Key Insights from the First Decade of TAVR in the U.S.

David J. Cohen, M.D., M.Sc.

Director, Clinical and Outcomes Research
Cardiovascular Research Foundation

Director of Academic Affairs
St. Francis Hospital and Heart Center

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Disclosures

Grant Support/Drugs

- MyoKardia/BMS

Grant Support/Devices

- Edwards Lifesciences
- Boston Scientific
- Corvia
- I-Rhythm

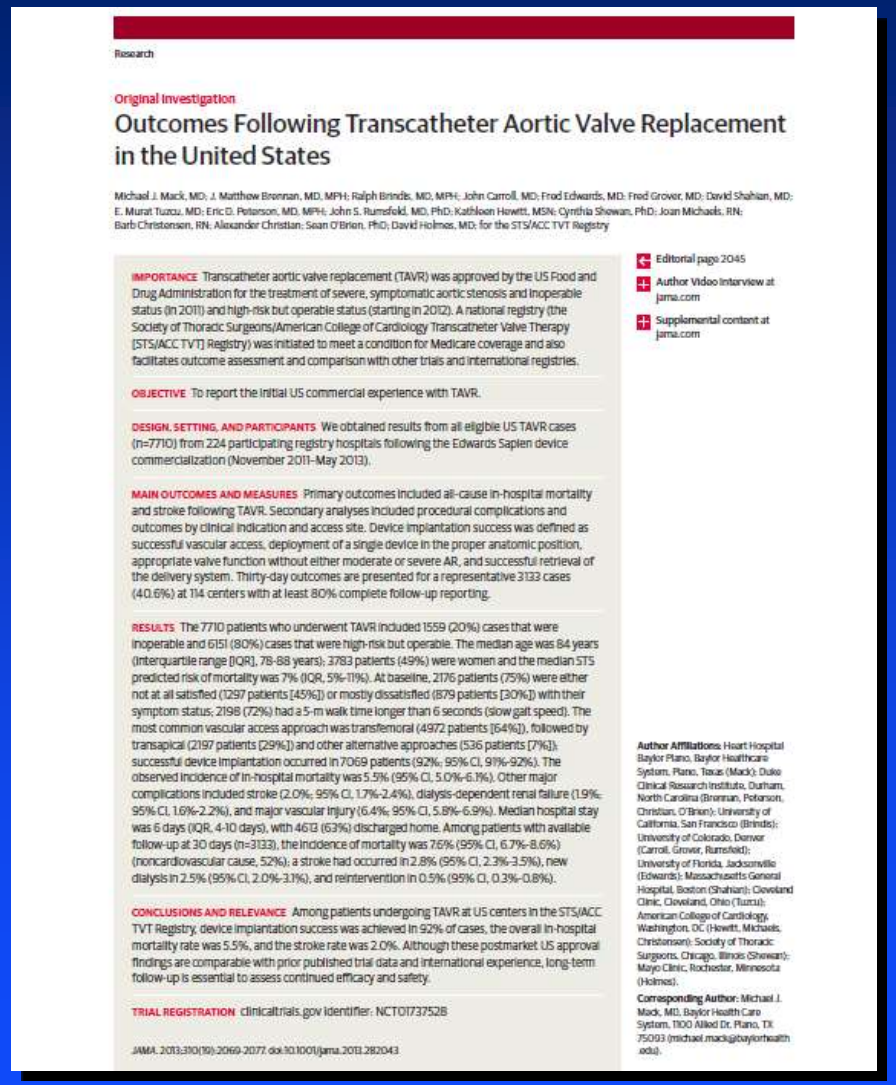
- Abbott Vascular
- CathWorks
- Phillips
- Zoll/Therox

Consulting/Advisory Boards

- Medtronic
- Boston Scientific
- Corvia

- Edwards Lifesciences
- Abbott Vascular
- Impulse Dynamics

What is the TVT Registry?



Research

Original Investigation

Outcomes Following Transcatheter Aortic Valve Replacement in the United States

Michael J. Mack, MD; J. Matthew Brennan, MD, MPH; Ralph Brindis, MD, MPH; John Carroll, MD; Fred Edwards, MD; Fred Grover, MD; David Shahian, MD; E. Murat Tuzcu, MD; Eric D. Peterson, MD, MPH; John S. Rumsfeld, MD, PhD; Kathleen Hewitt, MSN; Cynthia Shewan, PhD; Joan Michaels, RN; Barb Christenson, RN; Alexander Christian; Sean O'Brien, PhD; David Holmes, MD; for the STS/ACC TVT Registry

IMPORTANCE Transcatheter aortic valve replacement (TAVR) was approved by the US Food and Drug Administration for the treatment of severe, symptomatic aortic stenosis and inoperable status (in 2011) and high-risk but operable status (starting in 2012). A national registry (the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy [STS/ACC TVT] Registry) was initiated to meet a condition for Medicare coverage and also facilitates outcome assessment and comparison with other trials and international registries.

OBJECTIVE To report the initial US commercial experience with TAVR.

DESIGN, SETTING, AND PARTICIPANTS We obtained results from all eligible US TAVR cases (n=7710) from 224 participating registry hospitals following the Edwards Sapien device commercialization (November 2011-May 2013).

MAIN OUTCOMES AND MEASURES Primary outcomes included all-cause in-hospital mortality and stroke following TAVR. Secondary analyses included procedural complications and outcomes by clinical indication and access site. Device implantation success was defined as successful vascular access, deployment of a single device in the proper anatomic position, appropriate valve function without either moderate or severe AR, and successful retrieval of the delivery system. Thirty-day outcomes are presented for a representative 3133 cases (40.6%) at 114 centers with at least 80% complete follow-up reporting.

RESULTS The 7710 patients who underwent TAVR included 1559 (20%) cases that were inoperable and 6151 (80%) cases that were high-risk but operable. The median age was 84 years (interquartile range [IQR], 78-88 years); 3783 patients (49%) were women and the median STS predicted risk of mortality was 7% (IQR, 5%-11%). At baseline, 2176 patients (75%) were either not at all satisfied (1297 patients [45%]) or mostly dissatisfied (879 patients [30%]) with their symptom status; 2198 (72%) had a 5-m walk time longer than 6 seconds (slow gait speed). The most common vascular access approach was transfemoral (4972 patients [64%]), followed by transapical (2197 patients [29%]) and other alternative approaches (536 patients [7%]); successful device implantation occurred in 7069 patients (92%; 95% CI, 91%-92%). The observed incidence of in-hospital mortality was 5.5% (95% CI, 5.0%-6.1%). Other major complications included stroke (2.0%; 95% CI, 1.7%-2.4%), dialysis-dependent renal failure (1.9%; 95% CI, 1.6%-2.2%), and major vascular injury (6.4%; 95% CI, 5.8%-6.9%). Median hospital stay was 6 days (IQR, 4-10 days), with 4613 (63%) discharged home. Among patients with available follow-up at 30 days (n=3133), the incidence of mortality was 7.6% (95% CI, 6.7%-8.6%) (noncardiovascular cause, 52%); a stroke had occurred in 2.8% (95% CI, 2.3%-3.5%), new dialysis in 2.5% (95% CI, 2.0%-3.1%), and reintervention in 0.5% (95% CI, 0.3%-0.8%).

CONCLUSIONS AND RELEVANCE Among patients undergoing TAVR at US centers in the STS/ACC TVT Registry, device implantation success was achieved in 92% of cases, the overall in-hospital mortality rate was 5.5%, and the stroke rate was 2.0%. Although these postmarket US approval findings are comparable with prior published trial data and international experience, long-term follow-up is essential to assess continued efficacy and safety.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT01737528

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Author Video Interview at jama.com

Supplemental content at jama.com

Author Affiliations: Heart Hospital Baylor Plano, Baylor Healthcare System, Plano, Texas (Mack); Duke Clinical Research Institute, Durham, North Carolina (Brennan, Peterson, Christian, O'Brien); University of California, San Francisco (Brindis); University of Colorado, Denver (Carroll, Grover, Rumsfeld); University of Florida, Jacksonville (Edwards); Massachusetts General Hospital, Boston (Shahian); Cleveland Clinic, Cleveland, Ohio (Tuzcu); American College of Cardiology, Washington, DC (Hewitt, Michaels, Christenson); Society of Thoracic Surgeons, Chicago, Illinois (Shewan); Mayo Clinic, Rochester, Minnesota (Holmes).

Corresponding Author: Michael J. Mack, MD, Baylor Health Care System, 1100 Allied Dr, Plano, TX 75093 (michael.mack@baylorhealth.edu).

- Originally created in 2011 as part of the original NCD for TAVR
- Collects data on all patients undergoing "commercial" TAVR in the US (required for Medicare payment)
- Standardized data elements and definitions→ more reliable than claims data
- Designed primarily as QI tool, but also supports strategic and investigator-initiated research
- Also has led to approval of TAVR for selected "off-label" uses (e.g., ViV TAVR, alternative access)

Insights from the TVT Registry

- Trends in TAVR procedures and outcomes
- Drivers of improved outcomes
- Impact of TAVR on the landscape of treatment for severe aortic stenosis

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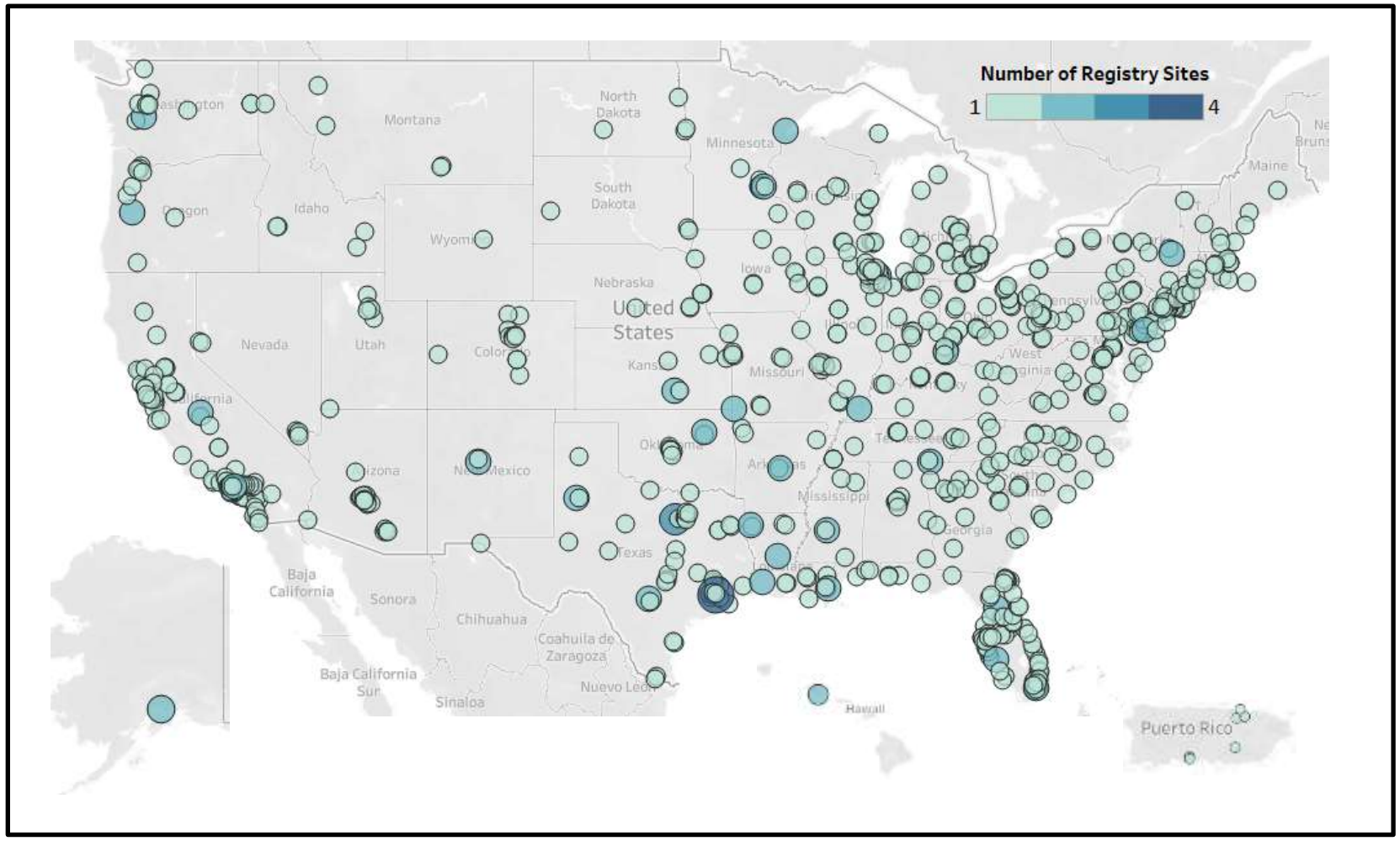
TVT Registry Sites



- 777 sites performing TAVR as of Q2 2021→ now over 800
- All states represented
- >500 sites performing MitraClip and other mitral valve interventions

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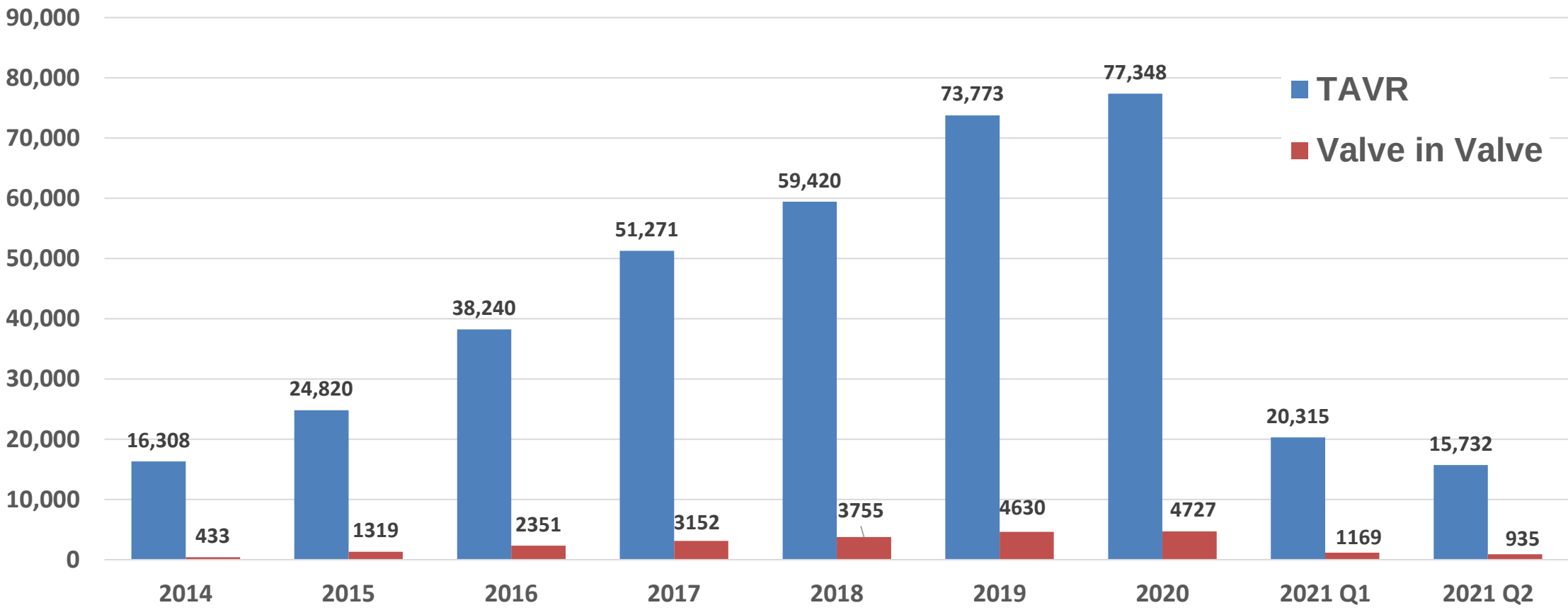
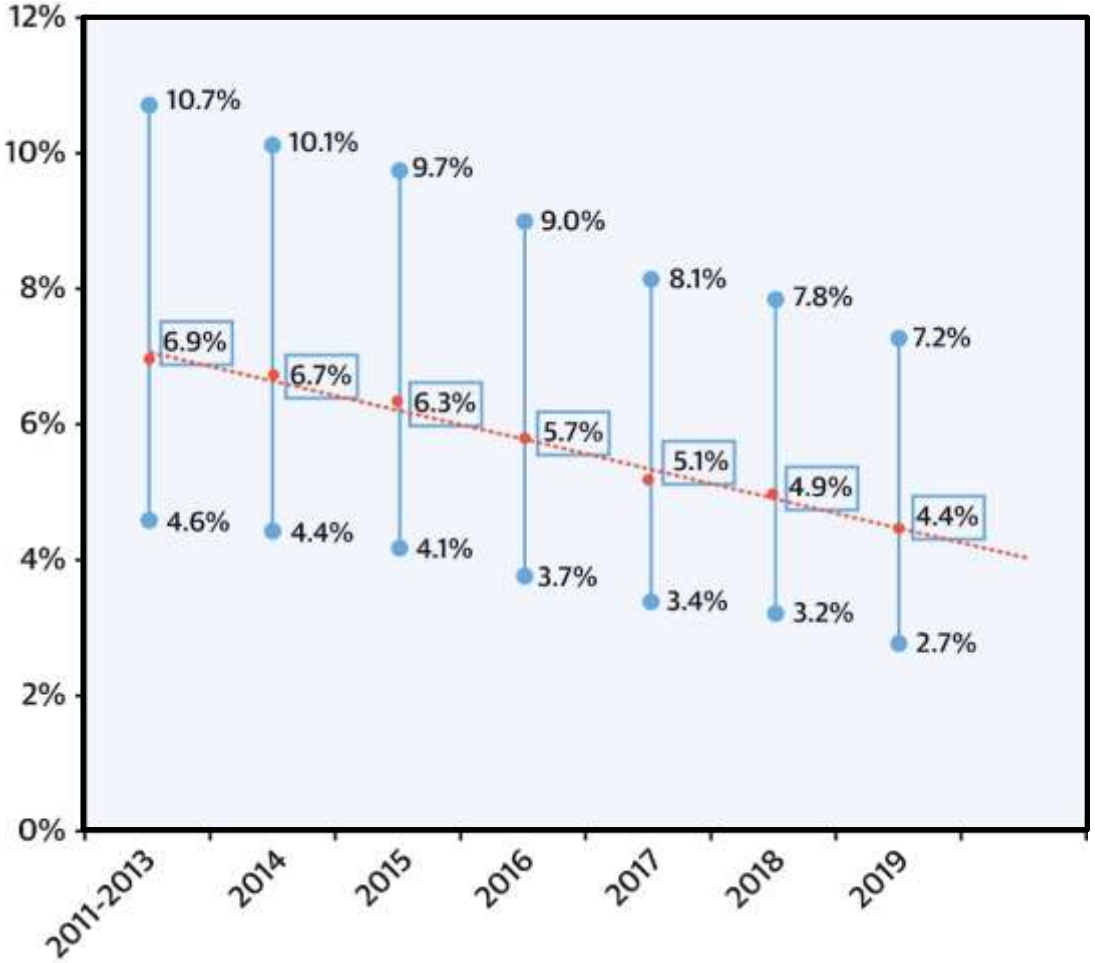
Annual Procedure Volumes: TAVR

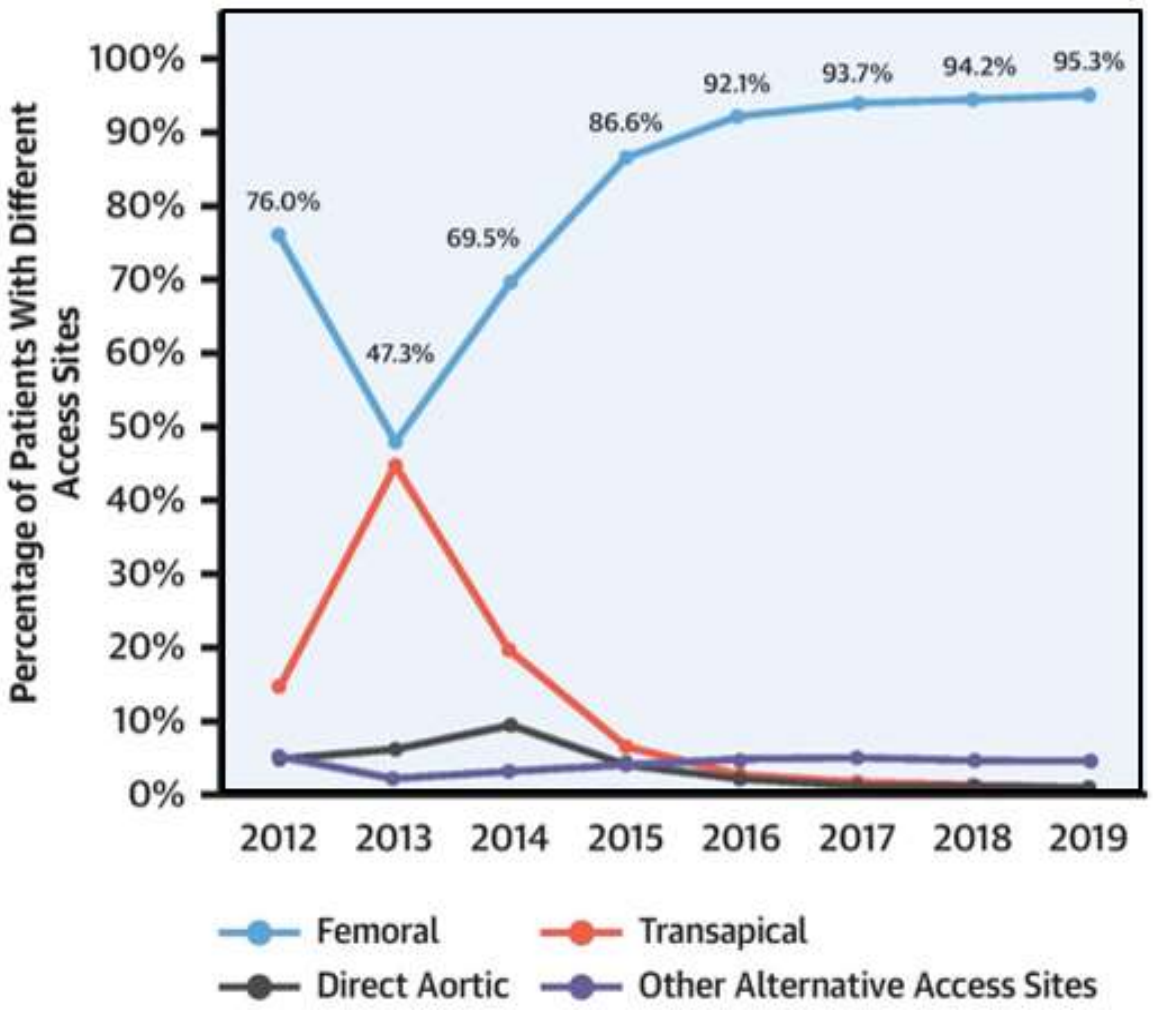


Changes in Patients and Access

Median (IQR) STS-PROM

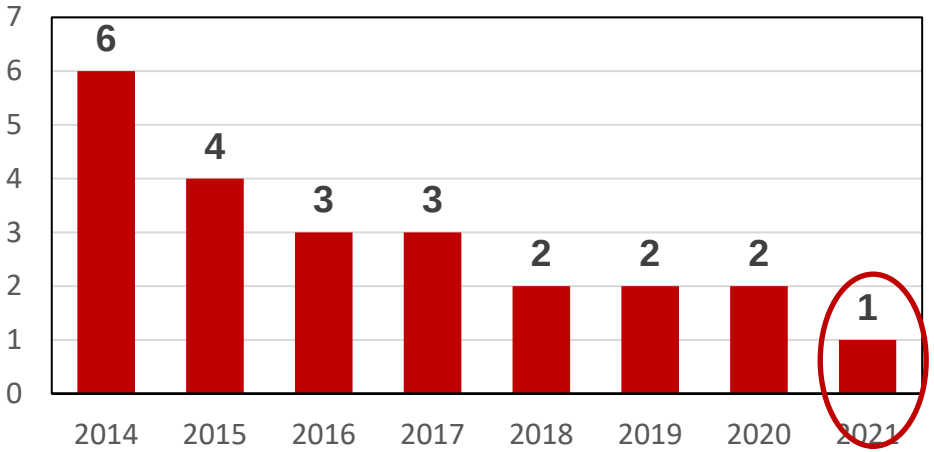


Access Sites

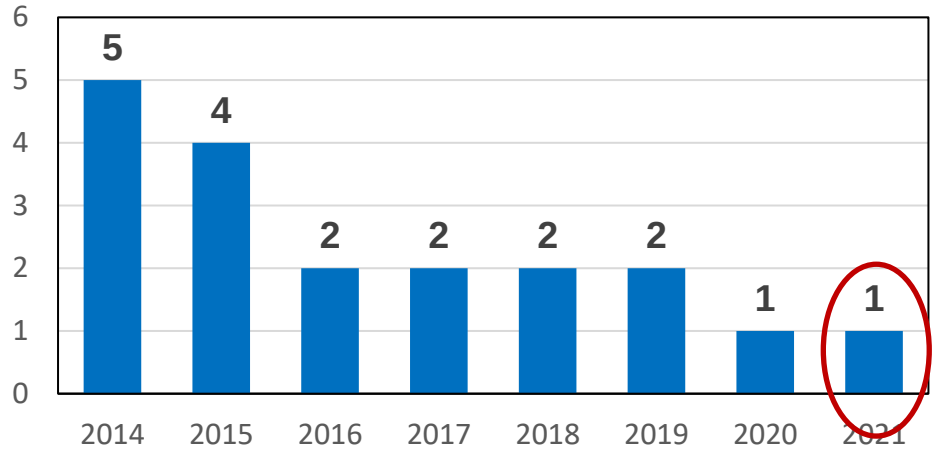


TAVR Outcomes: Length of Stay

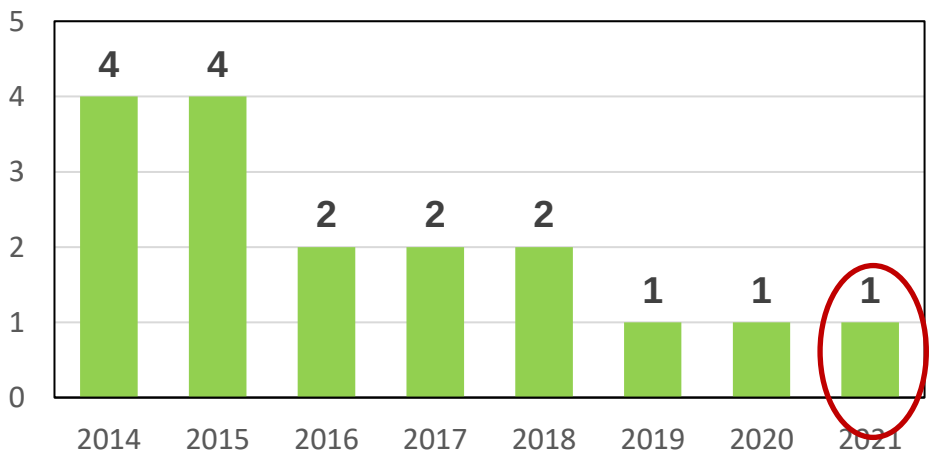
High Risk



Intermediate Risk



Low Risk



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What is driving the improvement in TAVR outcomes?

- Analysis of 161,000 TAVR procedures from 2011-2018
  - Outcomes: 30-day mortality, 30-day major complications, 1-year mortality
- To “disentangle” the multiple potential effects, we serially adjusted for different mediator clusters
  - *Demographics: age, sex*
  - *Non-CV comorbidities: diabetes, severe lung dz, home O2, eGFR, dialysis*
  - *CV comorbidities: prior MI, PAD, prior stroke, AF, MR, TR, EF, baseline health status*
  - *Device factors: sheath size, access site*
  - *Non-Device procedural factors: anesthesia type, cerebral protection*

Patient Characteristics Over Time

Non-CV Comorbidities	2011/12 n=2875	2013 n=4390	2014 n=11,226	2015 n=19,566	2016 n=30,987	2017 n=42,612	2018 n=49,540	p-value
Age	84 y	84 y	84 y	83 y	82 y	82 y	81 y	<0.001
Female	49%	55%	48%	48%	47%	46%	46%	<0.001
Lung disease	15%	12%	14%	13%	12%	10%	9%	<0.001
Home oxygen	17%	12%	12%	11%	10%	9%	8%	<0.001
Est. GFR	55	56	56	57	58	59	59	<0.001
Diabetes	38%	35%	38%	38%	38%	39%	39%	<0.001

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Procedural Characteristics Over Time

Procedural Factors	2011/12 n=2875	2013 n=4390	2014 n=11,226	2015 n=19,566	2016 n=30,987	2017 n=42,612	2018 n=49,540	p-value
Access site								<0.001
Femoral	85%	63%	81%	89%	94%	95%	95%	
Apical, aortic, caval	14%	35%	17%	8%	3%	2%	1%	
Axillary, subclavian, carotid	1%	1%	3%	3%	3%	4%	4%	
Sheath size								<0.001
22-24 French	98%	96%	27%	7%	2%	1%	<1%	
18-22 French	2%	3%	64%	54%	15%	12%	9%	
14-17 French	1%	1%	9%	39%	83%	87%	90%	
General anesthesia	97%	98%	93%	82%	65%	52%	44%	<0.001
Contrast volume	125 mL	110 mL	110 mL	105 mL	100 mL	90 mL	85 mL	<0.001

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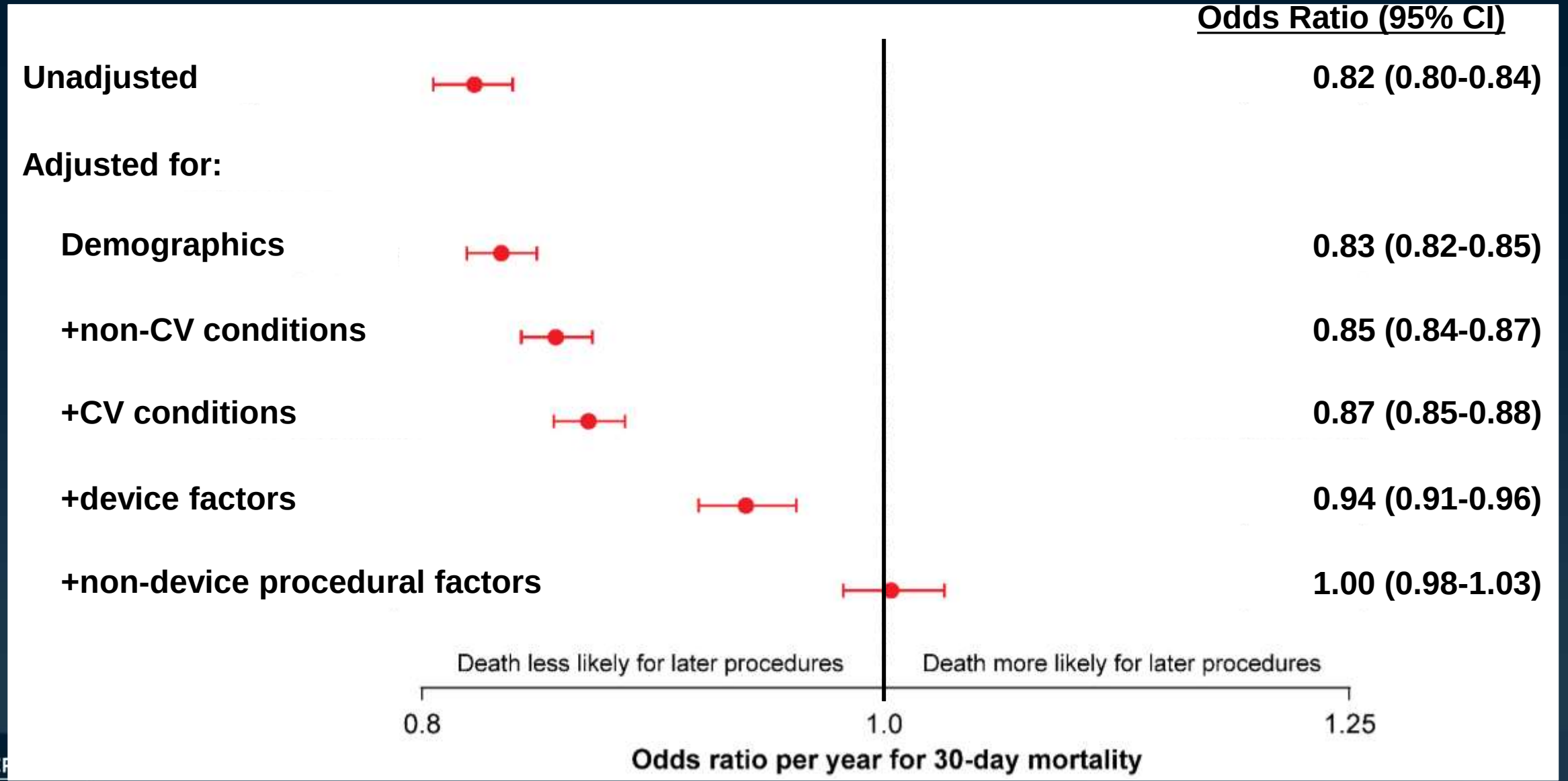
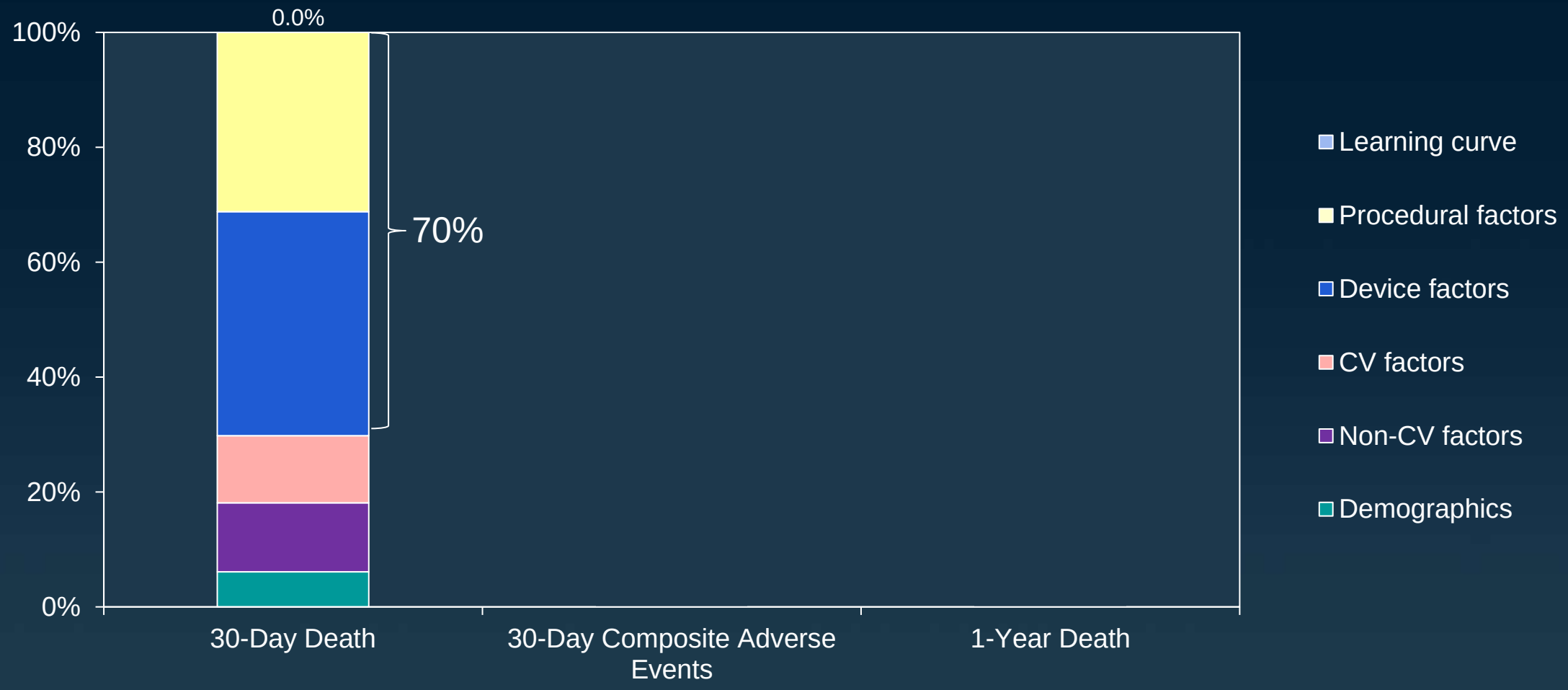
30-Day Death



*OR represents the adjusted change in mortality per year

Improvement Explained by Each Cluster



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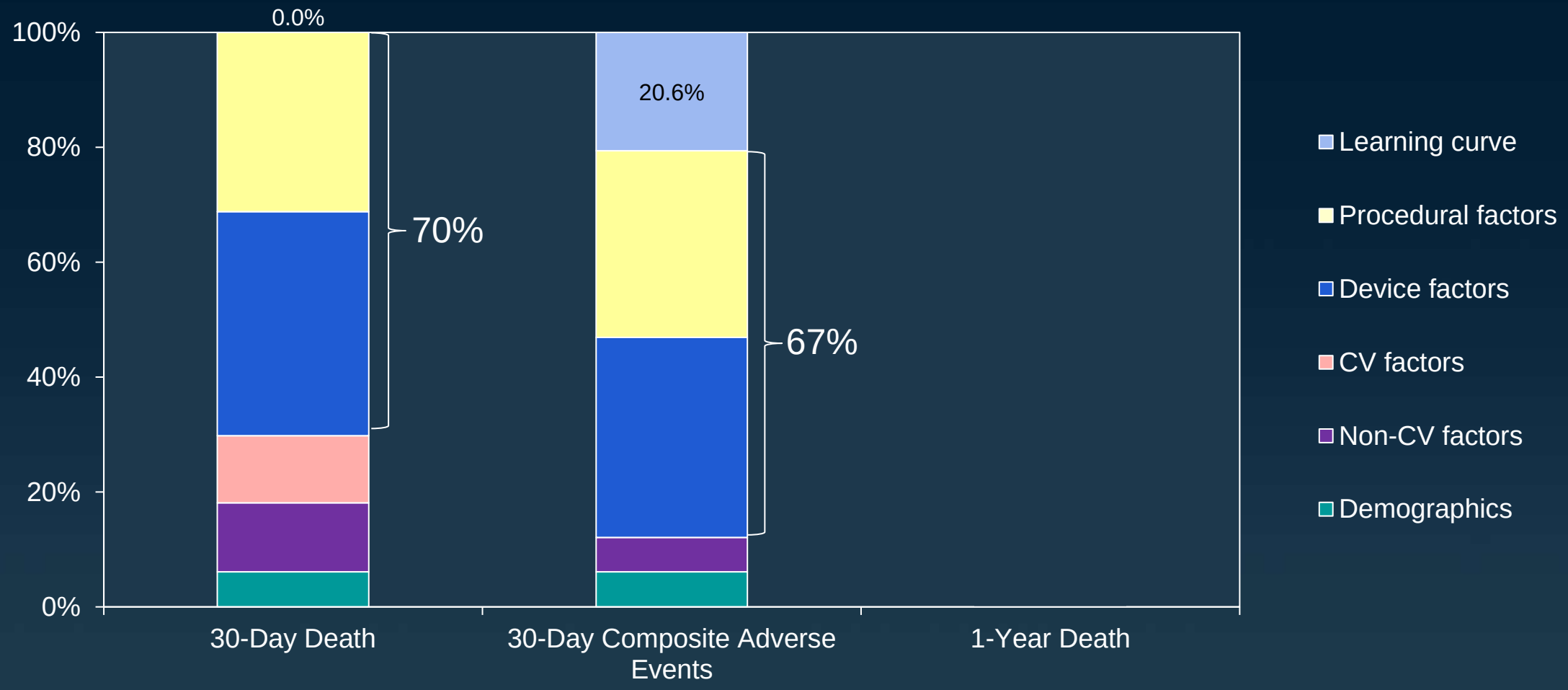

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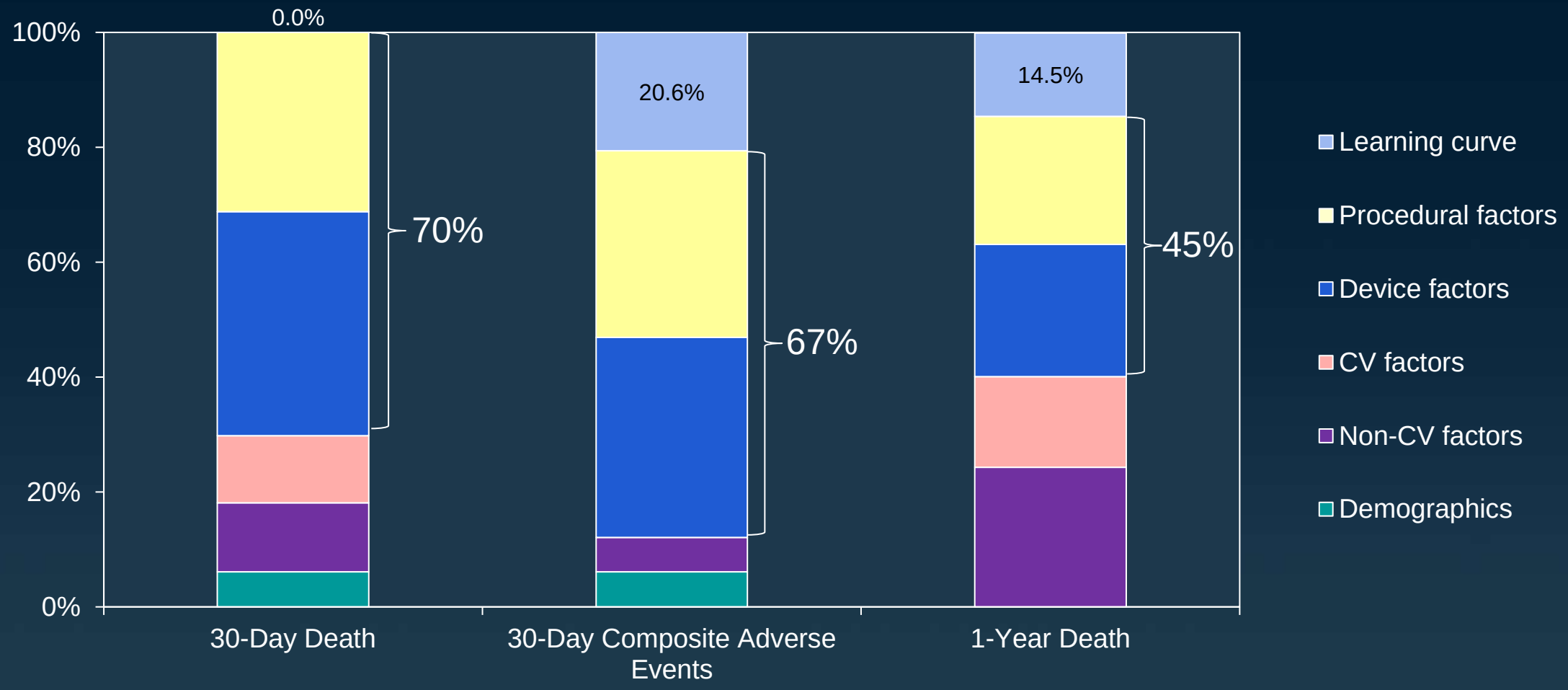

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Impact of TAVR Introduction at the Population Level

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Trends in Transcatheter and Surgical Aortic Valve Replacement Among Older Adults in the United States

Makoto Mori, MD,[a,b,*] Aakriti Gupta, MD, MS,[b,c,*] Yun Wang, PhD,[b,d] Torsten Vahl, MD,[c] Tamim Nazif, MD,[c] Ajay J. Kirtane, MD, SM,[c] Isaac George, MD,[e] Celina M. Yong, MD, MBA, MSc,[f,g] Oyere Onuma, MD, MSc,[h] Susheel Kodali, MD,[c] Arnar Geirsson, MD,[a] Martin B. Leon, MD,[c] Harlan M. Krumholz, MD, SM[b,i,j]

ABSTRACT

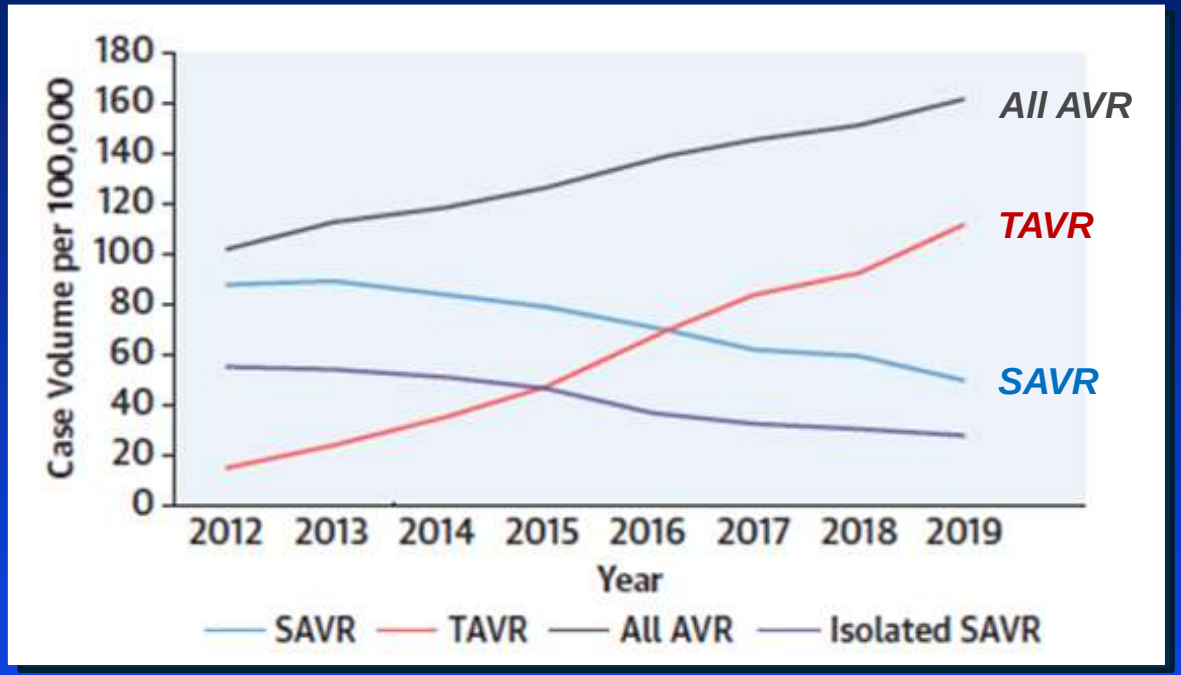
BACKGROUND Recent trends, including survival beyond 30 days, in aortic valve replacement (AVR) following the expansion of indications for transcatheter aortic valve replacement (TAVR) are not well-understood.

OBJECTIVES The authors sought to characterize the trends in characteristics and outcomes of patients undergoing AVR.

METHODS The authors analyzed Medicare beneficiaries who underwent TAVR and SAVR in 2012 to 2019. They evaluated case volume, demographics, comorbidities, 1-year mortality, and discharge disposition. Cox proportional hazard models were used to assess the annual change in outcomes.

RESULTS Per 100,000 beneficiary-years, AVR increased from 107 to 156, TAVR increased from 19 to 101, whereas SAVR declined from 88 to 54. The median [interquartile range] age remained similar from 77 [71-83] years to 78 [72-84] years for overall AVR, decreased from 84 [79-88] years to 81 [75-86] years for TAVR, and decreased from 76 [71-81] years to 72 [68-77] years for SAVR. For all AVR patients, the prevalence of comorbidities remained relatively stable. The 1-year mortality for all AVR decreased from 11.9% to 9.4%. Annual change in the adjusted odds of 1-year mortality was 0.93 (95% CI: 0.92-0.94) for TAVR and 0.98 (95% CI: 0.97-0.99) for SAVR, and 0.94 (95% CI: 0.93-0.95) for all AVR. Patients discharged to home after AVR increased from 24.2% to 54.7%, primarily driven by increasing home discharge after TAVR.

CONCLUSIONS The advent of TAVR has led to about a 60% increase in overall AVR in older adults. Improving outcomes in AVR as a whole following the advent of TAVR with increased access is a reassuring trend.
(J Am Coll Cardiol 2021;78:2161-2172) © 2021 Published by Elsevier on behalf of the American College of Cardiology Foundation.



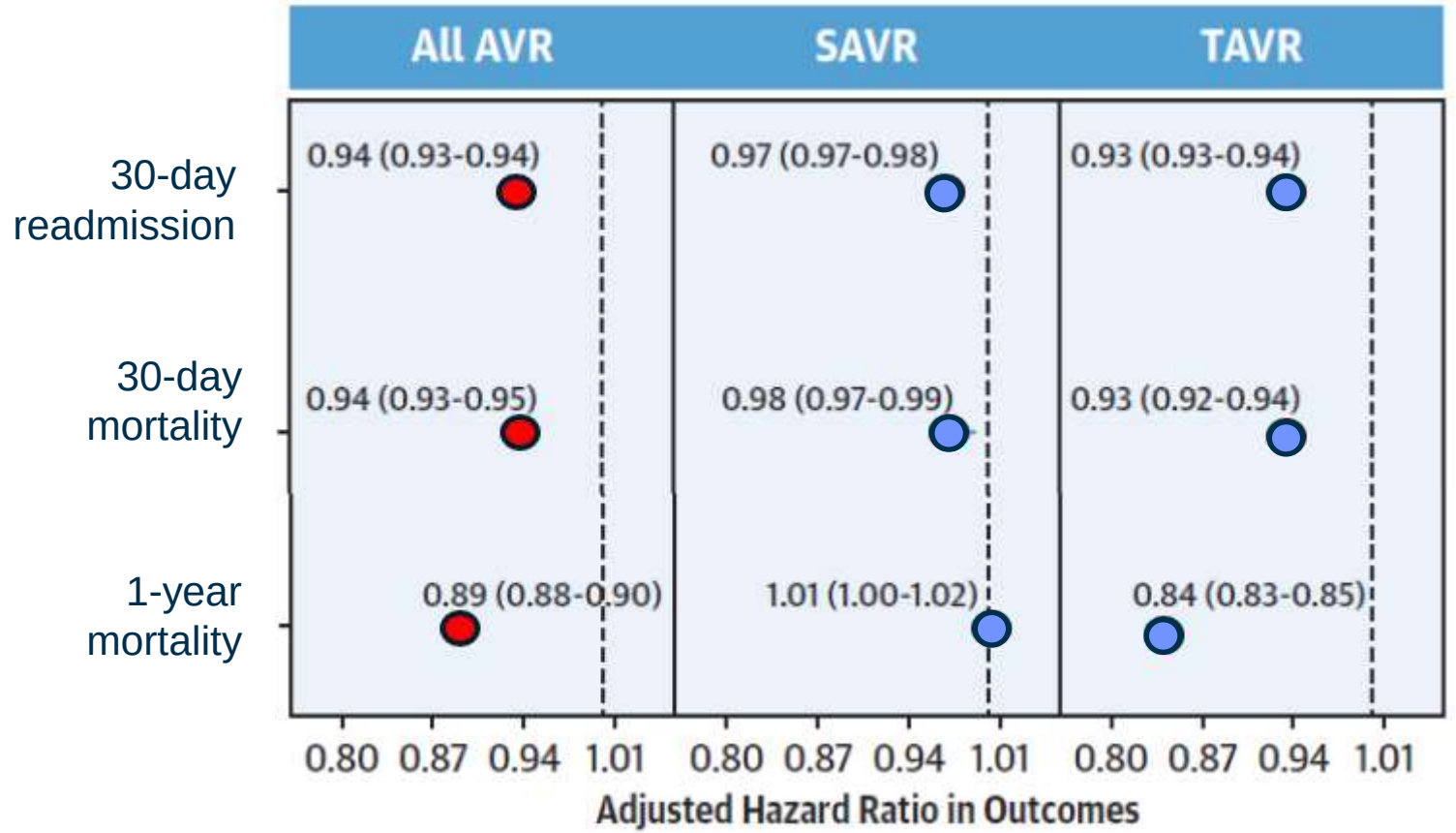
Volume Changes (per capita)

- TAVR ↑ 600%
- SAVR ↓ 40%
- Overall AVR ↑ 60%

Mori M, et al. JACC 2021;78:2161-72

Impact of TAVR Introduction on AVR Outcomes

Change in Risk-Adjusted Outcome (per Year)



- Significant improvement in overall AVR outcomes at population level
- Benefits driven by shift of higher risk patients to TAVR (with continued improvement in outcomes) and limitation of SAVR to the youngest/healthiest pts

Mori M, et al. JACC 2021;78:2161-72

Summary

- Over the first decade of commercial TAVR in the US, outcomes have improved dramatically
- The main drivers of these improvements have been device innovation and technical/procedural advances, particularly for short-term mortality
- In addition, operator and institutional experience continue to play a major role in reducing complications and optimizing efficiency
- Despite reduction in the use of SAVR, availability of TAVR has led to significant growth in overall AVR volumes, with improvement in both short and longer-term mortality for all patients (win/win)

Summary-2

- Availability of detailed clinical data at the population level has been essential to gaining these insights and will likely continue to drive quality improvement and innovation as the field of structural heart intervention continues to expand