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Racial and ethnic healthcare disparities in patients undergoing laser lead extraction

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ABSTRACT

Background: The rate of cardiovascular implantable electronic device infections (CIEDIs) has mirrored or exceeded the increased use of implantable cardiac devices in the United States. The presence of racial and ethnic disparities associated with CIEDIs has not been published. Our aim is to describe the presence of racial and ethnic disparities with respect to the management of CIEDIs.

Methods: We reviewed a prospective single-center registry for patients undergoing removal of an implantable cardiac device between 1/2004 and 1/2016. 1173 consecutive patients underwent device extraction. 699 patients were identified as having an infection, 305 were identified as Caucasian and 394 were minorities (91 African Americans, 303 Hispanics). Patients had pre-operative transesophageal echocardiograms (TEEs) and collection of blood and exudate cultures. All underwent complete hardware extraction; leads were removed through the use of locking stylets and traction or laser extraction. En-bloc capsulectomy was performed with intraoperative specimen collection from pocket tissue, exudate, lead tips, and vegetations.

Results: Minority patients were: younger (67.9 ± 14.5 years vs 72.4 ± 13.2 years), had a higher proportion of male gender, diabetes, and chronic renal failure ($p < 0.001$). Minorities experienced a higher rate of complications during extraction and a longer hospitalization (15.3 ± 9.9 days versus 17.4 ± 13.4 days, $p < 0.001$). There was no significant difference between the proportion of types of infection in both groups.

Conclusion: Minority patients with CIEDIs experienced more procedural complications during extraction and had a significantly longer length of index hospitalization than Caucasian patients.

1. Introduction

In the past twenty-five years there has been an unprecedented increase in the use of implantable cardiac devices in the United States [1]. Unfortunately, the rate of cardiovascular implantable electronic device infections (CIEDIs) has mirrored this increased use of implantable cardiac devices – with some studies suggesting that there has been a disproportionate increase in the rate of CIEDIs [2, 3]. These studies suggest that the disproportionate increase in device infections may be related to the increased access to patients of varying racial and socioeconomic backgrounds, and to patients with increased comorbidities [2, 3].

CIEDIs are associated with a high cost, both with respect to resource utilization and patient mortality. The mean cost for a hospitalization attributed to a CIEDIs ranges from $31,149 to $55,003. Additionally, CIEDIs are associated with an estimated 8.4 to 11.6 fold increase in mortality when compared to hospitalizations attributed to noninfectious, cardiac device complications [4].

The literature published regarding racial and ethnic disparities and different aspects of device therapy has been limited. Some studies have described limited access to pacemakers, defibrillators, and cardiac resynchronization therapy amongst African Americans and patients from low-socioeconomic groups [5]. There has been no literature regarding access of these therapies to Hispanic patients. The presence of racial and ethnic disparities with respect to the management of CIEDIs, to the best of our knowledge, has not been published.

In this study, we reviewed a cohort of prospectively identified individuals that were referred to our facility with an infection of an implantable cardiac device. These patients all ultimately underwent laser lead extraction. Our objective was to assess and describe any healthcare disparities based on ethnic and racial differences present in the management and outcomes of these patients.

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2. Methods

2.1. Patient population

We reviewed a prospective registry for all patients undergoing removal of an implantable cardiac device at a single high-volume tertiary cardiovascular referral center between January 1, 2004, and June 15, 2016. Any subject who underwent extraction of a cardiac device, regardless of indication, met the criteria for inclusion in this review. 1173 consecutive patients underwent device extraction during this time period. From this population, a total of 699 patients were then identified as having a suspected or confirmed infection on the basis of a combination of clinical, laboratory and imaging data. Upon presentation to our facility, patients self-identified their race and ethnicity. From this population, 305 patients were identified as Caucasian and 394 patients were classified as minorities, consisting of 91 African Americans and 303 Hispanics. Information such as patient demographics; comorbidities; procedure characteristics; extraction techniques; hospital outcomes and data pertaining to follow-up visits were included in a comprehensive database. The information was recorded by a trained data collector and each patient was given a unique identifier to maintain privacy. Proper approval from the appropriate institutional review board was attained.

2.2. Study protocol

A prospective and well-defined care protocol was implemented for patients undergoing device extraction due to a suspected or confirmed infection. All patients upon admission had chest x-rays, PA and lateral, and some had CAT scans. Transthoracic echocardiograms were done in all patients. Blood and exudate (when present) cultures along with Transesophageal echocardiograms (TEEs) were performed preoperatively in all the patients. In the operating room, all patients underwent complete hardware extraction; leads were removed through the use of locking stylets and traction or by using laser extraction (Spectranetics©). En-bloc capsulectomy was performed in all patients. In the majority of cases, specimens were collected intraoperatively from pocket tissue, exudate, lead tips, vegetations and blood; a second TEE was also performed in most patients during the extraction procedure. The wounds were closed primarily with 2-0 nylon and subcutaneous drains were used. If the patient was pacer-dependent, a temporary pacer was placed during device extraction. Throughout the entire admission and for every patient, a single infectious disease consultation service was utilized; a uniform antimicrobial approach was tailored to each patient using operative, echocardiographic and microbiologic data.

2.3. Definitions

The terms extraction, procedural clinical success, procedure failure, major and minor complications were defined in accordance with the Heart Rhythm Society Expert Consensus document from 2009 [6]. Pocket infection was defined as clinical evidence of infection at the generator site, including erythema; warmth; tenderness; fluctuation; wound dehiscence; device erosion or purulent drainage. Cardiac device-related infective endocarditis (CDIE) was defined as the presence of vegetation on a device lead or a valve along with clinical or microbiological evidence of device associated infection, namely the presence of a pocket infection; bacteremia or systemic inflammatory response syndrome [6].

2.4. Echocardiograms

Both transthoracic and transesophageal echocardiograms were reviewed by a certified cardiologist echocardiographer.

2.5. Statistical analysis

Variable distributions were determined. Continuous variables were expressed as mean SD. Categorical variables were expressed as percents. Continuous variables were compared using *t*-tests for independent samples. Nominal variables were compared using the 2 test or Fisher exact test if expected cell values were 5. The level of significance was set at 0.05. Multivariable linear and logistic regression was used to determine whether racial differences remained consistent after adjusting for potential confounding variables. All analyses were conducted using JMP PRO version 12 (SAS Institute Inc.; Cary, NC) statistical software.

3. Results

3.1. Patient population

The study population contained 699 total patients. This population was separated into two groups: Caucasians (n = 305) and minorities, composed of Hispanics and African Americans (n = 394). Table 1 contains more information regarding the demographics for and a comparison between both groups. There was a statistically significant difference between the average age between both groups, with minorities being on average approximately 5 years younger. Additionally, there was a difference in the proportion of males between the groups. There were no other statistically significant differences with respect to any other demographic variable between the groups.

Table 1
Clinical characteristics for Caucasian and minority groups.

	Caucasians (n = 305)	Minorities (n = 394)	*p*
Age (mean ± SD)	72.4 ± 13.2	67.9 ± 14.5	<0.001
Gender, n (%)			
Male	246 (80)	277 (87)	0.002
Female	60 (20)	40 (13)	
Body mass index	27.2 ± 7.3	27.7 ± 7.1	0.30
Comorbidities, n (%)			
HTN	261 (86)	348 (88)	0.17
DM	108 (35)	211 (54)	<0.0001
CAD	211 (69)	246 (62)	0.12
CKD, GFR < 30	51 (17)	90 (23)	0.04
Cr	1.7 ± 1.7	2.0 ± 2.3	0.02
HIV	4 (1)	3 (1)	0.42
CHF, n (%)[a]	302 (99)	390 (99)	
NYHA I	104 (34)	63 (42)	0.06
NYHA II	43 (14)	46 (12)	0.29
NYHA III	107 (35)	120 (31)	0.17
NYHA IV	48 (16)	61 (16)	0.77
Ejection fraction	36 ± 14	36 ± 16	0.72
Hgb (g/dl)	11.9 ± 2.2	11.5 ± 2.	0.03
WBC (g/dl)	8.8 ± 3.9	8.4 ± 4.2 g	0.85

HTN = hypertension, DM = diabetes mellitus, CAD = coronary artery disease, CKD = chronic kidney disease, GFR < 30 ml/min/m^2 encompasses stages 4 and 5, Cr = creatinine, CHF = congestive heart failure, NYHA = New York Heart Association, Hgb = hemoglobin, WBC = white blood cell count.
[a] Four minority patients and one Caucasian patient did not have congestive heart failure. Two Caucasian patients did not have a NYHA classification.

3.2. Comorbidities

As shown in Table 1, there were some differences with respect to comorbidities. Minorities had a larger proportion of diabetes mellitus type II and more advanced chronic kidney disease. Advanced chronic kidney disease was defined as stages 4 and 5, or having a GFR of <30 ml/min/m^2. Minority patients had a lower average hemoglobin upon presentation to our facility than Caucasians (11.5 ± 2.2 versus 11.9 ± 2.2 g/dl, respectively, $p = 0.03$), but comparable white blood cell count (8.4 ± 4.2 g/dl and 8.8 ± 3.9 g/dl, $p = 0.85$). There was no statistically significant difference between the groups based on the number of comorbidities per patient ($p = 0.17$) (Table 2).

3.3. Death and length of hospitalization

There was not a statistically significant difference between the number of patients that died during their index hospitalization between Caucasians and minorities (8% and 10%, respectively) (Table 3). Excluding the patients that died during their index hospitalization, there was a significant difference between the length of hospitalization between both groups, with minorities on average being hospitalized 2 days longer (15.3 ± 9.9 vs 17.4 ± 13.4 days, $p = 0.01$, Table 3). This effect remained significant (beta = 2.00, 95% CI 0.01–4.00, $p = 0.05$) in

Table 2
Distribution of comorbidities per patient between minority (n = 394) and Caucasian (n = 305) groups.[a]

No. of comorbidities	Caucasians	Minorities
1	16 (5)	20 (5)
2	67 (22)	62 (16)
3	93 (30)	129 (33)
4	96 (31)	133 (34)
≥5	34 (12)	50 (12)

Data are presented as n (%).
[a] $p = 0.17$, Chi-Square test.

Table 3
Device properties and clinical outcomes for the minority and Caucasian groups.

	Caucasians (n = 305)	Minorities (n = 394)	p
Length of hospitalization[a]	15.3 ± 9.9 days	17.4 ± 13.4 days	0.01
Time from admission to extraction	7.21 ± 63.9 days	4.16 ± 6.4 days	0.41
Death during index	18 (6)	23 (6)	0.97
Hospitalization devices, n (%)			0.10
PM	122 (40)	145 (37)	
ICD	111 (36)	160 (40)	
CRT-ICD	70 (23)	89 (23)	
CRT-PM	3 (1)	0 (0)	
Leads, n (%)			0.30
Total	734	896	
Atrial	282 (38)	355 (38)	
Ventricular	380 (52)	460 (51)	
Coronary sinus	72 (10)	81 (9)	
Lead time (mo.)	32.4 ± 39.6 (n = 291)	34.6 ± 43.7 (n = 374)	0.5
Approach, n (%)			
Subclavian	296 (97)	382 (98)	0.60
Femoral	0 (0)	2 (0)	
Transatrial	2 (1)	3 (1)	
Subclavian + Femoral	4 (1)	2 (0)	
Subclavian + Sternotomy	3 (1)	4 (1)	
Subclavian + Transatrial	1 (0)	1 (0)	
Complications, n (%)			
Minor	18 (6)	26 (7)	0.03
Major	5 (1)	12 (3)	0.01
Deaths	1	4	0.13
Composite events	23 (8)	38 (9)	0.001

PM = pacemaker, ICD = implantable cardiac defibrillator, CRT-ICD = cardiac resynchronization therapy implantable cardiac defibrillator, CRT-PM = cardiac resynchronization therapy pacemaker.
[a] Patients that died during index hospitalization were excluded from length of hospitalization.

multivariable regression analysis when adjusted for baseline differences in comorbidities, diabetes, and renal function (eGFR).

3.4. Devices

There was not a statistically significant difference between the proportion of pacemakers, defibrillators, CRT-D and CRT-PMs between both groups (Table 3).

3.5. Leads and lead time

There were a total of 734 chronic endovascular leads (atrial, 282; ventricular, 380; coronary sinus, 72 in the Caucasian group and a total of 896 chronic endovascular leads (atrial, 355; ventricular, 460; coronary sinus, 81)) in the minority group (Table 3). There was no significant difference between the proportion of the types of leads between both groups. The mean lead time was on average 2 months longer for the minority group; however, this difference was not statistically significant.

3.6. Extraction timing, approach and complications

There was no statistically significant difference between Caucasians and Minorities with respect to the time from admission to extraction (7.21 ± 63.8 days versus 4.1 ± 6.4 days, respectively, $p = 0.41$). The most common approach in both groups was the Subclavian route and there was no statistically significant difference with respect to the approach used between both groups (Table 3). Both major and minor complications were grouped together for each population to create a composite of adverse events and there was a statistically significant difference ($p = 0.001$). When the proportion of minor and major complications were analyzed separately the difference in the proportion amongst the two groups remained significant (0.03, 0.01 respectively). This effect remained significant (OR = 1.81, 95% CI 1.03–3.22, $p = 0.03$) in multivariable logistic regression analysis when adjusted for baseline differences in comorbidities, diabetes, and renal function (eGFR).

3.7. Microbiology and type of infections

Table 4 demonstrates a summary of the microbiological data and distribution between both populations. There was no statistically significant difference between the proportion of causative organisms between both populations with respect to pocket infections ($p = 0.75$) or bacteremia ($p = 0.54$), but there was a statistically significant difference with respect to CDIE ($p = 0.02$). Caucasian patients had an increased proportion of infections caused by MRSA, MSSE, and other gram positives. Conversely, there were more gram negative organisms and cases attributed to MRSE in the minority group.

4. Discussion

The present findings demonstrate that there are significant racial and ethnic disparities present with respect to cardiovascular implantable electronic device infections. Our minority cohort of patients was on average 5 years younger and had infections associated with typically less virulent organisms than our Caucasian cohort, yet despite these findings their total hospitalization length of stay was approximately 2 days longer on average. Minority patients had a higher proportion of diabetes mellitus and chronic kidney disease. These patients were

Table 4
Microbiological distribution and fatalities for Caucasian (n = 304) and minority (n = 394) patients.

Diagnosis	MRSA	MSSA	MRSE	MSSE	Other Gram positive	Gram negative	Fungal	No growth	Total patients
Minorities[a]									
CDIE[c]	45 (17)[b]	36 (13)	32 (12)	25 (9)	21 (8)	24 (9)	3 (1)	85 (31)	271 (68)
Pocket infection	7 (7)	4 (4)	14 (14)	4 (4)	5 (5)	4 (4)	2 (2)	61 (60)	101 (26)
Bacteremia[c]	7 (31)	1 (5)	5 (23)	0 (0)	7 (31)	1 (5)	1 (5)	–	22 (6)
Deaths	7 (30)	4 (17)	6 (26)	3	1	0	0	4	23[d] (6)
Total (% of infections)	59 (15)	41 (10)	51 (13)	29 (7)	33 (8)	29 (7)	6 (2)	146 (37)	394
Caucasian									
CDIE[c]	42 (19)	30 (14)	21 (9)	36 (16)	34 (15)	10 (5)	4 (2)	49 (22)	222 (73)
Pocket infection	6 (8)	1 (1)	9 (12)	3 (4)	4 (5)	2 (3)	0 (0)	48 (65)	73 (24)
Bacteremia	4 (44)	2 (22)	0 (0)	0 (0)	3 (33)	0 (0)	0 (0)	–	9 (3)
Deaths	6	1	2	2	4	1	0	3	18[d] (6)
Total (% of infections)	52 (17)	32 (11)	30 (10)	39 (13)	42 (14)	12 (4)	4 (1)	97 (32)	304

[a] There was no statistically significant difference between the proportion of Caucasian and minority patients with CDIE, bacteremia, and pocket infection cases, $p = 0.18$.
[b] There was no statistically significant difference between the proportion of causative organisms between both populations with respect to pocket infections ($p = 0.75$) or bacteremia ($p = 0.54$), but there was a significant difference with respect to CDIE ($p = 0.02$).
[c] 7 cases of CDIE and 1 case of bacteremia in Minorities and 4 cases of CDIE in Caucasians were polymicrobial.
[d] 3 deaths in the minorities and 1 death in the Caucasians were polymicrobial.

more likely to experience minor and major procedural complications during laser lead extraction. As access to implantable cardiac devices for minority patients continues to increase, elucidating the root cause of these differences will become increasingly important - as these disparities may have serious ramifications for our health care system.

Disparities have been described with respect to the delivery of multiple aspects of care in cardiology lines of service [7–13]. Significant racial disparities with respect to the availability of cardiac catheterizations [7], PTCA, and CABG for minorities compared to Caucasian patients, with the former being 22–97% less likely to undergo such procedures - despite appropriate candidacy [7, 14]. Within cardiac electrophysiology, racial and gender disparities regarding the availability of implantable cardiac devices has been well described. Female patients and African American patients were routinely less likely to be offered an implantable cardiac defibrillator – with the worst subset being African American women [5, 9–11]. These racial disparities with respect to defibrillator usage were subsequently linked with worse long-term mortality by Groeneveld et al., with African Americans being over 30% less likely to receive a device despite experiencing the same decrease as Caucasians when implanted – this equated to a 20% increase in mortality over their follow-up period [15]. The literature with respect to disparities and cardiovascular implantable electronic device infections is essentially non-existent. Sohail et al. demonstrated that female patients with CIEDIs have a >45% increase in long-term mortality compared to male patients, despite there being no difference with the index hospitalization and 30 day follow-up [16]. Our manuscript, to the best of our knowledge, is the first description of racial and ethnic disparities with respect to the management of implantable cardiac device infections.

In our experience, minority patients presenting with a CIEDI were on average five years younger and had a higher proportion of males than our Caucasian cohort. This finding is congruent with the findings by Yancy et al. in that Hispanic and African American heart failure patients tend to be younger than Caucasian patients [8]. With respect to comorbidities, minorities had a higher proportion of chronic kidney disease, which has been identified as a risk factor for the development of CIEDI [16]. Minority patients had a statistically significant increase in the complication rate associated with laser lead extraction, both with minor (6% versus 7%) and major complications (1 versus 3%), despite having a higher proportion of male patients (female gender is associated with a higher complication rate) and being younger on average. Additionally, both groups had relatively shorter lead dwell times, 32 and 34 months, which was comparable to those in the LEXICON trial. These complication rates are comparable with national averages [6, 17, 18]. With respect to microbiology, there was no difference in the proportion of types of infection, namely pocket infections, bacteremia, and device endocarditis. While there was no statistically significant difference regarding causing organisms and pocket infections and bacteremia, there was a difference with respect to device endocarditis. Caucasian patients had more infections involving MRSA, MSSE, MSSA, and other gram positive; minority patients had slightly more cases associated with MRSE and gram negatives. This distribution of causative microbes is congruent with our prior report [17].

The changing demographics in the United States and the impact that these disparities may have on our health care system places an onus on our community to identify the causes and implement policies to mitigate them. The U.S. Census Bureau projects that by 2042, Hispanic and African American populations will constitute approximately 45% of the total population. Given that the average cost associated with a CIEDI ranges from $14,360 to $16,498 for pacemakers and up to $28,676–$53,349 for defibrillators and CRT devices [4], along with the fact that there are 467,000 pacemaker or defibrillator related procedures performed annually in the United States [19], these disparities will likely have a gradually increasing impact.

The cause of these disparities is unclear and likely multifactorial. Possible causes include the impact of socioeconomic differences, health literacy, adherence, cultural differences affecting the quality of provider to patient communication, access to care, as well as a presumed lack of trust amongst minorities in the health care establishment [5, 8, 10]. There have been certain interventions described that have been demonstrated improved patient outcomes in this population. Cultural competency training was showed to improve health care quality, provider knowledge and attitudes, and patient satisfaction and health [8].

The Robert Wood Johnson Foundation (RWJF)-supported initiative Expecting Success demonstrated that hospital-based QI efforts based on tracking performance metrics by race and ethnicity yielded overall improvement in quality [20]. Several other multi-center registries centered on other cardiac conditions and procedures have demonstrated success in significantly reducing racial disparities [8].

The American College of Cardiology's Coalition to Reduce Racial and Ethnic Disparities in Cardiovascular Disease Outcomes (credo) and the RWJF have been instrumental in identifying and implementing interventions to reduce these disparities. Given the fact that only one-third of surveyed cardiologists acknowledged the existence of racial and ethnic health care disparities, with even fewer conceding such disparities in their own practice-settings [8], simply being aware of this issue is a significant step.

4.1. Study limitations

Our study had several limitations. The study was retrospective in nature. Only patients undergoing laser lead extraction were included; therefore, a selection bias could have been present. Even though the study population consisted of 699 patients, the sample size was limited and originated from a single center. Future studies should evaluate the role of socioeconomic factors and their impact on access and outcomes related to laser lead extraction. Lastly, because our institution is a cardiovascular tertiary referral center, our patient population tended to present with advanced disease.

5. Conclusion

Minority patients with CIEDIs experienced more procedural complications during extraction and had a significantly longer length of index hospitalization than Caucasian patients.

Conflict of interest

The authors report no relationships that could be construed as a conflict of interest.

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