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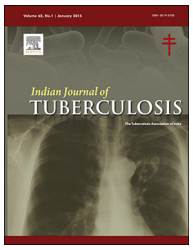

Original Article

Prediction equations for spirometry in adults in western India

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ABSTRACT

Background: Spirometry is an essential investigation in pulmonology. The predicted normal spirometry values depend on various physiological parameters. This study was conducted to collect updated information on pulmonary functions in normal adults from western India.
Material and methods: A prospective observational study was undertaken at a tertiary hospital in Mumbai enrolling healthy subjects, 18–75 years, with ethnic origin from western India. Spirometry measurements were carried out as per ATS/ERS-2005 guidelines using a non-heated Fleish Pneumotachograph spirometer. Data was analyzed using SPSS for Pearson's correlation analysis, multiple linear regressions and log transformations of variables to get the best prediction equations.
Results: 310 subjects (185 males, 125 females) were included. Lung function values were higher in men as compared to women. In multivariate linear regression models, age and height were major predictor variables for all spirometry parameters. Addition of weight as a determinant variable did not make significant contribution to the models except for PEFR in males and F_{75} in females. Regression equations were established for FVC, FEV_1, FEV_1/FVC ratio, PEFR, $F_{25–75}$, F_{50}, and F_{75}. The standard-error-of-estimate was provided to enable computation of lower limits of normal for these parameters.
Conclusion: We propose regression equations for spirometry variables developed using the current standards for adult West Indian population fulfilling the long-felt need for updated equations.

1. Introduction

Spirometry is a vital investigation carried out by most pulmonologists. Interpretation of spirometry data classifies the severity of the underlying obstructive or restrictive abnormality. However, the interpretation of normal and disease depends on the predicted values. The predicted values depend mainly on anthropometry parameters, gender and ethnicity, though environmental, genetic, socioeconomic, and technical factors also contribute. Wide variations have been observed in diverse ethnic groups. Studies conducted in the

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different regions of India suggest the same diversification due to presence of various ethnic groups in our country.[1] Not only India in the US also NHANES and Strong heart studies[2] have pointed out the differences in various racial groups. Inappropriate choice of prediction equations may lead to errors in interpretation of spirometry data affecting management.[1] Therefore, it is imperative that locally valid equations be used in pulmonary function laboratories. Initial studies in Mumbai date back to 1970s.[3] However, no study has been conducted in west Indian population after 1987[4] to know the compatibility of predicted values. Technical and procedural aspects of spirometry have undergone major changes since then and the most recent statement of standardization was published by the task force of the American Thoracic Society and the European Respiratory Society (ATS-ERS) in 2005.[5] A significant cohort effect also exists such that the general health of a population undergoes changes due to changes in the environmental exposures. Thus, there is an urgent need to regularly update prediction equations in any population. No study has been carried out after the previously mentioned ones[3,4] in western India using the 2005 standardization of spirometry. In order to address this gap in information, we carried out a study to develop prediction equations for spirometry parameters for the western Indian population.

2. Material and methods

This was a prospective observational study carried out at a tertiary hospital in Mumbai as a part of the Indian Council of Medical Research (ICMR) study conducted from March 2009 to March 2012 at four centers nationwide after ethics approval. The sample size taken for the various centers was Mumbai 310 (185 males, 125 females), Delhi 685 (489 males, 196 females), Bangalore 407 (275 males, 132 females), and Kolkata 238 (92 males, 146 females). The data was analyzed at the Delhi center which was the coordinating center. Subjects aged 18 years and above were drawn after a written informed consent from a wide social and economic background, both urban and rural, from the eligible attendants of patients, healthy volunteers from Institutions, general public, private, and public sector offices. The minimum sample size recommended for multivariate regression analysis for lung function parameters is 150.[6] Age distribution matched the adult population of India according to the Census 2011 data.[7] After taking a written informed consent, detailed history and examination were done. A standardized respiratory questionnaire, based on the British Medical Research Council questionnaire was administered. A chest X-ray was performed. Smokers, subjects with past or current history of chronic respiratory diseases, thoracic cage abnormalities, cardiac or systemic diseases, recent upper or lower respiratory tract infection, and those not willing to give consent were excluded. Spirometry was done in all subjects. Spirometry was carried out according to the standardization recommendations of the American Thoracic Society/European Respiratory Society Task Force.[5] A Fleisch Pneumotach spirometer (KOKO, nSpire, UK) was used. The handle of the pneumotach contained the analog-to-digital converter and the digital signal was fed into the computer for analysis by nSpire software. The spirometer was calibrated daily according to the manufacturer's instructions using a 1 L syringe. The room temperature, barometric pressure, and humidity were noted and entered into the software. Then, details of the subject including date of birth, gender, height, and weight were entered. The maneuvers were performed in the sitting position with a nose-clip applied. The subject was asked to inhale completely and rapidly with a pause of <1 s at TLC and exhale with maximum force until no more air was expelled out while maintaining an upright posture. At the completion of expiration and on signal from the technician, the subject was asked to inhale completely. The maneuver was monitored on the computer screen. Throughout the procedure, loud verbal encouragement was given to obtain the expiratory and inspiratory maneuvers completely with maximal force. The technician observed the subject for distress, and also the computer display during the test to help ensure maximal effort with quality control as recommended by the ATS/ERS Task Force. The physician was always present to supervise. Quality control was ensured as described in the ATS-ERS statement.

Statistical analysis was done at the Delhi center. It was carried out using SPSS 20.0 (SPSS Inc., Chicago, USA) and Graph Pad Prism 4.01 (Graph Pad Inc., USA) software. Data from men and women was analyzed separately. Data was presented as mean $\pm$ SD, and as percentages as appropriate. Pearson's correlation analysis and univariate regression, both linear and nonlinear, were carried out to identify the significant predictor variables from among age, height, and weight for each of the dependent variables. Prediction equations were developed using the multiple linear regression procedure. Linear and nonlinear models were developed. Log transformations of dependent and other transformations of the independent variables were carried out to get the best model. Final models were selected considering simplicity and ease of clinical application, highest predictive capability (R^2), and satisfaction of assumptions of regression analysis. The goodness of fit was examined by testing for independence of predictor variables and the normality of the residuals. Unusual and influential observations were examined. These included outliers (standardized residuals more than ± 3), points with high leverage, and high influence. Analysis was repeated excluding these observations to determine their impact on the models and the original models were retained if the effect on the equations was small and inconsequential. Bland Altman analysis was carried out to evaluate the agreement of predicted and observed values to check for accuracy of the models. Internal validation of the derived models was done using the boot-strap resampling procedures, which were based on 2000 replications, size equal to original sample and with replacement separately for each gender. For each bootstrapped sample, new models were developed using the predictors present in the final model. The bias in regression coefficient (RC) of each predictor was calculated by the difference between average RC value from bootstrapped samples and RC value obtained from original sample. The previous equations in the same population[4] were applied to the study sample and data was compared with predicted values from the current equations using the unpaired ''t'' test.

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