The GLOBAL FACT Registry: a world-wide registry with core lab analysis of Fenestrated Anaconda™ for complex aneurysms

Clark Zeebregts

Professor of Vascular Surgery
University Medical Center Groningen
Department of Surgery
Division of Vascular Surgery
Groningen, The Netherlands
Speaker name:
Clark Zeebregts

I have the following potential conflicts of interest to report:

- [✓] Consulting (Terumo Aortic)
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [✓] Other(s): Received research grants from W.L. Gore & Associates, LeMaitre Vascular, Atrium Maquet Getinge Group, and Cook Medical
Overview of fenestrated endografts

- Cook Zenith® Fenestrated
- Vasculyte Fenestrated Anaconda™
- Off-the-shelf Endologix Ventana™
- Jotec E-xtra® Engineering design

Concept

- Infra-renal sealing and fixation
- Peaks in anterior-posterior orientation
- Alignment markers on left valley

- Supra-renal fixation and sealing
- Valleys in anterior-posterior orientation
- Vessel cradled in anterior valley
- Markers on left peak hook
Worldwide numbers

Total implants to date: 2903*

Quarterly Implants

* Data recorded November 27, 2018
### Implantated devices

#### By type of device

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Straight Leg</td>
<td>8</td>
</tr>
<tr>
<td>Tapered Leg</td>
<td>66</td>
</tr>
<tr>
<td>Flared Leg</td>
<td>21</td>
</tr>
<tr>
<td>Tapered Cuff</td>
<td>61</td>
</tr>
<tr>
<td>Straight Cuff</td>
<td>31</td>
</tr>
<tr>
<td>Flared Cuff</td>
<td>24</td>
</tr>
<tr>
<td>Extra Long Body</td>
<td>153</td>
</tr>
<tr>
<td>Fenestrated Valley Long Body</td>
<td>18</td>
</tr>
<tr>
<td>Standard</td>
<td>272</td>
</tr>
<tr>
<td>Short Body</td>
<td>36</td>
</tr>
<tr>
<td>Long Body</td>
<td>1008</td>
</tr>
<tr>
<td>Joined Bodies</td>
<td>253</td>
</tr>
<tr>
<td>Fenestrated Valley</td>
<td>172</td>
</tr>
<tr>
<td>Augmented Valley</td>
<td>643</td>
</tr>
<tr>
<td>Tapered AUI</td>
<td>18</td>
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<tr>
<td>Non-fen AUI</td>
<td>3</td>
</tr>
<tr>
<td>Fenestrated AUI</td>
<td>116</td>
</tr>
</tbody>
</table>

#### By number of fenestrations

- 0 fenestrations: 26
- 1 fenestrations: 193
- 2 fenestrations: 889
- 3 fenestrations: 917
- 4 fenestrations: 843
- 5 fenestrations: 33
- 6 fenestrations: 2
Literature Fenestrated Anaconda
Multicenter retrospective analysis - methods

- Retrospective cohort study
- All clinics worldwide >15 treated cases*
- Potentially >850 cases

- Primary outcome
  - Re-intervention free survival

- Secondary outcome
  - Survival
  - Target vessel patency
  - Procedural type Ia endoleak
  - Follow-up results

* The International Fenestrated Anaconda™ Study Group
P. Bungay, Royal Derby Hospital, Derby, UK; MM. Sabaihal, R. Moore, Alberta Health Services, Calgary, Canada; M. Delbridge, Norfolk and Norwich University Hospitals, Norwich, UK; MMPJ. Reijnen, Rijnstate Hospital, Arnhem, The Netherlands; A. de Niet, IFJ. Tielliu, CJ. Zeebregts, University Medical Center Groningen, Groningen, The Netherlands; R. Meerwaldt, Medisch Spectrum Twente, Enschede, The Netherlands; S. Langer, Marien-Hospital Witten, Witten, Germany; AP. Papaioannou, A. Stehr, Evangelisches Krankenhaus Mülheim, Mülheim and der Ruhr, Germany; WP. Ngu, R. Birk, R. Lakshminarayan, Hull and East Yorkshire Hospitals NHS Trust, Kingston upon Hull, UK
Multicenter retrospective analysis - results

- 271 cases
- 9 centers (Netherlands, Germany, U.K., Canada)
- Median age 75 yrs (IQR 70-79)
- M : F 238 : 33
- eGFR 67.6 ml/min/1.73 m²

<table>
<thead>
<tr>
<th></th>
<th>Value/%</th>
</tr>
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<tbody>
<tr>
<td>BMI</td>
<td>27.9 (±4.3)</td>
</tr>
<tr>
<td>Hypertension (SVS≥1)</td>
<td>79.9</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>21.0</td>
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<tr>
<td>Peripheral artery disease</td>
<td>19.9</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>13.7</td>
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<tr>
<td>Hypercholesterolemia</td>
<td>74.0</td>
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<tr>
<td>Cardiac status (SVS≥1)</td>
<td>50.0</td>
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<tr>
<td>Pulmonary status (SVS ≥1)</td>
<td>35.9</td>
</tr>
<tr>
<td>Smoker (yes + previous)</td>
<td>68.7</td>
</tr>
</tbody>
</table>
Multicenter retrospective analysis - procedural results

- General anesthesia: 95.9%
- Cut-down access: 98.9%
- Additional cranial access: 42.4%
- Fenestrations: 733 (mean 2.7)
Multicenter retrospective analysis - early results

- Assisted primary technical success: 87.5%
- Procedural type Ia endoleak: 8.5%
- Type Ia endoleak at 30 days:
  - Spontaneous resolved: 56.5%
  - Treated: 4.3%
- eGFR: 65.7 ml/min/1.73m²
  - vs. preoperative: p=0.195
30-day mortality: 12 (4.4%)

Reasons for death:
- 1 Aneurysm rupture, despite treatment
- 1 Bowel ischemia - target vessel stenosis/occlusion
- 2 Bowel ischemia - target vessel emboli
- 2 Bowel ischemia, eventually leading to multiple organ failure
- 2 Multiple organ failure with unknown cause
- 1 Cardiac failure
- 1 Cardiac failure and cerebral infarction
- 1 Septic shock secondary to necrotizing fasciitis
- 1 Undiagnosed carcinoma
Reasons for technical failure

- 1 remaining type Ib EL, despite ballooning. During 30d post-op Amplatzer AII and elongation AIE, sealed Ib EL.
- 1 unable to stent CA, EL through fenestrations, placement of cuff.
- 3 type Ib EL, spontaneous resolved.
- 1 type Ib EL after surgery, no follow-up after 30 days was available.
- 1 type Ib EL and ballooning was done within 30days post-op.
- 1 unable to cannulated RRA, accepted. No EL.
- 1 unable to cannulated LRA and SMA, finally re-sheated and removed. Medtronic Endurant placement, RRA stent left in situ. Patient died 2 days later of unknown causes.
- 1 death within 1 day of cardiac failure.
- 1 unable to advance the endograft and the procedure was aborted.
Multicenter retrospective analysis - follow-up

- Median follow-up
  - all: 1.12 yrs (IQR 0.31 - 2.56)
  - >30 days: 1.43 yrs (IQR 0.66 - 2.96)

- Re-intervention-free survival
  - 1-yr: 86.5 ± 2.4%
  - 3-yrs: 77.9 ± 3.7%
Overall survival
- 1-yr: 89.7 ± 2.0%
- 3-yrs: 80.1 ± 3.3%

Reasons for death
- 1 aneurysm-related (graft infection with fabric failure), in 1 case target vessel occlusion lead to death (occl of renals, AIE bypass, eventually occlusion and death)
- Malignancy: 10
- Cerebral disease: 2
- Respiratory disease: 4
- Renal disease, unrelated to FEVAR: 2
- Cardiovascular: 5
- Unknown: 7
Multicenter retrospective analysis - follow-up

- Target vessel patency
  - 1-yr: 96.3 ± 0.8%
  - 3-yrs: 92.2 ± 1.6%

- eGFR 58.5 ml/min/1.73m²
  - $p=0.000$, vs. pre-operative
Multicenter retrospective analysis - discussion

- Cases include first placed cases of the Fenestrated Anaconda™
- Low technical success due to type Ia endoleak, but resolving spontaneously in most cases
- High target vessel patency at one year
- One-year survival is comparable to current literature
- Prospective registries or randomized trials still lacking
GLOBAL FACT multicenter prospective registry

- Study title
  - Global Fenestrated Anaconda™ Clinical Study
  - Global FACT (FACT-001)

- Study type
  - Global, multi-centre, prospective, non-interventional study of a custom device

- Sample size ~160 patients
  - Maximum 25 cases per site

- 12 to 15 planned sites

- 2 year recruitment period

- 10 year follow-up
Currently 37 patients recruited in the study.

11 sites active (in Australia, Austria, Canada, Netherlands and UK).

Several other sites pending activation (in France, Italy and Germany).

Primary data publications will occur at 1 year, 2 year, 5 year and 10 year endpoints.

Initial publication (30 day data) anticipated Apr-Jun 2020.

* The GLOBAL FACT study group
N. Burfitt, London Imperial, London, UK; D. Gerrard, Frimley Park, Frimley, UK; R. Williams, J McCaslin, Freeman Hospital, New Castle, UK; K. Sieunarine, Hollywood Medical Center, Perth, Australia; P. Chu, Epworth Richmond Hospital, Melbourne, Australia; R. Moore, Peter Lougheed Center, Calgary, Canada; J. Falkensammer, A. Assadian, Wilhelminenspital, Vienna; M. Gargiulo, A. Stella, Policlinico S. Orsola Malpighi, Bologna, Italy; D. Midy, CHU Bordeaux, France; J. Brunkwall, Uniklinik Köln, Germany, M. Espinola, Hospital Dpreca, Santiago, Chili; MMPJ. Reijnen, Rijnstate, Arnhem, The Netherlands; A. de Niet, IFJ. Tielliu, CJ. Zeebregts, University Medical Center Groningen, Groningen, The Netherlands; R. Meerwaldt, Medisch Spectrum Twente, Enschede, The Netherlands; R. Kropman, Antonius Hospital, Nieuwegein, The Netherlands
Conclusion

- Acceptable early and mid-term results with Fenestrated Anaconda™
- Possibility to treat different and more angulated anatomy
- Increased number of endoleaks, probably not relevant as most of them resolve spontaneously
- Long-term results are needed
Thank you for your attention and welcome to ESCVS 22-25 May 2019 in Groningen, The Netherlands!

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• MMPJ. Reijnen, MD, PhD, Rijnstate, Arnhem, The Netherlands
• A. de Niet, IFJ. Tielliu, Cj. Zeebregts, MD, PhD, University Medical Center Groningen, Groningen, The Netherlands
• R. Meerwaldt, MD, PhD, Medisch Spectrum Twente, Enschede, The Netherlands
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• WP. Ngu, MD, R. Birk, MD and R. Lakshminarayan, MD, Hull and East Yorkshire Hospitals NHS Trust, Kingston upon Hull, United Kingdom