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

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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, and validated quality of life questionnaires.

RESULTS: We studied 1057 patients (95.2% male) with a mean 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 (X ± SD). 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 results and clinical variables, socioeconomic status, and validated quality of life questionnaires. The questionnaire was a useful tool for identifying fragile patients who, in addition to having poorer clinical status and lung function measurements, have 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 estudiábamos 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 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 del St. George’s Respiratory Questionnaire (SGRQ).

RESULTADOS: Estudiábamos a 1.057 pacientes (un 95.2% varones), con una edad media ± desviación estándar de 67 ± 9 años y volumen espiratorio forzado en el primer segundo (FEV1), expresado en porcentaje, del 41.8 ± 13.3%. La puntuación media del cuestionario de impacto fue de 6.3 ± 3.1. Las actividades de mayor afectación fueron deporte y ocio,
The traditional ones for predicting disease progression.4

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.5 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 tolerance and body mass index (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.6-8 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 COPD, defined by FEV₁ of less than 70% of predicted9 and a history of symptoms that required treatment changes; number of emergency department visits or hospital admissions; treatments; lung function measurements; socioeconomic status; and validated HRQL measures, specifically the St George’s Respiratory Questionnaire (SGRQ).8,6 We 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 predicted and a FEV₁/forced vital capacity ratio of less than 70%10,11; 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); 3) 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 4) 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 score12; 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.
with relevant legislation. The structure, content, and purpose of the database in compliance with relevant legislation. The Spanish authorities were notified of the existence of the database and password, and patient confidentiality was guaranteed by not posting the data 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, coordinating center. All data received were entered into a database located in the data recording and analysis center (Drug Farma, Madrid, Spain). The Spanish authorities were notified of the existence of the database and password, and patient confidentiality was guaranteed by not posting the data online (www.eime.es). Each researcher was given a user name and password, and patient confidentiality was guaranteed by not including any identifying data.

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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 (10) 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). 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;
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.

**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. 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, who studied 611 patients in 5 outpatient
departments, and by de Miguel Díez and colleagues, 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.

The main aim of this study was to determine the impact of COPD on ADLs. We used a modified version of the...
questionnaire published by Remmard and colleagues 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

### TABLE 2

<table>
<thead>
<tr>
<th>Perception of Health</th>
<th>All</th>
<th>Fragile Patients</th>
<th>Nonfragile Patients</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social activity</td>
<td>52.8</td>
<td>54.4 (19.2%)</td>
<td>43.3 (19.8%)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Emotional activity</td>
<td>61.4</td>
<td>61.4 (23.2%)</td>
<td>57.6 (21.9%)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Physical activity</td>
<td>37.4</td>
<td>37.4 (21.7%)</td>
<td>33.3 (19.8%)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>
| Impact              | 6.3 (3.1) | 10.3 (1.4) | 5.0 (2.2) | <.001

### TABLE 3

<table>
<thead>
<tr>
<th>Degree of Limitation in Activities of Daily Living in the Study Population (n=1056)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity</td>
</tr>
<tr>
<td>Sport and leisure</td>
</tr>
<tr>
<td>Habitual physical activity</td>
</tr>
<tr>
<td>Social activities</td>
</tr>
<tr>
<td>Family activities</td>
</tr>
<tr>
<td>Sleep</td>
</tr>
<tr>
<td>Household chores</td>
</tr>
<tr>
<td>Sex life</td>
</tr>
</tbody>
</table>

### Table Notes

- **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.
- **T**-test
- **Mann-Whitney** test
- **Fisher exact test
- **Reference values taken from Roca and colleagues.**
We found a correlation between SGRQ and impact on ADLs. Using the same impact questionnaire, 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 severity and impact on ADLs. Using the same impact questionnaire, Rennard and colleagues 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. 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 was very close to the mean score of 46 reported by de Miguel Díez 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 the 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 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 Ábal Arca, Bernardino Alcázar Lanagran, José Daniel Alcázar Ramírez, José Luis Aller Álvarez, Juan Almagro López, Fátima Almagro Mújica, Enrique Alonso Mallo, Fernando Álvarez Carreño, Mohamed Anuar Hakimi, Juan Antonio Amores García, Pilar Andrés Ruaza, Ada Luz Andreu Rodríguez, Antonio Antón Albués, Antonio Pablo Arenas Vacas, Jose Arriaga Sánchez, Jesús Arribas Barceló, Marta Azkola Rodríguez, Nuria Avisbal Portillo, Adolfo Balora Villar, Pedro Raúl Bidal, Emilio Barbera Sánchez, Santiago Bardají Font, José Manuel Barragán Casas, Francisco Barragán Márquez, Abdallah Beik Breik, Andrés M. Bejarano Guillelín, Bejarano Martínez, María del Carmen Bermejo Navas, Miguel Betianbol Mantana, Marina Blanco Aparicio, Rosana Blavia Ayoy, Antonio Bovd Ribé, Juan Manuel Bravo Santervás, Josu Bronte Bienzobas, José Bujalance Zafría, Ana Bustamante Ruif, Gabriel Calero Blázquez, José Luis Calpe Calpe, Felipe Camacho González, Emilio Caparrós López, José Antonio Carratalá Torregrosa, José Ángel Carretero Gracia, María Teresa Casasús Sot, Evaristo del Castillo, Carmen Castillo Aguilisah, Elisabeth Castillo Díaz, Rafael Castrodeza Sanz, Pilar Cebollero Rivas, José Celldrán Gil, Miguel Ángel Cisca Vifanov, Caristina Cisneros Serriano, Isaioso Cobo Moreno, Antonio Colom Ferrer, Montserrat Contreras Díaz, Alberto Capelastegui Sainz, Pedro J. Cordero Rodríguez, Víctor José Cuervo González, Carlos de Abajo Cacurral, Enrique de Casimiro Calabuig, Alfredo de Diego Damiá, Rafael de los Reyes Cruz, Daniel del Castillo Otero, Salvador Díaz Lobato, José Antonio Díez Pedreira, Antonio Díez Herranz, Juan Antonio Domingo Moreza, Christian Domingo Ribas, María José Domínguez Lozano, Ana María Domínguez Martínez, Jordi Dorca Sagardó, José Miguel Durán Alama, Vicent Manuel Eguía Arribas, Walid El Jawal, Teresa Elías Hernández, Luis Manuel Embróns Costa, Cristina Esteban González, Sonia Fernández, Estrella Fernández Fabrilles, Jesús Fernández Francés, María del Carmen Fernández García, Jesús Fernández Guerra, Sonia María Fernández Rosas, Emilio Fernández Vázquez, Susana Flores Martín, Miguel Ángel Franco Campos, Fundación Universitaria de Las Palmas, Miguel Gallego Díaz, Marta García Clemente, Pedro García de la Mata, Julio García de Pedro, Ricardo García Luján, Francisco García Rio, Patricia García Sidro, Cristina García Vadillo, Ignacio García Talavera, José Antonio Gil Cartis, María Concepción Gil Carvajal, Julio Gil Rubio, Juan...

REFERENCES


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 questionnaire created by the authors for this study. It is provided here for comprehension purposes only.