Shock-related anxiety and sexual function in adults with congenital heart disease and implantable cardioverter-defibrillators

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BACKGROUND An increasing number of adults with congenital heart disease (CHD) require implantable cardioverter-defibrillators (ICDs), yet little is known about their impact on psychological well-being and sexual function.

OBJECTIVE To assess shock-related anxiety in adults with CHD and its association with depression and sexual function.

METHODS A prospective, multicenter, cross-sectional study was conducted on adult patients with CHD with (ICD^+) and without (ICD^-) ICDs. The Florida Shock Anxiety Scale was administered to patients with ICD^+ and the Beck Depression Inventory-II to all patients. Men completed the Sexual Health Inventory for Men, and women completed the Female Sexual Function Index.

RESULTS A total of 180 adults with CHD (ICD^+: n = 70; ICD^-: n = 110; median age 32 years [interquartile range 27–40 years]; 44% women) were enrolled. The complexity of CHD was classified as mild in 32 (18%), moderate in 93 (52%), and severe in 54 (30%) subjects. In ICD recipients, a high level of shock-related anxiety was identified (Florida Shock Anxiety Scale score 16; interquartile range 12–23.5), which was slightly higher than the median score for ICD recipients in the general population ($P = .057$). A higher level of shock-related anxiety was associated with poorer sexual function scores in both men (Spearman's $\rho = -.480$; $P < .001$) and women (Spearman's $\rho = -.512$; $P < .01$). It was also associated with self-reported depressive symptomatology (Spearman's $\rho = .536$; $P < .001$).

CONCLUSIONS Adults with CHD and ICDs demonstrate a high level of shock-related anxiety, which is associated with lower sexual functioning scores in men and women. These results underscore the need for increased clinical attention related to ICD-related shock anxiety and impaired sexual function in this population.

KEYWORDS Implantable cardioverter-defibrillator; Congenital heart disease; Anxiety; Depression; Sexual function

ABBREVIATIONS **BDI-II** = Beck Depression Inventory-II; **BMI** = body mass index; **CHD** = congenital heart disease; **CI** = confidence interval; **ED** = erectile dysfunction; **FSAS** = Florida Shock Anxiety Scale; **FSFI** = Female Sexual Function Index; **ICD** = implantable cardioverter-defibrillator; **SHIM** = Sexual Health Inventory for Men

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Introduction

An increasing number of adults with congenital heart disease (CHD) are receiving implantable cardioverter-defibrillators (ICDs) as primary or secondary prevention therapy against sudden cardiac death. Improved awareness of risk factors for malignant ventricular arrhythmias, together with major advances in ICD technology, have led to expanding indications for device therapy in this unique and heterogeneous population.[1] Patients with tetralogy of Fallot constitute the largest subgroup of ICD recipients among adults with CHD.[2] Prior studies have quantified the rates of ICD discharges, identified associated factors, and characterized ICD-related complications, including the high prevalence of inappropriate shocks (30%–40%).[2–4] Similarly, high rates of inappropriate shocks have been described in other subgroups of adults with CHD.[5]

Although life-saving benefits of ICD therapy in carefully selected candidates are well established, psychological effects of living with an ICD can be considerable. Levels of clinical

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anxiety and depression have been estimated to be 13%–38% and 9%–15%, respectively.[6] Concerns expressed by ICD recipients have included apprehensions regarding potential shocks,[7] fear of death,[8] and interference with social interactions and sexual function.[9] In adults with CHD, in particular, little is known about the impact of ICDs on psychological well-being and sexual function. We, therefore, conducted a prospective, multicenter, cross-sectional study on adults with CHD in order to assess shock-related anxiety and explore potential associations with depression and sexual function.

Methods

Study population

Consecutive patients were prospectively enrolled from the following participating adult CHD outpatient clinics within the Alliance for Adult Research in Congenital Cardiology: Children's Hospital of Pittsburgh, Pittsburgh, PA; Nationwide Children's Hospital, Columbus, OH; Children's Hospital, Boston, MA; and Montreal Heart Institute, University of Montreal, Quebec, Canada. Qualifying patients with ICDs were invited to participate in the study along with contemporary controls. Inclusion criteria consisted of a confirmed diagnosis of CHD and age $\geq$18 years. Patients who lacked cognitive competency to complete questionnaires were excluded, as were those unable to read and understand English or French. Since sexual activity within 4 weeks is a prerequisite to complete the Sexual Health Inventory for Men (SHIM) and Female Sexual Function Index (FSFI), patients who did not engage in sex within this period were likewise excluded. The study was approved by each center's institutional review board. All patients provided written informed consent to participate.

Demographic and clinical variables

Pertinent data collected during subject interview and chart review included age, sex, ethnicity, and type and complexity of CHD. The complexity of CHD was categorized as mild, moderate, or severe in accordance to the classification scheme proposed by the American College of Cardiology, which considers the underlying cardiac anomaly and postoperative status.[10]

Well-validated measures were used to assess shock-related anxiety, depression, and sexual function. The Florida Shock Anxiety Scale (FSAS) was administered to ICD recipients. It is a 10-item tool designed to provide a quantitative measure of ICD-related anxiety.[11] Scores reflect anxiety about the ability to cope with the impact of a shock, rather than overall confidence with the device itself. Respondents rate each item on a 5-point Likert scale, ranging from 1 (not at all) to 5 (all the time). The total FSAS score is determined by summing the items, with higher values representing greater shock anxiety. Investigative analyses of the FSAS have demonstrated that it is composed of a 2-factor structure characterized by a "consequence" score, related to device firing (eg, anxiety over creating a scene), and a "trigger" score, related to device firing (eg, intrusive anxiety about inadvertent shock during sexual activity). The FSAS questionnaire was translated into French for the current study by using a process of translation, back translation, and revision.

The Beck Depression Inventory-II (BDI-II) was used to assess subjects' level of depressive symptomatology.[12] It is a 21-question (multiple-choice) self-report inventory that is composed of items relating to symptoms of depression such as hopelessness and irritability, feelings of guilt or being punished, and physical symptoms such as fatigue and weight loss. For the BDI-II, the total score ranges from 0 to 63 and is interpreted as follows: 0–9 normal; 10–16 mild depression; $>$17 clinical depression; 17–20 borderline; 21–30 moderate; 31–40 severe; $>$40–63 extreme.[13] It has been translated and validated in multiple languages, including French.

Sexual function in men and women was assessed with the SHIM and FSFI questionnaires, respectively. The SHIM is a widely used scale for screening and diagnosing erectile dysfunction (ED) and its severity, and it has been translated and validated in more than 30 languages, including French.[14] Diagnostic evaluations have shown the SHIM to have high sensitivity and specificity, better reliability than a single-item self-assessment of ED severity, and good correlations with improvement in erections and treatment satisfaction. Responses to 5 items are based on a Likert rating scale, with a total ranging from 1 to 25 and higher scores indicating better sexual health. Patients with a score of 21 or less may have evidence of ED. The total score for the 5-question SHIM questionnaire used as a diagnostic aid in the outpatient evaluation of ED ranges from 5 to 25 and is interpreted as follows: 5–7 severe; 8–11 moderate; 12–16 mild to moderate; 17–21 mild; 22–25 none. Similarly, the FSFI is a reliable, validated, 19-item self-report questionnaire that assesses sexual function in women in 6 separate dimensions: desire, arousal, lubrication, orgasm, satisfaction, and pain.[15] It was developed for the specific purpose of assessing domains of sexual functioning in clinical trials and has been validated in women with a variety of conditions, including orgasmic disorder, hypoactive sexual desire disorder, menopause, pregnancy, and in healthy controls. The full-scale score range for the FSFI questionnaire used in the assessment of female sexual dysfunction ranges from 2 to 36, and a cutoff score of 26.55 was correctly classified as dysfunctional.[16] For the current study, the FSFI questionnaire was translated into French by using a process of translation, back translation, and revision.

Statistical analysis

Normally distributed continuous variables are presented as mean $\pm$ SD. Nonnormally distributed continuous variables (by using Komolgorov-Smirnov tests) are presented as median and interquartile range. Categorical variables are presented as frequencies and percentages. To determine whether the adult CHD population in this study had different FSAS scores compared to all patients with ICDs, we used the Mann-Whitney *U* test to compare the differences in medians