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ORIGINAL RESEARCH

Clinical and economic outcomes after surgical aortic valve replacement in Medicare patients

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Background: Aortic valve replacement (AVR) is the standard of care for patients with severe, symptomatic aortic stenosis who are suitable surgical candidates, benefiting both non-high-risk and high-risk patients. The purpose of this study was to report long-term medical resource use and costs for patients following AVR and validate our assumption that high-risk patients have worse outcomes and are more costly than non-high-risk patients in this population.

Methods: Patients with aortic stenosis who underwent AVR were identified in the 2003 Medicare 5% Standard Analytic Files and tracked over 5 years to measure clinical outcomes, medical resource use, and costs. An approximation to the logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) based on administrative data was used to assess surgical risk, with a computed logistic EuroSCORE $>$ 20% considered high-risk.

Results: We identified 1474 patients with aortic stenosis who underwent AVR, of whom 1222 (82.9%) were non-high-risk and 252 (17.1%) were high-risk. Among those who were non-high-risk, the mean age was 73.3 years, 464 (38.2%) were women, and the mean logistic EuroSCORE was 7%, whereas in those who were high-risk, the mean age was 77.6 years, 134 (52.8%) were women, and the mean logistic EuroSCORE was 37%. All-cause mortality was 33.2% for non-high-risk and 66.7% for high-risk patients at 5 years. Over this time period, non-high-risk patients experienced an average of 3.9 inpatient hospitalizations and total costs of $106,277 per patient versus 4.7 hospitalizations and total costs of $144,183 for high-risk patients.

Conclusion: Among elderly patients undergoing AVR, long-term mortality and costs are substantially greater for high-risk than for non-high-risk individuals. These findings indicate that further research is needed to understand whether newer approaches to aortic valve replacement such as transcatheter AVR may be a lower cost, clinically valuable alternative.

Keywords: aortic valve, replacement, health economics

Introduction

According to data from the Nationwide Inpatient Sample, the number of aortic valve replacement (AVR) procedures has grown significantly over the years, with approximately 67,500 procedures performed in the US in 2010.[1] Medicare beneficiaries constitute 63% of all patients undergoing AVR.[1] With the aging of the population, the prevalence of aortic valve disease and valve replacement surgery is expected to continue this growth trend. Many published studies have documented the clinical advantages of AVR in patients with severe, symptomatic aortic stenosis.[2–13] AVR improves clinical outcomes including mortality, reduces symptoms, and improves patient quality of life. Nevertheless, for patients at high risk of surgical mortality, options become increasingly limited, and the potential benefit of AVR must outweigh both the surgical risk as well as risk associated with no treatment at all. For this patient population, new, minimally invasive AVR treatments may be their only viable treatment option.[14,15]

Rapidly rising health care costs in the US have caused policymakers to seek increasingly an understanding of the cost-effectiveness of new technologies in order to ensure cost containment while maintaining and improving patient care. High mortality rates coupled with high end-of-life treatment costs for patients with aortic stenosis make this disease an area of particular interest. While AVR remains the standard of care for patients with severe aortic stenosis, few studies have effectively captured the long-term medical care resource utilization and costs for patients following AVR.

Due to the high prevalence of aortic stenosis in older patients, the Medicare population provides a "real-world" representation of the clinical progression of the disease and the associated resource use and costs. Using Medicare claims data, this study seeks to describe the costs and resource use associated with surgical treatment in both non-high risk and high-risk patients.

Materials and methods

Data sources and study population

This study used the Medicare Standard Analytic Files (SAFs), 5% sample for 2001–2008. While data from 2003 was used to identify the patient population, data from the previous 2 years were used to identify chronic conditions and previous surgeries for risk adjustment, and data out to 2008 were used to identify 5-year costs and outcomes. These files contain all claims (physician, inpatient, outpatient, skilled nursing, home health, hospice, durable medical equipment suppliers, and other suppliers) from a 5% random sample of Medicare beneficiaries enrolled in the fee-for-service Medicare program. Each patient receives a unique identifier that allows claims to be linked across time for longitudinal analysis of health resource use (services, length of stay), medical costs (Medicare payments), and clinical outcomes (defined by diagnosis and procedure codes, death date). Furthermore, the SAF (denominator) provides information on patient demographics including age, race, and other enrolment-related beneficiary information.

Patients included in this study were first identified by selecting a broader population of both medically managed and surgically treated patients with severe symptomatic aortic stenosis using physician, inpatient, and outpatient claims from 2003 containing an International Classification of Diseases 9th Clinical Modification (ICD9-CM) diagnosis (395.0, 395.2, 396.0, 396.2, 395.1, 395.9, or 424.1, or 746.3) or procedure code (ICD-9-CM 35.01, 35.96, 35.21, 35.22, or Current Procedural Terminology [CPT] code 92986, 33405) indicating the presence of aortic stenosis. Medically managed patients with severe aortic stenosis were identified based on the presence of a hospital admission with a principal diagnosis of heart failure (ICD-9 DX 398.91, 402.01, 402.11, 402.91, 404.01, 404.11, 404.91, 404.03, 404.13, 404.93, 428.0, 428.1, 428.20, 428.21, 428.22, 428.23, 428.30, 428.31, 428.32, 428.33, 428.40, 428.41, 428.42, 428.9) or a balloon valvuloplasty procedure (35.01, 35.96, or CPT 92986) and no surgical AVR procedure. Surgically treated patients with severe, symptomatic aortic stenosis were defined by the presence of a surgical AVR procedure code (ICD9-CM PX 35.21, 35.22, CPT 33405). Continuous enrollment in both Medicare parts A and B for the entire follow-up period or until death was also required.

Outcome measures

Mortality, myocardial infarction rate, and stroke rate were all tracked as clinical outcomes. The SAF (denominator) was used to obtain the date of death. A patient was classified as having had a myocardial infarction if there was at least one hospital admission with a principal diagnosis of myocardial infarction (ICD-9 DX 410.01, 410.11, 410.21, 410.31, 410.41, 410.51, 410.61, 410.71, 410.81, 410.91). Strokes were defined by a hospitalization with a principal diagnosis of stroke (ICD9 DX 430, 431, 434.00, 434.01, 434.10, 434.11, 434.90, 434.91, 435.0, 435.1, 435.3, 435.8, 435.9, 436, 997.02). Additional outcomes that were tracked included rates of repeat AVR, valvuloplasty, admission to a hospice (presence of a hospice claim), admission to a skilled nursing facility (presence of a skilled nursing facility claim), number of acute inpatient hospitalizations (number of acute inpatient claims), hospital days (sum of acute inpatient length of stay), and skilled nursing facility days (sum of skilled nursing facility length of stay).

Costs were measured as payments made by the Medicare program for medical services reported on Medicare parts A and B claims and excluded beneficiary cost sharing, such as coinsurance and deductibles. Costs were computed based on all types of claims and accumulated over the 5-year follow-up period. Additionally, average follow-up costs per patient per year were calculated by dividing a patient's total follow-up costs by the number of years of follow-up time. Total follow-up costs exclude costs incurred during the index quarter, which are primarily due to costs associated with the surgical AVR procedure. The robustness of the SAF data allowed us to examine and report on various other components of cost and resource use, which are presented in the tables. These components were determined based on Medicare claim type, bill type, and provider number.

Risk stratification and adjustment

Patients included in the study were classified into high-risk and non-high-risk groups for risk stratification using the logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation, http://www.euroscore.org/logisticEuroSCORE.htm). Although the risk score calculator developed by the Society for Thoracic Surgery may be more appropriate for use in a US patient population, its application in claims data is not possible because the methodology and formula have not been published. The logistic EuroSCORE predicts surgical mortality for patients undergoing open heart surgery using patient-specific clinical criteria and risk factors including age, gender, comorbid conditions, and previous procedures. We used the SAF (denominator) to obtain the continuous age variable of the patient at the beginning of 2003 to determine age. Each of the other risk factors were determined on the presence of ICD9-CM DX and PX codes on certain claims from the 2 years prior to a patient's index event or index hospitalization. The specific codes used to define each logistic EuroSCORE covariate are provided in Appendix A. All of the risk factors except for age were treated as dummy variables. The values for each patient were included in the logistic EuroSCORE model. High-risk patients were identified by a logistic EuroSCORE $\geq$ 20%, which has been a definition used to identify high-risk AVR patients in other studies and clinical trials.[16]

Further risk adjustment to account for comorbid conditions not already included in the logistic EuroSCORE model was employed using Medicare's Hierarchical Condition Categories (HCCs). The HCC methodology is used by Medicare to calculate risk-adjusted costs and payments to Medicare Advantage plans, and we used these HCCs to define clinically relevant conditions.[17] Under this methodology, diagnosis codes on inpatient, outpatient, and physician claims are used to identify comorbid conditions. These comorbid conditions as well as other patient demographic variables are used to calculate an HCC score to adjust monthly Medicare Advantage capitation payments. The risk scores are indexed to a value of 1.0, which represents the costliness of the average Medicare beneficiary. Therefore, a calculated risk score of 2.0 indicates that a patient is twice as costly as the average. In our study, HCC score was only used to report baseline patient characteristics, but we used several clinically relevant HCC groups to adjust for comorbid conditions in the multivariate models.

Statistical analysis

Continuous variables are expressed as the mean ± standard deviation and were compared using *t*-tests. Categorical variables were compared using Fisher's exact test and are presented as frequencies and percentages. A Cox regression model was used to predict clinical outcomes. Ninety-five percent confidence intervals and hazard ratios are reported for clinical outcomes. A number of covariates including age, gender, race, region, individual logistic EuroSCORE components, clinically relevant comorbid Medicare HCC conditions, and length of follow-up were used to adjust for baseline differences. Individual logistic EuroSCORE components and HHC categories were used rather than the actual scores because we wanted to understand the conditions that are most significant in predicting outcomes. All analyses were performed using SAS version 9.2 (SAS, Cary, NC), and a two-sided *P* value of 0.05 was considered to be statistically significant.

Results

Patient population

A total of 3624 patients with severe, symptomatic aortic stenosis (both medically managed and surgically treated) were identified in the 2003 Medicare SAF 5% sample. From this group, 1474 (41%) patients were identified as having been surgically treated. The baseline characteristics presented in Table 1 show that their mean age was 74.0 years, 40.7% were women, 93.1% were white, and 51.1% were from the East Region. While the mean logistic EuroSCORE for the group was 12%, 17.1% of the patients had a score $\geq$ 20% and were considered high-risk. The mean HCC score for the group was 2.9, indicating health care costs about three times that of the average Medicare beneficiary.

Patients also had a significant number of comorbid conditions associated with the logistic EuroSCORE covariates, including unstable angina (30.7%), previous cardiac surgery (20.6%), and recent myocardial infarction (17.6%). Additionally, patients had clinically meaningful comorbid HCC conditions, including heart failure (71.4%), cardiac arrhythmias (71.0%), cardiorespiratory failure and shock (33.7%), and vascular disease (26.0%). Not surprisingly, statistically significant differences were found between the high-risk and non-high-risk groups for all logistic EuroSCORE covariates. Several additional comorbid conditions were statistically significant between the high-risk and non-high-risk groups, including certain manifestations of diabetes, renal failure and dialysis, ischemic stroke, and protein calorie malnutrition.

Table 1 Baseline patient characteristics: surgically treated patients with severe aortic stenosis

Characteristic	All patients (n = 1474)	HR (n = 252)	NHR (n = 1222)	*P* value
Age (mean, SD, median)*	74.0	77.6	73.3	<0.0001
Female (%)	40.7%	52.8%	38.2%	<0.0001
White (%)	93.1%	93.7%	93.0%	0.729
East region (CMS regions 1–4)	51.1%	51.6%	51.0%	0.861
Central region (CMS regions 5–7)	34.3%	36.1%	33.9%	0.497
West region (CMS regions 8–10)	14.7%	12.3%	15.1%	0.246
Logistic EuroSCORE comorbidity components (%)				
Chronic pulmonary disease	9.1%	17.5%	7.4%	<0.0001
Extracardiac arteriopathy	14.9%	31.3%	11.5%	<0.0001
Neurologic dysfunction	7.0%	19.4%	4.4%	<0.0001
Previous cardiac surgery	20.6%	63.1%	11.8%	<0.0001
Medicare ESRD beneficiary (serum creatinine > 200)	3.9%	9.5%	2.8%	<0.0001
Active endocarditis	5.0%	13.5%	3.2%	<0.0001
Critical preoperative state	17.6%	51.2%	10.7%	<0.0001
Unstable angina	30.7%	55.2%	25.6%	<0.0001
Left ventricular dysfunction	5.8%	13.1%	4.3%	<0.0001
Recent myocardial infarction	17.6%	36.9%	13.6%	<0.0001
Pulmonary hypertension	10.2%	21.8%	7.8%	<0.0001
Logistic EuroSCORE (mean, SD, median)	12%	37%	7%	<0.0001
Logistic EuroSCORE ≥ 0.20 (%)	17.1%	100.0%	0.0%	NA
Comorbid conditions not already included in logistic EuroSCORE (%) (Medicare HCC group)				
HCC7 – Metastatic cancer and acute leukemia	1.4%	**	**	0.811
HCC8 – Lung, upper digestive tract, and other severe cancers	1.1%	**	**	0.623
HCC9 – Lymphatic, head and neck, brain, and other major cancers	3.1%	**	**	0.780
HCC10 – Breast, prostate, colorectal and other cancers and tumors	13.2%	13.5%	13.1%	0.865
HCC15 - Diabetes with renal or peripheral circulatory manifestation	7.1%	15.5%	5.3%	<0.0001
HCC16 – Diabetes with neurologic or other specified manifestation	5.6%	5.6%	5.6%	0.995
HCC18 – Diabetes with ophthalmologic or unspecified manifestation	2.8%	**	**	0.997
HCC19 – Diabetes without complication	23.3%	26.6%	22.7%	0.180
HCC21 – Protein-calorie malnutrition	6.7%	13.9%	5.2%	<0.0001
HCC38 – Rheumatoid arthritis and inflammatory connective tissue disease	7.5%	6.0%	7.9%	0.297
HCC55 – Major depressive, bipolar, and paranoid disorders	4.1%	**	**	0.882
HCC79 – Cardiorespiratory failure and shock	33.7%	51.6%	30.0%	<0.0001
HCC80 – Congestive heart failure	71.4%	88.5%	67.9%	<0.0001
HCC81 – Acute myocardial infarction	**	**	**	0.521
HCC82 – Unstable angina and other acute ischemic heart disease	5.9%	8.3%	5.4%	0.072
HCC92 – Specified heart arrhythmias	71.0%	81.7%	68.7%	<0.0001
HCC96 – Ischemic or unspecified stroke	11.3%	16.7%	10.2%	0.0003
HCC100 – Hemiplegia/hemiparesis	2.2%	4.4%	1.8%	0.012
HCC104 – Vascular disease with complications	10.2%	17.1%	8.8%	<0.0001
HCC105 – Vascular disease	26.0%	31.7%	24.8%	0.022
HCC108 – Chronic obstructive pulmonary disease	5.2%	7.5%	4.7%	0.060
HCC119 – Proliferative diabetic retinopathy and vitreous hemorrhage	1.5%	**	**	0.003
HCC130 – Dialysis status	3.6%	9.1%	2.5%	<0.0001
HCC131 – Renal failure	8.3%	15.9%	6.7%	0.0001
HCC score (mean, SD, median)	2.85	4.14	2.58	<0.0001

Notes: *Part of the Logistic EuroSCORE; **≤10 patients.

Abbreviations: CMS, Centers for Medicare and Medicaid Services; ESRD, end-stage renal disease; HCC, Hierarchical Condition Category; SD, standard deviation; HR, high-risk; NHR, non-high-risk; EuroSCORE, European System for Cardiac Operative Risk Evaluation.

Clinical outcomes

Results of the unadjusted clinical outcomes analysis indicated that almost 40% of patients had died by the end of the study period, with 61.1% of patients still alive at the end of 5 years (Figure 1). High-risk patients had significantly lower survival rates than non-high-risk patients ($P < 0.0001$), with rates of 33.3% and 66.8% at 5 years, respectively. Mean follow-up time across all patients was 3.8 years, while the high-risk group was 2.7 and the non-high-risk group was 4.0 ($P \leq 0.0001$).

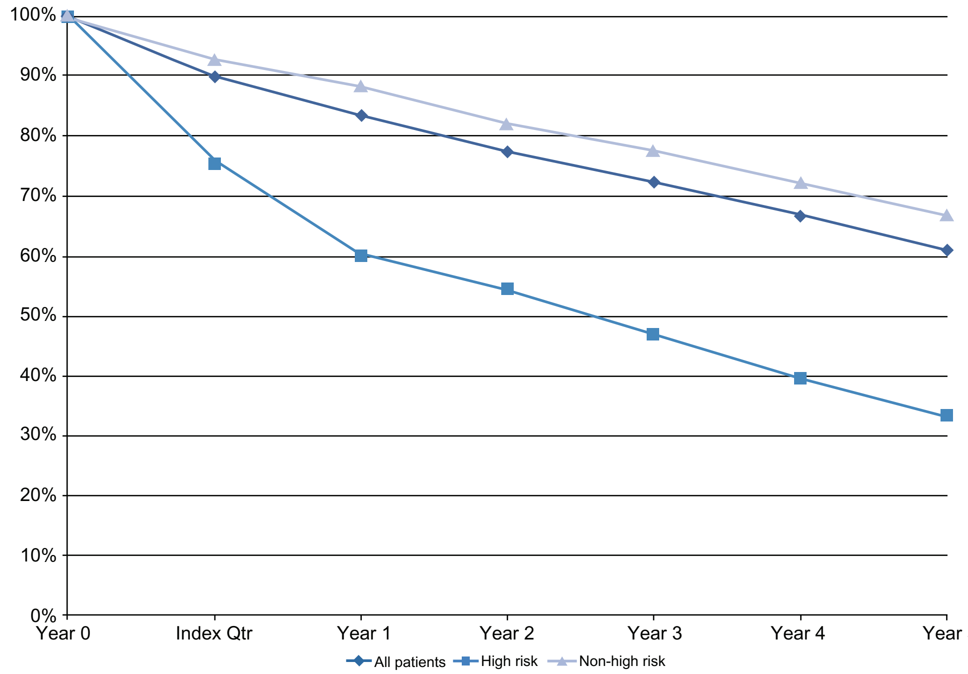

Figure 1 Survival rates over 5 years for the overall population (all patients), high-risk patients, and non-high-risk patients.
Note: Percentages indicate the proportion of patients alive at the end of each year.

Additionally, a larger proportion of high-risk patients also experienced myocardial infarctions (4.8% versus 2.0%, $P = 0.009$) and strokes (7.5% versus 6.6%, $P = 0.601$) during the 5-year follow-up period (Table 2).

Significant predictors of mortality included patient age, three separate logistic EuroSCORE components (neurologic dysfunction, Medicare ESRD status, critical preoperative state), and five comorbid conditions, even after adjusting for confounding factors (Table 3). The risk stratification variable defined by a logistic EuroSCORE > 20%, was not included in the final model because the individual logistic EuroSCORE components were used in the model. Medicare ESRD beneficiaries were found to have a more than three-fold increase in risk of death (95% CI 1.97–6.65, $P < 0.0001$). Similarly, patients in a critical perioperative state and those suffering from metastatic cancer and acute leukemia both demonstrated significant increases in risk of death of more than 2.5 times (95% CI 2.07–3.08 and 1.54–4.31, respectively).

Resource use and costs

An analysis of health care resource use (Table 4) over the 5-year period revealed an average of 4.0 acute inpatient hospitalizations (3.0 excluding index hospitalization) per patient, with high-risk and non-high-risk patients incurring 4.7 and 3.9 admissions, respectively ($P = 0.003$, 3.7 and 2.9 admissions excluding index event). On average, patients were hospitalized for 32.0 days, with high-risk patients incurring 46.6 days and non-high-risk patients incurring 29.0 days ($P \leq 0.0001$). Overall, 1.4% of patients underwent a repeat AVR procedure, with the high-risk patients undergoing the procedure more frequently. Over half (64.3%) of all patients received home health care, while more than a third receiving skilled nursing facility care (37.1%). Approximately 68% of all patients needed some type of durable medical equipment to manage their care. Univariate results showed statistically significant differences between high-risk and non-high-risk patients for hospital admissions and hospital days, skilled

Table 2 Clinical outcomes at 5 years

Clinical outcome	5-year rate All patients	HR	NHR	*P* value
Survival (n, % of patients)	900, 61.1%	84, 33.3%	816, 66.8%	<0.0001
Follow-up years (mean)	3.8	2.7	4.0	<0.0001
Myocardial infarction (n, % of patients)	36, 2.4%	12, 4.8%	24, 2.0%	0.009
Stroke (n, % of patients)	100, 6.8%	19, 7.5%	81, 6.6%	0.601

Abbreviations: HR, high-risk; NHR, non-high-risk.

Table 3 Significant predictors of 5-year mortality

Covariate	Hazards ratio	95% CI	*P*
Patient demographics			
Age	1.023	1.012–1.035	<0.0001
Logistic EuroSCORE components			
Neurologic dysfunction	1.729	1.293–2.311	0.0002
Medicare ESRD beneficiary	3.619	1.969–6.653	<0.0001
Critical preoperative state	2.528	2.073–3.083	<0.0001
Comorbid conditions not already included in logistic EuroSCORE			
HCC7 – Metastatic cancer and acute leukemia	2.579	1.542–4.315	0.0003
HCC10 – Breast, prostate, colorectal and other cancers and tumors	1.369	1.079–1.738	0.010
HCC21 – Protein-calorie malnutrition	1.821	1.390–2.387	<0.0001
HCC79 – Cardiorespiratory failure and shock	1.650	1.383–1.969	<0.0001
HCC80 – Congestive heart failure	1.549	1.220–1.966	0.0003

Abbreviations: ESRD, end-stage renal disease; CI, confidence interval; HCC, Hierarchical Condition Category; EuroSCORE, European System for Cardiac Operative Risk Evaluation.

nursing facility admissions (49.6%, 34.5%, $P \leq 0.0001$), skilled nursing facility days (27.8, 16.3, $P = 0.001$), admissions to hospice care (12.3%, 7.4%, $P = 0.009$), admissions to long-term care hospitals (9.9%, 4.7%, $P = 0.001$), dialysis services (9.5%, 3.6%, $P \leq 0.0001$), and outpatient hospital care (83.7%, 95.7%, $P \leq 0.0001$).

Total health care costs (including index quarter costs) over the 5-year period were $112,758 per patient on average (Figure 2). The majority of costs were for acute inpatient hospitalizations ($69,338 [61.5%]), physician services ($19,644 [17.4%]), skilled nursing care ($5163 [4.6%]), and home health care ($4399 [3.9%]). The remaining costs were fairly evenly distributed among other types of health care services. Total 5-year costs were significantly different between the high-risk and non-high-risk groups ($144,183 versus $106,277 per patient, $P \leq 0.0001$). High-risk patients were 40% more costly than non-high-risk patients when inpatient hospital services were provided ($91,771 versus $64,712, $P \leq 0.0001$). Average skilled nursing ($8291 versus $4518, $P \leq 0.0001$), home health ($6642 versus $3937, $P = 0.0146$), and long-term hospital care ($4139 versus $1564, $P = 0.0006$) were all more costly for high-risk patients.

Total follow-up costs alone (excluding index quarter costs) over the 5-year period were $59,855. High-risk patients had 55% higher follow-up costs than non-high-risk patients ($85,731 versus $55,456). Hospital inpatient follow-up costs represented the largest proportion of total follow-up costs within each group, with 41.4% and 38.8% in the high-risk and non-high-risk groups, respectively. Inpatient follow-up costs for high-risk patients were $35,493, whereas the average inpatient hospitalization cost for non-high-risk

Table 4 Five-year health resource use

Health care resource	All patients	HR	NHR	*P* value
Acute inpatient (n, % patients)	1474, 100%	252, 100%	1,222, 100%	NA
Hospitalizations (mean, SD)*	4.0	4.7	3.9	0.003
Hospital days (mean, SD)*	32.0	46.6	29.0	<0.0001
Repeat AVR (n, % patients)	20, 1.4%	**	**	0.728
Valvuloplasty (n, % patients)	**	**	**	0.6496
Long-term care hospital (n, % patients)	83, 5.6%	25, 9.9%	58, 4.7%	0.001
Inpatient rehabilitation facility (n, % patients)	300, 20.4%	56, 22.2%	244, 20.0%	0.418
Skilled nursing facility (n, % patients)	547, 37.1%	125, 49.6%	422, 34.5%	<0.0001
Number of SNF days (mean, SD)	18.3	27.8	16.3	0.001
Hospice care (n, % patients)	121, 8.2%	31, 12.3%	90, 7.4%	0.009
Home health care (n, % patients)	948, 64.3%	156, 61.9%	792, 64.8%	0.380
Outpatient hospital care (n, % patients)	1381, 93.7%	211, 83.7%	1170, 95.7%	<0.0001
Physician/supplier services (n, % patients)	1474, 100%	252, 100%	1221, 100%	NA
Durable medical equipment use (n, % patients)	1000, 67.8%	170, 67.5%	830, 67.9%	0.887
Dialysis services (n, % patients)	68, 4.6%	24, 9.5%	44, 3.6%	<0.0001

Notes: *Includes index hospitalization; **≤10 patients.
Abbreviations: AVR, aortic valve replacement; HR, high-risk; NHR, non-high-risk; SD, standard deviation; SNF, skilled nursing facility.

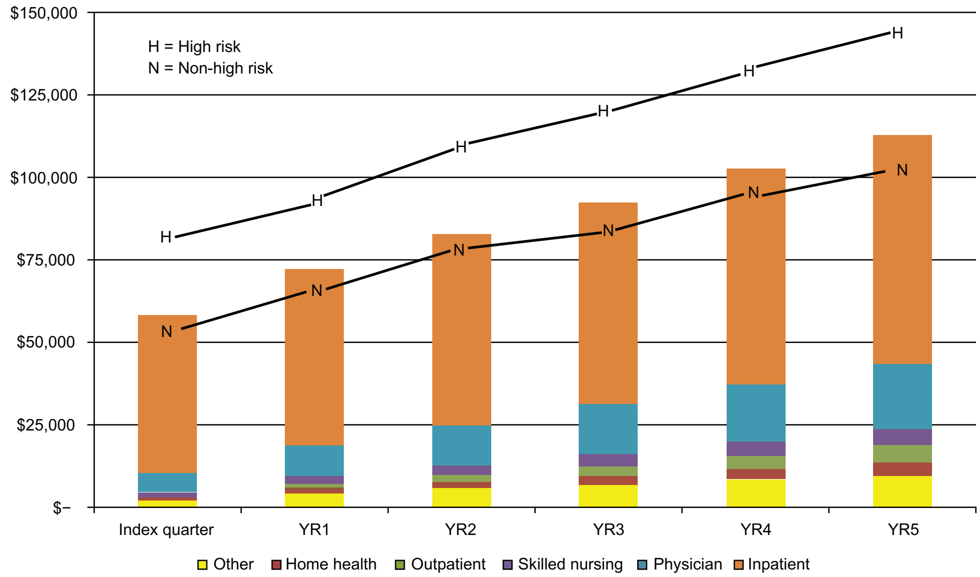

Figure 2 Average 5-year cumulative costs per patient.
Note: Mean cumulative costs per patient over a 5-year period, with total high-risk and non-high-risk costs over time highlighted.

patients during the follow-up period was $21,517. Limited survival at the end of the follow-up period may have decreased costs to a lower than expected level. Therefore, we also examined the average annual follow-up costs (total costs minus index hospitalization costs) per patient by dividing the patient's total follow-up costs by the number of follow-up years. The overall average follow-up costs per patient per year was $15,244, with high-risk patients being twice as costly per year as non-high-risk patients ($26,891 versus $13,686).

Discussion

In a Medicare sample of 1474 AVR patients, 17.1% had a EuroSCORE $\geq$ 20% and were considered high-risk. Not surprisingly, the high-risk group had worse outcomes and higher resource use and costs than the non-high-risk group. High-risk patients had significantly lower survival (33.3% versus 66.8%), higher rates of myocardial infarction (4.8% versus 2.0%) and stroke (7.5% versus 6.6%), more follow-up hospitalizations (3.7 versus 2.9), and required more post-acute care services in general. Total health care costs over the 5-year period reached $112,758 per patient overall, with the high-risk group driving costs higher ($144,183 versus $106,277 in the non-high-risk group). These results are consistent with our hypothesis that high-risk AVR patients are more costly and have worse outcomes than non-high-risk patients.

Recent results from PARTNER (Placement of AoRTic TraNscathetER Valve Trial) of high-risk patients undergoing transcatheter AVR are comparable with the results presented here. The PARTNER Cohort A study compared high-risk patients randomized to either transcatheter AVR or standard AVR, while the Cohort B study examined "inoperable" high-risk patients randomized to transcatheter AVR or standard medical care. Patients in the surgical AVR arm of the "operable" cohort had an average one-year survival rate of 73.2%, while those in the "inoperable" transcatheter AVR arm had a one-year survival rate of 69.3%.[14,15] The one-year survival rate found in the high-risk Medicare population in this study was 66.8%. Although somewhat lower, it should be noted that the average logistic EuroSCORE in our high-risk group was 36.8%, while operable AVR and inoperable transcatheter AVR patients in PARTNER had logistic EuroSCOREs of 29.2% and 26.4%, respectively.

In terms of resource use and costs, only results from the inoperable transcatheter AVR patient group have been published and can be compared with the high-risk patients in this study. The high-risk AVR population in this study incurred 3.7 subsequent hospitalizations over the 5-year follow-up period (with 1.4 total and 0.5 cardiovascular-related hospitalizations in the first year). The inoperable transcatheter AVR population incurred 1.02 total follow-up hospitalizations and 0.50 cardiovascular hospitalizations during the first year.[18] One-year costs for high-risk Medicare AVR patients in 2003 were $96,476. This compares with a total of $107,892 in one-year costs for the high-risk inoperable transcatheter AVR population.[18] The results found in this Medicare claims analysis compare well with high-risk transcatheter AVR patients. We await additional results from the surgical AVR arm of the PARTNER trial for additional comparisons.

The incidence of severe, symptomatic aortic stenosis is expected to increase with the aging of the population. Previous studies have demonstrated that outcomes are poor in untreated patients and that the only effective treatment is AVR.[2–13] Although our results demonstrating higher costs and worse outcomes for high-risk versus non-high-risk AVR patients may not be surprising, there have been no studies to date examining the health care costs and resource use in this patient population (the PARTNER trial focused on high-risk patients only.) Additionally, studies of other procedures only compare immediate surgical outcomes of high-risk and non-high risk patients. More limited data exist that compare long-term outcomes and especially costs for high-risk versus non-high risk patients. One example of benchmark data in this area is for abdominal aortic aneurysm repair. Steinmetz et al examined high-risk surgical and endovascular abdominal aneurysm repair compared with low-risk surgical abdominal aneurysm repair outcomes over 7 years.[19] However, no cost or resource use data were reported.

As with any study that uses administrative claims data to track outcomes and costs, there are limitations. First, administrative claims data were not originally designed to answer research questions; they exist as a byproduct of the health insurance claims payment process. Clinical conditions and procedures are identified in claims data using various diagnosis and procedure coding systems. Often times, the codes are ambiguous and do not allow enough specificity for tracking specific outcomes and risk factors of interest. The "costs" provided in the dataset must be defined as "payments" made by payers (or, alternatively, billed charges). The Medicare data probably specifically underestimate total costs due to incomplete Medicare-covered benefits, such as prescription drugs and the majority of skilled nursing services.

In spite of these limitations, claims data are often used for this type of longitudinal research. Additionally, claims data provide insight into outcomes of patient populations that are not required to meet the restrictive enrollment criteria of clinical trials and may be more representative of how patients are truly treated. The Medicare database in particular is one of the most comprehensive datasets available to study costs and outcomes in an elderly population. Because the majority of patients with aortic stenosis tend to be elderly, these data are ideal for understanding this group.

In our sample, a total of 1474 high-risk and non-high-risk Medicare patients underwent AVR during 2003. Because our data represent a 5% random sample of all Medicare beneficiaries during that year, we can project that approximately 30,000 Medicare patients had surgical AVR in 2003. Total costs for the patient population over the 5-year follow-up period can be estimated at \$3.4 billion (30,000 × \$112,758). Additionally, we found important differences in costs, health resource use, and outcomes between high-risk and non-high-risk patients, with high-risk patients incurring higher costs, more health resource use, and greater mortality. Importantly, even though high-risk patients tended to have higher mortality (thus, fewer years of follow-up), the average total follow-up costs per high-risk patient was 55% higher at \$85,731 versus \$55,456. These findings underscore the need for future studies comparing the outcomes and health care costs of high-risk patients treated with surgical AVR compared with those treated with transcatheter AVR to determine whether transcatheter AVR provides a lower cost but clinically beneficial solution to the management of these high-risk patients. This study provides detailed cost and health resource use data on both high-risk and non-high-risk surgical AVR patients, which is helpful in providing comparative cost benchmarks for new, minimally invasive approaches.

Disclosure

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Appendix

Appendix A Logistic EuroSCORE definitions

Risk factors	Definition
Patient-related factors	
Age	Age in years at the beginning of 2003
Gender	Female
Chronic pulmonary disease	At least one hospitalization or outpatient hospital visit with a principal diagnosis 4910, 49120, 49121, 49122, 4918, 4919, 4920, 4928, 4940, 4941, 496, 514, 515, 51883, 51884, 51889, 5199
Extracardiac arteriopathy	At least one hospitalization or outpatient hospital visit with a principal diagnosis, 4178, 43310, 43311, 43320, 43321, 43330, 43331, 43380, 43381, 43390, 43391, 43490, 43491, 4351, 4353, 4358, 4359, 4370, 44020, 44021, 44022, 44023, 44024, 44029, 44030, 44031, 44032, 4404, 4408, 44389, 4439, 4471, 4479
Neurological dysfunction	Any DX code, 2900, 29010, 29011, 29012, 29013, 29020, 29021, 2903, 29040, 29041, 29042, 29043, 2908, 2909, 3310, 3320, 3321, 340, 34200, 34201, 34202, 34210, 34211, 34212, 34280, 34281, 34282, 34290, 34291, 34292, 3431, 3432, 3434, 34400, 34401, 34402, 34403, 34404, 34409, 3441
Previous cardiac surgery	Cardiac surgery in quarters prior to the index quarter identified by any of the following DX, PX, or CPT codes. ICD-9 DX codes V421, V422, V4581. ICD-9 PX codes 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 3710, 3711, 3732, 3733, 3734, 3735, 3736, 3741, 3749, 3751. CPT Codes 33120, 33130, 33300, 33305, 33310, 33315, 33320, 33321, 33322, 33330, 33332, 33335, 33400, 33401, 33403, 33420, 33422, 33425, 33426, 33427, 33430, 33460, 33463, 33464, 33465, 33468, 33470, 33471, 33472, 33474, 33475, 33476, 33478, 33496, 33500, 33501, 33502, 33503, 33504, 33505, 33506, 33507, 33508, 33510, 33511, 33512, 33513, 33514, 33516, 33517, 33518, 33519, 33521, 33522, 33523, 33530, 33533, 33534, 33535, 33536, 33542, 33545, 33548, 33572, 33600, 33602, 33606, 33608, 33610, 33611, 33612, 33615, 33617, 33619, 33641, 33645, 33647, 33660, 33665, 33670, 33675, 33676, 33677, 33681, 33684, 33688, 33690, 33692, 33694, 33697, 33702, 33710, 33720, 33722, 33724, 33726, 33730, 33732, 33735, 33736, 33737, 33750, 33755, 33762, 33764, 33766, 33767, 33768, 33770, 33771, 33774, 33775, 33776, 33777, 33778, 33779, 33780, 33781, 33786, 33788, 33800, 33802, 33803, 33813, 33814, 33820, 33822, 33824, 33840, 33845, 33851, 33852, 33853, 33860, 33861, 33863, 33864, 33870, 33875, 33877, 33910, 33915, 33916, 33917, 33920, 33922, 33924, 33925, 33926, 33930, 33933, 33935, 33940, 33944, 33945
Serum creatinine	Patient is afflicted with ESRD and on dialysis during index year (ESRD indicator field in denominator file)
Active endocarditis	Any of the following DX codes appearing in the same quarter of the index hospitalization = 4210, 4211, 4219
Critical preoperative state	Certain DX or PX on the same index hospitalization claim. DX 42741, 4275, 5845, 5846, 5847, 5848, 5849, V1253, V4321. PX 3752, 3753, 3754, 3755, 3760, 3761, 3762, 3763, 3764, 3765, 3766, 3767, 3768.
Cardiac-related factors	
Unstable angina	Any DX code 4111
Left ventricular dysfunction	Any DX code 42820, 42821, 42822, 42823
Recent myocardial infarction	Any DX code within the index quarter or previous one quarter 41000, 41001, 41002, 41010, 41011, 41012, 41020, 41021, 41022, 41030, 41031, 41032, 41040, 41041, 41042, 41050, 41051, 41052, 41060, 41061, 41062, 41070, 41071, 41072, 41080, 41081, 41082, 41090, 41091, 41092
Pulmonary hypertension	Any DX code 4150 or 4160
Operation-related factors	
Emergent operation	Cardiac-related admission DX codes on patients who, on their AVR hospitalization claim, were admitted through the ER upon recommendation of the ER physician
Other than isolated CABG	NA
Surgery on thoracic aorta	NA
Postinfarct septal rupture	DX code 42971 on same claim as any AVR hospitalization occurring during index quarter

Abbreviations: AVR, aortic valve replacement; ER, emergency room; CABG, coronary artery bypass grafting; ESRD, end-stage renal disease; DX, diagnosis; PX, procedure; CPT, Current Procedural Terminology; NA, not applicable.