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Have Thoracic Endografting Outcomes Improved Since FDA Approval?

Castigliano M Bhamidipati, DO*, Damien J LaPar, MD, Gaurav S Mehta, MBBS, John A Kern, MD, Irving L Kron, MD, Gilbert R Upchurch Jr, MD, and Gorav Ailawadi, MD
Division of Thoracic and Cardiovascular Surgery, Department of Surgery, University of Virginia School of Medicine, Charlottesville, VA

Abstract

Objective—Thoracic endovascular aneurysm repair (TEVAR) is gaining acceptance since Food and Drug Administration approval in 2005. We hypothesize that, compared to open repair (OPEN), mortality and complication rate after TEVAR have continued to improve.

Methods—All patients who underwent thoracic and/ or thoracoabdominal aneurysm repair from 2005 to 2007 in the Nationwide Inpatient Sample were examined. Patients were stratified by TEVAR or OPEN. Demographics, hospital characteristics, and outcomes were analyzed. Multivariable logistic regression models for complications and in-hospital mortality were developed.

Results—A weighted total of 7,644 had TEVAR, while 32,948 patients underwent OPEN. TEVAR utilization increased from 5.5% (2005) to 24.1% (2007). Mortality for all patients undergoing thoracic aneurysm repair decreased yearly ($P<0.001$). Mortality (TEVAR: 7.3%, OPEN: 9.8%, $P<0.001$) and complication rate (TEVAR: 24.3%, OPEN: 42.1%, $P<0.001$) were superior with TEVAR. The unadjusted annual mortality (7%) and complication rate (24%) following TEVAR did not improve each year, however, after risk adjustment mortality after TEVAR steadily decreased annually. Moreover, risk adjusted mortality for OPEN has improved since 2005. Multivariate analysis revealed age and ruptured aneurysm were highly predictive of death ($P<0.001$, respectively), while TEVAR lowered the adjusted odds of death by 18% ($P<0.05$).

Conclusions—Mortality in patients undergoing repair of thoracic aneurysms has decreased in the United States since FDA approval of stent grafts in 2005. This is due to wider adoption of TEVAR, and improved mortality in patients undergoing TEVAR or open repair.

Keywords

Aneurysm; Endovascular procedures/stents; Outcomes

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Corresponding Author, Gorav Ailawadi, MD Division of Thoracic and Cardiovascular Surgery University of Virginia Health System P.O. Box 800679 Charlottesville, VA 22908 Office: 434-924-9314 Fax: 434-982-3885 gorav@virginia.edu.

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Introduction

The first endovascular repair of an infrarenal abdominal aortic aneurysm was reported by Parodi in 1991.¹ Soon thereafter, in 1992, the first endograft was developed and used to treat a descending thoracic aortic aneurysm (DTAA).² In 2005, the United States Food and Drug Administration (FDA) approved the Gore TAG® Thoracic Endoprosthesis (W. L. Gore & Associates, Inc., Flagstaff, AZ).³ Since then thoracic endovascular repair of aneurysms (TEVAR) has gained widespread adoption.

Open thoracic aneurysm repair is associated with significant morbidity resulting in poor long-term survival and prolonged hospitalization.⁴ Compared to open repair, TEVAR portends shorter hospital stay, improved early recovery, and less perioperative morbidity and mortality. With more centers offering on- and off-label TEVAR for complicated aortic diseases, endovascular repair is emerging as the preferred alternative to traditional open repair. Single institution results through the first two years using the Gore TAG® device were favorable.⁵ A recent report demonstrated significantly better mortality rates and shorter length of stay following TEVAR compared to open thoracic aneurysm repair.⁶ Even as favorable mid-term data become available,⁷⁻⁹ the effectiveness, national adoption, change in patient risk stratification and trends of TEVAR remain unknown.

Previous volume-outcome relationships of cardiovascular operations,¹⁰⁻¹² have shown that increasing experience is associated with improved clinical outcomes. Alternatively, we hypothesized that utilization of TEVAR has increased since FDA approval in 2005. Furthermore, we expect that mortality and complications have declined since 2005 with improving experience of thoracic endografting to treat aortic aneurysms.

Material and Methods

Data Source

Data was abstracted from the Nationwide Inpatient Sample (NIS) between 2005 and 2007. The NIS is the largest Healthcare Cost and Utilization Project (HCUP) all-payer inpatient database, sponsored by the Agency for Healthcare Research and Quality (AHRQ). The NIS contains data from more than 8 million hospital discharges annually from 1,056 hospitals located in 42 States, representing 90% of all US nonfederal hospital discharges (<http://www.hcup-us.ahrq.gov/nisoverview.jsp>).¹³ The AHRQ has developed appropriately scaled discharge weights to generate national estimates of hospitalizations from the NIS (<http://www.hcup-us.ahrq.gov/db/nation/nis/nisdbdocumentation.jsp>). These weights help compare hospitalization rates across years despite the varying number of states participating each year. The HCUP validates the NIS for biases by comparing it to other population-based datasets (<http://www.hcup-us.ahrq.gov/reports/methods.jsp>).

For this analysis, any missing cases more than 5% were excluded, imputations were not performed, while datasets were reviewed for any systematic missing values to be excluded from evaluation. Data reporting meets the NIS data-use agreement as established by HCUP. The NIS contains de-identified administrative level data, and was not considered human subjects research, hence being exempted from review by the University of Virginia's Human Investigation Committee.

Patients

Patients were selected with a primary diagnosis of thoracic and/ or thoracoabdominal aneurysm with and/ or without rupture who underwent repair, identified using the International Statistical Classification of Diseases and Related Health Problems 9 Clinical Modification (ICD-9-CM) codes*. The NIS database identifies up to 15 diagnoses and

procedure codes, which were queried to identify and select patients at least 18 years of age. Only patients with ruptured and/ or non-ruptured thoracic and/ or thoracoabdominal aneurysms who had undergone open surgical repair (OPEN) or thoracic endografting were included. Since cases are identified based on discharge level data, we included thoracoabdominal patients (6.7% of all aneurysm cases) in an attempt to comprehensively identify all aneurysms of the thoracic aorta that underwent repair.

Patient risk factors were assessed using 30 different AHRQ comorbidities developed by Elixhauser.¹⁴ The Elixhauser comorbidities have been shown to provide effective adjustments for mortality risk among surgical populations,¹⁵ and have been shown to be superior to the Charlson/Deyo weighted score.¹⁶ Aggregate co-morbidities were stratified into up to 1, 2 to 4, and at least 5 comorbidity groups.

Outcomes of Interest

In-hospital mortality, complications and discharge disposition following thoracic endografting were primary outcomes of interest. Complications were identified and limited to the hospital admission recorded ICD-9-CM codes. Routine discharge was considered discharge to home without services, while discharges against medical advice, or to a skilled nursing facility was considered non-routine. Because the NIS contains inpatient data only, complications occurring after hospital discharge cannot be evaluated. Several ICD-9-CM codes* were used to identify and aggregate complications into 8 categories – mechanical wound healing, postoperative infection, renal, pulmonary, gastrointestinal, cardiovascular, systemic, and procedure related.¹⁷

Statistical Analysis

The strength of association between variables was measured using appropriate hypothesis tests. The significance of differences between proportions for categorical variables was evaluated by the Pearson χ^2 test. While significant differences between mean values of continuous variables was assessed using single factor analysis of variance. Data are shown as number (N) with percentage by group (%), or mean with standard deviation (SD), except where indicated otherwise. Since our sample size was large, we could discover certain differences to be statistically significant even if the practical relevance of these differences are clinically less applicable. Therefore, we computed three different effect sizes to provide practical and clinical value for comparisons. Cohen's d was calculated for continuous data by using pooled standard deviations, and was appropriately weighted for unequal sample size.¹⁸ The phi (ϕ) coefficient was computed for χ^2 tests for independence with 1 degree of freedom (df), while Cramer's V was computed for variables with more than 1 df.¹⁹ We used the following thresholds to evaluate computed effect sizes: ≤ 0.32 (small), 0.33 to 0.55 (medium), and ≥ 0.56 (large).

Yearly unadjusted odds for any complication and mortality in TEVAR and OPEN patients were calculated. Similarly, risk adjusted models using covariates as described below were utilized to calculate odds ratios for any complication and mortality in these patients. Multivariable regression models for in-hospital mortality, any complication, and discharge disposition were developed to investigate the adjusted odds of death, by controlling for differences in case-mix (demographics, preoperative characteristics) and procedure (hospital characteristics, year of procedure, repair type). The reference variables were selected based on clinical observation, and included male gender, elective admission, OPEN surgery, large urban teaching hospital, and repair performed in 2007. Covariable selections for our models

*All ICD-9-CM codes can be made available to the reader upon receipt of an electronic request to the corresponding author (Gorav Ailawadi, MD) at ga3f@virginia.edu.

were made a priori based upon established volume associated outcomes literature. The models' predictive capacity to discriminate was measured using the area under the receiver operator characteristic curve (AUC). After excluding variables with missing values, more than 96% of the cases were included in the analysis, and had an AUC of at least 0.80. Adjusted odds ratios (AOR) are presented for each covariate along with their 95% confidence interval (CI). All data were analyzed using the Statistical Package for the Social Sciences™ 17 (SPSS Inc., An IBM Co., Chicago, IL).

Results

Patient demographics and risk factors

There were 7,644 (18.8%) TEVAR and 32,948 (81.2%) OPEN weighted cases that were reviewed (Figure 1). Following approval of thoracic endografting in 2005, DTAA cases undergoing TEVAR increased rapidly (TEVAR Cases: 2005 – 5.5%, 2006 – 24.9%, 2007 – 24.1%). Patient demographics, risk factors, and hospital characteristics between TEVAR and OPEN were compared (Table 1). TEVAR recipients were almost a decade older than OPEN patients. Female patients were more likely to undergo TEVAR ($P<0.001$), while patients with at least 2 comorbidities, and those admitted over the weekend, were more likely to be TEVAR recipients ($P<0.001$, respectively). A ruptured aneurysm was more than 2 fold likely to undergo treatment with TEVAR ($P<0.001$).

Tevar experience by year

TEVAR associated variables were compared by year (Table 2). The average age among TEVAR recipients was 65 years, and female patients underwent transcatheter repair most commonly in 2006 ($P<0.001$, respectively). Comorbidities among TEVAR recipients incrementally rose over the years ($P<0.001$). Pulmonary complications increased annually ($P<0.001$), while cardiovascular complications decreased with time ($P=0.007$). Hospital lengths of stay increased by almost 1 day per year since 2005 ($P<0.001$). Unadjusted hospital length of stay was highest in 2007 ($P<0.001$), while routine discharges were lowest in 2006 ($P<0.001$).

OPEN experience by year

Characteristics of OPEN cases were analyzed by year (Table 3). OPEN was performed on increasingly older patients over time, and like in TEVAR above, relatively more female patients underwent OPEN in 2006 ($P<0.001$, respectively). Elective admissions for OPEN were least frequent in 2006 ($P<0.001$). Similar to TEVAR patients, OPEN was performed in the face of increasing comorbidities more time ($P<0.001$). Cardiovascular and pulmonary complications following OPEN were most frequent in 2007 ($P<0.001$).

Complications Following TEVAR versus Open

Unadjusted complications following TEVAR and OPEN were determined (Table 1). Overall cardiovascular and pulmonary complications following thoracic aneurysm repair were lowest after TEVAR ($P<0.001$, respectively). Furthermore, hospital length of stay was lowest following TEVAR ($P<0.001$, respectively). OPEN was associated with less frequent routine discharge ($P=0.001$), greater incidence of any complication and higher in-hospital mortality ($P<0.001$, respectively).

Unadjusted complication rate following TEVAR remained constant at 24% per year. Compared to 2007, there was no change in the annual risk of any complication in TEVAR after accounting for clinical influences (2005: AOR 1.21, 95% CI 0.97-1.52; 2006: AOR 1.10, 95% CI 0.96-1.26). Similarly in OPEN, referent to 2007, the annual unadjusted risk

estimates were unchanged after other factors that impact complications were controlled (2005: AOR 0.99, 95% CI 0.93-1.05; 2006: AOR 0.98, 95% CI 0.92-1.05).

In-Hospital Mortality Following Aneurysm Repair

Although the unadjusted mortality after TEVAR did not change over time, the unadjusted mortality following OPEN improved (Table 4). Taken together, the difference in unadjusted mortality between these two procedures has narrowed over time (Figure 2, 2005: 3.5%, 2006: 2.7%, 2007: 1.8%). Since patients undergoing TEVAR had more comorbidities over time, risk adjusted mortality for TEVAR and open repair was evaluated. The adjusted risk estimates for mortality following TEVAR and OPEN have annually improved in a similar pattern.

Predictors of Routine Discharge, Complications, and Mortality

Multivariable logistic regression models were developed to identify risk factors associated with complications and mortality (Table 5). Age ($P<0.001$), female gender (AOR 1.23, 95% CI 1.13-1.33) and non-elective admission (AOR 2.11, 95% CI 1.89-2.35) independently increased the adjusted odds of death. TEVAR use lowered the adjusted odds of mortality (AOR 0.82, 95% CI 0.73-0.82) and any complication (AOR 0.47, 95% CI 0.40-0.54), while increasing the adjusted odds of the likelihood to home discharge (AOR 1.27, 95% CI 1.08-1.49).

Importantly, the year when TEVAR or OPEN were performed did not influence the risk of any complication or likelihood to home discharge ($P>0.90$ and $P>0.20$, respectively). Significantly and as noted above in the isolated procedure risk adjusted models, referent to 2007 overall mortality in all patients undergoing surgery for DTAA improved with time (2005: AOR 1.39, 95% CI 1.26-1.53; 2006: AOR 1.19, 95% CI 1.08-1.30).

Comment

This study presents the trends in the treatment of thoracic aortic aneurysms in a nationally representative database since FDA approval of thoracic stent grafts in 2005. As anticipated, the utilization of TEVAR has increased. During this period, unadjusted mortality and complication rates following TEVAR have not changed, while the case-complexity of patients undergoing TEVAR has increased. Importantly, the adjusted mortality following TEVAR has improved over time. Furthermore, the adjusted mortality for patients undergoing open aneurysm repair has also improved since 2005. The net result of these case-mix adjusted mortality data for both TEVAR and open surgery confirm that overall mortality in all patients undergoing DTAA repair in the US is improving following the availability of thoracic endografts.

Patients treated with TEVAR are different in many regards from those being treated with open repair. Specifically, TEVAR recipients were nearly 10 years older, had a larger number of comorbidities, and were more frequently non-elective. Despite this disparity, multivariate analysis in our study indicated that TEVAR was associated with improved mortality, a finding that is well supported by other series.^{4, 6, 7, 20-23} A study published in 2005 comparing TEVAR and open repair showed that endovascular repair was associated with good early outcomes, lower mortality and shorter hospital lengths of stay.²⁴ Since then, several studies have evaluated TEVAR in various populations. One small study comprising 44 patients evaluated the effect of age on TEVAR and found no difference in 30-day mortality between octogenarians (mean age, 84±2.7 years) and non-octogenarians.²¹ In contrast, our study found that both in-hospital mortality and complications were influenced by increasing age. More recently, a study reviewing data over a 9-year period found that

TEVAR had improved mortality, shorter hospitalization and lower intensive care unit stay.²⁶ Similarly, in the current study hospital length of stay was shorter with TEVAR as noted in other series.

In 2005, most centers performing TEVAR were still early in their learning curve with thoracic endografting procedures. Given the increase in use and wider application of TEVAR, it was anticipated that complication rates and in-hospital mortality would improve over time. However, the unadjusted complication rates did not improve as expected, likely due to “sicker” and more complex patients undergoing TEVAR each subsequent year. When these comorbidities were accounted for, the risk adjusted complication rates still did not improve. The unadjusted mortality with TEVAR remained constant, when comorbidities were accounted for, the risk adjusted mortality improved yearly. There are several potential explanations for these observations. First, it is possible that with FDA approval, experience with TEVAR is becoming more dilute such that more low volume centers are performing this procedure with liberalized inclusion criteria. Although TEVAR is less complex than open surgical repair, the subtleties of TEVAR cannot be overstated and greater individual center experience should decrease morbidity. Second, TEVAR is increasingly being performed in “sicker” patients with marginal anatomy. Although we are unable to comment on anatomic criteria, we speculate that less suitable patients with borderline anatomy for thoracic endografting, such as short necks/landing zones, angulated aortic arches, and heavily diseased iliofemoral vessels are being offered TEVAR. Thus as experience with TEVAR increases, more complex patients are being treated with this approach likely resulting in a greater unadjusted complication and mortality rate seen in our findings. A final potential explanation is that TEVAR has already reached the nadir of complication risk. However, this explanation is the least likely given that many centers are still learning this procedure. The annual improvement in adjusted mortality for TEVAR conceptually supports the fact that, greater experience since FDA approval of stent grafts is directly influencing outcomes.

Aneurysm morphology and anatomic location within the thoracic aorta (arch or supra-celiac) are expected to impact outcomes. Anecdotally, patients with less complex aortic aneurysm morphology during the early learning curve period were treated with stent grafting, and with improving confidence more patients with even complex disease were offered endografts. Significantly, early outcomes in the OPEN group might be slightly better a little earlier compared to later given certain patients with intermediate or complex comorbidities were less likely to be treated by endografting early in our analysis. Conversely, later “sicker” patients were more likely to receive TEVAR with improving experience. These trends within groups might partially explain the OPEN results over time, and perhaps support the improvement in outcomes after TEVAR.

The improved unadjusted and adjusted mortality for open aneurysm repairs is interesting and has several potential explanations. First, with the availability of stent grafts, there appears to be a shift in the treatment of “sicker” patients including those with ruptured DTAA and those with higher pre-morbid risk towards TEVAR. This also suggests that surgeons are appropriately selecting patients for TEVAR and open surgical repair. Another potential explanation is that patients who require open thoracic aneurysm repair are increasingly being treated at high volume and/or regional aortic centers. Finally, the techniques to minimize morbidity during open surgical repair including hybrid approaches, routine use of lumbar drains, and partial/ left heart bypass may be becoming more prevalent, although cannot be studied in this database.

As the experience with TEVAR grows and devices improve, the proportion of patients undergoing open repair is expected to decline. Patients who traditionally may not be

considered candidates for TEVAR including those patients with connective tissue disorders appears to be increasing.²⁷ However, the utilization of TEVAR from 2006 to 2007 also remained constant, a finding that was not expected. This is most likely due to defined anatomic limitations of commercially available stent grafts. As newer generation devices evolve, these anatomic criteria will be broadened and the range of patients with descending thoracic aneurysms will increase. It should be noted that this study was designed to only evaluate thoracic aneurysm disease, the only FDA approved indication for thoracic stent grafts. As such, patients with off-label use of TEVAR, including those with dissection, intramural hematoma, or blunt aortic injury were not included. It is likely that the utilization of TEVAR is increasing with the inclusion of these off-label diagnoses.

There are several important considerations that are highlighted through this analysis. Paramount is the fact that our observational work provides empirical evidence for effective evaluation of outcomes between groups by randomized trial. As confounders and effect modifiers are expected to be homogenous and distributed across both groups, we anticipate that randomization would resolve the better treatment for thoracic aneurysm repair. Importantly, cross over patients would help identify risk factors and characteristics for improved patient selection and reducing treatment mismatch in the future. Another important aspect to remember is that patients included in this research may not have met all criteria of instructions for use (IFU). Although the current study assumes compliance with IFU among recipients, the reality is that with increasing surgeon- and center-specific experience, IFU standards were likely marginalized.

There are a number of other limitations to note in this study. In this retrospective analysis, there is an inherent selection bias with limited data on the specific anatomy to assess the feasibility of TEVAR. The focus of this study was not to compare TEVAR to open surgery but rather to understand the utilization and morbidity trends over time after approval of endograft devices. Next, the NIS is a large database with the potential for erroneous miscoding among ICD-9-CM diagnostic and procedure codes. However, the NIS represents a random sampling of discharge level data that is externally and internally validated. Coding errors are expected to be homogeneously distributed across all groups, thus equally effecting the groups in this evaluation. Importantly, since the NIS contains only discharge data, real perioperative mortality and morbidity may be unknown if it occurs after discharge from the index operation. Moreover, specific techniques to decrease the morbidity with these approaches including the use of cardiopulmonary bypass or cerebrospinal fluid drainage cannot be evaluated in our analysis. Finally, the potential for an unmeasured confounder may remain, which is inherent to the constraints of the NIS data points. We are unable to adjust for other well-established surgical risk factors such as low perioperative albumin levels or poor nutritional status.

Conclusions

Endovascular repair of thoracic aneurysms is gaining acceptance with increasing utilization over time following FDA approval in 2005. TEVAR confers greater probability of discharge to home, lower complication rate, and decreased mortality. The complication rate following TEVAR has not improved, but the risk adjusted in-hospital mortality is declining with increasing experience. In addition, the unadjusted and adjusted mortality of open surgical repair appears to be improving since the availability of TEVAR. These initial findings are promising and portend a significant shift in the treatment paradigm for thoracic aneurysmal disease.

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Figure 1. Distribution of thoracic endografting and open repair in aneurysm cases by year
Thoracic Aneurysm Repair Trends Over time. TEVAR and OPEN treated aneurysm cases are shown by year.

Figure 2. In-hospital mortality trends of thoracic endografting and open repair over 3 years
Thoracic Aneurysm Mortality Trend Over Time. Postoperative TEVAR and OPEN in-hospital mortality trends are shown by year.

Table 1

Patient demographics and characteristics of Thoracic Endovascular Aneurysm Repair versus Open Repair

Variables*	TEVAR 7644 (18.8)	OPEN 32948 (81.2)	P	Effect Size
Thoracic Aorta	3844 (50.3)	15864 (48.1)	0.001	0.017 ^b
Thoracoabdominal Aorta	1093 (14.3)	1619 (4.9)	<0.001	0.147 ^b
Average Age, years	65.1 (16.9)	56.5 (20.5)	<0.001	0.458 ^c
Gender (Female)	2926 (38.4)	11115 (33.7)	<0.001	0.038 ^b
Race (Caucasian)	4014 (73.4)	19016 (80.2)	<0.001	0.079 ^a
Admission (Elective)	4164 (54.6)	17322 (52.6)	0.002	0.016 ^b
Risk factor,				
Anemia	794 (10.4)	3622 (11.0)	0.126	0.008 ^b
Congestive heart failure	67 (0.9)	541 (1.6)	<0.001	0.025 ^b
Chronic pulmonary disease	2225 (29.1)	5907 (17.9)	<0.001	0.109 ^b
Diabetes (Uncomplicated)	878 (11.5)	2692 (8.2)	<0.001	0.046 ^b
Hypertension	5126 (67.1)	17589 (53.4)	<0.001	0.108 ^b
Peripheral vascular disease	2485 (32.5)	12015 (36.5)	<0.001	0.032 ^b
Renal failure	1101 (14.4)	2203 (6.7)	<0.001	0.110 ^b
Composite comorbidities,				
Up to 1	2389 (31.3)	12373 (37.6)	<0.001	0.051 ^a
2 to 4	4703 (61.5)	18337 (55.7)	<0.001	
At least 5	552 (7.2)	2238 (6.8)	<0.001	
Average	2.3 (1.4)	2.1 (1.5)	<0.001	0.138 ^c
At least 1 Comorbidity	7008 (91.7)	28969 (87.9)	<0.001	0.046 ^b
Ruptured Aneurysm	484 (6.3)	959 (2.9)	<0.001	0.072 ^b
Admission (Weekend)	997 (13.0)	3621 (11.0)	<0.001	0.025 ^b
Bed Size (Large)	5655 (74.0)	25457 (77.3)	<0.001	0.086 ^a
Additional intervention [§] , per patient	4.9 (3.6)	6.6 (3.5)	<0.001	0.479 ^c
Length of stay, days	10.1 (12.5)	13.2 (16.3)	<0.001	0.213 ^c
Complications,				
Stroke/Neurologic	200 (2.6)	947 (2.9)	0.220	0.006 ^b
Pulmonary	807 (10.6)	6795 (20.6)	<0.001	0.101 ^b
Cardiovascular	336 (4.4)	4638 (14.1)	<0.001	0.115 ^b
Renal	29 (1.9)	235 (3.6)	0.001	0.038 ^b
Average	0.3 (0.6)	0.6 (0.8)	<0.001	0.388 ^b

Variables*	TEVAR 7644 (18.8)	OPEN 32948 (81.2)	P	Effect Size
Any Complication	1858 (24.3)	13872 (42.1)	<0.001	0.143 ^b
Home Discharge	5593 (73.2)	23467 (71.2)	0.001	0.017 ^b
In-hospital Mortality	554 (7.3)	3228 (9.8)	<0.001	0.034 ^b

* Shown as N (%) or Mean (SD)

§ Includes any ICD-9-CM procedure code

OPEN, Open Aneurysm Repair

TEVAR, Thoracic Endovascular Aneurysm Repair

^a Cramer's V

^b phi (φ) coefficient, or

^c Cohen's d calculated where appropriate Small Effect (≤0.32), Medium Effect (0.33-0.55), Large Effect (≥0.56)

Table 2

Unadjusted Thoracic Endografting Repair Trends (2005 through 2007)

Variables*	2005 661 (5.5)	2006 3791 (24.9)	2007 3192 (24.1)	P
Average Age, years	64.1 (18.4)	65.9 (15.8)	64.2 (17.7)	<0.001
Gender (Female)	206 (31.6)	1533 (40.5)	1187 (37.2)	<0.001
Admission (Elective)	381 (57.6)	2015 (53.2)	1769 (55.7)	0.031
Admission (Saturday/Sunday)	89 (13.5)	458 (12.1)	450 (14.1)	0.042
Additional intervention [§] , per patient	4.4 (3.4)	4.7 (3.3)	5.1 (3.9)	<0.001
Presence of Ruptured Aneurysm	29 (4.4)	226 (6.0)	229 (7.2)	0.012
Risk factor,				
Anemia	99 (15.0)	324 (8.5)	371 (11.6)	<0.001
Congestive heart failure	-	47 (1.2)	20 (0.6)	0.001
Chronic pulmonary disease	161 (24.4)	1139 (30.0)	924 (29.0)	0.012
Diabetes (Uncomplicated)	55 (8.3)	458 (12.1)	366 (11.5)	0.020
Hypertension	448 (67.7)	2544 (67.1)	2135 (66.9)	0.924
Peripheral vascular disease	201 (30.4)	1221 (32.2)	1063 (33.3)	0.301
Renal failure	77 (11.6)	532 (14.0)	493 (15.4)	0.025
Composite comorbidities,				
2 to 4	383 (57.9)	2305 (60.8)	2015 (63.1)	<0.001
At least 5	30 (4.5)	269 (7.1)	254 (8.0)	
Complications,				
Stroke/Neurologic	15 (2.3)	106 (2.8)	79 (2.5)	0.593
Pulmonary	39 (5.9)	385 (10.2)	383 (12.0)	<0.001
Cardiovascular	44 (6.7)	167 (4.4)	125 (3.9)	0.007
Renal	6 (4.5)	14 (1.8)	9 (1.4)	0.055
Average	0.3 (0.6)	0.3 (0.6)	0.3 (0.6)	<0.001
Any Complication	158 (23.9)	921 (24.3)	779 (24.4)	0.963
Length of stay, days	8.8 (9.8)	9.7 (11.9)	10.7 (13.7)	<0.001
Home Discharge	556 (84.1)	2727 (71.9)	2310 (72.4)	<0.001
In-hospital Mortality	45 (6.8)	277 (7.3)	232 (7.3)	0.916

* Shown as N (%) or Mean (SD)

[§] Includes any ICD-9-CM procedure code

Table 3

Unadjusted Open Repair Trends (2005 through 2007)

Variables*	2005 11460 (94.5)	2006 11440 (75.1)	2007 10048 (75.9)	P
Average Age, years	55.1 (21.9)	57.0 (19.9)	57.3 (19.5)	<0.001
Gender (Female)	3720 (32.5)	3998 (35.0)	3397 (33.8)	<0.001
Admission (Elective)	6131 (53.5)	5821 (50.9)	5370 (53.5)	<0.001
Admission (Saturday/Sunday)	1344 (11.7)	1200 (10.5)	1077 (10.7)	0.007
Additional intervention [§] , per patient	6.6 (3.5)	6.3 (3.2)	6.9 (3.7)	<0.001
Presence of Ruptured Aneurysm	312 (2.7)	397 (3.5)	250 (2.5)	<0.001
Risk factor,				
Anemia	1147 (10.0)	1093 (9.6)	1381 (13.7)	<0.001
Congestive heart failure	186 (1.6)	160 (1.4)	194 (1.9)	0.009
Chronic pulmonary disease	1930 (16.8)	2132 (18.6)	1846 (18.4)	0.001
Diabetes (Uncomplicated)	806 (7.0)	953 (8.3)	933 (9.3)	<0.001
Hypertension	5784 (50.5)	6089 (53.2)	5715 (56.9)	<0.001
Peripheral vascular disease	3691 (32.2)	4308 (37.7)	4015 (40.0)	<0.001
Renal failure	513 (4.5)	928 (8.1)	762 (7.6)	<0.001
Composite comorbidities,				
2 to 4	5992 (52.3)	6370 (55.7)	5975 (59.5)	<0.001
At least 5	567 (4.9)	784 (6.9)	886 (8.8)	
Complications,				
Stroke/Neurologic	328 (2.9)	381 (3.3)	238 (2.4)	<0.001
Pulmonary	2221 (19.4)	2355 (20.6)	2219 (22.1)	<0.001
Cardiovascular	1654 (14.4)	1474 (12.9)	1509 (15.0)	<0.001
Renal	83 (3.6)	76 (3.3)	76 (3.8)	0.623
Average	0.6 (0.8)	0.6 (0.8)	0.6 (0.8)	<0.001
Any Complication	4724 (41.2)	4670 (40.8)	4478 (44.6)	<0.001
Length of stay, days	13.9 (16.2)	12.6 (15.8)	12.9 (16.8)	<0.001
Home Discharge	8216 (71.7)	8232 (72.0)	7020 (69.9)	0.001
In-hospital Mortality	1177 (10.3)	1139 (10.0)	912 (9.1)	0.010

* Shown as N (%) or Mean (SD)

[§] Includes any ICD-9-CM procedure code

Table 4

Adjusted risk estimate for Thoracic Endovascular Aneurysm Repair and Open Repair

	Risk Estimate	2005	2006	2007
TEVAR				
Any Complication	Unadjusted	0.97 (0.80 - 1.18)	0.99 (0.89 - 1.11)	Reference
	Adjusted	1.21 (0.97 - 1.52)	1.10 (0.96 - 1.26)	
Mortality	Unadjusted	0.93 (0.67 - 1.30)	1.00 (0.84 - 1.21)	
	Adjusted*	1.66 (1.12 - 2.44)	1.46 (1.15 - 1.85)	
OPEN				
Any Complication	Unadjusted [§]	0.87 (0.83 - 0.92)	0.86 (0.81 - 0.91)	Reference
	Adjusted	0.99 (0.93 - 1.05)	0.98 (0.92 - 1.05)	
Mortality	Unadjusted*	1.15 (1.05 - 1.26)	1.11 (1.01 - 1.22)	
	Adjusted [§]	1.38 (1.24 - 1.53)	1.19 (1.07 - 1.32)	

Data shown as odds ratio (95% confidence interval)

* P<0.05

[§] P≤0.001

OPEN, Open Thoracic Aneurysm Repair

TEVAR, Thoracic Endovascular Aneurysm Repair

Table 5

Independent predictors of outcomes (select variables shown among 46 covariates in model)

Variables	In-hospital Mortality		Any Complication	
	AOR (95% CI)	P	AOR (95% CI)	P
Age, years	1.02 (1.017 - 1.022)	<0.001	1.01 (1.010 - 1.016)	<0.001
Gender (Female)	1.23 (1.134 - 1.329)	<0.001	1.03 (0.919 - 1.144)	0.658
Admission (Non-Elective)	2.11 (1.892 - 2.349)	<0.001	1.09 (0.942 - 1.253)	0.255
Ruptured Aneurysm	2.88 (2.499 - 3.309)	<0.001	1.16 (0.878 - 1.529)	0.299
Operation in 2005	1.39 (1.255 - 1.530)	<0.001	1.00 (0.879 - 1.148)	0.949
Operation in 2006	1.19 (1.079 - 1.301)	<0.001	1.00 (0.881 - 1.130)	0.973
TEVAR Repair	0.82 (0.730 - 0.914)	<0.001	0.47 (0.401 - 0.541)	<0.001

Valid data available 96%, AUC 0.8

Models were adjusted for patient demographics, risk factors, hospital characteristics, admission status, and year of procedure (2007)

AOR, Adjusted Odds Ratio

AUC, Area under the Receiver Operator Characteristic Curve

CI, Confidence Interval

OPEN, Open Thoracic Aneurysm Repair

TEVAR, Thoracic Endovascular Aneurysm Repair