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## EPIDEMIOLOGY

## Compromised Sexual Health Among Male Patients With Implantable Cardioverter Defibrillator: A Cross-Sectional Questionnaire Study



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### ABSTRACT

**Introduction:** In cardiac patients with implantable cardioverter defibrillator (ICD), sexual function is sparsely described.

**Aim:** To determine the prevalence and distribution of sexual dysfunction, and to describe whether primary or secondary prophylactic ICD indication and antitachycardia pacing (ATP) or shock is associated with sexual function.

**Methods:** A cross-sectional survey of men with an implanted ICD was conducted at 2 university hospitals in Denmark. Inclusion criteria were men over the age of 18 with an ICD. Exclusion criterion was no partner.

**Main Outcome Measure:** Sexual function was assessed by the International Index of Erectile Function questionnaire and data on implantation indication (primary/secondary prevention) and therapy such as ATP and shock (both appropriate and inappropriate) was obtained from the Danish ICD Register.

**Results:** Data from 415 questionnaires were analyzed (response rate 50.2%). Patients had a mean age of 63.9±12.1 years. Erectile dysfunction (ED) was present in 70% of patients, orgasmic dysfunction was present in 57.9% of patients, 82.8% had reduced sexual desire, 85.8% had intercourse satisfaction problems, and 76.9% experienced overall satisfaction problems (non-validated metric except for ED). Patients with an ICD on primary prophylactic indication had more sexual dysfunction and ED compared with patients with an ICD on secondary prophylactic indication. ATP therapy, but not shock, was associated with more ED.

**Conclusion:** Sexual dysfunction is common in patients with ICD and is not limited to ED, but also orgasmic function, desire, intercourse, and overall satisfaction are affected. Primary prophylactic ICD indication and ATP, but not shock therapy, is associated with compromised sexual function. **Palm P, Zwisler A-D, Svendsen JH. Compromised Sexual Health Among Male Patients With Implantable Cardioverter Defibrillator: A Cross-Sectional Questionnaire Study. Sex Med 2019;7:169–176.**

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**Key Words:** Sexual Dysfunction; Cardiovascular Patients; Erectile Dysfunction; Implantable Cardioverter Defibrillator

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## INTRODUCTION

Being able to function sexually is an important aspect of many peoples' lives and sexual dysfunctions have a negative impact on quality of life and well-being.<sup>1–3</sup> In cardiac patients treated with implantable cardioverter defibrillators (ICD), a device that detects and treats abnormal ventricular tachyarrhythmias by antitachycardia pacing (ATP) or high voltage shock, sexual function is sparsely described and further information is warranted. Indication for the ICD can be divided into primary prophylactic, in which patients have not previously suffered from cardiac arrest, but are expected to have a high risk of life-threatening arrhythmias vs secondary, in which patients have previously suffered from a cardiac arrest. Shocks can be divided into appropriate, in which the ICD provides a shock to a malign ventricular arrhythmia (the intended function), or inappropriate, in which the ICD fires when people are awake, either because of a technical error or a benign arrhythmia. Inappropriate shocks are often experienced as storms of shock, meaning that multiple shocks appear.

## Background

Male sexual dysfunction is defined as problems in relation to erectile dysfunction (ED), desire, orgasm, or ejaculation.<sup>4</sup> A common sexual disorder in cardiovascular disease patients is ED, defined as the inability to achieve and maintain an erection that enables satisfying sexual activity.<sup>4</sup> The underlying mechanism is often pathogenically related to cardiovascular disease, but may also be related to psychological issues or a side effect from medication.<sup>5,6</sup> ED is highly associated with age.<sup>7</sup> In ICD patients, several small studies reveal long-term abstinence or a decrease in sexual activity after the ICD implantation.<sup>8–11</sup> Besides ED, sexual problems in ICD patients have been described as overprotectiveness from the partner, lack of sexual interest, fear of death if the ICD did not fire, or fear of the ICD shock therapy.<sup>10–12</sup> Shock during sexual activity is experienced in varying degrees, from <1% to 18%.<sup>10,11,13</sup> Although shocks are infrequent, fear of the ICD firing during sexual activity seems to have a more profound impact because this is experienced in almost 30% of the included patients.<sup>10,11</sup> Moreover, studies show that therapy such as ATP or shock from the ICD may predict a poor psychological outcome such as anxiety and psychological distress,<sup>14–16</sup> although they do not show if this outcome is reflected on sexual function.

The majority of data on sexual health in ICD patients have all been collected using the same questionnaire instrument, “The sex after ICD questionnaire,” which was developed especially for ICD patients.<sup>11</sup> The instrument provides a thorough overview of the specific sexual problems in an ICD population, however, it does not possess the ability to detect trends over time and evaluate results of an intervention. Moreover, the instrument does not reflect the clinical definition of male sexual dysfunction that allows for comparison among other diagnostic groups. Finally, it does not cover the severity of ED.

The role of primary vs secondary prophylactic indication on psychological outcomes has been discussed previously, but no negative impact has been established in relation to patients' quality of life and distress,<sup>17</sup> although secondary prophylactic indication seems to affect partners' level of anxiety.<sup>15</sup> The indications' influence on sexual function has not yet been described.

Altogether, sexual dysfunction in ICD patients is poorly described. Therefore, the objective of this study was to determine the prevalence and distribution of sexual dysfunction. Furthermore, we hypothesized that patients who had ICD for secondary prophylaxis would have poorer sexual function compared with primary prophylaxis patients, and that patients receiving therapy or shock would have poorer sexual function.

## MATERIALS AND METHODS

### Study Design

This study was designed as a cross-sectional study and was conducted as a post hoc analysis postal survey as part of the recruitment process of the CopenHeart SF trial,<sup>18</sup> a randomized controlled trial (RCT) that evaluated the effect of a comprehensive rehabilitation program to decrease sexual dysfunction. Patients were recruited from 2 university hospitals in the Danish Capital Region. The sample includes male patients with ICD.

### Eligibility Criteria and Recruitment

Hospital records were screened consecutively according to date of ICD implantation in the period from March 2013 to June 2015. Inclusion criteria were men above the age of 18 with an ICD. Exclusion criterion was not having a partner at the time of answering the questionnaire. The following information was extracted from the hospital records: age and implantation date, as defined by the main CopenHeart SF trial.<sup>18</sup>

Questionnaires were sent by mail to 826 patients. Participants filled out a questionnaire concerning sexual function. All patients provided written consent after receiving information about the study.

### Data Sources

To investigate if implantation indication or therapy from the ICD was associated with a poor sexual outcome, data on implantation indication (primary/secondary prevention) and therapy such as ATP and shock (both appropriate and inappropriate) were obtained from the Danish ICD Register.<sup>19</sup>

Prevalence and distribution of sexual function was measured by the Danish version of the International Index of Erectile Function (IIEF).<sup>20,21</sup> It consists of 15 items including 5 domains: erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction. Higher scores indicate a better function. The total IIEF-15 summary score (minimum 5 points, maximum 75 points) is categorized as

“good” (60–75), “fair” (44–59), and “poor” (5–43) as defined in a non-validated metric by Budweiser et al.<sup>22</sup> The erectile function domain has a cut-off score to diagnose and divide ED into 4 levels of severity: severe erectile dysfunction score 6–10, moderate erectile dysfunction score 11–16, moderate to mild erectile dysfunction score 17–21, mild erectile dysfunction score 22–25, and score above 25 indicates no dysfunction. For the other domains, a dysfunction was determined if scores were: 8 or less for the orgasmic function domain, the sexual desire domain, the overall satisfaction domain, and a score of  $\leq 12$  for the intercourse satisfaction domain, which is a non-validated metric, but in line with another study by Platek et al.<sup>23</sup> The IIEF meets psychometric criteria for test reliability and validity, and has a high degree of sensitivity and specificity.<sup>21</sup>

### Study Size

The sample size has not been determined statistically, but was alone determined by the number of questionnaires generated in the CopenHeart SF RCT trial. Based on the already-enrolled patients in the main trial, the number of questionnaires distributed was 826.

### Statistical Methods

Data were tested for normality using the Kolmogorov-Smirnov test. Continuous data were presented as mean scores with corresponding SD and compared using either the Student's *t*-test or the Mann-Whitney depending on the normal distribution. Proportions were compared with the chi-square test. Responders were compared with non-responders according to demographic variables. For each analysis, persons with missing information on the included variables were excluded. This was done after the survey response. Logistic regression was used to explore associations of ATP and shock, and whether primary or secondary prophylactic indication had the greatest implication. Analyses were performed as age-adjusted univariate analyses with the 3 variables ATP, shock, and indication, and a multivariate analysis with age, ATP, time from ICD, and indication. All analyses were performed using SPSS software version 23.0 (SPSS Inc, Chicago, IL, USA). A *P* value  $< .05$  was considered statistically significant for all analyses.

### Ethics

The study complies with the Declaration of Helsinki, and was approved by the Danish Data Protection Agency (j.nr. 2007-58-0015) and by the Regional Ethics Committee (j.nr. H-4-2012-168).

### RESULTS

Of the 826 patients approached, 476 returned the questionnaire (response rate 57.6%), 25 returned the questionnaire but declined to fill it out, and 35 did not have a partner. Thus, a sample of valid 415 questionnaires were analyzed (Figure 1).

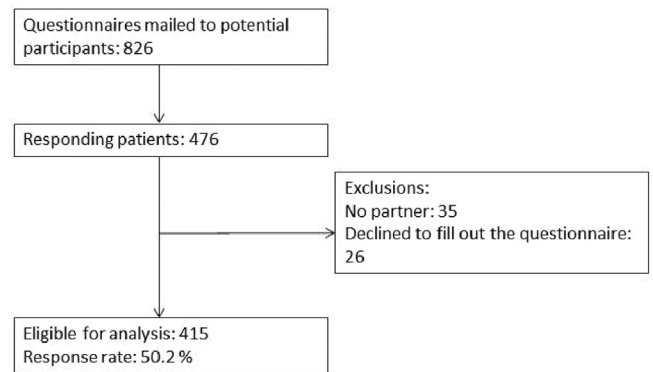


Figure 1. Flowchart.

The mean age of the study population was  $63.9 \pm 12.1$  with a range from 19–93 years. Participants had their ICD for a mean of  $4.9 \pm 3.8$  years (range 1–21) and 38 patients had a cardiac resynchronization therapy defibrillator. Patients had a mean of  $0.5 \pm 1.8$  appropriate shocks (range 0–18),  $0.2 \pm 1.4$  inappropriate shocks (range 0–33),  $5.1 \pm 42.4$  appropriate ATP (range 0–1,021), and  $0.6 \pm 5.8$  inappropriate ATP (range 0–110) (Table 1). The mean score on the total IIEF scores was  $39.6 \pm 24.2$  indicating a poor sexual function, and only 31% of the population had a good sexual function according to the total IIEF score (score 60–75). Mean scores on the other domains were as follows:  $14.5 \pm 11.4$  on the Erectile Function domain,  $5.6 \pm 4.3$  on the Orgasmic Function domain,  $6.0 \pm 2.3$  on the Sexual Desire domain,  $5.6 \pm 5.6$  on the Intercourse Satisfaction domain, and  $6.1 \pm 2.7$  on the Overall Satisfaction domain.

The prevalence of ED of any degree as an erectile function domain score below 25, was present in 70.5% of the patients. The distribution of ED was as follows: 29.6% normal erectile function, 7% mild ED, 7% mild to moderate ED, 7.5% moderate ED, and 48.9% severe ED. Advancing age (continuous) was highly associated with ED with an OR 1.11 95% CI: 1.08–1.13. When the age groups were stratified by decades (Table 2),  $>90\%$  of the patients  $>70$  years had ED defined as an erectile function domain score  $<25$ .

When the other IIEF domains were investigated separately the prevalence of orgasmic dysfunction was present in 57.9% of patients, 82.8% had lowered sexual desire, 85.8% had intercourse satisfaction problems, and 76.9% experienced problems related to overall satisfaction and when stratifying for primary vs secondary prophylactic indication, erectile function domain and the total IIEF score differed significantly in the 2 groups (Figure 2). Age was not significantly different between the primary prophylactic indication group and the secondary prophylactic indication group ( $P = .48$ ).

Analysis showed that mean intercourse satisfactions scores and mean overall satisfaction scores were statistically significant related to severity of ED ( $P < .001$ ). Lower scores were observed when ED severity increased (Table 3). The mean satisfaction score in the intercourse satisfaction domain as well as the mean scores in the overall satisfaction domain revealed that only

**Table 1.** Baseline variables for the participating ICD population

Variable	Responders	Non-responders	P*
N	415	411	
Age	64.4 ± 11.6	63.5 ± 12.8	.27
Time since ICD in years	5.1 ± 3.8	4.7 ± 3.7	.11
CRTD	19	19	.99
Number of appropriate ATP therapies	7.8 ± 11.3	2.3 ± 58.7	.06
Number of inappropriate ATP Therapies	0.6 ± 5.6	0.6 ± 6.1	.90
Number of appropriate high-voltage shock therapies	0.5 ± 1.7	0.44 ± 1.8	.55
Number of inappropriate high-voltage shock therapies	0.2 ± 1.8	0.2 ± 1.1	.98
Primary prophylactic indication	188	174	.44
Secondary prophylactic indication	224	232	

ATP = antitachycardia pacing; CRTD = cardiac resynchronization therapy defibrillator; ICD = implanted cardioverter defibrillator.

Values are n or mean±SD.

\*Significance test for responders vs non-responders using *t*-test for continuous variables and chi-square test for categorical variables.

patients without ED had a mean score consistent with good satisfaction.

When investigating the associations with ED, age-adjusted logistic regression showed that patients with primary prevention indication had a higher risk of having ED with an OR 2.06, 95% CI: 1.2–3.5 compared with patients having ICD on secondary prevention indication. Receiving ATP from the ICD compared with not receiving ATP was associated with ED OR 1.8, 95% CI: 1.1–3.2, orgasmic dysfunction OR 2.1, 95% CI: 1.3–3.5, lowered intercourse satisfaction OR 1.9, 95%

CI: 1.0–3.8, but not lowered sexual desire and overall satisfaction. We found no association with regard to shocks from the ICD, neither appropriate nor inappropriate, and no association with time from the ICD. In the multivariate analysis, ATP remained associated to ED OR 2.1, 95% CI: 1.1–3.8, but not indication.

## DISCUSSION

To our knowledge, this study is the first to address sexual dysfunction in a large male patient population with ICD using a validated generic instrument that reflects the male definition of sexual dysfunction. We found that sexual dysfunction was highly prevalent in ICD patients, with all domains affected. Patients with primary prophylactic indication suffered from a higher amount of sexual dysfunction including ED compared with patients having an ICD on secondary prophylactic indication. Sexual dysfunction was adversely affected by ATP, however, shock did not seem to have an impact.

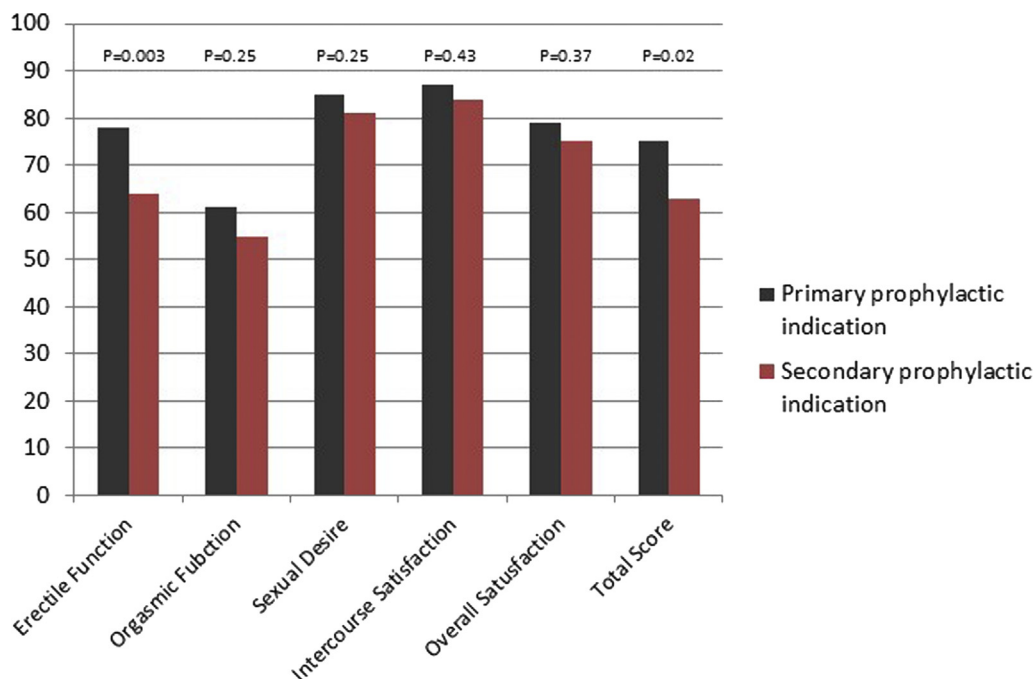
Our findings showed that more than 69% suffered from overall sexual dysfunction, and >70% from ED. ED increased with increasing age. The prevalence is higher than observed at matching age in the general population (38%),<sup>24</sup> higher than in an atrial fibrillation population (57%)<sup>23</sup> similar to patients with ischemic heart disease (75%)<sup>25</sup> though not as frequent as patients with heart failure (89%).<sup>26</sup> These proportions are not collected with the same instrument, the IIEF, however, they all reflect the clinical definition of male sexual dysfunction. Existing studies examining sexual problems in patients with ICD are not directly comparable with this present study because they use another instrument; however, problems with erection and desire have been reported in the studies by Berg et al<sup>10</sup> and Steinke et al,<sup>11</sup> who found erectile problems in 56% and 57% and desire problems in 29% and 38%, respectively, of their population. This is in contrast to this study, where ED was present in >70% of participants and sexual desire dysfunction in >82%. Previous study population samples were smaller, between 82 and up to 121 participants compared with 415 in this study. More patients in the Berg study had an ICD for primary prophylactic prevention indication 65% vs 45% in ours. Mean age in the 2 studies was 59 and 65, respectively, not differing from our study.

**Table 2.** Prevalence and severity of erectile dysfunction in all and according to age group in ICD patients

Prevalence of erectile dysfunction n (%)	19–40 y	41–50 y	51–60 y	61–70 y	71–80 y	81–93 y
	(n = 18)	(n = 34)	(n = 66)	(n = 132)	(n = 109)	(n = 11)
ED severity						
No ED (IIEF score >25)	16 (88.9)	20 (58.8)	27 (40.9)	39 (29.5)	6 (5.5)	1 (9.1)
Mild (IIEF score 22–25)	2 (11.1)	2 (5.9)	8 (12.1)	9 (6.8)	5 (4.6)	0 (0)
Mild to moderate (IIEF score 17–21)	0 (0)	1 (2.9)	5 (7.6)	11 (8.3)	9 (8.3)	0 (0)
Moderate (IIEF score 11–16)	0 (0)	2 (5.9)	8 (12.1)	10 (7.6)	7 (6.4)	1 (9.1)
Severe (IIEF score 6–10)	0 (0)	9 (26.5)	18 (27.3)	63 (47.8)	82 (75.2)	9 (81.8)

ED = erectile dysfunction; ICD = implantable cardioverter defibrillator; IIEF = International Index of Erectile Function.





**Figure 2.** Percentage of patients with dysfunction or affected satisfaction by domain of the International Index of Erectile Function. Patients were subcategorized by primary or secondary prophylactic indication. For each domain, dysfunction and affected satisfaction is defined as follows: a score of  $\leq 25$  for erectile function domain, a score of  $\leq 8$  for the orgasmic function domain, the sexual desire domain, the overall satisfaction domain and a score of  $\leq 12$  for the intercourse satisfaction domain.

A plausible explanation might be caused by the differences in the instrument. The IIEF is an instrument reflecting the clinical definition of sexual dysfunction, where the instrument used in both the Berg study and the Steinke study reflected areas relating to the ICD, such as fear of shock or fear of dying. Another reason for low sexual desire can be related to ED. It is well known that men with erectile problems tend to withdraw from their partner with a decrease in sexual response as a consequence. Men with low sexual response are more prone to have lack of sexual interest/ lowered desire.<sup>27</sup>

Of the 70% of the patients experiencing ED, 50% had severe ED, which completely prevents sexual intercourse. This is a high proportion of patients not being able to enjoy sexual activity in the form of sexual intercourse. It is well established that ED is highly prevalent in both patients suffering from ischemic heart disease and heart failure, the major patient groups receiving an ICD, and that the causes are primarily related to atherosclerosis but also anxiety and side effects to medication is known to have a substantial negative impact.<sup>5</sup> We were not able to adjust for any

of the potential causes in this cohort owing to limited descriptive data and therefore the result must be interpreted as an overall prevalence in a relatively large population sample of ICD patients.

The study revealed that a decrease in erectile function was associated with a decrease in both intercourse satisfaction and overall satisfaction, and that it was only patients without ED who experienced good intercourse and overall satisfaction. This implies that even patients with the mildest form of ED experience adverse impact on sexual satisfaction. The same trend is described by Makarem et al<sup>28</sup> in a group of hemodialysis patients. However, in this study, it was only overall satisfaction affected by ED and also patients with mild ED seemed to have a good overall satisfaction. In contrast, though not completely comparable, a study by Giraldi et al<sup>29</sup> found that in a randomly chosen Danish population, 11% of men suffering from ED were unsatisfied with their sexual life. ED was measured by the same instrument, the IIEF, but with a lower cut-off score for ED of  $\leq 21$ , probably resulting in a smaller group with ED compared with ours.

**Table 3.** Relationship between satisfaction scores and erectile dysfunction (ED) severity

	ED severity					P
	No ED	Mild	Mild to moderate	Moderate	Severe	
Mean Intercourse Satisfaction Score*	12.2±2.1	9.3±2.4	8.7±2.7	4.8±4.1	0.9±2.3	< .0001
Mean Overall Satisfaction Score*	8.4±1.5	7.1±1.6	6.4±1.6	5.6±2.0	4.4±2.4	< .0001

\*Significant on one-way ANOVA. Trend across groups. Scores are mean±SD.

Primary prophylactic prevention indication was associated with more sexual dysfunction compared with patients having ICD on secondary prophylactic indication. It has been hypothesized that patients with secondary prophylactic indication would have a larger amount of psychological distress as a result of index event such as cardiac arrest leading to the ICD implant<sup>30</sup> that could have influences on sexual function, however, our data could not confirm that. The majority of patients having an ICD for primary prophylactic indication are patients with ischemic heart disease, heart failure symptoms corresponding to New York Heart Association function class II and III despite optimal medical treatment,<sup>31</sup> reduced ejection fraction, which are all factors known to be associated with sexual dysfunction.<sup>5</sup> We have not been able to adjust for these factors in our analysis.

We found that patients receiving ATP from the ICD experienced more sexual dysfunction compared with patients not experiencing ATP, also when adjusting for age and indication. Many patients receiving ATP will not experience the ATP itself, but will feel the malign arrhythmia as palpitations and dizziness, which potentially might remind them of being chronically ill and vulnerable, all psychological impacts associated to outcomes such as anxiety and concerns<sup>32</sup> which potentially might reflect on sexuality as well. In a study by Hoekstra et al,<sup>33</sup> patients with heart failure without sexual dysfunction reported significantly higher emotional quality of life than those with sexual dysfunction, indicating a possible connection between psychological outcomes and sexual dysfunction.

## CLINICAL IMPLICATIONS

The IIEF is an easy self-administrable validated instrument that provides valuable information on patients' sexual function and it can easily be adopted in a clinical setting. Therefore, the routine use of IIEF for diagnosing sexual dysfunction should be considered in the ICD clinic. However, because the IIEF only evaluates the level of different dysfunctions and not the underlying cause, it should not serve as a single instrument. For patients with sexual dysfunction on the IIEF, a thorough sexual and medical history is important to plan the right treatment addressing sexual health. Treatment suggestions could include medical treatment with phosphodiesterase type 5 inhibitors, adjusting cardiovascular medication, psychosocial support, or risk factor reduction, including physical exercise.<sup>5</sup>

## STRENGTH AND LIMITATIONS

Self-reported outcomes are by nature subjective. However, in this study we used the IIEF, which is recognized as the gold standard in evaluating sexual dysfunction. The study is of a considerable size and includes a consecutively recruited population of ICD patients. The response rate was almost 58%, which is relatively high compared with other studies dealing with sexual matters.<sup>2,11</sup> The responders seemed to be similar to the

non-responders on the included variables, although it was not possible to analyze differences such as severity of disease, medication, and social factors. Furthermore, we were not able to adjust for hormone levels such as testosterone that might account for some of the sexual dysfunction measured. The major limitation to the study is that we were not able to adjust for important health variables such as vascular diseases, mental health, and medications associated with ED, nor was quality of the man's relationship with his sexual partner measured.

The cross-sectional design is limited in its ability to draw valid conclusions about firm associations or possible causality because the presence of risk factors and outcomes are measured simultaneously, and there is a risk that the study is either over- or underpowered because it lacks power calculation. Therefore, results should act primarily as hypothesis-generating for further studies.

## CONCLUSION

Sexual dysfunction is highly prevalent in ICD patients, and it is not limited to ED, but also affects desire, orgasm, and satisfaction in a negative way. Primary prophylactic ICD indication and ATP, but not shock therapy, is associated with compromised sexual function. Knowledge about ICD patients' sexual function is warranted and the present results may contribute to a better understanding of the subject. Further, this study highlights the need for a routine screening aimed at identification of patients with sexual dysfunction in the ICD clinic. Moreover, this study illustrates an unmet need for interventional studies to improve poor sexual outcome in this patient group.

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