



Emerging Evidence

Health Security Perceptions: Initial Psychometric Analysis of the Construct of Health Security in Chronic Illness Among Patients With a Cardiac Device

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ABSTRACT

Scale measuring the construct of “health security in chronic illness” (HSCI) was piloted in Canadian cardiac device patients (N = 176) enrolled in a remote-monitoring study at 2 timepoints. Analysis revealed a 2-factor solution, labeled as “support” and “certainty”. Patients reported receiving less support over time, but consistent health certainty. Patients with implantable cardioverter defibrillators felt less secure over time and reported lower levels of health security in chronic illness than pacemaker patients.

RÉSUMÉ

Une échelle mesurant le concept de la « sécurité en matière de santé en présence d'une maladie chronique » a fait l'objet d'un projet pilote auprès de patients canadiens porteurs de dispositifs cardiaques (N = 176) inscrits dans une étude de télésurveillance comportant deux évaluations. L'analyse a révélé une solution à deux facteurs, soit le soutien et la certitude. Les patients ont déclaré qu'ils recevaient moins de soutien au fil du temps, mais que la certitude quant à leur santé était constante. Les porteurs d'un défibrillateur cardiovertéur implantable se sentaient moins en sécurité au fil du temps et signalaient de plus bas niveaux de sécurité en matière de santé, relativement à leur maladie chronique, que les porteurs d'un stimulateur cardiaque.

Patients with cardiac implantable electronic devices (CIEDs), such as pacemakers (PMs) and implantable cardioverter defibrillators (ICDs), have reduced mortality among cardiac arrhythmic patients.¹ Patient-reported outcomes (PROs) have

emerged as a critical consideration in cardiac research, but optimal metrics remain to be identified. Although improved quality of life (QOL) with PMs has been reported,² this measure is mixed for ICD patients.³ Of course, these devices differ based on their functions: the ICD administers painful shocks, whereas the PM's timed pulses are painless. Nonetheless, these devices share the benefit of sustaining normal cardiac rate/rhythm. More-nuanced measures are needed to understand why CIED patients score differently on QOL assessments.

Novel metrics have provided distinctions from QOL,⁴ such as *patient acceptance* of device technology, described as

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understanding, recommending, and deriving benefit from their device.⁵ The Florida Patient Acceptance Survey (FPAS) was able to distinguish between pacemaker and ICD patients and was sensitive to changes within interventions.⁶ FPAS scores are moderately correlated with measures of QOL and are negatively correlated with psychosocial distress. Quantitative efforts to disentangle the impact of disease vs device on CIED patients provide more-selective information for potential intervention.

We postulated a construct termed “health security in chronic illness” (HSCI), defined as the expectation of reliable and desirable health in the near term. A scale was developed to assess HSCI; items were generated from expert input from cardiac psychologists, cardiologists, and electrophysiologists. The purpose of the study described in this paper was to develop the novel measure of HSCI in a Canadian sample of CIED patients over time.

Methods

Participants

Data were collected from 3 Canadian centres with cardiac electrophysiologists. Eligibility criteria for enrollment included the following: being aged ≥ 18 years; providing informed consent; and having CIEDs with remote patient monitoring (RPM).

Procedures

Standard of care for CIED patients after implantation involves a device check within 48 hours and after 6-8 weeks. Participants were from a larger multicentre study examining RPM.⁷ Enrollment started after the 8-week postoperative check.

Outcome measures

The Health Security in Chronic Illness (HSCI) Scale was developed to measure the novel construct using 24 items. Prior subscales were entitled as follows: Availability of Help; Preventive Action; Controlling Outcomes; and Future Expectations using a 5-point Likert scale (ratings ranging from strongly disagree to strongly agree).

The FPAS is an 18-item measure of device acceptance for CIED patients, with 4 subscales: Return to Life, Device-Related Distress, Positive Appraisal, and Body Image Concerns.⁵ The FPAS has been validated in several countries,^{5,6} with satisfactory internal consistency ($\alpha = 0.74$ to 0.89) for the total and the subscales.

The Florida Shock Anxiety Scale (FSAS) is a 10-item scale developed to evaluate anxiety surrounding ICD shocks.⁸ The scale has high internal consistency ($\alpha = 0.91$), split-half reliability ($\alpha = 0.92$), and test-retest reliability ($\alpha = 0.79$).

Statistical analyses

Descriptive statistics were analyzed first. Variables are reported with standard deviation (SD) for continuous data, and frequencies for categorical data. Factor structuring was done using Velicer’s Minimum Average Partial (MAP) Test and principal axis factoring (PAF) using oblique Oblimin rotation. Confirmatory factor analysis (CFA) was used for refinement.

Correlations to other measures were used to examine construct validity. Mixed-model analyses of variance (ANOVAs) were conducted to examine differences on health-related QOL measures from baseline to 12-month follow-up. Analyses were performed using SPSS, version 28 (IBM, Armonk, NY), and Just Another Statistics Program (JASP, version 0.16.3.0) was used for the CFA.

Results

Descriptive statistics

A total of 100 ICD patients and 76 pacemaker patients were included in the study ($N = 176$). Most of the patients in the ICD sample were men (71%), were middle-aged (62.5 ± 11.8 years), had been living with their device for 2.0 ± 2.3 years, had an indication for primary prevention (55%), had ischemic heart disease (55%), and were prescribed medication including β -blocker (88%), statin (68%), antiplatelet medication (68%), and/or angiotensin-converting enzyme inhibitor / angiotensin receptor blocker (51%). For all ICD participants, 6 device visits were made due to ICD shocks. For pacemaker patients, most of the sample were men (63.2%); were middle-aged (63.4 ± 16.5 years); had been living with their device for 2.7 ± 3.2 years; had an indication for atrioventricular nodal disease (32%), sinus node dysfunction (38%) or syncope (25%); had various cardiovascular history including atrial fibrillation or flutter (37%), ischemic heart disease (17%), or valvular disease (17%); and were prescribed medication including β -blocker (32%), antiplatelet medication (30%), and/or statin (29%).

HSCI: scale construction

A parallel analysis and the original and revised Velicer’s MAP Test suggested 4 factors.⁹ This structure was examined using PAF and the oblique Oblimin rotation. Items that did not load or loaded weakly onto factors were removed.

A CFA did not support the model and had poor fit. A 2-factor model was proposed and indicated good fit: $\chi^2 (64) = 77.579$; comparative fit index (CFI) = 0.99; Tucker-Lewis index (TLI) = 0.99; standardized root mean square residual (SRMR) = 0.08; root mean square error of approximation (RMSEA) = 0.04 (0.00 - 0.072). A cutoff of 0.375 was administered for factor loadings (Table 1). Thirteen items were retained (Fig. 1) and used to calculate validity and reliability, which was acceptable ($\alpha = 0.79$).

One factor appeared to reflect “support,” ($\alpha = 0.73$), which measures how much an individual feels supported in terms of health, by various external sources (eg, family, faith). The second factor—“certainty” ($\alpha = 0.76$)—appears to reflect how much individuals feel internally secure about their health or the future of their condition. The 2 subscales were moderately, positively correlated ($r = 0.34$). Scores at both timepoints were positively, moderately correlated for the certainty measure ($r = 0.43$) and the support measure ($r = 0.67$), suggesting test-retest reliability.

HSCI: analysis

A 2 x 2 mixed-model ANOVA was run to determine the effect of device type, time, and interactions on the newly

Table 1. Factor loadings for health security in chronic illness

Item	Single factor structure	Factor 1 (Support)	Factor 2 (Certainty)
1. I have the information that I need to be as healthy as possible.	0.51	—	—
2. I have the support that I need to be as healthy as possible.	0.58	0.75	—
3. I have access to the right health care providers to take care of my health.	0.48	0.74	—
4. I know what action to take if my health condition worsens.	0.34	—	—
5. If my health condition changes, I can get it back on track.	0.53	—	—
6. If my health condition changes, my health care providers can help me get it back on track.	0.66	0.86	—
7. If my health condition changes, my family can help me get it back on track.	0.6	0.71	—
8. If my health condition changes, my faith can help me get it back on track.	0.38	0.5	—
9. I can deal with my condition.	0.56	—	—
10. My health condition is stable and will not change much.	0.46	—	—
11. What I do now to take care of my health will help my health condition in the future.	0.45	—	—
12. I believe that I will die of old age.	0.54	—	—
13. I look forward to better health in the future.	0.39	—	—
14. I am not sure what to do to be healthy in the future.	0.48	—	0.63
15. I cannot pay for my health care as needed.	0.46	—	0.64
16. I don't know what symptoms of my condition that I should watch for.	0.25	—	0.44
17. I get mixed messages from different providers about what I need to do to take care of my health.	0.4	—	0.61
18. I don't know what to do if my condition worsens.	0.41	—	0.78
19. No one knows how hard it is to live with my condition.	0.46	—	0.62
20. My condition is dangerous on a day-to-day basis.	0.51	—	—
21. My condition is dangerous to me in the long run.	0.56	—	0.58
22. I do not believe that I will return to full physical functioning.	0.42	—	—
23. My health problems are not predictable.	0.37	—	—
24. It's hard to know when I will have "good days" or "bad days" as far as my health problems go.	0.37	—	0.39

constructed subscales. Results showed no significant main effect on device type for the support measure ($F(1, 93) = 0.04, P = 0.84, \eta^2 = 0.00$), with ICD patients ($M = 3.94$) reporting receiving a similar level of support, as compared to PM patients ($M = 3.96$). Results showed a significant main effect of time on the support measure ($F(1, 93) = 11.6, P < 0.001, \eta^2 = 0.11$), with baseline scores ($M = 4.08$) higher than follow-up scores ($M = 3.82$), suggesting that participants reported receiving less support over time, regardless of device type. Interaction between device type and time in terms of the support measure did not reach significance ($F(1, 93) = 3.8, P = 0.05, \eta^2 = 0.04$). A significant main effect of device type did occur for the certainty measure ($F(1, 89) = 6.36, P = 0.01, \eta^2 = 0.07$), with ICD patients ($M = 3.41$) reporting less certainty regarding their health than PM patients ($M = 3.76$). No significant main effect of time occurred ($F(1, 89) = 1.42, P = 0.24, \eta^2 = 0.02$). Also, no significant interaction occurred between device type and time in terms of the certainty measure ($F(1, 89) = 0.01, P = 0.91, \eta^2 = 0.00$).

Device acceptance: analysis

A 2 x 2 mixed-model ANOVA was used to assess device acceptance. No significant main effect occurred for device type ($F(1, 80) = 3.12, P = 0.08, \eta^2 = 0.04$), time ($F(1, 80) = 3.6, P = 0.06, \eta^2 = 0.04$), or their interaction ($F(1, 80) = 1.19, P = 0.28, \eta^2 = 0.02$).

Correlations among outcome measures

Correlations examined relationships between HSCI and existing heart patient measures. Certainty was positively, strongly correlated with device acceptance but was not related

to shock anxiety (for ICD). Support was not correlated with any other measure (Table 2).

Health security in chronic illness: final scale

The HSCI scale retained 13 items and 2 subscales—support and certainty (Fig. 1). All items and each subscale can be averaged for a total score. Higher scores indicate higher HSCI, and higher levels of support and certainty.

Discussion

This study developed the novel construct HSCI with CIED patients. Patients reported lower levels of support over time. As a standard, RPM patients are contacted only when an adverse event occurs. This can lead patients to view the technology that is intended to reassure them as instead a stimulus of fear. Because these data suggest that support remains valuable to patients over time, providers might do well to remind patients of their "safety net" (CIED) and health status at more frequent intervals.

Certainty remained stable over time, but ICD patients reported lower levels than PM patients. This difference may be due to disease severity or active device therapy (eg, ICD shocks). Certainty was positively, strongly correlated with device acceptance but unrelated to shock anxiety for ICD patients. Individuals who are more trusting of their device may be more certain about their health. This possibility is clinically relevant, as uncertainty about future health and perceived support are associated with psychosocial distress and health behavior.¹⁰

Support and certainty, as reflected by the subscales, have intuitive value, and higher levels of these factors are often what

Health Security in Chronic Illness

We want to understand what it is like for you to live with a medical condition. Below are some statements that describe personal beliefs about your condition. Please rate the extent to which you agree or disagree with each of the following statements by checking the most appropriate box.

Strongly Disagree **Mostly Disagree** **Neither Agree nor Disagree** **Mostly Agree** **Strongly Agree**
 1-----2-----3-----4-----5

Support

1. If my health condition changes, my health care providers can help me get it back on track
2. If my health condition changes, my family can help me get it back on track
3. If my health condition changes, my faith can help me get it back on track
4. I have access to the right health care providers to take care of my health
5. I have the support that I need to be as healthy as possible

Certainty

6. It's hard to know when I will have "good days" or "bad days" as far as my health problems go
7. I am not sure what to do to be healthy in the future
8. No one knows how hard it is to live with my condition
9. I don't know what to do if my condition worsens
10. I cannot pay for my health care as needed
11. I get mixed messages from different providers about what I need to do to take care of my health
12. I don't know what symptoms of my condition that I should watch for
13. My condition is dangerous to me in the long run

Figure 1. Final version of Health Security in Chronic Illness Scale.

shared decision-making attempts to accomplish in the pre-device period. An *ongoing* process for CIED patients may be needed.¹¹ Although RPM is beneficial, the increased reliance on RPM for CIED patients has reduced the opportunities for patient-provider discussions. Device function may be prioritized inadvertently over validation of the patient experience. The availability of measures that assess constructs such as HSCI may be a way for providers to monitor other important aspects of patient QOL.

This study had several limitations, as follows: (i) how HSCI relates to other constructs (aside from FPAS and FSAS), or whether it could be more specific to device and/or disease type (ie, number of shocks received, symptom burden) is unknown; (ii) PAF and CFA were used on the sample, limiting the confidence level in the existing factor structure¹²; (iii) no control group was used, making it difficult to ascertain the extent to which RPM and other

chronic medical conditions interacted; (iv) the patients in the sample were experienced with their device and may not experience fluctuations in QOL; (v) patients were not involved in scale construction, limiting the degree to which the approach was patient-centred; (vi) HSCI should be examined beyond rural Canada; and (vii) RPM patients may have unique considerations. However, other research suggests that RPM does not affect PROs, such as device acceptance (which is strongly correlated with the certainty measure in the current study).^{11,13} Even when RPM is added to usual care, PROs such as anxiety, depression, and device acceptance did not change.¹⁴ The following would be beneficial: examination of HSCI with a longitudinal approach; use of a control group or non-RPM sample; a larger, diverse sample; differing device implementation times (pre-implant, post-implant, and follow-up); examination of shock history for ICD patients, and applicability to other chronic diseases.

Overall, this pilot study provided further specificity regarding QOL among CIED patients.

Table 2. Correlation matrix for outcome measures

Column label	1	2	3	4
1. FPAS	—	—	—	—
2. FSAS	-0.37*	—	—	—
3. Certainty (HSCI scale)	0.59*	-0.14	—	—
4. Support (HSCI scale)	0.18	0.21	0.34*	—

FPAS, Florida Patient Acceptance Survey; FSAS, Florida Shock Anxiety Scale; HSCI, Health Security in Chronic Illness.

**P* < 0.01.

Ethics Statement

This research has adhered to the relevant ethical guidelines.

Patient Consent

The authors confirm that patient consent is not applicable to this article. This is a retrospective case report using de-identified data; therefore the IRB did not require consent from the patient.

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Disclosures

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