



Original Article

# Age, Sex, and Remote Monitoring Differences in Device Acceptance for Patients With Implanted Cardioverter Defibrillators in Canada

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## ABSTRACT

**Background:** Implantable cardioverter defibrillator (ICD) acceptance and shock anxiety are issues that clinicians should address to improve quality of life among device recipients. Previous findings have indicated that younger patients experience poorer device adjustment. The purpose of this study was to examine age and ICD-specific quality-of-life outcomes in a large sample of Canadian ICD patients. We tested the hypothesis that patient age is related to device acceptance and shock anxiety in an Alberta (Canada) ICD population.

**Methods:** The Florida Patient Acceptance Survey (FPAS) and Florida Shock Acceptance Survey (FSAS) were completed by ICD patients attending the Cardiac Implantable Electrical Device Clinics in Alberta. The population was dichotomized into those aged  $\leq 65$  years (younger)

## RÉSUMÉ

**Contexte :** L'acceptation d'un défibrillateur cardiovertéur implantable (DCI) et la crainte des chocs de DCI sont des problèmes auxquels les cliniciens devraient s'attaquer pour améliorer la qualité de vie des patients qui sont porteurs d'un DCI. Selon des observations antérieures, les plus jeunes patients ont davantage de mal à s'adapter au dispositif. L'étude avait pour objet l'examen des paramètres de la qualité de vie particuliers à l'âge et au port d'un DCI dans un vaste échantillon de patients canadiens porteurs de ce dispositif. Nous avons testé l'hypothèse voulant que l'âge du patient soit lié à l'acceptation du dispositif et à la crainte des chocs chez des Albertains porteurs d'un DCI.

**Méthodologie :** Les patients des cliniques de l'Alberta (Canada) des dispositifs cardiaques électroniques implantables qui étaient porteurs

The implantable cardioverter defibrillator (ICD) is a well-established therapy for primary and secondary prevention in patients at risk for arrhythmic death.<sup>1,2</sup> There are consistent data demonstrating the effect of ICDs on generic or global health-related quality of life (HRQoL),<sup>3</sup> which is associated with a patient's overall functioning and well-being. However,

patient-reported outcomes, such as ICD device acceptance and shock anxiety, may provide measures that are specific to the ICD population and can be more directly addressed in clinical cardiology settings.

The effects of age on cardiovascular disorders have generally indicated that younger patients manifest poorer HRQoL, compared with older patients.<sup>4</sup> Despite this finding, it remains unclear whether similar differences are present in younger versus older ICD patients. Previous efforts are notable for a high level of heterogeneity, and most studies consisted of relatively small numbers of younger patients.<sup>3,5</sup>

Little is known about the effects of sex, ICD shocks, and remote monitoring (RM) on device acceptance and shock anxiety. The purpose of this study was to examine ICD-specific device acceptance and shock anxiety in a large sample of

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**Ethics Statement:** This research has adhered to the relevant ethical guidelines.

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See page 489 for disclosure information.

and those aged > 65 years (older). Sex, ICD shock history, and remote monitoring use were also examined.

**Results:** Surveys were completed by 126 younger ( $53 \pm 11$  years; 79% male) and 216 older ( $74 \pm 6$  years; 85% male) patients. Younger, compared with older, patients had greater device-related distress ( $P < 0.001$ ) and more body-image concerns ( $P < 0.001$ ), but no differences in return to function or positive appraisal. Younger patients reported lower total device acceptance ( $P = 0.001$ ) and greater total shock anxiety ( $P < 0.001$ ) compared with older patients. **Conclusions:** ICD patients aged  $\leq 65$  years reported poorer device acceptance and greater shock anxiety than older patients. Younger patients may require targeted interventions addressing adjustment to the ICD, and impact of the ICD on body image. Moreover, education about the relatively low probability of shocks may alleviate shock anxiety in younger patients.

Canadian ICD patients. The primary goal was to identify how patient age affects device acceptance and shock anxiety among ICD patients. We tested the hypothesis that younger patients have less device acceptance and greater shock anxiety compared with older patients. The secondary goal was to examine factors such as sex, previous shock history, and RM use on these parameters. We hypothesized that ICD patients who are female, had had prior shocks, or were not using RM would have less device acceptance and greater shock anxiety.

## Methods

### Study design and participants

All patients with an ICD were invited to complete a survey during in-person clinic follow-up at the Cardiac Implantable Electrical Device Clinics in Southern Alberta (Calgary, Red Deer, and Lethbridge) and Northern Alberta (Edmonton), between December 2015 and June 2017. Completed surveys were returned to study personnel either in person on the day of follow-up or via mail. No additional patient-prompting follow-up occurred. A master list of patients who gave participation consent was generated to ensure that there were no duplicate entries from the same individual. Incapacitated patients without a surrogate decision maker were excluded. Participation in the study was voluntary, and no incentive or compensation was provided.

The study was approved by the Calgary Conjoint Health Research Ethics Board, and by the local ethics boards for each site. Written informed consent was obtained for each survey participant.

### Measures

The survey included questions regarding general demographics and device information. A global health visual analogue scale (VAS) from the EQ-5D (from EuroQol

d'un DCI ont rempli les questionnaires FPAS (*Florida Patient Acceptance Survey*) et FSAS (*Florida Shock Acceptance Survey*). Les patients ont été partagés en deux groupes selon leur âge, soit ceux de 65 ans et moins (plus jeunes patients) et ceux de plus de 65 ans (patients âgés). Nous avons aussi examiné les facteurs suivants : sexe, chocs de DCI antérieurs et utilisation d'une télésurveillance.

**Résultats :** Les questionnaires ont été remplis par 126 plus jeunes patients ( $53 \pm 11$  ans; 79 % d'hommes) et 216 patients âgés ( $74 \pm 6$  ans; 85 % d'hommes). Chez les plus jeunes patients, par rapport aux patients âgés, la détresse causée par le dispositif était plus grande ( $p < 0,001$ ) et il y avait davantage de préoccupations liées à l'image corporelle ( $p < 0001$ ), mais il n'y avait pas de différences pour ce qui est de la reprise des activités ou de l'évaluation positive du dispositif. Chez les plus jeunes patients, l'acceptation totale du dispositif était moindre ( $p = 0,001$ ) et la crainte des chocs était plus grande ( $p < 0,001$ ) que chez les patients âgés.

**Conclusions :** Chez les porteurs d'un DCI de 65 ans et moins, le dispositif était moins bien accepté, et la crainte des chocs était plus grande que chez les patients âgés. Chez les plus jeunes patients, des interventions ciblées axées sur l'adaptation au DCI et les répercussions du DCI sur l'image corporelle pourraient être nécessaires. De plus, l'éducation à propos de la probabilité relativement faible de subir des chocs pourrait réduire cette crainte chez les plus jeunes patients.

Group, 5 dimensions) was included to measure HRQoL.<sup>6</sup> Additionally, the Florida Patient Acceptance Survey (FPAS)<sup>7-9</sup> and the Florida Shock Anxiety Scale (FSAS)<sup>10,11</sup> were used to measure device-specific patient outcomes.

**Demographics.** Information on sex, age, prior ICD shock, RM use, marital status, and employment status were self-reported by patients.

Data on ICD indication, cardiac resynchronization therapy devices, and number of prior shocks were retrieved from patient medical databases for patients attending clinics in Southern Alberta.

**Global health VAS.** Global health was reported using a vertical "health thermometer" scale, a part of the EQ-5D, with anchors at 0 (worst imaginable health state) to 100 (best imaginable health state). The VAS was added after enrollment was underway, so 189 participants (55%) had missing global health scores.

**FPAS.** Patient acceptance is defined as "the psychological accommodation and understanding of the advantages and disadvantages of the device, the recommendation of the device to others, and the derivation of benefit in terms of biomedical, psychological, and social functioning."<sup>7</sup>

The FPAS is a well-validated measure of patient device acceptance. The survey consists of 18 items rated on a 5-point Likert scale ranging from 0 (strongly disagree) to 5 (strongly agree).<sup>8,9</sup> Of those items, 15 contribute to generating a total score and 4 subscales, which include return-to-function, device-related distress, positive appraisal, and body-image concerns. All scores are linearly converted into a score between 0 and 100, representing a continuum of acceptance. Higher scores in return-to-function and positive appraisal indicate greater acceptance, whereas higher scores in device-related distress and

body-image concerns indicate less acceptance. There is currently no validated cutoff for categorizing device acceptance into poor and good; however, some studies have identified “poor acceptance” as the lowest tertile of the FPAS total scores in their overall study cohorts.<sup>9,12</sup> In this study, the cutoff for poor acceptance (lowest tertile) was an FPAS total score of < 63. The mean score of all completed questions in each scale for that individual was used in the case of missing data.<sup>13</sup>

**FSAS.** The FSAS is used to measure shock-related anxiety in patients with ICD.<sup>10</sup> It consists of 10 items rated on a 5-point Likert scale ranging from 1 (not at all) to 5 (all of the time). In a clinical setting, a rating of 3 or higher may warrant attention for further discussion regarding the specific concern.<sup>11</sup> This generates a total score (sum) ranging from 10 to 50, and 2 subscores, the mean consequence score and mean triggers score. The first subscore is associated with fear and anxiety related to the consequences of shock, whereas the second is associated with fear or anxiety about triggering a shock. Higher scores represent greater levels of shock anxiety. Mean score of all completed questions in each scale for an individual were used in the case of missing data.<sup>13</sup>

### Statistical analysis

Demographic information is expressed as proportions for categorical data, and mean ± standard deviation for continuous variables. Categorical demographic variables were compared using the  $\chi^2$  test, or Fisher’s exact test if the minimum expected count assumptions were violated. Continuous variables (demographic, FPAS, and FSAS) were assessed using the Student *t* test, and verified with the Mann-Whitney *U* test.

Differences in FPAS and FSAS scores were examined according to age, sex, ICD shock history, and RM use. Individuals with no FPAS and FSAS data (*n* = 7) were excluded from the analyses. Individuals with missing demographic information were not stratified into the corresponding groups, and were excluded from the analyses. One individual had a subcutaneous ICD and was excluded from the analyses.

Patients were dichotomized by age into younger (aged ≤ 65 years) and older (aged > 65 years) groups. The age cutoff was determined based on the typical retirement age in Canada. Age-group categories (< 50 years, 50–59 years, 60–69 years, and ≥ 70 years) were also created to further evaluate the relationship of age to FPAS and FSAS scores. These age categories were compared using a 1-way analysis of variance.

All *P* values were 2-tailed, and statistical significance was set at *P* ≤ 0.05. All analyses were performed using STATA version 14 statistical software (StataCorp, College Station, TX).

## Results

### Demographics

A total of 350 surveys were received. Of these, 281 (80%) were from 2 large urban centres that comprise 74% of the Alberta population. This included 204 (58%) from Calgary and 77 (22%) from Edmonton. An additional 25 (7%) surveys from Lethbridge, and 44 (13%) from Red Deer, were received (Fig. 1). There were no differences in FPAS and FSAS outcomes between patients in the large urban centres (Calgary and Edmonton) and those in the smaller centres.

Participants from Southern Alberta contributed to 78% of all surveys received. Individuals who participated in the study represent approximately 12% of all ICD patients attending clinics in Southern Alberta (273 surveys from 2200 patients).

Baseline demographic data are summarized in Table 1. Among the total ICD cohort, 82% were male, and the mean age was 66 ± 13 years. Prior shock was experienced by 27% of ICD patients, and 75% were using RM. The mean time from initial ICD implantation to survey participation was 4.3 ± 4.6 years. In Southern Alberta, 67% of ICDs were implanted for primary prevention, and 24% of patients received a cardiac resynchronization therapy (CRT)-ICD. Factors such as ICD indication and the ability to work or drive did not have a significant impact on total FPAS and FSAS scores.

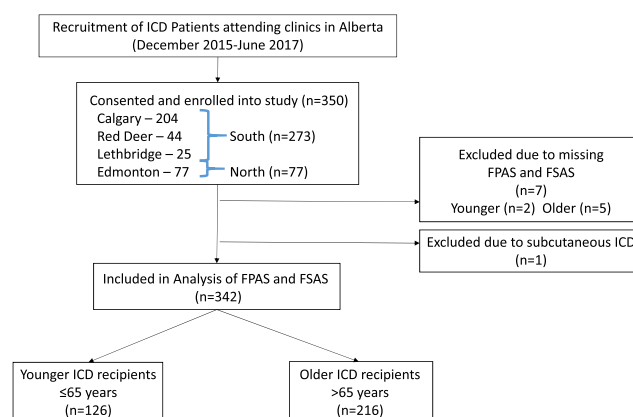
### Age and HRQoL

There were no significant differences in global HRQoL between younger and older patients (69 ± 18 vs 71 ± 18; *P* = 0.8).

Younger patients reported greater FPAS device-related distress (25 ± 20 vs 15 ± 19; *P* < 0.001) and more FPAS body-image concerns (22 ± 25 vs 8 ± 18; *P* < 0.001), compared with older patients (Table 2). Younger patients also reported less FPAS total device acceptance compared with older patients (76 ± 15 vs 81 ± 15; *P* = 0.001). There were no significant differences found between the 2 groups in FPAS return-to-function or FPAS positive appraisal (Table 2). Poor device acceptance was reported by 20% of younger patients, compared with 10% of older patients (*P* = 0.004).

Further, younger patients reported greater overall shock anxiety in the FSAS compared with older patients (17 ± 7 vs 14 ± 5; *P* < 0.001). Younger patients also reported higher scores on the FSAS mean consequence scale (1.6 ± 0.7 vs 1.3 ± 0.5; *P* < 0.001) and FSAS mean triggers scale (1.7 ± 0.7 vs 1.5 ± 0.7; *P* = 0.004) vs older patients.

**Age categories.** When patients were categorized into 4 age categories, there were significant differences in the measures of FPAS device-related distress (*P* < 0.001), FPAS body-image concerns (*P* < 0.001), and FPAS total device acceptance



**Figure 1.** Flow diagram identifying ICD patients participating in the study. ICD, implantable cardioverter defibrillator; FPAS, Florida Patient Acceptance Survey; FSAS, Florida Shock Anxiety Scale.

**Table 1. Demographic information for ICD patients**

Characteristic	Total (n = 350)	Aged ≤ 65 years (n = 126)	Aged > 65 years (n = 216)	P value
Age at enrollment, mean ± SD	66 ± 13	53 ± 11	74 ± 6	< 0.001
Male sex	82	79	85	0.15
Previous cardiac arrest	40	40	40	0.88
Previous shock	27	30	25	0.29
Remote monitoring use	75	74	76	0.66
Primary prevention ICD	67	42	58	0.56
Currently working	34	54	16	< 0.001
Married	69	64	71	0.18
Driving	88	87	88	0.89

Values are %, unless otherwise indicated. ICD, implantable cardioverter defibrillator; SD, standard deviation.

( $P = 0.02$ ) among the categories (Table 3). However, no differences were observed between age groups for FPAS return-to-function ( $P = 0.095$ ) or FPAS positive appraisal ( $P = 0.98$ ).

Patients in the oldest age category ( $\geq 70$  years) reported the least FPAS device-related distress and FPAS body-image concerns, as well as the greatest FPAS device acceptance. In contrast, the greatest differences in the scores consistently occurred in the younger age categories.

There were also significant differences between age categories in reported FSAS total shock anxiety ( $P < 0.001$ ), FSAS mean consequence ( $P < 0.001$ ), and FSAS mean triggers ( $P = 0.011$ ). Similarly, the oldest patients ( $\geq 70$  years) reported the least shock anxiety.

### Sex and HRQoL

As seen in Table 4, male patients reported lower FPAS return-to-function scores compared with female patients ( $64 \pm 26$  vs  $74 \pm 24$ ;  $P = 0.006$ ). There were no differences between male and female patients in FPAS device-related distress, FPAS positive appraisal, FPAS body-image concerns, or FPAS total device acceptance. Male and female patients were not different in FSAS mean consequence ( $1.4 \pm 0.6$  vs  $1.5 \pm 0.6$ ;  $P = 0.9$ ), FSAS mean triggers ( $1.5 \pm 0.7$  vs  $1.6 \pm 0.7$ ;  $P = 0.7$ ), or FSAS total shock anxiety ( $15 \pm 6$  vs  $16 \pm 6$ ;  $P = 0.9$ ).

Younger male patients reported more FPAS body-image concerns ( $20 \pm 23$  vs  $9 \pm 18$ ,  $P < 0.001$ ) and greater FPAS device-related distress ( $26 \pm 21$  vs  $15 \pm 19$ ;  $P < 0.001$ ) compared with older male patients (Supplemental Table S1). Younger female patients also reported more FPAS body-image concerns ( $26 \pm 32$  vs  $4 \pm 13$ ;  $P < 0.001$ ) and greater FPAS

device-related distress ( $22 \pm 17$  vs  $13 \pm 18$ ;  $P = 0.02$ ) compared with older female patients.

### RM and HRQoL

A response was provided by 305 of the 350 ICD patients regarding the use of RM for follow-up. Patients using RM ( $n = 228$ ; 75%) reported greater FPAS positive appraisal ( $88 \pm 17$  vs  $77 \pm 27$ ;  $P < 0.001$ ) and FPAS total device acceptance ( $81 \pm 14$  vs  $75 \pm 18$ ;  $P = 0.011$ ) compared with those who do not use RM (Table 5). However, no significant differences were observed with respect to FPAS return-to-function, FPAS device-related distress, or FPAS body-image concerns. FSAS total shock anxiety and global HRQoL were not different between the 2 groups.

When further stratified by age, younger ICD patients using RM reported greater FPAS device-related stress ( $24 \pm 20$  vs  $13 \pm 18$ ;  $P < 0.001$ ), FPAS body-image concerns ( $22 \pm 25$  vs  $6 \pm 14$ ;  $P < 0.001$ ), and FPAS total device acceptance ( $76 \pm 14$  vs  $83 \pm 13$ ;  $P < 0.001$ ) compared with older ICD patients using RM. Younger ICD patients using RM were not different in any FPAS measures compared with younger ICD patients not using RM. There were also no significant differences in any FPAS measures between older ICD patients using RM and older ICD patients not using RM.

### Previous shock and HRQoL

Among Southern Alberta patients who received prior ICD shocks, 29% had 1 shock, 58% had 2–10 shocks, and 13% had >10 shocks. One patient had a history of electrical storm, and 6% of patients had received an inappropriate shock. The mean time from the most recent shock to survey participation was  $29 \pm 42$  months.

**Table 2. FPAS and FSAS scores of young and old ICD patients**

Measure	Young (age ≤ 65 years) (n = 126)	Old (aged > 65 years) (n = 216)	P value
FPAS			
Return-to-function	66 ± 26	65 ± 25	0.91
Device-related distress	25 ± 20	15 ± 19	< 0.001
Positive appraisal	84 ± 20	85 ± 22	0.66
Body-image concerns	22 ± 25	8 ± 18	< 0.001
Total acceptance	76 ± 15	81 ± 15	0.001
FSAS			
Total shock anxiety	17 ± 7	14 ± 5	< 0.001
Mean consequence	1.6 ± 0.7	1.3 ± 0.5	< 0.001
Mean triggers	1.7 ± 0.7	1.5 ± 0.7	0.004

FPAS scores range from 0 to 100. Higher scores in return-to-function and positive appraisal indicate greater acceptance, whereas higher scores in device-related distress and body-image concerns indicate less acceptance. ICD, implantable cardioverter defibrillator; FPAS, Florida Patient Acceptance Survey; FSAS, Florida Shock Anxiety Scale.

**Table 3. FPAS and FSAS scores of ICD patients grouped by age in decades**

Measure	Aged < 50 years (n = 37)	Aged 50-59 years (n = 43)	Aged 60-69 years (n = 104)	Aged ≥ 70 years (n = 158)	P value
<b>FPAS</b>					
Return-to-function	74 ± 22	61 ± 29	63 ± 25	67 ± 25	0.095
Device-related distress	27 ± 20	28 ± 21	16 ± 17	16 ± 20	< 0.001
Positive appraisal	86 ± 16	85 ± 17	85 ± 23	84 ± 43	0.98
Body-image concerns	29 ± 27	22 ± 28	13 ± 20	7 ± 16	< 0.001
Total acceptance	76 ± 16	73 ± 16	79 ± 13	81 ± 16	0.020
<b>FSAS</b>					
Total shock anxiety	17 ± 8	18 ± 7	15 ± 5	13 ± 4	< 0.001
Mean consequence	1.7 ± 0.8	1.7 ± 0.7	1.4 ± 0.6	1.3 ± 0.4	< 0.001
Mean triggers	1.6 ± 0.7	1.8 ± 0.9	1.5 ± 0.7	1.4 ± 0.7	0.011

ICD, implantable cardioverter defibrillator; FPAS, Florida Patient Acceptance Survey; FSAS, Florida Shock Anxiety Scale.

For patients with prior shocks, there were no differences in global HRQoL compared with patients with no previous shock (69 ± 17 vs 73 ± 17; *P* = 0.1). There were also no significant differences in any of the FPAS subscores or total scores. Patients with prior shocks reported higher FSAS scores in the mean consequences scale (1.6 ± 0.7 vs 1.3 ± 0.5; *P* < 0.001) and mean triggers scale (1.7 ± 0.8 vs 1.4 ± 0.6; *P* = 0.006), and greater total shock anxiety (16.8 ± 6.8 vs 13.7 ± 4.9; *P* < 0.001) compared with patients with no previous shock.

Stratified by age, younger patients with prior shocks reported greater FPAS device-related distress (24 ± 20 vs 14 ± 16; *P* = 0.004), more FPAS body-image concerns (22 ± 28 vs 7 ± 14; *P* = 0.001), and greater total shock anxiety (20 ± 8 vs 15 ± 5; *P* = 0.001) compared with older patients with prior shocks (Supplemental Table S2). Younger patients with no prior shocks also reported greater device-related distress (25 ± 21 vs 14 ± 19; *P* < 0.001), more body-image concerns (21 ± 24 vs 9 ± 19; *P* < 0.001), and greater total shock anxiety (16 ± 6 vs 13 ± 4; *P* < 0.001) compared with older patients with no prior shocks.

## Discussion

### Age and device-related outcomes

In this large, population-based study, we found that younger ICD patients have less device acceptance, and they report greater device-related distress, more body-image concerns, and higher shock anxiety compared with older patients. The effect size was small but significant.<sup>14</sup> Further,

although shock anxiety was greater in younger patients, both groups reported only mild shock anxiety overall.<sup>15,16</sup> These results are consistent with previous findings, which have also indicated substantially greater device-related distress, more body-image concerns, and higher shock anxiety among younger ICD patients with underlying disease and primary prevention indication.<sup>12,16–18</sup> Findings from the current study provide further confirmation of the ICD patient experience, by using the same measurement tools to examine a larger group of individuals from both urban and other parts of Canada.

Previous studies have also suggested that younger ICD patients experience significant psychosocial and lifestyle adjustment issues following implantation, and that these problems last longer and are different from those experienced by older patients.<sup>5,19–21</sup> These studies, however, consisted of small sample sizes and focused primarily on young patients who were aged < 50 years.

Younger patients may report poorer outcomes than older patients because of the rapid and unexpected onset of an “age-inappropriate” illness.<sup>22</sup> Body-image concerns of younger patients may arise because of the scar associated with implantation in a highly visible area, and/or the size of the ICD under the skin. It is possible that younger patients are more sensitive to these issues due to device-related stigma and comparisons with other individuals in their age group, leading to increased social isolation and lowered self-esteem.<sup>5</sup> Additionally, younger patients may be adapting to living with a device at a more critical life stage.<sup>22</sup> For example, having an ICD and/or experiencing shocks may divert attention away from careers, hobbies, or family, which can also contribute to distress. The older patients in our study were individuals of retirement age, and therefore, many of the factors contributing to greater device-related distress in younger patients may not be relevant.

### Effects of the health care system

Many prior studies on device acceptance and shock anxiety have involved patients living in the United States, where health care coverage for most individuals is based on private insurance plans, which potentially introduces a level of financial stress on younger patients (below Medicare age) who undergo ICD implantation. The results of this study, involving Canadians living with universal health care, show that poorer outcomes persist in younger patients despite a

**Table 4. FPAS and FSAS scores of male and female ICD patients**

Measure	Male (n = 280)	Female (n = 59)	P value
<b>FPAS</b>			
Return-to-function	64 ± 26	74 ± 24	0.006
Device-related distress	19 ± 20	17 ± 18	0.27
Positive appraisal	84 ± 21	87 ± 21	0.84
Body-image concerns	13 ± 21	14 ± 26	0.64
Total acceptance	78 ± 15	82 ± 14	0.079
<b>FSAS</b>			
Total shock anxiety	15 ± 6	16 ± 6	0.86
Mean consequence	1.4 ± 0.6	1.5 ± 0.6	0.92
Mean triggers	1.5 ± 0.7	1.6 ± 0.7	0.71

ICD, implantable cardioverter defibrillator; FPAS, Florida Patient Acceptance Survey; FSAS, Florida Shock Anxiety Scale.

**Table 5. FPAS and FSAS scores of remote monitoring vs no remote monitoring**

Measure	No remote monitoring (n = 76)	Remote monitoring (n = 228)	P value
<b>FPAS</b>			
Return-to-function	65 ± 26	66 ± 25	0.59
Device-related distress	22 ± 21	17 ± 20	0.091
Positive appraisal	77 ± 27	88 ± 17	< 0.001
Body-image concerns	16 ± 24	12 ± 20	0.098
Total acceptance	75 ± 18	81 ± 14	0.011
<b>FSAS</b>			
Total shock anxiety	16 ± 7	15 ± 5	0.14
Mean consequence	1.5 ± 0.7	1.4 ± 0.5	0.088
Mean triggers	1.6 ± 0.7	1.5 ± 0.7	0.15

FPAS, Florida Patient Acceptance Survey; FSAS, Florida Shock Anxiety Scale.

public health care system, suggesting that a lack of adequate health care coverage is not responsible for these poorer outcomes in a non-Medicare-age population.

### Sex and device-related outcomes

Although one might expect sex-differences, our findings indicate that male and female patients did not report significant differences in overall device acceptance. In the FPAS subscales, females reported greater return-to-function, but no other differences were observed. These results are consistent with findings from a previous study that observed no sex differences in device acceptance.<sup>23</sup> Despite each study having a relatively large sample size, there were significantly fewer females than males in each study. Future studies could benefit from a larger female representation.

### RM and device-related outcomes

RM among ICD patients has substantially increased over the years. Although most patients perceive RM as an improvement of care,<sup>24–26</sup> a subset of patients maintain a preference for face-to-face visits.<sup>24</sup> A previous study observed no significant differences in device acceptance between patients who preferred RM compared with patients who preferred in-clinic follow-up.<sup>24</sup> The current study found that patients who use RM report greater total device acceptance and positive appraisal compared with those who do not, but no differences were seen in return-to-function, device-related distress, body-image concerns, or shock anxiety. These findings suggest that RM may improve select aspects of patient acceptance, and that this may occur regardless of patient preference for follow-up. It is also possible that patients who are able to conform to RM are different from those who are unable or unwilling to use RM. Future studies would benefit from identifying possible ways in which differences between these groups relate to differences in device acceptance. Future studies would have to be randomized to truly tease out these issues.

### Clinical implications

Patient-reported outcomes, such as device acceptance and shock anxiety, provide clinicians with actionable information to improve and address psychological distress and impaired quality of life. It can instigate targeted interventions for specific groups who are at a higher risk of experiencing poorer outcomes. For example, this may occur in the form of targeted support groups and psychosocial therapies (both online<sup>27,28</sup>

and in person), and increased patient education before and after implantation. Moreover, the use of patient-facing websites or social media outlets, to disseminate information and provide a platform for discussion, may be increasingly beneficial for younger patients.

### Study limitations

A main limitation of the study is that the data were collected using subjective, self-reported measures of HRQoL, device acceptance, and shock anxiety. These measures may be open to bias and misinterpretation. Moreover, patients self-selected to participate in the survey, and surveys were received from a small proportion of patients attending the clinics. It is therefore possible that these patients are not fully representative of all individuals with ICDs. There could have been a nonresponse bias associated with missing data, particularly for survey questions with sensitive content. In addition, the issue of minimally clinically important differences has not been settled for the FPAS and FSAS, but the absolute magnitude of differences between scores in this study suggests that they were likely clinically meaningful differences. Future research will need to continue to refine that aspect of measurement.

Potential confounders, such as cardiac etiology, non-cardiac-related conditions, and history of depression, anxiety, or mental health disorders were also not collected for this study. Individual psychological predisposition and/or previous psychological counselling, psychotherapy, or anti-anxiety drug therapy may have an influence on device acceptance postimplantation. Future studies would benefit from the inclusion and detailed discussion of these confounding variables. Finally, there were no pre-implant HRQoL data collected for comparison. If available, these data would further strengthen findings on the impact of device implantation on patients.

### Conclusions

Younger ICD patients report less device acceptance and greater shock anxiety compared with older patients. Younger patients may therefore benefit from targeted interventions and educational approaches addressing these specific device-related outcomes, which may also help to increase their overall quality of life. Future studies may add to these findings by examining changes in device-related outcomes over time in this patient population.

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## References

1. Moss AJ, Hall WJ, Cannom DS, et al. Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. Multicenter Automatic Defibrillator Implantation Trial Investigators. *N Engl J Med* 1996;335:1933-40.
2. Connolly SJ, Gent M, Roberts RS, et al. Canadian implantable defibrillator study (CIDS): a randomized trial of the implantable cardioverter defibrillator against amiodarone. *Circulation* 2000;101:1297-302.
3. Tomzik J, Koltermann KC, Zabel M, Willich SN, Reinhold T. Quality of life in patients with an implantable cardioverter defibrillator: a systematic review. *Front Cardiovasc Med* 2015;2:34.
4. Baert A, De Smedt D, De Sutter J, et al. Factors associated with health-related quality of life in stable ambulatory congestive heart failure patients: Systematic review. *Eur J Prev Cardiol* 2018;25:472-81.
5. Sears SF Jr, Burns JL, Handberg E, Sotile WM, Conti JB. Young at heart: understanding the unique psychosocial adjustment of young implantable cardioverter defibrillator recipients. *Pacing Clin Electrophysiol* 2001;24:1113-7.
6. Testa MA, Simonson DC. Assessment of quality-of-life outcomes. *N Engl J Med* 1996;334:835-40.
7. Burns JL, Serber ER, Keim S, Sears SF. Measuring patient acceptance of implantable cardiac device therapy: initial psychometric investigation of the Florida Patient Acceptance Survey. *J Cardiovasc Electrophysiol* 2005;16:384-90.
8. Pedersen SS, Spindler H, Johansen JB, Mortensen PT, Sears SF. Correlates of patient acceptance of the cardioverter defibrillator: cross-validation of the Florida Patient Acceptance Survey in Danish patients. *Pacing Clin Electrophysiol* 2008;31:1168-77.
9. Versteeg H, Starrenburg A, Denollet J, et al. Monitoring device acceptance in implantable cardioverter defibrillator patients using the Florida Patient Acceptance Survey. *Pacing Clin Electrophysiol* 2012;35:283-93.
10. Ford J, Finch JF, Woodrow LK, et al. The Florida Shock Anxiety Scale (FSAS) for patients with implantable cardioverter defibrillators: testing factor structure, reliability, and validity of a previously established measure. *Pacing Clin Electrophysiol* 2012;35:1146-53.
11. Kuhl EA, Dixit NK, Walker RL, Conti JB, Sears SF. Measurement of patient fears about implantable cardioverter defibrillator shock: an initial evaluation of the Florida Shock Anxiety Scale. *Pacing Clin Electrophysiol* 2006;29:614-8.
12. Bedair R, Babu-Narayan SV, Dimopoulos K, et al. Acceptance and psychological impact of implantable defibrillators amongst adults with congenital heart disease. *Int J Cardiol* 2015;181:218-24.
13. Habibovic M, Denollet J, Cuijpers P, et al. E-health to manage distress in patients with an implantable cardioverter-defibrillator: primary results of the WEBCARE trial. *Psychosom Med* 2014;76:593-602.
14. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. 2nd ed. Hillsdale, NJ: Erlbaum, 1988.
15. Morken IM, Isaksen K, Karlsen B, et al. Shock anxiety among implantable cardioverter defibrillator recipients with recent tachyarrhythmia. *Pacing Clin Electrophysiol* 2012;35:1369-76.
16. Tripp C, Huber NL, Kuhl EA, Sears SF. Measuring ICD shock anxiety: status update on the Florida shock anxiety scale after over a decade of use. *Pacing Clin Electrophysiol* 2019;42:1294-301.
17. James CA, Tichnell C, Murray B, et al. General and disease-specific psychosocial adjustment in patients with arrhythmogenic right ventricular dysplasia/cardiomyopathy with implantable cardioverter defibrillators: a large cohort study. *Circ Cardiovasc Genet* 2012;5:18-24.
18. Carroll SL, Markle-Reid M, Ciliska D, Connolly SJ, Arthur HM. Age and mental health predict early device-specific quality of life in patients receiving prophylactic implantable defibrillators. *Can J Cardiol* 2012;28:502-7.
19. Dubin AM, Batsford WP, Lewis RJ, Rosenfeld LE. Quality-of-life in patients receiving implantable cardioverter defibrillators at or before age 40. *Pacing Clin Electrophysiol* 1996;19:1555-9.
20. Vitale MB, Funk M. Quality of life in younger persons with an implantable cardioverter defibrillator. *Dimens Crit Care Nurs* 1995;14:100-11.
21. Sears SF, Todaro JF, Urizar G, et al. Assessing the psychosocial impact of the ICD: a national survey of implantable cardioverter defibrillator health care providers. *Pacing Clin Electrophysiol* 2000;23:939-45.
22. Sears SF, Matchett M, Conti JB. Effective management of ICD patient psychosocial issues and patient critical events. *J Cardiovasc Electrophysiol* 2009;20:1297-304.
23. Spindler H, Johansen JB, Andersen K, Mortensen P, Pedersen SS. Gender differences in anxiety and concerns about the cardioverter defibrillator. *Pacing Clin Electrophysiol* 2009;32:614-21.
24. Timmermans I, Meine M, Szendey I, et al. Remote monitoring of implantable cardioverter defibrillators: patient experiences and preferences for follow-up. *Pacing Clin Electrophysiol* 2019;42:120-9.
25. Ricci RP, Morichelli L, Quarta L, et al. Long-term patient acceptance of and satisfaction with implanted device remote monitoring. *Europace* 2010;12:674-9.
26. Morichelli L, Porfili A, Quarta L, Sassi A, Ricci RP. Implantable cardioverter defibrillator remote monitoring is well accepted and easy to use during long-term follow-up. *J Interv Card Electrophysiol* 2014;41:203-9.
27. Sears SF, Ford J. Seeking innovation in the delivery of psychosocial care for ICD patients. *Eur Heart J* 2020;41:1212-4.
28. Ford J, Littleton H, Lutes L, et al. Evaluation of an Internet-based intervention for ICD patients with elevated symptoms of posttraumatic stress disorder. *Pacing Clin Electrophysiol* 2019;42:521-9.

## Supplementary Material

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