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

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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: 2863*

Implanted devices
By type of device
- Fenestrated Valley: 188
- Extra Long Body: 908
- Flared Cuff: 32

By number of fenestrations
- 2: 466
- 3: 300
- 4: 105

Disclosure
- Consultant for Terumo Aortic
- Received research grants from W.L. Gore & Associates, LeMaitre Vascular, Atrium Maquet Getinge Group, and Cook Medical

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

Multicenter retrospective analysis - results

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

Procedural results
- General anesthesia 95.9%
- Cut-down access 98.9%
- Additional cranial access 42.4%
- Fenestrations 733
  - Mean: 2.7

Follow-up 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: 2.5%
  - Spontaneous resolved: 56.5%
  - Treated: 4.3%
- eGFR: 65.7 ml/min/1.73 m²
  - vs. pre-operation: p=0.035
- 30-day mortality: 12 (4.4%)

Multicenter retrospective analysis - follow-up

- Follow-up
  - Median follow-up: 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-yr: 77.9 ± 3.7%
  - eGFR 58.5 ml/min/1.73 m²
    - 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 37 patients recruited in the study.
- 10 sites active (in Australia, Canada, Netherlands and UK). *
- Several other sites pending activation (in Austria, Italy 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

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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!