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CME

# Trends in the Use and Outcomes of Ventricular Assist Devices Among Medicare Beneficiaries, 2006 Through 2011

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**CME Objective for This Article:** At the conclusion of this activity, the learner should be able to examine trends in mortality, readmission, and costs among Medicare beneficiaries receiving ventricular assist devices (VADs) and associations between hospital-level procedure volume and outcomes.

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# Trends in the Use and Outcomes of Ventricular Assist Devices Among Medicare Beneficiaries, 2006 Through 2011

**Objectives** This study sought to examine trends in mortality, readmission, and costs among Medicare beneficiaries receiving ventricular assist devices (VADs) and associations between hospital-level procedure volume and outcomes.

**Background** VADs are an option for patients with advanced heart failure, but temporal changes in outcomes and associations between facility-level volume and outcomes are poorly understood.

**Methods** This is a population-based, retrospective cohort study of all fee-for-service Medicare beneficiaries with heart failure who received an implantable VAD between 2006 and 2011. We used Cox proportional hazards models to examine temporal changes in mortality, readmission, and hospital-level procedure volume.

**Results** Among 2,507 patients who received a VAD at 103 centers during the study period, the in-hospital mortality decreased from 30% to 10% ($p < 0.001$), the 1-year mortality decreased from 42% to 26% ($p < 0.001$), and the all-cause readmission was frequent (82% and 81%; $p = 0.70$). After covariate adjustment, in-hospital and 1-year mortality decreased ($p < 0.001$ for both), but the all-cause readmission did not change ($p = 0.82$). Hospitals with a low procedure volume had higher risks of in-hospital mortality (risk ratio: 1.72; 95% confidence interval [CI]: 1.28 to 2.33) and 1-year mortality (risk ratio: 1.55; 95% CI: 1.24 to 1.93) than high-volume hospitals. Procedure volume was not associated with risk of readmission. The greatest cost was from the index hospitalization and remained unchanged ($204,020 in 2006 and $201,026 in 2011; $p = 0.21$).

**Conclusions** Short- and long-term mortality after VAD implantation among Medicare beneficiaries improved, but readmission remained similar over time. A higher volume of VAD implants was associated with lower risk of mortality but not readmission. Costs to Medicare have not changed in recent years. (J Am Coll Cardiol 2014;63:1395–404) © 2014 by the American College of Cardiology Foundation

Until the emergence of ventricular assist devices (VADs), treatment options for the 250,000 patients in the United States with end-stage heart failure were limited to heart transplantation. Yet, organ availability has allowed only ~2,000 transplantations each year (1–3). Patients with advanced heart failure often have comorbid conditions that preclude consideration of heart transplantation. The transition of implantable VADs from large, mechanically complex pulsatile devices best suited for short-term use to smaller continuous-flow pumps has increased acceptance of the technology as a therapeutic option (4).

Early experiences with VADs in community practice were accompanied by high morbidity, mortality, and costs (5). Efforts to improve outcomes have focused on enhancements in VAD technology (6,7), refinements in patient selection (8–11), organization of care around multidisciplinary teams (12), and patient-centered instruction (13). In addition, Joint Commission standards require surgeons to perform a minimum of 10 VAD placements within 3 years to achieve certification to use VADs as permanent therapy (14).

The Centers for Medicare & Medicaid Services (CMS) recently examined policies for reimbursement for VADs for Medicare beneficiaries. We sought to describe trends in short- and long-term mortality, readmission, volume-outcome relationships, costs among all fee-for-service Medicare beneficiaries receiving VADs between 2006 and 2011.

## Methods

**Data sources and study population.** We used a 100% sample of Medicare inpatient claims and associated denominator files for this study. The inpatient files contain institutional claims for services covered under Medicare Part A. We used information about procedures, diagnoses, service dates, admission urgency, and discharge status from these files. The denominator files contain demographic information, death dates (if applicable), and Medicare eligibility and enrollment history. We used data from 2005 through 2011, although data from the first year were used solely for identification of comorbid conditions and previous procedures for selected beneficiaries.

We identified all beneficiaries enrolled in fee-for-service Medicare who had a claim for an implantable VAD (International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM] procedure code 37.66) between January 1, 2006 and December 31, 2011. We required a diagnosis of heart failure (ICD-9-CM diagnosis code 428.x, 402.x1, 404.x1, or 404.x3) or cardiogenic shock (785.51) in any position on the claim for the hospital admission. We excluded beneficiaries who had a claim for any of the following procedures during the admission or in the 30 days before the VAD implantation: coronary artery bypass graft surgery (ICD-9-CM procedure code 36.1x), heart transplantation (37.51 or 37.52), open-heart

valvuloplasty without replacement (35.11–35.14), open-heart valve replacement (35.21–35.28), cardiotomy (37.11), or receipt of a nonimplantable VAD (37.62 or 37.65).

**Outcomes.** All outcomes were based on Medicare inpatient claims and mortality data. In-hospital outcomes of interest were total length of stay and post-procedure length of stay. We summarized mortality in 2 ways: in-hospital mortality and mortality within 1 year after VAD implantation. Among patients discharged alive, we also examined rates of heart transplantation, all-cause readmission, and cardiovascular readmission (diagnosis-related groups 104–112, 115–118, 121–145, 479, 514–518, 525–527, 535, 536, and 547–558 before October 1, 2007 or 215–238, 242–254, 258–262, and 280–316 on or after October 1, 2007) in the year after discharge. Data for patients who did not experience an event during the mortality or readmission follow-up period were censored at either the end of claims data availability on December 31, 2011, or the date of enrollment in a Medicare-managed care plan.

We also calculated payments made by Medicare to hospitals for inpatient care of these patients during the index hospitalization and, for those eligible, in the year after discharge. Patients eligible for the post-discharge cost analysis included those discharged alive who did not have data censored due to the end of claims data availability or to enrollment in Medicare-managed care. Patients who died or underwent heart transplantation were included, but reported costs reflect only the time that patients spent with the VAD implanted and do not include costs for or after a hospital admission for transplantation. We adjusted costs for inflation to 2010 U.S. dollars using the medical care component of the Consumer Price Index.

Finally, for the same patients eligible for the post-discharge cost analysis described, we counted the number of hospitalizations for acute care in the year after discharge.

**Comorbid conditions.** We identified diabetes mellitus, coronary heart disease, peripheral vascular disease, cerebrovascular disease, hypertension, chronic obstructive pulmonary disease, renal disease, liver disease, cancer, and valvular heart disease using previously validated coding algorithms (15,16). We also identified atrial fibrillation or flutter (ICD-9-CM diagnosis codes 427.31 or 427.32) and ventricular tachycardia (427.1). For all comorbid conditions, we searched diagnosis codes on claims from the VAD implantation admission and any inpatient stays in the previous year.

**Statistical analysis.** We present baseline patient characteristics by year of VAD implantation, showing categorical variables as frequency with percentage and continuous variables as mean with SD. To test for differences between years, we used the chi-square test for categorical variables and the Kruskal-Wallis test for continuous variables. We also present the number of VAD implantations per hospital in each year.

We present in-hospital mortality by year using frequencies with percentages. We present total length of stay and post-procedure length of stay by implantation year using both mean and SD and median and interquartile range. We tested for trends across years for each of these outcomes using the Cochran-Mantel-Haenszel nonzero correlation statistic. Tests involving length of stay were rank based.

We calculated the incidence of 1-year mortality, heart transplantation, all-cause readmission, and cardiovascular readmission by year using the cumulative incidence function to account for both data censoring and competing risks. We treated death and heart transplantation as competing risks for each other and for both readmission outcomes. This approach had the effect of describing event rates over the duration of each patient's VAD experience. We tested for differences between years using the Gray test.

We present costs for the index hospitalization and for inpatient care in the year after discharge, by implantation year, using both mean and SD and median and interquartile range. We tested for trends over time using rank-based Cochran-Mantel-Haenszel nonzero correlation statistics. To place post-discharge costs and number of hospitalizations from the VAD cohort in context, we compared them with post-discharge costs and number of hospitalizations from 2 other hospitalized cohorts: patients with heart failure (primary ICD-9-CM diagnosis code 428.x, 402.x1, 404.x1, or 404.x3) and patients undergoing heart transplantation (ICD-9-CM procedure code 37.51). We limited the heart failure cohort to patients 65 years of age and older and matched them by age, sex, and year of hospitalization in a 4:1 ratio to patients in the VAD cohort. We did not limit the heart transplantation cohort by age because of the limited number of patients and the nearly identical age distribution compared with the VAD cohort. We tested for differences in post-discharge costs and number of hospitalizations between each of these cohorts and the VAD cohort using the Wilcoxon test.

In a post-hoc analysis, we identified common reasons for readmission using the principal diagnoses of all inpatient readmission claims. We used regression models to estimate the relative risks associated with patient characteristics, comorbid conditions, hospital admission information, and year on in-hospital mortality, 1-year mortality, and 1-year all-cause readmission. We modeled in-hospital mortality using generalized linear model methods, specifying Poisson errors and a log link function, which allowed us to estimate relative risks directly (17). Use of random intercepts allowed us to account for clustering at the hospital level. We modeled both 1-year outcomes using competing risks regression methods (18). Results from this method are similar to results from Cox regression models, except that, like the cumulative incidence function, they also account for competing risks.

**Abbreviations and Acronyms**

CI = confidence interval

CMS = Centers for Medicare & Medicaid Services

ICD-9-CM = International Classification of Diseases-Ninth Revision-Clinical Modification

STS = Society of Thoracic Surgeons

VAD = ventricular assist device

We also explored associations between annual hospital procedure volume and each outcome. We categorized each hospital in each year as having low volume (1 to 3 implantations), medium volume (4 to 8 implantations), or high volume (≥9 implantations). We summarized patient-level outcomes in each group of hospitals as in the primary analysis. We tested for the association between volume and in-hospital mortality, controlling for year, using a stratified Cochran-Mantel-Haenszel nonzero correlation statistic. We tested for associations between procedure volume and the other outcomes, controlling for year, using a stratified Gray test. We estimated adjusted associations between procedure volume and patient-level outcomes by adding the procedure volume category to the regression models.

We used SAS version 9.3 (SAS Institute Inc., Cary, North Carolina) for all analyses. The Institutional Review Board of the Duke University Health System approved the study.

## Results

We identified 2,507 patients who received an implantable VAD at 103 centers between 2006 and 2011. Of those, 896 were elective procedures and 1,611 were nonelective procedures. Procedure volume increased from 192 in 2006 to 622 in 2011. Demographic characteristics and the prevalence of most comorbid conditions were consistent over time (Table 1). We observed increases in shock diagnosis (27% to 44%; $p < 0.001$) and elective admissions for VAD placement (25% to 41%; $p < 0.001$).

Table 2 shows the observed event rates. There were significant reductions over time in both in-hospital mortality (30% to 10%; $p < 0.001$) and 1-year mortality (42% to 26%; $p < 0.001$). The Online Figure shows the cumulative incidence curves for all-cause mortality by year. Total and post-procedure length of stay decreased over time from 46 days to 33 days ($p < 0.001$) and from 33 days to 24 days ($p < 0.001$), respectively. The incidence of heart transplantation within 1 year decreased from 32% to 14% ($p < 0.001$). Observed 1-year all-cause and cardiovascular readmission remained steady. Online Table 1 shows the results of the post-hoc analysis examining the contributing causes for readmission.

After multivariable adjustment, year of VAD implantation was a significant predictor of in-hospital and 1-year mortality but not all-cause readmission (Table 3). Compared with 2008, patients receiving a VAD in 2006 had a relative risk of 2.03 for in-hospital mortality and 2.18 for 1-year mortality. In contrast, patients receiving a VAD in 2011 had a relative risk of 0.60 for in-hospital mortality and 0.77 for 1-year mortality.

**Table 1** Characteristics of the Study Population by Year of Ventricular Assist Device Implantation

| | Year of Implantation | | | | | | |
|---|---|---|---|---|---|---|---|
| | 2006 (N = 192) | 2007 (N = 241) | 2008 (N = 310) | 2009 (N = 460) | 2010 (N = 682) | 2011 (N = 622) | p Value |
| Age, yrs | 57.9 ± 12.9 | 60.3 ± 12.1 | 58.0 ± 12.1 | 58.3 ± 12.4 | 60.7 ± 11.6 | 61.8 ± 12.4 | <0.001 |
| Male | 159 (82.8) | 202 (83.8) | 246 (79.4) | 379 (82.4) | 552 (80.9) | 499 (80.2) | 0.71 |
| Race | | | | | | | 0.82 |
| Black | 41 (21.4) | 51 (21.2) | 68 (21.9) | 106 (23.0) | 158 (23.2) | 135 (21.7) | |
| White | 139 (72.4) | 178 (73.9) | 220 (71.0) | 327 (71.1) | 490 (71.8) | 462 (74.3) | |
| Other/unknown | 12 (6.3) | 12 (5.0) | 22 (7.1) | 27 (5.9) | 34 (5.0) | 25 (4.0) | |
| Comorbid conditions | | | | | | | |
| Atrial fibrillation/flutter | 108 (56.3) | 134 (55.6) | 156 (50.3) | 225 (48.9) | 368 (54.0) | 435 (69.9) | <0.001 |
| Cancer | * | 11 (4.6) | * | 18 (3.9) | 24 (3.5) | 23 (3.7) | 0.61 |
| Cerebrovascular disease | 17 (8.9) | 23 (9.5) | 34 (11.0) | 53 (11.5) | 66 (9.7) | 73 (11.7) | 0.73 |
| Chronic obstructive pulmonary disease | 96 (50.0) | 126 (52.3) | 174 (56.1) | 267 (58.0) | 370 (54.3) | 449 (72.2) | <0.001 |
| Coronary heart disease | 124 (64.6) | 173 (71.8) | 214 (69.0) | 320 (69.6) | 471 (69.1) | 478 (76.8) | 0.005 |
| Diabetes mellitus | 67 (34.9) | 92 (38.2) | 132 (42.6) | 193 (42.0) | 302 (44.3) | 316 (50.8) | <0.001 |
| Hypertension | 127 (66.1) | 152 (63.1) | 199 (64.2) | 299 (65.0) | 486 (71.3) | 515 (82.8) | <0.001 |
| Liver disease | 13 (6.8) | 42 (17.4) | 41 (13.2) | 70 (15.2) | 135 (19.8) | 134 (21.5) | <0.001 |
| Peripheral vascular disease | 15 (7.8) | 21 (8.7) | 29 (9.4) | 49 (10.7) | 67 (9.8) | 113 (18.2) | <0.001 |
| Renal disease | 98 (51.0) | 133 (55.2) | 146 (47.1) | 210 (45.7) | 346 (50.7) | 416 (66.9) | <0.001 |
| Valvular heart disease | 106 (55.2) | 131 (54.4) | 131 (42.3) | 182 (39.6) | 268 (39.3) | 366 (58.8) | <0.001 |
| Ventricular tachycardia | 87 (45.3) | 146 (60.6) | 192 (61.9) | 266 (57.8) | 399 (58.5) | 386 (62.1) | 0.002 |
| Implantation information | | | | | | | |
| Shock diagnosis | 52 (27.1) | 88 (36.5) | 105 (33.9) | 174 (37.8) | 263 (38.6) | 275 (44.2) | <0.001 |
| Elective admission | 48 (25.0) | 77 (32.0) | 79 (25.5) | 171 (37.2) | 267 (39.1) | 254 (40.8) | <0.001 |
| Volume at implantation hospital† | | | | | | | <0.001 |
| Low (1–3) | 80 (41.7) | 80 (33.2) | 70 (22.6) | 91 (19.8) | 75 (11.0) | 69 (11.1) | |
| Medium (4–8) | 71 (37.0) | 89 (36.9) | 138 (44.5) | 164 (35.7) | 182 (26.7) | 249 (40.0) | |
| High (≥9) | 41 (21.4) | 72 (29.9) | 102 (32.9) | 205 (44.6) | 425 (62.3) | 304 (48.9) | |

Values are mean ± SD or n (%). *Data not shown when ≤10 patients. †Number of ventricular assist device implantations in the year during which the patient underwent an implantation.

**Table 2** Observed Event Rates by Year of Ventricular Assist Device Implantation

| | Year of Implantation | | | | | | |
|---|---|---|---|---|---|---|---|
| | 2006 (N = 192) | 2007 (N = 241) | 2008 (N = 310) | 2009 (N = 460) | 2010 (N = 682) | 2011 (N = 622) | p Value |
| Mortality | | | | | | | |
| In hospital | 57 (29.7) | 50 (20.8) | 49 (15.8) | 52 (11.3) | 85 (12.5) | 63 (10.1) | <0.001 |
| Within 1 yr | 79 (41.8) | 87 (36.3) | 83 (27.0) | 104 (22.9) | 176 (26.1) | 117 (25.7) | <0.001 |
| Total length of stay, days | | | | | | | <0.001 |
| Mean ± SD | 45.9 ± 41.5 | 46.8 ± 38.8 | 46.1 ± 31.4 | 40.1 ± 27.9 | 35.5 ± 25.3 | 32.9 ± 20.3 | |
| Median (IQR) | 35 (22–51) | 39 (24–58) | 39 (25–59) | 33 (22–48) | 30 (20–43) | 28 (20–40) | |
| Post-procedure length of stay, d | | | | | | | <0.001 |
| Mean ± SD | 32.9 ± 35.2 | 35.8 ± 37.1 | 33.0 ± 26.7 | 29.2 ± 23.9 | 25.6 ± 22.1 | 23.8 ± 17.4 | |
| Median (IQR) | 23 (14–37.5) | 27 (17–43) | 25 (15–42) | 22 (15–33) | 20 (14–30) | 18.5 (14–28) | |
| Index hospitalization costs to Medicare, $* | | | | | | | 0.21 |
| Mean ± SD | 204,020 ± 141,358 | 203,028 ± 95,283 | 220,071 ± 115,179 | 220,044 ± 132,029 | 211,056 ± 93,248 | 201,026 ± 81,461 | |
| Median (IQR) | 179,605 (145,008–229,220) | 186,257 (155,140–244,762) | 200,665 (166,815–262,248) | 204,750 (171,054–243,249) | 205,395 (170,631–248,635) | 196,715 (168,462–236,145) | |
| Eligible for post-discharge events† | 131 | 189 | 257 | 406 | 596 | 555 | |
| Post-discharge events within 1 yr | | | | | | | |
| All-cause readmission | 105 (81.8) | 157 (84.3) | 222 (87.5) | 336 (83.8) | 479 (81.9) | 344 (81.1) | 0.70 |
| Cardiovascular readmission | 61 (51.0) | 76 (42.1) | 121 (49.5) | 198 (50.7) | 270 (47.4) | 169 (42.6) | 0.42 |
| Heart transplantation | 40 (31.7) | 54 (29.0) | 87 (34.4) | 100 (25.2) | 114 (19.6) | 42 (13.8) | <0.001 |
| Eligible for post-discharge costs‡ | 127 | 188 | 253 | 393 | 538 | — | |
| Inpatient costs within 1 yr, $* | | | | | | | 0.01 |
| Mean ± SD | 41,532 ± 65,259 | 37,056 ± 55,980 | 38,062 ± 64,629 | 36,025 ± 49,765 | 40,217 ± 57,242 | — | |
| Median (IQR) | 13,081 (0–46,416) | 16,512 (0–45,691) | 15,440 (0–44,683) | 16,886 (2,078–48,462) | 19,067 (4,972–52,142) | — | |

Values are n (%) unless otherwise indicated. *Costs are expressed in 2010 U.S. dollars. †Number of patients eligible for heart transplantation and readmission events. ‡Number of patients discharged alive and not enrolled in Medicare-managed care during the subsequent year. Only costs "on VAD" are reflected. No costs are accrued after an admission for heart transplantation.

IQR = interquartile range.

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**Table 3** Results of Multivariable Models for Each Outcome

| | In-Hospital Mortality | | Mortality at 1 Year | | All-Cause Readmission at 1 Year | |
|---|---|---|---|---|---|---|
| | RR (95% CI) | p Value | HR (95% CI) | p Value | HR (95% CI) | p Value |
| Age (per 5 yrs) | 1.09 (1.04–1.14) | <0.001 | 1.11 (1.06–1.16) | <0.001 | 0.98 (0.95–1.00) | 0.04 |
| Male | 1.17 (0.90–1.53) | 0.24 | 1.13 (0.88–1.43) | 0.34 | 0.90 (0.79–1.03) | 0.12 |
| Race | | 0.86* | | 0.32* | | 0.90* |
| Black | 1.06 (0.82–1.38) | 0.64 | 1.15 (0.91–1.45) | 0.24 | 1.02 (0.89–1.16) | 0.81 |
| White | 1.00 (reference) | — | 1.00 (reference) | — | 1.00 (reference) | — |
| Other/unknown | 0.97 (0.65–1.44) | 0.88 | 1.22 (0.86–1.74) | 0.26 | 1.05 (0.84–1.32) | 0.67 |
| Comorbid condition | | | | | | |
| Atrial fibrillation or flutter | 0.95 (0.78–1.15) | 0.58 | 0.97 (0.81–1.16) | 0.74 | 1.09 (0.98–1.21) | 0.12 |
| Cancer | 1.34 (0.86–2.09) | 0.19 | 1.26 (0.82–1.93) | 0.29 | 0.88 (0.68–1.15) | 0.36 |
| Cerebrovascular disease | 1.65 (1.28–2.12) | <0.001 | 1.64 (1.31–2.06) | <0.001 | 1.04 (0.88–1.23) | 0.64 |
| Chronic obstructive pulmonary disease | 0.77 (0.64–0.94) | 0.009 | 0.85 (0.72–1.02) | 0.08 | 0.97 (0.87–1.08) | 0.62 |
| Coronary heart disease | 1.10 (0.87–1.39) | 0.43 | 1.17 (0.94–1.46) | 0.16 | 1.05 (0.93–1.18) | 0.46 |
| Diabetes mellitus | 1.13 (0.93–1.37) | 0.21 | 1.17 (0.98–1.39) | 0.09 | 1.13 (1.02–1.26) | 0.02 |
| Hypertension | 0.85 (0.68–1.07) | 0.16 | 0.94 (0.76–1.16) | 0.57 | 1.03 (0.91–1.16) | 0.68 |
| Liver disease | 2.21 (1.79– 2.72) | <0.001 | 2.06 (1.70–2.49) | <0.001 | 0.85 (0.74–0.98) | 0.03 |
| Peripheral vascular disease | 1.10 (0.82–1.47) | 0.52 | 1.07 (0.82–1.40) | 0.60 | 1.05 (0.89–1.23) | 0.56 |
| Renal disease | 1.37 (1.12–1.68) | 0.003 | 1.29 (1.07–1.55) | 0.008 | 1.00 (0.90–1.12) | 0.93 |
| Valvular heart disease | 0.73 (0.60–0.89) | 0.002 | 0.71 (0.59–0.85) | <0.001 | 1.00 (0.90–1.10) | 0.93 |
| Ventricular tachycardia | 0.79 (0.65–0.95) | 0.01 | 0.79 (0.66–0.93) | 0.005 | 0.97 (0.87–1.07) | 0.51 |
| Elective procedure | 0.80 (0.65–0.99) | 0.04 | 0.82 (0.68–0.99) | 0.04 | 1.00 (0.90–1.12) | 0.94 |
| Index diagnosis of shock | 0.87 (0.71–1.06) | 0.17 | 0.98 (0.82–1.17) | 0.82 | 0.83 (0.74–0.92) | <0.001 |
| Implantation year | | <0.001* | | <0.001* | | 0.82* |
| 2006 | 2.03 (1.44–2.87) | <0.001 | 2.18 (1.55–3.06) | <0.001 | 0.97 (0.75–1.25) | 0.82 |
| 2007 | 1.22 (0.86–1.74) | 0.26 | 1.53 (1.10–2.13) | 0.01 | 0.90 (0.73–1.12) | 0.35 |
| 2008 | 1.00 (reference) | — | 1.00 (reference) | — | 1.00 (reference) | — |
| 2009 | 0.70 (0.49–0.98) | 0.04 | 0.73 (0.52–1.02) | 0.06 | 1.00 (0.83–1.19) | 0.96 |
| 2010 | 0.70 (0.51–0.96) | 0.03 | 0.88 (0.65–1.18) | 0.38 | 0.91 (0.77–1.08) | 0.29 |
| 2011 | 0.60 (0.42–0.84) | 0.003 | 0.77 (0.56–1.05) | 0.10 | 0.94 (0.79–1.12) | 0.51 |

*Group p value.
CI = confidence interval; HR = hazard ratio; RR = risk ratio.

Over the study period, the proportion of VAD implantations at high-volume centers increased from 21% to 49% (Table 1). Mean procedure volume per hospital increased from 3 to 6 (Online Table 2). The number of hospitals increased from 64 to 103. The mean number of cumulative VAD implantations per hospital increased from 3.0 to 23.6. In 2006, 73% of hospitals were low-volume centers, 20% were medium-volume centers, and 6% were high-volume centers. In 2011, 34% of hospitals were low-volume centers, 43% were medium-volume centers, and 23% were high-volume centers.

Low-volume hospitals had higher inpatient and 1-year mortality than high-volume hospitals (Table 4). In contrast, observed event rates for all-cause and cardiovascular readmission were similar over time, and this observation was consistent within each volume group. Overall adjusted risk ratios associated with hospital procedure volume controlling for year showed that low-volume hospitals (1.72; 95% confidence interval [CI]: 1.28 to 2.33; $p < 0.001$) and medium-volume hospitals (1.33; 95% CI: 1.04 to 1.72; $p = 0.03$) had higher risks of in-hospital mortality than high-volume hospitals (Fig. 1). For 1-year mortality, low-volume hospitals had higher risk than high-volume hospitals (hazard ratio [HR]; 1.55; 95% CI: 1.24 to 1.93; $p < 0.001$); there was no significant difference between medium- and high-volume hospitals (HR: 1.12; 95% CI: 0.92 to 1.37; $p = 0.25$). There were no significant differences in all-cause readmission and cardiovascular readmission on the basis of hospital volume.

Mean Medicare payments for the index hospitalization were $210,021 (SD: $106,241), and mean Medicare payments for inpatient care at 1 year were $38,469 (SD: $57,258). Both amounts remained relatively unchanged over time. Among patients discharged alive after heart transplantation, mean Medicare payments for inpatient care at 1 year were $26,301 (SD: $51,966) ($p < 0.001$). The mean number of hospitalizations in the year after discharge were 2.0 for VADs (SD: 2.1) versus 1.6 for heart transplantations (SD: 1.9) ($p < 0.001$). Among patients 65 years of age and older, mean 1-year inpatient payments after discharge from a VAD hospitalization were $39,528 (SD: $55,999), and mean 1-year inpatient payments after discharge from a heart failure hospitalization were $23,813 (SD: $35,759) ($p < 0.001$). The mean number of hospitalizations in the year after discharge were 1.8 for VADs (SD: 2.1) and 1.9 for heart failure (SD: 1.9) ($p = 0.15$).

## Discussion

Temporal trends in outcomes associated with device technology, such as VADs, provide insights into the evolution and diffusion of the technology for clinical care. Our study had 5 important findings regarding VAD use and outcomes among fee-for-service Medicare beneficiaries. First, in-hospital and 1-year mortality rates after VAD implantation have improved. Second, although procedural volumes are improving, a large number of centers continue to implant limited numbers of VADs. Third, low VAD volume remains associated with higher in-hospital and 1-year mortality, but not with readmission. Fourth, the total length of stay associated with VAD implantations commonly exceeds 1 month, and readmissions are frequent. Finally, Medicare spending was unchanged over time, and the greatest cost was associated with the index hospitalization.

When first-generation pulsatile VADs were introduced, advanced heart failure and severity of illness coupled with technical challenges of surgical implantation made mortality reduction the primary focus for treating physicians. However, intermediate-term survival remained poor because of device-related complications (19). After the transition to more durable continuous-flow devices in 2008, survival improved to 55% at 2 years and continues to improve (4,20,21). We saw a similar trend in increased survival over time in our analysis, particularly after 2008. Also, implantation year was a significant predictor of in-hospital and 1-year mortality, with relative risk of mortality decreasing significantly after 2008. Although this decrease in mortality may be due to improvements in technology, there has also been a better understanding of appropriate patient selection with an emphasis on implantation in earlier stages of cardiogenic shock and more experience with implanting VADs and managing patients post-operatively.

In contrast, total length of stay for VAD implantation continues to exceed 30 days for most centers, and 1-year readmission rates remain high, driven largely by post-operative complications such as infection (22–24), bleeding (25–27), thrombosis (28), heart failure, and arrhythmias (29,30). Although stroke or transient ischemic attack is an important complication of VADs, it was not a frequent cause of readmission at 1 year in our study or in a recent analysis of readmissions (31). In contrast, infection is common in the driveline or pump pocket, and bleeding has become more prominent due to the unique physiology created by nonpulsatile blood flow.

We are now in a state of transition in the longitudinal care path of patients receiving VAD therapy. Although early survival has improved markedly, the transition from the operating room to the post-discharge environment demands attention. Most centers have established multidisciplinary teams of physicians, VAD coordinators, nurses, physical therapists, and others who specialize in identifying post-operative complications and managing patients to improve other outcomes such as readmission. However, VAD care is further complicated by multiple other problems, including caregiver burden and limited hospital infrastructure to manage patients with minimally pulsatile circulation. Further, there is a continually evolving knowledge base on

**Table 4** Observed Event Rates by Year and Hospital Implant Volume

| | Year | | | | | | |
|---|---|---|---|---|---|---|---|
| | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | p Value* |
| In-hospital mortality, % | | | | | | | <0.001 |
| Low procedure volume (1–3) | 38.8 | 28.8 | 14.3 | 16.5 | 18.7 | 10.1 | |
| Medium procedure volume (4–8) | 26.8 | 20.2 | 15.9 | 13.4 | 12.1 | 10.0 | |
| High procedure volume (≥9) | 17.1 | 12.5 | 16.7 | 7.3 | 11.5 | 10.2 | |
| 1-yr mortality, % | | | | | | | 0.03 |
| Low procedure volume (1–3) | 50.3 | 45.2 | 28.8 | 22.3 | 29.6 | 21.3 | |
| Medium procedure volume (4–8) | 37.5 | 33.8 | 20.3 | 30.1 | 25.6 | 24.3 | |
| High procedure volume (≥9) | 32.8 | 29.4 | 35.1 | 17.3 | 25.7 | 27.2 | |
| Heart transplantation at 1 yr, % | | | | | | | <0.001 |
| Low procedure volume (1–3) | 39.1 | 32.6 | 40.4 | 36.0 | 25.6 | 19.4 | |
| Medium procedure volume (4–8) | 37.1 | 28.6 | 38.5 | 28.6 | 23.6 | 13.6 | |
| High procedure volume (≥9) | 13.1 | 26.2 | 24.4 | 18.4 | 17.0 | 12.5 | |
| All-cause readmission at 1 yr, % | | | | | | | 0.39 |
| Low procedure volume (1–3) | 84.8 | 83.6 | 91.2 | 90.4 | 84.4 | 72.2 | |
| Medium procedure volume (4–8) | 83.5 | 82.7 | 84.9 | 84.4 | 82.8 | 87.4 | |
| High procedure volume (≥9) | 74.7 | 86.8 | 88.8 | 80.7 | 81.1 | 78.3 | |
| Cardiovascular readmission at 1 yr, % | | | | | | | 0.75 |
| Low procedure volume (1–3) | 56.8 | 36.0 | 33.6 | 59.3 | 58.1 | 24.3 | |
| Medium procedure volume (4–8) | 49.4 | 37.5 | 54.5 | 46.6 | 43.0 | 41.8 | |
| High procedure volume (≥9) | 46.4 | 52.5 | 53.2 | 50.5 | 47.6 | 45.9 | |

*Testing differences by hospital-level implantation volume, controlling for year.

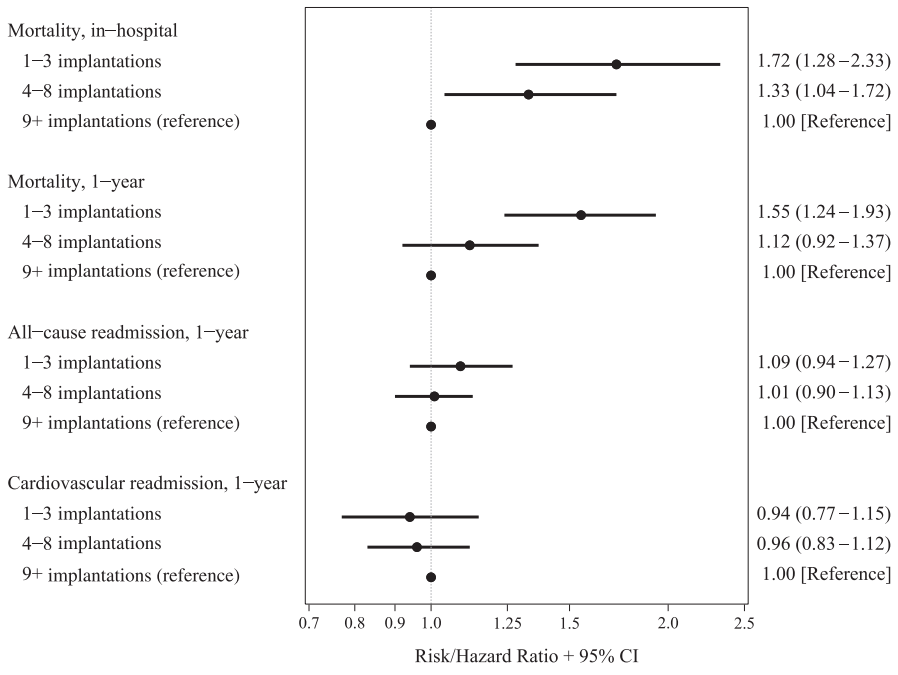


**Figure 1** **Adjusted Relative Risks of Each Outcome by Annual Volume of Ventricular Assist Device Implantation**

Risk ratios are shown for in-hospital mortality. Hazard ratios are shown for all other outcomes. All models control for patient characteristics, comorbid conditions, implantation admission information, and year of implantation (Table 3). p Values for differences between center volume categories by outcome are as follows: in-hospital mortality, $p = 0.002$; 1-year mortality, $p < 0.001$; 1-year all-cause readmission, $p = 0.48$; 1-year cardiovascular readmission, $p = 0.80$. CI = confidence interval.

the impact of nonpulsatile blood flow on circulation and the utility of existing therapeutics for common adverse events encountered during VAD support (32). We postulate that the required elements of this accruing provider knowledge base, psychosocial support, and healthcare infrastructure are likely to be concentrated at larger centers implanting a large number of VADs.

Conversely, the development of the clinical experience, optimal infrastructure, and care efficiency to provide the highest quality of care for patients undergoing VAD therapy may be limited in the large number of centers that implant a small number of VADs. We found that low-volume centers have higher risks of in-hospital and 1-year mortality compared with high-volume centers, but the minimal threshold for center volume is uncertain. Our findings suggest that implanting ≥9 VADs is associated with the lowest inpatient mortality, but this volume is substantially higher than the current certification requirements by the Joint Commission and CMS for a minimum of 10 VADs over a 3-year period. This number is also lower than the minimal implantation volume of 15 that provided benefit in a risk model derived from clinical trial data with a second-generation VAD (33). Our data also suggest that all-cause and cardiovascular readmission rates did not differ by center volume. Readmission is a complex issue due to comorbid conditions, post-procedure complications, socioeconomic status, and physician thresholds for readmission, among other factors. Understanding the factors that drive readmission is critical to making VAD therapy a viable option for patients with advanced heart failure.

Previous observational studies have shown a volume-outcome relationship in which surgical procedures improve with clinical experience (34,35). This phenomenon has also been observed to a limited extent among clinical trial patients receiving pulsatile VADs who had improvements in 1-year mortality with increasing institutional experience (36). Historically, examining VAD volume-outcome relationships outside clinical trials has been challenging given the limitations of registry information. Unlike the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) and the Society of Thoracic Surgeons (STS) registry, which record VAD information, Medicare data are not limited by patient consent (as is INTERMACS) or variability in chart abstraction (as is the STS registry). In addition, Medicare data include VADs implanted under coverage with evidence development (clinical trials) and capture costs, unlike the INTERMACS and the STS registry.

To our knowledge, ours is the first study to explore associations between center volume and outcomes in the modern VAD era in all Medicare fee-for-service beneficiaries. Although an INTERMACS report for CMS examined volume-outcome associations, the analysis excluded younger, disabled beneficiaries (54% of patients in

our analysis) (37). Our data suggest that VAD implantations should be concentrated at centers of excellence that perform a large number of procedures. This likely allows efficiency and standardization from a multidisciplinary care heart team. As centers grow in experience, so do standardized approaches to common problems. However, overcoming barriers to accessing advanced technology will require expansion of centers with experience. As new VAD centers develop, it will be important for them to link to leading centers to easily disseminate best practices and leverage experience. By having leading centers share best practices, there is potential to build collective knowledge of best practices in using new VAD technologies as they become available.

In our analysis, we observed no significant temporal changes in Medicare spending for VADs. There are a number of reasons for the lack of change. First, payment by Medicare for the index procedure has not changed significantly over time (38). Second, downstream costs are driven by readmission, which did not change during the study period. Although heart failure is generally costly compared with other Medicare diagnoses, our comparison among patients who were 65 years of age or older shows that there may be room for improvement after discharge from a VAD hospitalization. The mean 1-year inpatient costs after VAD hospitalization were higher than those in a matched cohort of patients discharged after a heart failure hospitalization. Similarly, mean 1-year inpatient costs for VAD hospitalization were higher than costs for patients discharged after a heart transplantation. These estimates did not include costs for skilled nursing, physician services, outpatient visits, home health care, physical and occupational therapy, durable medical equipment, and medications. Although the index hospitalization for VADs represents the largest cost to Medicare, subsequent inpatient costs may decrease over time as readmission rates after implantation decrease.

**Study limitations.** First, results from fee-for-service Medicare beneficiaries may not be generalizable to non-Medicare patients. Specifically, the total number of implantations at a particular center may not be accurately reflected by this analysis depending on the payer mix. However, national statistics show that Medicare paid for 48% of VAD implantations in 2011 (39), suggesting that our results provide important information from the perspective of the predominant payer. Second, this analysis used administrative claims without any clinical data such as type of device or initial intent of implantation. Although the type of device changed over time, our analysis accounts for temporal changes by year of implantation. Of note, most centers switched over quickly to continuous flow technology (4). Although we were unable to determine the intent of the device at the time of implantation, it may be appropriate to remove this designation because a patient's designation changes over time on the basis of the clinical condition (40). As for type of ventricular support, we were not able to distinguish between left and right ventricular or biventricular support specifically using ICD-9-CM procedure codes. Publicly reported data show that right ventricular and biventricular support is rare (4). Finally, there were measured and unmeasured confounders that may have influenced the results.

## Conclusions

In-hospital and 1-year mortality have improved over time, whereas hospital length of stay and readmission have remained relatively unchanged. Patients receiving VADs at low-volume centers have a significantly higher risk of in-hospital and 1-year mortality compared with those receiving VADs at high-volume centers, suggesting that center volume and experience are important for optimal care delivery in this area. In addition, examination of the relationship between center experience and outcomes may be useful as accreditation agencies and payers refine criteria for implantation sites.

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**Key Words:** heart failure ■ outcomes research ■ ventricular assist device.

**APPENDIX**

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