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## Spiritual well-being may buffer psychological distress in patients with implantable cardioverter defibrillators (ICD)

Elena Salmoirago Blotcher  
*University of Massachusetts Medical School*

*Et al.*

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## Spiritual well-being may buffer psychological distress in patients with implantable cardioverter defibrillators (ICD)

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| Complete List of Authors:     | Salmoirago-Blotcher, Elena; University of Massachusetts Medical School, Medicine<br>Crawford, Sybil; University of Massachusetts, Medicine<br>Tran, Chau; University of Massachusetts,<br>Goldberg, Robert; University of Massachusetts,<br>Rosenthal, Lawrence; University of Massachusetts, Medicine<br>Ockene, Ira; University of Massachusetts, Medicine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
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| Abstract:                     | <p>Background Psychological distress is common in patients with implantable cardioverter defibrillators (ICDs) and has been associated with a worse prognosis. We examined whether spiritual wellbeing is associated with reduced psychological distress in patients with ICDs.</p> <p>Methods We used the Functional Assessment of Chronic Illness Therapy-Spiritual Wellbeing (FACIT-SWB) questionnaire and the Hospital Anxiety and Depression Scale (HADS) to measure spiritual wellbeing and overall psychological distress. Multivariate linear regression was used to explore the relationship between these variables.</p> <p>Results The study sample included 46 ICD outpatients (32 M, 14 F; age range 43-83). We found an inverse association between HADS and FACIT-SWB scores, persisting after adjustment for demographics, anxiety/depression, medications, therapist support, and functional status (<math>F = 0.001</math>; <math>\beta = -0.31</math>, CI: -0.44, -0.19).</p> <p>Conclusion Spiritual wellbeing was independently associated with lower psychological distress in ICD outpatients. Spiritual wellbeing may act as a protective factor against psychological distress in these high-risk patients.</p> |
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## ABSTRACT

**Background** Psychological distress is common in patients with implantable cardioverter defibrillators (ICDs) and has been associated with a worse prognosis. We examined whether spiritual wellbeing is associated with reduced psychological distress in patients with ICDs.

**Methods** We used the Functional Assessment of Chronic Illness Therapy-Spiritual Wellbeing (FACIT-SWB) questionnaire and the Hospital Anxiety and Depression Scale (HADS) to measure spiritual wellbeing and overall psychological distress. Multivariate linear regression was used to explore the relationship between these variables.

**Results** The study sample included 46 ICD outpatients (32 M, 14 F; age range 43-83). We found an inverse association between HADS and FACIT-SWB scores, persisting after adjustment for demographics, anxiety/depression, medications, therapist support, and functional status ( $F = 0.001$ ;  $\beta = -0.31$ , CI: -0.44, -0.19).

**Conclusion** Spiritual wellbeing was independently associated with lower psychological distress in ICD outpatients. Spiritual wellbeing may act as a protective factor against psychological distress in these high-risk patients.

**KEY WORDS:** prevention; spirituality; heart failure; cardioverter defibrillators

## INTRODUCTION

Primary and secondary prevention trials have consistently shown the efficacy of implantable cardioverter defibrillators (ICDs) in preventing sudden cardiac death and life-threatening arrhythmias compared to anti-arrhythmic agents alone. According to guidelines published in 2008,[1] the ICD is now the treatment of choice not only for patients with documented life-threatening arrhythmias, but also for patients with impaired cardiac function (ejection fraction <35%), regardless of previous arrhythmic episodes.

However, as an increasing number of patients have received ICDs, several device-related problems have surfaced.[2] Although most patients adapt fairly well to living with an ICD over time, a significant proportion of patients will experience psychological problems, with estimates reaching up to 38% for clinically significant anxiety.[3] Young age (<50 years), female gender, poor device understanding, and experiencing multiple ICD shocks are important risk factors for the development of psychological problems in these patients.[3]

Psychological and emotional well-being in ICD patients is important for several reasons. Anxiety and depression may contribute to cardiovascular mortality and morbidity of patients with coronary heart disease[4, 5] and emotional[6, 7] and mental[8] stress may have a detrimental effect on cardiac perfusion and function. Reduced heart rate variability,[9, 10] impaired baro-reflex control,[11, 12] and alterations in the coagulation system[13] have been considered as possible mechanisms for the negative effect of anxiety and depression on cardiac outcomes.

Although it is uncertain whether spirituality may have a positive impact on physical health in patients with cardiovascular disease,[14] current evidence suggests that it may protect these patients from emotional distress and improve their quality of life. Spiritual well-being

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3 appears to have a protective effect on depression in patients with heart failure,[15] and faith can  
4 play a role in the emotional health of individuals recovering from a stroke[16, 17] or with severe  
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6 chronic disabilities.[18] In addition, pilot spiritual interventions and holistic rehabilitation  
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8 programs addressing the spiritual needs of cardiac patients have shown promising results in  
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10 improving the quality of life and psychological well-being of these patients.[19-21]  
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15 However, little is known about the possible role of spiritual well-being in buffering  
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17 psychological distress in patients with ICDs, despite several indications that the spiritual  
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19 dimension has often been neglected in these patients. Although ICD carriers are often survivors  
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21 of a cardiac arrest, have advanced heart failure and have to face difficult end-of life decisions,  
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23 the educational material provided to ICD patients typically addresses only the  
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25 technical/educational aspects of the ICD experience while ignoring its emotional and spiritual  
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27 dimensions.[22] Clinicians are often pressed for time and they are often not forthcoming in the  
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29 discussion of end-of-life issues with their patients.[23]  
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34 The purpose of this study was to evaluate whether better overall spiritual well-being may  
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36 be associated with lower psychological distress in a group of outpatients who underwent ICD  
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38 implantation.  
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## 41 METHODS

### 42 43 *Design and population*

44  
45 We conducted a cross-sectional analysis on baseline data collected from 46 patients  
46  
47 screened for participation in a pilot study of a mindfulness-based intervention for patients with  
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49 ICDs. The study was conducted at the University Campus of the UMass Memorial Medical  
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51 Center in Worcester, MA. All consecutive patients scheduled for an ICD related procedure at the  
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53 catheterization lab were screened for study eligibility within a month of the ICD procedure.  
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3 Patients were eligible if they were >21 years old, able to understand and speak English, and had  
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5 access to a telephone; exclusion criteria included inability/unwillingness to give informed  
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7 consent; signs of cognitive impairment; New York Heart Association functional class>III or  
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9 otherwise clinically unstable; pending coronary bypass or heart transplantation; co-morbid life-  
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11 threatening conditions; and ongoing severe depression or psychosis. The Blessed Orientation  
12  
13 Memory and Concentration test[24] was used to screen patients for cognitive impairment and  
14  
15 subjects with scores  $\geq 10$  were excluded. Screening for ongoing depression and psychosis was  
16  
17 based on DSM criteria of major depressive disorder or psychosis as documented by the physician  
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19 in the patient's chart at the time of the most recent medical evaluation. All eligible patients  
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21 received a letter inviting them to participate in the study and once they expressed interest, a  
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23 screening visit was scheduled. After confirmation of study eligibility and provision of informed  
24  
25 consent, patients completed a series of self-administered questionnaires. The study protocol was  
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27 approved by the Committee for the Protection of Human Subjects at the University of  
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29 Massachusetts Medical School.  
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### 36 *Psychological distress*

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38 Psychological distress (outcome variable) was assessed using the Hospital Anxiety and  
39  
40 Depression Scale (HADS). [25] This is a 14-item self-administered questionnaire with two sub-  
41  
42 scales measuring anxiety and depression, with higher scores indicating greater psychological  
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44 morbidity. The use of the HADS questionnaire has been validated in cardiac patients [26] and is  
45  
46 particularly useful in these patients since it focuses on cognitive symptoms of psychological  
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48 distress instead of physical symptoms, which may be similar to those resulting from the  
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50 underlying cardiac disease. A cut-off of 8 is used for the two subscales, while a cut-off score of  
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3 10 is usually recommended for the total score. Total HADS scores of 10 or higher indicate the  
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5 presence of psychological distress.  
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### 8 *Spiritual well-being*

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10 The primary predictor variable was overall spiritual well-being, assessed using the  
11  
12 Functional Assessment of Chronic Illness Therapy-Spiritual Well Being (FACIT-SWB). This is  
13  
14 a 12 item self-reported measure of spiritual well-being that has shown high internal consistency,  
15  
16 reliability, and convergent validity with other measures of religion/spirituality in individuals with  
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18 chronic diseases.[27] This instrument includes two subscales measuring different domains of  
19  
20 spiritual well-being – a meaning/peace subscale assessing to what extent an individual  
21  
22 experiences peace, harmony, and a sense of meaning, and a faith subscale evaluating the extent  
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24 to which a patient finds strength or comfort in his religious beliefs. The range for the total score  
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26 is 0-48, with higher scores indicating greater spiritual well-being.  
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### 31 *Demographic characteristics and other covariates*

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34 Information was collected at baseline on patient demographic characteristics and medical  
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36 history. Demographic characteristics were collected by means of self-reported questionnaires and  
37  
38 included age, gender, income, marital status, education, and racial/ethnic background.  
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40 Information on cardiac diagnosis, previous diagnosis of anxiety or depression, current use of  $\beta$ -  
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42 blockers, anti-arrhythmics, anxiolytics and antidepressants, indication for ICD implantation  
43  
44 (primary vs. secondary prevention), type and time since ICD procedure, prior ICD shocks, New  
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46 York Heart Association class, and ejection fraction (EF: End diastolic volume - End systolic  
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48 volume/End diastolic volume from an echocardiogram or a ventriculogram) was gathered from  
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50 the Medical Record. Functional status was measured using the physical limitation subscale of the  
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52 Seattle Angina Questionnaire.[28] Patients were also asked to report the number of times they  
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3 engaged in physical exercise and whether they met with any therapist or spiritual counselor  
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5 during the previous four weeks.  
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### 7 8 *Statistical analysis* 9

10 We conducted a preliminary analysis to evaluate the appropriateness of the model's  
11 assumptions, and assess correlations between covariates to avoid collinearity in the multivariate  
12 model. The distribution of baseline demographic and clinical characteristics were compared  
13 between patients with high ( $\geq 50^{\text{th}}$  percentile for this population) and low ( $\leq 50^{\text{th}}$  percentile)  
14 spiritual well-being using t-test (or Wilcoxon) for continuous variables and two-tailed Fisher  
15 exact test to compare proportions.  
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24 The association between psychological distress and spiritual well-being was assessed  
25 using linear regression models. Variables that may confound the association between spiritual  
26 well-being and psychological distress (age, gender, income, education, marital status, prior  
27 depression or anxiety, use of antidepressants or anxiolytics, cardiovascular disease severity, and  
28 functional status) showing an association with the outcome ( $p \leq 0.10$ ) were included in a  
29 multivariate linear regression model. Results are presented as unadjusted and adjusted beta  
30 coefficients (with confidence intervals), where the null hypothesis was that  $\beta_1 = 0$ . P values  
31  $< 0.05$  were considered to be statistically significant. All analyses were performed using STATA  
32 10 (2007) statistical software (StataCorp, LP; College Station, TX).  
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## 46 RESULTS 47

48 Forty-six outpatients (32 M, 14 F) aged 43-83 years (mean, 65 years) completed a series  
49 of questionnaires at the initial screening visit (Table 1). Eighty-five percent of the study sample  
50 was in New York Heart Association class II or higher and the mean ejection fraction was 0.3 (SD  
51 0.13). Half of the participants had total HADS scores higher than 10, the threshold indicating the  
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3 presence of psychological distress. Mean FACIT-SWB scores were  $35 \pm 8$  (scale range 0 - 48). No  
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5 patient reported to have met a spiritual counselor during the previous month, and 13% reported  
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7 meeting with a therapist or social worker.  
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10 Patients with FACIT-SWB scores above the 50<sup>th</sup> percentile (Table 2) had significantly  
11  
12 lower HADS scores as well as a lower prevalence of psychological distress compared to patients  
13  
14 with FACIT-SWB scores below the 50<sup>th</sup> percentile. Although most differences were not  
15  
16 statistically significant due to the relatively small sample size, they were also older, more  
17  
18 frequently married, less educated, and had a lower prevalence of a prior diagnosis of anxiety or  
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20 depression and of use of antidepressants or anxiolytics, while the severity of clinical conditions  
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22 did not differ between groups as indicated by similar mean ejection fraction values and  
23  
24 prevalence of prior cardiac arrest and ICD shocks.  
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29 Table 3 shows the results of the unadjusted and adjusted linear regression models.  
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31 Psychological distress scores were significantly and inversely associated with FACIT-SWB  
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33 scores (Figure 1). In multivariate models, spiritual well-being was significantly associated with  
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35 lower psychological distress independently of demographics (model 2); of a previous diagnosis  
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37 of anxiety or depression, use of anxiolytics or antidepressants and counseling (model 3); and of  
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39 physical exercise or functional status (model 4).  
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## 44 DISCUSSION

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46 Despite indications that spirituality is an important component of the psychological well-  
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48 being of patients with severe chronic diseases,[29-31] a limited number of studies have  
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50 examined its characteristics in patients with cardiovascular disease.[15, 16, 32] A possible  
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52 explanation for the limited interest in this topic in the cardiology literature is that spirituality is  
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54 an elusive concept, encompassing both subjective dimensions that are difficult to define and  
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3 operationalize, and more easily measurable, objective dimensions such as frequency of spiritual  
4 activities or spiritual/religious affiliation.[33]  
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8 This is the first paper describing the characteristics associated with spiritual well-being in  
9 patients living with an ICD and investigating the possible impact of spiritual well-being on the  
10 self-reported psychological health of these patients. In our study, patients with higher spiritual  
11 well-being had significantly less psychological distress and a lower prevalence of concurrent  
12 psychiatric morbidity and psychotropic drug use compared to patients with lower spiritual well-  
13 being. On the other hand, clinical conditions and functional status were similar between the two  
14 groups, suggesting that differences in psychological well-being were independent from the  
15 severity of the cardiac condition. There was an inverse linear relationship between psychological  
16 distress scores and spiritual well-being scores that persisted after taking into account a number of  
17 possible confounding variables.  
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31 The limited data currently available describing the role of spiritual well-being in patients  
32 with chronic cardiovascular disease is typically based on patients with advanced heart failure.  
33 These studies, usually qualitative or cross-sectional in nature, have shown the centrality of  
34 spirituality in the life of patients and caregivers alike [34, 35] and its association with better  
35 quality of life [36] and adjustment to advanced heart failure.[37]  
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43 Our results are consistent with those of a cross-sectional analysis showing a strong  
44 inverse association between spiritual well-being and depression in 60 patients with heart failure,  
45 independent of gender, income, social support, physical symptoms, and health status.[15] This is  
46 not surprising, considering that ICD patients usually have concomitant heart failure and, in fact,  
47 85% of our patients were in NYHA class II or III. One important addition of our paper to the  
48 current literature is that we adjusted for other important confounders such as co-morbid  
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3 depression or anxiety, psychotropic medications, and ongoing psychosocial support.

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5 Furthermore, patients with ICDs are somewhat unique among patients with heart failure, in that  
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7 they often have experienced a cardiac arrest (21% of our population) and usually have more  
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9 severe cardiac conditions.  
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13 Several limitations need to be kept in mind in interpreting the results of the present study.  
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15 The first concerns our choice of the instrument to assess spiritual well-being. The FACIT-SWB  
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17 is a measure of spiritual well-being, and not of spirituality, and has been criticized because of the  
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19 overlap with measures of psychological well-being.[30, 38] However, the finding of an inverse  
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21 association between spiritual well-being and psychological distress has been consistently  
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23 reported in various populations using different measures of spirituality and psychological  
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25 distress.[30, 39] Furthermore, in our analysis the association between spiritual well-being and  
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27 psychological distress was still evident after we accounted for psychological co-morbidity, use of  
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29 psychotropic medications, and support from therapists, thus suggesting that spiritual well-being  
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31 may uniquely contribute to reducing overall psychological distress. An additional limitation is  
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33 that we limited our assessments to one dimension of spirituality, namely its emotional aspects,  
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35 while we did not address other components such as affiliation or frequency of spiritual practice.  
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37 Moreover, due to the cross-sectional nature of this study, resulting in the assessment of spiritual  
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39 well-being and psychological distress at the same point in time, we cannot draw conclusions  
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41 about the direction of this association. We also cannot exclude the possibility of selection bias,  
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43 since this analysis was conducted on data collected as part of the baseline assessments of patients  
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45 screened for participation in a pilot randomized clinical trial. The prevalence of anxiety and  
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47 depression in our study, however, are consistent with that reported in similar studies of ICD  
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49 outpatients. [3, 40] The vast majority of our study population was white, and our findings may  
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3 not be generalizable to minority populations in which dimensions of spirituality other than  
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5 spiritual well-being, such as attendance at worship services or spiritual beliefs, could be more  
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7 relevant.  
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10 In conclusion, spiritual well-being was independently associated with lower  
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12 psychological distress in a group of outpatients with ICDs. These findings need to be confirmed  
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14 in larger and diverse populations and in prospective studies. In consideration of the possible  
15  
16 unique contribution of spiritual well-being to the overall psychological well-being and quality of  
17  
18 life of patients with ICDs, the spiritual-existential dimension of the experience of living with an  
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20 ICD should probably receive more attention in the care of these patients.  
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28  
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32  
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35 Authors contributions: Elena Salmoirago-Blotcher designed the study, collected the data,  
36  
37 conducted the data analysis, and wrote the manuscript draft; Sybil Crawford provided statistical  
38  
39 advice and revised the manuscript; Chau Tran contributed to the study design and data  
40  
41 collection; Robert Goldberg, Ira Ockene and Lawrence Rosenthal revised the manuscript. All  
42  
43 authors approved the final version of the manuscript for publication.  
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48 Presentations: This study has been accepted as a poster presentation at the annual conference of  
49  
50 the Society of Behavioral Medicine (New Orleans April 2012  
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55 to produce the manuscript.  
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11 Medicine (NCCAM F32AT005048)

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14 Ethical Approval: The study protocol and all study materials were approved by the Committee  
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16 for the Protection of Human Subjects at the University of Massachusetts Medical School (Docket  
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18 H-13078).  
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Table 1. Baseline demographic and clinical characteristics of the study sample\*

|                                      |             |
|--------------------------------------|-------------|
| n                                    | 46          |
| Age (mean, SD)                       | 65.0 (10.5) |
| Males                                | 32 (69.6)   |
| White-non Hispanic                   | 43 (93.5)   |
| Hispanic                             | 2 (4.3)     |
| Asian                                | 1 (2.2)     |
| High School                          | 13 (28.3)   |
| Some college                         | 14 (30.4)   |
| College graduate                     | 10 (21.7)   |
| Post graduate                        | 9 (19.6)    |
| Married or in committed relationship | 35 (76.1)   |
| Separated/divorced/single            | 11 (23.9)   |
| How hard to pay for basics†          |             |
| Not at all hard                      | 26 (56.5)   |
| Somewhat hard                        | 13 (28.3)   |
| Very hard                            | 6 (13.0)    |
| Does not know                        | 1 (2.2)     |
| Coronary heart disease               | 29 (63.0)   |
| Idiopathic dilated cardiomyopathy    | 9 (19.6)    |
| Other                                | 8 (17.4)    |
| Prior cardiac arrest                 | 10 (21.7)   |

Table 1 – Baseline demographic and clinical characteristics of the study sample (cont.)\*

|                                                                                    |                   |
|------------------------------------------------------------------------------------|-------------------|
| New ICD                                                                            | 27(58.7)          |
| ICD upgrade                                                                        | 4 (8.7)           |
| Battery change/lead revision                                                       | 9 (19.6)          |
| ICD shocks/storms                                                                  | 6 (13.0)          |
| Months from ICD procedure (median (25 <sup>th</sup> -75 <sup>th</sup> percentile)) | 1.45 (0.56, 14.2) |
| Beta-blockers                                                                      | 40 (86.9)         |
| Anxiolytics                                                                        | 10 (21.7)         |
| Anti-depressants                                                                   | 11 (23.9)         |
| Ejection fraction (mean (SD))                                                      | 0.30 (0.13)       |
| New York Heart Association class                                                   |                   |
| I                                                                                  | 7 (15.2)          |
| II                                                                                 | 16 (56.6)         |
| III                                                                                | 13 (28.2)         |
| FACIT-SWB score (mean, SD)                                                         | 35.4 (8.6)        |
| Prior diagnosis of depression                                                      | 11(23.9)          |
| Prior diagnosis of anxiety                                                         | 9 (19.6)          |
| Total HADS score>10                                                                | 23 (50)           |
| Have seen a spiritual counselor ‡ during past month                                | 0 (0)             |
| Have seen a therapist§ during past month                                           | 6 (13.0)          |
| Physical exercise at least 30 min/week during previous months                      | 21 (45.7)         |

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3 \* Values are n (%) unless otherwise indicated  
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6 † Food, housing, medical care and heating  
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8 ‡ Priest, minister, rabbi or spiritual guide  
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10 § Psychologist, psychiatrist, or clinical social worker  
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12 ICD = Implantable cardioverter Defibrillator; HADS= Hospital Anxiety and Depression Scale;  
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14 FACIT-SWB = Functional Assessment of Chronic Illness Therapy-Spiritual Well Being  
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Table 2. Baseline sample characteristics according to spiritual well-being status

|                                                | High spiritual well-being (FACIT-SWB $\geq$ 36.5) | Low spiritual well-being (FACIT-SWB<36.5) | P value <sup>†</sup> |
|------------------------------------------------|---------------------------------------------------|-------------------------------------------|----------------------|
| N                                              | 23                                                | 23                                        |                      |
| Age (mean, CI)                                 | 69.2 (65.8, 72.6)                                 | 60.8 (56.1, 65.5)                         | 0.0114               |
| Females                                        | 50.0 (7)                                          | 50.0 (7)                                  | 1.00                 |
| College or post-graduate education             | 15.2 (7)                                          | 26.1 (12)                                 | 0.48                 |
| Married or in committed relationship           | 54.3 (19)                                         | 45.7 (16)                                 | 0.49                 |
| Not at all hard to pay for basics <sup>‡</sup> | 42.3 (11)                                         | 57.7 (15)                                 | 0.36                 |
| Somewhat hard                                  | 69.2 (9)                                          | 30.8 (4)                                  |                      |
| Very hard                                      | 50 (3)                                            | 50 (3)                                    |                      |
| Does not know                                  | 1 (100)                                           | 0 (0)                                     |                      |
| Coronary heart disease                         | 55.2 (16)                                         | 44.8 (13)                                 | 0.70                 |
| Prior cardiac arrest                           | 50 (5)                                            | 50 (5)                                    | 1.00                 |
| New ICD                                        | 48.2 (13)                                         | 51.8 (14)                                 | 0.52                 |
| ICD shocks/storms                              | 50.0 (3)                                          | 50.0 (3)                                  | 0.66                 |
| Prior diagnosis of depression                  | 27.3 (3)                                          | 72.7 (8)                                  | 0.16                 |
| Prior diagnosis of anxiety                     | 44.4 (4)                                          | 55.6 (5)                                  | 1.00                 |
| Counselors                                     | 33.3 (2)                                          | 66.7 (4)                                  | 0.67                 |
| Beta-blockers                                  | 50 (20)                                           | 50 (20)                                   | 1.00                 |
| Anxiolytics                                    | 40.0 (4)                                          | 60.0 (6)                                  | 0.72                 |

|                                                              |                   |                   |        |
|--------------------------------------------------------------|-------------------|-------------------|--------|
| Anti-depressants                                             | 27.3 (3)          | 72.7 (8)          | 0.16   |
| Ejection fraction (mean, CI)                                 | 0.29 (0.26, 0.33) | 0.30 (0.23, 0.37) | 0.69   |
| Functional status (mean, CI)                                 | 64.4 (55.7, 73.0) | 53.8 (42.7, 64.8) | 0.17   |
| Total HADS score (mean, CI)                                  | 6.7 (4.4, 9.0)    | 13.8 (11.4, 16.2) | 0.0001 |
| HADS score>10                                                | 21.7 (5)          | 78.3 (18)         | 0.0001 |
| Physical exercise at least 30 minutes/week during past month | 61.9 (13)         | 38.1 (8)          | 0.236  |

\* Values are n (%) unless otherwise indicated

† Wilcoxon or 2-sided Fisher exact test

‡ Heating, groceries, and health insurance

ICD = Implantable cardioverter Defibrillator; HADS= Hospital Anxiety and Depression Scale;

FACIT-SWB = Functional Assessment of Chronic Illness Therapy-Spiritual Well Being



Table 3. Results of the unadjusted and adjusted linear regression models testing the association between total HADS scores and FACIT-SWB scores

|         | $\beta$ | 95% CI       | R squared |
|---------|---------|--------------|-----------|
| Model 1 | -0.32   | -0.37, -0.13 | 0.44      |
| Model 2 | -0.30   | -0.43, -0.17 | 0.56      |
| Model 3 | -0.32   | -0.45, -0.20 | 0.67      |
| Model 4 | -0.31   | -0.44, -0.19 | 0.69      |

Model 1: unadjusted

Model 2: adjusted for demographics (age, marital status, financial status)

Model 3: adjusted for variables included in model 2 + prior depression and anxiety, use of psychotropic drugs, counselors/therapists during past month

Model 4: adjusted for variables included in model 3 + functional status, and physical exercise

HADS= Hospital Anxiety and Depression Scale; FACIT-SWB = Functional Assessment of Chronic Illness Therapy-Spiritual Well Being

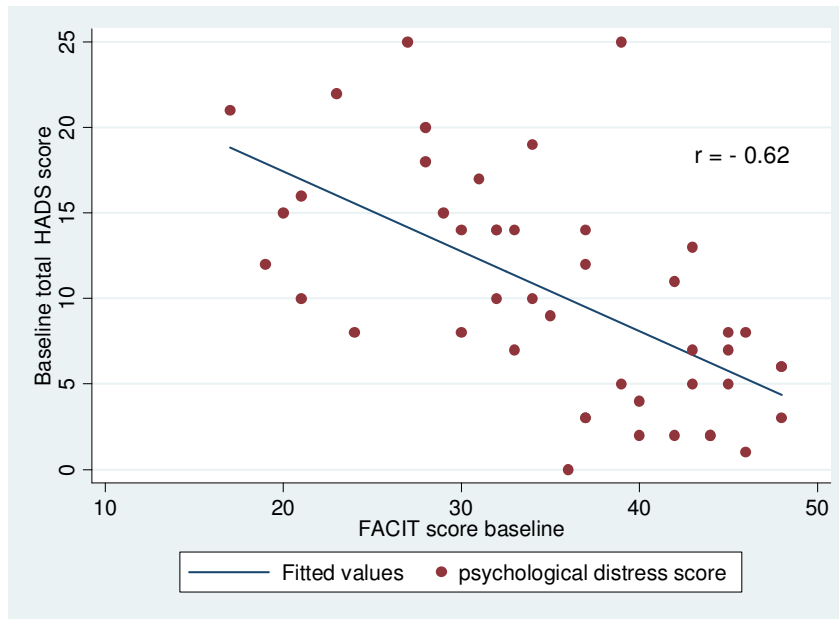


Figure 1. Unadjusted association between overall psychological distress and spiritual well-being