HHS Public Access

Author manuscript

J Sex Med. Author manuscript; available in PMC 2021 May 01.

Published in final edited form as:

J Sex Med. 2020 May ; 17(5): 892–902. doi:10.1016/j.jsxm.2020.01.028.

Patient and Partner Sexual Concerns during the First Year after an Implantable Cardioverter Defibrillator: A Secondary Analysis of the P+P Randomized Clinical Trial

Megan M Streur, PhD[1], **Lindsey A Rosman, PhD**[2], **Samuel F Sears, PhD**[3], **Elaine E Steinke, PhD**[4], **Elaine A Thompson, PhD**[1], **Cynthia M Dougherty, PhD**[1]

[1]University of Washington, School of Nursing, Department of Biobehavioral Nursing and Health Informatics, Seattle, WA, USA

[2]University of North Carolina, School of Medicine, Department of Medicine, Division of Cardiology, Chapel Hill, NC, USA

[3]Department of Psychology, Department of Cardiovascular Sciences, East Carolina University, Greenville, NC, USA

[4]Wichita State University, School of Nursing, Wichita, KS, USA

Abstract

Background: Sexual concerns and changes in sexual activity are common among patients and their intimate partners after an implantable cardioverter defibrillator (ICD).

Aims: Our aims were to: 1) describe patient and partner sexual activity and related concerns from the time of an initial ICD implant through 12-month follow-up, and 2) identify factors predictive of return to sexual activity and fears associated with sexual activity.

Methods: This secondary descriptive analysis was conducted with data from a randomized controlled trial (2009–2015) designed to compare two interventions for patients (Patient-Only) and for patients and their partners (Patient + Partner) following implant of an initial ICD. The sample included 105 patients and their intimate partners who reported sexual activity during the 24 months *prior to* ICD implant.

Outcomes: The *Sexual Concerns Inventory* (SCI) was used to assess sexual activity and related concerns.

Results: Study participants were 72% male, mean age 65.6 ± 10.6; partners were 64% female, mean age 63 ± 11.6. Sexual activity increased post-ICD: 73% of patients reported no sexual intercourse during 2 months prior to study enrollment, whereas only 46% reported no sexual intercourse during the 2 months prior to 12-month follow-up. Reductions in sexual concerns were

Corresponding author: mstreur@uw.edu, cindyd@uw.edu.

Conflict of Interest: “None”

evident 1 month post implant, with continued reductions through 12 months (patient 6.48 ± 4.03 to 5.22 ± 3.38, p = 0.004; partner 6.93 ± 4.01 to 5.2 ± 3.56, p < 0.001). Patient physical health predicted sexual activity 3 months post implant (p = 0.04); general ICD concerns (p < 0.001) predicted patient ICD-related sexual fears at 3 months. At 12 months, baseline general ICD concerns (p < 0.02) predicted sexual fears.

Clinical Implications: ICD patients and partners report low levels of sexual activity at the time of initial ICD implant, with reported increases in sexual activity over the 12-month recovery period: Sexual concerns were highest immediately post ICD implant.

Strengths & Limitations: Notably, the major strengths of this study were the repeated measures and longitudinal study design; the main limitation of the study was the lack of a 'usual care' control group.

Conclusion: Sexual activity at the time of an initial ICD implant is low, and sexual concerns are most prominent for both patients and partners immediately post implant. Baseline physical health predicts subsequent sexual activity at 3 months, while general ICD-related worry predicts sexual fears at 3 and 12 months.

Keywords

implantable cardioverter defibrillator; sexual behavior; intimate partner

Introduction

The mortality benefits of implantable cardioverter defibrillators (ICDs) are well established,[1] yet many ICD patients and their partners struggle to return to a 'new normal' post-implant. Alteration in sexual activity is a common concern for patients with an ICD.[2–5] In a recent survey, 70% of male ICD patients reported erectile dysfunction and over 80% reported reductions in sexual desire and problems with intercourse satisfaction.[5] In one survey, one-third of ICD patients and their partners experienced diminished interest in sex.[3] Patients and partners cite apprehension, fear, and over protectiveness as factors that influence interest in sex, often linked to concerns that sexual activity could trigger a cardiac event or ICD shock.[3,6] Research to date indicates that a substantial proportion of patients and their partners have misconceptions about the safety and efficacy of their ICD in relation to sexual activity. American Heart Association (AHA) guidelines indicate sexual activity is safe to resume for most patients, except for individuals with sub-optimally controlled arrhythmias or those for whom moderate physical activity precipitates ventricular arrhythmias.[7,8]

In the general population, nearly half of all men and women report some form of sexual problem or concern.[9] Erectile difficulty is the most common problem in men, affecting 37% of adult men 57–85 years of age, whereas low desire (43%) is the most common problem reported by women of the same age.[10] The prevalence of sexual activity decreases with age[9,10] and declining health status.[9] Using a nationally representative probability sample of adults, Lindau[9] described 67% of men 65–74 years of age and 38.5% of men 75–85 years of age reported sexual activity with a partner in the previous 12 months, compared to 39.5% and 16.7% of similarly aged women. Compared to adults with excellent or good self-rated

health status, those with fair or poor health reported the lowest rates of sexual activity (47.1% for men and 26.2% for women).[9]

While these data suggest that alterations in sexual activity are common among ICD recipients, little is known about long-term sexual outcomes or adjustment among ICD couples. Prior research on sexual activity in ICD couples has been limited by methodological issues (e.g. small samples, cross-sectional study designs), markedly curtailing understanding of sexual activity during the first-year post-ICD implant. Moreover, descriptions of changes in sexual concerns and activity over time are sparse. Since sexual problems may adversely affect long-term treatment compliance with cardiovascular medications and impair quality of life,[11] efforts to understand whether sexual problems persist and potentially worsen over time are needed to inform patient counseling and expectations about sexual recovery. The purpose of this study was to describe patient and partner sexual activity and concerns during the 12 month period following an initial ICD. Secondarily, we examined characteristics that predict return to sexual activity and sexual fears post-ICD at 3 and 12 months post-ICD implant. Thus, this study addresses a significant gap in the literature related to long-term sexual outcomes among ICD recipients, providing important insights into the sexual concerns of ICD patients and partners.

Materials and Methods

The Primary Study

This is a secondary descriptive analysis of data from a prospective 2-group blocked randomized controlled trial (N=301 dyads) conducted between 2009 and 2015. The blocking variable was ICD indication, defined as primary versus secondary prevention of sudden cardiac arrest (SCA). Randomization was performed using a computer algorithm based on balancing principles outlined by Popock.[12] The primary study compared outcomes between a Patient-Only (P-Only) and a Patient + Partner (P+P) intervention during the first-year following initial ICD implant. A complete description of the larger study is reported elsewhere.[13] In brief, the primary study showed that the P+P intervention was superior to the P-Only intervention for the patient outcomes of self-reported physical symptoms, depression, self-efficacy, outcome expectations, and knowledge, and for the partner outcomes of caregiver burden, self-efficacy, and knowledge.[14] There were no statistically significant differences in sexual concerns between patient or partner groups over time.[14]

Participants were enrolled within 24 hours of hospital discharge from 17 medical sites in the Pacific Northwest and Southeast U.S. *Inclusion criteria* were: 1) first ICD implant for primary or secondary prevention of SCA, 2) intimate partner (spouse, lover or life partner) living at the same residence, 3) proficient in English, and 4) telephone access for 1-year after ICD implant. *Exclusion criteria* were: 1) clinical co-morbidities that impaired cognitive and physical functioning, 2) Orientation-Memory-Concentration Test (Short BLESSED) score > 6,[15,16] 3) age < 21 years, 4) Alcohol Use Disorders Identification Test (AUDIT-C) score > 4 for alcohol use,[17] and 5) Alcohol, Smoking and Substance Involvement Screening Test (ASSIST 2.0) score > 4 for daily non-medical use of opiates or hallucinogens.[18]

Procedure.—The University of Washington Institutional Review Board approved the trial research procedures. Participants provided written informed consent and were given a small stipend for participation. After baseline data were collected, individuals were randomized to one of the two intervention conditions, stratified by ICD indication, age, sex and the Charlson Co-morbidity Index.[19] Data were collected from patients and their partners five times: hospital discharge, 1-, 3-, 6-, and 12-months post-ICD implant. Pre-specified primary and secondary outcomes included physical functioning, psychological adjustment, healthcare utilization, and relationship impact. All participants received usual care from their healthcare providers.

Study intervention conditions.—Intervention elements were derived from Social Cognitive Theory[20] and the earlier study, "Experiences of Recovery Following Sudden Cardiac Arrest."[21,22] Intervention goals were to assist patients and their partners to manage physical symptoms, resume ADLs and exercise, manage anxiety and depression, prepare for ICD shocks and management, and understand when to activate the emergency medical system.

The *P-Only intervention* included 4 elements: 1) a booklet that described other patients' experiences during the first year of ICD recovery coupled with a discussion of managing recovery issues, 2) weekly Nurse Telephone Support (NTS) call to each patient for 8 weeks, with additional follow-up calls at 10 and 12 weeks, 3) Nurse Pager, a toll-free pager providing access to a research nurse 24 hours, 7 days/week, and 4) a video produced by the manufacturer of each patient's ICD device. The *P+P Intervention* included the same 4 elements as P-Only, plus integration of the partner into the intervention process through: 1) six telephone-based partner group sessions, 2) a partner-focused booklet, 3) partner access to the Nurse Pager, and 4) seven partner-focused video segments on topics covered in NTS calls. Patient participants in both study conditions received treatment as usual from their health care providers.

The Present Study

Sample.—The sample for this secondary analysis was drawn from the larger sample of 301 dyads (150 randomized to P+P, 151 to P-Only). Patients in both intervention conditions received the same intervention, therefore we combined participants into one group for this analysis. Of the full sample, 35% (N = 105) of patients reported having engaged in sexual intercourse during the 24 months *prior to* ICD implant: these 105 patients and their matched partners were included in this study. The 24 month period was chosen to ensure an adequate sample size with recent enough sexual activity that resumption of sexual activity would be reasonable to anticipate.

Measures.—Demographic information collected for each participant included self-reported age, sex, race/ethnicity, education level, employment status, and income.

Sexual Concerns Inventory (SCI) evaluates concerns about engaging in sexual activity after an ICD, with separate versions for patients and partners.[3,6] The measure includes a total of 8 items. Items 1 through 5 are scored with a Likert-type rating ranging from 0 = never to 3 = frequently. The SCI total score is calculated by summing the scores of items 1 through 5.

The sixth item measuring frequency of sexual activity during the past two months is rated as 0 = not at all, 1 = once a month, 2 = once a week, 3 = twice a week, or 4 = more than twice a week. The last two items include a fill-in-the-blank item asking how many months have passed since engaging in sexual intercourse, and an optional open-ended item asks participants to identify other sexual concerns. To date, the SCI is the only available measure developed specifically to assess sexual concerns in individuals with an ICD. A detailed definition of sexual intercourse was provided to study participants, which included vaginal, anal or finger penetration, and/or oral sex.

Charlson Co-Morbidity Index (CCI) is a validated measure used to classify the number and severity of comorbid conditions.[19] The CCI is a sensitive and widely used indicator of comorbidity status, including among individuals with cardiovascular disease[23] and sexual dysfunction.[24] Several cardiac and non-cardiac conditions are included in the index, including myocardial infarction, heart failure, peripheral vascular disease, cerebrovascular accident, dementia, chronic obstructive pulmonary disease, connective tissue disease, peptic ulcer disease, liver disease, diabetes mellitus, hemiplegia, kidney disease, tumor, leukemia, lymphoma, and AIDS. In scoring, comorbidities are weighted based on severity.

Short Form Health Survey (SF-36) assesses both physical and mental health.[25,26] Two composite summary scales of physical (PCS) and mental health (MCS) are derived. For this sample, Cronbach's reliability was 0.83 for PCS and 0.86 for MCS.

State-Trait Anxiety Inventory (STAI-S) is a 20-item assessment of trait and state anxiety; only state anxiety was assessed in this study. The STAI is sensitive to changes in response to interventions in SCA populations.[27] Cronbach's reliability for this sample was 0.95.

Patient Health Questionnaire (PHQ-9) measures depressed mood and provides an index of depression severity. The measure correlates highly ($r = 0.84$) with mental health professional assessments of depression symptom severity.[28,29] Cronbach's reliability was 0.82.

ICD Patient Concerns Questionnaire (ICDC) is a 20-item inventory used to assess the number and severity of concerns and worries experienced by individuals living with an ICD.[30] The inventory correlates moderately with anxiety (r = 0.50 in this sample).

Dyadic Adjustment Scale (DAS) is a 32-item scale with four subscales that capture dyadic satisfaction, cohesion, expression, and consensus.[31] Cronbach's reliability was 0.93 for the total scale.

Analysis.—Patient and partner characteristics were described using proportions for categorical variables and means (SD) for continuous variables. Generalized estimating equations (GEE) were used to estimate mean change in sexual concerns and activity from baseline to 12-month follow-up for the SCI total score and the SCI items 1–6, separately. Repeated measures were assumed to have a first-order autoregressive correlation structure; robust variance estimators were used. Across-time differences were evaluated using the Wald chi-square test. GEE and Wald chi-square test were also used to separately estimate mean change in sexual concerns and activity by sex and by intervention condition. The separate analysis by sex should be interpreted with caution due to the small number of

female patients and male partners in the sample. Wilcoxon signed ranks test were conducted post-hoc to compare the frequency of patient-reported sexual activity between each time point.

Multivariable logistic regression was used to explore for factors predictive of sexual activity and multivariate linear regression was used to examine factors predictive of ICD-related sexual fear at 3- and 12-months post ICD implant. Potential predictors included in the analyses were age, sex, ICD indication, co-morbidity profile (CCI), physical health (SF-36 PCS), anxiety (STAI), depression (PHQ-9), general ICD Concerns (ICDC), dyadic adjustment (DAS), intervention condition (P-Only vs P+P), lack of interest in sex, over protectiveness of partner, and difficulty with erection.

For the outcome variables, sexual activity was based on the SCI item that inquired about sexual activity during the past 2 months (dichotomized yes = 1, no = 0). Sexual fear was based on two SCI items (fear of cardiac arrest if ICD does not fire during sex, and fear the ICD will fire during sex). Statistical analyses were conducted with IBM SPSS (V19) using two-tailed tests of statistical significance with $p < 0.05$.

Also, patient and partner free-text responses to the open-ended sexual concerns question were coded and evaluated to determine the presence of other concerns, beyond the scope of SCI. Concerns were categorized and counts within these categories were determined at baseline, 3- and 12-months. Open-ended comments were initially coded by two authors with experience in qualitative research (MS and LR). The codes were reviewed and a final coding structure approved by two additional authors with qualitative research experience (ET and CD).

Results

Patient and Partner Characteristics

This study included 105 dyads that reported engaging in sexual intercourse during the 24 months *prior to* ICD implant (Table 1). Of these, 102 (97%) intimate dyads identified as heterosexual, and 3 (3%) identified as gay or lesbian. The patient sample was primarily male (72%) with a mean age of 65.6 ±10.6, while partners were primarily female (64%) with a mean age of 63 ±11.6. The sample was predominantly Caucasian both for patients (91%) and for partners (89%). More patients received an ICD for primary (57%) than secondary prevention (43%). Study attrition was low, with a patient drop-out of 7% and partner drop-out of 6% at the 12 month study visit.

Sexual Activity

Most patients (73%) reported no sexual intercourse during the 2 months prior to study enrollment, with 16% reporting monthly intercourse and 11% reporting weekly intercourse during the same timeframe. Overall, the frequency of sexual activity reported by patients and partners increased across the 12-month recovery period (Table 2). At 12 months, less than half (46%) of the patients reported no sexual intercourse in the past 2 months, 33% reported monthly intercourse, 12% weekly, and 2% twice weekly: We conducted post-hoc comparisons of the frequency of patient-reported sexual activity across time using Wilcoxon

signed ranks test (Figure 1), where significant increases in sexual activity were observed from baseline to 1, 3, and 12 months. Similarly, when male and female patients and partners were analyzed separately, similar increases in sexual activity were seen across time (Supplemental Table 1). Likewise, patients and partners in both the P-Only and P+P intervention arms both reported statistically significant increases in sexual activity over the 12 months of study follow-up (Supplemental Table 2).

Sexual Concerns

At baseline, over half (55%) of the patients and 41% of partners reported an occasional or frequent lack of interest in sex. Sexual fears and concerns were common; 52% of patients and 68% of partners reported their partner was occasionally or frequently overprotective; 30% of patients and 26% partners reported occasionally or frequently fearing that the ICD would fire during sex; and 26% of patients and 34% of partners reported occasional or frequent fear that cardiac arrest would occur if the ICD did not fire if necessary during sex.

Significant and sustained improvements in sexual concerns (Table 2) were evident as early as 1-month post-implant for both patients and partners ($p = 0.004$ and $p < 0.001$, respectively), specifically in partner over protectiveness, fear that ICD would fire during sex, and fear of cardiac arrest if the ICD did not fire. Interest in sex and difficulty with an erection did not change significantly between baseline and 12-month follow-up for either patients or partners. Sub-group analyses by sex demonstrated significant improvements in total sexual concerns for female patients and partners ($p = 0.04$ and $p < 0.001$), but not for male patients or partners ($p = 0.05$ and $p = 0.17$; Supplemental Table 1). Similarly, female patients and partners demonstrated significant reduction in concern regarding their partner's overprotectiveness ($p = 0.003$ and $p = 0.002$), but males did not ($p = 0.08$ and $p = 0.15$). Female patients were the only group that showed significant increases in interest in sex ($p = 0.03$). Both male and female patients and partners demonstrated significant reductions in fear that the ICD would fire during sex. There was no decrease in the fear of cardiac arrest if the ICD did not fire for male or female patients, but this fear decreased for male and female partners ($p = 0.02$ and $p < 0.001$) over the 12 months of follow-up. Sub-group analyses by intervention condition (P-Only and P+P groups) showed that patients in the P+P intervention reported statistically significant improvements in total sexual concerns ($p = 0.001$) and partner overprotectiveness ($p = 0.003$), whereas similar improvements were not evident for patients in the P-Only intervention (Supplemental Table 2). On the other hand, partners in the P-Only intervention reported statistically significant improvements in partner overprotectiveness ($p = 0.003$) and fear that the ICD might fire during sex ($p < 0.001$), while similar improvements were not evident for partners in the P+P intervention. Other indicators of sexual concerns and activity showed similar improvement for the two intervention conditions.

Patient and partner comments in response to open-ended questions about their sexual concerns are summarized in Table 3. At baseline, 23 (22%) patients and 39 (40%) partners provided responses to the open-ended question, with fewer respondents at subsequent time-points. Some comments were redundant with the scored SCI items (e.g. erectile dysfunction). At baseline, the most frequently cited patient concerns were fear of the ICD

firing or malfunctioning and pre-morbid limitations in sexual activity, while partners focused on physical health and pre-morbid limitations to sexual activity.

Predicting Patient-Reported Sexual Activity and Sexual Fears

Sexual activity at 3 months was influenced only by physical health (SF-36 PCS, OR= 1.9, p = 0.04) in the multivariable logistic regression analysis, and none of the variables predicted sexual activity at 12 months. Thus, at 3 month follow-up, the odds of engaging in sexual activity was an average of 2 times more likely with every 1 point increase in baseline physical health (SF-36 PCS), signaling the centrality of physical health for engaging in sexual activity.

Examined singly, age and baseline ICD concerns, anxiety, and depression were significant predictors of 3- and 12-month sexual fears. When all predictors were examined simultaneously using multivariate linear regression (Table 4), only general ICD concerns (ICDC) predicted patient ICD-related sexual fears at 3 ($\beta = 0.54$, $p < 0.001$) and 12-months ($\beta = 0.32$ $p = 0.02$) post implant. At 3 months, the effect of baseline depression (PHQ-9) trended toward significance ($\beta = 0.24$, $p = 0.05$) in the multivariate analysis.

We also examined if a history of SCA or the use of cardiac resynchronization therapy (CRT) influenced sexual activity and/or sexual fear at 3 and 12 month follow-up. Neither SCA or CRT predicted sexual activity at 3 months. On the other hand, a history of SCA predicted lower sexual fears ($\beta = -0.21$, $p = 0.04$) at 3 months, but CRT did not. Neither SCA nor CRT predicted sexual activity or sexual fears at 12 months.

Discussion

This study addresses a notable gap in the literature related to changes in patient and partner sexual concerns during the first year following initial ICD implant. Our findings, generally congruent with earlier research,[3,6,32] confirm that sexual fears and concerns were common for both ICD patients and their partners. Steinke,[3] using a cross-sectional ICD survey of patients and partners, found levels similar to our findings for baseline patient and partner over protectiveness (56%, 59%, respectively), fear of ICD firing (29%, 30%), and fear of cardiac arrest (24%, 32%). Our longitudinal study, however, extends this research by revealing that sexual concerns improved significantly by 1-month post-implant and continued to improve, though modestly, through the 12-month follow-up period. Overall, sexual concerns reported at the time of hospital discharge indicate that patients and partners may benefit from receiving specific information and guidance from health care providers regarding safely resuming sexual activity prior to hospital discharge.[6,8]

In contrast to our findings, prior research has shown that patients commonly experience reductions in sexual activity following ICD implant.[3,32,33] Steinke[3] showed that 78% of patients reported being sexually active prior to ICD implant, whereas only 55% reported being sexually active post-implant. Berg[32] reported that 67% of patients were sexually active prior to ICD implant and 52% were sexually active 6-months post implant. In contrast, in the present study sample 27% of the patients reported being sexually active during the 2 months prior to ICD implant, increasing to 47% by 12-month follow-up. One possible explanation

for the divergent levels of reported sexual activity is that the prior studies were qualitative[33] or cross-sectional[3,32] in design, sometimes requiring that participants recall patterns of sexual activity from years prior.[3] In comparison, although recall of sexual activity within the past 24-months determined which participants were included in this study sample, the data were collected prospectively at baseline and at repeated time points across 12 months following an ICD implant. Further, our measure of sexual activity referenced behavior within the past 2 months, minimizing the risk of recall bias. It is possible that responses in the earlier studies may have been more prone to recall bias than the present study. In addition to differences in the timing of follow-up, it is plausible to assume that the increase in sexual activity reported following ICD implant might be associated with the interventions, both of which were designed to improve psychosocial and physical health outcomes, including guidance on resuming physical activity. However, there was no treatment-as-usual control condition, so we could not distinguish the influence of intervention exposure compared to usual treatment.

Examining for independent predictors of sexual activity, physical health was the only significant predictor of sexual activity, and general ICD-related worries of ICD-related sexual fears. Improved physical health is likely to improve patient physical deficiency and male sexual dysfunction capacity to engage in sexual activity. In a recent randomized trial, Palm[35] found that a sexual rehabilitation program for cardiac patients, comprised of physical exercise training, pelvic floor exercises, and psychoeducation, resulted in improved erectile function when compared to usual care. However, earlier studies indicate that from 3–19% of patients do not engage in sexual activity due to fear that the ICD will fire.[38,39] Fear of the ICD firing, however, is only one of many reasons patients may avoid sexual activity. Cutitta[2] surveyed 443 ICD patients in the United States and reported that 65% (N = 286) were capable of having sex, but 48% of those capable chose to avoid sexual activity. Reasons cited for avoidance included not only fear of shock (3%) but also lack of desire (24%), increased heart rate (6%), physician instructions (2%), and other undisclosed reasons (34%).

Hormonal status was not evaluated in this study, thus testosterone level could not be included as a covariate in the multivariable analysis. Corona[34] demonstrated that reduced testosterone levels are associated with erectile dysfunction and reductions in the frequency of sexual intercourse. Further, chronic cardiovascular disease, cardiac medications, and invasive procedures are associated with testosterone deficiency and erectile dysfunction.[36,37] Future research is warranted to examine the role of hormonal status on male sexual function and activity pre- and post-ICD implantation.

Our longitudinal results indicate that many intimate dyads resume sexual activity over the year following ICD implant. In addition, our findings confirm a high level of sexual inactivity and concerns that exist for patients with an ICD and their partners both pre- and post-implant. Intervention studies focused on physical activity and psychosocial concerns post ICD implant are ideal for examining sexual concerns and activity, as these areas are highly intertwined.[8] These findings, taken together with prior research, suggest that timely interventions may improve sexual function, and reducing concerns may be indicated to enhance return to sexual activity. Our research showed that female patients and partners initially endorse more sexual concerns than males, suggesting that different intervention

strategies may be indicated for males and females. Information regarding safely engaging in sex after an ICD in the early post-implant period, and dealing with long-term changes in sexual desire and sexual function is highly relevant for both the patient and partner. Further, patients and partners with poor physical health may benefit from exercise training, as well as targeted education on strategies to promote physical intimacy despite physical limitations.

Strengths & Limitations

The original study was designed to compare two forms of the post-ICD intervention, and consequently there was no 'usual care' control group, nor a control group without an ICD implant. Thus, all patients with an ICD participated in the intervention, making it impossible to distinguish if patient participation in the intervention was associated with change in patient sexual concerns or activity. Intervention condition did not predict patient sexual concerns. In addition, testosterone levels were not assessed, consequently the influence of hormonal status on patient sexual concerns could not be explored. The study design, however, specifically the repeated measurement and longer-term follow-up, provides the most reliable description available on changes in sexual concerns and activity following initial ICD implant for patients and partners.

Conclusions

ICD patients and partners report low levels of sexual activity at the time of an initial ICD implant and sexual activity increases over a 12-month recovery period. Sexual concerns are highest immediately after an ICD implant, and tend to resolve as time passes with return to sexual activity. Common concerns related to resumption of sexual activity (e.g., fear of ICD firing inappropriately, fear of ICD not firing when needed) should be addressed in the early post-implant period, when concerns are most evident. Physical health is an important predictor of sexual activity following ICD implant. Addressing concerns and physical limitations may ease patient and partner fears, thereby helping patients and partners feel ready to resume sexual activity.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

References

1. Bardy G, Lee K, Mark D, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. New England Journal of Medicine. 2005;352(3):225–237. [PubMed: 15659722]
2. Cutitta K, Woodrow L, Ford J, et al. Shocktivity: ability and avoidance of daily activity behaviors in ICD patients. Journal of Cardiopulmonary Rehabilitation and Prevention. 2014;34(4):241–247. [PubMed: 24667666]
3. Steinke EE. Sexual concerns of patients and partners after an implantable cardioverter defibrillator. Dimensions of Critical Care. 2003;22(2):89–96.
4. Van Den Broek K, Habibović M, Pedersen S. Emotional distress in partners of patients with an implantable cardioverter defibrillator: A systematic review and recommendations for future research. Pacing and Clinical Electrophysiology. 2010;33(12):1442–1450. [PubMed: 20946298]

5. Palm P, Zwisler A, Svendsen J, Giraldi A, Rasmussen M, Berg S. Compromised sexual health among male patients with implantable cardioverter defibrillator: A cross-sectional questionnaire study. Sexual Medicine. 2019;7(2):169–176. [PubMed: 30674447]
6. Steinke EE, Gill-Hopple K, Valdez D, Wooster M. Sexual concerns and educational needs after an implantable cardioverter defibrillator. Heart & Lung. 2005;34(5):299–308. [PubMed: 16157184]
7. Levine G, Steinke E, Bakaeen F, et al. Sexual activity and cardiovascular disease: A scientific statement from the American heart association. Circulation. 2012;125(8):1058–1082. [PubMed: 22267844]
8. Steinke E, Jaarsma T, Barnason S, et al. Sexual counseling for individuals with cardiovascular disease and their partners: A consensus document from the American heart association and the ESC council on cardiovascular nursing and allied professions (CCNAP). Circulation. 2013;128(18):2075–2096. [PubMed: 23897867]
9. Lindau S, Schumm L, Laumann E, Levinson W, O'Muircheartaigh C, Waite L. A study of sexuality and health among older adults in the United States. New England Journal of Medicine. 2007;357(8):762–774. [PubMed: 17715410]
10. Herbenick D, Reece M, Schick V, Sanders S, Dodge B, Fortenberry J. Sexual behavior in the United States: results from a national probability sample of men and women ages 14–94. The Journal of Sexual Medicine. 2010;7(5):255–265. [PubMed: 21029383]
11. Scranton R, Goldstein I, Stecher V. Erectile dysfunction diagnosis and treatment as a means to improve medication adherence and optimize comorbidity management. Journal of Sexual Medicine. 2013;10(2):551561.
12. Pocock S Clinical trials: A practical approach. John Wiley and Sons; 1983.
13. Dougherty CM, Thompson EA, Kudenchuk PJ. Development and testing of an intervention to improve outcomes for partners following receipt of an implantable cardioverter defibrillator in the patient. Advances in Nursing Science. 2012;35(4):359–377. [PubMed: 23107992]
14. Dougherty C, Thompson E, Kudenchuk P. Patient plus partner trial: A randomized control trial of two interventions to improve outcomes following an initial implantable cardioverter defibrillator. Heart Rhythm. 2019;16(3):453–459. [PubMed: 30340060]
15. Katzman R, Brown T, Fuld P, Peck A, Schechter R, Schimmel H. Validation of a short orientation-memory-concentration test of cognitive impairment. American Journal of Psychiatry. 1983;140(6):734–739. [PubMed: 6846631]
16. Morris JC, Heyman A, Mohs RC, et al. The consortium to establish a registry for alzheimer's disease (CERAD). part I. clinical and neuropsychological assessment of alzheimer's disease. Neurology. 1989;39(9):1159–1165. [PubMed: 2771064]
17. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): An effective brief screening test for problem drinking. Ambulatory care quality improvement project (ACQUIP). Alcohol use disorders identification test. Archives of Internal Medicine. 1998;158(16):1789–1795. [PubMed: 9738608]
18. Humeniuk R, Ali R, Babor TF, et al. Validation of the alcohol, smoking and substance involvement screening test (ASSIST). Addiction. 2008;103(6):1039–1047. [PubMed: 18373724]
19. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: Development and validation. Journal of Chronic Diseases. 1987;40(5):373–383. [PubMed: 3558716]
20. Bandura A Social cognitive theory: An agentic perspective. Annual Review of Psychology. 2001;52:1–26.
21. Dougherty CM, Benoliel JQ, Bellin C. Domains of nursing intervention after sudden cardiac arrest and automatic internal cardioverter defibrillator implantation. Heart & Lung. 2000;29(2):79–86. [PubMed: 10739483]
22. Dougherty CM, Pyper GP, Benoliel JQ. Domains of concern of intimate partners of sudden cardiac arrest survivors after ICD implantation. Journal of Cardiovascular Nursing. 2004;19(1):21–31. [PubMed: 14994779]
23. Amin M, Witt C, Waks J, et al. Association between the Charlson comorbidity index and outcomes after implantable cardioverter defibrillator generator replacement. Pacing and Clinical Electrophysiology. 2019;42(9):1236–1242. [PubMed: 31355952]

24. Boeri L, Capogrosso P, Ventimiglia E, et al. Does Calculated Free Testosterone Overcome Total Testosterone in Protecting From Sexual Symptom Impairment? Findings of a Cross-Sectional Study. The Journal of Sexual Medicine. 2017;14(12):1549–1557. [PubMed: 29198510]
25. Ware JE. Standards for validating health measures: Definition and content. Journal of Chronic Diseases. 1987;40(6):473–480. [PubMed: 3298292]
26. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. conceptual framework and item selection. Medical Care. 1992;30(6):473–483. [PubMed: 1593914]
27. Bloom L Psychology and cardiology: Collaboration in coronary treatment and prevention. Professional Psychology. 1979;10(4):485–490.
28. Gilbody S, Richards D, Brealey S, Hewitt C. Screening for depression in medical settings with the patient health questionnaire (PHQ): A diagnostic meta-analysis. Journal of General Internal Medicine. 2007;22(11):1596–1602. [PubMed: 17874169]
29. Wittkampf KA, Naeije L, Schene AH, Huyser J, van Weert HC. Diagnostic accuracy of the mood module of the patient health questionnaire: A systematic review. General Hospital Psychiatry. 2007;29(5).
30. Frizelle D, Lewin B, Kaye G, Moniz-Cook E. Development of a measure of the concerns held by people with implanted cardioverter defibrillators: The ICDC. Br J Health Psychol. 2006;11:293–301. [PubMed: 16643700]
31. Spanier G Measuring dyadic adjustment: New scales for assessing the quality of marriage and similar dyads. Journal of Marriage and Family. 1976;38(1):15–28.
32. Berg S, Elleman-Jensen L, Zwisler A, et al. Sexual concerns and practices after ICD implantation: Findings of the COPE-ICD rehabilitation trial. European Journal of Cardiovascular Nursing. 2013;12(5):468–474. [PubMed: 23303767]
33. Palacios-Ceña D, Losa Iglesias M, Losa M, Fernández-de-Las-Peñas C, Salvadores-Fuentes P. Living with life insurance: A qualitative analysis of the experience of male implantable defibrillator recipients in Spain. Journal of Clinical Nursing. 2011;20(13):2003–2013. [PubMed: 21362076]
34. Corona G, Mannucci E, Ricca V, et al. The age-related decline of testosterone is associated with different specific symptoms and signs in patients with sexual dysfunction. International Journal of Andrology. 2009;32(6):720–728. [PubMed: 19226406]
35. Palm P, Zwisler A, Svendsen J, et al. Sexual rehabilitation for cardiac patients with erectile dysfunction: A randomised clinical trial. Heart. 2019;105(10):1–8. [PubMed: 30541875]
36. McCabe MP, Sharlip ID, Lewis R, et al. Risk Factors for Sexual Dysfunction Among Women and Men: A Consensus Statement From the Fourth International Consultation on Sexual Medicine 2015. Journal of Sexual Medicine. 2016;13(2):153–167. [PubMed: 26953830]
37. Lotti F, Maggi M. Sexual dysfunction and male infertility. Nature Reviews Urology. 2018;15(5):287–307. [PubMed: 29532805]
38. Kuhl E, Dixit N, Walker R, Conti J, Sears S. Measurement of patient fears about implantable cardioverter defibrillator shock: An initial evaluation of the Florida shock anxiety scale. Pacing and Clinical Electrophysiology. 2006;29(6):614–618. [PubMed: 16784427]
39. Groeneveld P, Matta M, Suh J, Yang F, Shea J. Quality of life among implantable cardioverter-defibrillator recipients in the primary prevention therapeutic era. Pacing and Clinical Electrophysiology. 2007;30(4):463–471. [PubMed: 17437568]

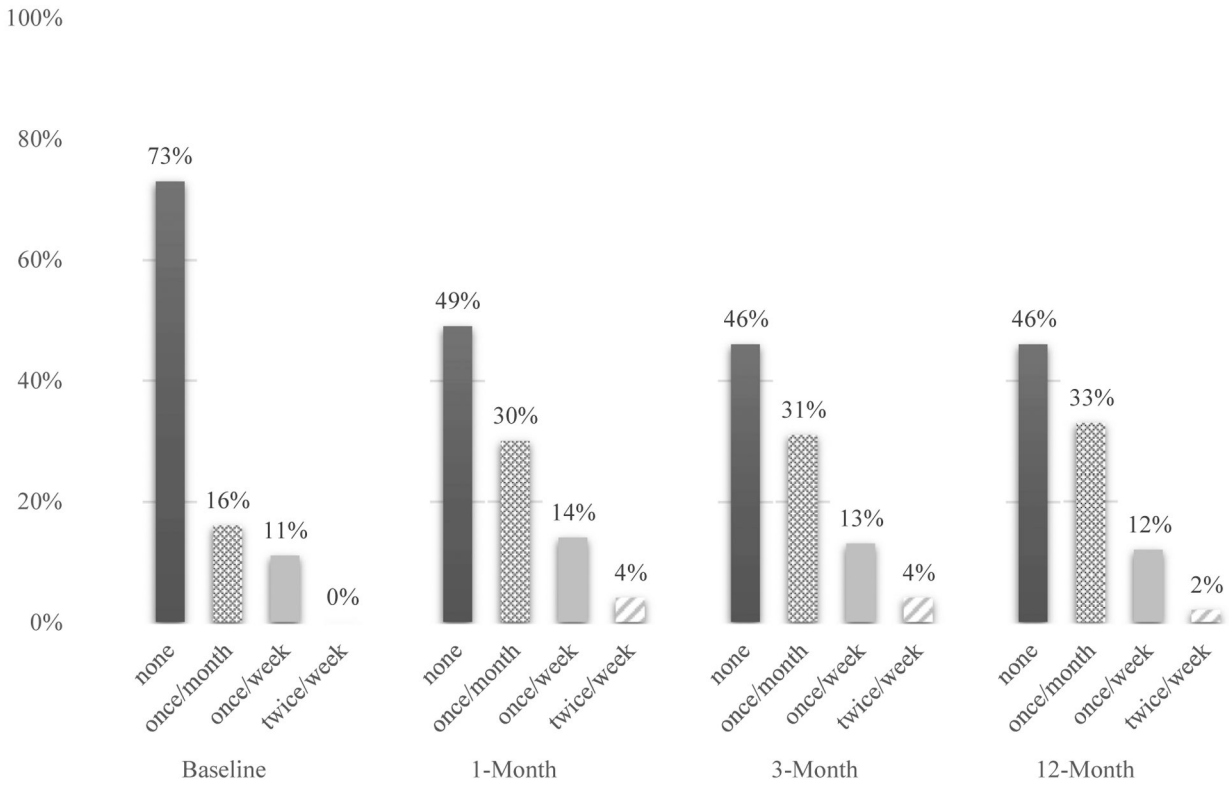

Figure 1.

Patient Reported Frequency of Sexual Activity from Initial ICD Implant (Baseline) through 12 Months Post ICD Implant. Each bar graph above illustrates the proportion of patients reporting the frequency of their sexual activity as none, once per month, once per week, or two or more times per week during the prior two months, asked at baseline, 1, 3, and 12 months. Initially, 73% of patients reported no sexual activity within the past two months. Using Wilcoxon signed ranks tests, we examined for shifts in the proportion of patients reporting some increase in frequency of sexual activity. Significant increases were observed from baseline to 1 month ($p<0.001$), with a similar pattern evident from baseline to 3 months ($p<0.001$) and baseline to 12 months ($p<0.001$). The pattern remained stable across time, with no significant changes from 1 to 3 months ($p=0.518$), 1 to 12 months ($p=0.147$), or 3 to 12 months ($p=0.435$).

Table 1.

Baseline Demographic and Clinical Characteristics of Patients and Partners

Characteristic	Current Study Patients (N=105)	Primary Study Patients* (N=196)	Current Study Partners (N=105)	Primary Study Partners* (N=196)
Intervention Condition				
P-Only	54 (51%)	97 (50%)	54 (51%)	97 (50%)
P+P	51 (49%)	99 (51%)	51 (49%)	99 (51%)
Sex, N (%)				
Male	76 (72)	146 (75)	30 (29)	48 (25)
Female	29 (28)	50 (26)	75 (71)	148 (76)
Ethnicity, N (%)				
Caucasian	96 (91)	178 (91)	93 (89)	173 (88)
Hispanic/Latino	3 (3)	3 (2)	4 (4)	5 (3)
Black/African	3 (3)	9 (5)	3 (3)	7 (4)
American Indian/Alaskan	2 (2)	4 (2)	3 (3)	6 (3)
Asian/Pacific Islander	1 (1)	2 (1)	2 (2)	5 (3)
Education, N (%)				
High school or less	54 (52)	77 (39)	44 (42)	73 (37)
Some college/college grad	34 (32)	71 (36)	37 (35)	77 (39)
Graduate School (Master, Doctorate)	14 (13)	37 (19)	13 (12)	27 (14)
Vocational Training/other	3(3)	11 (6)	11 (11)	18 (9)
Employment, N (%)				
Unemployed/disabled/other	21 (20)	46 (24)	11 (11)	32 (16)
Retired	50 (48)	80 (41)	47 (45)	75 (38)
Part/Full-time employment	34 (32)	70 (36)	47 (45)	88 (45)
Household Income, N (%)				
No Information	3 (3)	4 (2)		
<$10,000–29,999	16 (15)	45 (23)	---	---
$30,000–89,999	66 (63)	98 (50)		
$90,000 or more	20 (19)	49 (25)		
ICD Indication, N (%)				
Primary Prevention	60 (57)	120 (61)	---	---
Secondary Prevention	45 (43)	76 (39)		
Age (years), mean (SD)	65.6 (10.6)	63.4 (12.5)	63.6 (11.1)	61.8 (13.0)
Charlson Co-morbidity Index, mean (SD)	2.4 (1.4)	2.3 (1.5)	0.72 (0.97)	0.72 (1.1)
Cardiac Resynchronization Therapy, N (%)	31 (30)	60 (31)	---	---
History of Sudden Cardiac Arrest, N (%)	20 (19)	46 (24)	---	---
Ejection Fraction, mean (SD)	33.2 (13.8)	34.6 (14.6)	---	---

*Data from patients and partners from the primary study who were excluded from present study due to no reported sexual activity in past 24 months.

Table 2.

GEE Repeated Measures: Change in Patient and Partner Sexual Concerns and Sexual Activity from Baseline to 12 Months

SCI Item[a,b]	Baseline	1 Month	3 Months	6 Months	12 Months	p-value
Patient						
Total Sex Concerns	6.48 (4.03)	5.45 (3.35)	5.17 (3.53)	5.43 (3.66)	5.22 (3.38)	**0.004**
Lack of interest	1.58 (1.24)	1.33 (1.19)	1.54 (1.16)	1.53 (1.22)	1.48 (1.16)	0.41
Partner overprotective	1.53 (1.09)	1.28 (1.06)	1.13 (1.05)	1.22 (1.03)	1.15 (1.06)	**0.004**
Fear ICD will fire during sex	0.95 (1.15)	0.55 (0.82)	0.45 (0.85)	0.54 (0.9)	0.47 (0.8)	**<0.001**
Fear cardiac arrest if ICD does not fire	0.88 (1.07)	0.62 (0.84)	0.54 (0.89)	0.56 (0.9)	0.6 (0.82)	**0.03**
Difficulty with erection[c]	1.68 (1.22)	1.82 (1.24)	1.67 (1.19)	1.77 (1.18)	1.84 (1.18)	0.78
No sexual activity past 2 months N (%)[d]	77 (73%)	48 (49%)	47 (46%)	45 (45%)	45 (46%)	**<0.001**
Partner						
Total Sex Concerns	6.93 (4.01)	5.27 (3.53)	4.9 (3.8)	4.83 (3.44)	5.2 (3.56)	**<0.001**
Lack of interest	1.32 (1.19)	1.18 (1.18)	1.2 (1.18)	1.13 (1.14)	1.27 (1.14)	0.78
Partner overprotective	1.84 (1.02)	1.52 (1.02)	1.42 (1.01)	1.34 (1)	1.38 (1.03)	**<0.001**
Fear ICD will fire during sex	0.94 (1.13)	0.51 (0.87)	0.51 (0.91)	0.41 (0.77)	0.44 (0.75)	**<0.001**
Fear cardiac arrest if ICD does not fire	1.21 (1.12)	0.75 (0.96)	0.61 (0.99)	0.62 (0.88)	0.66 (0.89)	**<0.001**
Difficulty with erection[c]	1.72 (1.3)	1.63 (1.32)	1.42 (1.35)	1.48 (1.32)	1.61 (1.38)	0.18
No sexual activity past 2 months N (%)[d]	72 (69%)	57 (58%)	58 (56%)	54 (54%)	51 (52%)	**0.03**

[a] SCI: Sexual Concerns Inventory. SCI total score and individual item means reported.

[b] Other than sexual activity, values in cells are mean (SD), based on patient/partner ratings using scored response options, ranging from 0 = never to 3 = frequently.

[c] The question about difficulty with erection varied by sex: females (heterosexual) were asked to rate their partner's level of difficulty with an erection, while males were asked to rate their own difficulty.

[d] GEE p-value based on mean (SD).

Table 3.

Frequency of Patient and Partner Responses to Open-ended Sexual Concern Questions

Response Category	Baseline (N)[a]	3–Months (N)[a]	12-Months (N)[a]
Patient			
Concern about ICD malfunction or firing due to sex	6	--	1
Pre-morbid history of limited sex activity	6	3	4
Sexual dysfunction/erectile dysfunction	4	4	5
Concerns about cardiac medications effecting erectile dysfunction	3	3	1
Needs/wants information on sex with an ICD	2	--	1
Fear of inducing cardiac symptoms during sex (dyspnea, tachycardia, etc.)	2	--	1
Patient or partner physical health or medical problems interfere with sex activity	1	4	1
Patient or partner lack of interest in sex	2	2	1
Concerns about pressure on chest/ICD during sex	1	--	--
Have discussed sex concerns with physician and/or attempted treatment for sex problems	1	1	--
Relates changes in sex life to the aging process	--	1	1
Sex life unchanged since ICD	--	--	1
Partner			
Concern about ICD malfunction or firing due to sex	5	1	--
Pre-morbid history of limited sex activity	8	4	2
Sexual dysfunction/erectile dysfunction	5	3	4
Needs/wants information on sex with an ICD	2	--	--
Fear of inducing cardiac symptoms in patient during sex (dyspnea, tachycardia, etc.)	1	1	--
Patient or partner physical health or medical problems interfere with sex activity	8	4	1
Patient or partner lack of interest in sex	1	3	7
Concerns about pressure on chest/ICD during sex	2	--	--
General concerns about patient's cardiac health	3	--	--
Believes sex will cause cardiac event in patient/safety concerns	3	--	--
Adapted sex to overcome cardiac and other medical issues	2	--	2
Concern that patient will worry about sex with an ICD	1	--	--
Sex life improved recently	--	--	1
Sex life unchanged since ICD	--	--	1

[a]N represents the frequency of each sexual concern reported on the open-ended question on the Sexual Concerns Inventory. Some patients reported more than one concern, while other patients did not respond or responded "none" to this open-ended question.

Table 4.

Regression Models Predicting Patient Reported Sexual Activity and Sexual Fears at 3 and 12 Months Post ICD Implant

Baseline Predictors	3-Months Post Implant				12-Months Post Implant			
	B	SE	Wald χ^2	p-value	B	SE	Wald χ^2	p-value
	Sexual Activity[a]							
Age	0.04	0.03	1.42	0.23	0.003	0.03	0.01	0.91
Sex	−0.35	0.65	0.29	0.59	0.24	0.69	0.12	0.73
ICD indication, Primary vs. Secondary	0.56	0.59	0.88	0.35	0.99	0.60	2.77	0.10
Charlson co-morbidity Index	−0.07	0.20	0.13	0.72	0.11	0.21	0.29	0.59
Physical health, SF-36 PCS	**0.63**	**0.31**	**4.26**	**0.04**	0.38	0.30	1.68	0.19
Anxiety, STAI-S	−0.01	0.03	0.07	0.79	0.000	0.03	0.00	0.99
Depression, PHQ-9	0.04	0.08	0.29	0.59	0.03	0.08	0.14	0.71
ICD concerns, ICDC	−0.004	0.02	0.03	0.86	−0.01	0.02	0.35	0.56
Lack of interest	0.02	0.28	0.01	0.94	−0.03	0.28	0.01	0.92
Partner overprotective	−0.24	0.30	0.66	0.42	−0.05	0.31	0.02	0.88
Difficulty with erection[c]	−0.18	0.26	0.45	0.50	−0.02	0.27	0.004	0.95
Intervention Group	0.49	0.58	0.72	0.40	0.78	0.56	1.93	0.17
Baseline Predictors	**β**	**SE**	**t**	**p-value**	**β**	**SE**	**t**	**p-value**
	Sexual Fears[b]							
Age	0.03	0.02	0.29	0.77	0.05	0.02	0.38	0.70
Sex	−0.05	0.31	−0.58	0.56	0.08	0.35	0.74	0.46
ICD indication, Primary vs. Secondary	0.03	0.30	0.28	0.78	0.06	0.32	0.57	0.57
Charlson co-morbidity Index	0.02	0.10	0.27	0.79	0.02	0.11	0.16	0.88
Physical health, SF-36 PCS	0.05	0.02	0.54	0.59	0.07	0.16	0.55	0.58
Anxiety, STAI-S	−0.04	0.02	−0.31	0.76	0.02	0.02	0.12	0.90
Depression, PHQ-9	0.24	0.04	1.98	0.051	0.03	0.05	0.21	0.83
ICD concerns, ICDC	**0.54**	**0.01**	**5.12**	**<0.001**	**0.33**	**0.01**	**2.47**	**0.02**
Dyadic adjustment, DAS	0.15	0.01	1.52	0.13	0.08	0.01	0.62	0.54
Intervention Group	−0.16	0.28	−1.88	0.06	−0.14	0.30	−1.31	0.20

Abbreviations: ICD: Internal Cardioverter Defibrillator. ICDC: ICD Patient Concerns Questionnaire. PCS: Physical Composite Score. STAI-S: State Trait Anxiety Index-State. PHQ-9: Patient Health Questionnaire. DAS: Dyadic Adjustment Scale. CRT-D: Cardiac Resynchronization Therapy Defibrillator.

[a] Analyses using multivariable logistic regression.

[b] Analyses using multivariate linear regression.

[c] The question about difficulty with erection varied by sex: females (heterosexual) were asked to rate their partner's level of difficulty with an erection, while males were asked to rate their own difficulty.