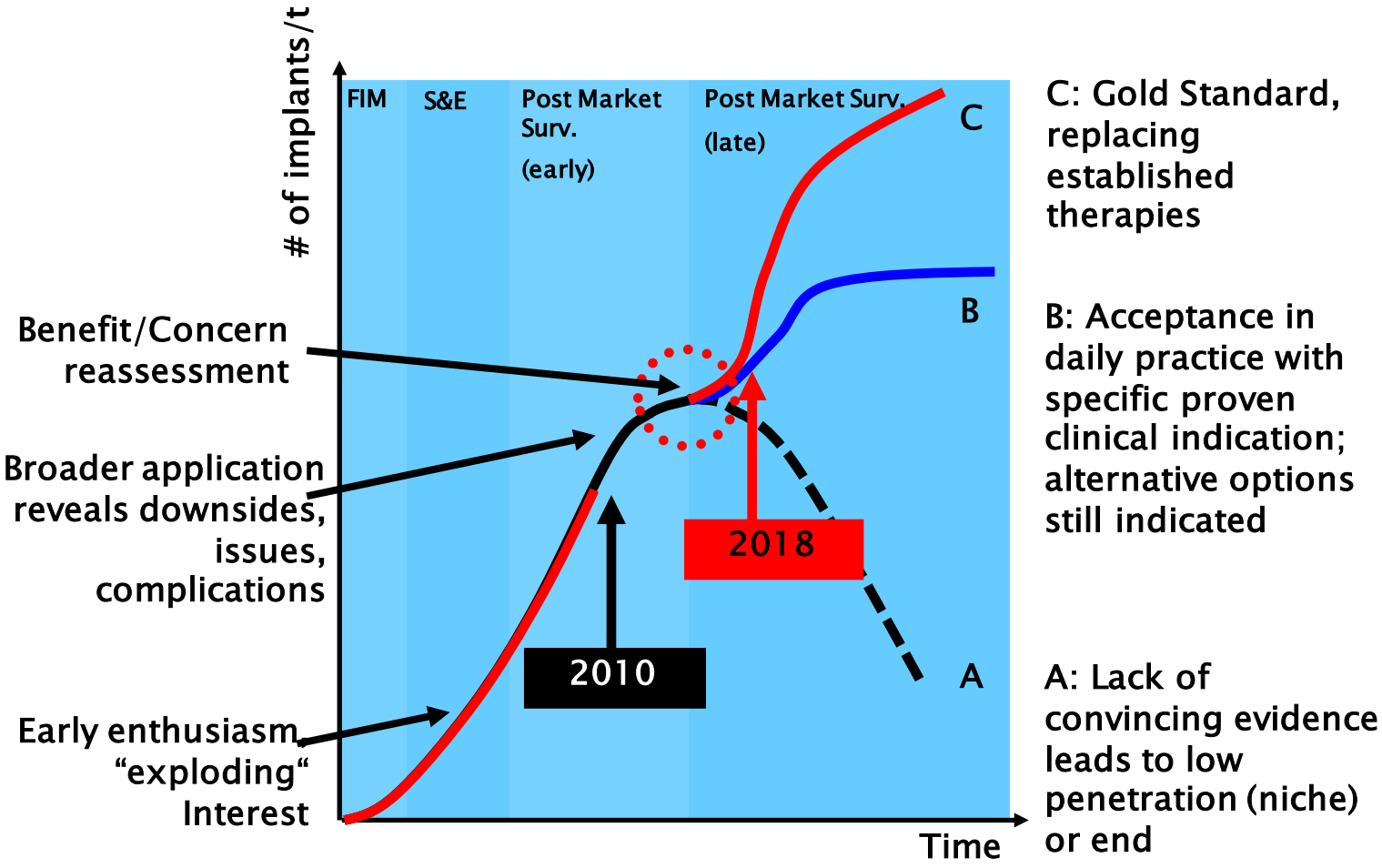
Em 2018 TAVI será o tratamento dominante da estenose aórtica e tornar-se-à o “Gold standart”

In 2018 TAVI will be the leading treatment for aortic stenosis and will become the Gold Standard for the treatment of this disease

**Lino Patrício MD, PhD**
**H.S.Marta - Lisboa**
**H.E.Santo - Évora**

# 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

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 21, 2010 VOL. 363 NO. 17

# 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.)

From Columbia University Medical Center/NewYork–Presbyterian Hospital, New York (M.B.L., C.R.S., J.W.M.); Medical City Dallas, Dallas (M.M., D.L.B.); Stanford University Medical School, Stanford (D.C.M.), and Edwards Lifesciences, Irvine (J.J.A., W.N.A.) — both in California; Cleveland Clinic Foundation, Cleveland (L.G.S., E.M.T.); University of British Columbia and St. Paul's Hospital, Vancouver, Canada (J.G.W.); Cedars–Sinai Medical Center, Los Angeles (G.P.F., R.R.M.); Emory University School of Medicine, Atlanta (P.C.B., R.A.G.); Washington Hospital Center, Washington, DC (A.D.P.); Hospital of the University of Pennsylvania, Philadelphia (J.E.B., H.C.H.); Duke University Medical Center, Durham, NC (P.S.D., J.L.P.); and London School of Hygiene and Tropical Medicine, London (D.W., S.P.). Address reprint requests to Dr. Leon at Columbia University Medical Center/NewYork–Presbyterian Hospital, 173 Fort Washington Ave., Heart Center, 2nd Fl., New York, NY 10032, or at ml2398@columbia.edu.

*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.

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The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JUNE 9, 2011 VOL. 364 NO. 23

# 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

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D., Raj R. Makkar, M.D., Lars G. Svensson, M.D., Ph.D., Susheel K. Kodali, M.D., Vinod H. Thourani, M.D., E. Murat Tuzcu, M.D., D. Craig Miller, M.D., Howard C. Herrmann, M.D., Darshan Doshi, M.D., David J. Cohen, M.D., Augusto D. Pichard, M.D., Samir Kapadia, M.D., Todd Dewey, M.D., Vasilis Babaliaros, M.D., Wilson Y. Szeto, M.D., Mathew R. Williams, M.D., Dean Kereiakes, M.D., Alan Zajarias, M.D., Kevin L. Greason, M.D., Brian K. Whisenant, M.D., Robert W. Hodson, M.D., Jeffrey W. Moses, M.D., Alfredo Trento, M.D., David L. Brown, M.D., William F. Fearon, M.D., Philippe Pibarot, D.V.M., Ph.D., Rebecca T. Hahn, M.D., Wael A. Jaber, M.D., William N. Anderson, Ph.D., Maria C. Alu, M.M., and John G. Webb, M.D., for the PARTNER 2 Investigators*

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 mleon@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.

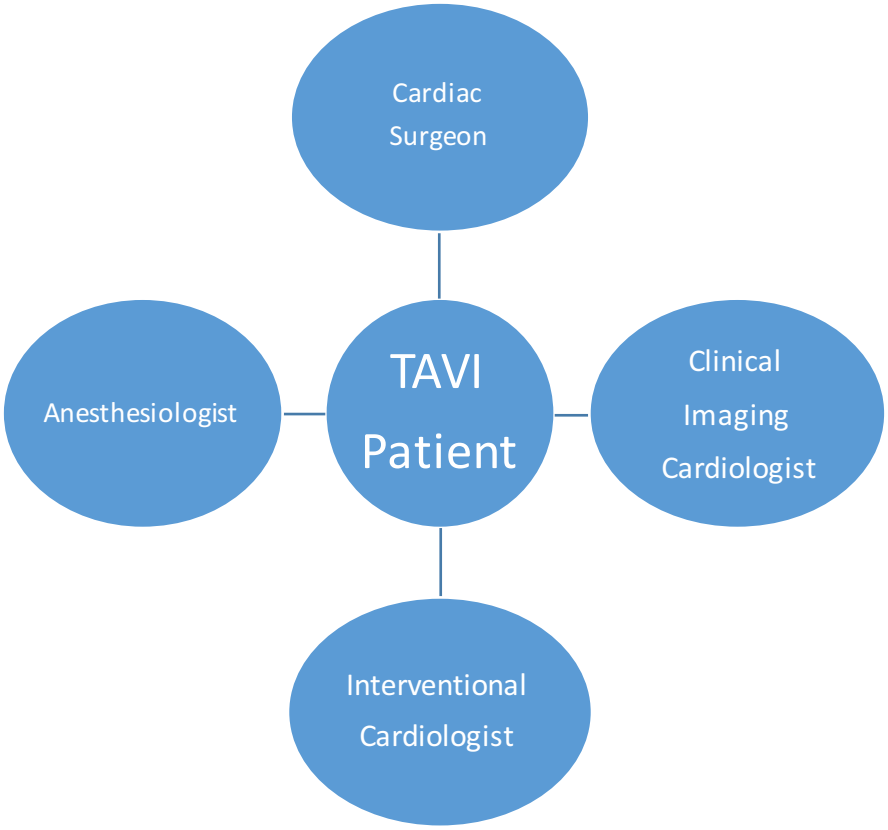
This article was published on April 2, 2016, at NEJM.org.

DOI: 10.1056/NEJMoa1514616

# 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



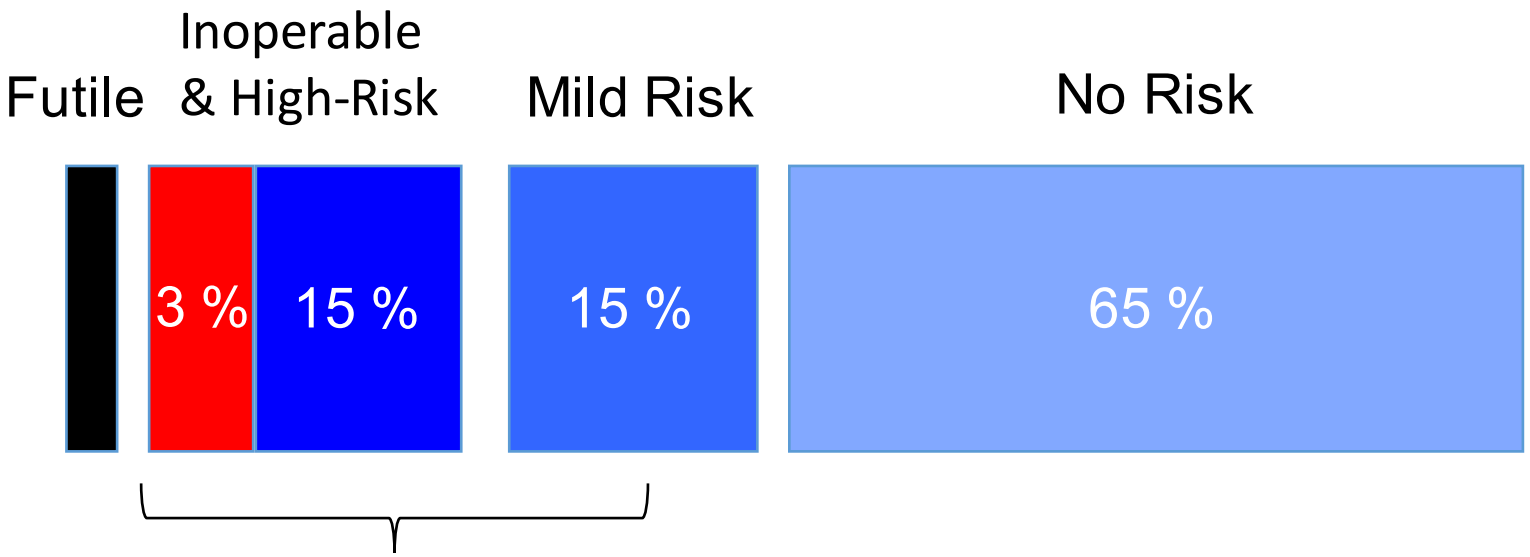
## TAVI the Gold Standard in a new world

- **Population ageing and management of multimorbidities**
- **Development and Adoption of medical imaging techniques**
- **Simplicity of processes and control of costs**

# TAVI the Gold Standard in a new world

- **Population ageing and management of multimorbidities**
- **Development and Adoption of medical imaging techniques**
- **Simplicity of processes and control of costs**

# Indications of TAVI vs sAVR (2007-2018)



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.)

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."

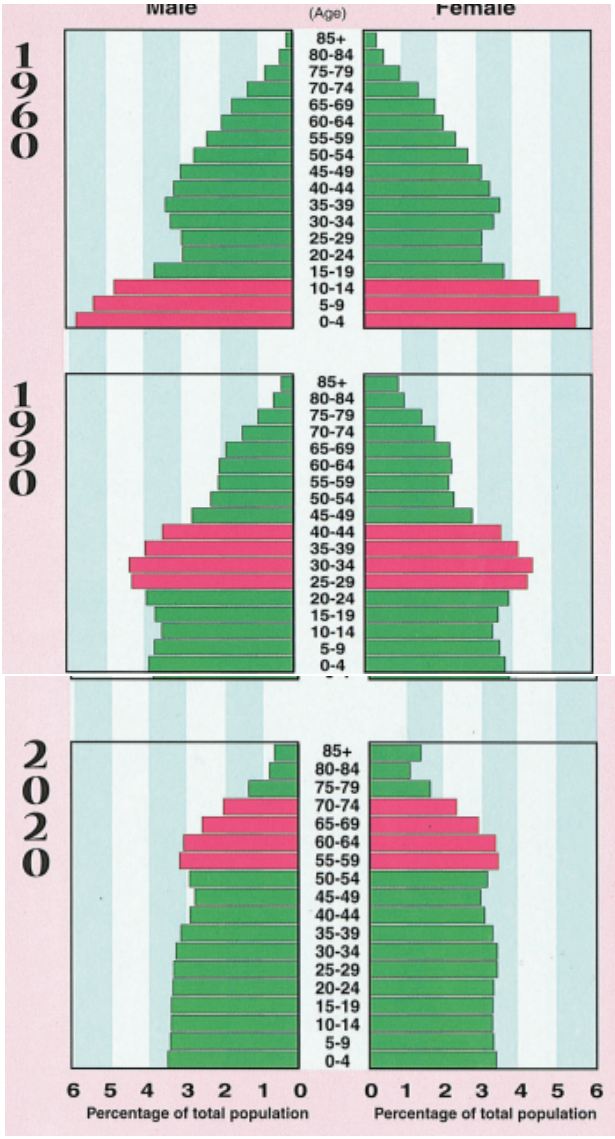
WHEN referring to the Portuguese director Manoel de Oliveira, it is now — and has been for some time — customary to affix the phrase "world's oldest active filmmaker." The operative word is "active." Mr. Oliveira, who turns 100 in December, has made at least one movie a year since 1990 (when he was 82). 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

# 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).

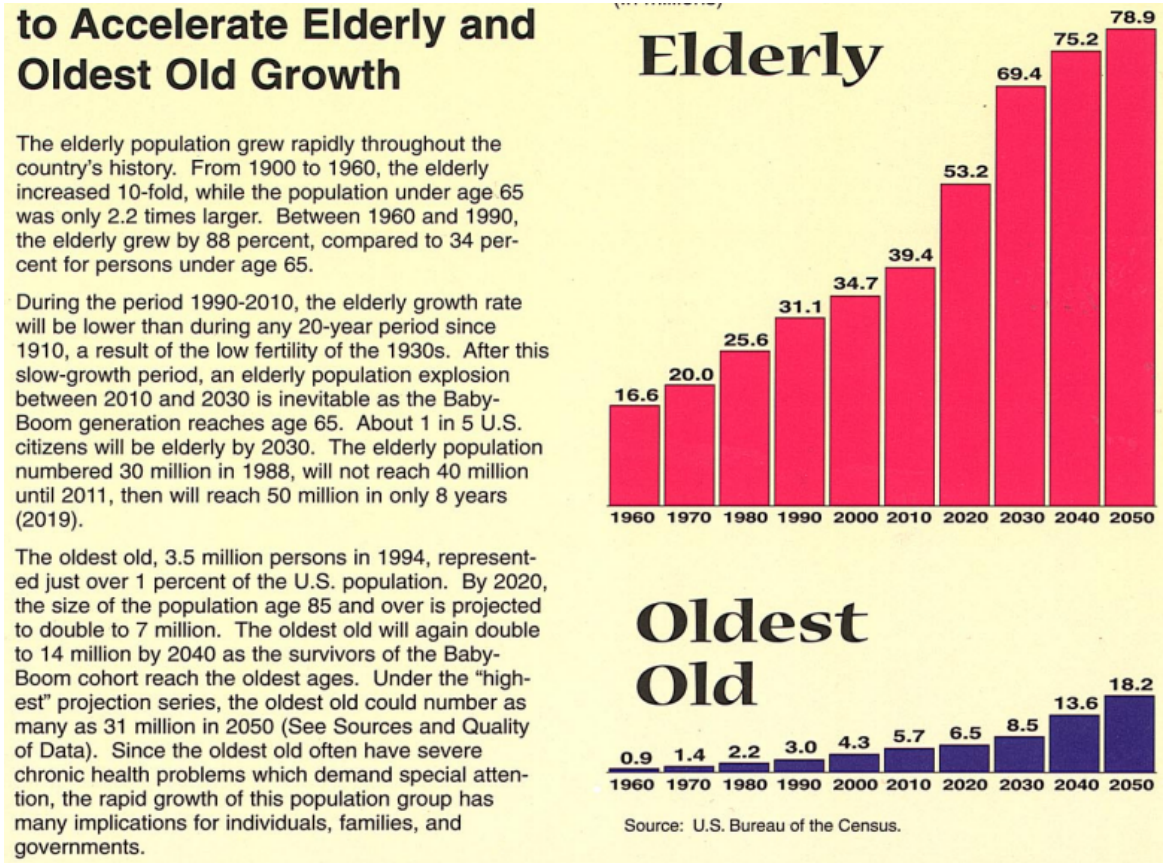
Between 1990 and 2020, the population age 65 to 74 would grow 74 percent under middle series projections, while the population under age 65 would increase only 24 percent.




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

# Elderly 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.

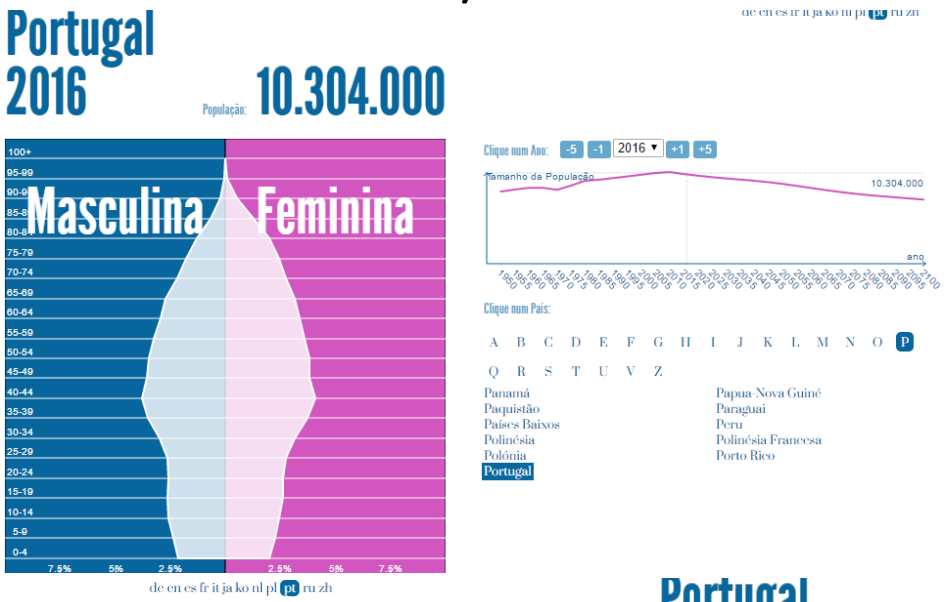
During the period 1990-2010, the elderly growth rate will be lower than during any 20-year period since 1910, a result of the low fertility of the 1930s. After this slow-growth period, an elderly population explosion between 2010 and 2030 is inevitable as the Baby-Boom generation reaches age 65. About 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).

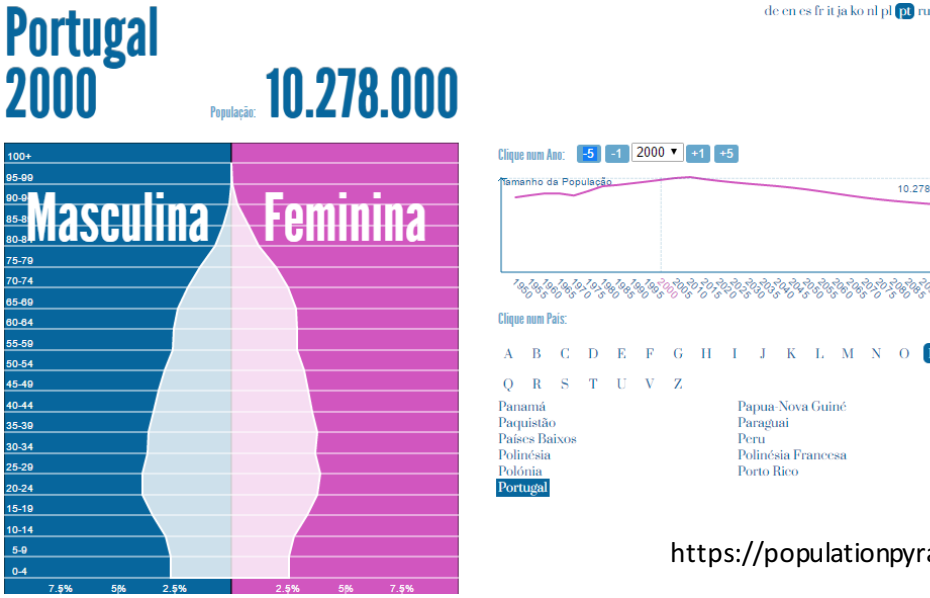
The oldest old, 3.5 million persons in 1994, represented just over 1 percent of the U.S. population. By 2020, the size of the population age 85 and over is projected to double to 7 million. The oldest old will again double to 14 million by 2040 as the survivors of the Baby-Boom cohort reach the oldest 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.

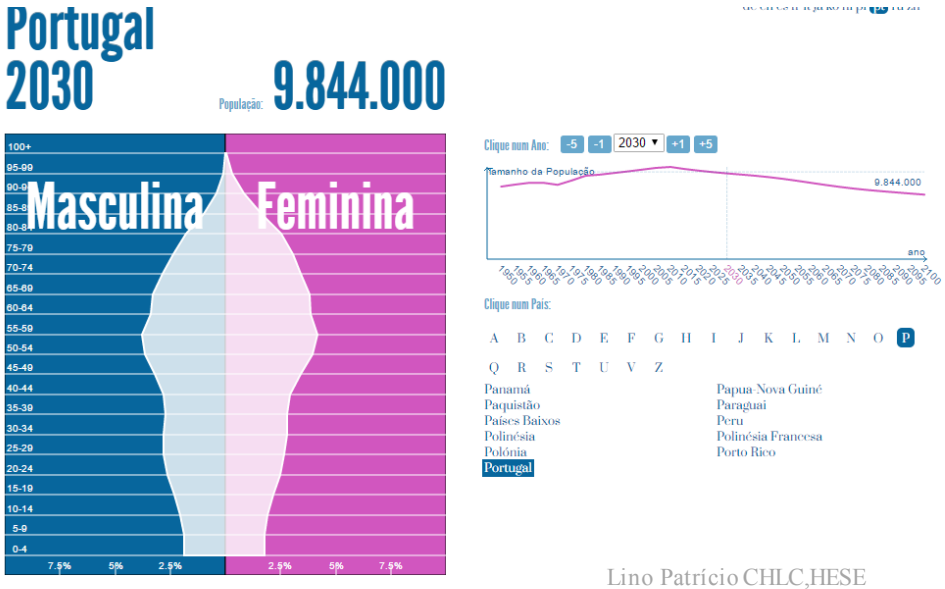


https://www.census.gov/population/international/files/97agewc.pdf

# Elderly Boom



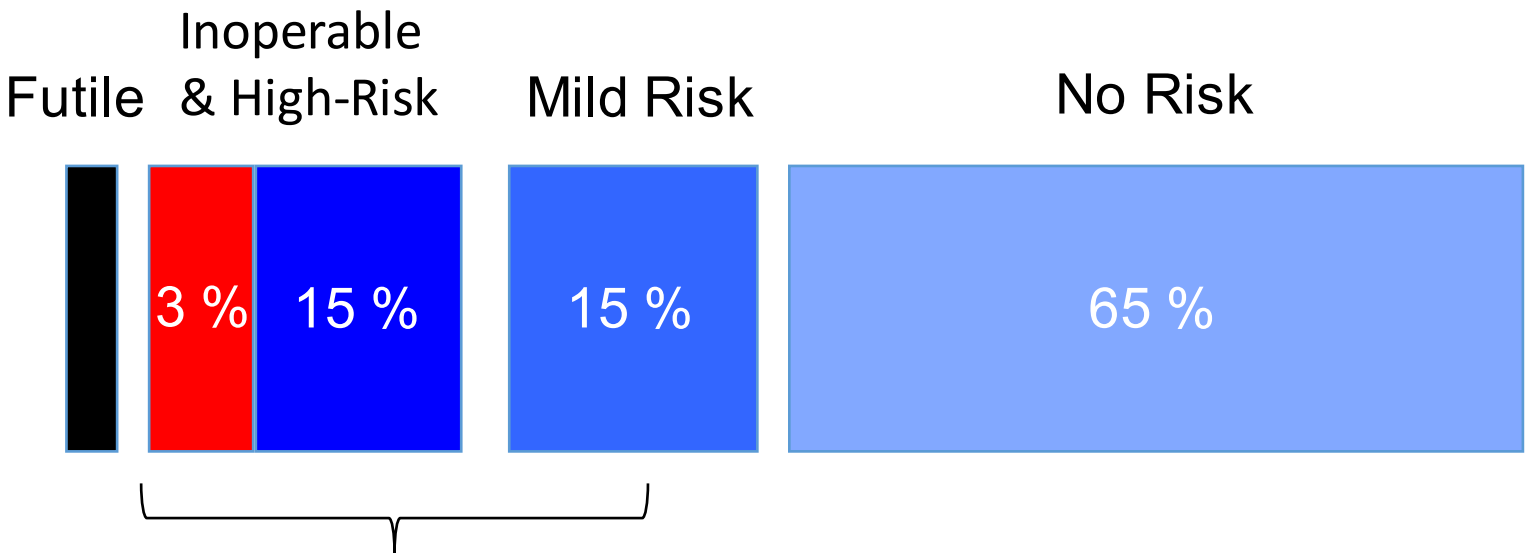




https://populationpyramid.net/pt/portugal/2000/

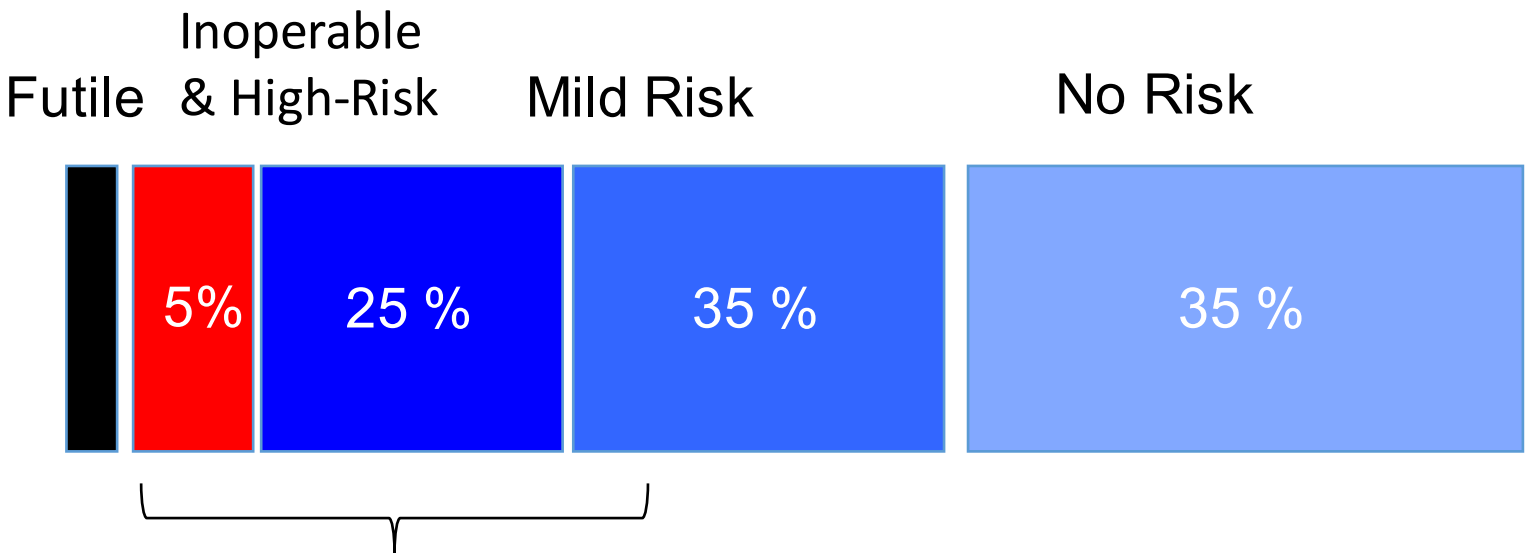
# Risk Assessment
## STS Risk Estimate, Frailty, Major Organ System Dysfunction, and Procedure-Specific Impediments

| | **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%<br>**AND** | 4% to 8%<br>**OR** | >8%<br>**OR** | Predicted risk with surgery of death or major morbidity (all-cause) >50% at 1 y<br>**OR** |
| Frailty | None<br>**AND** | 1 index (mild)<br>**OR** | 2 or more indices (moderate-to-severe)<br>**OR** | |
| Major organ system compromise not to be improved postoperatively | None<br>**AND** | 1 organ system<br>**OR** | No more than 2 organ systems<br>**OR** | 3 or more organ systems<br>**OR** |
| Procedure-specific impediment | None | Possible procedure-specific impediment | Possible procedure-specific impediment | Severe procedure-specific impediment |

# Indications of TAVI vs sAVR (2007-2018)



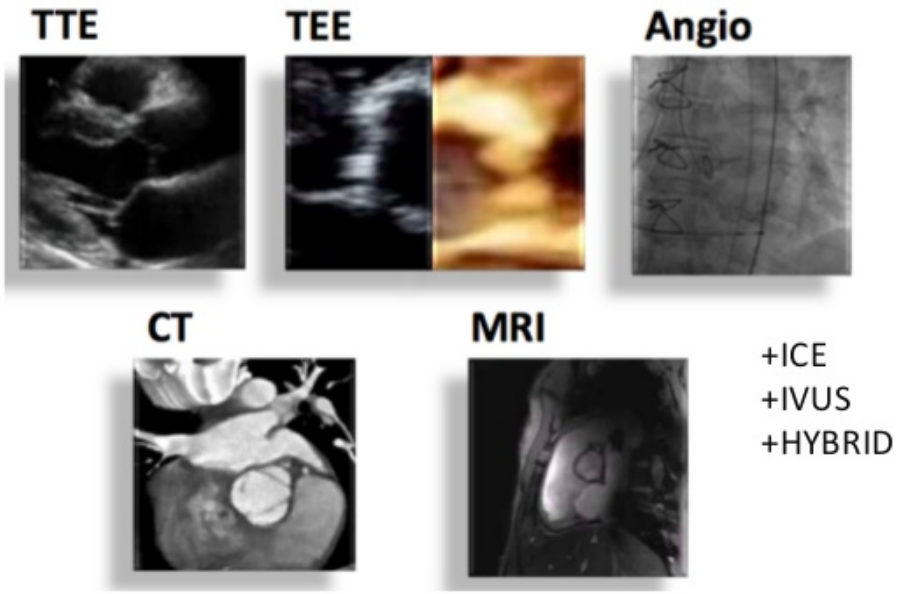
# Indications of TAVI vs sAVR (2007-2018)



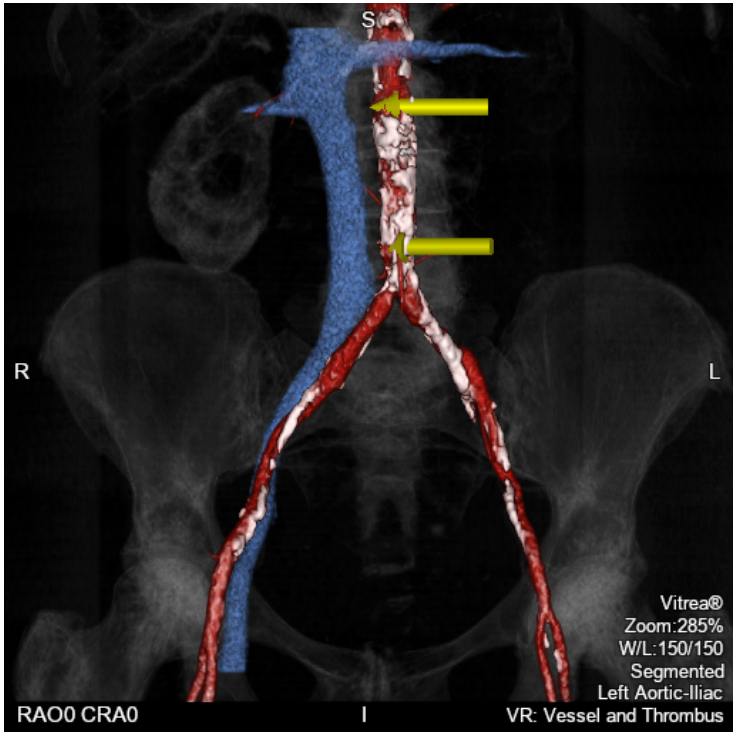
# TAVI the Gold Standard in a new world

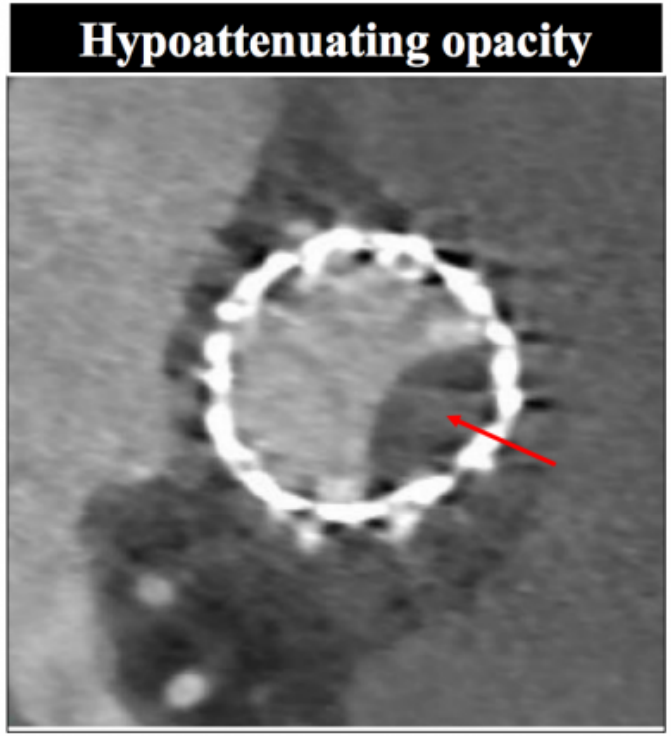
- Population ageing and management of multimorbidities
- **Development and Adoption of medical imaging techniques**
- Simplicity of processes and control of costs

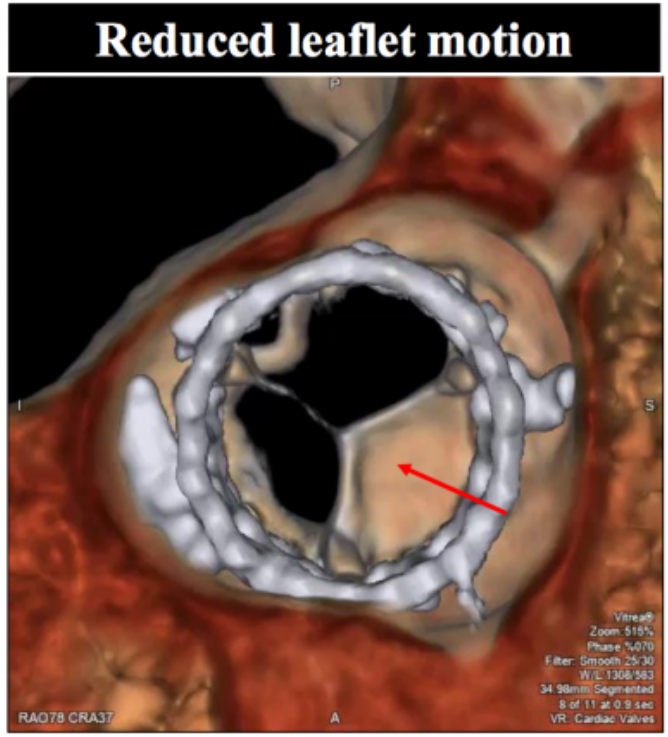
# Development and Adoption of medical imaging techniques



# Development and Adoption of medical imaging techniques



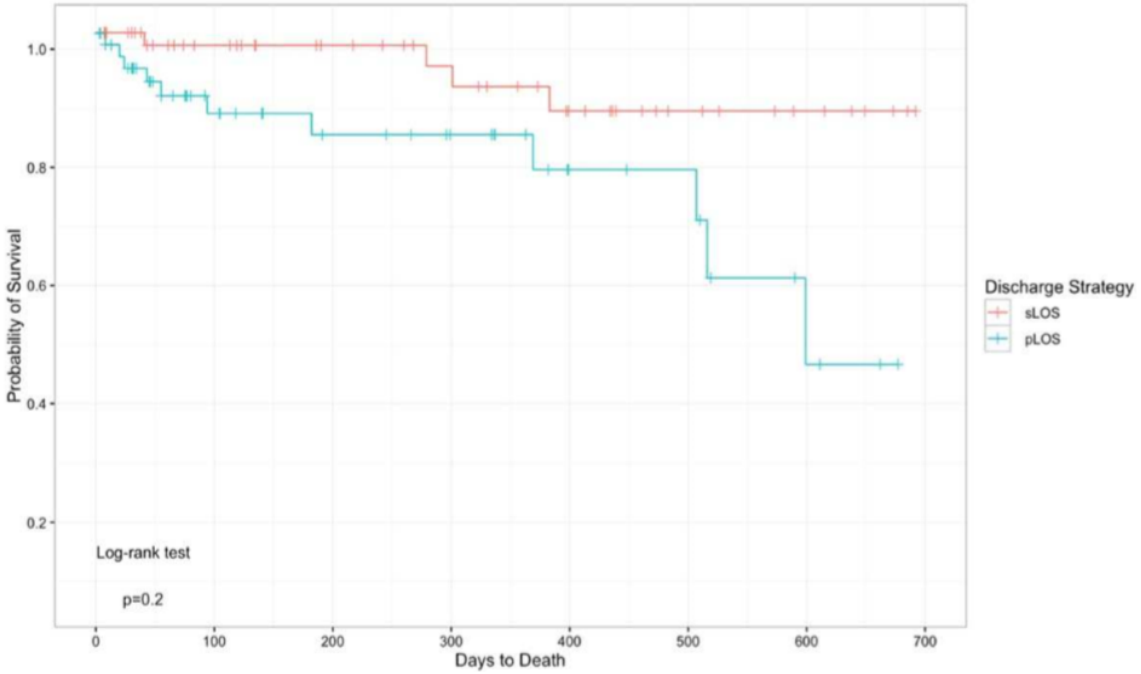
# TAVI the Gold Standard in a new world

- Population ageing and management of multimorbidities
- Development and Adoption of medical imaging techniques
- **Simplicity of processes and control of costs**

# Simplicity of processes and control of costs

## Safety of shorter length of hospital stay for patients undergoing minimalist transcatheter aortic valve replacement

**Conclusion:** In appropriately selected patients, sLOS following minimalist TAVR approach in an experienced and high volume center is feasible and safe. Implementing such a strategy may reduce medical costs with the potential clinical benefit of early re-habilitation for the elderly TAVR population.



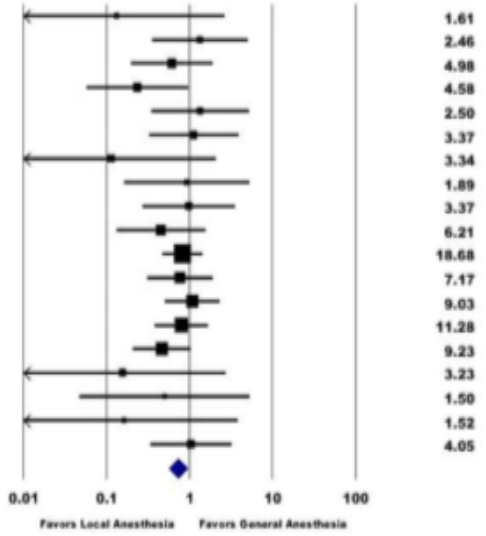

Catheter Cardiovasc Interv. 2018;91:345–353

## Comparison of local versus general anesthesia in patients undergoing transcatheter aortic valve replacement: A meta-analysis

**Conclusion:** Our meta-analysis suggests that use of LA for TAVR is associated with a lower 30-day mortality, shorter procedure time, fluoroscopy time, ICU LOS, hospital length of stay, and reduced need for inotropic support.

| Study name | MH risk ratio | Lower limit | Upper limit | Events / Total: Local Anesthesia | Events / Total: General Anesthesia | Relative weight |
|---|---|---|---|---|---|---|
| Behan | 0.13 | 0.01 | 2.63 | 0 / 9 | 1 / 3 | 1.61 |
| Dehedin | 1.34 | 0.35 | 5.05 | 3 / 34 | 6 / 91 | 2.46 |
| Bergmann | 0.61 | 0.20 | 1.91 | 6 / 100 | 5 / 51 | 4.98 |
| Ben-Dor | 0.24 | 0.06 | 0.97 | 3 / 70 | 4 / 22 | 4.58 |
| Motloch | 1.34 | 0.35 | 5.21 | 5 / 41 | 3 / 33 | 2.50 |
| Yamamoto | 1.13 | 0.33 | 3.91 | 10 / 130 | 3 / 44 | 3.37 |
| Babaliaros | 0.11 | 0.01 | 2.08 | 0 / 70 | 4 / 72 | 3.34 |
| Balanika | 0.93 | 0.16 | 5.30 | 2 / 41 | 3 / 57 | 1.89 |
| Attizzani | 0.98 | 0.27 | 3.55 | 5 / 116 | 4 / 91 | 3.37 |
| Gauthier | 0.45 | 0.13 | 1.57 | 3 / 66 | 11 / 110 | 6.21 |
| Petronio | 0.83 | 0.47 | 1.44 | 38 / 961 | 17 / 355 | 18.68 |
| Kesimci | 0.77 | 0.31 | 1.91 | 7 / 72 | 10 / 79 | 7.17 |
| Brecker | 1.08 | 0.50 | 2.33 | 13 / 245 | 12 / 245 | 9.03 |
| D'Errigo | 0.80 | 0.38 | 1.68 | 12 / 310 | 15 / 310 | 11.28 |
| Kiramijyan | 0.46 | 0.21 | 1.04 | 23 / 467 | 7 / 66 | 9.23 |
| Jabbar | 0.16 | 0.01 | 2.73 | 0 / 71 | 6 / 145 | 3.23 |
| Miles | 0.50 | 0.05 | 5.32 | 1 / 44 | 2 / 44 | 1.50 |
| Palermo | 0.16 | 0.01 | 3.84 | 0 / 44 | 1 / 21 | 1.52 |
| Debry | 1.04 | 0.34 | 3.23 | 4 / 52 | 9 / 122 | 4.05 |
| | 0.73 | 0.57 | 0.93 | 135 / 2943 | 123 / 1961 | |

MH risk ratio and 95% CI




Heterogeneity: $Tau^2$=0.00; $Chi^2$= 13.1, $df$= 18, $P$=.78; $I^2$= 0%
Test for overall effect: $Z$= -2.50 ($P$=.01)

Catheter Cardiovasc Interv. 2017;1–13

## Simplicity of processes and control of costs

- ✓ When TAVR is performed with transfemoral percutaneous approach, local anesthesia, no routine post-procedural intensive care admission, an early discharge (<3 days) can be adopted in most TAVR patients

- ✓ Avoiding peri-procedural complications and minimizing pace-maker implantation rate are key to allow early patient discharge

- ✓ When properly selected, patients discharged early, have low risk of adverse events and readmissions in the first 30 days

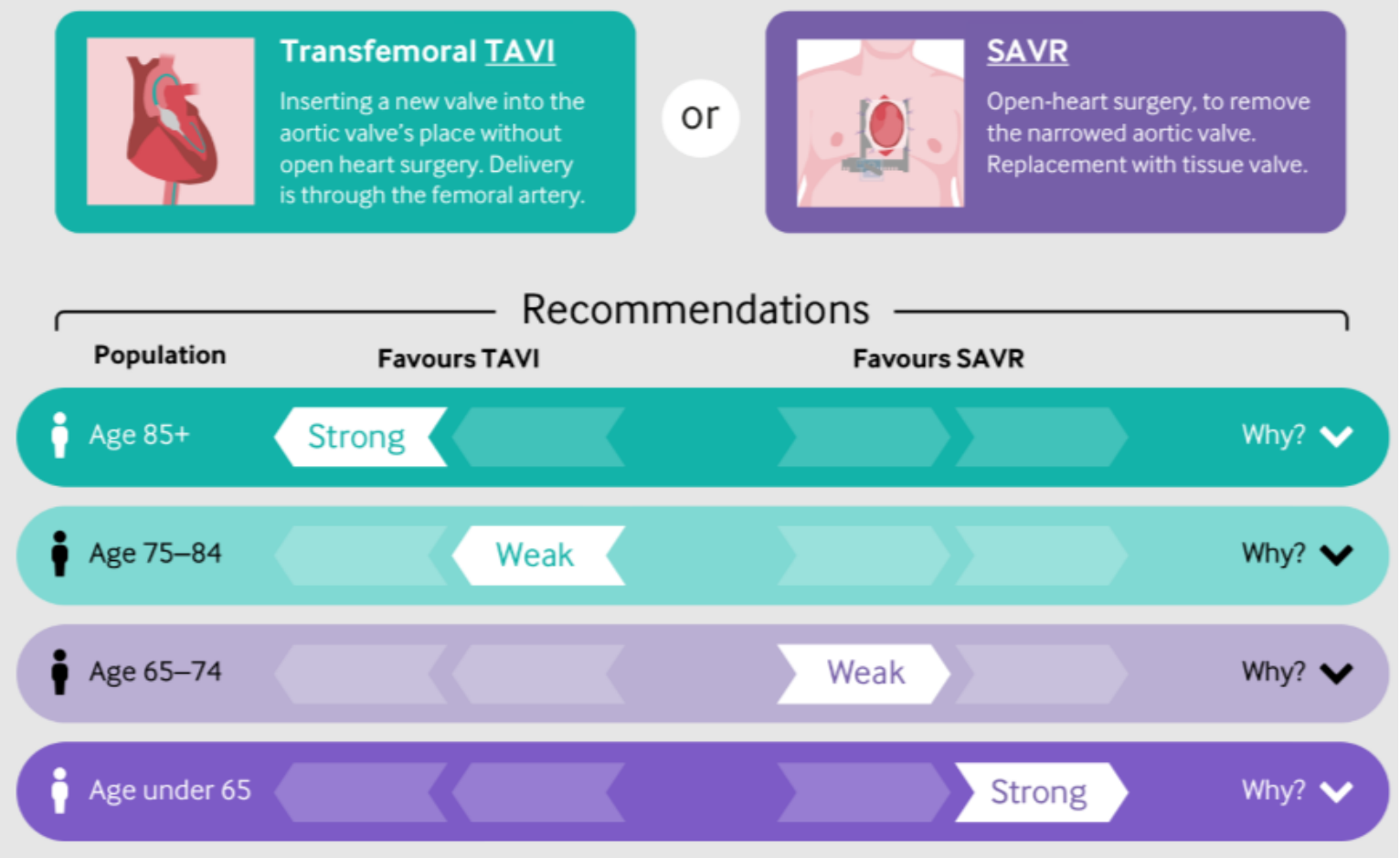
Catheter CardiovascInterv. 2018;91:354–355.

# TAVI the Gold Standard in a new world

- Population ageing and managemen[illegible]ltimorbidities
- Development and Ado[illegible]medical imaging techniques
- Simplicity[illegible]sses and control of costs

TAVI durability regarding Patient age

# TAVI durability regarding Patient Age



# TAVI durability regarding Patient Age

- TAVI should be compare to SAVR bioprosthesis
  - ✓Failure median time 18 years
  - ✓<65 years - Failure median time 14,5 years
  - ✓>65 years - Failure median time 21,4

Mansen et al(AnnThoraSurg2017)

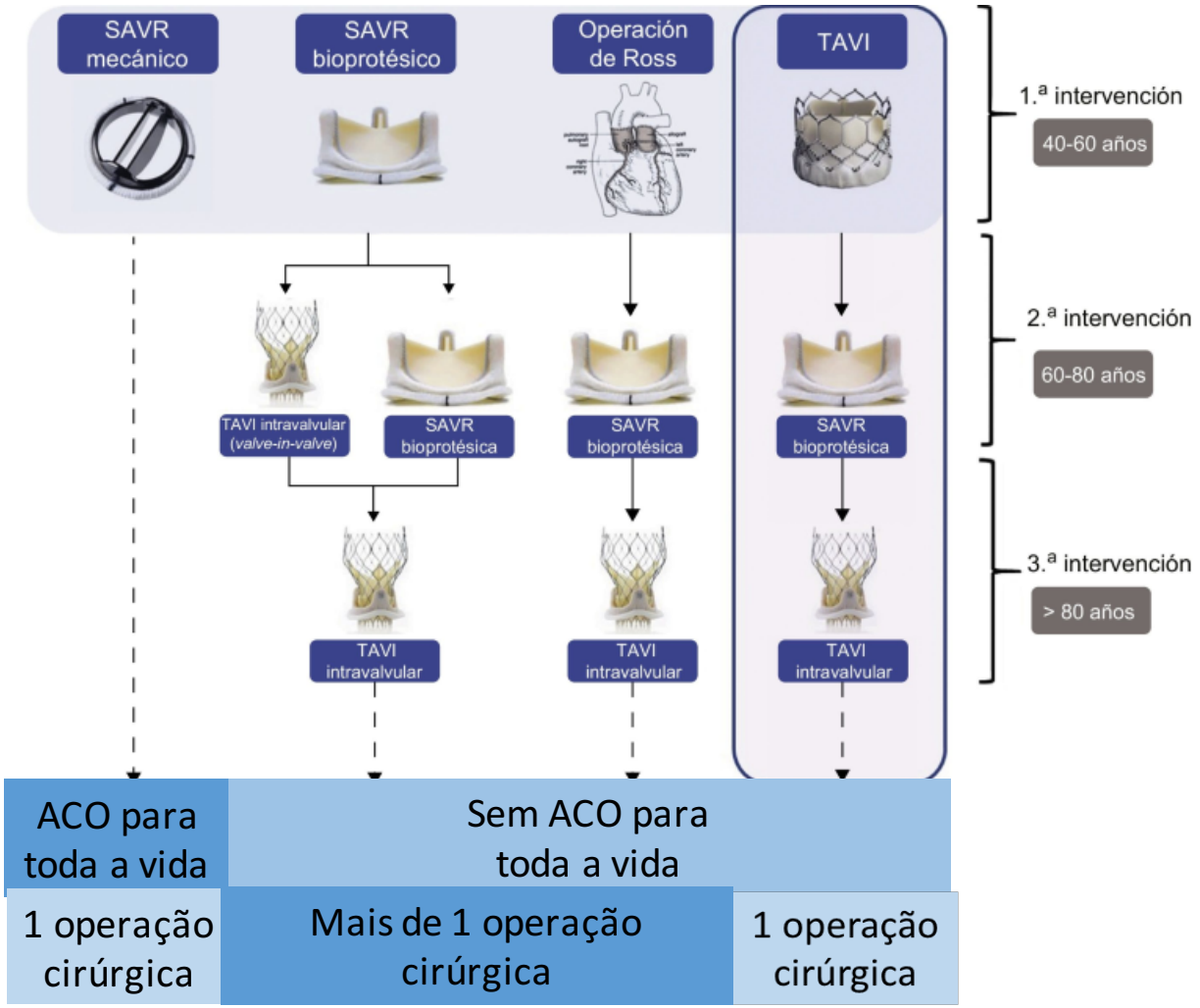
- Early degeneration factors
  - ✓Age
  - ✓VinV
  - ✓Dimension < 23 mm
  - ✓No anticoagulation

DelTrigo et al(JACC2016)

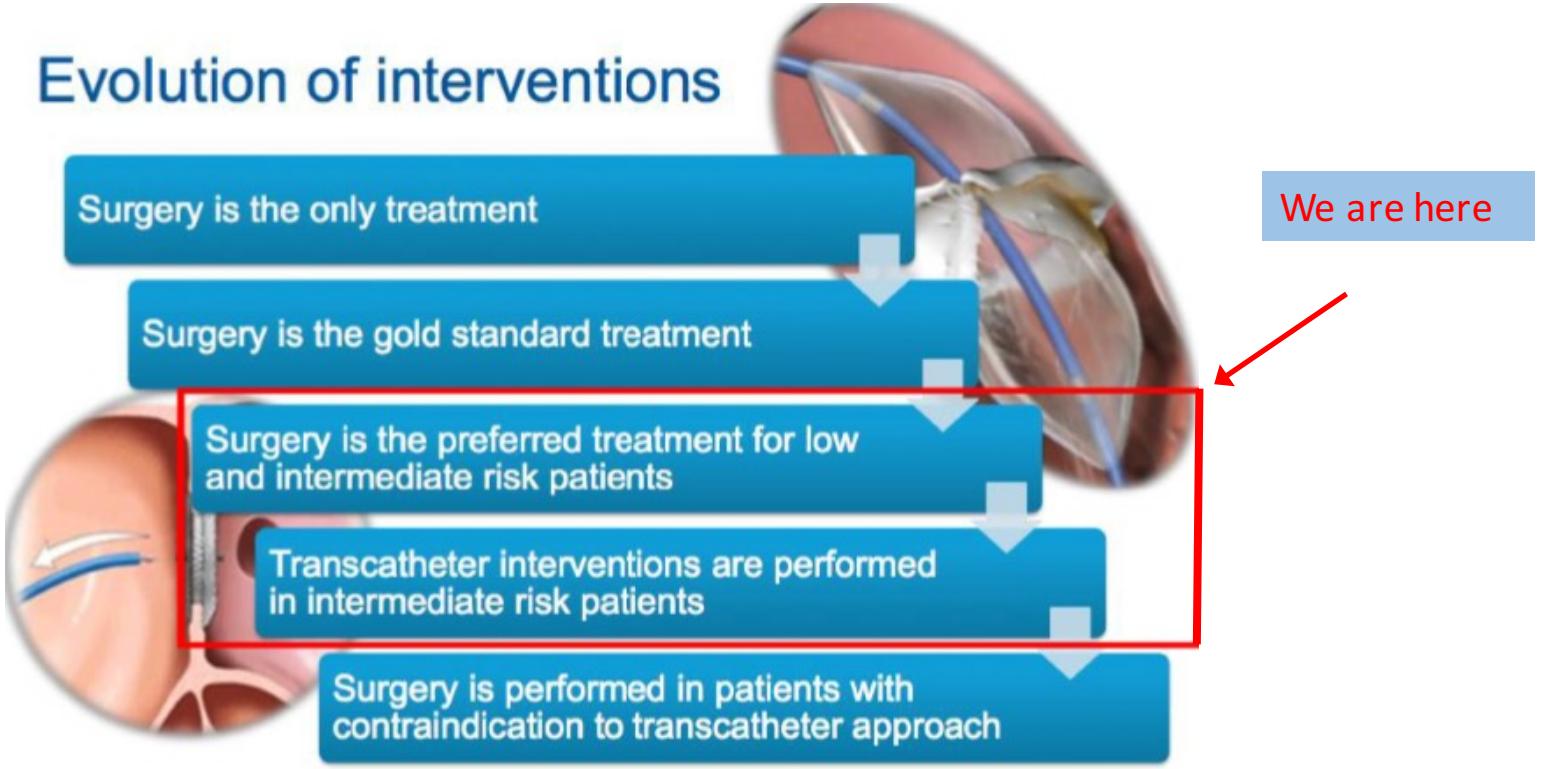
- Evaluation difficulty of durability in > 80 years low risk

(NOTION - Low risk medium age 79,8 years)

# TAVI durability regarding Patient Age



# TAVI the Gold Standard in a new world



**TAVI the Gold Standard in a new world**

## New Guidelines 2018

| | | |
|---|---|---|
| SAVR is recommended in patients who are not suitable for TAVR as assessed by the Heart Team | I | B |

# 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

**Who can not understand that the world has changed**

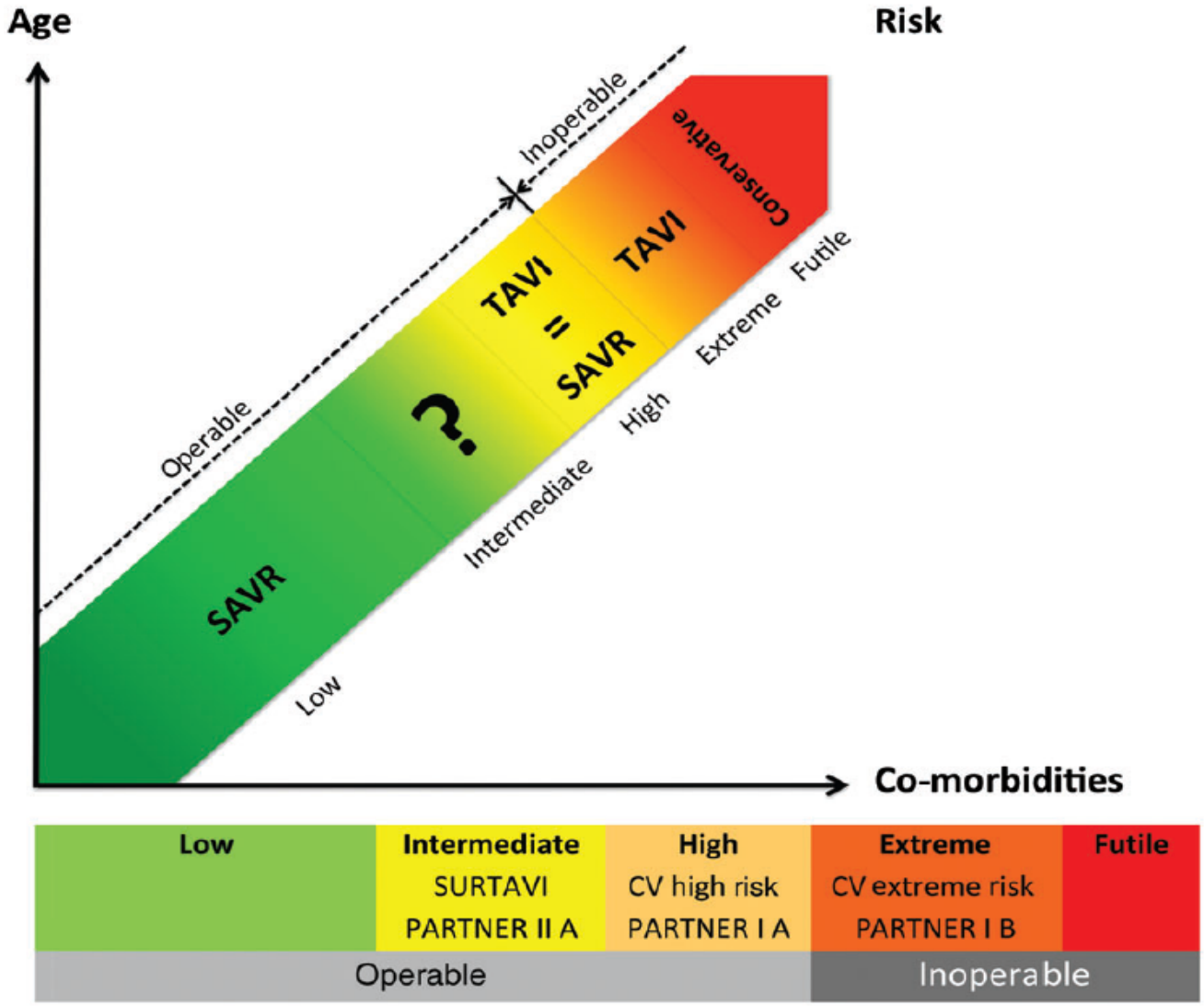
**Will be doing the same techniques ... but not for long time!**

Life, what is but a dream?

**Alice's Adventures in Wonderful Land**

**Lewis Carroll**

# Intermediate risk aortic Stenosis

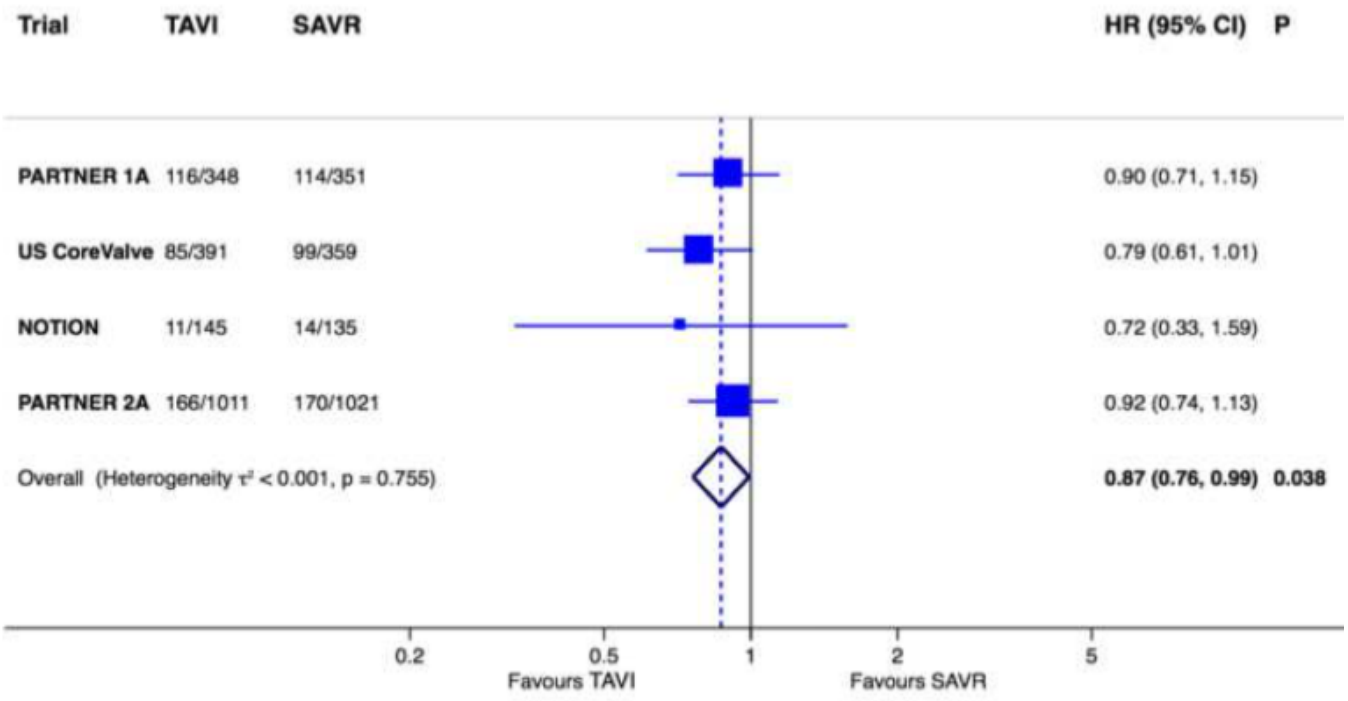


# TAVI vs SAVR
# Patient Subgroups

| 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 | ? |

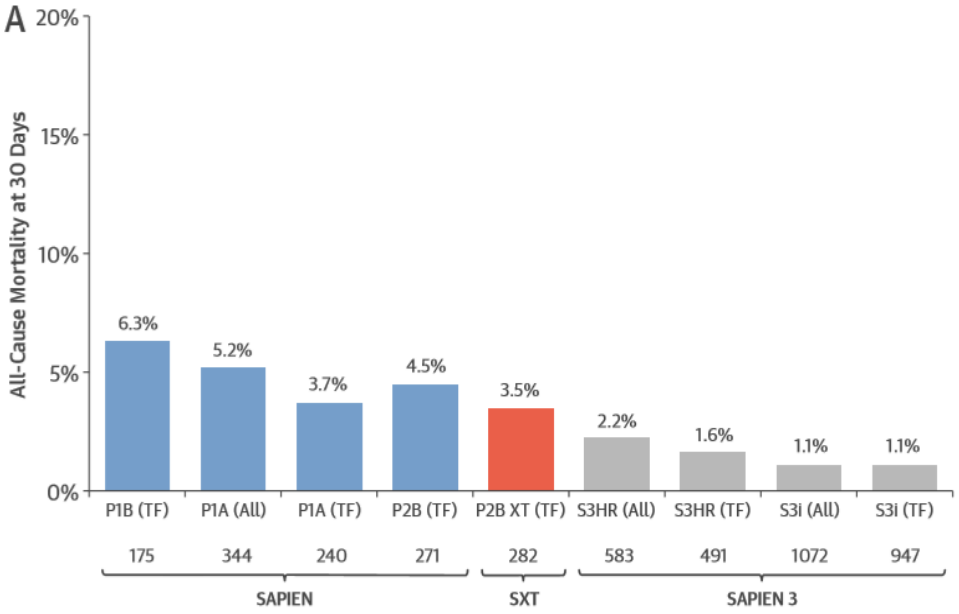
* Death or death/non-fatal stroke

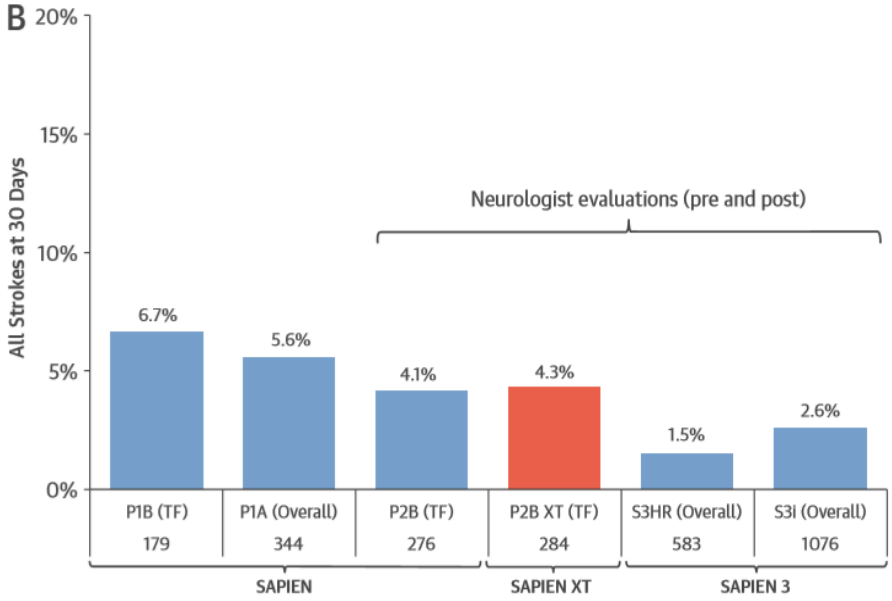
# TAVI vs SAVR
# RCT – meta-analysis
# All cause mortality




Siontis et al EHJ 2016

# Temporal trends of mortality and stroke after TAVI



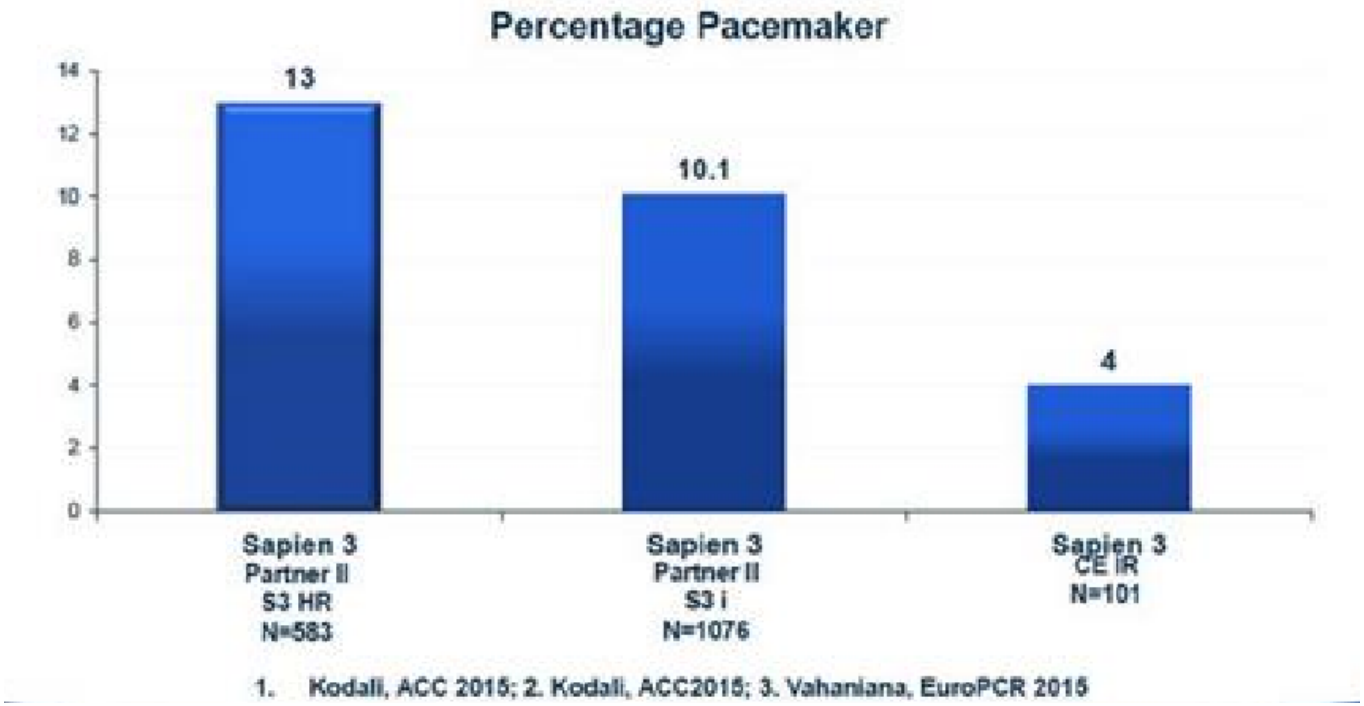

Herrmann HC Thranscatheter Cardiovascular Therapeutics 2015

# Multivariable Predictors of 3-Year All-Cause Mortality

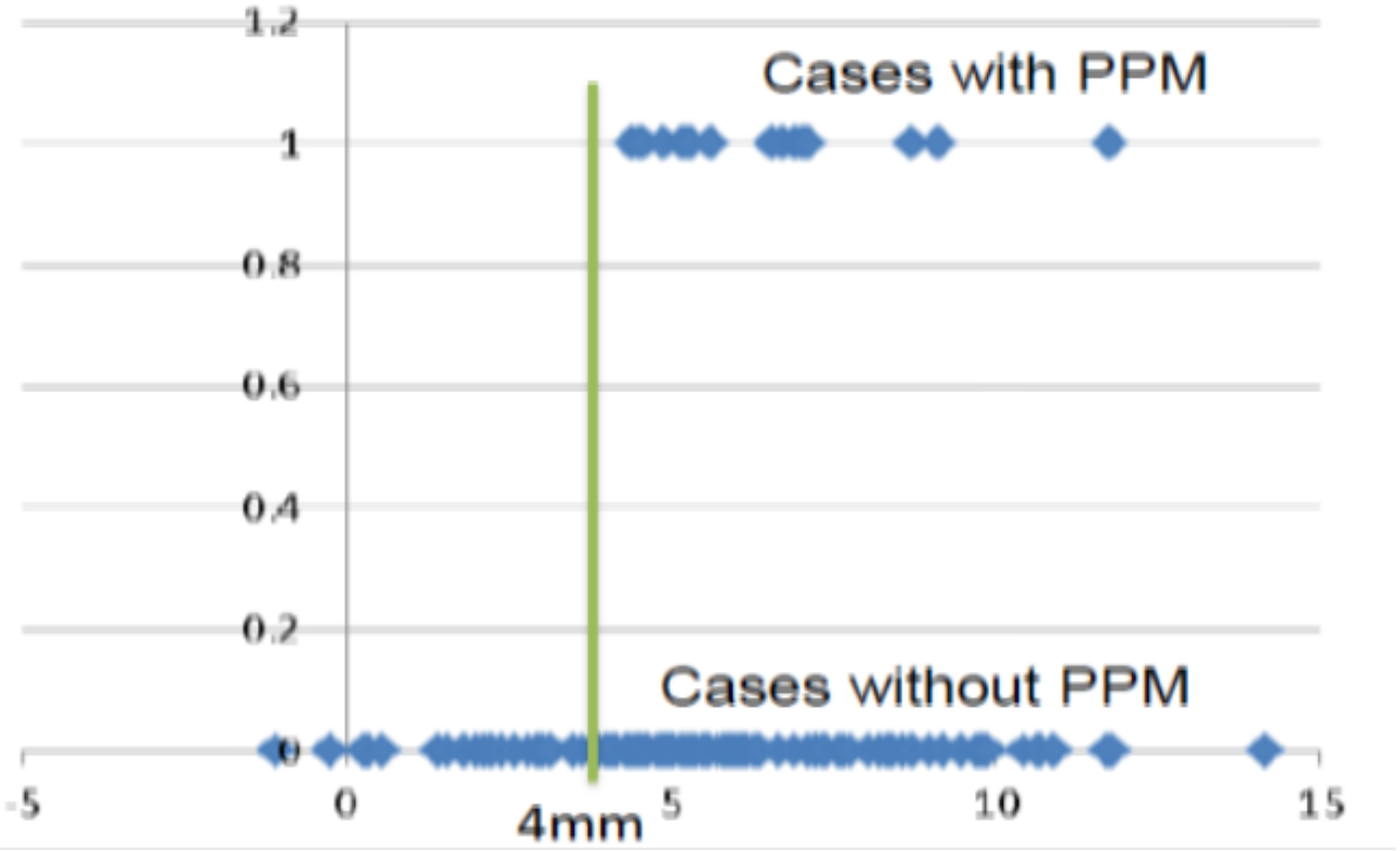
| | Patients (n) | Events (n) | 3-Yr Death Rate (%) | Univariable Analysis | | Multivariable Analysis | |
|---|---|---|---|---|---|---|---|
| | | | | Unadjusted HR (95% CI) | p Value | Adjusted HR (95% CI) | p Value |
| Logistic EuroSCORE | | | | | | | |
| <20 | 2,341 | 847 | 36.9 | 1.00 | | 1.00 | |
| 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.

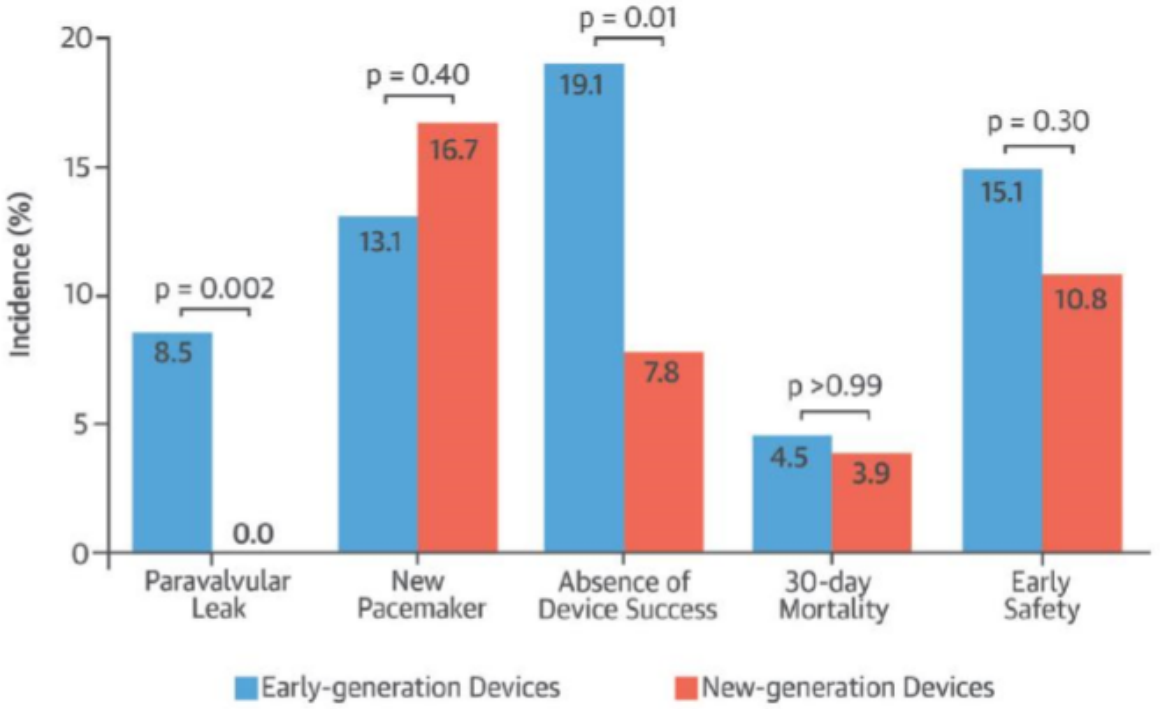
# PPM
# Deployment Technique



# PPM according to frame Depth

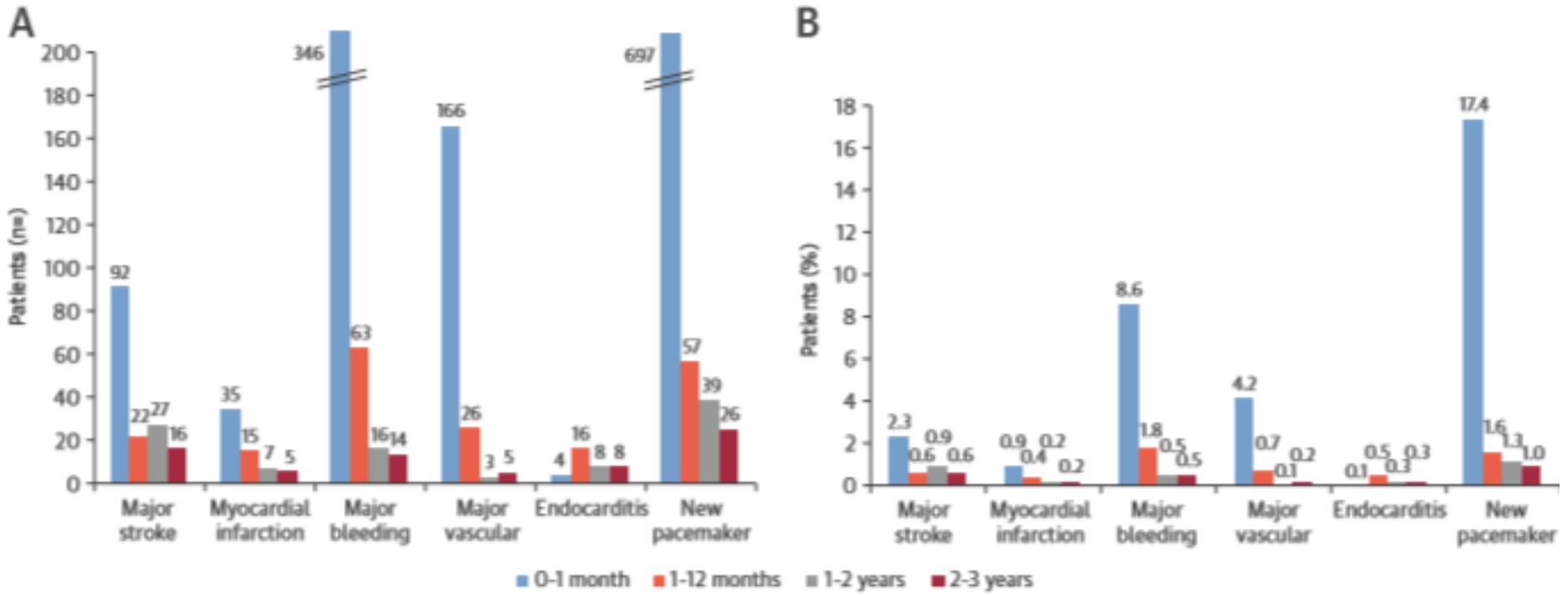


# Bicuspid aortic valve



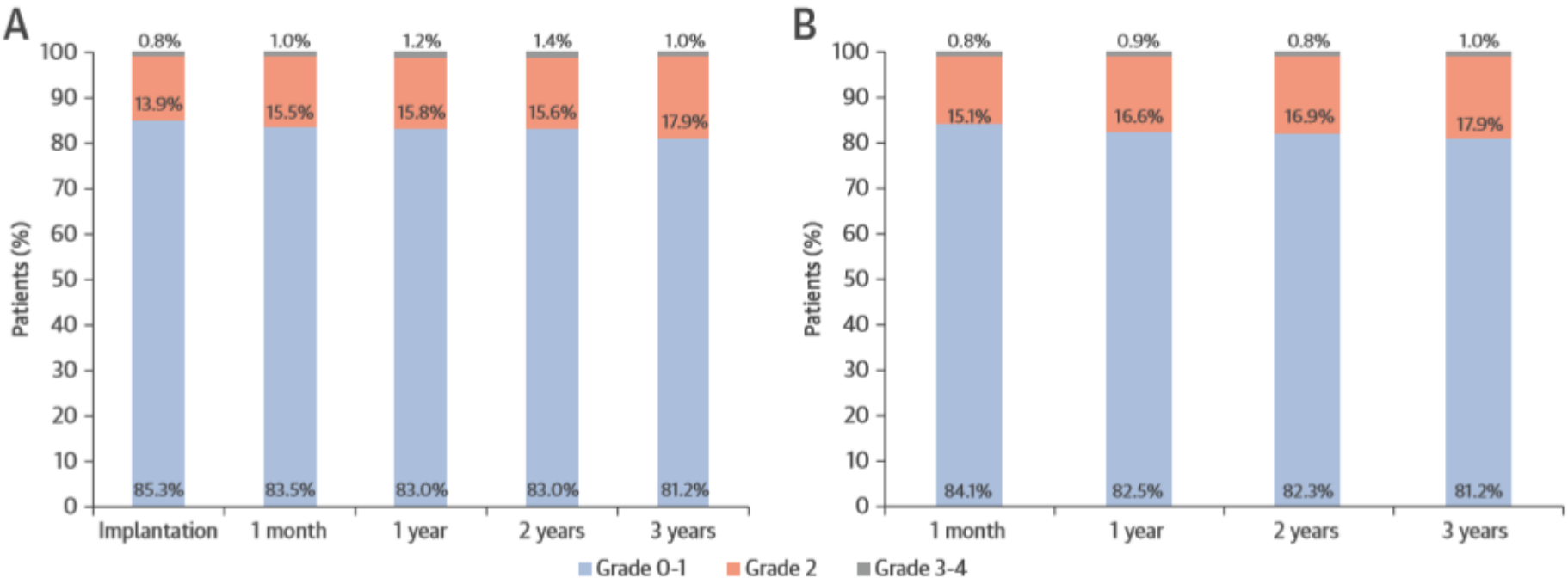

Yoon SH et JACC 2016;68:1195

# Cardiovascular Events Occurring at Different Time Periods After TAVR



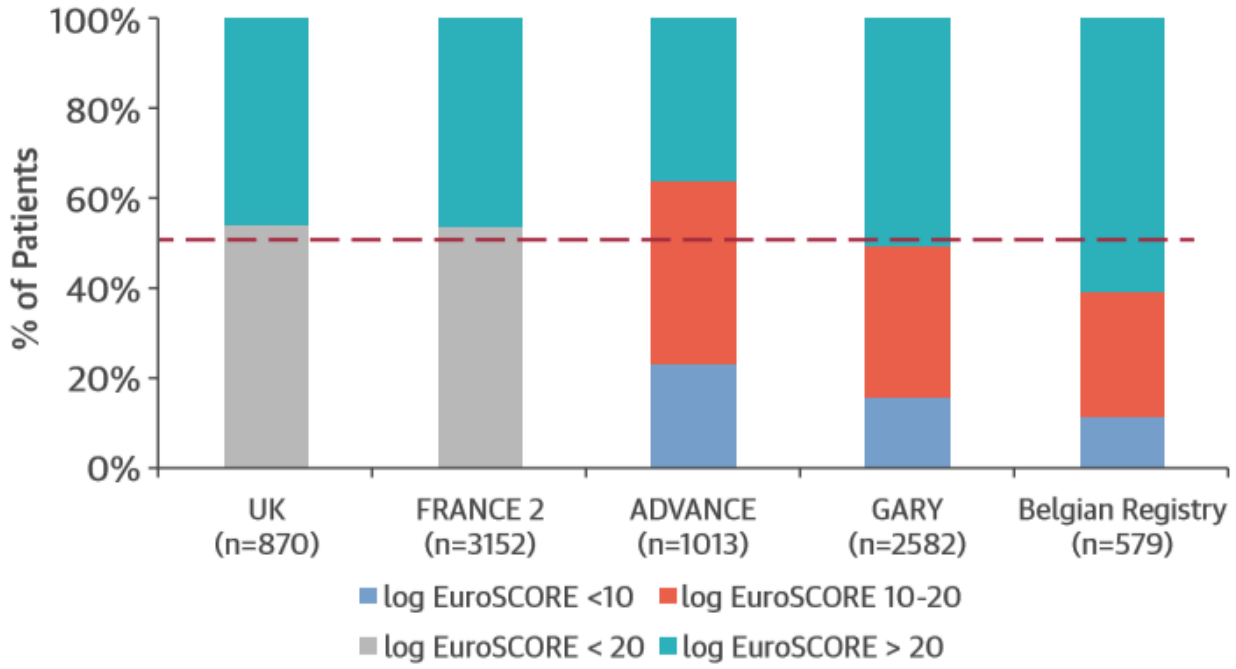

Gilard, M. et al. J Am Coll Cardiol. 2016;68(15):1637–47.

# Echocardiographic Evaluation of Periprosthetic AR During Follow-Up

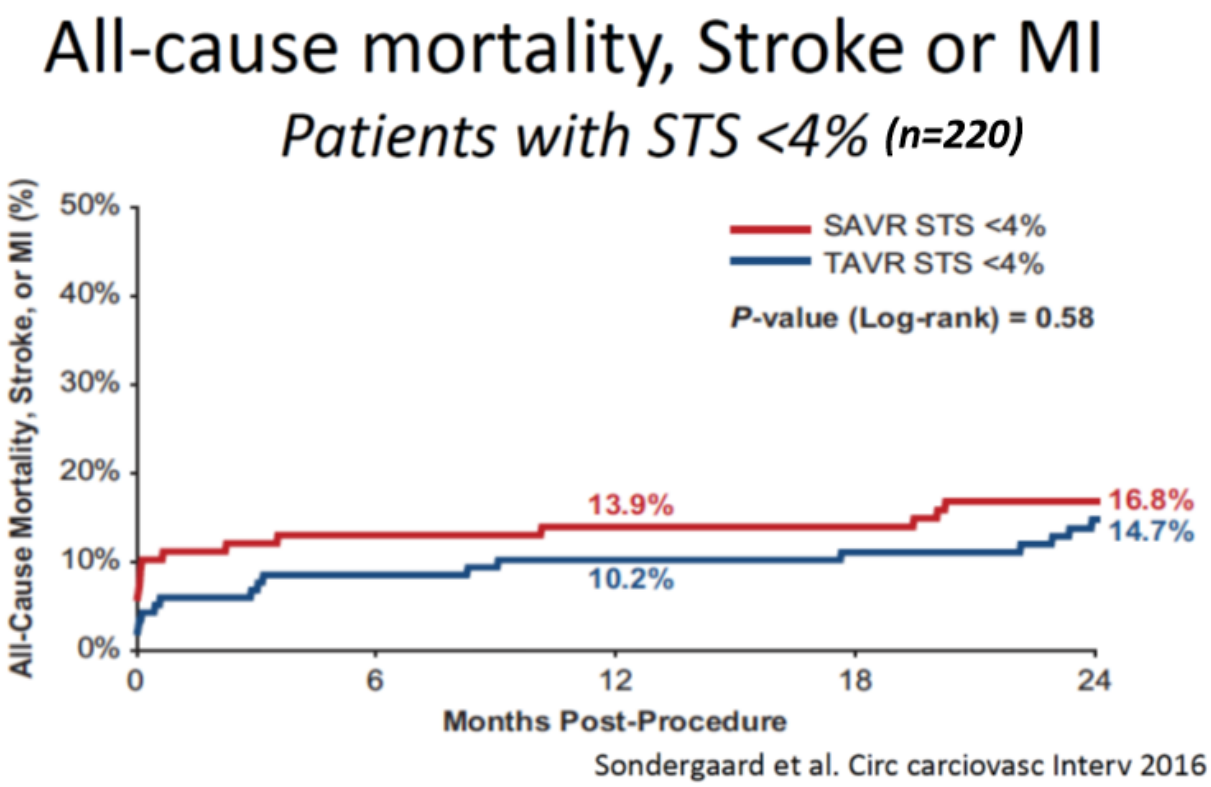



Gilard, M. et al. J Am Coll Cardiol. 2016;68(15):1637–47.

# Risk Profile of European TAVI Registries



# NOTION Trial
# Allcomers (TAVI vs sAVR)



# 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

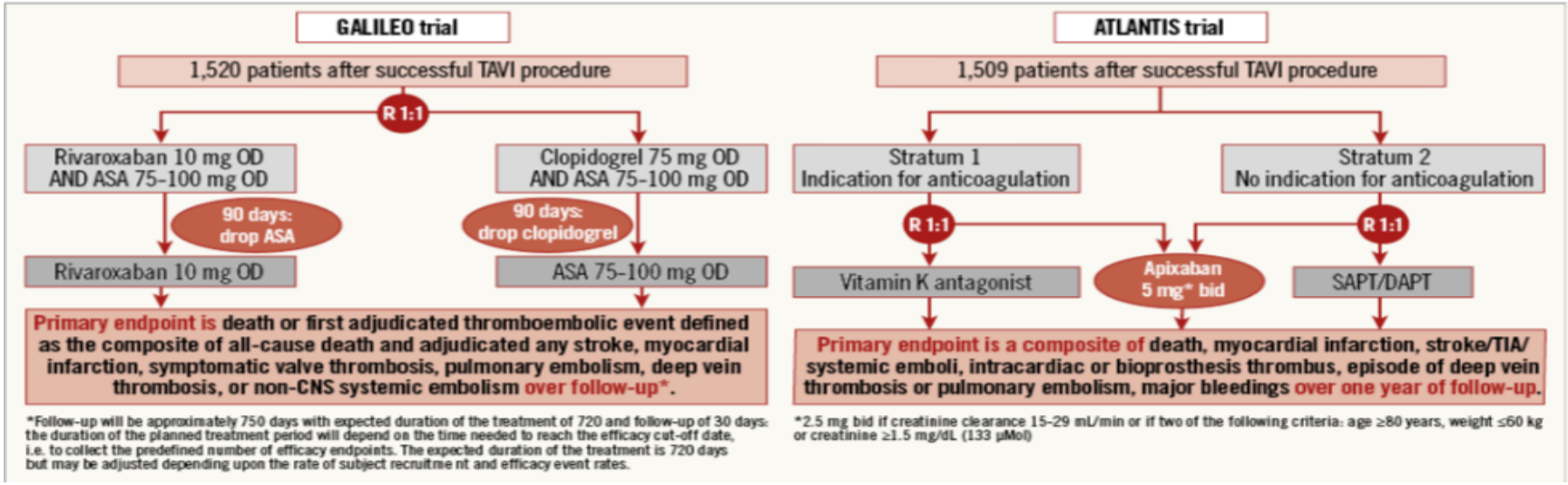
- Bicuspid valve (n=100)
- Valve in Valve (n=100)
- Alternate access (n=100)

# Treatment Decision

## OAC with warfarin patient INR 2-3

| | 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.**

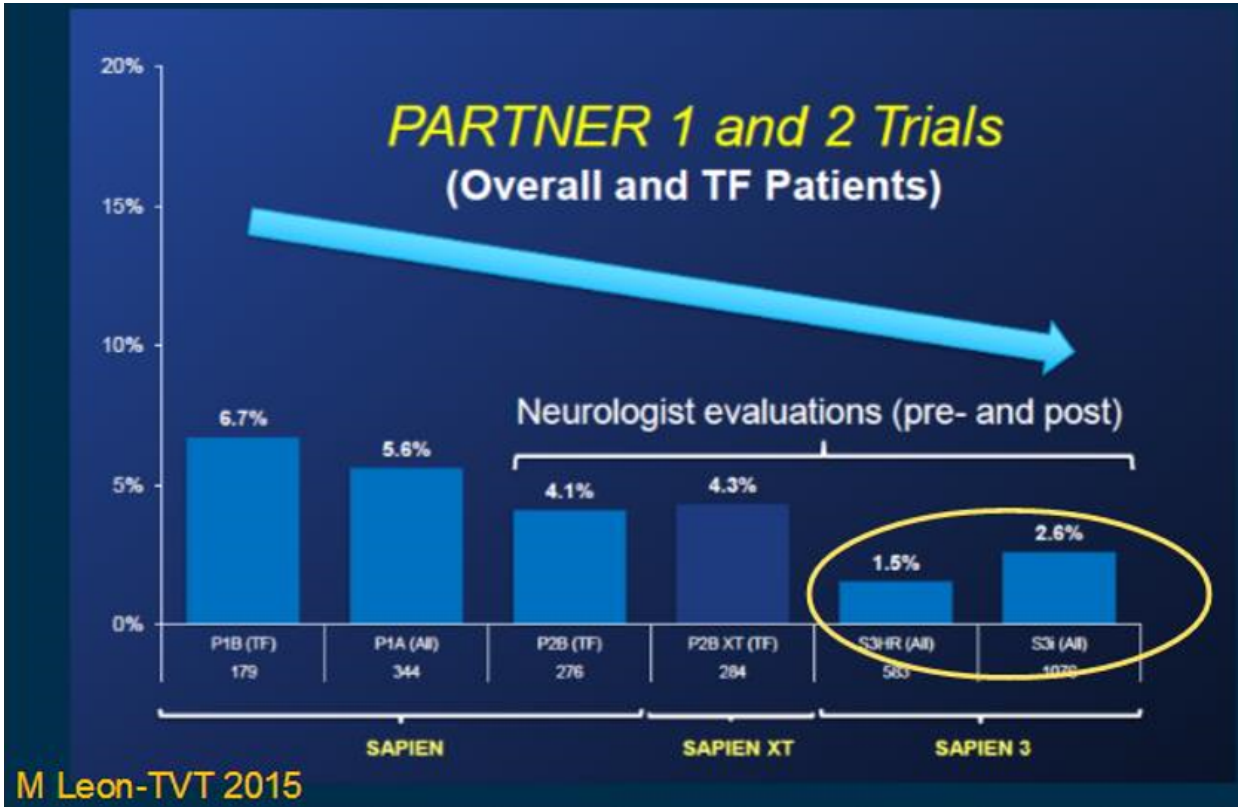
# Last Remarks

- 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

# Strokes 30 days



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