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SHORT REPORT

Over diagnosis of chronic obstructive pulmonary disease in an underserved patient population

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Introduction: While cross-national studies have documented rates of chronic obstructive pulmonary disease (COPD) misdiagnosis among patients in primary care, US studies are scarce. Studies investigating diagnosis among uninsured patients are lacking.

Objective: The purpose of this study is to identify patients who are over diagnosed and thus, mistreated, for COPD in a federally qualified health center.

Methods: A descriptive study was conducted for a retrospective cohort from February 2011 to June 2012. Spirometry was performed by trained personnel following American Thoracic Society recommendations. Patients were referred for spirometry to confirm previous COPD diagnosis or to assess uncontrolled COPD symptoms. Airway obstruction was defined as a forced expiratory volume in the first second of expiration (FEV_1) to forced vital capacity ratio less than 0.7. Reversibility was defined as a postbronchodilator increase in FEV_1 greater than 200 mL and greater than 12%.

Results: Eighty patients treated for a previous diagnosis of COPD (n = 72) or on anticholinergic inhalers (n = 8) with no COPD diagnosis were evaluated. The average age was 52.9 years; 71% were uninsured. Only 17.5% (14/80) of patients reported previous spirometry. Spirometry revealed that 42.5% had no obstruction, 22.5% had reversible obstruction, and 35% had nonreversible obstruction.

Conclusion: Symptoms and smoking history are insufficient to diagnose COPD. Prevalence of COPD over diagnosis among uninsured patient populations may be higher than previously reported. Confirming previous COPD diagnosis with spirometry is essential to avoid unnecessary and potentially harmful treatment.

Keywords: chronic obstructive pulmonary disease, COPD, misdiagnosis, over diagnosis, spirometry, uninsured, underserved

Introduction

Chronic obstructive pulmonary disease (COPD) is a common, preventable, and treatable disease characterized by progressive airflow limitation. Associated with airway chronic inflammatory response and by lung noxiousness to particles or gases, COPD is the third leading cause of death in the US and has an estimated worldwide prevalence of 10% in people over 40 years.[1] The annual cost of treatment per COPD patient in the US is $4,119 (USD); additionally, indirect nonmedical care costs of $1,527 (USD) per patient are known.[2] While other leading causes of death in the US have declined steadily, COPD death rates have doubled since 1970.[3]

COPD disproportionately afflicts those of lower socioeconomic status and older adults, creating reluctance to diagnose and treat patients.[4] The Global Initiative for

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Chronic Obstructive Lung Disease report in 2011, emphasizing the significance of this disease, confirmed that spirometry is a requirement for COPD case definition.[5]

Spirometry has the distinct advantage of being a reproducible measurement of lung function that is superior to peak expiratory flow because of greater reliability and specificity.[6] Symptom based and clinical diagnosis contributes to misdiagnosis and mistreatment.[7,8] Additionally, spirometry can distinguish between asthma and COPD.[9]

Only one US study has investigated the prevalence of COPD misdiagnosis with spirometry.[10] However, generalizability of this study was limited: patients were gathered from primary care practices in Colorado and Scotland.[10] Studies investigating COPD diagnosis among the uninsured are absent. The purpose of this study is to evaluate clinically diagnosed COPD patients with spirometry to ascertain COPD misdiagnosis in an underserved population.

Methods

A descriptive study was conducted at a federally qualified health center following institutional review board approval. The retrospective cohort from February 2011 to June 2012 included all patients who were referred by primary care providers for spirometry testing available at the health center to confirm a previous COPD diagnosis or for better management of uncontrolled COPD symptoms. Spirometry was done according to procedures recommended by the American Thoracic Society using the Burdick SpiroCard® (Cardiac Science, Hannover, Germany).[11] Spirometry for each patient was performed by personnel who had undergone training on how to use the spirometry program. Personnel were also trained on device calibration, as well as recording all procedure relevant data. A series of questions was asked to the patients to identify contraindications for spirometry testing. Patients with acute respiratory illness were rescheduled after infection resolution and symptom improvement. All referred patients did not use a short acting beta agonist within 6 hours, a long acting beta agonist within 12 hours, ipratropium within 6 hours, tiotropium within 24 hours, or theophylline within 24 hours of the test. A forced expiratory volume in the first second of expiration to forced vital capacity (FEV_1/FVC) ratio above or equal to 0.7 was designated as no obstruction.[5] FEV_1/FVC ratio below 0.7 required further evaluation with postbronchodilator testing.

For postbronchodilator testing, 400 µg of beta2 agonist (albuterol) with a spacer was administered. Following the administration of the beta2 agonist and a 15 minute waiting period, postbronchodilator spirometry values

were reassessed. Increased $FEV_1 > 12\%$ and >200 mL when compared with baseline confirmed reversibility.[12]

Patients were categorized as either no obstruction, reversible obstruction, or nonreversible obstruction. Differences by age and pack year history for each group were assessed using analysis of variance and tabulation of mean and standard deviation. Statistical significance was assumed at $P \leq 0.05$.

Results

Eighty patients were referred for spirometry testing. Out of the 80 patients referred, 72 had a previous diagnosis of COPD (72 out of 444 patients at the clinic) and eight were on anticholinergic inhalers but had no previous COPD diagnosis (eight out of 51 patients at the clinic). The average age was 52.9 ± 7.7 years. The majority of patients were self-pay patients (71.3%), Caucasians (88.8%), and females (60%). Across all patients, average pack years was 37.9 ± 26.1. Five patients in this study never smoked, three had previous COPD diagnosis, and two were on anticholinergic inhalers but had no previous COPD diagnosis. All five patients had spirometry results consistent with no obstruction. In the group of patients with previous COPD diagnosis, three patients claimed that COPD diagnosis was made prior to the age of 35 years. Spirometry results showed no obstruction for two of those patients and reversible obstruction for the third patient. Additionally, in the group of patients with previous COPD diagnosis, 18 patients did not remember when they were first diagnosed with COPD, and only 14 patients remembered having spirometry or pulmonary function testing. Table 1 includes all characteristics of patients referred for spirometry.

Spirometry revealed 34 patients (42.5%) with no obstruction, 18 patients (22.5%) with reversible obstruction, and 28 patients (35%) with nonreversible obstruction (Figure 1). Younger patients ($P = 0.004$) and patients who had fewer pack years of exposure ($P = 0.013$) were more likely to be in the no obstruction group. Patients in the nonreversible obstruction group were more likely to be older and had 1.7 times more tobacco exposure.

Discussion

Spirometry confirms COPD diagnosis in the primary care setting.[13–15] However, a Vermont survey found that only 66% of primary care respondents owned a spirometer and that spirometry was only performed on half of COPD patients.[16] In our study, only 14 patients (17.5%) reported a previous spirometry or pulmonary function testing. When spirometry

Table 1 Characteristics of patients referred for spirometry

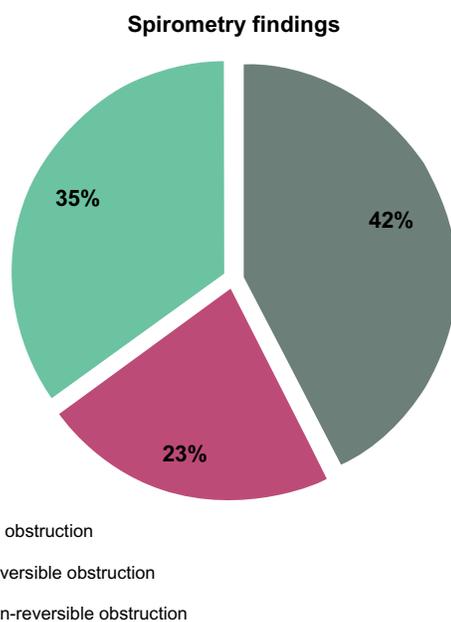| Characteristics	All patients (n = 80)	Spirometry results		
		No obstruction (n = 34)	Reversible obstruction (n = 18)	Nonreversible obstruction (n = 28)
Age, years (mean ± standard deviation)	52.9 ± 7.7	50.5 ± 7.9	51.7 ± 6.9	56.7 ± 6.8
Male (n, %)	32 (40.0)	12 (35.3)	10 (55.6)	10 (35.7)
Insurance status (n, %)				
Self-pay	57 (71.3)	22 (64.7)	17 (94.4)	18 (64.3)
Medicaid	12 (15.0)	7 (20.6)	1 (5.6)	4 (14.3)
Private insurance	1 (1.3)	0 (0.0)	0 (0.0)	1 (3.6)
Medicare	10 (12.5)	5 (14.7)	0 (0.0)	5 (17.9)
Race (n, %)				
Caucasian	71 (88.8)	29 (85.3)	17 (94.4)	25 (89.3)
African American	8 (10.0)	5 (14.7)	1 (5.6)	2 (7.1)
Native American	1 (1.3)	0 (0.0)	0 (0.0)	1 (3.6)
Smoking history (pack years ± standard deviation)	37.9 ± 26.1	28.3 ± 21.7	42.2 ± 23.0	46.8 ± 29.5
Inhalers (n, %)				
LABA and ICS	46 (57.5)	17 (50.0)	12 (66.7)	17 (60.7)
LABA	5 (6.3)	2 (5.9)	1 (5.6)	2 (7.1)
Beta2 agonist	73 (91.3)	30 (88.2)	18 (100.0)	25 (89.3)
Anticholinergic and beta2 agonist	11 (13.8)	5 (14.7)	2 (11.1)	4 (14.3)
Anticholinergic (short)	5 (6.3)	3 (8.8)	1 (5.6)	1 (3.6)
Anticholinergic (long)	44 (55.0)	19 (55.9)	9 (50.0)	16 (57.1)
Any anticholinergic inhalers	55 (68.8)	26 (76.5)	10 (55.6)	19 (67.9)
Any inhaler	80 (100.0)	34 (100.0)	18 (100.0)	28 (100.0)

Abbreviations: ICS, inhaled corticosteroids; LABA, long acting beta2 agonist.

is not used, practitioners use smoking history and clinical features for COPD diagnosis which lacks sensitivity.[17] Additionally, spirometry differentiates between asthma and COPD which have different therapy goals and treatment plans. Reliance on nonspecific symptoms of dyspnea, cough,

Spirometry findings

35%
42%
23%

- No obstruction
- Reversible obstruction
- Non-reversible obstruction

Figure 1 Spirometry findings of patients with previous chronic obstructive pulmonary disease or anticholinergic inhalers (n = 80).

and wheezing has resulted in health practitioners responding to two physiologically different diseases in the same manner.[5,18,19] Inappropriate diagnosis leads to inappropriate symptom management and ignorance of underlying etiology. Unnecessary medications, poor management, and side effects associated with inappropriate medications increase the overall cost while potentially harming the patient. Known side effects associated with medications used by these patients may include angioedema, anaphylaxis, bronchospasm, arrhythmia, glaucoma, and adrenal suppression.[20]

The presence of over diagnosis in the current series of COPD patients – 42.5% – is consistent with reports outside of the US. International studies have examined the prevalence of COPD misdiagnosis due to lack of spirometry. COPD misdiagnosis was 31% in Australia,[7] 28.6% in Belgium,[9] 25.8% in Norway,[21] 27.2% in the UK,[22] and 49.8% in Greece.[23] One study which combined patients from Colorado and Scotland documented a 51.6% COPD misdiagnosis (Table 2).[10]

Studies vary in their definition of reversible obstructions. Due to literature inconsistency and discrepant guidelines, we decided to only consider results that showed no obstruction ($FEV_1/FVC \geq 0.7$) as a clear COPD misdiagnosis. Although being diagnosed with or treated for COPD, 42.5% of our patients showed no obstruction on spirometry. Given that some of the patients who had reversible obstruction could

Table 2 Comparison of studies that highlighted the magnitude of chronic obstructive pulmonary disease over diagnosis

Author	Year	Country	Sample size	Setting	Rate of COPD over diagnosis	Variables associated with COPD over diagnosis
Walters et al[7]	2011	Australia	341	Ambulatory practices	31%	Higher BMI and self-reported allergic rhinitis or hay fever
Buffels et al[9]	2012	Belgium	312	Family medicine teaching practices	28.6%	Not done
Melbye et al[21]	2011	Norway	376	General office practices	25.8%	Not reported
Jones et al[22]	2008	United Kingdom	580	Primary care practices	27.2%	Not reported
Sichletidis et al[23]	2007	Greece	319	Primary care centers	49.8%	Not done
Tinkelman et al[10]	2006	Scotland-US	597	Primary care centers	51.6%	Not reported
Ghattas et al	2013	US	80	Primary care practice	42.5%	Not reported

Abbreviations: BMI, body mass index; COPD, chronic obstructive pulmonary disease.

have asthma and not COPD, prevalence of COPD misdiagnosis could be higher in this series. Since the only study performed in the US included patients from Scotland and Colorado,[10] the prevalence of COPD misdiagnosis in the US remains unclear. Additionally, our results may be more representative of uninsured and underserved patients.

Lower European COPD misdiagnosis could be linked to emphasis on spirometry in ambulatory settings.[18] Low utilization of spirometry in the US may be attributed to factors such as unawareness of the value of spirometry, lack of access, busy settings, and lack of device training.[16] Another major challenge is provider perception of test uncertainty and the inability to interpret spirometry data.[24] Incorporating training seminars to educate health professionals has shown promise, increasing spirometry use by 59% in a 3 month period following training.[16]

This study is the first to examine COPD misdiagnosis and prevalence of spirometry in a group of solely American patients. Study limitations include patient recall bias and data entry errors in the medical record. The current series was only referred for spirometry based on the individual provider's preferences to manage uncontrolled COPD or to confirm previously diagnosed COPD. Therefore, current data may not be representative and should be viewed as a pilot investigation to assess COPD in an underserved population. However, current data suggest that there is a problem with COPD over diagnosis in the underserved population and that problem could be significant due to the lack of resources. The underserved population may have more risk for fragmented care and lack of access to health care resources which could

make them more vulnerable to such issues. More research in this area is needed, especially in the underserved population. Justification of offering free or discounted spirometry service could be explored based on anticipated cost avoidance of misdiagnosed COPD cases.

Conclusion
Symptoms and smoking history are insufficient to diagnose COPD. Prevalence of COPD over diagnosis in uninsured patient populations may be higher than previously reported. Confirming COPD diagnosis with spirometry is essential to avoid unnecessary and potentially harmful over treatment.

Disclosure
The authors report no conflicts of interest in this work

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