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ORIGINAL INVESTIGATIONS

Should Transcatheter Aortic Valve Replacement Be Performed in Nonagenarians?

Insights From the STS/ACC TVT Registry

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ABSTRACT

BACKGROUND Data demonstrating the outcome of transcatheter aortic valve replacement (TAVR) in the very elderly patients are limited, as they often represent only a small proportion of the trial populations.

OBJECTIVES The purpose of this study was to compare the outcomes of nonagenarians to younger patients undergoing TAVR in current practice.

METHODS We analyzed data from the Society of Thoracic Surgeons/American College of Cardiology TVT (Transcatheter Valve Therapy) Registry. Outcomes at 30 days and 1 year were compared between patients ≥90 years versus <90 years of age using cumulative incidence curves. Quality of life was assessed with the 12-item Kansas City Cardiomyopathy Questionnaire.

RESULTS Between November 2011 and September 2014, 24,025 patients underwent TAVR in 329 participating hospitals, of which 3,773 (15.7%) were age ≥90 years. The 30-day and 1-year mortality rates were significantly higher among nonagenarians (age ≥90 years vs. <90 years: 30-day: 8.8% vs. 5.9%; $p < 0.001$; 1 year: 24.8% vs. 22.0%; $p < 0.001$, absolute risk: 2.8%, relative risk: 12.7%). However, nonagenarians had a higher mean Society of Thoracic Surgeons Predicted Risk of Operative Mortality score (10.9% vs. 8.1%; $p < 0.001$) and, therefore, had similar ratios of observed to expected rates of 30-day death (age ≥90 years vs. <90 years: 0.81, 95% confidence interval: 0.70 to 0.92 vs. 0.72, 95% confidence interval: 0.67 to 0.78). There were no differences in the rates of stroke, aortic valve reintervention, or myocardial infarction at 30 days or 1 year. Nonagenarians had lower (worse) median Kansas City Cardiomyopathy Questionnaire scores at 30 days; however, there was no significant difference at 1 year.

CONCLUSIONS In current U.S. clinical practice, approximately 16% of patients undergoing TAVR are ≥90 years of age. Although 30-day and 1-year mortality rates were statistically higher compared with younger patients undergoing TAVR, the absolute and relative differences were clinically modest. TAVR also improves quality of life to the same degree in nonagenarians as in younger patients. These data support safety and efficacy of TAVR in select very elderly patients.
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ABBREVIATIONS AND ACRONYMS

AS = aortic stenosis

CI = confidence interval

IRB = institutional review board

KCCQ-12 = 12-item Kansas City Cardiomyopathy Questionnaire

KCCQ-os = overall summary score of the 12-item Kansas City Cardiomyopathy Questionnaire

MI = myocardial infarction

QOL = quality of life

TAVR = transcatheter aortic valve replacement

It is estimated that the number of people age ≥90 years (nonagenarians) in the United States will quadruple by the year 2050 to reach 8.7 million (1). As such, clinicians are being confronted with an increasing number of nonagenarians with severe aortic stenosis (AS), which significantly reduces quality of life and survival. Due to the morbidity and mortality of surgical aortic valve replacement in patients at advanced age, surgery is often denied to very elderly patients (2,3). Over the last 10 years, transcatheter aortic valve replacement (TAVR) has emerged as a viable treatment option for patients with severe AS who are inoperable or at high surgical risk, prolonging survival and improving quality of life in the majority of patients (4,5). However, the effect of TAVR in nonagenarians is largely unknown, as they represent only a small fraction of patients enrolled in the pivotal clinical trials. A few small, single-center series have reported outcomes of TAVR in the very elderly and showed acceptable results (6–9). Due to this lack of outcomes data for TAVR in the very elderly, decision-making for TAVR in nonagenarians is complicated. As such, the aim of this study was to compare the procedural, 30-day, and 1-year outcomes of nonagenarians with patients age <90 years undergoing TAVR in current clinical practice using comprehensive data from the STS/ACC (Society of Thoracic Surgeons/American College of Cardiology) TVT (Transcatheter Valve Therapy) Registry.

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METHODS

THE STS/ACC TVT REGISTRY. The TVT Registry collects clinical information including patient demographics, comorbidities, functional status, quality of life, and procedural details in addition to post-operative, 30-day, and 1-year outcomes using standardized definitions on virtually all patients undergoing TAVR with a commercially approved device in the United States (10,11). The Chesapeake Central Institutional Review Board (IRB) and the Duke University School of Medicine IRB approved the registry. Both IRB committees granted a waiver of informed consent and authorization for this study.

STUDY COHORT. Nonagenarians were defined as patients age ≥90 years at the time of the procedure, and a small number of centenarians were included in this study (n = 24). TVT Registry clinical records for procedures performed from November 2011 through September 2014 were linked to Medicare administrative claims using direct patient identifiers (name and social security number) by the Centers for Medicare & Medicaid Services (CMS). Per the CMS National Coverage Determination for reimbursement, all patients were required to have site documentation of echocardiographically defined severe AS and an assessment by 2 cardiothoracic surgeons who independently deemed the patients as at high or prohibitive surgical risk of mortality from surgical aortic valve replacement. Of the 24,025 index TVT procedure records, 8,502 were not linked to Medicare, either because of patient nonparticipation in the Medicare Parts A and B fee-for-service program at the time of the index procedure or an inability to link the index admission to a Medicare inpatient claim. For quality of life, the study cohort was limited to procedures performed on or before July 17, 2014, for 30-day assessment and procedures on or before August 1, 2013, for 1-year assessment to allow for appropriate follow-up.

STUDY ENDPOINTS. Primary outcomes studied included death, stroke, rehospitalization due to heart failure, aortic valve reintervention, myocardial infarction (MI), and quality of life (QOL) at 30 days and 1 year. QOL was assessed with the 12-item Kansas City Cardiomyopathy Questionnaire (KCCQ-12), a 12-item condensed psychometrically valid version of the full Kansas City Cardiomyopathy Questionnaire (KCCQ) (12). A disease-specific health status survey originally developed to describe and monitor health status in patients with heart failure, the KCCQ has also been validated in patients with aortic stenosis (13). For this study, we focused on the overall summary score of the 12-item Kansas City Cardiomyopathy Questionnaire (KCCQ-os), which ranges from 0 to 100 with higher scores indicating less symptom burden, less physical and social limitations, and better quality of life.

paper represent those of the author(s) and do not necessarily represent the official views of the NCDR or its associated professional societies identified at CVQuality.ACC.org/NCDR. Dr. Szerlip has served as a speaker for Edwards Lifesciences. Dr. Vemulapalli has received research grants from Abbott Vascular, Boston Scientific, and the American College of Cardiology. Dr. Holper has been a consultant to Boston Scientific and Asahi Intecc. Dr. Rumsfeld is Chief Science Officer of the NCDR. Dr. Mack is an uncompensated member of the executive committee of the PARTNER (Placement of Aortic Transcatheter Valve) trial of Edwards Lifesciences. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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