A Randomized Trial of Two Types of Nurse-Assisted Home Care for Patients With COPD*

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Study objectives: **Whereas pulmonary rehabilitation reduces symptoms and improves the quality of life of patients with COPD and is recommended in management guidelines, few patients have access to rehabilitation services. The purpose of this study was to investigate the effectiveness of increasing access to selected components of pulmonary rehabilitation by providing nurse-assisted home care that was composed of patient education, efforts to improve patient self-management skills, and enhanced follow-up.**
Design: **We conducted a 6-month, randomized, controlled trial.**
Setting: **Primary care clinics associated with an urban academic health system.**
Patients: **Patients were $\geq$ 45 years of age with a physician diagnosis of COPD, and had a $\geq$ 20-pack-year smoking history, had experienced at least one respiratory symptom during the past 12 months, and had airflow obstruction (ie, FEV_1/FVC ratio, $< 70\%$; FEV_1, $< 80\%$).**
Interventions: **Four nurses were trained in the use of the Global Initiative for Chronic Obstructive Lung Disease guidelines, and two of the four nurses received additional training in collaborative management. Patients were randomly assigned to usual care (UC), nurse-assisted medical management (MM), or nurse-assisted collaborative management (CM).**
Measurements: **The main outcome measures were of generic (Medical Outcome Study 36-item short form [SF-36], illness intrusiveness) and disease-specific (St. George's respiratory questionnaire [SGRQ]) quality of life and self-reported health-care utilization.**
Results: **Overall, 151 patients (UC group, 51 patients; MM group, 49 patients; and CM group, 51 patients) completed the study, their average age was 69 years, and 56.9% were women. The average change in the SF-36 general health domain for the MM group vs the UC group was 1.1 (95% confidence interval [CI], -7.9 to 11.2), and for the CM group vs the UC group the average change was 2.5 (95% CI, -7.0 to 12.3). The corresponding changes in SGRQ total domain were -2.9 (95% CI, -9.8 to 4.1) and -2.6 (95% CI, -9.5 to 4.3). There was no change in the number of self-reported emergency department visits or hospitalizations, but the utilization of these services was infrequent.**
Conclusion: **The findings of our investigation and those from the published literature suggest that interventions to enhance patient education, self-management skills, and follow-up among patients with COPD do not result in clinically meaningful improvements in health status or self-reported health-care utilization. Moreover, future studies of disease management programs for patients with COPD need to evaluate interventions that address associated comorbidities, exercise, and social support.** *(CHEST 2005; 128:2017–2024)*

Key words: disease management; home care services; hospitalization; pulmonary disease, chronic obstructive; quality of life; randomized controlled trial; rehabilitation

Abbreviations: BSI = Brief Symptom Inventory; CES-D = Centers for Epidemiologic Studies-Depression; CM = collaborative management; GOLD = Global Initiative for Chronic Obstructive Lung Disease; MM = medical management; SF-36 = Medical Outcome Study 36-item short form; SGRQ = St. George's respiratory questionnaire; UC = usual care

COPD is a common and growing cause of morbidity and mortality and is associated with a large economic burden worldwide.[1] In response to the public health burden of COPD, several international guidelines have been published on the optimal management of patients with COPD.[2] However, there are many potential barriers to the implementation of guideline recommendations.[3,4] In particular, whereas pulmonary rehabilitation is recommended in the guidelines because it reduces symptoms and improves the quality of life of patients with COPD,[5] few patients have access to rehabilitation services.[6] Therefore, methods are needed to improve access to pulmonary rehabilitation.

Because pulmonary rehabilitation is most often provided at specialized centers and is composed of a number of components, one approach that may improve access is to offer only the essential components that are necessary for improving health outcomes at other locations.[7] However, little is known about which components of comprehensive pulmonary rehabilitation programs are essential (ie, medical and functional assessment by a multidisciplinary team, patient education, self-management training, psychosocial interventions, exercise, and enhanced follow-up). The purpose of this study was to investigate the effectiveness of increasing access to selected components of pulmonary rehabilitation by providing nurse-assisted home care that was composed of patient education, efforts to improve patient self-management skills, and enhanced follow-up.

Materials and Methods

Study Design, Subjects, and Setting

This was a randomized, controlled trial of patients with COPD cared for by primary care physicians from 17 primary care clinic sites, which are part of an urban academic health center. All of the patients who were $\geq$ 45 years of age with a COPD-related diagnosis code (from the *International Classification of Diseases, Ninth Revision* codes 491, 492, 496) during the period from September 2000 to August 2001 (n = 2,120) were selected from an electronic claims database and were sent a letter informing them of the study with an invitation to participate. Interested persons were asked to answer brief screening questions to determine their eligibility. The University of Florida Health Science Center/Jacksonville Institutional Review Board approved the project.

Case Definition

To be eligible for the study, patients had to fulfill three criteria based on smoking history, respiratory symptoms, and spirometric testing results. Eligible persons had to be a current or former smoker with at least a 20-pack-year smoking history and at least one respiratory symptom (eg, cough, shortness of breath, or wheeze) during the past 12 months. Persons who fulfilled the smoking and respiratory symptom criteria also had to demonstrate airflow obstruction (ie, FEV_1/FVC ratio, < 70%; and

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FEV_1, < 80% predicted). Spirometry was performed in the subject's home by the study coordinator (B.B.), following American Thoracic Society standards[8] using a MicroLoop (Micro Medical Ltd; Kent, UK).

Intervention

Prior to randomization and intervention group assignment, the study coordinator obtained informed consent and collected the baseline data. Patients were randomly assigned to one of three intervention groups (usual care [UC], nurse-assisted medical management [MM], or nurse-assisted collaborative management [CM]) using a computer-generated random list. The study coordinator provided patients in the UC group with two educational booklets from the American Lung Association that were relevant to COPD[9,10] and advised them to follow the recommendations of their physician, which may have also included recommendations from a pulmonary physician if one was consulted.

The MM and CM interventions were provided by a total of four nurses (two per group) who were randomly assigned to an intervention group and trained separately (by D.C.). Both groups of nurses received approximately 8 h of training in standardized MM using the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines.[7] The training was composed of two 4-h sessions that included 3.5 h of lecture and 4.5 h of problem-based learning using six case scenarios. The case scenarios were designed to reinforce lecture material concerning the diagnosis of COPD, the assessment of COPD severity, patient self-management, smoking cessation, follow-up, and formation of an action plan for exacerbations. Overall, the goal of the MM intervention by the nurses was to enhance patient knowledge about COPD, their symptoms, and optimal MM.[7]

In addition to the 8 h of training in MM, the nurses assigned to the CM intervention received approximately 8 additional hours of training in "collaborative care," which is patient-centered and intended to facilitate the adoption of healthy behaviors, including lifestyle and self-management skills.[11] The CM intervention was designed to enhance the MM intervention. The materials and topics used for this component of the intervention were adapted from the American College of Physicians[12] and Rollnick et al.[13] The training focused on the specific skills of establishing rapport, setting an agenda, assessing readiness to change, tailoring information and feedback, and reducing resistance. Training in these skills was composed of 1.5 h of lectures on the principles of collaborative management, and 6.5 h of interactive sessions with observation, discussion, and feedback using three different formats, including five case scenarios, critique of three videotaped interviews, and two role plays.

Nurses in both groups maintained a written log of contact duration and topics addressed with their patients (Table 1). The categories of topics addressed included review of symptoms and medications; education about COPD, symptoms, and medications; smoking cessation; a written action plan for worsening symptoms; and completion of a letter to their primary care physician describing the patient's status and, if indicated, suggestions for modifying management to be consistent with GOLD guidelines. The initial contact by the nurses was conducted in the patient's home, and subsequent contact was intended to occur at least once a month by telephone.

Data Collection

Two major categories of data that were collected included determinants of health status and health outcomes. The data items that were considered potential determinants of health status were demographic characteristics, smoking history, comor-