



# EuroValve

October 24-25 2014

**Symposium: diagnostic and treatment of  
patients with aortic regurgitation**

**IS THERE A PLACE FOR TRANSCATHETER VALVE  
IMPLANTATION?**

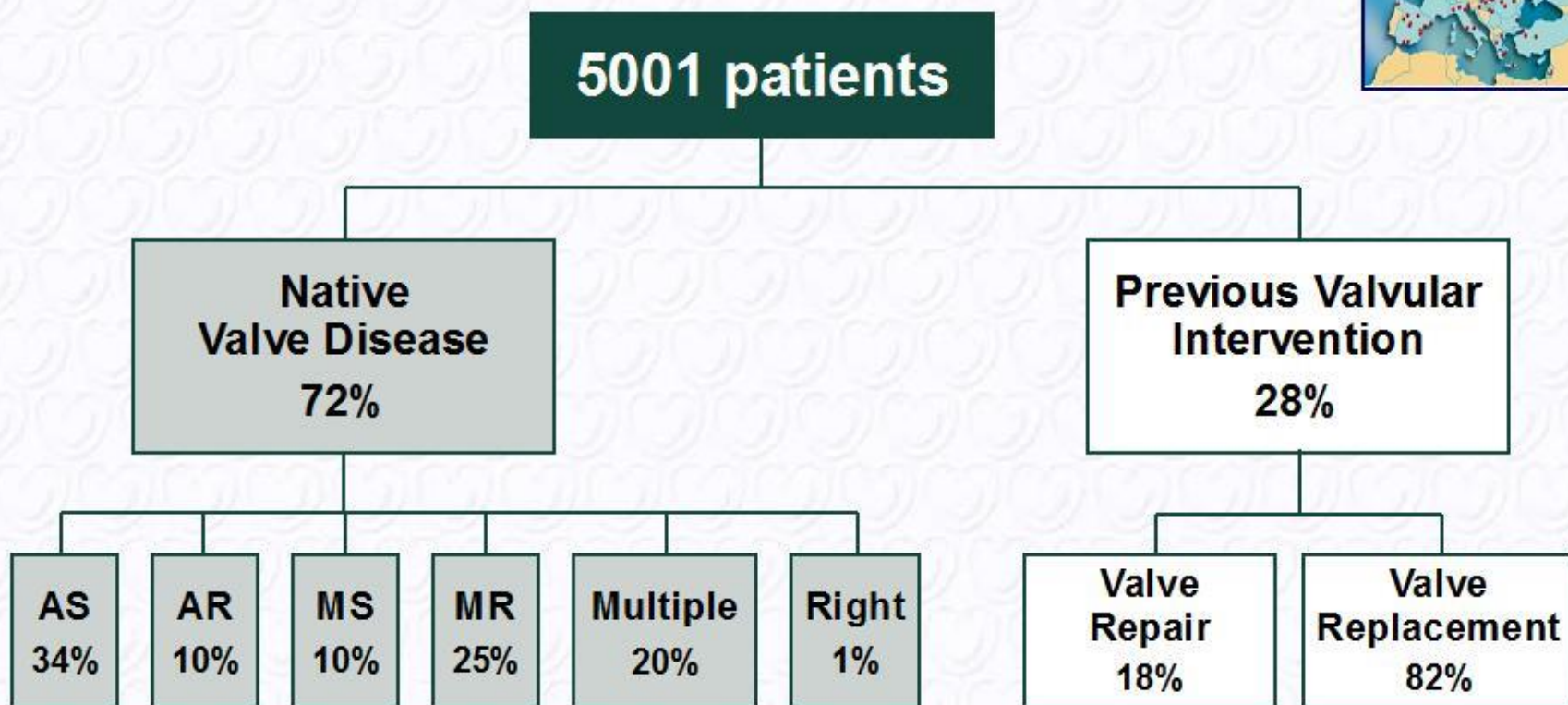
***Prof. Giovanni Esposito***

*Dipartimento di Scienze Biomediche Avanzate*

*Università degli Studi di Napoli, Federico II*



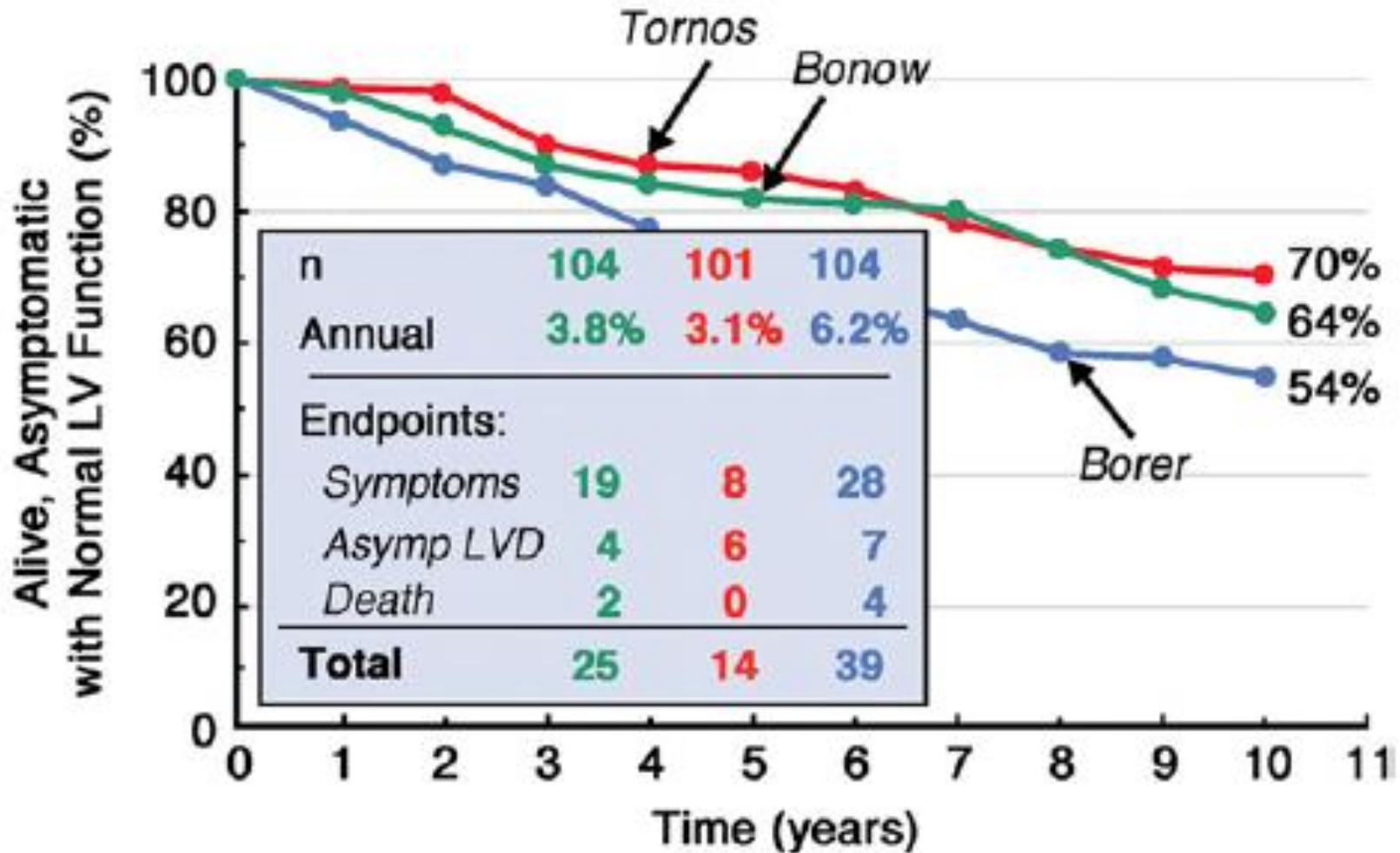
# Distribution of Valvular Heart Diseases in the Euro Heart Survey



Third valvulopathy

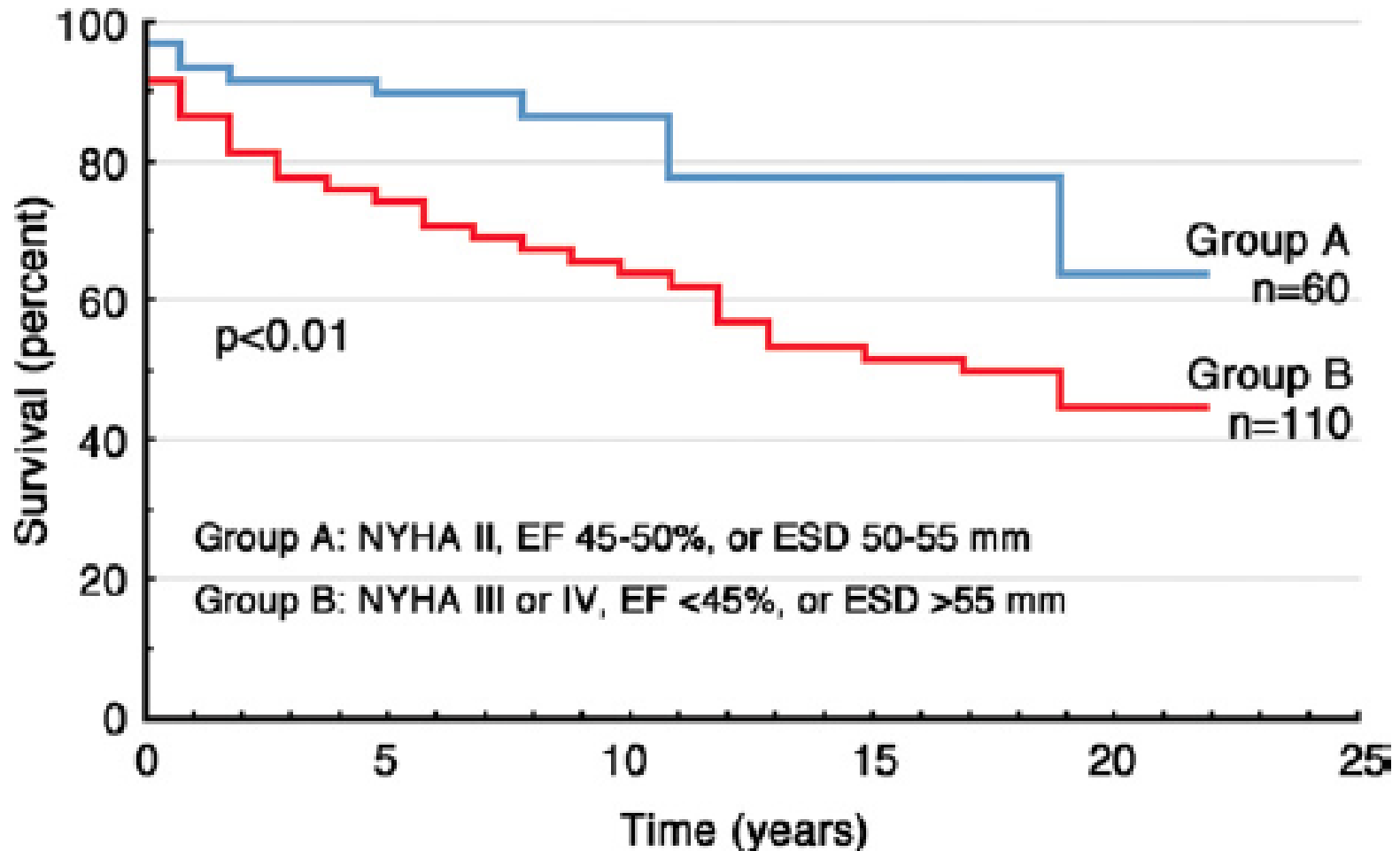
# Aortic regurgitation:

## *Natural History in Asymptomatic Patients*



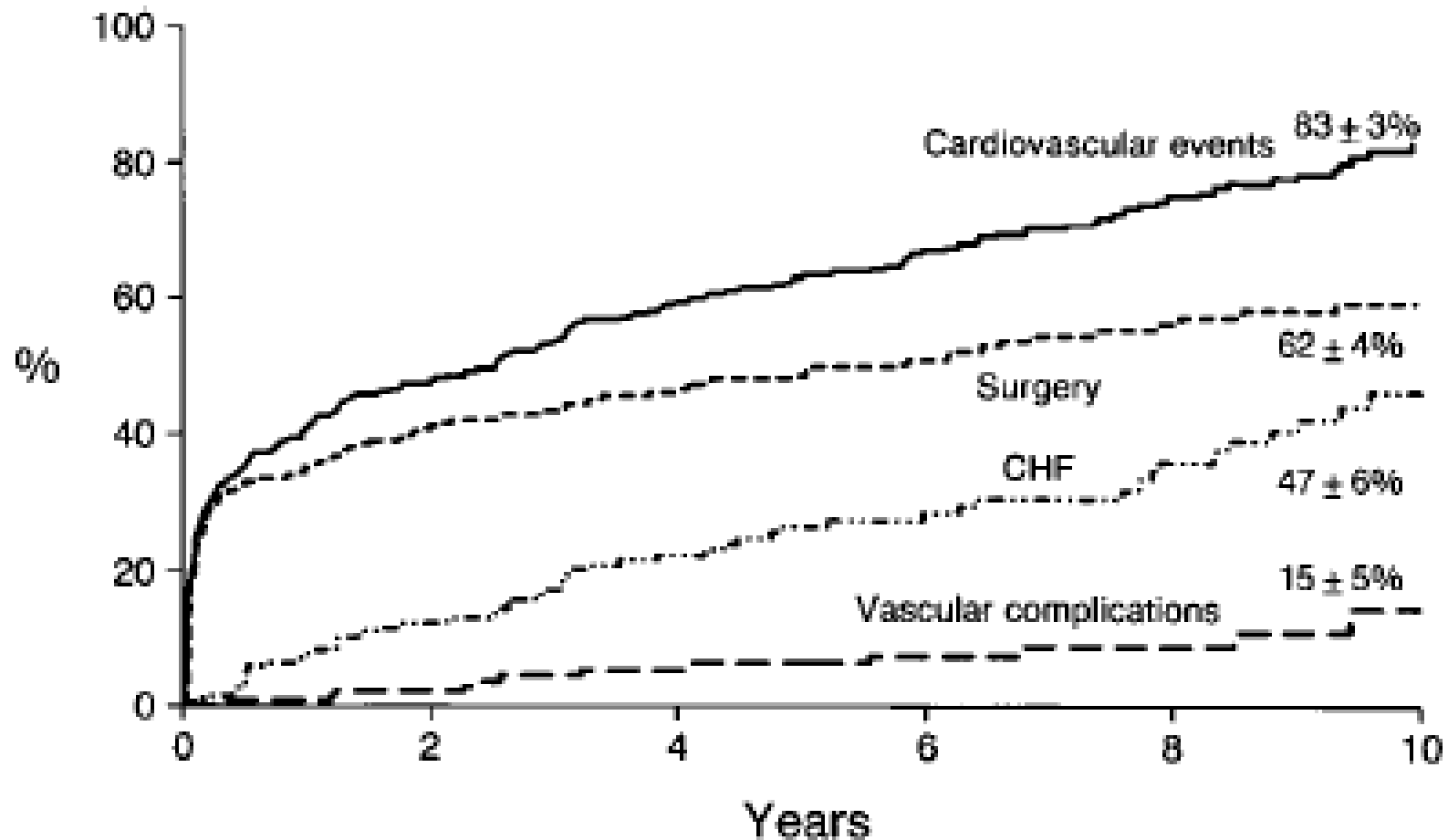
# Aortic regurgitation: *Natural History in Symptomatic Patients*

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# Aortic regurgitation: *Conservative treatment and events*

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# Aortic regurgitation:

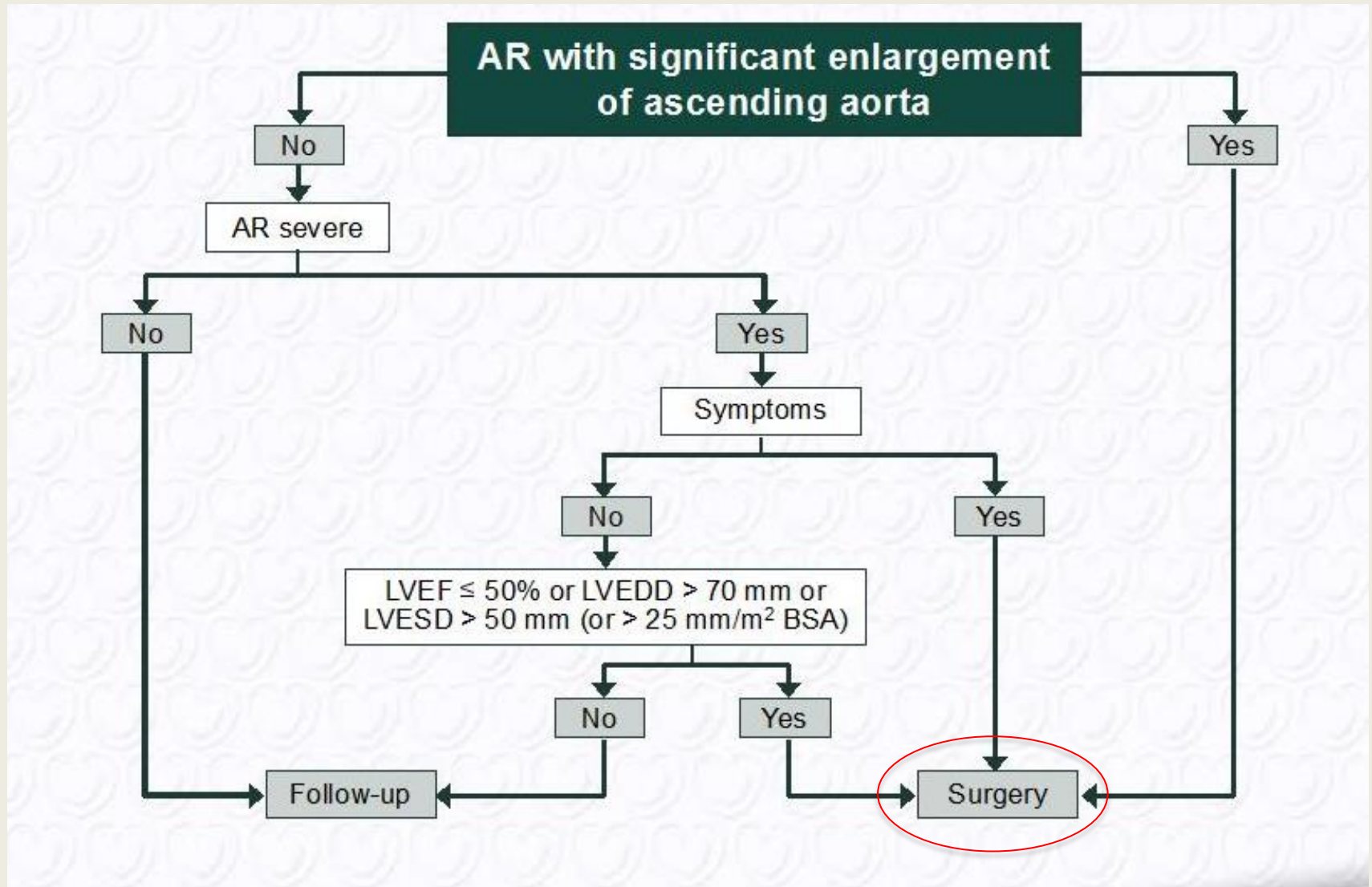
## *Natural History*

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Asymptomatic	%/Y
• Normal LV function (~good prognosis)	
– Progression to symptoms or LV dysfunction	< 6
– Progression to asymptomatic LV dysfunction	< 3.5
– 75% 5-year survival	
– Sudden death	< 0.2
• Abnormal LV function	
– Progression to cardiac symptoms	25
• Symptomatic (Poor prognosis)	
– Mortality	> 10

**TX: Medical → Surgery BEFORE LV dysfunction**

# Aortic regurgitation: *Management*



# Aortic regurgitation: *Indications for surgery*

	Class	Level
Surgery is indicated in symptomatic patients.	I	B
Surgery is indicated in asymptomatic patients with resting LVEF $\leq$ 50%.	I	B
Surgery is indicated in patients undergoing CABG or surgery of ascending aorta, or on another valve.	I	C
Surgery should be considered in asymptomatic patients with resting EF $>$ 50% with severe LV dilatation: LVEDD $>$ 70 mm, or LVESD $>$ 50 mm or LVESD $>$ 25 mm/m <sup>2</sup> BSA.	IIa	C

Indication	ACC/AHA	ESC/EACTS
Symptomatic patients	Class I	Class I
Undergoing CABG or surgery on aorta or another valve	Class I	Class I
<b>Asymptomatic patients</b>		
LV systolic dysfunction (EF $\leq$ 50%)	Class I	Class I
Severe LV dilation (LVEDD $>$ 75 mm or ESD $>$ 55 mm)	Class IIa	—
Progressive LV dilation (LVEDD $>$ 70 mm or ESD $>$ 50 mm)	Class IIb	Class IIa



# Aortic regurgitation: *Management*

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## Is there a place for TAVI or re-TAVI ?

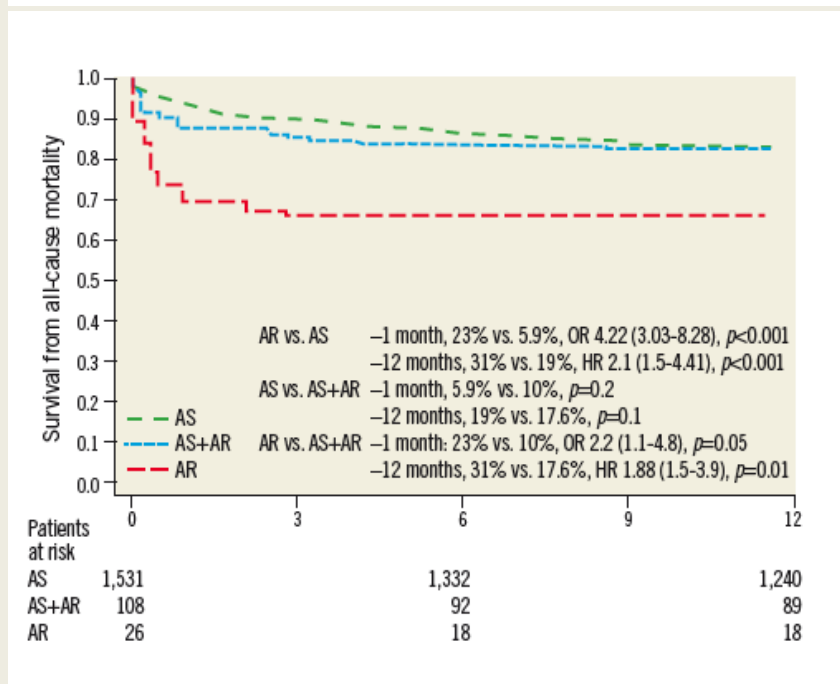
Patients with **severe aortic regurgitation** and at **high or extreme surgical risk** for whom conventional surgical aortic valve replacement may be unsuitable and who might benefit from transcatheter-based therapy.

Patients with **severe aortic regurgitation** following TAVI or AVR

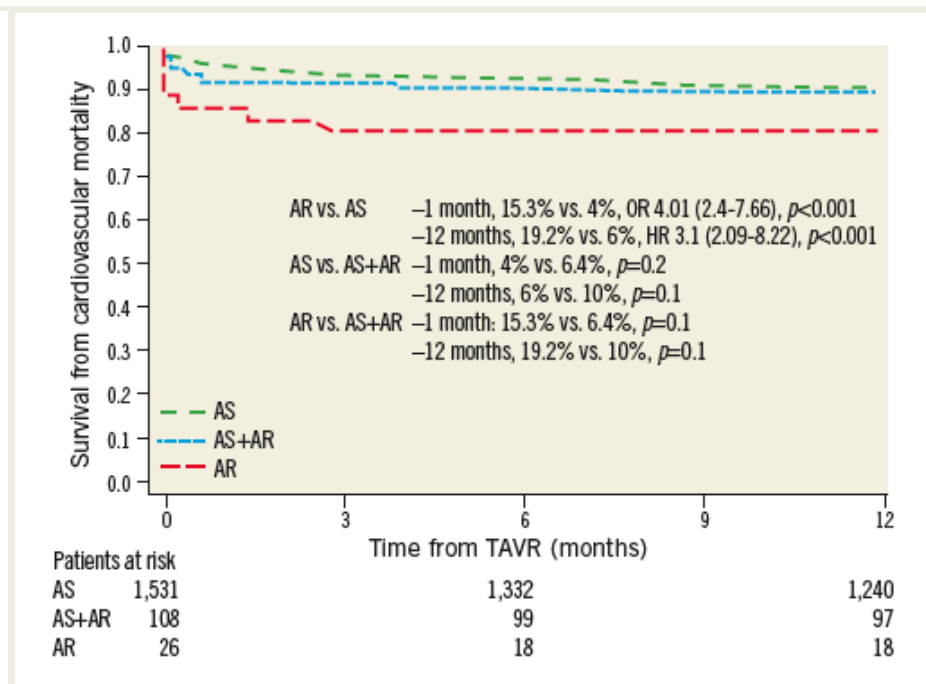
**Still an off-label indication?**

# CoreValve implantation for severe aortic regurgitation: a multicentre registry

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All-cause mortality



Cardiovascular mortality

# Native aortic regurgitation and TAVI

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**CLINICAL RESEARCH**

**Interventional Cardiology**

## Transcatheter Aortic Valve Implantation for Pure Severe Native Aortic Valve Regurgitation

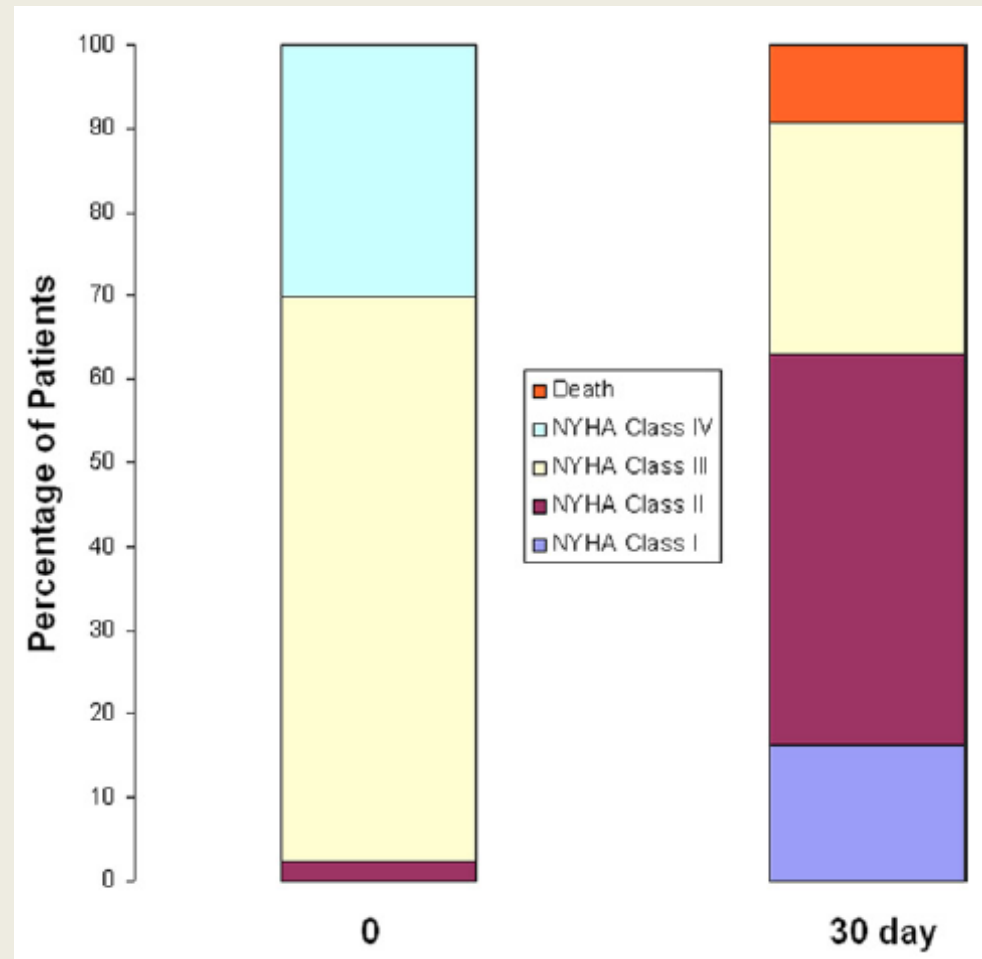
David A. Roy, MD,\* Ulrich Schaefer, MD, PhD,† Victor Guetta, MD,‡ David Hildick-Smith, MD,§ Helge Möllmann, MD,|| Nicholas Dumonteil, MD,¶ Thomas Modine, MD,# Johan Bosmans, MD,\*\* Anna Sonia Petronio, MD,†† Neil Moat, MBBS, MS,‡‡ Axel Linke, MD,§§ Cesar Moris, MD,|||| Didier Champagnac, MD,¶¶ Radoslaw Parma, MD, PhD,## Andrzej Ochala, MD,## Diego Medvedofsky, MD,‡ Tiffany Patterson, MD,‡‡ Felix Woitek, MD,§§ Marjan Jahangiri, MD,\* Jean-Claude Laborde, MD,\* Stephen J. Brecker, MD\*

# Native aortic regurgitation and TAVI

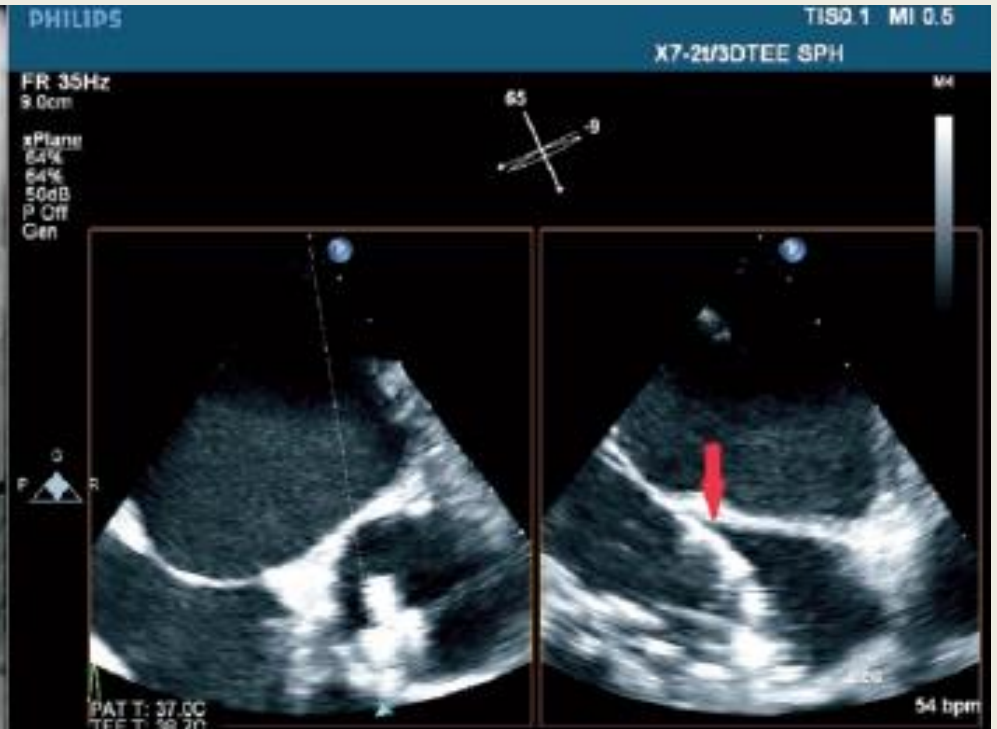
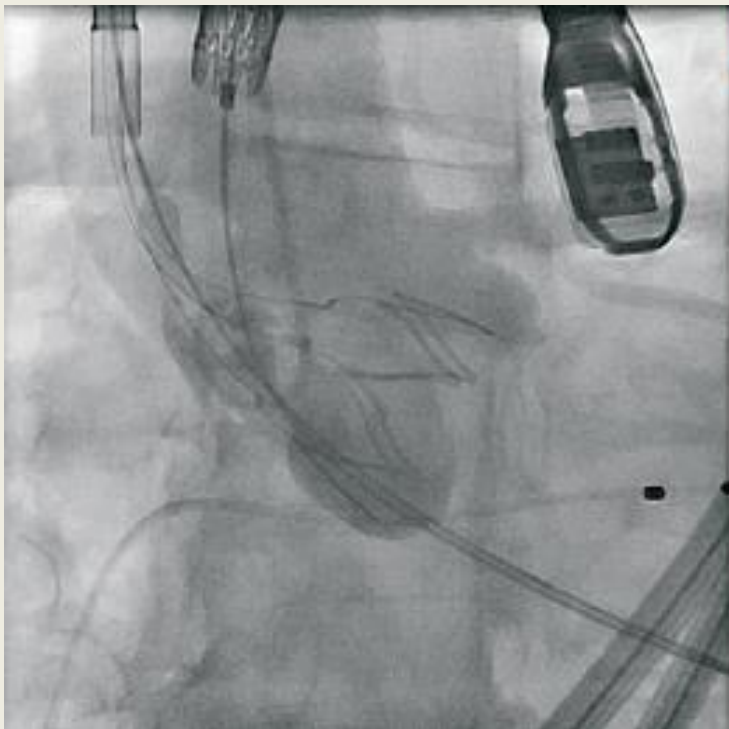
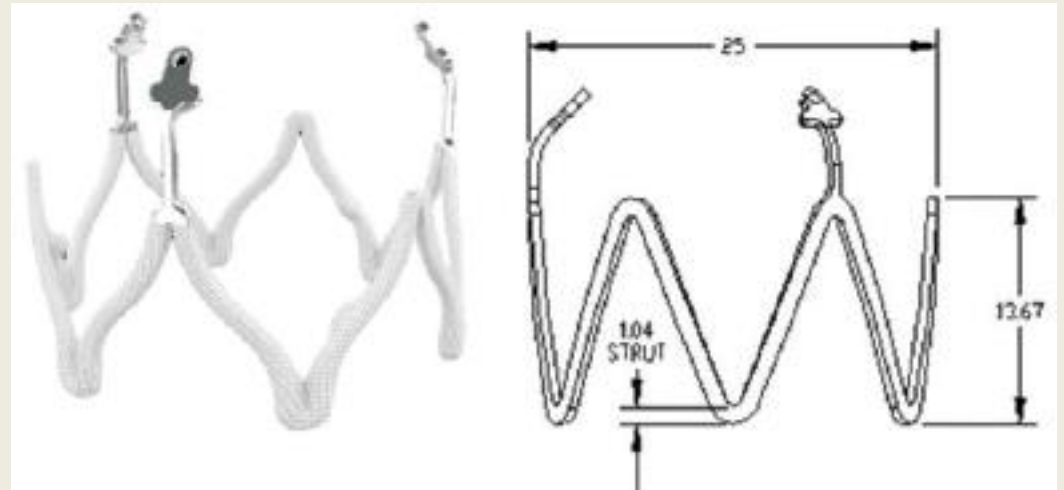
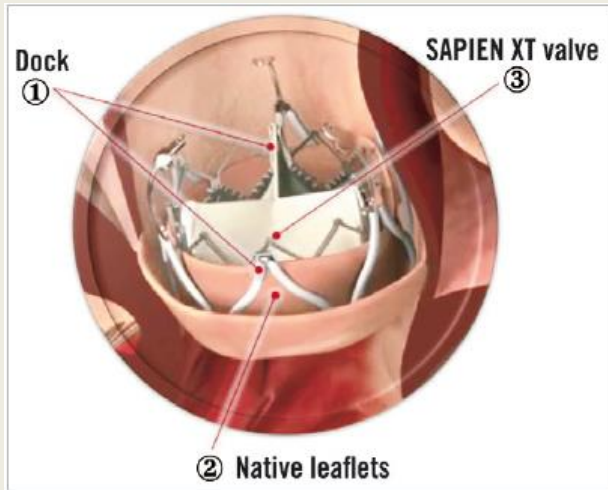
## Clinical and Safety Outcomes According to VARC

Mortality	
30-day all-cause	4 (9.3%)
30-day cardiovascular	1 (2.3%)
12 month all-cause	6/28 (21.4)
12-month cardiovascular	3/28 (10.7)
Major stroke (30 days)	2 (4.7)
Major bleeding	8 (18.6)
Acute kidney injury (stage 3)	2 (4.7)
Myocardial infarction	0
Access site complications	6 (14.0)
Major	3 (7.0)
Minor	3 (7.0)
VARC procedure success	32 (74.4)

43 patients



# Transcatheter aortic dock for patients with aortic regurgitation



# Native aortic regurgitation and TAVI

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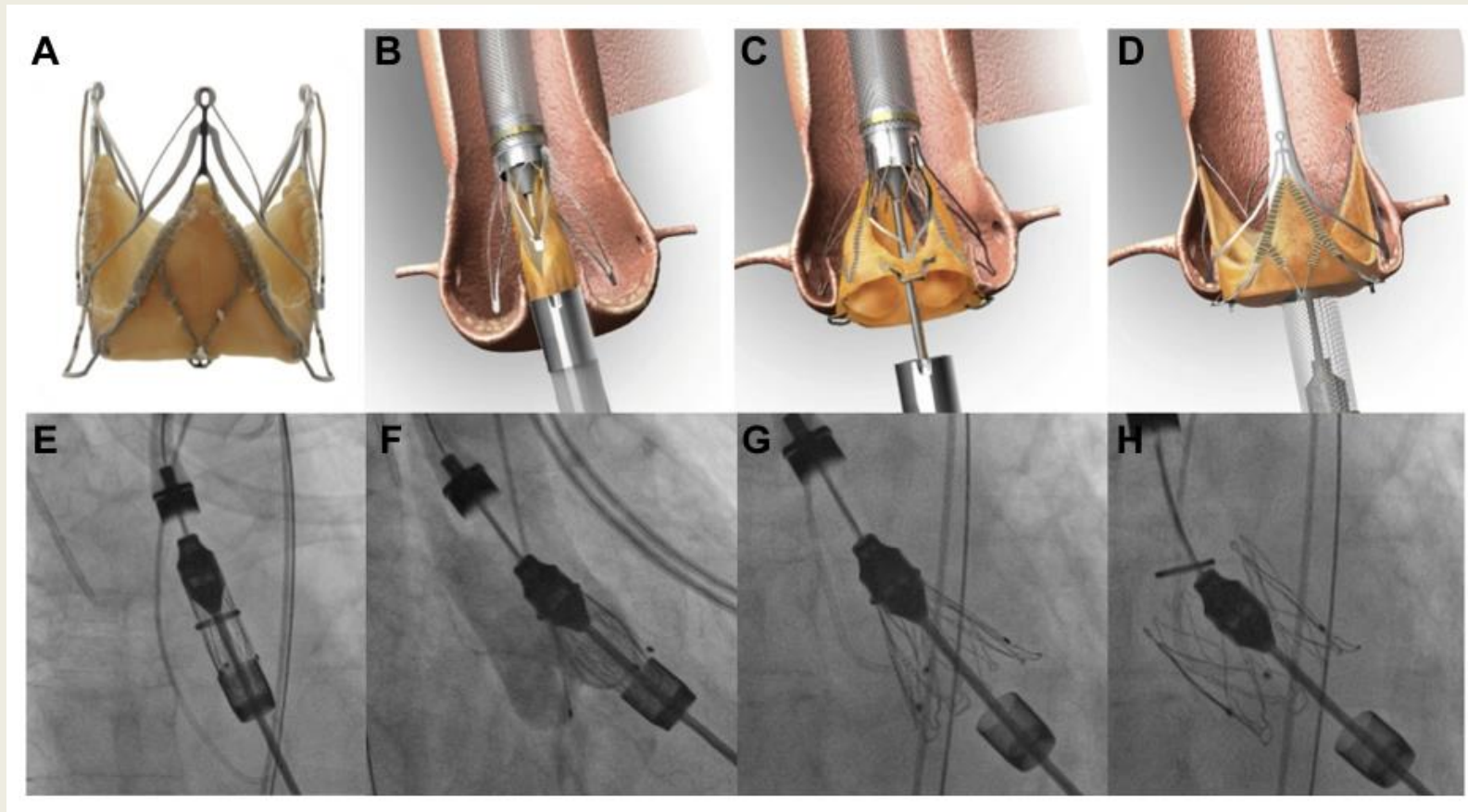
<http://dx.doi.org/10.1016/j.jcin.2014.05.014>

## Initial German Experience With Transapical Implantation of a Second-Generation Transcatheter Heart Valve for the Treatment of Aortic Regurgitation

Moritz Seiffert, MD,\* Ralf Bader, MD,† Utz Kappert, MD,‡ Ardawan Rastan, MD,§ Stephan Krapf, MD,|| Sabine Bleiziffer, MD,¶ Steffen Hofmann, MD,# Martin Arnold, MD,\*\* Klaus Kallenbach, MD,†† Lenard Conradi, MD,\* Friederike Schlingloff, MD,‡ Manuel Wilbring, MD,‡ Ulrich Schäfer, MD,‡ Patrick Diemert, MD,\* Hendrik Treede, MD\*

# Native aortic regurgitation and TAVI

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# Native aortic regurgitation and TAVI

**TABLE 3 VARC-2 Defined Endpoints**

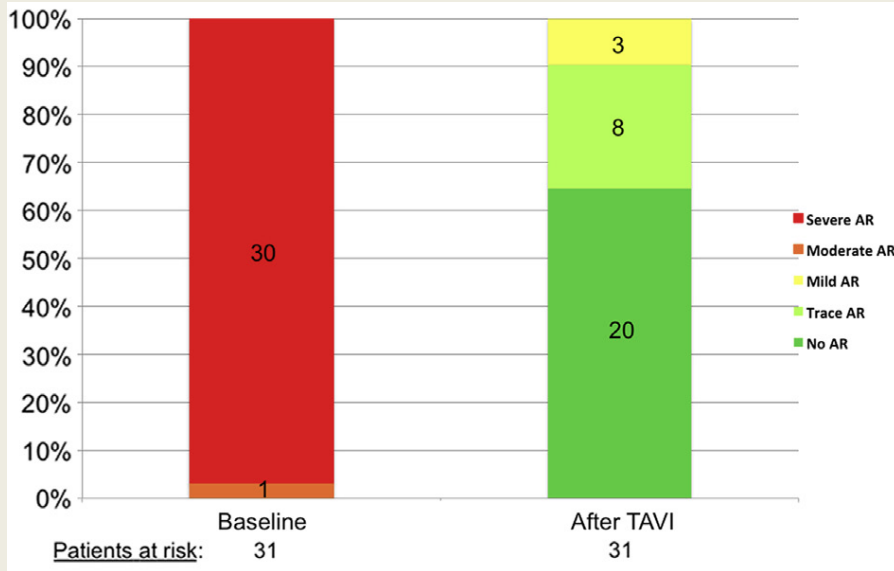
Myocardial infarction	0
Cerebrovascular event	0
Bleeding, major or life-threatening	3 (9.7)
Access site complication	
Minor	1 (3.2)
Major	3 (9.7)
Acute kidney injury	
Stage 1 or 2	6 (19.3)
Stage 3	1 (3.2)
Permanent pacemaker implantation	2 (6.4)*
ICU stay, days	3.2 ± 2.8
In-hospital stay, days	10.8 ± 5.6
Device success	30 (96.8)
Combined early safety endpoint, 30 days	6 (19.3)
All-cause mortality, 30 days	4 (12.9)
Cardiac mortality, 30 days	1 (3.2)
All-cause mortality, 6 months	6 (19.3)
Cardiac mortality, 6 months	1 (3.2)



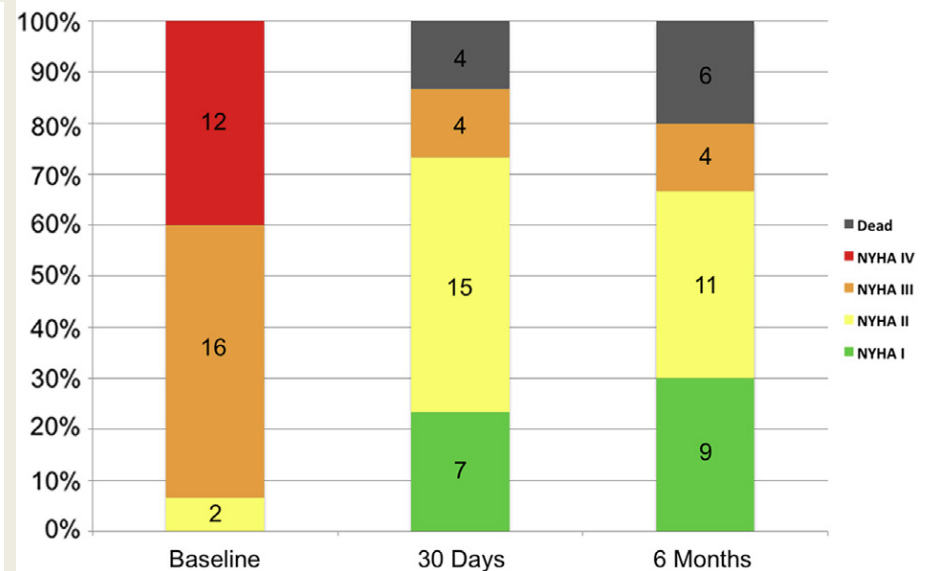
# Native aortic regurgitation and TAVI

31 patients

AR post-TAVI



NYHA class post-TAVI



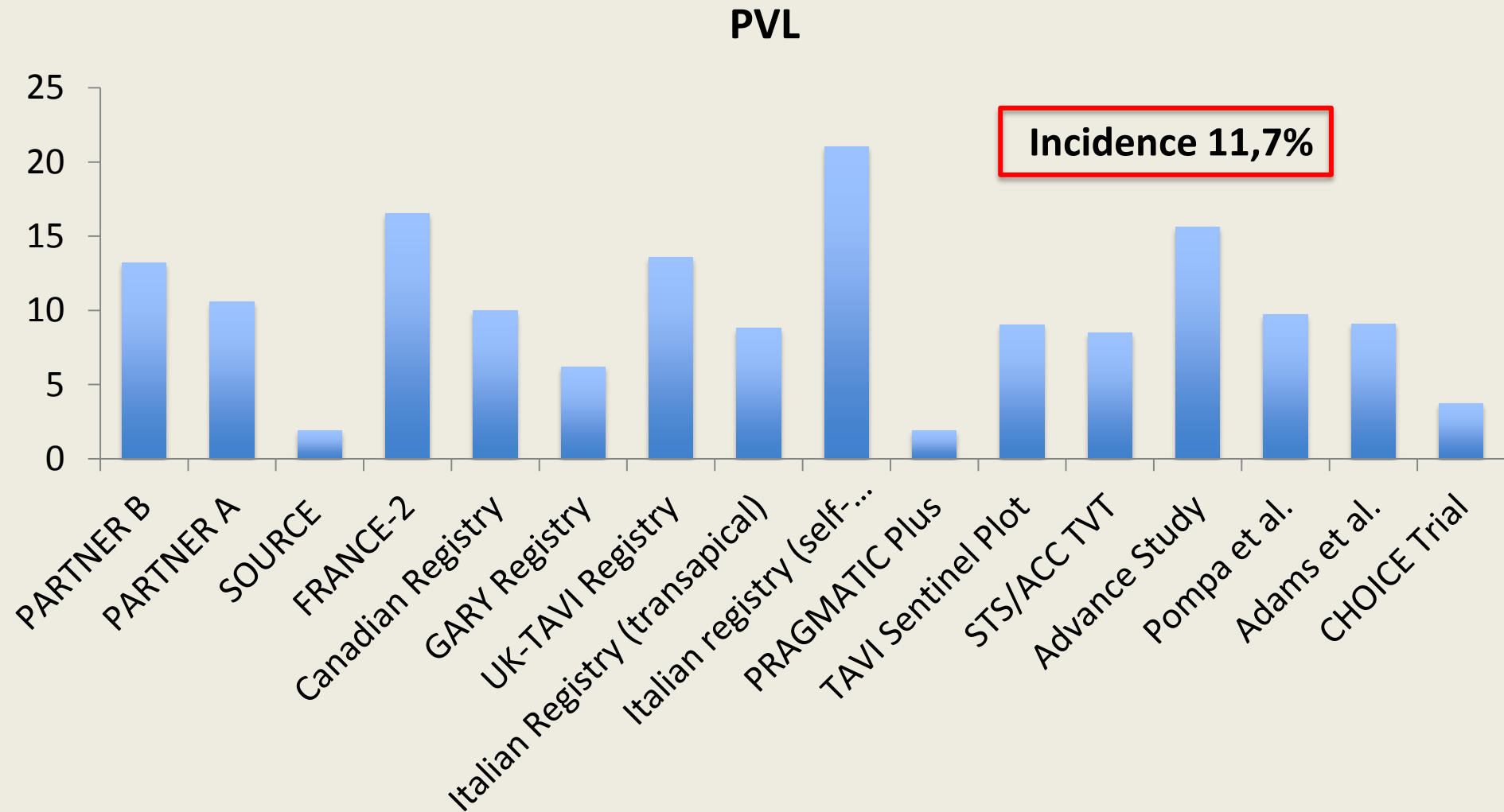
# Aortic regurgitation

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- 1. Native aortic regurgitation**
- 2. Para-valvular leak: more frequent**
  - High implantation
  - Low implantation
  - Valve dimensions (undersizing)
- 3. Intra-prosthetic: less frequent**
  - Leaflets damage

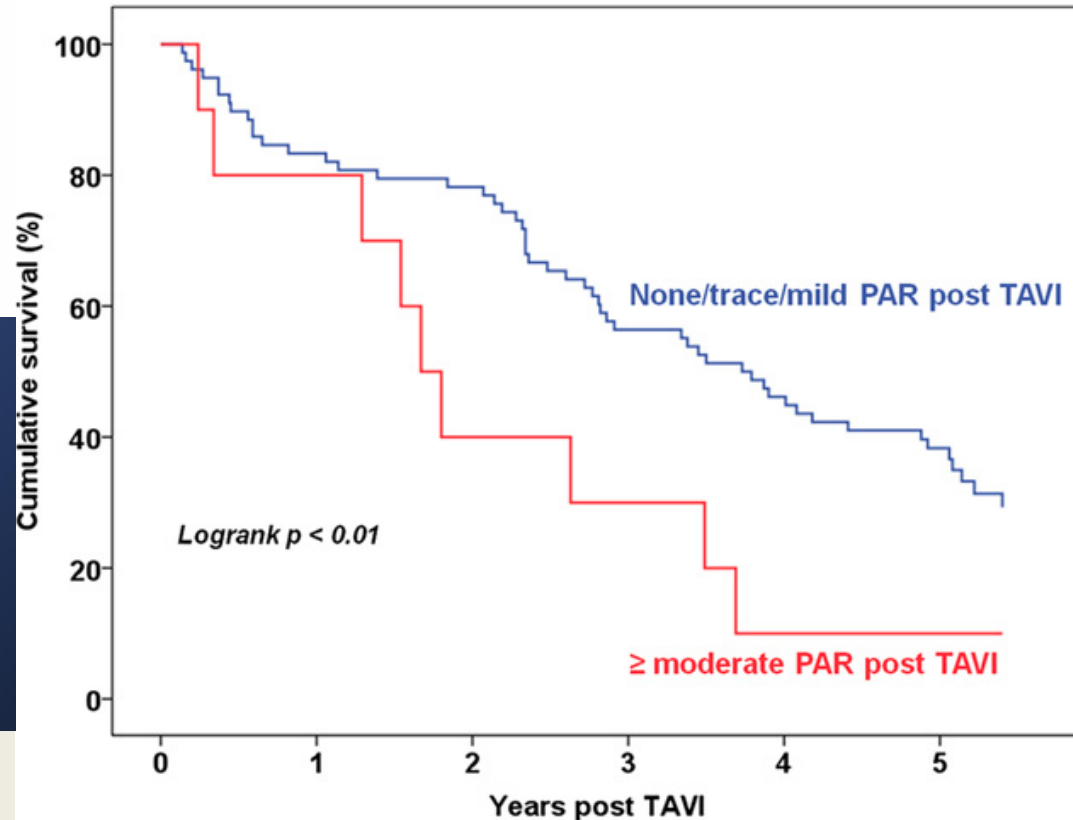
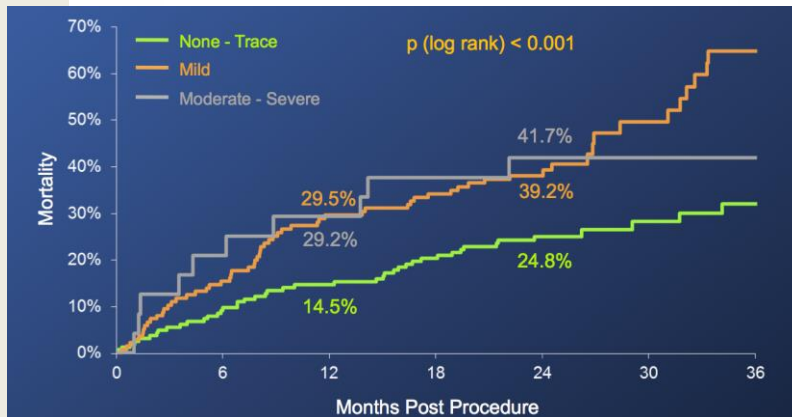
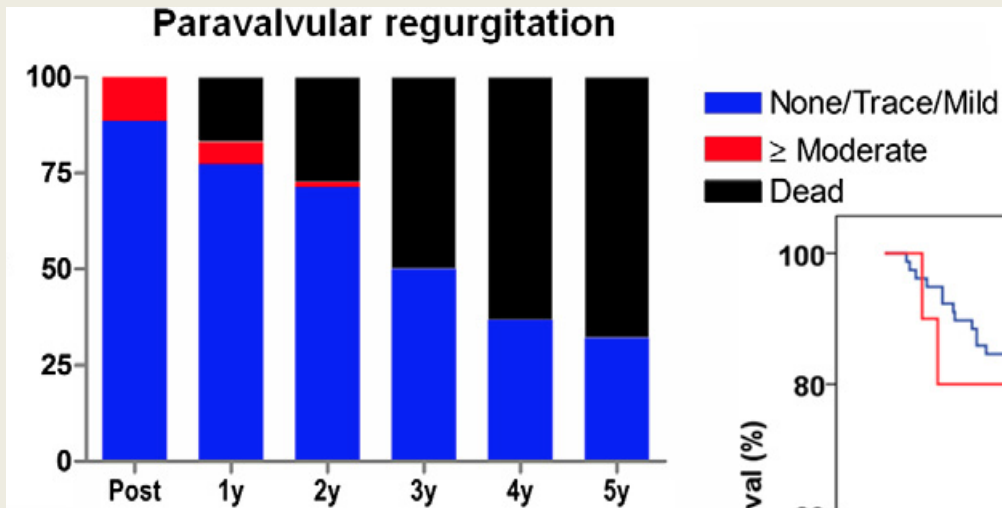
# Para-valvular leak

*Incidence in biggest trials and registries*



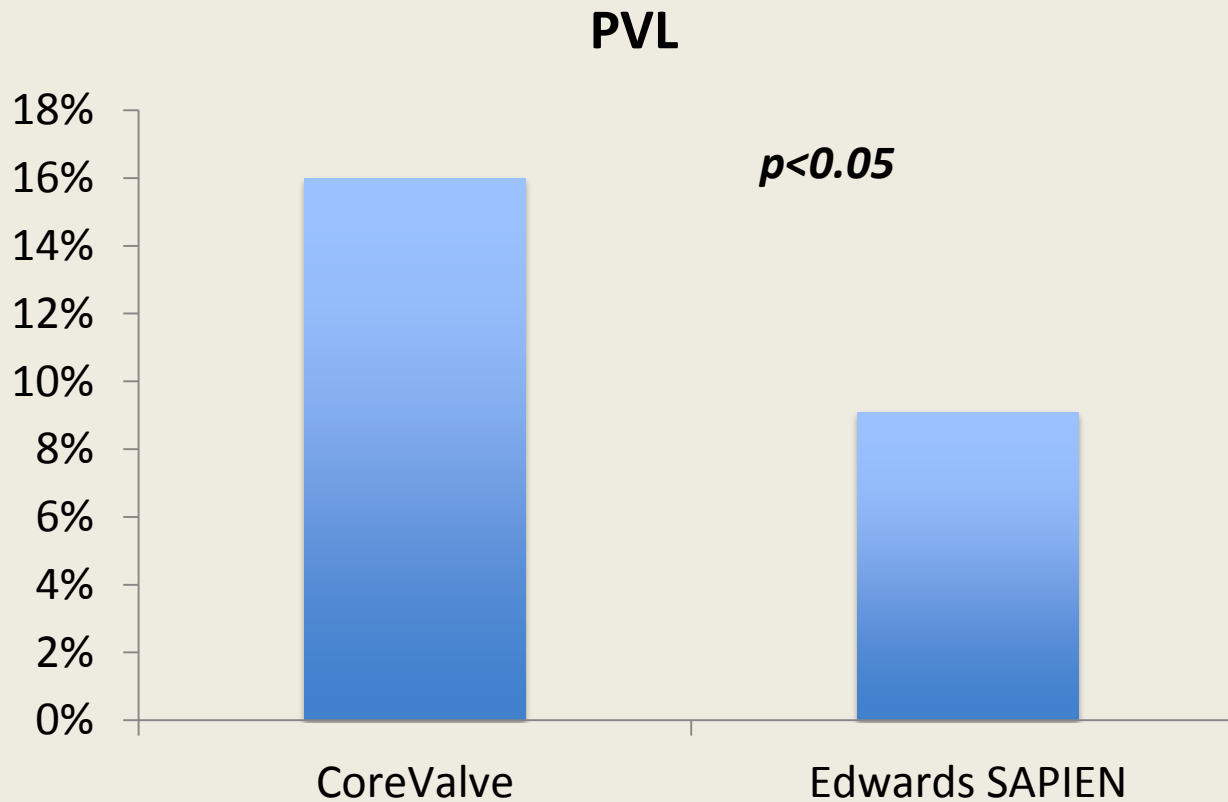
# Para-valvular leak

## *Incidence and impact on mortality*



# Para-valvular leak in first generation devices

*Different valve, different incidence*



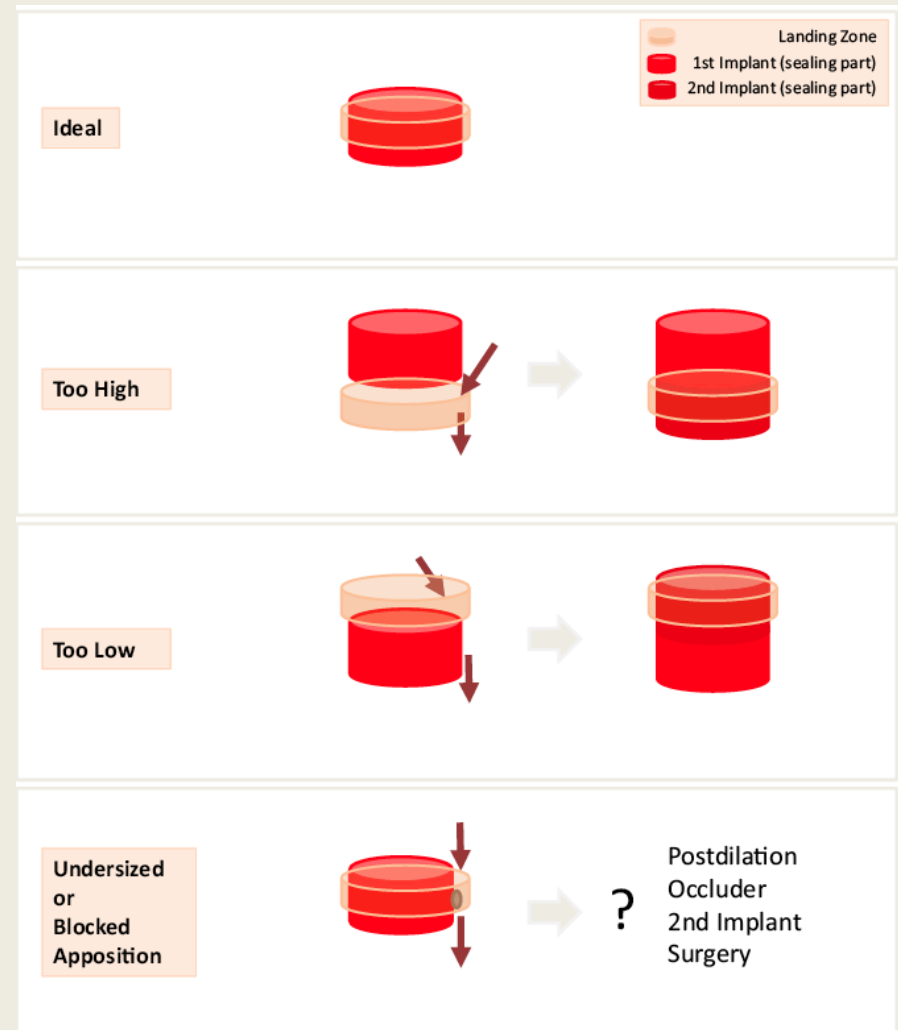
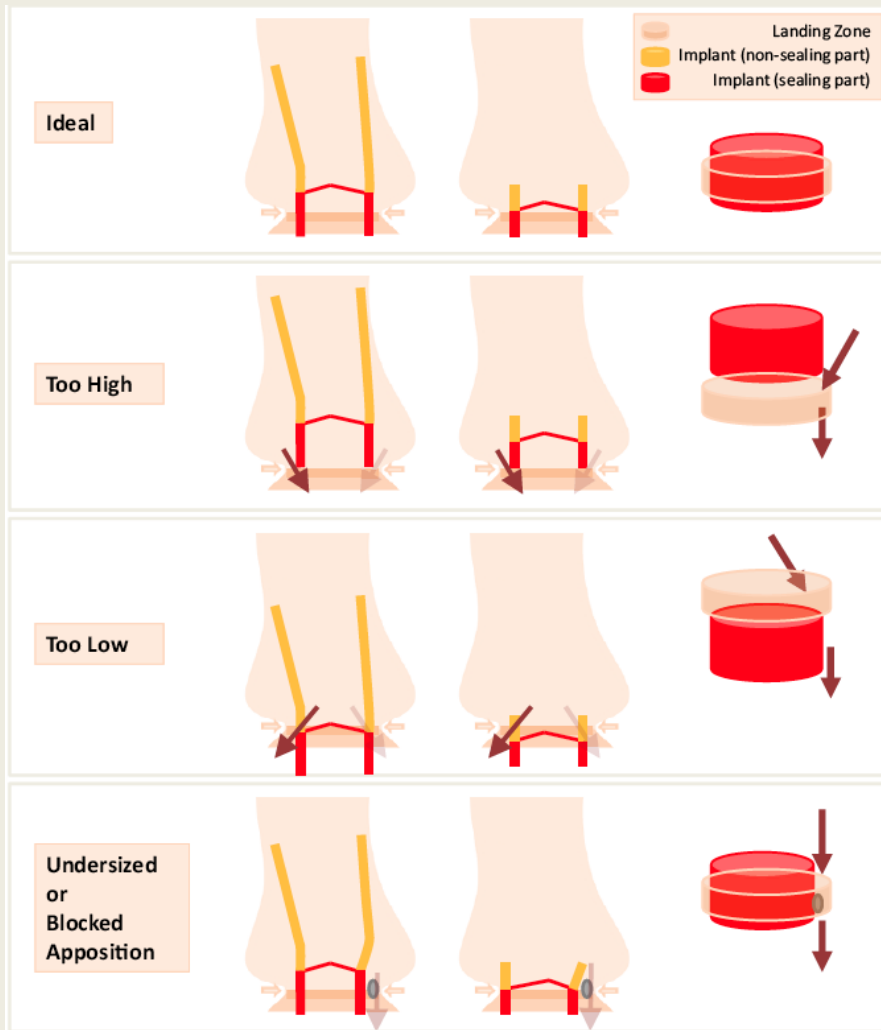
*Athappan et al. J Am Coll Cardiol. 2013 Apr 16;61(15):1585-95.*

# Para-Valvular Leak

## Mechanisms

## How to treat

## Valve-in-Valve



# TAVI and aortic regurgitation

## *Conclusions*

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- Preliminary experiences (registries) are available for the use of TAVI in patients with severe aortic regurgitation at high risk for surgery.
- TAVI represents a valid option for the treatment of para-valvular regurgitation and intra-prosthetic regurgitation as a valve-in-valve procedure.
- Both CoreVALVE and Edwards SAPIEN have shown feasibility and good results, in this subset.
- New generation and repositioning devices are able to limit residual AR following TAVI.
- Ad hoc studies are necessary to evaluate outcome of new generation devices and to consider TAVI as a frontline treatment option for high risk patients with native severe AR.