Controversies: TAVI is preferred in all high-risk patients

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Disclosure

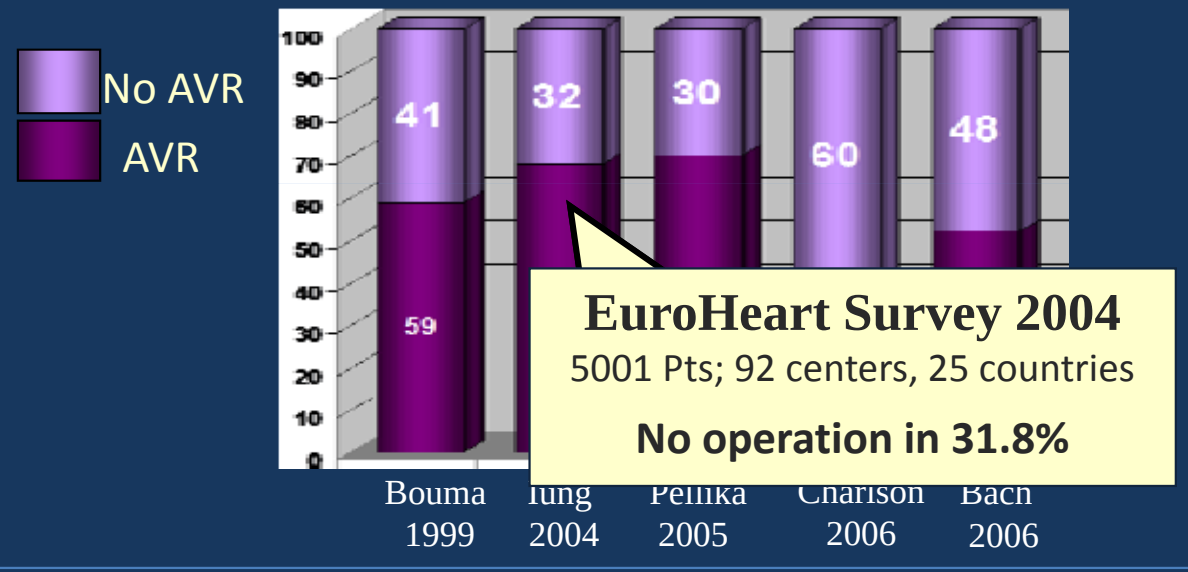
Consultant / Proctor for Edwards Lifesciences

In symptomatic AS, surgical AVR is urgent and life saving. It has been the standard of care for decades

Rational of TAVI:

Offering a therapeutic solution to thousands of patients with symptomatic AS left untreated

One third of the patients are not operated



High surgical risk is the leading reason for declining surgery:

Very old age, cardiac or non-cardiac comorbidities

What are the risks of surgical AVR in the subset of high risk patients *in the real life ?*

Thourani VH et al , Ann Thorac Surgery 2011
Dpt of Cardiac Surgery, Emory University School of Medicine, Atlanta, USA

4 Centers, 159pts, Mean Age 76.1 + 11.2
STS Score 16.3 + 6.3%

- Stroke		4.4%
- PM		5%
- Multiorgan failure		6.9%
- Pneumonia		7.5%
- Dialysis		8.2%
- Length of stay		12.6+11.0
- In-hospital mortality		16.4%
- Survival	1y	70.9%
	3y	56.8%
	5y	47.4%

What about::

- Pain ?
- Bleeding, Transfusion ?
- Re-operation for bleeding ?
- Scar infection ?
- Psychological disorders ?
- Length of rehabilitation ?
- Transfer to nursing home ?

How do the results of TAVI compare with surgical AVR in the subset of high risk patients ?

PARTNER US randomized trial: Symptomatic Severe Aortic Stenosis

Oct 2010: Martin Leon et al
June 2011: Craig Smith et al

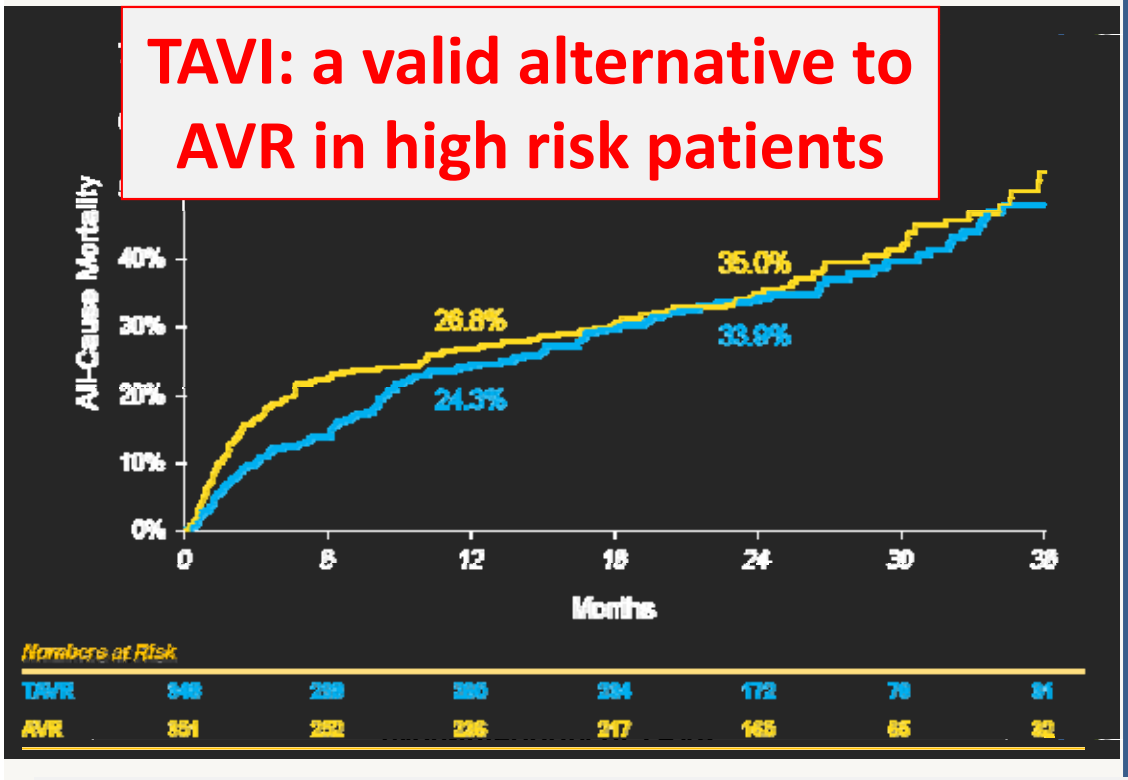
The NEW ENGLAND JOURNAL of MEDICINE

March 2012: S. Khodali et al
May 2012: R. Makkar et al

N= 700

Cohort A: High Risk
2 Years Mortality

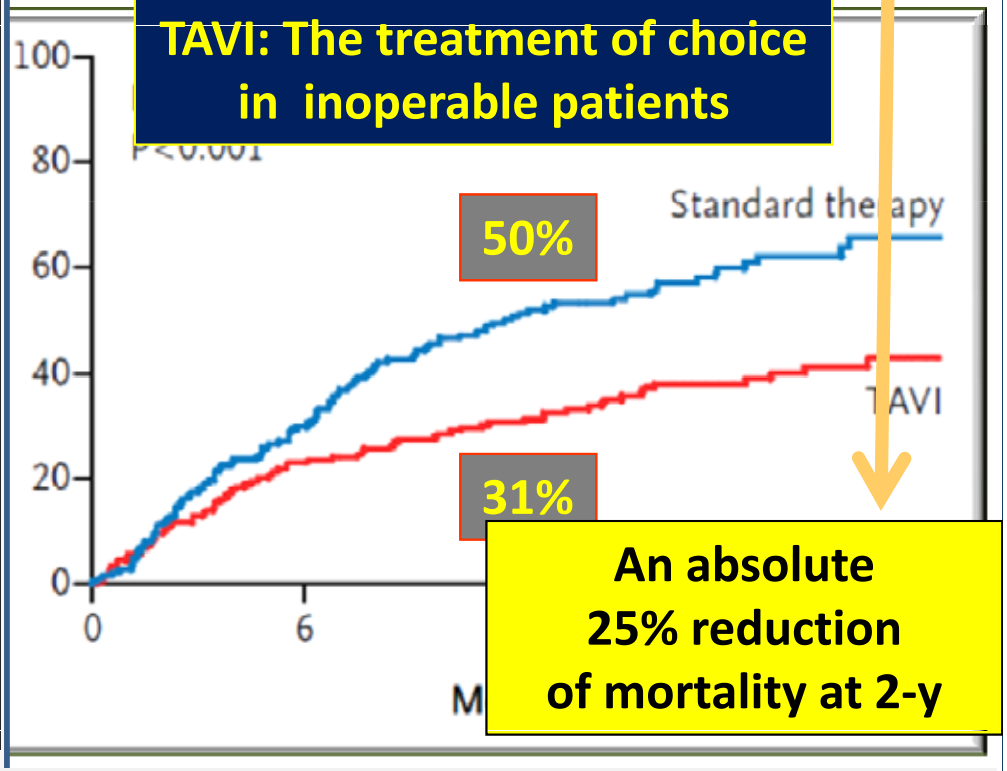
TAVI: a valid alternative to AVR in high risk patients



N= 358

Cohort B: inoperable
2 Years Mortality

TAVI: The treatment of choice in inoperable patients



An absolute 25% reduction of mortality at 2-y

Marked and long lasting Q.O.L. improvement

PARTNER Cohort A (High Risk Patients)

Different hazards with TAVI and AVR

TAVI

- More ***strokes*** at 30 days (3.8 vs. 2.1%, p=0.20) and at one year (5.1% vs. 2.4%, p=0.07)
- More **vascular *complications*** (11.0% vs. 3.2%, p<0.001)

AVR

- More ***major bleeding*** (9.3% vs. 19.5%, p<0.001)
- More ***new onset AF*** (8.6% vs. 16.0%, p<0.001)

- More para-valvular regurgitation associated with TAVI (p<0.001)

- Symptom improvement favored TAVI at 30 days but similar to AVR at one year

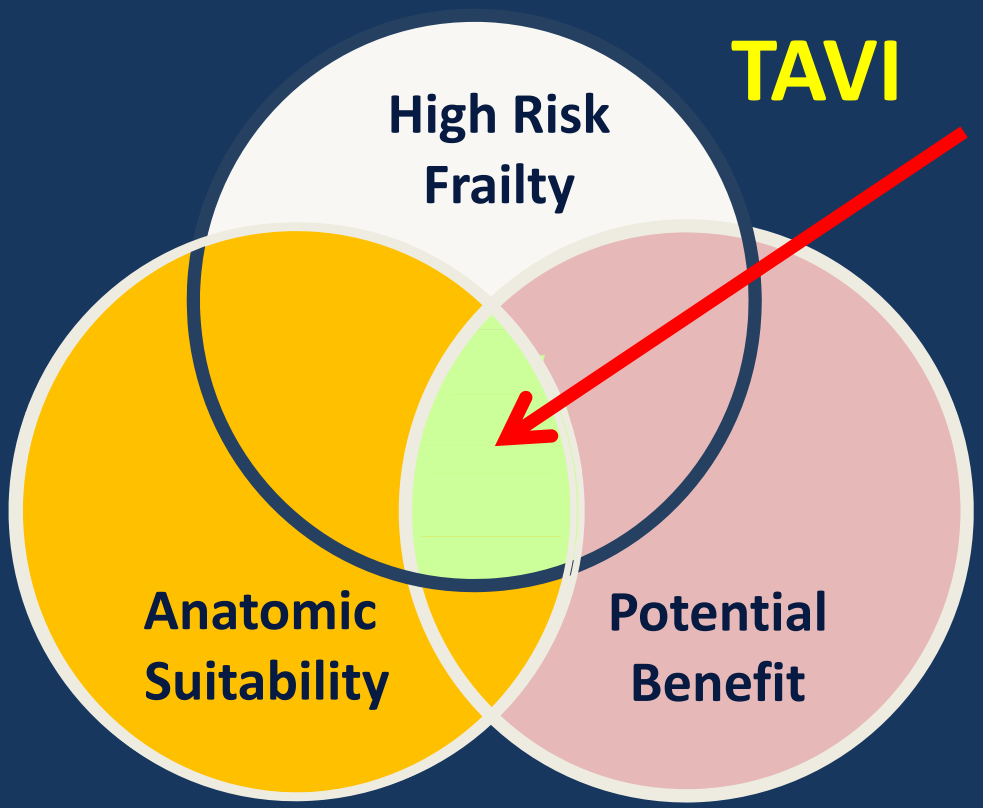
- **TAVI and AVR: both acceptable therapies in high risk patients**
- **Differing peri-procedural hazards should influence case-based decision-making**

Registries and PARTNER-US driven recommendations

ESC Guidelines 2012

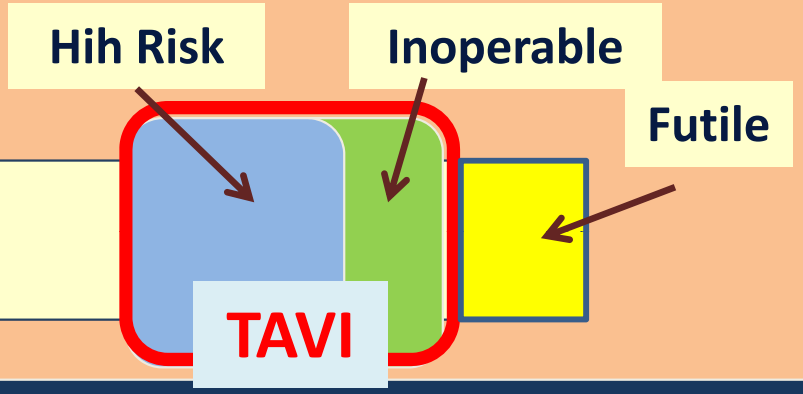
Recommendation	Class	Level
TAVI should be considered in high-risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a 'heart team' based on the individual risk profile and anatomic suitability.	II a	B

TAVI should only be undertaken with a multidisciplinary « Heart Team » including cardiologists and cardiac surgeons and other specialists if necessary



80%

Low / Intermediate risk: AVR



USA: PARTNER-US driven recommendations

ACC/AATS/SCAI/STS Expert Consensus

Class I:

- **Heart Team required**
- **On-site cardiac surgery**
- **Inoperable Patients**

Class IIa:

- **High-risk operable as an alternative to surgery; determined by heart team and case-based decisions**

➢ In high risk patients, the indication of TAVI relies on a mutidisciplinary (Heart Team) evaluation: clinical status, formal and relative contra-indications, anatomical suitability to TAVI

2013: Selection of TAVI patients

Those who know best the patient should be associated to the decision

General practitioner

Referent cardiologist

Radiologist

Patient's relatives

Patient himself !

Anesthesiologist

The Heart ValveTeam

Echocardiographist

Research Nurse

Geriatrician

Other Specialists

Cardiac surgeon

Interventional Cardiologist

Ongoing technological advances will improve the safety of TAVI and reinforce the indication in high risk patiens

Severe Vascular (3-18%)

Impact on survival

- Lower size devices
- Improved closure devices
- Other approaches (transaortic)

Stroke (2-7%)

Impact on survival

- Detection of high risk patients
- Embolic protection devices
- Modified anticoagulation strategy

Paravalvular AR (5% > grade 2)

Impact on survival

- Optimal screening of native valve anatomy and Ca distribution
- More accurate ways of valve sizing and positioning
- New valves, repositionability

AV Block (PM)

(Edwards 3-12% CoreValve 16-35%)

- Positioning issue: new valves and delivery systems
- New imaging technologies

Since 2010, remarkable technological advances limit the value of recommendations based on previous registries and PARTNER trial

Edwards devices

Edwards Sapien

Stainless steel frame

PARTNER-EU
SOURCE (EU)
PARTNER US
(> 4 000 Pts)

2 sizes: 23, 26mm

*Sheath : **22F &***

TF: Surgical cut

RetroFlex

TF: 50%

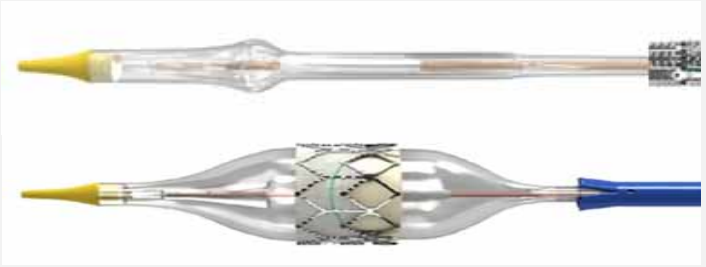
TF: 85%

Cobalt chromium frame

FRANCE 2 (F)
GARY (D)
Other National Registries
SOURCE XT
Pilot EU registry
(> 10 000 Pts)

Sapien XT

3 sizes: 23, 26, 29mm



*e-Sheath: **16F, 18F, 20F***

TF Percutaneous approach

NovaFlex

Since 2010, remarkable technological advances limit the value of recommendations based on previous registries

CoreValve devices

Generation 1
25F

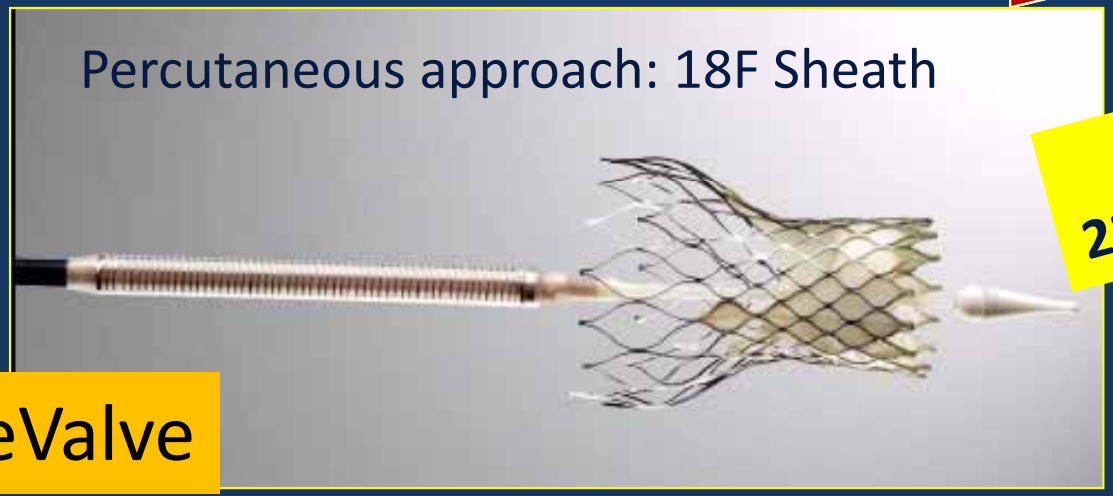
Generation 2
21F

Generation 3
18F

Generation 4
18F

2004-2005 **From 2006** **2010**

CoreValve



SIZES
23, 26, 29, 31mm

AccuTrak Delivery System

Italian Registry

German Registry TF

Other National Registries

Worldwide Experience

ADVANCE Registry

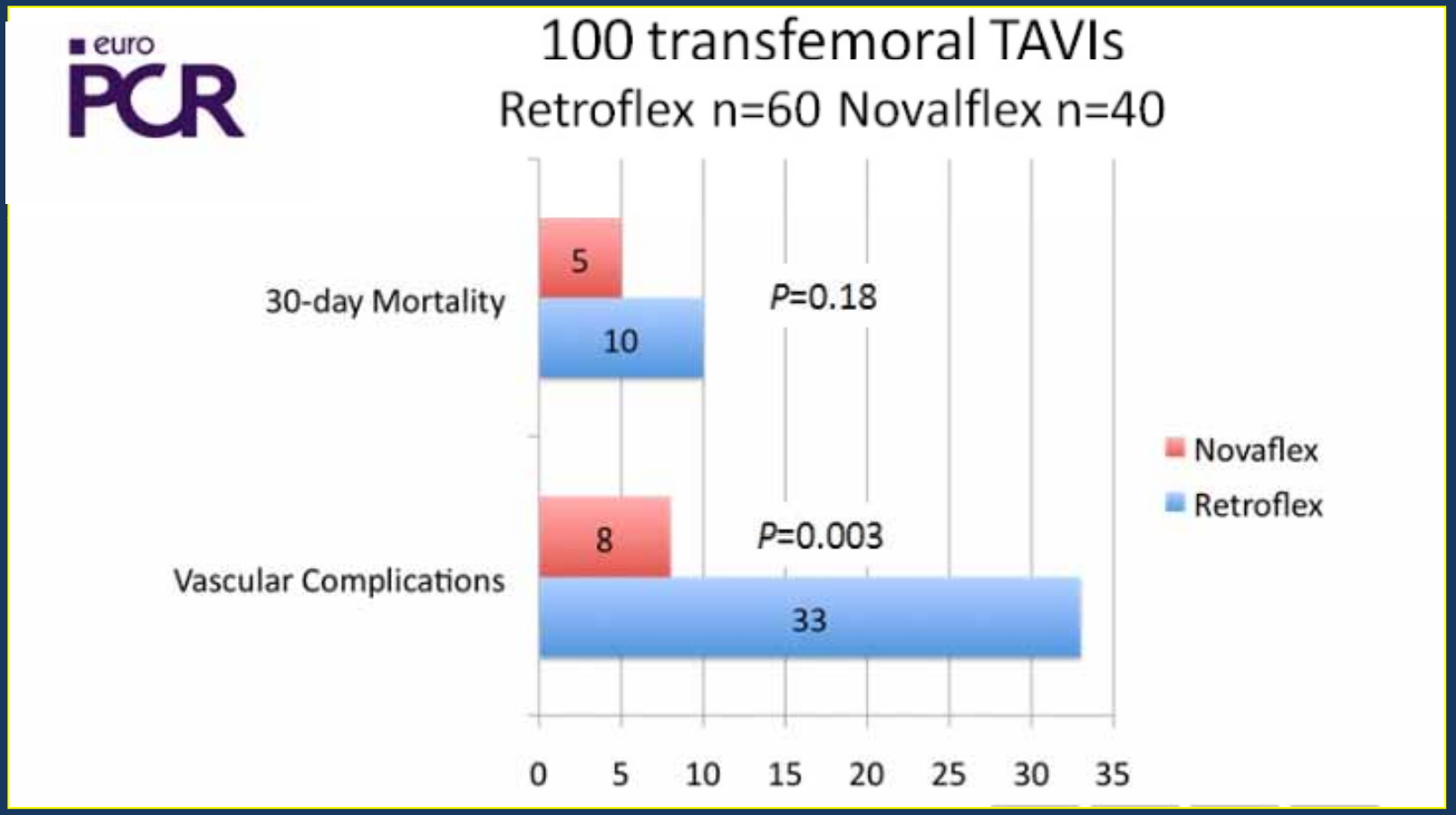
European Experience

US Pivotal High Risk Study

US Pivotal Extreme Risk Study

Improved results with Sapien XT (NovaFlex) compared to Edwards Sapien (RetroFlex)

2012: SOURCE vs SOURCE XT Registry



Improved mortality and vascular complications

Improved results with Sapien XT (NovaFlex) compared to Edwards Sapien (RetroFlex)

2012: PARTNER 2 US randomized trial

Non operable Cohort (ACC 2013)

Vascular and Bleeding Events:
At 30 Days (AT)

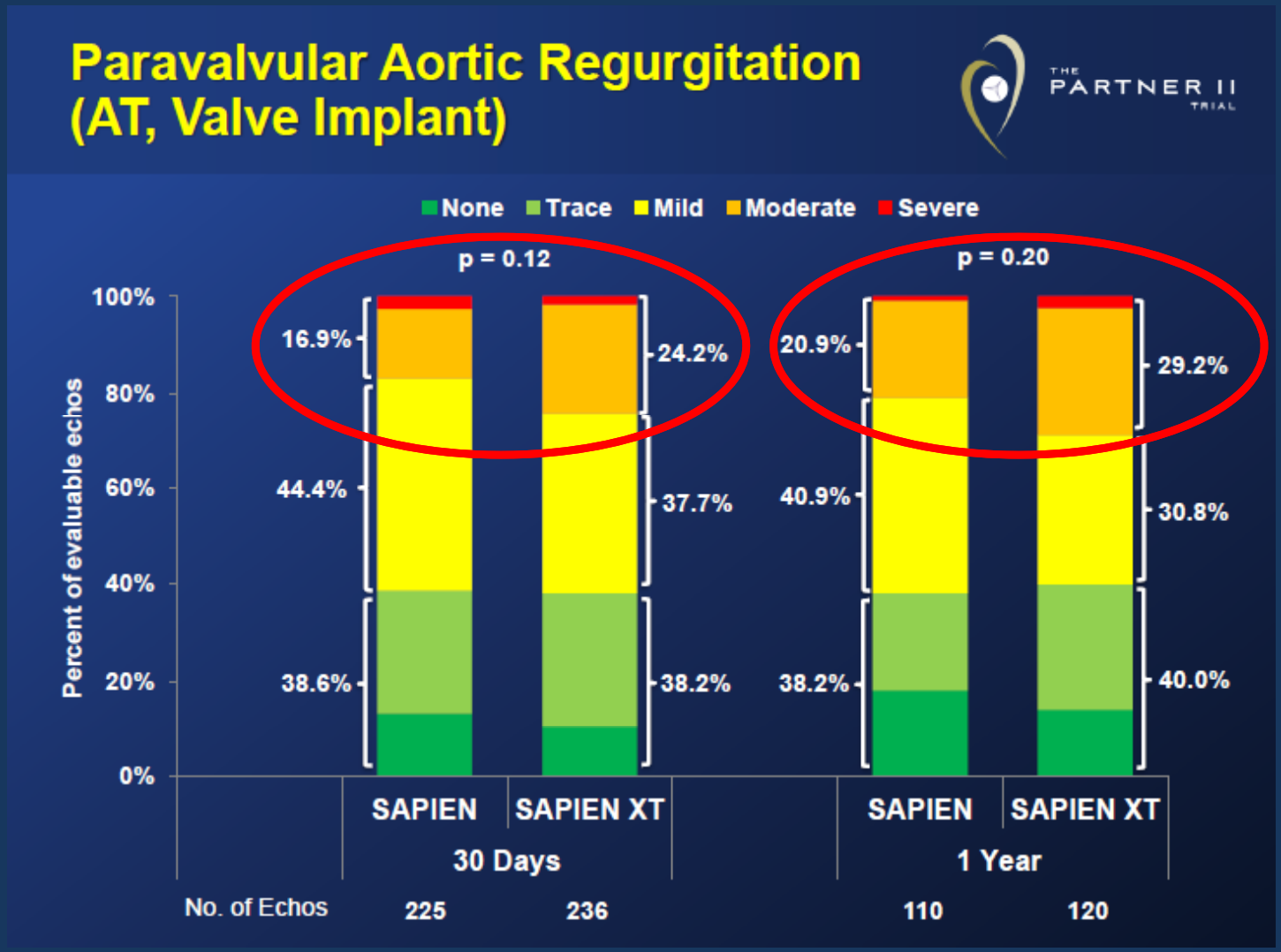
THE PARTNER II TRIAL

	SAPIEN (n=271)		SAPIEN XT (n=282)		
Events	**n**	**%**	**n**	**%**	**p-value**
Vascular:					
Major	42	15.5	27	9.6	0.04
Minor	20	7.4	14	5.0	0.23
Bleeding:					
Disabling	34	12.6	22	7.8	0.06
Major	44	16.4	44	15.7	0.84
Patients with transfusions	80	29.5	73	25.9	0.40

Paravalvular leak remains an issue

2012: PARTNER 2 US randomized trial

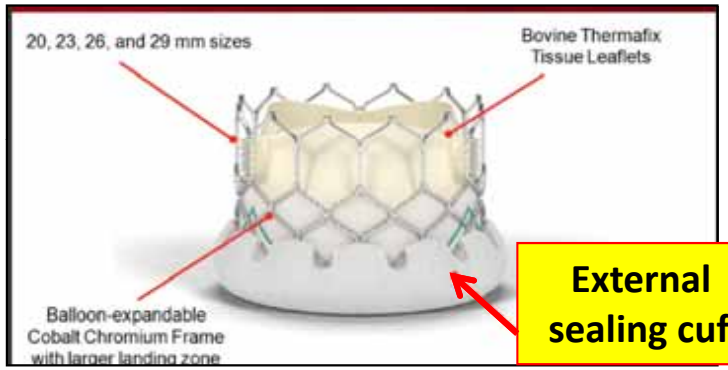
Non operable Cohort (ACC 2013)

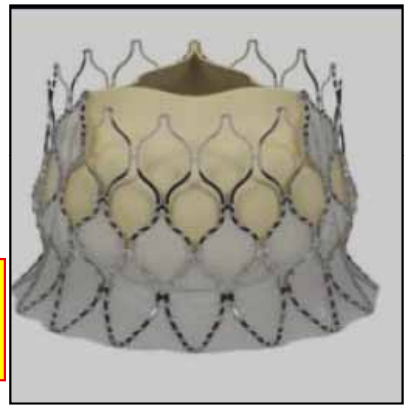


Upcoming new valve designs (2013) are on the way to further improve most of the remaining safety issues

Paravalvular AR, vascular complications, PM

EDWARDS





Sapien 3

Balloon expandable

Specially designed to reduce Paravalvular AR

Centera

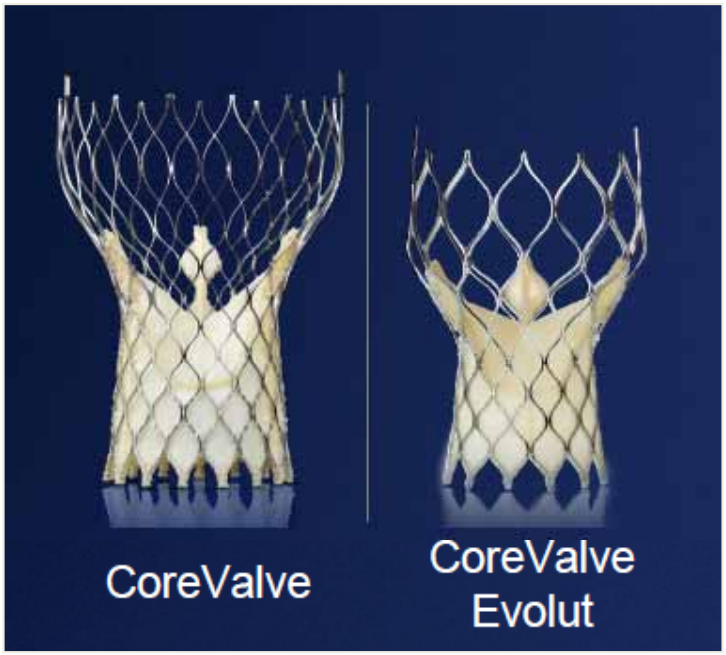
Self expandable

Single operator

Subcoronary position

Low profile: 14F E-Sheath

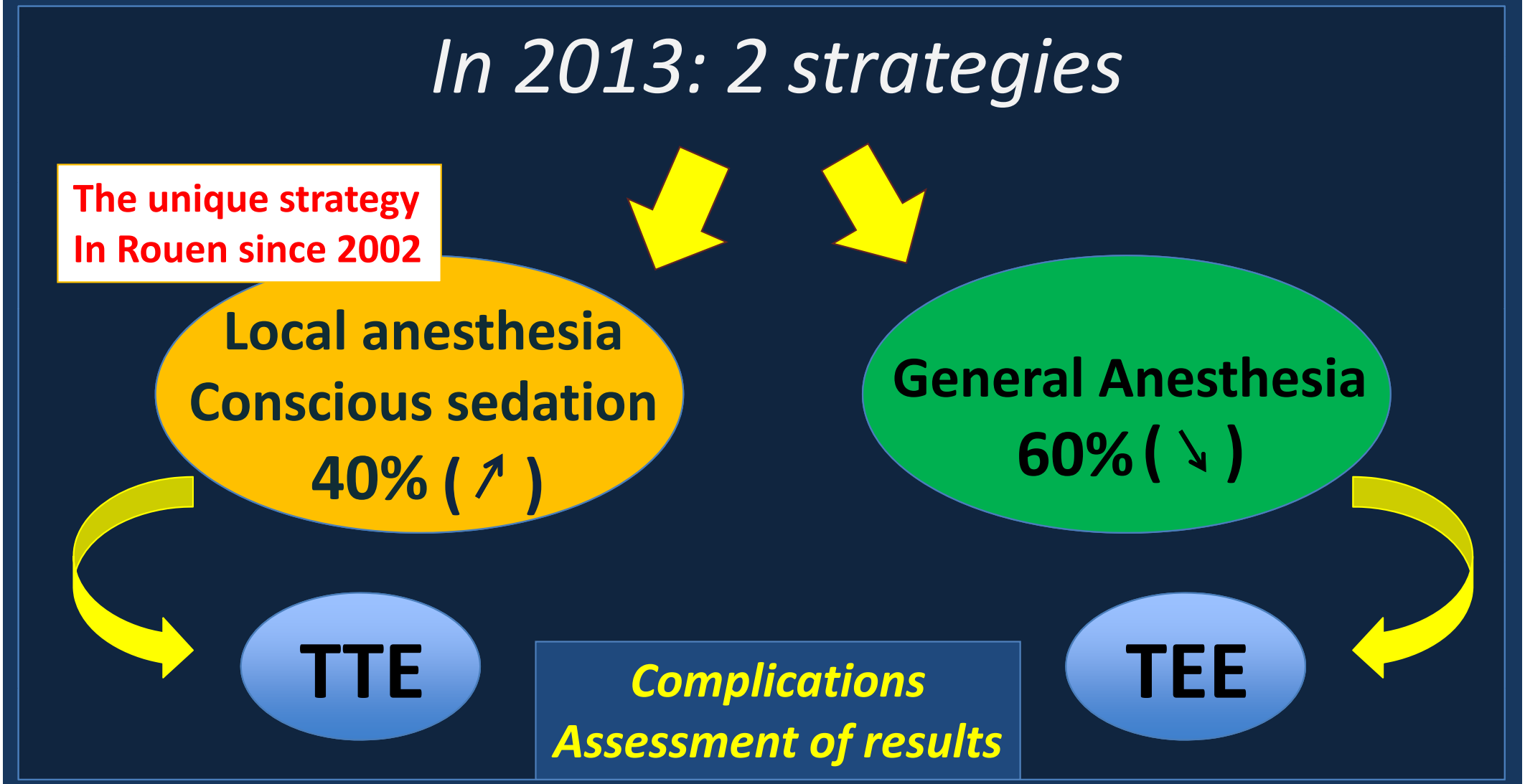
COREVALVE



CoreValve Evolut ™

New hight and shape
Improved sealing and coaptation

In 2013, new strategies for TF TAVI (85%) further facilitate the choice of TAVI in high risk patients



Minimized strategy = Local anesthesia, FA preclosing

overnight in ICU, discharge at Day-2, back home

New devices and minimized strategy

My personal wish: TAVI to all high and low-risk elderly patients

- General anesthesia
- Sternotomy
- Scar
- Scar infection
- Pain
- 4 days ICU
- 3W in-hospital
- Rehabilitation program

86-year old lady
EuroSCORE **16%**
AVR

84-year old man
EuroSCORE **22%**
TAVI (TF)

Similar good outcome on long term

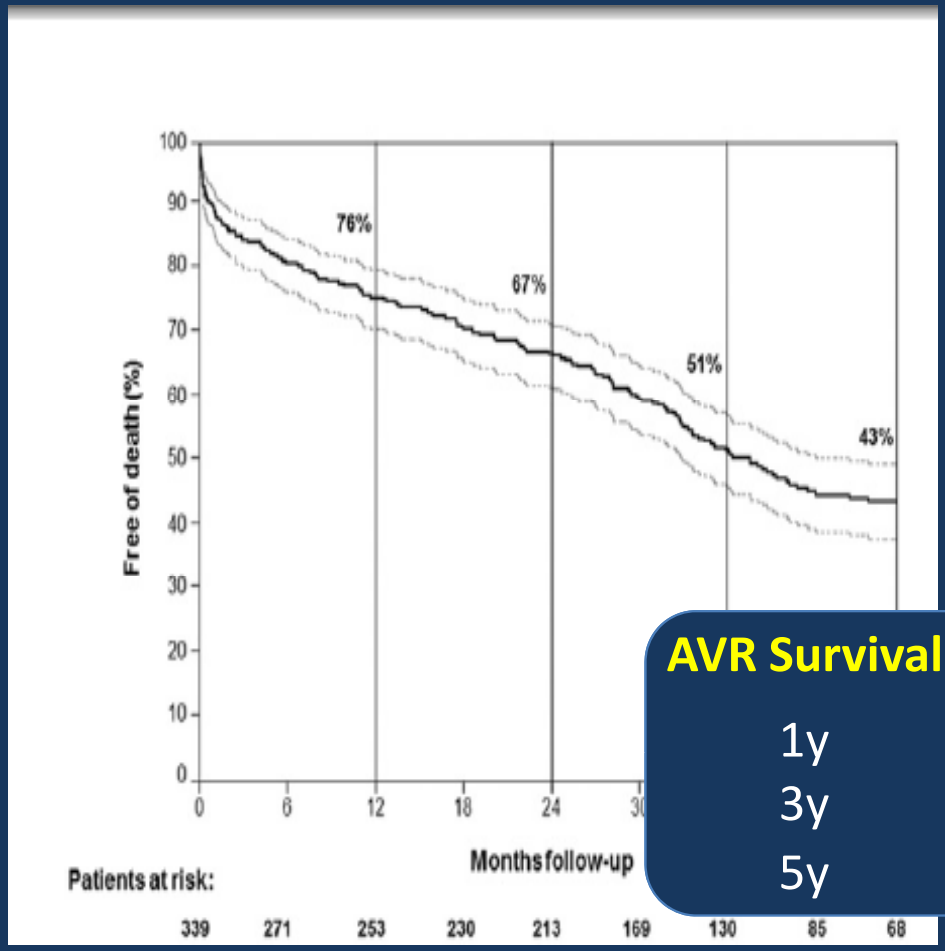
What would be your personal choice?

- Local anesthesia
- FA puncture
- Prostar 10F
- No scar
- No pain
- 1 Day ICU
- Discharge at Day-2
- Back home

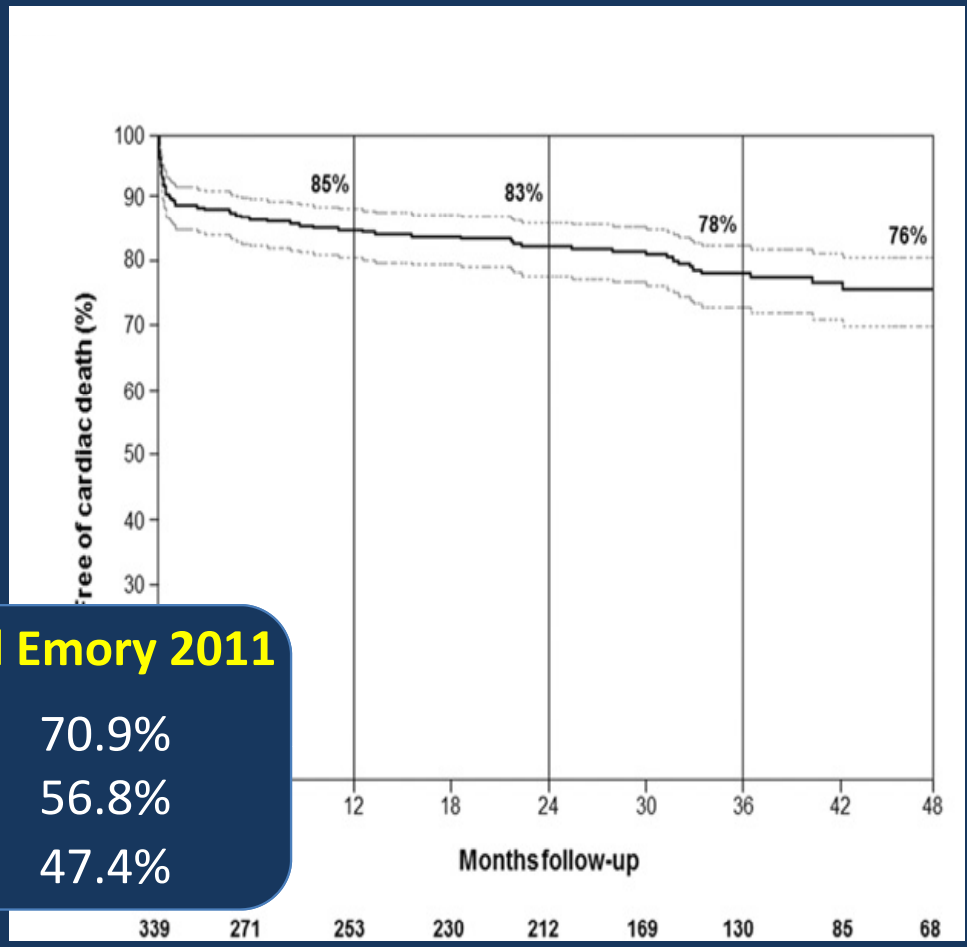
Are the long-term results of TAVI inferior to AVR in the subset of high-risk patients?

Canadian Multicentric Experience, 339 Pts, 42+15 months

Patients free of death at 4-year



Patients free of cardiac death at 4-year



AVR Survival Emory 2011

1y	70.9%
3y	56.8%
5y	47.4%

Long-Term Outcomes After Transcatheter Aortic Valve Implantation

Josep Rodes-Cabau et al., JACC 2013;60:1864-75

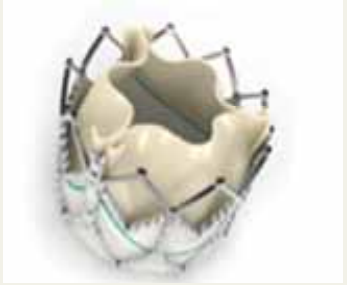
Should we worry about valve + platform durability ?

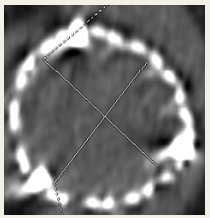
Sapien XT vs Edwards Surgical Bioprosthesis

Perimount Magna

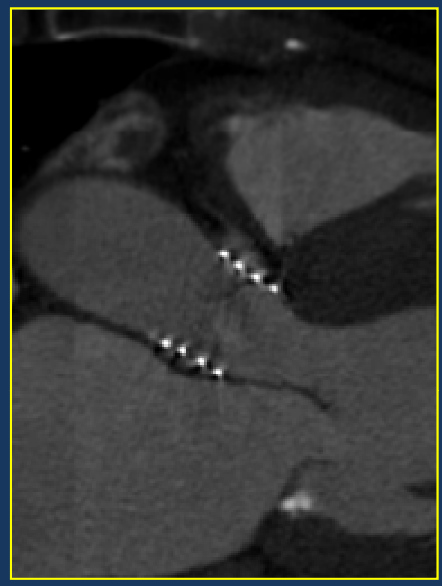
AVR

Edwards XT





TAVI



Similar physical properties

- Treated bovine pericardium valve
- Similar matched leaflets technology
- Circumferential opening in 95%
- Hemodynamics compare favorably

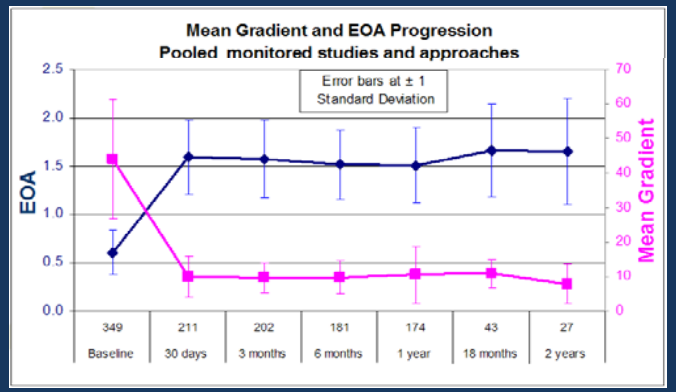
Similar subcoronary intra-annulus position

Away from surrounding structures

Coronary arteries

Mitral Valve

IV Septum



- Anecdotical cases of valve degenerescence reported
- Not a single case of valve degenerescence in our group since 2002

Our world champion, Mr D… 88 y/o

7 years post-TAVI

No change in valve function, normal life

Rouen May 13, 2012 Celebration of 10 years anniversary of FIM-TAVI

04-2013:
7 years echo control

Conclusions

In 2013

High risk AS patients can be efficiently treated by:

- *Surgical AVR, an old and well established technology*
- *TAVI, a less invasive and rapidly evolving technology*

- **In all high-risk ELDERLY patients, *after appropriate evaluation of all screening data with the Heart Team* and discussion with the patient and relatives, *TAVI can be considered the best option***

- **In high risk YOUNGER patients (<75y) the lack of information concerning long term (10y) device durability must be explained to the patient and relatives, as well as the way of treating any valve dysfunction in the future (valve-in-valve or AVR). The choice of AVR or TAVI can be left to the patient decision**