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Predictors of Implantable Cardioverter Defibrillator (ICD) Shocks During the First Year

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Abstract

Background and Research Objective—The purpose of this study was to predict implantable cardioverter defibrillator (ICD) shocks using demographic and clinical characteristics in the first year after implantation for secondary prevention of cardiac arrest.

Subjects and Methods—A prospective design was used to follow 168 first time ICD recipients over 12 months. Demographic and clinical data were obtained from medical records at the time of ICD insertion. ICD shock data were obtained from ICD interrogation reports at hospital discharge, 3, 6, and 12 months. Logistic regression was used to predict ever receiving an ICD shock using background characteristics.

Results and Conclusions—Subjects received an ICD for secondary prevention of sudden cardiac arrest, were 64.1 years old, 89% Caucasian, 77% male, with a mean ejection fraction (EF)% = 33.7 +14.1%. The cumulative % of ever receiving an ICD shock was 33.3% over 1 year. Three variables predicted shocks in the first year: history of COPD (OR 4.42, 95% CI 1.2-16.4, p = 0.03), history of CHF (OR 3.55, 95% CI 1.4-9.3, p = 0.01), and documented ventricular tachycardia (VT) at the time of ICD implant (OR 10.05, 95% CI 1.8-55.4, p = 0.01). High levels of anxiety approached significance (OR = 2.82, p = 0.09). The presence of COPD, CHF, or VT at ICD implant were significant predictors of receiving an ICD shock in the first year post-ICD. Because ICD shocks are distressing, painful, and associated with greater mortality, health care providers should focus attention on prevention of shocks by controlling VT, careful management of HF symptoms, reducing the use of short acting beta agonist medications in COPD, and perhaps recognizing and treating high levels of anxiety.

Keywords

implantable cardioverter defibrillator; ICD; shocks; sudden cardiac arrest

Introduction

Receiving shocks is a physically painful and emotionally distressing event experienced by those living with an implantable cardioverter defibrillator (ICD) [1-5]. Shocks decrease quality of life and increase health care utilization [2]. From multivariate risk profiles, approximately 50-60% of patients will receive a ICD shock within 9 ± 11 months after implantation, an average

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of 2.3 shocks/patient /year [6-9]. The longer a person has had the ICD the less accurate they are at remembering how many shocks they received [4].

Past predictors of receiving an ICD shock after implantation includes inducible monomorphic ventricular tachycardia (VT) or sustained or non-sustained VT at time of ICD implant [10-12], history of VT at the time of myocardial infarction (MI) [13], sedentary life style [5], past history of renal failure [14], ejection fraction $\leq 35\%$ [12], emotional distress [11,37], depression [16], smoking [17], not taking beta blocker medication [13], and elevated B-type natriuretic peptide (BNP) above the 50th percentile (283 ng/L) [18].

Inappropriate ICD shocks can be caused by problems associated with the device such as lead failure, physical damage to the device, far field atrial sensing, diaphragmatic potentials, T wave oversensing, and electrical noise [1,36]. In addition, atrial fibrillation [2,19], supraventricular arrhythmias, NYHA Class I heart failure [19], and single chamber ICDs are associated with more inappropriate ICD shocks.

After having an ICD implanted, any shock increases the chance of cardiac mortality by twofold [20]. Those who experience frequent shocks are at a high risk for experiencing cardiac arrhythmia and sudden cardiac death, even when shocks are appropriate [1]. Pathological studies have demonstrated fibrosis and acute cellular injury in the hearts of patients who have had recent shocks [21]. The occurrence of electrical storms from an ICD (> 3 distinct ICD shocks in a 24 hour period) is related to increased morbidity and mortality. These deaths usually occurred within the first three months after of an electrical storm [21,22].

After an ICD shock, patients express high levels of anxiety, anger, stress, depression, fear and poor quality of life [23,24]. ICD shocks lead to greater psychological distress for family members as well [23,25]. The experience of having a shock erodes psychological defense mechanisms and confidence, creating feelings of uncertainty about the future [5,26]. Having one or more shocks within the first year after implantation is associated with a significant decline in reported physical and mental functioning [3]. Anxiety scores of those receiving ICD shocks has been reported to be similar to those with panic disorder [26]. Receiving 5 or more shocks [2] or 6 or more shocks has been documented to result in reduced patient well being, whether ICD shocks are appropriate or inappropriate [27]. Receiving multiple and repeated ICD shocks results in post-traumatic stress disorder (PTSD) or reactive depression in approximately 15-30% of the patients who are living with an ICD [28,29].

ICD shock intensity can be rather severe, rated as 4.0 on a 0-5 scale [4]. After an ICD shock individuals are fearful that activity will trigger another shock. Multiple shocks were the most frightening for patients, causing them to wonder if the device was really working or if the ICD would even kill them [23,24]. It is not uncommon for individuals to avoid activities that have caused an ICD therapy or activity they perceive might result in an ICD therapy. This avoidance of activities that might cause an ICD discharge has been associated with reduced quality of life [4,5,26]. This decreased functioning, if present, occurs during the first 6 months after implantation, and is followed by acceptance as the patient realizes the device is essential for their well-being [5]. ICD shocks can act as an "illness scoreboard", with the more shocks a person receives being correlated with a greater illness burden. [26].

If health care providers can predict who is most likely to receive an ICD shock after implantation, interventions to prevent and avoid ICD shocks can be implemented. In doing so, the quality of life and overall adjustment of patients will be enhanced and mortality will be reduced.

The purpose of this paper is to report baseline clinical characteristics that predicted the receipt of an ICD shock during the first year after implantation in persons who had an ICD for the

secondary prevention of sudden cardiac arrest. This is a secondary analysis of data collected initially to test the effects of a nursing intervention on psychological functioning in the first year subsequent to ICD implantation.

Methods

This study used a longitudinal randomized clinical trial to test the effects of a combined education and telephone intervention delivered by trained cardiovascular nurses when compared to usual care. Study participants were sudden cardiac arrest (SCA) survivors or those with malignant ventricular arrhythmias who received an ICD for the first time. Measurements were collected at hospital discharge, and at three, six and 12 months post-hospitalization. All research procedures were reviewed and approved by hospital Institutional Review Boards (IRB) and the academic IRB prior to contact with potential participants.

Protocol

Potential participants were identified during hospitalization by site coordinators in 10 medical centers in the Pacific Northwest. Those interested in the study were contacted by telephone the day after hospital discharge by the researchers, who explained the study and obtained verbal consent to participate. Written informed consent and baseline measures were completed during the first week after hospital discharge. Participants were recruited to participate in a nursing intervention study that focused on psychological recovery following ICD implantation. While they were in that study, ICD shock data from each study participant was recorded. The nursing intervention was a telephone intervention that was delivered during the first eight weeks after hospital discharge. The nursing intervention program had no effect on the number of ICD shocks received by participants, therefore the entire group was combined for these analyses.

Sample

Study participants (N= 168) included individuals who had experienced a first sudden cardiac arrest or life threatening arrhythmia requiring ICD implantation for secondary prevention based on established guidelines [30]. Additional criteria included the ability to read, speak, and write English, having telephone access, and willingness to be followed for 1 year. Individuals were excluded from the study if they had significant clinical co-morbidities that impaired cognitive and physical functioning, or if they were less than 21 years of age. Confirmation of the need for ICD implantation was verified through medical records and EPS reports. All participants were screened with the Short Blessed cognitive screening tool [31] at recruitment. Short Blessed scores of 10 or greater indicated cognitive impairment too severe for participants in this study received usual care as provided by the hospital and health care providers in the community. Usual care consisted of standardized hospital-based education about the ICD and outpatient follow-up clinic visits at times and frequency as designated by their current health care providers.

ICD shock measurement

ICD shock information was collected subjectively from participants as they experienced an ICD shock and reported it to their health care provider. Then, ICD interrogation reports of ICD shocks were obtained from the provider who completed the ICD interrogation. All ICD shocks received were included in these analyses. Subjects who were enrolled into the clinical trial had to have experienced a ventricular arrhythmia and/or out of hospital ventricular fibrillation (VF) cardiac arrest to be enrolled in the study. Patients were not enrolled in the study if they received an ICD for primary prevention of SCA without having a previous history of ventricular arrhythmia. There were no patients in the study who had a bi-ventricular ICD implanted.

Clinical variables

Baseline demographic and clinical variables were collected from self-report and/or from medical records review at the time of study entry. Anxiety was measured using the state version of the State-Trait Anxiety Inventory (STAI) [40]. Depression was measured using the Centers for Epidemiologic Studies-Depression Scale (CES-D) [41].

Analysis

Baseline demographic and clinical characteristics were used to create a multi-variate risk profile for predicting those who did or did not receive a shock in the first year subsequent to receiving an ICD. Data are summarized as mean \pm SD. The significance was defined as $p \leq 0.05$ using a two-tailed test. A statistical model for predicting ever receiving an ICD shock over 12 months after ICD implant was created using a stepwise multiple logistic regression model. Baseline demographic and clinical characteristics were used as the independent variables in the analysis. Statistical significance of bivariate relationships between the outcome variable of ever receiving an ICD shock and the independent variables was evaluated by either Chi-Square statistics for categorical variables or analysis of variance (ANOVA) for continuous variables. The effect of the independent variables on the outcome was measured by odds ratio (OR). All statistical analyses were conducted using the Statistical Package for the Social Sciences (SPSS, 14.0).

Results

Sample Characteristics

Over a 21 month period, 243 SCA survivors were referred for participation in the study. Of these 243, eight (3.3%) did not return baseline questionnaires within 1 month of hospital discharge and were not offered admission to the study, 28 (11.5%) were ineligible because of no documented ventricular arrhythmia, 18 (7.4%) did not want to continue after reviewing the questionnaire packet, 20 (8.2%) refused participation on the telephone or could not be contacted after hospital discharge, and one person wanted to be paid more money to participate. The remaining 168 (69%) SCA survivors were followed for 1 year after ICD implantation.

The average age was 64.1 ± 12.28 years, with most participants being Caucasian (89%) and male (76%). The majority of SCA survivors were in a relationship with a spouse or significant intimate partner (79%), and 98.2% lived in an independent living situation with that partner. At baseline, the cognitive capabilities of participants resulted in an average of two "errors" on the Short Blessed screening tool. The average combined household income was \$30,000-49,999 (33%) and over half of the participants (64.3%) were retired from full-time work. The average level of education was "some college" for 26.6%, and 41.1% had a two year college degree or higher degree (Table I).

The average body mass index was 28.32 cm/m³, defined as overweight by NHLBI criteria. A total of 116/168 individuals were considered overweight I at the time of study entry. The average ejection fraction for the sample was 33.7%. The most common reason for ICD implant was documented ventricular fibrillation (VF) or ventricular tachycardia (VT) at electrophysiological testing (EPS), with 39% having had survived out of hospital VF cardiac arrest. Charlson co-morbidity index scores [17] averaged 4.34, indicating that persons in the study had a number of other co-morbid disease conditions at the time or study entry.

ICD Shocks

Out of a total of 168 patients at baseline hospital discharge, 51 received 1 ICD shock in the first year, a cumulative shock event rate of 33.3%. Three individuals received 1 or more ICD shocks while they were still hospitalized and before going home (1.7%). The cumulative ICD

shock rate was the following: 12.6% received an ICD shock between hospital discharge and 1 month, 7.5% between 1 and 3 months, 7.1% between 3 and 6 months, and 17.3% between 6 and 12 months. Of the 51 who received an ICD shock, 34 (66.6%) received only 1 ICD shock in the first year. Twelve of these 51 (23.5%) received 4 or more shocks in a 24 hour period during the 12 month follow-up period. One person experienced 119 ICD shocks in 1 day caused by atrial tachycardia and atrial fibrillation. The average (mean \pm SD) number of ICD shocks received by any person who received a shock was 2.25 ± 1.15 between hospitalization and 1 month (range 1-12), 1.58 ± 0.48 between 1 and 3 months (range 1-4), 3.45 ± 0.99 between 3 and 6 months (range 1-18, excluding the person who got 119 shocks), and 2.73 ± 1.28 between 6 and 12 months (range 1-8).

The baseline clinical characteristics that were associated with receiving an ICD shock between 1 and 3 months were: 1) ejection fraction (EF) \leq 35% and 2) Charlson Co-morbidity score. Characteristics associated with receiving and ICD shock between 3 and 6 months were 1) documented VT lasting > 30 seconds and 2) not taking a beta blocker. Characteristics associated with receiving an ICD shock between 6 and 12 months were: 1) documented VT lasting > 30 seconds and 2) not taking a beta blocker. Characteristics associated with receiving an ICD shock between 6 and 12 months were: 1) documented VT lasting > 30 seconds and 2) a past history of CHF (Table II).

Comparisons between subjects who did or did not experience an ICD shock in the 12 month period following ICD implant were conducted using chi-square analyses (Table III). There were significant differences between the groups in reason for ICD implant, history of chronic obstructive pulmonary disease (COPD), and congestive heart failure (CHF). Subjects that had experienced an ICD shock in the twelve-months after implant had a greater occurrence of COPD, CHF, or had their ICD implanted for unmonitored syncope with VT lasting > 10 seconds.

Multiple logistic regression analyses were used to predict the baseline clinical characteristics associated with receiving an ICD shock within 12 months. All variables were entered into the model simultaneously (Table IV). Characteristics with a predictive value less than 0.50 were excluded from the final model. The predictors of receiving a shock within the first twelve months after having an ICD placed included: 1) COPD (OR = 3.10, p = 0.04), 2) CHF (OR = 3.10, p = 0.04), and 3) implantation of ICD for unmonitored syncope and VT greater lasting > 10 seconds (OR = 4.45, p = 0.02). This was a significant model (p < 0.001) and accounted for 11% of the variance in having a shock within 12 months. Statistics indicated that the model fit the data well (Hosmer and Lemeshow, $\chi^2 = 0.52$, p = 0.77). High anxiety at the time of ICD implanted, approached statistical significance (OR=2.82, p = 0.09).

During the 12 month follow-up period, 5/168 (2.9%) died from congestive heart failure. Of these 5 who died, 1 person had received at least 1 ICD shock during the first year after receiving an ICD. However, ICD shocks were not found to be a significant predictor of mortality in this study.

Discussion

The results of this study indicate that one third (33.3%) of patients who received an ICD for the secondary prevention of sudden cardiac arrest experienced at least 1 shock in the first year after implantation. A medical history of CHF, COPD, or receiving an ICD for documented VT was more often associated with receiving an ICD shock than those not having these characteristics. ICD shocks in our study were not significantly associated with an increased mortality. These findings are consistent with other reports from the literature. Moreover, these data were collected prospectively while other studies have collected the data retrospectively relying on the accuracy of medical record entries and patient reports.

Recent reports that have examined predictors of ICD shock within the first year following implantation point to reason for ICD implant, renal insufficiency, smoking, use of beta blockers, and clinical risk scores. Clinical risk scores are derived based on the reason for implant, serum creatinine level, and QRS duration. This new scoring method is highly predictive of time to appropriate ICD shock [34].

A new finding of this study was the association between occurrence of ICD shocks and a history of COPD. This may be due to acceleration of heart rate frequently seen with the use of short-acting metered-dose inhalers containing beta agonists [33]. Elevated heart rate frequently precedes an ICD shock. Furthermore, hypokalemia occurs with the administration of beta agonists due to the intracellular shift of potassium into skeletal muscle. Hypokalemia is a risk factor for cardiac arrhythmias including VT and VF.

Heart failure can play a role in the occurrence of ICD shock. In patients where the left ventricular ejection fraction (LVEF) was <20% there is a strong association with receiving a shock [34]. Additionally, when the LVEF is <35%, there is a 7 times higher risk of dying, and this risk increases 16 fold when multiple shocks occur [20]. Patients with NYHA Class III heart failure are 2 times as likely to receive a shock as people with Class I/II. It was also found that if the device had a longer detection time, fewer therapies occurred [1]. NYHA Class IV was found to be an independent predictor of appropriate ICD therapy in those with biventricular defibrillators [35].

As seen in other studies [2,13], we found that beta blockers seem to exert a modulating influence on the occurrence of ICD shocks, with less than 1/3rd of patients receiving beta blockers received an ICD shock in the first year. Similarly Hreybe [13] in a large cohort of 230 patients with ICD implant found the 1-year shock free survival significantly increased from 48% to 61% in the presence of beta blockers. These data suggest an antiarrhythmic protective effect of beta blockers.

We did not find a significant relationship between anxiety and depression and ICD shocks in the first year. We may have reached this result because STAI scores \geq 40 are defined as high anxiety [40], and were used in this analysis. However, high levels of anxiety and the occurrence of ICD shocks approached statistical significance in this analysis, p = 0.09. Our data suggests that psychological distress at the time of ICD implant may be related to subsequent ICD shock frequency. Other authors have demonstrated the important relationship between mood disturbance and ICD therapies after controlling for ejection fraction, type of arrhythmia history, and use of anti-arrhythmic medications [37]. In addition, concerns about the ICD at the time of implant have also been linked to ICD therapies [38].

While we did not find smoking to be a significant predictor for the occurrence of ICD shocks, 32% of those that smoked experienced an ICD shock in the first year. Smoking, in addition to being implicated in heart and vascular disease, continues to exact its toll by causing arrhythmias. Although the exact mechanism causing arrhythmias is unknown [17], when a patient stops smoking the rates of sudden cardiac death decrease markedly. Sanchez et al reported 37.5% of patients that smoked had an ICD discharge within the first month following implant. Smoking was a better predictor of an appropriate ICD discharge than other variables such as age, ejection fraction, QT interval, QRS duration, diabetes, COPD, or use of medications such as ACE inhibitors, β -blocker use [17]. This supports the importance of smoking cessation programs for individuals with an ICD implant in order to maximize quality of life and reduce ICD shock occurrence.

Conclusions

It is clear that preventing and avoiding shocks after an ICD is important to reduce mortality, psychological distress, and health care utilization. Our data suggests that actions by health care providers and patients that could reduce the number of ICD shocks includes controlling VT, careful management of HF symptoms, perhaps reducing the use of short acting beta agonist medications in COPD. Attention to the role of anxiety in producing ICD shocks in future investigations is warranted. In addition, stopping smoking, taking beta blocker medications, managing anxiety and depression, treating atrial fibrillation and supraventricular arrhythmias, and close follow-up of ICD function to detect device malfunction will potentially reduce ICD shocks. Future studies are needed that prospectively evaluate interventions and treatments to obviate the occurrence of ICD shocks in an effort to provide sound scientific evidence to guide treatment of this particularly vulnerable patient population.

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$\label{eq:sample characteristics} \begin{array}{c} \mbox{Table I} \\ \mbox{Sample Characteristics (N=168), mean \pm SD or N (%) } \end{array}$

Variable		
Age (mean + SD)		64.1 ± 12.31
Body mass index (cm/ m^3) (mean + SD)		28.32 ± 6.34
Short Blessed score(mean + SD)		2.46 ± 2.86
Ejection fraction (mean + SD)		33.77 ± 13.6
Charlson Co-morbidity Index (mean + SD)		4.34 ± 2.34
Prior MI N (%)		96 (57.1)
Partner (%)	With partner	132 (78.6)
Gender (%)	Male	129 (76.3)
	Caucasian	149 (89.2)
	Am. Indian/Alaska	4 (2.4)
Ethnicity (%)	Asian/PI	4 (2.4)
	Black/African	7 (4.2)
	Other	3 (1.8)
	some H.S.	19 (11.3)
	H.S. Grad	39 (23.2)
	A.A./Tech Grad	20 (11.9)
Education (%)	college grad	20 (11.9)
	> college grad	25 (14.8)
	some college/other	45 (26.6)
Employment (%)	Employed	60 (35.7)
	< \$10k	5 (3.4)
	\$10k - \$29,999k	39 (26.5)
	\$30k - \$49,999k	49 (33.3)
Income (%)	\$50k - \$69,999k	23 (15.6)
	\$70k - \$89,999k	16 (10.9)
	> \$90k	15 (10.2)
	VF cardiac arrest	65 (38.8)
ICD reason (%)	Sustained VT with syncope	16 (9.5)
	VF or VT on EPS	87 (51.7)

ICD reason=reason for initial ICD (implantable cardioverter defibrillator) implant.

EPS = electrophysiology study.

SD=standard deviation

Table II

Associations between receiving an ICD shock at a specified time period and baseline characteristics (N=51)

ICD shock	Variable	Chi-square (χ^2)	р
1-3 months	$EF \le 35\%$	4.82	0.03
	Charlson Co-morbidity score	4.81	0.03
3-6 months	VT > 10 seconds	12.40	0.009
	Beta blocker	3.59	0.05
6-12 months	VT > 10 seconds	6.44	0.05
	CHF	9.70	0.002

ICD = implantable cardioverter defibrillator

EF=ejection fraction

VT=ventricular tachycardia

CHF=congestive heart failure

Table III

Associations between Baseline Characteristics and Receiving an ICD shock or not over 12 months

Variable N(%)	No shocks (n=117)	Shock (n=51)	χ ²	р
Age			6.23	0.28
< 30	4 (100%)	0 (0 %)		
30-39	0 (0 %)	0 (0 %)		
40-49	9 (50 %)	9 (50 %)		
50-59	24 (72.7 %)	9 (27.3 %)		
60-69	38 (71.7 %)	15 (28.3 %)		
70-79	33 (33 %)	12 (26.7 %)		
> 80	9 (60 %)	6 (40 %)		
Gender-male	88 (68.2 %)	41 (31.8 %)	0.53	0.47
ICD reason [*]				
VF cardiac arrest	48 (73.8 %)	17 (26.2 %)	0.89	0.35
Sustained VT with syncope	13 (81.3 %)	3 (18.8 %)	1.13	0.29
Unmonitored syncope & VT > 10 sec	5 (38.5 %)	8 (61.5 %)	6.48	0.01
VT lasting ≥ 30 seconds	4 (44.4 %)	5 (55.6%)	2.86	0.91
VT or VF inducible on EPS	47 (72.3 %)	18 (27.7 %)	0.36	0.55
Taking beta blocker medication	73 (68.9 %)	33 (31.1 %)	0.08	0.78
Diabetes Mellitus	31 (72.1 %)	12 (27.9 %)	0.16	0.69
COPD	8 (47.1 %)	9 (52.9 %)	4.56	0.03
Hypertension	62 (66.7 %)	31 (33.3 %)	0.87	0.35
Congestive Heart Failure	47 (60.3 %)	31 (39.7 %)	6.07	0.01
Carotid artery stenosis	9 (90 %)	1 (10 %)	2.08	0.15
Stroke	16 (59.3 %)	11 (40.7 %)	1.64	0.20
Liver/Renal disease	12 (70.6 %)	5 (29.4 %)	0.01	0.93
Sedentary lifestyle	45 (65.2 %)	24 (34.8 %)	1.09	0.30
Current smoker	26 (68.4 %)	12 (31.6 %)	0.04	0.85
Myocardial Infarction	63 (67.7 %)	30 (32.3 %)	0.14	0.71
Ejection Fraction ≤ 30 %	49 (66.2%)	25 (33.8%)	0.38	0.53
$BMI \ge 25$	77 (66.4%)	39 (33.6%)	1.89	0.17
Depression ≥ 16 on CES-D	29 (76.3 %)	9 (23.7 %)	1.03	0.31
Anxiety ≥ 40 on STAI	43 (78.2 %)	12 (21.8 %)	2.82	0.09
Ethnicity			1.79	0.76
White	104 (69.3 %)	46 (30.7 %)		
American Indian/Alaska	2 (66.7 %)	1 (33.3 %)		
Asian/Pacific Islander	4 (100 %)	0 (0 %)		
Black/African	5 (71.4 %)	2 (28.6 %)		
Other	2 (66.7 %)	1 (33.3 %)		
Charlson Comorbidity Score (mean, SD) *	4.31 (2.29)	4.31 (2.44)	0.10	0.75
Short Blessed (mean, SD) *	2.44 (3.02)	2.39 (2.71)	0.01	0.92

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* ICD reason=reason for initial ICD implant.

- ICD= implantable cardioverter defibrillator.
- COPD=chronic obstructive pulmonary disease.

BMI=body mass index.

- STAI=State-Trait Anxiety Inventory
- CES-D=Centers for Epidemiologic Studies-Depression Scale

* F statistic by ANOVA.

Final Logistic Regression Model

Variable	Model R ²	В	Wald	þ	Odds Ratio	Confidence Interval
constant	60.0	-1.51	29.26	0.00	0.22	
Documented VT > 10 seconds		1.49	5.81	0.02	4.45	1.32-14.98
COPD		1.13	4.38	0.04	3.10	1.08 - 8.91
CHF		0.82	2.37	0.02	2.28	1.14 - 4.56
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Dougherty and Hunziker

COPD=chronic obstructive pulmonary disease

VT=ventricular tachycardia

CHF=congestive heart failure