

Classifying the severity of COPD: are the new severity scales better than the old?

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SUMMARY

BACKGROUND: Forced expiratory volume in 1 second cut-off points establish the severity of chronic obstructive pulmonary disease (COPD).

OBJECTIVES: To compare how the American Thoracic Society (ATS), the British Thoracic Society (BTS), the Global Initiative for COPD (GOLD) and the ATS-European Respiratory Society (ATS-ERS) guidelines for rating COPD severity predict several significant outcomes.

DESIGN: Five-year prospective cohort study. Spirometry was performed and health-related quality of life (HRQoL) assessed using the Short Form 36 Health Survey and the Saint George's Respiratory Questionnaire. Hospital admissions resulting from COPD exacerbation and mortality during a 5-year follow-up period were recorded.

RESULTS: In all guidelines, the number of admissions was directly associated with COPD severity. The sensi-

tivity and specificity for 5-year respiratory mortality were respectively 0.21 and 0.97 for the GOLD/ATS-ERS, 0.51 and 0.79 for the BTS, and 0.37 and 0.89 for the ATS guidelines. A similar pattern was seen for all-cause mortality. For HRQoL, statistically significant differences between guidelines were seen only for the BTS and ATS scales.

CONCLUSIONS: These guidelines did not consistently stratify patients with regard to 5-year mortality and HRQoL. Although the BTS system was slightly superior, none of the guidelines were closely related to these outcomes. Other instruments are needed for a better determination of the severity of COPD.

KEY WORDS: chronic obstructive pulmonary disease; disease severity; guidelines; hospital admissions; mortality; quality of life

IN AN ATTEMPT to standardise the diagnosis and treatment of patients with chronic obstructive pulmonary disease (COPD), several guidelines have been published: the American Thoracic Society (ATS) guidelines in 1995,¹ the British Thoracic Society (BTS) guidelines in 1997,² the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines in 2001,³ and consensus guidelines from the ATS-European Respiratory Society (ATS-ERS) in 2004.⁴ Each of these considers forced expiratory volume in 1 second (FEV₁) to be the fundamental parameter for determining the severity of COPD.

As the proposed FEV₁ cut-off points in these guidelines are not evidence-based, they may not correlate closely with outcomes. Although there is currently a trend toward the use of multidimensional severity classification systems,^{5,6} these scores have not yet been included in published guidelines. Furthermore, in all of these scoring systems, FEV₁ plays a role, and thus contributes to the variability in patient severity scores, depending on the cut-off points used.

This study was designed to determine which of the key classifications of severity best identifies hospitalisation due to severe exacerbation of COPD, 5-year mortality, and health-related quality of life (HRQoL).

METHODS

Between February 1998 and February 1999, we prospectively recruited 611 consecutive COPD patients who routinely visited one of five out-patient clinics affiliated to a general teaching hospital, Hospital de Galdakao-Usansolo, Vizcaya, with a catchment area population of 300 000.

Patients were included in the study if they had been diagnosed with COPD at least 6 months previously and had been under treatment for at least 6 months. Patients had to have been stable, defined as no increase in respiratory symptoms or changes in treatment, for 6 weeks prior to inclusion. Other inclusion criteria were FEV₁ <80% of predicted, with an FEV₁/forced expiratory vital capacity (FVC) quotient

of <70% and a negative bronchodilation test with a change in FEV₁ of <200 ml and under 15% of the baseline value (all values obtained following bronchodilation). Patients were excluded from the study if they had asthma, extensive pulmonary tuberculosis or neoplastic processes. All patients were followed for a period of 5 years.

Spirometry was conducted at entry in the study following the criteria of the ATS⁷ and the Spanish Society of Pneumology and Thoracic Surgery (SEPAR),⁸ using a Master-Scope-PC spirometer (Erich Jaeger GmbH & Co, KG, Wuerzburg, Germany). Theoretical values were those defined by the European Community for Steel and Coal.⁹

Disease severity was characterised using FEV₁ cut-off points included in the ATS,¹ BTS,² GOLD³ and ATS-ERS⁴ guidelines. Both the GOLD and ATS-ERS guidelines include four stages with identical FEV₁ cut-off points: Stage I (mild), FEV₁ ≥80%; Stage II (moderate), FEV₁ 50–80%; Stage III (severe), FEV₁ 30–49%; and Stage IV (very severe), FEV₁ <30%. Given that all the patients in our study had FEV₁ <80%, we eliminated Stage I of the GOLD/ATS-ERS guidelines and renamed Stage II as 'mild', Stage III as 'moderate' and Stage IV as 'severe' to make these categories more comparable with the ATS and BTS categories.

Information on all hospital admissions due to exacerbation of COPD during the 5-year follow-up period was obtained by telephone once in Year 3 and by personal interview in Year 5, and confirmed by checking the database from our hospital, which is the patients' referral hospital. Vital status was initially determined by telephone interview. All reported deaths and dates of death were confirmed by reviewing medical reports and by examining the hospital database and public death registries. In all cases, cause of death was based on the hospital reports and public death registries. When death occurred outside the hospital, the research team analysed all data and established the cause of death.

HRQoL was assessed using the generic Short Form-36 Health Survey (SF-36)¹⁰ and the disease-specific Saint George's Respiratory Questionnaire (SGRQ).¹¹ We used versions validated for Spanish populations.^{12,13} These questionnaires were filled out at the beginning of the study to assess the association between HRQoL and severity classifications.

Patients provided verbal informed consent to take part in the study. The study was approved by the Hospital de Galdakao-Usansolo research committee.

Statistical analysis

We present mean and standard deviations for continuous variables and frequencies and percentages for categorical variables. To study the association between vital status and hospitalisations after 5 years of follow-up among severity categories for each

guideline, we used the χ^2 and Fisher's exact tests for categorical variables. For continuous variables, as HRQoL generic and specific measures, the analysis of variance test was performed with the Scheffé test for multiple comparisons among severity categories of each guideline.

Each guideline was also dichotomised (mild vs. moderate/severe or mild/moderate vs. severe categories) to compare their predictive ability of mortality. We then estimated the sensitivity, specificity, positive (PPV) and negative predictive values (NPV) for each guideline. Sensitivity was defined as the percentage of patients identified as having severe COPD among those who died, specificity as the percentage of non-severe subjects among those who did not die, and accuracy as the percentage of screening results, both positive and negative, that were correct. PPV was defined as patients who died among those classified as severe, and NPV as patients who did not die among those classified as non-severe.

To estimate the area under the curve (AUC) parameter for each severity guide we used logistic regression models, with mortality as the dependent variable and each classification class as the independent variable in separate models. All effects were considered significant at $P < 0.05$. All statistical analyses were performed using SAS for Windows statistical software, version 8.2 (SAS Institute, Inc, Cary, NC, USA).

RESULTS

Of the 729 patients in the initial cohort, 63 were not included because they were aged >81 years and were therefore unlikely to complete the 5-year follow-up study, 27 patients had recently been diagnosed with cancer, 11 patients had sensorial problems, 6 patients had been diagnosed with Alzheimer or dementia and 11 suffered from other diseases that made it difficult for them to undergo the different tests.

A final total of 611 consecutive patients therefore participated in the study. The clinical characteristics of the sample have been described elsewhere.¹⁴ The mean age was 67.2 ± 8.4 years. The percentage of male patients was 97.7%. Mean FEV₁ was 1.37 ± 0.46 l and $49.7\% \pm 14.6\%$ of the predicted value.

The classification criteria of severity according the guidelines are shown in Table 1. The three severity classifications yielded significantly different distributions of the patients (Figure 1).

Hospitalisations for COPD exacerbations and mortality

There were 341 hospitalisations up to the first follow-up at 3 years and a total of 537 up to the end of the study. Rates of hospitalisation for exacerbations of COPD increased with increasing severity across all three classification systems. Overall, 26.6% of patients categorised as having mild COPD by the GOLD/

Table 1 Spirometric criteria of COPD severity classification according to GOLD/ATS-ERS, BTS and ATS guidelines*

	Mild COPD FEV ₁ %	Moderate COPD FEV ₁ %	Severe COPD FEV ₁ %
GOLD/ATS-ERS	<50 to 80	30 to 49	≤29
BTS	<60 to 80	40 to 59	≤39
ATS	≥50	35 to 49	≤34

*Disease severity characterised using FEV₁ cut-off points included in the guidelines. In GOLD/ATS-ERS guidelines the stages are renamed as follows: Stage II = mild, Stage III = moderate, and Stage IV = severe, to make the categories more comparable with the ATS and BTS categories, and Stage I (FEV₁ > 80%) was excluded.

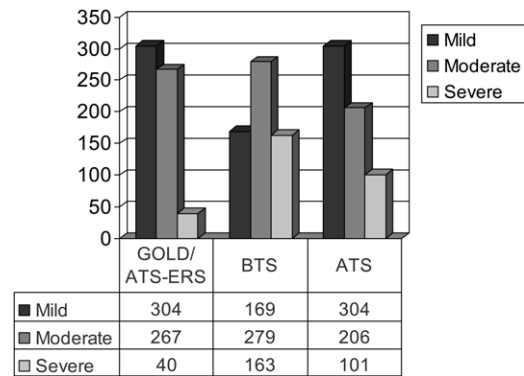
COPD = chronic obstructive pulmonary disease; GOLD = Global Initiative for Chronic Obstructive Lung Disease; ATS-ERS = American Thoracic Society–European Respiratory Society; BTS = British Thoracic Society; FEV₁ = forced expiratory volume in 1 s.

ATS-ERS and ATS guidelines were hospitalised at least once over the 5 years of follow-up, compared with 23.1% of those in the BTS mild COPD category. In total, 55% of the patients classified as severe by the GOLD/ATS-ERS, 43.6% by the ATS and 41.7% by the BTS guidelines were hospitalised.

No significant differences were observed in hospitalisation rates across the three classification systems (Table 2).

The mortality rate was 27.2% (166 patients) over the 5 years of follow-up: 81 patients (48.2%) died as a result of COPD exacerbation and another 16 (9.6%) died from other respiratory causes; 40 patients (24.1%) died of cardiovascular or cerebrovascular causes, 26 (15.7%) of neoplasms and a variety of other causes, while the cause of death could not be determined from the records for 3 patients.

For all three classification systems, respiratory (Figure 2) and all-cause mortality increased with increasing COPD severity (Table 3). The AUC was 0.69 for

**Figure 1** Distribution of the sample of COPD patients according to the different guidelines. GOLD = Global Initiative for Chronic Obstructive Lung Disease; ATS-ERS = American Thoracic Society–European Respiratory Society; BTS = British Thoracic Society.

GOLD/ATS-ERS, 0.70 for BTS and 0.69 for ATS criteria.

The sensitivity, specificity, PPV and NPV for respiratory mortality for the different sets of guidelines are presented in Table 4. The BTS guidelines yielded the highest sensitivities and NPVs, while the GOLD/ATS-ERS yielded the highest specificities and PPVs.

Health-related quality of life

Measures of HRQoL varied across and between the three classification systems. As evaluated by the SGRQ, HRQoL was not significantly different between the GOLD/ATS-ERS moderate and severe stages in all domains (Table 5). In the ATS and BTS classifications, differences were generally observed between the three stages, with two exceptions: ‘impact’ in the SGRQ was similar in the ATS moderate (Stage II) and severe

Table 2 Number of hospitalisations according to GOLD/ATS-ERS, BTS and ATS classifications of COPD severity

COPD severity	Age, years mean (SD)	Comorbidities mean (SD)	Patients hospitalised for COPD exacerbations by number of hospitalisations		
			0 n (%)	1–2 n (%)	≥3 n (%)
GOLD/ATS-ERS					
Mild ^a	66.1 (8.9)	1.8 (1.3)	223 (73.4) ^c	57 (18.7)	24 (7.9) ^c
Moderate ^b	67.5 (8.1)	1.5 (1.2)	181 (67.8) ^c	53 (19.8)	33 (12.4)
Severe ^c	65.7 (6.8)	1.2 (0.9)	18 (45) ^{a,b}	13 (32)	9 (22.5) ^a
BTS					
Mild ^a	65.6 (9.5)	1.8 (1.2)	130 (76.9) ^c	30 (17.7)	9 (5.3) ^c
Moderate ^b	67.1 (8.2)	1.6 (1.3)	197 (70.6) ^c	54 (19.4)	28 (10)
Severe ^c	67.2 (7.6)	1.3 (1.1)	95 (58.3) ^{a,b}	39 (23.9)	29 (17.8) ^a
ATS					
Stage I (mild) ^a	66.1 (8.9)	1.8 (1.3)	223 (73.4) ^c	57 (18.7)	24 (7.9) ^c
Stage II (moderate) ^b	67.5 (8.4)	1.5 (1.2)	142 (68.9)	42 (20.4)	22 (10.7)
Stage III (severe) ^c	66.8 (7.0)	1.3 (1.1)	57 (56.4) ^a	24 (23.8)	20 (19.8) ^a

Superscript letters indicate differences between the three respective severity categories at $P < 0.017$, by each hospitalisation category.

GOLD = Global Initiative for Chronic Obstructive Lung Disease; ATS-ERS = American Thoracic Society–European Respiratory Society; BTS = British Thoracic Society; COPD = chronic obstructive pulmonary disease; SD = standard deviation.

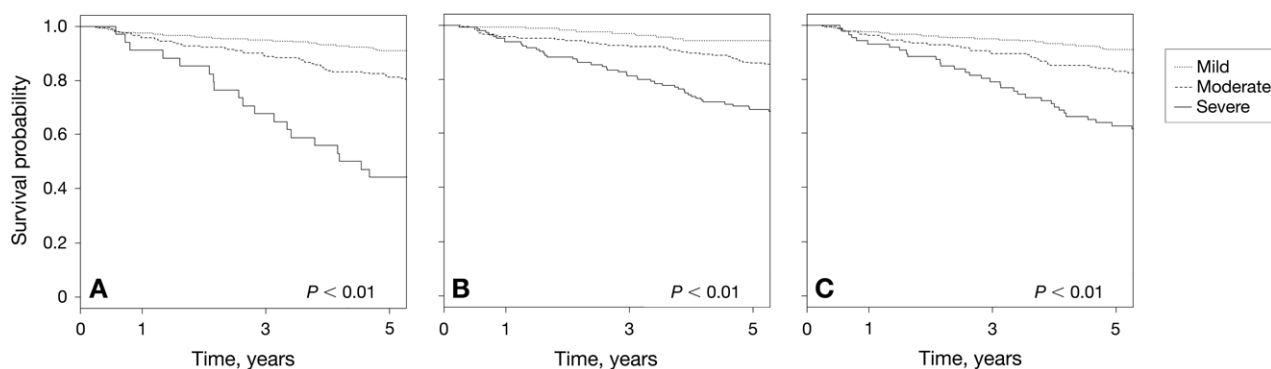


Figure 2 Survival curves for respiratory mortality according to the severity classification of **A)** GOLD, **B)** BTS and **C)** ATS guidelines. GOLD = Global Initiative for Chronic Obstructive Lung Disease; BTS = British Thoracic Society; ATS = American Thoracic Society.

Table 3 Respiratory and all-cause mortality rates by GOLD/ATS-ERS, BTS and ATS classifications of COPD severity*

	Mortality by COPD severity		
	Mild dead/alive (% dead)	Moderate dead/alive (% dead)	Severe dead/alive (% dead)
Respiratory mortality (n = 97)			
GOLD/ATS-ERS	25/249 (9.1)	52/182 (22.2)	20/14 (58.8)
BTS	9/147 (5.8)	38/203 (15.8)	50/95 (34.5)
ATS	25/249 (9.1)	36/146 (19.8)	36/50 (41.9)
All-cause mortality (n = 166)			
GOLD/ATS-ERS	55/249 (18.1)	85/182 (31.8)	26/14 (65.0)
BTS	22/147 (13.0)	76/203 (27.2)	68/95 (41.7)
ATS	55/249 (18.1)	60/146 (29.1)	51/50 (50.5)

* Statistically significant differences were observed between the three respective severity categories of each set of guidelines, by respiratory or all-cause mortality ($P < 0.017$).

GOLD = Global Initiative for Chronic Obstructive Lung Disease; ATS-ERS = American Thoracic Society–European Respiratory Society; BTS = British Thoracic Society; COPD = chronic obstructive pulmonary disease.

(Stage III) patients, and ‘symptoms’ were similar in the BTS mild and moderate patients.

For the SF-36, statistically significant differences were observed only in the areas of ‘physical function’, ‘role—physical’, and ‘general health’ across the three levels of COPD severity. In the ATS and BTS classifications, ‘physical function’ and ‘general health’ varied between the three levels of disease, while SF-36 scores were similar in the GOLD/ATS-ERS mild and moderate severity categories. In the ‘role—physical’ domain, the BTS classification showed differences between mild severity and moderate or severe COPD (Table 6).

DISCUSSION

This comparative study of four systems of classification of the severity of COPD demonstrated wide variations in the percentage of patients classified in

Table 4 Sensitivity, specificity, positive and negative predictive values of 5-year respiratory and all-cause mortality by GOLD/ATS-ERS, ATS and BTS classifications of COPD severity

Cut-off points	Sensitivity	Specificity	Positive predictive value	Negative predictive value
Respiratory mortality				
GOLD/ATS-ERS				
Mild vs. moderate/severe	0.74	0.56	0.27	0.91
Mild/moderate vs. severe	0.21	0.97	0.59	0.85
ATS				
Mild vs. moderate/severe	0.74	0.56	0.27	0.91
Mild/moderate vs. severe	0.37	0.89	0.42	0.87
BTS				
Mild vs. moderate/severe	0.91	0.33	0.23	0.94
Mild/moderate vs. severe	0.51	0.79	0.35	0.88
All-cause mortality				
GOLD/ATS-ERS				
Mild vs. moderate/severe	0.67	0.56	0.36	0.81
Mild/moderate vs. severe	0.16	0.97	0.65	0.75
ATS				
Mild vs. moderate/severe	0.67	0.56	0.36	0.82
Mild/moderate vs. severe	0.31	0.89	0.50	0.77
BTS				
Mild vs. moderate/severe	0.87	0.33	0.33	0.87
Mild/moderate vs. severe	0.41	0.79	0.42	0.78

GOLD = Global Initiative for Chronic Obstructive Lung Disease; ATS-ERS = American Thoracic Society–European Respiratory Society; BTS = British Thoracic Society; COPD = chronic obstructive pulmonary disease.

Table 5 Health-related quality of life as measured by the SGRQ by GOLD/ATS-ERS, BTS and ATS classifications of COPD severity

	Mild COPD ^a mean (SD)	Moderate COPD ^b mean (SD)	Severe COPD ^c mean (SD)
GOLD/ATS-ERS			
SGRQ activity	47.2 (20.1) ^{b,c}	58.9 (20) ^a	66.5 (19.9) ^a
SGRQ impact	28.5 (18.3) ^{b,c}	36.8 (19.4) ^a	38.4 (20.5) ^a
SGRQ symptoms	38.5 (20.3) ^{b,c}	45.4 (20.9) ^a	50.2 (23.1) ^a
SGRQ total	35.9 (17.2) ^{b,c}	44.9 (17.7) ^a	48.9 (18.7) ^a
BTS			
SGRQ activity	44.9 (20) ^{b,c}	52.8 (19.8) ^{a,c}	63.9 (19.8) ^{a,b}
SGRQ impact	26.2 (17.7) ^{b,c}	32.9 (19.3) ^{a,c}	39.2 (19) ^{a,b}
SGRQ symptoms	36.6 (19.7) ^c	41.2 (21.1) ^c	50 (20.4) ^{a,b}
SGRQ total	33.7 (16.5) ^{b,c}	40.4 (17.9) ^{a,c}	48.5 (17.2) ^{a,b}
ATS			
SGRQ activity	47.2 (20.1) ^{b,c}	57.7 (20) ^{a,c}	64.4 (19.6) ^{a,b}
SGRQ impact	28.5 (18.3) ^{b,c}	35.4 (19.5) ^a	40.2 (19.1) ^a
SGRQ symptoms	38.5 (20.3) ^{b,c}	43.4 (21.1) ^{a,c}	51.3 (20.5) ^{b,c}
SGRQ total	35.9 (17.2) ^{b,c}	43.5 (17.9) ^{a,c}	49.4 (17.1) ^{b,c}

Statistically significant differences ($P < 0.05$) between the three respective severity categories (ANOVA and Scheffé test for multiple comparisons): ^a = different from the mild category; ^b = different from the moderate category; ^c = different from the severe category.

SGRQ = St George's Respiratory Questionnaire; GOLD = Global Initiative for Chronic Obstructive Lung Disease; ATS-ERS = American Thoracic Society-European Respiratory Society; BTS = British Thoracic Society; COPD = chronic obstructive pulmonary disease; SD = standard deviation; ANOVA = analysis of variance.

the different degrees of the COPD, as well as differences in the ability to predict respiratory and all-cause mortality and the association with HRQoL outcomes measured by specific and generic measures over a 5-year follow-up period. Taking those classified as 'severe', the BTS had higher sensitivity for 5-year respiratory and all-cause mortality than the other classification systems, but all three showed low sensitivity but higher specificity. The GOLD/ATS-ERS classification system had the highest specificity for respiratory and all-cause mortality when classifying severe patients, while the BTS had the lowest. The ATS classification system always yielded intermediate values. Overall, however, sensitivity, specificity, PPV and NPV were relatively poor for mortality.

If these classification systems are used as a tool for estimating the patient's propensity for developing a negative outcome, the BTS is slightly more effective, particularly in predicting respiratory mortality, than the ATS or GOLD/ATS-ERS systems, although none of them meet strict prognostic criteria with such poor sensitivities.

The need for a classification system for COPD severity that reliably covers various aspects of the disease is evident.^{5,6} FEV₁ is the first parameter used, both to establish diagnosis and to determine the severity of the disease. We chose to evaluate the BTS and the GOLD/ATS-ERS classification systems because they are the most widely used, and the ATS system because its cut-off points are used in the body mass, airflow obstruction, dyspnoea and exercise capacity index⁵ and the health activity dyspnoea obstruc-

Table 6 Health-related quality of life as measured by the SF-36 by GOLD/ATS-ERS, BTS, and ATS classifications of COPD severity

	Mild COPD ^a mean (SD)	Moderate COPD ^b mean (SD)	Severe COPD ^c mean (SD)
GOLD/ATS-ERS			
Physical function	65.7 (21.5) ^{b,c}	58.1 (22.8) ^{a,c}	45.6 (26.3) ^{a,b}
Physical role	81.3 (33.7)	72.9 (37.5) ^c	68.1 (42.4) ^b
Bodily pain	69.4 (28.1)	73.3 (27.1)	74.1 (26.9)
General health	50.4 (22.4) ^c	43.2 (20.3) ^c	34.9 (18.8) ^{a,b}
Vitality	61.7 (24)	59.4 (22.7)	55.2 (22.9)
Social functioning	84.7 (22.1)	84.4 (21.7)	83.1 (25.7)
Emotional role	81.3 (35.7)	85.3 (32.2)	91.7 (26.9)
Mental health	74.6 (22)	77.4 (20.7)	75.8 (21)
BTS			
Physical function	67.9 (20.6) ^{b,c}	62.3 (22) ^{a,c}	51.7 (24.3) ^{a,b}
Physical role	81.9 (34.6) ^{b,c}	78.1 (34.7) ^a	69.2 (39.1) ^a
Bodily pain	69.3 (27.3)	70.5 (27.9)	75.2 (27.2)
General health	52.9 (22.3) ^{b,c}	46.2 (21.4) ^{a,c}	39.4 (19.8) ^{a,b}
Vitality	62.7 (24.2)	59.9 (23.4)	58.3 (22.3)
Social functioning	83.7 (22.9)	85.3 (21.7)	83.7 (22.3)
Emotional role	80.1 (36.8)	84.2 (33.5)	86.7 (30.4)
Mental health	74.0 (21.5)	76.7 (22)	76.6 (20.1)
ATS			
Physical function	65.7 (21.5) ^{b,c}	59.5 (22.6) ^{a,c}	50.2 (24.5) ^{a,b}
Role physical	81.3 (33.7) ^c	74.0 (37.2)	68.8 (40.1) ^a
Bodily pain	69.4 (28.1)	73.0 (27.1)	74.2 (27)
General health	50.4 (22.4) ^{b,c}	44.5 (20.4) ^{a,c}	37.3 (19.3) ^{a,b}
Vitality	61.7 (24)	60.1 (23.2)	56.3 (21.6)
Social functioning	84.7 (22.1)	84.8 (21.5)	83.3 (23.8)
Emotional role	81.3 (35.7)	85.3 (32.5)	87.8 (29.7)
Mental health	74.6 (22)	78.1 (20.5)	75.4 (21.1)

Statistically significant differences ($P < 0.05$) between the three respective severity categories (ANOVA and Scheffé test for multiple comparisons): ^a = different from the mild category; ^b = different from the moderate category; ^c = different from the severe category.

SF = Short Form; GOLD = Global Initiative for Chronic Obstructive Lung Disease; ATS-ERS = American Thoracic Society-European Respiratory Society; BTS = British Thoracic Society; COPD = chronic obstructive pulmonary disease; SD = standard deviation; ANOVA = analysis of variance.

tion score.⁶ On applying these classification systems we found that the distribution of disease severity of our patient cohort varied greatly.

Tsoumakidou et al. found that the GOLD cut-off points best predicted future hospitalisations due to COPD exacerbation, whereas no statistically significant correlation could be found for the BTS and ATS systems.¹⁸ Our study did not find significant differences between the scales as a predictor of hospitalisation. In their study, mortality was 8% among GOLD 'moderate' patients and 4% among GOLD 'severe' patients. When these investigators used the ATS FEV₁ cut-off points, mortality was 10% among Stage II (moderate) patients and 4% among Stage III (severe) patients. According to the BTS classification, however, higher mortality rates were associated with greater severity of COPD, and statistically significant differences were observed between mortality rates in each level of disease severity. It should be noted that this study included only a small number of patients ($n = 67$) and the follow-up was relatively short (18 months). Tsoumakidou et al. also found that the cut-off points proposed by the BTS, GOLD and ATS-ERS guidelines

were not adequate to establish a prognosis of mortality because they did not discriminate between patients classified as having moderate COPD and those classified as having severe disease. Our results generally corroborate these data with a larger number of patients, a longer follow-up period and different results in relation to each set of guidelines. We would like to highlight that the high number of hospitalisations found even for mild COPD patients may be related not only to the FEV₁ but also to other potential factors such as age, hypersecretory states or hospitalisations in the previous year.

Very few studies have evaluated the associations between the various classifications of COPD severity and HRQoL. Antonelli-Incalzi et al. found significant differences in the HRQoL (SGRQ) between stages known as IIa and IIb at that time as of the GOLD classification, but not between consecutive Stages 0-I, I-IIa (now known as 'mild' and 'moderate' stages) and IIb-III (now 'severe' and 'very severe').¹⁵ This suggests that the frontier marked by FEV₁ = 50% establishes a turning point in the evolution of COPD. This coincides with findings from our study, where the HRQoL among GOLD/ATS-ERS mild patients was clearly differentiated from HRQoL among moderate and severe patients. In our study, however, no statistical differences in HRQoL were observed between patients classified as moderate and severe by the GOLD/ATS-ERS system, which is an important limitation, whereas differences in scores of more than 4 points (considered a clinically relevant change)¹¹ were observed across the ATS and BTS severity classifications in most SGRQ domains.

Using HRQoL measured by the SGRQ, Ferrer et al. confirmed that the ATS cut-off points adequately classified degrees of COPD severity.¹⁶ We found that both the ATS and BTS assessments correctly classified patients, with one exception: in the 'symptoms' domain of the SGRQ, we did not observe any differences between BTS Stage I (mild) and Stage II (moderate) patients. Contrary to the findings of Ferrer et al., we did not observe differences in the 'impact' domain of the SGRQ between ATS Stages II (moderate) and III (severe). The SGRQ 'impact' scores of ATS Stage I (mild) and Stage II (moderate) patients were similar in both studies. However, in ATS Stage III patients, those with the most severe COPD, the difference between their cohort and ours would be clinically significant: 47 vs. 40. One explanation for this difference is that the patients classified as severe by Ferrer et al.¹⁶ were recruited at hospital, and therefore had more severe COPD than the patients from our out-patient facilities.

A study by Hajiro et al., which used the BTS classification, did not demonstrate differences in the 'symptoms' section of the SGRQ between 'mild' and 'moderate' patients.¹⁷ We also found no difference. Hajiro et al. found no differences in the 'impact' section be-

tween the BTS mild and moderate groups; however, we observed a difference in these two groups according to the BTS classification.

Our study has several strengths, including its long duration (5 years of follow-up), the number of patients included and the strong outcomes used (hospitalisations, mortality and HRQoL).

The limitations of our study should also be noted. We excluded patients with FEV₁ >80%, corresponding to the GOLD/ATS-ERS Stage I classification, as mentioned in the Methods, because these were the inclusion criteria of our study. However, patients with FEV₁ >80% are seldom hospitalised for COPD exacerbations, and have significantly lower rates of mortality and significantly higher HRQoL. Furthermore, we had a relatively small number of patients in the GOLD/ATS-ERS very severe category, with a cut-off point of FEV₁ <30%. Our subjects were recruited from general medical out-patient facilities, unlike the majority of published studies, which tend to include patients recruited and followed exclusively in the hospital setting.

A final limitation is that the overwhelming majority of patients in our study were males. We feel that this does not imply patient selection bias, as we included all the patients that fulfilled our selection criteria. Instead, it reflects the epidemiology of COPD in Spain. Other recent COPD studies conducted in Spain also show a preponderance of males.^{16,19} Our results should be generalised to females with caution.

In summary, this study demonstrated differences between the classifications of COPD severity determined by various guidelines. The BTS classification was slightly superior in predicting respiratory mortality. The BTS, ATS and GOLD/ATS-ERS guidelines were equivalent for predicting hospitalisation due to exacerbations of COPD. For HRQoL, the ATS and BTS classifications were best for proper patient stratification. Our findings support the cut-off points in the BTS system as the best classification of patients with regard to severity and prognosis. Given the poor sensitivity and specificity of all four systems, our study highlights the need to evaluate the cut-off points of these established guidelines with relation to robust outcomes and then establish cut-off points that reflect these relationships. If the predictive capability of the FEV₁ relation to outcomes such as hospitalisation for COPD exacerbation, mortality or HRQoL cannot be improved, it may be time to determine the severity of COPD using instruments such as the BODE-index or HADO score,^{5,6} which incorporate other variables with the aim of better classifying the severity of COPD and capturing the multidimensional nature of COPD.

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R É S U M É

CONTEXTE : La gravité de la bronchopneumopathie chronique obstructive (BPCO) est établie par les différentes valeurs-limites du volume expiratoire maximum par seconde.

OBJECTIFS : Comparer de quelle manière les directives de l'American Thoracic Society (ATS), de la British Thoracic Society (BTS), de la Global Initiative for Chronic Obstructive Lung Disease (GOLD) et l'ATS-European Respiratory Society (ATS-ERS) assurent la codification de la gravité de la BPCO, permettent de prévoir différentes données importantes.

SCHEMA : Etude prospective de cohorte pendant 5 ans. On a pratiqué la spirométrie et évalué la qualité de vie en matière de santé (HRQoL) grâce à une enquête de santé du type SF-36 ainsi qu'au Questionnaire Respiratoire de St Georges. On a enregistré les admissions hospitalières provenant d'exacerbations de la BPCO ainsi que la mortalité au cours d'une période de suivi de 5 ans.

RÉSULTATS : Quelle que soit la directive utilisée, le nombre d'admissions est directement en association avec la gravité de la BPCO. La sensibilité et la spécificité pour la mortalité respiratoire à 5 ans ont été respectivement de 0,21 et 0,97 pour les directives GOLD/ATS-ERS, de 0,51 et 0,79 pour celles de la BTS et de 0,37 et 0,89 pour celles de l'ATS. Des résultats similaires ont été observés pour la mortalité toutes causes. En ce qui concerne la HRQoL, des différences statistiquement significatives n'ont été observées que pour les échelles de la BTS et de l'ATS.

CONCLUSIONS : Les directives n'ont pas stratifié de manière homogène les patients en matière de mortalité à 5 ans et de la HRQoL. Quoique le système du BTS ait été légèrement supérieur, aucune de ces directives n'est en relation étroite avec ces données. Il est nécessaire d'utiliser d'autres variables pour améliorer la classification de la gravité de la BPCO.

R E S U M E N

MARCA DE REFERENCIA : Los puntos de corte del volumen espiratorio forzado en el primer segundo determinan la gravedad de la enfermedad pulmonar obstructiva crónica (EPOC).

OBJETIVOS : Comparar la capacidad de clasificar la gravedad de las guías American Thoracic Society (ATS),

British Thoracic Society (BTS), Global Initiative for COPD (GOLD), and ATS-European Respiratory Society (ATS-ERS) respecto a importantes resultados.

MÉTODOS : Estudio prospectivo de 5 años. Se realizó una espirometría y se utilizó el SF-36 y el Saint George's Respiratory Questionnaire para evaluar la calidad de vida

relacionada con la salud (HRQoL). Se registró las hospitalizaciones por exacerbación de la EPOC y la mortalidad durante 5 años.

RESULTADOS : En todas las guías, el número de hospitalizaciones estuvo relacionado con la gravedad de la EPOC. La sensibilidad y especificidad para la mortalidad respiratoria fue 0,21 y 0,97 para GOLD/ATS-ERS, 0,51 y 0,79 para la BTS, y 0,37 y 0,89 para la ATS. Un comportamiento similar se demostró para la mortalidad general. En la HRQoL solo se encontraron diferencias

estadísticamente significativas para las guías de la BTS y ATS.

CONCLUSIONES : Aunque la BTS fue ligeramente superior, ninguna de las guías estratificó de forma consistente a los pacientes respecto a la mortalidad a los 5 años y la HRQoL. Es necesario utilizar otros instrumentos para clasificar mejor la gravedad de la EPOC.
