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Relationship Between Hospital Surgical Aortic Valve Replacement Volume and Transcatheter Aortic Valve Replacement Outcomes

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ABSTRACT

OBJECTIVES The aim of this study was to examine whether hospital surgical aortic valve replacement (SAVR) volume was associated with corresponding transcatheter aortic valve replacement (TAVR) outcomes.

BACKGROUND Recent studies have demonstrated a volume-outcome relationship for TAVR.

METHODS In total, 208,400 fee-for-service Medicare beneficiaries were analyzed for all aortic valve replacement procedures from 2012 to 2015. Claims for patients <65 years of age, concomitant coronary artery bypass grafting surgery, other heart valve procedures, or other major open heart procedures were excluded, as were secondary admissions for aortic valve replacement. Hospital SAVR volumes were stratified on the basis of mean annual SAVR procedures during the study period. The primary outcomes were 30-day and 1-year post-operative TAVR survival. Adjusted survival following TAVR was assessed using multivariate Cox regression.

RESULTS A total of 65,757 SAVR and 42,967 TAVR admissions were evaluated. Among TAVR procedures, 21.7% (n = 9,324) were performed at hospitals with <100 (group 1), 35.6% (n = 15,298) at centers with 100 to 199 (group 2), 22.9% (n = 9,828) at centers with 200 to 299 (group 3), and 19.8% (n = 8,517) at hospitals with ≥300 SAVR cases/year (group 4). Compared with group 4, 30-day TAVR mortality risk-adjusted odds ratios were 1.32 (95% confidence interval: 1.18 to 1.47) for group 1, 1.25 (95% confidence interval: 1.12 to 1.39) for group 2, and 1.08 (95% confidence interval: 0.82 to 1.25) for group 3. These adjusted survival differences in TAVR outcomes persisted at 1 year post-procedure.

CONCLUSIONS Total hospital SAVR volume appears to be correlated with TAVR outcomes, with higher 30-day and 1-year mortality observed at low-volume centers. These data support the importance of a viable surgical program within the heart team, and the use of minimum SAVR hospital thresholds may be considered as an additional metric for TAVR performance. (J Am Coll Cardiol Intv 2020;13:335–43) © 2020 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

AVR = aortic valve replacement

CMS = Centers for Medicare and Medicaid Services

HMO = health maintenance organization

NCD = national coverage determination

SAVR = surgical aortic valve replacement

TAVR = transcatheter aortic valve replacement

Transcatheter aortic valve replacement (TAVR) has emerged as an established treatment strategy for patients with symptomatic aortic stenosis who are inoperable or at high or intermediate risk (1–5). This has brought practice change, which is now reflected in contemporary studies showing an overall reduction in isolated surgical aortic valve replacement (SAVR) volumes and a decrease in comorbidities among SAVR patients (6–8). The promising results of 2 recent randomized clinical trials in low-risk patients are monumental (9,10) and could inevitably shift the pendulum even further toward TAVR as the preferred choice over SAVR in all patients, despite an overall increase in total aortic valve replacement (AVR) volumes at TAVR sites (11).

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Concomitantly, we have witnessed an increasing confidence in TAVR use as accumulating operator experience and volume, innovations in valve design and technology, and improvements in patients selection have led to significant reductions in morbidity and mortality after TAVR (1,12–16). These findings have further fueled the ongoing debate on minimum procedure volume requirements for TAVR operators and programs and spurred the Centers for Medicare and Medicaid Services (CMS) to reexamine its national coverage determination (NCD) for TAVR, which was developed in 2012 in an effort to support rational dispersion of TAVR technology in the United States (17). This was a major discussion point at the most recent Medicare Evidence Development and Coverage Advisory Committee meeting, while evidence on the impact of percutaneous coronary intervention, SAVR, and TAVR volumes on TAVR outcomes was further investigated. As part of their efforts, the professional societies recently updated their consensus document to emphasize the importance of maintaining some volume requirements for TAVR while also shifting the focus to more direct measures of quality of care (18). However, the relationship between hospital SAVR volume on TAVR outcomes, which is very germane in the current era of TAVR, remains unclear. In this study, we sought to determine whether hospital volume of SAVR was associated with corresponding TAVR outcomes. We hypothesized that increasing SAVR volume would predict better TAVR outcomes.

METHODS

STUDY POPULATION. We examined inpatient records using the Medicare Provider Analysis Review and Master Beneficiary Summary File data for all Medicare fee-for-service beneficiaries who underwent AVR procedures between January 1, 2012, and December 31, 2015. We used relevant International Classification of Disease codes for SAVR and TAVR to query the CMS inpatient claims file (Online Table S1). Records for which these procedures were associated with diagnosis-related groups other than 216 to 221 (International Classification of Diseases-9th Revision-Clinical Modification) or 306 and 307 (International Classification of Diseases-10th Revision-Clinical Modification) were sequestered from this study. The master file included a total of 250,877 unique claims. To facilitate longitudinal follow-up, subjects who had more than 1 month of health maintenance organization (HMO) coverage were excluded, resulting in 208,400 unique claims of beneficiaries not enrolled in an HMO at any point during the study years. Concomitant coronary artery bypass grafting surgery and other heart valve or other major open heart procedures were excluded, as were secondary or subsequent admissions for AVR (Online Figure S1). This study was approved by our Institutional Review Board, and the requirement to obtain informed consent was waived.

DATA COLLECTION AND DEFINITIONS. Pre-operative comorbidities and chronic conditions were derived from the chronic conditions file, using coded diagnoses and procedures in the year prior to surgery. These covariates were chosen on the basis of their comparability with the Society of Thoracic Surgeons risk factors (19), inclusion in the Charlson score (20), potential for confounding with our outcomes of interest, and clinical judgement (Online Table S1). Major bleeding was defined as post-procedural bleeding or the presence of any of the following not listed as present on admission: hemorrhage, hematemesis, gastrointestinal bleeding, acute post-hemorrhage anemia, adverse anticoagulation reaction (excluding heparin-induced thrombocytopenia), and hemorrhage due to anticoagulation, epistaxis, cardiovascular bleeding, or pulmonary bleeding/hemoptysis.

OUTCOMES OF INTEREST. Our primary outcomes of interest included 30-day and 1-year survival following TAVR. Survival was calculated in days from the procedure date until death date or through December 31, 2017, if alive. Death of death was

TABLE 1 Characteristics and Comorbidities of Isolated Transcatheter Aortic Valve Replacement Patients According to Surgical Aortic Valve Replacement Volume Groups

	Group 1 (10–99 SAVRs/Year) (n = 9,324)	Group 2 (100–199 SAVRs/Year) (n = 15,298)	Group 3 (200–299 SAVRs/Year) (n = 9,828)	Group 4 (≥300 SAVRs/Year) (n = 8,517)	p Value
Age, yrs	82.8 ± 7.4*	82.8 ± 7.4	82.7 ± 7.5	83.3 ± 7.5	0.001
Age ≥85 yrs	4,409 (47.3)*	7,319 (47.8)*	4,607 (46.9)*	4,342 (51.0)	0.001
White race	8,730 (93.6)	14,363 (93.9)	9,297 (94.6)	8,039 (94.4)	0.001
Female	4,565 (49.0)*	7,214 (47.2)	4,670 (47.5)	4,042 (47.5)	0.025
Dyslipidemia	8,045 (86.3)*	13,390 (87.5)*	8,550 (87.0)*	7,590 (89.1)	0.001
Hypertension	8,986 (96.4)	14,790 (96.7)	9,475 (96.4)	8,243 (96.8)	0.327
Diabetes mellitus	4,164 (44.7)*	6,992 (45.7)	4,455 (45.3)	3,951 (46.4)	0.051
Peripheral vascular disease	88 (0.9)	124 (0.8)	77 (0.8)	69 (0.8)	0.327
Anemia	6,545 (70.2)*	10,856 (71)*	6,992 (71.1)*	6,339 (74.4)	0.001
COPD	3,472 (37.2)*	5,724 (37.4)*	3,556 (36.2)*	3,047 (35.8)	0.009
Chronic kidney disease without dialysis	4,748 (50.9)	7,908 (51.7)	5,067 (51.6)	4,367 (51.3)	0.734
Coronary artery disease	20 (0.2)	30 (0.2)	22 (0.2)	15 (0.2)	0.716
Atrial fibrillation	3,397 (36.4)*	5,796 (37.9)*	3,841 (39.1)	3,310 (38.9)	0.001
Ischemic heart disease	8,832 (94.7)	14,667 (95.9)	9,307 (94.7)	8,211 (96.4)	0.001
Previous myocardial infarction	544 (5.8)	963 (6.3)	611 (6.2)*	477 (5.6)	0.115
Congestive heart failure	7,700 (82.6)*	13,123 (85.8)*	8,571 (87.2)*	7,553 (88.7)	0.001
Liver disease	153 (1.6)	265 (1.7)	172 (1.8)	169 (2.0)	0.001
Home O_2	44 (0.5)	75 (0.5)	45 (0.5)	27 (0.3)	0.001
Charlson score	6 (5–7)	6 (6–7)	6 (6–7)	6 (6–7)	0.001
History of Alzheimer's disease	296 (3.2)	496 (3.2)	335 (3.4)	288 (3.4)	0.764
History of depression	1,980 (21.2)*	3,048 (19.9)*	2,052 (20.9)	1,658 (19.5)	0.039
Prior PCI	1,717 (18.4)	3,140 (20.5)	1,972 (20.1)	1,754 (20.6)	0.001
Prior CABG	1,665 (17.9)	2,974 (19.4)	1,938 (19.7)	1,732 (20.3)	0.001

Values are mean ± SD, n (%), or median (interquartile range). *Statistically significant on the basis of the Wald chi-square test when compared pairwise with the reference group of very high SAVR volume (≥300 cases/yr).

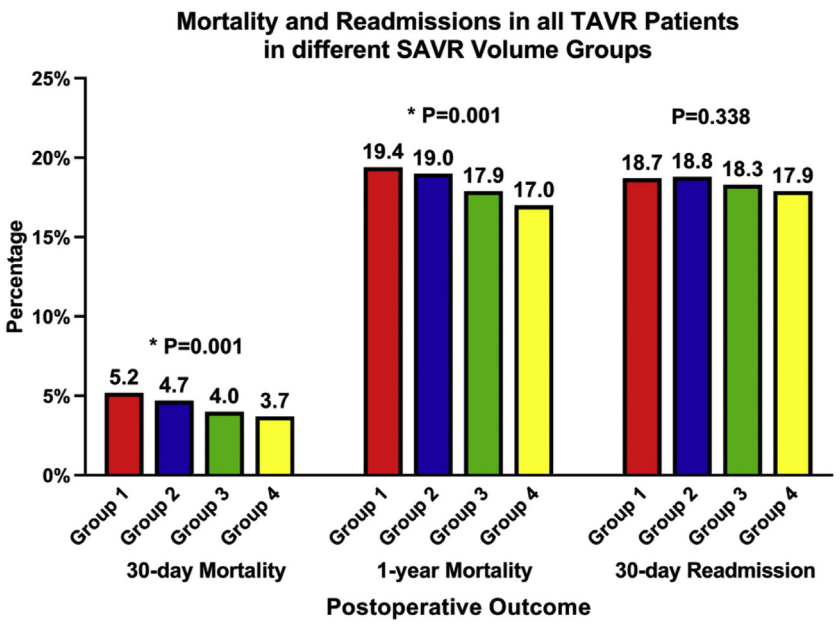
CABG = coronary artery bypass grafting; COPD = chronic obstructive pulmonary disease; PCI = percutaneous coronary intervention; SAVR = surgical aortic valve replacement.

provided from the National Death Index. Secondary outcomes were obtained from the CMS inpatient file and included acute kidney injury, permanent stroke, permanent pacemaker implantation, hospital and intensive care unit length of stay, discharge to a skilled nursing facility, and early reoperation rates, defined as redo TAVR within 30 days of the index procedure date.

STATISTICAL ANALYSES. For comparative analysis, hospital SAVR experience was stratified into 4 groups on the basis of overall distribution and according to the annual mean SAVR procedures over all 4 years, after ensuring that hospital decile ranks for SAVR cases had remained stable over the study period (Online Figures S2 and S3). To ensure reliable estimates, data from centers that did not perform at least 10 annual SAVR procedures and at least 1 annual TAVR procedure were sequestered. Continuous variables were tested for distribution and compared using analysis of variance for normally distributed variables, or Kruskal-Wallis 1-way analysis of variance if not normally distributed, and are presented as mean ± SD or median (interquartile range), as appropriate. Binary variables are presented as number and percentage and were compared using chi-square tests with Bonferroni correction for multiple comparisons. Temporal trends in total AVR and annual case volumes of TAVR within each SAVR group were assessed using the Cochrane-Armitage trend test.

Logistic regression analysis was conducted to evaluate risk-adjusted 30-day and 1-year mortality rates. Thirty-day mortality was also evaluated using generalized linear mixed models, using institution as the source of random effects, to account for differences in baseline characteristics and clustering of patients within hospitals. Longitudinal survival was assessed using a forward-entry Cox proportional hazards model. Because covariates were identified in part by examining the previous year's claims, the Cox model excluded records from 2012. Variables evaluated for all logistic regression or Cox models include

FIGURE 1 Comparison of Post-Operative Mortality and Readmissions After Transcatheter Aortic Valve Replacement According to Different Surgical Aortic Valve Replacement Volume Groups



Group 1 includes <100 surgical aortic valve replacement (SAVR) cases/year, group 2 includes 100 to 199 SAVR cases/year, group 3 includes 200 to 299 SAVR cases/year, and group 4 includes 300 or more SAVR cases/year. Unadjusted 30-day mortality and 1-year mortality were significantly higher in group 1 compared with groups 3 and 4. There was no statistical difference in unadjusted 30-day readmissions between the groups.

all those presented in **Table 1** and Online Table S1. An interaction term for surgery year and volume quintile was entered in all models to control for confounding due to institutional experience changes over time.

To assess the association between SAVR volume and TAVR volume, we first examined the correlation and partial correlation, controlling for institution. We found that both estimates were nearly identical (Pearson R = 0.726; by partial correlation = 0.725) suggesting that the correlation between the 2 variables (SAVR volume and TAVR volume) was nearly completely independent of the individual institution itself. Furthermore, given such a powerful predictive correlation between SAVR volumes and TAVR volumes, and the fact that up to 65% of the variability in TAVR volume was predicted by SAVR volume, we elected not to adjust for TAVR volumes in our regression models, because in doing so, we would violate the independence of observations assumption, among other flaws.

We also performed sensitivity analysis by including HMO patients, transfemoral approach TAVR patients only, and TAVR era before and after 2014 (to reflect U.S. Food and Drug Administration approval of TAVR in high-risk and intermediate-risk patients). The p values are presented, with a 2-sided p value < 0.05 as the criterion of significance. All analyses were conducted using SPSS version 23.0 (IBM, Armonk, New York) or R version 3.4.1 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

PATIENT CHARACTERISTICS. A total of 65,757 SAVR and 42,967 TAVR admissions were evaluated from 1,208 hospitals (Online Figures S2 and S3). Baseline characteristics for the 4 SAVR groups are listed in **Table 1**. Group 1 (10 to 99 SAVR cases/year) consisted of 9,234 TAVR patients (21.7%), group 2 (100 to 199 SAVR cases/year) consisted of 15,298 TAVR patients (35.6%), group 3 (200 to 299 cases/year) consisted of 9,828 TAVR patients (22.9%), and group 4 (≥300 cases/year) consisted of 8,517 TAVR patients (19.8%). The majority of the differences between the various groups were nominally statistically significant. In general, patients in groups 3 and 4 exhibited worse baseline characteristics than those in groups 1 and 2. The greatest baseline differences between group 4 and group 1 were in the proportion of patients

who were 85 years or older (51% vs. 47.3%), with atrial fibrillation (38.9% vs. 36.4%), ischemic heart disease (96.4% vs. 94.7%), and congestive heart failure (88.7% vs. 82.6%, respectively; $p < 0.05$ for all). Baseline characteristics by surgery year for each of the SAVR groups are summarized in Online Tables S2 to S5.

POST-OPERATIVE OUTCOMES. The transfemoral approach was used more frequently in group 4 (89.3%) compared with group 1 (86.9%) (Online Table S6). In group 4, the incidence of permanent pacemaker implantation (8.1% vs. 5.7%), major bleeding (17.7% vs. 16.4%), and early reoperation (0.3% vs. 0.1%) were significantly higher compared with group 1 ($p < 0.05$ for all). Although there was no clinical difference in median intensive care unit and hospital length of stay between the groups, a higher proportion of patients in group 4 were discharged to skilled nursing facilities compared with those in group 1 (27.4% vs. 26.9%; $p = 0.001$). In general, unadjusted 30-day mortality after TAVR was significantly higher in group 1 versus groups 3 and 4. The unadjusted 30-day TAVR mortality rates in groups 1, 2, 3, and 4 were 5.2%, 4.7%, 4.0%, and 3.7%, respectively ($p = 0.001$) (**Figure 1**).

ASSOCIATION BETWEEN SAVR VOLUME AND TAVR OUTCOMES. We observed an association between SAVR volume and TAVR outcomes at 30 days and 1 year. Risk-adjusted 30-day and 1-year mortality and overall all-cause mortality are shown in **Table 2**. Compared with group 4, the 30-day risk-adjusted odds ratios were 1.32 (95% confidence interval: 1.18 to 1.47) for group 1, 1.25 (95% confidence interval: 1.12 to 1.39) for group 2, and 1.08 (95% confidence interval: 0.82 to 1.25) for group 3. When controlling for age, race, and sex, the adjusted survival differences in TAVR outcomes persisted at 1 year post-procedure (Online Tables S7 to S9). All relevant statistical interaction terms were tested within the model, and none proved statistically significant. In our multivariate Cox proportional hazards model, groups 1 and 2 had a 0.07- and 0.06-fold higher risk for all-cause mortality compared with group 4 (**Figure 2**).

TEMPORAL TRENDS IN VOLUME AND OUTCOMES. Annual TAVR volume increased from 6,427 cases in 2012 to 23,209 cases in 2015, a 261% rate of growth (Online Figure S4). The ratio of annual TAVR volume to annual SAVR volume increased during the study period. There was also temporal variability in annual TAVR volumes in the different SAVR groups (Online Figure S5). Likewise, we observed temporal decreases in annual unadjusted 30-day TAVR mortality in all SAVR groups (Online Figure S6).

TABLE 2 Surgical Aortic Valve Replacement Volume Intergroup Comparisons of Risk-Adjusted Estimates of Mortality in Isolated Transcatheter Aortic Valve Replacement Patients

	Adjusted Outcome		
	Effect Estimate	95% CI	p Value
All-cause mortality			
SAVR volume (reference: ≥300 cases/yr or group 4)	HR: 1.000	—	0.001
Group 1 vs. group 4	HR: 1.071	1.031–1.112	0.001
Group 2 vs. group 4	HR: 1.057	1.007–1.109	0.026
Group 3 vs. group 4	HR: 1.051	1.015–1.089	0.006
30-day mortality			
SAVR volume (reference: ≥300 cases/yr or group 4)	OR: 1.000	—	0.001
Group 1 vs. group 4	OR: 1.317	1.182–1.467	0.001
Group 2 vs. group 4	OR: 1.246	1.119–1.387	0.001
Group 3 vs. group 4	OR: 1.075	0.923–1.252	0.353
1-yr mortality			
SAVR volume (reference: ≥300 cases/yr or group 4)	OR: 1.000	—	0.001
Group 1 vs. group 4	OR: 1.145	1.078–1.216	0.001
Group 2 vs. group 4	OR: 1.125	1.062–1.191	0.001
Group 3 vs. group 4	OR: 1.078	0.997–1.166	0.353

Adjusted all-cause mortality on the basis of multivariate Cox regression model. Adjusted 30-day and 1-yr mortality on the basis of multivariate logistic regression models. Details of each model are summarized in Online Tables S8 to S10. Group 1 includes <100 SAVR cases/yr, group 2 includes 100 to 199 SAVR cases/yr, group 3 includes 200 to 299 SAVR cases/yr, and group 4 includes 300 or more SAVR cases/yr.

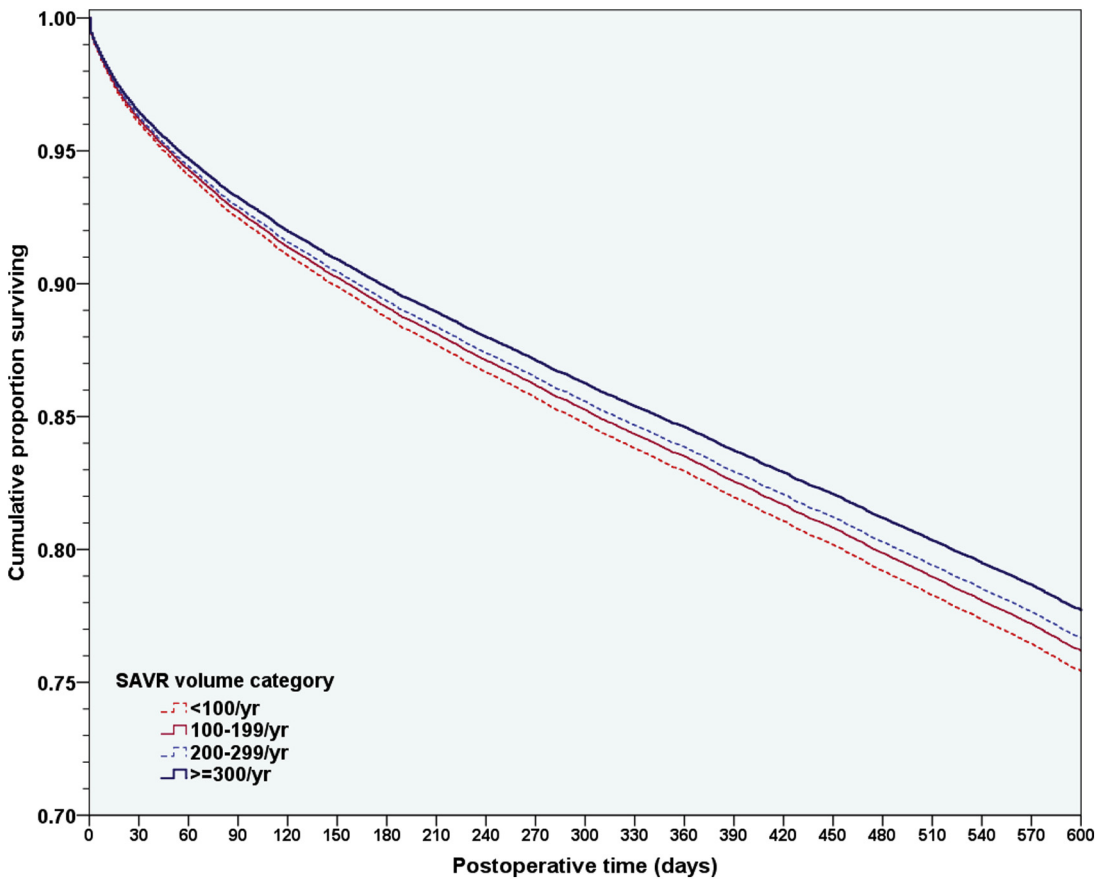
CI = confidence interval; HR = hazard ratio; OR = odds ratio; SAVR = surgical aortic valve replacement.

SUBGROUP AND SENSITIVITY ANALYSIS. The subgroup analysis in excluded HMO patients showed results that were consistent with our main findings, although the effect estimates were attenuated (Online Table S10). We further stratified group 1 into <50 SAVR cases/year (1,146 TAVR patients [3%]) and 50 to 99 SAVR cases/year (7,569 TAVR patients [20%]). Both these groups had similar baseline characteristics and unadjusted 30-day mortality (7.7% vs. 7.8%), and our overall outcomes did not change (Online Table S11, Online Figure S7). In our sensitivity analysis of transfemoral TAVR patients only, our results remained robust (Online Figure S8, Online Tables S12 and S13). Similar findings were observed when looking at surgical era in our time-dependent analysis (Online Figure S9). Finally, although the random effects from the institutions were small in our generalized liner mixed model, the fixed effects of SAVR volume on TAVR outcomes persisted (Online Table S14).

DISCUSSION

Current criteria for the accreditation of TAVR centers remain an area of ongoing debate, together with a paucity of robust data examining the impact of hospital SAVR volume on TAVR outcomes. Understanding this intricate relationship is crucial as CMS re-examines minimum volume requirements in its NCD for TAVR. This nationally representative study

FIGURE 2 **Adjusted Cox Survival Curves for Isolated Transcatheter Aortic Valve Replacement Patients, Stratified by Hospital Surgical Aortic Valve Replacement Volume**

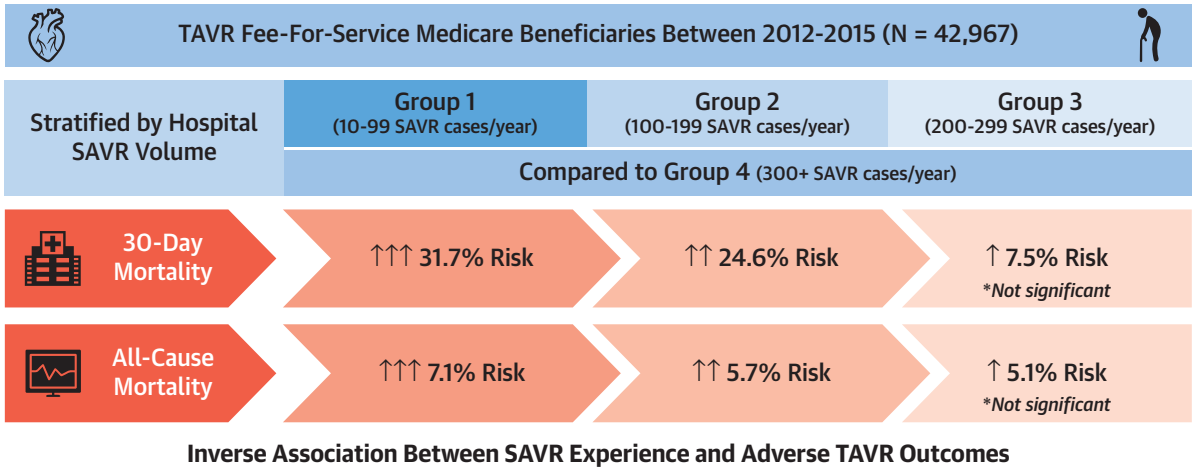


Group 1 includes <100 surgical aortic valve replacement (SAVR) cases/year, group 2 includes 100 to 199 SAVR cases/year, group 3 includes 200 to 299 SAVR cases/year, and group 4 includes 300 or more SAVR cases/year. Groups 1 and 2 are associated with significantly higher risk for all-cause mortality compared with group 4 (the reference group).

demonstrated that SAVR volume alone was an independent predictor of mid-term TAVR outcomes, which persisted in the risk-adjusted analyses. This study also highlighted an inverse association between hospital SAVR experience and adverse TAVR outcomes, which was pronounced beyond 100 SAVR cases. In our sensitivity analysis, our findings remained robust even after accounting for HMO patients, patients undergoing transfemoral TAVR only, and era of surgery (i.e., 2014). These findings not only shed light on a lingering question of the influence of SAVR volume on TAVR outcomes but also emphasize the importance of sustaining a viable SAVR program within the heart team to achieve improved TAVR outcomes (**Central Illustration**).

Several recent studies have demonstrated a strong inverse relationship between TAVR volume and outcomes (14,16). For instance, a recent analysis of the Society of Thoracic Surgeons/American College of Cardiology TVT (Transcatheter Valve Therapy) Registry found that increasing TAVR site volume was associated with lower in-hospital risk-adjusted mortality, vascular complications, and bleeding, which appeared to persist up to 400 cases (14). Similar relationships between procedure volume and outcomes have been reported for mitral and aortic valve surgery (21–23). However, the relationship between SAVR volume and TAVR outcomes has not been well elucidated. A recent study, which also used the CMS claims data, found that hospital SAVR volume alone was not associated with better TAVR outcomes but rather the combination of high TAVR and SAVR volumes (24). Our findings contradict their findings in that SAVR volume was directly associated with TAVR

CENTRAL ILLUSTRATION **Association Between Surgical Aortic Valve Replacement Volume and Transcatheter Aortic Valve Replacement Outcomes**



Inverse Association Between SAVR Experience and Adverse TAVR Outcomes

Hirji, S.A. et al. J Am Coll Cardiol Intv. 2020;13(3):335–43.

SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement.

outcomes. The discrepancy in our findings could be attributed to a few reasons. First, their study included HMO patients, which could have introduced bias and uncertainty in their estimation of longitudinal outcomes by design. Even though we excluded HMO patients from our study, our findings remained robust after including HMO patients in our sensitivity analysis. Second, to avoid confounding and reduce bias in interpretation, we only included isolated cases of TAVR procedures that were tied to specific diagnosis-related group codes during the index hospitalization. Finally, unlike their study which used a binary cutoff of 97 SAVR cases, we examined the impact of SAVR volumes beyond 100 and found that the association was more pronounced, which persisted in our adjusted analysis.

Our analysis is unique and further adds to the available research by examining the relationship between the 2 surgical procedures (SAVR and TAVR) with different teams involved. How well both these teams interact in the context of a multidisciplinary heart team is essential and is in part one of the factors we believe has contributed to the overall success of TAVR programs nationally. The ideal heart team also includes anesthesia, intensivists, nursing staff members, and specialist surgical and medical teams, which work closely with cardiac surgeons and cardiologists. Together, these teams provide an avenue for promoting interdisciplinary dialogue, the creation of robust support networks, and the dissemination of surgical and nonsurgical knowledge as it pertains to patient care. We suspect that this intricate but important interaction between SAVR expertise and TAVR experience among the heart team stakeholders most likely explains the observed inverse association between SAVR volume and TAVR outcomes in our study. The importance of this concept was shown by the recent NCD to continue with the heart team requirement. Thus, relationship with SAVR volume may indicate that surgeon involvement in the heart team has an effect. However, this study was not designed to compare outcomes between non-heart team systems and those using heart teams.

This study has important practice and policy implications. In 2012, CMS proposed minimum volume requirements as part of its NCD and for reimbursement purposes. For example, one of the requirements was to have centers perform a minimum of 50 SAVR procedures annually. More recently, some clinicians have proposed the revision of existing NCD guidelines because of two important concerns. First, there is concern that SAVR volumes could decrease further, which might make it difficult to maintain TAVR accreditation, especially at low-volume centers. Second, minimum requirements could also pose a barrier to entry for new centers interested in performing

TAVR that cannot meet SAVR requirements. Despite the ongoing debate surrounding the importance of heart teams in patient management, as some centers are considering transitioning into TAVR centers of excellence, the utility of these teams cannot be underestimated, even though CMS revised the minimum volume requirements in the recent NCD. Nonetheless, our findings underscore the integral role of cardiac surgeons within the heart team and essentially imply that SAVR experience (through accumulating volume) closely determines the success of the TAVR program. Our findings are also pertinent to both existing hospitals already performing TAVR and new hospitals trying to establish a new TAVR practice. Hence, we strongly believe that continuing to invest resources and personnel to both the SAVR and TAVR programs will be important for overall TAVR outcomes.

Although our findings did not reveal an exact cutoff for a minimal SAVR volume requirement for institutions in the context of TAVR, our study provides useful data to help inform physicians, patients, and CMS policy makers as we continue to seek to further improve patient mortality and morbidity. As previously pointed out, "TAVR is more than just a procedure. It is a party of a comprehensive treatment program that embraces team-based care by experienced clinicians with shared decision marking" (25). As we anticipate additional growth of TAVR in the years ahead in light of recent Food and Drug Administration approval in low-risk patients (12,26), it becomes essential to monitor device and procedural performance, establish quality assurance and improvement initiatives, and importantly ensure successful integration of new TAVR programs especially, at low-volume centers. In this regard, quality control for TAVR procedures, especially given intersite variability (27) in outcomes, will be key through ongoing collaboration among TAVR device manufactures, professional societies, the Food and Drug Administration, and CMS. Likewise, minimal SAVR volume thresholds will provide a framework to reliably benchmark outcomes over time in the setting of existing hospital practice variations to ensure the long-term success of emerging TAVR technologies.

STUDY LIMITATIONS. First, the CMS database is a hospital claims database without access to individual medical records and is subject to the shortcomings of other administrative datasets. Coding-related inconsistencies could have resulted in overestimation or underestimation in our findings, although we adjusted for several confounders. The CMS data preclude detailed assessment of patient presentation, procedural and echocardiographic details, and Society of Thoracic Surgeons risk scores. Because of the nature of the database, frailty was difficult to assess formally. Given that the study period ended in 2015, and the fact that TAVR is a very dynamically changing field, it is possible that our findings may not adequately reflect current clinical practice and outcomes. Thus, our findings must be interpreted with context. Furthermore, although our analysis was based on a large number of patients, the results cannot be extrapolated to those who did not meet our inclusion criteria (e.g., HMO patients, those undergoing concomitant coronary artery bypass grafting or other valvular surgery).

CONCLUSIONS

Total hospital SAVR volume appears to be correlated with TAVR outcomes, with higher 30-day and 1-year mortality observed at low-volume centers. These data support the importance of a viable surgical program within the heart team, and the use of minimum SAVR hospital thresholds may be considered as an additional metric for TAVR performance.

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PERSPECTIVES

WHAT IS KNOWN? There exists a volume-outcome relationship for TAVR.

WHAT IS NEW? There appears to be an inverse association between hospital SAVR experience and adverse TAVR outcomes, with higher 30-day and 1-year mortality observed at low-volume centers.

WHAT IS NEXT? Although the importance of a viable surgical program within the heart team cannot be underestimated, further research on the use of minimum SAVR hospital thresholds should be explored as an additional metric to evaluate TAVR performance.

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KEY WORDS aortic valve replacement, heart valve prosthesis

APPENDIX For supplemental tables and figures, please see the online version of this paper.