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Trends in isolated aortic valve replacement in the United States in the early phase of expansion of TAVR

Harun Kundi [a], David J. Cohen [b], Jordan B. Strom [a], Linda Valsdottir [a], Changyu Shen [a], Eunhee Choi [a], Jeffrey J. Popma [a], Robert W. Yeh [a,*]

[a] Richard A. and Susan F. Smith Center for Cardiovascular Outcomes Research, Division of Cardiovascular Medicine, Beth Israel Deaconess Medical Center, United States of America
[b] Saint Luke's Mid-America Heart Institute, Kansas City, MO, United States of America

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ABSTRACT

This study aimed to evaluate changes in volume, risk profile, and outcomes among elderly individuals undergoing isolated aortic valve replacement (AVR) after TAVR approval in the United States. Retrospective cohort study of patients ≥65 years old with at least one procedural code for isolated SAVR or TAVR among the Medicare beneficiaries between January 1, 2009 and December 31, 2014. A total of 137,563 hospitalizations for isolated AVR between 2009 and 2014 were included (SAVR: 102,968 [74.9%]; TAVR: 34,595 [25.1%]). Overall AVR volumes increased by 21.8% per year after TAVR introduction, compared with 2.3% prior ($p \ll 0.001$). Changes in SAVR volumes were similar both before and after TAVR introduction, (2.3% per year growth before vs. 2.1% after, $p = 0.24$). Although patient risk profiles increased among the AVR population (predicted 30-day mortality 4.0% in 2009 vs. 5.4% in 2014; p for trend =0.048), observed 30-day mortality (4.0% in 2009 vs. 3.9% in 2014; p for trend =0.96) and 1-year mortality (10.8% in 2009 to 12.2% in 2014; p for trend =0.069) rates remained stable. Among elderly U.S. patients enrolled in the Medicare, the introduction and the dissemination in the early phase of TAVR was associated with an expansion of AVR to high risk patients, without an observed reduction in the use of SAVR. This expansion was associated with similar mortality among all AVR patients, despite an increase in patient risk.

1. Introduction

Symptomatic severe aortic stenosis is associated with high mortality without treatment and is currently the most common reason for valve replacement in elderly Americans, occurring in an estimated 4.6% of individuals over age 75 [1,2]. While surgical aortic valve replacement (SAVR) has been the mainstay of treatment for decades, high operative mortality has historically precluded some from receiving treatment [3]. More recently, however, transcatheter aortic valve replacement (TAVR) has permitted an alternative treatment for patients with severe aortic valve stenosis, based on clinical trials demonstrating comparable or even superior results compared with SAVR among patients at extreme, high, intermediate and low risk for surgery [4–11].

While the number of patients undergoing TAVR now exceeds SAVR in the United States (U.S.) [12], data on contemporary trends in aortic valve replacement (AVR) remain limited. In particular, the extent to which the introduction of TAVR has influenced the profile and numbers of patients undergoing any form of AVR, whether surgical or transcatheter, in the U.S. has not been comprehensively evaluated. Specifically, the extent to which TAVR has simply displaced SAVR or, alternatively, allowed patients who were not previously being treated to undergo valve replacement in the U.S. has not been well-studied. Finally, the impact of the availability of TAVR on long-term mortality in patients with severe aortic stenosis is unknown. We sought to address these questions within a retrospective cohort study of Medicare beneficiaries undergoing isolated AVR over the past decade.

2. Methods

2.1. Study population

Medicare & Medicaid Services (CMS) Medicare Provider and Review (MedPAR) database utilized for this study is a 100% sample of administrative billing claims for inpatient hospitalizations [13,14]. Patients aged 65 and older were included in the study if they had at least one procedural code for SAVR (defined by International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM] codes 35.21 or 35.22) or TAVR (ICD-9-CM codes 35.05 for transfemoral or 35.06 for transapical) between January 1, 2009 and December 31, 2014 [15]. Patients who underwent concomitant valve or coronary artery bypass graft surgeries (defined in Supplemental Table 1) during the hospitalization for AVR were excluded from the study.

* Corresponding author at: Richard A. and Susan F. Smith Center for Cardiovascular Outcomes Research, Beth Israel Deaconess Medical Center, 375 Longwood Ave, Fourth Floor, Boston, MA 02215, United States of America.
E-mail address: ryeh@bidmc.harvard.edu (R.W. Yeh).

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2.2. Covariates and outcomes

Diagnosis codes corresponding to patient-level covariates were identified (Supplemental Table 1). Variables were ascertained from secondary diagnosis codes listed as "present on admission" during the hospitalization for AVR as well as from principal and secondary diagnosis codes from all hospitalizations for 1-year prior to procedure date. Because the number of codes contained within the CMS files increased after 2011, we used only the first 10 diagnosis codes for each patient to limit the potential for increasing comorbidity ascertainment over time [16].

The primary outcome was 30-day all-cause mortality as determined through linkage to the Medicare Denominator File. As well as, 1-year all-cause mortality was also determined through linkage to the Medicare Denominator File.

2.3. Statistical analysis

Continuous variables are presented as means and standard deviations (SD), and categorical variables are presented as frequencies and percentages. The study period was divided into pre-TAVR and post-TAVR periods based on the date of US first performed of TAVR on August 25, 2011. Tests for trend (Chi-squared for categorical and Non-parametric test for continuous variables) were used to assess for changes in covariates and outcomes in the entire cohort as well as in isolated TAVR or SAVR over time.

To assess volume changes, we first determined the number of total patients in Medicare Denominator File annually and then indexed volume measures to population size, with 2005 as the base year. Overall isolated AVR, SAVR and TAVR volumes (per 100,000 beneficiaries) were plotted over the study period. A piecewise linear model was used to separately examine trends in annualized procedural volumes for isolated AVR and SAVR, in which the change in slope between the pre-TAVR (before August 2011) and post-TAVR (after September 2011) periods was compared to evaluate for significance.

To further examine whether the extent to which patient risk profiles changed after TAVR introduction, we estimated the predicted risk of 30-day mortality with SAVR for each patient in the sample. Specifically, we used a generalized linear mixed effects model using a logit link, incorporating hospital site as a random effect, to predict the risk of 30-day mortality in the SAVR cohort between January 1, 2009 and August 25, 2011 (pre-TAVR period). Variables were selected for inclusion in the model by means of a stepwise selection algorithm, using a p-value for inclusion and for remaining in the model of ≪0.05. Finally, model variables and coefficients (presented in Supplemental Table 2) (derived in the pre-TAVR period) were used to estimate the predicted 30-day mortality (assuming treatment with SAVR) for each patient in the sample, as a measure of overall patient risk. The risk profiles of AVR patients were then compared across years. In order to examine trends in 30-day mortality, multivariable logistic regression models were built using all covariates to calculate expected 30-day mortality by year in the overall cohort and separately in the TAVR and SAVR cohorts.

Crude and predicted mortality were also compared across time in the overall cohort and separately in the TAVR and SAVR cohorts. All analyses were then repeated in subgroups defined according to age (≪75, 75–79, 80–84 and ≥85 years). All statistical analyses were performed in STATA version 15.0 (Stata Corporation, College Station, TX) and SAS version 9.4 (SAS Institute, Cary, NC) using a two-tailed alpha ≪0.05 to define statistical significance.

No extramural funding was used to support this work. The authors are solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the paper and its final contents. The study was approved by the institutional review board of Beth Israel Deaconess Medical Center with a waiver of informed consent for retrospective data analysis.

3. Results

A total of 305,921 hospitalizations during which AVR was performed were identified during the study period. After exclusion of 168,358 patients because of age ≪ 65 (N = 4397), concomitant valve surgery (N = 84,204), or coronary artery bypass grafting (N = 115,352), a total of 137,563 hospitalizations for isolated AVR were ultimately included in the analytic sample. Of these, 102,968 (74.9%) were for SAVR and 34,595 (25.1%) were for TAVR (Supplemental Fig. 1).

3.1. Volume trends

Population-standardized volumes for SAVR and TAVR volumes both increased after the introduction of TAVR (Fig. 1). While the growth rate of SAVR decreased slightly post-TAVR approval (2.1% per year) compared to prior (2.3% per year), this difference was not statistically significant (p = 0.24). Between 2011 and 2014, there was an increase in the rate of SAVR among those aged ≪80 (≪75 years-old: 12.6 to 14.8 per 100,000 beneficiaries per year; 75–79 years-old: 7.7 to 8.0) but not among those ≥80 years-old (80–84 years-old 7.3 to 6.3; ≥85 years-old 4.9 to 3.0). TAVR volumes (per 100,000 beneficiaries) increased in all age subgroups over time, with the largest increase in those older than 85 years-old (0.5 in 2011 to 13.8 in 2014) (Supplemental Fig. 2).

3.2. Trends in comorbidities

The mean age of AVR recipients increased significantly after the introduction of TAVR from 76.6 ± 6.7 years in 2009 to 79.0 ± 7.7 in 2014 (p for trend ≪0.001) (Table 1). Predicted 30-day mortality increased in the overall cohort from 4.0% in 2009 to 5.4% in 2014 (p for trend = 0.048) (Table 1). The largest increase in predicted 30-day mortality was observed in the ≥85 year-old subgroup (5.9% in 2009 to 6.6% in 2014; p for trend ≪0.001) (Fig. 2).

Among SAVR patients, predicted mortality decreased from 4.0% in 2009 to 2.9% in 2014 (p for trend =0.049) (Supplemental Table 3), as well as in all age subgroups, with the largest decline observed in the ≥85 year-old subgroup (5.9% in 2009 to 4.8% in 2014; p for trend ≪0.001) (Supplemental Fig. 3). Among TAVR patients, predicted mortality (assuming treatment with SAVR) remained stable from (6.7% in 2009 to 6.3% in 2014; p for trend = 0.54) (Supplemental Table 4).

3.3. Trends in outcomes

While 30-day crude mortality rates remained stable (4.0% in 2009 to 3.9% in 2014; p for trend = 0.96) in the overall AVR population, it decreased in the SAVR (4.0% in 2009 to 2.8% in 2014; p for trend = 0.043) and TAVR (7.0% in 2009 to 5.1% in 2014; p for trend = 0.004) groups. Expected 30-day mortality remained stable in the entire cohort (4.0% in 2009 to 3.2% in 2014; p for trend = 0.27) and in both isolated SAVR (4.0% in 2009 to 3.3% in 2014; p for trend = 0.21) and TAVR (7.0% in 2011 to 5.2% in 2014; p for trend = 0.089) cohorts (Table 2).

While 1-year mortality rates remained stable in the overall AVR population (in 2009 10.8% to in 2014 12.2%; p for trend =0.069) it decreased in the SAVR (10.8% in 2009 to 7.1% in 2014; p for trend = 0.005) and TAVR (in 2011 25.3% to in 2014 17.8%; p for trend ≪0.001) population (Table 2). Additionally, 1-year crude mortality rates were consistently decreased after the introduction of TAVR in the isolated SAVR population in all age subgroups. The largest decline in 1-year mortality was also observed in the ≥85 years-old subgroup undergoing SAVR (16.9% in 2009 to 13.4% in 2014; p for trend≪0.001) (Supplemental Fig. 4).

4. Discussion

In this nationwide analysis of trends in hospitalizations for AVR, total isolated AVR volume, including SAVR volume, increased after the introduction of TAVR, leading to a net expansion of patients receiving treatment for severe aortic stenosis. During this early phase of TAVR introduction in the U.S., the growth of TAVR use led primarily to the expansion of AVR to an elderly and higher risk population, rather than to displacement of SAVR. Expansion of AVR to this population was reflected in an overall increase in the risk of patients being treated. Despite the increasing risk of the overall AVR population, however, observed 30-day and 1-year mortality remained stable.

Our study extends similar findings observed in Germany over the period of 2007–2013, demonstrating that the introduction of TAVR was associated with a neutral effect on SAVR volumes and an overall improvement in in-hospital outcomes [17]. While the introduction of TAVR was associated with a mild decline in SAVR volumes in Europe [17], the current study demonstrates that SAVR volumes have continued to increase in the U.S.—at least during the first 3.5 years after the introduction of TAVR. More recently, a French nationwide study demonstrated that overall AVR volume increased and in-hospital mortality rates declined over the period of 2007–2015 [18].

A recent study from U.S. Medicare data [15] and Society for Thoracic Surgery Transcatheter Valve Therapies registry [19] also reported similar trends in overall AVR volumes. Our study expands on the previous

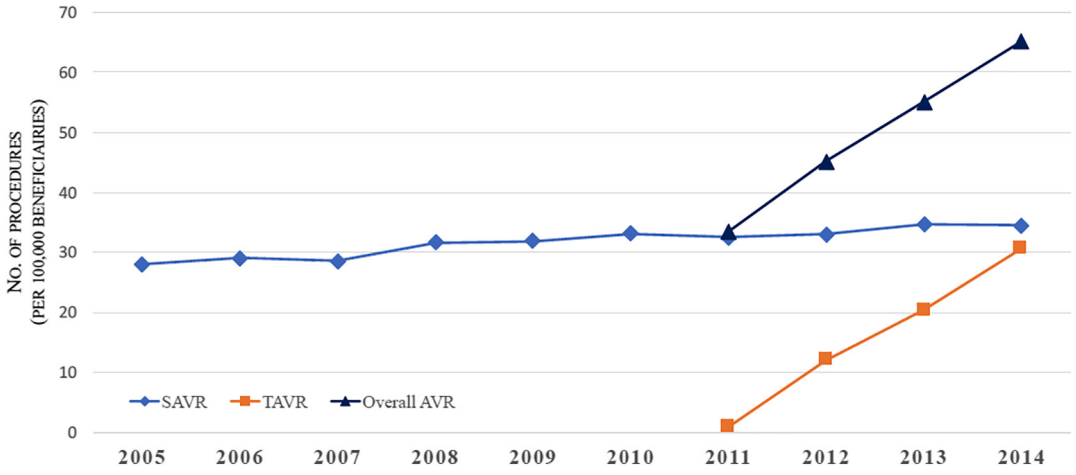

Fig. 1. Changes in population-standardized volume of AVRs recipients.

U.S. analysis in several ways. First, our subgroup analysis observed a decline in SAVR volume only in patients older than age 80, with the largest increase in TAVR volume in this age category as well. Second, we demonstrated that long-term mortality rates also remained stable among AVR recipients despite an increased predicted-mortality. Third, we showed that expected mortality did not significantly change in overall AVR and both in TAVR and SAVR population during the study time period. Additionally, our findings also demonstrated a significant improvement in outcomes including 30-day and 1-year mortality for individuals undergoing SAVR and TAVR after the introduction of TAVR. For SAVR, the reduction in mortality might mainly be due to improved patient selection—preferentially shifting higher risk patients from SAVR to TAVR over time. For TAVR, the reduction in mortality might be due to both patient selection as well as improving technique and devices [20].

We also found that predicted 30-day mortality (based on pre-TAVR period in SAVR population) in overall AVR recipients increased, but decreased in SAVR population. These findings suggest TAVR approval led to a shift of higher surgical risk patients from SAVR to TAVR. This was particularly true in the extreme elderly, as large declines in 30-day predicted mortality were observed in those older than ≥85 years-old undergoing SAVR population. Despite some shifts of the highest risk patients from SAVR to TAVR over time, the overall rate of increase in

Table 1
Patient's characteristics of overall AVR population over the study period.

	2009 $n = 15,638$	2010 $n = 16,594$	2011 $n = 17,338$	2012 $n = 23,858$	2013 $n = 29,600$	2014 $n = 34,535$	p Value for trend
Surgical aortic valve replacement, %	100	100	97.1	72.7	63.0	51.8	≪0.001
Transcatheter aortic valve replacement, %	0	0	2.9	27.3	37.0	48.2	≪0.001
Age, years (mean ± SD)	76.6 ± 6.7	76.8 ± 6.8	77.1 ± 7.0	78.4 ± 7.5	78.7 ± 7.7	79.0 ± 7.7	≪0.001
Men, no. of pts. %	53.0	54.1	53.1	53.7	54.2	54.3	0.58
Chronic heart failure, %	40.3	40.3	42.6	50.0	55.3	57.6	≪0.001
Diabetes mellitus, %	24.4	25.3	25.8	27.1	27.6	28.2	0.019
Smoker, %	15.0	14.4	13.1	13.0	12.7	11.2	0.006
Coronary artery disease, %	42.8	43.6	43.3	47.2	47.9	48.3	≪0.001
Prior myocardial infarction, %	9.2	9.3	9.3	11.3	11.2	10.9	0.043
Prior percutaneous coronary intervention, %	5.5	5.8	6.3	9.5	10.7	13.0	≪0.001
Prior valvular surgery, %	1.3	1.1	1.1	1.2	1.2	1.2	0.97
Prior coronary artery bypass graft surgery, %	10.3	10.6	10.4	12.1	11.8	10.3	≪0.001
Peripheral vascular disease, %	4.5	4.4	4.3	5.1	4.9	4.7	≪0.001
Atrial fibrillation, %	44.5	44.4	46.1	44.6	45.1	44.3	0.96
Left bundle branch block, %	3.1	2.8	3.1	3.3	3.7	4.3	0.55
Right bundle branch block, %	2.3	2.1	2.2	2.2	2.4	2.2	0.53
Cerebrovascular disease, %	9.9	9.9	10.3	10.5	10.8	10.6	0.44
Endocarditis, %	1.6	1.4	1.3	1.2	1.0	0.8	≪0.001
Chronic kidney disease without dialysis, %	14.4	15.6	18.4	23.0	21.4	23.4	≪0.001
Renal dialysis, %	0.3	0.5	0.5	0.8	0.8	0.9	0.045
Liver disease, %	2.9	3.0	3.2	3.4	3.3	3.5	0.38
Chronic obstructive pulmonary disease, %	24.0	23.4	24.4	26.4	26.9	27.1	0.015
Home O_2, %	0.7	0.9	1.3	2.5	2.8	3.1	≪0.001
Obesity, %	10.2	10.1	11.7	11.7	12.0	11.2	0.20
Dementia, %	0.8	0.8	0.8	0.9	1.1	0.7	0.84
Malnutrition, %	3.5	3.7	4.0	4.8	4.7	4.9	0.043
Anemia, %	42.3	45.4	48.6	49.4	49.3	48.3	0.001
Decubitus Ulcer, %	1.7	1.7	1.7	2.0	2.2	2.3	0.18
Difficulty in Walking, %	9.3	10.8	13.0	15.3	16.6	15.3	≪0.001
Episodic mood disorders, %	0.7	0.8	0.7	0.8	0.9	0.9	0.55
Incontinence, %	0.7	0.7	0.7	0.8	0.6	0.5	0.58
Muscle weakness, %	0.7	1.1	1.4	2.4	2.7	3.2	≪0.001
Predicted 30-day mortality, %	4.0	4.0	4.2	4.5	5.2	5.4	0.048

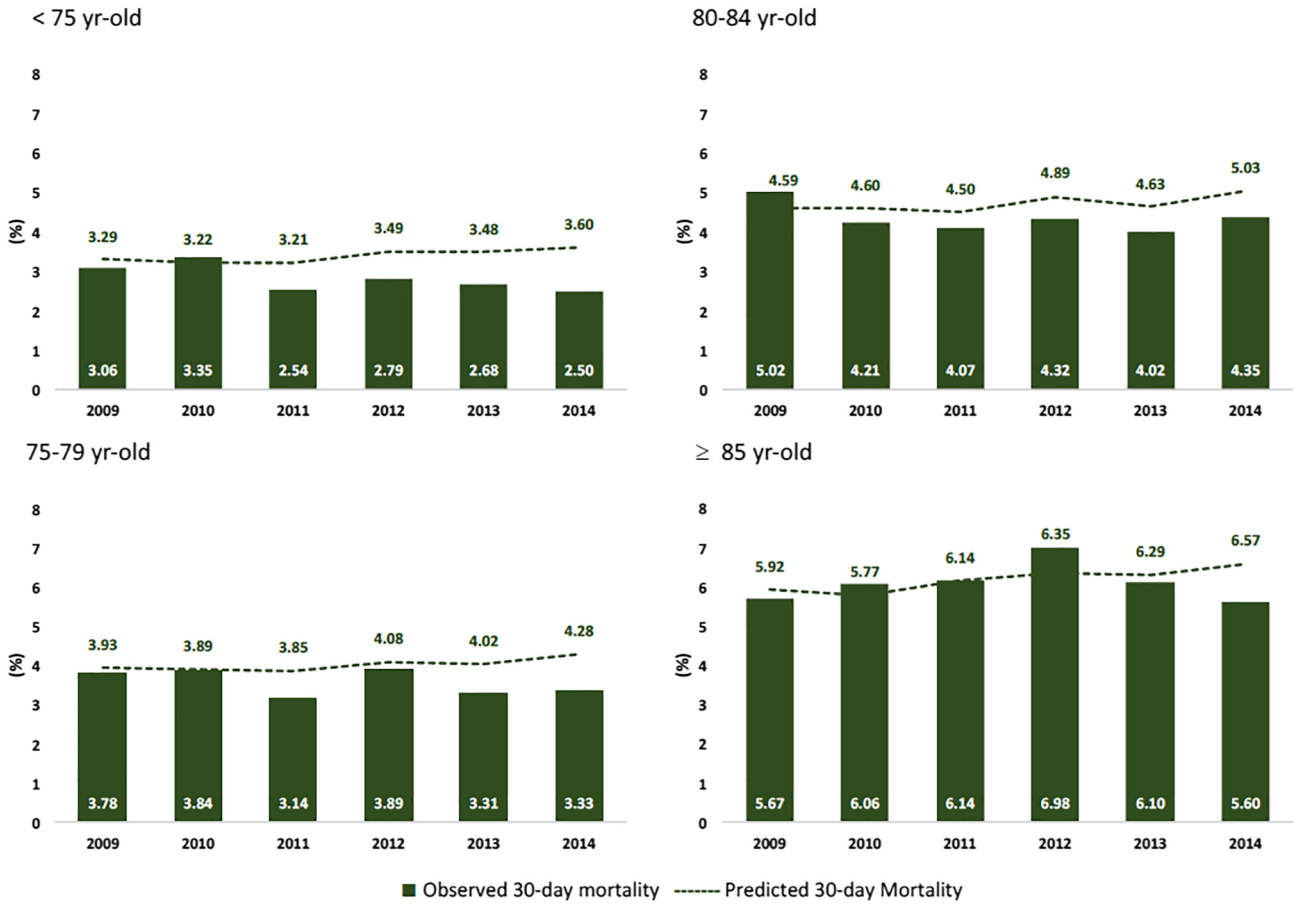

Fig. 2. Changes in observed and predicted 30-day mortality rates in overall AVR recipients by age subgroups.

SAVR volumes was similar before and after the introduction of TAVR, suggesting that the introduction of TAVR has broadened eligibility for AVR rather than simply displacing traditional surgical approaches.

This study has several limitations. First, the study is retrospective and based on administrative data and is therefore subject to residual confounding from unmeasured variables, as well as inaccuracies in coding. Second, we cannot discern whether improvement in outcomes over time may be a reflection of improvement in surgical and procedural techniques or changes in patient selection over time. Third, due to limited granularity in the administrative dataset, traditional surgical risk scores such as the Society for Thoracic Surgery Predicted Risk of Mortality (STS PROM) [21,22] or logistic EuroSCORE [23] could not be determined for each patient. Fourth, our predicted 30-day mortality might not be properly characterized particularly in TAVR population due to lack of some risk factors such as porcelain aorta, frailty. Fifth, we were not able to identify the prostheses type of TAVR such as balloon or self-expandable. Sixth, the patterns observed may not reflect overall trends in countries outside the U.S. where the introduction of TAVR has been shaped heavily by the FDA approval and CMS reimbursement processes. Finally, our study findings should be interpreted in the context of only the early phase of expansion of TAVR (only higher risk patients) since our study time period was limited to 2009–2014, before the approval for TAVR for intermediate risk patients in the US.

Table 2
Outcomes of the study in overall AVR and both TAVR and SAVR population over the study period.

Outcomes	2009	2010	2011	2012	2013	2014	p Value for trend
30-day mortality							
Overall aortic valve replacement							
Observed, %	4.0	4.0	3.6	4.3	4.0	3.9	0.96
Expected, %	4.0	4.1	3.5	3.8	3.5	3.2	0.27
Surgical aortic valve replacement							≪0.001
Observed, %	4.0	4.0	3.5	3.4	2.8	2.8	0.043
Expected, %	4.0	4.1	3.5	3.6	3.2	3.3	0.21
Transcatheter aortic valve replacement							
Observed, %	–	–	7.0	6.8	5.9	5.1	0.004
Expected, %	–	–	7.0	6.9	6.2	5.2	0.089
1-year mortality							
Entire cohort, %	10.8	10.7	10.5	13.5	12.8	12.2	0.069
SAVR, %	10.8	10.7	10.1	9.4	8.2	7.1	0.005
TAVR, %	–	–	25.3	24.5	20.5	17.8	≪0.001

5. Conclusion

The initial introduction and expansion of TAVR was associated with the continued growth of isolated SAVR with no clear decrease from the pre-TAVR period. However, within the oldest subgroup, there was a clear reduction in the use of SAVR and preferential substitution of TAVR. These changes in patient selection were associated with concurrent reductions in 30-day and 1-year mortality among SAVR and TAVR recipients. As a result, overall 30-day mortality and 1-year mortality remained stable despite treatment of increasing numbers of high-risk patients undergoing AVR.

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Conflict of interest statement

The following authors have no conflicts of interest to declare: JBS, DJC, CS, and JJP. Dr. Popma reports grants from Medtronic, Abbott Vascular, and Direct Flow Medical and personal fees from Boston Scientific, Cordis, and Direct Flow Medical, outside the submitted work. Dr. Cohen reports research grants from Edwards Lifesciences, Medtronic, Boston Scientific, and Abbott Vascular and personal fees from Edwards Lifesciences and Medtronic. Dr. Yeh reports investigator initiated grant funding from Abiomed, grant support from Boston Scientific, and consulting from Abbott, Medtronic, and Teleflex, outside the submitted work.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2019.06.061.

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