Comparative Outcomes of Surgical and Transcatheter Aortic Valve Replacement for Aortic Stenosis in Nonagenarians

Chad J. Zack, MD[a], Fahad Al-Qahtani, MD[b], Akram Kawsara, MD[b], Mohammed Al-Hijji, MD[a], Ali Hama Amin, MD[b], and Mohamad Alkhouli, MD[b,*]

Transcatheter aortic valve replacement (TAVR) emerged as a promising alternative to surgical aortic valve replacement (SAVR) in extreme-aged patients with severe aortic stenosis (AS). Data on the outcomes of TAVR or SAVR in nonagenarians are limited. The Nationwide Inpatient Sample was used to identify patients aged 90 years or older who underwent TAVR or SAVR from 2004 to 2013. In-hospital morbidity and mortality were assessed. From 2004 to 2013, 9,066 (national estimate) nonagenarians underwent aortic valve replacement. After the introduction of TAVR, most nonagenarians were treated with TAVR (76%) compared with SAVR (24%). A total of 1,847 nonagenarians who underwent SAVR (n = 1,152) or TAVR (n = 695) were included in the analysis. In-hospital mortality was similar between patients who underwent SAVR (6.4%) compared with TAVR (6.5%; p = 0.29). Vascular complications were more common after TAVR (11.9% vs 6.3%, p <0.001), whereas blood transfusion (46.2% vs 33.7%, p <0.001), and acute kidney injury (25.8% vs 20.4%, p = 0.009) were more common after SAVR. Pacemaker implantation and stroke rates were similar between the 2 groups. In a propensity-matched analysis of 630 patients who underwent isolated TAVR (n = 315) or SAVR (n = 315), in-hospital mortality was similar for (6.0% for SAVR vs 7.9% for TAVR, p = 0.35). SAVR was associated with higher rates of acute kidney injury (24.1% vs 16.8%, p = 0.02) and blood transfusion (46.0% vs 35.2%, p = 0.001), whereas TAVR was associated with increased rates of vascular complications (10.2% vs 6.0%, p = 0.07). Stroke (4.1% vs 4.1%, p = 0.99) and pacemaker implantation rates were also similar (13.0% vs 9.2%, p = 0.12) between the TAVR and SAVR groups, respectively. In conclusion, in nonagenarians, both SAVR and TAVR can be performed with acceptable in-hospital outcomes. Referral for aortic valve replacement in these patients should not be precluded based on age alone. **(Am J Cardiol 2017;119:893−899)**

The nonagenarian population is steadily increasing and is projected to increase by nearly fourfold over the next 30 years.[1] Calcific aortic stenosis (AS) is common in patients aged more than 80 years with a prevalence of 9.8%.[2] Surgical aortic valve replacement (SAVR) has been the traditional standard curative treatment of severe AS. However, many nonagenarians are not offered SAVR due to the concern that the risk associated with advanced age may lead to poor postoperative outcomes.[1,3,4] Transcatheter aortic valve replacement (TAVR) has emerged as a promising alternative for extreme-aged patients with similar improvement in quality of life as younger patients.[1,5] To date, outcomes data on SAVR and TAVR in nonagenarians are limited to single-center reports and a single randomized clinical trial.[1,3,4,6−11] We aim to investigate real-world contemporary outcomes of SAVR and TAVR in nonagenarians using a nationwide US registry.

Methods

The National Inpatient Sample (NIS) was used to derive patient relevant information from January 2004 to December 2013. The NIS is the largest publicly available all-payer administrative claims-based database and contains information about patient discharges from approximately 1,000 nonfederal hospitals in 45 states. It contains clinical and resource utilization information on 5 to 8 million discharges annually, with safeguards to protect the privacy of individual patients, physicians, and hospitals. These data are stratified to represent approximately 20% of US inpatient hospitalizations across different hospital and geographic regions. National estimates (NEs) of the entire US hospitalized population were calculated using the Agency for Healthcare Research and Quality sampling and weighting method.[12]

Patients aged 90 years and older with a discharge diagnosis of aortic valve stenosis (*International Classification of Diseases-Ninth Revision-Clinical Modification* [ICD-9-CM] codes 424.1, 395.0, 395.2, 396.2, 746.3) who underwent SAVR (ICD-9-CM procedure codes 35.20 and 35.21) or

[a]Department of Cardiovascular Disease, Mayo Clinic, Rochester, Minnesota; and [b]Division of Cardiovascular Disease, Department of Medicine, West Virginia University, Morgantown, West Virginia. Manuscript received October 8, 2016; revised manuscript received and accepted November 21, 2016.

See page 898 for disclosure information.

*Corresponding author: Tel: (304) 598-4687; fax: (304) 599-0860.
E-mail address: Mohamad.Alkhouli@wvumedicine.org (M. Alkhouli).

0002-9149/16/$ - see front matter © 2016 Elsevier Inc. All rights reserved.
http://dx.doi.org/10.1016/j.amjcard.2016.11.045

TAVR (ICD-9-CM procedure codes 35.05 and 35.06) during the study period were identified in the NIS database.

Outcomes of SAVR and TAVR: Baseline patient's comorbidities and procedural characteristics were described. The primary outcome of interest was in-hospital mortality. Procedure-related trends and morbidity were assessed. Predictors associated with death before discharge for patients undergoing both SAVR and TAVR were also identified.

Comparative outcomes analysis: We aimed to perform a comparative outcomes analysis between nonagenarian patients undergoing TAVR and SAVR. We anticipated significant heterogeneity between the SAVR and TAVR groups with regards to demographic and co-morbid characteristics. To account for potential confounding factors and to reduce the effect of selection bias, propensity scores were derived using logistic regression and a matching model was developed to derive 2 matched groups for comparison. After excluding patients who underwent concomitant cardiac surgery, patients who underwent "isolated" SAVR or TAVR were entered into a nearest neighbor 1:1 variable ratio, parallel, balanced propensity matching model using a caliper of 0.05. Propensity scores were derived from 41 hospital, clinical, and demographic covariates including the Elixhauser Co-morbidity Index (Supplementary Table 1). After matching, excellent balance (c-statistic = 0.82) was observed between the 2 comparison groups. The primary end point was in-hospital death. Secondary outcomes included procedural mortality defined as death occurring on the same hospital day as SAVR or TAVR, vascular complications, pacemaker implantation, cerebral vascular accidents, acute kidney injury, blood transfusion, cardiac tamponade, length of stay, hospital charges, and discharge disposition.

Patient relevant descriptive statistics are presented as frequencies with percentages for categorical variables and as means with SDs for continuous variables. Baseline characteristics were compared between the groups using a Pearson chi-square test and Fisher's exact test for categorical variables and an independent samples *t* test for continuous variables. Trend weights were appropriately adjusted to account for revisions in NIS sampling design beginning in 2012 to produce consistent NEs. A Cochran-Armitage test was used to evaluate trends in aortic valve replacement in nonagenarians. Univariate and multivariate logistic regression was performed to estimate odds ratios with 95% CIs to determine predictors of in-hospital mortality in nonagenarian patients undergoing SAVR or TAVR. To control for differences between the SAVR and TAVR groups, we performed a 1:1 propensity score−matched analysis. Matched categorical variables were presented as frequencies with percentages and compared using the McNemar's test. Matched continuous variables were presented as means with SDs and compared using a paired-samples *t* test. A type I error rate of <0.5 was considered statistically significant. All statistical analyses were performed using SPSS version 22 (IBM Corporation, Armonk, New York) and SAS version 9.3 (SAS Institute, Cary, North Carolina).

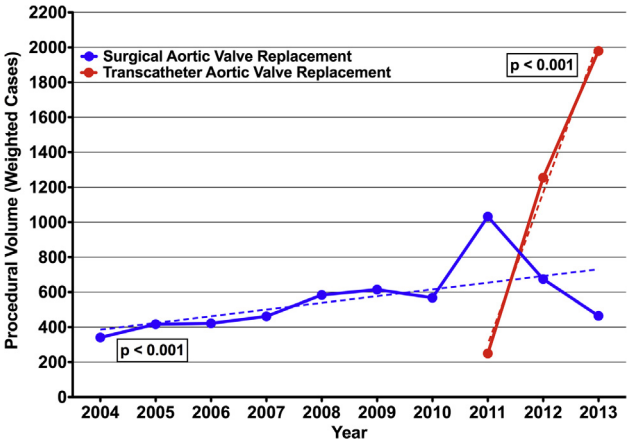

Figure 1. Temporal trends of surgical and aortic valve replacement in nonagenarian patients in the United States 2004 to 2013.

Results

Characteristics of the study population: A total of 1,847 nonagenarian patients with severe AS who underwent aortic valve replacement from 2004 to 2013 were included representing a NE of 9,066 patients. There was a sevenfold increase in aortic valve replacements in nonagenarians from 341 (NE) procedures in 2004 to 2,445 (NE) procedures in 2013 (Figure 1). Patient mean age was 91.1 ± 1.6 (range = 16) years and 90.2 ± 0.8 (range = 7) years in the SAVR and TAVR groups, respectively. Patients in the TAVR group tended to have a larger percentage of co-morbid conditions. Baseline patient-level characteristics are listed in Table 1. After the Food and Drug Administration approval of TAVR in November 2011, most nonagenarians with severe AS were treated with TAVR (74%) compared with SAVR (26%). Most aortic valve replacements were performed at teaching institutions (87.1% for TAVR and 72.9% for SAVR). Over half of the patients undergoing SAVR (50.3%) also underwent more than 1 cardiovascular procedure compared with 3.2% of patients undergoing TAVR ($p < 0.001$; Supplementary Table 2). Baseline characteristic of patients undergoing isolated TAVR or SAVR (without concomitant procedures) are listed in (Supplementary Table 3).

Outcomes of TAVR and SAVR: In-hospital death occurred in 6.4% and 6.5% of nonagenarians undergoing TAVR and SAVR, respectively ($p = 0.29$). Compared with patients who underwent TAVR, those who underwent SAVR had higher incidence of acute kidney injury, new-onset dialysis, blood transfusions but less vascular complications requiring surgery (Table 2). There was no difference in the rates of stroke and the need for permanent pacemaker between the TAVR and the SAVR groups. Hospital length of stay was longer in the SAVR group, but hospital charges were higher in the TAVR group. TAVR patients were more likely to be discharged directly to home compared with patients undergoing SAVR. In-hospital outcomes of patients who underwent isolated TAVR or SAVR are outlined in