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Improved Outcomes and Value in Staged Hybrid Extent II Thoracoabdominal Aortic Aneurysm Repair

Robert B. Hawkins, MD¹, J. Hunter Mehaffey, MD¹, Adishesh K. Narahari, BS¹, Amit Jain, MD², Ravi K. Ghanta, MD¹, Irving L. Kron, MD¹, John A. Kern, MD¹, and Gilbert R. Upchurch Jr, MD¹

¹Department of Surgery, University of Virginia, Charlottesville, VA

²Department of Surgery, Division of Vascular Surgery, University of Cincinnati, Cincinnati, Ohio

Abstract

Objective—Complex Crawford extent II thoracoabdominal aortic aneurysms (TAAA) can be treated in a hybrid manner with proximal thoracic endovascular aneurysm repair, followed by staged distal open thoracoabdominal repair. The purpose of this study was to evaluate the outcomes and healthcare associated value of this new method compared to traditional open repair over 10 years.

Methods—A prospectively collected database was used to identify all patients with extent II TAAA undergoing repair at a single institution between 2005 and 2015. Patient characteristics, post-operative outcomes, and incidence of major adverse events (MAE = renal failure, spinal cord ischemia, death) were compared. After adjusting for time since surgery, value was analyzed looking at quality (1/MAE) divided by cost (total health system cost). This is multiplied by a constant to set the value of open TAAA repair to 100.

Results—A total of 113 consecutive patients underwent extent II TAAA repairs, of which 25 (22.1%) had a staged hybrid approach with a median of 129 days between procedures. No baseline differences in demographic or comorbidity variables existed between groups (p>0.05). The hybrid group had shorter operative time (255 vs 306 minutes; p=0.01), shorter postoperative length of stay (LOS) (10.1 vs 13.3 days; p=0.02), as well as reduced blood loss (1300 vs 2600 mL; p=0.01) at the time of open operation. Despite higher rates of acute kidney injury in the hybrid group (76.0% vs 51.1%, p=0.03) there was no difference in renal failure (8.0% vs 4.5%, p=0.84) The incidence of MAE was lower in the staged hybrid group (20.0% vs 48.9%; p=0.01), without a difference in hospital mortality (4.0 vs 3.4%, p=0.89). Median total cost was higher in the hybrid

Corresponding Author: Gilbert R. Upchurch Jr. MD, GRU6N@virginia.edu, Department of Surgery, University of Virginia, PO Box 800679, Charlottesville, VA 22908, Phone: (434) 243-6334.

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group (\$112,920 vs \$72,037, p=0.003). Value was improved in the hybrid group by 56% using mean cost and 178% by median cost.

Conclusions—The 20% major adverse event rate associated with staged hybrid repair of extent II TAAA was significantly decreased compared to open repair, with a relative reduction of over 50%. Despite higher total hospital costs, staged hybrid repair had 56% to 178% higher healthcare related value compared to standard open repair. In an era of increasing focus on costs and quality, staged hybrid repair of extensive TAAAs is associated with fewer complications than open TAAA repair resulting in a good value investment from a resource utilization perspective.

Introduction

Thoracoabdominal aortic aneurysms (TAAA) have a dismal, progressive course with an inflection point at 7cm where over 40% will rupture. 1-3 Since no effective medical therapy currently exists, standard treatment involves open surgical replacement of the aneurysmal aorta. Crawford classification categorizes TAAAs, where extent II involves the longest length of aorta from the left subclavian artery to the aortoiliac bifurcation. Typically repair of extent II aneurysms involves replacement of the descending and abdominal aorta to the bifurcation. As these repairs are the most extensive performed for aortic aneurysms, they are associated with the highest complication rates. 3-8

Extent II aneurysm repair has incrementally evolved and protocols currently emphasize multimodal organ protection.^{3, 9-11} This includes permissive hypothermia, circulatory support with selective renal and visceral perfusion, cerebrospinal fluid drainage, and aggressive reimplantation of segmental arteries. Newer evidence suggests that staged hybrid repair can supplement these techniques to further reduce morbidity.¹²⁻¹⁸ The results suggest that thoracic endovascular repair followed by open distal repair is a safe and reasonable repair strategy. However, there is limited evidence regarding outcomes compared to open repair. Additionally, staged hybrid repair requires multiple procedures that are likely to attract critique in an era of value based care models. New technology is associated with high development costs and these charges will require justification with improved outcomes.

The concept of health care related value was most eloquently promoted by Porter and Teisberg where they describe restructuring our health system to maximize health outcomes per dollar spent. P Critical to this idea is shifting from a provider and volume based analysis of outcomes to a patient centered analysis of efficiency. This idea is separate from cost-effectiveness analyses, and instead encompasses quality, efficiency, costs and complications. The result is a simple metric, a ratio of outcomes to cost. This idea is being translated into alternative payment models that reward value, with CMS aiming to have 50% of alternative based payments related to value and quality by 2018. The purpose of the present study was to compare morbidity, mortality, cost and value for staged hybrid versus open repair of extent II thoracoabdominal aneurysms. We hypothesized that patients will have improved outcomes with the staged hybrid approach, but this new technology will be associated with increase healthcare costs resulting in similar value for the care of these complex patients.

Methods

Study Population

The records of 113 consecutive patients that underwent Crawford Extent II thoracoabdominal aneurysm repair between 2005 and 2015 were identified from a prospectively maintained database of aortic patients at our institution as well as an institutional Vascular Quality Initiative (VQI) database. Patients underwent either single stage open surgical repair or staged hybrid repair with TEVAR of the proximal aorta followed by open surgical repair of the distal aorta. The methodology has been previously described in detail with 18 of the 113 patients included in prior reports. ^{14, 15} Briefly, TEVAR was performed with stent graft placement from the left subclavian artery to just above the celiac artery. Left carotid-subclavian artery bypass was performed at the discretion of the surgeon, but typically prior to any planned coverage of the left subclavian artery by the TEVAR. Distal repair was performed by thoracoretroperitoneal approach with a branched Dacron graft sewn directly to the proximal stent graft.

Inclusion criteria were Crawford extent II classification, while no exclusion criteria were applied. The database includes preoperative characteristics, operative details and short-term outcomes. Our institutional Clinical Data Repository (CDR) was queried to identify which Crawford Extent II thoracoabdominal aneurysm repair patients also underwent TEVAR. Detailed chart review was performed for all patients to capture complications and long-term outcomes. Detailed cost and charge information was obtained from the institutional CDR. The University of Virginia Institutional Review Board approved this study with exemption of consent due to the retrospective nature of the analysis (IRB Protocol # 17900).

Measures

Patients were stratified into open or hybrid repair defined as TEVAR performed on the proximal aspect of the TAAA followed by open repair of the remaining distal aneurysm. Acute kidney injury was defined as an increase in creatinine of 0.5 mg/dL or new dialysis. The primary outcome of composite major adverse event (MAE) was defined as renal failure, spinal cord ischemia or death. Secondary outcomes included in-hospital results, cost, and value. To account for inflation, cost data was adjusted to 2015 dollars using the market basket for the Center for Medicare and Medicaid Services (CMS) Inpatient Prospective Payment System. Value was calculated as inverted outcomes divided by cost. ^{23, 24} This is multiplied by a constant to set the value of open TAAA repair to 100 where an increasing number indicates increasing value. This equates to:

[(1/MAE)/Mean Cost] * 5, 158, 348

Statistical Analysis

Continuous variables are represented as mean and standard deviation if normally distributed, otherwise presented as median and interquartile range (IQR), while categorical variables as number and percentage. Univariate analysis was used to evaluate baseline characteristics and short-term outcomes. Continuous variables were analyzed by Mann-Whitney U Test or

Student's T-Test as appropriate, while categorical variables were assessed by Chi-Squared Test. All analyses were performed with SAS Version 9.4 (SAS Institute, Cary, NC) and significance was determined by an alpha < 0.05.

Results

Study Population

A total of 113 consecutive patients underwent Crawford extent II thoracoabdominal aneurysm repair during the study period, of whom 25 (22.1%) had a staged hybrid approach. The median year of intervention for the open cohort was 2009 and for the staged hybrid cohort was 2011. The baseline characteristics of the two groups are displayed in Table I, with no statistically significant differences identified. While the mean creatinine prior to open repair was higher for the staged hybrid cohort, this did not reach statistical significance (1.3 mg/dL vs 1.1 mg/dL, p=0.24). The median time between TEVAR and open repair in the staged hybrid group was 129 days (IQR 55-396).

Procedural Outcomes

The TEVAR procedure methods and results are displayed in Table II. Endoleaks were identified in 9 patients, 5 of whom required reintervention for type Ia endoleaks. One patient with a history of stage III chronic kidney disease developed renal failure. Almost 50% of patients required a carotid-subclavian bypass, with a median time from bypass to TEVAR of 2 days. Overall, the median length of stay was 6 days and median days before the staged open repair was 129.

Operative characteristics for open TAAA repair (excluding TEVAR) did differ between hybrid and standard open patients, as demonstrated in Table III. The surgical component of hybrid cases involved more frequent use of cerebrospinal fluid drainage, left heart bypass, and selective visceral and renal perfusion. Despite the increased adjunctive techniques, mean operative time was lower (256 min vs 306 min, p=0.01).

There was no statistical difference in in-hospital mortality (4.0% vs 3.4%, p=0.89) also shown in Table III. While there was a higher rate of acute kidney injury in the hybrid cohort (76% vs 51%, p=0.03), AKI resolved in 89% of hybrid patients and 91% of standard open repair patients (p=0.84). Consequently, there was no significant difference in rate of renal failure requiring dialysis (8% vs 4.5%, p=0.84). The composite measure of death, spinal cord ischemia and renal failure was significantly lower in the hybrid repair cohort (20% vs 49%, p=0.01). Additionally, the median length of stay after open repair was significantly lower for the hybrid patients (10 days vs 13 days, p=0.04).

Cost and Value

Detailed cost and charge data are represented in Table IV. The median hospital cost for the open surgical component was significantly lower for the hybrid repair cohort (\$54,518 vs \$72,037, p=0.03). However, the median hospital cost for the TEVAR procedure was \$51,352. Thus, the total median cost for hybrid TAAA repair was significantly higher than conventional open operation (\$112,920 vs \$72,037, p=0.003). It is important to note that the

standard open repair cohort had significantly higher variation in cost, where the mean cost for hybrid repair was \$144,714 versus \$112,897 for the standard open group (p=0.15) (Figure 1).

Total physician charges were significantly higher in the staged hybrid group (\$72,021 vs 23,570, p<0.0001) due to additional charges during TEVAR (Table IV). However, the physician charges for the TAAA open repair were not significantly different (\$33,913 vs \$23,570, p=0.11). Using the standard open procedure as the benchmark for value, the staged hybrid procedure has increased value (Table V). The value is increased by 56% when using median hospital cost and by 78% when mean costs are utilized.

Discussion

Repair of extent II TAAA is associated with a high rate of morbidity, with an overall 42% rate of composite major adverse events in this single center experience. However, the MAE rate for staged hybrid repair was significantly lower than standard open rate at 20% compared to 49%. Staged hybrid TAAA repair was associated with a significantly lower rate of spinal cord ischemia. While acute kidney injury rates were higher in the hybrid repair cohort, the high rate of recovery resulted in no difference in the rate of renal failure requiring dialysis. The median total cost was significantly higher in the staged hybrid cohort at \$113,000 compared to \$72,000 for the standard open repair. Considering both major adverse events and cost, staged hybrid repair represents better value by over 58% compared to the standard open repair technique.

Spinal cord ischemia can be a life altering complication that occurs with unfortunately high frequency after extent II TAAA repair ranging from 7% to over 30%. ^{5, 7, 8, 25} The rates of spinal cord ischemia demonstrated in this analysis are consistent with the literature, and were significantly lower in the group undergoing staged hybrid repair at 8% compared to 19% in the standard open repair cohort. The hybrid repair methodology effectively converts an extent II TAAA into an extent III/IV TAAA. These less extensive aneurysm repairs are associated with much lower rates of spinal cord ischemia. ^{7, 26} Additionally, it has been previously demonstrated that staged open procedures, first thoracic aneurysm repair followed by distal abdominal repair, was associated with a decreased rate of spinal cord injury from 17% to 0%. ²⁷ Our results demonstrate that this outcome can be replicated using TEVAR. An additional benefit may come from temporary aneurysm sac perfusion associated with type 1b endoleaks partially perfusing the spinal cord until the open surgery. ²⁸ While the reduction seen with staged hybrid repair is confounded by a higher rate of lumbar drain use, this likely does not account for the 50% reduction in MAE.

Renal failure after standard open repair of extent II TAAA is 16-26% in contemporary series.^{5, 7, 29} The rate of AKI after TEVAR varies with complexity of lesion and definition of kidney injury, but has been reported to be between 17-23%.^{30, 31} It is therefore not surprising to see increased AKI in our staged hybrid group since these patients are undergoing a previous procedure causing renal insult in one fifth of all patients. Despite a median interval of 129 days between TEVAR and open distal repair, they still experienced increased frequency of AKI. Other limited reports of staged hybrid repair indicate similar

renal failure rates as reported in this single center study.¹⁸ Despite higher rates of AKI, detailed analysis reveals low incidence of progression to renal failure. These results suggest selective renal perfusion is effective and staged hybrid repair does not increase the risk for renal failure.

The resource utilization associated with the TEVAR component of the hybrid repair is not trivial, and is in fact higher than isolated TEVAR.³² This is not surprising considering almost 50% requiring a carotid-subclavian bypass. This not only impacted the cost, but also resulted in a 6 day median length of stay. Importantly, the open surgery component was significantly less costly for the hybrid cohort compared to the standard open group. The most likely explanation relates to the lower rate of major adverse events associated with hybrid repair. It has been demonstrated that complications are the most significant predictor of increased costs, and this effect is consistent across a wide variety of surgeries evaluated.³³ This effect is even more predictive of cost than the Society of Thoracic Surgeons Predicted Risk of Mortality, the gold standard risk prediction model.³⁴ These analyses demonstrate the importance of costs associated with treating complications, including supplementary supporting therapies/medications and longer stays with boarding and staffing costs.

The evaluation of surgical costs should not be completed in isolation. The important question is what outcomes are associated with the costs of care? This is becoming an increasing emphasis with changing reimbursement models. The rise of Accountable Care Organizations, pay-for-performance, bundled payments, and global billing is forcing consideration of value. This can be applied to surgery by comparing a ratio of cost to complications as previously demonstrated by Yount and colleagues.^{23, 24} This metric allows a reasonable assessment of short-term outcomes in relation to cost. The major complications associated with TAAA repair include renal failure, spinal cord ischemia and death. A composite of these measures is a reasonable assessment of major adverse events. Using this metric, we demonstrate that despite increased cost, staged hybrid repair represents reasonable value. The decreased rate of MAE more than compensates for increased hospital costs resulting in an increase in value of between 56% and 78%. This variability is due to high cost outliers associated with standard open repair as demonstrated in the box and whiskers plot. The median costs represent a conservative estimate of value at 156% for hybrid repair. However, to better account for the high-cost outliers, the mean costs demonstrate an even larger value increase at 178%. The outliers are likely due to open repair being associated with not only an increased complication rate but increased complication severity.

This study is limited by the single center, retrospective nature of the analysis with a potential for selection bias. While baseline characteristics were mostly similar, a higher percentage of hybrid repair patients had prior aortic dissection. Additionally, surgical practices changed over time and this is apparent and clearly explained in the operative characteristics. Additionally, there may be dropout bias from patients who underwent TEVAR but did not progress to open repair. A thorough review of records was performed and no patients that fit this description were identified. Additionally, others have reported no deaths or major adverse events associated with initial TEVAR prior to distal repair. ¹⁸ Finally, value would ideally be assessed in a risk-adjusted manner such as has been previously done in the

cardiothoracic surgery literature. 24 Robust risk models are unfortunately unavailable although baseline assessment of patients demonstrated similar comorbidities and risk factors.

Although not available for analysis in this cohort, entirely endovascular TAAA repair represents another opportunity to assess the value of technological innovation. Current spinal cord ischemia rates are high, but as the technology advances and adjuncts such as temporary aneurysm sac perfusion help decrease this rate, its value should be assessed.²⁸

Conclusion

The 20% major adverse event rate associated with staged hybrid repair of extent II TAAA was significantly decreased compared to open TAAA repair, with a relative reduction of over 50%. Despite higher total hospital costs, staged hybrid repair had 56% to 78% higher healthcare related value compared to standard open repair. In an era of increasing focus on costs as well as quality, staged hybrid repair of extensive aortic aneurysms is associated with fewer complications than open repair resulting in a good value investment from a resource utilization perspective.

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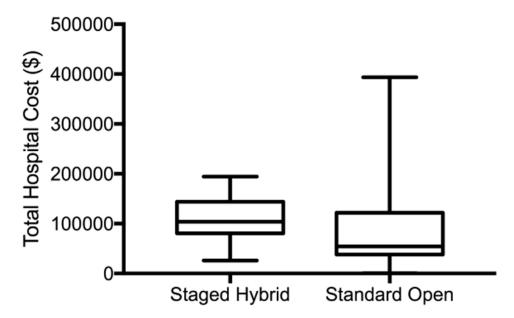


Figure 1. Total Hospital CostBox and Whiskers plot for the total hospital cost demonstrating the median, interquartile range, and range.

Table I Demographics and Comorbidities

Baseline Characteristics	Staged Hybrid (n=25)	Standard Open (n=88)	p-value
Age	53 ± 17	58 ± 17	0.15
Sex (male)	16 (64.0%)	52 (59.1%)	0.66
Coronary Artery Disease	8 (32.0%)	38 (33.6%)	0.32
Chronic Kidney Disease	5 (20.0%)	18 (20.5%)	0.96
Chronic Obstructive Pulmonary Disease	5 (20.0%)	30 (34.1%)	0.18
Diabetes Mellitus Type 2	4 (16.0%)	13 (14.8%)	0.88
Hyperlipidemia	12 (48.0%)	42 (47.7%)	0.98
Hypertension	17 (68.0%)	60 (68.2%)	0.99
Tobacco Use	15 (60.0%)	55 (62.5%)	0.82
Prior Descending Aortic Dissection	23 (92.0%)	30 (34.1%)	< 0.0001

Table II
Thoracic Endovascular Aortic Aneurysm Repair (TEVAR) Characteristics

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TELEVIA D. CI	
TEVAR Characteristics	Incidence
Percutaneous Access	11 (44.0%)
Carotid-Subclavian Bypass	12 (48.0%)
Lumbar Drain	21 (84.0%)
Endoleak	9 (36.0%)
Reintervention	5 (20.0%)
Spinal Cord Ischemia	0 (0%)
Non-Fatal Myocardial Infarction	0 (0%)
Length of Stay (days) ‡	6 [4,7]
Days Between Procedures ‡	129 [62,163]

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[‡] presented as median and interquartile range due to skewedness

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Table III

Thoracoabdominal Aneurysm Repair (TAAA) Surgical Characteristics and Outcomes

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Operative Characteristics	Staged Hybrid [†] (n=25)	Standard Open (n=88)	p-value
Lumbar Drain	23 (92.0%)	54 (61.4%)	0.01
Left Heart Bypass	24 (96.0%)	54 (61.4%)	0.001
Celiac Artery Perfusion	12 (48.0%)	17 (19.3%)	0.01
Superior Mesenteric Artery Perfusion	13 (52.0%)	19 (21.6%)	0.01
Renal Artery Perfusion	12 (48.0%)	18 (20.5%)	0.01
Operative Time (minutes)	256 ± 97	306 ± 80	0.01
Estimated Blood Loss (mL)	1319 ± 1645	2601 ± 2859	0.01
Short-Term Outcomes			
In-hospital mortality	1 (4.0%)	3 (3.4%)	0.89
Spinal Cord Ischemia	2 (8.0%)	17 (19.3%)	0.18
Acute Kidney Injury	19 (76.0%)	45 (51.1%)	0.03
Renal Failure	2 (8.0%)	4 (4.5%)	0.84
Non-Fatal Myocardial Infarction	1 (4.0%)	3 (3.4%)	0.99
Reoperation	9 (36.0%)	27 (30.7%)	0.61
Length of Stay (days)	10.1 ± 4.0	13.3 ± 12.3	0.04
Major Adverse Event	5 (20.0%)	43 (48.9%)	0.01

Table IV Median hospital costs and physician charges

Financial Outcomes	Staged Hybrid	Standard Open	p-value
TEVAR Hospital Cost	51,352 (42,048-88,105)	-	
TEVAR Physician Charges	13,724 (11,129-25,401)	-	
TAAA Repair Hospital Cost	54,518 (44,738-77,619)	72,037 (47,678-149,766)	0.032
TAAA Repair Physician Charges	33,913 (20,801-64,816)	23,570 (15,670-51,322)	0.111
Total Hospital Cost	112,921 (100,511-154,416)	72,037 (47,678-149,766)	0.003
Total Physician Charges	72,021 (37,016-100,520)	23,570 (15,670-51,322)	< 0.0001

All costs were adjusted for medical inflation and presented as median 2015 dollars (interquartile range). TEVAR = Thoracic Endovascular Aortic Aneurysm Repair; TAAA = Thoracoabdominal Aneurysm

Table V

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Value Comparison

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Component Variables	Staged Hybrid (n=25)	Standard Open (n=88)	p-value
Major Adverse Event	5 (20.0%)	43 (48.9%)	0.017
Total Cost (median)	\$112,921	\$72,037	0.003
Value	156	100	

Total cost was adjusted for inflation and represents 2015 dollars.