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Effectiveness of a Specific Program for Patients With Chronic Obstructive Pulmonary Disease and Frequent Exacerbations

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OBJECTIVE: Patients with chronic obstructive pulmonary disease (COPD) and a history of frequent exacerbations are a target population of particular interest from both a clinical and an economic standpoint. The objective of this study was to evaluate the effectiveness of a program designed specifically to manage patients in this subgroup.

PATIENTS AND METHODS: This was a 1-year randomized controlled trial designed to compare the effectiveness of a specific program (SP) with that of conventional management (CM) in a group of patients with a high frequency of exacerbations (3 or more per year). Within-group and between-group comparisons were carried out for a number of variables related to the patients' medical care, dyspnea, health-related quality of life (HRQL), inhaler technique, and pulmonary function.

RESULTS: A total of 26 patients were enrolled in the study (all men). The mean (SD) age was 73 (8) years, and mean forced expiratory volume in 1 second (FEV_1) expressed as a percentage of the reference value was 43% (15%). Exacerbations requiring hospital care (emergency department visits and/or admission) decreased in both groups: by 24.4% (*P* not significant) in the CM group and 44.1% (*P*=.061) in the SP group. Hospital admissions decreased 73.3% in the SP group and increased 22% in the CM group (*P*<.001). While length of hospital stay decreased 77.3% in the SP group, this figure almost doubled in the CM group (*P*=.014). Dyspnea, HRQL, and inhaler technique improved in both groups. FEV_1 fell by 46 mL/year in the CM group and increased 10 mL/year in the SP group (*P* not significant).

CONCLUSIONS: The use of a simple program to manage selected patients with a history of frequent exacerbations produces a significant reduction in the number of hospital admissions, an improvement in HRQL, and may improve prognosis.

Key words: *Chronic obstructive pulmonary disease. Exacerbations. Hospitalization. Education.*

Eficacia de un programa específico para pacientes con EPOC que presentan frecuentes agudizaciones

OBJETIVO: Los pacientes con enfermedad pulmonar obstructiva crónica que presentan frecuentes agudizaciones (AEPOC) constituyen una población diana de especial interés, tanto desde el punto de vista clínico como económico. El objetivo del estudio es evaluar la eficacia de un programa específico (PE) dirigido a este subgrupo de enfermos.

PACIENTES Y MÉTODOS: Se ha realizado un estudio prospectivo, aleatorizado y controlado de un año de duración, en el que se ha comparado la eficacia del PE frente al tratamiento convencional (TC) en un grupo de pacientes con exacerbaciones frecuentes (3 o más AEPOC al año). Se efectuaron comparaciones intragrupo e intergrupo en diversos parámetros asistenciales, disnea, calidad de vida relacionada con la salud (CVRS), técnica inhalatoria y función pulmonar.

RESULTADOS: Se incluyó en el estudio a 26 pacientes (todos varones), con una edad media (± desviación estándar) de 73 ± 8 años y volumen espiratorio forzado en el primer segundo, en porcentaje del valor de referencia, del 43 ± 15%. Las exacerbaciones que precisaron atención hospitalaria (visitas a urgencias y/u hospitalizaciones) disminuyeron en ambos grupos: un 24,4% (p = no significativo) en el grupo TC y un 44,1% (p = 0,061) en el grupo PE. Las hospitalizaciones se redujeron un 73,3% en el grupo de intervención, mientras que se incrementaron un 22% en el TC (p < 0,001). Los días de hospitalización disminuyeron un 77,3% en el PE, mientras que aumentaron casi el doble para el TC (p = 0,014). La disnea, la CVRS y la técnica inhalatoria mejoraron en ambos grupos. El volumen espiratorio forzado en el primer segundo presentó un descenso de 46 ml/año en grupo TC, mientras que se incrementó 10 ml/año para el grupo PE (p = no significativo).

CONCLUSIONES: El empleo de un programa sencillo, dirigido a pacientes seleccionados con exacerbaciones frecuentes, comporta una reducción significativa del número de las hospitalizaciones, mayor CVRS y quizá mejor pronóstico.

Palabras clave: *Enfermedad pulmonar obstructiva crónica. Exacerbaciones. Hospitalización. Educación.*

Introducción

Exacerbations play a very important role in the natural history of chronic obstructive pulmonary disease (COPD) and have a clear influence on the health-related quality of life (HRQL) of patients with this disease.[1] Since exacerbations place a heavy burden on the health

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care system, their economic impact is high.[2,3] Finally, they even represent an adverse prognostic factor.[4] On average, patients with COPD have between 1 and 4 exacerbations per year.[5] However, the distribution and severity of these episodes varies between patients. In the ISOLDE trial, which prospectively followed up patients with moderate to severe COPD for 3 years, up to 20% of patients had no exacerbations.[6] In an outpatient study of COPD patients with less severe disease and milder exacerbations, Miravitlles et al[5] reported that 31% of patients had 3 or more exacerbations a year. In a series of patients managed in a respiratory clinic setting, we found that 60% of patients experienced no exacerbations requiring hospital care while a small subgroup (10%-12%) presented frequent exacerbations that gave rise to a hospital visit.[2] It is our opinion that this group of frequent exacerbators constitutes a target population. Around 60% of all hospital visits (both emergency department visits and hospital admissions) were generated by this small group of patients,[2] who are individuals with advanced lung disease characterized by high comorbidity, poor HRQL,[7] accelerated lung function decline,[8] and a poor prognosis.[4]

From a strategic standpoint, it would appear necessary to reduce the frequency of exacerbations, and several therapeutic options have been shown to be useful in achieving this goal. Pharmacological treatments that reduce exacerbations by 25% to 30% include inhaled corticosteroids,[6] long-acting bronchodilators,[9,10] and combinations of long-acting β_2-agonists and inhaled corticosteroids.[11] Antioxidants such as N-acetylcysteine[12] and pulmonary rehabilitation[13] are 2 other treatments that have been associated with reductions in the exacerbation rate, although there is less evidence supporting the use of these last 2 treatments. There is also some evidence for the effectiveness of the influenza vaccination[14] and patient education, although there is still no consensus on the latter.[14-16] Combined coordinated use of all of these resources in conjunction with strategies aimed at optimizing and maximizing preventative treatment could potentially be of great use, particularly in the subgroup of patients at higher risk for exacerbations. The objective of this study was to evaluate the effectiveness of a program designed specifically to manage COPD patients with a history of frequent exacerbations comprising an educational program and regular clinical monitoring at a specialized respiratory clinic.

Patients and Methods

Study Population

This was a 1-year prospective randomized controlled trial that compared the usefulness of a specific program (SP) with that of conventional management (CM) in COPD patients with a history of frequent exacerbations. Patients with COPD were considered to be frequent exacerbators if they had had 3 or more exacerbations requiring hospital treatment (emergency department visits and/or hospitalization) during the year preceding the study. An exacerbation was defined as any sustained increase from baseline in respiratory symptoms requiring a change in regular medication and generating the need for medical attention.[17] The COPD diagnosis was based on the presence of a smoking history (current or prior smoker) of at least 20 pack-years and of a mostly irreversible airflow limitation defined as a postbronchodilator ratio of forced expiratory volume in 1 second (FEV_1) to forced vital capacity (FVC) of less than 70%. Excluded from the trial were patients who had been previously diagnosed with bronchial asthma, bronchiectasis, cystic fibrosis, or upper airway limitation, and individuals with bronchiolitis secondary to systemic diseases. All the patients treated in our clinic who fulfilled the definition of frequent exacerbator during the course of 2001 were enrolled.

Specific Program

The key components of the SP were a schedule of monthly clinical visits to a specialized clinic and a short educational program. At each monthly visit, in addition to their personal medical consultation, patients attended a group educational session led by the nursing team (4-6 patients). Patients and their families also attended an informative session that included an explanation of COPD and recommendations on how to manage the disease (anti-smoking advice, use of inhalers, exercise, nutrition, sleeping habits, etc). The educational program was supported by specially designed printed material.[18] Patients were not instructed in self-management of exacerbations, and no self-management plan was provided.

Pharmacological treatment was standardized; all the patients received ipratropium bromide regularly, long-acting inhaled β_2-adrenergic agonists, high doses of inhaled corticosteroids (1000 μg/day of fluticasone), and salbutamol ad libitum. Both the choice of the long-acting β_2-agonist (formoterol or salmeterol) and the prescription of a combination treatment (N-acetylcysteine, oral theophyllines or other drugs) were decided on a patient-by-patient basis by the attending specialist. None of the patients received maintenance oral corticosteroids, and none of them underwent pulmonary rehabilitation, domiciliary noninvasive mechanical ventilation, or lung reduction surgery. All current smokers were enrolled in a smoking cessation program. The treatment of any exacerbations that occurred during the 1-year study period was not standardized, all such treatment being left to the judgment of the attending physician in each case.

Conventional Management

The patients assigned to the CM group received the same treatment as the patients in the SP group. However, in the CM group, consultation with a specialized physician only took place once every 3 months. Furthermore, these patients did not attend the educational program, though did receive information about COPD and how to manage the disease, including nutritional advice and insistent recommendations about the need for physical exercise (a daily walk). They received instruction on proper inhaler technique at the first visit.

Study Variables

In stable situation (4 weeks without exacerbation), prior to randomization, and after 1 year of follow-up, the following data were collected prospectively: age, smoking history, baseline symptoms, comorbidity, and HRQL. Dyspnea was assessed using a modified Medical Research Council scale.[19]