CONOCEPOC 2020

Study promoted by the Spanish Society of Pneumology and Thoracic Surgery (SEPAR)

INTRODUCCIÓN

Chronic obstructive pulmonary disease (COPD) is considered a major health problem due to its high prevalence and mortality, along with its high socio-health impact, both in terms of consumption of health resources and loss of quality of life of patients. It is currently included in the priority plans of health systems[1], as it is already considered the third cause of death[2,3] and one of the main causes of frequent consultations and responsible for hospital admissions[4].

COPD has a high prevalence, according to data from the epidemiological study EPI-SCAN II[5], carried out recently in Spain, affecting 12.4% of the population over 40 years of age, and whose prevalence is estimated to increase due to the gradual ageing of the population and tobacco exposure. In addition, this study identifies a worrying increase in under-diagnosis, which reaches 81.7%, with respect to previous data, and with significant differences between the autonomous communities in Spain. The IBERPOC[6] study, carried out in 1997 in Spain, revealed that 78.2% of the cases confirmed by spirometry in that study had no previous diagnosis of COPD. These results were repeated in the EPISCAN I study[7] conducted 10 years later, which showed an underdiagnosis of 73%. A significant proportion of patients, in whom the lack of diagnosis prevents the provision of specific treatment and more active actions for the prevention of infections and the cessation of the smoking habit, which would change their prognosis.

The factors that influence this underdiagnosis are multiple and complex, although, being able to deepen their knowledge will allow the establishment of efficient strategies in the improvement of the diagnostic process of this disease. A diagnostic process that is based on some necessary premises, such as recognizing and giving importance to the symptoms by the population for the search of health care, and, in turn, the awareness of evaluating the respiratory symptoms through the application of spirometry by health professionals.

Studies conducted in Spain in 2005[8] and 2011[9] showed that there was little knowledge about COPD, and that many people with respiratory symptoms did not seek medical attention, and there was little use of spirometry. CONOCEPOC I study, conducted in Spain in 2011, cross-sectional, observational, epidemiological study, by means of a telephone interview with a representative sample aged of those 40-80 years living in all 17 regions of Spain. A study that showed that in Spain many people with respiratory symptoms did not seek medical attention and did not try to quit smoking. It also showed that there was a general lack of knowledge about COPD. Only 17.0% spontaneously reported they knew the term COPD. with marked variability in the regions ($p < 0.05$).Valencia was the region with the highest degree of ignorance of COPD (91%), while Aragon was the lowest (73.7%). Yet, COPD is considered a severe disease, just under angina pectoris. Compared to other diseases such as cancer or cardiovascular disease, the secular lack of public knowledge about COPD may largely explain the historical disproportion between the magnitude of the problem and its low impact on public opinion, the reduced perception of need and urgency to alleviate the problem, and the scarce allocation of resources for care and funding for research. The CONOCEPOC initiative aims to promote the realization of a correct and earlier diagnosis of COPD in Spain.

In the last 10 years strategic interventions have been carried out by Scientific Societies and the Administration, such as informative and awareness campaigns for the population, as well as the implementation of training and equipment programs to

improve the practice of spirometry. However, despite these actions, recent data from the EPI-SCAN II study[5] reveal a worrying increase in underdiagnosis.
The objective of the CONOCEPOC II 2020 study is to determine the current level of knowledge about COPD and its determinants in the general population of Spain and to analyze the differences between autonomous communities. In addition to evaluating the changes that have taken place almost ten years later, and providing knowledge about the determinants of the underdiagnosis shown in the EPI-SCAN II study, and turn increasing awareness of the importance of COPD.

MAIN OBJETIVE

To assess the general population's knowledge about COPD and sources of information.

SECONDARY OBJETIVES

1. To assess the prevalence of respiratory symptoms and clinical management referred
   2.1 To assess to consulte a physician
   2.2 To assess the use of spirometry referred
   2.3 To assess the frequency of inhaled treatment and the difficulty in its use
2. To assess the respiratory disorders of the population
3. To assess the respiratory disorders and its characteristics
4. To assess the percentage of population without diagnosis and with the presence of COPD risk factors (high risk of COPD) and its characteristics

METHODOLOGY

1.-STUDY DESIGN:

This is a cross-sectional observational epidemiological study (descriptive) through a single telephone interview in Spain (peninsular), Balearic Islands and Canarias Islands, promoted by the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR).

2.-STUDY POPULATION:

- The reference population is all subjects resident in these territories over 40 years of age.
- The target population (eligible in the first instance) is made up of all people with the a for ementioned characteristics that live in Spanish homes with a private telephone.
- The sampling population is made up of the eligible population that meets the specific selection requirements (appropriate age quotas) in each stratum (habitat and geographic area).
- The final sample of the study is made up of all the people who, meeting all the previous requirements, were located and agreed to be interviewed by telephone.

Participation is voluntary, confidential and anonymous, by means of randomly dialing fixed telephone numbers. According to data from the National Statistics Institute (INE) survey of 2019, 77% of households in Spain have a fixed-line telephone[10].

3.-SAMPLE SIZE AND DEFAULT SIZE METHOD:

The aim of this study is to analyze the needs and gaps and other characteristics on knowledge of COPD in Spain sample representative of the population of our country by autonomous communities, sex, age strata (4 age groups) and habitat (rural: $\leq$10,000 and urban:>10,000 habitants).

3.a-Sample distribution

The basic criteria for distribution of the sample are the following:

- Proportional distribution of the population by sex
- Proportional distribution of the population aged 40 years and above according to age ranges (40-50 years, 51-60, 61-70, ≥71).
- Fixation (corrected) of the number of interviews by habitat strata (rural: ≤10,000 habitants and urban:>10,000 habitants) according to their distribution in the Spanish population (INE 2001).
- Distribution by sex, age ranges and habitat within each autonomous communities.
- The quotas by Autonomous Community are 384

3.b.-Selection of the sample and each sample unit:

La selección de la muestra se realize mediante marcación aleatoria de números de teléfonos fijos dentro de la Comunidad Autónoma correspondiente.

When dialing a telephone number there are several possibilities, namely:

- That the number does not correspond to a dwelling or home; in this case the phone is removed and marks another preselection substitute randomly swim by the computer (OTHERS).
- Let no one answer the phone: it automatically goes to a "pending" mailbox; the number will go up to four times (in different hours or days), if the result is the same (no contes ta) is removed from the sample and is recorded as uncontacted.
- Some household member rejects the interview; is counted as REJECTION.
- That there is an eligible individual (within quotas) but is absent: the phone goes to a "postponement" mailbox with the day / time that the interviewee will presumably be present at home.

3.c.-Sample default:

Previous Assumptions:

The calculation of the sample size to obtain an unbiased estimate of the distribution of the parameter in the population when the response variable is discrete (dichotomous) and assuming simple random sampling in each study area (geographic area), is based on the application of The following general formula:

$$n = \frac{Z^2_{1-a/2}\, P(1-P)}{d^2}$$

The final sample size will depend on the error ***e*** allowable estimate; of the associated random error: ***s,*** of the value of the real parameter in the population: ***m*** and of the confidence level of the estimate: ***a.***

For an error of the estimate of 4% and a confidence level of 95%, accepting (based on previous studies) 20% as the best estimator of the population parameter, replacing the values in the previous formula, the minimum number of subjects to study would be:

- **384 in each autonomous community**
  384 individuals x 17 geographical areas = **6528 individuals**

The global sample thus obtained would be representative for each of the autonomous community as well as for each age group.

Data collection
The questionnaire on respiratory symptoms and diagnosis of the survey was based on that of the European Commission of Steel and Coal (ECSC), a questionnaire that has been translated and validated[13], including questions on knowledge of COPD, the use of spirometry and perception of the seriousness of other chronic diseases, identical to that used in previous studies[8,9]. In addition, questions were included about alternative forms of tobacco. The complete questionnaire is attached as Appendix 1.
Spontaneous knowledge of COPD is assessed without any guidance from the interviewer. Those who spontaneously knew about COPD are asked to list the symptoms that are directly related to the disease. Suggested' knowledge of COPD is investigated in respondents who have no spontaneous knowledge of the disease. A high risk of COPD is defined as those subjects aged 55 years or older, with a cumulative tobacco use of at least 20 packets per year and chronic respiratory symptoms. Shortness of breath is assessed by the modified Medical Research Council (mMRC) scale and is considered significant dyspnoea with a score of at least 3 (when walking on a flat)[11].

The main variable is knowledge of COPD
The secondary variables are:

- Tobacco use and respiratory symptoms referred
- Consulte a physician and use of spirometry referred.
- The respiratory disorders referred
- Frequency of inhaled treatment and the difficulty in its use referred.

4. Statistical analysis

In the descriptive analysis, qualitative variables are presented with their frequency distribution; quantitative variables are summarized with their mean and standard deviation (SD) and quantitative variables showing an asymmetric distribution are summarized with the median and interquartile range (IQR). Comparisons are made between study groups. The association between qualitative variables is evaluated with the Chi-square test $\chi 2$ or Fisher's exact test, in the case that more than 25% of those expected were less than 5. For quantitative variables, means are compared using the Student t test or the analysis of variance ANOVA (if the groups have more than 2 categories) or the Mann-Whitney U test or the Kruskall Wallis test (if the groups have more than 2 categories) in case the quantitative variables did not fit a normal distribution. For all tests a significance value of 5% is accepted. Data processing and analysis is performed using the IBM SPSS Statistics v21 statistical package.

5. ETHICAL ASPECTS

This study will be carried out in accordance with the ethical principles underlying the latest version of the Helsinki Declaration accepted by local authorities and in line with Good Clinical Practice (GCP) and the requirements of the Spanish regulations in force.

All subjects included will be asked for oral consent. The study will be approved by the Ethics Committee of the San Carlos Clinical Hospital and will be carried out in accordance with the principles of the Helsinki Declaration and the new Organic Law 3/2018, on Personal Data Protection and guarantee of digital rights, in force since 7 December 2018.
Subjects shall also have the right to limit the processing of incorrect data, to request a copy or to transfer to a third party (portability) the data they have provided for the study, to the extent applicable.
The respondent must explain to each subject the nature of the study, its purposes, procedures, estimated duration and benefits related to participation in the study, as well as any inconvenience that the study may cause. Each participant should be advised that his or her participation in the study is voluntary and that he or she may leave the study at any time

6.-SURVEY

Good morning, I call you from a research cabinet. The Spanish Society of Pulmonology and Thoracic Surgery (SEPAR) is conducting a study on the health of the Spanish population.
Participation in this study is voluntary and all data collected is anonymous. The only drawback for you will be the trouble of answering a few short questions, it won't take you more than 10 minutes. Do you agree to participate and give us your consent to collect your answers in order to analyze them anonymously? Thank you very much

SOCIODEMOGRAPHIC DATA

Could you indicate…
S1.- How old are you? _____
< 40 years ***→Finish interview.***
- ☐ 40-50 years
- ☐ 51-60 years
- ☐ 61-70 years

>70 ☐ years

S2.- Sex *(write down without asking according to the name -if possible-)*:
Man ☐
☐ Woman

S3.- CCAA*:
- ☐ Andalucía
- ☐ Aragón
- ☐ Asturias
- ☐ C.Madrid
- ☐ Canarias
- ☐ Cantabria
- ☐ Castilla-La Mancha
- ☐ Castilla-León
- ☐ Cataluña
- ☐ Extremadura
- ☐ Galicia
- ☐ Islas Baleares
- ☐ La Rioja
- ☐ Navarra

* *If **you** do **not** indicate COPD in C3 respond to C4. If you indicate COPD in C3 go to C5.*

□ País Vasco
□ Valencia
□ R.Murcia

S4.- Hábitat*:
□ ≤10.000 habitants
□ >10.000 habitants

KNOWLEDGE - COPD DIAGNOSTIC

C1.- Could you indicate, on a scale of 0 (very bad) to 10 (very good), how do you consider your state of health? └┴┘

C2.- Do you currently have a respiratory illness?
□ Yes→*Go to C3.*
□ No →*Go to C4.*
□ Ns/Nc→*Go to C4.*

Spontaneous knowledge

C3.- Could you indicate which or which?? *(**Do not** read options)*
□ COPD (Chronic Obstructive Pulmonary Disease)
□ Asthma
□ Chronic bronchitis
□ Emphysema
□ Others

C4.- Do you know what COPD (Chronic Obstructive Pulmonary Disease) is?
□Yes →What are the main symptoms? (*Do not read*)
□ Morning cough
□ Bites in breathing
□ Expectoration
□ Drowning
□ Other
□No (*Go to C5*)

(Read) As you know, COPD is a chronic obstructive pulmonary disease that encompasses a set of pathologies such as chronic bronchitis and emphysema and is characterized by choking sensation, coughing, wheezing and fatigue caused by smoking.

C5.- Do you know the disease now? □ No □ Yes

C6.- throught which media did you hear about the disease?
□ Media (press, radio, TV)
□ Doctors
□ Pharmacist
□ Family member / acquaintance with it

*Consult **only** those that have **not** been mentioned in C3*.

C7.- Have you been diagnosed with any of the following diseases?

	Yes	No	Don't Know
COPD	□	□	□
Asthma	□	□	□
Chronic bronchitis	□	□	□

Emphysema □

*If **you** do **not** indicate COPD, chronic bronchitis or Emphysema in C3 **and** C7 go to E1.*

CHARACTERISTICS of COPD (all respondents)

P1.- Do you smoke?

□ Yes, Smoker P.1.1.1.- How many cigarettes do you smoke a day? _____

P.1.1.2.- How many years have you smoked? _____

P.1.1.3.- Have you tried to quit on occasion?

□ Yes → □P1.1.4.- How manytimes? _____

□ No

□ No, former smoker

P.1.2.2.- How many cigarettes did he smoke a day? _____

P.1.2.3.- How many years have you smoked? _____

□ No, you have never smoked

P2.- At least 2 years ago do you suffer from morning cough, more or less uninterruptedly, for more than 3 months a year?

□ Yes □ No

P3.- At least 2 years ago do you experience cough with expectoration (cough with sputum), more or less uninterruptedly, for more than 3 months a year?

□ Yes □ No

P4.- Do you have breath sounds or noises, more or less uninterruptedly, for more than three months a year?

□ Yes □ No

P5.- Do you feel conscious feeling of shortness of breath (difficulty taking air rather than expelling it)? *(Read options)*

□ No
□ When climbing a slope or two floors
□ When climbing a floor
□ When walking on level
□ At rest

*If you have indicated any of the following symptoms: Yes in P2, P3, P 4 or **not** indicated No in P5.*

P5.- Have you consulted your doctor about these problems? *(cite if necessary cough, cough with sputum and / or lack of air, as answered)*

□ No
□ Yes (specify):

With whom?

□ GP
□ Lung specialist

Have you ever had a spirometry (blowing through a device)?

□ No □ Yes

P6.- Have you ever had emergencies due to the worsening of these problems? *(cite if necessary cough, cough with sputum and / or lack of air, as answered)*

□ No
□ Yes (specify how many times in the last year):

P7 Do you treatment for respiratory symptoms?

□ No
□ Yes→T2. Specify treatment *(read options)*:
  □ Inhalers or Medications *If you have indicated any go to P 8E1*
  □ Oxygen

P.8 Would you be so kind as to indicate on a scale from 0 (not difficult) to 10 (very difficult) how you see the performance of your inhaled treatment?

COPD PERCEPTION

F1.- Could you indicate, on a scale of 0 (absence severity) to 10 (maximum severity), how do you consider COPD serious? _____

F2.- Would you be so kind as to indicate on a scale from 0 (absence severity) to 10 (maximum severity) how do you consider each of the following diseases?

Diabetes…… _____
Hypertension…… _____
Angina pectoris…… _____
Ulcer Stomach…… _____
Osteoarthritis-Arthritis…… _____

Thank you very much for your help.

5.-BUDGET

It is a scientific project in which no payment will be made to the researchers and their participation will be for the knowledge of what such a study can bring.

For the development of the study, a grant has been requested for research projects of the Spanish Society of Pneumology and Thoracic Surgery. This funding will be allocated for the conduct of the field survey by Saatchi Health and statistical analysis.

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