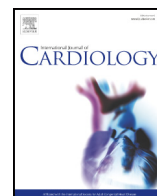




Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: [www.elsevier.com/locate/ijcard](http://www.elsevier.com/locate/ijcard)

## Quality of life metrics in arrhythmogenic right ventricular cardiomyopathy patients: The impact of age, shock and sex

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### ARTICLE INFO

#### Article history:

Received 27 March 2017

Received in revised form 18 July 2017

Accepted 9 August 2017

Available online xxxxx

#### Keywords:

Arrhythmogenic right ventricular cardiomyopathy

Quality of life

Psychology

Cardiomyopathy

### ABSTRACT

**Background:** Arrhythmogenic right ventricular cardiomyopathy (ARVC) patients face many medical and psychosocial challenges. However, the quality of life (QOL) outcomes of these patients remains largely unexplored.

**Methods:** 159 ARVC patients completed a psychosocial survey including the Short Form Health Survey, Florida Shock Anxiety Scale, and Florida Patient Acceptance Survey. These cross-sectional data were used to examine the general and device-specific QOL of these patients compared to normative samples, and to determine the impact of age, shock and sex on these outcome measures.

**Results:** ARVC patients reported lower physical and mental QOL compared to a normative U.S. sample. Compared to an implantable cardioverter defibrillator (ICD) sample, they reported higher mental and physical QOL. Compared to a hypertrophic cardiomyopathy sample, they reported lower physical but higher mental QOL. ARVC patients aged 18–35 reported significantly lower mental QOL than older patients. Male patients with no implantable defibrillator shock history reported significantly higher mental QOL scores than those with shock history. Shock anxiety scores were significantly higher among individuals who had experienced at least one shock. Female ARVC patients reported significantly higher shock anxiety and lower mental QOL compared to male patients.

**Conclusion:** ARVC patients report lower mental and physical QOL than a U.S. normative sample, but report mostly superior QOL compared to relevant cardiac samples. Younger ARVC patients, female patients, and those who have experienced at least one device shock are at risk for psychosocial difficulties, including poorer QOL outcomes.

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### 1. Introduction

Arrhythmogenic right ventricular cardiomyopathy (ARVC) is an inherited cardiomyopathy characterized by the progressive replacement of the myocardium in the right ventricle with fibrofatty tissue that can foster cardiac arrhythmias and heart failure. The condition affects 1 in 2000 to 1 in 5000 Americans [1,2]. The common course of treatment for ARVC is the placement of an implantable cardioverter defibrillator (ICD) to prevent sudden cardiac arrest [3].

ARVC patients may be at risk for psychosocial difficulties due to the adjustments psychologically and behaviorally necessary to limit the impact of the disease. Psychologically, ARVC patients must adjust to the diagnosis and impact of living with a heritable condition [4] and accept the prospects of living with an ICD and the possibilities of ICD shocks [5,6]. Moreover, earlier work has demonstrated a greater potential risk of ICD shocks in ARVC patients, with a 50% to 80% appropriate ICD shock rate in a 3–5 year follow-up period [7].

Behaviorally, strenuous exercise limitations are now recommended based on available evidence of its relationship to disease progression [8,9]. Collectively, the ARVC patient faces challenges that may directly and indirectly impact quality of life (QOL).

Previous work examining the psychosocial impact of ARVC in a small sample found that patients are likely to experience clinically significant anxiety (33%) and depression (9%) and face psychosocial issues with device acceptance [10]. However, the general QOL of this patient population has not been explored. Additionally, while female sex has been identified as a risk factor for poor QOL outcomes in the broader ICD literature [11], sex differences related to QOL have not been found among ARVC patients. The purposes of the current study are to (1) examine the psychosocial impact of ARVC by examining general and device-specific QOL in a large sample and (2) examine the impact of age, ICD shock, and sex on QOL outcomes.

### 2. Materials and methods

#### 2.1. Participants

Study participants were enrolled in the Johns Hopkins ARVC Registry and then recruited through 3 main sources: (1) patients referred to the program for an evaluation or treatment

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of ARVC, (2) individuals contacted the program through the Johns Hopkins- sponsored website [ARVD.com](http://ARVD.com) and indicated they were interested in joining research, and (3) attended the annual ARVC Family Conference.

Participants must have enrolled or re-enrolled in the ARVC Registry between February 2009 and November 2010. Individuals in the registry who met the following criteria were invited to participate in the study: (1) had an ICD for primary or secondary prevention of ventricular tachycardia (2) had a clinical diagnosis of ARVC, (3) could speak English, and (4) were 18 years or older. All subjects gave written informed consent to participate, and all aspects of the study were approved by the Johns Hopkins School of Medicine Institutional Review Board, and subsequently approved by the Medicine Institutional Review Board at East Carolina University.

## 2.2. Measures

### 2.2.1. Medical history variables

De-identified demographic and clinical variables obtained from the Johns Hopkins ARVC Registry included sex, date of birth, ARVC diagnosis, family history, genetic mutation status, and date of and clinical indication for first ICD implant. Those who met family history criteria were given a positive family history indicator, according to the 2010 Revised Task Force Criteria for the diagnosis of ARVC [12,13]. Self-reported history of ICD shock was confirmed through medical records submitted to the ARVC Registry.

### 2.2.2. Device-specific QOL

The *Florida Patient Acceptance Survey* is a valid and reliable 18-item measure used to assess device acceptance [14]. The Florida Patient Acceptance Survey sums to create a total acceptance score, with scores ranging from 0 to 100. Higher scores indicate better acceptance. The Florida Patient Acceptance Survey is an internally consistent (Cronbach's  $\alpha = 0.83$ ) and valid self-report measure [14].

### 2.2.3. Device-specific anxiety

The Florida Shock Anxiety Scale is a reliable and valid measure of shock-related anxiety, was used to measure device-specific anxiety [15]. The 10-item instrument utilizes a five-point Likert scale ranging from 1 (not at all) to 5 (all the time). A total score, ranging from 10 to 50, is summed to measure shock anxiety, with higher scores indicating higher levels of anxiety.

### 2.2.4. General QOL

The Short Form Health Survey is a reliable and valid 12-item questionnaire used to measure physical and mental health from a patient perspective [16]. It can be particularly useful as a generic measure of QOL compared to disease-specific instruments. The items within the Short Form Health Survey are broken down into two summary scores: (1) the Mental Component Summary and (2) the Physical Component Summary. Scores on these two composite summaries range from 0 to 100, with higher scores indicating better QOL.

## 2.3. Procedure

Prior to data collection, participants provided consent and were then given the choice of completing paper questionnaires, providing responses over the telephone, or submitting responses online via Survey Monkey, Inc. software ([www.surveymonkey.com](http://www.surveymonkey.com)).

## 2.4. Data analysis

Descriptive statistics were employed to examine the mental and physical composite scores from the Short Form Health Survey. These scores were then compared to established norms after calculating Cohen's  $d$  effect sizes, and a one-way analysis of variance was performed to examine age-related comparisons.

To examine the impact of shock (i.e., the presence or absence of ICD shock) on general and device-specific QOL, parametric statistics were utilized. Shock history was categorized as a dichotomous variable, as initial analyses breaking shock history into three groups (i.e., 0 shocks, 1–4 shocks, and  $\geq 5$  shocks) found no statistically significant difference in the dependent variables based on this factor. A factorial multiple analysis of variance was used to examine the impact of shock and sex on Mental Component Summary and Physical Component Summary scores (given by the Short Form Health Survey), and Florida Patient Acceptance Survey and Florida Shock Anxiety Scale total scores. Univariate  $F$ -tests were performed to further examine main effects.

## 3. Results

### 3.1. Descriptive analyses

Participants were 159 ARVC patients between the ages of 18 and 80 (mean age of 45.7 years,  $SD = 13.6$ ) who had an ICD. Of note, the sample sizes for analyses vary based on missing data. The majority of participants received ICD implantation due to secondary prevention (59.7%). The sample included a similar number of men and women, with 48.3% male participants.

#### 3.1.1. General QOL

Descriptive statistics were performed to examine the general QOL of ARVC patients according to the Mental Component Summary and Physical Component Summary of the Short Form Health Survey. These results are displayed in Table 1. ARVC patients reported generally favorable physical (Physical Component Summary  $M = 46.5$ ,  $SD = 10.2$ ) and mental summary scores (Mental Component Summary  $M = 48.5$ ,  $SD = 10.2$ ), as the Physical Component Summary and Mental Component Summary represent T-scores with a mean of 50 and a standard deviation of 10 based on U.S. general population sample normative data.

It was hypothesized that Short Form Health Survey scores among ARVC patients would be lower than average U.S. normative scores and similar to normative scores of relevant clinical samples. This hypothesis was generally supported. Compared to the general population, ARVC patients reported lower physical and mental summary scores ( $d = -0.3$ ). Compared to a sample of ICD patients with multiple cardiac etiologies, ARVC patients reported higher physical summary and mental summary scores ( $d = 0.9$  and  $0.3$ , respectively). Compared to hypertrophic cardiomyopathy patients, ARVC patients reported lower physical health scores ( $d = -0.4$ ) and higher mental health scores ( $d = 0.3$ ).

#### 3.1.2. Age-based comparisons

Age-based comparisons were performed after stratifying the sample into three age groups. Separate one-way analyses of variance were performed to explore the impact of age on Mental Component Summary and Physical Component Summary scores of the Short Form Health Survey. Subjects were divided into three groups according to their age (Group 1: 18 to 34; Group 2: 35–54; Group 3: 55 and older). There was a statistically significant difference at the  $p < 0.05$  level in Mental Component Summary scores for the three age groups ( $F(2,142) = 21.6$ ,  $p < 0.0001$ ). A Tukey HSD post-hoc analysis indicated that ARVC patients 18–35 reported significantly lower mental summary scores ( $M = 41.3$ ,  $SD = 10.9$ ) compared to patients aged 35–54 ( $M = 49.3$ ,  $SD = 9.5$ ) and to those 55 or older ( $M = 54.7$ ,  $SD = 6.6$ ). These results are shown in Table 2. There was no evidence that the mean physical summary scores significantly differed between the three age groups.

#### 3.2. $2 \times 2$ factorial multiple analysis of variance results

A  $2 \times 2$  factorial multivariate analysis of variance was conducted to determine the effect of sex and shock on the four dependent variables: mental health-related QOL (as measured by the Mental Component Summary of the Short Form Health Survey), physical health-related QOL (as measured by the Physical Component Summary of the Short Form Health Survey), device acceptance (as measured by the Florida

**Table 1**  
Comparison of SF-12 scores from ARVC sample to relevant samples.

	ARVC		General population			ICD			HCM		
	n	M(SD)	n	M(SD)	$d$	n	M(SD)	$d$	n	M(SD)	$d$
PCS	159	46.5(10.2)	12,998	49.9(9.8)	-0.3	227	37(11)	0.9	56	50.5(9.8)	-0.4
MCS	159	48.5(10.2)	12,998	51.5(9.2)	-0.3	227	45(11)	0.3	56	45.6(12.2)	0.3

ARVC = Arrhythmogenic right ventricular cardiomyopathy; ICD = implantable cardioverter defibrillator; HCM = hypertrophic cardiomyopathy; PCS = Physical Component Summary of the Short Form Health Survey; MCS = Mental Component Summary of the Short Form Health Survey.

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