

Current Status of TAVR in Korea and US: Introduction to TP-TAVR Registry

Duk-Woo Park, MD, PhD

Professor of Medicine, University of Ulsan College of Medicine,
Heart Institute, Asan Medical Center, Seoul, Korea

Conflict of Interest Statement

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

Consulting Fees/Honoraria

Consulting Fees/Honoraria

Consulting Fees/Honoraria

Company

Edwards LifeSciences

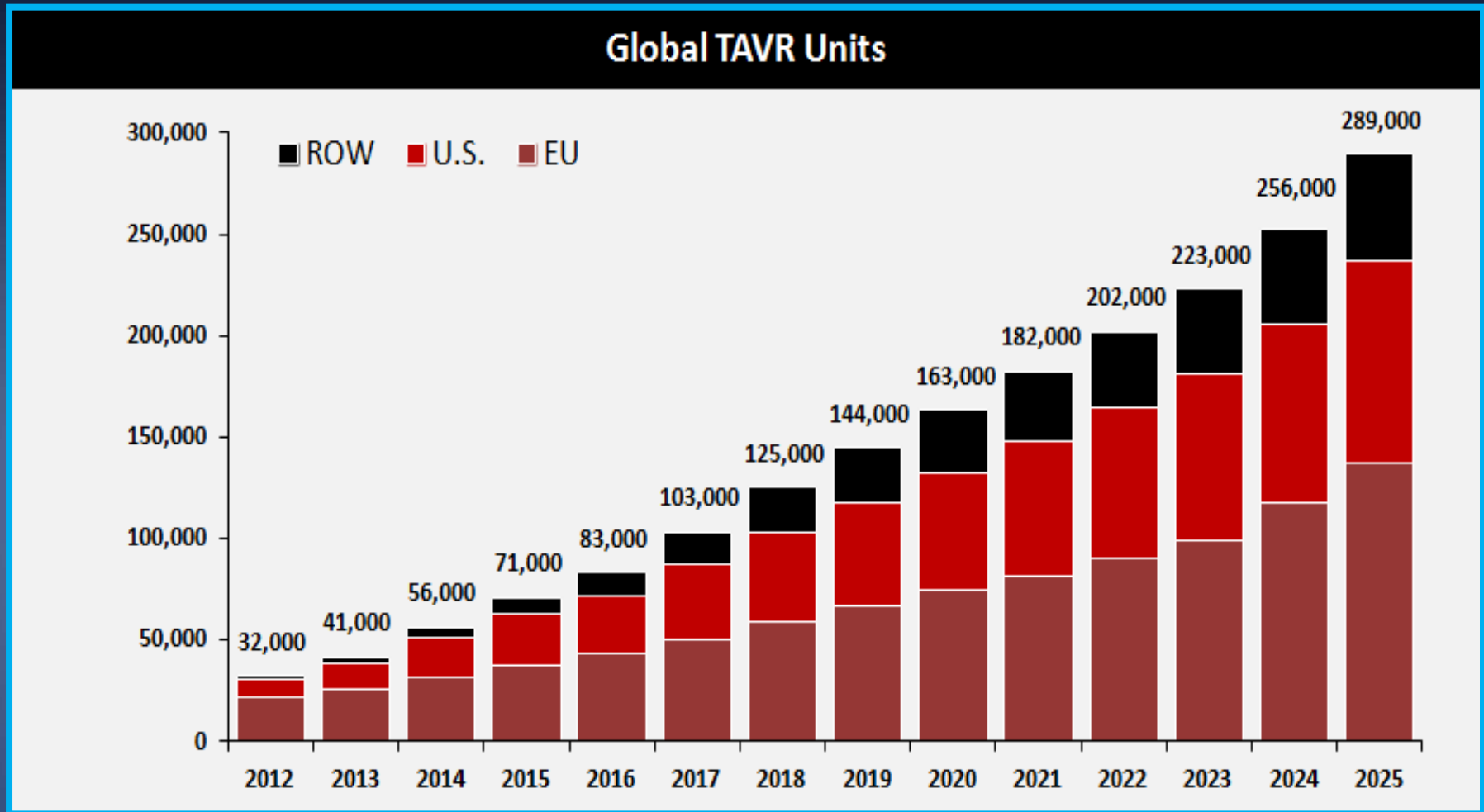
Medtronic Inc

Boston Scientific

RCT Chains of TAVR

| Trial Name | STS Score | Age |
|--|-----------|-----|
| Inoperable Population | | |
| PARTNER IB Trial (2010) | 11.6 | 83 |
| High Risk Population (>8) | | |
| PARTNER IA Trial (2011) | 11.8 | 84 |
| CoreValve US Pivotal Trial (2014) | 7.4 | 83 |
| Intermediate Risk Population (4-8) | | |
| PARTNER II Trial (2016) | 5.8 | 82 |
| Low Risk Population (<4) | | |
| NOTION Trial (2015) | 3.0 | 79 |
| PARTNER III (2019) | 1.9 | 73 |
| Evolut Low Risk Trial (2019) | 1.9 | 74 |

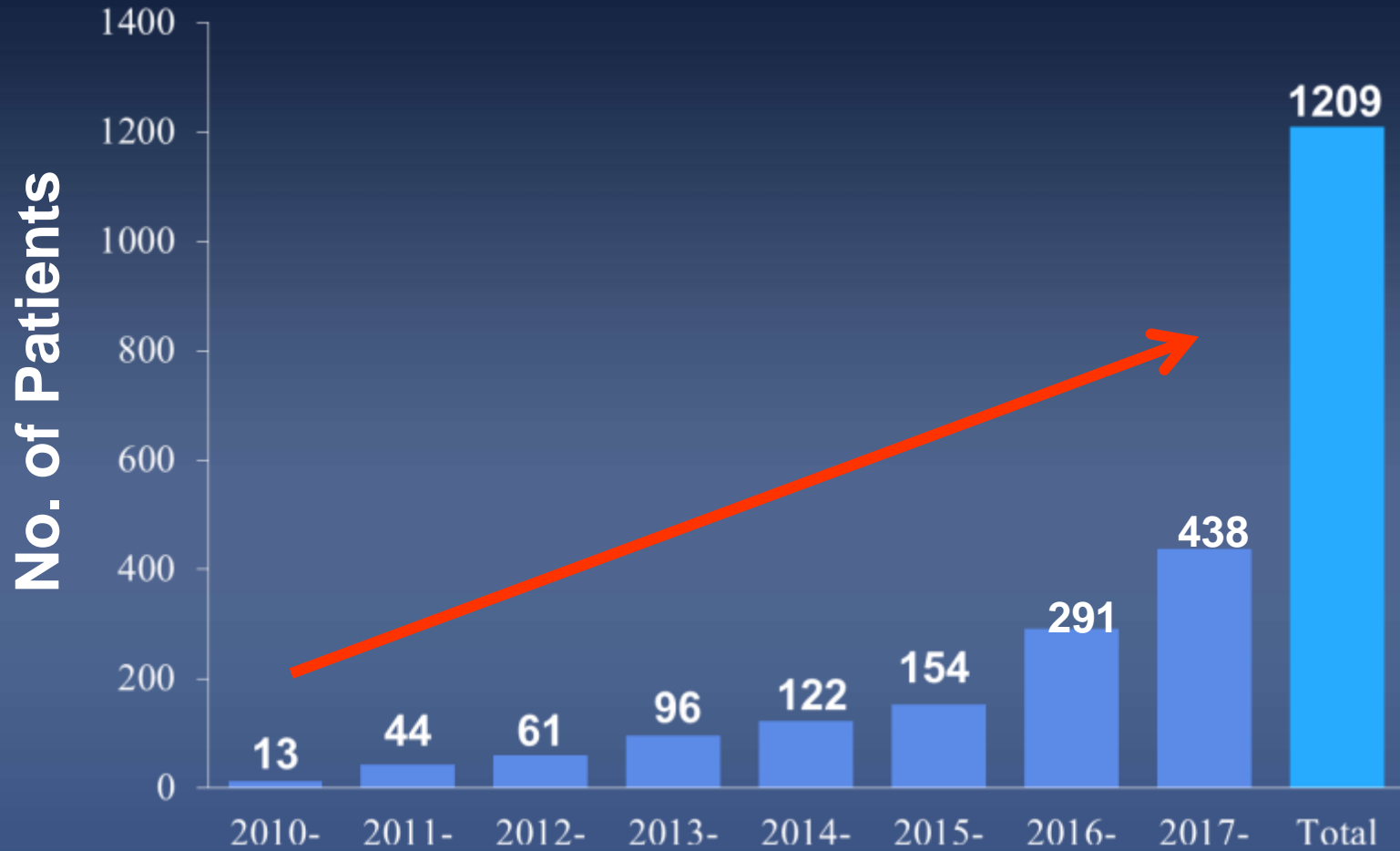
Estimated Global TAVI Procedure Growth



SOURCE: Credit Suisse TAVI Comment –January 8, 2015. ASP assumption for 2024 and 2025 based on analyst model. Revenue split assumption in 2025 is 45% U.S., 35% EU, 10% Japan, 10% ROW

Current Status in TAVR in Korea

TAVR in Korea (2010~2017)

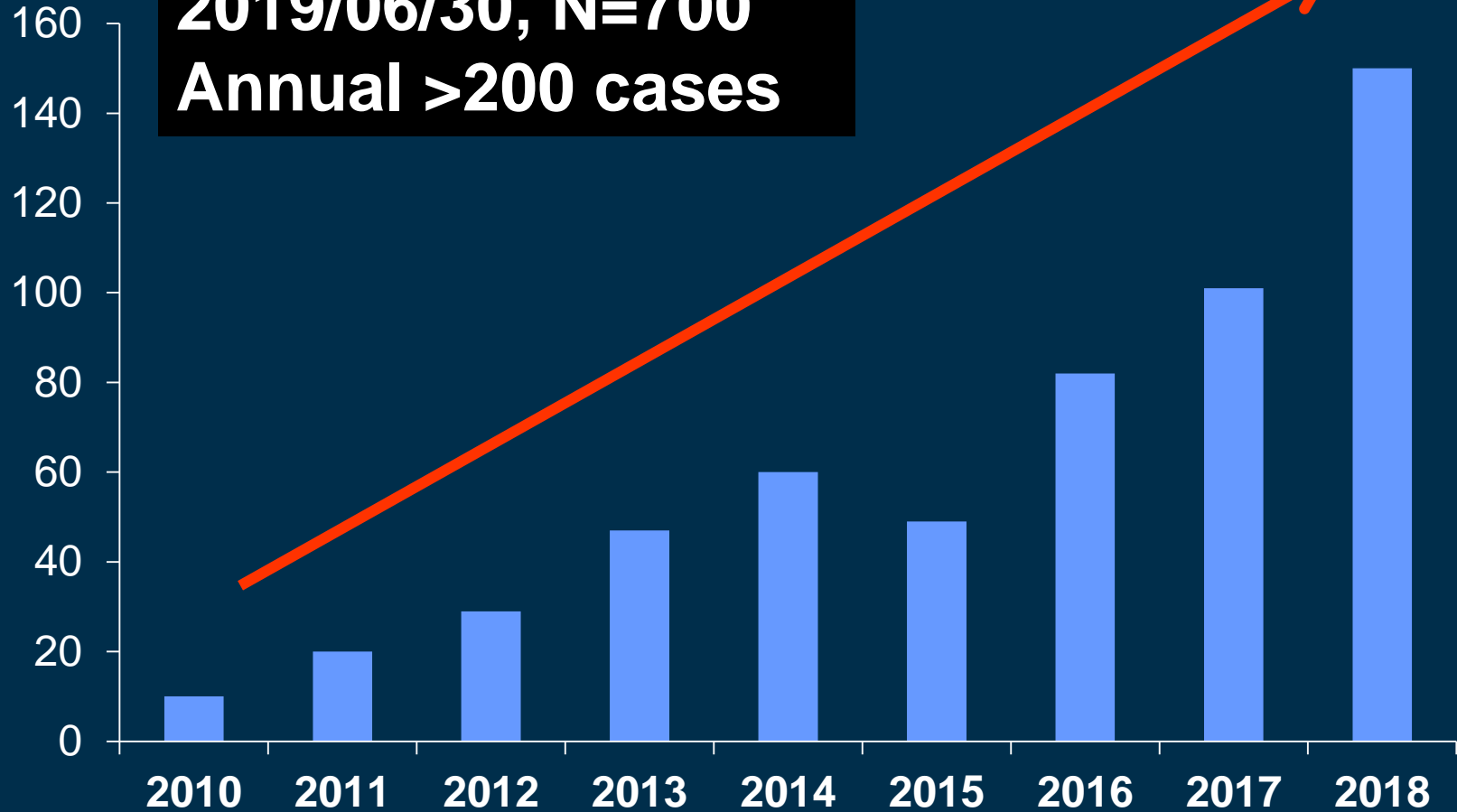


Current TAVR Status in Korea

| | N=623 |
|----------------------------|--------------------|
| Approach | |
| Femoral | 614 (97.8%) |
| Apical | 11 (1.8%) |
| Subclavian | 3 (0.5%) |
| Operation room | |
| Hybrid room | 358 (57.0%) |
| Cath room | 270 (43.0%) |
| Anesthesia duration (mins) | 131.5±43.2 |
| General anesthesia | 533 (84.9%) |
| Conscious sedation | 95 (15.1%) |

TAVR in Asan Medical Center

TAVR No.



TAVR in AMC

1. Good Collaborative “Heart Team”,
“Surgeon Interventionist”
2. Simplification of the Procedure,
“Minimalist Approach (more than 95%)”
3. Consistent, Meticulous CT Measurement,
“Own CT Algorithm for Device Selection”

TAVR in AMC

| | N = 533 |
|-----------------------------|--------------------|
| Age, years | 78.9 ± 5.2 |
| Male sex | 261 (49.0%) |
| BMI, kg/m ² | 23.9 ± 3.3 |
| Logistic Euroscore (%) | 14.9 ± 11.7 |
| STS risk score (%) | 4.1 ± 3.0 |
| DM | 175 (32.8%) |
| Hypertension | 424 (79.5%) |
| Atrial fibrillation | 75 (14.1%) |
| Coronary artery disease | 201 (37.7%) |
| Previous MI | 25 (4.7%) |
| Previous stroke | 65 (12.2%) |
| Peripheral vascular disease | 29 (5.4%) |
| Chronic Kidney Disease | 157 (29.5%) |
| COPD | 115 (21.6%) |
| LV Ejection fraction, % | 58.5 ± 10.9 |

30 Days Outcomes TAVR in AMC

Standard Performance (VARC-2) for
High-Risk AS patients (@ 30 days)*

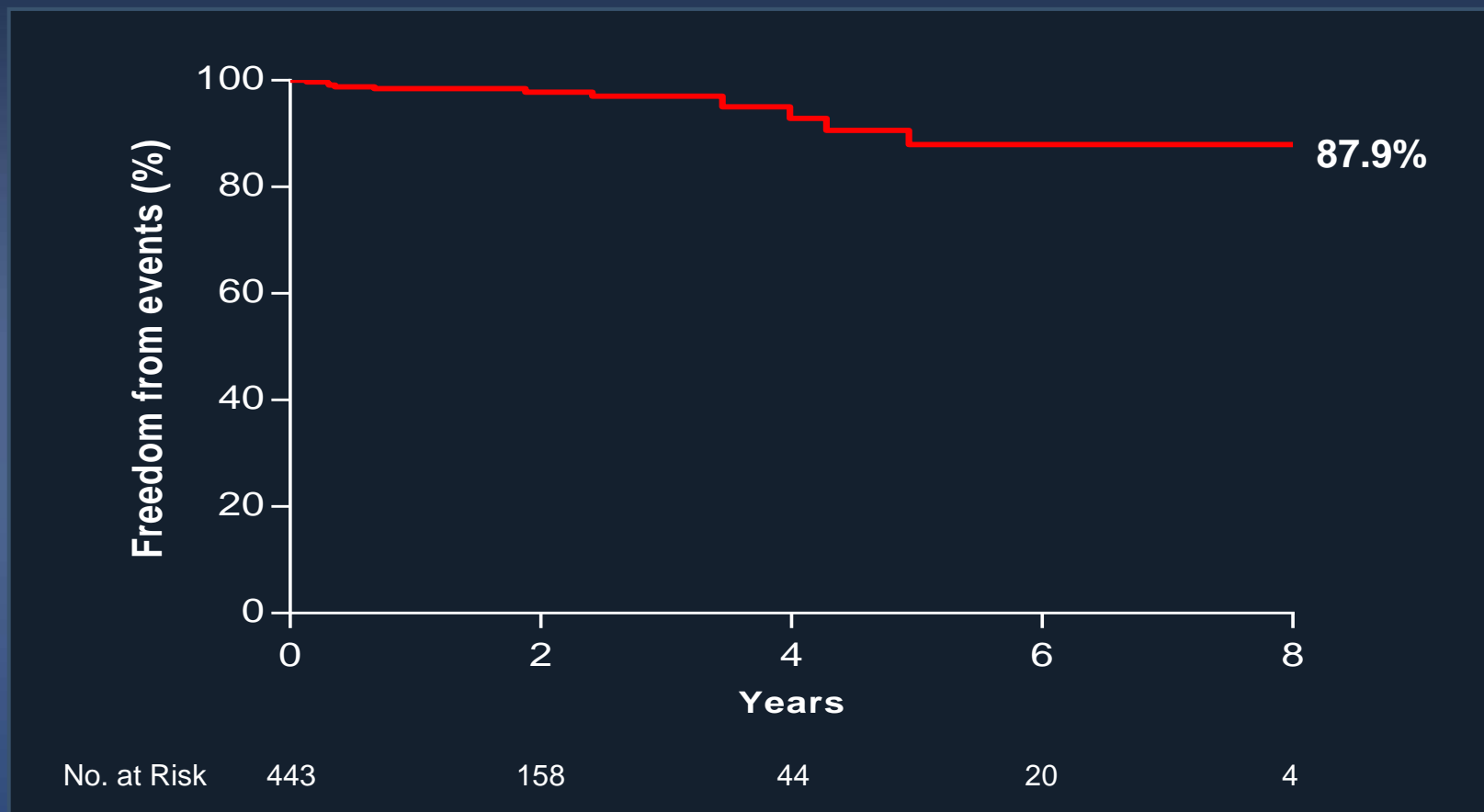
| | | <i>Asian 2017</i> | <i>AMC 2018</i> | <i>AMC “MAC”</i> |
|------------------------------|-------|-----------------------|---------------------|----------------------|
| All-cause mortality | < 3% | 2.5% | 2.2% | 1.3% |
| Major (disabling) strokes | < 2% | 2.2% | 0.7% | 0.9% |
| Major vascular complications | < 5% | 5.0% | 3.6% | 3.1% |
| New permanent pacemakers | < 10% | 9.5% | 8.7% | 8.2% |
| Mod-severe PVR | < 5% | 9.8% | 2.9% | 4.4% |

VARC* Vascular Academic Research Consortium

Durability of TAVR

443 pts from 2010 (> 5 years FU)

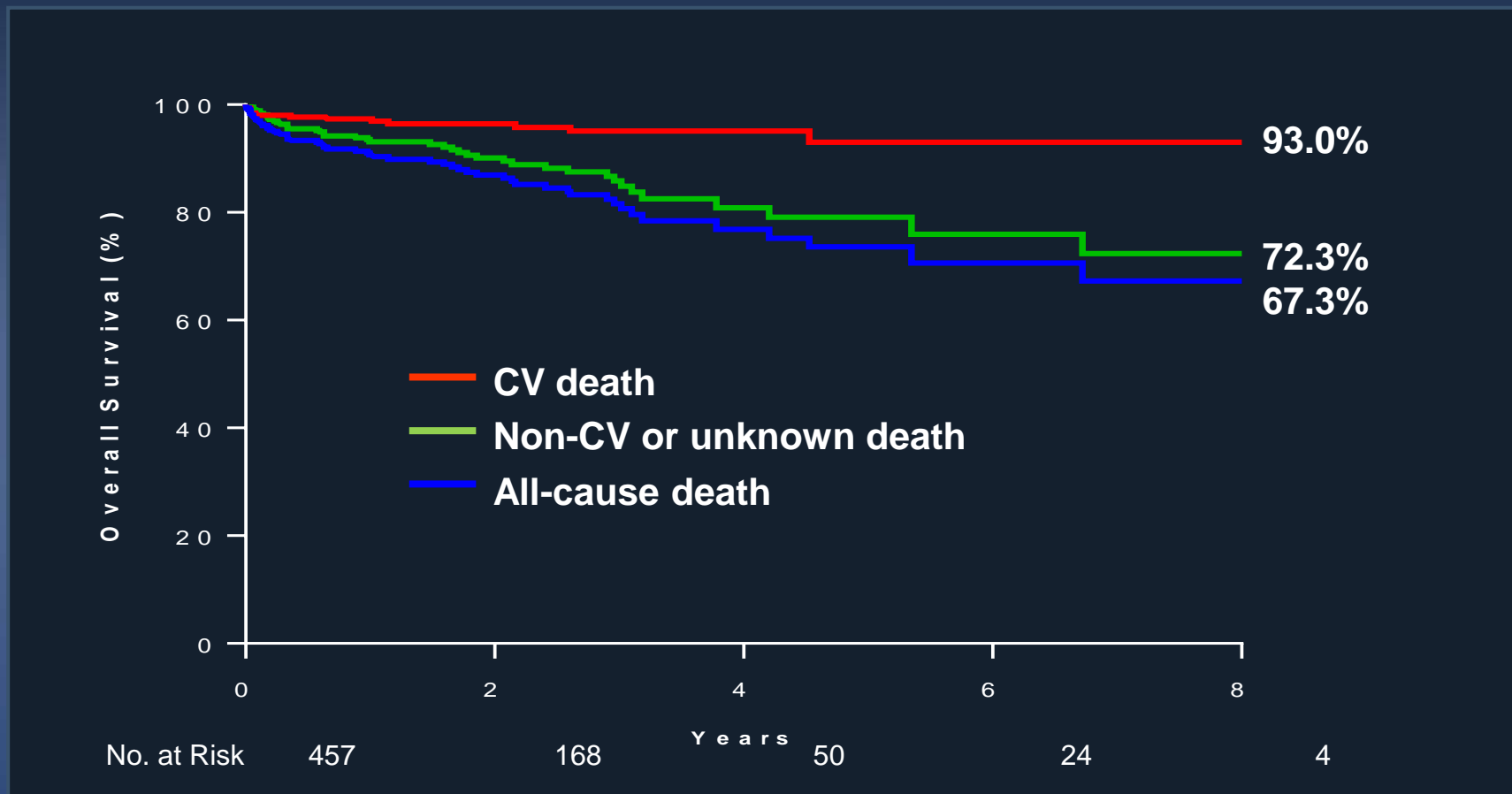
Freedom from Re-operation or Re-intervention



TAVR in AMC

443 pts from 2010 (> 5 years FU)

8 Year Survival

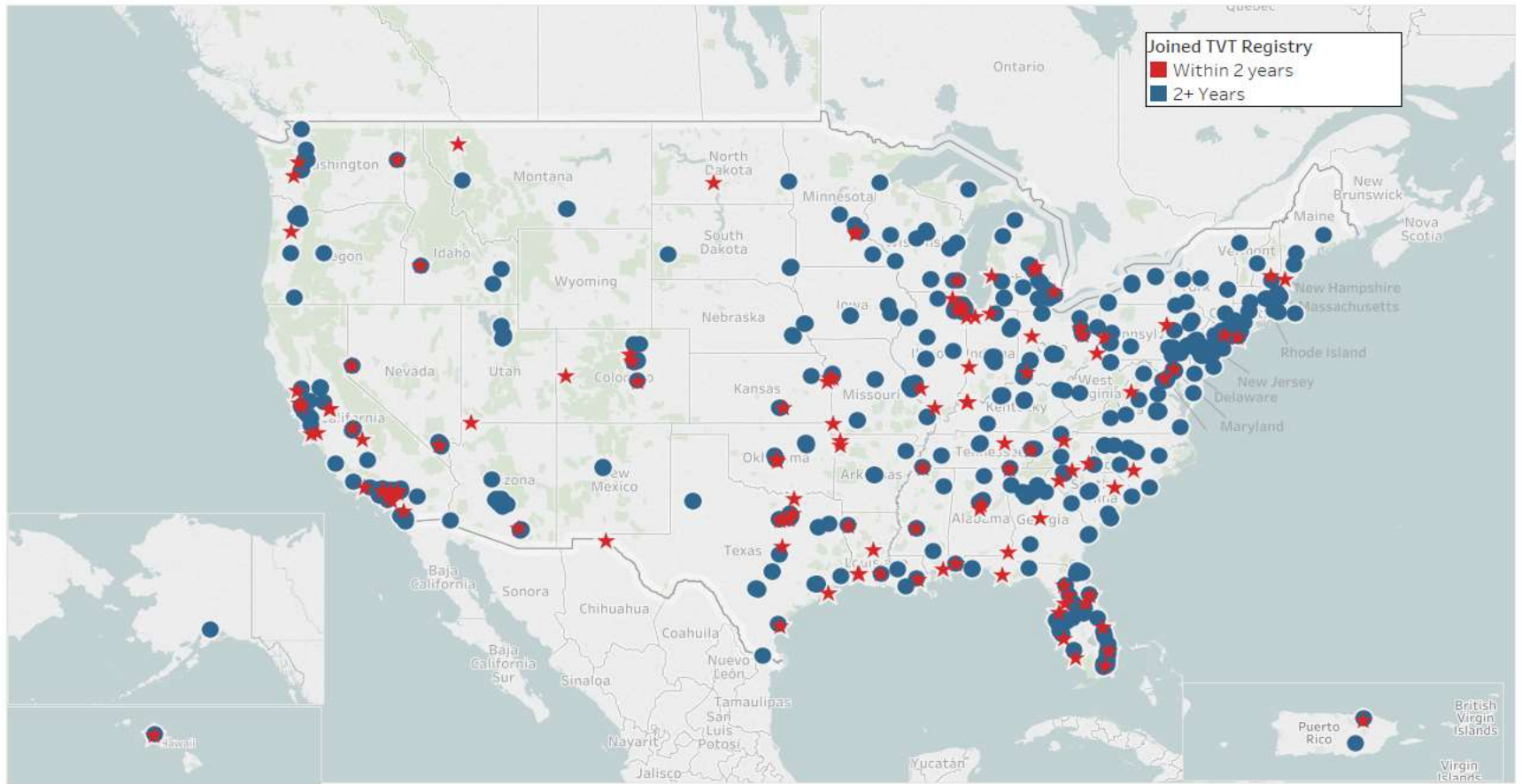


Current Status in TAVR in U.S.

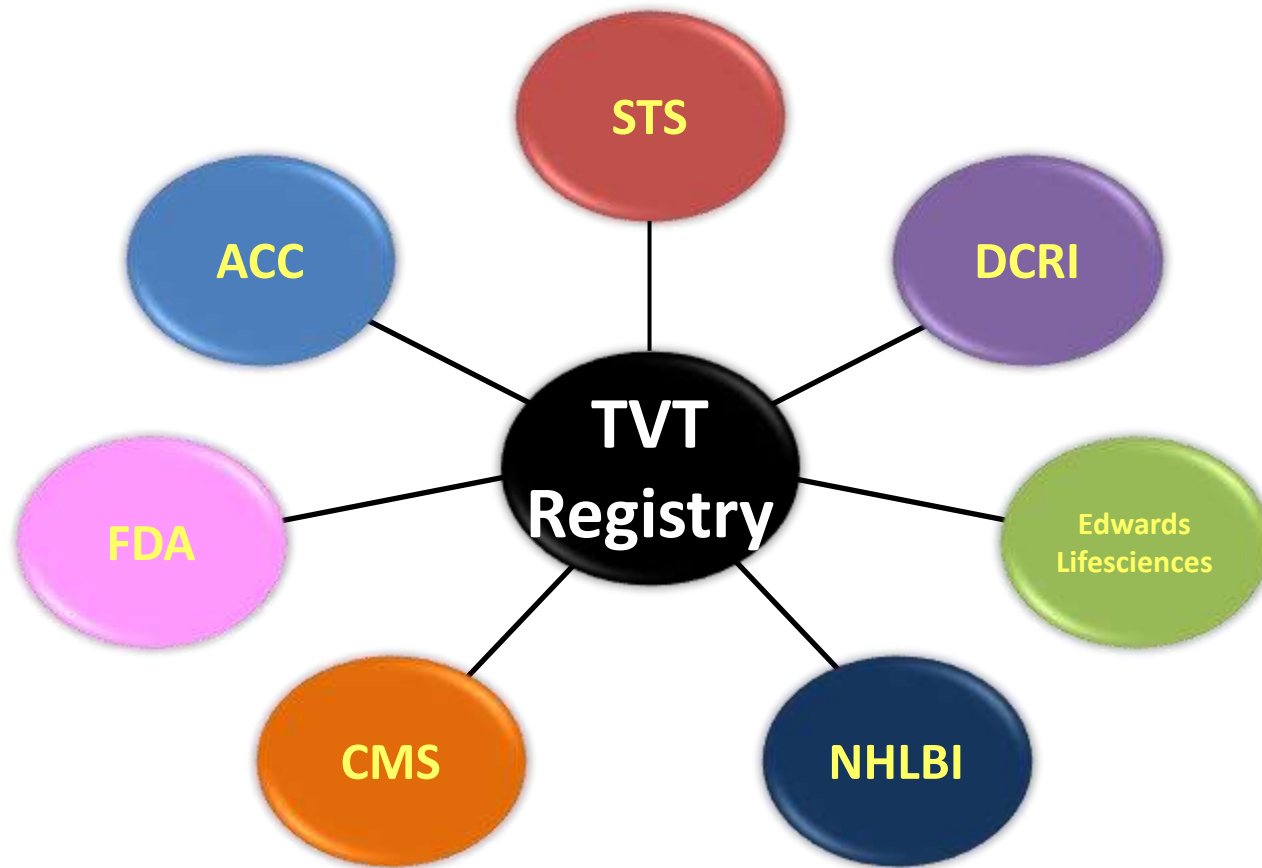
STS/ACC TVT Registry

TVT Registry Site Distribution

602 institutions in 51 states/U.S. territories

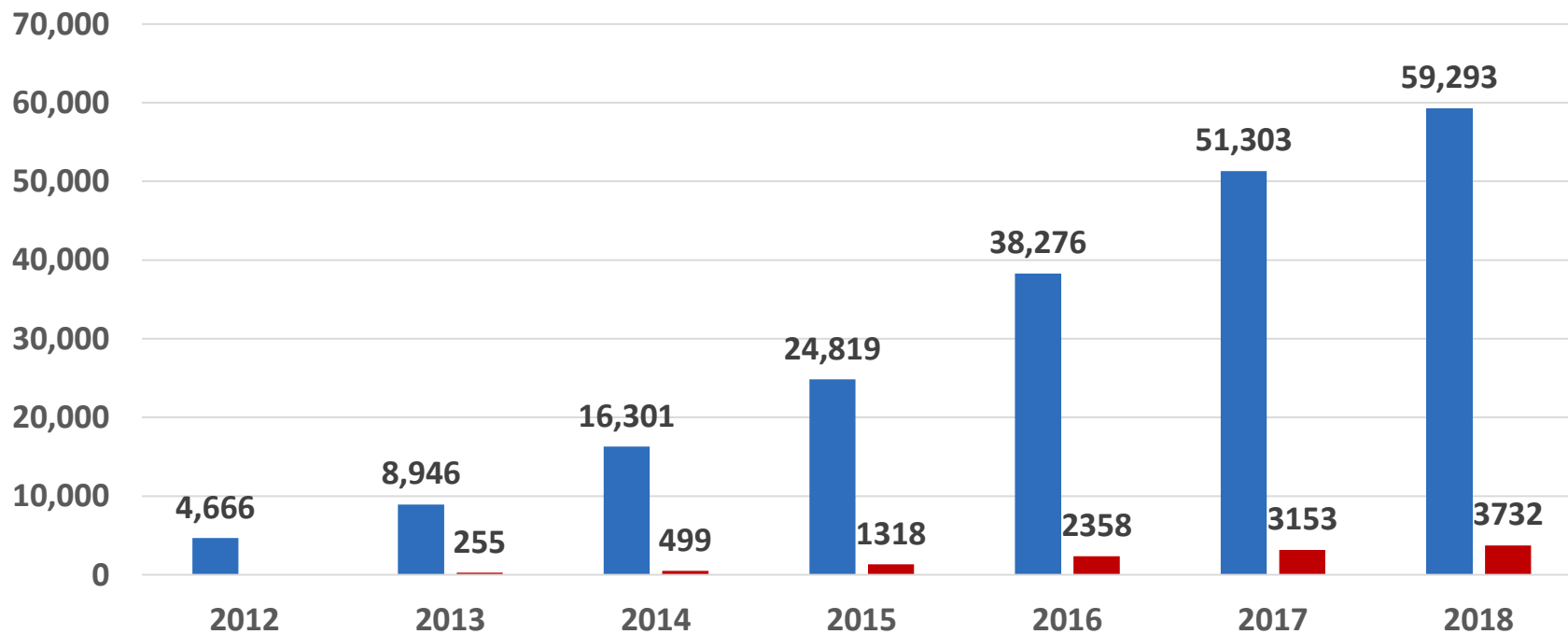


The Collaborative Partners



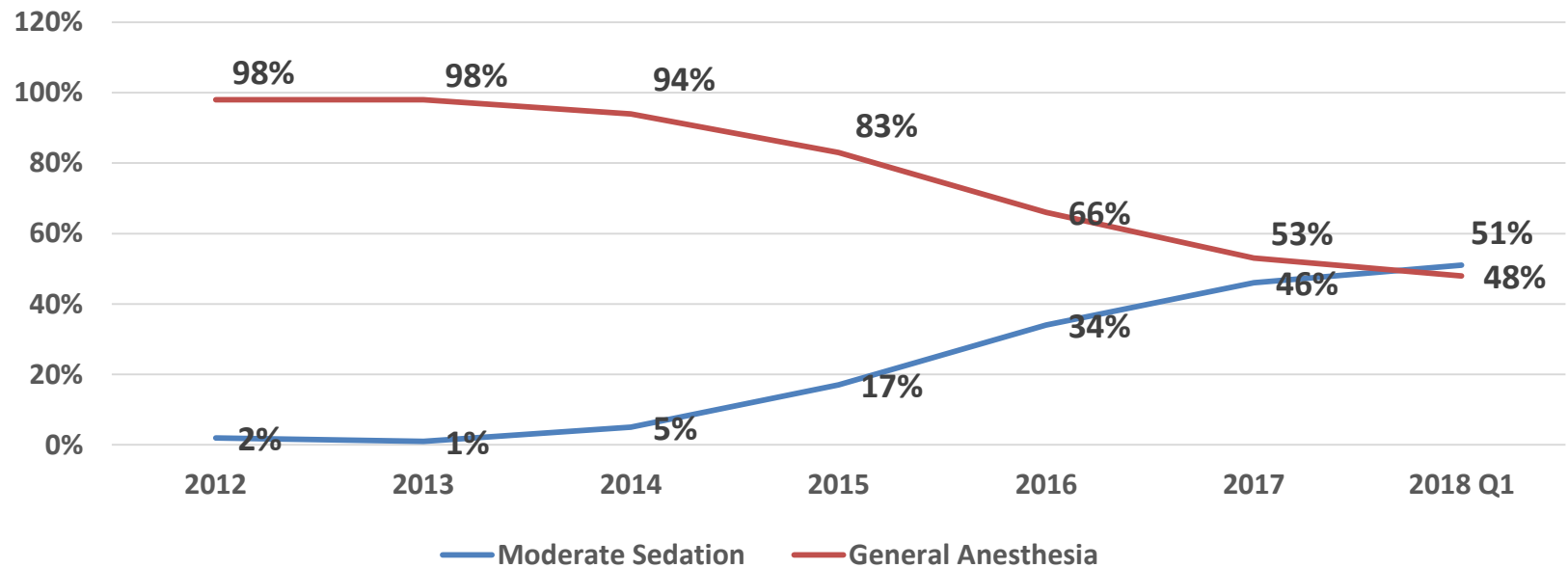
TVT Registry

TAVR and TAVR ViV Procedures

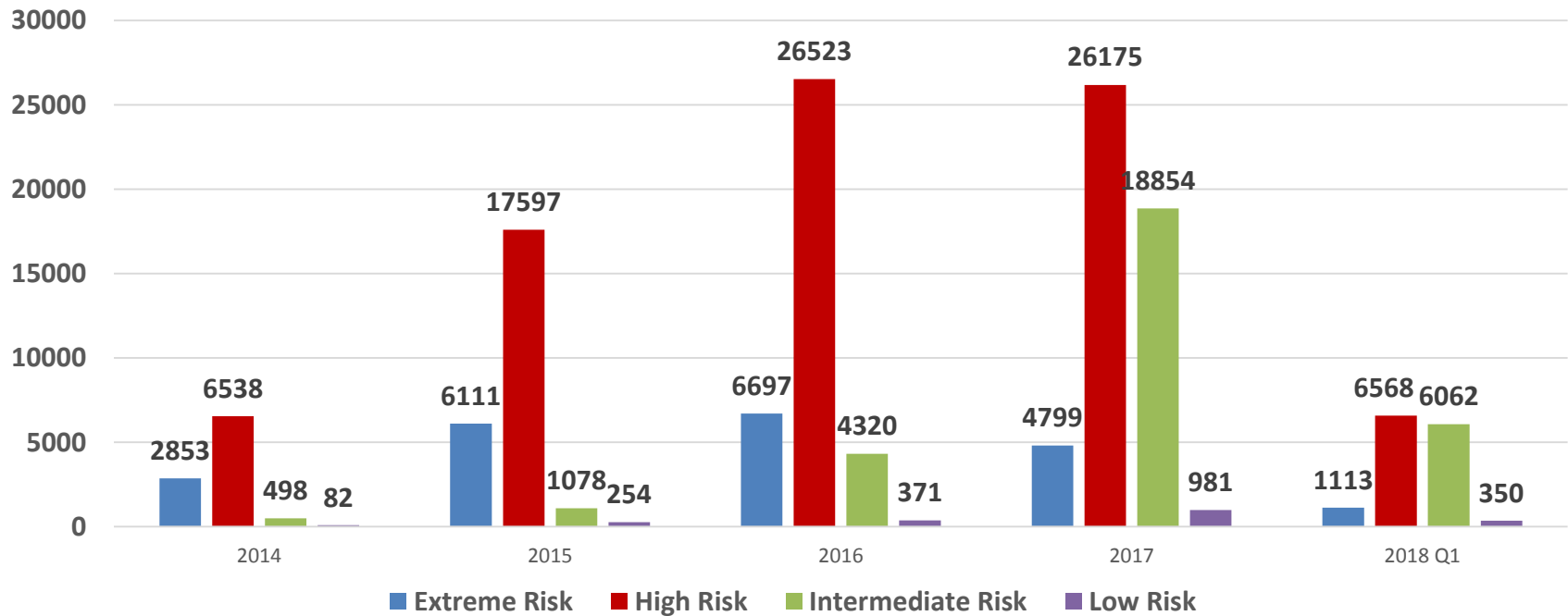


TVT Registry Datamart Data as of 6/6/19

Type of Anesthesia

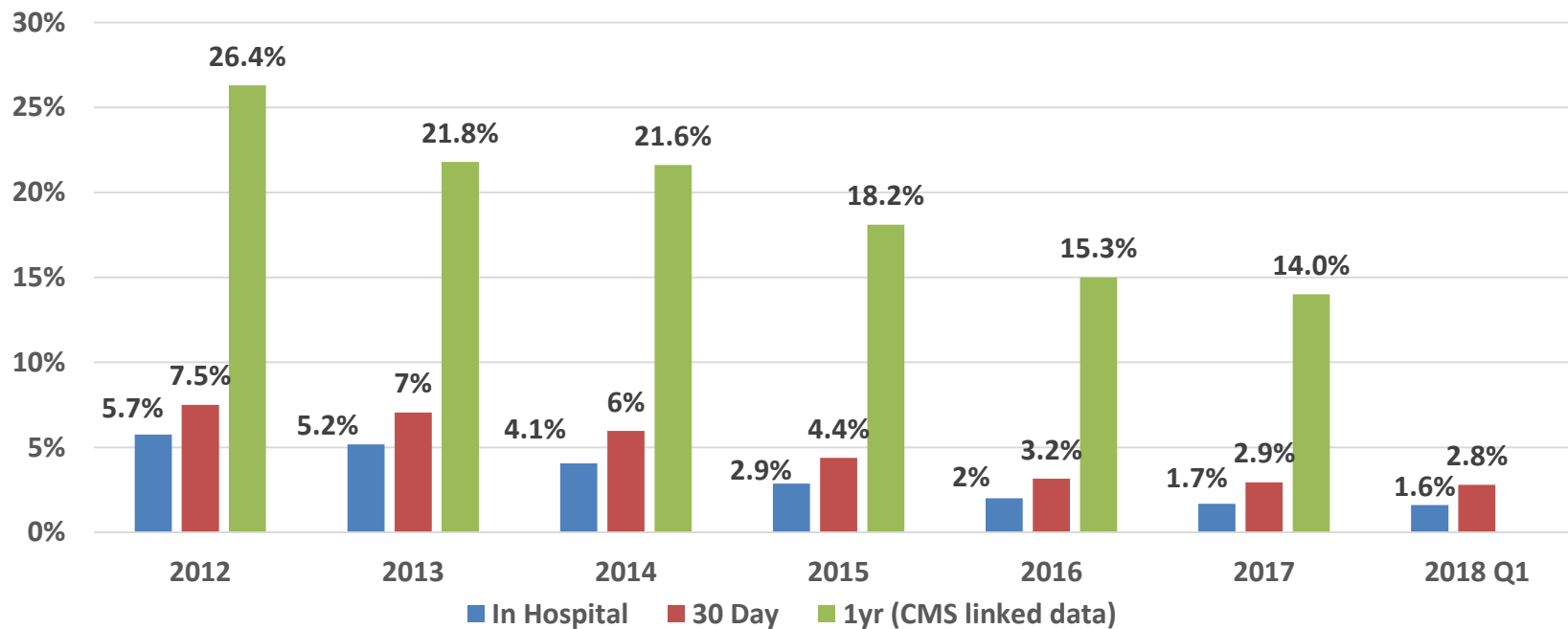


Heart Team Reason for TAVR Procedure



Mortality After TAVR

In-Hospital, 30 Day, and One Year Mortality



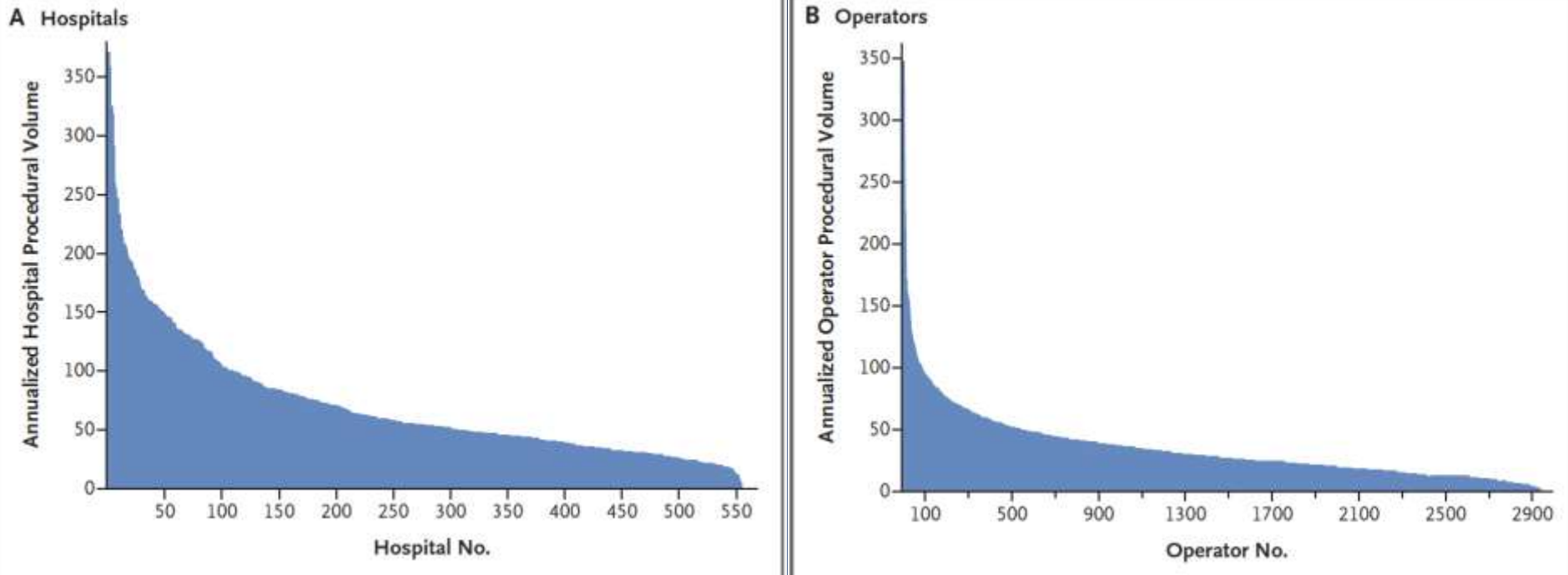
SPECIAL ARTICLE

HOSPITAL AND OPERATOR PROCEDURAL VOLUMES

Between January 1, 2015, and December 31, 2017, a total of 113,662 TAVR procedures with commercially approved devices were performed at 555 hospitals by 2960 operators (Fig. S1 in the Supplementary Appendix). The main analysis population included 96,256 transfemoral TAVR procedures performed at 554 sites by 2935 operators.

Figure 1. Annualized Hospital and Operator Volume of Transfemoral Transcatheter Aortic-Valve Replacement (TAVR) Procedures.

Shown are histogram distributions for 96,256 transfemoral TAVR procedures performed at 554 hospitals (Panel A) by 2935 operators (Panel B).

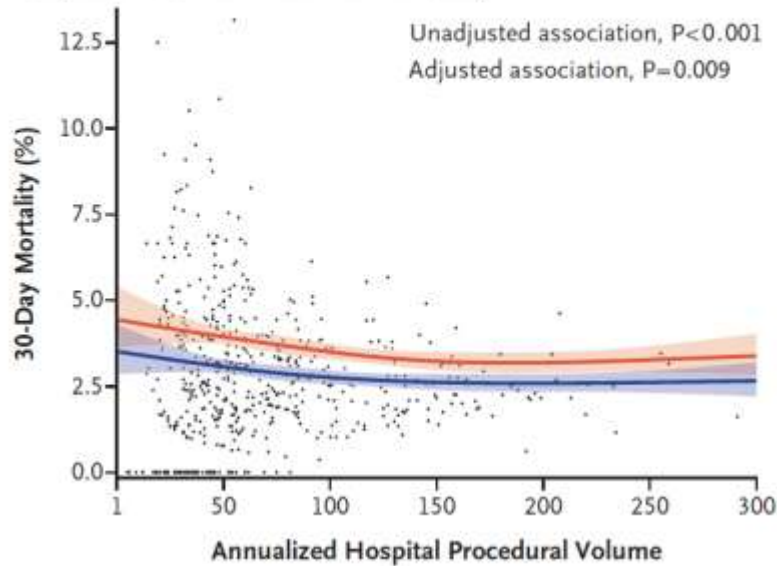


- The **median annualized** hospital procedural volume (**per-center**) was **54** (IQR, 36 to 86) and operator procedural volume (**per-operator**) was **27** (IQR, 17 to 43).

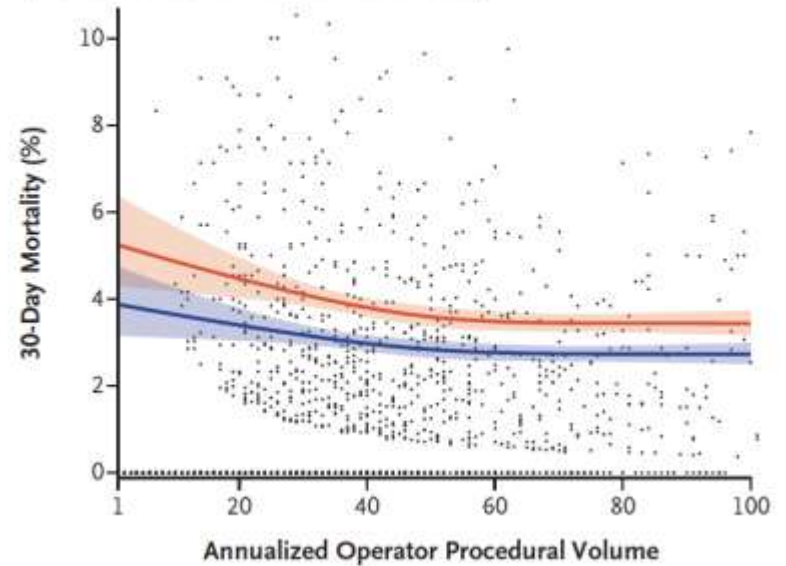
7 hospitals performed at least **250 cases** per year.

— Unadjusted — Adjusted

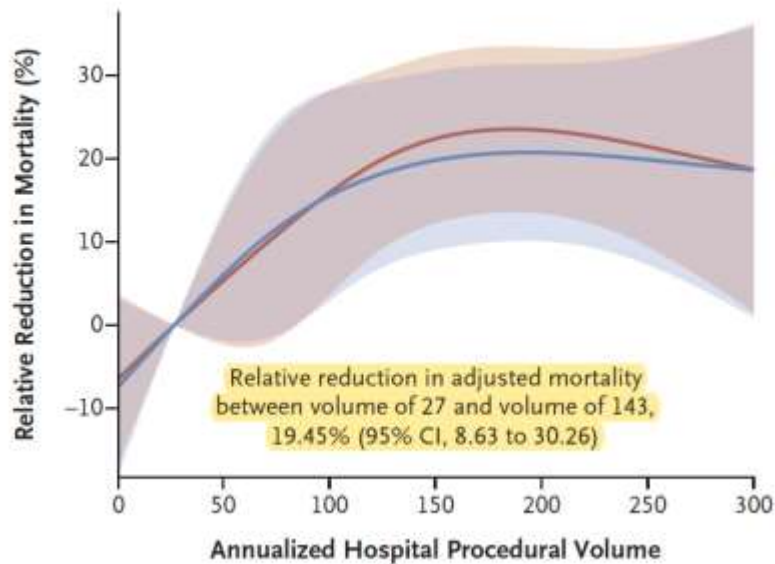
A Hospital Procedural Volume and Mortality



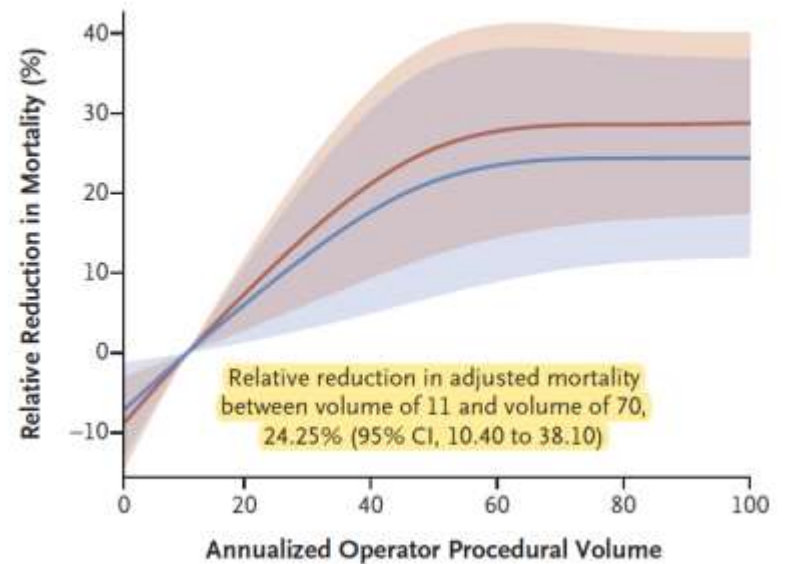
B Operator Procedural Volume and Mortality



C Mortality with Respect to Hospital Procedural Volume



D Mortality with Respect to Operator Procedural Volume



What Is Next?

International Registry : Racial Disparity

Racial Disparities in the Utilization and Outcomes of Structural Heart Disease Interventions in the United States

Mohamad Alkhouli, MD; Fahad Alqahtani, MD; David R. Holmes, MD; Chalak Berzingi, MD

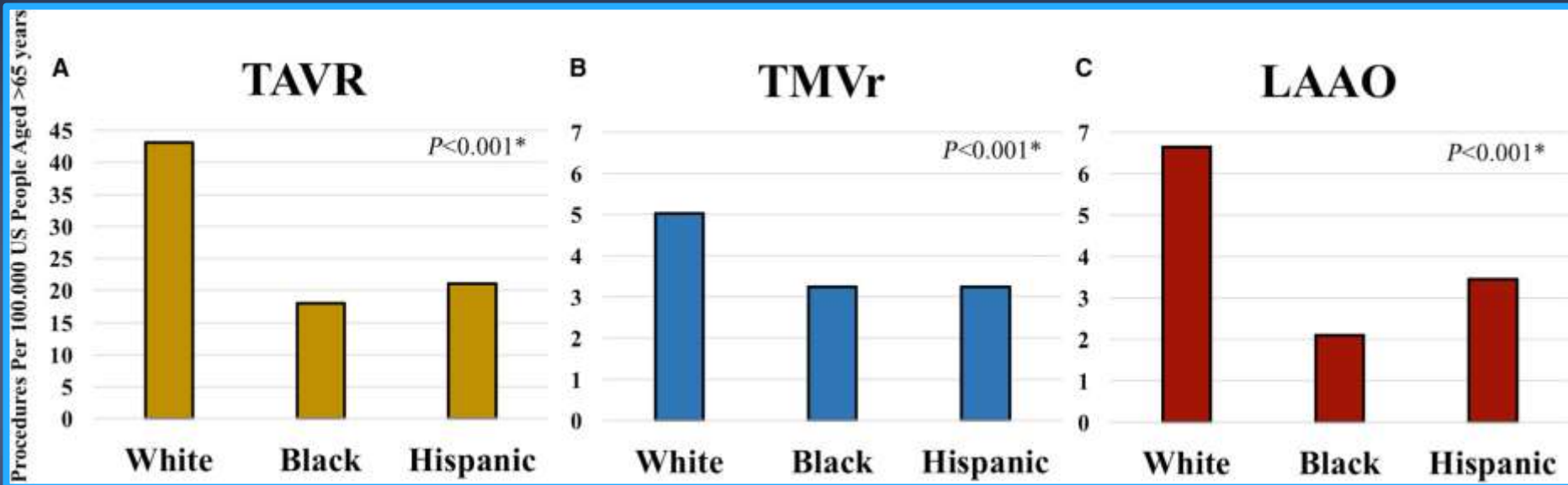
Background—Data on race- and ethnicity-based disparities in the utilization and outcomes of structural heart disease interventions in the United States are scarce.

Methods and Results—We used the National Inpatient Sample (2011-2016) to examine racial and ethnic differences in the utilization, in-hospital outcomes, and cost of structural heart disease interventions among patients ≥ 65 years of age. A total of 106 119 weighted hospitalizations for transcatheter aortic valve replacement, transcatheter mitral valve repair, and left atrial appendage occlusion were included. The utilization rates (defined as the number of procedures performed per 100 000 US people >65 years of age) were higher in whites compared with blacks and Hispanics for transcatheter aortic valve replacement (43.1 versus 18.0 versus 21.1), transcatheter mitral valve repair (5.0 versus 3.2 versus 3.2), and left atrial appendage occlusion (6.6 versus 2.1 versus 3.5), respectively ($P < 0.001$). Black and Hispanic patients had distinctive socioeconomic and clinical risk profiles compared with white patients. There were no significant differences in the adjusted in-hospital mortality or key complications between patients of white race, black race, and Hispanic ethnicity following transcatheter aortic valve replacement, transcatheter mitral valve repair, or left atrial appendage occlusion. No difference in cost was observed between white and black patients following any of the 3 procedures. However, Hispanic patients incurred modestly higher cost with transcatheter mitral valve repair and left atrial appendage occlusion compared with white patients.

Conclusions—Racial and ethnic disparities exist in the utilization of structural heart disease interventions in the United States. Nonetheless, adjusted in-hospital outcomes were comparable among white, black, and Hispanic patients. Further studies are needed to understand the reasons for these utilization disparities. (*J Am Heart Assoc.* 2019;8:e012125. DOI: 10.1161/JAHA.119.012125.)

Key Words: aortic stenosis • atrial fibrillation • left atrial appendage • mitral valve regurgitation • transcatheter aortic valve implantation

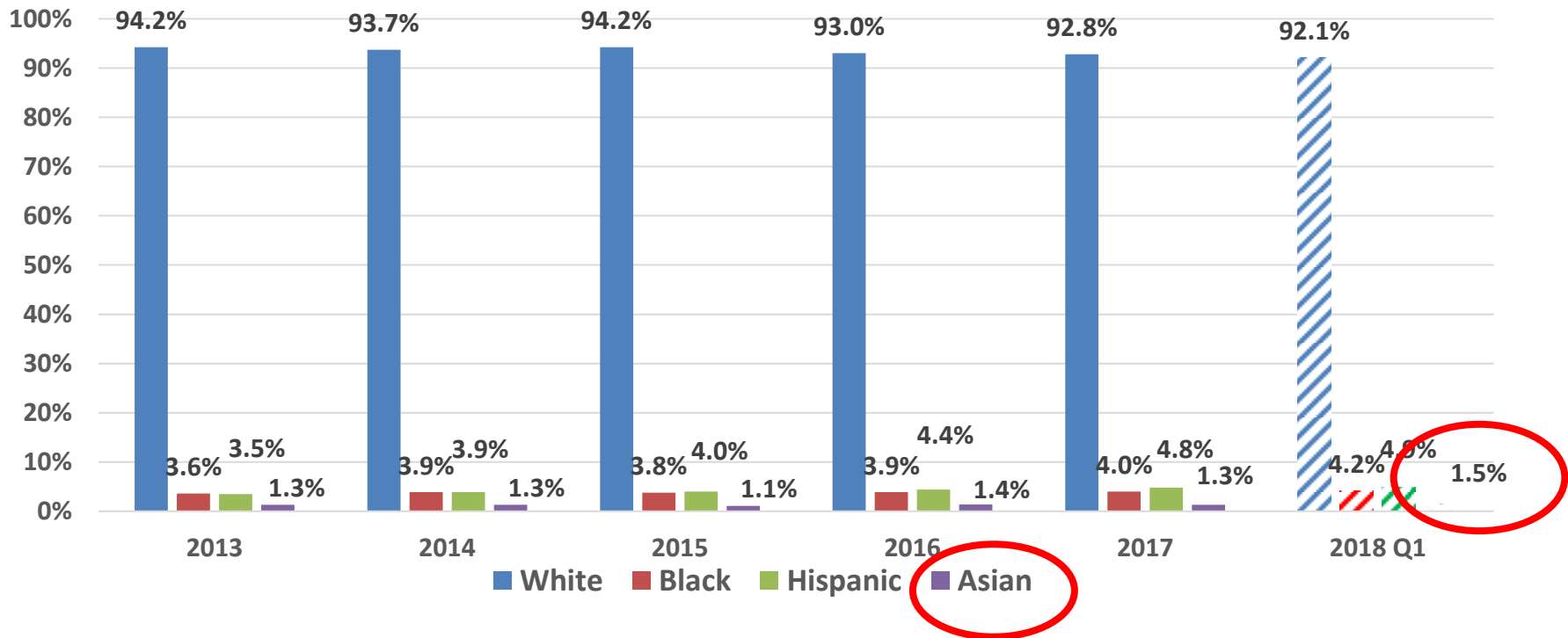
Racial and Ethnic Differences in the Utilization of Structural Heart Interventions



Racial and Ethnic Differences in In-Hospital Outcomes After TAVR

| In-Hospital Outcomes | Race/Ethnicity | Unadjusted Rate | Adjusted Rate | OR | 95% CI | P Value | Bonferroni Adjusted P Value |
|------------------------|----------------|-----------------|---------------|------|--------------|---------|-----------------------------|
| Death | White | 2.8% | Reference | | | | |
| | Black | 2.1% | 2.20% | 0.79 | 0.63 to 0.99 | 0.04 | 0.11 |
| | Hispanic | 3.3% | 2.38% | 1.12 | 0.91 to 1.38 | 0.28 | 0.84 |
| Stroke | White | 2.3% | Reference | | | | |
| | Black | 2.6% | 2.31% | 1.01 | 0.79 to 1.28 | 0.21 | 0.99 |
| | Hispanic | 2.3% | 2.19% | 0.95 | 0.67 to 1.09 | 0.96 | 0.62 |
| Pacemaker | White | 12.6% | Reference | | | | |
| | Black | 13.0% | 13.40% | 1.06 | 0.96 to 1.17 | 0.25 | 0.74 |
| | Hispanic | 15.4% | 16.21% | 1.29 | 1.17 to 1.41 | <0.001 | <0.001 |
| New dialysis | White | 1.1% | Reference | | | | |
| | Black | 1.6% | 1.20% | 1.11 | 0.87 to 1.42 | 0.40 | 0.90 |
| | Hispanic | 1.8% | 1.24% | 1.13 | 0.89 to 1.44 | 0.32 | 0.95 |
| Vascular complications | White | 7.0% | Reference | | | | |
| | Black | 6.6% | 6.40% | 0.92 | 0.81 to 1.05 | 0.22 | 0.67 |
| | Hispanic | 9.5% | 10.21% | 1.46 | 1.30 to 1.63 | <0.001 | <0.001 |
| Nonhome discharge | White | 25.3% | Reference | | | | |
| | Black | 25.4% | 24.50% | 1.00 | 0.93 to 1.09 | 0.95 | 0.99 |
| | Hispanic | 21.8% | 21.50% | 0.85 | 0.78 to 0.92 | <0.001 | <0.001 |

TAVR Demographics



Evaluation of Clinical Outcomes of Transcatheter Aortic Valve Replacement in the TransPacific Population

The TP TAVR Registry

(The TransPacific Transcatheter Aortic Valve Replacement Registry)

A MULTINATION, MULTICENTER PROSPECTIVE STUDY

Sponsor-Investigator :

Seung-Jung Park, MD, PhD, South Korea

Principal Investigator :

Alan Ching Yuen Yeung, MD, US

James D. Flaherty, MD, US

Investigator Initiated Study

TP-TAVR Registry

Rationale and Opportunities

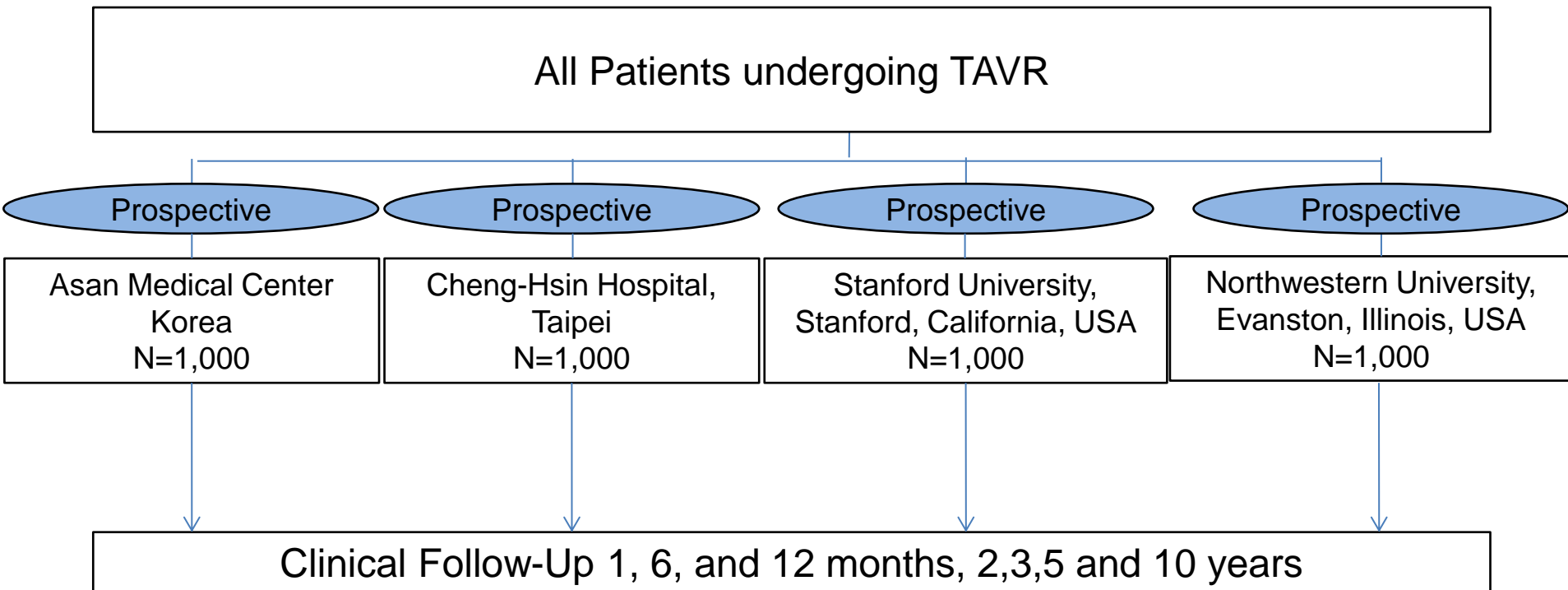
- Less than <1% of TAVR in US in Asians
- TAVR late-comer in many Asian countries.
- Smaller annulus, valve size, and small access in Asians and its long-term outcomes.
- Frequent bicuspid valve in Asians.
- High prevalence of female gender in the older age groups in the Asian population.
- Culture of global learning will allow bi-directional education and optimal patient-care.

How?

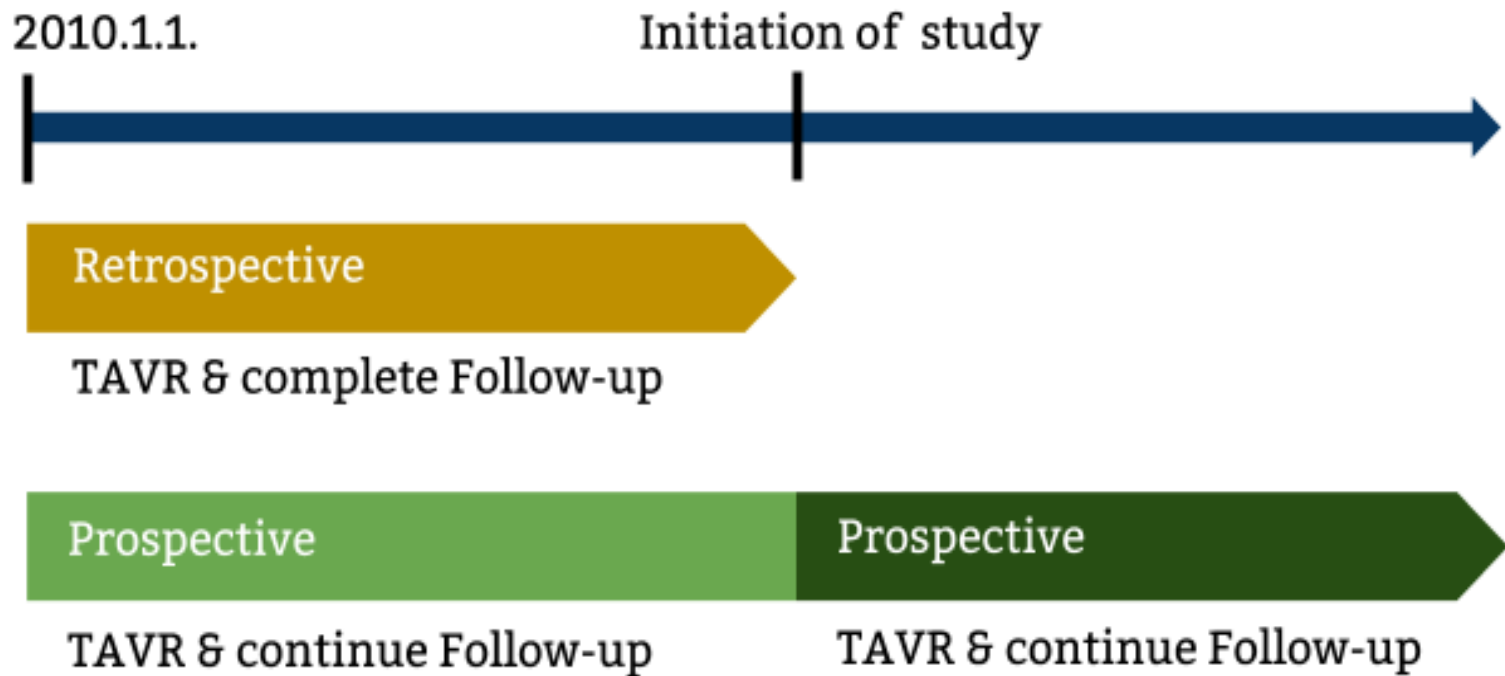
4 Major Centers

1. Stanford University, California, USA
2. Northwestern University, Illinois, USA
3. Asan Medical Center, Seoul, Korea
4. Cheng-Hsin General Hospital, Taipei

TransPacific TAVR (TP-TAVR) Registry



TransPacific TAVR (TP-TAVR) Registry



TP-TAVR Registry

[Home](#) > [Search Results](#) > Study Record Detail

Transpacific TAVR Registry (TP-TAVR)



The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT03826264

Recruitment Status ⓘ : Recruiting

First Posted ⓘ : February 1, 2019

Last Update Posted ⓘ : June 25, 2019

See [Contacts and Locations](#)

Sponsor:

Seung-Jung Park

Collaborator:

CardioVascular Research Foundation, Korea

Information provided by (Responsible Party):

Seung-Jung Park, Asan Medical Center

Study Details

Tabular View

No Results Posted

Disclaimer

How to Read a Study Record

Study Description

Brief Summary:

This registry evaluates the long-term outcome of Transcatheter aortic valve replacement (TAVR) in real-world clinical practice.

E-CRF for TP-TAVR Registry



PREV AMIC Upload Overseas Upload SDV Log SDV Log EVENT ADJUDICATION QIA ADMIN REPORT LOGOUT

TP-TAVR Home New Case Subject List Query

+ TP-TAVR Home

Study Status

| No | Research Institutes | Investigator | Month | Total | Violation | Withdraw | Last Date | Query | | |
|-------|------------------------------------|-------------------|-------|-------|-----------|----------|-----------|--------|-----------|----------|
| | | | | | | | | Issued | Completed | Approved |
| 1 | 서울아산병원 | 박승경 | 0 | 0 | 0 | 0 | | 0 | 0 | 0 |
| 2 | Stanford University Medical Center | Alan C. Yeung | 0 | 0 | 0 | 0 | | 0 | 0 | 0 |
| 3 | Northwestern Memorial Hospital | James D. Flaherty | 0 | 0 | 0 | 0 | | 0 | 0 | 0 |
| Total | | | 0 | 0 | 0 | 0 | | 0 | 0 | 0 |

Notice 닫기

| No | Subject | Writer | Date of Write |
|----|---------|--------|---------------|
|----|---------|--------|---------------|

Research Questions in TP-TAVR

| Number | Title of Topics | Hypothesis of Study (Rationale and Purpose) |
|--------|--|--|
| 1 | Racial and Ethnic Disparities in Anatomy, Procedural Characteristics, and Outcomes | <ol style="list-style-type: none"> 1. East Asian population have specifics of TAVR procedure (i.e., (smaller annulus size, smaller valve implant size and more delayed adoption of TAVR) compared to Western population. 2. To determine anatomic and procedural characteristics and outcomes in Western and Eastern population. |
| 2 | International Variation in and Factors Associated Patient-Prosthesis Mismatch (PPM) | <ol style="list-style-type: none"> 1. Owing to smaller size of anatomy and implanted valve, the incidence and risk of PPM is not concerned in East Asian population. 2. To determine the incidence, risk factors, and associated outcomes of PPM in Western and Eastern population. |
| 3 | Inherent Ethnic Difference in the Incidence and Outcomes of TAVR for Bicuspid vs. Tricuspid AS | <ol style="list-style-type: none"> 1. Bicuspid AS is more common in Asian population and pivotal RCT conducted to obtain US Food and Drug Administration approval excluded bicuspid anatomy. 2. To compare the outcomes of TAVR with a balloon-expandable valve for bicuspid vs tricuspid aortic stenosis. |
| 4 | International Variation in post-TAVR antiplatelet therapy and associated outcomes. | <ol style="list-style-type: none"> 1. The optimal antiplatelet strategy is undefined, and little is known about practice patterns. 2. To describe contemporary practice patterns of antiplatelet therapy and their relationship to outcomes post-TAVR including leaflet thrombosis. |
| 5 | Contemporary Pattern and Comparative Outcomes of Balloon-Expandable vs. Self-Expandable Valves in TAVR: the Insights from International Registry | <ol style="list-style-type: none"> 1. To compare pattern of use over time and associated outcomes between balloon-expandable vs. self-expandable TAVR in the Western and East Asian Patients |

TP-TAVR Registry

- TAVR in US and Korea is a standard procedure for patients with symptomatic severe AS.
- Owing to different clinical and anatomic features, racial disparity may exist with respect to procedural and long-term clinical outcomes.
- Although large-sized national registries (i.e. TVT, Asian, etc...) exists, more dedicated clinical, anatomic, and imaging variables (CT, echo, frailty, cognitive function... etc) are still lacking.
- Well planned and designed TP-TAVR registry will provide more compelling evidence to understand the international-ethnic disparity of TAVR procedures and outcomes.