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SOCIOECONOMIC AND ETHNIC DISPARITIES IN THE USE OF BIVENTRICULAR PACEMAKERS IN HEART FAILURE PATIENTS WITH LEFT VENTRICULAR SYSTOLIC DYSFUNCTION

Objectives: Biventricular pacing (BiV) is an important therapy for symptomatic heart failure (HF) patients with reduced left ventricular (LV) ejection fraction (EF). The aim of our study was to determine if ethnic disparities in use of BiV in HF patients with LV systolic dysfunction are independent of socioeconomic status.

Design, Setting, Participants: Data collected on 32,911 hospitalized HF patients with EF≤35% from Pennsylvania hospitals that implanted BiVs in 2004 and 2005 were submitted to the Pennsylvania Health Care Cost Containment Council. Multivariate analysis used patient clinical, insurance and hospital characteristics to identify independent predictors of BiV in symptomatic HF patitents with EF≤35%.

Main Outcome Measures: Use of BiV in symptomatic HF patients with LV systolic dysfunction.

Results: BiV was implanted in 2,065/ 15,861(13%) Whites, 182/3107(5.9%) African Americans and 175/1301(13.5%) others. Older age, male sex, intraventricular conduction delay and prior myocardial infarction or bypass surgery (all P<.001) were positively associated with BiV while diabetes (P<.01), higher EF or higher MediqualTM Atlas severity score (both *P*<.0001) were negatively associated with BiV. Adjusting for these variables, African American ethnicity (odds ratio [OR] .56, 95% CI,.46-68, *P*<.0001) and poverty, comparing the poorest quintile to other quintiles (OR .86, 95% CI, .76-98, P<.02), were associated with less BiV, independent of fixed effects of hospitals (P<.0001) and a positive association of BiV with Medicare vs Medicaid (P < .01).

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Conclusions: In a large statewide sample, BiV was implanted less frequently in African Americans and in lower-income patients, independent of clinical, hospital and insurance characteristics, identifying persisting disparities in use of advanced cardiac technology. (*Ethn Dis.* 2013;23[3]:275–280)

Key Words: Heart Failure, Biventricular Pacing, Ethnicity, Poverty

Introduction

Heart failure patients with a left bundle branch morphology or widened QRS interval are at increased risk for worsening congestive heart failure and sudden cardiac death. Cardiac resynchronization therapy by biventricular pacing (BiV) is an important advance in therapy for symptomatic heart failure patients with left ventricular (LV) systolic dysfunction and conduction delay resulting in dyssynchronous wall motion. By restoring coordinated LV contraction, BiV therapy improves LV function, resulting in a 20% to 50% decreased risk of hospitalization and a 19% to 37% decreased risk of death in patients receiving optimal medical therapy. 1-4 According to the ACC/AHA 2008 Guidelines, BiV pacemaker is a Class I indication for symptomatic heart failure patients with a left ventricular

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ejection fraction ≤35%, a QRS duration ≥.12 seconds and sinus rhythm.⁵

It has been previously shown that African Americans are less likely to receive advanced cardiac procedures such as cardiac catheterization and percutaneous coronary intervention when hospitalized with an acute myocardial infarction (AMI).6-11 Socioeconomic and sex disparities in the use of advanced cardiac procedures have also been identified in patients with AMI.6-7,12 A recent study by Farmer et al analyzing National Cardiovascular Data Registry (NCDR) ICD Registry data identified lower use of BiV in African Americans and Hispanics compared to Whites. 13 Piccini et al analyzed data from the American Heart Association's Get With the Guidelines Heart Failure Program and identified lower use of BiV in African Americans compared to Whites or others, but neither study elucidated whether this is independent of socioeconomic status as well as other established risk factors. 13-14 Our study utilized data on the use of cardiac resynchronization therapy in heart failure patients hospitalized in Pennsylvania to examine factors associated with ethnic disparities in the use of this technology.

METHODS

Patient Population

Patients discharged from Pennsylvania hospitals between January 1, 2004 Our study utilized data on the use of cardiac resynchronization therapy in heart failure patients hospitalized in Pennsylvania to examine factors associated with ethnic disparities in the use of this technology.

and December 31, 2005 with a International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code for congestive heart failure as a principle diagnosis (428.xx, 398.91) were included in the study. The data were collected by the Pennsylvania Health Care Cost Containment Council (PHC4), an independent state agency that collects treatment information, hospital charges, and financial data on millions of inpatient hospital discharges annually from all hospitals in Pennsylvania. During the study period PHC4 required that all general and specialty acute care hospitals in Pennsylvania collect clinical data for each patient in 35 specific treatment categories by chart abstraction at the time of hospital discharge, including all clinical characteristics needed to derive the MediqualTM Atlas Outcomes severity score. 12 Patients were included in the study based on the principle discharge diagnosis and not by diagnosis related group or procedure codes. For patients who had more than one hospitalization for congestive heart failure in the study period, the discharge related to placement of a biventricular device was used. Patients with missing data were not included in the study.

Of the 32,911 heart failure patients with LV ejection fraction ≤35% hospitalized in Pennsylvania in 2004 and 2005, 10,161 patients were excluded

because they were admitted to hospitals that did not perform BiV. Of the patients admitted to hospitals that did not perform BiV, the percentage that were African American was 6.2% as compared to study patients admitted to hospitals that performed BiV in which 15.3% were African American. Of the study population patients admitted to hospitals that did not perform BiV, the percentage that were low income was 17.9% as compared to study patients admitted to hospitals that performed BiV in which 28.1% were low income. Therefore, African American and low income patients were not more likely to be admitted to hospitals that did not perform BiV. A total of 2,481 patients were excluded due to missing data or were aged <30 or >90, resulting in a study population of 20,269 patients.

Study Variables

Baseline clinical variables included 22 laboratory values and 19 key clinical findings that were obtained by chart abstraction from each hospitalization to calculate the Mediqual Atlas outcomes severity score for each study patient. Patients were then grouped into none, minimal, moderate, severe or maximal categories based on their Atlas outcomes severity score. Additional clinical variables were obtained for each patient from the ICD-9-CM codes. The presence of an intraventricular conduction delay (IVCD) was abstracted from the EKG report by chart review and entered as a categorical variable. Categories for race included White, African American, and other, based on self-report by patients at the time of admission. Each patient's income was estimated by assigning the median household income in the patient's ZIP code. Income data from the 2000 US Census report were used for this study. There are limitations in the use of ZIP code as a proxy for individual income; ZIP codes provide a measure of area level socioeconomic status. However, prior large population studies including the Multiple Risk

Factor Intervention Trial (MRFIT) have used ZIP code-based income to estimate an individual's socioeconomic status. In the MRFIT study, low ZIP code-based income was a predictor of long-term risk-adjusted mortality.¹⁵

Statistical Analysis

Patients who did or did not undergo resynchronization therapy were compared by *t* tests for continuous variables and Chi square tests for categorical variables using SAS software. To identify independent effect of socioeconomic status and race on the use of BiV pacemakers, multiple logistic regression analysis was performed with forced entry of covariates.

Patient characteristics that were assessed in the study were age, sex, prior coronary bypass surgery, history of myocardial infarction, history of stroke, diabetes, hypertension, hypercholesterolemia, and renal failure. Univariate analysis of age revealed that older age was associated with an increasing likelihood of receiving cardiac resynchronization therapy until age 84, at which time the likelihood decreased. In addition, univariate analysis of decreasing ejection fraction by increments of 5% identified an increased likelihood of receiving cardiac resynchronization therapy, but when the ejection fraction was less than 15% there was a lower likelihood of receiving cardiac resynchronization therapy. Therefore, additional variables for age >83 and ejection fraction >15% were added to the logistic regression analysis to account for these non-linear relationships. The presence of an IVCD was identified by chart abstraction of the EKG report and entered as a binary variable. The MediqualTM Atlas severity score (based on 19 key clinical findings and 22 laboratory values) was entered in the logistic regression analysis as a dichotomous variable after assigning patients to one of two groups; low severity group (patients in the none, minimal, or moderate categories of Atlas severity)

Table 1. Clinical characteristics of heart failure patients receiving or not receiving CRT

Variable	Cardiac Resynchronization Therapy (n=2422)	No Cardiac Resynchronization Therapy (n=17847)	P
Age, years	70.8 ± 10.6	69.4 ± 12.7	.0001
Female	647 (26.7)	6658 (37.3)	<.0001
African American	182 (7.5)	2925 (16.4)	<.0001
Diabetes	705 (29.1)	5624 (31.5)	<.02
Ejection fraction, %	22 ± 7.4	24.2 ± 8.0	<.0001
Prior myocardial infarction	519 (21.4)	2308 (12.9)	<.0001
Prior stroke	90 (3.7)	533 (3.0)	NS
Prior CABG	467 (19.3)	1947 (10.9)	<.0001
IVCD on EKG	1336 (55.2)	7006 (39.3)	<.0001
High Atlas severity score	19 (13.2)	5724 (32.4)	<.0001
Prior PTCA	181 (7.4)	975 (5.5)	<.0001
Hypertension	877 (36.2)	6508 (36.5)	NS
Hypercholesterolemia	687 (28.4)	4225 (23.7)	<.0001
Renal failure	39 (1.6)	330 (1.8)	NS

Data are n (%) unless otherwise indicated.

CABG, coronary artery bypass grafting; IVCD, intraventricular conduction delay; PTCA, percutaneous transluminal coronary angioplasty.

and high severity group (patients in the severe or maximal categories of Atlas severity).

Hospital characteristics included non-profit and for-profit status, rural vs urban location and the capability of performing open heart surgery. Of 52 hospitals in Pennsylvania implanting BiV pacemakers, 45 were located in federally defined metropolitan areas and 7 were located in rural areas, 34 hospitals performed open heart surgery and 18 hospitals did not. To analyze the effect of the individual hospital on receiving a BiV pacemaker, a dummy variable was created for every hospital and each hospital was compared to the hospital performing the median number of BiV procedures. This variable was a stronger predictor of receiving a biventricular pacemaker than the other hospital characteristics, therefore it was included in the multiple logistic regression analysis. Categories of insurance type included commercial, Medicare, Medicaid, self-pay and other. Income was analyzed as a categorical variable separated into five quintiles. The lowest income group, quintile one, was used as a reference group to which the remaining quintiles were compared.

RESULTS

BiV pacemakers were implanted in 2,422 of 20,269 hospitalized heart failure patients with an ejection fraction ≤35%; 2205 patients had a BiV pacemaker implanted in combination with an internal cardioverter defibrillator and 217 patients had only a BiV pacer implanted. BiV pacers were implanted in 2,065/15,861(13%) Whites, 182/3107 (5.9%) African Americans and 175/1301(13.5%) others. Baseline clinical characteristics of patients receiving cardiac resynchronization therapy (BiV pacemaker or BiV-ICD) and of patients not receiving cardiac resynchronization therapy are compared in Table 1. Patients receiving cardiac resynchronization therapy were older and more likely to be male than patients not undergoing cardiac resynchronization therapy. Patients with hypercholesterolemia, prior myocardial infarction, prior percutaneous coronary intervention, coronary bypass surgery or with intraventricular conduction delay were more likely to receive cardiac resynchronization therapy. Patients with diabetes mellitus were less likely to receive cardiac resynchronization therapy. Patients receiving cardiac resynchronization therapy had lower MediqualTM Atlas severity score of key clinical findings and lower mean LV EF.

Fewer Medicaid patients (107/1672, 6.4%) received cardiac resynchronization therapy than patients with commercial insurance (461/4023, 11.5%) or with Medicare (1839/14,282, 12.9%), (both P < .05). Similar to Medicaid patients, 7 (4.9%) of 144 self-pay patients and 8 (5.4%) of 148 patients with other insurance received cardiac resynchronization therapy (both P=NS). Of 1017 patients admitted to for-profit hospitals, 141 (13.9%) received cardiac resynchronization therapy, compared to 2281 (11.9%) of 19,252 patients admitted to non-profit hospitals ($P \le .05$). Of 2311 patients admitted to a rural hospital, 274 (11.9%) received cardiac resynchronization therapy, compared to 2148 (12%) of 17,958 patients admitted to an urban hospital (P=NS). Of 16,853 patients admitted to a hospital performing open heart surgery, 2,058 (12.2%) received cardiac resynchronization therapy, compared to 364 (10.7%) of 3,416 patients admitted to a hospital that did not perform open heart surgery (P<.01).

After adjusting only for age and sex, logistic regression analysis identified African Americans as less likely to receive a BiV (OR .46, 95% CI, .39–54, *P*<.0001). When adjusting only for age and sex, low income patients were less likely to receive a BiV (OR .66, CI .60–74, *P*<.001). When ethnicity and income level were both included in the model, after adjusting for age and sex, African Americans were less likely to receive a BiV (OR .52, CI .44–62, *P*<.0001) and low income patients were less likely to receive a BiV (OR .81, CI .72–90, *P*<.001).

Table 2 outlines the results of the multiple logistic regression analysis including all of the clinical, demographic, insurance and hospital predictors of receiving cardiac resynchronization therapy. With adjustment for covariates,

Table 2. Multivariate analysis of predictors of receiving cardiac resynchronization therapy including ethnicity and socioeconomic status

Variable	Odds Ratio (95% Confidence Interval)	P
Age (per decade)	1.19 (1.12–1.26)	<.0001
Female	.73 (.66–.81)	<.0001
Diabetes	.89 (.8199)	<.05
Prior myocardial infarction	1.33 (1.18–1.49)	<.0001
Prior CABG	1.48 (1.30–1.67)	<.0001
IVCD on EKG	1.93 (1.76–2.12)	<.0001
Ejection fraction (per 5% decrease in EF)	1.17 (1.02–1.35)	<.05
Atlas severity score (high vs. low)	.28 (.2532)	<.0001
Medicare vs. Medicaid	1.39 (1.10-1.78)	<.02
African American	.56 (.4668)	<.0001
Low income	.86 (.76–.98)	<.02

CABG, coronary artery bypass grafting; IVCD, intraventricular conduction delay.

the likelihood of receiving cardiac resynchronization therapy was greater with older age, male sex, prior myocardial infarction or coronary bypass surgery, presence of an intraventricular conduction delay on EKG, and lower ejection fraction. The likelihood of receiving cardiac resynchronization therapy was less with diabetes and higher Atlas severity score. The dummy variable reflecting fixed effects of the hospitals was a significant predictor of receiving cardiac resynchronization therapy (P<.0001). Patients with Medicare insurance were more likely to receive cardiac resynchronization therapy as compared to Medicaid insurance independent of the clinical and hospital variables. Clinical variables that did not enter the model included history of hypercholesterolemia, hypertension, renal failure, and prior stroke or PTCA.

African Americans were less likely to receive cardiac resynchronization therapy (OR .56, CI .46–68, *P*<.0001) after accounting for the clinical, insurance and hospital variables. In addition, the lowest income quintile, as compared to the other quintiles, was independently associated with a lower likelihood of receiving cardiac resynchronization therapy (OR .86, CI .76–98, *P*<.02).

After controlling for all of the significant risk factors in the final model, there were no significant interactions found between ethnicity and

sex, ethnicity and low income, ethnicity and payer type or between ethnicity and whether the hospital performs open heart surgery.

DISCUSSION

In a large statewide database of patients with heart failure due to left ventricular systolic dysfunction, our study demonstrates that after accounting for clinical, hospital and insurance characteristics, African Americans and low income patients in Pennsylvania are significantly less likely to receive cardiac resynchronization therapy, independent of each other. Although socioeconomic and racial disparities in coronary revascularization procedures have been welldocumented, 6-12 the impact of race and income on implantation of cardiac devices has not been as extensively studied. In particular, there are few data available simultaneously assessing both ethnic and socioeconomic disparities in the use of cardiac resynchronization therapy in symptomatic heart failure patients. Thus, the results of this study contributes significantly by identifying poverty level as a predictor of a lower likelihood of receiving advanced cardiac technology independent of ethnicity.

Farmer et al recently analyzed initial data from the National Cardiovascular Data Registry (NCDR) ICD Registry ...our study demonstrates that after accounting for clinical, hospital and insurance characteristics, African Americans and low income patients in Pennsylvania are significantly less likely to receive cardiac resynchronization therapy, independent of each other.

which includes all Medicare patients receiving a CRT device since 2005. They found that cardiac resynchronization therapy eligible African Americans and Hispanic patients were less likely to receive a device compared to White patients. 13 A recent study by Piccini et al analyzed patients with symptomatic heart failure admitted to hospitals participating in the American Heart Association's Get With the Guidelines Heart Failure Program and found that African Americans were less likely to receive cardiac resynchronization therapy than Whites (OR .45; CI .36-75, P < .0001). They suggested the lower rate of resynchronization therapy in African Americans reflected the lower prevalence of QRS delay among blacks with congestive heart failure that has been previously identified. In our study, we accounted for the presence of an intraventricular conduction delay on electrocardiogram and despite this, African Americans were less likely to receive cardiac resynchronization therapy.

Data from over 26,000 patients with left ventricular ejection fractions ≤40% in the ADVANCENT multicenter registry were analyzed by El-Chami et al, who found that after adjusting for clinical variables, education and insurance type, women and African Americans were less

likely to receive a pacemaker, ICD, BiV pacemaker or BiV-ICD. 16

Several previous reports have characterized racial and sex disparities in the use of implantable cardioverter defibrillators. A prior study by Hernandez et al, reviewed data from the American Heart Association Get With the Guidelines Heart Failure Program and found that ICDs were used more frequently in men and Whites after adjusting for other clinical variables.¹⁷ In a study by Thomas et al of patients in the ADVANCENT registry with prior myocardial infarction and an ejection fraction ≤35%, African American patients were significantly less likely to receive ICDs for primary prevention of sudden cardiac death. Of 7,830 eligible patients, Blacks had a 38% lower chance of receiving ICDs compared to Whites after adjusting for clinical and socioeconomic characteristics (odds ratio=.62, 95% confidence interval .50-75, P < .001). 18

Groenveld et al examined changes in racial disparity in implantable cardioverter defibrillator implantation among Medicare patients hospitalized with ventricular arrhythmias from 1990 to 2000 and found that the disparity diminished over time but did not disappear. He suggested that a portion of the narrowing of the gap was due to less geographic variation in the use of ICDs between areas with predominantly Black population and areas that are largely White. 19 In addition, Groenveld et al evaluated the rate of ICD implantation and cardiac procedures in Black and White Medicare patients who survived cardiac arrest. Black patients aged 66 to 74 were less likely to undergo ICD implantation despite finding that ICD implantation was independently associated with reduced mortality among both Black and White patients. 20

When Groenveld et al examined the issue of racial disparities in the use of emerging medical technologies among Medicare patients from 1989 to 2000,

he found that Blacks were significantly less likely to receive dual-chamber pacemakers and that hospitals with a larger percentage of Black patients were less likely to perform the procedures suggesting that hospital characteristics are a factor in racial disparity of procedure use.²¹

Stanley et al used the National Hospital Discharge Survey to compare ICD use in patients at risk for sudden death in 2 time periods; 1996-1998 and 1999-2001. Although they discovered a 40% decline in disparity between the two time periods, major racial disparities in ICD use persisted.²² When Udell et al evaluated the use of ICDs in Ontario, Canada, they found that men were more likely to receive an ICD as were patients living in a higher socioeconomic neighborhood.²³ A sex bias in ICD implantation was also noted by Lin et al from the Mayo Clinic, who examined all ICDs implanted in Olmstead County, Minnesota between 1989 and 2004.24

The reasons for ethnic and socioeconomic disparities in the use of cardiac resynchronization therapy are unclear. A report by the Institute of Medicine suggests that factors at multiple levels including patient, health care provider and health system can lead to health care disparities.²⁵ African American and low socioeconomic patients may be more likely to receive their care at hospitals that do not perform this procedure, a consideration that does not apply to our analysis limited to hospitals that implanted BiV devices. In our study population, a higher percentage of African Americans and low income patients from the source study population were in hospitals that implanted BiV pacemakers. Groeneveld et al suggested that limited access to new technologies is an important cause of racial disparities in cardiovascular care.21 However, Piccini et al did not find that hospitals treating more African Americans implanted fewer cardiac resynchronization therapy devices.¹⁴

Furthermore, physicians may view African Americans and low income patients as having a higher severity of illness, which may influence their willingness to refer their patients for cardiac resynchronization therapy. However, a prior study by Kressin et al did not find that racial differences in invasive cardiac procedure rates were explained by differences in disease severity²⁶ and in our study ethnic and socioeconomic disparities were independent of a widely-used summary measure of overall disease severity.

Prior studies suggest that African Americans and low income patients are less willing to undergo an invasive procedure, which is one possible explanation for these disparities. There is conflicting data regarding this proposed explanation as outlined by Thomson et al, where patient referral accounted for only a small percentage of the disparity in use of cardiac procedures in low income and African American patients.²⁷

Since cardiac resynchronization therapy is an elective procedure and hospitals performing biventricular implantation procedures are limited, there may be referral bias in regards to cardiac resynchronization therapy. Cardiac resynchronization therapy is a relatively new procedure and despite guideline recommendations, there continues to be debate over which patients should receive this therapy leading to differences in the rates of acceptance by physicians of its utility. This potential for differences in rate of referral may impact the use of cardiac resynchronization therapy in African Americans and low income patients. We included only hospitals that perform cardiac resynchronization therapy and adjusted for individual hospitals; however, there may be unmeasured differences in hospital characteristics that may influence the use of cardiac resynchronization therapy. Data analysis from our study was not able to provide possible solutions to the socioeconomic and ethnic disparities

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seen, however, an article by Peterson et al offer some possible explanations.²⁸

Study Limitations

There are several limitations of our study. Information on physician and hospital referral patterns was not available and may have influenced which patients underwent cardiac resynchronization therapy. Data as to whether the heart failure patients in this study were treated primarily by a cardiologist were not available. Data were available on presence of an intraventricular conduction delay, but not actual QRS duration, which may have impacted which patients received cardiac resynchronization therapy. During the study period the ACC/AHA guidelines for cardiac resynchronization therapy were being updated, which may have influenced payer coverage decisions, particularly of low-income patients.

CONCLUSION

In a large statewide database of patients hospitalized with heart failure, cardiac resynchronization therapy was used less often in African Americans and in lower income patients, independent of clinical, hospital and insurance characteristics. Patients with Medicaid insurance were less likely to receive cardiac resynchronization therapy than Medicare insurance patients.

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AUTHOR CONTRIBUTIONS

Design and concept of study: Casale, Devereux Acquisition of data: Casale, Wolf, Pei Data analysis and interpretation: Wolf, Pei Manuscript draft: Casale, Devereux Statistical expertise: Casale, Wolf, Pei, Devereux