

# **TAVR – Moving to Lower Risk: STS or Age Per Se?**

Duk-Woo Park, MD, PhD

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

# Conflict of Interest Statement

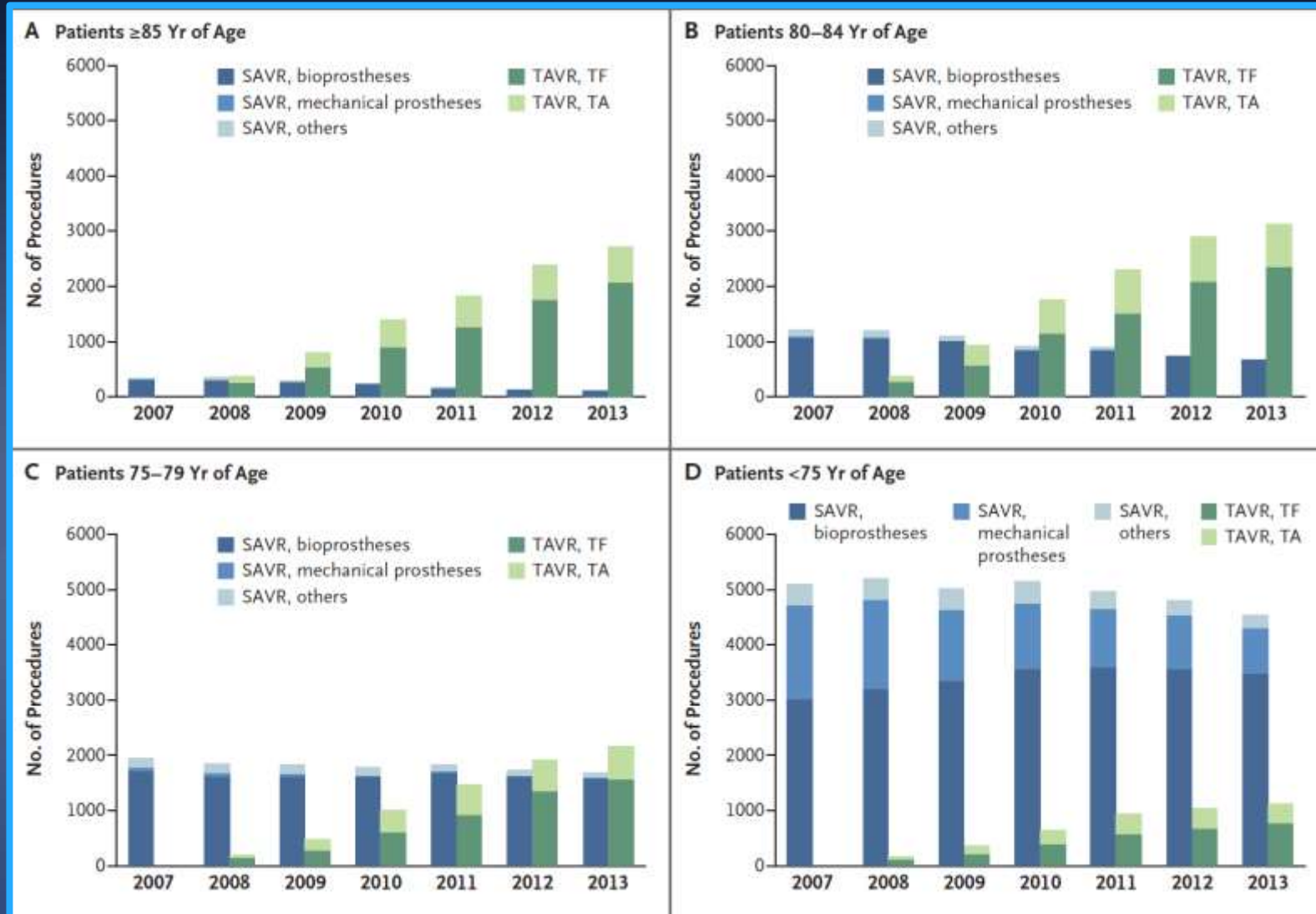
- I received lecture fees from
  - Edwards Lifesciences
  - Medtronic, and
  - Boston Scientific

# RCT of TAVR:

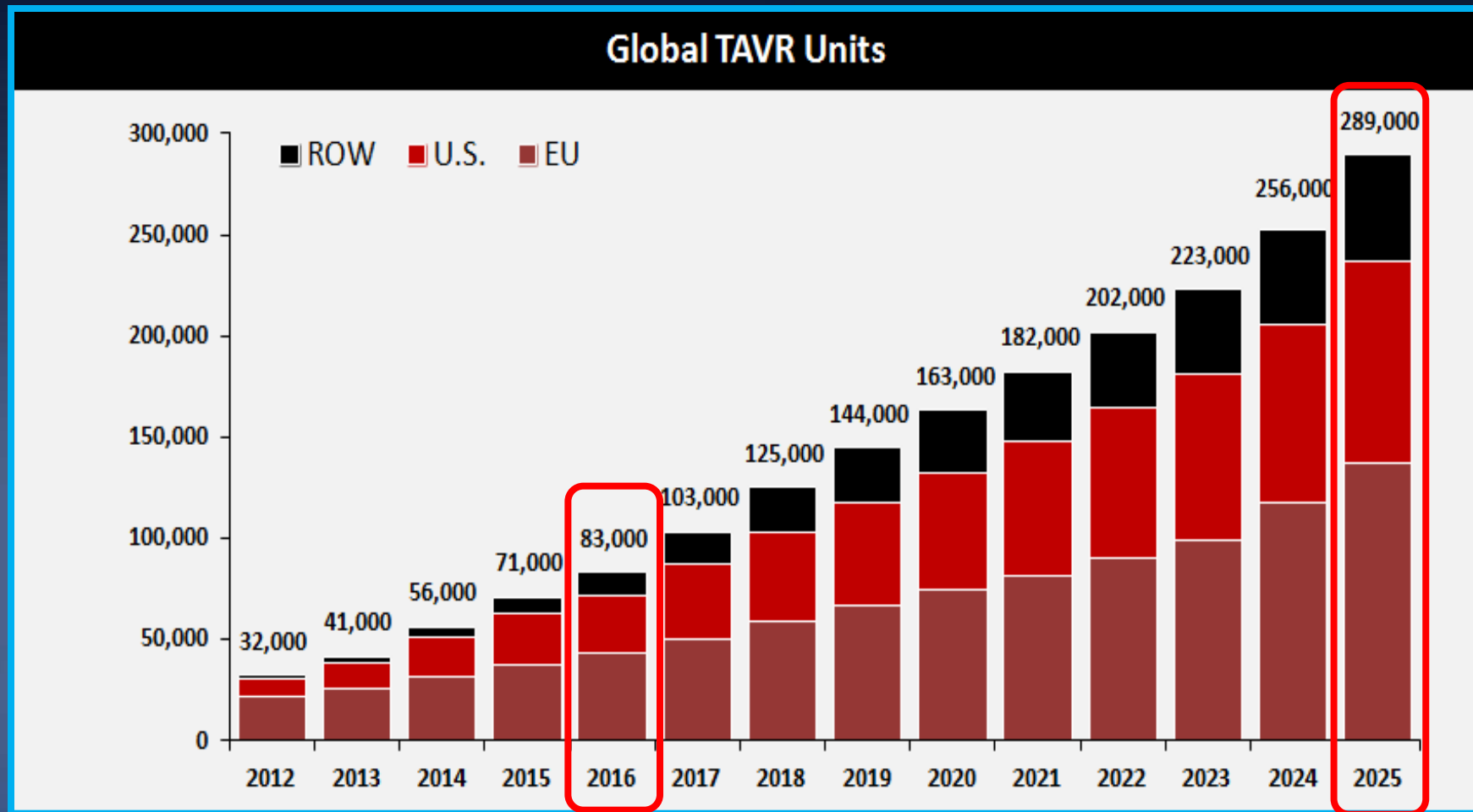
## Chain From High to Low-Risk

Trial Name	STS Score	Age
<b>Inoperable Population</b>		
PARTNER IB Trial	11.6	83
<b>High Risk Population</b>		
PARTNER IA Trial	11.8	84
CoreValve US Pivotal Trial	7.4	83
<b>Intermediate Risk Population</b>		
PARTNER IIA Trial	5.8	82
SURTAVI	4.4	80
<b>Low Risk Population</b>		
NOTION Trial	3.0	79

# TAVR: “Rapid Applicability in Real World” in Germany from 2007 to 2013



# Estimated Global TAVI Procedure Growth

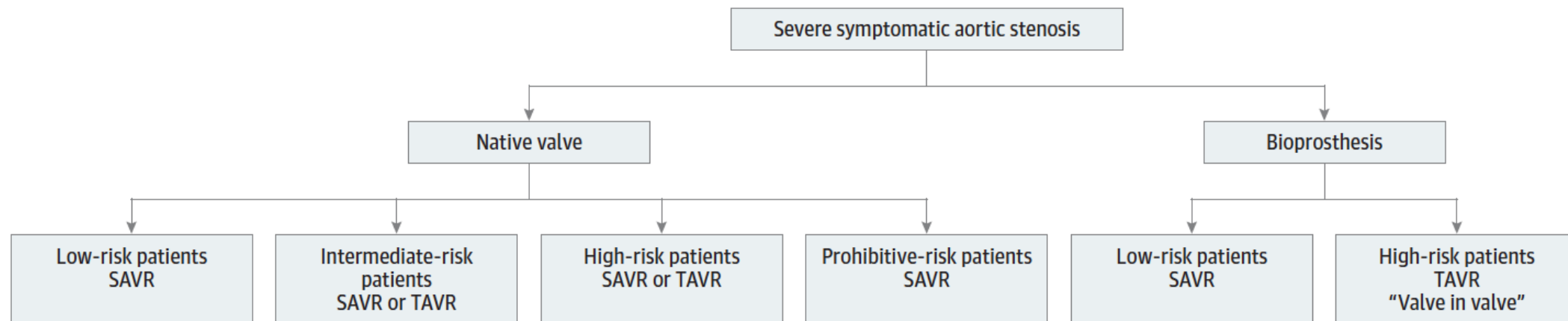


SOURCE: Credit Suisse TAVI Comment –January 8, 2015. ASP assumption for 2024 and 2025 based on analyst model. Revenue split assumption in 2025 is 45% U.S., 35% EU, 10% Japan, 10% ROW

# Guidelines Update on Indications for Transcatheter Aortic Valve Replacement

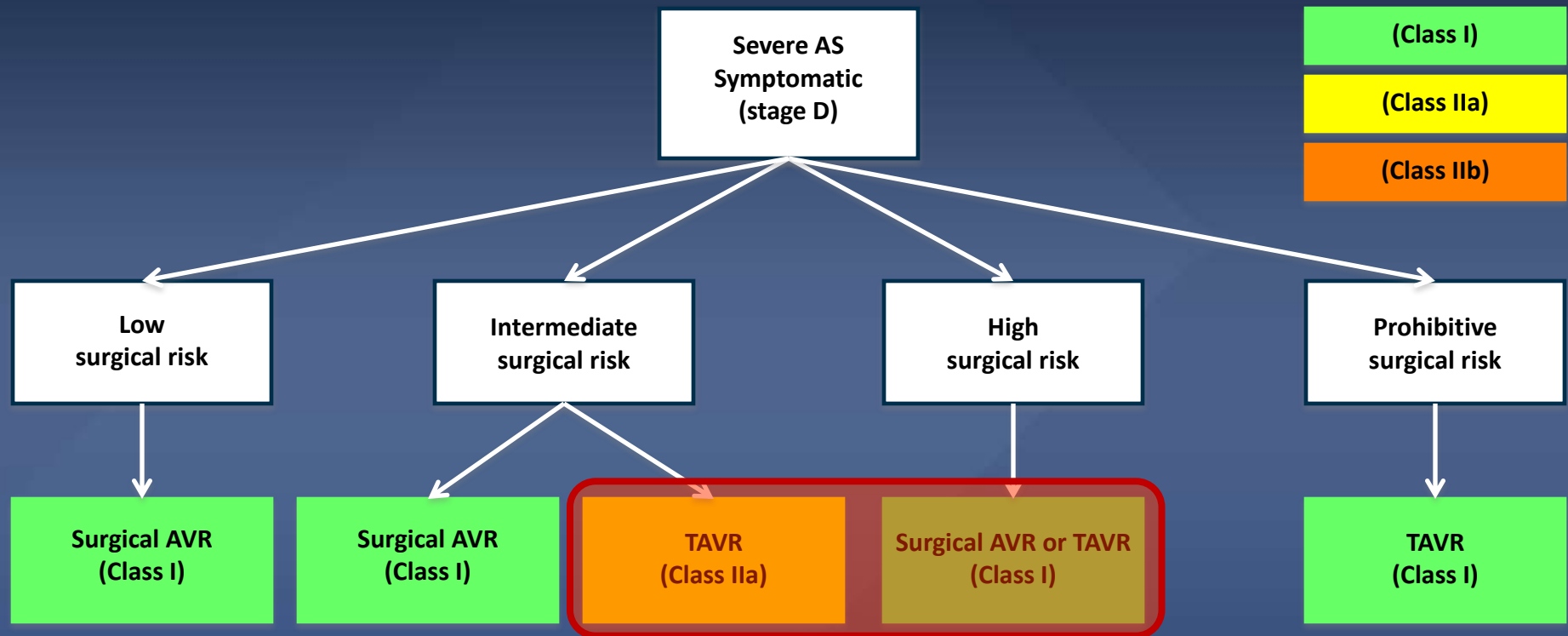
Rick A. Nishimura, MD; Patrick T. O’Gara, MD; Robert O. Bonow, MD

Figure. Choice of Intervention for Patients With Severe Symptomatic Aortic Stenosis



# 2017 AHA/ACC Focused Guideline Update

## Severe Symptomatic AS



# The PARTNER 3 Trial Study Design

Symptomatic Severe Calcific Aortic Stenosis

Low Risk ASSESSMENT by Heart Team  
(STS < 4%, TF only)



1:1 Randomization  
(n=1228)

TF - TAVR  
(SAPIEN 3)

Surgery  
(Bioprosthetic Valve)

CT Imaging Sub-Study (n=200)

CT Imaging Sub-Study (n=200)

Actigraphy/QoL Sub-Study (n=200)

Actigraphy/QoL Sub-Study (n=200)

**PRIMARY ENDPOINT:**

Composite of all-cause mortality, all strokes,  
or re-hospitalization at 1 year post-procedure

Follow-up: 30 days, 6 mos, 1 year and annually through 10 years

PARTNER 3  
Registries



Alternative Access  
(n=100)  
(TA/TAo/Subclavian)

Bicuspid Valves  
(n=100)

ViV (AV and MV)  
(n=100)



# EVOLUT R Low-Risk Trial

Heart Team Evaluation  
Two Cardiac Surgeons and One Interventional Cardiologist  
Low Surgical Risk (predicted mortality risk <3%)

National Screening Committee  
One Cardiac Surgeons and One Interventional Cardiologist  
Confirm Low Risk for TAVR and SAVR

**1:1 Randomization (N=1,256)**

TAVR

SAVR

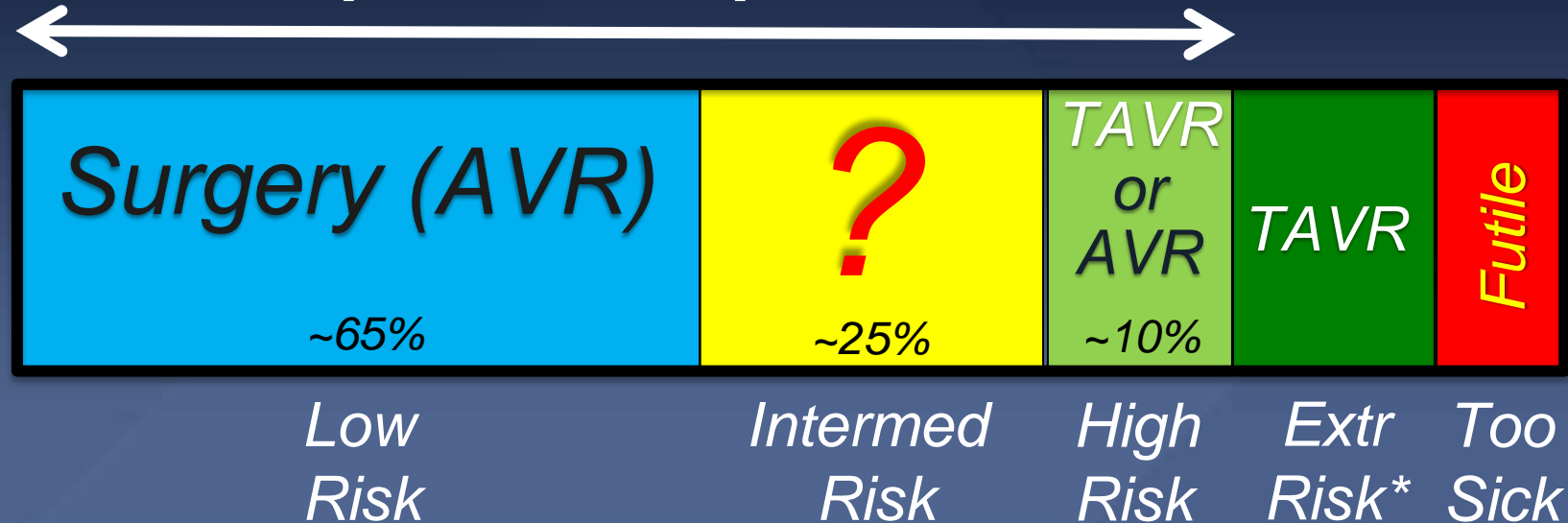
Leaflet sub-  
study N=200

4D CT for LTI

Leaflet sub-  
study N=200

# Role of the Heart Team Assessing Risk

Operable AS patients



## TAVR in 2017

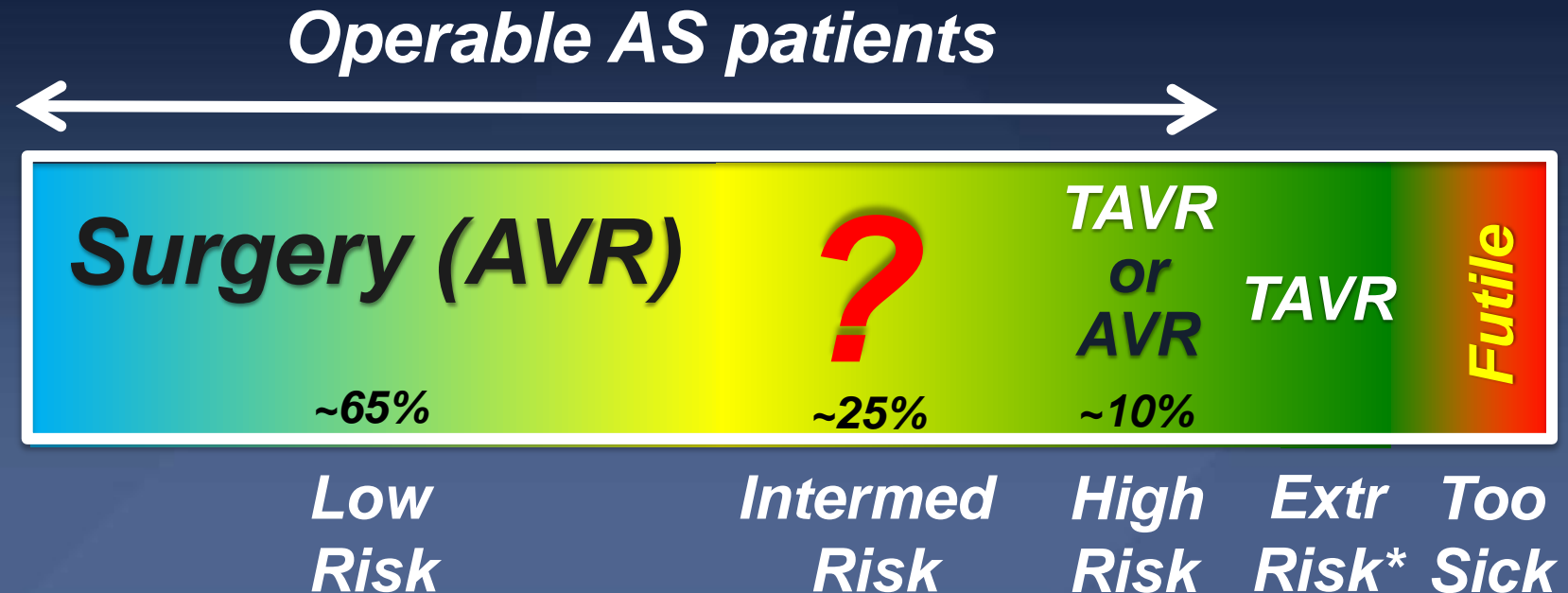
irresponsible,  
reckless

“equipoise”

OK preferred No

\* Extreme risk = “inoperable”

# Role of the Heart Team Assessing Risk



TAVR in 2017

*irresponsible, reckless*      “equipoise”      OK preferred      No

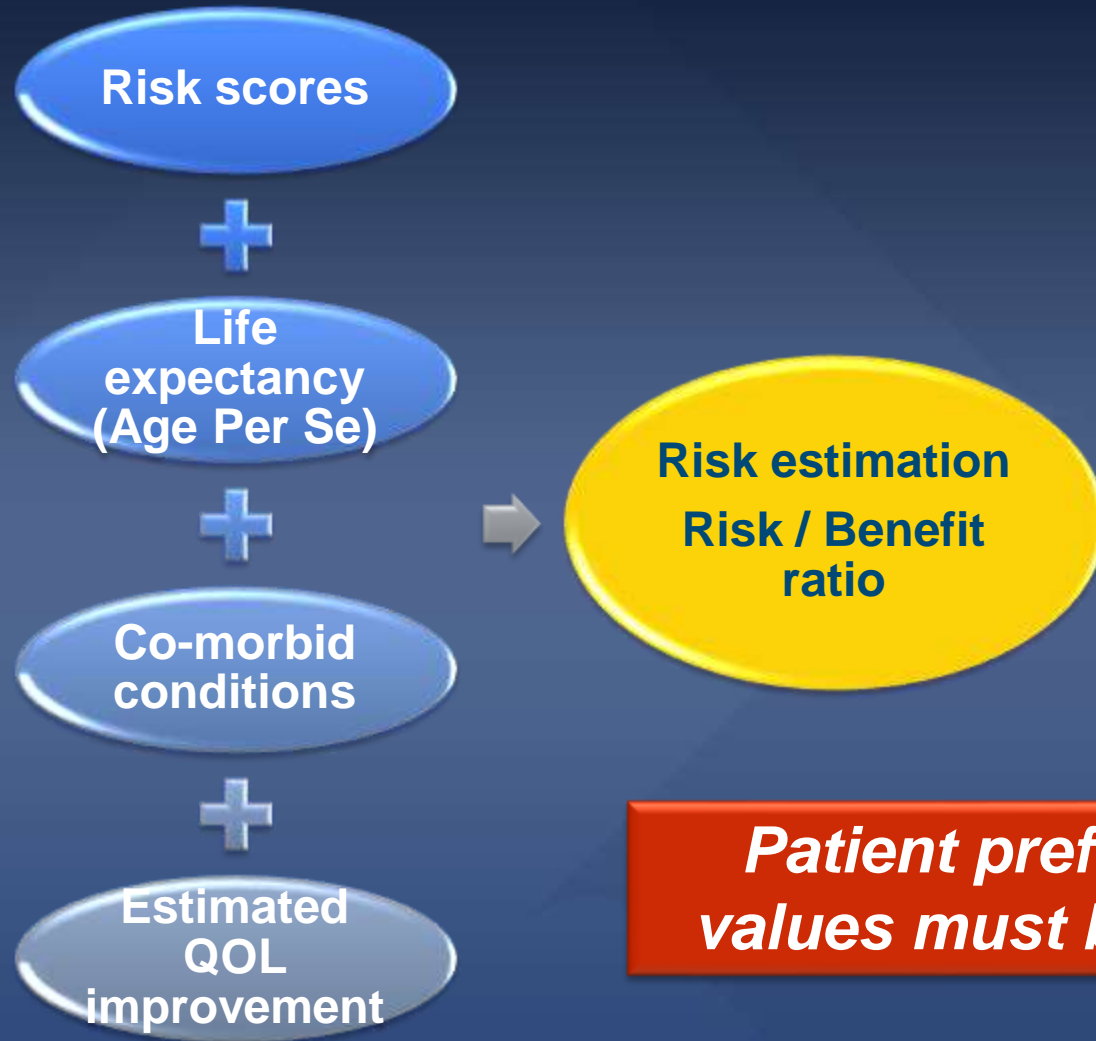
\* Extreme risk = “inoperable”

# Heart Team Dilemma for TAVR

## Real Patients Stories...

1. 87 year male, no comorbidity, STS score 2.
2. 73 year female, DM/HTN, preserved LV function, STS score 3. Strongly prefer TAVR.
3. 67 year male, DM/HTN/smoking/hyperlipidemia, STS score 2 and patient deemed a surgical candidate, but patient refuses SAVR because he takes care of debilitated wife.

# Heart Team Discussion: TAVR Candidates





# PRACTICE

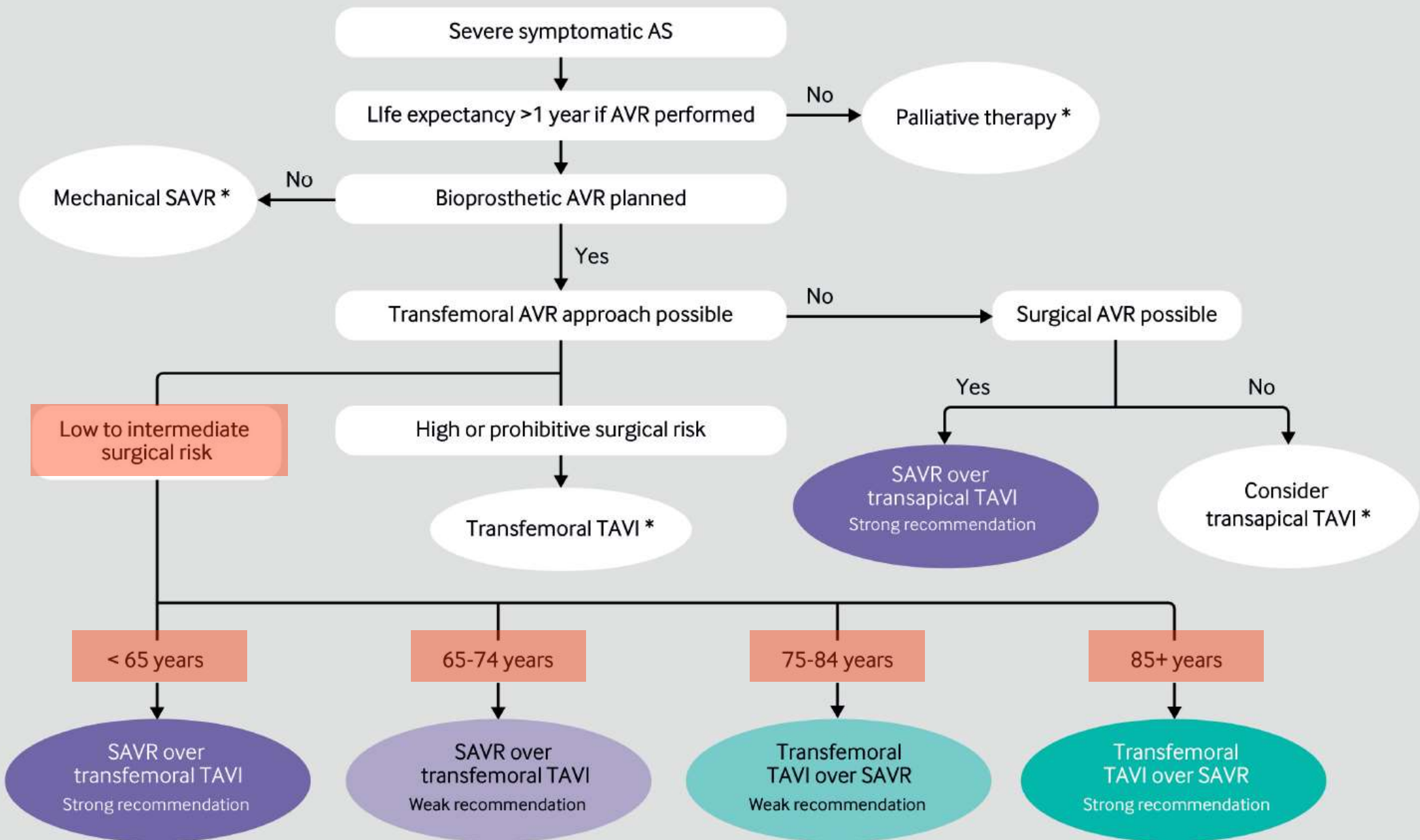
## RAPID RECOMMENDATIONS

# Transcatheter or surgical aortic valve replacement for patients with severe, symptomatic, aortic stenosis at **low to intermediate surgical risk**: a clinical practice guideline



OPEN ACCESS

In patients with symptomatic severe aortic stenosis but at lower risk of perioperative death, how do minimally invasive techniques compare with open surgery? Prompted by a recent trial, an expert panel produced these recommendations based on three linked rapid systematic reviews



\* Management of this group of patients is outside the scope of the systematic reviews and these recommendations

# What Should Be Guaranteed for Low-Risk, Younger Patients for TAVR?

1. Longevity: durability
2. Safety: stroke risk,  
new pacemaker



**In the near future, young age is not an exclusion criteria for TAVR anymore...**

## ***Longevity of Artificial Aortic Valve!!!***

**Mechanical  
Surgical Valves**



*>90% survival at 10 yr*

**Bioprosthetic  
Surgical Valves**



*Limited to 10-15 years*

**Bioprosthetic  
TAVR Valves**



*Might be >10 Years*

# Current available data about THV durability.....

# **PARTNER 5-year FU in Lancet (March, 2015)**

**5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial**

*Samir R Kapadia, Martin B Leon, Raj R Makkar, E Murat Tuzcu, Lars G Svensson, Susheel Kodali, John G Webb, Michael J Mack, Pamela S Douglas, Vinod H Thourani, Vasilis C Babaliaros, Howard C Herrmann, Wilson Y Szeto, Augusto D Pichard, Mathew R Williams, Gregory P Fontana, D Craig Miller, William N Anderson, Jodi J Akin\*, Michael J Davidson†, Craig R Smith, for the PARTNER trial investigators*

**5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial**

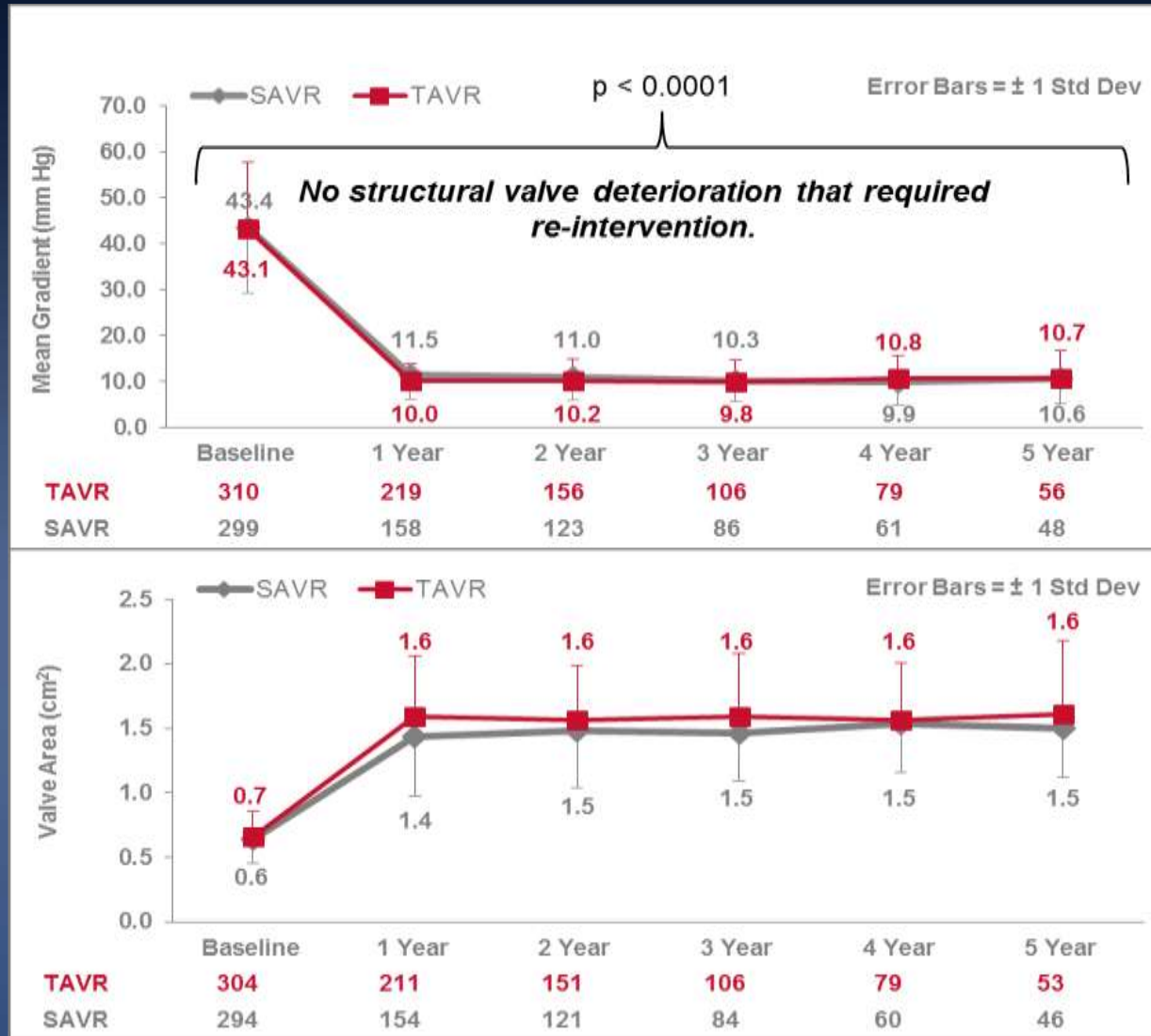
*Michael J Mack, Martin B Leon, Craig R Smith, D Craig Miller, Jeffrey W Moses, E Murat Tuzcu, John G Webb, Pamela S Douglas, William N Anderson, Eugene H Blackstone, Susheel K Kodali, Raj R Makkar, Gregory P Fontana, Samir Kapadia, Joseph Bavaria, Rebecca T Hahn, Vinod H Thourani, Vasilis Babaliaros, Augusto Pichard, Howard C Herrmann, David L Brown, Mathew Williams, Jodi Akin\*, Michael J Davidson†, Lars G Svensson, for the PARTNER 1 trial investigators*

# Mean Gradient & Valve Area (AT)

## Cohort B - All Patients



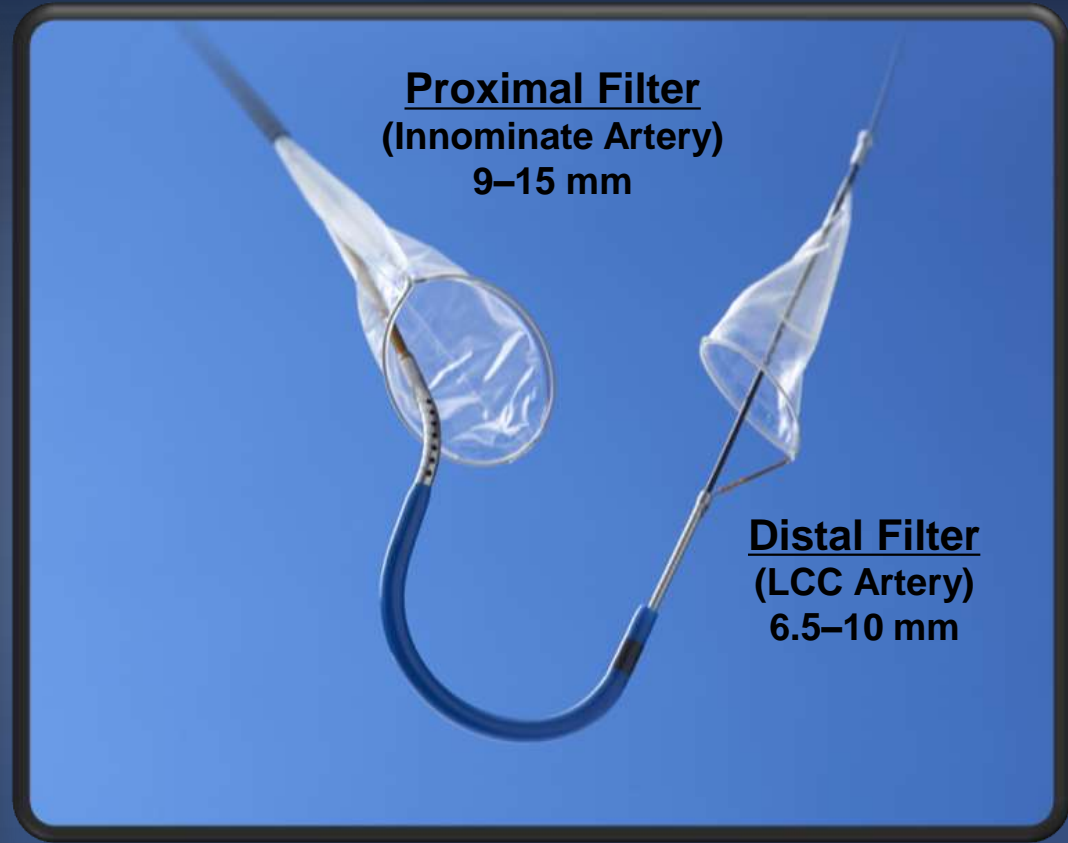
# The PARTNER Trial (Cohort A): 5-Year Data



# TAVR in Low-Risk, Young Patients

## Stroke Prevention

### Cerebral Embolic Protection (CEP)

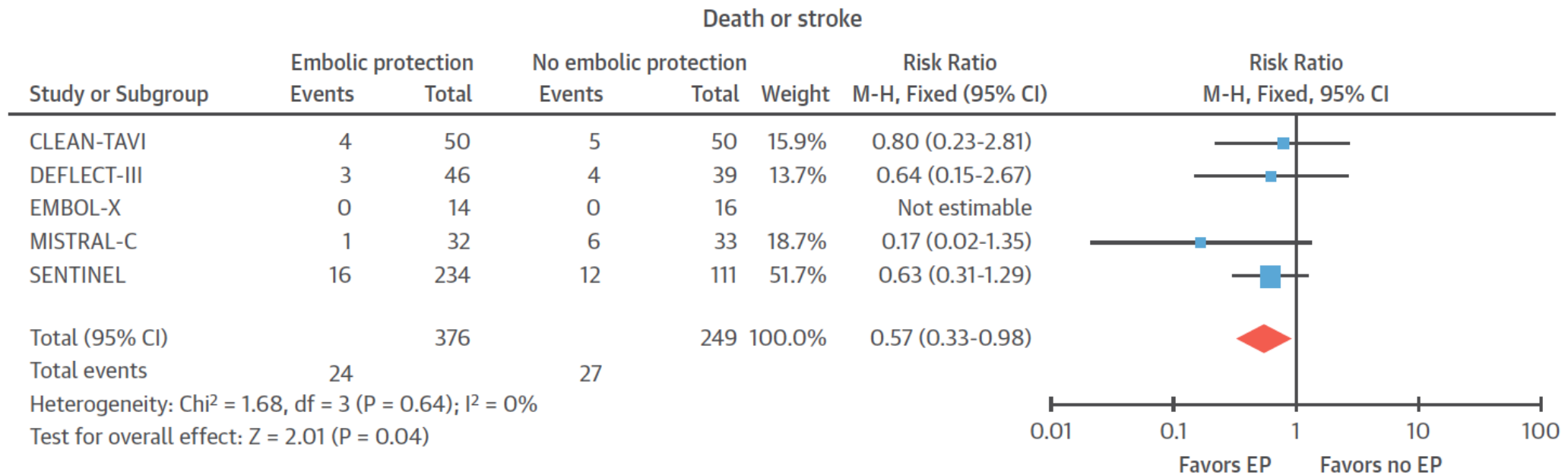




# NeuroProtection During TAVR

## Clinical Events Meta-Analysis of 5 RCTs

**FIGURE 1** Clinical Outcomes in Patients Undergoing TAVR With Versus Without Embolic Protection Devices



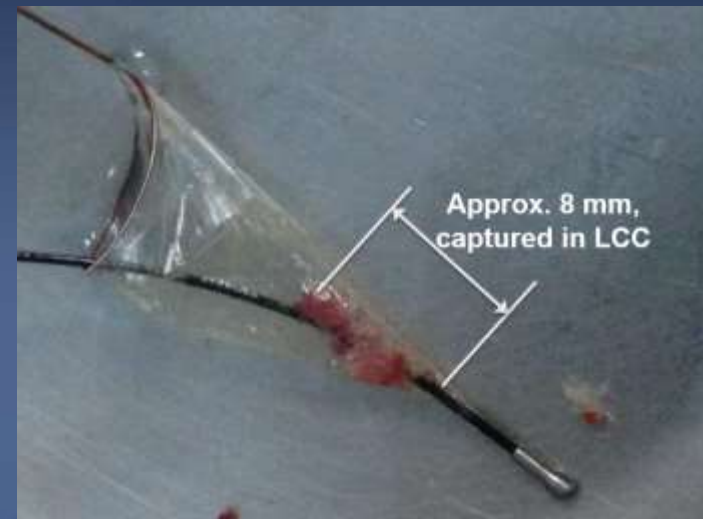
Pooled effect estimates for the risk of death or stroke according to the use of cerebral embolic protection versus not during TAVR. CI = confidence interval; CLEAN-TAVI = Claret Embolic Protection and TAVI; DEFLECT-III = A Prospective, Randomized Evaluation of the TriGuard HDH Embolic Deflection Device During TAVI; EP = embolic protection; M-H = Mantel-Haenszel; MISTRAL-C = MRI Investigation With Claret; SENTINEL = Cerebral Protection in Transcatheter Aortic Valve Replacement; TAVR = transcatheter aortic valve replacement.

# Is Cerebral Protection Necessary?

**It Is More Essential for  
Low Risk, Younger Patients**



**Would you take a  
chance and drive  
without a seatbelt?**



**You never know  
when you'll need  
protection**



# TAVR in Low-Risk, Young Patients

## Conduction Disturbances

- Marked variability in 30-day PPM rates among different TAVR systems (from  $< 10\%$  = optimal to  $> 30\%$  = unacceptable).
- Several predictors of PPM; including baseline RBBB, implant depth, and TAVR type.
- Still controversial remained regarding impact of new PPM on late mortality.
- Most “new” generation TAVR systems and improving operator technique have resulted in lowering new pacemaker implantation.

# TAVR in the Future

- Guidelines will need to adapt to the rapidly evolving TAVR evidence base

## TAVR in low risk surgical patients

- Availability of TAVR is likely to inform new indications for valve replacement

## Moderate AS in primary cardiomyopathy or low EF? Asymptomatic severe AS?

- Durability and need for pacemakers need to be resolved as TAVR moves to younger patients
- Judgment of the Heart Team remains essential in patient selection for TAVR, especially for lower risk, younger patients