The Impact of Screening Tools on Diagnosis of Chronic Obstructive Pulmonary Disease in Primary Care

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Background: Chronic obstructive pulmonary disease (COPD) is frequently misdiagnosed or undiagnosed, which can delay disease management interventions.

Purpose: The Screening, Evaluating and Assessing Rate CHanges of diagnosing respiratory conditions in primary care 1 (SEARCH1) study assessed whether screening using the COPD Population Screener (COPD-PS) questionnaire to detect COPD risk factors and symptoms, with or without a handheld spirometer (copd-6) to detect airflow limitation, can increase yields of COPD diagnosis and respiratory-related clinician actions in primary care.

Design: A prospective, multi-center, pragmatic, comparative-effectiveness, cluster-randomized study conducted from September 2010 to October 2011 (data analyzed from December 2011 to January 2013).

Participants: Men and women aged ≥ 40 years visiting their participating primary care practice for any reason.

Intervention: Practices were randomized to three study arms: COPD-PS + copd-6, COPD-PS alone, and usual care (no interventions). No practices received any specific education about COPD or its diagnosis.

Main outcome measures: The primary endpoint was yield of new clinical COPD diagnosis; the secondary endpoint was yield of respiratory-related clinician actions.

Results: Of 9,704 patients enrolled, 8,770 had no prior COPD diagnosis and were included in endpoint analyses. Both interventions significantly increased COPD diagnostic yield over 8 weeks. Compared with a mean yield of 0.49% (0.13%) (controls), yields were 1.07% (0.20%) (OR=2.20, 95% CI=1.26, 3.84, p=0.006) and 1.16% (0.22%) (OR=2.38, 95% CI=1.38, 4.13, p=0.002) for COPD-PS and COPD-PS+copd-6 study arms, respectively. Respiratory-related clinician actions were not significantly different across study arms.

Conclusions: Office-based assessment can significantly increase COPD diagnosis by primary care physicians. Future trials must evaluate whether screening can improve outcomes for patients with COPD.

(Am J Prev Med 2014;47(5):563–575) © 2014 American Journal of Preventive Medicine

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0749-3797/$36.00
http://dx.doi.org/10.1016/j.amepre.2014.07.030

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Introduction

Chronic obstructive pulmonary disease (COPD) is a common, preventable disorder characterized by chronic inflammation of the airways and persistent airflow limitation that progressively worsens with age. It is a leading cause of morbidity and mortality in the U.S. The hallmark symptoms of COPD are exertional dyspnea, increased sputum production, and chronic cough.[1] Exposure to cigarette smoke and other noxious particles are the best-studied risk factors for COPD; however, other factors such as age, genetics, and infections may also play a significant role.[1]

An estimated 24 million adults in the U.S. have COPD, yet most remain undiagnosed or misdiagnosed.[2,3] The slow progression of COPD means that its early symptoms often go unrecognized by both patients and physicians despite substantial deterioration in health status and increased risk of mortality.[4] Patients may consider symptoms as natural consequences of aging or their smoking habit and delay seeking medical help. Instead, patients often adapt their lives in order to avoid the more troubling symptoms, such as exertional dyspnea. As a consequence, initial diagnosis and intervention generally occur only when the disease has progressed to an advanced stage and the patient has a significantly decreased functional status.[5–7]

At present, there is no consensus on an optimum approach to identify individuals with COPD. Spirometry is required to confirm a diagnosis of COPD[1]; however, the U.S. Preventive Services Task Force and American Thoracic Society recommend against the use of spirometry as a COPD screening test in the general population.[8,9] As a potential alternative, recent studies[10,11] suggest that screening for COPD risk factors and symptoms using a COPD questionnaire, followed by case-finding using a handheld spirometric device to detect airflow limitation, may offer an easy and feasible method to identify symptomatic patients, at risk of COPD, who could benefit from diagnostic spirometry.

Previous studies suggest that this approach is reliable to detect significant airflow obstruction in the general population[10,11] and may increase early, accurate diagnosis of COPD in a general practice setting.[11] However, no studies have conclusively shown that these methods provide measurable benefits to COPD diagnosis, compared with usual primary care procedures.

The COPD Population Screener (COPD-PS, QualityMetric Incorporated, Lincoln RI) is a five-item, self-administered questionnaire validated as a screener for individuals at high risk of COPD in the general population.[12] It comprises three COPD-related questions (concerning dyspnea, sputum production, and activity limitation) and questions regarding smoking history and age. The copd-6 (Vitalograph, Buckingham, United Kingdom) is a handheld spirometric device that measures lung function parameters, including forced expiratory volume in 1 and 6 seconds (FEV_1 and FEV_6, respectively), and may be used to detect airflow limitation.

In diagnostic spirometry, a post-bronchodilator FEV_1/forced vital capacity (FVC) ratio <0.7 is required to confirm persistent airflow limitation and a diagnosis of COPD.[1] FEV_1/FEV_6 and FEV_1/FVC correlate well, suggesting that FEV_1/FEV_6 may act as an effective surrogate for FEV_1/FVC to detect airflow limitation.[13,14] The objective of the Screening, Evaluating and Assessing Rate CHanges of diagnosing respiratory conditions in primary care 1 (SEARCH1) study was to evaluate whether screening using the COPD-PS, either alone or in tandem with the copd-6, could impact COPD diagnosis and respiratory-related clinician actions in a population of adults visiting primary care offices among a sample of U.S. family and internal medicine outpatient practices, as compared with usual care procedures at these sites.

Methods

Study Design

This prospective, multi-center, pragmatic, comparative-effectiveness, cluster-randomized study evaluated the impact of population-based COPD screening using the COPD-PS questionnaire (Figure 1), alone and in combination with case-finding using the copd-6 handheld spirometric device. The primary endpoint of this trial was the yield of COPD diagnoses in primary care practices. The trial was conducted from September 2010 to October 2011.

Study Sites

Primary care practice sites throughout the U.S. were invited to participate by the regional investigators. The practice could not be currently screening for COPD and had to agree to accept randomization to any of the three arms. To reduce bias, a cluster design was used in which primary care practice sites (not individual patients) were randomized. Participating practices were randomized in a 1:1:1 ratio to three study arms: COPD-PS + copd-6, COPD-PS alone, and usual care.

In the combined COPD-PS+copd-6 arm, eligible patients were screened using the COPD-PS questionnaire. If they scored ≥ 5 (of a possible 10) on the questionnaire, their lung function (FEV_1 and FEV_6) was then assessed using the copd-6 spirometric device. Eligible patients at sites in the COPD-PS study arm were screened using the COPD-PS questionnaire alone. Patients attending practices randomized to the usual care arm received neither the COPD-PS nor copd-6. Primary care sites did not receive any specific additional education about COPD or its diagnosis, nor were they informed that the study was related to COPD.

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