Active aneurysm sac management; the missing link of EVAR?

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Disclosure

Speaker name:
Michel Reijnen

I have the following potential conflicts of interest to report:

- Consultant

- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

☐ I do not have any potential conflict of interest
Is EVAR undergoing a paradigm shift?

Sac dynamics have always been a robust indicator of EVAR durability but without distinction between stable and regressing aneurysms.

**NEW EVIDENCE** suggests there is a reason to differentiate.

Regressing sacs are linked to better long term outcomes.
Is EVAR undergoing a paradigm shift?
New evidence links sac shrinkage to better outcomes

17,096 total subjects in 8 studies (8,518 patients with sac shrinkage & 8,578 patients without shrinkage) subjected to EVAR between 1997-2018²
Isolated type II endoleaks

AAA sac dynamics

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

What is active sac management?

**EVAR** alone does not directly address the sac
- Biologically active thrombus triggers acute and chronic inflammation
- Endoleak perfuses/pressurizes sac

**EVAR with active sac management also treats the sac**
- Designed to promote stable clot formation, without chronic inflammation
- Intended to improve sac regression
Sac embolization during EVAR

Outcomes of endovascular aneurysm repair with contemporary volume-dependent sac embolization in patients at risk for type II endoleak

Michele Piazza, MD, Francesco Squizzato, MD, Marco Zavatta, MD, Mirko Menegolo, MD, Joseph J. Ricotta 2nd, MD, Sandro Lepidi, MD, Franco Grego, MD, and Michele Antonello, MD, Padova, Italy, and Atlanta, Ga

Table IV. Aneurysm sac volume variation compared with the preoperative volume

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A</th>
<th>Group B</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTA ≤3 months</td>
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<td></td>
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<tr>
<td>Volume variation</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>cm³</td>
<td>+2.7 ± 12.8</td>
<td>-1.2 ± 5.8</td>
<td>.05</td>
</tr>
<tr>
<td>%</td>
<td>+2.3 ± 11.1</td>
<td>-0.9 ± 4.3</td>
<td>.05</td>
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<tr>
<td>CTA at 6 months</td>
<td></td>
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<td></td>
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<tr>
<td>Volume variation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cm³</td>
<td>-2.2 ± 14.2</td>
<td>-10.6 ± 17.1</td>
<td>.007</td>
</tr>
<tr>
<td>%</td>
<td>-1.7 ± 15.3</td>
<td>-7.5 ± 10.6</td>
<td>.02</td>
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<tr>
<td>CTA at 12 months</td>
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<tr>
<td>Volume variation</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>cm³</td>
<td>-2.9 ± 32.2</td>
<td>-18.9 ± 26.6</td>
<td>.02</td>
</tr>
<tr>
<td>%</td>
<td>-2.1 ± 26.8</td>
<td>-14.2 ± 16.7</td>
<td>.02</td>
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<tr>
<td>CTA at 24 months</td>
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<tr>
<td>Volume variation</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>cm³</td>
<td>-4.6 ± 25.9</td>
<td>-27.3 ± 24.7</td>
<td>.008</td>
</tr>
<tr>
<td>%</td>
<td>-2.9 ± 21.5</td>
<td>-21.6 ± 17.2</td>
<td>.005</td>
</tr>
</tbody>
</table>

CTA, Computed tomography angiography.

aData are presented as the mean ± standard deviation (cm³ and %).
bStatistically significant.
Sac embolization using coils

- Sac embolization significantly reduces the incidence of type II endoleaks
  - At discharge: 8/26 vs. 33/44 (p < .001)
  - At 12 months: 5/25 vs. 32/44 (p < .001)
- Failure of sac embolization is related to
  - Higher endoluminal residual sac volume
  - Lower concentration of coils implanted

Complete filling of the aneurysmal sac seems to be the key factor driving success

Coils cause significant scatter on follow-up imaging

Shape Memory Polymer

- High volume embolic material for **space filling**
- High surface area of porous scaffold induces long fluid residence times, low shear rates; Leads to **stasis** and **thrombus formation**
- **Progressive healing** of thrombus to mature tissue
- Radiolucent for **imaging clarity** and minimal imaging artifact
Sac Management with Shape Memory Polymer

Goals:

• Stable clot formation within porous matrix
• Biodegradable with collagen formation
• No chronic inflammation
• Improve imaging visibility
• Induce sac shrinkage
AAA Sac Embolization with Shape Memory Polymer

- FIH experience, prophylactic AAA sac management
- 18 patients, 2 German centers, 2019-2021
- IMPEDE-FX, IMPEDE-FX RapidFill
- 100% technical success
- Sac regression in all patients with ≥3m follow-up (mean 11m)
- Sac regression even in presence of small T2 endoleaks
- No morbidity or mortality related to treatment

Conclusion: Sac management with Shape Memory Polymer appears feasible and safe in small case series
• Prospective, multicenter safety trial
• 35 patients
• 100% technical success
  • Mean volume of embolic material 52 mL (8 to 119 ml)
  • Mean IMPEDE-FX RapidFill devices 12 (5-27)
• No device- or procedure-related MAEs
• Two device-related SAEs (post implantation syndrome)
• Four reinterventions related to EVAR procedure for:
  • Type 1a endoleak
  • EVAR limb stenosis
  • EVAR limb occlusion
  • Partial coverage of left renal artery with EVAR graft
AAA-SHAPE Sac Filling Technique

*Post-EVAR*
Exchange GW for 6F catheter

*Post-EVAR*
Baseline Sacogram

Quadrant filling of sac via 6F catheter

Distribution of the polymer plugs ~100% volume fill

Final Angiogram after catheter removal and re-ballooning of limb
AAA-SHAPE Imaging Follow-up (Core Lab)

**Definitions**
- **Regress**: >= 5mm or 10% mL reduction
- **Stable**: <5 mm or 10% mL reduction & <5mm or 10% mL expansion
- **Expand**: >=5mm  or 10% mL expansion

**Std. EVAR**
- **ENGAGE**: Li et al. ENGAGE Registry. Accepted for publication.

**Preliminary data from an ongoing clinical investigation, data subject to change**

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**Diameter Change >5mm**
- AAA-SHAPE 6 months N=33: 39% Regress, 61% Stable, 0% Expand
- AAA-SHAPE 1 year N=27: 56% Regress, 44% Stable, 0% Expand
- Std. EVAR VQI 1 year: 40% Regress, 35% Stable, 25% Expand
- Std. EVAR ENGAGE 1 Year: 46% Regress, 49% Stable, 5% Expand

**Volume Change >10%**
- AAA-SHAPE 6 months N=33: 61% Regress, 36% Stable, 3% Expand
- AAA-SHAPE 1 year N=27: 78% Regress, 19% Stable, 4% Expand
- Std. EVAR VQI 1 year: Not Reported
- Std. EVAR ENGAGE 1 Year: Not Reported
Subjects with T2 endoleak with follow-up

Type 2 Endoleaks (Core Lab)

Preliminary data from an ongoing clinical investigation, data subject to change
Innovative solutions for active sac management

- TripleMed AneuFix Procedure
- Kardiosis Endoprosthesis
- Life Seal Vascular Solution
Summary

- A paradigm shift is emerging, and a shrinking aneurysm should likely become the goal of future EVAR, as 1-year stable sacs are not always benign.

- Type II endoleaks play an important role in sac remodeling after EVAR.

- Active sac management may prove to be an important addition to standard EVAR, but the most effective technique, patient stratification and cost-effectiveness still needs to be defined.
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