Brief Report

Race-Neutral Spirometry to Predict Residual Volume in COPD Patients: The Pittsburgh Residual Volume Calculator

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***Running Head*: Spirometry-Based RV Prediction in COPD**

***Keywords*:**air trapping**;** bronchoscopic lung volume reduction; endobronchial valve**;** pulmonary function test**;** emphysema

***Abbreviations*:** COPD: chronic obstructive pulmonary disease; RV: residual volume; GLI: Global Lung Function Initiative; FEV1: forced expiratory volume in 1 second; FVC: forced vital capacity; SCCOR: Specialized Center for Clinically Oriented Research; ROC: Receiver Operating Characteristics Curve; SD: standard deviation; RV_{est}%: estimated residual volume percent predicted;

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Abstract

Body plethysmography, the accepted standard for measuring residual volume (RV), a marker of hyperinflation used in selection for lung volume reduction procedures, has limited availability in resource-constrained settings. We previously developed and validated a spirometry-based model to estimate RV in COPD; however, that model predated race-neutral GLI reference equations and was not easily applied to real world decision making. Applying GLI global reference equations to spirometric measures from 450 adults with COPD from the University of Pittsburgh SCCOR cohort, we used fractional polynomial multiple regression analysis to determine an estimated RV % predicted (RV_{est}%) from spirometric and demographic data: RV_{est}% = 909.17+4.09*FVC% - 93.15*$\sqrt{FVC}$%-208.12*FEV1/FVC-2.01*Age-11.05*1(if male). This demonstrated strong predictive accuracy (R^2 = 0.72). For RV ≥150%, ≥175%, and ≥200% predicted, AUCs: 0.89, 0.92, and 0.91, respectively. At RV_{est}% ≥172, sensitivity for RV ≥175% (the most accepted inclusion threshold for volume reduction procedures) was 94% and specificity was 90Predicted probability for a given patient's RV_{est}% at various true RV cutpoints, corresponding to e.g., lung volume reduction selection thresholds, can then be determined using a second provided formula. This race-neutral "Pittsburgh RV Calculator" prediction model to estimate RV can support referral decisions for lung volume reduction in under-resourced environments. (see https://www.estimaterv.com/)

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Introduction:

Chronic obstructive pulmonary disease (COPD) presents with significant unmet needs for effective treatment and management. Precision approaches based on unique biologic or physiological attributes have allowed progress in precision targeting of the right therapy to the right patient. Lung volume reduction procedures offer one such precision therapy targeting patients with an emphysema dominant phenotype and significant air trapping designated by elevations in end expiratory Residual Volume (RV).

Body Plethysmography is the accepted standard to measure RV, but its availability is limited geographically by preference and resources due to equipment cost and greater technical complexity[1-3]. We have previously applied spirometry and demographic data to estimate RV in COPD patients[4]. The availability of this model enables primary care or geographically more remote centers without access to body plethysmography to estimate the likelihood and magnitude of hyperinflation purely based on the more accessible spirometry measurements.

Our prior publication did not apply the more recent race neutral GLI spirometry reference equations that are the current standard recommendation within our specialty guidelines[5, 6]. Further, the outputs of our prior report were not easily applied to decision making. In this paper, we applied GLI Global reference equations to the spirometric measures to estimate RV. We further present logit modeling equations to allow the clinician user to define the likelihood of an individual patient's spirometry and demographic characteristics to be associated with residual volume values above cut points of 150, 175, and 200% predicted. Such cutoffs, in the context of other clinical and imaging characteristics, are common thresholds used in determining candidacy for surgical and bronchoscopic volume reduction. While this model is not intended to fully replace gold standard plethysmographic measurements, it may provide clinicians with insight

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into when the additional effort and expense of formal lung volume testing is justified, including for the evaluation of hyperinflation and potential referral to lung volume reduction programs.

Methods: Adults (age > 40 years) with at least 10 pack-year tobacco use, and FEV1/FVC<0.7 were recruited in the Specialized Center for Clinically Oriented Research (SCCOR) cohort at the University of Pittsburgh (N = 450) using methodology for physiologic measurements as previously described[4, 7]. We applied GLI Global race neutral reference equations to the spirometric measures to calculate the estimated RV predicted value for each study participant[3, 8]. The protocol was approved by the University of Pittsburgh Institutional Review Board, and each participant signed a written informed consent. We used fractional polynomial multiple regression analysis to determine an estimated RV% predicted (RV_{est}%) from FEV1/FVC, FVC% predicted, age, and sex. Agreement between estimated and observed RV% was assessed with Bland-Altman analysis. Then, we used three logit models to calculate the coefficients and intercepts of RV_{est}% for three measured RV cut points, i.e., 150%, 175%, and 200%. We used the Receiver Operating Characteristics Curve (ROC) and the Youden index to calculate the diagnostic performance and optimum cut off for RV_{est}% to determine each cut point.

Results: The mean (SD) age was 64 (7.2) years, 54% were male, and 95% were White. The mean (SD) of measured FEV1/FVC, and FVC% were 0.48 (0.15), 87 (24), respectively. The mean (SD, range) for measured RV% was 170 (71, 56-454). The Estimated Residual Volume % predicted (RV_{est}%) prediction equation by multiple regression was:

formula 1: $RV_{est}\% = 909.17+4.09*FVC\% - 93.15*\sqrt{FVC}\%-208.12*FEV1/FVC-2.01*Age-11.05*1(\text{if male})$

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The R-squared of the model was 0.72. The Bland-Altman plot showed a mean difference of 0.2, and 95% limits of agreement -75.2- 75.6 between measured and RV_{est}% (Figure 1).

The frequency of measured >150%, >175%, and >200% was 49%, 38%, and 30%, respectively. The parameters of the logit model for each of these cut points and their diagnostic performances are presented in Table 1.

The best cut points for RV_{est}% to determine each of these categories were 167, 172, and 176. The RV_{est}% has 94% Sensitivity, 90% specificity, with a 9.3 positive likelihood ratio to diagnose hyperinflation using RV >175%. The performance of each cut point for hyperinflation diagnosis is presented in Table 2.

In patients with RV_{est}% > 172, which is the optimum cut point for predicting an RV >175% (Table 2), the probability of having a hyperinflation as determined by RV>175%, is 85% (posterior odds = prior odds* LR+, Table 2). This RV_{est}% increases the odds of hyperinflation diagnosis by 128-fold (Diagnostic OR, Table 2).

Predictive performance: The slope (intercept) of the calibration plot for an RV cut off of 175%, and 1.00 (-0.11), and (Figure 1B) with positive net benefit for the prediction model across various thresholds compared to other decisions (Figure 1C). The slopes (intercepts) of calibration plots for RV of 200% were 0.90 (0.02) and 1.05 (-0.11). The decision curve for these RV cut points showed positive net benefit as well (data not presented).

Clinical Vignette: A 70-year-old male with severe exertional dyspnea, with spirometry revealing an FVC equal to 78% predicted using GLI global reference equations and FEV1/FVC of 0.22 is seen in a primary care clinic with severe emphysema reported on his chest CT scan.

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Plethysmography lung volume testing is not easily accessed, however the clinician would like to know whether this patient is likely to have sufficient lung hyperinflation to be considered for referral for lung volume reduction intervention. The $RV_{est}\%$ was calculated using *formula 1*:

$RV_{est}\% = 909.17+4.09*78 - 93.15*\sqrt{78}-208.12*0.22-2.01*70-11.05*1 = 208\%$

The predicted probability of this man having an RV >175% (see Table 1, *formula 2*) is

$$\frac{1}{1+e^{(-10.23+0.05*208)}} = 90\%$$

A tool is available online that utilizes the above formulas to calculate $RV_{est}\%$ and it's probability of having a measured RV that e.g. meets lung volume reduction criteria.

https://www.estimaterv.com/

Discussion: In this letter, we have adapted our RV prediction model to accommodate spirometric measures calculated based on GLI global race neutral reference equations. The ""Pittsburgh RV Calculator" estimated RV using patient demographic and spirometric measures agrees with the RV measured by plethysmography. The incorporation of race-neutral reference equations into our prediction model is consistent with recent guidelines and could improve assessment in all populations based on most recent guidelines. Our original Predictor selection was guided by physiologic plausibility. We hypothesized that FEV_1/FVC would capture the degree of airflow obstruction and associated hyperinflation, whereas FVC would reflect the consequences of incomplete lung emptying and air trapping, after accounting for age and sex. Importantly, the strong performance of the model in both derivation and validation cohorts within the original manuscript demonstrates that accurate estimation of plethysmographic lung volumes can be achieved using a simple set of readily available spirometric variables without dependence on less accessible clinical data.

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Surgical and bronchoscopic volume reduction procedures have been shown to improve lung function, quality of life, and exercise tolerance and prolong survival[9]. These procedures are underutilized in patients, in part related to difficulty and lack of experience in obtaining and interpreting measures of lung hyperinflation. Lack of access to gold standard plethysmography assessment is a crucial barrier in the selection of patients for these procedures in low resource and community settings[1-3]. We use logit modeling to determine the likelihood of an individual patient's metrics exceeding clinically meaningful hyperinflation cut points. The RV_{est}% has an excellent area under the curve to determine hyperinflation for RVs above 150, 175, and 200 % predicted. The threshold of RV >175 % predicted has the greatest evidence base in selecting patients within pivotal bronchoscopic volume reduction clinical trials in patients with heterogeneous emphysema. Whereas, RV values above 200% predicted are recommended for more homogeneous patients, and in patients with the most ideal heterogeneous emphysema distribution, selection of patients with less hyperinflation to the 150% predicted range has been associated with clinical improvement[10-14].

Beyond selection for volume reduction procedures, measures of hyperinflation associate better than conventional FEV1 with important outcomes such as quality of life and survival[15, 16]. An association of residual volume with increased risk of coronary artery disease has been postulated to reflect the impact of hyperinflation on systemic inflammatory response[17]. Such findings thus further support the application of our RV estimate model to large epidemiologic studies containing spirometric but not lung volume metrics.

A limitation of our model is the underrepresentation of Black Patients in the model development. While our cohort was predominantly white (>90%), reflecting ongoing challenges in recruiting and retaining underrepresented populations in medical research, this does not diminish the

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importance of applying race neutral equation modeling. Current ATS/ERS guidance endorses its use across all patient populations, making it important to understand the performance in real-world cohorts, including predominantly white populations and the smaller number of Black patients included in the cohort. Moreover, the limited racial diversity of our cohort is not unique; the GLI plethysmography equations were themselves derived exclusively from participants of European ancestry as "Data from non-European ancestry populations were insufficient to develop multi-ethnic equations[18]." Consequently, examining the impact of race-neutral equations within our cohort remains clinically relevant and aligned with the most recently updated pulmonary function testing standards. We further acknowledge that, while z-scores are appropriately recommended by ERS/ATS for physiologic interpretation, corresponding z-score thresholds have not replaced percent-predicted values in the clinical-trial evidence base or established eligibility criteria for lung-volume-reduction interventions and were not the target of our model development.

In conclusion, we provide "Pittsburgh RV Calculator", a prediction model to estimate residual volume as a measure of lung hyperinflation using race-neutral spirometry reference values. This model has excellent test characteristics to predict lung hyperinflation. This tool could be useful in a non-specialty or under-resourced environment to improve decision making in referral for lung volume reduction treatment.

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Table 1- Logit model parameters to predict hyperinflation at different cut off using RV_{est}%*.

Measured RV cut point	Frequency	Coefficient of RV_{est}%	Intercept	Area Under ROC
>150%	0.49	0.05	-8.33	0.89
>175%	0.38	0.05	-10.23	0.92
>200%	0.30	0.05	-10.70	0.91

*The predicted probability for each cut point can be calculated from this equation:

formula 2: $Predicted\ Probability = \frac{1}{1+e^{(Intercept+Coeffecient*\mathrm{RVest\%})}}$

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Table 2- Test characteristics of RV_{est}% for hyperinflation diagnosis.

Measured RV cut point	Optimum cut point for RV_{est}%	Sensitivity*	Specificity*	LR+*	LR-*	Diagnostic OR*
>150%	167	0.84	0.93	12.9	0.167	77.2
>175%	172	0.94	0.90	9.28	0.072	128
>200%	176	0.98	0.84	6.04	0.027	223

* For optimum cut point

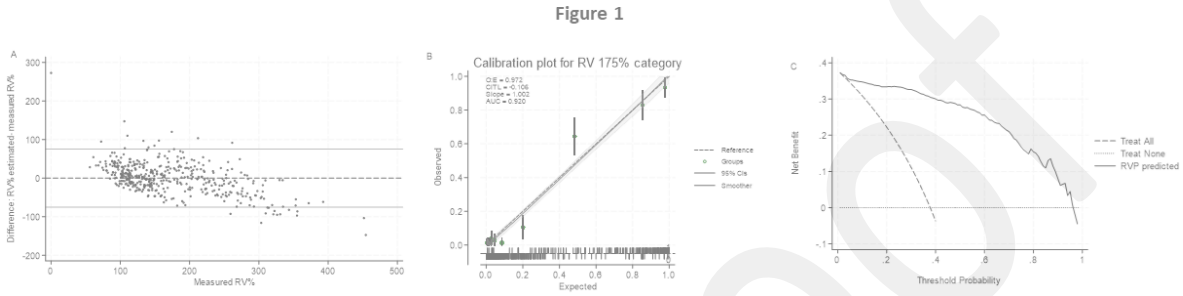
LR = Likelihood Ratio

OR = Odds Ratio

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Figure 1- A) Bland-Altman plot of predicted RV. The dashed line shows the average difference, and the solid lines show the limit of agreement. B) The calibration plot of RV predicted for the RV binary of 175%. C) The Decision curve plot for the RV% predicted for a cut point of 175%.



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