International Journal of Arrhythmia

LETTER TO THE EDITOR

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Trends in cardiovascular death related to mechanical complications of cardiac electronic devices in the United States from 1999 to 2020

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Abstract

Background While cardiac implantable electronic devices (CIED) are increasingly used, real-world data on the mortality rate due to mechanical complications of CIED is scarce.

Objective This study aimed to determine longitudinal trends in mortality attributed to mechanical complications of CIED.

Methods We queried the Centers for Disease Control and Prevention's Wide-Ranging Online Data for Epidemiologic Research and performed serial cross-sectional analyses of national death certificate data for mechanical complications of CIED-related mortality among the United States population aged ≥ 35 years from 1999 to 2020. Cardiovascular disease (ICD-10: I00–I99) was listed as the underlying cause of death, and mechanical complication of the cardiac electronic device (ICD-10: T82.1) was stated as the contributing cause of death. We calculated age-adjusted mortality rates (AAMRs) per 1,000,000 individuals. Linear regression was used to calculate for the significance of the annual percent of changes in AAMRs.

Results 1237 cardiovascular deaths related to mechanical complications of CIED were identified between 1999 and 2020. The AAMR dropped significantly from 0.45 per 1,000,000 individuals in 1999 to 0.21 per 1,000,000 individuals in 2020 ($p < 0.01$). Cumulative AAMRs were higher in males than females (0.39 per 1,000,000 individuals vs. 0.26 per 1,000,000 individuals, $p < 0.01$), higher in White populations than African American populations (0.32 per 1,000,000 individuals vs. 0.30 per 1,000,000 individuals, $p < 0.01$), and higher in the rural areas than in the urban areas (0.50 per 1,000,000 individuals vs. 0.27 per 1,000,000 individuals, $p < 0.01$).

Conclusion While the cardiovascular deaths related to mechanical complications of CIED were decreasing over the past decades, disparities in the AAMRs across sex, races and geographical region still present.

Keywords Mechanical complications, Cardiac implantable electronic device, Cardiovascular deaths, Age-adjusted mortality rates

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Introduction

The number of cardiac implantable electronic device (CIED) implantation continues to increase annually. Early complications following the CIED implantation were reported at an incidence of 4.4–8.5% within 90 days of discharge, and a 10-year longitudinal study revealed a mechanical complication rate of 25% [1–3]. Given the growing number of CIED implants worldwide, it is crucial to assess the mechanical safety of CIED in the contemporary era. This is particularly important in rural areas, where the residents encounter greater public health challenges and had higher rates of mortality [4].

Methods

Centers for Disease Control and Prevention's Wide-Ranging Online Data for Epidemiologic Research (CDC WONDER) is a publicly available online database that contains public health data, including mortality data since the year 1999. Death certificate data from the United States (U.S.) CDC WONDER were analyzed from 1999 to 2020 for mechanical complication of cardiac electronic device related mortality among the U.S. population age ≥ 35 years using code from the International Statistical Classification of Diseases and Related Health Problems-10th Revision (ICD-10: T82.1). The lists of mechanical complications were device malfunctions that include mechanical breakdown or obstruction, displacement, leakage, malposition, perforation, and protrusion [5]. Cardiovascular disease (ICD-10: I00–I99) was listed as the underlying cause of death and mechanical complication of the cardiac electronic device was stated as the contributing cause of death. Those aged 34 years or below were excluded due to data confidentiality in this age group. Crude and age-adjusted mortality rates (AAMRs) per 1,000,000 population were calculated by standardizing cardiovascular deaths (CVDs) related to mechanical complication of cardiac electronic devices to the year 2000 U.S. population). Linear regression was used to calculate for the significance of the annual percent of changes in AAMRs. Our study does not require institutional review approval as the population data is de-identified and publicly available.

Results

In the 22-year study period, a total of 1237 CVDs related to mechanical complication of CIED were identified between 1999 and 2020. Of these, 45.0% occurred in those aged 85 years and above, 27.1% occurred in those aged 75–84 years, 15.0% occurred in those aged 65–74 years, 8.4% occurred in those aged 55–64 years, 3.5% occurred in those aged 45–54 years, and 1.0% occurred in those aged 35–44 years (Table 1). Overall, there was a significant decrease in annual trends for the AAMR from 0.45 per 1,000,000 individuals in 1999 to 0.21 per 1,000,000 individuals in 2020 during the study period ($p < 0.01$) (Fig. 1). When stratified by sex, cumulative AAMRs for the span of 22-year were higher in males than females (0.39 per 1,000,000 individuals vs. 0.26 per 1,000,000 individuals, $p < 0.01$). When stratified by race, White population had higher AAMRs than African American populations (0.32 per 1,000,000 individuals vs. 0.30 per 1,000,000 individuals, $p < 0.01$), while the data of AAMRs for the American Indian and Asian were unavailable.

When AAMRs were stratified by census regions, the Midwest region (Census Region 2) had the highest AAMRs of 0.36 per 1,000,000 individuals, followed by the South region (Census Region 3, 0.35 per 1,000,000 individuals), the Northeast region (Census Region 1, 0.30 per 1,000,000 individuals) and the West region (Census Region 4, 0.27 per 1,000,000 individuals) (Fig. 2). Further subgroup analysis revealed that the Midwest and South regions had higher percentage of population living in rural areas (Table 2). The AAMRs were notably higher in the rural areas than in the urban areas (0.50 per 1,000,000 individuals vs. 0.27 per 1,000,000 individuals, $p < 0.01$) (Fig. 3).

Discussion

This study provides some insights into the trends of CVDs related to mechanical complications of CIED in real-world settings. Our study suggests that CVDs related to mechanical complications of CIED decreased significantly from the year 1999 to 2020. This observation is probably due to advances in procedural technology and the development of new and safer implantation tools and techniques [6]. Higher mortality was seen in rural areas than in urban areas, where easy access to specialists and tertiary care centers was likely limited [7]. This emphasizes that mortality disparity in rural regions remains a major concern, and greater attention is warranted to improve these populations' survival and clinical outcomes.

There are a few limitations in our study, first, due to the nature of the death certificate data, accurate assessment of the cause of death cannot be determined. Second, the database consists of no clinical and imaging data, therefore we are unable to further characterize the clinical

Table 1 Demographic characteristics of cardiovascular death related to mechanical complications of cardiac electronic devices

Demographic	1999–2009, n (%)	2010–2020, n (%)	Percentage Change (%)
	n = 736	n = 501	–
Average annual percent change, (95% CI)	−4.13 (−6.55 to 1.65)	−6.19 (−9.32 to −2.94)	–
Sex			
Female	402 (54.62)	248 (49.50)	−5.12%
Male	334 (45.38)	253 (50.50)	+5.12%
Age of death, year			
35–44	8 (1.09)	5 (1.00)	−0.09%
45–54	23 (3.13)	20 (3.99)	+0.86%
55–64	46 (6.25)	58 (11.58)	+5.33%
65–74	98 (13.32)	87 (17.37)	+4.05%
75–84	231 (31.39)	104 (20.76)	−10.63%
85+	330 (44.84)	227 (45.31)	+0.47%
Race			
Black or African American	73 (9.92)	42 (8.38)	−1.54%
White	655 (88.99)	451 (90.02)	+1.03%
Census Region			
Region 1 Northeast Region	150 (20.38)	90 (17.96)	−2.42%
Region 2 Midwest Region	194 (26.36)	117 (23.35)	−3.01%
Region 3 South Region	262 (35.60)	194 (38.72)	+3.12%
Region 4 West Region	130 (17.66)	100 (19.96)	+2.30%
Urbanization			
Rural	213 (28.94)	129 (25.75)	−3.19%
Urban	523 (71.06)	372 (74.25)	+3.19%

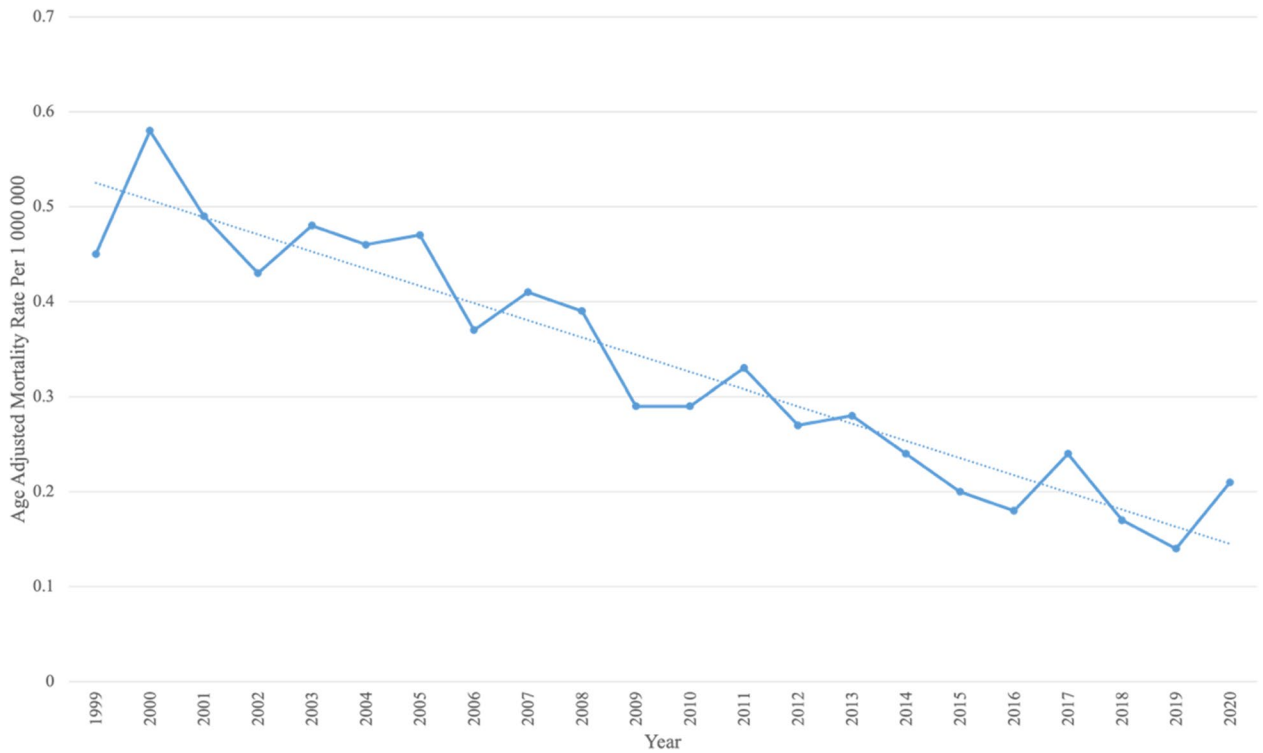

Fig. 1 Trends in age-adjusted mortality rates of cardiovascular death related to mechanical complications of cardiac electronic devices between 1999 and 2020

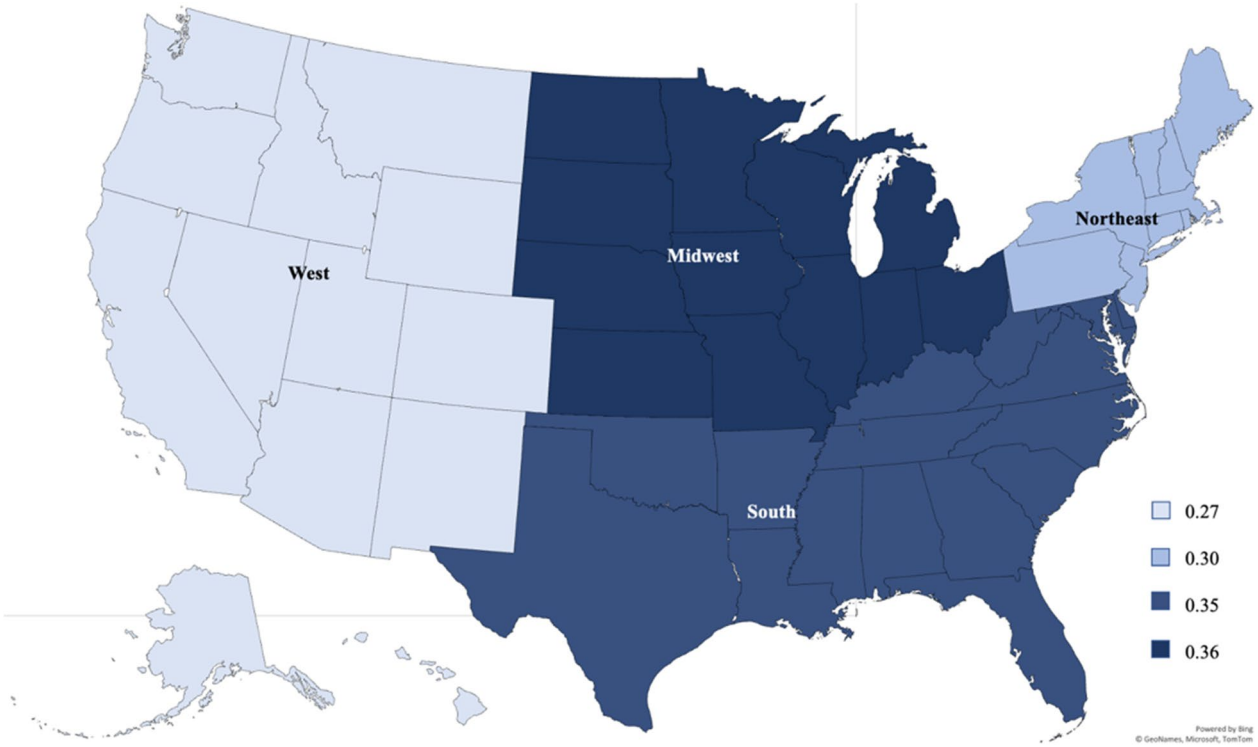

Fig. 2 Age-adjusted mortality rates of cardiovascular death related to mechanical complications of cardiac electronic devices, stratified by Census regions

Table 2 Age-adjusted Mortality Rates of Cardiovascular Death Related to Mechanical Complications of Cardiac Electronic Devices in Different Census Regions

Census Region	Overall AAMR (per 1,000,000 individuals)	Percentage of population in rural region (%)	Percentage of population in urban region (%)
Midwest	0.36	26.5	73.5
South	0.35	24.9	75.2
Northeast	0.30	17.5	82.5
West	0.27	12.7	87.3

status of the population. Third, using ICD-10 codes as filter criteria imposes another limitation where the temporal relationship between cardiovascular disease and mechanical complications of cardiac electronic devices cannot be ascertained. Last, the database has no information on the severity of the clinical issues and the types of devices implanted. Hence, we are not able to determine the association of the complications to the specific procedures.

Conclusion

While the cardiovascular deaths related to mechanical complications of CIED were decreasing over the past decades, our study showed that disparities in the AAMRs across sex, races and geographical region still present. Specific public health measures need to be improved to address these disparities.

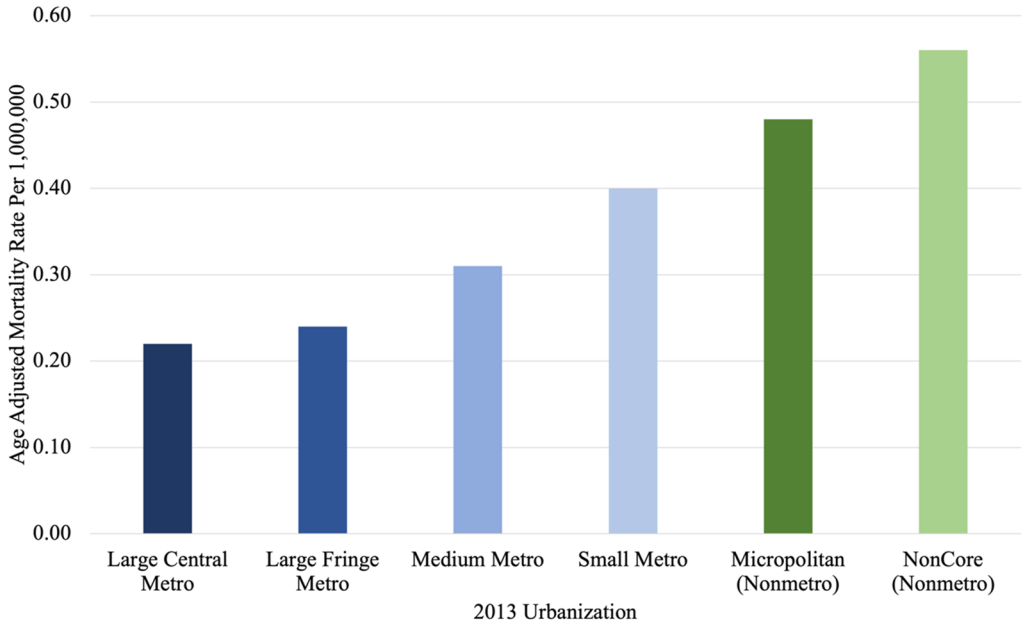

Fig. 3 Age-adjusted mortality rates of cardiovascular death related to mechanical complications of cardiac electronic devices between 1999 and 2020, stratified by 2013 urbanization

Abbreviations

AAMR	Age-adjusted mortality rate
CIED	Cardiac implantable electronic device
CDC WONDER	Centers for disease control and prevention's wide-ranging online data for epidemiologic research
CVD	Cardiovascular death
ICD-10	International classification of diseases, tenth revision
U.S.	United States

Acknowledgements
Not applicable.

Author contributions
BJS analyzed and interpreted the data. MCT and YHY were major contributors in writing the manuscript. JLT reviewed the data and improved the manuscript writing. All authors read and approved the final manuscript.

Funding
This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Availability of data and materials
The datasets generated and/or analysed during the current study are available in the Centers for Disease Control and Prevention's Wide-Ranging Online Data for Epidemiologic Research (CDC WONDER) repository, https://wonder.cdc.gov/.

Declarations

Ethics approval and consent to participate
Our study does not require institutional review approval as the population data is de-identified and publicly available.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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Received: 14 May 2023 Accepted: 24 July 2023
Published online: 01 September 2023

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