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BIOLOGICAL, BEHAVIORAL, AND PSYCHOSOCIAL ATTRIBUTES OF INDIVIDUALS WITH COPD

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BIOLOGICAL, BEHAVIORAL, AND PSYCHOSOCIAL ATTRIBUTES OF INDIVIDUALS WITH COPD

DISSERTATION

A dissertation submitted in partial fulfillment of the
requirements for the degree of Doctor of Philosophy in the
College of Nursing at the University of Kentucky

By

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Lexington, KY

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2018

ABSTRACT OF DISSERTATION

BIOLOGICAL, BEHAVIORAL, AND PSYCHOSOCIAL ATTRIBUTES OF INDIVIDUALS WITH COPD

The purpose of this dissertation was to evaluate the biological, behavioral, and psychosocial attributes of individuals diagnosed with chronic obstructive pulmonary disease (COPD). Specific aims were to: 1) explore the predictive power of spirometry measures for event-free survival in patients with heart failure and suspected COPD, focusing on the differences in survival between those with and without airflow limitation; 2) examine the psychometric properties of the Multidimensional Scale of Perceived Social Support (MSPSS) in patients with concomitant COPD and heart failure; and 3) test the efficacy of a theory-based, multidimensional, self-care educational intervention using an eHealth platform on measures of symptom severity and variability, anxiety and depressive symptoms, perceived self-care ability, perceived self-care adherence, and self-care information needs (knowledge) in a sample of adult patients with stable COPD.

Specific aim one was addressed by evaluation of the predictive power of spirometry measures (forced expiratory volume/second [FEV_1], forced vital capacity [FVC], and the ratio of FEV_1/FVC) for event-free time to combined hospitalization/mortality after controlling for clinical and sociodemographic variables. This analysis revealed that those patients with airflow limitation were 2.2 times more likely to experience hospitalization/mortality compared to those without airflow limitation. The second specific aim was addressed with a psychometric evaluation of the Multidimensional Scale of Perceived Social support (MSPSS) which included determination of internal consistency reliability, the factor structure and construct validity by hypothesis testing in participants with comorbid COPD and heart failure. The MSPSS was a valid and reliable instrument to measure perceived social support in patients with comorbid COPD and heart failure. The third specific aim was addressed by a trial of an eHealth educational intervention in participants with COPD (N = 20). This intervention resulted in significant change in symptom severity evaluation in patients categorized as having medium symptom severity for the following symptoms: distress due to cough,

chest tightness, dyspnea with activity and fatigue; these symptoms were perceived as more severe in the intervention period. Anxiety, depressive symptoms and perceived self-care ability were unchanged; however, perceived self-care adherence scores improved, and knowledge needs were significantly reduced after the intervention.

KEYWORDS: Chronic Obstructive Pulmonary Disease, Self-Care, Self-Management, eHealth, Symptom Burden

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April 9, 2018
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BIOLOGICAL, BEHAVIORAL, AND PSYCHOSOCIAL ATTRIBUTES OF INDIVIDUALS WITH COPD

By

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April 9, 2018
Date

This work is dedicated to my loving wife Julia and my parents, Mark and Darlene. Thank you for your unwavering support and for putting up with me these past three years.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER ONE

Introduction

Chronic obstructive pulmonary disease (COPD) is predicted to be the third leading cause of death worldwide by 2030.[1] In the United States, 15 to 22 million people are currently diagnosed with COPD; the deaths from COPD are estimated to rise 30% in the next 10 years. [2,3] This disease is progressive, irreversible and characterized by persistent airflow limitation and respiratory symptoms.[4] As COPD progresses, symptoms often become more severe, physical and psychological responses are elicited, and risk for hospitalization increases. Breathlessness or dyspnea is the most common symptom reported by those with COPD, followed by cough, troublesome mucous, wheezing, and chest tightness.[5-10] Furthermore, approximately 40% of patients with COPD have clinical anxiety, and approximately 25% experience clinically significant depressive symptoms.[11,12] Due to the high symptom burden and progressive nature of COPD, it is necessary for patients to perform a variety of self-care activities to maintain homeostasis.

Self-care is defined as the process by which individuals with chronic disease attain optimal health through learned, intentional actions that include symptom recognition and response, adherence to prescribed treatment and medications, intentional lifestyle alterations, regular interaction with health care professionals, and evaluation of these actions.[13] The increased incidence and prevalence of COPD has been the impetus for the development of education and training programs focused on development of effective self-care behaviors; these structured, and multi-faceted interventions aimed to educate, motivate, engage, and support patients to adapt their health behaviors and develop skills to provide relief of symptoms, slow the progression of disease, improve

physical functioning, improve health related quality of life and prevent exacerbations that require hospitalization. [4,14-17] Effective self-care for patients with COPD improved health-related quality of life (HRQoL),[15,18] reduced dyspnea,[19] decreased risk for all-cause hospitalization,[19-21] and reduced anxiety and depressive symptoms.[22,23] However, only 40% of patients with COPD demonstrate prolonged retention of self-care behaviors.[24]

Consequences of poor self-care behaviors may result in quicker disease progression, increased morbidity and premature mortality; patients with COPD have an average life expectancy of 5.8 years less than age-adjusted healthy controls and are at 70% to 90% increase likelihood of death if they have comorbid cardiovascular disease.[19,25,26] However, self-care is a still a relatively new concept that has been understudied in this population. There is currently no consensus as to what constitutes appropriate self-care behaviors for patients with COPD; self-care behaviors taught to patients often vary from practitioner to practitioner,[19,27] may not be evidence-based, and the patient's pre-existing self-care abilities are not always taken into consideration.[13] Furthermore, studying patient self-care is particularly challenging in that patients spend a majority of time away from the healthcare setting, and researchers are often reliant on periodic self-reports of patient subjective assessment of disease-state. Although there is a lack of research outlining standardized self-care recommendations, the consequences of performing self-care are clear; it is imperative that researchers develop and test standardized self-care interventions to promote sustainable self-care behaviors

Traditionally, researchers used objective measures to gauge self-care efficacy and only recently have researchers begun to study the effects of self-care behaviors on

subjective outcomes such as HRQoL, perceived treatment adherence, perceived self-care ability and anxiety/depressive symptoms.[19,21] Previous investigators concluded effective self-care for patients with COPD increased HRQOL by 5% – 6.5%[15,18] and reduced anxiety and depression scores by an average of 2.7% to 18.4%.[22,23,28] Moreover, findings and conclusions from a recent Cochrane review examining the benefits of self-care behaviors on outcomes further supported the effectiveness of self-care on outcomes such as HRQoL, anxiety, mortality and hospitalizations.[19] Zwerink and colleagues concluded that the self-care interventions were effective at improving outcomes, however these investigators could not conclude which self-care behaviors were best at improving outcomes; tested self-care interventions were too heterogeneous.[19] Although desirable outcomes resulted after implementing self-care interventions, there is a lack of evidence to support which interventions should be taught to patients with COPD; this reflects the current state of the science in self-care for patients with COPD. Additionally, there are limited research studies that evaluated the relationships between self-care and other key outcomes such as symptom burden, psychological distress, perceived treatment adherence, perceived self-care ability and self-care information needs (knowledge) in patients with COPD. Therefore, the purpose of this dissertation was to evaluate the relationship between the biological, psychosocial and behavioral self-care attributes on outcomes in individuals with COPD.

Patients with comorbid COPD and heart failure share numerous commonalities such as the age of the affected population, cigarette smoking as a risk factor, presence of systemic inflammation, periodic episodes of disease exacerbation that require hospitalization, and dyspnea as a prominent symptom.[29] Up to one third of patients

diagnosed with heart failure (HF) exhibit some degree of COPD, and approximately 40% of patients diagnosed with COPD have heart disease.[30,31] Despite the high prevalence of comorbid disease and similarities in clinical presentation, the relationship of airflow limitation and combined all-cause hospitalization/mortality has not been explored in patients with heart failure. Chapter Two is a report of an analysis of spirometry measures made in patients with heart failure who were suspected to have comorbid COPD. This secondary analysis explored the predictive power of forced vital capacity (FVC), forced expiratory volume in one second (FEV_1), and the ratio between the two (FEV_1/FVC), for event-free survival in these patients. Cox proportional hazard modeling was used to examine the relationship between spirometry measures and all-cause hospitalization/mortality with and without adjusting for demographic and clinical covariates. Cox proportional hazards regression models compared all-cause hospitalization/mortality between those with and without airflow limitation. Those with airflow limitation were 2.2 times more likely to be hospitalized or die compared to those without (HR: 2.20, 95% CI 1.06 – 4.53, p = .03) Those in New York Heart Association functional class III/IV were 73% more likely to have an event (HR: 1.73, 95% CI 1.00 – 3.01, p = .05) when compared with those in NYHA class I/II. Patients who had never smoked were 62% (HR: 0.38; 95% CI 0.17 - 0.81, p = .01) less likely to have a health-related hospitalization/death.

Often, when pulmonary function decreases (indicating disease progression), key outcomes such as health related quality of life (HRQoL), functional capacity and cognition may also decline. As the disease progresses, it is common for patients to have caregivers, friends, family or significant others to help them manage their disease.

Chapter Three contains a psychometric evaluation of the Multidimensional Scale of Perceived Social Support (MSPSS) in a sample of patients with comorbid COPD and heart failure. The MSPSS measures perceived social support from friends, family, and significant others. The MSPSS was evaluated for internal consistency with Cronbach's α and the split-half technique. Construct validity of the MSPSS was assessed with a factor analysis and hypothesis testing. The MSPSS demonstrated excellent internal consistency with Cronbach's alpha consistently above .90. Factor analysis yielded a 3-factor solution, with items loading appropriately on the Friend, Family and Significant Other subscales. Hypothesis testing supported our hypothesis that higher levels of perceived social support predicted higher self-care management score ($F [11, 291] = 2.463$, $R^2 = .051$, $B = .151$, $p = 0.03$). The MSPSS is a valid and reliable instrument to measure perceived social support in patients with comorbid COPD and heart failure.

There is a lack of evidence about the immediate effects of self-care interventions on key outcomes, particularly symptom burden (severity of distress due to cough, chest tightness, distress due to mucous production, dyspnea with activity, dyspnea at rest, fatigue, anxiety, and depressive symptoms). Chapter 4 reports a test of a theory-based, multidimensional, self-care educational intervention using an eHealth platform, on symptom severity and variability, anxiety and depressive symptoms, perceived self-care ability, self-care adherence, and self-care information needs (knowledge) needs in patients with COPD. Multilevel growth models were constructed to examine symptom severity and variability. Repeated measures analysis of variance examined the effect of the intervention on anxiety and depressive symptoms, and perceived self-care ability at the end of week 1, 2 and the conclusion of the reporting period. Paired t-tests determined

the effect of the intervention on perceived self-care adherence and self-care information needs (knowledge).

Growth model analyses revealed that participants categorized as having medium symptom severity at baseline perceived the following symptoms as more distressful during the intervention period: distress due to cough (b = 10.16, 95% confidence interval [CI] 1.95 – 18.40, $t(83)$ = 2.46, p = .02), chest tightness (b = 8.47, $t[103]$ = 2.06, p = .04), dyspnea with activity (b = 13.18, $t[82]$ = 1.97, p = .05), and fatigue (b = 16.48, $t[134]$ = 3.89, p < .01). However, those categorized as high severity at baseline reported significantly lower severity of chest tightness after the intervention (b = -8.15, $t[113]$ = -2.03, p = .04). There were no demonstrated effects of the intervention on symptom variability, anxiety, depressive symptoms or perceived self-care ability. However, there were improvements in perceived self-care adherence (baseline - 58.1 $\pm$ 19.3, post intervention - 67.6 $\pm$ 12.2, p = .025) and self-care information needs (knowledge) scores (baseline - 13.7 $\pm$ 3.1, post intervention - 11.3 $\pm$ 1.8, p = .012) after implementation of the intervention.

Chapter Five concludes the dissertation with an overall summary of findings from the included manuscripts and the conclusions derived from these studies. Furthermore, in this chapter, implications for practice, as well as future directions for research in this population are proposed.

CHAPTER TWO

Airflow limitation more than doubles the risk for hospitalization/mortality in patients with heart failure.

Synopsis

Comorbid chronic obstructive pulmonary disease (COPD) is found in approximately one third of patients with heart failure (HF). Survival in patients with COPD generally decreases as lung function declines. However, the association between lung function, hospitalization and survival is less clear for patients with HF. This manuscript reported a secondary data analysis about the predictive power of spirometry measures for the combined variable, hospitalization/mortality, in patients with HF. This analysis revealed that participants with airflow limitation were 2.2 times more likely to be hospitalized or die compared to those without airflow limitation. Those in NYHA functional class III/IV were 73% more likely to have an event when compared with those in NYHA class I/II. Patients who had never smoked were 62% less likely to have a health-related hospitalization/death. Thus, there is an increased need to screen and appropriately manage patients with heart failure and airflow limitation to reduce the risk for hospitalization/mortality.

Introduction

Chronic heart failure (HF) and chronic obstructive pulmonary disease (COPD) are two of the top four causes of global mortality; HF and COPD account for approximately 21.5 million deaths/year worldwide.[1,32] Up to one third of patients diagnosed with HF also exhibit some degree of COPD, and approximately 40% of patients diagnosed with COPD have heart disease.[30,31] HF and COPD share a number of commonalities that include the age of the affected population, cigarette smoking as a risk factor, presence of systemic inflammation, periodic episodes of disease exacerbation that require hospitalization, and dyspnea as a prominent symptom.[29] Individuals diagnosed with concomitant heart disease and COPD are two to five times more likely to die of heart disease or stroke compared to those with heart disease alone.[29,30] These two chronic diseases are also associated with a number of other worse patient outcomes.

Prior investigators found that patients with comorbid COPD and HF reported decreased health-related quality of life, higher prevalence of anxiety and depressive symptoms, as well as the highest hospitalization rates among individuals with chronic diseases.[33-35] Specifically, patients with heart failure reported 2.5 times poorer health related quality of life scores and 52% worse functional capacity scores, demonstrated 2.5 to 3 times worse depression and anxiety scores compared to healthy individuals, and accounted for 25.6% of all hospitalizations.[36,37] In patients with COPD, up to 99% of patients reported symptoms that impaired activities of daily living, and 7% to 80% reported feeling anxious and/or depressed.[38,39] Patients with COPD were also 85% more likely to be diagnosed with an anxiety disorder, and twice as likely to be hospitalized for exacerbations when compared to healthy people. [13-16] In 2009, patients with COPD

accounted for approximately 16% of all hospitalizations.[37] Other investigators found the combination of COPD and comorbid HF was associated with a 2.8 times greater likelihood of worse quality of life, and a dyspnea burden 2 to nearly 3 times greater than those with HF only.[40,41] Thus, HF and COPD have a high symptom burden, poor outcomes and require significant healthcare utilization.

Spirometry provides measures of inhaled and exhaled lung volumes, lung capacity, and rates of gas flow.[4] Spirometry results provide information about the ability to ventilate, and can be used as a screening measure, diagnostic measure, or a means of disease monitoring.[42] Diagnostic pulmonary function tests are more comprehensive and include measures of respiration like diffusion capacity, the degree to which oxygen is transferred from inhaled gas to erythrocytes in pulmonary circulation. Spirometry is used to evaluate pulmonary conditions but is not commonly used in patients with HF unless they have a suspected concomitant pulmonary condition. For this study, we used spirometry measures to evaluate pulmonary ventilation in patients with HF and suspected airflow limitation; these measures included forced vital capacity (FVC; liters), forced expiratory volume in one second (FEV_1; liters at one second), and the ratio between the two (FEV_1/FVC).

FVC is the maximum volume of air that is forcibly exhaled after a full inspiration; the residual volume remains in the lungs and when added to the FVC provides the total lung capacity. FVC is measured in liters and like FEV_1, is compared to a predicted value based on sex, age, height and weight.[4,43] FEV_1 is the volume of air forcefully exhaled in one second after a full inspiration; it provides an evaluation of airflow. When the FEV_1 is less than 80% of the predicted value, airflow limitation is present.[4,43] The ratio of FEV_1 to

FVC, also known as the Tiffeneau-Pinelli index, is the proportion of vital capacity that an individual can forcefully exhale in the first second, and may be used to differentiate obstructive from restrictive disease and identify disease severity.[4,43] An $FEV_1/FVC < 0.70$ is the global standard cut point for airflow obstruction/COPD.[4] In those individuals with $FEV_1/FVC < .70$ after bronchodilator administration, individuals are then classified based on severity of airflow limitation (Table 1.).

Spirometry measures that revealed airflow limitation were associated with poorer outcomes that included worse quality of life, more hospitalizations, and mortality in patients with COPD.[44-46] Spirometry indices predicted mortality in patients with COPD, and those with reduced FEV_1 and FVC, had 43% to 50% higher associated risks for mortality compared to those with normal values.[47] Despite the overlap in signs, symptoms, and pathological presentations, spirometry is not regularly performed in patients with HF; thus, the relationship between spirometry measures and combined hospitalization/mortality in patients with HF and airflow limitation has not been systematically studied.[46,48,49] Therefore, the purpose of this study was to explore the predictive power of spirometry measures on event-free survival in patients with HF and suspected airflow limitation. The specific aims were to: 1) determine the proportion of patients with HF who exhibited airflow limitation ($FEV_1 < 80\%$) and met the spirometry criteria for COPD ($FEV_1/FVC < 70\%$); and 2) determine the independent predictive power of FEV_1, FVC, and FEV_1/FVC on a combined endpoint of hospitalization/mortality, while controlling for age, gender, ethnicity, smoking history, body mass index, left ventricular ejection fraction, and New York Heart Association (NYHA) functional class.

Methods

Design and Sample

This was a secondary analysis of data from a registry of three prospective, longitudinal studies conducted between 2008-2011.[50-52] Each of the study protocols were reviewed and approved by respective Institutional Review Boards. These studies conformed to the principles outlined in the Declaration of Helsinki. Informed, written consent was obtained from all participants after they were approached by a trained research nurse who confirmed patient eligibility, explained the study requirements, and all risks. Individuals were included if they had a primary diagnosis of HF, read/spoke English, had no obvious signs of cognitive impairment, and were at least 18 years old.[50-52] Patients were recruited from a southern academic medical center in the United States. For this analysis, we filtered the original data registry to obtain only those cases with complete data for specific sociodemographic and clinical variables that might confound our analyses, and for our variables of interest, spirometry measures (FVC, FEV_1, FEV_1/FVC) and the outcome, time to combined hospitalization/mortality. There were 137 participants with complete data included in this secondary analysis.

Measures

Demographic and Clinical Variables

Sociodemographic and clinical data were collected by patient interview and review of medical records. Demographic variables included age, gender, and ethnicity. Clinical variables included smoking status, left ventricular ejection fraction (LVEF), New York Heart Association (NYHA) functional class, and body mass index (BMI).

Spirometry

Spirometry measures were obtained from enrolled patients to determine the prevalence and degree of occult airflow limitation. All spirometry measures were made by fully trained respiratory therapists according to the American Thoracic Society's guidelines for acceptability and reproducibility of lung function testing.[43,53] GOLD criteria[4] were used to establish cut points for airflow limitation and COPD. Per GOLD criteria, airflow limitation was defined as [actual FEV_1/predicted FEV_1] < 80%; this was the cut point used to identify participants with airflow limitation for this analysis.[4] Airflow obstruction (COPD) was defined as a FEV_1/FVC < 70%; this is the cut point used to identify patients with probable COPD for this analysis.[4]

Combined Hospitalization/Mortality

The outcome of interest in this study was time to the composite end-point of all-cause combined hospitalization/mortality. Patients in this study were followed for up to four years (maximum = 1454 days), and data about all hospitalizations and mortality were collected. Every patient previously identified family member or specified friend was contacted with monthly phone calls to evaluate health status. Events reported were confirmed by review of medical records or death certificate. All events were confirmed and classified by a trained cardiac nurse and heart failure expert.

Data Analysis

Patient characteristics were summarized using means, standard deviations or frequencies. Participants were grouped based on the FEV_1 % of predicted with 0.80 used as the cut point, and were divided into those with airflow limitation or no airflow

limitation.[4] These groups were compared with an independent t-test, Chi-square, or Fisher's exact analysis based upon level of measurement and distribution of data. To respond to Specific Aim 1, patients were grouped based on FEV_1 value; individuals with an FEV_1 of < 80% of predicted were considered to have airflow limitation; those with an FEV_1 < 70% of predicted were categorized as COPD.

To address Specific Aim 2, we performed Cox proportional hazard modeling. The relationship between spirometry values and the composite outcome of combined all-cause hospitalization/mortality was tested with and without adjusting for age, gender, ethnicity, smoking status, LVEF, and BMI. First, spirometry data (FEV_1, FVC and FEV_1/FVC) were analyzed as continuous variables independently and with the control variables, using Cox proportional hazards regression to examine the overall effect of spirometry on combined all-cause hospitalization/mortality. Then, Cox proportional hazards regression modeling was conducted using participant classification of those with airflow limitation (FEV_1 < 80%) and/or presence of COPD (FEV_1/FVC < .70), with and without control variables. All test assumptions were evaluated prior to analysis. All data analyses were performed using SPSS version 24.0 (IBM, Armonk, NY), and a p value of ≤ 0.05 was considered significant.

Results

Characteristics of the participants

Participants in this study were primarily male (68%), Caucasians (79%) who were 60 $\pm$ 12 years of age (Table 2.). Slightly more than half of participants were in NYHA functional class I or II (52%), and on average the LVEF was 36 $\pm$ 15%. Approximately

42% of participants reported never smoking, while 18% reported they were current smokers. Baseline spirometry measures averaged FVC of 2.98 $\pm$ 0.90 L (74% of predicted value), an FEV_1 of 2.24 $\pm$ 0.68 L/sec (69% predicted value), and FEV_1/FVC of 0.75 $\pm$ 0.08. Only 10% of participants had received a prior diagnosis of COPD. The follow up period for the composite outcome of hospitalization/mortality ranged from 7 days to 1454 days. There were 199 hospitalizations during this period and 9 participants died. Mean time to first event was 378 $\pm$ 270 days.

Prevalence of airflow limitation

We first categorized patients based on FEV_1 and FEV_1/FVC (Table 3). Overall, 74% (n = 102) of participants exhibited some degree of airflow limitation (FEV_1 < 80% predicted value) and 26 (19%) participants met the spirometry criterion for COPD (FEV_1/FVC $\leq$ 0.70). Only 14 participants were previously diagnosed with COPD; thus, 9% of total participants met spirometry criterion for COPD, but had not been diagnosed.

Association of spirometry measures as continuous variables with event-free survival

Cox proportional hazard regression demonstrated no significant effect of FVC, FEV_1, or FEV_1/FVC on event free survival when treated as continuous variables, with and without controlling for potential confounding demographic and clinical variables (Table 4.) The overall Cox proportional hazard regression was insignificant; there was no significant effect of spirometry measures independently or after controlling for potential confounding variables on all-cause hospitalization/mortality. However, FEV_1 was significantly correlated with time (days) until first event ($r = .22$, $p = .01$), which indicated that as FEV_1 decreased (greater airflow limitation), time to event was shorter.

Association of spirometry groups and event-free survival

In simple Cox regression modeling (Table 5.), airflow limitation (FEV_1 < 80%) independently predicted all-cause event-free survival (HR: 2.40, 95% CI 1.22 – 4.69, p = .01). After controlling for age, gender, ethnicity, smoking status, LVEF, and BMI, patients who demonstrated airflow limitation had 2.2 times the risk of hospitalization/mortality (HR: 2.20, 95% CI 1.06 – 4.53, p = .03) when compared to patients with no airflow limitation (Figure 1). Those in NYHA class III/IV were 73% more likely to have an event (HR: 1.73, 95% CI 1.00 – 3.01, p = .05) when compared with those in NYHA class I/II; conversely, if patients reported they had never smoked, they were 62% (HR: 0.38; 95% CI 0.17 - 0.81, p = .01) less likely to have a health-related hospitalization/death when compared to patients who currently had or ever had a smoking habit.

Discussion

We found that a majority of participants with HF (73%) had some degree of airflow limitation, and approximately 19% of participants met diagnostic criteria for COPD based on spirometry; 9% (n = 12) of these patients were unaware their spirometry measures were consistent with a diagnosis of COPD. Moreover, a FEV_1 < 80% was highly associated with our combined composite endpoint of hospitalization/mortality; NYHA functional class III/IV was also associated with increased risk for hospitalization/mortality. Never smoking was associated with a reduced risk for an event. There was no association between FVC, FEV_1/FVC (as continuous or categorical), age, gender, ethnicity, LVEF, or BMI with event-free survival in this sample of patients with HF.

Other investigators have explored the prevalence of airflow limitation and COPD in patients with HF; in prior research studies, 49% - 81% of patients with HF demonstrated airflow limitation and 11% - 39% of patients met spirometry criterion for COPD.[46,48,49,54,55] In our sample of patients with HF, we found that the prevalence of airflow limitation (74%) and COPD (19%) was similar. However, there was considerable variability in the characteristics of the participants in prior studies, the procedures and equipment used, and criteria used to identify airflow limitation. For example, Arnaudis and colleagues[48] studied patients with more advanced HF (higher proportion of patients in NYHA III/IV) who were clinically unstable; while Bektas and colleagues[54] studied patients with less advanced disease (higher proportion of NYHA class I/II) who were clinically stable. Bektas and colleagues[54] also measured patient spirometry after administration of a bronchodilator; while Plesner and colleagues[46] measured spirometry without bronchodilator. Wada and colleagues[55] used a handheld spirometer and diagnostic criteria based on FEV_1/FEV_6 to identify airflow limitation, rather than conventional office-based measures and GOLD criteria.[4] Plesner and colleagues [46] used standardized, calibrated spirometry equipment and the European Respiratory Society's standards and guidelines; other investigators did not clearly describe the procedure and equipment used.[49] Thus, there is a clear need for investigators to use standardized, calibrated equipment and procedures for spirometry measures, and criteria for airflow limitation, so that reported results between studies will be comparable.

Few prior investigators explored the association of spirometry measures with all-cause hospitalization or mortality in patients with HF.[46,48,49] We analyzed the overall effect of airflow limitation, rather than diagnosis of COPD in our analyses and found that

patients with any degree of airflow limitation had more than twice the risk of hospitalization/death. Similarly, Plesner and colleagues[46] found that FEV_1 was independently associated (HR 1.43, 95% CI 1.21 – 1.68, $p < .001$) with all-cause mortality after adjusting for similar potential confounding variables; however, Arnaudis and colleagues[48] reported FEV_1 was significantly associated with all-cause mortality only in the presence of verified COPD (GOLD stage II: HR: 2.28, 95% CI 1.218–4.25; $p = 0.01$; GOLD stage III/IV: HR: 2.81, 95% CI 1.03–7.69; $p = 0.044$). Other investigators developed inconsistent conclusions about COPD ($FEV_1/FVC < 0.70$) as a significant prognostic indicator of event-free survival. Plesner and colleagues[46] concluded that a COPD diagnosis was not significantly associated with all-cause mortality after controlling for demographic and clinical variables (HR: 1.26, 95% CI: 1.85-1.87, $p = .26$);[46] similarly, Mascarenhas and colleagues[49] also concluded that a diagnosis of COPD was not significantly associated with all-cause mortality after controlling for potential confounding variables (HR: 1.40, 95% CI 0.88-2.24).[49] Thus, our findings are consistent with previous investigators and demonstrate that airflow limitation rather than COPD diagnosis was associated with increased risk for all-cause hospitalization/mortality.

Overall, our participant characteristics were similar to those in previous studies.[46,48,49] However, our results must be weighed cautiously when compared to the results of other studies. Our sample averaged a 12% lower proportion of patients in NYHA class I/II than in our analyses; our participants were 4 years younger on average, we had 6% fewer males on average, and had a 6% greater average LVEF compared to those in other investigations.[46,48,49] We also studied a different endpoint from other investigators. We combined time to first hospitalization and mortality, rather than solely

hospitalization or mortality.[46,48,49] We studied this endpoint to determine the association between airflow limitation and time to both events in this population. Thus, our findings demonstrated a significant association between airflow limitation and hospitalization/mortality in our patients with HF. This finding could aid in the identification of patients likely to require hospitalization and may permit optimization of both cardiac and pulmonary function and improvement in outcomes.

We also found that NYHA class III/IV and never smoking were significantly associated with all-cause hospitalization/mortality. We found that worse functional class was associated with 73% greater likelihood of an event (HR: 1.73, 95% CI 1.00 - 3.01, p = .05). Several other investigators found that worse functional class was associated with 2 to 2.25 times greater likelihood of all-cause mortality.[46,48,49] Our results are consistent with previous investigators; thus, as functional class worsened, there was a consistently increased risk for all-cause hospitalization/mortality. We also found that never smoking was protective for our endpoint, all-cause hospitalization/mortality. Our participants who had never smoked reduced their risk of hospitalization/mortality by 62% compared to those who were current smokers or had previously smoked (HR: 0.38, 95% CI, 0.17 – 0.81, p < .01). Plesner and colleagues also found that current smokers had a 64% greater risk of mortality compared to non-smokers (HR: 1.64, 95% CI 1.10 – 2.43, p = .014).[46]

Limitations

This study was a secondary data analysis; thus, we could include only the variables measured in the primary studies. We also had no ability to appraise data for accuracy or evaluate fidelity to study protocols. However, spirometry measures were made in a pulmonary function laboratory using standardized equipment, procedures and

highly trained personnel. Our spirometry data were measured without the use of bronchodilation. Thus, our estimates of the prevalence may have included those with some degree of reversible airflow limitation. All data were evaluated for accuracy by the original investigative team and all data were double entered and evaluated for entry accuracy prior to analysis.

Conclusions

A majority of our participants demonstrated some degree of airflow limitation. Airflow limitation more than doubled the risk of all-cause hospitalization/mortality in our patients with HF. Worse NYHA functional status was also associated with shorter survival time; never smoking reduced the likelihood of hospitalization/mortality. Spirometry measures may be useful in patients with HF, as tailored management of airflow limitation may improve all-cause survival.

Implications for practice

- Airflow limitation was common (74%) in this group of individuals with HF.
- Airflow limitation increased risk of hospitalization/death by 220%.
- Worse NYHA functional class was associated with 73% increased risk of shorter survival time.
- Non-smokers were 62% less likely to be hospitalized/die compared to smokers.
- Patients with HF may be unaware they have airflow limitation or occult COPD; approximately 10% of patients did not have a previous diagnosis of COPD but met spirometry criteria for COPD.

Table 2.1. Classification of airflow limitation severity based on FEV_1 in patients with $FEV_1/FVC < 0.70$

GOLD Stage	Severity	FEV_1
GOLD Stage 1	Mild	$FEV_1 > 80\%$ predicted
GOLD Stage 2	Moderate	$50\% \leq FEV_1 \leq 80\%$ predicted
GOLD Stage 3	Severe	$30\% \leq FEV_1 \leq 50\%$ predicted
GOLD Stage 4	Very Severe	$FEV_1 < 30\%$ predicted

Abbreviations: GOLD, Global Initiative for Obstructive Lung Disease; FEV_1, Forced Expiratory Volume in one second

Source: From the *Global Strategy for the Diagnosis, Management and Prevention of COPD*, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017. Available from: http://goldcopd.org/.

Table 2.2. Participant characteristics

	Total sample N = 137	Airflow Limitation [FEV_1 < 80% predicted] n = 102 (74%)	No Airflow Limitation [$FEV_1 \geq$ 80% predicted] n = 35 (26%)	P value
Age in years	60 ± 12	59 ± 11	63 ± 13	.28
Gender				
Male	93 (68%)	70 (69%)	23 (66%)	.75
Ethnicity				
Caucasian	108 (79%)	75 (74%)	33 (94%)	**.01**
Other	29 (21%)	27 (26%)	2 (6%)	
Smoking History				
Current smoker	24 (18%)	21 (21%)	3 (9%)	.25
Stopped smoking	56 (41%)	41 (40%)	15 (43%)	
Never smoked	57 (42%)	40 (39%)	17 (49%)	
BMI	32.7 ± 7.7	33.4 ± 7.7	30.7 ± 7.2	.13
LVEF %	36 ± 15	35 ± 15	39 ± 14	.15
Prior Diagnosis of COPD?	14 (10%)	14 (13%)	1 (3%)	.12
Spirometry: $FEV_1/FVC < 0.70$	26 (19%)	26 (26%)	0 (0)	-
NYHA Functional Class				
I/II	71 (52%)	49 (48%)	22 (63%)	.13
III/IV	66 (48%)	53 (52%)	13 (37%)	

Values are mean ± SD or f (%)

Comparisons were performed with independent t tests, Chi square or Fisher's exact test based on level of measurement and distribution of data.

Table 2.2, Cont.

Abbreviations: FEV_1, forced expiratory volume in one second; FVC, forced vital capacity; NYHA, New York Heart Association Functional Class; LVEF, left ventricular ejection fraction; BMI, body mass index

Table 2.3. Baseline spirometry for participants

Spirometry Measure	Total sample (n = 137)	Airflow Limitation (FEV_1 < 80% predicted value) (n = 102)	Normal Airflow ($FEV_1 \geq 80\%$ predicted value) (n = 35)
FVC measured in liters Predicted FVC for the total sample Percent predicted	2.98 ± .90 4.03 ± .95 74.8 ± 18	2.81 ± 0.87	3.34 ± 0.87
FEV_1 measured in liters Predicted FEV_1 for the total sample Percent Predicted	2.24 ± .68 3.23 ± .78 70.2 ± 18	2.06 ± 0.64	2.66 ± 0.65
FEV_1/FVC (%) Predicted FEV_1/FVC for total sample	75.27 ± 8.65 80.64 ± 2.20	73.64 ± 9.05	80.03 ± 5.01
Values are mean ± SD or f (%) Abbreviations: FEV_1, forced expiratory volume in one second; FVC, forced vital capacity			

Table 2.4. Cox Regression Modeling: Spirometry Measures as Continuous Variables with and without Covariates on Combined All-Cause Hospitalization/Mortality

	Variables in Model	Exp (β)	95% CI	p value
Block 1 [a]	FVC	.71	.19 – 2.56	.60
	FEV_1	1.35	.22 – 8.32	.75
	FEV_1/FVC	.98	.92 – 1.04	.46
Block 2 [b]	Age	1.03	.99 - 1.05	.08
	Male	.67	.34 - 1.36	.19
	Caucasian	.64	.31 – 1.33	.23
	Never smoked	.36	.16 – .79	.01
	NYHA Class III/IV	1.85	1.06 - 3.22	.03
	LVEF	1.01	.99 - 1.03	.33
	BMI	1.02	.98 - 1.06	.20
	FVC	.80	.19 – 3.30	.76
	FEV_1	1.49	.20 – 11.00	.69
	FEV_1/FVC	.98	.92 – 1.04	.49

Abbreviations: FEV_1, forced expiratory volume in one second; FVC, forced vital capacity; NYHA, New York Heart Association Functional Class; LVEF, left ventricular ejection fraction; BMI, body mass index;

Omnibus Tests of Model Coefficients: [a] $X^2 = 2.31$, $p = .51$; [b] $X^2 = 18.83$, $p = .09$

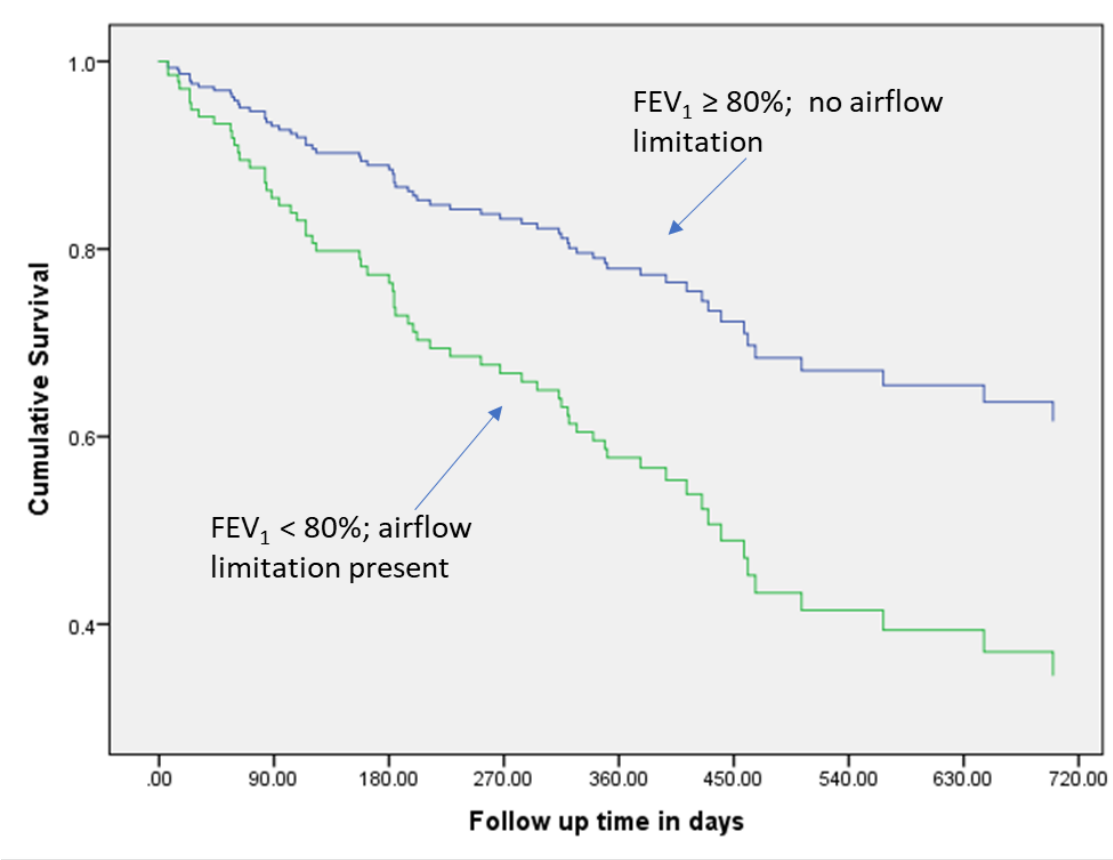
Table 2.5. Cox Regression Modeling: Spirometry Measures using GOLD Cut points with and without Covariates on Combined All-Cause Hospitalization/Mortality

	Variables in Model	Exp (β)	95% CI	p value
Block 1 [a]	FEV_1 < 80%	2.40	1.22 – 4.69	**.01**
	FEV_1/FVC < 0.70	.93	.50 – 1.74	.82
Block 2 [b]	Age	1.02	.99 - 1.05	.07
	Male	.74	.34 - 1.24	.19
	Caucasian	.76	.36 – 1.61	.48
	Never smoked	.38	.17 – .81	**.01**
	NYHA Class III/IV	1.73	1.00 - 3.01	**.05**
	LVEF	1.01	.99 - 1.03	.17
	BMI	1.02	.98 - 1.05	.37
	FEV_1 < 80%	2.20	1.06 – 4.53	**.03**
	FEV_1/FVC < 0.70	.90	.44 – 1.83	.77

Abbreviations: FEV_1, forced expiratory volume in one second; FVC, forced vital capacity; NYHA, New York Heart Association Functional Class; LVEF, left ventricular ejection fraction; BMI, body mass index;

Omnibus Tests of Model Coefficients: [a] $X^2 = 7.83$, p = **.03**; [b] $X^2 = 22.03$, p = **.02**

Figure 2.1. Kaplan-Meier plots: spirometry and all-cause event-free survival (X^2 = 22.03, p = .02)



CHAPTER THREE

The Multidimensional Scale of Perceived Social Support in patients with Comorbid COPD and Heart Failure: A psychometric analysis.

Synopsis

Chronic disease self-management is complex and multidimensional; individual ability to perform self-management behaviors is influenced by comorbid conditions, somatic awareness, and perceived social support. Optimal performance of complex self-management behaviors requires individuals have the support of their friends, family members, and significant others. This secondary data analysis reported the psychometric properties of the Multidimensional Scale of Perceived Social Support (MSPSS) in patients with comorbid chronic obstructive pulmonary disease (COPD) and heart failure (HF). The MSPSS demonstrated excellent internal consistency with Cronbach's alpha consistently above .90. Factor analysis yielded a 3-factor solution, with items loading appropriately on the Friend, Family and Significant Other subscales. Hypothesis testing supported our hypothesis that higher levels of perceived social support predicted higher self-care management score. We concluded the MSPSS is a reliable and valid instrument to measure perceived social support in patients with comorbid COPD and HF.

Introduction

Chronic and obstructive pulmonary disease (COPD) and chronic heart failure (HF) are responsible for over 21 million deaths annually, and are two of the top four causes of global mortality.[1,32] It is estimated that up to 52% of patients with HF have comorbid COPD.[56] Comorbid COPD and HF are associated with a higher incidence of other cardiovascular diseases, such as atrial fibrillation/flutter and hypertension.[57] Moreover, the risk of developing HF among patients with COPD is 450% greater compared to healthy adults.[58] COPD and HF are progressive and irreversible; patients are taught about daily self-care behaviors to maintain functional ability, reduce symptom burden, and maintain quality of life.[13,19] Chronic disease self-care is complex and multidimensional; individual ability to perform self-care behaviors is influenced by comorbid conditions, somatic awareness, and perceived social support.[13,59,60]

Optimal performance of complex self-care behaviors requires individuals to have the support of their friends, family members, and significant others. Perceived social support plays an important role in outcomes such as self-care ability, depression, and anxiety in patients with COPD. Previous investigators found that higher levels of perceived social support was associated with higher self-care abilities ($r = 0.252$; $P = 0.012$), and was a significant predictor of reduced depression ($\beta = -0.25$, $F(6, 85) = 5.10$, $p < .01$) and anxiety ($\beta = -0.20$, $F(6, 85) = 5.61$, $p < .01$).[59,61,62] Furthermore, lower levels of social support significantly predicted higher anxiety symptoms ($F (11, 418) = 34.9$, $p < .001$, R^2 adj = .47). Increased loneliness was moderately associated with worsening depressive symptoms ($r = -.587$; $p < .001$) and reduced feelings of social support (r =

−.471; p < .01).[63,64] Thus, perceived social support is an important factor in patient outcomes in those with COPD.

In patients with HF, perceived social support has been shown to predict level of self-care ability (β = .33; p = .0002),[65] and in a seminal study conducted by Riegel and Carlson,[66] patients who underwent an intervention to improve peer and social support demonstrated a 8.7% increase in perceived self-care management ability (r = 0.46; moderate effect), and a 6% increase in self-care confidence (r = 0.62; moderate/large effect).[66] In contrast, poorer social support was an independent predictor of reduced health-related quality of life (β = −.132; *P* < .001), worse depressive symptoms (sβ = −.467; *P* < .001) and was associated with a 50% increased risk of hospitalization and death.[67,68] Thus, there is an apparent association between social support and key outcomes in patients with HF.

It is unclear whether patients with comorbid chronic conditions like COPD and HF may require more perceived social support compared with individuals who have a single chronic condition. It is plausible that the additive self-care requirements from each disease would warrant greater perceived social support. It is vital that the instruments used to measure perceived social support have psychometric rigor in patients with comorbid conditions, so that the data obtained are reliable, valid and useful. Thus, the purpose of this secondary analysis was to examine the psychometric properties of the Multidimensional Scale of Perceived Social Support in patients with comorbid COPD and HF. The specific aims of this study were to provide evidence of internal consistency reliability and construct validity by factor structure and hypothesis testing. We

hypothesized that higher perceived social support scores would predict better self-care management.

Methods

Design and Sample

This study was a secondary data analysis from a large, multicenter HF registry. This registry contains data from 4,076 inpatient and outpatient participants who were recruited from cardiology centers located in the Southern and Midwest United States.[51,56,67-72] Recruitment and inclusion criteria were consistent across studies; study participants had a confirmed diagnosis of HF with either preserved or reduced ejection fraction, had a left ventricular ejection fraction (LVEF) $\leq$ 40%, were 18 years or older, and had not had a myocardial infarction within three months of enrollment. The selected participants (N = 303) had complete data for demographic (gender, age, ethnicity, marital status, years of education, smoking history) and clinical variables (diagnosis of HF, diagnosis of COPD, LVEF, body mass index [BMI], New York Heart Association [NYHA] functional class), and scores on the Multidimensional Scale of Perceived Social Support (MSPSS), and self-management scores from the Self-Care for Heart Failure Index (SCHFI).

Measures

Demographic and clinical variables were collected by interview of patients and review of medical records. Demographic variables collected included gender, age, ethnicity, marital status, years of education and smoking history. Clinical variables include current diagnosis of COPD and HF, LVEF, BMI and NYHA functional class.

Perceived Social Support

There is no consensus definition of perceived social support. However, perceived social support is generally considered to be the physical, cognitive and psychological benefits of interacting with other people.[73] Zimet and colleagues[74] developed the Multidimensional Scale of Perceived Social Support (MSPSS) to measure perceived availability and sufficiency of support from family, friends and significant others.[74] The MSPSS is a self-report instrument with 12 items that are rated on a 7-point Likert scale, ranging from 1 "strongly disagree" to 7, "strongly agree"; this instrument has 3 subscales; family, friends, and significant other. "Significant other" is intentionally undefined so that the respondent can identify their own significant other(s).[74,75] The MSPSS is scored by summing the responses of the 12 items; total scores range from 12 to 84, and higher scores indicate higher levels of perceived social support. The three subscales are also scored individually and may be used independently in analyses.[74,75]

Internal consistency for this instrument in patients with HF previously ranged from 0.85 to 0.94.[68,76] During the initial instrument development, internal consistency for the subscales ranged from .85 to .91, and test-retest reliability ranged from .72 to .85;[74,75] internal consistency for the family, friends and significant other subscales in patients with HF were .94, .94, and .94 respectively.[77] Adequate construct validity was demonstrated by repeated extraction of three factors in patients with HF[77] as well as other populations including undergraduate students, pediatric residents, European adolescents, pregnant women and patients with end stage renal disease.[74,75,77,78]

Self-Care Management

Self-care management is the process by which individuals with chronic disease attain optimal health through learned, intentional actions that include symptom recognition and response, adherence to prescribed treatment and medications, intentional lifestyle alterations, regular interaction with health care professionals, and evaluation of these actions.[13] Self-care management was measured with the Self-Care Management subscale of the Self-Care of Heart Failure Index (SCHFI).[79] The SCHFI comprises three subscales labeled self-care maintenance, self-care management, and self-care confidence; each scale is measured and evaluated independently.[79] Only the self-care management subscale was used for our analyses because it assesses symptomatic patients and their ability to perform management level behaviors, which are theoretically indicative of self-care mastery.[80] This subscale contains six items that measure symptom recognition, implementation of treatment strategies, and evaluation of treatment strategies. This subscale uses a 4-point Likert scale where 1 signals *rarely or never*, 2 signals *sometimes*, 3 indicates *frequently*, and 4 indicates *always or daily*. The six item scores are summed, then transformed to produce a standardized range of potential self-care management scores from 0 to 100; higher scores indicate better self-care management ability.[79] A score of 70 or greater indicates adequate self-care management.[79] Cronbach's alpha for this subscale is acceptable and ranges from .597 to .70.[79,80] Evidence of construct validity for the SCHFI and self-care management subscale is strong, with consistent extraction of three independent factors (for each of the three subscales) and consistent loading of the appropriate questions on the self-care management construct.[79,80]

Procedure

The participants included in this secondary data analysis were recruited after each study was approved by the respective Institutional Review Board. All participants provided informed consent. Data were collected by nurse researchers who were trained to perform the study procedures. Nurse researchers were present during the data collection process to aid participants as needed. All data were double entered into a data spreadsheet (SPSS version 21, Armonk, NY) and evaluated for errors prior to analyses. We filtered the data registry to obtain those participants with complete data for the demographic, clinical and research variables of interest.

Data Analysis

Descriptive statistics, frequencies, means with standard deviations, and proportions were used to characterize the participants. To analyze the internal consistency of the MSPSS, Cronbach's alpha was calculated for the total instrument and three subscales. Item-item correlations were analyzed to ensure all correlation coefficients were above 0.3 and below 0.9. Split-half reliability analyses were also conducted for the total scale. A principal components factor analysis with a direct oblimin rotation was conducted to examine the factor structure of the 12-item MSPSS. Sampling adequacy was confirmed by a Kaiser-Meyer-Olkin measure above 0.5.[81] Bartlett's test of sphericity was conducted to assess if correlations between items were sufficiently large to conduct the analysis; a significant level of $< .05$ was used as the cut point for this analysis.[81] To further examine the construct validity of the MSPSS, hypothesis testing was performed

using multiple linear regression. We hypothesized that higher perceived social support score was a predictor of better self-care management score after controlling for age, gender, ethnicity, marital status, living situation, smoking status, education level, BMI, LVEF, and NYHA class. All data analyses were conducted using SPSS Version 24.0 (IBM, Armonk, NY). An a priori α level of ≤ 0.05 was used to determine significance.

Results

Characteristics of the participants

Participants with comorbid COPD and HF (N = 303) were primarily male (63%), Caucasians (65%) aged 61 $\pm$ 12 years on average (Table 1.) A majority of these participants were married or cohabiting (60%) and 74% reported living with someone. Approximately two thirds (62%) of participants were classified as NYHA class III/IV with an average LVEF of 37 $\pm$ 15%. A majority of participants had a prior smoking habit but had quit (43%), and 19% were current smokers. The average participant had 12.4 $\pm$ 3.6 years of education. Total perceived social support scores were moderately high with an average score of 63.5 $\pm$ 17.3 Average self-care management scores (55 $\pm$ 20) were below the recommended cutoff of 70, indicating poor self-management scores in these participants.

Internal Consistency Reliability

The MSPSS demonstrated excellent internal consistency yielding a Cronbach α = 0.93 for the total instrument, 0.95 for the Friend subscale, 0.92 for the Family subscale, and 0.92 for the Significant Other subscale. Analysis of item-item correlations ranged from .347 - .884. Cronbach's α did not increase during removal of each item during

reliability assessment. Split-half reliability analyses of the MSPSS resulted in a Spearman-Brown coefficient of .92; a Spearman-Brown coefficient above .80 indicates adequate correlation between split halves, and a good indicator of internal consistency of the MSPSS in this sample.[81]

Construct Validity

A principal components analysis was conducted on the 12 items of the MSPSS with a direct-oblimin rotation for this sample of patients with comorbid COPD and HF (Table 2.). A preliminary analysis was conducted to ensure the data were appropriate for further analysis by evaluation of the Kaiser-Meyer-Olkin statistic and Bartlett's test of sphericity. The Kaiser-Meyer-Olkin measure ensured sampling adequacy for this analysis with a KMO = .880, which is well above the recommended cutoff of ≥ 0.60.[81] Bartlett's test of sphericity (X^2 (66) = 3393.17, $p < .001$) indicated that the correlations between items were sufficiently large to conduct the analysis.[81] An initial analysis was conducted to obtain eigenvalues for each factor. Three factors had eigenvalues greater than Kaiser's criterion of 1 and accounted for 82.4% of the total variance; factor one had an eigenvalue of 6.89, accounting for 57.4% of the total variance, and the other two factors combined for 14.7% (eigenvalue 1.77) and 10.2% (eigenvalue 1.23) of the total variance.[82,83] The scree plot clearly supported a three-factor solution evidenced by a modest drop off after the third factor. Thus, three factors were retained for the final analysis. A factor cut-off was set at 0.40, with loadings below .40 eliminated from the final model.[84] As a result, there were no cross loadings of items between the three factors. Items that clustered on the same factor suggested that component 1 represented the Family subscale, component 2 represented the Friends subscale and component 3 the Significant Other subscale. The

extraction of three factors with no cross loadings replicated the original instrument development and provided support for the three-factor structure in those with comorbid COPD and HF.[74,75]

Multiple linear regression was used to evaluate construct validity of the MSPSS (Table 3.). We hypothesized that higher perceived social support score would be an independent predictor of better self-care management score after controlling for age, ethnicity, marital status, living alone, education level, smoking history, BMI and NYHA functional class. All variables were entered into the regression model in one block. The assumptions of linearity, independence of errors, homoscedasticity, outliers, and normality of residuals were evaluated and met before interpretation of results. In this model, perceived social support score significantly predicted self-care management score ($F[11, 291] = 2.463$, $p < .01$, $R^2 = .085$, adj $R^2 = .051$). Specifically, higher LVEF ($B = -.234$, $p < .01$) and better perceived social support score ($B = .151$, $p = 0.03$) were significant predictors of self-care management scores. Higher perceived social support was predictive of higher self-care management score; for every 1 unit increase in the MSPSS score, there was an associated 0.151 unit increase in self-care management score. For every 1% increase in LVEF, there was a 0.234 decrease in self-care management score. No other covariates were significant predictors of self-care management.

Discussion

We provided evidence that the MSPSS is a valid and reliable instrument when used to measure perceived social support in patients with comorbid COPD and HF. Our results supported the MSPSS as a highly reliable instrument with Cronbach's α consistently above .90 in these participants. Results from our factor analysis using

principal components yielded a 3-factor structure consistent with the factor structure elicited during the original scale development and with previous investigators.[74,75,77] We also conducted hypothesis testing to further test the construct validity of the MSPSS. We found that perceived social support score and LVEF significantly predicted self-care management score, which further supported the construct validity of the MSPSS in this population.

Our results demonstrated excellent internal consistency. However, Cronbach's α surpassed the recommended threshold of .90, indicating potential redundancy within the scale. Several items examined in the item-item correlation matrix had coefficients near .90; the correlation coefficient between item 6 (My friends really try to help me) and 7 (I can count on my friends when things go wrong) was .868; the correlation coefficient between item 9 (I have friends with whom I can share my joys and sorrows) and 12 (I can talk about my problems with my friends) was .884. High item-item correlations suggested redundant examination of perceived social support from friends. To further test for redundancy, the examination of Cronbach's α with deletion of items from the scale was conducted; Cronbach's α did not decrease below .90 when items were deleted, indicating redundancy was unlikely. Thus, our findings support strong reliability of the MSPSS in patients with COPD and HF.

A factor analysis using principal components with a direct oblimin (oblique) rotation yielded a 3-factor structure with items loading on each of the friend, family and significant other subscales. These results are consistent with previous factorial validity testing of the MSPSS; in patients with HF,[77] pregnant women,[75] adolescents,[75,78] and undergraduate students.[74] A three-factor structure was produced with items corresponding

to the dimensions of friends, family and significant other. The findings of our analysis are consistent with previous investigator's findings and support a three-dimension solution in patients with concomitant COPD and HF.

Previous investigators have supported the importance of perceived social support in performing self-care in COPD and HF populations separately; however, to our knowledge, investigators have not tested the association of perceived social support with self-care scores in patients with comorbid COPD and HF. Our results confirmed findings from previous investigators who found that higher levels of perceived social support were associated with better self-care management score.[59,62,65,66] Thus, social support is an important factor to consider when measuring self-care management for those with comorbid conditions such as COPD and HF.

Additionally, we also observed that LVEF was a predictor of self-care management score. For every 1% increase in LVEF, there was a 0.234 decrease in self-care management score. This finding is consistent with previous investigators who studied self-care management in patients with HF alone. Lee and colleagues [85] found that worse functional class (NYHA III/IV) and higher ejection fraction were significant predictors of poorer consulting behaviors; consulting behaviors were defined as actions taken by patients to seek guidance about worsening symptoms.[85] Patients with poor consulting behaviors scored an average 12.3 points lower on the self-care management subscale of the SCHFI compared to those patients who had good consulting behaviors.[85] Patients who did not have highly burdensome symptoms or greater functional impairment may have not needed to engage in self-care management behaviors;[85,86] the self-care management subscale is most relevant to symptomatic patients.[80] Thus, patients with a

higher LVEF likely had a lower symptom burden, which required less self-care management; subsequently, these patients may not have fully developed self-care skills.

Limitations

The participants included in this secondary data analysis were derived from a registry of patients with HF; thus, we had no control over the variables measured or the data collection process and could not appraise the data for accuracy or validity. The MSPSS and the SCHFI are self-report instruments and may be subject to social desirability bias. However, all data collection procedures were designed to reduce the potential for bias, and data input was evaluated by the original investigators for accuracy prior to analysis.

Conclusion

The MSPSS was demonstrated to be a reliable and valid measure of perceived social support from friends, family and significant others in patients with COPD and HF. Further studies are warranted to determine the psychometric properties of the MSPSS in patients with solely COPD, as well as to examine the relationship between comorbidities, perceived social support and self-care.

Table 3.1. Sample Characteristics (N = 303)

Variable	f (%) or mean ± SD
Age in years	61 ± 12
Gender	
Male	192 (63)
Ethnicity	
Other	105 (35)
Caucasian	198 (65)
Marital Status	
Single/Widowed	64 (20)
Married/cohabitate	181 (60)
Divorced/Separated	58 (19)
Live with someone	
Yes	225 (74)
Education in years	12.4 ± 3.6
Smoking History	
Current smoker	25 (34.7)
Non-smoker	47 (65.3)
BMI	31.5 ± 7.9
LVEF	37 ± 15
NYHA class	
I/II	116 (38)
III/IV	187 (62)
Perceived Social Support (MSPSS)	
Total score	64 ± 17
Friend subscale	19 ± 8
Family subscale	22 ± 7
Significant Other subscale	23 ± 7
Self-care management (SCHFI subscale)	55 ± 20

Table 3.1, Cont.

Abbreviations: BMI, body mass index [kg/m^2], LVEF, left ventricular ejection fraction, NYHA, New York Heart Association functional class

Table 3.2. Rotated Pattern Matrix of the Multidimensional Scale of Perceived Social Support in patients with COPD and HF (N = 303)

Item		Rotated Factor Loadings		
		Factor		
		1	2	3
Friend Support	6. My friends really try to help me.	.037	**-.895**	-.013
	7. I can count on my friends when things go wrong.	.014	**-.936**	.016
	9. I have friends with whom I can share my joys and sorrows.	-.012	**-.914**	-.035
	12. I can talk about my problems with my friends.	.024	**-.931**	.003
Family Support	3. My family really tries to help me.	**.929**	-.019	.070
	4. I get the emotional help and support I need from my family.	**.895**	-.004	-.052
	8. I can talk about my problems with my family.	**.773**	-.086	-.081
	11. My family is willing to help me make decisions.	**.903**	.027	-.004
Significant Other Support	1. There is a special person who is around when I am in need.	.116	.140	**-.867**
	2. There is a special person with whom I can share my joys and sorrows.	-.100	-.088	**-.913**
	5. I have a special person who is a real source of comfort to me.	-.030	-.116	**-.877**
	10. There is a special person in my life who cares about my feelings.	.071	.002	**-.834**
Initial Eigenvalues		6.890	1.767	1.227
Rotated Eigenvalues (direct oblimin)		5.143	5.115	5.274

Table 3.3. Multiple Linear Regression Variables Predicting Self-Care Management Score (N = 303)

Model Variable	**Unstandardized Coefficient**	**Standard error of the coefficient**	**Standardized coefficient**	**P value**
Age	.112	.107	.065	.30
Gender	3.546	2.711	.084	.19
Ethnicity	.010	2.416	.000	.99
Marital Status	.937	1.394	.043	.50
Living Situation	-.189	2.825	-.004	.95
Education Level	.141	.350	.025	.69
Smoking History	1.778	1.163	.096	.13
BMI	.153	.163	.059	.35
LVEF	-.319	.084	-.234	< **.01**
NYHA Class	1.175	1.644	.044	.48
Perceived Social Support (MSPSS total score)	.151	.070	.128	**.03**
Abbreviations: NYHA, New York Heart Association Functional Class; LVEF, left ventricular ejection fraction; BMI, body mass index; MSPSS, Multidimensional Scale of Perceived Social Support R^2 = .085, adjusted R^2 = .051, df = 11, model *F* statistic = 2.463, p = **.006**				

CHAPTER FOUR

Effect of an eHealth Self-Care Educational Intervention on Symptom Severity and Variability, Psychological Distress, Self-Care Ability, and Treatment Adherence and Knowledge in Patients with COPD.

Synopsis

Patients with chronic obstructive pulmonary disease (COPD) experience a variety of burdensome symptoms and are at higher risk of developing psychological symptoms like anxiety and depressive symptoms compared with healthy individuals. Due to the high symptom burden and progressive nature of COPD, healthcare providers prepare patients with COPD to perform considerable self-care at home. This manuscript reported a study about the effect of a theory-based, self-care education program on symptom severity and variability, anxiety and depressive symptoms, perceived self-care ability, self-care adherence, and perceived knowledge needs in patients with COPD. This intervention resulted in significant change in symptom severity evaluation in subsets of patients. Perceived self-care ability was unchanged; however, perceived self-care adherence scores improved, and knowledge needs were significantly reduced after the intervention.

Introduction

Chronic obstructive pulmonary disease (COPD) is predicted to be the third leading cause of death worldwide by 2030.[1] In the United States, the estimated prevalence of COPD ranged from 15 to 22 million (7-9% of the U.S population).[2,3] Up to 99% of patients with COPD reported daily symptoms like dyspnea and fatigue, and 7% to 80% of patients with COPD described feeling anxious and/or depressed. COPD patients are 85% more likely to be diagnosed with an anxiety disorder compared to healthy controls, and twice as likely to be hospitalized for acute exacerbations.[23,38,87] Due to the high symptom burden and progressive nature of COPD, healthcare providers prepare patients with COPD to perform considerable self-care at home. However, Nici and colleagues[24] suggested that approximately 60% of patients with COPD do not demonstrate prolonged retention of self-care behaviors.

In the middle range theory of self-care of chronic illness, self-care is defined as the process by which individuals with chronic disease attain optimal health through learned, intentional actions that include symptom recognition and response, adherence to prescribed treatment and medications, intentional lifestyle alterations, regular interaction with health care professionals, and evaluation of these actions.[16] The increased incidence and prevalence of COPD has been the impetus for the development of education and training programs focused on self-care behaviors for these patients. These structured, multi-faceted interventions aimed to educate, motivate, engage, and support patients to adapt their health behaviors and develop skills to prevent exacerbations requiring hospitalization, and to provide relief of symptoms. [4,14-17]

There is a plethora of evidence to support an association between self-care interventions and decreased dyspnea burden in this population; patients receiving self-care interventions exhibit a 4.1%, to 16.6% decrease in dyspnea post-intervention compared to controls.[88-90] However, researchers have yet to demonstrate whether self-care interventions have a significant effect on other highly burdensome symptoms such as distress due to cough, chest tightness, distress due to mucous production, or fatigue. Previous investigators have concluded that patients with COPD experienced an assortment of symptoms with varying levels of intensity and variability throughout the day, and from day to day; during any given day, 45.4% of people experience dyspnea, 60.1% had troublesome cough, 70.9% reported distress from mucous, 45.4% had chest tightness, and 43.3% reported wheezing.[5,91] Longitudinal symptom data in this population are lacking. Prior investigators predominately assessed symptom severity and variability using a cross-sectional approach, which failed to adequately capture daily symptom profiles over time.[5,6,91] Consequently, researchers have been unable to examine the relationship between longitudinal trends in symptom variability and self-care strategies aimed to reduce symptom burden.

Patients with COPD also experienced symptoms related to their mental health. Approximately 7-80% of patients with COPD described daily anxiety with up to 40% reporting symptoms consistent with clinical anxiety and 25% with clinically significant depressive symptoms.[12,23,92] Previous investigators concluded that self-care interventions had no effect on anxiety and depression scores compared to those of a control group.[88,89,93-95] However, poor or ineffective management of anxiety or depressive symptoms was independently associated with a 1.89 and 2.98 increased risk of

hospitalization, respectively.[28] These investigators concluded that anxiety and depressive symptoms were important outcomes for patients with COPD, and future research is warranted to explore the relationships between self-care and mental health outcomes.

To date, studies of self-care interventions have been primarily longitudinal with periodic measures of outcomes collected monthly over the course of 3 to 12 months.[88]Studies of symptom severity and variability have primarily been cross-sectional and have not examined symptom patterns in patients with COPD. Prior investigators have not tested the effect of a self-care intervention on disease-related symptoms in the period immediately following an intervention. Thus, it is unclear how quickly improvement occurs after an intervention.

Previous self-care interventions have improved health related quality of life by 4.87% – 6.5%,[15,18] reduced dyspnea scores by an average 16.6%,[88] decreased risk for all-cause hospitalization by 40%,[20,21,88] reduced anxiety by an average 2.7%, and reduced depression by an average of 2.9%.[22,23] However, evidence is lacking about the immediate effects of self-care interventions on perceived symptom severity and variability (distress due to cough, chest tightness, distress due to mucous, dyspnea, or fatigue), perceived self-care ability, self-care adherence, and self-care knowledge. We also lack data about the use of electronic strategies for intervention delivery in this patient population. Thus, the purpose of this study was to test the effect of a theory-based, self-care education program using an eHealth platform on measures of symptom severity and variability (distress due to cough, chest tightness, distress due to mucous, dyspnea with activity, dyspnea at rest, fatigue, anxiety, and depressive symptoms), perceived self-care ability, self-care adherence, and self-care information needs (knowledge) in a sample of adult patients

with stable COPD. We hypothesized that participants would report lower levels of symptom severity and variability, reduced anxiety and depression scores, better perceived self-care ability and perceived self-care adherence, and fewer self-care information needs during the intervention period (Days 8 – 21) compared to the pre-intervention period (Day 1 – 7).

The aim of this study was to evaluate the effect of a 14-day, theory-based, eHealth, self-care educational intervention on symptom severity and variability scores (distress due to cough, chest tightness, distress due to mucous production, dyspnea with activity, dyspnea at rest, fatigue, anxiety, and depressive symptoms), perceived self-care ability scores, perceived self-care adherence scores (nutrition, physical activity, mental health, breathing control, medical management, environment modification, and exacerbation planning), and self-care information needs (knowledge scores) with baseline measures in a group of stable patients with COPD (N = 20).

METHODS

Design

A quasi-experimental, simple, unbalanced, interrupted time series design (21 days) was used to determine the effect of an eHealth self-care educational intervention. A simple unbalanced design was chosen so that participants served as their own control (Days 1 – 7 no intervention, Days 8-21 intervention). Efficacy of the eHealth intervention was determined by comparing data from the pre-intervention phase (Days 1-7) to data from the intervention period (Days 8-21). Measures of symptom severity and variability, perceived self-care adherence, self-care ability, and perceived COPD-specific knowledge

needs were collected in a group of stable patients with COPD. Symptom data were measured daily to evaluate symptom severity and variability. Measures of anxiety, depression, and perceived self-care ability were measured at baseline, Day 8, Day 15 and Day 21. Perceived self-care adherence and self-care information needs were measured at baseline and on Day 21.

Sample

Patients age 40 to 70 years of age who were in the clinic for a routine follow up visit with a primary or secondary diagnosis of COPD at a reigonal, community hospital-affiliated pulmonary clinic in the southern United States, were screened for eligibility. Patients were candidates for inclusion if they: 1) had a confirmed diagnosis of COPD verified by pulmonary function tests demonstrating moderate to severe disease according to GOLD criteria[4] (forced expiratory volume in one second [FEV_1]/ forced vital capacity [FVC] <70% and FEV_1 < 80%); 2) had stable disease state defined by absence of an exacerbation in last three months; 3) had access to home Wi-Fi internet; 4) could read, write and speak English; and 5) had a cell-phone with text messaging capabilities. Patients were excluded if they had: 1) presence of symptomatic cardiovascular diseases or severe systemic diseases (end-stage liver or renal disease, systemic lupus erythematosus or malignancy); 2) impaired eyesight prohibiting accurate visualization of tablet font as evidenced by failure to correctly read the tablet home screen application list; 3) cognitive impairment as demonstrated by a score of < 2 on the Mini-Cog; or 4) low health literacy as evidenced by a score of more than four incorrect responses on the Newest Vital Sign instrument.

A required sample size of 18 patients with at least 8 complete time points was determined by an a priori power analysis estimate. This estimate was based on a one-way repeated measures analysis of variance (ANOVA) power estimation with Greenhouse-Geisser approximation, obtained using nQuery Advisor,[96] which assumed there were 8 time-periods; 8 was the maximum number allowed by the software. With approximately 18 participants completing the trial, an alpha level of .05, and assuming that successive observations from the same participant had a modest correlation of at least 0.3, the power of the repeated measures F test to detect a medium effect size should exceed 69% to detect changes in outcomes in the time period pre-intervention to the intervention period. Two additional participants were added in case of attrition for a final sample size of 20 participants.

Measures

Clinical and sociodemographic variables

Sociodemographic variables included age, sex, ethnicity, highest education level, marital status, employment status, and living situation. Clinical data included height, weight, body mass index (BMI), spirometry measures (forced expiratory volume/second [FEV_1], forced vital capacity [FVC], FEV_1/FVC, reference FEV_1, reference FVC and reference FEV_1/FVC), GOLD stage (indicator of severity of disease), number of exacerbations in past year, smoking status (packs per day and pack years), and current prescribed medications. These data were obtained from medical record review and interview.

Symptom severity and variability

Symptom severity and variability were defined as the individual evaluation of the degree of intensity and self-perceived change in disease-related symptoms over the course of 24 hours for symptoms that included distress due to cough, chest tightness, distress due to mucous, dyspnea with activity, dyspnea at rest, and fatigue. A modified version of the Daily Symptom Scale (DSS)[97] was used to measure symptom severity and variability. The 6-item, modified DDS (symptom diary) prompted the participants to rate the severity of their symptoms daily. Symptoms were rated on a 100-point visual analog scale (VAS) where 0 was absence of a symptom and 100 was the most distressful the symptom could be.[97] The DDS has been shown to be reliable in patients with similar chronic conditions such as cardiovascular disease and heart failure.[97] Face validity of the modified DDS was confirmed by two pulmonary care experts. Reliability of a computerized visual analog scale has been shown to be low to moderate with test-retest reliability coefficient of 0.44 – 0.56 and strong convergent validity was demonstrated with non-computerized measures.[98]

Anxiety and depressive symptoms

Anxiety is a feeling of worry, nervousness, or unease, typically about an imminent event or something with an uncertain outcome.[99-101] Depressive symptoms can be characterized by feelings of sadness, loss of interest and potential suicidality.[102] The Hospital Anxiety and Depression Scale (HADS) was used to measure anxiety and depression.[103] The HADS is a 14-item self-report questionnaire with a 7-item anxiety subscale and 7-item depression subscale. The anxiety subscale (HADS-A) reflects a state of generalized anxiety and the depression subscale (HADS-D) primarily focuses on the

concept of anhedonia commonly experienced in depression. Each question is rated on a 4-point Likert scale ranging from 0 - absence to 3 - extreme presence. Each subscale can be used independently, and scores range from 0-21 for each subscale; a total score out of 42 is calculated, with higher scores indicating greater levels of anxiety, depression and overall psychological distress.[103,104] Subscale scores of eight or higher indicate probable anxiety and/or depressive symptoms; the HADS has well established validity, reliability and diagnostic accuracy for measurement of anxiety and depressive symptoms in patients with COPD.[103,105-108]

Self-care ability

Self-care ability was defined as, "the core behavioral and cognitive abilities which presumably contribute to sustainable well-being".[109] Self-care ability was measured with the Self-Management Ability Scale-Short (SMAS – S),[109] a shortened version of the SMAS-30.[110] It is an 18-item questionnaire that has been used in patients with COPD[111,112] and other chronic illnesses.[111] The SMAS-S total score assesses self-management ability with items in six sub-scales that include taking initiative, investment behavior, variety, multi-functionality, self-efficacy and positive frame of mind.[18,110,113] The taking initiative, investment behavior, and positive frame of mind subscales are scored on a 6-point Likert scale, with responses ranging from "never" to "very often". The variety subscale is scored on a 6-point Likert scale with responses ranging from "none" to "more than six". The multi-functionality subscale is scored on a 5-point Likert scale with responses ranging from "strongly disagree" to "strongly agree". The self-efficacy subscale uses a 5-point Likert scale with responses ranging from "I'm certain that I cannot" to "I'm certain I can". Each sub-scale can be used independently, or all 18

questions can be used as a total composite score for self-care ability. The higher the score, the better the perceived self-care ability; total scores can range from 18 to 102, and there is no established cutoff for this scale.[109] The six sub-scales had satisfactory internal consistency with Cronbach's α ranging from 0.69 to 0.77. Construct validity was determined using confirmatory factory analysis and hypothesis testing, which yielded unidimensionality among each of the subscales, underlying factors measured the theoretical constructs of self-care ability, and moderate to high correlation with other established measures of self-care and well-being in patients with COPD and other similar chronic illnesses.[109,111]

Self-care adherence

Self-care adherence was defined as the extent to which an individual follows the self-care recommendation/prescription.[114] Self-care adherence was measured with a modified version of the Medical Outcome Study Specific Adherence Scale (MOS-SAS).[114] The modified MOS-SAS is an eight-item instrument that assesses adherence for each of the seven self-care domains included in this study. These included nutrition and diet, physical activity, mental health, breathing control, medical management, environment modification, and exacerbation planning. The MOS-SAS evaluates, "How often have you done each of the following in the past week?" and each answer is measured on a 6-point Likert scale ranging from 0-none of the time, to 5-All of the time. Each response is weighted to achieve a range of possible total score of 0–100; all items are added then averaged and there are no established cut points for this scale.[115] Internal consistency for the MOS-SAS ranged from 0.50 to 0.78 in similar chronic disease populations who require sustained, lifelong treatment (diabetes, hypertension and heart

failure).[114] Strong convergent validity has been established in the MOS-SAS with other measures of self-care maintenance, self-care management and self-care confidence in cardiovascular populations.[116]

Self-care information needs

Self-care information needs were defined as the content required by an individual so they can perform self-care.[117] Self-care information needs were measured with the Lung Information Needs Questionnaire (LINQ).[117] The LINQ is a 16-item questionnaire developed to assess self-care information needs and COPD knowledge in patients with COPD.[117] Six domains comprise the LINQ; these include disease knowledge, medicines, self-management, smoking, diet, and exercise. Item scores for each domain are added to achieve a range of total scores from 0 to 25, with higher scores indicating higher information needs. There is no set cutoff for adequacy of informational needs. LINQ total score has satisfactory internal consistency with a Cronbach's α of 0.62.[117] Test-retest reliability for the total score was good (0.89) and for the six subscales, coefficients ranged from 0.66 to 0.98.[117] A series of focus groups that included patients with COPD and expert healthcare providers supported the content validity of the LINQ in measuring information needs in patients with COPD.[117]

Intervention

The educational intervention contained seven self-guided modules (Table 1.) These modules included nutrition and diet, physical activity and exercise, medications, breathing control, mental health, environment, and exacerbation planning. The educational modules contained material written at a fifth-grade reading level, and

imbedded videos. Information included in each module was derived from current self-care research evidence, [13-15,21,88,118-120] as well as current clinical guidelines from organizations that included the Global Initiative for Obstructive Lung Disease (GOLD),[4] American Lung Association,[121,122] American Thoracic Society,[123] and COPD Foundation.[124,125] All information was appropriate for individuals at any level of self-care proficiency. The educational intervention was housed on a password-protected webpage accessible via the study website, accessed by participants using a tablet computer. Participants were sent a text message containing a password to access the educational intervention eight days after completion of the baseline measures.

Text messaging to promote adherence

Participants also received daily text messages from the investigator (Days 2- 21). The text messages were sent between 1600 and 1900 every day, to remind the participant to complete their daily measures. Each text message was sent individually to maintain patient confidentially. Text messages were designed based upon the transtheoretical model of Prochaska and colleagues;[126] specifically two experiential processes of change were targeted, consciousness raising and dramatic relief. Moreover, the text messages were targeted and tailored to each participant as outlined by Noar and Harrington.[127] Text messages were tailored to reinforce targeted behaviors.

Procedure

Recruitment and enrollment

The Baptist Health Lexington and University of Kentucky Medical Institutional Review Boards approved this study. Eligible patients were approached by the principal

investigator who introduced himself and explained the purpose of the visit upon conclusion of the interaction with their pulmonologist. Before enrollment, potential participants were screened for mild cognitive impairment using the Mini-Cog©[128] and for adequate health literacy using the Newest Vital Sign.[129] Upon determination of adequate health literacy and absence of cognitive impairment, potential participants were asked whether they had in-home Wi-Fi and a cell-phone with text messaging capabilities. After enrollment, participants were provided with and trained in the use of a tablet-computer (Amazon Fire Tablet, 8 gigabytes, 7th generation); training included how to change settings (power on/off, volume, charging, accessibility display, Wi-Fi connection), how to access and complete a daily symptom diary, how to access the intervention education materials, and how to access and complete the other required instruments. Each participant was also given written instructions and reminders about when and how to access the components of the intervention, and how to contact the principal investigator if problems occurred. The tablet-computer was fully unlocked and pre-loaded with a link to the website with the intervention.

Baseline data collection took place in an empty exam room. All measures (Day 1 – 21) were completed wirelessly using an encrypted data collection system (Research Electronic DataCapture [REDCap]), housed behind a firewall at the University of Kentucky. Participants were given instructions to connect their tablet computer to their home Wi-Fi to ensure accessibility to the website. All data were automatically transmitted to REDCap upon completion of each instrument.

Baseline measures

Baseline measures were obtained for symptom severity (DDS for distress due to cough, chest tightness, distress due to mucous, dyspnea with activity, dyspnea at rest, and fatigue), anxiety and depressive symptoms (HADS), perceived self-care ability (SMAS-S), perceived self-care adherence (MOS-SAS) and self-care information needs (knowledge; LINQ). Participants completed the measures independently or with the help of their caregiver; the PI was present for assistance in using the tablet.

Daily Measures

Participants were asked to complete a daily symptom diary for the next 20 consecutive days (Table 2.), at a time of their choosing using the tablet-computer. On the website, there was a dedicated daily symptom diary section that contained separate links to each respective daily symptom diary. Participants were also informed that there would be additional measures of anxiety, depressive symptoms and perceived self-care ability on Days 8 and 15; at the end of the study (Day 21) participants repeated all measures.

Data management

Data files were assessed for missing data points and evaluation of data distributions in preparation for analysis. Data were screened using frequency distributions to evaluate the degree of missing data and the presence of outliers. Missing data were not imputed and were left missing. Outliers and leverage points were left unadjusted.

Data analysis

Descriptive statistics including means (standard deviations) and frequencies (percent) were used to characterize the sample. Symptom severity was determined for each symptom by calculating the mean of symptom ratings pre-intervention, during the

intervention period, and across the entire 21-day reporting period for each participant. Participants were then categorized into tertiles of low (n = 7), medium (n = 6) or high severity (n = 7) for each symptom, based upon the pre-intervention mean (day 1 – 7). Symptom variability was determined by calculating the standard deviation of symptom ratings pre-intervention, during the intervention period, and across the 21-day reporting period for each participant. Based upon the standard deviations calculated in the pre-intervention period, patients were then categorized into tertiles of low (n = 7), medium (n = 6) or high variability (n = 7) for each symptom.

To determine the effect of the intervention on symptom severity and variability, multilevel growth models (MGMs) were constructed using the fixed effects of symptom severity group (low, medium high), symptom variability group (low, medium, high), intervention status (pre-intervention [Day 1-7] or intervention period [Day 8 – 21]), symptom severity group by intervention status, and symptom variability group by intervention status; each participant was modeled as a random effect with random intercepts and random slopes, using an identity covariance structure, and all estimations were made using maximum likelihood estimation. Each growth model was constructed to examine symptom severity (distress due to cough, chest tightness, distress due to mucous, dyspnea with activity, dyspnea with rest, and fatigue) as a function of time; time was centered on zero (Days 0-20). To determine the best fitting model for predicting change in symptom severity, a sensitivity analysis analyzing the -2Log Likelihood (-2LL) was conducted. Two MGMs were constructed and compared for each symptom; in the first model, symptom severity group (low, medium, high) and symptom severity group by intervention status were imputed as factors; in the second model, symptom variability

group (low, medium, high) and symptom variability group by intervention status were imputed as factors.

To examine the consistency of symptom variability between the pre-intervention and intervention periods, a series of McNemar tests were conducted. Symptom variability was determined by calculating the standard deviation of symptom scores for each symptom, during the pre-intervention period and intervention period; based on the standard deviations, participants were placed into low or high symptom variability groups. The median standard deviation for each symptom in the pre-intervention period was used as a reference point to categorize participants into either high or low variability. For each symptom, 10 participants were in each category for the pre-intervention period. Then, standard deviations were calculated for the intervention period; values were assessed using the median standard deviation from the pre-intervention period. Using the median value from the pre-intervention period, participants were then categorized as low or high variability for the intervention period. By using the pre-intervention median value as a reference point, participants could be evaluated for improvement or worsening of standard deviation values for each time period.

To further examine the effects of the intervention, three repeated measures ANOVAs (RM-ANOVA) were conducted to compare mean scores for anxiety, depressive symptoms and perceived self-management ability at baseline to measures collected on, Day 7, Day 15 and Day 21. Paired sample t-tests were conducted to compare mean perceived self-care adherence and perceived self-care information needs scores between pre and post intervention. All analyses were performed using SPSS version 24 (IBM, Armonk, NY) with an a priori $\alpha = 0.05$ to indicate significance.

RESULTS

Characteristics of the participants

A total of 133 patients were screened for eligibility (Figure 1.). Thirty-seven patients met eligibility criteria and were screened for cognitive function and health literacy; 17 were excluded. Nine patients were excluded for mild cognitive impairment, 5 were excluded for inadequate health literacy, 2 were excluded due to an inability to use the tablet, and 1 declined the invitation.

Participants (n = 20) in this study were primarily female (65%), obese (mean BMI 30.2 $\pm$ 7.6) Caucasian (90%), and on average 62 $\pm$ 7 years of age (Table 3.). A majority of participants had at least a high school education (60%), were single, widowed, or divorced (65%), and were not working due to disability, retirement or lack of employment (60%). A majority of the participants were categorized GOLD stage III/IV (55%); the mean % predicted FEV_1 was 43 $\pm$ 15%. On average, participants reported 1.5 $\pm$ 1.2 exacerbations requiring hospitalization in the prior year. Eight participants (40%) reported they were current smokers, while 50% of participants had quit smoking at some point. On average, participants had 6.6 $\pm$ 4.6 comorbidities and were prescribed 12.9 $\pm$ 6.6 daily medications. Participants submitted 401 (95.5%) daily symptom diaries. Fourteen participants (74%) completed 100% of their daily diaries. Six participants contacted the investigator with issues using the tablet or website. One participant was lost to follow up on Day 11 due to an exacerbation requiring hospitalization.

Symptom severity and variability

Symptoms were measured daily by participants for 21 days using a 0 to 100 VAS (Table 2.). At baseline, score for distress due to cough averaged 26.6 $\pm$ 25.4, for chest tightness 28.8 $\pm$ 24.1, distress due to mucous 27.9 $\pm$ 22.3, for dyspnea with activity 45.4 $\pm$ 27.8, for dyspnea at rest 25.8 $\pm$ 26.1, and fatigue 38 $\pm$ 26.8. Paired sample t-tests were used to compare mean values between baseline and intervention scores. There were no significant differences in means between the two time periods for the six symptoms.

To determine whether symptom severity group or symptom variability group were predictors of symptom scores over time, we conducted a sensitivity analysis for each MGM. Results from sensitivity analyses revealed that symptom group severity and the interaction term of symptom group severity by intervention status produced lower -2LL statistics for all six symptoms; thus, all reported MGM results hereafter reflect the effects of symptom severity group. MGM analyses determined there was no significant effect of the intervention on average symptom severity for any of the six symptoms (p = .08 – 0.97). However, there were significant interactions of severity group by intervention status for distress due to cough, chest tightness, dyspnea with activity, and fatigue (Table 4; Figure 2.). Those who were in the medium tertile for distress due to cough at baseline demonstrated an increase in reported distress due to cough after the intervention (*b* = 10.16, 95% confidence interval [CI] 1.95 – 18.40, *t*(83) = 2.46, p = .02) compared to those in the other two tertiles. Individuals in the medium tertile for severity of chest tightness at baseline reported significantly worse severity after the intervention (*b* = 8.47, *t*[103] = 2.06, p = .04); while those in the high tertile reported significantly lower severity of chest tightness after the intervention (*b* = -8.15, *t*[113] = -2.03, p = .04). Dyspnea with

activity in the medium tertile increased after the intervention (b = 13.18, t[82] = 1.97, p = .05). Those who were in the medium tertile for fatigue at baseline also reported a significant increase in distress (b = 16.48, t[134] = 3.89, p < .01) compared to the low or high tertile.

A series of McNemar tests was conducted to examine the consistency between the number of participants in high or low variability group between the pre-intervention and intervention periods (Table 5.). There were no significant differences in proportion of participants categorized as high or low symptom variability from the pre-intervention period to the intervention period.

Comparison of anxiety, depressive symptoms, and perceived self-care ability

Anxiety, depressive symptoms, and perceived self-care ability scores were measured four times (baseline, Day 8, 15 and 21) and compared with RM-ANOVA (Table 6.). At baseline, anxiety scores averaged 6.6 $\pm$ 3.3, depressive symptoms 5.6 $\pm$ 3.5, and perceived self-care ability averaged 58.9 $\pm$ 12. There were no significant differences in scores among the measurement times (p = .62; p = .66; p = .07, respectively).

Comparison of self-care adherence and self-care information needs

Perceived self-care adherence and perceived self-care information needs were measured at baseline and on Day 21 after completion of the intervention. Baseline mean scores were compared to scores obtained on Day 21 with paired t-tests. Perceived self-care adherence scores increased significantly post intervention (baseline - 58.1 $\pm$ 19.3, post intervention - 67.6 $\pm$ 12.2, p = .025). Perceived self-care information needs were

significantly reduced after the intervention (baseline - 13.7 $\pm$ 3.1, post intervention - 11.3 $\pm$ 1.8, $p = .012$).

DISCUSSION

We tested the use an eHealth educational intervention for patients with COPD and evaluated its effect on symptom reporting, perceived anxiety and depressive symptoms, perceived self-care ability, adherence and needed knowledge. Symptom scores reported during the pre-intervention time period were of low to moderate severity, indicating that symptom burden for these participants was relatively modest. The most burdensome symptom was dyspnea with activity, which is common for participants with moderate to severe disease state. Participants in the middle tertile of reported symptom severity at baseline perceived that certain symptoms (distress due to cough, chest tightness, dyspnea with activity and fatigue) were more severe after the intervention. Those in the highest tertile for chest tightness severity reported less burdensome distress during the intervention period. There were no significant changes in anxiety, depressive symptoms, or perceived self-care ability after the intervention. However, perceived self-care adherence scores significantly improved, and self-care information needs were significantly reduced after the intervention.

Our participants interacted with the intervention and were adherent to completion of the study instruments. This level of interaction was consistent with previous investigators who tested an eHealth intervention and used tailored text messaging to promote adherence; adherence to daily symptom diaries and/or intervention activities have been reported to be as high as 92% to 99%. [130-132] The engagement of our participants with the study may be attributed to a number of factors. First, the daily

tailored and targeted text messages were sent to participants to promote completion of daily diaries; previous investigators have shown that targeted and tailored text messaged aimed to promote desired behaviors resulted in higher completion rates in studies assessing adherence in chronic illness.[133,134] Second, the participants included in this sample were a non-probability sample; thus, they were willing to participate and engage upon enrollment. Third, the intervention was built to be engaging by using plain, understandable language that was applicable to patients at any level of self-care proficiency, and information was presented with a variety of different mediums (text, pictures, and videos) to prevent boredom with the intervention. Thus, it is plausible these strategies were successful.

Using baseline symptom severity measures, participants were placed in tertiles that represented low, medium and high severity of each symptom. Multilevel growth models were constructed using the symptom severity group (low, medium high), intervention status (pre-intervention [Day 1-7] or intervention [Day 8 – 21]), and the interaction term of symptom severity group by intervention status as factors. We found several significant interactions between symptom severity group and the intervention, which indicated the effect of the intervention was dependent on the severity group. Those participants who were in the low symptom severity tertile at baseline reported no significant changes in perceived symptoms over the 21-day reporting period. Participants in the medium tertile group, reported a significant increase in severity of distress due to cough ($p = .02$), chest tightness ($p = .04$), dyspnea with activity ($p = .05$), and fatigue ($p < .01$). Participants in the high severity tertile for chest tightness ($p = .04$) reported a significant reduction in this symptom over time. Those participants in the medium

severity tertile likely became more aware of their daily symptoms using the daily diary; thus, the educational intervention may have helped them evaluate their symptoms differently, potentially more accurately. Those participants in the high severity tertile for chest tightness reported a less severe symptom during the intervention period; thus, participants determined that their distress due to chest tightness was reduced after the intervention. Participants either experienced reduced symptom severity or the educational intervention altered their evaluation of this symptom. Also, symptoms determined to be maximal can only improve. Thus, the change in symptom evaluation was dependent on their baseline severity perception of symptoms.

Previous investigators have examined the effects of a self-care interventions on symptom burden over the course of 3, 6 and 12 month follow-up periods.[87,120,135] In a recent meta-analysis of studies about the effects of self-care interventions on outcomes, the investigators concluded that self-care interventions decreased symptom burden by 6.6% on average.[87] However, in a number of the trials included in this meta-analysis, the investigators determined that symptom burden remained unchanged or increased after implementation of a self-care intervention.[136-139] Bourbeau[137] and Monninkhof[136] found no changes in symptom burden at 4 and 12-month follow up. Taylor and colleagues[139] found an increase in symptom burden by 4.7% at six month follow up; McGeoch and colleagues found an increase in symptom burden by 4.7% at 12 months post intervention.[138] These investigators proposed several explanations for this. First, the intervention potentially raised awareness of the individual to disease-related symptom perception; thus, the reported symptom severity increased over time.[138,139] Second, the observed symptom severity in previous studies was low to moderate at baseline; this may

have limited the ability to detect minute changes in symptoms over time.[138] Third, the intervention tested may have been ineffective at changing symptom perception.[136-139] [140,141] It is possible that the intervention in these studies did not affect symptom severity, and reported symptom severity remained unchanged or increased naturally over time. Moreover, the measures used may not have been sensitive enough to detect a small degree of change in symptoms. Previous investigators have concluded that the severity and variability of reported symptom burden varied from 10% to 20%,[142,143] which indicated that patients may have difficulty conceptualizing symptom experience as a number. These investigators also reported symptoms like pain were easier for patients to conceptualize as a number when compared to others like fatigue; investigators also suggested that patients may not regularly quantify some symptoms making perception of a symptom score difficult and insensitive to small changes.[142,143]

We proposed that the participants in the middle tertile experienced an increase in symptom burden (distress due to cough, chest tightness, dyspnea with activity and fatigue) due to a combination of an increased focus on symptom perception, and the educational content about symptom monitoring. Previous investigators[13,16,144] have hypothesized that regular monitoring of symptoms increased perception and sensitivity to symptom change and resulted in participants actualizing their symptoms more accurately. In our educational intervention, participants were provided education to aid in identifying each symptom, and to evaluate the severity at that time; this may have resulted in an increased somatic awareness, with more sensitive symptom recognition, evaluation, and interpretation. There is also evidence to suggest that those with more severe disease might be less sensitive to change in symptom severity, and these individuals might be

worse at performing self-management behaviors, such as responding to changes in symptom severity.[140,144] Bringsvor and colleagues[140] proposed that as participant symptom burden increased, they reported fewer health-directed behaviors (i.e. symptom monitoring, physical activity, relaxation), which then may have negatively influenced symptom burden and severity. Previous investigators have examined patient ability to recall daily symptoms throughout any given day, day to day or weekly.[142,145] Investigators found that patient report of average symptom experience over a week were not as precise as measures of symptom experiences made at their lowest (least burdensome) or highest (most burdensome) time point.[143] Thus, more frequent evaluation may be more precise. In our study, patients in the medium tertile experienced the greatest symptom change over time and with daily evaluations were more aware of these changes. Our participants in the low and high symptom severity tertiles likely had more consistent symptom experiences. However, further studies are necessary to examine the relationship between symptom severity and symptom perception in patients with COPD.

On average, our participants did not meet the HADS cut points for presence of anxiety and depressive symptoms. There were no significant changes in anxiety and depressive symptom scores between baseline measures and those made on 8, 15 or 21. We hypothesized that there would be a decrease in the anxiety scores and decrease or no change in depression scores after the intervention. However, our results did not support our hypothesis. Some previous investigators also found that self-care interventions had no effect on anxiety and depression;[92-94] while other investigators reported improvement in anxiety and depression scores after an intervention.[89,146,147] Investigators who found no improvement generally studied participants with low anxiety and depression scores;

anxiety and depression subscale scores on average were less than 5.5 for the HADS subscales in these participants.[92-94] However, those investigators who reported improvement in anxiety and depression scores studied participants whose anxiety and depressive symptoms scores indicated more severe symptoms.[146,147,89] Thus, self-care interventions improved anxiety and depression scores when participants were actually anxious and had depressive symptoms. Our participants did not report a significant degree of anxiety and depressive symptoms at baseline; thus, there was no improvement. Clearly, the initial degree of mental distress will influence the degree of change possible.

At baseline, our participants reported a moderate to high level of perceived self-care ability. We recruited a convenience sample of patients from a local pulmonary clinic. It is likely that those who were interested in and volunteered for participation in this study were already engaged in self-care activities to some degree. A majority of our participants completed more than a high school education, and we screened for adequate health literacy and satisfactory cognitive function; thus, our participants may not represent the typical patient with COPD.

The lack of change in perceived self-care ability could be due to the short time period of the study or a lack of sensitivity of the SMAS-S to small change. Self-management abilities comprise a set of skills that are meant to be practiced, used and perfected over time; thus, self-care ability might continue to improve over time and not be reflected in these initial scores. A number of prior studies measured indices of self-care ability such as keeping follow up appointments, completing daily symptom diaries, taking prescribed medications, monitoring for changes in symptoms and contacting providers for suspected exacerbations.[148-150] Investigators for these studies reported no

change or a gradual decline of adherence to taking medications as prescribed, smoking habits or cessation, attending pulmonary rehabilitation, and reporting increasing symptom severity to practitioners.[148-150] Researchers postulated that this decline in self-care behaviors could be due to a loss of interest in self-care, increased complexity in prescribed treatment regimen, and poor quality of care from providers.[24,149] Additionally, Cramm and Nieboer [151] reported that higher perceived quality of care from providers and productive patient-professional interactions were significant predictors of higher perceived self-care ability scores in patients with COPD. However, previous investigators who examined self-care ability implemented a high dose of their intervention through repeated, structured interventions over the course of days to weeks; while we designed our intervention to be less structured and as a smaller dose. Thus, it is likely that our short time frame and low dose were not adequate to produce change. It is also possible that since perceived self-care ability was already moderately high in our participants, it is likely the intervention did not provide a dose adequate to produce an improvement and a probable ceiling effect was observed.

Our participants did demonstrate significant improvement in perceived self-care adherence and reduction in perceived self-care information needs. On average, our participants improved their perceived self-care adherence by 9.5% and reduced their perceived self-care information needs by 9.6% after the two-week intervention period. This is consistent with previous investigators who examined the impact of self-care interventions on adherence and self-care knowledge.[152,153] Leiva-Fernandeza and colleagues[152] tested a multidimensional self-care intervention and demonstrated that the experimental group improved perceived adherence by 30.5% compared to control. Smit

and colleagues,[153] assessed treatment adherence to smoking cessation behaviors (a component of self-care); participants were 85% to 99% more likely to abstain from smoking at one week and at 6 month follow up. Although the length of our intervention was brief (two weeks), we observed improvement in perceived self-care adherence and reduction in self-care information needs. Results from prior studies indicated that multidimensional self-care interventions were effective at improving treatment adherence, reduced perceived information needs, and led to sustained behavior change in patients with COPD.[152,153] Our study is similar to previous investigators in that we implemented a multifaceted and tailored intervention. However, we used an eHealth mode of delivery. Our results supported this strategy and demonstrated that participants actively engaged, learned and increased perceived adherence to self-care behaviors with a remote, electronic intervention that required minimal provider assistance. Future studies are needed to examine the long-term impact of self-care adherence and information needs using eHealth educational interventions in patients with COPD.

Limitations

There are several limitations of this study. The sample for this study was small and limited power to detect differences for some of our analyses. Although we were adequately powered for our MGM analyses, the measures may not have had sufficient sensitivity to detect change. This was a non-probability sample of relatively well educated participants with adequate health literacy and normal cognitive function. Second, self-report instruments were used in this study, which introduced the potential for social desirability and response bias. However, the variables we measured were subjective; thus, self-report was the only appropriate way to measure them.[154] Third, the

intervention exposure was of short duration because this was the initial step in the evaluation of dose response to this intervention. In addition, our participants did not report anxiety or depressive symptoms using the HADS. This instrument might not have been sensitive in this group of individuals; however, the HADs has been used in other samples of patients with COPD.[89,93-95,146,147] Also, our sample of participants had a high level of perceived self-care ability; thus, we were unable to determine whether the intervention can produce a change in people with low perceived self-care ability.

Conclusion

These participants had a low to moderate degree of symptom burden; dyspnea with exertion was the symptom with greatest severity. Our theory-based, self-care educational intervention delivery via electronic platform produced change in perception of distress due to cough, chest tightness, dyspnea with activity and fatigue in participants with a moderate degree of symptom burden; for those with high symptom burden for chest tightness, there was a significant decrease in reported symptom. The intervention produced an improvement in perceived self-care by nearly 10% and reduced perceived knowledge needs by almost 10%; thus, further testing of this intervention is supported. This study served as a preliminary study to support that patients with moderate to severe COPD have the ability to routinely record their symptoms remotely and participate in self-guided self-care education modules.

Table 4.1. Description of the seven educational components included in the intervention

Self-Care Component	Primary Content Covered	Delivery/ Teaching Style Used
Nutrition/Diet	1. Caloric intake and weight management 2. Macronutrients 3. Meal timing and portions 4. Water consumption 5. Vitamins, minerals, and dietary supplements	Print, Pictures, Informational Videos,
Physical Activity and Exercise	1. Physical activity promotion 2. Recommended exercises for people with COPD 3. Amount of exercise per day/week 4. Breathing control while exercising 5. Developing prolonged exercise habits	Print, Pictures, Videos, Interactive Videos
Medications	1. Compiling an accurate list of medications 2. Knowing the timing and dosing of daily medications 3. Pharmacological and non-pharmacologic ways to manage acute symptom onset 4. Establishing the most common side effects of different medications 5. Establishing an action plan for when symptoms need acute treatment	Print, Pictures, Videos, Interactive Videos

Table 4.1, Cont.

Breathing Control	1. Pursed lip breathing 2. Diaphragmatic/belly breathing 3. Utilizing rest to prevent dyspnea 4. Postural positioning for optimal breathing 5. Using relaxation techniques to combat the anxiety-dyspnea cycle	Print, Pictures, Videos, Interactive Videos
Mental Health	1. Identification of life stressors 2. Developing a plan to combat common life stressors 3. Utilization of breathing techniques to reduce anxiety/dyspnea 4. Non-traditional ways to cope with anxiety: meditation, mindfulness, muscle relaxation, biofeedback, and distraction therapy 5. Identifying anxiety and depressive symptoms	Print, Pictures, Videos, Interactive Videos
Environmental Modification	1. Smoking cessation/avoiding lung irritants 2. Involvement of caregiver/significant other/friend/family with medical care 3. Promoting social interaction 4. Energy conservation 5. Modifying living arrangements	Print, Pictures, Videos
Exacerbation Planning	1. Developing an action plan 2. Establishing symptom norms and knowing when to seek help 3. Identifying where is most appropriate to seek medical treatment	Print and Pictures

Table 4.1, Cont.

	4. Identifying early warning signs of worsening symptoms 5. Medication uses when symptoms become worse	

Table 4.2. Timing of variable measurements

Baseline measures without intervention							
Week 1	Day 1 – consent Sociodemographic Symptoms Depression/Anxiety Perceived Self-Care COPD Knowledge Self-care Adherence	Day 2 Symptoms	Day 3 Symptoms	Day 4 Symptoms	Day 5 Symptoms	Day 6 Symptoms	Day 7 Symptoms
Measures during intervention							
Week 2	Day 8 Symptoms Depression/Anxiety Perceived Self-Care	Day 9 Symptoms	Day 10 Symptoms	Day 11 Symptoms	Day 12 Symptoms	Day 13 Symptoms	Day 14 Symptoms
Week 3	Day 15 Depression/Anxiety Perceived Self-Care	Day 16 Symptoms	Day 17 Symptoms	Day 18 Symptoms	Day 19 Symptoms	Day 20 Symptoms	Day 21 Symptoms Depression/Anxiety Perceived Self-Care COPD Knowledge Self-care Adherence

Table 4.3 Characteristics of participants

Characteristic	**Total Sample** **N = 20**
Age in years	62 ± 7
Female	13 (65%)
Ethnicity	
Caucasian	18 (90%)
Highest Education Level	
Less than high school	8 (40%)
High School Graduate or above	12 (60%)
Marital Status	
Single	8 (40%)
Married	7 (35%)
Widowed/Divorced	5 (25%)
Smoking Status	
Current Smoker	8 (40%)
Quit Smoking	10 (50%)
Never Smoker	2 (10%)
Employment Status	
Employed	8 (40%)
Disabled/Sick Leave	6 (30%)
Retired/ Unemployed	6 (30%)
Live Alone	6 (30%)
GOLD Stage	
II	9 (45%)
III	5 (25%)
IV	6 (30%)
BMI in kg/m^2	30.2 ± 7.6
Number of Comorbidities	6.6 ± 4.6

Table 4.3, Cont.

Number of Exacerbations in Previous Year	1.5 ± 1.2
Number of Medications Prescribed	12.9 ± 6.6
FEV_1 in liters per second	1.17 ± .43
% predicted FEV_1	43 ± 14.9
FVC in liters	2.5 ± .73
FEV_1/FVC	48 ± 13.4
Values are mean ± SD or f (%) Abbreviations: GOLD, Global Initiative for Obstructive Lung Disease Stage; BMI, body mass index; FEV_1, forced expiratory volume in one second; FVC, forced vital capacity	

Table 4.4. Comparison of symptom severity at baseline with intervention values by tertiles

Symptom Severity Group	Mean severity rating pre-intervention (Day 0 – 6) M ± SE	Mean severity rating intervention (Day 7 – 20) M ± SE	P value
Distress due to Cough [a]			
Low	7.16 ± 3.13	6.90 ± 2.97	.82
Medium	29.96 ± 4.93	40.03 ± 4.70	**.02**
High	63.76 ± 4.02	60.71 ± 3.90	.24
Distress due to Mucous [b]			
Low	7.46 ± 4.79	11.79 ± 4.55	.15
Medium	33.44 ± 4.36	33.12 ± 4.13	.79
High	55.84 ± 5.28	55.51 ± 5.26	.76
Chest Tightness [c]			
Low	7.42 ± 3.36	6.40 ± 3.13	.43
Medium	35.41 ± 4.50	43.30 ± 4.20	**.04**
High	60.48 ± 4.10	52.37 ± 3.92	**.05**
Dyspnea with activity [d]			
Low	8.92 ± 4.28	9.71 ± 3.91	.74
Medium	51.18 ± 5.23	63.96 ± 4.79	**.05**
High	66.64 ± 3.29	66.95 ± 3.07	.95
Dyspnea with rest [e]			
Low	5.84 ± 3.14	9.47 ± 2.96	.10
Medium	38.02 ± 3.74	39.98 ± 3.53	.42
High	73.52 ± 5.71	68.07 ± 5.65	.93
Fatigue [f]			
Low	9.32 ± 4.52	15.93 ± 4.06	.06
Medium	40.12 ± 4.46	56.64 ± 4.17	< **.01**
High	70.24 ± 4.82	66.70 ± 4.38	.30

Table 4.4, Cont.

Analyses based on primary outcome variable (symptom severity scores [range 0 – 100]
[a]**Fixed effects:** intervention status F(1,383.34) = 3.03, p = .08; severity group F(2,20.44) = 67.35, p < .01; intervention status*severity group F(2, 383.38) = 7.71, p < .01;
[b]**Fixed effects**: intervention status F(1,380.75) = 1.09, p = .34; severity group F(2,20.23) = 23.30, p < .01; intervention status*severity group F(2, 381.66) = . 62, p = .43;
[c]**Fixed effects:** intervention status F(1,384.24) = 0.08, p = .78; severity group F(2,20.66) = 55.14, p < .01; intervention status*severity group F(2, 384.07) = 8.71, p < .01;
[d]**Fixed effects:** intervention status F(1,382.63) = 7.08, p < .01; severity group F(2,20.82) = 73.35, p < .01; intervention status*severity group F(2, 382.93) = 4.62, p = .01;
[e]**Fixed effects:** intervention status F(1,388.54) = .01, p = .97; severity group F(2,20.26) = 61.05, p < .01; intervention status*severity group F(2, 385.84) = 2.43, p = .09;
[f]**Fixed effects:** intervention status F(1,384.47) = 10.90, p < .01; severity group F(2,20.87) = 48.26, p < .01; intervention status*severity group F(2, 384.45) = 8.37, p < .01

Table 4.5. Comparison of symptom variability at baseline and intervention

Symptom	Pre-Intervention	Intervention Period	P value
Distress due to Cough	10 (50%)	10 (50%)	1.00
Distress due to Mucous	10 (50%)	6 (30%)	.22
Chest Tightness	10 (50%)	5 (25%)	.13
Dyspnea with Activity	10 (50%)	6 (30%)	.22
Dyspnea with Rest	10 (50%)	12 (60%)	.69
Fatigue	10 (50%)	6 (30%)	.22
Values are frequency (%) The proportion of participants in the high symptom variability category pre-intervention were compared to the intervention period using McNemar tests.			

Table 4.6. Comparison of mean scores for symptoms, anxiety, depressive symptoms, perceived self-care ability, adherence and information needs (n = 19)

Variable	Baseline	Day 8	Day 15	Day 21	P Value
HADS - anxiety [0 – 21]	6.6 ± 3.3	6.8 ± 3.9	6.2 ± 4.1	6.3 ± 4.3	.62
HADS – depression [0 – 21]	5.6 ± 3.5	5.8 ± 3.1	5.5 ± 3.3	6.1 ± 3.4	.66
Perceived Self-care Ability (SMAS-18) [12 – 84]	58.9 ± 12	55.5 ± 13.5	54.3 ± 14.5	57.4 ± 14.5	.07
Self-care Adherence [0 – 100]	58.1 ± 19.3	-	-	67.6 ± 12.2	**.03**
Self-care Information Needs [0 – 25]	13.7 ± 3.1	-	-	11.3 ± 1.8	**.01**
Symptom variable	Pre-intervention period		Intervention-period		
Distress Due to Cough	26.6 ± 25.4		27.8 ± 26.2		.59
Chest Tightness	28.8 ± 24.1		28.1 ± 24.4		.79
Distress due to Phlegm	27.9 ± 22.3		29.3 ± 23.3		.68
Dyspnea with Activity	45.4 ± 27.8		48 ± 28.9		.27
Dyspnea at Rest	25.8 ± 26.1		27.4 ± 24.3		.48
Fatigue	38 ± 26.8		44.8 ± 27.2		.08

Values are mean ± SD; bracketed information [] are ranges of total possible scores
Comparisons were performed with paired t-tests, or repeated measures analysis of variance, based on the number of repeated measures.

Table 4.6, Cont.

Abbreviations: HADS, Hospital Anxiety and Depression Scale; SMAS-18, Self-management Ability Scale – 18-item version

Figure 4.1. Screening and Enrollment Flow Diagram

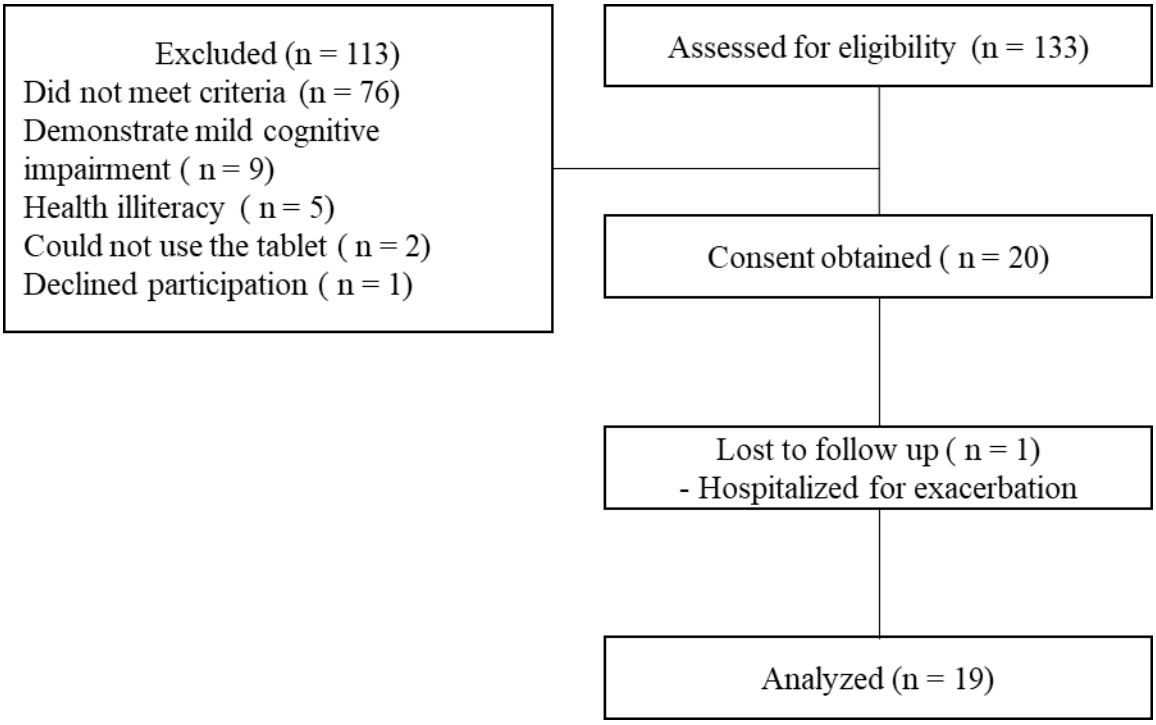
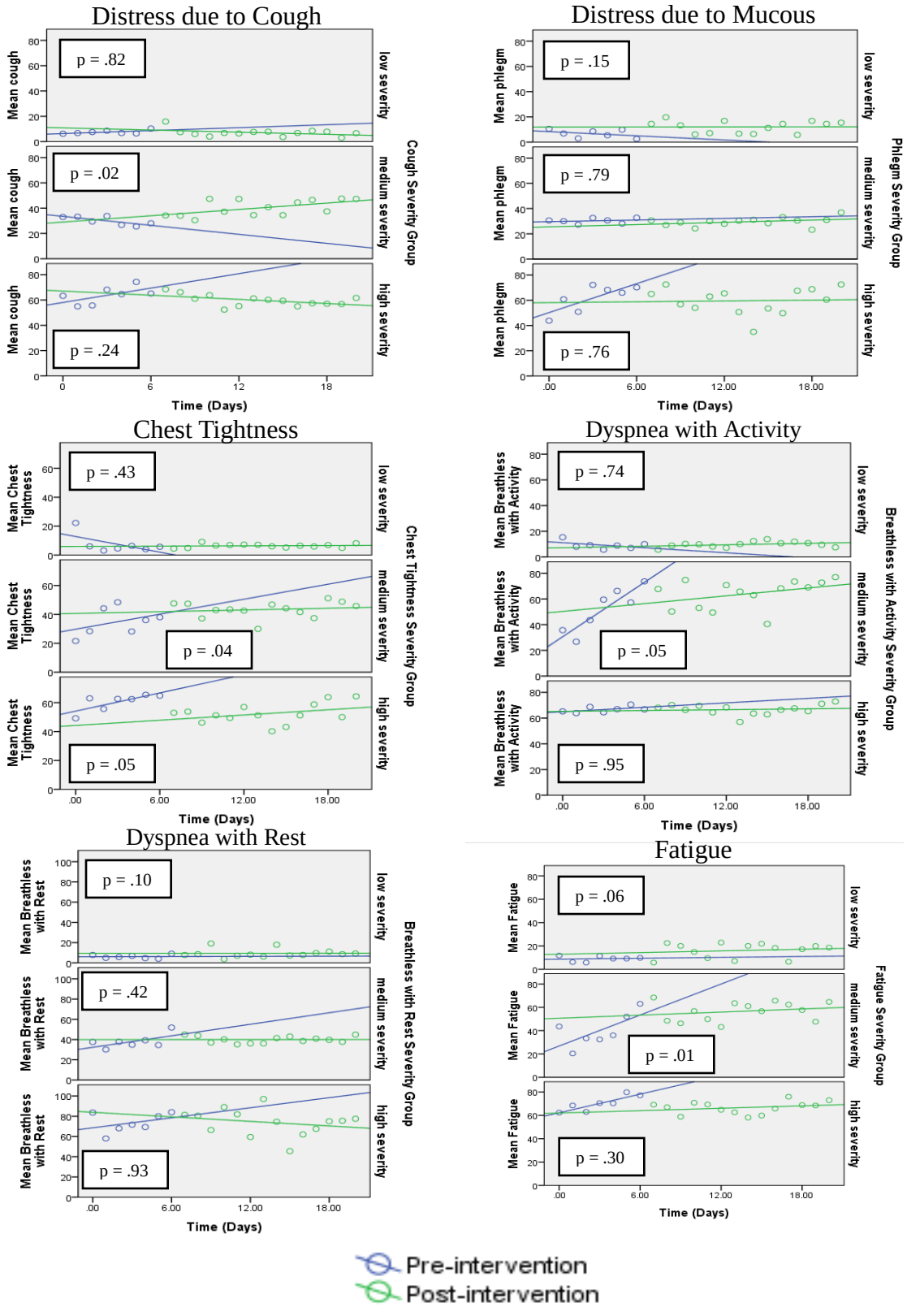


Figure 4.2. Trends in symptom severity over time, stratified by symptom severity group (low, medium, high).



CHAPTER FIVE

Conclusions

Summary of findings

The purpose of this dissertation was to evaluate the relationship between biological, psychosocial and behavioral self-care attributes and outcomes in individuals with COPD. COPD affects millions of people worldwide, and as COPD progresses, symptoms become more severe, physical and psychological responses are elicited, and risk for hospitalization increases.[1] As the prevalence and burden of COPD increases, patients are taught and expected to perform a variety of self-care activities to maintain physical, mental, and psychosocial homeostasis. Although research evidence exists to support the effectiveness of self-care in the reduction of the risk for hospitalization, increase in health-related quality of life, and significant decreases in symptoms such as dyspnea, anxiety and depressive symptoms,[15,18,21,88] the relationship between self-care behaviors, symptom burden and perceived self-care ability remain unclear.

The first manuscript was a report of a secondary data analysis in which we explored the predictive power of forced vital capacity (FVC), forced expiratory volume in one second (FEV_1), and the ratio between the two (FEV_1/FVC) for event-free survival in patients with heart failure and airflow limitation. The second manuscript was a report of a psychometric evaluation of the Multidimensional Scale of Perceived Social Support (MSPSS) in a sample of patients with comorbid COPD and heart failure. The third manuscript reported the testing of a self-care educational intervention using an eHealth platform, in which symptoms, anxiety, depressive symptoms, perceived self-care ability,

perceive self-care adherence and self-care information needs (knowledge) were evaluated before and after the intervention.

Patients with comorbid COPD and heart failure share numerous commonalities including predisposing risk factors, symptom presentation, and periodic disease exacerbations. Approximately one-third to 40% of patients diagnosed with heart failure are also diagnosed COPD.[30,31] Although airflow limitation may be present in a significant proportion of patients with heart failure, the relationship between airflow limitation and combined all-cause hospitalization/mortality had not been explored in patients with heart failure and suspected airflow limitation. In the second chapter, we presented a secondary data analysis examining the predictive power of spirometry measures (forced vital capacity [FVC], forced expiratory volume in one second [FEV_1], and the ratio between the two [FEV_1/FVC]) for event free survival in patients with a primary diagnosis of heart failure. Airflow limitation resulted in a 2.2 times greater risk of hospitalization or death compared to those patients without airflow limitation. Individuals who were in NYHA functional class III/IV were 73% more likely to be hospitalized or die compared to those with less severe disease (NYHA functional class I/II), and patients who had never smoked were 62% less likely to have a health-related hospitalization/death. Regularly measuring airflow limitation in patients with comorbid heart failure and COPD may permit more effective management and provide an opportunity to reduce hospitalization/mortality in these patients. Future research studies should focus on the development and testing of tailored self-care strategies for individuals with comorbid diseases.

Due to the high symptom burden, complex treatment regimens, and decrease in functional capacity, patients with COPD may have caregivers, friends, family or significant others assist them to manage their disease, symptoms, and prescribed treatments. Chapter Three contains a report of a psychometric evaluation of the Multidimensional Scale of Perceived Social Support (MSPSS) in patients with comorbid COPD and heart failure. The MSPSS was evaluated for internal consistency, split-half reliability, construct validity with factor analysis, and hypothesis testing. Findings revealed that in patients with comorbid COPD and heart failure, the MSPSS had excellent internal consistency, and good split-half reliability. Factor analysis yielded a 3-factor solution with instrument items loading appropriately on each of the three subscales of the MSPSS. Hypothesis testing further supported construct validity; perceived social support scores predicted higher self-care management scores. We concluded the MSPSS was a valid and reliable instrument to measure perceived social support in patients with comorbid COPD and heart failure. Further research is warranted to examine the impact of perceived social support on key outcomes in individuals with COPD and heart failure, such as symptom burden, anxiety, depression, self-care ability, and survival.

There is a lack of evidence about the immediate effects of self-care interventions on key outcomes, particularly symptom burden (severity of distress due to cough, chest tightness, distress due to mucous, dyspnea with activity, dyspnea at rest, fatigue, anxiety, and depressive symptoms). The third paper in this dissertation reported a test of a theory-based, multidimensional, self-care educational intervention on key outcomes in patients with COPD. Intervention components included modules about diet, breathing control, mental health, physical activity, medications, environment modification and

exacerbations; outcome measures were symptoms (distress due to cough, chest tightness, distress due to mucous, dyspnea, fatigue, anxiety and depressive symptoms) perceived self-care ability, and self-care information needs (knowledge). Growth models were constructed to examine the impact of the intervention on symptom severity and variability. Repeated measures analysis of variance examined the effect of the intervention on anxiety and depressive symptoms, and perceived self-care ability at the end of week 1, 2 and the conclusion of the reporting period. Paired t-tests determined the effect of the intervention on perceived self-care adherence and self-care information needs (knowledge). This intervention resulted in significant change in symptom severity evaluation in patients categorized as having medium symptom severity for distress due to cough, chest tightness, dyspnea with activity and fatigue; these symptoms were perceived as more severe in the intervention period. Anxiety, depressive symptoms and perceived self-care ability were unchanged; however, perceived self-care adherence scores improved, and knowledge needs were significantly reduced after the intervention.

Our findings described the immediate impact of a self-care intervention on symptom evaluation, as well as perceived self-care adherence and self-care information needs (knowledge). Future studies will provide additional data. First, future studies are needed to examine the hypothesis that baseline symptom severity has an impact on the effect of self-care interventions. Second, further exploration is warranted regarding the effect of tailored self-care interventions on anxiety and depressive symptoms in patient with COPD. Since our patients were not exhibiting substantial anxiety or depressive symptoms at baseline, it is difficult to draw conclusions regarding the effects of the intervention on these outcomes. Third, longitduinal studies with time periods up to one

year are needed to evaluate the long term effects of self-care interventions on variables such as symptom burden, self-care adherence and information needs using eHealth educational interventions in patients with COPD. Furthermore, an increased dose of the intervention, addition of a control group, and accounting for the time of year (to account for expected seasonal fluctuations) are warranted.

Impact of dissertation on the state of the science

There are few investigators who have examined the effect of a self-care intervention on symptoms such as distress due to cough, chest tightness, distress due to mucous and fatigue in patients with COPD. Although researchers have established that symptom burden was a significant clinical problems in patients with COPD, self-care interventions have not been found to improve symptom perception with the exception of dyspnea, anxiety and depressive symptoms.[19,120] Although investigators have tested interventions to improve self-care in patients with COPD, the most recent American Thoracic Society and GOLD guidelines for management of stable COPD provided minimal recommendations for self-care behaviors.[4,155] Current recommendations included taking medications as prescribed, smoking cessation, and reporting increased symptom severity or potential exacerbations to providers; future research is needed to establish evidence-based guidelines and recommendations for other aspects of self-care including, diet/nutrition, mental health, physical activity, and environment modification.

In this dissertation, my research findings have: 1) identified the influence of comorbid disease (heart failure and COPD) on key outcomes, hospitalization and survival; 2) tested the psychometric rigor of a measure of perceived social support in patients with comorbid chronic conditions (COPD and heart failure); 3) concluded

perceived social support is a significant predictor of perceived self-care management ability in patients with comorbid COPD and heart failure; 4) demonstrated that an electronic, educational intervention altered the perception of symptom severity in subsets of patients and increased self-care adherence and knowledge in patients with COPD; 5) demonstrated that patients with COPD recorded daily symptom evaluation with high rates of adherence; 6) supported that this short dose of an intervention improved perceived self-care adherence and reduced knowledge needs; and 7) demonstrated that this selected sample of patients with COPD were able to interact with the intervention, given the short exposure, and received benefit from the intervention.

There are limitations of this dissertation. Two of the three manuscripts reported retrospective data analyses; thus, we could not control for other variables that may have influenced the evaluated patient outcomes. These secondary analyses were also limited in terms of data collected; for the survival analyses, there were limited number of participants with confirmed spirometry values indicating presence of airflow limitation and COPD. For the third study, the sample was small and had limited power to detect differences for some of our analyses. Although we were adequately powered for our growth curve analyses, the measures may not have had sufficient sensitivity to detect change. Furthermore, all of the instruments used in this study were self-report, which introduced the potential for social desirability and response bias. However, the variables we measured were subjective; thus, self-report is the only suitable way to measure them.[154] Future objective measures of self-care adherence, medication adherence, physical activity, and nutritional intake should be used to compare actual to perceived variables.

Further systematic research studies are needed to determine the most effective strategies to improve self-care in this population. Future studies should aim to identify key health behaviors that would promote optimal health for patients with COPD and test those behaviors for improvements in outcomes. Moreover, subsequent studies should aim to examine the validity of self-reported symptom burden measures, especially for symptoms such as distress due to cough, chest tightness, distress due to mucous and fatigue. Finally, investigators should focus on exploring the short-term and long-term impact of self-care interventions on symptom burden, anxiety, depression, sustained adherence, morbidity and mortality.

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Educational Background

Year	Degree	Institution
2014	Bachelor of Science in Nursing	University of Kentucky, Lexington, KY

Professional Positions Held

Dates	Institution and Location	Position
08/2015 – Present	Baptist Health Lexington, Lexington, KY.	Fellow/Research Consultant
01/2015 – Present	University of Kentucky Chandler Medical Center 9 MICU, Lexington, KY.	Staff nurse

Scholastic and Professional Honors

2018 Daisy Award. University of Kentucky Chandler Medical Cener

2017 Millennium Scholarship. University of Kentucky College of Nursing

2015 Baptist Health Fellowship and Research Scholarship

2014 Sigma Theta Tau International Honor Society of Nursing Senior Student Award

Professional Publications

Bowles L, Lengerich A, Davies C, Bugajski A. (in press). Effect of Music on Mood, Motivation, and Exercise among patients in a Cardiac Rehabilitation Program. *Creative Nursing.*

Fultz A, Walker M, Lengerich A, Bugajski A. (in press). Job satisfaction of medical imaging technologists: A current look at work environment, communication, and leadership. *Radiologic Technology.*

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