Percutaneous Therapies for Aortic Stenosis

"Percutaneous aortic valve replacement:
Lessons learned with
the CoreValve prosthesis"

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Concepts in Contemporary Cardiovascular Medicine
George R. Brown Convention Center
Houston, TX

Presenter Disclosure Information

Name: R Bonan

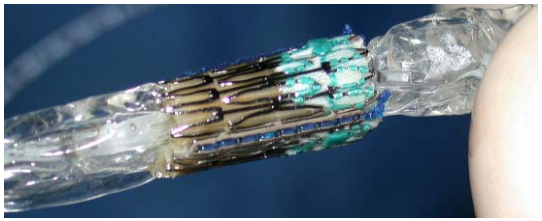
Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

Company Name	Relationship
CoreValve	Consultant/Stock owner

Percutaneous Aortic Valve Replacement

CoreValve

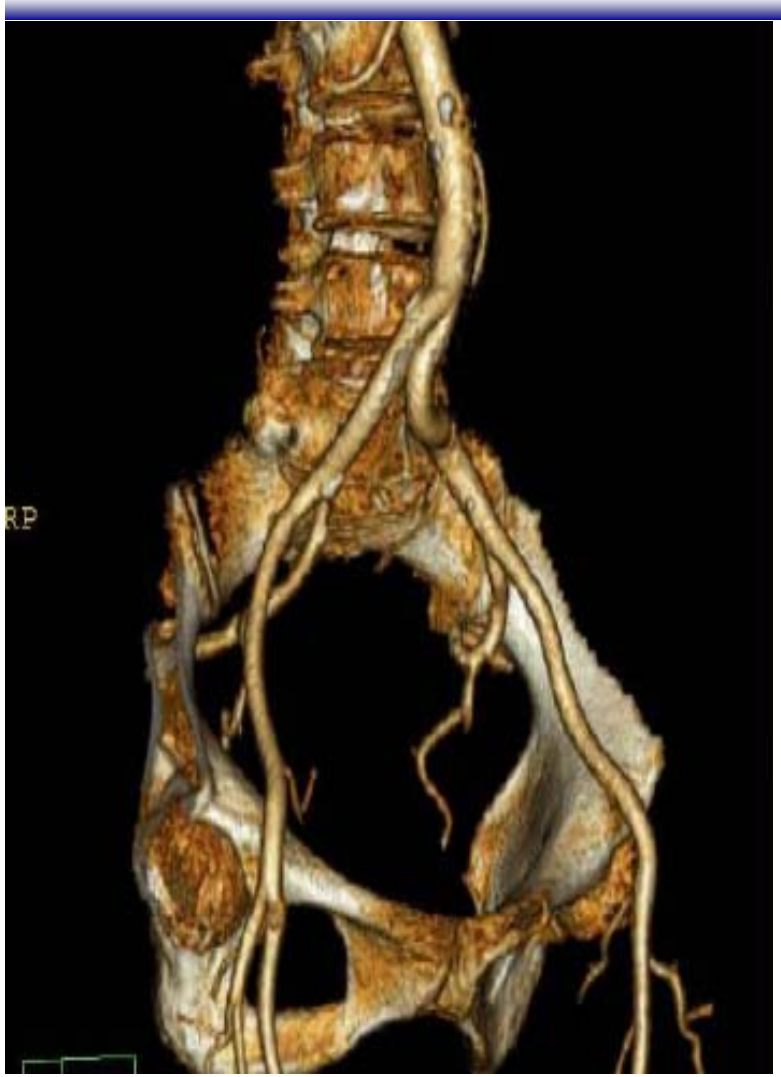
- Self expandable
- Porcine pericardium
- Retrograde
- Transapical *soon*
- 18 Fr
- No more CP assistance



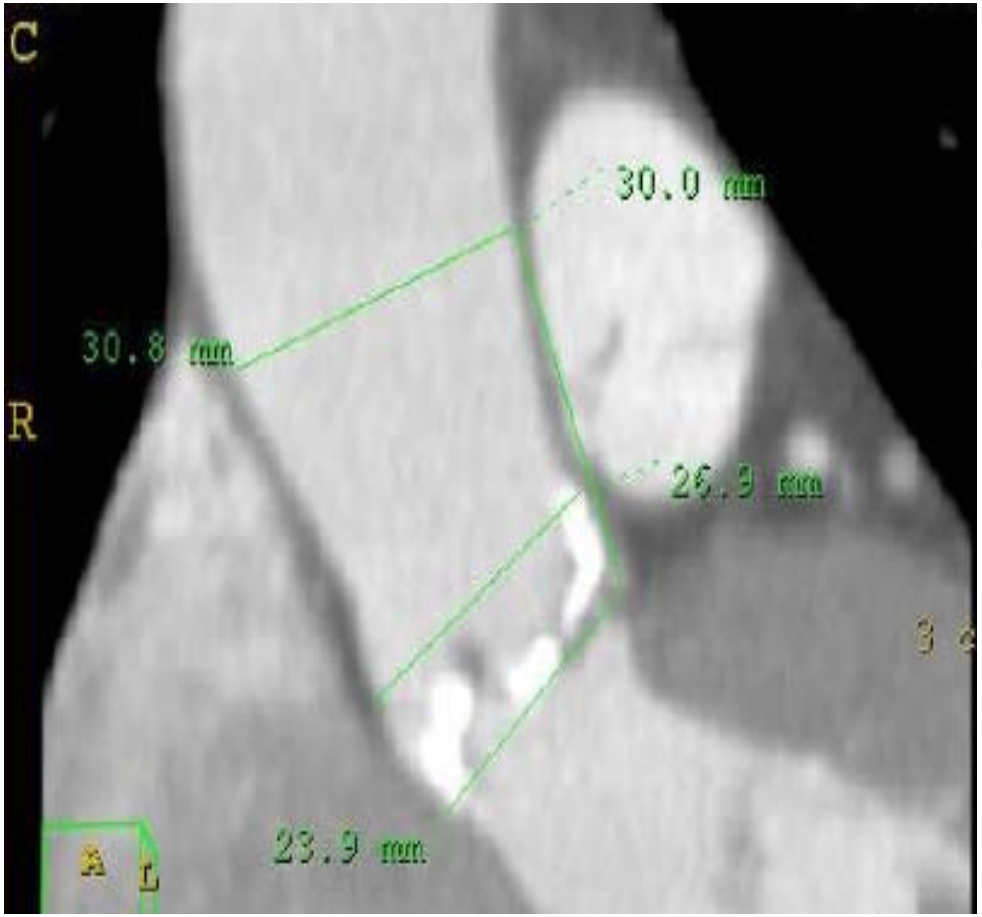
Cribier-Edwards

- Balloon expandable
- Equine pericardium
- Retrograde (ante.)
- Transapical
- 24 Fr
- Rapid pacing

Access Site Assessment

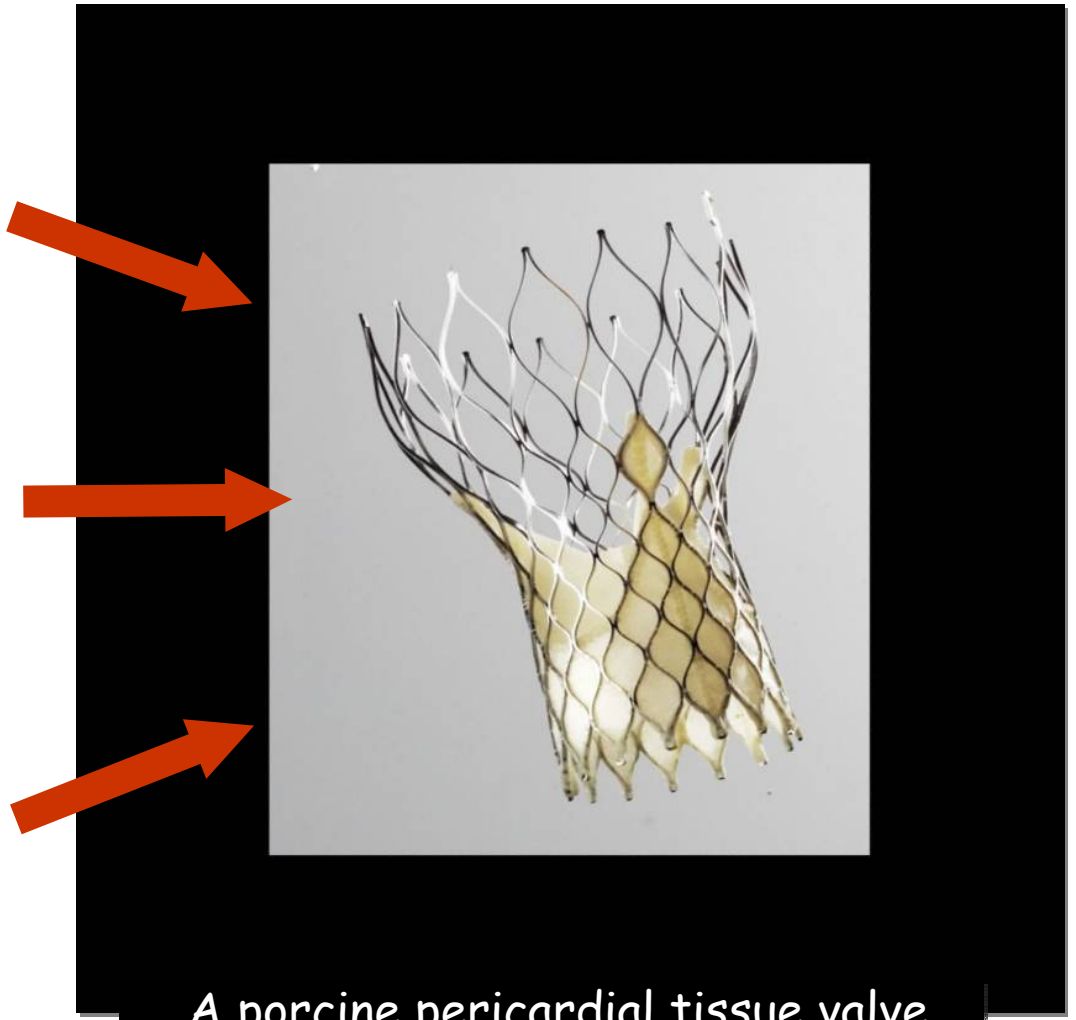


Morphological Quantification



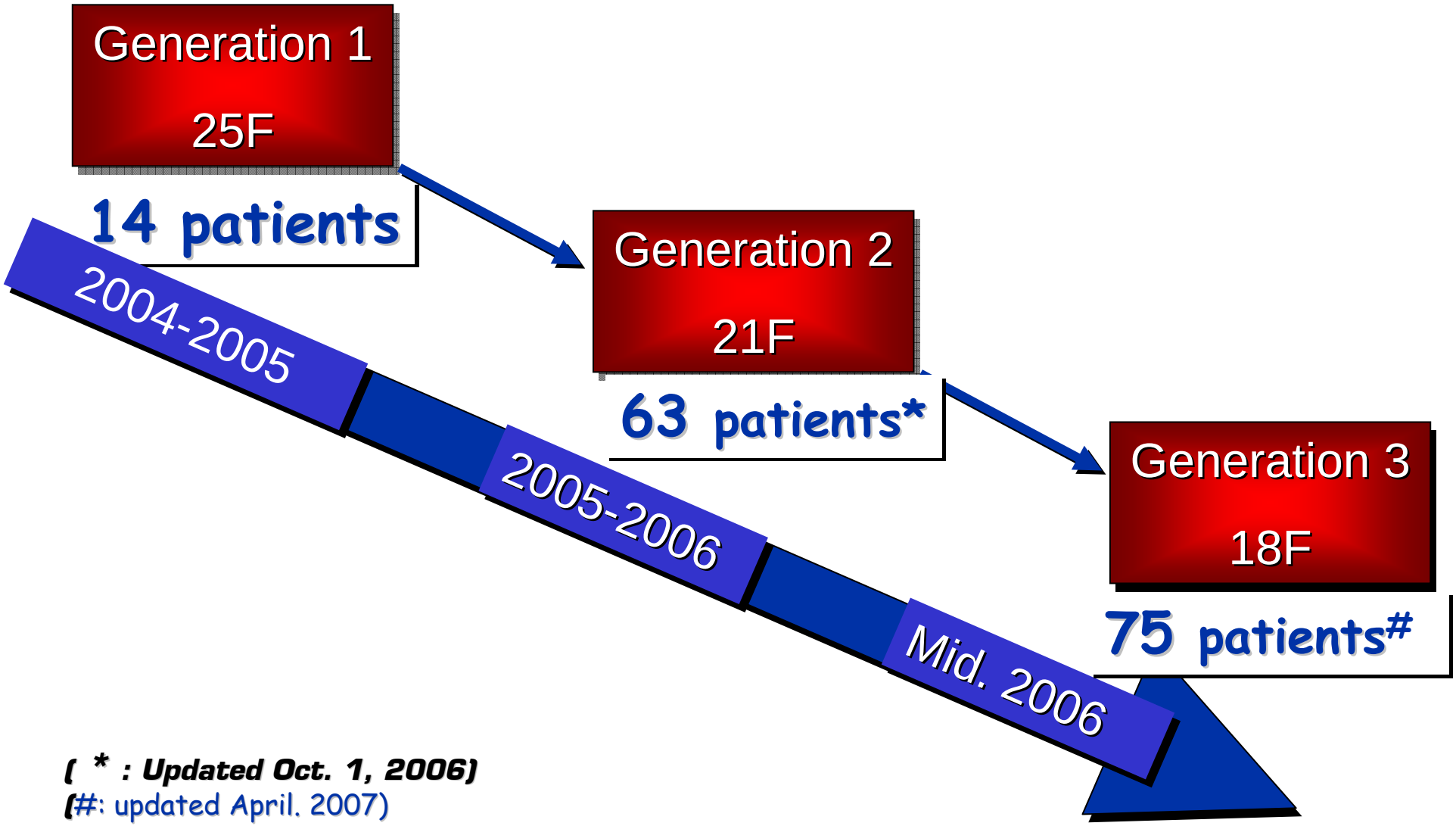
CoreValve Self-Expanding Bioprosthesis (Generation II, 21 Fr)

- **HIGHER PART**: low radial force area
- **MIDDLE PART**: functional valve area with 3 leaflets – frame constrained to avoid coronaries (convexo-concave)
- **LOWER PART**: high radial frame force pushes aside the native calcified leaflets



A porcine pericardial tissue valve fixed to the frame with PTFE sutures

CoreValve Revalving™
Clinical Experience



*(* : Updated Oct. 1, 2006)*
(#: updated April. 2007)

CoreValve Generation 2
Self-Expanding Bioprosthesis

7 Centers
(Sept 2005- Sept 2006)

Grube E., Gerckens U.: ***Siegburg, Germany***
23

Schuler G., Linke A.: ***Leipzig, Germany***
14

Bonan R.: ***Montreal, Canada*** 11

Den Heijer P.: ***Breda, Netherlands*** 7

Serruys P.W., De Jaegere P.: ***Rotterdam, Netherlands*** 5

Bosmans A.: ***Antwerp, Belgium*** 2

Benit B.: ***Hasselt, Belgium*** 1

(Updated Oct. 4, 2006)

Inclusion Criteria Gen.2 (21F Catheter)

- **Native aortic valve disease**
  - Severe AS: AVAI≤0.6 cm^2/m^2
- **23mm ≥AV annulus ≥20mm**
- **Sino-Tubular Junction ≤45mm**

- **Age≥80 y**
- **Logistic EuroSCORE ≥20%**
- **Age ≥ 65 y**

+1 or more

- Liver cirrhosis - Child class A-B
- Pulmonary insufficiency: VMS<1L
- Previous cardiac surgery
- PHT: PAP>60mmHg
- Recurrent P.E's
- RV failure
- Hostile thorax (radiation, burns,etc)
- Severe connective tissue disease
- Cachexia

High-Risk patients 50
Inoperable patients 13

(Updated Oct 1, 20(

Patient Characteristics

Patients		63
Age		80.9 ± 6.5 [64-94]
Gender		44 females (70%)
ECHO	Pre-gradient Max (mmHg)	60.4 ± 16 [33-95]
	Pre-gradient Mean	41.2 ± 15 [19-80]
	AVA ($cm^{2)}$	0.64 ± 0.2 [0.3-1.1]
Pre LVEF (%)		51.1 ± 17.4 [15-78]
NYHA	Class II	7(11 %)
	III	35(55 %)
	IV	22(34 %)
Logistic EuroSCORE		25.4 ±15 [7-69]
High-risk group		23.4 ±14 [7-69]
Non-operable group		31.6 ±16 [20-63]

(Updated Oct 1, 20

Complications

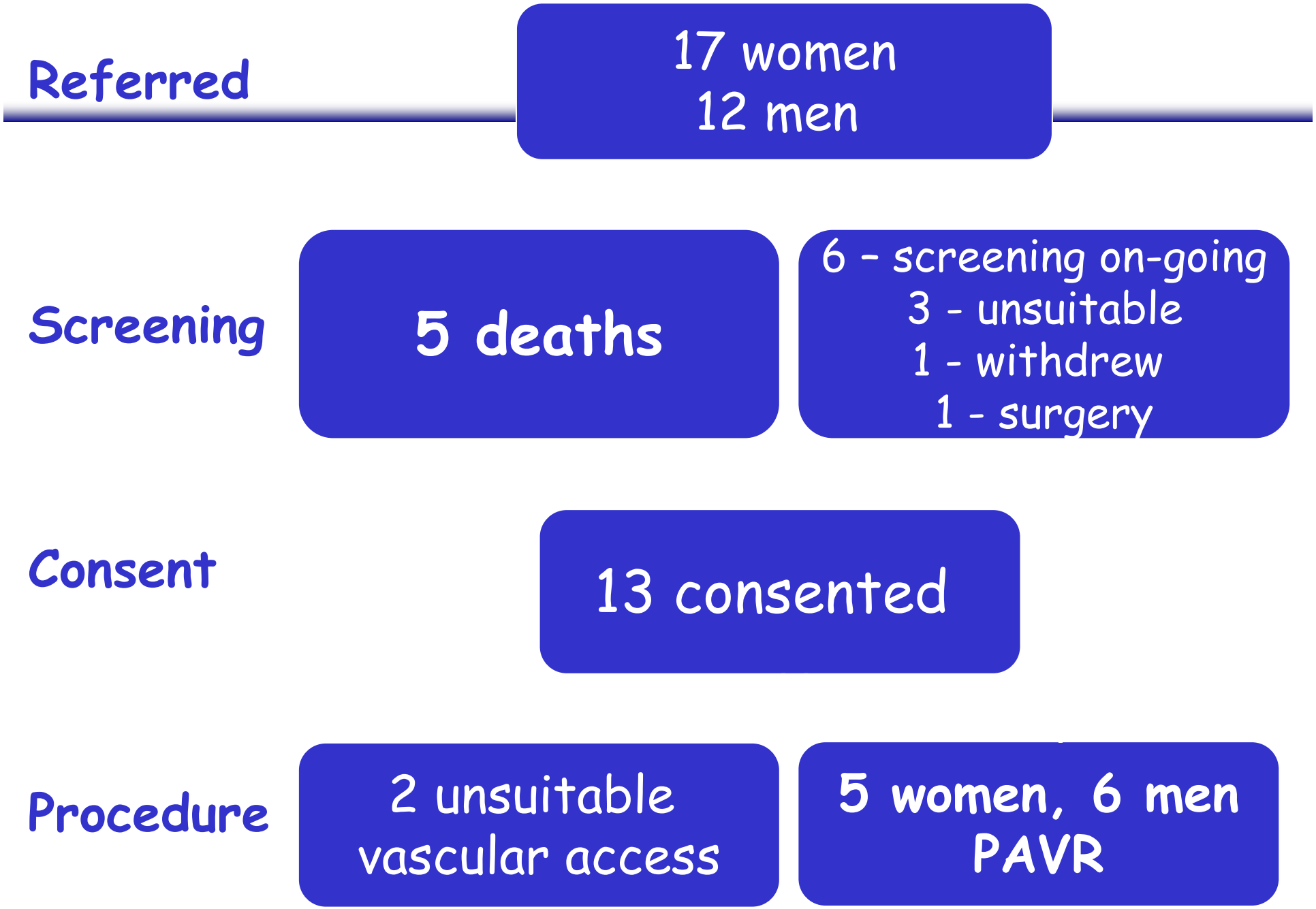
In-hospital major complications

	High-Risk (50)	Inoperable (13)	Overall (63)
logistic EUROSCORE	23.4 %	31.6%	25.4%
In-hospital mortality	4(8%)	4(31%)	8(13%)
Conversion to surgery	4(8%)*	-	4 (7%)
Discharged, alive and well	43(82%)	7(54%)**	50(80%)

*High risk group: 1 surgical conversion death

**Inoperable group: 2 patients had BAV alone

(Updated Oct. 1, 2006)

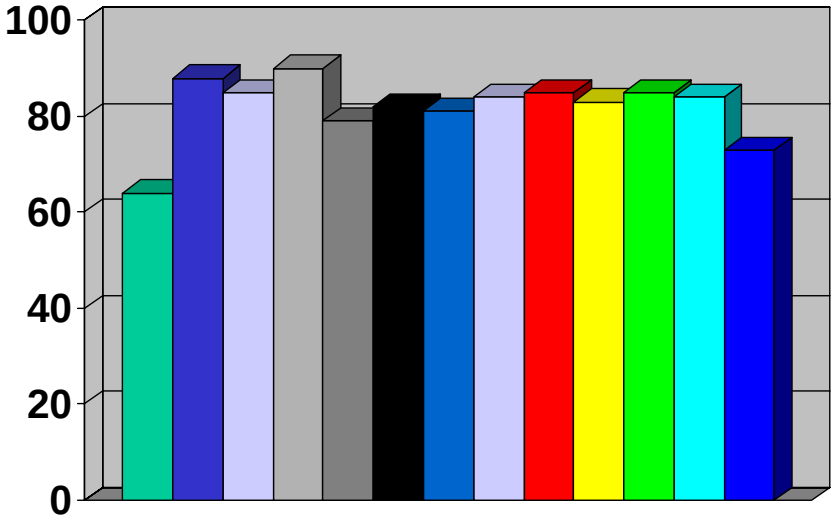

Referred
17 women
12 men
Screening
5 deaths
6 – screening on-going
3 - unsuitable
1 - withdrew
1 - surgery
Consent
13 consented
Procedure
2 unsuitable
vascular access
5 women, 6 men
PAVR

Case	Gender	Age	Patient comorbidity	Logistic Euro-Score	Age ≥65 + Risk Factor
RC*	F	64	**Pulmonary fibrosis; FEV_1 = 0.4**	**5**	–
LL*	M	88	Arteriopath; COPD	11	√
JV*	F	85	Comorbidity	19	√
YB#	F	90	Severe kyphoscoliosis	12	√
RD	M	79	Arteriopath; CABG	42	√
RP	F	82	Connective tissue disease	28	√
RW	F	81	Pulmonary cachexia	36	√
KS	M	84	Heart failure	43	√
JPS	M	85	Arteriopath; COPD	37	√
JP	M	83	COPD	23	√
GD	M	85	CABG Renal failure	38	√
RB	M	84	Cardiac Surgery	47	√
MK	F	73	CVD; Jehova's witness	48	√

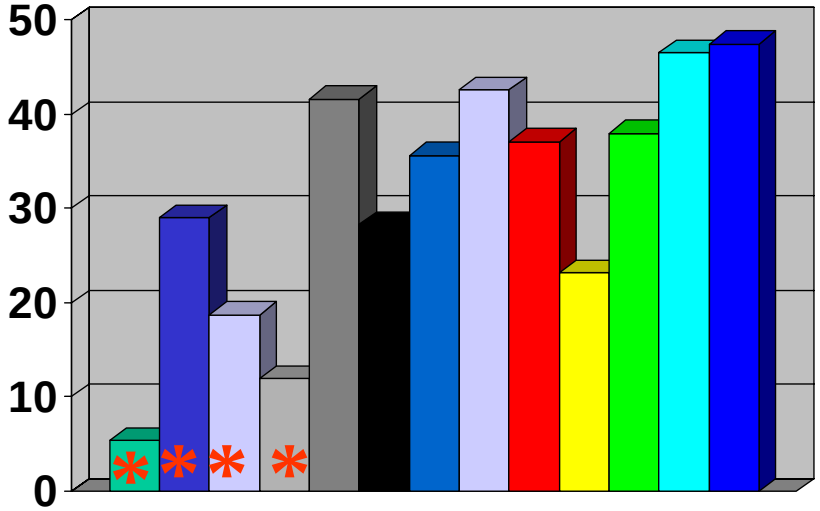
* Refused by Surgery; # Failure/Successful Surgery 6 m later

Characteristics of consecutive consenting patients

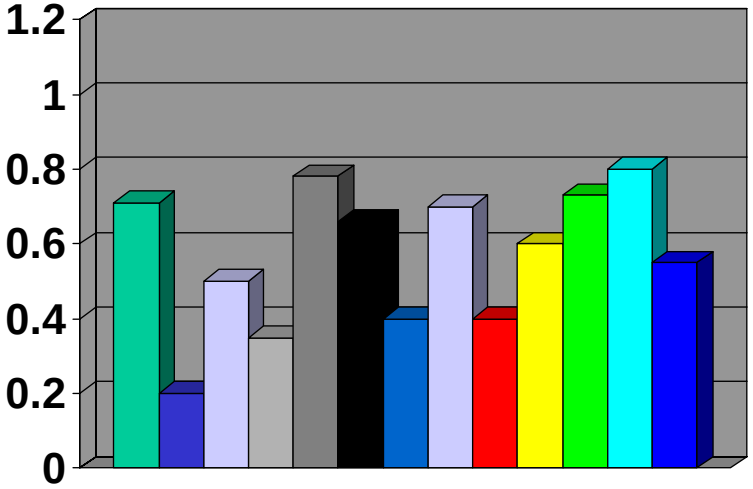
Mean age, yrs = 82



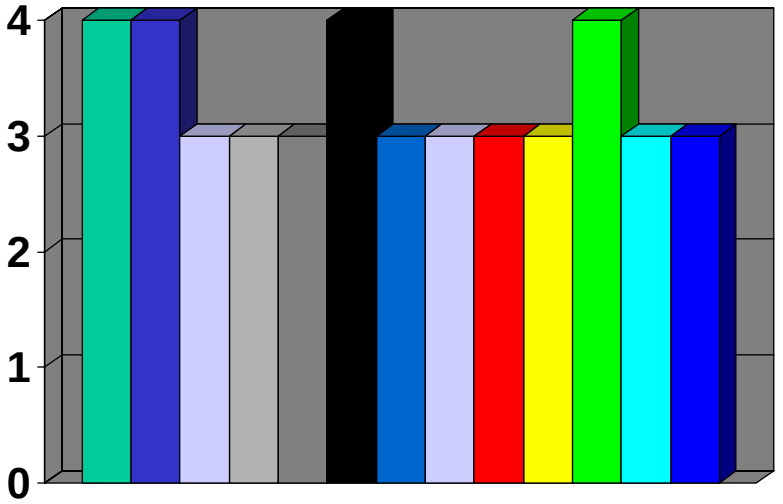
Median Log. Euroscore, % = 36



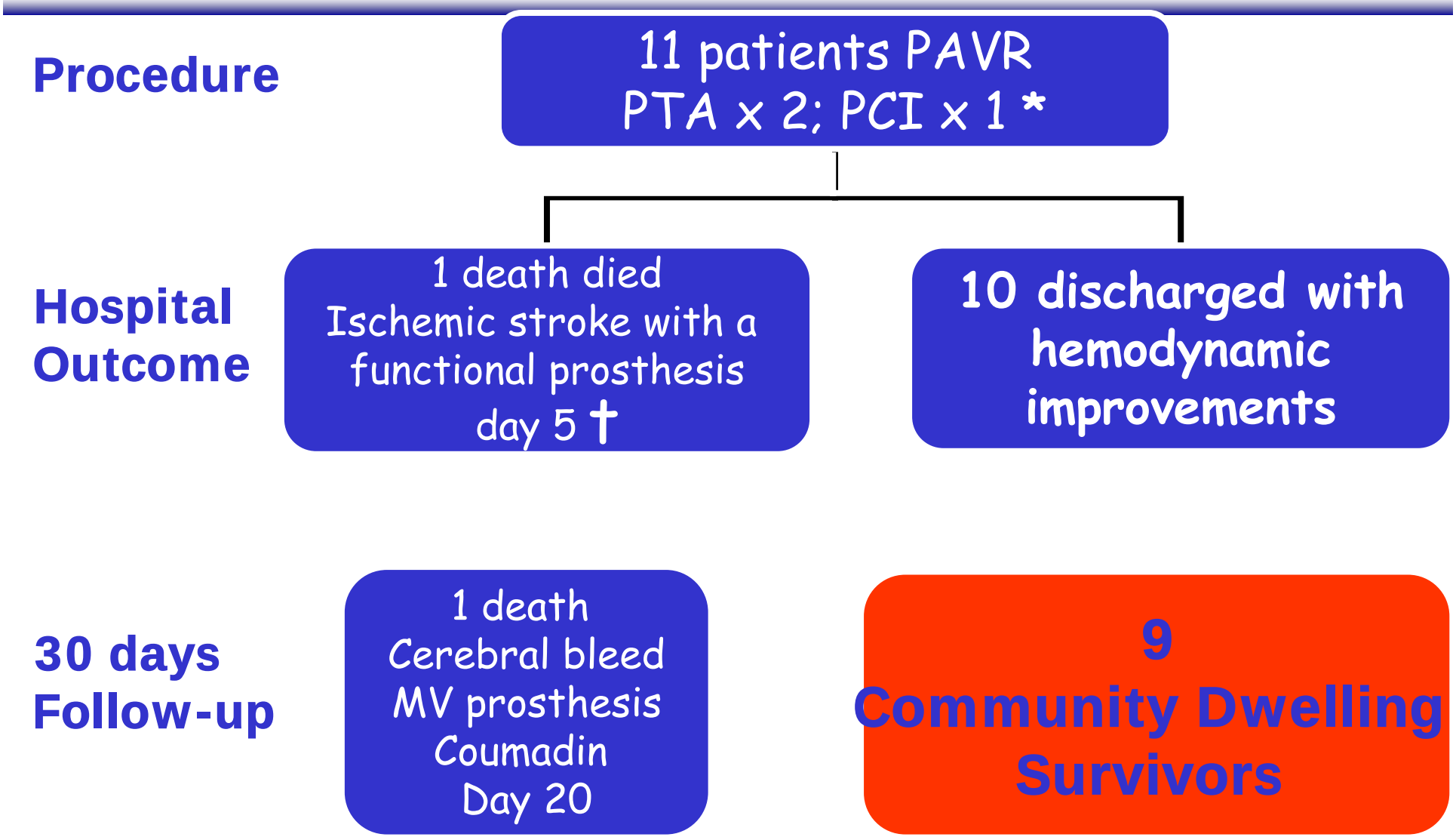
Aortic valve area, cm^2 = 0.56



NYHA functional class = 3

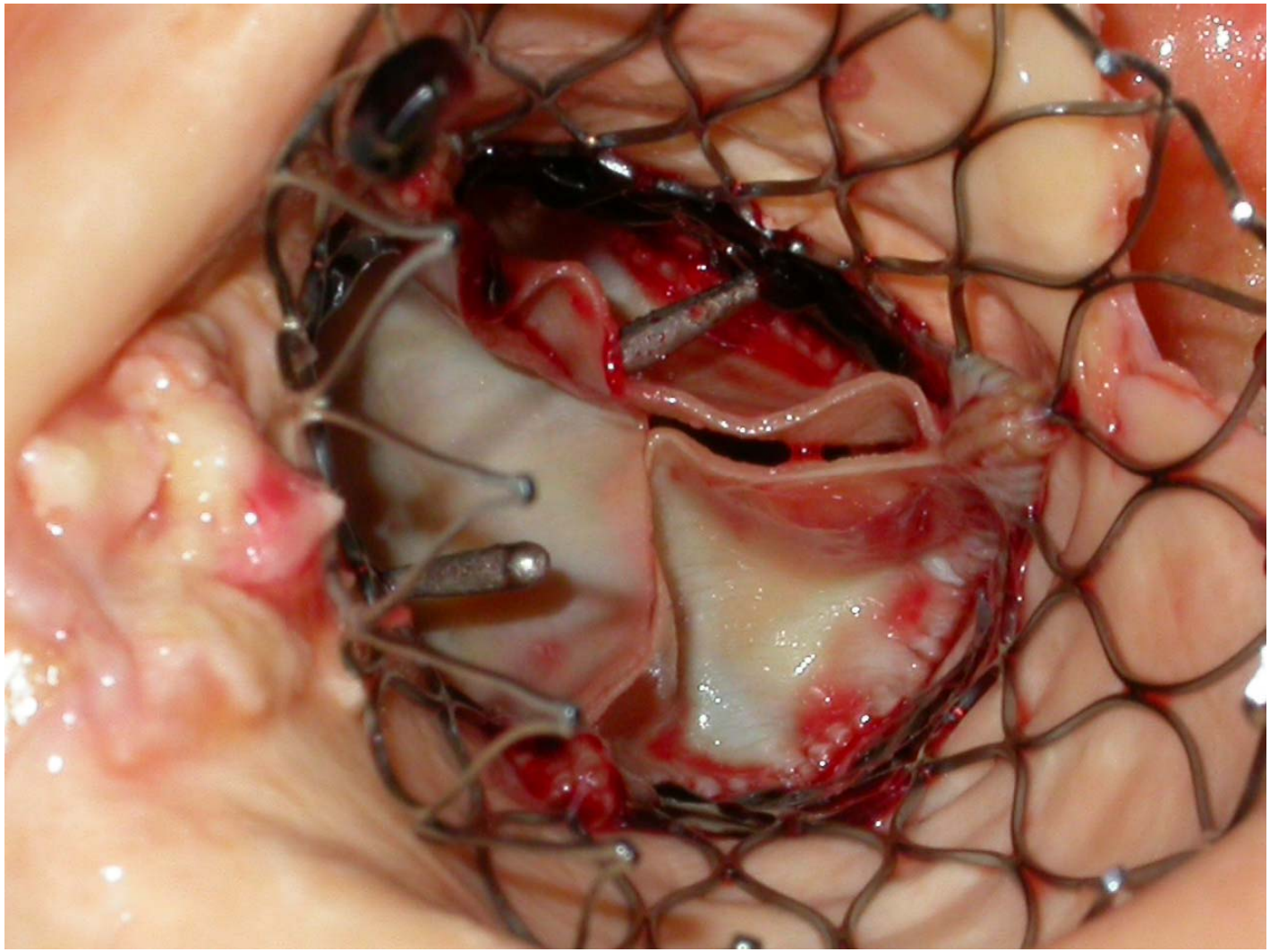


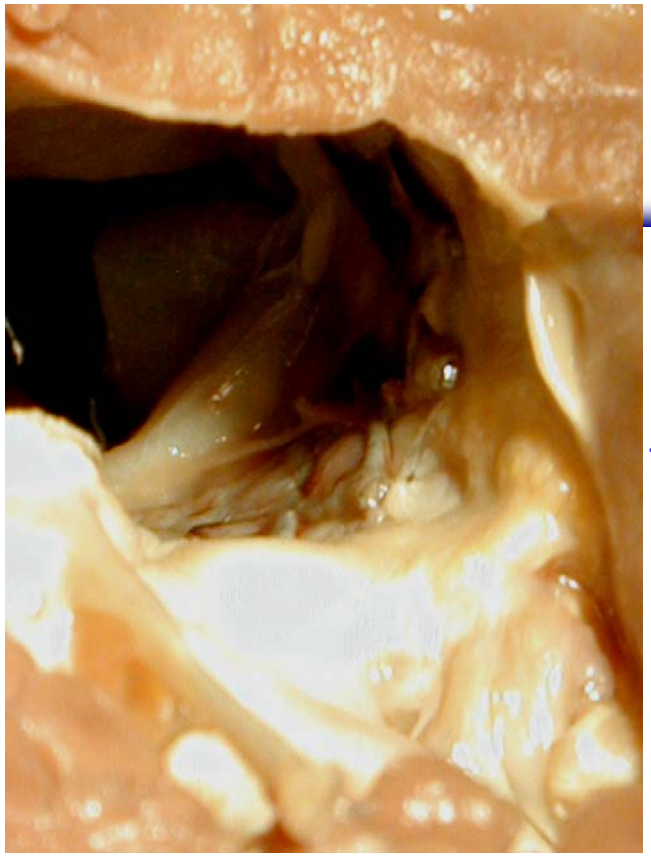
Montreal Heart Institute PAVR Outcomes



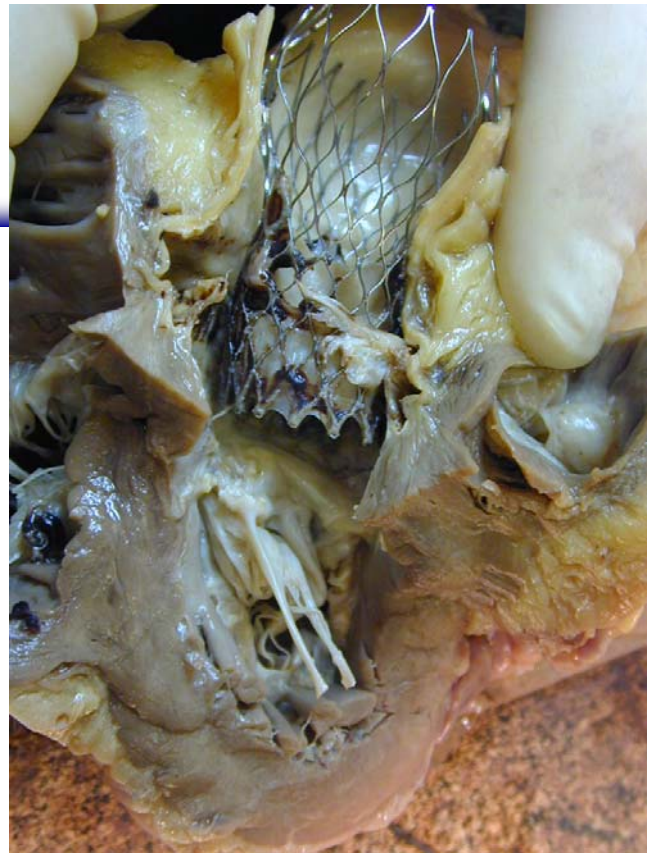
*EuroIntervention 2006;2: 257-61; †CCI in press

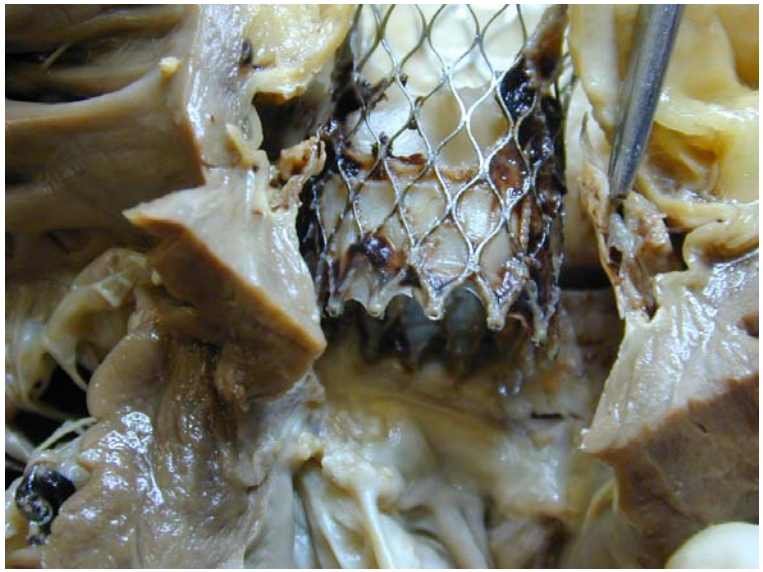
CoreValve : Coronary Ostia



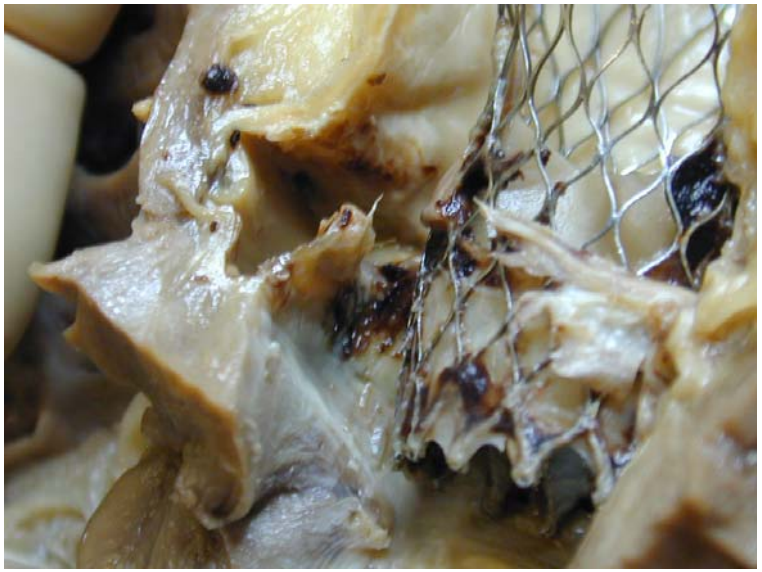


Relation between
the Prosthesis
and
the Anterior Mitral leaflet





Relation between
the Prosthesis
and
Aortic leaflets



Procedure & hospital outcomes

	Findings
Median (IQR) procedure time, min	30 (26, 44)
New PPM, n (%)	3 (27%)
New LBBB, n (%)	4 (36%)
CKMB elevation	
> normal	100%
> X 5 ULN	27%
Blood transfusion	82%
Platelet transfusion	18%
Median (IQR) duration of admission, days	4 (1, 7)
ICU	12.5 (5.5, 30)

Procedural complications

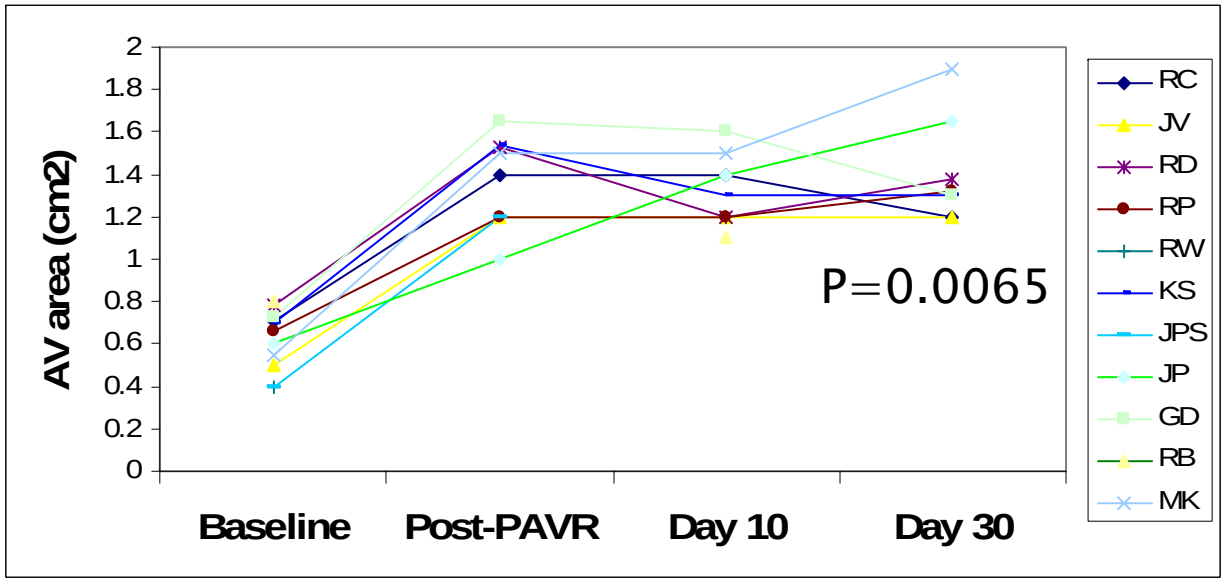
	N	%
Cardiac death	0	0
Non-cardiac death *	1	9
CKMB > x 5ULN #	3	27
Bradyarrhythmia	4	36
Emergent PCI / surgery	0	0
Stroke *	1	9
Major bleeding *	2	18

* Same patient

Post PAVR thallium = no ischemic defect

Aortic valve area and function post-CoreValve PAVR

Aortic Valve Area

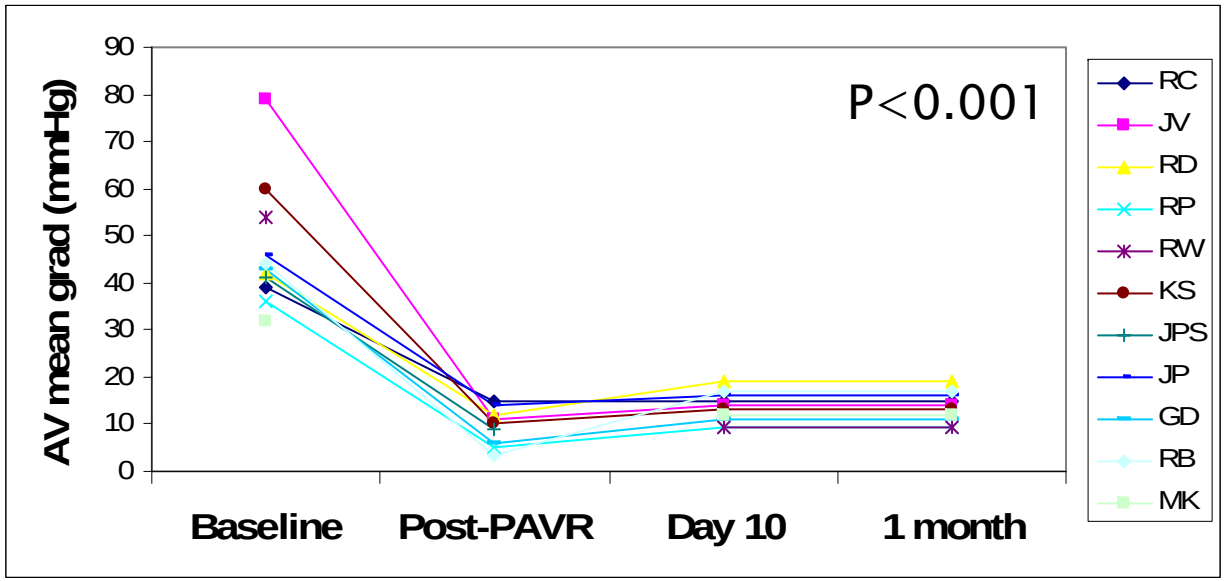


AV area (cm^2)

Baseline = 0.56

1 month = 1.3

Mean Aortic Valve Gradient

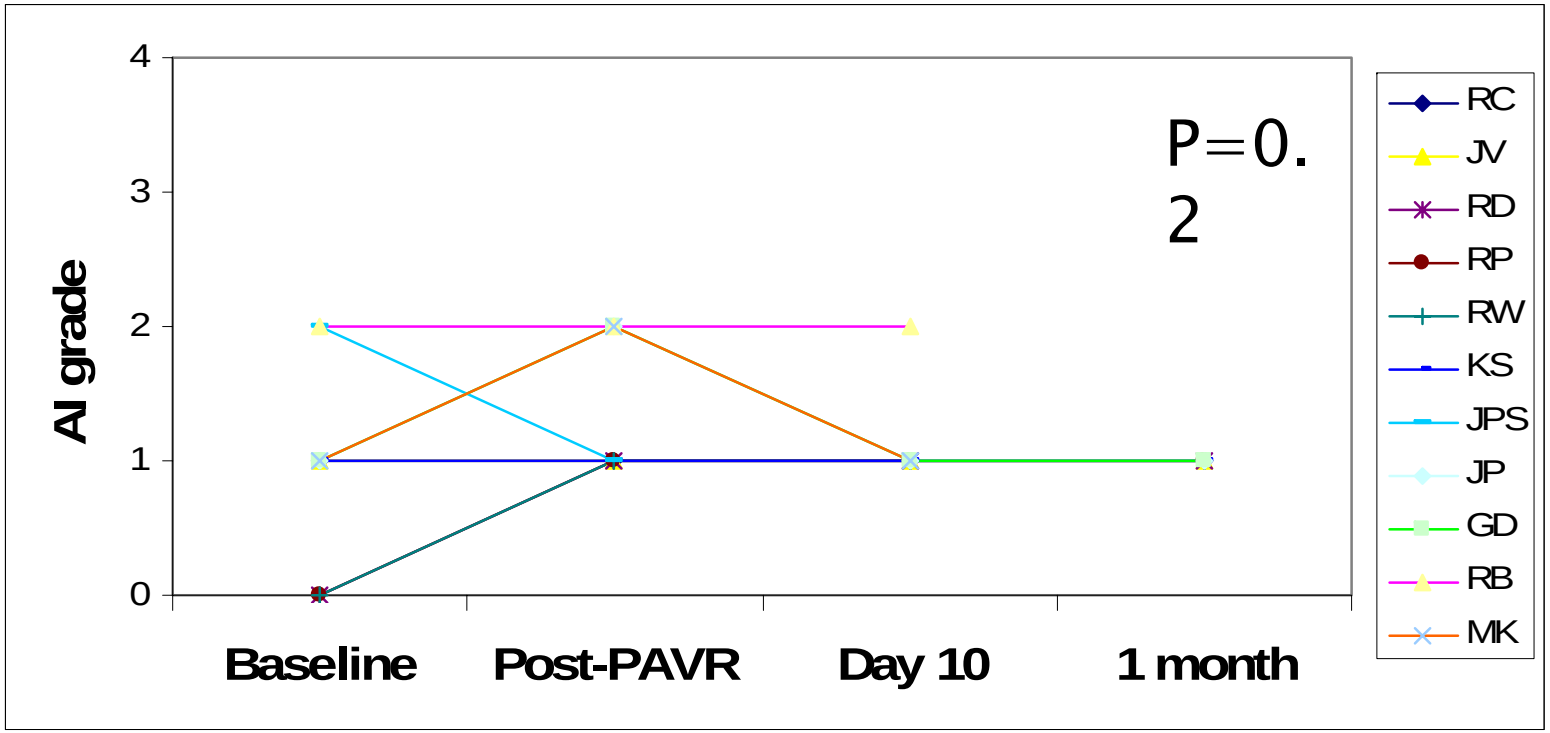


Mean AV area grad. (cm^2)

Baseline = 52

1 month = 9

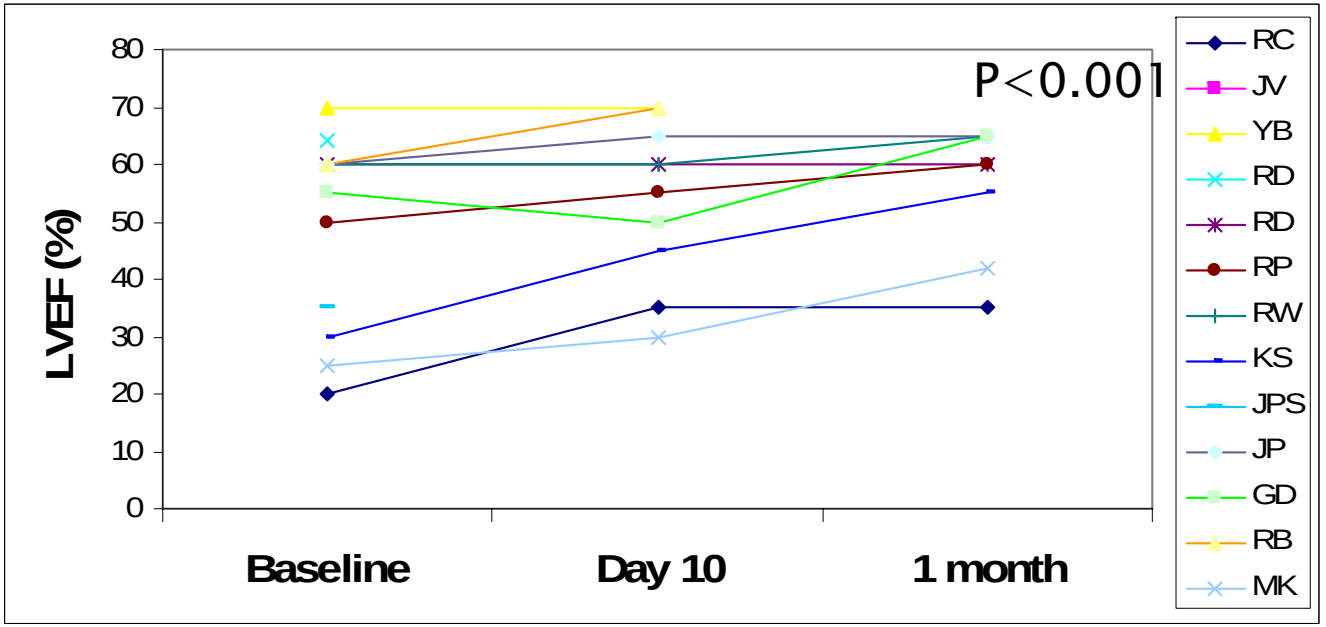
Aortic valve regurgitation grade post-CoreValve PAVR



A I	1	1	1	1
No. Pts	11	11	10	8

Improvement in left ventricular systolic function

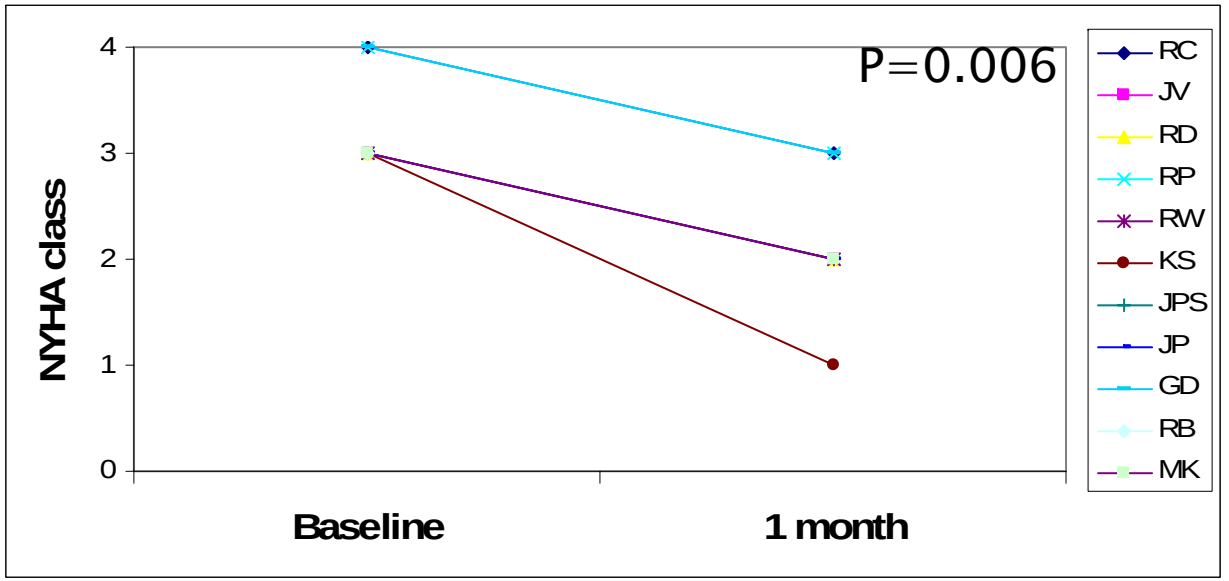
LVEF



Mean LVEF (%)	49	54	56

Functional and biochemical assessments post-CoreValve PAVR

NYHA

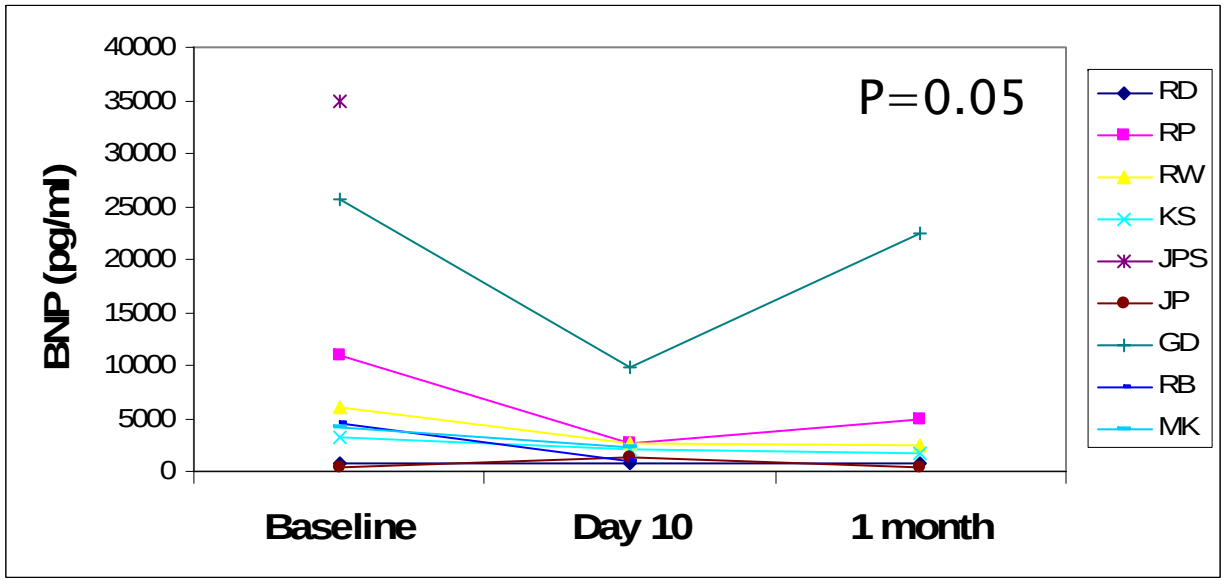


Median NYHA

Baseline = 3

1 month = 2

NT-BNP



Mean NTBNP (pg/ml)

Baseline=10058

1 month = 5419

Cumulative 30 day adverse events

	N	%
Cardiac death	0	0
Non-cardiac death *	2	18
CKMB > x 5ULN	3	27
Bradyarrhythmia	4	36
Emergent PCI / surgery	0	0
Stroke	1	9
Major bleeding	2	18

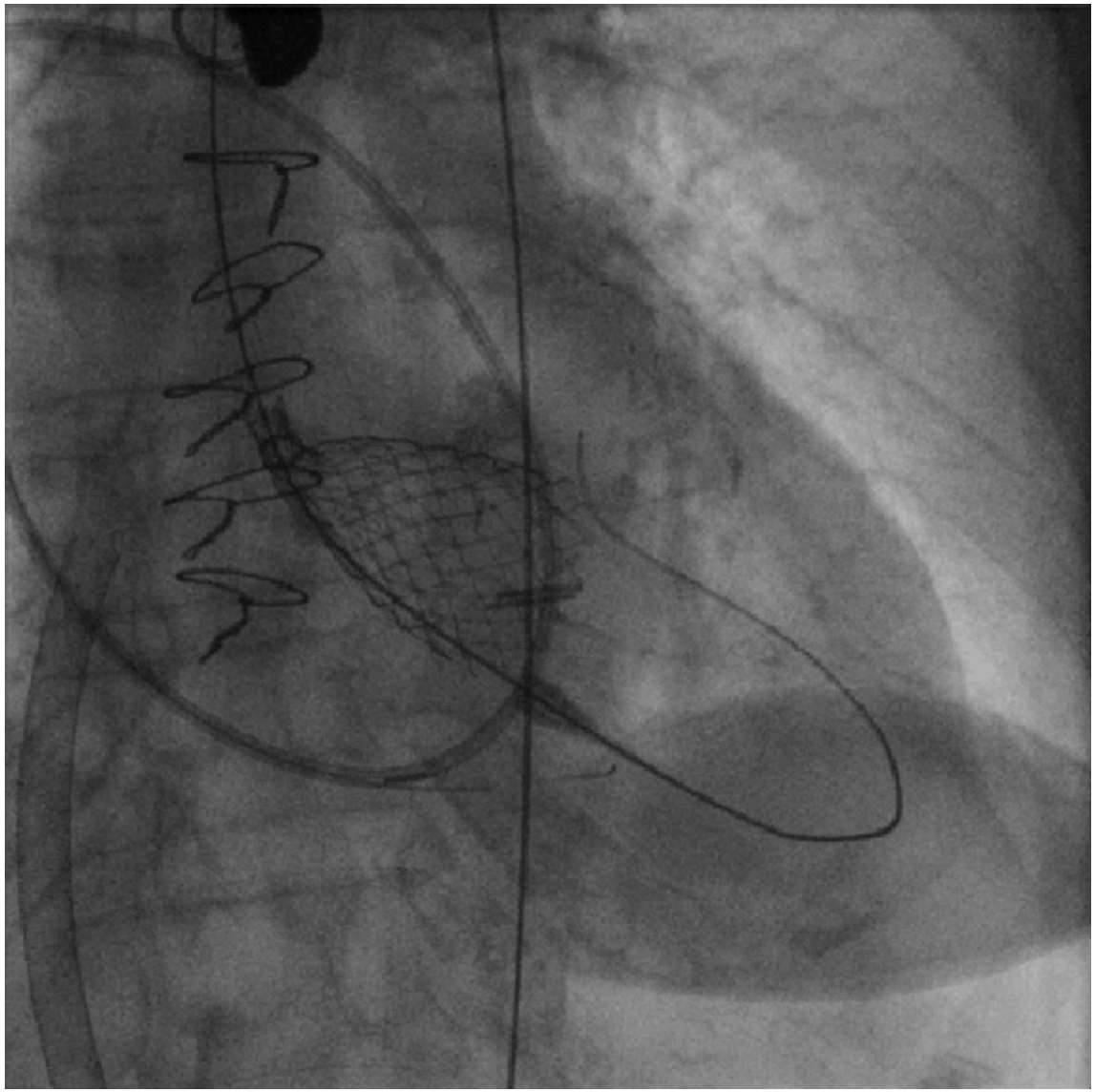
* 1 non-cardiac death at 20 days – cerebral hemorrhage / I

Summary

- PAVR in high-risk patients is feasible
- Haemodynamic & functional improvements in survivors
- Periprocedural morbidity is significant & related to vascular complications
- Co-morbid burden may influence early outcomes

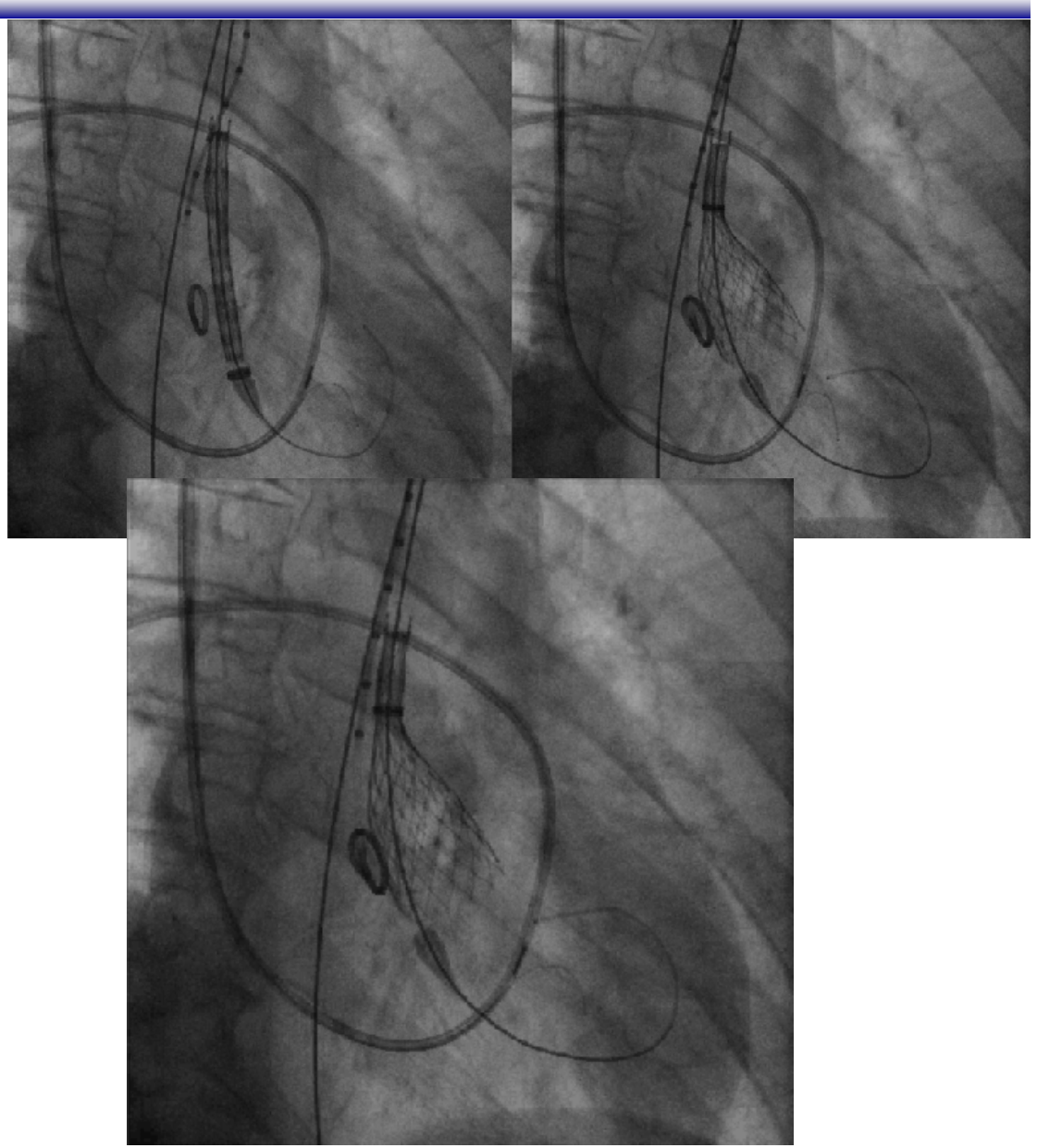
22 PAVR at MHI

- First 9:
  General Anesthesia, TEE,
  Surgical cardio-pulmonary by pass,
  21 Fr
- Next 8:
  General Anesthesia, TEE,
  Tandem Heart support,
  1x21Fr and 7x18Fr
- Last 5:
  Light Sedation,
  Preclosed w/ Prostar 10Fr
  18 Fr



Now! it is really a Cath-Lab procedure

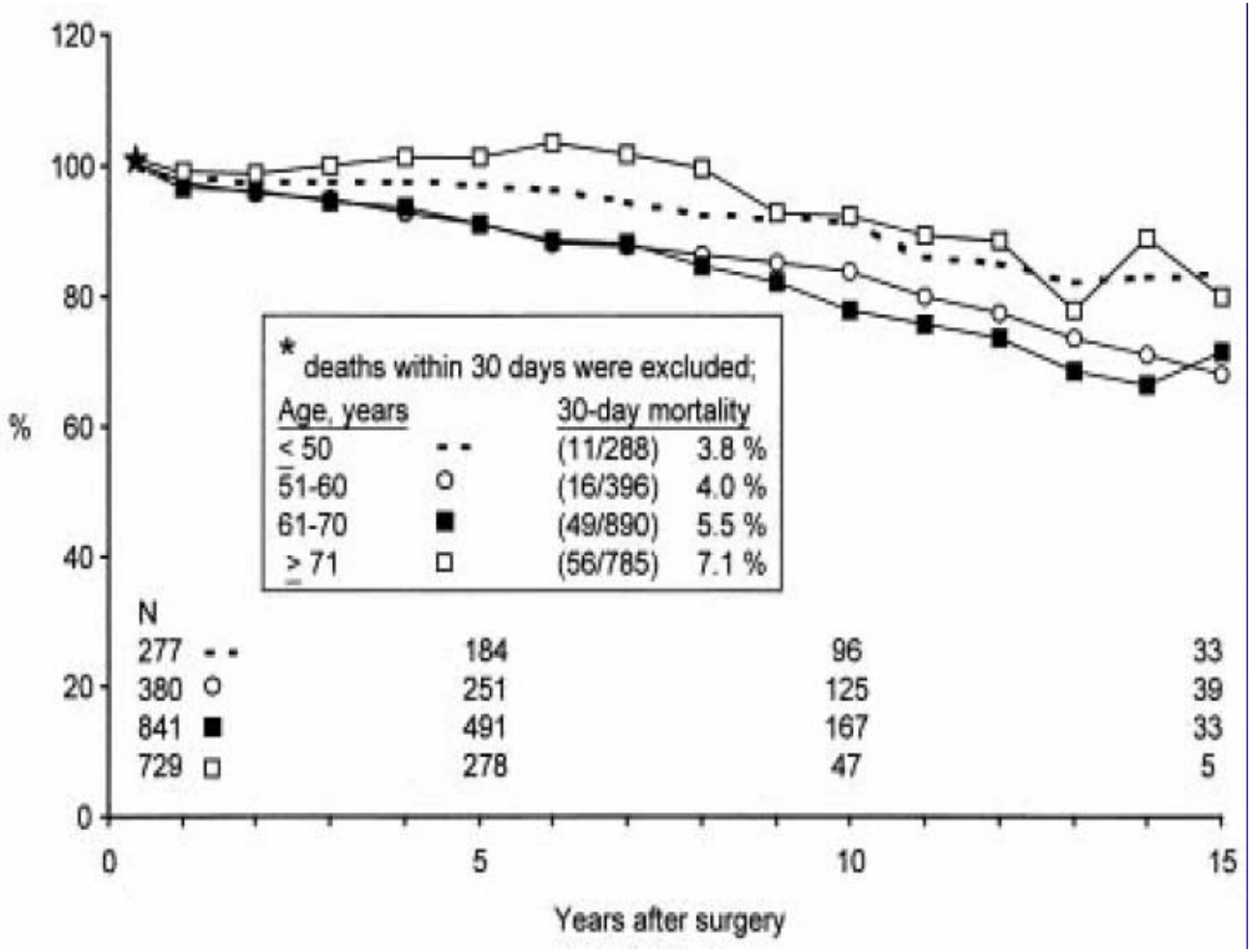
- Since Nov 9th …. 18 Fr At Siegburg, Lepzig & Montreal
- No Cut-down (totally percutaneous: Prostar 10Fr)
- No "support" (Cardiac assistance or pacing)
- No anesthesia (light sedation)



Comparison 21 vs 18 Fr

	21 Fr (50)	18 Fr (36)
Local Anesthesia	-	25%
No Surgical Cut-down	12%	42%
No Hemodynamic support	-	64%
Procedural Time	188±55	148±50

Late Survival After Aortic Valve Replacement



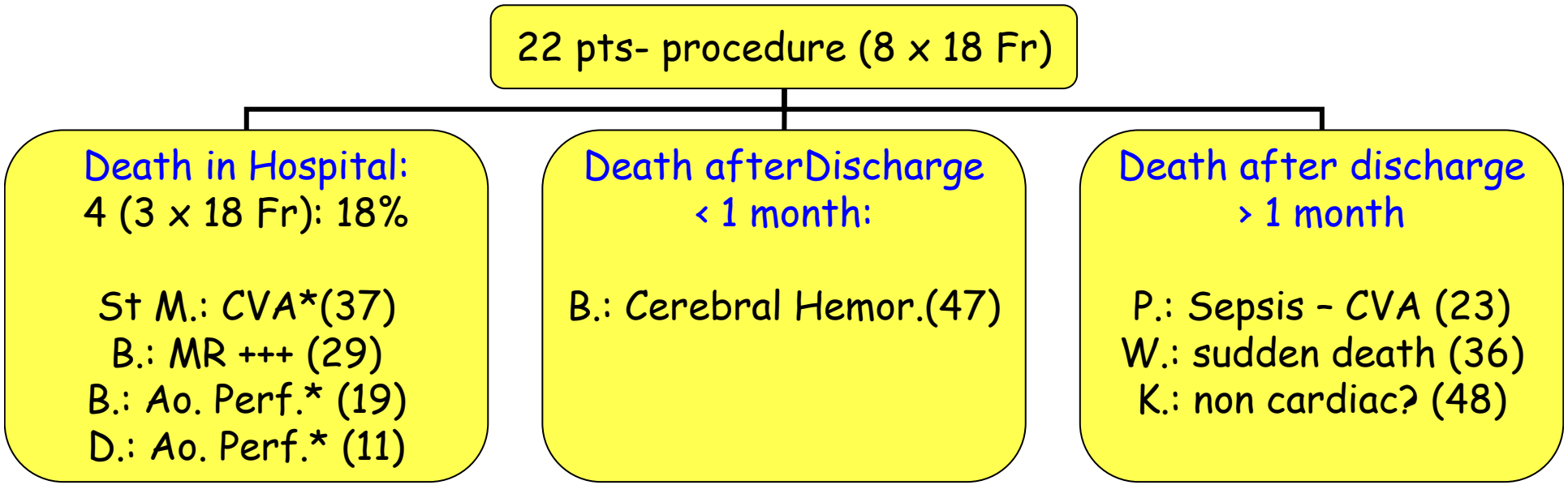
Kvidal et al. JACC 2000; 35: 747

Operative Mortality / Comorbidity

Euro Heart Survey on Valvular Heart Disease

1231 Patients operated in 92 centers from April to July 2001

Mortality MHI



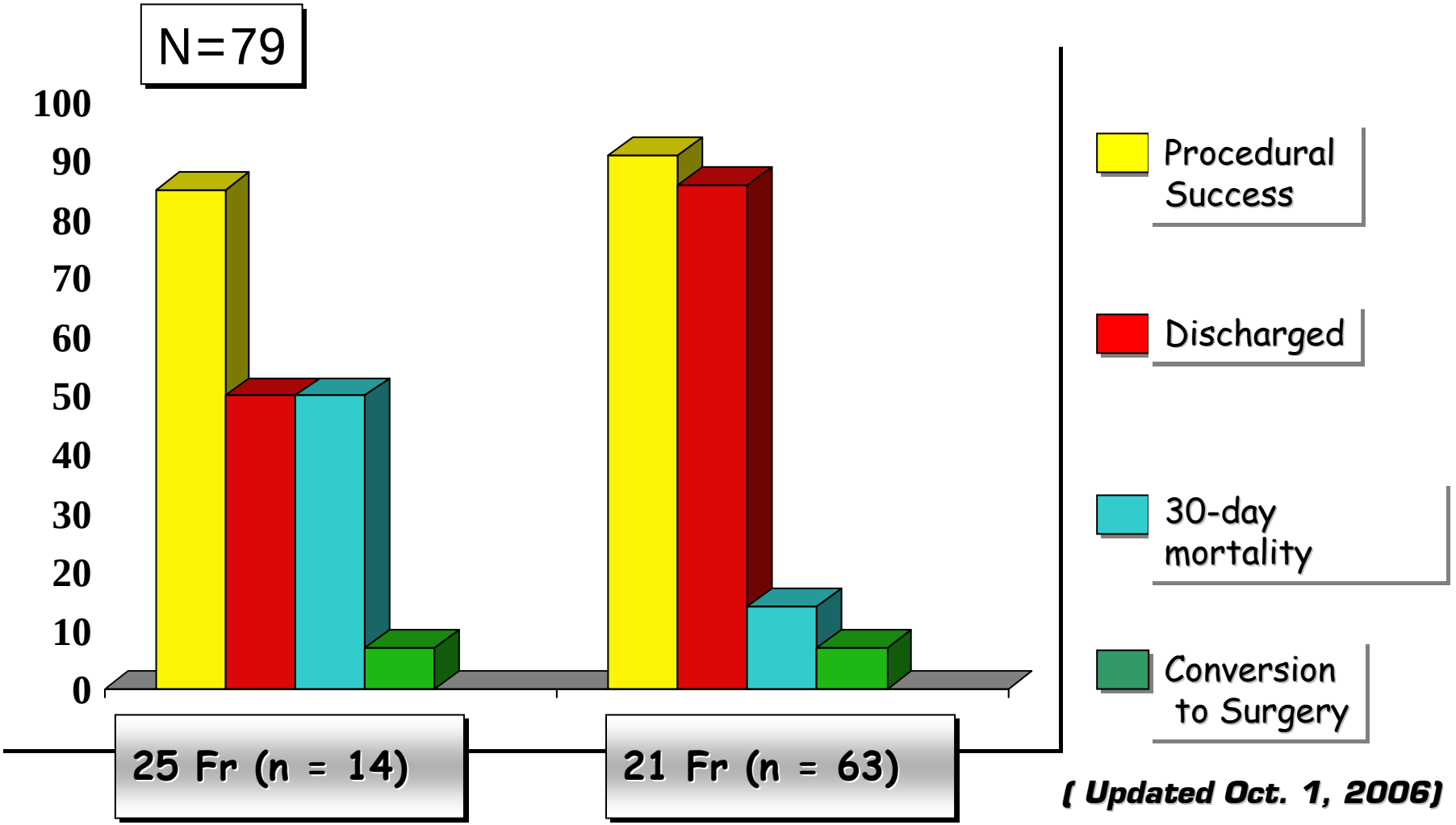
*: procedure related mortality : 14%, mean Logistic Euroscore > 30%

Lessons learned

- Patient selection: anatomy, co-morbidities…
- Evolution to a real percutaneous procedure:
  - Light sedation
  - "Preclosed" with Prostar 10 Fr
  - No support needed: "active" leaflets
- Learning curve: 18 Fr
- Still reserved for High Risk patient, but…

Thank you

Initial Clinical Experience



(Updated Oct. 1, 2006)

Percutaneous Aortic Valve Replacement

- The 21F Revalving™ CoreValve (Generation 2)
  - Clinical Experience in native AS
  - High-risk or inoperable patients
  - 63 patients*
- 30 day data available on 1st 54 patients

(* : Updated Oct. 1, 2006)

Mortality ICM