

# EVAR 5-Year Results with Small vs. Large AAAs: Is Big Really Worse?

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## Disparate outcome after endovascular treatment of small versus large abdominal aortic aneurysm

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*Objectives:* The size of an abdominal aortic aneurysm is the most important parameter for determining whether repair is appropriate. This decision, however, must be considered in the context of long-term outcome of treatment, balancing risk for rupture with mortality from the initial procedure and all subsequent secondary procedures necessary when durability is not ideal. Information on the results of endovascular repair of small versus large aneurysms has not been available.

*Methods:* Preoperative imaging studies and postoperative outcome were assessed in 700 patients who underwent endovascular repair of abdominal aortic aneurysm over 6 years at a single institution. Patients were divided into two groups: 416 patients (59.4%) with aneurysms smaller than 5.5 cm in diameter and 284 patients (40.6%) with aneurysms 5.5 cm or larger in diameter. Outcome variables were assessed with the Kaplan-Meier method and the log-rank test.

*Results:* Patients with small and large aneurysms were comparable with regard to all baseline parameters assessed, with the single exception of a small increase in age (2.3 years) in patients with large aneurysms ( $P = .031$ ). While there were no differences in rate of type II endoleaks, mid-term changes in sac diameter, or aneurysm rupture between the two groups, at 24 months patients with large aneurysms had more type I leaks ( $6.4\% \pm 2.3\%$  vs  $1.4\% \pm 0.6\%$ ;  $P = .011$ ), device migration ( $13\% \pm 4.0\%$  vs  $4.4\% \pm 1.8\%$ ;  $P = .006$ ), and conversion to open surgical repair ( $8.2\% \pm 3.2\%$  vs  $1.4\% \pm 1.1\%$ ;  $P = .031$ ). Of greatest importance, at 24 months patient survival was diminished ( $71\% \pm 4.6\%$  vs  $86\% \pm 2.8\%$ ;  $P < .001$ ) and risk for aneurysm-related death was increased ( $6.1\% \pm 2.6\%$  vs  $1.5\% \pm 1.0\%$ ;  $P = .011$ ) in the group with large aneurysms.

*Conclusions:* Outcome after endovascular repair of abdominal aortic aneurysm depends on size; results appear inferior in patients with larger aneurysms. These differences attain importance when choosing between observation and repair, balancing risk for rupture against size-dependent outcome. (*J Vasc Surg* 2003;37:1206-12.)

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- EVAR for large AAA more likely results in
  - Endoleak
  - Conversion
  - Migration
  - AAA related death
- Multiple EVAR Devices
- Populations with differing ages
  - Large AAA patients older

## Endovascular aneurysm repair at 5 years: does aneurysm diameter predict outcome?

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**Objective:** The appropriate size threshold for endovascular repair of small abdominal aortic aneurysms (AAA) is unclear. We studied the outcome of endovascular aneurysm repair (EVAR) as a function of preoperative aneurysm diameter to determine the relationship between aneurysm size and long-term outcome of endovascular repair.

**Methods:** We reviewed the results of 923 patients treated in a prospective, multicenter clinical trial of EVAR. Small aneurysms were defined according to two size thresholds of 5.5 cm and 5.0 cm. Two-way analysis was used to compare patients with small aneurysms (<5.5 cm, n = 441) to patients with large aneurysms (≥5.5 cm, n = 482). An ordered three-way analysis was used to compare patients with small AAA (<5.0 cm, n = 145), medium AAA (5.0 to 5.9 cm, n = 461), and large AAA (≥6.0 cm, n = 317). The primary outcome measures of rupture, AAA-related death, surgical conversion, secondary intervention, and survival were compared using Kaplan-Meier estimates at 5 years.

**Results:** Median aneurysm size was 5.5 cm. The two-way comparison showed that 5 years after EVAR, patients with small aneurysms (<5.5 cm) had a lower AAA-related death rate (1% vs 6%,  $P = .006$ ), a higher survival rate (69% vs 57%,  $P = .0002$ ), and a lower secondary intervention rate (25% vs 32%,  $P = .03$ ) than patients with large aneurysms (≥5.5 cm). Three-way analysis revealed that patients with small AAAs (<5.0 cm) were younger ( $P < .0001$ ) and were more likely to have a family history of aneurysm ( $P < .05$ ), prior coronary intervention ( $P = .003$ ), and peripheral occlusive disease ( $P = .008$ ) than patients with large AAAs. Patients with smaller AAAs also had more favorable aortic neck anatomy ( $P < .004$ ). Patients with large AAAs were older ( $P < .0001$ ), had higher operative risk ( $P = .01$ ), and were more likely to have chronic obstructive pulmonary disease ( $P = .005$ ), obesity ( $P = .03$ ), and congestive heart failure ( $P = .004$ ). At 5 years, patients with small AAAs had better outcomes, with 100% freedom from rupture vs 97% for medium AAAs and 93% for large AAAs ( $P = .02$ ), 99% freedom from AAA-related death vs 97% for medium AAAs and 92% for large AAAs ( $P = .02$ ) and 98% freedom from conversion vs 92% for medium AAAs and 89% for large AAAs ( $P = .01$ ). Survival was significantly improved in small (69%) and medium AAAs (68%) compared to large AAAs (51%,  $P < .0001$ ). Multivariate Cox proportional hazards modeling revealed that aneurysm size was a significant independent predictor of rupture ( $P = .04$ ; hazard ratio [HR], 2.195), AAA-related death ( $P = .03$ ; HR, 2.007), surgical conversion ( $P = .007$ ; HR, 1.827), and survival ( $P = .001$ ; HR, 1.351). There were no significant differences in secondary intervention, endoleak, or migration rates between small, medium, and large AAAs.

**Conclusions:** Preoperative aneurysm size is an important determinant of long-term outcome following endovascular repair. Patients with small AAAs (<5.0 cm) are more favorable candidates for EVAR and have the best long-term outcomes, with 99% freedom from AAA death at 5 years. Patients with large AAAs (≥6.0 cm) have shorter life expectancy and have a higher risk of rupture, surgical conversion, and aneurysm-related death following EVAR compared to patients with smaller aneurysms. Nonetheless, 92% of patients with large AAAs are protected from AAA-related death at 5 years. Patients with AAAs of intermediate size (5 to 6 cm) represent most of the patients treated with EVAR and have a 97% freedom from AAA-related death at 5 years. (*J Vasc Surg* 2006;44:920-30.)

## Endovascular aneurysm repair at 5 years: does aneurysm diameter predict outcome?

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- AneuRx trial data
- Small AAA has less risk of
  - Death
  - AAA related death
  - Conversion
- Comparison groups not similar
  - Age
  - Morphology
  - CHF
  - COPD
  - Operative risk

## Midterm results of the multicenter trial of the Powerlink bifurcated system for endovascular aortic aneurysm repair

Jeffrey P. Carpenter, MD, for the Endologix Investigators,\* *Philadelphia, Pa*

**Purpose:** We assessed the results of abdominal aortic aneurysm (AAA) repair with the Powerlink bifurcated endovascular graft compared with open AAA repair.

**Method:** A prospective controlled multicenter trial of the Powerlink system for endovascular aneurysm repair was conducted at 15 sites as part of a pivotal US Food and Drug Administration trial. Between July 2000 and March 2003, 258 patients (192 test patients, 66 control patients) were enrolled. Stent grafts were oversized by 10% to 20% relative to computed tomography scan (CT)-based diameter measurements. All repairs were performed in the operating room through 1 surgically exposed femoral artery and a contralateral 9F sheath percutaneously placed. Results were assessed with contrast material-enhanced CT scans and plain abdominal x-ray studies at 1, 6, and 12 months, and annually postoperatively.

**Results:** Patients were followed up for a mean of 22 months (median, 24 months). Technical success was achieved in 97.9% of patients, with 4 failed insertions (3 early conversions because of deployment issues, 1 access failure). There were no significant differences in mortality between the Powerlink and control groups, and only 1 death was procedure-related. Blood loss (341 mL vs 1583 mL;  $P < .0001$ ), operative time (136 minutes vs 222 minutes;  $P < .0001$ ), intensive care unit stay (0.78 days vs 4.1 days;  $P < .0001$ ), and hospital length of stay (3.3 days vs 9.5 days;  $P < .0001$ ) were significantly less in the Powerlink cohort compared with the control group. There were significantly fewer adverse events (myocardial infarction,  $P = .0131$ ; renal failure,  $P = .0042$ ; gastrointestinal complications,  $P = .0125$ ) in the perioperative period in the Powerlink cohort compared with the control group, but in the longer follow-up interval adverse event-free survival was equivalent between groups ( $P = .456$ , log-rank test). At the time of the first-month CT scan, endoleaks were noted in 25 patients, yielding a 30-day endoleak rate of 22.7%. Type II endoleaks predominated, and there were no type III or IV endoleaks. Secondary procedures were performed in 19 patients (10%), for treatment of endoleak ( $n = 10$ ), limb obstruction ( $n = 7$ ), and other causes ( $n = 2$ ). There were 3 graft migrations (2.2%), 1 of which resulted in an endoleak. There were no ruptures, graft fabric defects, or wire fractures. Significant reduction in mean AAA diameter and volume was noted at every follow-up interval. Increase in AAA diameter was noted in only 1.5% of patients at 24 months.

**Conclusion:** The Powerlink system appears safe, and effectively protects patients from AAA rupture over the intermediate term. The graft and stent materials have thus far been free from failure and fatigue. Percutaneous contralateral limb access facilitates graft placement in patients with disadvantaged access routes. Endovascular aneurysm repair with the Powerlink system produces significantly fewer early adverse events compared with open AAA repair, but mortality is equivalent with both procedures. Careful follow-up over the longer term is necessary to ensure the durability of these results. (*J Vasc Surg* 2004;40:849-59.)

Midterm results of the multicenter trial of the Powerlink bifurcated system for endovascular aortic aneurysm repair

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- Controlled trial of EVAR vs. open repair
- “Low risk” trial
- 187 evaluable test patients
  - 100 AAA >5cm
  - 87 AAA <5cm
- 58 controls
- 30 month mean f/u
- M2S core lab



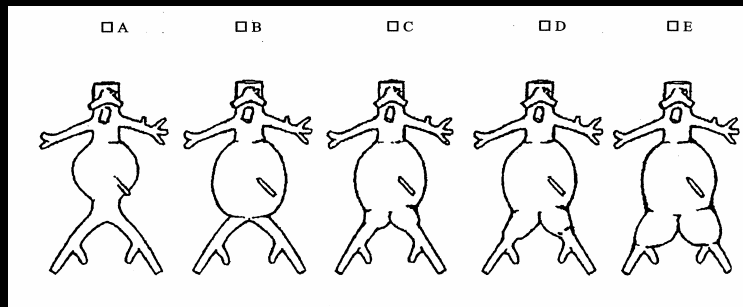
## Demographics

Characteristic	PowerLink (≤50 mm) Mean (SD) N	PowerLink (>50 mm) Mean (SD) N	Control Mean (SD) N	P-value	P-value L vs S
Age	72.4 (6.7) 100	73.9 (7.4) 87	69.1 (8.1) 58	<b>0.0013</b>	0.3603
Height (m)	1.76 (0.08) 89	1.75 (0.09) 77	1.74 (0.09) 55	0.6466	0.4234
Weight (kg)	89.0 (16.1) 90	83.9 (15.7) 78	85.6 (16.8) 55	0.1077	0.7941
BMI	28.7 (4.2) 89	27.2 (4.8) 164	28.1 (4.7) 55	0.0860	0.2112
Male	88 (88%)	78 (90%)	51 (88%)	0.9345	0.8182
Female	12 (12%)	9 (10%)	7 (12%)		
White	91 (91.92)	81 (94.19)	52 (92.86)	0.8125	0.3798
Non-white	8 (8.08)	5 (5.81)	4 (7.14)		

Endologix U.S. Multicenter Trial

Condition	PowerLink (≤50 mm) N (%)	PowerLink (>50 mm) N (%)	Control N (%)	P-value	P-value (L vs S)
Coronary Artery Disease	48 (48.00)	38 (43.68)	34 (58.67)	0.2064	0.5605
Myocardial Infarction (≤ 6 mos ago)	3 (3.00)	1 (1.15)	3 (5.17)	0.4310	0.6246
Myocardial Infarction (> 6 mos ago)	27 (27.00)	17 (19.54)	15 (25.86)	0.4676	0.2998
Angina	12 (12.00)	12 (13.79)	7 (12.07)	0.9401	0.8273
Congestive Heart Failure	6 (6.00)	6 (6.90)	2 (3.45)	0.7308	1.0000
Hypertension	66 (66.00)	52 (59.77)	40 (68.97)	0.4648	0.3620
Valvular Disease	3 (3.00)	3 (3.45)	4 (6.90)	0.4226	1.0000
Arrhythmia	20 (20.00)	10 (11.49)	4 (6.90)	0.0569	0.1614
Prior CABG	27 (27.00)	25 (28.74)	16 (27.59)	0.9827	0.8704
COPD	33 (33.00)	27 (31.03)	15 (25.86)	0.6641	0.8754
History of Smoking	83 (83.00)	72 (82.76)	49 (84.48)	0.9758	0.1538
Renal Failure	4 (4.00)	1 (1.15)	1 (1.72)	0.5773	0.3744
Diabetes	13 (13.00)	11 (12.64)	11 (18.97)	0.5072	1.0000
PAOD	15 (15.00)	15 (17.24)	10 (17.24)	0.9038	0.6944
Coagulopathy	1 (1.00)	1 (1.15)	0 (0.00)	1.0000	1.0000
Cerebrovascular Disease	19 (19.00)	18 (20.69)	8 (13.79)	0.5621	0.8546
Liver Disease	5 (5.00)	3 (3.45)	1 (1.72)	0.6316	0.7261
Previous Abdominal Surgery	47 (47.00)	42 (48.28)	21 (36.21)	0.3152	0.8842

Endologix U.S. Multicenter Trial



Grade	PowerLink (≤50 mm) n/N (%)	PowerLink (>50 mm) n/N (%)	Control n/N (%)	P-value	P-value (L vs S)
A	49 (49.49)	30 (34.48)	19 (32.76)	<b>&lt;0.0001</b>	0.2260
B	40 (40.40)	46 (52.87)	18 (31.03)		
C	7 (7.07)	8 (9.20)	9 (15.52)		
D	3 (3.03)	1 (1.15)	2 (3.45)		
E	1 (1.01)	1 (1.15)	10 (17.24)		

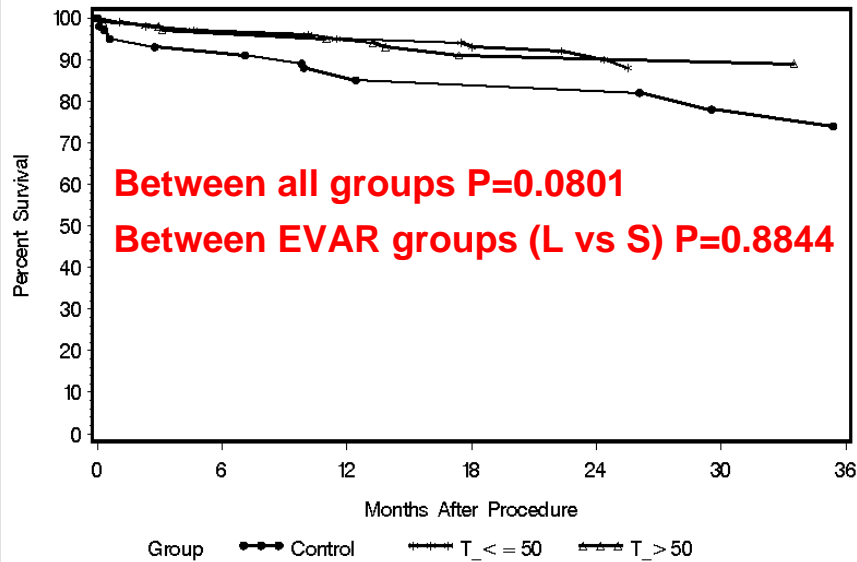
Endologix U.S. Multicenter Trial

# Perioperative Results

Variable	PowerLink (≤50mm) Mean (SD) N Median (Min, Max)	PowerLink (>50mm) Mean (SD) N Median (Min, Max)	Control Mean (SD) N Median (Min, Max)	P-value	P-value (L vs S)
ICU Stay (Days)	0.70 (1.5) 98* 0.50 (0.0, 14.2)	0.75 (0.9) 86* 0.83 (0.0, 6.1)	4.4 (8.8) 55* 2.0 (0.0, 56.0)	<0.0001	0.2683
Hospital Stay (Days)	3.3 (3.8) 100 2.0 (1.0, 30.0)	3.1 (1.8) 87 3.0 (1.0, 14.0)	9.5 (7.8) 56** 7.0 (3.0, 57.0)	<0.0001	0.0863
Blood Loss (ml)	330.4 (437.5) 98* 200.0 (0.0, 3000.0)	341.9 (375.3) 85* 250.0 (0.0, 2000.0)	1661.2 (1662.1) 57* 1200.0 (50.0, 10763.0)	<0.0001	0.2896
Operative Time (min)	117.0 (54.8) 100 105.0 (49.0, 465.0)	151.2 (64.1) 86** 139.0 (33.0, 345.0)	226.4 (102.3) 57** 200.0 (66.0, 480.0)	<0.0001	<0.0001
Anesthesia Time (min)	162.6 (68.0) 97*** 153.0 (44.0, 480.0)	209.4 (90.7) 83*** 194.0 (58.0, 503.0)	298.2 (111.6) 55*** 279.0 (28.0, 580.0)	<0.0001	0.0002

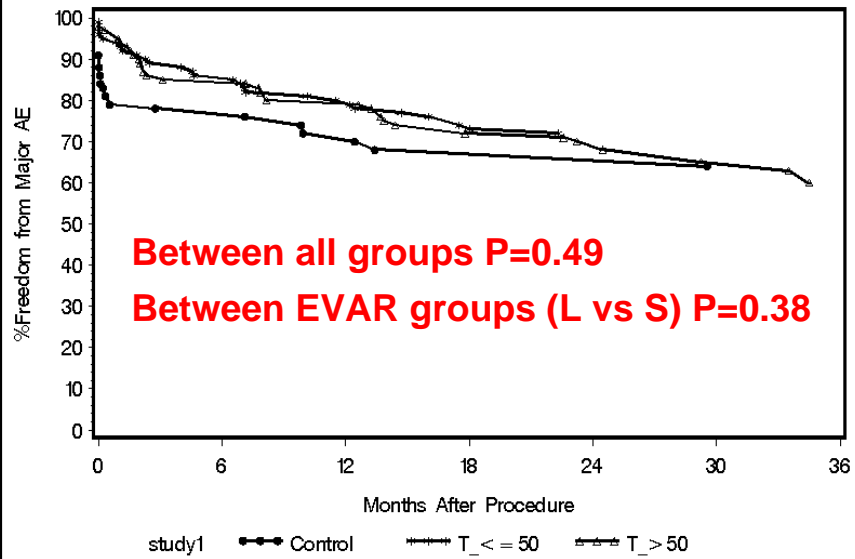
Endologix U.S. Multicenter Trial

## 36-month Survival Curve



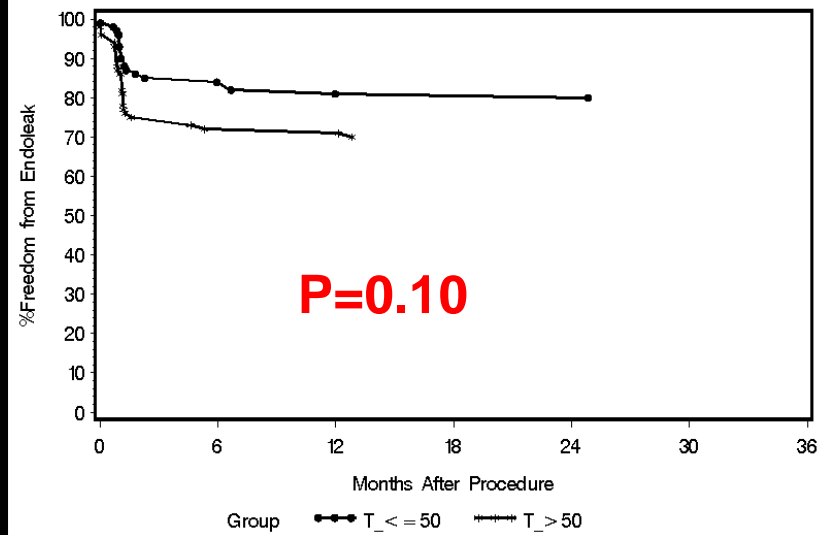
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## Freedom from Major Adverse Events



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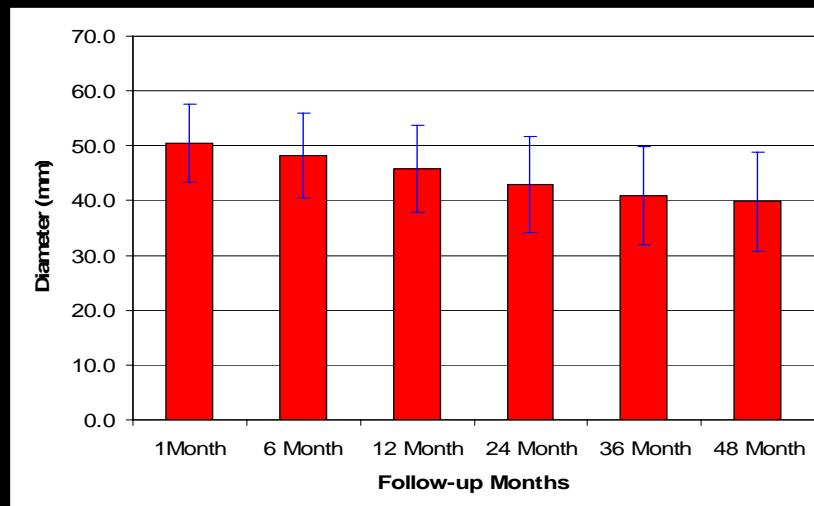
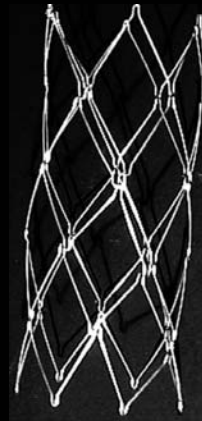
## Freedom from Endoleak



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## Endologix U.S. Multicenter Trial

- Migrations in 4 patients (2.3%)
  - No difference large vs. small
- Secondary procedures in 24 patients
  - No difference large vs. small
- No aneurysm ruptures
- No wire fractures
- No graft material failures



- Sac regression in 82% by 48 months
- No difference large vs. small

*Endologix U.S. Multicenter Trial*

# Conclusion

- When conditions of patient demographics and device selection are controlled, there is no size-dependent difference in mortality or morbidity for EVAR.
- EVAR offers perioperative advantages over open AAA repair for both morbidity and mortality.

## Endologix Investigators

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*Endologix U.S. Multicenter Trial*