Best Practice in fEVAR in 2016

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Disclosure of Interest

Speaker name: ....Barend Mees............................................

• I have the following potential conflicts of interest to report:
  • Consulting
  • Employment in industry
  • Shareholder in a healthcare company
  • Owner of a healthcare company
  • Other(s)

• X I do not have any potential conflict of interest
Indications for fEVAR in 2016

Pararenal Aneurysms

Juxtarenal

Suprarenal

Type IV TAAA

Failed EVAR
# fEVAR versus Open Repair

<table>
<thead>
<tr>
<th></th>
<th>Nordon et al. 2009\textsuperscript{39}</th>
<th>Rao et al. 2014\textsuperscript{34}</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Open Repair</td>
<td>fEVAR</td>
</tr>
<tr>
<td>Number of Studies</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>Number of Patients</td>
<td>1164</td>
<td>368</td>
</tr>
<tr>
<td>Perioperative Mortality (%)</td>
<td>3.6</td>
<td>1.4</td>
</tr>
<tr>
<td>Major Complications (%)</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Permanent Dialysis (%)</td>
<td>1.4</td>
<td>1.4</td>
</tr>
<tr>
<td>Chronic Renal Failure (%)</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Secondary Interventions (%)</td>
<td>2.6</td>
<td>15</td>
</tr>
<tr>
<td>Target Vessel Patency (fEVAR; 1 year; %)</td>
<td>-</td>
<td>92</td>
</tr>
</tbody>
</table>

NS indicates not specified.
fEVAR versus open juxtarenal repair

- Less invasive
- For unfit patients
- Lower mortality and morbidity
- Custom-made devices
- More extensive coverage of aorta
Pararenal AAA

Infrarenal Aneurysm (short neck)  Juxta/Suprarenal Aneurysm
Workstation / 3D-imaging
Target vessel distance
Determine clock position
Target vessel length

20.5 mm

30.4 mm
FEVAR planning (1)
FEVAR planning (2)

1. Double with scallop 20mm
   - @ 12:15
   - 10 mm from top
   - 21 mm from top
   - 10 mm from top
   - 10 mm from top

2. Large fen
   - @ 12:15
   - 24 mm from top
   - 10 mm from top
   - 10 mm from top

3. Small fen
   - @ 10:15
   - 32 mm from top
   - 22 mm from top
   - 22 mm from top

4. Small fen
   - @ 10:15
   - 39 mm from top
   - 22 mm from top
   - 22 mm from top

- Double diameter reducing ties
- Low profile fabric

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NON STANDARD DEVICE REQUEST

1. REINFORCED SCALLOP #1
   - WIDTH: 10mm
   - HEIGHT: 10mm
   - CLOCK: 12:03
   - IVG: 10mm

2. REINFORCED LARGE FENESTRATION #1
   - WIDTH: 10mm
   - HEIGHT: 10mm
   - DIST FROM PROX EDGE: 40mm
   - CLOCK: 10:15
   - IVG: 10mm

3. REINFORCED SMALL FENESTRATION #1
   - WIDTH: 10mm
   - HEIGHT: 10mm
   - DIST FROM PROX EDGE: 40mm
   - CLOCK: 10:15
   - IVG: 10mm

4. REINFORCED SMALL FENESTRATION #2
   - WIDTH: 10mm
   - HEIGHT: 10mm
   - DIST FROM PROX EDGE: 40mm
   - CLOCK: 10:15
   - IVG: 10mm

- Double diameter reducing ties
- Low profile fabric

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Please note the following:
1. By signing this graft plan you are confirming that the patient has consented to the provision of their personal information to Cook Medical. The patient understands that in order to plan and manufacture the requested device, Cook Medical may share this personal information with other Cook Group companies in the United States, Australia, Denmark, United Kingdom and Ireland and has consented to this personal information being shared.
2. You are confirming that all clinically important features (eg. fenestration size/orientation, gold marker placement, sealing stents) are included in this graft design prior to your approval.
3. Unsigned plans or alterations may lead to a delay in the supply of this device. Please sign and date each page. If you wish to alter any part of this plan please initial and date each change.

---

Patient ID: [Redacted]
Doctor: Prof. Schurink
Hospital: UMC Maastricht, Netherlands
Date of Procedure:

Signatures:
Fenestrated grafts

- Zenith Fenestrated (Cook)
- Anaconda Fenestrated (Vascutek)
- Ventura (Endologix)
- Bolton Medical
- Jotec
- Surgeon modified FEVAR
- In situ FEVAR
Cook Zenith Fenestrated CE

- Three modules:
  - Fenestrated tube
  - Bifurcated body
  - Iliac leg

- Max. 3 fenestrations
Cook Zenith Fenestrated CE
Cook Zenith Fenestrated Custom Made

- More options in design
- Limitations in position and distance between fenestrations
- Long-term durability and experience
Cook P-Branch

Sobocinski et al. JEVTR 2012;19:165-172
Anaconda Fenestrated
Fenestrated Anaconda

• Fenestrations:
  – of any size
  – on any position
• Repositionable
• Flexible for angulated anatomy
• Cannulation from below and/or above
Fenestrated Anaconda
Which stent?

Uncovered

Covered

From: Ricotta et al.. Perspect Vasc Surg Endovasc Ther 2008;20: 174-87
Which stent?

Covered vs uncovered

• Freedom of stenosis @ 24 months:
  - Uncovered 92%
  - Covered 97%


287 patients
518 renal arteries
Complex Custom Made (T)EVAR in Maastricht UMC

- fEVAR for pararenal AAA: 84
- f/bEVAR for TAAA: 96
- f/bEVAR for aortic arch aneurysm: 9
fEVAR in Maastricht UMC

• Patients
  – Men: 89%
  – Age: 61–88 (75) years
  – AAA diameter: 47–89 (65) mm
  – Previous aortic surgery: 35%
fEVAR in Maastricht UMC

- Procedure:
  - 1F + 1Sc 4%
  - 2F + 1Sc 45%
  - 3F + 1Sc 45%
  - 4F 6%

231 target vessels stented

Last 2 years: 80%
3F + 1Sc or 4F
fEVAR in Maastricht UMC

• Outcome:
  – Technical success 94.6%
  – 30-d mortality 4.1%
  – Target vessel patency 95.9%
  – Endoleak
    • Type 1 & 3 7%
  – Renal Insufficiency
    • Mild / Temporary 35%
    • Dialysis 3%
fEVAR in Maastricht UMC

Trends since 2014

• One third of our fEVAR cases are fEVAR after EVAR (13 from 34)

• Two thirds of our fEVAR cases with percutaneous access (24 from 34)
Limitations of fEVAR

• Planning:
  – Human factor!

• Production time:
  – 6-8 weeks

• Access:
  – Often bilateral 20-22 Fr

• Procedure:
  – Radiation and contrast load
## Procedure characteristics

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>SD</th>
<th>Min.</th>
<th>Max.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DAP (Gy cm²)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>130</td>
<td>131</td>
<td>15</td>
<td>514</td>
</tr>
<tr>
<td>EVAR</td>
<td>116</td>
<td>122</td>
<td>32</td>
<td>481</td>
</tr>
<tr>
<td>TEVAR</td>
<td>62</td>
<td>46</td>
<td>15</td>
<td>166</td>
</tr>
<tr>
<td><strong>FEVAR</strong></td>
<td>217</td>
<td>159</td>
<td>47</td>
<td>514</td>
</tr>
</tbody>
</table>

**Fluoroscopy time (min:s)**

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<thead>
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<th>SD</th>
<th>Min.</th>
<th>Max.</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>25:26</td>
<td>19:47</td>
<td>1:49</td>
<td>97:47</td>
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<tr>
<td>EVAR</td>
<td>19:46</td>
<td>8:21</td>
<td>7:16</td>
<td>38:31</td>
</tr>
<tr>
<td>TEVAR</td>
<td>9:44</td>
<td>7:20</td>
<td>1:49</td>
<td>26:25</td>
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<tr>
<td><strong>FEVAR</strong></td>
<td>49:07</td>
<td>21:50</td>
<td>23:27</td>
<td>97:59</td>
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</table>

**Iodinated contrast volume (ml)**

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<th>Min.</th>
<th>Max.</th>
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<tbody>
<tr>
<td>All</td>
<td>92</td>
<td>40</td>
<td>40</td>
<td>200</td>
</tr>
<tr>
<td>EVAR</td>
<td>84</td>
<td>32</td>
<td>50</td>
<td>150</td>
</tr>
<tr>
<td>TEVAR</td>
<td>89</td>
<td>49</td>
<td>40</td>
<td>170</td>
</tr>
<tr>
<td><strong>FEVAR</strong></td>
<td>116</td>
<td>36</td>
<td>65</td>
<td>200</td>
</tr>
</tbody>
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Fusion Guidance (1)
fEVAR after fEVAR
fEVAR for rAAA
fEVAR for rAAA
State of the art fEVAR 2016

- fEVAR has become an established therapy for pararenal AAA
- fEVAR for pararenal AAA has excellent short- and medium term results
- Off-the-shelf fEVAR is needed for (sub) acute treatment
State of the art fEVAR 2016

- Plan your graft design yourself
- Aim for adequate seal in normal aorta
- Covered stents for target vessels
- Fusion imaging to reduce radiation and contrast load
- Increasing fEVAR after EVAR
- Percutaneous access