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ORIGINAL RESEARCH

Impact of an Automated Best Practice Alert on Sex and Race Disparities in Implantable Cardioverter-Defibrillator Therapy

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BACKGROUND: Implantable cardioverter-defibrillators (ICDs) are indicated in patients with severe left ventricular dysfunction, but many eligible patients do not receive them, especially women and Black patients. Our group had previously demonstrated that a best practice alert (BPA) improves overall rates of electrophysiology referrals and ICD implantations. This study examined the impact of a BPA by sex and race.

METHODS AND RESULTS: This is a cluster randomized trial of cardiology (n=106) and primary care (n=89) providers who were randomized to receive (BPA, n=93) or not receive (No BPA, n=102) the alert and managed 1856 patients meeting primary prevention criteria for ICD implantation (965 BPA and 891 No BPA). After a median follow up of 34 months, 630 (34%) patients were referred to electrophysiology, and 522 (28%) patients received an ICD. Compared with the No BPA arm, patients in the BPA arm saw a modest differential increase in the rate of electrophysiology referrals at 18 months in men (+4%) compared with women (+7%) but a profound increase in Black patients (+16%) compared with White patients (+2%), thus closing the sex and race gaps. Similar trends were noted for rates of ICD implantation.

CONCLUSIONS: Use of a BPA improves rates of electrophysiology referrals and ICD implantations in all comers with severe cardiomyopathy and no prior ventricular arrhythmias but has a more pronounced impact in women and Black patients. The use of a BPA at the point of care is an effective tool in the fight against sex and race inequities in health care.

Key Words: best practice alert ■ electronic medical records ■ implantable defibrillator ■ race ■ sex

Sudden cardiac death is a leading cause of mortality in the United States, claiming 230 000 to 350 000 lives annually.[1–3] Randomized controlled trials have demonstrated that implantable cardioverter-defibrillators (ICDs) reduce all-cause mortality by decreasing the risk of sudden cardiac death among patients with severe left ventricular dysfunction.[4,5] Accordingly, the American College of Cardiology, American Heart Association, and Heart Rhythm Society recommend ICD implantation for primary prevention of sudden cardiac death among patients with left ventricular ejection fraction ≤35%.[1,6] Despite these guideline recommendations, many eligible patients do not receive ICD therapy, especially women and racial and ethnic minorities.[7–10] The reasons underlying the underuse of ICD therapy in qualified primary prevention patients deserve further investigation. Studies have found that provider nonreferral was highly associated with ICD underuse in the primary prevention setting, followed by patient refusal.[11,12]

Several patient and provider barriers to adequate use of ICD therapy have been reported.[13] Patients may refuse device implantation because of their inability to grasp their risk with and without an ICD, especially in the absence of symptoms. They may also have concerns over undergoing invasive initial implantation and subsequent battery changeout procedures and may fear the potential

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CLINICAL PERSPECTIVE

What Is New?

- The use of a best practice alert delivered through the electronic health record improves the rates of referrals to the cardiac electrophysiology service and of implantable cardioverter-defibrillator implantations in all comers with severe cardiomyopathy and no prior known ventricular arrhythmias.
- The impact of the best practice alert on improving electrophysiology service referrals and implantable cardioverter-defibrillator implantations is most pronounced in women and Black patients.

What Are the Clinical Implications?

- The use of best practice alert at the point of care may be an effective tool in the fight against sex and race inequities in health care.

Nonstandard Abbreviations and Acronyms

BPA	best practice alert

negative impact the ICD may have on their quality of life.[14] These fears have unfortunately been fueled in recent decades by numerous device and lead recalls. Other factors, such as device cost or lack of insurance coverage, may also play a role in ICD underuse. Lastly, provider-related limitations, such as inadequate physician education and time constraints that limit their ability to identify eligible patients, have also been implicated.[15]

Best practice alerts (BPAs) delivered through the electronic medical record have been shown to influence provider recommendations and clinical practice.[16–18] Our group had previously demonstrated in a cluster randomized trial setting that the use of a BPA delivered at the point of care, reminding providers to consider referring patients with low left ventricular ejection fraction (≤35%) to an electrophysiologist for evaluation for ICD implantation resulted in significant increase in referral rates and actual device implantations.[18] Given the established lower rates of ICD implantation for primary prevention of sudden cardiac death in women and racial minorities,[7,8,10] we examined in the present study the impact of BPAs on ICD referrals and implantations by sex and race of eligible patients.

METHODS

Study Design

The data that support the findings of this study are available from the corresponding author upon reasonable request. This research protocol, which is a post hoc analysis of the ALERT-ICD (Cluster Randomized Trial Examining the Impact of Automated Best Practice Alert on Rates of Implantable Cardioverter Defibrillator Therapy)[18] trial, was approved by the University of Pittsburgh Institutional Review Board, which waived the need for informed consent. As previously described,[18] physicians from General Internal Medicine (n=89) and the Heart and Vascular Institute (n=106) at the University of Pittsburgh Medical Center were randomized to receive (BPA arm, n=93) or not receive (No BPA arm, n=102) a custom-designed alert delivered to providers through the outpatient electronic health record (EpiCare, Verona, WI) between January 1, 2013 and December 31, 2015. Provider randomization was stratified by EpiCare cost centers (n=19), which correspond to the various General Internal Medicine and Heart and Vascular Institute clinics at the University of Pittsburgh Medical Center system. The process of randomization was performed by EpiCare personnel such that the research team was blinded to provider-arm assignments. The BPA displayed a message to providers recommending referral to the cardiac electrophysiology service if the patient being seen had any documented left ventricular ejection fraction ≤35% in the preceding 365 days and did not have an implanted ICD, as determined by the absence of diagnostic and procedural codes in the patient's problem list. Once the BPA appeared, providers could either ignore it or initiate electrophysiology referral for possible ICD implantation.

Of the overall ALERT-ICD trial[18] cohort (n=1906) of patients, 1856 patients had a self-identified race (Black or White) coded as part of their medical record. Patients' charts were then manually reviewed by chart abstractors for each of the following types of encounters occurring after the study start date of July 1, 2013: (1) referral to the electrophysiology service, which was considered the primary outcome of interest for this analysis and (2) ICD implantation procedure. Events were censored at the time of last follow-up or August 1, 2016, whichever occurred first. A total of 965 patients were included in the BPA arm and 891 patients in the No BPA arm.

Statistical Analysis

For descriptive purposes, continuous variables are reported as median (range) and categorical variables are reported as frequencies and percentages. Baseline differences between the primary treatment groups by sex (men or women) and race (Black or White) were tested using Mann-Whitney tests for continuous variables and χ^2 tests for categorical variables. Time to electrophysiology referral and ICD implantation is plotted using Kaplan-Meier curves and compared by sex and race for patients in the BPA and No BPA arms of the trial using the log-rank test. Cox proportional hazards models are used to compute hazard ratios (HRs) and 95% CIs for all comparisons. Statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC) and SPSS version 26.0 (IBM, Armonk, NY).

RESULTS

Patient Population

Table 1 details the baseline characteristics of all patients included in the present analysis, stratified by sex and race. Analyzing these data according to patients' sex, women were slightly older than men, had a lower body mass index, were less likely to consume alcohol

Table 1. Characteristics of Study Population by Sex and Race

	Total	White men	White women	Black men	Black women	*P* value
No. of patients	1856	1114	512	129	101	
Demographics						
Age at contact, y	68.5 (19.1–97.6)	69.3 (19.1–97.6)	72.2 (20.2–95.2)	57.0 (26.8–86.8)	58.8 (20.7–88.5)	<0.001
Body mass index	28.4 (14.5–224)	28.6 (14.5–224)	27.3 (14.5–73.4)	30.3 (17.6–64.1)	30.1 (18.7–57.3)	<0.001
Body surface area	2.0 (1.1–3.2)	2.1 (1.1–3.2)	1.7 (1.2–2.7)	2.1 (1.6–3.2)	1.8 (1.4–2.6)	<0.001
Alcohol use	568 (30.6%)	395 (35.5%)	100 (19.5%)	49 (38.0%)	24 (23.8%)	<0.001
Tobacco use	977 (52.6%)	638 (57.3%)	203 (39.6%)	70 (54.3%)	66 (65.3%)	<0.001
Clinical conditions						
Hypertension	1284 (69.2%)	766 (68.8%)	346 (67.6%)	102 (79.1%)	70 (69.3%)	0.091
Diabetes	629 (33.9%)	379 (34.0%)	165 (32.2%)	49 (38.0%)	36 (35.6%)	0.618
Coronary artery disease	1036 (55.8%)	706 (63.4%)	249 (48.6%)	47 (36.4%)	34 (33.7%)	<0.001
Atrial fibrillation	724 (39.0%)	501 (45.0%)	173 (33.8%)	33 (25.6%)	17 (16.8%)	<0.001
QRS duration	108 (63.0–226)	112 (66.0–226)	106 (63.0–220)	100 (66.0–216)	94.0 (70.0–188)	<0.001
QRS paced	137 (7.4%)	102 (9.2%)	28 (5.5%)	6 (4.7%)	1 (1.0%)	0.001
Left bundle branch block	319 (17.2%)	170 (15.3%)	125 (24.4%)	10 (7.8%)	14 (13.9%)	<0.001
Ejection fraction	30.0 (8.0–35.0)	30.0 (8.0–35.0)	30.0 (10.0–35.0)	27.3 (10.0–35.0)	27.5 (10.0–35.0)	<0.001
LVESD, cm	4.6 (1.4–8.0)	4.6 (1.4–8.0)	4.3 (1.9–7.6)	4.9 (1.8–8.0)	4.7 (2.6–6.8)	<0.001
LVEDD, cm	5.5 (2.8–8.9)	5.6 (3.1–8.9)	5.2 (2.8–8.2)	5.8 (2.8–8.2)	5.6 (3.2–8.0)	<0.001
Systolic blood pressure	124 (64.0–226)	123 (64.0–188)	126 (80.0–226)	130 (80.0–198)	128 (92.0–194)	0.002
Diastolic blood pressure	73.0 (30.0–129)	72.0 (30.0–120)	72.0 (38.0–129)	80.0 (49.0–120)	80.0 (39.0–122)	<0.001
Serum sodium, mEq/L	139 (122–154)	139 (124–154)	139 (125–148)	138 (122–145)	139 (126–144)	0.002
Serum creatinine, mg/dL	1.1 (0.1–16.8)	1.1 (0.1–14.0)	0.9 (0.4–7.6)	1.2 (0.6–7.5)	0.9 (0.4–16.8)	<0.001
Medication use						
β-Blockers	1365 (73.5%)	819 (73.5%)	374 (73.0%)	99 (76.7%)	73 (72.3%)	0.843
ACEi/ARB	1153 (62.1%)	694 (62.3%)	303 (59.2%)	90 (69.8%)	66 (65.3%)	0.136
Spironolactone	234 (12.6%)	127 (11.4%)	71 (13.9%)	19 (14.7%)	17 (16.8%)	0.221
Digoxin	183 (9.9%)	108 (9.7%)	61 (11.9%)	10 (7.8%)	4 (4.0%)	0.068
Other diuretics	956 (51.5%)	529 (47.5%)	288 (56.3%)	78 (60.5%)	61 (60.4%)	<0.001
Class I AAD	7 (0.4%)	2 (0.2%)	5 (1.0%)	0 (0.0%)	0 (0.0%)	0.074
Class III AAD	33 (1.8%)	25 (2.2%)	8 (1.6%)	0 (0.0%)	0 (0.0%)	0.128
Amiodarone	91 (4.9%)	67 (6.0%)	19 (3.7%)	5 (3.9%)	0 (0.0%)	0.019
Statins	1050 (56.6%)	681 (61.1%)	275 (53.7%)	59 (45.7%)	35 (34.7%)	<0.001
Study arm						
BPA received						0.848
No BPA	891 (48.0%)	542 (48.7%)	240 (46.9%)	59 (45.7%)	50 (49.5%)	
BPA	965 (52.0%)	572 (51.3%)	272 (53.1%)	70 (54.3%)	51 (50.5%)	

Continuous variables are presented as median (range). AAD indicates antiarrhythmic drug; ACEi/ARB, angiotensin-converting enzyme inhibitor/angiotensin receptor blocker; BPA, best practice alert; LVEDD, left ventricular end-diastolic diameter; and LVESD, left ventricular end-systolic diameter.

or tobacco, and had less comorbidities including coronary artery disease, atrial fibrillation, and elevated serum creatinine. Women were more likely to have cardiac conduction abnormalities in the form of left bundle branch block. Examining these data according to patients' race, Black patients were significantly younger than White patients, had a higher body mass index and blood pressure, and were less likely to have coronary artery disease and atrial fibrillation. Black patients were also more likely to be prescribed diuretics but less likely to be on statin lipid-lowering therapy.

Outcomes of Men Versus Women

Over a mean follow-up of 34 months, 630 (450 men and 180 women) patients were referred to the cardiac electrophysiology service and 522 (370 men and 152 women) patients were implanted with an ICD. In the overall cohort (BPA and No BPA), women, compared with men, were 23% less likely to be referred to the cardiac electrophysiology service (HR, 0.77 [95% CI, 0.65–0.92]; *P*=0.003; Figure 1A) and 20% less likely to receive ICD therapy (HR, 0.80 [95% CI, 0.66–0.96]; *P*=0.021; Figure 1B). When examining the rate of referrals to electrophysiology by sex in the No BPA arm, women were significantly less likely to be referred (HR, 0.68 [95% CI, 0.52–0.89]; *P*=0.006; Figure 2A), but this was reduced when providers were exposed to the BPA (HR, 0.84 [95% CI, 0.67–1.06]; *P*=0.15; Figure 2B) with no significance for the interaction between sex and BPA (*P*=0.24). A similar trend was noted for the end point of ICD implantation (Figure 2C and 2D); however, this did not reach statistical significance given a smaller number of events.

Outcomes of Black Versus White Patients

Over a mean follow-up of 34 months, 630 (555 White and 75 Black) patients were referred to the cardiac electrophysiology service, and 522 (453 White and 69 Black) patients were implanted with an ICD. For the overall cohort (BPA and No BPA), Black patients, compared with White patients, had similar rates of referral to the cardiac electrophysiology service (HR, 0.95 [95% CI, 0.75–1.21]; *P*=0.71, Figure S1A) and of ICD device implantation (HR, 1.08 [95% CI, 0.84–1.39]; *P*=0.52, Figure S1B). Interestingly, when examining the rate of referrals to electrophysiology by race in the No BPA group, Black patients exhibited a trend toward less referrals (HR, 0.73 [95% CI, 0.49–1.09]; *P*=0.13; Figure 3A), but this trend was reversed in the BPA group (HR, 1.15 [95% CI, 0.85–1.57]; *P*=0.34; Figure 3B), with a trend toward significance for the interaction between race and BPA (*P*=0.076). A similar reversal of pattern was noted for ICD implantation (Figure 3C and 3D).

Change in Rates of Electrophysiology Referrals and ICD Implantations With BPA Use by Sex and Race

Table 2 details the absolute change in the rates of electrophysiology referrals and ICD implantations at 18 months of follow-up for patients in the BPA versus No BPA arms of the trial by sex and race. Compared with the No BPA arm, patients in the BPA group saw an increase in their rates of electrophysiology referrals and ICD implantation for men and women of both races. Importantly, the increase in these rates was modest for men and women (4%–7%), with a slight advantage for

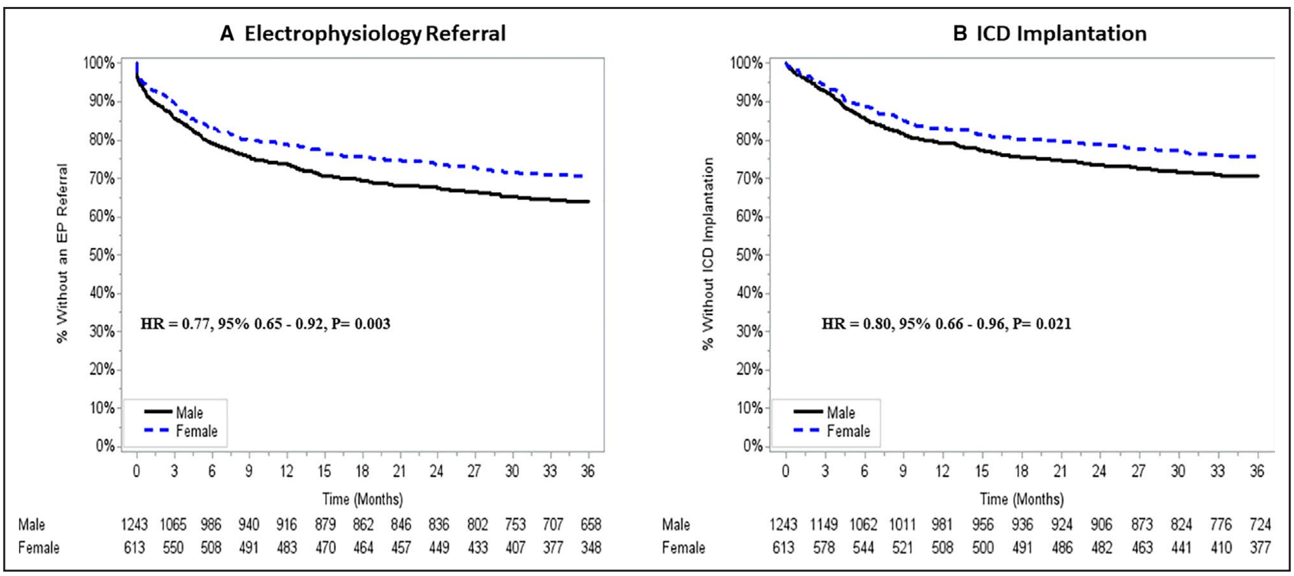

Figure 1. Kaplan-Meier survival curves showing time to electrophysiology (EP) referral for women vs men (A) and time to implantable cardioverter-defibrillator (ICD) implantation for women vs men (B).
HR indicates hazard ratio.

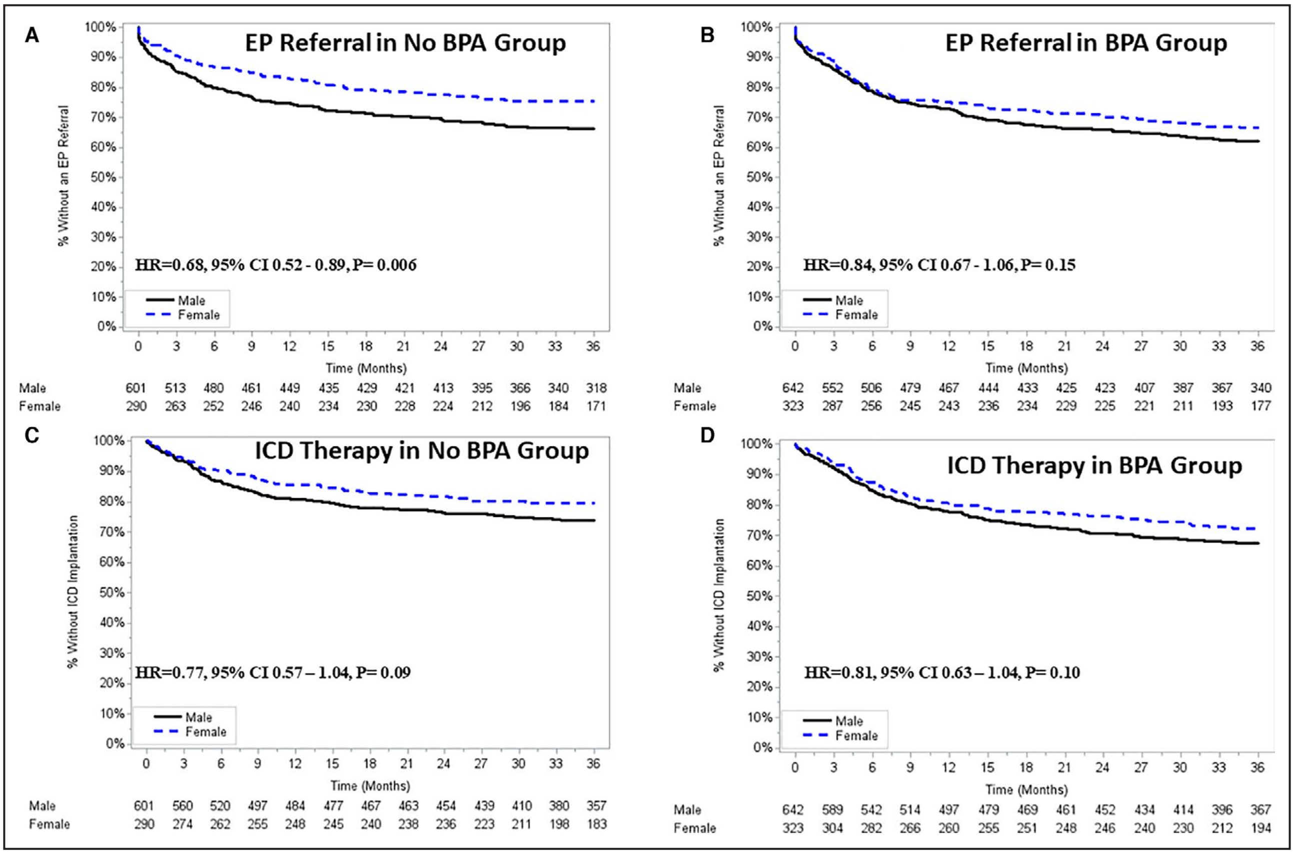

Figure 2. Kaplan-Meier survival curves showing time to electrophysiology referral for women vs men in the No BPA arm (A), electrophysiology referral for women vs men in the BPA arm (B), ICD implantation for women vs men in the No BPA arm (C), and ICD implantation for women vs men in the BPA arm (D).
BPA indicates best practice alert; EP, electrophysiology; HR, hazard ratio; and ICD, implantable cardioverter-defibrillator.

women. Black patients had a profound change in their rates of electrophysiology referrals and ICD implantations on the order of a 14% to 16% absolute increase compared with White patients, who only saw modest increases in these end points on the order of 2% to 3%. Table S1 details the benefit of providers receiving versus not receiving a BPA on the outcomes of electrophysiology referrals and ICD implantation for White men, White women, Black men, and Black women. Here again, the impact of BPA was more pronounced in women and Black patients compared with White men, as noted in the magnitude of the reported HRs.

Impact of Provider–Patient Sex Concordance on Electrophysiology Referrals and ICD Implantations

We examined the impact of concordance between the provider's and the patient's sex on the rates of electrophysiology referrals and ICD implantations. Providers were 23% women and 77% men. The provider–patient sex concordance was as follows: male provider–male patient (62.5%), male provider–female patient (30%), female provider–male patient (5%), female provider–female patient (2.5%). Overall provider–patient concordance was 65%. Sex concordance between patient and provider showed a trend toward impacting the rates of electrophysiology referrals (HR, 1.18 [95% CI, 0.99–1.42]; *P*=0.07) but not of ICD implantations (HR, 1.12 [95% CI, 0.91–1.37]; *P*=0.27). A similar analysis by provider–patient race concordance was not possible given that the providers' race could not always be ascertained, and that a large number of providers were of Asian or Southeast Asian descent, and therefore establishing racial concordance between them and their patients, who are predominantly White or Black, could not be done.

DISCUSSION

Our data demonstrate that for the primary prevention of sudden cardiac death, a documented low left ventricular ejection fraction (≤35%) in the electronic health record is less likely to result in referral to the electrophysiology service and in ICD implantation in women compared with men and in Black patients compared

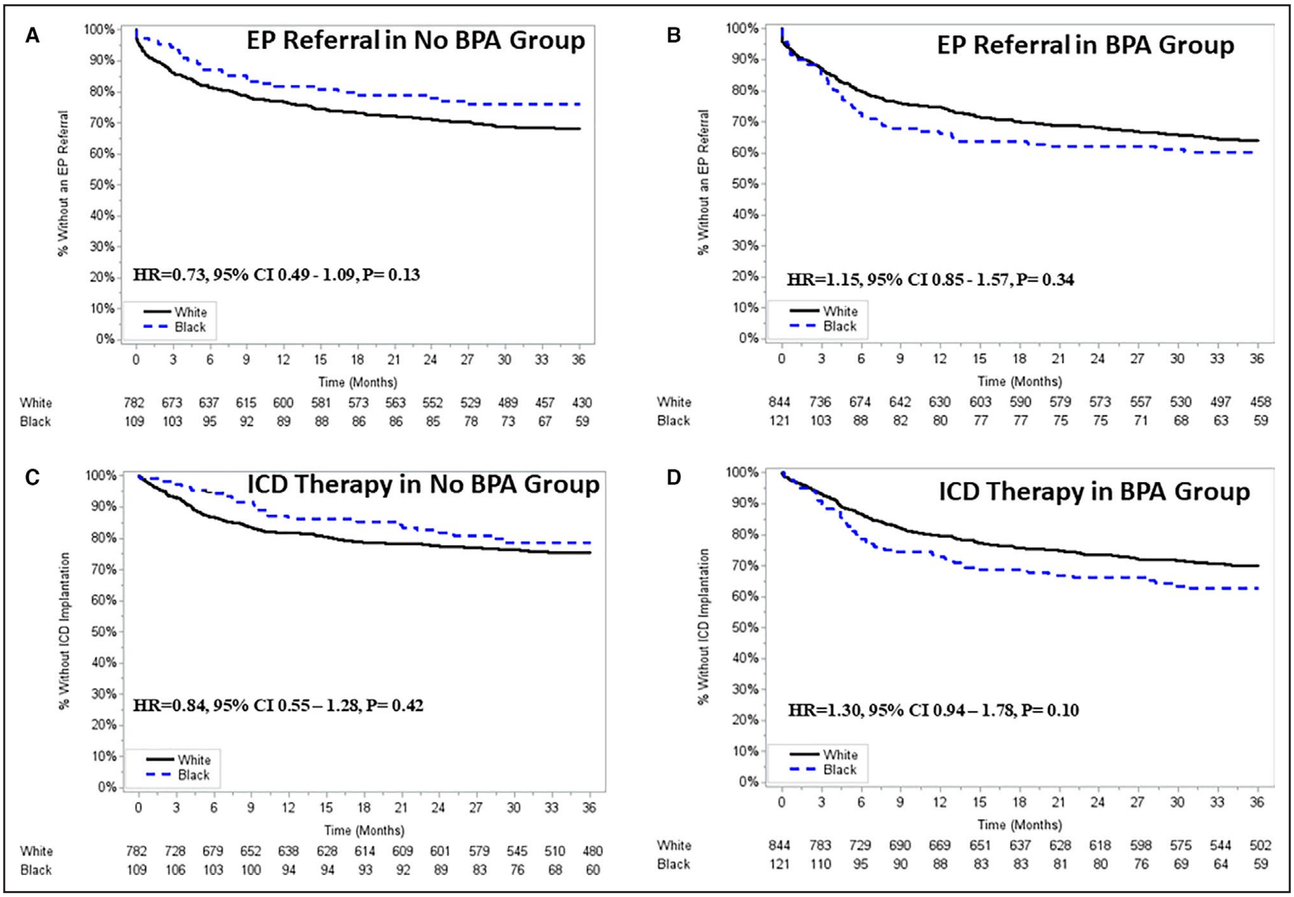

Figure 3. Kaplan-Meier survival curves showing time to electrophysiology referral for Black vs White patients in the No BPA arm (A), electrophysiology referral for Black vs White patients in the BPA arm (B), ICD implantation for Black vs White patients in the No BPA arm (C), and ICD implantation for Black vs White patients in the BPA arm (D).
BPA indicates best practice alert; EP, electrophysiology; HR, hazard ratio; and ICD, implantable cardioverter-defibrillator.

with White patients. Importantly, a BPA delivered to general practitioners or cardiologists at the point of care, significantly reduced the sex gap in these end points and significantly improved referral patterns for Black patients. These data demonstrate, in a randomized controlled setting, that a BPA intervention at the point of care can modify provider behavior and influence clinical outcomes and could therefore be used to improve adherence to guideline recommendations. Importantly, our data showed a modest differential impact of the BPA on provider recommendations by sex but a more profound impact by race. The absolute increase in the rate of electrophysiology referrals and ICD implantations was nearly 8-fold (16% versus

Table 2. Assessment of Change in Rates of EP Referrals and ICD Implantations at 18 Months of Follow-Up in BPA Versus No BPA Patients by Sex and Race

Sex	No BPA		BPA		Change	
	Men	Women	Men	Women	Men	Women
EP referral	34%	26%	38%	33%	+4%	+7%
ICD implantation	27%	21%	32%	27%	+5%	+6%
Race	**No BPA**		**BPA**		**Change**	
	White	Black	White	Black	White	Black
EP referral	33%	25%	35%	41%	+2%	+16%
ICD implantation	26%	21%	29%	35%	+3%	+14%

BPA indicates best practice alert; EP, electrophysiology; and ICD, implantable cardioverter-defibrillator.

2%) higher for Black patients compared with White patients.

The underlying mechanisms of this differential impact of the BPA by sex and race are likely multifactorial. A lack of familiarity with guidelines has long served as an explanation for provider behavior.[15] The overall low referral patterns demonstrated in our cohort could be attributable in part to providers' unfamiliarity with guideline recommendation for ICD therapy in the context of severe cardiomyopathy. One could postulate that providers' implicit bias may also be at play,[10,19] whereby providers may unconsciously overlook referrals for women or Black patients to the electrophysiology service for consideration of ICD therapy. Explicit biases and structural racism, which have also been strongly implicated in health care inequities, cannot be excluded.[20,21] Furthermore, providers may incorrectly assume lower risk, less benefit, or prohibitive cost of therapy in these patient demographics.[22] Regardless, in the presence of a BPA, the sex gap in electrophysiology referrals was closed because of a modestly higher impact of the BPA in women versus men but mostly because of improved rates in both sexes. In Black patients, the impact of the BPA on electrophysiology referrals showed a strong trend toward significance compared with White patients, by nearly reversing the relationship in favor of more electrophysiology referrals and ICD implantations among Black compared with White participants. The positive but smaller impact of the BPA in men and White patients is likely reflective of the educational value of the BPA, absent other biases.

The findings of the present study are encouraging because they demonstrate that an automated BPA based on objective patient data that are incorporated into the electronic health record and activated at the point of care can alter provider behavior. This creates the opportunity for health systems to invest in creating clinical pathways, informed by published guideline recommendations, to educate and remind providers in real time of best practices. This would elevate the level of practice of all providers for all patients and would create more uniformity in health care delivery. Judging by our present finding, groups that have been excluded from evidence-based practices, specifically women and Black patients, may benefit the most from these interventions. However, one major limitation of such BPAs is that they may lead to provider fatigue if the volume of alerts is too high.[23,24] They could also slow down care delivery, particularly if a BPA is empowered to put a hard stop to the flow and progress of patient encounters.

Limitations

The present study has limitations. First, the original ALERT-ICD trial[18] from which the present data are extracted was performed at a single institution. Therefore, our results may not be readily applicable to other practice settings in different geographical areas and with dissimilar patient and provider demographics. Still, the University of Pittsburgh Medical Center is a large regional health system that provides care for patients across the Commonwealth of Pennsylvania and beyond, with hospitals ranging from small rural to urban quaternary care centers, therefore having wide representation. Second, our study is likely underpowered for performing subgroup analyses, particularly as they relate to racial minorities. In more than one instance, our analyses revealed trends, some of which did not reach statistical significance. Nevertheless, the consistency of these trends across several analyses and for different end points provides assurance that the conclusions drawn are supported by the data. In addition, our data lack information on the reasons why some patients referred to electrophysiology did not receive an ICD. Lastly, our results depend on the accuracy of coding of clinical and demographic information in the electronic health records.

CONCLUSIONS

Our data demonstrate that a BPA delivered through the electronic health record to providers caring for patients with severe cardiomyopathy improves rates of electrophysiology referrals and ICD therapy in all patients, modestly more in women compared with men and drastically more in Black patients compared with White patients. These data suggest a major role for BPAs and other objective tools that can and should be incorporated into daily clinical practice to overcome bias and get us closer to achieving health care equity in cardiology and across all medical and surgical disciplines.

ARTICLE INFORMATION

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Supplemental Material

Table S1
Figure S1

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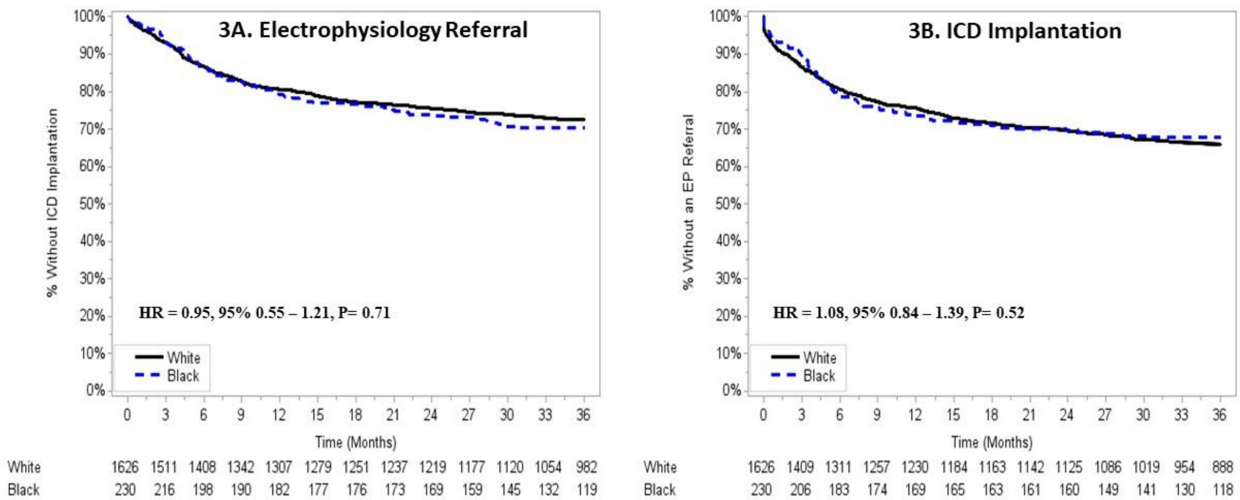
SUPPLEMENTAL MATERIAL

Table S1. Hazard ratios for patients in the BPA versus No BPA arms of the trial for the endpoints of EP referrals and ICD implantations by sex and race of patients.

	EP REFERRALS			**ICD IMPLANTATION**		
	Hazard Ratio	**95% Confidence Interval**		**Hazard Ratio**	**95% Confidence Interval**	
		Lower	***Upper***		***Lower***	***Upper***
White Men	1.09 *	1.09	1.33	1.28*	1.02	1.60
White Women	1.25	0.89	1.75	1.23	0.85	1.79
Black Men	1.78	0.93	3.38	1.6	0.81	3.12
Black Women	1.78	0.87	3.15	2.3*	1.04	5.08

(*) Significant at the $P<0.05$ level; EP = electrophysiology; ICD = implantable cardioverter defibrillator

Figure S1. Kaplan-Meier survival curves showing time to electrophysiology referral for Black vs. White patients (A) and time to ICD implantation for Black vs. White patients (B).



HR indicates hazard ratio; 95% CI indicates 95% confidence interval.