Impact of Patient Demographic and Social Factors on Implantable Cardioverter Defibrillator Implantation

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ABSTRACT. The clinical success of implantable cardioverter-defibrillators (ICDs) is well established for patients with cardiovascular disease at risk for sudden cardiac death. The positive impact of ICD implantation has led to a number of studies on the medical indications for ICD implantation, patient selection, treatment models, and clinical outcomes. While studies to date indicate disparities in implantation rates based on gender and race, less is known about other factors that affect implantation rates. The purpose of this retrospective study was to analyze records of heart failure patients with indications for ICD implantation to determine if significant correlations exist for implantation rates with regards to primary demographic factors of age, gender, and race and ethnicity, and secondary social factors of primary language and religion. Data were collected for patients with an echocardiogram indicating heart failure and a left ventricular ejection fraction less than 35% and then compared with records for ICD implantations. Statistical analysis was performed to identify trends and determine if demographic and social factors impact implantation rates. The analysis indicated that race and religious preference significantly impacted implantation rates (p = 0.016 and 0.005, respectively) and gender impacted echocardiogram rates. Minority participants and those reporting no religious preference were less likely to receive ICD therapy than their non-minority and religious counterparts. Females received fewer echocardiograms than male participants. While these results are similar to previous studies linking race to lower implantation rates, no difference was found in implantation rates based on gender. Of particular significance, religious preference was a significant predictor of ICD implantation.

KEYWORDS. demographic factors, religion, race, gender, implantable cardioverter-defibrillator, sudden cardiac death.

Introduction

Cardiovascular disease is responsible for one in every 2.9 deaths in the United States. Extensive research into etiology, disease process, and therapies has provided strong evidence supporting appropriate diagnosis and treatment of cardiovascular disease. Implantation of an implantable cardioverter-defibrillator (ICD) is a successful therapy for reducing mortality in cardiac patients with lethal arrhythmias, heart failure, and risk factors for sudden cardiac death. The clinical success of ICDs is well established for patients with cardiovascular disease and risk factors for sudden cardiac death. The Centers for Disease Control estimate that 4.0 million inpatient hospital discharges each year are the result of cardiovascular disease. Sudden cardiac death can be the result of a fatal arrhythmia, such as ventricular tachycardia, and occurs frequently with advanced systolic heart failure with left ventricular ejection fraction less
than 35%. Implantation of an ICD is an evidence-based therapy which has been shown to reduce mortality in cardiac patients with systolic heart failure and risk factors for sudden cardiac death. ICDs were first introduced in the 1980s and approved by the United States Food and Drug Administration (FDA) in 1985 for patients with cardiovascular disease following two cardiac arrests. Technological advances improved patient outcomes and increased the rates of implantation. In the decade following FDA approval of ICDs, a number of large multi-site clinical trials were conducted to study the efficacy of ICDs as a therapeutic and prophylactic treatment for cardiovascular disease and sudden cardiac death.

Following the standardization of practice guidelines for the implantation of ICDs, several studies were conducted to identify trends in implantation rates. A 2005 study used data from the MedPar Medicare database to identify patients nationwide implanted with ICDs from 1990 to 2000. The researchers found significant racial and geographic disparities in implantation rates. In 2009, a similar study was conducted using the same MedPar database identifying patients implanted with ICDs during 1997 through 2003. The researchers also found significant disparities in implantation rates. African American patients were less likely to be implanted than Caucasians patients, and women were also less likely to be implanted than men. Most alarmingly, the study revealed that rates of disparate care were worse by 2003 than at the beginning of the study in 1997. A 2012 publication examined the difference in implantation rates based on gender using the Ontario (Canada) ICD Database for patients referred to an electrophysiologist for ICD implantation between February 2007 and July 2010. The authors determined that men and women were equally likely to receive an ICD after referral. The results of this study suggested that the lower volume of ICD implantations is the result of decreased referrals rather than decreased implantation once the referral has been made.

In 2012, a study was published using National Cardiovascular Data Registry (NCDR) ICD Registry data describing the clinical characteristics of the patients with implantation records included in the registry. The authors found that of the 275,273 implantation records reviewed, 82.8% of the patients were male and 81.3% were Caucasian. This indicates a significantly disproportionate number of male and Caucasian patients in relation to the overall United States population.

Research and statistical analysis have established disparate cardiovascular mortality rates based upon the gender, race and ethnicity, and socioeconomic status of patients. Despite the large number of studies identifying a significant disparity in implantation rates, few studies have definitively identified the causes of these disparities. The goal of this study was to determine if significant correlations exist for rates of ICD implantation with regards to patient demographics and social factors at the University of Mississippi Medical Center (UMMC). Demographic factors including age, gender, race, and ethnicity were assessed, but implantation rates were also assessed based on language and religious preference.

**Methods**

This study was approved by the Institutional Review Board at UMMC. Data were collected from electronic health records for those patients with an echocardiogram indicating heart failure and left ventricular ejection fraction (LVEF) less than 35% who were rendered service from January 2005 through February 2012. These records were compared with ICD implantation records to determine which patients received the therapy. The standard inclusion criteria utilized in previous studies were history of myocardial infarction, heart failure or systolic dysfunction and a LVEF of less than 40%, 35%, or 30%, as determined by echocardiography.

This project utilized a LVEF of 35% and an indication of heart failure. Previous studies have identified race and ethnicity as American Indian or Alaska Native, Asian, Native Hawaiian or Pacific Islander, African American, Caucasian, and Hispanic. This study utilized the previously mentioned categories so as to allow for comparison to existing literature and United States Census data.

Standard age and gender data also followed United States Census Bureau formats. Primary language was reported as English speaking and Non-English speaking. Religion was reported as indicating a religious preference of Christian, a religious preference of other, and not indicating a religious preference. Records for non-residents were excluded, as were those for patients 18 years of age or less.

The data used in this retrospective chart review were abstracted from the UMMC University Heart electronic health record database. UMMC is the only academic medical center in Mississippi and is the largest provider of medical services in the state. Patients aged 18 years and older who were rendered services from January 1, 2005, through February 1, 2012, were included in the cohort. The data were collected from echocardiogram records for those patients with an echocardiogram indicating an LVEF less than 35%. We searched patient records meeting those criteria for a diagnosis or indication of heart failure. The list of included patients generated from the initial data collection step was used to pull demographic and social data. The list of patients was then utilized to search the database to identify which patients received ICD therapy. Once the researcher had received the data, all records were reviewed in detail prior to analysis to ensure accuracy and eliminate errors. After duplicate and incomplete records were removed, a total of 3,896 unique patient records were available for analysis.

**Statistical analysis**

The social and demographic data points were analyzed using the chi-squared test to compare implantation rates. The health record data were compared to United States
Census Bureau data for demographic trends based upon the patient’s residence location (United States and Mississippi) and assessed using the chi-squared goodness of fit test. Census data for 2010 were used. The data were analyzed to identify trends in the demographic and social factors of the patients, as compared to the Mississippi and United States populations. Chi-squared tests were then used to identify differences in demographic and social factors in relation to ICD implantation rates for each group, and results were confirmed with linear regression analysis.

Results
The median age of the cohort was 58.8 years. Women constituted 37.2% of the study sample, as compared with 50.8% of the US population.17 Of the total study participants, 3,844 reported race and 3,381 reported ethnicity: 63.1% (n=2,425) of the participant population indicated a minority race, as compared to 42.0% for Mississippi, 40.0 for the South region and 36.3 nationally.18 Chi-squared goodness of fit tests were conducted for patients reporting race as minority and not minority within the study population as compared to the United States, the South Region, and Mississippi populations. The results of the analysis indicate that the number of patients reporting race as a minority in the study population was significantly different from that of the other three populations ($\chi^2$ 760.58, 512.80, 407.47; p < 0.05).

Of the total study participants, 3,643 reported primary language: 99.2% (n=3,617) of the participant population indicated English as the primary language, as compared to 96.2% of the total United States population and 96.3% of Mississippians.16 Chi-squared goodness of fit tests were conducted for the study population as compared to the United States and Mississippi populations. The results of the analysis indicated that the number of patients reporting English as a primary language in the study population was not significantly different from that of the other two populations ($\chi^2$ 3.408, 3.181; p > 0.05).

Of the total study participants, 3,813 reported a religious preference. Utilizing the American Religious Identification Survey (ARIS) classifications of “Christian”, “Other Religion,” and “No Religion”, the participant population reported 89.4% Christian (n=3408), 3.5% (n=132) Other Religion, and 7.2% (n=273) reported No Religion. The results of the analysis indicate that religious preference reported by participants in the study population was significantly different from that of the other two populations ($\chi^2$ 42.24, 124.92, 181.51; p > 0.05).

Primary demographic factors
Patients aged 65 years and older constituted 2,615 of the 3,896 total records analyzed. Patients aged 18–64 years constituted 1,281 of the total records (Table 1). The results of chi-squared analysis indicate that older patients are not less likely than their younger counterparts to receive ICD implantation therapy when clinically indicated (p=0.715). Linear regression was performed with age serving as the independent variable and implantation rate serving as the dependent variable (p=0.715). Female patients constituted 1,451 of the 3,896 records (Table 1). Based upon these results, female patients are not less likely than their male counterparts to receive ICD implantation therapy when clinically indicated (p=0.06). In addition to the results of the chi-squared analysis, linear regression analysis was performed, with gender serving as the predictor variable and implantation rate serving as the dependent variable, and confirmed that gender did not accurately affect implant rates (p=0.327).

Non-Caucasian patients constituted 2,424 of the 3,843 total records analyzed (Table 1). Based on these results, minority patients are less likely than their non-minority counterparts to receive ICD implantation therapy when clinically indicated (p=0.016). Linear regression with race and ethnicity serving as the predictor variable and implantation rate serving as the dependent variable showed no statistical difference in implant rates based on race (p=0.016).

Secondary social factor analysis
Patients who indicated a primary language of English constituted 3,617 of the 3,643 total records analyzed (Table 1). Based upon these results, non-English-speaking patients are not less likely than their English speaking counterparts to receive ICD implantation therapy when clinically indicated (p=0.475). Linear regression analysis with primary language serving as the predictor variable

| Table 1: Implantable cardioverter-defibrillator (ICD) implant rates by category |
|-----------------------------|-----------------|-----------------|
| Characteristic              | ICD implanted, % (n) | p value ($\alpha=0.05$) |
| Older patients, ≥65 years   | 17.0 (n=445)     | 0.715            |
| Younger patients, <65 years | 17.5 (n=224)     | 0.327            |
| Male                        | 17.6 (n=431)     | 0.016            |
| Female                      | 16.4 (n=238)     | 0.005            |
| Caucasian                   | 19.2 (n=272)     | 0.475            |
| Non-Caucasian               | 16.1 (n=391)     |                  |
| English as primary language | 18.2 (n=659)     |                  |
| Non-English as primary      | 15.4 (n=4)       |                  |
| No religion reported        | 11.4 (n=31)      |                  |
| Religion reported           | 18.0 (n=638)     |                  |
and implantation rate serving as the dependent variable revealed no difference between groups \((p = 0.709)\).

Patients reporting no formal religion constituted 273 of the 3,813 total records analyzed, with 3,450 indicating a formal religious preference (Table 1). Patients indicating no formal religious preference are less likely than those who report a religious preference to receive ICD implantation therapy when clinically indicated \((p = 0.005)\). Linear regression analysis was performed with religious preference serving as the predictor variable and implantation rate serving as the dependent variable, confirming the interaction between religious preference and ICD implantation \((p = 0.016)\). Patients indicating no formal religious preference are less likely to receive ICD implantation therapy when clinically indicated than patients who report a religious preference.

As race and religion were the only two factors which indicated a statistically significant difference in implantation rates, the percentage of non-minority participants indicating a religious preference was compared to the percentage of minority participants indicating a religious preference to assess for an interaction between race and religious preference: 91.01% of non-minority participants reported a religious preference \((n = 2,206 \text{ of } 2,424)\). This is nearly identical to the 91.12% of minority participants who indicated a religious preference \((n = 1,293 \text{ of } 1,419)\). The implantation rates for these groups were also compared and the data are presented in Table 1.

### Conclusions

The goal of this research was to determine if patient demographic and social factors significantly impact ICD implantation rates. Unlike many other studies, this patient population includes a large number of minorities. Also, the range of social factors that could affect ICD implant rates was extended to include primary language as English or other and religious preference. These results are in agreement with previous studies indicating lower rates of therapy in minorities, but show no difference in implantation rates based on gender. A patient’s primary language preference affects the patient–physician interaction and could affect the decision to proceed with recommended therapy, but this analysis shows no difference in implant rates based on language. To our knowledge, this is the first study to assess the effect of religious preference on rates of ICD implantation and show that patients who have declared a religious preference are actually more likely to undergo ICD implant than those who report no religion.

### Discussion

Current recommendations for ICD implantation have been published for some time, and implantation has clearly demonstrated clinical benefits in multiple patient populations. However, fewer than half of patients meeting implant criteria eventually undergo therapy. There are of course boundaries to implantation based on risk of the procedure and cost, but some of the lack of therapy may relate to remaining uncertainties about the utility of ICD therapy itself. There is an active and healthy debate about the importance of ICD therapy with advancing age. There is a persistent disparity in implant rates in women and minorities, suggesting that there may be a perceptual bias regarding the utility of therapy in these populations. Identification of disparities is of primary importance, as it should direct efforts to correct these by assessing barriers to implantation. This study extends previous work to include factors such as primary language and religious preference as factors associated with ICD implant.

The finding that language does not create disparate care is encouraging. Hospital practice at the study institution includes use of trained medical translators for patients who do not speak English, and allowing good communication may be responsible for this result. The indication that having a formal religious preference is associated with higher rates of ICD implant is to our knowledge a novel finding. While patient factors such as age, race, and gender are immediately apparent to the physician, religion is not; typically, religious status is not actively addressed during the clinical interview unless the subject is broached by the patient. While the number of patients reporting no religious preference in this study is small, it suggests a direction for further study. The presumption of some investigators has been that it is physician bias that leads to disparity in the type of care offered—a question of equal importance is whether there are cultural or ideological biases on the part of the patient that affect the care accepted. If this is the case, then strategies to assess these and provide focused education may be critical in correcting disparities in care.

### Limitations

There are potential limitations to this research. An assumption of this study is that if a patient received an echocardiogram which indicated an LVEF of less than 35% and a diagnosis of heart failure, then the patient would be eligible for an ICD implantation. Comorbidities and complications do exist that might otherwise clinically contraindicate the implantation of the device. While this could account for the relatively low percentage of implants in this study (only 17%), the risk that this limitation adversely impacted one demographic or social group more than another is minimal.

Another limitation that might impact the number of patients reporting ICD implantation therapy would be the use of a single site for the study. It is plausible that a small number of participants received an echocardiogram which indicated an LVEF of less than 35% and a diagnosis of heart failure, and decided to receive ICD implantation therapy at an alternate facility. This patient choice to receive therapy elsewhere would not be captured and thus the data would indicate the patient had not received the therapy at all. While this could also account for the lower percentage overall of the number of participants who received the therapy, the risk that...
this limitation adversely impacted one demographic or social group more than another is also minimal.

References


