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Research Letter

Are There Disparities in the Utilization of the Impella Device in Acute Myocardial Infarction and Cardiogenic Shock in the United States?

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The first percutaneous microaxial left ventricular assist device's (Impella; Abiomed) use has significantly increased since its Food and Drug Administration (FDA) clearance for short-term mechanical circulatory support in severe left ventricular failure in 2008.[1] More recently, the FDA has expanded indications for the Impella device in patients with acute myocardial infarction and cardiogenic shock (AMICS). While utilization of the Impella has increased annually,[2,3] disparities in growth patterns in the device's dissemination in the United States among different demographic and socioeconomic groups remained unknown. Previous studies have shown significant racial and socioeconomic disparities in access to other novel cardiovascular devices (eg, transcatheter aortic valve replacements).[4,5] Thus, we aim to evaluate patterns of growth of Impella device use in AMICS in the US across specific demographic and socioeconomic subgroups, to evaluate potential disparities in care.

We identified patients with AMICS who underwent percutaneous coronary intervention and received an Impella from 2015 to 2021 in Medicare fee-for-service claims using previously used International Classification of Diseases 10 Clinical Modification and Procedure Coding System Codes.[3] We excluded patients who received veno-arterial extracorporeal membrane oxygenation. We evaluated patterns of annual growth in the use of the Impella device in this cohort, stratified by age, sex, race, and socioeconomic status (SES) with low SES defined as being dually eligible for Medicare and Medicaid insurance. We examined temporal trends in the likelihood of receiving Impella among AMICS patients using generalized linear regression with Bernoulli distribution and identity link function and including a continuous variable for calender year for each prespecified subgroup of age, sex, race, and SES. We then evaluated trends in 30-day mortality among patients who received Impella in the overall cohort and among the subgroups.

In this cohort, we identified 9138 patients who presented with AMICS and received Impella between 2015 and 2021. The mean age was 72.7 years and 66.8% were male. Overall, Impella use increased during the study period from 9.1% to 21.5% of AMICS patients (mean annual change, +2.14%; 95% CI, 1.93%-2.34%; $P < .0001$) (Figure 1A-D). This increase in Impella use was consistent among subgroups of age (mean annual change, +2.30% [95% CI, 2.01%-2.58%] for those ≤74 years [$P < .0001$] and +1.98% [95% CI, 1.69%-2.27%] for those >74 years [$P < .0001$]), sex (mean annual change, +1.76% [95% CI, 1.46%-2.07%] in females [$P < .0001$] and +2.38% [95% CI, 2.10%-2.65%] in males [$P < .0001$]), race (mean annual change, +1.98% [95% CI, 1.22%-2.75%] in blacks [$P < .0001$] and +2.09% [95% CI, 1.86%-2.31%] in Whites [$P < .0001$]) and SES (mean annual change, +2.09% [95% CI, 1.62%-2.55%] in those with low SES [$P < .0001$] and +2.15% [95% CI, 1.92%-2.37%] in those with nonlow SES [$P < .0001$]). Finally, there were no significant changes in 30-day mortality during the study period (Figure 1E-H).

In this study, we observed an increase in utilization of Impella use in the overall cohort that was consistent among all subgroups without an increase in mortality during the same period. This increase follows the FDA approval of Impella use in patients with AMICS in 2016. However, unlike in other novel cardiovascular devices and cardiovascular care,[4,5] we showed no significant disparities related to race or SES in the dissemination of the Impella use. This is possibly due to the severity of patient presentation in AMICS that guide clinical decision-making, rapid dissemination of the Impella in different markets, and limited barriers to use in hospitals. In addition, we noted no changes in 30-day mortality, which largely represents the existing high mortality associated with cardiogenic shock and the current state of the field with no current interventions proven to significantly improve the outcomes of this population. While this study leverages a large claims database of Medicare beneficiaries, it likely has limited generalizability to younger cohorts and other racial groups not included. Future studies will need to evaluate dissemination and disparities in Impella use in other populations. In conclusion, we showed no significant disparities related to race and SES in the dissemination of the Impella, which have been noted in other cardiovascular diseases and care.

Keywords: disparities; growth; Medicare; percutaneous microaxial left ventricular assist device; real world data.

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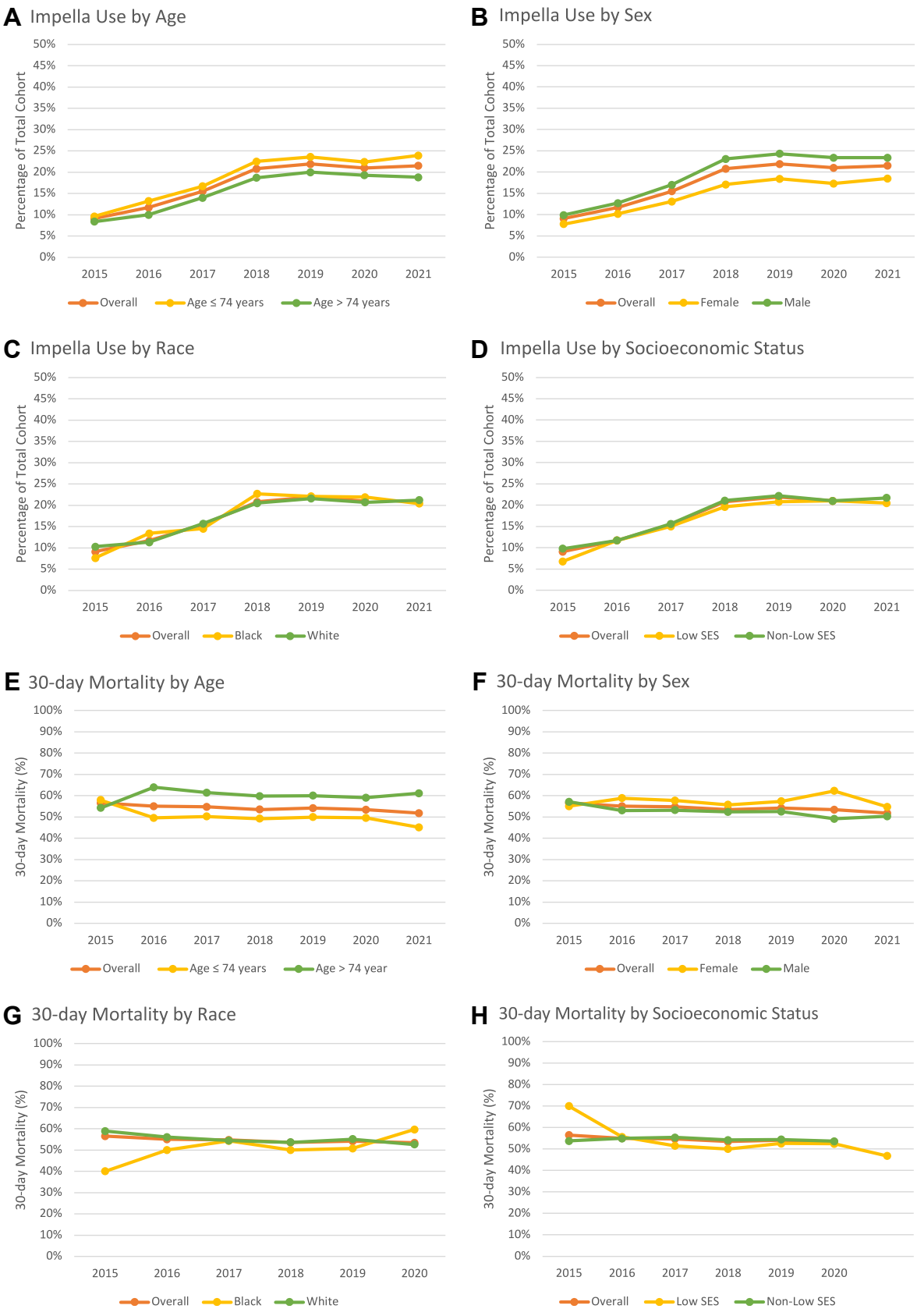

Figure 1.

Trends in Impella use (A-D) and 30-day mortality (E-H) among patients presenting with acute myocardial infarction and cardiogenic shock (AMICS) who underwent percutaneous coronary intervention and received an Impella by age, sex, race, and socioeconomic status.

Declaration of competing interest

Robert W. Yeh received research grant funding and consulting fees Abbott Vascular, Boston Scientific and Medtronic. Zaid I. Almarzooq, Siling Li, Yang Song, Eric A. Secemsky, and Duane S. Pinto report no conflicts of interest.

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Ethics statement and patient consent

The study was approved by the institutional review board of Beth Israel Deaconess Medical Center with a waiver of informed consent.

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