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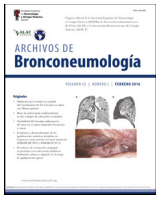

Original Article

GOLD Staging System is Appropriate to Predict Mortality in Older People With Chronic Obstructive Pulmonary Disease

Claudio Pedone[a], Renato Giua[a,*], Nicola Scichilone[b], Vincenzo Bellia[b], Raffaele Antonelli-Incalzi[a]

[a] Area di Geriatria, Università Campus Bio-Medico di Roma, Rome, Italy
[b] Dipartimento Biomedico di Medicina Interna e Specialistica (Di.Bi.MIS), Università di Palermo, Palermo, Italy

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ABSTRACT

Introduction: In the new GOLD classification the reduction of FEV1, expressed as percentage of predicted value (FEV1PP), is considered an important prognostic factor. However, the use of FEV1PP may introduce bias, especially if based on equations derived from populations different from the one under study. We evaluated how well the GOLD classification stratifies the mortality risk when FEV1PP is based on an equation developed in the same population that gave rise to cases, externally developed equations, or as FEV1 divided by cubed height ($FEV1/Ht^3$).
Methods: We studied 882 participants aged ≥65 years. Bronchial obstruction was defined using a fixed cut-off of 0.7 for FEV1/FVC. Predicted values of FEV1 were derived from equations based on the same sample of the cases included in this study and from the European Respiratory Society equations. Severity of bronchial obstruction was also classified according to quartiles of $FEV1/Ht^3$.
Results: All the classification systems showed a non-statistically significant linear tendency with 5-years mortality risk. For the 15-years mortality, the linear trend across severity stages is more evident for GOLD classifications, with significant increments in the hazard ratio. Stratification by $FEV1/Ht^3$ could better discriminate the functional status of participants.
Conclusion: The severity of bronchial obstruction according to GOLD classes may stratify mortality risk better than quartiles of $FEV1/Ht^3$, whereas the second seems to be more suited to stratify the risk of clinical outcomes. Concerns about the use of externally developed reference values to calculate FEV1PP do not seem confirmed, at least for GOLD classification.

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El sistema de estadificación GOLD es adecuado para predecir la mortalidad en personas de edad avanzada con enfermedad pulmonar obstructiva crónica

Palabras clave:
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RESUMEN

Introducción: En la nueva clasificación GOLD, la reducción del FEV_1 expresada como porcentaje del valor predicho (FEV_1PP) se considera un factor pronóstico importante. Sin embargo, usar el FEV_1PP puede introducir sesgos, especialmente si se basa en ecuaciones derivadas de poblaciones diferentes de la que se estudia. Se ha evaluado cómo de adecuadamente estratifica GOLD el riesgo de mortalidad cuando el FEV_1PP se basa en una ecuación desarrollada con la misma población en la que se dieron los casos, usando ecuaciones desarrolladas externamente, o con el FEV_1 dividido por la altura al cubo (FEV_1/A^3).

Abbreviations: BODE index, Body-Mass Index, Airow Obstruction, Dyspnea, and Exercise Capacity Index; COPD, chronic obstructive pulmonary disease; ERS, European Respiratory Society; FEV1, Forced Expiratory Volume in 1 second; $FEV1/Ht^2$, FEV1 divided by height squared; $FEV1/Ht^3$, FEV1 divided by height squared or cubed; FEV1PP, FEV1 expressed as the percent of the predicted value; FEV1-ERS, FEV1 expressed as the percent of the value predicted by ERS equations; FEV1-SARA, FEV1 expressed as the percent of the value predicted by estimating equations derived from SaRA study; FVC, forced vital capacity; FVCPP, FVC expressed as the percent of the predicted value; GOLD, Global Initiative for Obstructive Lung Disease; postBD, post-bronchodilator; SaRA, Salute Respiratoria nell'Anziano – Respiratory Health in the Elderly; SGRQ, Saint George Respiratory Questionnaire.

* Corresponding author.
E-mail address: renatogiua@alice.it (R. Giua).

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Métodos: Estudiamos a 882 participantes de edad ≥65 años. La obstrucción bronquial se definió utilizando un punto de corte fijo de 0,7 para FEV_1/FVC. Los valores pronosticados de FEV_1 se derivaron de ecuaciones basadas en la misma muestra de los casos incluidos en este estudio y de las ecuaciones de la *European Respiratory Society*. La gravedad de la obstrucción bronquial también se clasificó de acuerdo con los cuartiles de FEV_1/A^3.
Resultados: Todos los sistemas de clasificación mostraron una tendencia lineal estadísticamente no significativa en el riesgo de mortalidad a 5 años. Para la mortalidad a 15 años, la tendencia lineal a través de los diferentes estadios de gravedad es más evidente para los estadios GOLD, con incrementos significativos en la razón de riesgo. La estratificación por FEV_1/A^3 podría discriminar mejor el estado funcional de los participantes.
Conclusión: La gravedad de la obstrucción bronquial según la estadificación GOLD puede estratificar mejor el riesgo de mortalidad que los cuartiles de FEV_1/A^3. Sin embargo, lo segundo parece el método más adecuado para estratificar el riesgo de resultados clínicos. Las reticencias respecto al uso de valores de referencia desarrollados externamente para calcular FEV_1PP no parecen confirmarse, al menos para la clasificación GOLD.
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Introduction

For several years, the grading of chronic obstructive pulmonary disease (COPD) severity proposed by the Global Initiative for Obstructive Lung Disease (GOLD) has been based on Forced Expiratory Volume in 1 second (FEV1) only. This classification could not adequately predict clinical outcomes[1,2] and therefore other prognostic indices, such as the BODE index[3] have been proposed to stratify the severity of COPD. In 2011, the GOLD proposed a new classification of COPD severity that in addition to the level of FEV1 reduction also took into account severity of symptoms and frequency of exacerbations,[4] thus generating a panel of four different stages of disease severity (A through D). This new classification, however, does not seem to have better prognostic capacity,[5] and the GOLD group has recently proposed a new classification that merges the GOLD 2007 and GOLD 2011 classes.[6] In this document, the severity of obstruction expressed as reduction of FEV1 is still considered a very important prognostic factor at the population level.

One potential issue with the GOLD classification is that FEV1 is expressed as the percent of the value predicted by estimating equations (FEV1PP). This approach may introduce bias, and it has been shown that GOLD classification can lead to misclassification of older patients.[7,8]

Due to these limitation, alternative ways of standardizing FEV1 have been proposed, such as FEV1 standardized residuals, FEV1 divided by height squared or cubed ($FEV1/Ht^3$) or expressed as a function of the sex-specific first percentile.[9] $FEV1/Ht^3$ may be more informative than FEV1PP to predict clinical outcomes even in elderly patients.[9–11] Our hypothesis is that part of the suboptimal prognostic capacity of the GOLD stratification comes from the use of equations developed in population that are different from the one that gives raise to the COPD cases. In this study, we evaluated how well the GOLD classification stratifies the mortality risk when FEV1 is expressed as percentage of the value predicted by an equation developed in the same population that gave rise to cases, externally developed equations, or as $FEV1/Ht^3$.

Methods

Study population

Between January 1996 and July 1999 a total of 1970 participants were recruited within the context of the SaRA (Salute Respiratoria nell'Anziano – Respiratory Health in the Elderly) study. Details on the SaRA project are available elsewhere.[12] This is a multi-center Italian project investigating various aspects of chronic airway diseases in people ≥65 years of age attending pulmonary or geriatric outpatient clinics for any reason. Participants were in stable conditions when the spirometry was performed. Enrollment was on a consecutive basis. The study design was approved by the Ethical Committee of the coordinating center (#276/2012). From this dataset, we selected 1296 participants with post-bronchodilator (postBD) spirometry. We then excluded people with a history of asthma ($N = 224$). Of the remaining participants, information on vital status as of December 2010 was available for 882; these patients had clinical and spirometric characteristics comparable to those of subjects lost to follow-up. Causes of death were derived from death certificates, and were available for 74% of participants.

Pulmonary function tests

All the centers were equipped with an identical fully computerized water-sealed Stead-Wells spirometer (Baires System; Biomedin; Padua, Italy) that met the standards of the American Thoracic Society recommendations for diagnostic spirometry.[13] At baseline, tests were performed with a standardized technique in all centers and a quality control process was successfully implemented: all the centers achieved a high quality performance in spirometry.[12] Obstruction was defined using a fixed cut-off of 0.7 for FEV1/forced vital capacity (FVC) considering the postBD spirometry. Predicted values of FEV1 were derived from equations based on the same sample of the cases included in this study (FEV1-SARA)[14] and the European Respiratory Society (FEV1-ERS).[15] FEV1PP was categorized according to the classes proposed by the GOLD guidelines to stratify severity of obstruction ($FEV1PP \geq 80\%$, $80\% < FEV1PP \geq 50\%$, $50\% < FEV1PP \geq 30\%$, and $FEV1PP < 30\%$). Severity of bronchial obstruction was also classified according to quartiles of $FEV1/Ht^3$.

Analytic approach

The demographic and clinical characteristics were compared across COPD severity groups defined using FEV1-SARA. We included in this analysis the distance walked in 6 min, expressed as percent predicted,[16] and comorbid diseases such as ischemic heart disease, heart failure, and stroke. Smoking was analyzed as cumulative exposure (pack-years). The multi-dimensional BODE index was also included, as it is able to predict mortality in older people.[17] The SaRA questionnaire did not include a specific item on exacerbations, therefore we combined two of the Saint George Respiratory Questionnaire (SGRQ) items ("During the past 3 months how many

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