Evaluation of a Home Hospitalization Program in Patients With Exacerbations of Chronic Obstructive Pulmonary Disease

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OBJECTIVE: We carried out a randomized controlled trial to evaluate the efficacy of a home hospitalization (HH) program for patients hospitalized for exacerbation of chronic obstructive pulmonary disease (COPD).

PATIENTS AND METHODS: Patients who were clinically stable and had stable arterial blood gases were randomized to the conventional hospitalization group or the HH group.

RESULTS: Of the 88 patients evaluated, 40 (20 in each group) were enrolled. No differences were observed in baseline characteristics, in clinical recovery, or arterial blood gases between the 2 groups at discharge. At 1-month follow up there were no differences in mortality or in the number of readmissions. The mean length of hospitalization in patients with HH was 9.2 days (4 days in hospital and 5 days at home), compared to 12.2 days in patients with conventional hospitalization.

CONCLUSIONS: Our results show that a hospital-supervised HH program including the participation of pneumologists and nursing staff allows for the recovery of patients hospitalized for exacerbation of COPD who have stable symptoms and arterial blood gases with no increase in the rate of readmission, relapse, or therapeutic failure.

Key words: *Chronic obstructive pulmonary disease. COPD. Home hospitalization. Early discharge*.

Evaluación de un programa de hospitalización domiciliaria en pacientes con EPOC agudizada

OBJETIVO: Se ha realizado un estudio prospectivo, controlado y aleatorizado en grupos paralelos con el fin de evaluar la eficacia de un programa de hospitalización domiciliaria (HD) en pacientes ingresados en el hospital por agudización de la enfermedad pulmonar obstructiva crónica (EPOC).

PACIENTES Y MÉTODOS: Los pacientes que cumplían criterios de estabilidad clínica y gasométrica al tercer día se aleatorizaron al grupo de hospitalización convencional o al grupo HD.

RESULTADOS: De los 88 pacientes valorados se incluyó a 40 (20 en cada grupo). No se apreciaron diferencias en las características basales, en la recuperación clínica ni en la gasometría al alta entre ambos grupos. Al mes de seguimiento no hubo diferencias en la mortalidad ni en el número de readmisiones. La estancia media de los pacientes con HD fue de 9,2 días (4 días en el hospital y 5 días en su domicilio), frente a los 12,2 días que permanecieron los pacientes en el hospital.

CONCLUSIONES: Nuestros resultados demuestran que un programa de HD controlado desde el hospital, con participación de neumólogos y personal de enfermería, en enfermos ingresados con exacerbación de la EPOC que cumplen unos requisitos de estabilidad clínica y gasométrica, permite la recuperación del paciente sin un aumento en la tasa de reingresos, recaídas o fracasos terapéuticos.

Palabras clave: *Enfermedad pulmonar obstructiva crónica agudizada. EPOC. Hospitalización domiciliaria. Alta temprana.*

Introduction

Chronic obstructive pulmonary disease (COPD) is one of the most prevalent diseases in the western world, and interest in it has increased considerably in recent years.[1-3] The results of the IBERPOC study[4] have called attention to the importance of the problem in Spain, where prevalence is 9% in the age group from 40 to 69 years old and 20% in those over 65 years.[4] Exacerbation is an event of considerable importance in the natural history of COPD. Several studies have shown that COPD patients suffer an average of 2 exacerbations per year,[5] and that 1 out of 6 requires hospitalization, which is associated with high cost.[6] In 1995 the cost generated by patients with COPD was estimated at 160 000 million pesetas (€961.92 million), of which 48 000 million (€288.58 million) were attributable to direct health care costs.[7] Such costs of COPD in the IBERBOC study were even higher—75 150 million pesetas (€451.80 million).[6] It is important to point out that hospitalization accounts for the greatest share of direct health care costs—between 36.3% and 43%.[6,8]

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In view of the great economic burden generated by the hospitalization of patients with COPD exacerbations, new models aiming to optimize health care resources have been developed in recent years. Short-stay units, respiratory day hospitals and overnight units, and home health care programs are good examples of such models.[9-14] More recently, there has been growing interest in what has come to be known as home hospitalization (HH). This can be defined as a specific health care resource that makes it possible to treat a selected group of patients by providing them with an infrastructure without which they would have to remain in hospital.[15,16]

While several studies have recently evaluated the results of home treatment of patients with COPD exacerbations, experience with this type of program is still scarce. The designs of the studies available are very different in terms of the protocol used and the inclusion and exclusion criteria applied. Furthermore, there are still doubts concerning the type of patient who can benefit from this promising health care alternative and the conditions of such a program. In view of the need to define the specific criteria of clinical stability and stability of arterial blood gases required to identify patients who could be included in a HH program and to define protocols for both physician and nurse interventions, we designed a study whose aim was to evaluate the efficacy of a HH program for patients with exacerbations of COPD admitted to our hospital.

TABLE 1
Inclusion and Exclusion Criteria

Inclusion criteria
Diagnosis of chronic obstructive pulmonary disease (COPD)
Nonspecific exacerbation requiring hospital admission
Age <85 years
Living fewer than 20 km from the hospital
Having a telephone at home
Suitable social and family environment
Giving informed consent
Exclusion criteria
Living alone
Major comorbidity: neoplasias, other chronic or uncontrolled diseases
Mental disability
Active alcoholism
Inability to understand the program and participate in it
Admission to intensive care unit
Need for noninvasive ventilation

TABLE 2
Criteria of Clinical Stability and Stability of Arterial Blood Gases*

	Include (and Randomize)	Exclude
General health status	Good	Fair-poor
Borg scale score	≤ day 1	> day 1
Bronchospasm	Mild-moderate: decreased rhonchi and wheezing	Severe: continued bronchospasm
Glycemia	Normal or moderate hyperglycemia (controlled)	Needs intravenous insulin
Hematocrit	<60%	≥60%
Peak flow rate	≥ day 1	< day 1
Chest x-ray	Signs of COPD	Complications: pleural effusion, pneumothorax
ECG	Normal or nonspecific changes	Severe arrhythmia or signs of acute ischemia
Arterial blood gases	PaO_2>60 mm Hg with oxygen via nasal cannulae at a flow rate of <3 L/min	PaO_2<60 mm Hg with oxygen via nasal cannulae at a flow rate of <3 L/min
	$PaCO_2$<55 mm Hg	pH <7.35
	$PaCO_2$>55 mm Hg with no evidence of encephalopathy with pH >7.35	

*COPD indicates chronic obstructive pulmonary disease; ECG, electrocardiogram.

Patients and Methods

Study Design

We designed an open controlled trial in which patients were randomized to parallel groups. The study was approved by our hospital's Ethics Committee. All patients gave their written consent using the informed consent forms approved by the committee.

Patient Selection

Patients were selected consecutively from those admitted to the pneumology department for exacerbation of COPD. After ensuring that they met all the inclusion criteria and none of the exclusion criteria (Table 1), they were informed about the study, invited to participate, and asked for their written consent.

Methods

On admission (day 1) a medical history was taken and a physical examination performed. Blood samples were taken for biochemistry and white blood cell count. Chest x-rays in 2 views, arterial blood gas measurements, and an electrocardiogram were taken, and forced expiratory volume in 1 second (FEV_1) measured. All patients received standard treatment according to the recommendations of the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR),[17,18] based on the use of bronchodilators (β-2 agonists and anticholinergics), antibiotic therapy, and a course of systemic corticosteroids, in addition to the patient's usual medication. Supplemental oxygen was given and the flow titrated to maintain arterial oxygen saturation above 90% or PaO_2 more than 60 mm Hg. Smoking was evaluated and the number of pack-years estimated for each patient. The most recent spirometry data were collected for analysis, and if such data were unavailable, spirometry was performed 1 month after discharge.

Patients were evaluated again 72 hours after admission (day 3) and at this time we determined whether they met the criteria of clinical and arterial blood gas stability shown in Table 2. Those who did were assigned randomly either to the

intervention group (HH), or the control group (conventional hospitalization). Patients who did not yet meet the stability criteria on day 3 were evaluated again on the following days by the same methods until they could be assigned to 1 of the 2 groups.

HH Protocol

The conventional hospitalization group remained on the ward with the same therapeutic protocol that was applied to the HH group and with the usual ward protocol. Patients assigned to the HH group were transported by ambulance to their homes and on the same day were visited by the pneumologist and nurse in charge. The pneumologist examined the patient and checked the treatment protocol and the communication channels set up for requesting programmed and emergency medical attention. A schedule of physician visits was also established: the first on the day the patient was taken home, the last just before discharge, and another at an intermediate point. Patients also had a follow up visit at the hospital outpatient department 1 month after discharge.

The nursing care plan included general care of the patient, evaluation of health status, taking of vital signs, performing required complementary tests (blood tests, urinalysis, arterial blood gases, electrocardiogram), and filling in charts and progress records on self-copying paper, so that a copy could remain in the patient's home and another could be kept in the hospital. The nurse also provided health education (general nature of COPD, first-line intervention for smoking cessation, use of inhalers, oxygen therapy). Nurse visits were scheduled to coincide with medication (every 12 hours), thus allowing the nurse to administer intravenous medication if necessary.

The physician in charge was a pneumology research fellow attached to the hospital's pneumology department and was in regular contact with the nurse in charge. The patient had 24-hour phone access to the nurse for consultations and requests for medical assistance. The nurse then decided on a course of action, either solving the problem or notifying the physician, as occurs on the ward of a conventional hospital.

Study Variables

The main study variable was the number of therapeutic failures in each group. In the conventional hospitalization group, therapeutic failure was considered to be any of the following: need for admission to the intensive care unit (ICU), clinical deterioration requiring modification of the treatment protocol, appearance of nosocomial infections, or other major complications. In the HH group, therapeutic failure was defined as an unfavorable outcome requiring transfer to the hospital.

Secondary variables analyzed were number of calls for consultation or medical assistance, number of relapses at 1 month of follow up, and extent of smoking cessation among smokers. The number of hospital admissions saved in the HH groups was also determined.

Statistical Analysis

Quantitative variables are expressed as means (SD), and qualitative variables as absolute values and percentages. The Mann-Whitney test was used for the comparison of quantitative variables and the Fisher exact test for qualitative variables.

TABLE 3
Patient Characteristics*

	HH (n=20)	CH (n=20)	*P*
Age, years	66 (9)	66 (9)	NS
Sex, M/W	17/3	17/3	NS
Pack-years	50 (27)	49 (33)	NS
Number of patients on DOT	5	3	NS
Previous admissions	2.15 (3)	1.45 (1)	NS
FEV_1, mL	1500 (572)	1354 (600)	NS
FEV_1, %	55 (17)	52 (11)	NS
FVC, mL	2753 (899)	2782 (840)	NS
FVC, %	79 (18)	76 (9)	NS
PaO_2 on admission, mm Hg	57 (7)	57 (10)	NS
$PaCO_2$ on admission, mm Hg	38 (8)	36 (8)	NS
PaO_2 on discharge, mm Hg	68 (6)	71 (9)	NS
$PaCO_2$ on discharge, mm Hg	40(5)	40(8)	NS

*Data are given as mean (SD) unless otherwise indicated. HH indicates home hospitalization; CH, conventional hospitalization; M/W, man/woman; DOT, domiciliary oxygen therapy; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; NS, not significant.

Results

During the study period, 88 patients were admitted to our department with COPD exacerbations. Of these patients, 48 were excluded for the following reasons: 20 patients did not meet inclusion criteria, 18 did not reach the required levels of clinical stability and stability of arterial blood gases, and 3 abandoned the study. Thus, 40 patients were included in the study, 20 of whom were assigned to the HH group and 20 to the conventional hospitalization group. The patient characteristics of those included in the study are shown in Table 3. There were no significant differences between the 2 groups with respect to age, sex, smoking habit, history of long-term home oxygen therapy, previous hospital admissions, or lung function and arterial blood gas values upon admission. At discharge from either care model, there were no differences in clinical recovery or arterial blood gas values between the 2 groups.

There were no significant differences in the number of calls for consultation or medical assistance (1 call in the HH group compared to 2 in the conventional hospitalization group), but there were differences in the number of calls for emergency assistance (4 calls in the conventional hospitalization group compared to none in the HH group). We did find significant differences in the number of relapses during the 1-month follow-up period (5 patients in the conventional hospitalization group presented signs and symptoms of exacerbation during this period compared to none in the patients treated at home). There was 1 case of therapeutic failure in each group. One patient treated in the hospital had an unfavorable outcome; the patient had to be admitted to the ICU and subsequently died. One patient in the HH group had to be readmitted to the hospital with nonspecific abdominal pain, the cause of which remained undetermined after study. There were no differences in smoking habits between the 2 groups upon admission (8 patients in the HH group and 10 in

the control group were smokers), although at 1-month follow up a greater number of patients in the HH group had remained abstinent: 2 were still smoking in the HH group and 8 in the control group ($P<.05$).

The mean length of hospitalization for patients in the HH group was 9.2 days (4 days in the hospital and 5 at home), compared to 12.2 days for the conventional hospitalization group ($P<.05$).

Discussion

No objective criteria have been clearly established to define the optimal moment for discharge of patients requiring hospitalization for COPD exacerbations. Current guidelines are imprecise, usually mentioning subjective factors that depend on physician or patient perceptions alongside markers of clinical stability and the correction of variables indicative of respiratory insufficiency. Such criteria are very unlikely to be universally applicable.[17,19] In view of the increasing importance currently given to the concept of "mean length of stay," several authors have approached the question of ideal length of stay with a view to patients not staying in the hospital longer than strictly necessary. Conclusions have varied. Thus, Mushlin et al[20] established 6.9 days as the ideal duration, while Roselle and D'Amico[21] recommended up to 18 days in patients with frequent readmissions. HH programs for COPD patients provide an infrastructure allowing a selected group of patients to be treated at home during periods of exacerbation, with a consequent reduction in duration of hospital stay.[15] Several authors have reported positive experiences with HH in controlled[22] and uncontrolled studies.[23] The study of Gravil et al[23] is considered the first study of HH in patients with COPD exacerbations. Some controlled studies have used early discharge from the emergency room with home support,[24-26] while others, like those of Cotton et al,[27] Sala et al,[28] and Antoñana et al[29] also used early discharge, but with patients remaining on the ward for a period of time before going home, as in our study.

The problems associated with a HH program center primarily around demonstrating its effectiveness, establishing the moment at which the patient can leave the hospital to continue treatment at home, and defining the minimal infrastructure needed for home treatment. To define when a patient can be considered ready to continue treatment at home, we established criteria of clinical stability and stability of arterial blood gases not previously defined as such in the literature. Other fundamental criteria considered in evaluating whether a patient was ready to continue treatment at home were as follows: improvement of dyspnea assessed on the Borg scale, increase in peak flow compared to values on admission, and the absence of significant polycythemia (hematocrit <60%), together with the absence of evidence of arrhythmias or evidence of acute ischemia in the electrocardiogram. Other authors, like Davies et al,[25] consider the need for intravenous treatment to be grounds for exclusion from HH programs, but we do not share this opinion. If the home care infrastructure is adequate, the need for intravenous medication does not require remaining in hospital. In the present study we successfully used conventional systems for administering intravenous medication (winged infusion set) or devices specifically designed for administration by patients themselves, such as Intermate (Baxter, Deerfield, Ill, USA).[30]

Stability of arterial blood gases is a criterion that must be included in a HH program for COPD exacerbations. The presence of respiratory acidosis or the failure to attain acceptable PaO_2 levels with low-flow oxygen therapy make home management of these patients impossible, as such circumstances generally require that noninvasive ventilation be set up in a hospital setting. Our study showed that it is feasible, however, to have patients on oxygen therapy in HH, even if they were not previously receiving oxygen, provided they meet criteria for stable arterial blood gases. In our study, 15 patients (75%) in the HH group received home oxygen therapy. Of these, 5 were already receiving oxygen in hospital, and 10 still presented respiratory insufficiency when taken home. Other studies show differences in the number of patients receiving home oxygen therapy. The number of such patients was lower in the study of Skwarska et al[24] (8% of patients) and in that of Davies et al[25] (only 3 patients) than in ours. We do not believe that hypoxemia necessarily makes a patient ineligible for HH, provided there is adequate infrastructure and that the requirement of stable arterial blood gases is met, as in our study.

A noteworthy aspect of the studies mentioned above is the high percentage of patients living alone. The British Thoracic Society[31] recommends hospital admission in these circumstances, although it is not a strict criterion for exclusion from a HH program. The social isolation and episodes of anxiety and depression in this context can be considerable. Thus, in our opinion, it is advisable that there be someone present who is responsible for caring for the patient, unless there is adequate social support, as in the study of Davies et al,[25] in which 24 patients had social support available for 20 hours. In our study, due to the lack of social services characteristic of our setting, living alone was considered a criterion for exclusion.

The available studies have taken different approaches to the fundamental question of the infrastructure needed to implement a HH program. In the studies of Gravil et al,[23] Antoñana et al,[29] and Ojoo et al,[26] home visits were scheduled on a daily basis, but in other studies the frequency of home visits was sometimes left to the discretion of the nursing staff responsible for monitoring the patient at home. For example, Davies et al[25] scheduled 2 visits per day for the first 3 days, with subsequent visits left to the judgment of the nursing staff. In our study, we set up a protocol of 2 nurse visits (following the scheme of Davies et al[25]), but with the knowledge that the scheme could be individualized and

adapted to the individual patient's situation, so that a single visit could be made in certain cases. However, we believe it is important that HH programs be able to offer 2 nurse visits per day for those patients who might need them.

An aspect that was of great concern to us when we were designing our study was that of defining the physician's participation in the HH program. In the studies described, there was no direct monitoring by physicians of patients assigned to the HH group, and their progress was in the hands of the nurse. Information collected by the nurse is not by itself sensitive to important clinical status changes and does not provide the level of monitoring appropriate for the patient's clinical status, which we must remember would ordinarily require hospitalization. We believe that it is essential for the physician to monitor patient progress and give the discharge order to assure that HH care is of the same quality as inpatient care. In our study, 3 physician visits were scheduled: the first upon the patient's arrival at home and the last just before discharge, with another visit at some intermediate point. From the legal standpoint, it may be essential to provide some kind of supervision by a physician while the patient remains in a HH program, as required by the Ethics Committee of our hospital. The physician in charge must assume responsibility for the treatment and for the patient's progress, detect any problems that may arise, and decide if and when the patient should be readmitted to hospital or discharged from the HH program. We believe that the physician should be a pneumologist from the respiratory medicine service of the referral hospital for the public health care area.

All the studies have shown favorable outcomes for patients in HH programs, with no differences between such patients and those receiving inpatient care. Our results were consistent with those studies, with no differences in therapeutic failure rates in the HH and conventional hospitalization groups. Anecdotally, we found that a greater number of the patients who were active smokers had remained abstinent at 1-month follow up in the HH group. This aspect has not been analyzed in previous studies, and might be an object of further study.

The length of time during which patients were monitored at home has varied considerably in the literature. The mean length of hospitalization in patients in our HH group was 9.2 days (4 days in hospital and 5 at home). Cotton et al[27] monitored their patients for up to 24 days. The authors attribute this length of hospitalization to the special characteristics of their patients, who were very dependent on hospital care, and to the lack of experience with HH on the part of the nursing staff responsible for the program. In the study of Sala et al[28] the length of HH was 7.3 days and 7.2 days in the study of Antoñana et al.[29]

With regard to lung function, it is noteworthy that the patients in our study had a FEV_1 of 1.5 L (55%), higher than the FEV_1 reported in other studies (0.8 L in that of Davies et al,[25] and 0.85 L in that of Ojoo et al[26]) and closer to the FEV_1 reported by Sala et al[28] (45%). This probably reflects the health status of the patients admitted with COPD exacerbations in our setting, where the lack of primary care resources, the nonexistence of home care programs, and the excessive demand for emergency room attention inevitably lead to the admission of patients with milder disease. In addition, the usual lack of organization in health care, with patients scattered throughout our hospital, was also responsible for the prolonged mean length of stay (12.2 days) in COPD patients in comparison to other studies, although it is similar to the duration reported for our practice setting.[32]

The present study did not include cost analysis, although we do have data available from other studies. Thus, according to Skwarska et al,[24] expenditure for patients included in HH programs was £871 compared to £1271 for conventional hospitalization. Cotton et al[27] reported 221 bed-days saved per year, and Skwarska et al,[24] 441 bed-days saved per year. In the present study, there was a considerable reduction in the length of hospitalization in patients assigned to the HH group. However, we do not believe that the aim of HH programs for patients with COPD exacerbations should be to demonstrate economic savings. The creation of such a new health-care infrastructure should be considered as a possible way of redistributing hospital beds and optimizing the available health resources, rather than filling hospitals with patients who could be treated in their own homes.

Our results showed the efficacy of a hospital-supervised HH program with the participation of a pneumologist and nursing staff in selected patients admitted for COPD exacerbations. The infrastructure necessary for such a program should include both medical and nursing staff. The nursing staff needs to be flexible and should be able to offer 1 or 2 visits per day if necessary. Communication channels between the patient and the HH team must also be established so that the team can attend to any incidents that might occur in the course of home treatment. Our study supports the usefulness of HH programs in patients with COPD exacerbations. For such programs to be implemented the legal framework needs to be defined and the protocol of interventions established by health-care authorities.

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