Specialist
Vascular Surgeons

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

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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 IIId
- 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