

Title page

a. Title: Diabetes-specific food insecurity is associated with impaired heart rate variability independent of glycemic control: Exploratory findings among Latinos with type 2 diabetes

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d. Footnotes to the title disclosing:

(i) Links to supporting data deposited in repositories such as Dryad or figshare, as well as the DOI for the data deposit;

Not applicable

(ii) A list of abbreviations and their definitions for all abbreviations used in the text if there are 3 or more;

HRV, Heart rate variability

ECG, electrocardiogram

SDNN, standard deviation of the R-R interval

FI, Food insecurity

T2DM, type 2 diabetes

CALMS-D, Community health educators Assisting Latinos Manage Stress and Diabetes

A1C, glycated hemoglobin concentrations

VLF, very low frequency

LF, low frequency

HF, high frequency

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1 Abstract

2 Background. Food insecurity (FI), diabetes prevalence, and poor diabetes outcomes all
3 disproportionately affect Latinos in the U.S. Heart rate variability (HRV) is reflects
4 autonomic tone and is associated with glycemic control and predicts mortality in type 2
5 diabetes. It is unknown whether food insecurity is related to HRV and, if so, whether
6 glycemic control accounts for this association.

7 Objective. This exploratory, cross-sectional study examined FI and HRV among U.S.
8 Latinos with type 2 diabetes.

9 Methods. Participants reported demographics, socioeconomic status, and FI including
10 the 6-item USDA food security module and a one-item measure of diabetes-specific
11 food security. Participants wore an ambulatory electrocardiogram monitor for 24 hours.
12 In the time domain, HRV was assessed with the standard deviation of the R-R interval
13 (SDNN). In the frequency domain, the power spectrum was integrated over three
14 frequency bands-very low frequency (VLF), low frequency (LF), and high frequency
15 (HF), and then natural log transformed. Unadjusted ANOVA and ANCOVA adjusting for
16 age, gender, A1c, and indicators of socioeconomic status compared food security
17 groups on HRV.

18 Results. Participant mean age was 59.7 (SD=10.9) years and 73% were women. Of the
19 n=94 participants, 63 reported FI according to the USDA food security module and 46
20 reported FI according to the diabetes-specific measure. Mean A1c was 8.6% (SD=1.7)
21 and was marginally higher among those reporting diabetes-specific FI than those
22 reporting diabetes-specific food security. Participants who reported diabetes-specific FI
23 had lower SDNN, VLF, LF, and HF HRV with effect sizes in the small-to-medium range.

24 Differences remained significant even after controlling for age, gender, socioeconomic
25 hardship, and A1c. The 6-item USDA food security module was not associated with
26 HRV. Conclusions. Diabetes-specific FI may be a unique risk factor for poor health
27 outcomes among U.S. Latinos. Efforts to address FI could benefit diabetes outcomes.

28

29 Keywords

30 Food insecurity, heart rate variability, type 2 diabetes, Latinos

31
32

Introduction

33 Food insecurity (FI) is the limited or uncertain ability to acquire nutritionally
34 adequate and safe foods (1). FI is associated with increased risk for type 2 diabetes
35 mellitus (T2DM) (2) and, among persons with diabetes it is associated with poor
36 glycemic control (3). In 2015, 12.7 percent of U.S. households (15.8 million households)
37 were food insecure, and the prevalence was higher for Latino households (19.1 percent)
38 than for non-Hispanic White households (10.0%) (4). Prospective studies have shown
39 that FI hastens mortality in the general population and among and medically
40 compromised persons in North America (5, 6).

41 The mechanisms through which FI hastens mortality are unknown. Heart rate
42 variability (HRV) is one putative mechanism. HRV quantifies the beat-to-beat changes
43 in heart rate caused by changes in autonomic activity and reflects autonomic tone. Low
44 HRV is an early finding in diabetic cardiac autonomic neuropathy (7) and may be
45 present as early as at diabetes diagnosis (8). Poor glycemic control is associated with
46 lower HRV (9). Low HRV is a strong predictor of mortality in the setting of diabetes (10).

47 Patients with diabetes are asked to follow specific nutritional guidelines. Patients
48 may have food security, i.e., access to nutritionally adequate and safe foods, yet still be
49 financially unable to select foods the types of foods recommended for their diabetes
50 management. Several validated scales are used to measure FI, most of which largely
51 measure the ability to acquire *enough* food (11, 12). That is, they assess food security
52 as it pertains to food quantity. And, whereas the commonly used 6-item USDA scale
53 does make reference to the ability to acquire “the types of foods desired”, it does not

54 reference the ability to acquire the healthy foods typically recommended for diabetes
55 management, e.g., high fiber, low fat foods such as whole grains and vegetables.

56 The objective of this exploratory, cross-sectional analysis among low-income
57 Latinos with T2DM was to examine the relationships among the 6-item USDA food
58 insecurity measure, diabetes-specific FI, and HRV and to determine whether glycemic
59 control accounts for any association.

60 Materials and Methods

61 We analyzed cross-sectional baseline data from the Community Health
62 Educators Assisting Latinos Manage Stress and Diabetes (CALMS-D) trial, registered at
63 clinicaltrials.gov as NCT01578096 (13, 14). Participants were recruited from an inner-
64 city clinic if they were adult residents of Hartford, CT, Latino/Hispanic, Spanish-
65 speaking, with T2DM \geq 6 months, and glycosylated hemoglobin concentrations (A1C) \geq
66 7.0%. Patients were excluded for: medical instability or intensive medical treatment;
67 bipolar disorder or thought disorder; suicide attempt or psychiatric hospitalization in the
68 past 2 years; alcohol problems; or enrollment in another research study.

69 The CALMS-D trial was approved by the institutional review boards involved and
70 all participants provided written informed consent. At a morning home visit, participants
71 provided informed consent, provided a fasting venous blood sample, answered
72 questionnaires that were verbally administered by interviewers in preferred language
73 (English or Spanish) and were compensated \$10. Next, participants were instrumented
74 with 7-lead, 3-channel ambulatory ECG monitors (Holters), GE Medical (Milwaukee, WI)
75 Marquette Series 8500 direct (amplitude-modulated) recorders. Participants were de-
76 instrumented after 24 hours.

77 Measures

78 Food Insecurity.

79 We measured diabetes-specific FI with the question, “In the past year, has it
80 happened to you that you did not have enough money to buy the food you should eat
81 for your diabetes?” We defined a “yes” response as diabetes-specific FI and a “no”
82 response as diabetes-specific food security. This question was designed specifically for
83 this study. The English and Spanish CALMS-D survey questions were piloted and
84 revised in an iterative fashion with the target community. The final questions
85 demonstrated excellent content and face validity as previously reported (13).

86 We also measured FI using the 6-item USDA Food Security Module (15, 16). A
87 raw score of 0-1 indicates high or marginal food security, 2-4 indicates low food
88 security, and 5-6 indicates very low food security. We also used scores of 0 vs >0 to
89 dichotomize participants as either food secure or food insecure (17). Finally, we also
90 calculated a total sum score for a continuous measure of food security.

91 Heart Rate Variability.

92 HRV was assessed as in our previous studies (18). Holter recordings were
93 scanned by an experienced technician. As described in the literature (19), each tape
94 was manually processed and edited and then analyzed with customized software. The
95 R-R interval data file was edited to remove ectopics and noise, and gaps filled in by
96 interpolated linear splines. In the time domain, we assessed the standard deviation of
97 each normal-to-normal beat, or SDNN (i.e., each normal R-R interval). The power
98 spectrum was computed using a fast Fourier transform with a Parzen window and
99 corrected for attenuation due to windowing and sampling. The power spectrum was

100 integrated over three frequency bands (19)- very low frequency (VLF) 0.0033 to < 0.04
101 Hz; low frequency (LF) 0.04 to <0.15 Hz; and high frequency (HF) 0.15 to 0.40 Hz. As
102 expected, HRV values in the frequency domain were non-normal, so were natural log
103 transformed (20).

104 Covariates

105 Age and gender were per self-report. A1c was assayed from venous blood
106 samples in the University of Connecticut clinical laboratory using high pressure liquid
107 chromatography. To isolate the effect of FI from other sources of economic hardship,
108 we controlled for socioeconomic indicators including educational attainment (high
109 school graduate/GED or less than high school graduate/GED), and total monthly
110 household income including government assistance. We also controlled for self-
111 reported financial strain over the past 12 months, on a scale from 1= "We have enough
112 and can save" to 4= "We don't have enough and we have great difficulties" (21).

113 Data Analysis

114 Data were analyzed using SPSSv21. ANOVA was used to detect unadjusted
115 differences in HRV indices between FI groups, and ANCOVA was used for the same
116 analyses adjusted for covariates. Partial eta squared values were calculated for each
117 ANOVA as an indicator of effect size. Multiple linear regression was performed to
118 examine the relationship between continuous FI scores and HRV indices. Alpha was set
119 at 0.05.

120 Results

121 One hundred and twenty one individuals participated in baseline assessments for
122 the Community Health Educators Assisting Latinos Manage Stress and Diabetes
123 (CALMS-D) trial. Of those, n=11 did not have HRV data, data from n=15 required >20%

124 interpolation so were excluded from analysis and one individual did not provide food
125 security data. This yielded a final n=94 for analysis. See table 1 for participant
126 characteristics.

127 Using our diabetes-specific food security item, 48 reported diabetes-specific food
128 security and 46 reported diabetes-specific FI. Using the USDA 6-item food security
129 module, 31 participants were food secure and 63 were food insecure. HRV values were
130 substantially lower than reported for a healthy, middle-aged sample (SDNN=96 vs 141)
131 (19).

132 In ANOVA, participants who reported diabetes-specific FI had lower SDNN,
133 lnVLF, lnLF, and lnHF than participants who reported diabetes-specific food security. In
134 ANCOVA, when covariates were added to the model, results for SDNN, lnVLF, and lnLF
135 remained significant, all $p < .05$. Results for lnHF remained significant with all
136 demographic and socioeconomic covariates, but were reduced to $p = .06$ with the
137 inclusion of A1c, although A1c was not a significant predictor of lnHF. A1c was a
138 significant predictor of lnVLF and lnLF. Results indicated partial eta squared values
139 ranging from .05 for SDNN and VLF to .06 for LF and HF, each of which indicates a
140 small-to-medium effect size for the association between diabetes-related FI and HRV.

141 In ANOVA, using the USDA 6-item food insecurity module to classify participants
142 as having high or marginal food security vs low food security vs very low food security,
143 food security status was not associated with any HRV index, all $p > .20$. Using the USDA
144 6-item food insecurity module to dichotomize participants as food secure or food
145 insecure, food security status was not associated with any HRV index, all $p > .30$. In

146 regression, using the total sum score on the USDA 6-item scale, food security score
147 was not associated with any HRV index, all p 's>.44.

148 Discussion

149 The main finding from this exploratory study is that among low-income Latinos
150 with T2DM, individuals who report diabetes-specific FI have lower HRV than individuals
151 who report diabetes-specific food security. Specifically, individuals who cannot afford to
152 buy the foods that they believe are necessary for diabetes self-management have lower
153 HRV. Our findings also suggest that diabetes-specific FI is associated with HRV through
154 mechanisms other than, or in addition to, glycemic control. Whereas FI worsens
155 glycemic control, and glycemic control worsens HRV, the link between FI and HRV is
156 not solely due to glycemic control. Further, diabetes-specific FI was related to HRV
157 independent of common socioeconomic indicators. This implies that diabetes-specific FI
158 uniquely exerts deleterious effects on the autonomic system above and beyond
159 commonly accepted poverty proxies. To our knowledge, these are the first data linking
160 FI with HRV.

161 Previous work has demonstrated that social adversity is related to lower HRV.
162 This includes racial minority status, social class, cumulative life stress (22), and poverty
163 (23). Yet, here we demonstrate that even among minorities of low socioeconomic
164 status, diabetes-specific FI exerts a unique effect on HRV above and beyond other
165 socioeconomic stressors.

166 Several studies have shown that low HRV is predictive of early mortality, even
167 after controlling for other risk factors. In the Framingham Heart Study, a one standard
168 deviation difference in the lnLF power nearly doubled the risk of all-cause mortality (24).

169 Similar findings have been reported in other studies and appear to be especially strong
170 among persons with diabetes (10). Thus our findings have important implications for
171 diabetes-related health outcomes. Whereas we are limited by a cross-sectional design
172 and we were unable to follow the sample for mortality, our findings might suggest that
173 HRV is one mechanism through which FI increases risk for early mortality. Limitations
174 include secondary data analysis, cross-sectional design, small sample, and a subjective
175 measure of diabetes-specific FI. Putative mediators such as nutritional composition,
176 energy intake, and psychological distress should be tested to understand the various
177 potential mechanisms through which diabetes-specific FI may impair autonomic
178 function. These limitations are generally outweighed by the study's strengths including a
179 hard-to-reach clinical sample, state of the art HRV assessment, and a novel, simple and
180 clinically relevant research question.

181 Conclusions

182 Participants who reported diabetes-specific FI had lower HRV than those who
183 reported diabetes-specific food security. If these exploratory findings are replicated,
184 efforts to end, decrease, or mitigate the effects of FI could have beneficial effects on
185 diabetes outcomes.

186

187

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188 Statement of authors' contributions to manuscript: JW and RPE designed the study; RL
189 analyzed the HRV data; JW performed statistical analysis; JW, RL, and ABM wrote the
190 manuscript; SSP and GD supervised data collection; JC supervised recruitment; all
191 authors contributed to the review and editing of the manuscript. All authors read and
192 approved the final version of this paper.

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Table 1. Participant characteristics by diabetes-specific food security status.

| Characteristic | Total (n=94) | Diabetes-Specific Food Secure (n=48) | Diabetes-Specific Food Insecure (n=46) | P-Value |
|---------------------------------|---------------|--------------------------------------|--|---------|
| Age in years | 59.70 ± 10.90 | 61.98 ± 10.59 | 57.37 ± 10.81 | .041* |
| Gender | | | | .026* |
| Female | 69 (73%) | 40 (83%) | 29 (63%) | |
| Marital Status | | | | .659 |
| Single | 64 (68%) | 34 (71%) | 30 (65%) | |
| Language Speak | | | | .541 |
| English & Spanish | 52 (55%) | 25 (52%) | 27 (59%) | |
| Spanish only | 42 (45%) | 23 (48%) | 19 (41%) | |
| Years in U.S. | 35.80 ± 14.39 | 36.72 ± 15.27 | 34.85 ± 13.54 | .533 |
| Employment Status | | | | .325 |
| Employed | 0 (0%) | 0 (0%) | 0 (0%) | |
| Unemployed looking for work | 15 (16%) | 5 (10%) | 10 (22%) | |
| Unemployed not looking Disabled | 26 (28%) | 14 (29%) | 12 (26%) | |
| | 53 (56%) | 29 (60%) | 24 (52%) | |

| | | | | |
|--------------------------|------------------|-------------------|------------------|-------|
| Educational Attainment | | | | .359 |
| Less than high school | 68 (72%) | 37 (77%) | 31 (67%) | |
| Monthly Household Income | | | | .176 |
| \$0 - 1000 | 63 (67%) | 37 (77%) | 26 (57%) | |
| \$1001 - 1500 | 26 (28%) | 8 (17%) | 18 (39%) | |
| \$1501 -2000 | 2 (2%) | 1 (2%) | 1 (2%) | |
| \$2001 – 3000 | 3 (3%) | 2 (4%) | 1 (2%) | |
| >\$3000 | 0 (0%) | 0 (0) | 0 (0%) | |
| Financial Strain | 2.53 ± 0.84 | 2.21 ± 0.74 | 2.87 ± 0.81 | .000* |
| A1c mmol/mol IFCC | 70.06 ± 18.49 | 66.73 ± 18.20 | 73.47 ± 18.35 | .079 |
| A1c % NGSP | 8.56 ± 1.69 | 8.26 ± 1.67 | 8.87 ± 1.68 | .079 |
| SDNN | 95.80 ± 28.16 | 102.12 ± 24.15 | 89.35 ± 30.67 | .028* |
| InVLF | 6.44 ± 0.84 | 6.64 ± 0.77 | 6.24 ± 0.86 | .022* |
| InLF | 5.31 ± 1.02 | 5.56 ± 1.00 | 5.05 ± 1.03 | .014* |
| InHF | 4.53 ± 1.11 | 4.78 ± 1.11 | 4.28 ± 1.06 | .028* |

Values are n (%) or mean \pm SD. Chi square tests were performed to examine differences in FI status on categorical variables and t-tests were performed for continuous variables.

All HRV values are unadjusted.

IFCC=International Federation of Clinical Chemistry; NGSP=National Glycohemoglobin Standardization Program; SDNN= standard deviation of the R- R interval; InVLF=

natural log transformed very low frequency; lnLF= natural log transformed low frequency; lnHF= natural log transformed high frequency

Financial strain was measured on a 4-point Likert scale from 1= “We have enough and can save”, to 4= “We don’t have enough and we have great difficulties”.