The usage of covered balloon expandable stents in ch-EVAS procedures

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Disclosures:

Consultant for Medtronic, Endologix

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Speaker fee: Maquet Getinge Group
Endovascular Treatment Juxta-Renal AAA

- CMD “gold-standard” but temporal and manufacturing constraints
- Significant “turndown” rate
- 7% early reintervention, 28% mortality in sealing zone 6

Banno et al JVS 2014; 60: 31
Globalstar Circulation 2012; 125: 2707
Patel et al JVS 2015; 62: 319
EVAR and Parallel Grafts for Juxta-Renal AAA

- Near universal applicability
- Early results better than expected – durability?
  - Issue is seal – gutters / endoleaks
  - 13% early endoleak
- Improved seal with polymer based technology?

*Linblad et al EJVES 2015; 50: 722*
EVAS and Parallel Grafts
Parallel Grafts and EVAS – Technique

- Plan to increase sealing zone to at least 2cm
  - 7F sheaths placed in target vessels
- Inflate Nellix stents first and then visceral stents
- Keep balloons inflated whilst endobags filled and polymer cures
Chimney stentgrafts

**Balloon-expandable (Advanta V12)**

- Double PTFE layer
- 5mm - 8mm diameter
- over 6/7F sheath
- 22mm, 38mm and 59mm length
Chimney stentgrafts

Self-expanding (Viabahn)

- PTFE layer
- 5mm - 8mm diameter
- over 7F/8F sheath
- length (50-250mm)
Why V12?

- Fluoroscopic visualization
- Precise placement
- Radial force
- Evidence in the literature
Why V12?

- Flexibility of the skeleton of the abdominal devices
- Radial force of the chimney devices
In-vitro analysis shows V12 less compressed with Nellix
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


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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
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

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![Graph showing cumulative freedom from chimney graft related reinterventions over time in months. Patients at risk: 128, 105, 92, 84, 64, 52, 38. Chimney’s at risk: 187, 152, 138, 125, 93, 75, 52. Standard errors: 0.04, 0.04, 0.04, 0.04, 0.04, 0.04, 0.03.]
Case example #1

Male, 76 years
Former nephrectomy left, aorto-bi-iliac prosthesis
Sacculair proximal anastomotic aneurysm, 6.1 cm
Case example #1

Bilateral brachial access (percutaneous), 7 fr sheaths, fixed-core wires (Cook)
- Advanta stentgrafts, proximal at level of bare stents Nellix
Case example #1
Case example #1
Case example #2

Male, 73 years
Conical neck (27 → 33 mm)
Former abdominal surgery (complicated diverticulitis)
Case example #2

Bilateral brachial access (percutaneous), 7 fr sheaths, fixed-core wires (Cook)
Case example #2

Balloon support
Case example #2

Length measurement (Nellix)
Case example #2

Bilateral brachial access (percutaneous), 7 fr sheaths, fixed-core wires (Cook)

Advanta stentgrafts, proximal at level of bare stents Nellix
Position of Advanta stentgrafts / Nellix stentframes

Top of Advanta stentgrafts = Top of the (bare) stent of the Nellix
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 EVAR, 5 EVAS)
- Endpoints typical of EVAR therapy in complex AAA
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
Procedural Characteristics

78% balloon expandable stents / 22% self expanding stents
Freedom from Mortality By Seal Zone

<table>
<thead>
<tr>
<th>Zone</th>
<th>Survival Rate</th>
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<tbody>
<tr>
<td>Zone 9</td>
<td>100%</td>
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<tr>
<td>Zone 8</td>
<td>88%</td>
</tr>
<tr>
<td>Zone 7</td>
<td>93%</td>
</tr>
<tr>
<td>Zone 6</td>
<td>76%</td>
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</tbody>
</table>

Survival Estimates: At Risk

|       | 9 | 9 | 8 | 7 | 7 | 5 | 4 | 4 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 30    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 71    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 12    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
Freedom from Secondary Intervention

<table>
<thead>
<tr>
<th></th>
<th>30d</th>
<th>1 yr</th>
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<tbody>
<tr>
<td></td>
<td>94%</td>
<td>89%</td>
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</table>
## Secondary Intervention

<table>
<thead>
<tr>
<th></th>
<th>Endoleak</th>
<th>Chimney Stent</th>
<th>Nellix</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Early</strong></td>
<td>1.9% (3)</td>
<td>2.6% (4)</td>
<td>1.9% (3)</td>
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<tr>
<td>(n=154)</td>
<td></td>
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<tr>
<td><strong>Late</strong></td>
<td>2.8% (4)</td>
<td>3.5% (5)</td>
<td>0.7% (1)</td>
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<td>(n=142)</td>
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Target Vessel Patency

Celiac 100%
SMA 100%
RRA 99%
LRA 98%
Ch-EVAS with V12 stentgrafts in pararenal AAAs

- Promising use of new technology
  - Theoretical advantages in using polymer based sealing
    - Early results acceptable
    - Long term results and endograft durability
V12 stentgrafts ~ SEG in ch-EVAR/S

- Necessary radial force
- Better visualization
- Shorter lengths

- Limitation: tortuous visceral arteries
Total Enrollment* = 187

<table>
<thead>
<tr>
<th>Centre</th>
<th>Investigator</th>
<th>Enrolled</th>
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<tbody>
<tr>
<td>St George’s Hospital</td>
<td>Matt Thompson (ASCEND PI)</td>
<td>50</td>
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<tr>
<td>Auckland City Hospital</td>
<td>Andrew Holden (ASCEND PI)</td>
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<td>University Hospital Mainz</td>
<td>Marwan Youssef</td>
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<td>Augsburg Hospital</td>
<td>Rudolf Jakob, Sebastian Zerwes</td>
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<td>Arnhem Hospital</td>
<td>Michel Reijnen</td>
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<tr>
<td>Vascular Clinic IHT - Warszawa</td>
<td>Piotr Szopinski</td>
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<td>Marien Hospital Kevelaer</td>
<td>Patrick Berg</td>
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<tr>
<td>University Hospital Poznan</td>
<td>Gregrorz Oszkinis</td>
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*Data cut April 14, 2016