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Transcatheter Aortic Valve Replacement Outcomes in Nonagenarians Stratified by Transfemoral and Transapical Approach

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Background. Survival and other outcomes of nonagenarians undergoing transcatheter aortic valve replacement (TAVR) in the Medicare population are unclear.

Methods. Patients aged 65 years and older who underwent TAVR from November 2011 through 2013 were considered for inclusion.

Results. The study consisted of 18,283 patients and 19.3% were aged 90 years or older. Compared with patients younger than 90 years, patients 90 years or older were less likely to have a number of comorbidities, including previous myocardial infarction (17.5% versus 21.8%), previous coronary artery bypass grafting (20.0% versus 35.0%), and chronic obstructive pulmonary disease (25.4% versus 39.0%) among others. The 30-day and 1-year mortality rates were 8.4% versus 5.9% ($p = 0.0001$) and 25.4% versus 21.5% ($p = 0.0001$) in the older and younger groups, respectively (odds ratio [OR] 1.47, 95% confidence interval [CI]: 1.28 to 1.70, $p = 0.0001$). Patients 90 years and older were more likely to undergo pacemaker insertion (11.1% versus 8.3%, $p = 0.0001$). Among

nonagenarians, compared with the transapical group, patients undergoing transfemoral TAVR had lower 30-day (7.2% versus 13.6%, $p = 0.0001$) and 1-year (23.8% versus 31.6%, $p = 0.0001$) mortality rates, were more likely to be discharged home (54.4% versus 34.1%, $p = 0.0001$), and had lower 30-day readmission rates (23.8% versus 31.8%, $p = 0.0001$). After adjustment for patient characteristics, transapical TAVR was an independent predictor of 30-day mortality rate (OR 1.94, 95% CI: 1.48 to 2.56, $p = 0.0001$) and readmission (OR 1.46, 95% CI: 1.19 to 1.80, $p = 0.0003$).

Conclusions. In patients undergoing TAVR, although 30-day and 1-year mortality rates were slightly worse for nonagenarians than their younger counterparts, long-term survival was still encouraging, with 75% of nonagenarians living to 1 year. Transapical TAVR was associated with worse outcomes in nonagenarians.

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Transcatheter aortic valve replacement (TAVR) has increasingly emerged as an alternative to surgical AVR for patients at higher operative risk [1–5]. In addition, recent data have demonstrated comparable outcomes with surgical AVR in a moderate risk cohort, with subsequent expansion of Food and Drug Administration (FDA) approval [6–8]. The elderly comprise a disproportionate share of those at higher risk of operation and are often subsequently denied surgical AVR [9].

Consequently, it seems that increasingly more of our elderly patients with severe aortic stenosis will have TAVR available as a therapeutic option. A recent transcatheter valve therapy (TVT) registry analysis demonstrated a higher 30-day (8.8% versus 5.9%) and 1-year mortality rate in nonagenarians undergoing TAVR compared with patients younger than 90 years [10]. Although numerically worse, the 1-year survival of nonagenarians remained favorable. This analysis was limited by the large proportion of patients that could not be linked to the Medicare database, possibly affecting the generalizability of the survival analysis. In addition, outcomes were not stratified by transfemoral (TF) or transapical (TA) access, the latter of which has been associated with inferior outcomes in some data sets [11, 12]. A number of other outcomes, such as readmission, pacemaker implantation, among others, also remain unclear

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Abbreviations and Acronyms

CABG	= coronary artery bypass grafting
CI	= confidence interval
CMS	= Centers for Medicare and Medicaid Services
FDA	= Food and Drug Administration
ICD-9	= International Classification of Diseases, Ninth Revision
LOS	= length of stay
OR	= odds ratio
PARTNER	= Placement of Aortic Transcatheter Valves
TA	= transapical
TAVR	= transcatheter aortic valve replacement
TF	= transfemoral
TVT	= transcatheter valve therapy

among this very elderly but enlarging cohort. Therefore, the purpose of this study was to further characterize the outcomes of nonagenarians undergoing TAVR in comparison with younger patients with the use of the Medicare database.

Patients and Methods

Data were obtained from the Centers for Medicare and Medicaid Services (CMS). The Vital Status file was used to provide the most recent death information for the study cohort. The study was approved by the institutional review board, which waived the requirement for informed consent. All Medicare beneficiaries aged 65 years and older who underwent TAVR (International Classification of Diseases, Ninth Revision [ICD-9] 35.05 for TF, 35.06 for TA) from November 2011 to December 2013 were considered for inclusion. Patients with less than 1 year of Medicare Part A coverage were excluded from this study. The Vital Status file was used to determine survival. Comorbidities were identified using the ICD-9 Clinical Modification diagnostic codes from all hospitalizations occurring in the 1-year period preceding and including the index admission for TAVR, excluding stroke, which did not include index admission. Patients were divided into the following groups: all patients undergoing TAVR younger than 90 years (<90 all TAVR), all patients undergoing TAVR aged 90 years and older (≥ 90 all TAVR), patients aged 90 years and older undergoing TF (≥ 90 TF), and patients aged 90 years and older undergoing TA (≥ 90 TA). Patients younger than 90 years were included to provide a frame of reference for our outcomes.

Postoperative events and complications were also determined using the following ICD-9 codes: permanent pacemaker implantation, 37.80 to 37.83; reoperation, 35.21, 35.22; acute blood loss anemia/postoperative hemorrhage, 285.1, 998.1X; respiratory complications (pneumonia postoperative or aspiration, respiratory insufficiency after operation, transfusion-related acute lung injury), 997.3,

507.0, 518.4, 518.52, 518.7; surgical site infection, 958.3, 998.5; postoperative stroke, 997.02; postoperative shock, 998.0; and venous thromboembolism, 415.1, 451.1, 451.2, 451.81, 453.8. Readmission for stroke/transient ischemic attack or heart failure was based on primary admission diagnosis: stroke/transient ischemic attack (433.X to 436.X, 438.X, 997.02; heart failure, 402.X1, 404.X1, 404.X3, 428.X ["X" represents any number]). Survival curves were calculated using the cumulative proportion of patients surviving. Expected survival was based on an age-matched US cohort [13]. Wilcoxon rank-sum tests and χ^2 tests of independence were used to compare characteristics between patients. We used hierarchical logistic regression to produce adjusted odds ratios (ORs), accounting for clustering within hospitals as well as baseline characteristics in Table 1. Adjusted outcomes for 30-day mortality rate and readmission are presented in Figure 1. "Effect of age ≥ 90 yrs" represents the effect of age 90 years or older among all TAVR patients; "effect of TA access" represents TA versus TF access on patients 90 years or older. All analyses were performed using SAS Enterprise Guide version 9.4 (SAS Institute Inc, Cary, NC).

Results*Baseline Characteristics: Younger than 90 Years Versus 90 Years or Older*

The study population consisted of 18,283 patients; 14,752 of these were younger than 90 years and 3,531 were 90 years or older (19.3%). The overall median study age was 84 years. The median ages of the cohorts younger than 90 years and 90 years or older were 82 and 92 years, respectively ($p = 0.0001$). Compared with patients younger than 90 years, patients 90 years or older were more likely to be women and were less likely to have a number of comorbidities, including previous myocardial infarction (17.5% versus 21.8%, $p = 0.0001$), previous coronary artery bypass grafting (CABG; 20.0% versus 35.0%, $p = 0.0001$), or a history of chronic obstructive pulmonary disease (25.4% versus 39.0%, $p = 0.0001$). Patients 90 years or older were more likely to have a history of congestive heart failure (83.6% versus 79.5%, $p = 0.0001$) (Table 1).

Baseline Characteristics: TF Versus TA in Nonagenarians

Comparing TF with TA patients in nonagenarians, patients with TF access were less likely to be women (49.6% versus 63.7%, $p = 0.0001$), have had previous CABG operation (18.7% versus 25.6%, $p = 0.0001$), previous valve/structural heart operation (13.8% versus 17.6%, $p = 0.0117$), a history of stroke (7.8% versus 11.5%, $p = 0.0021$), or chronic obstructive pulmonary disease (24.6% versus 28.7%, $p = 0.0299$). Both groups had a median age of 92 years (Table 1).

Operative Characteristics and Outcomes

Access type and survival outcomes are presented in Table 2. In patients 90 years or older, 81.3% of procedures

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