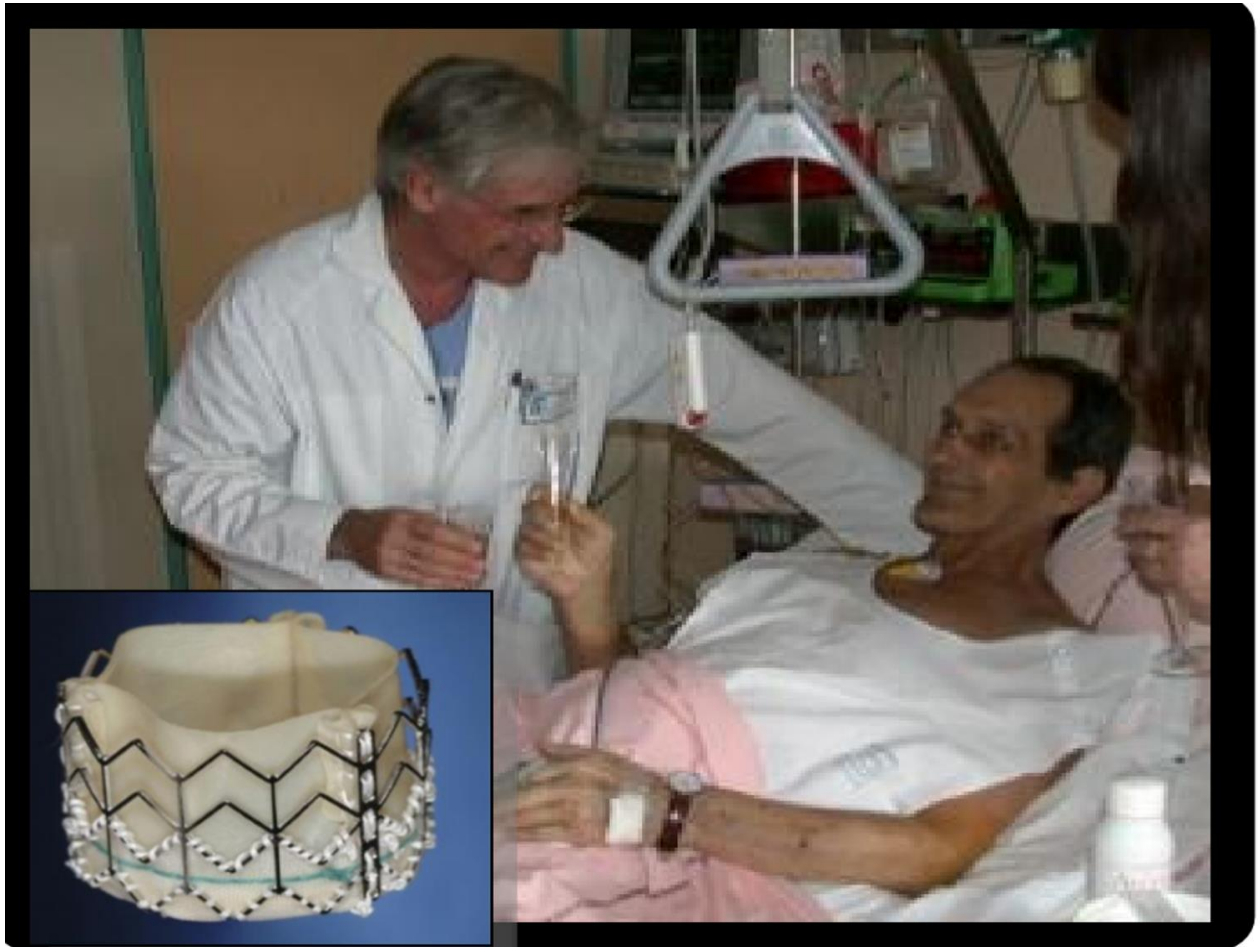
The revolution of TAVI, my personal journey

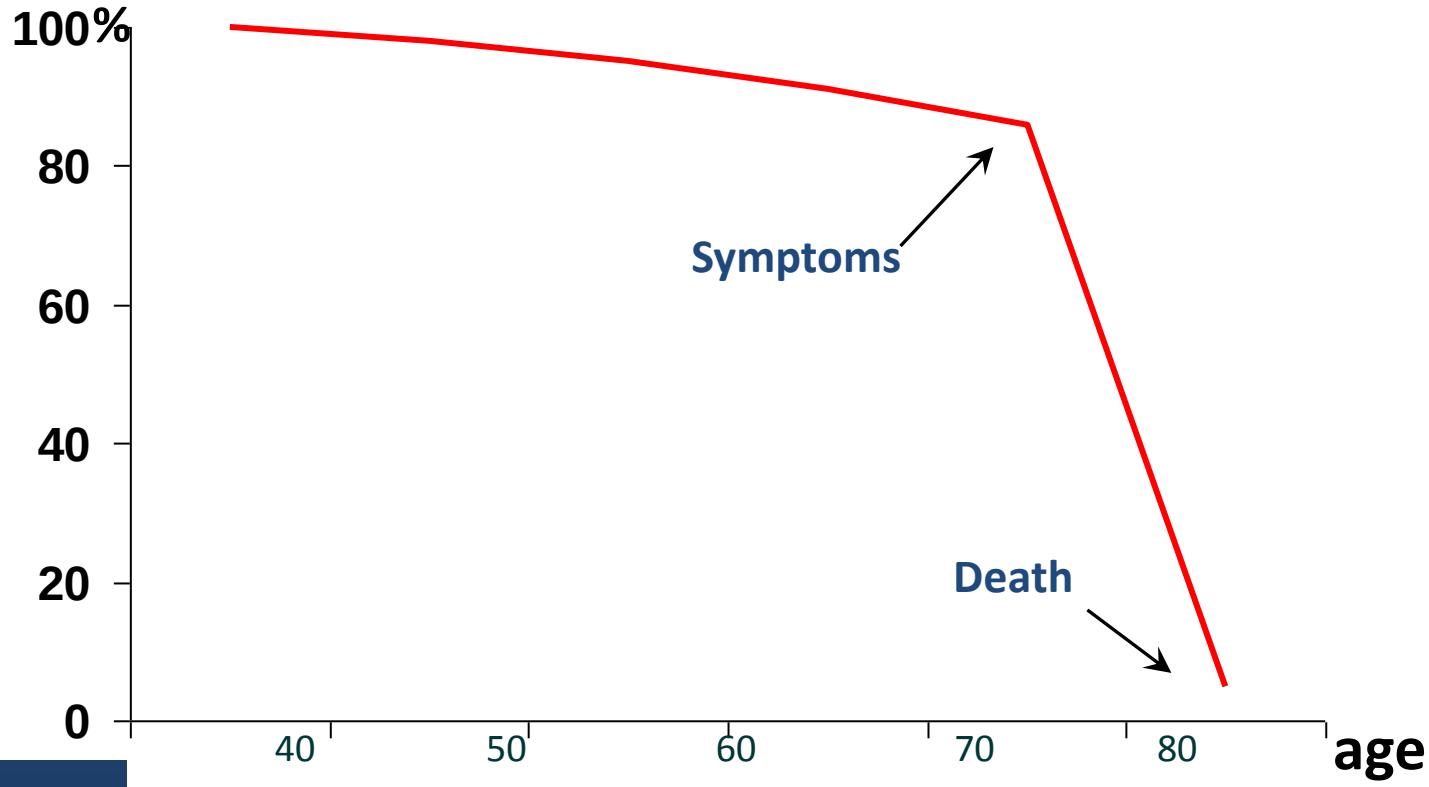
MC MORICE, FESC, FACC

Massy France

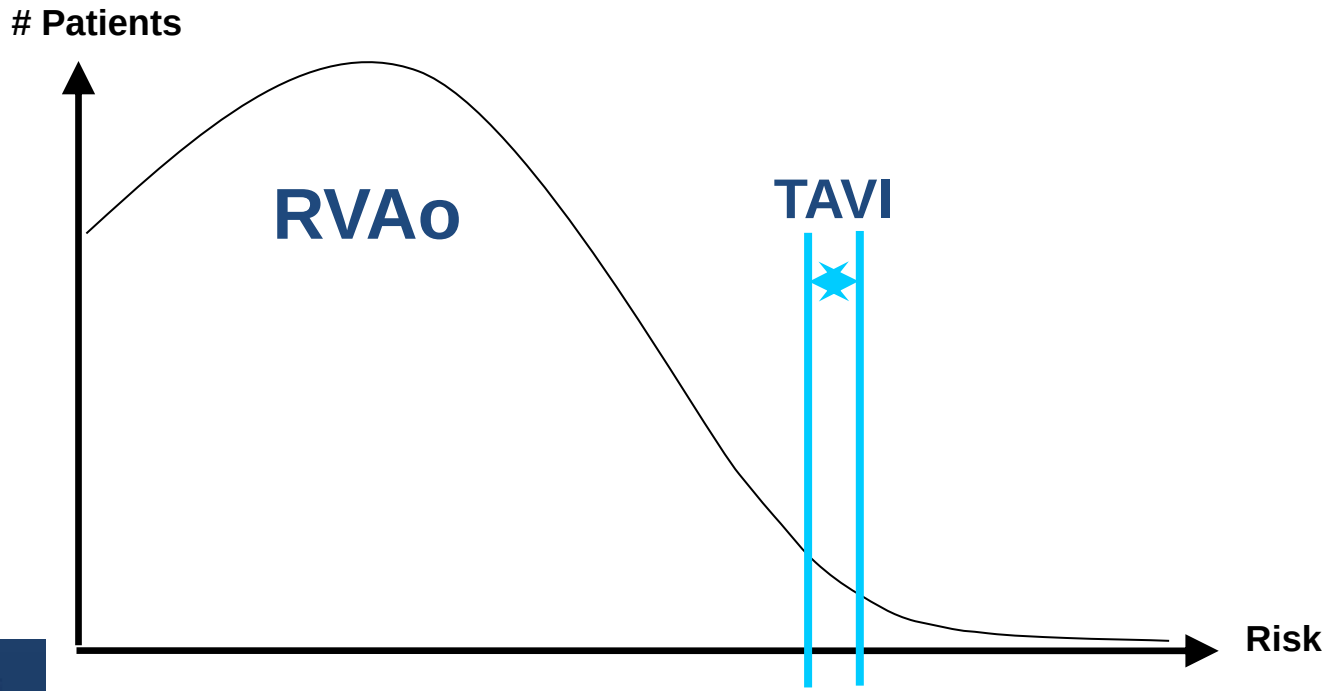
- I MC Morice have no conflict of interest to disclose relative to this lecture



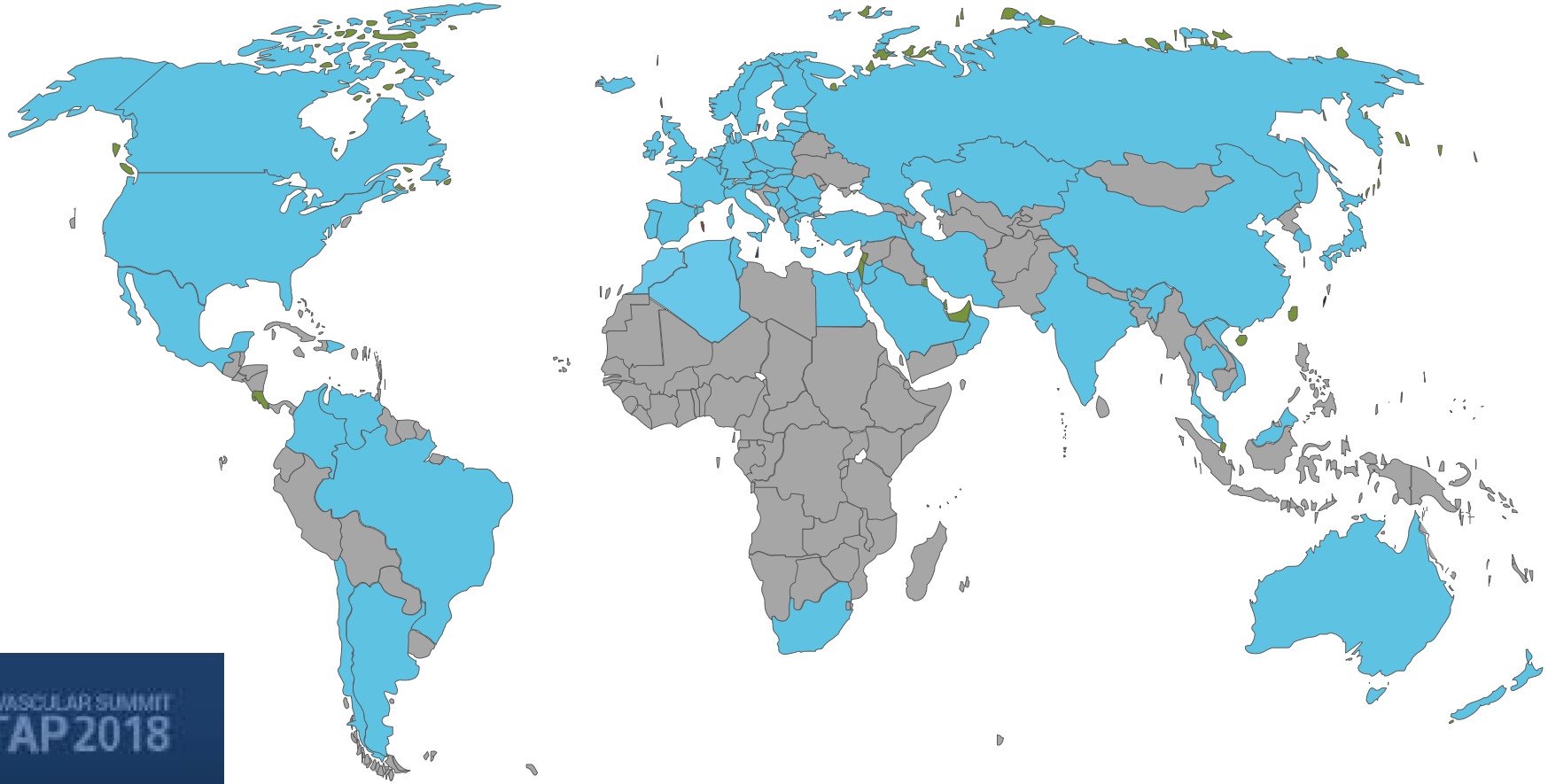
Natural history of aortic stenosis



From compassionate cases



> 300 000 cases in > 70 countries !



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TCTAP 2018

The *RAVEL study*,
presented by *Dr. Marie-Claude Morice*,
European Society of Cardiology,
September 4, 2001, Stockholm

The New England
Journal of Medicine

VOLUME 346 JUNE 6, 2002 NUMBER 23

A RANDOMIZED COMPARISON OF A SIROLIMUS-ELUTING STENT WITH A STANDARD STENT FOR CORONARY REVASCULARIZATION

MARIE-CLAUDE MORICE, M.D., PATRICK W. SERRUYS, M.D., PH.D., J. EDUARDO SOUSA, M.D., JEAN FAJADET, M.D., ERNESTO BAN HAYASHI, M.D., MARCO PERIN, M.D., ANTONIO COLOMBO, M.D., G. SCHULER, M.D., PAUL BARRAGAN, M.D., GIULIO GUAGLIUMI, M.D., FERENC MOLNAR, M.D., AND ROBERT FALOTICO, PH.D., FOR THE RAVEL STUDY GROUP*

ABSTRACT

Background The need for repeated treatment of restenosis of a treated vessel remains the main limitation of percutaneous coronary revascularization. Because sirolimus (rapamycin) inhibits the proliferation of lymphocytes and smooth-muscle cells, we compared a sirolimus-eluting stent with a standard uncoated stent in patients with angina pectoris.

Methods We performed a randomized, double-blind trial to compare the two types of stents for revascularization of single, primary lesions in native coronary arteries. The trial included 238 patients at 19 medical centers. The primary end point was in-stent late luminal loss (the difference between the minimal luminal diameter immediately after the procedure and the diameter at six months). Secondary end points included the percentage of in-stent stenosis of the luminal diameter and the rate of restenosis (luminal narrowing of 50 percent or more). We also analyzed

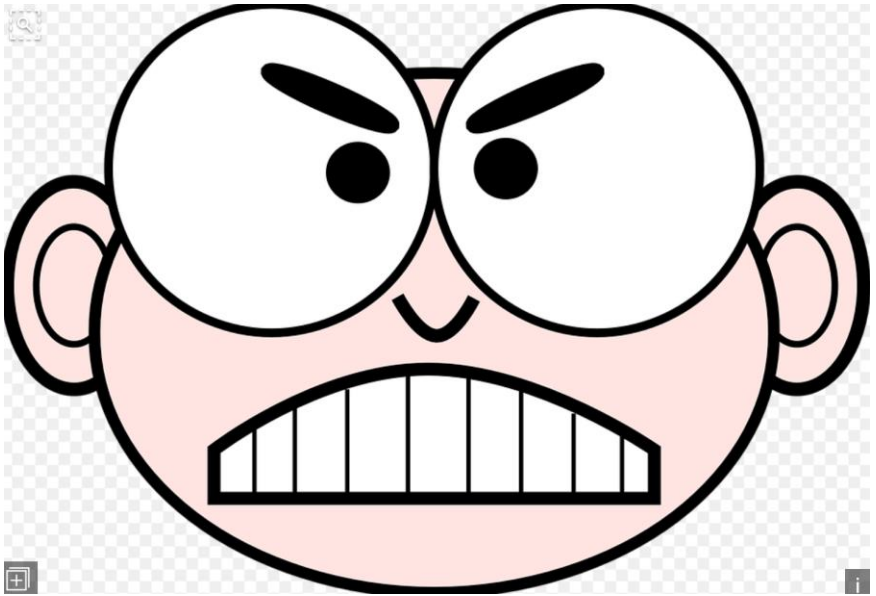
THE growing use of stents has improved the results of percutaneous coronary revascularization.[1-5] However, in-stent restenosis continues to limit the long-term success of this approach.[6,7] For example, in a recent randomized comparison of coronary-artery bypass surgery and stenting in patients with multivessel disease, additional revascularization procedures were performed within one year in 21.0 percent of patients who had undergone stenting, as compared with 3.8 percent of patients treated surgically.[8]

In controlled trials, several pharmaceutical agents have failed to inhibit restenosis after coronary interventions.[9] In contrast, the systemic and local delivery of sirolimus (rapamycin), a macrocyclic lactone that inhibits cytokine-mediated and growth-factor–mediated proliferation of lymphocytes and smooth-muscle cells, reduced neointimal proliferation in studies in

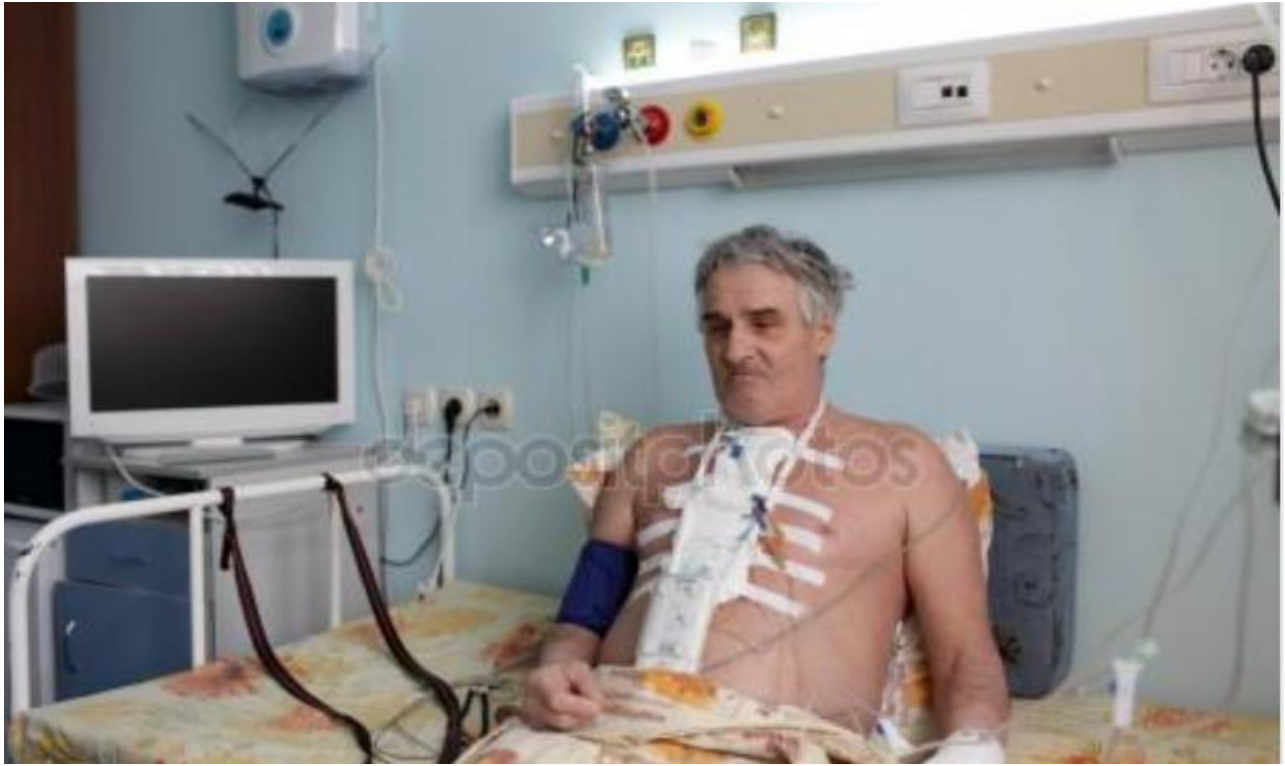
Edwards XT

Corevalve

Some surgeons……

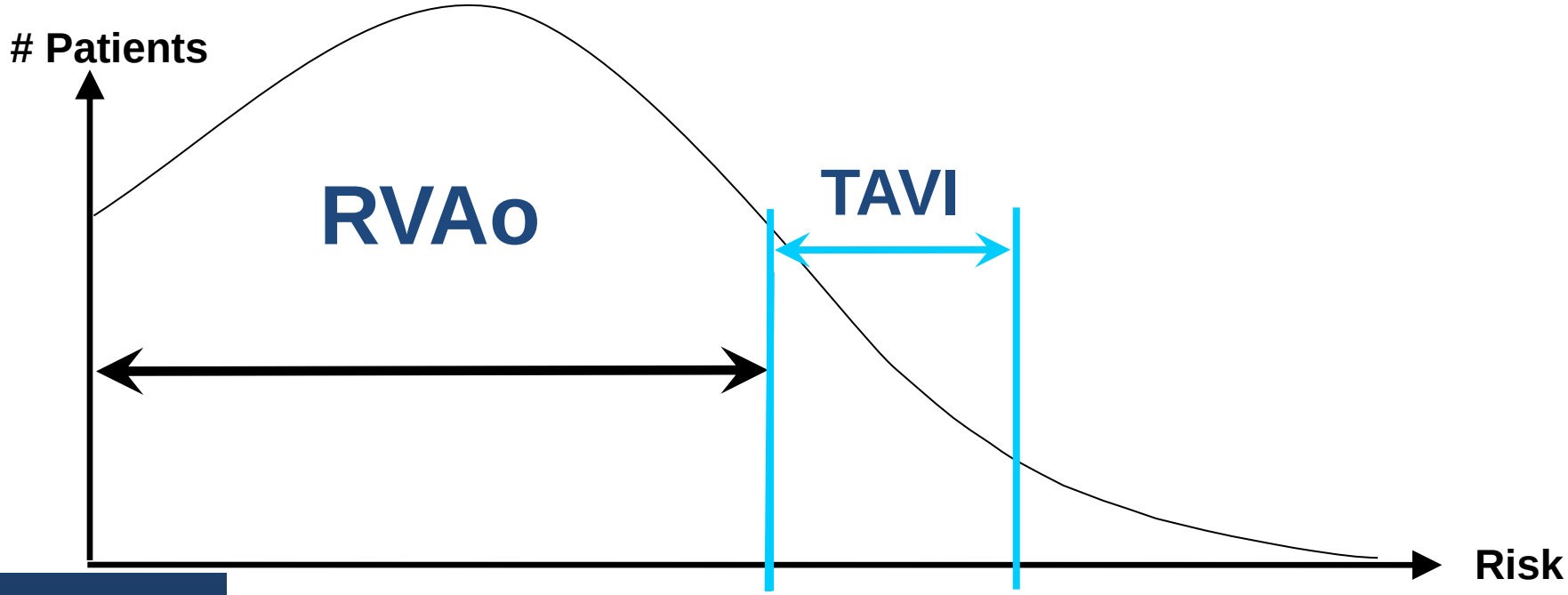


Some conservative cardiologists



Our patients were doing so well!

It was an unmet need



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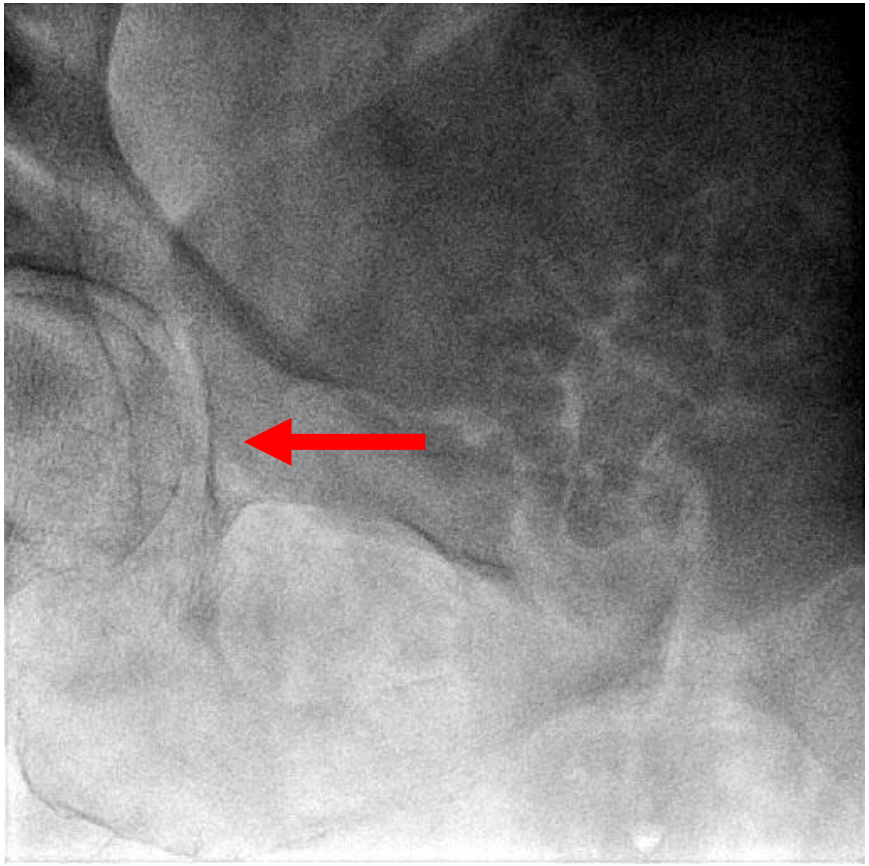

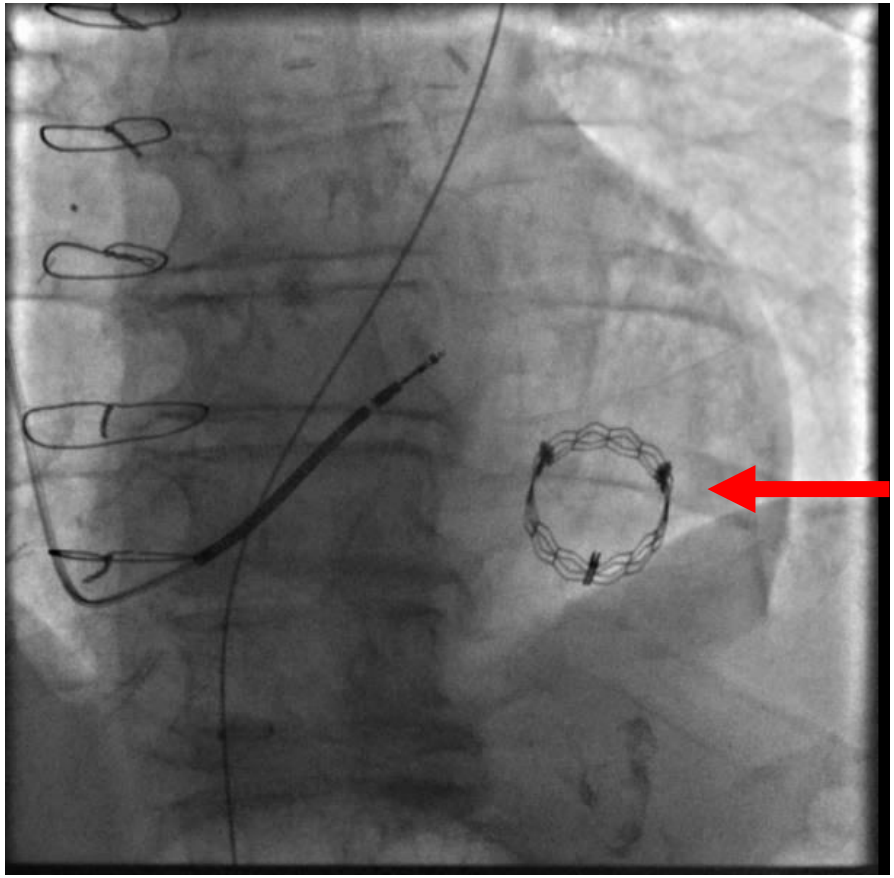

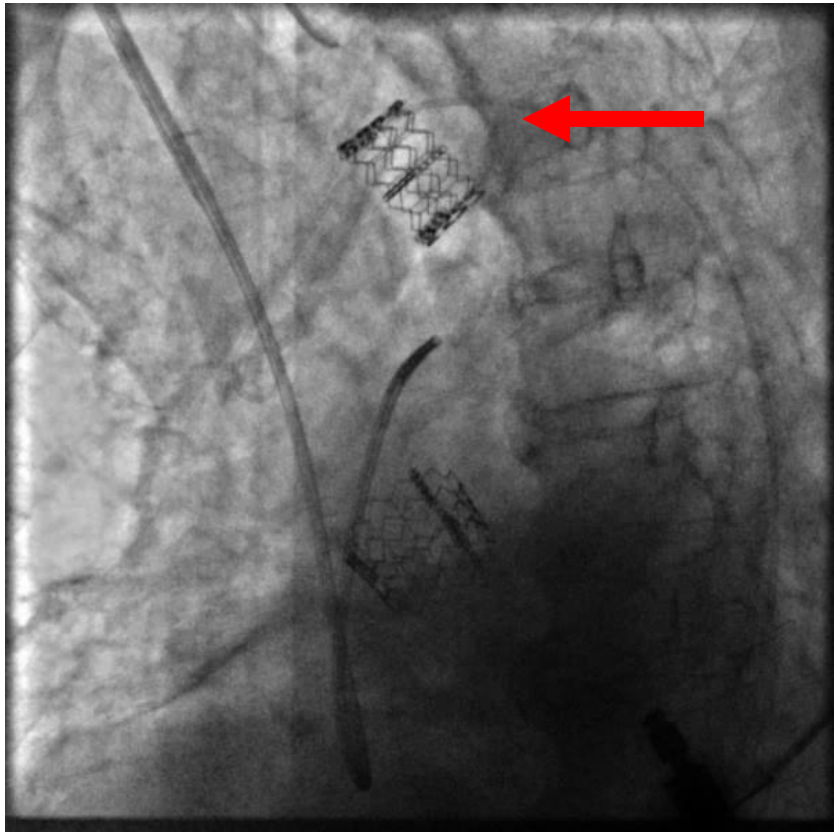

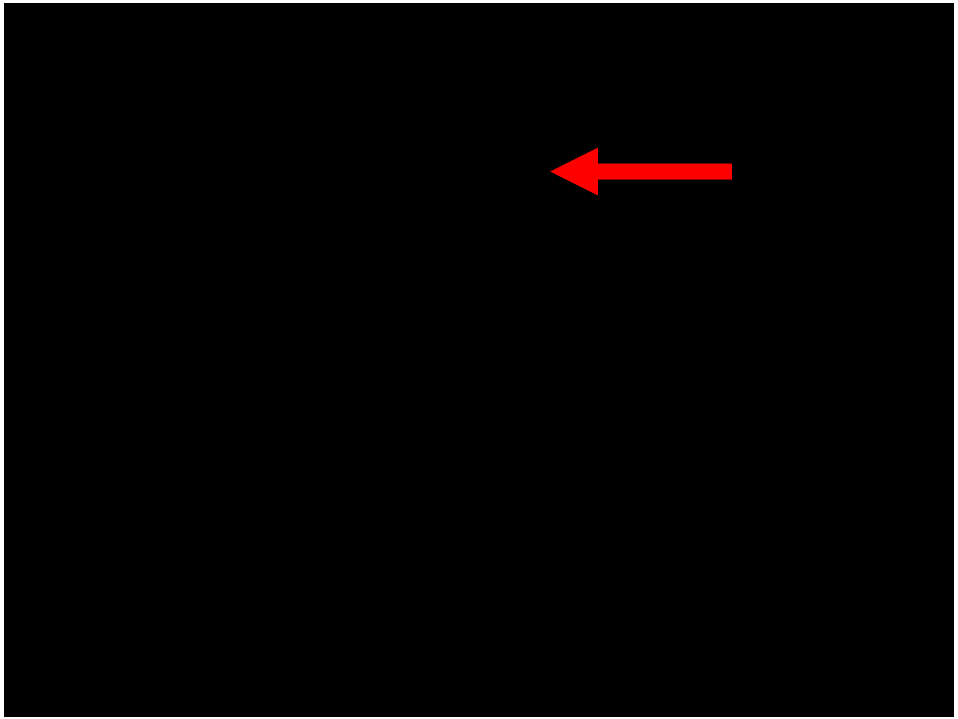

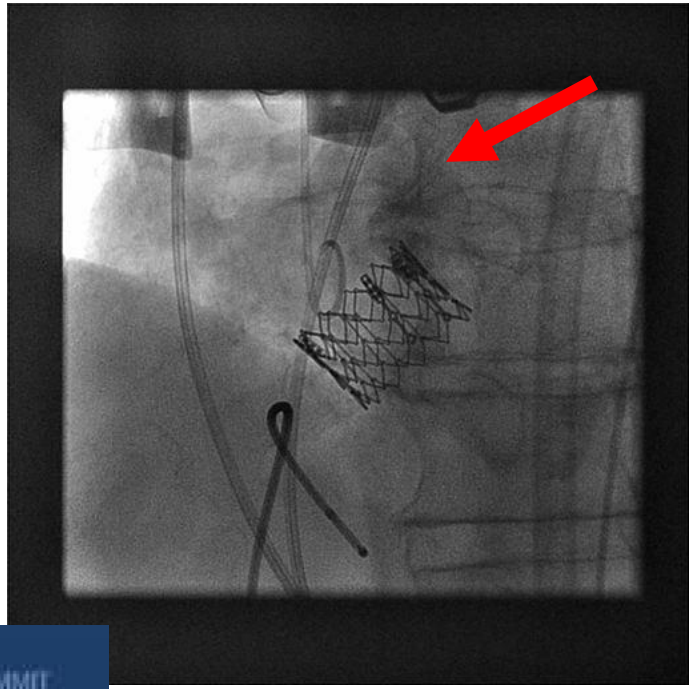

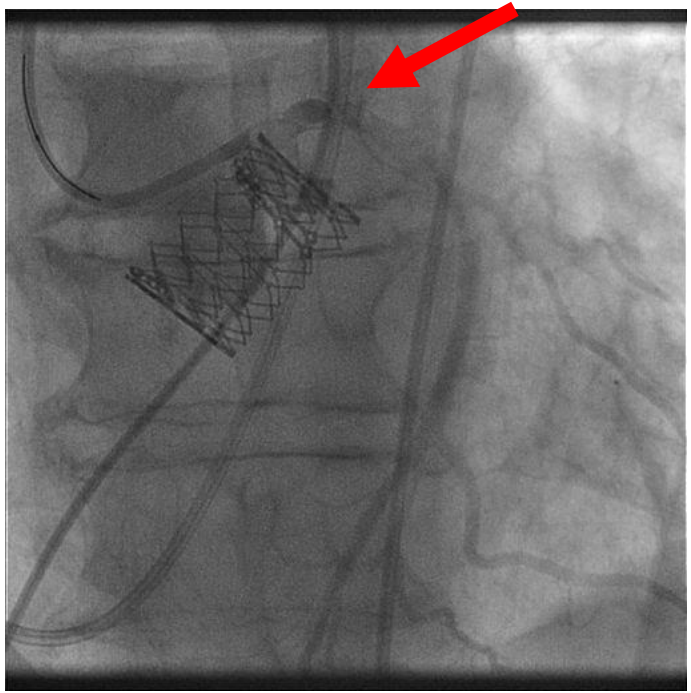

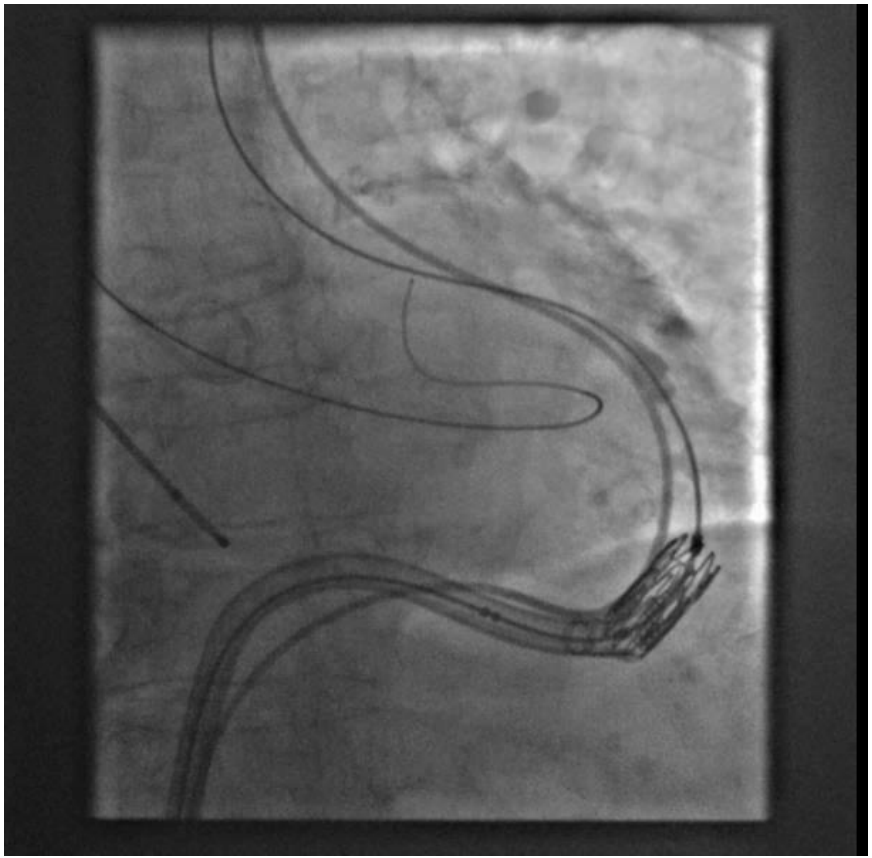

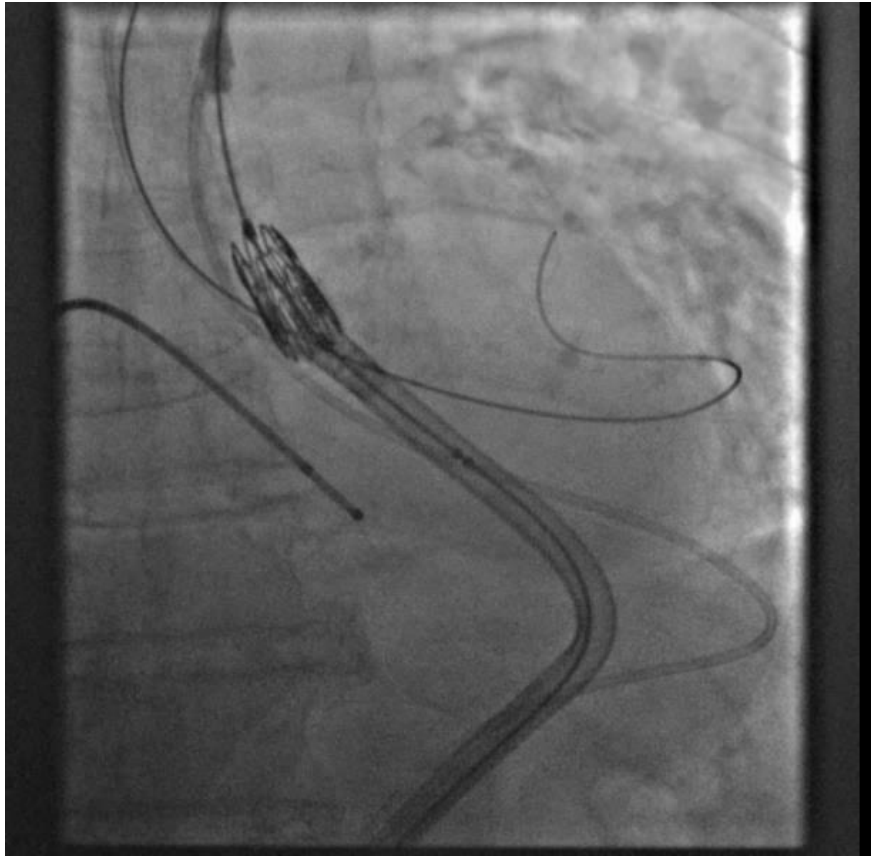


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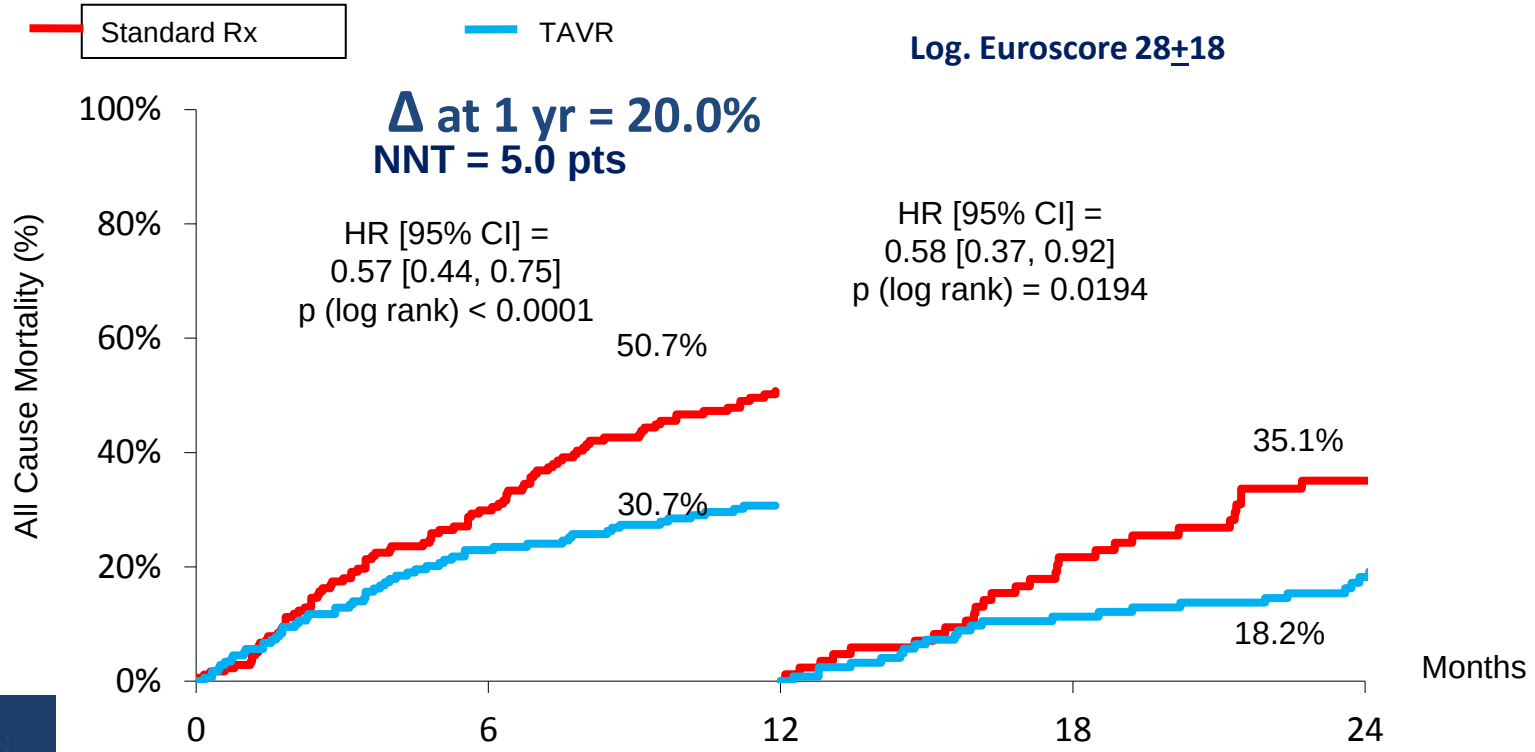
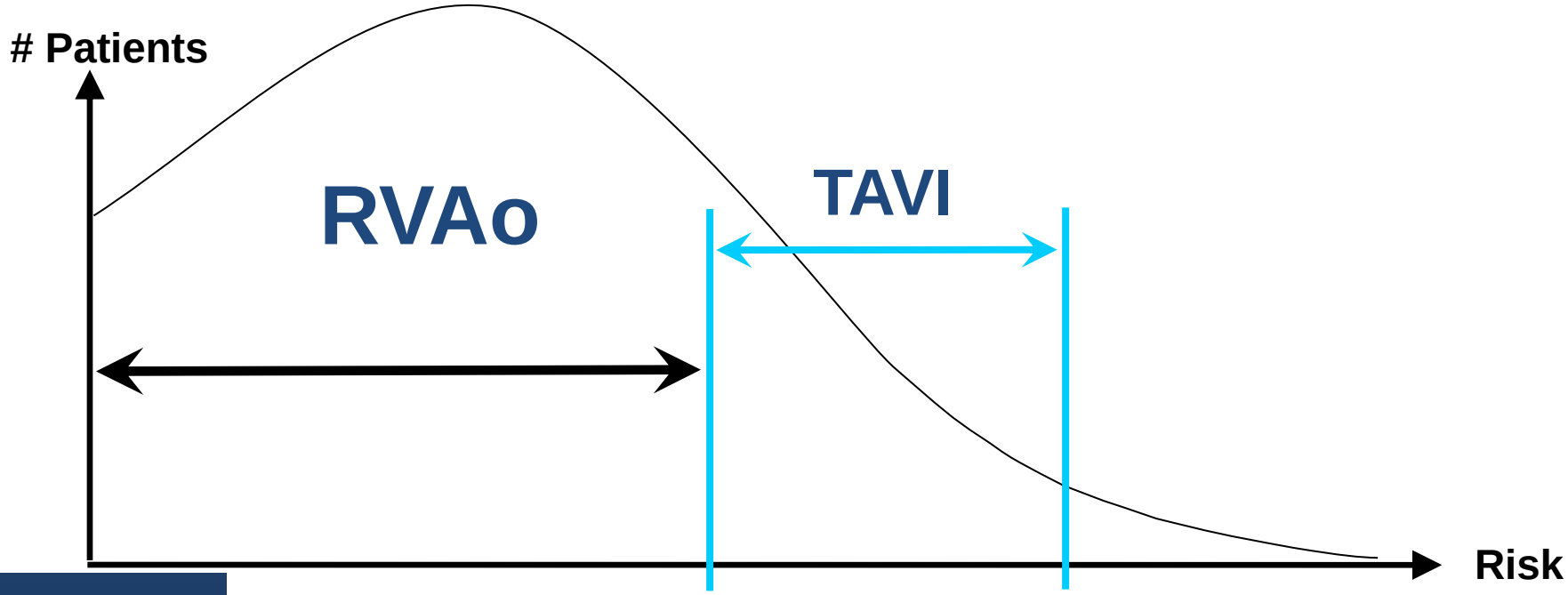
Partner 1: Surgical Contraindication



Kodali et al. NEJM 2011

To High Risk Patients

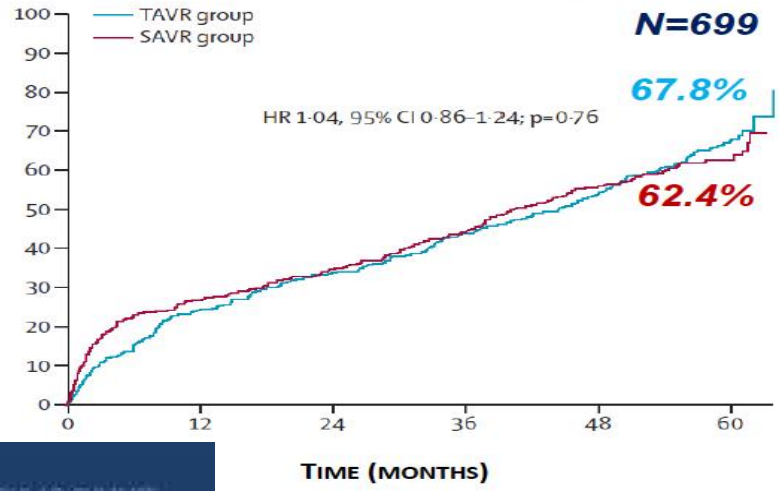


TAVI vs Surgical aortic valve replacement:
High-Risk patients

PARTNER 1A: 5-Year Follow-up

Mack MJ et al. *Lancet* 2015

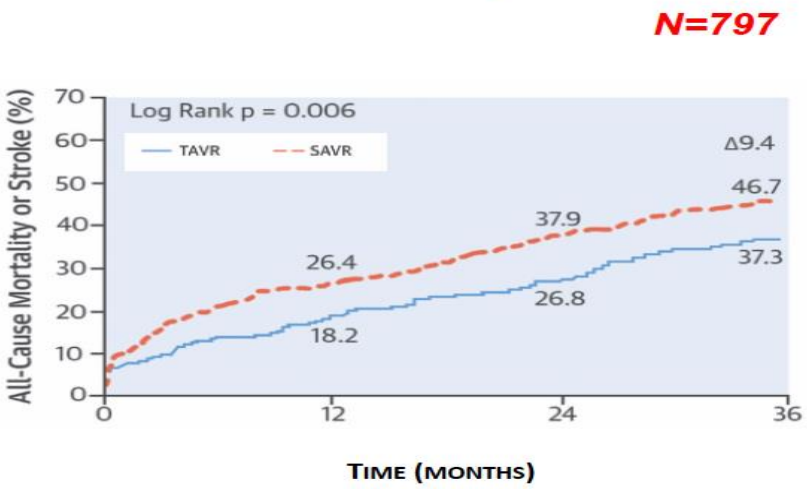
All-cause Mortality



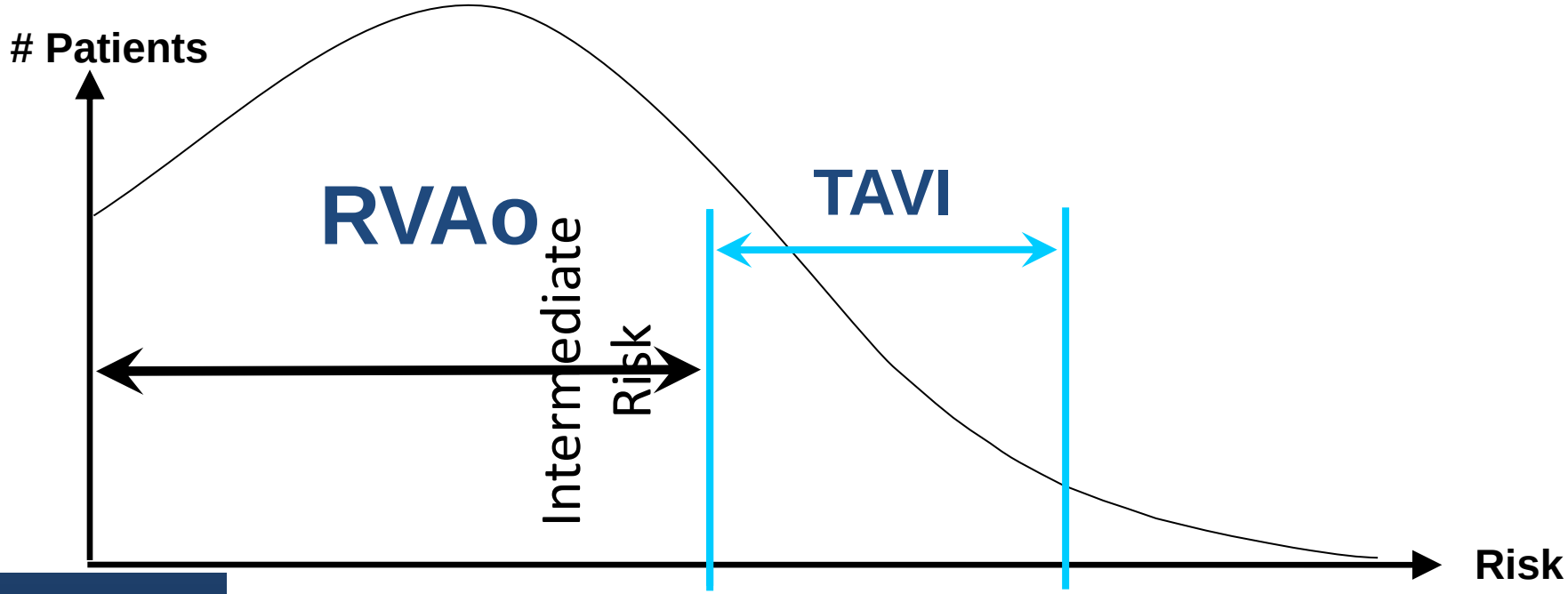
CoreValve High-Risk: 3-Year Follow-up

Deeb M et al. *J Am Coll Cardiol* 2016

All-cause Mortality or Stroke



And Intermediate Risk patients



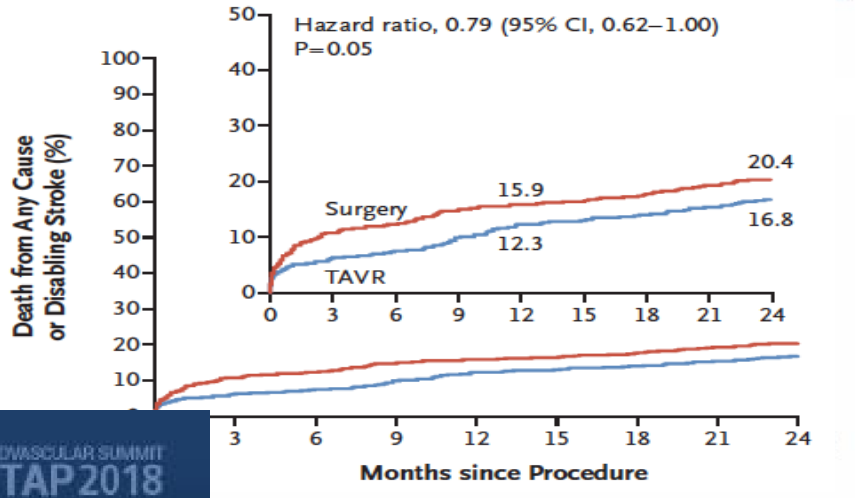
TAVI vs Surgical aortic valve replacement: Intermediate-Risk and All-comers Pts

PARTNER 2A: 2-Year Follow-Up

Leon MB et al. *N Engl J Med* 2016

All-cause Mortality or Stroke

N=2032

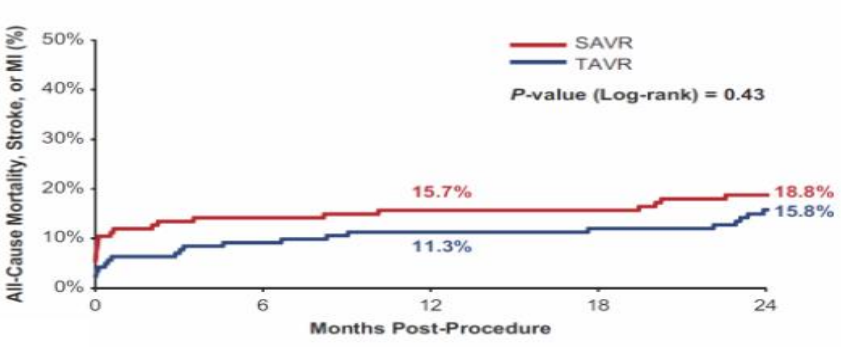


NOTION: 2-Year Follow-Up

Søndergaard L et al. *Circ Cardiovasc Interv 2016*

All-cause Mortality, Stroke, or MI

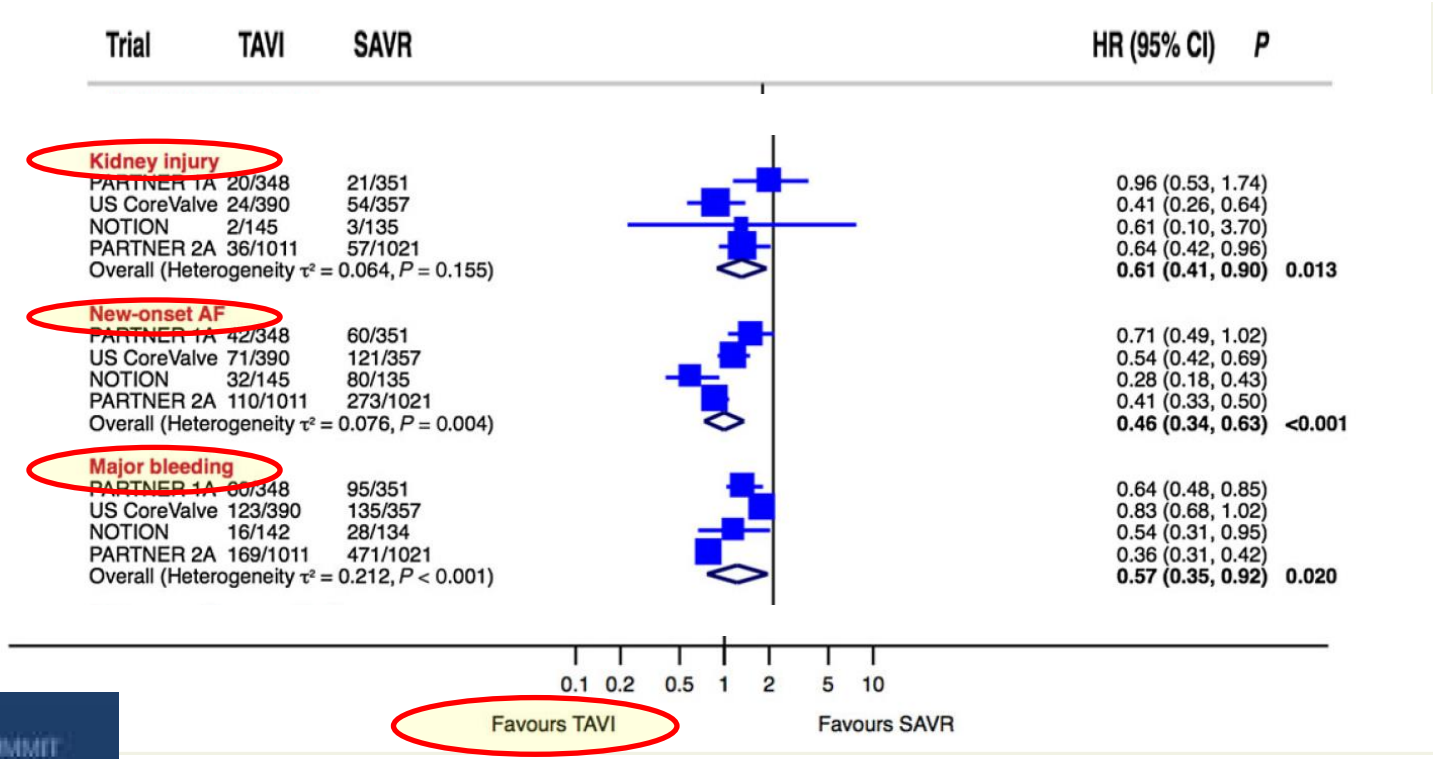
N=280



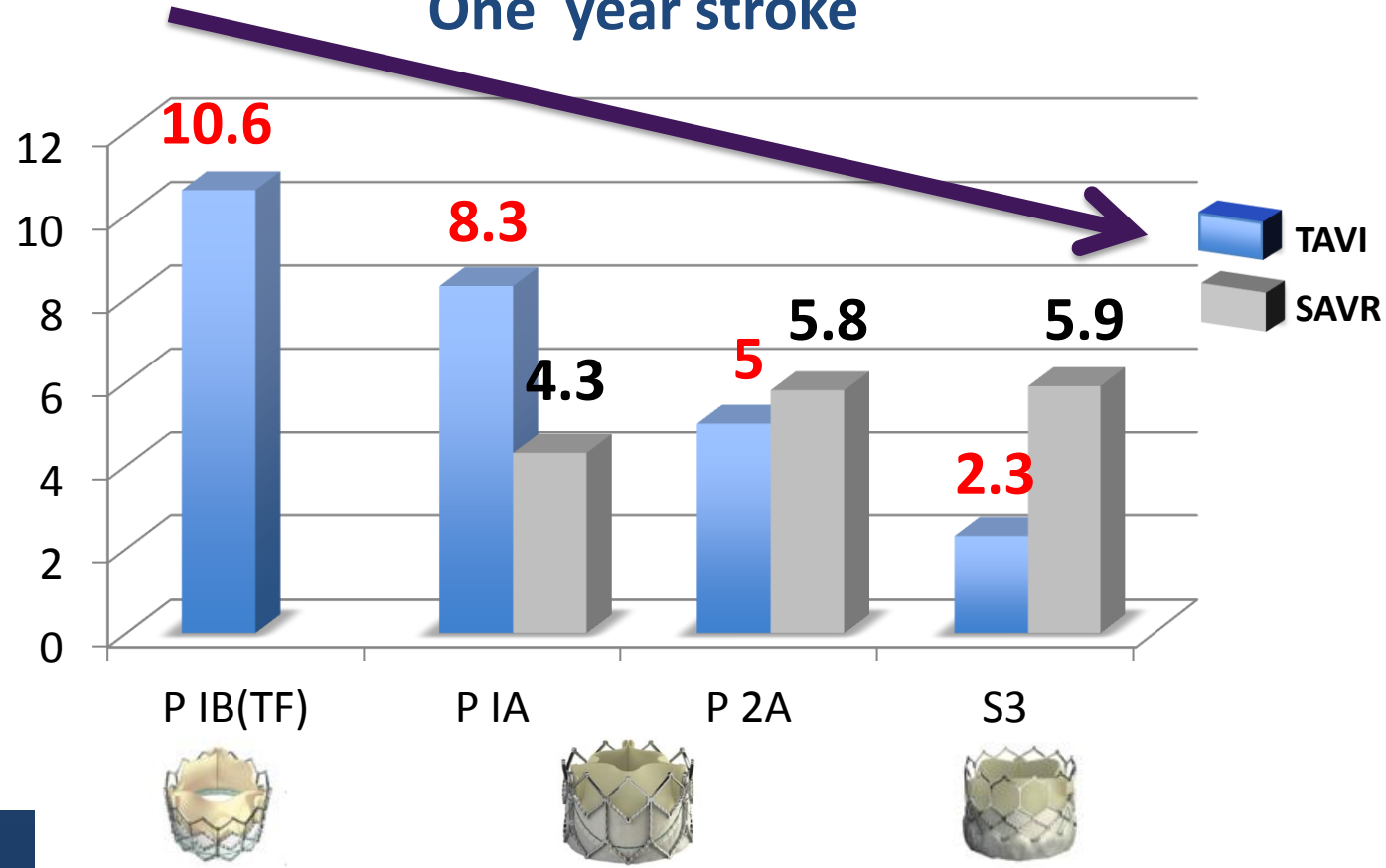
TAVI vs Surgical aortic valve replacement: Metanalysis of randomised trials

Siontis et al. Eur heart j 2016; 37: 3503-12

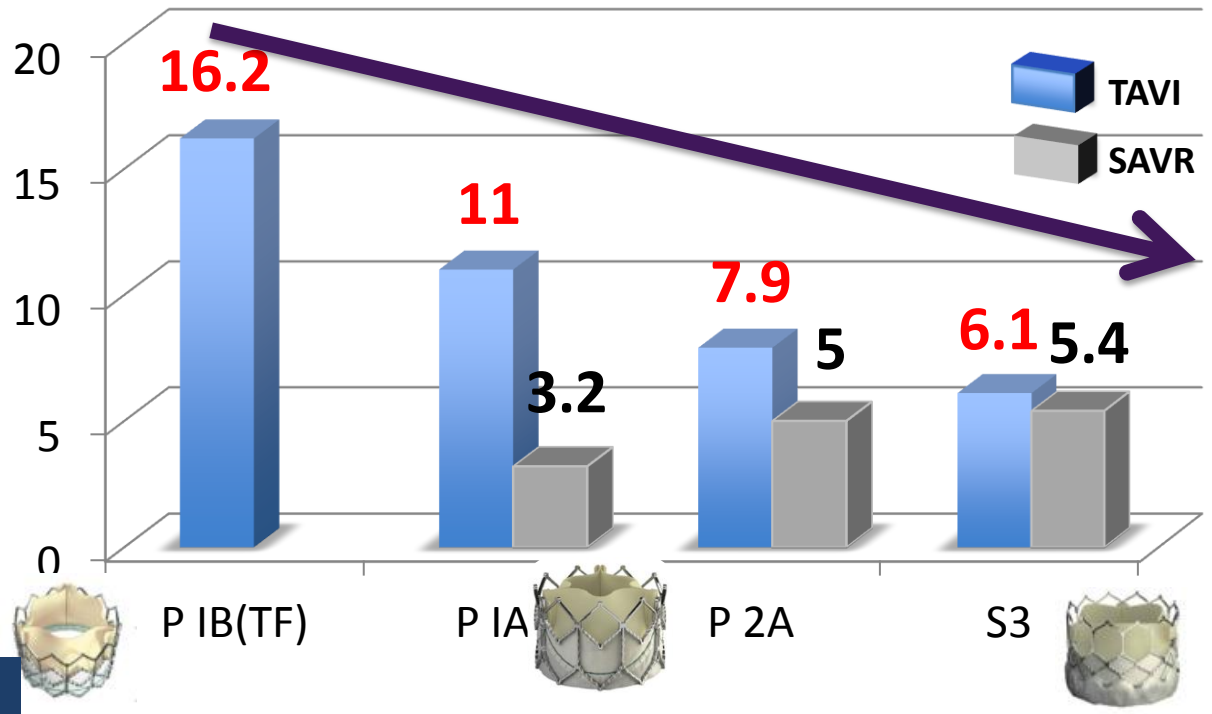
Complications: Kidney injury , new onset of AF, Major Bleeding



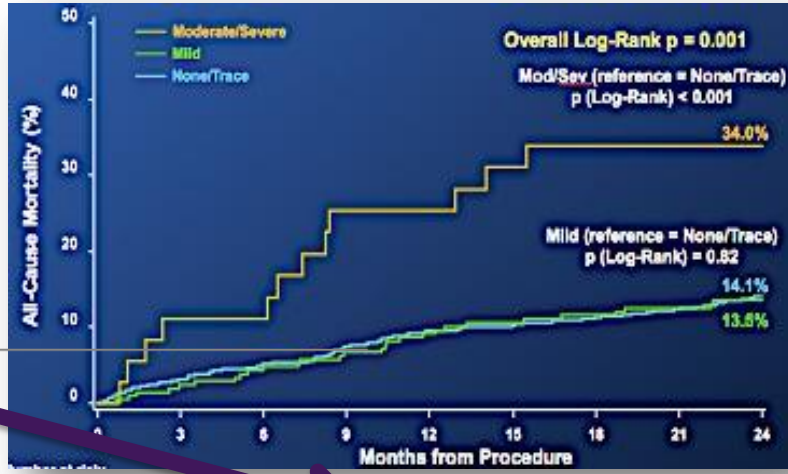
One year stroke

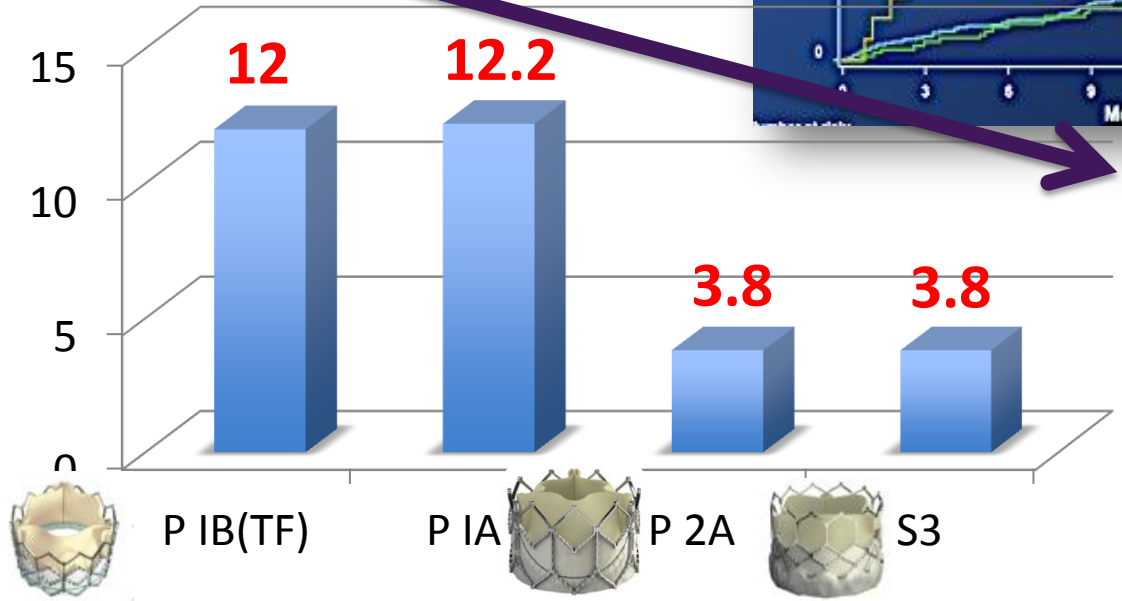


Vascular major complications

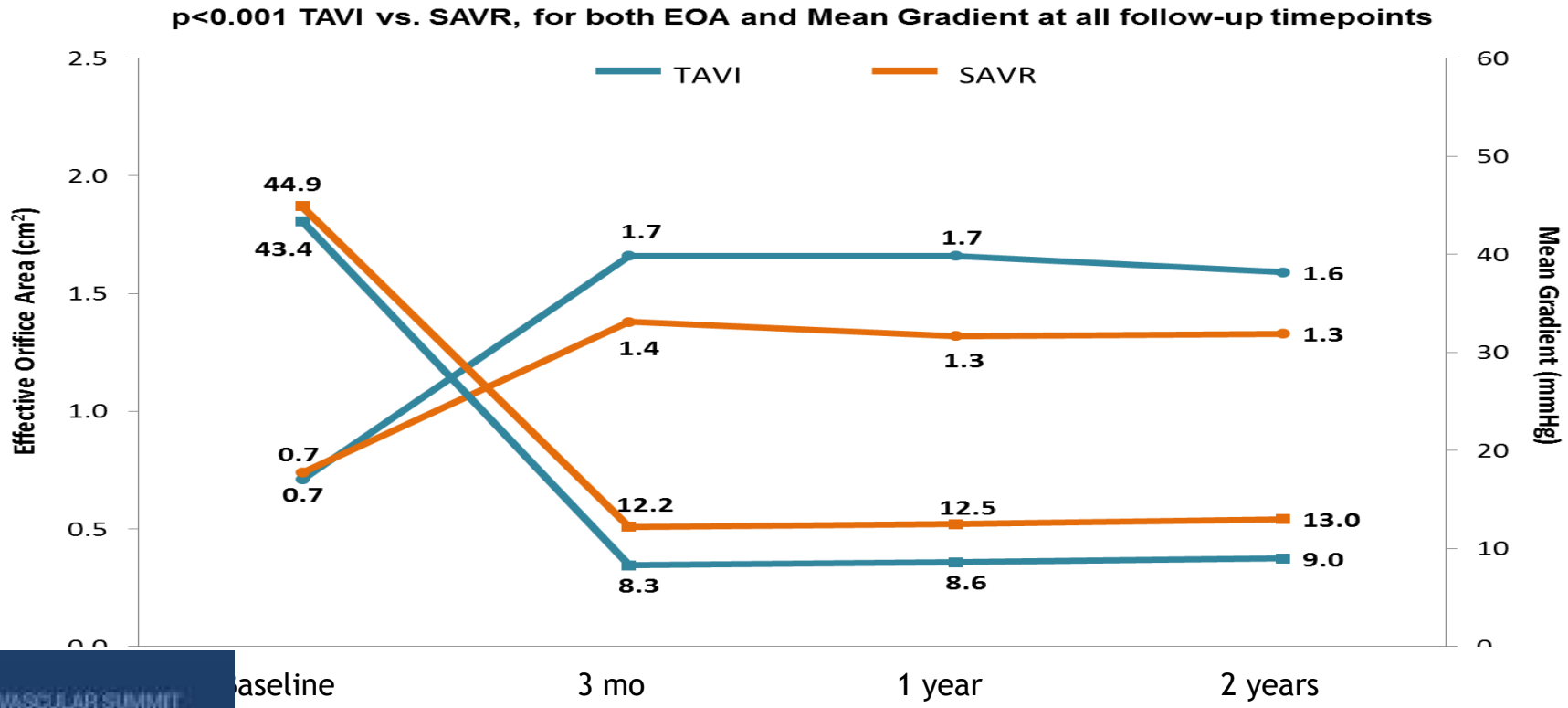


Moderate to severe Paraprosthetic regurgitation





Notion Trial



TAVI in Low-risk Pts: Ongoing Trials

PARTNER 3 NCT02675114	CoreValve NCT02701283	NOTION-2 NCT02825134
Low surgical risk as assessed by Heart Team		
STS < 4%	STS < 3%	STS < 4%
Sample Size		
N=1,228	N=1,200	N=992
1:1 Randomization TAVI Vs. SAVR		
SAPIEN 3	Evolut R	Any CE-approved device
Primary Endpoint		
All-cause mortality, Any strokes, or re-hospitalization at 1 year	All-cause mortality, any stroke, life-threatening bleeding, major vascular complications, or AKI at 30-day	All-cause mortality, myocardial infarction, or any stroke at 1-year

TAVI at institutions without cardiovascular surgery departments why

Darren Mylotte
McGill University Health Centre
Canada

Stuart J Head
Erasmus University Medical Center
Netherlands

Arie Pieter Kappetein
Erasmus University Medical Centre
Netherlands

Nicolo Piazza
McGill University Health Centre
Canada

EuroIntervention 2014 Sep;10(5):539-41

Conclusion

*In 2018, we are far from the end of the TAVI odyssey and the potential of this disruptive technology remains explosive

We will treat other valves (mitral, tricuspid) but I seems difficult to c imagine that it will represent the same revolution as TAVI was.

Conclusion

*In 2017, we are far from the end of the TAVI odyssey and the potential of this disruptive technology remains explosive
We will treat other valves (mitral, tricuspid) but I cannot imagine that it will represent the same revolution as TAVI was.

* Nobody could have anticipated the growth of TAVI in the last decade
Whether TAVI will become the standard of care and surgery the exception to the rule in the 10 years to come is uncertain, but appears possible…..

This is TAVI!

This is TAVI!