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Practice Patterns for Thoracic Aneurysms in the Stent Graft Era: Health Care System Implications

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Abstract

Background—The FDA approved the first thoracic aneurysm endograft in 2005. However because the United States lacks a thoracic aneurysm endovascular repair registry, implications of FDA endograft approval on surgical management of thoracic aneurysms in clinical practice are unknown.

Methods—Retrospective review of thoracic aneurysm repair rates for 2000–07 and analysis of patient characteristics and complications for 2006 and 2007 cohorts uses the National Inpatient Sample. ICD-9 codes were used to identify unruptured descending thoracic aneurysm cases undergoing either thoracic endovascular aortic repair (39.73) or Open Repair (38.45).

Results—Thoracic aneurysm Open Repair averaged 3.3 per million from 2000–2002 and increased to 5.6 per million in 2003 with introduction of 16 slice CT scanners. In 2005 endovascular repair was 1.2 repairs per million, which increased dramatically to 6.1 repairs per million in 2006. In 2007, endovascular repair decreased to 4.8 repairs per million while Open Repair rate was 3.1 repairs per million. The 2006 and 2007 Open Repair cohorts had more favorable baseline characteristics compared to the endovascular cohort. Open Repair mortality was significantly greater than endovascular mortality in 2006 (estimated relative risk=8.48, 95% CI 3.03–23.75), but not in 2007 (estimated relative risk=0.71, 95% CI 0.12–4.24). Length of stay was greater for Open Repair in 2006 and 2007.

Conclusions—Thoracic endovascular aortic repair has been rapidly adopted in the United States resulting in increased treatment of thoracic aortic aneurysms. Despite older age and comorbidities, endovascular repair had better outcomes and shorter hospital stays.

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Keywords

Aneurysm (descending); Endovascular Stents

Introduction

In 2005 the FDA approved the first thoracic aortic endograft for descending thoracic aneurysm repair (TAG device, W.L. Gore, Flagstaff, AZ) in the United States (US). In May and June of 2008, the FDA approved two more thoracic endografts, Zenith TX2 (Cook Incorporated, Bloomington, IN) and Talent (Medtronic Vascular, Santa Rosa, CA). Following introduction of these devices our institution witnessed increased utilization of thoracic endovascular aneurysm repair (TEVAR), which prompted this review of thoracic aneurysm repair trends using the National Inpatient Sample (NIS). TEVAR is reported to offer benefits such as lower early morbidity and mortality,^{1–8} shorter operating times, decreased blood loss, and decreased hospital length of stay (LOS).^{3, 6, 9} However, peripheral vascular complications, paralysis and endoleaks (inadequate seal of the endografts) are associated with TEVAR.^{1, 2} TEVAR patients require rigorous life-long surveillance with CT scans for endoleaks and stent-graft migration.

Unlike Europe, the US does not have a thoracic endovascular stent registry. Consequently, national practice patterns, long-term outcomes, and patient characteristics in US clinical practice environments are largely unknown. This lack of data raises questions about current trends in thoracic aortic aneurysm repair. This report examines national TEVAR and Open Repair utilization trends, changes in utilization rates, and implications for management of thoracic aortic disease.

Material and Methods

The National Inpatient Sample (NIS) was used to evaluate unruptured descending thoracic aneurysm (UDTAA) repair rates from 2000–2007. NIS characteristics have been described previously; our description of the NIS is concise.^{10, 11} The NIS is a stratified sample representing 20% of all hospitals in the US sponsored by Agency for Healthcare Research and Quality. NIS data can be weighted to generate national estimates and used to examine in-hospital outcomes. Long term outcomes cannot be examined using the NIS.

ICD-9 codes were used to identify cases included in the analysis. We used previously described NIS exclusion criteria to identify descending thoracic aneurysm repairs.¹² Briefly, cases were ages 18 years and older, underwent thoracic aneurysm repair (38.45 and 39.73) and had an unruptured thoracic aneurysm diagnosis (441.2). Cases with both endovascular and Open Repair codes, ruptured thoracic aneurysms (441.1) or thoracoabdominal aneurysms (441.6 and 441.7) were excluded. Ruptured thoracic aneurysms were excluded because inclusion would distort outcome analysis of elective repairs. Annual repair rates were calculated by adjusting annual repair volume using annual 18+ population estimates provided by the US Census Bureau.¹³ Comparisons for age, gender, race and disposition after discharge with respect to repair type were examined for all included cases. Trends for abdominal aneurysm repair (38.44 and 39.71), unruptured thoracic aneurysm diagnosis (441.2) and thoracic CT scans (87.41) were analyzed by recording number of primary procedure or primary diagnosis codes and adjusting for annual population estimates.¹⁴

Comorbidities, complications and mortality were analyzed separately for 2006 and 2007 cohorts. Comorbidities and complications were identified using ICD-9 codes (Table 1). A random effects meta-analysis of yes/no events (comparing use to non-use of the procedure) provided an overall estimate of relative risk Open Repair: TEVAR, 95% confidence limits,

and a two-sided p-value.¹⁵ To control for institution, which we believed represented the most important confounder, only hospitals performing both TEVAR and Open Repairs were included. Institution was the sampling unit, not the individual. Due to small size of the subject pool available in matched institutions, statistical analysis examining gender and race as additional control variables was not possible. The same basic method, adjusting for institution, was used to compare age and length of stay using a mean of mean analysis.¹⁶ Results were similar whether including or excluding centers performing only one of the two procedures. We also performed fixed effects meta-analysis using the Cornfield-Mantel-Haenszel method for in-hospital mortality; that analysis agreed with the above and is not reported.

Results

National Thoracic Aneurysm Repair Trends

Open Repair for unruptured descending thoracic aneurysms (UDTAA) averaged 3.3 repairs per million from 2000 to 2002 for people 18 years and older (Figure 1). In 2003, Open Repair increased to 5.6 repairs per million, correlating with an increase in UDTAA diagnosis and introduction of more advanced 16 slice CT scanners (Figure 2). TEVAR was approved by the FDA in March 2005. TEVARs for UDTAA reported in 2005 NIS numbered 285, which, when adjusted for annual population estimate, equals 1.3 repairs per million. In 2005, Open Repair volume decreased to 3.7 repairs per million. In 2006, TEVAR increased dramatically to 6.2 repairs per million resulting in total repair rates of 9.9 repairs per million. TEVAR and Open Repair in 2007 were similar to 2006 rates. Similar TEVAR and Open Repair rates correlated with stable diagnosis rates for UDTAA despite a dramatic increase in the number of thoracic CT scans in 2007 (Figure 2). In 2007, estimated number of TEVARs and Open Repairs for UDTAA was 1,103 and 702 respectively.

As shown in Figure 3, age and repair type appear to be associated for the overall 2007 cohort. Open Repair was the predominant repair type for patients in the 50–59 age group while TEVAR was the main repair type for patients older than 70 years old. Female patients represented 29.77% of all repair patients. There was no observable gender impact on repair type with 62.67% of female patients receiving TEVAR and 60.93% of male patients receiving TEVAR. In the overall cohort, whites represented 75.74% of all UDTAA repairs in 2007, Blacks represented 10.45%, and Hispanics represented 6.34%. However, minorities were more likely to receive TEVAR than whites with 71.43% of Blacks and 94.12% of Hispanics receiving TEVAR vs. 60.59% for Whites.

Abdominal Endovascular Aortic Repair (EVAR)

For comparison purposes, when abdominal aneurysm endovascular technology (EVAR) was introduced, a similar dramatic switch to endovascular technology was noted, but after a brief rise the total abdominal aortic aneurysm (AAA) repair rate remained the same (Figure 4). Specifically, in September 1999, the FDA approved the Aneurx abdominal stent graft system (Medtronic, Santa Rosa CA). In 2001 an increase in total AAA repair occurred from approximately 120 to almost 160 repairs per million, which correlated with a dramatic increase in EVAR volume from approximately 10 repairs per million in 2000 to approximately 50 repairs per million in 2001. However, in subsequent years total AAA repair rate remained relatively constant at approximately 140 repairs per million with continued increases in EVAR reaching almost 100 repairs per million in 2007.

2006 and 2007 Cohort Analyses: Hospitals Performing both TEVAR and Open Repair

Forty-one hospitals in 2006 and 39 hospitals in 2007 performed both TEVAR and Open Repair. This hospital subgroup represents 35.96% in 2006 and 36.11% in 2007 of hospitals

in the NIS performing UDTAA repairs. For both 2006 and 2007 cohorts, mean age of TEVAR patients was older than Open Repair patients. In 2006, mean age was 69.7 years for TEVAR vs. 61.5 years for Open Repair with a similar trend in 2007, 69.8 years and 59.7 years respectively ($P < .01$). Similar trends were observed in 2006 and 2007 cohorts, with TEVAR patients more likely to have the following comorbidities: chronic kidney disease, chronic obstructive pulmonary disease, diabetes, and be a current or previous smoker (Table 2).

In 2007, the estimated relative risk (RR) for in-hospital mortality was similar for Open Repair vs. TEVAR (RR = 0.71, $P = .70$) (Table 3). However, in 2006 the RR for mortality with Open Repair vs. TEVAR was considerably elevated (RR = 8.48, $P < .01$). Analysis of complications showed statistically significant less cardiac and respiratory complications with TEVAR in 2006; this trend continued in 2007. The RR for cardiac complications for Open Repair vs. TEVAR was 5.85 ($P = .02$) in 2006 and 5.36 ($P < .01$) in 2007. The RR for prolonged ventilation lasting longer than 96 hours was 6.78 ($P = .01$) in 2006 with a similar trend in 2007, RR = 4.61 ($P = .05$). Not surprisingly, increased RR for prolonged ventilation in 2006 and 2007 corresponded with a trend for increased RR of tracheostomy in 2007. In 2006 and 2007 TEVAR patients had a shorter length of stay (LOS) than Open Repair patients (2006: 6 days vs. 9 days, $P < .01$; 2007: 6.5 days vs. 8.5 days $P = .10$). Inadequate sample sizes in the 2006 subgroup prevented analysis of peripheral vascular disease, hematomas, tracheostomy and sepsis. Inadequate sample sizes in the 2007 subgroup prevented analysis of sepsis.

Disposition Analysis

Analysis of the 2007 cohort revealed that the majority of TEVAR and Open Repair patients were discharged home (83.99% vs. 77.89%). However, TEVAR patients were more likely to be discharged home without home health care than Open Repair patients (67.00%, 95% CI (60.34, 73.65) vs. 43.22%, 95% CI (30.51, 55.93)). Similar number of TEVAR and Open Repair patients were discharged to skilled nursing and intermediate care facilities (13.16% (95% CI (8.93, 17.39) vs. 17.95%, 95% CI (8.46, 27.45)).

Comment

Our study confirms that a dramatic shift in the treatment paradigm for UDTAA is occurring in the United States with rapid adoption of TEVAR. We found the total number of UDTAA repairs in patients 18 years and older has increased 2.9 fold from 2000 to 2007. In 2000 there were 613 Open Repairs. In 2007 there were 702 Open Repairs and 1,103 TEVARs totaling 1,805 UDTAA repairs.

Orandi et al. and Schwarze et al. hypothesized and we agree that TEVAR trends are mirroring EVAR trends showing increased endovascular and decreased Open Repair utilization.^{10, 11} This study adds evidence that elderly patients are more likely to receive endovascular repair for both thoracic and abdominal aneurysms.^{10, 11} The current findings support earlier results showing that despite increased comorbidities for TEVAR patients, perioperative mortality and complications as well as LOS are lower for TEVAR than Open Repair.¹¹

Orandi et al. reported no significant differences for in-hospital mortality for TEVAR (7.7%) vs. Open Repair (6.4%) for the 2005 cohort ($P = .49$).¹¹ Although our 2007 hospital-matched analysis showed the mortality for Open Repair was also similar to that of TEVAR (1.35% vs. 1.91% respectively), the 2006 matched analysis showed a higher mortality with Open Repair. The reason for this discrepancy in mortality is unknown. The discrepancy between the 2006 and 2007 in-hospital mortality in the matched analysis may be influenced

by hospital volume and/or surgeon volume. Neither hospital nor surgeon volume were assessed in the matched analysis due to small sample sizes that were inadequate to perform the analysis.

Reasons for increased UDTAA repair

Overall increases in UDTAA repairs may be related to an increased pool of patients as it appears TEVAR was offered to older patients that previously may have been judged inoperable because the risk-benefit ratio of the procedure was not considered acceptable. The 2007 NIS cohort analysis revealed that TEVAR patients were older with more comorbidities than Open Repair patients. Alternatively, increased UDTAA repair rates may reflect the use of TEVAR in smaller aneurysms, although we could not directly investigate aneurysm size using NIS data. The literature for small AAA repair using EVAR is still developing with limited consensus on whether EVAR is appropriate for small AAA.¹⁷ Additional research for long-term outcomes and incidence of repair for small aneurysms is needed for both TEVAR and EVAR.

Advances in CT technology may be another contributing factor related to increased repair of UDTAA. In 2002, the 16 slice CT scanner became available. In 2003 increases in UDTAA diagnosis and UDTAA repair paralleled increased utilization of thoracic CT scans (Figures 1 and 2). Similarly, in the 1970s and 1980s advances in 2-dimensional echocardiography and the introduction of CT were associated with increases in diagnosis of UDTAA.¹⁸ In 2007 another rise in CT scan utilization was noted and may reflect postoperative surveillance CT scans for TEVAR, but more likely reflects increased emergency room use of the so called “triple rule out” CT scan (for pulmonary embolus, coronary artery disease and thoracic aortic disease).¹⁹

The Implications of Increased TEVAR utilization

The implications of increased TEVAR utilization must be considered carefully. The use of thoracic endografts is relatively new. It is prudent to examine data and concerns raised from the EVAR experience. Although TEVAR has rapidly been adopted into clinical practice, long term data is lacking which is a concern in light of the EVAR experience. European Registry (EUROSTAR) results reveal a small risk of late ruptures and aneurysm-related deaths after EVAR, raising concerns that similar risks may apply to TEVAR.²⁰ The FDA has issued a warning expressing similar concerns regarding lack of long-term EVAR outcomes data.²¹

In addition to possible late ruptures, endoleaks and graft failure are important outcomes which necessitate the need for vigilant monitoring after endovascular intervention. EVAR data have shown higher complication rates when follow-up is less than recommended.²⁹ Patient compliance with follow-up may be more important for TEVAR than EVAR; the rate of type I proximal seal endoleaks are reported to occur more frequently after TEVAR than EVAR due to anatomical differences in the thoracic aorta.²² Logistical difficulties regarding long term patient follow-up in clinical practice must be acknowledged. Even in the setting of the Gore TAG thoracic stent clinical trial, which reported that late endoleaks occurred in 4% of trial subjects, patient follow-up was less than anticipated.²

Given the lack of data currently available, TEVAR should only be used in anatomically appropriate patients who understand the importance of long-term follow up and are willing to be compliant with surveillance recommendations. Younger patients requiring repair of thoracic aneurysms should be explicitly informed about the need for annual CT scan surveillance for endoleaks and may be better served with Open Repair as mortality rates for Open Repair have improved dramatically in recent years. A 2008 expert consensus panel

reported a 4.8% 30 day Open Repair mortality at centers of excellence.²³ However, for elderly patients who may be considered unfit for Open Repair, TEVAR appears a viable option, at least in the short term.^{3, 24–26}

Off label use of TEVAR

According to NIS data, 3,257 TEVARs were performed in the US in 2007. However based on exclusion criteria in this study it appears only 1,103 TEVARs were used for UDTAA. This discrepancy illustrates the use of stent-grafts for hybrid procedures and other aortic pathology in addition to UDTAA. Given the rapid adoption of TEVAR, future comparative effectiveness research focusing on patient outcomes from actual clinical practice including off label utilization is warranted.

Public Health Implications

Epidemiological data for thoracic aortic disease is limited and continued monitoring of the trends in UDTAA repair is warranted. Prior studies have shown the incidence of UDTAA is increasing with our growing elderly population including patients with many comorbidities.^{18, 27} Data from clinical trials are limited by restrictive inclusion criteria, small study populations, and use of historical controls, which may not reflect the typical clinical practice.^{1, 4, 9} An additional consideration is the cost of open versus endovascular thoracic aneurysm repair. Data on short term costs indicate that inpatient hospital costs are greater for Open Repair than TEVAR despite much higher endograft costs for TEVAR.²⁸ Additional research on the long term outcomes, costs and quality of life are needed to determine the best surgical option for these patients.

Limitations

The results and conclusions which can be drawn from analyzing the NIS data are limited because the NIS does not collect data on clinical variables. The main limitation of this study is that results from the matched institution analysis may not be generalizable to hospitals that do not perform *both* TEVAR and Open Repair. ICD-9 codes were used to identify descending thoracic aneurysms only because thoracic endografts are currently only FDA approved for UDTAA. Thus, ascending aneurysm repairs were not assessed in this study.

Conclusion

In summary, a dramatic shift in treatment of thoracic aortic disease is occurring in the United States towards TEVAR with an overall increase in thoracic aortic repair. TEVAR is being offered to older patients with more comorbidities. Further comparative effectiveness research is required to understand the long-term clinical and financial implications of the choice of repair for patients with thoracic aortic disease.

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Figure 1. Unruptured Descending Thoracic Aneurysm Repair, 2000–2007

Rates for repair of unruptured descending thoracic aneurysms (UDTAA) with open and thoracic endovascular aortic repair (TEVAR) were adjusted for US Census Bureau annual population estimates.

Figure 2. Unruptured Thoracic Aneurysm Diagnosis and Thoracic CT Scan Utilization, 2000–2007

Trends for unruptured thoracic aneurysm diagnosis and thoracic CT scan utilization were determined by identifying the number of unruptured thoracic aneurysms and of thoracic CT scans coded as the principle diagnosis / procedure and adjusting with annual US Census Bureau population estimates.

Figure 3. Age Group vs. Repair Type for Unruptured Descending Thoracic Aneurysms, 2007 NIS Cohort

Number of unruptured descending thoracic aneurysm repairs by age group and repair type (Open Repair vs. Thoracic Endovascular Aortic Repair (TEVAR)) for the NIS 2007 cohort.

Figure 4. Abdominal Aortic Aneurysm Repair, 1995–2007

Trends for abdominal aortic aneurysm (AAA) repair rates were determined by identifying number of principle procedures coded as Open Repair or Endovascular Aortic Repair (EVAR) and adjusting with annual US Census Bureau population estimates.

Table 1**ICD-9 Codes for Comorbidities and Complications**

Comorbidities	ICD-9 Codes
Hypertension	401.0–405.99
Coronary Artery Disease	414.00–414.99
Previous Myocardial Infarction	412
Congestive Heart Failure	428.0–428.9
Chronic Kidney Disease	585.1–586.0
Diabetes	250.00–250.90
Peripheral Vascular Disease	440.20–440.29
COPD	490–496
Current or previous smoker	305.1, V15.82
Complications	
In-hospital Mortality	--
Cardiac Complication	997.1
Transfusion	99.0–99.09
Hematoma	998.12
Hemorrhage	998.11
Respiratory Complication	486, 518.5, 9973
Ventilation > 96 hrs	96.72
Tracheostomy	31.1–31.29
Acute Renal Failure	584–584.9
Postoperative Stroke/TIA	997.02, 435–435.9
Peripheral Vascular Complications	997.2
Sepsis	995.91–995.92
Graft Problem	996.1, 996.62, 996.70, 996.74

Table 2

Comorbidities from Meta-analysis of 2006 and 2007 NIS cohorts at only those institutions performing *both* TEVAR and Open Repair.

	2006					2007				
	Open Repair	TEVAR ^a	RR ^b	95% CI ^c	P Value	Open Repair	TEVAR ^a	RR ^b	95% CI ^c	P Value
Hypertension	76.18%	78.63%	0.97	(0.81, 1.16)	0.72	70.21%	77.83%	0.90	(0.74, 1.11)	0.32
CAD	21.16%	25.07%	0.84	(0.41, 1.73)	0.64	8.41%	23.37%	0.36	(0.12, 1.07)	0.06
Prior MI	3.66%	6.09%	0.60	(0.13, 2.81)	0.52	2.70%	11.15%	0.24	(0.03, 2.06)	0.19
CHF	10.40%	9.02%	1.15	(0.52, 2.58)	0.73	9.23%	5.37%	1.72	(0.50, 5.93)	0.39
CKD	2.03%	12.05%	0.17	(0.05, 0.57)	<0.01	10.38%	23.37%	0.44	(0.18, 1.08)	0.07
COPD	27.48%	32.27%	0.85	(0.53, 1.38)	0.51	18.28%	33.51%	0.55	(0.29, 1.02)	0.06
Diabetes	5.69%	16.85%	0.34	(0.13, 0.90)	0.03	4.83%	10.07%	0.48	(0.15, 1.48)	0.2
PVD	0.00%	5.08%	0	-	-	0.30%	7.39%	0.04	(0, 1.30)	<.01
Smoking	12.64%	36.37%	0.35	(0.18, 0.69)	<0.01	25.40%	33.39%	0.76	(0.44, 1.30)	0.32

^aThoracic Endovascular Aortic Repair

^bEstimated Relative Risk

^c95% Confidence Interval

Table 3

Complications from Meta-analysis of 2006 and 2007 NIS cohorts at only those institutions performing *both* TEVAR and Open Repair.

	2006					2007				
	Open Repair	TEVAR ^a	RR ^b	95% CI ^c	P Value	Open Repair	TEVAR ^a	RR ^b	95% CI ^c	P Value
In-Hospital Mortality	9.79%	1.16%	8.48	(3.03, 23.75)	<0.01	1.35%	1.91%	0.71	(0.12, 4.24)	0.7
Cardiac Complications	7.13%	1.22%	5.85	(1.34, 25.48)	0.02	10.85%	2.02%	5.36	(1.82, 15.81)	<0.01
Transfusion	32.52%	15.77	2.06	(1.22, 3.48)	<0.01	29.36%	20.68%	1.42	(0.77, 2.63)	0.26
Hematoma	0	2.91	0	-	-	1.35%	3.85%	0.35	(0.07, 2.63)	0.22
Hemorrhage	7.13%	3.45	2.07	(0.41, 10.46)	0.38	5.28%	1.69%	3.12	(0.43, 22.71)	0.26
Respiratory Complications	23.37%	8.29%	2.82	(1.27, 6.25)	0.01	16.01%	6.92%	2.31	(0.96, 5.56)	0.06
Prolonged Ventilation	13.41%	1.98%	6.78	(1.51, 30.51)	0.01	10.70%	2.32%	4.61	(0.99, 21.46)	0.05
Tracheostomy	0.00%	0	-	-	-	7.51%	1.91%	3.92	(0.79, 19.53)	0.09
Acute Renal Failure	8.35%	3.52	2.37	(0.75, 7.46)	0.14	6.53%	5.16%	1.26	(0.29, 5.44)	0.75
Postop Stroke/TIA	3.66%	2.66%	1.38	(0.31, 6.14)	0.67	0.30%	2.05%	0.14	(0.02, 1.36)	0.09
PVC	2.44%	4.61%	0.53	(0.07, 4.28)	0.55	0.25%	1.78%	0.14	(0.01, 1.29)	0.08
Sepsis	0.00%	0.00%	-	-	-	0.00%	0.34%	0	-	-
Graft Problem	2.85%	4.76%	0.60	(0.09, 4.01)	0.60	4.05%	6.69%	0.61	(0.12, 3.17)	0.55

^aThoracic Endovascular Aortic Repair

^bEstimated Relative Risk

^c95% Confidence Interval