Out of Hospital Sudden Death in a Rural Population: Low Rates of ICD Underutilization Among Decedents

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Abstract

Introduction: The implantable cardioverter defibrillator (ICD) reduces mortality in patients at risk for potentially life-threatening arrhythmias. Access and distribution of ICDs in rural or economically disadvantaged populations is suspected to be low. This study examined Out of Hospital Premature Natural Death data and electronic medical record (EMR) data to identify rates of non-implantation of ICDs in a sample of decedents in eastern North Carolina.

Methods and Results: Death certificate information on 1,316 decedents were matched with EMR data (N = 967, 73.4%). Chart review indicated that 98 (14.1%) patients had a left ventricular ejection fraction (LVEF) measurement of ≤40 and 70 (7.2%) potential ICD candidates with a LVEF ≤35 were identified. Of the 70 identified patients, 5 (7.1%) did not meet criteria because LVEF subsequently improved. Of the remaining 65 patients, 32 (49.2%) already received an ICD or a wearable cardioverter-defibrillator (WCD), and 33 patients (50.7%) met ICD implantation criteria but had not received one. The reasons identified for non-implantation of ICDs included: limited life expectancy secondary to comorbidities, principally chronic kidney disease (CKD) (N=11, 17%), lack of physician adherence to guidelines (N=9, 14%), lost to follow-up (N=7, 11%), patient refusal (N=5, 8%), and patients yet to commence guideline directed medical therapy (N=1, 2%). Among our cohort of 967 individuals who died unexpectedly at home, 9 (0.9%) patients may have avoided unexpected death with an ICD/WCD.

Conclusion: This study using decedent data shows low rates of ICD-underutilization in a rural population, but also emphasizes the role that advanced comorbidities such as CKD play in ICD-underutilization.

Key Words: ICD-utilization, out of hospital death, premature death, heart failure with reduced ejection fraction

Introduction

Cardiovascular disease is a leading cause of death in the United States with more than 356,000 cases of out of hospital cardiac arrest annually, of which more than 90% are fatal.[1-2] In developed nations, 50-75% of cardiovascular deaths occur out of hospital.[3] Prophylactic implantation of implantable cardioverter defibrillators (ICDs) for prevention of sudden cardiac death (SCD) has been shown to reduce mortality among individuals who are at high risk and guidelines have established appropriate use criteria for ICDs for the prevention of SCD.[4-10] However, penetrance of ICD therapy is thought to be low, generally estimated at 30-40% of the eligible population with some studies reporting as low as 10% penetrance.[4,11-14] This under-utilization has been attributed to health disparities between gender, race, and insurance access.[5-6] Other factors such as comorbidities, regional disparities, physician and patient preference, and barriers to healthcare access may also result in under-utilization. For example, Parkash and colleagues (2017) found that when compared to urban clinics, rural clinics without on-site cardiac electrophysiology services had a lower rate of referral for ICD implantation and higher rate of refusal of ICDs.[7] Under-penetrance of ICD implantation would be expected to lead to an excess of sudden cardiac death in the community but, whilst the penetrance of ICD implantation is known, the number of deaths we fail to prevent is not.

Decedent research via use of death certificate data to inform retrospective clinical research is a novel approach that maximizes the scope of time in a target study population. We studied the population suffering *O*ut of *H*ospital *P*remature *N*atural *D*eath (OHPND), which we define as all non-cancer, non-traumatic deaths occurring in the community in the age range 18-74 years. We examined all victims of OHPND in a large rural community in eastern North Carolina (eNC) to determine how many met standard criteria for prophylactic ICD implantation but had not received one. The eNC population contains a large number of socially and medically isolated people, known to have a high incidence of vascular disease.[15] The OHPND cohort was assessed from a survey of death certificates and eligibility for ICD implantation was assessed from medical record review.

Methods

All OHPND victims from 29 eNC counties (total population: 1.4 million) were identified for calendar year 2016. Death certificate data were acquired from the North Carolina State Center for Health Statistics (https://schs.dph.ncdhhs.gov/). OHPND cases were defined as deaths occurring in adults 18-74 years old who died from natural causes, outside a hospital or medical facility, and were both a resident of and died in the same county. Traumatic deaths (accident, suicide, drug overdoses, etc.) were excluded, as were deaths where the primary cause was cancer. Primary cause of death was determined using International Classification of Diseases, 10th Revision.

A total of 1316 OHPND cases were identified among residents of 29 counties that make up eNC in 2016. Eligibility for ICD implantation was determined from a review of electronic medical records (EMR) data provided by the predominant local healthcare provider (Vidant Health Systems). Cases without Vidant EMRs or Care Everywhere records from outside providers were excluded from analysis. Of the 1,316 OHPND cases in 2016, 247 (18.8%) were identified as veterans on the death certificate. For the purposes of this study, we did not obtain access to medical records from the VA which may account for a portion of missing EMR data.

An initial screen was conducted to identify individuals with a left ventricular ejection fraction (LVEF) of $\leq$40% by any mode of measurement. Identified cases were then adjudicated independently through a detailed chart review by two experienced electrophysiologists to determine whether they met guideline approved criteria for ICD implantation.[10] Cases that met guidelines for ICD implantation were excluded from analysis when chart review indicated there was evidence of ICD refusal after a consult with a cardiologist, the patient was lost to follow-up, there existed pre-existing conditions and comorbidities that excluded them from placement, the patient died before they were placed on guideline directed medical therapy (GDMT), and when an ICD had already been placed. A full list of patient principal medical problems and comorbidities were identified from the EMR using the principle problem list, patient history, medication lists, Care Everywhere records, and patient chart notes within 1 year prior to death.

During adjudication, limited life expectancy was determined based on chart review of these sources. All cases were assigned a comorbidities value based on the Charlson's Comorbidity Index (CCI) to determine relative severity of comorbidities. Distance in miles from Vidant Medical Center was determined using patient addresses obtained from death certificates.

Continuous variables are reported as mean ± standard deviation and categorical variables are presented as count and percentage unless otherwise noted. Odds ratios were obtained using individual logistic regressions for the most prevalent comorbidities to identify predictors of being disqualified from implantation due to pre-existing conditions. A multivariate logistic regression was performed to determine the strength of comorbidities in predicting disqualification for implantation when other comorbidities are considered. An independent t-test was used to determine if a difference in CCI was present between groups and chi-square tests were used to evaluate group differences in demographic variables. Statistical significance was indicated by p value ≤ 0.05

Results

Adjudication: In 2016, a total of 1,316 OHPND were recorded in 29 counties in eNC. Of these deaths, 967 (73.4%) individuals had local EMRs available, or Care Everywhere records from outside hospitals. A flow chart of the patient selection process is presented in Figure 1. After an initial chart review, 400 (41.4%) patients had some sort of cardiac imaging on file. We identified 98 (14.1%) patients with an LVEF measurement of ≤ 40 and 70 (7.2%) potential ICD candidates with a LVEF ≤ 35. Of these, 5 patients (7.1%) did not meet criteria because LVEF subsequently improved. Of the remaining 65 patients, 32 (49.2%) had already received an ICD or a wearable cardioverter-defibrillator (WCD), and 33 patients (50.7%) met ICD implantation criteria but had not received one. Two groups (Qualified and Disqualified) were created from these remaining patients (Figure 1). Patients in the Disqualified group included those with a limited life expectancy due to advanced comorbid conditions (N=11). Patients in the Qualified group included those who: refused implant (N=5), were lost to follow up (N=7), were not yet on GDMT (N=1), and those who otherwise did not receive an ICD (N=9) due to guideline nonadherence. Thus, among our cohort of 967 individuals who died unexpectedly at home, we were able to identify 9 (0.9%) patients who might have avoided unexpected death with an ICD/WCD. Table 1 shows the demographic and clinical characteristics of the cohort of potential ICD recipients.

Impact of Demographics and Clinical Characteristics: The most prevalent comorbidities in our sample included: hypertension, hyperlipidemia, coronary artery disease, diabetes, smoking, chronic kidney disease (CKD), chronic obstructive pulmonary disease, atrial fibrillation, and myocardial infarction. There were no significant differences in distribution of sex ($\chi 2(1) = 0.025$, $p = 0.876$) or race ($\chi 2(1) = 2.213$, $p = 0.137$) between patients in Qualified group and those who received an ICD/WCD compared to those in the Disqualified group (Table 1).

Using individual logistic regressions, the occurrence of CKD or hypertension were the only diagnoses able to significantly classify group membership, $\chi 2(1) = 6.727$, p = 0.009 and $\chi 2(1) = 4.659$, p = 0.031, respectively. Diagnosis of CKD explained 25.6 percent (Nagelkerke R2) of the variance between the two groups and correctly classified 75.8% of cases. Patients with CKD were 7.88 times more likely to be in the Disqualified group compared to patients without CKD. Hypertension explained 18.3% (Nagelkerke R2) of the variance between the two groups and correctly classified 72.7% of cases. Patients with hypertension were only slightly more likely to be in the Disqualified group (0.084, Haldane-Anscombe correction applied). All prevalent comorbidities were included in a multivariate logistic regression. After accounting for all other comorbidities, only CKD remained significant in being able to classify group membership (p = 0.031), see Table 2. The median CCI score for all 65 patients was 6 (interquartile range: 4 - 8). Limited life expectancy, determined through physician adjudication, was found in 17% (n = 11) of patients. On average, patients in the Disqualified group had a higher CCI score than those in the Qualified group, 7.2 and 4.7, respectively, 95% CI [-4.5 to -0.4], p = 0.014.

Impact of Distance from Tertiary Care Center: We evaluated the distance traveled to Vidant Medical Center between those who received an ICD/WCD, those in the Qualified group, and those in the Disqualified group. Distance in miles traveled by patients who received an ICD/WCD (median = 31.1, IQR = 27.0) and Qualified patients (median = 45.5, IQR = 22.9) had a normal distribution, while distance traveled by the Disqualified group of patients was shown to have a bimodal distribution (patients traveling less than 50 miles median = 14.1, IQR = 19.4 and patients traveling more than 50 miles median = 90.8, IQR = 21.0). A Kruskal-Wallis H test showed no significant differences in distance travelled between the three groups ($\chi^2(2) = 2.317$, $p = 0.314$).

Discussion

We examined the use and under-use of ICDs among victims of OHPND in the adult population under age 75 in a large, rural, socioeconomically and ethnically diverse region in eNC. Using a sample of 1,316 decadents matched with EMR data, our results indicated that only 9 patients out of 967 (0.9%) met criteria for defibrillator implantation but had not received one. These results are generally encouraging in that the urban-rural divide did not impact use of defibrillation technology in this sample. These promising findings may be attributed to the presence of a tertiary care center in the area. Previous work using the Get with The Guidelines-Heart Failure registry showed a higher rate of ICD implantation in tertiary institutions compared to areas without tertiary institutions.[11] However, many decedents had no EMRs and were excluded from the study. The causes identified for ICD non-implantation among potential candidates were heterogeneous with limited life expectancy due to advanced comorbidities being the largest contributor (16.9%). This is in contrast to previous studies that identified guideline nonadherence as the major contributor. In the current study using decedent data, physician non-adherence accounted for only 13.8% of patients not receiving an ICD. Other reasons identified for ICD non-implantation were patient refusal (8%), loss to follow up (11%) and not yet on GDMT (2%). In contrast to findings from other studies, race and gender were not significant factors affecting the implantation of ICD in our study.[16-17]

It is important to understand that, even among decedents with available medical records, there were likely more in whom death might have been prevented. But if left ventricular systolic function (the primary driver of prophylactic defibrillator implantation) is not assessed during life, the opportunity for potentially lifesaving therapy may be missed. Among decedents without medical records available to us, a proportion likely received healthcare outside our system and a proportion received no healthcare. We assume that decedents receiving health care outside our system had a similar chance of receiving a defibrillator as those in our system. But among those receiving no healthcare, there exists no opportunity to be assessed for a defibrillator.

The prevalence of comorbid diseases near the time of death (hypertension, hyperlipidemia, coronary artery disease, diabetes mellitus, tobacco abuse, CKD) were similar when patients with limited life expectancy (Disqualified group) were compared to patients who either received an ICD/WCD (N = 32) or were in the Qualified group (Table 2). However, the patients with limited life expectancy had higher CCI scores compared to other patients. This is because patients in the limited life expectancy group had either more advanced diseases or higher burden of other contributing comorbidities. The American College of Cardiology (ACC) guidelines recommend that ICDs be implanted in patients with meaningful life expectancy greater than 1 year.[18] The presence of advanced comorbidities decreases life expectancy and may prevent patients from receiving an ICD who otherwise qualify based on their left ventricular function. Ruwald and colleagues (2017) showed an association between increasing co-morbidity burden and increasing mortality risk with a greater than 50% mortality risk at 4 years in patients with comorbidity burden not related to heart failure of greater than or equal to 3.[19] In our group of patients with limited life expectancy, the average number of comorbidities excluding heart failure was 10. Further analysis of the comorbidity data showed that patients with CKD were about 8 times more likely to be disqualified from receiving an ICD, suggesting CKD with its complications is a particularly important life-limiting comorbidity in our study population.

While previous studies have examined the impact of comorbidity burden, ICD refusal, and patients lost to follow-up, these and similar factors were not found to be major contributors to rates of ICD non-implantation.[13] In contrast, our findings suggest that even after considering the maximum time frame in which to intervene, cardiologists are ultimately only able to improve implantation rates in a small number of patients through guideline adherence alone. In rural areas, lowering barriers such as low health literacy, lack of transportation, financial resources, and healthcare coverage, and low emphasis on regular preventative visits may be more impactful on implantation rates than addressing physician non-adherence. Future research can focus on risk-stratifying patients with comorbid conditions to identify eligible patients early and on ways to increase preventative healthcare as well as the impact of social determinants, such as distance from medical facilities, on comorbidity burden and ICD implantation.

The strengths of this study included the novel use of decedent data and matched EMR data to examine the penetrance or missed penetrance of defibrillator technology. We target the population of eNC, which is a racially diverse, socioeconomically disadvantaged population and a good representation of a rural population. Through an in-depth chart review by independent EP adjudicators, we ascertained the most comprehensive and accurate comorbid conditions, as well as clinical context to judge whether an ICD was indicated. For example, we found the typical EHR locations to identify comorbidities such as history and problem lists, consistently missed conditions hidden in other sources such as medicine lists and scanned files from clinical encounters under different health systems. By looking at decedent data, we were able to analyze the utilization of ICDs allowing for the maximum time frame for physicians to adhere to guidelines regarding the implantation of ICD. Possible limitations in the generalizability of our data include the presence of a tertiary care center, and studies of other rural areas may not yield comparable results to the current study in the absence of a tertiary center. The results of this study were limited by the inclusion of military veterans who have unique health needs and no records were available to adjudicate their medical history.

Conclusion:

This study using decedent and EMR data in a rural population showed low rates of ICD non-utilization among a population of patients in whom it might have been lifesaving. By extensive chart review, we identified that comorbid diseases play a major role in limiting the implantation of ICDs. CKD in particular, was associated with non-implantation of ICDs.

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Tables

	All (n = 65)	Qualified or Received ICD/WCD (n = 54)	Disqualified (n = 11)	*p-value
Age at Death, y	63 (8.2)	63 (8.2)	65 (8.3)	0.527
Male, %	46 (70.8)	38 (70.4)	8 (72.7)	0.876
Caucasian, %	34 (52.3)	26 (48.1)	8 (72.7)	0.137

*Comparison of Qualified + Received ICD/WCD to Disqualified Group

Table 1. Demographic variables by group.

			Univariate Analysis	Multivariate Analysis
	All (n = 65)	Disqualified (n = 11)	p-value	p-value
Hypertension, %	61 (93.8)	9 (81.8)	0.031*	0.999
Hyperlipidemia, %	48 (73.8)	8 (72.7)	0.437	0.202
Coronary Artery Disease, %	45 (69.2)	7 (63.6)	1.000	0.847
Diabetes, %	38 (58.5)	6 (54.5)	0.210	0.071
Smoker, %	36 (55.4)	5 (45.5)	0.128	0.429
Chronic Kidney Disease, %	32 (49.2)	7 (63.6)	0.009*	0.031*
COPD, %	29 (44.6)	3 (27.3)	0.598	0.997
Atrial Fibrillation, %	24 (36.9)	4 (36.4)	0.595	0.102
Myocardial Infarction, %	21 (32.3)	3 (27.3)	0.437	0.158

*p <0.05

Table 2. Prevalence of comorbidities in the overall sample and the Disqualified group. P values reported from the univariate analysis and multivariate analysis classifying group membership based on comorbidity diagnosis.

Figures

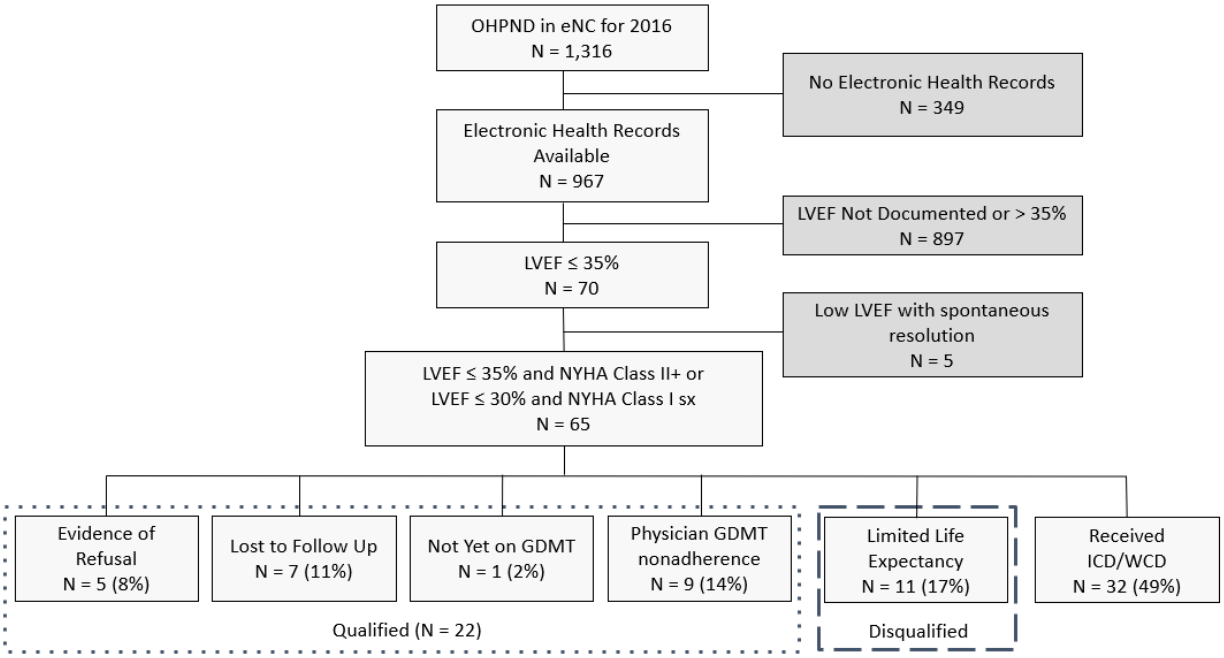

Figure 1. Flow chart of the patient selection process.