77.39	21.133	4.981	1.302	23	0.206
Baseline VIEW™ score	88.57	91.365	34.533	51.67	53.165	12.531	1.268	23	0.217

Values are presented with mean and standard deviation. Ethnicity of the participants: Western, Northern, and Southern part of India

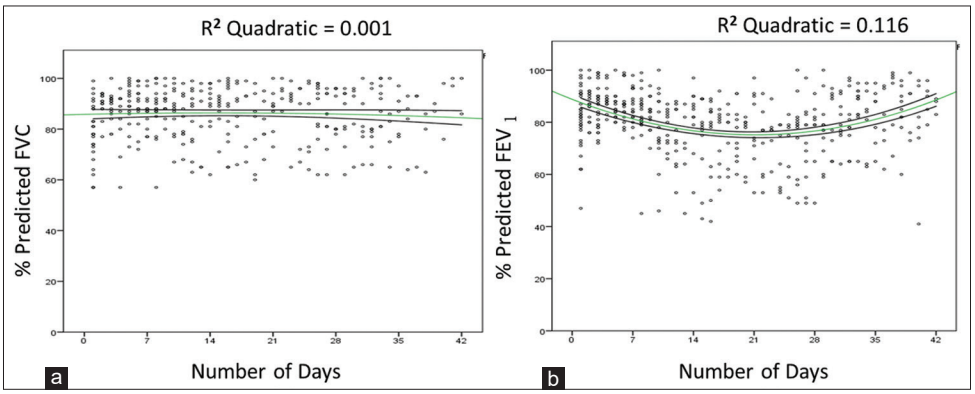

Figure 1: Bland-Altman plots showing the trend of spirometry findings. (a) FVC: Forced Vital Capacity, (b) FEV: Forced Expiratory Volume

were recorded one to three times daily from *day 1* to *day 42 (*6 weeks).

The mean age for males was 34.14 + 8.5 and for females, it was 25.39 + 4.6. The mean baseline VIEW™ score was 88.57 and 51.67 for males and females, respectively. [Table 2].

Figure 1a and b depicts the results of spirometry performed by participants. As shown in Figure 1a, the percent predicated FVC values were calculated in comparison with the number of days for which spirometry was performed. The results shown in the graph confirm that there was no gradual or substantial increase or decrease in the FVC values due to COVID-19.

Figure 1b illustrates the results for calculated percent predicated FEV_1 after 42 days. In the current study, the curve-shaped graph [Figure 1a] showed normal FEV_1 values after 42 days of spirometry performance. As depicted in graph, FEV_1 reduced slightly up to 21–28 days but it got normalized around 42 days. In this study, instead of evaluating a maneuvre, FEV_1 and FVC have been examined individually for acceptability. The patients' efforts to do spirometry twice every day till the end of the 42-day period were the only reason for these favorable results.

Evaluation of SpO_2 and VIEW™ score

As this study was dealing with COVID-19 patients, it was critical to assess the saturation of oxygen followed by spirometer parameters and calculate the VIEW™ score based on the results obtained from the entire study. Initially, even when blood oxygen levels were high or slightly low, few individuals complained of shortness of breath or coughing. But over a period of time, the oxygen levels were normalized as shown in Figure 2a. These first modest variations in oxygen levels could have been caused because of patients' initial mental and physical health difficulties. This research suggests that spirometric observations can be significantly correlated to oxygen saturation levels [Table 3].

The VIEW™ score, which defines the patient's health status, was calculated based on the analyzed lung function values. As previously noted, FVC and FEV_1 are critical factors in determining the prominence of pulmonary functions. The FVC levels did not gradually increase or decrease, however, the FEV_1 values did initially decrease around 21 to 28 days of testing before normalizing at the end of the trial. In Figure 2b, the observed VIEW™ score is related to the variation in FEV_1 observations. The VIEW™ score and FEV_1 are proportional in an indirect manner. As seen, a linear decrease in FEV_1 values between 21 and 28 days is associated with an increase in VIEW™ score during the same period. Increasing or decreasing FEV_1 observations influence patients' health and well-being, which can be demonstrated by assessing their VIEW™ score. In the end, it was found that FEV_1 was normal in all of the patients, indicating that their health was not deteriorating and it was stabilizing. These findings can be compared with the VIEW™ score output shown in Figure 2. The exact association between observed FEV_1 and VIEW™ score was determined using a correlation graph. Figure 2c shows that there is a positive association between the VIEW™ score and FEV_1. This can also be seen by looking at the statistical correlation in Table 3.

The Pearson coefficient is derived based on the observations collected throughout the investigation and is shown in Table 3. The graphed results are positively associated with those obtained following statistical analysis shown in Table 3. FEV_1

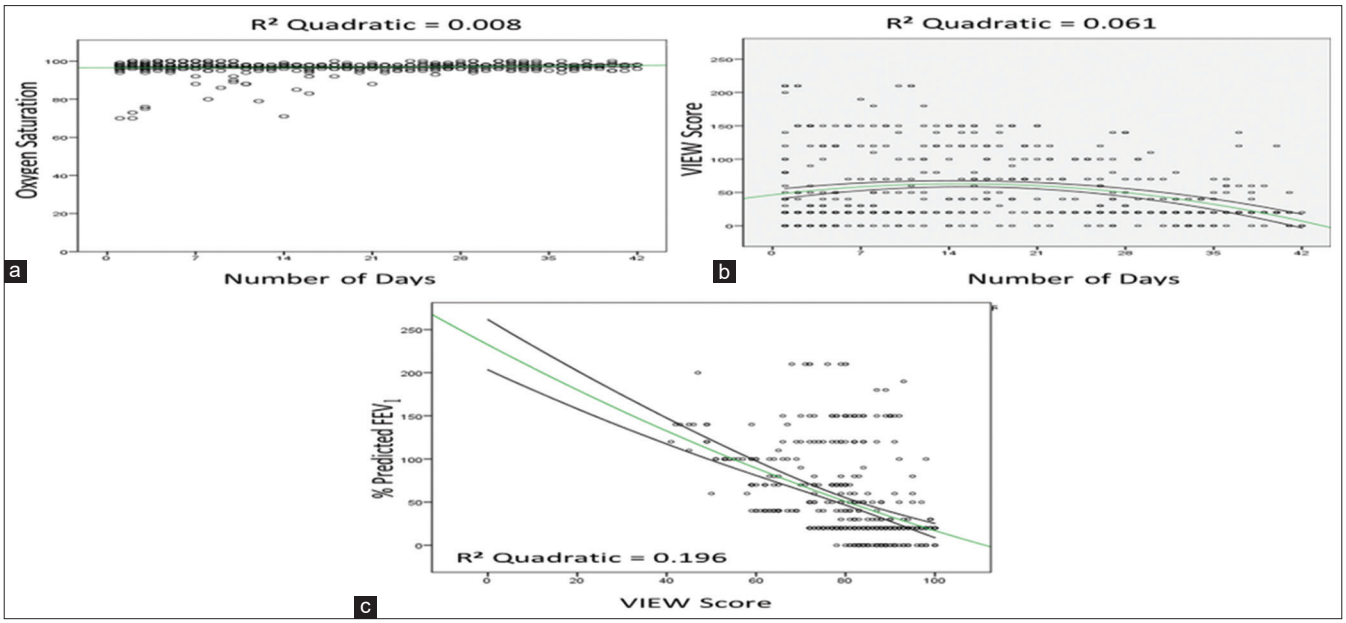

Figure 2: Bland–Altman plots expressing oxygen saturation in patients (a) and view score evaluation based on the studied vital lung function parameters (b). Correlation graph signifying the relation between VIEW score and FEV_1 (c)

Table 3: Pearson correlation for comparison with the observations

	O_2 Saturation	VIEW™ Score
PFVC		
Pearson Correlation	0.051	−0.130
Sig. (two-tailed)	0.812	0.536
n	25	25
$PFEV_1$		
Pearson Correlation	0.054	−0.468*
Sig. (two-tailed)	0.801	0.018
n	25	25
PFVC/FEV_1 ratio		
Pearson Correlation	−0.005	−0.222
Sig. (two-tailed)	0.981	0.286
n	25	25
O_2 saturation		
Pearson Correlation	1	−0.458*
Sig. (two-tailed)		0.024
n	25	25

**Correlation is significant at the 0.01 level (two-tailed). *Correlation is significant at the 0.05 level (two-tailed)

and VIEW™ score, as well as oxygen saturation and VIEW™ score, have a significant correlation with each other at 0.01 and 0.05 significance levels.

Discussion

This prospective observational study demonstrates the monitoring and recording of spirometric and other vital observations in patients diagnosed with COVID-19. Patients who were discharged from the hospital and were quarantined at home for less than 14 days were recommended to perform spirometry in an environment where a healthy person would not be at risk of infection. Patients in the hospital were instructed to perform spirometry in a private room or in a controlled environment where no risk of infection to a healthy individual, healthcare workers, or other patients existed. The stated scenarios show that the online home monitoring application developed by BRIOTA for patients diagnosed with COVID-19 is viable and reliable, with high patient satisfaction. The FEV_1 and FVC measures taken at home and in hospitals showed a strong correlation, indicating that they are an excellent way to keep track of a patient's health. Thus early detection of complications through such method will be helpful for the physician and will also prevent unnecessary hospitalization, especially during pandemics, which will be beneficial to reduce the burden on healthcare system.

The outcomes of spirometry were relevant and acceptable. As demonstrated in Figure 1a and b, there was no alteration in FVC until the end of the trial, but a steady decline in FEV_1 was noted in the middle of the study, indicating the patients' unstable circumstances. However, at the end of the study, FEV_1 measurements were found to be normal, indicating that the patients' health had stabilized.

The internal variability and conformity to the daily spirometry at home were high. The internal variability and good concordance of home and hospital spirometry in our study is a reflection of investigations with some other home monitoring applications for other chronic lung conditions.[10,11] Furthermore, the variability of the home spirometry readings in the current study was similar to a prior study done by Morlion *et al.*[12] who had utilized home monitoring of pulmonary function in lung transplant recipients via the internet, showed positive feasibility, and provided reproducible data.

Obtaining repeatable results is the best indicator that the patient achieved the maximum FEV_1 and FVC and that she or he was

capable of.[13] The degree of repeatability, as measured by the grading system, guides the level of confidence in the interpretation of results. As a result, spirometry testing in the workplace or at home could be a noninvasive and extremely successful way to monitor a member's lung capacity and well-being as predicted by Kuller *et al.*[14] in his study. Figure 1a and b depicts the results of spirometry performed by participants. As shown in Figure 1a, the percent predicated FVC values were calculated in comparison with the number of days for which spirometry was performed. The results shown in the graph confirm that there was no gradual or substantial increase or decrease in the FVC values due to COVID-19. Generally, an increase or decrease in FVC is considered as a crucial element causing obstruction of airflow and chronic bronchitis. In contrast to the current study, Saad *et al.*[15] reported a clinically significant increase in FVC among **chronic obstructive pulmonary disease (**COPD) patients and Huang *et al.*[16] detected abnormalities in the pulmonary function tests, i.e. values of FVC, FEV_1/FVC ratio less than 80% of predicted values in his study on COVID-19 patients.

Besides FVC, the other factor essential to evaluate lung capacity and function is FEV_1.

In this study, like FVC, FEV_1 also showed normal values on spirometry. Similar results were noted by Lewis *et al.*[17] while Huang *et al.*[16] detected abnormal values of FEV_1. Similarly Fumagalli *et al.*[18] in his study on COVID-19 pneumonia patients noted significant alterations in lung function.

In our study, oxygen saturation levels were measured after the spirometric functions. The Bland-Altman (B and A) analysis was used to assess and depict the level of agreement (LoA) between oxygen levels and the number of experimental days, as mentioned above in the results section. The B and A graph in Figure 2a presents SpO_2 readings taken with a pulse oximeter.

Later, using VIEW™ system, VIEW™ score for the patients was evaluated. This score is responsible to determine the health status of the patients. As explained in the result section, VIEW™ score is completely dependent on the observations acquired from the patients. A significant correlation has been established between VIEW™ score and FEV_1 as well as VIEW™ score and SpO_2 levels. A gradual decrease in FEV_1 and an increase in VIEW™ score shows a positive link and was also proved by performing statistical analysis. A significant correlation was observed between the VIEW™ score and FEV_1.

The results of the current study revealed a significant correlation between FEV_1, SpO_2 levels, and VIEW™ score. As a result, this novel home monitoring SpiroPRO™ handheld spirometer device and VIEW™ mobile application developed by BRIOTA Private Limited technology appears suitable for use in daily practice and future research.

In this study, we made the first step to enhance the health and wellness of patients by using a smartphone-based tool to record daily spirometric and SpO_2 observations and access lung functions of COVID-19 patients.

Our approach may also enable real-time remote communication between the patient and the physician, who can provide advice based on the patient's self-measured vital statistics. This was extremely important for patients who are unable to leave their homes due to a quarantine enforced by the COVID-19 outbreak. In this regard, our approach was appropriate for use in conjunction with the emergency management organizational model, providing a useful tool to assist citizens with telephone triage and to facilitate particularly critical care for patients.

Finally, it should be noted that the proposed solution can improve care not only for COVID-19 patients at home but also for chronic patients, especially those affected by cardiovascular diseases.

Conclusion

In the current study, a novel artificial intelligence technology was used, which gave early advice or indicated deterioration in lung function. Physicians can effortlessly prescribe this VIEW™ technology for monitoring and controlling the symptoms of high-risk patients who are in danger of respiratory infection.

Limitation

The only limitation observed in this study was adherence to the system. Adherence was found to be good until 28 days but unfortunately started to reduce at the end of the study. In future prospects, we propose to improve the efficacy and adherence of this system and plan to access the health and wellness of not only COVID-19 patients but also severe chronic disease patients.

Ethical approval and/or Institutional Review Board (IRB)

Approval is to be submitted within this file document: Ethical Approval received from IEC of Symbiosis International (Deemed University), Pune, Maharashtra, India and Approval No. is SIU/IEC/150 dated 13/06/2020.

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Conflicts of interest

There are no conflicts of interest.

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