TAVI: “do extremo ao baixo risco” - O que será necessário alcançar?

TAVI*: from very high to low risk – What needs to be reached?*

Lino Patrício MD, PhD

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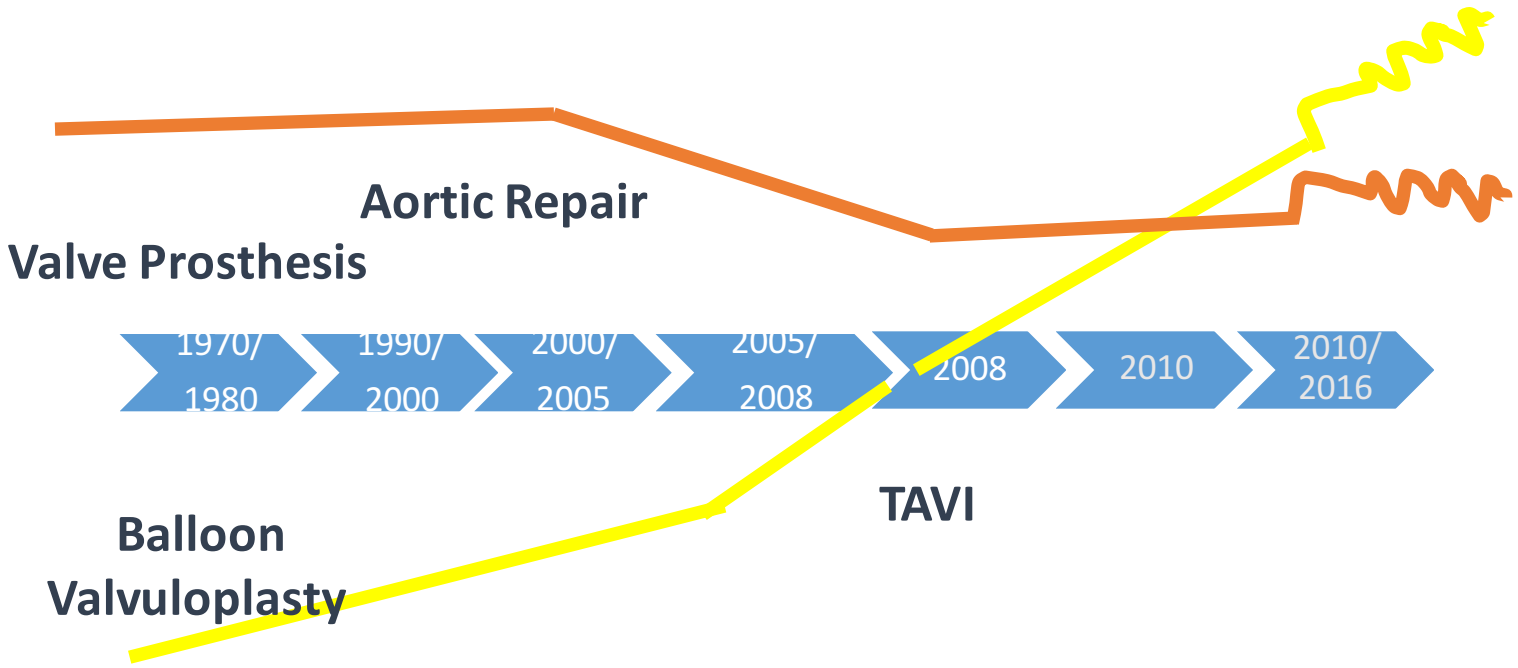
H.E.Santo - Évora

Aortic Valve Treatment
Recent Cardiology History



The NEW ENGLAND JOURNAL of MEDICINE

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Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela S. Douglas, M.D., John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators*

ABSTRACT

BACKGROUND

Many patients with severe aortic stenosis and coexisting conditions are not candidates for surgical replacement of the aortic valve. Recently, transcatheter aortic-valve implantation (TAVI) has been suggested as a less invasive treatment for high-risk patients with aortic stenosis.

METHODS

We randomly assigned patients with severe aortic stenosis, whom surgeons considered not to be suitable candidates for surgery, to standard therapy (including balloon aortic valvuloplasty) or transfemoral transcatheter implantation of a balloon-expandable bovine pericardial valve. The primary end point was the rate of death from any cause.

RESULTS

A total of 358 patients with aortic stenosis who were not considered to be suitable candidates for surgery underwent randomization at 21 centers (17 in the United States). At 1 year, the rate of death from any cause (Kaplan–Meier analysis) was 30.7% with TAVI, as compared with 50.7% with standard therapy (hazard ratio with TAVI, 0.55; 95% confidence interval [CI], 0.40 to 0.74; P<0.001). The rate of the composite end point of death from any cause or repeat hospitalization was 42.5% with TAVI as compared with 71.6% with standard therapy (hazard ratio, 0.46; 95% CI, 0.35 to 0.59; P<0.001). Among survivors at 1 year, the rate of cardiac symptoms (New York Heart Association class III or IV) was lower among patients who had undergone TAVI than among those who had received standard therapy (25.2% vs. 58.0%, P<0.001). At 30 days, TAVI, as compared with standard therapy, was associated with a higher incidence of major strokes (5.0% vs. 1.1%, P=0.06) and major vascular complications (16.2% vs. 1.1%, P<0.001). In the year after TAVI, there was no deterioration in the functioning of the bioprosthetic valve, as assessed by evidence of stenosis or regurgitation on an echocardiogram.

CONCLUSIONS

In patients with severe aortic stenosis who were not suitable candidates for surgery, TAVI, as compared with standard therapy, significantly reduced the rates of death from any cause, the composite end point of death from any cause or repeat hospitalization, and cardiac symptoms, despite the higher incidence of major strokes and major vascular events. (Funded by Edwards Lifesciences; ClinicalTrials.gov number, NCT00530894.)

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*The investigators, institutions, and research organizations participating in the Placement of Aortic Transcatheter Valves (PARTNER) trial are listed in the Supplementary Appendix, available at NEJM.org.

This article (10.1056/NEJMoa1008232) was published on September 22, 2010, at NEJM.org.

N Engl J Med 2010;363:1597-1607.

The NEW ENGLAND JOURNAL of MEDICINE

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Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients

Craig R. Smith, M.D., Martin B. Leon, M.D., Michael J. Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., Mathew Williams, M.D., Todd Dewey, M.D., Samir Kapadia, M.D., Vasilis Babaliaros, M.D., Vinod H. Thourani, M.D., Paul Corso, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart J. Pocock, Ph.D., for the PARTNER Trial Investigators*

ABSTRACT

BACKGROUND

The use of transcatheter aortic-valve replacement has been shown to reduce mortality among high-risk patients with aortic stenosis who are not candidates for surgical replacement. However, the two procedures have not been compared in a randomized trial involving high-risk patients who are still candidates for surgical replacement.

METHODS

At 25 centers, we randomly assigned 699 high-risk patients with severe aortic stenosis to undergo either transcatheter aortic-valve replacement with a balloon-expandable bovine pericardial valve (either a transfemoral or a transapical approach) or surgical replacement. The primary end point was death from any cause at 1 year. The primary hypothesis was that transcatheter replacement is not inferior to surgical replacement.

RESULTS

The rates of death from any cause were 3.4% in the transcatheter group and 6.5% in the surgical group at 30 days (P=0.07) and 24.2% and 26.8%, respectively, at 1 year (P=0.44), a reduction of 2.6 percentage points in the transcatheter group (upper limit of the 95% confidence interval, 3.0 percentage points; predefined margin, 7.5 percentage points; P=0.001 for noninferiority). The rates of major stroke were 3.8% in the transcatheter group and 2.1% in the surgical group at 30 days (P=0.20) and 5.1% and 2.4%, respectively, at 1 year (P=0.07). At 30 days, major vascular complications were significantly more frequent with transcatheter replacement (11.0% vs. 3.2%, P<0.001); adverse events that were more frequent after surgical replacement included major bleeding (9.3% vs. 19.5%, P<0.001) and new-onset atrial fibrillation (8.6% vs. 16.0%, P=0.006). More patients undergoing transcatheter replacement had an improvement in symptoms at 30 days, but by 1 year, there was not a significant between-group difference.

CONCLUSIONS

In high-risk patients with severe aortic stenosis, transcatheter and surgical procedures for aortic-valve replacement were associated with similar rates of survival at 1 year, although there were important differences in periprocedural risks. (Funded by Edwards Lifesciences; Clinical Trials.gov number, NCT00530894.)

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Smith at Columbia University Medical Center–New York Presbyterian Hospital, 177 Fort Washington Ave., Milstein Bldg. 7-435, New York, NY 10032, or at crs2@columbia.edu.

*The investigators, institutions, and research organizations participating in the Placement of Aortic Transcatheter Valves (PARTNER) trial are in the Supplementary Appendix, available at NEJM.org.

N Engl J Med 2011;364:2187-98.

ORIGINAL ARTICLE

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

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ABSTRACT

BACKGROUND

Previous trials have shown that among high-risk patients with aortic stenosis, survival rates are similar with transcatheter aortic-valve replacement (TAVR) and surgical aortic-valve replacement. We evaluated the two procedures in a randomized trial involving intermediate-risk patients.

METHODS

We randomly assigned 2032 intermediate-risk patients with severe aortic stenosis, at 57 centers, to undergo either TAVR or surgical replacement. The primary end point was death from any cause or disabling stroke at 2 years. The primary hypothesis was that TAVR would not be inferior to surgical replacement. Before randomization, patients were entered into one of two cohorts on the basis of clinical and imaging findings; 76.3% of the patients were included in the transfemoral-access cohort and 23.7% in the transthoracic-access cohort.

RESULTS

The rate of death from any cause or disabling stroke was similar in the TAVR group and the surgery group (P=0.001 for noninferiority). At 2 years, the Kaplan–Meier event rates were 19.3% in the TAVR group and 21.1% in the surgery group (hazard ratio in the TAVR group, 0.89; 95% confidence interval [CI], 0.73 to 1.09; P=0.25). In the transfemoral-access cohort, TAVR resulted in a lower rate of death or disabling stroke than surgery (hazard ratio, 0.79; 95% CI, 0.62 to 1.00; P=0.05), whereas in the transthoracic-access cohort, outcomes were similar in the two groups. TAVR resulted in larger aortic-valve areas than did surgery and also resulted in lower rates of acute kidney injury, severe bleeding, and new-onset atrial fibrillation; surgery resulted in fewer major vascular complications and less paravalvular aortic regurgitation.

CONCLUSIONS

In intermediate-risk patients, TAVR was similar to surgical aortic-valve replacement with respect to the primary end point of death or disabling stroke. (Funded by Edwards Lifesciences; PARTNER 2 ClinicalTrials.gov number, NCT01314313.)

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Leon at Columbia University Medical Center, 161 Ft. Washington Ave., 6th Floor, New York, NY 10032, or at rmleon@crf.org.

*A complete list of investigators in the Placement of Aortic Transcatheter Valves (PARTNER) 2 trial is provided in the Supplementary Appendix, available at NEJM.org.

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TAVI- SAVR Recomendations

TABLE 1 Summary of Recommendations for AS: Choice of Surgical or Transcatheter Intervention

	COR	LOE
SAVR is recommended in patients who meet an indication for AVR with low or intermediate surgical risk	I	A
For patients in whom TAVR or high-risk SAVR is being considered, members of a Heart Valve Team should collaborate to provide optimal patient care	I	C
TAVR is recommended in patients who meet an indication for AVR for AS who have a prohibitive surgical risk and a predicted post-TAVR survival >12 months	I	B
TAVR is a reasonable alternative to SAVR in patients who meet an indication for AVR and who have high surgical risk	IIa	B
Percutaneous aortic balloon dilation may be considered as a bridge to SAVR or TAVR in severely symptomatic patients with severe AS	IIb	C
TAVR is not recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of AS	III: No benefit	B

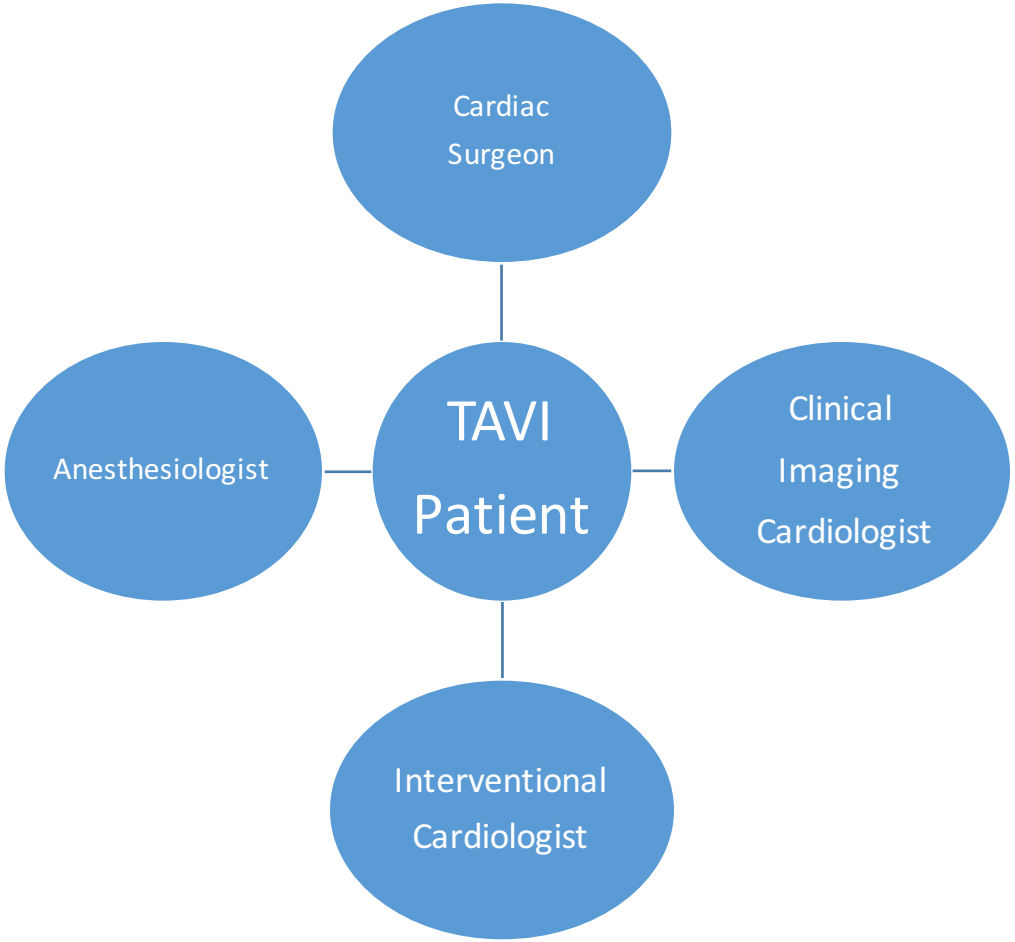
Adapted from Nishimura et al. (5).

AS = aortic stenosis; AVR = aortic valve replacement; COR = Class of Recommendation; LOE = Level of Evidence; SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement.

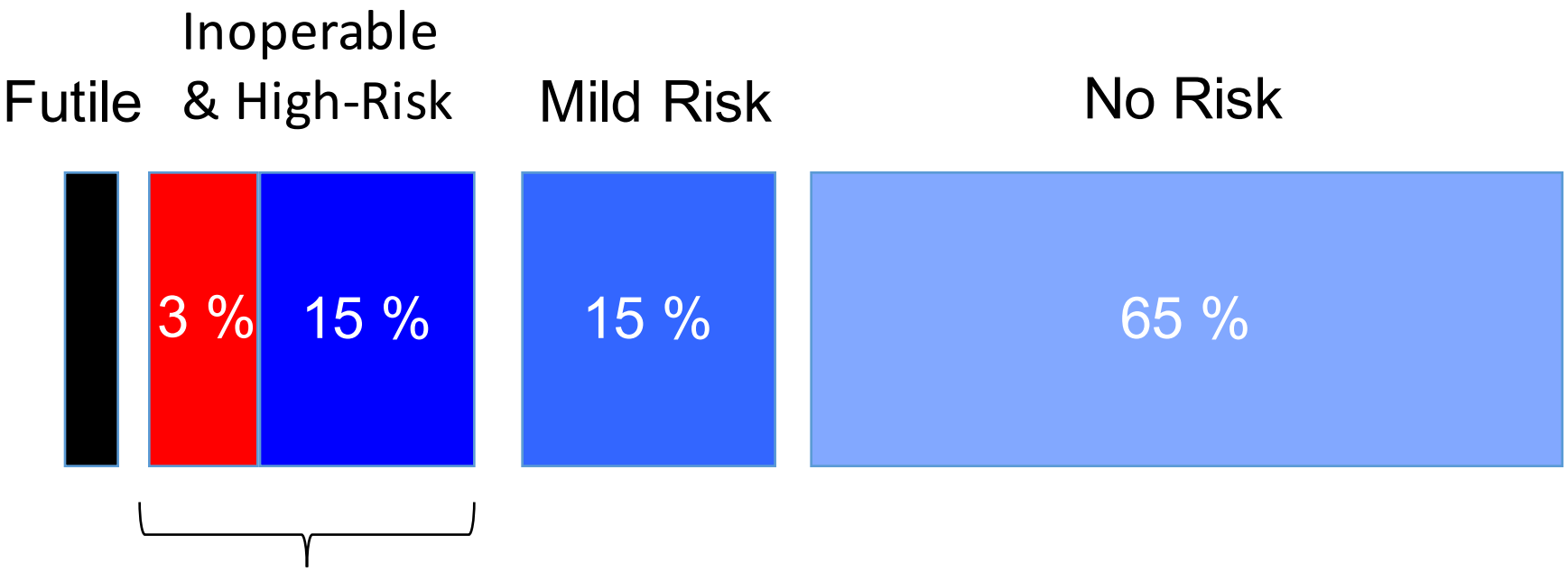
TAVI Program is a disruptive reality

- **Innovation adoption**
- **Heart Team work**
- **Patient Selection and Ethical issues**
- **Reimbursements and costs**

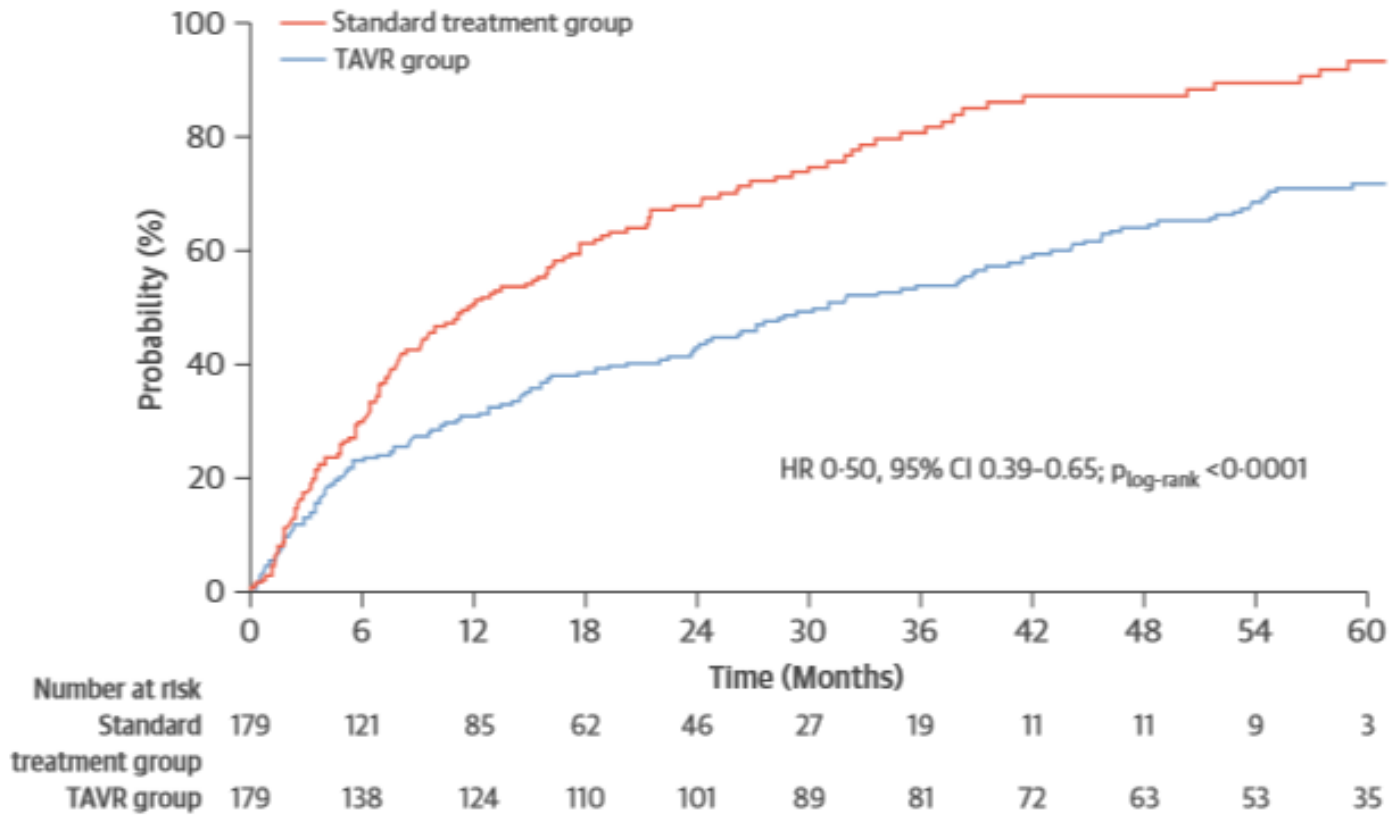
TAVI Program is a disruptive reality
Heart Team work



Indications of TAVI vs sAVR (2007-2017)

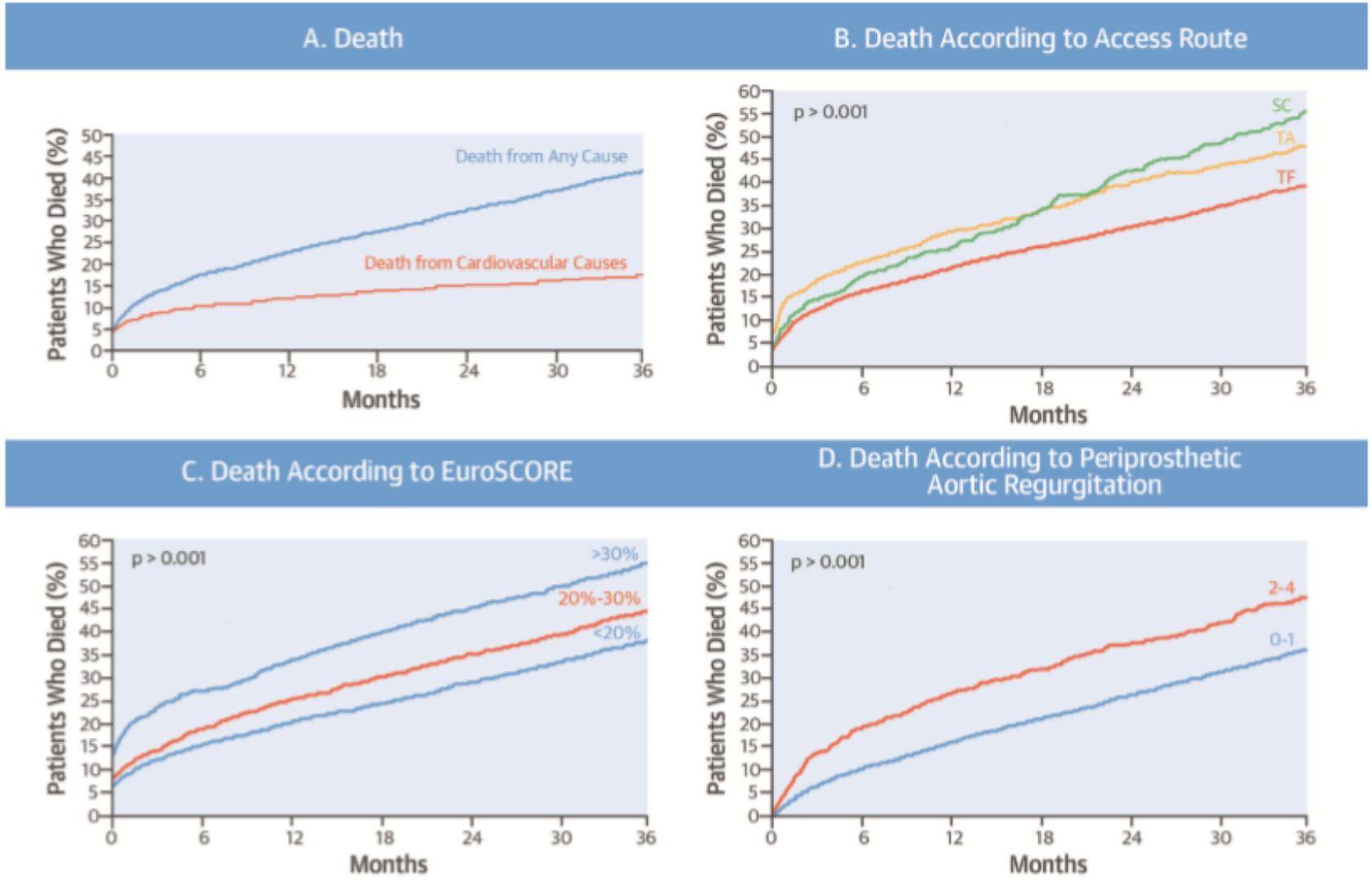


Effects on Mortality in TAVI PARTNER 1B
Prohibitive risk patients



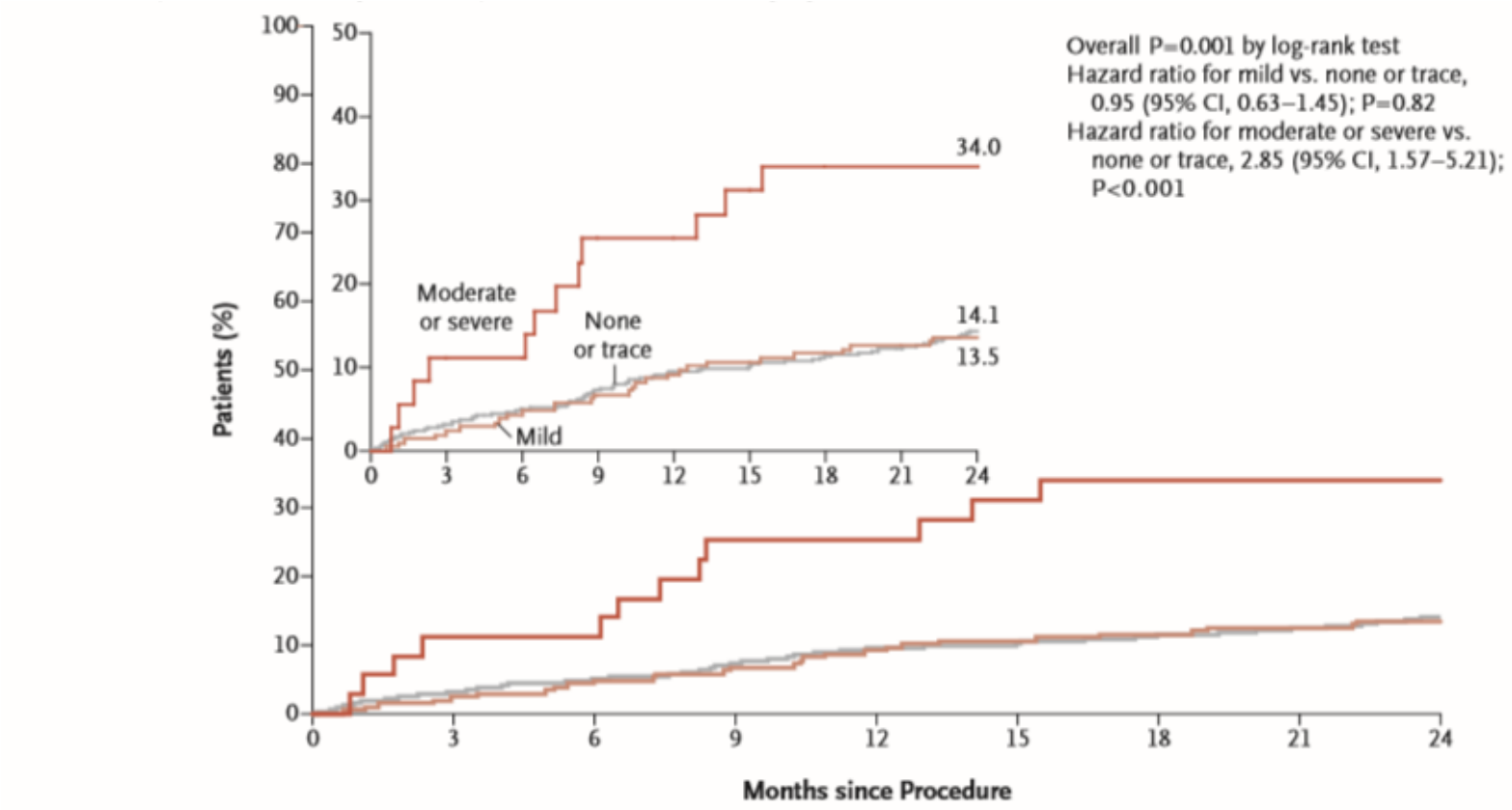
Kapadia SR. Lancet 2015;385:2485-91

Late Outcomes of TAVR in High-Risk Patients
3-Year Follow-Up



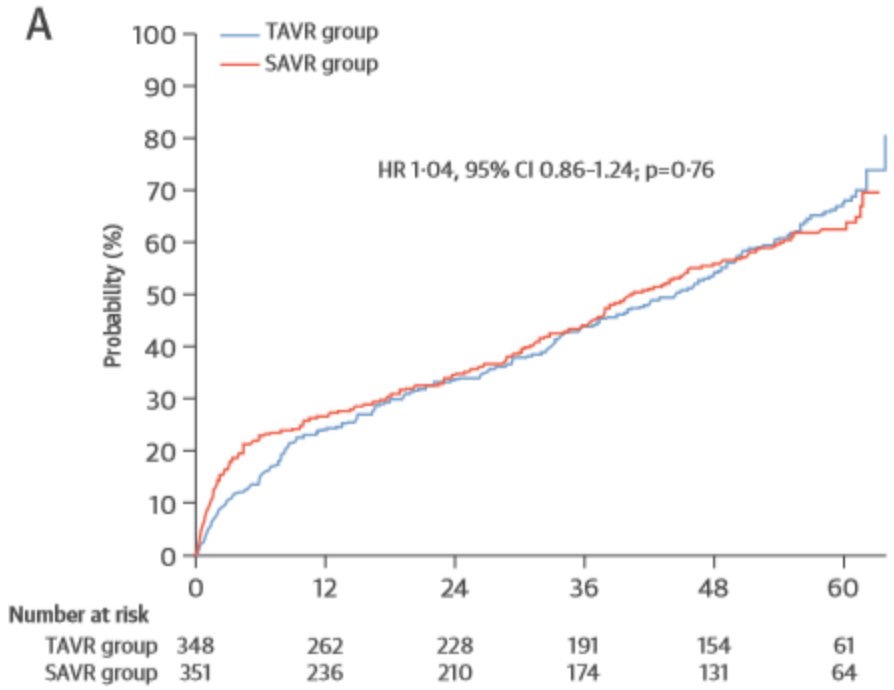
Gilard, M. et al. J Am Coll Cardiol. 2016;68(15):1637-47.

Death from Any Cause, According to Severity of Paravalvular Aortic Regurgitation

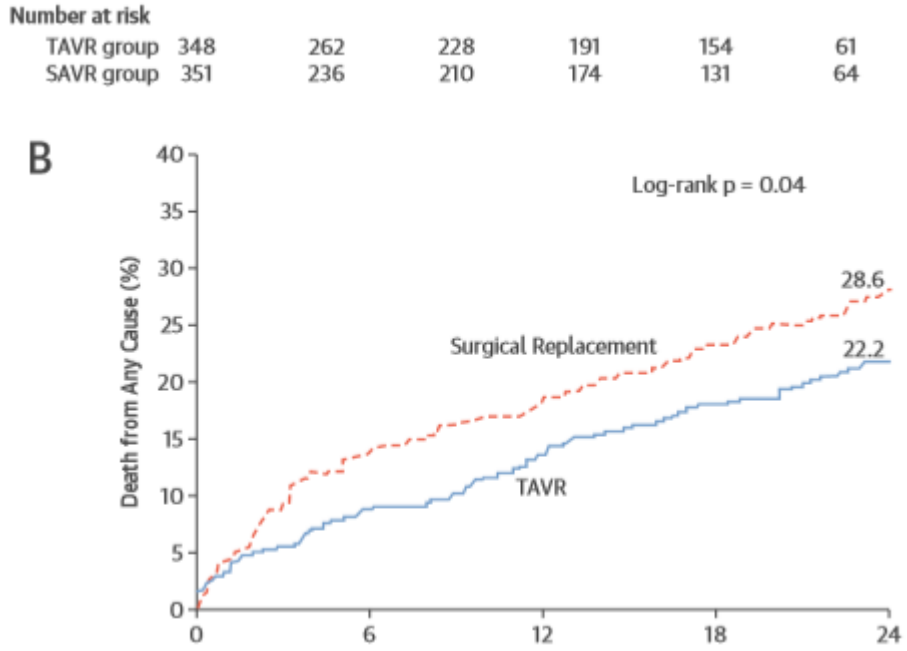


No. at Risk									
None or trace	701	678	664	647	628	621	612	605	585
Mild	210	204	199	194	188	184	182	180	175
Moderate or severe	36	32	32	26	26	24	22	22	21

Effects on Mortality in TAVI PARTNER 1A and Corevalve US Pivotal Trial



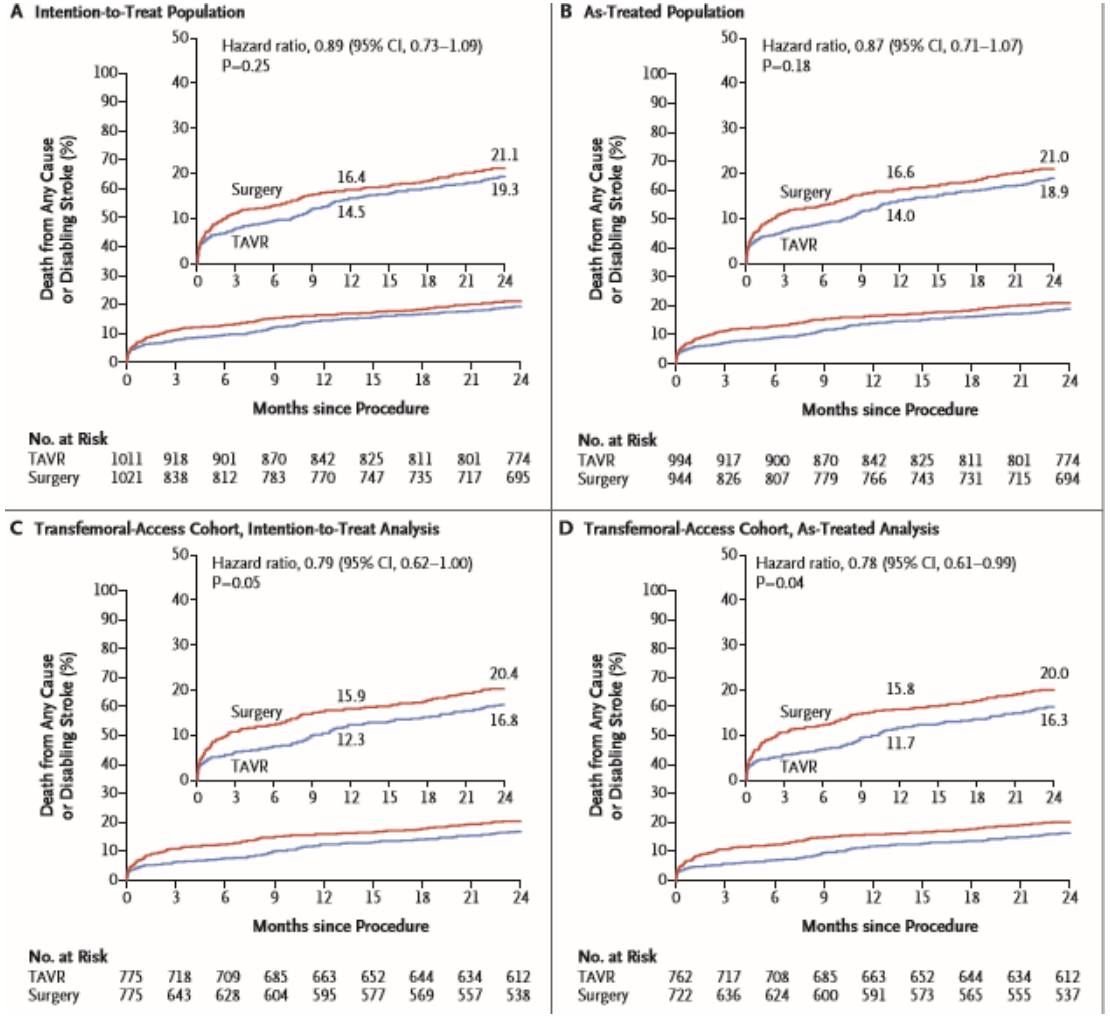
Mack MJ Lancet 2015; 385:2477-84



Reardon MJ. J Am Coll Cardiol 2015;66:113-21

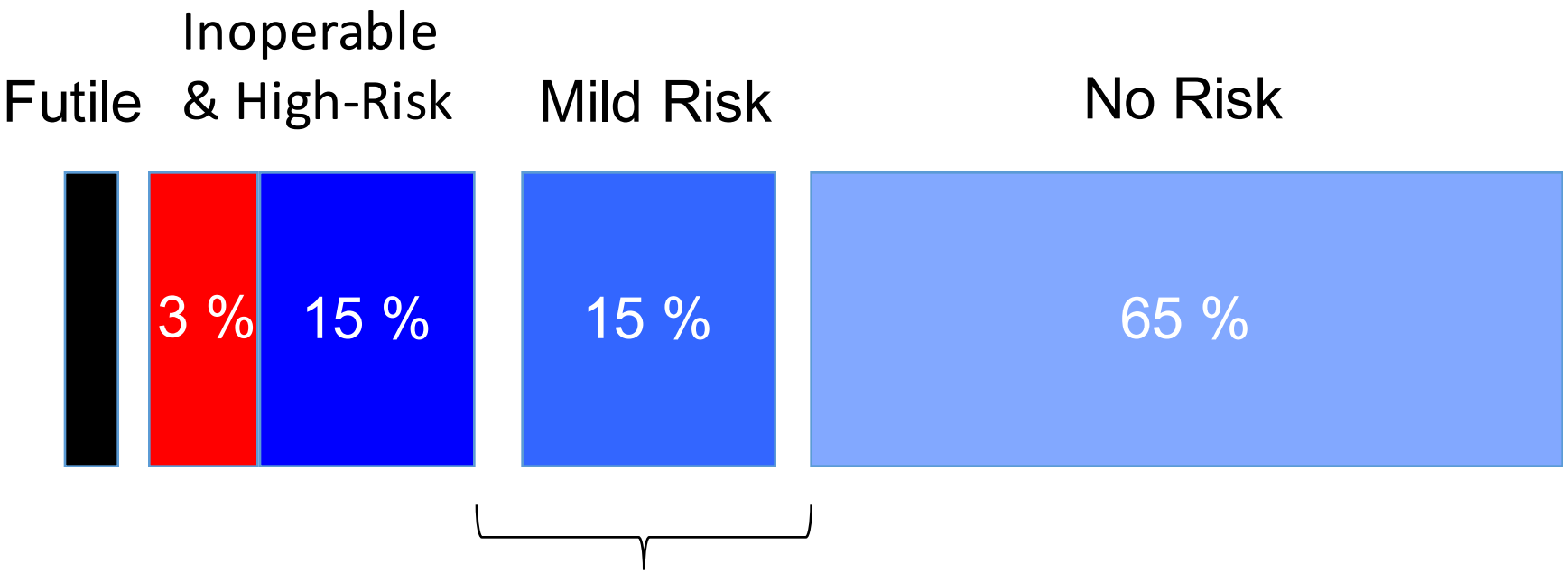
PARTNER 2

Time-to-Event Curves for the Primary Composite End Point



N Engl J Med 2016

Indications of TAVI vs sAVR (2017- ….)



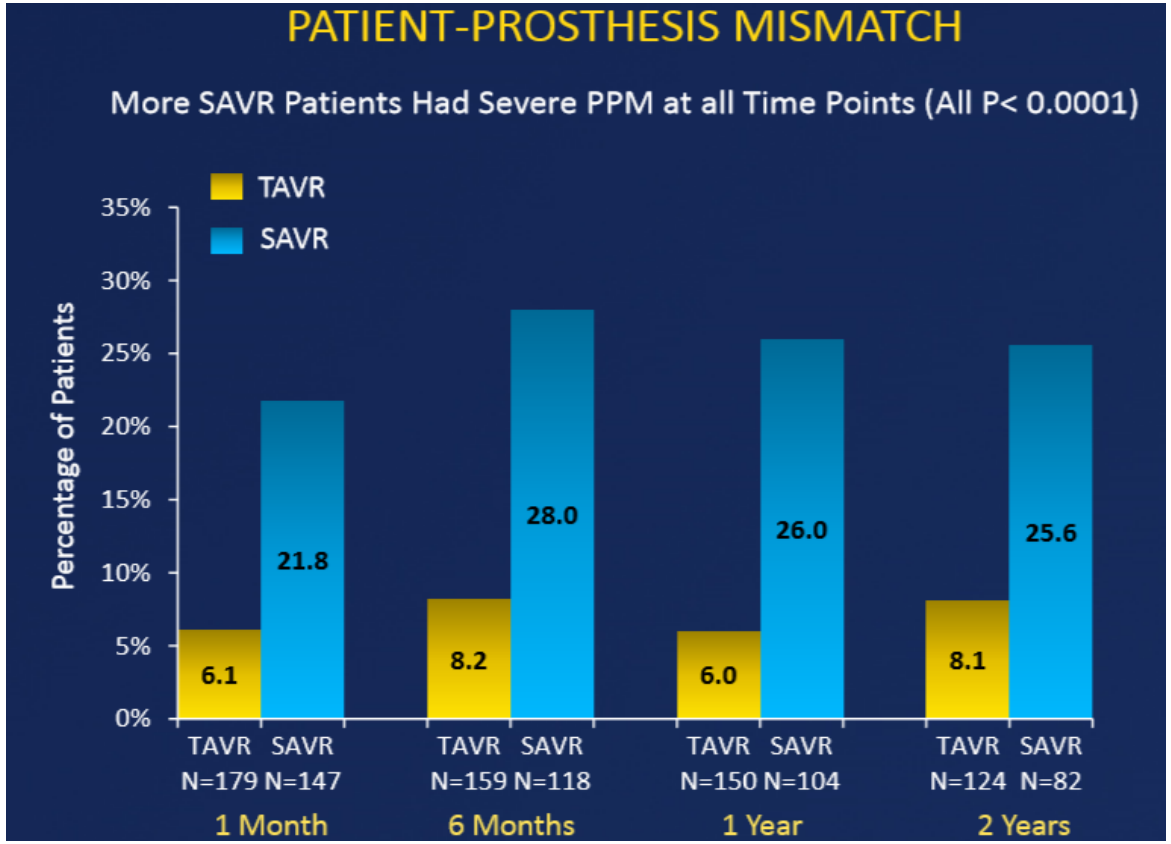
Patients clinical status :

Ongoing Randomized Trials
What we already learned ?

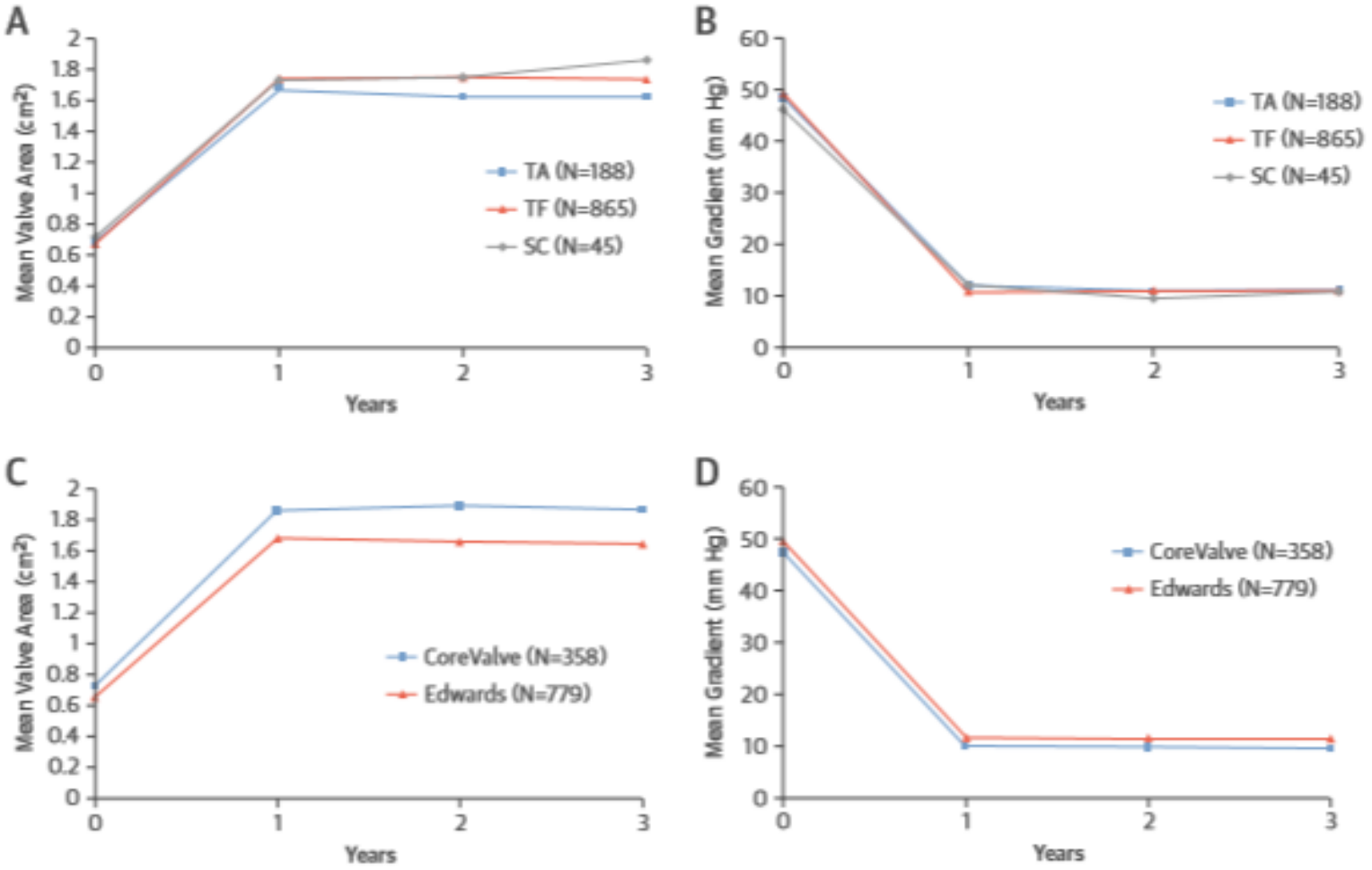
TAVI Corevalve US Pivotal Trial STS ≤ 7@ 2 years

OTHER 2-YEAR CLINICAL OUTCOMES

Event, KM rates (no. of patients)	TAVR N=202	SAVR N=181	P Value
Major stroke	6.1 (12)	10.1 (15)	0.309
Major vascular complication	8.2 (16)	2.2 (4)	0.013
Life-threatening or disabling bleeding	20.2 (44)	34.9 (67)	0.001
Acute kidney injury	5.0 (10)	15.6 (28)	0.0006
New atrial fibrillation/flutter	23.3 (47)	34.8 (63)	0.013
Permanent pacemaker	27.7 (56)	10.5 (18)	<0.0001



Echocardiographic Evaluation of Valve Performance Before and After TAVR and During 3-Year Follow-Up

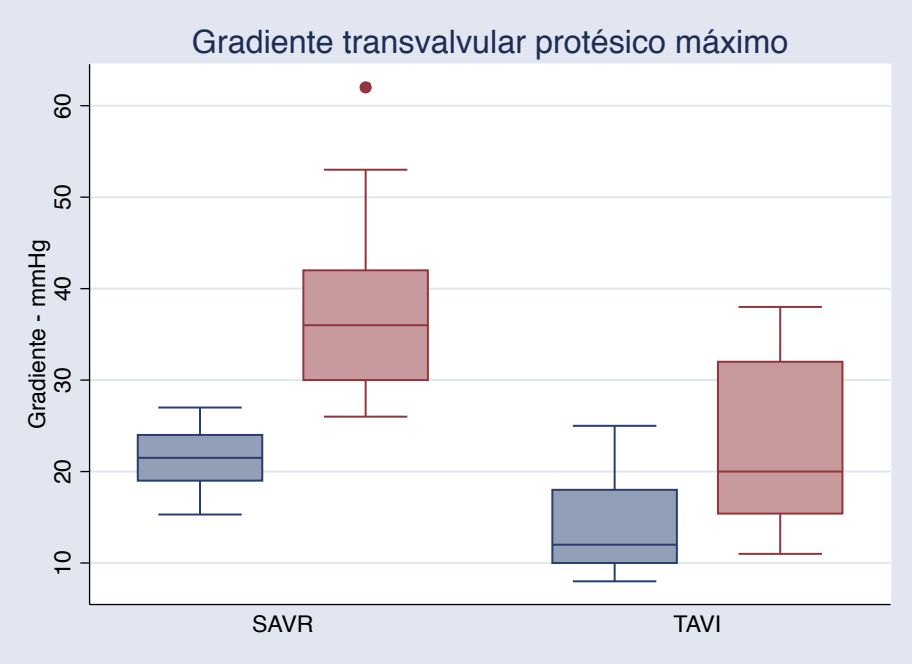


Gilard, M. et al. J Am Coll Cardiol. 2016;68(15):1637–47.

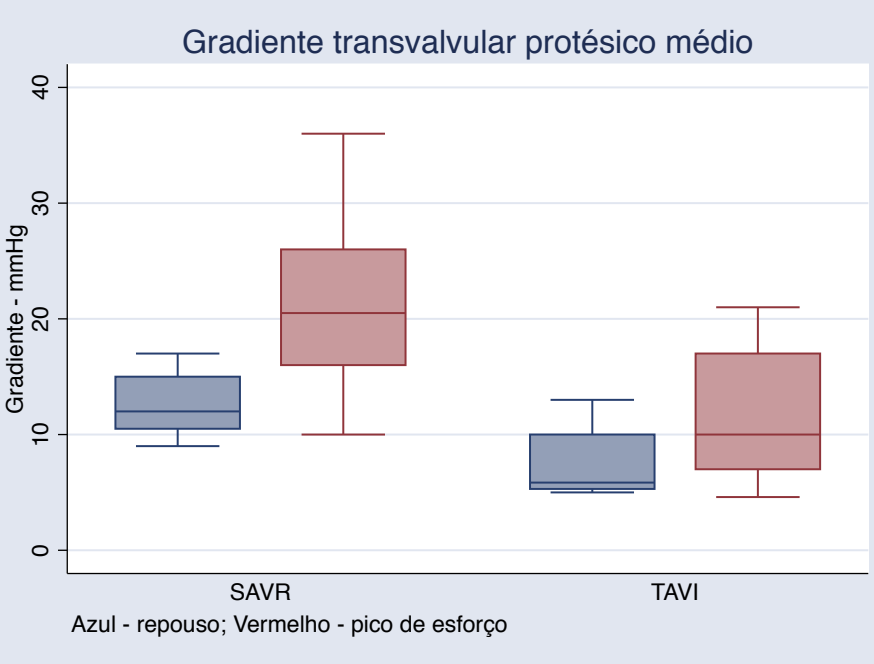
Prostheses Aortic Gradient During Exercise

Hemodynamic Assessment of Percutaneous Versus Surgical Bioprostheses for Aortic Stenosis During Exercise: A Pilot Study

Results



P=0,003 para repouso e p= 0,004 para pico de esforço



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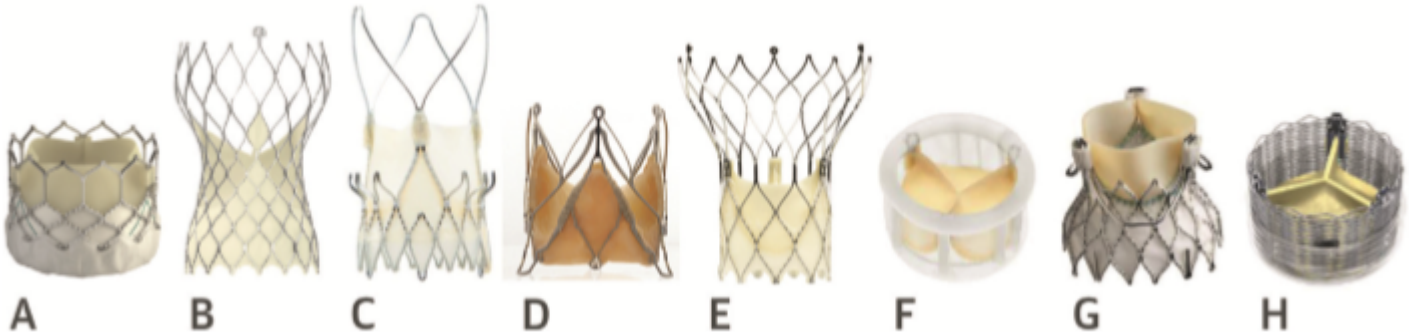
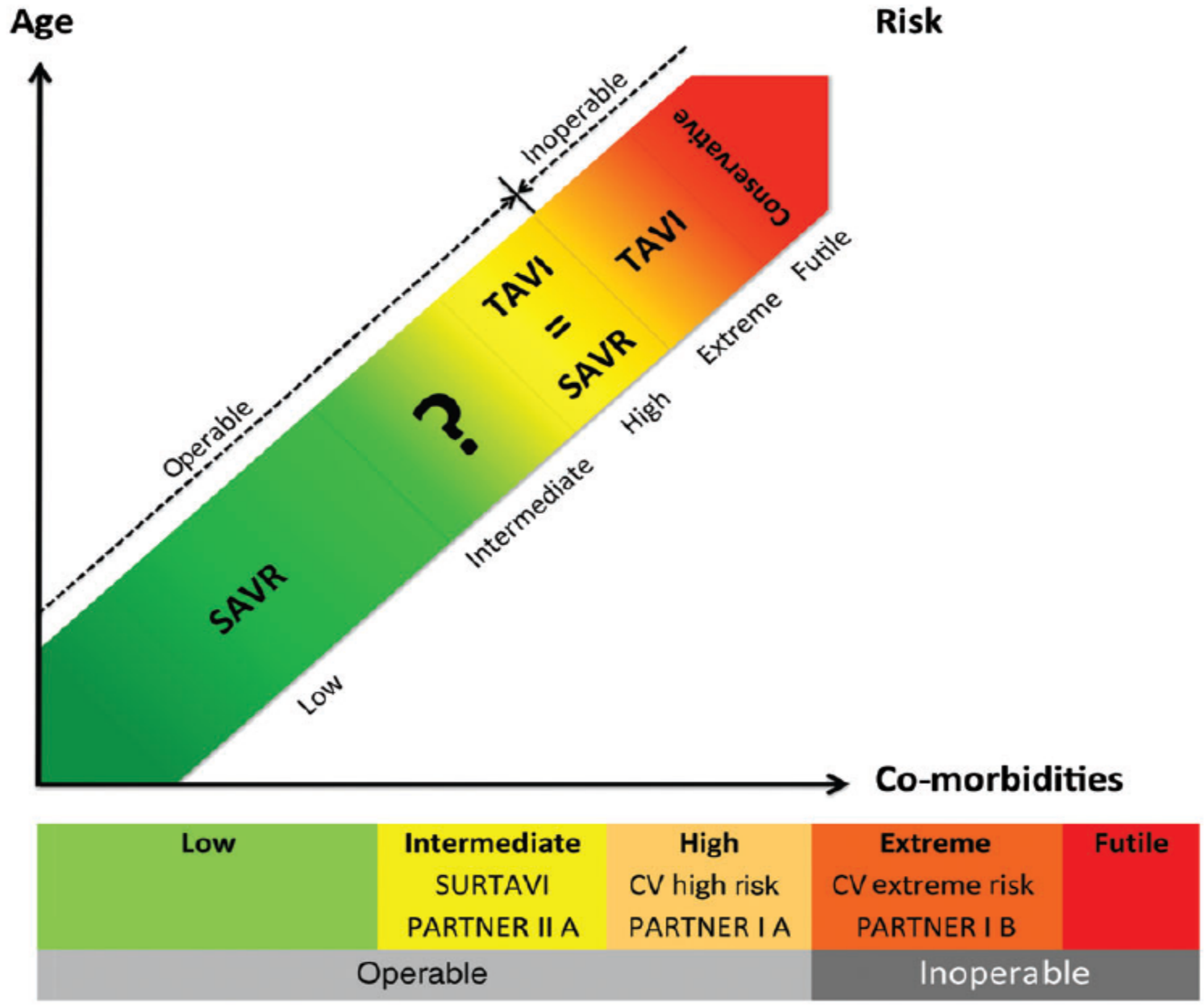
New TAVI Systems



- Lower profiles > 40% reduction
- Improve operator ease of use
- Increase range of valve sizes
- Predictable and precise valve positioning
- Retrievable and repositionable features
- Reduced paravalvular regurgitations

Intermediate risk aortic Stenosis

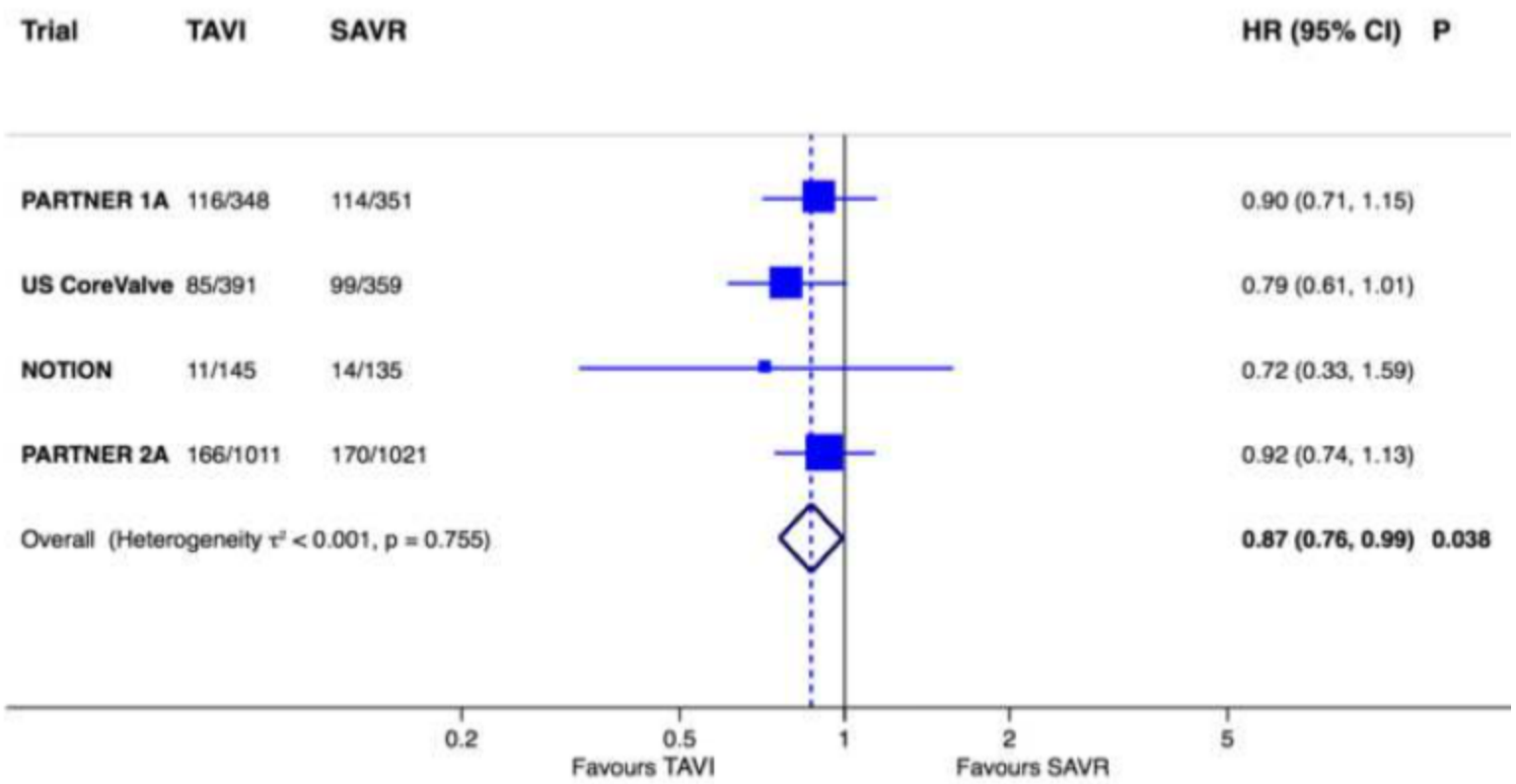


TAVI vs SAVR
Patient Subgroups

Subgroup	Trial	Design	N	Outcome*
High risk	PARTNER 1A	RCT	699	TAVI = SAVR
	CoreValve Pivotal	RCT	795	TAVI > SAVR
Intermediate risk	Partner 2	RCT	2032	TAVI ≥ SAVR (TF)
	CoreValve Pivotal (subgroup)	RCT	383	TAVI > SAVR
	SURTAVI	RCT	1600	?
	S3i	Observational (prop'y matched vs P2 SAVR)	2021	TAVI > SAVR
Low risk	NOTION 1	RCT	280	TAVI = SAVR
	PARTNER 3	RCT	1228	?
	EVOLUT Low risk	RCT	1256	?
	NOTION 2	RCT	992	?

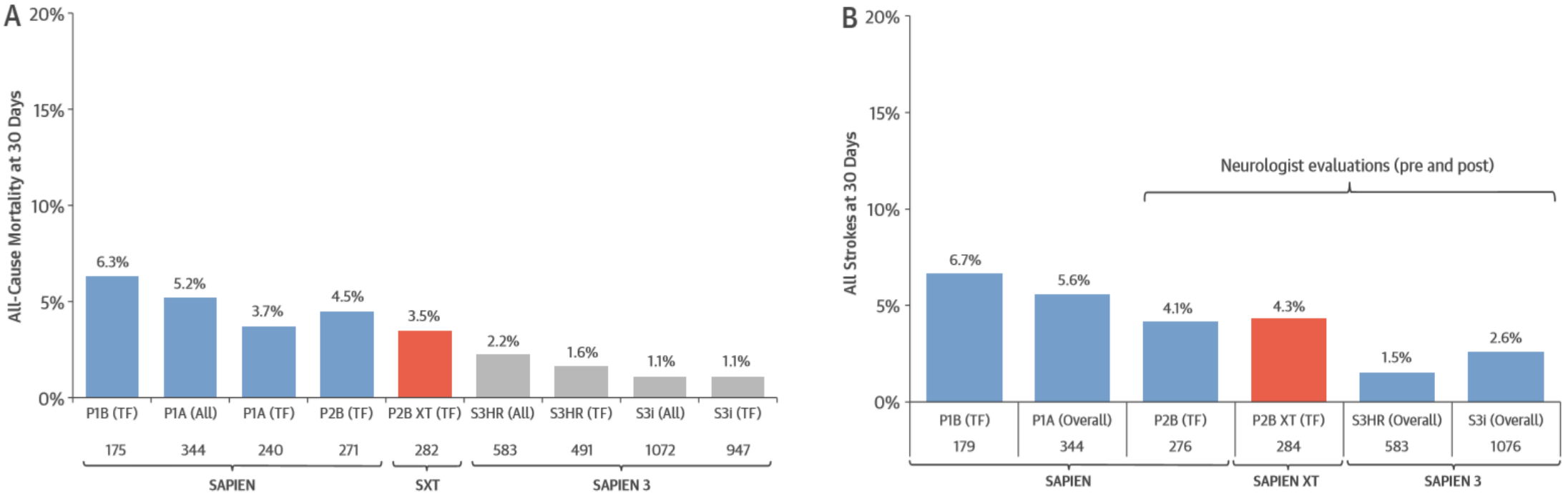
* Death or death/non-fatal stroke

TAVI vs SAVR
RCT – meta-analysis
All cause mortality



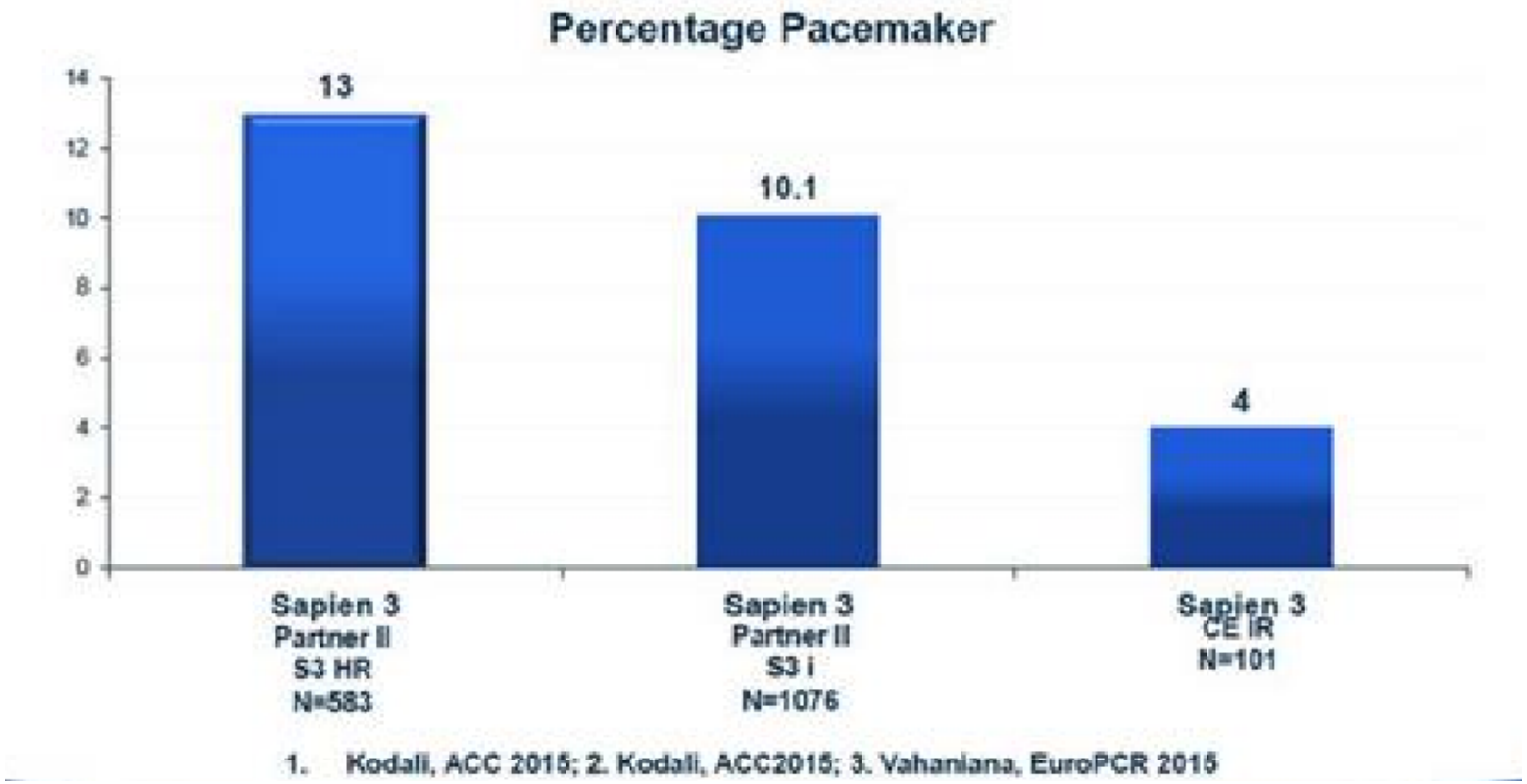
Siontis et al EHJ 2016

Temporal trends of mortality and stroke after TAVI



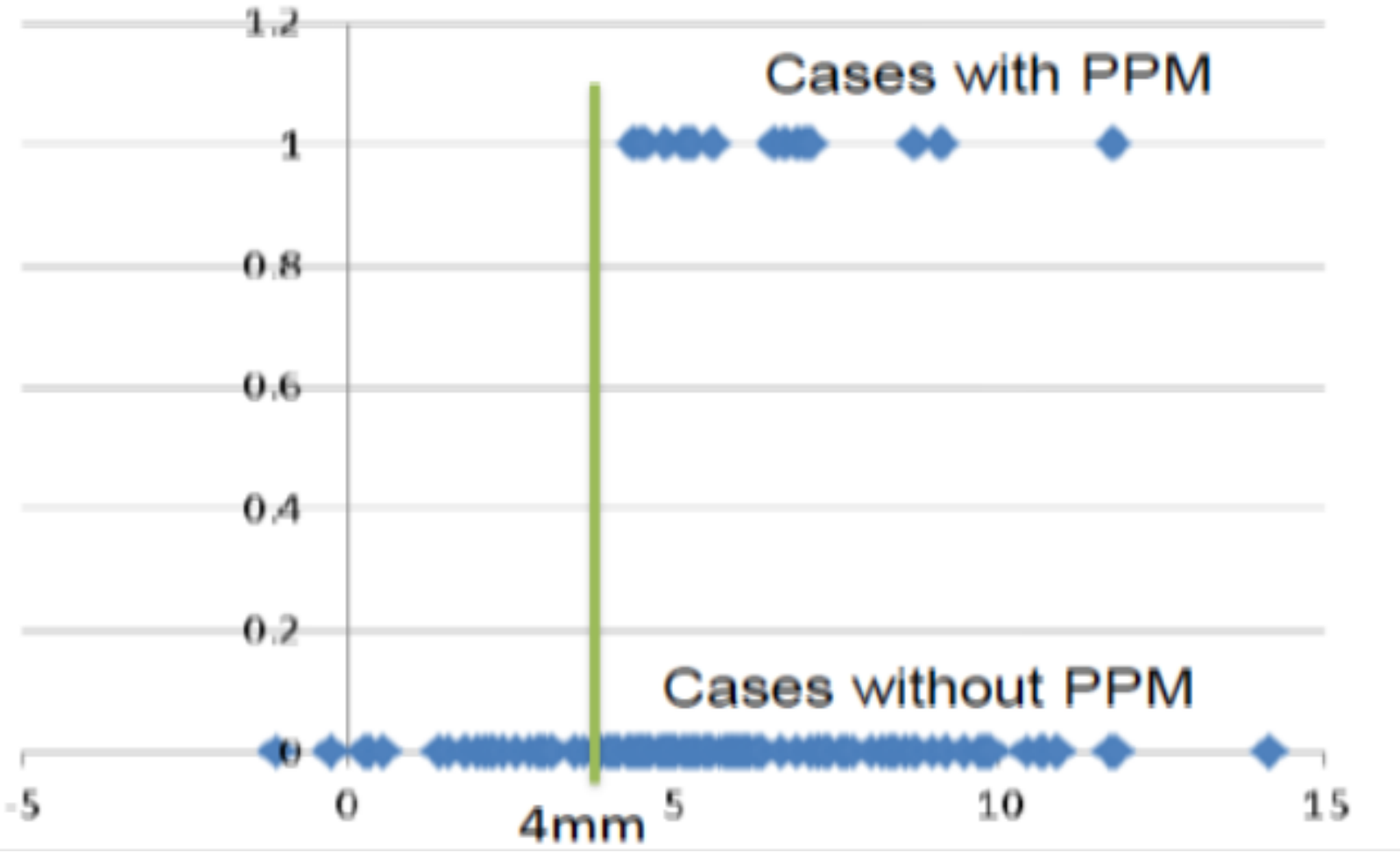
Herrmann HC Thranscatheter Cardiovascular Therapeutics 2015

PPM
Deployment Technique

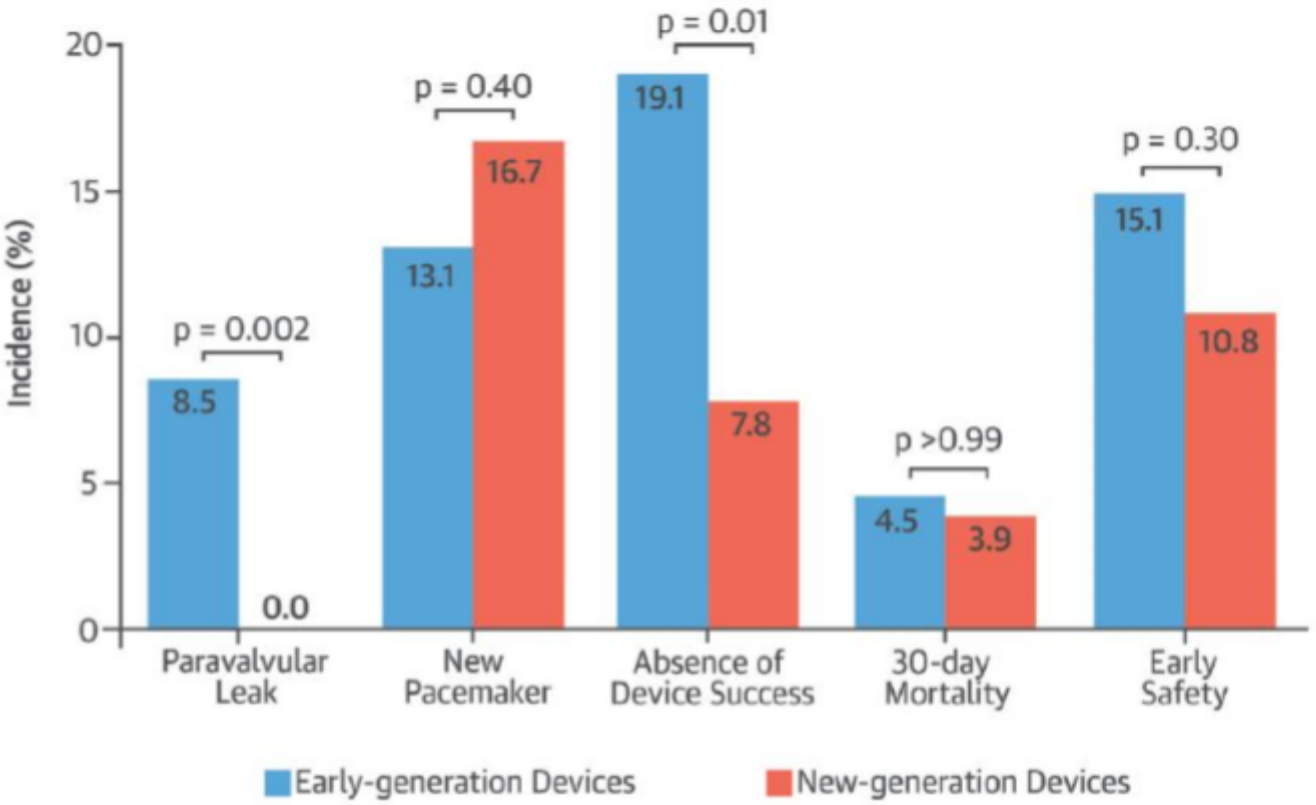


1. Kodali, ACC 2015; 2. Kodali, ACC2015; 3. Vahaniana, EuroPCR 2015

PPM according to frame Depth

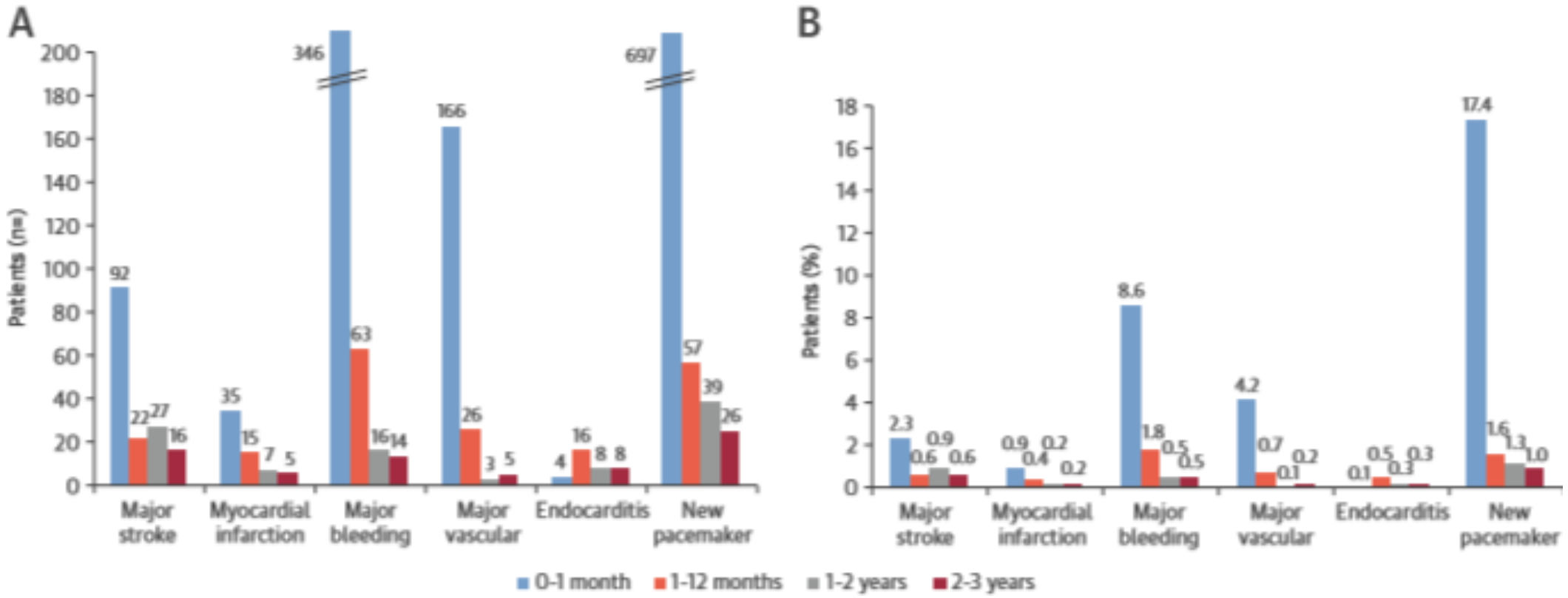


Bicuspid aortic valve



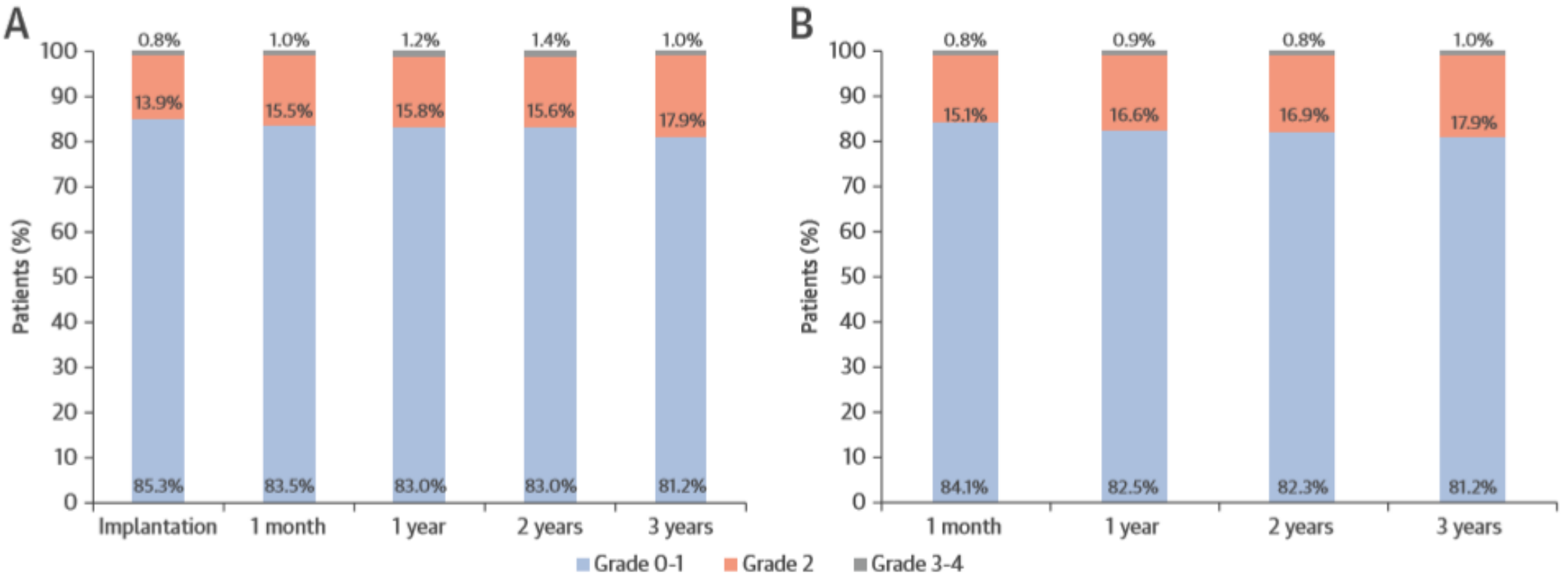
Yoon SH et JACC 2016;68:1195

Cardiovascular Events Occurring at Different Time Periods After TAVR



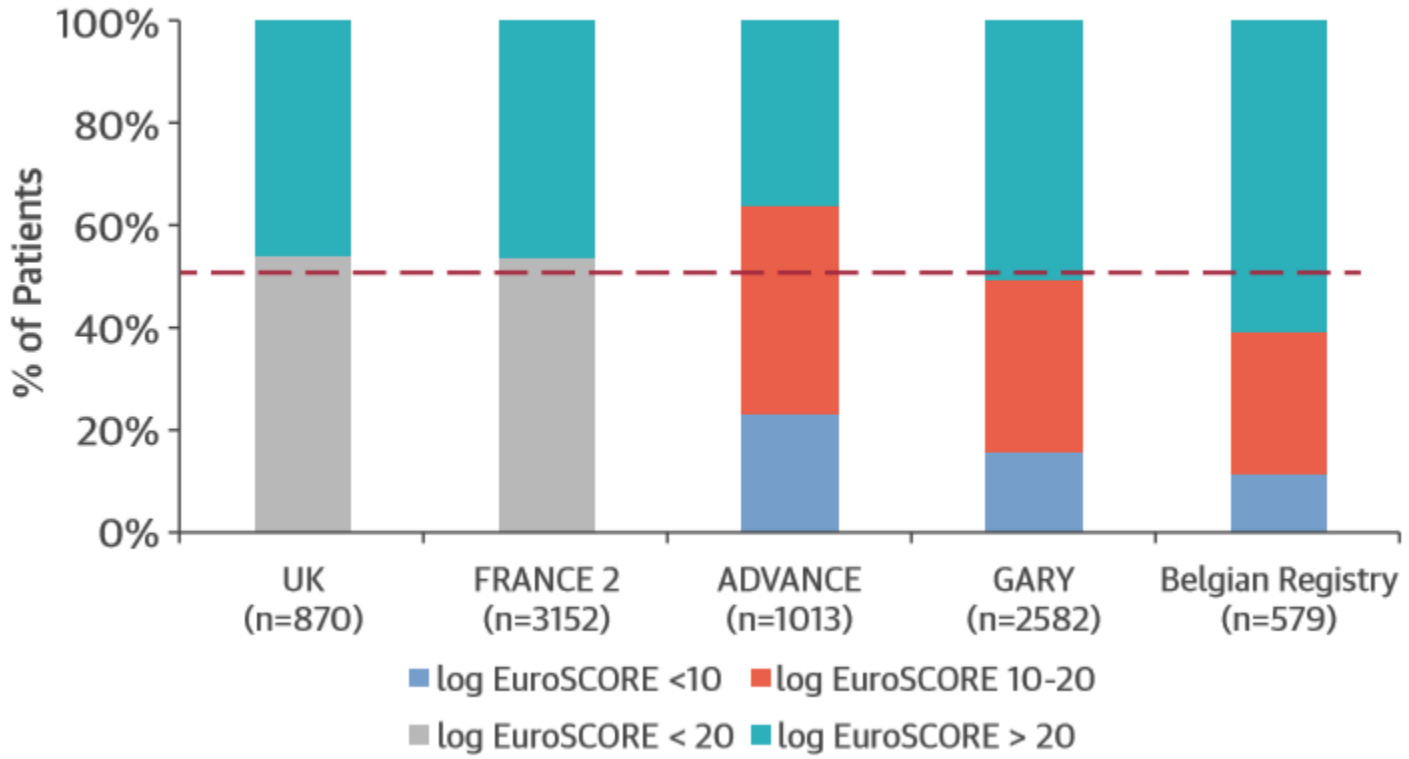
Gilard, M. et al. J Am Coll Cardiol. 2016;68(15):1637–47.

Echocardiographic Evaluation of Periprosthetic AR During Follow-Up



Gilard, M. et al. J Am Coll Cardiol. 2016;68(15):1637–47.

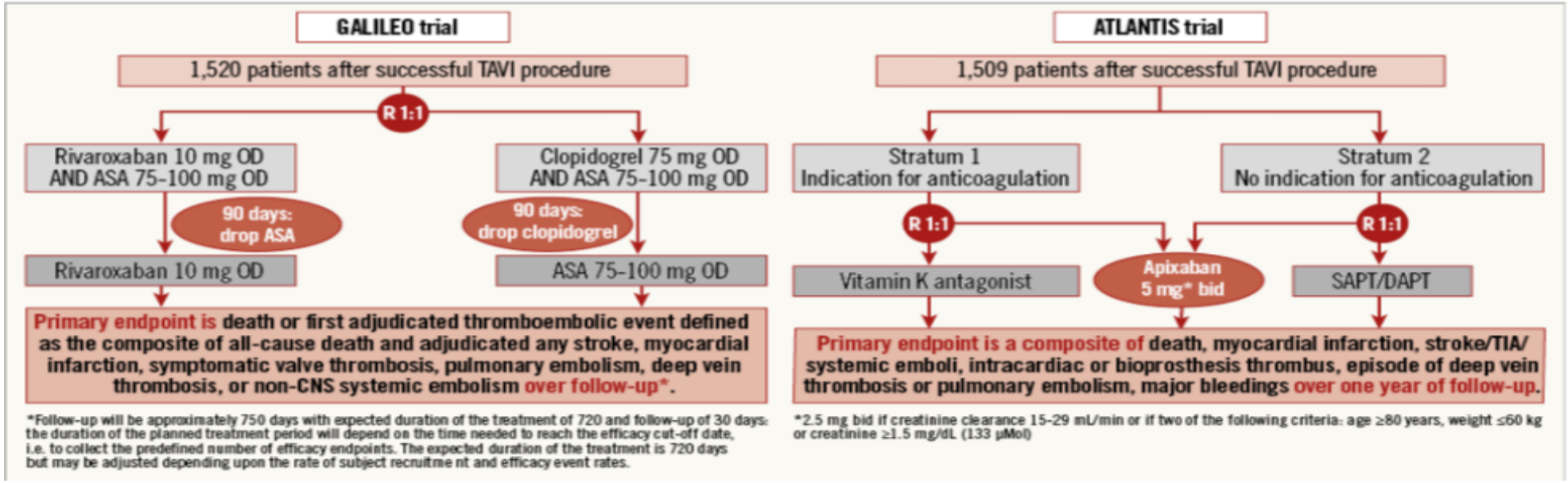
Risk Profile of European TAVI Registries



NOAC Treatment

	European guideline and consensus	AHA/ACC guidelines	ACCF/AATS/SCAI/STS consensus	Canadian Society position statement
Aspirin	Low-dose indefinitely	Low-dose (75-100 mg/day) indefinitely	81 mg/day indefinitely	Low-dose indefinitely
Additional antiplatelet therapy	Thienopyridine early after TAVI	Clopidogrel 75 mg/day for 6 months	Clopidogrel 75 mg/day for 3-6 months	Clopidogrel for 1-3 months
Oral anticoagulation	VKA alone in patients with AF but no CAD (VKA+antiplatelet therapy if AF and recent stent implantation, as per CAD guidelines)		VKA if indicated (no clopidogrel)	VKA if indicated (avoid triple therapy unless definite indication)

AF: atrial fibrillation; CAD: coronary artery disease; TAVI: transcatheter aortic valve implantation; triple therapy: dual antiplatelet therapy plus vitamin K antagonist; VKA: vitamin K antagonist

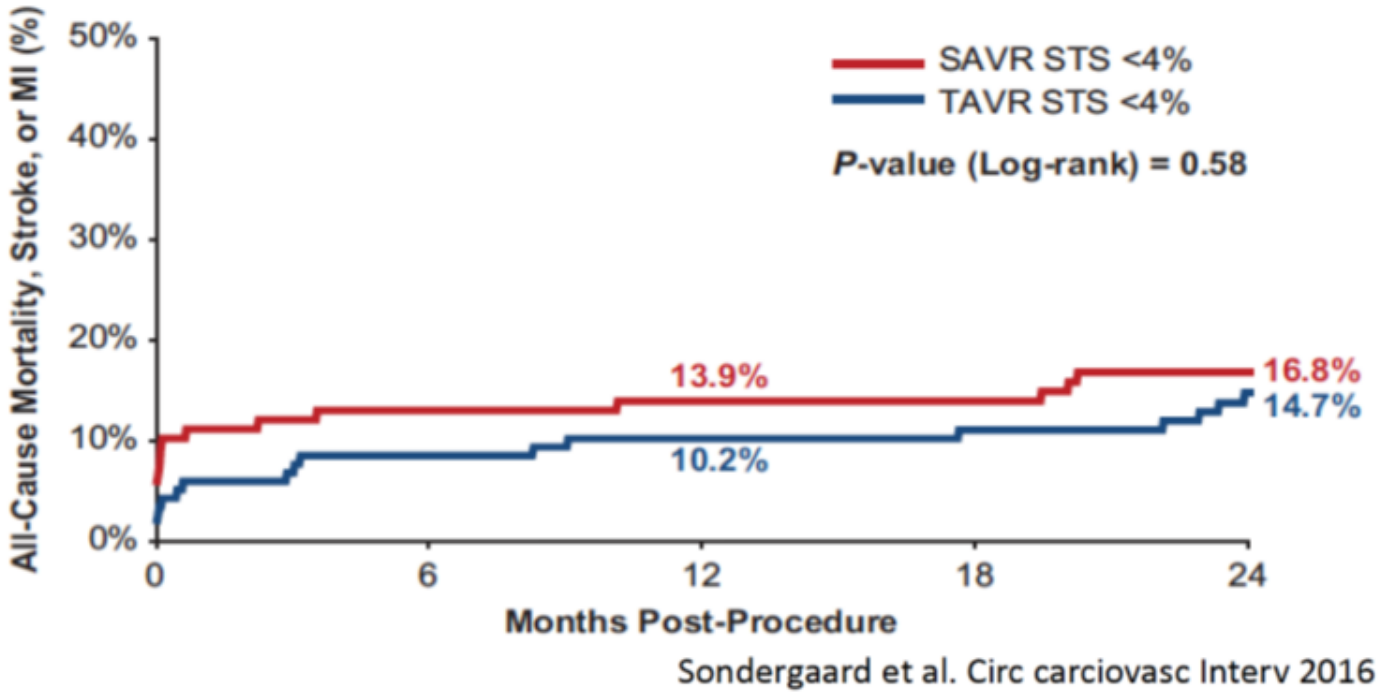


Giuseppe Gargiulo, EuroIntervention.2015 Sep;11 Suppl.

NOTION Trial
Allcomers (TAVI vs sAVR)

All-cause mortality, Stroke or MI

Patients with STS <4% ***(n=220)***



Sondergaard et al. Circ carciovasc Interv 2016

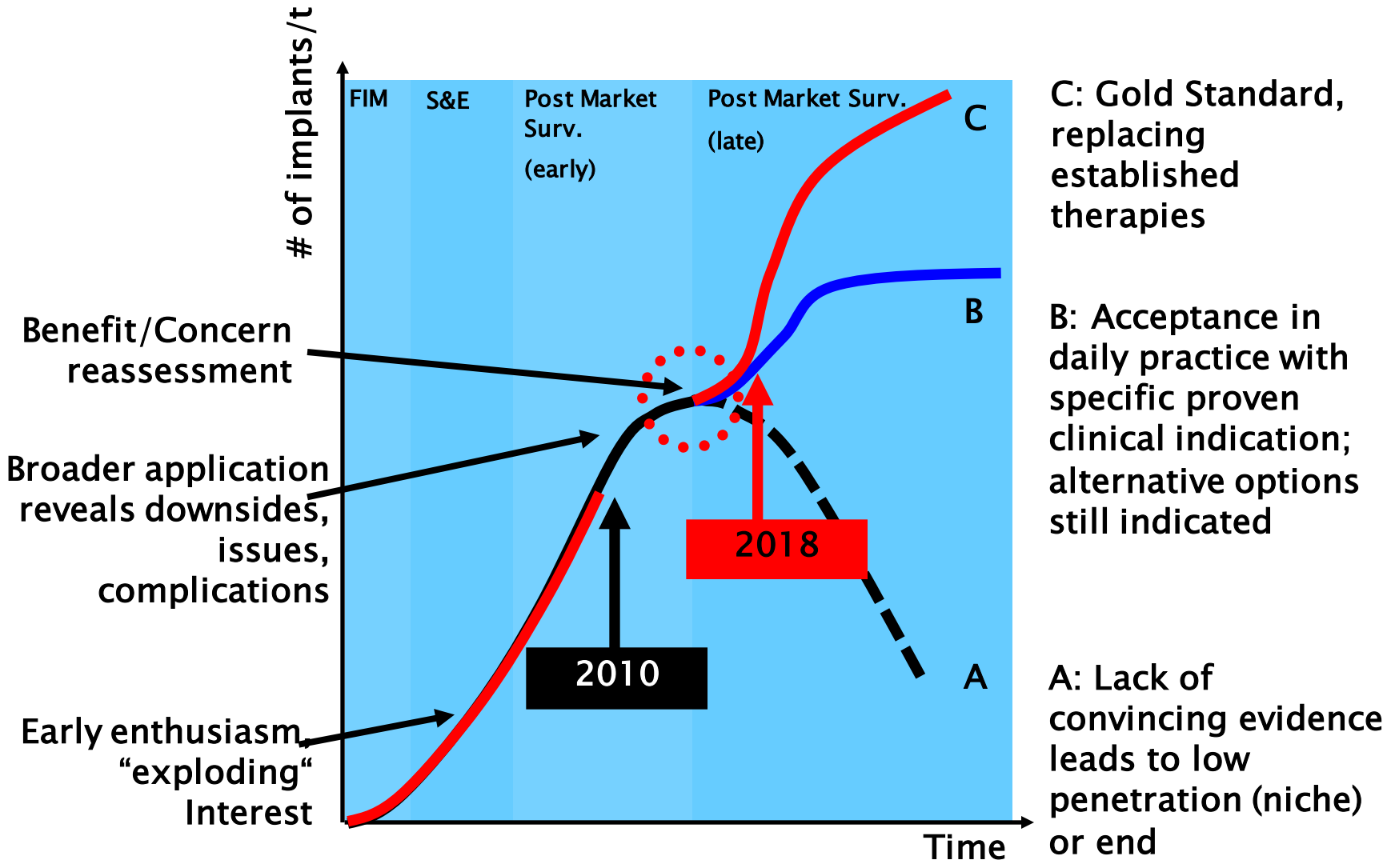
TAVI vs SAVR: Low risk RCTs

- PARTNER 3 (n=1228) 1:1 STS<4, 10yr FU
- Evolut R (n=1256) 1:1 STS<3, 10yr FU
- NOTION 2 (n=992) 1:1 STS<4, age <75yrs

PARTNER 3 Registries

- Bicuspid valve (n=100)
- Valve in Valve (n=100)
- Alternate access (n=100)

General Course of Device Adoption and TAVI experience



C: Gold Standard, replacing established therapies

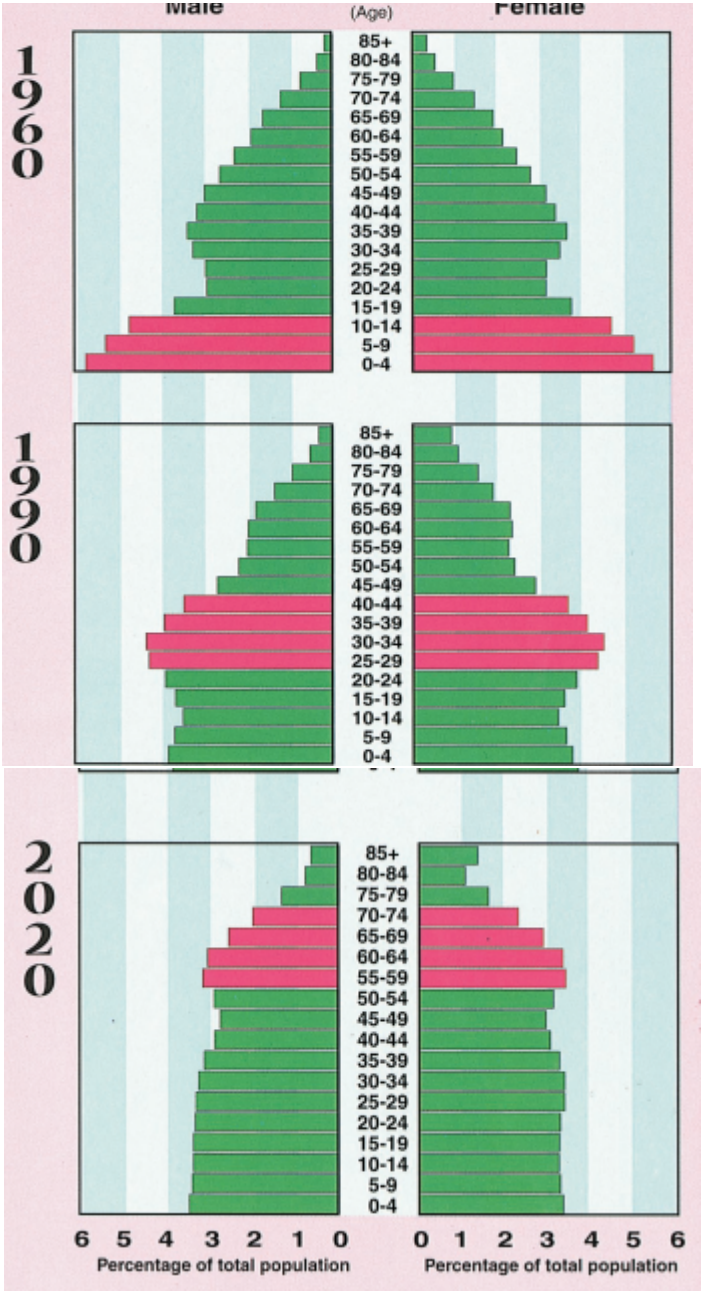
B: Acceptance in daily practice with specific proven clinical indication; alternative options still indicated

A: Lack of convincing evidence leads to low penetration (niche) or end

From Pyramid to Rectangle
The Progression of Aging

By 2020, the Baby Boomers will be pre- and early-retirement ages (55 to 64 years) and the young old ages (65 to 74years).

Between 1990 and 2020, the population age 65 to 74 would grow 74 percent under middle series projections, while the population under age 65 would increase only 24 percent.

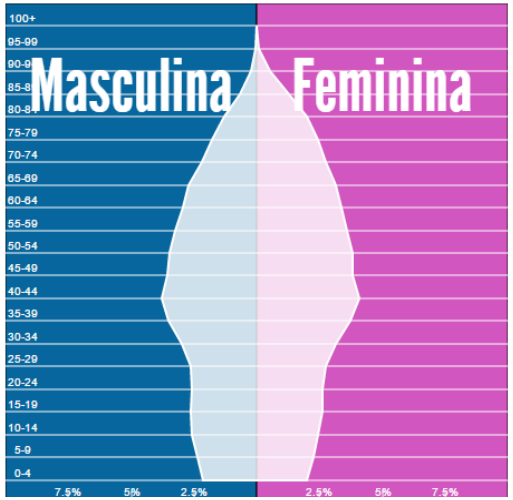


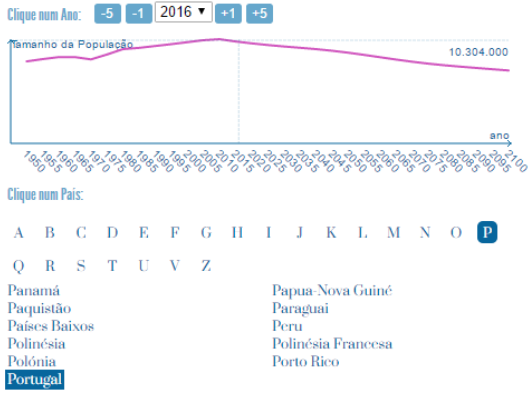
https://www.census.gov/population/international/files/97agewc.pdf

Elderly Boom

Portugal 2016

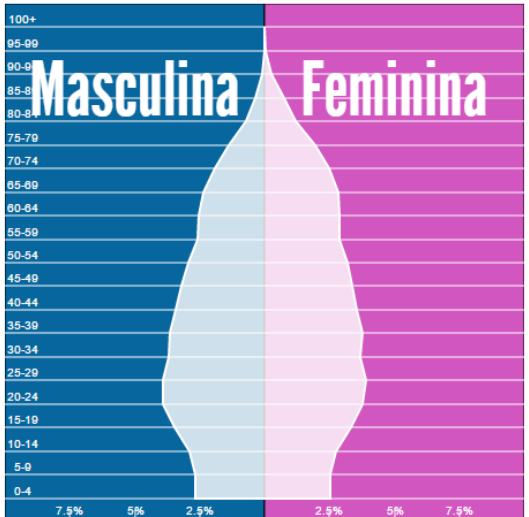
População: 10.304.000

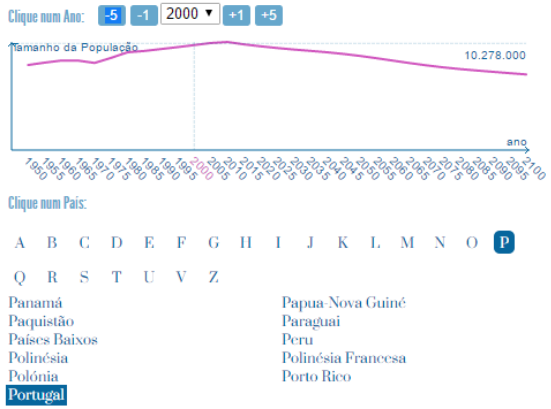




Portugal 2000

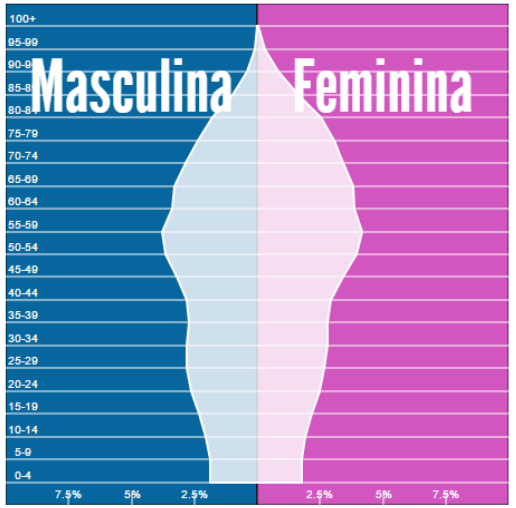
População: 10.278.000

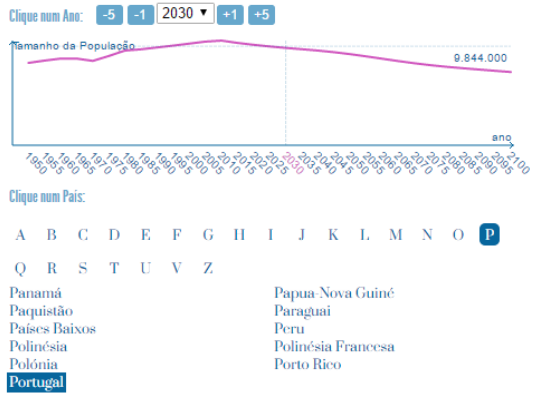




Portugal 2030

População: 9.844.000

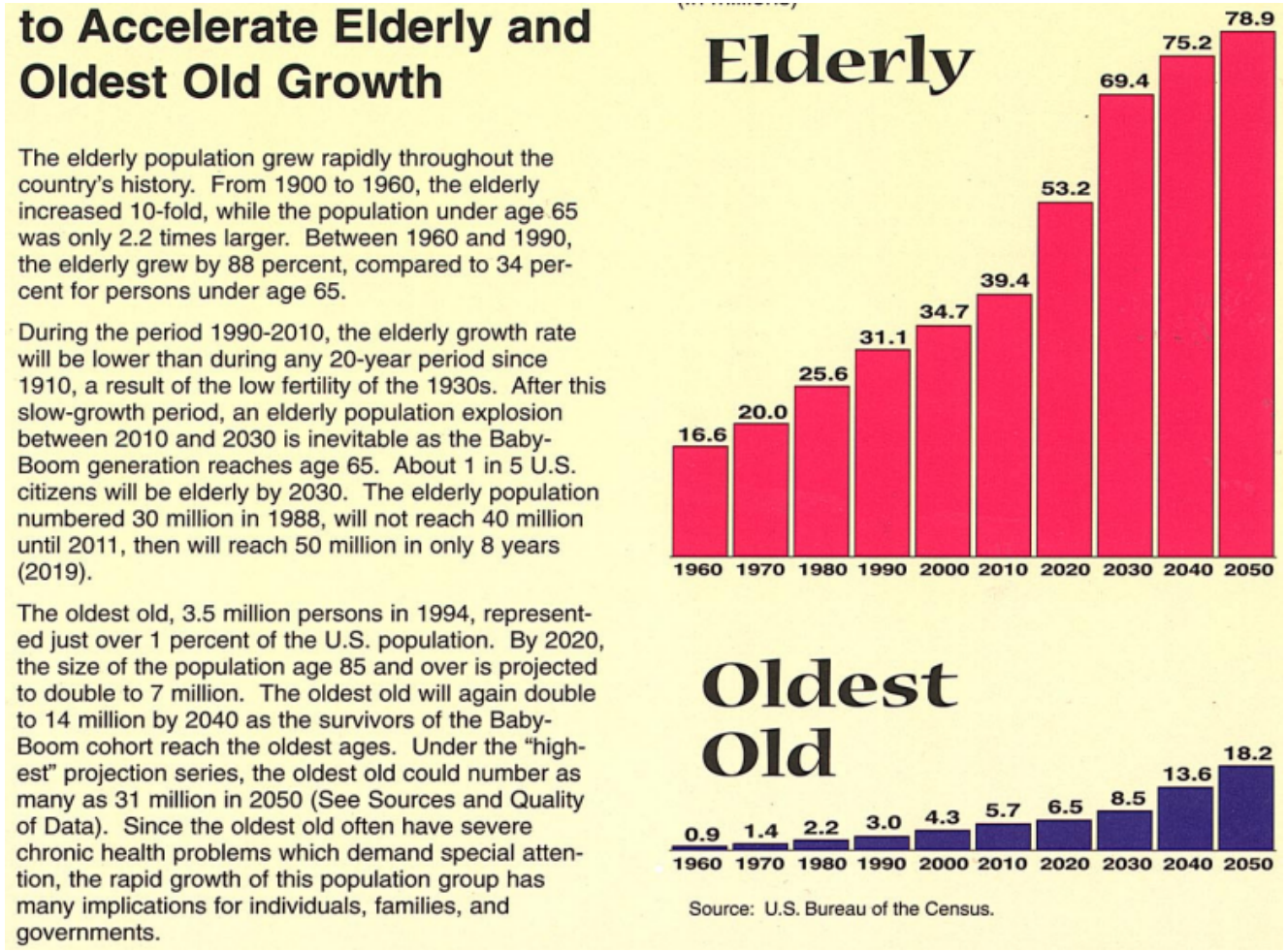




https://populationpyramid.net/pt/portugal/2000/

Elderly and Oldest old Boom

- 50 years old patient: 31.5 years
- 70 years old patient: 14.9 years
- 80 years old patient: 8.7 years
- 90 years old patient: 4.6years



to Accelerate Elderly and Oldest Old Growth

The elderly population grew rapidly throughout the country's history. From 1900 to 1960, the elderly increased 10-fold, while the population under age 65 was only 2.2 times larger. Between 1960 and 1990, the elderly grew by 88 percent, compared to 34 percent for persons under age 65.

During the period 1990-2010, the elderly growth rate will be lower than during any 20-year period since 1910, a result of the low fertility of the 1930s. After this slow-growth period, an elderly population explosion between 2010 and 2030 is inevitable as the Baby-Boom generation reaches age 65. About 1 in 5 U.S. citizens will be elderly by 2030. The elderly population numbered 30 million in 1988, will not reach 40 million until 2011, then will reach 50 million in only 8 years (2019).

The oldest old, 3.5 million persons in 1994, represented just over 1 percent of the U.S. population. By 2020, the size of the population age 85 and over is projected to double to 7 million. The oldest old will again double to 14 million by 2040 as the survivors of the Baby-Boom cohort reach the oldest ages. Under the "highest" projection series, the oldest old could number as many as 31 million in 2050 (See Sources and Quality of Data). Since the oldest old often have severe chronic health problems which demand special attention, the rapid growth of this population group has many implications for individuals, families, and governments.

https://www.census.gov/population/international/files/97agewc.pdf

The New York Times

The Portuguese director Manoel de Oliveira in 1999.

Mr. Oliveira's movies are often described as painterly or theatrical. His camera frame functions as a proscenium, and his actors tend to deliver their lines with a declamatory stiffness, sometimes facing the camera. This mode of direct address is in keeping with Mr. Oliveira's notion of interactive cinema. "Each film must be finished by the spectators," he said. (He also recognizes the comic potential of breaking the fourth wall. In "Abraham's Valley" someone interrupts a monologue on the fall of Western civilization by tossing a cat at the camera.)

WHEN referring to the Portuguese director Manoel de Oliveira, it is now — and has been for some time — customary to affix the phrase "world's oldest active filmmaker." The operative word is "active." Mr. Oliveira, who turns 100 in December, has made at least one movie a year since 1990 (when he was 82). His late-career surge, a gratifyingly long goodbye, defies preconceptions of what an artist's twilight period should be. Mr. Oliveira's undaunted productivity is remarkable, as is the undimmed creative vigor of his films.

Leonor Silveira in Manoel de Oliveira's "Abraham's Valley" (1993), a "Madame Bovary" update made when the director was in his 80s. Madragoa Filmes

But he would be the first to caution against making too much of his longevity. "Nature is very capricious and gives to some what it takes from others," he said. "I see myself being more admired for my age than for my films, which, being good or bad, will always be my responsibility. But I am not responsible for my age."

Multivariable Predictors of 3-Year All-Cause Mortality

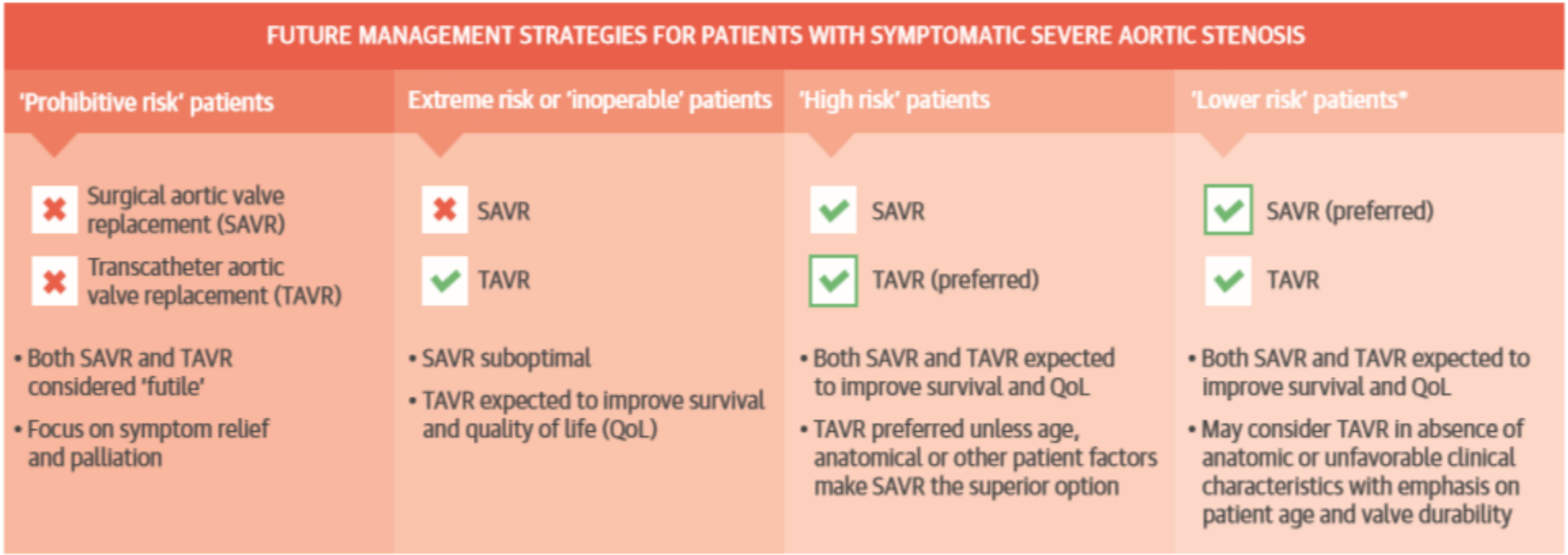
				Univariable Analysis		Multivariable Analysis	
	Patients (n)	Events (n)	3-Yr Death Rate (%)	Unadjusted HR (95% CI)	p Value	Adjusted HR (95% CI)	p Value
Logistic EuroSCORE							
<20	2,341	847	36.9	1.00		1.00	
20-30	936	396	43.2	1.23 (1.10-1.40)	<0.001	1.13 (0.99-1.30)	0.08
>30	917	481	53.4	1.70 (1.52-1.90)	<0.001	1.52 (1.33-1.73)	<0.001
Sex							
Male	2,125	949	45.4	1.00		1.00	
Female	2,076	782	38.5	0.81 (0.73-0.89)	<0.001	0.80 (0.72-0.90)	<0.001
Body mass index, kg/m^2							
≥30	754	283	38.2	1.00		1.00	
18.5-29.9	3,301	1,370	42.3	1.15 (1.02-1.31)	0.03	1.15 (0.99-1.33)	0.08
<18.5	136	71	53.6	1.59 (1.23-2.06)	<0.001	1.76 (1.29-2.40)	<0.001
Dialysis							
No	4,077	1,655	41.4	1.00		1.00	
Yes	107	69	66.1	2.04 (1.61-2.60)	<0.001	1.65 (1.21-2.24)	0.001
Rhythm							
Sinus	3,064	1,140	38.0	1.00		1.00	
Atrial fibrillation	1,079	567	53.3	1.61 (1.46-1.78)	<0.001	1.67 (1.49-1.88)	<0.001
NYHA functional class							
I or II	1,037	345	33.8	1.00		1.00	
III or IV	3,154	1,378	44.6	1.43 (1.27-1.61)	<0.001	1.39 (1.21-1.60)	<0.001
Approach							
Transfemoral	3,064	1,190	39.6	1.00		1.00	
Transapical	735	342	47.7	1.33 (1.18-1.49)	<0.001	1.28 (1.11-1.48)	<0.001
Subclavian	242	132	55.4	1.53 (1.28-1.83)	<0.001	1.50 (1.22-1.85)	<0.001
Type of prosthesis							
Self-expandable	1,413	625	45.1	1.00			
Balloon-expandable	2,774	1,098	40.3	0.88 (0.79-0.97)	0.008	–	–
Need for permanent pacemaker implantation							
No	3,504	1,436	41.4	1.00		1.00	
Yes	697	295	45.4	1.09 (0.96-1.23)	0.18	1.18 (1.02-1.37)	0.02
Post-implant periprosthetic AR grade							
0-1	3,072	1,085	36.0	1.00		1.00	
2-4	529	245	47.1	1.49 (1.29-1.71)	<0.001	1.50 (1.30-1.73)	<0.001
All patients	4,201	1,731					

Gilard, M. et al. J Am Coll Cardiol. 2016;68(15):1637–47.

Risk Assessment
STS Risk Estimate, Frailty, Major Organ System Dysfunction, and Procedure-Specific Impediments

	Low Risk (must meet ALL criteria in this column)	**Intermediate Risk (any 1 criteria in this column)**	**High Risk (any 1 criteria in this column)**	**Prohibitive Risk (any 1 criteria in this column)**
STS PROM	<4% **AND**	4% to 8% **OR**	>8% **OR**	Predicted risk with surgery of death or major morbidity (all-cause) >50% at 1 y **OR**
Frailty	None **AND**	1 index (mild) **OR**	2 or more indices (moderate-to-severe) **OR**	
Major organ system compromise not to be improved postoperatively	None **AND**	1 organ system **OR**	No more than 2 organ systems **OR**	3 or more organ systems **OR**
Procedure-specific impediment	None	Possible procedure-specific impediment	Possible procedure-specific impediment	Severe procedure-specific impediment

TAVR Future Expectations and Barriers



Vahl. T.P. et al. J Am Coll Cardiol. 2016: 67(12):1472–87.

Valve for Life

Missão

Facilitar o acesso dos doentes valvulares ao tratamento percutâneo com vista à redução da morbilidade e mortalidade destes doentes.

Last Remarks

- TAVI has evolved as an important and mature alternative to SAVR for patients with high or prohibitive surgical risk
- Patient screening and procedure techniques have been modified by heart team approach and technical advances
- Expansion of clinical indications will be an important theme for intermediate/low risk patients

Last Remarks

- While the risk and burden of TAVI will continues to decline many patients will continues to have comorbidities and frailty associated with aging, and these patients will define the limits and benefits from TAVI

- The cost associated with TAVI combined with the major increase in the number of patients who are eligible will present enormous challenges to health care budgets around the world

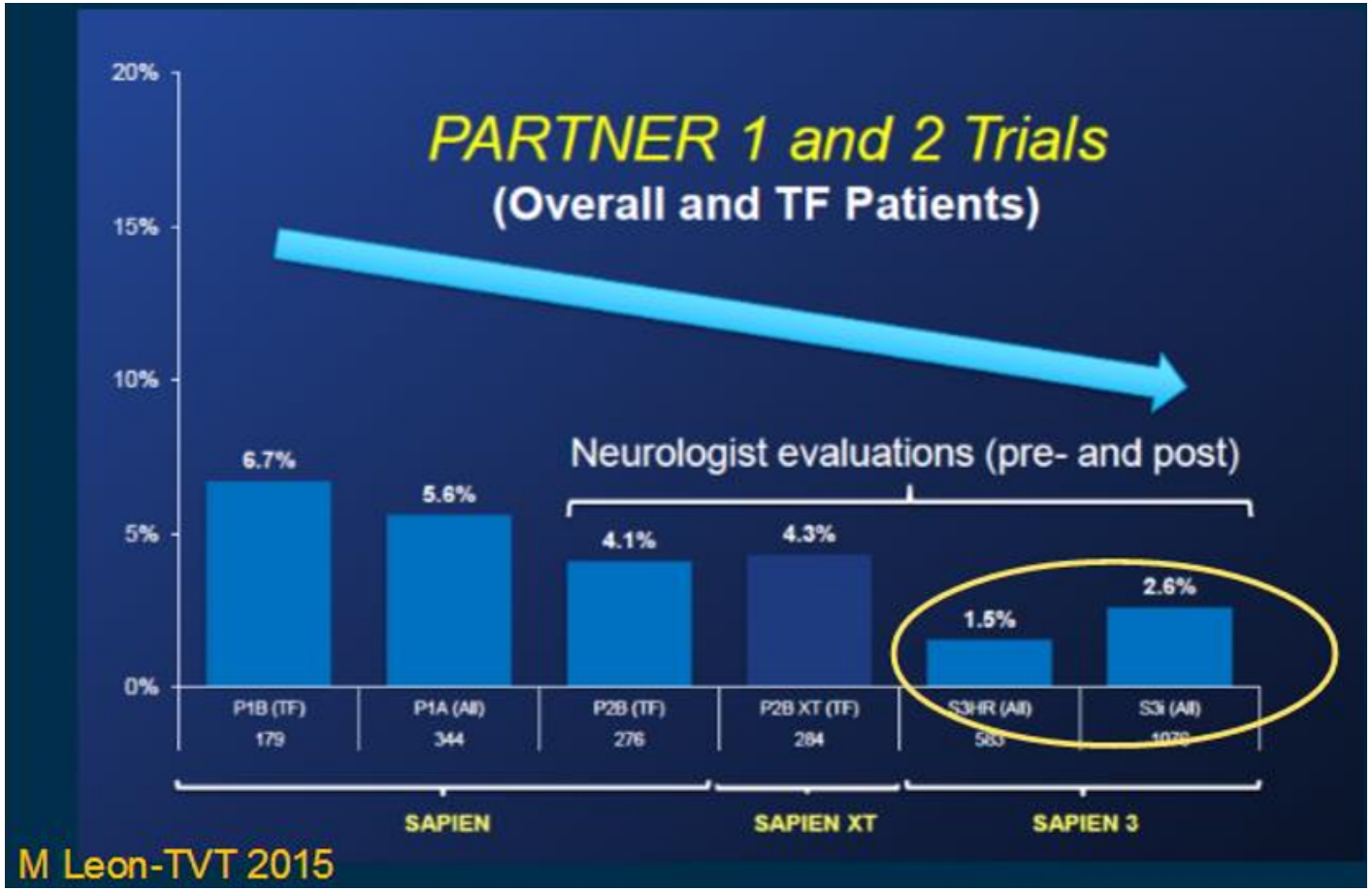
- TAVI is one of the most important advances of modern medical adventure

Life, what is but a dream?

Alice's Adventures in Wonderful Land

Lewis Carroll

Strokes 30 days



Mortality and Stroke in TAVI Corevalve US Pivotal Trial @ 3 years