



Specialist Vascular Surgeons

**Para-renal, Supra-renal and Para-visceral AAA:
Custom-made devices for B/FEVAR**

© 2025 Specialist Vascular Surgeons. All rights reserved.

This presentation is for informational purposes only and may not be copied, distributed, or used without written permission from the author.

Para-renal, Supra-renal and Para-visceral AAA: Custom-made devices for B/FEVAR

Dr Pradeep P. Mistry

Dr Ian R. Grant

Introduction

- EVAR
 - More prevalent repair for AAA
 - Limitations w.r.t. anatomic suitability:
 - Aortic neck length
 - Angulation of neck
 - Thrombus in neck
 - Diameter of aortic bifurcation
 - Iliac artery aneurysms
 - Access vessels
- Higher complications, mortality and cost.

Instructions for use (IFU)

- Dependant on:
 - Characteristics of graft design
 - Conformity of graft to anatomy of aneurysm
- Advances in endovascular surgery for AAA:
 - Expand indication
 - Challenge limits within the IFU

Instructions for use (IFU)

- Consensus to define attitude of Italian vascular surgeons to standard EVAR outside of IFU
 - 15% agreed with statements in the 1st round of Delphi.
 - Confirmed discrepancy between Guidelines and daily clinical practice.

Fenestrated and Branched grafts

- Expand indication of standard EVAR beyond infra-renal AAA
 - Juxta-renal (<4mm neck)
 - Para-renal (no neck, involves at least one renal artery)
 - Para-visceral (involves both renals and SMA, not celiac)
 - Suprarenal
- Custom-made
 - Per individual patient
 - Combination of fenestrations or branches
- Expensive, but
 - Enables endovascular repair rather than open operation

Fenestrated and Branched grafts: Technique

- Percutaneous access or cut downs onto the groins
- Over-the-wire techniques and fluoroscopy to place CMD into the aorta
 - Fenestrations placed adjacent to visceral and renal arteries.
- Large sheath in the contra-lateral groin
 - Insert multiple smaller longer sheaths to access CMD from below,
 - and exit respective fenestrations for cannulation of target vessels.
- Deployment of CMD device.
- Deployment of bridging covered stents into target vessels
- Proximal part of each stent graft is flared
 - Creates seal between CMD and bridging stent
- Standard EVAR completes procedure
- Access site closure.

Fenestrated and Branched grafts:

Key role players to successful outcomes

- Patient selection
- Technical considerations
- Staging of procedures
- Adjuncts to anaesthesia
- Type and extent of pathology at hand
- Institutional expertise
- Experience

Fenestrated and Branched grafts: Challenges

- Timeous approval for funding
 - Expensive technologies
- Long design and production time
- Lack of availability of hybrid theatre facilities (especially state hospitals)
- Absence of high-volume aortic centres

Challenges:

South African Landscape

- Two-tiered healthcare system
- ± 9 million people have access to private health care
- GDP in 2nd quarter of 2021
 - R1131 billion with a growth of 1%
- Rated 37th richest country in the world
 - 49.2% of adult population lives below the upper bound poverty line
 - 80% do not have private health insurance
 - Depend on state for health care
 - Private health care perceived to be of good standard

Challenges:

South African Landscape

- Advanced technologies (Fenestrated and Branched EVAR)
 - Increase the cost of treatment.
 - More insured people buy down to basic health care insurance to save costs
 - Unemployment rate = 34.4%
- NHI will make:
 - Make F/BEVAR unaffordable and unsustainable.
 - Contribute to high turn down rate for F/BEVAR
 - Only 11 performed in state sector (Western Cape 4 and Free State 7)

Challenges:

Institutional Experience and Expertise

- Vascular surgical team needs to be familiar with procedure-specific requirements
 - Vascular surgeons
 - Operating room staff
 - Radiographers
 - Theatre nurses
 - Anaesthetists
- Post-operative
 - ICU → multi-disciplinary specialist team of intensivists, pulmonologists, nephrologists and cardiologists.
- Hybrid theatre essential
- No high volume centres for complex aortic aneurysms in SA

Literature Review

- EVAR
 - initially for high-risk patients
- EVAR trials
 - Good risk patients benefit most
- Is FEVAR most beneficial for high risk patients?
 - Not necessarily
 - Focus on
 - Projected life expectancy

Literature Review

- Most para-renal, para-visceral and supra-renal aneurysms in SA:
 - Open repair if fit for surgery
 - F/BEVAR is not readily available or accessible
 - Published data show
 - FEVAR in para-renal and juxta-renal aneurysms compare well to standard EVAR
 - Better outcomes compared to F/BEVAR for thoraco-abdominal aneurysms and dissections

Planning and Technical considerations

- Patient selection beyond just fitness for surgery and life expectancy
- Technical considerations
- Device specific IFU
- Angulation of the supra- and infra-renal neck
- Iliac artery tortuosity

Contra-indications to FEVAR and BEVAR

- Extreme angulations of aorta around visceral vessels
- Thrombus loaded shaggy aorta around visceral vessels
- Stenoses of visceral vessels and early branches
- Infections and connective tissue disorders.

Design of the CMD

- CT angiography of the chest, abdomen and outflow to the limbs.
 - Calibre of access vessels important
 - 1mm slices
 - Distance between fenestrations: 6mm – 8mm.
- Fenestrations: aortic wall lies adjacent to the graft
 - Higher risk of type 3 endoleaks
 - Better long term patency
- Branches: distance is longer between the aortic wall and graft.
 - Lower risk of type 3 endoleaks
 - Poor patency

Design of the CMD:

FEVAR / BEVAR devices available

- Cook
- Jotec
- Anaconda
- Treovance – pending approval

Design of the CMD

- Scallops / wide fenestration to increase seal zone:
 - Celiac trunk or SMA
 - Allows for stenting of renal fenestration
→ place scallop over celiac /SMA without placing bridging stent.
 - Adequate seal zone above the renal ostia (>2cm)

Comparison

Standard FEVAR (2 vessel-renal artery stents)
with or without scallop for SMA

VS

Complex FEVAR / BEVAR
(stenting of all 4 visceral vessels)

→ No significant major differences

- Technical success rate
- Mortality
- durability

Outcomes:

Between juxta-renal and para-renal aneurysm and FEVAR

- No studies with separate data
- Meta-analysis of 1804 complex F/BEVAR from 14 studies:
 - Pooled technical success = 96.0%
 - Type 1 and 3 endoleaks = 7.6% & 2.5%
 - Temporary and permanent kidney injury = 13.19% & 0.71%
 - Spinal cord ischaemia = 2.0%
 - Aneurysm related mortality = 0.6%
 - Pooled estimate for re-intervention = 15.7%

Outcomes: VASSA FEVAR/BEVAR registry since 2015

| Complications | Para-renal (n32) | Juxta-renal (n71) | Thoraco-abdominal (CMD & T-Branch) (n48) |
|-------------------|---------------------|----------------------|--|
| Technical success | 94.23% | 95.58% | 95% |
| 30-day Mortality | 3 | 3 | 17% |

- Outcomes for complex F/BEVAR for thoraco-abdominal aneurysm differ from F/BEVAR for juxta-renal and para-renal repairs.
- Higher complication rates with complex F/BEVAR compared to standard fenestrated EVAR (18% vs 4%)

Outcomes:

Long sealing zones

- Important to secure durable repair
- Decrease risk of long term type 1a and 1b endoleaks
- 20mm of healthy aorta needed.
- Increasing risk of spinal cord ischaemia
- Mal-deployment of main stentgraft

Retrospective study from Ann Arbor:
Outcomes of open surgical repair (OSR) and FEVAR for
para-renal and juxta-renal AAA
Hospital volume outcome relationship

| | OSR (n403) | FEVAR (n186) | P-Value |
|--------------------------|---------------|-----------------|---------|
| 30 day Mortality | 10.7% | 2.9% | <.001 |
| Dialysis | 11.3% | 1.8% | <.001 |
| Post operative pneumonia | 6.8% | 0.3% | <.001 |
| Transfusion | 39.4% | 10.4% | <.001 |
| Median hospital stay | 9 days | 3 days | |

- Endoleaks (mainly type II) 6.1% at 1 year follow up.
- No FEVAR conversions to open aortic repair.
- Hospital FEVAR procedural volume – not associated with 30-day mortality or myocardial infarction.

Study from Netherlands:

Peri-operative outcomes after repair using ZFEN (FEVAR Zenith Fenestrated Endovascular graft (ZFEN Cook medical, Bloomington, Ind) with open complex AAA repair and infra-renal EVAR: A nationwide multi-centre registry.

| | FEVAR (n220) | OSR (n181) | P-Value | EVAR (n6424) (Compared to FEVAR) | P-Value |
|--------------------------|-----------------|---------------|---------|---|---------|
| Peri-operative mortality | 1.8% | 8.8% | 0<.001 | 0.8% | <0.084 |
| Renal dysfunction | 1.4% | 7.7% | <0.002 | 0.7% | <0.19 |
| Overall complications | 11% | 33% | <.001 | 7.7% | <0.09 |

- After adjustment, no significant differences between EVAR and FEVAR

USA based multi-centred series of long term outcomes and secondary interventions related to F/BEVAR

- 681 patients
- Re-interventions at 1 year = 18%
- Re-intervention at 5 years = 41%
- Most re-interventions done with percutaneous endovascular techniques – not affecting long term survival
- Long term surveillance is of paramount importance

Complications of Bridging stents

- Endoleaks
 - between the main body and bridging stents (proximal)
 - Type IIIc
 - Between bridging stent and target vessel
 - Type Ic
 - Tears or fractures in bridging stents
 - Type IIIId
- In-stent stenosis
- Stent occlusion
- Stent separation from target vessels.
- Poor long term outcomes, rupture and increased aneurysm related mortality (untreated)
- Currently no dedicated bridging stents for F/BEVAR.
 - Balloon mounted stents – more precise deployment and higher radial force
 - Self expanding covered stents - lower profile and more conformable to vessel wall – used for branches.
- No recommendation due to lack of evidence
 - Currently clinician preference, availability and cost

Accessory renal arteries during FEVAR

- Open surgery
 - Accessory renal arteries included in anastomosis in a Carel patch
- FEVAR
 - Accessory renal arteries >4mm if it does not compromise repair or patency
 - Preservation associated with low complication rates and good patency.
 - Lower early renal dysfunction
 - Higher freedom for mid term renal dysfunction.
- Renal artery <4mm
 - Not suitable for fenestration
 - Should be covered or embolised
- Incorporation of small vessels associated with
 - Lower technical success
 - High risk of arterial rupture
 - Kidney loss
 - Lower patency rate at 1 year

Imaging

- Adequate imaging is key
- CTA in conjunction with fluoroscopy
 - Reduce use of DSA
 - Decrease radiation
 - Decrease contrast usage
 - Decrease screening time
- Recent meta-analysis report
 - Less contrast use of 79ml
 - Decreased fluoroscopic time of 14min
 - Reduced procedure time 59min

Intra-operative cone beam CT with or without contrast

- Complex EVAR
 - Provides additional info:
 - Type I and III endoleaks
 - Stent compression
 - Kinking
 - Dissection
 - Extra radiation exposure and extra-iodinated contrast usage
 - Benefits
 - Diagnose and address early technical errors

Cone beam CT

- Single centre prospective study (no multicentre studies available)
 - 154 pts
 - Positive findings in 43 (28%) with 21 (49%) patients requiring further intervention
- According to this study, DSA would have missed the diagnosis in 11 (21%) patients
- Feasibility
 - To replace the early post operative CT scan

Future directions

- VASSA has created the Complex Aortic Working Group (CAWG)
 - Health care professionals meet to discuss planning and execution of potential procedures
 - Share advice and expertise
 - Use for stakeholder engagement to interact with VASSA regarding:
 - Safe and efficient use of technologist to benefit patients
- CAWG to play significant role in future registry info and research projects regarding complex aortic technologies in SA

Future directions

- Improve establishment of centres of excellence in tertiary state institutions
- Easily accessible Hybrid theatres for vascular surgery for
 - Training of fellows
 - Improved service delivery in state sector
- Radiation exposure needs further study
 - High radiation dosage
 - Long term stochastic or deterministic effects
 - Reduce radiation risk to patients and operators
 - Routine fusion overlay techniques
 - Evaluate routine use of cone beam CT
 - IVUS technology benefits?
 - Could improve technical outcome, fluoroscopic time, decrease radiation and operating time.

Recommendations

- Elective F/BEVAR using CMD should be 1st line therapy in
 - high risk surgical patients with para-renal / para-visceral / supra-renal AAA(>55mm in males and >50mm in females) provided they have:
 - Reasonable life expectancy
 - Favourable aneurysm anatomy
 - Patient consent
 - Class IIa, Level C
 - Standard surgical risk patients with para-renal / para-visceral / supra-renal AAA (>55mm in males and >50mm in females) provided they have:
 - Favourable anatomy
 - Patient preference
 - Class IIa, Level C

Recommendations

- FEVAR for para-renal/para-visceral/supr-arenal AAA
 - Limit aortic coverage to reduce risk of spinal cord ischaemia, without compromise to proximal sealing zone. Class IIa, Level C
 - Preserve large accessory renal arteries (>4mm). Class IIb, Level C

Recommendations

- Intra-operative fusion overlays should be used during FEVAR for para-renal /para-visceral / supra-renal AAA,
 - Reduce radiation exposure
 - Reduce contrast use
 - Reduce screening time
 - Reduce operative time. Class IIa, Level B
- Consider on-table cone beam computed tomography imaging for completion control
 - Class IIb, Level C