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# Outcomes of Open v. Endovascular Repair of Descending Thoracic and Thoracoabdominal Aortic Aneurysms

Running head: Open v. endovascular aneurysm repair

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#### ABSTRACT

*Background:* Open repair is the standard of care for patients with descending thoracic and thoracoabdominal aortic aneurysms. Although effective, surgery carries a high risk of morbidity and mortality. Endovascular stent-grafts were introduced to treat these aneurysms in patients considered too high risk for open repair. Early results are promising, but later results are incompletely known. Therefore, we sought to compare short- and intermediate-term outcomes of open versus endovascular repair for these aneurysms.

*Methods:* From 2000–2010, 1,053 patients underwent open (n=457) or endovascular (n=596) repair of descending thoracic and thoracoabdominal aortic aneurysms at Cleveland Clinic. To balance patient characteristics between these groups, propensity-score matching was performed, yielding 278 well-matched pairs (61% of possible pairs). Endpoints included short- and long-term outcomes.

*Results:* In matched patients, compared with endovascular stenting, open repair achieved similar inhospital mortality (n=23/8.3% vs n=21/7.6%, P=.8) and occurrence of paralysis and stroke (n=10/3.6% vs n=6/2.2%, P=.3), despite longer postoperative stay (median 11 vs 6 days), more dialysis-dependent acute renal failure (n=24/8.6% vs n=9/3.3%, P=.008), and prolonged ventilation (n=106/46% vs n=17/6.3%, P<.0001). Open repair resulted in better 10-year survival than endovascular repair (52% vs 33%, P<.0001), and aortic reintervention was less frequent (4% vs 21%, P<.0001). Despite a decrease in the first postoperative year, average aneurysm size did not recover to normal range after endovascular stenting.

*Conclusions:* Open repair of descending thoracic and thoracoabdominal aneurysms can achieve acceptable short-term outcomes with better intermediate-term outcomes than endovascular repair.

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Open repair, pioneered by E. Stanley Crawford, has long been the standard of care for patients with descending thoracic and thoracoabdominal aortic aneurysms.<sup>1</sup> Although effective, open repair carries a high risk of morbidity and mortality, with paraplegia or paraparesis occurring in 16% in early large series.<sup>1,2</sup> Endovascular stent-grafts were introduced to treat descending thoracic aortic aneurysms in patients considered high risk for open repair.<sup>3</sup> Custom fenestrated stent-grafts and branched grafts expanded their application to patients with thoracoabdominal aortic aneurysms.<sup>4-7</sup> Early results demonstrated feasibility with lower morbidity compared with open repair. Thus, their use extended to moderate- and low-risk patients.<sup>8,9</sup>

Because stent-grafts exclude—not remove—aneurysms, patients remain at risk of endoleaks, persistent aneurysmal growth, and in need of repeat interventions. Thus, despite excellent early outcomes with endovascular treatment, these and other late outcomes remain incompletely known.

Nevertheless, the less invasive nature of endovascular stent-grafts is preferred by patients, and in many centers, endovascular repair has replaced open repair as the treatment of choice.<sup>10,11</sup> Endovascular repairs increased by 60% between 1998 and 2007, while the number of open repairs stayed the same.<sup>12</sup> However, large comparison studies of open versus endovascular repair are lacking. Therefore, we compared our short- and intermediate-term outcomes of open versus endovascular descending thoracic and thoracoabdominal aortic aneurysm repair.

## PATIENTS AND METHODS

## Patients

From 1/2000 to 1/2010, 1,053 patients underwent open (n=457) or endovascular (n=596) descending thoracic or Crawford extent I, II, or III thoracoabdominal aortic aneurysm repair at Cleveland Clinic. Those undergoing Crawford type IV thoracoabdominal aortic aneurysm repair or endovascular repairs using non-commercial or homemade devices were excluded. Endovascular repairs increased from 24% in 2000 and 2001 to 69% in 2008 and 2009 (Figure 1).

## Patient Data and Characteristics

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Clinical data were extracted from the Cleveland Clinic Cardiovascular Information Registry, supplemented by medical records review. Data used in this study were approved for use in research by the Cleveland Clinic Institutional Review Board, with patient consent waived.

Patients undergoing open repair were younger and more likely to have had a prior stroke (17% vs 8.7%), prior cardiac surgery (56% vs 38%), or to have connective tissue disorder (13% vs 3.2%) (Table 1). Those undergoing endovascular repair were more likely to have an emergency operation (21% vs 5.3%) and smaller aortas 2 cm distal to the left subclavian artery (4.1 vs 4.7 cm) and 2 cm proximal to the celiac artery (3.9 vs 4.5 cm).

## Endovascular Stent-Grafts, Arch Vessel Coverage, and Spinal Protection

Stents were generally oversized by 20%, with a 2-cm landing zone targeted. However, given the retrospective nature of this study, we could not determine if all patients met these criteria.

Among the 278 patients in the endovascular group, 82 (29%) had coverage of 1 or more arch vessels. Forty-eight of these 82 underwent revascularization of the left subclavian, vertebral, or left carotid artery. Patients with aberrant right subclavian arteries also underwent revascularization of that artery. Most patients, 41 of 48 (85%), underwent revascularization before the index operation, with 5/48 undergoing same-day revascularization and 2/48 undergoing revascularization after the index operation.

Spinal protective strategies included cerebral spinal fluid drainage in 61% of patients undergoing open surgery and 62% of endovascular patients. Postoperatively, mean arterial pressure was targeted at >90 mmHg, and open surgical patients received intrathecal papaverine.

#### **Endpoints**

The primary endpoint was all-cause time-related mortality. Follow-up was obtained by clinic visit, telephone, responses to mailed surveys, or written correspondence. Vital status from active follow-up was augmented by information from the Social Security Death Master File, accessed 10/31/2011. In the endovascular group, 50% of survivors were followed >7.7 years, 25% >9.9 years, and 10% >11.7 years (Supplemental Figure E1). In the matched open repair group (see following text), follow-up was

conducted similarly; 50% were followed >6.9 years, 25% >9.4 years, and 10% >12.2 years (Supplemental Figure E1).

Secondary endpoints included operative morbidities, postoperative length of stay, and intermediate-term aortic reintervention and aneurysm growth. Reintervention included any surgical or endovascular aortic procedure related to the index surgery. Planned staged procedures or reinterventions on other non-contiguous segments of the aorta were not counted as reinterventions. To monitor aneurysm growth after endovascular repair, we collected and measured all available postoperative computed tomography (CT) scans for patients whose preoperative descending thoracic aorta was  $\geq$ 5 cm at the level of T8, 767 scans for 327 patients.

## Data Analysis

Analyses were performed using SAS software version 9.4 (SAS Institute, Cary, NC). Continuous variables are summarized as mean $\pm$ standard deviation or as median (15th, 85th percentiles) when values were skewed. Categorical data are summarized as frequencies and percentages. Uncertainty is expressed by confidence limits analogous to  $\pm$ 1 standard error (68%). Group comparisons were made using the chi-squared and Wilcoxon rank-sum tests. Standardized mean differences were used for comparison of preoperative characteristics.<sup>13</sup>

## Propensity-Score Matching

To account for differences in preoperative characteristics when comparing outcomes, propensity-score matching was performed.<sup>14</sup> Multivariable logistic regression was used first to identify factors associated with open versus endovascular repair using a machine-learning approach (parsimonious model).<sup>15</sup> For this, 1,000 bootstrap data sets were analyzed considering all variables in Appendix E1, with retention of variables appearing in more than 50% of models (Supplemental Table E1). To this parsimonious model we added variables from each organized group of variables in Appendix E1 to generate the propensity model (C-statistic .85). Greedy matching using the resulting propensity score yielded 278 well-matched

pairs of endovascular and open repairs (61% of possible pairs; Supplemental Figure E2 and Supplemental Table E2).<sup>16</sup>

In developing these models, we used 5-fold multiple imputation with the Markov chain Monte Carlo technique.<sup>17</sup> Propensity scores calculated from each of the 5 resulting models were averaged to yield the scores used for matching.

## Time-to-Event Analysis

Survival was assessed nonparametrically by the Kaplan-Meier method and parametrically by a multiphase nonproportional hazards model.<sup>18</sup> The latter involved resolving the number of hazard phases for instantaneous risk of death (hazard function) and estimating shaping parameters.

Cumulative number of reinterventions per patient across time was estimated by Nelson's nonparametric method<sup>19</sup> and parametrically by the multiphase hazard method.<sup>18</sup> Further reintervention was assessed after each reintervention by the modulated renewal method, accounting for the competing risk of death (Appendix E2).

## Postoperative Aneurysm Growth

Progression of aortic size after endovascular repair was estimated using multivariate longitudinal analysis based on repeated CT measurements of the aorta at 10 levels. A nonparametric boosting approach, implemented using the R package BoostMLR, was used for jointly modeling these measurements as vertically correlated longitudinal responses. Ensemble mean of measurements at the 10 levels and correlation among repeated measurements were modeled separately.

## RESULTS

## Extent of Repair

In the matched cohorts, despite matching for aortic anatomy, open repair was more extensive than endovascular repair: 120 patients (44%) had open descending thoracic aorta repair and 153 (56%) thoracoabdominal aortic repair, compared with 163 (59%) and 115 (41%), respectively, for endovascular repair (P=.001).

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## Early Morbidity and Mortality: Matched Cohorts

Open and endovascular repair groups experienced similar in-hospital mortality (8.3% vs 7.6%; Table 2), spinal cord ischemia (4% vs 5.1%), permanent paralysis/paraplegia (3.6% vs 2.2%), and stroke (5.4% vs 3.3%). Open repair patients experienced more acute renal failure (8.6% vs 3.3%), respiratory failure (46% vs 6.3%), and sepsis (8.3% vs 4.7%), and they had longer median intensive care unit length of stay, 5 (2.8, 13) versus 3 (1.2, 6) days, and longer postoperative length of stay, 11 (7, 22) versus 6 (4, 14) days.

## Intermediate-Term Outcomes: Matched Cohorts

## Survival and Risk Factors for All-Cause Mortality

Survival after open repair was higher than after endovascular repair (P<.0001; Figure 2): 89%, 88%, 74%, and 52% at 6 months, 1, 5, and 10 years after open repair versus 87%, 82%, 55%, and 33% after endovascular repair. Instantaneous risk of all-cause mortality was high immediately after operation, rapidly declined to a constant underlying phase of risk, then rose gradually (see Figure 2, inset). Risk was lower after open repair during the constant hazard phase (P<.0001).

## Aortic Reintervention

There were 13 aortic reinterventions after open and 39 after endovascular repair. Freedom from reintervention at 1, 5, and 10 years after open repair was 99%, 98%, and 96%, compared with 96%, 88%, and 79% after endovascular repair. Considering all reinterventions (repeated-events analysis), early hazard peaked about 2 days postoperatively (Figure 3, inset), similar for open and endovascular repair groups (P=.9); however, there was a higher risk of aortic intervention after endovascular repair in the late hazard phase (P<.001). Interventions per 100 patients at 1 year, 5 years, and 10 years was 2.4, 5.0, and 8.4 after open repair versus 3.6, 14, and 31 after endovascular repair. The higher risk in the endovascular group was due to a higher risk of repeated reinterventions (Figure 4).

Indications for reintervention differed between groups. After open repair, reinterventions were for pseudoaneurysm (n=6), residual aneurysm (n=3), patch aneurysm (n=2), and false lumen perfusion (n=2). In contrast, after endovascular repair, interventions were for types Ia (n=16), Ib (n=11), and III (n=8) endoleaks, pseudoaneurysm (n=2), retrograde dissection (n=1), and stent kink (n=1).

## Postoperative Aneurysm Growth

In patients undergoing endovascular repair, initial decrease in mean aorta size from 6.8 to 5.8 cm, with the nadir at 2 years, was followed by a slow increase (Figure 5).

## COMMENT

Although our open and endovascular repair groups were well matched with respect to preoperative aneurysm size and extent, open repair was more extensive. This was perhaps due to the custom nature and lag time required for fabricating thoracoabdominal stent-grafts, whereas descending thoracic aorta stentgrafts were readily available off the shelf. In open repair, extending a repair into the abdominal aorta requires minimal additional preparation and was done with a low threshold. That for the same anatomy endovascular repair extended to less of the aorta is a limitation of the technology, and the higher number of reinterventions may reflect this.

As shown by others,<sup>3-12</sup> patients undergoing endovascular repair had less postoperative morbidity and shorter intensive care unit and postoperative lengths of stay. However, we did not find a difference in paraplegia/paralysis. In the 2 decades preceding this study, advances in spinal cord protection, including left heart bypass, hypothermia, intrathecal papaverine, reimplantation of intercostal and lumbar arteries, and cerebral spinal fluid drainage, contributed to low occurrence of spinal cord injury.<sup>20-25</sup> We also found similar early survival among propensity-matched patients. This conflicts with early published series and the meta-analysis by Cheng and colleagues<sup>26</sup> showing higher 30-day mortality after open repair. However, most studies in that meta-analysis were small or were industry-sponsored registries of highly selected patients with mixed pathologies, and 30-day mortality was 14% after open repair compared with 6% after endovascular repair. In contrast, mortality in our study's open repair group was 8%, in line with large real-world databases, including the Medicare database,<sup>27</sup> the nationwide inpatient sample database,<sup>28,29</sup> and the report by Coselli and colleagues.<sup>30</sup> In addition, a volume–outcome relationship has been demonstrated for open repair.<sup>31,32</sup>

Beyond the early hazard phase, we found that survival was higher after open than endovascular repair. Although 56% 5-year survival in the endovascular group is similar to that of other large published

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series, 5-year survival of 74% after open repair is higher than in most published reports. However, no randomized trials are available that compare long-term outcomes between these modalities. Observational studies show either no difference in early mortality or an early advantage for endovascular repair, but beyond the short term, many showed greater survival with open repair,<sup>27</sup> and any early mortality advantage for endovascular repair disappeared within the first 2 years after surgery.<sup>26,32</sup> This higher late mortality with endovascular repair was also found after abdominal aortic repair.<sup>33,34</sup>

Reasons for this difference in late mortality are unclear but may relate to patient selection and device-related failure. Stent-grafts only exclude aneurysms, and their long-term success depends on having suitable landing zones. Generally, 2 cm of normal-sized aorta is recommended, but many times this criterion is not met, increasing vulnerability for type Ia and Ib endoleaks, the leading cause of reinterventions after endovascular repair in our study. Also, because patients undergoing endovascular repair have less extensive repair than those having open repair, more of their residual aorta is at risk. Although we saw an initial decrease in aneurysm sac size, after year 2, mean size slowly increased. This was also described by Desai and colleagues,<sup>35</sup> who reported only modest aneurysmal size regression from 6.1 to 5.5 cm at 5 years after endovascular repair.

Among the most important lessons we learned were need for meticulous spinal cord protection and importance of landing zones. Currently, all patients undergoing descending aorta treatment receive cerebral spinal fluid drainage. Patients with arch vessel stent-graft coverage receive arch vessel revascularization, and elephant trunks and frozen elephant trunks are performed with greater frequency to augment landing zones of descending aortic stent-grafts.

## Limitations

Our study is limited by its observational design: Patients were not randomized and were subject to selection bias of the operating surgeon. It spanned 10 years that included pre– and post– Food and Drug Administration approval of endovascular stent-grafts and incorporates our early experience with the technology. To fairly compare outcomes, patients were matched only on preoperative variables, including aneurysm characteristics,<sup>14</sup> but this resulted in a number of patients undergoing both open and

#### Journal Pre-proof

endovascular repair being unmatched because of their dissimilar preoperative characteristics. This, and relatively uncommon operations, reduced the power of the study to detect differences in outcomes. Despite multiple attempts to contact all patients through various means of communication, follow-up was incomplete, and cause of death in most circumstances was unknown. For these reasons, and the unreliability of death certificates for cause or mode of death, all-cause mortality was selected as an endpoint. Follow-up CT studies were opportunistic and not predetermined in all patients; hence, patients receiving CT imaging were prone to be those with complications related to endoleak and persistent aneurysmal enlargement. Our experience is drawn from a single high-volume center, and outcomes may not be generalizable to other centers.

## Conclusions

Despite the unclear long-term durability of stent-grafts, the perioperative safety profile and lower morbidity associated with endovascular repair has made it the treatment of choice in patients with descending aorta disease with suitable anatomy, a trend that is unlikely to change. Lifelong, rigorous follow-up is mandatory for these patients, with a plan for diagnosis and intervention in cases with aneurysm sac growth. In patients with poor landing zones or in young, low-risk patients with long life expectancy, open surgery should still be preferred.

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	<b>BEFORE MATCHING</b>				AFTER MATCHING					
	<b>Open</b> (n=457)		Endovascular (n=596)		Std.	<b>Open</b> (n=278)		Endovascular (n=278)		Std.
Characteristic	n <sup>a</sup>	No. (%) or Mean+SD	n <sup>a</sup>	No. (%) or Mean+SD	Diff. (%)	n <sup>a</sup>	No. (%) or Mean+SD	n <sup>a</sup>	No. (%) or Mean+SD	Diff. (%)
Demographics		11100112.52			0				111000000	
Age (y)	457	63±12	596	69±13	50	278	66±11	278	66±13	-0.17
Male	457	288(63)	596	356(60)	-6.8	278	171(62)	278	175(63)	3.0
Preoperative CT Scan										
Aneurysm size (cm)	421	6.4±1.4	536	5.9±1.4	-36	251	6.3±1.3	255	6.3±1.2	-3.1
Aneurysm location										
Between left carotid and left subclavian	326	3.7±0.83	468	3.5±0.57	-29	198	3.6±0.66	212	3.6±0.63	-1.6
Immediately after left subclavian	264	4.0±1.0	453	3.6±0.78	-40	174	3.8±0.76	192	3.8±0.97	11
2 cm distal to left subclavian	384	4.7±1.4	509	4.1±1.2	-46	236	4.5±1.3	233	4.5±1.4	-0.5
Mid-descending aorta	414	6.2±1.4	536	5.8±1.4	-29	246	6.1±1.4	255	6.1±1.3	5.9
2 cm proximal to celiac	401	4.5±1.3	509	3.9±1.1	-51	240	4.3±1.2	238	4.2±1.2	-6.9
Celiac, immediately above	257	4.4±1.2	433	3.8±1.0	-62	162	4.3±1.1	186	4.2±1.2	-12
Between celiac and SMA	349	4.0±1.1	477	3.3±0.97	-61	213	3.8±0.94	217	3.7±1.1	-8.8
Between SMA and renal	360	3.6±1.1	485	3.1±0.95	-45	216	3.4±0.97	224	3.4±1.0	-6.0
Immediately after renal	336	3.5±1.3	483	3.0±1.2	-42	204	3.5±1.4	222	3.3±1.3	-11
Aortic bifurcation	213	3.0±1.3	420	2.6±0.9	-39	144	2.8±1.0	180	2.8±1.0	-5.0

## Table 1. Patient Characteristics Before and After Propensity-Score Matching

Cardiac comorbidities										
Prior cardiac operation	457	256(56)	595	229(38)	-31	278	140(50)	278	137(49)	4.3
Heart failure	457	40(8.8)	578	49(8.5)	-1.0	278	25(9.0)	274	22(8.0)	-3.5
Myocardial infarction	457	96(21)	575	95(17)	-12	278	51(18)	272	59(22)	8.4
Noncardiac comorbidities										
Hypertension	457	411(90)	581	517(89)	-3.0	278	252(91)	274	245(89)	4.1
Diabetes	453	36(7.9)	573	73(13)	16	274	29(11)	271	27(10)	-2.0
COPD	457	167(37)	579	177(31)	-13	278	99(36)	273	98(36)	0.61
Prior stroke	457	78(17)	576	50(8.7)	-25	278	38(14)	273	28(10)	-11
Creatinine (mg•dL <sup>-1</sup> )	455	1.2±0.76	574	1.3±1.0	15	277	1.2±0.82	269	1.2±0.78	73
Connective tissue disorder	454	59(13)	591	19(3.2)	-36	277	23(8.3)	276	17(6.2)	-8.3
Operation										
Urgent/emergency	457	24(5.3)	593	127(21)	49	278	18(6.5)	276	17(6.2)	-1.3

<sup>a</sup>Patients with data available.

COPD=chronic obstructive pulmonary disease; CT=computed tomography; SD=standard deviation; SMA=superior mesenteric artery.

## Table 2. Clinical Outcomes/Complications of Propensity-Matched Groups

	()	Open n=278)	Ende (r		
<b>Outcomes/Complications</b>	n <sup>a</sup>	No. (%)	n <sup>a</sup>	No. (%)	<i>P</i> -value
Hospital death	278	23(8.3)	278	21(7.6)	.8
Paralysis/paraplegia	278	11(4)	274	14(5.1)	.5
Permanent paralysis/paraplegia	278	10(3.6)	274	6(2.2)	.3
Permanent stroke	278	15(5.4)	274	9(3.3)	.2
Dialysis	278	24(8.6)	275	9(3.3)	.008
Respiratory failure	230	106(46)	272	17(6.3)	<.0001
Intensive care unit length of stay (d)	278	2.8/5.0/13	278	1.2/3.0/6.0	<.0001
Postoperative length of stay (d)	278	7.0/11/22	278	4.0/6.0/14	<.0001
Sepsis	278	23(8.3)	274	13(4.7)	.09
Reoperation for bleeding	278	11(4)	276	6(2.2)	.2

<sup>a</sup>Patients with data available.

## FIGURE LEGENDS

- Figure 1:Yearly percentage (red circles) of patients undergoing open versus endovascular repair of<br/>descending or thoracoabdominal aortic aneurysms. Smooth line is a loess fit.
- Figure 2: Survival stratified by surgical approach in matched cohorts undergoing open (red lines and squares) and endovascular (Endo; blue lines and circles) repair of descending thoracic or thoracoabdominal aortic aneurysm. Each symbol represents a death positioned on the vertical axis by the Kaplan-Meier estimator; vertical bars are confidence limits equivalent to  $\pm 1$  standard error. Solid lines are parametric estimates enclosed within dashed 68% confidence bands. Inset is instantaneous risk of death (hazard function) for each of these groups.
- Figure 3: Cumulative number of reinterventions per patient for the propensity-matched open and endovascular (Endo) cohorts, expressed on vertical axis as number per 100 patients (repeated-events analysis). Format is as in Figure 2. Inset shows instantaneous risk of reintervention (hazard function) for each cohort.
- Figure 4: Probability of reintervention stratified by number of prior reoperations and initial procedure. Red lines represent open patients' first reoperation, while blue and cyan lines represent endovascular patients' first and second reinterventions, respectively. Symbols represent a reintervention positioned by nonparametric estimates, and vertical bars represent asymmetric 68% confidence limits equivalent to ±1 standard error. Dashed line indicates no events as yet beyond this time point. These conditional probability curves depict the likelihood of reintervention given no competing risks have occurred. Modulated renewal analysis indicated that the endovascular (Endo) approach was

associated with more reinterventions (P=.002) and that occurrence of reinterventions begat more reinterventions (P<.0001).

Figure 5: Spaghetti plot and mean trend of mid-descending thoracic aorta size for patients undergoing endovascular repair. Red lines represent patients who underwent reintervention.

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