HCAi
Department of Health Care Access and Information

Welcome to the

California Cardiovascular Outcomes Reporting Program (CCORP)
Clinical Advisory Panel (CAP)
Meeting
November 10, 2025

We will begin the meeting soon!

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Item #1: Call to Order, Welcome, and Roll Call

Ralph Brindis, M.D., M.P.H., F.A.C.C., CAP Chair (or designee)

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Ground Rules – Hybrid Meeting

- Bagley-Keene Open Meeting Act will be followed
- CAP members need to be visible on camera. If a member is unable to appear on video due to connectivity challenges, the member must announce the technical reason for turning off their camera.
- Public Comment on each item and at end of meeting
  - If a member of the public is joining via Teams press the "hand raise" feature OR dial *5 on your telephone
  - All members of the public will be kept on mute throughout the meeting
  - Members of the public will not have access to the video function
- No delegates, substitutes, or proxies for members
- Meeting minutes prepared after each meeting
- Materials posted on website

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Public Comment

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Item #2: Meeting Minutes from April 15, 2025

Ralph Brindis, M.D., M.P.H., F.A.C.C., CAP Chair (or designee)

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Public Comment

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Item #3: Subcommittee Meeting Minutes from August 13, 2025

Ralph Brindis, M.D., M.P.H., F.A.C.C., CAP Chair (or designee)

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Public Comment

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Item #4: HCAI Director's Office Report

Scott Christman, Chief Deputy Director, HCAI (or designee)

Public Comment

Item #5: Office of Information Services Report

Christopher Krawczyk, Ph.D., Chief Analytics Officer, HCAI (or designee)

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Public Comment

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Item #6: Nomination of CAP Chair

Christopher Krawczyk, Ph.D., Chief Analytics Officer, HCAI (or designee)

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Public Comment

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Item #7: California Cardiovascular Outcomes Reporting Program (CCORP) Updates

Shannon Conroy, Ph.D., M.P.H., CCORP Manager, HCAI (or designee)

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Statutory Role of Clinical Advisory Panel

- Recommend interventional cardiovascular procedures for public reporting - California Health and Safety Code 128745(c)(2)
- Recommend data elements (may be from STS or other databases) - 128745(c)(3-4)
- Review and approve development of the risk-adjustment model to be used in preparation of the outcome report - 28748(d)(3)
- Consult on report materials - 128748(e)
- Review physician statements - 128750(b)(3)

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CCORP CABG 2023 Data Update

- 2023 Hospital-level Coronary Artery Bypass Graft (CABG) outcomes report released September 10th
- Upcoming data visualizations
  - CABG readmissions within 30 day of discharge related to post-operative complications
  - CABG volume per capita and mortality rates by age, race and assigned sex at birth

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CCORP CABG Ongoing Work

2024 CABG Data

- Data audit– 18 hospitals completed October 16th
- 117 hospitals performing CABG
  - Regional Medical Center of San Jose discontinued CABG in 2023

2025 CABG Data

- 118 hospitals performing CABG
  - Palmdale Regional Medical Center resumed their CABG program. (They had paused their program in 2019)
  - Adventist Health Lodi started performing CABGs October 2025.
  - Providence St. Joseph-Eureka stopped performing CABGs Dec 2024. This represents a loss of CABGs in that geographic area. The closest hospital performing CABGs is 140 miles away in Redding.

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CCORP TAVR, PCI, and DxCath Update

Transcatheter Aortic Valve Replacement (TAVR)

- 2023 hospital-level outcomes report released January 30
  - 85 hospitals, 3 TAVR hospitals not included
- 2024 data received from STS/ACC TVT Registry
  - Methods and risk-models shared today

Percutaneous Coronary Intervention (PCI)

- 2023 hospital-level outcomes report released June 2025
- 2024 data – 24 hospitals, data restructuring complete
- Work on methods and risk-models underway

- 2019-2023 California Diagnostic Catheterization (DxCath) Volume by Sociodemographic Categories data visualization released June 2025

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CCORP Collaborative and Outreach

- Ongoing outreach and helpdesl for hospitals
- Bi-monthly calls with CABG/TAVR hospitals
- California Cardiovascular Quality Collaborative (CCQC) - California Society of Thoracic Surgeons (STS) and all cardiac data managers

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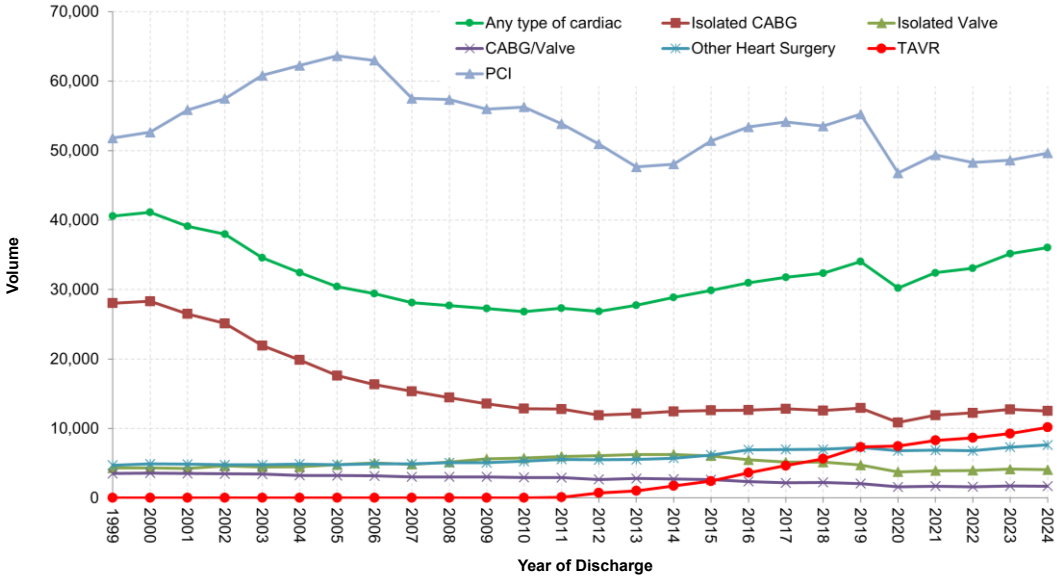
Volume of Cardiovascular Procedures and Interventions, 1999-2024



21 Source: HCAI Administrative Data (inpatient, ambulatory surgery, emergency department)
Abbreviations: Coronary Artery Bypass Graft (CABG), Percutaneous Coronary Intervention (PCI), Transcatheter Aortic Valve Replacement (TAVR)

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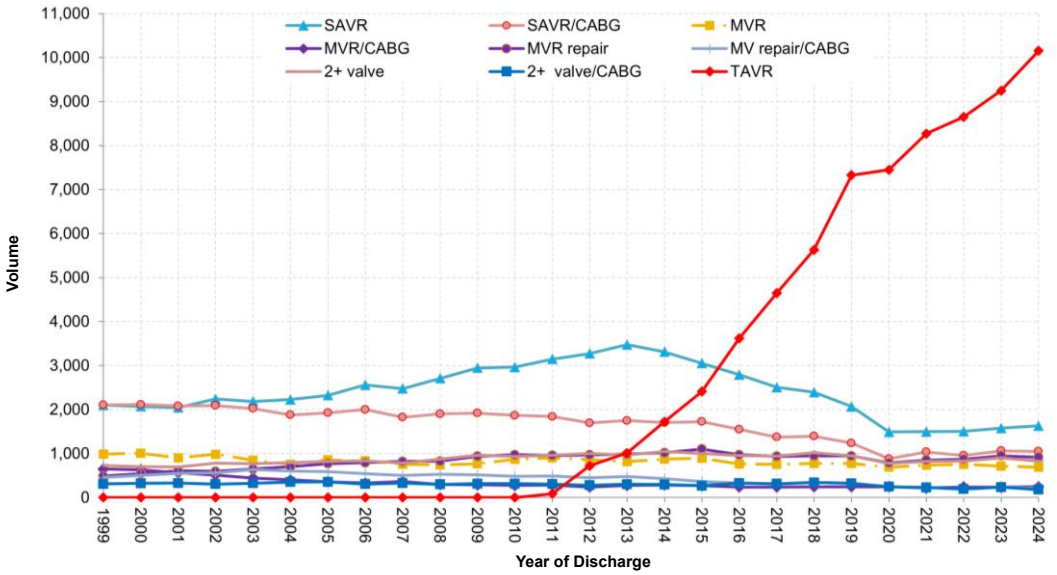
Volume of Valve Procedures and Interventions 1999-2024



22 Source: HCAI Administrative Data (inpatient, ambulatory surgery, emergency department)
Abbreviations: Coronary Artery Bypass Graft (CABG), Mitral Valve Replacement (MVR), Surgical Aortic Valve Replacement (SAVR), Transcatheter Aortic Valve Replacement (TAVR)

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Public Comment

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Item #8: 2024 Risk-Adjusted Mortality Outcome for Transcatheter Aortic Valve Replacement (TAVR)

Mark Kishiyama, Ph.D., Research Scientist, HCAI (or designee)

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Proposed Risk Models for the 2024 Transcatheter Aortic Valve Replacement (TAVR) Outcomes Public Report

Mark Kishiyama, PhD
Department of Health Care Access and Information
November 10, 2025

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The Society of Thoracic Surgeons | AMERICAN COLLEGE of CARDIOLOGY

TAVR Volume & Hospitals: 2024

- **TAVR Program 2024**
  - Data Source: National Cardiovascular Data Registry's (NCDR's) Society of Thoracic Surgeons (STS)/American College of Cardiology (ACC) Transcatheter Valve Therapies (TVT) Registry
  - TAVR volume: 10,024
  - Hospitals: 85

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HCAi Department of Health Care Access and Information

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TAVR In-hospital/30-day Mortality 2024

- Deaths: 155 (1.55%)
- Candidate Risk Factors
  - Combination of 51 total Risk Factors from the TVT (Desai et al., 2021) & Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2) Models
  - 20 variables were significant from the bivariate analysis

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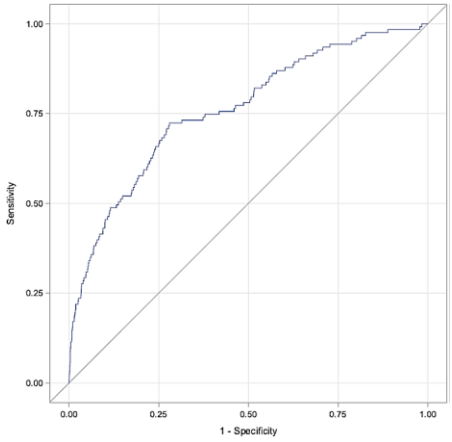
TAVR In-hospital/30-day Mortality 2024

Refined Model
- 12 Risk Factors (see handout)
- C-statistic: 0.7607
- Bootstrap validation:
  - Mean C-Statistic: 0.7765
- Hosmer-Lemeshow = 0.1077



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TAVR In-hospital/30-day Mortality 2024

- Handout 1
- Risk Factors (12 – significant risk factors in bold):
  - **Acuity**
  - Age Group
  - **Body Surface Area (BSA)**
  - Carotid Artery Stenosis
  - Chronic Lung Disease (CLD)
  - Gender
  - **Glomerular Filtration Rate (GFR) Stage**
  - **Hemoglobin**
  - **Kansas City Cardiomyopathy Questionnaire (KCCQ)-12 Summary Score**
  - Race
  - Transient Ischemic Attack (TIA)/Cerebrovascular Accident (CVA)
  - **Tricuspid Regurgitation**

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TAVR In-hospital/30-day Mortality 2024

Decile	Cases	Observed Events	Predicted Events	Difference	95% CI of Predicted Events	
1	932	2	2.25	0.25	1.06	5.88
2	933	4	3.43	-0.57	1.86	6.74
3	933	3	4.31	1.31	2.43	8.08
4	933	7	5.28	-1.72	2.98	9.83
5	933	11	6.38	-4.62	3.61	11.80
6	933	4	7.76	3.76	4.34	14.58
7	933	3	9.64	6.64	5.27	18.42
8	933	18	12.78	-5.22	6.75	25.15
9	933	18	19.03	1.03	9.66	38.39
10	932	53	52.14	-0.86	23.88	108.38

No overall systematic over or under estimation of event at the extremes

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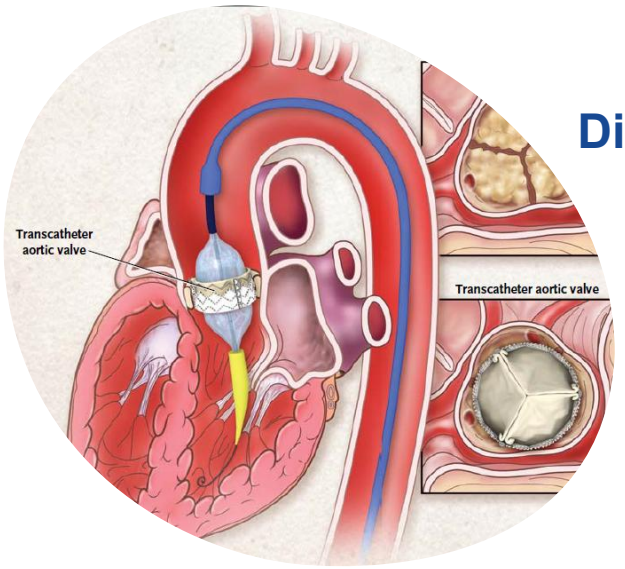

Discussion

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Public Comment

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Item #9: 2024 Risk-Adjusted Stroke Outcome for TAVR

Mark Kishiyama, Ph.D., Research Scientist, HCAI (or designee)

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TAVR In-hospital/30-day Stroke 2024

- Strokes: 179 (1.79%)
- Candidate Risk Factors
  - Combination of 51 total Risk Factors from the TVT (Desai et al., 2021) & Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2) Models
  - 8 variables were significant from the bivariate analysis

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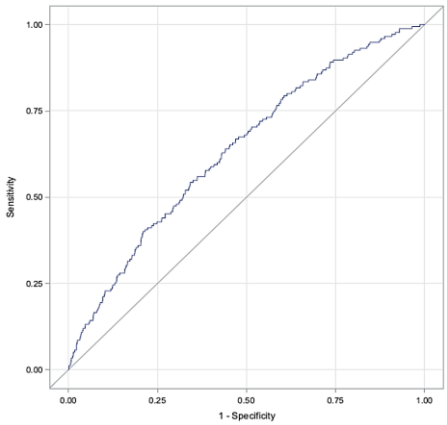
TAVR In-hospital/30-day Stroke 2024

Refined Model

- 9 Risk Factors (see handout)
- C-statistic: 0.6371
- Bootstrap validation:
  - Mean C-Statistic: 0.6505
- Hosmer-Lemeshow = 0.9555



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TAVR In-hospital/30-day Stroke 2024

- Handout 2
- Risk Factors (9 – significant risk factors in bold):
  - **Acuity**
  - Age Group
  - Body Surface Area (BSA)
  - Dementia
  - Gender
  - **Prior Surgical Aortic Valve Replacement (SAVR)**
  - Race
  - **Transient Ischemic Attack (TIA)/Cerebrovascular Accident (CVA)**
  - **Transcatheter Valve Therapy (TVT) Access Site**

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TAVR In-hospital/30-day Stroke 2024

Decile	Cases	Observed Events	Predicted Events	Difference	95% CI of Predicted Events	
1	989	6	6.04	0.04	2.28	18.88
2	993	9	11.73	2.73	6.59	22.16
3	987	11	13.73	2.73	9.76	19.90
4	990	12	14.61	2.61	10.70	20.42
5	990	18	15.40	-2.60	10.91	22.16
6	991	17	16.48	-0.52	11.26	24.86
7	989	19	17.64	-1.36	12.44	25.72
8	990	20	19.24	-0.76	12.32	31.04
9	990	26	23.13	-2.87	14.03	39.19
10	988	37	37.00	0.00	19.28	72.86

No overall systematic over or under estimation of event at the extremes

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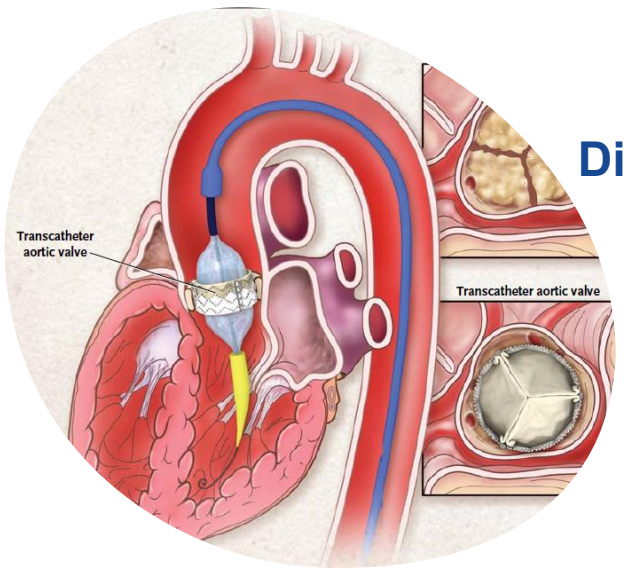

Discussion

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Public Comment

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Item #10: TAVR Interventional Studies

Andrew Rassi, M.D., Interventional Cardiologist (or designee)

Ralph Brindis, M.D., M.P.H., F.A.C.C., CAP Chair (or designee)

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Update on Transcatheter Aortic Valve Replacement Studies

HCAI - Clinical Advisory Panel Meeting
November 10, 2025

Andrew N. Rassi, MD, FACC, FSCAI
Director, Structural Heart Program, Kaiser Permanente, San Francisco Medical Center
Assistant Clinical Professor of Medicine, University of California, San Francisco

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Disclosures

- Principal or sub-investigator on clinical trials sponsored by industry
  - Edwards, Medtronic, Boston Scientific, Abbott, Laplace, Pi-Cardia, Products and Features
  - Institutional funding (no personal payments)
- DSMB member
  - Anteris

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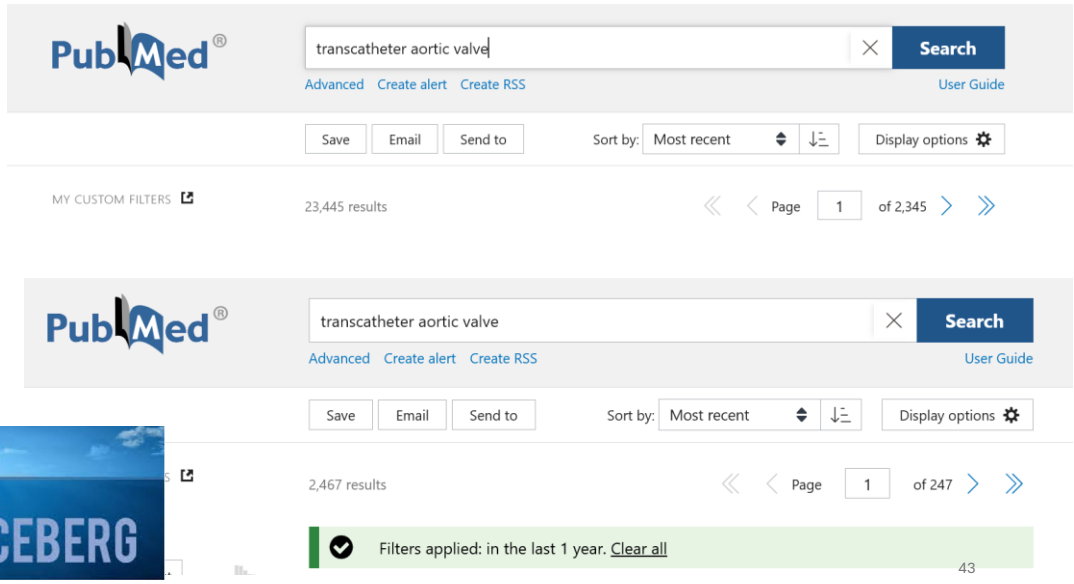
TAVR Trial Updates in 20 min or less



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Aortic Stenosis

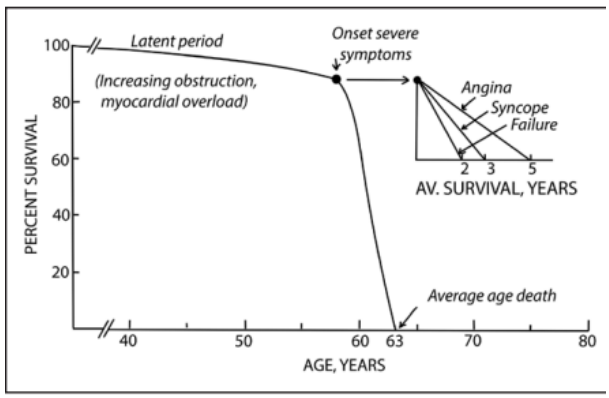
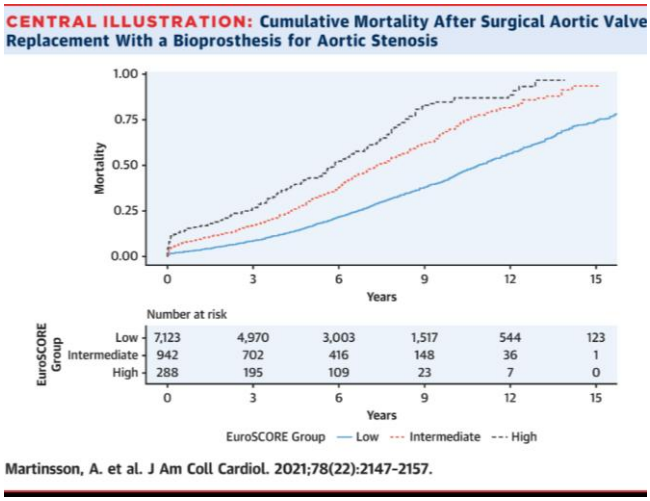


Figure. Valvular aortic stenosis in adults.
Average course (postmortem data). Reproduced from Ross and Braunwald[4] with permission of the publisher. Copyright © 1968, American Heart Association.



Martinsson, A. et al. J Am Coll Cardiol. 2021;78(22):2147-2157.

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The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 21, 2010 VOL. 363 NO. 17

Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela S. Douglas, M.D., John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators*

Transcatheter Aortic Valve Replacement Using a Self-Expanding Bioprosthesis in Patients With Severe Aortic Stenosis at Extreme Risk for Surgery

Jeffrey J. Popma, MD,* David H. Adams, MD,† Michael J. Reardon, MD,† Steven J. Yakubov, MD,§ Neal S. Kleiman, MD,‖ David Heimansohn, MD,‖ James Hermiller, Jr, MD,‖ G. Chad Hughes, MD,¶ J. Kevin Harrison, MD,¶ Joseph Coselli, MD,# Jose Diez, MD,# Ali Kafi, MD,** Theodore Schreiber, MD,** Thomas G. Gleason, MD,†† John Conte, MD,‡‡ Maurice Buchbinder, MD,§§ G. Michael Deeb, MD,‖‖ Blasé Carabello, MD,¶¶ Patrick W. Serruys, MD, PhD,## Sharla Chenoweth, MS,*** Jae K. Oh, MD,††† for the CoreValve United States Clinical Investigators

Boston, Massachusetts; New York, New York; Houston, Texas; Columbus, Ohio; Indianapolis, Indiana; Durham, North Carolina; Detroit and Ann Arbor, Michigan; Pittsburgh, Pennsylvania; Baltimore, Maryland; Palo Alto, California; Rotterdam, the Netherlands; and Minneapolis and Rochester, Minnesota

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 28, 2016 VOL. 374 NO. 17

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D., Raj R. Makkar, M.D., Lars G. Svensson, M.D., Ph.D., Susheel K. Kodali, M.D., Vinod H. Thourani, M.D., E. Murat Tuzcu, M.D., D. Craig Miller, M.D., Howard C. Herrmann, M.D., Darshan Doshi, M.D., David J. Cohen, M.D., Augusto D. Pichard, M.D., Samir Kapadia, M.D., Todd Dewey, M.D., Vasilis Babaliaros, M.D., Wilson Y. Szeto, M.D., Mathew R. Williams, M.D., Dean Kereiakes, M.D., Alan Zajarias, M.D., Kevin L. Greason, M.D., Brian K. Whisenant, M.D., Robert W. Hodson, M.D., Jeffrey W. Moses, M.D., Alfredo Trento, M.D., David L. Brown, M.D., William F. Fearon, M.D., Philippe Pibarot, D.V.M., Ph.D., Rebecca T. Hahn, M.D., Wael A. Jaber, M.D., William N. Anderson, Ph.D., Maria C. Alu, M.M., and John G. Webb, M.D., for the PARTNER 2 Investigators*

ORIGINAL ARTICLE

Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients

M.J. Reardon, N.M. Van Mieghem, J.J. Popma, N.S. Kleiman, L. Søndergaard, M. Mumtaz, D.H. Adams, G.M. Deeb, B. Maini, H. Gada, S. Chetcuti, T. Gleason, J. Heiser, R. Lange, W. Merhi, J.K. Oh, P.S. Olsen, N. Piazza, M. Williams, S. Windecker, S.J. Yakubov, E. Grube, R. Makkar, J.S. Lee, J. Conte, E. Vang, H. Nguyen, Y. Chang, A.S. Mugglin, P.W.J.C. Serruys, and A.P. Kappetein, for the SURTAVI Investigators*

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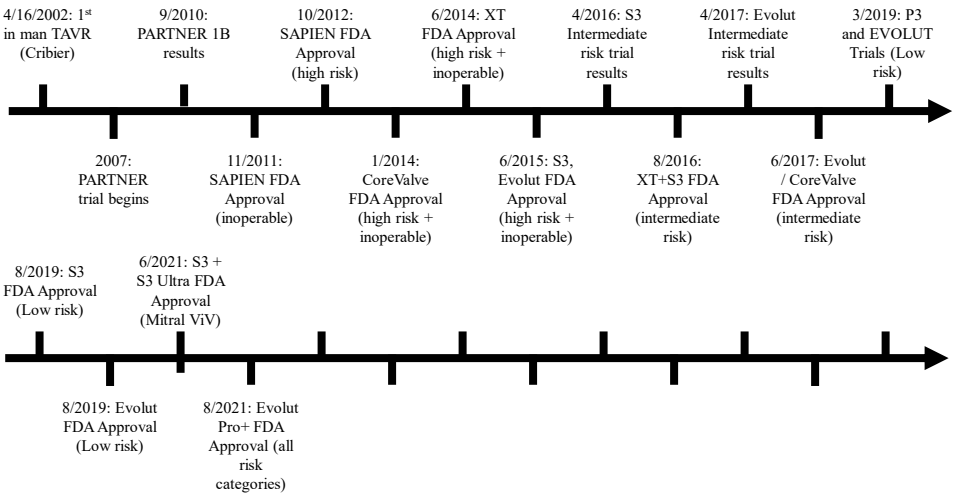
TAVR Timeline

(high-> intermediate-> low surgical risk risk approval)



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TAVR: High→ Intermediate→ Low Surgical Risk

- Improvements in outcomes/safety profile
  - Improved 30-day and 1-year survival
  - Fewer strokes
  - Less major bleeding
  - Reduction in pacemaker rates, paravalvular leak
  - Shorter LOS, less hospital readmissions

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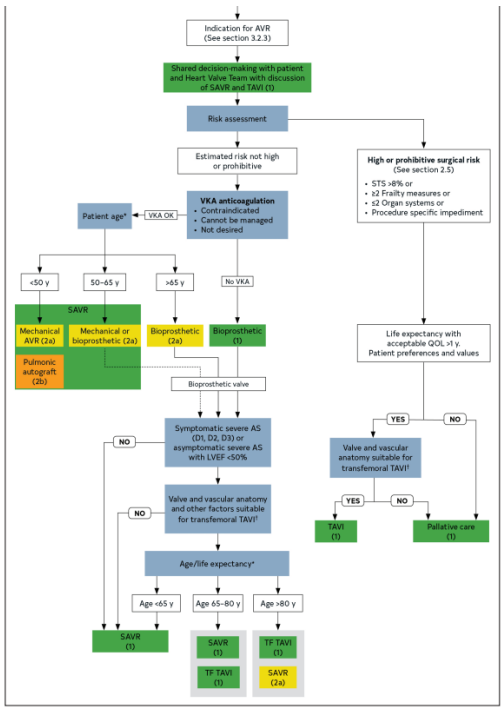
2020 ACC/AHA Valvular Heart Disease Guidelines



Otto CM et al. Circulation 2021;143:e72-e227

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What matters to patients?

- Is this a safe procedure?
- Will I feel better?
- Will I live longer?
- How long will the valve last?
  - Future treatment options

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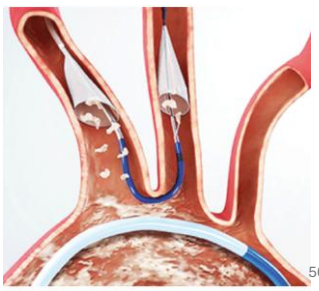
Stroke and TAVR

- Cerebral embolic protection (Sentinel) approved by FDA, 2017
  - Based on reduction in MRI findings
- Utilization varies among TAVR centers
- PROTECTED TAVR Trial failed to demonstrate reduction in clinical outcomes (2022)



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Routine Cerebral Embolic Protection during Transcatheter Aortic-Valve Implantation

Rajesh K. Kharbanda, Ph.D.,[1,2] James Kennedy, M.Sc.,[3] Zahra Jamal, M.Sc.,[4] Matthew Dodd, Ph.D.,[4] Richard Evans, B.A.,[4] Kiran K. Bal, M.Pharm.Sci.,[4] Alexander D. Perkins, M.Sc.,[4] Daniel J. Blackman, M.D.,[3] David Hildick-Smith, M.D.,[5] Adrian P. Banning, M.D.,[6] Andreas Baumbach, Ph.D.,[6,43] Peter Ludman, M.D.,[7] Stephen Palmer, M.Sc.,[7] Rodney H. Stables, D.M.,[10,11] Robert Henderson, D.M.,[12] Clare Appleby, Ph.D.,[13] James Cotton, M.D., Ph.D.,[14,15] Nick Curzen, Ph.D.,[3] Muhiddin Ozkor, M.D.,[16] Jonathan Byrne, M.B., Ch.B.,[16] Rajesh Aggarwal, M.D.,[16] Rajiv Das, M.D.,[17] Sagar Doshi, M.D.,[17,18] Stuart Watkins, M.D.,[19,20] Douglas F. Muir, M.B., Ch.B.,[21] Richard Anderson, M.D.,[28] Saqib Chowdhary, Ph.D.,[37] Richard Varcoe, Ph.D.,[22] Stephen Dorman, B.M., B.Ch.,[23] Sam Firoozi, M.D.,[24] Raj Chelliah, M.B., Ch.B.,[25] Colum Owens, M.D.,[25] Simon Redwood, M.D.,[26] Bernard Prendergast, D.M.,[27] Javaid Iqbal, Ph.D.,[29] Karim Ratib, M.B., Ch.B.,[30] Ciprian Dospinescu, Ph.D.,[31] Venkatesan Suresh, M.D.,[32] Nicholas Cruden, Ph.D.,[33] Thirumaran Rajathurai, D.M.,[34,35] Iqbal S. Malik, Ph.D.,[36] Andrew Wiper, M.B., Ch.B.,[41] Charis Costopoulos, Ph.D.,[42] Ayush Khurana, M.Phil.,[42] Amerjeet Banning, Ph.D.,[44] and Tim Clayton, M.Sc.,[4] for the BHF PROTECT-TAVI Investigators*

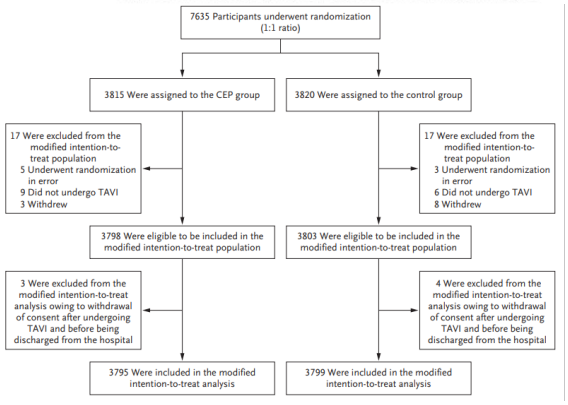

Table 1. Demographic and Clinical Characteristics of the Participants.*

Characteristic	CEP Group (N=3798)	Control Group (N=3803)
Demographic		
Age — yr	81.2±6.5	81.3±6.5
Female sex — no. (%)	1484 (39.1)	1461 (38.4)
Race or ethnic group — no. (%)†		
White	3547 (93.4)	3543 (93.2)
Asian, Black, mixed, or other	60 (1.6)	61 (1.6)
Not known	191 (5.0)	199 (5.2)
Clinical		
Hypercholesterolemia treated with drugs — no./total no. (%)	2358/3722 (63.4)	2259/3737 (60.4)
Hypertension treated with drugs — no./total no. (%)	2558/3738 (68.4)	2528/3753 (67.4)
Medically treated diabetes — no./total no. (%)	793/3793 (20.9)	767/3798 (20.2)
Previous TIA — no./total no. (%)	319/3762 (8.5)	291/3754 (7.8)
Previous stroke — no./total no. (%)	217/3763 (5.8)	235/3754 (6.3)
Known dementia or cognitive impairment — no./total no. (%)	31/3762 (0.8)	38/3747 (1.0)
Other neurologic disease — no./total no. (%)	112/3764 (3.0)	122/3751 (3.3)
Coronary artery disease — no./total no. (%)	1234/3565 (34.6)	1168/3550 (32.9)
History of congestive heart failure — no./total no. (%)	531/3758 (14.1)	482/3765 (12.8)
Previous TAVI — no./total no. (%)	15/3798 (0.4)	17/3801 (0.4)
History of atrial fibrillation or flutter — no./total no. (%)	1256/3751 (33.5)	1269/3753 (33.8)
History of peripheral vascular disease — no./total no. (%)	262/3424 (7.7)	255/3397 (7.5)
Bovine, or other, head and neck vessel anatomy — no./total no. (%)	491/3684 (13.3)	463/3662 (12.6)
Bicuspid valve anatomy — no./total no. (%)	322/3713 (8.7)	305/3727 (8.2)
EuroSCORE II‡		
No. of participants evaluated	2896	2921
Median (IQR)	2.4 (1.6–4.1)	2.4 (1.6–4.0)
Mean aortic-valve gradient		
No. of participants evaluated	3589	3592
Median (IQR) — mm Hg	43 (35–53)	43 (35–52)
Left ventricular function — no./total no. (%)		
Good: LVEF ≥50%	2803/3679 (76.2)	2835/3688 (76.9)
Fair: LVEF 30–49%	671/3679 (18.2)	662/3688 (18.0)
Poor: LVEF <30%	205/3679 (5.6)	191/3688 (5.2)
Aortic-valve calcification — no./total no. (%)		
Not severe	1946/3734 (52.1)	1911/3720 (51.4)
Severe	1788/3734 (47.9)	1809/3720 (48.6)
LVOT calcification — no./total no. (%)		
Not severe	3565/3709 (96.1)	3574/3710 (96.3)
Severe	144/3709 (3.9)	136/3710 (3.7)

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BHF-PROTECT TAVI Trial

Table 2. Primary and Secondary Outcomes.*

Outcome	CEP Group (N=3798)	Control Group (N=3803)	Treatment Effect	
			Risk Difference (95% CI)†	Risk Ratio (95% CI)†
	no./total no. (%)		percentage points	
Primary outcome				
Stroke within 72 hr after TAVI or before discharge, if sooner	81/3795 (2.1)	82/3799 (2.2)	−0.02 (−0.68 to 0.63)‡	0.99 (0.73 to 1.34)‡
Ischemic stroke	80/3795 (2.1)	82/3799 (2.2)		
Hemorrhagic stroke	1/3795 (<0.1)	0/3799		
Secondary outcomes				
Disabling stroke within 6 to 8 wk after TAVI¶	47/3795 (1.2)	53/3799 (1.4)	−0.2 (−0.7 to 0.4)	0.89 (0.60 to 1.31)
Ischemic stroke	47/3795 (1.2)	53/3799 (1.4)		
Hemorrhagic stroke	0/3795	0/3799		
Severe stroke within 72 hr after TAVI or before discharge, if sooner‖	18/3795 (0.5)	19/3799 (0.5)	0.0 (−0.3 to 0.3)	0.95 (0.50 to 1.80)
Ischemic stroke	18/3795 (0.5)	19/3799 (0.5)		
Hemorrhagic stroke	0/3795	0/3799		
Death within 72 hr after TAVI or before discharge, if sooner	29/3795 (0.8)	26/3799 (0.7)	0.1 (−0.3 to 0.5)	1.12 (0.66 to 1.89)
Death or stroke within 72 hr after TAVI or before discharge, if sooner	108/3795 (2.8)	104/3799 (2.7)	0.1 (−0.6 to 0.8)	1.04 (0.80 to 1.36)
Death	29/3795 (0.8)	26/3799 (0.7)		
Nonfatal stroke	79/3795 (2.1)	78/3799 (2.1)		
Death, stroke, or TIA within 72 hr after TAVI or before discharge, if sooner	126/3795 (3.3)	117/3799 (3.1)	0.2 (−0.6 to 1.0)	1.08 (0.84 to 1.38)
Death	29/3795 (0.8)	26/3799 (0.7)		
Nonfatal stroke	79/3795 (2.1)	78/3799 (2.1)		
TIA	18/3795 (0.5)	13/3799 (0.3)		

* A total of three participants in the CEP group and four participants in the control group withdrew consent before discharge from the hospital and are excluded. CI denotes confidence interval.
† The confidence intervals for the secondary outcomes are not adjusted for multiplicity and should not be used to infer treatment effect.
‡ P=0.94.
§ Disabling stroke was defined by a score on the modified Rankin scale of 2 or higher (on a scale from 0 to 6, with higher scores indicating greater disability) and an increase of at least 1 point from the preprocedure baseline modified Rankin scale score.
¶ The last observation was carried forward for four participants in the CEP group and one participant in the control group.
‖ Severe stroke was defined by a National Institutes of Health Stroke Scale score of 10 or higher (on a scale from 0 to 42, with higher scores indicating more severe stroke).

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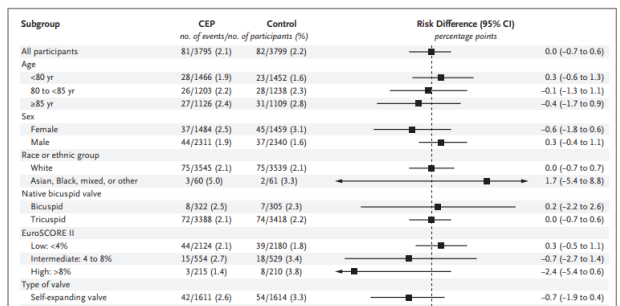

Figure 2. Incidence of Stroke within 72 Hours after TAVI or before Hospital Discharge (If Discharge Occurred Sooner) According to Subgroup.

The confidence intervals are not adjusted for multiplicity and should not be used to infer treatment effect. Race or ethnic group was reported by the participant. Values for the European System for Cardiac Operative Risk Evaluation II (EuroSCORE II) range from 0 to 100%, with higher values indicating a greater risk of death.

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BHF-PROTECT TAVI Trial

- Potential limitations
  - "Intention to treat" vs "as treated" analysis
    - Filter not used per protocol in 19% of cases
    - 9% of cases were not suitable for CEP use
- Does this represent a failure of CEP?

Table S4: Breakdown of CEP deployment in the intention-to-treat population

	n/N (%)
CEP deployed according to the protocol (both filters)	3058/3768 (81.2)
CEP not deployed according to the protocol	710/3768 (18.8)
• CEP not deployed because of unsuitable anatomy	317/3768 (8.4)
• CEP partially deployed (one filter)	239/3768 (6.3)
• Other: including device dislodged or removed before the end of the procedure, device failure, emergency complications preventing CEP use, use of the right radial access for the aortogram, lack of trained staff available, and non-specified reasons	154/3768 (4.1)

CEP filter data was not available for 30 participants. Three participants in the control group received CEP.

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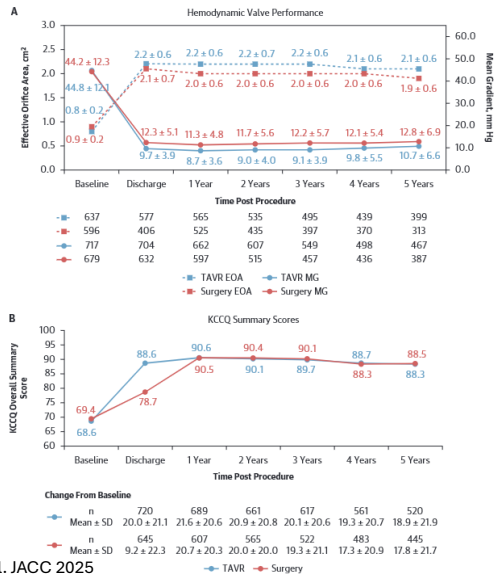
5-Year Outcomes After Transcatheter or Surgical Aortic Valve Replacement in Low-Risk Patients With Aortic Stenosis

John K. Forrest, MD,[a] Steven J. Yakubov, MD,[b] G. Michael Deeb, MD,[c] Henal Gada, MD,[d] Mubashir A. Mumtaz, MD,[e] Basel Ramlawi, MD,[f] Tanvir Bajwa, MD,[g] John Crouch, MD,[h] William Meehl, DO,[i] Stephane Leung Wai Sang, MD,[j] Neal S. Kleiman, MD,[k] George Petrossian, MD,[l] Newell B. Robinson, MD,[l] Paul Sorajja, MD,[l] Ayman Iskander, MD,[l] Pierre Berthoumieu, MD,[l] Didier Tchetche, MD,[l] Christopher Feindel, MD,[m] Eric M. Horlick, MD,[m] Shigeru Saito, MD,[n] Jae K. Oh, MD,[o] Yoojin Jung, PsyD,[p] Michael J. Reardon, MD,[q] the Low Risk Trial Investigators[a]



Forrest et al. JACC 2025

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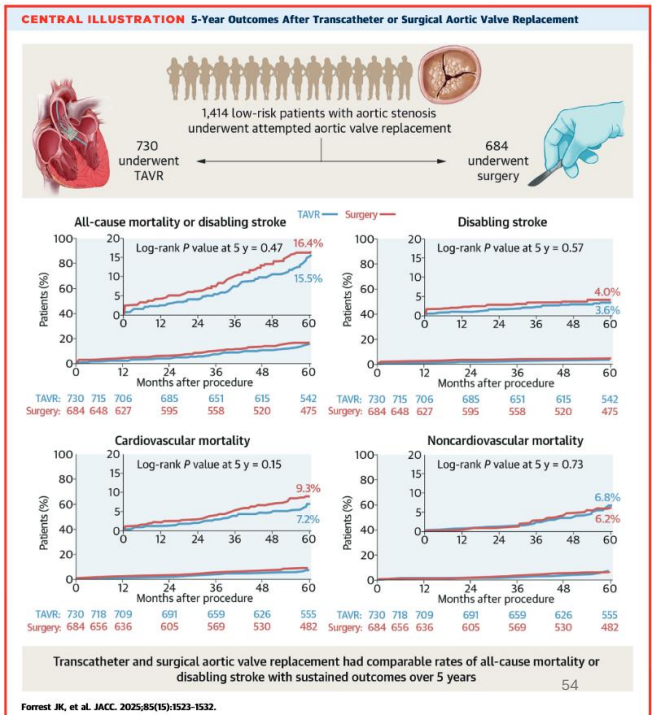
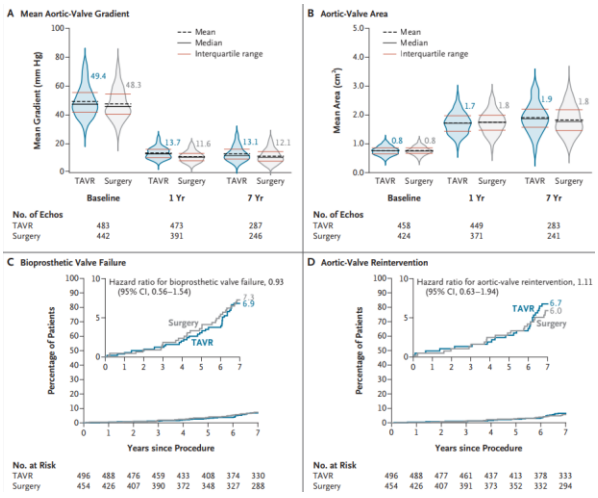
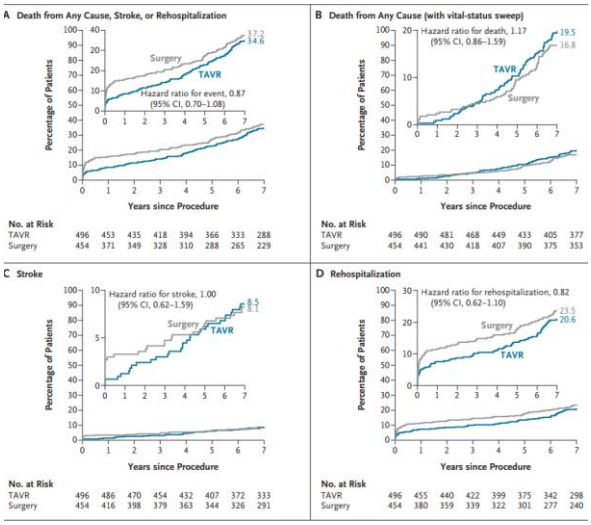


ORIGINAL ARTICLE

Transcatheter or Surgical Aortic-Valve Replacement in Low-Risk Patients at 7 Years

Martin B. Leon, M.D.,[1,2] Michael J. Mack, M.D.,[3] Philippe Pibarot, D.V.M., Ph.D.,[4] Rebecca T. Hahn, M.D.,[1,2] Vinod H. Thourani, M.D.,[5] S.H. Kodali, M.D.,[1,2] Philippe Généreux, M.D.,[6] Samir R. Kapadia, M.D.,[7] David J. Cohen, M.D.,[2,8] Stuart J. Pocock, Ph.D.,[2,9] Yiran Zhang, M.S.,[10] Molly Szerlip, M.D.,[3] Julien Ternacle, M.D., Ph.D.,[11] S. Chris Malaisrie, M.D.,[12] Howard C. Herrmann, M.D.,[13] Wilson Y. Szeto, M.D.,[12] Mark J. Russo, M.D.,[14] Vasilis Babaliaros, M.D.,[15] Tamim Nazif, M.D.,[1,2] John G. Webb, M.D.,[16] and Raj R. Makkar, M.D.,[17] for the PARTNER 3 Investigators*





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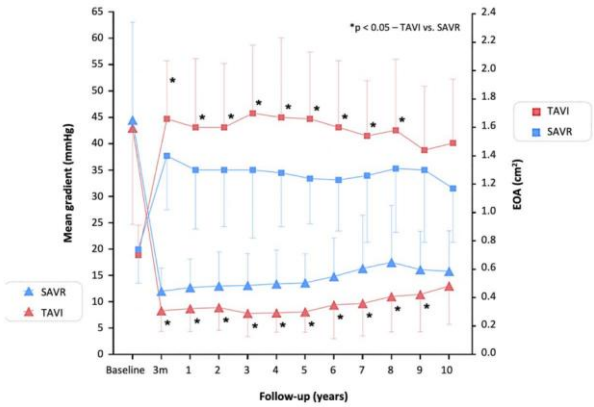
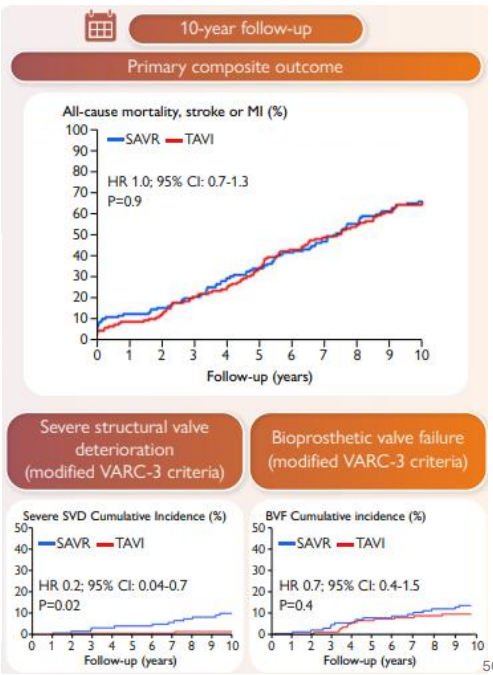
Transcatheter or surgical aortic valve implantation: 10-year outcomes of the NOTION trial

Hans Gustav Hørsted Thyregod [1]*†, Troels Højsgaard Jørgensen[2†], Nikolaj Ihlemann[3], Daniel Andreas Steinbrüchel[1‡], Henrik Nissen [4], Bo Juel Kjeldsen[5], Petur Petursson[6], Ole De Backer[2], Peter Skov Olsen[1], and Lars Søndergaard[2]





Thyregod et al. EHJ 2024 56

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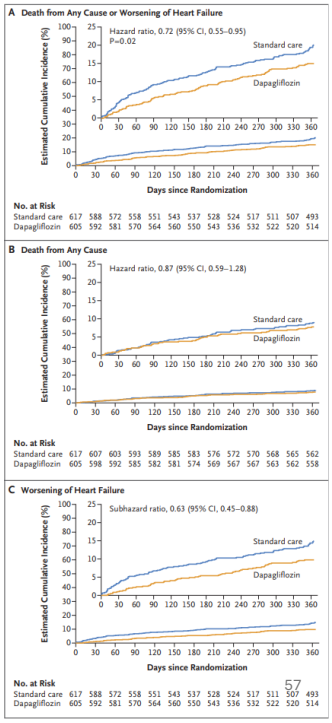
Dapagliflozin in Patients Undergoing Transcatheter Aortic-Valve Implantation

S. Raposeiras-Roubin,[1-3] I.J. Amat-Santos,[4,5] X. Rossello,[1,4,6,7] R. González Ferreiro,[2] I. González Bermúdez,[2] D. Lopez Otero,[4,8] L. Nombela-Franco,[9] L. Gheorghe,[10] J.L. Diez,[11] C. Baladrón Zorita,[4,5] J.A. Baz,[2,4] A.J. Muñoz García,[12] V. Vilalta,[13] S. Ojeda-Pineda,[4,14] J.M. de la Torre Hernández,[15] J.G. Cordoba Soriano,[16] A. Regueiro,[17] P. Bordes Siscar,[18] J. Salgado Fernández,[19] B. Garcia del Blanco,[4,20] R. Martín-Reyes,[21] R. Romaguera,[22] C. Moris,[23] S. García Blas,[4,24] J.A. Franco-Peláez,[25] I. Cruz-González,[4,26] D. Arzamendi,[27] N. Romero Rodríguez,[28] F. Díez-del Hoyo,[29] S. Camacho Freire,[30] F. Bosa Ojeda,[31] J.C. Astorga Burgo,[32] E. Molina Navarro,[33] J. Caballero Borrego,[34] V. Ruiz Quevedo,[35] Á. Sánchez-Recalde,[36] V. Peral Disdier,[6] E. Alegría-Barrero,[37] J. Torres-Llergo,[38] G. Feltes,[39,40] J.A. Fernández Díaz,[41] C. Cuellas,[42] G. Jiménez Britez,[43] J. Sánchez-Rubio Lezcano,[44] C. Barreiro-Pardal,[45] I. Núñez-Gil,[9,40,46] E. Abu-Assi,[47] A. Iñiguez-Romo,[2,4] V. Fuster,[1,48] and B. Ibáñez,[1,4,25] for the DapaTAVI Investigators*



Raposeiras-Roubin et al. NEJM 2025

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Aortic Stenosis and LV remodeling

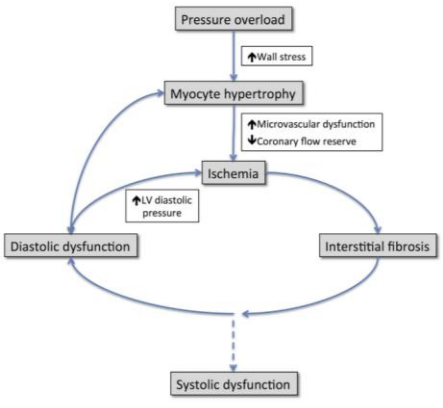

Figure 2. Pathophysiologic mechanisms of left ventricular (LV) remodelling.

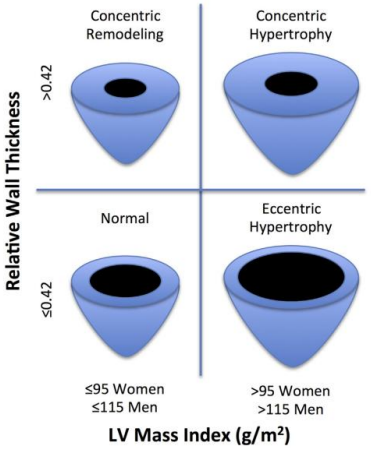

Figure 1. Left ventricular (LV) geometric patterns of remodelling. Adapted with permission from Ganau et al with permission from Elsevier.[11]

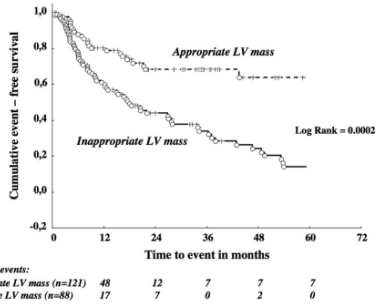

Figure 4. Event-free survival curves in patients with appropriate (**dotted line**) or inappropriately high (**continuous line**) left ventricular (LV) mass in asymptomatic severe aortic stenosis (AS). Reproduced from Cioffi et al.[27] with permission from BMJ Publishing Group Ltd.

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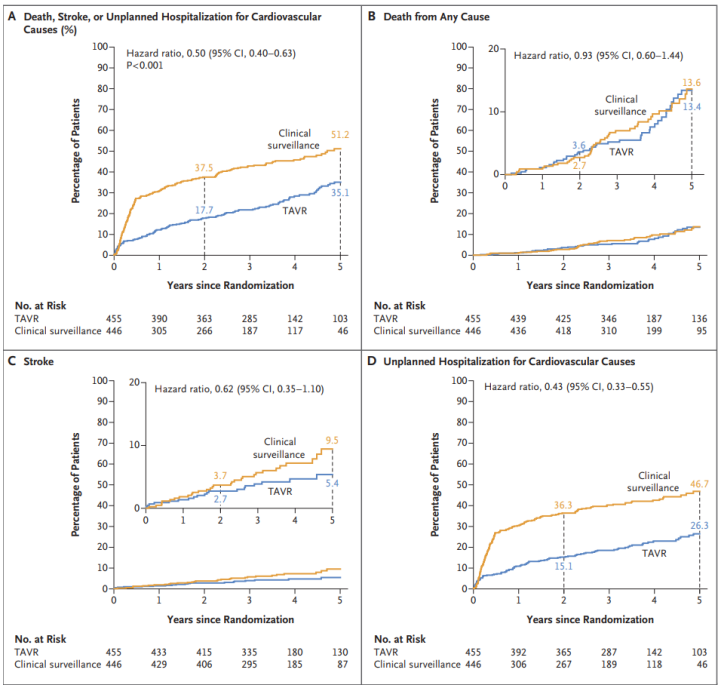

Transcatheter Aortic-Valve Replacement for Asymptomatic Severe Aortic Stenosis

P. Généreux, A. Schwartz, J.B. Oldemeyer, P. Pibarot, D.J. Cohen, P. Blanke, B.R. Lindman, V. Babaliaros, W.F. Fearon, D.V. Daniels, A.K. Chhatriwalla, C. Kavinsky, H. Gada, P. Shah, M. Szerlip, T. Dahle, K. Goel, W. O'Neill, T. Sheth, C.J. Davidson, R.R. Makkar, H. Prince, Y. Zhao, R.T. Hahn, J. Leipsic, B. Redfors, S.J. Pocock, M. Mack, and M.B. Leon, for the EARLY TAVR Trial Investigators*

TRIAL END POINTS

The primary end point was a composite of death from any cause, stroke, or unplanned hospitalization for cardiovascular causes. Any aortic-valve intervention in the clinical surveillance group (including conversion to aortic-valve replacement) within 6 months after randomization or aortic-valve reintervention in the TAVR group within 6 months after the trial procedure was considered for the purposes of the primary end-point analysis to be an unplanned hospitalization for cardiovascular causes. The 6-month time interval was chosen to reflect the earliest recommended time point for routine follow-up according to current guidelines. Additional details are provided in Section E in the Supplementary Appendix.

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A few examples of unanswered questions…

- TAVR durability
  - Is one platform superior to another?
- Lifetime management
  - TAVR-in-TAVR options
  - Leaflet modification techniques
- TAVR for bicuspid anatomy?
  - Lacking randomized data, inherent selection bias in available literature
- Optimal anticoagulation/antiplatelet post-TAVR
  - Should we mirror surgical approach?
- Technical aspect of procedure to reduce complications
  - Does use of cerebral embolic protection devices reduce risk of stroke?
- Optimal Timing of TAVR
  - Can we prevent irreversible myocardial fibrosis and improve outcomes?

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Thank you!

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Public Comment

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Item #11: TAVR Trials of Asymptomatic Patients

Rita F. Redberg, M.D., Cardiologist (or designee)
Ralph Brindis, M.D., M.P.H., F.A.C.C., CAP Chair (or designee)

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TAVR in Asymptomatic Patients

The Latest Evidence and Appropriate Use Concerns

Rita F. Redberg, MD MSc, FAHA, FACC
Professor of Medicine
UCSF

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Today's Outline

- Standard of Care for Asymptomatic Severe Aortic Stenosis
- EARLY TAVR: Results and Quality Concerns
- Implications for Appropriate Use

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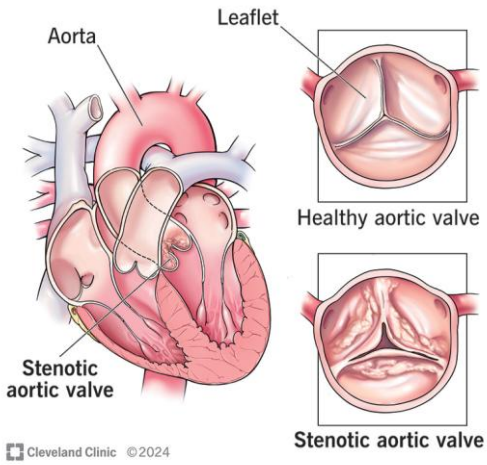
Natural History of Aortic Stenosis

- Many, many years asymptomatic
- Asymptomatic patients are at low risk for death
- Mortality risk increases when symptoms occur to 50% at 2 years after symptom onset



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Asymptomatic Severe Aortic Stenosis: Recommendations

- Monitor :
  - Progression to symptoms (LOE A)
  - Level of evidence **low** for:
    - LVEF <50% (LOE B-NR)
    - Cardiac surgery for other indications (LOE B-NR)

COR	LOE	Recommendations
1	A	1. In adults with severe high-gradient AS (Stage D1) and symptoms of exertional dyspnea, HF, angina, syncope, or presyncope by history or on exercise testing, AVR is indicated.[1–7]
1	B-NR	2. In asymptomatic patients with severe AS and an LVEF <50% (Stage C2), AVR is indicated.[8–11]
1	B-NR	3. In asymptomatic patients with severe AS (Stage C1) who are undergoing cardiac surgery for other indications, AVR is indicated.[12–16]

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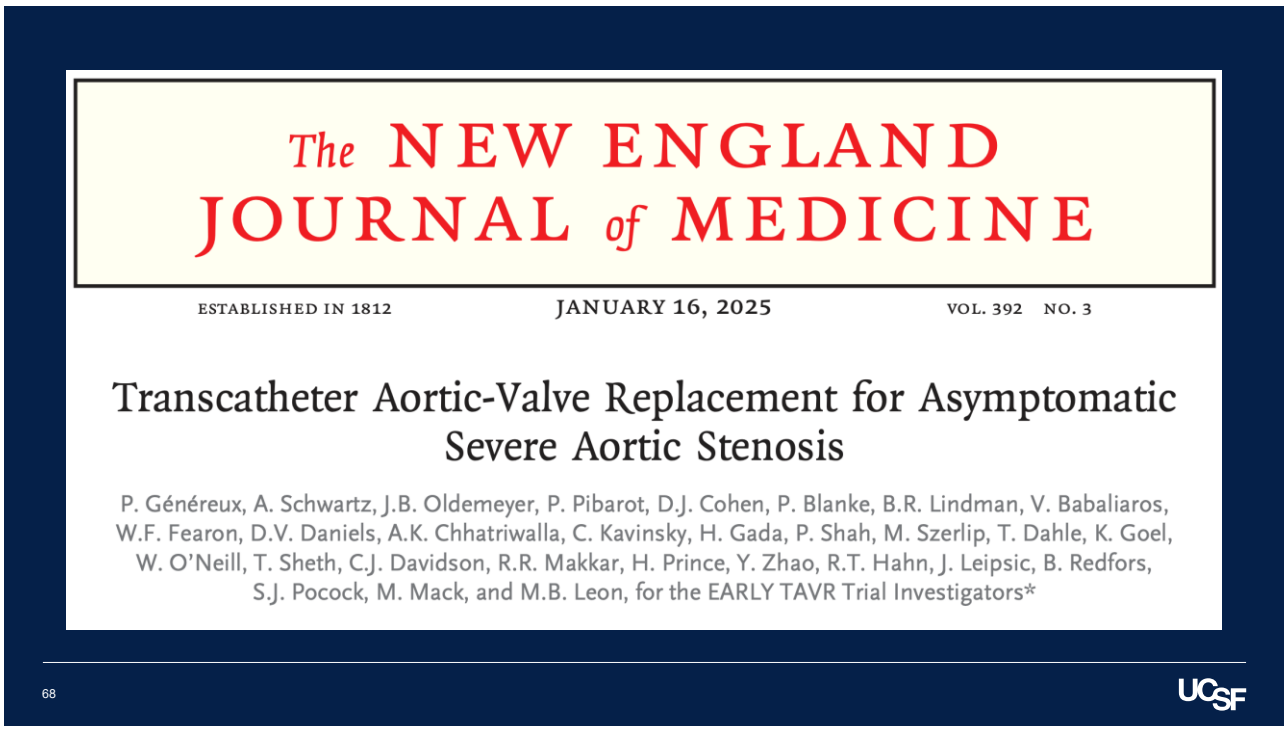

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Financial Relationships with Edwards

- Total general payments: $2,295,875
- Number of general payments: 3963

Author Name	Total Amount of General Payments	Number of General Payments
Philippe Généreux, M.D.	$195,420.36	420
Allan Schwartz, M.D.	$4,578.36	23
J. Bradley Oldemeyer, M.D.	$32,402.08	207
David J. Cohen, M.D.	$150,719.26	56
Brian R. Lindman, M.D.	$13,821.11	50
Vasilis Babaliaros, M.D.	$13,305.16	66
William F. Fearon, M.D.	$388.41	3
David V. Daniels, M.D.	$262,361.37	464
Adnan K. Chhatriwalla, M.D.	$28,577.09	152
Clifford Kavinsky, M.D., Ph.D.	$88,515.14	160

Author Name	Total Amount of General Payments	Number of General Payments
Hemal Gada, M.D.	$32,484.43	39
Pinak Shah, M.D.	$95,830.99	147
Molly Szerlip, M.D.	$61,881.25	251
Thom Dahle, M.D.	$236,237.52	383
Kashish Goel, M.D.	$364,798.20	232
William O'Neill, M.D.	$15,297.09	92
Charles J. Davidson, M.D.	$38,729.13	139
Raj R. Makkar, M.D.	$50,314.19	471
Rebecca T. Hahn, M.D.	$35,131.30	151
Michael Mack, M.D.	$75,971.42	233
Martin B. Leon, M.D.	$499,110.77	224

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Financial Relationships with Edwards

- Total research funding payments: $59,889,578
- Number of research funding payments: 2769

Author Name	Total Amount of Research Funding	Number of Research Funding Payments
Philippe Généreux, M.D.	$2,403,756.45	160
Allan Schwartz, M.D.	$0.00	0
J. Bradley Oldemeyer, M.D.	$2,899,737.00	173
David J. Cohen, M.D.	$7,430,769.00	30
Brian R. Lindman, M.D.	$4,041,471.69	178
Vasilis Babaliaros, M.D.	$2,587,785.31	197
William F. Fearon, M.D.	$31,885.31	8
David V. Daniels, M.D.	$1,797,411.19	148
Adnan K. Chhatriwalla, M.D.	$2,836,513.80	290
Clifford Kavinsky, M.D., Ph.D.	$833,083.77	129

Author Name	Total Amount of Research Funding	Number of Research Funding Payments
Hemal Gada, M.D.	$1,246,064.24	171
Pinak Shah, M.D.	$2,090,707.64	195
Molly Szerlip, M.D.	$958,281.31	164
Thom Dahle, M.D.	$809,921.58	42
Kashish Goel, M.D.	$4,725.00	1
William O'Neill, M.D.	$3,650,938.52	268
Charles J. Davidson, M.D.	$5,517,819.33	250
Raj R. Makkar, M.D.	$7,704,490.26	274
Rebecca T. Hahn, M.D.	$53,460.00	3
Michael Mack, M.D.	$1,015,287.92	70
Martin B. Leon, M.D.	$11,975,468.21	18

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EARLY TAVR

- 901 patients with asymptomatic severe aortic stenosis randomized either to receive TAVR or clinical surveillance (CS)
  - Asymptomatic status confirmed for 90% w/treadmill stress test
- Mean age of 76 years
- Surveilled patients could convert/crossover to TAVR after developing symptoms
- Composite primary outcome of death, stroke, and unplanned hospitalizations*

***including conversion to AVR (mainly TAVR) in first 6 months – reasoning is that this is before "planned" monitoring**

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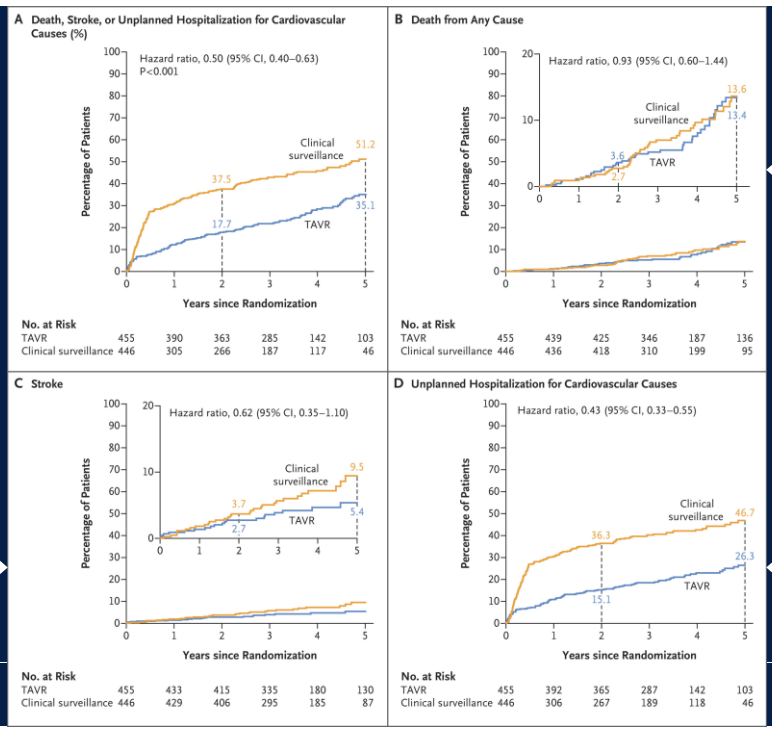
No impact on strokes



No impact on deaths

Main driver of primary outcome

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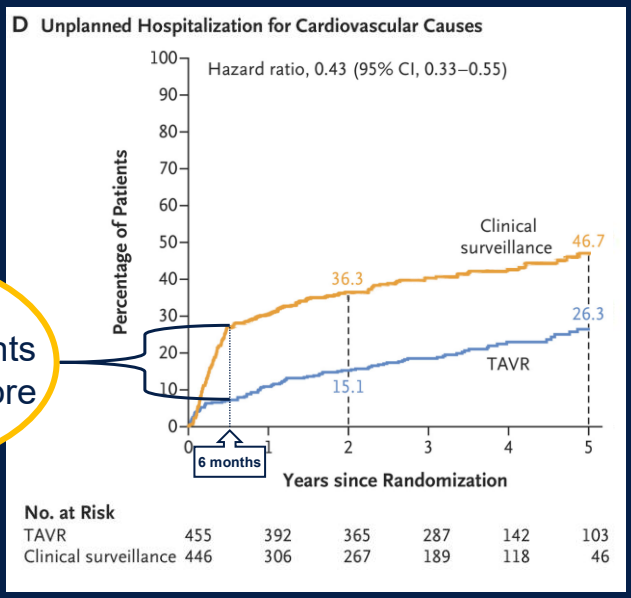
Looking Closer at Unplanned Hospitalizations:

26% of clinical surveillance patients received AVR before 6 months



Unplanned hospitalizations were driven by conversion to AVR in the clinical surveillance arm.

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Cardiovascular Business
FOR LEADERS IMPROVING ECONOMICS, OPERATIONS & OUTCOMES

Q&A: Cardiologist and EARLY TAVR co-author questions study's execution

Michael Walter | June 13, 2025 | Cardiovascular Business | TAVR

Hemal Gada, MD

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"Many [patients] participated because they wanted a TAVR. When patients landed in the clinical surveillance arm, though, how do you think they felt? They are naturally going to be wishing they had landed in the other arm. They are going to have subtraction anxiety."

- Hemal Gada, MD, EARLY TAVR co-author

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"You can see it in the Kansas City Cardiomyopathy Questionnaire (KCCQ) scores, which help track a patient's quality of life. Patients who "converted" to TAVR in the first three months had the absolute worst KCCQ scores; their lives just went to complete trash. Why is that? Well, it's because of subtraction anxiety. This is actually exactly what subtraction anxiety looks like."

- Hemal Gada, MD, EARLY TAVR co-author

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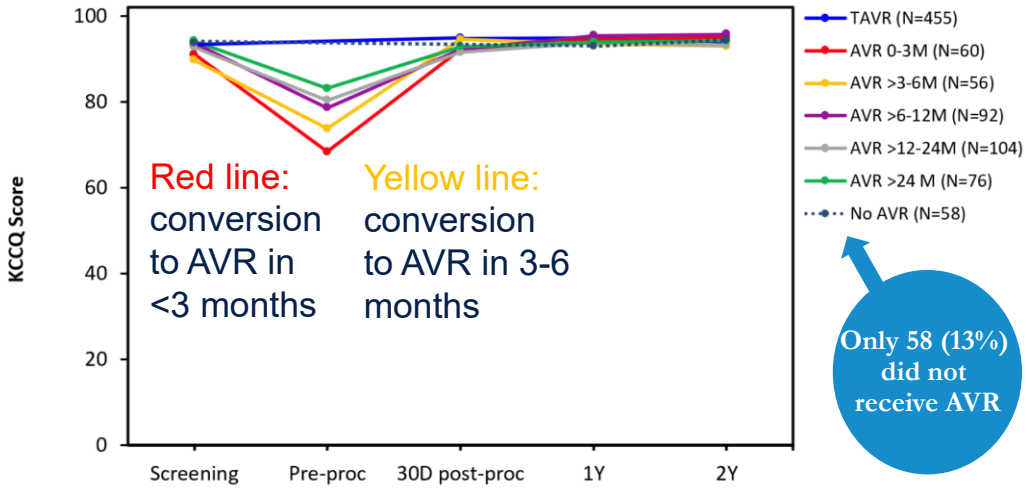
Figure S6. KCCQ Scores by Treatment and Timing of Conversion to AVR



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Inconsistent with Stress Test Performance

Table S1. Treadmill Stress Test Information

	TAVR (N=455)	CS (N=446)
Able to perform treadmill stress test — no. (%)	**411 (90.3)**	**405 (90.8)**
Treadmill stress test done — no.		
Bruce	118	130
Modified Bruce	244	236
Naughton	46	35
Other*	3	4
Actual METs	6.1 ± 2.2	6.1 ± 2.4
Predicted METs — %	102.3 ± 32.3	103.1 ± 34.9
Patients with ≥100% age- and sex-adjusted METs — no./total no. (%)	205/411 (49.9)	192/405 (47.4)

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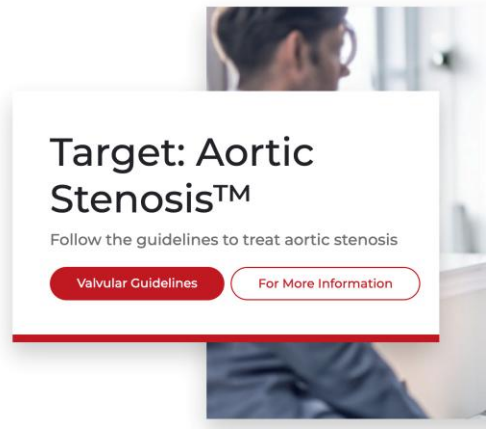
EARLY TAVR: Results Summary

- No mortality or stroke benefit
- Unplanned hospitalizations benefit driven by conversion to AVR in first 6 months, mostly by progressive signs and symptoms in this study which lacked a placebo control arm
- Reduced heart failure hospitalizations and improvements in functional status and quality of life measures not reliable in unblinded study
  - Patients, investigators, and the independent clinical events committee were aware of treatment assignment

American Heart Association.



Sponsor

Edwards Lifesciences is the national sponsor of American Heart Association's Target: Aortic Stenosis.

Edwards

Learn more about Edwards Lifesciences

What Does This Mean for Appropriate Use?

- Follow patient clinically
  - No evidence that repeating echo regularly leads to better outcomes
  - Does increase anxiety
- Waiting for AVR until symptoms develop will not increase risk of death or stroke
- No high-quality evidence that early TAVR improves functional status/quality of life or mortality
- There are multiple risks to early (premature) TAVR or SAVR

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UCSF

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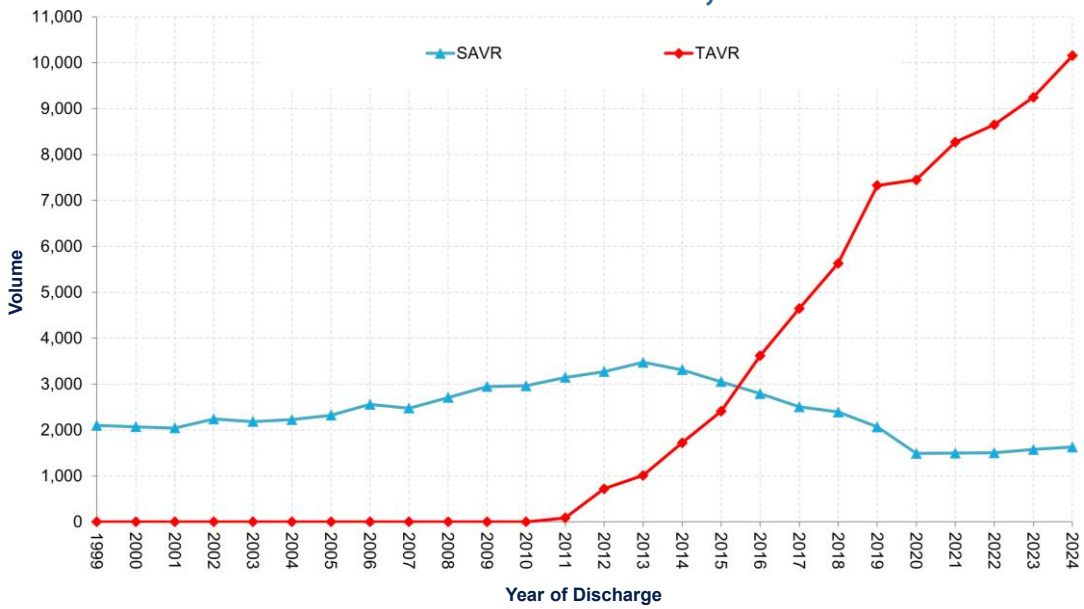
SAVR and TAVR Volume, 1999-2024



Source: HCAI Administrative Data (inpatient, ambulatory surgery, emergency department)
Abbreviations: Surgical Aortic Valve Replacement (SAVR), Transcatheter Aortic Valve Replacement (TAVR)

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Public Comment

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Item #12: Expanding Cardiovascular Outcomes Reporting

Ralph Brindis, M.D., M.P.H., F.A.C.C., CAP Chair

Christopher Krawczyk, Ph.D., Chief Analytics Officer, HCAI (or designees)

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CCORP Mandate

- The department shall publish at least one risk-adjusted outcome report for coronary artery bypass graft surgery, transcatheter aortic valve replacement, or any type of interventional cardiovascular procedure for procedures performed in the state.
- For any type of interventional cardiovascular procedure other than coronary artery bypass graft surgery or transcatheter aortic valve replacement, the department shall only select from interventional cardiovascular procedures recommended by the clinical panel, not to exceed one additional interventional cardiovascular procedure every three years.
- California Health and Safety Code Section **128745.**(c)(2).

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CAP Subcommittee Members

Members reflect, as much as possible, the broad constituency of the CAP

- **Ralph G. Brindis, M.D., M.P.H., F.A.C.C. (Chair)**
  Interventional Cardiologist (Retired)
- **Cheryl Damberg, Ph.D.**
  Healthcare Researcher
- **Andrew Rassi, M.D.**
  Interventional Cardiologist
- **Maribeth Shannon, M.S.**
  Consumer Representative
- **Richard J. Shemin, M.D.**
  Cardiovascular Surgeon

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Evaluation Considerations for Expanding Cardiovascular Outcomes Reporting

- Feasibility and data collection
- Cost and data quality (including auditing)
- Volume of CV procedure significant for meaningful impact in cardiac care
- Population impact for equitable cardiac care across CA
- Evidence-based and best practices for cardiac interventional procedures to impact cardiovascular outcomes
- Timeliness of reporting (pool data across multiple years may delay release of report)
- Opportunities for health care quality improvement and appropriateness of care

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Cardiovascular Interventional Procedures Discussed for Future Reporting

- All PCI
- Surgical aortic valve replacement (SAVR)
- Atrial fibrillation (A-Fib) ablation
- Carotid revascularization
  - Carotid endarterectomy
  - Carotid artery stenting
- Thoracic aortic procedures
- Peripheral Vascular procedures
- Electrophysiology procedures
- Implantable cardioverter defibrillators (ICDs)

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Additional Topics of Interest

- Appropriate use of TAVR (AUC under development at ACC)
- One-year mortality as an outcome of existing procedures (PCI and CABG)
- Longitudinal data and evaluating procedure combinations over time (e.g., PCI and CABG; TAVR and SAVR)
- Potential data gaming, particularly around 30-day mortality outcome, opportunities for quality control
  - HCAI Audits CABG clinical data
  - HCAI is not directly involved in auditing TAVR clinical data
- Assessment of Ambulatory CV Surgery Centers (ASCs)

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Potential Additional Analyses for TAVR

- Trends by patient demographics – assessing equity
- Volume to outcome relationships
- Volume relative to Population-density
- Clinical indicators for procedures

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HCAI Data Assets Opportunities

- HCAI patient administrative data to explore TAVR trends
- Potential of Healthcare Payments Database (HPD) - claims and encounter data across care settings
  - Quality-to-cost analysis
  - Linking CABG clinical data

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Subcommittee Recommendation Summary

- Importance of taking more time to evaluate options
- Procedures identified for further investigation
  - Atrial fibrillation ablation
  - Carotid revascularization procedures (Carotid endarterectomy and Carotid artery stenting)
  - Peripheral Vascular procedures
- Invite clinical experts to future CAP meetings
- Explore additional analyses of existing procedures

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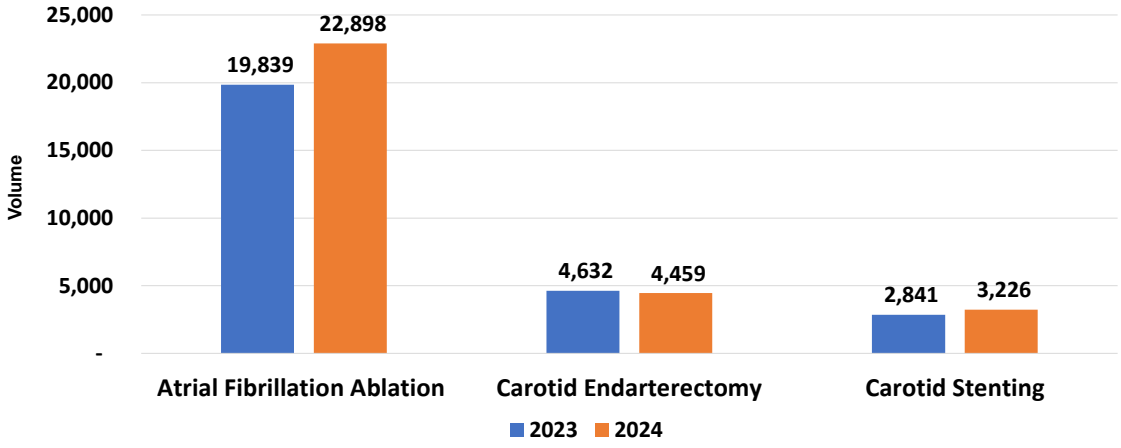
Atrial Fibrillation (A-Fib) Ablation and Carotid Revascularization Procedure Volume, 2023 and 2024



Source: HCAI Administrative Data (inpatient, ambulatory surgery), 2023-2024

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Subcommittee Requested Further Information from HCAI

- What is currently permissible under the current TVT Registry data agreement?
- What is possible with amendment of the agreement, particularly regarding clinical indicators and longitudinal data?
- What are opportunities for leveraging other HCAI data assets, such as HPD.
- HCAI will need to evaluate statutory and regulatory requirements, as well as institutional processes

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HCAI Updates for Potential TAVR Analyses

- What is currently permissible under the current TVT Registry data agreement?
  - HCAI can use TVT TAVR data for internal quality improvement purposes. Any other analyses would need to be reviewed and approved by American College of Cardiology Foundation
- What is possible with amendment of the agreement, particularly regarding clinical indicators and longitudinal data?
  - HCAI would need to explore further including timeframe for amendment

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Solicit Recommendations from the CAP

Discussion Questions for CAP

- What types of analyses are most valuable to the panel?
- What are the top priorities, considering HCAI's limited resources?

Potential Additional Analyses for TAVR*

- Trends by patient demographics
- Volume to outcome relationships
- Population-density /volume relationship
- Clinical indicators for procedures

*In accordance with Health and Safety Code §128745 and with input from CAP, as appropriate.

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Public Comment

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Item #13: CCORP Public Reporting

Shannon Conroy, Ph.D., M.P.H., CCORP Manager, HCAI (or designee)

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CABG Data Reporting Requirements

§ 97172. Required Reporting

- (a) A hospital where coronary artery bypass graft (CABG) surgery is performed shall file a report semiannually with the Office. This Section shall not apply to a hospital where all CABG surgeries performed are on patients under 18 years of age on the date of surgery.
- (b) A report shall contain a record for each CABG surgery patient 18 years or older on the date of surgery who was discharged from the hospital during the reporting period, pursuant to Section 97176

Title 22 of the California Code of Regulations (CCR) § 97172

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CABG Cases for Public Reporting

- Include all CABG cases where the preoperative plan was a CABG
- Cases to be excluded from Public Reporting
  - Second CABG within 30 days of initial CABG
  - No Coronary Artery Disease (documented)
  - CABG due to trauma (e.g., stabbing, car accident)
  - Unplanned CABG
    - Complication of Aortic Valve Replacement (AVR)/Mitral Valve Replacement (MVR)/valve misadventure
    - Intent was not a CABG
- Hospitals provide documentation for any cases they feel should be excluded
- Documentation reviewed by HCAI staff and/or consulting cardiologist to make determination.

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Public Comment

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Item #14: Public Comment

Ralph Brindis, M.D., M.P.H., F.A.C.C., CAP Chair (or designee)

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Item #15: Adjournment

Ralph Brindis, M.D., M.P.H., F.A.C.C., CAP Chair (or designee)

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Handout #1: Logistic Regression Risk Model for TAVR In-hospital/30-day Mortality, 2024

Risk Factor		Frequency			Coefficient	Standard Error	P-value	Odds Ratio (OR)	95% CL	
		N	Total	%					Lower Level	Upper Level
Intercept					-0.45	1.10	0.6791			
Acuity	Elective	76	8,075	0.9%	Reference					
	Emergency/Salvage/Cardiac Arrest	**5**	**22**	**22.7%**	**2.56**	**0.58**	**<.0001**	**12.97**	**4.13**	**40.76**
	Shock/Inotrope/ Support Device	**12**	**220**	**5.5%**	**1.16**	**0.34**	**0.0006**	**3.20**	**1.64**	**6.23**
	Urgent	**30**	**1,011**	**3.0%**	**0.63**	**0.23**	**0.0073**	**1.87**	**1.19**	**2.97**
Age Group	<70	15	1,125	1.3%	Reference					
	>=70	108	8,203	1.3%	0.09	0.30	0.7563	1.10	0.61	1.98
Body Surface Area (BSA)					**-0.99**	**0.42**	**0.0188**	**0.37**	**0.16**	**0.85**
Carotid Artery Stenosis	No	106	8,559	1.2%	Reference					
	Yes	17	769	2.2%	0.39	0.28	0.1587	1.48	0.86	2.54
Chronic Lung Disease (CLD)	No	86	7,625	1.1%	Reference					
	Yes	37	1,703	2.2%	0.38	0.21	0.0636	1.47	0.98	2.21
Gender	Male	66	5,438	1.2%	Reference					
	Female	57	3,890	1.5%	-0.18	0.21	0.3988	0.84	0.55	1.27
Glomerular Filtration Rate (GFR) Stage	GFR stage 1,2,3	92	8,640	1.1%	Reference					
	GFR stage 4-5	**31**	**688**	**4.5%**	**0.79**	**0.24**	**0.0011**	**2.20**	**1.37**	**3.53**
Hemoglobin					**-0.16**	**0.05**	**0.0020**	**0.85**	**0.77**	**0.94**
Kansas City Cardiomyopathy Questionnaire (KCCQ)-12 Summary Score					**-0.01**	**0.00**	**0.0027**	**0.99**	**0.98**	**1.00**
Race	White	88	6,855	1.3%	Reference					
	Asian	12	528	2.3%	0.10	0.33	0.7691	1.10	0.57	2.13
	Black	1	207	0.5%	-1.46	1.02	0.1525	0.23	0.03	1.72
	Hispanic	18	1,408	1.3%	-0.33	0.27	0.2218	0.72	0.42	1.22
	Other	4	330	1.2%	-0.19	0.52	0.7192	0.83	0.30	2.31
Transient Ischemic Attack (TIA)/Cerebrovascular Accident (CVA)	No	98	7,939	1.2%	Reference					
	Yes	25	1,389	1.8%	0.23	0.24	0.3283	1.26	0.79	2.00
Tricuspid Regurgitation	Not Severe	108	9,051	1.2%	Reference					
	Severe	**15**	**277**	**5.4%**	**0.95**	**0.30**	**0.0016**	**2.59**	**1.43**	**4.67**

Bolded text indicates statistically significant (p≤0.05).

Handout #2: Logistic Regression Risk Model for In-hospital/30-day TAVR Stroke, 2024

Risk Factor		Frequency			Coefficient	Standard Error	P-value	Odds Ratio (OR)	95% CL	
		N	Total	%					Lower Level	Upper Level
Intercept					-3.97	0.78	<.0001			
Acuity	Elective	141	8,410	1.7%	Reference					
	Emergency/Salvage/ Cardiac Arrest	**3**	**38**	**7.9%**	**1.86**	**0.62**	**0.0028**	**6.42**	**1.90**	**21.68**
	Shock/Inotrope/Support Device	6	264	2.3%	0.37	0.43	0.3804	1.45	0.63	3.34
	Urgent	25	1,185	2.1%	0.25	0.22	0.2590	1.28	0.83	1.98
Age Group	<70	13	1,203	1.1%	Reference					
	>=70	162	8,694	1.9%	0.43	0.30	0.1487	1.54	0.86	2.74
Body Surface Area (BSA)					-0.33	0.34	0.3236	0.72	0.37	1.39
Dementia	No	170	9,803	1.7%	Reference					
	Yes	5	94	5.3%	0.91	0.48	0.0559	2.48	0.98	6.31
Gender	Male	93	5,760	1.6%	Reference					
	Female	82	4,137	2.0%	0.11	0.17	0.5422	1.11	0.79	1.56
Prior Surgical Aortic Valve Replacement (SAVR)	No	173	9,409	1.8%	Reference					
	Yes	**2**	**488**	**0.4%**	**-1.58**	**0.72**	**0.0277**	**0.21**	**0.05**	**0.84**
Race	White	129	7,203	1.8%	Reference					
	Asian	12	576	2.1%	0.05	0.32	0.8723	1.05	0.57	1.95
	Black	2	225	0.9%	-0.71	0.72	0.3203	0.49	0.12	2.00
	Hispanic	26	1,511	1.7%	-0.06	0.22	0.7931	0.94	0.61	1.46
	Other	6	382	1.6%	-0.12	0.42	0.7744	0.89	0.39	2.03
Transient Ischemic Attack (TIA)/Cerebrovascular Accident (CVA)	No	136	8,433	1.6%	Reference					
	Yes	**39**	**1,464**	**2.7%**	**0.49**	**0.19**	**0.0079**	**1.64**	**1.14**	**2.35**
Transcatheter Valve Therapy (TVT) Access Site	Femoral	163	9,600	1.7%	Reference					
	Non-Femoral	**12**	**297**	**4.0%**	**0.87**	**0.31**	**0.0050**	**2.38**	**1.30**	**4.34**

Bolded text indicates statistically significant (p≤0.05).

Handout #3: TAVR Volume STS/ACC TVT Registry Data and HCAI Administrative Data, 2024

Hospital	STS/ACC TVT Registry Volume	HCAI Administrative Volume	Volume Difference Between TVT Registry and HCAI
Adventist Health Glendale	136	139	-3
Adventist Health Specialty Bakersfield	39	42	-3
Adventist Health St. Helena	70	71	-1
Adventist Health White Memorial	60	61	-1
Alta Bates Summit Medical Center	118	133	-15
Antelope Valley Medical Center	111	111	0
Bakersfield Memorial Hospital	100	100	0
California Pacific Medical Center – Van Ness Campus	159	180	-21
Cedars – Sinai Medical Center	681	753	-72
Community Hospital of the Monterey Peninsula	60	60	0
Community Memorial Hospital – San Buenaventura	91	92	-1
Dominican Hospital	63	64	-1
Doctors Medical Center	96	97	-1
Eisenhower Medical Center	210	204	6
El Camino Health	126	129	-3
Emanate Health Inter – Community Hospital	49	50	-1
Enloe Health	135	134	1
French Hospital Medical Center	82	82	0
Fresno Heart and Surgical Hospital	131	131	0
Garfield Medical Center	34	34	0
Good Samaritan Hospital – San Jose	51	51	0
Henry Mayo Newhall Hospital	37	38	-1
Hoag Memorial Hospital Presbyterian	108	115	-7
Huntington Hospital	128	128	0
John Muir Medical Center – Concord Medical Center	147	150	-3
Kaiser Foundation Hospital – Fontana	159	159	0
Kaiser Foundation Hospital – Los Angeles	282	290	-8
Kaiser Foundation Hospital – San Francisco	395	436	-41
Kaiser Foundation Hospital – Santa Clara	342	345	-3
Kaweah Health Medical Center	81	81	0
Keck Hospital of USC	106	110	-4
UC Irvine Health – Lakewood	40	41	-1
Loma Linda University Medical Center	182	185	-3
Loma Linda University Medical Center – Murrieta	72	72	0
Los Robles Hospital & Medical Center	91	94	-3

Hospital	STS/ACC TVT Registry Volume	HCAI Administrative Volume	Volume Difference Between TVT Registry and HCAI
Marian Regional Medical Center	69	69	0
MarinHealth Medical Center	97	97	0
Memorial Medical Center – Modesto	107	107	0
MemorialCare Long Beach Medical Center	86	88	-2
MemorialCare Orange Coast Medical Center	75	74	1
MemorialCare Saddleback Medical Center	73	74	-1
Mercy General Hospital	366	365	1
Mills-Peninsula Medical Center	102	107	-5
Providence Mission Hospital	72	72	0
NorthBay Medical Center	18	19	-1
Northridge Hospital Medical Center	44	44	0
Palomar Medical Center	42	43	-1
PIH Health Good Samaritan Hospital	79	84	-5
PIH Health Whittier Hospital	30	31	-1
Pomona Valley Hospital Medical Center	31	31	0
Providence Little Company of Mary Medical Center – Torrance	41	40	1
Providence Saint John's Health Center	92	93	-1
Providence Saint Joseph Medical Center	44	43	1
Providence St. Joseph Hospital (Orange)	218	220	-2
Riverside Community Hospital	66	65	1
Ronald Reagan UCLA Medical Center	166	166	0
Saint Agnes Medical Center	131	132	-1
Salinas Valley Health Medical Center	85	85	0
San Antonio Regional Hospital	72	72	0
Santa Barbara Cottage Hospital	127	128	-1
O'Connor Hospital	28	26	2
Providence Santa Rosa Memorial Hospital – Montgomery	122	124	-2
Scripps Memorial Hospital – La Jolla	474	488	-14
Scripps Mercy Hospital	109	109	0
Sequoia Hospital	28	28	0
Sharp Chula Vista Medical Center	93	93	0
Grossmont Hospital	73	78	-5
Sharp Memorial Hospital	100	104	-4
Shasta Regional Medical Center	142	142	0
St. Bernardine Medical Center	58	58	0
St. John's Regional Medical Center	49	48	1
St. Joseph's Medical Center of Stockton	111	111	0
Providence St. Jude Medical Center	74	74	0

Hospital	STS/ACC TVT Registry Volume	HCAI Administrative Volume	Volume Difference Between TVT Registry and HCAI
Stanford Health Care	267	291	-24
Stanford Health Care Tri-Valley	44	44	0
Sutter Medical Center – Sacramento	290	293	-3
Temecula Valley Hospital	94	91	3
Torrance Memorial Medical Center	127	128	-1
Tri-City Medical Center	47	38	9
UC San Diego Health La Jolla – Jacobs Medical Center & Sulpizio Cardiovascular Center	119	116	3
UCLA West Valley Medical Center	11	11	0
UC Davis Medical Center	189	162	27
UC Irvine Health – Orange	101	101	0
UC San Francisco Medical Center	119	126	-7
Washington Hospital – Fremont	50	49	1

Data Source: National Cardiovascular Data Registry, STS/ACC TVT Registry™ v. 3.0
HCAI Administrative Data (inpatient, ambulatory surgery, emergency department), 2024