ORIGINAL ARTICLES

Effectiveness and Efficiency of a Specialized Unit in the Care of Patients With Chronic Obstructive Pulmonary Disease and Respiratory Insufficiency

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OBJECTIVE: In the absence of a clear health care model for the management of patients with chronic obstructive pulmonary disease and chronic respiratory insufficiency, we evaluated the effectiveness and efficiency of a specialized outpatient unit for these patients managed by the hospital's respiratory medicine department.

PATIENTS AND METHODS: This was a 1-year prospective study of a group of patients for whom historical control data were available. The mean (SD) descriptive data for the 124 patients (105 men) were as follows: age, 69 (7) years; forced vital capacity, 64.6% (16.1%); forced expiratory volume in the first second (FEV_1), 35.6% (12.8%); PaO_2, 56.6 (8.3) mm Hg; $PaCO_2$, 49.8 (6.7) mm Hg. Forced spirometry and arterial blood gas analysis were performed at 3-monthly visits. Participants completed a quality-of-life questionnaire (Guyatt's Chronic Respiratory Disease Questionnaire) at the beginning and end of the study. The following variables were analyzed: forced spirometry, arterial blood gases, quality of life, number of emergency visits and hospital admissions, mean length of stay in hospital, reduction in the number of inpatient bed-days, mean cost of emergency visits, mean cost of hospital stays for both the Catalan Health Service (CHS) and the hospital, mean total cost per patient for the CHS and the hospital, and aggregate cost for the CHS and the hospital. The results were compared with data for the preceding year taken from the hospital records.

RESULTS: Significant improvement was found in forced vital capacity and PaO_2 (which went from 56.6 [8.2] mm Hg to 59.1 [8.9] mm Hg during the prospective part of the study); FEV_1 also tended to improve (875 [282] mL as against 912 [321] mL), but this change was not significant (*P*=.17). A significant reduction was observed in the following variables: $PaCO_2$; hospital admissions, 1.16 (1.15) in the historical control period compared to 0.67 (1.17) during the prospective study; emergency visits, 2.06 (1.9) as against 1.5 (2.1); mean length of stay in hospital, 14.2 (19) compared to 8.1 (16) days; total number of inpatient bed-days (756 inpatient bed-days were saved in the study period); mean cost of emergency visits and hospital stays for both the hospital (€2246 [€3007] in the historical period as against €1297 [€2639] with the new management system) and for the CHS; and the aggregate cost both for the hospital (€40 011 in the historical control period as against €6048 with the new model) and the CHS (€238 513 as against €152 312). The quality-of-life score improved, but the change was not significant.

CONCLUSIONS: The change in the health care model used to manage these patients led to an improvement in care (effectiveness) as well as a marked reduction in costs (greater efficiency) for both the funding entity (CHS) and for the care provider (the hospital). No change was observed in the quality of life as reported by the patients.

Key words: *COPD. Specialized unit. Cost minimization. Effectiveness. Efficiency.*

Efectividad y eficiencia de una consulta monográfica hospitalaria para pacientes con EPOC e insuficiencia respiratoria

OBJETIVO: Puesto que no existe un modelo asistencial claro para la atención a los pacientes con enfermedad pulmonar obstructiva crónica e insuficiencia respiratoria crónica, se ha evaluado la efectividad y eficiencia de una consulta externa hospitalaria monográfica controlada por el Servicio de Neumología.

PACIENTES Y MÉTODOS: Se ha realizado un estudio prospectivo de un año de seguimiento con control histórico. La población estaba constituida por 124 pacientes (105 varones; edad media ± desviación estándar de 69 ± 7 años; capacidad vital forzada: 64,6 ± 16,1%; volumen espiratorio forzado en el primer segundo: 35,6 ± 12,8%; presión arterial de oxígeno: 56,6 ± 8,3 mmHg; presión arterial de anhídrido carbónico: 49,8 ± 6,7 mmHg). En cada visita trimestral se practicaron una espirometría forzada y una gasometría arterial, y al inicio y al final del estudio se pasó un cuestionario de calidad de vida (Chronic Respiratory Disease Questionnaire, elaborado por Guyatt). Se estudiaron las siguientes variables: espirometría forzada, gasometría arterial, calidad de vida, número de ingresos en urgencias y planta, duración media de la hospitalización, ahorro de días de hospitalización, coste medio de las visitas en urgencia, coste medio de las hospitalizaciones para el Servei Català de la Salut (SCS) y el hospital, coste medio total por paciente para el SCS y el

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hospital, y coste agregado para el SCS y el hospital. Los resultados se compararon con los datos de los pacientes registrados en la Corporació Parc Taulí durante el año previo.

RESULTADOS: Se observó una mejoría estadísticamente significativa de la capacidad vital forzada y presión arterial de oxígeno (56,6 ± 8,2 frente a 59,1 ± 8,9 mmHg); el volumen espiratorio forzado en el primer segundo mejoró (875 ± 282 frente a 912 ± 321 ml), pero sin significación (p = 0,17), así como un descenso significativo de la presión arterial de anhídrido carbónico, número de ingresos en planta (1,16 ± 1,15 frente a 0,67 ± 1,17) y urgencias (2,06 ± 1,9 frente a 1,5 ± 2,1), duración media de la hospitalización (14,2 ± 19 frente a 8,1 ± 16 días) y días total de hospitalización (se ahorraron 756 días de hospitalización), coste medio de visitas en urgencias y hospitalización para el hospital (2.246 ± 3.007 frente a 1.297 ± 2.639 €) y el SCS, y costes agregados tanto para el hospital (–40.011 frente a –6.048 €) como para el SCS (238.513 frente a 152.312 €). El índice de calidad de vida mejoró, pero no significativamente.

CONCLUSIONES: El cambio de la atención sanitaria de estos pacientes ha generado una mejoría asistencial (efectividad) reduciendo notablemente los costes económicos (eficiencia) tanto para el financiador (SCS) como para el proveedor de servicios sanitarios (hospital), sin que se hayan observado cambios en la calidad de vida de los pacientes.

Palabras clave: *EPOC. Consulta monográfica. Minimización de costes. Efectividad. Eficiencia.*

Introduction

The overall prevalence of chronic obstructive pulmonary disease (COPD) in our area of reference is 7.2%.[1] Of these patients, 1% have a forced expiratory volume in the first second (FEV_1) under 50%, and in 0.4% this figure is under 35%.[1] The cost of healthcare for these patients is rising continuously both as a result of the increase in life expectancy of the population and because of the need for long-term care.[2]

In the health care model currently used in Spain, primary care physicians are responsible for managing the care of most patients with mild to moderate COPD, but no clear model exists defining the best approach to the care of patients with severe COPD. At present, the care of these patients is dealt with in 3 different ways: *a)* management by primary care physicians with an occasional visit to the hospital outpatient unit for a consultation with a respiratory specialist, *b)* a combination of primary and hospital care, or *c)* a management program carried out almost entirely by a hospital-based pulmonologist. In practice, owing to the absence of access barriers to the health care system, these patients are able to consult clinicians at any level.

As early as 1920, the Dawson report recommended that epidemiological criteria should inform the organization and design of care services, the distribution of resources, and medical training.[3] Since then, the countries of western Europe have developed their health systems with a view to devising care models that are appropriate from the clinical point of view and as economical as possible. A reasonable initial approach to the problem is, therefore, to implement an alternative care model and study it against data available for similar populations, making possible a cost-minimization study. The main objective of our study was to assess the repercussions of a new health care model based on a specialized hospital unit (SHU) on the health and quality of life of patients with severe COPD and chronic respiratory insufficiency, and to quantify the economic burden of such a model borne by the care provider (the hospital) and the funding entity (the Catalan Health Service [CHS]).

Patients and Methods

This was an observational study of patients for whom historical control data were available. It was carried out in the Corporació Parc Taulí (CPT) in Sabadell, a 752-bed hospital serving a catchment population of 350 000. The patients in the study were followed for 1 year. The variables studied after they were enrolled in the SHU had been assessed in all the patients during the year preceding the study (historical control data). The historical control and financial data were taken from the records of the Admissions and Scheduling Department, the Epidemiology Department, the Planning Department, and the Contracts and Invoicing Unit of the CPT.

Patients

The following inclusion criteria were defined: *a)* severe COPD (FEV_1 ≤50% of predicted); *b)* PaO_2 ≤65 mm Hg; and *c)* clinical stability, gasometric stability (variation in PaO_2 of ≤5 mm Hg), and spirometric stability (variation in post-bronchodilation FEV_1 of <15%) during the 3 months prior to inclusion in the study. The exclusion criteria were as follows: *a)* clinical history of asthma, *b)* restrictive ventilatory defect, *c)* sleep apnea-hypopnea, *d)* treatment with respiratory analeptics or experimental drugs, and *e)* malignant disease.

In the calculation of sample size, the variables indicative of clinical efficacy (number of emergency visits and hospital admissions) were considered. In the absence of any literature providing guidance on this type of unit, the experience of the present research group[4] (who observed a reduction in the number of hospital admissions similar to that reported by other authors) was considered to be valid and reliable. Skawarska et al[5] and Cotton et al[6] obtained similar results in prospective studies, although the patients they studied had less severe COPD than those in our population. In a prospective study comparing 2 care models different from those evaluated in our study (home care and conventional care) but in a population with a similar COPD and chronic respiratory insufficiency profile to our sample, Farrero et al[7] managed to reduce the number of admissions in the home care group by approximately 50%. Therefore, the calculation of the number of patients that needed to be evaluated in order to analyze the data on emergency visits and hospital admissions was based on the prior results of the present group of researchers.

– Calculation of the N value for the analysis of the number of emergency visits: assuming an alpha risk of 0.05 and a beta risk of 0.10 in a bilateral comparison, 86 subjects were

required to detect a difference of 0.44 or more emergency visits. A standard deviation of 1.25 was assumed, and it was estimated that 1% of patients would be lost to follow-up.

– Calculation of the N value for the analysis of the number of hospital admissions: assuming an alpha risk of 0.05 and a beta risk of 0.10 in a bilateral comparison, 71 subjects were required to detect a difference of 0.35 or more hospital admissions. A standard deviation of 0.9 was assumed, and it was estimated that 1% of patients would be lost to follow-up.

Methods

Participants were enrolled from among the patients referred to and admitted to the SHU who volunteered to take part in the study.

The care model was based on the creation of a hospital unit specialized in the treatment of these patients and the following protocol: *a)* an initial visit with a complete medical history, a physical examination, forced spirometry including a bronchodilator test (using reference values for a Mediterranean population),[8] arterial blood gas analysis, carboxyhemoglobin measurement, nocturnal pulse oximetry, a quality-of-life assessment using Guyatt's Chronic Respiratory Disease Questionnaire (CRQ),[9] an electrocardiogram, chest radiography, and complete blood tests; *b)* at 3-monthly visits, the clinical course of the disease was assessed, forced spirometry and arterial blood gas analysis were carried out, and carboxyhemoglobin was measured; *c)* the final visit included assessment of clinical course, a physical examination, forced spirometry testing, arterial blood gas analysis, carboxyhemoglobin measurement, and quality-of-life assessment.

The following clinical variables were assessed prospectively: anthropometric data, forced spirometry, arterial blood gas analysis, carboxyhemoglobin, and quality of life. The variables analyzed retrospectively (historical control data) and prospectively were number of emergency visits, number of hospital admissions, and number of inpatient bed-days.

The financial variables studied were mean cost of emergency visits, mean cost of hospital admissions for the CHS and the CPT, mean cost of outpatient visits, ambulance costs paid by the CHS during the prospective study, cost for the CPT of the forced spirometry testing during the 1-year care plan managed by the SHU, mean total cost per patient for the CHS and the CPT, and aggregate cost for the CHS and the CPT. We studied direct costs and not indirect or intangible costs.

The health care provider (CPT) was funded by the CHS in accordance with the contract between these 2 entities. Among the invoicing particularities that affect the provider, the following are of interest: *a)* since the cost of spirometry and arterial blood gas analysis were included in the payment per outpatient or inpatient consultation, spirometric testing was treated exclusively as a loss for the hospital and not as an expense for the CHS; *b)* since the cost of regular visits was a fixed annual fee per patient, this item is included in both the calculation of the accumulated cost for the CHS and as income for the CPT; *c)* the cost of hospitalization was a fixed monthly amount per patient; and *d)* the CHS paid the cost of ambulance trips directly to the Catalan Medical Transport Consortium.

The aggregate cost generated by the care of these patients for the CHS was calculated as follows:

Profit or loss per admission – cost of forced spirometry + payment for return visits to the outpatient clinic + cost of emergency visits.

The formula used to calculate aggregate cost for the CHS was as follows:

Cost of emergency visits + cost of hospital admission + cost of return visits to the outpatient clinic + cost of ambulance transportation.

Statistical Analysis

The statistical analysis was carried out using the SPSS statistical package, version 10 for Windows. A *P* value less than .05 was considered statistically significant. A descriptive analysis of the data consisted of frequency tables for qualitative variables and descriptive statistics for quantitative variables. Nonparametric methods were used when the distribution of the data was not normal. The Wilcoxon matched-pairs signed ranks test was used to detect differences between the values before and after the 1-year specialized outpatient unit program.

The study protocol was approved by the hospital ethics committee.

Results

Patients

The study included the first 124 patients (105 men and 19 women) who were followed for 1 year. The mean (SD) age of the patients was 69 (7) years and the mean body mass index was 26.8 (5.2) kg/m^2. A total of 543 forced spirometry tests, 721 blood gas analyses, and 709 carboxyhemoglobin measurements were carried out. At the beginning of the prospective study, 12.9% of the patients were current smokers and 26% had polycythemia.

Clinical Variables

No significant changes were observed in anthropometric variables. While forced vital capacity and PaO_2 had improved significantly by the end of the study, the improvement in FEV_1 and $PaCO_2$ was not significant (Figure 1).

Overall quality of life, evaluated with the CRQ in 44 patients at the beginning and end of the study period, tended to improve but not significantly. Dyspnea was the only domain in which the improvement reached significance (Figure 2).

Analysis of the data on emergency visits, hospital admissions, and inpatient bed-days (Figure 3) revealed significant reductions in all 3 variables after patients enrolled in the SHU. Emergency visits were reduced by 65, hospital admissions by 60, and inpatient bed-days by 756 (the equivalent of 2 bed-years). Analysis by subgroups based on the severity of spirometric and gas exchange findings also revealed better results during the period of SHU management than during the historical control period (Tables 1 and 2).

By the end of the prospective study period, lung function had improved so much in 26 patients that they no longer fulfilled the gas exchange criteria for respiratory insufficiency, while the condition of 14 patients had

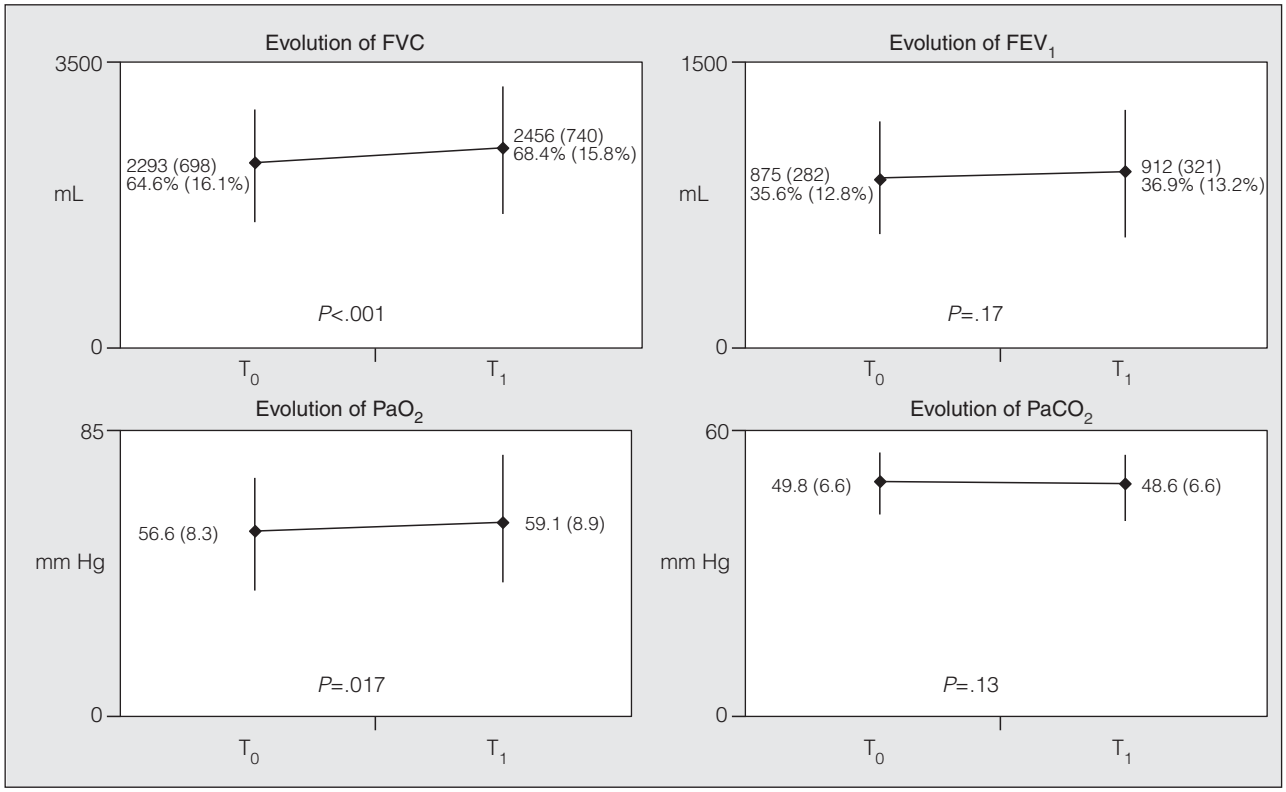

Figure 1. Evolution of ventilatory function and arterial blood gases. FVC indicates forced vital capacity; FEV_1, forced expiratory volume in the first second; T_0, historical control period; and T_1, prospective study period.

deteriorated. In the group of patients who improved, a significant improvement in lung function was found in conjunction with a significant reduction in the number of both emergency visits and hospital admissions. In the group of patients whose condition deteriorated, no changes were observed in forced spirometry or in the number of emergency visits or hospital admissions.

Economic Variables

Figure 4 shows the mean cost during both the historical control period and the prospective study period (SHU care management) of outpatient consultations, emergency visits, and hospital admission for the CHS and the CPT respectively. Note the statistically significant improvement in all the variables. Analysis of aggregate costs revealed that the new care model resulted in marked savings for the SCS and made it almost possible to balance the budget in the case of the CPT (Figure 5). The mean total cost per patient for the SCS and the CPT went from €1923 (€1748) to €1220 (€1794) and from €–322 (€1846) to €–48 (€1439), respectively.

Discussion

The Spanish government currently spends around 9% of the gross domestic product on public health (over €24 040 484 175.35).[10] Some 70% of this total budget is allocated by the therapeutic decisions of doctors at the

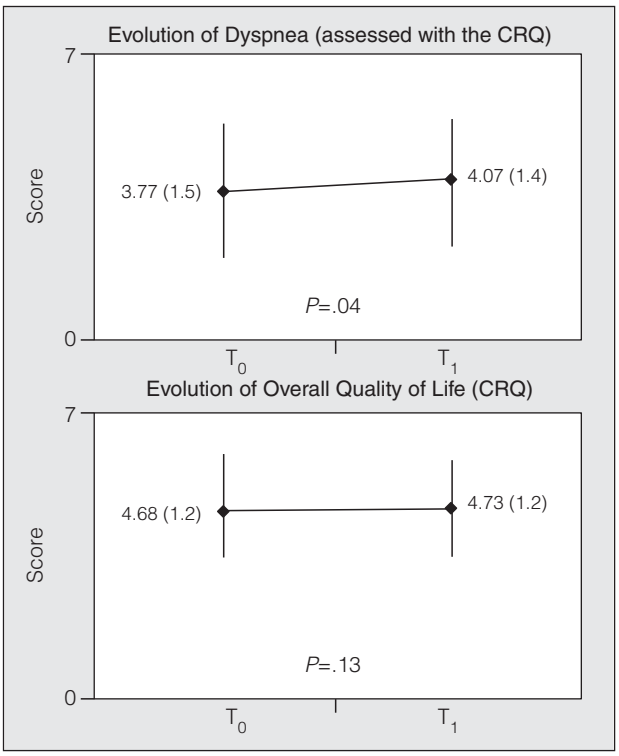

Figure 2. Evolution of the overall quality-of-life score and of the score for dyspnea in the Chronic Respiratory Disease Questionnaire (CRQ). Data are given as means (SD). T_0 indicates the historical control period; and T_1, prospective study period.

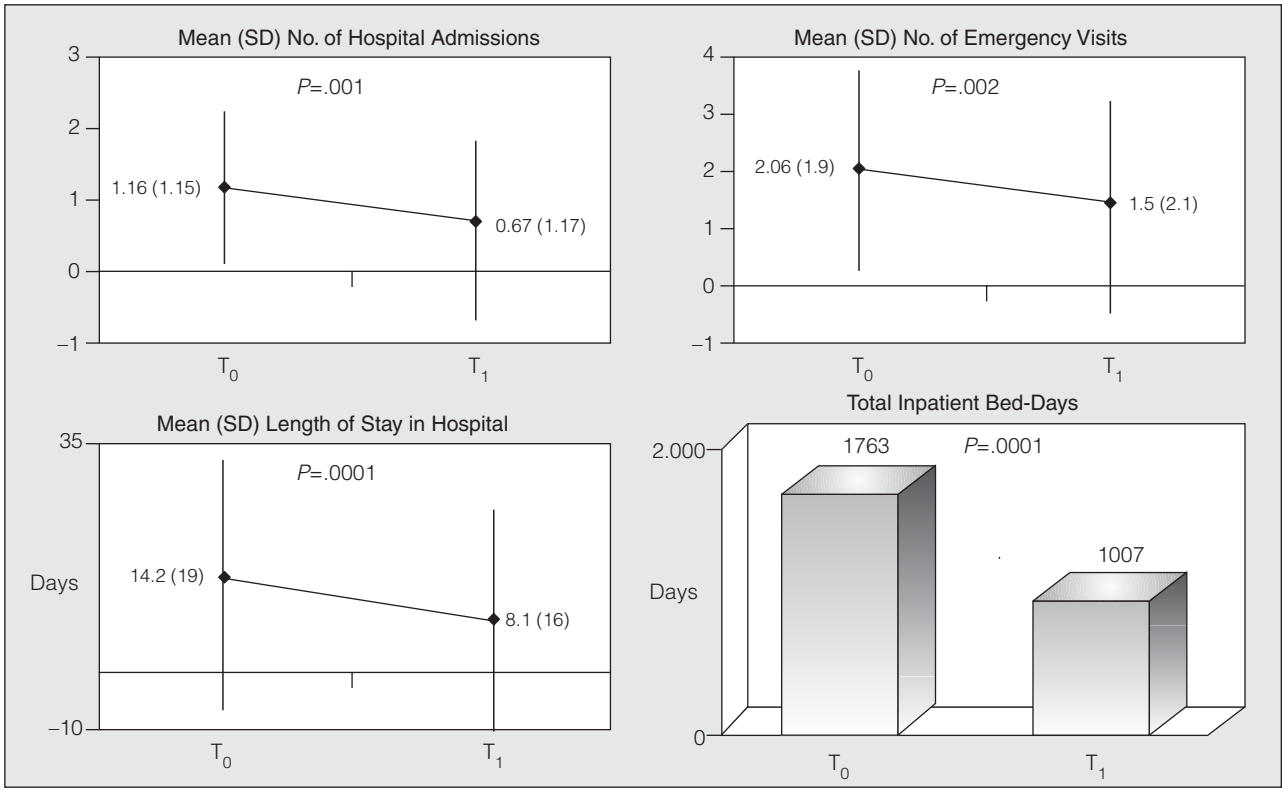

Figure 3 Evolution of the number of hospital admissions, emergency visits, length of stay in hospital, and total inpatient bed-days. T_0 indicates the historical control period; and T_1, prospective study period.

level of health micromanagement and clinical management[11,12] Accordingly, if we are to improve the allocation of the health budget, we must reduce the gap between efficacy and effectiveness through more efficient management of the factors susceptible to modification in each disease.

Following the recommendations of the Dawson Report, the design of this study is based on prior epidemiological studies carried out in the hospital's area of reference between 1990 and 1995. The originality of the design lies in 2 distinct but complementary aspects: *a)* a new health care model that

TABLE 1
Evaluation of the Number of Emergency Visits, Hospital Admissions, and Inpatient Bed-Days by the Severity of Spirometric Findings During Both the Historical Control Period (HCP) and After Enrollment in the Specialized Hospital Unit (SHU)*

	FEV_1 ≤35%		FEV_1 >35%	
	HCP	SHU	HCP	SHU
No. of emergency visits per patient	2.3 (2)	1.6 (2)	1.6 (1.7)	1.4 (2)
No. of hospital admissions per patient	1.2 (1.2)	0.7 (1.3)	0.5 (0.8)	1.4 (1.2)
No. of inpatient bed-days per patient	16 (22)	9 (18)	12 (15)	7 (15)

*The data are expressed as means (SD).
FEV_1 indicates forced expiratory volume in the first second.
The *P* value was significant (*P*<.05) in all the comparisons between the 2 groups (HCP and SHU), except in the comparison between the number of emergency visits per patient in the subgroup with an FEV_1 of less than 35%.

TABLE 2
Evaluation of the Number of Emergency Visits, Hospital Admissions, and Inpatient Bed-Days by Severity of Gas Exchange Findings During Both the Historical Control Period (HCP) and After Enrollment in the Specialized Hospital Unit (SHU)*

	PaO_2 ≤55 mm Hg		PaO_2 >55 mm Hg	
	HCP	SHU	HCP	SHU
No. of emergency visits per patient	2.1 (1.8)	1.7 (2.5)	2 (2)	1.3 (1.8)
No. of hospital admissions per patient	1.4 (1.2)	0.9 (1.5)	0.9 (1)	0.5 (0.8)
No. of inpatient bed-days per patient	18 (23)	12 (22)	11 (15)	5.5 (10)

*The data are expressed as means (SD).
The *P* value was significant (*P*<.05) in all the comparisons between the HCP and the care period after enrollment in the SHU.

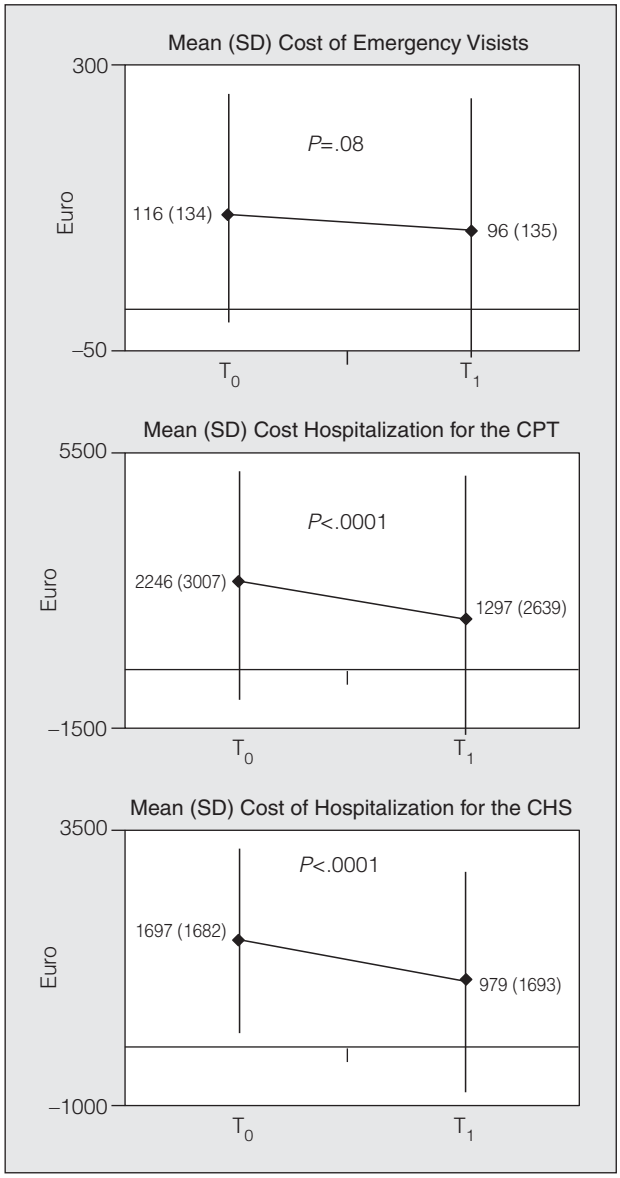

Figure 4. Evolution of the mean cost of emergency visits and of hospital admissions for the Corporación Parc Taulí (CPT) and for the Catalan Health Service (CHS). T_0 indicates the historical control period; and T_1, prospective study period.

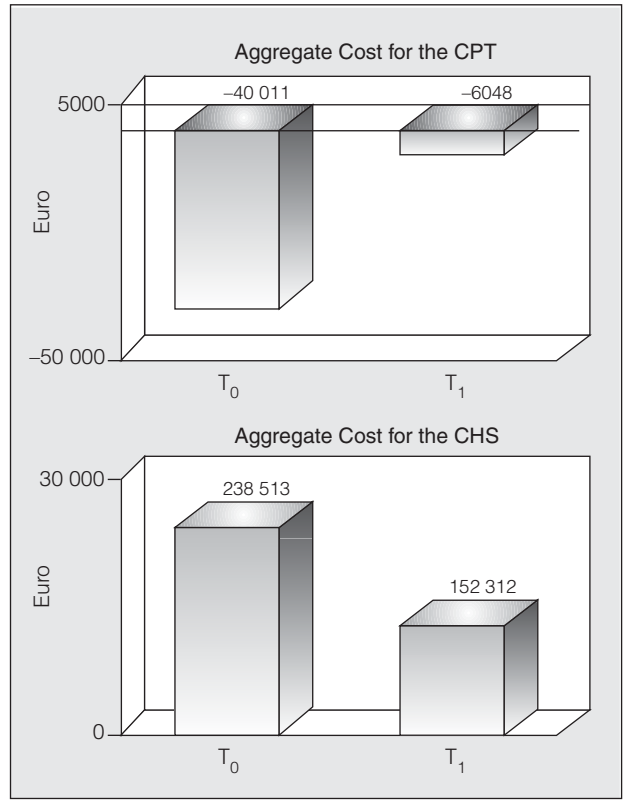

Figure 5. Aggregate costs for the Corporació Parc Taulí (CPT) and the Catalan Health Service (CHS). T_0 indicates historical control period; and T_1, prospective study period.

introduces barriers regulating access to the system based on a rational design; and *b)* the evaluation of the clinical and economic outcomes (effectiveness and efficiency) produced by the improvements achieved by the new model. A new care model designed on the basis of evidence-based medical data was implemented, and both the clinical response of the patients treated and the economic performance of the model were assessed under real (rather than ideal) conditions.

All the variables studied confirmed the effectiveness of the model. While not statistically significant, the improvement observed in FEV_1 was relevant from a clinical standpoint. Forced vital capacity improved significantly, indicating a decrease in residual volume or, what amounts to the same thing, a reduction in air trapping. The mean daytime PaO_2 improved significantly, and carbon dioxide retention tended to decrease slightly. It is also interesting to note that after 1 year attending the SHU, 26 patients had improved so much that they no longer met the criteria for respiratory insufficiency. The downward trend in carboxyhemoglobin levels indicates that the improvement in oxygenation was maintained at night.

The prevalence of current smokers at the beginning and the end of the study period was 12.9% and 10.5% respectively, indicating that the SHU had no material impact on smoking addiction. It should be noted that the only tobacco cessation intervention undertaken was the physician's recommendation, which was repeated at every visit. Moreover, no variable measuring the effectiveness of this intervention was included in the design because the aim of the protocol was not to study tobacco cessation.

With respect to the burden on the health care system, a significant reduction was observed in the number of emergency visits, hospital admissions, and inpatient bed-days. The reason for this reduction in inpatient bed-days may have been twofold: firstly, patients experienced fewer clinical crises; and, secondly, a care unit was available to deal quickly and efficiently with the patients who were admitted to the hospital. This aspect was not studied, but in either case the beneficial result would be attributable to the new health care

model. It is also very interesting to note that the new model resulted in a saving of 756 inpatient bed-days, thereby increasing the admissions capacity of the 22-bed Respiratory Medicine Department by 10% without any increase in expenditure. Furthermore, we should point out that in our evaluation we considered the number of emergency visits at the primary care level to be zero during the historical control period, thereby voluntarily underestimating the demand for medical care on the part of these patients during that period in order to ensure the strictest possible data comparison.

One in every 3 people visits an emergency department annually,[13] and in 80% of these cases the decision to seek emergency care is taken by the patient.[14] Of all the visits to these services, respiratory diseases account for up to 34% of the diagnoses on discharge in some hospitals.[15] An additional problem stems from the readmission of patients to the emergency department. Between 3.4%[16] and 9.36%[15] of patients are readmitted. Observation units that monitor patients who have received emergency care have been created in order to address this problem, and it is precisely patients with respiratory problems who have the highest rates of occupancy in these units—as high as 11% in some cases.[17] Therefore, our new model helped to reduce the number of emergency visits and stays in the observation units attached to these departments. Moreover, since the decision to visit the emergency department is made in most cases by the patient, the change of attitude on the part of the population studied, which consisted in replacing visits to the emergency department with management carried out by the SHU, reveals a qualitative change in the demand for care due, at least in part, to the clinical improvement achieved and the patient's satisfaction with the model.

We found no data in the literature on this type of care model that could be used in a reliable comparison with the model implemented in our hospital. The previously mentioned study by Farrero et al[7] was a prospective comparison of 2 groups of patients with COPD who had characteristics similar to those of our population. The reduction in the use of hospital resources they achieved was also similar. However, the question must be posed whether it is more useful to create new hospital-based home-care programs or to implement hospital-based programs involving the collaboration of the existing primary care network. The literature in English includes a study by Gravil et al[18] that deals with the home treatment of exacerbations in patients with COPD. While that study is somewhat different from ours, a point to emphasize is that our care model led to a high rate of home treatment for exacerbations and that our patients presented more severe COPD and chronic respiratory insufficiency. For this reason, in our opinion the question of how these patients should be managed must be studied in patients with more severe disease than those studied by Gravil et al.

With respect to quality of life, it should be emphasized that the only intervention undertaken to modify the participants' quality-of-life was the change in the care model and the benefits this brought about, including the reduction in the number of emergency department visits, a factor closely related to quality of life in these patients.[19] The only domain in which the improvement was statistically significant was dyspnea, and this corresponded to the improvement in lung function.[20] In any case, the fact that the patients adhered to the new care model certainly indicates a certain degree of satisfaction. We could say that their attitude illustrates how a credence good, such as a consultation with a specialist, may be converted into an experience good. Applying the postulates of the competitive market, the premise that individuals are rational, that they reveal their preferences by their actions, and that they are the best judge of their own welfare would also support the hypothesis that the specialized hospital-based management program favors the quality of life of this group of patients.

In order to properly evaluate the efficiency of the SHU for COPD patients, we must take into account that, with a view to minimizing the methodological criticism leveled at studies based on historical control data, we omitted the following items from the historical control calculation: the cost of consultations with the primary care physician, emergency care in primary care clinics or in the home, and the spirometric testing requested by primary care physicians. These items should have been included in the analysis as expenditures funded by the CHS. An overall appraisal reveals that the improved effectiveness was accompanied by improved efficiency. The new model helped to reduce the deficit previously generated by these patients for the CPT, and the saving for the CHS was considerable. Moreover, 2 hospital beds were made available for other occupants throughout the whole year. This outcome can be evaluated in different ways: it can be seen as representing an increase in the level of care offered by the hospital without any increase in resources, or it could be said—if we only take into account the financial saving—that the CPT's prior deficit has been turned into a profit and that the profit for the CHS was much greater than first expected.

It is generally accepted today that many clinical decisions have their origin in organizational habits or routines. Consequently, more precise delimitation of the field of action will tend to reduce interindividual differences among the professionals attending patients with a specific disease, favor closer adherence to international guidelines and standards, and minimize variation in practice-patterns. On the other hand, the more clinical decisions are taken at lower levels, the greater the speed of response of the organization, and in the context of medical care a fast response often represents greater effectiveness. It is clear that these strategies lead to more informed decisions and reduce the administrative overload at the higher levels of decision making. As clinical and research data are highly specific, such information is expensive to

transmit, making it advisable that decisions be taken at the most well-informed levels. All these requisites are fulfilled by a SHU run by a single physician specialized in the disease of the patients attended.Variability in practice patterns is undoubtedly an important problem in medical practice. This is defined as the existence of systematic—that is, nonrandom—variations in the standardized rates of treatments (or of diagnostic procedures) at a given level of aggregation.[21] McPherson (the physician who created the definition of variability in medical practice) identified 3 causes of systematic variation from the epidemiological standpoint: uncertainty in cases where the available research is insufficient; clinical ignorance due to a lack of familiarity with the results of research; and informed preference for an alternative treatment. None of these 3 criteria applies in the case of the SHU, a unit that is in a position to carry out further research if necessary. A specialized unit also serves to reduce the likelihood of clinical ignorance on the part of the physician (who works continuously with the same disease) and works against personal preferences that can easily be refuted by the results of evidence-based medicine.

The difference between efficacy and effectiveness is that the conditions under which medical practice is evaluated in the case of efficacy are ideal whereas in the case of effectiveness they are real. Quality is understood to be the difference between efficacy and effectiveness. The effectiveness of a service or device diminishes as more extensive use is made of it. In the case of our SHU, outcomes improved over those of the historical control period, indicating improved quality of medical care; furthermore, the clear delimitation of the population the SHU aimed to treat helped to limit the loss of effectiveness of the unit.

How does our study fit into the literature? Some authors have concluded that early discharge with home treatment supported by varying levels of care is a possible option for patients with COPD exacerbations.[6,19] Postma[22] poses the question whether patients with COPD exacerbations can benefit from a care model based on early home treatment and emphasizes the fact that an informed and appropriate decision cannot be made without reliable information on the patient's baseline situation. Moreover, if the model is to be relevant from the epidemiological standpoint, this information should also be available to the primary care doctors, who are often the first care providers to make decisions about the measures to be taken.[23] The population of patients we treated had more severe COPD than the participants of most studies, so that we have made advances on defining the type of patient that might benefit from this care model.

We should introduce the overall evaluation of the efficiency of the COPD SHU by highlighting the importance of including a cost study to complement the clinical evaluation. Almost 30 years have elapsed since Cochrane[24] said that if effectiveness had been researched but very little, efficiency had hardly been studied at all.[25,26] He went on to say that, from the therapeutic standpoint, there were 3 types of inefficiency: *a)* the use of ineffective treatments or the use of effective therapies when they are not appropriate; *b)* use of an incorrect treatment site, that is, administering treatment in an unsuitable environment; and *c)* an inappropriate length of stay in hospital. A specialized unit that tries to adhere closely to international guidelines (which are not often followed[27]) clearly addresses the first point. Moreover, we are in a position to refine drug prescriptions, thereby rationalizing pharmacological expenditure.[28] We can also address the second concern by specifying how, where, and when exacerbations should be treated. Our influence in the case of Cochrane's third point is less obvious because the SHU does not directly control length of stay in hospital on a case-by-case basis, but it does control the number of candidates for admission and thereby influences the aggregate number of inpatient bed-days. In this way the SHU does contribute to a reduction in one of the most expensive components of the cost associated with the care of these patients.[26,29]

In summary, the evaluation of the results shows that the care plan studied fulfills recommended guidelines[30] and functions as a "Paretian" model in that it slows down the deterioration in the quality of life of these patients, significantly improves the clinical variables studied, and reduces the expenditure of both the funding entity (CHS) and the care provider (hospital).

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