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Impact of Transcatheter Technology on Surgical Aortic Valve Replacement Volume, Outcomes, and Cost

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Background. **Transcatheter aortic valve replacement (TAVR) represents a disruptive technology that is rapidly expanding in use. We evaluated the effect on surgical aortic valve replacement (SAVR) patient selection, outcomes, volume, and cost.**

Methods. **A total of 11,565 patients who underwent SAVR, with or without coronary artery bypass grafting (2002 to 2015), were evaluated from the Virginia Cardiac Services Quality Initiative database. Patients were stratified by surgical era: pre-TAVR era (2002 to 2008, n = 5,113), early-TAVR era (2009 to 2011, n = 2,709), and commercial-TAVR era (2012 to 2015, n = 3,743). Patient characteristics, outcomes, and resource utilization were analyzed by univariate analyses.**

Results. **Throughout the study period, statewide SAVR volumes increased with median volumes of pre-TAVR: 722 cases/year, early-TAVR: 892 cases/year, and commercial-TAVR: 940 cases/year (p = 0.005). Implementation of TAVR was associated with declining Society of Thoracic Surgeons predicted risk of mortality among SAVR patients (3.7%, 2.6%, and 2.4%; $p < 0.0001$), despite increasing rates of comorbid disease. The mortality rate was lowest in the current commercial-TAVR era (3.9%, 4.3%, and 3.2%; p = 0.05), and major morbidity decreased throughout the time period (21.2%, 20.5%, and 15.2%; $p < 0.0001$). The lowest observed-to-expected ratios for both occurred in the commercial-TAVR era (0.9 and 0.9, respectively). Resource utilization increased generally, including total cost increases from $42,835 to $51,923 to $54,710 ($p < 0.0001$).**

Conclusions. **At present, SAVR volumes have not been affected by the introduction of TAVR. The outcomes for SAVR continue to improve, potentially due to availability of transcatheter options for high-risk patients. Despite rising costs for SAVR, open approaches still provide a significant cost advantage over TAVR.**

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There are three main forces with tremendous potential to increase the number of patients who are eligible for aortic valve replacement. The aging population in the United States is expected to expand the number of Americans older than age 65 from 44.7 million in 2013 to 98 million by 2060 [1]. The prevalence of aortic stenosis in this population ranges from 1.3% to 9.8%, increasing with age [2]. Yet owing to perceived risk, 30% to 40% of symptomatic patients are not referred for surgical intervention [3]. Finally, there is increasing evidence regarding the poor outcomes of patients with asymptomatic aortic stenosis managed medically that may benefit from expanded surgical indications for replacement [4].

Transcatheter aortic valve replacement (TAVR) has revolutionized the treatment of aortic stenosis, providing a safe and less invasive alternative, albeit with limited mid- and long-term follow-up. In addition to being the

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Abbreviations and Acronyms

AI	= aortic insufficiency
BMI	= body mass index
CABG	= coronary artery bypass grafting
CCU	= coronary care unit
CI	= confidence interval
CLD	= chronic lung disease
CMS	= Centers for Medicare & Medicaid Services
CPB	= cardiopulmonary bypass
CVA	= cerebrovascular accident
ICU	= intensive care unit
IPPS	= Inpatient Prospective Payment Sample
IQR	= interquartile range
LVEF	= left ventricular ejection fraction
MACRA	= Medicare Access and Children's Health Insurance Program Reauthorization Act
MR	= mitral regurgitation
NA	= not available
O:E	= observed-to-expected ratio
OR	= odds ratio
OT	= occupational therapy
PARTNER B	= Placement of Aortic Transcatheter Valves, Cohort B
PCI	= percutaneous coronary intervention
pRBC	= packed red blood cells
PROM	= predicted risk of mortality
PROMM	= predicted risk of mortality or major morbidity
PT	= physical therapy
SAVR	= surgical aortic valve replacement
STS	= The Society of Thoracic Surgeons
TAVR	= transcatheter aortic valve replacement
VCSQI	= Virginia Cardiac Services Quality Initiative

standard of care for inoperable patients with a reasonable life expectancy, TAVR is now approved for both moderate- and high-risk patients due to noninferiority compared with surgical aortic valve replacement (SAVR) [5]. There is conflicting evidence regarding outcomes in low-risk patients, and multiple industry-sponsored trials are underway to address this population [6–9]. More mature transcatheter markets suggest that future increases in aortic valve replacement volume may be entirely treated by transcatheter procedures, directly competing with SAVR [10].

Although recent data have suggested that surgical volume continues to increase with the introduction of TAVR, contemporary and large regional data are limited [11, 12]. There continue to be many unknowns regarding TAVR, including how adoption will proceed at smaller institutions, future cost changes, and long-term durability. With the rapidly changing landscape, our study aims to identify the effect that commercialization of TAVR has had on SAVR volume, patient risk profiles, and outcomes.

Patients and Methods

Patient Data

The Virginia Cardiac Services Quality Initiative currently includes 18 hospitals and cardiac surgical practices in the Commonwealth of Virginia that captures approximately 99% of adult cardiac surgical cases in the Commonwealth. Virginia Cardiac Services Quality Initiative clinical and cost data acquisition and matching has been described previously [13, 14]. Clinical data are collected from each participating institution using The Society of Thoracic Surgeons (STS) data entry forms. The Virginia Cardiac Services Quality Initiative database pairs STS clinical data with hospital patient discharge information. Clinical variables use standard STS definitions, including for operative mortality (in-hospital and 30-day) and major morbidity (permanent stroke, renal failure, prolonged ventilation, deep sternal wound infection, and reoperation).

Patient records for isolated SAVR and SAVR with coronary artery bypass grafting (CABG; n = 11,565) were identified from January 1, 2002, through June 30, 2016, excluding patients with endocarditis. Patients were stratified for analysis by surgical era: pre-TAVR era (2002 to 2008, n = 5,113), early-TAVR era (2009 to 2011, n = 2,709), and commercial-TAVR era (2012 to 2015, n = 3,743). Hospitals were classified as TAVR performing if they performed the procedure in the early-TAVR era. Six hospitals met this criterion, and only since 2015 have other hospitals begun performing TAVR. For cost analyses, patients were excluded for missing or zero total cost. Patients in the first 6 months of 2016 (n = 478) were included only in the case volume analysis after extrapolating for the rest of the year. The University of Virginia Institutional Review Board granted exemption due to lack of Health Insurance Portability and Accountability Act patient identifiers (IRB #19457).

Cost Data

STS clinical data are matched with Uniform Billing-04 files, and before 2013 was matched with Uniform Billing-92 files, with a successful matching rate of 99%. These files are used to calculate charges that are classified by International Classification of Diseases, Ninth Revision (ICD-9)–based revenue codes. Estimated costs are derived from publicly available cost-to-charge ratios submitted to the Centers for Medicare & Medicaid Services (CMS) by each institution. The cost and charge data are then categorized by phase of care for analysis (total stay, diagnostics, interventions, general care, other), as summarized in Supplemental Table 1. To account for medical specific inflation, cost data were adjusted to 2015 dollars using the market basket for the CMS Inpatient Prospective Payment System.

Statistical Analysis

Baseline characteristics, operative trends, and short-term outcomes were analyzed by univariate analysis. The χ^2 test was used for categoric variables and the Kruskal-Wallis test for continuous variables. Categoric data were