Mid-term results from ANCHOR and how these clinical insights affect my clinical practice

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DISCLOSURES

- Consultant for Medtronic, Getinghe, Bentley Innomed
- Research Grant: Hyperview
- Co-founder: Endovascular Diagnostics B.V.
HELIX™ ENDOANCHOR™ IMPLANT SYSTEM

- Supersede strength of a hand-sewn anastomosis\(^1\)

- Mechanically prevent aorta-endograft separation\(^2\)

\(^1\) Melas et al. JVS. 2012;55(6):1726-33
\(^2\) Tassiopoulos AK et al. JVS. 2017;66(1):45-52
ANCHOR REGISTRY: PRIMARY ARM

N=716 patients treated with EndoAnchor™ Implants at Index EVAR

Reasons for EndoAnchoring
- 57.3% Concern for Late Failure
- 21.9% Prevention of Neck Dilatation
- 20.1% Treatment of Type la at Index

87.9% ASA Class III/IV
18.2% Urgent/Emergent Cases

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18.2% Urgent/Emergent Cases

Hostile Necks: 88.6%
- <15mm, >28mm, >60°, Conical, Ca²⁺/Thrombus >50%

Infrarenal Diameter: 23.9 mm
Infrarenal Angulation: 36.6°
Neck Length: 15.0 mm (median) 17.3 mm (mean)
Conical Neck (>10%/10mm): 41.7%

Aneurysm Diameter: 59.0 mm
Conical Neck (>10%/10mm): 41.7%

Male: 78%
Female: 22%
Mean Age: 73.3 Years

*Data cut June 13, 2019*
ANCHOR REGISTRY: PRIMARY ARM (N=716 pts)

- Endograft Delivered Successfully: 98.2% (at intended location)
- Successful Implantation of EndoAnchors at Index: 98.7% (at intended location)
- EndoAnchor Adequately Penetrated Aortic Wall: 95.9%

Hostile Necks: 88.6%

*Data cut June 13, 2019*
ANCHOR REGISTRY: PRIMARY ARM (N=716 pts)

- No migration through 4yrs
- Type Ia endoleak at 4yrs: 3.4% [4/117]
- Through 4yrs, Freedom from 2nd Endo Proc to treat Type Ia’s: 97.7%

Hostile Necks: 88.6%
ANCHOR REGISTRY, therapeutic use in revision setting

Indications for EndoAnchor Implants, 246

100% Failed EVAR revisions:
- 13% Migration
- 53.3% Type Ia Endoleak
- 19% Combination
- 23% Urgent/Emergent Cases

Male: 85%    Female: 15%
Mean Age: 78 Years

EndoAnchors placed 4.6 years post-Index EVAR (mean)

Index EVAR  Avg 4.6 yrs to EVAR failure  EndoAnchor placement  4 years follow-up  Outcomes 8-9 years after Index EVAR
ANCHOR REGISTRY, therapeutic use in revision setting

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ANCHOR REGISTRY, revision cohort, anatomical characteristics

**Hostile Necks: 85.6%**
*Per the SVS definition*

- **Infrarenal Diameter:** 25.9 mm (median)
- **Infrarenal Angulation:** 30°
- **Neck Length:** 15 mm (median)
- **Aneurysm Diameter:** 68 mm (median)
- **Conical Neck (>10%/10mm):** 41.2%

<table>
<thead>
<tr>
<th>Neck Length &lt; 15 mm</th>
<th>42.6% (80/188)</th>
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<tbody>
<tr>
<td>Neck Calcium ≥ 2 mm</td>
<td>18.4% (40/217)</td>
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</table>
## ANCHOR REGISTRY: REVISION COHORT

### Technical Success
Investigator defined successful deployment of EndoAnchor implants at their intended location

- **Avg. duration of Procedure (min)**: 126
- **95.1% Revision**

### Aortic Wall Penetration
EndoAnchor Implants adequately penetrated the aortic wall

- **Avg. time to EndoAnchor implants (min)**: 20
- **93.1% Revision**

- **Avg. number of EndoAnchor implants**: 7

*Data cut June 13, 2019*
**Technical Success**
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**Aortic Wall Penetration**
EndoAnchor Implants adequately penetrated the aortic wall

- **93.1% Revision**

**Kaplan-Meier Estimates**

<table>
<thead>
<tr>
<th>Through 3 years</th>
<th>Through 4 years</th>
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<tbody>
<tr>
<td>Freedom from ACM</td>
<td>60.9%</td>
</tr>
<tr>
<td>Freedom from ARM</td>
<td>91.1%</td>
</tr>
<tr>
<td>Freedom from type Ia endoleak</td>
<td>66.1%</td>
</tr>
<tr>
<td>Freedom from 2nd Procedures for Type Ia endoleak</td>
<td>84.3%</td>
</tr>
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*Data cut June 13, 2019*
10 pts at 4yrs experienced AAA sac enlargement

- 6/10 (60%) were off-label for the endograft at baseline including:
  - Excessive thrombus, Wide neck, Severe angulation, Short neck, Too few EndoAnchors
- The other 4/10 (40%) had persistent/late type IIs driving sac enlargement

*Data cut June 13, 2019
These sac dynamic data highlight the challenges treating failed EVAR pts.

For those at high risk of disease progression, this revision cohort demonstrates the clinical value of treating these patients at index instead of waiting for the EVAR to fail.
Propensity Matched Comparison With and Without EndoAnchors

More Competent Proximal Seal Enhances AAA Remodeling

In a propensity-matched study design, increased rate of AAA sac regression

Methodology
- Pre-EVAR CTs by core lab
- Neck lengths >20 mm
- 2 cohorts:
  - 99pts EVAR
  - 99pts EVAR+EndoAnchor
- Propensity matching on 19 variables

Muhs, BE et al. JVS. 2018 June;67(6): 1699-1707
Analysis of the position of EndoAnchor implants in therapeutic use during endovascular aneurysm repair

Seline R. Goudeketting, MSc, Kim van Noort, MSc, Jenske J. M. Vermeulen, BSc, Kenneth Ouriel, MD, William D. Jordan Jr, MD, Jean M. Panneton, MD, Cornelis H. Slump, MSc, PhD, and Jean-Paul P. M. de Vries, MD, PhD, Nieuwegein, Enschede, and Groningen, The Netherlands: New York, NY: Atlanta, Ga; and Norfolk, Va

Methods:
Two groups of patients from Anchor Registry (multiple endograft devices)

Total of 580 individual EndoAnchors assessed

No Type Ia at first post-op scan: N=53
Persistent Type Ia at first post-op scan: N=33
EndoAnchor Penetration

Penetration of each EndoAnchor defined as:

**Good**: Penetration of \( \geq 2 \text{ mm} \) in the aortic wall

**Borderline**: Penetration of \(< 2 \text{ mm}\) or a gap remained between the endograft and the aortic wall

**No**: Did not penetrate into the aortic wall

Deployment angle also analyzed
Proper EndoAnchor Penetration Drives Procedural Success

Resolved Type Ia Endoleak (Successful)  
N = 53

Persistent Type Ia Endoleak (Unsuccessful)  
N = 33

Legend
- Red: No penetration
- Orange: Borderline penetration
- Green: Good penetration

EndoAnchor deployment beyond recommended use induces failed penetration

EA distribution in successfully treated type IA endoleaks

EA distribution in successfully treated type IA endoleak with exclusion of those beyond recommended use

Legend:
- Red: No penetration
- Orange: Borderline penetration
- Green: Good penetration
Angle of EndoAnchor Penetration also matters

Ideally, EndoAnchors should be deployed perpendicular to the aortic wall 90-degree orthogonal and longitudinal angle

CONCLUSIONS

• 4 years results of EndoAnchors in primary setting is associated with
  • No migration
  • Low incidence of type IA endoleaks (3.4%)
  • >60% of AAA sacs with regression through 4 yrs of FU

• 4 year results from ANCHOR revision cohort demonstrate
  • Acceptable percentage of aneurysm-related mortality
  • Relatively low need for 2nd procedures to treat type Ia’s
  • Stable of regression AAA sac diameter in 73.5% of patients

• Proper deployment of EndoAnchors within recommended use is key to success
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