DECADES OF EVAR RCTs and Registries: what do they tell us?

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DISCLOSURE
Medtronic: consulting, sales training

EVAR-1

Stent-grafts used in EVAR 1 Trial
4 Years after Randomization – EVAR vs. OPEN

- Post-operative complications were higher in the EVAR group
- Re-intervention rate of 20% in EVAR vs. 6% in OR group
- All-cause mortality was similar (28%)
- Persistent reduction in aneurysm-related deaths in the EVAR group (4% vs. 7%)

Aneurysm-Related Mortality through 4 years

- > 50% of aneurysm-related mortality after 30 days due to aneurysm rupture

Graft-related complications lead to rupture

Charing Cross 2010
- The EVAR 1 trial at 10 years:
  - EVAR has a lower operative mortality, But
  - at 6 years the advantage of aneurysm-related mortality is lost

ENGAGE Global Registry

Largest Contemporary EVAR Registry with single manufacturer’s stent graft ENDURANT

- 1263 Patients
- 30 Countries
- 6 Continents
- Real world patients - Real world practice - Standard follow-up

- 14 publications and > 100 presentations at major International/National conferences characterizing ENDURANT clinical outcomes
Multicenter Prospective RCT of 1252 patients (626 patients in each arm) who had aneurysms of 5.5cm or larger

Patient considered anaesthetically fit for an open repair

Enrollment period: September 1999 – August 2004

Follow-up (min-max): 5–10 yrs. (median 6 years)

Multiple 1st Gen endografts used: 51% Zenith, 33% Talent, 7% Excluder, 4% AneuRx, 5% ‘other’

“Real-world all-comers” Registry

1263 patients consecutively enrolled (2009-2011)

Follow-up: 30-day, annual visits through 10 years

Single 4th generation device: Endurant (Medtronic)

Extensive monitoring on-going

100% data review

Independent data monitoring (100% endpoints)

Independent Clinical Event Committee

Lower complications led to fewer reinterventions in ENGAGE vs. EVAR 1

13% vs. 20%

35% Reduction

No difference in all cause mortality

3% difference aneurysm-related mortality

No difference in ACM

5% difference ARM

ENGAGE vs OSR (EVAR 1 Cohort)
### Summary

- **Landmark EVAR 1 trial demonstrated:**
  - early benefit of EVAR could be maintained through 4 yrs.
  - but at the cost of higher reintervention rates
  - Early benefit of EVAR was lost by 6 yrs. with >50% of late deaths due to rupture after EVAR
- **Direct correlation between postop complications and reinterventions**
- **ENGAGE:** Lower complications = lower reinterventions (35% reduction)
- **ENGAGE:** lower ARM, lower post EVAR rupture mortality

### Conclusions

- Newer generation devices can reference data from **EVAR 1** to benchmark clinical performance
- The **ENGAGE** registry demonstrates how EVAR evolution has contributed to improved patients outcomes
- Large real world registries (like ENGAGE) will hopefully allow us to gain insight on how to customize patient follow-up, which will increase the cost-effectiveness of EVAR.
- Longer-term data necessary to determine if durability is maintained (ENGAGE follow-up will extend to 10 years)