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Sex Differences in Mortality and Morbidity following Repair of Intact Abdominal Aortic Aneurysms

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Abstract

Objective—Medicare studies have shown increased perioperative mortality in women compared to men following endovascular and open AAA repair. However, a recent regional study of high-volume centers, adjusting for anatomy but limited in sample size, did not show sex to be predictive of worse outcomes. This study aims to evaluate sex differences after intact AAA repair in a national clinical registry.

Methods—The Targeted Vascular module of NSQIP was queried to identify patients undergoing EVAR or open repair for intact, infrarenal AAA from 2011–2014. Univariate analysis was performed using the Fisher Exact test and Mann-Whitney test. Multivariable logistic regression was utilized to account for differences in comorbidities, aneurysm details, and operative characteristics.

Results—We identified 6,661 patients (19% women) who underwent intact AAA repair (87% EVAR; women 83% vs. men 88%, $P < .001$). Women were older (median age 76 vs. 73, $P < .001$), had smaller aneurysms (median 5.4 cm vs. 5.5 cm, $P < .001$), and more COPD (22% vs. 17%, $P < .001$). Amongst patients undergoing EVAR, women had longer operative times (median 138 [IQR 103–170] vs. 131 [106–181] minutes, $P < .01$) and more often underwent renal (6.3% vs. 4.1%, $P < .01$) and lower extremity revascularization (6.6% vs. 3.8%, $P < .01$). After open repair, women had shorter operative time (215 [177–304] vs. 226 [165–264] minutes, $P = .02$), but women less frequently underwent lower extremity revascularization (3.1% vs. 8.2%, $P = .03$). Thirty-day mortality was higher in women after EVAR (3.2% vs. 1.2%, $P < .001$) and open repair (8.0% vs. 4.0%, $P = .04$). After adjusting for repair type, age, aneurysm diameter, and comorbidities, female sex was independently associated with mortality (odds ratio [OR] 1.7, 95% confidence interval [CI]: 1.1 – 2.6; $P = .02$) and major complications (OR 1.4, CI: 1.1 – 1.7; $P < .$

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01) after intact AAA repair. However, after adjusting for aortic size index rather than aortic diameter, the association between female sex and mortality (OR 1.5, CI: 0.98 – 2.4; P = .06) and major complications (OR 1.1, CI: 0.9 – 1.4; P = .24) was reduced.

Conclusions—Women were at higher risk for 30-day death and major complications after intact AAA repair. Some of this disparity may be explained by differences in aortic size index, which should be further evaluated to determine the ideal threshold for repair.

Introduction

Sex differences have been reported in the pathophysiology, presentation, and outcomes following repair of abdominal aortic aneurysm (AAA).^{1–5} Women are less likely to develop AAA;^{1, 6–10} however, when they do, they have a faster rate of aneurysm growth,⁵ a 4-fold higher risk of rupture, a tendency to rupture at smaller diameter,¹¹ and a 3-fold higher mortality following rupture compared to men.¹² While this may suggest that women should have a lower size threshold for repair, many studies have shown that women have worse outcomes following repair of intact AAAs, making it difficult to identify the optimal threshold for intervention. Studies using large multi-center administrative databases have demonstrated higher perioperative mortality rates for women after elective endovascular abdominal aortic aneurysm repair (EVAR).^{4, 13, 14} However, single-center and regional studies show the mortality rates after elective EVAR to be more comparable.^{1, 8–10}

AAA diameter has long been used as a marker for the risk of rupture; however, prior studies were based on male-dominated populations.^{12, 15–17} Furthermore, there is mounting evidence suggesting that AAA diameter may not be the optimal measure of when intervention is warranted,¹¹ and by using the current diameter thresholds for repair,¹⁸ we are repairing women at a more advanced aneurysm size. This novel data may also explain some of the reported differences seen in previous work.

Given the lack of consensus in the current literature, the primary objective of this study is to perform a contemporary analysis of the association between female sex and 30-day mortality following EVAR and open AAA repair. The secondary endpoint of this study is to compare AAA diameter to aortic size index in a mortality risk prediction model.

Methods

The Beth Israel Deaconess Medical Center Institutional Review Board approved this study and waived informed consent due to the use of de-identified data.

Population

This is a retrospective cohort study using the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) Targeted Vascular module. All patients undergoing EVAR and open abdominal aortic aneurysm repair from 2011 to 2014 were identified. Only those patients with an infrarenal proximal aneurysm extent were included, with all patients with juxtarenal, pararenal, suprarenal, and type IV thoracoabdominal aneurysm extent excluded. All patients with rupture were excluded. Type of repair was stratified by EVAR versus OSR. The targeted NSQIP is a national registry

developed in 2011 that collects patient demographics, operative details, and 30-day outcomes from patients undergoing surgical procedures at more than 65 self-selected hospitals. Further information is available at www.facs.org/quality-programs/acs-nsqip.

Variables

Demographics, comorbid conditions, operative details, and 30-day postoperative outcomes were identified for all patients. Body mass index (BMI) and body surface area (BSA) were calculated for each patient using height and weight information. We used the standard formula for BMI: $BMI = \text{weight (kg)}/\text{height (m}^2)$, and the Dubois and Dubois formula¹⁹ for BSA: $BSA = [\text{weight (kg)}^{0.425} \times \text{height (m)}^{0.725}] \times 0.20247$. Aortic side index (ASI) was defined as aortic diameter/BSA.^{11, 20} A single preoperative creatinine value was used to estimate the glomerular filtration rate (GFR) for each patient using the Modification of Diet in Renal Disease Study equation.²¹ Anemia was defined as preoperative hematocrit < 35 d/L. Prior abdominal surgery was defined by the NSQIP as any prior open abdominal surgery. Symptomatic patients were defined as those patients with intact aneurysms who underwent repair for the presence of symptoms, dissection, embolization, or thrombosis. Postoperative complications were defined as those that occurred within 30-days. Postoperative renal dysfunction was defined by NSQIP as a creatinine increase > 2 mg/dL or new dialysis requirement. Perioperative transfusion was any transfusion intraoperatively or in the first 30 postoperative days. A composite variable of major complications was created and composed of myocardial infarction, renal dysfunction, pulmonary embolus, ventilator dependence > 48 hours or reintubation, stroke, ischemic colitis, lower extremity ischemia requiring reintervention, postoperative aneurysm rupture, and return to the OR.

Statistical Analysis

Categorical variables were presented as percentages. Continuous, non-normal variables were presented as median (interquartile range (IQR)). Differences between cohorts were assessed using the Fisher's exact test for categorical variables and the Mann Whitney U test for continuous variables, where appropriate. Logistic regression was utilized to assess the independent association between female sex and 30-day mortality and major complications. Separate models were created for all repairs, EVAR, and open repair. Purposeful selection was used to identify covariates for inclusion in our multivariable models. This method includes variables identified on univariate analysis with $P < .1$ for each endpoint of interest and clinically relevant factors shown to be associated with adverse events in previous studies.²² The models were initially run with aortic diameter, which was then replaced by aortic size index in a sensitivity analysis. All tests were 2-sided, and a P-value of less than 0.05 was considered significant. Statistical analysis was conducted using STATA version 14.1 (StataCorp LP, College Station, TX), and figures were developed using Prism 6 (GraphPad, La Jolla, CA).

Results

Demographics

We identified 6,611 patients (19% women) who underwent AAA repair (87% EVAR). Women were less likely than men to undergo EVAR (84% vs. 88%, $P < .001$).

Demographics and comorbid conditions are shown in Table I. Women were older and, for those undergoing EVAR, were less likely white. Women had smaller aneurysm diameters (EVAR: 5.3 cm vs. 5.5 cm, $P < .001$; Open: 5.6 cm vs. 5.9 cm, $P < .01$) but larger aortic size indices (EVAR: 3.1 vs. 2.8, $P < .001$; Open: 3.3 vs. 2.9, $P < .001$), and were more likely to be symptomatic (EVAR: 13% vs. 8.7%, $P < .001$; Open: 25% vs. 18%, $P = .04$). Women were more likely to have COPD, an estimated glomerular filtration rate < 30 , preoperative anemia, and a history of prior open abdominal surgery. Among patients undergoing EVAR, women were more likely to smoke and have hypertension but less likely to have diabetes. Other comorbid conditions, including congestive heart failure (CHF) and end-stage renal disease requiring dialysis were similar between sexes.

Operative Details

Operative variables are shown in Table II. Among EVAR patients, women had longer operative times (median 132 vs. 128 minutes, $P < .01$) and more frequently underwent concurrent renal revascularization (6.6% vs. 4.0%, $P < .001$). Women were less likely to have bilateral percutaneous access (25% vs. 29%, $P = .03$), and less frequently used Cook Zenith (17% vs. 22%) and Medtronic Endurant (29% vs. 31%) grafts, but more frequently used Endologix Powerlink (11% vs. 8%) and Gore Excluder (38% vs. 35%) grafts. Use of iliac conduit was similar between females and males (7.7% vs. 6.4%, $P = .11$), but concurrent lower extremity revascularization intraoperatively was more frequent in women (5.8% vs. 3.6%, $P < .01$).

Women were more likely to have a retroperitoneal (vs. transabdominal) approach for open AAA repair (25% vs. 15%, $P < .01$). Women had shorter operative times (215 vs. 226 minutes, $P = .02$) and were less likely to undergo concurrent lower extremity revascularization (5.3% vs. 9.9%, $P = .047$). There was not a significant difference in renal revascularization rates between sexes during open repair (5.3% vs. 4.0%, $P = .43$).

Outcomes

Unadjusted 30-day outcomes are shown in Table III. Mortality was higher for women after EVAR (2.9% vs. 1.1%, $P < .001$) and open AAA repair (8.2% vs. 4.0%, $P = .03$). Women were more likely to be transfused perioperatively (EVAR: 16% vs. 8.4%, $P < .001$; Open: 72% vs. 68%, $P = .02$). Following EVAR, major complications occurred more frequently in women (9.6% vs. 5.8%, $P < .001$). Rates of the following complications were higher among women: stroke (0.7% vs. 0.1%, $P < .01$), lower extremity ischemia (2.8% vs. 1.1%, $P < .001$), reoperation (5.7% vs. 3.8%, $P < .01$), and wound infection (3.1% vs. 1.3%, $P < .001$). Women had longer hospital lengths of stay (2 days vs. 1 day, $P < .001$) and were more likely discharged to a skilled nursing facility (13% vs. 5.9%, $P < .001$).

Following open repair, major complications were more common in women, although this did not reach statistical significance (22% vs. 18%, $P = .31$). Rates of the following complications were higher among women: stroke (1.5% vs. 0.2%, $P = .049$), ventilator > 48 hours (15% vs. 8.3%, $P < .01$), and reintubation (12% vs. 6.7%, $P = .02$). Women had longer intensive care unit (3 days vs. 2 days, $P < .001$) and hospital (7 days vs. 6 days, $P < .001$)

lengths of stay and were more likely discharged to a skilled nursing facility (28% vs. 16%, $P < .001$).

After multivariable analysis (Table IV), female sex was independently associated with mortality (Odds Ratio (OR) 2.1, 95% Confidence Interval (CI): 1.2 – 3.5) and major complications (OR 1.4, CI: 1.1 – 1.8) after EVAR. Following open repair, mortality (OR 1.9, CI: 0.9 – 4.0) and major complications (OR 1.3, CI: 0.8 – 1.9) were higher among women, with a similar effect size to EVAR, but failed to reach statistical significance likely due to smaller numbers. The overall model, adjusting for repair type, showed a similar effect for risk associated with female sex (mortality: OR 1.9, CI: 1.2 – 2.9; major complications: OR 1.3, CI: 1.1 – 1.7). However, after substituting aortic size index for aortic diameter in each of these models, the association of female sex with mortality (EVAR: OR 1.5, CI: 0.98 – 3.0; Open: OR 1.5, CI: 0.8 – 3.1) and major complications (EVAR: OR 1.2, CI: 0.9 – 1.6; Open: OR 1.1, CI: 0.7 – 1.6) was reduced (Figure 1).

Discussion

In this study, the impact of female sex on 30-day outcomes following both endovascular and open repair of abdominal aortic aneurysms was evaluated. Mortality and major complications were more frequent in women following EVAR and open repair. Even after adjusting for age, comorbid conditions, and aneurysm diameter, female sex remained associated with mortality and major complications following EVAR. The odds ratios of mortality in women compared to men were the same following EVAR and open repair, although significance was lost in the open group, likely due to smaller numbers. Additionally, women had smaller AAA diameter overall but larger ASI at time of repair, and after adjusting for ASI, women no longer had increased risk of mortality or morbidity, which may support the belief that women are undergoing intact repair later than men.

The 4% thirty-day mortality rate found in men is comparable to other contemporary studies of open abdominal aortic aneurysm repair. However, the 8% mortality rate observed in female patients was significantly higher than that found in male patients in our study and higher than contemporary standards.^{23–26} Most prior studies comparing sex differences in outcomes following open AAA repair are nearly 10 years old and are likely not reflective of contemporary EVAR-dominated practice and improvements in intensive care.^{4, 27} Even these studies, however, show lower mortality rates of 5–6% in women following open repair of intact AAA. A more contemporary series found female patients to have higher unadjusted mortality than male patients following open repair of intact aneurysms, with 4% mortality in women and 2% in men.¹ The improved rates these authors found likely reflect the study population of regional, mostly high-volume centers in New England. Conversely, the higher rate in the current study may in part be due to the large percentage of symptomatic aneurysms among female patients in this NSQIP cohort, which have been associated with higher mortality and postoperative complications.²⁸ After adjusting for symptom status and other demographic and comorbid conditions, female sex fails to reach statistical significance as a predictor of mortality following open AAA repair, likely due to limited number in our open repair cohort, as the effect size is similar to the overall and EVAR models.

The improvement in outcomes seen with EVAR compared to open repair has not, unfortunately, eliminated the sex disparity in outcomes. Our study supports previous work using national databases such as Medicare,¹⁴ the Nationwide Inpatient Sample,⁴ and NSQIP,¹³ which all found women to have a higher perioperative mortality compared to men following EVAR, but differs from smaller single-institution or regional studies which found no difference.^{1, 8–10} Even after adjustment for preoperative differences, women were still at higher risk for mortality after EVAR than men in our study. However, adjusting for aortic size index actually did mitigate the disparity in outcomes.

While prior studies have been disparate on mortality differences following EVAR and open repair, they have repeatedly shown that women have higher rates of perioperative complications following repair.^{1, 8–10} In this study, women had a higher overall composite morbidity rate compared to men following EVAR, with a trend toward higher morbidity following open repair. Specifically, women had higher rates of stroke after both procedures, higher rates of lower extremity ischemia and reintervention after EVAR, and higher rates of pulmonary complications after open repair. The differences in reintervention following EVAR may be related to graft-related complications and possibly related to more complex anatomy, which has previously been suggested as an explanation of the worse outcomes following repair. While access-related issues have previously been implicated,^{1, 29} similar rates of iliac conduit use between male and female patients were found in this population. Female patients were also more likely to have longer intensive care unit and hospital lengths of stay, and were less likely to be discharged home, which has been previously demonstrated in multiple series.^{1, 13, 30} This may be explained by the propensity for women to act as caregivers within their family unit and to outlive their spouses.

Multiple possible etiologies of the sex differences observed following EVAR and open AAA repair have been proposed, including older age in women, higher rates of undiagnosed cardiovascular disease,⁸ and more complex aneurysms with smaller, more diseased access vessels.^{8, 19, 30–34} It is well established that women have faster-growing aneurysms, a four-fold higher rate of rupture, and rupture at smaller diameters compared to men.^{1, 4, 5, 12, 35} Therefore, it may seem logical that women should be repaired at a smaller aneurysm diameter; however, this decision must be weighed against the known increased perioperative mortality associated with female sex. Unfortunately, female patients have been underrepresented and often not included in landmark randomized controlled trials and natural history studies of abdominal aortic aneurysms, including the OVER, ADAM, DREAM, and EVAR-1 trials.^{36–39} This work highlights the important of future studies dedicated to understanding the natural history and ideal threshold for repair of abdominal aortic aneurysms in female patients.

Another potential explanation for why women rupture at smaller diameters is that they tend to have smaller baseline aortic diameters, given their overall smaller body size. Therefore, an index of aortic diameter to body surface area (or aortic size index) has been proposed as a potentially more useful threshold for repair for female patients.¹¹ This measure has been incorporated into a nomogram used by the Society of Thoracic Surgeons for threshold for repair of ascending thoracic aortic aneurysms,²⁰ but is still rarely incorporated into clinical decision making in vascular surgery. By identifying that women have smaller aneurysms

when measured by diameter but larger by ASI, and then showing that accounting for this discrepancy reduces some of the increased mortality and morbidity risk in women, our study suggests that further analyses should be conducted to determine the ideal threshold for AAA repair, by either aortic size index or aortic diameter.

This study has several limitations, in particular those subject to use of a clinical registry, such as errors in coding, missing data, and limited variable definitions. Additional limitations include knowledge of only 30-day postoperative outcomes and the inability to assess long-term sex differences including mortality, endoleak, and other aneurysm-related complications. The dataset is also limited in its ability to provide some aneurysm-specific anatomy details, such as presence of thrombus, aortic neck length and angulation, and access vessel size. Additionally, hospital and surgeon operative volume cannot be adjusted for in the analysis as these data are not available in the NSQIP. However, the targeted vascular module does provide additional variables previously not available, including aneurysm diameter, graft type, conduit use, and symptom status.

Conclusion

After adjusting for aneurysm diameter, women are at higher risk than men for 30-day death and major complications after intact AAA repair. However, adjusting for aortic size index reduces these differences, suggesting that ASI may be a better indicator threshold than AAA repair for female patients. Further studies to evaluate the exact ASI threshold for intervention are necessary to implement this method clinically.

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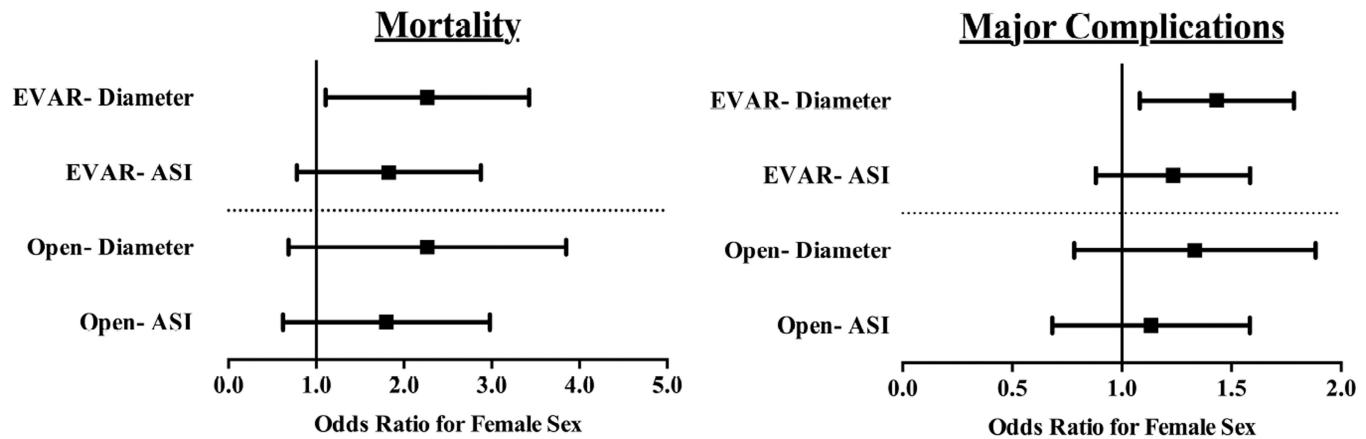


Figure 1.

Adjusted odds ratios for the relationship between female sex on mortality and major complications, stratified by repair type, after adjusting for diameter versus aortic size index (ASI).

Demographics and comorbidities, comparing female to male patients, stratified by type of AAA repair.

Table I

% or Median (IQR)	EVAR		Open Repair		P-value
	Women N=1,048	Men N=4,727	Men N=207	Women N=207	
Age	77 (71–83)	74 (68–80)	<.001	74 (68–79)	69 (63–75) <.001
White Race	89	93	<.001	92	90 .56
Body Mass Index	27 (23–31)	28 (25–31)	<.001	26 (22–29)	27 (25–31) <.001
Symptomatic	13	8.7	<.001	25	18 .04
History of Smoking	33	30	.03	47	43 .42
Functional Dependence	6.1	2.3	<.001	3.4	1.3 .07
Comorbidities:					
Hypertension	83	80	.02	85	80 .12
CHF	1.5	1.5	1.0	1.9	1.3 .50
COPD	22	17	<.01	26	15 <.001
Estimated GFR < 30	5.3	3.5	<.01	7.3	2.7 <.01
Dialysis	0.7	1.2	.14	1.9	0.6 .11
Diabetes	13	17	<.01	12	13 .90
Anemia	24	16	<.001	25	15 <.01
Prior Abdominal Surgery	34	23	<.001	35	21 <.001
Diameter, cm					
	5.3 (5–6)	5.5 (5.1–6.1)	<.001	5.6 (5.2–6.2)	5.9 (5.2–7) <.01
Aortic Size Index	3.1 (2.8–3.6)	2.8 (2.5–3.2)	<.001	3.3 (2.9–3.7)	2.9 (2.5–3.5) <.001

cm: centimeters, CHF: congestive heart failure, COPD: chronic obstructive pulmonary disease, GFR: glomerular filtration rate

Operative characteristics comparing female to male patients, stratified by type of AAA repair.

% or Median (IQR)	EVAR		Open Repair		P-value
	Women	Men	Women	Men	
EVAR-Specific					
Operative Time, minutes	132 (103–178)	128 (99–168)	<.01	215 (165–264)	.02
Renal Revascularization	6.6	4.0	<.001	5.3	.43
LE Revascularization	5.8	3.6	<.01	5.3	.047
Open-Specific					
Retropertitoneal			25	15	<.01
Other Abdominal Procedure			1.5	2.4	.58

Thirty-day postoperative outcomes comparing female to male patients by type of repair.

Table III

% or Median (IQR)	EVAR		Open Repair			
	Women	Men	P-value	Women	Men	P-value
Death	2.9	1.1	<.001	8.2	4.0	.03
Major Complications	9.6	5.8	<.001	22	18	.31
Stroke	0.7	0.1	<.01	1.5	0.2	.049
MI	1.6	1.0	.11	1.9	2.4	1.0
Ventilator >48hr	1.2	0.8	.36	15	8.3	<.01
Reintubation	1.7	1.1	.12	12	6.7	.02
Pulmonary Embolus	0.2	0.2	1.0	0.5	0.3	.58
Renal Complication	1.3	0.9	.22	3.4	4.8	.56
Ischemic Colitis	0.8	0.6	.38	3.9	2.4	.33
Any Transfusion	16	8.4	<.001	72	68	.30
LE Ischemia	2.8	1.1	<.001	1.5	2.9	.32
Aneurysm Rupture	0.1	0.1	1.0	0.5	0.6	1.0
Reoperation	5.7	3.8	<.01	7.3	8.6	.66
Wound Infection	3.1	1.3	<.001	1.9	2.4	1.0
ICU LOS	0 (0-1)	0 (0-1)	<.01	3 (1-5)	2 (1-4)	<.001
Hospital LOS	2 (1-3)	1 (1-2)	<.001	7 (6-10)	6 (5-9)	<.001
Discharge to SNF	13	5.9	<.001	28	16	<.001

MI: myocardial infarction, ICU: intensive care unit, LOS: length of stay, SNF: skilled nursing facility

Table IV

Multivariable regression comparing female to male patients for mortality and major complications, after adjusting for demographics and comorbidities, including aneurysm diameter. Additional covariates, listed below, were all significant except when marked with parentheses.

	OR	95% CI	P-Value
MORTALITY			
All Repairs ^a	1.9	1.2 – 2.9	< .01
EVAR ^b	2.1	1.2 – 3.5	< .01
Open Repair ^c	1.9	0.9 – 4.0	.09
MAJOR COMPLICATIONS			
All Repairs ^d	1.3	1.1 – 1.7	.01
EVAR ^e	1.4	1.1 – 1.8	.01
Open Repair ^f	1.3	0.8 – 1.9	.27

^aAdjusts for: diameter, repair type, age, symptoms, BMI, COPD, hypertension, kidney disease, anemia, (prior abdominal surgery)

^bAdjusts for: diameter, age, symptoms, BMI, smoking, COPD, kidney disease, anemia, (prior abdominal surgery)

^cAdjusts for: (diameter), age, (symptoms), (kidney disease), anemia, (prior abdominal surgery)

^dAdjusts for: diameter, repair type, age, symptoms, smoking, COPD, hypertension, kidney disease, anemia, (prior abdominal surgery)

^eAdjusts for: diameter, (age), symptoms, BMI, COPD, hypertension, kidney disease, anemia, (prior abdominal surgery)

^fAdjusts for: diameter, (age), (symptoms), (COPD), (kidney disease), anemia, (prior abdominal surgery)