

Outcomes of Treatment of Nonagenarians With Severe Aortic Stenosis

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Background. Because nonagenarians with aortic stenosis (AS) often present as frail with more comorbid conditions, long-term outcomes and quality of life are important treatment considerations. The aim of this report is to describe survival and functional outcomes of nonagenarians undergoing treatment for AS by surgical aortic valve replacement (SAVR) and transcatheter aortic valve replacement (TAVR).

Methods. This is a retrospective analysis of all patients aged 90 years or more undergoing treatment for AS between 2007 and 2013 at two centers. Outcomes were compared between SAVR and TAVR. Long-term survival was compared with an age- and sex-matched population from the Social Security Actuarial Life Table.

Results. In all, 110 patients underwent treatment for isolated AS (20 SAVR and 90 TAVR). Mean age was 91.85 ± 1.80 years, and 50.9% were female. The Society of Thoracic Surgeons mean predicted risk of mortality was

$11.11\% \pm 5.74\%$. Operative mortality was 10.9% (10.0% SAVR; 11.1% TAVR); 2.7% of patients had a stroke. The TAVR patients were more likely to be discharged home (75.9% versus 55.6% for SAVR, $p = 0.032$). Mean follow-up was 1.8 ± 1.5 years, with a 1-year and 5-year survival of 78.7% and 45.3%, respectively, which approximated the US actuarial survival. There was a significant improvement in quality of life as measured by the Kansas City Cardiomyopathy Questionnaire at 1 year compared with baseline.

Conclusions. Treatment of AS approximates natural life expectancy in select nonagenarians, with no significant difference in long-term survival between SAVR and TAVR. Importantly, patient quality of life improved at 1 year. With appropriate selection, nonagenarians with severe AS can benefit from treatment.

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Between 1980 and 2010, the number of people aged 90 or greater in the United States increased from 720,000 to 1.9 million [1]. As the incidence of aortic stenosis (AS) increases with age [2], the need for treatment of nonagenarians with the disease has become more frequent. Generally, nonagenarians are more frail and have more comorbid conditions compared with younger cohorts that often can preclude surgical aortic valve replacement (SAVR) [3]. Additionally, it has been demonstrated that severe, symptomatic AS results in a marked decrease in functionality and quality of life for patients with the disease [4]. As elderly patients have a shorter life expectancy than the general population, it is important to also consider the quality of life (QOL) outcomes in these patients when making treatment decisions. Transcatheter aortic valve replacement (TAVR) has emerged as an alternative treatment for high-risk and inoperable patients with severe AS [5, 6]. We report the outcomes of nonagenarians with AS treated with SAVR or TAVR.

Patients and Methods

The approval of this study was granted by the Institutional Review Board at both centers, with individual patient consent waived as this is a retrospective study. In all, 110 consecutive patients aged 90 years or more at The Heart Hospital Baylor Plano and Medical City Dallas Hospital between 2007 and 2013 underwent primary isolated SAVR or TAVR for the treatment of severe, symptomatic AS. Severe, symptomatic AS was defined as having an aortic valve area less than 1.0 cm^2 , aortic valve peak aortic velocity (V_{\max}) of 4 m/s or more, and mean gradient more than 40 mm Hg on transthoracic echocardiogram, with symptoms of exertional dyspnea or decreased exercise tolerance, angina, or syncope [7]. Patient demographics and comorbid conditions as defined by The Society of Thoracic Surgeons (STS) were considered, along with the risk score calculations from the STS predicted risk of mortality (PROM).

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Abbreviations and Acronyms

ADL	= activities of daily living
AS	= aortic stenosis
KCCQ	= Kansas City Cardiomyopathy Questionnaire
NYHA	= New York Heart Association
O:E	= observed to expected mortality ratio
PROM	= predicted risk of mortality
QOL	= quality of life
SAVR	= surgical aortic valve replacement
STS	= The Society of Thoracic Surgeons
TAVR	= transcatheter aortic valve replacement

Eligibility for SAVR or TAVR was determined by a multidisciplinary heart team. For patients undergoing SAVR, specific details of surgical technique were determined by the individual cardiac surgeon, and a minimally invasive approach was used in most patients. All procedures were performed by an interventional cardiologist and cardiac surgeon, with approach depending on access characteristics. The procedures were done with the Sapien (n = 67) or Sapien XT valve (n = 19 [Edwards Lifesciences, Irvine, CA]) or CoreValve (n = 4 [Medtronic, Minneapolis, MN]).

Frailty Measurements

Frailty was assessed using four commonly accepted metrics: serum albumin, gait speed, Katz Activities of Daily Living (ADL) score, and grip strength [8]. Serum albumin was used as a marker of malnutrition and wasting [9]. A serum albumin value of less than 3.5 mg/dL was considered low. Gait speed was measured by having qualified patients walk 5 meters (16.4 feet) in a designated, well-lit, open hallway at a "comfortable pace" as per the STS database guidelines [10]. If needed, patients were allowed to use a cane, walker, and oxygen support. The patient's independence was assessed through the completion of the Katz ADL survey [11]. The dominant hand grip strength of each patient was measured in kilograms and collected three times using a dynamometer. Frailty testing began at Medical City Dallas Hospital in 2008 and at The Heart Hospital Baylor Plano in 2012 and was only performed on outpatients evaluated in the valve clinic.

Quality of Life Measurements

A baseline Kansas City Cardiomyopathy Questionnaire (KCCQ) was completed as a measure of disease-specific health status at baseline, 30 days, and 1 year. Patients were instructed to complete the 23-item self-administered questionnaire that addresses specific health domains pertaining to heart failure: physical limitation, symptoms, QOL, social limitation, symptom stability, and self-efficacy—the first four of which are combined into an overall summary scale. Values for the domains range from 0 to 100, with higher scores indicating lower symptom burden and better quality of life [12]. A KCCQ summary score greater than 75 corresponds to New York Heart

Association (NYHA) class I, 60 to 75 to NYHA class II, 45 to 60 to NYHA class III, and less than 45 to NYHA class IV [13].

Outcome Assessment

The primary study endpoints were 1-year mortality and QOL assessment. Secondary endpoints included 30-day mortality, postoperative major morbidity as defined by the STS, length of hospital stay, and discharge disposition (home or secondary health care facility). Major morbidity included stroke, renal failure, prolonged ventilation (more than 24 hours), deep sternal wound infection, and need for cardiac reoperation, as defined by the STS [14]. The observed to expected mortality ratio (O:E) was calculated as the percent of patients classified as operative mortality divided by the predicted number based on the STS PROM as a percent.

Long-Term Follow-Up

Long-term survival was determined by a search of the Social Security Death Master File from the US Social Security Administration. The number of days between the date of surgery and the mortality date was used for the long-term survival portion of the study. For patients still alive at the study cutoff date, no mortality date was given, and these patients were considered to be censored for the purposes of the survival analysis. All-cause mortality was considered. The long-term survival of study patients was compared with the Social Security Actuarial Life Tables 2009 for nonagenarians. For the table, the period life expectancy at a given age is the average remaining number of years expected before death for a person at that exact age born on January 1, using the mortality rates for 2009 over the course of his or her remaining life (<http://www.ssa.gov/oact/stats/table4c6.html>). Survival was also stratified by treatment method for TAVR (transapical versus transfemoral).

Data Management and Statistical Analysis

Categorical variables are presented as proportions and number of events of number of patients, with comparisons between groups carried out using χ^2 statistics, or the Fisher exact test for small sample sizes. Continuous variables are summarized as mean \pm SD with comparison between groups by *t* test or nonparametric Wilcoxon test as appropriate. Any *p* values of 0.05 or less are usually considered as statistically significant, leading to rejection of the null hypothesis. Kaplan-Meier curves were constructed using elapsed time from procedure until death, or right censored at last follow-up. Differences between strata were tested using the nonparametric log rank test.

To create a US population comparison curve, the data from the Social Security Actuarial Life Table (<http://www.ssa.gov/oact/stats/table4c6.html>) was used. A sample population was created using the same male/female ratio at each age group as in our study group. Using the probability of death from the table for the appropriate age and sex, the number of survivors at the end of the year was calculated. This group was then brought forward 1 year using that year's probability. This was repeated for 5

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