Prediction Equations for Calculating Maximal Inspiratory Pressure from Spirometry and Thoracic Ultrasound After COVID-19 with Gastroesophageal Reflux Disease in Indonesian Adults: A Cross-sectional Study

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ABSTRACT

Background: *This study aimed to determine the prediction equations for calculating maximal inspiratory pressure using spirometry and thoracic ultrasonography (USG) after COVID-19 with gastroesophageal reflux disease (GERD).* ***Methods:*** *This cross-sectional study was conducted from January to December 2022 and included Indonesian adults recruited by consecutive sampling after they developed COVID-19 with GERD symptoms. The following tests were used: spirometry (forced vital capacity (FVC) and forced expiratory volume in 1 s (FEV_1); thoracic USG (left diaphragm excursion (LDE) and right diaphragm excursion (RDE); and respirometry (maximal inspiratory pressure (MIP). The data were analyzed using Pearson correlational analysis and multiple linear regression.* ***Results:*** *Sixty-two participants were recruited: mean age 37.23 ± 9.76 years and average MIP 49.85 ± 18.13 cmH_2O. MIP correlated significantly with FVC (r = 0.307; p = 0.015), LDE (r = 0.249; p = 0.051), FEV_1(r = 0.186; p = 0.147), and RDE (r = 0.156; p = 0.221). We developed two models based on their applicability. Model 1 provides an MIP prediction equation for health facilities that have only spirometry: 23.841 – (20.455 × FEV_1) + (26.190 × FVC). Model 2 provides an MIP prediction equation for health facilities that have both spirometry and thoracic USG: 3.530 – (20.025 × FEV_1) + (25.354 × FVC)*

+ (4.819 × LDE). ***Conclusion:*** *In this study, measures of respiratory function correlated significantly with diaphragm excursion. MIP can be predicted from spirometry and thoracic USG data. Healthcare facilities can choose the prediction equation model that best meets their situation.*

Keywords: *COVID-19, prediction equation, maximum inspiratory pressure, spirometry, thoracic ultrasound.*

INTRODUCTION

The COVID-19 virus causes post-acute sequelae, commonly referred to as "long COVID", which can lead to respiratory and gastrointestinal symptoms and disability. Long COVID can also impact multiple organ systems.[1] In terms of respiratory symptoms, it can cause restriction type of respiratory dysfunction.[2] Farr et al. reported that 76% of patients have functional abnormalities of the diaphragm muscle after severe COVID-19.[3] COVID-19 can also cause gastrointestinal symptoms such as gastroesophageal reflux disease (GERD) by affecting the lower esophageal sphincter through the crural diaphragm. The diaphragm supports and regulates pressure to maintain lower esophageal sphincter (LES) integrity. Diaphragmatic dysfunction weakens the LES, leading to gastric content reflux and worsening GERD symptoms. [4]

The COVID-19 pandemic has increased the prevalence of GERD from 24.8% to 34.2%, according to Al-Mohamed et al.'s research of 198 patients in Jordan.[5] In a study conducted by Fauzi et al., which analyzed 9800 patients in Indonesia, the prevalence of GERD was found to be 67.9% in the pandemic group and 61.8% in the pre-pandemic group.[6] Ma et al. discovered that COVID-19 patients have a hazard risk (HR) of 1.41, which means that patients with COVID-19 have a 14.1% higher chance of developing GERD than those who don't have COVID-19.[7] Long COVID has emerged as a significant and unprecedented challenge for healthcare professionals.[8]

Evaluation of inspiratory muscle function is important for screening patients and monitoring treatment. A respirometer evaluates inspiratory muscle strength using the maximal inspiratory pressure (MIP) value. However, this device may not be available in every healthcare facility.

This study aimed to establish prediction equations for MIP values using spirometry and thoracic ultrasonography (USG) data. We hypothesized that equations to predict MIP could be generated from these data.

METHODS

In this cross-sectional study, we collected data from medical records at Persahabatan Hospital in Jakarta. All patients were recruited consecutively and evaluated based on the inclusion and exclusion criteria outlined below. Each participant was given a clear explanation of the study objectives and was required to sign an informed consent form. Only those who signed the informed consent form were included in the study.

The study included adult men or women who were admitted to the COVID ward and had experienced a moderate COVID-19 infection, with clinical signs of pneumonia such as fever, cough, dyspnea, and fast breathing with moderate COVID-19 treatment. However, they did not show any signs of severe pneumonia, including a SpO2 level of less than 90% on room air.[9] All symptoms must have occurred no more than 6 months before the start of the study, GERD questionnaire (GerdQ) score >7,[10,11] age 18–60 years, willingness to participate, and ability to understand and follow the study instructions. The exclusion criteria were a history of ventilator use during hospitalization, uncontrolled heart or lung disease, pregnancy or breastfeeding, history of abdominal, spine, or thoracic surgery, postural abnormality (severe scoliosis or kyphosis), use of medication for dyslipidemia for >1 year, or use of gastrointestinal prokinetic medication for >1 month. The study was conducted in the Department of Physical Medicine and Rehabilitation, Persahabatan Hospital, from January to December 2022. The study protocol received clearance from the Ethical Committee of Persahabatan Hospital (Ethics Number:

100/KEPK-RSUPP/1/2022). Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis (TRIPOD) guidelines were followed in the study's conduct and reporting.[12]

The study began with anamnesis and primary data collection, which comprised a GerdQ, MIP, forced vital capacity (FVC), forced expiratory volume in 1 s (FEV_1), and measures of diaphragm excursion (DE). The GerdQ score was used to confirm GERD symptoms. MIP was measured in cmH_2O using a respiratory pressure meter (MicroRPM; CareFusion Micro Medical, Kent, UK). The measurement started with the patient seated. The patient was then asked to exhale maximally to measure the residual volume and then to inhale maximally through the MicroRPM and to hold this for 1–2 s. The measurement was repeated three times, and the analysis used the highest value.[13] Spirometry was used to measure FVC (%), and FEV_1 (ml), and the highest of three measurements for each variable was used in the analysis.[14,15] Thoracic USG was used to measure DE (cm).[4,16] The DE was classified as left diaphragm excursion (LDE) and right diaphragm excursion (RDE). The evaluation of DE was conducted in collaboration with a thoracic radiologist who was blinded to all patient information. All data and results were kept confidential from the patients. The measurement protocol has been registered with Indonesia's intellectual property right (HAKI) number EC00202311324.

All data were analyzed using SPSS Statistics version 23.0 for Windows (SPSS Inc., Chicago, IL, USA) by statisticians who weren't involved in the assessment. Univariate analysis was used to evaluate the data distribution, and Pearson correlational analysis was used to assess the relationships between MIP and other variables. Multiple linear regression was used to create the two MIP prediction models: model 1 for healthcare facilities with equipment for spirometry only and model 2 for healthcare facilities with equipment for spirometry and thoracic USG. The analysis excludes any missing data. The significance threshold was set at a p-value of 0.05. We calculated that the study required a minimum of 50 participants to complete the linear regression analysis.[17]

The study was internally validated using the bland-Altman analysis. The data used to create prediction models will be resampled to validate the method. Comparison of mean difference and interval of agreement between the base model and 10 validation models of repetition. The coefficient interval for this validation was set at 95%.[18]

RESULTS

Figure 1 presents a flow chart of participant recruitment according to the TRIPOD guidelines. A study conducted at Persahabatan Hospital in Jakarta involved the screening of medical records of 599 patients. Out of these, 537 were excluded from the study as they either did not have GERD

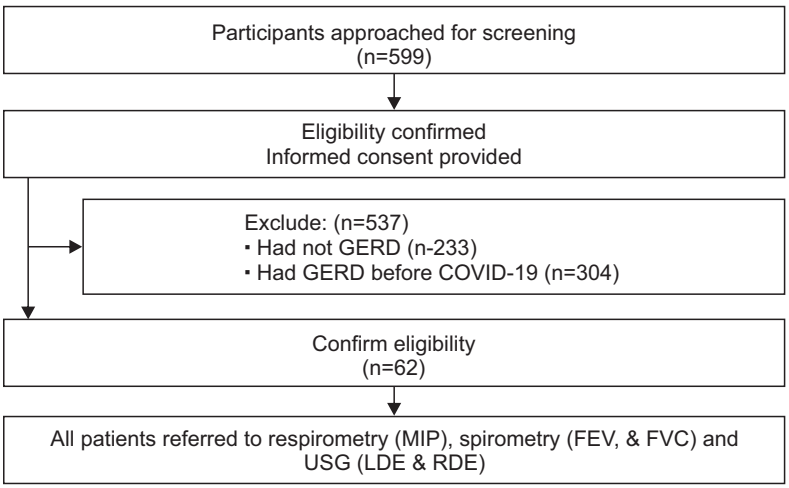

Figure 1. Flow chart of participant enrollment and analysis according to Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis (TRIPOD) guidelines.

(n = 233) or had GERD before COVID-19 (n = 304). Ultimately, only 62 eligible patients were enrolled in the study. There were no missing data.

The patients were 34 men (55%) and 28 women (45%) aged between 21 and 60 years. Two patients (2%) smoked. The characteristics of the study participants are shown in **Table 1**.

Table 1. Characteristic of the study participants.

Characteristic	n (%)
Sex	
Male	34 (54.8%)
Female	28 (45.2%)
Age (years)	37.23 ± 9.76
Smoking status	
Not smoking	60 (97.8%)
Smoking	2 (2.2%)
Inspiratory muscle function (respirometry)	
MIP (cmH_2O)	49.85 ± 18.13
Lung function (spirometry)	
FEV_1 (ml)	2.39 ± 0.57
FVC (%)	2.86 ± 0.62
Diaphragm excursion (USG)	
RDE (cm)	4.78 ± 0.92
LDE (cm)	4.50 ± 0.84

Data reported as number (%) or mean ± SD

Table 2 shows the results of the multivariate analysis with Pearson correlational analysis between the dependent variable (MIP) and independent variables (FEV1, FVC, RDE, and LDE). All variables (FEV_1, FVC, RDE, and LDE) correlated positively with MIP.

Table 2. Correlations between MIP and FEV_1, FVC, RDE, and LDE.

Variable	r	p*
FEV_1	0.186	0.147
FVC	0.307	0.015
RDE	0.156	0.221
LDE	0.249	0.051

*Pearson correlational analysis

Based on the results presented in Table 2, a multivariate analysis was conducted and included two prediction models according to the type of healthcare facilities. Model 1 was developed for healthcare facilities that use only spirometry, and model 2 for healthcare facilities that use both spirometry and thoracic USG. The prediction equations for the two models are as follows:

Model 1 = $23.841 - (20.455 \times FEV_1) + (26.190 \times FVC)$

Model 2 = $3.530 - (20.025 \times FEV_1) + (25.354 \times FVC) + (4.819 \times LDE)$.

From the prediction equations above, constant values of 23.841 and 3.530 were obtained from the linear regression. The RDE was not included in the prediction equations because it was insignificant for predicting MIP. **Table 3** and **Table 4** summarize the prediction model and its variables. The coefficients of determination of MIP were 0.156 in model 1 and 0.205 in model 2. The r values for models 1 and 2 were 0.395 and 0.453, respectively.

Table 3. Prediction equation and its variable.

Model summary						
Model	Variable	Unstandardized Coefficients		Standardized Coefficients		
		B	Standard Error	Beta	t	p
1	FEV_1	-20.455	9.823	-0.641	-2.082	0.042
	FVC	26.190	8.979	0.897	2.917	0.005
2	FEV_1	-20.025	9.617	-0.627	-2.082	0.042
	FVC	25.354	8.799	0.869	2.881	0.006
	LDE	4.819	2.545	0.222	1.894	0.063

Table 4. Summary of the models for the prediction equations

Model summary*								
Model	*r*	r^2	Adjusted r^2	Q1	Q2	Q3	Residual**	
							Minimum	Maximum
1	0.395***	0.156	0.128	–12.21	0.27	8.45	–2.181	2.874
2	0.453****	0.205	0.164	–10.14	–0.28	8.02	–2.221	2.885

Model 1: prediction equation model from spirometry with the requirements for linear regression met.
Model 2: prediction equation model from spirometry and thoracic USG with the requirements for linear regression met.
*Dependent variable; **standard residual value; ***predictor: constant, FEV_1 (spirometry), FVC (spirometry); ****predictor: constant, FEV_1 (spirometry), FVC (spirometry), LDE (thoracic USG)

Table 5. Internal validation for prediction equations model 1 and 2

	Mean	LoA Min*	LoA Max**
Model 1			
Basic Model	0,00	-32,64	32,64
Validation Model 1	-0,62	-34,27	33,03
Validation Model 2	-1,56	-33,25	30,14
Validation Model 3	2,05	-29,97	34,08
Validation Model 4	-1,37	-30,66	27,91
Validation Model 5	-0,04	-32,05	31,97
Validation Model 6	0,77	-32,22	33,77
Validation Model 7	1,27	-33,03	35,57
Validation Model 8	-0,22	-33,44	33,00
Validation Model 9	0,67	-29,32	30,67
Validation Model 10	-1,68	-33,60	30,25
Model 2			
Basic Model	0,00	-31,68	31,68
Validation Model 1	-1,02	-33,56	31,53
Validation Model 2	-1,77	-32,55	29,00
Validation Model 3	2,25	-28,62	33,12
Validation Model 4	-1,46	-29,34	26,42
Validation Model 5	-0,29	-31,09	30,52
Validation Model 6	0,84	-30,96	32,63
Validation Model 7	1,04	-32,28	34,36
Validation Model 8	0,07	-31,75	31,90
Validation Model 9	0,71	-28,14	29,55
Validation Model 10	-1,91	-32,75	28,92

*Limit of Agreement Minimum (LoA Min)
**Limit of Agreement Maximum (LoA Max)

Results of internal validation of model 1 (spirometry only) and model 2 (spirometry and USG) using the Bland-Altman analysis can be seen in **Table 5**. Model 1 maximal mean data was 2,05 with the maximal limit of agreement for model 1 was 35.57 cmH2O. Model 2 maximal mean was 2,25 with maximal limit of agreement for model 2 was 34.36 cmH2O.

DISCUSSION

In this study, we investigated whether MIP prediction equations could be created using data from the types of tests available in various healthcare facilities. The MIP prediction equation for model 1 was designed for healthcare facilities using only spirometry, and model 2 used both spirometry and thoracic USG. Spirometry and Thoracic USG were chosen because they are more widely available in healthcare facilities than respirometry.

Prediction equations of MIP reported in previous studies by Sriboonreung et al.[19], Pessoa et al.[20], and Lista-Paz et al.[21] were compiled from pulmonary function tests, sex, age, and body weight. Moeliono et al. created a prediction equation using the measurement of thoracic expansion.[22] Our study examined the feasibility of using spirometry and thoracic USG to predict MIP in healthcare facilities with limited resources and equipment. The American Thoracic Society recommends using a portable handheld mouth respiratory pressure meter (e.g., MicroRPM) to measure respiratory muscle function and MIP. Thoracic USG can be used to measure diaphragmatic excursion.[23]

The patients included in our study were adults aged 21–60 (mean 37.23 ± 9.76 years) who had had COVID-19 within six months. This age range is consistent with that reported by Ford et al., who found that COVID-19 is more common in adults.23 It is recommended that these paper prediction equations be used only for adults with gastrointestinal symptoms after COVID-19.

These MIP prediction equations may be applicable in different healthcare facility settings. Healthcare facilities with only spirometry can use model 1, and those with spirometry and thoracic USG can use model 2 to predict MIP. These two

prediction equations can serve as alternative predictors of MIP if respirometry is unavailable.

The diaphragm, particularly on the crural side, is believed to control lower esophageal sphincter tone and prevent gastroesophageal reflux, which can cause various gastroesophageal symptoms. Prolonged lung inflammation near the rural side of the diaphragm results in decreased respiratory function in adults post-COVID-19 with gastroesophageal symptoms.[15]

The mean MIP value for all patients in our study was 49.85 ± 18.13 cmH_2O. This MIP value is lower than those reported by Sriboonreung et al.[19] (92.87 ± 27.19 cmH_2O) and Lista-Paz et al.[21] (126.7 ± 27.8 in men and 98.74 ± 24.1 in women). The primary reason for the lower MIP in our study may be that the patients had not recovered fully from COVID-19 infection at the time of data collection. Other factors that can influence MIP are age, sex, and body weight.[25–27]

All variables examined in our study correlated positively with MIP. Sriboonreung et al. and Lista-Paz et al. found positive correlations between study variables and MIP. Our study's prediction models 1 and 2 produced significant positive correlation coefficients for MIP (r = 0.453 and r = 0.395, respectively). Sriboonreung et al. MIP predictions model from pulmonary functional test results and sex has moderate correlation coefficients for MIP (r = 0.684).[19] The coefficients of determination for models 1 and 2 were 0.128 and 0.168, respectively; that is, the independent variables in these regression models could explain 12.8% and 16.8% of the variation of the dependent variable. The higher the value, the better the prediction equation.[19,21] Models 1 and 2 had poor reliability, with intraclass correlation coefficient values of 0.304 and 0.290, respectively.[28]

Figure 2 summarizes post-COVID-19 symptoms and their parameters. Health facilities or hospitals without respirometers to evaluate respiratory muscle strength can use the prediction equations along with all other suitable parameters.

Strengths and Limitations

The study's novelty lies in its approach to predicting MIP value using a new prediction equation. All eligible patients were included, which helped to ensure an unbiased selection of participants. The MIP, FEV_1, FVC, and DE data were collected by certified examiners who were blinded to the patient's diagnosis, which helped

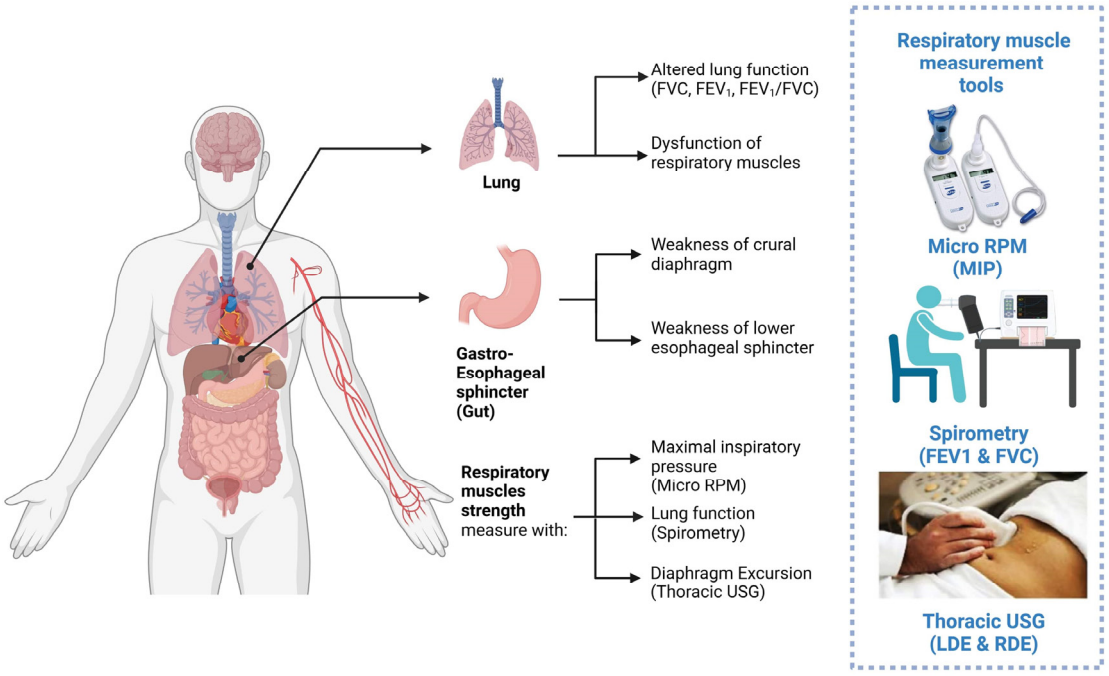

Figure 2. Post COVID-19 dysfunction and its parameters. (Created by Biorender)

to ensure reliability and validity. There were no missing data.

This study's limitations include the population being limited to patients with gastrointestinal symptoms assessed within 6 months of having COVID-19. Due to time constraints, further research and external validation within the same population are necessary to validate the prediction equations and improve their accuracy.

CONCLUSION

The correlation between respiratory function and DE underscore the intricate relationships between these physiological elements. Developing equations to predict MIP by integrating spirometry and thoracic USG data represents a significant advance. However, to assess comprehensively the efficacy of exercise therapy for improving MIP, further in-depth studies are needed to evaluate the progressive changes in MIP after therapy.

The predictive equations described here have potential applicability across diverse healthcare settings by offering a standardized and versatile tool for assessing respiratory function. This potential universality ensures these equations can be used easily in different clinical environments, contributing to a more holistic understanding and management of respiratory conditions. The study results can be applied to a specific population. These prediction equations will help calculate MIP using alternative tools such as spirometry and thoracic USG when a respirometer is unavailable.

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CONFLICT OF INTEREST

The authors declare no conflict of interest in this research.

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