

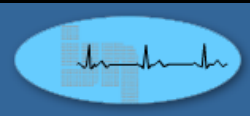


INSTITUT JANTUNG NEGARA  
National Heart Institute

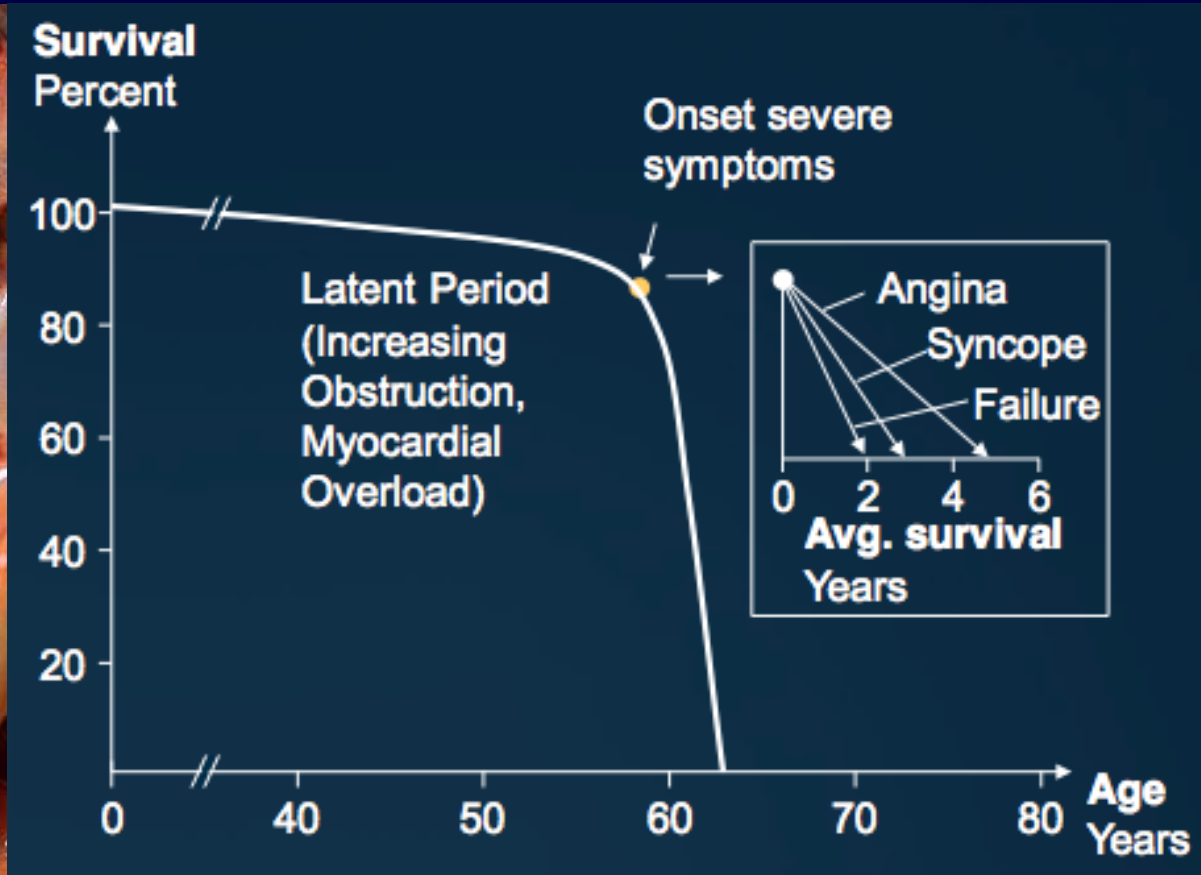
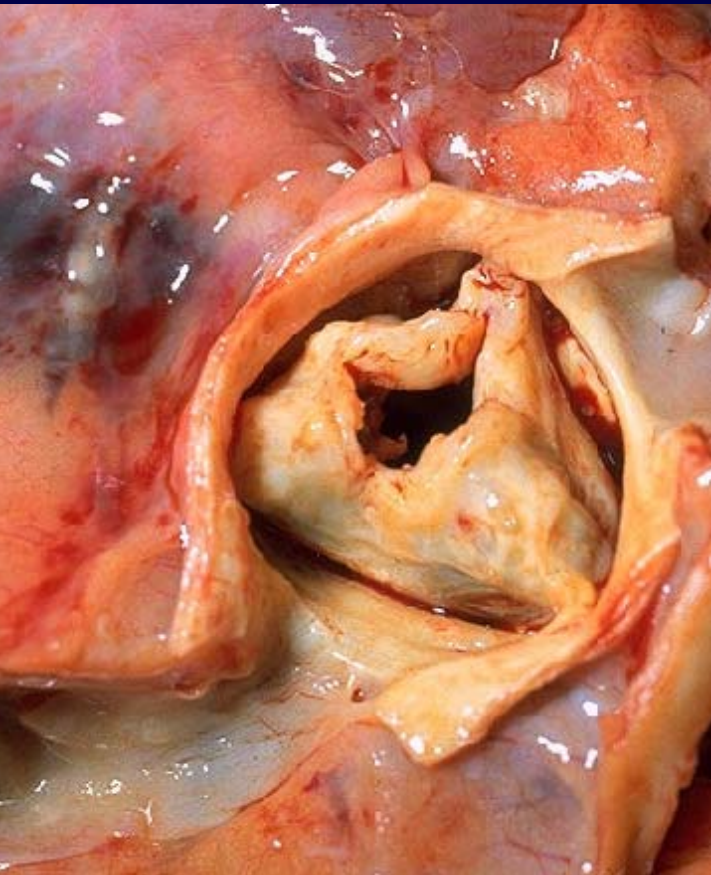


# Transcatheter Aortic Valve Implantation : The Malaysian Experience

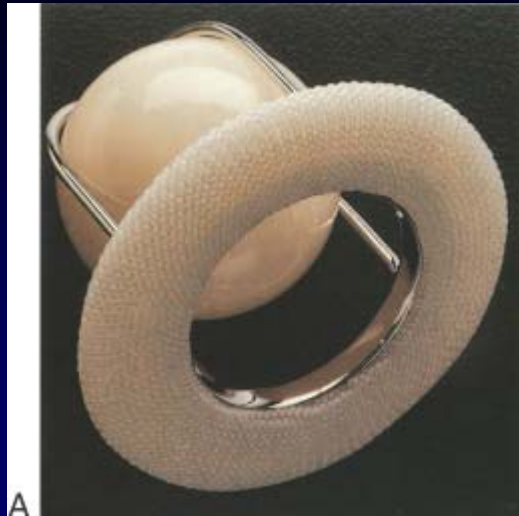
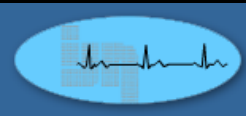
ROSLI Mohd Ali  
Head  
Department of Cardiology  
National Heart Institute  
Kuala Lumpur



# Aortic valve stenosis



# Mechanical heart valves



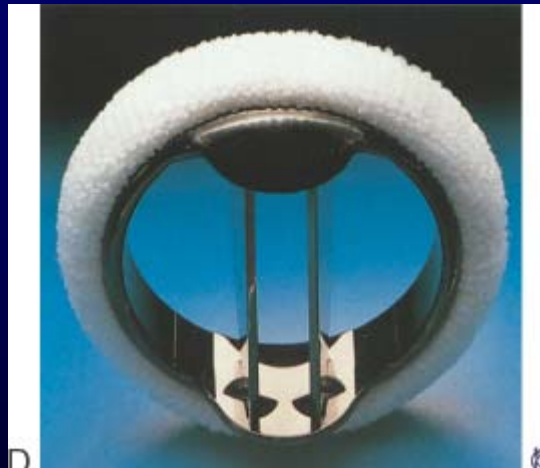
*Starr-Edwards  
caged-ball valve.*



*The Omniscience  
valve*



*Medtronic-Hall valve.*



*St. Jude bi-leaflet valve*



*The CarboMedics  
bi-leaflet valve.*

# Bioprosthetic valves.



## Stented valves



*Hancock valve*

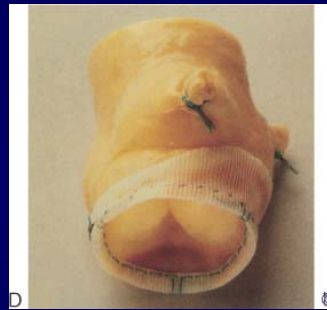


*Carpentier-Edwards valve*

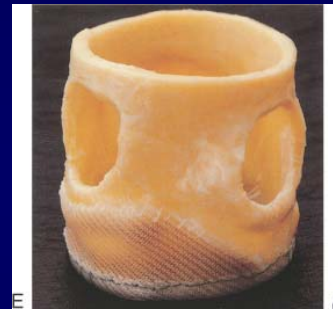


*Medtronic Intact valve.*

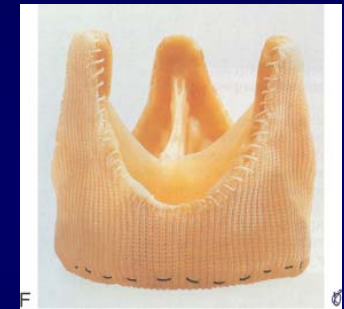
## Stentless valves:



*Medtronic Freestyle stentless valve*

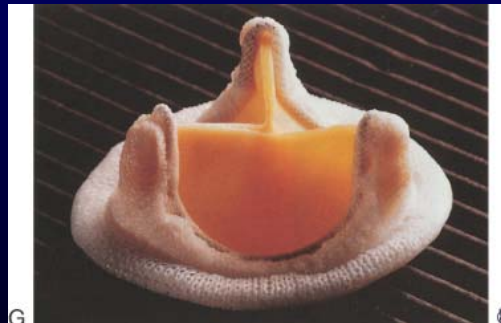


*Edwards Prima stentless valve*



*St. Jude Medical Toronto SPV stentless valve.*

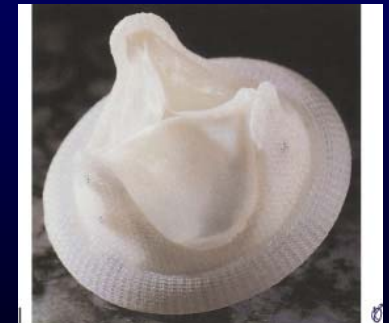
## Pericardial valves:



*Carpentier-Edwards pericardial valve*



*Sorin Pericarbon pericardial valve*



*Autologous pericardial valve*

European Heart Journal (2003) 24, 1231–1243



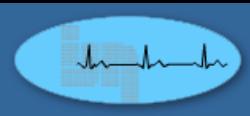
ELSEVIER



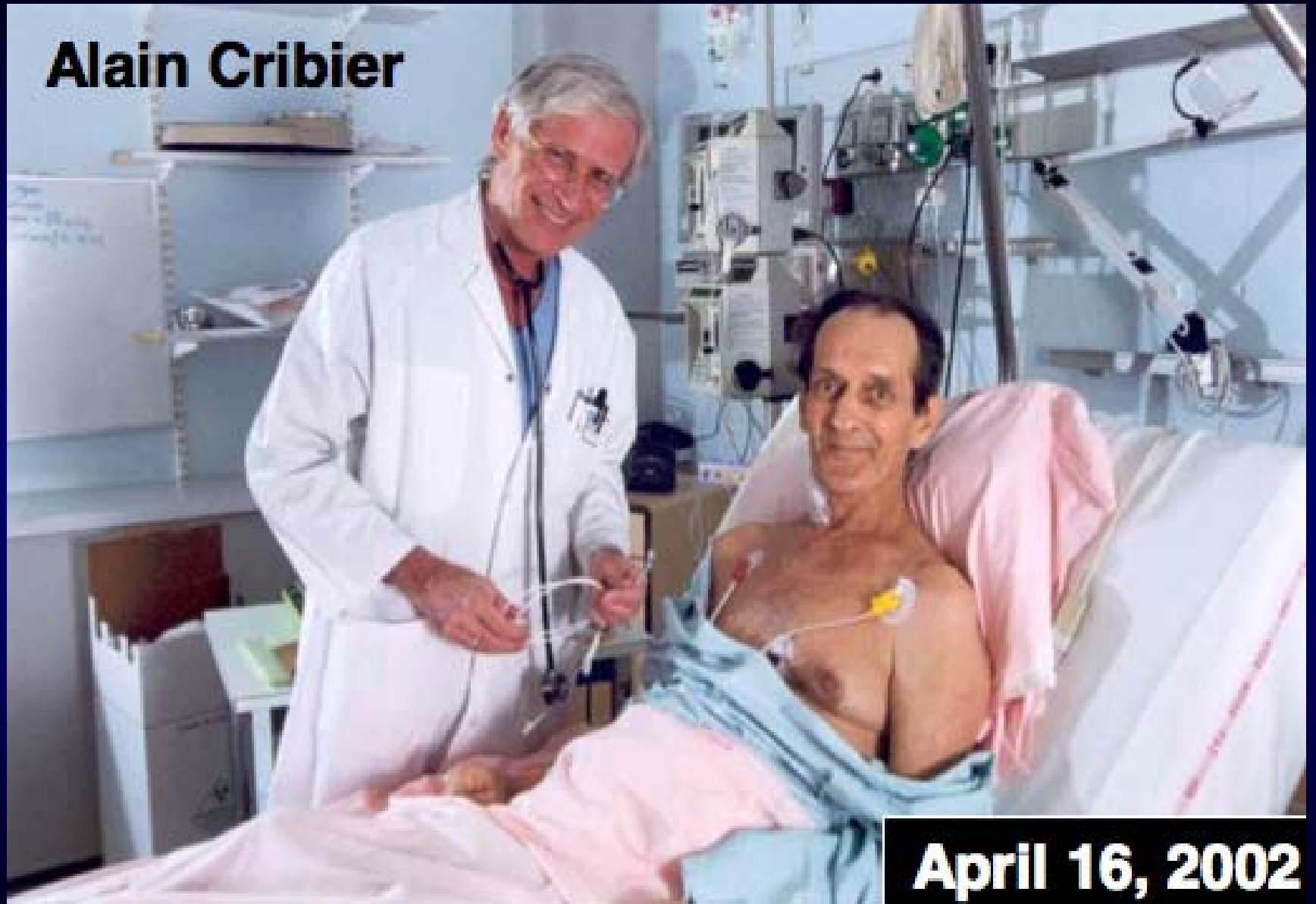
EUROPEAN  
SOCIETY OF  
CARDIOLOGY

## A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease

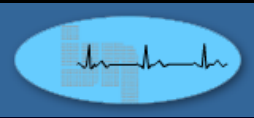
**31% of patients with severe heart valve disease are not operated**



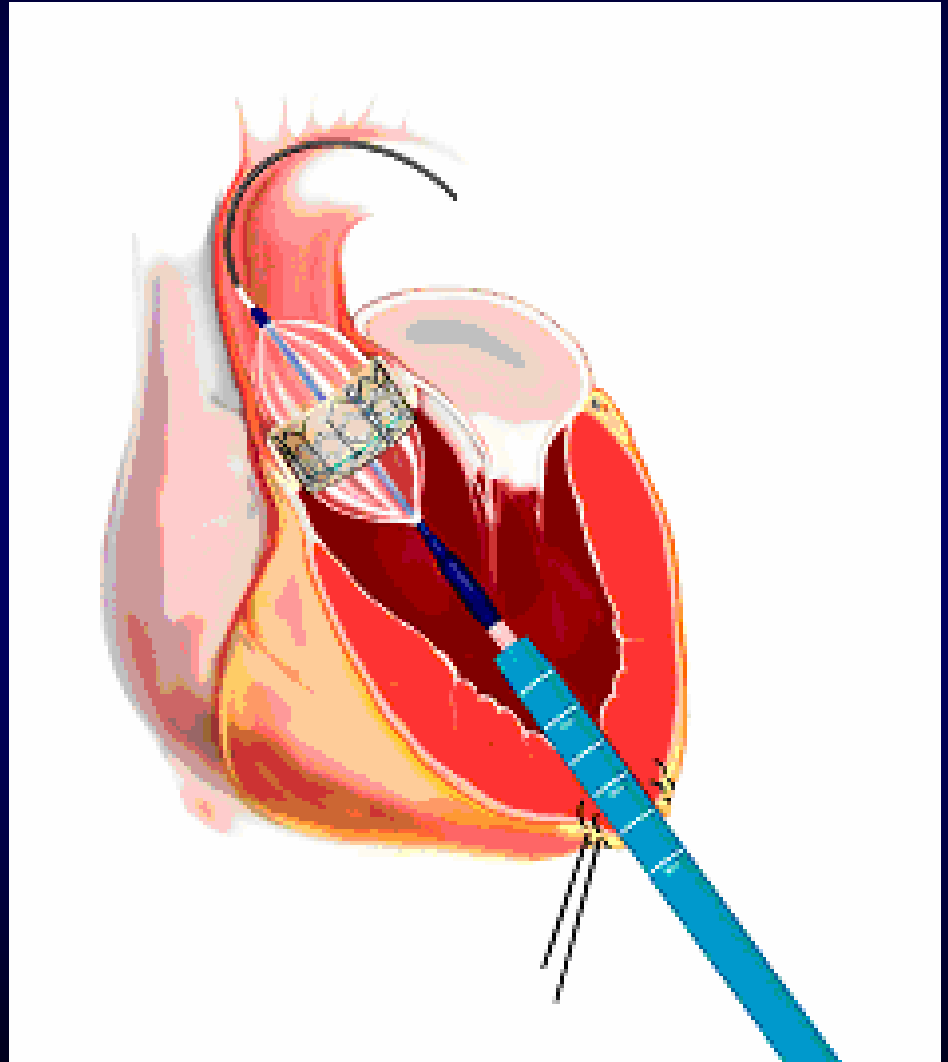
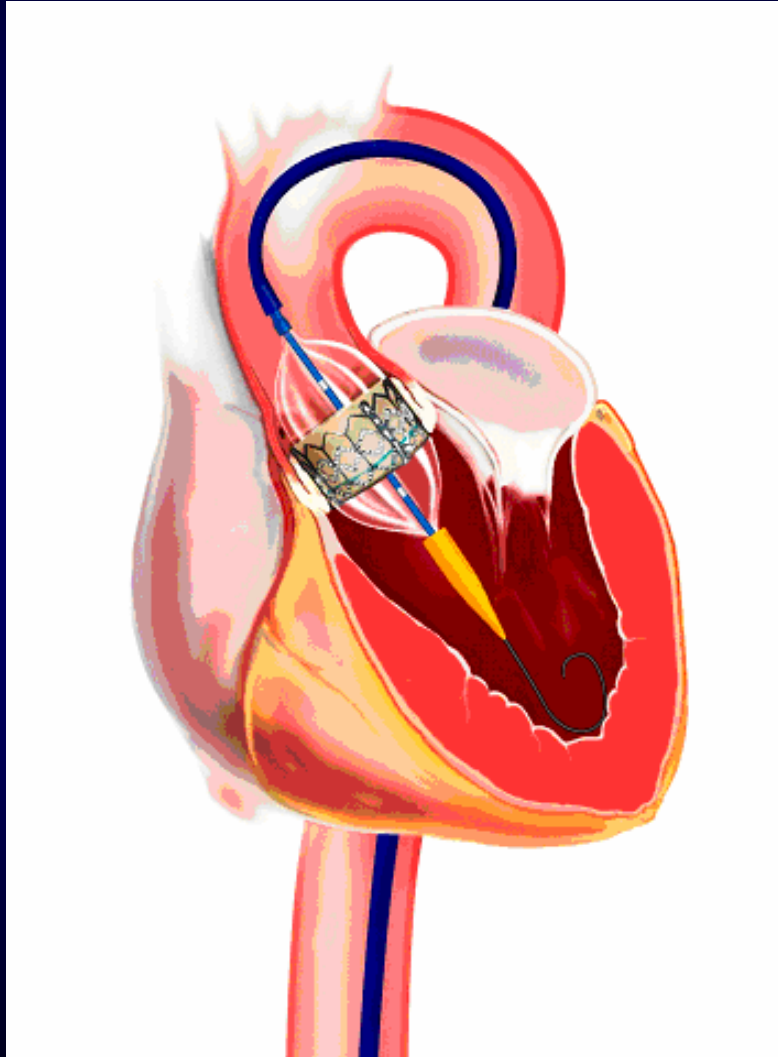
**Alain Cribier**

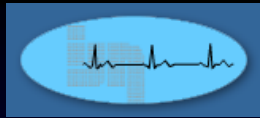


**April 16, 2002**

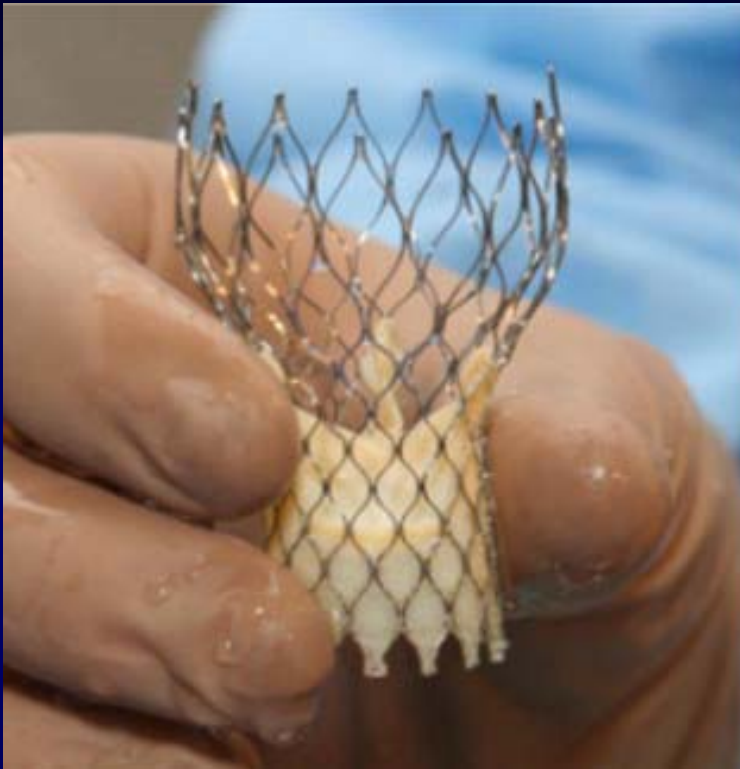


# Edward Sapien Valve Transfemoral & transapical access





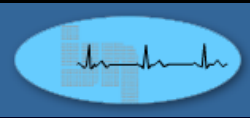
# CoreValve



Self-expanding nitinol frame & porcine pericardium

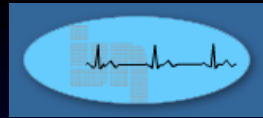
Length 50 mm, 18 Fr = 6 mm

Two sizes:      - small valve;  $\varnothing$  26 mm, annulus 20-23 mm  
                     - large valve;  $\varnothing$  29 mm, annulus 23-27 mm



# CoreValve

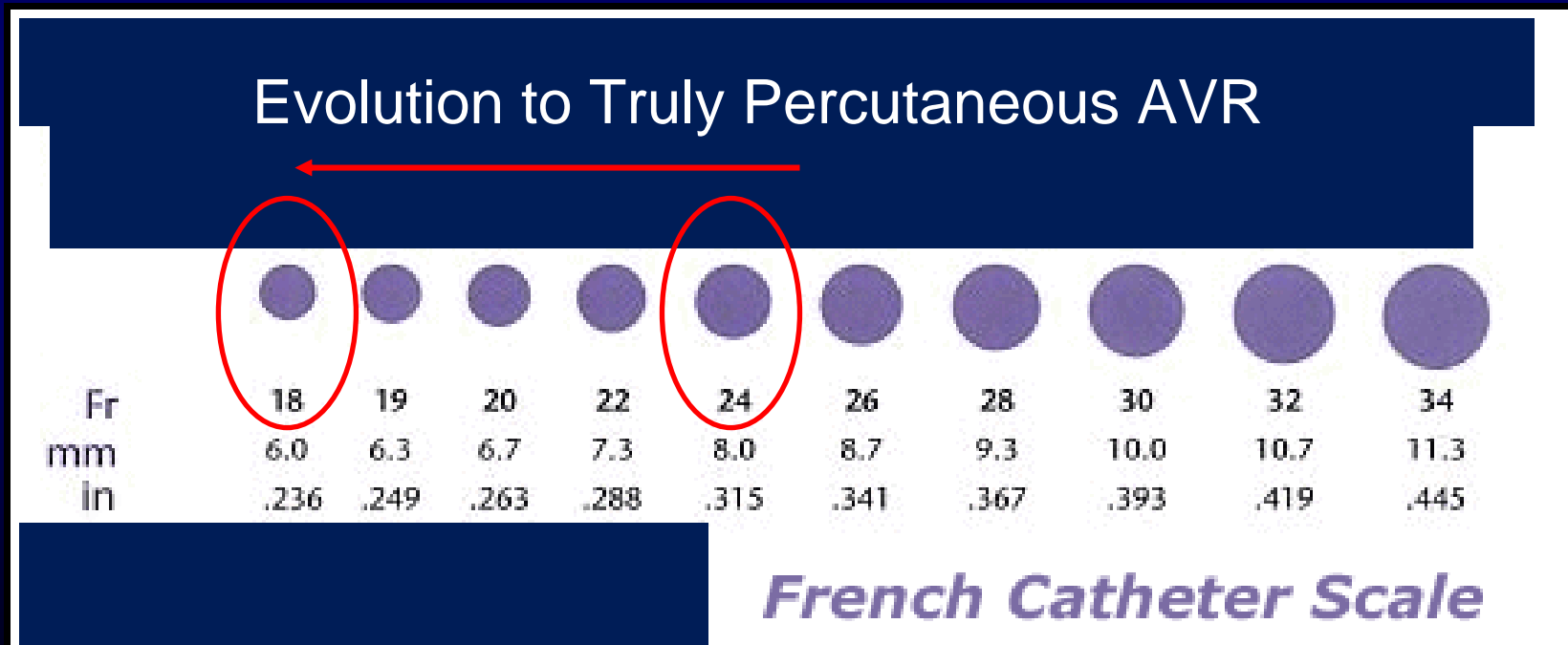


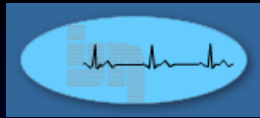


## Evolution of Self-Expanding TAVI

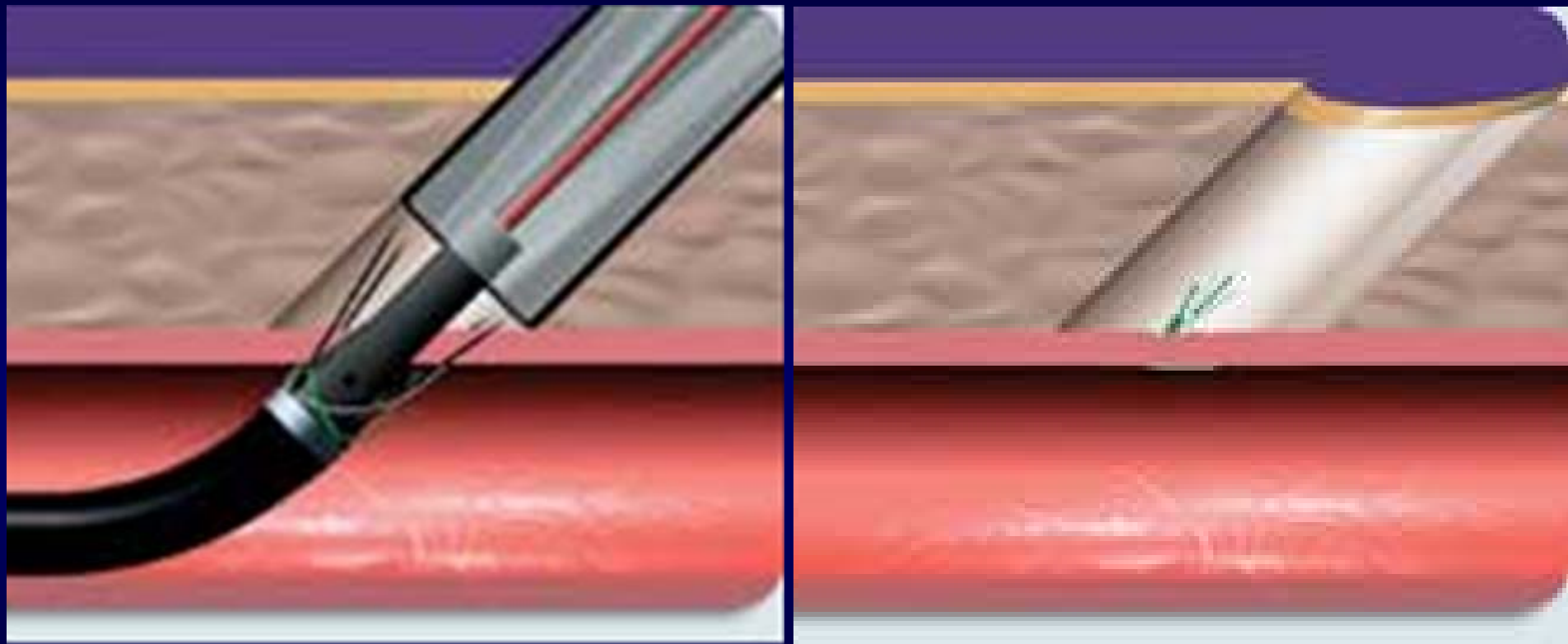
The CoreValve clinical experience includes three product generations:

- 1<sup>st</sup> generation (25F) - Proof of concept
- 2<sup>nd</sup> generation (21F) - Safety & efficacy study
- 3<sup>rd</sup> generation (18F) - Safety & efficacy study + Post CE Registry





# ProSTAR (Abbott)

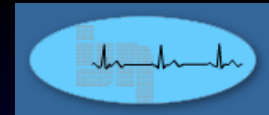


Percutaneous Without Cutdown  
Under Local Anesthesia



# 1st Patient – Femoral Artery Access





# CoreValve Procedure

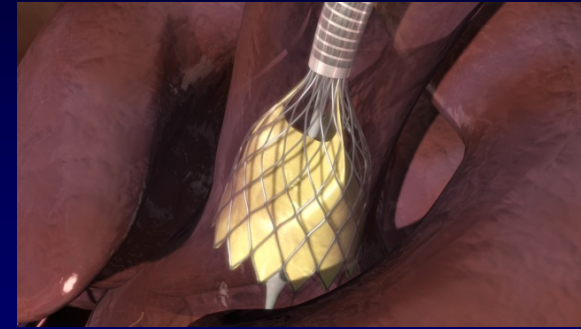
## Slow and Step Deployment Allows Repositionability



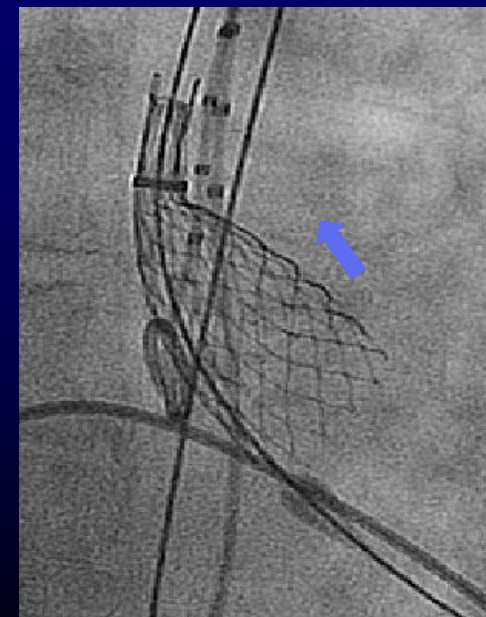
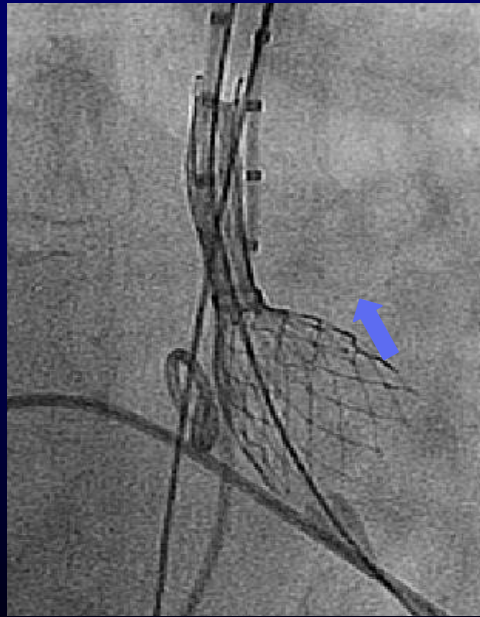
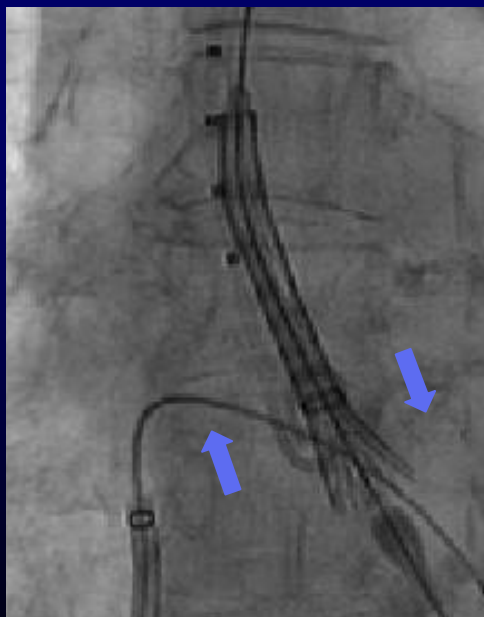
Before annular contact



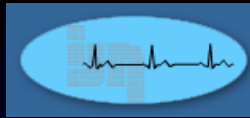
After annular contact



Before device release



# Partner trial



## Symptomatic Severe Aortic Stenosis

**ASSESSMENT: High-Risk AVR Candidate**  
3,105 Total Patients Screened

**Total = 1,057 patients**

2 Parallel Trials:  
Individually Powered

N = 699

**High Risk**

**ASSESSMENT:  
Transfemoral  
Access**

Yes

No

**Transfemoral (TF)**

**Transapical (TA)**

1:1 Randomization

1:1 Randomization

N = 244

N = 248

N = 104

N = 103

**TF TAVR**

**AVR**

VS

**TA TAVR**

**AVR**

VS

**Primary Endpoint: All-Cause Mortality at 1 yr  
(Non-inferiority)**

**Inoperable**

N = 358

**ASSESSMENT:  
Transfemoral  
Access**

Yes

No

1:1 Randomization

Not In Study

N = 179

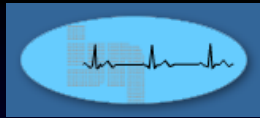
N = 179

**TF TAVR**

**Standard  
Therapy**

VS

**Primary Endpoint: All-Cause Mortality  
Over Length of Trial (Superiority)**  
**Co-Primary Endpoint: Composite of All-Cause Mortality  
and Repeat Hospitalization (Superiority)**



# Partner Cohort B

## *The* NEW ENGLAND JOURNAL *of* MEDICINE

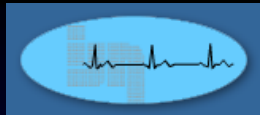
ESTABLISHED IN 1812

OCTOBER 21, 2010

VOL. 363 NO. 17

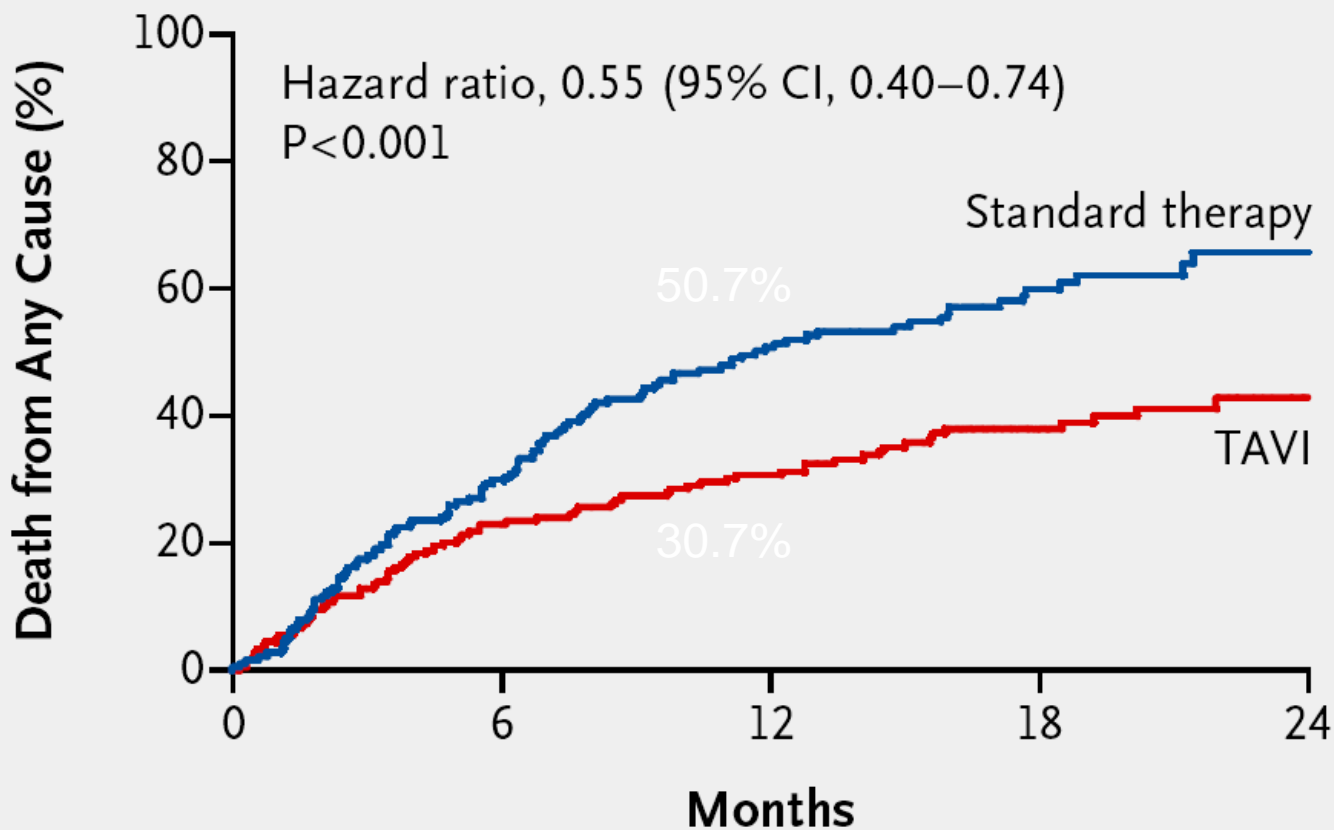
### Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D.,  
Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D.,  
Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D.,  
Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela S. Douglas, M.D.,  
John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D.,  
and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators\*



# Partner Cohort B

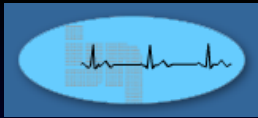
A



### No. at Risk

TAVI	179	138	122	67	26
Standard therapy	179	121	83	41	12

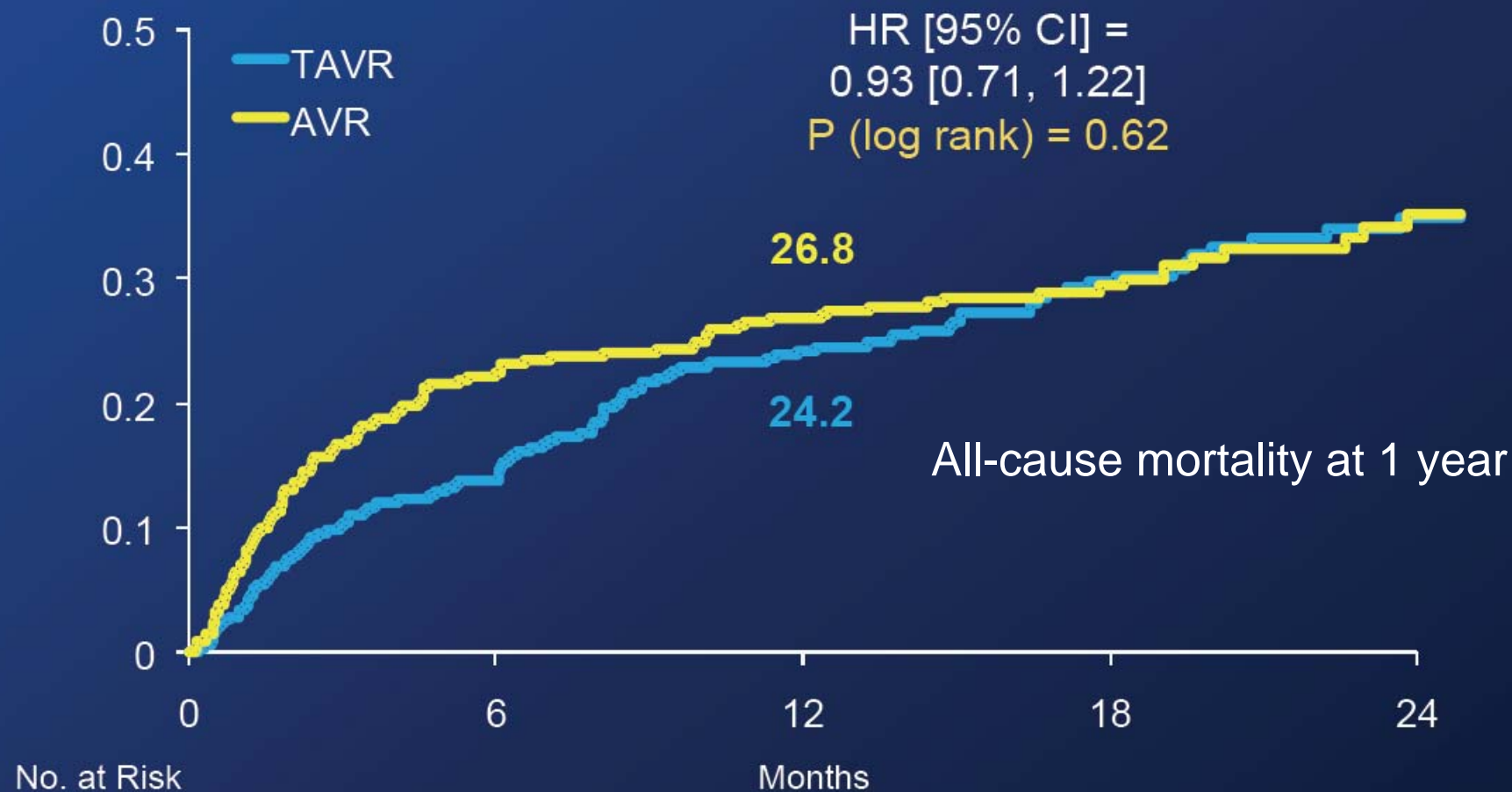
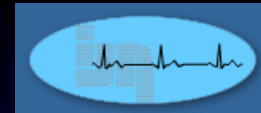
# Partner Cohort A



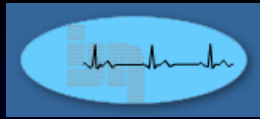
Randomized = 699 patients



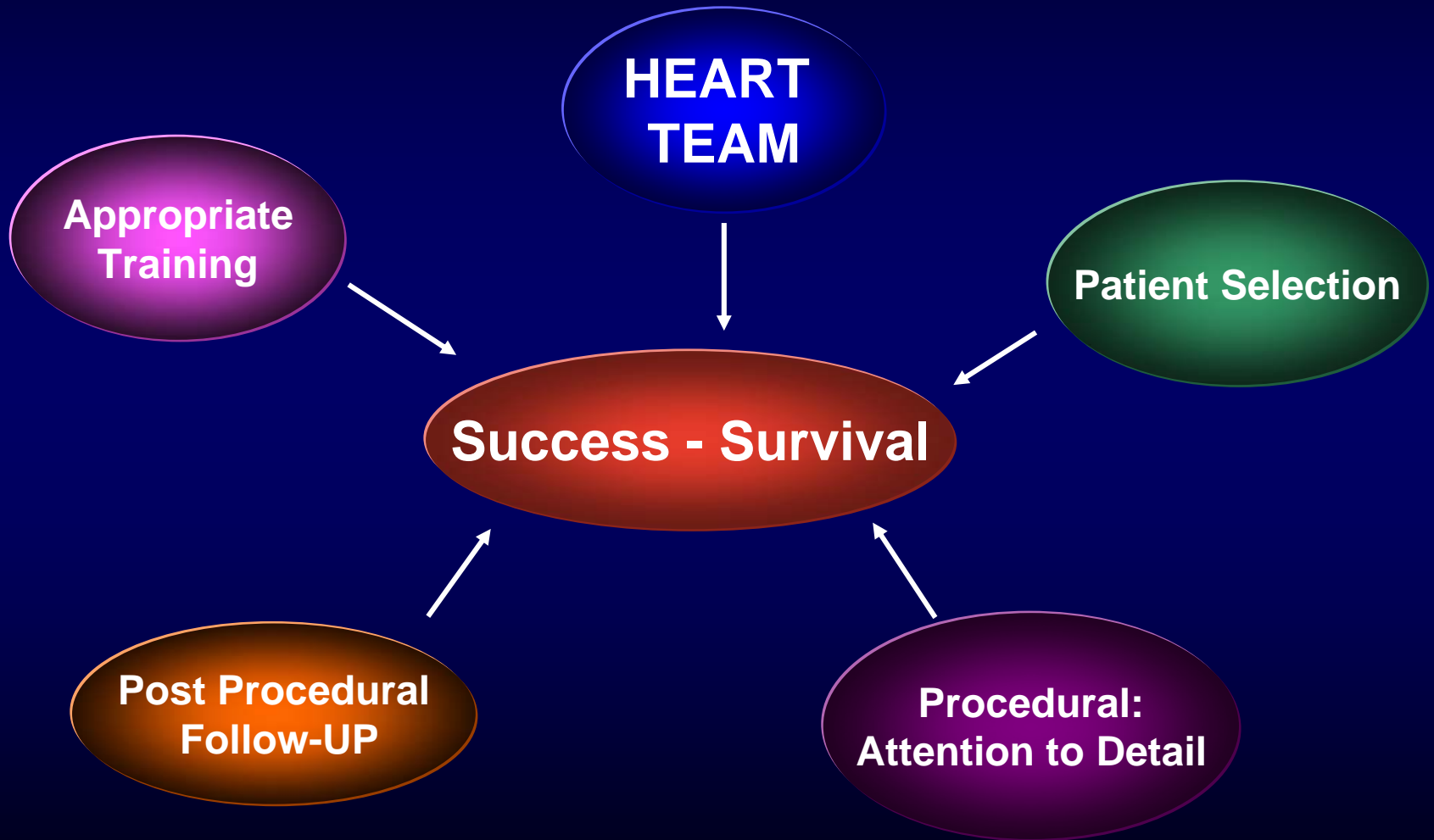
# Partner Cohort A

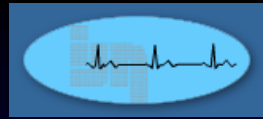


TAVR	348	298	260	147	67
AVR	351	252	236	139	65



# Key Factors for Successful Outcome





# Patient Selection is Critical !

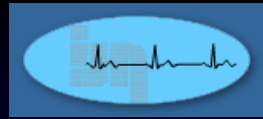
Need to ensure a successful programme

Patient safety & clinical benefits

Outcome data (under scrutiny)

Cost issues (funding)

A lot of work is needed in preparing a patient



# Clinical Assessment

Severe symptomatic AS

Elderly age group

General condition

General well being before being symptomatic

High surgical risk & wishes to have something done



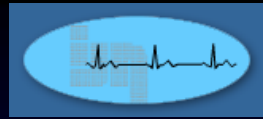
# Patient EuroSCORE Form

For more information  
<http://euroscore.org>

Patient Name: _____	
Date of Birth: _____ - _____ - _____ (yyyy-mm-dd)	
<b>Patient Factors</b>	
Age	please fill in age ----->
Sex	<input type="checkbox"/> Female
Chronic pulmonary disease	<input type="checkbox"/> Yes
Extracardiac arteriopathy	<input type="checkbox"/> Yes
Neurological dysfunction	<input type="checkbox"/> Yes
Previous cardiac surgery	<input type="checkbox"/> Yes
Serum creatinine >200 $\mu\text{mol/L}$	<input type="checkbox"/> Yes
Active endocarditis	<input type="checkbox"/> Yes
Critical preoperative state	<input type="checkbox"/> Yes
<b>Cardiac Factors</b>	
Unstable angina	<input type="checkbox"/> Yes
Moderate LV dysfunction ( $30\% \geq \text{LVEF} > 50\%$ )	<input type="checkbox"/> Moderate
Poor LV dysfunction ( $\text{LVEF} < 30\%$ )	<input type="checkbox"/> Poor
Recent myocardial infarct	<input type="checkbox"/> Yes
Pulmonary hypertension	<input type="checkbox"/> Yes
<b>Operation Factors</b>	
Emergency	<input type="checkbox"/> Yes
Other than isolated CABG	<input checked="" type="checkbox"/> Yes
Surgery on thoracic aorta	<input type="checkbox"/> Yes
Postinfarct septal rupture	<input type="checkbox"/> Yes

Additive EuroSCORE = 2

Logistic EuroSCORE (mortality %) = 1.51%



## Echocardiography (required)

- Additional aortic root imaging

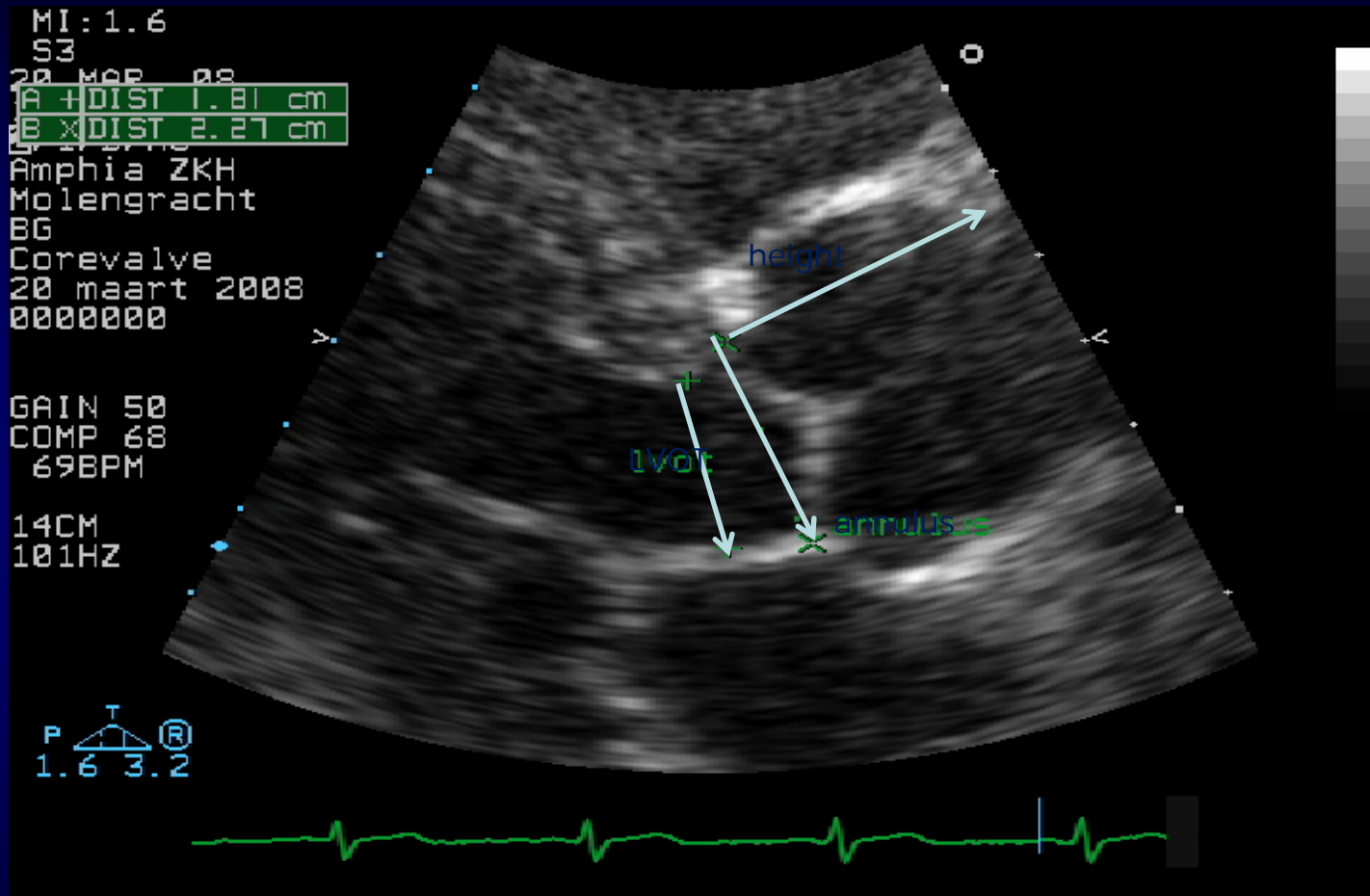
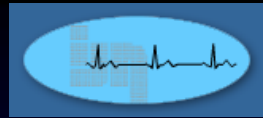
- Coronary Angiography (required)

- Coronary anatomy
- Aortic root anatomy
- Arch anatomy
- Abdominal aorta
- Peripheral vasculature

- CT Imaging (recommended)

- Aortic root and arch anatomy
- Abdominal aorta
- Peripheral vascular anatomy
- 3D rendering

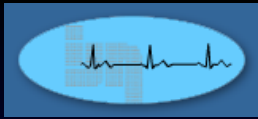
# Annulus – LVOT measurement



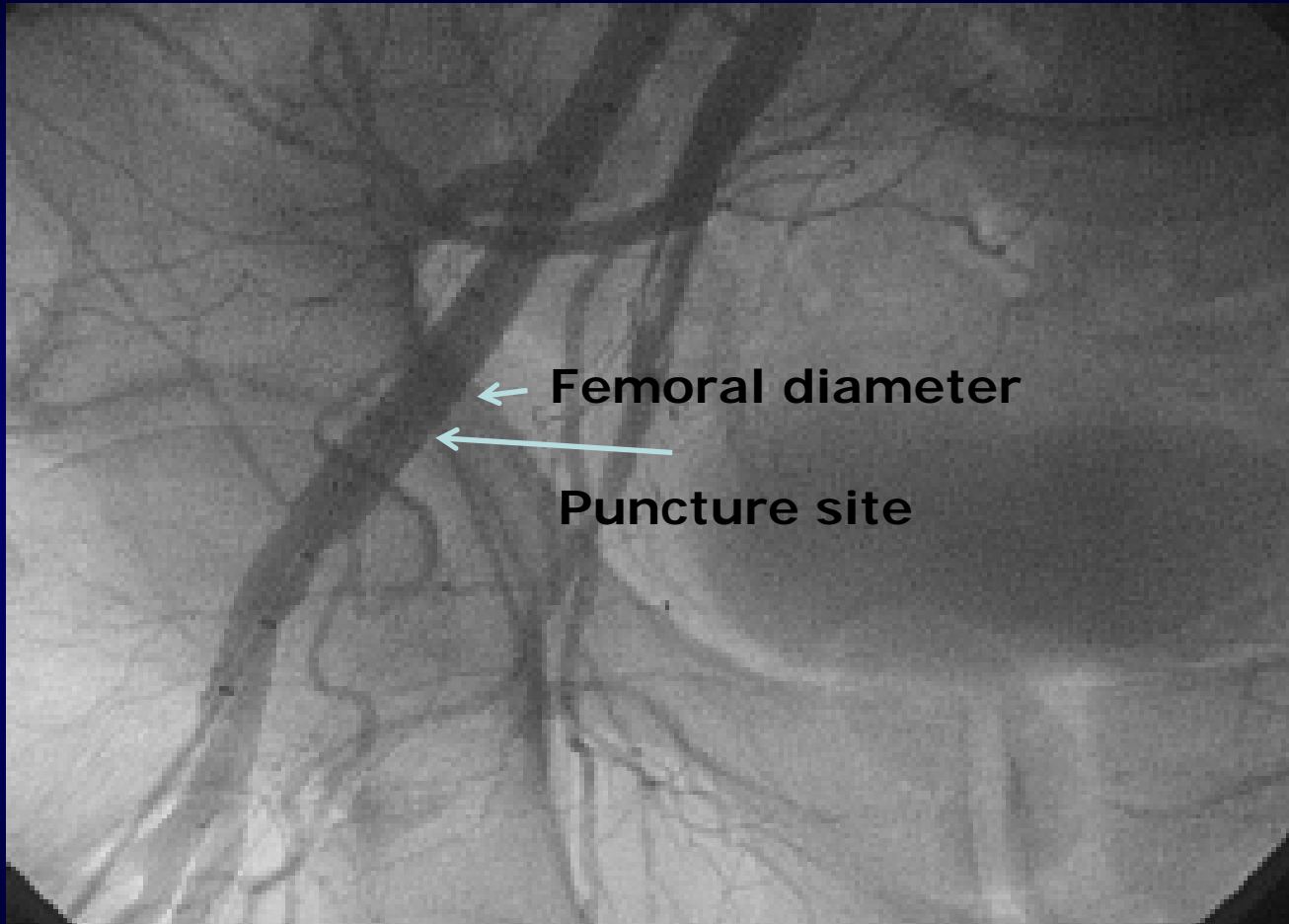
Annulus diameter 20 – 27 mm

Sinus of Valsalva Height  $\geq$  15 mm

Subaortic stenosis – not present



## Angio of Femoral Arteries



Femoral / iliac diameter  $\geq 6$  mm in non-diabetic  
(preferred  $> 7$  mm)



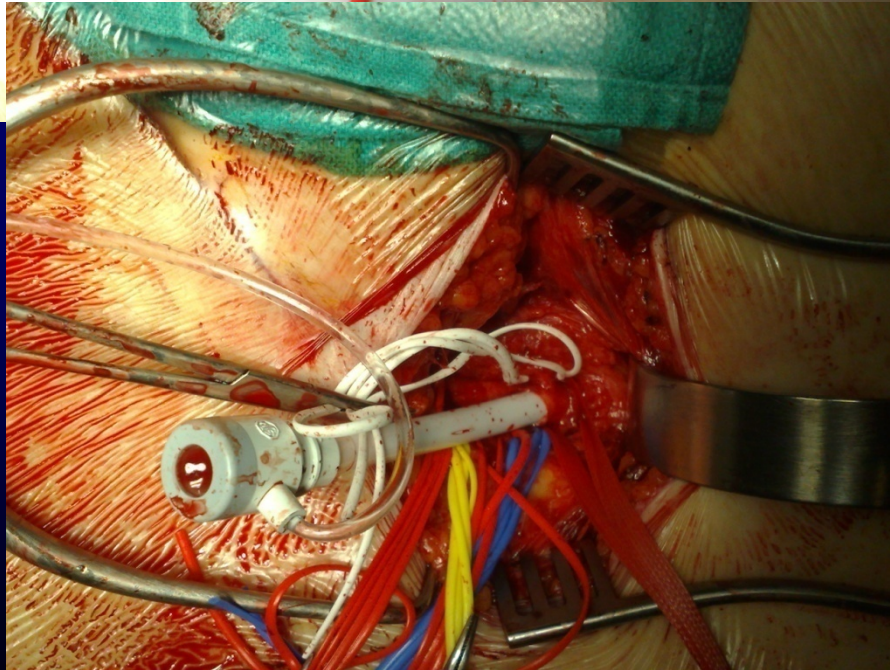
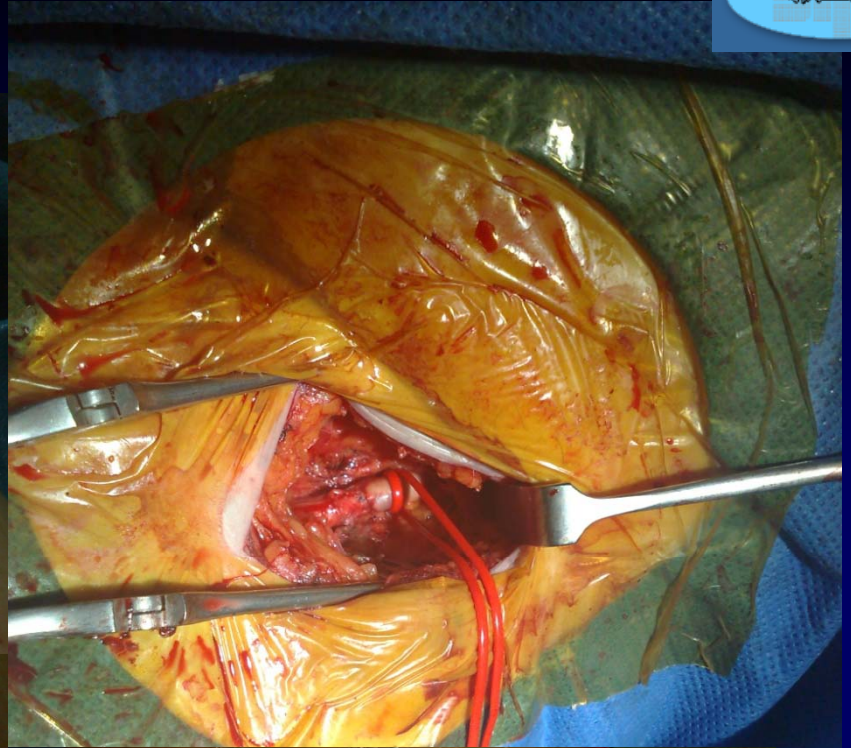
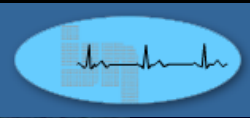
# Coronary Angiogram



Severe stenosis in proximal segment  
Should be treated prior to TAVI

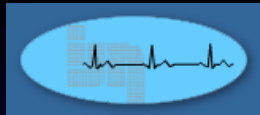


# Access Cut-down

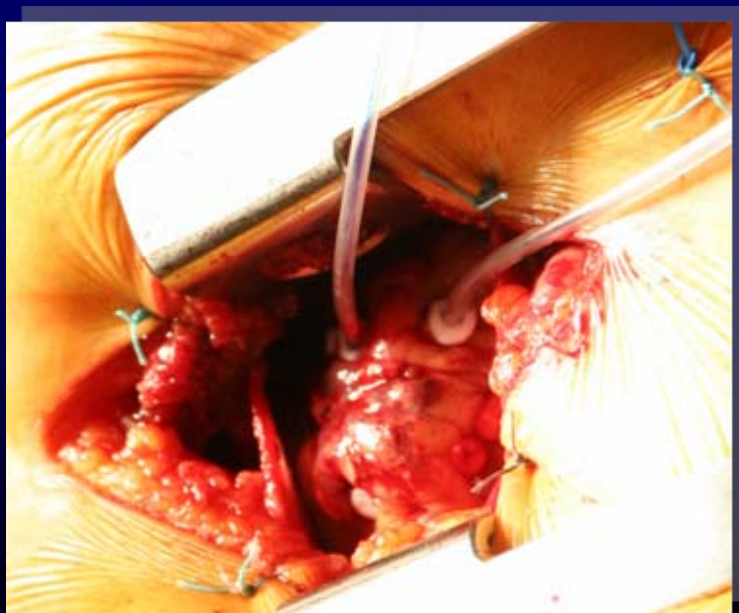
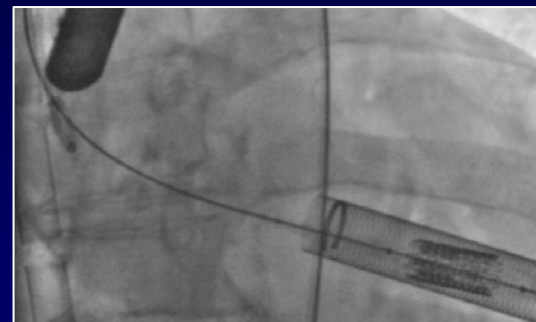
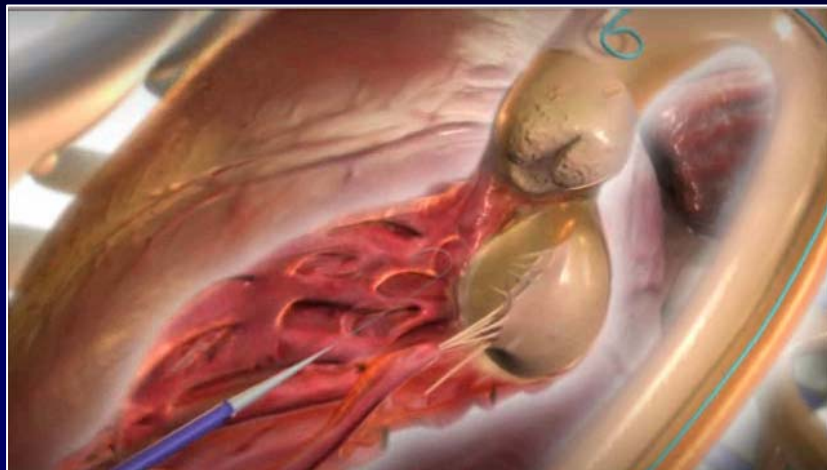


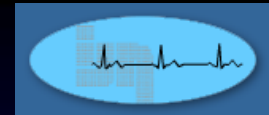
# Subclavian/axillary access





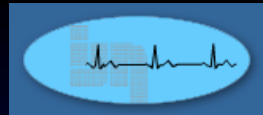
# Edwards Sapien trans-apical approach





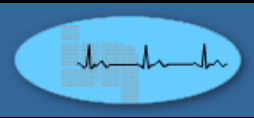
# IJN Experience: Baseline characteristics (n=16)

Variables	Patients
Mean age	76 ± 4
Sex male (%)	13 (81%)
Mean body mass index	25.98 ± 8
Coronary artery disease	10 (62.5%)
Hypertension	10 (62.5%)
Diabetes Mellitus	3 (18.8%)
Chronic renal failure	2 (12.5%)
Anaemia + Chronic Myeloid Leukaemia	3 (18.8%)
Others (chronic lung disease, previous cancer, Atrial Fibrillation, Myaesthesia Gravis)	4 (25%)



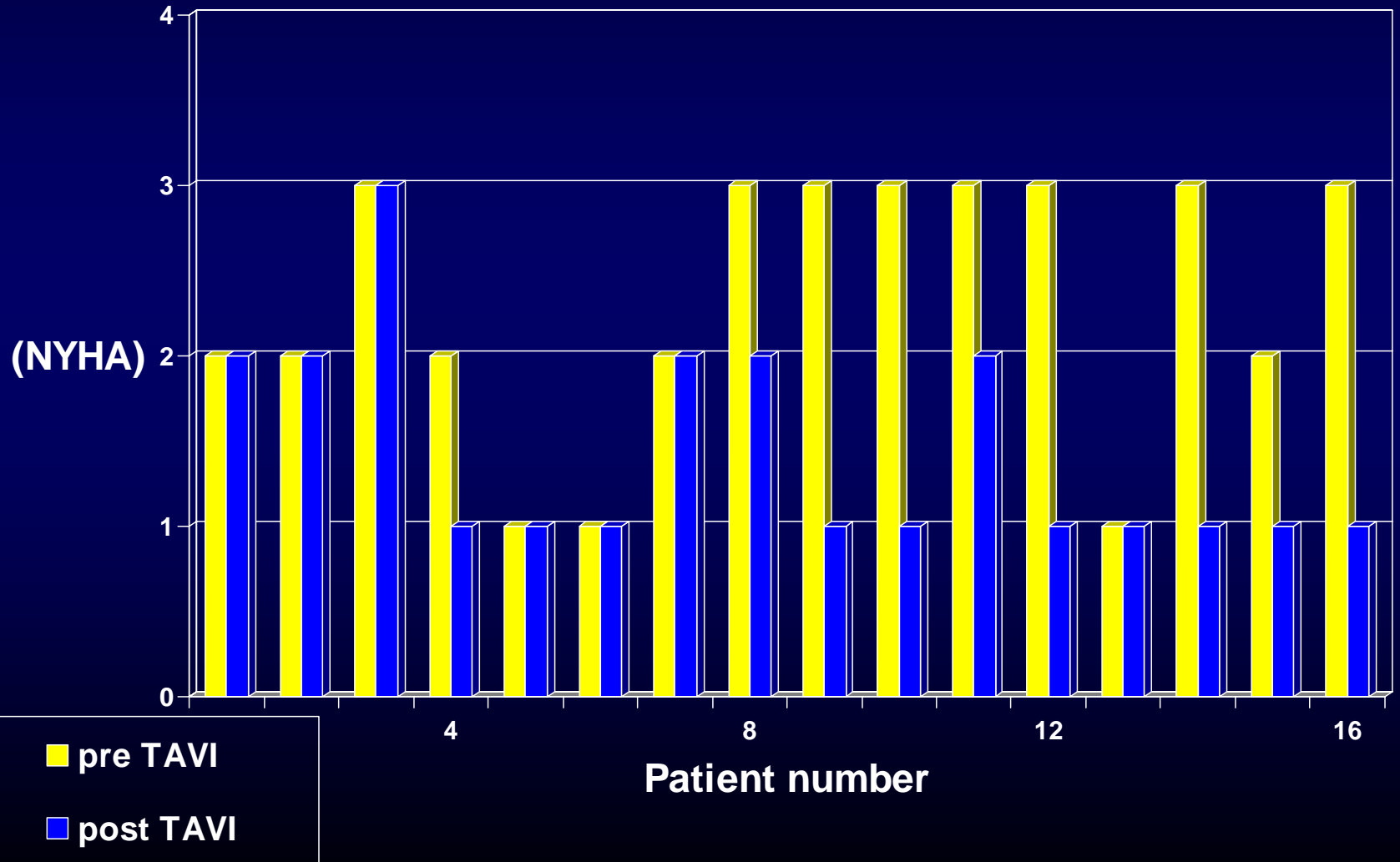
# Baseline characteristics

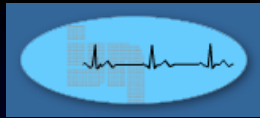
Variables	No
Mean functional class (NYHA)	2.3 ± 0.8
Echo :	
Mean aortic valve area (cm)	0.57 ± 0.13
Mean aortic peak gradient (mmHg)	97 ± 28
Mean ejection fraction (%)	61 ± 8
Median hospital stay (days)	8



# RESULTS

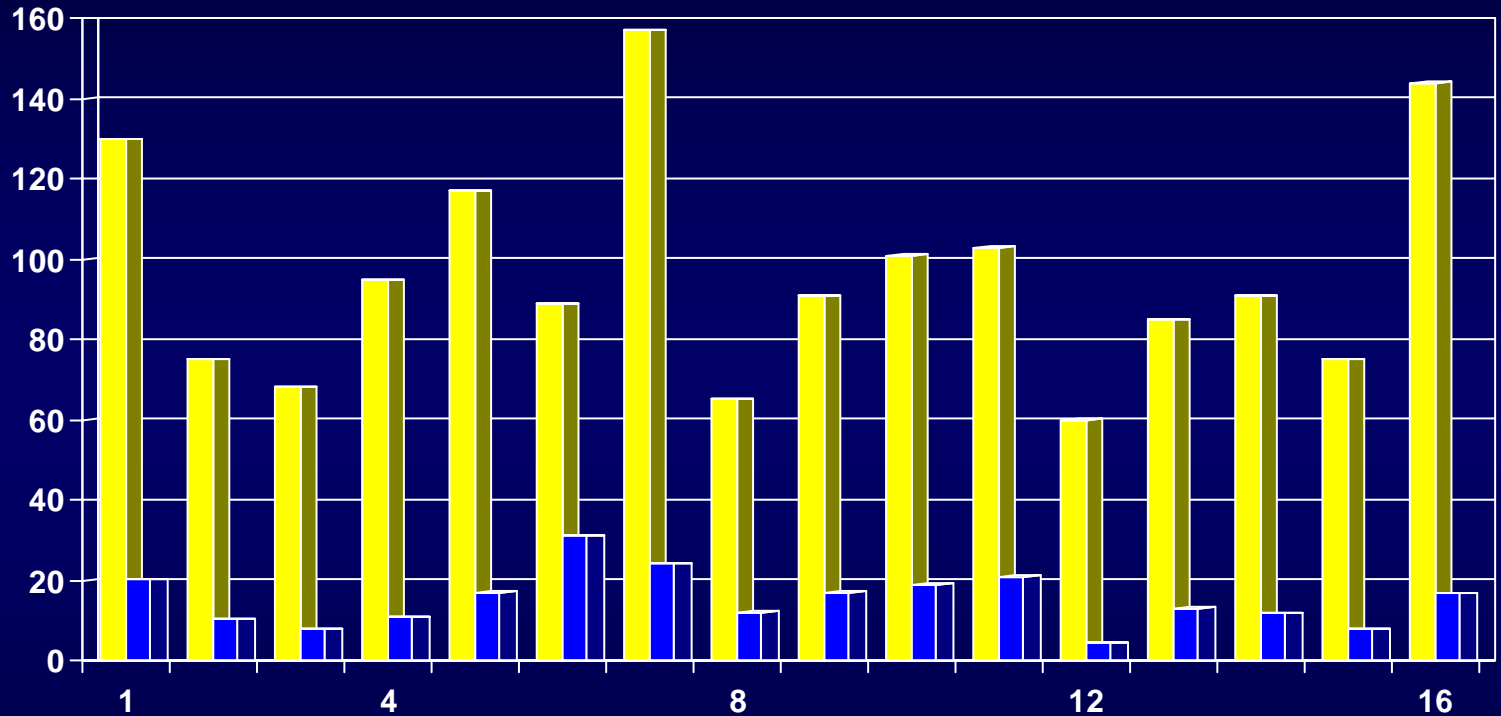
New York Heart Classification NYHA ( $p=0.003$ )





# Aortic valve peak gradient ( $p < 0.001$ )

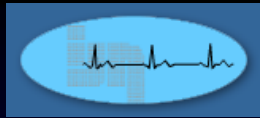
AV peak  
gradient  
(mm Hg)



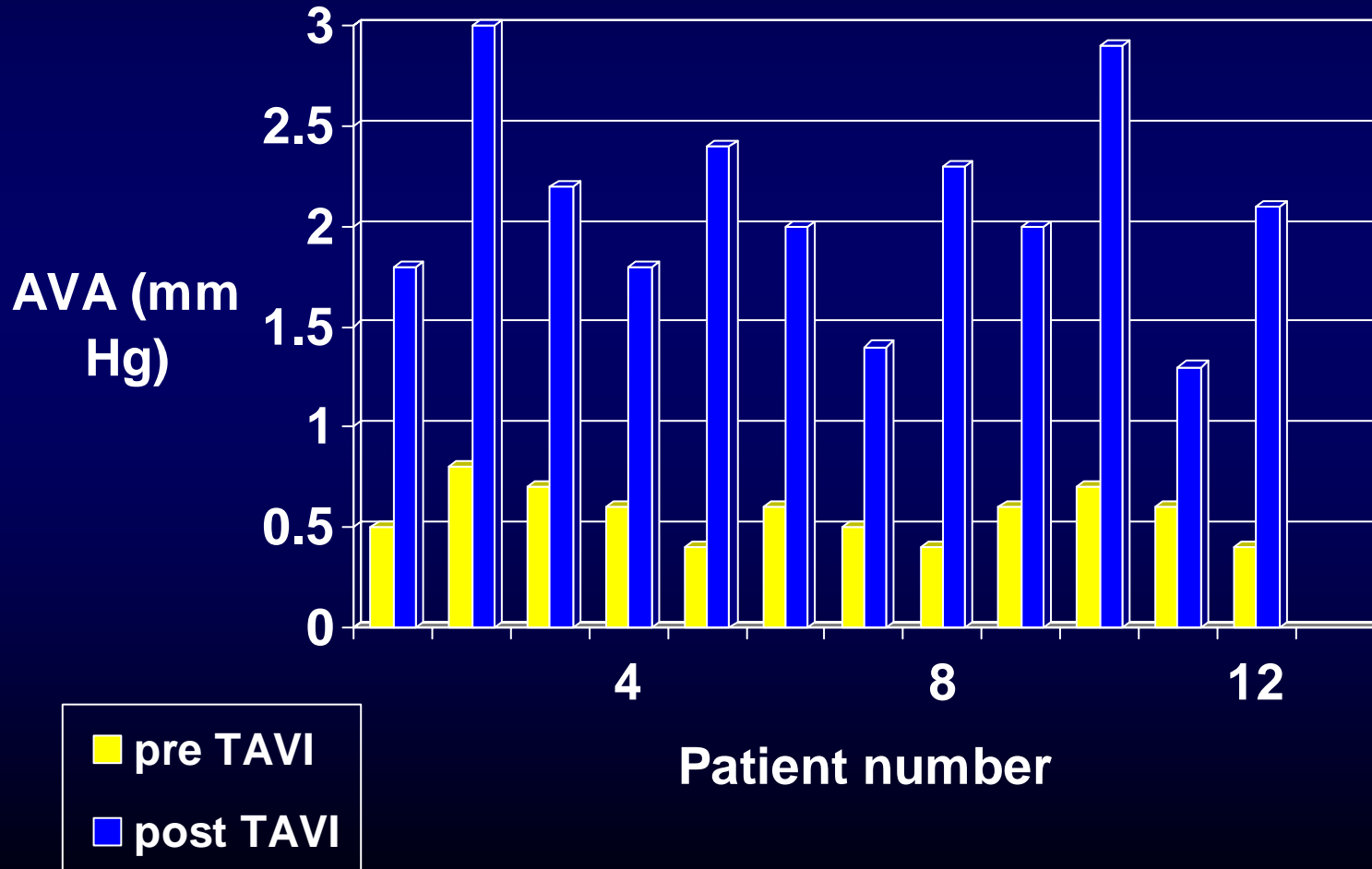
Patient number

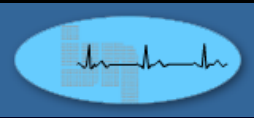
■ pre TAVI

■ post TAVI

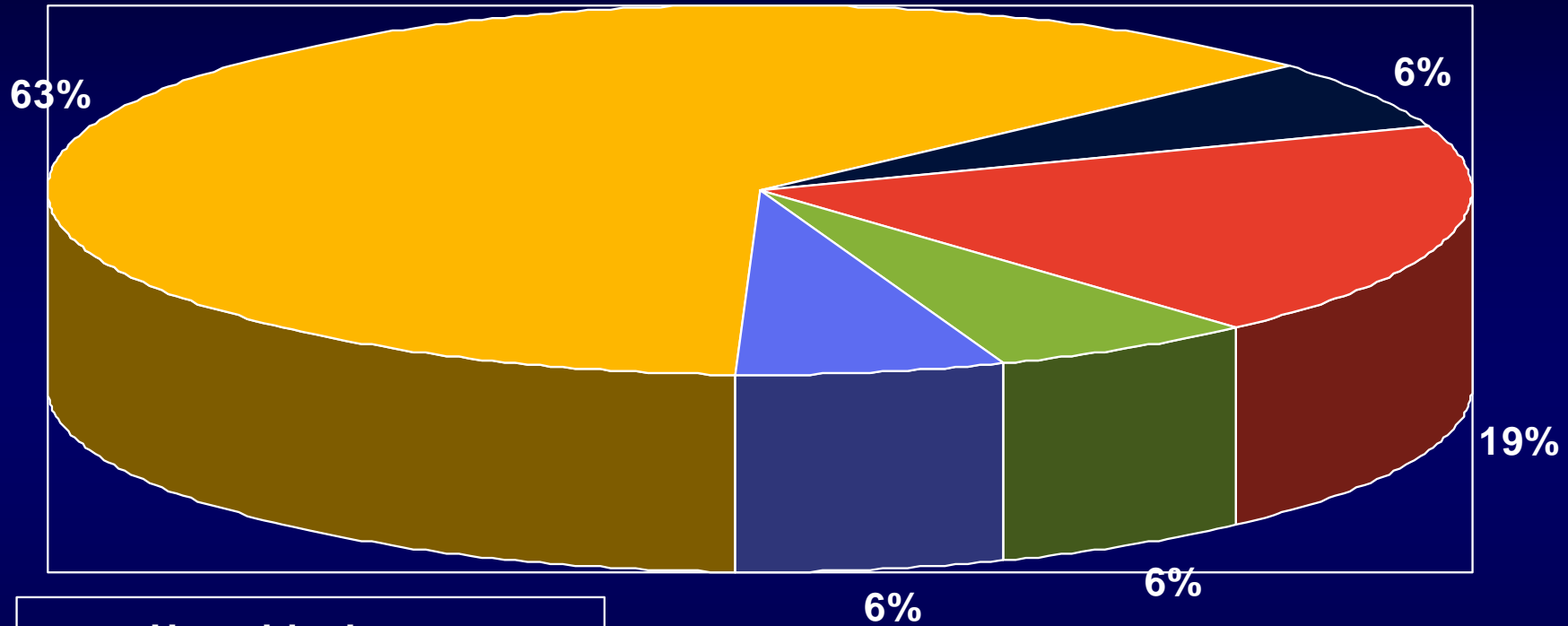


# Aortic Valve Area (AVA) ( $p < 0.001$ )

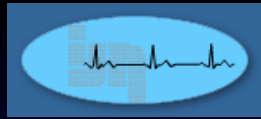




# Complications (within 3 months)



- Heart block
- CVA
- Acute MI
- Uneventful
- Infected hematoma



# Conclusions

- The transcatheter aortic valve replacement programme requires a dedicated & committed TEAM approach
- Attention to detail at every juncture is crucial for a successful programme
- Has a steep and in-depth learning curve
- Encourage all to get involved !