

# The revolution of TAVI, my personal journey

MC MORICE, FESC, FACC

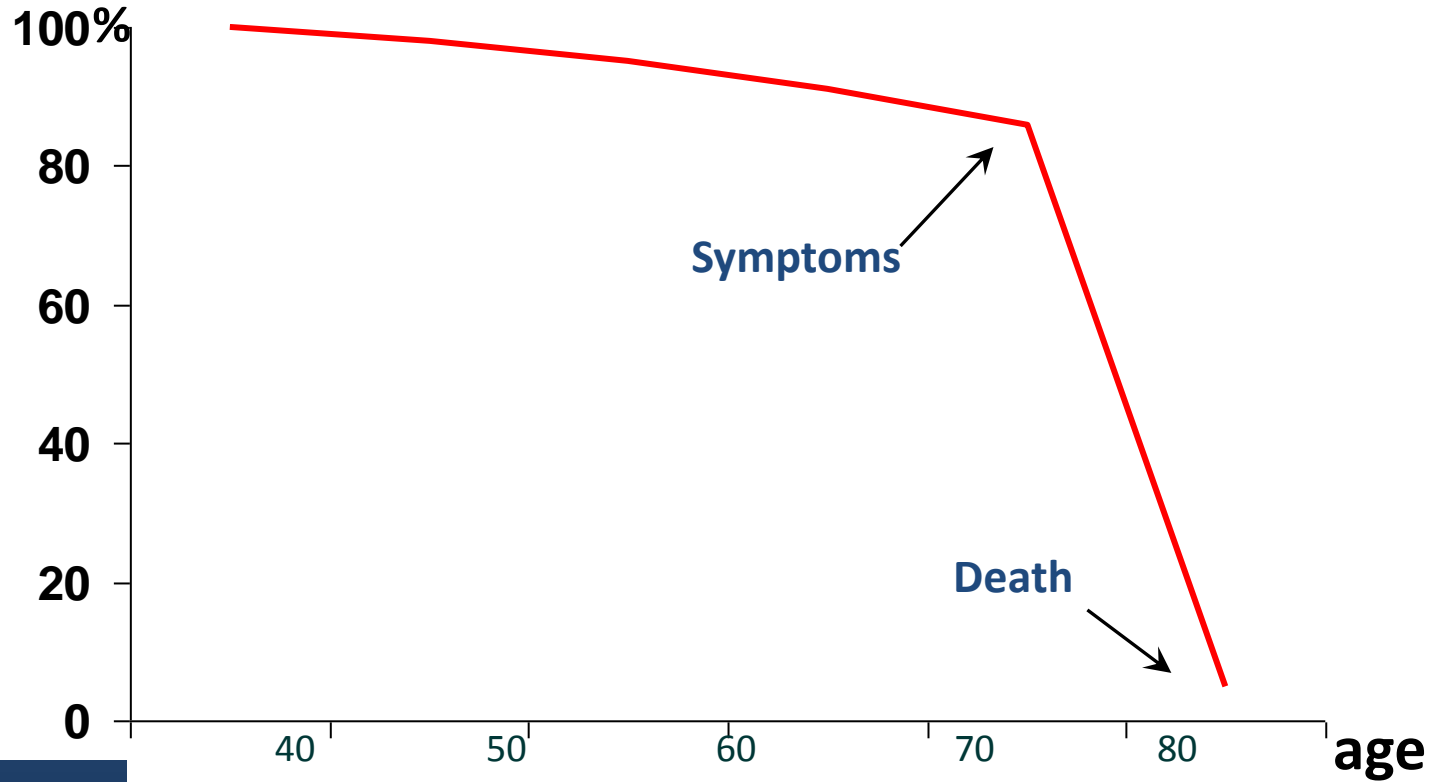
Massy France

CARDIOVASCULAR SUMMIT  
TCTAP 2018

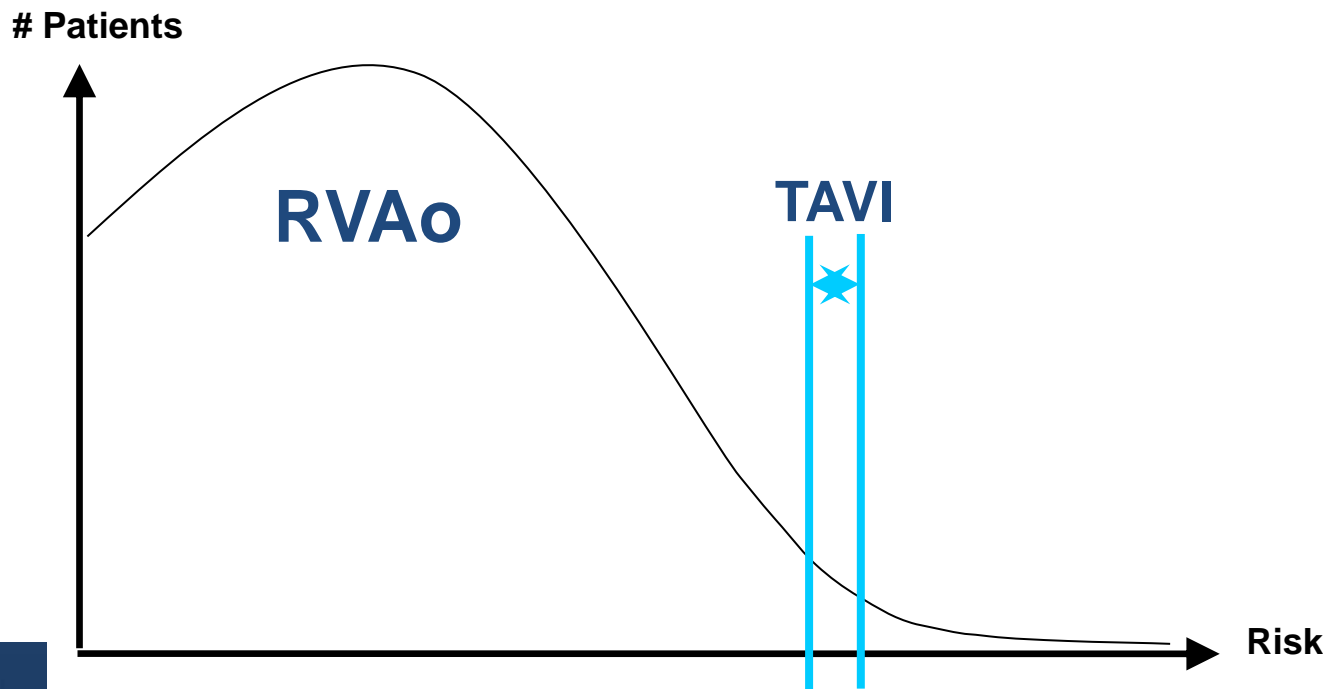
- I MC Morice have no conflict of interest to disclose relative to this lecture



# Natural history of aortic stenosis



# From compassionate cases





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

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

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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.<sup>1-5</sup> However, in-stent restenosis continues to limit the long-term success of this approach.<sup>6,7</sup> 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.<sup>8</sup>

In controlled trials, several pharmaceutical agents have failed to inhibit restenosis after coronary interventions.<sup>9</sup> 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.....

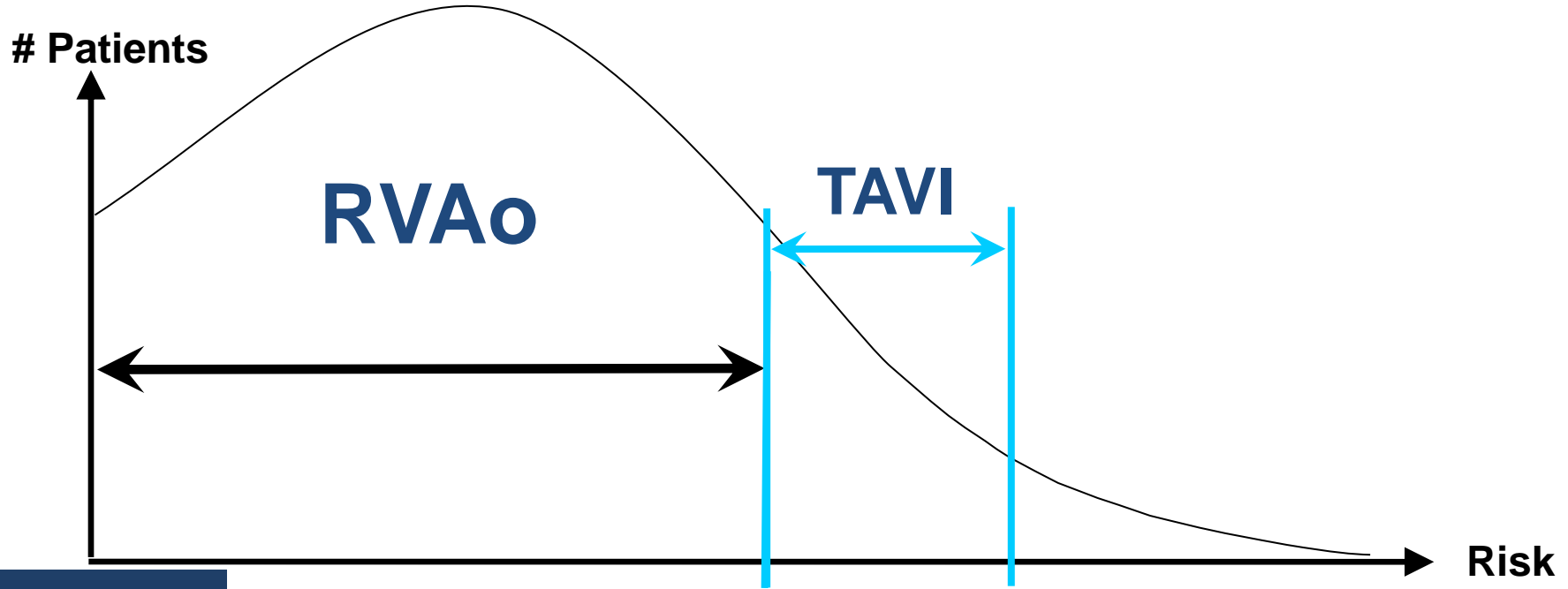


Some conservative cardiologists

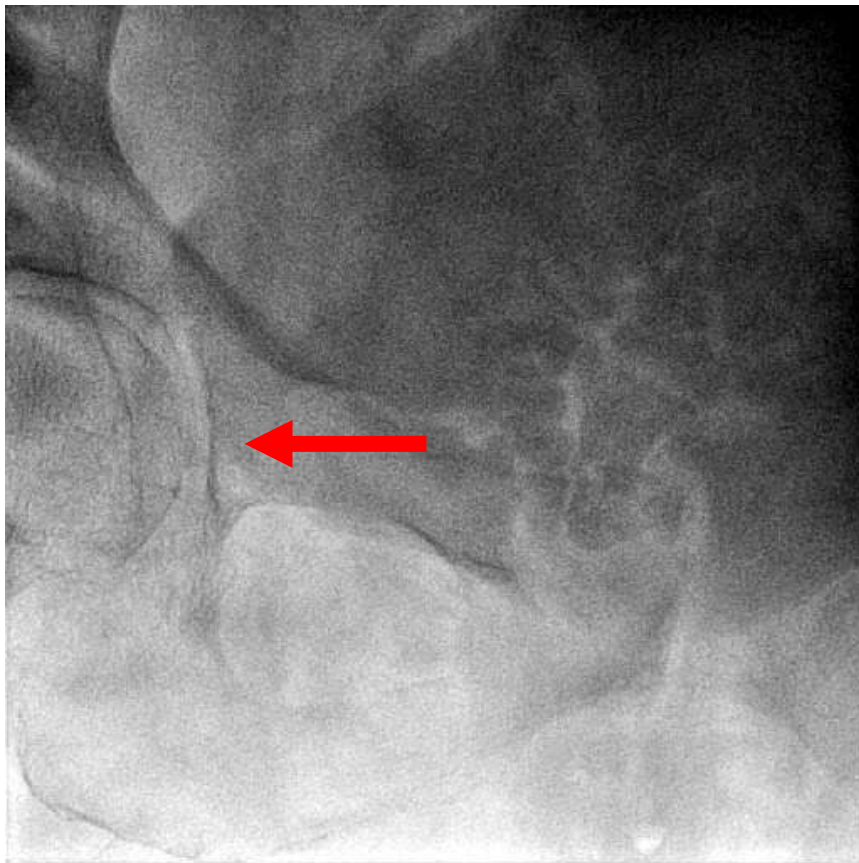


Our patients were doing so well!

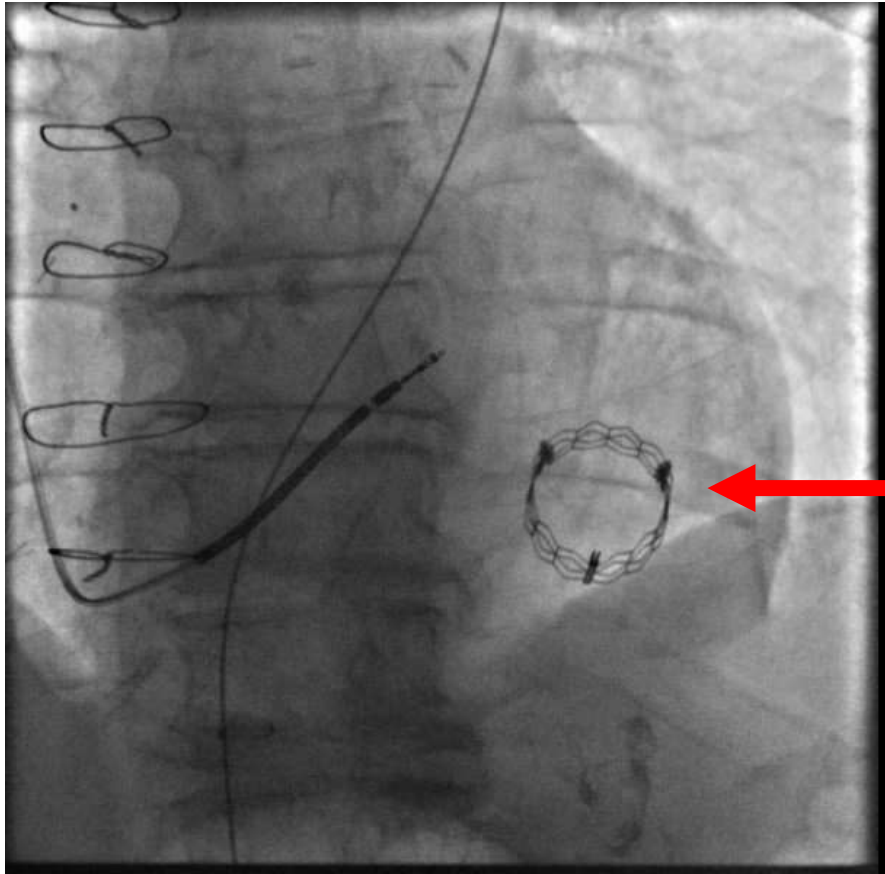
# It was an unmet need

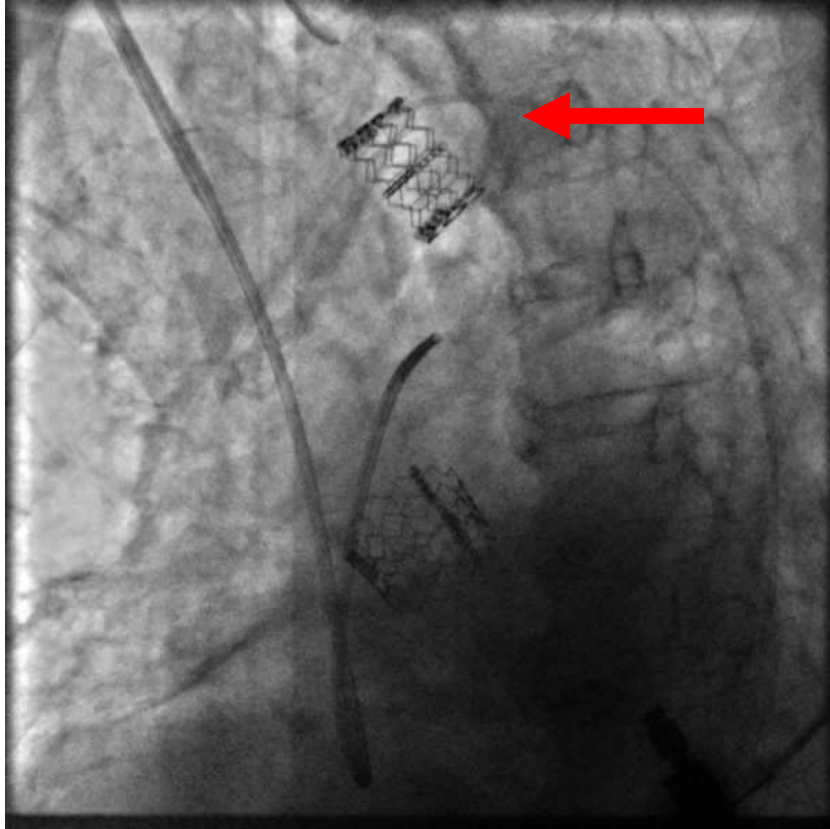




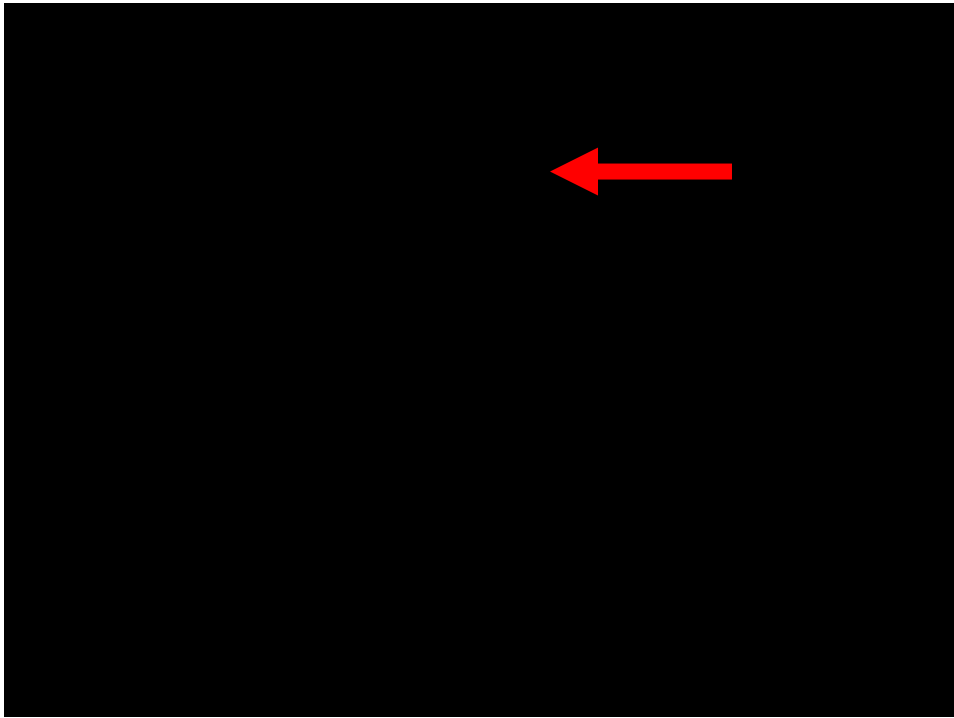


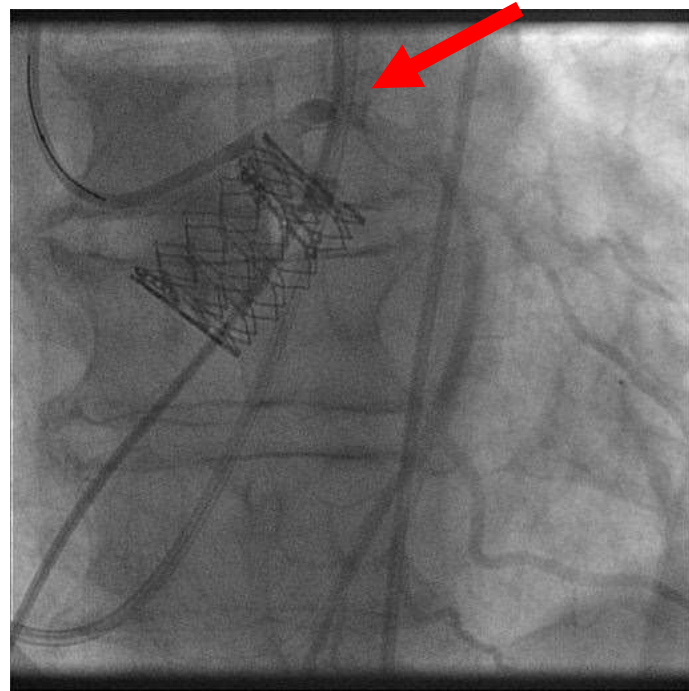
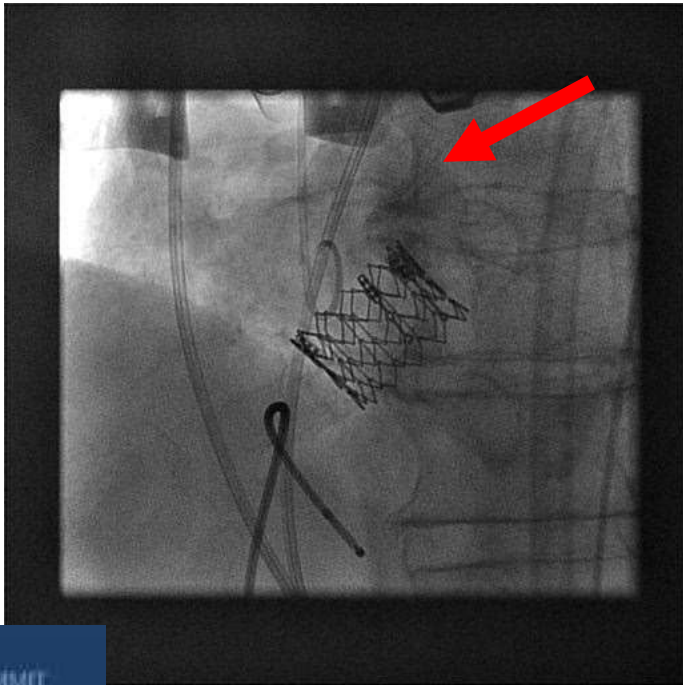


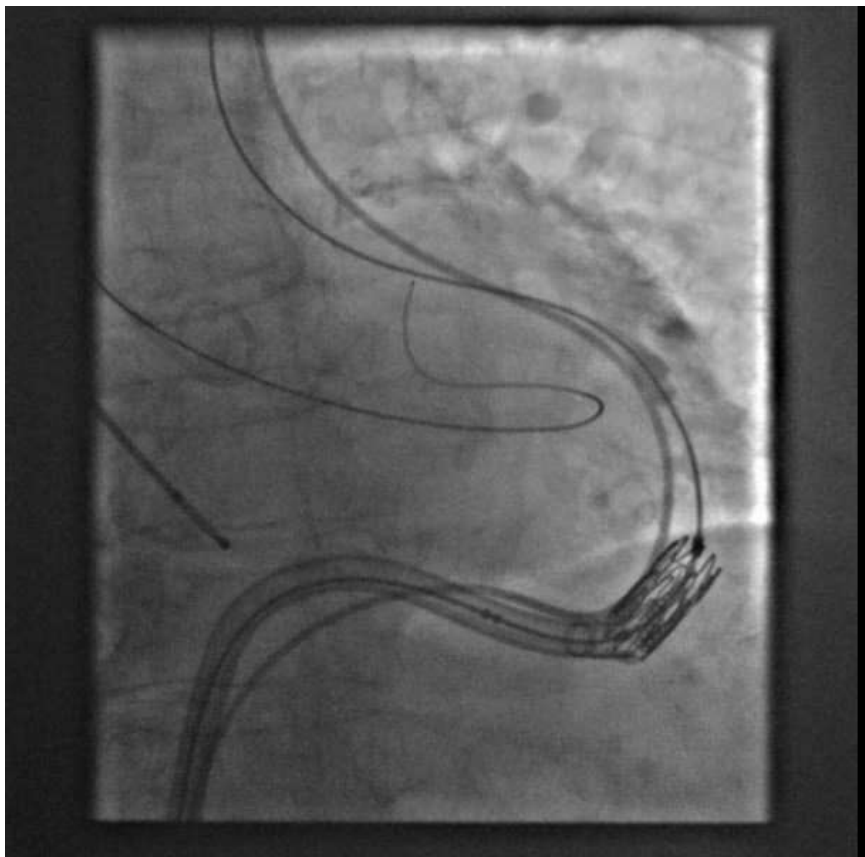
















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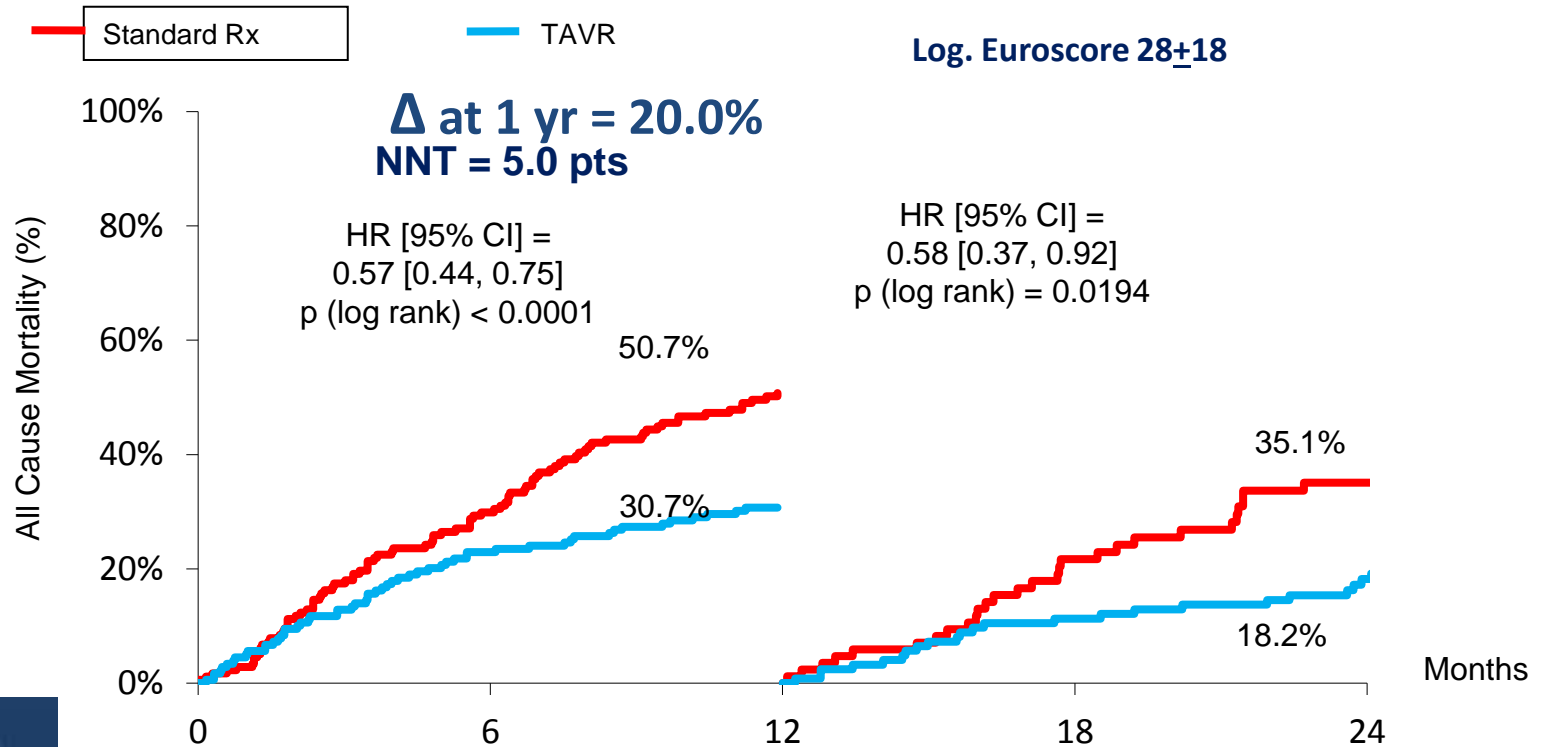




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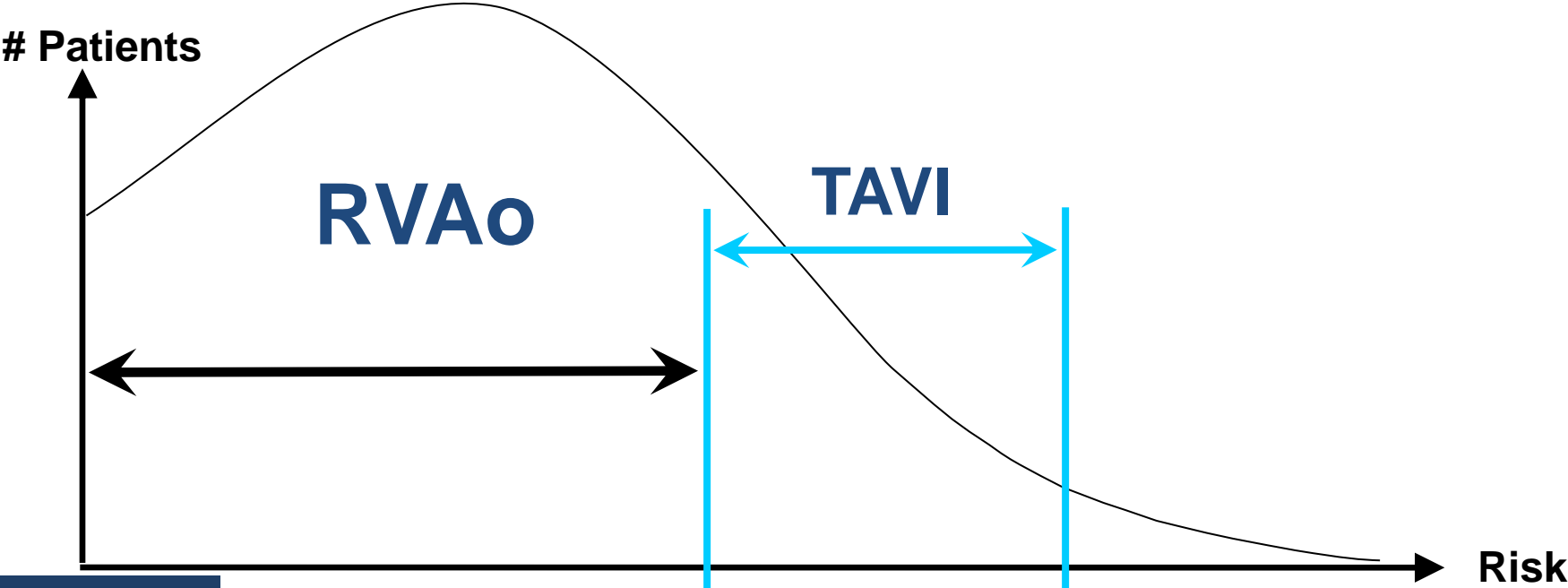


# Partner 1: Surgical Contraindication



Kodali et al. NEJM 2011

# To High Risk Patients



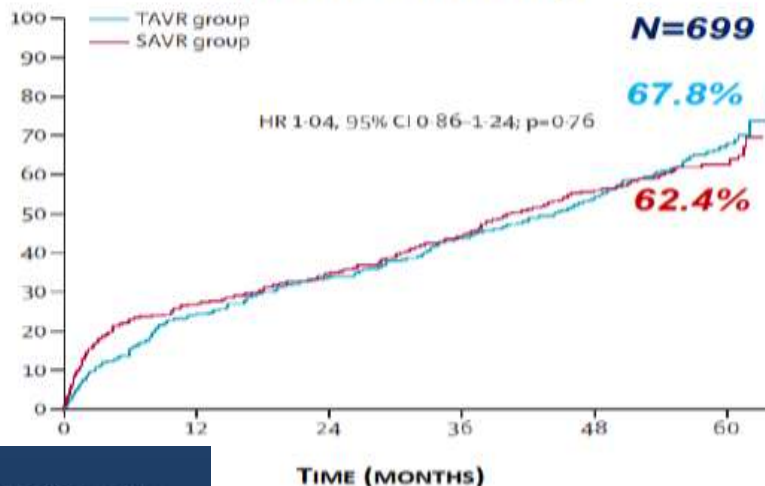


# TAVI vs Surgical aortic valve replacement: High-Risk patients

## PARTNER 1A: 5-Year Follow-up

Mack MJ et al. *Lancet* 2015

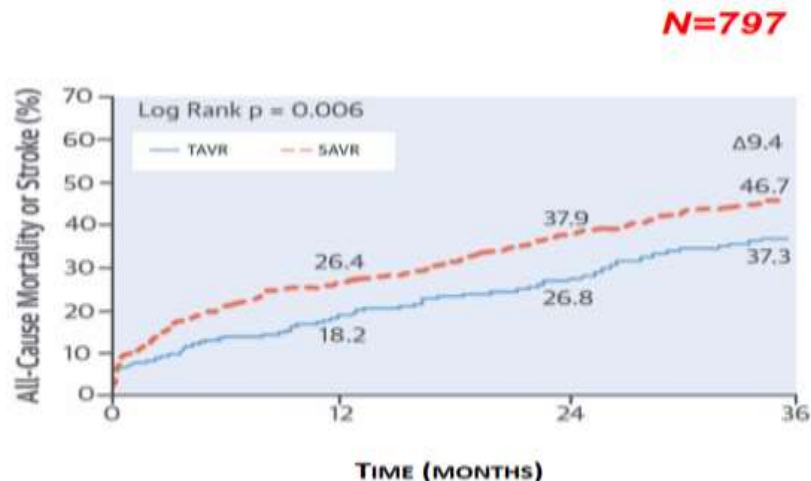
### All-cause Mortality



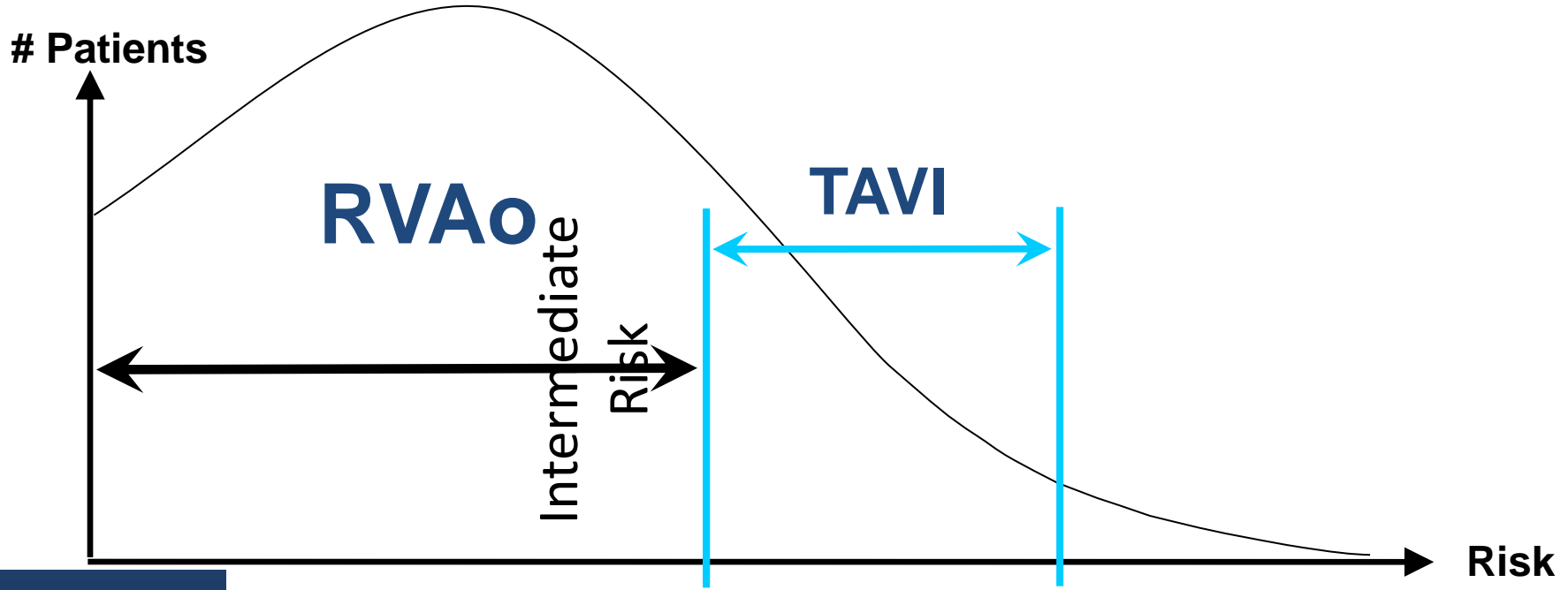
## CoreValve High-Risk: 3-Year Follow-up

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

### All-cause Mortality or Stroke



# And Intermediate Risk patients



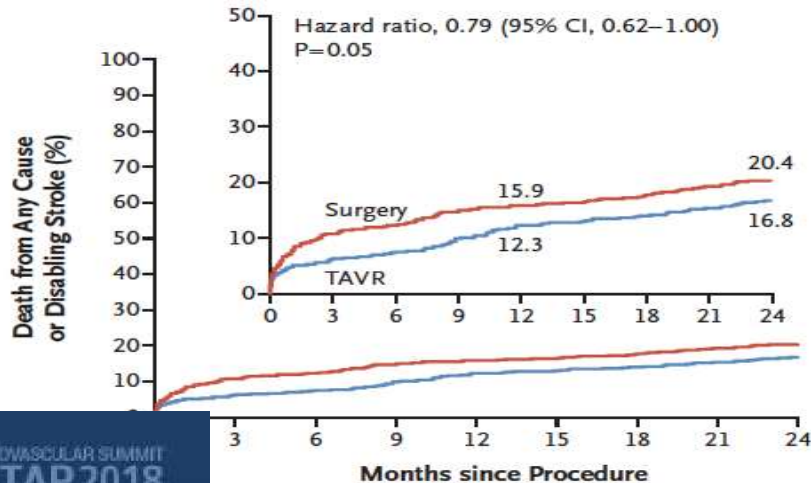
# TAVI vs Surgical aortic valve replacement: Intermediate-Risk and All-comers Pts

## PARTNER 2A: 2-Year Follow-Up

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

**All-cause Mortality or Stroke**

**N=2032**

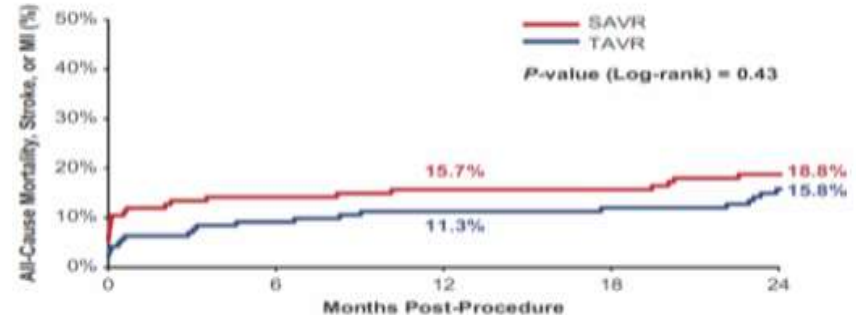


## NOTION: 2-Year Follow-Up

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

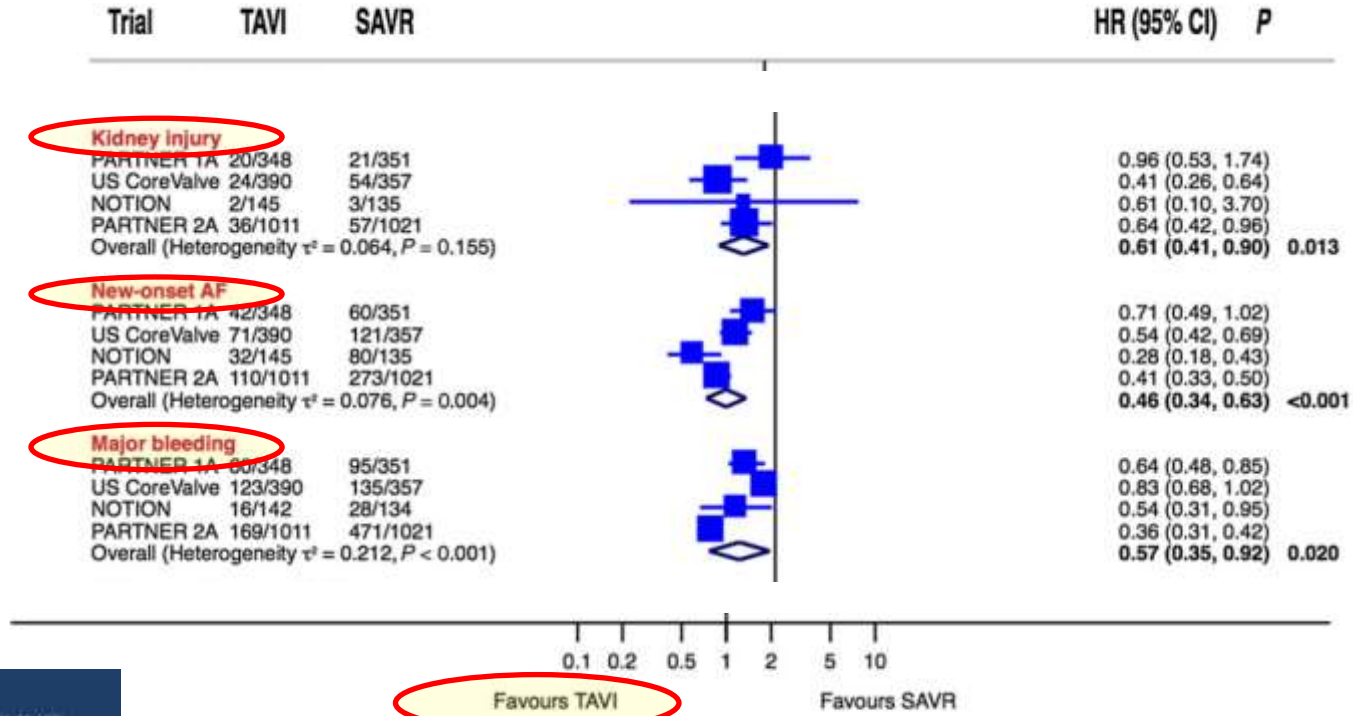
Death from any cause

Trial	TAVI	SAVR	HR (95% CI)	P
PARTNER 1A	116/348	114/351	0.90 (0.71, 1.15)	
US CoreValve	85/391	99/359	0.79 (0.61, 1.01)	
NOTION	11/145	14/135	0.72 (0.33, 1.59)	
PARTNER 2A	166/1011	170/1021	0.92 (0.74, 1.13)	
Overall (Heterogeneity $\tau^2 < 0.001, P = 0.755$ )			<b>0.87 (0.76, 0.99)</b>	<b>0.038</b>

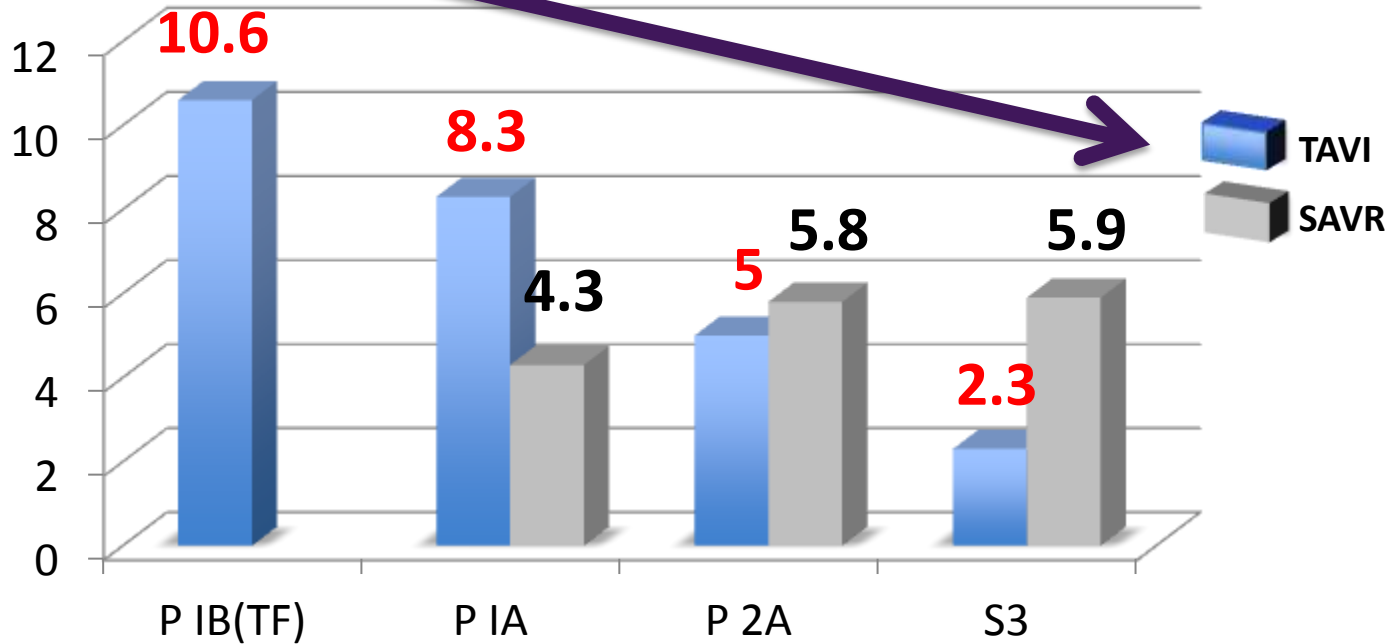
**Access route**

Transfemoral	4	<0.001	0.80 (0.69, 0.93)	0.024
Transthoracic	2	<0.001	1.17 (0.88, 1.56)	

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



# One year stroke



P IB(TF)



P IA

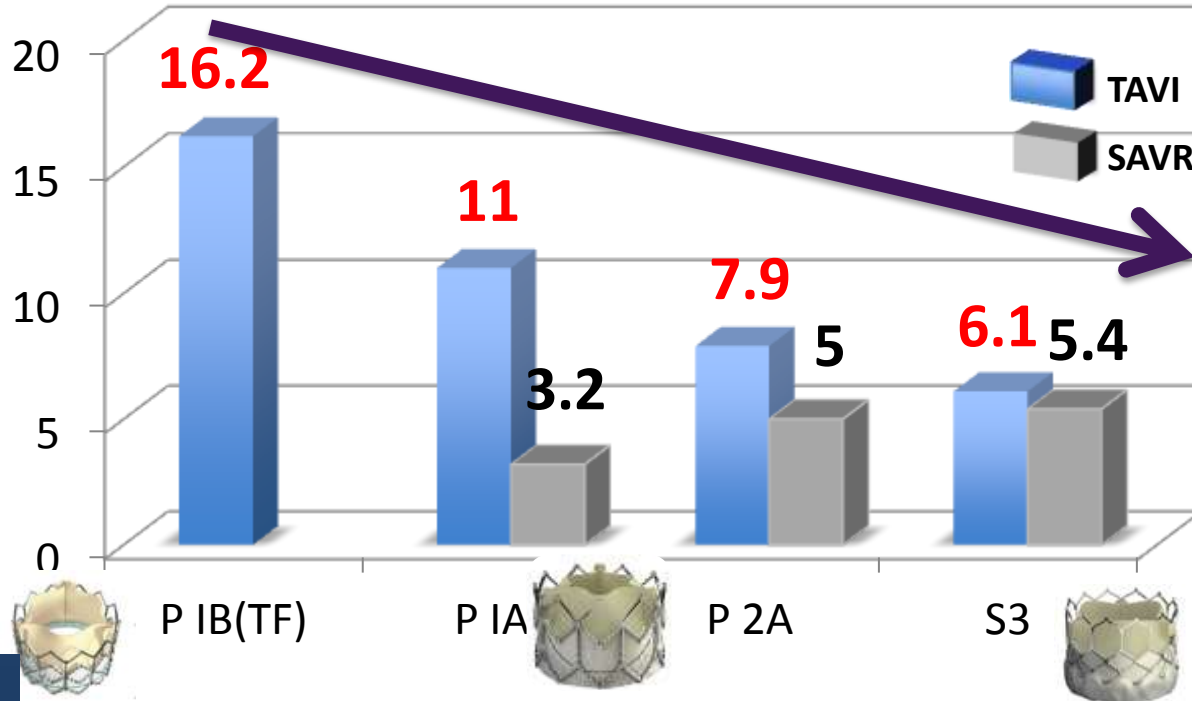


P 2A

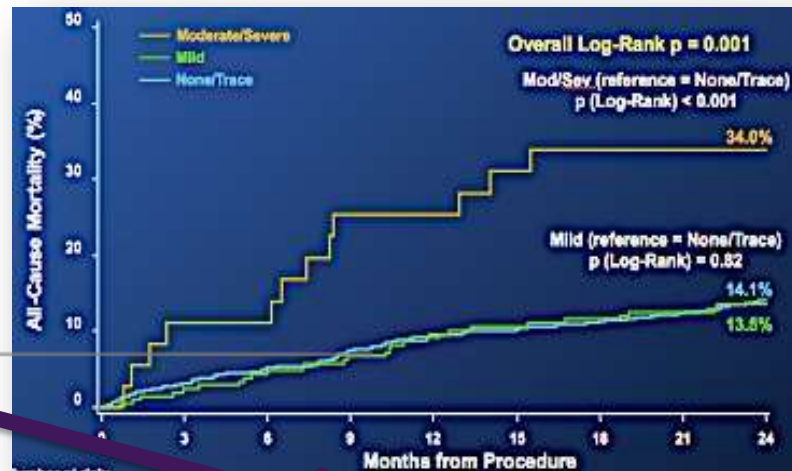
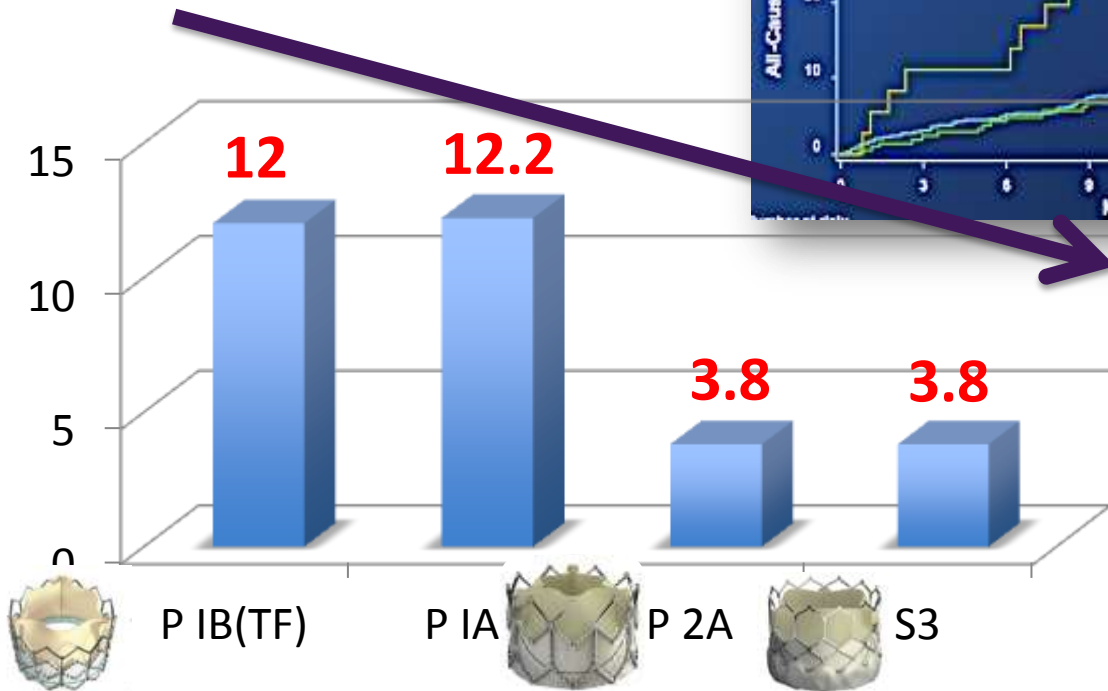
S3



# Vascular major complications



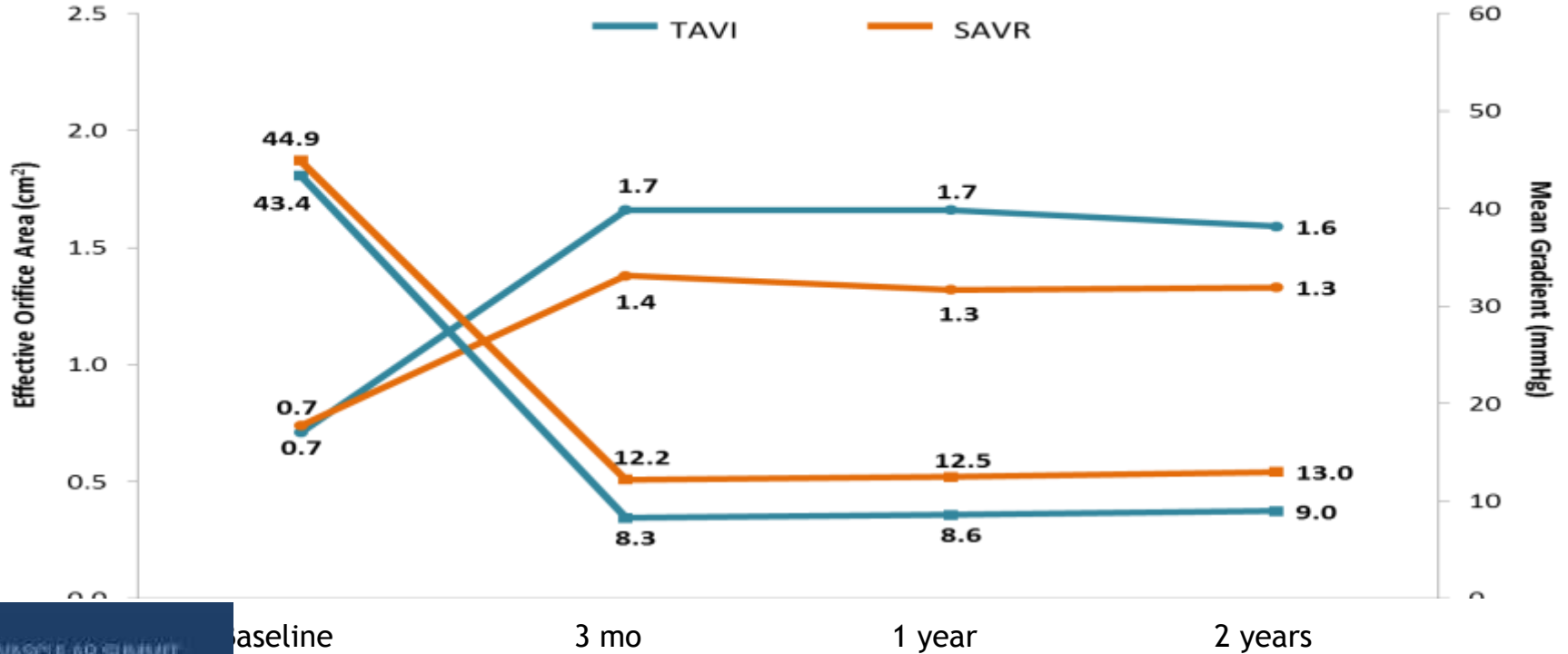
# Moderate to severe Paraprosthetic regurgitation





# Notion Trial

p<0.001 TAVI vs. SAVR, for both EOA and Mean Gradient at all follow-up timepoints



# TAVI in Low-risk Pts: Ongoing Trials

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

# TAVI at institutions without cardiovascular surgery departments why

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Canada

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Netherlands

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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!**

