Review

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Trends in complications of cardiac and vascular prosthetic devices, implants, and grafts mortality rate in the United States (1999–2020)

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Abstract

To analyze mortality rates due to complications of cardiac and vascular prosthetic devices, implants, and grafts in the United States, International Classification of Diseases, Tenth Revision, codes were used on the Centers for Disease Control and Prevention Wide-Ranging OnLine Data for Epidemiologic Research (CDC WONDER) database to retrieve death certificate data between the years 1999 and 2020 for patients aged 55 and above. Age-adjusted mortality rates (AAMRs), per 100 000 people, and annual percentage change along with their respective 95% confidence intervals were also calculated. Complications of cardiac and vascular prosthetic devices, implants, and grafts were responsible for 91 539 deaths among adults aged 55 years and older. The overall AAMR decreased from 9.2 in 1999 to 3.4 in 2020. AAMRs for men were higher than for women (overall AAMR men: 7.5; women: 4.5). Stratifying patients according to race the order of AAMRs from highest to lowest was as follows: non-Hispanic Black or African American (6.8), NH White: (5.9), NH American Indian or Alaska Native (5.7), Hispanic or Latino (4.0) and lastly NH Asian or Pacific Islander (3.2). State wise the top 90th percentile states with regard to mortality included West Virginia, South Carolina, Mississippi, North Dakota, and Alabama. In census regions the South had the highest AAMR (6.2) followed by the Midwest (6.0), the Northeast (5.4), and the West (5.1) with nonmetropolitan areas having higher AAMRs (7.0) than metropolitan areas (5.4). Further research and a more individualized pattern of treatment of older patients are necessary moving forward.

Keywords: age-adjusted mortality rates, cardiac and vascular prosthetic devices, implants, and grafts, demographics

Introduction

Based on the 2019 report by the American Heart Association, cardiovascular diseases are associated with the majority of mortality in the United States, as well as across the globe[1]. Valvular heart disease involving valvular malfunction, coronary heart disease, and cardiac myopathy are some of the conditions that involve physical damage to the cardiovascular tissues, culminating in functional limitations[2]. The gold standard management for valvular heart disease involves surgical valve replacement, which includes bioprosthetic and mechanical valves as per the indications and patients' choice[3]. In the year 2022, approximately 180 000 surgical valve replacement procedures were performed in the United States[4]. Moreover, vascular prostheses, comprising Dacron fabric or expanded Teflon, have a wide range of applications such as cardiovascular reconstruction, repair of aneurysm or trauma, and hemodialysis[5].

While prosthetic devices increase the quality of life and survival outcomes in patients with cardiac disease, they may have several complications, with variable mortality and morbidity[6]. For instance, the calcification of prosthetic vascular grafts is one of the major challenges encountered in cardiac and vascular surgery, posing harm to the long-term performance of prostheses[7]. Similarly, prosthetic valve endocarditis is related to significant morbidity and mortality[8]. Compared to bioprosthetic valves, mechanical valves are associated with higher mortality rates among patients undergoing simultaneous aortic valve replacement and coronary artery bypass graft[9]. Other complications that result in significant mortality and morbidity include prosthetic valve thrombosis, heart failure, and sudden cardiac death[10,11].

Despite therapeutic advances in the treatment of valvular heart diseases and vascular pathologies, there is a lack of real-world mortality data on the complications of vascular and cardiac prostheses in the United States. Therefore, we aimed to analyze the mortality rates and trends associated with the complications of cardiac and vascular prosthetic devices, grafts, and implants in the country.

Methods

Population and study setting

The study utilized the Centers for Disease Control and Prevention Wide-Ranging OnLine Data for Epidemiologic

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Research (CDC WONDER) database to investigate deaths caused by complications of cardiac and vascular prosthetic devices, implants, and grafts from 1999 to 2020, using International Classification of Diseases, Tenth Revision (ICD-10) codes T82.0–T82.9. Data from death certificates across all 50 states and the District of Columbia were analyzed. The study focused on individuals aged 55 and older at the time of death. The research examined death records from the Multiple Causes of Death Public Use registry to identify cases where complications of cardiac and vascular prosthetic devices, implants, and grafts were either a contributing factor or the primary cause of death. Approval from a regional institutional review board was not required as the study relied on de-identified public data. The study adhered to STrengthening the Reporting of Observational Studies in Epidemiology (STROBE) standards for reporting observational research. The CDC WONDER database has been previously valuable in studying cardiovascular mortality trends. The age range for older adults was set between 55 and 85 years old and above, consistent with criteria used in previous research[12,13].

Data abstraction

The dataset includes population figures, year of occurrence, place of death, demographic details, geographical breakdowns, state-specific information, and distinctions between urban and rural settings. Deaths occur in various settings such as hospitals, homes, hospices, nursing homes, and long-term care facilities. Demographic data include gender, age, race, and ethnicity, with categories like White non-Hispanics (NH), NH Black or African Americans, Latino or Hispanics, NH American Indians or Alaska Natives, and NH Asian or Pacific Islanders. The data, sourced from death certificates, has been used in previous studies utilizing the WONDER database[14]. Population classification followed the National Center for Health Statistics Urban-Rural Classification Scheme, with urban areas including large metropolitan areas (1 million or more) and medium/small metropolitan areas (50 000–999 999), and rural areas having fewer than 50 000 people, as per the 2013 US Census[15]. Geographically, the Northeast, Midwest, South, and West were the four main regions based on US Census Bureau criteria[16].

Statistical analysis

We calculated mortality rates per 100 000 individuals, adjusting for age, to examine regional trends in deaths related to complications of cardiac and vascular prosthetic devices, implants, and grafts from 1999 to 2020. These rates were analyzed by year, gender, race/ethnicity, state, and urban/rural status, with 95% confidence intervals (CIs) provided. Crude mortality rates were determined by dividing the total deaths from mechanical complications of heart valve prosthesis by the corresponding US population for each year. Age-adjusted mortality rates (AAMR) were standardized to the 2000 US population. We used the Joinpoint Regression Program (Version 5.0.2, National Cancer Institute) to calculate the annual percentage change (APC) and its 95% CI in AAMR. This study aimed to analyze annual changes in national complications of cardiac and vascular prosthetic device mortality[17,18]. The log-linear regression models detected significant changes in AAMR over time. APCs were classified as increasing or decreasing based on whether the slope differed significantly from zero, using a significance level of $P < 0.05$.

Results

Between 1999 and 2020, complications related to cardiac and vascular prosthetic devices, implants, and grafts were responsible for 91 539 deaths among adults aged 55 years and older (Table 1, Supplemental Digital Content, Table 1, http://links.lww.com/MS9/A649).

Of the 91 289 deaths with recorded locations, 81.67% occurred in medical facilities, 6.2% in nursing homes or long-term care facilities, 1.59% in hospices, and 9% at home (Supplemental Digital Content, Table 2, http://links.lww.com/MS9/A649).

Annual trends for complications of cardiac and vascular prosthetic devices, implants, and grafts AAMR

The overall AAMR for these complications in older adults was 5.7 (95% CI: 5.7–5.8). The AAMR for these complications decreased from 9.2 (95% CI: 9–9.5) in 1999 to 3.4 (95% CI: 3.2–3.5) in 2020, with an increase in APC of 0.8621 (95% CI: −4.7591 to 5.8989) from 1999 to 2001. These APC values decreased to a significant −5.7310 (95% CI: −6.9053 to −5.4439) from 2001 to 2020 (Fig. 1, Supplemental Digital Content, Tables 3 and 4, http://links.lww.com/MS9/A649).

Complications of cardiac and vascular prosthetic devices, implants, and grafts AAMR stratified by sex

Between 1999 and 2020, deaths related to complications were comparable between older males (55.3%) and females (44.7%) (Table 1). On analysis, men had consistently higher AAMRs than women during the analyzed years [overall AAMR men: 7.5 (95% CI: 7.4–7.5); women: 4.5 (95% CI: 4.5–4.6)]. Starting in 1999, adult men had an AAMR of 12 (95% CI: 11.6–12.5), which fell to 4.6 (95% CI: 4.4–4.8) in 2020 (APC: −5.2428, 95% CI: −5.7478 to −4.7459). Imitating this decreasing trend, the complications of cardiac and vascular prosthetic devices, implants, and grafts AAMR for women fell from 7.3 (95% CI: 7–7.6) in 1999 all the way up to 2.4 (95% CI: 2.3–2.5) in 2020. For men, a significant APC value of −5.2428 (95% CI: −5.7478 to −4.7459) showed a decreasing trend in mortality from 1999 to 2020. In women, The APC values from 1999 to 2001 showed an increasing trend of 1.6026 (95% CI: −2.916 to 4.7915). This trend showed a significant decrease from 2001 to 2020 (APC: −6.2216, 95% CI: −6.7014 to −5.9681) (Fig. 1, Supplemental Digital Content, Tables 3 and 4, http://links.lww.com/MS9/A649).

Complications of cardiac and vascular prosthetic devices, implants, and grafts AAMR stratified by race/ethnicity

During the study period, NH Whites (81.3%) exhibited the highest proportion of overall deaths attributed to complications followed by NH Black or African Americans (10.9%), Hispanic or Latinos (5.2%), NH Asian or Pacific Islanders (2.1%) and NH American Indian or Alaska Natives (0.6%) (Table 1). Analysis revealed varying rates across different populations. NH Black or African American patients had the highest AAMR: 6.8 (95% CI: 6.6–6.9), followed by NH White: 5.9 (95% CI: 5.8–5.9), NH American Indian or Alaska Native: 5.7 (95% CI: 5.2–6.3), Hispanic or Latino 4 (95% CI: 3.9–4.2), and NH Asian or Pacific Islander populations 3.2 (95% CI: 3.1–3.4).

Table 1

Demographic characteristics of deaths due to complications of cardiac and vascular prosthetic devices, implants, and grafts in older adults in the United States, 1999–2020.

Variable	Complications of cardiac and vascular prosthetic devices, implants, and grafts–related deaths, n (%)	AAMRs[a] (95% CI) per 100 000
Overall population	91,539 (100)	5.7 (5.7–5.8)
Sex		
Male	50,648 (55.3)	7.5 (7.4–7.5)
Female	40,891 (44.7)	4.5 (4.5–4.6)
Census region		
Northeast	16,737(18.3)	5.4 (5.3–5.5)
Midwest	21,372 (23.3)	6 (5.9–6.1)
South	36,095 (39.4)	6.2 (6.1–6.2)
West	17,335 (18.9)	5.1 (5–5.2)
Race/Ethnicity		
NH American Indian or Alaska Native	516 (0.6)	5.7 (5.2–6.3)
NH Asian or Pacific Islander	1912 (2.1)	3.2 (3.1–3.4)
NH Black or African American	9990 (10.9)	6.8 (6.6–6.9)
NH White	74 219 (81.3)	5.9 (5.8–5.9)
Hispanic or Latino	4710 (5.2)	4 (3.9–4.2)
Urbanization		
Metropolitan	71 461 (78.1)	5.4 (5.4–5.5)
Nonmetropolitan	20 078 (21.9)	7 (6.9–7.1)
Place of death[a]		
Medical facility	74 560 (81.5)	-
Decedent's home	8231 (9.0)	-
Hospice facility	1457 (1.6)	-
Nursing home/ long-term care facility	5665 (1.5)	-
Others	1376 (0.3)	-
Unknown	250	-

AAMR, age-adjusted mortality rates; NH, non-Hispanic.
[a]AAMRs are not applicable for place of death.

For NH Black or African Americans, death rates increased significantly from 1999 to 2001 (APC: 12.8549, 95% CI: 3.4132–20.5906). This trend showed a notable decrease from 2001 to 2014 (APC: −6.3962, 95% CI: −8.6416 to −5.7609). This trend further decreased from 2014 to 2020 (APC: −2.1137, 95% CI: −4.4389 to 3.4144). NH White populations experienced a decreasing trend from 1999 to 2001 (APC: −0.3325, 95% CI: −5.0819 to 3.2662). This trend showed a significant decrease from 2001 to 2020 (APC: −5.7538, 95% CI: −6.9439 to −5.4708). NH American Indian or Alaska Native populations showed an increase in mortality trend from 1999 to 2001 (APC: 28.6231, 95% CI: −4.6927 to 76.5568), which was followed by a significant decrease from 2001 to 2020 (APC: −5.2293, 95% CI: −17.6285 to −3.5507). Similar trends were observed in Hispanic or Latinos from 1999 to 2001 (APC: 11.5393, 95% CI: −2.7429 to 25.2911), From 2001 to 2012, a significant decreasing trend was noticed with (APC: −6.8904, 95% CI: −13.0116 to −5.8334). This was followed by a further decline in mortality trends (APC: −2.6872, 95% CI: −4.7295 to 3.5175) from 2012 to 2020. In NH Asian or Pacific Islander populations, a significant decrease in mortality trends was seen from 1999 to 2020 with APC values of −5.7522 and CI ranging from −6.9177 to −4.4999 (Fig. 2, Supplemental Digital Content, Tables 3 and 5, http://links.lww.com/MS9/A649).

Complications of cardiac and vascular prosthetic devices, implants, and grafts AAMR stratified by geographic region

States

States exhibited a wide range of AAMRs, from 3.3 (95% CI: 3.1–3.5) in Massachusetts to 10.7 (95% CI: 10.1–11.2) in Mississippi. States in the top 90th percentile for death rates (West Virginia, South Carolina, Mississippi, North Dakota, and Alabama) had AAMRs almost double those in states in the lower 10th percentile (Virginia, Utah, New York, Montana, Massachusetts, California, and Colorado) (Fig. 3, Supplemental Digital Content, Table 6, http://links.lww.com/MS9/A649).

Census region

Of the total deaths, 39.4% occurred in the South, 23.3% in the Midwest, 18.9% in the West, and 18.3% in the Northeast (Table 1). When analyzing mortality rates by census region, the South had the highest AAMRs 6.2 (95% CI: 6.1–6.2), followed by the Midwest 6 (95% CI: 5.9–6.1), the Northeast 5.4 (95% CI: 5.3–5.5), and the West 5.1 (95% CI: 5–5.2).

With regard to APC values, the South region showed a significant decreasing trend in mortality from 1999 to 2020 (APC: −5.9127, 95% CI: −6.3412 to −5.4961). The Midwest region also showed a similar decreasing trend in mortality with APC −5.4942 and a 95% CI spanning from −5.9952 to −5.0167. Parallel significant decreasing trends and values were seen in the Northeast region from 1999 to 2020.(APC: −5.4145, 95% CI: −6.1223 to −4.7804). The West region displayed a fall in mortality trends from 1999 to 2020 with APC −4.6920 (95% CI: −5.3133 to −4.0429) (Fig. 4, Supplemental Digital Content,, Tables 3 and 7, http://links.lww.com/MS9/A649).

Urbanization

Overall, 78.1% of deaths occurred in nonmetropolitan areas with 21.9% taking place in metropolitan ones (Table 1). Nonmetropolitan areas showed higher AAMRs than metropolitan areas. The overall nonmetropolitan AAMRs were 7 (95% CI: 6.9–7.1), while the AAMRs for metropolitan areas were 5.4 (95% CI: 5.4–5.5). From 1999 to 2001, fatality trends showed an increase with APC values of 1.7467 (95% CI: −5.0007 to 6.7714). With APC values of −5.4030 (95% CI: −7.7467 to −4.992), this trend decreased significantly from 2001 to 2020. A similar trend was seen in metropolitan areas; from 1999 to 2001, the trend slightly increased showing APC values of 0.8946 (95% CI: −4.2469 to 4.7958). Similar to nonmetropolitan areas, trends in metropolitan also showed a significant decrease in APC: −5.8786 (95% CI: −6.6129 to −5.5795) (Fig. 5, Supplemental Digital Content, Tables 3 and 8, http://links.lww.com/MS9/A649).

Discussion

In this study, we reported several key findings from the analysis of mortality rates associated with the complications of cardiac

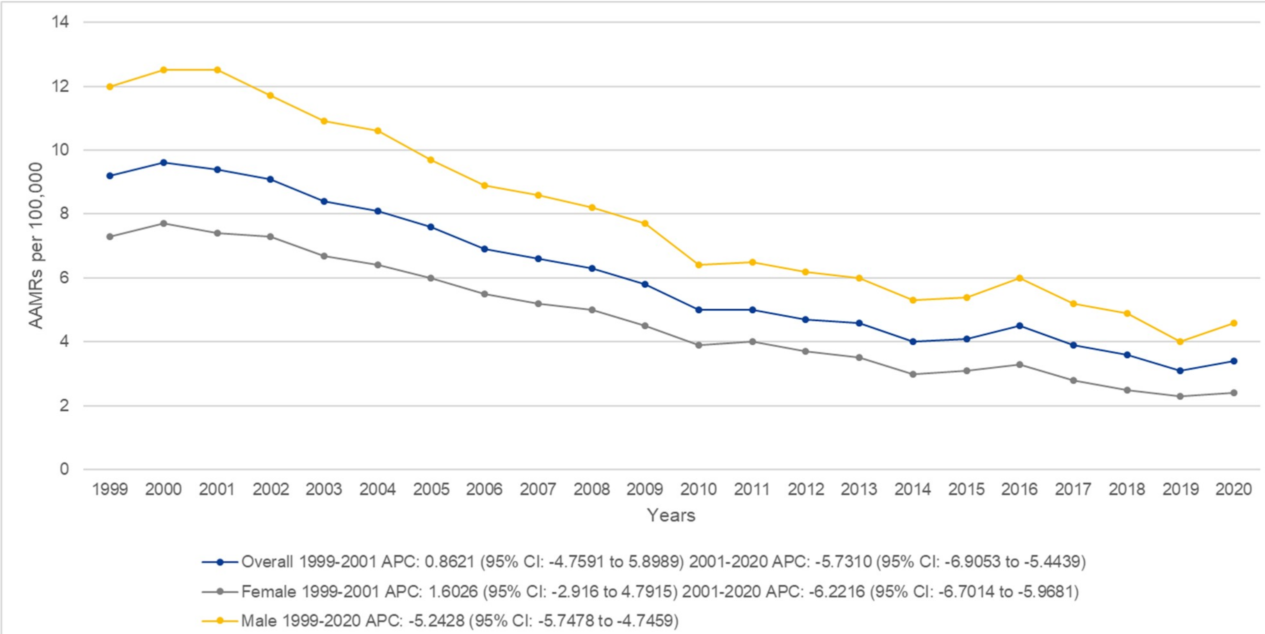

Figure 1. Overall and sex-stratified complications of cardiac and vascular prosthetic devices, implants, and grafts–related AAMRs per 100 000 in adults aged 55 and above in the United States, 1999–2020. AAMR, age-adjusted mortality rate; APC, annual percentage change; CI, confidence interval.

and vascular prosthetic devices, implants, and grafts in the United States during 1999–2020. First, the overall AAMR was found to decline during this period, with over 91 000 deaths due to complications in adults ≥55 years of age. Second, the overall mortality rates were higher among males and NH Blacks or African Americans, with death rates significantly increased during 1999–2001. Third, the nonmetropolitan areas had comparatively higher AAMRs compared to the metropolitan areas. Fourth, the mortality rates based on the census region indicated the highest and the lowest AAMRs in the South and the West regions, respectively.

The decreasing mortality trends related to the complications of cardiac and vascular prostheses observed in our study are consistent with the findings of a recent CDC WONDER database study, which demonstrated a decline in the overall AAMR of valvular heart disease and its subtypes[19]. Our study reported that the majority of the deaths occurred within the medical facilities. In a recent study, Chan *et al*. demonstrated a decrease in in-hospital mortality during 1996–2018 for surgical mitral valve replacement, despite an elevated risk profile of the patients in the United Kingdom. This is paralleled by the upward trend in the adoption of biological prosthetic devices for surgical valve replacement[20]. Moreover, in an Australian cohort of over 13 000 patients, analysis of the real-world evidence on the use of aortic valve replacement indicated that bioprosthetic valves were associated with lower rates of stroke, hemorrhage, acute myocardial infarction, cardiovascular mortality, and all-cause mortality compared to mechanical valves. On the contrary, the study reported higher comparatively reoperation rates in bioprosthetic valves after 6–10 years of intervention. The authors concluded that cardiovascular and all-cause mortality rates were significantly lower in older patients with bioprosthetic valves compared to mechanical valves[21]. This is similar to the findings of our study, which suggest that the overall AAMRs decreased in older adults during the 1999–2020 period.

There is substantial variation in the existing literature regarding gender-based mortality rates of complications associated with cardiac and vascular prosthetic devices. Women were found to have significantly higher 30-day mortality rates and complications following transcatheter aortic valve replacement, significantly higher overall in-hospital mortality rates following valve replacement surgery, and significantly longer mean length of hospital stay and higher in-hospital mortality rates following surgical aortic valve replacement compared to their male counterparts[22–24]. On the contrary, the studies reported comparable in-hospital mortality rates for men and women undergoing aortic valve and mitral valve surgeries for replacements and reconstructions[25,26].

Our study findings reported higher AAMRs in nonmetropolitan areas compared to metropolitan areas. In the context of valve replacement programs in metropolitan and nonmetropolitan areas, Nathan *et al* demonstrated that the majority of the new transcatheter aortic valve replacement programs were developed in hospitals in the metropolitan areas. Moreover, hospitals with these programs relatively catered to patients who were less socioeconomically disadvantaged, and the residents had higher rates of valve replacement[27]. Another study also established comparatively higher rates of aortic valve replacement at urban centers; however, there were no statistically significant differences in the in-hospital mortality between urban and rural hospitals[28]. The rural areas were found to have significantly better health outcomes, more likely due to low-risk patients presenting to the rural hospitals for isolated aortic valve replacement and aortic valve replacement with coronary artery bypass grafting[29]. Within the major metropolitan

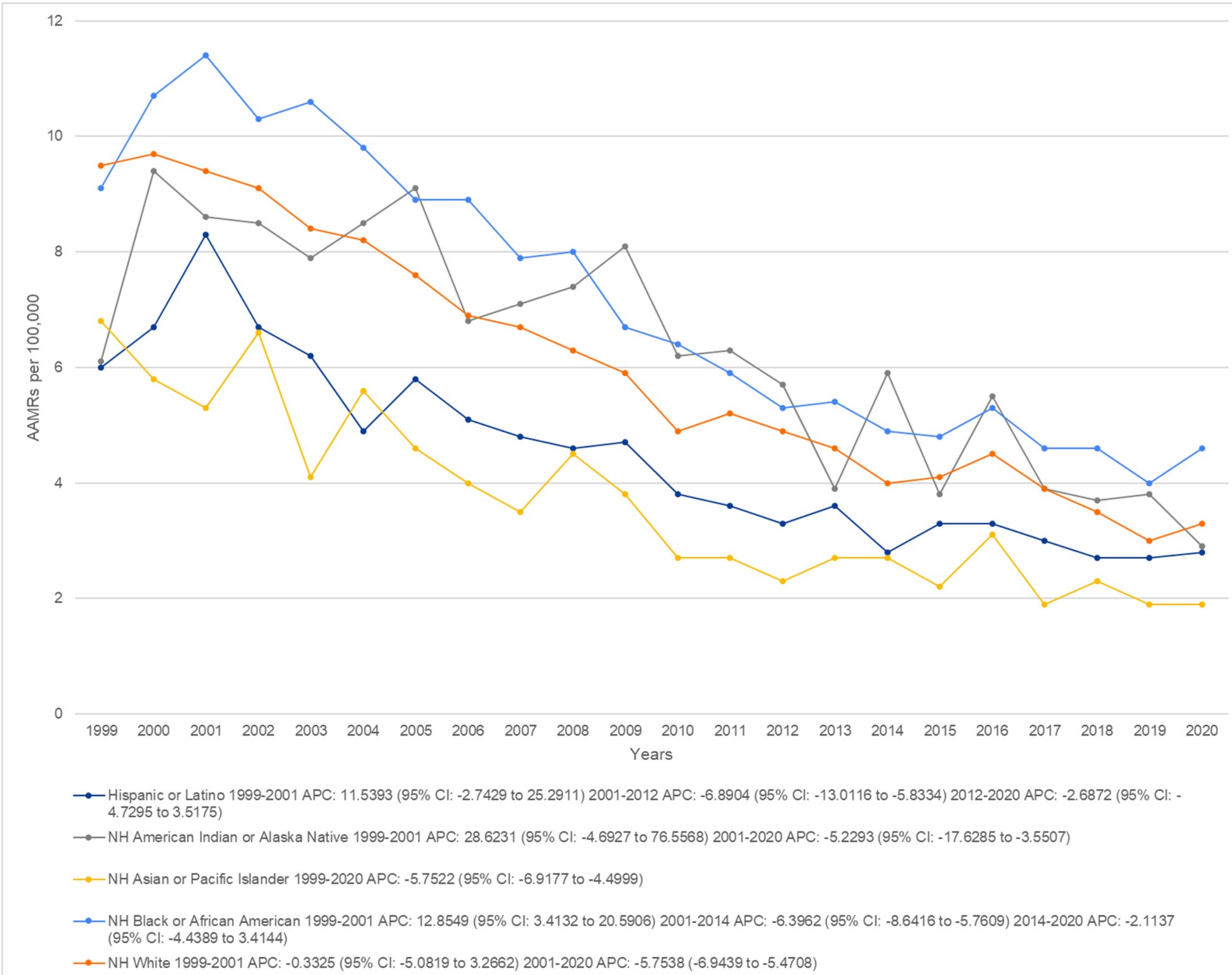

Figure 2. Complications of cardiac and vascular prosthetic devices, implants, and grafts – related AAMRs per 100 000 stratified by race in adults aged 55 and above in the United States, 1999–2020. AAMR, age-adjusted mortality rate; APC, annual percentage change; CI, confidence interval; NH, non-Hispanic).

areas in the United States, there are racial and socioeconomic disparities in accessibility to transcatheter aortic valve replacement, with lower rates of valve replacement in Black, Hispanic, and socioeconomically disadvantaged patients[30]. Similarly, low socioeconomic status was associated with poorer survival outcomes and higher morbidity, mortality, renal failure, and stroke rates[31].

While our study reported higher overall mortality rates in NH Blacks or African Americans during the 1999–2020 period, other studies reported lower risk-adjusted mortality in African Americans compared to Whites. However, the risk profile and comorbidities burden were notably higher in African Americans, suggesting the lack of access to preventive health services[32,33]. In addition to this, the mortality odds were found to be significantly raised for uninsured, Medicare, and Medicaid patients[34]. Black patients are also at a greater risk for readmission after discharge following mitral valve surgery[35]. Besides in-hospital mortality rates, White patients are reported to have significantly higher odds of permanent pacemaker implantation and implantable cardioverter-defibrillator and significantly lower odds of acute kidney injury and myocardial infarction[36]. Compared to Caucasians, Asian Americans were found to have a greater risk of mortality and complications following surgical aortic valve replacement, further highlighting racial disparities in the health care system[19]. In a study exploring mortality trends in young patients undergoing coronary artery bypass grafting during 2004–2018, the authors reported higher deaths among Black patients compared to White patients[37]. It is imperative that studies assessing mortality trends also consider the baseline risk profile, insurance status, and residence in the subgroup analysis.

Limitations

While our study has provided valuable insights into the morality trends associated with complications of cardiac and vascular prosthetic devices, implants, and grafts based on gender, race, and geographic region, it is important to consider the existing limitations in the study. First, the death certificates in the CDC WONDER database used as a primary data source are potentially liable to human error. Second, the reporting biases in the cause of death, demographics classification, and loss of data can

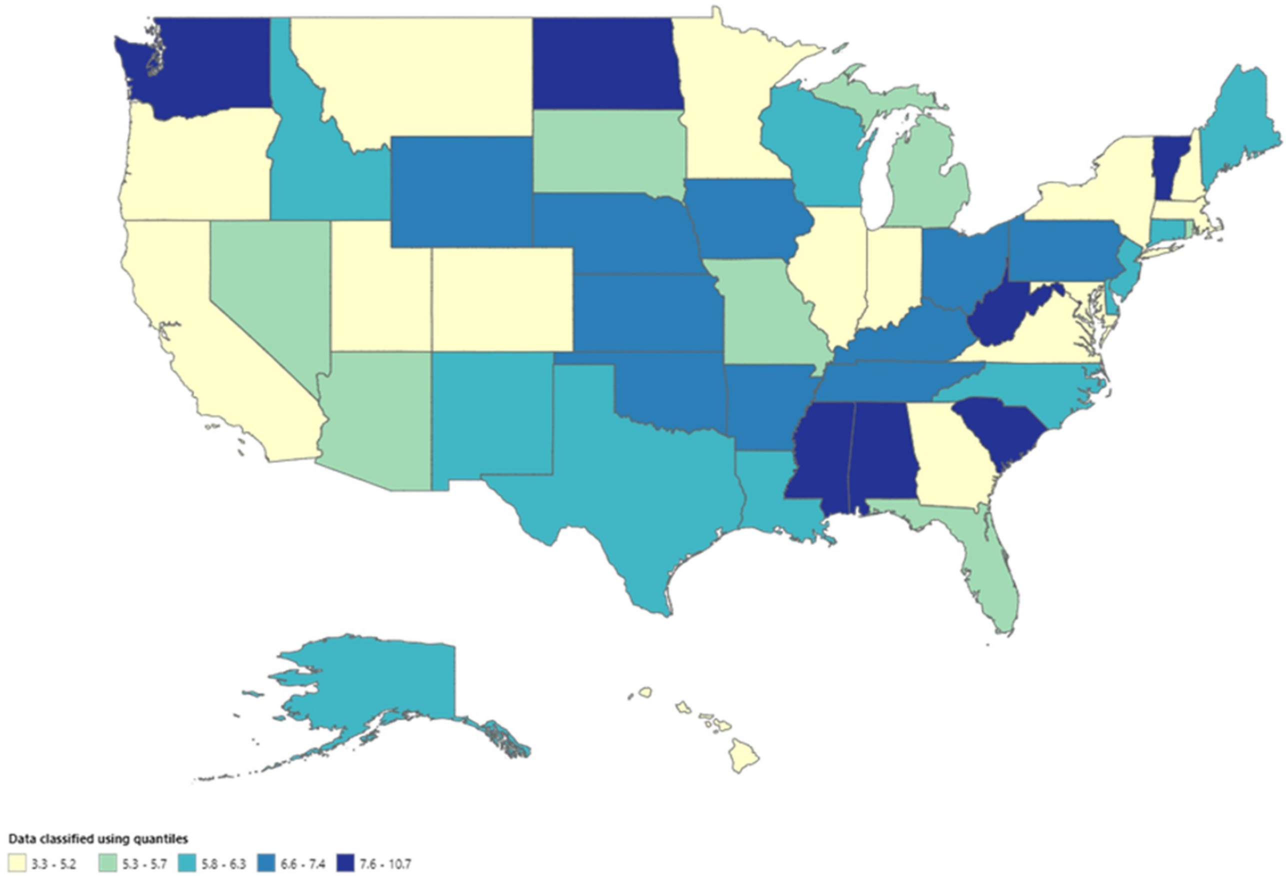

Figure 3. Complications of cardiac and vascular prosthetic devices, implants, and grafts – related age-adjusted mortality rates per 100 000 stratified by state in adults aged 55 and above in the United States, 1999–2020 ranging from 3.3 to 10.7.

result in under-reporting of the mortality data. Third, the utilization of ICD-10 codes further adds to the misclassification bias, misinterpretation of data, and limited ability to understand the clinical associations of the cause of valvular heart disease and complications of cardiac and vascular prostheses implants and grafts. Fourth, our study did not conduct a subgroup analysis for patients with different prosthetic devices/implants or complication subtypes. Lastly, since our study included only mortality data from complications, conclusions regarding the incidence of complications could not be drawn. Notwithstanding the abovementioned limitations, our study is the first to provide a comprehensive analysis of the death rates and mortality trends associated with cardiac and vascular prosthesis implants and grafts. Future studies may benefit from exploring prevalence and mortality data related to specific complications of cardiac and vascular prosthesis implants and grafts across various sociodemographic groups.

Conclusion

After an in-depth analysis of the CDC WONDER database for mortality rates pertaining to complications of cardiac and vascular prosthetic devices, implants, and grafts, we can conclude an overall decrease in AAMRs for older adults with the highest AAMRs in men, the NH Black and African American race, West Virginia, Midwest, and nonmetropolitan areas. Our findings call upon cardiothoracic surgeons to take a more population and region-sensitive approach when implementing procedures in older patients to reduce mortality rates from complications. Furthermore, they necessitate additional, more impactful research into the potential risk factors that can link and offer significant explanations as to why these trends were observed.

Ethical approval

This study was exempted from the institutional review board's approval because it uses publicly available data that are de-identified.

Consent

Informed consent was not required for this review.

Sources of funding

There was no funding granted/taken for this review.

Figure 4. Complications of cardiac and vascular prosthetic devices, implants, and grafts – related AAMRs per 100 000 stratified by census region in adults aged 55 and above in the United States, 1999–2020. AAMR, age-adjusted mortality rate; APC, annual percentage change; CI, confidence interval).

Author contribution

H.A.U.R.: Conceptualization, data curation, formal analysis, writing – original draft. A.S.: Data curation, writing – original draft. M.A.A.F.: Conceptualization, writing – original draft. A.M.: Data curation, writing – original draft. M.A.H.: Data curation, writing – original draft.

Conflicts of interest disclosure

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

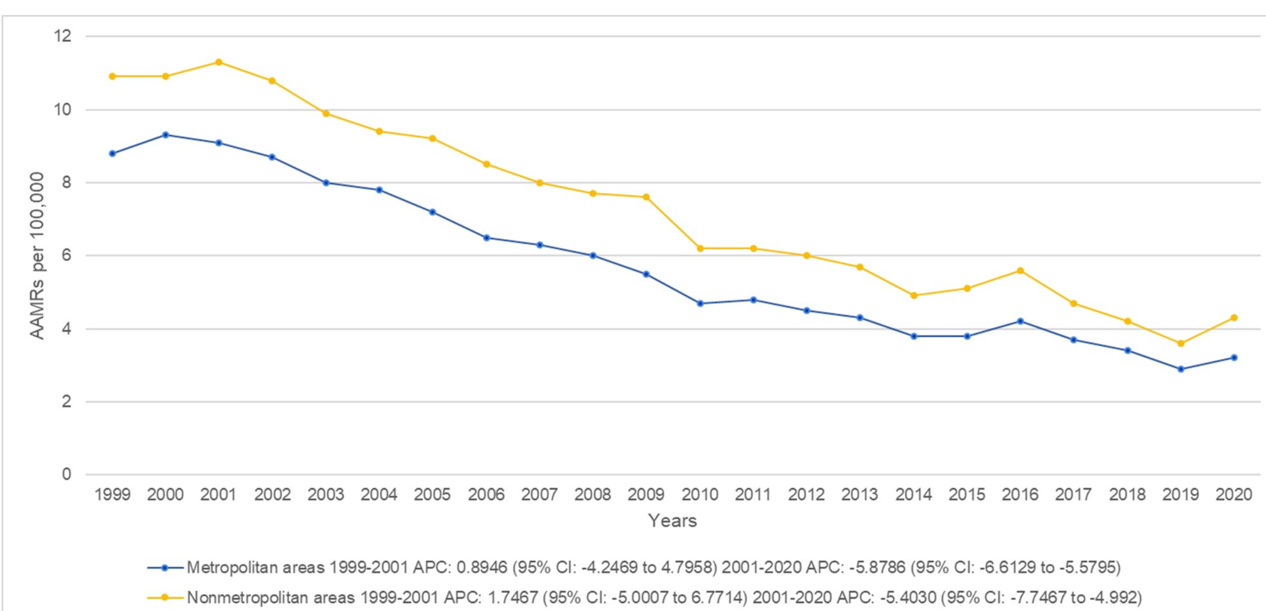

Figure 5. Complications of cardiac and vascular prosthetic devices, implants, and grafts – related AAMRs per 100 000 stratified by urbanization in adults aged 55 and above in the United States, 1999–2020. AAMR, age-adjusted mortality rate; APC, annual percentage change; CI, confidence interval).

Research registration unique identifying number (UIN)

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Provenance and peer review

The paper was not invited.

Data availability statement

The dataset supporting the conclusions of this article is included in this article.

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