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RESEARCH LETTER

Diagnostic Inaccuracies in COPD: Misdiagnosis, Race and Gender Disparities

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Introduction

COPD is a respiratory condition that is highly prevalent and suspected in the presence of clinical symptoms, such as dyspnea, cough with sputum production, exercise limitation, wheezing, and progressive respiratory failure.[1] A diagnosis of COPD requires confirmation through spirometry, as recommended by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, with FEV_1/FVC ratio of less than 0.70 or below the lower limit of normal required for definitive diagnosis.[1]

Despite current GOLD guidelines, some clinicians rely on clinical history and physical examination alone to make the diagnosis, forgoing spirometry. Many factors contribute to this practice amongst clinicians, including a perception that spirometry is time-consuming, complicated, and burdensome. This reliance on clinical judgment alone leads to a lack of confirmatory pulmonary function testing (PFT) amongst patients displaying symptoms that could be consistent with a diagnosis of COPD. As a result, patients may experience a delay in accurate diagnosis, or failure to diagnose COPD entirely (underdiagnosis).

Inaccurate diagnosis of COPD has significant implications for patient care. A recent study found between 55% and 62% of patients with clinically diagnosed COPD do not have obstruction on spirometry.[2] Of the patients with a false diagnosis of COPD, 45% were on inhalers or alternate respiratory therapies, leading to increased financial burden and exposure to unnecessary harmful side effects.[2] Additionally, recent studies show overdiagnosed COPD patients were more likely to be hospitalized, utilize the Emergency Department, and attend outpatient visits than those without a diagnosis of COPD.[3] Patients with undiagnosed moderate to severe COPD were also more frequently hospitalized than patients without COPD, highlighting how improper diagnosis contributes to healthcare burden and increases cost to patients and the healthcare system.[3] For example, studies have demonstrated that black participants are less likely to be diagnosed by clinicians with COPD despite spirometric obstruction, which further contributes to discrepancies in diagnosis.[4]

Our primary study objective was to assess the prevalence of overdiagnosis and underdiagnosis of COPD at our institution and the impact of demographic factors, including race, gender, and patient locale, on PFT analysis and testing practices. By way of comparison, we evaluated the frequency of alternative testing (echocardiography) in patients presenting with symptoms potentially consistent with COPD.

Materials and Methods

This was a retrospective analysis that received design approval from the Wake Forest University/Atrium Health Institutional Review Board (IRB). The protocol was determined exempt from informed consent as data acquired was de-identified and anonymized. The study was conducted in accordance with the Declaration of Helsinki.

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Data was acquired via query of the electronic health record from two Atrium Health Wake Forest system hospitals between January 2016 and December 2022. Both sites conducted spirometry in accordance with ATS guidelines with a standardized approach at sites within our institution. Adult patients aged 40 and older with clinical diagnosis of COPD defined by ICD-10 codes (ie, J41.0. J 43.9, J44.0) were included for analysis. Clinical diagnosis of COPD appeared in the patients' medical chart, either within the problem list or a clinical encounter. Exclusion criteria were diagnosis of cystic fibrosis, alpha-1-antitrypsin deficiency, and patients with spirometry before clinical diagnosis was identified.

Patients that had a clinical diagnosis of COPD were evaluated to determine if they underwent spirometric testing and/or echocardiography after their clinical diagnosis. Spirometry results were categorized as normal (FEV1/FVC $\geq$ 0.7 and FEV1 AND FVC $\geq$ LLN), obstructed (FEV1/FVC < 0.7), or preserved ratio with impaired spirometry (PRISM; FEV1/FVC $\geq$ 0.7 AND FEV1 and/or FVC < LLN). The number of days from clinical diagnosis to PFT was also determined.

Demographic data was evaluated for differences in race, gender, and socioeconomic status (SES). SES indicators were determined from address geocoded to ZIP code census data, and rural versus metropolitan status was determined using USDA rural-urban classifications (<5 or >5 cut off). Ethnicity was categorized as Black, White, Hispanic, Asian, or other, with patients potentially having multiple classifications. Gender was recorded based on assignment at birth.

Results

A total of 27,830 patients fulfilled criteria of clinical diagnosis of COPD without benefit of PFT confirmation. Patient demographics are shown in Table 1. 4,530 (16%) of these patients subsequently underwent PFT within our system and 23,300 (84%) never had spirometry. Of patients who had PFTs, 2,892 (64%) demonstrated obstruction, 725 (16%) were normal, and 913 (20%) had PRISM. Among patients with a clinical diagnosis of COPD, 12,199 (44%) had echocardiography performed within our system. A greater proportion of non-white patients underwent PFT compared to whites (21% compared to 15%, respectively). Confirmation percentage was defined as the percentage of patients with a clinical diagnosis who were confirmed to have obstruction on PFT. Confirmation percentage was greater in white patients

Table 1 Patient Characteristics

	Overall	PFT = No	PFT = Yes	P-value
	27,830	23,300	4530	
Age, median [Q1, Q3]	67.0 [58.0,75.0]	67.0 [59.0,75.0]	64.0 [57.0,71.0]	<0.001
Female, n (%)	14,111 (50.7)	11,768 (50.5)	2343 (51.7)	0.139
Male, n (%)	13,719 (49.3)	11,532 (49.5)	2187 (48.3)	
Race, n (%)				<0.001
White	23445 (84.2)	19,818 (85.1)	3627 (80.1)	
Black	3589 (12.9)	2810 (12.1)	779 (17.2)	
Asian	68 (0.2)	59 (0.3)	9 (0.2)	
Hispanic	211 (0.8)	158 (0.7)	53 (1.2)	
Other	517 (1.9)	455 (2.0)	62 (1.4)	
Past/Present Smoker, n (%)	23,694 (85.1)	19,513 (83.7)	4181 (92.3)	<0.001
USDA classification, n (%)				<0.001
Metro	24957 (89.7)	20,815 (89.3)	4142 (91.4)	
Rural	2873 (10.3)	2485 (10.7)	388 (8.6)	
Echo, n (%)	12,199 (43.8)	9304 (39.9)	2895 (63.9)	<0.001
Days of observation for PFT, median [Q1, Q3]	223.0 [4.0, 1192.5]		223.0 [4.0, 1192.5]	

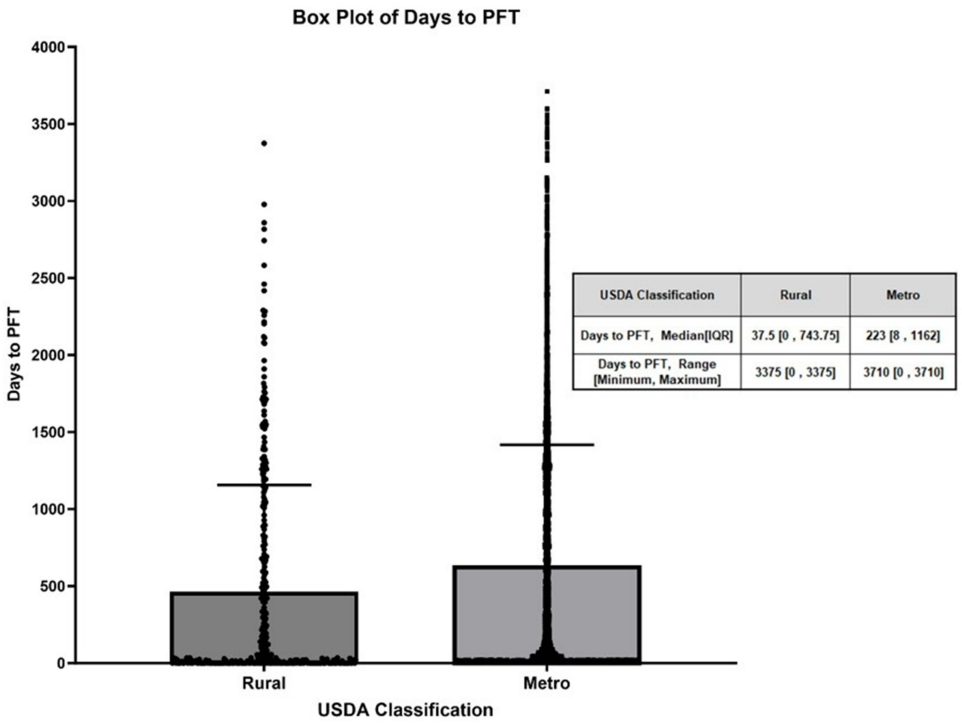

Figure 1 Box plot showing Median and Inter Quartile range (IQR) of days to PFT by USDA Classification.

compared to non-whites (66% vs 54%, $p < 0.001$). Male and female gender were tested with similar frequency (16% and 17%, respectively, $p=0.139$). Confirmation percentage, however, was higher among men (73% vs 55% in women, $p < 0.001$). The median number of days (IQR) after clinical diagnosis of COPD until PFT confirmation was longer for non-whites compared with whites [511 (15, 1258) vs 171 (0, 1163), $p<0.001$], and longer for women compared to men [325 (8, 1231) vs 162 (0, 1146) days, $p<0.001$]. Patients in rural and metro areas were equally likely to undergo PFT; however, patients residing in a rural location were more likely to undergo testing sooner than patients in a metro area [31 (0, 670) vs 267 (7, 1221) days, $p<0.001$] (Figure 1).

Discussion

This study demonstrates that only a minority of patients with a clinical diagnosis of COPD undergo confirmatory PFT. In fact, patients with a clinical diagnosis of COPD were nearly three times more likely to have an echocardiogram than PFTs. Less than two-thirds of those tested with PFT had obstruction. Contrary to our assumptions, non-whites were more likely than whites to be tested. However, the confirmation percentage was greater in whites versus non-whites and in men versus women. Also contrary to expectations, patients residing in a rural locale were tested sooner than those residing in an urban location.

Our findings highlight a worrisome pattern of underutilization of PFTs among patients with a clinical diagnosis of COPD. This relationship is demonstrated in prior studies. A Canadian study found that only 35% of patients with a recent diagnosis of COPD underwent PFT.[5] The range of confirmatory testing in the literature is 30–50%.[5] In our study, the proportion of patients receiving confirmatory PFT was even lower (16%). PFTs clarify and define the diagnosis of COPD and should be utilized to avoid incorrect diagnosis. Clinical diagnosis without confirmatory testing leads to patients treated unnecessarily and increases healthcare burden.[2,3] Additionally, we found significant overdiagnosis of COPD in our population, with only 64% of PFTs confirming obstruction. Overdiagnosis of COPD also has profound consequences and leads to unnecessary prescriptions, side effects, and strain on the healthcare system due to misallocation of resources.

Non-white patients in our study were more likely than whites to receive testing for COPD but were less likely to have confirmed obstruction when tested. This is in contrast to prior literature – underdiagnosis has been shown to be higher

among minority groups (44% of non-white patients compared with 29% of whites), a trend consistent across disease severity.[4] Racial disparities affect COPD diagnostic accuracy, influenced by factors such as access to health care, cost, transportation, education, health insurance, and cultural beliefs. One possible explanation for our finding that non-white patients are more likely to undergo testing could be clinician bias, where providers may perceive black patients to be at higher risk for COPD or order tests more frequently due to higher clinical uncertainty in black patients. Further studies are necessary to shed light on this.

Gender differences also influence diagnostic accuracy for COPD. Our study found no difference in frequency of testing between men and women, but higher diagnostic accuracy in men (less obstruction, ie overdiagnosis in women). Previous studies have shown that women experience greater dyspnea with less pronounced airflow obstruction.[6] Consequently, while their PFTs may not reveal clear obstruction, there may be subtle abnormalities that affect diagnostic accuracy. Women also present with more atypical symptoms, influencing how often clinicians refer for spirometry compared with alternate testing.[6]

Our study also challenges assumptions surrounding access to healthcare in rural versus urban locations. Contrary to our expectations, rural patients were tested with PFT sooner compared with those in metro areas. This diverges from previous studies that have found that rural COPD patients have more difficulty accessing healthcare services compared with those in urban locations.[7] While patients in urban areas have closer proximity to facilities providing spirometry, this proximity may also lead to increased demand for PFTs to be done in those locations, causing longer wait times for PFT appointments. Since patients with PFT performed prior to a diagnosis of COPD were excluded from our study, this also could have biased our results if urban patients were more likely to have testing done before their diagnosis of COPD was made.

We also found that patients with a clinical diagnosis of COPD were much more likely to undergo echocardiography testing than PFTs, suggesting PFT is underutilized in this population while echocardiography may be overutilized. Heart disease, including heart failure, is a common co-morbidity associated with COPD. Heart failure and COPD can have similar symptoms that are difficult for patients to characterize when asked by their physician. This overlap in symptoms contributes to the dilemmas faced by clinicians in obtaining an accurate diagnosis and may contribute to underdiagnosis of COPD. To our knowledge, limited research has been conducted to determine the frequency of echocardiography testing in COPD patients. In our study, compared to spirometry, echocardiography was used more liberally to evaluate dyspnea. This highlights the importance of considering COPD in patients presenting with dyspnea and the need for diagnostic pathways to ensure the appropriate utilization of healthcare testing. It may be prudent to screen patients presenting for ECG and echocardiography testing and refer for spirometry to reduce the underdiagnosis of COPD.

Our study has several potential limitations. One limitation of our analysis is that there may be unaccounted for confounding. For example, our finding that rural patients underwent PFT sooner than urban patients may be influenced by other factors. It is possible that urban patients were more impoverished than the rural patients, did not identify PFT as an important contributor to their health, or may have had more difficulty getting time off from work to undergo PFT. Additionally, variability in timing of clinical diagnosis and follow-up may have contributed to our findings. For example, if a patient received their clinical diagnosis near the end of the study period, these patients may not have had an opportunity to have confirmatory PFT at the time of our data collection, which may account for some of our results, such as longer time to testing for non-white patients. Finally, our data are limited to a single health system, and it is unclear if these results can be extrapolated to other health systems or geographic areas.

Conclusion

Our study emphasizes important disparities in accurate diagnosis of COPD. Many patients with a high clinical suspicion for COPD do not undergo PFT to confirm their diagnosis. This leads to patients who are inappropriately labeled as COPD and, as a result, may receive improper diagnosis, workup, and treatment. Non-white patients and women with a clinical diagnosis of COPD had lower confirmation percentage of obstruction when undergoing PFTs. Further studies are needed to determine if utilization of a systematic approach for pulmonary function testing leads to improved diagnostic accuracy and proper diagnosis for patients, including non-whites and women.

Disclosure

Dr. Jill Ohar serves on the following advisory boards as a consultant: Chiesi Pharma, AstraZeneca, Viatris, Mylan, Theravance, Verona, and Genetech; legal consultation for Wallace & Graham, SWMW, Morgan Lewis & Bockius, Poisson, Poisson, Bowers, Simmons Hanly, Roven Law, Coffey law, Fox Rothschild, Wise; inhale study for COPD Foundation; Spiromics for NIH. She is supported by Teva and Orchid under grant # 0000-0002-2757-6806. The aforementioned advisory boards and funders had no role in the design; the collection, analysis, and interpretation of the data; the writing of the manuscript. The authors report no other conflicts of interest in this work.

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