

Impact of Chronic Obstructive Pulmonary Disease on Activities of Daily Living: Results of the Multicenter EIME Study

Francisco Javier Álvarez-Gutiérrez,^a Marc Miravittles,^b Miriam Calle,^c Elena Gobartt,^d Francisco López,^e Antonio Martín,^f and the EIME Study Group*

^aServicio de Neumología, Red Respira RTIC 03/11 ISCIII, Hospital Virgen del Rocío, Sevilla, Spain.

^bServei de Pneumologia, Institut Clínic del Tòrax (IDIBAPS), Red Respira RTIC 03/11 ISCIII, Hospital Clínic, Barcelona, Spain.

^cServicio de Neumología, Red Respira RTIC 03/11 ISCIII, Hospital Clínic San Carlos, Madrid, Spain.

^dR&D Department, Boehringer Ingelheim, Barcelona, Spain.

^eNufarm 21, Madrid, Spain.

^fR&D Department, Pfizer, Madrid, Spain.

OBJECTIVE: The aim of this study was to determine the impact of chronic obstructive pulmonary disease (COPD) on activities of daily living in a large group of patients in Spain who responded to a specific questionnaire. A second aim was to explore the practical utility of the questionnaire and determine which variables could be used to identify “fragile” patients or patients in greater need of attention. To do this, we examined the relationship between questionnaire results and clinical variables, lung function measurements, socioeconomic status, and validated quality of life questionnaires.

METHODS: We conducted an observational, descriptive, multicenter, cross-sectional study in which 227 respiratory specialists from all over Spain collected data from 1057 patients with COPD. Each patient was given a specific questionnaire containing 7 items that measured the extent to which COPD affected different aspects of their lives. The patients rated each item on a scale of 0 to 2, depending on the level of impact. Total possible scores, thus, ranged from 0 to 14, and patients with a score of 9 or higher were classified as fragile. We then explored the relationship between questionnaire results and clinical variables, socioeconomic status, spirometric values, and quality of life as measured by the St George’s Respiratory Questionnaire (SGRQ).

RESULTS: We studied 1057 patients (95.2% male) with a mean (SD) age of 67 (9) years and a mean predicted forced expiratory volume in 1 second (FEV₁) of 41.8% (13.3%). The mean questionnaire score was 6.3 (3.1). The activities that were affected most were sport and leisure, habitual physical activity, and sex life (major impact reported by 52.5%, 30.3%, and 20.2% of patients, respectively). We found a correlation between questionnaire scores and known disease severity markers such as SGRQ scores, dyspnea, number of exacerbations, and FEV₁ in liters. Patients included in the fragile category were older and had a lower socioeconomic status.

CONCLUSIONS: COPD impact questionnaire scores correlated well with SGRQ scores and the usual clinical variables and lung function measurements for evaluating disease severity (dyspnea, FEV₁, and exacerbations). The questionnaire could, therefore, be a useful tool for identifying fragile patients who, in addition to having poorer clinical status and lung function measurements, have a lower socioeconomic status.

Key words: *Chronic obstructive pulmonary disease. COPD. Health-related quality of life. Fragile patient.*

Impacto de la EPOC en la vida diaria de los pacientes. Resultados del estudio multicéntrico EIME

OBJETIVO: Realizamos el estudio con el propósito de conocer, a través de un cuestionario específico, el impacto de la enfermedad pulmonar obstructiva crónica (EPOC) sobre las actividades de la vida diaria en un grupo amplio de pacientes en España. Asimismo estudiamos su relación con parámetros clínicos, funcionales y socioeconómicos, y con escalas validadas de calidad de vida, para evaluar su utilidad en la práctica habitual y determinar qué variables pueden definir a los pacientes “frágiles” o que requieren una mayor atención.

MÉTODOS: Se ha realizado un estudio observacional, descriptivo, multicéntrico y transversal, con la participación de 227 neumólogos de toda España, que incluyó a pacientes con el diagnóstico de EPOC. A todos éstos se les pasó un cuestionario específico con 7 preguntas que medían el impacto de la enfermedad sobre aspectos de la vida diaria. Las respuestas se valoraron de 0 a 2, según el grado de afectación, lo que supone un intervalo entre 0 y 14 unidades. Definimos al paciente como “frágil” si presentaba valores iguales o mayores de 9 en el cuestionario de impacto. Se evaluó la relación entre la escala de impacto y variables clínicas, situación socioeconómica, espirometría y calidad de vida medida con el cuestionario específico St. George’s Respiratory Questionnaire (SGRQ).

RESULTADOS: Estudiamos a 1.057 pacientes (un 95,2% varones), con una edad media (\pm desviación estándar) de 67 \pm 9 años y volumen espiratorio forzado en el primer segundo (FEV₁), expresado en porcentaje, del 41,8 \pm 13,3%. La puntuación media del cuestionario de impacto fue de 6,3 \pm 3,1. Las actividades con mayor afectación fueron deporte y ocio,

The EIME study was funded by Boehringer Ingelheim and Pfizer.

*The researchers that formed part of the EIME Study Group are listed at the end of the article.

Correspondence: Dr. F.J. Álvarez-Gutiérrez.
Alcalde Manuel del Valle, Edificio Cónsul, portal 6, 1.º, A. 41008 Sevilla, España.
E-mail: fag01se@saludalia.com

Manuscript received November 29, 2005. Accepted for publication April 4, 2006.

actividad física habitual y vida sexual (muchacha afectación en el 52,5, el 30,3 y el 20,2% de los pacientes, respectivamente). Encontramos relación entre la puntuación del cuestionario y parámetros conocidos de gravedad (SGRQ, disnea, número de agudizaciones y FEV₁ expresado en litros). Los pacientes definidos como frágiles tenían mayor edad y menor nivel tanto cultural como económico.

CONCLUSIONES: El cuestionario de impacto de la EPOC se correlaciona bien con los clásicos parámetros clínicos y funcionales de valoración de la gravedad de la enfermedad (disnea, FEV₁ y exacerbaciones) y con el cuestionario de calidad de vida relacionada con la salud SGRQ. Así pues, podría ser un instrumento útil para identificar un perfil de paciente frágil, que presenta, además de una peor situación clínica y funcional, una situación socioeconómica más desfavorecida.

Palabras clave: EPOC. Calidad de vida relacionada con la salud. Paciente frágil.

Introduction

Chronic obstructive pulmonary disease (COPD) is a common cause of illness and death that places considerable demands on health care systems in developed countries. In Spain, it is believed that 8% to 10% of the adult population and over 20% of the male population over the age of 65 years may have COPD.¹ Disease severity and progression have traditionally been measured using clinical markers such as decline in lung function measured by forced expiratory volume in 1 second (FEV₁), dyspnea score, and number of exacerbations and hospital admissions. More recently, however, variables such as exercise tolerance² and body mass index³ (BMI) have been introduced and have proven useful in combination with the traditional ones for predicting disease progression.⁴ The impact of COPD on activities of daily living (ADLs), however, has received little attention. Health-related quality of life (HRQL) scores have been used in addition to physiological and even clinical measurements to evaluate health status and the impact of disease on patient well-being.^{5,6} Although HRQL questionnaires address important aspects related to respiratory symptoms and their impact on daily life, they neglect others such as how disease affects patients' social, family, or work relationships, or sex life, for example. A few years ago, a telephone interview study of the impact of COPD conducted in 8 countries among patients with a self-reported history of the disease found that they tended to underestimate the severity of their condition in many aspects.⁷ Over a third of those interviewed, for example, stated that they had stopped working because of their disease and respondents under 65 years experienced as many restrictions to their social, family, and sex lives as those over 65 years. Sometimes they reported experiencing more. However, as the study did not measure disease severity according to FEV₁, or analyze correlations between variables and standardized HRQL scores, it is impossible to determine whether impact questionnaires such as that used in the 8-country study are an effective means of identifying particularly "fragile" COPD patients, ie, patients in need of greater attention.

The aim of this study was to describe how COPD influenced ADLs in affected patients in our setting using a purpose-designed impact questionnaire. We analyzed the relationship between impact scores and a series of independent variables such as clinical parameters, lung function measurements, socioeconomic status, and validated HRQL measures, specifically the St George's Respiratory Questionnaire (SGRQ).^{5,6} We also investigated whether any of these variables could be used to identify fragile patients.

Methods

Study

The EIME study was an observational, descriptive, multicenter, cross-sectional survey designed to assess the impact of COPD on patients. All of the participants had stable COPD and were monitored by respiratory medicine specialists in an outpatient setting. The study methods are described in detail in a previous publication that describes determining factors of quality of life in COPD patients.⁸ Briefly, 250 respiratory medicine specialists from all over Spain were asked to gather information on unselected COPD patients they had seen in the winter of 2004. Of these 250 specialists, 227 finally participated in the study. The study was reported to the Spanish health authorities and complied with national regulations relative to observational studies. All the data entered in the database was coded to maintain confidentiality.

Population

The study population comprised adult COPD patients who visited outpatient respiratory medicine departments in different parts of Spain. Inclusion criteria were: 1) age over 40 years with COPD, defined by FEV₁ of less than 70% of predicted⁹ and a FEV₁/forced vital capacity ratio of less than 70%;¹⁰ 2) clinical stability, defined by an interval of at least 6 weeks since the patient's last exacerbation; 3) smoking (current or former) with a smoking history of at least 10 pack-years; and 4) consent to participate in study. Exclusion criteria were: 1) no smoking history; 2) diagnosis of bronchial asthma, cystic fibrosis, or bronchiectasis that were clinically significant or not due to COPD (tuberculosis, childhood infections, immune deficiencies, severe mobility, or cognitive disorders), or diagnosis of serious chronic disease other than COPD that could limit ADLs (active neoplastic disease, acquired immune deficiency syndrome, heart failure, serious kidney or liver failure, etc); and 3) inability to complete an HRQL questionnaire.

Data Collection

Data were collected in face-to-face interviews during the patients' visits to the respiratory medicine specialist and recorded on case report forms. A comprehensive purpose-designed clinical questionnaire was used to solicit the information required. The questionnaire addressed the following aspects: medical history; level of education; socioeconomic status; clinical assessment of COPD; Medical Research Council (MRC) dyspnea score¹¹; number of exacerbations, defined by deterioration of symptoms that required treatment changes; number of emergency department visits or hospital admissions; treatments; lung function measurements; and HRQL score obtained using the SGRQ completed by patients during visit.

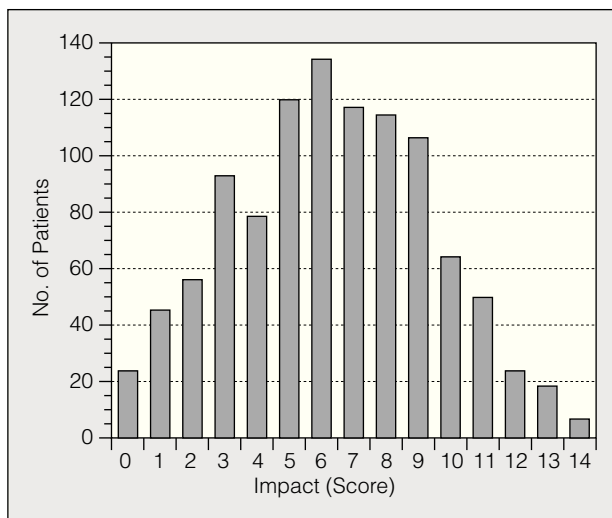


Figure 1. Distribution of impact questionnaire scores (fragile ≥ 9 ; nonfragile < 9).

Ideally, spirometry and bronchodilator tests should also have been performed during the visit, but as this was not possible, we used test results from the preceding 6 months (stable phase).

The impact of COPD on ADLs was quantified using a translated and modified version of the questionnaire used by Rennard and colleagues⁷ in their international survey. The questionnaire contained 7 items that measured the impact of COPD on ADLs (Appendix). Patients rated each item according to the following scale: 0 (no limitation), 1 (little or some limitation), 2 (considerable limitation). The total possible score, therefore, was 14. Patients who scored 9 or more were placed in the fragile category and those who scored less than 9 were placed in the nonfragile category. Nine was the 75th percentile score.

Researchers were able to access and complete the questionnaire online (www.eime.es). Each researcher was given a user name and password, and patient confidentiality was guaranteed by not including any identifying data.

Researchers could also choose to complete a printed version of the questionnaire and send it by ordinary mail to the coordinating center. All data received were entered into a database located in the data recording and analysis center (Drug Farma, SA, Madrid, Spain). The Spanish authorities were notified of the structure, content, and purpose of the database in compliance with relevant legislation.

Statistical Analysis

The main dependent variable was the impact of COPD on ADLs as measured by the 7 questionnaire items. The independent variables were clinical variables, socioeconomic data, HRQL scores, and lung function measurements as discussed above.

Quantitative variables were expressed as means (SD) and qualitative variables as frequencies and percentages. The χ^2 and Fisher exact tests were used to analyze relationships between qualitative data. The Mann-Whitney test was used for nonnormally distributed variables and small sample groups. Impact questionnaire scores were correlated with all the independent variables using analysis of variance. Statistical significance was set at a value of $P < .05$. All the data were analyzed using the statistics software package SAS 6.04 (SAS Institute, Cary, North Carolina, USA).

Results

Information was received for a total of 1124 patients recruited by the 227 respiratory specialists who participated in the study. Forty-three patients were excluded because they did not meet the lung function criterion, and 25 were excluded because they had never smoked ($n=13$) or because they had a smoking history of less than 10 pack-years ($n=12$). The final number of patients enrolled was therefore 1057 (95.4% men and 4.6% women), and the mean (SD) age was 66.8 (9) years (range, 40-90 years).

The mean score on the impact questionnaire was 6.3 (3.1). The distribution of these scores is shown in Figure 1. As one of our aims was to identify patients in greater need of attention, we established the 75th percentile value of 9 as our arbitrary cutoff for fragility. Tables 1 and 2 show the socioeconomic and clinical characteristics of our sample, respectively. Of particular note is the low educational level of the sample: just over 20% of patients had secondary education or higher. Middle socioeconomic status was predominant (63.3%) and over 73% of patients were pensioners. It is also interesting to note that 10.1% of patients were on sick leave, mostly due to COPD (9%) (Table 1). We found significant socioeconomic differences between fragile and nonfragile patients. The first group was significantly older, had a lower socioeconomic status, and included fewer home owners and more pensioners (Table 1). As far as smoking is concerned, almost 20% of the population were active smokers and the number of pack-years (53.5 [29.8]) was high. Consumption was greater in fragile patients than in the nonfragile ones. The main clinical symptom was dyspnea (experienced by 97.3% of patients) and mild and moderate dyspnea predominated. This was the only symptom for which we did not find significant differences between fragile and nonfragile patients (Table 2). When dyspnea was evaluated on the MRC scale, we found that a significant majority of fragile patients reported higher grades of severity (Figure 2). The mean number of exacerbations in the preceding 12 months was 2.2 (2.7). We also found significant differences between fragile and nonfragile patients in terms of number of exacerbations, emergency department visits due to COPD, hospital admissions, and presence of concomitant diseases (Table 2). The mean FEV₁ was 41.8% (13.2%), and the majority of patients (49.5%) had severe disease according to the Global Initiative for Chronic Obstructive Lung Disease staging system (Table 2). Lung function impairment was significantly greater in fragile patients compared to nonfragile patients: 85% had FEV₁ values of less than 50% of predicted (Figure 2). BMI scores were also significantly lower in these patients (Figure 2). The mean SGRQ score was 47.6 (20.2), and differences between fragile and nonfragile patients in terms of symptoms, activity, and impacts were significant (Table 2).

Table 3 shows the restrictions experienced by patients in terms of the different activities addressed by the impact questionnaire. As can be seen, sport and leisure, habitual physical activity, and sex life were affected most.

Finally, we found that impact score correlated best with overall SGRQ score ($F=77.78$; $P < .0001$), dyspnea ($F=33.07$;

TABLE 1
Sociodemographic Characteristics of Patients*

	All	Fragile Patients	Nonfragile Patients	P
Sample, n	1057	270 (25.5%)	786 (74.4%)	
Age, mean (SD), y (n=1051 [267/784])	66.8 (9.0)	68.2 (8.7)	66.3 (9.0)	.046†‡
Sex, n	1053	268	785	.316§
Men	1005 (95.4%)	255 (95.1%)	750 (95.5%)	
Women	48 (4.6%)	13 (4.9%)	35 (4.5%)	
Marital status, n	1048	268	780	.041†§
Married	866 (82.6%)	214 (79.9%)	652 (83.6%)	
Divorced/separated	33 (3.1%)	9 (3.4%)	24 (3.1%)	
Single	58 (5.5%)	10 (3.7%)	48 (6.2%)	
Widowed	91 (8.7%)	35 (13.1%)	56 (7.2%)	
Level of education, n	1055	270	785	.001†§
Inability to read or write	38 (3.6%)	13 (4.8%)	25 (3.2%)	
Incomplete primary education	412 (39.1%)	130 (48.1%)	282 (35.9%)	
Complete primary education	375 (35.5%)	88 (32.6%)	287 (36.6%)	
Secondary education	160 (15.2%)	24 (8.9%)	136 (17.3%)	
Higher education	70 (6.6%)	15 (5.6%)	55 (7%)	
Economic level, n	1050	269	781	.0006†§
Low	323 (30.8%)	110 (40.9%)	213 (27.3%)	
Medium	668 (63.6%)	147 (54.6%)	521 (66.7%)	
High	59 (5.6%)	12 (4.5%)	47 (6%)	
Home owners, n	1048	265	783	.0095†
Yes	970 (92.6%)	235 (88.7%)	735 (93.9%)	
No	78 (7.4%)	30 (11.3%)	48 (6.1%)	
Employment status, n	1050	270	780	<.0001†§
Unemployed	15 (1.4%)	5 (1.9%)	10 (1.3%)	
On sick leave	107 (10.2%)	40 (14.8%)	67 (8.6%)	
Retired	779 (74.2%)	216 (80.0%)	563 (72.2%)	
Employed	149 (14.2%)	9 (3.3%)	140 (17.9%)	
Current social situation, n	1052	270	782	.0006†§
Receiving social benefits	4 (0.4%)	3 (1.1%)	1 (0.1%)	
Living in nursing or retirement home	5 (0.5%)	5 (1.9%)	0 (0%)	
Living with relatives	270 (25.7%)	71 (26.3%)	199 (25.4%)	
Living with partner	695	173 (64.1%)	522 (66.8%)	
Living alone	78	18 (6.7%)	60 (7.7%)	

*Values are shown as number of patients (percentage), unless otherwise indicated.

†Statistically significant difference.

‡Mann-Whitney test.

§ χ^2 test.

|| Fisher exact test.

$P < .001$), number of exacerbations ($F = 14.22$; $P < .0002$), and FEV_1 in liters ($F = 11.22$; $P < .008$) (Figure 3).

Discussion

The present study has shown that COPD has a considerable impact on ADLs in patients. The administration of a simple, quick questionnaire can show which aspects of daily life are most affected by the disease and also identify patients who are particularly fragile, either due to the severity of their disease or the existence of social, economic, or occupational factors that could interfere with the management of their disease or complicate its progression.

EIME was a descriptive study of the impact of COPD on patients that involved the participation of 227 respiratory medicine specialists from all over Spain. As patients were enrolled consecutively, in principle the study population cannot be considered representative of the COPD population in Spain, an important point to bear in mind when interpreting the results of the study.

Nonetheless, the fact that a large number of patients, respiratory medicine specialists, and outpatient centers

from all over Spain participated in the study means that its results provide quite a clear picture of the COPD patients who visit respiratory medicine outpatient departments in Spain in terms of their socioeconomic, clinical, and lung function status and the impact of disease on ADLs. In a previous analysis of the EIME study in which patient quality of life was investigated, we found that the SGRQ score was the only variable that was significantly and independently associated with a prior history of exacerbations and hospital admissions.⁸ In this study we have analyzed the practical utility of using a questionnaire specifically designed to assess the impact of COPD on patients' ADLs and investigated correlations between the resulting scores and known disease severity markers such as lung function measurements, socioeconomic variables, and SGRQ scores.

A first observation of note was that the sociodemographic data revealed that a large proportion of patients in our study population were male, pensioners, upper middle aged, and of a low educational level. These findings are consistent with recent ones for Spain published by Esteban and colleagues,¹² who studied 611 patients in 5 outpatient

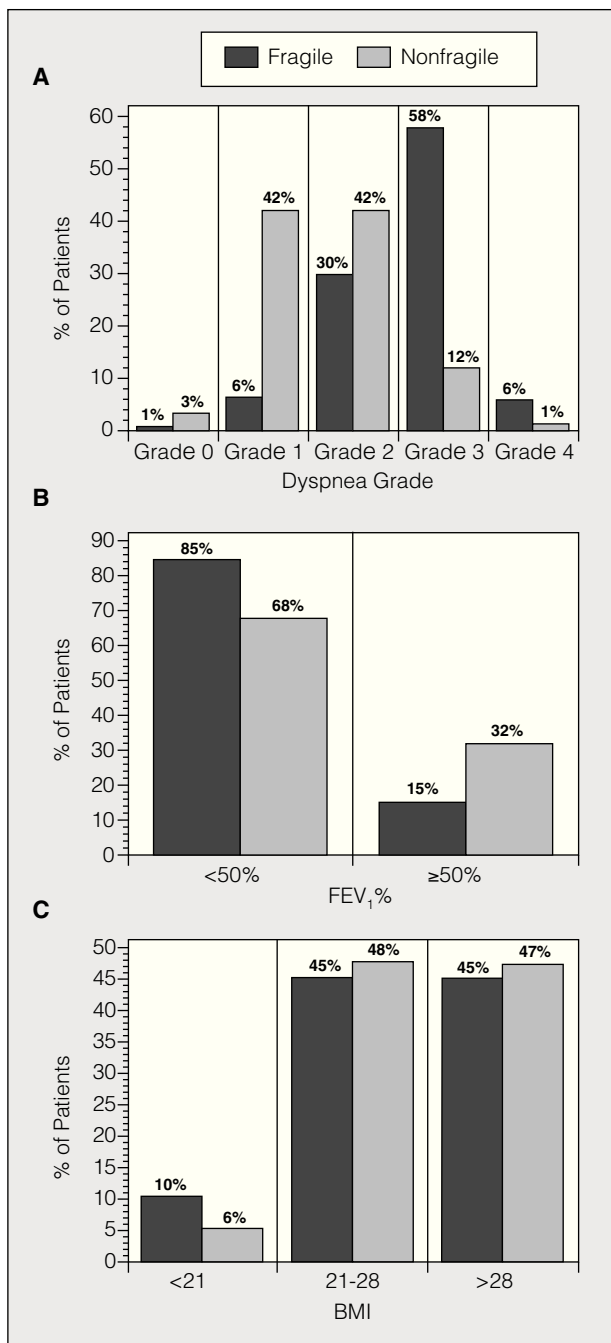


Figure 2. Differences between fragile and nonfragile patients in terms of dyspnea score measured on the Medical Research Council scale, lung function impairment measured by forced expiratory volume in 1 second (FEV₁% of predicted), and body mass index (BMI). Probabilities: A: $P < .001$ (χ^2 test with continuity correction [CC]); B: $P < .001$ (Fisher exact test); C: $P = .036$ (CC).

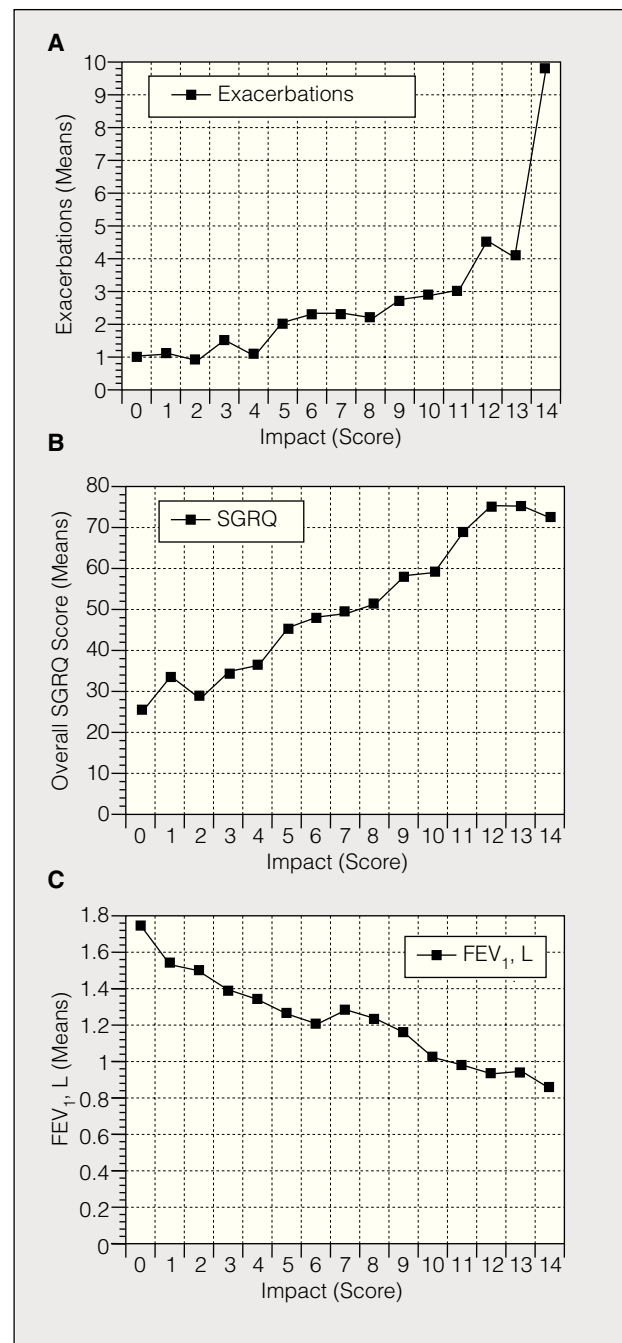


Figure 3. Relationship between impact score and clinical, lung function, and quality of life variables. A: Exacerbations: $P < .001$ ($F = 14.22$, analysis of variance [ANOVA]). B: Overall St George's Respiratory Questionnaire (SGRQ) score: $P < .001$ ($F = 11.22$, ANOVA). C: Forced expiratory volume in 1 second (FEV₁) in liters: $P < .001$ ($F = 77.78$, ANOVA).

departments, and by de Miguel Díez and colleagues,¹³ who studied 560 patients randomly selected by primary care physicians and respiratory medicine specialists from all over Spain.

The majority of patients lived with partners or relatives, and very few lived alone (7.6%) or in nursing or retirement

homes (0.5%). These findings are similar to others in the literature recently, such as the aforementioned study by Esteban et al, but they differ from situations reported in other countries where more COPD patients live alone.¹⁴

The main aim of this study was to determine the impact of COPD on ADLs. We used a modified version of the

TABLE 2
Smoking Habit, Clinical Parameters, Lung Function Measurements, and Quality of Life*

	All	Fragile Patients	Nonfragile Patients	P
Smoking, n†	1039	266	773	.822‡
Active smokers	204 (19.6%)	51 (19.2%)	153 (19.8%)	
Ex-smokers	835 (80.4%)	215 (80.8%)	620 (80.2%)	
Pack-years (n=893)	53.5 (29.8)	56.9 (31.7)	52.3 (29.1)	.044§
Symptoms, n	1056	270	786	
Cough	586 (55.5%)	154 (57.0%)	432 (55.0%)	.571
Expectoration	442 (41.9%)	113 (41.9%)	329 (41.9%)	> 0.99
Dyspnea	1020 (96.6%)	266 (98.5%)	754 (95.9%)	.026§¶
No. of exacerbations (n=1029 [263/766])	2.2 (2.7)	3.2 (3.4)	1.8 (2.3)	<.0001§
Unscheduled visits to doctor (n=1027[260/767])	2.1 (2.9)	3.2 (3.9)	1.7 (2.4)	<.001§
No. of visits to emergency departments due to COPD (n=1032 [265/767])	1.1 (1.9)	1.8 (2.4)	0.8 (1.7)	<.001§
No. of hospital admissions due to COPD (n=1029 [265/764])	0.6 (1.4)	1.0 (1.8)	0.5 (1.2)	<.001§
FEV ₁ , L (n=1020 [263/757])	1.3 (0.4)	1.1 (0.4)	1.3 (0.4)	<.001§
FEV ₁ , %# (n=995 [255/740])	41.8 (13.3%)	36.2 (13.1%)	43.8 (12.8%)	<.001§
FEV ₁ , GOLD	995	255	740	<.001§‡
Very severe	198 (19.9%)	96 (37.6%)	102 (13.8%)	
Severe	523 (52.6%)	120 (47.1%)	403 (54.5%)	
Moderate	274 (27.5%)	39 (15.3%)	235 (31.8%)	
Concomitant diseases (n=1037 [268/769])				<.001§¶
Yes	62%	72.8%	58.3%	
No	38%	27.2%	41.7%	
SGRQ (n=1056 [270/786])				
Overall score	47.8 (20.2%)	63.4 (17.2%)	42.5 (18.4%)	<.001§
Symptoms	52.9 (22.8%)	55 (20.3%)	48.4 (21.8)	<.001§
Activity	61.4 (23.2%)	77.6 (18.6%)	55.8 (21.9%)	<.001§
Impact	38.7 (21.7%)	54.4 (19.2%)	33.3 (19.8%)	<.001§
Impact score (n=1056 [270/786])	6.3 (3.1)	10.3 (1.4)	5.0 (2.2)	<.001§

*Data are shown as number of patients (percentage) or means (SD).
 FEV₁ indicates forced expiratory volume in 1 second; GOLD, Global Initiative for Chronic Obstructive Lung Disease; SGRQ, St George's Respiratory Questionnaire.
 †A group of 17 patients were excluded from this analysis as it was not known whether they were active or ex-smokers.
 ‡χ² test.
 §Statistically significant differences.
 ||Mann-Whitney test.
 ¶Fisher exact test.
 #Reference values taken from Roca and colleagues.

TABLE 3
Degree of Limitation in Activities of Daily Living in the Study Population (n=1056)

Activity	No Limitation	Minor Limitation	Major Limitation	No Information
Sport and leisure	15.5%	26.8%	52.5%	5.3%
Habitual physical activity	6.3%	63.3%	30.3%	0.2%
Social activities	31.5%	58.2%	9.3%	1.0%
Family activities	37.4%	53.8%	8%	0.9%
Sleep	41.1%	50.3%	8%	0.7%
Household chores	31.6%	48.7%	14%	5.8%
Sex life	24.1%	47.4%	20.2%	8.4%

questionnaire published by Rennard and colleagues⁷ and had physicians question their patients on varying aspects of their daily lives. The second aim of the study was to analyze the relationship between scores obtained and a range of independent variables such as socioeconomic characteristics, clinical parameters, lung function measurements, and SGRQ scores. By doing so, we sought to assess the practical utility of the questionnaire and determine a patient profile that would help to identify patients requiring greater attention. Any patients who scored 9 or higher on the impact questionnaire were placed in our

fragile category. The score of 9 corresponded to the 75th percentile value of distribution of observed impact scores.

On analyzing the relationship between socioeconomic variables and fragility, we found that we were able to define a social profile for fragile patients that was characterized by older age, a lower level of education and economic status, and a greater probability of being single, widowed, or living in a nursing or retirement home. Although certain patients may share certain variables such as impaired clinical or lung function and socioeconomic status, and social activity is dealt with by the impact

questionnaire, we believe that socioeconomic status may be an independent variable that exerts a negative effect on other daily activities performed by the patient. The literature contains several reports of how low socioeconomic status is associated with greater impact on ADLs as measured by traditional quality of life.¹⁴⁻¹⁶ This may indicate that COPD needs to be studied from a broader perspective that includes social aspects.

We found a good correlation between impact scores and known severity markers such as dyspnea, exacerbations, FEV₁ values, and SGRQ scores, as well as significant differences between fragile and nonfragile patients.

It is known that there is a weak correlation between degree of dyspnea and COPD severity (as measured by FEV₁)¹⁷ as dyspnea is affected by a range of physiological and psychological factors.¹⁸ Nonetheless, several studies have shown that dyspnea measured using simple scales such as the MRC scale correlates well with the ability to perform ADLs. Bestall and colleagues,¹⁷ for example, showed that the ability to perform ADLs decreased with increased dyspnea, while Garrod and colleagues¹⁹ found a close correlation between disease severity and MRC grade 3-5 dyspnea when validating an ADL questionnaire for use in COPD patients. The present study also found a significant relationship between MRC dyspnea scores and impact on ADLs. Using the same impact questionnaire, Rennard and colleagues⁷ found that the majority of patients they interviewed underestimated the severity of their disease. While most of them considered they had mild or moderate dyspnea, their impact scores showed considerable evidence of ADL limitations, frequent loss of work due to COPD among those aged under 65 years, and repeated use of emergency and medical services in general. Although the majority of fragile patients had severe dyspnea, over 37% stated that their condition was moderate or mild.

This highlights the importance of using measurement tools other than traditional lung function tests and dyspnea scales as these alone cannot evaluate the true impact of disease on daily life.

The introduction of HRQL questionnaires was a step forward in this respect. Studies of patients with COPD have shown that quality of life is weakly or moderately correlated with lung function test results and more closely correlated with dyspnea and exercise intolerance.^{17,20} Although they are useful measurement tools, HRQL questionnaires mainly address aspects related to respiratory symptoms and how these affect daily life. They do not provide information on broader aspects such as social, affective, or professional relationships. In addition, they need to be self-administered and this can limit their widespread use among COPD patients and even call their validity into question when used, for example, with patients who are elderly, or have a low level of education, or reading or comprehension problems.

Our patients had a mean SGRQ score of 47.9, which places them at the limit of the 95th percentile of scores for the general Spanish population of the same age group. This score is very similar to the mean score of 46 reported by de Miguel Díez¹³ for a group of 460 COPD patients monitored by respiratory medicine specialists in Spain. We found a close correlation between SGRQ and impact

scores, and we also found significant differences between fragile and nonfragile patients for all the domains of the SGRQ, which supports the validity of the impact questionnaire.

Our study, however, has limitations: its cross-sectional design means that selection bias may have occurred and we did not use a duly adapted and validated version of the original questionnaire. If use of the questionnaire is to become widespread in our setting, then its cultural equivalence, reliability, and sensitivity to changes will first need to be demonstrated in a further study.

In conclusion, scores from our COPD impact questionnaire correlated well with clinical variables, traditional disease severity markers (dyspnea, FEV₁, and exacerbations) and SGRQ questionnaire scores. The questionnaire has added value, however, as it can be used to probe for new information. In our case, we were able to create a fragile patient profile, characterized by impaired clinical and lung function status, and a poorer socioeconomic background.

Investigators Who Participated in the EIME Study

José Abal Arca, Bernardino Alcázar Lanagan, José Daniel Alcázar Ramírez, José Luis Aller Álvarez, Juan Almagro López, Fátima Almagro Múgica, Enrique Alonso Mallo, Fernando Álvarez Carreño, Mohamed Amir Hakmi, Juan Antonio Amores García, Pilar Andrés Ruzafa, Ada Luz Andreu Rodríguez, Antonio Antón Albisu, Antonio Pablo Arenas Vacas, Josep Armengol Sánchez, Jesús Arribas Barcelona, Marta Arzola Rodríguez, Nuria Avisbal Portillo, Adolfo Baloira Villar, Pedro Baños Hidalgo, Enric Barbeta Sánchez, Santiago Bardagi Forns, José Manuel Barragán Casas, Francisco Barragán Márquez, Abdallah Beik Beik, Andrés M. Bejarano Guillén, Carlos Bejarano Martínez, María del Carmen Bermejo Navas, Miguel Betanbol Manzana, Marina Blanco Aparicio, Rosana Blavia Anoy, Antonio Bové Ribé, Juan Manuel Bravo Santervás, Josu Bronte Blenzobas, José Bujalance Zafra, Ana Bustamante Rufí, Gabriel Calero Blázquez, José Luis Calpe Calpe, Felipe Canseco González, Emilio Caparrós López, José Antonio Carratalá Torregrosa, José Ángel Carretero Gracia, María Teresa Casamitja Sot, Evaristo del Castillo, Carmen Castillo Aguilar, Elisabeth Castillo Díaz, Rafael Castrodeza Sanz, Pilar Cebollero Rivas, José Celdrán Gil, Miguel Ángel Ciscas Vilanova, Carolina Cisneros Serrano, Isidoro Cobo Moreno, Antonio Colom Ferrer, Montserrat Contreras Díaz, Alberto Capelastegui Sainz, Pedro J. Cordero Rodríguez, Víctor José Cuervo González, Carlos de Abajo Cucurull, Enrique de Casimiro Calabuig, Alfredo de Diego Damiá, Rafael de los Reyes Cruz, Daniel del Castillo Otero, Salvador Díaz Lobato, José Antonio Díaz Pedreira, Antonio Diez Herranz, Juan Antonio Domingo Morera, Christian Domingo Ribas, María José Domínguez Lozano, Ana María Domínguez Martínez, Jordi Dorca Sagarzal, José Miguel Durán Alama, Víctor Manuel Eguía Astibia, Walid El Jawal, Teresa Elías Hernández, Luis Manuel Entrenas Costa, Cristóbal Esteban González, Sonia Fernández, Estrella Fernández Fabrilles, Jesús Fernández Francés, María del Carmen Fernández García, José Fernández Guerra, Sonia María Fernández Rozas, Emilio Fernández Vázquez, Susana Flórez Martín, Miguel Ángel Franco Campos, Fundación Universitaria de Las Palmas, Miguel Gallego Díaz, Marta García Clemente, Pedro García de la Mata, Julia García de Pedro, Ricardo García Luján, Francisco García Río, Patricia García Sidro, Cristina García Vadillo, Ignacio García Talavera, José Antonio Gil Cartés, María Concepción Gil Carvajal, José Gil Rubio, Juan

Manuel Gómez Gutiérrez, Mario Gómez Luque, Fulgencio González Garrido, María Cruz González Villaescusa, María Ángeles Gotor Lázaro, Encarnación Dolores Granados Valverde, José Vicente Greses Giner, José Antonio Gullón Blanco, Guillermo Guzmán Dávila, José Luis Heredia Budó, Enrique Hernández García, Jesús R. Hernández Hernández, Luis Herrero Hermida, Raúl Hidalgo Carvajal, María Ángeles Hidalgo Rico, Jesusa Hortensia Canto, Fernando Iglesias Río, Isabel Isidro Montes, Beatriz Jara Chinarro, Nicolás Jiménez López, Jesús Jiménez López, María Purificación Jiménez Santolama, Antonio Ladaria Ferrer, Montserrat León Fábregas, Encarnación López Gabaldón, Jorge López García, Antonia Galán Davila, María Milagrosa López Gordo, Antolín López Viña, José Luis López-Campos, Daniel Luna Sabaté, Mariano Marcew Letosa, Luis Marco Jordán, Pedro Marcos Velázquez, Alejandra Marín Arquedes, Francisco Márquez Varela, María Belén Martín Martínez, Miguel Ángel Martín Pérez, Esperanza Martín Zapatero, María Teresa Martínez Martínez, Eva Martínez Moragón, Dolores Martínez Rodríguez, Fernando Martín-Vivaldi Martínez, José Alberto Martos Velasco, Sagrario Mayoralas Alises, María Teresa Melgosa Camarero, Joaquina Mínguez Villena, Carmen Monasterio Ponsa, María Dolores Mota Godoy, Javier Moraza Cortes, María José Muñoz Martínez, Ana María Navarro Oller, Felipe Nicolau Prairie, José Nieto Serrano, José Luis Orcastegui Candial, Julio Ordiales Fernández, Francisco Manuel Páez Codeso, Ana Palacios Bartolomé, Mercedes Palau Benavent, Javier Palicio Sopena, Miguel Ángel Palma Otero, María José Pavón Fernández, Jaime Pavón Freire, Germán Peces-Barba Romero, Concha Pellicer Ciscar, Pedro Penela Penela, José María Peñas Herrero, Antonio Pérez Artilles, Luis A. Pérez de Llano, Alicia Pérez Rodríguez, Fernando Pignatelli Albarracín, Vicente Plaza Moral, Pedro Plaza Valía, Luis Ponce de León Martínez, Bartolomé Poyato González, María Sol Prats Bardaji, Juan Pujol Ribó, José Ignacio Quintana González, Ventura Rabeli Santacana, Mercedes Ramón Capilla, Jacinto Ramos González, Feliu Renom Sotorra, Jesús Ribas Sola, Juan Antonio Riesco Miranda, Salvador Rocafort Lorenzo, Raquel Rodríguez Díez, Eugeni Rodríguez Flores, Juan Luis Rodríguez Hermosa, Luis Rodríguez Pascual, Enrique Rodríguez Quinzanos, Gema Rodríguez Trigo, José Romero Morillo, Víctor Félix Romero Sanz, Amparo Rosa Sánchez, Gemma Rubinos Cuadrado, Francisco José Ruiz López, José Sala Félix, Julio Sánchez de Cos Escuin, Jesús Fernando Sánchez Gómez, Eloy Sánchez Haya, Ignacio M. Sánchez Hernández, Amparo Rosa Sánchez Serrano, Fernando J. Sánchez-Toril López, Jesús Sancho Chinesta, Javier Santamaría de Torres, María Candelaria Santana Rodríguez, María Luisa Sanz Sánchez, Pilar Sanz Sanz, Conrado Shum Funk, Adolfo Simón Rodríguez, Manuel Agustín Sojo González, Segismundo Solano Reina, Juan José Soler Cataluña, Isabel María Suárez Toste, Juan Carlos Tapia Regidor, Xavier Tarrago Res, Pablo Teller Juste, Enrique Temes Montes, Rosa María Tomás Mas, Julio Torres Jiménez, Javier Ugedo Urrueza, Isabel Urrutia Landa, José Manuel Valencia Gallardo, Carmen Valentí Ardanuay, José Manuel Valle Vázquez, Rosa Vázquez Oliva, María Isidora Verdugo Cartas, Alejandro Veres Racamonde, Manuel Viña Justrubo, Francisco Villa Arellano, Juan José Villarreal Balza de Valejo, Jordi Zapater Pérez, Gabriel Zubillaga.

REFERENCES

1. Sobradillo V, Miravittles M, Gabriel R, Jiménez Ruiz CA, Villasante C, Masa JF, et al. Geographical variations in prevalence and underdiagnosis of COPD. Results of the IBERPOC multicenter epidemiological study. *Chest*. 2000;118:981-9.
2. Celli B, Cote CG, Marín JM, Casanova C, Montes de Oca M, Méndez RA, et al. The body-mass index, airflow obstruction, dyspnea, and exercise capacity index in chronic obstructive pulmonary disease. *N Engl J Med*. 2004;350:1005-12.
3. Gerardi DA, Lovett L, Benoit-Connors ML, Readon JZ, ZuWallack RL. Variables related to increased mortality following outpatient pulmonary rehabilitation. *Eur Respir J*. 1996;9:431-5.
4. Landbo C, Prescott E, Lange P, et al. Prognosis value of nutritional status in chronic obstructive pulmonary disease. *Am J Respir Crit Care Med*. 1998;157:1791-7.
5. Jones PW, Quirk FH, Baveystock CM, Littlejohns OA. Self-complete measure of health status for chronic airflow limitation. The St. George's Respiratory Questionnaire. *Am Rev Respir Dis*. 1992;145:1321-7.
6. Ferrer M, Alonso J, Prieto L, Plaza V, Monsó E, Marrades R, et al. Validity and reliability of the St George's Respiratory Questionnaire after adaptation to a different language and culture: the Spanish example. *Eur Respir J*. 1996;9:1160-6.
7. Rennard S, Decramer M, Calverley PMA, Pride NB, Soriano JB, Vermeire PA, et al. Impact of COPD in North America and Europe in 2000 subjects perspective of confronting COPD International Survey. *Eur Respir J*. 2002;20:799-805.
8. Miravittles M, Calle M, Álvarez-Gutiérrez F, Gobartt E, López F, Martín A, and the EIME group. Exacerbations, hospital admissions and impaired health status in chronic obstructive pulmonary disease. *Qual Life Res*. 2006;15:471-80.
9. Roca J, Sanchis A, Agustí-Vidal A, Segarra F, Navajas D, Rodríguez Roisin R, et al. Spirometric reference values from a Mediterranean population. *Bull Eur Physiopatol Respir*. 1986;22: 271-4.
10. Barberà JA, Peces Barba G, Agustí AGN, Izquierdo JL, Monsó E, Montemayor T, et al. Guía clínica para el diagnóstico y tratamiento de la enfermedad pulmonar obstructiva crónica. *Arch Bronconeumol*. 2001;37:297-316.
11. Mahler DA, Wells CK. Evaluation of clinical methods for rating dyspnea. *Chest*. 1998;93:580-6.
12. Esteban C, Moraza J, Aburto M, Quintana JM, Capelastegui A. Descripción de una muestra de pacientes con enfermedad pulmonar obstructiva crónica atendidos en las consultas del área de neumología dependientes de un hospital. *Arch Bronconeumol*. 2003; 39:485-90.
13. de Miguel Díez J, Izquierdo Alonso JL, Rodríguez González-Moro JM, de Lucas Ramos P, Bellón Cano JM, Molina París J. Calidad de vida en la enfermedad pulmonar obstructiva crónica. Influencia del nivel de asistencia de los pacientes. *Arch Bronconeumol*. 2004;40: 431-7.
14. Skwarska E, Cohen G, Skwarski C, Lamb C, Bushell D, Parker S, et al. Randomised controlled trial of supported discharge in patients with exacerbations of chronic obstructive pulmonary disease. *Thorax*. 2000;55:907-12.
15. de la Iglesia Martínez F, de la Fuente Cid R, Ramos Polledo V, Pellicer Vázquez C, Nicolás Miguel R, Diz-Lois Martínez F. Análisis factorial de la calidad de vida relacionada con la salud de los pacientes con enfermedad pulmonar obstructiva crónica estable. *Arch Bronconeumol*. 2001;37:410-6.
16. McSweeney AJ, Grant I, Heaton RK, Adams KM, Timms RM. Life quality of patients with chronic obstructive pulmonary disease. *Arch Intern Med*. 1982;142:473-8.
17. Bestall JC, Paul EA, Garrod R, Garnham R, Jones PW, Wedzicha JA. Usefulness of the Medical Research Council (MRC) dyspnea scale as a measure of disability in patients with chronic obstructive pulmonary disease. *Thorax*. 1999;54:581-6.
18. Marín JM. Manifestaciones clínicas: la disnea y su importancia en el paciente con EPOC. *Arch Bronconeumol*. 2001;37 Supl 1: 8-13.
19. Garrod R, Bestall JC, Paul EA, Wedzicha JA, Jones PW. Development and validation of a standardized measure of activity of daily living in patients with severe COPD: the London Chest Activity of Daily Living Scale (LCADL). *Respir Med*. 2000;94:589-96.
20. Jones PW. Health status measurement in chronic obstructive pulmonary disease. *Thorax*. 2001;1956:880-7.
21. Ferrer M, Villasante C, Alonso J, Sobradillo V, Gabriel R, Vilagut G, et al. General population norms of the St George's respiratory questionnaire: a strategy to facilitate interpretation of quality of life scores. *Eur Respir J*. 2002;19:405-13.

APPENDIX

Questionnaire on Impact of COPD on Activities of Daily Living*

1. Sport and leisure (swimming, cycling, petanque, etc)
2. Habitual physical activity (walking, climbing stairs, etc)
3. Social activities (visiting friends, going to the cinema, going to the bar, etc)
4. Family activities (family get-togethers, looking after grandchildren, etc)
5. Sleep
6. Household chores (sweeping, dusting, etc)
7. Sex life

Answers: 0 (not at all)

1 (some, a little)

2 (a lot)

*This is a close translation of the modified Spanish version of the original questionnaire⁷ created by the authors for this study. It is provided here for comprehension purposes only.