Psychometric Testing of the Heart Failure Somatic Awareness Scale

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Abstract

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Background: Self-management of heart failure relies on patients to assess their symptoms, but their ability to do so is often difficult to determine. The 12-item self-report Heart Failure Somatic Awareness Scale (HFSAS) was developed to measure awareness of and distress secondary to heart failure symptoms. The purpose of this study was to test the psychometric properties of the HFSAS.

Methods and Results: Feasibility and discriminant validity of the HFSAS were tested in 49 patients admitted for an exacerbation of heart failure. The HFSAS was acceptable to patients and discriminated between HF symptoms and anxiety ($r = 0.25$, p 0.08). When reliability and validity were tested in 201 patients with acute heart failure, Theta reliability was adequate (0.71). The HFSAS was low to moderately correlated with general bodily awareness ($r = 0.48$). No difference was found based on gender but younger patients had higher mean and median HFSAS scores (more distress). The HFSAS was a significant predictor of symptom duration prior to seeking care for heart failure; higher scores were associated with longer delay before seeking care.

Conclusion: The HFSAS is reliable with content, discriminant, and construct validity. Evaluation of its usefulness in teaching patients to monitor daily symptoms is needed.

Key Words: Somatic awareness, instrument development, heart failure, symptoms

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Heart failure is a significant public health problem that affects 5 million Americans.[1] As a chronic and progressive clinical syndrome, heart failure negatively affects a patient's quality of life with unpleasant symptoms affecting well being, activities of daily living, and increases the risk of multiple hospitalizations for management of escalating symptoms. The ability of patients to monitor symptoms and maintain a complex regimen of multiple medications is essential for quality of life, avoidance of acute exacerbations and repeated hospital admissions. Nevertheless, self-management of heart failure is difficult because of the non-specific symptom profile and the insidious nature of worsening symptoms. Thus, somatic awareness, defined as sensitivity to physical sensations and bodily activity secondary to physiological change, may improve patient ability to monitor symptoms. In this article, the development and testing of an instrument measuring the awareness or perception of heart failure symptoms is reported.

Any personal description of symptoms is subjective by nature and therefore open to question.[2] Aside from daily monitoring of body weight, however, the self-management of heart failure relies on self-assessment of symptoms. Such self-assessments are often what bring patients to the attention of health care providers. Therefore, self report of symptoms is extremely valuable for clinicians.

Existing instruments measuring somatic awareness are general in nature and not cardiac or heart failure specific.[3, 4] No measure of self-reported somatic awareness or perception of common heart failure symptoms is presently available. Those instruments that are heart failure specific are for the purpose of assessing the physical impact of

symptoms on activities of daily living,[5] limit symptom assessment to fatigue and dyspnea,[6] exclude perceived symptom severity,[7] or measure patient response to symptoms in relation to effects on quality of life.[5, 6]

Available instruments that address facets of general somatic awareness are not directed toward heart failure symptoms per se. Some are measures of general bodily awareness,[3] emotion-related bodily responses,[8] beliefs about bodily attentiveness,[4] and bodily awareness specific to the symptom of palpitations.[9] Other instruments assess distress associated with common physical symptoms[10] or separate the components of the symptom experience into occurrence and distress level for symptoms that are not specific to heart disease.[11]

Although none of these measures are heart failure specific, investigators have studied somatic or general bodily awareness in heart failure patients. Baas and colleagues[12] used the Body Awareness Questionnaire[4] to explore the relationship between body awareness and somatization among patients with heart failure or after heart transplant. No differences in physiologic body cues or specific symptoms were found related to age, gender, or treatment. Nor were there differences in bodily awareness with regard to negative mood states such as anxiety or depression. Body awareness as related to physiological cardiac parameters was not reported in the study.

Despite emphasis on symptom monitoring in treatment guidelines for heart failure,[13] available instruments remain limited to quality of life, number of symptoms and symptom impact. None are adequate measures of perception or awareness of heart failure signs and symptoms. As noted earlier, instruments measuring general bodily awareness are not sufficiently focused on cardiac related symptoms. As the constellation of

symptoms typical of heart failure can be both nonspecific (e.g., fatigue) and acute (e.g., paroxysmal nocturnal dyspnea), both are needed for any measure that would be useful in monitoring symptom distress, patterns, and duration whether symptoms are subtle or overt. Therefore, the development of a symptom specific instrument addressing both prodromal or early symptoms, as well as acute symptoms of a heart failure, was undertaken.

Instrument Development

The Heart Failure Somatic Awareness Scale (HFSAS) is a 12 item Likert-type scale to measure awareness and perceived severity of signs and symptoms specific to heart failure. Heart failure, primarily an illness of older adults, often incurs fatigue, so ease of administration and participant burden are important considerations. Furthermore, previous studies report both age and gender as factors affecting symptom reporting.[14-18] Consequently, evaluation for the presence of both age and gender bias was considered in the development and evaluation of this instrument.

The HFSAS was limited to12 items to reflect the most common signs and symptoms of heart failure. A 4 point Likert-type scale was used to address these symptoms, and if present, to ascertain how much the patient was bothered by them at any point during the previous week. An even number of Likert responses was used as the instrument was designed to assess an event, not force a choice. Patients determined a symptom as present or not, and then scored the perceived severity on a 0 to 3 scale as follows: 0 = Not at all; 1 = A little, slightly; 2 = A great deal, quite a bit; and 3 = Extremely, could not have been worse. Symptoms scored as 0 are symptoms not experienced by the patient. Scores range from 0 to 36 with higher scores reflecting higher

perceived somatic awareness and symptom distress. Pedal edema, one common sign, is addressed in 2 separate items to account for patients who change footwear to accommodate swelling. The HFSAS is written in lay terminology and has a second grade reading level.

Content validity

The symptom list was derived from a review of the literature and previous studies citing symptom lists for heart failure.[19-21] Two nursing experts in the area of heart failure reviewed the symptom list to establish content validity. No recommendations to edit, add or delete items were suggested.

Method

Testing of the HFSAS was divided into 2 phases which are presented in sequential order for the reader. In phase1, feasibility factors including ease of administration, comprehensibility for the patients, and subject burden were evaluated. Phase 1 also included discriminant validity testing to address the relationship between the trait of anxiety and the HFSAS. The ability to discriminate between awareness of heart failure symptoms and symptoms secondary to anxiety was of concern for physiological and psychological reasons. Physiologically, sympathetic nervous system stimulation is a normal compensatory response to escalating heart failure symptoms resulting in an increased heart rate.[22] Psychological anxiety can also produce sympathetic stimulation with similar symptoms, such as increased heart rate and sweating. Furthermore, patients in acute heart failure may experience difficulty breathing. Sympathetic symptoms of anxiety secondary to shortness of breath and emergent hospital admission are expected among patients with heart failure. Therefore, discriminate validity of the HFSAS was

evaluated as the ability to discriminate between psychological anxiety and symptom distress specific to heart failure. We hypothesized that the HFSAS would measure awareness of symptom distress and not anxiety.

The Spielberger Trait Anxiety Inventory Form X-2[23] was used to assess the correlation between proneness toward anxiety and somatic awareness as measured by the HFSAS. The Spielberger Trait Anxiety Inventory is a 20-item, 4 point Likert-type scale measuring a person's general ongoing, typical level of anxiety. Scores range from 20 to 80 points, with higher scores representing greater proneness to anxiety. Internal consistency and reliability of the scale is high (alpha coefficients of >0.89 for Trait Scale). Test-retest reliability correlations are reported between r =0.73 and r = 0.84.[23]

Phase 2 analysis addressed construct and criterion validity and reliability testing. To determine construct validity, an exploratory factor analysis was performed by varimax rotation of the principal components. Consistent with the definition of criterion-related validity, which is the utility of an instrument to predict some behavior external to the instrument itself, [24, 25] the HFSAS was evaluated for its usefulness as a predictor of symptom duration. In patients with heart failure, symptom severity is related to symptom duration,[19] with symptom duration, severity and novelty predicting care-seeking in community dwelling elders.[16] Further construct analysis compared the HFSAS to a general measure of somatic awareness, the Modified Somatic Perception Questionnaire, and tested for differences between general or symptom specific bodily awareness in relation to symptom duration.

Phase 2 analysis also included an exploration of variability in HFSAS scores to assess for potential bias. The HFSAS scores were divided into quintiles to examine for

relationships between the HFSAS scores and age, gender and duration of heart failure symptoms.

Both phases testing the HFSAS were limited to community dwelling adult patients emergently hospitalized with a diagnosis of acute heart failure. Patients enrolled in Phase 1 were excluded from participating in Phase 2. Patients were enrolled if they made their own health care decisions and understood or read English. Patients with obvious cognitive impairment or unstable medical status were excluded. Cognitive status was evaluated by the medical and nursing staff caring for the patient. Patients who met the eligibility criteria and the Framingham Diagnostic criteria for heart failure[21] were enrolled from acute care facilities in the northeast region of the United States. Institutional Review Board approval was secured from all appropriate authorities and informed written consent was obtained prior to participation.

Phase 1 Procedure

Phase 1 testing was completed in the emergency department phase by patients admitted to a community hospital for symptom management. Participants completed the HFSAS and the Spielberger Trait Anxiety Inventory.

Phase 1 Sample

A convenience sample of 49 patients admitted with acute heart failure was enrolled. The primarily Caucasian sample was 63% female with a mean age of 73 years.

Phase 1 Results

All patients completed the surveys without difficulty. Patients reported that the HFSAS items were clear as to content and easy to answer with respect to heart failure symptoms. The HFSAS had a mean score of 18.96 (SD 2.9) and a range of 13 to 25 out

of a possible score of 36. The Spielberger Trait Anxiety Inventory had a mean score of 47 (S.D. 7.5) out of 80 and the Cronbach's alpha coefficient was 0.92. There was no significant correlation between trait anxiety and the HFSAS ($r = 0.25$, p 0.08) supporting discriminant validity of the HFSAS and the hypothesis that the HFSAS measured awareness of symptom distress and not anxiety.

Phase 2 Procedure

Three sites were utilized in this phase, including one urban and one suburban tertiary care hospital and a community hospital. Patients were enrolled by the principal investigator or trained research assistants over a 15-month period, from October 2001 until January 2003. At their request, the questionnaires were read to the vast majority of the patients. Visual difficulties secondary to aging are a concern to elderly patients when completing surveys.[26] As patients with heart failure are generally older, the option to have the instruments read to the patient was incorporated into the procedure. Interviews were done during the hospital stay and completed as soon as possible after admission to minimize the confounding influence of patient recall; 87% of the patients were enrolled within 3 days of admission. Demographic and clinical data were collected by interview and review of the medical record.

Phase 2 Sample

The convenience sample consisted of 201 participants. The mean age of the sample was 70 years (± 12) and 39% were 75 years of age and older (Table 1). There were more males than females and the sample was predominately white. More than half of the patients reported previous admissions for acute heart failure. The majority of the patients had co-morbid illnesses typical of heart failure, including coronary artery

disease, hypertension, and diabetes. A minority (11%) participated in a heart failure clinic for management of their illness.

Twenty-eight potential subjects declined to participate, including 14 females and 14 males who, except for one Black male, were Caucasian. Reasons offered included time, the perception that the information was not important because they were elderly or lack of interest. The demographic characteristics of the final sample are typical of the geographic area. The subjects who declined participation were demographically similar to the final sample.

Phase 2 Results

In the phase 2 sample, the mean score on the HFSAS was 13.17 (S.D. 5.52) with a range of 0 to 29 out of a possible maximum score of 36. There were significant differences in HFSAS scores by age, with younger patients having higher median and mean scores (Table 2). Differences in median HFSAS scores based on gender did not reach statistical significance ($p = 0.08$). The greatest variability in HFSAS scores occurred in relation to duration of symptoms of acute heart failure such as acute dyspnea (Figure 1). As indicated by the left to right increase in box plot size in Figure 1, patients reporting the highest levels of distress secondary to the symptoms of heart failure had the most variability in terms of length of endurance of these symptoms prior to seeking care. Symptom duration did not differ significantly for patients who had been previously admitted for symptom management of heart failure and those admitted for the first time.

Reliability Testing

The reliability of the HFSAS was assessed utilizing Theta reliability, an amplified Cronbach's alpha useful for instruments with discrete items.[24] Cronbach's alpha, based

on interitem correlations, is most useful when correlations range between 0.30 and 0.40.[27] Only eight of these 66 interitem correlations fell into or above this range (0.31- 0.65) indicating that the items are largely discrete. Thus, theta reliability was appropriate. Theta reliability values are interpreted similar to Cronbach's alpha.

Initial reliability of the HFSAS, calculated after the first 50 participants of phase 2 were enrolled, was 0.78. The theta was retested with the full final sample of 201 participants, including the first 50 participants. Theta reliability was 0.71 in the final sample. No item would have increased the reliability coefficient if deleted, so all 12 items were retained for the final HFSAS.

Validity Testing

Construct validity

To assess the constructs associated with the HFSAS, an exploratory factor analysis was conducted using a principle component analysis with varimax rotation. Results of the analysis produced a 4-factor solution using the criterion of an Eigenvalue greater than 1.0;[28] 58% of the variance in scores was explained (Table 3). The 4 HFSAS factors corresponded to the pathophysiology associated with heart failure. Factor I included the more acute heart failure symptoms of orthopnea, dyspnea, and paroxysmal nocturnal dyspnea. Factor II was comprised of the two items addressing symptoms related to peripheral edema. Factor III, with the exception of the symptom of cough, assessed items related to symptoms typically associated with myocardial infarction. Cough had the lowest factor loading (0.381) of all 12 symptoms. Factor IV represented the early symptoms of heart failure decompensation and included fatigue, weight gain, and dyspnea on exertion. Weight gain also loaded on Factor II, but was retained in Factor

IV where it had the highest loading. Similarly, dyspnea loaded on Factor IV and was retained in Factor I with the higher loading.

The HFSAS was analyzed for convergent and divergent construct validity in comparison with general somatic awareness as measured by the Modified Somatic Perception Questionnaire. The HFSAS had a low to moderate correlation with general somatic awareness (Spearman ‘s rho r = 0.48), indicating that the instruments measure something in common, but not the same construct.

Criterion-related validity

The HFSAS was examined for its ability to predict duration of symptoms prior to care-seeking for acute heart failure. The HFSAS score was a significant predictor of symptom duration, with higher scores associated with increased time from symptom onset to arrival at the hospital. That is, in spite of increased somatic awareness, patients delayed longer. Further analysis revealed that the pattern of symptom onset was accountable for this counter intuitive result. Patients with a gradual symptom onset waited until their symptoms reached a severe level prior to seeking care. The HFSAS was also a significant predictor of duration of acute symptoms in the linear regression model after adjusting for demographic and clinical factors known to influence the symptom experience (Table 4).[19, 29-31] The duration of acute symptoms increased approximately one hour for every one point increase in the HFSAS score. Similarly, an increase in the HFSAS score was associated with an increase in duration of dyspnea, acute dyspnea, and dyspnea on exertion. Acute dyspnea was defined as a sudden onset or increase over baseline levels of chronic dyspnea. Dyspnea on exertion was shortness of breath noticed only with activity. A subscale of the HFSAS measuring the acute symptoms as a group

(dyspnea, orthopnea, paroxysmal nocturnal dyspnea, and dyspnea on exertion) was predictive of an increase in acute dyspnea duration. The Modified Somatic Perception Questionnaire was not a significant predictor of symptom duration in the regression model, but HFSAS was predictive, after controlling for other factors such as age and pattern of symptom onset. Based on these analyses, the HFSAS was judged to have construct and criterion-related validity.

Discussion

Patients with heart failure are asked to monitor their symptoms on a daily basis to facilitate early interventions that may avert hospitalization. Availability of a reliable and valid measure of somatic awareness may be useful in assisting patients to become more aware of symptoms. In particular, attention to and care of the early symptoms of heart failure decompensation is important in averting unnecessary hospitalizations. This first test of the HFSAS is promising. The HFSAS was shown to be reliable with content, discriminate, and construct validity. No gender bias was evident in scores.

The reliability of the HFSAS was adequate to support further testing, but it was lower than anticipated, which may reflect the limited number of items or the variable symptom profile among patients with heart failure. Borderline reliability could reflect the brevity of the instrument, which was intentional to minimize participant burden. In an effort to improve reliability, further development and testing of the HFSAS will address adding items that assess symptoms that are difficult to measure. Dyspnea on exertion is one such factor, since patients tend to decrease activity in order to accommodate symptoms.[32]

Somatic awareness, when measured with the symptom specific HFSAS, was a significant predictor of duration of symptoms, thus supporting validity of the instrument. The Modified Somatic Perception Questionnaire, a general somatic tool, was less effective in predicting symptom duration. An instrument such as the HFSAS may enhance the ability of patients and health care providers to monitor symptom acuity based on patient status at baseline.

Interestingly, patients who had previously experienced an exacerbation of heart failure did not seek care any sooner than patients admitted for first time exacerbation of illness. One possible explanation is that previous experience with decompensation in heart failure does not provide sufficient knowledge for patients to avoid a hospital admission. These results contrast with those of Francque-Frontiero et al.[33] who found that experience with heart failure predicted self-care ability. Another potential explanation for this difference in findings is the outcome variable. Francque-Frontiero et al. found that patients with more experience had better self-care, but they did not assess the adequacy of self-care to prevent hospitalization, as we did. Our results suggest that it may take more than first hand experience to teach patients how to avoid rehospitalization.

The accuracy or validity of patient self reports is regularly questioned. Meek and colleagues,[2] studying a small sample of stable patients with chronic obstructive pulmonary disease, reported accurate recall of the average intensity of symptom experiences for a 2 week period. After regression analysis, however, the authors concluded that patient recall of symptom intensity for the 2 previous weeks was influenced by current symptom intensity. That is, when current symptoms are mild, the severity of relatively recent symptoms may be down-rated. Therefore, it may be advisable

to have patients evaluate the number and intensity of symptoms currently being experienced, as well as those in the recent past. In a secondary analysis of heart failure patients in the SOLVD clinical trial,[34] patient self report of physical status predicted hospitalization as well as or better than physiologic or clinician assessments. In a study of acute and prodromal symptoms in women with myocardial infarction, McSweeney reported accurate symptom recall based on acceptable test-retest scores 7 to 14 days later.[35]

Although not always feasible, asking patients to rate symptoms may require validation from others.[36] Additionally, it may be difficult for patients with chronic, omnipresent symptoms to objectively rate their degree of distress especially when it involves incremental change, which must be assessed in the context of daily life. For example, a patient may feel a symptom is severe, but rate the discomfort as less bothersome if able to continue with daily activities. Qualitative studies of persons with heart failure illustrate that patients learn to live with symptoms over time.[37, 38]

The HFSAS was tested in patients hospitalized for acute decompensated heart failure. The reliability and validity of the HFSAS among patients with chronic stable heart failure has not yet been explored and test-retest reliability has not been established. Furthermore, the effect of reading to the patient needs to be determined. A lack of ethnic diversity in the sample is also a limitation to generalizability.

Despite these limitations, the HFSAS may be useful in studies designed to improve symptom recognition and self-management. Using the HFSAS to establish baseline status may be clinically valuable in gauging the importance of the daily ebb and flow of symptoms. Fostering awareness of the early symptoms of decompensation may

avert repeated hospital admission for symptom management. The ultimate goal is to facilitate effective self-monitoring of the symptoms of heart failure in this growing population.

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Table 1. Sociodemographic characteristics of the Phase 2 sample (n = 201).

Age (years)	Mean 70 (SD ±12)
Gender	n and %
Female	88 (44%)
Marital Status	
Married	99 (49%)
Widowed	62 (31%)
Divorced, separated, never married	40 (20%)
Race	
White	191 (95%)
Black	8 (4%)
Hispanic	2 (1%)
Education	
Less than 12 years	58 (29%)
High School Diploma	69 (34%)
Some college	45 (22%)
Bachelors Degree	15 (8%)
Graduate Degree	14 (7%)
Co-morbid Illness	
Coronary Artery Disease	142 (71%)
Hypertension	144 (72%)
Diabetes	106 (53%)

Table 2. Phase 2 HFSAS scores by quintile of age.

	1	2	3	4	5
AGE	**37-60**	**61-70**	**71-75**	**76-80**	**81-97**
N in stratum	52	46	30	36	37
Mean	15.4	13.6	12.2	10.9	12.5
Standard Deviation	6.4	4.8	6.6	3.6	4.5
***Median**	**15**	**13.5**	**12**	**10.5**	**12**
Minimum	0	0	0	4	3
Maximum	29	25	28	20	23

Kruskal-Wallis test

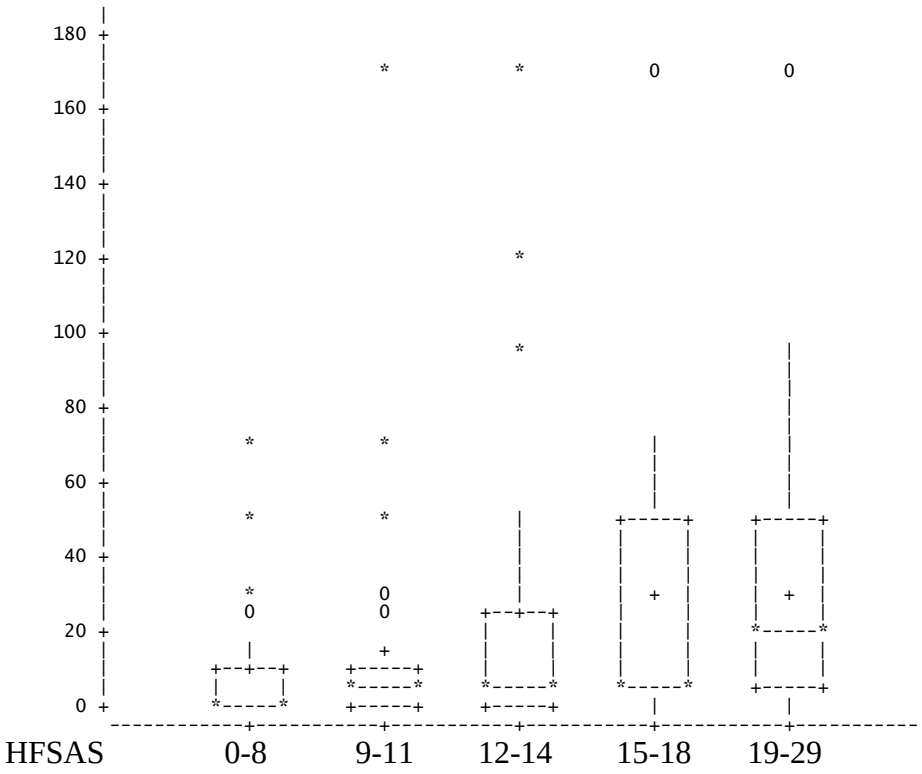
*p-value = 0.002

Table 3. Factor Loadings in the Rotated Factor Matrix for the 12-item HFSAS (n = 201)

Item	Factor 1	Factor 2	Factor 3	Factor 4
I could feel my heart beat get faster			.523	
I could not breathe if I lay down	.819			
I felt pain in my chest			.644	
I had an upset stomach			.738	
I had a cough			.381	
I was tired				.627
I could not catch my breath	.619			.523
My feet were swollen		.877		
I woke up at night because I could not breathe	.732			
My shoes were tighter than usual		.874		
I gained 3 or more pounds in the past week		.472		.501
I could not do my usual daily activities because I was short of breath				.709
Eigenvalue	2.86	1.75	1.25	1.08
Percentage of variance	23.8	14.5	10.4	9.0
Cumulative percent	23.8	38.4	48.8	57.8

An underlined value indicates loading of an item on 2 factors.

Figure 1. Duration of acute symptoms in hours by quintile of the HFSAS score.



\+ indicates the mean duration of acute symptoms in each quintile.

For example, in the HFSAS quintile of 19-29, the mean is 32.2 hours.

----- indicate the median duration of acute symptoms.

0 and * indicate the outliers in each quintile.

Table 4. Estimated change in duration of acute symptoms associated with HFSAS scores among subjects with acute symptoms ≤ 72 hours: n = 171.

	Beta	SE	p
Heart Failure Somatic Awareness	.88	.25	.0007
Controlling for			
Previous heart failure experience	.87	.26	.001
Age (continuous)	.80	.26	.002
Age > 75 years (dichotomous)	.84	.26	.001
Living alone (dichotomous)	.89	.26	.0006
< High School (dichotomous)	.82	.26	.002
Insulin dependent (dichotomous)	.90	.26	.0006
Male gender (dichotomous)	.91	.26	.0005
Sudden symptom onset(dichotomous)	.78	.25	.002
General Body Awareness (MSPQ)	1.26	.30	<.0001

Unstandardized Beta scores interpreted in hours

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Abstract: Objective: The purpose of this study was to test the efficacy of a heart failure (HF) training program on patients' ability to recognize and respond to changes in HF symptoms. The primary aim was to compare event-free survival at 90 days.
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Conclusions: HF symptom awareness training appeared to have an early but not sustained benefit resulting in no difference in 90-day event-free survival. However, larger improvement in self-care maintenance and confidence scores in the intervention group compared to usual care is promising. As a result, embedding meaningful symptom monitoring strategies in self-care maintenance interventions may be a realistic therapeutic target.

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***2) Title Page (including Author info and Acknowledgements)**

Heart Failure Symptom Monitoring and Response Training: A Pilot Study

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As a chronic illness, heart failure (HF) negatively affects quality of life with symptoms that limit activities of daily living and increase the risk of acute hospitalization.[1, 2] Effective self-care, with daily symptom monitoring and knowledgeable decision-making about symptoms when they occur, can help patients with HF maintain an acceptable quality of life and avoid repetitive hospitalizations. Symptom monitoring is particularly difficult because symptoms such as fatigue and cough are not specific to HF. Many patients with HF have comorbid conditions that can mask or mimic HF symptoms. Furthermore, symptoms vary from patient to patient, can increase insidiously over time, and are often misattributed to normal aging or a less threatening illness.[3] Symptom monitoring difficulties arise when patients try to distinguish a progression in HF symptom severity (signaling an acute exacerbation) from that of a comorbid illness, normal age-related changes in physical health, or chronic baseline symptoms.

Despite patient education on self-care, emergent hospital admission for acute symptom management remains common among patients with HF. Patients routinely report experiencing symptoms for a week or more before seeking care for an exacerbation.[4-6] The reasons for this delay are multifactorial, but symptom characteristics, patterns of symptom onset, and failure to recognize symptoms are related to longer delay.[3, 7-10] Clearly, better methods of teaching HF patients how to recognize and manage their symptoms are needed. The purpose of this study was to test the efficacy of a HF symptom training program, the HF Symptom Monitoring Awareness & Response Training (HF SMART), on patients' ability to recognize and respond to changes in HF symptoms. The primary aim was to compare event-free survival at 90 days in participants randomized to the HF SMART intervention versus those receiving usual care.

BACKGROUND AND SIGNIFICANCE

Difficulties with symptom recognition have been reported by both newly diagnosed and patients relatively more experienced with HF.[3] Horowitz and colleagues identified recognition, interpretation and response to symptoms as limitations to seeking timely medical intervention, with difficulty sensing an increase over baseline symptoms as particularly problematic.[3] Patients sought care for the more acute symptoms of HF after early symptoms of HF decompensation were missed. Failure to see HF as a chronic illness that required daily monitoring and management also impeded effective self-care. If symptoms were not severe, they were not attended to.

Patient education, a cornerstone of HF treatment, is directed at promoting self-care by focusing on adherence to therapy and monitoring of symptoms. Patients are instructed to monitor for signs and symptoms of volume overload (weight gain, edema, increasing dyspnea, and fatigue). Written materials describing the essential elements of self-care are usually provided to patients. Despite these efforts, readmission rates are over 30% 3 months[11-13] after initial hospitalization and as high as 47% at 6 months.[14, 15] Clearly, knowledge alone is insufficient to improve outcomes.

Tested strategies designed to improve HF outcomes generally can be divided into two categories. One type is intense follow-up of patients by health care providers (e.g., frequent phone calls)[13, 16-24] and the other aims to enhance patient self-care.[11, 12, 25] Not surprisingly, intense follow-up by health care providers decreased HF admissions in recent meta-analyses.[26-28] However, trials of enhanced self-care activities were even more effective in decreasing HF-related readmissions than those using intense follow-up strategies (RR 0.66 vs. RR 0.72-0.76). In other words, self-care interventions decreased admissions by 34% compared to 26% with

intense follow-up.[29] It should be noted that the effect of self-care was implied in many of the studies, as it was not explicitly measured in all investigations included in the meta-analysis. Finally, increased intensity of the provider follow-up did not always yield better outcomes. For example, Shah et al[23] reported a high readmission rate despite optimization of medications, frequent medical surveillance, and patient education for self-directed diuretic adjustment.

Clinical trials of enhanced patient self-care interventions decreased readmission rates in three of the five studies specifically targeting self-care practices.[11, 12, 25, 30, 31] The effective self-care interventions included education[11, 25, 30] with intermittent telephone follow-up.[25, 30] One study that was not effective in decreasing readmissions tested a brief educational intervention that began during hospitalization with a follow-up home visit within 10 days after discharge.[12] Patients could call the study nurse between discharge and the home visit if problems occurred. Self-care abilities improved, however, readmission rates were not statistically different between the intervention and the control group (p=.06). The other study tested a tailored message based on patients' perceived benefits and barriers to self-care.[31] In the subjects receiving the tailored messages, barriers and benefits of medications, diet, and self-monitoring all improved over a one month period but readmission rates and quality of life did not differ between the intervention and control groups at one month. Although education was an emphasis of all these trials, the elements associated with improved self-care remain unclear, although confidence in the ability to perform self-care has been shown to be important to improving self-care.[32, 33]

The optimal strategy for promoting HF self-care should be straightforward, standardized, and useful for a variety of health care providers in a variety of settings (hospital,

private practice, clinics). Interventions that could be easily incorporated into existing routines (e.g., discharge teaching) and subsequently reinforced by any health professional would be an important adjunct to current practice. The intervention tested in this pilot study was intended to fill this gap.

Intervention

The HF SMART intervention was developed from theory,[34-40] published literature, and our preliminary studies on response to HF symptoms.[5, 10] The HF SMART intervention, directed at symptom monitoring and response, is embedded in the Theory of HF Self-Care[40] (**Figure 1**). In this theory, self-care is defined as a naturalistic decision making process comprised of self-care maintenance, self-care management, and self-care confidence.[40] Respectively, these components of self-care are maintenance or adherence behaviors that prevent an acute exacerbation of HF (e.g., daily weighing), self-care management or the ability to recognize and respond to symptoms when they occur (e.g., take an extra diuretic for shortness of breath) and confidence in the ability to perform self-care.[41] Confidence in self-care, not actually a part of the self-care decision-making process, has been shown to be an important influence on self-care behaviors.[32, 33]

The intervention consisted of provision of a weight scale and HF self-care booklet, a 6-minute walk test, instruction on daily symptom graphing (tailored to participants), and a home visit to review the training. Excluding the home visit, the intervention takes 20 to 30 minutes to complete. HF SMART uses an interactive exercise to compare sensations of dyspnea and fatigue at rest and immediately after activity. Commonly patients are asymptomatic at rest so an important component of HF SMART was teaching patients to evaluate symptoms associated

with activity. Participants also were instructed to evaluate symptoms as clusters as opposed to discrete entities. As the early symptoms of HF decompensation such as fatigue and weight gain are not specific to HF, assessing symptoms as clusters aids identification of symptoms as HF-related or not.

The intervention uses somatic awareness (*How hard is it to breathe? Is my breathing the same, better or worse than yesterday?*) and cognitive awareness techniques (*Are my symptoms related to HF?).* The manner in which techniques are integrated is designed for incorporation into the patient's usual daily physical activity routine (e.g. bathing and dressing). Associating daily symptom monitoring with activities like hygiene and dressing serves a dual purpose. One, using a typical routine provides a schedule for the activity and two; hygiene activity helps to benchmark the level of dyspnea and fatigue day to day. The HF SMART protocol also prescribes a time and provides a context for repetitive self-monitoring of symptoms. A daily Symptom Graph was provided and reviewed to help patients track and graph symptoms (dyspnea, fatigue, weight, presence or absence of edema), and respond to symptoms (e.g. contact with health care providers). Directions on daily symptom monitoring including an example of a symptom graph with a change in symptom status were provided on a laminated card.

Individual HF symptom profiles were determined using the HF Somatic Perception Scale,[42] discussed further below, to account for potential variability in symptoms between patients. Dyspnea was a focus of the protocol because it was the most commonly reported symptom in our preliminary studies[5, 43] and others examining delay in care-seeking for acute HF.[4, 6] To mimic the sensation of dyspnea, the 6-minute walk test was used stimulate respiratory effort and link the change in somatic sensation associated with activity. Respiratory

effort and fatigue were rated at rest and immediately after the 6-minute walk test using a visual analogue scale.[44] Ratings of dyspnea and fatigue with activity ranging from 0 (no symptoms) to 10 (dyspnea or fatigue as bad as it can be) were then entered on the symptom graph. The Symptom Graph focused on fatigue and dyspnea because persistent fatigue and dyspnea on exertion at time of discharge have been reported in slightly more than 40% of patients hospitalized with acute HF.[45] The Symptom Graph was altered for patients whose most frequent or bothersome symptoms were other than dyspnea and fatigue. Each Symptom Graph accommodated 15 days of recorded signs and symptoms and used pressure sensitive paper to simultaneously create a copy for the participant. Participants were asked to return completed graphs to the investigator using preaddressed stamped envelopes. To support treatment fidelity, all interventions were done by the principal investigator (C.J.), audiotaped, and audited for content by a research assistant.

RESEARCH DESIGN AND METHODS

A randomized control trial was used to pilot test the effect of a HF symptom training intervention on time to first event defined as death or a HF hospitalization. Participants diagnosed with chronic HF (n=105) were randomized to the HF SMART intervention or usual care. Six participants did not complete enrollment or died during their index admission, resulting in 99 individuals available for this analysis (**Figure 2**). All participants received weight scales and a HF self-care booklet published by the Heart Failure Society of America.[46] Participants randomized to the intervention group received one-on-one training on how to recognize and respond to symptoms. The primary hypothesis was that time to first event would be longer in HF patients who received the HF SMART intervention. The secondary hypothesis

was that improvements in HF self-care behaviors would be greater in patients who received the HF SMART intervention compared with those in the usual care arm. Human subjects' approval was obtained from Stony Brook University and Stony Brook University Medical Center and all participants provided written informed consent.

Sample

Convenience sampling was used to enroll participants with a confirmed diagnosis of chronic HF. Criteria for study enrollment included English-speaking community dwelling adults making their own health care decisions and availability of a telephone for follow up interviews. Participants had to be cognitively intact as determined by a score of 24 or greater on the Mini-Mental State Exam.[47,48] Exclusion criteria included HF due to high output states (e.g. hyperthyroidism), major psychiatric illness, major uncorrected hearing impairment, planned discharge to a skilled nursing care facility, or terminal illness that would impede participation in a longitudinal trial. The rationale for these inclusion/exclusion criteria was the aim to include adults likely to engage in HF self-care.

The sample was drawn from a New York suburban tertiary care hospital and surrounding community between February 2007 and January 2011. Eligible patients were identified during hospitalization, by referral from attending cardiologists and other community health care providers, or in response to study advertisements. The principal investigator or a research assistant approached patients who agreed to screening, described the study, obtained informed, written consent, and confirmed eligibility. Secondary contact information was collected at enrollment in anticipation of loss to follow-up due to change of address, death, or other difficulties with contacting participants.

Approximately 20% of patients in our prior studies had a high comorbidity score as measured by the Charlson Index.[49] Therefore, to obtain a similar distribution, we balanced participants by comorbidity score (low, moderate, high) prior to randomization into the HF SMART program or usual care.

Outcome Measures

At enrollment, demographic, clinical, comorbidity data, overall perceived health and source of follow-up care (community/university health care provider or heart failure clinic) were collected on all participants by interview and chart review. In addition, all participants completed baseline measures of HF symptom awareness and self-care at baseline, which were repeated at 3-months. At 3 months, data were collected by telephone so participants were provided with a copy of the various scale answer choices to facilitate the process.

Comorbidity was measured at enrollment using the interview format of the Charlson Index.[49] Patients were queried about preexisting diseases (e.g., ulcer disease, diabetes). Most conditions are scored with 1 point although some (e.g., hemiplegia, cirrhosis) are assigned >1 point. Scores can range from 0 to 34 but every study participant had a score $\geq$1 because all had HF. Responses were summed, weighted, and indexed into one of three categories (low, moderate, or high) according to the published method. Validity was demonstrated by the instrument authors when comorbidity category predicted mortality, complications, health care resource use, length of hospital stay, discharge disposition, cost.

The HF Somatic Perception Scale (HFSPS v.3) is an 18-item 6-point Likert scale used to assess awareness and perceived distress of HF symptoms. The HFSPS asks how much the participant was bothered by 18 common HF symptoms during the last week and provides 6

response options ranging from 0 (not at all) to 5 (extremely). Scores range 0 to 90 with higher scores indicating higher perceived distress. The Cronbach's coefficient alpha was .87 in this sample.

Self-care was measured using the Self-Care of Heart Failure Index (SCHFI v.5), a 19-item scale capturing self-care maintenance, self-care management, and self-care confidence. Higher scores indicate better self-care. Discriminant and construct validity have been demonstrated previously.[41] Cronbach's alpha on the SCHFI maintenance, management, and confidence scales were 0.65, 0.45, and 0.75 in this sample, respectively.

The primary outcome variable was defined as the composite end point of time to first event of HF hospitalization, emergency department admission for HF or HF-related cause and death. For example, a HF-related cause may be new onset atrial fibrillation or dehydration related to over diuresis. Events were tracked using the electronic hospital records of Stony Brook University Hospital. Subjects also were telephoned at 1- and 3-months and asked about all hospitalizations, emergent physician contacts and visits (i.e. telephone contact for symptom complaints), and admissions to outside hospitals. In addition, county death records were reviewed to ascertain vital status on any subject lost to follow-up.

Data Analysis

Standard descriptive statistics were used to describe subjects' baseline sociodemographic, clinical characteristics and scale scores. Categorical variables were summarized by frequencies and proportions and continuous variables were summarized by the mean, median, standard deviation, and range. Chi square and student's t tests were used to examine differences based on group assignment. Kaplan-Meier analysis was used to test the

hypothesis that time to first event would be longer in HF patients who received the HF SMART intervention. Time to first hospitalization for HF or death from any cause was calculated based on the time point when participants assumed self-care activities (e.g. discharge date). Results were coded to indicate whether or not a first event occurred within 90 days. As a complementary analysis, differences in discrete-time survival (any event within 90-day) were quantified using a chi square test. Finally, differences between groups in improvements to self-care were quantified using *t*-tests without assuming equal variance; Hedges' *g* were quantified as standardized indices of effect size. All analyses were conducted using IBM SPSS v.19.0.0 (Chicago, IL). An intention-to-treat analysis was performed.

Results

The sample (n= 99) was predominately male, elderly, Caucasian, and married (**Table 1**). The majority of participants was educated at a high school level or had some college and most had an annual family income less than $40,000 per year. Few received care in a HF clinic or program. Most were taking an ACE inhibitor and a beta-blocker and had survived HF for approximately 5 years. Most were in NYHA class III or IV and had a low or moderate number of comorbid conditions. There were no significant differences between the intervention (n=48) and control (n=51) groups on any sociodemographic or clinical characteristic. There were no differences in self-care scores at baseline (**Table 2**).

Of the 99 patients in the analysis, 27 were hospitalized for a HF-related event and four died within 90 days. The intervention group reported more events but number of events did not significantly differ between groups (usual care = 11 events (20%), intervention group = 16 events (33.3%); χ^2 (with Yates continuity correction) = 1.18, p=.26). The mean ± standard error

survival time was 76.2 ± 4.0 days in the usual care group. In the intervention group, the mean survival time was 76.7 ± 3.8 days. There was no difference in survival time between groups (Log Rank χ^2 = 1.53, p=0.216) (**Figure 3**).

Of the three SCHFI subscale scores, only self-care maintenance scores were acceptable (score of 70 or greater) at 90 days (**Table 2**). In paired *t*-tests, the intervention group had significantly improved self-care maintenance, management and confidence scores (all p<.01), and the usual care group had significantly improved self-care maintenance and management (both p<.01). Absolute and relative improvements in self-care maintenance were numerically superior in the intervention group compared with usual care (18.0 vs. 12.9 points; Hedges' *g* = 0.270), but the differences between groups were not statistically significant. Similarly, absolute and relative improvements in self-care confidence were numerically superior in the intervention group compared with usual care (10.2 vs. 4.8 points; Hedges' *g* = 0.253); these differences were not statistically significant. In contrast, improvements in self-care management were numerically greater in the usual care group compared with the intervention group; this effect was small (Hedges' *g* = -0.153) and insignificant (p=0.70).

Discussion

Targeting symptom recognition and response to improve self-care and decrease HF readmissions was the primary strategy used in this study. Prior to this study, no researchers have examined symptom awareness training for patients with HF. However, training to increase patient awareness of symptoms of diabetes and asthma has been reported.[50, 51] The HF symptom awareness training tested in this study appeared to have an early benefit that was not sustained and resulted in no difference in event-free survival at 90 days. As the rate of

events was low in this sample, detecting a difference was not likely. Furthermore, we may have diluted the effect of the symptom training intervention by providing weight scales to *all* participants in this study. Koelling and colleagues reported more frequent weighing behavior 30 days after a one-hour one-on-one HF discharge education protocol compared to usual care (66% vs 51%).[30] Over half of all participants in the current study reported weighing themselves frequently or always at enrollment. At 90 days, daily weights increased to 93.1% in the intervention group and 77.1% in usual care. In addition to one other investigator, we have reported more consistent weight monitoring if the patient owned or was provided a scale.[52, 53]

Another potential explanation for the increased number of events in the intervention group is use of a daily symptom graph. Eastwood and colleagues reported a similar outcome using a symptom diary. They provided a heart health diary to 124 patients and followed them for 6 months.[54] Diary users had 47% more clinic visits than nonusers and 35% more telephone contacts. In this study, teaching patients to graph symptoms daily was intended to improve self-care capacity by prompting appropriate attention and response to symptoms. Although not significantly different, there were more events in the intervention group.

Baseline self-care scores were abysmal in both groups. Self-care maintenance, the first step in self-care, includes daily treatment adherence plus weight *and* symptom monitoring. Typically, HF patients are told which HF-related symptoms to monitor. The problem is they err in interpreting their symptoms using contexts derived from unrelated experiences (i.e. coughs due to a cold) or expectations (i.e. I am tired because I am old). We proposed that by providing both a physical and cognitive context for the interpretation of HF symptoms, patients would have the tools to improve their self-care resulting in fewer emergent hospitalizations for

symptom management. Self-care management scores had a numerically larger improvement in the usual care group, which is counterintuitive and possibly due to measurement error. The internal consistency of self-care management also was poor in this sample further cautioning interpretation of these results. However, the larger improvement in self-care maintenance and confidence scores in the intervention group compared to usual care is promising. As a result, embedding meaningful symptom monitoring strategies in self-care maintenance interventions may be a realistic therapeutic target. Largely a consequence of significant improvements in self-care in both groups, the effect sizes in this study were small; thus, a large number of participants are needed to show significant improvements in self-care and reductions in clinical events in future studies.

The small sample size was a limitation. Enrollment was challenging partly due to competing studies, inconsistent referrals and reluctance to participating in a longitudinal study. The primarily Caucasian sample limits the generalizability of the results, but is reflective of the geographic area where the study was conducted. Other limitations included an inability to blind the individual collecting follow-up data by telephone. Participants were told not to tell the telephone interviewer to which group they were assigned. However, it was not uncommon for intervention participants to volunteer their status.

Conclusions

HF disease management programs with an emphasis on self-care activities are reported to positively affect all-cause hospitalizations more than telephone contact or follow-up with a primary care physician.[29] The HF SMART symptom training intervention was designed to be a brief, low cost, and feasible intervention in the context of the often time limited process

allotted to hospital discharge education. Increasing the dose of the intervention, particularly within the first 30 days post discharge may improve the duration of the effect. Lastly, determining the self-care capacity of patients also may assist in determining the appropriate dose of a symptom training intervention and follow up care.

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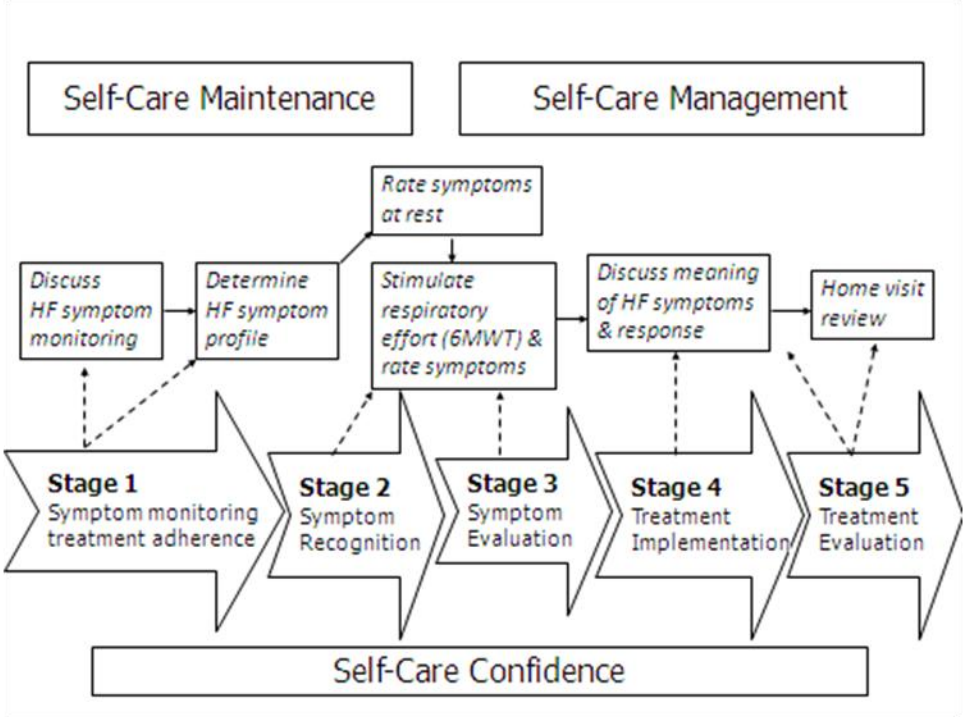
Figure

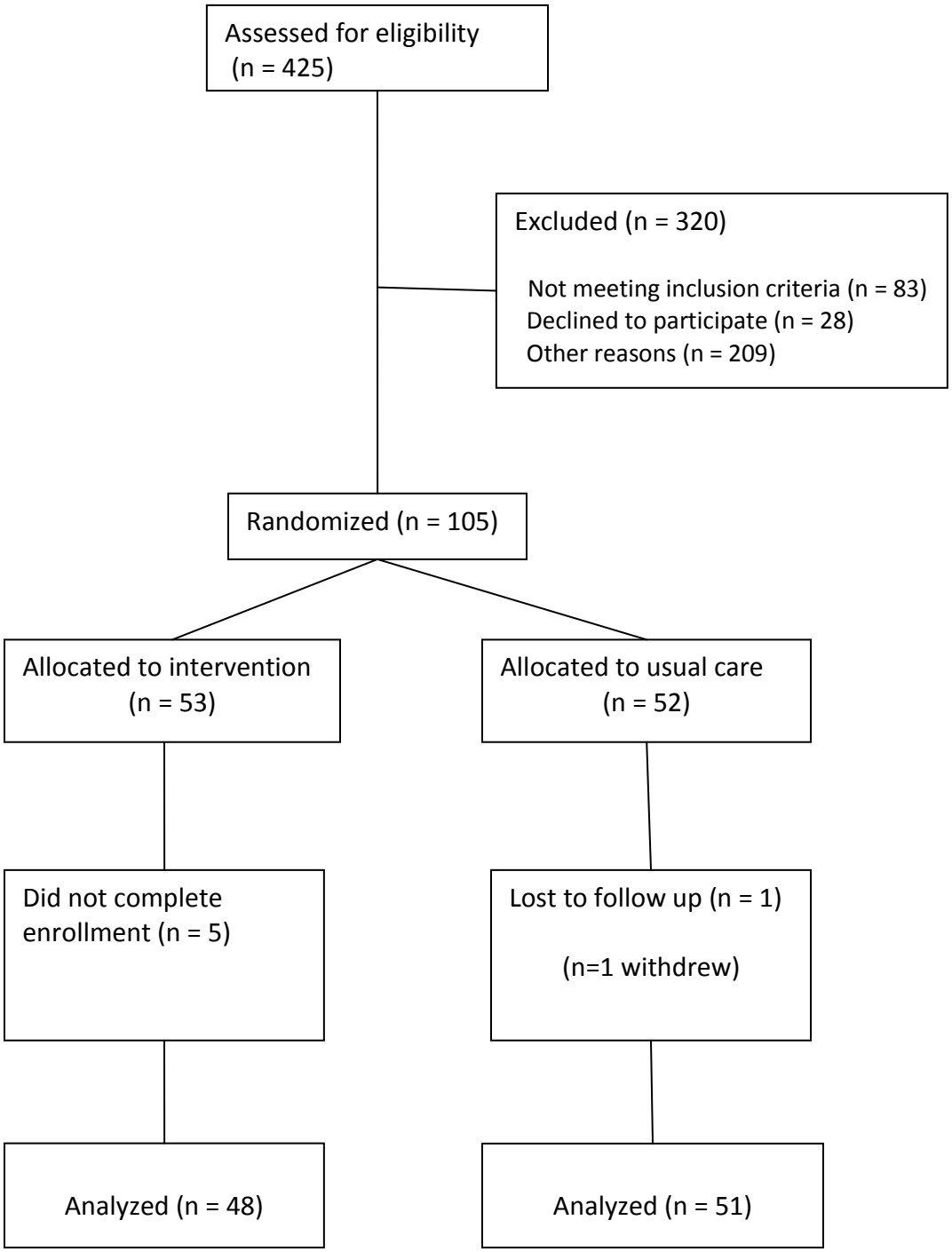
Figure 1. HF SMART intervention* embedded in the Self-Care of Heart Failure model



*HF SMART intervention in italics

Figure

Figure 2. CONSORT diagram showing the flow of participants



Table

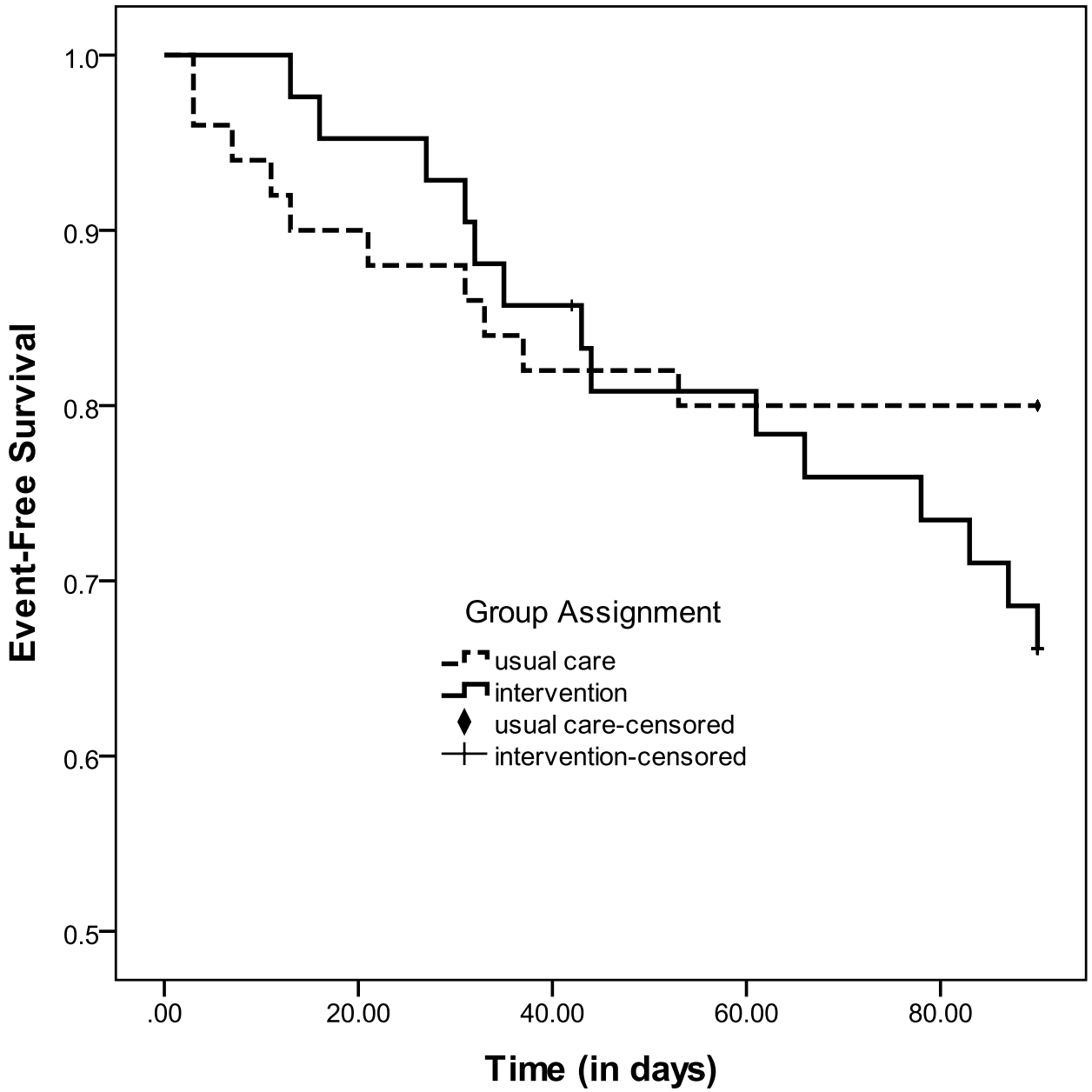
Table 1. Description of the Sample (N=99). N and valid percent shown unless otherwise noted.

Variable	Total Sample (N=99)	Intervention Group (n=48)	Usual Care Group (n=51)
Male gender	67 (67.7)	32 (66.7)	35 (68.6)
Age (mean ± standard deviation [SD])	67.7 ± 12.1	67.8 ± 12.7	67.7 ± 11.6
Race/ethnicity			
Caucasian	88 (88.9)	43 (89.6)	45 (88.2)
African-American	7 (7.1)	2 (4.2)	5 (9.8)
Hispanic	3 (3.0)	2 (4.2)	1 (2.0)
Other	1 (1.0)	1 (2.1)	0
Marital status			
Married	57 (57.6)	27 (56.3)	30 (58.8)
Widowed	17 (17.2)	7 (14.6)	10 (19.6)
Divorced, separated, never married	25 (25.3)	14 (29.2)	11 (21.6)
Living arrangements			
Lives alone	26 (26.3)	13 (27.1)	13 (25.5)
Lives with others	73 (73.7)	35 (72.9)	38 (74.5)
Highest level of education			
Less than 12 years	16 (16.2)	8 (16.7)	8 (15.7)
High school diploma	30 (30.3)	11 (22.9)	19 (37.3)
Some college/associate degree	28 (28.3)	16 (33.3)	12 (23.5)
Baccalaureate degree	12 (12.1)	6 (12.5)	6 (11.8)
Graduate degree	13 (13.1)	7 (14.6)	6 (11.8)
Total household income			
Less than $40,000/year	40 (40.4)	24 (50.0)	16 (31.4)
$40,000-69,999/year	27 (27.3)	9 (18.8)	18 (35.3)
$70,000 or more/year	16 (16.2)	8 (16.7)	8 (15.7)
Don't know or refused	16 (16.2)	7 (14.6)	9 (17.6)
Overall perceived health			
Excellent or very good	14 (14.1)	8 (16.7)	6 (11.8)
Good	24 (24.2)	11 (22.9)	13 (25.5)
Fair	38 (38.4)	16 (33.3)	22 (43.1)
Poor	23 (23.2)	13 (27.1)	10 (19.6)
Attend a HF clinic ∞			
Yes	28 (28.9)	15 (31.9)	13 (26)
No	69 (71.1)	32 (68.1)	37 (74)
Taking an ACE-inhibitor	55 (55.6)	26 (54.2)	29 (56.9)
Taking an ARB	14 (14.1)	6 (12.5)	8 (15.7)
Taking a beta blocker	86 (86.9)	43 (89.6)	43 (84.3)
New York Heart Association (NYHA) functional class ∞			
Class I or II	15 (15.2)	5 (10.4)	10 (19.6)
Class III	47 (47.5)	25 (52.1)	22 (43.1)
Class IV	37 (37.4)	18 (37.5)	19 (37.3)
Charlson Comorbidity Category			

Mild	39 (39.4)	19 (39.6)	20 (39.2)
Moderate	44 (44.4)	22 (45.8)	22 (43.1)
Severe	16 (16.2)	7 (14.6)	9 (17.6)
HF type			
Systolic dysfunction	35 (35.4)	16 (33.3)	19 (37.3)
Diastolic dysfunction	29 (29.3)	15 (31.3)	14 (27.5)
Mixed HF	29 (29.3)	13 (27.1)	16 (31.4)
Unknown	6 (6.1)	4 (8.3)	2 (3.9)
Years with HF (mean ± SD) ∞	5.5 ± 5.5	5.2 ± 5.3	5.9 ± 5.6
HF Somatic Perception Scale score	34.1 ± 18.1	34.7 ± 20.0	33.6 ± 16.5

∞ missing data

Figure 3. Kaplan Meier Survival Curve for days to event separated by treatment group. The lines cross which indicates a possible benefit at the beginning of the intervention, which lasted approximately 30-45 days. Overall, however, there was no difference in the hazard of events comparing the usual care and intervention groups.



Table

Table 2. Improvement in Self-care of HF scores between baseline and 90 days.

Variable	**Intervention Group** *Mean (SD)*	**Usual Care Group** *Mean (SD)*	**t value (p)**
Self-Care Maintenance			
Baseline	56.8 (*22.0*)	57.5 (*24.0*)	0.15 (.88)
90 days	76.9***** (*18.4*)	70.8***** (*21.2*)	-1.2 (.24)
Absolute Change	18.0 (20.8) †	12.9 (17.1)†	1.07 (0.14)
Relative Change	48.5% (72.4%)	33.8% (47.4%)	0.93 (0.18)
Self-Care Management			
Baseline	48.2 (*19.3*)	43.8 (*21.1*)	-1.0 (.30)
90 days	60.4 (*27.2*)	61.1 (*22.5)*	.098 (.92)
Absolute Change	15.9 (27.9)†	19.8 (22.8)†	-0.54 (0.70)
Relative Change	60.8% (96.2%)	94.3% (151.1%)	-0.94 (0.82)
Self-Care Confidence			
Baseline	54.3 (*17.2*)	54.4 (*16.9*)	.02 (.98)
90 days	65.2 (*19.1*)	60.5 (*20.7*)	-.93 (.36)
Absolute Change	10.2 (20.3)†	4.8 (21.6)	1.03 (0.15)
Relative Change	29.2% (56.6%)	16.8% (44.2%)	0.96 (0.17)

***** A score of 70 or higher is considered adequate.

† Significant improvement ($p<0.01$) from baseline to 90 days by paired *t*-tests

Title Page: Include Author Information and any acknowledgements on this page ONLY

Psychometric analysis of the Heart Failure Somatic Perception Scale as a measure of patient symptom perception

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Heart failure (HF) is a significant health problem that affects nearly 6 million Americans.[1] Mortality and costs associated with HF are high. Among patients with HF, approximately half die within 5 years of diagnosis and costs are estimated to be over $30 billion annually.[1,2] Repetitive hospitalization for management of HF signs and symptoms is common and contributes to high costs associated with this syndrome.

HF is characterized by a variable illness trajectory and symptom profile.[3-8] Consequently, determining prognosis is challenging for health care providers. Existing risk prediction models using objective clinical indicators are not always effective. Generalizability also may be limited based on populations used for testing the models and omission of the patient experience, particularly perception of symptoms and associated burden on activities of daily living.[9,10] Symptoms of HF drive care-seeking, healthcare utilization and predict quality of life and survival.[11-14] Although symptoms of HF predict survival, discrepancies exist between patients' and health providers' perceptions of HF symptoms and associated burden.[15-17] Accordingly, patient perception of symptoms, together with objective clinical indicators, is of potential value for prediction of both morbidity and mortality risk in this population.

The effect of HF symptom burden on survival has been investigated using measures that vary in method, number and type of symptoms assessed.[6,13,14,17,18] Symptoms have been extrapolated from quality of life measures,[18] measured with HF symptom instruments[13,14] and study-specific questionnaires,[17] and documented in symptom dairies.[6] Timeframes for symptom reports range from daily assessment to a one month recall and the number of symptoms assessed range between four and eighteen.

Variation in methods used to assess symptoms and associated burden may partially explain differences in findings related to symptoms and survival. Two studies of survival using four similar physical HF symptoms reported conflicting results.[6,18] In a study using symptoms extrapolated from the Minnesota Living with HF questionnaire, an emotional symptom cluster predicted event-free survival, but the 4-item physical symptom cluster (shortness of breath, fatigue/increased need to rest, fatigue/low energy, difficulty sleeping) did not.[18] Conversely, Moser and colleagues reported a four-fold increased risk of a clinical event using comparable physical symptoms. In the Moser study, a 30-day symptom diary was used to assess shortness of breath, swelling, fatigue, and difficulty sleeping.[6] The widest array of symptoms was used in a third study of HF symptoms and survival.[13] Survival was examined using version 3 of the HF Somatic Perception Scale (HFSPS), an 18-item physical HF symptom measure.[19] HFSPS scores were combined with depression, anxiety and hostility scores. Moderate to severe symptom burden profiles were associated with increased risk of clinical events (HR 1.82 to 2.06) when controlling for demographic and clinical variables.[13] Total scores of physical and psychological measures were used to delineate symptom profiles as mild, moderate or severe in nature.

There is substantial variation in how symptoms are experienced, reported by HF patients and documented by clinicians.[6,8,20,21] Importantly, evidence suggests that patient report of symptoms and the associated burden is important in relation to health outcomes. In a retrospective analysis of 4537 HF patients, those reporting fewer numbers of symptoms had both higher hospital death rates and 30-day mortality.[22] Furthermore, patients with fewer symptoms were less likely to receive effective cardiac medications compared with those

reporting multiple symptoms. As the study was a retrospective chart review, it is not possible to determine whether symptoms were indeed absent, not reported or simply not documented.

The number and severity of HF symptoms may be useful and important predictors of clinical risk. Therefore, the purpose of this study was to quantify the validity and prognostic value of patient perception of a full range of HF symptoms using a HF-specific physical symptom measure. The internal consistency of the HF Somatic Perception Scale v.3 was examined and followed by examination of the prognostic value of the full 18 item scale and subscales to predict event-free survival over one year as a measure of validity.

Method

A secondary analysis was conducted of 2 convenience samples with HF Somatic Perception Scale (HFSPS) data; one that assessed symptoms pre-randomization in a trial focused on symptom management[12] and one that evaluated symptoms among community-dwelling participants of two observational studies of heart failure symptoms.[13,23] Sampling criteria was similar between the samples. Inclusion criteria included (*a*) a confirmed diagnosis of HF, (*b*) able to read and comprehend fifth grade English, (*c*) reachable by telephone, (*d*) absence of major cognitive impairment, and (*e*) willing and able to provide informed consent. Exclusion criteria included (*a*) major uncorrected hearing impairment, (*b*) major psychiatric illness (e.g. schizophrenia), (*c*) major uncorrected visual impairment, (*d*) not expected to live for months, and (*e*) reversible HF (e.g. HF due to high output states). Human subjects approval was secured from each of the principal investigator's institutions.

Measurement

Physical HF symptoms were measured using the HFSPS, V.3, an 18-item Likert scale.[19] The HFSPS asks participants how much they are bothered by symptoms in the past week using 5 response options ranging from 0 (I did not have the symptom) to 5 (extremely bothersome). Scores are summed with higher values indicating higher symptom burden.

Convergent validity provides evidence of validity by examining the correlation between different measures of a construct. To support convergent validity, correlation of theoretically-related construct measures should be high.[24,25] The Kansas City Cardiomyopathy Questionnaire (KCCQ) is a 23-item Likert scale health status measure that assesses physical function, symptoms, social function, self-efficacy, and quality of life among patients with HF.[26] The KCCQ is a reliable and valid measure of health status responsive to change clinical status. The 6-item Physical Limitation subscale of the (KCCQ) was used to examine convergent validity. Scores range 1 to 36 on the Physical Limitation subscale. Higher scores indicate better function. The reliability of the Physical Limitation subscale is acceptable with a Cronbach's alpha of 0.90. We hypothesized that the correlation between the HFSPS and KCCQ Physical Limitation subscale would be significant.

Discriminant validity examines differentiation of constructs that are theoretically different. To support discriminant validity, correlation between two different constructs should be low.[24,25] The Self-Care of HF Index (SCHFI) was used to quantify self-care.[27] The SCHFI v.6.2 is a 22-item scale using a 4-point self-report response format to measure self-care maintenance (adherence behaviors), self-care management (response to symptoms) and self-care confidence. The 6-item Self-Care Management score was used to examine discriminant validity for this analysis because it reflects how quickly participants recognized and responded

symptoms as opposed to the physical experience of symptoms. Symptom recognition options ranged from 0 (I did not recognize it as a symptom of HF) to 4 (very quickly). Response to symptoms options included rating the likelihood of taking action to manage symptoms (e.g. taking an extra diuretic, reducing fluid intake) from 1 (not likely) to 4 (very likely). Scores are standardized to range from 0 to 100 with higher values indicated better symptom response behaviors. The Self-Care Management subscale of the SCHFI is multidimensional with a two factor structure representing symptom evaluation and treatment implementation. Therefore, a global reliability index is used to assess internal consistency. The global reliability index derived from the weighted least squares means and variance is 0.77 and 0.76 respectively.[28] We hypothesized that the correlation between the HFSPS and SCHFI Self-Care Management subscale would be weak and insignificant.

We completed a review of the electronic medical record at 1 year looking specifically for HF-related emergency room visits, hospitalizations or mortality. For the vast majority of events data were extracted directly from discharge summaries all participants received care locally and were part of an extensively-linked electronic medical record system. We also contacted study participants by phone to inquire about events that occurred outside of the health system network; we solicited sufficient detail directly from participants or their family members to determine whether or not the event was primarily related to their HF or for other reasons. All events underwent adjudication by two separate evaluators until 100% agreement was reached about the underlying reasons for emergent healthcare utilization.

Analysis

HFSPS item response means and standard deviations, and corrected inter-item

correlations were quantified. Item difficulty was assessed by quantifying the proportion of participants who provided the best possible response (I did not have this symptom). Item difficulty of 0.3 indicates that many (70%) participants had difficulty with the symptom, and item difficulty of 0.7 indicates that few (30%) participants had difficulty with the symptom; between 0.3 and 0.7 is the best range for item difficulty. Item discrimination was quantified by comparing item difficulty between participants with HFSPS total scores in the top and bottom thirds of the distribution. Confirmatory factor analysis was performed using M*plus* v.6 (Los Angeles, California). Geomin (oblique) rotation was chosen for this analysis using weighted least square parameter estimation with mean- and variance-adjusted statistics. Results are presented in rotated factor loadings and standard errors. To assess model fit, overall model χ^2 tests, comparative fit indices (CFI), Tucker-Lewis indices (TLI), root mean square errors of approximation (RMSEA), standardized root mean square residuals (SRMSR), normed fit index (NFI), and adjusted goodness-of-fit index (AGFI) were calculated using common thresholds of acceptability.[29] As the HFSPS was developed as a unidimensional scale, Cronbach's alpha was calculated as an index of internal consistency. Pearson's correlations were used to quantify convergent (KCCQ physical limitations score) and discriminant validity (SCHFI Self-Care Management). Finally, Cox proportional hazards modeling was performed using Stata MP v13 (College Station, TX) to quantify 1-year HF event-risk (emergency room visit or hospitalization for HF or all-cause death) as a function of the HFSPS scores. The proportional hazards assumption was justified based on Schoenfeld residuals. Hazard ratios (HR) and 95% confidence intervals (CI) are presented. To account for the influence of many other factors, the influence of symptom profiles on event-free survival was adjusted for the Seattle HF Score. The Seattle HF

Score was calculated based on the original model developed by Levy and colleagues.[10] In brief, demographic (i.e. age, gender) objective clinical indices (i.e. ischemic etiology, NYHA functional class, left ventricular ejection fraction, systolic blood pressure, hemoglobin, % lymphocyte count, uric acid, sodium, cholesterol) and HF treatment (i.e. beta blocker, angiotensin converting enzyme inhibitor, allopurinol, diuretic dose, statin use, and device therapy) were multiplied by respective slope coefficients[10] to generate a single composite risk-prediction score that in this sample ranged from -0.16 to 3.34.

Results

The samples used in this psychometric analysis are presented in **Table 1**. In brief, the sample was predominantly male (63.2%), Caucasian (85.2%) older adults (mean age = 62.6±12.8 years). A majority of participants (67.2%) had NYHA class III/IV symptoms.

Average inter-item correlations on the HFSPS ranged from 0.32 (It was hard for me to breath) to 0.35 (I had a cough) (**Table 2).** Item difficulty ranged from 0.09 (I was tired – the most commonly experienced symptom) to 0.66 (paroxysmal nocturnal dyspnea – the least commonly experienced symptom). Most items were discriminatory regarding the top and bottom 33.3% of physical HF symptom burden. In contrast, having a cough, being tired, and waking up at night to urinate were not helpful in discriminating between participants who reported least versus most burdensome physical HF symptoms because they were either highly-prevalent or because they were relatively normally distributed across response options.

The confirmatory factor analysis of the HFSPS is presented in **Table 3**. Several fit indices reached and others were close to reaching thresholds of acceptability; thus, the fit of the HFSPS as a single scale could be improved. The best fit exploratory factor analysis of the HFSPS is also

presented in **Table 3**. The resulting subscales were labeled according to dominant features as "dyspnea," "chest discomfort," "early and subtle" and "edema." Considering these four factors, the fit of the HFSPS was improved considerably.

Cronbach's alpha of the 18-item HFSPS was 0.90. Single item deletion did not result in significant improvement of internal consistency. Cronbach's alpha was 0.89 on the 6-item dyspnea subscale. Cronbach's alpha was 0.75 on the 7-item "early and subtle" subscale as well as the edema subscale. The chest discomfort subscale had a Cronbach's alpha of 0.68.

Convergent validity testing of the HFSPS with the KCCQ Physical Limitations score, and discriminant validity testing of the HFSPS with the SCHFI Self-Care Management are presented in **Table 4**. There were strong correlations between both the HFSPS and subscales and the KCCQ Physical Limitations score indicating similarity between measures of theoretically-related constructs. The HFSPS and subscales were not correlated with SCHFI Self-Care Management score confirming discriminant validity. Convergent and discriminant validity testing was limited to the total HFSPS and subscales for "dyspnea" and "early and subtle" subscales as the "chest discomfort" and "edema" subscales had few items.

The results of predictive validity testing are presented in **Table 5**. The 18-item HFSPS, 6-item dyspnea subscale, and 7-item early and subtle subscale were significantly associated with 1-year event-risk when controlling for the Seattle HF Score. Survival curves depicting event-free survival differences across a gradient of physical symptoms by HFSPS tertiles are presented in **Figure 1**. The severe symptom tertile is associated with markedly increased risk of HF-related clinical risks compared with the low symptom tertile on the 18-item HFSPS (HR=1.65, p=0.048),

6-item dyspnea subscale (HR=1.70, p=0.029) and 7-item early and subtle subscale (HR=1.99, p=0.010).

Discussion

The HFSPS is a valid and reliable measure of symptoms in HF in this sample of 378 adults with symptomatic HF. The HFSPS total, "dyspnea" and "early and subtle" subscale scores predicted HF event-free survival independent of a commonly used prognostication model.[10] Thus, the analysis indicates that patient perception of the physical symptoms of HF adds value when predicting clinical events.

The "dyspnea subscale" is a robust subscale with good reliability and validity that examines a full range and severity of dyspnea symptoms related to HF. We found that the dyspnea subscale was effective in predicting HF-related clinical events. Clinical events were adjudicated for HF specific events in this study. Conversely, dyspnea did not predict HF-related hospitalizations in the study by Ekman.[17] However, only two dyspnea symptoms were assessed and one (orthopnea) was assessed as present or absent. Similarly, dyspnea did not predict cardiac events in the study by K. Lee and colleagues.[18] A potential explanation of is that dyspnea was limited to one item and clustered with fatigue and sleep disturbance in the survival analysis. The flexibility of using the HFSPS dyspnea subscale is of interest for clinical and research use.

Assessment of the early and subtle symptoms of HF has clinical value. We found that increased severity of the early and subtle HF symptoms is associated with almost two times the risk of a clinical event within one year. Fatigue as a singular symptom (RR=1.09, p=0.018)[17] or clustered with other early and subtle symptoms (HR=1.00, p=0.011)[14] was a significant

predictor of HF event risk in other studies. Accordingly, there are important implications of this finding for both patients and health care providers. First, patients often have difficulty recognizing and responding to escalation in burden of the subtle nonspecific symptoms of HF.[20,30] Lack of attention to early and subtle signs of decompensation may contribute to delay in self-management and or care-seeking.[20] Patients with HF are typically instructed to monitor daily weights as an objective measure of increasing congestion. However, a disassociation between weight and dyspnea has been reported potentially increasing the importance of assessing additional symptom parameters.[31-33] Second, among patients with HF, cognitive impairment is common, can be subtle, and potentially impedes symptom reporting.[34-36] Despite the prevalence of cognitive impairment in this population, it is infrequently documented in the medical record by health care providers.[37] Educating patients regarding the importance of monitoring the early and subtle symptoms of HF that are commonly attributed to less threatening illness is warranted. Involving family and significant others in the education may improve effectiveness in detecting insidious increases in symptom severity. Taken together, evidence suggests that assessment of a full range of HF symptoms may be useful in evaluating therapeutic outcomes, predicting survival, and informing clinical decision making.

Strengths and Limitations

There are several strengths and limitations to be considered in interpreting these results. Strengths of this analysis lie in use of a HF-specific symptom scale and prospective documentation of symptom burden. Use of the HFSPS also afforded assessment of a full range of symptoms including those potentially not reported by patients unless specifically asked. The

survival analysis was strengthened by adjusting for clinical and treatment variables known to influence survival.

Limitations include a primarily male Caucasian sample limiting generalizability of the findings. In addition, the fit indices in this analysis were not perfect, but very good by most metrics. Although survival analyses are robust with smaller samples, additional testing of the predictive validity of the HFSPS and subscales is needed. Future testing also is needed to examine differential item functioning by gender, race, ethnicity and other factors.

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What is New (bulleted list of 2-3 highlights from article)

What's New and Important?

- Patient perception of HF symptoms is an effective predictor of 1-year survival
- The HFSPS Dyspnea subscale can be used alone to predict 1-year survival. It has validity and strong internal consistency.
- Early and subtle symptoms of HF also have value in predicting 1-year survival.

Table

Table 1: Characteristics of the sample (n=378)

	Sample 1 (n=105)	Sample 2 (n=273)	Full Sample (n=378)
Patient Characteristics:	mean±SD, n (%), median [IQR]	mean±SD, n (%), median [IQR]	mean±SD, n (%), median [IQR]
Age (years)	67.9±12.3	57.3±13.2	62.6±12.8
Female	33 (31.4%)	106 (38.8%)	139 (36.8%)
Non-Hispanic Caucasian	93 (88.6%)	229 (83.9%)	322 (85.2%)
Married/Living with Partner	62 (59.1%)	173 (63.4%)	235 (62.2%)
Charlson Comorbidity Index (weighted)	3.1±1.5	2.3±1.4	2.5±1.3
General Heart Failure Characteristics:			
Time with heart failure in months:	48 [12-102]	49 [16-96]	49 [14-98]
NYHA Functional Class:			
Class I/II	17 (16.3%)	106 (38.8%)	123 (32.5%)
Class III	48 (46.2%)	157 (57.64%)	205 (54.2%)
Class IV	39 (37.5%)	10 (3.7%)	49 (13.0%)
Left ventricular ejection fraction (%)	37.5±16.8	28.3±12.4	32.8±14.0
Prescribed a β-blocker	91 (86.7%)	248 (90.8%)	339 (89.7%)
Prescribed an ACE-I or ARB	64 (61%)	223 (81.7%)	287 (75.9%)
Serum sodium (mEq/L)	138.9±3.8	137.8±3.3	138.3±3.4
Serum BUN-to-creatinine ratio (mg/dL:1)	23.6±8.8	20.2±9.5	21.8±9.1

Abbreviations: ACE-I = Angiotensin Converting Enzyme-Inhibitor, ARB = Angiotensin Receptor Blocker, BUN = blood urea nitrogen, IQR = interquartile range, NYHA = New York Heart Association, SD = standard deviation.

Table

Table 2: Item Responses, Inter-item Correlation and Discrimination for the Heart Failure Somatic Perception Scale (n=378)

Item	I did not have this symptom	Not at all		→		Extremely	Mean ± SD	Inter-item correlation	Discrimination
1. I could feel my heart beat get faster	50.1%	14.2%	16.7%	9.3%	6.3%	3.3%	1.17±1.45	0.345	0.413
2. I could not breathe if I lay down flat	51.3%	5.2%	14.5%	8.7%	13.7%	6.6%	1.48±1.75	0.330	0.718
3. I felt discomfort or pain in my chest	51.2%	10.1%	16.7%	11.5%	7.9%	2.5%	1.22±1.49	0.344	0.447
4. I had an upset stomach	55.7%	6.8%	18.3%	10.3%	5.7%	3.0%	1.13±1.46	0.346	0.437
5. I had a cough	40.8%	15.1%	20.8%	11.2%	6.6%	5.5%	1.44±1.53	0.353	0.259
6. I was tired	9.1%	8.5%	25.5%	17.9%	23.4%	15.7%	2.85±1.50	0.331	0.203
7. I could not catch my breath	39.7%	5.8%	18.9%	14.5%	12.1%	9.0%	1.81±1.75	0.324	0.787
8. My feet were swollen at the end of the day	47.0%	14.2%	11.7%	11.2%	6.8%	9.0%	1.44±1.71	0.339	0.473
9. I woke up at night because I could not breathe	66.0%	6.6%	9.6%	5.5%	7.4%	4.9%	0.96±1.56	0.335	0.633
10. My shoes were tighter than usual…	59.7%	9.0%	10.7%	9.0%	6.0%	5.5%	1.09±1.58	0.340	0.505
11. I gained weight in the past week	56.5%	10.7%	12.9%	9.4%	6.6%	3.8%	1.10±1.51	0.347	0.399
12. I could not do my usual activities because of SOB	32.0%	10.9%	17.5%	15.3%	14.2%	10.1%	1.99±1.74	0.325	0.694
13. Getting dressed made it hard to breathe	51.0%	11.5%	15.6%	8.8%	8.8%	4.4%	1.26±1.56	0.326	0.751
14. My clothes felt tighter around my waist	59.3%	11.7%	11.2%	7.1%	6.3%	4.4%	1.02±1.50	0.336	0.533
15. I woke up at night because I had to urinate	16.7%	25.4%	23.0%	16.4%	11.5%	7.1%	2.02±1.48	0.350	0.200
16. I had to rest more than usual during the day	23.9%	10.7%	25.8%	16.2%	14.8%	8.5%	2.13±1.60	0.330	0.499
17. It was hard for me to breathe	41.3%	10.1%	15.0%	12.3%	12.6%	8.7%	1.71±1.76	0.323	0.859
18. I did not feel like eating	53.8%	14.8%	13.9%	9.8%	4.1%	3.6%	1.06±1.42	0.345	0.485

Table

Table 3: Confirmatory and Exploratory Factor Analysis for the 18-Item Heart Failure Somatic Perception Scale (n=378)

	HFSPS	Dyspnea	Chest Discomfort	Early Subtle	Edema
1. I could feel my heart beat get faster	0.51±0.04		0.78±0.05		
2. I could not breathe if I lay down flat	0.77±0.02	0.69±0.05			
3. I felt discomfort or pain in my chest	0.53±0.04		0.68±0.07		
4. I had an upset stomach	0.49±0.05			0.43±0.07	
5. I had a cough	0.38±0.04			0.35±0.09	
6. I was tired	0.71±0.03			0.72±0.06	
7. I could not catch my breath	0.89±0.01	0.78±0.07			
8. My feet were swollen at the end of the day	0.71±0.03				0.77±0.06
9. I woke up at night because I could not breathe	0.76±0.03	0.72±0.06			
10. My shoes were tighter than usual at the end of the day	0.74±0.03				0.78±0.06
11. I gained weight in the past week	0.50±0.04				0.52±0.06
12. I could not do my usual activities because I was short of breath	0.83±0.02	0.59±0.09			
13. Getting dressed made it hard to breathe	0.81±0.02	0.58±0.07			
14. My clothes felt tighter around my waist	0.66±0.04			0.53±0.06	
15. I woke up at night because I had to urinate	0.38±0.04			0.27±0.07	
16. I had to rest more than usual during the day	0.73±0.03			0.76±0.06	
17. It was hard for me to breathe	0.92±0.01	0.79±0.08			
18. I did not feel like eating	0.50±0.04			0.48±0.08	
Goodness of Fit					
χ^2 (df)	1176 (135)		358 (87)		
p-value	<0.001		<0.001		
RMSEA‡	0.143		0.091		
SRMR	0.100		0.046		
CFI	0.880		0.969		
NFI	0.867		0.960		
TLI	0.864		0.945		
AGFI	0.849		0.929		

Abbreviations: AGFI = Adjusted Goodness-of-fit Index; CFI = Comparative Fit Index; df = degrees of freedom; NFI = Normed Fit Index; RMSEA = root mean square error of approximation; SRMR = standardized root mean square residuals; TLI = Tucker-Lewis Index.

Thresholds for Acceptable Fit

AGFI ≥ 0.85
CFI and TLI ≥ 0.95
NFI ≥ 0.90
RMSEA = 0.05-0.08
SRMR <1.0

Table

Table 4: Convergent and Discriminant Validity for the Heart Failure Somatic Perception Scale

Linear correlations	KCCQ Physical Limitations	SCHFI Self-Care Management
HFSPS	-0.544†	0.181
HFSPS dysnea	-0.529†	0.182
HFSPS early	-0.390†	0.106

† $p<0.0001$ for all correlations with Bonferroni correction for multiple measures
Abbreviations: HFSPS = Heart Failure Somatic Perception Scale; KCCQ = Kansas City Cardiomyopathy Questionnaire; SCHFI = Self-Care of Heart Failure Index (v6).

Table

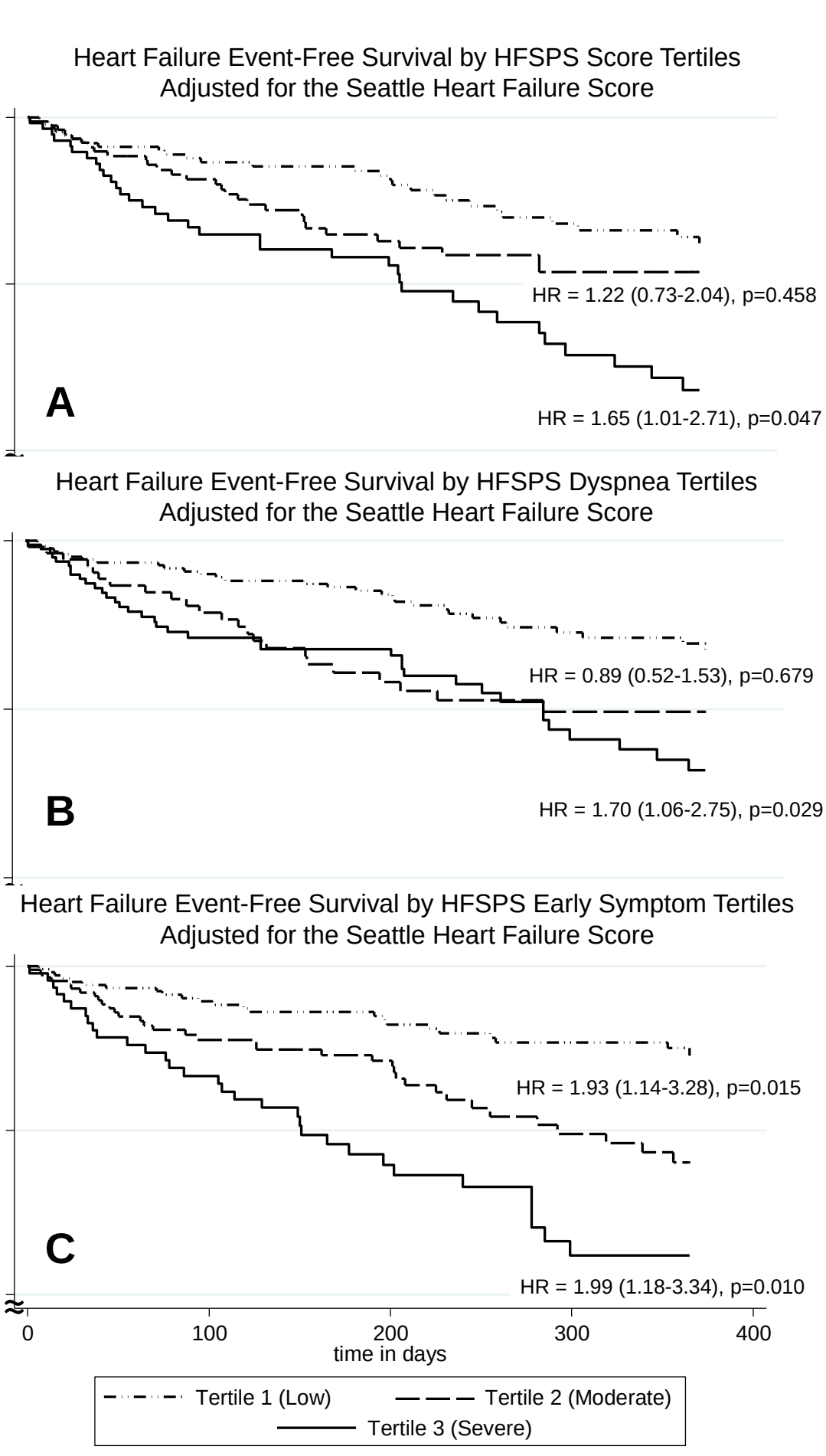
Table 5: Predictive Validity for the Heart Failure Somatic Perception Scale

365-day	Adjusted Hazard Ratio†	95%CI	p-value
HFSPS	1.012	1.001-1.024	0.038
HFSPS dyspnea	1.031	1.003-1.060	0.031
HFSPS early	1.030	1.003-1.058	0.028

† adjusted for the Seattle Heart Failure Score

Abbreviations: HFSPS = Heart Failure Somatic Perception Scale

Figure


Heart Failure Event-Free Survival by HFSPS Score Tertiles
Adjusted for the Seattle Heart Failure Score
HR = 1.22 (0.73-2.04), p=0.458
A
HR = 1.65 (1.01-2.71), p=0.047
Heart Failure Event-Free Survival by HFSPS Dyspnea Tertiles
Adjusted for the Seattle Heart Failure Score
HR = 0.89 (0.52-1.53), p=0.679
B
HR = 1.70 (1.06-2.75), p=0.029
Heart Failure Event-Free Survival by HFSPS Early Symptom Tertiles
Adjusted for the Seattle Heart Failure Score
HR = 1.93 (1.14-3.28), p=0.015
C
HR = 1.99 (1.18-3.34), p=0.010
0
100
200
300
400
time in days
Tertile 1 (Low)
Tertile 2 (Moderate)
Tertile 3 (Severe)

Key words-Keywords must be compatible with MeSH headings in Medline

KEY WORDS: heart failure; symptoms; survival; factor analysis, statistical