
TAVR for Low Risk Patients: Interventionalist's Viewpoint

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Disclosure Statement of Financial Interest

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

- Grant/Research Support
- Scientific Advisory Board
- Executive Physician Council

Company

- Edwards Lifesciences, Abbott
- Medtronic, Abbott
- Boston Scientific Corp



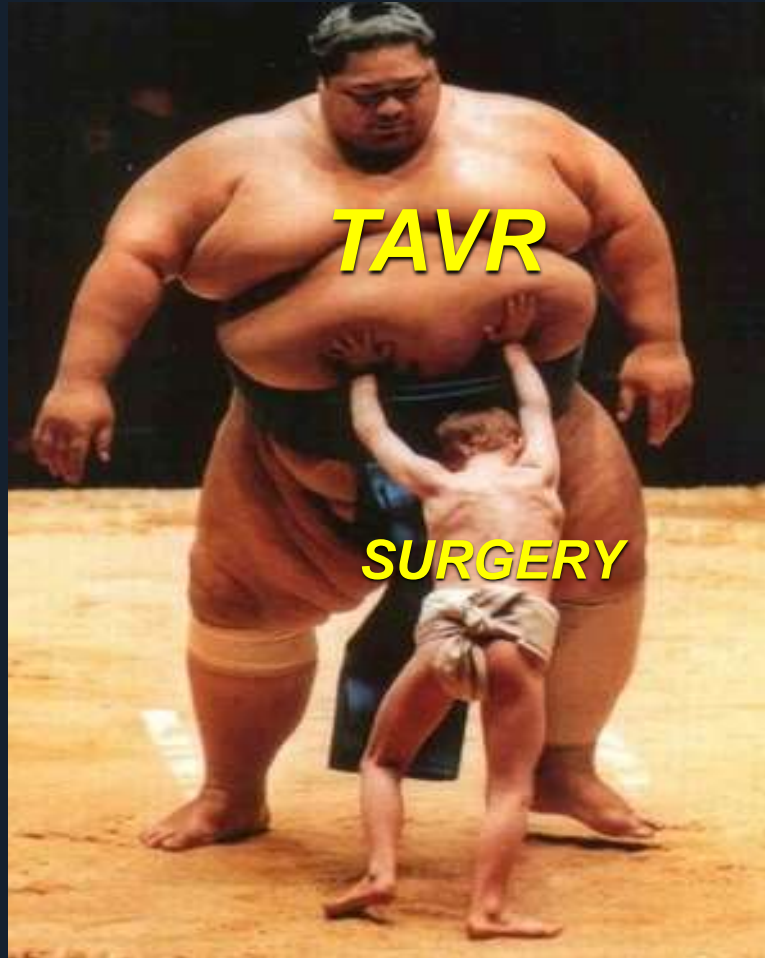
TAVR – The Early Years

Rules of Engagement



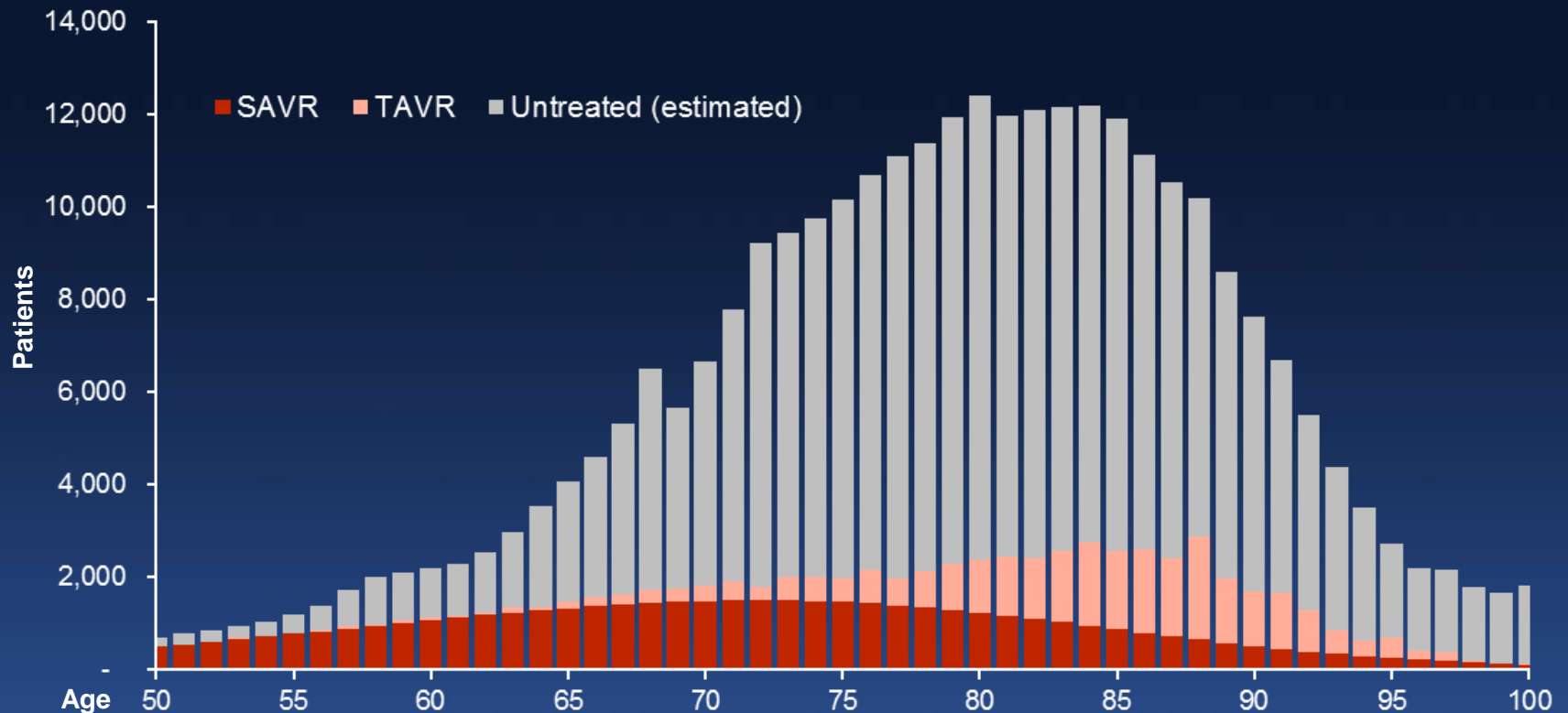
TAVR - Now

Rules of Engagement



AS Patients Undiagnosed and Untreated

2015 Severe Symptomatic AS Patients in the U.S.¹



(1) Nkomo 2006, Iivänäinen 1996, Aronow 1991, Bach 2007, Freed 2010, Jung 2007, Pellikka 2005, Brown 2008, Thourani 2015,

Aortic Stenosis Redefined:

Functional Classification

Mild AS	Moderate AS Symptoms -	Moderate AS Symptoms +	Severe AS Symptoms -	Severe AS Symptoms +		
				PARTNERS		
		TAVR-UNLOAD	EARLY-TAVR	Low	Inter	High Ext

**Active
Surveillance**



≈2020

2016

*All things being equal,
less-invasive therapies
will always reign supreme!*



***If TAVR = Surgery,
TAVR will become the
“accepted” therapy for AS!***

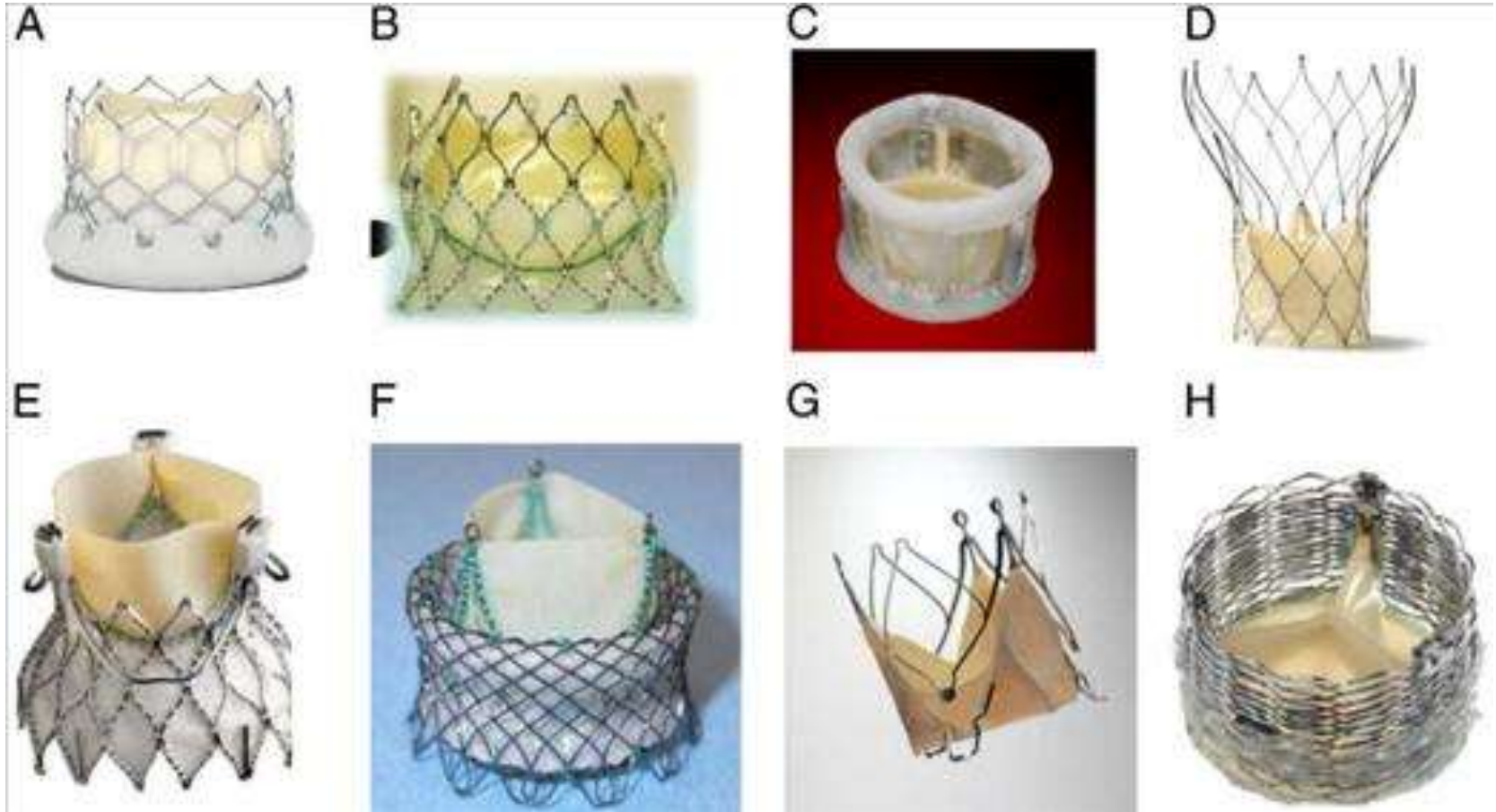
TAVR in ALL Patients

Obstacles to Overcome



1st Base
Para-valvular
leak

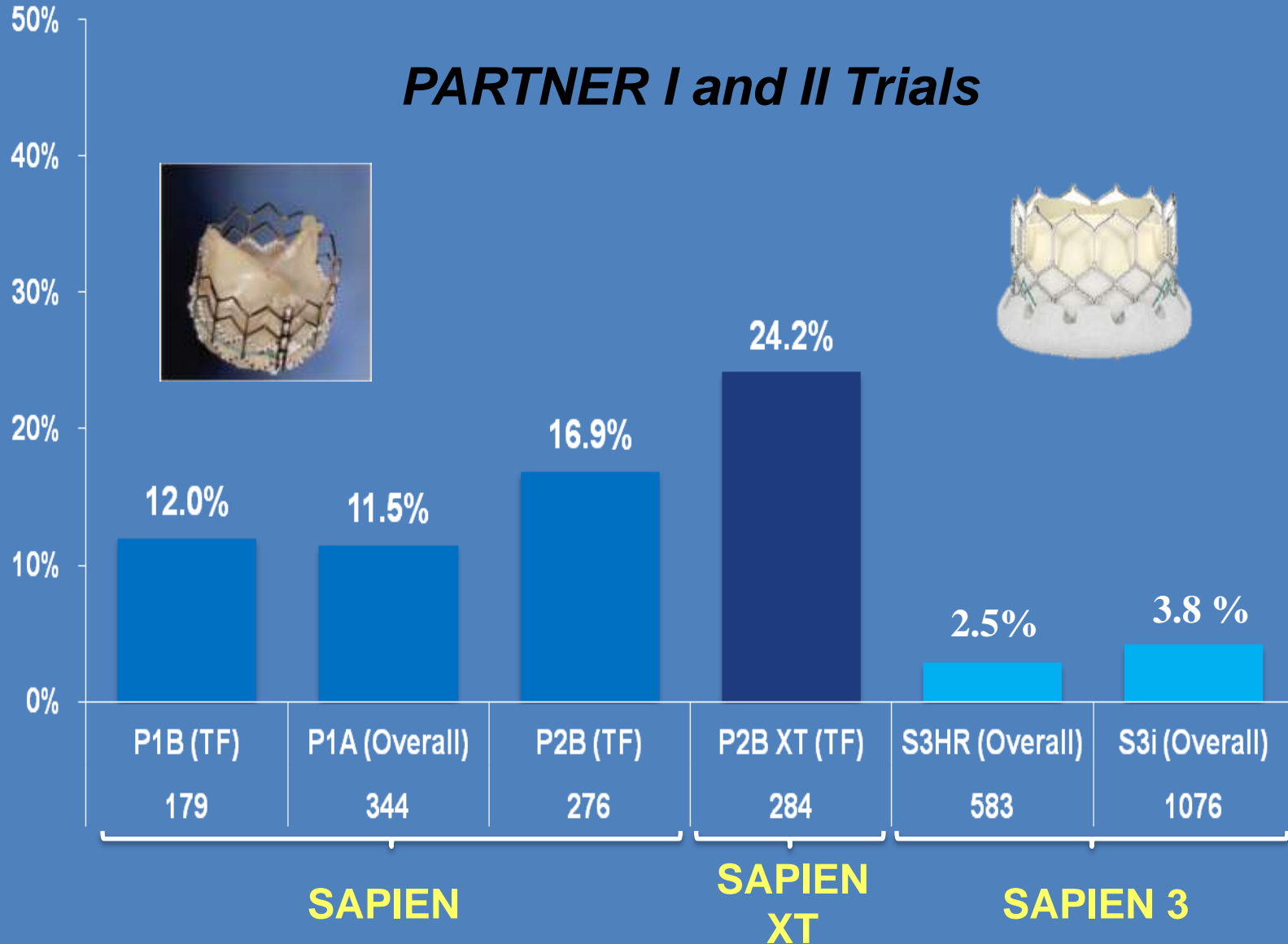
New Generations of Transcatheter Heart Valves to Prevent PVR



Moderate/Severe PVR at 30 Days

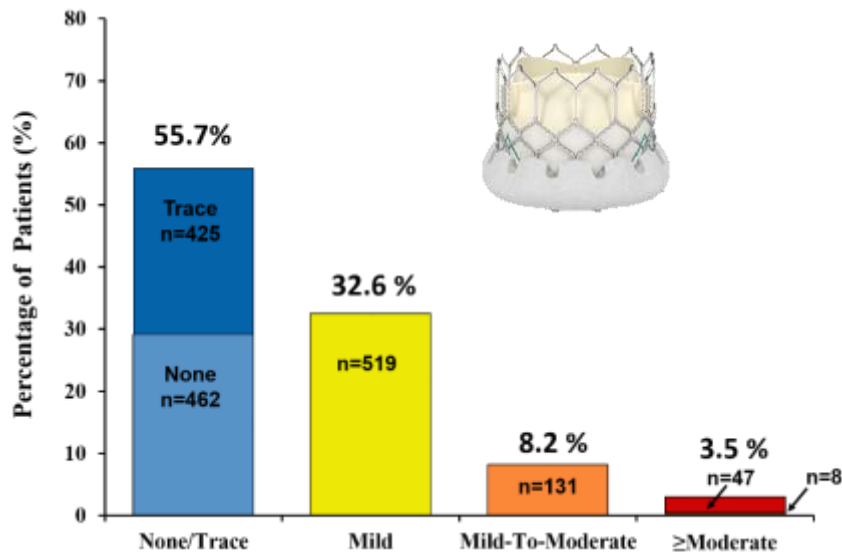
Edwards SAPIEN Valves

PARTNER I and II Trials



Prevalence of Paravalvular Regurgitation with New Generations of THVs

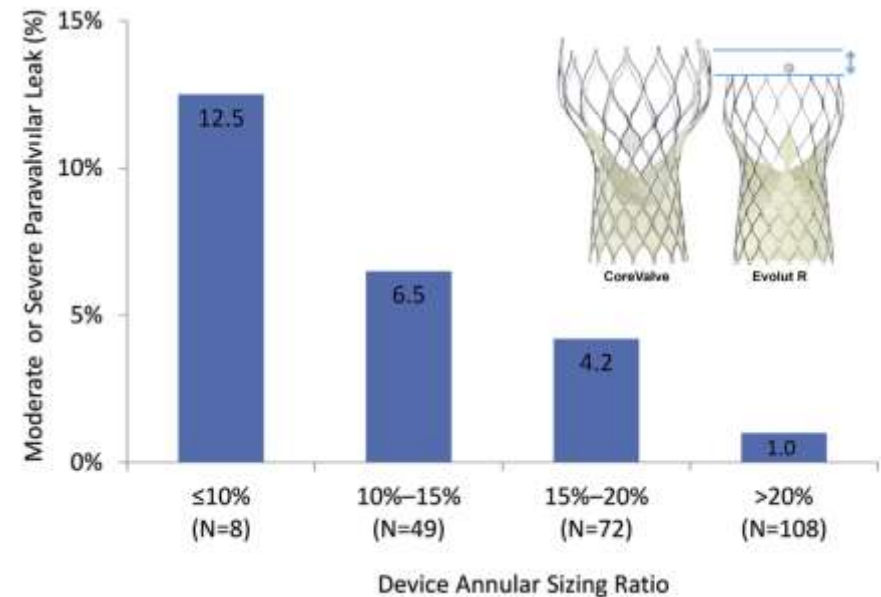
PARTNER 2 – SAPIEN 3 Registry



3.5 % \geq Moderate PVR
40.8% Mild PVR

Pibarot et al. TCT 2016

EVOLUT R US Study



5.7 % \geq Moderate PVR
32.6 % Mild PVR

Popma, JACC Int 2017; 10: 268-275

TAVR in ALL Patients

Para-valvular Regurgitation

- Most “new” generation TAVR systems have technical features resulting in lower PVR frequency
- Aortic valvar complex anatomy (esp. calcification) and operator technique (e.g. valve sizing and implant position) are important contributors.
- Intra-procedural assessment especially in the era of “minimalist” TAVR and treatment thresholds remain controversial.

TAVR in ALL Patients

Obstacles to Overcome



TAVR in ALL 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 re: impact of new PPM on late mortality, BUT most agree that the “overall” affect of new PPM is negative (hospital logistics, costs, LV function, and other late outcomes). But is it more than SAVR?

TAVR in ALL Patients

Obstacles to Overcome



3rd Base
Bicuspid
valves

TAVR in ALL Patients

Bicuspid Valve Disease

- Cannot claim victory over lower-risk AS patients until the challenges of treating bicuspid AVs with TAVR are overcome!
- Classification schemes and imaging diagnoses (CT and echo) are controversial.
- Myriad of other issues, including: aortopathy, extreme patterns of calcification, correct valve sizing, technique differences (e.g. valve positioning), and complications (esp. PVR and rupture).
- At present, remains a “data-poor zone”!



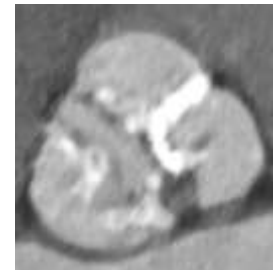
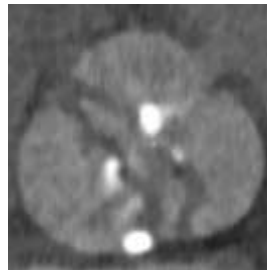
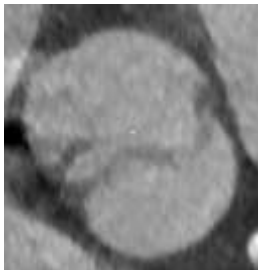
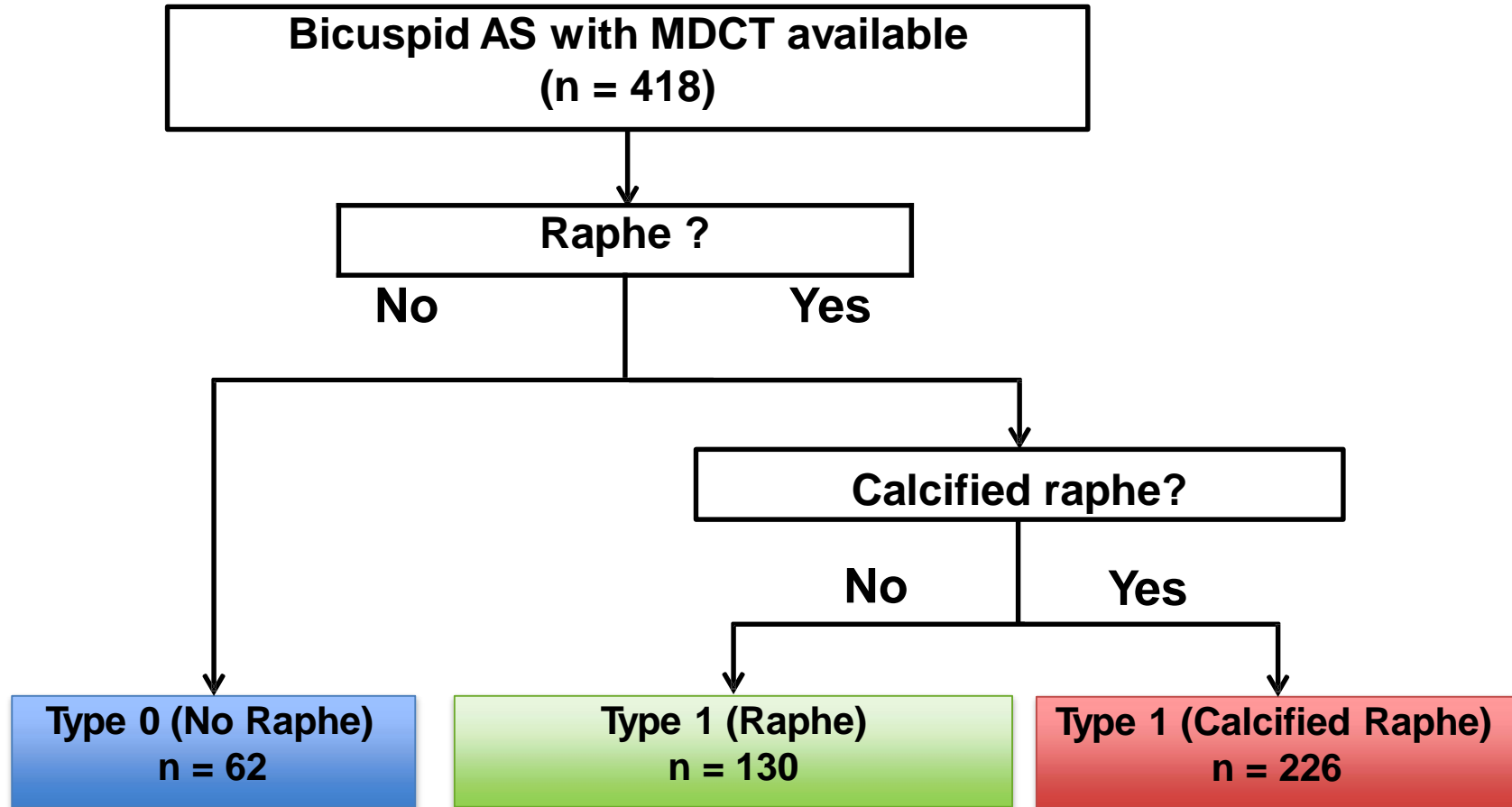
The Impact of Bicuspid Aortic Valve Morphology on Outcomes After TAVI

Sung-Han Yoon, MD

On Behalf of Bicuspid AS TAVR Registry

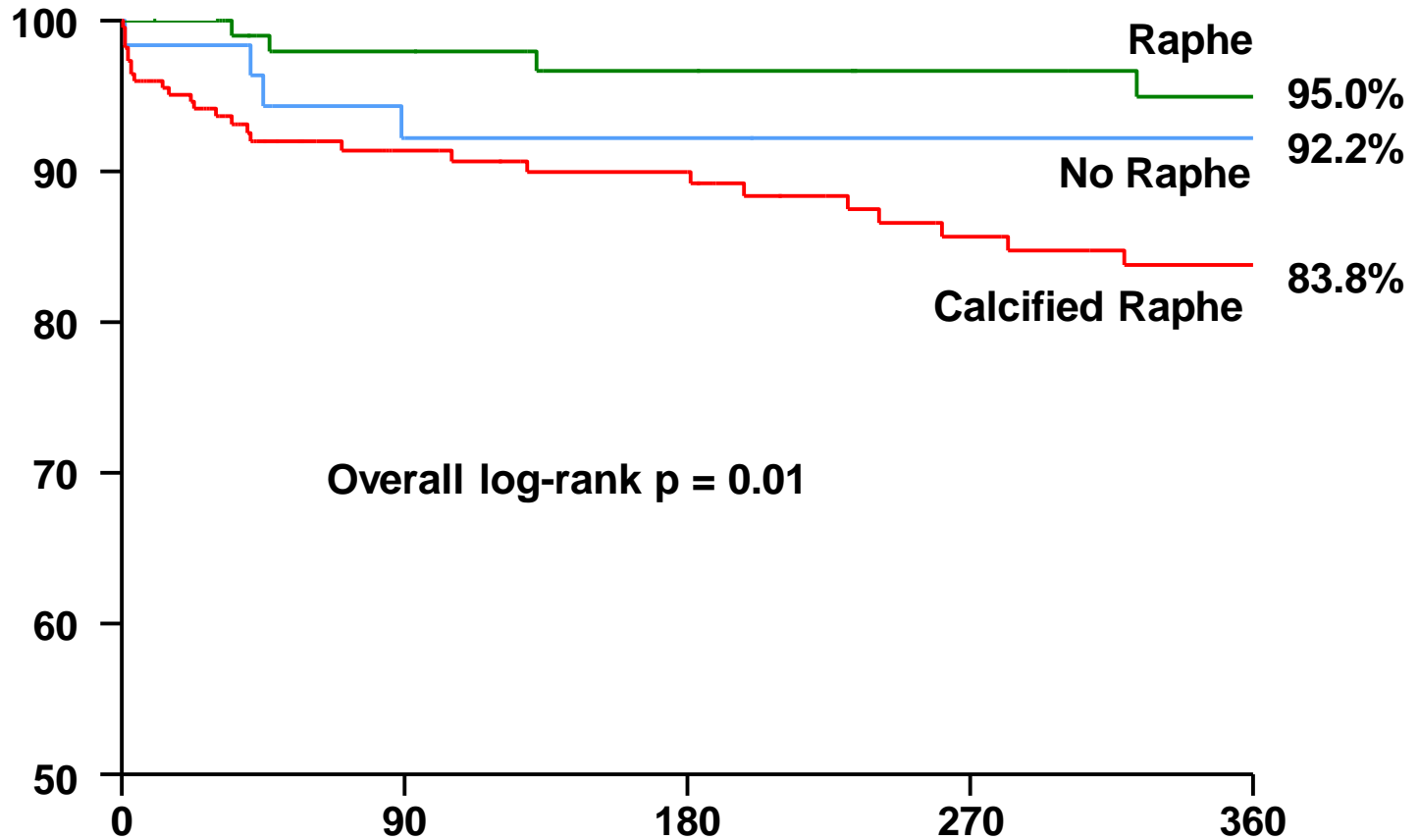


Study Design



Cumulative Survival at 1 Year

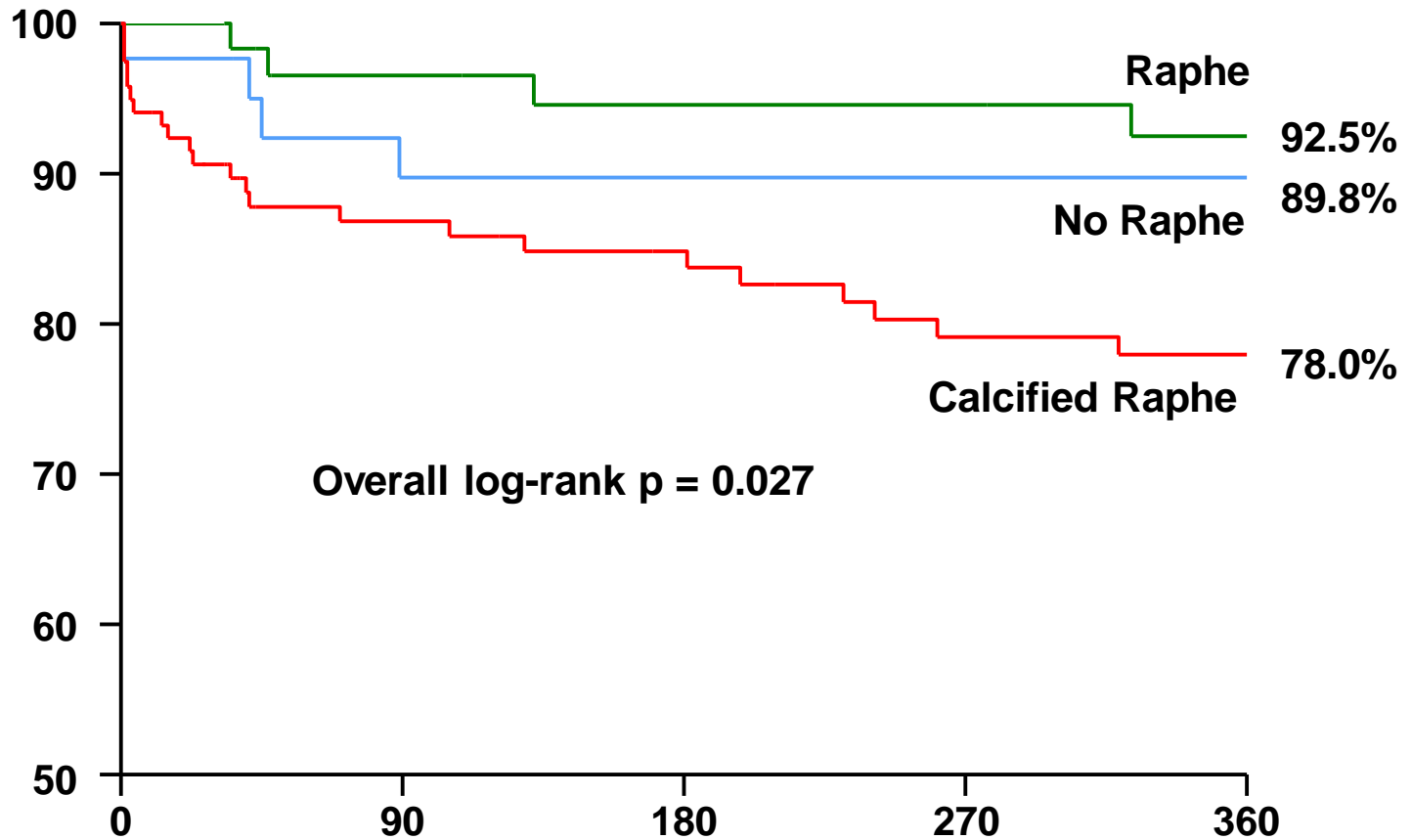
Overall Cohort



No. at Risk	62	Days	35
No Raphe		42	
Raphe	130	73	52
Calcified Raphe	226	123	87

Cumulative Survival at 1 Year

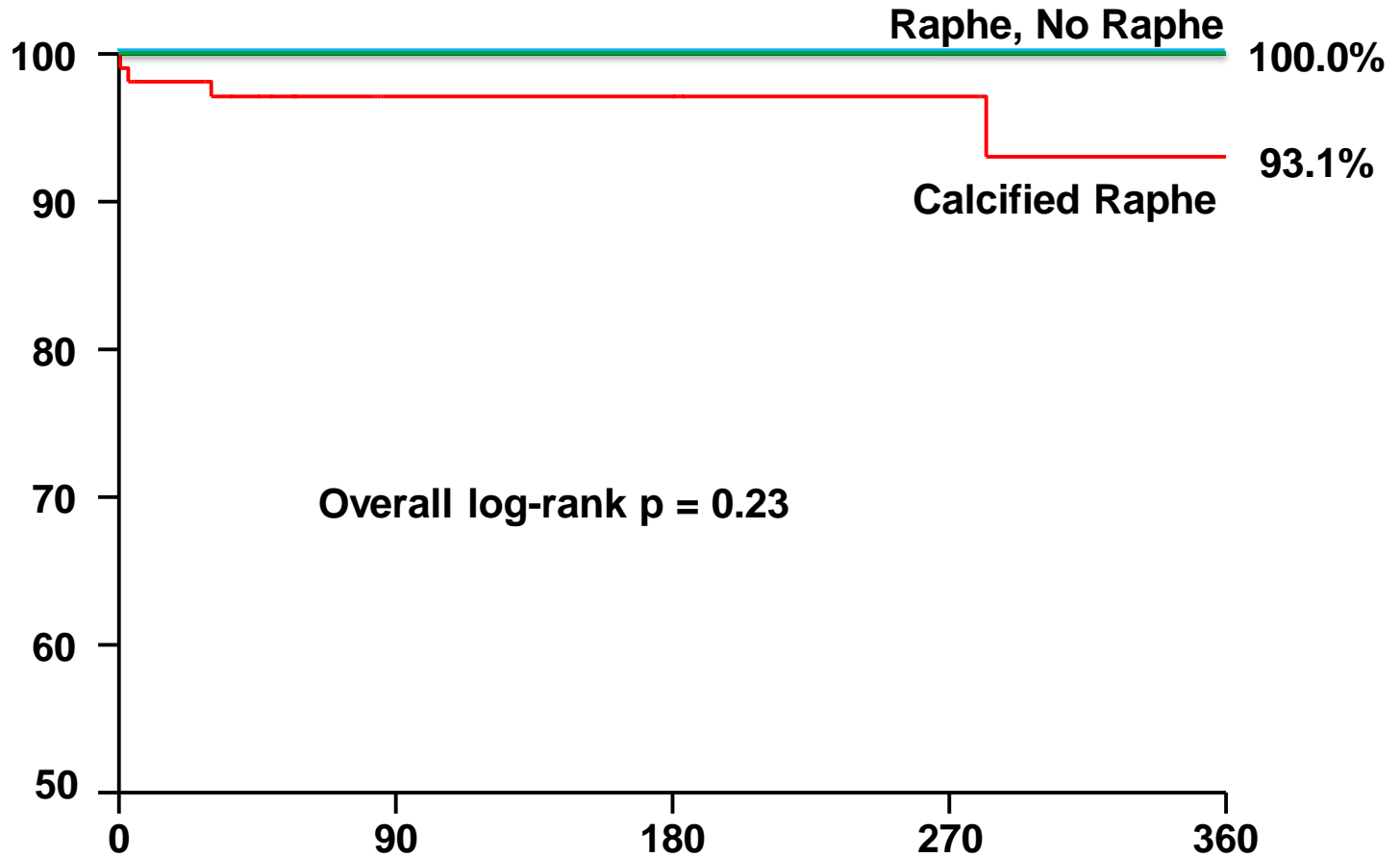
Early-generation Devices



No. at Risk	43	Days	27
No Raphe	32		
Raphe	48		42
Calcified Raphe	82		67

Cumulative Survival at 1 Year

New-generation Devices



No. at Risk	19	Days	8
No Raphe	10		
Raphe	65	25	10
Calcified Raphe	107	41	20

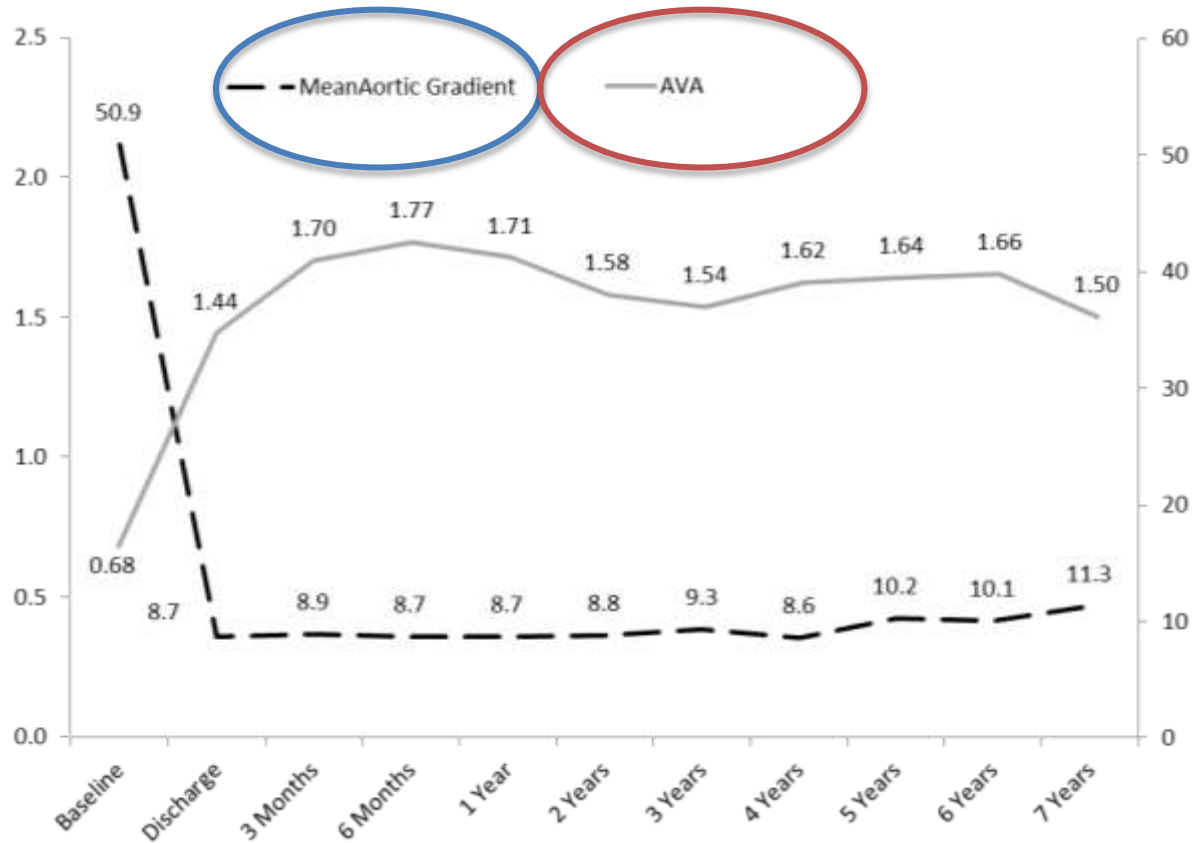
TAVR in ALL Patients

Obstacles to Overcome



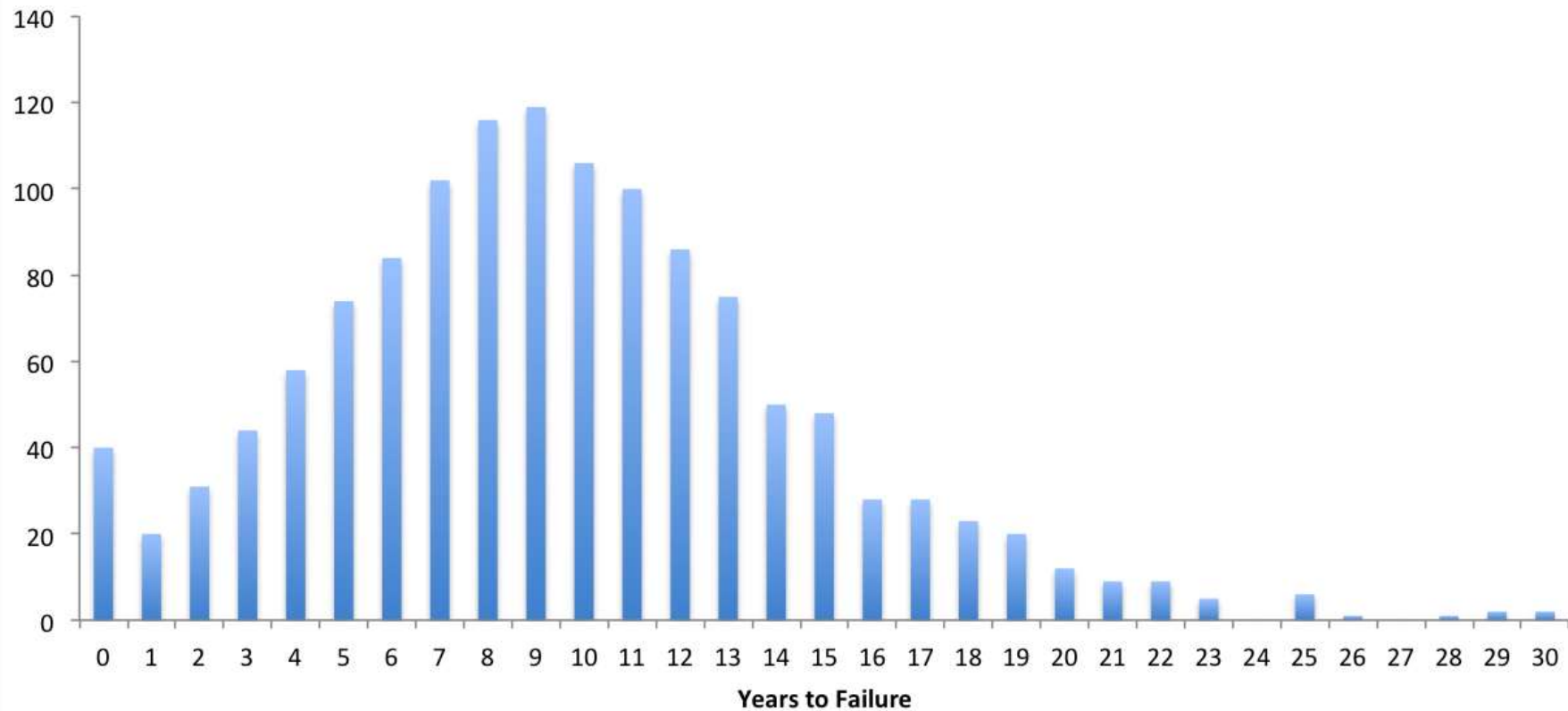
HOMERUN
*Durability &
thrombosis*

2343 Patients in Italian Registry



- The rates of mild and moderate PVL did not change from discharge (53.8% and 14.1%) to last available follow up (51% and 16%), $p=0.65$.

Time to Failure - All aortic VIVID Cases (n = 1304)



TAVR in ALL Patients

Durability and Thrombosis

- The issue of early TAVR-associated valve leaflet thickening with impaired motion and thrombosis must be resolved - frequency, clinical implications, and requirement for AC therapies!
- Advanced definitions of valve durability, including serial echo hemodynamic assessments, must be applied to BOTH surgical and transcatheter bioprosthetic valves.
- Durability concerns are mitigated by the rapidly evolving transcatheter valve-in-valve alternatives.

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=1,228)

TF - TAVR
(SAPIEN 3)

CT Imaging Sub-Study (n=200)

Actigraphy/QoL Sub-Study

Surgery
(Bioprosthetic Valve)

CT Imaging Sub-Study (n=200)

Actigraphy/QoL Sub-Study

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=50)

Aortic ViV
(n=100)

Mitral ViV or ViR
(n=100)