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ORIGINAL RESEARCH

Clinical audit of COPD in outpatient respiratory clinics in Spain: the EPOCONSUL study

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Background: Chronic obstructive pulmonary disease (COPD) outpatients account for a large burden of usual care by respirologists. EPOCONSUL is the first national clinical audit conducted in Spain on the medical care for COPD patients delivered in outpatient respiratory clinics. We aimed to evaluate the clinical interventions and the degree of adherence to recommendations in outpatients of current COPD clinical practice guidelines.

Methodology: This is an observational study with prospective recruitment (May 2014–May 2015) of patients with a COPD diagnosis as seen in outpatient respiratory clinics. The information collected was historical in nature as for the clinical data of the last and previous consultations, and the information concerning hospital resources was concurrent.

Results: A total of 17,893 clinical records of COPD patients in outpatient respiratory clinics from 59 Spanish hospitals were evaluated. Of the 5,726 patients selected, 4,508 (78.7%) were eligible. Overall, 12.1% of COPD patients did not fulfill a diagnostic spirometry criteria. Considerable variability existed in the available resources and work organization of the hospitals, although the majority were university hospitals with respiratory inpatient units. There was insufficient implementation of clinical guidelines in preventive and educational matters. In contrast, quantitative evaluation of dyspnea grade (81.9%) and exacerbation history (70.9%) were more frequently performed. Only 12.4% had COPD severity calculated according to the Body mass index, airflow Obstruction, Dyspnoea and Exercise capacity (BODE) index. Phenotype characteristics according to Spanish National Guideline for COPD were determined in 46.3% of the audited patients, and the risk evaluation according to Global initiative for chronic Obstructive Lung Disease was estimated only in 21.9%.

Conclusion: The EPOCONSUL study reports the current situation of medical care for COPD patients in outpatient clinics in Spain, revealing its variability, strengths, and weaknesses. This information has to be accounted for by health managers to define corrective strategies and maximize good clinical practice.

Keywords: chronic obstructive pulmonary disease, clinical audit, medical care, adherence, clinical guidelines

Introduction

There are a number of clinical practice guidelines (CPG) aimed to systemize the medical care in chronic obstructive pulmonary disease (COPD),[1–5] and quality standards of care for COPD patients.[6,7] However, their real-life implementation is far from perfect. Different studies have reported considerable variability in COPD medical care between different professionals, hospitals, and countries,[8–12] and frequent inconsistencies with CPG recommendations.[13,14]

Several clinical audits of inpatient care in COPD have been conducted in the last decade. The recent, landmark European Clinical COPD Audit[12] carried out in

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13 European countries, and various initiatives at the national level (UK,[8] Spain,[9] and Scandinavian countries[15]), provided relevant information on unstable COPD management and its variability. However, we have less evidence surveying outpatient care, even though COPD, as a highly prevalent and chronic disease, is one of the most frequent reasons for seeking medical attention and accounts for 10% of primary care and 30% of respiratory outpatient care visits.[16] Most previous studies explored single aspects, such as the diagnosis[17] or the prescribing pattern,[18–21] or health care database management analysis, such as the studies from Sweden[22] and Finland,[23] often having limited sample size of patients and/or centers.[10,24] To our knowledge, no audit at the national level has been performed of outpatient specialized care in COPD.

In this study, we present the results of the EPOCONSUL study, the first national audit which evaluated the adequacy of medical care in COPD according to official Spanish guideline Spanish National Guideline for COPD (GesEPOC), and describes the material and organizational resources of outpatient respiratory clinics in Spain.

Methods

Study design

EPOCONSUL is an observational cross-sectional study with prospective case recruitment in outpatient respiratory clinics for a period of 12 months (May 2014–May 2015). The sample population was selected from patients seen for a consultation at the participating centers during the recruitment period. Recruitment was intermittent and prospective during the year, and every 2 months each investigator recruited the first 10 patients diagnosed with COPD and seen in the outpatient respiratory clinic. The inclusion criteria were patients aged >40 years, smokers or ex-smokers (of at least 10 pack-years) with COPD diagnosed on the basis of spirometric tests (FEV_1/FVC post-bronchodilation <0.7 or FEV_1/FVC pre-bronchodilation <0.7 and $FEV_1 \leq 80\%$, if there is no bronchodilation reversibility testing available). The exclusion criteria were no previous follow-up for at least 1 year in a respiratory outpatient clinic and patients that currently participate in clinical trials or research projects related to COPD. The information gathered was historical in nature as for the clinical data of the last and previous consultations, where the information about hospital resources was concurrent.

Study organization and participating hospitals

A Scientific Committee made up of pulmonologists and epidemiologists designed the study, determined the variables, coordinated the work process, and data analysis. A company specialized in information services and consulting for the health care sector (IMS Health, Madrid, Spain) was in charge of supervising the database and the work of the local investigators.

There was an official invitation to participate in the study from the Spanish Society of Pneumology and Thoracic Surgery to all the respiratory units in Spain with respiratory outpatient clinics according to the 2012 Registry of the Ministry of Health. From the 175 public hospitals in the National Health System invited, 59 participated (33.3%). The catchment population was estimated for each Autonomous Community of Spain from the catchment population assigned to each participating hospital according to population census data of 2015. The participating hospitals and investigators are detailed in Supplementary material S1.

Patient selection

Clinical records of all patients scheduled for visit in the outpatient respiratory clinic on the assigned day (the first working day of every second month) were selected for review. Subsequently, patients identified as diagnosed with COPD were reevaluated to determine if they met the inclusion/exclusion criteria. The sampling process is described in a Strengthening the reporting of observational studies in epidemiology flow chart (Figure 1).[25]

Variables selection

The Scientific Committee elaborated a preliminary version of the Case Report Form that was shared and discussed with a panel of local pulmonologists and investigators in a face-to-face meeting and subsequently, via email. The final questionnaire contained 46 hospital-oriented and 153 patient-oriented variables, all described in Supplementary material S2. The variables were separated in 3 groups: 1) on available resources and work organization; 2) on patient characteristics; and 3) on clinical practice models: interventions undertaken during the consultation, and at the last audited visit.

The degree of current CPG implementation of the main statements according to GesEPOC 2012[3] and strategy Global initiative for chronic Obstructive Lung Disease (GOLD) 2013[2] were evaluated as described in Supplementary material S3.

Data acquisition and processing protocol

At the beginning of the study the investigators completed a questionnaire about their hospital, and the resources and work process in their respective outpatient respiratory clinic.

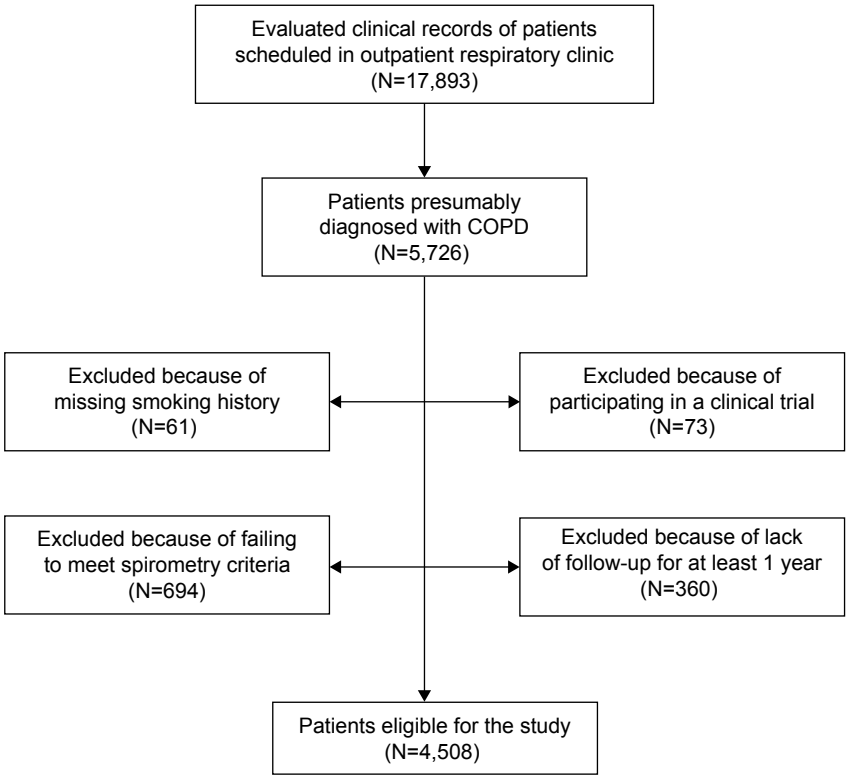

Figure 1 Strengthening the reporting of observational studies in epidemiology flow chart of the sampling process.
Abbreviation: COPD, chronic obstructive pulmonary disease.

To preserve the blinding of the clinical performance evaluation, the investigators were not the treating physicians of the study cases.

The database was externally checked on a daily basis to identify errors, inconsistent and missing values. Values considered extreme or inconsistent with other related values were returned to the local investigators for verification and modification as needed.

Ethical aspects

The protocol was approved by the Ethics Committee of the Hospital Clínico San Carlos (Madrid, España; internal code 14/030-E), certifying that it complied with the ethical principles formulated in the Declaration of Helsinki regarding medical research and preservation of the confidentiality of patient data. Current research laws in Spain (Ley be Investigación Biomédica de 2007 and Ley de Protección de Datos de 1999) explicitly state there is no need of either Ethics Review Board approval or individual consent for retrospective assessments of data obtained from usual clinical care for audit and research purposes, such as in our study. The protocol was also approved by the local Ethics Committee of every participating hospital.

To avoid modifications of the usual clinical practice and preserve the blinding of the clinical performance evaluation, the medical staff were not informed about the audit. Patient data were coded and their confidentiality preserved according to Spain's law regulations. The Scientific Committee had the responsibility to guarantee the scientific and methodological accuracy of the study, and the quality control of all data collected.

Statistical analysis

Descriptive results are presented both at patient level and on hospital level. Qualitative variables are presented by absolute and relative frequency (%). The quantitative variables are summarized as median, interquartile range (IQR) and minimum–maximum. Significance of variability by area/hospital was explored by Kruskal–Wallis or chi-square tests, depending on the nature of the variable between the different participant centers. Data were processed using the the Statistical Package SPSS, version 15.0. P-values <0.05 were considered statistically significant.

To evaluate the degree of CPG implementation, criteria of good clinical practice and quality standards were classified into 3 categories: clinical evaluation of the patient, disease evaluation, and therapeutic interventions. The number of quality standards met on patient-level and hospital-level were analyzed in each category.

Results

A total of 17,893 clinical records of patients attended in outpatient respiratory clinics were evaluated during the study period, and the clinical records of patients presumably diagnosed with COPD (5,726 records) were selected. Those patients who met all the inclusion and none of the exclusion criteria were 4,508 (78.7%). The exclusion criteria are described in Figure 1.

Characteristics of the participating centers

A total of 59 centers (33.7% of the potentially eligible) from 16 out of the 17 Spanish Autonomous Communities participated in the EPOCONSUL study (except La Rioja region with 322,000 inhabitants representing 0.68% of the total population of Spain). The catchment population assigned for the participating hospitals in every Autonomous Community is summarized in Table 1. The estimated population covered by the EPOCONSUL study was 18,104,350 representing ~39.3% of the Spanish population.

The characteristics of the participating hospitals are represented in Table 2. The majority were university hospitals (83.1%) and with >20 respiratory care beds (83.7%). However, there was wide variability in the resources and organization of the centers.

Characteristics of the audited patients

The main characteristics of the 4,508 patients evaluated are presented in Table 3. Most of them were male (86%), of advanced age (median of 69.7 years), and with significant comorbidities. Overall, 23% were active smokers, and their COPD was mostly symptomatic and with severe airflow obstruction.

Diagnostic procedures

The main diagnostic procedures are described in Table 4. An important proportion of patients followed in outpatient respiratory clinics were referred by their primary care (44.7%), already had a long follow-up period in the outpatient respiratory clinic (median 4 years; IQR 3.5–5 years) and 50.4% were scheduled for a follow-up appointment in <6 months.

Clinical interventions

The main clinical interventions during the last patient consultation are summarized in Table 5. The grade of dyspnea and the exacerbation history were evaluated in most patients, 81.9% and 70.9% of them, respectively. Only 12.4% had COPD severity calculated according to the Body mass index, airflow Obstruction, Dyspnoea and Exercise capacity (BODE) index. Phenotype characteristics according to GesEPOC were determined in 46.3% of the audited patients, and the risk evaluation according to strategy Global iniciative for chronic Obstructive Lung Disease (GOLD) was estimated only in 21.9%, again all with a considerable variability between centers.

Adherence to current CPG

Adherence to the main CPG statements is summarized in Table 6. All the good clinical practice standards were only applied to a small number of patients evaluated during the

Table 1 Participating hospitals and catchment population by Autonomous Community

Region of Spain	Number of participating hospitals	Population assigned for admission	Population of the Autonomous Community	Catchment population of the EPOCONSUL study (%)
Andalucía	10	2,784,083	8,424,102	33
Aragón	2	597,000	1,346,293	44.3
Asturias	1	250,000	1,081,487	23.1
Islas Baleares	2	575,000	1,113,114	51.6
País Vasco	4	1,285,000	2,184,606	58.8
Islas Canarias	1	700,000	2,126,769	32.9
Cantabria	2	395,000	593,121	66.6
Castilla y la Mancha	4	1,186,014	2,115,334	56
Castilla y León	4	1,119,086	2,558,463	43.7
Cataluña	5	1,657,000	7,539,618	22
Extremadura	1	273,977	1,109,367	24.7
Galicia	2	970,000	2,795,422	34.7
Madrid	11	3,484,995	6,489,680	53.7
Murcia	3	770,175	1,470,069	52.3
Navarra	1	517,020	642,051	80.5
Valencia	6	1,540,000	5,117,190	30
Total	59	18,104,350	46,064,635	39.3

Notes: Data are presented as numbers. The percentages refer to the total population number. There was no participating hospital in La Rioja, the 17th Autonomous Community in Spain.

Table 2 Characteristics of the participating hospitals and the resources of the respiratory units (N=59)

Variables	%	Median	IQR	Min–Max
Public University Hospital	83.1			
Inpatient respiratory clinic available	83.1			
Number of inpatient respiratory beds ≥20 beds	83.7	30	20–35.5	10–66
Number of pulmonology staff members				
≥5 staff	81.4	10	5–13	1–28
Pulmonology residents present	67.8	4	3.25–8	1–12
Minutes of first time general respiratory outpatient visit				
<15	6.8	20	15–30	10–60
15–19	33.9			
≥20	59.3			
Minutes of follow-up general respiratory outpatient visit				
≤10	47.5	12	10–15	5–60
11–14	8.5			
≥15	44.1			
Nursing respiratory outpatient clinic available	45.8			
Specialized COPD outpatient clinic available	47.5			
Minutes of first time specialized COPD outpatient visit				
<15	3.4	20	15–30	1–60
15–19	21.7			
≥20	72.9			
Minutes of follow-up general respiratory outpatient visit				
≤10	30.5	15	10–15	0–60
11–14	5			
≥15	64.4			
Nurse available in specialized COPD outpatient clinic	27.5			
Functional respiratory laboratory available				
Spirometry	100			
Diffusing capacity	100			
Plethysmography	100			
Respiratory muscle strength	84.7			
6MWT available	94.9			
Inhalation technique educational program available	30.5			
Cardiopulmonary exercise testing available	62.7			
Respiratory rehabilitation program available	74.6			
Hospital-based	61.4			
Home-based	6.8			
Mixed	31.8			
Alfa-1-antitrypsin genetic testing available	67.8			
Written COPD nutritional protocol available	13.0			
Sputum eosinophil count available	44.1			

Note: Data are represented as percentages.
Abbreviations: COPD, chronic obstructive pulmonary disease; IQR, interquartile range (on hospital-level); 6MWT, 6-minute walk test.

study. However, there was a better adherence to the statements in the clinical evaluation category, with 3 out of 6 evaluated good clinical practice criteria met in 65.5% of the patients. On the contrary, CPG implementation was inferior in the disease characteristics category, with 4 out of 8 evaluated criteria met in only 30.1% of patients; again, with considerable variability between centers (median 27%; IQR 13.3%–48.8%). The poorest adherence to the quality standards was observed in the therapeutic interventions category, with only 22.4% of the subjects fulfilling 3 out of 5 criteria. Overall, only 18.3% of patients fulfilled all 6 criteria at the first clinical evaluation; 1.5% of patients fulfilled all 8 criteria at the COPD evaluation; and 9.3% of patients fulfilled all 5 criteria at the therapeutic intervention.

Discussion

This work describes the adherence to current medical care guidelines for COPD in outpatient respiratory clinics in Spain. To our knowledge, this is the first national audit in this setting. Although clinical interventions in COPD have been evaluated in previous works, different to our study, they involve small samples of patients or hospitals,[10,24] or deal with specific aspects of COPD care.[17–20]

Clinical audits have been traditionally used in health care as a tool to collect information about the care delivered and, accordingly, as a process for quality improvement. They help to identify the problem areas and offer extremely valuable information for health care professionals and administrators, both focused on a clinical practice that complies with quality standards. Communicating results to the health professionals has been regarded as a strategy for self-correction of their clinical practice.[26,27] In this context, the present study attempts to raise awareness about the need to improve outpatient clinical care in COPD and to serve as a starting point for pulmonologists and health care administrators to analyze the detected deficiencies in COPD outpatient care, and consider corrective interventions.

Our study has several strengths and limitations. The main strength is its sample size and representativity, being a nationwide study with regional representation, and the sequential data collection over 1 year using a standardized protocol which avoided seasonal bias and prevented the inclusion of cases without a reliably established COPD diagnosis. A study with such population coverage should provide information on the adherence to the Spanish guideline GesEPOC and to the patterns of diagnosis and treatment with the GOLD strategy and offers a quite realistic picture of the clinical characteristics of the COPD patient, the usual clinical practice models, the available resources and the work organization in Spanish Respiratory units. Furthermore, most centers are university hospitals with respiratory inpatient clinics and pulmonology residents, but

Table 3 Descriptive data of the evaluated patients at both patient and hospital level

Variables	Patients (N=4,508)		Hospitals (N=59)		
	N	Percent or median (IQR)	Median	IQR	Min–Max
Gender (male, %)	4,508	86	87.5	82.1–93.2	60–100
Age (years)	4,508	69.7 (63–77.7)	70	69–72	64–76.5
≤55		8.5	8.2	5.8–11.7	1.7–33.3
56–69		38.7	38.1%	30–42.6	16.6–58.2
≥70		52.8	53.3	47.1–61.7	31.7–78.3
Pack-years	4,508	47 (34–70)	45	40–51	10–190
Active smokers (%)	4,508	23.1	22	18–29	6.5–37.5
BMI (kg/m^2)	4,499	28.0 (24.4–31.1)	27.8	26.6–28.5	24.3–30.5
≤21		7.1	6.7	4.1–9.2	0–20
≥30		32.1	31.4	26.2–37.7	10.1–66.7
Charlson index	4,508	2 (1–4)	2	2–3	1–9
≥3	4,508	44.9	44.5	40–56.6	20–78.3
Dyspnea (mMRC) ≥2	3,099	60.2	61.1	46.3–76.2	20–100
CAT questionnaire >10	869	62.4	64	47.9–83.8	0–100
Chronic bronchitis criteria	4,508	41.7	41	28.3–51	0–85.5
Chronic colonization	4,508	6.0	5	3.2–8.3	0–27
Symptoms suggestive of asthma	4,508	26.5	18.3	10.8–35	0–95
FEV_1 (%)	4,508	52.4 (38–65)	52	49–55	36–71
<30		10.5	9.6	5–13.5	0–27.2
≥30–<50		35.4	35.7	29.3–40.5	0–65.3
≥50–<80		46.8	48.4	41.3–56.9	25–100
≥80		7.3	5.1	0–10.7	0–20
Bronchodilator reversibility (%)	2,809	9.7 (3–13)	7	5–9	1–14
Number of moderate/severe exacerbations in the last year	3,196	1.1 (0–2)	1	0–1	0–3
Number of hospital admissions in the last year	2,851	0.5 (0–1)	0	0–0	0–2
BODE value	632	3.9 (3–5)	4.5	3–5.5	1–8
BODEx value	321	3.4 (2–5)	3.5	3–5	1–7.5
GOLD group					
A	985	22.7	14.3	0–25.9	0–66.7
B		18.7	16.7	0–24.1	0–100
C		18.7	20	9.8–33.3	0–62.5
D		39.9	40	23.5–55.6	0–100
GesEPOC phenotype					
Non-exacerbator	2,086	44.4	41.7	27.4–54.3	0–100
Exacerbator with chronic bronchitis		22.6	21.1	9.7–29.7	0–51.9
Exacerbator with emphysema		18.1	16.7	11.1–23.5	0–100
ACOS		14.9	14.3	8.7–22.2	0–75
LAMA monotherapy	4,391	10.0	10	4.8–15.3	0–33
LAMA–LABA combination	4,391	22.7	20.3	14.5–27.9	8.5–71.4
LABA + CSI combination	4,391	7.7	6.7	3.4–9.8	0–29
Triple therapy (LAMA + LABA + CSI)	4,391	49.1	50.8	39.3–60.3	0–71.2
Long-term oxygen therapy	4,508	26.6	25	17.1–33.3	0–53
Home ventilation	4,508	7.5	5	2.5–11.6	0–100
Respiratory rehabilitation	4,508	9	5	0–11.8	0–46.7

Note: Average value expressed as the mean (standard deviation) or absolute (relative) frequency depending on the nature of the variable.

Abbreviations: BMI, body mass index; CAT, COPD assessment test; CSI, inhaled corticosteroids; GesEPOC, Spanish National Guideline for COPD; GOLD, Global initiative for chronic Obstructive Lung Disease; IQR, interquartile range; LABA, long-acting beta-2 agonists; LAMA, long-acting antimuscarinic agents; mMRC, modified Medical Research Council; BODEx index, body mass index, airflow obstruction, dyspnoea and exacerbations; ACOS, ACOS asthma-COPD overlap syndrome; BODE, body mass index, airflow obstruction, dyspnoea and exercise capacity.

with differences in the available resources and work organization between the participating hospitals, for example, the number of pulmonology staff members, inpatient beds or the availability of a specialized COPD outpatient clinic. This way our study provides novel information relating to the degree of actual compliance guidelines with available resources and clinical presentation.

Nevertheless, there are some limitations that have to be considered. First, the selection of participating centers was not random; they were selected based on their previous

Table 4 Diagnostic procedures conducted during the follow-up at both patient- and hospital-level

Variables	Patients (N=4,508)		Hospitals (N=59)			*P*-value*
	N	Percent or median (IQR)	Median	IQR	Min–Max	
Bronchodilator reversibility testing	4,508	86	65	50–85	0–98.3	<0.001
Arterial blood gases measured on any occasion	4,508	63.9	67.5	49.2–81.7	25–100	<0.001
Alfa-1-antitrypsin serum testing levels available	4,508	22.1	17.5	7.9–30	0–69.4	<0.001
Lung volumes measured on any occasion	4,508	42.8	43.3	19.7–65	0–99.2	<0.001
Diffusion capacity measured on any occasion	4,499	49	55	28.3–67.8	0–92.1	<0.001
6MWT carried out on any occasion	4,508	27.3	22.5	8.3–48.3	0–93.3	<0.001
Cardiopulmonary exercise testing carried out on any occasion	3,099	3.7	3.3	0–5	0–19.7	<0.001
BODE index calculated on any occasion	869	14	5.4	1.7–22.5	0–74.6	<0.001
CAT questionnaire evaluated on any occasion	4,508	19.3	8.9	1.7–35.6	0–100	<0.001
Chest CT scan carried out on any occasion	4,508	58.9	60	50–71.7	28.9–90.2	<0.001
Comorbidities identified in the clinical record	4,508	81.5	85.7%	78.3–91.9	41.3–100	<0.001
Delivered to respiratory outpatient clinic from						
Primary care	3,594	44.7	47.2	27.5–56.5	0–98.3	<0.001
Emergency		6.9	6.3	2.2–11.5	0–27.4	
Department inpatient care		20.7	18	12–25.9	0–57.5	
Scheduled follow-up visits (months)						
<6	4,386	50.4	47.4	39.7–59	16.9–90.7	<0.001
6–12		33.2	33.3	26.3–41.4	8.1–61	
>12		16.4	13.3	7.4–22	0–54.2	
Respiratory care follow-up (years)	4,508	4 (2–7)	4	3.5–5	2–7.5	<0.001

Notes: Average value expressed as the mean (standard deviation) or absolute (relative) frequency depending on the nature of the variable. *Calculated for the variability between centers using test de Kruskal–Wallis or chi-square test, depending on the nature of the variable.

Abbreviations: BODE, body mass index, airflow obstruction, dyspnoea and exercise capacity; CAT, COPD assessment test; CT, computerized tomography; IQR, interquartile range; 6MWT, 6-minute walk test.

Table 5 Clinical interventions at the time of the last follow-up visit at both patient- and hospital-level

Variables	Patients (N=4,508)		Hospitals (N=59)			*P*-value*
	N	Percent or median (IQR)	Median	IQR	Min–Max	
Evaluation of dyspnea grade	4,508	81.9	87.5	82.1–93.2	60–100	<0.001
Number of moderate or severe exacerbations in the last 12 months recorded	4,508	70.9	73.3	59.5–88.3	18.3–100	<0.001
Number of hospital admissions in the last 12 months collected	4,508	63.2	66.9	50.8–86.2	10.8–100	<0.001
Data on regular exercise collected	4,508	41.0	61.1	46.3–76.2	20–100	<0.001
COPD diagnosis established in the visit report	4,508	89.4	97.5	83.5–98.8	40–100	<0.001
COPD severity defined in the report	4,508	74.7	84.3	61.7–91.8	3.2–100	<0.001
By which criteria						
FEV_1		81.3	91.1	66.4–99	2.2–100	
BODE		12.4	4.5	0–16.4	0–74.5	
BODEx		6.2	1.9	0–8.1	0–62.5	
GOLD-type defined in the report	4,508	21.9	8.3	0.8–32.9	0–91.1	<0.001
COPD phenotype according to GesEPOC defined in the report	4,508	46.3	46.7	27.4–67.5	1.7–100	<0.001
Current COPD treatment listed in the report	4,508	95.3	97.5	93.5–99.2	71.7–100	<0.001
Treatment adherence evaluated	4,508	0	31.7	17.9–61.7	1.7–100	<0.001
Inhalation technique evaluated	4,508	27.1	44.5	40–56.6	20–78.3	<0.001
Grade of satisfaction with inhalation device evaluated	4,508	17.1	7.6	1.7–23.2	0–100	<0.001
Adverse effects of medication collected	4,508	22	12.4	5–27.5	0–100	<0.001
Specific intervention for smoking cessation in active smokers offered	2,929	22.4	20	10.1–27.5	0–73	<0.001
Have arterial blood gases been measured on any occasion in patients on long-term oxygen therapy?	1,199	90.2	95.2%	90–100	46–100	<0.001
Regular exercise recommended during the visit	4,508	41.2	36.1	15.1–63.4	0–100	<0.001
Influenza annual vaccination recorded	4,508	42.7	64	47.9–83.8	0–100	<0.001
Pneumococcal vaccination recorded	4,508	25.3	41	28.3–51	0–85.5	<0.001
Any change in current medication advised	4,508	22.5	5	3.2–8.3	0–27	<0.001

Notes: Average value expressed as the mean (standard deviation) or absolute (relative) frequency depending on the nature of the variable. *Calculated for the variability between centers using test de Kruskal–Wallis or chi-square, depending on the nature of the variable.

Abbreviations: BODEx index, body mass index, airflow obstruction, dyspnoea and exacerbations; COPD, chronic obstructive pulmonary disease; GesEPOC, Spanish National Guideline for COPD; GOLD, Global initiative for chronic Obstructive Lung Disease; IQR, interquartile range.

Table 6 Adherence to the main clinical practice guidelines statements

Criteria of good clinical practice evaluated in EPOCONSUL	Results EPOCONSUL study	Patients (N=4,508)		Hospitals (N=59)			*P*-value[†]
	No of criteria met	N	%	Median	IQR	Min–Max	
During clinical evaluation (criteria)							
1. Was dyspnea grade evaluated on current visit?	6 criteria	4,508	18.3	14.6	5–30	0–100	<0.001
2. Was the number of hospital admissions in the last 12 months recorded during current visit?							
3. Was the number of moderate or severe exacerbations in the last 12 months collected during current visit?	>3 criteria	2,952	65.5	70.0	46.7–89.3	11.7–100	<0.001
4. Was current smoking habit collected?	≤3 criteria	1,556	34.5	30	10.7–53.3	0-88.3	<0.001
5. Was regular exercise data collected during current visit?							
6. Are comorbidities identified in the clinical record?							
During COPD evaluation (criteria)							
1. Alfa-1-antitrypsin serum level determination available?							
2. COPD spirometry severity defined in the report?	8 criteria	4,508	1.5	0	0–0.8	0–14.6	<0.001
3. COPD GOLD type defined in the report?							
4. COPD phenotype according to GesEPOC defined in the report?	>4 criteria	1,355	30.1	27	13.3–48.8	0–89.3	<0.001
5. 6MWT carried out on any occasion?							
6. Diffusion capacity measured on any occasion?							
7. Lung volumes measured on any occasion?	≤4 criteria	3,153	69.9	73	51.2–86.7	10.7–100	<0.001
8. Chest CT scan carried out on any occasion in exacerbator phenotype?							
During therapeutic intervention							
1. Current COPD treatment listed in the report?							
2. Is treatment adherence evaluated in any way?	5 criteria	4,508	9.3	3.3	0–15	0–45.1	<0.001
3. Is inhalation technique evaluated in any way?	>3 criteria	1,008	22.4	12.5	2.5–40	0–100	<0.001
4. Is Pneumococcal vaccination collected?							
5. Is exercise advised during the visit?	≤3 criteria	3,500	77.6	87.5	60–97.5	0–100	<0.001

Notes: Clinical practice criteria (GesEPOC and GOLD) evaluated in the study is classified into 3 categories: clinical evaluation, disease evaluation and therapeutic interventions. The number of criteria of good clinical practice met in each category was analyzed in patients evaluated. Average value expressed as the mean (standard deviation) or absolute (relative) frequency depending on the nature of the variable. [†]Calculated for the variability between centers using test de Kruskal–Wallis or chi-square test, depending on the nature of the variable.

Abbreviations: 6MWT, 6-minute walk test; COPD, chronic obstructive pulmonary disease; CT, computerized tomography; IQR, interquartile range; GOLD, global initiative for chronic obstructive lung disease; GesEPOC, Spanish National Guideline for COPD.

participation in clinical audits on COPD and their interest to participate. In spite of these limitations we believe that our sample is representative of the current situation in the country, given the acceptable population coverage and the representation of 16 out of 17 Autonomous Communities of Spain, except La Rioja with 0.68% of the total population. We should also remember that every clinical audit has an intrinsic limitation of missing values (not available) in spite of the inclusion methodology and the periodic supervision of the database.

When looking at the resources, the most noteworthy point is perhaps the limited number of respiratory units with nursing outpatient clinics, even among those with specialized COPD outpatient clinics. There is also an important lack of educational programs on inhalation technique despite the predominance of university hospitals with pulmonology residency programs and inpatient respiratory clinics. Another issue worth mentioning is that less than half of the centers had specialized COPD outpatient clinics. If available, they usually have waiting lists similar to those of the general respiratory outpatient clinics and they frequently do not have a supporting nurse. Given that specialized COPD outpatient clinics in COPD patient care have not demonstrated effectiveness so far, we believe that analyzing these data will provide valuable information. It is also remarkable that, in spite of the availability to perform a 6-minute walk test (6MWT) in the majority of the centers and of cardiorespiratory exercise testing, the number of tests carried out is low, which is in disagreement with current recommendations according to GesEPOC.[3–5] Only 27.3% of the audited patients in our study had performed a 6MWT, bearing in mind that most were patients with severe airflow obstruction or GOLD D group. This finding corresponds to those of previous audits explored adherence to recommendations, in spite of having minor sample size, such as the one by Nardini et al (2012,

Campania, Italy),[10] where the test was only carried out in 30.7% of the audited patients, or the one by López-Campos (2014, Andalucía, Spain), in only 9.7%.[24] The reasons for the poor use of 6MWT have not been specifically looked at, but are probably related to work organizational issues, or unit's resources limiting the accessibility of the test, or may be even related to the reluctance of health professionals to change in spite of their knowledge of CPG. At any rate, this finding should raise concern as an area for urgent change. Also, an important number of centers offer the genetic testing for alpha-1-antitrypsin deficiency (67.8%), but its determination was carried out only occasionally, in 22.1%. These data support the high rate of underdiagnosis[28] of this deficiency and this seems to be due to lack of awareness among pulmonologists to request this accessible, simple, and cheap test.

Regarding the profile of the COPD patient followed in respiratory outpatient clinics, most of them have been followed for several years, with a low percentage of discharge (5%), with severe or very severe airflow obstruction and symptomatic COPD with few exacerbations treated with triple inhalation therapy. These results are similar to those from the CHAIN cohort[29,30] of COPD patients followed in respiratory outpatient clinics.

From the recommendations derived from the clinical evaluation of patients, the most complied with were dyspnea grade evaluation and exacerbation history recollection, in contrast to those related to functional and disease severity quality standards. In this context, although CPG are not protocols, it is difficult to justify why >75% of COPD patients with long-term follow-up in respiratory clinics do not have a multidimensional disease evaluation to establish their prognosis, or why over half of patients have never had their lung volumes measured.

When exploring therapeutic interventions, we see poor implementation of educational programs and preventive measures. For example, only 22% of actively smoking COPD patients have been offered a specific cessation intervention, and pneumococcal vaccination has been offered only to 25.3%. These were patients frequently on triple and quadruple therapy, yet only one-fourth of them were evaluated for correct inhalation technique. In spite of the expected availability and knowledge of CPG among pulmonologists, an important number of COPD patients do not receive the standard recommended care in outpatient clinics. Again, the variability detected between centers has to be pointed out, with differences 2- to 4-fold between the different respiratory units. It could be explained in part with the smaller number of cases in some of the centers, but could also be due to other factors, such as heterogeneity of resources and organization among centers; heterogeneity of COPD itself, and of patients' needs; and accessibility and security of data source in patient files. We think it necessary to study the possible relations between these factors, in order to deal with the next challenge, to move from data collection to better patient care, which means to define and undertake improvement strategies.

Conclusion

EPOCONSUL is the first national audit of COPD in outpatient respiratory clinics in Spain. Its results highlight the disparity between guidelines and clinical practice of health care professionals who provide care for COPD patients, with both lights and shades. It is important to remember that the clinical presentation of diseases is normally variable and that these recommendations are not always evidence-based. Also, as a retrospective study, can only evaluate the information writing in the clinical history.

Our results confirm previous studies realized with limited sample size and show significant variability in terms of the available resources and work organization, the patient characteristics and clinical practice models . Such information must be accounted for by health care professionals and administrators, in order to correct the deficiencies and establish better clinical practices.

Further clinical audits are necessary to evaluate the impact of complying with quality standards on clinically significant results, such as exacerbations and mortality.

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Author contributions

MCR, JLL-C, BAN, JBS, JJS-C, JMRG-M are the study's Scientific Committee. MEFF carried out the statistical analysis and MCR designed the study and wrote the manuscript. The rest of the authors recruited patients and reviewed the manuscript. All authors contributed toward data analysis, drafting and revising the paper and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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