Update on the fenestrated Anaconda endograft for F/EVAR: worldwide experience from the global FACT registry

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Disclosure

Speaker name: Clark Zeebregts.

I have the following potential conflicts of interest to report:

- Consulting (Terumo Aortic)
- Other(s): Received research grants from W.L. Gore & Associates, LeMaitre Vascular, Atrium Maquet Getinge Group, and Cook Medical
Concept

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

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

Total implants to date: 2969

Data recorded January 18, 2019
### Implanted devices

#### By type of device

<table>
<thead>
<tr>
<th>Category</th>
<th>Subcategory</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leg</td>
<td>Straight Leg</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Tapered Leg</td>
<td>69</td>
</tr>
<tr>
<td></td>
<td>Flared Leg</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>Extra Long Body</td>
<td>1</td>
</tr>
<tr>
<td>Cuff</td>
<td>Tapered Cuff</td>
<td>62</td>
</tr>
<tr>
<td></td>
<td>Straight Cuff</td>
<td>31</td>
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<td></td>
<td>Flared Cuff</td>
<td>24</td>
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<tr>
<td></td>
<td>Extra Long Body</td>
<td>170</td>
</tr>
<tr>
<td></td>
<td>Fenestrated Valley Long Body</td>
<td>19</td>
</tr>
<tr>
<td>Bifurcated CFD</td>
<td>Standard</td>
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<tr>
<td></td>
<td>Short Body</td>
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<tr>
<td></td>
<td>Long Body</td>
<td>1018</td>
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<td></td>
<td>Joined Bodies</td>
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<td></td>
<td>Fenestrated Valley</td>
<td>173</td>
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<tr>
<td></td>
<td>Augmented Valley</td>
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<tr>
<td></td>
<td>Tapered AUI</td>
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<td></td>
<td>Non-fen AUI</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Fenestrated AUI</td>
<td>117</td>
</tr>
</tbody>
</table>

#### By number of fenestrations

![Bar chart showing the distribution of fenestrations by type of device](chart.png)
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; M.M. Sabalbal, R.S. Moore, Alberta Health Services Calgary, Canada; M. Delbridge, Norfolk and Norwich University Hospitals, UK; M.M.P.J Reijnen, J.W. Lardenoije, Rijnstate Hospital, Arnhem, The Netherlands; K. Oikonomou, P. Kasprzak, Universitätsklinikum Regensburg, Regensburg, Germany; S. Mylonas, J. Brunkwall, University Hospital Cologne, Köln, Germany; R. Meerwaldt, R. Geelkerken, Medisch Spectrum Twente, Enschede, The Netherlands; A. Papaioannou, A. Stehr, Evangelisches Krankenhaus Mülheim, Mülheim an der Ruhr, Germany; C.J. Zeebregts, I.F.J. Tielliu, A. de Niet, UMCG, Groningen, The Netherlands; S. Langer, Marien-Hospital Witten, Witten, Germany; W.P. Ngu, R. Birk, R. Lakshminarayanan, Hull and East Yorkshire Hospitals NHS Trust, Kingston upon Hull, UK.
Multicenter retrospective analysis - results

- 335 cases
- 11 centers (Netherlands, Germany, U.K., Canada)
- Median age 74 yrs
- M : F 292 : 43
- eGFR 67.6 ml/min/1.73 m²

- Procedural results
  - General anesthesia 96.7%
  - Cut-down access 91.6%
  - Additional cranial access 42.0%
  - Fenestrations 920 (mean 2.7)

<table>
<thead>
<tr>
<th></th>
<th>Value/%</th>
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</thead>
<tbody>
<tr>
<td>BMI</td>
<td>27.6 (±4.2)</td>
</tr>
<tr>
<td>Hypertension (SVS≥1)</td>
<td>79.1</td>
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<tr>
<td>Diabetes mellitus</td>
<td>19.7</td>
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<tr>
<td>Peripheral artery disease</td>
<td>20.9</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>13.4</td>
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<tr>
<td>Hypercholesterolemia</td>
<td>64.8</td>
</tr>
<tr>
<td>Cardiac status (SVS≥1)</td>
<td>47.3</td>
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<tr>
<td>Pulmonary status (SVS ≥1)</td>
<td>31.0</td>
</tr>
<tr>
<td>Smoker (yes + previous)</td>
<td>66.4</td>
</tr>
</tbody>
</table>
Multicenter retrospective analysis - early results

- Assisted primary technical success: 88.4%
- Procedural type Ia endoleak: 6.9%
- Type Ia endoleak at 30 days: 2.5%
  - Spontaneous resolved: 56.5%
  - Treated: 4.3%
- eGFR: 65.2 ml/min/1.73m²
  - vs. preoperative: p=0.00
- 30-day mortality: 14 (4.2%)
Multicenter retrospective analysis - follow-up

- **Follow-up**
  - **Median follow-up**
    - all: 1.2 yrs (IQR 0.4 - 2.6)
    - >30 days: 1.4 yrs (IQR 0.7 - 2.9)

- **Re-intervention-free survival**
  - 1-yr: 83.6 ± 2.2%
  - 3-yrs: 71.0 ± 3.7%
Multicenter retrospective analysis - follow-up

- Overall patient survival
  - 1-yr 89.8 ± 1.8%
  - 3-yrs 79.2 ± 3.0%

- Target vessel patency
  - 1-yr 96.4 ± 0.7%
  - 3-yrs 92.7 ± 1.4%

- eGFR 59.3 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**
GLOBAL FACT multicenter prospective registry

- Currently 39 patients recruited in the study.

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

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

- 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 Dipreco, Santiago, Chili; MMPJ. Reijnen, Rijnstate, Arnhem, The Netherlands; A. de Niet, IFJ. Tielliu, C. Zeебregts, University Medical Center Groningen, Groningen, The Netherlands; R. Meerwaldt, Medisch Spectrum Twente, Enschede, The Netherlands; R. Kropman, Antonius Hospital, Nieuwegein, The Netherlands
Conclusions

- Acceptable 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 awaited
Announcement

Thank you for your attention and welcome to ESCVS 22-25 May 2019 in Groningen, The Netherlands!
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