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Clinical Research Study

## Social Determinants of Health in Women With Heart Failure: Prospective Observational Cohort Study



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### ABSTRACT

**Objective:** The social determinants of health (SDoH) account for 80%-90% of modifiable contributors to health outcomes for chronic diseases such as heart failure. Knowledge gaps exist on how SDoH influences hospitalization rates in women with heart failure. Our aim was to evaluate the relationship between the baseline SDoH status of women with heart failure with subsequent all-cause and cardiovascular hospitalization.

**Methods:** This is a prospective observational longitudinal cohort study of women diagnosed with heart failure with 6-month follow-up. The subjects completed SDoH assessment by the Institute of Medicine. Monthly follow-ups were performed to assess for hospitalization events.

**Results:** A total of 92 patients with at least 1 follow-up clinic visit were included. The mean age was  $66 \pm 15$  years and 80% had nonischemic cardiomyopathy as the etiology of heart failure. New York Heart Association (NYHA) Classifications I-II were the most common ( $n = 66$ , 71.8%). In total, 51 patients (55.4%) had overall high-risk SDoH (4 or more SDoH domains at risk). By the 6-month follow-up, 22 (23.9%) patients were hospitalized for any cause; 8 patients (8.7%) were hospitalized for cardiovascular causes. There were no deaths. In multivariate logistic regression analysis, the high-risk SDoH group had a higher odds ratio for all-cause hospitalization (OR 5.31, 95% CI 1.59-17.73). In addition, Kansas City Cardiomyopathy Questionnaire 12-item (KCCQ-12) scores, surrogate for quality of life, were worse in the high-risk SDoH group.

**Conclusion:** SDoH adversely impacts hospitalizations and quality of life in women with heart failure. Future efforts for screening and interventions should evaluate the SDoH at all levels, including the individual health care provider, institutional, and national levels.

#### What Is Known

- Social determinants of health are an important contributor to health outcomes in cardiovascular disease, including heart failure.
- Women have an increased risk of adverse social determinants of health in cardiovascular disease.

#### What the Study Adds

- Presence of multiple risk domains of social determinants of health in women with heart failure is an increased risk of all-cause hospitalization, including both cardiovascular and noncardiovascular hospitalization.
- Presence of multiple risk domains of social determinants of health in women with heart failure has worse quality of life.

#### Introduction

Heart failure is a complex clinical syndrome that results from impairment of ventricular filling or ejection of blood.<sup>1</sup> The life-long risk of developing heart failure after 40 years of age is 20% in the United States.<sup>1</sup> The prevalence of heart failure is higher in men than in women before the age of 80. However, the hospitalization for women with heart failure increased from 2005 to 2014.<sup>2-4</sup> In 2017, there were 1.2 million heart failure hospitalizations in the United States. There was a steady decrease in heart failure hospitalization from 2002 to 2013.<sup>4</sup> This is likely attributed to the advances in the therapeutic domain for treatment of heart failure, due to novel medical and device therapies.<sup>5-8</sup> Although there were advances in medical therapies for heart failure, the social determinants of health (SDoH) account for 80%-90% of modifiable contributors to health outcomes for heart failure.<sup>4,9,10</sup> There is yet unmet demand to assess social determinants in routine clinical practice.

**Abbreviations:** SDoH, social determinants of health; KCCQ-12, Kansas City Cardiomyopathy Questionnaire 12-item; QOL, quality of life; NYHA, New York Heart Association.

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The World Health Organization (WHO) defines SDoH as “circumstances in which people are born, grow up, live, work and age and the systems put in place to offer health care and services to community.”<sup>11</sup> Social and behavioral factors including low income, low levels of education, lack of exercise, unhealthy nutrition, and stress have adverse effects on the development and progression of chronic diseases.<sup>12</sup> Patients with these risk factors are challenged with the cost of medication and care in addition to basic food and living needs.<sup>13</sup> The additional burden can negatively impact adherence to medication and dietary regimens.<sup>14</sup> The presence of these risk factors leads to an increased rate of re-hospitalization within 90 days after an initial heart failure admission.<sup>15,16</sup> Having even one of these risk factors leads to worse hospitalization outcomes.<sup>16</sup> In addition, women are more vulnerable and more likely to have a higher sociodemographic risk for poor outcomes in cardiovascular disease.<sup>10</sup> Women with heart failure are more symptomatic and have a lower health-related quality of life (QOL), more depression, and more significant impairments in activities of daily living than men.<sup>17,18</sup> Furthermore, the presence of heart failure leads to increased risk of all-cause hospitalization.<sup>19</sup> Also, socioeconomic deprivation in people with heart failure is linked to increased risk of death and hospitalization largely due to an excess of noncardiovascular events.<sup>20</sup> To that end, the aim of the current study was to assess the relationship between the SDoH status of women with heart failure and hospitalization over 6 months.

## Methods

The current study was a prospective longitudinal observational cohort study performed at two of our institution’s outpatient clinics from September 2019 to August 2020. The study population included adult female patients with a diagnosis of heart failure (both subtypes with reduced ejection fraction and preserved ejection fraction) seen at our clinic. Inclusion criteria were: women 18 years or older and prior diagnosis of heart failure (both reduced and preserved ejection fraction subtype). Exclusion criteria were severe cognitive impairment and end-stage renal failure on hemodialysis. To reduce a possible selection bias, all consecutive subjects meeting the criteria were approached to be enrolled in the current study. The study was approved by the University of South Florida Institutional Review Board (PRO00040968). All subjects provided informed consent to participate in the study. Patients or the public were not involved in the design, conduct, reporting, or dissemination plans of our research.

### Data Collection and Measures

After enrollment, participants completed the Institute of Medicine Measures of Social and Behavioral Determinants of Health,<sup>21</sup> and the Kansas City Cardiomyopathy Questionnaire 12-item (KCCQ-12).<sup>22</sup> The Institution of Medicine’s SDoH domain was comprehensive, including financial resource strain, stress, depression, physical activity, tobacco use, alcohol consumption, social connection or isolation, and intimate partner violence.<sup>21</sup> KCCQ-12 is a frequently utilized questionnaire designed for the assessment of QOL in patients with heart failure in clinical trials and real-world data.<sup>23</sup> Baseline clinical characteristics were retrieved from electronic medical records, including cardiovascular-related comorbidities, heart failure etiology, current New York Heart Association (NYHA) class, and current medications. Following baseline assessment, monthly follow-up phone calls (or in-person clinic visits if within time frame) were performed from months 1 to 6, assessing medication changes, hospitalization events, primary care visits, vital status, and NYHA class and KCCQ-12. The baseline and follow-up phone calls were performed by senior clinical research associate (NT). Hospitalizations based on patient report and review of electronic medical record was performed. The cause of hospitalization was determined through phone interview, a review of the electronic medical record, and designated primary problem.

Classification for being at-risk in SDoH domains was based on the Institute of Medicine Feasibility study by Giuse<sup>21</sup> with some modifications. We categorized “high-risk SDoH group” based on the number of at-risk SDoH domains each subject had. We did not designate an *a priori* number of at-risk SDoH domains to be considered “high-risk SDoH group.” Instead, we designated as “high-risk SDoH group” when the proportion of subjects with a certain number of at-risk SDoH domains are relatively similar to each other (ie, number of subjects with high-risk SDoH group and low-risk SDoH group are relatively similar. In our study, proportion of patients with more than 4 domains of SDoH at risk was 55% so designated as “high-risk” group). We utilized KCCQ-12 for the assessment of QOL. The primary outcome was all-cause hospitalization or death. Secondary outcome was cardiovascular hospitalization or death. The outcome was assessed by self-report during phone interview/clinic visit and electronic medical record review. Initially, we hypothesized that the absolute difference in all-cause hospitalization or death would be at least 20% between high- and low-risk SDoH. In order to detect a statistically significant difference with 2-sided  $\alpha = 0.05$  and 80% power, we planned for recruitment of 182 women over a 6-month follow-up period.

### Data Analysis

Data were collected and managed using the REDCap electronic data management system hosted at the University of South Florida.<sup>24</sup> Continuous variables were presented as mean  $\pm$  standard deviation or median with interquartile range, depending on the normality of the data. Categorical data were compared using the chi-squared test. Various multivariate logistic regression models were performed for association with hospitalization. All statistical analysis was performed through RStudio.<sup>25</sup> All authors (including DHL and JF) had full access to all the data in the study and take responsibility for the data integrity and analysis.

## Results

A total of 92 patients who had at least 1 follow-up clinic visit after baseline assessment were included in the analysis. The average age was  $66.3 \pm 15.1$  years. The baseline cardiovascular characteristics are summarized in Table 1. The primary etiology of heart failure was nonischemic cardiomyopathy (80.4%) followed by ischemic cardiomyopathy (19.6%). Most patients were in Class I or II (71.8%) compared to Class III (28.3%). Baseline characteristics classified by the type of cardiomyopathy are summarized in Supplemental Table 1 (available online).

The baseline survey results of individual survey questions within each of the ten domains of SDoH questionnaire are summarized in Supplemental Table 2 (available online). The individual domains of SDoH were dichotomized into “low-risk” and “high-risk” and are summarized in Table 2. The more common SDoH domains at risk in our cohort of female patients with heart failure were suboptimal exercise (82.6%), low education attainment (51.1%), perceived stress (50%), and lack of social connection (45.7%). Less common SDoH domains included presence of intimate partner violence (5.4%) and alcohol misuse (12.0%). None of the individual domain levels were significantly associated with all-cause hospitalization (Supplemental Table 3, available online). The percentage of subjects with the presence of more than 3 domains of SDoH at risk was 79.3% and more than 4 domains of SDoH at risk was 55.4%. To ensure equal distribution between groups, we designated the patients with 4 or more SDoH domains at risk as an overall “high-risk SDoH group.” The rate of all-cause or cardiovascular hospitalizations was similar between the 3 or higher (26% or 8.2% for all-cause or cardiovascular) and 4 or higher (33.3% or 9.8%) in the higher-risk group. We have summarized the cause of hospitalization on an individual level (Supplemental Table 4, available online). The KCCQ-12 subscale and total scores of all categories were significantly lower (worse) in the high-risk SDoH group when compared to the low-risk SDoH group, summarized in Table 3.

**Table 1**  
Baseline Clinical Characteristics (n = 92).

Characteristic	Value
Age, mean (SD)	66.3 ± 15.1
Race N (%)	
White	63 (68.5%)
Black	29 (31.5%)
Hispanic	28 (30.4%)
BMI, mean ± SD, kg/m <sup>2</sup>	31.7 ± 9.6
BSA, mean ± SD	1.9 ± 0.3
Hypertension, n (%)	78 (84.8%)
Hyperlipidemia, n (%)	57 (62.0%)
Diabetes mellitus, n (%)	35 (38.0%)
Type 1	1 (2.9%)
Type 2	34 (97.1%)
Chronic kidney disease (CKD), n (%)	36 (39.1%)
Cerebrovascular accident, n (%)	7 (7.6%)
Transient ischemic attack, n (%)	7 (7.6%)
Hospital admission in past 12 months, n (%)	43 (46.7%)
Hospital readmission within the 30 days following hospital admission, n (%)	10 (23.3%)
Congestive heart failure classification	
CHF <sub>r</sub> EF	35 (38.0%)
CHF <sub>m</sub> rEF	6 (6.5%)
CHF <sub>p</sub> EF	51 (55.4%)
Left ventricular ejection fraction (%)	46% ± 12%
Cause of heart failure, n (%)	
Ischemic cardiomyopathy	18 (19.6%)
Nonischemic cardiomyopathy	74 (80.4%)
NYHA Classification, n (%)	
Class I	9 (9.8%)
Class II	57 (62.0%)
Class III	26 (28.3%)
Class IV	0
Kansas City Cardiomyopathy Questionnaire score (range 0-100)	
Physical limitation score, mean ± SD (n = 85)	55.6 ± 30.5
Symptom frequency score, mean ± SD (n = 92)	66.4 ± 28.9
Quality of life score, mean ± SD (n = 92)	62.1 ± 33.2
Social limitation score, mean ± SD (n = 87)	57.3 ± 34.8
KCCQ-12 summary score, mean ± SD (n = 92)	61.4 ± 27.8

Data presented as mean ± standard deviation or number (percentage) depending on the type of data. BMI = body mass index; BSA = body surface area; CHF<sub>m</sub>rEF = congestive heart failure with mildly reduced ejection fraction; CHF<sub>p</sub>EF = congestive heart failure with preserved ejection fraction; CHF<sub>r</sub>EF = congestive heart failure with reduced ejection fraction; KCCQ = Kansas City Cardiomyopathy Questionnaire; SD = standard deviation.

**Table 2**  
Individual Domains of Social Determinants of Health at Risk.

Individual domains of SDoH	Number (%)
SDoH race at risk	28 (30.4%)
SDoH education at risk	47 (51.1%)
SDoH financial stress at risk	40 (43.5%)
SDoH stress at risk	46 (50.0%)
SDoH depression at risk	21 (22.8%)
SDoH exercise at risk	76 (82.6%)
SDoH tobacco use at risk	38 (41.3%)
SDoH alcohol at risk	11 (12.0%)
SDoH social connection at risk	42 (45.7%)
SDoH intimate violence at risk	5 (5.4%)

Data presented as number (percentage). Total N = 92. SDoH = social determinants of health.

In addition, high-risk SDoH group was associated with worse KCCQ-12 quartile classification (OR 0.47; 95% confidence interval (CI) 0.30-0.76; P = .001).

Hospitalization was assessed at each encounter and is summarized in Table 4. Percentage of all-cause hospitalization at 6 months was 23.9% (n = 22). Percentage of cardiovascular hospitalization at 1 month and 6 months was 2.2% (n = 2) and 8.7% (n = 8), respectively. The causes of cardiovascular hospitalization were heart failure exacerbation, atrial fibrillation, or chest pain. There were no deaths at 6 months.

Patients in the high-risk SDoH group had a higher odds ratio for all-cause hospitalization (OR 3.6, 95% CI 1.2-10.83), but not cardiovascular hospitalization (OR 1.38, 95% CI 0.31-6.14). There were no baseline cardiovascular clinical characteristics associated with cardiovascular hospitalization (data not shown). Chronic kidney disease had a higher odds ratio for all-cause hospitalization (OR 3.82, 95% CI 1.40-10.43). Patients with nonischemic cardiomyopathy as etiology of heart failure had a tendency toward an increased odds ratio for all-cause hospitalization in univariate analysis. Due to the relatively low number of events of all-cause hospitalization (n = 22), we were able to perform several separate models of multivariate logistic regression analysis with adjustment of a single clinically significant variable (presence of diabetes mellitus, CKD and NYHA classification). In multivariate logistic regression analysis, the high-risk SDoH group had an increased odds ratio for all-cause hospitalization after adjusting for covariates (see Table 5).

**Discussion**

In this prospective observational cohort study, we showed that women with heart failure with more than 4 SDoH risk factors are more likely to experience hospitalization from any cause within 6 months. In contrast, there was no association between the higher-risk category of SDoH and cardiovascular hospitalization. This is likely due to low rates of cardiovascular hospitalization as we enrolled the patients during regular outpatient visits, not during their index hospitalization, which

**Table 3**  
Difference in Baseline KCCQ-12 Scores Based on SDoH Risk.

Variables (mean ± SD)	SDoH high-risk (n = 51)	SDoH low-risk (n = 41)	P value
Physical limitation score (n = 85)	49.3 ± 32.3	63.9 ± 26.0	0.028
Quality of life score (n = 92)	53.7 ± 36.1	72.6 ± 26.0	0.004
Symptom frequency score (n = 92)	57.7 ± 31.1	77.3 ± 21.8	0.001
Social limitation score (n = 87)	46.6 ± 37.0	70.4 ± 26.8	0.001
KCCQ-12 summary score (n = 92)	52.8 ± 29.9	72.1 ± 20.6	<0.001
KCCQ-12 quartiles			0.011
Very poor to poor (0-24)	1 (2.4%)	11 (21.6%)	
Poor to fair (25-49)	5 (12.2%)	10 (19.6%)	
Fair to good (50-74)	12 (29.3%)	15 (29.4%)	
Good to excellent (75-100)	23 (56.1%)	15 (29.4%)	

Student T-test was performed to compare the KCCQ subscale and summary score based on SDoH risk. Data presented as mean ± standard deviation.

**Table 4**  
Hospitalizations by 6 Months (N = 92).

Outcome variables	Number (percentage)
All-cause hospitalization at 6 months, n (%)	22 (23.9%)
Cardiovascular hospitalization at 1 month, n (%)	2 (2.2%)
Cardiovascular hospitalization at 6 months, n (%)	8 (8.7%)
Mortality at 6 months, n (%)	0

Data presented as number (percentage).

could lead to higher rates of hospitalization.<sup>4,26</sup> The rate of cardiovascular hospitalization was 8.7% at 6 months cumulatively with no mortality. This may be the reason we did not find any clinical risk factors associated with cardiovascular hospitalization, including SDoH.

Women with heart failure are at risk for poor prognosis, especially within minority racial or ethnic backgrounds, including black race.<sup>10</sup> Sterling et al. reported that having any SDoH risk was associated with worse 90-day mortality in a large cohort (total n = 690, women 44%)<sup>16</sup> but not with 30- or 90-day heart failure hospitalization.<sup>15</sup> There were no data on all-cause hospitalization. Similar risk domains existed within the SDoH with important differences such as the inclusion of rural residence, poor public health infrastructure, health professional shortage area, and zip code-level poverty, given the nature of their study design on a national scale. There was no difference in mortality or hospitalizations between sex.<sup>15</sup> In contrast, our study sample was derived from 2 clinics in close proximity to a single university institution. Interestingly, Sterling et al. did not include data on physical activity. In a large-scale observation study of postmenopausal women with heart failure, sedentary behavior (more than 4.6 hours of sitting per day) was associated with increased heart failure hospitalizations.<sup>27</sup> In this study, there was a higher proportion of at-risk women in the lower education domain compared to Sterling et al. (51% vs 23.5%, respectively), as well as a lack of social connection or network (45.7% vs 13%). The higher rates of social isolation scores may be at least partially attributable to our study's occurrence during the COVID-19 pandemic. Other SDoH domains at risk in our population were lack of exercise and more stress, which were not captured in other studies. None of the individual do-

main of SDoH had a statistically significant association with all-cause hospitalization.

Another key finding of the current was the poor QOL as assessed by KCCQ-12 in the high-risk SDoH group. Of note, patients who were hospitalized for any cause had lower/worse scores in the KCCQ-12 questionnaire in the QOL and physical limitation domain (Table 6). The KCCQ questionnaire does not assess mental and social aspects of heart failure-related patient-reported outcomes.<sup>28</sup> Therefore, incorporating the SDoH risk assessment into routine clinical practice would not overlap with the KCCQ-12 questionnaire.

The use of SDoH risk assessment and KCCQ-12 may provide a foundation for possible interventions that could improve health outcomes. Examples of intervention include asking patients about SDoH, identifying biases by providers, and providing ample social work resources. For a detailed review of interventions to improve the SDoH of women with cardiovascular disease, please refer to the review by Lindley et al.<sup>10</sup> This study highlights the clinical importance of screening for SDoH in women with heart failure. Furthermore, it invites further research on predictive indices of pertinent clinical and nonclinical factors in women with heart failure and on actionable measures to address high-risk SDoH cohorts. This contribution could overcome the current paucity of risk and outcomes data for women in cardiovascular disease trials. A recent review proposed a multiple-level enactment, including at the individual, institution, and national scale, to change social determinants in women with cardiovascular disease.<sup>10</sup> On an individual level, this may start with asking individual patients about SDoH.

This study has several limitations. First, the sample size was small. We initially planned to recruit 182 subjects to detect crude absolute difference in all-cause hospitalization of 20% between high- and low-risk SDoH groups. Despite not achieving the *a priori* sample size due to difficulty recruiting patients during the COVID-19 pandemic, we recruited 92 subjects, and in the final analysis, we still observed 21.1% absolute difference in predesignated primary outcome (33.3% vs 12.2%). In addition, these effects persisted with higher rates of all-cause hospitalization after adjusting for covariates. In multivariate analyses, this difference was attenuated likely due to sample size and type II error in which we were unable to detect an association if one truly existed. It is also possible that our sample size underestimated the expected difference in the

**Table 5**  
Risk of SDoH on Clinical Outcome.

Outcomes	Unadjusted			Adjusted		
	OR	95% CI	P value	OR	95% CI	P value
All-cause hospitalization 6 months	3.6	1.2-10.83	0.0227	5.31	1.59-17.73	0.0066
- Adjusted for CKD				4.83	1.47-15.85	0.0095
- Adjusted for DM				3.48	1.14-10.57	0.0280
- Adjusted for NYHA				3.26	1.07-9.97	0.0384
CV hospitalization 6 months	1.38	0.31-6.14	0.6749			

**Table 6**  
KCCQ Score Based on Hospitalization Outcome.

KCCQ category	No hospitalization (N = 70)	All-cause hospitalization (N = 22)	P value
KCCQ12-PL	59.4 ± 27.6	43.5 ± 36.6	0.042
KCCQ12-QL	66.1 ± 32.0	49.4 ± 34.4	0.039
KCCQ12-SF	68.9 ± 27.9	58.6 ± 31.3	0.144
KCCQ12-SL	60.3 ± 33.1	47.8 ± 39.0	0.154
KCCQ12 summary	64.5 ± 25.8	51.4 ± 31.9	0.053
	No CV hospitalization (N = 84)	CV hospitalization (N = 8)	
KCCQ12-PL	57.4 ± 29.0	38.5 ± 40.6	0.096
KCCQ12-QL	64.1 ± 32.5	40.6 ± 35.2	0.055
KCCQ12-SF	67.6 ± 28.1	54.9 ± 36.8	0.241
KCCQ12-SL	58.5 ± 34.0	44.8 ± 42.7	0.289
KCCQ12 summary	63.0 ± 26.6	44.7 ± 35.8	0.075

Student T-test was performed to compare the KCCQ subscale and summary score based on all-cause hospitalization and no hospitalization. Data presented as mean ± standard deviation.

KCCQ = Kansas City Cardiomyopathy Questionnaire; PL = physical limitation; QL = quality of life; SF = symptom frequency; SL = social limitation.

outcome. In addition, we were able to capture all hospitalization events based on patient encounters and telephone follow-up with the advantage of a prospective observational study. Interestingly, despite being amid the COVID-19 pandemic, none of our patients were hospitalized due to primary COVID-19 infection. However, COVID-19 can manifest as cardiovascular disease, including heart failure exacerbation. Unfortunately, we did not ask about COVID-19 infection, which limits our ability to attribute the cardiovascular-related hospitalization to COVID-19. Another limitation of our study is that the patients were from single-center university-based clinics in southwest Florida. There is significant geographical heterogeneity in heart failure-related deaths.<sup>29</sup> Thus, results cannot be generalized to other US geographic locations. Also, the follow-up of 6 months is relatively short. However, we had sufficient number of events to show that SDoH status affects hospitalization. In fact, social determinants affected the hospitalization as soon as 30 days.<sup>15</sup> Further studies specifically investigating SDoH in women with heart failure in multiple institutes with a longer follow-up may overcome this in the future. The strength of our study is the utilization of a well-established SDoH questionnaire developed by the Institute of Medicine. The questions were well received by patients and were comprehensive to capture different aspects of each domain of SDoH.

In conclusion, SDoH have an adverse impact on all-cause hospitalizations in women with heart failure. Future efforts for screening and interventions should occur at the individual health care provider, institution, and national levels.

#### Declaration of Competing Interest

All authors have nothing to disclose.

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#### Supplementary materials

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