

# Discussion: FRANCE-TAVI registry

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# Disclosures



None

# SAVR



Inoperable/Extreme-risk

# TAVR

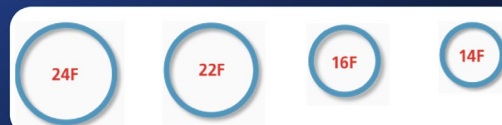


High-risk  
Intermediate-risk  
Low-risk

Mechanical valve  
Asymptomatic  
Bicuspid AS

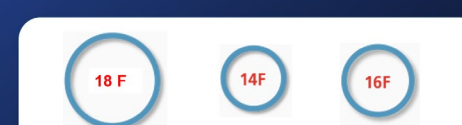
Which valve?  
Class effect?

## Edwards THV



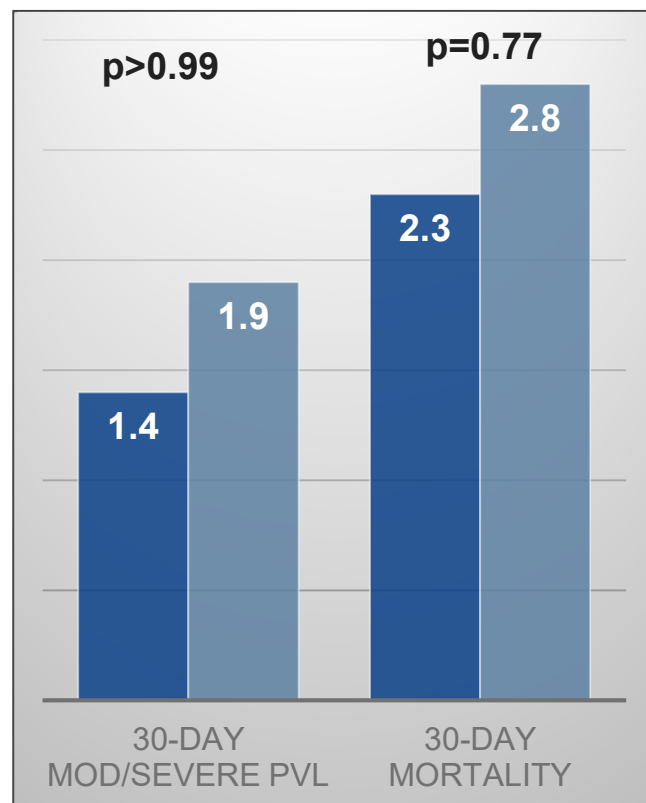
\* Sheath compatibility for a 23 mm valve

## Medtronic THV



## SOLVE-TAVI

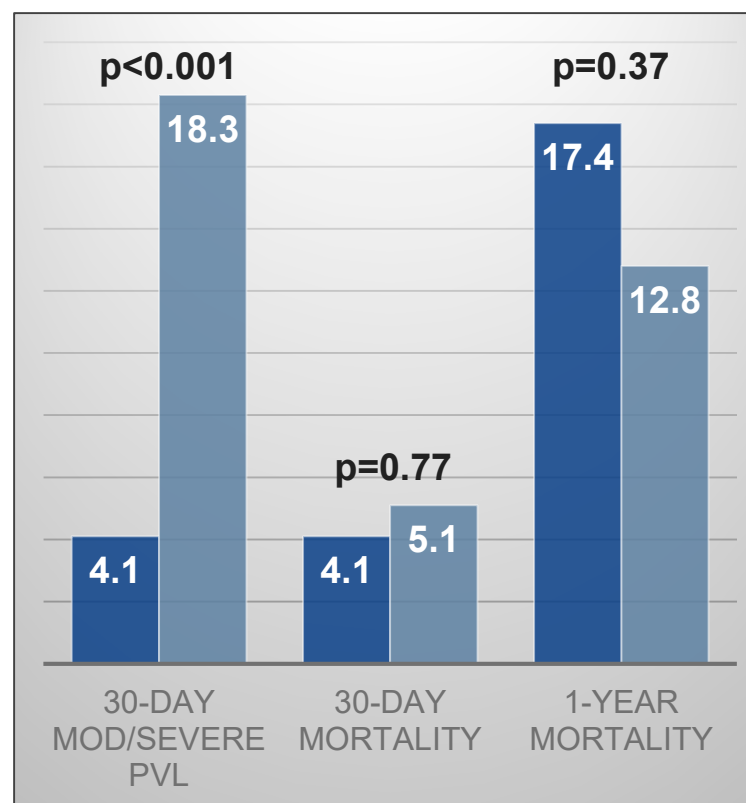
STS 7.8%  
Sapien S3 (n=219) vs.  
Evolut R (n=219)



Thiele H. TCT 2018

## CHOICE

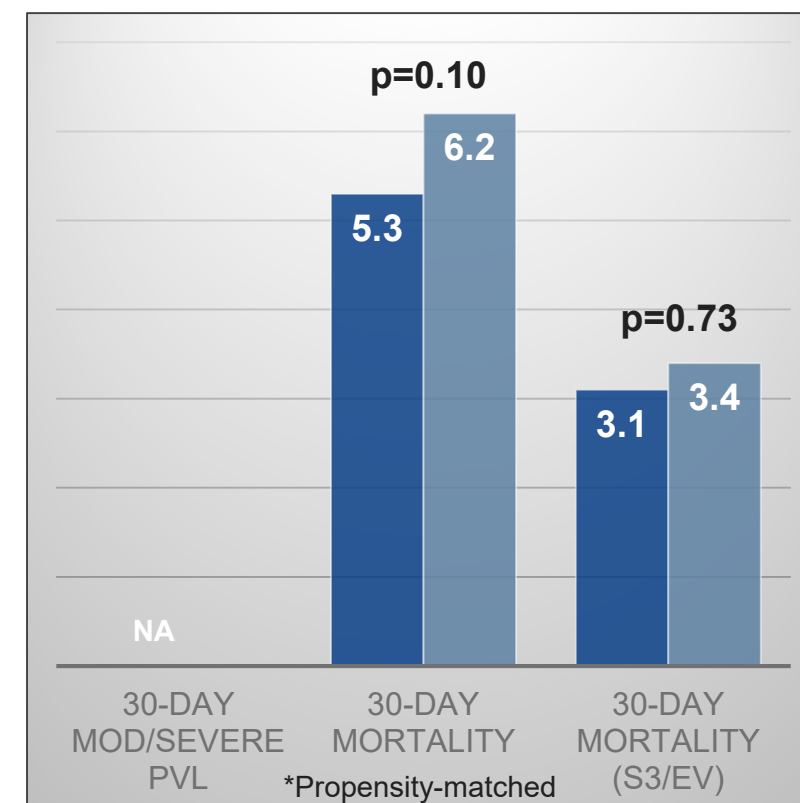
STS  $\geq 10\%$ /inoperable  
Sapien XT (n=121) vs. CoreValve  
(n=120)



Abdel-Wahab M. JAMA 2014; Abdel-Wahab M. JACC 2015

## CENTER registry

STS 6.5%  
BE (n=4,096) vs. SE (n=4,096)\*



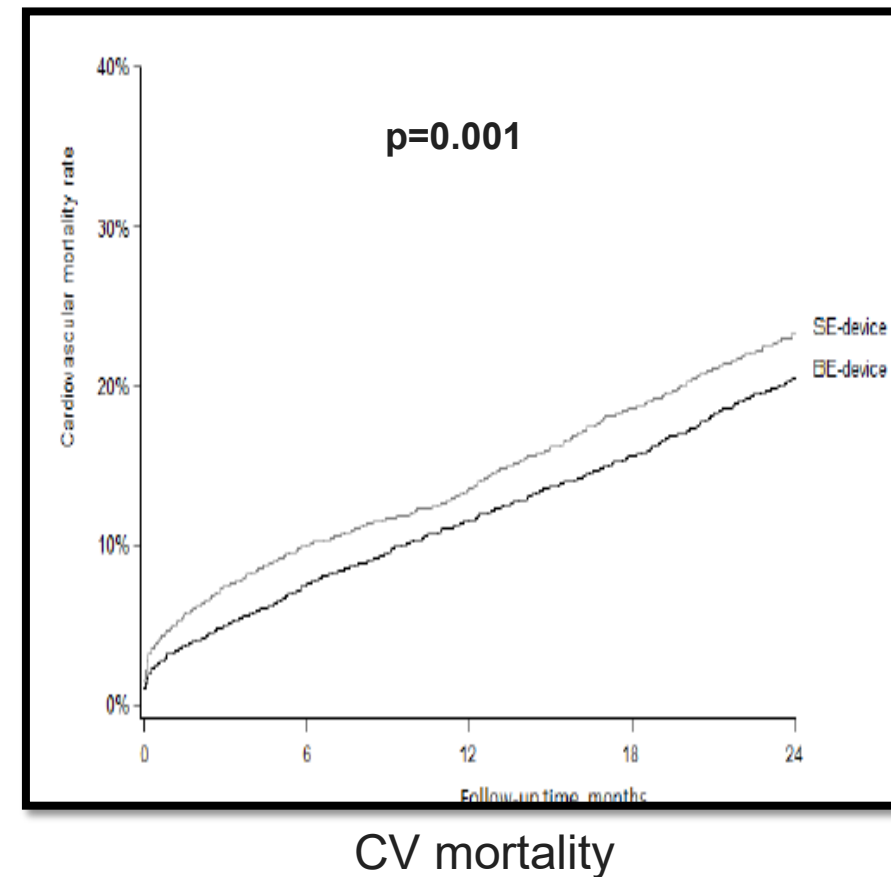
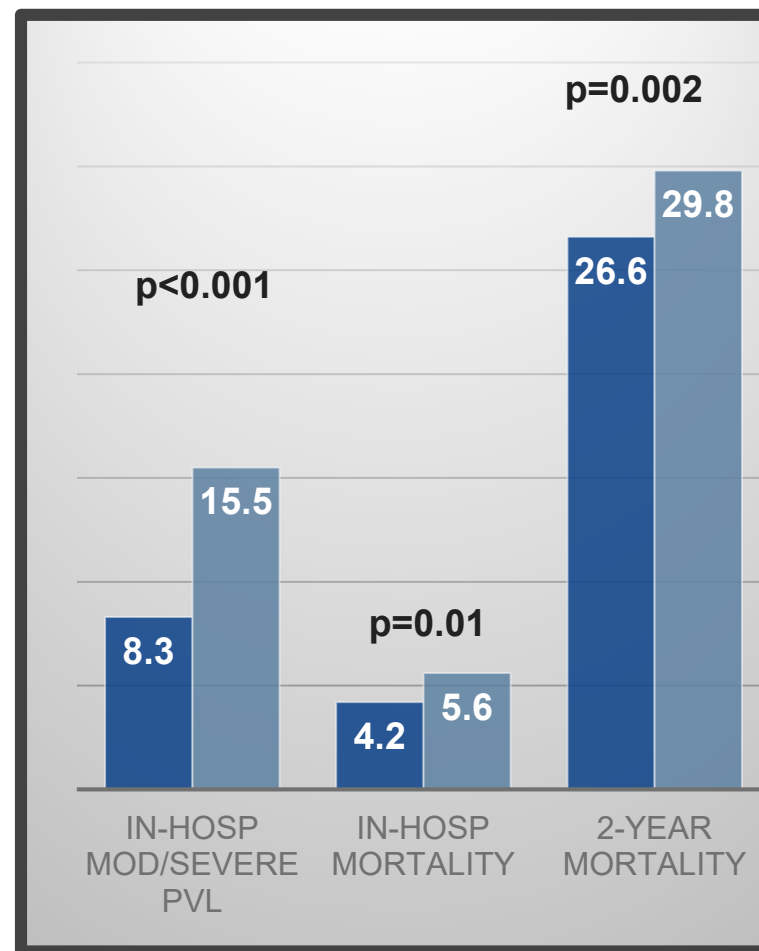
Vlastra W. EHJ 2019

# FRANCE-TAVI registry



- 2013-2015
- 48/50 sites
- EuroSCORE: 14.5%
- High risk: 37%
- TF access: 81%
- Conscious sedation: 47%
- No ViV

- BE (n=3910) vs. SE (n=3910)
- ? Sapien S3 (n=2440) vs. Evolut (2,435)

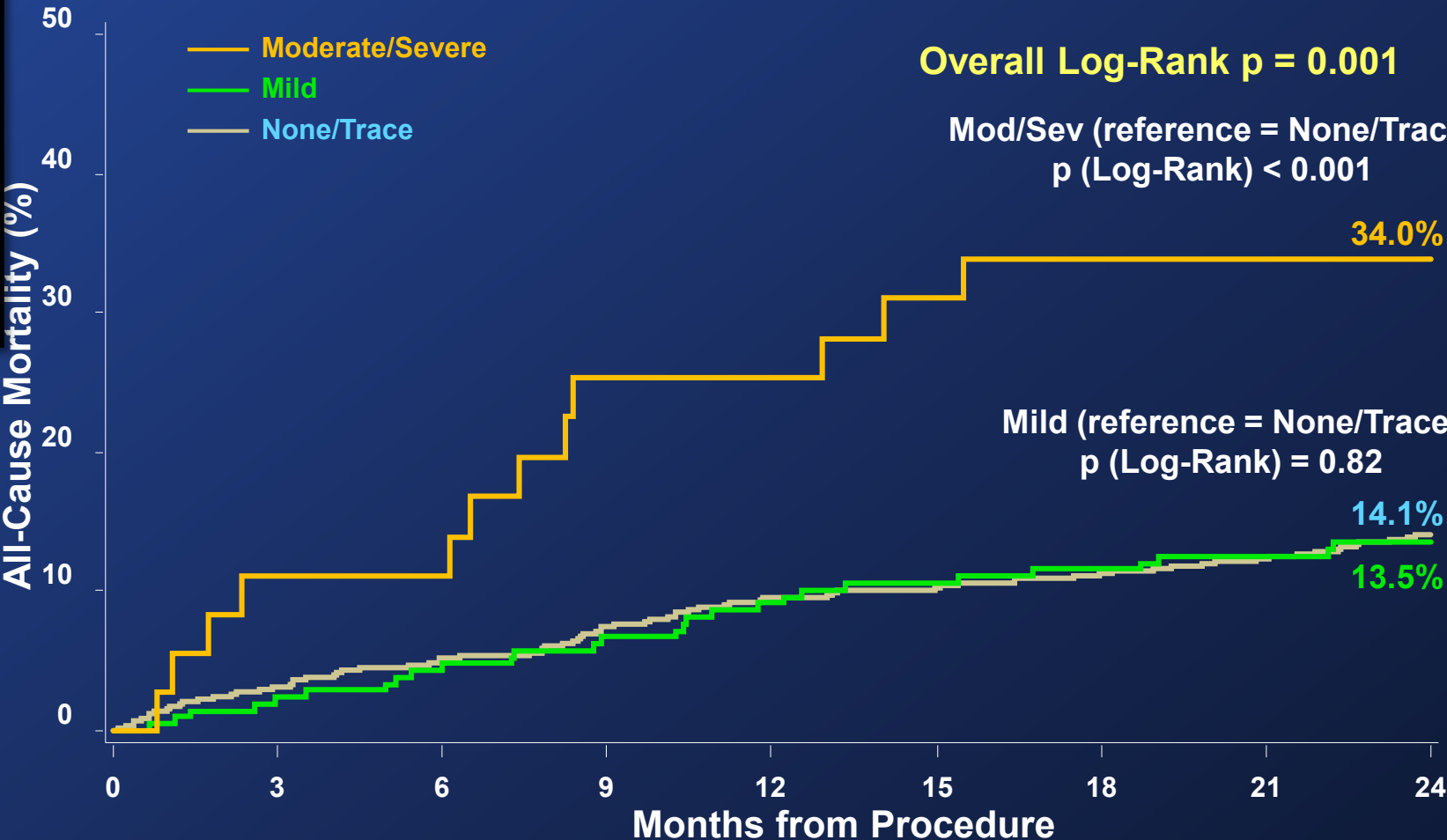
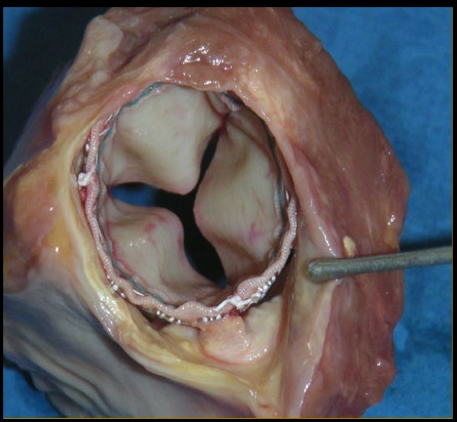


# Things to consider



- Hazardous to make causal inferences from observational data
- Biological plausibility
  - Valve design: Less radial strength with SE vs. BE
  - Association of PVL with mortality

# Severity of PVL at 30 Days and All-cause Mortality at 2 Years



Number at risk:

Moderate/Sev	36	32	32	26	26	24	22	22	21
Mild	210	204	199	194	188	184	182	180	175
None/Trace	701	678	664	647	628	621	612	605	585

# Things to consider



- Hazardous to make causal inferences from observational data
- Biological plausibility
  - Valve design: Less radial strength with SE vs. BE
  - Association of PVL with mortality
  - Early hazard: patient or device? Are sicker patients receiving SE valves?
  - Other complications: ↑ pacemaker rate with SE vs. BE – can impact mortality
  - Valve hemodynamics, EOA ↑, patient-prosthesis mismatch ↓ with SE vs. BE
- Not completely contemporary (2015; valve generations?), no echo core lab
- Other more recent data

Kumbhani DJ. JACC 2016

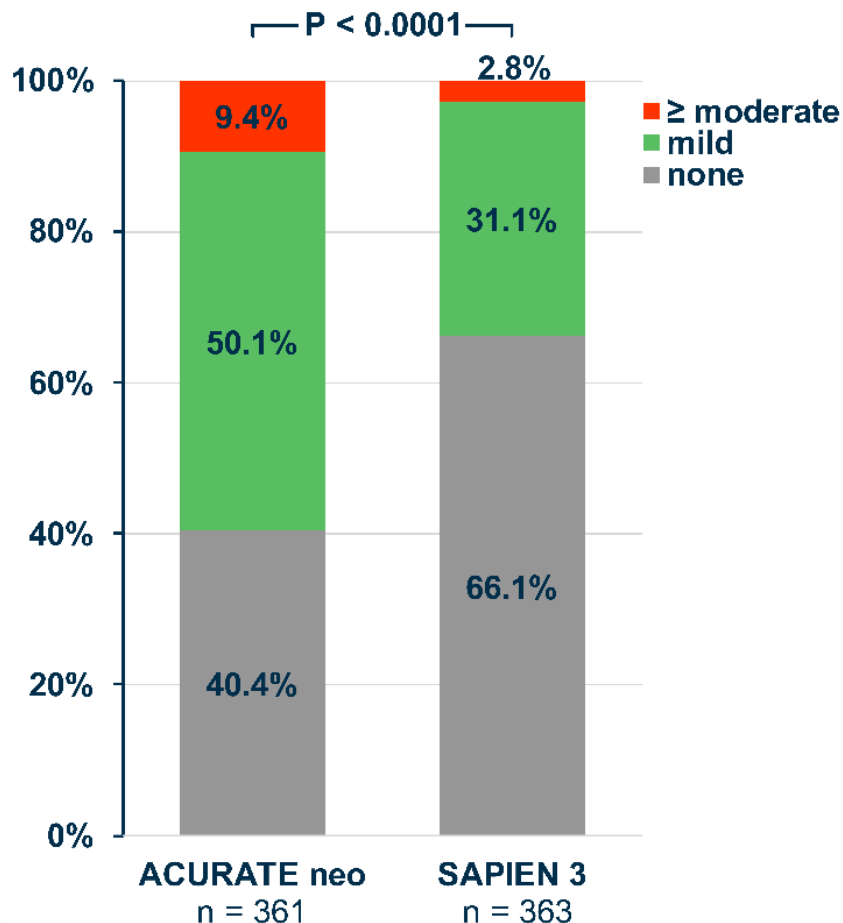
Hahn R. JACC CV Img. 2019

Herrmann H. JACC 2018

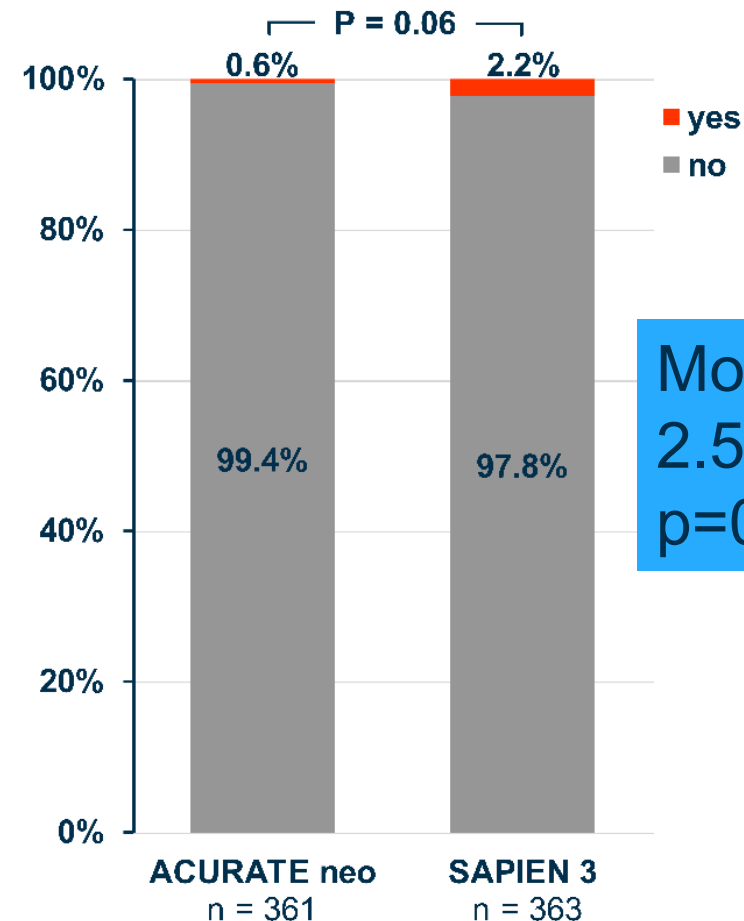


# Echocardiographic Valve Performance

## Paravalvular Aortic Regurgitation



## Mean Gradient $\geq 20$ mmHg AND EOA $\leq 0.9$ - $1.1$ cm<sup>2</sup> and/or DVI < 0.35



Mortality  
2.5% vs. 0.8%,  
p=0.09

# FlexNav DS Cohort: Clinical Outcomes at 30 Days



**Primary endpoint: 7% major vascular complications**

VARC 2 Endpoint	RCT Portico valve N=381	RCT Commercial valve N=369	FlexNav DS Cohort N=100
All-Cause Mortality	3.5%	1.9%	0.0%
Cardiovascular Mortality	3.2%	1.7%	0.0%
Disabling Stroke	1.6%	1.1%	0.0%
Life-Threatening Bleeding Requiring Transfusion	4.5%	3.6%	4.0%
Acute Kidney Injury Requiring Dialysis	1.1%	0.8%	0.0%
Major Vascular Complications	9.6%	6.3%	7.0%
New PPI	27.7%	11.6%	14.6%
Moderate or Greater PVL	6.3%	2.1%	6.5%

Data presented as Kaplan-Meier Estimate Event Rates % (n of subjects with an event)

# Design considerations



- Statistical methods appropriate
- IPTW similar results
- Falsification endpoint analysis similar
- Despite this, possibility of residual confounding exists

# Final thoughts

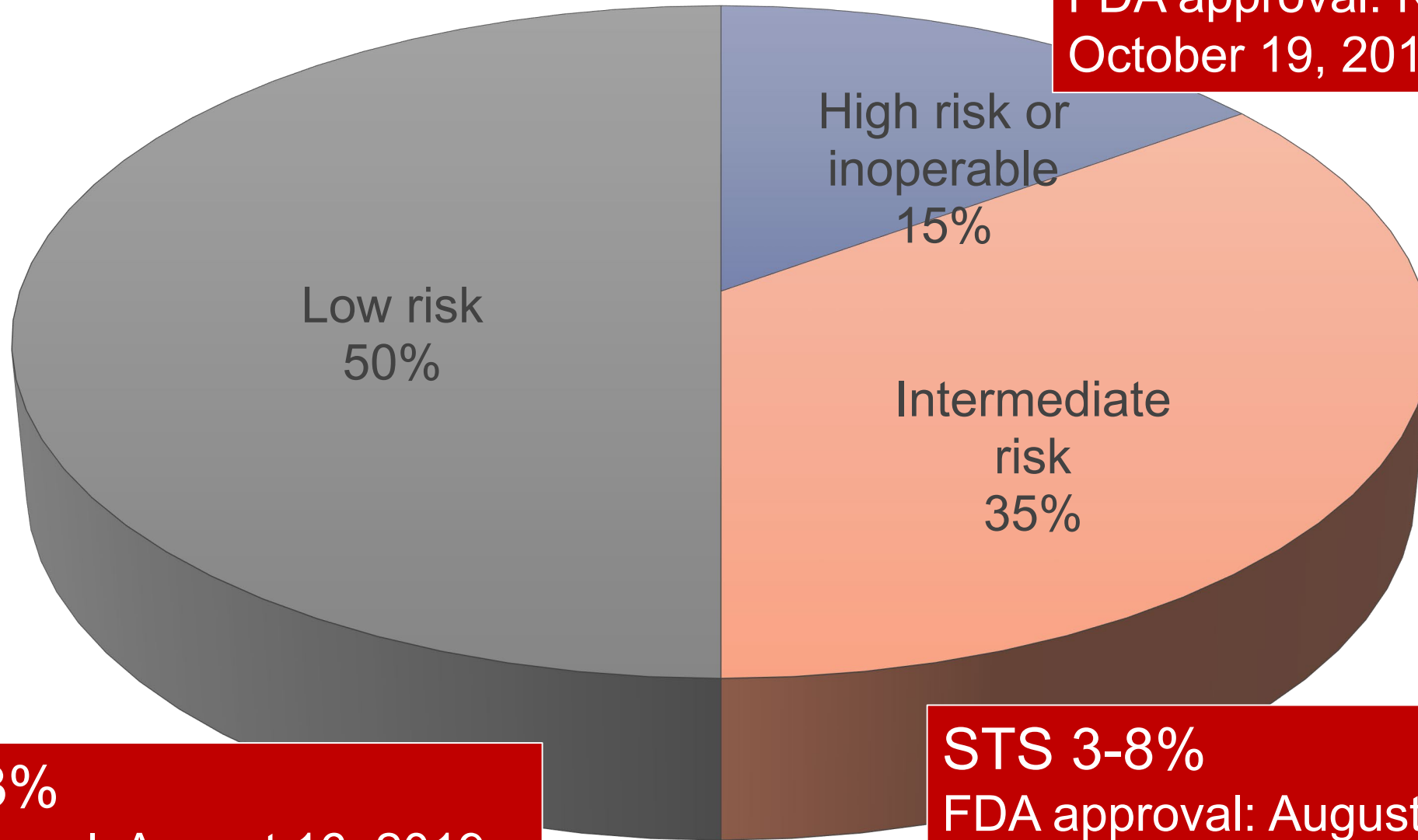


- Intriguing analysis
- Inherent differences between TAVR valves
  - May be incorrect to assume a class effect
  - Important to match patient to valve
- The field urgently needs head-to-head comparison trials
  - Device success (PVL), complications (pacemaker)
  - Hemodynamic performance (EOA, gradients)
  - Hard endpoints: long-term important as we expand the eligible patient pool
  - Cost



STS  $\Rightarrow$  8%

FDA approval: Nov 2, 2011/  
October 19, 2012



STS  $<$  3%

FDA approval: August 16, 2019

STS 3-8%

FDA approval: August 18, 2016