TAVR: March to the Lower Risk
Cardiologist perspective

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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	Company
Consulting Fees/Honoraria	Edwards Lifesciences
Proctoring-Training activities/Honoraria	Edwards Lifesciences

TAVI: Where Are We Today?

An incredible expansion worldwide

Edwards-Valves

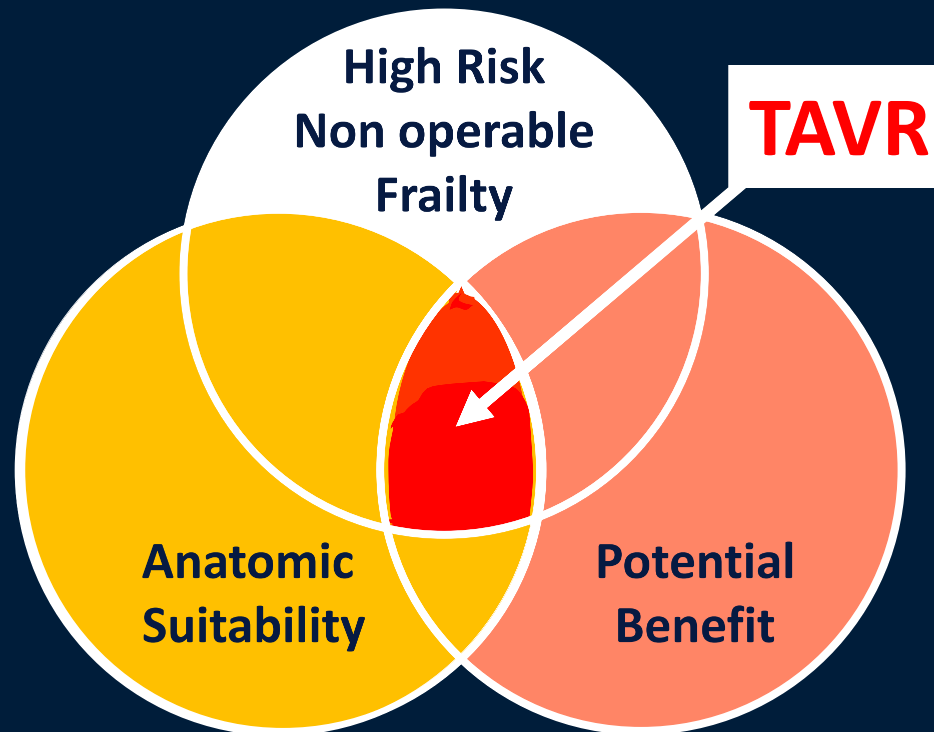
CoreValve

~ 300 000 TAVI procedures in 10 years
> 700 centers OUS, > 500 centers in USA
TAVI available in 65 countries around the world
> 70 000 TAVI in 2015, expected growth of 40% / year

In 2015: Current Guidelines Are Freezing TAVR in the Past

ESC Guidelines 2012 / US Guidellines 2014

Decison must be confirmed by a « Heart Team »

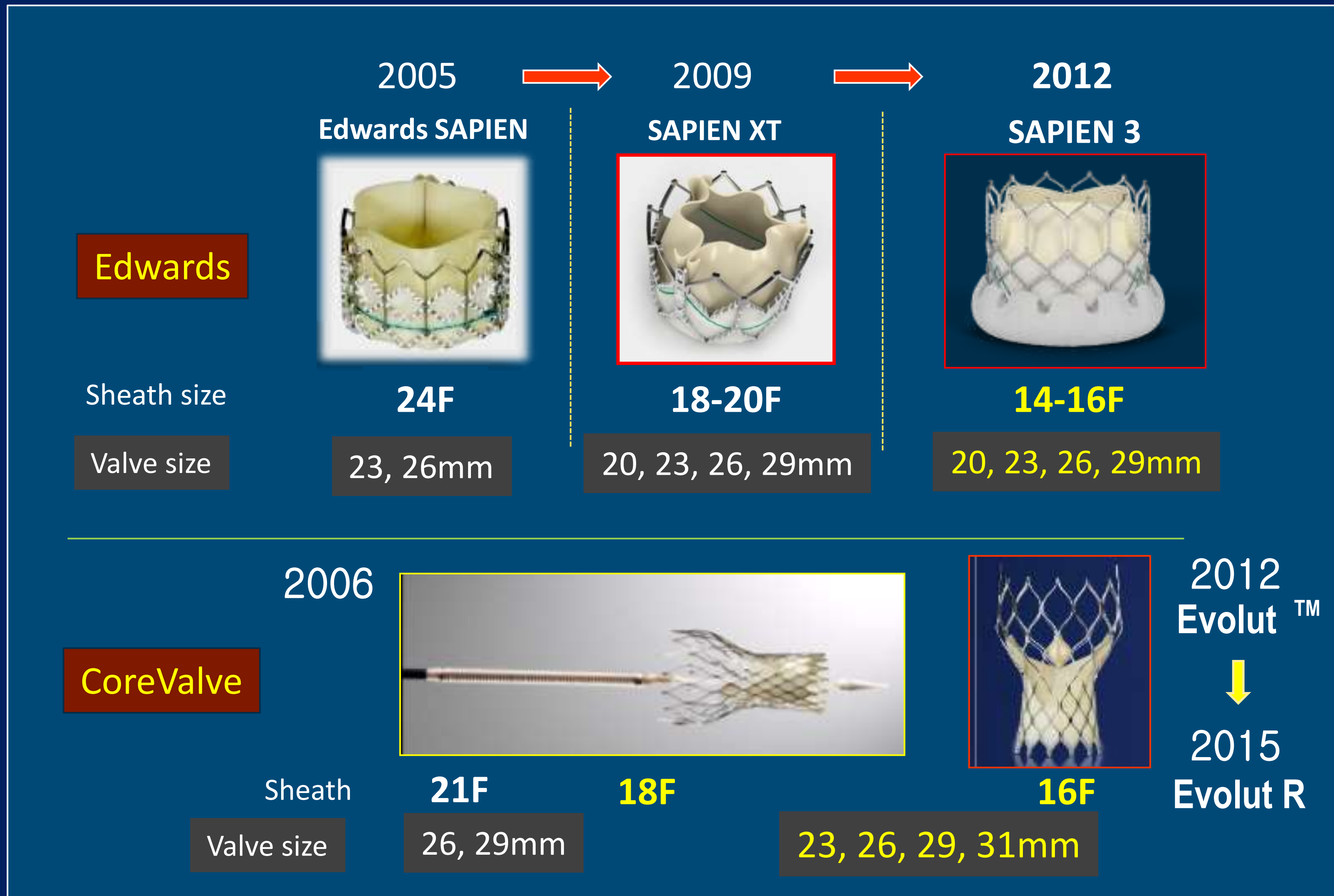


Cardiac Surgery On-site

« Intermediate » risk patients (Log Euroscore < 10-20%, STS Score < 4-10%) are not candidates to TAVI

Advanced Valves and Delivery Systems, Have Changed the World of TAVI

Improved techniques, safety, and results



In 2016, The March to Lower Risk is Ongoing
What do we need to know ?

Done

Propensity score analysis of TAVR vs SAVR in lower risk patients

2013: OBSERVANT Study
2016: PARTNER 2S3i

Done

Evidence-based trials in lower risk patients

2015: NOTION Study
2016: PARTNER 2A

Done

Improved devices and strategies making TAVI safer, simpler and cost effective

New TAVR Systems
Minimalist TF-TAVR

Ongoing

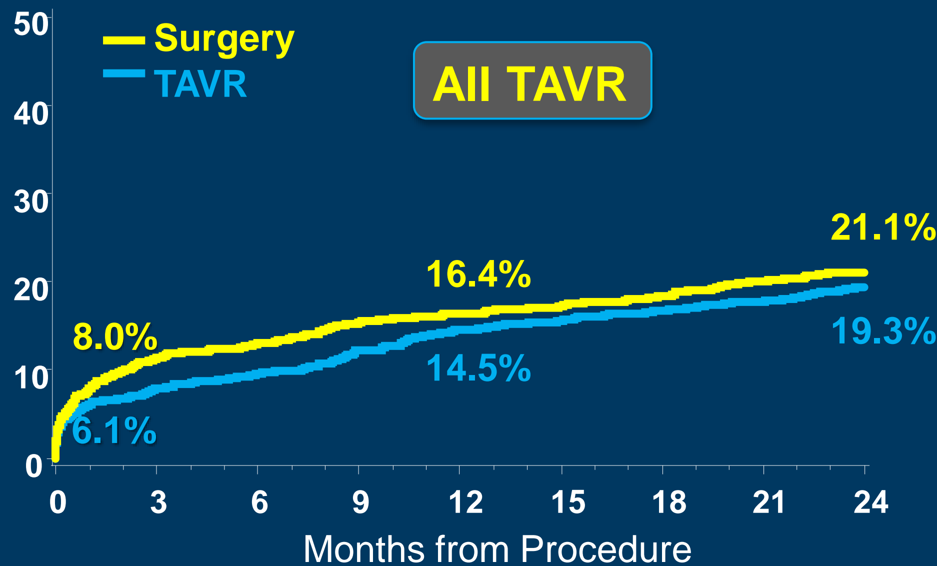
Assessment of Valve + Platform durability on long term

5 years
(PARNER 2A & 2B)

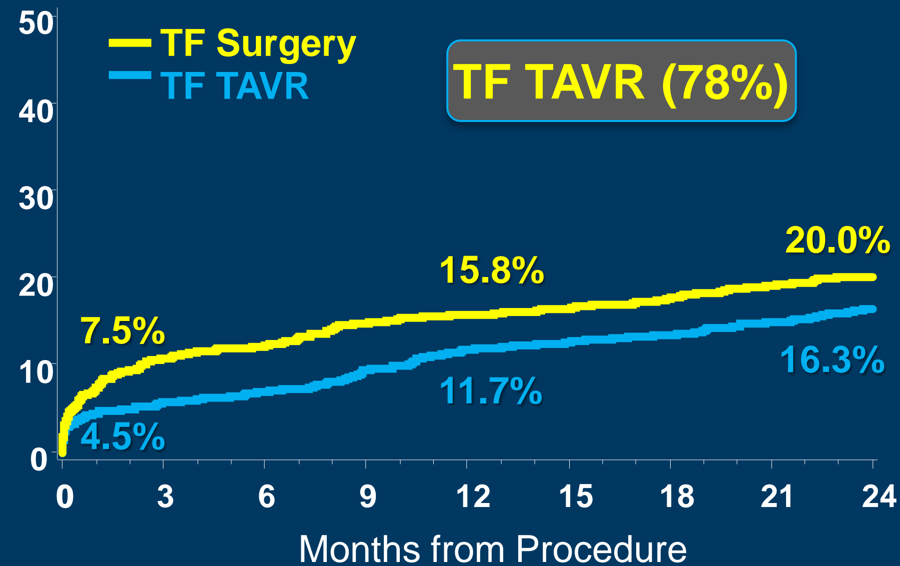
The PARTNER 2A Trial (SAPIEN XT) Primary Endpoint (ITT) at 2 years

All-Cause Mortality or Disabling Stroke

1



Primary Non-Inferiority Endpoint Met



Superiority of TF-TAVR vs Surgery

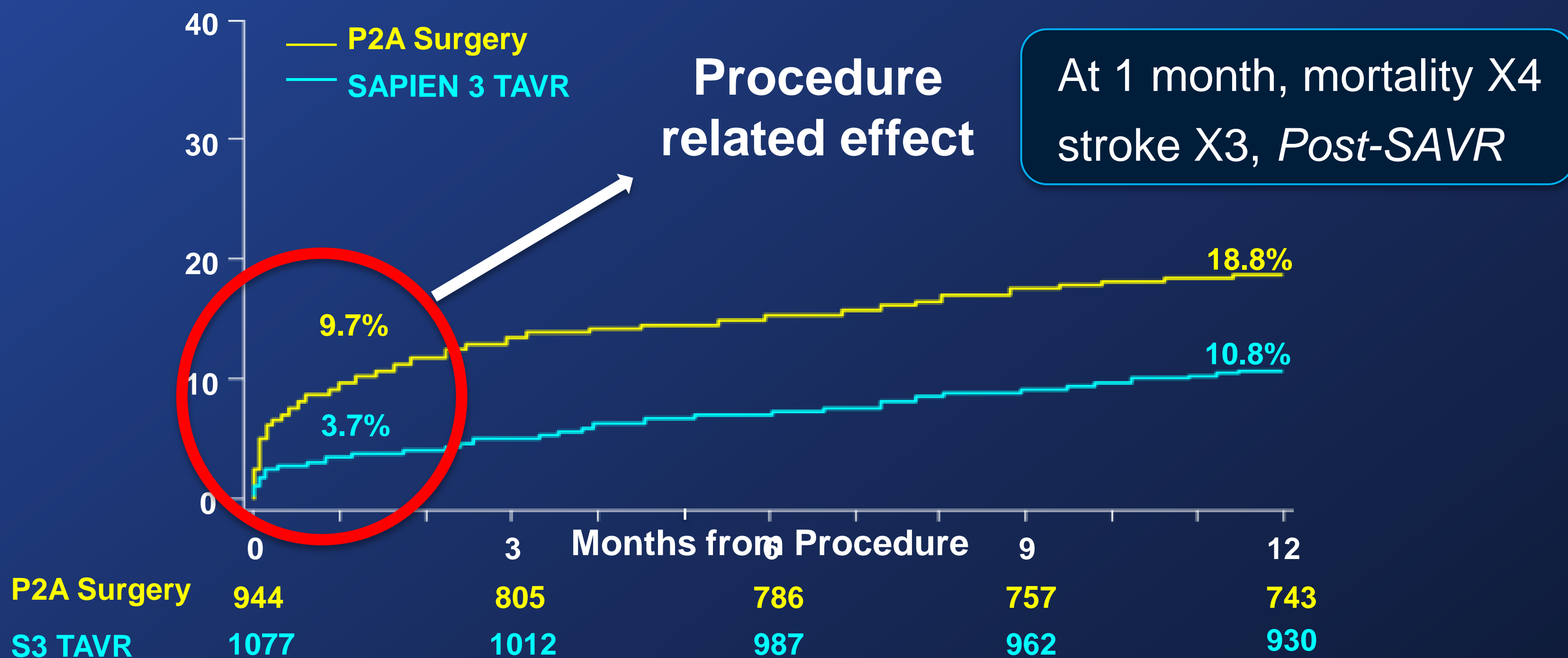
ITT: p = 0.05, AT: p = 0.04).

TAVR reduced AKI, severe bleeding, new AF and L.O.S. Surgery reduced vascular complications and PVL

From C. Smith et al, ACC 2016. NEJM 03-2016

The PARTNER S3i trial: SAPIEN 3 (PARTNER 2) vs SAVR (PARTNER 2A), propensity score analysis

All-Cause Mortality and All Stroke (AT)



Primary Endpoint – Superiority of TAVR achieved (p<0.001)

Death, Stroke, or AR ≥ Mod at 1 Year

Superiority of SAVR on PVL (p<0.001) but moderate to severe PVL = 1.5% only at 1 year with TAVR

From V. Thourani et al, ACC 2016. Lancet 03-2016

In lower risk patients, real life is clearly beyond both guidelines and randomized trials

- In Europe, TF-TAVR (90% of cases with new generation devices) is already the preferred option for patients older than 80, *whatever the STS score*
- Older patients are often referred to the cardiologists by the surgeons themselves
- In this subset of patients, valve durability on long term is not an issue
- The « minimalist transfemoral » approach is increasingly accepted (local anesthesia, no TEE, early discharge)

SAPIEN 3: Ease of use, improved results and safety: Key factors for the march to lower risk

2016: TAVR in real life

84 Y/0 patient, EuroScore 8

- Minimalist TF approach
  Local anesthesia
  No pain, no scar
- Procedure duration: 40 min
- No AR, no other complication
- Total L.O.S.: 5 Days

Discharge at Day 2 Post-TAVR

How can we see the future of TAVR ?

GUIDELINES
EU 2012
US 2014

NEW GUIDELINES

NEW GUIDELINES

High Risk
Inoperable
Frail

Intermediate

Low Risk > 75y

Low Risk > 65y

Default strategy
for all comers

SAVR in
-Younger patients (< 65y ?)
-Calcific bicuspid
-Massively calcific AS

2015 | 2016 | 2020

PARTNER II

Prospective ?

PARTNER III

Other randomized ?

New strategies/new devices

ISSUES
-THV durability ?
-PPM, Strokes (EPD?)
-Reaccess Cor Arteries
-Post-TAVI Med Strategy

Minimalist TF-TAVI expanding

- Concept of Heart Team and Scoring revisited
- AGE = major factor
- Well informed patient / relatives at the « heart » of the heart team decision (TAVI or SAVR)

Benchmark
New TAVI systems=
Results comparable to SAVR at ≥ 10 years

Conclusions

- **In 2016**, TAVR has entered a new era with remarkable technology enhancements leading to dramatic improvement of outcomes
- TAVR should be soon recognized as an alternative to SAVR in lower risk patients. The patients should be clearly informed of the two possible options
- Within 5 years, the impact of TAVR will continue to grow and TAVR might become the default strategy for a majority of AS patients, SAVR remaining an alternative option in suboptimal TAVR indication