Gender, Racial, and Health Insurance Differences in the Trend of Implantable Cardioverter-Defibrillator (ICD) Utilization: A United States Experience Over the Last Decade

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ABSTRACT

Prior studies have highlighted disparities in cardiac lifesaving procedure utilization, particularly among women and in minorities. Although there has been a significant increase in implantable cardioverter-defibrillator (ICD) insertion, socioeconomic disparities still exist in the trend of ICD utilization. With the use of the Nationwide Inpatient Sample from 2003 through 2011, we identified subjects with ICD insertion (procedure code 37.94) and cardiac resynchronization defibrillator (procedure code 00.50, 00.51) as codified by the *International Classification of Diseases, Ninth Revision, Clinical Modification*. Overall, 1020 076 ICDs were implanted in the United States from 2003 to 2011. We observed an initial increase in ICD utilization by 51%, from 95 062 in 2003 to 143 262 in 2006, followed by a more recent decline. The majority of ICDs were implanted in men age ≥ 65 years. Implantation of ICDs was $2.5\times$ more common in men than in women (402 per million vs 163 per million). Approximately 95% of the ICDs were implanted in insured patients, and 5% were used in the uninsured population. There has been a significant increase in ICD implantation in blacks, from 162 per million in 2003 to 291 per million in 2011. We found a significant difference in the volume of ICD implants between the insured and the uninsured patient populations. Racial disparities have narrowed significantly in comparison with those noted in earlier studies and are now more reflective of the population demographics at large. On the other hand, significant gender disparities continue to exist.

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Additional Supporting Information may be found in the online version of this article.

Introduction

Sudden cardiac arrest (SCA) accounts for >350 000 deaths each year in the United States¹ and 50% of cardiovascular mortality.² Heart failure (HF) with left ventricular systolic dysfunction is a major cause of SCA. Large randomized controlled trials (RCTs) have demonstrated a survival benefit with implantable cardioverter-defibrillator (ICD) implantation in this group of patients, irrespective of HF etiology.^{3–6} Current American College of Cardiology/American Heart Association/Heart Rhythm Society (ACC/AHA/HRS) guidelines recommend ICDs as a class IA⁷ indication for primary prevention of SCA in patients with chronic systolic HF with left ventricular ejection fraction <35% and for secondary prevention in survivors of cardiac arrest due to ventricular fibrillation or hemodynamically unstable sustained ventricular tachycardia. Despite this, <50% of the eligible individuals actually receive ICDs.^{8,9} Underutilization of ICD is further magnified by gender and racial disparities. Prior studies have highlighted these disparities.^{10,11} Such disparities often exist for newly approved technologies or procedures and may persist for years.^{12,13} The degree to which the overall utilization of ICD therapy and disparities in its use have changed in the past decade has not been reported. Hence, we aimed to use the nation's largest hospitalization database to determine (1) the temporal trend of ICD utilization over the last decade and (2) whether gender, race, and insurance-payer disparities have changed over the last decade.

Methods

We used the Nationwide Inpatient Sample (NIS) to determine rates of ICD use and disparity. The NIS, part of the Agency for Health Care Research and Quality (AHRQ) Healthcare Cost and Utilization Project (HCUP), contains information on all discharges from a 20% stratified sample of community hospitals in the United States.¹⁴ The NIS contains clinical and resource-use information with safeguards to protect the privacy of individual patients, physicians, and hospitals.

The NIS data have been used to identify, track, and analyze national trends in health care usage, access, disparity of care, and hospitalization rate and outcomes for various diagnoses and major procedures.^{14–17} Annual data quality assessments of the NIS are performed that guarantee the internal validity of the database, and comparisons against data sources like the American Hospital Association Annual Survey Database, the National Hospital Discharge Survey, and the MedPAR inpatient data from the Centers for Medicare & Medicaid Services strengthen the external validity of the NIS.¹⁸

Our target population consisted of patients who underwent ICD insertion from 2003 to 2011, identified with *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9 CM) procedure codes of 37.94 (ICD implantation) and 00.50 and 00.51 (for cardiac resynchronization defibrillator [CRT]). We excluded all participants age <18 years and observations with missing data on age, patient sex, and mortality.

Statistical Analysis

Software packages Stata IC version 11.0 (StataCorp, College Station, TX) and SAS version 9.4 (SAS Institute, Inc., Cary, NC) were utilized for the analyses, which accounted for the complex survey design and clustering. Baseline characteristics were studied according to various insurance types. Differences between categorical variables were tested using the χ^2 test, and differences between continuous variables were tested using 1-way analysis of variance.

Because NIS represents a 20% stratified random sample of US hospitals, the population at risk forming the denominator was 20% of the US census population of adults age >18 years for any given year.^{19,20} Therefore, utilization rates were calculated by dividing the number of ICD insertions available in the NIS dataset in a given year by 20% of the US Census population age >18 years for that year.¹⁸ The ICD insertion rate was also calculated in subgroups of race (white, black, and Hispanics, and others), sex, and according to insurance status (Medicare, Medicaid, private insurance, uninsured) and hospital location in different US regions (Northeast, Midwest, South, West). For categorical variables such as the annual change in ICD utilization rate, the χ^2 test of trend for proportions was used utilizing the Cochran-Armitage test via the “ptrend” command in Stata.²¹ A *P* value <0.05 was considered significant.

Results

The data consisted of 1 020 076 ICDs implanted in the United States from 2003 to 2011. Baseline characteristics of the study population, including various insurance types, are summarized in Table 1 (see also Supporting Information, Table 1, in the online version of this article). The majority of these ICDs were implanted in the Medicare population (64.5%), followed by patients with private insurance (25%), Medicaid (6.1%), and uninsured patients (4.4%). More than half of ICDs were implanted in patients age ≥ 65 years, 72.9% were men, and 58.8% were white. The majority of ICDs were implanted in large hospitals (74.6%), urban locations (95.6%), the South (37.9%), and in teaching hospitals (61.5%).

Utilization of ICDs increased by 51% from 95 062 in 2003 to 143 262 in 2006, which corresponds to 330 ICDs per 1 million US population in 2003 and 483 ICDs per 1 million US population in 2006, respectively. We observed a decline in ICD utilization from 2006 to 2011; during 2011, as few as 86 457 ICDs were implanted in the United States, which corresponds to 280 ICDs per 1 million US population in 2011 (Figure 1A, Table 2). (For further details, see Supporting Information, Table 2, in the online version of this article.)

Throughout the study period, there were major differences in ICD utilization in men and women. In 2003, 76% of ICDs were implanted in men and 24% in women, which corresponds to 511 ICDs per 1 million men and 155 ICDs per 1 million women population in the United States. The percentage of ICD utilization in women increased gradually from 2003 to 2011, and during 2011, 29.7% of ICDs were implanted in women, which corresponded to 163 ICDs per million women in the United States (Figure 1B). However, a large discrepancy still remained. The ICD utilization per million population was lower in the black population as compared with the white population until 2006. The ICD

Table 1. Baseline Characteristics of the Study Population According to Type of Insurance

Variable	Medicare	Medicaid	Private	Uninsured	Overall	P Value
Unweighted, n (%)	134 346 (64.6)	12 625 (6.1)	51 687 (24.9)	9261 (4.5)	207 919	
Weighted, n (%)	658 325.1 (64.5)	62 089.0 (6.1)	254 460.9 (25)	45 200.6 (4.4)	1 020 076	
Age, y, %						<0.001
<65	13.8	89.6	78.5	83.7	37.6	
≥65	86.2	10.4	21.5	16.3	62.4	
Sex, %						<0.001
M	72.6	64.3	74.9	76.6	72.9	
F	27.4	35.7	25.1	23.5	27.2	
Race, %						<0.001
White	62.1	36.7	57.5	48.8	58.8	
Black	8.1	22.6	9.7	16.5	9.7	
Hispanic	4.6	13.5	4.6	8.6	5.3	
Others	3.2	7.4	3.8	5.8	3.7	
Missing	22.1	19.9	24.4	20.3	22.5	
Median HHI category for patient Zip code, % ^a						<0.001
0–25	26.2	41.2	20.0	31.2	25.8	
26–50	26.2	26.0	24.0	26.2	25.6	
51–75	24.0	18.8	26.2	22.6	24.2	
76–100	21.5	10.0	27.5	15.5	22.0	
Hospital bed size, %						<0.001
Small	7.7	4.9	7.2	5.5	7.3	
Medium	17.5	17.9	17.6	18.4	17.6	
Large	74.3	76.5	74.8	75.0	74.6	
Hospital location, %						<0.001
Rural	4.3	3.8	2.7	4.1	3.9	
Urban	95.2	95.5	96.9	94.9	95.6	
Hospital region, %						<0.001
Northeast	21.2	23.6	23.1	16.7	21.6	
Midwest or North Central	25.2	20.9	26.0	18.3	24.9	
South	38.8	35.6	34.2	48.5	37.9	
West	14.7	19.9	16.8	16.5	15.7	
Teaching status, %						<0.001
Nonteaching	40.0	31.5	35.0	35.6	38.0	
Teaching	59.5	67.9	64.6	63.3	61.5	

Abbreviations: F, female; HHI, household income; M, male.

^aThis represents a quartile classification of the estimated median HHI of residents in the patient's Zip code. These values are derived from Zip code demographic data obtained from Claritas. The quartiles are identified by values of 1 to 4, indicating the poorest to wealthiest populations. Because these estimates are updated annually, the value ranges vary by year. (http://www.hcup-us.ahrq.gov/db/vars/zipinc_qrtl/nisnote.jsp)

Figure 1. Graphs showing (A) overall ICD utilization in the United States over the study period and (B) ICD utilization in men and women. Abbreviations: ICD, implantable cardioverter-defibrillator.

utilization in the black population has seen a significant increase since initial years (before 2006). Hispanics had the lowest ICD utilization per million population (Figure 2; see also Supporting Information, Table 2, in the online version of this article).

For most of the study period, the Northeast region had the highest number of ICD insertions per 1 million population. The relative increase in ICD utilization was highest (relative increase of 37.9%; $P < 0.001$) in the South during the initial years (until 2006), and the relative decrease of ICD utilization was higher (relative decrease of 61.5%; $P < 0.001$) in the Midwest region, as compared with other regions of United States, during the latter years (after 2006).

More than 95% of ICDs were implanted in the insured patient population. The ICD utilization among the uninsured increased from 3.2% in 2003 to 5.2% in 2011, which

corresponds to 73 per 1 million uninsured patients in 2003 and 92 per 1 million uninsured patients in 2011 (Figure 3, Table 2). (For further details, see Supporting Information, Table 2, in the online version of this article.)

Discussion

There are 4 significant findings of our study. First, ICD utilization increased from 2003 to 2006 and trended downward thereafter. Second, there has been a definite increase in ICD utilization among minority races, most significantly in the black population. Third, although there has been a sustained rise in the percentage of women getting ICD placements, the disparity in prevalence of ICD implantation between men and women continues to exist. Fourth, there is a remarkable difference in utilization rates

Table 2. Baseline Characteristics of Study Population, 2003–2011

Variable	2003	2004	2005	2006	2007	2008	2009	2010	2011	P Value for Trends
Overall	95 062	11 370	127 207	143 262	124 210	119 134	116 941	94 268	86 457	<0.001
Age, y, %										
<65	36.8	35.7	36.4	38.5	37.8	38.4	37.6	39.2	38.8	
≥65	63.2	64.3	63.6	61.5	62.2	61.6	62.4	60.8	61.2	
Sex, %										
M	76.0	75.1	74.3	73.0	72.3	72.1	71.2	70.9	70.3	<0.001
F	24.1	24.9	25.7	27.0	27.7	27.9	28.8	29.1	29.7	<0.001
Race, %										
White	56.7	57.9	56.1	57.5	56.1	59.9	60.7	62.8	63.7	<0.001
Black	6.4	7.5	6.8	8.7	10.3	10.3	11.0	13.7	14.4	<0.001
Hispanic	4.5	3.9	5.1	5.1	5.9	4.9	6.1	6.0	6.7	<0.001
Others	2.7	2.5	3.2	2.6	4.0	4.9	4.9	4.2	4.6	
Missing	29.7	28.2	28.7	26.1	23.6	19.9	17.3	13.3	10.6	<0.001
Primary payer, %										
Medicare	66.3	65.9	66.2	64.7	64.1	62.7	64.6	62.4	63.6	<0.001
Medicaid	4.4	4.5	5.7	5.6	6.0	6.5	7.0	8.0	7.6	<0.001
Private	26.0	25.9	24.7	25.5	25.1	25.5	23.3	24.7	23.6	<0.001
Uninsured	3.2	3.8	3.4	4.2	4.8	5.3	5.1	5.0	5.2	
Hospital region, %										
Northeast	23.0	22.3	20.7	20.2	21.6	19.6	22.5	25.2	20.9	<0.001
Midwest or North Central	25.6	26.0	24.1	25.3	25.3	24.5	25.1	24.5	22.7	<0.001
South	36.7	38.8	38.3	40.9	36.2	39.2	36.6	34.4	38.4	<0.001
West	14.7	12.9	16.9	13.6	16.9	16.7	15.9	15.9	18.0	<0.001
Median HHI category for patient's Zip code, % ^a										
0–25	22.5	23.4	25.6	24.6	27.2	26.6	27.1	27.3	28.0	
26–50	24.8	25.0	24.9	26.0	25.2	27.8	26.5	25.1	24.6	
51–75	26.5	24.3	25.2	24.6	22.5	23.2	22.8	23.7	25.6	
76–100	23.4	25.2	22.0	22.8	22.2	20.2	20.8	21.3	19.9	

Abbreviations: F, female; HHI, household income; M, male.

^aThis represents a quartile classification of the estimated median HHI of residents in the patient's zip code. These values are derived from zip code-demographic data obtained from Claritas. The quartiles are identified by values of 1 to 4, indicating the poorest to wealthiest populations. Because these estimates are updated annually, the value ranges vary by year. (http://www.hcup-us.ahrq.gov/db/vars/zipinc_qrtl/nisnote.jsp.)

between the insured and the uninsured, which has been consistent throughout the entire period of the study.

The total number of ICD placements increased from 95 062 in 2003 to 143 262 in 2006, followed by a gradual decline from 2006 to 2011 to 86 457, where the levels seen were lower than those in 2003. We hypothesize that the initial spike largely may have been driven by the expansion of the eligibility criteria for ICD implantation following publication of large RCTs, including Multicenter Automatic Defibrillator Implantation Trial (MADIT) I and II,

MADIT-CRT, and the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) trials.^{3–6} Reduction in mortality, as noted in these trials, led to the 2005 ACC/AHA²² guidelines for HF to include ICD placement as a class I indication for primary prevention of SCA in patients with HF and reduced ejection fraction of <30%. During the same year, the Centers for Medicare & Medicaid Services²³ also agreed to reimburse ICD implantation in eligible patients for primary prevention of SCA. The subsequent decline in ICD utilization after 2006 is consistent with findings from the Get

Figure 2. Graphs showing ICD utilization in different races, with (A) ICD utilization per 1 million US population and (B) percentage of ICD utilization in different races. Abbreviations: ICD, implantable cardioverter-defibrillator.

With the Guidelines–Heart Failure (GWTG-HF) program. Using the GWTG-HF registry, Al-Khatib et al suggested that there might be a plateauing of ICD placements between 2008 and 2009.⁹ We extended this study period to 2011 and could conclude that the observed utilization plateau actually marked the beginning of a decline in implantation rates. We speculated that the decline in utilization in later years could be due to the improved preservation of systolic function in HF patients secondary to advances in management and prompt revascularization in patients with myocardial infarction, thereby leading to a decrease in the number of eligible participants. It could additionally be due to lead and device recalls, coupled with fines and penalties levied for inappropriate ICD usage, that raised suspicions about safety of some of the ICD devices and may have reduced implantation rates.^{23–25}

Previous studies have shown that gender and racial disparities in the utilization of novel cardiovascular procedures often persist for years.¹² Our observation of gender disparities in ICD utilization is in agreement with many other studies published earlier, but those studies were limited to registry data or were not contemporary.⁹ In contrast, the NIS provides real-world estimates of utilization and distribution of various cardiovascular procedures in subtypes of race, gender, and different insurance subgroups. Schuchert et al reported that women had a better response to CRT when compared with men.²⁶ We also found that the percentage increment in ICD utilization among women was not as robust as that reported by studies using registry data. Registries may over-represent self-reported data from hospitals generally motivated in regard to quality improvement and implementation of guidelines. However,

Figure 3. Graphs showing ICD utilization in different insurance categories, with (A) ICD utilization per 1 million US population and (B) percentage of ICD utilization in different insurance categories. Abbreviations: ICD, implantable cardioverter-defibrillator.

these trends may not hold true for all hospitals in the United States. The prevalence of ICD implantation in men was twice that of women. From ages 40 to 79, the incidence of HF is higher in men (7.8%) than in women (4.5%), and women tend to develop HF later in life as compared with men (8.6% for men compared with 11.5% for women for age >80 years).²⁷ The lower rate of ICD utilization in

women cannot be explained by the lower incidence of HF in women. Physicians may tend to be more cautious and implement more stringent criteria in enrolling women for ICD placement, as suggested by Daugherty et al.²⁸ Another explanation for the lower numbers of implantations in women could be the underrepresentation (<30%) of women in the major RCTs supporting ICD use.

There has been an increase in ICD placements among nonwhite races over the course of the studied time period. The increase is most striking among the black population. The increase in ICD utilization among black and other minority races may be due to increased awareness among physicians regarding the disparities and also due to improved adherence to guidelines for HF management.

Our analysis is among the first to report disparities in ICD utilization among insured and uninsured patient populations eligible for ICDs. There is a striking difference in the number of ICDs placed between the insured and the uninsured. It is important to note that >95% of ICDs were implanted in insured patients and <5% in uninsured patients. The most likely explanation for this disparity is cost. Out-of-pocket payment for the procedure without any insurance coverage is beyond the financial capabilities of almost all patients. Patients without insurance may also be more likely to have other social, financial, and medical complexities that may result in first presentation with advanced heart disease and overall poor ICD candidacy. Other potential explanations could be a complex amalgamation of physiological (comorbidities, race-based increased predisposition), cultural, and socioeconomic factors (education, poverty, transportation, access to cardiologists for frequent follow-ups). Further studies need to be done to determine whether recent changes in health care with the passage of the Affordable Care Act have helped reverse this trend. Whether the previously uninsured population now entering the health care system will change the discrepancies in ICD implantations remains to be seen.

Study Limitations

The most significant limitation of this study is that the NIS consists of primarily administrative data susceptible to coding error, incomplete clinical history data, and limited to a single hospitalization. However, annual data quality assessments of the NIS maintain the internal validity of the database.

The severity of HF symptoms (as recorded by New York Heart Association class) and reason for ICD implantation (primary or secondary) are not available in the database. However, the primary objectives of this study were to evaluate ICD utilization trends and how gender, racial, and insurance differences changed over the last decade in the United States. The intricacies involved in physician-patient discussion on ICD implantation and decisions made based on them would not be available from the database. Patient-related factors, such as access to care and understanding of their medical condition; physician-related factors, like familiarity with current guidelines and risk appetite; and hospital-related factors, like infrastructural support system for ICD placement, are not adequately captured and would not be represented in the findings of our study. Despite these limitations, our study represents real-world experience with a large sample size. It is free from selection bias and covers all observations irrespective of age and insurance status of the patients. It is unlikely that insufficient clinical-outcome information in the database affected our study because outcomes were not the focus of our study.

Conclusion

Utilizing the largest national hospitalization database in the United States, we found a striking difference in the volume of ICD implantations between insured and the uninsured patient populations. Racial disparities in utilization of ICDs have narrowed significantly in comparison with earlier studies, but gender disparities continue to exist. Continued efforts to further bridge this gap in the utilization of a proven lifesaving therapy are warranted.

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