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Validation and reproducibility of the Could it be questionnaire for the diagnosis of chronic obstructive pulmonary disease

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Abstract:
Introduction:
Chronic obstructive pulmonary disease (COPD) is a frequently misdiagnosed pathology. The use of diagnostic questionnaires can be an alternative to deal with this problem; however, the validity of these instruments is not known locally.

Objectives:
Validate the Could it be COPD questionnaire for the diagnosis of COPD in the Colombian population.

Methods:
Prospective cohort study with analysis of diagnostic test and reliability, in a sample of patients over 40 years of age who attended the pulmonary function laboratory of a hospital care center to whom the Could it be COPD questionnaire was applied and spirometry and pre and post B2 flow/volume curve were performed. COPD criteria were considered according to the American Thoracic Society.

Results:
1276 subjects were analyzed and 17.9% (228/1276) had a diagnosis of COPD. In the general population, the average age was 65.7 years (SD: 12.12), 46.5% (590/1276) male and 46.2% (587/1276) had a smoking history. A cut-off point of 3 of the Could it be COPD questionnaire showed a sensitivity of 55.26% (95% CI: 48.9 - 62.2%) with a specificity of 67.74% (95% CI: 65.0 - 70.7 %). The AUROC of the Could it be COPD was 0.642 (95% CI: 0.603 - 0.679%) (p< 0.001).

KEYWORDS

COPD.
Could it be.
Questionnaire.
Validation.
Reproducibility.

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Conclusions:
The Could it be COPD questionnaire has good reproducibility and regular validity for the identification of individuals with COPD. It is considered necessary to carry out other validation studies with other available tools.

PALABRAS CLAVE

EPOC.
Could it be COPD.
Cuestionario.
Validación.
Reproducibilidad.

Validación y reproducibilidad del cuestionario Could it be para el diagnóstico de enfermedad pulmonar obstructiva crónica

Resumen:
Introducción:
La enfermedad pulmonar obstructiva crónica (EPOC) es una patología frecuentemente mal diagnosticada. El uso de cuestionarios de diagnóstico puede ser una alternativa para afrontar este problema. Sin embargo, la validez de estos instrumentos no se conoce localmente.

Objetivos:
Validar el cuestionario Could it be COPD para el diagnóstico de EPOC en la población colombiana.

Métodos:
Estudio de cohorte prospectivo con análisis de prueba diagnóstica y confiabilidad, en una muestra de pacientes mayores de 40 años que acudieron al laboratorio de función pulmonar de un centro de atención hospitalaria a quienes se les aplicó el cuestionario Could it be COPD y espirometría y pre y post. Se realizaron curvas flujo/volumen B2. Se consideraron los criterios de EPOC según la American Thoracic Society.

Resultados:
Se analizaron 1276 sujetos y el 17,9% (228/1276) tenía diagnóstico de EPOC. En la población general, la edad promedio fue de 65,7 años (DE: 12,12), el 46,5% (590/1276) eran hombres y el 46,2% (587/1276) tenían antecedentes de tabaquismo. Un punto de corte de 3 del cuestionario Could it be COPD mostró una sensibilidad del 55,26% (IC 95%: 48,9 - 62,2%) con una especificidad del 67,74% (IC 95%: 65,0 - 70,7%). El AUROC del Could it be COPD fue de 0,642 (IC 95%: 0,603 - 0,679%) (p< 0,001).

Conclusiones:
El cuestionario Could it be COPD tiene buena reproducibilidad y validez regular para la identificación de personas con EPOC. Se considera necesario realizar otros estudios de validación con otras herramientas disponibles.

GILTZA-HITZAK

BGBK.
Izan liteke BGBK - galdetegia.
Balidazioa.
Erreproduzigarritasuna.

Biriketako gaixotasun buxatzaile kronikoa diagnostikatzeko Could it be galdetegia baliozkotzea eta erreproduzitzea

Laburpena:
Sarrera:
Biriketako gaixotasun buxatzaile kronikoa (BGBK) gaizki diagnostikatutako patologia bat da. Diagnostiko-galdetegiak erabiltzea alternatiba bat izan daiteke arazo horri aurre egiteko. Hala ere, tresna horien baliozkotasuna ez da lokalki ezagutzen.

Helburuak:
Could it be COPD galdetegia baliozkotzea, Kolonbiako biztanlerian BGBK diagnostikatzeko.

Metodoak:
Kohorte prospektiboaren azterketa, proba diagnostikoaren eta fidagarritasunaren analisiekin, ospitale-arretako zentro bateko birika-funtzioko laborategira joan ziren 40 urtetik gorako pazienteen lagin batean. Paziente horiei Could it be COPD galdetegia eta espirometria eta aurre eta post galdetegia aplikatu zitzaizkien. B2 fluxu-bolumen kurbak egin ziren. BGBKren irizpideak kontuan hartu ziren, American Thoracic Society-ren arabera.

Emaitzak:
1276 subjektu aztertu ziren, eta % 17,9k (228/1276) BGBK diagnostikoa zuen. Biztanleria orokorrean, batez besteko adina 65,7 urtekoa izan zen (DE: 12,12), % 46,5 (590/1276) gizonezkoak ziren eta % 46,2k (587/1276) tabakismo-aurrekariak zituzten. Could it be COPD galdetegiko 3 puntuko ebakidura-puntu batek % 55,26ko sentikortasuna erakutsi zuen (KT % 95:48,9 - % 62,2), % 67,74ko espezifikotasunarekin (KT % 95:65,0 - % 70,7). Could it be COPDaren AUROCa 0,642 izan zen (IC % 95: 0,603 - % 0,679) ($p < 0,001$).

Ondorioak:
Could it be COPD galdetegiak erreproduzigarritasun ona du eta BGBK duten pertsonak identifikatzeko balio erregularra. Beharrezkotzat jotzen da beste balidazio-azterlan batzuk egitea eskura dauden beste tresna batzuekin.

Introduction

Chronic obstructive pulmonary disease (COPD) is a preventable and treatable disease characterized by the presence of respiratory symptoms and persistent airflow limitation, generally caused by significant exposure to noxious particles or gases[1,2]. COPD is one of the main causes of morbidity and mortality, the worldwide prevalence ranges from 8% to 10% of individuals older than 40 years 3,4 . Although it is a disease with a high prevalence, more than 50% of subjects with COPD are not diagnosed, generating bad outcomes and high costs in their medical care[1,3].

Efforts to increase the diagnosis of COPD have focused on the use of initial detection tools such as portable spirometers, peak flow meters and standardized questionnaires, either alone or in combination, being able to identify people at high risk before performing a diagnostic spirometry[5,6,7]. However, the use of diagnostic tools other than spirometry should be validated to assess the accuracy of these clinical strategies, where standardized questionnaires could be an effective method to detect COPD cases[5-7].

Among the different questionnaires is the Could it be COPD, which consists of five questions based on the review of the clinical characteristics and risk factors for the disease 8. Their original validation was performed through a retrospective analysis of the Third National Health and Nutrition Examination Survey data set, where they found a sensitivity of 85%, specificity of 45%, a positive predictive value (PPV) of 38%. and a negative predictive value (NPV) of 88% 9. It is important to generate a great impact in the reduction of undiagnosed COPD, making it necessary to validate the clinical questionnaires in the population of other countries 6,8,9. The objective of this study is to validate the Could it be COPD questionnaire for the diagnosis of COPD in the Colombian population.

Methods

A prospective cohort study was carried out, with analysis of reliability and validity of the diagnostic test in a population of subjects who attended the outpatient service for pre and post B2 flow-volume curve spirometry in the pulmonary function laboratory of the Clínica Universidad de La Sabana (Chía, Colombia), during the period from October 2018 to May 2020.

Elegibility criteria

Subjects older than 40 years with good quality spirometry and who had time to complete the questionnaire were included. Subjects who did not agree to participate in the study, individuals with any physical or mental condition that would limit the completion of the questionnaire or spirometry were excluded. The COPD criterion was considered as a FEV1/FVC ratio < 0.7 post B2 according to American Thoracic Society [10].

Variables

Initially, information was collected on age, sex, presence of respiratory symptoms, smoking history, exposure to wood smoke, and COPD or asthma history. In subjects who underwent spirometry, weight, height, Forced Vital Capacity (FVC), Forced Expiratory Volume in the First Second (FEV1) and the FEV1/FVC ratio were evaluated. Finally, the Could it be COPD questionnaire was applied. The subjects were summoned to a second medical appointment in the outpatient clinic to perform the questionnaire again, thus analyzing the reproducibility.

The Could it be COPD questionnaire in the Spanish ver-

sion consists of five questions: Do you cough several times most days? Do you bring up phlegm or mucus most days? Do you get out of breath more easily than others your age? Are you older than 40 years? Are you a current smoker or an ex-smoker? Each question is given a score of 1 and a value equal to or greater than 3 is considered a risk of presenting the disease.

Sample size

To calculate the sample size, data from the Calverley et al. study were used, where a minimum of 737 subjects were required, for a confidence interval of 95% and precision of 5% in a diagnostic test study[11].

Statistical analysis

The data was obtained through an electronic form that automatically recorded them in an Excel database for subsequent verification of their values by the researchers. To search for transcription errors and their correction, the database was subsequently analyzed using the SPSS 25 statistical program.The qualitative variables were summarized in frequency and percentages, if the distribution was normal, the quantitative variables in means and standard deviation. Subsequently, sensitivity, False Positives (FP), specificity, False Negatives (FN), PPV, NPV, Positive Likelihood Ratio (LR+), Negative Likelihood Ratio (LR-), Number Needed to Diagnose (NND), Number Needed to Misdiagnose (NNDM), Youden index and Area Under the Receiver Operating Characteristic Curve (AUROC), with their respective 95% confidence intervals, were calculated. Significant $p < 0.05$ was considered.

An AUROC of 0.5 was considered an absence of discriminatory ability, 0.51 to 0.60 almost zero discriminatory ability, 0.61 to 0.69 fair, 0.7 to 0.8 acceptable, 0.8 to 0.9 excellent, and greater than 0.9 outstanding. In the Intraclass Correlation Coefficient (ICC), it is considered a low correlation <0.30, regular 0.30 to 0.50, moderate 0.50 to 0.70, good 0.70 to 0.90 and very good >0.90[12].

Ethical considerations

The research protocol follows the international ethical guidelines of the Declaration of Helsinki, the national ethical considerations of resolution 8430 of 1993 and the data protection law 1581. Additionally, research protocol was presented and approved by the research subcommittee of the Faculty of Medicine of the Universidad de La Sabana and by the ethics committee of the Clínica Universidad de La Sabana.

Results

1276 subjects were analyzed and 17.9% (228/1276) had a diagnosis of COPD figure 1. In the general population, the average age was 65.7 years (SD: 12.12), 46.5% (590/1276) male and 46.2% (587/1276) had a smoking history. **Table I** describes the general characteristics of the population.

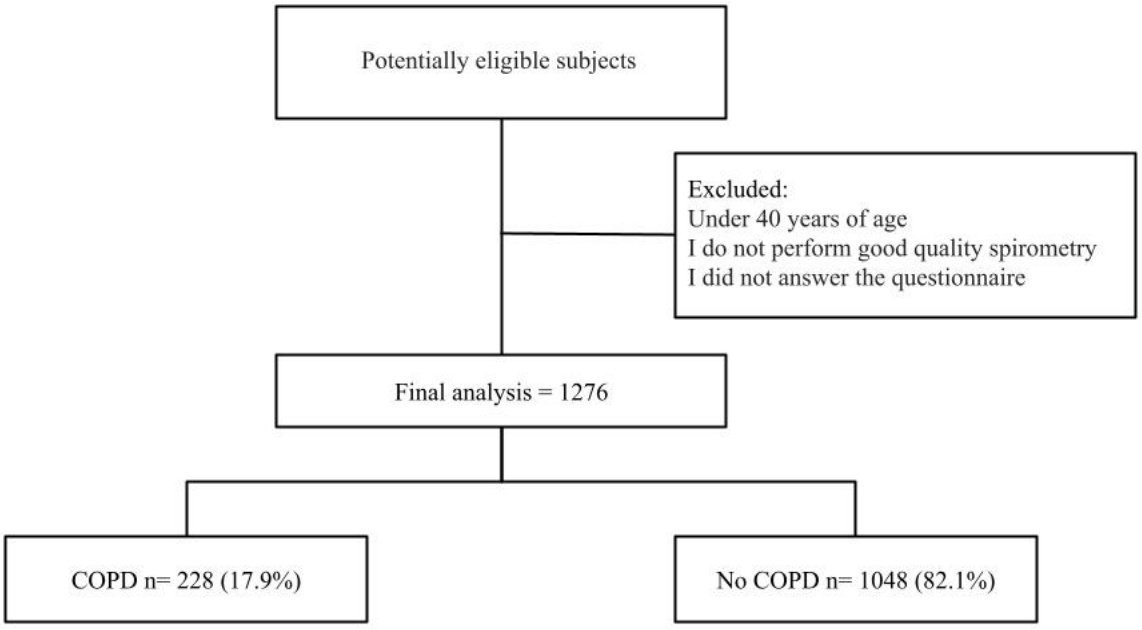

Figure 1. Flow chart of the study population.

Notes: COPD: Chronic obstructive pulmonary disease.

Table I
Baseline characteristics of the study population

	Total population n=1276	COPD n=228	No COPD n=1048	p-value
Age, years x (SD)	65.7 (12.12)	71.6 (11.41)	64.4 (11.91)	<0.001
Male n (%)	590 (46.5)	139 (61.0)	451 (43.3)	<0.001
Respiratory symptoms n(%)	1030 (81.6)	203 (89.2)	827 (79.0)	<0.001
Age onset of symptoms x (de)	58 (16.13)	60 (17.98)	58 (15.23)	0.016
Wheezing (%)	366 (29.07)	99 (43.3)	267 (25.0)	<0.001
Smoking n (%)	587 (46.2)	120 (53.7)	467 (45.3)	0.027
IPY x (de)	15 (24.74)	21 (28.91)	13 (23.35)	<0.001
Passive smoker n (%)	202 (16.2)	36 (16.6)	166 (16.8)	0.923
Years of exposure x (de)	26 (17.32)	14 (14.44)	21 (15.76)	<0.001
Wood smoke exposure n (%)	779 (61.0)	159 (70.0)	620 (59.5)	0.003
Years of exposure x (de)	21 (4.67)	25 (4.72)	21 (4.63)	0.002
History of atopy n (%)	366 (29.2)	99 (43.9)	267 (25.4)	<0.001
Previous diagnosis of COPD n (%)	279 (22.7)	114 (50.1)	165 (16.9)	<0.001
Previous diagnosis of Asthma n (%)	144 (11.4)	40 (18.3)	104 (10.0)	0.001

Notes: COPD, chronic obstructive pulmonary disease; x, average; SD, standard deviation; n, number ; IPY, index packages year.

Table II
Lung function

	Total population n=1276	COPD n=228	No COPD n=1048	p-value
Weight kg x(SD)	70.83 (13.60)	69.44 (13.91)	71.14 (13.52)	0.087
Size cm x(SD)	159.72 (9.59)	160.43 (9.08)	159.57 (9.70)	0.218
FCV preB2 L x(SD)	3.06 (0.98)	2.71 (0.92)	3.14 (0.98)	<0.001
FCV postB2 L x(SD)	3.14 (0.96)	2.93 (0.97)	3.19 (0.95)	<0.001
FEV1 preB2 L x(SD)	2.33 (0.82)	1.59 (0.63)	2.48 (0.60)	<0.001
FEV1 postB2 L x(SD)	2.45 (0.84)	1.77 (0.65)	2.59 (0.80)	<0.001
FEV1 % Cambio x(SD)	6.92 (9.04)	13.70 (14.05)	5.50 (6.79)	<0.001
FEV1/FCV preB L x(SD)	75 (11.35)	58.46 (9.72)	79.01 (7.89)	<0.001
FEV1/FCV postB2 L x(SD)	78 (10.10)	60.07 (8.28)	81.23 (5.54)	<0.001

Notes: COPD, chronic obstructive pulmonary disease; x, average; SD, standard deviation; kg, kilograms; cm, centimeters; L, liters; FVC, forced vital capacity; FEV1, forced expiratory volume in the first second; FEV1/FVC, ratio forced vital capacity and forced expiratory volume in the first second.

Subjects with a diagnosis of COPD presented an average pre B2 FVC of 2.71 liters (SD: 0.92) and an average post B2 FEV1/FVC of 60.07 liters (SD: 8.28), in subjects without COPD the average post B2 FEV1/FVC of 81.23 liters (SD: 5.54) **table II**. The characteristics of the questionnaire in the study population are described in **table III**.

Validity analysis of the Could it be COPD questionnaire

A cut-off point of 3 of the Could it be COPD questionnaire showed a sensitivity of 55.26% (95% CI: 48.9 - 62.2%) with a specificity of 67.74% (95% CI: 65.0 - 70.7 %), a PPV of 27.8% (95% CI: 23.6 - 31.9%), NPV of 87.3% (95% CI: 84.9 - 89.9%) and LR+ 1.73% (95% CI: 1.50% - 2.0%) , LR- 0.65% (95% CI: 0.65 The AUROC of the Could it be COPD was 0.642 (95% CI: 0.603 - 0.679%) (p< 0.001) **figure 2**. The reproducibility of the questions showed agreement with a Kappa of 0.356 (95% CI: 0.21 - 0.502), 0.549 (95% CI: 0.412 - 0.687), 0.469 (95% CI: 0.339 - 0.599), 0.671 (95% CI: 0.511 - 0.831) and 0.866 (95% CI: 0.791-0.942), respectively for each question, with a p<0.001 and a Cronbach's Alpha 0.71.- 0.76%) **table IV**.

Table III

Could it be COPD questionnaire.

	Total population n=1276	COPD n=228	No COPD n=1048	p-value
Do you cough several times most days? n (%)	366 (29.0)	85 (37.0)	281 (27.0)	0.002
Do you bring up phlegm or mucus most days? n (%)	281 (22.0)	71 (31.0)	210 (20.0)	<0.001
Do you get out of breath more easily than others your age? n (%)	395 (31.0)	123 (54.0)	272 (26.0)	<0.001
Are you older than 40 years? n (%)	1260 (99.0)	226 (99.0)	1034 (99.0)	0.573
Are you a current smoker or an ex-smoker? n (%)	581 (46.0)	121 (53.0)	460 (44.0)	0.012
Could it be COPD Score x(SD)	2.26 (1.09)	2.75 (1.12)	2.15 (1.06)	<0.001
Could it be COPD score >3 points n (%)	464 (36.0)	126 (55.0)	338 (45.0)	<0.001
Could it be COPD score <3 points puntos n (%)	812 (64.0)	102 (45.0)	710 (68.0)	<0.001

Notes:chronic obstructive pulmonary disease; x, average; SD, standard deviation; n, number.

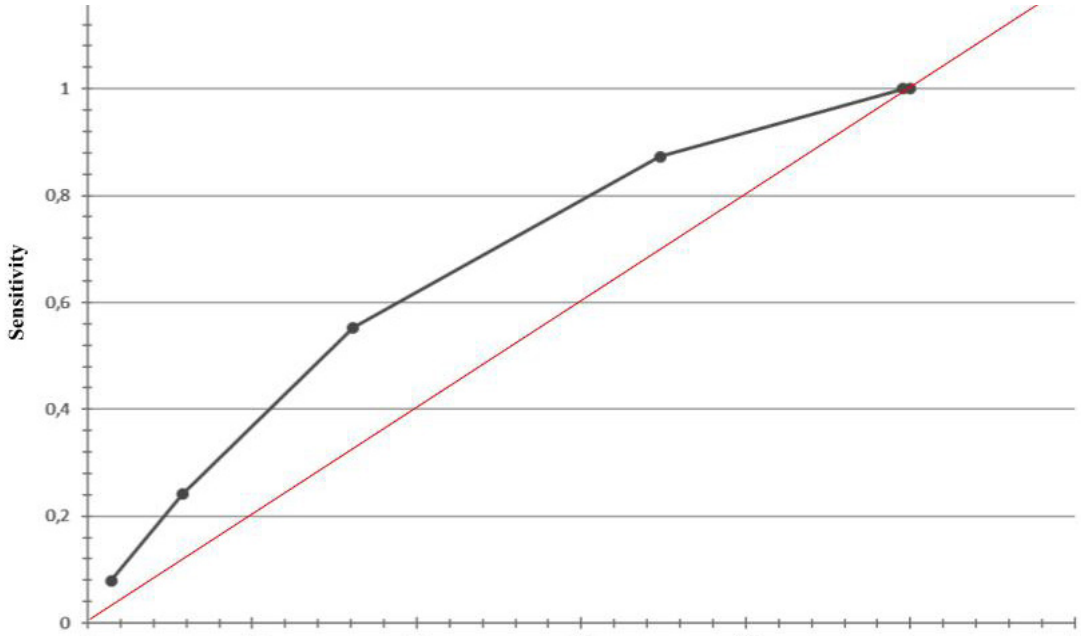

Figure 2. Area under the receiver operating characteristic curve of the Could it be COPD

Table IV
Could it be COPD questionnaire performance by score

Score	COPD	No COPD	S	PF	E	FN	PPV	PNV	LR+	LR-	NND	NNDM	YI
0	0	9	100%	100%	0,00%	0,00%	12,2	0	1	0	0	1	0,01
1	29	310	100%	99,14%	0,85%	0,00%	18,90	93,6	1	0	116,64	1,08	0,08
2	73	391	87,28%	69,56%	30,43%	12,79%	21,1	92,4	1,25	0,41	5,64	1,21	0,17
3	71	217	55,26%	32,25%	67,74%	44,70%	31,5	87,3	1,73	0,65	4,34	1,29	0,23
4	37	91	24,12%	11,54%	88,45%	75,94%	31,5	64,1	2,08	0,85	7,95	1,14	0,12
5	18	30	7,89%	2,86%	97,13%	92,13%	38,7	83,8	2,75	0,92	19,87	1,05	0,05
Total:	228	1048											

Notes: COPD, chronic obstructive pulmonary disease; S, Sensitivity; FP, False Positives; E, Specificity; FN, False Negatives; PPV, Positive Predictive Value; NPV, Negative Predictive Value; LR, Likelihood ratio; NND, number needed to diagnose; NNDM, Number Needed to Misdiagnose; YI, Youden Index.

Discussion

This study evaluated the performance of the Could it be COPD questionnaire for the diagnosis of COPD, whose diagnostic validity showed a regular performance for a diagnostic test. All the questions in the questionnaire had significant responses in their different options to distinguish the disease. Respiratory symptoms and a smoking history were more frequent in the COPD population.

Calverley et al.[11] determined whether symptoms and medical history can identify subjects at higher risk of COPD using the Could it be COPD questionnaire. The diagnostic performance presented a sensitization of 77% to 86%, a specificity between 40% to 63%, a PPV had a range of 33% to 42% and the FP rate varied from 58% to 67%, values regardless of age and smoking history. In our cohort, lower sensitivity and specificity were described, probably due to the heterogeneity of the respiratory pathologies in the population in contrast to that described by Calverle, where only subjects with a smoking history and risk factors for the development of COPD were analyzed.

In the population without risk factors, without respiratory symptoms or initial stages of the disease, the usefulness of the use of questionnaires for the detection of COPD is reduced 6,13. Rokach et al.14 evaluated the performance of the Could it be COPD questionnaire together with other demographic variables in 1001 smokers and ex-smokers; 18% (180/1001) presented airflow obstruction. The multiple logistic regression analysis described good discrimination capacity for age, body mass index, and questionnaire score ≥3 points with an AUROC of 0.763, similar data described in our population, which included subjects with and without risk factors.

The daily variability of symptoms in COPD can be related to its severity, adherence to treatment, and exposure to external agents or environmental conditions, the most variable symptoms being dyspnea, cough, and expectoration[15]. In this study, variability was described with the first three questions of the Could it be COPD questionnaire, which were related to respiratory symptoms such as cough, expectoration, and dyspnea.

Underdiagnosed subjects may have symptoms and risk factors where simple questionnaires can be useful to define the spirometric study 6,16. However, we found a percentage of underdiagnosis of 49% with a sensitivity of 42% and a specificity of 73%, values that can eventually be exceeded by other available tools such as LFQ, CDQ, COPD-PS or PUMA questionnaires 16,17. Early detection of under-diagnosed patients can reduce care costs in COPD management and it has been considered that reducing under-diagnosis can improve patient care and quality of life[18].

Limitations

Single-center study that limits external validation of its results. However, the number of subjects analyzed is adequate to support the results.

The prevalence of COPD in the patients included in our study was slightly lower than that reported in the PUMA study for Colombia (17.9% vs. 20.1%) 19,20, and the PPV and NPV of the diagnostic test can be affected. More studies are needed to validate this questionnaire for the diagnosis of COPD.

Conclusion

The Could it be COPD questionnaire has good reproducibility and regular validity for the identification of individuals with COPD. It is considered necessary to carry out other validation studies with other available tools.

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