

Measurement of Patient Confidence in Self-Management of Atrial Fibrillation: Initial Validation of The Confidence in Atrial fibrillation Management (CALM) Scale

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Abstract

Abstract Background: The patient experience of atrial fibrillation (AF) involves several daily self-care behaviors and ongoing confidence to manage their condition. Currently, no standardized self-report measure of AF patient confidence exists. The purpose of this study is to establish the reliability and validity of a newly developed confidence in AF management measure. **Methods:** This study provides preliminary analysis of the Confidence in Atrial Fibrillation Management (CALM) scale, which was rationally developed to measure patient confidence related to self-management of AF. The scale was provided to a sample of AF patients N=120, (59% male) electronically through a patient education platform. Principle components analysis (PCA) and Cronbach's alpha were employed to provide preliminary assessment of the validity and reliability of the measure. **Results:** PCA identified a four-factor solution. Internal consistency of the CALM was considered excellent with Cronbach's $\alpha = .910$. Additional PCA confirmed the value of a single factor solution to produce a total confidence score for improved utility and ease of clinical interpretation. **Conclusions:** Initial assessment of a novel scale measuring patient confidence in managing AF provided promising reliability and validity. Patient confidence in self-management of AF may prove useful as a key marker and endpoint of the patient experience beyond QOL.

Measurement of Patient Confidence in Self-Management of Atrial Fibrillation:

Initial Validation of The Confidence in Atrial fibrillation Management (CALM) Scale

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Conclusions: Initial assessment of a novel scale measuring patient confidence in managing AF provided promising reliability and validity. Patient confidence in self-management of AF may prove useful as a key marker and endpoint of the patient experience beyond QOL.

Introduction

Atrial fibrillation (AF) is the most common dysrhythmia, affecting 3.5 million people worldwide, and is associated with an increased risk for stroke.¹ AF is a progressive condition that involves medical management such as rate control, rhythm control, and anti-coagulation, as well as lifestyle change and self-management behaviors.^{2,3} AF is also associated with significant psychologic distress, particularly for patients who are symptomatic, perceive AF to be dangerous, or have low AF health literacy⁴; research to date suggests high rates of anxiety and depression, 35% and 20%, respectively, in AF samples.⁵ Daily management of AF involves adherence to medical therapies (e.g rate/rhythm control, stroke prophylaxis), management of comorbidities, abstinence from smoking, avoiding alcohol consumption, and sustaining regular physical activity.⁶ Collectively, the psychological and behavioral aspects of coping with and managing AF contribute to the key outcomes of symptom reduction and quality of life.^{7,8,9,10,11}

Current research approaches have generally relied on quality of life measures to capture the entirety of the patient experience. For example, the Atrial Fibrillation Effect on Quality-of-life (AFEQT) questionnaire was developed to explicitly measure patients' perceptions of their symptoms, functional impairment, treatment

concerns, and satisfaction with treatment.¹² The reliance on QOL measures to capture the totality of the patient experience focuses on the desired endpoint(s), but may overlook possible process and intervention targets such as: self-assessment, self-care maintenance, management, and confidence that have demonstrated value in heart failure treatment.^{13,14} The development of a patient confidence measure for AF patients may broaden the lens for examination of the patient experience and provide additional understanding and targets for intervention. The purpose of this study was to test the reliability and validity of a stand-alone measure of confidence in self-management of AF, the **C**onfidence in **A**trial Fibril**L**ation Management (CALM) scale.

Methods

This study was part of a larger project assessing the utility of a web-based self-care intervention for AF patients, within the context of the COVID-19 pandemic. Patients were recruited from the patient panel of electrophysiologists at the University of North Carolina through electronic outreach. Patients who consented and were enrolled in the intervention study completed several electronic surveys prior to and following the intervention, including surveys of demographic information, health information, and knowledge/attitudes/beliefs about COVID-19, as well as other validated surveys.

For the purposes of this study, patient responses on the CALM, PROMIS-29, and AFEQT were analyzed. The PROMIS-29 is a widely validated and used assessment of general quality of life including eight domains: pain intensity and interference, fatigue, sleep disturbance, physical functioning, depression, anxiety, and ability to participate in social roles and activities.¹⁵ The AFEQT is a well-established and widely used, four-factored descriptive measure of disease-specific patient quality of life, with demonstrated validity and reliability (internal consistency >.88 on all factors).¹² This measure is used to describe the patient experience of AF, specifically symptoms, daily activities, and perceptions of treatment (i.e. concerns and satisfaction). Medical record review was conducted to obtain information about health and relevant comorbidities. This study was approved by the Institutional Review Board at the University of North Carolina at Chapel Hill (IRB #20-1121).

Items for the CALM measure were patterned after items from the Self-care of Heart Failure Index (SCHFI) (REF: Riegel) and modified by a cardiac electrophysiologist (AG) and clinical health psychologist (SFS) to tailor them to AF. Next, multiple AF providers including medicine, psychology, and nursing provided feedback on relevance and comprehensiveness of the items to reflect the patient experience with confidence and AF. The preliminary items were then employed in the current study.

Statistical Analyses . The current study utilized survey responses, prior to intervention, in order to establish the validity of a stand-alone measure of confidence in self-management of AF, the CALM, and to describe and compare scores on this measure with other survey data (e.g. AFEQT).

Principle Components Analysis (PCA) was used to analyze the 16-item CALM measure, in order to group variables into key components. A varimax rotation was employed to simplify each component, minimizing the amount of variance within each component and maximizing the variance between components. Cronbach's alpha was then used to assess reliability of the total measure, as well as the reliability of the individual components.

Correlational analyses and independent samples t-tests were then used to assess the relationships and differences in scores on several demographic, health, and QOL variables.

Results

Demographic and self-reported AF-related information, including relevant comorbidities, reports on health behavior, psychologic diagnoses, PROMIS scores, and AFEQT scores for this sample is provided in Table 1.

Demographics

Age and BMI	m(SD); range	m(SD); range
Age	71.83 years (± 11.14); 24-97 years	71.83 years (± 11.14); 24-97 years

Demographics

BMI	29 (± 8.06)	29 (± 8.06)
Gender	n (%)	n (%)
Men	71 (59%)	71 (59%)
Women	49 (41%)	49 (41%)
Marital Status	n (%)	n (%)
Married or Partnered	93 (78%)	93 (78%)
Single	14 (12%)	14 (12%)
Widowed	8 (7%)	8 (7%)
Divorced	6 (5%)	6 (5%)
Race	n (%)	n (%)
White/Caucasian	116 (97%)	116 (97%)
Black/African American	1 (1%)	1 (1%)
Hispanic	2 (2%)	2 (2%)
Other	1 (1%)	1 (1%)
Occupational Status	n (%)	n (%)
Employed	25 (21%)	25 (21%)
Retired or Unemployed	77 (64%)	77 (64%)
Unknown	18 (15%)	18 (15%)
Medical Information		
AF Type	n (%)	n (%)
Paroxysmal	90 (75%)	90 (75%)
Persistent or Permanent	28 (23%)	28 (23%)
Unsure	1 (1%)	1 (1%)
History of Surgical Intervention for AF	n (%)	n (%)
Ablation	47 (39%)	47 (39%)
Left Atrial Appendage Occlusion	5 (4%)	5 (4%)
Cardioversion	53 (44%)	53 (44%)
Medication Management of AF	n (%)	n (%)
Anticoagulant	93 (78%)	93 (78%)
Beta-Blocker	79 (66%)	79 (66%)
Calcium Channel Blocker	12 (10%)	12 (10%)
Anti-arrhythmic	49 (41%)	49 (41%)
CHA₂DS₂VASc Scores	n (%)	n (%)
0	4 (3%)	4 (3%)
1	21 (18%)	21 (18%)
2+	95 (79%)	95 (79%)
Comorbidities	n (%)	n (%)
Hypertension	67 (56%)	67 (56%)
Obstructive Sleep Apnea	45 (38%)	45 (38%)
Coronary Artery Disease	34 (28%)	34 (28%)
Congestive Heart Failure	30 (25%)	30 (25%)
Chronic Lung Disease	29 (24%)	29 (24%)
Prior Myocardial Infarction	16 (13%)	16 (13%)
Stroke (TIA/CVA)	16 (13%)	16 (13%)
Diabetes	14 (12%)	14 (12%)
Chronic Kidney Disease	13 (10.8%)	13 (10.8%)
Psychological and Behavioral Information		
Alcohol Use	n (%)	n (%)
Mild (1 or less drinks per week)	26 (34%)	26 (34%)
Moderate (7 or less drinks per week)	33 (43%)	33 (43%)

Demographics

Heavy (8+ drinks per week)	16 (21%)	16 (21%)
Tobacco Use	n (%)	n (%)
Current	2 (2%)	2 (2%)
Prior	54 (45%)	54 (45%)
Never	64 (53%)	64 (53%)
AFEQT Scores	m (SD)	m (SD)
AFEQT Score	77.43 (± 17.46)	77.43 (± 17.46)
Psychiatric Diagnoses (per chart review)	n (%)	n (%)
Major Depressive Disorder (MDD)	16 (13%)	16 (13%)
Generalized Anxiety Disorder (GAD)	18 (15%)	18 (15%)
PROMIS Measure Scores		
Domain	mean raw score rounded (SD)	T score
Physical Function	17 (3.6)	43.4
Fatigue	9 (4.0)	51.0
Pain Interference	6 (2.8)	52.0
Depressive Symptoms	6 (2.9)	51.8
Anxiety Symptoms	7 (3.3)	53.7
Social Roles & Activities	15 (4.4)	50.0
Sleep Disturbance	9 (3.6)	48.4

CALM Validity and Reliability

Initial Factor Analysis . The CALM measure contains 16-items related to various aspects of care, asking patients to indicate the level of confidence they feel in each aspect (i.e. no confidence, somewhat confident, very confident, extremely confident). These 16 items were entered into a PCA with varimax rotation and yielded four components; analysis yielded 68% of variance in items was explained by these four components (Table 2). The factor loadings were relatively free of multiple loadings and no items warranted deletion.

Table 2. CALM Components

External Support (In general, how confident are you that...)	Factor Loadings Sub Scale	Factor Loadings Full Scale
Your doctor understands your AFib condition?	.799	.581
You can get the emotional support you need to manage your AFib?	.605	.549
You can get the practical support you need to manage your AFib?	.731	.790
You can follow the treatment advice you have been given?	.535	.696
You can reach your doctor or nurse for guidance?	.662	.614
Awareness of Change (In general, how confident are you that..)		
You can get the information you need about your AFib condition?	.586	.828
You can evaluate the severity of your symptoms?	.799	.716

External Support (In general, how confident are you that...)	Factor Loadings Sub Scale	Factor Loadings Full Scale
You can recognize changes in your health if they occur?	.836	.699
You know when to seek emergency medical attention?	.682	.702
Self-Care and Relief (In general, how confident are you that...)		
You can keep yourself free of AFib symptoms?	.783	.567
You are doing what you can to manage your AFib?	.493	.716
You can do something to relieve your symptoms of AFib?	.813	.656
You can evaluate if a remedy works for you?	.607	.671
Safety (In general, how confident are you that...)		
You will not die during an episode of AFib?	.678	.600
You are not having a heart attack during an episode of AFib?	.750	.646
You will not have a stroke during an episode of AFib?	.855	.428

Higher Order Factor Analysis . These 16 items were then entered into a PCA with a predetermined number of components to extract, 1, in order to determine if total scores could be used and interpretable; results suggested that a total score was supported, with each item producing correlations between .428 and .828 (Table 3). Internal consistency of the CALM was considered excellent with Cronbach’s $\alpha = .910$. Totals and subscale scores by section are presented in Table 3.

Table 3. CALM Scores

Measure	Highest Possible	Lowest Possible	m (SD)	Highest Score in Sample	Lowest Score in Sample
CALM: Total Confidence	48	0	29.1 (8.7)	48	9
CALM: External Support	15	0	10.7 (2.9)	15	4
CALM: Awareness of Change	12	0	7.5 (2.9)	12	1
CALM: Self-Care and Relief	12	0	5.7 (2.7)	12	0
CALM: Safety	9	0	5.2 (2.1)	9	1

Comparisons of Demographic and Health Variables. Pearson correlation analysis did not indicate a significant relationship between age and confidence in self-management of AF ($p = .468$) or BMI and confidence and AF self-management ($p = .5$).

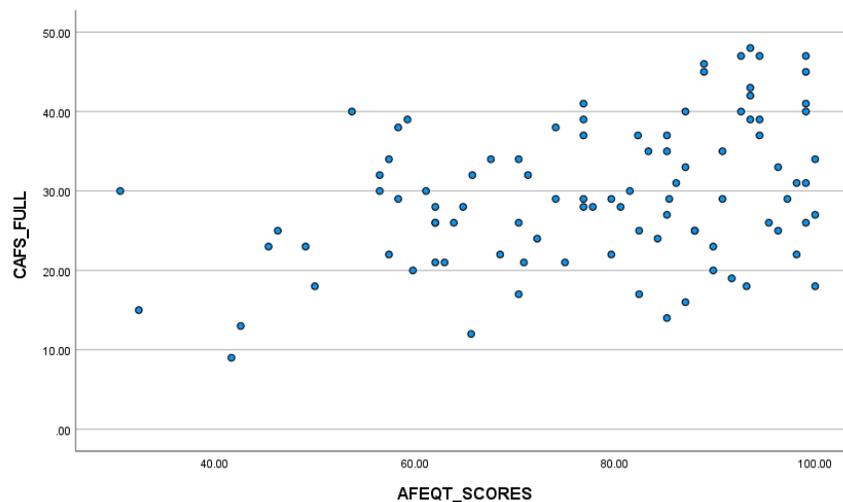
Independent samples t-tests were used to assess differences in CAFS scores between different demographic, health, and AF specific variables. Interestingly, results indicated no significant differences between mean scores for women ($m = 29.7$, $SD = 8.8$) and men ($m = 28.7$, $SD = 8.7$), $t(100.394) = -.608$, $p = .545$. No significant differences were detected between those with CHA_2DS_2VASc scores of two or more and those with one or less $t(48.1) = -.602$, $p = .550$. There were also no significant differences between those with

past diagnoses of MDD ($m = 27.5, SD = 8.4$) and those without ($m = 29.3, SD = 8.8$), $t(15.7) = .743, p = .468$. However, there was a significant difference between scores for those with past diagnoses of GAD ($m = 25.3, SD = 6.6$) and those without ($m = 29, SD = 9.0$), $t(31.2) = 2.49, p = .018$, likely indicating that those with anxiety have less confidence in self-management of AF than those without anxiety.

Related to procedural treatment of AF, an independent samples t-test suggested no significant difference in confidence scores between those patients who had undergone an ablation for AF management ($m = 30.2, SD = 7.0$) and those who had not ($m = 28.7, SD = 9$), $t(103.3) = -.945, p = .347$. There was also no significant difference in confidence scores between those who had undergone an LAA occlusion ($m = 26.2, SD = 3.1$) than those who had not ($m = 29.5, SD = 8.7$), $t(7.59) = 1.98, p = .085$. Interestingly, there was a significant difference in confidence scores between those who had undergone a cardioversion for AF ($m = 32, SD = 7.2$) and those who had not ($m = 27.4, SD = 9.0$), $t(104.4) = -.297, p = .004$, suggesting those who had undergone cardioversion had significantly more confidence in self-management of AF.

Related to medication for AF management, independent samples t-tests indicated that there were no significant differences between those patients prescribed anticoagulants ($m = 29.8, SD = 8.6$) and those that were not ($m = 26.6, SD = 8.9$), $t(36.0) = -1.58, p = .123$, or between those who were prescribed beta-blockers ($m = 29.4, SD = 9.0$) and those that were not ($m = 28.2, SD = 8.6$), $t(63.6) = -.659, p = .513$. Interestingly, there was a significant difference between those who were prescribed anti-arrhythmic medications ($m = 32.7, SD = 7.9$) and those that were not ($m = 26.7, SD = 8.6$), $t(97.0) = -3.767, p < .001$, suggesting that individuals prescribed anti-arrhythmic medications for AF had greater confidence in self-management than individuals without anti-arrhythmic medications.

Comparison with Quality of Life . Lastly, a simple linear regression analysis was used to assess the ability of the CALM total scores to predict AF quality of life using AFEQT total scores (Figure 1). Results of this analysis suggested that CALM total scores predicted increased AFEQT total scores ($r^2 = .142, p < .001$). In other words, greater confidence in AF self-management predicted better quality of life with AF, with 14.2% of variance in quality of life being explained by confidence in AF self-management.



Discussion

The current study examined a new scale for measuring patient confidence in self-management of AF. Initial reliability and validity metrics were promising and suggest potential utility though further validation testing is warranted. The CALM measure containing 16 self-report items underwent principle component analysis and a four-factor solution was identified. The major aspects included scales of external support, awareness of change, self-care and relief, and safety. Additional analyses indicated that a total confidence score could

be derived and was psychometrically sound. Confidence in AF was similar between men and women, but significantly different between patients with and without a documented anxiety disorder, those with the experience of cardioversion, and those who have taken anti-arrhythmic medication.

These data suggest that background experiential variables may exert some influence on perceptions of AF and QOL. Previous studies have linked the experience of cardioversion with better QOL reports and the presence of anxiety to worse QOL.^{16,17} The utility of the CALM was further established, as total confidence was a significant predictor of AF QOL, but only accounted for 14% of the variance. Therefore, this initial work indicates that the CALM provides a brief, easy-to-use in-clinic measure of patient confidence in AF self-management with some promising validity that should be used in conjunction with QOL measures. With additional validation and testing, AF confidence may serve as a target for clinical interventions and ongoing clinical care. Confidence in AF self-management could provide a process measure for achieving successful self-care and better QOL.

Patient confidence or self-efficacy in managing chronic disease has been well-examined and generally confidence tends to diminish as the illness burden increases.¹⁸ This finding is particularly relevant as patients with AF are likely to have multiple co-morbidities, multiple treatment modalities, and multiple risk factors to address suggesting a high degree of management burden.¹¹ Previous examination of confidence in AF self-management was completed by employing an online survey of women with AF.¹⁰ Results indicated that the most salient item of the survey emphasized, “taking active role in my health is important in how I feel.” Confidence in cardiovascular conditions has not been as well-studied but when the construct of confidence was studied, researchers generally focused on confidence in one target behavior.⁹

The awareness and measurement of patient attitudes and patient confidence represents a new avenue for cardiac electrophysiology. The history of cardiac electrophysiology has primarily focused on technologic advances and procedural based improvements. The emergence of data related to the potential value of risk factor management in AF has prompted increased attention to multi-disciplinary care to improve outcomes regardless of treatment strategy.¹⁹ The identification of cardiac fitness, obesity, alcohol use, sleep apnea, and other risk factors indicates that patients increasingly must be equal partners with cardiac electrophysiology teams.²⁰ Psychological confidence represents a necessary, but not sufficient, component of achieving better health outcomes. The introduction of a brief, clinic-ready AF confidence measure (i.e. CALM measure) could provide information about how patients perceive their capability and potentially how patient education, and behavioral intervention are likely to be effective. In short, patients who do not believe that they are capable of acquiring sufficient social and informational support, making changes, engaging in effective self-care and feeling safe again to return to physical activities are probably less likely to benefit without targeted intervention. Future research must examine this notion empirically, but it seems plausible.

Despite the promise the CALM holds for understanding patient confidence in self-management of AF, the study has some limitations. First, it should be noted that the sample was mostly white (97%) with only one Hispanic and two African American participants. Convenience sampling was solely utilized in this round of testing of the CALM. Future studies using the CALM should focus on more diverse samples in order to test the generalizability of the findings. Secondly, the study was conducted during COVID-19, therefore we cannot entirely exclude unknown potential confounding effects of the pandemic. Patient experience and self-care behaviors may not accurately represent this population’s reality under non-pandemic conditions. Social support may be limited and may have affected that set of items on the measure. Thus, continued research using the CALM to understand patient confidence in self-management of AF is needed considering the complexity of self-care, clinical management, and understanding of AF. Further research is needed to establish clinically meaningful cut-off scores to indicate the need for intervention.

The current study establishes the reliability and validity of a new patient reported outcome measure of confidence in atrial fibrillation, The **C**onfidence in **A**trial Fibril**L**ation**M**anagement (CALM) scale, providing a total score and subscales of confidence. Additional analyses indicate that AF confidence is a significant predictor of AF QOL. As multidisciplinary care for AF continues to mature, greater attention and intervention on the patient experience and psychological functioning will likely become important. Preliminary data

suggests the new measure, CALM, will benefit from additional psychometric testing. We seek to make the measure widely available for use at no charge for future research as we hope it becomes a useful addition to understanding the patient experience alongside AF QOL.

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