

Quality of Life in Patients With Heart Failure With Recovered Ejection Fraction

Peter Wohlfahrt, MD, PhD; Jose Nativi-Nicolau, MD; Mingyuan Zhang, MS; Craig H. Selzman, MD; Thomas Greene, PhD; Jorge Conte, MD; Joshua E. Biber, MBA; Rachel Hess, MD, MS; Favel L. Mondesir, PhD, MSPH; Omar Wever-Pinzon, MD; Stavros G. Drakos, MD, PhD; Edward M. Gilbert, MD; Line Kemeyou, MD; Bernie LaSalle, BS; Benjamin A. Steinberg, MD, MHS; Rashmee U. Shah, MD; James C. Fang, MD; John A. Spertus, MD; Josef Stehlik, MD, MPH

IMPORTANCE Heart failure with recovered ejection fraction (HFrecEF) is a recently recognized phenotype of patients with a history of reduced left ventricular ejection fraction (LVEF) that has subsequently normalized. It is unknown whether such LVEF improvement is associated with improvements in health status.

OBJECTIVE To examine changes in health-related quality of life in patients with heart failure with reduced ejection fraction (HFrEF) whose LVEF normalized, compared with those whose LVEF remains reduced and those with HF with preserved EF (HFpEF).

DESIGN, SETTING, AND PARTICIPANTS This prospective cohort study was conducted at a tertiary care hospital from November 2016 to December 2018. Consecutive patients seen in a heart failure clinic who completed patient-reported outcome assessments were included. Clinical data were abstracted from the electronic health record. Data analysis was completed from February to December 2020.

MAIN OUTCOMES AND MEASURES Changes in Kansas City Cardiomyopathy Questionnaire overall summary score, Visual Analog Scale score, and Patient-Reported Outcomes Measurement Information System domain scores on physical function, fatigue, depression, and satisfaction with social roles over 1-year follow-up.

RESULTS The study group included 319 patients (mean [SD] age, 60.4 [15.5] years; 120 women [37.6%]). At baseline, 212 patients (66.5%) had HFrEF and 107 (33.5%) had HFpEF. At a median follow-up of 366 (interquartile range, 310-421) days, LVEF had increased to 50% or more in 35 patients with HFrEF (16.5%). Recovery of systolic function was associated with heart failure-associated quality-of-life improvement, such that for each 10% increase in LVEF, the Kansas City Cardiomyopathy Questionnaire score improved by an mean (SD) of 4.8 (1.6) points ($P = .003$). Recovery of LVEF was also associated with improvement of physical function, satisfaction with social roles, and a reduction in fatigue.

CONCLUSIONS AND RELEVANCE Among patients with HFrEF in this study, normalization of left ventricular systolic function was associated with a significant improvement in health-related quality of life.

Author Affiliations: University of Utah School of Medicine, Salt Lake City (Wohlfahrt, Nativi-Nicolau, Zhang, Selzman, Greene, Conte, Biber, Hess, Mondesir, Wever-Pinzon, Drakos, Gilbert, Kemeyou, LaSalle, Steinberg, Shah, Fang, Stehlik); Center for Cardiovascular Prevention, Charles University in Prague, First Faculty of Medicine and Thomayer Hospital, Prague, Czech Republic (Wohlfahrt); Now with Xcenda, Warrensburg, Missouri (Biber); Saint Luke's Mid America Heart Institute, Kansas City, Missouri (Spertus); Division of Cardiovascular Medicine, University of Utah Health, Salt Lake City (Stehlik); Institute for Clinical and Experimental Medicine, Prague, Czech Republic (Wohlfahrt).

Corresponding Author: Josef Stehlik, MD, MPH, Division of Cardiovascular Medicine, University of Utah Health, 50N Medical Dr, 4A100 SOM, Salt Lake City, UT 84132 (josef.stehlik@hsc.utah.edu).

JAMA Cardiol. 2021;6(8):957-962. doi:10.1001/jamacardio.2021.0939
Published online May 5, 2021.

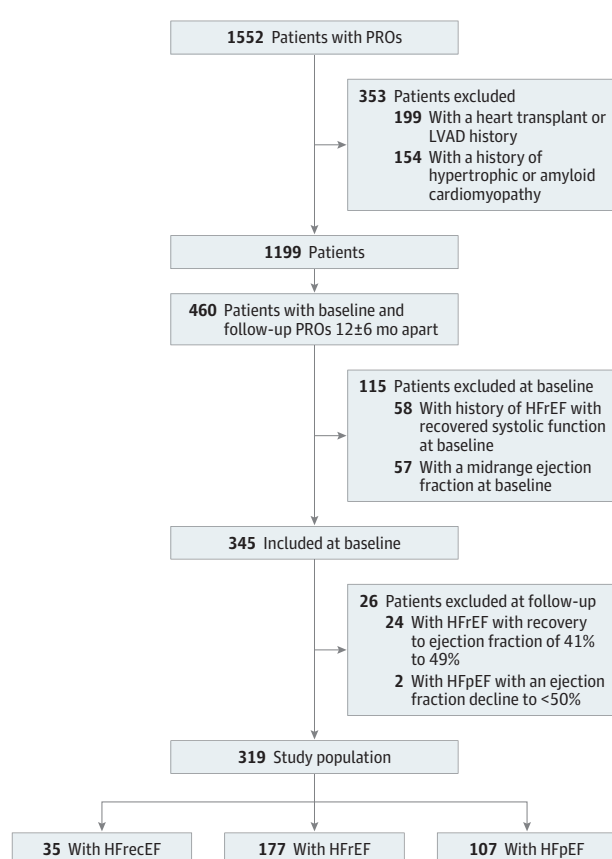
The phenotype of patients with a history of heart failure with reduced ejection fraction (HFrEF) that has improved has been recently labeled as heart failure with recovered ejection fraction (HFrecEF).^{1,2} Yet little is known about health status in this patient group, which can provide unique insight from the patient's perspective. Patient-reported outcomes (PROs) provide objective quantification of patients' symptoms, function, and health-related quality of life (hrQoL).³ Also, PROs are associated with the risk of adverse clinical events.⁴ Recent advances allow time-efficient electronic PRO capture with real-time implementation.⁵ The aim of this study was to **examine hrQoL changes in patients with HFrEF whose LVEF recovered and compare their hrQoL trajectory with patients with HFrEF whose LVEF remained reduced and those with heart failure with preserved EF (HFpEF).**

Methods

Population

This **prospective** study took place at a heart failure (HF) clinic at a tertiary academic medical center, where we imple-

Figure 1. Study Flowchart



HFpEF indicates heart failure with preserved ejection fraction; HFrecEF, heart failure with recovered ejection fraction; HFrEF, heart failure with reduced ejection fraction; LVAD, left ventricular assist device; PROs, patient-reported outcomes.

Key Points

Question How does health-related quality of life change in patients with heart failure and reduced ejection fraction (HFrEF) whose left ventricular ejection fraction recovers to 50% or more?

Findings This prospective cohort study shows that patients with HFrEF whose left ventricular ejection fraction recovered to 50% or more over a 1-year follow-up had significant improvement in health-related quality of life. Each 10% improvement in left ventricular ejection fraction resulted in a mean increase of 4.8 points on the Kansas City Cardiomyopathy Questionnaire summary score.

Meaning This study describes and quantifies changes in health-related quality of life associated with normalization of left ventricular systolic function in patients with HFrEF.

mented PRO assessment into the routine clinical workflow. Patients with HF who completed an initial PRO and a subsequent PRO in the time window of 12 ± 6 months between November 2016 to December 2018 were included. We excluded patients with HFrEF and a history of recovered systolic function before the study start, patients with midrange LVEF (41%-49%) at baseline, patients with HFrEF and systolic function recovery to LVEF of 41% to 49% during follow-up, and patients with HFpEF and systolic decline to an ejection fraction less than 50% during follow-up. Patients with a history of hypertrophic or amyloid cardiomyopathy, heart transplant, and left ventricular assist device implantation were also excluded.

PRO Instruments

We used the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) as a **HF-specific health status tool**.³ For generic health status assessment, we used the Visual Analog Scale and 4 computer adaptive testing instruments from the Patient-Reported Outcomes Measurement Information System (PROMIS): physical function, fatigue, depression, and satisfaction with social roles and activities.

Definition of Heart Failure Types

Left ventricular ejection fraction (LVEF) closest to the time of PRO assessment was used to define HF types. The LVEF was documented at a median time of 17 (interquartile range, -80.5 to 0) days before PRO assessment. A diagnosis of HFrecEF was defined by an LVEF of 40% or less at baseline and LVEF of 50% or more at follow-up; HFrEF was defined by an LVEF of 40% or less at baseline and follow-up and HFpEF by an LVEF of 50% or more at study entry and follow-up. Determination of LVEF and clinical history for HF type was done by manual **electronic health record** data review.

Statistical Analysis

We reported descriptive statistics as means (SDs), medians (interquartile ranges), or frequencies (with percentages). Clinical characteristics were compared between HF types using **analysis of variance, Kruskal-Wallis, or χ^2 tests**, which used

Table. Patient Characteristics by Heart Failure Type^a

Variable	Participants, No. (%)			P value
	HFrEF	HFpEF	HFpEF	
No. of patients	35	177	107	NA
Age, mean (SD), y	55.5 (18.0)	60.1 (14.7)	62.4 (15.5)	.06
Female	14 (40)	52 (29.4)	54 (50.5) ^b	.002
BP, mean (SD), mm Hg				
Systolic	113.0 (11.4)	111.9 (16.0)	122.7 (16.6) ^c	<.001
Diastolic	71.3 (10.7)	68.5 (11.1)	71.5 (10.6)	.06
Heart rate, mean (SD), beats/min	78.5 (13.3)	78.7 (14.4)	76.9 (14.9)	.59
BMI, mean (SD)	28.6 (7.2)	30.9 (7.0)	34.5 (11.1) ^c	<.001
LVEF change during follow-up, %	27.9 (8.0)	1.6 (7.7) ^d	0.7 (8.1) ^d	<.001
Marital status				
Married	17 (49)	102 (58)	67 (63)	.59
Insurance				
Self-pay	2 (6)	10 (5.6)	3 (2.8)	.33
Commercial	17 (49)	66 (37.3)	38 (35.5)	
Medicaid	3 (9)	17 (9.6)	8 (7.5)	
Medicare	13 (37)	84 (47.5)	58 (54.2)	
Clinic visits, median (IQR)	5 (3-7)	4 (3-7)	3 (2-5) ^b	.003
Comorbidities				
Coronary artery disease, No.	18 (51.4)	115 (65.0)	48 (44.9) ^b	.003
Atrial fibrillation, No.	15 (42.9)	72 (40.7)	42 (39.3)	.93
History of a malignant condition, No.	4 (11.4)	26 (14.1)	17 (15.9)	.81
Anemia, No./total No. ^e	5/24 (21)	25/117 (21.4)	21/72 (29)	.44
Chronic kidney disease, No./total No. ^e	9/31 (29)	68/161 (42.2)	35/93 (38)	.36
Diabetes, No.	9 (26)	62 (35.0)	48 (44.9)	.08
Hypertension, No.	23 (66)	109 (61.6)	82 (76.6) ^b	.03
Obesity, No./total No. ^e	11/35 (31)	89/192 (46.4)	66/105 (62.8) ^b	.005
Chronic obstructive pulmonary disease, No.	3 (9)	23 (13.0) ^d	21 (19.6)	.17
Peripheral artery disease, No.	4 (11)	11 (6.2)	8 (7.5)	.55
Obstructive sleep apnea, No.	8 (23)	54 (30.5)	51 (47.7) ^c	.004
Stroke, No.	3 (9)	18 (10.2)	11 (10.3)	.95
Drug abuse, No.	3 (9)	3 (1.7)	2 (1.9)	.05
Dementia, No.	1 (3)	2 (1.1)	4 (3.7)	.33
Heart surgery, No.	3 (9)	40 (22.6)	17 (15.9)	.10
Pharmacotherapy				
Angiotensin-converting enzyme inhibitor	26 (74)	93 (52.5)	53 (49.5) ^d	.03
Angiotensin II receptor blockers	5 (14)	51 (28.8)	22 (20.6)	.10
Angiotensin receptor-neprilysin inhibitors	0	3 (1.7)	0	.30
β-Blocker	33 (94)	163 (92.1)	62 (57.9) ^c	<.001
Diuretics	23 (66)	123 (69.5)	76 (71.0)	.84
Furosemide dose, median (IQR), mg ^f	40 (40-80)	40 (40-80)	60 (40-80)	.16
Aldosterone antagonist	21 (60)	111 (62.7)	40 (37.4) ^b	<.001
Warfarin	10 (29)	41 (23.2)	23 (21.5)	.69
Antiplatelet	17 (49)	99 (55.9)	51 (47.7)	.36
Statin	14 (40)	106 (59.9)	65 (60.7)	.07
Digoxin	5 (14)	46 (26.0)	6 (5.6) ^b	<.001
Anti-arrhythmic	2 (6)	20 (11.3)	5 (4.7)	.13

(continued)

Table. Patient Characteristics by Heart Failure Type^a (continued)

	Participants, No. (%)			
Variable	HFrecEF	HFrEF	HFpEF	P value
Laboratory results				
Creatinine, median (IQR), mg/dL	1.03 (0.82-1.15)	1.19 (0.95-1.39)	1.03 (0.82-1.22) ^b	.002
Estimated glomerular filtration rate, mean (SD), mL/min/1.73m ²	71.1 (25.4)	65.2 (25.3)	68.3 (22.8)	.37
Blood urea nitrogen, mean (SD), mg/dL	22.0 (9.2)	25.6 (14.2)	21.1 (9.1) ^b	.02
Sodium, mean (SD), mEq/L	138.6 (3.1)	137.5 (2.6)	137.6 (3.0)	.13
Potassium, mean (SD), mEq/L	4.28 (0.35)	4.33 (0.44)	4.17 (0.42) ^b	.01
Hemoglobin, mean (SD), g/dL	14.1 (1.8)	13.9 (2.2)	13.5 (1.8)	.31
Hematocrit, mean (SD), %	43.0 (7.0)	42.3 (6.3)	41.8 (5.3)	.70
Change in patient-reported outcome scores, mean (SD) ^g				
Kansas City Cardiomyopathy Questionnaire	15.3 (19.9)	5.8 (20.2) ^d	2.2 (19.8) ^d	.009
Visual Analog Scale	8.3 (39.1)	2.1 (24.8)	−0.5 (25.6)	.26
Depression	−1.8 (5.6)	0.5 (8.6)	−1.1 (7.5)	.15
Fatigue	−3.1 (7.1)	−0.2 (7.9)	−0.7 (7.6)	.17
Physical function	4.3 (9.4)	−1.0 (6.9) ^d	−0.4 (6.4) ^d	.001
Satisfaction with social roles	4.6 (7.9)	0.5 (7.4) ^d	0.5 (8.1) ^d	.02

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); HFpEF, heart failure with preserved ejection fraction; HFrecEF, heart failure with recovered ejection fraction; HFrEF, heart failure with reduced ejection fraction; IQR, interquartile range.

SI conversion factors: To convert creatinine to $\mu\text{mol/L}$, multiply by 88.4; urea nitrogen to mmol/L , multiply by 0.357; sodium and potassium to mmol/L , multiply by 1.0; hemoglobin to g/L , multiply by 10.0; hematocrit to a proportion of 1.0, multiply by 0.01.

^a The threshold for significant differences is $P < .019$ under the Tukey-Cramer multiple range test for 3 simultaneous comparisons.

^b $P < .019$ vs HFrEF.

^c $P < .019$ vs HFrecEF and HFrEF.

^d $P < .019$ vs HFrecEF.

^e Reported for variables with missing values.

^f Furosemide dose represents dose of furosemide or a furosemide equivalent dose for patients receiving other loop diuretics.

^g Score at follow-up minus score at baseline.

a nominal significance level of .019 to account for the 3 pairwise comparisons between the 3 HF groups under a Tukey-Kramer multiple comparison adjustment. In graphs, mean (SE) values are shown. Paired t tests were used to analyze longitudinal changes in PROs within each HF group. Data analysis was completed from February to December 2020 with SPSS version 21 (IBM Corporation).

Results

Of 1199 patients without a history of hypertrophic or amyloid cardiomyopathy, heart transplant, and left ventricular assist device implantation, 460 accrued the intended follow-up and completed PROs at 12 ± 6 months after study enrollment. We further excluded 58 patients with HFrEF history with recovered systolic function at baseline and 57 patients with mid-range EF at baseline. As a result, 319 patients with HF were included in the analyzed group (mean [SD] age, 60.4 [15.5] years; 120 women [37.6%]). A study flowchart is shown in Figure 1.

At baseline, 212 patients (66.5%) had HFrEF and 107 (33.5%) had HFpEF. At a median follow-up of 366 (interquartile range, 310-421) days, LVEF increased to 50% or more in 35 of the patients with HFrEF (16.5%). Baseline clinical characteristics of patients in the 3 HF groups are shown in the Table.

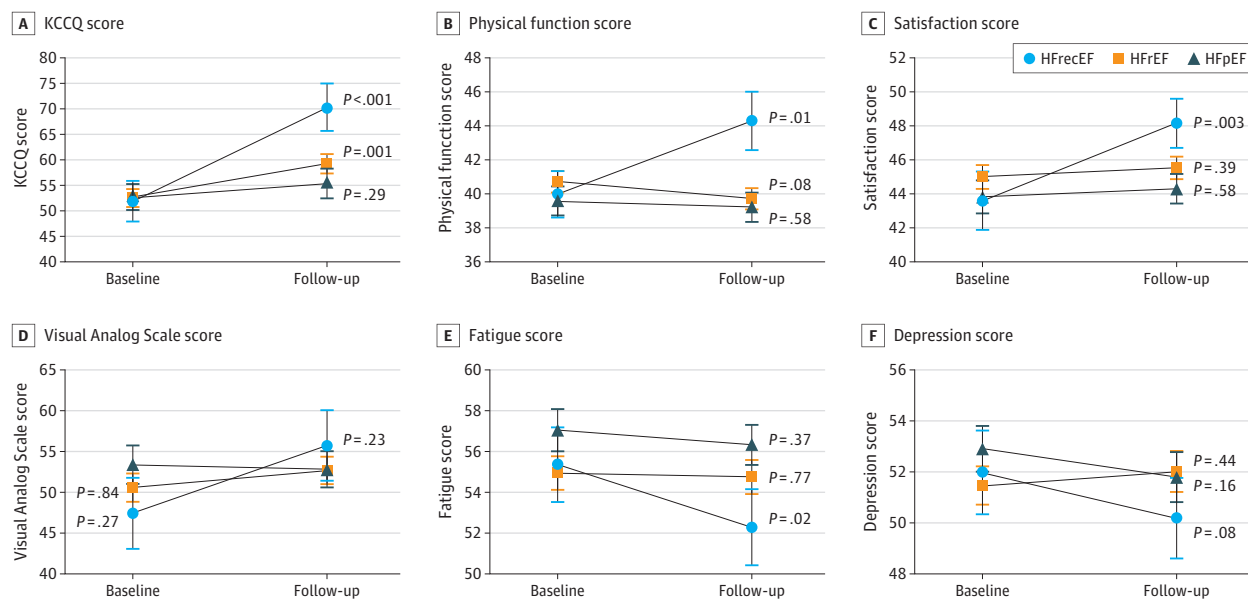
Trajectory of hrQoL

Recovery of systolic function was associated with improvement in HF-specific quality of life. Between baseline and follow-up, KCCQ-12 score in the HFrecEF group increased by a mean (SD) of 15.3 (19.9) points ($P < .001$; Figure 2). Furthermore, the change was associated with the degree of LVEF improvement; for each 10% increase in LVEF, the KCCQ-12 score improved by a mean (SD) of 4.8 (1.6) points ($P = .003$). Improvement in hrQoL in patients with HFrecEF was also seen as measured by PROMIS in the domains of physical function (mean [SD] change, 4.3 [9.4]; $P = .01$), satisfaction with social roles and activities (mean [SD] change, 4.6 [7.9]; $P = .003$), and fatigue (mean [SD] change, -3.1 [7.1]; $P = .02$; Figure 2). PROMIS depression score and Visual Analog Scale showed similar absolute improvements, but the difference did not reach statistical significance.

In patients with HFrEF whose LVEF did not normalize at follow-up, a mean (SD) increase of 5.8 (20.2) points was seen between baseline and follow-up ($P = .001$) on the KCCQ-12, while there was no significant change in any of the remaining hrQoL metrics. Patients with HFpEF showed no significant change in hrQoL between baseline and follow-up (Figure 2).

Between-group differences of PRO score change among patients with HFrecEF, HFrEF, or HFpEF are shown in the Table. The mean (SD) changes in the KCCQ-12 overall sum-

Figure 2. Quality of Life Change Between Baseline and Follow-up by Heart Failure Category



KCCQ indicates Kansas City Cardiomyopathy Questionnaire.

mary score (HFrecEF, 15.3 [19.9]; HFrEF, 5.8 [20.2]; HFpEF, 2.2 [19.8]; $P = .009$) and mean (SD) PROMIS scores of physical function (HFrecEF, 4.3 [9.4]; HFrEF, -1.0 [6.9]; HFpEF, -0.4 [6.4]; $P = .001$) and satisfaction with social roles (HFrecEF, 4.6 [7.9]; HFrEF, 0.5 [7.4]; HFpEF, 0.5 [8.1]; $P = .02$) were significantly different. The change in PROMIS scores of depression and fatigue were in a similar direction, although the between-group difference did not reach statistical significance.

Discussion

Several studies have shown lower mortality in HFrecEF compared with HFpEF and HFrEF.^{1,6-9} In addition to survival, patients with HF are especially concerned with their hrQoL.¹⁰ Yet, there are important gaps in our understanding of how recovery of systolic function is associated with patients' perceived hrQoL.

In this prospective cohort study, we found that among patients with HFrEF, normalization of systolic function was associated with significant improvements in HF-specific hrQoL and better physical function, satisfaction with social roles, and less fatigue. Furthermore, we were able to quantify the association of LVEF improvement with HF-specific QoL; every 10% increase in LVEF was associated with a mean 4.8-point increase in KCCQ-12 overall summary score. Based on previous studies,^{11,12} a mean change in the range of 3.6 to 5.0 points in KCCQ-12 overall summary scores is considered clinically significant.

Patients with HFrEF whose LVEF did not normalize in follow-up showed a much smaller improvement in KCCQ-12 scores. This change in HF-specific QoL perhaps demonstrates

the favorable outcome of HF therapies that may not be associated with a change in myocardial contractility and LVEF. There was no difference between baseline and follow-up in the generic PRO scores in this group. None of the PRO scores differed between baseline and follow-up in the HFpEF group.

Limitations

Our single-center cohort followed up at a tertiary HF center may not be representative of the whole HF population. Also, not all patients who were cared for in the HF clinic opted to complete PROs. However, key clinical patient characteristics are similar to those observed in other HF studies. While HF phenotyping was based on manual data review, electronic health records were used to populate the research data set. Thus, some potentially important clinical variables, such as HF duration, were not available. In the HFrecEF group, absolute changes in Visual Analog Scale and PROMIS depression scores were similar to the other metrics, but the differences were not statistically significant, which could be because of the lesser sensitivity of these measures, limited power, or a lack of improvement in other comorbidities that prevented greater improvements in these assessments. Comorbidities have been described to have a sizeable association with general hrQoL in patients with HF.¹³

Conclusions

Normalization of left ventricular systolic function in patients with HFrEF resulted in significant improvement in various aspects of patient hrQoL. In this study, there was a direct association between the extent of LVEF increase and the degree of HF-specific QoL improvement.

ARTICLE INFORMATION

Accepted for Publication: March 1, 2021.

Published Online: May 5, 2021.
doi:10.1001/jamacardio.2021.0939

Author Contributions: Drs Wohlfahrt and Stehlik had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: Wohlfahrt, Nativi-Nicolau, Zhang, Selzman, Conte, Hess, Stehlik.

Acquisition, analysis, or interpretation of data:

Wohlfahrt, Nativi-Nicolau, Zhang, Greene, Conte, Biber, Mondesir, Wever-Pinzon, Drakos, Gilbert, Kemeyou, LaSalle, Steinberg, Shah, Fang, Spertus, Stehlik.

Drafting of the manuscript: Wohlfahrt, Steinberg.

Critical revision of the manuscript for important intellectual content: Nativi-Nicolau, Zhang,

Selzman, Greene, Conte, Biber, Hess, Mondesir, Wever-Pinzon, Drakos, Gilbert, Kemeyou, LaSalle, Shah, Fang, Spertus, Stehlik.

Statistical analysis: Nativi-Nicolau, Zhang, Greene, Kemeyou.

Obtained funding: Selzman, Stehlik.

Administrative, technical, or material support:

Zhang, Selzman, Biber, Hess, Gilbert, LaSalle, Steinberg, Fang, Stehlik.

Supervision: Selzman, Wever-Pinzon, Drakos, Gilbert, Steinberg, Fang, Stehlik.

Conflict of Interest Disclosures: Dr Wohlfahrt reported grants from the American Heart Association during the conduct of the study. Dr Nativi-Nicolau reported clinical trial and/or consulting involvement with Pfizer, Alnylam, Akcea, and Eidos outside the submitted work. Dr Conte reported grants from American Heart Association during the conduct of the study. Mr Biber reported enrollment as a PhD candidate within the University of Utah School of Medicine; he is a former employee of Optum Patient Insights. Dr Hess reported data safety monitoring board membership from Astellas Pharmaceuticals outside the submitted work. Dr Drakos reported personal fees from Abbott outside the submitted work. Dr Steinberg reported grants from the National Institutes of Health/National Heart, Lung, and Blood Institute during the conduct of the study. Dr Shah reported grants from the National Heart, Lung, and Blood Institute, a donation from Women as One, and personal fees from American College of Cardiology outside the submitted work. Dr Fang reported grants from the American Heart Association during the conduct of the study and outside the submitted work and additional relationships with Novartis, Amgen, and the National Institutes of Health. Dr Spertus reported personal fees from Novartis, Janssen, Bayer, Merck,

Amgen, Myokardia, United Healthcare, and Blue Cross Blue Shield of Kansas City outside the submitted work; in addition, Dr Spertus had a patent and copyright to the Seattle Angina Questionnaire, Kansas City Cardiomyopathy Questionnaire, and Peripheral Artery Questionnaire with royalties paid, as well as equity in Health Outcomes Sciences. Dr Wever-Pinzon reported grants from the National Heart, Lung, and Blood Institute. Dr Stehlik reported grants from the American Heart Association and personal fees from Medtronic. No other disclosures were reported.

Funding/Support: This work was funded by the American Heart Association, Strategically Focused Heart Failure Research Networks (grant 16SFRN31890003 [Dr Stehlik]), the National Center for Advancing Translational Sciences of the National Institutes of Health (grant UL1TR002538 [Dr Greene]), Ministry of Health of the Czech Republic (grant NV 19-09-00125 [Dr Wohlfahrt]), and the National Heart, Lung, and Blood Institute of the National Institutes of Health (grants K23HL143156 [Dr Steinberg]; K23 HL150322-01A1 [Dr Wever-Pinzon]). The American Heart Association provided funding for assessment of patient-reported outcomes and supported salaries of the investigators. The National Institutes of Health and the Ministry of Health of the Czech Republic provided salary support and training support for the investigators.

Role of the Funder/Sponsor: The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

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