Insights from the PROTAGORAS/PERICLESES Registries: impact on ChEVAR results

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- Consulting

- Employment in industry

- Stockholder of a healthcare company

- Owner of a healthcare company

- Other(s)

- I do not have any potential conflict of interest
Published reports about ch-EVAR
Limitations

Plethora of single-center series with limited number of patients

Wide variety of aortic pathologic processes

Several combinations of off-the-shelf devices
Collected World Experience About the Performance of the Snorkel/Chimney Endovascular Technique in the Treatment of Complex Aortic Pathologies

The PERICLES Registry

Konstantinos P. Donas, MD,* Jason T. Lee, MD,† Mario Lachat, MD,‡ Giovanni Torsello, MD, PhD,§ and Frank J. Veith, MD,* on behalf of the PERICLES investigators

Objectives: We sought to analyze the collected worldwide experience with use of snorkel/chimney endovascular aneurysm repair (EVAR) for complex abdominal aneurysm treatment.

Background: EVAR has largely replaced open surgery worldwide for anatomically suitable aortic aneurysms. Lack of availability of fenestrated and branched devices has encouraged an alternative strategy utilizing parallel or snorkel/chimney grafts (ch-EVAR).

Methods: Clinical and radiographic information was retrospectively reviewed and analyzed on 517 patients treated by ch-EVAR from 2008 from 2014 by prearranged defined and documented protocols.

Results: A total of 119 patients in US centers and 398 in European centers were treated during the study period. US centers preferentially used Zenith stent-grafts (54.2%) and European centers Endurant stent-grafts (62.2%) for the main body component. Overall 898 chimney grafts (49.2% balloon expandable, 39.6% self-expanding covered stents, and 11.2% balloon expandable bare metal stents) were placed in 692 renal arteries, 156 superior mesenteric arteries (SMA), and 50 celiac arteries. At a mean follow-up of 17.1 months (range: 1–70 months), primary patency was 94%, with secondary patency of 95.3%. Overall survival of patients in this high-risk cohort for open repair at latest follow-up was 79%.

Conclusions: This global experience represents the largest series in the ch-EVAR literature and demonstrates comparable outcomes to those in published reports of branched/fenestrated devices, suggesting the appropriateness of broader applicability and the need for continued careful surveillance. These results support ch-EVAR as a valid off-the-shelf and immediately available alternative in the treatment of complex abdominal EVAR and provide impetus for the standardization of these techniques in the future.

Keywords: abdominal aortic aneurysm, endovascular, fenestrated, thoracoabdominal, vascular

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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- **128** patients with pararenal pathologies and the intention to treat by Endurant™ and BECS (Advanta V12) as chimney graft

- **3-year** Kaplan-Meier analysis

Key results from PERICLES/PROTAGORAS studies

• 1. Significant shrinkage of the aneurysm sac

• 2. Low incidence of persistent type IA endoleaks in case of a sealing zone of 20mm and oversizing of 30%
Open issues

• Cerebrovascular events?

• Optimal combination of abdominal device and chimney graft?

• Long-term results?
Unpublished insights from the PROTAGORAS/PERICLES Registries:
impact on ChEVAR results

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I. Unpublished topic

Major Adverse Cardiac and Cerebrovascular Events
(MACCE)

Submitted to VAM 2017
Cerebrovascular events

Stroke 1.89%
MACCE 8.47%

<table>
<thead>
<tr>
<th>Multivariate</th>
<th>OR</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1.03</td>
<td>.98-1.08</td>
<td>.229</td>
</tr>
<tr>
<td><strong>Aneurysm Rupture</strong></td>
<td>5.32</td>
<td>1.73-16.33</td>
<td>.003</td>
</tr>
<tr>
<td>Suprarenal aneurysm</td>
<td>2.28</td>
<td>.92-5.65</td>
<td>.073</td>
</tr>
<tr>
<td>Multiple chimney grafts</td>
<td>0.65</td>
<td>.26-1.62</td>
<td>.362</td>
</tr>
<tr>
<td><strong>Bilateral access</strong></td>
<td>2.79</td>
<td>1.04-7.45</td>
<td>.040</td>
</tr>
<tr>
<td>OR Time (per hour)</td>
<td>1.32</td>
<td>1.08-1.61</td>
<td>.005</td>
</tr>
</tbody>
</table>
II. Unpublished topic

Idealy combination of abdominal device and chimney graft
Best performance for Endurant™ in vitro regarding Freedom from chimney graft compression and gutters area were found in combination with the Advanta™ V12¹
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, c 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
PRIMARY CHIMNEY GRAFT PATENCY

The PROTAGORAS study
FREEDOM FROM REINTERVENTION

SUBGRUP ANALYSIS from PERICICLES Registry regarding Endurant and BECS (st. significant outcomes, p<.05):

Hazard of chimney graft occlusion -

- **7.2 times** greater in patients with Excluder + V12 devices compared to MDT + V12 devices (HR: 7.2, 95% CI: 1.9 to 27.3).

- **3.7 times** greater in patients with Zenith + V12 devices compared to MDT + V12 devices (HR: 3.7, 95% CI: 1.4 to 10.0).

- **Unpublished data**
- **Submitted to JACC**
SUBGRUP ANALYSIS from PERICLES Registry regarding Endurant and BECS (st. significant outcomes, p<.05):

Hazard of intraoperative type IA endoleak:

- **5.1 times** greater in patients with Excluder + V12 devices compared to MDT + V12 devices (OR: 5.1, 95% CI: 2.0 to 12.8).

- **3.4 times** greater in patients with Zenith + V12 devices compared to MDT + V12 devices (HR: 3.4, 95% CI: 1.4 to 8.0).

- Unpublished data

- Submitted to JACC
Late Outcomes of 244 patients from PERICLES cohort

4-year mean follow-up (range, 2.5-10)

Presented at VAM 2016
### Anatomic & Device Characteristics

#### Snorkel Grafts  n=387

<table>
<thead>
<tr>
<th>Anatomical Location</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Renal</td>
<td>146</td>
</tr>
<tr>
<td>Left Renal</td>
<td>178</td>
</tr>
<tr>
<td>Acc. Renal</td>
<td>11</td>
</tr>
<tr>
<td>SMA</td>
<td>42</td>
</tr>
<tr>
<td>Celiac</td>
<td>10</td>
</tr>
</tbody>
</table>

- **Balloon-expandable (Covered)**: 55.7%
- **Self-expanding (Covered)**: 38.1%
- **Balloon-expandable (Bare Metal)**: 6.2%
Sac regression

Mean Pre-op Sac Diameter (mm) 63.6±13.4
Mean Latest F/U Sac Diameter (mm) 55.5±17.1
<table>
<thead>
<tr>
<th>Time</th>
<th>Primary Patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>95.8%</td>
</tr>
<tr>
<td>2 year</td>
<td>94.7%</td>
</tr>
<tr>
<td>3 year</td>
<td>94.1%</td>
</tr>
<tr>
<td>4 year</td>
<td>92.5%</td>
</tr>
<tr>
<td>5 year</td>
<td>90.1%</td>
</tr>
</tbody>
</table>
### Persistent/Late IA Endoleak

#### Type 1a endoleak

(\(n=14\)) 5.9%

(\(n=7\)) 2.9%

- **Re-intervention:**
  - **Univariate**
    - Neck Diameter >30mm: 5.06, 1.67-15.2, \(p=0.004\)
    - Complete absence of infrarenal neck: 2.92, 0.89-9.58, \(p=0.076\)
  - **Multivariate**
    - Neck Diameter >30mm: 4.86, 1.42-16.5, \(p=0.012\)
    - Complete absence of infrarenal neck: 2.61, 0.86-8.89, \(p=0.126\)
Conclusions from unpublished late results of ch-EVAR

- Significant regression of the aneurysm sac
- Long-term branch patency after Ch-EVAR of 90% at 5 years
- Low incidence of late Type Ia endoleak following Ch-EVAR
- Occurs more frequently in patients with larger native neck diameters >30mm, complete absence of infrarenal neck, short sealing zone of less than 20mm
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