

# Expanding the indications of TAVR

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Seoul, TCT-AP April 30, 2015

# Disclosure Statement of Financial Interest

Within the past 12 months, I have had a financial interest/arrangement or affiliation with the organization(s) listed below.

## Affiliation/Financial Relationship

- Consulting Fees/Honoraria
- Proctoring–Training activities/Honoraria

## Company

- Edwards Lifesciences
- Edwards Lifesciences

# TAVR: Where are we today?

*An incredible expansion worldwide*



Edwards-Valves



CoreValve

- > 200 000 TAVR procedures in 10 years
  - > 650 centers OUS
  - > 250 centers in USA

# TAVR: Where are we today ?

## An dramatic growth of procedures



Courtesy of Mike Weinstein: J.P. Morgan

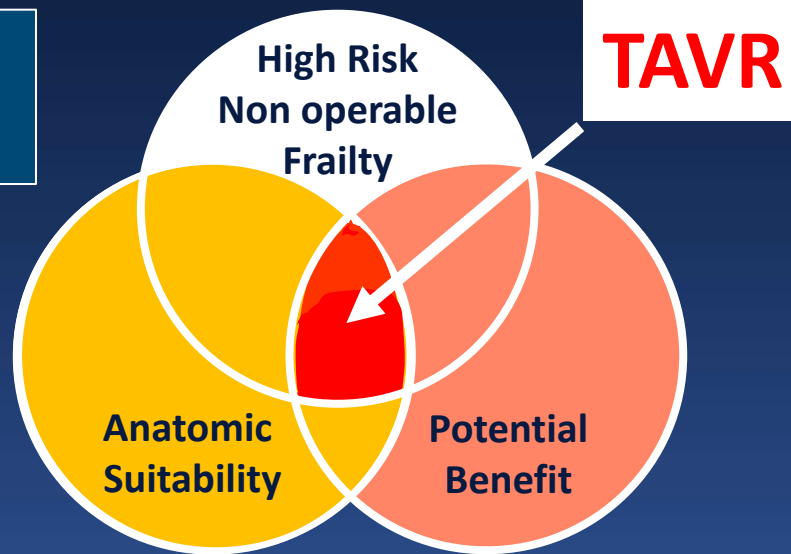
**2014:** France: > 5000 TAVR / year  
Germany: > 8000 TAVR / year

# 2014: Indications freeze TAVR in the past

ESC Guidelines 2012 / US experts Consensus 2012

Decision confirmed by  
a « Heart Team »

Cardiac Surgery  
On-site



Low and  
intermediate  
risk patients  
are not  
candidates  
to TAVR

## PARTNER US:

**TAVR:** New technology, 1st generation devices (Edwards SAPIEN)  
Early experience of teams

**SAVR:** Most experienced cardiac surgeons  
Well established treatment for 50 years

# Trend to treat lower risk patients in all recent registries

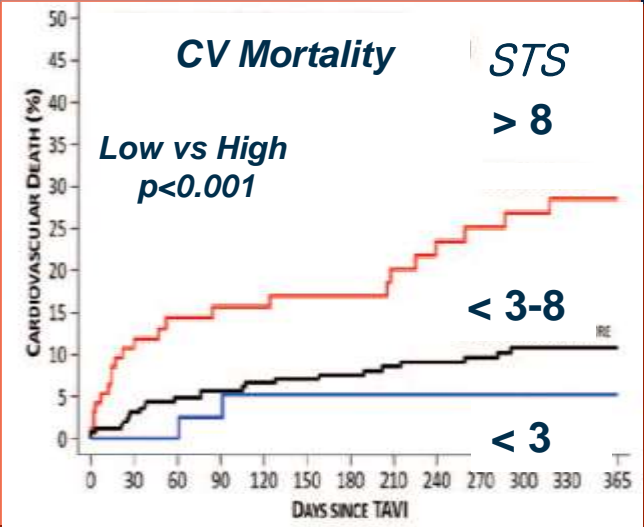
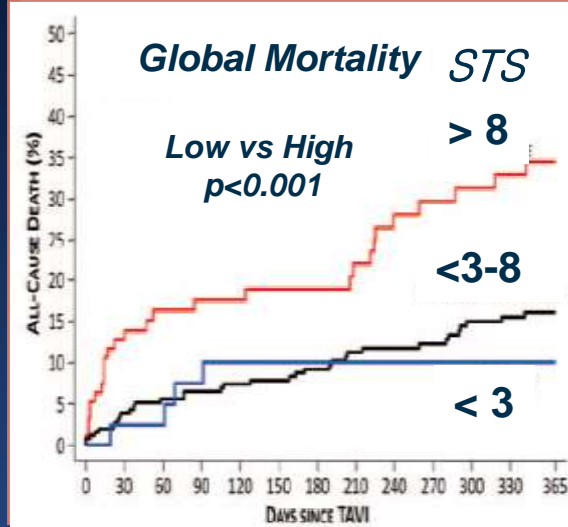
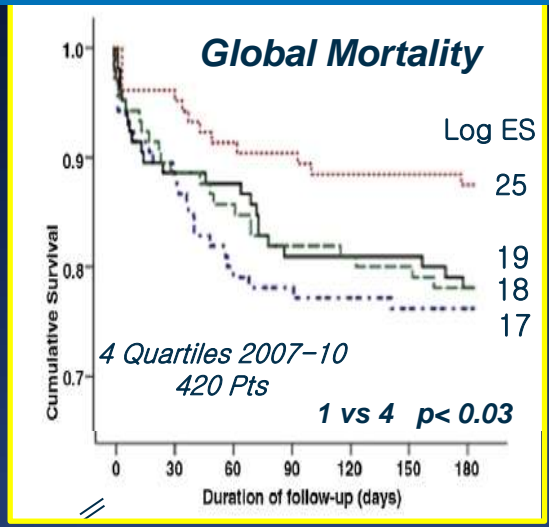


	2007-2009	2010-2011
<b>Log EuroScore</b>	FRANCE : 25.6%	FRANCE 2 : ↘ 21.9%
	SOURCE : 25.8%	SOURCE XT : ↘ 20.5%
	ADVANCE : 23.0%	ADVANCE ↘ 19.2%
<b>STS</b>	2009 PARTNER 1	↪ 11.8%
	2011-13 Post Market US	↪ 7.0%
	2013 CHOICE	6.0%
	2013 US CoreValve Pivotal	7.4%

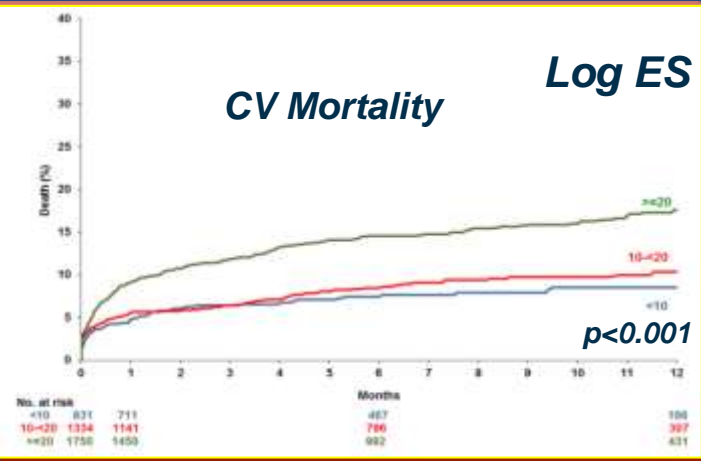
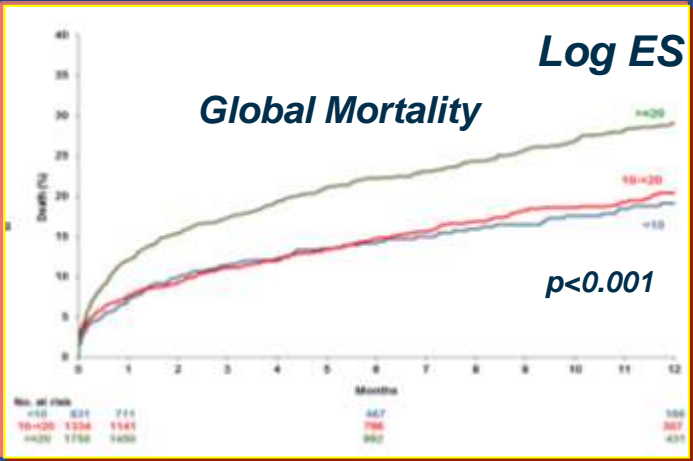
# TAVR: Higher Survival in Lower Risk Patients

Lange et al, JACC 2012

Wenaweser et al. EHJ 2013 286 Pts 2007-2011



Gilard et al, NEJM 2012 FRANCE 2 3915 Pts 2007 - 2012



**Lower risk Pts**  
 Patients with risk factors not captured in Log ES

# TAVR and SAVR: Similar Survival in Propensity-Matched Score Analysis

784 patients (Bern, Munich, Rotterdam)



*Piazza et Al, JACC Cardiovasculat Int 2013*



Improvement of devices and strategies to make TAVI: SAFER, faster, simpler, cost-effective

Almost achieved

Trials in specific subsets of pts

- Lower risk patients

*SURTAVI (EU), PARTNER II*

Pending

▪ Valve-in-Valve Degenerated Bioprosthesis

Done

## Where are we going ? Expanding the indications

5 years  
9-y in Rouen

Assessment of valve + Platform durability on longterm

On the way

Devices and procedural cost / reimbursement  
Regulatory issues

# Solving the issue of complications: *A key factor for the expansion of TAVR*

**Severe Vascular  
(3-16%)**

- **Lower size devices, new prosthesis**
- **Improved closure devices**
- **New approaches (TAo, Carotid)**

**Stroke  
(2-7%)**

- **Detection of high risk patients**
- **Emboic protection devices**
- **Modified anticoagulation strategy**

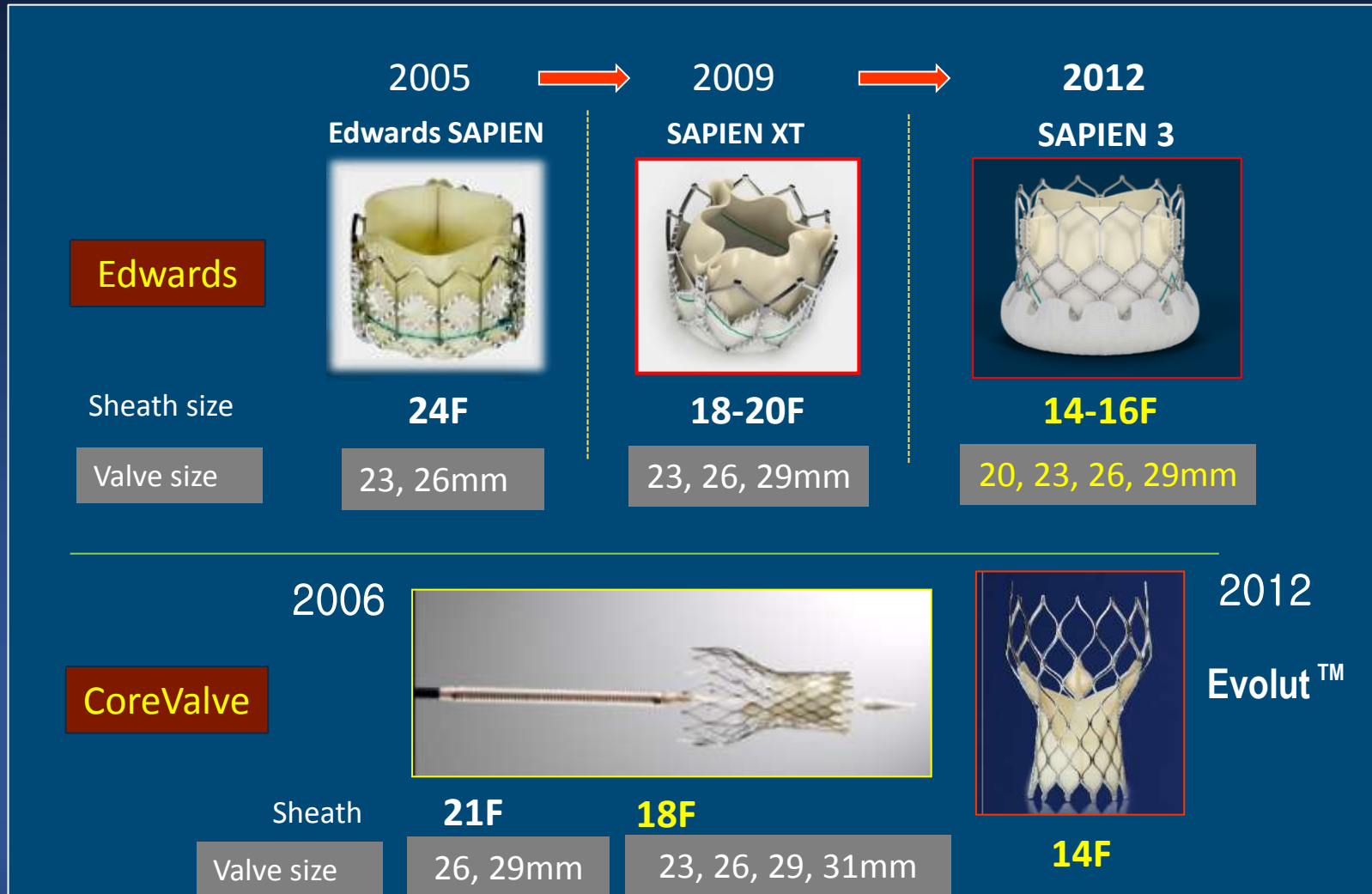
**Paravalvular AR  
(5% > grade 2)**

- **CT for annulus sizing (area)**
- **New imaging technologies**
- **New prosthesis**

**AV Block (PM)  
(Edwards 3-12% , CoreValve 16-35%)**

- **New prosthesis and delivery systems**

# Expansion of TAVR with advanced valves and delivery systems



# 2014: Last Generation Devices

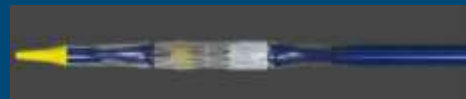
*Life threatening complications almost gone*

**A major advance for expanding TAVR to lower risk pts**



External cuff

SAPIEN 3



E-Sheath 14-16F

TF > 80%  
« Minimalist approach »  
Increasingly accepted

## The SAPIEN 3 Trial

Early Experience (Learning Curve)

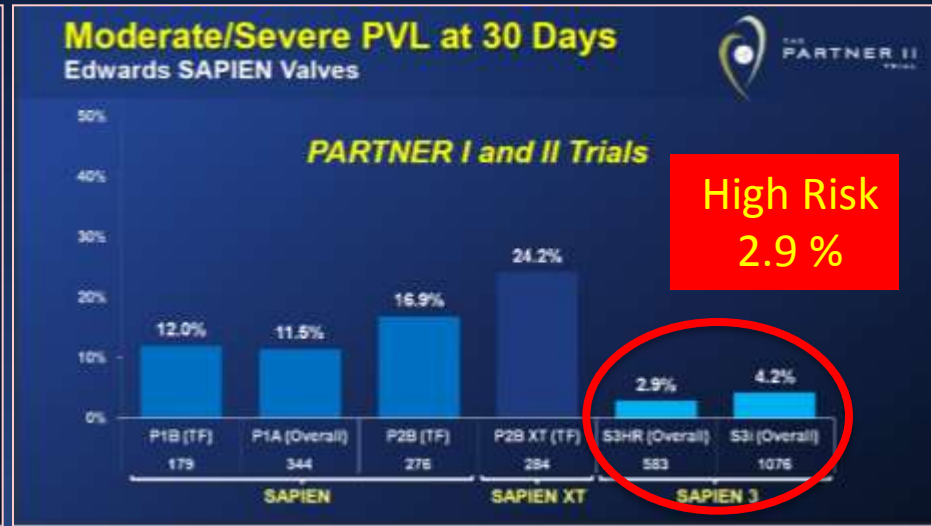
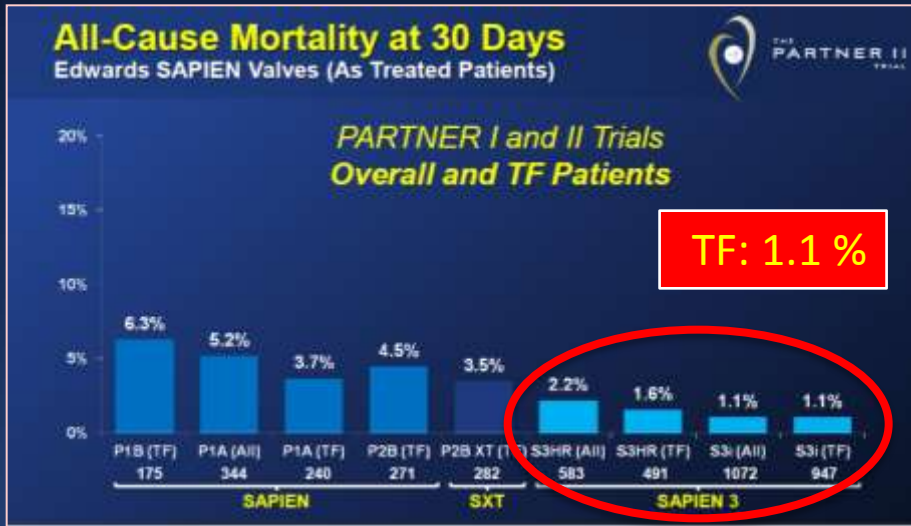
N= 150, Age: 83.6, TF & TA  
High and Intermediate Risk

### TF results N= 96

30-D Mortality:	<b>1.1%</b>
Stroke:	<b>1.0%</b>
PVL moderate:	<b>2.6%</b>
Vascular complic:	<b>5.2%</b>
PPM:	12%
Preclosing:	96% TF

J. Webb, PCR 2014

# Decreased complications in high risk and intermediate risk patients with Sapien 3



Mortality at 30-D

PVL at 30-D

### Strokes At 30 Days (As Treated Patients)

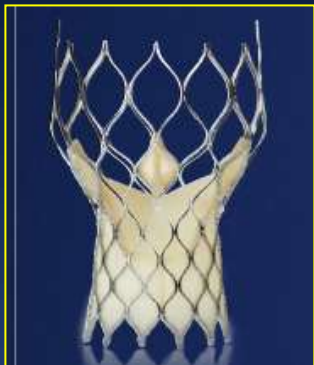
THE PARTNER II TRIAL

Events (%)	S3HR Overall (n=583)	S3HR TF (n=491)	S3HR TA/TAo (n=92)	S3i Overall (n=1076)	S3i TF (n=951)	S3i TA/TAo (n=125)
All	1.54	1.63	1.09	2.60	2.42	4.00
Disabling*	0.86	0.81	1.09	1.02	0.95	1.60
Non-Disabling	0.69	0.81	0	1.58	1.47	2.40
TIA	0.69	0.61	1.09	0.37	0.42	0

Disabling Strokes  
TF < 1%

Susheel Kodali, MD, Outcomes at 30 Days with the Sapien 3 TAVR System ACC 2015

# Improved safety (PVL, Vascular, PM) with other new generation devices ?



CoreValve Evolut  
*Improved sealing*



DF medical  
*Repositionable, retrievable*



BS Sadra SJ Portico  
*Repositionable, retrievable*



Edw Centera Accurate  
*Self seating features*



Jena Valve Engager  
*Native leaflets incorporated*



# TF cost-effective minimalist approach will help expanding the indications of TAVR

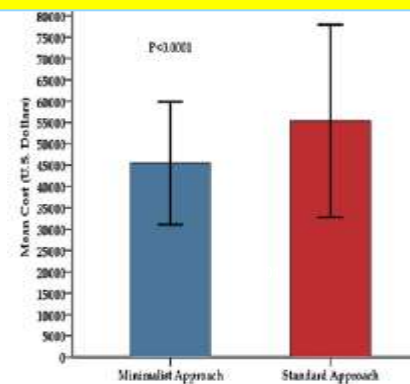


Emory Hospital, Atlanta, USA

Cost Saving : US\$ 15 000

- Same results and outcome
- Decreased resource utilization, hospital stay, & cost

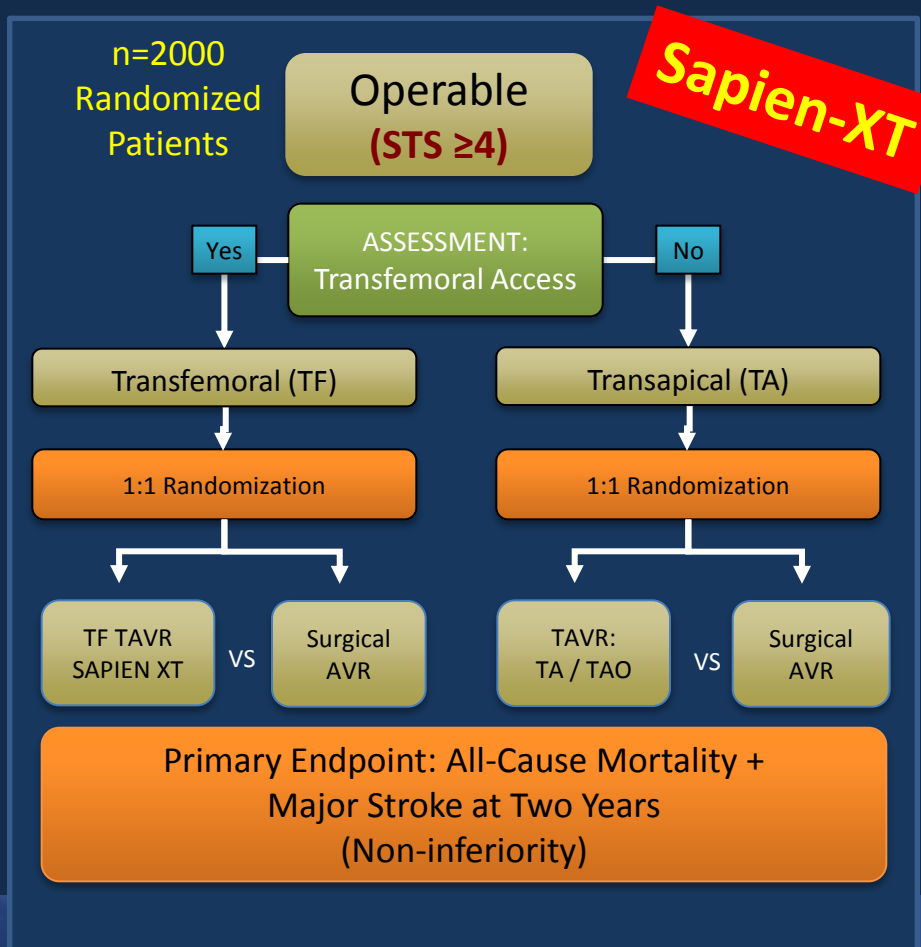
*Babaliaros et al, JACC Interv 2014*



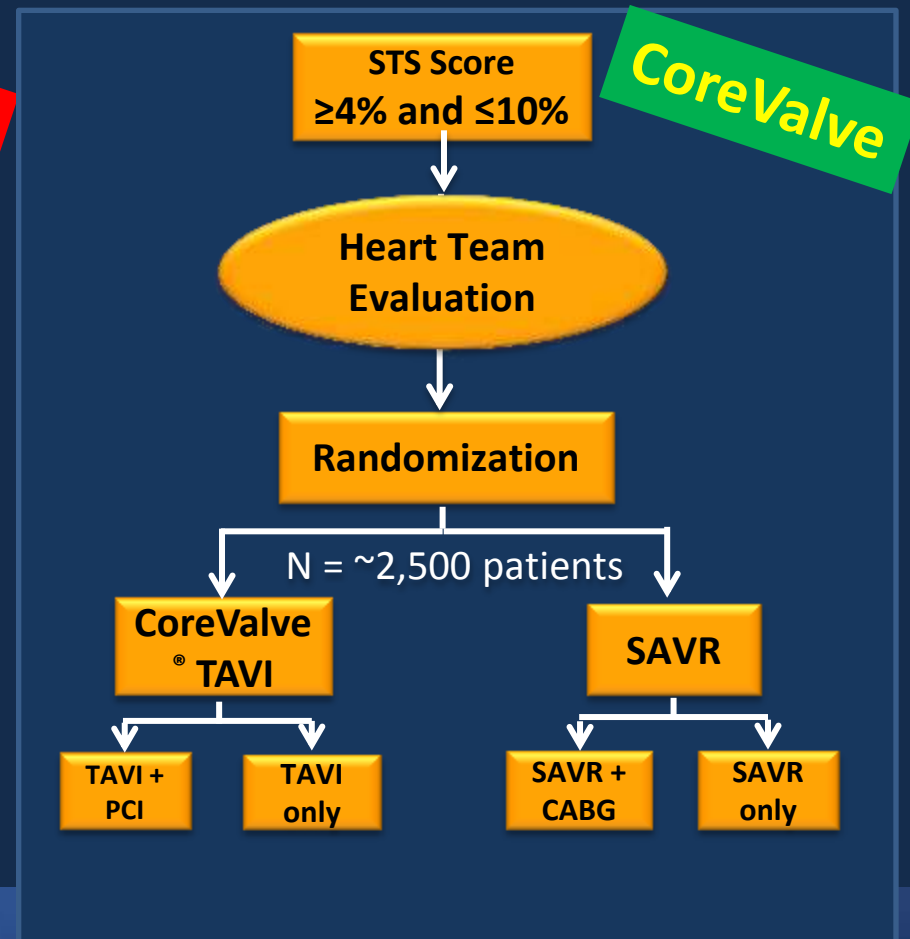
Comparative cost: minimalist vs standard

# Evidence-based comparison of SAVR vs TAVR in intermediate risk patients

## Edwards PARTNER 2 Trial



## CoreValve<sup>®</sup> SURTAVI Trial

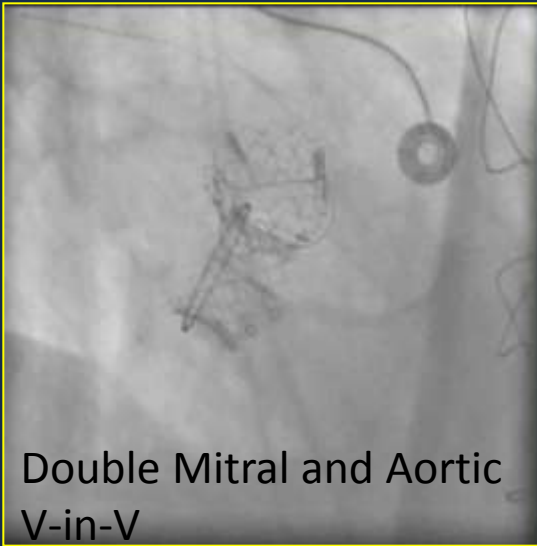




# Expansion of TAVR – Failed bioprosthesis

## Global Valve-in Valve Registry

Dvir et al Circulation 2012; 459 Pts

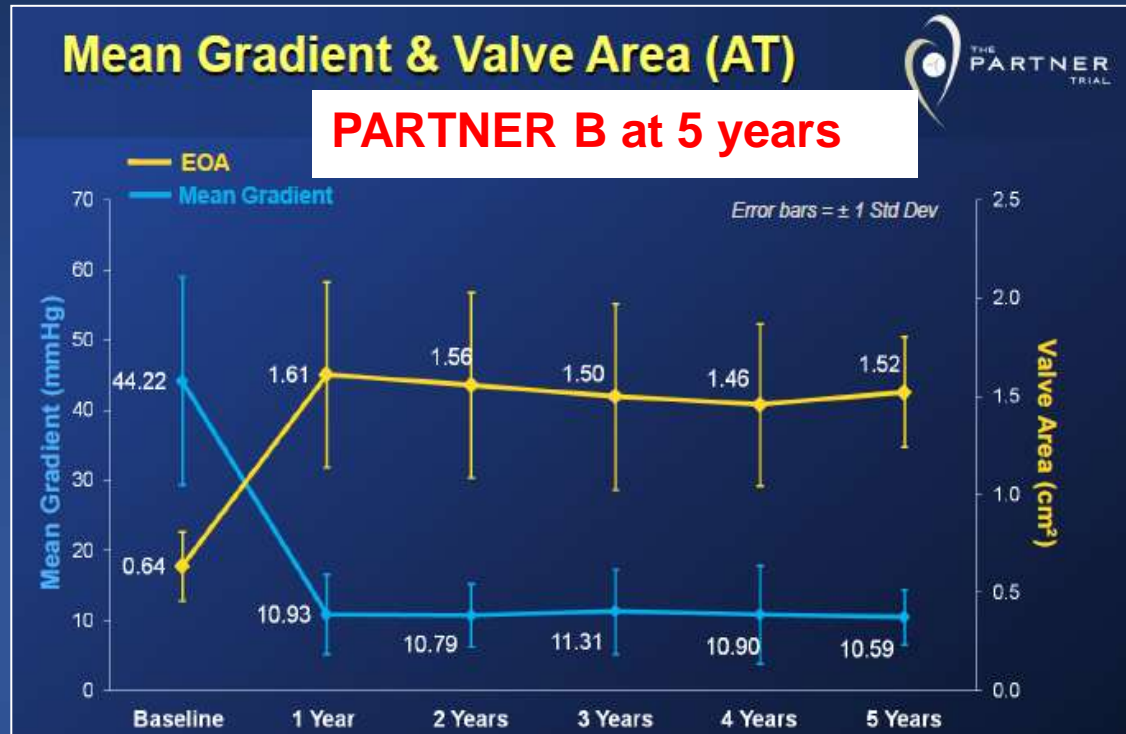


- Good short and mid term results
- Promising results with Sapien XT 20mm and Evolut CoreValve
- Lower gradient with CoreValve in small sizes
- Transfemoral access preferred

Valve-in-Valve is a therapeutic option in failed surgical bioprosthesis, as in failed TAVR prosthesis

# Valve failure in TAVR is not an issue at 5 years in the elderly population

- Rarely reported
- 1 case (at 6 years) since 2002 in our series



Kodali, TCT 2014

# Competition with SAVR on durability is open

*Our world champion: 9 years*



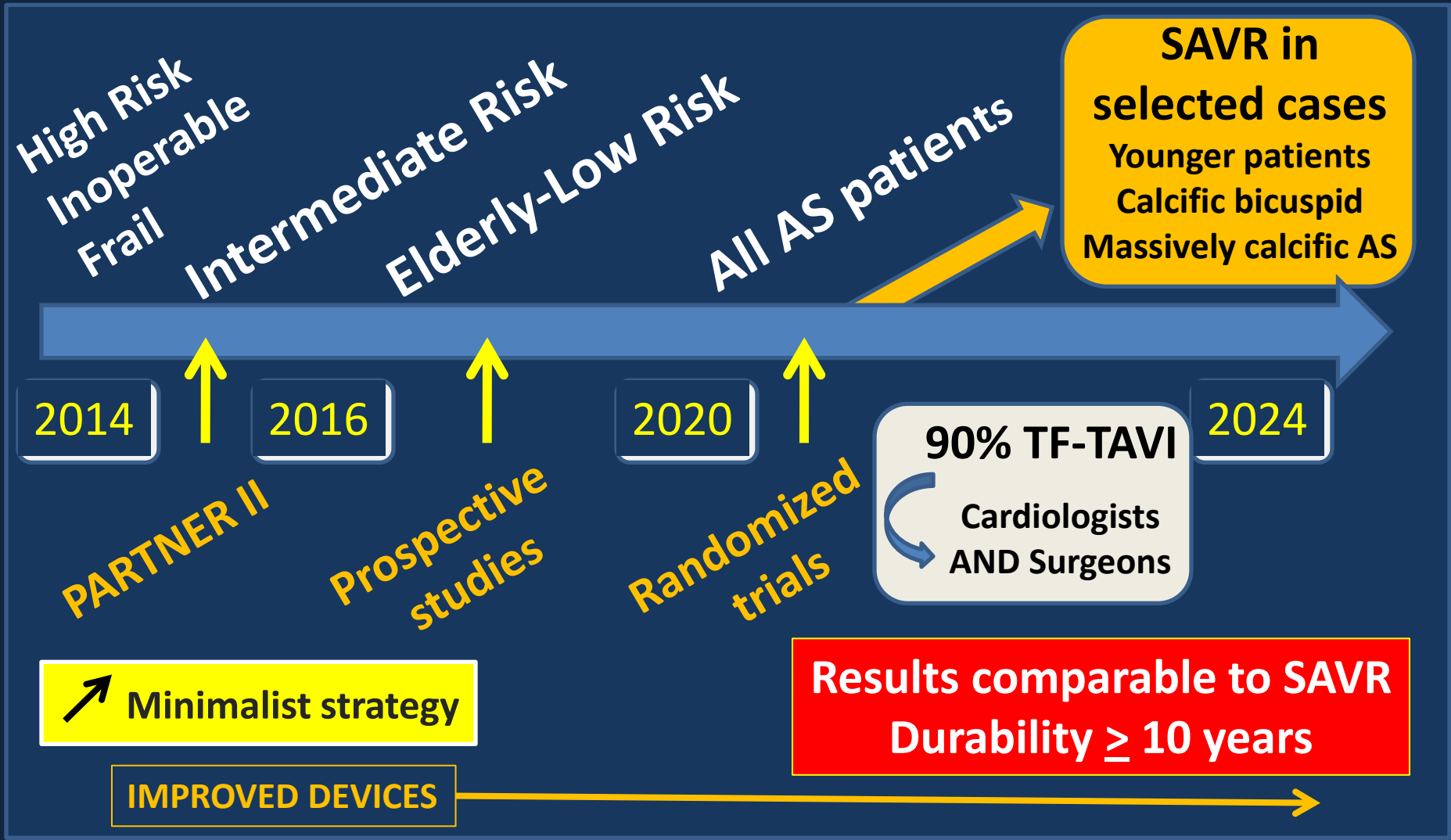
SAPIEN Valve  
Feb 2006

2015: 90 y/o  
9 Years  
Follow-up

Unchanged  
Valve function

Normal life

# My optimistic vision of the future of TAVR



# Expansion and future of TAVR

**2014**

TAVR is indicated in patients who are not optimal candidates to surgery



**2024**

SAVR is indicated in patients who are not optimal candidates to TAVR !