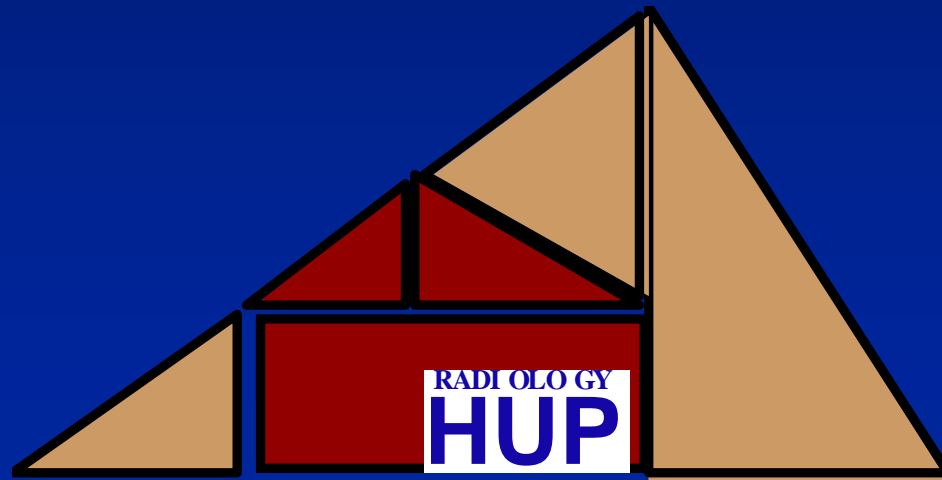
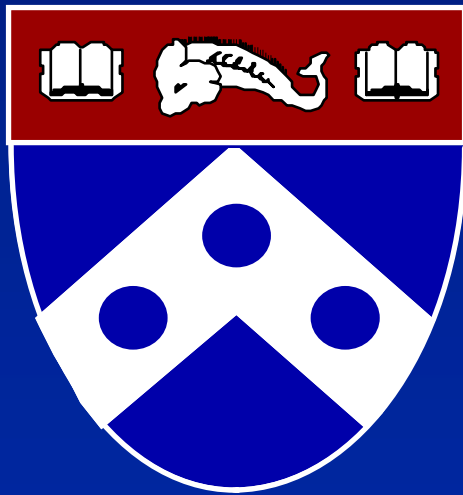


Should Your Father Have a Stent-Graft?

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My Dad



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Why should your dad be concerned about stent-grafts?

- Every vascular stent, thrombectomy device, etc. approved by the FDA in the past 10 years had to undergo a **prospective, randomized** trial with **long-term** endpoints for efficacy.
- Aortic stent-grafts were approved based on **short-term** outcomes in **case-controlled** series, **NOT** based on whether they prevent AAA rupture!!

Those who fail to learn from history are doomed to repeat it

- A decade of experience with laparoscopic cholecystectomy has consistently shown a higher complication rate with greater long-term disability and death than open repair.
- The desire for minimally-invasive therapy is driven by PATIENT DEMAND, MARKETING, and INDUSTRY, not by evidence-based medicine.

Why Should Your Dad Have a Stent-Graft?

Compared to open repair...

Can grafts be placed with equal success?

Do they exclude AAA?

Do they decrease periop morbidity & mortality?

Do they prevent rupture?

Do they improve survival?

Do they decrease hospitalization and cost?

Do they provide increased access to repair for high-risk patients? If so, is mortality improved?

Technical Success

Open

- 98%

Stent

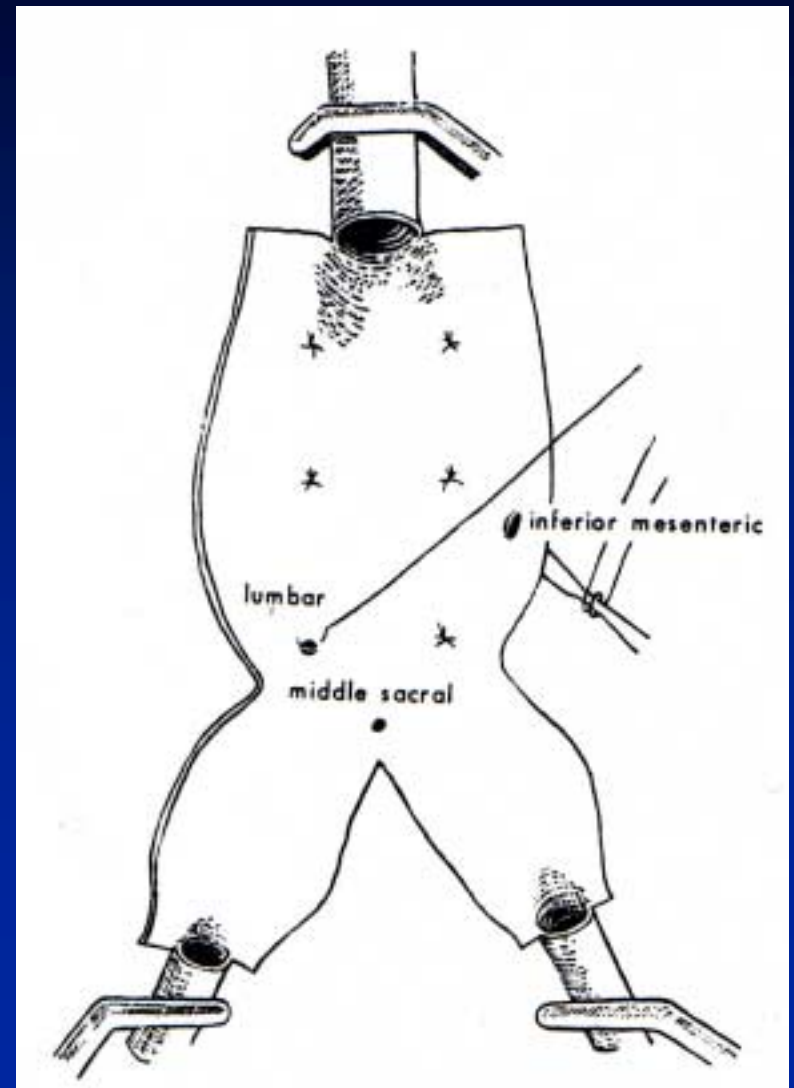
- 90%
pro



ions.

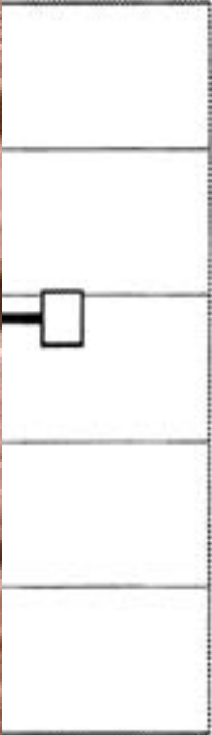
Aneurysm Exclusion: Open Repair

“Profuse bleeding from lumbar arteries usually occurs.” “An assistant controls bleeding by pressure with a gauze pad, which is moved progressively downward as their internal orifices are controlled individually by figure-of-eight sutures.”





doleak



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Peri-op Morbidity & Mortality



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Prevention of Rupture

Open 3%-5% leak/rupture at 5-10 years

Ancure n=194 @3 yrs , 55@4yrs

5 late conversions, no ruptures in U.S.

Aneurix n=865 @ 2 yrs, 303 @ 3 yrs

33 conversions, 8 ruptures, mean 17 mo (3wks-26 mo)

Zenith n=109 @ 2 yrs

3 conversions, 3 ruptures within 28 mo.

Europe n=759 @ 2 yrs

56 conversions, 12 ruptures. Risk of rupture 1% annually.

Australia n=400

9 ruptures at mean 17 mo.

Prevention of Rupture:

The jury is still out

Titles from J Vasc Surg, Feb. 2001:

“Is proximal aortic neck dilation after endovascular aneurysm exclusion a cause for concern?”

“Midterm durability of AAA endograft repair: a word of caution”

“Results of aortic endograft trial: impact of device failure beyond 12 months”

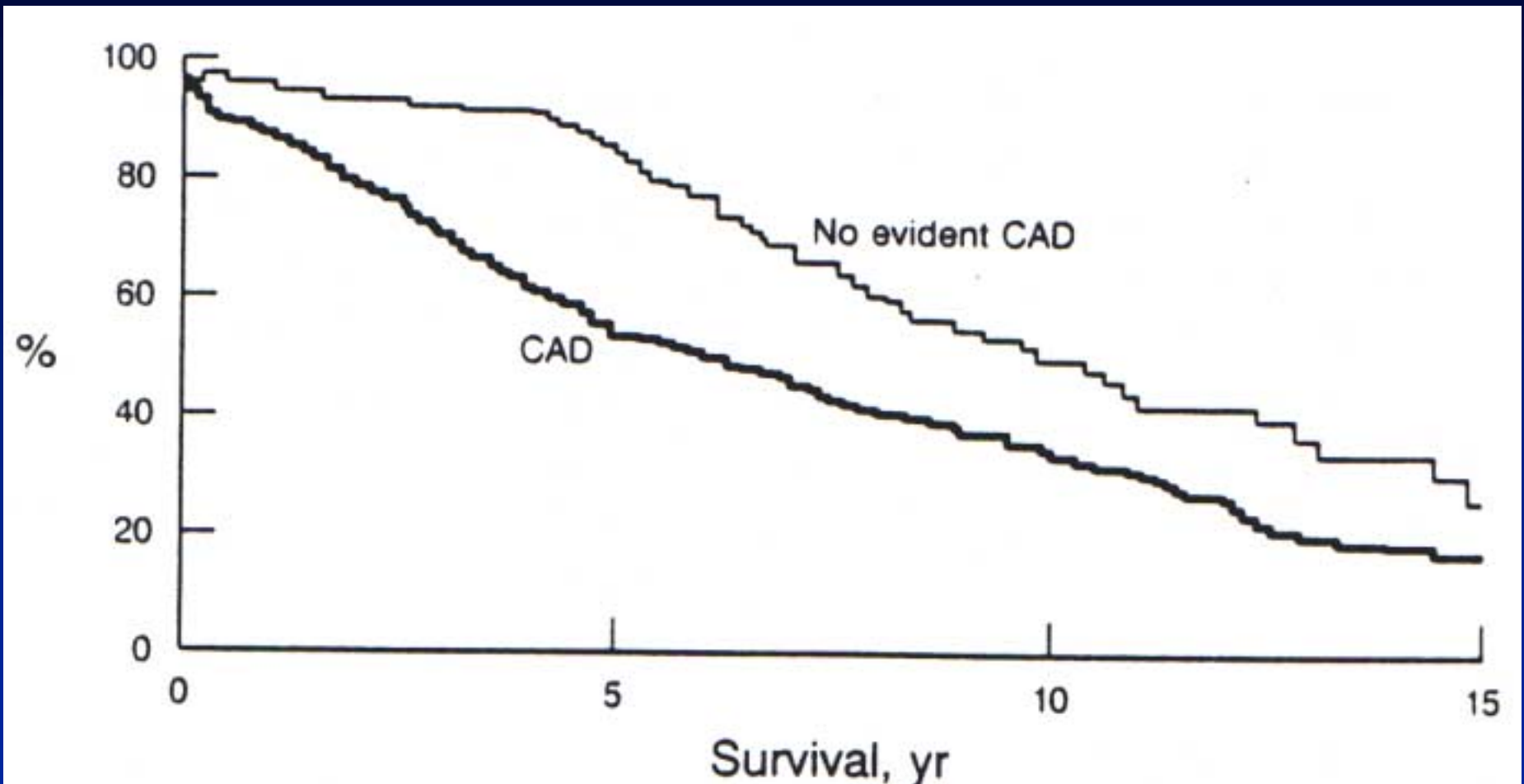
“Concerns for durability of the proximal AAA endograft fixation from a 2-year and 3-year longitudinal study”

JVS Feb 2002: “Device migration...:113 cases with a minimum follow-up of 2 years”

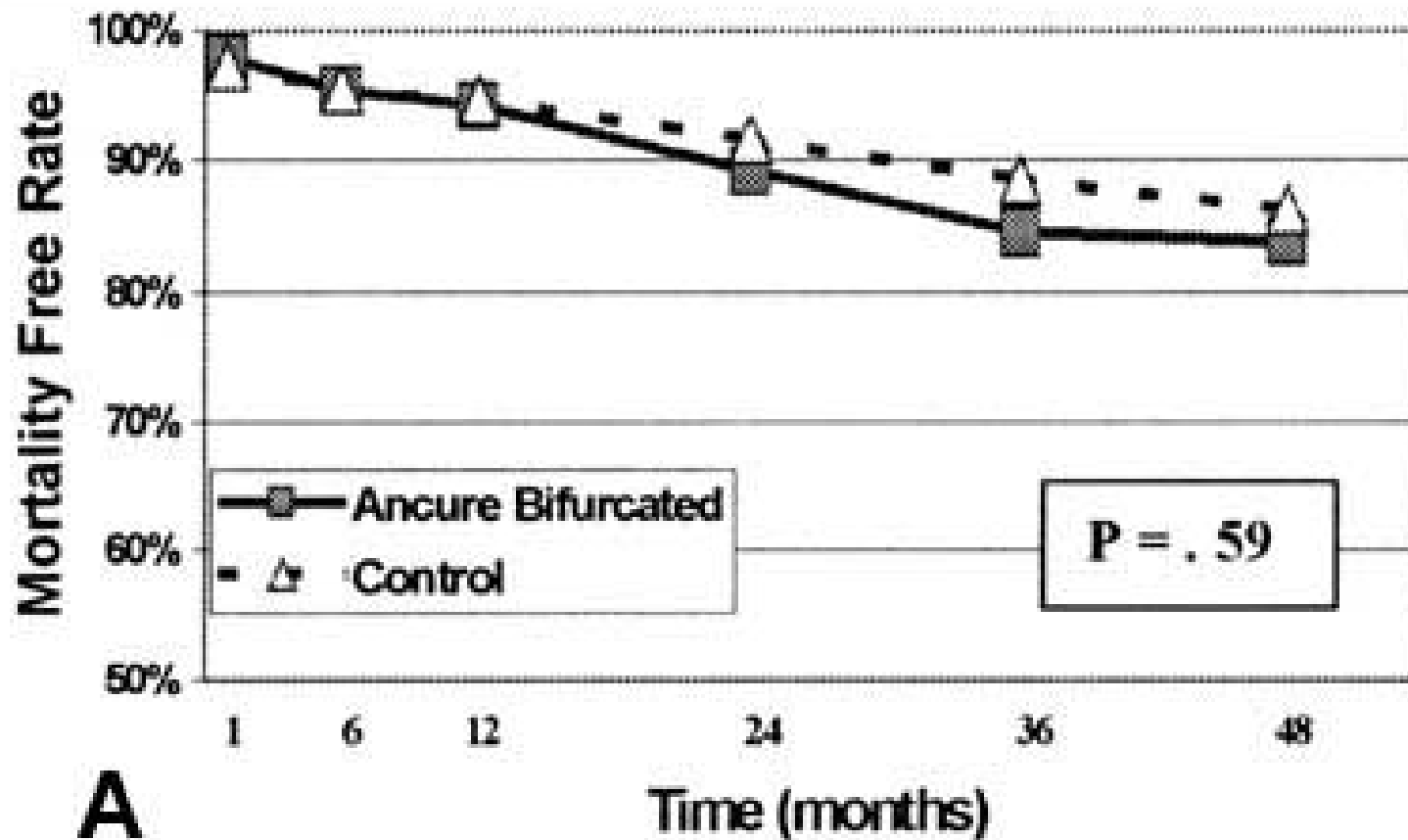
AAA Sac Shrinkage

- Ancure:** 26.3% no shrinkage at 3 yrs.
21% increased neck diameter
- AneuRx:** 39% no shrinkage at 2-4 years
- Zenith:** 40% no shrinkage at 2 yrs.
- MGH:** 12% no shrinkage
- Penn:** 32% no shrinkage at 1 year

Survival after Open Repair



Survival Open vs. Stent-Graft: Ancure



Survival: Open vs Stent-graft

Australia 3-yr survival

open 85%

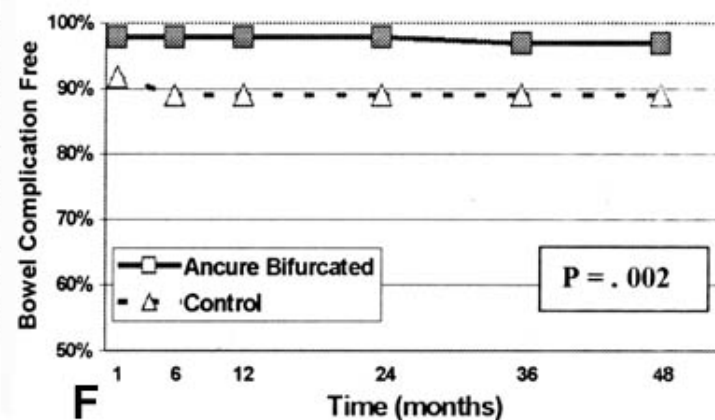
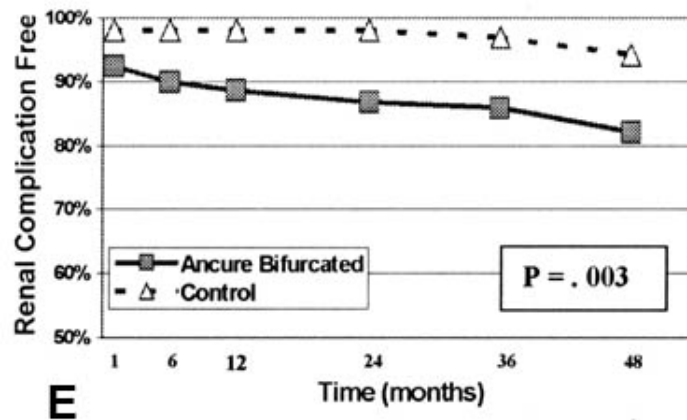
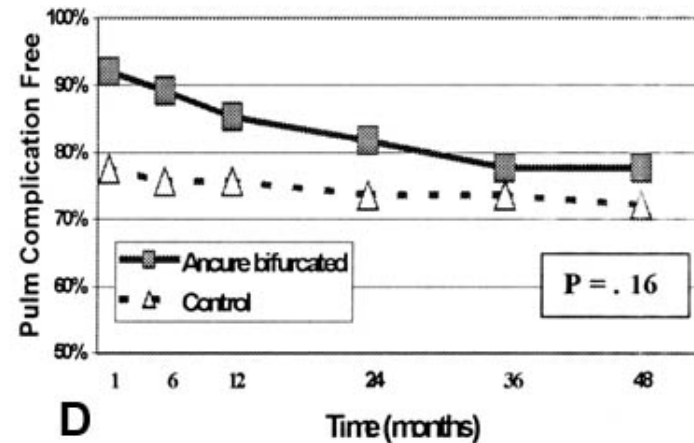
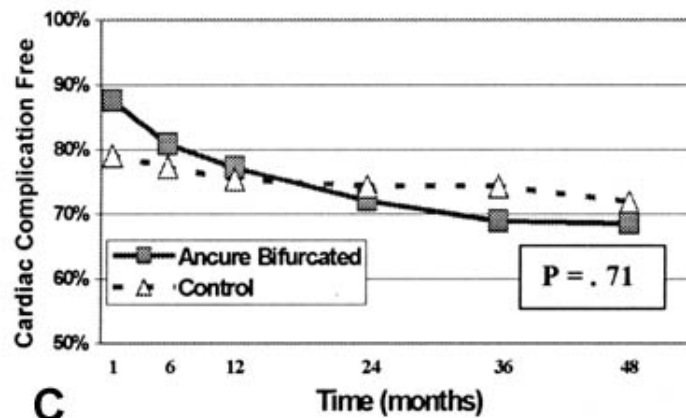
stent-graft 96% (p=.004)

83% with primary graft fxn

Eurostar

12% of deaths within 4 years related to stent-graft

Long-term Morbidity: Open vs Stent-graft



Mortality: High Risk

Hollier, 1986 n=106 high-risk patients

- **Mortality of open repair 5.7%**

Emory: 7.8% vs 1.9% for low risk

Talent High-Risk (n=152): 3.3%

UCSF high-risk (n=116):

- **Death/major morbidity 1.7%/12% overall, 0%/3.4% in second half**

High Risk: Eurostar Registry

SURVIVAL	1yr	2yr	3yr	4yr
Low Risk (n=2525)	93%	86%	83%	72%
“Unfit for surgery” (n=399)	82%	76%	66%	53%
“Unfit for anesthesia” (n=151)	83%	74%	(p=0.0001)	
Hypothetical no repair (assuming 11% annual rupture rate)	79%	63%	50%	40%

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Should Your Dad Have a Stent-Graft?

Compared to open repair...

Can grafts be placed with equal success?

CLOSE

Do they exclude AAA?

NO

Do they decrease periop morbidity & mortality?

NO

Do they prevent rupture?

DON'T KNOW

Should Your Dad Have a Stent-Graft?

Compared to open repair...

Do they improve survival?

NO

Do they decrease hospitalization and cost?

NO

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POSSIBLY

Should Your Dad Have a Stent-Graft?



NOT MY DAD

How about *your* mother-in-law?