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Open vs. Endovascular AAA repair: Factors in Clinical Decision Making

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Vascular Surgery and
Endovascular Interventions

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College of Physicians & Surgeons
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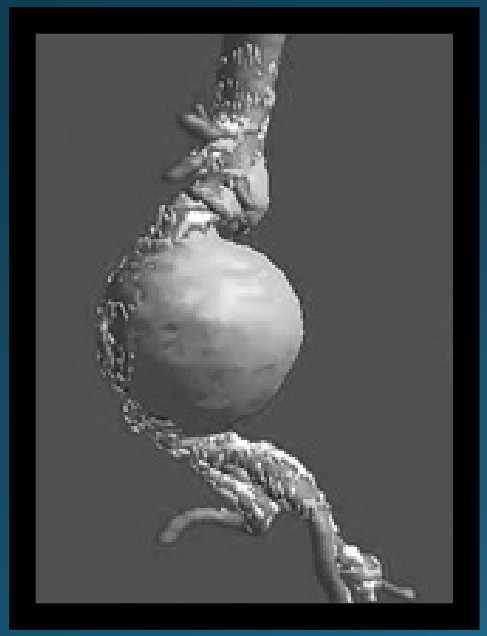
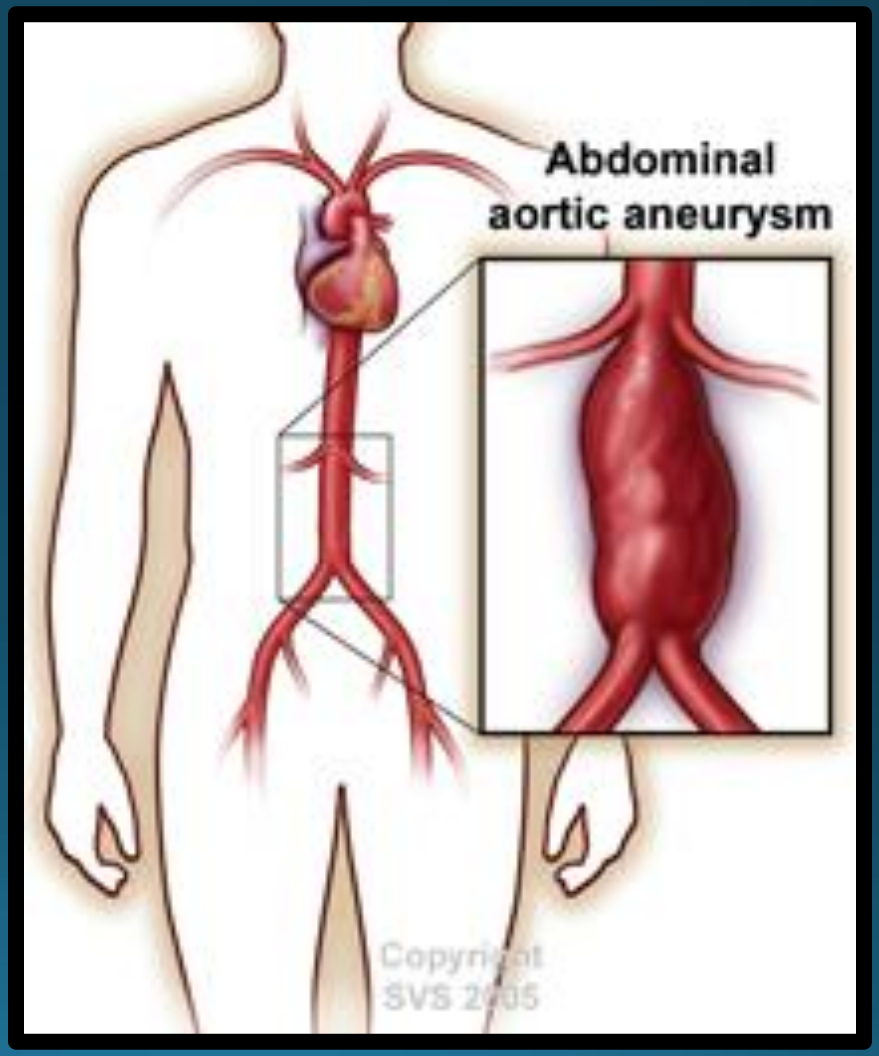


Disclosures

- None



SVS Guidelines

The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm

Elliot L. Chaikof, MD, PhD,[a] Ronald L. Dalman, MD,[b] Mark K. Eskandari, MD,[c] Benjamin M. Jackson, MD,[d] W. Anthony Lee, MD,[e] M. Ashraf Mansour, MD,[f] Tara M. Mastracci, MD,[g] Matthew Mell, MD,[b] M. Hassan Murad, MD, MPH,[h] Louis L. Nguyen, MD, MBA, MPH,[i] Gustavo S. Oderich, MD,[j] Madhukar S. Patel, MD, MBA, ScM,[a,k] Marc L. Schermerhorn, MD, MPH,[a] *and* Benjamin W. Starnes, MD,[l]

Boston, Mass; Palo Alto, Calif; Chicago, Ill; Philadelphia, Pa; Boca Raton, Fla; Grand Rapids, Mich; London, United Kingdom; Rochester, Minn; and Seattle, Wash

- Symptoms: Asymptomatic -> Rupture
- **Size:**
  - Rate of growth: **>1cm/yr.**
  - Size consensus: **5.5 cm men**
    5 cm women
    >4 cm select

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J Vasc Surg 2018;67:2-77

Treatment Options

- Traditional open surgical repair
- Endovascular stent graft repair

Regional Open Repair Results

Contemporary outcomes of open complex abdominal aortic aneurysm repair

Sarah E. Deery, MD,[a] Robert T. Lancaster, MD, MPH,[a] Donald T. Baril, MD,[b] Jeffrey E. Indes, MD,[c] Daniel J. Bertges, MD,[d] Mark F. Conrad, MD, MMSc,[a] Richard P. Cambria, MD,[a] and Virendra I. Patel, MD, MPH,[a] *Boston, Mass; Pittsburgh, Pa; New Haven, Conn; and Burlington, Vt*

- **VSGNE regional quality initiative (2003-2011)**
  - 14 Hospitals / 79 Surgeons
    - **Mean = 3.9±1.6/yr.**

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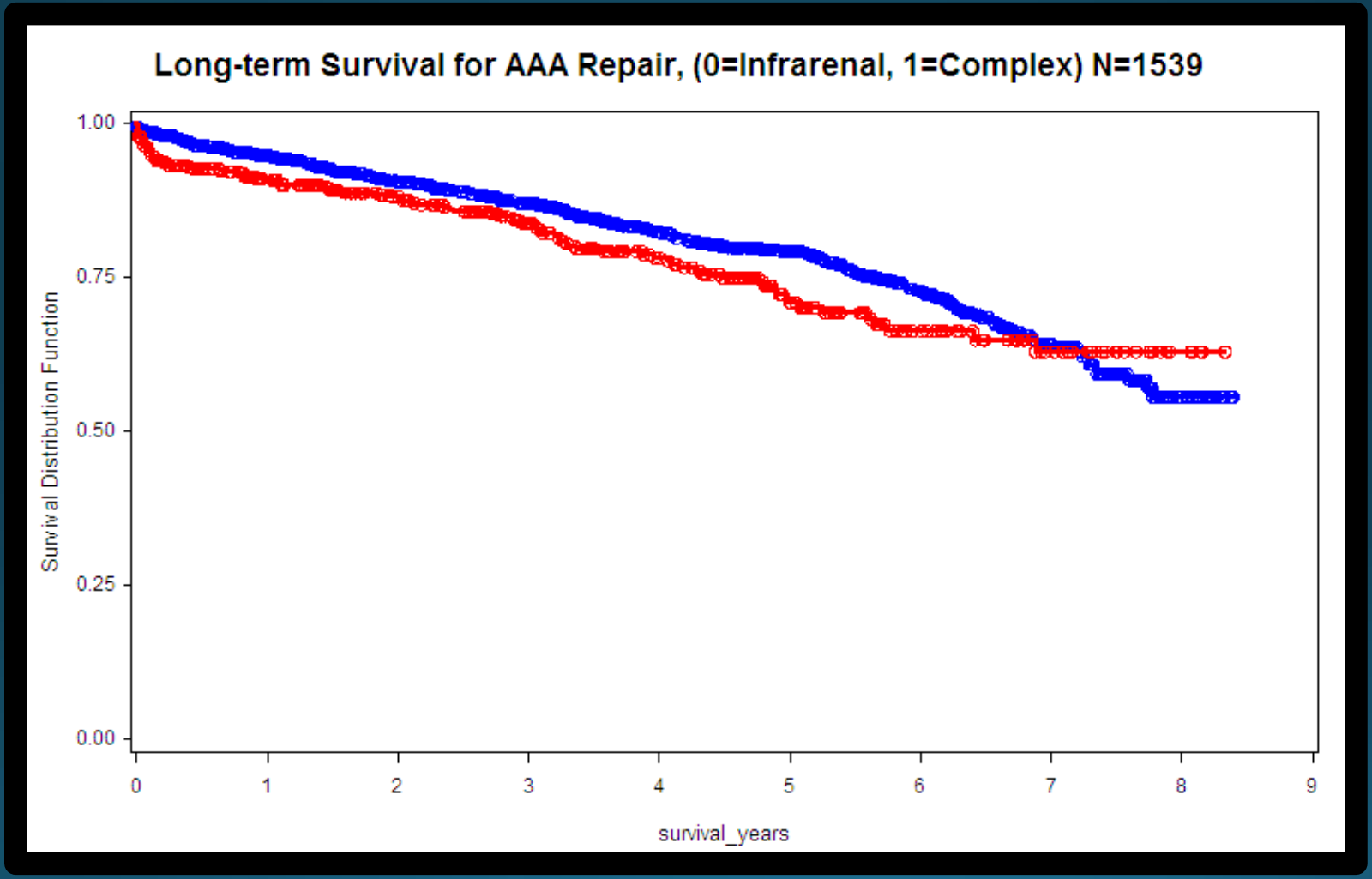
J Vasc Surg 2016;63:1195 - 200

Outcomes


Long-term Survival for AAA Repair, (0=Infrarenal, 1=Complex) N=1539
Survival Distribution Function
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
6
7
8
9
survival_years

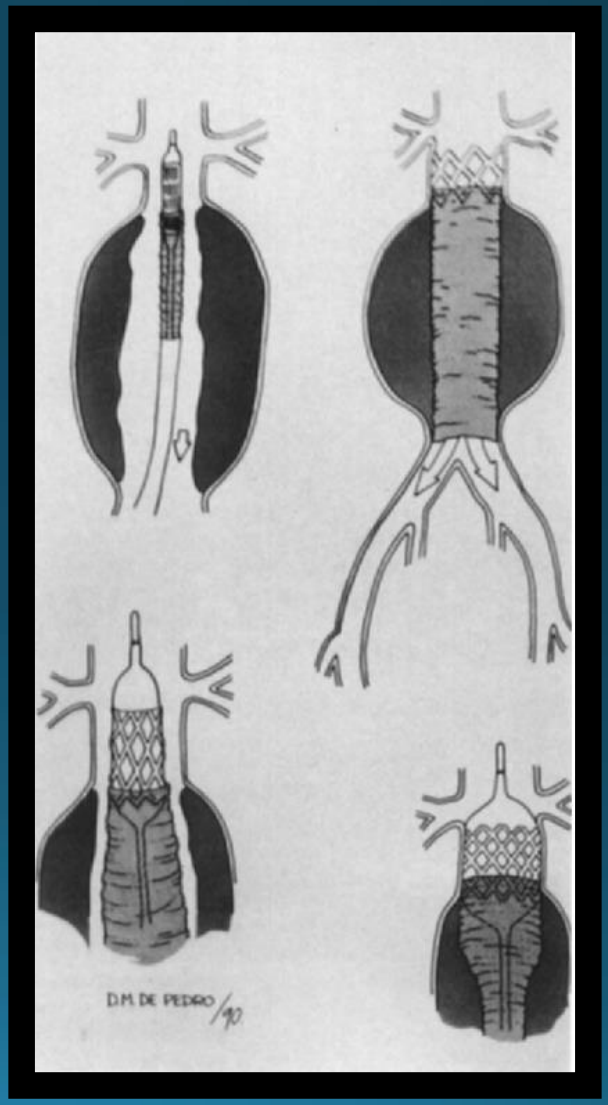
Historic Operative Mortality

1 - 2% in referral-based reports

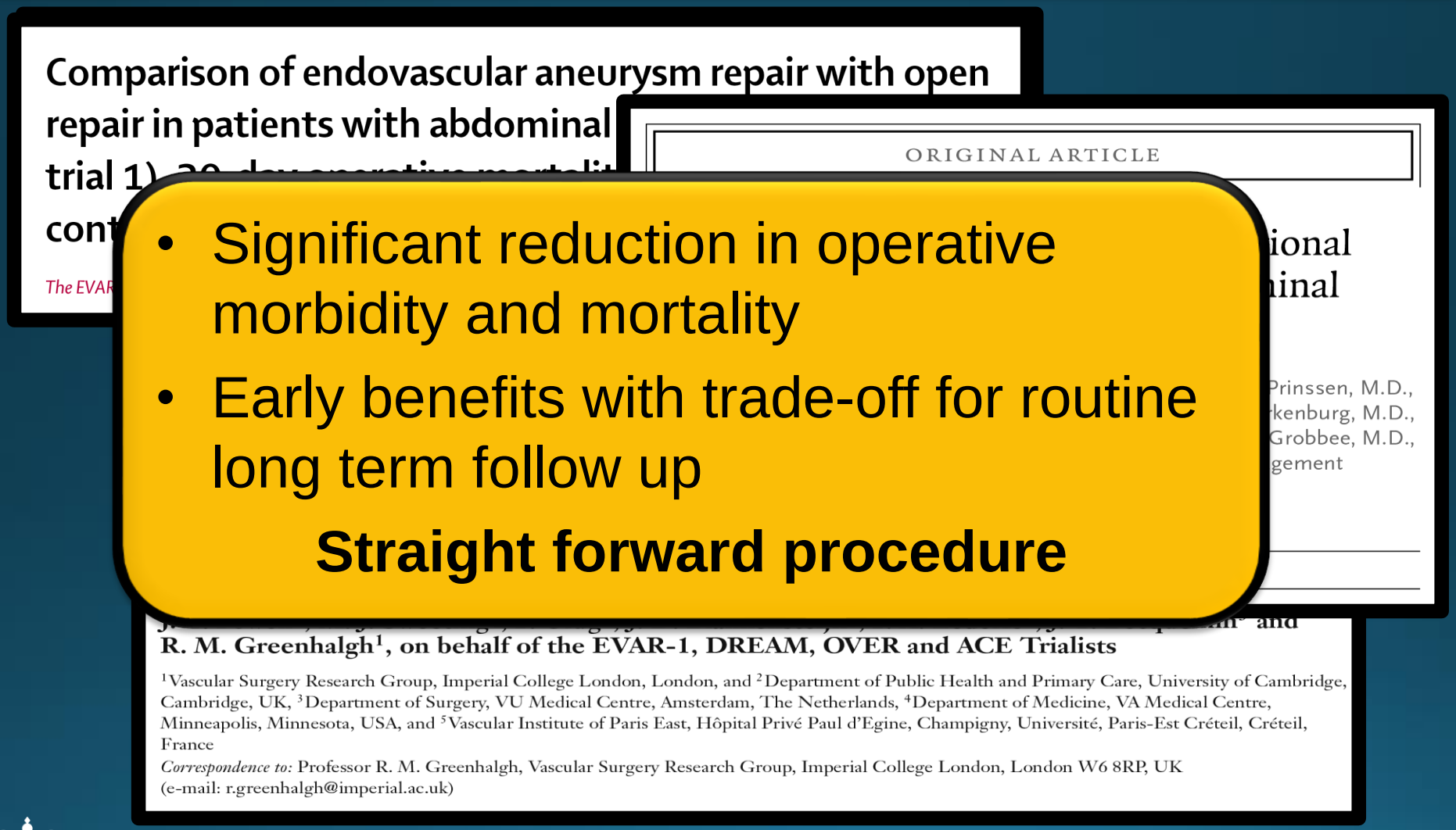
5 - 7% in population-based series

Endovascular Repair - EVAR

In the early 1990s, Volodos in the Ukraine and Parodi, Palmaz, and Barone in Argentina introduced a less invasive endovascular method for AAA repair



Level I EVAR Results



- Significant reduction in operative morbidity and mortality
- Early benefits with trade-off for routine long term follow up

Straight forward procedure

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EVAR - Trends

Decrease in total aneurysm-related deaths in the era of endovascular aneurysm repair

Kristi
Ami

-51

	2001	2003	2006
Open	61%	48%	28%
EVAR	39%	52%	**72%**

Ag
ope ic
aneurysm in the United States, 2001-2006

Margaret L. Schwarze, MD,[a] Yang Shen, BA,[b] Joshua Hemmerich, PhD,[c] and William Dale, MD, PhD,[c] *Madison, Wis; and Chicago, Ill*

J Vasc Surg 2009;50:722-9

EVAR – Intermediate Failures

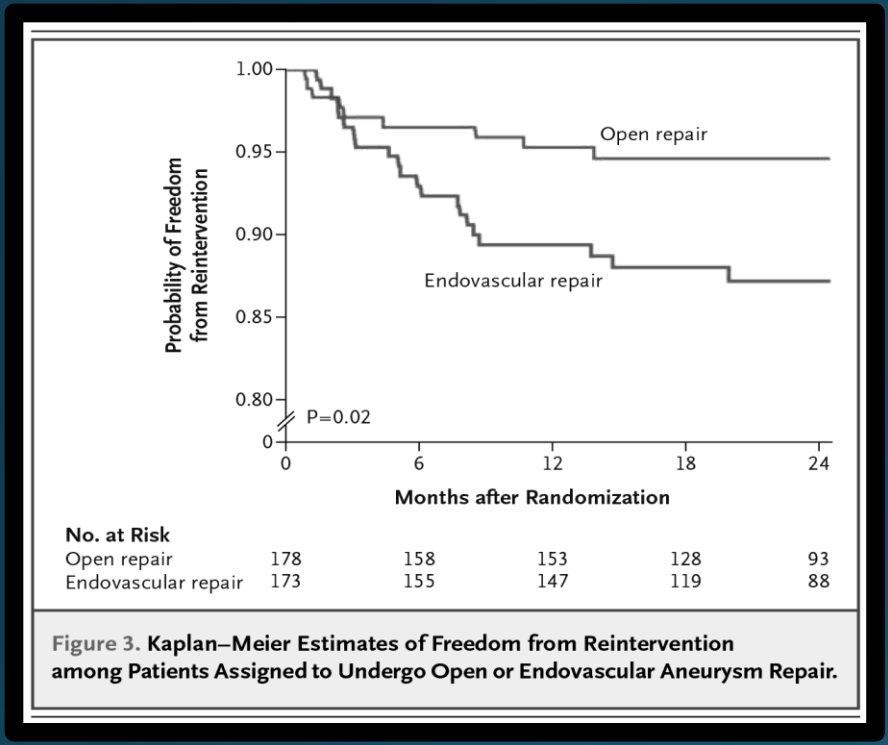
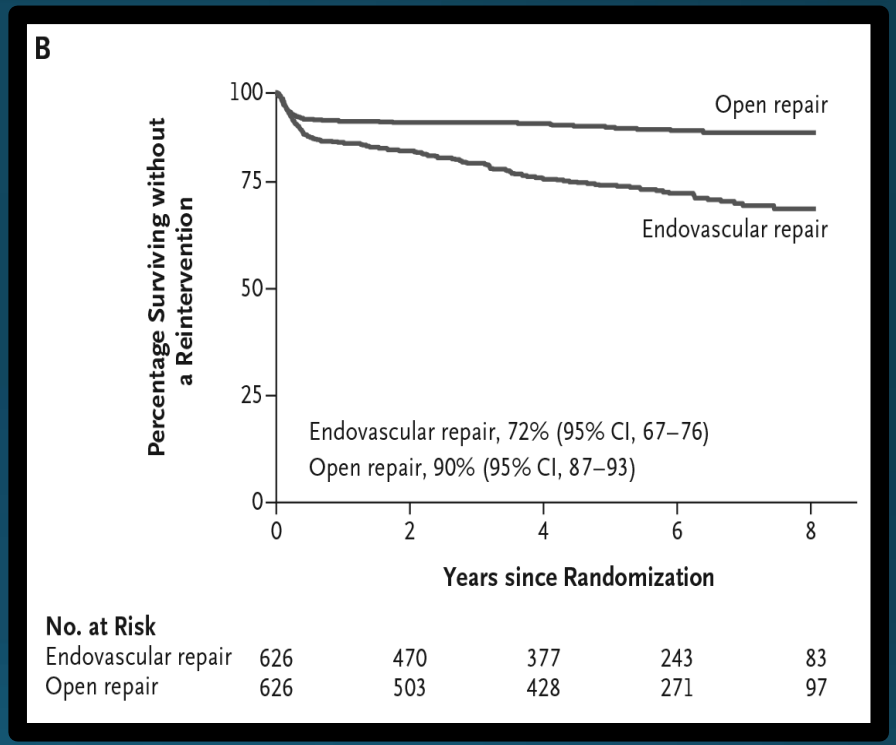


Figure 3. Kaplan–Meier Estimates of Freedom from Reintervention among Patients Assigned to Undergo Open or Endovascular Aneurysm Repair.



DREAM Trial

13% ~ 2yrs.

NEJM 2005;352:2398-405

EVAR I Trial

~40% ~ 8yrs.

NEJM 2010

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Late Failures

Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair

Aneurysm-related mortality

All patients	56/626 (9%)	1·1	45/626 (7%)	0·9	1·24 (0·84–1·83)	1·31 (0·86–1·99)	0·21
0–6 months	14/626 (2%)	4·6	30/626 (5%)	10·0	0·46 (0·24–0·87)	0·47 (0·23–0·93)	0·031
>6 months to 4 years	12/599 (2%)	0·6	8/581(1%)	0·4	1·48 (0·60–3·62)	1·46 (0·56–3·83)	0·44
>4–8 years	14/474 (3%)	0·9	4/464 (1%)	0·2	3·46 (1·14–10·52)	3·11 (0·99–9·72)	0·05
>8 years	16/339 (5%)	1·3	3/333 (1%)	0·2	5·50 (1·60–18·89)	5·82 (1·64–20·65)	0·0064

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See Online for appendix

for aneurysm-related mortality, p=0·031), but beyond 8 years of follow-up open-repair had a significantly lower mortality (adjusted HR 1·25, 95% CI 1·00–1·56, p=0·048 for total mortality; and 5·82, 1·64–20·65, p=0·0064 for aneurysm-related mortality). The increased aneurysm-related mortality in the EVAR group after 8 years was mainly attributable to secondary aneurysm sac rupture (13 deaths [7%] in EVAR *vs* two [1%] in open repair), with increased cancer mortality also observed in the EVAR group.

Interpretation EVAR has an early survival benefit but an inferior late survival compared with open repair, which needs to be addressed by lifelong surveillance of EVAR and re-intervention if necessary.

Lancet 2016;38:2366-74

Late Failures - Medicare

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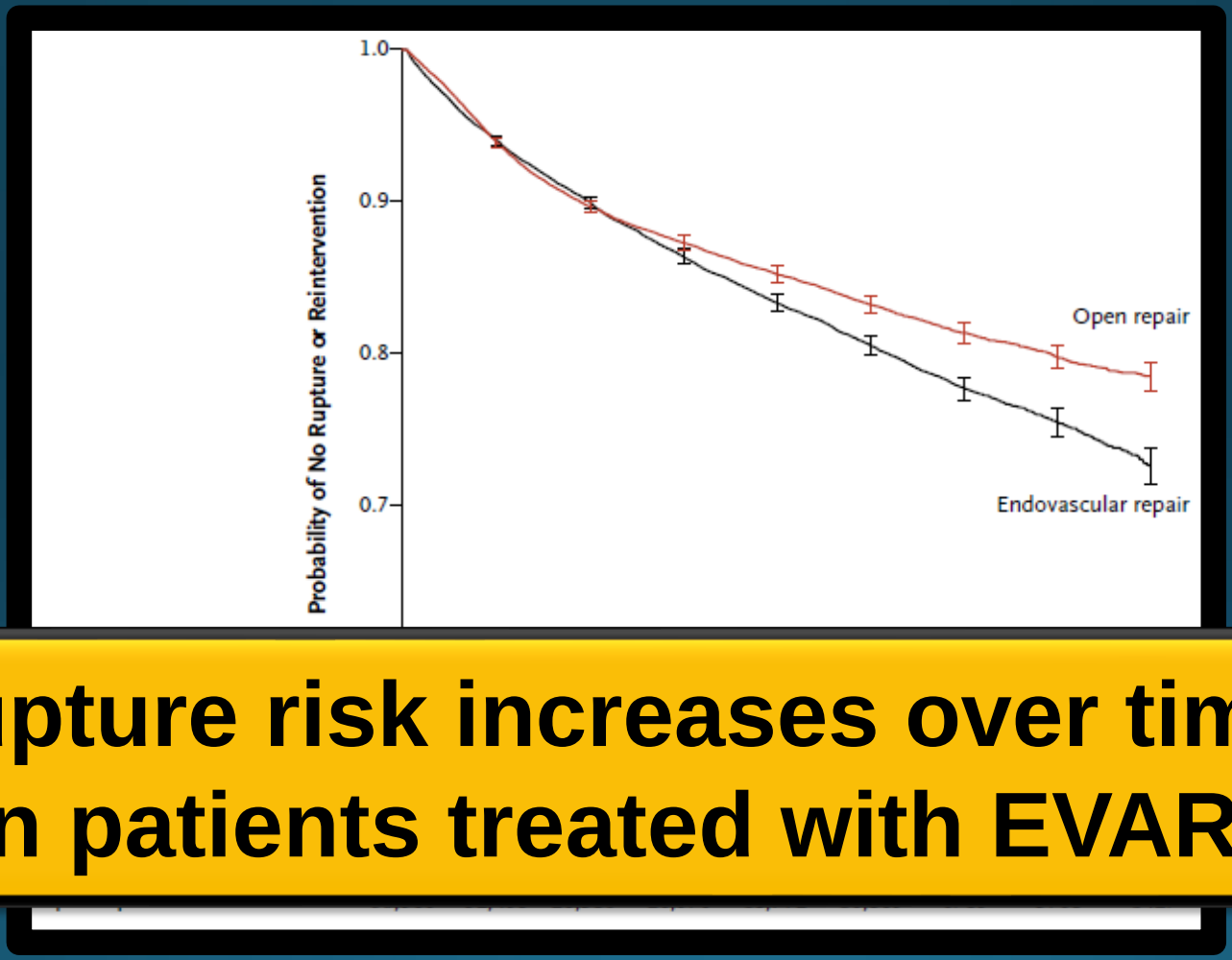
NEJM 2015; 373:328 - 338

Late Failures - Medicare



Rupture risk increases over time in patients treated with EVAR

NEJM 2015; 373:328 - 338

FDA Warning Letter

Endovascular Graft Systems: Letter to Health Care Providers - Type III Endoleaks Associated with Use – 9/28/2017

•Report any of the following to MedWatch, the FDA Safety Information and Adverse Event Reporting Program Online Voluntary Reporting Form:

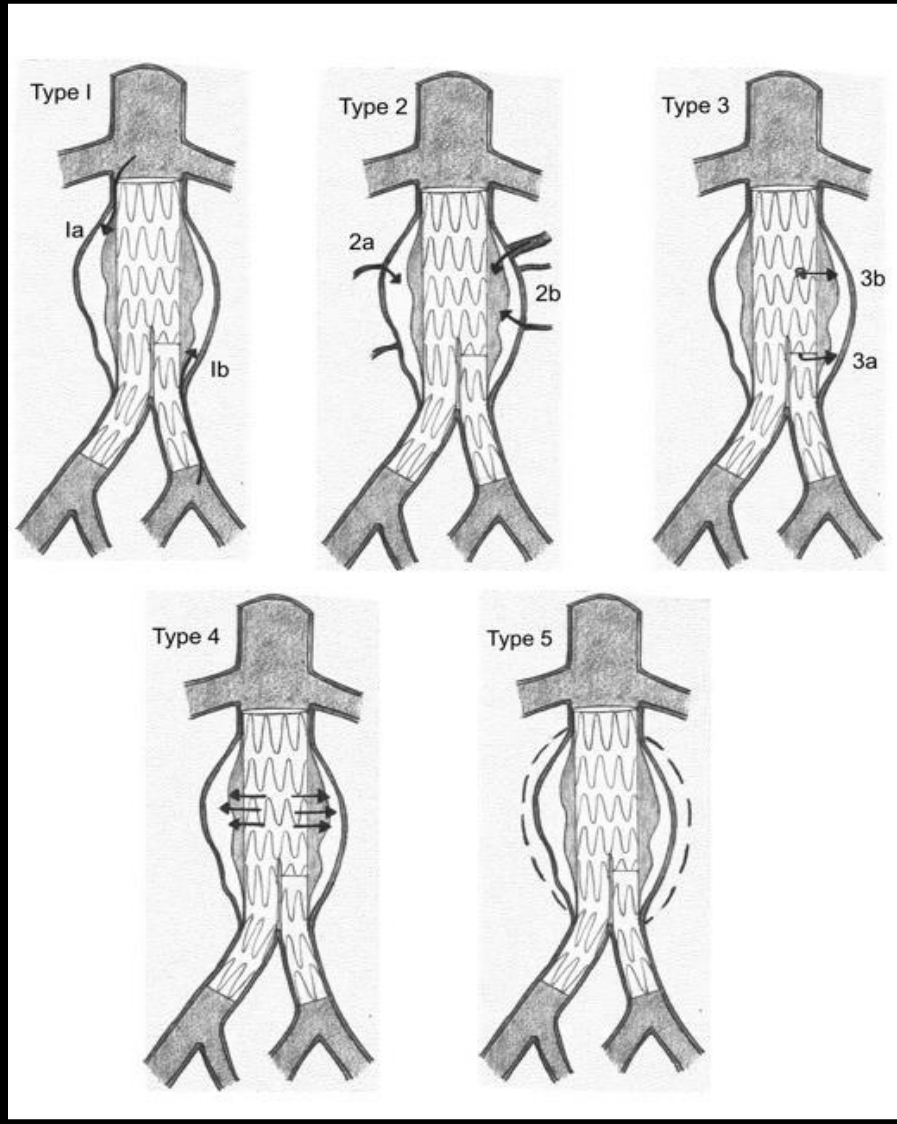
- early or late device-related adverse events–including Type IIIa and IIIb endoleaks–associated with the use of endovascular graft systems in EVAR;
- device-related adverse events that occur as a result of a secondary intervention to treat Type III endoleaks.

Causes of Failures

Endoleaks

– Type I and III need repair

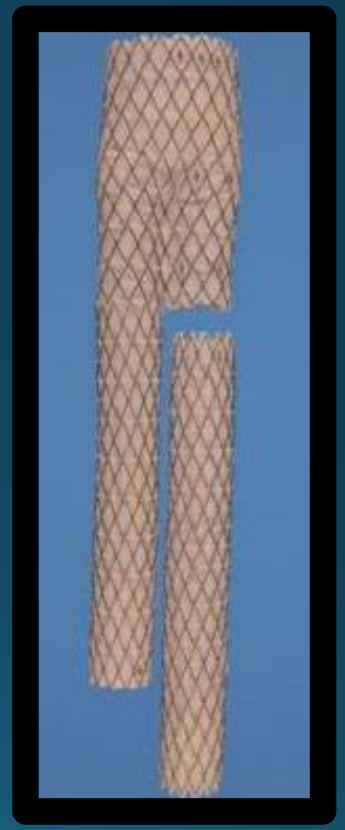
– Type II most common - ?benign?



Causes of Failures

Component problems

- Separation
- Fabric porosity
- Material failure



EVAR - Anatomic Requirements

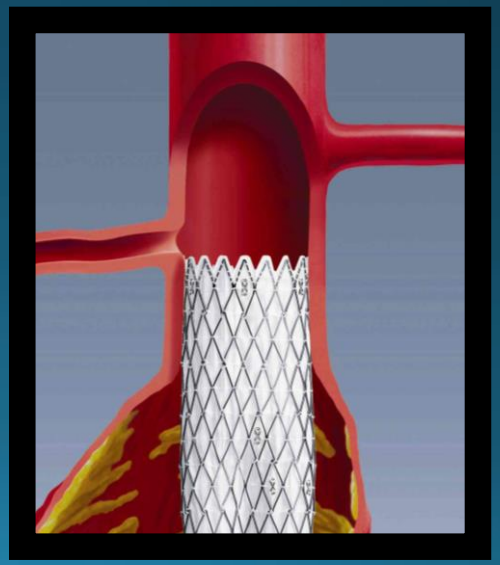
- **Proximal neck angulation > 60°**
  - 70% complication rate
- **Optimal neck length**
  - Ideal > 1.5cm (longer better)
- **Neck quality**
  - No thrombus
  - Eccentric calcium
  - Normal aorta

Strict IFU requirements for each device

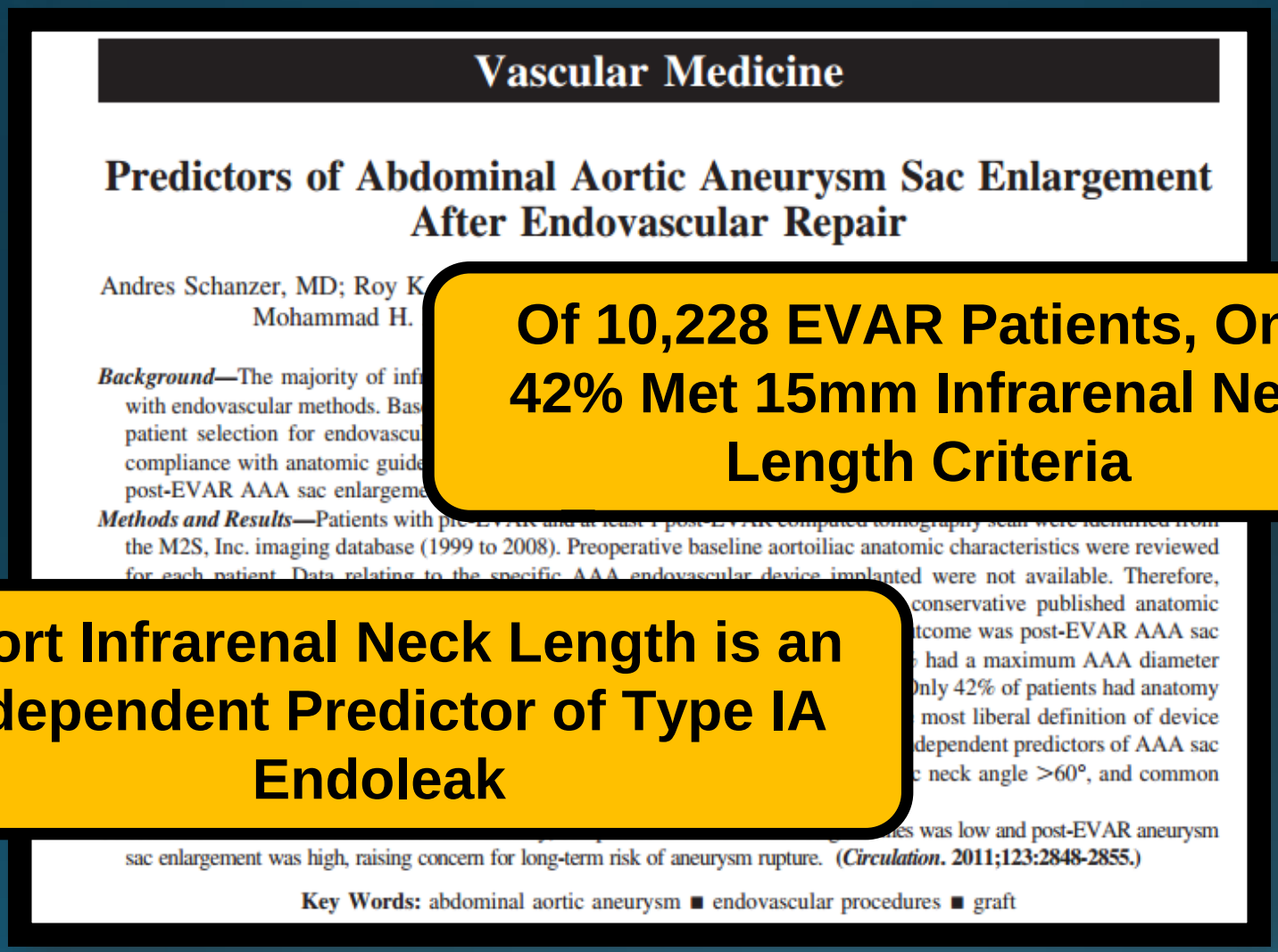
Causes of Failures

Neck Failure

- Neck degeneration
  - Outward remodeling
  - Large diameter grafts likely treating diseased vessel
- Device migration / disruption



IFU Violations



Vascular Medicine

Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair

Andres Schanzer, MD; Roy K
Mohammad H.

***Background*—**The majority of infr
with endovascular methods. Bas
patient selection for endovascul
compliance with anatomic guide
post-EVAR AAA sac enlargeme

***Methods and Results*—**Patients with pr
the M2S, Inc. imaging database (1999 to 2008). Preoperative baseline aortoiliac anatomic characteristics were reviewed
for each patient. Data relating to the specific AAA endovascular device implanted were not available. Therefore,
conservative published anatomic
tcome was post-EVAR AAA sac
had a maximum AAA diameter
Only 42% of patients had anatomy
most liberal definition of device
dependent predictors of AAA sac
neck angle >60°, and common

es was low and post-EVAR aneurysm
sac enlargement was high, raising concern for long-term risk of aneurysm rupture. (*Circulation*. 2011;123:2848-2855.)

Key Words: abdominal aortic aneurysm ■ endovascular procedures ■ graft

Of 10,228 EVAR Patients, Only 42% Met 15mm Infrarenal Neck Length Criteria

Short Infrarenal Neck Length is an Independent Predictor of Type IA Endoleak

Circulation 2011; 123:2848-2855)

Diverse Morphologies

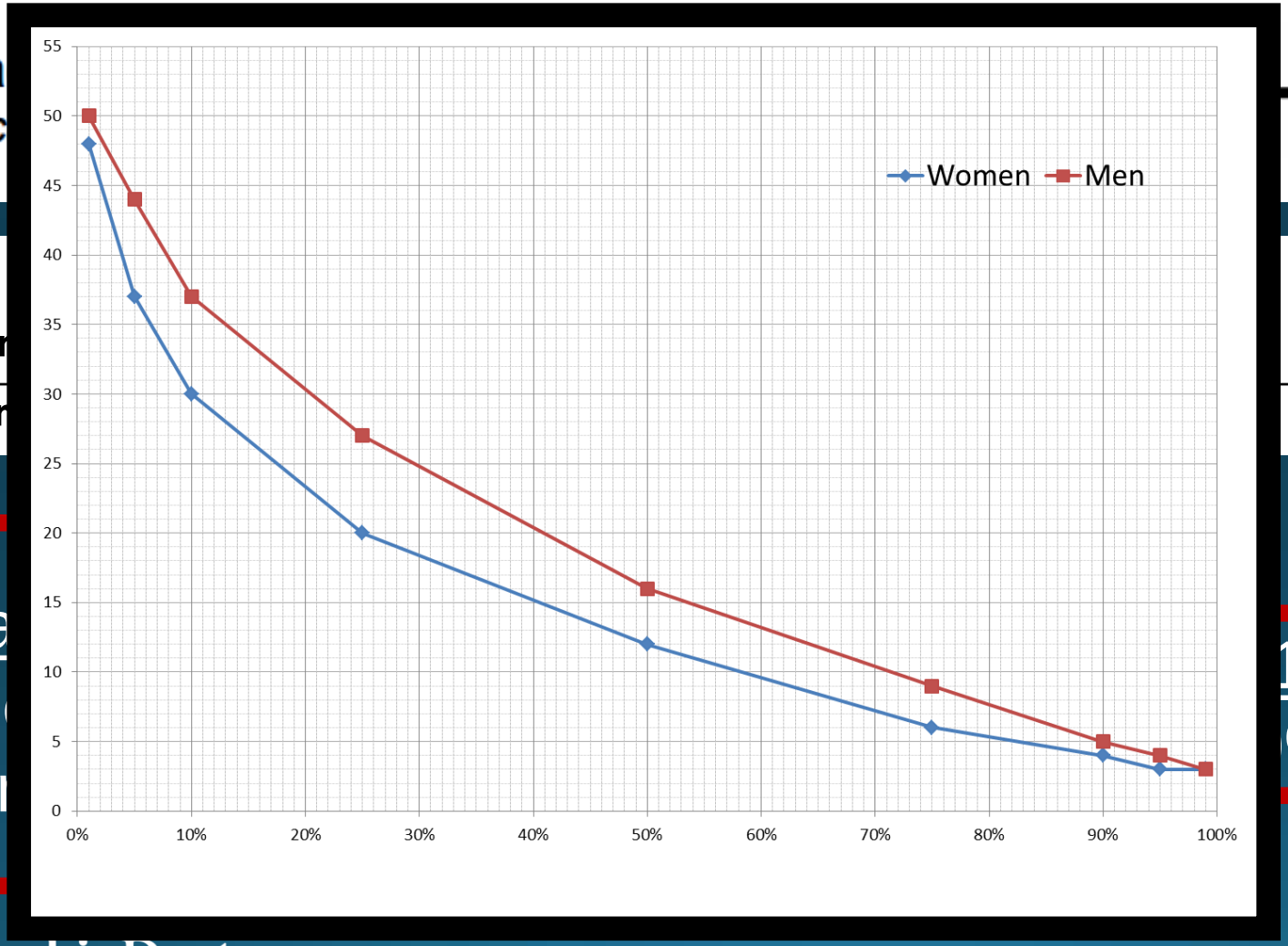
Chara
A Critic

HOP

percer	95	99
neck ler	44	50

Media
M
Wo

15mm
%



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Clinical Decision Making

- **Given failure (ARM) of EVAR, how should we decide on how best to treat patients → OPEN vs. EVAR?**

Decision making - Etiology

- **Degenerative (>90%)**
- **Inflammatory – endo**
- **Dissection – likely open**
- **Traumatic – endo**
- **Congenital / connective – open**
- **Mycotic / Infectious – open**

Decision Making - Anatomy

- **Endoleak risk:**
  - Increases with patent lumbar pairs
  - IMA patency
  - ? Anti-coagulation

- **Ideal neck anatomy:**
  - Longer better
  - Avoid angulation
  - Larger diameter = abnormal aorta

Decision Making - Survival

- Young patients with prolonged life expectancy are more likely to suffer ARM with EVAR

- ESRD poor survival
- Age >80 lower survival
- Advanced cardiac / pulmonary disease

ACE Trial

A randomized controlled trial of endovascular aneurysm repair versus open surgery for

- **Prospective Randomized**
- **High volume centers**
- **Low and moderate risk patients**
- **316 patients --> 3 yrs. follow up**
- **Open repair as safe as EVAR at 30 days**
- **3 yr. results favor Open repair**

J Vasc Surg 2011; 53:1167 - 73

Decision Making - Risks

- **Risk stratification tools should be used to guide clinical decision making**

Eslami NSQIP

Description of a risk pre
postoperative mortality
aneurysm repair

Mohammad H. Eslami, MD, MPH[a], De

- NSQIP 2005-20
- 1(76% EVAR /
- 18917 procedu
- All elective pro
- Mortality 1.7%

- Age > 70
- Female gender
- Functional dependence
- COPD
- MI
- Vascular disease
- Weight loss
- Creatinine >1.5, >2.0
- Hct > 30

Model

Variables	Points
Treatment	
OAR	5
EVAR	0
Age	
Age: ≥70 years	4
Age <70 years	0
Sex	
Female	2
Male	0
Functionally independent	
No (dependent patient)	4
Yes	0
Comorbidities	
COPD	2
Myocardial disease	1
Peripheral vascular disease	1
Weight loss	
Yes	5
No	0
Laboratory values	
Cr, mg/dL	
<1.5	0
≥1.5-2	2
≥2	3
HCT, mg/dL	
≥30	0
<30	4
ASA classification	
Mild	0
Severe	1
Life-threatening/moribund	4

ASA, American Society of Anesthesiology; *COPD*, chronic obstructive pulmonary disease; *Cr*, creatinine; *EVAR*, endovascular abdominal aortic aneurysm (AAA) repair; *HCT*, hematocrit; *OAR*, open AAA repair.

Sum of points	POD probability, %	Proportion of subjects with points	Sensitivity	Specificity
0	0.25	1.4	0.0000	0.9999
1	0.31	6.7	0.0000	0.9999
2	0.38	5.4	0.0000	0.9998
3	0.48	3.4	0.0036	0.9993
4	0.59	4.6	0.0036	0.9987
5	0.74	12.3	0.0109	0.9983
6	0.92	13.3	0.0182	0.9975
7	1.14	10.6	0.0364	0.9957
8	1.41	8.8	0.0618	0.9927
9	1.75	6.6	0.0800	0.9889
10	2.17	6.7	0.1273	0.9811
11	2.68	4.8	0.1818	0.9705
12	3.31	4.6	0.2509	0.9534
13	4.09	3.4	0.3164	0.9309
14	5.04	2.3	0.4036	0.8979
15	6.19	1.8	0.4764	0.8522
16	7.59	1.1	0.5455	0.8041
17	9.27	0.8	0.6291	0.7370
18	11.28	0.4	0.7091	0.6708
19	13.66	0.3	0.7782	0.5827
20	16.44	0.2	0.8473	0.4758
21	19.66	0.1	0.8982	0.3412
22	23.34	<0.1	0.9527	0.2174
23	27.48	0.1	0.9636	0.1710

J Vasc Surg 2017;65:65-75

VSGNE / VQI Model

From the New England Society for Vascular Surgery

External validation of Vascular Study Group of New England risk predictive model of mortality after elective abdominal aorta aneurysm repair in the Vascular Quality Initiative and comparison against established models

- **VSGNE 2003 – 2012**

  4431 pts. / 1.4% mortality

- **VQI 2010 – 2015**

  16989 / 0.9% mortality

J Vasc Surg 2018;67:143-50

VSGNE / VOI Model

Parameter	*Points*
Treatment	
EVAR	0
OAR (infrarenal)	
OAR (suprarenal)	
Aneurysm size, mm	
<65	
≥ 65	
Age, years	
≤75	
>75	
Gender	
Male	
Female	
Comorbidities	
Myocardial disease	
Cerebrovascular disease	
Chronic obstructive pulmonary disease	
Laboratory value	
Creatinine, mg/dL	
<1.5	
1.5 to <2	
≥2	2

EVAR, Endovascular aneurysm repair; *OAR*, open aneurysm repair.

Points	*Probability of mortality, %*	*Proposed risk designation*
0	0.12	Low-risk group
1	0.20	
2	0.34	
3	0.59	
4	1.00	
5	1.71	Medium-risk group
6	2.91	
7	4.90	
8	8.14	High-risk group
9	13.2%	
10	20.75	
11	31.05	Prohibitive high-risk group
12	43.63	
13	57.10	
14	69.59	

J Vasc Surg 2018;67:143-50

Final thoughts

- **We are over treating with EVAR**

- **Risk stratification tools should be used to guide clinical decision making**

Final Thoughts

- **Low / Moderate risk patients - considered open repair at high volume centers**
  - Especially true for young patients given long term ARM with EVAR

- **EVAR patients have increased long term risk:**
  - Careful monitoring of patients is essential

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1-844-RxAorta

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Thank You!!