The Benefits of EVAR Are Age Dependant: Lessons From Long Term Outcomes in The UK

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Disclosures

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Acknowledgements

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  – Amundeeep Johal
  – Sam Waton
  – David Cromwell
EVAR-I Trial Outcomes

Continued benefit to 4 years lost at 6 years
Equivalent long-term all cause and aneurysm-related mortality
Increased EVAR complications and re-intervention

Rate and Predictability of Graft Rupture After Endovascular and Open Abdominal Aortic Aneurysm Repair
Data From the EVAR Trials

Thomas R. Wyss, MD, Louise C. Brown, PhD, Janet T. Powell, MD, and Roger M. Greenhalgh, MA, MD, MCh, FRCS

Objective: To assess the rate and factors associated with rupture after endovascular aneurysm repair (EVAR) or open repair (OR) of abdominal aortic aneurysm.

Background: Graft rupture after EVAR has been reported, often preceded by graft-related complications. Graft rupture has also been reported after OR.

Methods: By July 2009, a total of 148 elective EVARs and 864 elective ORs were performed in the United Kingdom EVAR trials 1 and 2. Patients were followed up for complications, reinterventions, and rupture. The incidence of rupture was explored in relation to baseline anatomy and subsequent complications in a Cox regression analysis.

Increased EVAR complications and re-intervention could lead to higher graft-related complications and mortality. The outcome of endograft rupture is associated with high mortality. However, graft-related complications after EVAR are frequent, and the EVAR-2 trial registry has indicated mild increases in long-term all-cause and aneurysm-related mortality due to increased EVAR complications and re-intervention.

The equivalent long-term all cause and aneurysm-related mortality is due to the increased EVAR complications and re-intervention.

New results from the EVAR-2 trial registry indicate that increased EVAR complications and re-intervention could lead to lower graft-related complications and mortality. The outcome of endograft rupture is associated with high mortality. However, graft-related complications after EVAR are frequent, and the EVAR-2 trial registry has indicated mild increases in long-term all-cause and aneurysm-related mortality due to increased EVAR complications and re-intervention.

Annals of Surgery • Volume 252, Number 5, November 2010

Patients fit for OR were entered into EVAR trial 1 and randomized to either EVAR or OR. Patients unfit for OR were entered into EVAR trial 2 and randomized to either EVAR or no intervention. Patients have been followed for mortality, complications, reinterventions, and rupture with regular CT imaging requested at 1 and 3 months post-endovascular repair and annually thereafter for all patients. The trial closed at the end of December 2009 and follow-up was complete; 94% in EVAR trial 1 and 97% in EVAR trial 2, with all deaths and deaths from aneurysm-related events. Patients who had undergone successful aneurysm-related events by a surveillance committee. The EVAR-2 trial registry has indicated mild increases in long-term all-cause and aneurysm-related mortality due to increased EVAR complications and re-intervention.

New results from the EVAR-2 trial registry indicate that increased EVAR complications and re-intervention could lead to lower graft-related complications and mortality. The outcome of endograft rupture is associated with high mortality. However, graft-related complications after EVAR are frequent, and the EVAR-2 trial registry has indicated mild increases in long-term all-cause and aneurysm-related mortality due to increased EVAR complications and re-intervention. Patients who had undergone successful aneurysm-related events by a surveillance committee. The EVAR-2 trial registry has indicated mild increases in long-term all-cause and aneurysm-related mortality due to increased EVAR complications and re-intervention.
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*

Summary

Background  Short-term survival benefits of endovascular aneurysm repair (EVAR) versus open repair of intact abdominal aortic aneurysms have been shown in randomised trials, but this early survival benefit is lost after a few years. We investigated whether EVAR had a long-term survival benefit compared with open repair.

Methods  We used data from the EVAR randomised controlled trial (EVAR trial 1), which enrolled 1252 patients from 37 centres in the UK between Sept 1, 1999, and Aug 31, 2004. Patients had to be aged 60 years or older, have aneurysms of at least 5.5 cm in diameter, and deemed suitable and fit for either EVAR or open repair. Eligible patients were randomly assigned (1:1) using computer-generated sequences of randomly permuted blocks stratified by centre to receive either EVAR (n=626) or open repair (n=626). Patients and treating clinicians were aware of group assignments, no masking was used. The primary analysis compared total and aneurysm-related deaths in groups until mid-2015 in the intention-to-treat population. This trial is registered at ISRCTN (ISRCTN55703451).

Findings  We recruited 1252 patients between Sept 1, 1999, and Aug 31, 2004. 25 patients (four for mortality outcome) were lost to follow-up by June 30, 2015. Over a mean of 12.7 years (SD 1.5; maximum 15.8 years) of follow-up, we recorded 9.3 deaths per 100 person-years in the EVAR group and 8.9 deaths per 100 person-years in the open-repair group (adjusted hazard ratio [HR] 1.11, 95% CI 0.97–1.27, p=0.14). At 0–6 months after randomisation, patients in the EVAR group had a lower mortality (adjusted HR 0.61, 95% CI 0.37–1.02 for total mortality; and 0.47, 0.23–0.93 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.
EVAR-I Trial: 15 Year Survival

EVAR has…an inferior late survival compared with open repair
Lifelong surveillance and re-intervention if necessary
The World Is Evolving
Sceptics of the EVAR Trial Conclusions

• ‘Its historical and endovascular practice continues to evolve…..’

• Effect of learning curve and specialisation

• The trials weren’t powered for long term outcomes

• Over-intervention in EVAR-1 trial in some patients

• Under-intervention in others (type 1 and 3 leaks)

• Loss to surveillance is not a fault of the technique
Patient Preference
Patient Preference

• 84% of patients on surveillance would opt for EVAR over OR despite durability concerns

• Major concerns
  – Operative mortality
  – Risk of major organ failure

• Least concern
  – Surveillance
  – Re-intervention

Winterborn et al JVS 2009 49:567-81
Aims of Study

• Analyse long term (7 year) outcomes of OR/EVAR in large scale UK datasets
• Retrospective analysis of hospital episode statistics (HES) and mortality (ONS), 2006-13
• Stratified by age and comorbidity
• Restricted mean survival time
Aims of Study

• Analyse long term outcomes of OR/EVAR in large scale ‘real world’ datasets
• Retrospective analysis of hospital episode statistics (HES) and mortality (ONS), 2006-13
• Stratified by age and comorbidity
• Restricted mean survival time
• 29,285 repairs (13,036 OR, 16,249 EVAR)
Overall Outcomes: Survival

Number at risk

- oAAA: 13024, 11378, 9824, 8195, 6688, 5142, 3535, 1958
- EVAR: 16247, 13801, 10502, 7495, 4910, 2930, 1482, 561

Analysis Time (Months)
Mortality: <70 years, no comorbidities

Number at risk

- Open
  - 2010: 1882
  - 2011: 1645
  - 2012: 1395
  - 2013: 1165
  - 2014: 930
  - 2015: 669
  - 2016: 417

- EVAR
  - 2010: 1117
  - 2011: 1016
  - 2012: 823
  - 2013: 640
  - 2014: 462
  - 2015: 301
  - 2016: 171
  - 2017: 64

Graph showing the number at risk over analysis time (months) for open and EVAR procedures.
Mortality: 70-74 years, no comorbidities
Mortality: 75-79 years, no comorbidities
Mortality: >80 years, no comorbidities

Analysis Time (Months)

Number at risk

Open 782 674 593 511 423 331 226 117
EVAR 1792 1571 1209 872 581 320 154 58

Open EVAR

Mortality: >80 years, no comorbidities
Mortality: <70 years, with comorbidities

Number at risk

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Mortality: 70-74 years, with comorbidities

Analysis Time (Months)

Number at risk

Open 2038 1741 1490 1235 983 725 481 271
EVAR 2382 2048 1552 1115 727 408 225 87

EVAR

Open

Open

EVAR
Mortality: 75-79 years, with comorbidities

Number at risk
- Open: 1924 1611 1368 1125 886 649 418 240
- EVAR: 3000 2479 1836 1236 781 457 217 69

Analysis Time (Months)
- Open
- EVAR

St George's Vascular Institute
Mortality: >80 years, with comorbidities

Number at risk

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Analysis Time (Months)
Ruptured Aneurysm Mortality

Kaplan-Meier Time to Rupture Estimates

Analysis Time (Months)

Number at risk

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- **EVAR**
- **Open**
Ruptured Aneurysm Mortality >80 years

![Graph showing Kaplan-Meier Time to Rupture Estimates for Open and EVAR procedures.](graph_image)

- **Number at risk**
  - Open
    - 1161
    - 1066
    - 957
    - 809
    - 675
    - 534
  - EVAR
    - 3188
    - 2540
    - 1959
    - 1377
    - 897
    - 525

- **Analysis Time (Months)**
  - 0
  - 12
  - 24
  - 36
  - 48
  - 60

- **Percentage Surviving Rupture**
  - 100
  - 95
  - 90

**Kaplan-Meier Time to Rupture Estimates**

**Ruptured Aneurysm Mortality >80 years**

**Analysis Time (Months)**

**Number at risk**

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<th>Procedure</th>
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**St George's Vascular Institute**

IML LINC January 2017
Conclusion

• UK data suggests equivalent outcomes for EVAR and OR to 7 years, if ‘fit’

• The early benefit of EVAR is larger in old/unfit

• In the unfit, the early EVAR benefit is lost <3 years

• Surveillance will remain essential after EVAR

• But death from rAAA remains an unusual event

• Multiple limiting factors need further investigation
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