

The Future of TAVR: A Master's Perspective

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New York City

Disclosures - Martin B. Leon, MD

TCTAP 2019; Seoul, Korea; April 27-30, 2019

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

Financial Relationship

- Research Support
- Consulting Fees*
- Other

Company

Abbott, Boston Scientific,
Edwards Lifesciences, Medtronic

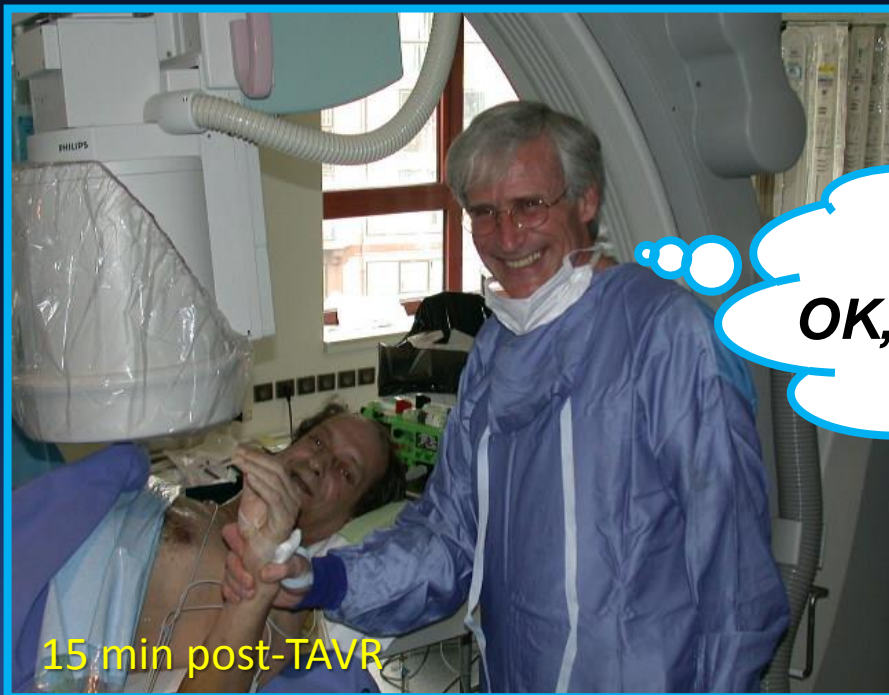
Abbott, Boston Scientific, Gore,
Medtronic, Meril Life Sciences

Edwards Lifesciences**

*Medical or scientific advisory board meetings

** Co-PI PARTNER Trials; travel-related expenses only

Dr. Alain Cribier - *First-in-Man PIONEER*



OK, What Now?

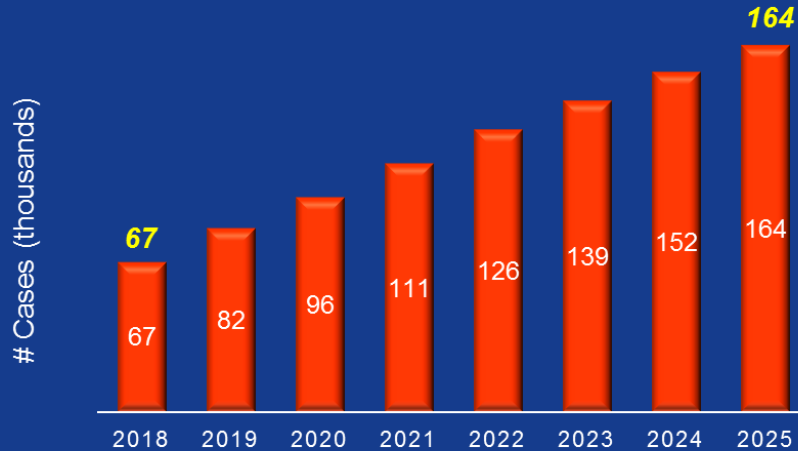
April 16, 2002

TAVR 2019

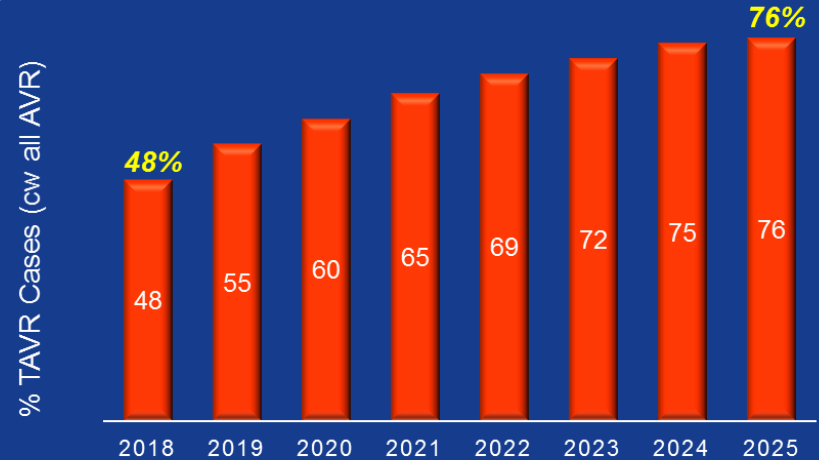
No one could have predicted...

1. Rapid TAVR technology evolution
2. TAVR procedural refinements and simplification
3. Avalanche of TAVR clinical evidence
4. Heart valve team acceptance
5. Explosive TAVR growth worldwide

Estimated US TAVR Growth



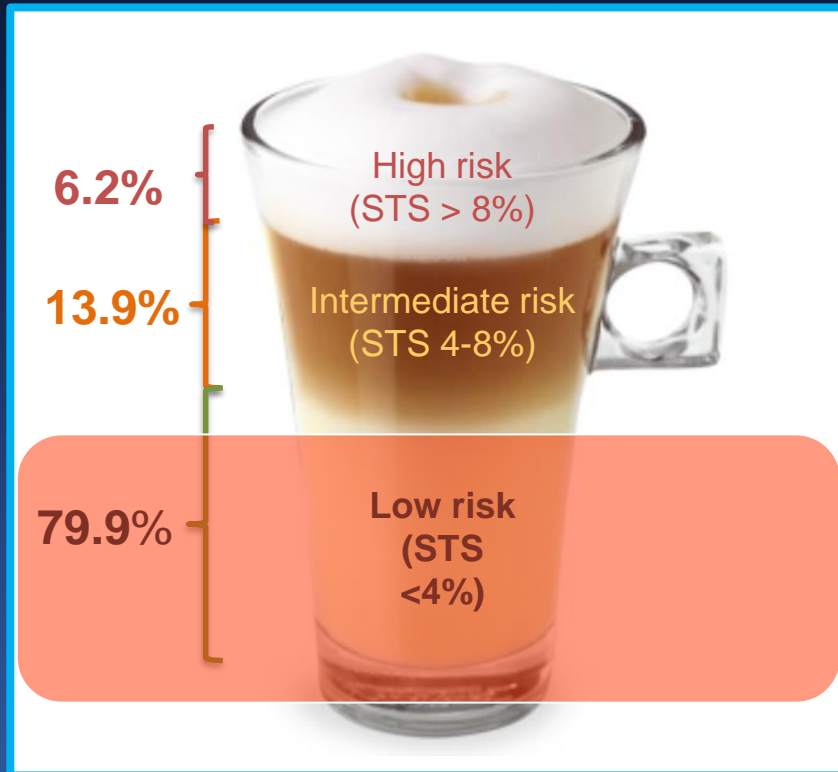
**2018 - 2025 the US TAVR Market
will Increase 2.5X!**



**In the US, by 2025, >75% of all AVR
will be TAVR!**

The Importance of Low-Risk Patients

STS Database (141,905 pts)



Contemporary Real-World Outcomes of Surgical Aortic Valve Replacement in 141,905 Low-Risk, Intermediate-Risk, and High-Risk Patients

Vinod H. Thourani, MD, Rakesh M. Suri, MD, DPhil, Rebecca L. Gunter, MD, Shubin Sheng, PhD, Sean M. O'Brien, PhD, Gorav Ailawadi, MD, Wilson Y. Szeto, MD, Todd M. Dewey, MD, Robert A. Guyton, MD, Joseph E. Bavaria, MD, Vasilis Babaliaros, MD, James S. Gammie, MD, Lars Svensson, MD, PhD, Mathew Williams, MD, Vinay Badhwar, MD, and Michael J. Mack, MD

Ann Thorac Surg 2015;99:55-61

The 'holy grail' is the 80% of aortic stenosis patients receiving surgery who are in the low-risk category!

PARTNER Trials



PARTNER 3

- RCT 1:1
- vs. Surgery
- N = 1000 pts

Low
Risk

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

OCTOBER 21, 2010

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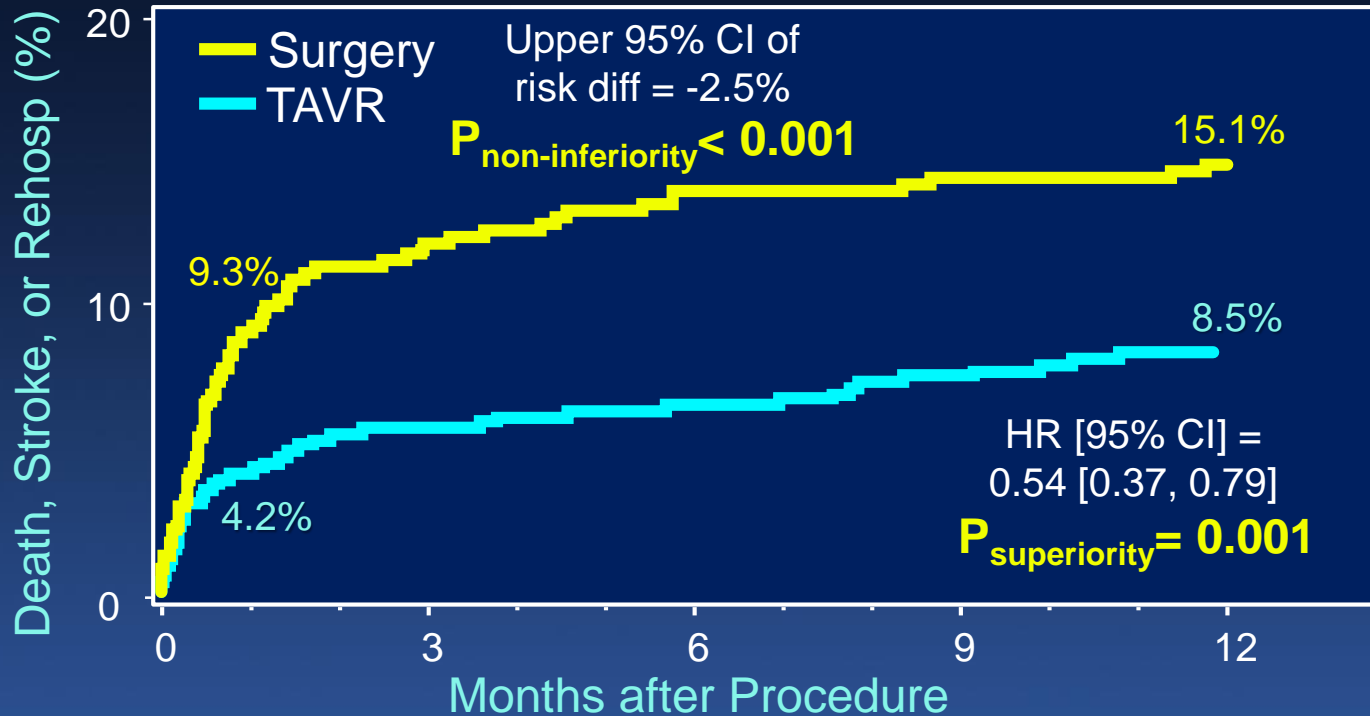
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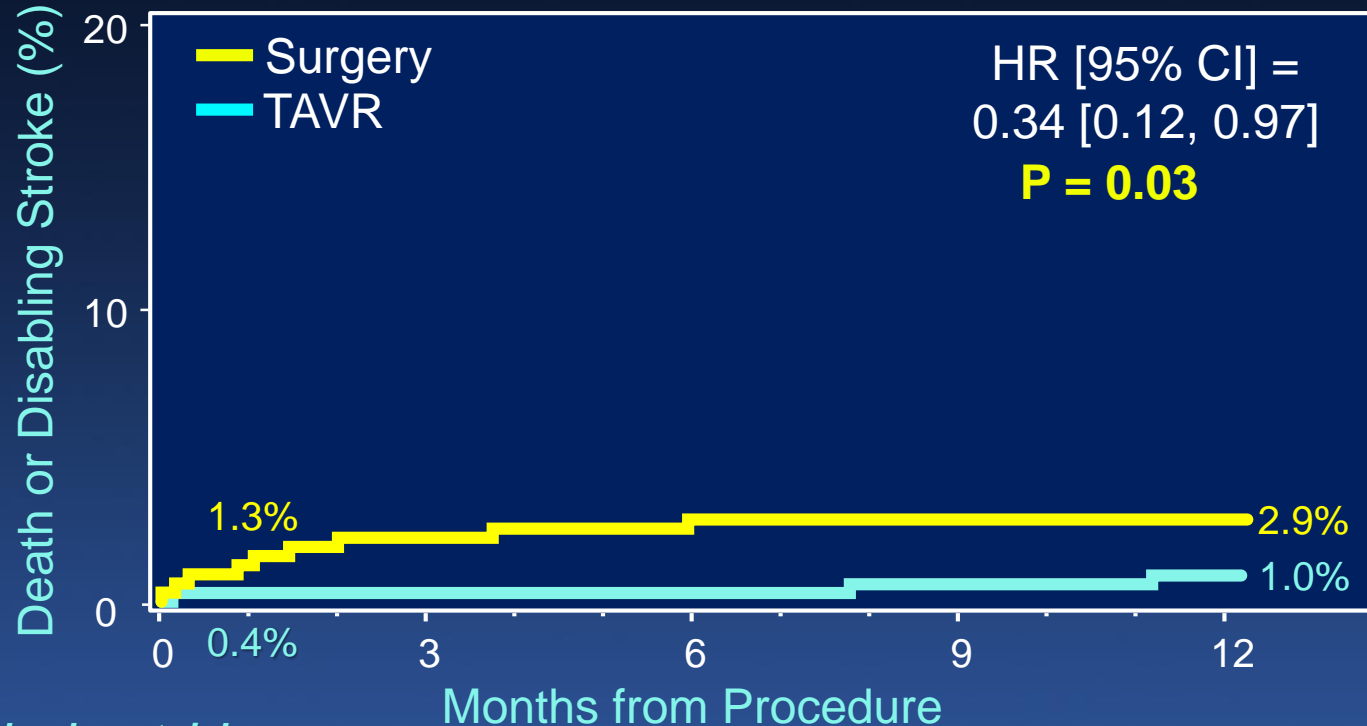
Primary Endpoint



Number at risk:

Surgery	454	408	390	381	377	374
TAVR	496	475	467	462	456	451

Death or Disabling Stroke

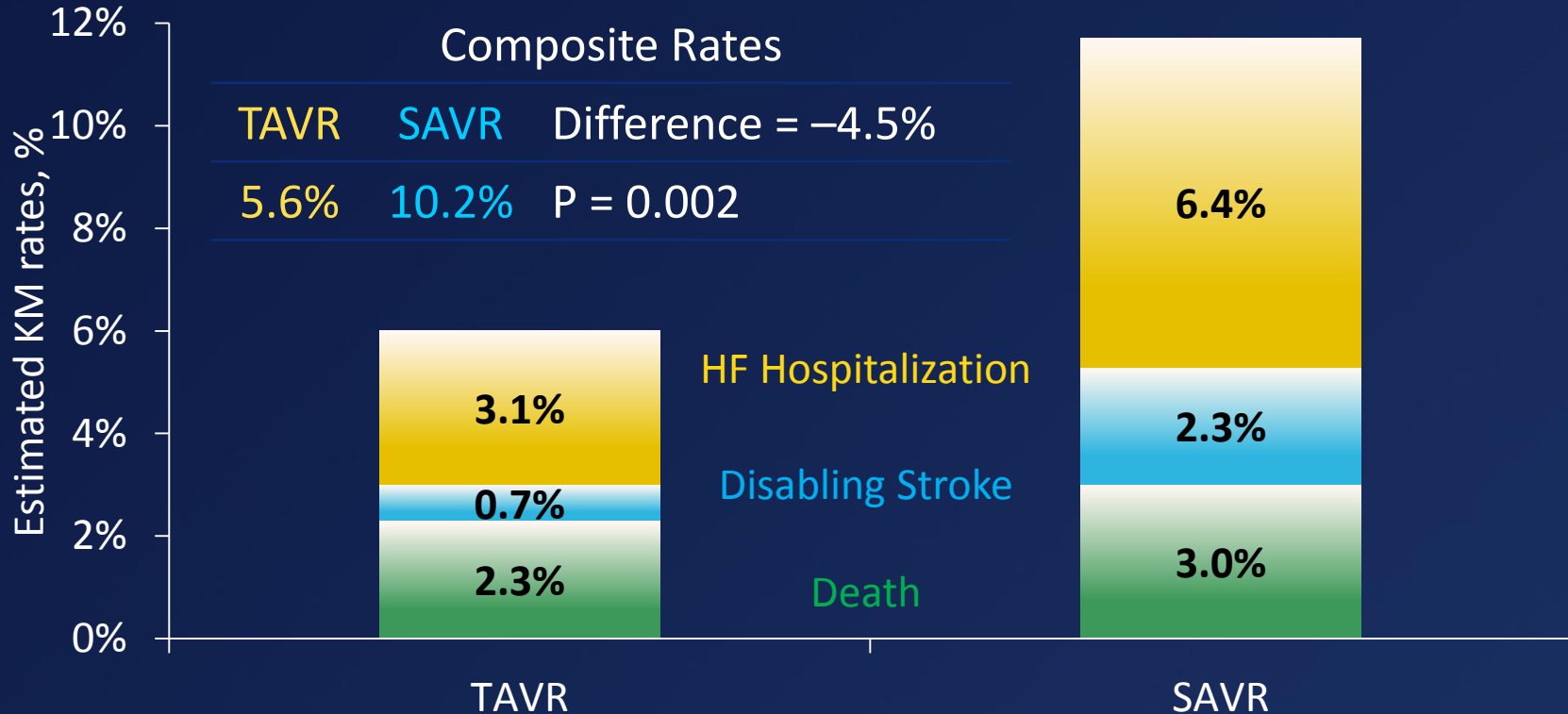


Number at risk:

Surgery	454	444	436	432	430	426
TAVR	496	494	494	493	491	488

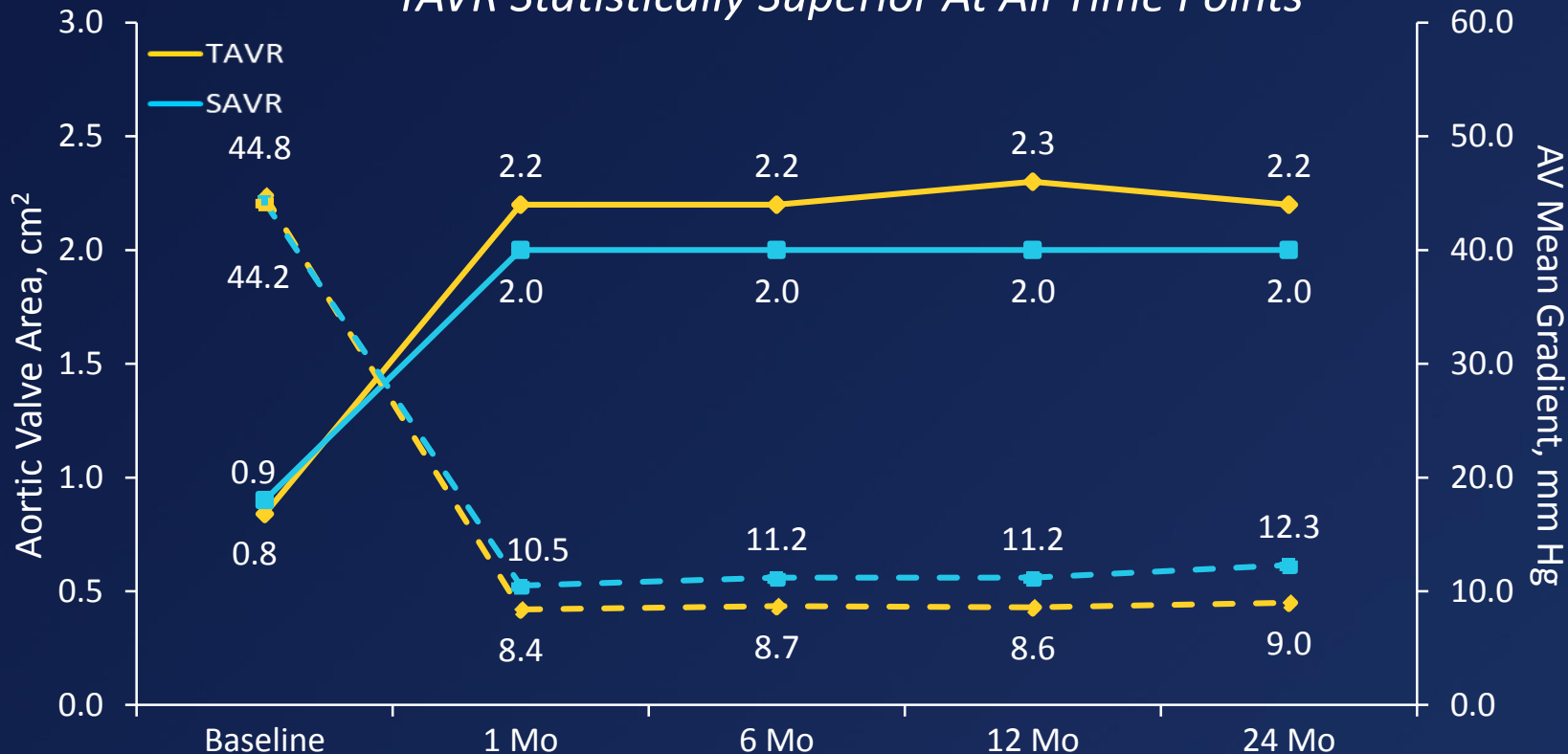
Clinical Implications

Death, Disabling Stroke and Heart Failure Hospitalizations to 1 Year



Valve Hemodynamics

TAVR Statistically Superior At All Time Points



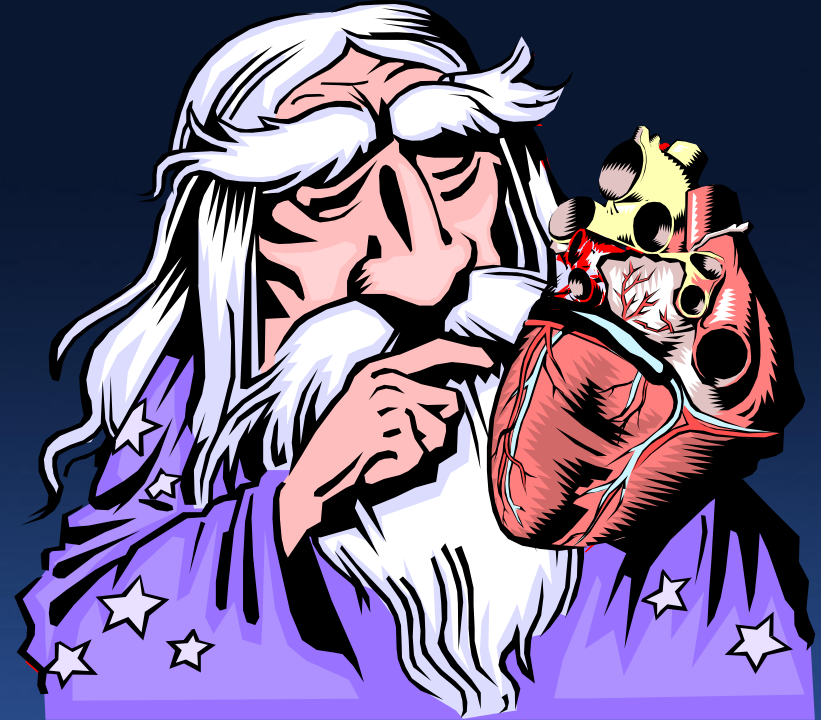
TAVR 2019



Who does well with TAVR?
Who does well with surgery?

TAVR 2019

*What the future
will bring...*



TAVR 2019 – *The Future*

- The success of TAVR therapy has catalyzed a ‘second wave’ of clinical studies to explore the expansion of clinical indications (even beyond current surgery).
 - ✓ Bicuspid AV disease
 - ✓ AS + concomitant disease (CAD, MR, AF)
 - ✓ Severe asymptomatic AS
 - ✓ Moderate AS + CHF
 - ✓ High-risk severe AR

The EARLY TAVR Trial

Asymptomatic Severe AS and 2D-TTE (PV $\geq 4\text{m/s}$ or AVA $\leq 1\text{ cm}^2$)
Exclusion if patient is symptomatic, age < 65 yo, EF $< 50\%$, concomitant surgical indications, or STS > 8

Treadmill Stress-Test

Stress-Test Normal

CTA and Angiography
TF- TAVR eligibility

Early-TAVR Randomized Trial

Randomization 1:1
Stratified by STS (< 3 vs ≥ 3)

TF-TAVR

Clinical
Surveillance

Stress-Test Abnormal

Early TAVR Registry

1109 pts, 75 US sites

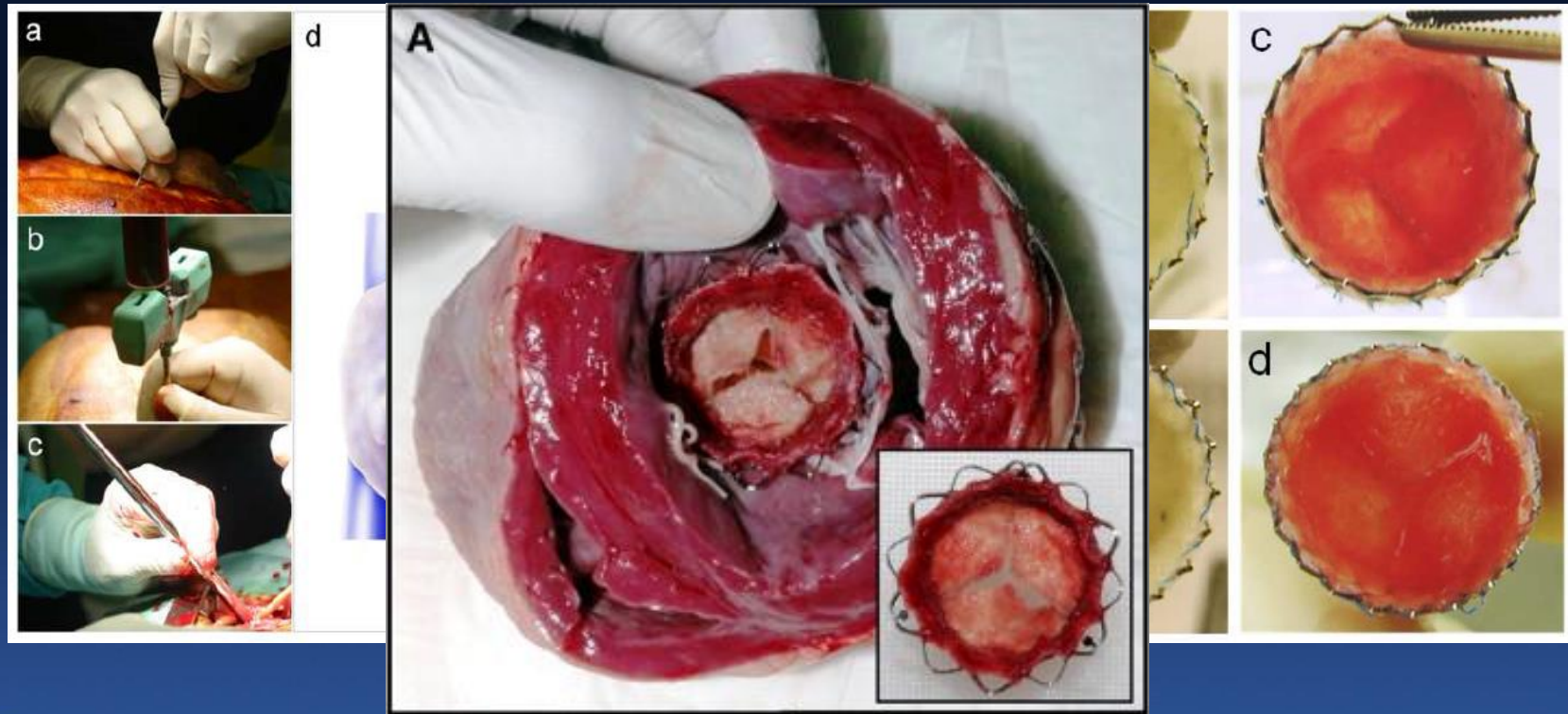
Primary Endpoint (superiority): 2-year composite of all-cause mortality, all strokes, and repeat hospitalizations (CV)

Principal Investigators:
Philippe Généreux, Allan Schwartz
Chair: Martin B. Leon

TAVR 2019 – *The Future*

- The success of TAVR therapy has catalyzed a ‘second wave’ of clinical studies to explore the expansion of clinical indications (even beyond current surgery).
- There are many innovative TAVR-related technologies which are being actively explored!

Zurich Tissue Engineered Heart Valve

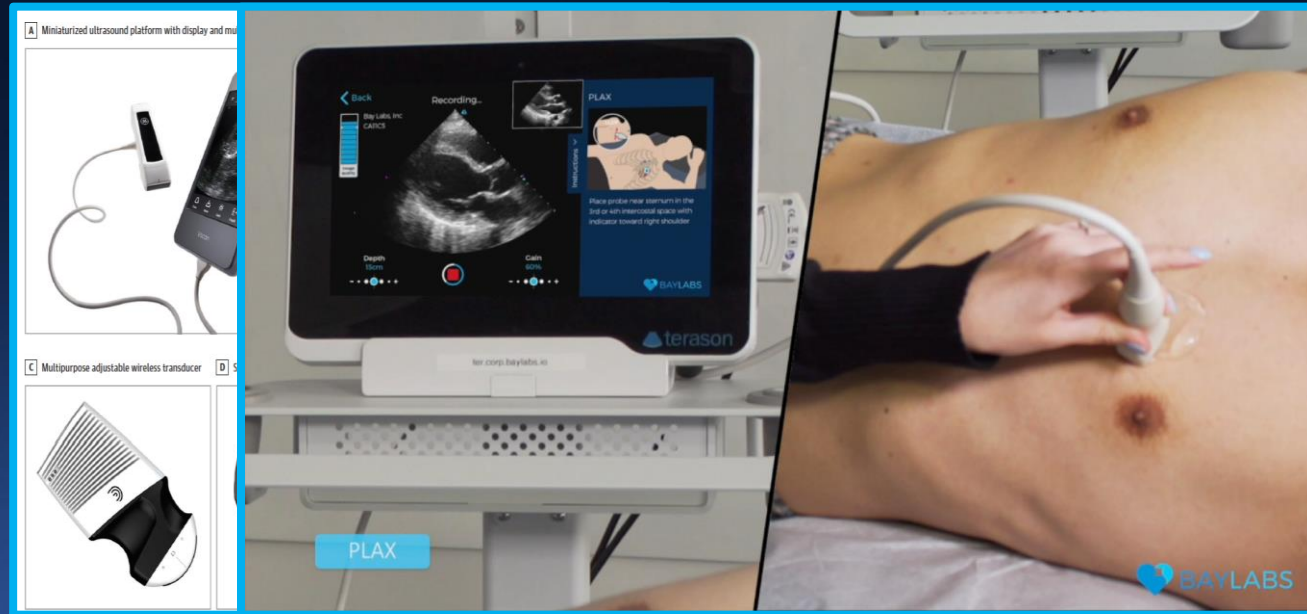


Novel AS Imaging Technology

Bay Labs – Echo acquisition

Available hand-held POCUS devices

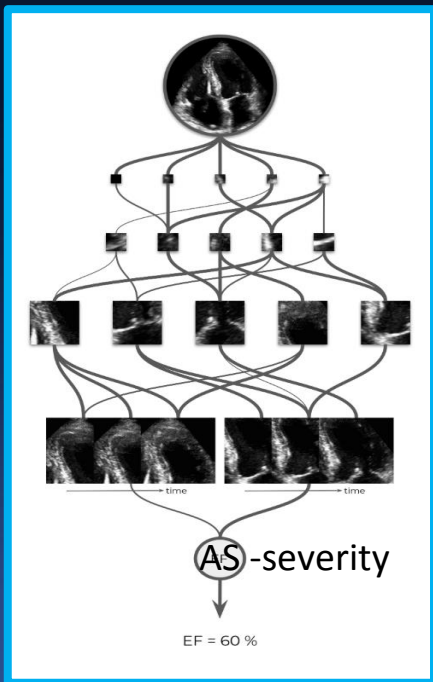
Prompts for BL echo acquisition



JAMA Cardiology 2018

Novel AS Imaging Technology

Bay Labs – Echo interpretation (AI/DL)



Training: > 25,000 complete AS echo studies

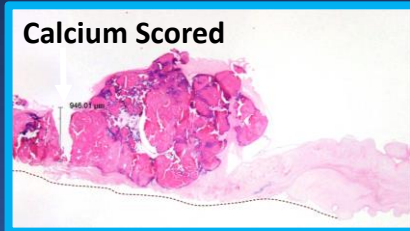
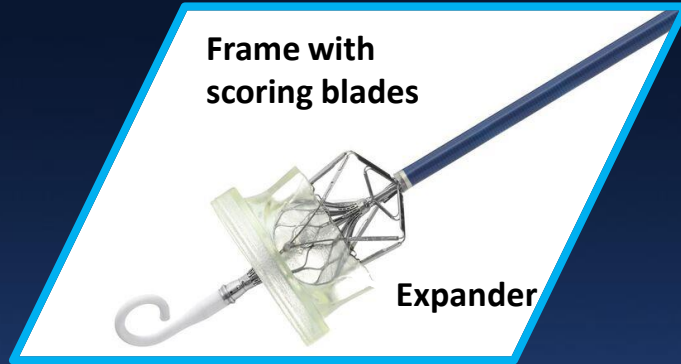
Input: PLAX and PSAX shown to the pre-trained network

Output: network integrates responses and makes diagnosis of valvular heart disease, rheumatic vs. non-rheumatic, and estimates the severity of AS (when present)

TAVR Accessory Devices

Aortic Valve Remodeling

Leaflex AVRT



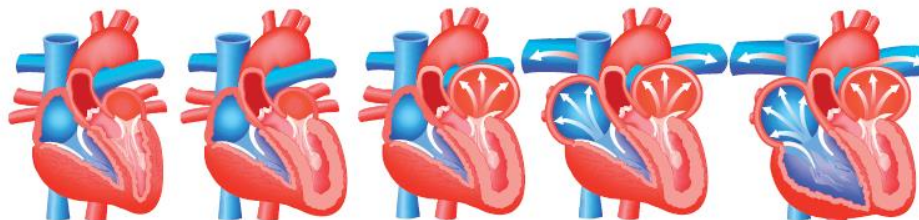
- Mechanical scoring blades fracture leaflet calcium and improve leaflet mobility
- 13 Fr catheter
- Non-occlusive (no PM)
- Can be used as (1) stand-alone, (2) bridge to TAVR/SAVR or (3) preparation for TAVR (heavily calcified valves)

TAVR 2019 – *The Future*

- The success of TAVR therapy has catalyzed a ‘second wave’ of clinical studies to explore the expansion of clinical indications (even beyond current surgery).
- There are many innovative TAVR-related technologies which are being actively explored!
- In the future, AS classification schemes and therapy trigger points will be redefined.

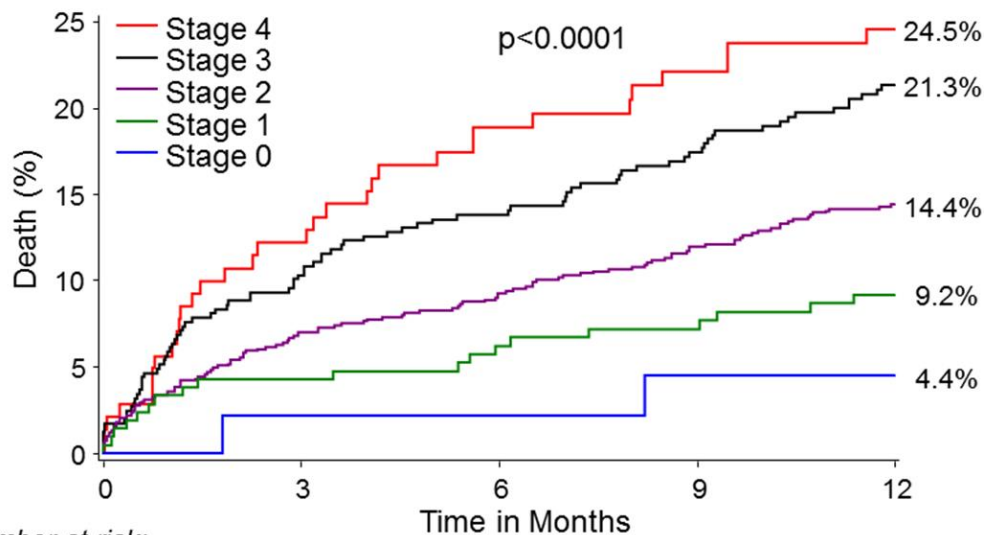
Staging classification of aortic stenosis based on the extent of cardiac damage

Philippe G n reux^{1,2,3}, Philippe Pibarot⁴, Bj rn Redfors^{1,5}, Michael J. Mack⁶, Raj R. Makkar⁷, Wael A. Jaber⁸, Lars G. Svensson⁸, Samir Kapadia⁸, E. Murat Tuzcu⁸, Vinod H. Thourani⁹, Vasilis Babaliaros⁹, Howard C. Herrmann¹⁰, Wilson Y. Szeto¹⁰, David J. Cohen¹¹, Brian R. Lindman¹², Thomas McAndrew¹, Maria C. Alu¹³, Pamela S. Douglas¹⁴, Rebecca T. Hahn^{1,13}, Susheel K. Kodali^{1,13}, Craig R. Smith¹³, D. Craig Miller¹⁵, John G. Webb¹⁶, and Martin B. Leon^{1,13*}



	Stage 0	Stage 1	Stage 2	Stage 3	Stage 4
Stages/Criteria	No Cardiac Damage	LV Damage	LA or Mitral Damage	Pulmonary Vasculature or Tricuspid Damage	RV Damage
Echocardiogram		Increased LV Mass Index >115 g/m ² (Male) >95 g/m ² (Female)	Indexed left atrial volume >34mL/m ²	Systolic Pulmonary hypertension ≥60 mmhg	Moderate-Severe right ventricular dysfunction
		E/e' >14	Moderate-Severe mitral regurgitation	Moderate-Severe tricuspid regurgitation	
		LV Ejection Fraction <50%	Atrial Fibrillation		

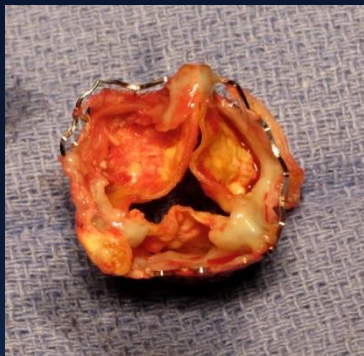
Staging classification of aortic stenosis based on the extent of cardiac damage



TAVR 2019 – *The Future*

- There are also many ‘gaps’ in TAVR knowledge which must be addressed (e.g. valve leaflet abnormalities, late TAVR SVD/durability, coronary access considerations, and optimal adjunctive pharmacotherapy).

Durability Concerns



Coronary Angiography and Percutaneous Coronary Intervention After Transcatheter Aortic Valve Replacement

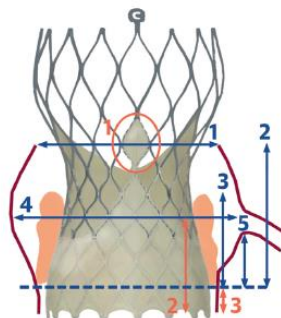


Matias B. Yudi, MBBS,^a Samin K. Sharma, MD,^a Gilbert H.L. Tang, MD, MSc, MBA,^b Annapoorna Kini, MD^a

CENTRAL ILLUSTRATION Coronary Reaccess After TAVR

Factors Impacting Coronary Access

Imaging Evaluation



Anatomical

1. Sinotubular junction dimensions
2. Sinus height
3. Leaflet length and bulkiness
4. Sinus of Valsalva width
5. Coronary height

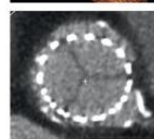
Device and Procedural

1. Commissural tab orientation
2. Sealing skirt height
3. Valve implant depth

Fluoroscopy



MDCT



Yudi, M.B. et al. J Am Coll Cardiol. 2018;71(12):1360-78.

TAVR 2019 – *The Future*

- There are also many ‘gaps’ in TAVR knowledge which must be addressed (e.g. valve leaflet abnormalities, late TAVR SVD/durability, coronary access considerations, and optimal adjunctive pharmacotherapy).
- By all meaningful criteria, TAVR has been a **BREAKTHROUGH** Technology in the management of patients with aortic stenosis!

The PARTNER 3 Trial



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What Do Henry Kissinger and Mick Jagger Have in Common?



They are Both Proud NYC TAVR Patients!!!

