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Magnitude of Negative Impact of Preoperative Heart Failure on Mortality During Aortic Valve Replacement in the Medicare Population

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Background. **In patients with severe aortic stenosis, the development of heart failure (HF) prior to aortic valve replacement (AVR) is associated with worse prognosis. We sought to quantify the effect of progressive HF on mortality during AVR in the Medicare population over a 10-year period.**

Methods. **Medicare beneficiaries 65 or greater years of age who underwent primary isolated AVR from 2000 through 2009 were included (n = 114,135). Logistic regression and Cox proportional hazards were used to model adjusted operative mortality (OM) and long-term survival, according to the presence of preoperative HF and its duration (≤ 3 vs > 3 months).**

Results. **The incidence of preoperative comorbidities was high, and it was higher in patients with preoperative HF, compared with those without. Preoperative HF dramatically increased adjusted OM, odds ratio (OR) 1.57 (95% confidence interval [CI], 1.48 to 1.67). Preoperative HF greater than 3 months conferred a significant increase in adjusted OM compared with HF 3 months or less, OR 1.43 (95% CI, 1.32 to 1.55). Similarly, preoperative HF increased the likelihood of long-term mortality by 50%, hazard ratio (HR) 1.48 (95% CI, 1.45 to 1.51). Long-term mortality was higher for patients with longer duration of preoperative HF as compared with those without preoperative HF, HR 1.81 (95% CI, 1.75 to 1.87) and compared with patients with HF 3 months or less, HR 1.26 (95% CI, 1.23 to 1.30).**

Conclusions. **The magnitude of the negative impact of preoperative HF on operative mortality and long-term survival of elderly patients undergoing primary isolated AVR is significant with 50% increased likelihood of adverse outcome. Duration of preoperative HF is also significantly related to mortality. These data support AVR in the elderly prior to the development of HF.**

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Aortic stenosis (AS) is the most common acquired valvular heart disease in the elderly [1]. Although patients may remain asymptomatic for some time, most patients with asymptomatic, hemodynamically significant AS go on to develop heart failure (HF) symptoms within 5 years [2]. The development of heart failure prior to aortic valve replacement (AVR) portends worse prognosis. A recent report from Belgium demonstrated a significantly higher operative mortality for patients with New York Heart Association (NYHA) class III-IV compared with NYHA I-II symptoms. Furthermore, they noted that symptomatic heart failure decompensation within the month prior to surgery was not uncommon and conferred a dramatically increased risk of operative mortality, even in low risk patients [3]. The purpose of our investigation was to quantify the effect of progressive heart failure on mortality during primary isolated AVR in the Medicare population over a 10-year period.

Material and Methods

Data Sources

Data for this study came from the Centers for Medicare and Medicaid Services (CMS). Included are the Medicare Provider Analysis and Review (MEDPAR) files and

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corresponding Beneficiary Annual Summary Files (BASF) from 1999 through 2009. The MEDPAR files provide data on institutional claims for inpatient services covered under part A. The BASF files contain information on patient demographics, eligibility, enrollment, summarized service utilization and payment, and chronic condition flags for eligible beneficiaries. Additionally, the Vital Status file as of February 2012 was used to provide current date of death information to calculate long-term survival.

Patient Cohort

The study included Medicare beneficiaries 65 or greater years of age who underwent primary isolated AVR (ICD-9-CM [International Classification of Diseases, Clinical Modification, 9th edition] codes 35.21 and 35.22) from 2000 through 2009, excluding patients with prior or concomitant procedures, congenital heart disease, and ventricular support devices (Appendix). Patients with missing sex (gender) information, endocarditis, and patients with ICD-9-CM codes reflective of both a tissue and a mechanical valve during the same admission were also excluded. Finally, patients with Medicare status codes 20 (disabled without end-stage renal disease [ESRD]), 21 (disabled with ESRD), and 31 (ESRD only, not aged) were also excluded from the analysis, as these patients are not elderly.

The first hospitalization documenting aortic valve replacement during the 10-year period from 2000 through 2009 was identified as the "index" admission. Patients were excluded if they did not have 12 months of Medicare Part A and Part B coverage in the year preceding their index admission. Demographic and comorbidity data were obtained from the MEDPAR file. Comorbidities were determined using the ICD-9-CM diagnostic codes from both the index admission and any hospitalizations during the 12-month period before the index admission. Atrial fibrillation determination was based on documentation in the Chronic Condition Warehouse (CCW) of earliest indication of atrial fibrillation that preceded the index admission date as well as the primary and secondary ICD-9-CM diagnostic codes from hospitalizations during the 12-month period before the index admission. Operative mortality was defined according to the standard STS definition; hospital mortality or 30-day mortality, whichever is longer.

Statistical Analysis

In order to assess the impact of preoperative heart failure, patients were identified with the presence or absence of documentation of HF in the year leading up to their index admission. It was also noted whether this documentation was present more than 3 months prior to their index admission. The χ^2 tests of independence were used to compare those with and without preoperative HF on categoric variables, while the Wilcoxon rank sum tests were used for continuous outcomes. Logistic regression was used to model operative mortality as a function of preoperative heart failure. Adjusted odds ratios are presented, accounting for the baseline patient and surgery characteristics. Survival curves using the Kaplan-Meier method were generated to examine long-term survival. Expected mortality rates reflecting age- and sex-matched subjects from the US population were calculated using the National Vital Statistics Reports (2007) from the Centers for Disease Control and Prevention [4].

Cox proportional hazards (PH) models were used to predict long-term mortality while adjusting for baseline characteristics. Adjusted hazard ratios reflecting the relative increase or decrease in likelihood of death over the follow-up period are presented. Similar analyses were performed to assess the impact of duration of preoperative HF. Within the subset of patients with preoperative HF, follow-up analyses examined the relationship between long-term mortality and previous hospital admissions with a primary diagnosis of HF through survival curves. Given the nature of the observed mortality rates, a high mortality phase immediately after surgery followed by a fairly constant hazard of death thereafter, secondary analyses using Cox PH models were performed to model long-term mortality beyond 6 months to assess the potential impact of violations of the Cox PH model [5]. All analyses were performed using SAS v9.3 (SAS Institute Inc, Cary, NC).

Results

Baseline Characteristics

The incidence of preoperative comorbidities was high, and it was higher in patients with preoperative HF compared with those without (Table 1). Overall, 42.9% of the patients had preoperative HF. Those with preoperative HF were more likely to have COPD, stroke, peripheral vascular disease, renal failure, prior MI, and atrial fibrillation, among others. In addition, patients with preoperative HF were more commonly admitted

Table 1. Baseline Characteristics

Variable	Overall n = 114,135	HF− n = 65,144	HF+ n = 48,991	*p* Value
Age - median (IQR)	77 (72–81)	76 (72–81)	78 (73–83)	0.0001
Age ≥ 75 (years)	62.8%	59.3%	67.4%	0.0001
Female	51.2%	49.9%	52.9%	0.0001
White	92.7%	94.1%	90.9%	0.0001
Hypertension	61.8%	62.6%	60.8%	0.0001
Diabetes	23.5%	20.1%	28.0%	0.0001
PVD	4.4%	3.8%	5.2%	0.0001
Stroke	9.1%	8.3%	10.1%	0.0001
COPD	18.1%	12.3%	25.9%	0.0001
Respiratory failure	8.1%	3.9%	13.7%	0.0001
Renal failure/ESRD	9.5%	5.3%	15.2%	0.0001
Atrial fibrillation	24.2%	17.4%	33.2%	0.0001
Prior MI	9.1%	5.1%	14.4%	0.0001
Non-elective admission	48.0%	37.5%	62.1%	0.0001

COPD = chronic obstructive pulmonary disease; ESRD = end-stage renal disease; HF = heart failure; HF− = without preoperative HF; HF+ = with preoperative HF; IQR = interquartile range; MI = myocardial infarction; PVD = peripheral vascular disease.