

# SHOULD SMALL AAAs BE TREATED ?

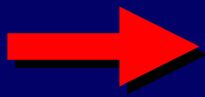


*Bruce A. Perler, M.D.*

**13th Annual MIIT  
Interventional Radiology &  
Endovascular Therapy Seminar**



# **AAA: COMPLICATIONS**



**RUPTURE**

**THROMBOSIS**

**EMBOLIZATION**

# AAA REPAIR: MARYLAND 1990 - 1995



**RUPTURED**

**ELECTIVE**

**PATIENTS**

**527**

**2,335**

**MORTALITY**

**47%**

**3.5%**

# TREATING SMALL AAAs

## RATIONALE

- Patients Don't Get Younger
- Patients Don't Get Healthier
- Surveillance Expensive & Risky
- Aneurysms Don't Get Smaller
- Small AAA Repair Easier
- More Amenable To EVAR

THE PREMISE:

**The Purpose of Treating AAAs is To  
Prevent Rupture To **Save Lives****

THE QUESTION:

**Does Treating Small AAAs **Save Lives**?**

THE ANSWER:

**→ ABSOLUTELY NOT !!!**

## AAA RUPTURE vs SIZE

**SIZE (cm)**

**% RUPTURE (5Yr)**

**→ < 4.0**

**2%**

**→ 4.0 – 5.0**

**3% - 12%**

**> 5.0**

**25% - 41%**

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# **SMALL AAA MANAGEMENT**

## ***THE JOHNS HOPKINS APPROACH***

**AAA < 5.0 cm:**

- **ECHO q 6 mos**

**REPAIR if:**

- **↑ 0.5 cm in 6 mos**
- **> 5.0 cm**

**→ NO RUPTURES !!!**



# **SMALL AAAs: SELECTIVE APPROACH**

*Kingston General Hospital (1976 – 1992)*

**PATIENTS:** 492 (AAA < 5.0 cm):  
ECHO or CT q 6 mos

**OPERATE:** > 5.0 cm or ↑ 0.5 cm / 6 mos

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**AAA REPAIR:** 201 (41%)

- .... >5 cm (78%)
- .... ↑ 0.5 cm (12%)
- .... Other (10%)

**NO AAA REPAIR:** 291 (59%) Mean F/U= 42 Mos

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 **NO RUPTURES !!!**

# AAA REPAIR: OLMSTEAD COUNTY, MN

<u>AAA SIZE</u>	<u>OP. MORT</u>	<u>5-YR. SURVIVAL</u>	<u>EXPECTED 5-Yr SURVIVAL</u>
$\leq 5$ cm	2.6%	62%	83%
$> 5$ cm	5.5%	60%	77%
<b>TOTAL</b>	<b>4.6%</b>	<b>61%</b>	<b>70%</b>

# UK SMALL AAA TRIAL: 1990- - 1995

**PATIENTS: 1090 (4.0 – 5.5 cm)**

**60 – 76 Yrs (86% Male)**

**Follow-Up: 6 – 10 (mean, 8 ) Yrs**



**OPERATION: 527**

**→ Op Mortality: 5.8%**

**ECHO: 563**

**- q 3 mos (5.0 – 5.5 cm)**

**- q 6 mos (< 5.0 cm)**

**... SX**

**... 1.0 cm / Yr**

**... Other Repair**

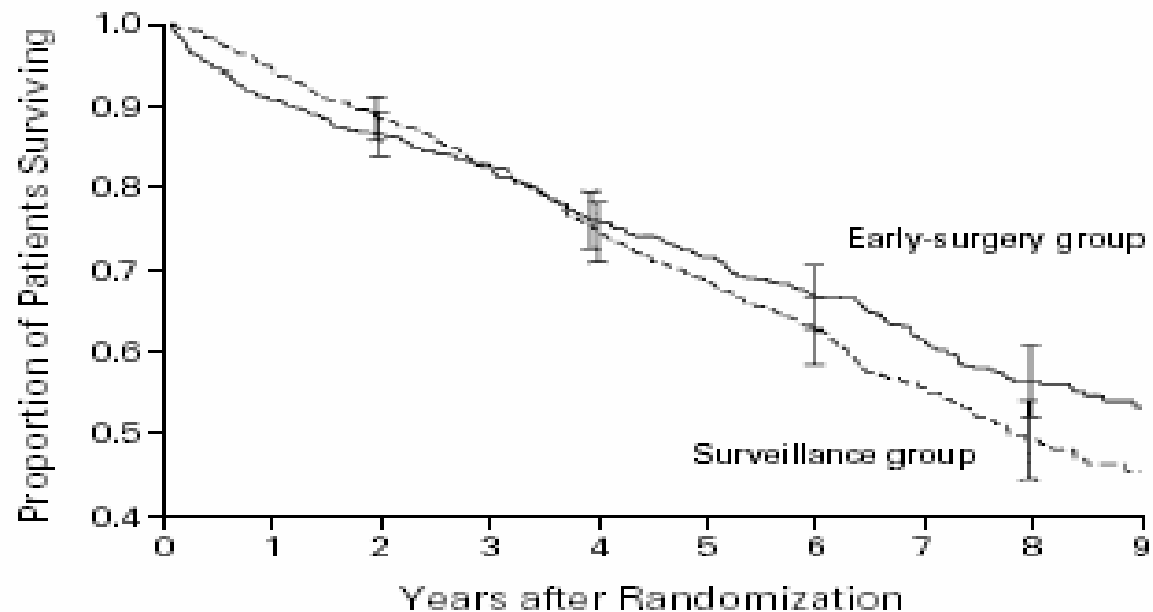


**LATE OPERATION: 321 (61%)**

**→ Op. Mortality: 7.1%**

# UK SMALL AAA TRIAL: 1990- - 1995

## LONG-TERM SURVIVAL



No. AT Risk

Surveillance group	527	497	468	437	394	363	316	173	97	41
Early-surgery group	563	513	489	465	429	402	371	253	154	66

# ADAM: VA COOPERATIVE TRIAL

**PATIENTS: 1136 (4.0 – 5.4 cm)**

**50 – 79 Yrs**

**Follow-Up: 3.5 - 8 (mean, 4.9 ) Yrs**

**OPERATION: 569**

**→ Op Mortality: 2.7%**

**ECHO: 567**

**q 6 mos (< 5.0 cm)**

**... SX**

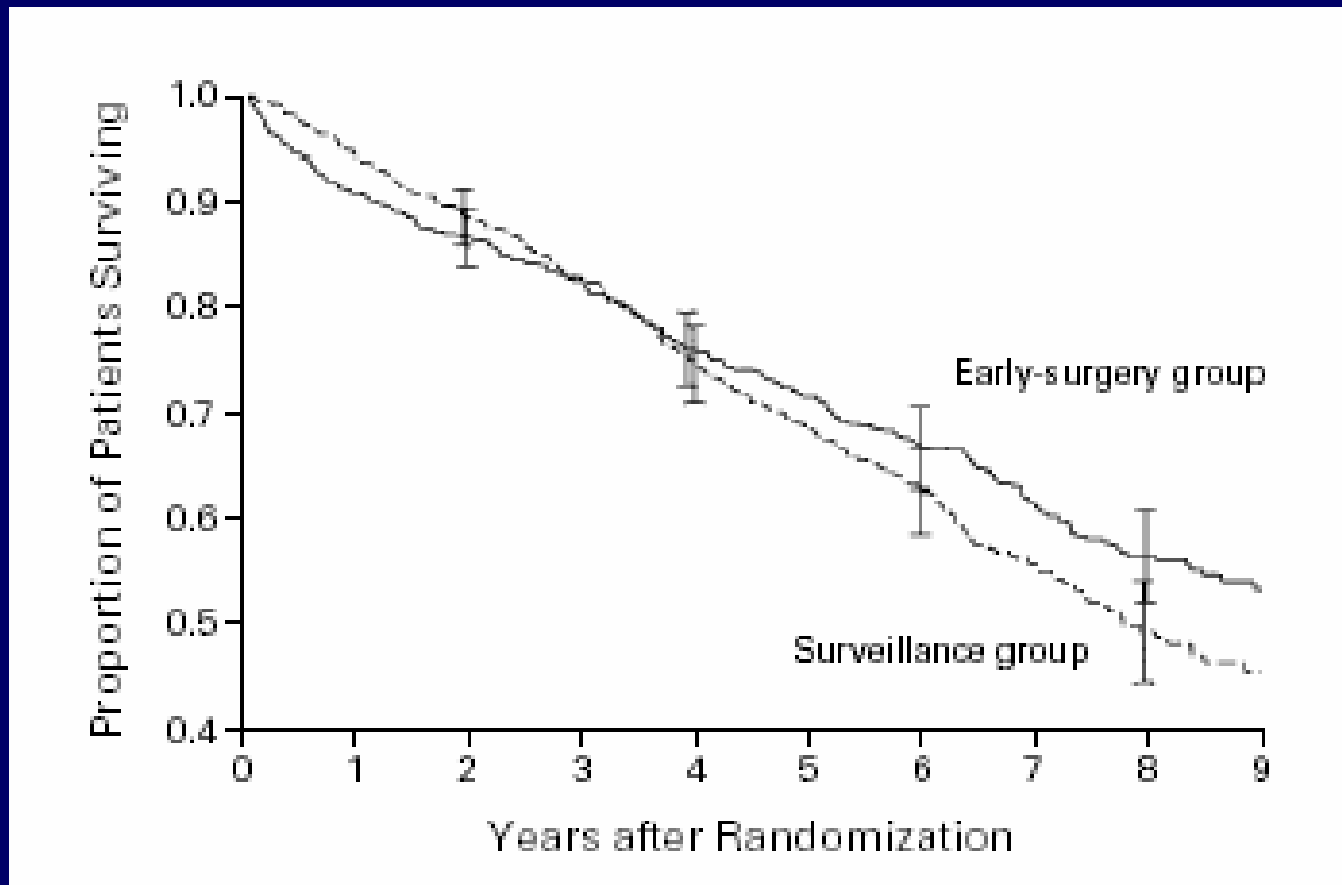
**... 5.5 cm**

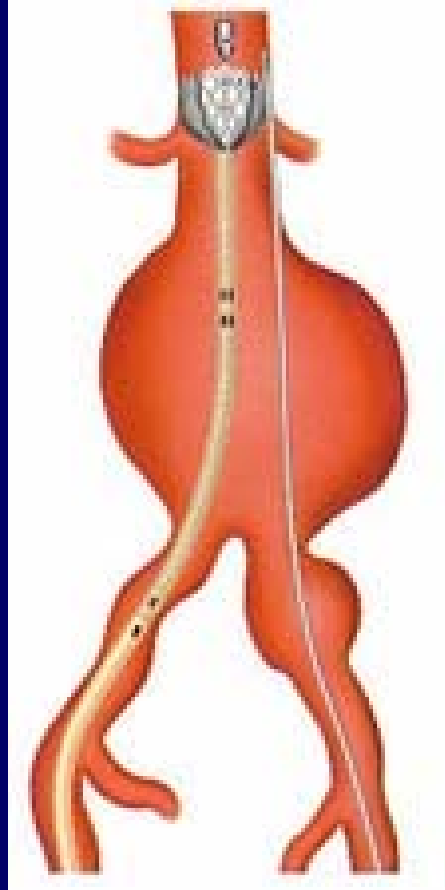
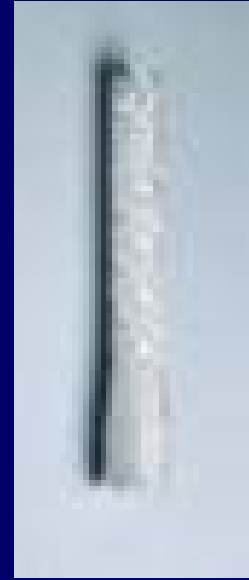
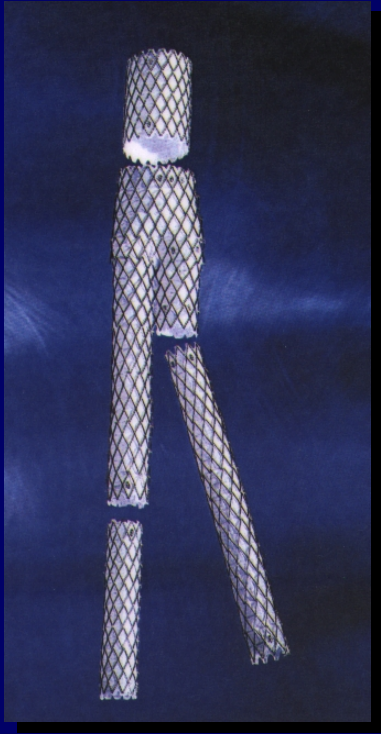
**LATE OPERATION: 349 (61.6%)**

**→ Op Mortality: 2.1%**

# ADAM: VA COOPERATIVE TRIAL

## LONG-TERM SURVIVAL





# STENT GRAFTS

## CURRENT STATUS



- **Stent Graft AAA Repair Here to Stay**
- **Stent Grafts Valuable Part of Armamentarium**
- **Stent Graft Technology in Infancy**
- **Early Results Not Necessarily Predictive  
of Long Term Success**

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➔ **LONG-TERM SURVEILLANCE CRITICAL!**

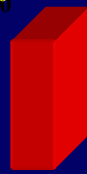
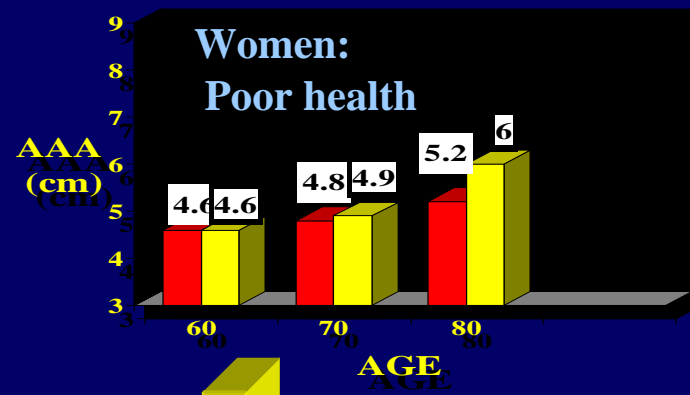
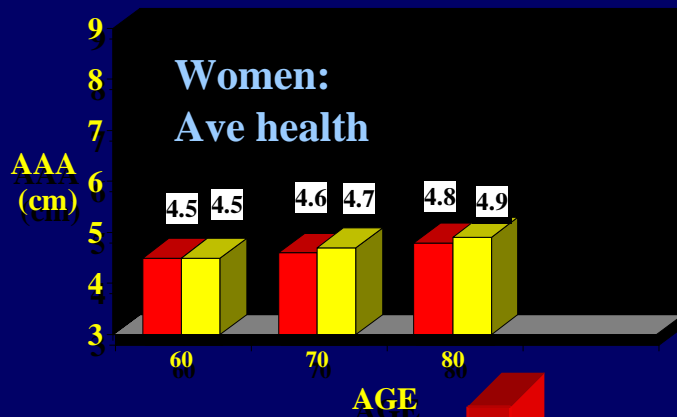
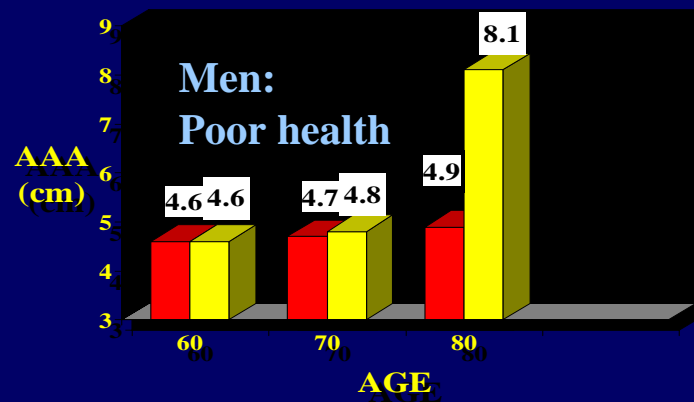
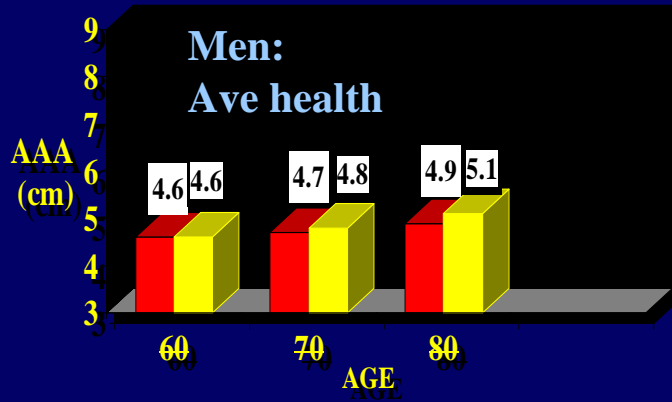
➔ **REINTERVENTION IS COMMON**

# “ENDO-GRAFTO-KYPHO-SCOLIOSIS”



# SIZE THRESHOLD FOR AAA REPAIR

## - Markov Decision Analysis -



Endovascular



Open

(Dartmouth-Hitchcock, 1999)

# AORTIC STENT GRAFTS

*Cleveland Clinic (n= 703)*

## SECONDARY PROCEDURES

**104 PATIENTS (15%): 124 PROCEDURES**

***MORTALITY ..... 6.3%***

**LATE OPEN CONVERSION: 11 PATIENTS (1.9%)**

***MORTALITY ..... 18%***

# AORTIC STENT GRAFTS

*Cleveland Clinic*

## LATE AAA RUPTURE

**Incidence:** 0.7% / Year

**Mortality:** 33%

# STENT GRAFT AAA REPAIR: EUROSTAR

## *LATE FAILURES*

**PATIENTS: 2,464**

**CENTERS: 88**

**F/U:  $\leq$  4 Yrs (mean, 12.2 months)**

**→ RISK OF RUPTURE ..... 1% // Yr**

**Mortality ..... 64%**

**→ RISK OF LATE CONVERSION ..... 2% // Yr**

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**→ RISK OF LATE FAILURE ..... 3% // Yr**

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# AORTIC STENT GRAFTS

## The AneuRx FDA Trial

### LATE AAA RUPTURE

<b><u>INCIDENCE:</u></b>	1 Yr .....	0.4%
	2 Yrs .....	2.6%

- CAUSES:**
- Endoleak / AAA Enlargement**
  - Inadequate Fixation**
  - Device Integrity: Fabric/Stent Graft Failure**

# **AORTIC STENT GRAFTS**

## **The AneuRx FDA Trial**

### **SECONDARY OUTCOMES**

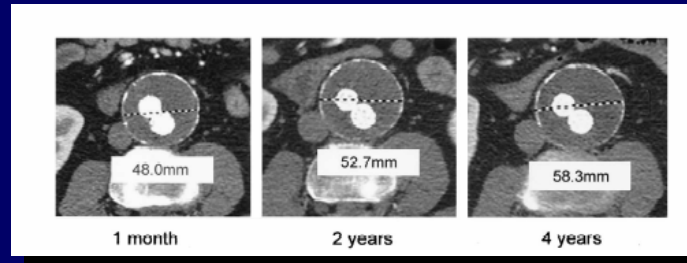
	<b><u>30 d</u></b>	<b><u>6 m</u></b>	<b><u>1 Yr</u></b>	<b><u>4 Yr</u></b>
<b>Graft Migration</b>	<b>0.3%</b>	<b>1.1%</b>	<b>2.2%</b>	<b>9.5%</b>
<b>AAA Enlargement</b>	<b>9.3%</b>	<b>5.8%</b>	<b>7.0%</b>	<b>13.5%</b>

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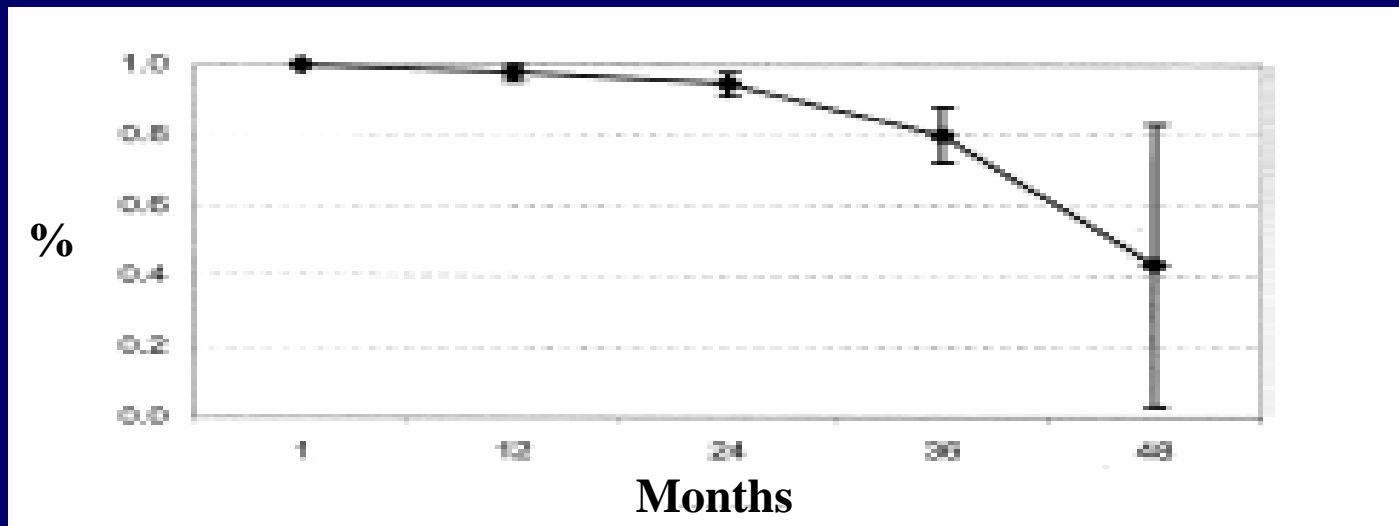
*J Vasc Surg 2003;37:904-908*

*Medtronic Jan 2004 Clinical Update*

# AAA ENLARGEMENT: Excluder Stent Graft



## FREEDOM-FROM-AAA EXPANSION





December 17, 2003

**FDA Public Health Notification:  
Updated Data on Mortality Associated with  
Medtronic AVE AneuRx® Stent Graft System**  
(You are encouraged to copy and distribute this information)

Dear Colleague:

In April 2001, we issued a public health notification on problems associated with endovascular grafts for repair of abdominal aortic aneurysm (AAA) (<http://www.fda.gov/edrh/safety/aaa.html>). This notification is to provide you with updated information on the mortality risks associated with the AneuRx® Stent Graft System when implanted for the prevention of AAA rupture, so that you can make a more informed decision about using this product to treat your patients. This information is based on an analysis of the extension of an investigational premarket study, which began in March of 1996, and involved a subgroup of 942 patients, followed through October 2<sup>nd</sup>, 2002.

This Public Health Notification focuses on the AneuRx® device, as it is the only currently marketed device with long-term clinical follow-up. Two other commercially available stent graft systems are not included in this notice because appropriate long-term data are not currently available for these devices.

**Background**

Our earlier notification identified several serious adverse events, including aneurysm ruptures, in patients treated with the AneuRx® Stent Graft. Since then, we have worked with the manufacturer, Medtronic AVE, as well as other sources, to obtain more complete follow-up data for the premarket cohort of patients who received the flexible model of the AneuRx® Stent Graft. These patients were considered good candidates for treatment with conventional open surgery. Certain categories of high risk patients were excluded from the study: American Society of Anesthesiology grade above IV; morbid obesity; acute renal failure or chronic dialysis; active systemic infection; less than one year of life expectancy; leaking aneurysm; aortic dissection; and aortic-iliac occlusive disease<sup>1</sup>.

Our analysis assessed aneurysm-related death rates in patients treated with the AneuRx® Stent Graft. We defined aneurysm-related death to include deaths from rupture of the AAA or from any procedure intended to treat the AAA. If a death occurred within one month of any procedure intended to treat the AAA, it was presumed to be aneurysm-related, unless there was evidence to the contrary.

**Study results**

The analysis showed that the perioperative (within 30 days) aneurysm-related death rate associated with the AneuRx® Stent Graft was 1.5% (14/942). Following implantation, an additional 8 AAA related deaths were identified during the subsequent 3 years of follow-up covering 2,080 patient years, for an annualized late mortality rate of 0.40% per year. This FDA analysis estimates an AAA-related death rate of 1.9% at one year post-implant, 2.2% at two years post-implant, and 2.7% at three years post-implant.

“.....mortality in patients with an AneuRx ... probably exceeds that in patients who undergo an open procedure, within three years or more...”

# **SMALL AAAs SHOULD NOT BE TREATED**

## **THE EVIDENCE**

- **Natural History Studies**
- **Surveillance Studies**
- **Retrospective Studies**
- **Randomized Prospective Clinical Trials**
- **Stent Graft Technology in Evolution**