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Contemporary Evaluation of Mortality and Stroke Risk after Thoracic Endovascular Aortic Repair

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Abstract

Objective—Over the past decade, thoracic endovascular aortic repair (TEVAR) has increased as a treatment option for a variety of aortic pathologies. Despite this rise in the use of thoracic stent grafts, real-world outcomes from a robust, adjudicated, contemporary dataset have yet to be reported. Previous studies have shown peri-procedural mortality rates between 1.5%-9.5% and procedure-related stroke rates of 2.3%-8.2%. With advances in device engineering and increased physician experience, we hypothesized that the rates of these complications would be reduced in a more recent sample set. The purpose of this study was to determine current rates of mortality and stroke after TEVAR, identify risk factors that contribute to thirty-day mortality, and develop a simple scoring system that allows for risk stratification of patients undergoing TEVAR.

Methods—We examined the 30-day mortality rate following TEVAR using the 2013-2014 American College of Surgeons National Surgical Quality Improvement Program database. Patients undergoing TEVAR for all aortic pathology were identified using procedure codes. Bivariate analyses were performed to evaluate the association of pre-, intra- and post-operative variables with 30-day mortality, followed by multivariable logistic analysis using pre-operative variables only, with P<.10 as criteria for model entry. The predictive logistic model was internally validated by cross validation. Variables included in the multivariable model were used to develop a risk score.

Results—Eight hundred twenty-six patients were included. The thirty-day mortality and stroke rate were 7.63% (n=63) and 4.5% (n= 37), respectively. In regression analysis, mortality was

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independently associated with age ≥80 years (odds ratio [OR] 2.32, 95% confidence interval [CI] 1.25-4.31), emergency case (OR 2.61, 95% CI 1.39-4.90), ASA classification >3 (OR 2.89, 95% CI 1.34-6.24), transfusion >4 units in the 72 hours prior to surgery (OR 2.86, 95% CI 1.30-6.28), pre-operative creatinine ≥1.8 mg/dL (OR 2.07, 95% CI 1.05-4.08), and pre-operative white blood cell count ≥12 × 10^9/L (OR 2.65, 95% CI 1.41-4.96). Incorporating these factors, a six-point risk score was generated and demonstrated high predictability for overall thirty-day mortality.

Conclusions—Recent data from a national, retrospective dataset demonstrate that high perioperative mortality and stroke rates have persisted over the last decade. The risk score derived from this dataset is simple and convenient and serves as a prognostic tool in the pre-operative risk stratification of patients being evaluated for thoracic endovascular aortic repair.

Introduction

Since U.S. Food and Drug Administration approval in 2005, thoracic endovascular aortic repair (TEVAR) has gained popularity as a minimally-invasive treatment option for a range of thoracic aortic pathologies. Indications for the procedure have expanded from thoracic aortic aneurysm alone to include acute and chronic aortic dissection, penetrating aortic ulcer, ruptured thoracic aortic aneurysm, and traumatic aortic injury. It has rapidly become the procedure of choice for treating patients with thoracic disease processes.[1–4]. Numerous prospective, non-randomized and multi-institutional trials have demonstrated reduced or non-inferior morbidity and mortality rates compared with open surgical repair.[5–9]

Over the past decade, both stent graft devices and techniques have evolved to refine the TEVAR procedure. Despite the widespread use of this technology, we still lack evidence to support a set of defined patient- and procedure-related variables that may be consistently assessed in efforts to reduce perioperative TEVAR morbidity and mortality. To improve outcomes, it is necessary to focus our attention on the most recently available study period during which procedural implementation has been largely unchanged. The aim of this study was to use the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database from 2013-2014 to identify risk factors associated with thirty-day mortality following thoracic endovascular aortic repair for all thoracic aortic pathology and develop a scoring system for evaluating pre-operative risk in patients being considered for the procedure.

Methods

Data Acquisition

Patients undergoing TEVAR for all aortic pathology were identified from the 2013-2014 ACS NSQIP Participant Use Files using Current Procedural Terminology (CPT) codes, 33880 and 33881. Pre-operative through thirty-day post-operative data are prospectively collected by trained surgical clinical reviewers at each participating hospital to generate a representative sample of eligible cases. The annual participant use file user guide provides standardized definitions for each variable, and the data are abstracted by examining patient medical records, communicating with treating physicians, and directly contacting patients as necessary.[10] The 2013 and 2014 Participant Use Files contained adult patient-level data from

435 and 517 hospitals, respectively. For HIPAA-compliance, the distribution of cases per participating center is not disclosed. There were no exclusion criteria for this retrospective cohort study. The patient data are de-identified; informed consent was not required, and the study was determined to be exempt from Institutional Research Board review.

Data Collection

Demographic and pre-operative variables considered included sex, race (Caucasian or not Caucasian), transfer status (from home or not from home), emergency case, American Society of Anesthesiologists classification (I/II, normal healthy or mild systemic disease, or III/IV/V, severe systemic disease that is or is not a constant threat to life or moribund), diabetes mellitus (no or oral medication/insulin dependent), smoking status (within one year of operation), dyspnea (none or moderate exertion/at rest), ventilator dependence (ventilator-assisted respiration in the 48 hours prior to surgery, excluding treatment of sleep apnea with CPAP), chronic obstructive pulmonary disease, congestive heart failure, hypertension requiring medication, dialysis, disseminated cancer, weight loss (>10% in last 6 months), steroid use, bleeding disorder, functional status prior to surgery (independent or partially/totally dependent), pneumonia, urinary tract infection, transfusion (>4 units in the 72 hours prior to surgery), pre-operative wound infection, systemic sepsis (systemic inflammatory response syndrome or sepsis/septic shock), pre-operative white blood count ($\leq 12\times10^9$/L or $>12\times10^9$/L), pre-operative hematocrit, pre-operative creatinine (<1.8 mg/dL or ≥1.8 mg/dL)[11], pre-operative albumin, and age (<80 years or ≥80 years). Age was separated into two groups above and below this particular cut-off age as vascular surgeons are increasingly faced with making treatment decisions for older patient populations.[12–14]

Intra-operative variables considered included surgical specialty, principal anesthesia technique, left subclavian coverage, thoracic aortic dissection, and wound classification (clean or clean-contaminated/contaminated/dirty-infected). Post-operative variables considered included superficial surgical site infections, pneumonia, unplanned intubation, pulmonary embolism, ventilator dependence (>48 hours), acute renal failure, progressive renal insufficiency, urinary tract infection, cerebrovascular accident, cardiac arrest requiring cardiopulmonary resuscitation, myocardial infarction, transfusions, deep venous thrombosis requiring therapy, sepsis, septic shock, total hospital length of stay, length of stay >30 days, readmission, and unplanned reoperation. The variable, days from operation to death, was used to determine which patients had the primary outcome, thirty-day all-cause mortality. Thirty-day post-operative stroke was evaluated as a secondary outcome.

Statistical Analysis

In descriptive analyses, categorical variables are represented as frequency (%) while continuous variables are reported as mean +/- standard deviation. Bivariate analyses with the outcome of thirty-day all-cause mortality were conducted for pre-, intra-, and post-operative variables using χ^2 test or Fisher's exact test for categorical variables or t-test for continuous variables (Appendix A). These analyses were repeated with the outcome of thirty-day post-operative stroke for pre-and intra-operative variables only. A multivariable logistic regression model for thirty-day mortality was constructed using backward selection with P<.10 as stay criteria. Pre-operative variables with P<.10 in bivariate analysis and less than 5%

missing data were considered in the initial model. Variables included in the model were assessed for potential interaction. Additional variables of clinical significance were selected for model entry. The c-statistic, or area under the curve, and the Hosmer-Lemeshow goodness of fit test were used to evaluate the model. Variables incorporated in the model were used to generate a risk score. Points were assigned to risk factors significant at P< 05 by rounding their parameter estimates to the closest integer. The risk score was used to calculate predicted probabilities for thirty-day mortality, which were plotted against observed probabilities to assess calibration of the model.

The model underwent internal validation by leave-one-out cross validation, for which one observation was set aside from the entire study population, and a model was fitted to the remainder of the data. The model was used to predict the outcome for the 'missing' observation, and the process was repeated with each observation in the study cohort. Again, the c-statistic was used to evaluate the models produced in the validation method. All statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC).

Results

Between 2013 and 2014, a total of 826 patients (441 men, 322 women) underwent TEVAR and were included in the analysis. The mean age was 68.2 ± 12.7 years, and 68.8% of patients identified as Caucasian. Of the procedures performed, 188 (22.8%) were considered emergent while 396 (48.0%) were considered elective, and 211 (25.5%) patients were transferred from a facility other than home. Patient demographics and pre-operative characteristics for the study population are outlined in Table I. In descending order of frequency, the most common indications for which the procedure was performed are as follows: 334 thoracic aortic aneurysms without rupture (40.4%), 153 thoracic aortic dissections (18.5%), 79 thoracoabdominal aortic aneurysms without rupture (9.6%), 50 thoracic aortic aneurysms with rupture (6.1%), 43 thoracoabdominal aortic dissections (5.2%), 25 abdominal aortic aneurysms without rupture (3.0%), 14 aortic dissections of unspecified site (1.7%), 18 thoracoabdominal aortic aneurysms with rupture (2.18%), and 6 abdominal aortic aneurysms with rupture (0.7%). Patients observed to have abdominal aortic indications were presumed to have thoracic indications with concomitant abdominal indications. TEVAR was performed by a vascular surgeon in a total of 787 (95.3%) cases, and 292 (35.4%) procedures involved coverage of the left subclavian artery (Appendix B).

The thirty-day all-cause mortality in this patient population was 7.6% (n=63), with the mortality rate in the subset of patients undergoing elective cases being 2.3% (n= 9). 313 (37.9%) patients experienced at least one post-operative complication (Table II). The post-operative stroke rate was 4.5% (n=37) while the rate of post-operative acute renal failure was 2.7% (n=22). The median total length of hospital stay was 5 days (IQR 3-10 days). Ninety-two patients (11.1%) were readmitted within thirty days with 69 (8.4%) requiring unplanned reoperation (Table II).

In bivariate analysis, demographic and pre-operative variables found to be significantly associated with thirty-day mortality included age ≥80 years (P=.033), transfer status (P<. 0001), emergency case (P<.0001), American Society of Anesthesiologists (ASA)

classification >3 (P<.0001), ventilator requirement within 48 hours of surgery (P<.0001), dialysis requirement (P=.014), history of bleeding disorder (P=.0078), acute pneumonia (P=.022), transfusion >4 units of packed red blood cells in the 72 hours prior to surgery (P<.0001), systemic sepsis (P<.0001), white blood cell count $>12\times10^9$/L (P<.0001), decreased hematocrit (P=.0067), creatinine ≥1.8 mg/dL (P=.0046), and decreased albumin (P=.0003) (Table I). No intra-operative variables were significantly associated with thirty-day mortality in bivariate analysis (Appendix B). Patients with any post-operative complication (P<.0001), specifically pneumonia (P=.017), unplanned intubation (P<.0001), ventilator requirement >48 hours (p<.0001), acute renal failure (P=.0007), progressive renal insufficiency (P=.016), cerebrovascular accident (P<.0001), cardiac arrest requiring cardiopulmonary resuscitation (P<.0001), and septic shock (P<.0001), need for intra-operative or post-operative blood transfusions (P<.0001), or unplanned reoperation (P=.0014) had a higher risk of thirty-day mortality, compared to those who did not have the respective complication (Table II).

For the outcome of thirty-day post-operative stroke, the following demographic and pre-operative variables were noted to be significantly associated in bivariate analysis: transfer status (p=0.01), emergency case (p=0.008), transfusion >4 units in the 72 hours prior to surgery (p=0.03), open wound or wound infection prior to surgery (p=0.03), white blood count $>12 \times 10^9$/L (p=0.02), and creatinine ≥1.8 mg/dL (p=0.004) (Appendix C). The only intra-operative variable found to be significantly associated with the outcome was left subclavian coverage (p=0.08).

For thirty-day mortality, fourteen pre-operative variables met entry criteria for the multivariable model. Following backward logistic regression, the final model was comprised of six independent predictors (Table III),including age ≥80 years (odds ratio [OR] 2.32, 95% confidence interval [CI] 1.25-4.31), emergency case (OR 2.61, 95% CI 1.39-4.90), ASA classification >3 (OR 2.89, 95% CI 1.34-6.24), transfusion >4 units in the 72 hours prior to surgery (OR 2.86, 95% CI 1.30-6.28), pre-operative creatinine ≥1.8 mg/dL (OR 2.07, 95% CI 1.05-4.08), and pre-operative white blood cell count $\geq11 \times 10^9$/L (OR 2.65, 95% CI 1.41-4.96) The multivariable model performed well, with a c-statistic of 0.81, and the Hosmer-Lemeshow goodness-of-fit test yielded a non-significant P of 41. Using cross-validation, the model was satisfactory in discrimination with a c-statistic of 0.76.

In the final logistic regression model represented in Table III, the parameter estimates for all significant variables associated with thirty-day mortality rounded most closely to one. Thus each risk factor was assigned an equal weight, and calculation of the risk score was simplified to the number of risk factors identified by the model present in a given patient, ranging from 0-4+. Comparing predicted to observed probabilities for the outcome, increasing risk score was correlated with higher rates of thirty-day mortality. When stratified by 0 (n=241), 1 (n=265), 2 (n=179), 3 (n=104), or 4+ (n=37) risk factors, the predicted probability of thirty-day mortality was 1.33%, 3.40%, 8.41%, 19.34%, and 38.49%, respectively (Figure 1).

Discussion

As diagnostic and treatment strategies advance, the applications of TEVAR continue to change. Frequent re-examination of the risk factors employed in the clinical evaluation of patients is helpful in treatment decision analysis and for appropriate counseling of patients. This study examined pre-operative risk factors for thirty-day mortality after thoracic endovascular aortic repair in 826 patients using the ACS NSQIP database from 2013-2014 and developed a simple six-point risk score. In this cohort, all-cause mortality was observed to be 7.6%. Compared to prior studies, minimal change has been seen in the rate of this outcome, which has ranged from 3-9.5% in the last decade.[15–17] We suspect that these outcomes are influenced by the increasing eligibility of the patient population, the new generations of stent grafts, and the modifications to operating room technique.[18–20] For instance, even within our study period, the U.S. Food and Drug Administration approved the use of the conformable Gore TAG device for the new indication of isolated aortic lesion in 2013, soon followed by the Medtronic Captivia Valiant graft in early 2014. These regulatory changes are typically followed by an investigational device exemption trial targeting the latest diagnostic indication, and stringent inclusion and exclusion criteria may result in a selection bias towards patients with more favorable outcomes. The mortality rate of 7.6% noted in our study supports similar rates reported in certain industry-sponsored studies while contrasting from lower ones seen in other investigational device exemption trials.[2,3,6,18,21] Our finding, reported from a nationally sampled adjudicated dataset, offers a more representative value of the outcome observed at centers performing the procedure across the country.

Using a recent large real-world dataset, we identified a number of pre-operative variables that were risk factors for 30-day all-cause mortality and utilized them to create a clinical tool for stratification and counseling of patients under consideration for TEVAR. The lack of consistency in risk factors for mortality found across studies, even those completed with the same database, speaks to the dynamic environment in which TEVAR is being performed. It is likely that studies spanning similar or longer time periods are drawing conclusions from different patient populations.

Previous studies have identified variables associated with mortality using multivariable models.[15–17,22,23] Most recently, Kilic et al. used the 2005-2012 ACS NSQIP database to generate a 30-point composite risk score composed of ten risk factors, including age >70 years, BMI <30 kg/m^2, chronic obstructive pulmonary disease, functional status prior to surgery, pre-operative blood urea nitrogen >25 mg/dL, pre-operative white blood cell count $>12 \times 10^9$/L, emergency case, left subclavian artery coverage, thoracoabdominal extension, and mesenteric debranching.[24] Compared with the former risk score, the one developed in our study does not require stratification of patients into low, medium, or high risk tiers. Instead, predicted probability of the outcome may quickly be assessed based solely on number of risk factors present, as identified by the multivariable model.

Though many risk factors, varying from older age to emergency case, have repeatedly been associated with thirty-day mortality,[24,25] the model we constructed using this contemporary dataset also yielded many different predictors. Of note, we did not find left subclavian artery

coverage to be a significant risk factor for mortality, though it has previously been found to be predictive of both stroke and mortality.[24,26] Similarly, chronic obstructive pulmonary disease was not significant in bivariate analysis nor did it remain in the multivariable model, unlike prior findings.[15,17,24] Our results might suggest that these variables pertaining to more localized processes did not influence the outcome of mortality to the same extent in this sample population while risk factors frequently representative of systemic alterations in health status, such as elevated white blood cell count or increased red blood cell transfusion requirement, were found to be significant. While several of the identified risk factors may not be altered, others offer opportunities for pre-operative optimization. For instance, patients found to have significantly elevated creatinine level may be medically optimized from a renal point of view, should timing of the procedure allow. Any intervention would then have to be investigated to assess its impact on outcomes.

Limitations of the study include those inherent in any retrospective dataset analysis as well as specific constraints associated with the NSQIP database. First, many patient- and procedure-related variables, including comprehensive past surgical history or maximum aortic diameter, required to draw more informed conclusions about this patient population are not captured in the dataset. We acknowledge a potential for inter-provider variation in procedure designations and coding patterns and an inability to verify patient-level information given the de-identified nature of the database. Another consideration is that an adjunct procedure performed on any given patient during a separate hospital admission, either as a component of a staged procedure or for a separate indication, could be unaccounted for in the database, resulting in information bias. For these reasons, we chose not to evaluate the contribution of adjunct procedures towards or away from the outcomes of mortality or stroke. We recognize that other studies have incorporated procedures performed concurrently with TEVAR in their analyses to approximate their associations with outcomes of interest, and we need only bear in mind that these estimates could stray from the true value in either positive or negative direction.[23] Also, the NSQIP database does not include several post-operative complications often examined following endovascular procedures. Many of these missing variables, whether it be paraplegia or presence of endoleak, are recognized as chronic conditions or long-term outcomes and are challenging to identify accurately in the 30-day post-operative window. More extensive examination of these outcomes would be better suited for a study population with a longer follow-up period.

Although the data are entered by trained clinical reviewers using consistent variable definitions, differences in interpretation are possible and random errors in completion and accuracy may occur. The vast majority of variables included in the analysis were complete, and more specifically, none of the variables meeting selection for logistic regression modeling had missing values, demonstrating the rigor with which the database is maintained. Additionally, the model we developed had good discrimination in predicting mortality after TEVAR and continued to have acceptable discrimination with cross validation.

In terms of clinical application of the model developed, the variables incorporated in the risk score may all be found easily with the quick review of a patient's medical record, so such a pre-operative assessment would be quite feasible. Moving forward, coupled with clinical

judgment, identification of these risk factors and consolidation of these identified variables into a simple prognostic tool, may assist in the prospective, pre-operative assessment of a patient's suitability for TEVAR. Alternatively, the patient and healthcare team would be aware prior to surgery if the patient were considered to be at increased risk for poor outcomes, prompting closer postoperative monitoring or planning for anticipatory interventions. We have taken initial steps towards prospective application of the risk score as well as external validation with our institutional series of TEVAR patients. Future research will pursue a multi-institutional dataset containing more anatomic or procedure-focused variables in order to offer a better measure of its utility.

Conclusion

From the most recent sample of the ACS NSQIP database, we found that perioperative mortality and stroke rates have remained high after TEVAR. Of the variables identified as significant risk factors for thirty-day all-cause mortality, many were representative of overall decline in health status or systemic disease, with higher ASA classification having the greatest magnitude of effect in the multivariable model. We incorporated these variables into a risk score that is simple and convenient and may serve as a prognostic tool in the pre-operative risk stratification of patients being evaluated for TEVAR. Considering the contrast between predictors identified in our study and those found in other studies looking at mortality, we require additional evidence, ideally through prospective application of the risk score, to evaluate the reliability of our model and substantiate its applicability to diverse patients with indications for TEVAR.

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Appendix A. Study classification of variables

Categorical Variables	
Demographic	*Intra-operative*
Sex	Specialty
Race	Principal anesthesia technique
Hispanic ethnicity	Left subclavian coverage
	Thoracic aortic dissection
Pre-operative	Wound classification
Transfer status	
Emergency case	*Post-operative*
ASA classification	Complication
Comorbidity	Any
Diabetes mellitus	Superficial surgical site infection
Smoking within one year	Pneumonia

Categorical Variables	
Dyspnea	Unplanned intubation
Ventilator dependent	Pulmonary embolism
Severe chronic obstructive pulmonary disease	Ventilator >48 hours
Congestive heart failure within 30 days	Acute renal failure
Hypertension requiring medication	Progressive renal insufficiency
Currently on dialysis	Urinary tract infection
Disseminated cancer	Cerebrovascular accident
Steroid use for chronic condition	Cardiac arrest requiring CPR
Weight loss >10% within 6 months	Myocardial infarction
Bleeding disorder	Transfusions, intra-operative or post-operative
Functional Status	DVT/thrombophlebitis
Acute Conditions	Sepsis
Pneumonia	Septic shock
Urinary tract infection	Length of hospital stay >30 days
Transfusion >4 units within 72 hours	Any readmission
Open wound or wound infection	Unplanned reoperation
Systemic sepsis	
Pre-operative laboratory values	
White blood count (10^9/L)	
Creatinine (mg/dL)	
CPR, cardiopulmonary resuscitation; *DVT*, deep vein thrombosis.	
Continuous Variables	Continuous Variables
Pre-operative	*Demographic*
Pre-operative laboratory values	Age (years)
Hematocrit (%)	
Albumin[c] (g/dL)	*Post-operative*
	Total length of hospital stay (days)

CPR, cardiopulmonary resuscitation; *DVT*, deep vein thrombosis.

Appendix B. Intra- operative outcomes in patients undergoing TEVAR from 2013-2014 and univariate comparisons with 30-day mortality

		30-day Mortality		
Characteristic	**Study Population (n=826)**	**No (n= 763)**	**Yes (n=63)**	**P[a]**
Specialty, *N (%)*				0.76
Vascular	787 (95.3)	726 (92.2)	61 (7.8)	
Not Vascular	39 (4.7)	37 (94.9)	2 (5.1)	
Principal anesthesia technique, *N (%)*				0.25

		30-day Mortality		
Characteristic	**Study Population (n=826)**	**No (n= 763)**	**Yes (n=63)**	**P[a]**
General	802 (97.1)	739 (92.1)	63 (7.9)	
Not general	24 (2.9)	24 (100.0)	0 (0.0)	
Left subclavian coverage, *N (%)*				0.31
Yes	292 (35.4)	266 (91.1)	26 (8.9)	
No	534 (64.6)	497 (93.1)	37 (6.9)	
Thoracic dissection, *N (%)*				
Yes	153 (18.5)	137 (89.5)	16 (10.5)	0.14
No	673 (81.5)	626 (93.0)	47 (7.0)	
Wound classification, *N (%)*				0.20
Clean	815 (98.7)	754 (92.5)	61 (7.5)	
Not clean	11 (1.3)	9 (81.8)	2 (18.2)	

[a]Pearson χ^2 or Fisher's exact test, as appropriate.

Appendix C. Demographic, pre- and intra-operative characteristics of patients undergoing TEVAR from 2013-2014 and univariate comparisons with 30-day stroke

	30-day Stroke		
Characteristic	**No (n= 789)**	**Yes (n=37)**	**P[a]**
Age (years), *mean ± SD*			0.73
18-79, *N (%)*	621 (95.4)	30 (4.6)	
80-90+, *N (%)*	168 (96.0)	7 (4.0)	
Sex, *N (%)*			0.78
Male	451 (95.3)	22 (4.7)	
Female	338 (95.7)	15 (4.3)	
Race, *N (%)*			0.11
Caucasian	547 (96.3)	21 (3.7)	
Not Caucasian	242 (93.8)	16 (6.2)	
Hispanic ethnicity[b], *N (%)*			1.00
Yes	18 (100.0)	0 (0.0)	
No	688 (95.7)	31 (4.3)	
Transfer status, *N (%)*			0.01
From home	594 (96.6)	21 (3.4)	
Not from home	195 (92.4)	16 (7.6)	
Emergency case, *N (%)*			0.008
Yes	173 (92.0)	15 (8.0)	
No	616 (96.5)	22 (3.5)	

	30-day Stroke		
Characteristic	**No (n= 789)**	**Yes (n=37)**	**P[a]**
ASA classification, *N (%)*			0.20
≤3	361 (96.5)	13 (3.5)	
>3	428 (94.7)	24 (5.3)	
Comorbidity			
Diabetes mellitus, *N (%)*			0.14
Yes	102 (92.7)	8 (7.3)	
No	687 (96.0)	29 (4.0)	
Smoking within one year, *N (%)*			0.27
Yes	252 (94.4)	15 (5.6)	
No	537 (96.0)	22 (4.0)	
Dyspnea, *N (%)*			0.78
Yes	115 (95.0)	6 (5.0)	
No	674 (95.6)	31 (4.4)	
Ventilator dependent, *N (%)*			0.12
Yes	24 (88.9)	3 (11.1)	
No	765 (95.7)	34 (4.3)	
Severe chronic obstructive pulmonary disease, *N (%)*			0.52
Yes	139 (96.5)	5 (3.5)	
No	650 (95.3)	32 (4.7)	
Congestive heart failure within 30 days, *N (%)*			1.00
Yes	29 (96.7)	1 (3.3)	
No	760 (95.5)	36 (4.5)	
Hypertension requiring medication, *N (%)*			0.81
Yes	652 (95.6)	30 (4.4)	
No	137 (95.1)	7 (4.9)	
Currently on dialysis, *N (%)*			0.13
Yes	40 (90.9)	4 (9.1)	
No	749 (95.8)	33 (4.2)	
Disseminated cancer, *N (%)*			1.00
Yes	4 (100.0)	0 (0.0)	
No	785 (95.5)	37 (4.5)	
Steroid use for chronic condition, *N (%)*			0.46
Yes	44 (93.6)	3 (6.4)	
No	745 (95.6)	34 (4.4)	
Weight loss >10% within 6 months, *N (%)*			1.00
Yes	16 (100.0)	0 (0.0)	
No	773 (95.4)	37 (4.6)	
Bleeding disorder, *N (%)*			0.12

	30-day Stroke		
Characteristic	**No (n= 789)**	**Yes (n=37)**	**P[a]**
Yes	93 (92.1)	8 (7.9)	
No	696 (96.0)	29 (4.0)	
Functional status, *N (%)*			1.00
Independent	755 (95.4)	36 (4.6)	
Not independent	34 (97.1)	1 (2.9)	
Acute Conditions			
Pneumonia, *N (%)*			1.00
Yes	774 (95.4)	37 (4.6)	
No	15 (100.0)	0 (0.0)	
Urinary tract infection, *N (%)*			1.00
Yes	785 (95.5)	37 (4.5)	
No	4 (100.0)	0 (0.0)	
Transfusion >4 units within 72 hours, *N (%)*			0.03
Yes	37 (88.1)	5 (11.9)	
No	752 (95.9)	32 (4.1)	
Open wound or wound infection, *N (%)*			0.03
Yes	12 (80.0)	3 (20.0)	
No	777 (95.8)	34 (4.2)	
Systemic sepsis, *N (%)*			0.38
None	716 (95.7)	32 (4.3)	
SIRS, sepsis or septic shock	73 (93.6)	5 (6.4)	
Pre-operative laboratory values			
White blood count (10^9/L), *N (%)*			0.02
<12	671 (96.3)	26 (3.7)	
>12	118 (91.5)	11 (8.5)	
Hematocrit (%), *mean ± SD*	36.4 ± 5.8	35.4 ± 7.0	0.37
Creatinine (mg/dL), *N (%)*			0.004
<1.8	697 (96.4)	26 (3.6)	
>1.8	92 (89.3)	11 (10.7)	
Albumin[c] (g/dL), *mean ± SD*	3.4 ± 0.6	3.4 ± 0.6	0.71
Specialty			0.69
Vascular	752 (95.5)	35 (4.5)	
Not vascular	37 (94.9)	2 (5.1)	
Principal anesthesia technique			1.00
General	766 (95.5)	36 (4.5)	
Not general	23 (95.8)	1 (4.2)	
Thoracic aortic dissection			0.35
Yes	144 (94.1)	9 (5.9)	

	30-day Stroke		
Characteristic	**No (n= 789)**	**Yes (n=37)**	**P[a]**
No	645 (95.8)	28 (4.2)	
Left subclavian coverage			.08
Yes	274 (93.8)	18 (6.2)	
No	515 (96.4)	19 (3.6)	
Wound classification			1.00
Clean	778 (95.5)	37 (4.5)	
Not clean	11 (100.0)	0 (0.0)	

SIRS, systemic inflammatory response syndrome.

[a] oPearson χ^2, Fisher's exact test or unpaired t-test, as appropriate.

[b] 89 values categorized as 'Unknown' for Hispanic ethnicity.

[c] 301 values missing for albumin

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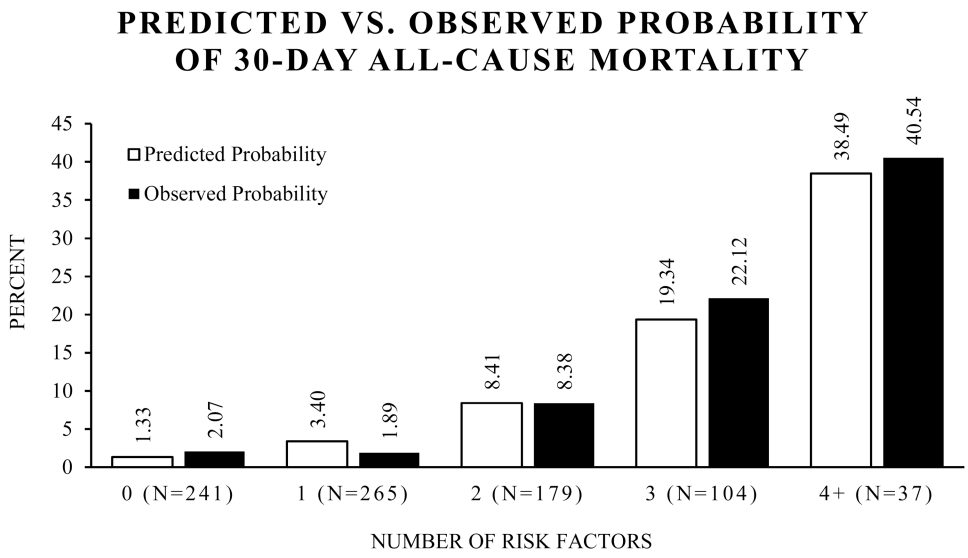

Figure 1. Probability of 30-day mortality based on number of risk factors present in patients undergoing TEVAR from 2013-2014

Table I

Demographic and pre-operative characteristics of patients undergoing TEVAR from 2013-2014 and bivariate comparisons with 30-day mortality

		30-day Mortality		
Characteristic	**Study Population (n=826)**	**No (n=763)**	**Yes (n=63)**	**p[a]**
Age (years), *mean ± SD*	68.2 ± 12.7			0.03
18-79, *N (%)*	651 (78.8)	608 (93.4)	43 (6.6)	
80-90+, *N (%)*		155 (88.6)	20 (11.4)	
Sex, *N (%)*				0.28
Male	473 (57.3)	441 (93.2)	32 (6.8)	
Female		322 (91.2)	31 (8.8)	
Race, *N (%)*				0.51
Caucasian	568 (68.8)	527 (92.8)	41 (7.2)	
Not Caucasian		236 (91.5)	22 (8.5)	
Hispanic ethnicity[b], *N (%)*				1.00
Yes	18 (2.2)	17 (94.4)	1 (5.6)	
No		667 (92.8)	52 (7.2)	
Transfer status, *N (%)*				<.0001
From home	615 (74.5)	584 (95.0)	31 (5.0)	
Not from home		179 (84.8)	32 (15.2)	
Emergency case, *N (%)*				<.0001
Yes	188 (22.8)	151 (80.3)	37 (19.7)	
No		612 (95.9)	26 (4.1)	
ASA classification, *N (%)*				<.0001
≤3	374 (45.3)	365 (97.6)	9 (2.4)	
>3		398 (88.0)	54 (12.0)	
Comorbidity				
Diabetes mellitus, *N (%)*				0.16
Yes	110 (13.3)	98 (89.1)	12 (10.9)	
No		665 (92.9)	51 (7.1)	
Smoking within one year, *N (%)*				0.07
Yes	267 (32.3)	253 (94.8)	14 (5.2)	
No		510 (91.2)	49 (8.8)	
Dyspnea, *N (%)*				0.65
Yes	121 (14.7)	113 (93.4)	8 (6.6)	
No		650 (92.2)	55 (7.8)	
Ventilator dependent, *N (%)*				<.0001
Yes	27 (3.3)	18 (66.67)	9 (33.3)	
No		745 (93.2)	54 (6.8)	

		30-day Mortality		
Characteristic	**Study Population (n=826)**	**No (n=763)**	**Yes (n=63)**	**p[a]**
Severe chronic obstructive pulmonary disease, *N (%)*				0.73
Yes	144 (17.4)	134 (93.1)	10 (6.9)	
No		629 (92.2)	53 (7.8)	
Congestive heart failure within 30 days, *N (%)*				0.49
Yes	30 (3.6)	27 (90.0)	3 (10.0)	
No		736 (92.5)	60 (7.5)	
Hypertension requiring medication, *N (%)*				0.73
Yes	682 (82.6)	631 (92.5)	51 (7.5)	
No		132 (91.7)	12 (8.3)	
Currently on dialysis, *N (%)*				0.01
Yes	44 (5.3)	36 (81.8)	8 (18.2)	
No		727 (93.0)	55 (7.0)	
Disseminated cancer, *N (%)*				1.00
Yes	4 (0.5)	4 (100.0)	0 (0.0)	
No		759 (92.3)	63 (7.7)	
Steroid use for chronic condition, *N (%)*				0.16
Yes	47 (5.7)	41 (87.2)	6 (12.8)	
No		722 (92.7)	57 (7.3)	
Weight loss >10% within 6 months, *N (%)*				0.35
Yes	16 (1.9)	14 (87.5)	2 (12.5)	
No		749 (92.5)	61 (7.5)	
Bleeding disorder, *N (%)*				0.008
Yes	101 (12.2)	86 (85.1)	15 (14.9)	
No		677 (93.4)	48 (6.6)	
Functional status, *N (%)*				0.33
Independent	791 (95.8)	732 (92.5)	59 (7.5)	
Not independent		31 (88.6)	4 (11.4)	
Acute Conditions				
Pneumonia, *N (%)*				0.02
Yes	15 (1.8)	11 (73.3)	4 (26.7)	
No		752 (92.7)	59 (7.3)	
Urinary tract infection, *N (%)*				0.27
Yes	4 (0.5)	3 (75.0)	1 (25.0)	
No		760 (92.5)	62 (7.5)	
Transfusion >4 units within 72 hours, *N (%)*				<.0001
Yes	42 (5.1)	29 (69.0)	13 (31.0)	
No		734 (93.6)	50 (6.4)	
Open wound or wound infection, *N (%)*				0.32

		30-day Mortality		
Characteristic	**Study Population (n=826)**	**No (n=763)**	**Yes (n=63)**	**p[a]**
Yes	15 (1.8)	13 (86.7)	2 (13.3)	
No		750 (92.5)	61 (7.5)	
Systemic sepsis, *N (%)*				<.0001
None	748 (90.6)	704 (94.1)	44 (5.9)	
SIRS, sepsis or septic shock		59 (75.6)	19 (24.4)	
Pre-operative laboratory values				
White blood count (10^9/L), *N (%)*				<.0001
<12	697 (84.4)	661 (94.8)	36 (5.2)	
>12		102 (79.1)	27 (20.9)	
Hematocrit (%), *mean ± SD*	36.4 ± 5.9	36.6 ± 5.8	34.3 ± 6.1	0.007
Creatinine (mg/dL), *N (%)*				0.005
<1.8	723 (87.5)	675 (93.4)	48 (6.6)	
≥1.8		88 (85.4)	15 (14.6)	
Albumin[c] (g/dL), *mean ± SD*	3.4 ± 0.6	3.5 ± 0.6	3.1 ± 0.7	0.0003

SIRS, systemic inflammatory response syndrome.

[a] Pearson χ^2, Fisher's exact test or unpaired t-test, as appropriate.

[b] 89 values categorized as 'Unknown' for Hispanic ethnicity.

[c] 301 values missing for albumin

Table II

Post-operative outcomes in patients undergoing TEVAR from 2013-2014 and bivariate comparisons with 30-day mortality

		30-day mortality		
Characteristic	**Study Population (n=826)**	**No (n= 763)**	**Yes (n=63)**	**p[a]**
Complication				
Any, *N (%)*				<.0001
Yes	313 (37.9)	257 (82.1)	56 (17.9)	
No		506 (98.6)	7 (1.4)	
Superficial surgical site infection, *N (%)*				1.00
Yes	9 (1.1)	9 (100.0)	0 (0.0)	
No		754 (92.3)	63 (7.7)	
Pneumonia, *N (%)*				0.02
Yes	54 (6.5)	45 (83.3)	9 (16.7)	
No		718 (93.0)	54 (7.0)	
Unplanned intubation, *N (%)*				<.0001
Yes	55 (6.7)	39 (70.9)	16 (29.1)	
No		724 (93.9)	47 (6.1)	
Pulmonary embolism, *N (%)*				1.00
Yes	4 (0.5)	4 (100.0)	0 (0.0)	
No		759 (92.3)	63 (7.7)	
Ventilator >48 hours, *N (%)*				<.0001
Yes	58 (7.0)	41 (70.7)	17 (29.3)	
No		722 (94.0)	46 (6.0)	
Acute renal failure, *N (%)*				0.0007
Yes	22 (2.7)	15 (68.2)	7 (31.8)	
No		748 (93.0)	56 (7.0)	
Progressive renal insufficiency, *N (%)*				0.02
Yes	3 (0.4)	1 (33.3)	2 (66.67)	
No		762 (92.6)	61 (7.4)	
Urinary tract infection, *N (%)*				0.69
Yes	23 (2.8)	21 (91.3)	2 (8.7)	
No		742 (92.4)	61 (7.6)	
Cerebrovascular accident, *N (%)*				<.0001
Yes	37 (4.5)	24 (64.9)	13 (35.1)	
No		739 (93.7)	50 (6.3)	
Cardiac arrest requiring CPR, *N (%)*				<.0001
Yes	38 (4.6)	9 (23.7)	29 (76.3)	
No		754 (95.7)	34 (4.3)	

		30-day mortality		
Characteristic	**Study Population (n=826)**	**No (n= 763)**	**Yes (n=63)**	**p[a]**
Myocardial infarction, *N (%)*				0.12
Yes	16 (1.9)	13 (81.2)	3 (18.8)	
No		750 (92.6)	60 (7.4)	
Transfusions, intra-operative or postoperative, *N (%)*				<.0001
Yes	220 (26.6)	179 (81.4)	41 (18.6)	
No		584 (96.4)	22 (3.6)	
DVT/thrombophlebitis, *N (%)*				0.03
Yes	22 (2.7)	18 (81.8)	4 (18.2)	
No		745 (92.7)	59 (7.3)	
Sepsis, *N (%)*				1.00
Yes	16 (1.9)	15 (93.7)	1 (6.3)	
No		748 (92.3)	62 (7.7)	
Septic shock, *N (%)*				<.0001
Yes	15 (1.8)	7 (46.7)	8 (53.3)	
No		756 (93.2)	55 (6.8)	
Total length of hospital stay (days), *median (interquartile range)*	5 (3-10)			
mean ± SD		8.1 ± 9.1	8.1 ± 7.8	0.98
Length of hospital stay >30 days, *N (%)*				0.40
Yes	21 (2.5)	21 (100.0)	0 (0.0)	
No		742 (92.2)	63 (7.8)	
Any readmission, *N (%)*				0.10
Yes	92 (11.1)	89 (96.7)	3 (3.3)	
No		671 (91.8)	60 (8.2)	
Unplanned reoperation, *N (%)*				0.001
Yes	69 (8.4)	57 (82.6)	12 (17.4)	
No		706 (93.3)	51 (6.7)	

CPR, cardiopulmonary resuscitation; *DVT*, deep vein thrombosis.

[a]Pearson χ^2, Fisher's exact test or unpaired t-test, as appropriate.

Table III

Multivariable associations of demographic and pre-operative variables with 30-day mortality in patients undergoing TEVAR from 2013-2014

Covariate	Odds ratio (95% confidence interval)	P
Age ≤80 years	2.32 (1.25-4.31)	0.008
Emergency case	2.61 (1.39-4.90)	0.003
ASA classification >3	2.89 (1.34-6.24)	0.007
Pre-operative transfusion >4 units within 72 hours	2.86 (1.30-6.28)	0.009
Creatinine ≥1.8 mg/dL	2.07 (1.05-4.08)	0.036
White blood count ≥12 10^9/L	2.65 (1.41-4.96)	0.002