#### **BRIEF REPORT**

# Outcomes in Older Patients Undergoing Surgical Aortic Valve Replacement With Concomitant Procedures



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espite the expanded use of transcatheter aortic valve replacement (TAVR), surgery remains an important treatment option for patients with aortic valve disease, particularly when accompanied by multivalvular disease, ascending aortic dilation, or extensive coronary artery disease. Although transcatheter therapies have been used in combination with percutaneous coronary intervention<sup>2</sup> and with mitral and tricuspid valve interventions, these combinations have not been systematically compared with surgery. A recent randomized trial in patients with aortic stenosis and multivessel coronary artery disease demonstrated that TAVR + percutaneous coronary intervention led to superior outcomes compared with SAVR + coronary

## What is the clinical question being addressed?

What are the outcomes of SAVR with and without concomitant procedures in elderly patients?

### What is the main finding?

Nearly 50% of SAVR patient undergo concomitant procedures, which are associated with high short- and long-term mortality. These findings should motivate rigorous investigation of alternative surgical and catheter-based approaches for these challenging patient subsets.

artery bypass graft surgery (CABG), driven mainly by reductions in all-cause mortality.<sup>2</sup> These findings suggest that such clinical trials are feasible and that long-standing assumptions regarding the optimal management of older patients with aortic valve disease and additional cardiac conditions should be reevaluated as novel treatment options emerge.

The Society of Thoracic Surgeons Adult Cardiac Surgery Database Operative Risk Calculator provides risk-based assessment of predicted 30-day mortality that varies by procedure.4 For example, the predicted 30-day mortality for a 75-year-old man with minimal comorbidities, stable angina, and severe aortic regurgitation is approximately 1.2% for isolated aortic valve replacement but increases to 2.8% for SAVR + CABG. However, risk scores for SAVR with concomitant mitral or tricuspid valve procedures are not available, and decisions about these options are generally left to the local Heart Team because data on intermediate- and long-term outcomes are limited. To better understand the outcomes of patients undergoing concomitant procedures with SAVR as well as the potential role of transcatheter therapies in patients with multivalvular disease, an inventory of outcomes associated with aortic valve replacement and concomitant procedures is needed.

We used data from the Fee-for-Service CMS database to identify patients who underwent SAVR

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Kundi et al

FIGURE 1 Baseline Characteristics and Kaplan-Meier All-Cause Mortality Curves Among Patients Undergoing Isolated SAVR and SAVR With **Concomitant Procedures** Kaplan Meier Mortality Rate, % Number Age % Women % Frail 30-Day One Year Five Year Isolated SAVR 56,354  $73 \pm 5$ 41.1 18.7 2.3 5.6 19.1 3.2 18.0 SAVR + Aorta Replacement 9.386 72 + 532.8 15.4 6.6 39.6 SAVR + TV Intervention 333  $74 \pm 6$ 50.2 39.0 7.5 19.2 SAVR + MV Intervention 5,467  $74 \pm 6$ 52.2 7.7 17.8 37.5 36.1 SAVR + CABG 26.4 36,811  $75 \pm 6$ 24.6 18.1 3.6 8.5 SAVR + CABG + Aorta Replacement 2,568  $73 \pm 5$ 22.3 16.1 7.6 12.8 26.1 SAVR + CABG + MV Intervention 1,837 75 ± 6 39.1 35.4 11.7 24.7 49.1 100 All-Cause Mortality (%) 75 50 25 0 2 3 4 5 1 2 3 5 Years SAVR + TV Intervention - SAVR + CABG + MV Intervention SAVR + MV Intervention SAVR + CABG + Aorta Replacement - SAVR + Aorta Replacement - SAVR + CABG Isolated SAVR Isolated SAVR CABG = coronary artery bypass surgery; MV = mitral valve; SAVR = surgical aortic valve replacement; TV = tricuspid valve.

between January 1, 2017 and December 31, 2022. To minimize confounding from complex or reoperative surgical scenarios, we included only those patients for whom SAVR was listed as the principal procedure (02RF0\*) and excluded patients with a history of prior cardiac surgery, infective endocarditis, or acute coronary syndrome at the time of the index admission. Concomitant procedures were identified based on secondary International Classification of Diseases-10th Revision Procedure Coding System (ICD-10 PCS) codes and included CABG (0210\*, 0211\*, 0212\*, 0213\*), additional surgical valve interventions (mitral: 02RG0\*, 02QG0\*, tricuspid: 02RJ0\*, 02QJ0\*), and thoracic aorta (ascending/arch) replacement (02RX0\*). Frailty was assessed using the Hospital Frailty Risk Score, a validated tool based on administrative data, with Hospital Frailty Risk Score >5

indicating frailty.5 The key study outcome was allcause mortality by procedure type, which was estimated based on the Master Beneficiary Summary File and displayed as unadjusted Kaplan-Meier curves and Kaplan-Meier rates at 30 days, 1 year, and 5 years from the date of surgery. This study was approved by the Sterling Institutional Review Board with a waiver of informed consent for the retrospective analysis of deidentified data.

Among 112,756 patients undergoing SAVR as the primary procedure, 56,402 (50.0%) underwent a concomitant procedure, including 36,811 (32.6%) with SAVR + CABG, 5,800 (5.1%) with SAVR + mitral or tricuspid valve intervention, 9,386 (8.3%) with SAVR + replacement of the thoracic aorta, 2,568 (2.3%) with SAVR + CABG + replacement of the thoracic aorta, and 1,837 (1.6%) with SAVR + CABG +

additional valve intervention. Mean age ranged from 72-75 years depending on the condition. Compared with patients undergoing isolated SAVR, patients undergoing SAVR + CABG were less likely to be female, whereas patients undergoing SAVR + mitral valve intervention were more likely to be female. Frailty prevalence was 19.4% overall but varied by procedure type.

The median follow-up duration was 3.1 years (Q1-Q3: 1.3-4.6 years). The 30-day mortality rate for isolated SAVR was 2.3% but was substantially higher for patients undergoing concomitant CABG or any other valve intervention. Notably, 30-day mortality was 5-fold higher (11.7%) in patients undergoing SAVR + CABG + mitral valve intervention. With the exception of SAVR + thoracic aorta replacement, observed mortality rates were substantially higher across all concomitant procedures at both 1 year and 5 years. These differences were most striking for patients undergoing SAVR + MVR + CABG (1-year mortality rate: isolated SAVR 5.6% vs SAVR + CABG + mitral valve intervention 24.7%; 5-year mortality rate: 19.1% vs. 49.1%) (Figure 1).

Our findings differ from recent data from the PARTNER 3 (Placement of Transcatheter Aortic Valve 3) trial, which found no significant differences in mortality between isolated SAVR and SAVR + concomitant procedures.<sup>6</sup> However, that study focused exclusively on low-risk patients with severe aortic stenosis, whereas our cohort included all Medicare Fee-for-Service beneficiaries aged 65 and older regardless of predicted surgical mortality and included patients undergoing planned multivalve interventions (who were excluded from PARTNER 3). Our study thus provides complementary insights into the outcomes of SAVR + concomitant procedures in an older, higher-risk population and may help inform future evaluations of transcatheter approaches for multivalve disease.

This study has several important limitations. First, as with any analyses based on administrative claims data, our study lacked detailed clinical information such as echocardiographic findings, symptom burden, and functional status. Second, we restricted our study to patients with a primary ICD-10-PCS code for SAVR; nonetheless, unmeasured clinical factors such as valve morphology or coexisting conditions may still have influenced the surgical decisions. Third, procedural groupings were based on ICD-10-PCS codes, which may be subject to misclassification

and do not capture nuances in surgical technique or disease severity.

These findings have several important implications for both clinical care and future research. With the increasing use of TAVR to treat lower-risk and younger patients with aortic stenosis,7 patients requiring concomitant CABG or additional valve intervention represent an increasingly large proportion of elderly patients undergoing SAVR in current practice. By providing contemporary data on both short- and mid-term outcomes for these patients, our study helps to fill a critical knowledge gap that may inform both patients and their physicians considering these procedures. Given the relatively high mortality rates for these combined procedures, these data should motivate and inform future research on novel surgical and transcatheter approaches for these challenging patient subgroups. At a minimum, we believe that these findings provide a strong rationale for registries to assess outcomes for patients with aortic valve disease and concomitant coronary artery disease and/or multivalve disease, ultimately leading to focused randomized trials to inform clinical practice.

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Dr J. Popma is a former employee of Medtronic and reports nonvested equity in Medtronic. Dr Granada is the cofounder of Cephea Valve Technologies (Abbott) and CEO of the Cardiovascular Research Foundation. Dr Leon has received institutional research support from Edwards Lifesciences, Medtronic, Boston Scientific, and Abbott; and has received consulting/advisory board participation for Foldax, Anteris, JenaValve, Medinol, SoloPace, and Bain Capital. Dr George has received grant support from Medtronic, Boston Scientific, and Edwards Lifesciences; and has received consulting honoraria from Zimmer Biomet, Atricure, Neosurgery, Neptune Medical, Abbvie, Johnson & Johnson, Durvena, Boston Scientific, Edwards Lifesciences, Medtronic, Encompass Medical, Summus Medical, Abbott SJM, BCI, Xeltis, Innocardiac, and KIS Medical. Dr Latib has received research grant support from Concept Medical; and has received consulting fees/honoraria from Abbott, Boston Scientific, Edwards Lifesciences, Medtronic, Philips, Tioga, NeoChord, and Nyra. Dr A. Popma's spouse is a former employee of Medtronic and reports nonvested equity in Medtronic. Dr Cohen has received institutional research support from Abbott, Edwards Lifesciences, Boston Scientific, Philips, and Zoll Medical; and has received consulting income from Abbott, Edwards Lifesciences, Boston Scientific, Medtronic, and Elixir Medical. All other authors have reported that they have no relationships related to the contents of this paper to disclose

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