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Late Mortality in Females After Endovascular Aneurysm Repair

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Abstract

Background—Abdominal aortic aneurysm (AAA) rupture is an adverse arterial remodeling event with high mortality risk. Since females have increased rupture risk with smaller AAAs (<5.5 cm), many recommend elective repair prior to 5.5 cm. Elective repair improves survival for large AAAs, but long-term benefits of endovascular aneurysm repair (EVAR) for small AAAs in females remains less understood. The objective of this study is to identify if differences in late mortality exist between females undergoing elective EVAR at our institution for small/slow-growing AAAs compared to those who meet standard criteria.

Methods—We retrospectively analyzed all patients that underwent EVAR for infrarenal AAA from 6/2009–6/2013. We excluded patients that were male, treated emergently or for iliac artery aneurysm, and that received renal/mesenteric artery stenting. Patients did not meet anatomic criteria if preoperative AAA diameter was <5.5 cm or enlarged <0.5 cm over 6 months. Late mortality was assessed from the Social Security Death Index.

Results—36/162 (22.2%) elective EVAR patients were female (mean follow-up 37.2 months). 20 (55.6%) patients met AAA size/growth criteria while 16 (44.4%) did not meet criteria. Despite comparable demographics, comorbidities, and complications, patients that did not meet criteria had higher late mortality (37.5% vs. 5%; *P*= .03) with a trend towards increased reoperation rate (25% vs. 5%; *P*= .48). Meeting size/growth criteria decreased odds of late death (OR .09; 95% CI 0.01–0.83).

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The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article.

Conclusion—There is increased late mortality in females receiving elective EVAR at our institution for small/slow-growing AAAs. This late mortality may limit the benefits of EVAR for this population.

Keywords

Endovascular Aneurysm Repair (EVAR); Abdominal Aortic Aneurysm (AAA); Female; Mortality; Aneurysm Diameter; Size Threshold

1. Introduction

Abdominal aortic aneurysm (AAA) rupture is associated with significant mortality and is lethal in 90% of patients.[1] Despite declining global incidence over the past two decades, AAA burden in the United States remains high, with aortic rupture accounting for >13,000 deaths annually.[2,3] Over this same time period, women have experienced a smaller decrease in AAA rupture rates compared to males, and continue to represent a disproportionate amount of AAA-related mortality.[4,5] Although AAA prevalence in women is approximately six times lower than men, females account for over 40% of AAA-attributable deaths.[6,7]

High AAA mortality rates in females have been partially attributed to gender variations in AAA rupture risk. Compared to AAAs in males, aneurysms in females rupture at smaller average diameters and are up to four times as likely to rupture at the same aneurysm size.[8–11] Additionally, females are more likely to present emergently and at an older age, while less likely to receive surgical intervention or be eligible for endovascular aneurysm repair (EVAR). These factors have contributed to the comparatively poor outcomes for females following elective and emergent AAA repair, including longer lengths of stay, lower rates of discharge to home, and increased early mortality. [5,12–15]

Increased rupture risk, worse outcomes after emergent repair, and potential for losing EVAR eligibility have led many surgeons to suggest smaller AAA size/growth thresholds for elective EVAR in females.[4,5,16–18] The survival benefit for elective open repair of large (≥5.5 cm) and/or fast growing (≥0.5 cm in 6 months) AAAs is well established, but the size indications and long-term outcomes for elective EVAR in females are less well understood. Elective EVAR has demonstrated improved early outcomes compared to traditional open repair, but these benefits appear to decrease over time and are less pronounced in females. [14,19–23] Additionally, Society for Vascular Surgery practice guidelines acknowledge increased rupture risk and potential benefit of repairing small aneurysms in women, but give weak recommendation for elective EVAR of AAAs <5.5 cm in females.[24,25] These recommendations are based on results from the Comparison of Surveillance Versus Aortic Endografting for Small Aneurysm Repair (CAESAR)[26] and Positive Impact of Endovascular Options for Treating Aneurysms Early (PIVOTAL)[27] trials. Both studies failed to demonstrate survival benefit for elective EVAR of small AAAs, but were underpowered to allow subgroup analysis in female patients.[26,27]

Data is lacking regarding late outcomes after EVAR in females, especially those with small AAAs. In order to better assess the benefit of EVAR in female patients at our institution, the

objective of this study is to identify if there are differences in late mortality between female patients undergoing elective EVAR for small, slow-growing AAAs compared to those that meet standard criteria.

2. Methods

Medical records from patients undergoing endovascular intervention from June 2009 to June 2013 were used to identify all patients that had received EVAR at our institution. Under an approved Institutional Review Board protocol and in accordance with the Helsinki Declaration of 1975 ethical standards on human experimentation, we performed retrospective evaluation of identified electronic medical records (EMRs) for study inclusion.

We collected patient demographics, insurance status, comorbidities, medication use, imaging studies, perioperative data, and clinical follow-up reports for all patients that underwent elective EVAR for infrarenal AAA during the study period. Charlson Comorbidity Index (CCI) was calculated based upon patient preoperative comorbidities. [28,29] All procedures were performed at a single institution by fellowship-trained vascular surgeons. Patients were excluded from analysis if they were male, had symptomatic or ruptured AAA, underwent concomitant treatment for iliac artery aneurysm, or received renal or mesenteric artery stenting at time of EVAR. Arterial vessel diameters, lengths, and angles were collected from preoperative 3-dimensional (3D) imaging, intraoperative angiograms, and operative reports. Iliac artery and aortic neck dimensions were compared to graft manufacturers' Instructions for Use (IFU) guidelines to determine if patients met endoprosthesis-specific IFU criteria. Preoperative AAA size was determined from last documented 3D imaging prior to intervention and was measured in axial views at level of maximum external aortic diameter. Preoperative AAA growth rate was determined from both 3D imaging and ultrasound surveillance reports and was compared with corresponding notes from our vascular clinic and outside records. These imaging variables were used to group female EVAR patients by whether they did or did not meet preoperative AAA size and/or growth criteria for elective intervention. Patients were considered to have met criteria if maximum AAA diameter was ≥5.5 cm or AAA diameter was <5.5 cm, but had grown ≥0.5 cm in ≤6 months. Conversely, patients were classified as not meeting aneurysm criteria if AAA diameter was <5.5 cm and without rapid growth.

The primary objective of this study was to compare late mortality rates after EVAR between females that did and did not meet preoperative AAA size or growth criteria. Secondary outcomes measures included comparison of 30-day morbidity/mortality and graft-related reoperation rates between cohorts.

Late mortality was defined as all-cause death >30 days after EVAR and was determined from the EMR and the Social Security Death Index. Criteria for 30-day morbidity were determined prior to data collection. Major complications were prospectively defined prior to data collection as new dysrhythmia requiring cardioversion or not resolved by discharge, acute decline in renal function (rise in postoperative Creatinine ≥0.5 mg/dL or new-onset dialysis), myocardial infarction (confirmed with EKG and troponin elevation), respiratory compromise (prolonged/repeat intubation or ventilator-associated pneumonia), clinically

significant bowel ischemia or pulmonary embolism, and iliac artery rupture. Minor complications were defined as clinically significant events that did not meet major complication criteria.

Continuous variables were reported as means with standard deviations and categorical variables were reported as frequencies with percentages. Independent samples t-test, Mann-Whitney *U* test, χ^2 test, and Fisher's Exact Test were used to compare patient variables where appropriate. Binary logistic regression was used to determine odds ratios (ORs) and confidence intervals (CIs) for late mortality. Kaplan-Meier plots were generated for survival analysis, with log-rank tests used to compare survival distributions between cohorts. All tests were performed in SPSS Version 22.0 (IBM Corp, Armonk, NY) using $P < .05$ as threshold for statistical significance.

3. Results

3.1 Baseline Characteristics

From June 2009 to June 2013, female patients accounted for 36 (22.2%) of the 162 elective EVARs performed at our institution. Of these 36 female patients, 20 (55.6%) had preoperative AAA diameter ≥5.5 cm or with rapid growth while 16 (44.4%) patients did not meet AAA size or growth criteria. Indications for intervention in patients that did not meet size or growth criteria included patient inability to tolerate rupture risk (13 [81.3%]), surgeon preference (two [12.5%]), and family history of AAA rupture (one [6.3%]). Decision to pursue surgical intervention in these patients were multifactorial, but were based upon surgeons' concern for AAA rupture without elective intervention. All patients had fusiform AAA morphology on 3D imaging and were admitted electively to the hospital with AAA as the primary diagnosis. There were no differences in preoperative demographics, insurance status, or individual comorbidities between groups, although patients that did not meet criteria had smaller mean AAA diameter (5.0 cm vs. 5.8 cm; $P = .004$) and were less likely to be taking an angiotensin-converting-enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB) (31.3% vs. 65%; $P = .04$). Patients that met criteria had higher mean CCI score compared to patients that did not meet criteria (2.25 vs. 1.38; $P = .08$), but this trend was not significant. (Table 1)

Bifurcated endoprosthesis graft use varied by surgeon and included GORER (17 [47.2%]), Medtronic® (seven [19.4%]), Endologix® (six [16.7%]), Cook® (four [11.1%]), and Trivascular® (two [5.6%]) devices. 11 (68.8%) patients with AAA <5.5 cm and without rapid growth met device-specific IFU criteria compared to 16 (80.8%) patients with AAA ≥5.5 cm or with rapid growth, but this difference did not meet significance ($P = .47$). Further comparisons of device usage and IFU criteria between cohorts are listed in Table 2.

3.2 Thirty-day Mortality & Morbidity

There were no deaths within 30-days of EVAR in either cohort. Patients that did and did not meet AAA criteria had similar major perioperative complication rates during this period (25% vs. 18.8%; $P = .74$). Major complications in the cohort that met criteria (N=5) included three cases of acute renal failure, one case of iliac artery rupture requiring graft extension, and one instance of new-onset arrhythmia not resolved at time of discharge. Major

complications in the cohort that did not meet criteria (N=3) included two iliac artery ruptures requiring graft extension or bypass and one pre-discharge myocardial infarction (full complications provided in Table 3). Frequency of vessel damage (requiring patch angioplasty, graft extension, or bypass) during access manipulation or graft deployment was also higher in patients that did not meet criteria (six [37.5%] vs. three [15.0%]; *P*= .39), but this did not reach significance. Additionally, patients that did and did not meet criteria had comparable ≤30 day minor complication rates (25% vs. 25%; *P*= .86) and ≤30 day readmission rates (10% vs. 6.3%; *P*= .86), with similar lengths of hospital stay and rates of discharge to home. (Table 4)

3.3 Late Mortality and Reoperation

Average patient follow-up was 37.2 ± 15.5 months from date of EVAR. There were a total of 7 patient deaths during this follow-up period (mean time to death 21.6 ± 15.8 months) with an all-cause mortality rate of 19.4%. Patients that did not meet AAA size or growth criteria had significantly higher late mortality compared to patients that did meet criteria (six [37.5%] vs. one [5%]; *P*= .03). Mean time to death in patients that did not meet criteria was 18.9 ± 15.5 months and the one death in the cohort that did meet criteria occurred at 37.7 months. There were a total of 5 graft-related reoperations during the follow-up period (mean time to reoperation 21.1 ± 16.5 months) with an overall reoperation rate of 13.8%. Indications for reoperation included critical limb ischemia, new-onset lower extremity claudication, external iliac artery dissection, and type 1 endoleak on surveillance imaging. Although reoperations were also more frequent in patients that did not meet AAA size or growth criteria (four [25%] vs. one [5%]; *P*= .48) and patients that did not meet IFU (two [22%] vs. three [11%]; *P*= .97), these trends did not achieve significance. Of note, there were no mortalities in patients that underwent graft-related reoperations during the follow-up period.

Using univariate logistic regression for the dependent variable death, patients that met preoperative AAA size and/or growth criteria had significantly decreased odds of late mortality (OR .09; 95% CI 0.01–0.83). Age, aneurysm size, meeting IFU criteria, and major complication were not found to have significant influence on odds of late mortality. (Table 5) Kaplan-Meier analysis found significant difference in survival distributions between patients that did and did not meet criteria (x^2= 4.55, *P*= .03), with cumulative proportion surviving at 4-years of 90% and 60.2% respectively. (Figure 1)

4. Discussion

Surgical guidelines and IFU guide evidence-based care and promote patient safety, yet in this real-world experience we found high rates of elective EVAR in females that did not meet traditional surgical criteria (44.4%) or device IFU (25%). Clinical evaluation for elective AAA treatment must balance a patient's individual rupture risk with the short and long-term morbidity/mortality associated with intervention. Females have increased rupture risk and rupture at smaller diameters compared to males.[9–11] Higher rupture risk combined with more recent findings of improved perioperative outcomes of EVAR compared to open AAA repair[30–32] have led many to suggest lower size thresholds for elective EVAR in women.[4,5,16–18]

Lawrence et al. have previously described differences in treatment rates for men and women with similar AAA diagnosis. Analysis of over 110,000 patients with AAA from the National Hospital Discharge Survey database between 1984 and 1994 found that despite a higher diagnosis of ruptured AAA in females compared to males (9.4% vs. 7.4%), women were less likely to undergo elective AAA repair compared to men (15.4% vs. 37.3%; $P< .001$) over the same time period.[4] Dillavou et al. observed similar trends in their analysis of Medicare patients with diagnosis of AAA between 1994 and 2003. Women had significantly less decline in rates of ruptured AAA compared to men (12.2% decrease vs. 29.3% decrease; $P< .001$) and were less likely to receive elective or emergent AAA repair, were older at time of repair, and had more prolonged hospital courses with decreased survival. Additionally, data from 2003 showed lower EVAR utilization rates in women compared to men (28% vs 44.3%; $P< .001$).[5] Both papers suggest that inappropriately high AAA size thresholds in females contribute to elevated rupture rates in women and limit the benefit of newer, less-morbid elective AAA interventions for this population.[4,5] Our study included only patients that received intervention and was not designed to control for patients that did not receive EVAR, ultimately limiting our determination of prevented ruptures due to early elective intervention in females that did not meet criteria.

Randomized studies comparing surveillance to open AAA repair (ADAM and UK Small Aneurysm trials) found overall rupture risk to be low in patients with small aneurysms (~1% per year) and failed to show benefit of immediate open repair compared to surveillance for AAAs <5.5 cm,[11,33–36] but neither study were powered for subgroup analysis of females. Meta-analysis of both studies found no survival benefit of immediate open repair vs. surveillance for women (HR .96; 95% CI, 0.52–1.77), but cautioned against therapeutic certainty of these findings given the small number of females in the combined cohort (N=179).[37] More recent randomized studies comparing immediate EVAR vs. surveillance of small aneurysms (CAESAR and PIVOTAL trials) also found no mortality benefit for prophylactic treatment of AAAs <5.5 cm, but again these findings could not be fit to the female population given the small percentage of female enrollment (4.2% and 13.3% respectively).[26,27]

Our results support withholding treatment for female patients who do not meet current AAA size or growth guidelines for intervention. In this series of females that underwent elective EVAR at our institution, those with small/slow-growing AAAs tended to have higher intraoperative vessel damage and reoperation rates with significantly increased risk of late mortality compared to those with large or fast-growing AAAs. In addition, meeting size or growth criteria significantly decreased odds of late death. These outcomes were observed despite a trend in higher mean CCI in females that did meet criteria. Although the practice of “watchful waiting” raises the potential of losing EVAR eligibility and operating on an older patient population, the perioperative and long-term morbidity/mortality risks associated with elective intervention in females should not be devalued in the treatment decision-making process.

Finally, there are several limitations that must be addressed in our study. The number of females that met inclusion criteria for analysis was relatively small. Our total population size prevented development of a multivariate logistic regression model to control for variable

interaction and to perform subpopulation analysis. Small sample size also increases our risk of type II error, or failing to detect true effects that are potentially present. Continued development of a prospective EVAR database at our institution will benefit further analysis of AAA diameter thresholds and EVAR outcome variables of interest. Additionally, while utilization of the Social Security Death Index to determine all-cause mortality in our cohort increases the validity of our late mortality data, we are unable to report specific cause of death for analysis of EVAR-specific mortality. Finally, as a single institution case series from a large tertiary referral center in the southeast United States, our findings may differ from other vascular practice groups and hospital systems. Larger collaborative studies are critical to the definitive validation of AAA size thresholds for EVAR in women.

5. Conclusion

Late outcomes for women following EVAR are understudied in the United States. While inherently limited by the smaller proportion of AAAs in the female vs. male population, the disproportionate percentage of AAA ruptures and deaths in women make this a topic of grave importance in need of further evaluation. There continues to be uncertainty regarding the optimum size threshold for elective EVAR in females. As displayed in this study, there is the potential for increased morbidity, reoperation, and late mortality with prophylactic intervention in females with small AAAs. Withholding intervention in women that do not meet elective guidelines, improving small aneurysm surveillance strategies, and incorporating this data into the treatment discussion with our patients may have long-term benefits on female EVAR outcomes.

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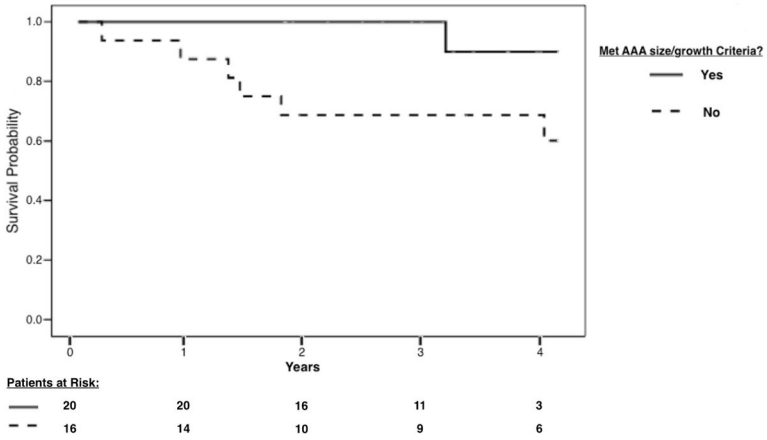

Figure 1.

Kaplan-Meier curves of postoperative survival in female elective EVAR patients that did (solid line) and did not meet (dotted line) preoperative abdominal aortic aneurysm size and/or growth criteria. Log-rank test found significant difference in survival distributions between cohorts during the follow-up period (x^2= 4.55, *P*= .03).

Table I

Preoperative characteristics of female elective EVAR patients.

	Met AAA size and/or growth criteria?		
	Yes (n = 20)	No (n = 16)	*P* value
Demographics:			
Age (y)	75.7 ± 7.2	73.4 ± 8.9	0.39
Private Insurance	10 (50)	11 (69)	0.26
AAA diameter (cm)	5.8 ± 1.1	5.0 ± 0.2	0.004**
Comorbidities:			
CCI	2.25 ± 1.59	1.38 ± 1.26	0.08
Smoker	18 (90)	15 (94)	1.00
COPD	12 (60)	9 (56)	0.82
Hypertension	18 (95)	15 (94)	1.00
Diabetes mellitus	6 (30)	2 (13)	0.26
Hyperlipidemia	15 (75)	12 (75)	1.00
Myocardial infarction	5 (25)	2 (13)	0.43
PCI	5 (25)	5 (31)	0.72
CABG	4 (20)	3 (19)	1.00
Heart failure	0 (0)	1 (6)	0.44
Stroke	3 (15)	1 (6)	0.61
Renal failure	3 (15)	0 (0)	0.24
Medication Use:			
ACE-I or ARB	13 (65)	5 (31)	0.04*
Statin	17 (85)	10 (63)	0.15
Aspirin	16 (80)	12 (75)	0.72
Coumadin or Plavix	7 (35)	7 (44)	0.59
Beta blocker	9 (45)	10 (63)	0.30

EVAR = endovascular aneurysm repair; AAA = abdominal aortic aneurysm; CCI = Charlson Comorbidity Index; COPD = chronic obstructive pulmonary disease; PCI = percutaneous coronary intervention; CABG = coronary artery bypass graft; ACE-I = angiotensin-converting-enzyme inhibitor; ARB = angiotensin receptor blocker.

AAA size/growth criteria for elective EVAR defined by Society for Vascular Surgery Practice Guidelines, 2009; CCI calculated using methods of Charlson et al., 1986.

Data presented as mean ± standard deviation where indicated or raw number (percentage).

* $p < .05$

** $p < .01$

Table II

Endoprosthesis use and IFU failure criteria for female elective EVAR patients.

	Met AAA size and/or growth criteria?		
	Yes (n = 20)	No (n = 16)	*P* value
Endoprosthesis Device:			
GORE® EXCLUDER®	6 (30)	11 (69)	0.04*
COOK® Zenith®	3 (15)	1 (6)	0.61
Endologix AFX™	5 (25)	1 (6)	0.20
Medtronic Talent®	1 (5)	3 (19)	0.30
Medtronic Endurant®	3 (15)	0 (0)	0.24
TriVascular Ovation™	2 (10)	0 (0)	0.49
Failed IFU Criteria	4 (20)	5 (31)	0.47
Insufficient neck length	1 (5)	5 (31)	0.05
Neck angle >60°	3 (15)	2 (13)	0.52

EVAR = endovascular aneurysm repair; AAA = abdominal aortic aneurysm; IFU = instructions for use.

AAA size/growth criteria for elective EVAR defined by Society for Vascular Surgery Practice Guidelines, 2009.

Data presented as raw number (percentage).

* $p < .05$

Table III

Complication frequencies for female elective EVAR patients.

	Met AAA size and/or growth criteria?	
	Yes (n = 20)	No (n = 16)
Major complications:		
Iliac artery rupture[a]	1 (5)	2 (13)
Renal failure[b]	3 (15)	0 (0)
Myocardial infarction	0 (0)	1 (6)
Arrhythmia[c]	1 (5)	0 (0)
Minor complications:		
Access vessel dissection[d]	2 (10)	4 (25)
Transfusion[e]	1 (5)	1 (6)
Altered mental status	0 (0)	2 (13)
Pneumonia[f]	1 (5)	0 (0)
Heart failure exacerbation[f]	0 (0)	1 (6)
Wound dehiscence	1 (5)	0 (0)
Seroma[g]	1 (5)	0 (0)

EVAR = endovascular aneurysm repair; AAA = abdominal aortic aneurysm.

[a] Rupture defined as extravasation of contrast on intraoperative angiography that required bypass or unplanned graft extension;

[b] Renal failure classified as new-onset Cr rise >0.5 mg/dL and/or need for emergent dialysis;

[c] Arrhythmias were new-onset and unresolved by time of discharge;

[d] Dissection required femoral endarterectomy and/or patch angioplasty for vessel closure;

[e] Transfusions performed in patients without history of chronic anemia and pre to post-operative hemoglobin change >3 g/dL;

[f] Exacerbations required hospital readmission;

[g] Seromas present at surgical access site and required drainage.

AAA size/growth criteria for elective EVAR defined by Society for Vascular Surgery Practice Guidelines, 2009.

Data presented as raw number (percentage).

Table IV

Perioperative and late events for female elective EVAR patients.

	Met AAA size and/or growth criteria?		
	Yes (n = 20)	**No (n = 16)**	***P* value**
Perioperative Events			
Postoperative endoleaks	6 (30)	6 (37.5)	0.64
Postoperative LOS (days)	2.9 ± 2.1	2.6 ± 2.3	0.46
Discharged home	18 (90)	15 (94)	1.00
≤30 Day Adverse Events			
Major complications	5 (25)	3 (19)	0.74
Minor complications	7 (35)	8 (50)	0.42
Vessel damage	3 (15)	6 (38)	0.39
Hospital readmissions	2 (10)	1 (6)	0.86
Late Events			
All-cause mortality	1 (5)	6 (38)	0.03*
Reoperations	1 (5)	4 (25)	0.48
Follow-up (months)	37.2 ± 11.6	37.2 ± 19.8	0.99

EVAR = endovascular aneurysm repair; AAA = abdominal aortic aneurysm; LOS = length of stay.

Perioperative events occurred during original hospital admission for elective EVAR; Late events occurred >30 days after date of initial procedure; AAA size/growth criteria for elective EVAR defined by Society for Vascular Surgery Practice Guidelines, 2009.

Data presented as mean ± standard deviation where indicated or raw number (percentage).

* $p < .05$

Table V

Univariate regression for late mortality risk in female elective EVAR patients.

	Late Mortality?				
	Yes (n = 6)	**No (n = 30)**	**OR**	**95% CI**	***P* value**
Age (y)					
Mean	76.6	74.2	1.04	0.93–1.16	0.48
SD	(± 10.5)	(± 7.4)			
Major complication (rate)					
Mean	0.29	0.21	1.28	0.31–5.36	0.73
SD	(± 0.76)	(± 0.49)			
AAA diameter <5.5 cm?					
Yes	6	19	0.32	0.03–3.00	0.32
No	1	10			
Met AAA size/growth criteria?					
Yes	6	10	0.09	0.01–0.83	0.03*
No	1	19			
Met IFU criteria?					
Yes	5	22	0.80	0.13–5.05	0.81
No	2	7			

EVAR = endovascular aneurysm repair; AAA = abdominal aortic aneurysm; OR = odds ratio; CI = confidence interval; IFU = instructions for use.

AAA size/growth criteria for elective EVAR defined by Society for Vascular Surgery Practice Guidelines, 2009.

* $p < .05$