Transapical and Transaortic Transcatheter Aortic Valve Replacement in the United States

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Background. **When transcatheter aortic valve replacement (TAVR) cannot be carried out through transfemoral access, alternative access TAVR is indicated. The purpose of this study was to explore inhospital and 1-year outcomes of patients undergoing alternative access TAVR through the transapical (TA) or transaortic (TAo) techniques in the United States.**

Methods. **Clinical records of 4,953 patients undergoing TA (n = 4,085) or TAo (n = 868) TAVR from 2011 to 2014 in The Society of Thoracic Surgeons (STS)/American College of Cardiology Transcatheter Valve Therapy Registry were linked to Centers for Medicare and Medicaid Services hospital claims. Inhospital and 1-year clinical outcomes were stratified by operative risk; and the risk-adjusted association between access route and mortality, stroke, and heart failure repeat hospitalization was explored.**

Results. **Mean age for all patients was 82.8 ± 6.8 years. The median STS predicted risk of mortality was significantly higher among patients undergoing TAo (8.8 versus 7.4, $p < 0.001$). When compared with TA, TAo was associated with an increased risk of unadjusted 30-day mortality (10.3% versus 8.8%) and 1-year mortality (30.3% versus 25.6%, $p = 0.006$). There were no significant differences between TAo and TA for inhospital stroke rate (2.2%), major vascular complications (0.3%), and 1-year heart failure rehospitalizations (15.7%). Examination of high-risk and inoperable subgroups showed that 1-year mortality was significantly higher for TAo patients classified as inoperable ($p = 0.012$).**

Conclusions. **Patients undergoing TAo TAVR are older, more likely female, and have significantly higher STS predicted risk of mortality scores than patients operated on by TA access. There were no risk-adjusted differences between TA and TAo access in mortality, stroke, or readmission rates as long as 1 year after TAVR.**

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Within the last decade, there has been a transformation of the surgical management of high- and extreme-risk patients with symptomatic, severe aortic stenosis. The Placement of Aortic Transcatheter Valve (PARTNER) trial demonstrated superiority of transcatheter aortic valve replacement (TAVR) over medical therapy for extreme-risk surgical patients and confirming the

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Abbreviations and Acronyms

AA = alternative access
CMS = Centers for Medicare and Medicaid Services
PROM = predicted risk of mortality
PVL = paravalvular leak
SAVR = surgical aortic valve replacement
STS = The Society of Thoracic Surgeons
TA = transapical
TAo = transaortic
TAVR = transcatheter aortic valve replacement
TF = transfemoral
TVT = transcatheter valve therapy

noninferiority of TAVR to surgical aortic valve replacement (SAVR) for high-risk surgical candidates [1–4]. The initial access route of choice has commonly been the transfemoral (TF) TAVR; however, for patients with severe peripheral arterial disease, alternative access (AA) routes, such as the transapical (TA), transaortic (TAo), transcarotid, or subclavian approaches, have been utilized [5].

Although individual institution have reported outcomes of AA TAVR [6], a larger, "real world" analysis since Food and Drug Administration approval for the balloon expandable valve in the United States has not been reported. In this retrospective study, we report the outcomes of patients operated on using the two most common AA TAVR routes (TA and TAo) as captured in The Society of Thoracic Surgeons (STS)/American College of Cardiology transcatheter valve therapy (TVT) registry.

Material and Methods

STS/American College of Cardiology TVT Registry

The TVT registry and its properties have been previously described [7]. Registry activities have been approved by a central Institutional Review Board, and the Duke University Institutional Review Board granted a waiver of informed consent and authorization for this study. Although not audited by a third party, data quality checks for the TVT registry were implemented both at the National Cardiovascular Data Registry data warehouse and the Duke Clinical Research Institute Analysis Center, including data quality feedback reports as well as data range and consistency checks. (For details of the organization and structure of the registry, the reader is referred to the previous report from the TVT registry [7].)

An analysis of the TVT registry from November 2011 to June 2014 revealed that 18,100 TAVR procedures were performed. During this period, AA TAVR was performed in 7,384 patients (40.8%). For purposes of reporting 1-year outcomes, the TVT registry was linked to the Centers for Medicare and Medicaid Services (CMS) claims data (67% linkage rate) using direct patient identifiers to evaluate longitudinal patient outcomes, including rehospitalizations and survival. Only patients in the TVT registry who had these confirmed follow-up data (n = 4,953; TA, n = 4,085, and TAo, n = 868) were included in the present study. The main reason for missing CMS-linked follow-up data was that the TVT registry patient was not covered by Medicare during the TAVR hospital admission.

Data Element Definitions TVT Registry

Data elements were collected using standardized definitions harmonized with the STS national database wherever possible. The clinical indication for TAVR (inoperable or high-risk status) was based on determination by two experienced local cardiac surgeons and was classified by the local heart team. Patients were considered inoperable if combined risk of death and irreversible severe morbidity was prohibitive for SAVR or if technical issues precluded surgery. Furthermore, for the purposes of this analysis, patients were classified according to their STS predicted risk of mortality (PROM) score into three categories: (1) STS PROM less than 8%; (2) STS PROM 8% to 15%; or (3) STS PROM greater than 15%.

Inhospital, 30-day, 6-month, and 1-year outcomes were reported by site to the TVT registry using standardized definitions, including harmonization with Valve Academic Research Consortium (VARC) and VARC-2 definitions for stroke, transient ischemic attack, aortic valve reintervention, major bleeding, and major vascular complications [8, 9]. All site-reported stroke, transient ischemic attack, and valve reintervention events were adjudicated by a board-certified cardiologist using a combination of site-reported clinical information and targeted chart reviews.

Centers for Medicare and Medicaid Services

The primary endpoint was all-cause mortality, which was identified with the Medicare denominator file. Secondary endpoints were identified with primary hospital diagnosis based on International Classification of Diseases, Ninth Revision, Clinical Modification, codes, and included rehospitalization for cerebrovascular accident (433.x1, 434.x1, 997.02, 436, 437.1, 437.9, 430, 431, 432.x), heart failure hospitalization (398.x, 402.x1, 404.x1, 404.x3, 428.x), and aortic valve reintervention (35.11, 35.21, 35.22, 35.01, 35.05, 35.06, 35.09).

Procedural Details

The patients in this cohort underwent surgery with the first-generation balloon expandable Sapien valve (Edwards Lifesciences, Irvine, CA), which at the time of study enrollment was the only commercially available transcatheter valve.

Statistical Analysis

Patients in the CMS-linked cohort (n = 4,953) were stratified based on surgical risk (high risk or inoperable/prohibitive risk). Baseline characteristics and hospital outcomes were compared. Continuous variables were compared using the Wilcoxon rank sum test, and categoric variables were compared using the Pearson χ^2 test. Cox proportional hazards regression modeling was performed to determine the association of technique with 1-year mortality. Variables included in the Cox model were selected based on clinical merit, including age, sex, renal failure, ejection fraction, prior aortic