A Direct Comparison of Long-Term Survival for Major Contemporary EVAR Devices using Big Data and Linkage Techniques

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Australian and New Zealand Society for Vascular Surgery

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Disclosures

Consultant to:
- Medtronic
- Abbott Vascular
- BD Bard
- Intervene
- Surmodics
- Philips Healthcare
- Nectero Medical
- Endospan
- Boston Scientific
- Vesteck
- W.L. Gore
- R3 Vascular
- Cook Medical
- Concept Medical
- Inari

Equity:
- EBR Systems
- Provisio Medical, inc
- Vesteck Inc

Background: EVAR Stent-grafts

- EVAR is now the dominant method of AAA repair
  - Reduced perioperative morbidity and mortality
  - Less blood loss
  - Less ICU utilization
  - Shorter LoS

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- EVAR stent-grafts differ however…
  - Design
  - Component materials
  - Deployment methods

Systematic Review of RCTs Comparing Stent-grafts

Cochrane Library
Cochrane Database of Systematic Reviews

Stent graft types for endovascular repair of abdominal aortic aneurysms (Review)

Duffy JMN, Rolph R, Clough RE, Modarai B, Taylor P, Waltham M

Authors' conclusions

Unfortunately, no data exist regarding direct comparisons of the performance of different stent graft types. Therefore, this review cannot recommend guidance to clinicians in their selection of stent graft types. High quality randomised controlled trials evaluating stent graft types in abdominal endovascular aneurysm repair are required.

Duffy JM, Rolph R, Waltham M. Stent graft types for endovascular repair of abdominal aortic aneurysms. Cochrane Database Syst Rev. 2015;2015(9):CD008447

Comparative Observational Studies

All have limitations…

- Some compared older stent-grafts no longer in clinical use[1,2]
- Others focused in-hospital patient outcomes[3]
- Small sample size, single institution[4-7]
- None investigated long-term mortality

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2. Ouriel K, Clair DG, Greenberg RK, et al. Endovascular repair of abdominal aortic aneurysms: device-specific outcome. J Vasc Surg. 2003;37(5):991-8.
3. Zetterlund SL, Deery SE, Soden PA, et al. Editor's Choice - Renal complications after EVAR with suprarenal versus infrarenal fixation among all users and routine users. Eur J Vasc Endovasc Surg. 2017;54(3):287-93.
4. Buck DB, Soden PA, Deery SE, et al. Comparison of Endovascular Stent Grafts for Abdominal Aortic Aneurysm Repair in Medicare Beneficiaries. Annals of vascular surgery. 2018;47:31-42.
5. Oliveira-Pinto J, Oliveira NFG, Bastos-Goncalves FM, et al. Long-term results after standard endovascular aneurysm repair with the Endurant and Excluder stent grafts. J Vasc Surg. 2020;71(1):64-74.
6. Abbruzzese TA, Havelock CJ, Brewster DC, et al. Outcomes following endovascular abdominal aortic aneurysm repair (EVAR): an anatomic and device-specific analysis. J Vasc Surg. 2008;48(1):19-28.
7. Maudet A, Dasoudi A, Cardon A, et al. Endovascular Treatment of Infrarenal Aneurysms: Comparison of the Results of Second- and Third-Generation Stent Grafts. Annals of vascular surgery. 2016;34:96-105

An Alternative Approach…

- Data linkage studies may have advantages over RCTs
  - Larger sample sizes
  - Fewer subjects lost to follow-up
- Linking clinical registries to administrative data sources
- These capture all the deaths (fact and also cause of death, based on death certificates)
- Adjustment for confounders using Propensity Score Matching

Our Aim…

To use linked clinical registry and administrative data to investigate differences in:

- Long term all-cause mortality (Primary Endpoint)
- Secondary intervention rates
- Secondary aortic rupture rates

Between contemporary EVAR stent-graft devices

Falster MO, etal European Journal of Vascular & Endovascular Surgery, https://doi.org/10.1016/j.ejvs.2022.11.005.

Data Linkage Methods

APDC

Admitted Patient Data Collection
- All inpatient episodes in NSW Hospitals
- Patient demographics
- Diagnoses (ICD-10-AM codes)
- Procedures performed

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NSW Registry of Births Deaths & Marriages

NSW BBDM
- All deaths in NSW

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NSW BBDM
- All deaths in NSW

NSW Health

NSW Cause of Death Unit Record File
- Fact of death data
- Underlying cause
- Contributing causes

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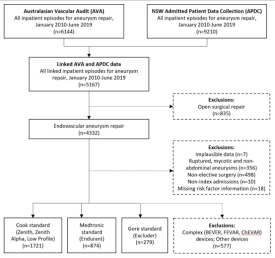
Flowchart



Results

- Between 2010-2019
- 2,874 EVAR for intact AAA
  - Cook Zenith Standard; n=1,721
  - Cook Complex (FEVAR or BEVAR); n=447
  - Medtronic, Endurant; n=884
  - Gore, Excluder; n=279

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- Patients who underwent EVAR were:
  - Medtronic and Complex Cook grafts had more >60mm aneurysms
  - More patients with a Standard Cook device had high ASA (4 or 5) scores
- After Propensity Score matching EVAR and OSR patient characteristics were similar between groups

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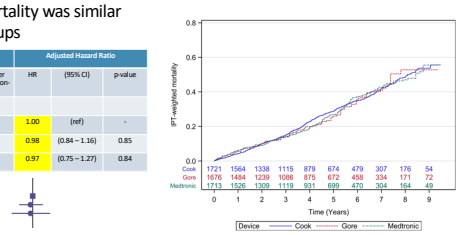
Results – All Cause Mortality

- All-cause mortality was similar between groups

	Unadjusted Rate of Outcome		Adjusted Hazard Ratio		
	n events / N persons	Rate per 100 person-years	HR	(95% CI)	p-value
All-cause mortality					
Cook (standard)	529 / 1721	7.1	1.00	(ref)	-
Medtronic	263 / 884	7.3	0.98	(0.84 – 1.16)	0.85
Gore	80 / 279	7.0	0.97	(0.75 – 1.27)	0.84



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Results – Cause Specific Mortality

- Cause specific mortality was similar between groups

	Unadjusted Rate of Outcome		Adjusted Hazard Ratio		
	n events / N persons	Rate per 100 person-years	HR	(95% CI)	p-value
Cardiovascular-related mortality					
Cook (standard)	133 / 1563	2.4	1.00	(ref)	-
Medtronic	78 / 771	2.9	1.10	(0.81 – 1.49)	0.55
Gore	20 / 252	2.4	0.85	(0.51 – 1.42)	0.53
Pulmonary-related mortality					
Cook (standard)	48 / 1563	0.9	1.00	(ref)	-
Medtronic	20 / 771	0.7	0.84	(0.46 – 1.51)	0.55
Gore	7 / 252	0.8	0.95	(0.39 – 2.34)	0.91
Cancer-related mortality					
Cook (standard)	92 / 1563	1.6	1.00	(ref)	-
Medtronic	47 / 771	1.7	1.05	(0.72 – 1.54)	0.80
Gore	15 / 252	1.8	0.99	(0.53 – 1.86)	0.98

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Results – AAA Specific Mortality

- AAA specific mortality was similar between groups

	Unadjusted Rate of Outcome		Adjusted Hazard Ratio		
	n events / N persons	Rate per 100 person-years	HR	(95% CI)	p-value
AAA-related mortality					
Cook (standard)	12 / 1563	0.2	1.00	(ref)	-
Medtronic	11 / 771	0.4	1.28	(0.56 – 2.96)	0.56
Gore	<5 / 252	0.1	0.95	(0.12 – 7.35)	0.96

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	n events / N persons	Rate per 100 person-years	HR	(95% CI)	p-value
AAA-related mortality					
Cook (standard)	12 / 1563	0.2	1.00	(ref)	-
Medtronic	11 / 771	0.4	1.28	(0.56 – 2.96)	0.56
Gore	<5 / 252	0.1	0.95	(0.12 – 7.35)	0.96

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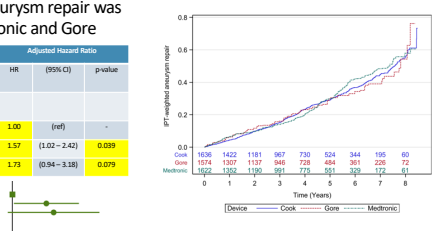
Results – Subsequent Aneurysm Repair

- Subsequent aneurysm repair was higher in Medtronic and Gore

	Unadjusted Rate of Outcome		Adjusted Hazard Ratio		
	n events / N persons	Rate per 100 person-years	HR	(95% CI)	p-value
Subsequent aneurysm repair					
Cook (standard)	52 / 1636	0.8	1.00	(ref)	-
Medtronic	44 / 815	1.5	1.57	(1.02 – 2.42)	0.039
Gore	14 / 263	1.5	1.73	(0.94 – 3.18)	0.079



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Conclusion

- There was no difference in long term mortality observed between endografts

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- There was no difference in long term mortality observed between endografts
- There was no difference in secondary intervention rates overall

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Conclusion

- There was no difference in long term mortality observed between endografts
- There was no difference in secondary intervention rates overall
- Medtronic and Gore endografts had higher rates of subsequent aneurysm repair

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