Implementation of a Screening Program for Patients at Risk for Posttraumatic Stress Disorder

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ABSTRACT

INTRODUCTION: Implantable cardioverter defibrillator (ICD) recipients who suffer from posttraumatic stress disorder (PTSD) are known to be associated with significant cardiac-specific mortality. Clinical observations suggest that PTSD is frequently undetected in ICD recipients followed up at electrophysiology (EP) outpatient clinics. Early recognition of PTSD is important to reduce the risk of serious manifestations on patient outcomes.

METHODS: All ICD recipients aged 19 years or older at the Washington University School of Medicine (WASHU) EP clinic, a large urban EP clinic, were invited to participate in the project. An informed consent letter with an attached primary care: posttraumatic stress disorder (PC: PTSD) survey was offered to the participants who met the inclusion criteria. Those who completed the survey were included in the project. Individuals with positive survey result were offered a referral to mental health services. Comparisons between PTSD and non-PTSD patients were done using a two-sample *t*-test for continuous variables. Using Fisher's exact test, PTSD prevalence was compared to the study by Ladwig et al in which prevalence was determined as the proportion of patients with positive findings of PTSD ($n = 38/147$). All analyses were conducted using SAS v9.4. The proportion of patients having PTSD was determined and an exact 95% confidence interval was evaluated based on the binomial distribution.

RESULTS: Using a convenience sample, 50 ICD recipients (33 males and 17 females) were enrolled. The project had a 30-day outcome period. Nine (18%) of the 50 participants had positive PC: PTSD findings and all these nine participants were referred to a mental health specialist. The current project demonstrated an 18% (9/50) PTSD prevalence rate when compared to a 26% (38/147) prevalence rate in the study by Ladwig et al ($P = 0.34$). Although this project did not demonstrate 20% PTSD prevalence rate, as hypothesized, the 18% PTSD prevalence rate is consistent with previous research.

CONCLUSION: The prevalence of PTSD noted in the current project is consistent with previous research and validates underrecognition of PTSD in ICD patients. Offering a referral to all ICD recipients at EP clinic visits with a positive PC: PTSD screening to a mental health specialist is an important step in reducing the risk of serious manifestations on patient outcomes.

KEYWORDS: anxiety, cognitive behavioral therapy, defibrillator, depression, emotion, evaluation, ICD, Implantable cardioverter-defibrillator, nursing, patient outcomes, post-traumatic stress disorder, psychological distress, psychosocial impact, PTSD, quality of life, QL, QOL, randomized controlled trial, sudden cardiac arrest, sudden cardiac death, SCA, SCD, support group

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Introduction

Sudden cardiac death (SCD) in the United States is linked to more than 450,000 deaths annually[1] and contributes to more than 30% (17.1 million) of all cardiovascular mortality worldwide.[2] Malignant dysrhythmias such as ventricular tachycardia evolving into ventricular fibrillation cause two-thirds of SCDs.[3] An implantable cardioverter defibrillator (ICD) is the recommended intervention for this high-risk patient population due to its advantage over pharmacologic treatment, resulting in a significant surge of ICDs implanted.[4] Therapy has focused on the identification of high-risk individuals for SCD including those with low ejection fraction or history of malignant dysrhythmias.[5] The ICD is designed to detect and treat these malignant ventricular dysrhythmias through antitachycardia pacing or shock therapy restoring a sinus rhythm.[6] Survival rates have improved over the past 20 years with ICD therapy,[7] noting a 30%–50% decrease in mortality.[6,8]

The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V), states that posttraumatic stress disorder (PTSD) is a condition that occurs in people who are unprotected against extreme stress or a traumatic life-threatening event, resulting in fear, helplessness, or horror.[9] A single ICD shock or an ICD storm (multiple consecutive ICD shocks) may lead to PTSD.[10] Patients who develop PTSD attempt to avoid reminders and have frequent thoughts of the event.[11] They have consistent adverse views and expectations

about themselves or their environment and demonstrate a hyperarousal syndrome.[11] Symptoms that persist for more than 30 days causing impairment in day-to-day functioning have been classified as PTSD.[11]

The DSM-V[11] reported the US lifetime PTSD prevalence rate of 8.7%.[12] The mechanism underlying the development of PTSD in ICD patients is not well documented.[9] It is not clear if life-threatening dysrhythmias provoke PTSD or whether ICD shocks trigger and maintain PTSD.[9]

With improved SCD survival rates, a higher postrecovery PTSD potential exists for ICD patients noting life-threatening events.[13,14] As a result, there is a relationship between adverse cardiac events and subsequent traumatic symptoms.[15] Post-survival patients are susceptible to reexperience the cardiac incident or ICD shocks. PTSD sufferers commonly encounter flashbacks of medical interventions and dreams of cardiac arrest and surgical procedures. In addition, episode reminders result in avoidance of situations causing tachycardia such as sexual activity, exercise, and arousal symptoms triggering obsessions with heart rate, chest pain, or insomnia.[12]

Many studies have suggested that an ICD increases the quality of life (QoL) for most recipients.[16] Although ICDs improve survival rates,[7] the severity of disease, comorbidities, underlying cardiac disease, life-threatening dysrhythmia, frequent ICD shocks or electrical storms, poor social support, younger age at implantation, gender, and/or a poor understanding of the therapy may increase anxiety, depression, and posttraumatic stress symptoms.[6,9,17] The incidence of PTSD in ICD recipients is approximately 20% with Type D personality, with comorbidities, and frequent shock therapy.[9] According to Shiga et al[9], ICD patients with Type D personality, known as a highly reactive stress disorder, may have an increased risk for developing anxiety. Ventricular dysrhythmias result in the provocation of anxiety among ICD recipients.[9,18] In addition, depression has been observed in approximately 30% of ICD recipients, and shock therapy may contribute to the persistence of depression.[9]

While the recipient may perceive the ICD shock (particularly ICD storm) as traumatic, it is important to note that the ICD population seems to differ from other PTSD populations in the development of PTSD symptoms. In non-ICD recipients, the subsequent trauma experience is not likely. The ICD recipient lives with the realistic and tactile threat every second of every day.[10]

Nursing Focus

Nursing is concerned with the diagnosis and monitoring of patients' responses to health problems, with health advancement and optimization, and with the prevention of disease.[19] Nurses serve a focal role in the development of interventions aimed at improving disease response, adaptation to the disease, and the ability to learn to live with chronic disease states.[4] Nurse scientists have published a great number of studies on the adaptation of patients following SCD, ICD implantation, and ICD shock therapy.[4] It is equally important to note that the vast majority of the behavioral and psychosocial interventions that intended to enhance QoL post ICD implantation were developed and tested by nurse scientists.[4]

Nursing interventions. Nursing interventions, aimed at decreasing the psychological stress of living with heart disease, have identified reductions in anxiety and depression.[20] Medical conditions such as severe depression and anxiety disorder can be diagnosed and treated.[6] Despite the acceptance of feelings as a significant part of the human condition, scientific knowledge of the effect of the clients' emotions on their ability to cope is limited.[21] Cardiac disease, including complications, will inevitably lead to a fundamental emotional reaction.[6] A defense mechanism is typically the primary emotional reaction linked to a healthy survival strategy.[6] Although the reaction demonstrates the patient's desire to develop healthy coping strategies,[21] it is clear that emotion affects the ways in which the patient copes with illness.

Education. Despite the advantage of ICD technology in survival rates, patients with an ICD experience a major disruption in their lives.[22] Guidelines for nursing care have been published, highlighting that education is essential for ICD recipients.[23] The guidelines focus on the patient's understanding of his or her condition, functions of the ICD, implantation procedure, preoperative and postoperative care, restrictions on activities of daily living, and discharge instructions.[22] The underlying supposition is that the patient will process and understand the information received as well as adapt to daily life activities.[24]

Review of Literature

An extensive literature search using Center for health evidence (CCHNE.net), CINAHL, ClinicalTrials.gov, Cochrane, Embase, Guidelines.gov, Medline, PubMed, and OVID was undertaken to search for publications describing PTSD in ICD recipients. Each database was searched for the most current evidence-based data, randomized controlled trial (RCT), systematic reviews including Evidence-based Practice Center, and Health Technology Assessment reviews and meta-analyses conducted between the years 2000 and 2015. Cohort or other prospective non-RCT designs were also considered. A total of 26 guidelines and systematic reviews arrived at diverse conclusions, provided different recommendations, and observed different effectiveness of therapies,[25] regarding PTSD in ICD patients. However, many guidelines identified trauma-focused psychological treatments as a preferred method viewing medications as an adjunct or a next-line treatment.[25] The range of participant inclusion criteria included the assessment of one of the following outcomes: PTSD symptoms, remission (no longer having symptoms), QoL, disability or functional impairment, or adverse events. Settings included outpatient and inpatient care, cardiovascular, electrophysiology (EP) clinic, primary care, and mental health care settings.

Ladwig et al.[26] found that experiencing SCD outside of the hospital setting resulted in an even greater prevalence of

PTSD (27%–38%) among ICD recipients. A total of 48.6% of the sample had clinically significant levels of PTSD at any one point in time.[26] ICD recipients with positive PTSD scores after device implantation were considerably more likely to have shock storm.[27] These rates dropped significantly in the first six months after ICD implantation to 15% and remained stable at one year.[27] von Känel et al.[28] found a 31% prevalence of PTSD in ICD patients two years post implantation. At five and a half years post ICD implant, the PTSD prevalence had increased to 36%.[28] A total of 19% of the participants had PTSD at both assessments, 12% had PTSD at baseline, and 18% had PTSD at the follow-up visit.[28] Likewise, elevated PTSD scores were associated with a 3.2 times greater likelihood of mortality within five years compared with ICD patients, with no to moderate symptom levels of PTSD, even after controlling for disease and demographic parameters.[26] Moreover, Ladwig et al.[26] reported that the relative mortality risk was 3.45 (adjusted for age, gender, diabetes, left ventricular ejection fraction, beta-blocker use, depression, and anxiety) in ICD recipients with PTSD (high Impacts of events scale-revised (IES-R) score) compared with those without PTSD.

Ladwig et al.[26] found that prior ICD shocks had no influence on the experience of PTSD symptoms. In addition, Kapa et al.[27] found that ICD recipients with shocks and those without shocks differed only in their scores on physical component of the short form-36 health survey (SF36). Therefore, regardless of the occurrence of ICD shock, the experience of cardiac arrest, or being told of the potential threat, there is no evidence highlighting the incidence of PTSD in the first year after implantation.[27]

Methods

PTSD in ICD recipients is known to be associated with 55% cardiac-specific mortality.[29] It is important to recognize PTSD symptoms early in this patient group due to the high risk of mortality and morbidity and equally important to ensure that they receive appropriate care to reduce their risk of detrimental outcomes. Clinical observations and an exhaustive literature review suggest that PTSD is frequently undetected in ICD recipients followed up at EP outpatient clinics. There were no known studies at the time of this project that screened ICD recipients all-inclusively, regardless of indication for the ICD implant on behalf of PTSD symptoms utilizing the PC: PTSD screen in the outpatient EP clinic. The focus of the project was to develop and implement a PTSD protocol using the PC: PTSD tool.

In our project, similar to the Ladwig et al.[26] study, age and gender were evaluated. However, the baseline cardiovascular disease state and indication for ICD implant were excluded intentionally. The current project focused on screening all ICD recipients, regardless of ICD indication with the PC: PTSD tool for symptoms of PTSD in the outpatient EP clinic. The focus of the Ladwig et al.[26] study was to evaluate for PTSD symptoms at baseline and predict long-term mortality risk in patients with ICDs. Although the focus of the study was different, both studies were performed in a similar urban and suburban outpatient clinic and all participants were screened for PTSD symptoms. Our project evaluated the PTSD prevalence and was compared accordingly in which prevalence was determined as the proportion of patients with positive symptoms of PTSD. Based on the previous research by Ladwig et al.[26], implementing the PC: PTSD screening tool to ICD recipients in an EP outpatient clinic would demonstrate a greater than 20% prevalence of PTSD.

Following the institutional review board's approval from the University of Alabama in Huntsville, Alabama, Washington University School of Medicine (WASHU) in St. Louis, Missouri, who approved a partial waiver of HIPAA authorization, the patients were screened for PTSD using the validated PC: PTSD tool (Appendix A). Patients older than 19 years of age, with an ICD, were eligible for inclusion in the project. The exclusion criteria included combative or confused patients without family support. The patients were asked to review the consent letter (Appendix B) and complete the attached PC: PTSD screening tool (Appendix A). ICD patients, who agreed to participate, were screened during their follow-up visits. All of the participants were identified through the electronic medical record (AllScripts) and recruited at WASHU in the EP clinic during their Usual customary care (UCC) visit. The research was conducted in accordance with the Declaration of Helsinki.

Implementation

Phase I of the project began with a presentation detailing the project goals, interventions, and expected outcomes to senior leadership, nursing management, and multidisciplinary office staff. A consent letter with the attached PC: PTSD screening tool was reviewed in detail (Appendices A–B). The PC: PTSD screening tool was developed by Annabel Prins et al.[30] (2003) and was designed for use in primary care or other medical settings to screen for PTSD. It is a four-question tool that includes an introductory sentence, prompting respondents regarding traumatic events. Prins et al.[30] (2003) suggested that any PC: PTSD screen should be considered positive for most participants with three "yes" responses to any item in the screen.

Phase II of the project began with the completion of the administration and provider and staff training. Patients were identified using Allscripts, Washington University's electronic medication record. All patients with an ICD aged 19 years and older were given the informed consent letter with the attached PC: PTSD survey. By the end of 12 days, 50 participants had completed the attached survey. Nine of the 50 participants had positive findings on the screening. Each patient with a positive PC: PTSD survey was referred to a mental health specialist for further evaluation and treatment. We expected a 20% prevalence rate of PTSD in the EP outpatient clinic of the participating patients.

Phase III of the project began when enrollment of 50 participants was met. SAS v9.4 software was used to calculate the prevalence of PTSD in ICD recipients in the EP outpatient clinic, and all data were compared to the work by Ladwig et al.[26], demonstrating a greater than 20% burden. The project coordinator tracked this information.

Framework

The biopsychosocial model (BPS), used as the framework for this project, assisted medical personnel in facilitating and/or promoting healthy client behaviors.[31] BPS entails the conceptualization and treatment of health problems as an interplay between biological factors, psychological factors, and social factors, culminating in the manifestation of symptoms.[32] The BPS is predicted to be the best theoretical framework capable of establishing a therapeutic process or producing an antitherapeutic effect on ICD patients suffering from PTSD.[33] Screening to identify ICD recipients who are currently suffering or are at risk of PTSD signifies the need for comprehensive, superior care, consistent with BPS.[31] The BPS allows healthcare professionals to expand their analyses, diagnoses, and treatment of illness.[34]

Evidenced-based interventions with proven patient outcomes are essential in clinical practice.[4] Nursing leadership requires promoting change and expanding the nurses' scope of practice. This requires the nurses to demonstrate leadership and educational reform in their practice.[4] The Institute of Medicine Report on "The Future of Nursing: Leading Change Advancing Health" endorsed the need for nurses to coordinate care among clinician and healthcare agencies, prevent occurrences of acute care episodes, and be involved in managing chronic illness and disease progression, resulting in prevention of rehospitalization.[35] Nurses are in an optimal position to affect important disease outcomes for patients and their families after ICD implantation.[4]

Evaluation

In this project, a structured PTSD screening protocol using the PC: PTSD tool was administered to all ICD patients in a large EP outpatient clinic in the Midwestern United States. A 30-day time frame was utilized to obtain consent and screen participants. The data were extracted from the electronic health record used in the facility.

Project costs. The costs of materials and staffing time were eliminated, as the health administrators determined that the evaluations of PTSD in post ICD implants met the current standard of care. There were no salary costs associated with the project.

Results

The purpose of this analysis was to determine the prevalence of PTSD among patients with ICD implants seen during outpatient EP clinic visits and to establish a referral protocol to mental health services for any positive PC: PTSD screen. A positive response to the PC: PTSD screen was defined by three "yes" responses to any of the four screen questions. The proportion of patients having PTSD and an exact 95% confidence interval based on the binomial distribution are presented in Table 1. Comparisons between PTSD and non-PTSD patients were done using a two-sample *t*-test for continuous variables and Fisher's exact test for categorical statistics (Table 2). PTSD prevalence was compared to Ladwig et al.[26] study prevalence using Fisher's exact test (Fig. 1). In the Ladwig et al.[26] study, prevalence was determined as the proportion of patients having a positive PTSD result (n = 38 of 147). All analyses were conducted using SAS v9.4.

A total of 50 ICD recipients (33 male and 17 female) participated in the project. A total of 18% of the participants had a positive PC: PTSD screen. Each participant with a positive PC: PTSD screen, nine patients in total, was referred to mental health specialists for further evaluation and treatment. When evaluating the PTSD symptoms from the time of the ICD implant (2009–2015), an increased burden of PTSD symptoms was observed in the group of participants with ICD implanted in 2015 (26%), compared to those with ICD implanted in 2009 (6%; Fig. 2). The evaluation of the responses to the PC: PTSD question demonstrated significant findings (Fig. 3). A total of 26% of the overall patient group experienced nightmares during the previous 30 days (P = 0.001). Within the same patient group, 31% reported symptoms of avoidance (P = 0.001). A total of 20% of these patients reported that they felt on guard (P = 0.001) and 24% of this group documented that they felt numb (P = 0.001). Ladwig et al.[26] study reported a notable 26% incidence rate compared to an 18% prevalence in the current sample (P = 0.34). This project did not demonstrate a 20% prevalence of PTSD symptoms as initially hypothesized. However, the project did demonstrate a significant 18% burden of PTSD.

Discussion

Growing evidence suggests that PTSD symptomatology is highly prevalent in EP clinic and harmful to psychosocial and physical health. The current project supports the need for routine screening for the presence of PTSD in the outpatient EP clinic based upon the evidence found in the literature review and project findings. Utilization of the PC: PTSD screen as

Table 1. Prevalence of PTSD in the outpatient EP clinic.

	FREQUENCY/ TOTAL = PERCENT	95% CI
Positive PC:PTSD Screen = Yes	9/50 = 18%	(8.6%, 31.4%)

Note: The proportion of patients having PTSD and an exact 95% confidence interval based on the binomial distribution.

Table 2. Summary of statistical findings.

OVERALL PC:PTSD	VARIABLE (N = 50) PC:PTSD	SCREEN = NO PTSD	SCREEN = YES PTSD	*P*-VALUE
Age	62.28 ± 15.68	64.93 ± 13.10	50.22 ± 21.98	0.08
Gender No. (%)				1.00
F	17 (34%)	14 (34%)	3 (33%)	
M	33 (66%)	27 (66%)	6 (67%)	
ICD Implant Year, No. (%)				0.30
2009	3 (6%)	3 (7%)	0 (0%)	
2010	6 (12%)	4 (10%)	2 (22%)	
2011	3 (6%)	2 (5%)	1 (11%)	
2012	7 (14%)	4 (10%)	3 (33%)	
2013	13 (26%)	12 (29%)	1 (11%)	
2014	5 (10%)	5 (12%)	0 (0%)	
2015	13 (26%)	11 (27%)	2 (22%)	
Q1 Had nightmares, No. (%)				<0.001
NO	37 (74%)	37 (90%)	0 (0%)	
YES	13 (26%)	4 (10%)	9 (100%)	
Q2 Avoidance, No. (%)				<0.001
NO	34 (69%)	34 (85%)	0 (0%)	
YES	15 (31%)	6 (15%)	9 (100%)	
Q2 On guard, No. (%)				<0.001
NO	40 (80%)	40 (98%)	0 (0%)	
YES	10 (20%)	1 (2%)	9 (100%)	
Q2 Felt numb, No. (%)				<0.001
NO	37 (76%)	36 (90%)	1 (11%)	
YES	12 (24%)	4 (10%)	8 (89%)	
Referral made (Positive PC: PTSD Screen), No. (%)				<0.001
NO	41 (82%)	41 (100%)	0 (0%)	
YES	9 (18%)	0 (0%)	9 (100%)	

Note: Comparisons between PTSD and non-PTSD patients were done using a two-sample *t*-test for continuous variables and Fisher's exact test for categorical statistics.

a standard of care in an EP clinic on all ICD recipients would help identify patients at increased risk for PTSD. Early recognition and referral to a mental health specialist provides comprehensive, superior care. Given the known association of increased morbidity and mortality in patients with cardiovascular disease and PTSD, this recommended practice standard becomes imperative for improved patient outcomes such as reducing the likelihood of future ICD shocks and increased mortality risk.

Limitations

The findings from this study should be interpreted in light of several limitations. First, the study sample was relatively small and located in a large EP outpatient clinic in an urban community. While this is an important group to study, given their underlying all-inclusive cardiac indicators for the recipient's implantable cardiac defibrillator, these results may not generalize to other populations. Second, though the PC: PTSD tool is a validated measure of PTSD, it has never been studied looking at the operating characteristics in the EP outpatient clinic to screen for PTSD symptoms.

Summary

There is an urgent need for a multidisciplinary approach to care for ICD recipients with PTSD symptoms as was demonstrated by the current project. The increased prevalence of PTSD in ICD patients measured by this study as 18% supports the need and is consistent with previous research. PTSD symptoms are a key source of emotional distress in patients with ICDs. These symptoms may persist for years; therefore, they should not be overlooked. EP clinicians should screen regularly for PTSD symptoms, and those with

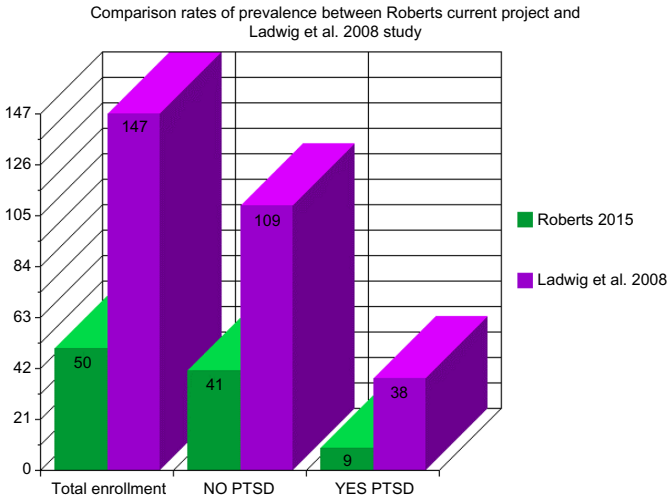

Figure 1. PTSD prevalence rate comparison.
Notes: PTSD prevalence was compared to Ladwig et al's, (2008), study prevalence using Fisher's exact test (Fig. 3). In the Ladwig et al's, (2008) study, prevalence was determined as the proportion of patients having a positive PTSD result (n = 38 out of 147). All analyses were conducted using SAS v9.4.

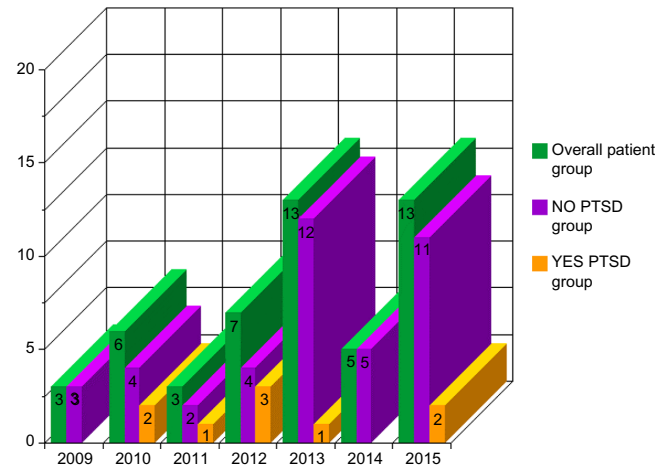

Figure 2. Prevalence of PTSD per the ICD implant year.
Notes: When evaluating the PTSD symptoms from the time of the ICD implant (2009 to 2015), an increased burden of PTSD symptoms was observed in the group of participants with ICD implanted in 2015, (26%) compared to those with ICD implanted in 2009, (6%).

positive results should be referred to a mental health specialist. Improved integration of mental health services in the EP clinic will better serve these high-risk patients. Future research is needed to validate the global prevalence of PTSD in EP clinics with ICD recipients. Subsequently, the magnitude of PTSD could be fully evaluated to determine if patient education and a referral protocol to mental healthcare services decrease the prevalence of PTSD and prevent detrimental health outcomes.

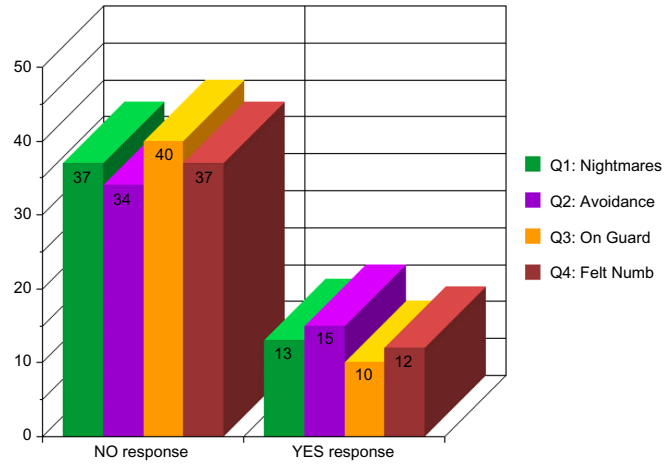

Figure 3. ICD recipient response to the PC: PTSD screen.
Notes: Twenty-six percent of the overall patient group experienced nightmares during the previous thirty days ($P = 0.001$). Within the same patient group, 31% reported symptoms of avoidance ($P = 0.001$). Twenty percent of these patients reported that they felt on guard $P = 0.001$). Twenty-four percent of this group documented that they felt numb ($P = 0.001$).

Author Contributions

Prepared concept, design and protocol: CRR. Development of a search strategy, selected studies, obtained papers, extracted data, appraised quality of trials, and entered data: CRR. Inclusion and exclusion of project and acquisition of data: CRR. Extracted the data and assessed risk of bias: CRR. Data entry and plausibility check: CRR, JEW. Analysis and interpretation of data: CRR, JEW. Performed the statistical analysis: CRR. Drafted final review: CRR. Prepared summary of findings in tables and figures: CRR. Kept the review up-to-date: CRR. Revised final report: CRR, MNF. Project supervision: JEW, HMH, MNF. Clinical and scientific advice: JEW, HMH, MNF. Assisted in preparing the concept, design and protocol: JEW, MNF. Assisted with the analysis and interpretation of data: JEW, MNF. Assisted with assessing the risk of bias: JEW. Assisted with keeping the review up-to-date: JEW, HMH. Contributed to drafting the manuscript: JEW, HMH, MNF. Statistical advice and data analysis: JEW, MNF. Assisting in correcting the final report: JEW. CRR and MNF had full access to all data during the project and took responsibility for the integrity of the data and the accuracy of the analysis. CRR, JEW, HMH, MNF were responsible for reviewing drafts of the manuscript. CRR, JEW, HMH, MNF commented on and approved the final version. All authors reviewed and approved of the final manuscript.

REFERENCES

1. Roger VL, Go AS, Lloyd-Jones DM, et al; American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Executive summary: heart disease and stroke statistics – 2012 update: a report from the American Heart Association. *Circulation*. 2012;125(1):188–97.
2. Whitworth JA, Chalmers J. World health organisation-international society of hypertension (WHO/ISH) hypertension guidelines. *Clin Exp Hypertens*. 2004;26(7–8):747–52.

3. Huikuri HV, Castellanos A, Myerburg RJ. Sudden death due to cardiac arrhythmias. *N Engl J Med*. 2001;345(20):1473–82.
4. 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. *ANS Adv Nurs Sci*. 2012;35(4):359–77.
5. Borbola J, Denes P, Ezri MD, Hauser RG, Serry C, Goldin MD. The automatic implantable cardioverter-defibrillator. Clinical experience, complications, and follow-up in 25 patients. *Arch Intern Med*. 1988;148(1):70–6.
6. Kikkenborg Berg S, Støier L, Moons P, Zwisler AD, Winkel P, Ulrich Pedersen P. Emotions and health: findings from a randomized clinical trial on psychoeducational nursing to patients with implantable cardioverter defibrillator. *J Cardiovasc Nurs*. 2015;30(3):197–204.
7. Goldberger Z, Lampert R. Implantable cardioverter-defibrillators: expanding indications and technologies. *JAMA*. 2006;295(7):809–18.
8. Burke JL, Hallas CN, Clark-Carter D, White D, Connelly D. The psychosocial impact of the implantable cardioverter defibrillator: a meta-analytic review. *Br J Health Psychol*. 2003;8(pt 2):165–78.
9. Shiga T, Suzuki T, Nishimura K. Psychological distress in patients with an implantable cardioverter defibrillator. *J Arrhythm*. 2013;29(6):310–3.
10. Sears SF, Hauf JD, Kirian K, Hazelton G, Conti JB. Posttraumatic stress and the implantable cardioverter-defibrillator patient: what the electrophysiologist needs to know. *Circ Arrhythm Electrophysiol*. 2011;4(2):242–50.
11. American Psychiatric Association, D.S.M.T. Force. *Diagnostic and Statistical Manual of Mental Disorders: DSM-5*. Washington, DC: American Psychiatric Association; 2013.
12. Tulloch H, Greenman PS, Tasse V. Post-traumatic stress disorder among cardiac patients: prevalence, risk factors, and considerations for assessment and treatment. *Behav Sci (Basel)*. 2014;5(1):27–40.
13. Fugate JE, Brinjikji W, Mandrekar JN, et al. Post-cardiac arrest mortality is declining: a study of the US National Inpatient Sample 2001 to 2009. *Circulation*. 2012;126(5):546–50.
14. Reinikainen M, Oksanen T, Leppänen P, et al; Finnish Intensive Care Consortium. Mortality in out-of-hospital cardiac arrest patients has decreased in the era of therapeutic hypothermia. *Acta Anaesthesiol Scand*. 2012;56(1):110–5.
15. O'Reilly SM, Grubb N, O'Carroll RE. Long-term emotional consequences of in-hospital cardiac arrest and myocardial infarction. *Br J Clin Psychol*. 2004;43(pt 1):83–95.
16. Sears SF, Todaro JF, Urizar G, et al. Assessing the psychosocial impact of the ICD: a national survey of implantable cardioverter defibrillator health care providers. *Pacing Clin Electrophysiol*. 2000;23(6):939–45.
17. Jacq F, Foulldrin G, Savouré A, et al. A comparison of anxiety, depression and quality of life between device shock and nonshock groups in implantable cardioverter defibrillator recipients. *Gen Hosp Psychiatry*. 2009;31(3):266–73.
18. Pedersen SS, van Domburg RT, Theuns DA, Jordaens L, Erdman RA. Concerns about the implantable cardioverter defibrillator: a determinant of anxiety and depressive symptoms independent of experienced shocks. *Am Heart J*. 2005;149(4):664–9.
19. American Nurses Association. *Nursing's Social Policy Statement: The Essence of the Profession*. Silver Spring, MD: American Nurses Association; 2010.
20. Dunbar SB, Dougherty CM, Sears SF, et al; American Heart Association Council on Cardiovascular Nursing, Council on Clinical Cardiology, and Council on Cardiovascular Disease in the Young. Educational and psychological interventions to improve outcomes for recipients of implantable cardioverter defibrillators and their families: a scientific statement from the American Heart Association. *Circulation*. 2012;126(17):2146–72.
21. Bowman GS. Emotions and illness. *J Adv Nurs*. 2001;34(2):256–63.
22. Sossong A. Living with an implantable cardioverter defibrillator: patient outcomes and the nurse's role. *J Cardiovasc Nurs*. 2007;22(2):99–104.
23. Dougherty CM. The natural history of recovery following sudden cardiac arrest and internal cardioverter-defibrillator implantation. *Prog Cardiovasc Nurs*. 2001;16(4):163–8.
24. Veseth-Rogers J. A practical approach to teaching the automatic implantable cardioverter-defibrillator patient. *J Cardiovasc Nurs*. 1990;4(2):7–19.
25. Jonas DE, Cusack K, Forneris CA, et al. AHRQ Comparative Effectiveness Reviews, in Psychological and Pharmacological Treatments for Adults with Posttraumatic Stress Disorder (PTSD). Rockville, MD: Agency for Healthcare Research and Quality (US); 2013.
26. Ladwig KH, Baumert J, Marten-Mittag B, Kolb C, Zrenner B, Schmitt C. Posttraumatic stress symptoms and predicted mortality in patients with implantable cardioverter-defibrillators: results from the prospective living with an implanted cardioverter-defibrillator study. *Arch Gen Psychiatry*. 2008;65(11):1324–30.
27. Kapa S, Rotondi-Trevisan D, Mariano Z, et al. Psychopathology in patients with ICDs over time: results of a prospective study. *Pacing Clin Electrophysiol*. 2010;33(2):198–208.
28. von Känel R, Baumert J, Kolb C, Cho EY, Ladwig KH. Chronic posttraumatic stress and its predictors in patients living with an implantable cardioverter defibrillator. *J Affect Disord*. 2011;131(1–3):344–52.
29. Edmondson D, Kronish IM, Shaffer JA, Falzon L, Burg MM. Posttraumatic stress disorder and risk for coronary heart disease: a meta-analytic review. *Am Heart J*. 2013;166(5):806–14.
30. Prins A, Ouimette P, Kimerling R, et al. The primary care PTSD screen (PC-PTSD): developing and operating characteristics. *Primary Care Psychiatry*. 2003;9:9–14.
31. Engel GL. The biopsychosocial model and the education of health professionals. *Ann N Y Acad Sci*. 1978;310:169–87.
32. Engel GL. The clinical application of the biopsychosocial model. *Am J Psychiatry*. 1980;137(5):535–44.
33. Drummond N. Quality of life with asthma: the existential and the aesthetic. *Sociol Health Illn*. 2000;22(2):235–53.
34. Stanfield P, Cross N, Hui YH. *Introduction to the Health Professions*. 6th ed. Burlington, MA: Jones & Bartlett Learning; 2012:xvi, 491.
35. Institute of Medicine. Institute of medicine committee on the Robert Wood Johnson foundation initiative on the future of nursing. *The Future of Nursing: Leading Change, Advancing Health*. Washington, DC: National Academies Press (US), National Academy of Sciences; 2011.

Appendix A

Primary Care PTSD Screen (PC-PTSD)

Description

The PC-PTSD is a 4-item screen that was designed for use in primary care and other medical settings and is currently used to screen for PTSD in veterans at the VA. The screen includes an introductory sentence to cue respondents to traumatic events. The authors suggest that in most circumstances the results of the PC-PTSD should be considered "positive" if a patient answers "yes" to any 3 items. Those screening positive should then be assessed with a structured interview for PTSD. The screen does not include a list of potentially traumatic events.

Scale

Instructions:

In your life, have you ever had any experience that was so frightening, horrible, or upsetting that, in the past month, you:

1. Have had nightmares about it or thought about it when you did not want to?

   YES / NO

2. Tried hard not to think about it or went out of your way to avoid situations that reminded you of it?

   YES / NO

3. Were constantly on guard, watchful, or easily startled?

   YES / NO

4. Felt numb or detached from others, activities, or your surroundings?

   YES / NO

Current research suggests that the results of the PC-PTSD should be considered "positive" if a patient answers "yes" to any three items.

Prins, Ouimette, & Kimerling, 2003

Appendix B

We invite you to participate in a research study being conducted by investigators from Washington University in St. Louis. The purpose of the study is to evaluate for symptoms of post-traumatic stress disorder in patients with an implantable cardioverter defibrillator.

If you agree to participate, we would like you to complete a brief four question survey about possible symptoms of PTSD. You are free to skip any questions that you prefer not to answer. It will take approximately five minutes of time to complete the survey.

The only risk to participation is that you may feel uncomfortable answering the questions about PTSD. You may or may not benefit from this study. If your survey responses reveal you have symptoms of PTSD, you will be offered a referral to a counselor. However we hope that others may benefit in the future from what we learn as a result of this study.

You will not have any costs for being in this research study. You will not be paid for being in this research study.

We will not collect your name or any identifying information about you. It will not be possible to link you to your responses on the survey.

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed. If you decide not to take part in the study or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

If you do not wish to participate in this study or want to end your participation in the study, return the survey without answering any of the questions. You will not be penalized or lose any benefits for which you otherwise qualify.

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Carmen Roberts, MSN, ANP-BC, 314-286-1597. If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445 or email hrpo@wusm.wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu/. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

Thank you very much for your consideration of this research study.