The role of Type II endoleaks on secondary endovascular procedures and overall sac dynamics

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• W.L. Gore and associates
• Medtronic
Type II endoleaks

• Most type II endoleaks spontaneously resolve, but about 10% persist and a subset causes AAA growth.  

• Delayed type II endoleaks are associated with an increased number of secondary interventions.

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:
1. Patients with an isolated type II endoleak
2. Patients with a type II endoleak that were later diagnosed with a type I endoleak
Isolated type II endoleak

Through 5-year follow up 197 (15.6%) patients were identified with an isolated type II endoleak

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>Smoking (%)</td>
<td>35.4% (68/192)</td>
<td>53.4% (465/871)</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>
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</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>Proximal neck diameter (mm)</td>
<td>23.1 ± 3.4</td>
<td>23.7 ± 3.5</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

Stable

Enlargement

Isolated type II endoleak patients experienced less AAA sac regression and greater AAA sac enlargement compared to patients without any documented endoleaks.

Aneurysm sac failure to regress after endovascular aneurysm repair is associated with lower long-term survival

Thomas F. X. O’Donnell, MD; Sarah E. Deery, MD, MPH; Laura T. Boitano, MD; Jeffrey J. Siracuse, MD; Marc L. Schermerhorn, MD; Salvatore T. Scali, MD; Andres Schanzer, MD; Robert T. Lancaster, MD, MPH; and Virendra I. Patel, MD, MPH, Boston and Worcester, Mass; Gainesville, Fla; and New York, NY

Not only sac expansion but any failure of the sac to regress is associated with higher long-term mortality, independent of reinterventions or endoleaks
Isolated type II endoleaks
Re-interventions

Through 5-Years
FF 2nd Endo Procedures
92.5% vs 79.2%
p=<0.0001
Isolated type II endoleaks

Aneurysm-related Mortality and Rupture

Through 5-Years

FF ARM

99.0% vs 99.5%

p=0.5721

Through 5-Years

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
  • Significantly more re-interventions

While demonstrating a low and similar;
  • AAA-related mortality
  • Rupture rate

Through 1-Yr, there were no differences in Health Status (EQ-5D)
Type II endoleak patients who later were diagnosed with a Type I endoleak

22 out of 1263 patients (1.7%)

Mean time between diagnosis of type II and type I endoleak
- 32 months (21-48 months)

Anatomy compared to patients with isolated type IIs only
- Neck length <15 mm 25% vs. 6.1% (p=0.003)

Incidence of AAA rupture
- 18.2% (4/22) vs. 0.51% (1/197) in patients with an isolated type II
Type II patients who later developed a Type I endoleak experienced:

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

Through 5-Years

FF Rupture

80.2% vs 99.5%

p=<0.001

Through 5-Years

FF ARM

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.

FF 2nd Endo Procedures
32.5% vs 79.2%

$p<=0.0001$
The burden of reinterventions

- Overall difference in mean cost between the open and EVAR at 1-year is £2194
- The difference increases gradually over 14 years to £3798

Most of the difference is the result of initial procedural costs and subsequent **reinterventions**

Results of Type II endoleak treatment

- Failure rate 38% for transarterial and 19% for translumbar embolization
- Despite “successful” treatment a large number of patients do not have a stable sac diameter
- NO ruptures in the failed treatment group
• Type II endoleaks have different clusters and not all are benign
• In some cases they could be associated with an undetected type I or III endoleak
• Type II endoleaks impact sac behavior and lead to less sac regression
• Re-interventions for type II endoleaks are costly and often ineffective
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