

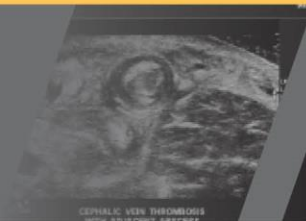
2024 MID-ATLANTIC CONFERENCE
12th ANNUAL CURRENT CONCEPTS IN
VASCULAR THERAPIES

2024



Hilton Virginia Beach Oceanfront
Virginia Beach, Virginia

APRIL 18-20



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Open Aortic Surgery
Remains Durable and
Right for Most Patients

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VCU Division of Vascular Surgery

Disclosures

- Terumo, Medtronic – Support for clinical trials

Outline

- We repair patients to prevent rupture
- If we select the right patients for repair, the repair needs to last

Before we get started...

- Complex endovascular repair may be right for *some* patients now
- F/BEVAR may be best *in the future*



Our Biases

FEVAR

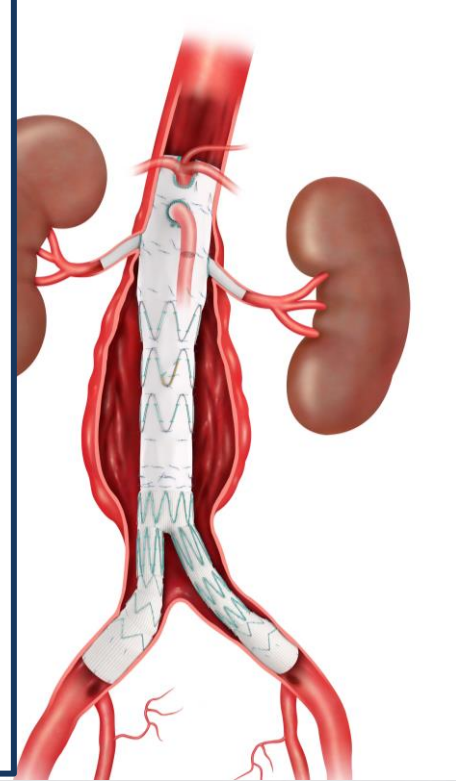
Open



Endova

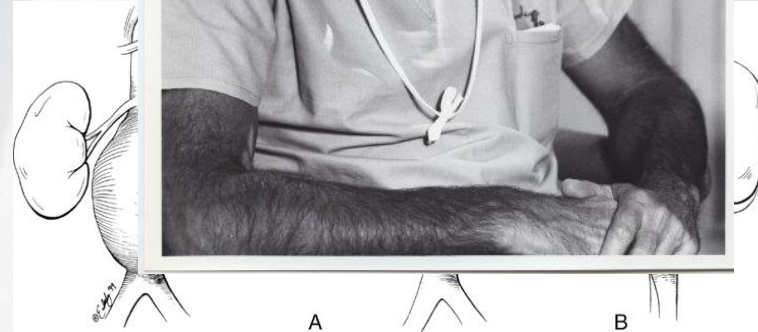
- Juxta- and pararenal aneurysm
 - At least 5 components
 - 5 seal zones
 - 4 component-to-component
- ? First FEVAR in 1996 in S. Korea by Joon Kim and Jae Hyung Park

EVERYBODY
LOVES
RAYMOND



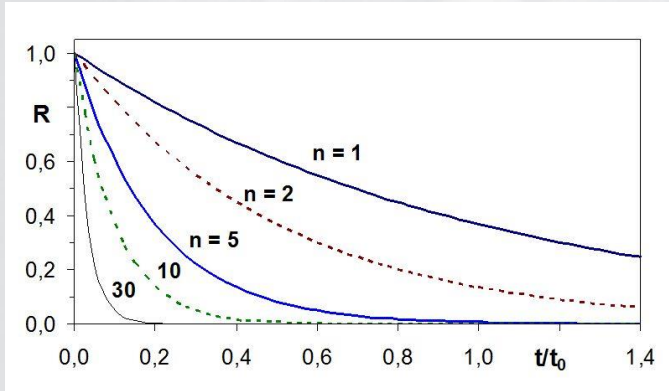
Open Repair

- Juxta- and pararenal aneurysm repairs
 - 1 graft (usually)
 - +/- spatulated proximal anastomosis
 - Occasional visceral re-implantation
- Dr. Cooley and DeBakey first reported in the 1950s



The burden of proof is on FEVAR

Reliability over time



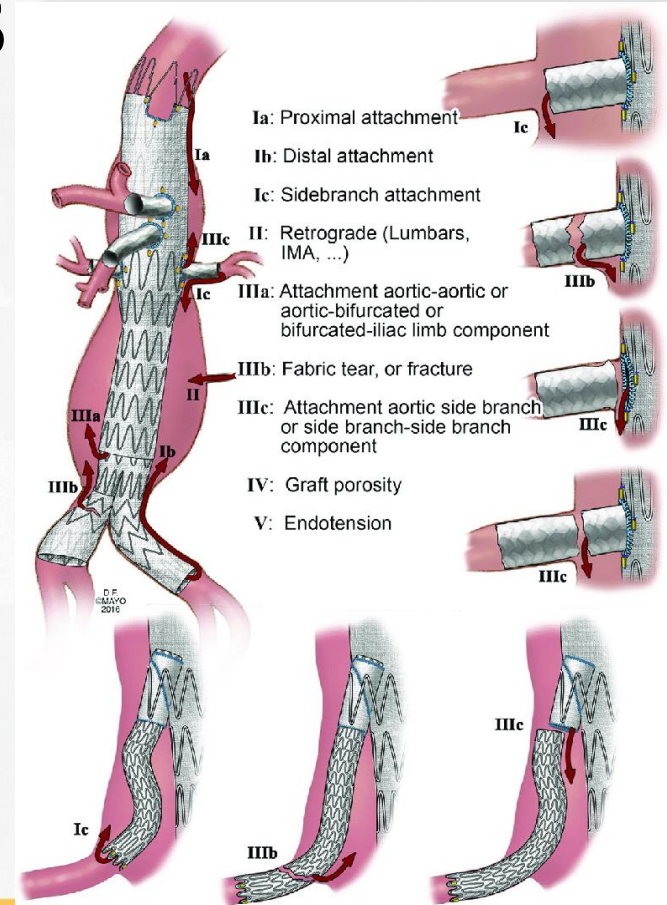
- Complex things are less reliable than simple things

$$R_{\text{total}} = R_1 * R_2 * R_3 \dots$$

$$R_{\text{total}} = 0.96_{\text{SMA}} * 0.95_{\text{R Renal}} * 0.95_{\text{L Renal}} * 0.97_{\text{Prox seal}} * 0.97_{\text{dist seal}} * \dots$$

Long Term Failure modes

| | Open | Endo |
|-----------------------------|------|------|
| Proximal neck degeneration | + | +++ |
| Iliac degeneration | | ++ |
| Component separation | | + |
| Branch seal zone leaks | | + |
| Branch vessel occlusion | + | + |
| Type II endoleak | | ++ |
| Cancer from surveillance CT | | + |



SYSTEMATIC REVIEW

Long Term Outcomes and Durability of Fenestrated Endovascular Aneurysm Repair: A Meta-analysis of Time to Event Data

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WHAT THIS PAPER ADDS

This meta-analysis, which approached the literature with a broad search strategy, delivers robust long term estimates for survival, freedom from re-intervention, target vessel patency, and one year sac regression after fenestrated endovascular aneurysm repair (FEVAR). These are important to inform contemporary discussions around the durability of FEVAR and may influence future practice when counselling patients on FEVAR during the consent process. The meta-analytical technique of pooling raw, patient level time to event data, directly extracted from Kaplan–Meier curves, is novel to the field of vascular surgery and to an extent enables this study to overcome challenges with study heterogeneity.

Objective: Despite widespread use, long term outcomes for fenestrated endovascular aneurysm repair (FEVAR) are uncertain. This meta-analysis reports long term survival, freedom from re-intervention, target vessel patency, and one year sac regression after FEVAR.

Data Sources: Systematic review and meta-analysis to pool time to event data according to PRISMA guidelines. The study was registered with the international prospective register of systematic reviews (PROSPERO) (ID: CRD42023401468).

Review Methods: Medline, Embase, and Cochrane databases were searched from 1992 – 2023; articles were independently screened by two authors. Publication of complete time to event data for any outcome of interest was an inclusion criterion. Raw Kaplan–Meier probabilities were directly extracted from published curves and pooled by random effects. Risk of bias was assessed using ROBINS I and certainty with GRADE.

Results: A total of 3 569 records were retrieved, 2 869 screened after duplicate removal, yielding 37 included studies ($n = 4 371$). The pooled mean age was 73.2 years (interquartile range [IQR] 72.2, 73.7) and 87.4% were male [95% confidence interval [CI] 85.8 – 88.9]. Pooled Kaplan–Meier estimated probabilities of survival ($n = 34$ studies, $n = 4 192$ patients) at one, three, and five years were 91.6% [95% CI 90.2 – 92.9], 80.8% [95% CI 78.0 – 83.2], and 65.1% [95% CI 60.9 – 69.1]. For freedom from re-intervention ($n = 24$, $n = 3 211$ patients) at one, three, and five years these were 90.2% [95% CI 87.3 – 92.7], 80.9% [95% CI 76.5 – 84.9], and 73.8% [95% CI 67.1 – 79.6]. For target vessel patency ($n = 13$, $n = 5805$ target vessels) at one, three, and five years, these were 96.6% [95% CI 94.9 – 98.0], 94.5% [95% CI 91.7 – 96.7], and 93.1% [95% CI 89.3 – 96.0]. Pooled estimate of sac regression ($n = 8$, $n = 560$) at one year was 40.2% [95% CI 28.9 – 52.7]. Risk of bias was judged as moderate in 11 studies and low for the remaining 26.

Conclusion: There are moderate to low certainty data supporting reasonable long term outcome estimates following fenestrated endovascular aneurysm repair. Beyond five years there is a lack of data in the literature.

Key words: Abdominal aortic aneurysm, Complex endovascular aneurysm repair, Endovascular procedures, Endovascular aneurysm repair,

Fenestrated endovascular aneurysm repair, Juxtarenal abdominal aortic aneurysm

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2024

The "Proof"

"Beyond five years there is a lack of data in the literature."

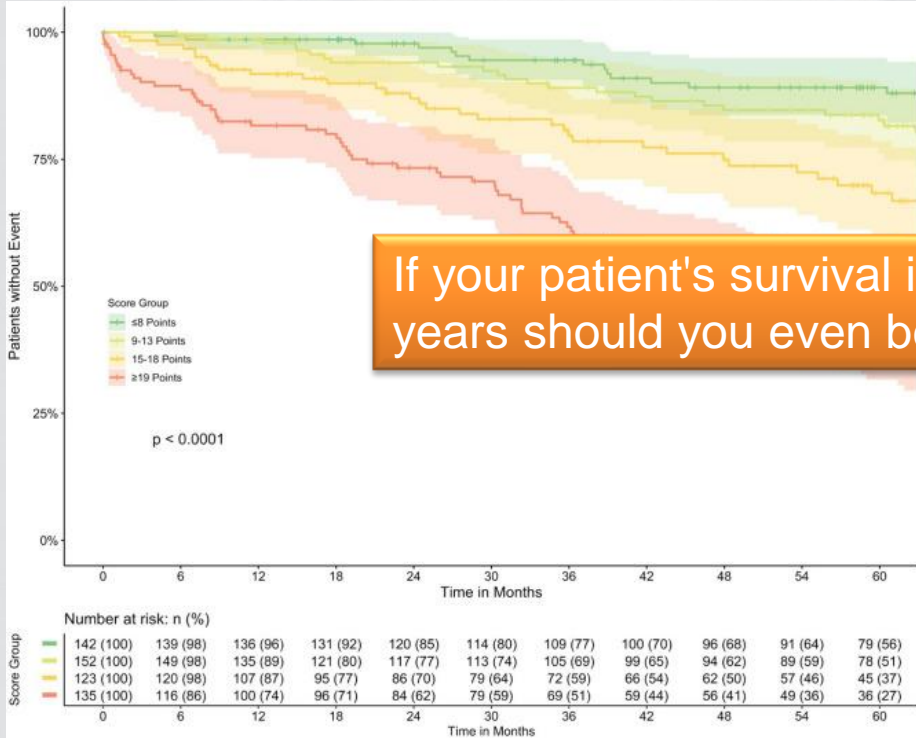
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Email address: arntjen.gulerult1@sbh.nhs.uk (Arntjen M. Gulerult).

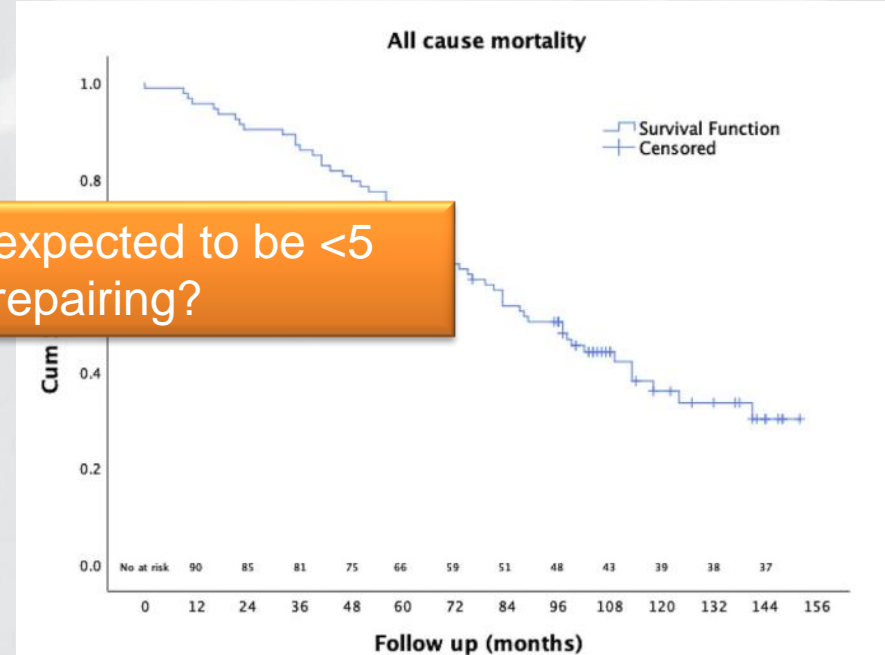
1078-5884/© 2023 The Author(s). Published by Elsevier B.V. on behalf of European Society for Vascular Surgery. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

<https://doi.org/10.1016/j.ejvs.2023.08.012>

Our patients live beyond 5 years



If your patient's survival is expected to be <math>< 5</math> years should you even be repairing?



Take a step back

- Who benefits from aneurysm repair?



To get the benefit of repair:

- Must be at risk of rupture
 - (have a large enough aneurysm)
- Patient must live long enough to realize the risk reduction

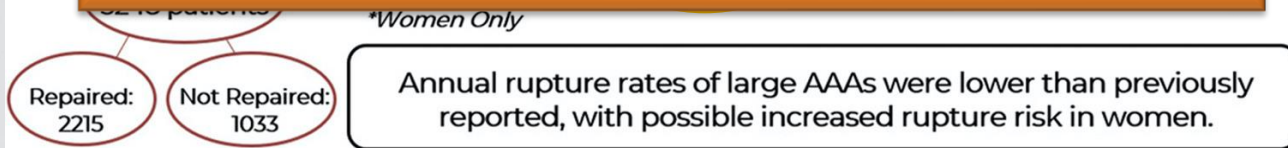
Moderate size AAAs have a low risk of rupture

Natural History of Large Abdominal Aortic Aneurysms (AAA) in Patients Without Timely Repair

 Multicenter retrospective cohort study  3248 patients with large, unrepaired AAAs

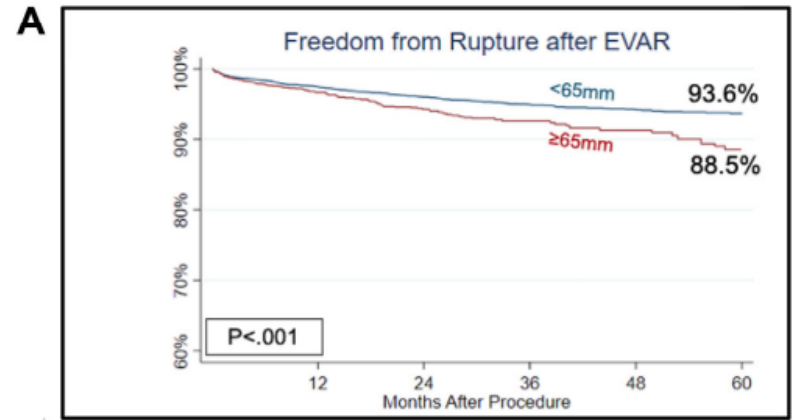
3-Year Cumulative Incidence of Rupture

Most centers use a higher threshold for complex aneurysms (>6cm)



BTW: EVAR of large aneurysms fare worse

- More room for endoleaks?
- More room for graft movement?
- Biologic difference?



| Inverse Probability Weighted number at risk | | | | | |
|---|--------|--------|--------|--------|--------|
| $<65\text{mm}$ | N=9056 | N=6213 | N=3945 | N=2338 | N=1208 |
| $\geq 65\text{mm}$ | N=8152 | N=5485 | N=3337 | N=1979 | N=945 |

From the Society for Vascular Surgery

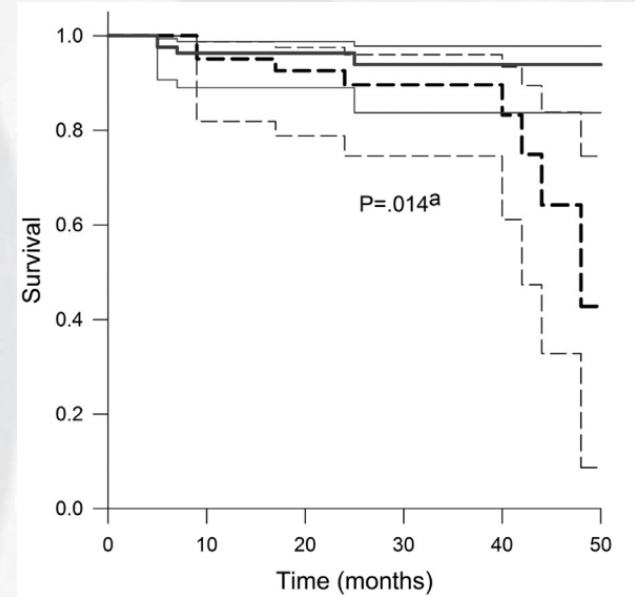


Late outcomes after endovascular and open repair of large abdominal aortic aneurysms

Livia E. V. M. de Guerre, MD,^{a,b} Kirsten Dansey, MD,^a Chun Li, MD,^a Jinny Lu, MD,^a Priya B. Patel, MD,^a Joost A. van Herwaarden, MD,^b Douglas W. Jones, MD,^c Philip P. Goodney, MD, MS,^d and Marc L. Schermerhorn, MD,^a Boston and Worcester, Mass; Utrecht, The Netherlands; and Lebanon, NH

Living long enough to benefit

- Survival is not impossible to predict
 - sarcopenia, CFS, SOF, PRISMA-7
- 50% 4-year survival in frail patients vs a 6% 3 year risk of rupture



Sarcopenia predicts poor long-term survival in patients undergoing endovascular aortic aneurysm repair



Daniel H. Newton, MD,^a Candice Kim, BS,^a Nathaniel Lee, MD,^a Luke Wolfe, MS,^a John Pfeifer, MD, FACS,^b and Michael Amendola, MD, FACS,^b Richmond, Va



Living long enough to benefit

- Of all patients with aneurysms needing repair, some have a poor prognosis with or without aneurysm repair (red)
- Some are clearly healthy enough for an open repair (green)
- Of the remainder (blue), how many are "unfit" for open repair?



Living long enough to benefit

Assessment of fitness for open repair in patients with infrarenal abdominal aortic aneurysms

Mitri K. Khoury, MD   • Micah A. Thornton, PhD • Matthew J. Eagleton, MD • ... Nikolaos Zacharias, MD • Anahita Dua, MD • Abhisekh Mohapatra, MD • Show all authors

Published: April 10, 2024 • DOI: <https://doi.org/10.1016/j.jvs.2024.04.020>

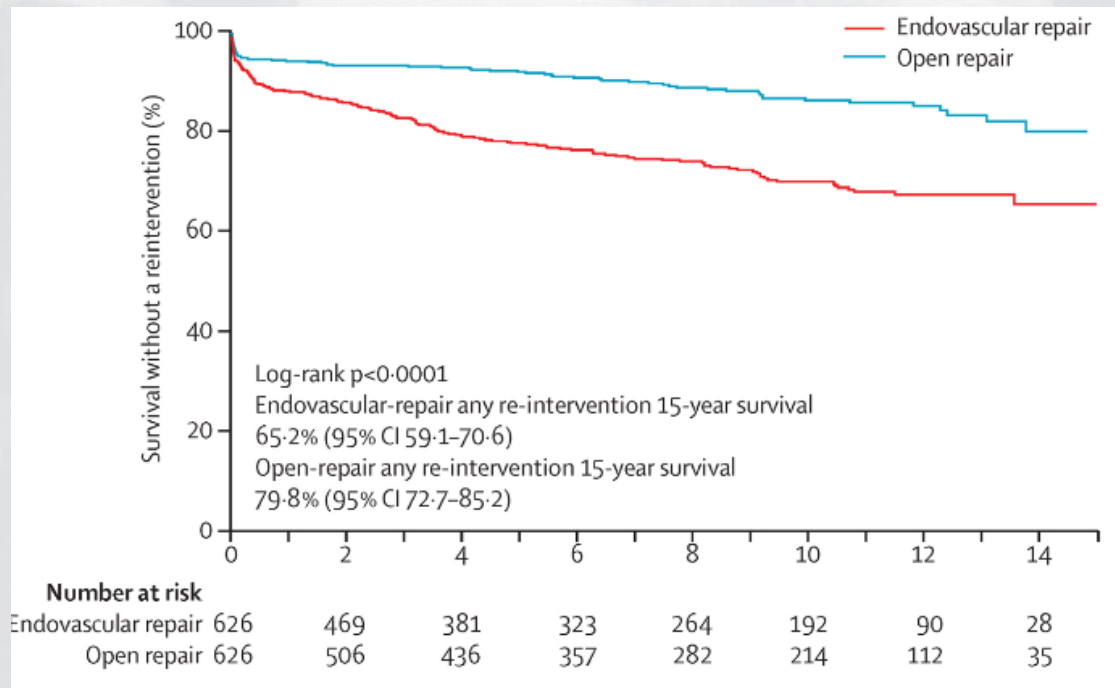
- Matched "unfit" patients with patients who underwent open repair in the VQI database.
- "There were no differences in early survival but open repair had better middle and late survival compared to EVAR over the course of 5 years."
- "Unfit" patients weren't so unfit for open repair.

Durability. It's kind of important.

The crux of my
argument

Reintervention

- EVAR 1 trial
 - Freedom from reintervention ~80% at 5 years
 - Did not improve over time

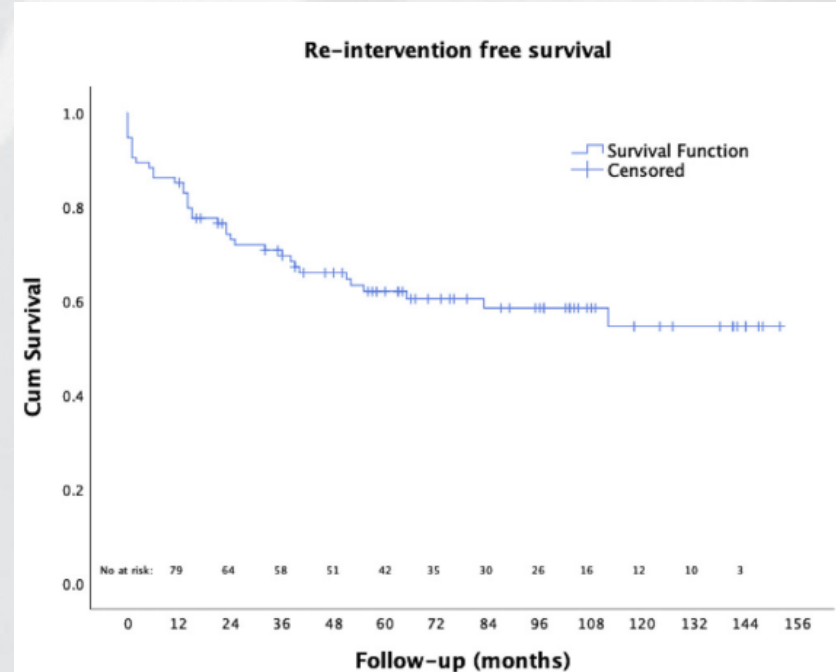


Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial

Rajesh Patel, Michael J Sweeting, Janet T Powell, Roger M Greenhalgh, for the EVAR trial investigators*

Reintervention in FEVAR

- Malmö Vascular Center, Sweden; JVS 2022
- 94 patients
- 40% reintervention rate at 5 years

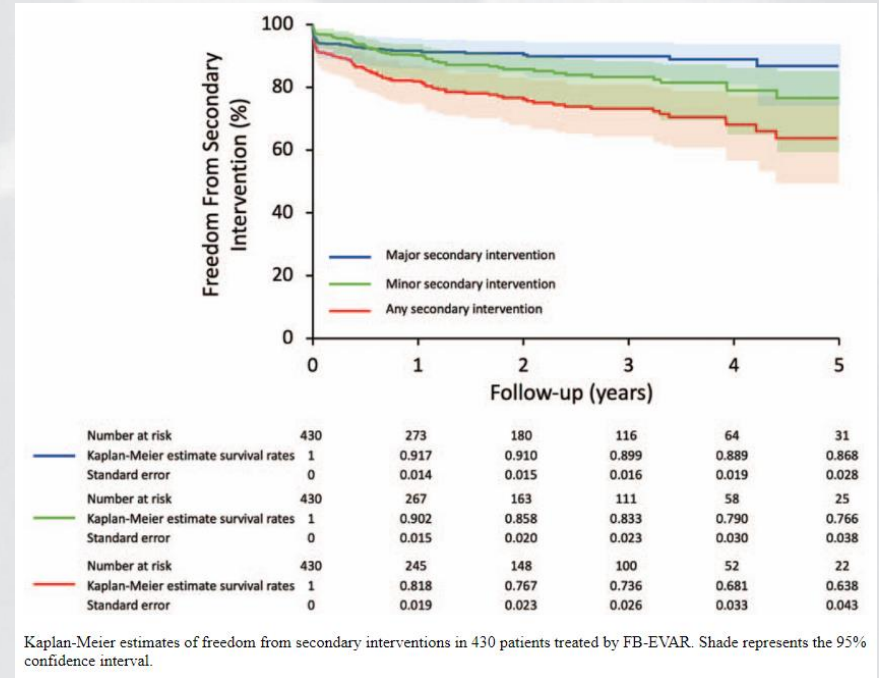


Long-term outcomes after fenestrated endovascular aortic repair for juxtarenal aortic aneurysms

Magnus Sveinsson, MD,^{a,b} Björn Sonesson, MD, PhD,^b Thorarinn Kristmundsson, MD, PhD,^{b,c} Nuno Dias, MD, PhD,^d and Timothy Resch, MD, PhD,^{b,d} Helsingborg and Malmö, Sweden; and Copenhagen, Denmark

Reintervention in FEVAR

- Mayo clinic in Annals of Surgery 2021
- 430 B/FEVARs
- ~40% reintervention rate at 5 years



ASA PAPER

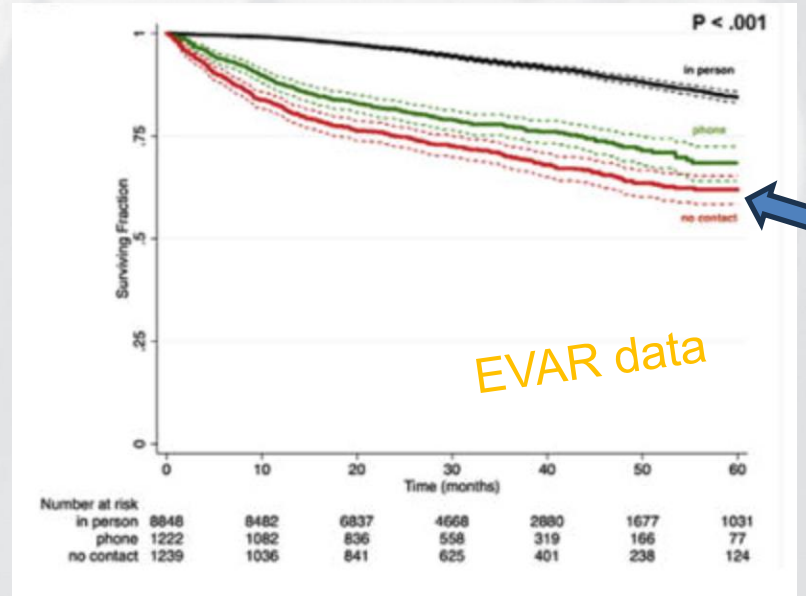
Midterm Outcomes of a Prospective, Nonrandomized Study to Evaluate Endovascular Repair of Complex Aortic Aneurysms Using Fenestrated-Branched Endografts

Gustavo S. Oderich, MD,* Emanuel R. Tenorio, MD, PhD,* Bernardo C. Mendes, MD,†
 Guilherme Baumgardt Barbosa Lima, MD,* Giuliana Barreira Marcondes, MD,*
 Naveed Saqib, MBBS,* Jan Hofer, RN,† Joshua Wong, MBE,* and Thaila A. Macedo, MD*†



Durability

- What happens when a 40% reintervention rate meets a 50% rate of follow up?
- 11,309 patients from VQI, linked with social security data
- Patients lost to follow up after EVAR have worse survival. Not surprising. No reintervention.



Endovascular aneurysm repair patients who are lost to follow-up have worse outcomes

Caitlin W. Hicks, MD, MS^a, Devin S. Zarkowsky, MD^b, Ian C. Bostock, MD, MS^b, David H. Stone, MD, MHS^b, James H. Black III, MD^b, Jens Eldrup-Jorgensen, MD^c, Philip P. Goodney, MD, MS^b, and Mahmoud B. Malas, MD, MHS^a

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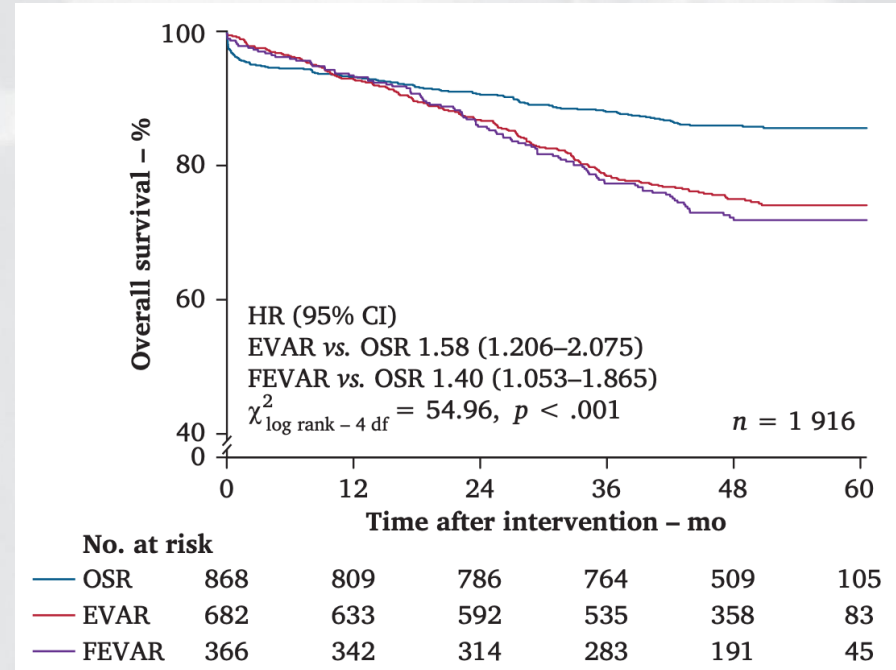
^cDivision of Vascular Surgery and Endovascular Therapy, Maine Medical Center, Portland, Me

**But what
about
FEVAR?**



FEVAR vs Open repair: UK-COMPASS

- UK-COMPASS prospective registry >2000 patients JAA/PAA
 - "there was very little support for an RCT due to a lack of equipoise, citing optimism among practitioners that FEVAR would give superior results"



**But that's
apples to
oranges...**



FEVAR vs Open repair: UK-COMPASS

- Propensity scoring

| |
|---------------------------------|
| <i>Age – y</i> |
| Missing |
| <i>Sex</i> |
| Female |
| Male |
| Missing |
| <i>Weight – kg</i> |
| Missing |
| <i>Height – cm</i> |
| Missing |
| <i>BMI – kg/m²</i> |
| Missing |
| <i>Neck length – mm</i> |
| Missing |
| <i>ASA grade</i> |
| 1, normal |
| 2, mild disease |
| 3, severe, not life threatening |
| 4, severe, life threatening |
| 5, moribund patient |
| Missing |
| <i>Haemoglobin – g/dL</i> |
| Missing |

| |
|---------------------------------------|
| <i>WBC count – ×10⁹ /L</i> |
| Missing |
| <i>Serum sodium – mmol/L</i> |
| Missing |
| <i>Serum potassium – mmol/L</i> |
| Missing |
| <i>Serum creatinine – mmol/L</i> |
| Missing |
| <i>Serum albumin – mmol/L</i> |
| Missing |
| <i>Abnormal ECG</i> |
| Abnormal |
| Normal |
| Missing |
| <i>Comorbidities</i> |
| None |
| Chronic heart failure |
| Chronic lung disease |
| Chronic kidney disease |
| Diabetes |
| Hypertension |
| Ischaemic heart disease |
| Stroke |

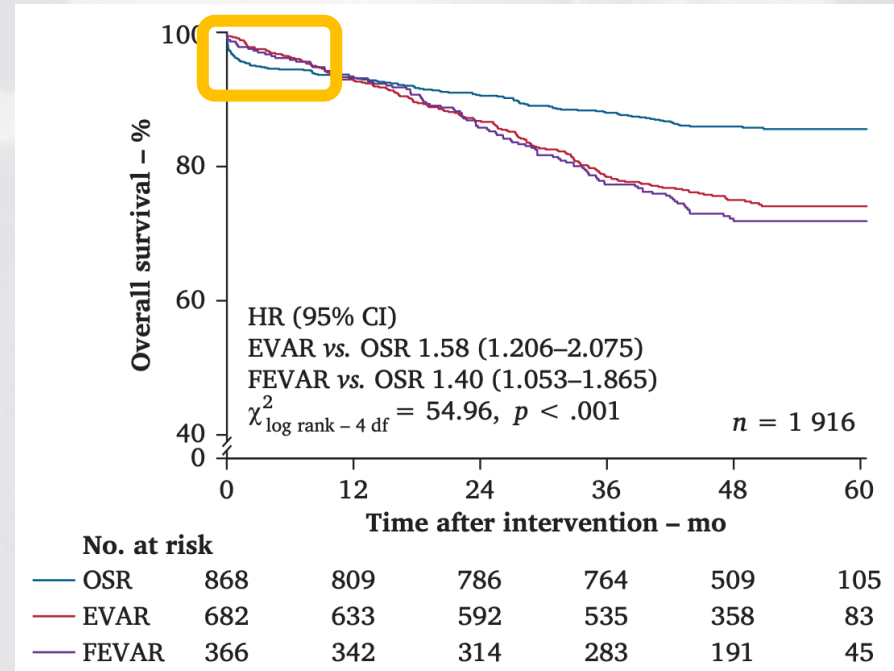
FEVAR vs Open repair: UK-COMPASS

- Long-term (3.5 years) results (after matching)
- “there is no doubt that the longer-term all-cause mortality is significantly better for open repair,” - JR Boyle @Vascular Society of Great Britian

| | | |
|------------------------|--------------------|-------|
| <i>Full population</i> | | |
| EVAR vs. OSR | 2.18 (1.608–2.95) | <.001 |
| FEVAR vs. OSR | 2.01 (1.463–2.772) | <.001 |
| <i>0–4 mm neck</i> | | |
| <i>Standard risk</i> | | |
| EVAR vs. OSR | 2.4 (0.822–6.984) | .11 |
| FEVAR vs. OSR | 1.64 (0.991–2.715) | .054 |
| <i>High risk</i> | | |
| EVAR vs. OSR | 2.02 (0.624–6.547) | .24 |
| FEVAR vs. OSR | 2.14 (0.952–4.805) | .066 |
| <i>5–9 mm neck</i> | | |
| <i>Standard risk</i> | | |
| EVAR vs. OSR | 3.55 (1.585–7.967) | .002 |
| FEVAR vs. OSR | 2.83 (1.208–6.639) | .017 |
| <i>High risk</i> | | |
| EVAR vs. OSR | 0.91 (0.337–2.456) | .85 |
| FEVAR vs. OSR | 1.95 (0.626–6.093) | .25 |
| <i>≥ 10 mm neck</i> | | |
| <i>Standard risk</i> | | |
| EVAR vs. OSR | 3.52 (1.973–6.291) | <.001 |
| FEVAR vs. OSR | 4.18 (1.802–9.676) | .001 |
| <i>High risk</i> | | |
| EVAR vs. OSR | 1.37 (0.652–2.885) | .41 |
| FEVAR vs. OSR | 0.79 (0.202–3.069) | .73 |

A Note on Short Term Outcomes

- Perioperative complications drive the short term differences
- What if we spent half the resources (\$\$) from FEVAR on improving open repair ?



**But patients
prefer FEVAR**



Patient Preference

- Patients would prefer no intervention at all
- Patients don't know what they want
- Our job to guide them

On training

- F/BEVAR is a self-fulfilling prophesy
- If we let our open repair skills atrophy, outcomes will be worse and endo repair will really be better

In Conclusion...

- You can ignore all available data at your patients' peril

In Conclusion...

- In the real world, for most patients a 40% reintervention rate is untenable
- Patients that benefit from aneurysm repair benefit the most from open repair
- Open repair is still right for most patients