Outcomes Of EVAR In Over 18,000 High-Risk Patients Ineligible For Open Repair: When Is EVAR Justified Over No Intervention In Such Patients: Why Is EVAR 2 No Longer Relevant

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No relationships with commercial companies.

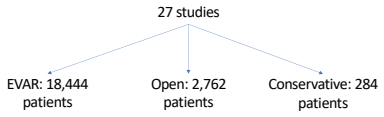
Information presented in this lecture is based on evidence.

- Patients with AAA are frail, have several comorbidities and reduced overall survival.
- EVAR-2 trial found that even though EVAR reduces the aneurysm-related mortality in patients physiologically ineligible for open repair, it does not increase the overall life expectancy.
- Controversy remains regarding benefits of EVAR compared to non-operative management in high risk patients with AAA.

Our primary objectives were:

- To investigate perioperative mortality rates of EVAR in high risk patients.
- To compare survival of EVAR versus non-operative management in high risk patients.
- To compare survival of EVAR in high risk versus low risk patients.

All published studies reporting EVAR in high risk patients



Variability in definitions of "high risk"

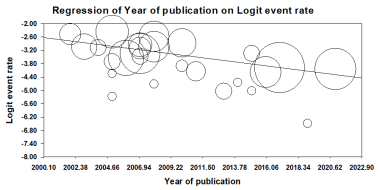
EVAR-2 criteria:

- MI or onset of angina within last 3 months
- Unstable angina
- Severe valve disease
- Significant arrhythmia
- Uncontrolled CCF
- Unable to walk up a flight of stairs without shortness of breath
- FEV1<1lt, PO2<8kPa, PCO2 >6.5kPa
- Serum Cr >200µmol/l

Pooled perioperative mortality of EVAR in high risk patients: 3% (95%CI 2.3%-4%)

- National Vascular Registry 2024 Annual Report: 0.3% in-hospital mortality
- National Surgical Quality Improvement Program: 1.2% 30-day mortality

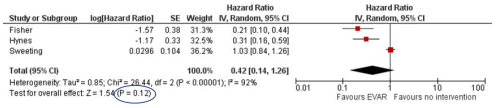
Decreasing perioperative mortality after EVAR in high risk patients over the years



EVAR high vs normal risk patients

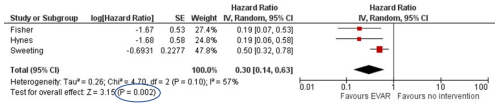
Outcome	Hazard ratio (95% CI)	P value
Perioperative mortality	2.33 (1.75-3.10)	<0.001
Overall mortality	3.50 (2.55-4.80)	<0.001
Aneurysm-related mortality	1.88 (1.61-2.20)	<0.001

EVAR vs conservative



Overall mortality

EVAR vs conservative



Aneurysm-related mortality

EVAR vs conservative for high risk patients

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	EVAR	No intervention	Relative (95% CI)	Absolute		
All-cause mortality												
5	observational studies	serious[1]	serious[2]	no serious indirectness	serious[3]	strong association[4]	-	-	HR 2.37 (0.79 to 7.08)	-	⊕⊕⊕⊕ VERY LOW	CRITICAL
Aneurysm-related mortality												
3	observational studies	serious[1]	serious[2]	no serious indirectness	no serious imprecision	strong association[4]	-	-	HR 3.34 (1.58 to 7.07)	-	⊕⊕⊕⊕ VERY LOW	CRITICAL

1 Failure to adhere to the intention to treat principle in a significant proportion of patients

2 Different definitions of high risk across studies

3 Low sample size, 95% CI includes both 1 and appreciable benefit or harm

4 HR >2

Is EVAR 2 still relevant?

ESA-Randomized Controlled Trial

Endovascular Repair of Abdominal Aortic Aneurysm in Patients Physically Ineligible for Open Repair

Very Long-term Follow-up in the EVAR-2 Randomized Controlled Trial

Michael J. Sweeting, PhD, Rajesh Patel, PhD,† Janet T. Powell, MD,† and Roger M. Greenhalgh, MD†, for the EVAR Trial Investigators*

- Recruitment: 1999-2004
- 30-day mortality in the EVAR group: 9%*
- Best medical therapy:
  a. Aspirin: 58% in EVAR group, 54% in no intervention group
  b. Statin: 39% in EVAR group, 40% in no intervention group

*EVAR trial participants. Lancet. 2005;365:2187-92.

What do the guidelines say?

ESVS 2024 Clinical Practice Guidelines on the Management of Abdominal Aorto-Iliac Artery Aneurysms

Recommendation 67			Unchanged
For patients with limited life expectancy, elective abdominal aortic aneurysm repair is not recommended, either open or endovascular repair.			
Class	**Level**	**References**	**ToE**
III	B	Greenhalgh *et al.* (2010)[2658]	

"A pragmatic definition of limited life expectancy is less than 2-3 years."

SVS 2018 practice guidelines on the care of patients with an abdominal aortic aneurysm

We suggest informing high-risk patients of their VQI perioperative mortality risk score for them to make an informed decision to proceed with aneurysm repair.	
Level of recommendation	2 (Weak)
Quality of evidence	C (Low)

"A pragmatic definition of limited life expectancy is less than 2-3 years."

NICE guideline 2020
Abdominal aortic aneurysm: diagnosis and management

The decision on whether repair is preferred over conservative management should be made jointly by the person and their clinician after assessment of a number of factors, including:

- aneurysm size and morphology
- the person's age, life expectancy, fitness for surgery, and any other conditions they have
- the risk of AAA rupture if they do not have repair
- the short- and long-term benefits and risks, and the other disadvantages of repair such as having to stay in hospital, the risks of the operation, the recovery period, the potential need for further procedures and the need for surveillance imaging appointments
- the uncertainties around estimates of risk for AAAs larger than 5.5 cm (measured inner-to-inner maximum anterior-posterior aortic diameter on ultrasound).

Take home messages

- There appears to be no consensus among vascular specialists on the definition of “high risk”.
- The perioperative mortality of EVAR in high risk patients has improved over time.
- EVAR may not prolong the life of high risk patients compared to conservative management.
- EVAR confers an aneurysm-related survival advantage over no intervention.
- Personalized management with shared decision-making is probably the optimal approach.