What is the clinical significance of Type II endoleaks?

5-year analysis from the ENGAGE registry

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Type II endoleaks

• Most type II endoleaks spontaneously resolve, but about 10% persist and a subset causes AAA growth $^{1,2,3}$

• Delayed type II endoleaks are associated with an increased number of secondary interventions $^{4}$

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Type II endoleaks

- Rupture due to persistent type II endoleak is rarely reported and estimated to occur in less than 1% of all type II endoleaks \(^1\)

- Previous studies showed up to 21% of patients that underwent a reintervention for a Type II endoleak had an occult type I or III endoleak \(^2\)

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ENGAGE Global Postmarket Registry

- March 2009 – May 2011 enrollment
- 1263 AAA patients treated with the Endurant® endograft
- 79 centers, 30 countries, 6 continents
- Inclusion of patients allowed at discretion of physician
- Patient follow-up per institutional SOPs

Two groups were analyzed in this subanalysis:

1. Patients with an isolated type II endoleak only
2. Patients with a type II endoleak that later presented with a type I endoleak
Isolated type II endoleak

Through the 5 yr follow up, 197 (15.6%) patients were identified with isolated type II endoleaks
### Isolated type II endoleaks

#### Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Isolated type II endoleak (n=197)</th>
<th>No endoleak (n=893)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>73.8 ± 8.1</td>
<td>72.7 ± 8.1</td>
<td>0.078</td>
</tr>
<tr>
<td>Male sex (%)</td>
<td>88.8 (175/197)</td>
<td>89.9 (803/893)</td>
<td>0.694</td>
</tr>
<tr>
<td><strong>Smoking (%)</strong></td>
<td><strong>35.4 (68/192)</strong></td>
<td><strong>53.4% (465/871)</strong></td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>81.0 (158/195)</td>
<td>73.8 (649/879)</td>
<td>0.036</td>
</tr>
<tr>
<td>Hyperlipidemia (%)</td>
<td>68.9 (131/190)</td>
<td>59.4 (498/838)</td>
<td>0.015</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>18.4 (36/196)</td>
<td>19.6 (172/878)</td>
<td>0.695</td>
</tr>
<tr>
<td>Cardiac disease (%)</td>
<td>56.3 (111/197)</td>
<td>53.1 (474/892)</td>
<td>0.414</td>
</tr>
<tr>
<td>Pulmonary disease (%)</td>
<td>24.2 (47/194)</td>
<td>25.9 (227/877)</td>
<td>0.632</td>
</tr>
<tr>
<td>Renal insufficiency (%)</td>
<td>15.9 (31/195)</td>
<td>14.9 (132/885)</td>
<td>0.729</td>
</tr>
</tbody>
</table>

#### Aneurysm characteristics

<table>
<thead>
<tr>
<th></th>
<th>Isolated type II endoleak (n=197)</th>
<th>No endoleak (n=893)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max diameter (mm)</td>
<td>59.3 ± 9.7</td>
<td>59.7 ± 11.3</td>
<td>0.633</td>
</tr>
<tr>
<td><strong>Proximal neck diameter (mm)</strong></td>
<td><strong>23.1 ± 3.4</strong></td>
<td><strong>23.7 ± 3.5</strong></td>
<td>0.032</td>
</tr>
<tr>
<td>Proximal neck length (mm)</td>
<td>27.5 ± 11.6</td>
<td>27.0 ± 12.6</td>
<td>0.585</td>
</tr>
<tr>
<td>Proximal neck angle (°)</td>
<td>31.2 ± 23.0</td>
<td>29.2 ± 23.2</td>
<td>0.284</td>
</tr>
</tbody>
</table>
Isolated type II endoleaks

AAA Sac Dynamics

- **Regression**: Isolated type II endoleaks patients experienced less AAA sac regression and greater AAA sac enlargement compared to patients without any documented endoleaks.

- **Stable**: All yearly comparisons between groups are statistically significant.

- **Enlargement**: All yearly comparisons between groups are statistically significant except year 1.

- **Less AAA sac regression and greater AAA sac enlargement** compared to patients without any documented endoleaks.
Isolated type II endoleaks

Re-interventions

Through 5-Years

FF 2\textsuperscript{nd} Endo Procedures

92.5\% vs 79.2\%

p=\textless0.0001

Figure 8: Kaplan-Meier Estimates for Freedom from Secondary Endovascular Procedures
Isolated type II endoleaks
Aneurysm-related Mortality and Rupture

Through 5-Years

FF ARM
99.0% vs 99.5%
p = 0.5721

FF Rupture
99.8% vs 99.5%
p = 0.2736
Isolated type II endoleaks

Clinical outcome

Through 5-Yr follow-up:

Patients with an isolated type II endoleak had

- Significantly worse positive AAA remodeling, and
- A significantly increased number of re-interventions

While demonstrating

- Very low and similar
  - Freedom from Aneurysm-related Mortality, and
  - Freedom from Rupture

Through 1-Yr, there were no differences in Health Status (EQ-5D) except for anxiety/depression
Interestingly, patients with type II endoleaks had better overall survival compared to patients without any documented endoleaks through 5 years. The Kaplan-Meier estimates show that the freedom from all-cause mortality was 67.0% for patients with type II endoleaks and 77.2% for those without, with a p-value of 0.0101.
Mean time between diagnosis of type II and type I endoleak

- 32 months (21-48 months)

Incidence of Aneurysm Rupture in these patients

- 18.2% (4/22) vs. 0.51% (1/197) in patients with isolated type IIIs only

Anatomy compared to patients with isolated type IIIs only

- Neck lengths <15 mm  
  25% vs. 6.1% (p=0.003)
Type II patients who later developed a Type I endoleak experienced:

- Significantly lower Freedom from AAA Rupture, and
- Significantly lower Freedom from AAA-related Mortality

Through 5-Years

Freedom from Aneurysm Rupture

80.2% vs 99.5%
p=<0.001

Freedom from Aneurysm-related Mortality

90.0% vs 99.5%
p=0.002
Type II patients who later developed a Type I endoleak underwent significantly more 2nd endovascular procedures through 5-years.

Through 5-Years
FF 2nd Endo Procedures
32.5% vs 79.2%
p=<0.0001
Summary

Through 5 years in the ENGAGE registry:

• Isolated type II endoleaks occurred in 15.6% of patients

• These isolated type IIIs are associated with:
  • Increased rates of sac enlargement and less sac regression, and
  • Significantly more endovascular re-interventions

• These isolated type IIIs did not negatively impact AAA ruptures or AAA-related mortality overall
Summary

- However, a small sub-group of patients with an isolated type II endoleak will later present with a type I endoleak (~11%, 22/197)

- This subsequent development of a type I endoleak results in a significant increase of aneurysm-related complications, specifically:
  - High rupture risk and high aneurysm-related mortality, requiring
  - Very high need for 2\textsuperscript{nd} endovascular re-interventions

- Identification of those patients that have a type II patients and later develop a type I is the future challenge, as a lower threshold of re-intervention may be warranted
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