Transcatheter aortic valve insertion in the nonagenarian patient

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See related commentaries on pages 721-3 and 723-4.

There are reports detailing conflicting outcomes of aortic valve replacement in nonagenarian patients, with some studies noting a high observed-to-expected mortality ratio.^{1,2} We hypothesized that transcatheter valve insertion would result in low operative mortality and reasonable long-term survival in this extremely elderly cohort of patients.

MATERIALS AND METHODS

The Mayo Clinic's institutional review board approved this study. We reviewed the records of 398 patients operated on with transcatheter aortic valve insertion from November 2008 through June 2014.

Data were recorded according to the standard definitions set forth in the Society of Thoracic Surgeons Adult Cardiac Database and the Valve Academic Research Consortium-2 (VARC-2) consortium document.³ Frailty was assessed on the basis of the 5-meter walk test, hand grip, serum albumin level, and the Katz Index of Independence in Activities of Daily Living; patients were considered frail if they failed to meet 3 out of 4 of the criteria.

Categorical data were reported as patient numbers with percentages, and continuous data were reported as median and range. Data were analyzed with the Fisher exact test, the Wilcoxon nonparametric rank test, and Kaplan-Meier estimates. The expected survival probabilities for the group of individuals matched on age, calendar year, and sex was based on a set of tables containing published survival probabilities for the US population, by interpolation between decades changing hazard values on each birthday.

From the group of 398 patients, a study cohort was created that included 46 nonagenarian patients (11.6%) with a median age of 91.5 years (90-95 years), 28 female patients (60.9%), and a median Society of Thoracic Surgeons predicted risk of mortality of 8.5% (4.0%-27.9%). Additional risk variables are reported in Table 1.

RESULTS

Transcatheter access was transfemoral in 24 patients (52.2%), transapical in 19 (41.3%), and transaortic in 3 (6.5%). Valve types included the SAPIEN valve (Edwards Lifesciences Corporation, Irvine, Calif) in 32 patients (69.6%), the SAPIEN XT in 6 (13.0%), the SAPIEN S3 in 7 (15.2%), and the CoreValve (Medtronic, Minneapolis, Minn) in 1 (2.2%).

TABLE 1. Baseline patient risk characteristics

Ejection fraction (median and range)	0.64 (0.25-0.80)
Ejection fraction $\leq 50\%$	12 (26%)
Diabetes	11 (23.9%)
Hypertension	40 (87.0%)
Chronic lung disease	19 (41.3%)
Peripheral vascular disease	26 (56.5%)
Cerebrovascular disease	17 (37.0%)
Previous stroke	9 (19.6%)
Previous cardiac operation	17 (37.0%)
Arrhythmia	13 (28.3%)
New York Heart Association functional class III or IV	40 (87.0%)
Mitral valve regurgitation moderate or greater	17 (37.0%)
Frailty, objective	4/14 (28.6%)
Domicile	
Minnesota or bordering state	40 (87.0%)
Nonbordering state	6 (13.0%)

Data represent numbers and percentages of patients except as noted.

Operative complications occurred in 22 patients (47.8%) and included prolonged ventilation in 3 patients (6.5%), permanent pacemaker placement in 3 (6.5%), stroke in 1 (2.2%), and dialysis in 1 (2.2%). Vascular injury occurred in 10 patients, and only in the transfemoral access group (45.5%)—the valve was a SAPIEN valve in 8 patients (25.0%; 7 major and 1 minor according to VARC-2 criteria) and SAPIEN S3 in 2 (28.6%; both minor according to VARC-2 criteria).

There were 2 treatment-related deaths (4.7%), 1 from stroke and 1 from multisystem organ failure. The observed-to-expected mortality ratio was 0.55. The median length of stay was 5 days (1-21) and did not differ according to vascular access method ($P = .333$). Discharge was to home in 18 cases (40.9%) and to a skilled nursing facility in 26 (59.1%).

Survival at 1 and 2 years was $84.6\% \pm 10.6\%$, and these data were similar to an age- and sex-matched control population, as reported in Figure 1 ($P = .286$). Median follow-up was 17.3 months (0-61.4 months), at which time 35 patients (76.1%) were alive. There was no difference in survival according to access method ($P = .438$) or discharge disposition ($P = .497$).

DISCUSSION

This study reports our experience with transcatheter aortic valve insertion in nonagenarian patients. Despite high predicted operative risk, outcomes were excellent with low operative stroke (2.2%) and death (4.7%) rates (observed-to-expected ratio 0.55). Follow-up through 2 years demonstrates survival similar to that of an age-

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FIGURE 1. Kaplan-Meier survival estimates of patients after transcatheter aortic valve insertion compared with an age- and sex-matched control population. TAVI, Transcatheter aortic valve implantation.

and sex-matched control population. Transcatheter valve replacement should not be denied to select patients.

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EDITORIAL COMMENTARY

Pushing the limits or the new normal? Transcatheter aortic valve replacement in nonagenarians

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See related article on pages 720-1.

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With a continuously aging population and an increased prevalence of severe aortic stenosis in the elderly, both surgeons and cardiologists are more frequently confronted with treatment decisions in a very complex patient population. By the year 2050, estimates indicate that the number of nonagenarians in the United States will increase from 2 to 8 million (Figure 1).¹ Advanced age is a key component in preoperative patient evaluation and risk estimation for patients undergoing surgical aortic valve replacement (SAVR). For patients aged >90 years in particular, surgical risk has been traditionally perceived as excessive, and many patients of this age were therefore not referred for SAVR by their physicians. Surgical