SOCRATES Randomized Controlled Clinical Trial Design: Physician-initiated trial comparing outcomes of ESAR and FEVAR in infrarenal short aortic neck aneurysms

Giovanni B Torsello
Emeritus Professor of Vascular Surgery
University of Münster
Germany

The Leipzig Interventional Course, 6-9 June 2023, Leipzig, Germany
Disclosures

I have the following potential conflicts of interest to report:

- Receipt of grants and research support (Medtronic)
- Participation in a company-sponsored speaker bureau (Medtronic)

- Receipt of honoraria and travel support
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company

- I do not have any potential conflict of interest

Speaker:
Giovanni B Torsello
Background

Hostile aortic neck can lead to loss of proximal seal over time

Short necks associated with increased risk of Type IA EL and secondary procedures\textsuperscript{1,2,3}

Options to either extend the seal zone proximally or reinforce seal zone

FEVAR is an option used to treat hostile neck anatomies\textsuperscript{1,2}

Concern of freedom from branch intervention\textsuperscript{3}

\begin{itemize}
  \item 94\% through 1 year
  \item 84\% through 5 years
\end{itemize}

\begin{table}
\centering
\begin{tabular}{l|c}
\hline
Fevar outcomes by Sveinsson et al.\textsuperscript{4} & \\
\hline
Overall survival through 3 years & 87.1\% ± 3.5\% \\
Death of aneurysm related causes through entire FU period & 5.3\% (5/94) \\
No. of patients requiring reintervention at any point during FU & 39.4\% (37/94) \\
Primary target vessel patency at 3 years & 90\% ± 2\% \\
\hline
\end{tabular}
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Heli-FX™ EndoAnchor™ System shows reinforcement of proximal seal\(^1\) and low rates of Type IA ELs\(^2-4\)

Five-year short neck analysis of ANCHOR Registry showed durability of treatment\(^5\)

<table>
<thead>
<tr>
<th>Kaplan Meier Freedom from Estimates through 5 years</th>
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<tbody>
<tr>
<td>FF All Cause Mortality</td>
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<tr>
<td>FF Aneurysm Related Mortality</td>
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<tr>
<td>FF Rupture</td>
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<td>FF Any secondary procedures</td>
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Retrospective analysis of 18 ESAR patients matched with 18 FEVAR patients suggest comparable early outcomes\(^6\)

Methods: Short neck AAA randomized trial (SOCRATES)

Purpose: To compare the safety and performance of ESAR and FEVAR for the treatment of AAA patients with infrarenal aortic proximal neck lengths 4 to 15 mm and minimum proximal sealing zone length of 8mm

Sponsor: Foundation for Cardiovascular Research and Education (FCRE), Germany

Collaborator: Medtronic Vascular, Inc., California, USA

Principal Investigators:
- Giovanni B. Torsello, University of Münster, Germany
- Brant Ullery, Providence Portland Medical Center, United States

Clinical Event Committee: Responsible for evaluating and adjudicating MAEs, specified clinical endpoints and determining their device- and procedure-relatedness

Core Laboratory: Responsible for independent image analysis
Methods: Trial Cohort

Up to 40 sites (US and EU)

*Countries participating in the SOCRATES Trial*

<table>
<thead>
<tr>
<th>Austria</th>
<th>Netherlands</th>
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<tr>
<td>Belgium</td>
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<td>Germany</td>
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Methods: Patient Selection

At least 204 subjects to be randomized (1:1)

- ESAR Arm: Endurant II/IIIs with Heli-FX EndoAnchor implants
- FEVAR Arm: Cook Zenith Fenestrated or Terumo Fenestrated Anaconda (EU only) stent graft systems

Subject Screening: Does patient meet all I&E criteria and provide informed consent?

Core Lab Review: Does subject meet anatomical criteria?

1:1 Randomization

Screening Failure

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Methods: Key Inclusion and Exclusion Criteria

Key Inclusion Criteria

- Proximal aortic neck length of 4 to 15mm and a minimum sealing zone of 8mm
- AAA anatomy meets overlapping requirements according to local/regional IFUs for available devices
  - Endurant II/IIIs stent graft system
  - Heli-FX EndoAnchor system
  - Terumo Fenestrated Anaconda (available in EU only) and/or
  - Cook Zenith Fenestrated Graft

Key Exclusion Criteria

- Subject has an aneurysm that is suprarenal, pararenal, thoracoabdominal, mycotic, inflammatory, or pseudoaneurysm
- Subject is presenting with thrombus or calcification of the proximal aneurysm neck: circumferential >50%
- Pre-op stenosis of the renal arteries > 50%
Methods: Primary Endpoints

Primary Effectiveness Endpoint:

A composite of technical success at index procedure, and freedom from type IA or type III Endoleak, freedom from aneurysm-related mortality (ARM), and freedom from secondary reinterventions through 12 months post index procedure.

Primary Safety Endpoint:

Freedom from MAE through 30 days post index procedure\(^1\)

\(^1\)MAEs defined as ACM, bowel ischemia, myocardial infarction, procedural blood loss >1000cc, access related complications, permanent paraplegia/paraparesis at 30 days, disabling stroke, respiratory failure, renal complications.
Methods: Secondary Endpoints

Procedural outcomes

- Total contrast volume
- Total fluoroscopy time
- Duration (minutes) of index procedure

Safety and Performance Outcomes

- Adequate penetration of Heli-FX EndoAnchor implants
- Clinical success
- Visceral artery patency or occlusion
- Freedom from type IA and III endoleaks
- Freedom from secondary reinterventions, aortic neck-related secondary interventions
- Freedom from aneurysm-related mortality
- Freedom from stent graft migration, conversion to open repair, AAA rupture
- Sac dynamics
- Overall SCI rate, include transient events
Methods: Follow Up and Trial Duration

Clinical and Imaging follow-up adhere to local societal guidelines and IFU recommendations

Follow-up visits at 1, 12, 24, and 36 months

Assessments to be performed at each visit:

- Physical exam and routine labs as per local standard of care
- Serum Creatinine to assess eGFR
- EQ5D questionnaire (at 1 and 12 months only)
- Adverse event and device deficiency assessment
- CT Angiogram*

*For subjects who develop renal impairment during the follow-up period and cannot tolerate contrast or undergo pre-treatment to receive contrast, an MRI/MRA or a CT without contrast and a duplex ultrasound may be performed to evaluate the stent graft device and aneurysm.
Summary

SOCRATES is a prospective, global, multicenter, randomized (1:1) trial to compare ESAR to FEVAR clinical outcomes in the treatment of AAA patients with infrarenal aortic proximal neck lengths 4 to 15 mm and minimum proximal sealing zone length of 8 mm.

It will be the first comparative trial of ESAR and FEVAR in treatment of patients ineligible for standard EVAR due to challenging anatomical criteria but within the IFUs of the two treatment modalities.

Enrollment ongoing!
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