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Examining the Effects of an Outpatient Palliative Care Consultation on Symptom Burden, Depression, and Quality of Life in Patients With Symptomatic Heart Failure

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Abstract

Background—We conducted this prospective comparative study to examine the feasibility and effectiveness of a palliative care consultation along with standard heart failure care in an outpatient setting regarding symptom burden, depression, and quality of life (QOL).

Methods and Results—Thirty-six patients (53.6 ± 8.3 years old) were referred for an outpatient palliative care consultation after discharge. Changes in symptom burden, depression, and QOL at 3 months were compared with 36 patients with symptomatic heart failure matched on age, sex, race, and New York Heart Association functional class. Improvements were observed in symptom burden, depression, and QOL in both groups over time (all P <.005), but were more pronounced in patients receiving a palliative care consultation (all P <.035).

Conclusions—A palliative care consultation may reduce symptom burden and depression and enhance QOL in patients with symptomatic heart failure. Larger-scale randomized controlled trials sufficiently powered to assess clinical outcomes are warranted to determine the efficacy of palliative care services in outpatient settings regarding symptom distress, depression, and QOL in patients with symptomatic heart failure.

Keywords

Heart failure; symptom burden; depression; quality of life; palliative care

Patients with heart failure (HF) often experience physical, psychologic, social, and existential distress; furthermore, diverse symptoms are common and result in moderate to severe distress during the last 6 months of life in patients with symptomatic HF.[1–4] Therefore, greater attention to symptom management and advocating for palliative care (PC) earlier in the HF trajectory may potentially reduce suffering from both physical and psychologic symptoms and lessen the distress associated with this incurable condition.[1]

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Disclosures
None.

However, research that focuses on the impact of PC on symptom burden, depression, and quality of life (QOL) in HF is still in its infancy. The current evidence for effectiveness of PC programs in HF are limited to a few retrospective studies.[5,6] The scope of such programs traditionally includes inpatient consultations, PC units, and inpatient and home hospice care; studies examining PC interventions in ambulatory care settings are limited, and to our knowledge, evidence to support the potential benefits of an outpatient PC consultation are not available.

The primary objective of the present study was to assess prospectively the feasibility and efficacy of implementing an outpatient PC consultation with standard HF care regarding symptom alleviation and QOL outcomes in a cohort of patients hospitalized for acute HF exacerbation, and to compare them to an age-, sex-, race-, and functional class– matched comparison group not receiving PC services. The specific aims of this study were to: 1) assess the feasibility of the planned study protocol of referring patients recently hospitalized for HF decompensation for PC consultation along with standard HF care with follow-up of outcomes planned at 3 months; 2) compare the impact of a PC consultation with standard HF care versus standard HF care alone on symptom burden, depression, and QOL (physical health, emotional health, overall QOL) at baseline and 3 months; 3) examine the relationships among sociodemographic characteristics and clinical variables and symptom burden, depression, and QOL in patients with symptomatic HF; and 4) assess the predictive power of a multivariate model that includes a PC consultation regarding symptom burden, depression, and QOL in patients with symptomatic HF.

Methods

Study Design, Setting, and Participants

This prospective case-control study was conducted at a single university-affiliated medical center. Participants were recruited from the inpatient setting during an episode of acute HF exacerbation through HF provider referrals; patients who agreed to participate in the study were given an appointment for an initial PC consultation at the time of hospital discharge. Adult patients (≥18 years old), who were willing to be referred for a PC consultation were eligible to participate in the study. Patients already receiving PC services or those who had any condition that resulted in: 1) decreased cognitive function (eg, dementia); 2) a life expectancy of <6 months (eg, malignant cancer); or 3) surgically implanted left ventricular assist device or implantable cardioverter-defibrillator were excluded from study participation.

Because the patient sample was small (n = 36), we randomly selected 36 patients hospitalized for HF exacerbation from a larger pool of 157 participants enrolled in another randomized controlled trial conducted by our group before the 3-month window of the present intervention and assessed them after 3 months, similar to the interval used for patients assigned to the PC intervention. The goal of the matching was to include subjects in the comparison group, balanced by sex, age, race, and New York Heart Association (NYHA) functional class, to increase our ability to compare them with intervention subjects regarding the study measures. The success of the matching was evidenced by the lack of large or statistically significant differences in the matching variables or other demographic variables (Table 1).

Procedures

The study protocol was approved by the appropriate Institutional Review Board; each of the participants provided informed consent. Participants completed survey instruments during a 20–30-minute telephone interview before and 3 months after the PC consultation. The 3-

month follow-up was chosen based on several studies included in a systematic review that specifically examined the effects of a PC consultation on symptom burden and QOL at the end of life.[7] Medical chart reviews were conducted to verify self-reported data.

Palliative Care Consultation

Participants were given appointments for a PC consultation before hospital discharge; the appointment was coordinated by the research staff who worked with the PC clinic and the HF disease management team to schedule both appointments on the same day. The PC consultation lasted ~50–120 minutes (median time 75 minutes); all participants were seen by a PC specialist (eg, one of 2 board-certified PC physicians or an advance practice nurse who had completed an extensive training program on PC that included a 40-hour didactic component and a 6-month clinically mentored practicum with a board-certified PC physician). During this visit, a full medical, physical, and psychologic assessment and a comprehensive screening intake were completed that included current treatment regimens and available resources (eg, social, financial, health care). The PC specialist evaluated participants' values, goals, and preferences and assessed areas where participants perceived the need for support (eg, physical disability, symptom control, emotional distress, illness understanding, clarification of treatment goals, advance care planning). A treatment plan was established based on the PC specialist's evaluation and included modifications in medication regimen, counseling, and education to enhance coping and problem-solving skills, as well as coordination of care. A complete consultation note with the interdisciplinary team's recommendations was dictated for the patient's electronic medical record as well as sent to the participant's HF care provider and primary care physician.

Measures

Participants were asked to provide sociodemographic (eg, age, sex, race/ethnicity, marital status, level of education) and clinical (eg, HF etiology and duration, ejection fraction, previous HF admissions, and medication regimen) data. Comorbidities were measured with the use of the Charlson Comorbidity Index (CCI), a 36-item tool with good reliability and validity that generates an age-adjusted weighted score based on the presence of various medical illnesses.[8]

Symptom burden was measured with the use of the Edmonton Symptom Assessment Scale (ESAS), a validated reliable instrument that has been used in primary care settings[9] and in HF patients.[10,11] Participants were asked to rate the severity of 9 individual symptoms: pain, fatigue, drowsiness, nausea, anxiety, depression, appetite, dyspnea, and sense of well-being, on a 0–10 numeric scale (0 = no symptom at all; 10 = symptom worst possible).[19] An overall symptom distress score (ESAS) was computed by summing the score for all 9 items (range 0–90); higher scores reflected worse symptom burden. The reliability of the ESAS for the present study (Cronbach α) was 0.82.

Depression was assessed with the use of the 9-item Patient Health Questionnaire (PHQ-9), a highly reliable and validated tool that measures depression severity.[12] Participants were asked to rate if specified problems bothered them during the previous 2 weeks using a scale of 0 to 3, with 0 indicating "not at all" and 3 indicating "nearly every day." The sum of the scores of the PHQ-9 (range 0–27) was used to compute the overall depression score; higher scores denoted higher levels of depression severity.[13]

Quality of life was measured with the use of the Minnesota Living With Heart Failure Questionnaire (MLHFQ), a 21-item disease-specific tool that measures various HF symptoms experienced by participants in the previous month that prevented them from

living as they wanted to.[14] The tool was designed to assess HF and HF treatment impact on physical, emotional, and overall QOL; a lower score on the MLHFQ indicates better QOL.[14]

Data Analysis

Preestablished criteria were used to assess the feasibility of implementing a PC consultation with disease-directed care for HF with follow-up of outcomes planned at 3 months (aim 1). The study protocol was deemed to be feasible if the recruitment rate and target completion of measures at 3 months were ≥60% for each time interval.

To analyze aims 2 and 3, descriptive statistics including means, ranges, standard deviations, and chi-square statistics were used to characterize the study population. Symptom burden, depression, and QOL were compared between PC participants and their counterparts with the use of the analysis of covariance statistic. First, we determined whether there were significant group differences in mean outcome scores over time. Then, to account for the possibility that similar group means might be found only because outcomes improved over time for one group while worsening for the other, we conducted analyses of group × time (G × T) interactions. To control for baseline group differences, we controlled for time 1 values by entering them as covariates in the analysis of covariance equation. The adjusted means presented herein account for the influence of the time 1 value. An exploratory analysis was performed to compare changes in the number of participants within each subgroup (participants who received a PC consultation and participants in the matched control group) who showed improvements (decrease of ≥1), remained stable (no change), or reported deterioration (increase of ≥1) for each of the individual symptoms on the ESAS.

For aim 4, Pearson product moment or Spearman rho correlations were calculated, depending on level of measurement, to identify variables that significantly correlated with symptom burden, depression, and QOL. Variables significant at ≤.10 or those that were theoretically relevant were included in a forced-entry multivariate linear regression model for each of the dependent variables. The adequacy of each model was examined and all assumptions of multiple regressions (normality, linearity, and equality of variance) met. All statistical analyses were carried out with the use of SPSS for Windows (version 18.1.0; SPSS, Chicago, Illinois); statistical significance was set at $P < .05$ for all analyses.

Results

Study Participants and Study Feasibility

From March 1, 2008, to July 30, 2008 (5 months), 57 patients with symptomatic HF were approached, of whom 42 consented (73.6% recruitment); 9 (60%) were not interested in participating, and 6 (40%) cited time requirements. Thirty-six (85.7%) of the 42 patients who signed informed consent came for a PC consultation. Three participants decided to withdraw from the study: 2 moved away, and 1 patient was lost to follow-up before the PC consultation. The sociodemographic and clinical characteristics of participants in the PC group versus the comparison group were similar (Table 1).

Participants were on average 53.6 ± 8.3 years old; predominantly male (71%), white (61%), married (68%), and NYHA functional class II (71%); and had a mean left ventricular ejection fraction of 25.3 ± 6.5%. The most common comorbidities were overweight/obesity (72%), coronary artery disease (58%), hypertension (54%), diabetes mellitus (29%), and major depression (29%); the proportion of participants with a history of smoking was moderately high (51%), but none of the participants in either group reported being current smokers. The majority of participants were prescribed beta-blockers (76%), diuretics (75%),

and/or angiotensin-converting enzyme inhibitors (74%); a very small proportion of participants were on opioids for pain management (31%) and/or antidepressants (20%).

An evaluation of participants' treatment plans showed that the PC consultation focused on advance care planning (100%), symptom management (81%), illness understanding (69%), and patient and family coping (50%). New medications were prescribed in 20 participants (53%): 6 (30%) were prescribed opioids, 4 (20%) were prescribed antidepressants, and 10 (50%) were prescribed both opioids and antidepressants. Seven participants (19%) required changes in their pain medications or antidepressants: 5 (38%) of the participants who were already taking pain medications received a new medication or were titrated up to optimize pain relief, and 2 participants (14%) already on antidepressants were given new prescriptions for their depression. Patients' HF treatment regimen remained unchanged during the 3-month observation period; none of the subjects were rehospitalized during the study duration. All 36 patients who completed the PC consultation also completed the 3-month follow-up telephone interview.

Comparative Data

Table 2 presents the baseline and 3-month follow-up data for the variables of interest. Patients in both groups demonstrated significantly lower levels of symptom burden ($P < .001$) and depression ($P = .002$) and better emotional health ($P = .001$) and overall QOL ($P < .001$). Physical health improved for patients in the PC group and worsened for patients in the comparative group. Over time, group differences were statistically significant in all outcomes. Participants who received a PC consultation were more likely to show improvements in fatigue ($P < .001$), pain ($P = .044$), well-being ($P = .035$), depression ($P = .029$), dyspnea ($P = .008$), and nausea ($P = .045$) than participants in the matched control group (Table 3). Furthermore, a greater proportion of patients in the matched control group showed worsening symptoms of fatigue (31% vs 11%; $P < .001$) and pain (28% vs 10%%; $P = .044$).

Univariate and Multivariate Findings

Table 4 presents the relationships between sociodemographic and clinical variables and symptom burden, depression, and QOL. Age was associated with symptom burden ($P = .004$); older participants had greater symptom distress. Gender was associated with emotional health ($P = .012$); women were more likely to have worse emotional health; and comorbidity scores were correlated with overall QOL ($P = .031$). Palliative care was associated with symptom burden, depression, physical health and QOL (all $P \leq .008$).

In a multivariate model, age, baseline symptom burden, depression, QOL, and PC accounted for 57% of the variance in symptom burden at 3 months. The same predictors accounted for 23% of the variance in depression at follow-up. Three multivariate models that included sex and comorbidity accounted for 75%, 37%, and 50% of the variance in physical health, emotional health, and overall QOL, respectively.

Discussion

Practicing and advocating for PC earlier rather than later in the HF disease trajectory is one way to address the need for more effective and humane care for individuals suffering with HF.[3] Although the benefits of outpatient PC consultation has affected quality and direction of care for cancer patients, the potential benefits of a PC consultation in patients with HF are less understood. The present study was conducted to assess the feasibility and effectiveness of implementing a PC consultation with disease-directed therapy on alleviating symptom burden and enhancing quality and direction of care for patients recently hospitalized for HF

de-compensation with significant symptom burden, marked depression, and reduced QOL. Our data corroborate that patients with HF suffer significant symptom distress at various stages of the HF trajectory.[1,15–19] As expected, participants in our sample who were older and experienced a greater number of comorbidities also reported greater symptom burden and poorer QOL; women reported more depressive symptoms than their male counterparts. Likewise, our findings are consistent with earlier studies that reported high prevalences of pain and symptom burden in HF patients that are equal to or higher than those of cancer patients.[20,21]

We also found that implementing a PC consultation was feasible and resulted in reduced symptom burden and depression and improved QOL in patients with symptomatic HF; these findings substantiate earlier research findings that outpatient PC referrals early in the disease trajectory enhance clinical management and care coordination for patients and families suffering with the burden of HF.[22] Our evidence and experience demonstrate the need to further examine the impact of a PC consultation to support patient and caregiver goals throughout the HF illness trajectory. Although we simply report on the benefits of a single PC consultation on symptom burden, depression, and QOL, our findings support current consensus to initiate a PC consultation earlier rather than later in the HF trajectory, preferably at the time of diagnosis or a hospitalization for HF exacerbation, and one that is adapted to the patient and environment and continue into the family's bereavement period.[3,22] Older adults and sicker patients, as well as women, warrant increased scrutiny when screening for patients at greatest risk for physical and psychosocial distress. The benefits of follow-up PC services remain to be examined.

Study Limitations

Our study has several limitations. First, our patient cohorts were small, allowing for the possibility of type II errors. In addition, participants were not individually randomized but rather matched on sociodemographic variables and functional class to optimize our ability to compare the effects of providing PC services to patients with symptomatic HF. Although nearly all baseline characteristics in the 2 groups were similar, we can not be sure that the differences in symptom burden, depression, and QOL at follow-up were indeed related to the PC intervention. For example, in the case of physical health, participants in the PC cohort improved and the participants in the comparative group worsened; we might argue that the PC consultation may have had the added benefit of improving QOL by reducing symptom burden, thus supporting the argument that a PC consultation for patients with symptomatic HF may be beneficial. However, the case-control design of the study limits our ability to say that the PC consultation resulted in better health outcomes. Our findings merely support the association between the PC consultation and symptom burden, depression, and QOL. Second, although we had a fairly homogeneous sample of patients receiving optimized medical treatment for their HF through a single tertiary care center, the study participants were considerably younger than the general population of HF patients; therefore, the results may not be generalizable to older patients in the community who are at greatest risks for symptom burden and who could potentially benefit the most from the implementation of an outpatient PC consultation. Finally, we simply report the short-term outcomes of implementing a PC consultation; clearly, additional studies that assess the long-term outcomes of a PC consultation along with standard HF care are warranted. Nevertheless, our findings justify a larger randomized controlled trial to test the effectiveness of including a PC consultation with disease-specific HF care on patient outcomes. Likewise, future studies that describe the specific components and nature of these clinical encounters and that assess the impact of specific components of PC services which actually led to improvements in outcomes in the present study are warranted. Finally, research trials that evaluate the impact of PC services on patient and family satisfaction,

clinical outcomes (eg, hospital readmissions, mortality), and resource utilization (emergency department and urgent care visits, length of hospital stay, utilization of home health services, cost-effectiveness) as well as health care providers' attitudes and perceptions are needed to better explicate the role of PC on overall outcomes of care.

Conclusion

The psychologic benefits of PC are well documented in cancer populations, but the results of implementing a PC consultation with standard HF care are less definitive. Based on the findings of the present study, a PC consultation is effective for the control of symptoms in symptomatic patients with HF seen in an outpatient setting. The benefits of PC services on symptom burden, depression, and QOL should be examined in a larger-scale randomized controlled trial sufficiently powered to assess clinical outcomes and to extrapolate the potential impact of implementing a PC consultation along with disease-directed therapy, wherein patients and families collaborate with health care providers to identify goals of care and determine how their care changes over time.

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Table 1

Baseline Sociodemographic and Clinical Characteristics

	All Participants (n = 72)	Palliative Care Group (n = 36)	Comparison Group (n = 36)	*P* Value
Age, y (mean ± SD)	53.6 ± 8.3	53.9 ± 8.0	53.3 ± 8.7	.789
Male, n (%)	51 (70.8%)	26 (72.2%)	25 (69.4%)	.795
Race, n (%)				1.000
Hispanic	10 (13.9%)	5 (13.9%)	5 (13.9%)	
White	44 (61.1%)	22 (61.1%)	22 (61.1%)	
Black	18 (25.0%)	9 (25.0%)	9 (25.0%)	
Married, n (%)	49 (68.1%)	25 (69.4%)	24 (66.7%)	.800
Employed, n (%)	26 (36.1%)	14 (38.9%)	12 (33.3%)	.261
Education, n (%)				.786
<High school	18 (25.0%)	7 (19.4%)	11 (30.6%)	
High school graduate	23 (31.9)	10 (27.8)	13 (36.1%)	
Some college	21 (29.2%)	10 (27.8%)	11 (30.6%)	
Completed college	10 (13.9%)	9 (25.0%)	1 (2.8%)	
Ejection fraction, % (mean ± SD)	25.3 ± 6.5	25.4 ± 5.2	26.0 ± 6.2	.668
Peak VO_2, mg kg^{-1} min^{-1} (mean ± SD)	13.7 ± 3.4	12.0 ± 2.9	14.5 ± 3.5	.164
Body mass index, kg/m^2 (mean ± SD)	27.2 ± 3.7	27.1 ± 4.0	27.3 ± 3.4	.877
Charlson Comorbidity Index (mean ± SD)	3.5 ± 1.4	3.7 ± 1.5	3.3 ± 1.3	.220
NYHA functional class, n (%)				.795
II	51 (70.8%)	25 (69.4%)	26 (72.2%)	
III	21 (29.2%)	11 (30.6%)	10 (27.8%)	
Hypertension, n (%)	39 (54.2%)	22 (61.1%)	17 (47.2%)	.237
Coronary artery disease, n (%)	42 (58.3%)	22 (61.1%)	20 (55.6%)	.633
Diabetes mellitus, type 2, n (%)	21 (29.2%)	12 (33.3%)	9 (25.0%)	.254
Overweight or obese, n (%)	52 (72.2%)	35 (69.4%)	27 (70.0%)	.633
Major depression, n (%)	21 (29.2%)	12 (33.3%)	9 (25.0%)	.437
Smoking (previous smoker), n (%)	37 (51.4%)	14 (38.9%)	23 (63.9%)	.048
Medications use, n (%)				
ACE inhibitors	53 (73.6%)	26 (72.2%)	27 (75.0%)	.789
Angiotensin receptor blockers	13 (18.1%)	7 (19.4%)	6 (16.7%)	.418
Beta-blockers	55 (76.4%)	26 (72.2%)	27 (73.6%)	.789
Diuretics	54 (75.0%)	23 (63.9%)	31 (86.1%)	.029
Digoxin	41 (56.9%)	21 (58.3%)	20 (55.6%)	.946
Pain medications	22 (30.5%)	11 (30.6%)	11 (30.6%)	.675
Antidepressants	14 (19.7%)	8 (22.2%)	6 (16.7%)	.551

ACE, angiotensin-converting enzyme; NYHA, New York Heart Association.

Table 2

Baseline and 3-Month Outcomes (n = 72), Mean ± SD

	Palliative Care Group (n = 36)		Standard HF Care Group (n = 36)			
Variable	**Baseline**	**3 mo**	**Baseline**	**3 mo**	***P* Value (time)**	***P* Value (G × T)**
Symptom burden (ESAS)[*,§]	37.1 ± 7.3	30.9 ± 4.2	37.3 ± 7.3	34.0 ± 3.7	.000	.031
Depression (PHQ-9)[†,§]	14.2 ± 5.5	8.7 ± 5.1	14.5 ± 5.9	13.4 ± 6.1	.002	.034
Quality of life (MLHFQ)[‡,§]						
Physical	15.6 ± 7.3	13.8 ± 8.7	16.3 ± 7.4	18.9 ± 6.2	.377	.000
Emotional	15.9 ± 5.8	11.8 ± 6.4	16.1 ± 6.2	15.6 ± 6.0	.001	.009
Overall	35.6 ± 12.3	25.7 ± 12.2	38.0 ± 11.9	33.7 ± 10.0	.000	.015

[*] Edmonton Symptom Assessment Scale.

[†] Patient Health Questionnaire.

[‡] Minnesota Living With Heart Failure Questionnaire.

[§] Higher scores indicate greater symptom interference and lower health-related quality of life.

Table 3

Comparison of Change in Symptoms Between Participants Receiving a Palliative Care Consultation (PC; n = 36) Versus Participants in a Matched Control Group (C; n = 36) at 3 Months, n (%)

	Improved*		Remained Stable		Deteriorated†			
	PC	C	PC	C	PC	C	χ^2	*P* Value
Fatigue	25 (69.4)	3 (3.8)	7 (19.4)	22 (61.1)	4 (11.1)	11 (30.5)	15.429	<.001
Pain	17 (47.2)	5 (13.8)	18 (50.0)	21 (58.3)	1 (10.0)	10 (27.7)	6.230	.044
Anxiety	16 (44.4)	5 (13.8)	16 (44.4)	25 (69.4)	4 (11.1)	6 (16.6)	2.939	.230
Well-being	21 (58.3)	6 (16.6)	15 (41.7)	30 (83.3)	0 (0)	0 (0)	4.433	.035
Depression	23 (63.9)	6 (16.6)	12 (33.3)	26 (72.2)	1 (2.8)	4 (11.1)	7.084	.029
Dyspnea	18 (50.0)	2 (5.5)	18 (50.0)	34 (94.4)	0 (0)	0 (0)	6.952	.008
Drowsiness	14 (38.9)	3 (8.3)	21 (58.3)	31 (86.1)	1 (2.8)	2 (5.5)	1.835	.400
Appetite	10 (27.8)	4 (11.1)	26 (72.2)	31 (86.1)	0 (0)	1 (2.7)	.532	.466
Nausea	16 (44.4)	1 (2.8)	19 (52.8)	34 (94.4)	1 (2.8)	1 (2.7)	6.207	.045

*Increase in score by ≥1 point.

†Decrease in score by ≥1 point.

Table 4

Correlational Matrix of Key Variables at 3 Months (n = 72)

	Group (PC)	Age	Sex	Comorbidity	NYHA	Symptom burden	Depression	Physical QOL	Emotional QOL	Overall QOL
1. Group (PC)										
2. Age	.032									
3. Sex	−.031	.209								
4. Comorbidity	.146	.057	−.047							
5. NYHA	.031	.043	−.008	.047						
6. Symptom burden[†,¶]	−.368[**]	.332[**]	.042	.156	−.031					
7. Depression[†,¶]	−.385[**]	.038	.039	.017	−.063	.136				
8. Physical QOL[§,¶]	−.320[**]	.075	−.025	.113	.129	.287[*]	.406[**]			
9. Emotional QOL[§,¶]	−.309[**]	.174	.295[*]	.169	.108	.322[**]	.116	.354[**]		
10. Overall QOL[§,¶]	−.340[**]	.081	.170	.254[*]	.185	.312[**]	.306[**]	.668[**]	.493[**]	

NYHA, New York Heart Association functional class; PC, palliative care; QOL, quality of life.

[*] $P < 0.05$.

[†] Edmonton Symptom Assessment Scale.

[‡] Patient Health Questionnaire.

[§] Minnesota Living With Heart Failure Questionnaire.

[¶] Higher scores indicate greater symptom interference and lower health-related quality of life.

[**] $P < 0.001$.