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Sex Is Associated With Differences in Individual Trajectories of Change in Social Health After Implantable Cardioverter-Defibrillator

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Social health is a dimension of quality of life, and refers to people's involvement in, and satisfaction with social roles, responsibilities, and activities. The implantable cardioverter-defibrillator is associated with changes in overall quality of life, but little is known about sex differences in individual trajectories of change in social health.

Methods and Results

We prospectively measured changes in 3 subscales of the SF-36v2 generic health questionnaire (role physical, role emotional, and social functioning), 2 Patient-Reported Outcomes Measurement Information System short forms (satisfaction with participation in social roles and satisfaction with participation in discretionary social activities), and the Florida Patient Acceptance Survey before and at 1, 2, and 6 months after implantation. Individual growth models of temporal change were estimated. The scores of the 6 indicators improved with time. The unconditional model demonstrated significant (fixed effects: $P<0.05$; covariance parameters: $P<0.10$) residual variability in the individual trajectories. In the conditional model, men and women differed significantly in their rates of change in the scores of 3 of the 6 measures. Although men's mean scores exceeded women's mean scores on all indicators at baseline (range of relative mean difference: 11.0% to 17.8%), the rate of women's change resulted in a reversal in relative standing at 6 months after implantation, with the mean scores of women exceeding the men's by 4.5% to 5.6%.

Conclusions

Men and women differed in their trajectories of change in social health, both in terms of their starting points (ie, baseline scores) and their rates of change.

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The implantable cardioverter-defibrillator (ICD) is the established therapy for the primary or secondary prophylaxis of sudden cardiac death in people with a wide range of cardiac pathologies.[1–4] Regardless of the treatment of their underlying cardiac condition, people who require an ICD must adapt to living with a unique and complex device.[5] There is substantial evidence about the prevalence of psychological distress,[6,7] and differences between the experiences of men and women have been reported.[8] Little is known about changes in social health, the capacity to fulfil social roles, responsibilities, and other functions of daily life.[9] Previous research has reported diminished social interactions and social avoidance behavior,[10,11] disruption to employment, exercise and sexual activity,[12,13] and difficulties with parenting and other caregiving responsibilities.[14,15] Limited evidence suggests that sex differences may exist in the trajectory of social health,[8] an important dimension of quality of life (QOL). The assessment of QOL is gaining clinical value as an indicator of patients' perspective on treatment, recovery, and outcomes.[16] In addition, providing clinicians with QOL information has been shown to improve clinician–patient communication, raise awarenevss of problems that would otherwise be unidentified, improve care plans, and enhance multidisciplinary collaboration.[17,18]

The purpose of the study was to investigate changes in social health in the first 6 months after ICD implantation. Social health encompasses the ability to engage in social roles (physically and emotionally), social functioning, and satisfaction with social roles and activities. The conceptualization of social health was grounded in the health-related QOL model proposed by Wilson and Cleary.[19] The model is applicable to clinical research[20] and has been widely applied to different patient populations.[21] We aimed to describe the change, if any, in self-reported social

WHAT IS KNOWN

- The implantable cardioverter defibrillator can be associated with changes in quality of life. Significant emphasis has been placed on the study of changes in mental health, especially anxiety and depression associated with implantable cardioverter defibrillator shocks.
- Social health is an important dimension of quality of life.

WHAT THE STUDY ADDS

- We found that social health improves in the first 6 months after implantable cardioverter defibrillator but men and women differ in their trajectory of change. Men's mean scores were higher than women's before implantation, but women improved at a faster rate in the first 6 months.
- Individual growth modeling provides novel analytic tools to study between- and within-group variation in change parameters and can inform clinical practice.

health, and to determine whether differences in the pattern of change could be predicted by a set of theoretically derived variables, including sex. We hypothesized that different variables were associated with change between measurement time points, and within the study cohort. To this end, the unique analytic interest was to explore the participants' individual trajectories of change (ie, change within the same person measured at several intervals), and across groups of people.

We differentiated a priori between the experiences of men and women in an effort to contribute to clinicians' awareness of the effect of sex on the early recovery after ICD and supporting the planning of follow-up interventions. In addition, the study was conducted with an interest in other candidate predictor variables drawn from current research, raised by the interdisciplinary clinical team, and consistent with the conceptual framework underpinning the study. These included indication for implantation (ie, primary and secondary), age, social support (ie, marital status), employment status, and the travel distance to specialized medical care given the unique constraints of Canadian geography. We further explored the relationship between the urgency of implantation, self-reported ICD shocks, and the experience of on-going cardiovascular symptoms.

Methods

Study Design and Sampling Frame

The study involved a prospective, longitudinal design. A consecutive series of adult patients implanted with a first ICD completed a set of standardized and validated questionnaires before implantation, and 1, 2, and 6 months after receiving the device. The time intervals were selected to focus on the early adaptation period, a potentially vulnerable period, which remains poorly described in the current literature, and which is amenable to timed and targeted interdisciplinary interventions to improve outcomes. Study participants were given the choice of completing the questionnaires using a paper- or Web-based format, which contained identical text and were intentionally visually similar.

Between April 2010 and June 2011, 308 consecutive elective and inpatients referred for their first ICD for primary or secondary prevention at a hospital in western Canada were screened for eligibility. Patients who received an ICD with cardiac resynchronization therapy function, were <18 years old, did not speak English, were unable to complete a written questionnaire, or did not provide informed consent were excluded. The study was approved by the institutional review committee (Providence Healthcare Research Ethics Board), and subjects provided informed consent.

Measures

Demographic and Clinical Variables

Demographic and clinical information was obtained with a baseline questionnaire (ie, before ICD implantation). The demographic and clinical variables included sex, age, New York Heart Association functional classification, previous cardiac revascularization (ie, percutaneous coronary intervention or coronary artery bypass graft surgery), coexisting conditions, left ventricular ejection fraction, urgency (ie, inpatient or elective outpatient), indication for implantation (ie, primary or secondary), and self-reported ICD shock history. To capture additional indicators associated with social function, marital status and employment status were recorded. Information was obtained from the participants' medical records.

Social Health

Three subscales of the SF-36v2, a generic health profile questionnaire with 36 items that measure 8 health domains, were used to measure social health: the 4-item role physical, the 2-item role emotional, and the 2-item social functioning subscales.[22] These subscales measure the extent to which physical health or emotional problems interfere with people's normal social activities and their capacity to perform their work or other regular daily activities, including accomplishing less than wanted, not doing work as carefully as usual, or reducing the amount of time spent on activities. Psychometric evaluation of the subscales has demonstrated that they perform similarly with average interitem correlation coefficients of 0.57 (role physical), 0.61 (role emotional), and 0.74 (social functioning) and with Cronbach α coefficients of 0.84, 0.83, and 0.85, respectively.[23] There is limited psychometric evaluation of the SF-36v2 subscales in the ICD population. In our data, the Cronbach α coefficients were evaluated at each measurement cycle, and were 0.94 for role physical (mean interitem correlation range: 0.79–0.82 across repeated measures), between 0.91 and 0.93 for role emotional (mean interitem correlation range: 0.77–0.82), and between 0.80 and 0.90 for social functioning (mean interitem correlation range: 0.66–0.82). The measurement equivalence and construct validity across sex of the SF-36 has been studied and confirmed in multiple populations, clinical settings, and languages.[24]

The use of the SF-36v2 is proprietary and licensed through QualityMetrics, which provides proprietary statistical analysis. To facilitate data analysis, we used the QualityMetrics Health Outcomes Scoring Software 4.0 User's Guide to develop IBM SPSS 19 syntax to recode and recalibrate the items as required, and to duplicate the scoring for each subscale.[25]

Satisfaction With Social Roles and Discretionary Social Activities

In collaboration with the US National Institutes of Health Roadmap for Medical Research Initiative, the Patient-Reported Outcomes Measurement Information System (PROMIS) is a collaborative effort of outcomes scientists that was initiated in 2004 to transform the selection and use of patient-reported outcome measurements in clinical research and practice evaluation. To develop item banks, the PROMIS researchers conducted a series of standardized item development phases.[26] PROMIS short forms were developed from large item banks. The findings of an extensive comparison with the overall bank and other well validated and widely accepted standard measures provide evidence of good reliability across sex and across the score distributions of these short forms.[9,27] However, there is no psychometric evidence specific to the ICD population; this study is the first to use selected PROMIS short forms to augment the study of social health in patients with ICDs to measure domains that can inform clinical practice and interdisciplinary follow-up programs.

The satisfaction with participation in social roles short-form measures people's satisfaction with their ability to do things with their family, meet the needs of their dependents, perform daily routines, run errands, work, and perform household chores. The satisfaction with discretionary social activities short form focuses on the ability to "do things for fun at home," "do things for… friends," "do leisure activities," and satisfaction with "current level of activities of activities with friends" and "level of social activities." Each short form contains 7 items and is correlated at 0.99 with its respective full-item bank.[9] When correlated with items of the SF-36v2 role physical, role emotional, and social functioning subscales, the 2 PROMIS instruments produced moderately sized correlations ranging from 0.44 to 0.59. This may indicate that the PROMIS short forms broaden the measurement of social health by measuring additional aspects of social functioning that are not fully captured in the SF-36.[9]

Device Acceptance

The Florida patient acceptance survey was developed from an original bank of 47 items identified through literature reviews, surveys, and interviews with clinicians and patients.[28] Device acceptance refers to the psychological accommodation to living with an ICD and the derivation of biomedical, psychological, and social functioning.[28] Higher scores indicate greater device acceptance. After initial validation and factor analysis, a 15-item scale was developed. Recent confirmatory analysis recommended the removal of 3 items to improve the instrument's performance, with reported Cronbach α coefficient ranging from 0.76 to 0.82.[29] We conducted our analyses using the summed scores of the 12-item instrument. We obtained a Cronbach α coefficient ranging from 0.84 to 0.88, with mean interitem correlation coefficients ranging from 0.32 to 0.39 for the 12-item scale, over repeated measures.

Statistical Analyses

We used the IBM SPSS19 (Armonk, NY) program to conduct the analyses. Descriptive statistics were used to report demographic and clinical characteristics of the sample. To facilitate the interpretation of the findings, the scores of all scales were rescaled to a standardized 0 to 100 possible range and the directionality of the scales was maintained. Missing data accounted for <2% of the total data. A single imputation procedure using the expectation maximization algorithm (IBM SPSS 19 Missing Value Analysis module) was performed to impute values for missing data at the item level before constructing the summed scale scores.

After recommendations by Heck,[30] we used an individual growth modeling approach to evaluate temporal change and differences in change trajectories by general. The use of individual growth modeling is a relatively new, powerful, and flexible approach that allows the use of all available data to analyze the interaction effects between time and other between-subject factors, and cross-level interactions (eg, the effects of between-subject variables on individual growth trajectories), and to estimate regression parameters from the individual growth models by treating the intercepts and slopes as random effects.[31,32] The focus is not whether there are differences in the between- and within-subjects' levels of a factor, but the extent to which the variance of the responses is influenced by this factor compared with the total variability of the data. Individual growth models provide relatively precise estimates of individual growth over time and greater statistical power to detect predictors of individual differences in change, even with relatively small samples and variation in the number and spacing of measurements.[33] The modeling technique allows for the study of both intra- and interindividual differences in the change parameters thus exploring the patterns of change and the effects at both the individual and the group levels, whereas estimating the change parameter with greater precision when the number of time waves is >2. This improves the reliability of the change parameters by reducing the SE of the within-subject change in the parameter estimates. The growth parameters include (1) intercepts, which pertain to starting point of the slope (or the value of the outcome variable at baseline), and (2) slopes, which represent the rates of change (we included both a linear component and a quadratic component to fit nonlinear curves). Individual growth models are more powerful than other methods in examining the effects associated with repeated measures because they model the covariance matrix (ie, fitting the true covariance structure to the data, rather than imposing a certain type of structure). The aim of the study's individual growth models development was to find models that used the least number of parameters while providing the best fit.[32,33]

The analytic approach, as recommend by Heck,[30] involved 3 steps. We first produced univariate descriptive change statistics of the 6 scales. We selected a threshold of 10% and a distribution-based 0.30 SD criterion as a meaningful indicator of the minimally important difference based on the recommendation provided by Osoba[21] that a change of 10% of the scale breadth (possible range) be taken as representing a definite change that is perceptible to patients (p. 9). In the second step, we constructed an unconditional individual growth model using the Linear Mixed Models program in IBM SPSS 19, which assumes that the outcome variable (ie, each selected scale) is linearly related to the fixed factors, random factors, and the covariates entered in a model. The aim was to estimate individual change over time and determine the most plausible shape of the change curves, and explore whether individual

differences in change curves are random or systematic. The latter is determined by evaluating the statistical significance in residual variability of the growth parameters (notably, the slopes).[31,33] Finally, having found systematic differences in individual change curves, the third step involved specifying a conditional model to test whether these differences could be explained by sex and other key covariates of interest derived from the current literature and of clinical interest to the interdisciplinary research team. These included age, indication for implantation, urgency, shock history, marital status, household size, employment status, and distance to electrophysiology services. This is done by examining whether these variables explain the residual variances in the rates of the participants' change.[31,34,35]

Results

Sample

There were 308 consecutive patients screened for study inclusion. The final sample consisted of 171 (74.0%) of the 231 eligible participants. Baseline measurements were obtained before device implant (median time=5.8 days). Follow-up measurements were conducted at 1 (n=149; 87.1%), 2 (n=140; 81.9%), and 6 (n=139; 81.3%) months after implantation either by means of a mailed paper questionnaire (68.4%) or a web-based format (31.6%). The flow chart of participant recruitment and retention is presented in Figure 1.

The sample consisted of 128 men (74.9%). The participants ranged in age from 18 to 81 years (mean=58.7 years; SD=14.5). Because of the vast geography of the catchment area, 61 (35.7%) participants were required to travel >100 km to obtain specialized medical care. At the time of their ICD implantation, 99 participants (57.9%) underwent a same-day admission and discharge elective procedure, whereas 72 participants (42.1%) were inpatients at the implanting center or transferred by ambulance from a referring community hospital. Most participants (65.5%) had a primary indication for an ICD. The self-reported prevalence rates of having had ≥1 ICD shock in the first month after implantation were 6.7% (n=10) within 1 month, 4.3% (n=6) between the first and second months, and 2.9% (n=4) between the second and sixth months (Table 1).

Step 1: Grouped Data—Presence and Direction of Change

The scores of the 6 indicators of social health improved with time. For the 3 SF-36v2 subscales, the absolute differences in mean scores between the first and last measurement occasions were 15.8 points on the 100-point scale for role physical, 7.3 for role emotional, and 14.3 for social functioning, whereas the relative percentage changes in these scores were 35.3%, 11.6%, and 23.7%, respectively. The 2 PROMIS short-form measures of social health exhibited similar changes with an absolute change in mean scores between the first and last measurement occasions of 16.4 points for satisfaction with participation in social roles, and 11.9 points for satisfaction with participation in discretionary social activities, which were relative improvements of 33.3% and 23.5%, respectively. The

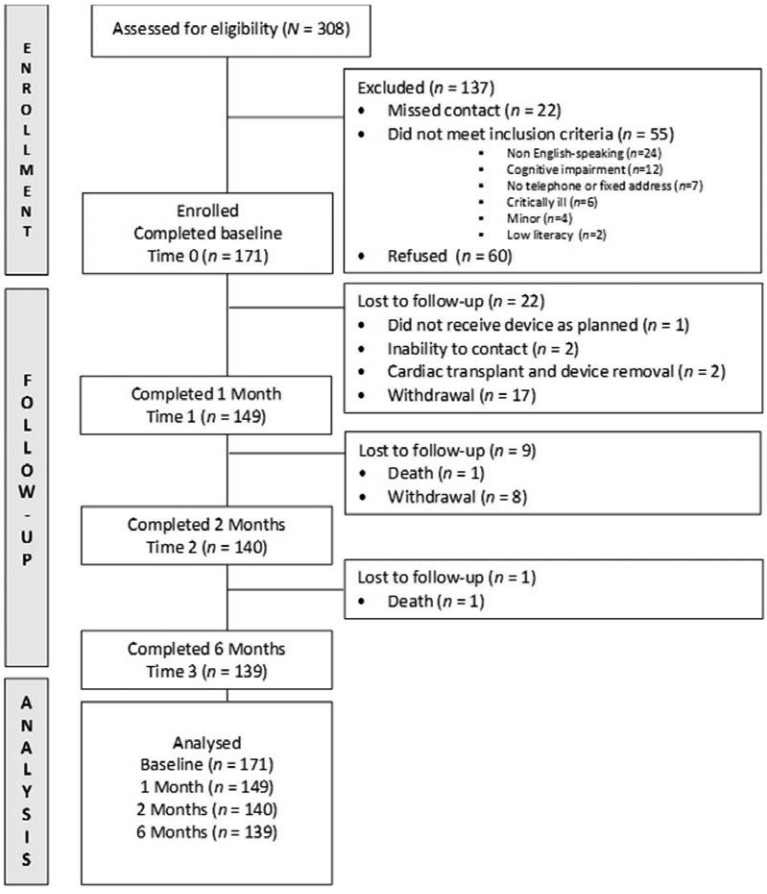

Figure 1. Flow chart of participant recruitment and retention.

Table 1. Patient Characteristics by Sex

Characteristic	Women n=43 (25.1%)	Men n=128 (74.9%)	*P* Value	All n=171 (100%)
	n (%)	n (%)		n (%)
Age, mean(SD)	58.7 (14.5)	62.0 (13.4)	0.17	61.2 (13.7)
Primary indication	25 (58.1)	89 (69.5)	0.17	114 (66.7)
NYHA Classification				
I	15 (34.9)	25 (19.5)	0.04	40 (23.4)
II	10 (23.3)	57 (44.5)	0.01	67 (39.2)
III	10 (23.3)	33 (25.8)	0.74	43 (25.1)
Unknown	8 (18.6)	13 (10.2)	0.15	21 (12.3)
Coronary artery disease	16 (37.2)	78 (60.9)	0.01	94 (55.0)
Percutaneous coronary intervention	11 (25.6)	39 (30.5)	0.55	50 (29.2)
Cardiac surgery	7 (16.3)	47 (36.7)	0.01	54 (31.6)
Myocardial infarction	9 (20.9)	56 (43.8)	0.01	65 (38.0)
Previous cardiac arrest	7 (16.3)	19 (14.8)	0.82	26 (15.2)
Ejection fraction, mean (SD)	41.1 (17.3)	35.4 (13.7)	0.03	36.8 (14.8)
Atrial fibrillation	12 (27.9)	43 (33.6)	0.49	55 (32.2)
Hypertension	16 (37.2)	61 (47.7)	0.24	77 (45.0)
Diabetes mellitus	7 (16.3)	43 (33.6)	0.03	50 (29.2)
Urgent inpatient	23 (53.5)	49 (38.3)	0.08	72 (42.1)
Social health indicators				
Married or common law	23 (53.5)	101 (78.9)	0.001	124 (72.5)
Employed	21 (48.8)	49 (38.3)	0.23	70 (40.9)
Lives alone	14 (32.6)	22 (17.2)	0.03	36 (21.1)

All characteristics except age were self-reported. Percentages rounded to first decimal place; may not add to 100% because of rounding. NYHA indicates New York Heart Association functional class.

*Does not sum to 100% because of exclusion of negative reports. No imputation performed.

mean scores of the Florida patient acceptance survey improved between the first and second months, and remained consistent at the 6-month measurement. The percentage change between the first and last measure was 6.9%. The distributions and patterns of change for the social health measures are presented in Table 2. According to the benchmarks delineated by Wyrwich,[36] the magnitude of change, with respect to what would be considered a minimally important difference, was moderate to large or large.

Step 2: Unconditional Model—Variation in Individual Change

The participants demonstrated improvements in their social health over time. The rate of change was statistically significant for the SF-36v2 role emotional (6.4 points over each observation), SF-36v2 social functioning (7.7 points over each observation), satisfaction with participation in social roles (6.2 points over each observation), satisfaction with participation in discretionary social activities (7.3 points over each observation), and patient acceptance of implantable cardiac device therapy (2.3 points over each observation) subscales.

Using an unstructured covariance matrix for all the models, we found that there was statistically significant individual variability in the linear rates of change for SF-36v2 role emotional, SF-36v2 social functioning, satisfaction with participation in social roles, and satisfaction with participation in discretionary social activities. However, an unstructured covariance matrix resulted in a model that failed to converge with 1000 iterations for the SF-36v2 role physical subscale, and thus the covariance parameters, and their corresponding test statistics and confidence intervals could not be computed. To address this issue, we specified a diagonal covariance matrix and were able to reach convergence, albeit with extremely wide confidence intervals.

At level 1 (within participants), there was a statistically significant residual variability noted in the average participant's score around her or his trajectory for the 6 social health measures. The models for SF-36v2 role emotional, SF-36v2 social functioning, satisfaction with participation in social roles, and satisfaction with participation in discretionary social activities all displayed evidence of variability in the rates of change (Table I in the Data Supplement).

In examining the level 2 (between participants) residuals, we also noted that the initial status (baseline) and growth rates were correlated for satisfaction with participation in discretionary social activities. The identification of individual trajectories of change warranted further model development to explore the effects of the selected predictors.

Step 3: Conditional Model—Time-Predictor Interaction Effects and Individual Trajectories of Change

Regardless of the variance of the intercepts, men and women differed significantly in their rates of change in the scores of SF-36v2 social functioning, satisfaction with participation in social roles, and satisfaction with participation in discretionary social activities. The different trajectories of men and women showed a similar pattern of change with women exhibiting worse social health status at baseline, experiencing a faster rate of change or improvement during the 6 months of follow-up, and achieving scores that exceeded the men's scores at the end of the observation period (Figure 2). The disparity in the absolute mean differences between the scores at baseline and at the 6-month follow-up ranged between 8.1 and 11.6 points for men, and 20.5 and 23.9 points for women. Although men's mean scores exceeded women's mean scores on all indicators at baseline (range of absolute mean difference: 7.0–9.6 points), the rate of change of women resulted in a reversal in standing at 6 months after implantation, with the mean score of women exceeding the men's by 2.8 to 4.1 (Table 3; Figure 3).

In addition to the identification of the sex-based differences in the participants' temporal changes in their social health indicators, we found some other salient subgroup trajectories of change. The participants that received their implant on an urgent inpatient basis had lower scores of the SF-36v2 social functioning subscale at baseline, but improved more rapidly and crossed over to reporting better scores compared with the relatively more medically stable elective outpatients. Marital status differentiated the change trajectories associated with

Table 2. Grouped Data: Descriptive Statistics and Change in Social Health Status

	Baseline	At 1 mo	At 2 mo	At 6 mo	Absolute Mean Difference*	Relative Mean Difference (%)†	Relative Mean Difference (SD)‡
SF-36v2 role physical§							
n	171	149	140	139			
Mean	44.8	43.3	54.3	60.6	15.8	35.3	0.52
SD	30.3	28.6	29.4	28.8			
Median	43.8	43.8	56.3	62.5			
SF-36v2 role emotional‖							
n	171	149	140	139			
Mean	62.8	65.6	72.9	70.1	7.3	11.6	0.23
SD	31.8	30.4	28.6	30.3			
Median	66.7	75.0	83.3	83.3			
SF-36v2 social functioning¶							
n	171	149	140	139			
Mean	60.3	66.1	73.6	74.6	14.3	23.7	0.48
SD	29.7	26.7	28.7	27.2			
Median	62.5	75.0	87.5	75.0			
Satisfaction with participation in social roles#							
n	171	149	140	139			
Mean	49.3	55.5	61.8	65.7	16.4	33.3	0.58
SD	28.4	28.9	29.1	27.4			
Median	50.0	57.1	69.6	71.4			
Satisfaction with participation in discretionary social activities**							
n	171	149	140	139			
Mean	50.7	57.4	60.7	62.6	11.9	23.5	0.39
SD	30.2	29.3	28.5	28.6			
Median	50.0	60.7	64.3	67.9			
Patient acceptance of implantable cardiac device therapy‡‡							
n		149	140	139			
Mean		69.6	74.9	74.4	4.8	6.9	0.27
SD		17.7	18.5	18.7			
Median		70.8	78.1	77.1			

*The difference in mean between the 6-month follow-up measure and baseline (ie, $\text{mean}_{(6\ mo)} - \text{mean}_{(baseline)}$).

†The difference in mean between the 6-month follow-up measure and baseline, relative to the baseline, presented as a percentage (ie, $\text{mean}_{(6\ mo)} - \text{mean}_{(baseline)} / \text{mean}_{(baseline)} \times 100$).

‡The absolute mean difference divided by the SD observed at baseline (ie, $\text{mean}_{(6\ mo)} - \text{mean}_{(baseline)} / \text{SD}_{(baseline)}$).

§Original item scaling 1 to 5; 4 items; Original score scale: 4 to 20.

‖Original item scaling 1 to 5; 3 items; Original score scale: 3 to 15.

¶Original item scaling 1 to 5; 2 items; Original score scale: 2 to 10.

#Original item scaling 1 to 5; 7 items; Original score scale: 7 to 35.

**Original item scaling 1 to 5; 7 items; Original score scale: 7 to 35.

‡‡Original item scaling 1 to 5; 12 items; Original score scale: 12 to 60.

SF-36v2 role emotional; the separated, divorced, or widowed participants exhibited the lowest scores during the entire course of follow-up, and the single participants achieved the greatest gains in their scores, over time. Indication for implantation was not a predictor of individual trajectories.

Discussion

The study was limited by the moderate sample size and number of measurement occasions; thus, the reader is cautioned to interpret the analyses within the context of this significant limitation. It was, in part, for this reason that we chose a statistical significance level of 0.10 to identify the remaining residual variance. We lacked information about potentially important patient characteristics, such as race and ethnicity, clinician-reported and longer-term shock history, and previous cardiac treatment (eg, previous pacemaker). The study would have been strengthened by having data that could have determined the temporal change trajectories beyond the 6 months studied. The selection of the early recovery period reflected a clinical interest to guide practice and processes of care at the healthcare center, but was likely

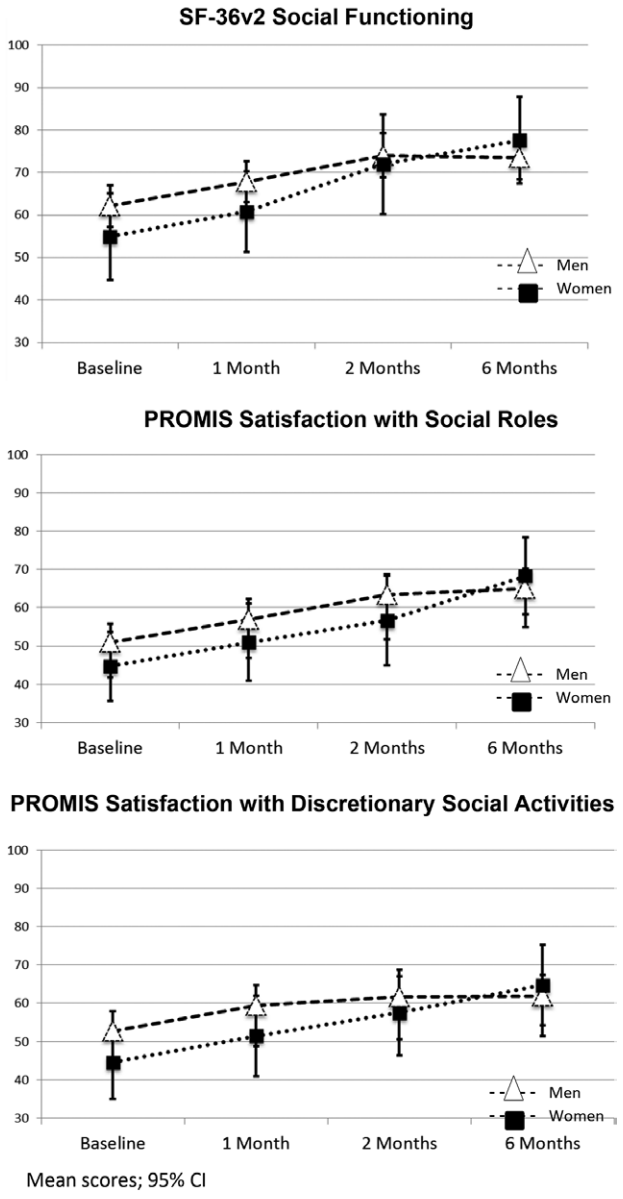

Figure 2. Sex-based trajectories of temporal change in social health (mean scores and 95% confidence intervals).

insufficient to understand the full trajectory of social health in the context of a permanently implanted device with lifetime implications related to surveillance, replacement requirements, and management of shock therapy. We cannot comment on the direction and trajectories of change identified in this study beyond the 6 months of follow-up.

The study contributes compelling new evidence that men and women differ in their trajectories of change in social health, both in terms of their starting points (ie, baseline scores) and their rates of change. The findings raise awareness of this aspect of people's health that remains poorly studied in the ICD population. The reasons for the differences found are probably multifactorial.

Sex Differences

The findings reported here echo previous cross-sectional research, which has raised concerns about sex disparities inpatient-reported outcomes in people with ICDs, with women reporting significantly poorer physical functioning and vitality,[37] higher anxiety, shock-related distress, depressive symptoms,[38,39] and difficulties in assuming social roles and responsibilities.[40] In contrast, in a systematic review of research focused on the effects of sex on disparities in psychological distress and QOL among patients with an ICD, researchers have found that sex did not significantly affect patient-reported outcomes in 26 of the 32 (80%) studies examined, leading to a conclusion that: there is insufficient evidence to conclude that sex per se is a major autonomous predictor for disparities (p. 798), and calls for caution about the clinical implications of the findings, further research sufficiently powered to reach more definitive conclusions.[41]

In our study, sex differences in trajectories may, to some extent, be associated with other patient characteristics that varied by sex. These differences provide some descriptive information about potential explanations for the observed differences in sex trajectories. The equivocal findings of this study and others' research may be related to many factors, including this study's specific focus on social health, the timing of measurement occasions, the selection of instruments, or other factors, such as response shift or differential item functioning.

Varying Trajectories

There are many possible explanations for the reported sex differences in social health trajectories. For example, previous research has highlighted that women exhibit greater catastrophizing tendencies, a phenomenon reported in the pain and psychological literature about a general catastrophic thinking style about medical events or somatic experiences that may predispose people to worse outcomes.[42] Although this discussion is speculative, it may shed light on how men and women evaluate their health status at the time of ICD implantation, and could inform patient teaching interventions.

Social support is an established influencing factor of patient outcomes. In a study of sex differences in the influence of social support on 1-year changes in functional status in older patients with heart failure, researchers found that women reported significantly less social support and poorer physical functioning at baseline, but the differences in clinically meaningful functional decline abated during the course of the first year of their treatment for heart failure.[43] This led the researchers to conclude that sex-directed strategies aimed at optimizing function may be of benefit in this population.

The finding in this study that sex differences abated over time, with men and women reporting similar outcomes at 6 months, raises questions about the shape and direction of change in the longer-term recovery period and adaptation to living with an ICD. We do not know whether the women continued to improve at a faster rate than the men, whether the men and women retained similar rates of change, or whether the men significantly worsened in the longer term. In particular, it may be worrisome to note the shape of the men's social health trajectories, and to speculate that they experienced a slower and possibly decelerating pattern of longer-term change. There is currently no research that has sufficiently addressed this question.

Table 3. Absolute and Relative Mean Differences in Social Health Status of Men and Women between Baseline and 6-Month Follow-Up

	Difference Between Baseline and 6 Mo Scores for Men		Difference Between Baseline and 6 Mo Scores for Women		Difference Between Men and Women at Baseline		Difference Between Men and Women at 6 Months	
	Absolute Mean Difference (Points)*	Relative Mean Difference (%)†	Absolute Mean Difference (Points)*	Relative Mean Difference (%)†	Absolute Mean Difference (Points)‡	Relative Mean Difference (%)§	Absolute Mean Difference (Points)‖	Relative Mean Difference (%)¶
SF-36v2 social functioning	10.2	16.1	21.3	37.8	7.0	11.0	–4.1	–5.6
Satisfaction with participation in social roles	11.6	21.8	23.9	53.8	8.9	16.7	–3.4	–5.2
Satisfaction with participation in discretionary social activities	8.1	15.1	20.5	46.4	9.6	17.8	–2.8	–4.5

*Absolute mean difference between baseline and 6-month scores for men or women is defined as the difference in mean between the 6-month follow-up measure and baseline (ie, $\text{mean}_{(6\ \text{months})}-\text{mean}_{(\text{baseline})}$).

†Relative mean difference between baseline and 6 months scores for men or women as a percentage is defined as the difference in mean between the 6-month follow-up measure and baseline, relative to the baseline, presented as a percentage (ie, $\text{mean}_{(6\ \text{months})}-\text{mean}_{(\text{baseline})}/\text{mean}_{(\text{baseline})}\times 100$).

‡Absolute mean difference in mean between men and women at baseline is defined as the difference in mean between men and women at baseline (ie, $\text{mean}_{(\text{men at baseline})}-\text{mean}_{(\text{women at baseline})}$).

§Relative mean difference between men and women at baseline as a percentage is defined as the difference in mean between men and women at baseline, relative to men's scores, presented as a percentage (ie, $\text{mean}_{(\text{men at baseline})}-\text{mean}_{(\text{women at baseline})}/\text{mean}_{(\text{men at baseline})}\times 100$).

‖Absolute mean difference in mean between men and women at 6 months is defined as the difference in mean between men and women at 6 months (ie, $\text{mean}_{(\text{men at 6 months})}-\text{mean}_{(\text{women at 6 months})}$).

¶Relative mean difference between men and women at 6 months as a percentage is defined as the difference in mean between men and women at 6 months, relative to men's scores, presented as a percentage (ie, $\text{mean}_{(\text{men at 6 months})}-\text{mean}_{(\text{women at 6 months})}/\text{mean}_{(\text{men at 6 months})}\times 100$).

A Faster Rate of Recovery

Recovery is inevitably influenced by biological (eg, sex) and social (eg, sex) factors. To date, the limited research available on sex differences has highlighted that although sudden cardiac death is less prevalent in women, at all ages, and occurs, on average, 10 years later in women than in men,[44] women with ICDs generally experience more anxiety and poorer QOL than do men. However, many of these studies have been inconclusive about the effects of sex.[41] The different trajectories of change identified in this study are congruent with research about other health conditions, which describes women's faster rates of recovery. For example, after standard knee arthroplasty, and in spite of greater functional limitations at the time of surgery, women were found to recover faster, gained better joint function, and experienced less pain in the early recovery period, compared with men.[45] Similarly, in a study of sex differences in the rate of fatigue development and recovery after musculoskeletal injury in the workplace,

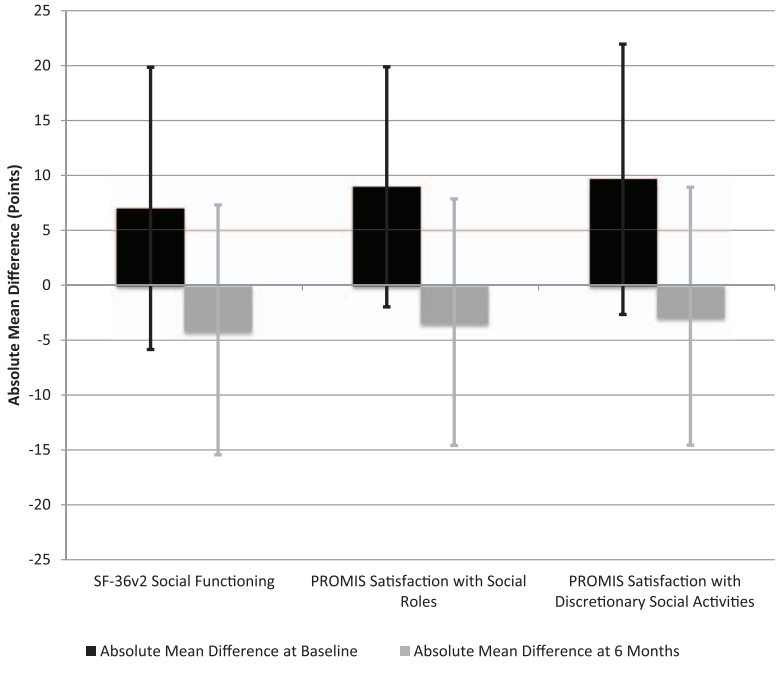

Figure 3. Absolute mean difference in social health status of men compared with women at baseline and 6-month follow-up (95% confidence intervals). PROMIS indicates Patient-Reported Outcomes Measurement Information System.

Albert[46] found that men experienced a greater relative loss of muscle strength, a higher rate of fatigue development, and a reduced capacity to maintain fatiguing contractions in their lower limbs, compared with women, thus decreasing their physical capacity and slowing their recovery. The reasons for these differences are currently not known, and more research is required to understand the mechanisms underpinning the different trajectories.

Conclusions

The ICD is a well-established protective device that augments the medical management of varying cardiac conditions by reducing the risk of mortality from sudden cardiac death. The permanency of the device and its implications on daily living can affect people's physical and emotional ability to resume their social roles, function, and activities. We found that the implantation of an ICD resulted in clinically important differences in the trajectory of men and women's social health during the initial 6-month recovery period.

We cautiously conclude that the findings of the study highlight important knowledge that warrants consideration in clinical practice. The implantation of the ICD is routinely preceded and followed by multidisciplinary interactions with patients focused on patient and family education, decision support, consent, discharge guidelines, and follow-up. The awareness of the overall improvement in social health over time, and the different trajectories experienced by men and women can enhance communication strategies. The findings may further inform the development of multidisciplinary interventions in the early recovery period to address alterations in social health, and improve overall outcomes and patients' QOL. In particular, the effects of shock on social health warrant investigation. Further research must be undertaken on the social components of health and differences between men's and women's trajectories of change before the association between sex and QOL in people with ICDs is more clearly understood.

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Disclosures

None.

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