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Impact of operative indication and surgical complexity on outcomes after thoracic endovascular aortic repair at National Surgical Quality Improvement Program Centers

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Introduction: **Thoracic endovascular aortic repair (TEVAR) devices are increasingly being utilized to treat aortic pathologies outside of the original Food & Drug Administration (FDA) approval for nonruptured descending thoracic aorta aneurysms (DTAs). The objective of this study was to evaluate the outcomes of patients undergoing TEVAR, elucidating the role of surgical and pathologic variables on morbidity and mortality.**

Methods: **National Surgical Quality Improvement Program (NSQIP) data were reviewed for all patients undergoing endovascular thoracic aorta repair from 2005 to 2007. The patients' operative indication and surgical complexity were used to divide them into study and control populations. Comorbid profiles were assessed utilizing a modified Charlson Comorbidity Index (CCI). Thirty-day occurrences of mortality and serious adverse events (SAEs) were used as study endpoints. Univariate and multivariate models were created using demographic and clinical variables to assess for significant differences in endpoints ($P \leq .05$).**

Results: **A total of 440 patients undergoing TEVAR were identified. When evaluating patients based on operative indication, the ruptured population had increased mortality and SAE rates compared to the nonruptured DTA population (22.6% vs 6.2%;$P < .01$ and 35.5% vs 9.1%;$P < .01$, respectively). Further analysis by surgical complexity revealed increased mortality and SAE rates when comparing the brachiocephalic aortic debranching population to the noncovered left subclavian artery population (23.1% vs 6.5%; $P = .02$ and 30.8% vs 9.1%; $P < .01$, respectively). Multivariate analysis demonstrated that operative indication was not a correlate of mortality or SAEs (odds ratio [OR], 0.95; $P = .92$ and OR, 1.42; $P = .39$, respectively); however, brachiocephalic aortic debranching exhibited a deleterious effect on mortality (OR, 8.75; $P < .01$) and SAE rate (OR, 6.67; $P = .01$).**

Conclusion: **The operative indication for a TEVAR procedure was not found to be a predictor of poor patient outcome. Surgical complexity, specifically the need for brachiocephalic aortic debranching and aortoiliac conduit, was shown to influence the occurrence of SAEs in a multivariate model. Comparative data, such as these, illustrate real-world outcomes of patients undergoing TEVAR outside of the original FDA-approved indications. This information is of paramount importance to various stakeholders, including third-party payers, the device industry, regulatory agencies, surgeons, and their patients. (J Vasc Surg 2011;54:1629-36.)**

The traditional treatment for pathologies of the thoracic aorta is surgical repair with interposition graft via an open thoracotomy. This treatment modality is associated with high rates of mortality and neurologic deficits, ranging from 8% to 9% and 7% to 16%, respectively, in previous high-volume studies.[1-3] Although the development of surgical adjuncts, including distal aortic perfusion, cerebrospinal fluid drainage, and epidural cooling has demonstrated decreased incidence of neurologic deficits, elevated mortality rates continue to plague patients undergoing open surgical repair.[4,5]

The introduction of endovascular stent grafts as a treatment option for descending thoracic aortic aneurysms occurred in the early 1990s.[6] Initially, patient outcomes were similar to those seen in patients undergoing open repair with adjuncts.[7] Other early studies with first-generation devices revealed either no benefit in patient outcomes or increased rates of endoleak and need for reintervention.[8,9] However, the phase II results for the Gore TAG thoracic endoprosthesis (W.L. Gore and Associates, Flagstaff, Ariz) in 2005 demonstrated superior results in regard to patient mortality and paraplegia compared to traditional treatments, as well as improved aneurysm sac exclusion compared to previous thoracic endovascular aortic repair (TEVAR) trials.[10] In the 5-year follow-up to this study, aneurysm-related mortality and neurologic complications continued to be significantly decreased compared to the open repair cohort while implementation of next generation devices improved sac exclusion.[11] These data have been replicated

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by other graft manufacturers. Furthermore, a meta-analysis comparing TEVAR to open surgical repair reinforced findings that the TEVAR cohort had improved outcomes, particularly related to 30-day mortality and paraplegia.[12]

Although the only Food & Drug Administration (FDA)-approved instruction for use of thoracic aortic endografts is for nonruptured descending thoracic aorta aneurysms (DTAs), endografts are increasingly being used to treat off-label pathologies. Thoracic endograft placement has been found to be efficacious and safe for use in the treatment of off-label pathologies such as type B aortic dissection, penetrating atherosclerotic ulcer, intramural hematoma, pseudoaneurysms, acute traumatic aortic disruption, and left subclavian artery aneurysms.[13-17] A majority of the studies investigating outcomes of patients who undergo TEVAR lump them into a single population, resulting in a paucity of literature comparing patients with TEVAR outcomes based on their operative indication, nonruptured DTA vs off-label pathology. The objective of this study was to evaluate the outcomes of patients undergoing TEVAR for off-label pathologies utilizing the American College of Surgeons - National Surgical Quality Improvement Project (ACS-NSQIP) databases and to elucidate the role of surgical and pathologic variables on morbidity and mortality.

METHODS

Database. The NSQIP began as a quality improvement initiative for the Veterans Affairs (VA) health system in 1994.[18] The NSQIP was extended into the private sector in (1999) based on the success of the program within the VA.[19] Currently, the NSQIP is commercially available to eligible high-volume hospitals across the United States, with 211 different sites enrolled as of 2008.[20]

Surgical patients are prospectively identified and randomly sampled. Medical records, operative logs, and patient interviews are used to obtain baseline clinical, demographic, perioperative, and 30-day postoperative data. Collected data are inserted into a database using an identical methodology for the VA and private sector. Data are gathered over the entirety of the 30-day postoperative period, including patients that have been discharged to the outpatient setting.

Case selection. The ACS-NSQIP databases were used to identify all cases of TEVAR performed from 2005 to 2007, based on the primary or concurrent Current Procedural Terminology (CPT) codes 33880, 33881, 33883, and 33886. Patients were then divided into two study and control populations, the first based on operative indication and the second on surgical complexity. The operative indication was defined using International Classification of Disease, 9th Revision, and Related Health Problems codes. The study population included all patients undergoing TEVAR for off-label pathologies, while the control population consisted of TEVAR cases for nonruptured DTA. The off-label pathologies identified included thoracic and abdominal aorta dissection, aneurysm rupture, and a variety of other conditions (see Appendix, online only). Furthermore, patients with complex anatomy were identified by CPT codes and encompassed the study population for surgical complexity. Surgical complexity was defined as requiring left subclavian artery (LSCA) coverage (CPT code 33880), visceral aortic debranching (CPT codes 35631 and 35281), or brachiocephalic aortic debranching (CPT codes 35626, 35606, 35695, 33889, or 33891). Patients with noncovered LSCA, defined as requiring neither of these maneuvers, comprised the control population. If a patient underwent coverage of the LSCA by an endograft but received an adjunctive procedure via brachiocephalic aortic debranching, he or she was excluded from the LSCA coverage subset and placed into the brachiocephalic aortic debranching cohort.

Demographic and clinical variables. Basic demographic data on each population was collected, including age and gender. To assess the patients' preoperative health, a modified Charlson Comorbidity Index (CCI) was calculated for each population.[21] Previous studies have shown that adapted CCI have been similar in efficiency and prognosis to the original CCI.[22,23] The comorbidities used to determine the modified CCI were chronic obstructive pulmonary disease, esophageal varices, ascites, peripheral vascular disease, cerebrovascular disease, hemiplegia, myocardial infarction, congestive heart failure, end-stage renal disease, dementia, diabetes mellitus, cancer, and age. Other clinical variables that were examined include history of hypertension, coronary artery disease, smoking, and preoperative creatinine. Surgical variables were also examined and included the American Society of Anesthesiology (ASA) classification, operative time, number of packed red blood cell (PRBC) units transfused intraoperatively, preoperative creatinine and hematocrit values, need for proximal stent deployment, creation of an aortoiliac conduit, and emergent nature of operation.

Outcome variables. The study endpoints were 30-day mortality, serious adverse events (SAEs), and composite events. SAEs were defined, as per the ACS-NSQIP data dictionary, as an occurrence of:

- Graft failure – mechanical failure of an extracardiac vascular graft or prosthesis, including need for balloon angioplasty;
- Myocardial infarction – a new transmural acute myocardial infarction occurring during surgery or within 30 days following surgery as manifested by new Q-waves on electrocardiogram;
- Cardiac arrest – the absence of cardiac rhythm or presence of chaotic cardiac rhythm that results in loss of consciousness requiring the initiation of any component of basic and/or advanced cardiac life support;
- Neurologic deficit – peripheral nerve damage may result from damage to the nerve fibers, cell body, or myelin sheath during surgery;
- Cerebrovascular accident (CVA) – patient develops an embolic, thrombotic, or hemorrhagic vascular accident or stroke with motor, sensory, or cognitive dys-

function (eg, hemiplegia, hemiparesis, aphasia, sensory deficit, impaired memory) that persists for >24 hours;

- Acute renal failure – in a patient who did not require dialysis preoperatively, worsening of renal dysfunction postoperatively requiring hemodialysis, ultrafiltration, or peritoneal dialysis;
- Required return to the operating room – returns to the operating room include all surgical procedures that required the patient to be taken to the surgical operating room for intervention of any kind.

Myocardial infarction was determined based on new Q-wave electrocardiogram changes, as cardiac isoenzyme testing is not part of the routine data collection. A third variable, composite events, was evaluated and defined as the occurrence of either mortality or SAE.

Statistical analysis. SAS software, version 9.2, of the SAS System for Windows (SAS Institute, Cary, NC) was used to generate the analysis. The χ^2, Wilcoxon, and *t* test were used to perform univariate analysis comparing population demographics, clinical variables, and study endpoints. Multivariate logistic regression analysis was also used to explore independent associations with clinical covariates. Pertinent study variables and clinical variables found to be significant on univariate analysis for the primary outcomes were included in the multivariate model. Furthermore, comorbid conditions were analyzed in the multivariate model by using the CCI, where an elevated CCI was defined as being greater than 4. Patients in the "ruptured aneurysm" cohort were excluded before performing multivariate analyses secondary to the inherent increased morbidity and mortality rates associated with these patients. Combining such a heterogeneous group of patients would have introduced an inherent bias to the results. All remaining clinical variables incorporated into the model were defined as being elevated or decreased by using the mean and one SD of the population as a whole. Odds ratios (ORs) and 95% confidence intervals were calculated using the variables identified as above. Throughout the article, data are presented as mean ± SD or median ± interquartile range with a *P* value of ≤ .05 being considered statistically significant. This study was approved by the Institutional Review Board of East Carolina University.

RESULTS

Patient population. Using the CPT codes for TEVAR listed above, a total of 440 patients were identified from 183 centers during the study period. Two hundred seventy-five patients underwent TEVAR for nonruptured DTA (62.5%), while TEVAR was performed in 165 patients for off-label pathologies, including thoracic aorta dissection (n = 106; 24.1%), aneurysm rupture (n = 31; 7.1%), and other conditions (n = 28; 6.4%). Two hundred eighty-seven patients had a noncovered LSCA (65.2%), 131 required LSCA coverage (29.8%), nine had visceral aortic debranching (2.0%), and 14 underwent brachiocephalic aortic debranching (3.2%). The remaining demographic and clinical characteristics of the patient population are described in Table I.

Table I. Characteristics of patients undergoing TEVAR from 2005 to 2007

	All (n = 440)
Demographic	
Age (years)	67.5 ± 14.5
Male	60.0%
Clinical	
Charlson Comorbidity Index	3 ± 2
ASA classification	3 ± 1
Hypertension	87.5%
Chronic obstructive pulmonary disease	20.5%
Coronary artery disease	33.6%
Diabetes	10.7%
Smoking history	32.3%
Dialysis	4.6%
Emergent	15.0%
Preoperative creatinine (mg/dL)	1.38 ± 1.32
Indication	
Nonruptured DTA	62.5%
Dissection	24.1%
Ruptured	7.1%
Other	6.4%
Surgical complexity	
Noncovered LSCA	65.2%
LSCA coverage	29.8%
Visceral aortic debranching	2.0%
Brachiocephalic aortic debranching	3.2%

ASA, American Society of Anesthesiologists; *DTA,* descending thoracic aorta aneurysm; *LSCA,* left subclavian artery; *TEVAR,* thoracic endovascular aortic repair.

Operative indication. The patients were initially stratified by operative indication and univariate analysis was conducted to compare the study and control populations (Table II). The control population was comprised of all patients undergoing TEVAR for nonruptured DTA. The thoracic aorta dissection and "other" populations were younger than the control population ($P < .01$), whereas the aneurysm rupture population was predominantly male ($P = .04$). Comparisons of the comorbid profiles of the populations found the thoracic aorta dissection and "other" populations to have decreased CCIs ($P < .01$) while the aneurysm rupture population was well matched. ASA classifications were elevated in the thoracic aorta dissection and aneurysm rupture populations ($P < .01$). Analysis of variables associated with the operation showed that the populations were well matched in regard to operative time and preoperative creatinine; however, the aneurysm rupture population required an increased amount of transfused PRBC units and had a decreased preoperative hematocrit compared to the control group ($P < .01$). The thoracic aorta dissection population also had a decreased preoperative hematocrit ($P < .01$). The study group had a significantly increased need for emergent TEVAR compared to the control group ($P < .01$). The study populations were comparable to the control population regarding the need for proximal stent deployment. When comparing aortoiliac conduit creation, the thoracic aorta dissection cohort

Table II. Characteristics and outcomes of patients undergoing TEVAR from 2005 to 2007, stratified by operative indication

		Operative indication			
	All (n = 440)	*Nonruptured DTA (n = 275)*	*Dissection (n = 106)*	*Rupture (n = 31)*	*Other (n = 28)*
Population					
Age (years)	67.5 ± 14.5	69.9 ± 12.4	62.3 ± 16.0[a]	74.1 ± 12.0	56.8 ± 18.8[a]
Male	60.0%	63.6%	57.6%	45.2%[b]	50.0%
Charlson Comorbidity Index	3 ± 2	4 ± 1	2 ± 3[a]	4 ± 2	2.5 ± 3[a]
ASA classification	3 ± 1	3 ± 1	4 ± 1[a]	4 ± 0[a]	3 ± 1
Case					
Operative time (minutes)	178.0 ± 112.2	180.4 ± 119.3	166.0 ± 81.7	167.6 ± 102.2	211.1 ± 144.4
PRBC transfusion (units)	0.93 ± 2.04	0.9 ± 2.1	0.7 ± 1.5	2.2 ± 3.2[a]	1.0 ± 1.4
Pre-op creatinine (mg/dL)	1.38 ± 1.32	1.3 ± 1.2	1.5 ± 1.6	1.6 ± 1.6	1.1 ± 0.8
Pre-op hematocrit (%)	36.2 ± 6.28	37.5 ± 6.1	33.9 ± 5.5[a]	33.2 ± 7.5[a]	36.1 ± 6.4
Emergent	15.0%	3.3%	26.4%[a]	74.2%[a]	21.4%[a]
Proximal grafts deployed	20.0%	20.0%	19.8%	22.6%	28.6%
Aortoiliac conduit	7.0%	8.4%	2.8%[b]	16.1%	0.0%
Surgical complexity					
Noncovered LSCA	65.2%	69.8%	63.2%	64.5%	53.6%
LSCA coverage	29.8%	27.6%	35.9%	32.3%	28.6%
Visceral aortic debranching	2.0%	2.9%	0.0%	0.0%	3.6%
Brachiocephalic aortic debranching	3.2%	2.6%	0.9%	3.2%	17.9%
Outcome					
Mortality	7.1%	6.2%	4.7%	22.6%[a]	7.1%
SAE	11.4%	9.1%	10.4%	35.5%[a]	10.7%
Cardiac arrest	3.6%	2.6%	4.7%	6.5%	7.1%
Myocardial infarction	0.5%	0.4%	0.0%	3.2%	0.0%
Graft failure	1.4%	1.5%	1.9%	0.0%	0.0%
Neurologic deficit	0.5%	0.7%	0.0%	0.0%	0.0%
CVA	6.1%	4.7%	4.7%	25.8%[a]	3.6%
Return to operating room	10.9%	9.8%	14.2%	6.5%	14.3%
Composite	13.4%	10.9%	11.3%	45.2%[a]	10.7%

ASA, American Society of Anesthesiologists; CVA, cardiovascular accident; *DTA,* descending thoracic aorta aneurysm; *LSCA,* left subclavian artery; *PRBC,* packed red blood cells; *SAE,* serious adverse events; *TEVAR,* thoracic endovascular aneurysm repair.

[a] $P < .01$ vs nonruptured DTA.

[b] $P \leq .05$ vs nonruptured DTA.

had a decreased incidence compared to the control population ($P = .05$). The thoracic aorta dissection and aneurysm rupture populations were well matched to the control group regarding surgical complexity; conversely, the "other" population was more likely to require brachiocephalic aortic debranching ($P < .01$). When evaluating patient outcomes, the only significant differences occurred between the ruptured aneurysm and control populations, where the ruptured aneurysm population had increased mortality, SAEs, and composite rates ($P < .01$). One patient undergoing TEVAR for a nonruptured DTA with a noncovered LSCA developed acute renal failure postoperatively. Due to the small incidence of this complication, it was not included in the multivariate regression models.

Surgical complexity. The patients were then stratified by surgical complexity, and univariate analysis again was performed to evaluate the study and control populations (Table III). The LSCA coverage population was older than the control group ($P = .03$); however, all of the remaining demographic, comorbid, and operative variables were comparable between the study and control populations. The visceral and brachiocephalic aortic debranching populations had increased operative times ($P < .01$) and the visceral aortic debranching cohort had increased PRBC transfusion requirements ($P < .01$). Preoperative creatinine was increased in the visceral aortic debranching population ($P = .05$). Brachiocephalic aortic debranching was performed more frequently for miscellaneous pathologies ($P < .01$), while the LSCA coverage and visceral aortic debranching populations were representative of the control group. Proximal stent deployment was required less in the LSCA coverage cohort ($P < .01$), whereas incidence of aortoiliac conduit creation was increased in this subset ($P < .01$). Aortoiliac conduits were also more frequent in the visceral aortic debranching population ($P < .01$). In comparing patient outcomes, the LSCA coverage population did not have an increased overall SAE rate; however, it was found to have an increased occurrence of CVA ($P = .02$). The LSCA coverage cohort had a decreased incidence of return to the operating room compared to the control population ($P = .02$). The visceral aortic debranching population had an increased incidence of neurologic deficits ($P < .01$), whereas the brachiocephalic aortic debranching population had a more profound effect on patient outcomes with increased rates of mortality ($P = .02$), SAE ($P < .01$), and composite events ($P = .03$).

Table III. Characteristics and outcomes of patients undergoing TEVAR from 2005 to 2007, stratified by surgical complexity

		Surgical complexity			
	All (n = 440)	*Noncovered LSCA (n = 287)*	*LSCA coverage (n = 131)*	*Visceral aortic debranching (n = 9)*	*Brachiocephalic aortic debranching (n = 14)*
Population					
Age (years)	67.5 ± 14.5	68.7 ± 14.5	63.9 ± 14.2[a]	72.3 ± 12.1	66.3 ± 13.9
Male	60.0%	62.1%	54.1%	57.1%	69.2%
Charlson Comorbidity Index	3 ± 2	3 ± 2	3 ± 2	4 ± 2	4 ± 2
ASA classification	3 ± 1	3 ± 1	3 ± 1	4 ± 1	4 ± 1
Case					
Operative time (minutes)	178.0 ± 112.2	167.4 ± 103.1	169.3 ± 99.5	433.1 ± 88.1[a]	329.0 ± 141.3[a]
PRBC transfusion (units)	0.93 ± 2.04	0.77 ± 1.66	1.04 ± 2.62	4.00 ± 2.83[a]	1.54 ± 1.66
Pre-op creatinine (mg/dL)	1.38 ± 1.32	1.31 ± 1.13	1.53 ± 1.67	2.23 ± 2.74[b]	1.36 ± 1.06
Pre-op hematocrit (%)	36.2 ± 6.28	36.1 ± 6.07	36.5 ± 7.19	35.8 ± 3.33	38.4 ± 4.35
Emergent	15.0%	14.7%	17.1%	0.0%	15.4%
Proximal grafts deployed	20.0%	25.7%	0.0%[a]	28.6%	15.4%
Aortoiliac conduit	7.0%	8.4%	2.3%[a]	42.9%[a]	0.0%
Indication					
Nonruptured DTA	62.5%	64.8%	55.9%	85.7%	46.2%
Dissection	24.1%	23.5%	29.7%	0.0%	7.7%
Rupture	7.1%	6.8%	8.1%	0.0%	7.7%
Other	6.4%	4.9%	6.3%	14.3%	38.5%[a]
Outcome					
Mortality	7.1%	6.5%	6.3%	0.0%	23.1%[b]
SAE	11.4%	9.1%	13.5%	14.3%	30.8%[a]
Cardiac arrest	3.6%	3.9%	1.8%	0.0%	15.4%[b]
Myocardial infarction	0.5%	0.3%	0.0%	0.0%	7.7%[a]
Graft failure	1.4%	1.6%	0.9%	0.0%	0.0%
Neurologic deficit	0.5%	0.3%	0.0%	14.3%[b]	0.0%
CVA	6.1%	3.9%	9.9%[b]	0.0%	15.4%[b]
Return to operating room	10.9%	13.4%	5.4%[b]	14.3%	0.0%
Composite	13.4%	11.7%	14.4%	14.3%	30.8%[b]

ASA, American Society of Anesthesiologists; CVA, cardiovascular accident; *DTA,* descending thoracic aorta aneurysm; *LSCA,* left subclavian artery; *PRBC,* packed red blood cells; *SAE,* serious adverse events; *TEVAR,* thoracic endovascular aneurysm repair.

[a] $P < .01$ vs simple.

[b] $P \leq .05$ vs simple.

Multivariate analysis. Logistic regression multivariate models were constructed to evaluate for possible covariates associated with adverse patient outcomes, including operative indication and surgical complexity (Tables IV and V). Operative indication was not found to have a deleterious effect on mortality (OR, 1.35; $P = .56$). Among the surgical complexity populations, the brachiocephalic aortic debranching cohort was found to be a correlate for mortality (OR, 8.75; $P < .01$). Other variables found to be correlates of mortality were an elevated ASA (OR, 3.30; $P < .01$), increased PRBC transfusion requirement (OR, 4.94; $P = .02$), and creation of an aortoiliac conduit (OR, 10.3; $P < .01$). When evaluating for covariates of SAEs, operative indication was not predictive of SAEs (OR, 0.85; $P = .68$); however, brachiocephalic aortic debranching was the lone surgical complexity cohort found to be a correlate for SAEs (OR, 6.67; $P < .01$). Creation of an aortoiliac conduit was the only other covariate associated with an elevated SAE rate (OR, 6.21; $P < .01$).

DISCUSSION

Despite lacking FDA approval, thoracic aortic endografts continue to be used to treat a wide range of pathologies, including those that require aortic debranching secondary to surgical complexity. A recent study investigating patient outcomes related to operative indication found that patients undergoing TEVAR for off-label pathologies experienced increased rates of mortality and spinal cord ischemia (SCI).[24] These findings suggest that the use of TEVAR for off-label pathologies provides equivalent mortality and SAE rates as when performed for nonruptured DTA. Although the aneurysm rupture cohort in this study had significant increases in all adverse patient outcomes, it also was associated with increased CCI, ASA classification, PRBC transfusion requirement, and rate of emergent operation, illustrating the grave prognosis of these patients.[25] Due to the inherent bias in this patient population, they were excluded before multivariate analyses. When the study and control populations were analyzed in the multivariate model, operative indication was not found to be a correlate of 30-day mortality or SAEs.

Emergent nature of the procedure did not correlate with increased mortality or SAE rates. Previous studies have reported similar findings as well.[24,26] The lack of significance for those undergoing emergent procedures may be explained by the finding that the patient populations with the highest mortality and SAE rates, aneurysm rupture, and

Table IV. Multivariate model for correlates of mortality in nonruptured patients undergoing TEVAR from 2005 to 2007

	Odds ratio	*95% Confidence interval*	P *value*
Descending thoracic aorta aneurysm	1.35	0.49-3.77	.56
LSCA coverage	1.28	0.45-3.63	.64
Brachiocephalic aortic debranching	8.75	1.69-45.2	<.01[a]
Visceral aortic debranching	0.16	0.01-2.62	.20
Elevated ASA (>3)	3.30	1.26-8.65	.01[a]
End-stage renal disease	1.74	0.83-3.66	.15
Increased CCI (>4)	1.93	0.74-5.02	.18
Increased operative time (>290 minutes)	0.77	0.20-2.91	.70
Increased PRBC transfusion (>3 units)	4.94	1.24-19.68	.02[b]
Aortoiliac conduit	10.3	2.67-39.64	<.01[a]

ASA, American Society of Anesthesiologists; *CCI,* Charlson Comorbidity Index; *LSCA,* left subclavian artery; *PRBC,* packed red blood cells; *TEVAR,* thoracic endovascular aneurysm repair.
[a]$P < .01$.
[b]$P \leq .05$.

Table V. Multivariate model for correlates of SAEs in nonruptured patients undergoing TEVAR from 2005 to 2007

	Odds ratio	*95% Confidence interval*	P *value*
Descending thoracic aorta aneurysm	0.85	0.38-1.87	.68
LSCA coverage	2.01	0.90-4.46	.09
Brachiocephalic aortic debranching	6.67	1.55-28.64	.01[a]
Visceral aortic debranching	1.27	0.16-9.84	.82
Elevated ASA (>3)	1.75	0.83-3.69	.14
Proximal extensions deployed	2.19	0.98-4.90	.06
Extended operative time (>290 minutes)	0.85	0.28-2.61	.78
Increased CCI (>4)	1.59	0.70-3.60	.78
CVA	1.66	0.66-4.13	.28
Hypertension	5.52	0.69-43.98	.11
Diabetes mellitus	0.15	0.02-1.16	.07
Increased PRBC transfusion (>3 units)	3.04	0.92-10.08	.07
Aortoiliac conduit	6.21	1.79-21.50	<.01[b]

ASA, American Society of Anesthesiologists; *CCI,* Charlson Comorbidity Index; *CVA,* cardiovascular accident; *LSCA,* left subclavian artery; *PRBC,* packed red blood cells; *SAEs,* serious adverse events; *TEVAR,* thoracic endovascular aneurysm repair.
[a]$P < .01$.
[b]$P \leq .05$.

brachiocephalic aortic debranching had drastic differences in need for emergent repair. The aneurysm rupture population by in large required emergent intervention, as expected, whereas a vast majority of the brachiocephalic aortic debranching cohort underwent elective procedures, likely due to the increased amount of planning necessary for these complex cases. The distinct differences between these two populations likely resulted in emergent nature of TEVAR not being identified as a correlate of mortality or SAEs.

The operative factors we found to significantly influence mortality and SAE rates were brachiocephalic aortic debranching and aortoiliac conduit creation. Univariate analysis demonstrated that coverage of the LSCA and visceral aortic debranching had a significantly increased occurrence of stroke and neurologic deficit, respectively, while brachiocephalic aortic debranching significantly impacted each of the adverse patient outcomes. Initially, studies suggested that intentional coverage of the LSCA could be performed without resulting in functional deficit or left upper extremity malperfusion.[27,28] However, more recent investigations have revealed that coverage of the LSCA without revascularization is a correlate of SCI and those patients at risk for the development of SCI or stroke may benefit from prophylactic adjunctive procedures to restore flow to the LSCA.[29,30] The data from this study support these findings that patients undergoing coverage of the LSCA are at an increased risk of adverse neurologic events.

Patients undergoing concurrent brachiocephalic aortic debranching had increased mortality, SAEs, and composite rates. Although they were well matched demographically and by comorbidities compared to the control group, these patients were subjected to prolonged operative times (averaging over 5 hours). Furthermore, a higher percentage of this population underwent TEVAR for pathologies other than nonruptured DTA, thoracic aorta dissection or aneurysm rupture, possibly indicating higher degrees of case complexity. The cumulative effects of these factors may explain the drastic increase in adverse outcomes observed in this population of patients, as previous studies evaluating carotid-subclavian bypass do not support such high morbidity and mortality rates.[31] These findings are representative of other studies investigating TEVAR with concurrent aortic debranching, demonstrating comparable neurologic deficit rates to open repair (4%-12%).[32-34] In studies in which patients are more likely to undergo a staged procedure, some authors have demonstrated that mortality and neurologic deficits approach those of TEVAR alone.[35] Conflicting data are found when TEVAR with aortic debranching is compared to open surgical repair. Some evidence suggests that the two populations have equivalent mortality and neurologic deficit rates, with the hybrid operation cohort having a significantly increased reintervention rate.[36] Conversely, when the hybrid operation population includes a vast majority of patients undergoing a staged procedure, some evidence suggests patients have improved mortality and neurologic deficit rates compared to the open surgical repair population.[37] When discussing patient outcomes after aortic debranching, it is important to recognize the selection bias associated with these procedures, as they are predominantly used in patients with profound comorbidities and considered to be unsuitable for other treatment modalities.

The utilization of the ACS-NSQIP databases causes certain inherent weaknesses in this study. First, the databases lack complete preoperative history, focusing mainly on cardiopulmonary comorbidities. The absence of an adequate history is pertinent, as others have demonstrated a correlation between previous aortic surgery and adverse outcomes in patients undergoing TEVAR.[30] Furthermore, due to the paucity of patient history, details related to the specific indication for operative repair are absent, such as aneurysm size and expansion, progression of dissection, uncontrolled pain, and end-organ ischemia. Next, ACS-NSQIP only records 30-day outcomes, preventing adequate patient follow-up. As such, it does not allow for the long-term surveillance of sac exclusion, endoleak, or graft migration. The absence of a reliable indicator of postoperative paraplegia or SCI illustrates another weakness, as the occurrence of this dreaded complication negatively impacts a patient's quality of life after thoracic aorta repair. The lack of a consistent definition for paraplegia or SCI may represent the low incidence of reported nonstroke neurologic deficits, where patients with postoperative paraplegia or SCI may have been mistakenly documented to have suffered a CVA, possibly explaining the increased incidence of CVA in this population compared to previously reported rates.[38] Other postoperative complications pertinent to endovascular aortic repair absent from this particular database are access complications, such as hematomas or pseudoaneurysms, distal embolization, visceral ischemia, and acute lower extremity ischemia. The exclusion of these complications prevents a complete analysis of patient outcomes.

Despite the shortcomings of the ACS-NSQIP, it allows for a generalized representation of patient outcomes after TEVAR, circumventing the biases of results produced from specialized aortic surgery centers. Trained reviewers from each individual center are responsible for the collection of patient data and outcomes, as opposed to nonclinician chart extractors. The data are then audited and adjudicated by a third party. This validated method of data collection allows ACS-NSQIP to be more reliable than other contemporary databases. Furthermore, the use of a nationwide database also permits for the compilation of a larger patient series over a shorter time period for a disease process that has historically had a low prevalence. The data presented herein represent the "real-world" experience with a recently approved technology, and demonstrate areas of divergence from the initial prospective clinical trials.

CONCLUSIONS

In an era where aortic endografts are increasingly being deployed in patients for off-label pathologies, the indication for TEVAR procedure was not found to be a predictor of poor patient outcome. Surgical complexity, specifically need for brachiocephalic aortic debranching and aortoiliac conduit, was shown to influence the occurrence of SAE in a multivariate model. Comparative data, such as these, illustrate "real-world" outcomes of patients undergoing TEVAR outside of the original FDA-approved indications. This information is of paramount importance to various stakeholders, including third-party payers, the device industry, regulatory agencies, surgeons, and their patients.

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AUTHOR CONTRIBUTIONS

Conception and design: BE, CD, FP, WB, CP, MS
Analysis and interpretation: BE, CD, MS
Data collection: BE, CD, MS
Writing the article: BE, CD, FP, WB, CP, MS
Critical revision of the article: BE, CD, FP, WB, CP, MS
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Appendix, online only. List of operative indications and their occurrences comprising the "other" cohort of patients undergoing TEVAR between 2005 and 2007

Operative indication	*Occurrences*
Acute bacterial endocarditis	1
Subclavian artery aneurysm	2
Coarctation of aorta	1
End-stage renal disease	1
Thoracic aorta injury	3
Mechanical complication of vascular device implant/graft	15
Mitral valve insufficiency	1
Other complication due to vascular device implant/graft	1
Rheumatic aortic stenosis	1
Subendocardial infarction	1
Takayasu's syndrome	1

TEVAR, Thoracic endovascular aortic repair.