



13th International Symposium
on Endovascular Therapeutics

Session 6

**CEC@SITE: UNMET NEEDS IN EVAR:
A FLAVOUR OF SITEupdate**



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on Endovascular Therapeutics

• Moderators:

- L. Kou(China)
- N. Mosquera (Spain)

Panellists:

- A. Katsargyris (Germany)
- R. Kolvelbach (Germany)
- X. Jia (China)
- L. Wang (China)
- A. Azizzadeh, (USA)
- I. Loftus (UK)



1. Durability concerns for EVAR: is this an unmet need or something from the past?
2. Sac filling technology: a real need or just another adjunctive issue trying to deal with type II?
3. Ancillary devices to secure fixation: is this something to explore?
4. Image guidance for procedure must evolve to an XRay free approach. Is this a real need?
5. Is now the time for a new deep technological change? In which direction?
6. Who should lead data and evidence collection to support EVAR practice? And how to do it?



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1. Durability concerns for EVAR: is this an unmet need or something from the past?



2008



2009

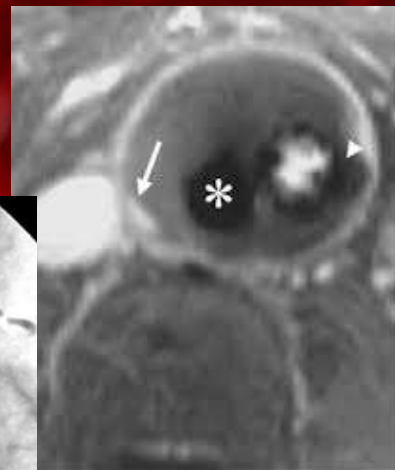
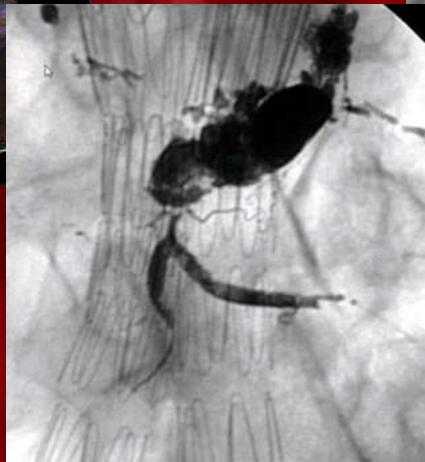
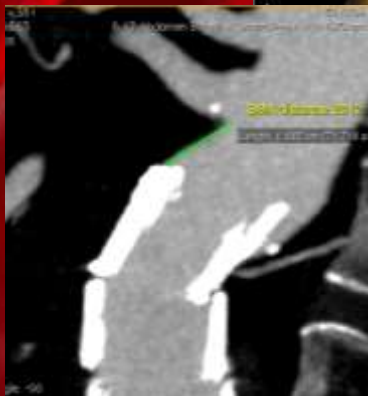
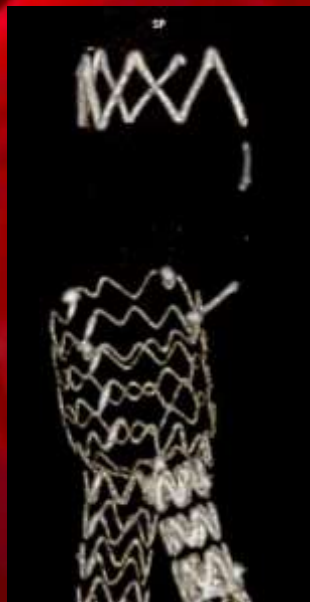


2016



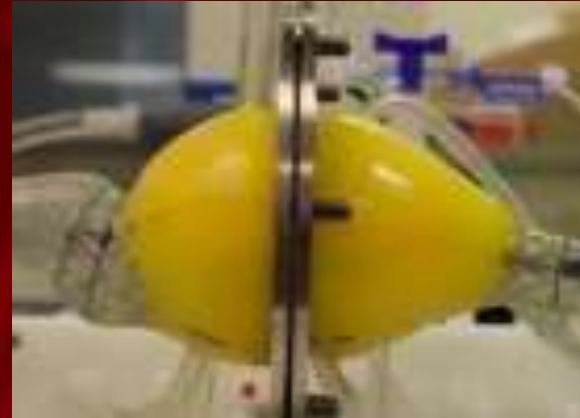
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1. Durability concerns for EVAR: is this an unmet need or something from the past?





2. Sac filling technology: a real need or just another adjunctive issue trying to deal with type II?





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3. Ancillary devices to secure fixation: is this something to explore?

Endurant II/IIIs stent graft receives FDA approval for short neck anatomies with Heli-FX EndoAnchor

11th October 2017



Medtronic has received US Food and Drug Administration (FDA) approval for the Endurant II/IIIs stent graft system to treat abdominal aortic aneurysm (AAA) patients with neck lengths down to 4mm and ≤ 60 degrees infrarenal angulation when used in combination with the Heli-FX EndoAnchor system. The expanded indication enables the Endurant II/IIIs stent graft to be used in conjunction with the Heli-FX EndoAnchor system to treat a wider range of patients with short, hostile aortic neck anatomies, independent of renal stenting.

EXPANDING PATIENT CARE OPTIONS

Medtronic provides the first CE Mark approved short neck solution independent of renal stenting.



INDICATED FOR NECKS $\leq 10\text{mm}$ DOWN TO 4mm

| | | |
|---------------------------------------------------|---|-------------------------------------|
| Endurant II/IIIs AAA Stent Graft System | + | Heli-FX EndoAnchor System |
|---------------------------------------------------|---|-------------------------------------|



4 mm neck length!!!



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4. Image guidance for procedure must evolve to an Xray-free approach. Is this a real need?





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5. Is now the time for a new deep technological change? In which direction?





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6. Who should lead data and evidence collection to support EVAR practice? And how to do it?



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 Sawerting, 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=0.011), 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 3.82, 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 [2%] 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; 388: 1264-74
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See Commented page 1216

*The EVAR trial investigators are listed in the appendix

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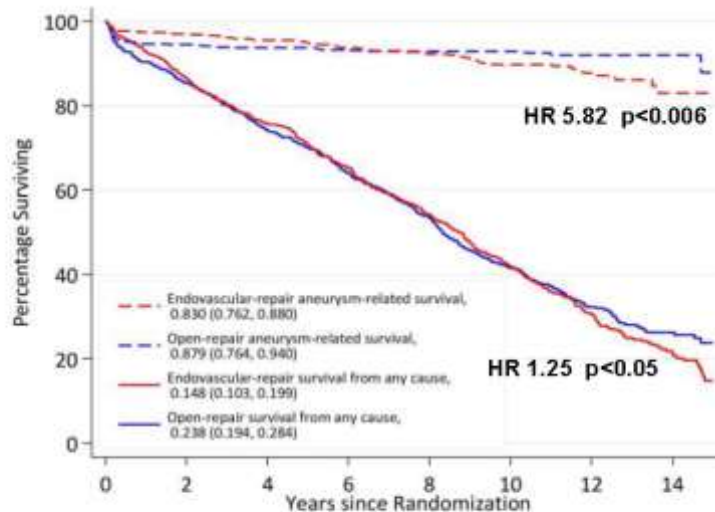
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See Online for appendix



| | 0 | 2 | 4 | 6 | 8 | 10 | 12 | 14 |
|---------------------|-----|-----|-----|-----|-----|-----|-----|----|
| Endovascular repair | 626 | 543 | 474 | 409 | 339 | 263 | 135 | 41 |
| Open repair | 626 | 534 | 464 | 399 | 333 | 257 | 143 | 50 |



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6. Who should lead data and evidence collection to support EVAR practice? And how to do it?

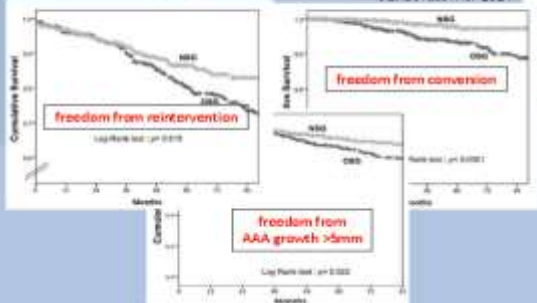
EVAR TODAY

- ✓ Evolution of technique and materials

Abdominal Aortic Endografting Beyond the Trials: A 15-Year Single-Center Experience Comparing Newer to Older Generation Stent-Grafts

Fabio Verzini, MD, PhD, FEBVS¹; Giacomo Isomaa, MD²; Paolo De Rango, MD, PhD, FEBVS¹; Gioele Simonetti, MD³; Gianbattista Parlani, MD⁴; Diletta Loschi, MD⁵; and Piergiorgio Cosi, MD, FRCS⁶

1412 consecutive elective EVAR from 1997 to 2011
J Endovasc Ther 2014





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European Journal of Vascular and
Endovascular Surgery

Volume 44, Issue 4, October 2012, Pages 369-375



Early Results from the ENGAGE Registry: Real-world Performance of the Endurant Stent Graft for Endovascular AAA Repair in 1262 Patients

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