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ORIGINAL RESEARCH

Patient-Reported Outcomes in a Multidisciplinary Electrophysiology-Psychology Ventricular Arrhythmia Clinic

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BACKGROUND: Ventricular arrhythmias (VAs) and their treatment have been associated with psychological distress and diminished quality of life (QOL). We administered a battery of patient-reported outcome measures (PROMs) to patients seeing an electrophysiologist and psychologist in a multidisciplinary VA clinic for patients referred for consideration of catheter ablation for sustained VAs or implantable cardioverter-defibrillator therapies.

METHODS AND RESULTS: In this retrospective study of the initial VA clinic visit, we analyzed PROMs of: anxiety and depression symptoms, visual analog scales for physical health status and quality of life, cardiac anxiety, implantable cardioverter-defibrillator acceptance, and implantable cardioverter-defibrillator shock anxiety. We quantitated baseline PROM score means and performed correlation analysis with clinical makers of cardiac and VA disease severity. We also performed an item-level analysis of each PROM question to quantify most frequent patient concerns. A total of 66 patients (56±15 years; 77% men) were included; 70% had prior implantable cardioverter-defibrillator shock, and 44% with prior VA ablation. Elevated symptoms of anxiety (53%) and depression (20%) were common. Younger patients had greater symptom burden of general health anxiety, cardiac anxiety, and shock anxiety, and lower device acceptance, but indices of VA burden such as number of ICD shocks and time since last ICD shock did not predict anxiety or depression. Item-level review of cardiac-specific PROMs revealed that >40% of patients expressed concern regarding resumption of physical activity, sex and employment.

CONCLUSIONS: Clinicians can expect elevated symptoms of depression, and cardiac and device-related anxiety among patients with VAs. Routine use of PROMs may elicit these symptoms, which were otherwise not predicted by arrhythmia burden. Review of individual PROM items can facilitate targeting specific patient concerns, which commonly involved physical activity.

Key Words: implantable cardioverter-defibrillator ■ patient-reported outcomes ■ quality of life ■ ventricular arrythmia ■ ventricular tachycardia

Ventricular arrhythmias (VAs), including ventricular fibrillation and ventricular tachycardia, are life-threatening in the acute setting and often become life-impacting chronic conditions for patients. Implantable cardioverter-defibrillators (ICDs) are one of the mainstays of treatment, and multiple studies have demonstrated their survival benefit.[1–4] However, ICD recipients with shocks and cardiac arrest survivors have increased psychological distress and poorer quality of life (QOL).[5–9] In addition, there is evidence to suggest that ICD recipients may experience device-related anxiety and depression even in the absence of ICD shocks.[10–12] Patient-reported outcome measures (PROMs) are beginning to be introduced in clinical settings and early experience with their clinical utility warrants attention.[13–15] PROMs are standardized, validated questionnaires completed by patients to measure subjective general or disease-specific health status or well-being.[13] PROMs are often used in research or clinical trial settings, but their role in "real-world" electrophysiology clinics requires further investigation.

Our institution initiated routine PROM administration at every clinic visit in a novel multidisciplinary

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CLINICAL PERSPECTIVE

What Is New?

- In a novel, multidisciplinary electrophysiology-psychology clinic for patients with ventricular arrhythmia, symptoms of anxiety and depression were not predicted by common clinical markers of cardiac or arrhythmia disease severity (eg, defibrillator shocks, ejection fraction) but were frequently detected by routine use of patient-reported outcome measure questionnaires.
- Analysis of individual items/questions within patient-reported outcome measures demonstrated that the most common sources of patients' anxiety and psychosocial symptoms were returning to physical activity, a normal sex life, and employment.

What Are the Clinical Implications?

- Clinicians should consider routine use of patient-reported outcome measures in the care of patients with ventricular arrhythmias, and frequently counsel them regarding physical exertion.

Nonstandard Abbreviations and Acronyms

CAQ	Cardiac Anxiety Questionnaire
FPAS	Florida Patient Acceptance Survey
FSAS	Florida Shock Anxiety Scale
HADS-A	Hospital Anxiety and Depression Scale-Anxiety
NYHA	New York Heart Association
PROM	patient-reported outcome measure
VA	ventricular arrhythmia

electrophysiology-psychology clinic for patients with VAs. In this study, we sought to describe baseline PROM scores on the initial clinic visit and assess their association with clinical markers of cardiac and arrhythmic disease severity. Furthermore, we analyzed the frequency of patient responses to each individual question/item within the PROMs in order to identify specific concerns and sources of psychosocial symptoms common to this population.

METHODS

Because of the sensitive nature of the psychological data collected for this study, requests to access the data set from qualified researchers trained in human subject confidentiality protocols may be sent to the corresponding author. Patients provided informed consent for both psychology counseling and the use of PROMs.

In this retrospective study, we included patients seen between 2018 and 2020 for an initial visit in our multidisciplinary VA clinic that included visits with an electrophysiologist and a clinical psychologist. Patients are referred to this clinic for consideration of VA catheter ablation for sustained VAs and/or ICD therapies. Before the visit with the providers, patients complete the following 3 general PROMs: physical health status and QOL visual analog scales,[16] New York Health Association (NYHA) class I to IV (higher class consistent with worsening functional capacity),[17] and Hospital Anxiety and Depression Scale (HADS).[18] In addition, they completed 3 cardiac-specific PROMs: Cardiac Anxiety Questionnaire (CAQ),[19] Florida Patient Acceptance Survey (FPAS),[20] and Florida Shock Anxiety Scale (FSAS).[12] All of these PROMs are performed before the first visit with the clinical psychologist in order to truly reflect the baseline psychosocial symptoms, and track the effect of sessions of the clinic and psychologist on follow-up PROMs. In the same clinic setting, patients subsequently have clinic appointments with the electrophysiologist, cardiac implantable device nurses/technicians, psychologist, and other cardiac specialists if indicated. Patients were excluded from this study if they had not completed all PROMs at their initial visit.

The physical health status and QOL visual analog scales are scored on a scale of 0 to 100 with a higher score reflecting better status. HADS has 14 items with two 7-item subscales named HADS-Anxiety (HADS-A) and HADS-Depression (HADS-D) with a maximum score of 21. Higher scores for each HADS subscale are consistent with worsening symptoms, with severity categorized into mild (8–10), moderate (11–14), and severe (15–21). The CAQ consists of 18 items with a score of 0 to 72, with an increased score corresponding to higher cardiac anxiety. While no published thresholds for severity of cardiac anxiety on CAQ have been published, in its initial development and validation study among cardiology patients referred specifically for psychological evaluation and treatment, the mean CAQ score was 30.[19] FPAS also consists of 18 items, with the score ranging from 18 to 90, and a higher score consistent with better device acceptance. Of the 18 items in FPAS, 15 items are part of the final total score and 3 filler items are included for clinical and research utility during original development. The questions comprise a total score plus 4 factors: return to function, device-related distress, body image concerns, and positive appraisal.[20] Prior studies have used lowest tertile cutoffs such as <63 or <67 to label poor or "nonacceptors" with no validated score documented.[21,22] FSAS comprises 10 items each with a 1 to 5 score for a maximum score of 50 and symptom severity grouped into

none-minimal (10–20), mild (21–30), moderate (31–40), and severe (41–50).[23] Clinical characteristics and data were extracted from the electronic medical record. This study was approved by the institutional review board at our institution with all procedures followed in accordance within institutional guidelines.

Statistical Analysis

We used SPSS statistical software (IBM) to analyze the data. We calculated total PROM scores consistent with published guidelines, and data are reported as mean±SD. The relationship between objective clinical markers with overall PROM scores was assessed using Pearson correlation analysis for continuous variables. In addition, we quantitated the frequency with which each item (question) in the 3 cardiac-specific PROMs (CAQ, FPAS, FSAS) was rated as a concern by patients in order to determine which specific psychosocial concerns were most prevalent among the cohort.

RESULTS

Clinical Characteristics

The cohort included 66 patients (56±15 years; 77% men) who had completed all PROMs at their initial visit; demographic and medical characteristics are presented in Table 1 (only 4 patients referred to the clinic during the study period failed to complete the PROMs and were excluded). All patients had a history of VAs and ICD implantation, 35% had a history of sudden cardiac arrest, 70% had experienced at least 1 ICD shock, and 39% had undergone at least 1 VA catheter ablation. Among patients who had a history of ICD shock, the average number of shocks was 8±16.

Table 1. Baseline Characteristics

Demographics	
No. of patients studied	66
Age, median (IQR), y	60 (46–70)
Men, n (%)	51 (77)
Clinical characteristics	
LVEF, median (IQR)	40% (30–55)
Ischemic cardiomyopathy, n (%)	22 (33)
Nonischemic cardiomyopathy, n (%)	40 (60)
Primary prevention ICD, n (%)	21 (32)
Secondary prevention ICD, n (%)	45 (68)
History of sudden cardiac arrest, n (%)	23 (35)
Prior ICD shock, n (%)	46 (70)
Prior VA catheter ablation, n(%)	26 (39)
Time since last ICD shock, median (IQR), y	1.1 (0.2–4.4)
No. of ICD shocks, median (IQR)	2 (1, 8)

ICD indicates implantable cardioverter-defibrillator; IQR, interquartile range; LVEF, left ventricular ejection fraction; and VA, ventricular arrhythmia.

Total PROM Scores

Patients reported primarily intermediate physical health status visual analog scale (57±16) and overall good QOL visual analog scale (65±18). Regarding the HADS PROM, symptoms that exceeded clinical thresholds for anxiety (HADS-A) were present in 53% (23% with mild symptoms, 20% with moderate, and 11% with severe), and symptoms of depression (HADS-D) were present in 20% (10% mild, 8% moderate, and 2% severe) of the cohort. The mean patient-reported NYHA class was 2.1±1.0, with 32% self-reporting as NYHA I, 35% as NYHA II, 21% as NYHA III, and 12% as NYHA IV. Our cohort's cardiac anxiety scores were 34±11. Our cohort's device acceptance (FPAS scores of 58±9) suggests poor device acceptance compared with previously published thresholds, which have been 63 to 67.[21,22] Overall, our cohort reported mild shock anxiety on FSAS with an average total score of 22±9, with 47% demonstrating mild anxiety, 12% moderate anxiety, and 3% severe anxiety.

Clinical Predictors of PROM Scores

Correlations between PROM scores and clinical characteristics are shown in Table 2. Patient age was found to have weak but statistically significant correlations with several of the anxiety-related PROMs, with younger patients having greater anxiety symptom burden. Age had an inverse correlation with HADS-A (R=−0.294, P=0.017), CAQ score (R=−0.374, P=0.002), and FSAS score (R=−0.0354, P=0.004), suggesting greater anxiety among younger patients. Age had a weak but direct correlation with the FPAS, suggesting greater device acceptance among older patients.

Lower left ventricular ejection fraction was associated with reduced physical health self-rating (R=0.317, P=0.010), but not with any of the anxiety or depression PROMs. There were no statistically significant correlations between any of the PROM scores and time since last shock or the total number of ICD shocks.

There were no statistically significant differences in PROM scores comparing patients with primary versus secondary prevention ICDs, with and without a history of sudden cardiac death, with and without prior catheter ablation, and with and without prior ICD shocks.

Individual Item-Level PROM Analysis

Tables 3 through 5 detail the specific items of the 3 cardiac-specific PROMs, and the frequency with which each item was selected as a concern by patients.

FPAS (Table 3) items revealed that a significant portion of patients reported satisfactory knowledge regarding their ICD (94%) and felt safe as a result of their ICD (83%). The majority of patients reported that they would receive an ICD again (80%), and 74%

Table 2. Correlations Between PROM Scores and Clinical Characteristics

	Age	Ejection fraction	Time since last shock	No. of shocks
Physical health status				
Pearson correlation	−0.074	0.317*	0.170	−0.150
Quality of life score				
Pearson correlation	0.161	0.082	0.114	−0.092
Anxiety Symptoms Score				
Pearson correlation	−0.294*	−0.009	−0.045	−0.158
Depression Symptoms Score				
Pearson correlation	−0.117	−0.074	−0.084	−0.080
Cardiac Anxiety Questionnaire Score				
Pearson correlation	−0.374†	−0.221	−0.090	0.045
Florida Patient Acceptance Survey Score				
Pearson correlation	0.364†	0.056	0.231	−0.135
Florida Shock Anxiety Scale Score				
Pearson correlation	−0.354†	−0.207	−0.087	0.167

PROM indicates patient-reported outcome measure.
*Correlation is significant at the P=0.05 level (range, 0.010–0.017).
†Correlation is significant at the P=0.01 level (range, 0.002–0.004).

believed that the device was the best treatment option. However, 39% expressed concerns about resuming physical activity, and only 41% had resumed a normal sex life. Few patients (5%–8%) reported feeling disfigured or less attractive because of the device.

CAQ analysis by item (Table 4) confirmed patients' concerns about physical exertion: 42% reported that they "take it easy as much as possible" and 35% reported that they avoid physical exertion. Nighttime symptoms of anxiety were rare (9%), and patients reported significant confidence in their medical team, with 83% reporting that they "feel safe being around a hospital, physician, or other medical facility" and only 6% reporting that they "worry that doctors do not believe [their] symptoms are real."

Table 3. Florida Patient Acceptance Survey

Item	Mostly or strongly agree	Percentage
Florida Patient Acceptance Survey–positive items		
I am knowledgeable about how the device works and what it does for me	62/66	93.9
The positive benefits of this device outweigh the negatives	58/66	87.9
I know enough about my device	57/66	86.4
I am safer from harm because of my device	55/66	83.3
I would receive this device again	52/65	80.0
My device was my best treatment option	49/66	74.2
I have returned to a full life	36/66	54.5
I am confident about my ability to return to work if I want to	32/63	50.8
I have continued my normal sex life	27/63	40.9
Florida Patient Acceptance Survey–negative items		
I am not able to do things for my family the way I used to	29/66	43.9
I am concerned about resuming my daily physical activities	26/66	39.4
When I think about the device, I avoid doing things I enjoy	12/66	18.2
Thinking about the device makes me depressed	12/66	18.2
I am careful when hugging or kissing my loved ones	10/66	15.2
It is hard for me to function without thinking about my device	6/66	9.1
I feel less attractive because of my device	5/66	7.6
I feel that others see me as disfigured by my device	4/66	6.1
I avoid my usual activities because I feel disfigured by my device	3/66	4.5

Table 4. Cardiac Anxiety Questionnaire

Item	Often or always	Percentage
I feel safe being around a hospital, physician or other medical facility	55/66	83.3
I pay attention to my heart beat	42/66	63.6
I take it easy as much as possible	28/66	42.4
I like to be checked out by a doctor	26/65	40.0
I check my pulse	25/66	37.9
I avoid physical exertion	23/66	34.8
I get frightened	21/65	32.3
I tell my family or friends	21/65	32.3
If tests come out normal, I still worry about my heart	20/66	30.3
I have difficulty concentrating on anything else	19/65	29.2
I can feel my heart in my chest	19/66	28.8
I avoid activities that make my heart beat faster	19/66	28.8
I avoid activities that make me sweat	16/66	24.2
I avoid exercise or other physical work	16/66	24.2
I worry that I may have a heart attack	14/65	21.5
My racing heart wakes me up at night	6/65	9.2
Chest pain/discomfort wakes me up at night	6/66	9.1
I worry that doctors do not believe my symptoms are real	4/66	6.1

Analysis of FSAS revealed that 26% of patients worry that exercise may cause their device to shock them. Eleven percent of patients reported fully avoiding sexual activity because of a concern that their ICD will fire, but only 2% were concerned that the shock would affect a partner they were in physical contact with at that time. The most frequently selected item on FSAS was fear of being alone when the ICD fires and needing help (34%).

DISCUSSION

Assessment of our cohort's PROM data noted that younger age correlated with increased anxiety but no clear association between batteries of VA burden and psychosocial symptoms, suggesting PROMs may be useful to detect these symptoms that would not be predicted by clinical arrhythmia burden. The evaluation of individual PROM items revealed information not immediately demonstrated by total PROM scores.

Overall, our cohort demonstrated a similar prevalence of anxiety (53%) and depression (20%) as reported in other studies of patients with ICD.[22,24] Our cohort's cardiac anxiety (CAQ) scores were 34±11, which is slightly higher than the CAQ scores (mean 30) in 2 prior cohorts of cardiology patients referred to psychologists.[19] As noted, younger age in our cohort demonstrated a statistically significant increase in anxiety (as per HADS-A, CAQ, and FSAS), and poorer ICD device acceptance. Prior studies in ICD recipients have similarly demonstrated increased anxiety in younger patients, although they used different PROMs than ours.[25] A recent study by Ng et al confirmed

Table 5. Florida Shock Anxiety Scale

Item	Most or all of the time	Percentage
I am afraid of being alone when the ICD fires and I need help	22/65	33.8
When I notice my heart beating rapidly, I worry that the ICD will fire	20/64	31.3
It bothers me that I do not know when the ICD will fire	18/64	28.1
I am scared to exercise because it may increase my heart rate and cause my device to fire	17/66	25.8
I have unwanted thoughts of my ICD firing	12/64	18.8
I worry about the ICD firing and creating a scene	8/64	12.5
I do not engage in (ie, I avoid) sexual activities because it may cause my ICD to fire	7/63	11.1
I do not get angry or upset because it may cause my ICD to fire	6/64	9.4
I worry about the ICD not firing sometime when it should	4/64	6.3
I am afraid to touch others for fear I'll shock them if the ICD fires	1/64	1.5

ICD indicates implantable cardioverter-defibrillator.

poorer device acceptance and greater anxiety among younger patients using FPAS (76±15) and FSAS (17±7) scores.[21] It should be noted that our cohort had lower device acceptance (FPAS 58±9) and slightly higher device-related anxiety (FSAS 22±9) than this study, which may be attributable to differences in patient populations (multiple Canadian centers versus one US institution) and more frequent prior ICD shocks (70% in our cohort versus 30% in Ng et al). The increased ICD-related anxiety and decreased device acceptance in younger-aged patients could be attributed to anxiety toward one's future career and life with the addition of an ICD, which yields a greater impact in younger patients, as theorized by Ng et al.[21]

Our study did not demonstrate a difference in PROM scores between patients with primary and secondary prevention ICD, unlike in the DenHeart (Self-Reported Health and Quality of Life at Hospital Discharge From a Heart Centre in Denmark) study, which demonstrated that patients with primary prevention ICDs had worse PROM scores (HADS-D, 12-Item Short Form Survey, Health-Related Quality of Life Questionnaire) than patients with secondary prevention (no difference noted in HADS-A),[26] which may be attributable to heterogenous study designs and methods.[27] For example, the DenHeart study obtained PROMs on discharge from patients after ICD implantation, while our cohort was an ambulatory population with varying time from ICD placement. Furthermore, the DenHeart study included 63% ICD implants for primary prevention compared with only 32% in our cohort.

Interestingly, we also did not note an association between PROM scores and time since last ICD shock or total number of ICD shocks. Other studies have noted a threshold-based response with worsening PROM scores (36-Item Short Form Survey), decreased physical activity, and poor QOL in patients with more ICD shocks.[27–29] We cannot exclude that our small sample size precluded identifying such an association. The fact that many of the common clinical markers of cardiac and arrhythmia disease severity (ICD shocks, ejection fraction, and sudden cardiac death) did not predict the degree of psychosocial symptoms detected by PROMs underscores the importance of routinely using PROM data for psychological evaluation and not only employing clinicians' judgment to assess who may be doing "poorly." Therefore, incorporating these PROMs for patients with VAs during clinical visits can help better understand their QOL and other concerns that may not be conveyed in the usual clinic visit.

Our item-level analysis of cardiac anxiety in our cohort demonstrated vital insight into our patient's sources of anxiety. For example, in our cohort ≈80% of patients felt their ICD devices were the best treatment and would opt to receive them again, but only 51% were confident to return to work and 55% were ready to return to a full life. By assessing these specific concerns, we are better able to address them and create targeted therapy. For instance, 34% of patients reported being concerned if their ICD fired and they were alone, in response to which the members of our VA clinic jointly prepare the patient and their family for ICD shocks by providing a verbal and/or written "shock plan" outlining the appropriate steps to be taken depending on number of ICD shocks received and subsequent symptoms.[30,31] For the 26% of patients who were scared to exercise and be physically active, we institute an exercise program or refer to cardiac rehabilitation to increase their confidence in physical activity. Meta-analysis of 5 randomized controlled trials and 1 nonrandomized trial demonstrated the safety of implementing home-based and supervised aerobic/strength training exercise for patients with reduced left ventricular ejection fraction and ICDs.[32] This study also noted improvement in cardiorespiratory fitness and reduction in frequency of ICD therapy in the exercise group with no exercise-induced ICD shocks. In addition, a recent prospective study of patients referred for cardiac rehabilitation demonstrated improvement in various PROMs along with earlier return to work in those with improved PROMs.[33]

Review of item-level concerns also noted that 41% of patients reported being able to return to sexual activity, which is consistent with other studies noting 47% of patients with an ICD being sexually active 12 months after ICD implantation.[34] The VA clinic can be vital at counseling patients, appropriately allowing them to return to sexual activity once their concerns are addressed.[35,36] By using item-level analysis of PROMs, the clinician is able to address specific patient concerns to improve their overall well-being, which may not be readily observed when reviewing overall PROM scores.

Limitations

This study's cohort sample size was small, which may have led to lack of statistical significance when analyzing clinical predictors of PROMs. In addition, our cohort had a 77% male population with prior data noting poorer PROMs in women.[25,37] We did not perform multiple testing corrections for the multiple correlations tested in Table 2, and thus may inflate our probability of type I error. However, our findings are noteworthy for the surprisingly low number of significant associations between clinical markers of arrhythmia severity and patient's actual psychosocial symptoms as reflected by PROMs, so multiple hypothesis correction would only have accentuated this finding. We did not extract the relationship between time from ICD implantation to study entry, and thus cannot determine whether patients who have had ICDs for a longer period may have improved PROM scores.

Future Directions

As we routinely administer the same battery of PROMs at every visit, we plan to analyze the change in PROM scores over time (and after routine psychological therapy) and investigate the factors that may influence these changes. Identifying predictors of which patients will respond (ie, improved PROMs) to our routine psychology counseling will help us provide recommendations for referral to psychology in clinics in which routine counseling for all VA patients is not available. Finally, the common specific concerns identified in our item-level analysis can be incorporated into the review of systems when seeing these patients in the clinic.

CONCLUSIONS

In a cohort of patients with VA referred for catheter ablation, anxiety (53%) and depression (20%) symptoms were commonly detected by routine PROM administration, and more frequently in younger patients. Return to physical activity, a normal sex life, and employment were the concerns most commonly cited by patients on our analysis of individual PROM items/questions, and clinicians should discuss and elicit these concerns when able.

ARTICLE INFORMATION

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