Selective intra-procedural AAA sac embolization during EVAR reduces the rates of type II endoleak

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Disclosure

Selective intra-procedural AAA sac embolization during EVAR reduces the rates of type II endoleak

Speaker name: Prof. Mauro Gargiulo

I have the following potential conflicts of interest to report:

X Consulting: Cook Medical
X PI Expand Registry
Employment in industry
Stockholder of a healthcare company
Owner of a healthcare company
Other(s)
Endoleak type II

AAA retrograde flow  10-25%
✓ Lumbar arteries
✓ Inferior mesenteric artery
✓ Other efferent vessels (polar, hypogastric, ecc)

Chaikof et al JVS 2002
Moll F et al EJVES 2011
Type II endoleak is an enigmatic and unpredictable marker of worse outcome after endovascular aneurysm repair.


Aneurysm Growth

FF Reintervention

no ELII

ELII

p < .0001

no ELII

ELII

p < .0001
Risk factors and consequences of persistent type II endoleaks

Freedom From Reintervention

![Graph showing the freedom from reintervention for transient and persistent type II endoleaks over 2 years with a p-value of < .001.](image)
Endoleak type II

- **Transient**  
  ≈ 80%

- **Persistent (> 6 months)**  
  8 - 23 %

*Abullarage et al J Vasc Surg 2010*

*Marchiori et al J Endovasc Ther 2011*
Indication to the treatment

- Translumbar sac embolization
- Embolization agents
- Post-embolization mean follow-up

**Type II EL + sac expansion**

44

**Coils and/or glue**

23 ± 20 months

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Outcomes of percutaneous endovascular intervention for type II endoleak with aneurysm expansion

Aziz et al, 
J Vasc Surg 2012
Outcomes of percutaneous endovascular intervention for type II endoleak with aneurysm expansion

Aziz et al, J Vasc Surg 2012

Persistent type II endoleak at latest follow-up

No difference in pre- and post- embolization sac growth rates
Persistent Type II Endoleak - Preventive approach

- New devices
- Selective pre-operative embolization
- Intraoperative AAA-sac embolization
Persistent Type II Endoleak - Preventive approach

✓ New devices

✓ Selective pre-operative embolization

✓ Intraoperative AAA-sac embolization
Persistent Type II Endoleak - Preventive approach

✓ Intraoperative AAA-sac embolization: When

✓ routinely

✓ selectively
Role of aneurysm sac embolization during EVAR in the prevention of type II endoleak-related complications

- Routinely AAA-sac embolization with standard dose of coils and fibrin glue

- 2 groups:
  . EVAR (group A)
  . EVAR + embolization (group B)
Role of aneurysm sac embolization during EVAR in the prevention of type II endoleak-related complications

Routinely AAA-sac embolization with standard dose of coils and fibrin glue

2 groups:
- EVAR (group A)
- EVAR + embolization (group B)

Results

Freedom from ELII

Routinely AAA-sac embolization does not significantly reduce ELIIp at 12-18 months
Persistent Type II Endoleak - Preventive approach

✓ Intraoperative AAA-sac embolization: When

✓ routinely

✓ selectively
Risk Factors for ELII - Literature

- AAA-sac thrombus load
- Lumbar arteries Ø > 2 mm
- IMA Ø > 3 mm
- Preoperative AAA large Ø
- Preoperative AAA-sac total volume > 125 cm³*

Persistently type II EL after EVAR

Predictive value of the AAA-thrombus volume

Gallitto E et al,
J Cardiovasc Surg 2018

Preoperative evaluation of Morphological Bi-dimensional Characteristics

<table>
<thead>
<tr>
<th>AAA diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>True lumen diameter</td>
</tr>
<tr>
<td>Thrombus thickness</td>
</tr>
<tr>
<td>Patent efferent vessels</td>
</tr>
<tr>
<td>Inferior mesenteric artery</td>
</tr>
<tr>
<td>Lumbar a</td>
</tr>
<tr>
<td>Sacral a</td>
</tr>
<tr>
<td>Polar renal a</td>
</tr>
<tr>
<td>N efferent patent vessels</td>
</tr>
</tbody>
</table>
Persistent type II EL after EVAR
Predictive value of the AAA-thrombus volume

Gallitto E et al,
J Cardiovasc Surg 2018

Preoperative evaluation of Morphological Tri-dimensional Characteristics

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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<tbody>
<tr>
<td><strong>Total Volume</strong></td>
<td>(VTot)</td>
</tr>
<tr>
<td><strong>Lumen Volume</strong></td>
<td>(VLu)</td>
</tr>
<tr>
<td><strong>Thrombus Volume</strong></td>
<td>(VTh)</td>
</tr>
<tr>
<td><strong>Percentage of Thrombus Volume</strong></td>
<td>(%VT)</td>
</tr>
</tbody>
</table>

![Image showing total volume, lumen volume, thrombus volume, and percentage of thrombus volume.](image)
Persistent type II EL after EVAR

Predictive value of the AAA-thrombus volume

Gallitto E et al, J Cardiovasc Surg 2018

Volume 147 cc
Volume 89 cc

Volume Thrombus < 40%
Patent Efferent Vessels ≥ 6
Persistent Type II Endoleak - Preventive approach

Intraoperative AAA-sac embolization

Selective in High Risk Patients
Patent Efferent Vessels $\geq 6$
Volume Thrombus $< 40\%$
Persistent Type II Endoleak - Preventive approach

✓ Intraoperative AAA-sac embolization: Technique

Surgical approach

Percutaneous approach

Destination
5 F – 45 cm
MRey Cook coils
IMWCE-38-16-45
Selective Intra-procedural AAA sac Embolization during EVAR reduces the rate of Type II Endoleak in **high risk** patients

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**High risk patient**

Patent Efferent Vessels ≥ 6  
Volume Thrombus < 40%

---

<table>
<thead>
<tr>
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<th>Not Embolized</th>
<th>Embolized</th>
</tr>
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<tbody>
<tr>
<td><strong>0 months</strong></td>
<td>75 %</td>
<td>31 %</td>
</tr>
<tr>
<td><strong>6 months</strong></td>
<td>68 %</td>
<td>27 %</td>
</tr>
<tr>
<td><strong>12 months</strong></td>
<td>73%</td>
<td><strong>20%</strong></td>
</tr>
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---

Mascoli C et al  
EJVES 2018
Selective Intra-procedural AAA sac Embolization during EVAR reduces the rate of Type II Endoleak in high risk patients

Mascoli C et al EJVES 2018

High risk patient

Patent Efferent Vessels ≥ 6
Volume Thrombus < 40%

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Persistent Type II Endoleak - Preventive approach

Intraoperative AAA-sac embolization

How to make it effective?
Retrospective study

EVAR, 2012 - 2015

EVAR - high risk for ELIIp underwent to intraoperative AAA - sac embolization
Method

3D morphological pre-operative characteristics

Volume
Method

3D Implant details

Residual Lumen Volume
Method

3D Implant details

<table>
<thead>
<tr>
<th>Residual Lumen Volume</th>
<th>Coils Concentration</th>
</tr>
</thead>
</table>

coil/cm³
# Results

- 61 AAA intraoperative AAA-sac embolization
- @ 12 months

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persistent EL II</td>
<td>14</td>
<td>23</td>
</tr>
<tr>
<td>no EL II p</td>
<td>47</td>
<td>77</td>
</tr>
</tbody>
</table>
# Results

<table>
<thead>
<tr>
<th></th>
<th>EL II p mean</th>
<th>No EL II p mean</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAA Volume (cm³)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Volume</td>
<td>174</td>
<td>151</td>
<td>.98</td>
</tr>
<tr>
<td>Thrombus Volume</td>
<td>61</td>
<td>57</td>
<td>.50</td>
</tr>
<tr>
<td>Endograft Volume</td>
<td>53</td>
<td>51</td>
<td>.62</td>
</tr>
<tr>
<td><strong>Residual Lumen</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Volume</strong></td>
<td>59</td>
<td>42</td>
<td>.009</td>
</tr>
<tr>
<td>Coils</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N coils</td>
<td>5</td>
<td>4</td>
<td>.11</td>
</tr>
<tr>
<td>Coils Concentration</td>
<td>0.09</td>
<td>0.18</td>
<td>.01</td>
</tr>
</tbody>
</table>
Results

Coils Concentration

Cutoff *

0.17 coil/ cm³

No one patient with Concentration of Coils > 0.17 developed ELIIp (P = .005)

* Youden J Statistic. Area (95% Intervallo di Confidenza [IC])

Vascular Surgery Unit – University of Bologna, Italy
How many coils are needed to make an effective ELIIp prevention?
**Embolization dose Algorithm**

Residual Lumen Volume $\times 0.17 =$

N of coils to obtain an Effective Sac thrombosis

<table>
<thead>
<tr>
<th>Residual Lumen Volume (cm$^3$)</th>
<th>N coils (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>5</td>
</tr>
<tr>
<td>40</td>
<td>7</td>
</tr>
<tr>
<td>50</td>
<td>9</td>
</tr>
<tr>
<td>60</td>
<td>10</td>
</tr>
<tr>
<td>70</td>
<td>12</td>
</tr>
<tr>
<td>80</td>
<td>14</td>
</tr>
<tr>
<td>100</td>
<td>17</td>
</tr>
</tbody>
</table>
Prospective study

EVAR, 2017 - 2018

EVAR - high risk for ELIIp underwent to Intraoperative AAA - sac embolization with a volume-tailored concentration of coils
Method

- **Volume tailored Embolization**
  - 40 patients (prospective)

- **Not volume tailored Embolization**
  - 98 patients (historical)
## Results

### Clinical / demographic

<table>
<thead>
<tr>
<th></th>
<th>Volume tailored embolization</th>
<th>Not volume tailored embolization</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N, %</td>
<td>N, %</td>
<td></td>
</tr>
<tr>
<td>Age (y)</td>
<td>75 (7)</td>
<td>73 (8)</td>
<td>.68</td>
</tr>
<tr>
<td>Sex (f)</td>
<td>2 (5)</td>
<td>4 (4)</td>
<td>1</td>
</tr>
<tr>
<td>Hypertension</td>
<td>34 (85)</td>
<td>87 (89)</td>
<td>.57</td>
</tr>
<tr>
<td>COPD</td>
<td>17 (42)</td>
<td>31 (32)</td>
<td>.24</td>
</tr>
<tr>
<td>Dyslipidaemia</td>
<td>26 (65)</td>
<td>62 (63)</td>
<td>1</td>
</tr>
<tr>
<td><strong>CRF</strong></td>
<td>16 (40)</td>
<td>17 (17)</td>
<td>.008</td>
</tr>
<tr>
<td>Smoke</td>
<td>19 (47)</td>
<td>22 (22)</td>
<td>.37</td>
</tr>
<tr>
<td><strong>BMI &gt; 30</strong></td>
<td>3 (8)</td>
<td>24 (24)</td>
<td>.03</td>
</tr>
<tr>
<td>ASA score ≥ 3</td>
<td>38 (95)</td>
<td>94 (96)</td>
<td>1</td>
</tr>
<tr>
<td>AOT</td>
<td>4 (10)</td>
<td>11 (11)</td>
<td>1</td>
</tr>
<tr>
<td>Double Ag</td>
<td>3 (8)</td>
<td>1 (1)</td>
<td>.07</td>
</tr>
<tr>
<td>Statin</td>
<td>24 (60)</td>
<td>56 (57)</td>
<td>.85</td>
</tr>
</tbody>
</table>
## Results

### Morphological / Implant details

<table>
<thead>
<tr>
<th>Coils</th>
<th>Volume tailored embolization</th>
<th>Not volume tailored embolization</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration</td>
<td>0.34 ± 0.11</td>
<td>0.10 ± 0.03</td>
<td>&lt; .0001</td>
</tr>
<tr>
<td>Number</td>
<td>10.3 ± 3.4</td>
<td>4.6 ± 1.4</td>
<td>&lt; .001</td>
</tr>
</tbody>
</table>

Vascular Surgery Unit – University of Bologna, Italy
## Results

### Persistent Type II EL

<table>
<thead>
<tr>
<th></th>
<th>Volume tailored embolization</th>
<th>Not volume tailored embolization</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>@ 6 months</td>
<td>5</td>
<td>23</td>
<td>.01</td>
</tr>
<tr>
<td>@ 12 months</td>
<td>5</td>
<td>21</td>
<td>.02</td>
</tr>
</tbody>
</table>
Selective intra-procedural AAA sac embolization during EVAR reduces the rates of type II endoleak

Conclusion

Selective intra-procedural AAA sac embolization is:

✓ safe and simple
✓ effective in ELIIp reduction in selected high risk patients
✓ the embolization dose algorithm according with the residual lumen volume can guarantee the effective N of coils that are needed to obtain a AAA sac thrombosis and a significant reduction of pELII