

Midterm survival after thoracic endovascular aortic repair in more than 10,000 Medicare patients

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Objective: Aneurysms and dissections of the descending thoracic aorta represent a complex substrate with a variety of therapeutic options. The introduction of thoracic endovascular aortic repair (TEVAR) has revolutionized the treatment of thoracic aortic disease. However, longitudinal analyses of post-TEVAR outcomes appropriately stratified by aortic disease remain limited.

Methods: A total of 11,996 patients undergoing TEVAR from 2005-2010 were identified from the Medicare/Centers for Medicare and Medicaid Services database. Patients were stratified by underlying aortic disease and the presence of Current Procedural Terminology (CPT) codes. Survival was assessed using Kaplan-Meier analysis. Cox proportional hazards analysis determined predictors of survival from TEVAR.

Results: After TEVAR, patients had a median survival of 57.6 months (95% confidence interval, 54.9-61.3 months). Although patients without CPT codes had significantly fewer recorded comorbidities, TEVAR survival was comparable between patients with and without CPT codes (56.3 vs 59.5 months, $P = .54$). The early and late incidence of death varied significantly by aortic disease. Patients with aortic rupture, acute aortic dissection, and aortic trauma had the highest early incidence of death, whereas late survival was highest in patients with acute aortic dissection, aortic trauma, and isolated thoracic aortic aneurysm. Although hospital TEVAR volume was not associated with survival, an independent hospital effect (determined by using a mixed-effect Cox model) associated certain hospitals with a hazard for death 50% of what it was at other hospitals.

Conclusions: TEVAR has been applied to a multitude of aortic diseases in the Medicare population; early and late post-TEVAR survival varies by aortic disease. The late incidence of death remains high in TEVAR recipients, although certain aortic diagnoses such as acute aortic dissection, aortic trauma, and isolated thoracic aortic aneurysm were associated with improved late survival. An independent hospital effect, but not hospital volume, is correlated with post-TEVAR survival. Future analyses of TEVAR outcomes using the Medicare database should adjust for underlying aortic diagnoses and the presence of CPT codes. (*J Thorac Cardiovasc Surg* 2015;149:808-23)

See related commentary on pages 823-4.

Since its introduction in 1992, thoracic endovascular aortic repair (TEVAR) has seen rapid adoption as a treatment modality for disease involving the descending thoracic aorta.¹⁻³

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Initial enthusiasm for TEVAR, spawned by its low procedural morbidity, has been tempered by sobering midterm outcomes, particularly in older patients with multiple comorbidities.^{4,5} Initially approved by the US Food and Drug Administration (FDA) only for the treatment of descending thoracic aortic aneurysms, TEVAR devices were often used off-label to treat catastrophes of the descending thoracic aorta—such as acute, complicated, type B aortic dissections and acute, traumatic aortic tears—with reasonable success.⁶⁻¹⁰ Several recently published guidelines favor TEVAR over surgery for the treatment (when feasible) of acute catastrophe of the descending thoracic aorta.^{11,12} An attempt to further broaden the indications for TEVAR to include uncomplicated chronic type B aortic dissection was undertaken with the Investigation of Stent Grafts in Patients with Type B Aortic Dissection trial (INSTEAD; comparing TEVAR to optimal medical management), the only randomized controlled trial of TEVAR ever completed; however, no improvement in 2- or 5-year all-cause mortality was shown, probably because of the high incidence of nonaneurysmal death (and thus the low overall survival benefit of TEVAR) in patients with uncomplicated type B aortic dissection.^{13,14} Several

Abbreviations and Acronyms

CPT	= Current Procedural Terminology
FDA	= US Food and Drug Administration
ICD-9	= International Classification of Diseases, ninth revision
TEVAR	= thoracic endovascular aortic repair

commercial devices have been approved for TEVAR, which have all been associated with good freedom from aneurysm-related death, although midterm all-cause mortality remains suboptimal.¹⁵⁻²⁰

Since FDA approval made TEVAR available for general clinical use in the United States, analyses of large US registries such as the Nationwide Inpatient Sample and US Medicare database have shown a dramatic rise in the use of TEVAR, although the rate of open repair of descending thoracic aortic aneurysms did not decrease appreciably.^{2,3} In particular, the US Medicare database provides unprecedented access to patient demographics, comorbidities, and operative characteristics while also providing long-term survival data; several studies have used this database to assess midterm outcomes after TEVAR and open repair of both descending thoracic aortic aneurysm and type B dissection.^{21,22} However, although specific subsets of TEVAR recipients have been studied, a broad overview is lacking of how TEVAR has been applied in US Medicare patients since the first TEVAR devices received FDA approval, particularly with respect to which types of aortic disease are being treated with TEVAR. Furthermore, prior analyses of the US Medicare database have not fully taken advantage of the variables available in the Medicare database to evaluate surgical complexity (eg, how arterial access was obtained, whether the left subclavian artery required coverage, whether additional procedures were required). The aim of our study was to evaluate the application of TEVAR in the US Medicare population since its approval by the FDA, with a particular focus on operative characteristics and making sure to stratify patients by aortic disease.

METHODS**Data Collection and Study Population**

We retrospectively reviewed data from the Centers for Medicare and Medicaid Services administrative database from 2005 to 2010. Patient demographics and survival data were obtained from the Beneficiary Summary file; International Classification of Diseases, ninth revision (ICD-9) diagnosis codes pertaining to the descending thoracic aorta and ICD-9 procedural codes pertaining to TEVAR were obtained from the MedPar file; patient comorbidities were obtained from the Chronic Conditions file; and surgeon billed Current Procedural Terminology (CPT) codes pertaining to prior and current surgical procedures were obtained from the Carrier file. Using data from the Chronic Conditions file to define patient comorbidities has been validated, particularly for conditions requiring regular physician follow-up, which is the case for TEVAR-treated descending thoracic aortic disease.²³ Patients

with an ICD-9 procedural code of 39.73 or a CPT code of 33880, 33881, 33883, 33884, 33886, 75956, 75957, 75958, or 75959 were designated as having undergone TEVAR and were included in our analysis (N = 11,996).^{24,25}

Determination of Aortic Disease

An algorithm was used to determine each patient's aortic disease from the ICD-9 diagnosis codes recorded at the index admission and at prior admissions. We classified patients as having 1 of 8 underlying aortic diseases: descending thoracic aortic rupture at the current admission (441.1, 441.3, 441.5, 441.6), thoracic aortic trauma at the current admission (901.0, 902.0), chronic aortic dissection (ie, aortic dissection diagnosed before the current admission) (441.0, 441.00, 441.01, 441.02, 441.03), acute aortic dissection (ie, aortic dissection not diagnosed before the current admission), thoracoabdominal aortic aneurysm (diagnosed either previously or at the current admission) (441.7), thoracic aortic aneurysm with concomitant abdominal aortic aneurysm (diagnosed either previously or at the current admission) (441.2, 441.4), isolated thoracic aortic aneurysm (441.2, in current or prior diagnoses), and descending thoracic aortic disease without a recorded diagnosis (441.9 or no other ICD-9 code previously described).

Statistical Analysis

We identified 999 US hospitals that performed between 1 and 477 TEVARs in Medicare patients during the study period. Because rigorous studies of both center volume and center-specific variation have shown them to be independently associated with postprocedural outcomes,²⁶ we included both variables in our analysis. A hospital was considered high volume if it performed ≥ 100 TEVARs in Medicare patients (15 hospitals met this criteria), and moderate volume if it performed 20 to 99 TEVARs in Medicare patients (122 hospitals met this criteria) over the study period (hospital Medicare TEVAR volume was used as a surrogate for overall hospital volume). Hospital-specific variation with respect to post-TEVAR survival was modeled as a random effect in a multivariate mixed-effect Cox model²⁷ that included all variables listed in Table 1 as covariates; this interhospital variation was statistically significant (likelihood-ratio test of $\theta = 0$: 10.78; $P = .001$), implying that hospital-specific variation is associated with post-TEVAR survival. In our multivariable analysis, in an effort to show the importance of hospital-specific variation, an independent hazard for postprocedural death was calculated for all 999 hospitals, and a dichotomous variable representing hospitals among the top third of post-TEVAR survival was generated to account for hospital variation in subsequent analyses.

The primary end point was all-cause mortality. Patients' vital status and date of death were validated with National Death Index data from 2005-2008 and with an internal Medicare determination of death (which itself informs the Social Security Death Master File) in patients for whom National Death Index data was unavailable; agreement between the National Death Index and Medicare death composite for vital status and date of death was $>99\%$.²⁸ Post-TEVAR survival distributions were estimated with the nonparametric Kaplan-Meier method²⁹; the log-rank test³⁰ was used to compare differences between survival distributions. Post-TEVAR survival for the entire cohort was compared to an age-/sex-/race-matched general US population cohort (data from the National Center for Health Statistics) using the 1-sample log-rank test as described by Finkelstein and colleagues.³¹

Univariate and multivariable Cox proportional hazards regression analyses³² assessed the effect of demographics, descending thoracic aortic disease, clinical comorbidities, prior operations, and surgical complexity on post-TEVAR survival. The proportional hazards assumption was tested with the Grambsch/Therneau method of plotting scaled Schoenfeld residuals³³; no significant deviations from the proportional hazards assumption were noted. Interactions between variables were explored, without any significant findings. Purposeful selection of covariates was used to create a multivariable model³⁴; variables hypothesized or previously shown to have clinical significance in TEVAR recipients were included along with novel variables that were plausibly significant ($P \leq .20$) on univariate analysis. Variables insignificant ($P > .05$) by the Wald test in our multivariable models but that were plausible predictors of survival were included in our final

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