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Original Article

Variability in the Performing of Spirometry and Its Consequences in the Treatment of COPD in Primary Care

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ABSTRACT

Background: Several studies have dealt with the use of spirometry in the treatment of chronic obstructive pulmonary disease (COPD) in Primary Care (PC), but few have analyzed its impact on the treatment of the patient with COPD.
Objectives: To evaluate the use of spirometry in the diagnosis and follow-up of COPD patients in PC, and its impact on treatment. To analyze the variation in the performing of spirometry between PC centers.
Methodology: A multicenter, observational and cross-sectional study of COPD patients seen in PC in Catalonia (Spain) during 2004-2005. A multilevel logistic regression model was used to identify factors associated with having spirometry and to determine the variation between the different centers.
Results: Twenty-one centers, including 801 patients, participated. Only 53.2% of them had diagnostic spirometry and the mean (standard deviation) FEV1(%) was 54.8% (18%). The registers of smoking habits, complementary tests and spirometry follow-up were more common among patients who had a diagnostic spirometry available compared with those who did not. No statistically significant differences were found regarding demographic, clinical, treatment and quality of life variables between patients with and without follow-up spirometry. Significant variation was observed in the percentage of diagnostic spirometries between different PC centers (variance = 0.217; $p < 0.001$).
Conclusion: Spirometry is underused in PC and performing it during follow-up is not associated with the different treatments guidelines or with a more complete approach to the disease. There is significant variation in the performing of spirometry among PC centers.

Variabilidad en la realización de la espirometría y sus consecuencias en el tratamiento de la EPOC en Atención Primaria

Palabras clave:
Enfermedad pulmonar obstructiva crónica
Espirometría
Atención Primaria
Tratamiento

RESUMEN

Antecedentes: Algunos estudios han abordado el uso de la espirometría en la enfermedad pulmonar obstructiva crónica (EPOC) en Atención Primaria (AP), y pocos han analizado su impacto en el tratamiento del paciente con EPOC.
Objetivos: Valorar la utilización de la espirometría en el diagnóstico y seguimiento de los pacientes EPOC en AP y su impacto en el tratamiento. Analizar la variabilidad en la realización de espirometrías entre los centros de AP.
Metodología: Estudio multicéntrico, observacional y transversal en pacientes EPOC atendidos en AP de Cataluña (España) durante 2004-2005. Se usó un modelo de regresión logística multinivel para identificar factores asociados con tener espirometría y determinar la variabilidad entre los diferentes centros.

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Resultados: Participaron 21 centros, que incluyeron 801 pacientes. Solo el 53,2% disponían de espirometría diagnóstica, la media (desviación estándar) del FEV1(%) fue 54,8% (18%). Los registros del hábito tabáquico, pruebas complementarias y espirometrías de seguimiento estuvieron más presentes entre los pacientes que disponían de espirometría diagnóstica respecto a aquellos que no la disponían. No se encontraron diferencias estadísticamente significativas respecto a variables demográficas, clínicas, tratamiento y calidad de vida entre pacientes con o sin espirometría de seguimiento. Se observó variabilidad significativa en el porcentaje de espirometrías diagnósticas entre los diferentes centros de AP (varianza = 0,217; p < 0,001).
Conclusión: La espirometría en AP está infrautilizada y su realización durante el seguimiento no se asocia a unas pautas distintas de tratamiento ni a un abordaje más completo de la enfermedad. Existe variabilidad significativa en la realización de espirometrías entre los centros de AP

Introduction

Chronic obstructive pulmonary disease (COPD) is a very prevalent health problem all over the world.[1] A recent study in a general Spanish population identified a prevalence of COPD of 10.2% in people aged 40-80 and an underdiagnosis 73%,[2] similar to what was observed in another study completed 10 years before.[3]

A possible cause of COPD underdiagnosis is the limited use of spirometry in the Primary Care (PC) setting.[4] There are some studies done in PC related with the use of spirometry for the detection and follow-up of COPD in high-risk smokers,[5] and others analyzing the causes of the underuse of spirometry.[6,7] Few studies, however, evaluate the use of spirometry in standard clinical practice in COPD in PC and how it influences the management of said disease. The study by Lee et al[8] related having spirometry with pulmonary symptoms and being young, while other studies analyzed the impact of the introduction of spirometry on the treatment of COPD patients in PC.[9,10] A study done in Spain more than 10 years ago found that the patients that underwent spirometry in PC presented less COPD complications as well as exacerbations or hospitalizations.[11]

An optimal knowledge of the current situation of spirometry use in standard clinical practice in COPD patients can improve the management of these patients at the PC level. Information generates knowledge and, possibly, changes in conduct that can favor standard clinical practice.

The objectives of the present study were: 1) to analyze the use of diagnostic spirometry and follow-up spirometry performed during the two years prior to inclusion in the study in the standard clinical practice of COPD patients in PC; 2) to find out the impact of spirometry in the treatment of COPD patients in PC; 3) to analyze the variability in the completion of spirometries between the different centers; 4) to identify the characteristics of the patients and the centers that could explain this variability.

Methods

Study Design and Population

A multicenter, cross-sectional, observational study carried out in PC settings. The present study constitutes the baseline visit of the prospective project entitled "Let's Help COPD Patients Live Better". The study was randomized with a 12-month follow-up, whose objective was to evaluate the effectiveness of a multidisciplinary strategy in improving the degree of clinical control and the quality of life of COPD patients compared with standard practice. The study protocol has already been published.[12] The sample size was calculated depending on the difference between the two intervention groups in the *St. George's Respiratory Questionnaire* (SGRQ)[13] 12 months after randomization. A sample size of 786 individuals (398 per intervention group) was necessary in order to detect a difference equal to or higher than 4.3 points on the SGRQ[14] between the two groups, with a standard deviation of 20.4, an alpha significance level of 0.05, a beta error of 0.20, and a loss-to-follow-up rate of 10%.

All the urban and semi-urban healthcare centers in the administrative area of the Costa de Ponent Healthcare Region (52 PC centers) in Barcelona were asked to participate in the study from 2004-2005. Twenty-one centers accepted participation, covering a population of 483,473 inhabitants from a middle-low socioeconomic background.

The patients included were of both sexes, ages 40 and up, with a diagnosis of COPD in their clinical histories and treated for this pathology over the course of the previous year at these PC centers. The exclusion criteria were: serious mental, visual and/or hearing alterations, diagnosis of asthma, tuberculosis or other chronic respiratory pathologies, terminal-phase pathology or no available telephone.

This study was approved by the Jordi Gol Ethics and Clinical Research Committee, Primary Care Research Institute.

Data Collection

The information was collected through audits of the data contained in the patient medical files and interviews with the patients themselves.

Information from the Patient Medical Files

This information included sociodemographic data, respiratory risk factors, comorbidities and lifestyle, diagnostic spirometry (spirometry registered in the clinical history at the time the diagnosis was made), COPD stage based on the forced expiratory volume in one second (FEV_1) parameter (%), criteria for chronic bronchitis, complementary tests, body mass index and tobacco habit. The information related with the follow-up included: follow-up spirometries (spirometries registered in the medical history during the control of the disease in standard clinical practice, performed during the two years prior to inclusion in the study), COPD stage based on the FEV_1 parameter (%), complementary tests during the previous two years, and number of exacerbations, healthcare resources, preventive actions and treatment received over the course of the year prior to inclusion in the study.

Information from Patient Interviews

Chronic symptoms, hospitalizations in the last year, administration of the SGRQ questionnaire translated to and validated in Spanish,[15] measurement of dyspnea according to an adapted version of the scale proposed by the *Medical Research Council* (MRC)[16] and the correct performance of the inhalation technique was evaluated following the guidelines of the SEPAR-SemFYC.[17]

We also collected additional information related to the presence of spirometers available in the centers and the teaching of residents.

Statistical Analysis

The result measurements were having diagnostic spirometry and follow-up spirometry in the two years prior to inclusion in the study.

The differences between groups were analyzed with the Chi-squared test or Fisher's exact test for categorical data and the Student's t test for continuous data or the corresponding non-parametric tests, depending on the case.

We applied multilevel statistical models[18,19] in order to identify the factors associated with the two result measurements and to find out whether there was variability in the result variables among the PC centers (meaning we consider the PC centers as random). In the case there was significant variability, we estimated the effect of the individual and center co-variables on the response variable, conditional model, through multi-level logistic regression using the *Full Maximum likelihood* estimation method via the iterative Laplace approximation. In the case that variability was found, a logistic regression model was carried out. The intraclass correlation coefficient was calculated,[20] which represents the influence of the PC centers on the response variable.[20,21]

For the "diagnostic spirometry" result variable, the variables that were considered in the initial regression model were: sex, age, bronchial hyperreactivity, childhood respiratory infections, years of evolution of the disease (time from diagnosis until inclusion in the study), chronic bronchitis criteria, emphysema criteria, occupational exposure, environmental exposure and tobacco habit. PC center variables were having a spirometer in the center and resident teaching.

For the "follow-up spirometry" result variable, we included the variables considered in addition to cough, sputum, diagnostic spirometry, exacerbations, visits to general practitioner, visits with the nurse, visits to the pulmonologist, electrocardiogram, blood work, spirometry in the center and resident teaching.

Age, sex and tobacco habit were considered clinically relevant variables and were included in the final models. We analyzed for colinearity, confusion (change in the estimators ≥ 20%) and/or interactions.[18,22] All the models were compared by means of the likelihood for ratio of positive test or the Akaike information criterion (AIC).

We calculated goodness-of-fit and diagnostic statistics of the logistic model in accordance with the Hosmer and Lemeshow methodology.[22] As for the multi-level model, this was constructed and its validity was evaluated following the recommendations of Raudenbush and Bryk.[18]

We found no influencing values or colinearity, and the two models presented good adjustment.

The level of significance of all the tests was 5%, with two tails. We used the HLM multilevel statistical package for Windows, version 10.1, and Stata/SE, version 9.1 (Stata Corp.).

Table 1
Baseline characteristics of the patients with chronic obstructive pulmonary disease

	COPD patients (N = 801)
Patient variables	
Sociodemographic characteristics	
Age (years), mean (SD)	70.2 (9.08)
Sex: male	700 (87.4)
Level of education	
None	301 (37.6)
Primary	443 (55.3)
Other	57 (7.1)
Tobacco consumption	
Non-smoker	118 (14.7)
Ex-smoker	527 (65.8)
Smoker	156 (19.5)
Comorbidity	
Metabolic diseases	588 (73.4)
Cardiovascular disease	241 (30.2)
Degenerative and joint processes	326 (40.8)
Anxiety and/or depression	130 (16.2)
Diagnosis	
Years of COPD evolution, median (interquartile range)	6 (4-10)
Diagnostic spirometry	426 (53.2)
Staging (n = 387)	
GOLD I (mild)	21 (5.4)
GOLD II (moderate)	222 (57.4)
GOLD III (serious)	116 (30)
GOLD IV (very serious)	28 (7.2)
Body mass index registered in medical history	136 (17)
Body mass index (kg/m^2), mean (SD)	28 (5)
Chronic symptoms	
Cough	388 (49.3)
Sputum	445 (56.4)
Evaluation of dyspnea	
Grade 1. Absence of dyspnea	145 (18.7)
Grade 2. Dyspnea walking quickly	333 (43)
Grade 3. Inability to keep in step	138 (17.8)
Grade 4. Need to stop and rest	113 (14.5)
Grade 5. Cannot leave the house	46 (5.9)
Exacerbations	
Exacerbations over the last year	472 (59.4)
Exacerbations; median (interquartile range)	472;1 (1-2)
Quality of life	
St. George's Respiratory Questionnaire, mean (SD)	
Symptoms	38.2 (21)
Activity	50.2 (25.1)
Impact	29.3 (19.3)
Total	37.1 (19.01)
Variables of the Primary Care centers	
Number of Primary Care centers	21
Spirometers in the Primary Care centers	13 (61.9)
Teaching of residents	12 (57.1)

The data are n (%), unless otherwise indicated.
COPD: chronic obstructive pulmonary disease; SD: standard deviation.

Results

Population Characteristics

The study population included a total of 801 COPD patients in 21 PC centers. The clinical and demographic characteristics are shown in table 1. Mean age was 70.2 (standard deviation [SD]: 9.08), the majority were men (87.4%) and the mean duration of the disease (time from diagnosis until inclusion in the study) was 7.7 years (SD: 5.8).

Diagnosis

Only 426 patients (53.2%) had diagnostic spirometry, and 90.9% of them had FEV_1 values in their clinical histories. The patients with diagnostic spirometry were significantly younger (69.1 years, SD: 8.8 versus 71.3 years, SD: 9.2; p = 0.0001) and had shorter COPD durations (6.4 years, SD: 4.04 versus 9.3 years, SD: 7.05; p < 0.001) than patients without spirometry. Mean FEV_1 was 54.8% (SD: 18) and 57.4% were in GOLD stage II. Tobacco habit was also registered more frequently in patients that had diagnostic spirometry (p < 0.05) (table 2).

The patients with diagnostic spirometry had undergone more complementary tests; in contrast, no significant differences were observed for severity level except for in the work-up, more frequently in mild patients (78.8% versus 69.4%; p < 0.05), and gasometry, more frequently in the most severe patients (16.8% versus 5.4%; p < 0.001). The patients with diagnostic spirometry more frequently presented follow-up spirometries during the previous 2 years compared with patients without diagnostic spirometry (61.7% versus 38.3%; p < 0.001), especially in the cases of mild patients (68.3% versus 57.6%; p < 0.05) (table 2).

Follow-up Patterns over the Last Two Years

Of the patients studied, 94.9% were being treated for their COPD by their family physician, and 34.6% had regular visits with the nursing staff. Only 407 patients (50.8%) had undergone a follow-up spirometry in the previous 2 years; 98% of these had the FEV_1 value in their medical files.

Table 2
Data from the medical history at the time of diagnosis in patients with and without diagnostic spirometry

	No spirometry, n = 375	Patients with diagnostic spirometry		
		Spirometry, n = 426	$FEV_1 \geq 50\%$, n = 243	$FEV_1 < 50\%$, n = 144
Registers at the moment of diagnosis				
Criteria for chronic bronchitis	40.5	59.5***	60.7	61.8
Chest radiography	39.8	74.6***	74.1	76.2
Electrocardiogram	26.1	41.5***	41.1	44.4
Blood work	49.9	74.5***	78.8	69.4*
Gasometry	3.8	9.5**	5.4	16.8***
Body mass index	14.4	19.2	18.9	20.8
Tobacco habit not registered in the clinical history	14	11.1*	12.5	10.4
Patients with follow-up spirometry in the previous two years	38.3	61.7***	68.3	57.6*

The data are %.
$FEV_1 \geq 50\%$ corresponds with stage I (mild) and stage II (moderate) of the GOLD COPD classification.
$FEV_1 < 50\%$ corresponds with stage III (serious) and stage IV (very serious) of the GOLD COPD classification.
The p values were calculated with the Chi-squared test, comparing patients with or without diagnostic spirometry and between patients with $FEV_1 \geq 50\%$ and $FEV_1 < 50\%$.
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

The patients with follow-up spirometry presented significantly more analyses, exacerbations registered in their clinical histories and appointments with the pulmonologist, as well as a lower percentage of hospitalizations and consultations with a private doctor than those that did not present follow-up spirometry. As the severity of COPD increased, so did the overall number of almost all the complementary tests and health-care resources (table 3).

Among the smokers, 37.6% of these patients had received no anti-tobacco advice, being significantly higher among patients without follow-up spirometries ($p < 0.05$). The scant percentage of advice given to patients about diet, exercise and treatment compliance is striking. Rehabilitation (3.2%) and physiotherapy (1.8%) were quite infrequent.

Treatment

95.9% of the patients followed some type of chronic treatment, and 40.8% were polymedicated (> 6 medications), which was more frequent among the patients who had no follow-up spirometry and among the more severe patients (table 4).

Specific COPD treatment was followed by 86.6% of patients, which was inhaled in 85.9% of cases, with a mean of 2.53 inhalers (SD: 1.05). The most often used medications were inhaled glucocorticoids (66.6%) and long-acting beta-2 adrenergics (57.5%). The prescription of medications was greater in patients that had no follow-up spirometry and among those with more severe disease. In general, there were no significant differences in the prescription habits

Table 3
Follow-up of the patients with chronic obstructive pulmonary disease with or without spirometry in the previous two years

	No spirometry, n = 394	Patients with follow-up spirometry in the previous two years		
		Spirometry, n = 407[a]	$FEV_1 \geq 50\%$, n = 237[a]	$FEV_1 < 50\%$, n = 162[a]
Complementary tests ordered in the previous two years				
Gasometry	8.6	9.8	5.1	16***
Lab work-up	69	76.9*	73.8	80.2
Electrocardiogram	42.6	44.5	40.5	50
Body mass index	31	31	31.6	29
Health-care resources ordered in the previous year				
Exacerbations registered in the patient medical history	54.9	63.9*	59.8	67.9
Hospitalizations (interview)	17.1	10.7*	4.9	18.8***
Private consultation	10.9	5.6**	4.4	7.6
Rehabilitation	2.6	3.8	2.6	5.7
Physiotherapy	1.3	2.3	0.9	4.4*
Appointment, Primary Care physician	93.6	96.1	94.9	97.5
Appointment, Primary Care nurse	33.2	36	35.2	35.8
Appointment, Primary Care pulmonologist	24.9	34.6**	30.4	41.4*
Advice given to patients in the previous year				
Among the smokers, anti-tobacco advice not given, n/N (%)	36/78 (46.2)	31/100 (31)*	17/55 (30.9)	13/41 (31.7)
Dietary advice	19.5	18.7	16.9	22.2
Exercise advice	15.2	16	13.9	19.8
Treatment compliance advice	15	14.7	13.5	16.7
Vaccines in the previous year				
Influenza	81.2	76.9	73	82.7*
Pneumococcus	74.6	71	68.8	74.1

The data are %.
$FEV_1 \geq 50\%$ corresponds with stage I (mild) and stage II (moderate) of the GOLD COPD classification.
$FEV_1 < 50\%$ corresponds with stage III (severe) and stage IV (very severe) of the GOLD COPD classification.
The p values were calculated with the Chi-squared test, comparing patients with or without follow-up spirometry in the previous two years and between patients with $FEV_1 \geq 50\%$ and $FEV_1 < 50\%$.
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.
[a]Out of the patients with spirometry, we only compared those who had the forced expiratory volume in one second (FEV_1) parameter (%), GOLD stage III + IV ($FEV_1 < 50\%$ predicted) against those in stage II ($FEV_1 \geq 50\%$).

Table 4
Treatment of the patients with chronic obstructive pulmonary disease with and without follow-up spirometry in the previous two years

	Total, N = 801	No spirometry, n = 394	Patients with follow-up spirometry in the previous two years		
			Spirometry, n = 407 [a]	$FEV_1 \geq 50$, n = 237 [a]	$FEV_1 < 50$, n = 162 [a]
General chronic treatment					
Patients with some chronic prescription	95.9	96.7	95.1	92	100***
Polymedicated patients (> 6 drugs)	40.8	44.6	37*	31.7	43.2*
Chronic prescriptions, mean (SD)	5.33 (3.11)	5.6 (3.15)	5.06 (3.05)*	4.78 (3.08)	5.37 (2.94)
Specific chronic treatment for COPD					
COPD Medication	86.6	87.1	86.2	78.9	96.9***
Inhalers	85.9	86.5	85.3	77.2	96.9***
Prescribed inhalers, mean (SD)	2.53 (1.05)	2.60 (1.04)	2.46 (1.06)	2.24 (1.009)	2.68 (1.08)
Short-acting beta-2 adrenergics	56.2	60.3	52.1*	47.1	56.7
Long-acting beta-2 adrenergics	57.5	58.9	56.1	50.3	61.8*
Ipratropium	41.2	38.8	43.6	39	49.7*
Tiotropium	22.8	22.4	23.1	20.3	26.1
Methylxantines	3	3.5	2.6	2.7	2.5
Inhaled glucocorticoids	66.6	70.3	63*	57.2	69.4*
Oral glucocorticoids	0.9	0.9	0.9	0.5	1.3
Oxygen therapy	3.2	4.1	2.3	0.5	4.5*
Mucolytics	7	7.6	6.4	4.7	8.6

The data are % or mean (standard deviation).
$FEV_1 \geq 50\%$ corresponds with stage I (mild) and stage II (moderate) of the GOLD COPD classification.
$FEV_1 < 50\%$ corresponds with stage III (severe) and stage IV (very severe) of the GOLD COPD classification.
The p values were calculated with the Chi-squared test or t-test, comparing patients with or without follow-up spirometry in the previous two years, and between patients with $FEV_1 \geq 50\%$ and $FEV_1 < 50\%$.
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.
[a] Out of the patients with spirometry, we only compared those with forced expiratory volume in one second FEV_1 parameter (%), GOLD stages III + IV ($FEV_1 < 50\%$ predicted) against those in stage II ($FEV_1 \geq 50\%$)[28].

depending on the presence or lack of follow-up spirometry. We only found a greater use of short-acting beta-2 adrenergics among the patients without spirometry (60.3% versus 52.1%; $p < 0.05$) and inhaled glucocorticoids (70.3% versus 63%; $p < 0.05$). The severity of COPD had a greater impact on the prescriptions (table 4).

Health-Related Quality of Life

Significant differences were observed in all the dimensions of the SGRQ depending on COPD staging, with poorer quality of life in severer patients ($p < 0.001$). The patients that did not have follow-up spirometry presented a higher score in the SGRQ questionnaire except in the dimension of symptoms. Statistically significant differences were only found in the activity dimension ($p < 0.05$) (table 5).

Variability of the Spirometries among the Different Centers; Result of the Multi-Level Analysis

In the case of the diagnostic spirometry, the non-conditional model estimated an expected rate of 52.2%, with a range of variation among PC centers from 32.7% to 71.1% (variance: 0.171; $p < 0.001$).

In the conditional model, the OR was observed to be significantly higher in those patients with a duration of COPD of less than 4 years compared with those with more than 15 years (table 6). The odds were also high in the patients with criteria for chronic bronchitis and low in the younger patients. A significant effect was not observed in patients who smoked. Once adjusted for the characteristics of the patients, statistically significant variability was still found in the prevalence of diagnostic spirometries among the PC centers (predicted rate: 62.2, range: 39.8-80.4; variance: 0.217; $p < 0.001$; ICC: 6.19%) (table 6). Additional analyses showed that said variability was mainly attributed to one center alone. The exclusion of this center did not change the results, except in the case of presenting environmental exposure, which was negatively associated with the result variable (OR: 0.76; 95% CI: 0.61-0.95; $p = 0.017$).

In the case of follow-up spirometry, no significant variability was found between centers. The patients with diagnostic spirometry presented a probability 2.51 times higher for having a follow-up spirometry compared with patients without diagnostic spirometry (95% CI: 1.76-3.57). Having had a visit to the pulmonologist and/or nurse and having follow-up lab work-up was positively and significantly associated with having follow-up spirometry (table 6).

Discussion

The most important result of our study is that around half of the patients considered COPD at the PC level had no spirometry to confirm their diagnosis. Diagnostic spirometry was the most important predictive variable for ordering follow-up spirometries in our COPD patient population. The use of spirometry during follow-up was associated at the same time with greater control of the COPD patient, with more visits to the PC doctor and interconsultations with a pulmonologist and fewer hospitalizations. However, surprisingly, this did not translate into an increase in the integral management recommended by the clinical practice guidelines, including rehabilitation, physiotherapy, vaccination and diet, nor was it associated with different therapeutic approach by the professionals. There was significant variability in the use of diagnostic spirometry between the different PC centers.

Spirometry is essential in the diagnosis and treatment of chronic respiratory diseases.[23] Although lately its use has spread at the primary healthcare level, it is still underused. Our results agree with other studies, such as those presented by Naberan et al[24] and Miravitlles et al[11] published more than 10 years ago, in which only 36% and 47%, respectively, of patients had undergone diagnostic spirometry. Meanwhile, in more recent studies this percentage oscillates between 38.4% and 58.4%.[9,25,26] These data indicate that, despite the insistent campaigns about the importance of COPD and the use of spirometry,[27] its use has not increased in PC. In our study, we have observed that patients with diagnostic spirometry underwent more complementary tests and follow-up spirometries. But it was interesting to observe that the advice on diet, exercise, treatment compliance, rehabilitation, physiotherapy and follow-up visits with the nursing staff were used in limited proportions regardless of the presence or absence of follow-up spirometries. On the other hand, in other previous studies it was observed that

Table 5
Results of the *St. George's Respiratory Questionnaire* for quality of life. Differences between the patients with chronic obstructive pulmonary disease with and without follow-up spirometry in the previous two years and according to staging

	Total, N = 801	No spirometry, n = 394	Patients with follow-up spirometry in the previous two years				
			Spirometry, n = 407	MD[a] (95% CI)	$FEV_1 \geq 50\%$, n = 237	$FEV_1 < 50\%$, n = 162	MD[b] (95% CI)
St. George's Respiratory Questionnaire							
Symptoms, n = 792	38.27 (21)	37.85 (21.40)	38.68 (20.63)	−0.83 (−2.1; 3.76)	35.41 (20.58)	42.90 (19.82)***	−7.49 (−11.6; −3.39)
Activity	50.26 (25.16)	52.39 (25.38)	48.21 (24.80)*	4.18 (−0.69; 7.66)	41.31 (23.62)	57.63 (23.43)***	−16.32 (−21; −11.6)
Impact, n = 798	29.33 (19.34)	29.59 (20.04)	29.07 (18.64)	0.52 (−3.21; 2.16)	24.71 (17.33)	34.97 (18.90)***	−10.26 (−13.9; −6.63)
Total, n = 791	37.09 (19.01)	37.68 (19.44)	36.52 (18.60)	1.16 (−3.81; 1.49)	31.52 (17.45)	43.19 (18.10)***	−11.67 (−15.3; −8.08)

The data are mean (standard deviation). CI: confidence interval.
The high values in the variables of the questionnaire indicate poorer quality of life.
The p values were calculated with the t-test.
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.
[a]Mean difference of means between patients with and without follow-up spirometry in the two previous years.
[b]Mean difference between patients with $FEV_1 \geq 50\%$ and $FEV_1 < 50\%$.

spirometry at the PC level improved the management of COPD patients.[9,10] These were intervention studies in which the impact of the introduction of spirometry was evaluated prospectively in the management of COPD patients in PC. Our study, however, was observational and cross-sectional, and it therefore did not determine the effect of the introduction of spirometry, but instead compared the management patterns of COPD patients depending on the existence of diagnostic or follow-up spirometry.

Coinciding with the results of other articles, the patients with follow-up spirometry presented fewer hospitalizations,[11] but on the contrary they presented more exacerbations registered in their clinical histories. We believe that this greater percentage of

Table 6
Factors associated with spirometry

Factors associated with diagnostic spirometry **Multi-level logistic regression model**			
Non-conditional model[a]			
Randomized parameters			
Variance of the PC center	Estimator		p value
	0.171		< 0.001
Conditional model			
Set parameters			
	Adjusted OR[b]	95% CI	p value
Age[c]	0.87	(0.79-0.95)	0.002
Sex (ref. females)	0.87	(0.46-1.67)	NS
Years COPD evolution (ref. > 15 years)			
0-4 years	7.39	(4-13.64)	< 0.001
5-9 years	3.34	(1.85-6.04)	< 0.001
10-14 years	2.76	(1.47-5.18)	0.002
Chronic bronchitis criteria (ref. No)	2.02	(1.45-2.82)	< 0.001
Tobacco habit (ref. non-smoker)			
Ex-smoker	1.12	(0.6-2.08)	NS
Smoker	1.05	(0.53-2.08)	NS
Random parameters			
Variance of the PC center	Estimator		p value
	0.217		< 0.001
ICC[d] (%)	6.19		
Factors associated with follow-up **Logistic regression model**[e]			
	Adjusted OR[e]	95% CI[f]	p value
Age[c]	0.94	(0.87-1.01)	NS
Sex (ref. women)	1.04	(0.54-2)	NS
Tobacco habit (ref. non-smokers)			
Ex-smokers	0.97	(0.53-1.80)	NS
Smokers	0.94	(0.56-1.62)	NS
Diagnostic spirometry (ref. No)	2.50	(1.75-3.59)	< 0.001
Appointment w/ pulmonologist (ref. No)	1.57	(1.18-2.11)	0.003
Appointment w/ nurse (ref. No)	1.33	(1.08-1.66)	0.007
Analysis (ref. No)	1.44	(1.06-1.98)	0.02

CI: confidence level; COPD: chronic obstructive pulmonary disease; NS: not significant; OR: odds ratio; PC: Primary Care; ref.: reference.
[a]Non-conditional model without predictors at each level, only the independent term and the random errors at the level of the individual and PC center.
[b]The adjusted odds ratio was based on the logistic regression model that included significant, confusing and clinically relevant variables.
[c]Age calculated for an increase of 5 years.
[d]ICC: intraclass correlation coefficient. The ICC measures the percentage of the total variance of the response variable, diagnostic spirometry, that is attributable to the PC centers.
[e]Goodness-of-fit test, Hosmer-Lemeshow, Chi-squared = 6.43; p value = 0.6.
[f]Robust standard errors adjusted for the 21 conglomerates / PC centers.

exacerbations could be due to a more precise follow-up and register of the exacerbations of those patients with spirometry, whereas if this increase were due to poorer treatment or greater severity of the patients, this would also be reflected in a higher number of hospitalizations. We believe that the frequency of hospitalizations is a more reliable variable, as it is more difficult to overlook by both patients and doctors.

In our study, the presence of follow-up spirometry in the previous 2 years did not modify the therapeutic approach of the professionals at the PC level, which suggests that there is a tendency towards homogenizing the treatment regardless of the presence or absence of spirometry, or rather the spirometry results and their therapeutic implications have not been correctly understood.

In spite of the recommendations made in the majority of clinical practice guidelines,[28] inhaled glucocorticosteroids were used in up to 66.6% of the patients in our study, especially in those that had no follow-up spirometry, as in other previous studies.[11,26] The use of inhaled glucocorticosteroids in mild patients meant a low adherence to clinical guidelines. In contrast, in patients without follow-up spirometry we observed a greater use of short-acting beta-2 agonists.

In general, the prescription of drugs was greater in patients who did not have follow-up spirometry and among those with greater spirometric alteration, which suggests a tendency towards empirical treatment.

As in other studies, we have observed greater difference in the treatment standards depending on COPD severity.[11,26]

The predictive factors of having diagnostic spirometry were having fewer years of evolution of the disease (which suggests a positive tendency towards using diagnostic spirometry) and having chronic bronchitis criteria. These results differ from those presented by Miguel Díez et al[25] done in the setting of pulmonology specialists and PC level, where the decisive factors were the level of care, the availability of the test in PC, place of residence and the situation of temporary sick leave due to COPD. In our study, the presence of spirometry in the center and teaching of residents were not predictive. The differences could be explained because our study was limited to the PC setting and some of the variables collected were different. Nevertheless, the results of this present study largely coincide with the results by Lee et al,[8] where the probability of having diagnostic spirometry was greater among patients with pulmonary symptoms and those of younger age.

Visits to the pulmonologist and/or nurse had a positive impact in the control of the COPD patients, leading to more follow-up spirometries.

Our study presents certain limitations. The diagnosis of COPD requires the demonstration of an obstructive ventilatory alteration, defined by a postbronchodilator FEV_1/FVC ratio (maximal forced expiratory volume in one second/forced vital capacity) lower than 70%, while the severity of COPD is evaluated depending on the value of postbronchodilator FEV_1.[28] This value is that which is most often registered,[26] although it must be kept in mind that this single register is not correct clinical practice.

In our study, we could not evaluate whether the diagnosis of COPD was correct. Only FEV_1 was evaluated as this was the value that we could more easily obtain from the patient histories, it was the value that was most frequently registered, it allows us to know the severity stage, and it has greater reliability compared with the rest of the spirometric parameters.[26] Another aspect to take into account is that each center used its own spirometer, therefore the reference values may not be the same. This limitation is inherent in observational multicenter studies, but it does not invalidate the conclusions of this present study.

On the other hand, there may have also been a lack of recording of other variables in the patient medical files, particular spirometries, as they could have been requested in private consultations. But our study was carried out in this manner as our objective was not to evaluate the correct file maintenance and diagnosis, but the common practice in the PC setting of COPD patients.

After analyzing individual and PC center variables and despite there being a small influence of the PC centers (ICC = 6.19%), we have confirmed that there is unexplained variability in the prevalence of spirometries at the time of diagnosis (variance = 0.217, $p < 0.001$). These results are along the same line as the study presented by Soriano et al,[29] where important variations were observed in the distribution of COPD in Spain, in prevalence as well as underdiagnosis and undertreatment. It would therefore be recommendable to study new characteristics of the patients, centers or professionals, which could explain this variability among centers. This variability can also be partly attributed to the heterogeneity of COPD itself, which warrants the completion of epidemiological studies to characterize the disease.[30,31] Lastly, we have observed that we are still a long way away from reaching the objectives set in COPD healthcare quality standards.[32]

Conclusion

Despite the importance of spirometry, its underutilization is still evident at the PC level. Spirometry testing does not guarantee either a later integral management approach of COPD or a treatment pattern in accordance with current guidelines.

It seems that the current reality of COPD management still has some gaps and variability amongst workgroups whose causes should be analyzed and corrected. This makes evident the need to improve the diagnosis and follow-up of these patients in Primary Care.

Conflict of interest

The authors declare having no conflict of interest.

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