Expanding the borders in the treatment of pararenal AAAs with Ch-EVAS

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Disclosure

Speaker name: Athanasios D. Giannoukas.

☐ I have the following potential conflicts of interest to report:

☐ Receipt of grants/research support

☒ Receipt of honoraria and travel support

☐ Participation in a company sponsored speakers‘ bureau

☐ Employment in industry

☐ Shareholder in a healthcare company

☐ Owner of a healthcare company

☐ I do not have any potential conflict of interest
chEVAR fo pararenal AAAs
An established endovascular approach
Why Ch-EVAR?

- A significant patient population is currently ineligible for EVAR due to short (<10 mm), wide (> 29 mm), angulated ( > 75°), or conical infrarenal necks (SWAC)

- Approx. 18% of patients are excluded from EVAR because of a short neck with insufficient sealing zone

- In suitable patients, the implantation of Chimneys might allow to create a new neck long enough to provide sufficient sealing zone to treat those patients with the EVAR technique
Pararenal aneurysms

Quite often in the everyday practice, we need:

- Off the shelf solution
- Efficient
- Durable
- Cost effective
PERICICLES Global registry

- 517 pts
- 119 from US and 398 Europe
- 898 chimney grafts
  - 692 renal arteries
  - 156 SMA
  - 50 celiac arteries

Pericles registry: New Neck length

- Infrarenal neck length
  
  4.8 ± 7.4 mm

- Neck length/seal zone changed to
  
  21.1 ± 12.7 (9-43) mm

Global registry

Technical success 97.1%
Endoleak type Ia at latest FU 5.8%

FU 17.1 months, 1-70

<table>
<thead>
<tr>
<th>Mean Pre-op Sac Diameter (mm)</th>
<th>65.9±21.6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean LatestF/U Sac Diameter (mm)</td>
<td>61.2±19.7, p.001</td>
</tr>
</tbody>
</table>
Pericles registry: Primary Patency and sac shrinkage

Mean Pre-op Sac Diameter (mm):
65.9 ± 21.6

Mean Latest F/U Sac Diameter (mm):
61.2 ± 19.7

p = 0.001

The PROTAGORAS study to evaluate the performance of the Endurant stent graft for patients with pararenal pathologic processes treated by the chimney/snorkel endovascular technique

Konstantinos P. Donas, MD, a,b Giovanni B. Torsello, MD, a,b Gianluca Piccoli, MD, c Georgios A. Pitoulias, MD, a,b,d Giovanni Federico Torsello, MD, e Theodosios Bisdas, MD, a,b Martin Austermann, MD, a,b and Daniele Gasparini, MD, c Münster, Germany; Udine, Italy; and Thessaloniki, Greece

- **128** patients with pararenal pathologies and the intention to treat by Endurant™ and Atrium Advanta™ V12 as chimney graft
- **Follow up:** 3 year Kaplan Mayer analysis

The PROTAGORAS study: Primary Chimney graft patency

95.7%

The PROTAGORAS study: Freedom from re-interventions

Chimney EVAR Limitations

A number of studies have shown a higher incidence of type 1A gutter endoleak and stroke compared to f-EVAR.

Pericles Registry 517 patients from 13 centers:

- Intra-operative type 1a endoleak 7.9%
- Type 1a endoleak at latest follow up 5.8%

Katsargyris et al, J Endovasc Ther 2014

K. Donas et. al, Ann Surg. 2015
Can we further optimise the chimney technique?
Chimney-Nelix (Ch-EVAS) for Challenging Neck Anatomy

- The compliant endobags may optimize the seal around parallel grafts and minimize the risk of type 1a gutter endoleak.
In Vitro Gutter Endoleak Analysis

- In Vitro testing by Jan Blankensteijn, Amsterdam
- New compliant model used, mimicking in-vivo situation
- No Type 1a "Gutter" Endoleaks
- Both Balloon Expandable and Self Expanding chimney configurations maintain patency and geometry

<table>
<thead>
<tr>
<th></th>
<th>ChEVAS</th>
<th>ChEVAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gutter Area (cm²)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6mm iCAST</td>
<td>0.25</td>
<td>0.561</td>
</tr>
<tr>
<td>6mm Viabahn</td>
<td>0.22</td>
<td>0.252</td>
</tr>
</tbody>
</table>

De Bruin et al. J Endovasc Ther 2013;20:184-90
Some problems...

- a high rate of graft failure, especially after 2 years of follow up

Harisson et al, Eur J Vasc Endovasc Surg 2018
The more proximal, the more secure...

Outcomes of endovascular aneurysm repair performed in abdominal aortic aneurysms with large infrarenal necks

Mauro Gargiulo, MD, PhD, Enrico Gallitto, MD, PhD, Helene Wattez, MD, Fabio Verzini, MD, PhD, Claudio Bianchini Massoni, MD, Diletta Loschi, MD, Antonio Freyrie, MD, PhD, and Stephan Haulon, MD, PhD, Bologna and Perugia, Italy, and Lille, France

Mean increase

- 11% for the lowest renal
- 3% to 5% at the level of the renal arteries
- <3% for the SMA and the CT
• Post-market registry of the Nellix System with Chimney Stents
• Open-label, single-arm, no prospective screening
• 200 patients, up to 10 international centers with 5y F/U
• 187 patients (154 primary, 9 rAAA, 25 Revision EVAR, 5 Revision EVAS)
• Endpoints typical of EVAR therapy in complex AAA

M Thompson et al, J Endovasc Ther 2018
De novo procedures 154

Single
40.3%
N=62
LRA = 33, RRA = 27
SMA = 1
Not Specified = 1

Double
35.1%
N=54
Both RA = 49
RA and SMA = 4
Not Specified = 1

Triple
17.5%
N=27
Both RA, SMA = 24
RA, SMA, CA = 2
Not Specified = 1

Quadruple
7.1%
N=11
Both RA, SMA, CA

M Thompson et al, J Endovasc Ther 2018
Early complications

<table>
<thead>
<tr>
<th></th>
<th>De Novo</th>
<th>Single</th>
<th>Double</th>
<th>Triple-Quadruple</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stroke 30-days</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.6% (4/154)</td>
<td>1.6%</td>
<td>1.9%</td>
<td>5.3%</td>
<td></td>
</tr>
<tr>
<td>(1/64)</td>
<td>(1/54)</td>
<td></td>
<td>(2/38)</td>
<td></td>
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<tr>
<td><strong>Severe renal complications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3% (2/154)</td>
<td>1.6%</td>
<td>1.9%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>(2/154)</td>
<td>(1/62)</td>
<td>(1/54)</td>
<td>(0/38)</td>
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</table>
### All Endoleak

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Type Ia</th>
<th>Type Ib</th>
<th>Type II</th>
<th>Type III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early (154)</td>
<td>1.9% (3)</td>
<td>0.6% (1)</td>
<td>1.3% (2)</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Late (136)</td>
<td>2.9% (4)</td>
<td>2.9% (4)</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
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</table>

### Type 1A Endoleak

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Single</th>
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<th>Triple-Quadruple</th>
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<tbody>
<tr>
<td>Early (154)</td>
<td>0.6% (1/154)</td>
<td>0% (0/62)</td>
<td>1.9% (1/54)</td>
<td>0% (0/38)</td>
</tr>
<tr>
<td>Late (136)</td>
<td>2.9% (4/136)</td>
<td>5.2% (3/58)</td>
<td>0% (0/51)</td>
<td>2.9% (1/34)</td>
</tr>
</tbody>
</table>

*M Thompson et al, J Endovasc Ther 2018*
Endoleak

**LEGEND**
- ASCEND Registry
  - Type Ia Endoleaks

**SURVIVAL ESTIMATES: At Risk**
- ASCEND Registry
  - Type Ia Endoleaks
  - 153 131 115 96 88 82 74 65 55 51 50 46 41

**30-Day**
- 99.3% ASCEND Registry
  - Type Ia Endoleaks

**1-Year**
- 95.7% ASCEND Registry
  - Type Ia Endoleaks
Secondary intervention

M Thompson et al, J Endovasc Ther 2018
Target Vessel Patency

- 100% CELIAC
- 100% SMA
- 99% RRA
- 98% LRA

Survival estimates: At Risk
Larissa University Hospital, Greece

- From 5/2016-9/2018 (28 months)
- 25 Ch-EVAR (out of 180 EVARs, 13.8%)
- 5 3x Ch-EVAR, 12 2x Ch-EVAR, 8 single Ch-EVAR
- 5 pts had previous aortic surgery (4 pts type I endoleak and 1 pt pararenal anastomotic aneurysm after previous OR)
- 13 Endurant (Medtronic), 10 Nellix (Endologix), 2 Incraft (Cordis)
Larissa University Hospital, Greece

- Technical success **100%**
- 30 day mortality: **12% - 3 pts**
- **1 stroke (4%)**
- At FU (mean **10.2 months**)
  - **1 target vessel occlusion (RA)**
  - **2 reinterventions (all endo)**
    - **1 limb relining (type III endoleak)**
    - **1 TV stenosis (1 SMA treated successfully)**
Case

Treating a pararenal aneurysm using ChEVAS with Nellix
Presentation

- 75 years old male patient
- COPD
- severe CAD
- ex-smoker
Pararenal AAA 6.2 cm
Unfit for open repair
Preference for endovascular repair
CTA
Decision

- Endovascular repair using the Chimney technique
- 3 chimneys (2 renals and SMA) for retaining an adequate proximal neck
CTA

Cel Tr

sEVAR  2xCh  3xCh

26.1 mm

14.0 mm

4.0 mm
Procedure details

- Operational time: 150 min
- Blood loss: 250 ml
- Volume Contrast medium: 170 ml
- Radiation exposure: 615 mGy (13.8 mGy/m²)
- Time exposure: 42 min 32 sec
Post-op period

- No renal or GI complications
- No cardiac complications (negative troponin levels)
- Ambulatory
- Discharged home the 4th post-op day
CTA 1st year
CTA 1\textsuperscript{st} year
CTA 1\textsuperscript{st} year
In conclusion

✓ ChEVAS is a promising new approach
✓ Potentially addresses a therapeutic gap
✓ ASCEND Registry provides encouraging early results
✓ Long term results are awaited to confirm durability
Thank you for your attention!!

Larissa University Hospital
SAVE THE DATE

May 9-11
2019
Larissa Imperial Hotel
Larissa, GREECE
http://www.live2019.gr