DEBATE: The Safe-AAA Study Emphasizes The Importance Of Ongoing Surveillance And Continuing EVAR Device Risk: Some EVAR Endografts Have Been Found To Have More Late Risks Than Others

Philip Goodney, MD, MS
Dartmouth Health / White River Junction VA Medical Center / Vascular Quality Initiative

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Disclosures

- FDA U01FD005478 (Sedrakyan = PI)
- NIA U01AG046830 (Skinner = PI)
- PCORI ME-1503-28261 (O'Malley = PI)
- NEST-CC Pilot Award (Sedrakyan = PI)
- AHA SFRN (Creager / Goodney = Project PI)
- SVS-PSO / Society for Vascular Surgery
- AHRQ R21 HS021581 (Goodney = PI)

Goals

- Review FDA panel in November 2021 outlining the role of device type in long-term EVAR outcomes.
- Summarize the SAFE-AAA Study
- Outline the Long term EVAR Assessment and Follow up (LEAF) System, our multi-stakeholder plan to meet FDA's goals for long-term post-EVAR surveillance

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FDA Executive Summary

Circulatory System Devices Panel Meeting

November 3, 2021

General Issues Panel

Real World Surveillance of AAA Endovascular Stent Grafts

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COMPARISON OF UNIBODY AND NON-UNIBODY ENDOGRAFTS FOR ABDOMINAL AORTIC ANEURYSM REPAIR IN MEDICARE BENEFICIARIES: THE SAFE-AAA STUDY

Eric A. Secemsky, MD, MSc
Robert W. Yeh, MD, MSc
Yang Song, MSc
Tianyu Sun, PhD
Jiaman Xu, MPH

Beth Israel Lahey Health

Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology
Beth Israel Deaconess Medical Center, Boston, MA
Harvard Medical School, Boston, MA

Beth Israel Deaconess Medical Center | Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology | HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

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Secemsky et al, Circulation 2023

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Primary Objective

- To evaluate the composite outcome of **late aneurysm rupture, endograft relining, endograft extension, conversion to open repair or all-cause mortality** following infrarenal EVAR with a unibody endograft compared with other commercially available non-unibody endografts in Medicare fee-for-service insurance claims data.

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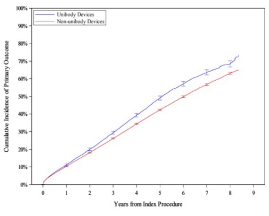
Primary Outcome

	Unibody (N=11,903)	Non-unibody (N=75,260)
Maximum Follow-Up Time, days	3,072	3,074
Median Follow-Up Time, days	1,218	1,250
Number of composite events, n	5,451	30,353
Cumulative Incidence of composite event at the End of Follow-Up, %	73.9%	65.0%
Adjusted Cumulative Incidence of composite event at the End of Follow-Up, %	73.4%	65.0%
Unadjusted HR (95% CI)	1.20 (1.17, 1.24)	
Adjusted HR (95% CI), NI p-value	1.19 (1.15, 1.22), NI p-value=1.00	



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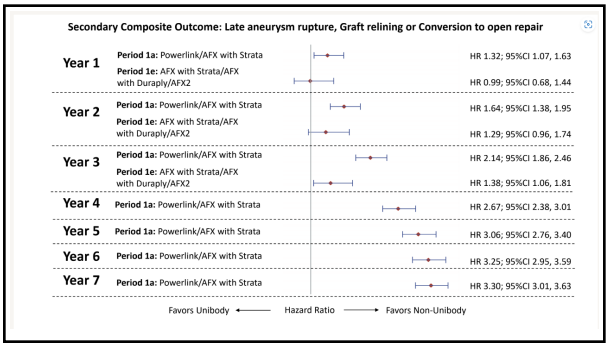

Conclusions

- Among **87,163 Medicare beneficiaries** who underwent infra-renal EVAR with either a unibody or non-unibody device from 2011 through 2017 and had a median follow-up of 1,218 days, unibody devices **failed to meet non-inferiority of the composite endpoint** in comparison with non-unibody devices using a relative non-inferiority margin of 5%.
  - **Findings were robust to evaluation of confounding**
    - Falsification endpoints suggest minimal unmeasured confounding
  - Risks of secondary endpoints **persisted in more contemporary time periods**, suggesting the possibility of continued risk associated with newer unibody endograft iterations.

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Device-specific long-term failures are important

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Vascular Implant Surveillance and Interventional Outcomes Network (VQI-VISION)

PRACTICE MANAGEMENT

The Vascular Implant Surveillance and Interventional Outcomes (VISION) Coordinated Registry Network: An effort to advance evidence evaluation for vascular devices

Greg Tsougranis, BS,[a,b,c] Jens Eldrup-Jorgensen, MD,[d] Daniel Bertges, MD,[e] Marc Schermerhorn, MD,[f] Pablo Morales, MD,[g] Scott Williams, MS, RAC,[h] Roberta Bloss, MS,[i] Jessica Simons, MD, MPH,[j] Sarah E. Deery, MD, MPH,[k] Salvatore Scali, MD,[l] Graham Roche-Nagle, MD, MBA, ME,[m] Leila Mureebe, MD, MPH, MMC,[n] Matthew Mell, MD,[o] Mahmoud Malas, MD, MHS,[p] Brian Pullin, MS,[q] David H. Stone, MD, MS,[a,r] Misti Malone, PhD,[a,s] Adam W. Beck, MD,[a] Grace Wang, MD, MS,[t] Danica Marinac-Dabic, MD, PhD,[u] Art Sedrakyan, MD, PhD,[v] and Philip P. Goodney, MD, MS[a,b] *Lebanon and Hanover, NH; White River Junction and Burlington, Vt; Portland, Me; Boston, Mass; Rockville, Md; Bloomington, Ind; Flagstaff, Ariz; Camesville, Fla; Toronto, Ontario, Canada; Durham, NC; Davis, San Diego, Calif; Birmingham, Ala; Philadelphia, Pa; New York, NY*

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RESEARCH

OPEN ACCESS

Use of linked registry claims data for long term surveillance of devices after endovascular abdominal aortic aneurysm repair: observational surveillance study

Philip Goodney,[1] Jialin Mao,[2] Jesse Columbo,[1] Bjoern Suckow,[1] Marc Schermerhorn,[1] Mahmoud Malas,[4] Benjamin Brooke,[5] Andrew Hoel,[6] Salvatore Scali,[7] Shipra Arya,[8] Emily Spangler,[9] Olamide Alabi,[10] Adam Beck,[9] Barbara Gladders,[1] Kayla Moore,[1] Xinyan Zheng,[1] Jens Eldrup-Jorgensen,[11] Art Sedrakyan,[2] on behalf of the Society for Vascular Surgery's Patient Safety Organization

Abstract

OBJECTIVE
To evaluate long term outcomes (reintervention and late rupture of abdominal aortic aneurysm) of aortic endografts in real world practice using linked registry claims data.

DESIGN
Observational surveillance study.

SETTING
282 centers in the Vascular Quality Initiative Registry linked to United States Medicare claims (2003-18).

PARTICIPANTS
20 489 patients treated with four device types used for endovascular abdominal aortic aneurysm repair were men, and median follow-up was 2.3 years (IQR 0.9-4.1 years). Crude five year reintervention rates were significantly higher for patients who received the early AFX device compared with the other devices: 14.9% (95% confidence interval 13.7% to 16.2%) for Excluder, 19.5% (18.1% to 21.1%) for Endurant, 16.7% (15.0% to 18.6%) for Zenith, and early 27.0% (23.7% to 30.6%) for the early AFX. The risk of reintervention for patients who received the early AFX device was higher compared with the other devices in propensity matched Cox models (hazard ratio 1.61, 95% confidence interval 1.29 to 2.02) and analyses using a surgeon level instrumental variable of >33% AFX grafts used in their practice (1.75, 1.19 to 2.59). The linked registry claims surveillance data identified

Late Endologix	1,972	1,289	781	367	<11

BMJ, first published on 10.1136/bmj.2022-071452 on 26 October 2022. Downlo

RESEARCH

OPEN ACCESS

Use of linked registry claims data for long term surveillance of

Secemsky et al Circulation 2023
Goodney et al BMJ 2022

Device-specific surveillance matters!

Accepted: 07 September 2022

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FDA Recommendations

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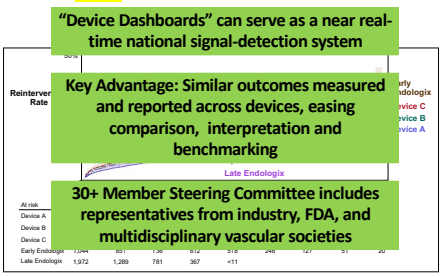
FDA Advisory Panel Recommendations on Lifelong Surveillance and Long-Term Postmarket Data Collection for Patients with AAA Endovascular Aortic Repair – Letter to Health Care Providers

- A real-world surveillance system should be created to collect data through 10 years post-EVAR.
- The surveillance system should assess the following clinical endpoints: all-cause mortality, aneurysm-related mortality, aortic rupture, and aortic reintervention.
- The surveillance system should be designed to capture imaging endpoints including endoleaks, aneurysm size, and device patency because these endpoints are associated with adverse clinical events.
- Collection of high-quality imaging data using standardized imaging protocols and core lab review may be most feasibly accomplished at selected clinical centers.

VQI-VISION and Kaiser Collaboratively Built LEAF for Long-Term EVAR Surveillance



Long-Term EVAR Follow Up (LEAF) Study Timeline and Deliverables

Phase 1
- Analyses of 2003-2018 data (current CMS DUA)
- Deliverable: Device-Specific SRS Report (2018 data)
- Timeline: 4-8 weeks from start date

Phase 2
- Analyses of 2003-2019 data (linkages and late-outcomes updated under current CMS DUA)
- Deliverable: Device Specific SRS Report (2019 data)
- Timeline: 2-5 months from start date

Phase 3
- New VRDC DUA- Analyses of most recent available data (2003 - present)
- Deliverable: Device-Specific SRS Report (up to present year)
- Timeline: 12 – 18 months from start date

Phase 4
- Phase 4a: Vascular Research Collaborative (VRC) – Led Chart Review:
  - VQI Centers to collect additional reporting via additional existing CRF
  - Deliverable: Additional CRF collected for device-specific analyses as prompted by Phases 1-3
  - Timeline 6-12 months from start date
- Phase 4b: Vascular Research Collaborative (VRC) – Led Chart Review and Imaging Upload and Review:
  - VQI Centers to collect additional images for Core Lab review for relevant questions
  - Deliverable: Additional imaging and clinical data collected and reviewed as prompted by Phases 1-3
  - Timeline 12-18 months from start date

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- Deliverable
- Timeline: 2

Phase 3
- New VRDC
- Deliverable
- Timeline: 1

Phase 4
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  - VQI Centers
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  - VQI Centers to collect additional images for Core Lab review for relevar
  - Timeline 12-18 months from start date

Multi-Stakeholder Collaborative Effort Between Real-World Data Sources and Industry Partners to ensure device-specific surveillance

First reports issued 12/2025

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Thank You

- Jialin Mao
- Art Sedrakyan
- VQI-VISION Steering Committee
- Kaiser Permanente (Paxton, Chang)
- VQI

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