Female-Specific Education, Management, and Lifestyle Enhancement for Implantable Cardioverter Defibrillator Patients: The FEMALE-ICD Study

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Background: Significant rates of psychological distress occur in implantable cardioverter defibrillator (ICD) patients. Research has demonstrated that women are particularly at risk for developing distress and warrant psychosocial attention. The major objectives were to implement and test the effectiveness of a female-specific psychosocial group intervention on disease-specific quality of life outcomes in outpatient female ICD recipients versus a wait-list control group.

Method: Twenty-nine women were recruited for the study. Fourteen women were randomized to the intervention group and participated in a psychosocial intervention focused on female-specific issues; 15 were randomized to the wait-list control group. All women completed individual psychological batteries at baseline and at 1-month follow-up measuring shock anxiety and device acceptance.

Results: Pre-post measures of shock anxiety demonstrated a significant time by group interaction effect with the intervention group having a significantly greater decrease (Pillai’s trace = 5.58, P = 0.026). A significant interaction effect (Pillai’s trace = 5.05, P = 0.046) was found, such that women under the age of 50 experienced greater reduction in shock anxiety than their middle-aged cohorts. Pre-post measures of device acceptance revealed a significant time by group interaction effect with the intervention group having significantly greater increases (Pillai’s trace = 5.80, P = 0.023).

Conclusions: Structured interventions for female ICD patients involving ICD-specific education, cognitive behavioral therapy strategies, and group social support provide improvements in shock anxiety and device acceptance at 1-month re-assessment. Young women appear to be an at-risk subgroup of this population and may experience more benefit from psychosocial treatment targeting device-specific concerns. (PACE 2010; 1–10)

implantable cardioverter defibrillator, women, psychosocial intervention, anxiety, device acceptance

Introduction

The implantable cardioverter defibrillator (ICD) is the treatment modality of choice for patients at risk for sudden cardiac death (SCD) and has proved superior to medication alone in large-scale trials.1–6 Despite the success of the ICD in preventing premature mortality in at-risk patients, the psychological effects of living with an ICD can be considerable, with estimates of clinical levels of anxiety and depression at 13–38% and 9–15%, respectively.7 Quality of life (QOL) research has revealed that ICD recipients report the same or better levels of QOL, compared to patients treated with anti-arrhythmics alone.8,9 However, ICD patients also experience concerns with the potential for shock,10 their potential mortality,11 how the device interferes with socialization,9 and concerns with sexual functioning.9 Specific at-risk groups of ICD recipients have been identified and include patients who are female, under the age of 50, and those with a history of shock.12 While the unequivocal impact of ICD implantation on these groups
Women experience a higher incidence of depression and anxiety after myocardial infarction (MI), stent implantation, or congestive heart failure (CHF), in comparison with males.15,20–24 Which presents a considerable risk of poorer health outcomes for females.25–26 The available research suggests that women are highly at risk for the development of distress after ICD implantation,12,16,19 possibly due to body satisfaction issues, sexuality, femininity, and socialization.29,30 Our recent research with a multi-site, international sample of ICD patients31 (N = 88) showed that young women (under the age of 50) reported significantly higher mean shock anxiety, death anxiety, and body image concerns than their older-aged cohorts. Additional studies have consistently demonstrated that female ICD patients experience higher levels of anxiety and depressive symptoms, worse functional outcomes, and more ICD-related concerns.32–34

Recent research indicates that ICD patients who receive shocks experience more depression and anxiety and have poorer adjustment to the device than patients who receive no shocks.35,36 Shock anxiety, the fear of ICD shock that may result in increased anxiety and avoidance behaviors,37 has emerged as a construct of interest, both in research and in clinical settings, particularly with regards to QOL. Results from the SCD-HeFT2 trial (N = 2,521) indicated that the ICD group had significantly improved self-reported QOL both 3 and 12 months after implantation versus patients treated with amiodarone alone.38 However, there were no QOL differences between groups at 30 months postimplantation. In general, patients who receive shocks after implantation generally report decreased QOL.10,39 However, the effect of shock on QOL may be less consistent when the duration of time between the occurrence of a shock and the measurement of QOL is conducted. For example, in the SCD-HeFT trial, effects of shock were particularly notable across dimensions if the shock had occurred closely to time of QOL measurement (i.e., within 30 days of the sampling).38 An alternative interpretation may be that the fear of a shock is more impacting than the actual shock. Even in the minority of ICD patients who do not experience shocks, shock anxiety may result in increased avoidance behaviors and a perceived limitation in performing everyday activities.12

More generally, device acceptance refers to the psychological accommodation and understanding of the device and its benefits.40 Patients who report high device acceptance also typically demonstrate improved psychosocial adjustment, as well as increased knowledge of the ability of the device to provide protection against sudden cardiac arrest. However, patients who report decreased device acceptance may experience poorer psychosocial adjustment, as well as devicespecific knowledge and understanding.

Initial intervention studies show that the use of cognitive behavioral therapy (CBT) with ICD patients can result in decreases in depression36,41 and anxiety,36,41 and increases in perceived adjustment36 and QOL.41 Sears and colleagues11 compared a CBT stress and shock management program for ICD patients delivered in either a 1-day workshop or 6-week group sessions. Results revealed a reduction of anxiety (P < 0.05) and cortisol concentration (P < 0.05) in both the 1-day workshop format and the 6-week format, suggesting that interventions involving ICD education and CBT strategies can reduce psychological distress, even in a 1-day format.11 A recent study by Dunbar and colleagues42 revealed that psychosocial intervention in ICD patients reduce anxiety and depression, and lower the probability of long-term depressive symptoms. Dunbar noted that the use of intervention focused on coping with illness, shock preparation, and addressing ICD-specific concerns poses particular utility in this population of patients.42 Psychosocial intervention research with ICD patients has generally included multiple components of CBT focusing on adaptive thinking and behavior and device-specific information related to managing patient and family emotional reaction to an ICD shock, ICD recall, or common disease management challenges.43

It has been suggested that innovative psychosocial treatment of ICD patients cannot be “one size fits all.”44 or in other words, treatment approaches must be tailored to the needs of various subpopulations. The establishment of ICD-specific concerns, particularly in female ICD patients,45 highlights the importance of closely related treatment approaches that are tailored to their unique set of symptoms. Research using cognitive behavioral interventions in the ICD population have well-established efficacy.11,36,41,42,46 Researchers have suggested that continued refinement of intervention approaches to customize individual needs for women remains an important objective.44,45

The provision of a CBT group intervention that addressed both device-specific concerns, such as stress, anxiety, and fear, as well as female-specific concerns, such as body image, sexual functioning, and relationship issues, is likely an appropriate step toward establishing a routine.
comprehensive care plan for female ICD patients. The purpose of the current pilot study was to examine the effects of a CBT intervention tailored specifically to females with ICDs across domains of psychosocial functioning.

Methods

Patients

Female ICD patients (N = 29) were recruited from outpatient cardiovascular clinics at Shands Hospital at the University of Florida. Patients were at least 18 years of age, able to read and write English, and had prior ICD implantation. Institutional review board approval for the study was obtained, and informed consent was acquired from each participant.

Procedures

After an introduction of the study and gathering of informed consent, women were randomized to one of two conditions, intervention (n = 14) or wait-list control (n = 15). Medical record review was conducted to obtain data on cardiovascular history, ICD placement duration, history of mental health problems or treatment, current pharmacologic regimen, cardiac risk factors, and shock history.

Women randomized to the intervention group participated in the intervention, choosing from a range of available dates on which to attend. The group intervention lasted approximately 4 hours. The foci of the intervention are summarized and broken down by hour in Table I. Also included in Table I are specific questions that were probed and explored during the intervention, in an effort to facilitate discussion among patients and create a female-specific approach to material. Figure 1 provides an example of written material provided to patients during the intervention and correspond directly to topics of discussion outlined in Table I.

Intervention group patients completed individual psychological assessment batteries before participating, which took approximately 15 minutes to complete. Upon completion of the psychosocial measures and participation in the intervention, patients were compensated with a $10 giftcard. One month after the intervention, patients completed follow-up psychosocial measures via mail. Women randomized to the wait-list control group completed the initial psychosocial measures at the time of recruitment and 1 month after recruitment via mail and were compensated with a $10 giftcard. They were then invited to participate in the intervention following their completion of data collection.

Measures

Shock Anxiety

The Florida Shock Anxiety Survey (FSAS) is a 10-item measure used to assess ICD-specific anxiety including the cognitive, behavioral, emotional, and social impacts of shock; alpha coefficients suggest good reliability (Cronbach’s = 0.91, split-half = 0.92). Higher scores on the FSAS indicate higher shock anxiety.

Device Acceptance

The Florida Patient Acceptance Survey (FPAS) is a valid and reliable 18-item measure used to assess patient acceptance of cardiac device treatment. Patient acceptance refers to achieving maximal benefit from a biomedical device such as an ICD. The FPAS is composed of four factors: (1) Return to Function, (2) Device-Related Distress, (3) Positive Appraisal, and (4) Body Image Concerns. The FPAS total score and subscale scores demonstrated both convergent and divergent validity with the SF-36, Atrial Fibrillation Symptom Severity Scale, Center for Epidemiologic Studies Depression Scale, State-Trait Anxiety Inventory Form, and the Illness Intrusiveness Rating Scale. Higher scores on the FPAS indicate greater levels of device acceptance.

Statistical Analyses

Descriptive and repeated measures analyses of variance (ANOVAs) were used to determine changes in scores between the groups. For all analyses, time (baseline, 1-month follow-up) was the within-subjects factor and treatment condition (intervention group vs control group) was the between-subjects factor. Statistical analyses were performed to evaluate the proposed hypotheses for this research project using the Statistical Package for the Social Sciences, Version 17.0 (SPSS-17; SPSS Inc., Chicago, IL, USA). Results were considered significant at the P < 0.05 level. In order to correct for violations of the Box-M test and the Levene’s test for the assumption of homogeneity of variance, the relatively conservative Pillai’s trace was used for the estimation of F-statistics in all analyses. When appropriate, Bonferroni corrections were applied to rectify the possibility of type I error.

Previous studies by Kohn and colleagues and Frizelle and colleagues demonstrate positive effects of psychosocial stress management on ICD recipients. While no studies were available that were directly comparable to this study, the small feasibility trial recently conducted by Sears and colleagues and examined psychosocial outcomes between an intervention group versus a
Table I.
Summary of Intervention

Part 1: Research Procedures and Introduction of Program
- Fill out psychosocial questionnaires
- Welcome, personal introductions, introduction to program, and agenda

Part 2: Heart Health
- Cardiac functioning and rhythm management
  How has treatment for cardiovascular disease been unique to you as women?
  Has implantation posed unique challenges for you as women?
- Understanding shock
  What was your shock experience like or what do you anticipate shock to be like?
  How did you respond or how do you plan to respond?
  What were challenges during and/or after shock or what challenges do you anticipate
  if you experience shock in the future?
- Developing a shock plan
  What is the best plan for you to manage a shock episode?
  What is known about spouses/partners and their reaction to shock?

Part 3: Stress and Anxiety
- Relationship between stress and anxiety
  How common is anxiety in female ICD patients?
  How do women and men differ in their responses to stress?
  What are unique sources of anxiety for female ICD patients?
- Relaxation strategies
- Improving emotional and physical health
  What can women do to improve their emotional health?
  How can women improve their cardiovascular health and risk factors?
  What strategies have you found helpful in reducing your anxiety and helping
  you feel invigorated as a female ICD patient?

Part 4: Being a Woman
- Family relationships
  How does ICD implantation affect your role as a wife, mother, daughter, etc.?
  How has your cardiovascular disease affected your family members?
  What can women do to enhance their role functioning?
- Changes in your body
  What are practical limitations of ICD implantation for women?
  How have changes in your body after implantation affected your body image?
  What are strategies for developing better body image and increasing confidence?
- Romantic relationships, sex, and intimacy
  Have you experienced changes in romantic relationships after ICD implantation?
  Do you have fears regarding sexual activity?
  What are strategies for increasing intimacy and addressing fears?

workshop group. Given these similarities, sample size determination for this study was based on effect sizes (Hedges’ $d$) from Sears et al.$^{11}$ for shock anxiety, $d = 0.71$ and patient device acceptance, $d = 0.57$.

When conducting analyses of variance, large effects sizes are identified as those values exceeding 0.4. Even using the most conservative value of 0.57, this would require approximately 26 subjects per group for the recommended power of 0.80 when alpha = 0.05 for two group comparisons. The average psychosocial effect size among those reported from the Sears et al.$^{11}$ trial is approximately 0.70; we used this effect size to conduct power analysis for this study. A projected sample size of $n = 30$ gives a power of 0.80 for this estimated effect size. Our sample population included a total of 29 participants, which was extremely close to our projected sample size, suggesting adequate power.

Results

Sample

Table II provides demographic and medical information for the total sample, intervention
Changes in Your Body

How we think and feel about our bodies and the way it looks form what is called our body image.

Regardless of how closely our actual bodies resemble our perception of how it looks, our body image affects our self-esteem and our relationships with others. While the way our bodies look may contribute to our attractiveness, this is in no way the only factor, and it is certainly not the most important one.

Your device implantation may have left you with visible reminders of your experience with heart disease. Many women who receive an ICD deal with a range of difficulties following their surgery, as they try to adjust to living life with a cardiac device, including:

- Dissatisfaction with their appearance
- Loss of femininity
- Reluctance to look at themselves naked
- Feeling less sexually attractive
- Dissatisfaction with their scar
- Doubting their attractiveness to partners

All this can make us lose confidence in the way we look, the way we feel about ourselves, and the way we present ourselves to other people. In other words, this can affect our body image.

How has your experience with your device affected the way you think and feel about your body?

Figure 1. Example written material provided during intervention.
VAZQUEZ, ET AL.

Table II.
Demographic and Medical Variables by Total Sample and Groups (%)

<table>
<thead>
<tr>
<th></th>
<th>Total Sample n = 29</th>
<th>Intervention n = 14</th>
<th>Control n = 15</th>
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<tbody>
<tr>
<td>Age (M ± SD)</td>
<td>55.6 ± 15.5</td>
<td>57.4 ± 14.8</td>
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<td>Ethnicity</td>
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<td>7.1</td>
<td>6.7</td>
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<td>Divorced</td>
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<td>28.6</td>
<td>26.7</td>
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<td>Some college</td>
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<td>46.7</td>
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<td>Associate’s degree</td>
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<td>University degree</td>
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<td>13.3</td>
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<td>Occupational Status</td>
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<td>21.4</td>
<td>20.0</td>
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<td>Homemaker</td>
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<td>7.1</td>
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<td>Retired</td>
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<td>42.9</td>
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<tr>
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<tr>
<td>Past</td>
<td>37.9</td>
<td>42.9</td>
<td>33.3</td>
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<tr>
<td>Current</td>
<td>3.4</td>
<td>7.1</td>
<td>0.0</td>
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<tr>
<td>Years with ICD (M ± SD)</td>
<td>3.78 ± 3.07</td>
<td>4.12 ± 3.75</td>
<td>3.46 ± 2.35</td>
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<td>Positive shock history</td>
<td>34.5</td>
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<td>72.4</td>
<td>64.3</td>
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<tr>
<td>Coronary artery disease</td>
<td>37.9</td>
<td>42.9</td>
<td>33.3</td>
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<td>Long QT syndrome</td>
<td>10.3</td>
<td>7.1</td>
<td>13.3</td>
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<tr>
<td>Prior sudden cardiac arrest</td>
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<td>28.6</td>
<td>20.0</td>
</tr>
<tr>
<td>Prior myocardial infarction</td>
<td>24.1</td>
<td>28.6</td>
<td>20.0</td>
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</table>

trace = 5.58, P = 0.026, η² = 0.17) than the control participants at 1-month follow-up. This reduction in shock anxiety in the intervention group was significant at the P = 0.05 level. Given the magnitude of change on the measure, this also represents clinically significant change in reported shock anxiety. Pre-post measures of device acceptance using the FPAS revealed a significant time by group interaction effect with the intervention group having significantly greater increases in reported device acceptance (Pillai’s trace = 5.80, P = 0.023, η² = 0.18) than the control participants. The intervention group increase in overall device acceptance was significant at the P < 0.01 level. Similarly, this magnitude of change also likely represents clinical significance in self-reported device acceptance.

Subgroup Analyses

Subgroup analyses were conducted to examine differences in self-reported shock anxiety and device acceptance among three age groups of females, as recent literature suggests significant differences in psychosocial functioning among varying aged females. Due to small sample sizes, caution is emphasized in the
interpretation of these analyses. For categorical age analyses, women in the intervention group were divided into three groups: young (≤50 years of age; n = 4), middle-aged (51–64; n = 6), or older (≥65 years of age; n = 4). Significant time by group interactions were found across the domains of shock anxiety, sexual functioning, and device acceptance. With regards to shock anxiety, a significant interaction effect (Pillai’s trace = 5.05, P = 0.046, $\eta^2_p = 0.32$) was found, such that women under the age of 50 experienced greater reduction in shock anxiety than their middle-aged cohorts. Notably, young women had higher rates of shock anxiety (M = 30.75) than middle- (M = 18.00) and older-aged (M = 22.00) women at baseline. All age groups showed reduction in shock anxiety from baseline to 1-month follow-up, on average. Significant time by group interactions were found for reported device acceptance at baseline and 1-month follow-up (Pillai’s trace = 9.35, P < 0.01, $\eta^2_p = 0.46$). Young women reported greater increases in device acceptance than both the middle- and older-aged groups, and women between the ages of 51 and 64 reported higher rates of device acceptance increase than women over 65. Again, it is notable that young women reported poorer device acceptance on average (M = 55.42) than middle-aged and older-aged women (M = 75.28 and M = 75.00, respectively). However, all groups reported greater increases in total device acceptance increased across time, on average.

**Discussion**

The major objectives of the current study were to investigate the effectiveness of a psychosocial intervention tailored for female ICD recipients on domains of psychosocial functioning. Results from this study indicated that psychosocial treatment for female ICD recipients is effective in improving disease-specific QOL outcomes across several domains. Historically, the provision of psychosocial interventions utilizing CBT strategies for the general ICD population has resulted in decreased anxiety and depression. While psychosocial treatment has demonstrated utility for the general ICD population, it has been suggested that these interventions are not “one size fits all,” and that interventions tailored to meet the specific needs of particular ICD subgroups are warranted. This is the first study to operationalize a customized treatment for women with ICDs and demonstrate its potential value for larger-scale treatment studies.

Intervention group members in the study reported significant reductions in shock anxiety and increases in device acceptance after participation in the intervention. The experience of ICD shock has been associated with poor QOL and has been implicated in the development of anxiety and depression. However, while a sizable portion of ICD patients will experience shock within the first year after implantation, the majority of patients will not. Despite these statistics, many more patients experience clinical symptoms of distress associated with shock fears than experience shock itself, suggesting that shock anxiety is an appropriate target for psychosocial treatment, regardless of shock history. It has been well established that patients desire more knowledge about their device. Patient education is an essential component to psychosocial treatment, particularly with regards to identifying and challenging ICD-specific concerns, such as how the device functions, events that may trigger shock, and what to do in the event of a shock. In this study, the delivery of psychoeducation regarding shock experience and developing a shock plan, as well as encouraging members to process their shock history were all components of the intervention, providing further evidence in the importance of ICD-specific education in decreasing shock anxiety and increasing device acceptance.

As in other studies of female ICD recipients, women under the age of 50 reported higher rates of shock anxiety and poorer rates of device acceptance than their older cohorts. While the absolute numbers for each age group were very small, results still showed greater rates of change in this group of females after participation in the intervention, suggesting that they are highly appropriate candidates for psychosocial treatment subsequent to device implantation. It could be argued that age findings were significant due to younger women reporting poorer rates of psychosocial functioning at baseline. However, it is unlikely that this is the case, as all age groups on average tended to improve across the course of the study.

Younger age has been identified as a predictor of future psychological difficulties in ICD
patients.\textsuperscript{8} Bainger and Fernsler\textsuperscript{32} reported that young age is associated with greater QOL deficits. Dubin and colleagues\textsuperscript{9} noted that ICD under the age of 40 notes QOL deficits related to ICD-specific concerns. In a recent review,\textsuperscript{33} researchers specifically identify younger recipients to be at highest risk for future psychological and QOL difficulties. As noted previously, our recent investigation of female ICD patients revealed that women under the age of 50 appear to be at greater risk for the development of psychosocial distress.\textsuperscript{31} Results from the current study further strengthen this body of literature, and emphasize the utility of tailored psychosocial treatment for this group of females.

**Strengths and Limitations**

When interpreting results from this study, there are several strengths and limitations that should be taken into consideration. Analyses evaluating this sample found participants to be relatively equivalent to each other in regards to demographic and medical variables. Despite power analyses suggesting an adequate sample size, our study population may be considered relatively small in the number of patients participating in data collection. This limitation may have resulted in reduced significant findings regarding the stated hypotheses. Subgroup analyses of different aged females should certainly be interpreted with caution, given the very small sample size of each group. A larger sample size would be necessary to more rigorously test any hypotheses; however, this information provides novel information to motivate future research.

Additionally, although this study was a longitudinal design, follow-up was only conducted at 1 month after the intervention. Future studies could certainly extend the follow-up period to a longer period of time to examine relative stability of effects of the intervention. This was beyond the scope of the current study but is certainly an avenue to pursue in the future.

Although the study included a control group, this was in the form of a wait-list control group, which poses unique limitations. The possibility of a future intervention may have influenced response characteristics of the wait-list control group in either a positive or negative way. Social contact and/or attention may have created a response bias in the control group. However, we felt a wait-list control group format was justified in order to offer the intervention to all participants in the study, so as not to limit the current standard of care at our facility or prompt ethical concerns of not providing treatment to a population potentially in need.

As with all research, consideration of self-report measures should be made; self-report measures may be influenced by patient demand characteristics, such as participant perception of how they should respond or would like themselves to be perceived. The measures used in assessing psychosocial functioning in patients were restricted to the use of standardized and validated measures that were chosen for their established reliability and validity in measuring the constructs of interest. These measures have been well validated in the ICD population. We also attempted to minimize the influence of demand characteristics by assuring confidentiality of responses and anonymity after data collection.

**Conclusions**

This study represents advancement in the development of appropriately tailored interventions for female ICD recipients, as part of comprehensive facilitative care for women with CVD. Sudden cardiac death remains the most common cause of mortality for both men and women. The ICD has emerged as the most efficacious treatment choice for those patients at risk for SCD,\textsuperscript{1–6} but while the number of women who undergo ICD implantation annually continues to increase,\textsuperscript{34} the existing literature focused on female ICD populations is largely lacking in both breadth and depth. While QOL after ICD implantation is largely dependent on the degree of psychological distress experienced by patients, psychosocial interventions targeted at reducing psychological distress can produce QOL outcomes that make ICD therapy beneficial.

Female ICD patients may experience improved health outcomes through a combination of optimal medical treatment and tailored psychosocial care, including the delivery of psychoeducation and affiliation with other females in a support group format. As therapies continue to advance, female ICD patients, particularly those under the age of 50, may benefit from well-established guidelines that take into consideration the unique issues women face with the implantation of a cardiac device. The current study establishes the utility of a female-specific psychosocial intervention involving ICD-specific education, CBT strategies, and group social support in producing improvements in shock anxiety and device acceptance. The continued investigation of the unique issues women face in living with an ICD, as well as effective treatment strategies, are noteworthy, as they could largely improve QOL, adjustment, and psychological fitness of female ICD recipients.
References


PSYCHOSOCIAL TREATMENT FOR WOMEN WITH ICDs


