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Measuring Health Status and Symptom Burden using a web-based mHealth Application in Patients with Heart Failure

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Abstract

Background: Symptoms of heart failure (HF) markedly impair a patient's health status. The aim of this study was to identify predictors of health status in a sample of racially and ethnically diverse patients with HF using a web-based mobile health (mHealth) application, *mi.Symptoms*.

Methods: We conducted a cross-sectional study at an urban academic medical center. Patients with HF self-reported symptoms using validated symptom instruments (e.g. Patient-Reported Outcome Measurement Information System) via the mHealth application, *mi.Symptoms*. The primary study outcome was health status, measured with the Kansas City Cardiomyopathy Questionnaire Clinical Summary Score. Data were analyzed using descriptive statistics and multiple linear regression.

Results: The mean age of the sample (n=168) was 58.7 (\pm 12.5) years, 37% were female, 36% were Black, 36% identified as Hispanic/Latino, 48% were classified as NYHA class III, and 44% reported not having enough income to make ends meet. Predictors of better health status in HF included higher physical function ($\beta = 0.89$, $p = 0.001$) and ability to participate in social roles and activities ($\beta = 0.58$, $p = 0.002$), and predictors of poorer health status were NYHA Class IV ($\beta = -$

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Declaration of Conflicting Interests

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11.68, $p = 0.006$) and dyspnea ($\beta = -0.77$, $p < 0.001$). The predictors accounted for 73% of the variance in health status.

Conclusion: Patient-centered interventions should focus on modifiable risk factors that reduce dyspnea, improve functional status, and enhance engagement in social roles to improve the health status of patients with HF.

Keywords

heart failure; mobile health; symptoms; social participation; physical function; health status

Introduction

Heart failure (HF) is a significant global health problem and is the fastest growing cardiovascular disease affecting approximately 26 million people worldwide.¹ HF is characterized by chronic and progressive symptoms that worsen over the course of the disease. Escalating HF symptoms and acute decompensation limit physical and social activities of daily living and increase the risk of hospitalizations.^{2,3} HF treatments represent 1–2% of the total healthcare expenditures in Europe and North America,⁴ and have an estimated cost of over \$39 billion annually in the U.S.⁵ In addition, HF is the most common cause for hospital admission and readmission, and the most expensive of all Medicare diagnoses in the U.S.⁵

Patients with HF have markedly worse self-reported health status, defined as exacerbated symptoms, limited physical and social function, and lower level of quality of life,^{6,7} compared to those with other chronic diseases.^{3,8} Health status reflects the multidimensional health conditions in HF patients' daily lives.⁷ Specifically, the health status of patients with HF is impaired by physical (dyspnea, fatigue, pain, sleep) and psychological symptoms (anxiety, depression, anger).^{9–11} Previous studies have identified the New York Heart Association (NYHA) class, age, gender, race, and financial status as factors influencing health status in patients with HF.^{10,12–14}

It is crucial to monitor and manage symptoms of HF to improve health status and decrease the risk of acute exacerbations and rehospitalizations.² Nevertheless, patients with HF struggle with self-care management^{15–17} and symptom perception.² Thus, mobile Health (mHealth) technology (e.g., smartphones, tablet computers) can be used at the point of need to facilitate the ability of HF patients to recognize their own symptoms, connect the symptoms to HF disease and communicate them with their healthcare providers. In particular, mHealth applications have been used with increasing frequency to quantify a patient's symptoms in the outpatient environment.¹⁸ Data collected via mHealth applications in the patient's home can be integrated into a patient's health profile and used by healthcare providers to provide insights into their health status between clinic visits. Leveraging the potential of mHealth technology, we developed a mHealth application, *mi.Symptoms* to facilitate the reporting of patient symptoms.¹⁹ As part of this study, we identified patient-reported symptoms and the health status of patients with HF collected using the *mi.Symptoms*.

Most previous studies that evaluate predictors of health status in HF have primarily included samples that have been predominantly Caucasian.^{9,14,20,21} Less is known about predictors of health status in racially and ethnically diverse patient populations. Furthermore, few studies have used a mHealth application to identify and report physical and psychological symptoms of HF and their associations with health status. mHealth applications can play an important role in helping patients with HF and healthcare providers discuss symptoms using a single, integrated mobile system, thereby enabling shared decision-making about medical plans and treatments. Accordingly, the aim of this study was to identify predictors of health status in a racially and ethnically diverse, urban sample of English and Spanish-speaking HF patients, using the mHealth web-application, *mi.Symptoms*.

Methods

Study Design and Participants

We conducted a cross-sectional study to examine symptoms and predictors of health status of patients with HF using the mHealth application, *mi.Symptoms*. We recruited patients with HF from a cardiac inpatient unit and an ambulatory cardiac clinic at an urban academic medical center in New York from October 2016 to January 2017. Eligible patients were identified using electronic health records. Patients were included if they met the following criteria: (1) diagnosed with HF confirmed by clinical exam, echocardiographic evidence, or a cardiologist, (2) willing and able to provide informed consent, (3) literate in English or Spanish, and (4) age 21 years or older. Patients were excluded if they had been diagnosed with dementia, active psychosis, or isolation precautions. All participants provided written informed consent in English or Spanish and were given \$35 as a token of appreciation for their time. Participants reported their symptom experience using the *mi.Symptoms* application developed by the research team to allow patients to report and communicate their symptoms with their healthcare providers. Participants used the *mi.Symptoms* application on an iPad and completed demographic survey questionnaires and perceived health status using the Qualtrics survey software. A more detailed description of the development and usability test of *mi.Symptoms* application can be found elsewhere.^{19,22} This study was approved by the Institutional Review Board of the Columbia University Medical Center.

Measurements

Sociodemographic questionnaire—The sociodemographic questionnaire collected information on age, gender, race, ethnicity, marital status, financial status, education, health literacy, participation in self-care management, type of heart failure, NYHA class, and total medications. Health literacy was measured using the Brief Health Literacy Screener that consists of 3 items with a Likert scale to assess the ability to understand health information and services needed to make medical decisions.²³ Patient activation was measured with the Patient Activation Measure-13.²⁴

Heart Failure Somatic Perception Scale—The Heart Failure Somatic Perception Scale (HFSPS) is an 18-item measure of HF-specific physical symptoms with total scores that range from 0 to 90 (Cronbach's alpha: 0.90).^{2,25} The HFSPS has five response options ranging from zero (I did not have the symptom) to five (extremely bothersome) with higher

scores indicating higher symptom burden.²⁵ The HFSPS includes a 6-item Dyspnea subscale with total scores that range from 0 to 30 (Cronbach's alpha: 0.89).^{2,25}

Patient Reported Outcomes Measurement Information System—To measure non-cardiac symptoms, including psychological symptoms, we used the Patient-Reported Outcome Measurement Information System (PROMIS®) short-form questionnaires²⁶: Pain Interference v1.0,²⁷ Fatigue v1.0,²⁸ Sleep Disturbance v1.0,²⁹ Depression v1.0,³⁰ Anxiety v1.0,³¹ Emotional Distress-Anger v1.1,³² Physical Function v2.0,³³ Applied Cognition-Abilities v2.0,³⁴ and Ability to Participate in Social Roles and Activities v2.0.³⁵ The PROMIS short forms each have four or five questions. Response options range from one to five. This measure uses a response pattern scoring that examines responses to each item for each participant. The response scores of each item are summed for the total raw score by adjusting for missing data. The raw scores are rescaled using the T-score to calculate a standardized score with a mean of 50 and a standard deviation of 10 for the general population in the U.S. The standardized T-score represents the final score for each patient. A higher PROMIS T-score indicates more of the concept being measured. A higher PROMIS score represents greater pain, greater fatigue, greater depression, greater anxiety, greater emotional distress-anger, better physical function, better cognition ability and better participation in social roles and activities. We chose the PROMIS measure because it is not disease specific, thus assessing psychological symptoms that are common across multiple health conditions. In addition, all of the PROMIS questionnaires are freely available and have Spanish versions with comprehensive linguistic validation.

Kansas City Cardiomyopathy Questionnaire Clinical Summary Score—The primary outcome of this study is health status, which was measured with the 23-item Kansas City Cardiomyopathy Questionnaire Clinical Summary Score (KCCQ).⁶ Health status is a composite outcome that consists of five domains including physical function, symptoms (frequency, severity, and recent change over time), social function, self-efficacy, and quality of life of patients with HF.⁶ The KCCQ is a reliable and valid measure with a Likert scale and five to seven response options. The scales are ranged from 0 to 100 with higher scores indicating fewer symptoms, better function and greater quality of life. Cronbach's alpha of the KCCQ scale in this study was 0.94.

Data analysis

Statistical analyses were conducted using the STATA version 13 (Stata Corporation Inc., College Station, TX, USA). Descriptive statistics including mean, standard deviation, frequency, and percentages were employed to characterize the participants of this study. Multiple linear regression analysis was used to identify predictors of health status in patients with HF. A p-value of 0.05 represented the threshold for determining statistical significance.

Results

Sociodemographic Characteristics of Study Participants

Table 1 illustrates the sociodemographic characteristics of all participants in this study. The sample (n=168) had a mean age of 58.7 (\pm 12.5) years, 37% of participants were female, and

36% were Black. Overall 36% of participants identified as Hispanic/Latino and 20% completed the study in Spanish. More than a third of the participants were married (38%), nearly half (44%) reported not having enough income to make ends meet, and most patients (47%) graduated from college. More than half of the participants (52%) had the ability to understand health information and services and 71% engaged in activities for self-care symptom management. Most patients (69%) had HF with reduced ejection fraction, 48% were classified as NYHA class III, and 65% had a left ventricular ejection fraction of less than 40%. The average number of medications taken per participant was 13 (± 5.2).

Table 2 shows the descriptive characteristics of HF patient-reported physical and psychological symptoms including the PROMIS® measure. In addition, the mean of the total score for the HFSPS was 42.9 (± 21.4) and the mean of the HFSPS Dyspnea subscale was 16.0 (± 9.8). The mean of KCCQ Health Status scores was 49.3 (± 27.2). All measurements used in this study had excellent or good internal consistency with Cronbach's alpha ranging from 0.87 to 0.95.

Patient-Reported Factors Associated with Health Status

In bivariate analyses, multiple patient-reported factors, including demographic characteristics (race, ethnicity, financial status, NYHA class), physical symptoms (physical function, dyspnea, pain, fatigue, sleep), psychological symptoms (anxiety, depression, anger), physical function, cognition abilities, and the ability to participate in social roles and activities were significantly associated with health status ($p < 0.001$). Age and gender were not associated with health status.

The predictors of health status in patients with HF are included in Table 3. Patients with high physical functional impairment (NYHA class IV) had a clinically significant 11.68-point decrease in the KCCQ health status score ($\beta = -11.68$, $p = 0.006$) compared to patients with a higher functional status (NYHA class II/III). Worsening dyspnea (a one-point increase in the HFSPS dyspnea score) was associated with a 0.77-point decrease in the KCCQ health status score ($\beta = -0.77$, $p < 0.001$). A 10-point increase in the PROMIS physical function score was associated with an 8.9-point increase in the KCCQ health status score ($\beta = 0.89$, $p = 0.001$). In addition, a 10-point increase in the PROMIS ability to participate in social roles and activities score was associated with a 5.8-point increase in the KCCQ health status score ($\beta = 0.58$, $p = 0.002$). The proportion of variance in the KCCQ score explained by NYHA class IV, physical function, dyspnea, and ability to participate in social roles and activities was 73%.

Discussion

This study identified HF symptoms and predictors of health status using a mHealth application in a racially and ethnically diverse, urban sample of HF patients. The findings from this study showed that patient-reported factors, including NYHA class, dyspnea, physical function, and ability to participate in social roles and activities were significantly associated with health status in HF.

In this study, we report that dyspnea is a distressing physical symptom that has a major impact on patient's overall health status. Ambrosy and colleagues³⁶ found that both physician-assessed and patient-reported dyspnea were not independently associated with post-discharge quality of life in HF. In contrast, Carlson et al.¹⁴ reported that shortness of breath was correlated with perceived health status; however, it was not a significant independent predictor. A plausible reason for the discrepancy in findings between studies could be due to different study instruments being used to measure dyspnea and perceived health status. Dyspnea is one of the most frequent complaints reported by patients and is associated with impaired functional ability.³⁷

Impaired ability to participate in social roles and activities negatively impacts patient's health status, consistent with previous studies.^{9,14} Patients with HF who have trouble doing all of activities with family or friends that they want to do report lower health status and risk feeling isolated.^{9,14} This is more relevant than ever with older adults living alone or farther from grown children³⁸ and the growing prevalence of "elder orphans" defined as "aged, community-dwelling individuals who are socially and/or physically isolated, without an available known family member or designated surrogate or caregiver."³⁹ These isolated older adults are at risk of poor physical and psychological health as well as increased mortality.³⁹

In this study, lower physical functioning was also significantly associated with lower perceived health status.⁹ Participation in social roles and physical function are both modifiable factors impacting health status. These findings suggest the need for increased attention on assessing participation in social roles and improvement in physical function to curb social isolation of older adults with HF and improve health status.

Limitations

This study has several limitations. First, this study was conducted on a small number of participants in an inpatient unit and outpatient setting at an academic medical center; thus, the findings from this study might not be generalizable to different healthcare settings and organizations. Patients in the inpatient setting completed tools using the *mi.Symptoms* application at different phases of their inpatient stay because time since admission was not part of the inclusion/exclusion criteria of this study. We recognize that patient's symptom experience varies over the course of the hospitalization. Second, this study was a cross-sectional study design; therefore, we were unable to evaluate causal relationships between symptoms and health status.

Future Directions

Results from this study point toward a number of areas for further research including the need to pay close attention to the measurement of dyspnea in multiple care settings. Further studies should also develop patient-centered interventions designed to help older adults with HF cope with social isolation since they have a high risk of social limitations. Finally, future studies should examine HF symptoms measured in the home environment because assessing for early symptom changes can help change the trajectory of HF. Given increasing popularity and sophistication of consumer health informatics technologies, mHealth

applications represent a major opportunity to identify HF symptoms and assess health status in the home environment. Such technology-based interventions should be designed with gerontechnological principles, given the unique technical needs of older adults who are disproportionately affected by HF.

Conclusion

Overall, patient-centered interventions should focus on modifiable risk factors that reduce dyspnea, improve functional status, and enhance engagement in social roles to improve the health status of patients with HF.

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Implications for Practice

- Both cardiac and non-cardiac symptoms, physical function, cognition ability, and participation in social roles and activities are significantly correlated with the health status of patients with heart failure.
- Dyspnea, NYHA class IV functional status, physical function and the ability to participate in social roles and activities are independent predictors of health status of patients with heart failure.
- Attention should focus on modifiable risk factors, including optimizing physical function and participation in social roles and activities to improve the health status of patients with heart failure.

Table 1.

Sociodemographic Characteristics of Patients with Heart Failure (N=168)

Characteristics	M (SD) or n (%)
Age (year)	58.7 (\pm 12.5)
Gender	
Female	62 (36.9)
Race	
Black	58 (36.0)
Asian and Other	52 (32.3)
White	51 (31.7)
Ethnicity	
Hispanic/Latino	60 (36.4)
Non-Hispanic/Latino	105 (63.6)
Spanish Speaking Interview	33 (19.6)
Marital Status	
Single	58 (34.5)
Married	64 (38.1)
Divorced/separated	22 (13.1)
Widowed	14 (8.3)
Living with domestic partner	10 (6.0)
Financial Status	
Not having enough income to make ends meet	73 (43.7)
Having enough to make ends meet	70 (42.0)
Having more than enough to make ends meet	24 (14.3)
Highest Level of Education	
Graduate degree	16 (9.5)
College	79 (47.0)
High school	73 (43.5)
Health Literacy	
Adequate	88 (52.4)
Inadequate	80 (47.6)
Patient Activation	
High activation	119 (70.8)
Low activation	49 (29.2)
Type of Heart Failure	
Heart failure with reduced ejection fraction	111(68.5)
Heart failure with preserved ejection fraction	40 (24.7)
Mixed	11(6.8)
NYHA Class	
II	39 (23.2)
III	81 (48.2)
IV	48 (28.6)

Characteristics	M (SD) or n (%)
Left Ventricular Ejection Fraction	
>50%	49 (30.4)
40–50%	8 (5.0)
<40%	104 (64.6)
Total Medications	13.0 (\pm 5.2)

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Table 2.

Physical and Psychological Symptom Scores

Measure	T-score (SD)	Raw score (SD)	Cronbach's alpha
PROMIS Pain	58.3 (11.3)	11.1 (6.0)	0.95
PROMIS Fatigue	57.5 (11.2)	12.48 (5.4)	0.89
PROMIS Sleep Disturbance	55.9 (11.3)	12.9 (7.2)	0.91
PROMIS Anxiety	57.0 (10.8)	9.4 (6.7)	0.87
PROMIS Depression	55.6 (11.4)	9.3 (6.9)	0.92
PROMIS Emotional Distress-Anger	51.9 (12.4)	12.0 (7.1)	0.93
PROMIS Physical Function	36.6 (8.0)	11.6 (4.8)	0.87
PROMIS Applied Cognition Abilities	51.2 (9.4)	14.8 (6.1)	0.88
PROMIS Ability to Participate in Social Roles and Activities	44.8 (9.2)	12.1 (5.2)	0.89

Abbreviation: SD: standard deviation

Table 3.

Predictors of Health Status (KCCQ score)

	Beta	SE	p-value
Age	0.03	0.11	0.794
Gender	1.66	2.76	0.547
Race	-1.54	1.66	0.355
Financial status	-3.71	1.98	0.063
NYHA class			
III	-4.83	3.42	0.161
IV	-11.68	4.16	0.006
HFSPS Dyspnea	-0.77	0.19	<0.001
Pain	-0.19	0.14	0.190
Fatigue	-0.03	0.19	0.884
Sleep Disturbance	-0.13	0.15	0.396
Anxiety	-0.16	0.21	0.428
Depression	-0.29	0.20	0.152
Emotional Distress-Anger	0.26	0.15	0.091
Physical Function	0.89	0.26	0.001
Applied Cognition Abilities	-0.08	0.18	0.668
Ability to Participate in Social Roles and Activities	0.58	0.19	0.002

Notes: $R^2=0.7302$, adjusted $R^2=0.6975$, $F(16, 132)=22.33$, $p < 0.001$

Abbreviations: NYHA: New York Heart Association functional class; HFSPS: Heart Failure Somatic Perception Scale; KCCQ: Kansas City Cardiomyopathy Questionnaire; SE: standard error