Percutaneous Aortic Valvuloplasty in 2009 Indications and Results

Ron Waksman, Augusto Pichard
Lowell Satler, Istik Ben dor

Washington Hospital Center, Washington DC

CRT2011

FEBRUARY 27-MARCH 1, 2011

OMNI SHOREHAM HOTEL WASHINGTON, DC

WWW.CRTONLINE.ORG

CORONARY

ENDOVASCULAR INTENSIVE

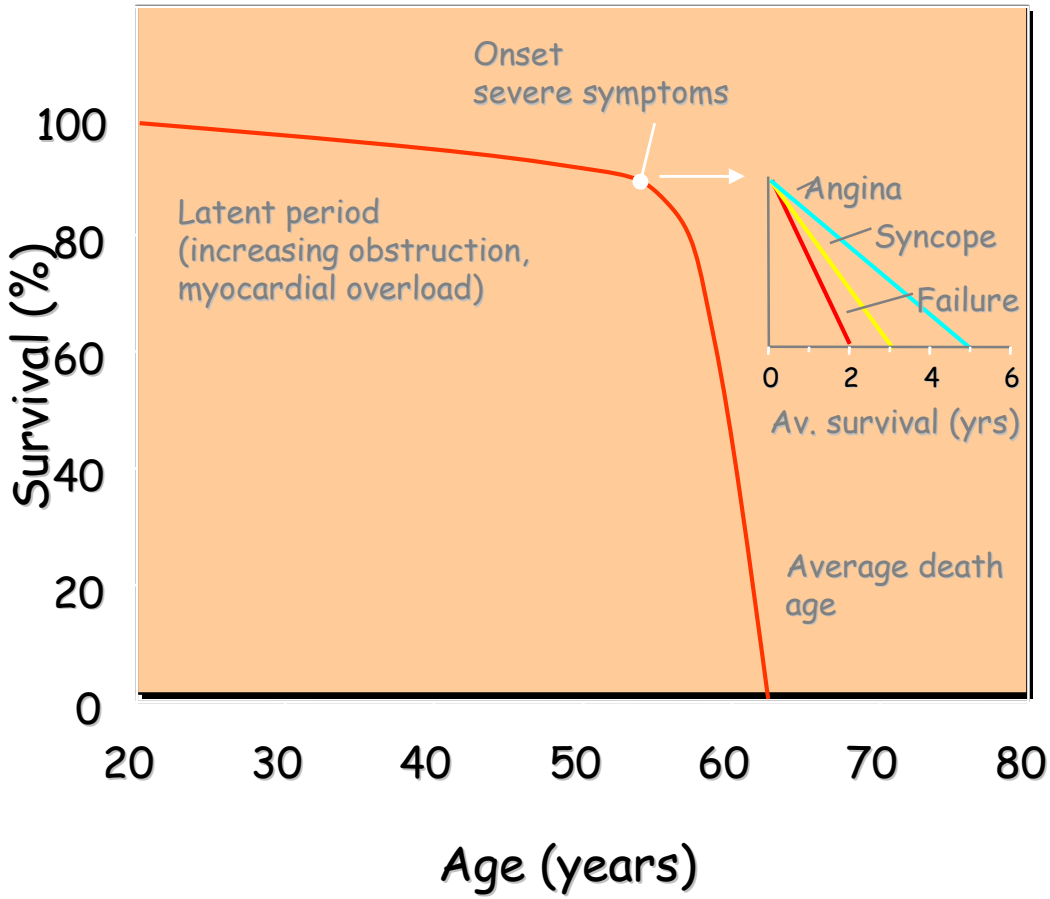
TECHNOLOGY

NURSE & TECH

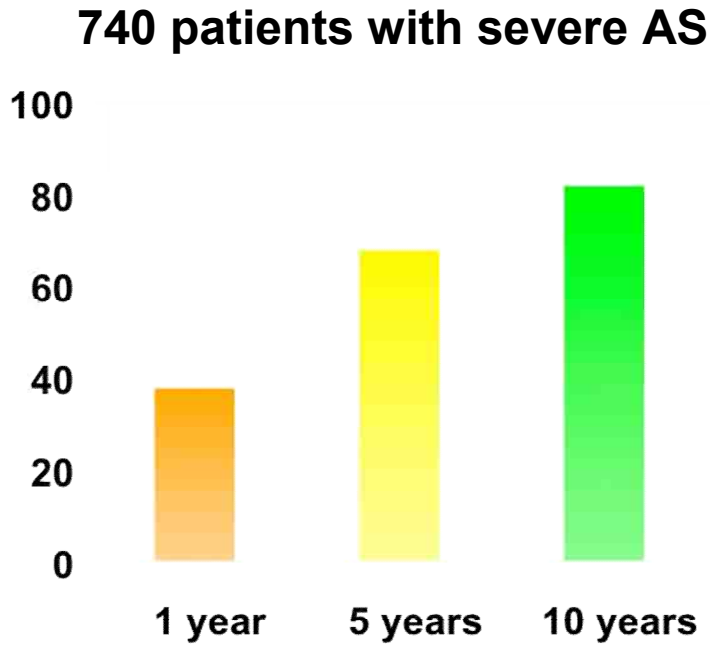
SCIENCE

Symptomatic aortic stenosis

One of the most common valve lesions in adults ~5% >75 years old



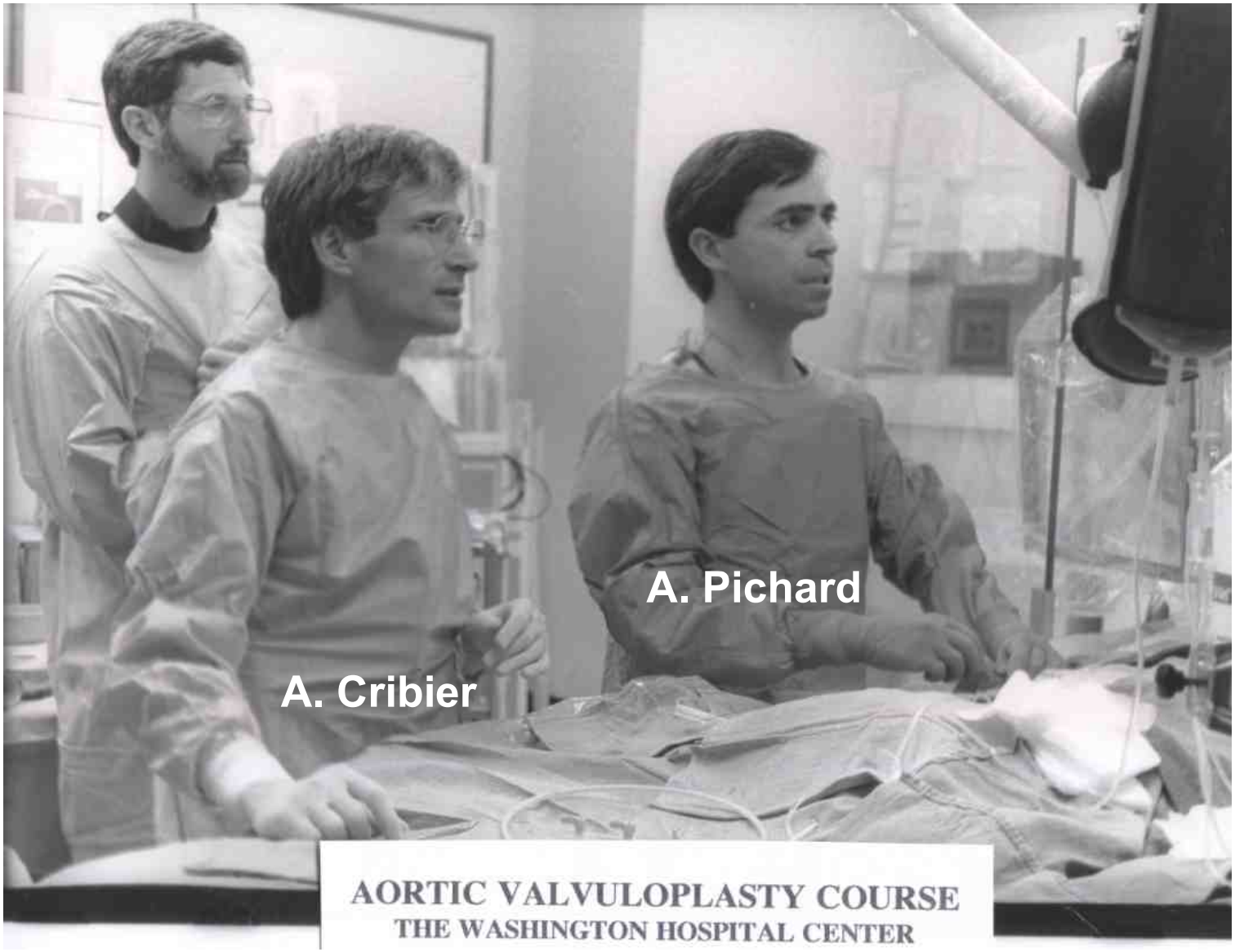
From Ross and Braunwald, Circulation 1968



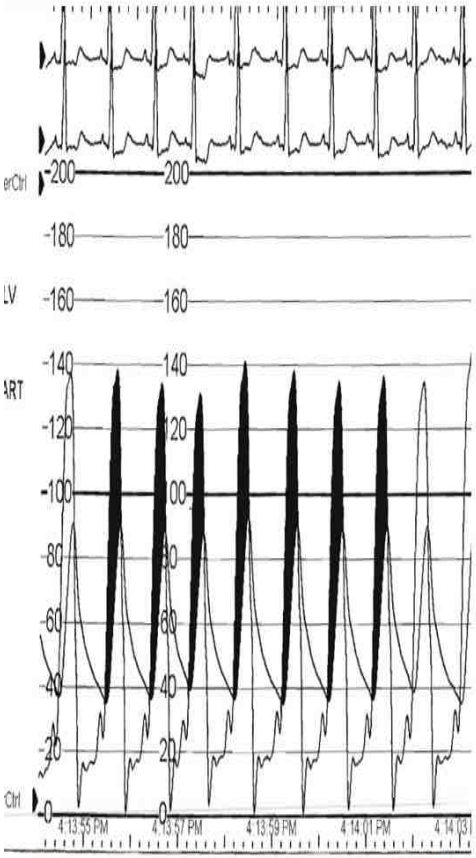
Natural History of Severe AS Managed without Surgery.
Ann Thorac Surg 2006; 82: 2111-5

Aortic Valvuloplasty Course

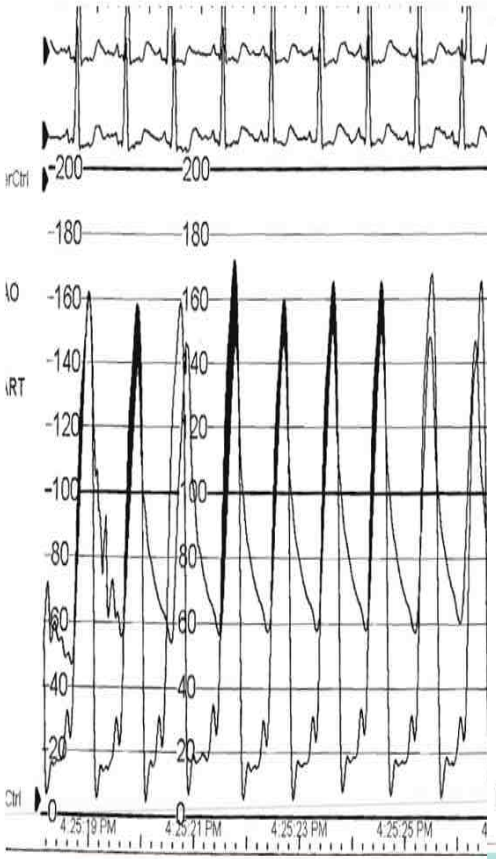
Washington Hospital Center 1987.



Good Results

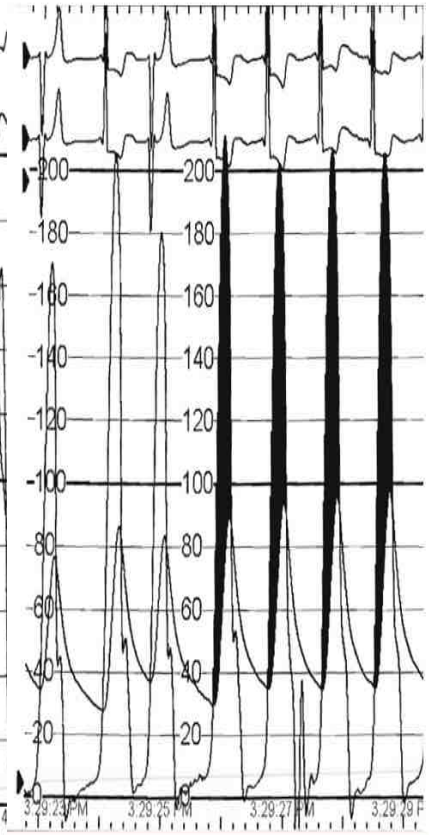


CO 3.4, Mean Grad 57, AVA .54

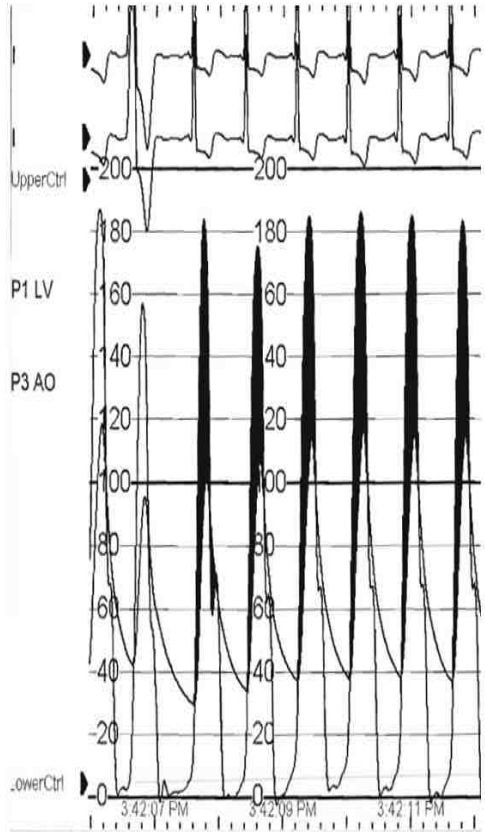


CO 3.6, Mean Grad 17, AVA 1.2

Sub Optimal Result

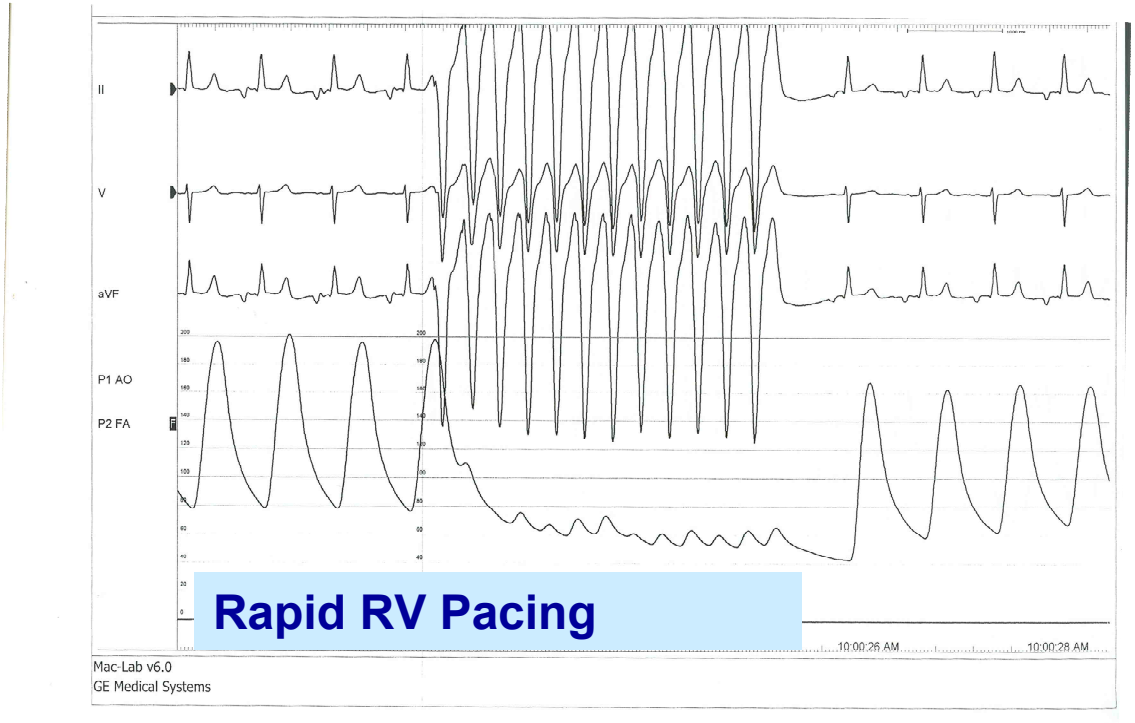


CO 6.2, Mean Grad 100, AVA .62

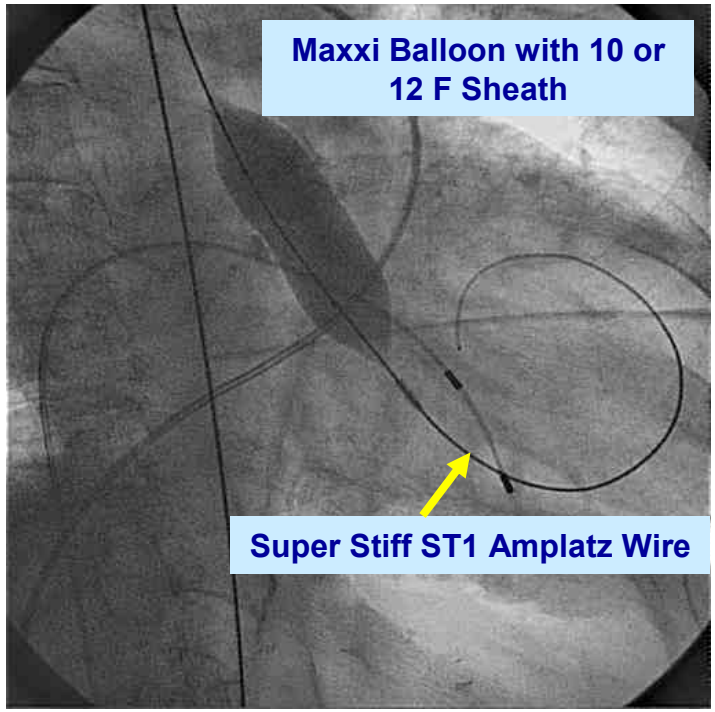


CO 6.2, Mean Grad 54, AVA .94

Technical Aspects



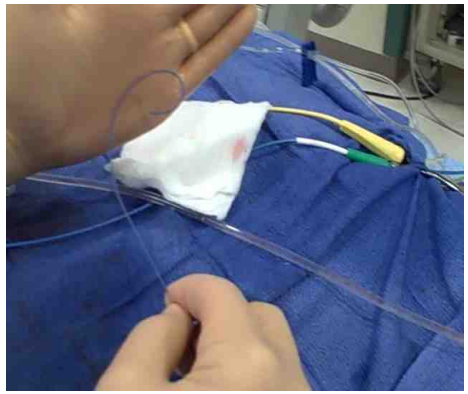
Rapid RV Pacing

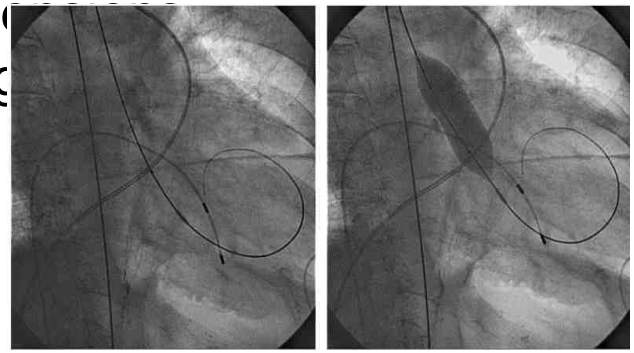


- Use Large balloon (guided by echo-CT-angio)
- Preclose with 6F Proglide
- Reverse Heparin at end of procedure

Procedure:

- Proglide pre closure and 9-13F sheath insertion
- Heparin 10-70 Unit/Kg
- We cross with an AL1.0 5F or JR 4.0 5F using a straight 0.038 inch Terumo wire.
- A pigtail catheter (5F) was exchanged
- Amplatz super stiff ST-1 (1 cm tip) shaped
- Balloon size was determined by analyzing dim on echocardiography, aortogram with marker pig cardiac tomography when available





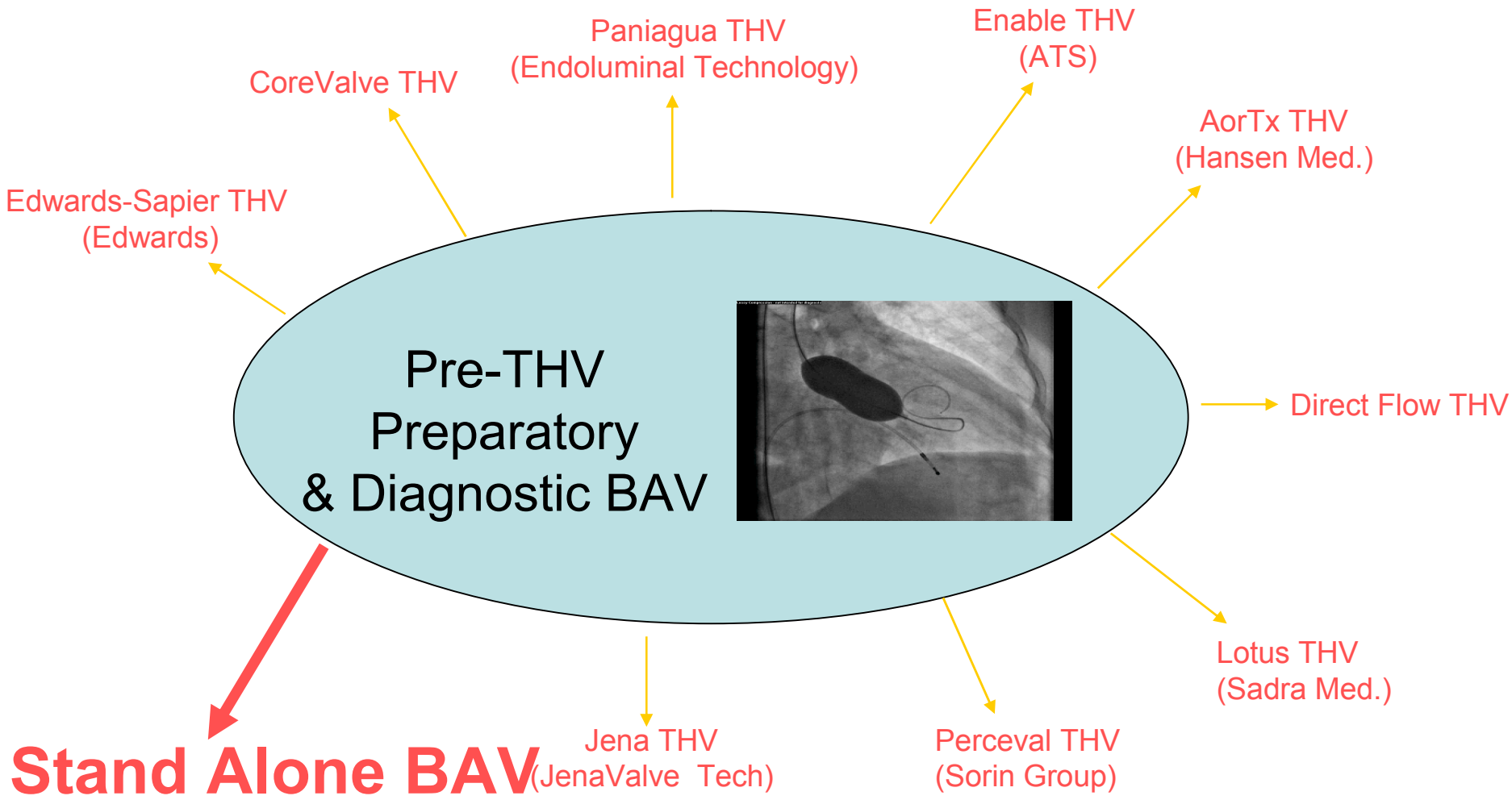
Procedure:

Screw in Temporary Pacer

Medtronic 6416-100 cm 3.5 F Pacer

Pacing at 180 bpm until the blood pressure falls <50 mmHg prior for deployment and to continue pacing until the balloon is fully deflated

BAV is Mandatory Prior to THV Implantation



Current Technology Limitations:

Standard aortic balloons are currently being used off label

- Provides no understanding of interaction between balloon and annulus at any given inflation diameter and pressure

Current balloons are hindered by the complex aortic valve anatomy

Choosing the appropriate balloon size is guesswork:

- "Is the patient big?" → 22 to 25 mm diameter
- "Is the patient small?" → 20 to 22 mm diameter
- Balloon to LVOT diameter ratio of 0.9 to 1.3 (Echocardiographic LVOT measurement often inaccurate)

Multiple Adverse Consequences of Current Aortic Valvuloplasty Technology

1. A strong tendency to undersize balloon (do no harm) results in:
   a) Inadequate improvement in AVA in stand alone BAV
   b) Small failure in ability to deliver THV across stenosed aortic valve
   c) Immobile calcified ridges adjacent to annulus are not adequately assessed and prepared

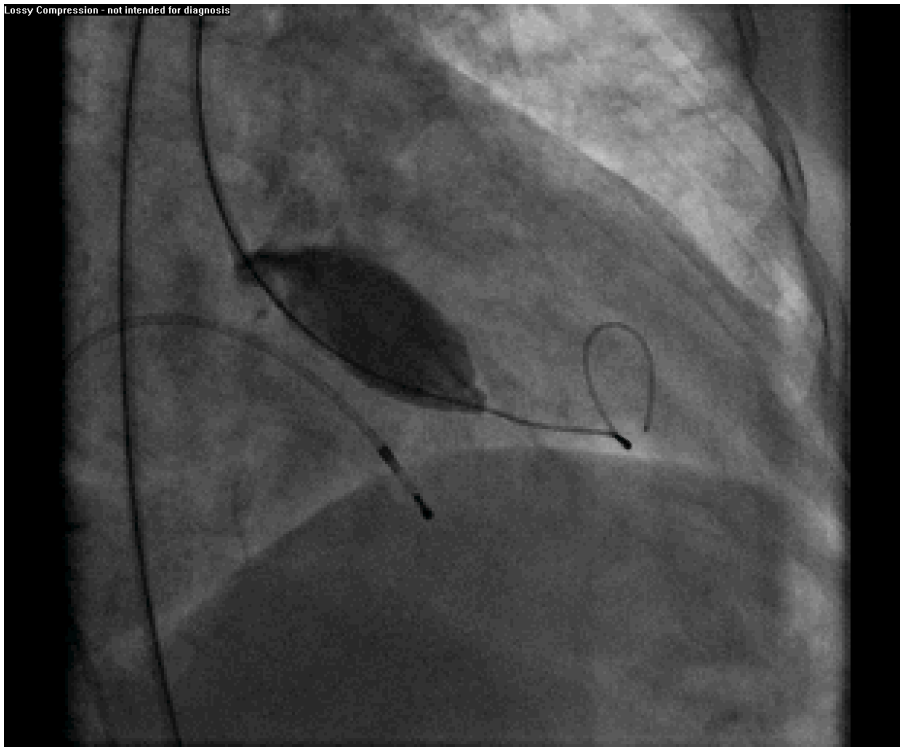
Adverse Consequences of Current Aortic Valvuloplasty Technology

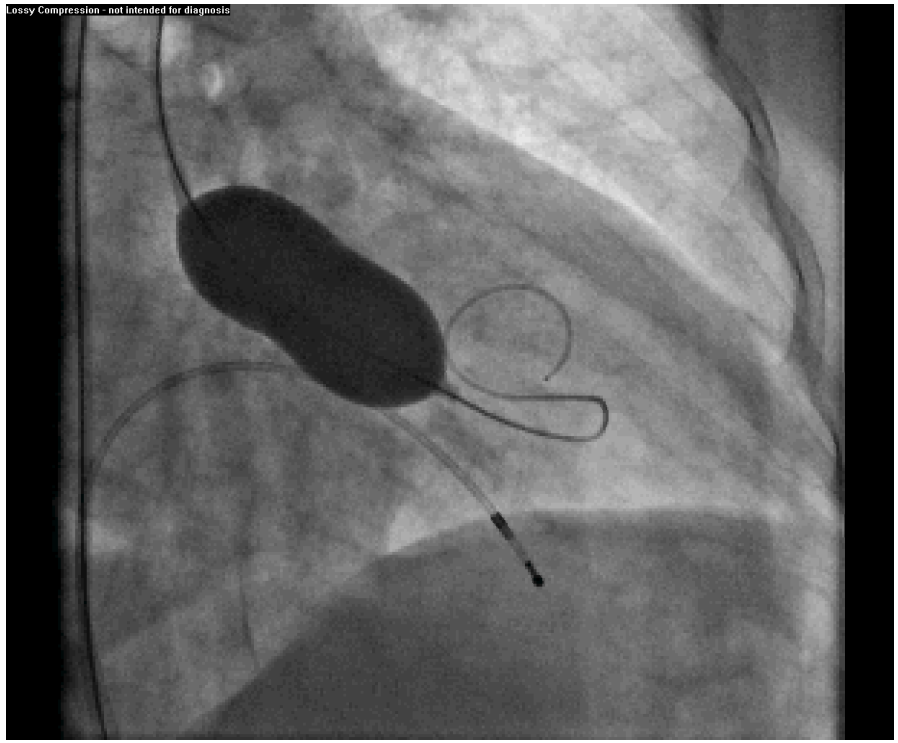
continued....

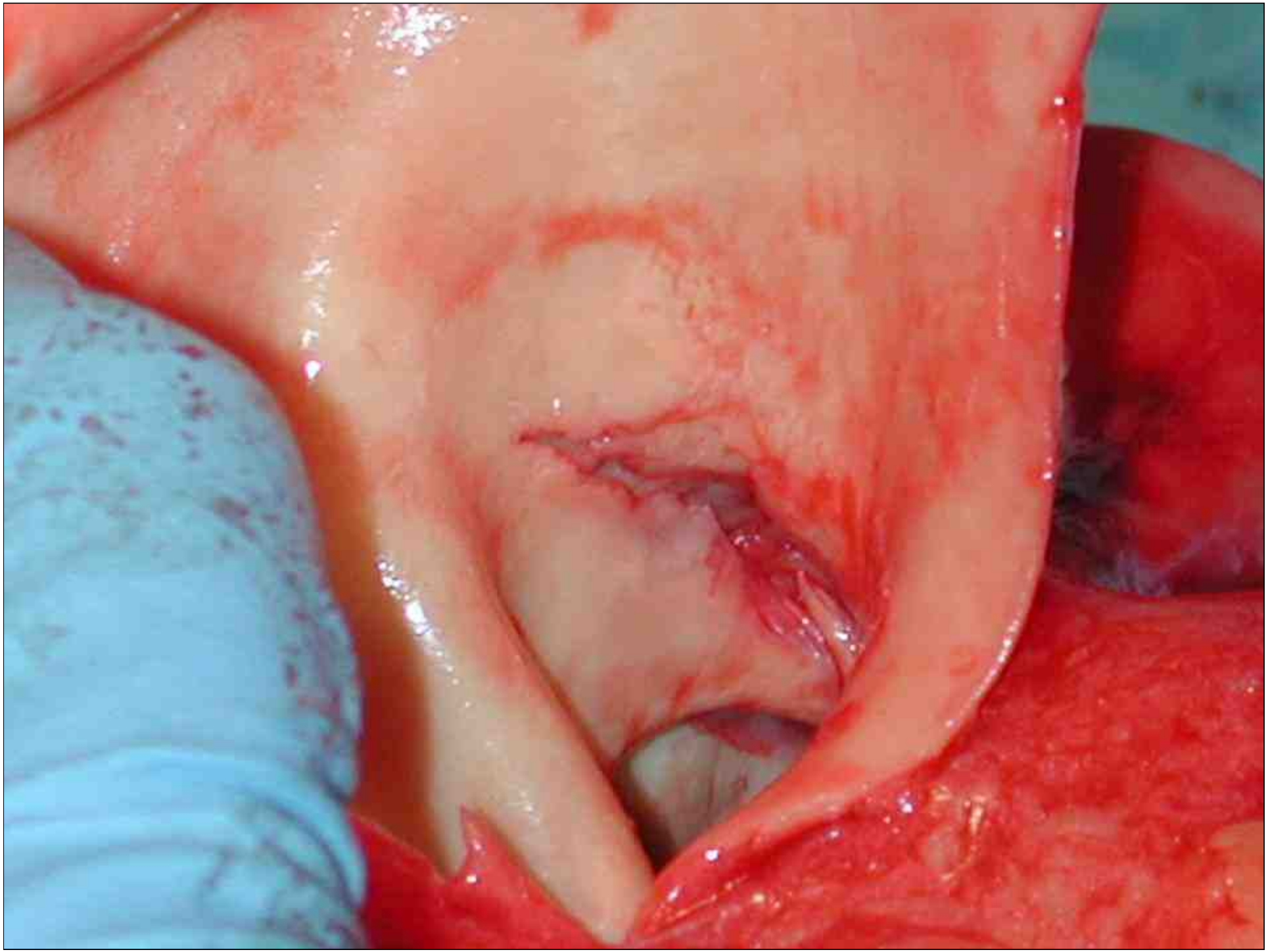
2. Catastrophic consequences can result from overly aggressive dilatation:

Aortic root dissection (occurs in 1-2%)

Balloon Over Inflation







What are the Causes of BAV Procedural Mortality?

210 consecutive BAVs at MHI

June 2003 to July 2008

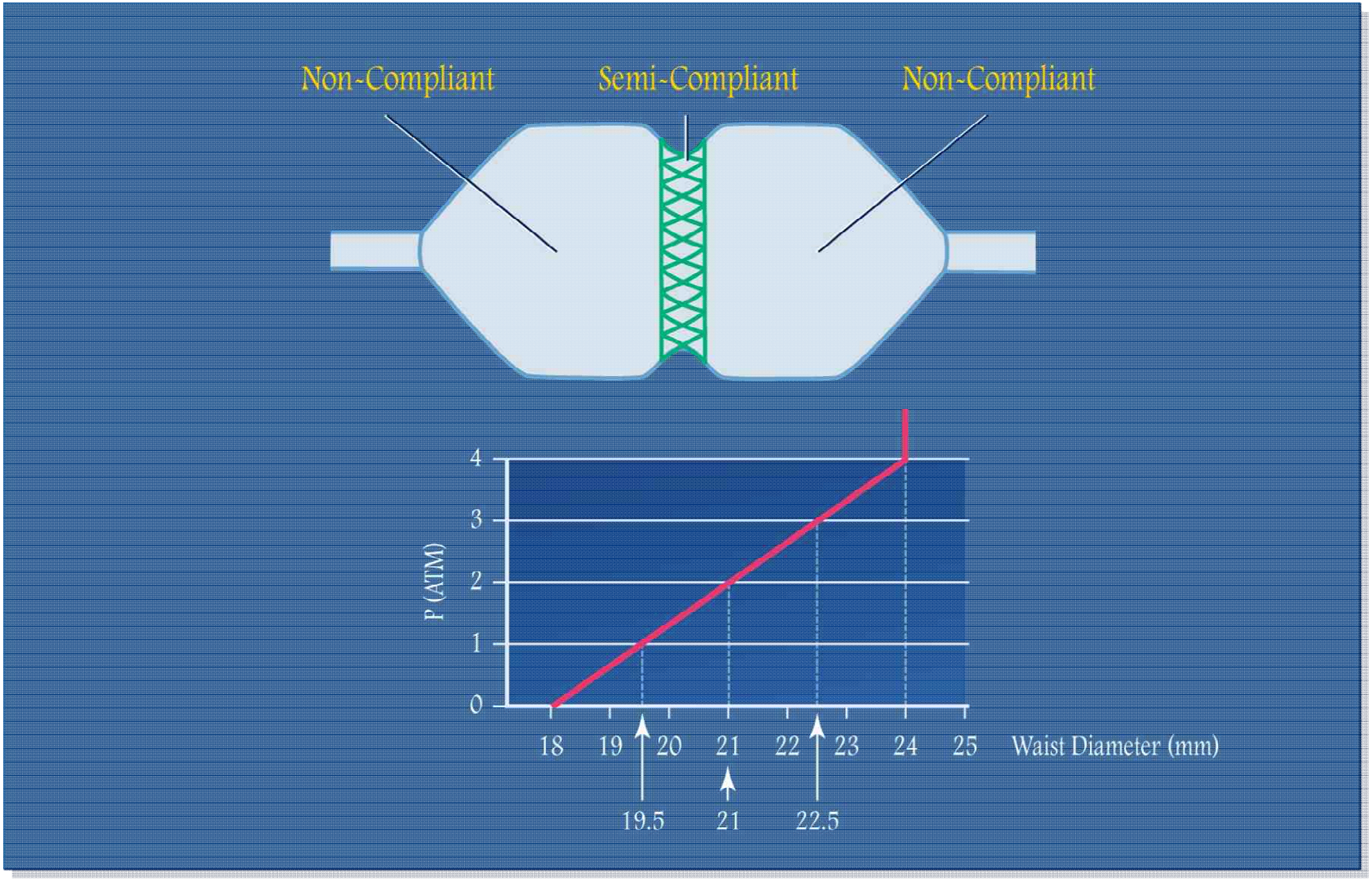
↓

Procedural mortality

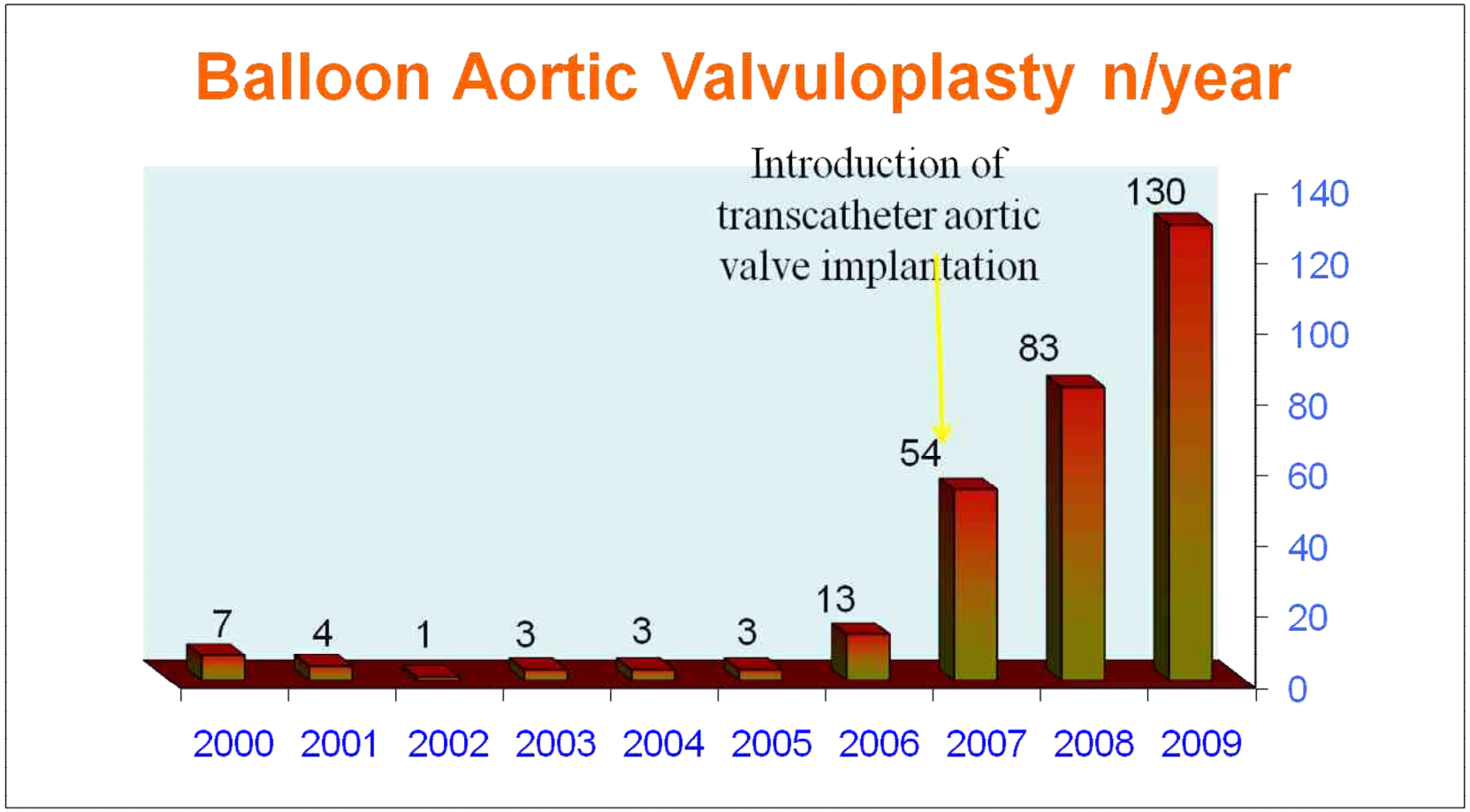
7/210 (3.3%)

- 4 aortic root dissections (2%)
- 1 electrical mechanical dissection
- 1 pulmonary hemorrhage
- 1 hemodynamic collapse (cause unknown)

(MHIF BAV database 210 consecutive patients)


Non-Compliant
Semi-Compliant
Non-Compliant
P (ATM)
4
3
2
1
0
18
19
20
21
22
23
24
25
Waist Diameter (mm)
19.5
21
22.5

Results (301 BAV procedures)



262 patients who underwent 301 BAV procedures among these 29 patients underwent 2 BAV, 8 patients underwent 3 BAV and 2 patients underwent 4 BAV procedures.

Symptomatic aortic stenosis

High risk/non operable

Washington Hospital Center
MedStar Health

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

469 patients with severe aortic stenosis screened for TAVI trial

- **107 (22.8%) enrolled in TAVI trial**
- **362 (77.2%) not eligible for TAVI trial**

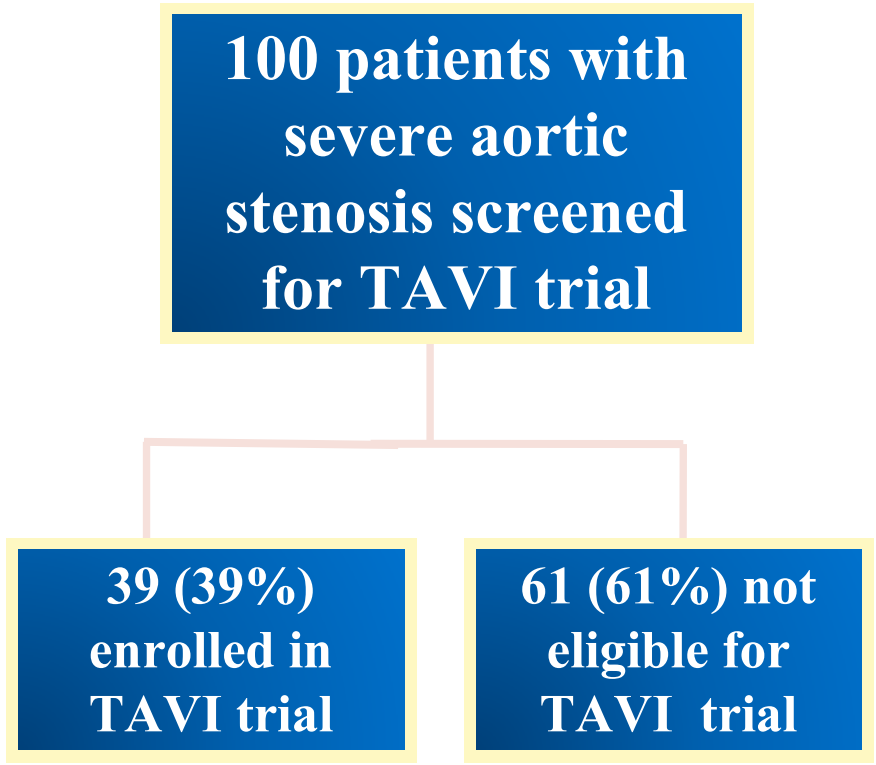
382 patients with severe aortic stenosis screened for TAVI trial

- **112 (29.3%) enrolled in TAVI trial**
- **270 (70.7%) not eligible for TAVI trial**

Symptomatic aortic stenosis

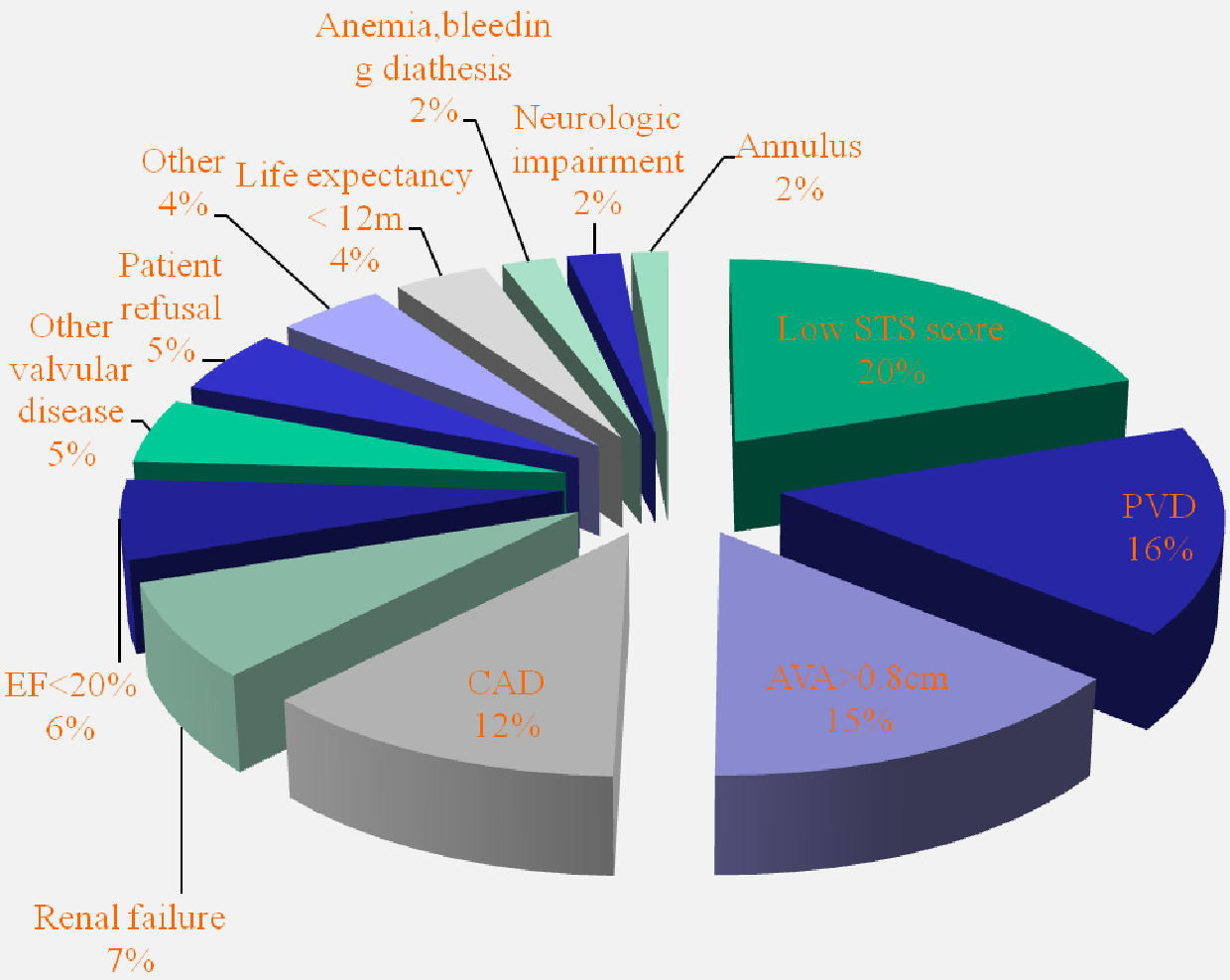
High risk/non operable

Erasmus MC: University Medical Center Rotterdam



EuroIntervention. 2008 Aug;4(2):169-72

Causes for ineligibility



- **75 (20.7%) had two reasons for rejection**
- **26 (7.1%) had three reasons for rejection**

Symptomatic aortic stenosis
High risk/non operable-BAV

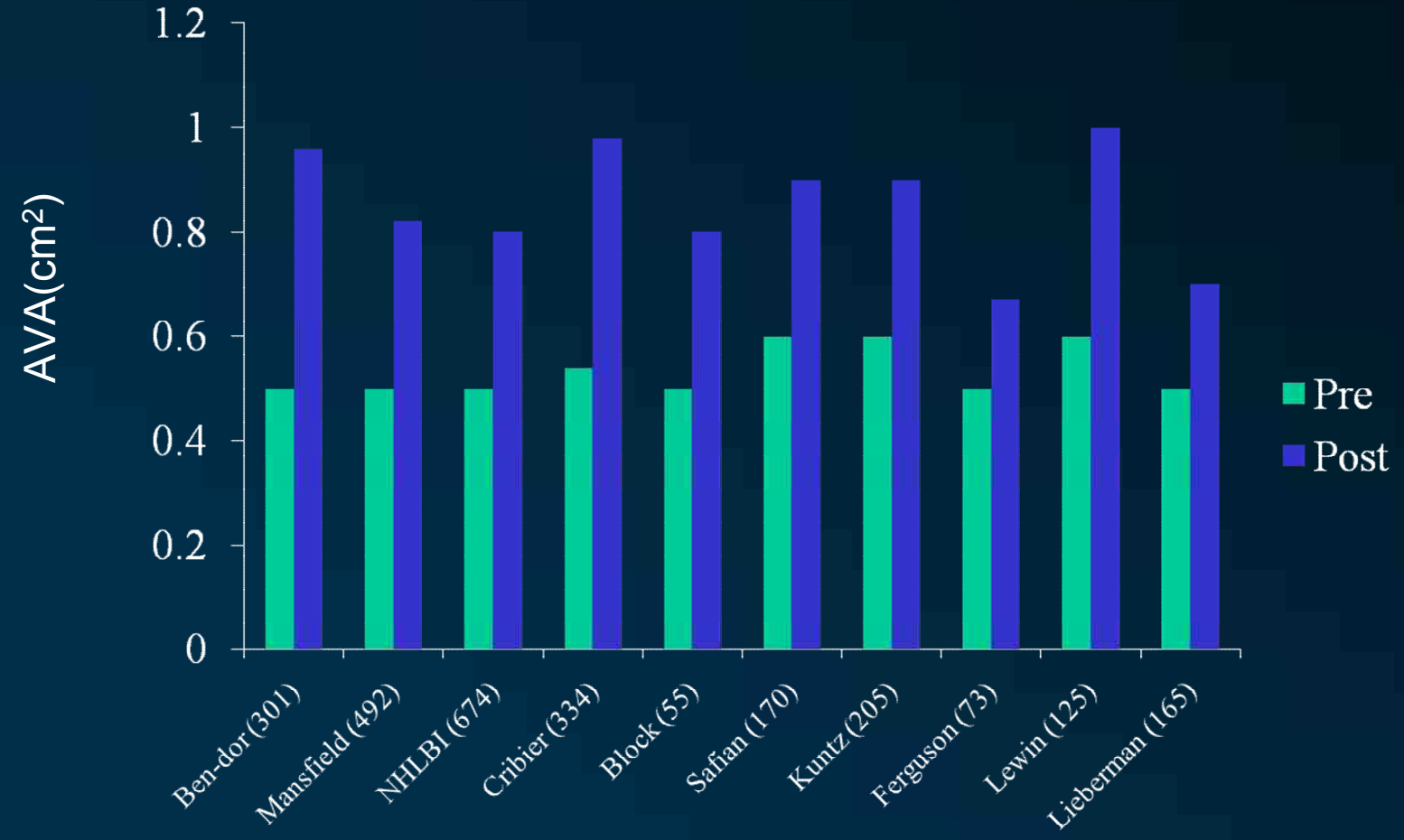
Improve symptoms

Mansfield Registry Data (n=492)

	Pre (%)	6m f/u (%)	p
CHF	54	49	ns
Fatigue	59	61	ns
Dyspnea	87	71	ns
NYHA III/IV	71	57	<0.05
Angina	53	33	<0.05
Syncope	23	12	<0.05

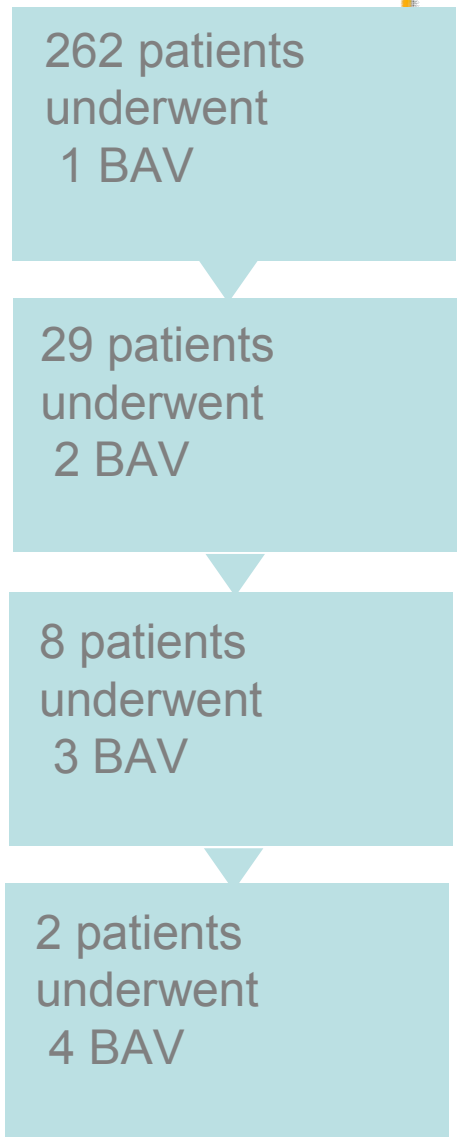
Symptomatic aortic stenosis
High risk/non operable-BAV

And it improves AVA

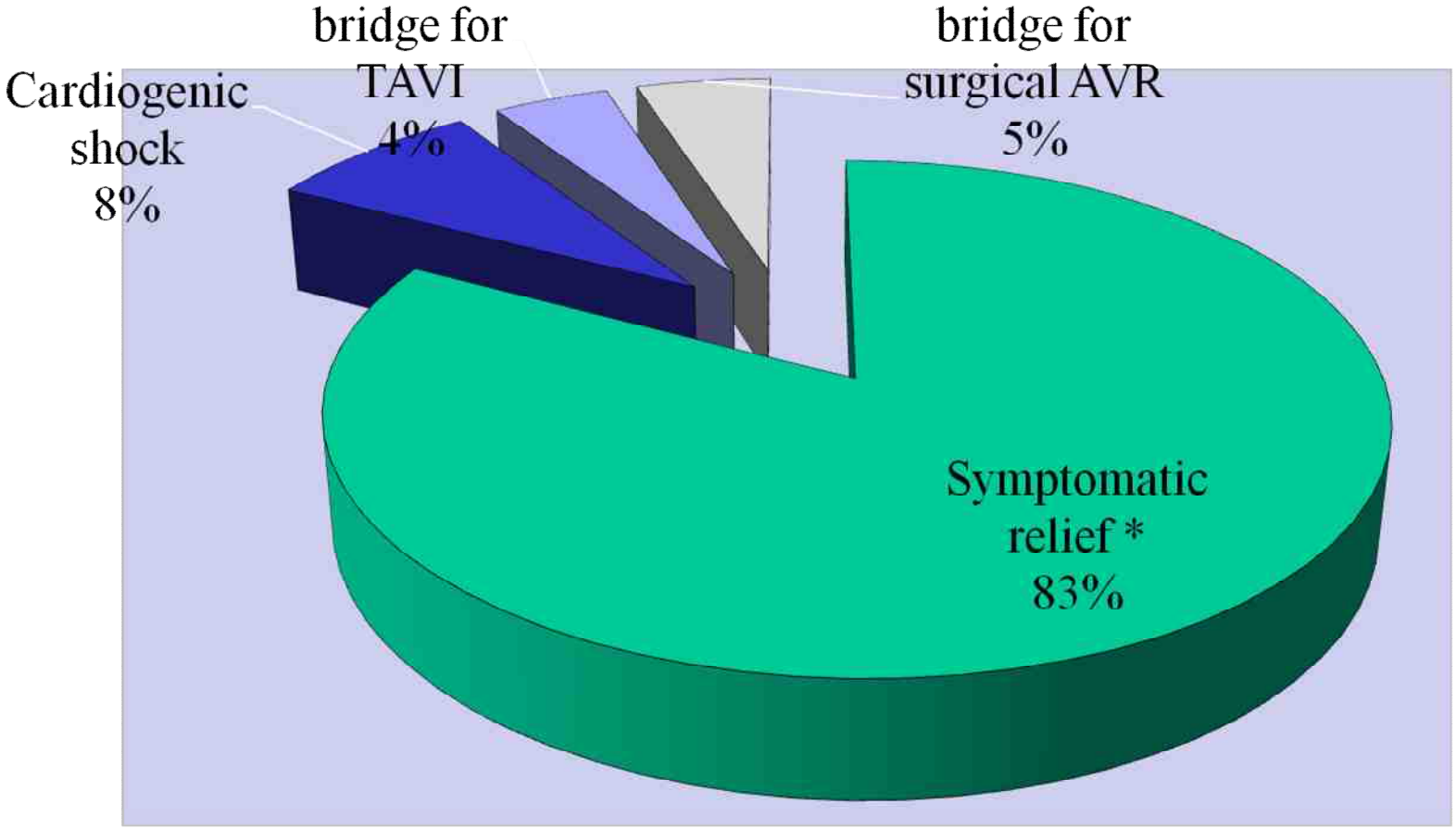


Washington Hospital Expireienc (262 patients 301 BAV procedures)

Follow up- Median time for follow-up was 181 [56, 436] days

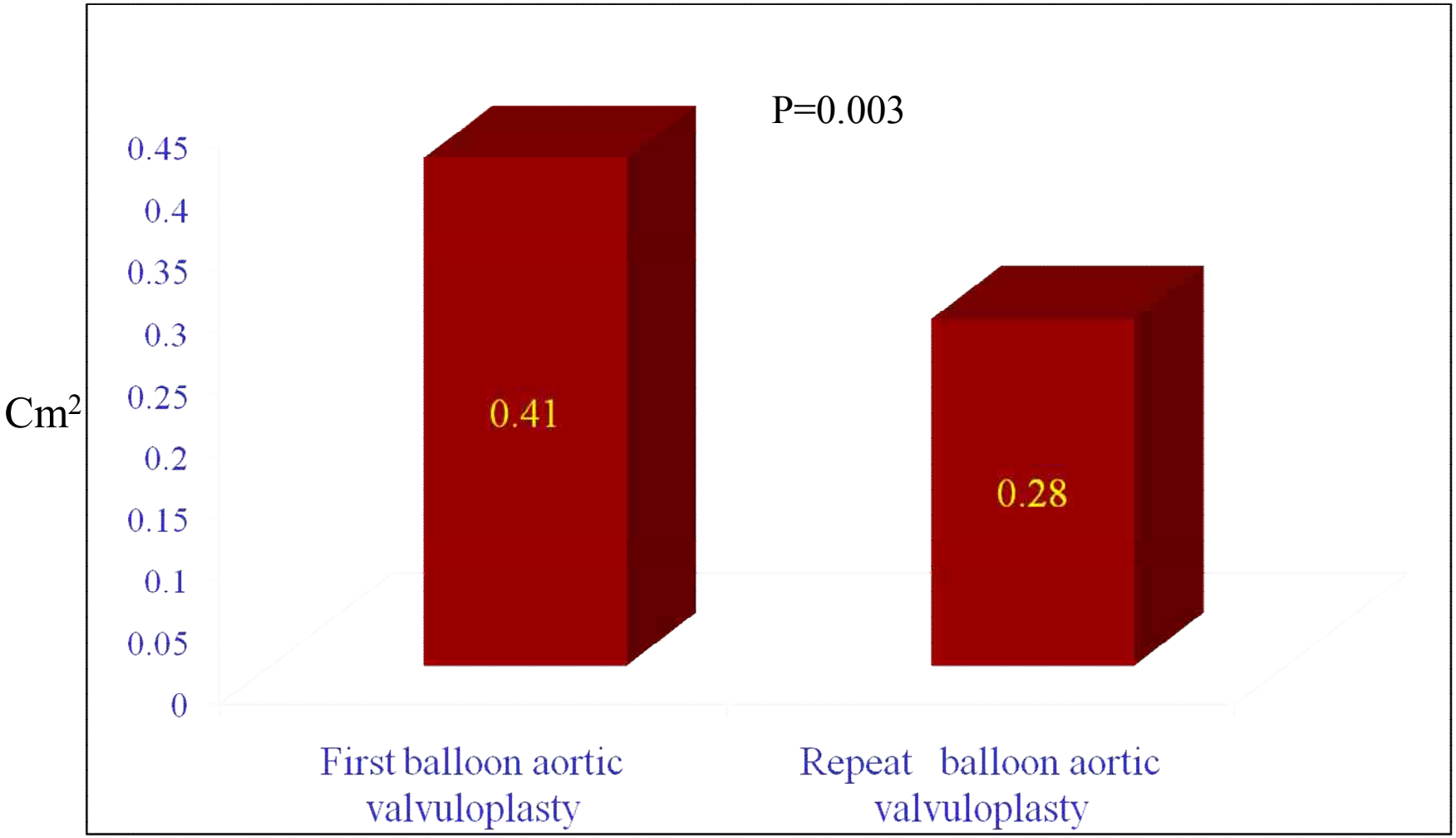


Indication for BAV (n=301)

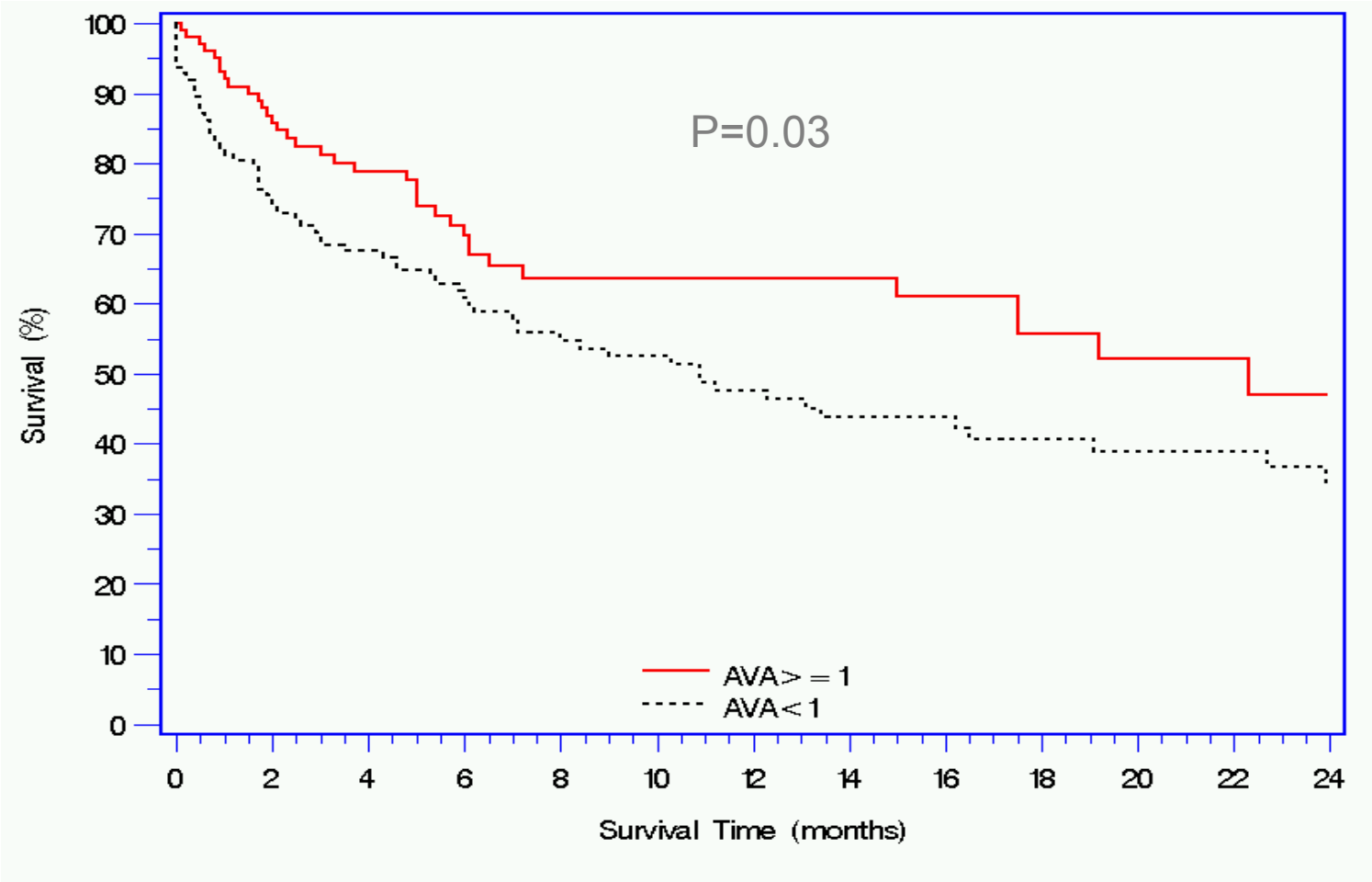


* Or evaluation of reversibility of severe left ventricular dysfunction/ evaluation of reversibility of severe mitral regurgitation and severe pulmonary hypertension

Delta increase in AVA: First vs. repeat procedure

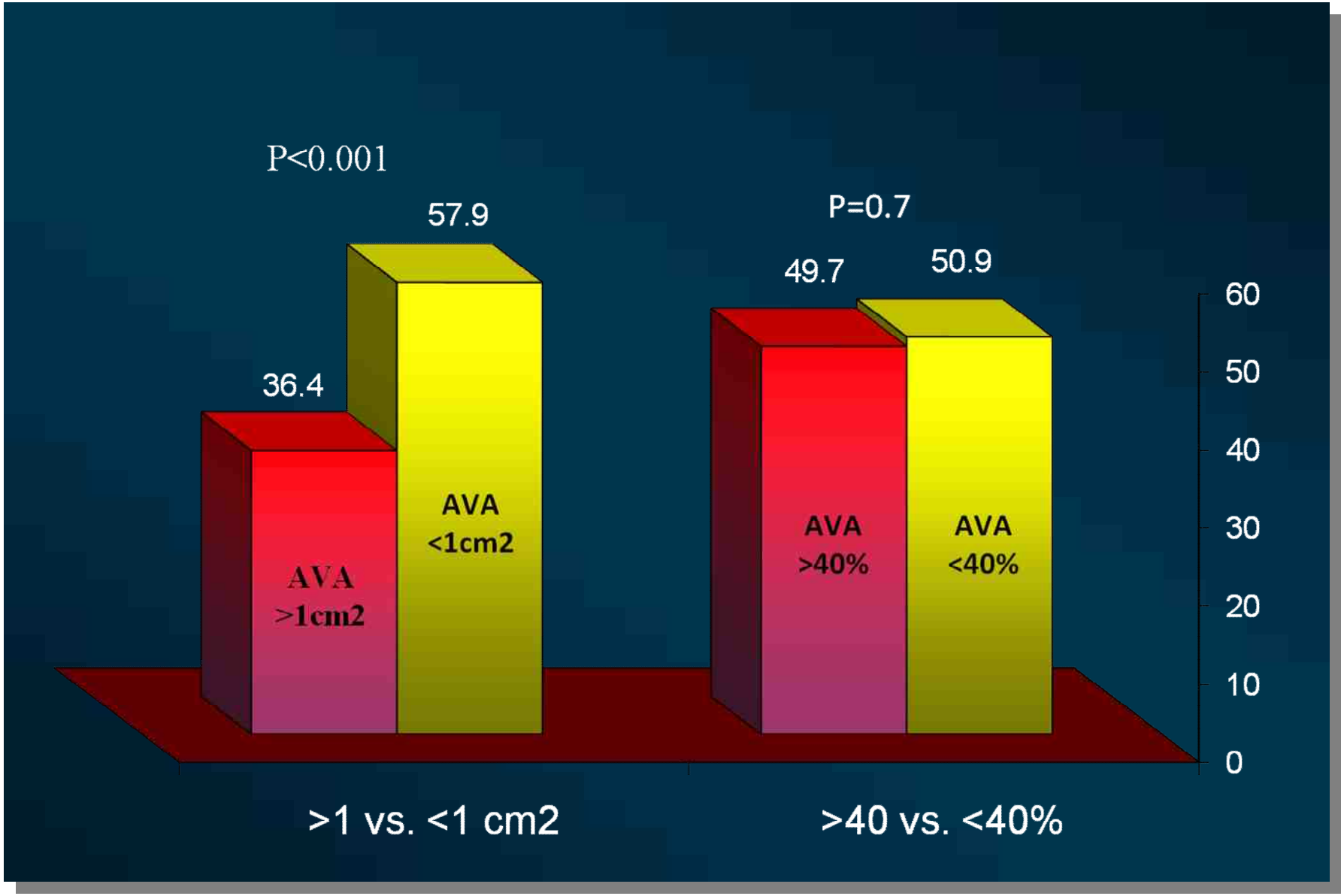


Mortality



During median (25th, 75th interquartiles) follow-up of 181 [56, 436] days the mortality rate was 131 (50%)

Mortality according to final AVA



Predictors for mortality

	Univariate Cox Analysis		
	Hazard ratio	**95% CI**	**P value**
Male	1.43	1.01-2.01	0.04
Cardiogenic shock	2.5	1.5-4.1	<0.001
NYHA class IV	2.97	1.9-4.5	<0.001
Renal failure	2.09	1.46-2.98	<0.001
Sodium level	0.95	0.9-0.99	0.01
Septal thickness	0.15	0.005-0.43	<0.001
Final aortic valve area	0.46	0.22-0.95	0.03
Aortic systolic pressure	0.99	0.98-1	0.03
Delta drop in hematocrit level	1.1	1.06 – 1.14	<0.001
Delta rise in creatinine level	1.42	1.22-1.67	<0.001
Delta rise in troponin level	1.02	1.0-1.03	0.04
Multivariate Cox Analysis			
Renal failure	2.23	1.09 – 4.54	0.01
NYHA class IV	4.91	1.88-12.8	0.001
Pulmonary pressure	1.03	1.01-1.06	0.01
Delta drop in hematocrit level	1.16	1.04-1.3	0.01

Complications %

N	Procedural Death	CVA	Tamponade	Severe AR	Vasc
NHLBI (674)	3	3	1	1	14
Mansfield Registry (492)	7.5	2.2	2	1	11
Cribier (334)	4.5	1.4	0.6	0	13.1
WHC (262)	1.6	1.9	0.3	1.3	6.9
Kuntz (219)	4.4	0	1	1	9
Agarwal (212)	1.1	0.4	0.4	1.1	13.5
Safian (170)	3.5	0	1.7	N/A	10
Lewin (125)	10.4*	3.2	0	1.6	9.6

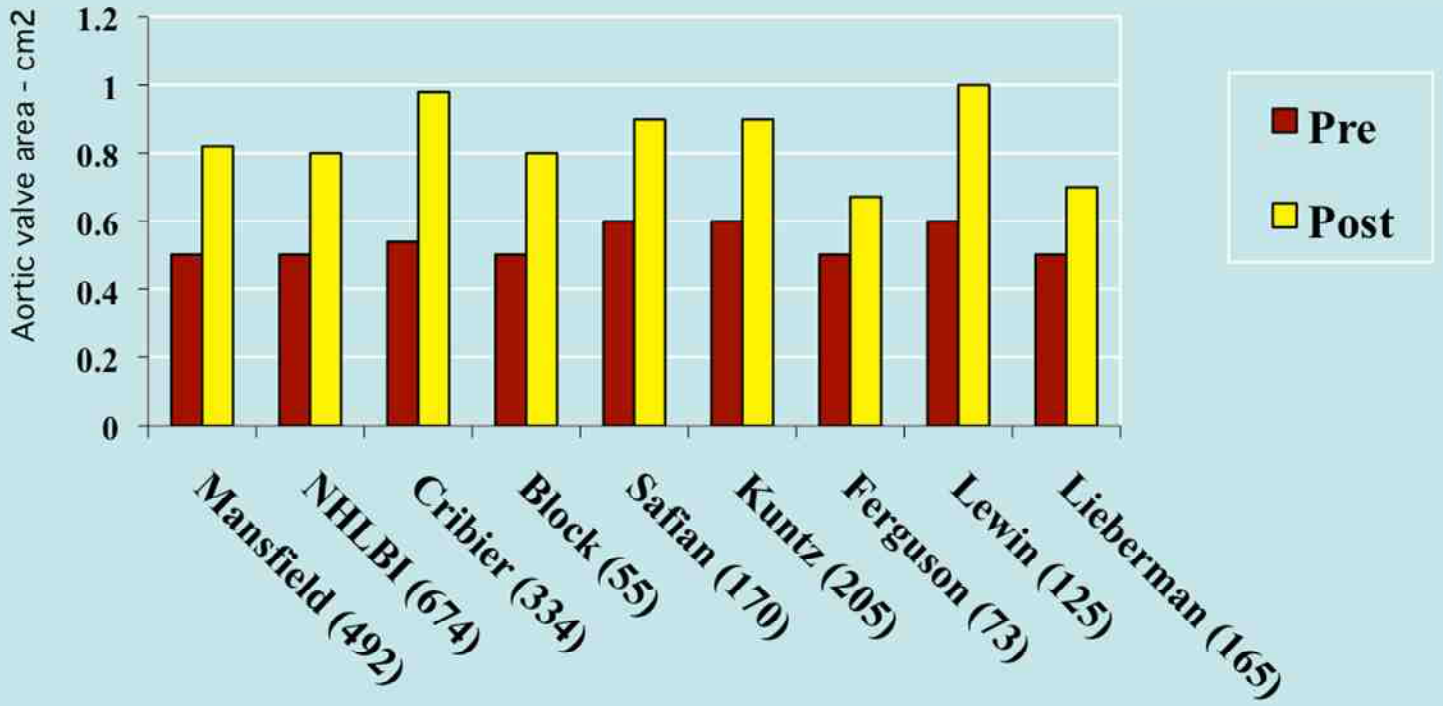
* In hospital mortality

Mortality %

	N	Procedural Death	1 year	2 years	3 years
NHLBI	(674)	3	45	65	77
Mansfield Registry	(492)	7.5	36	N/A	N/A
Cribier	(334)	4.5	24	34	N/A
WHC	(262)	1.6	42	59	N/A
Kuntz	(219)	4.4	25	40	47
Agarwal	(212)	1.1	36	53	72
Safian	(170)	3.5	36	N/A	N/A
Lieberman	(165)	N/A	39	59	75
Lewin	(125)	10.4*	38	N/A	N/A

* In hospital mortality

Hemodynamic Results of BAV



Increase of aortic valve area: 0.3-0.4 cm^2

PTAV can be Accomplished with Low Complication Rate

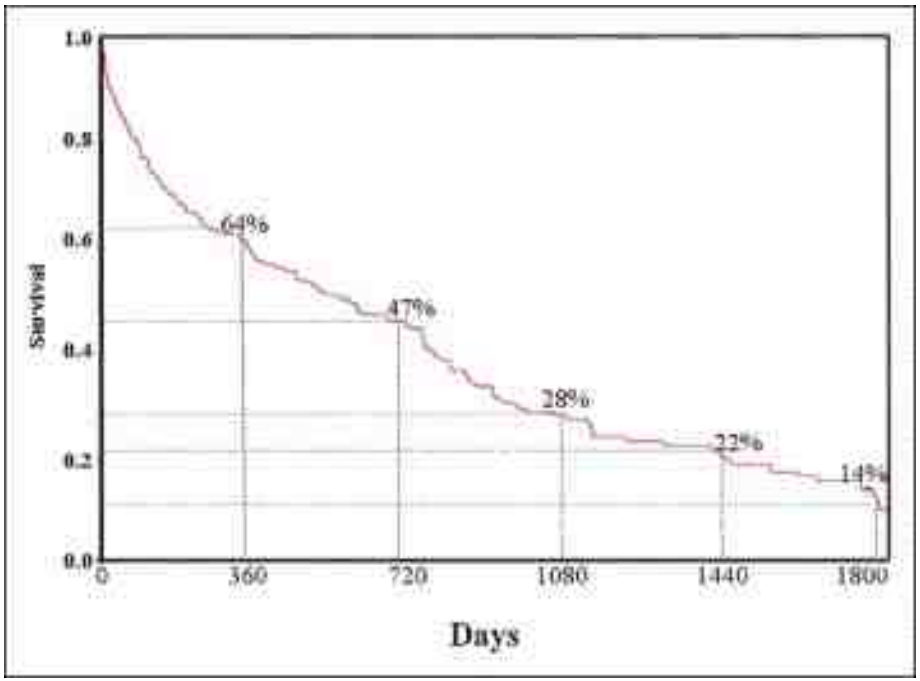
	WHC
Patients n=	196
In-Hospital Mortality	1.6%
Vascular complications	6.1%
Severe AI	1.6%
Stroke (mostly minor)	1.5%

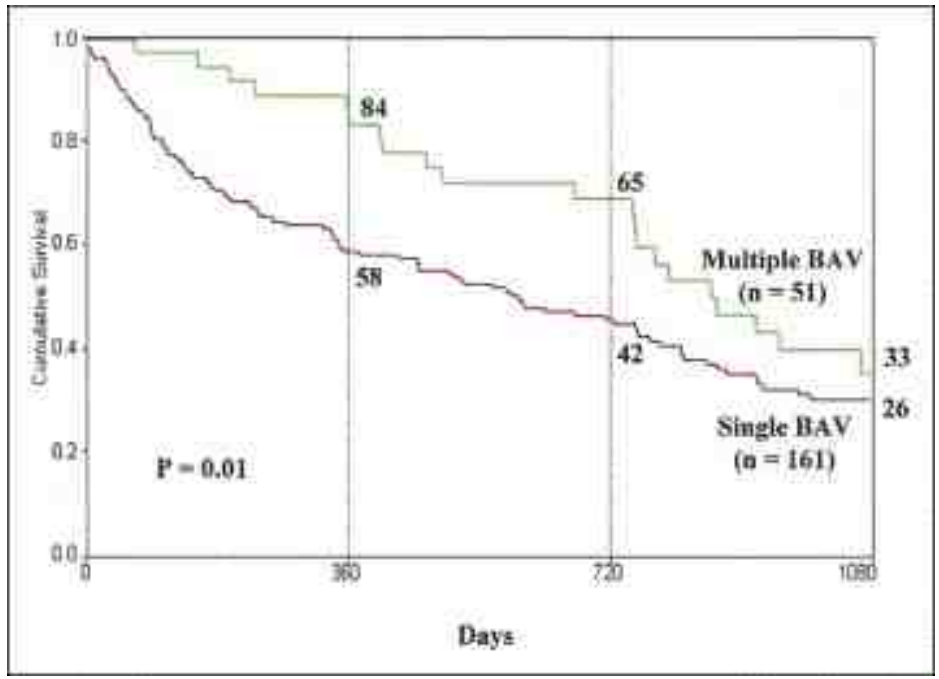
BenDor, Satler, Pichard et al. AHA 09

Survival after PTAV is Low.

Agarwal, Sharma et al. AJC 2005;95:43-7

212 cases

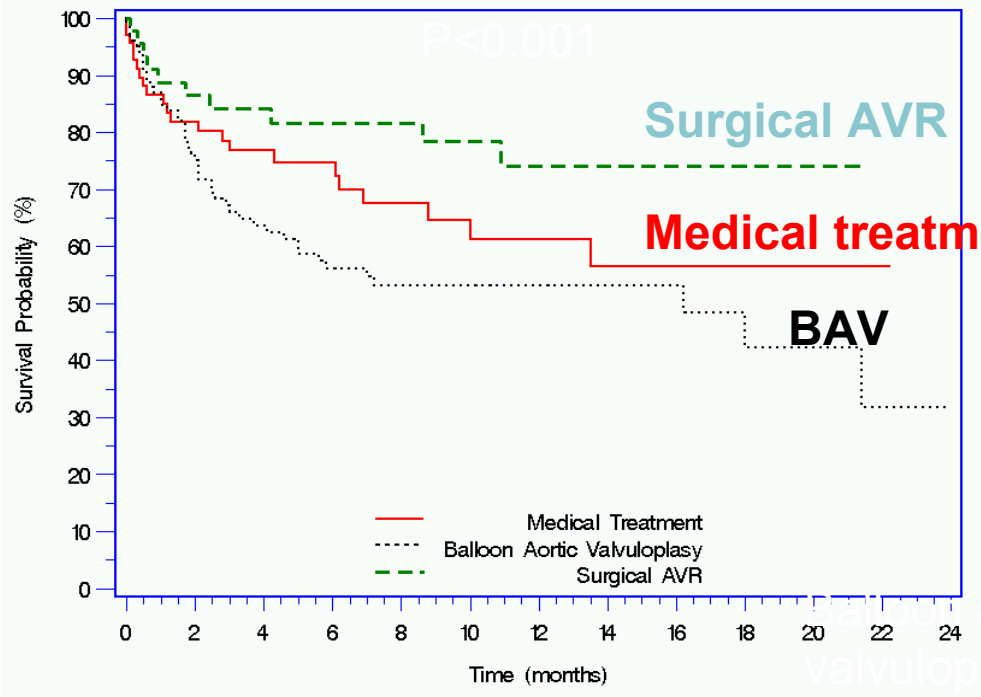




Survival after Single PTAV is Low

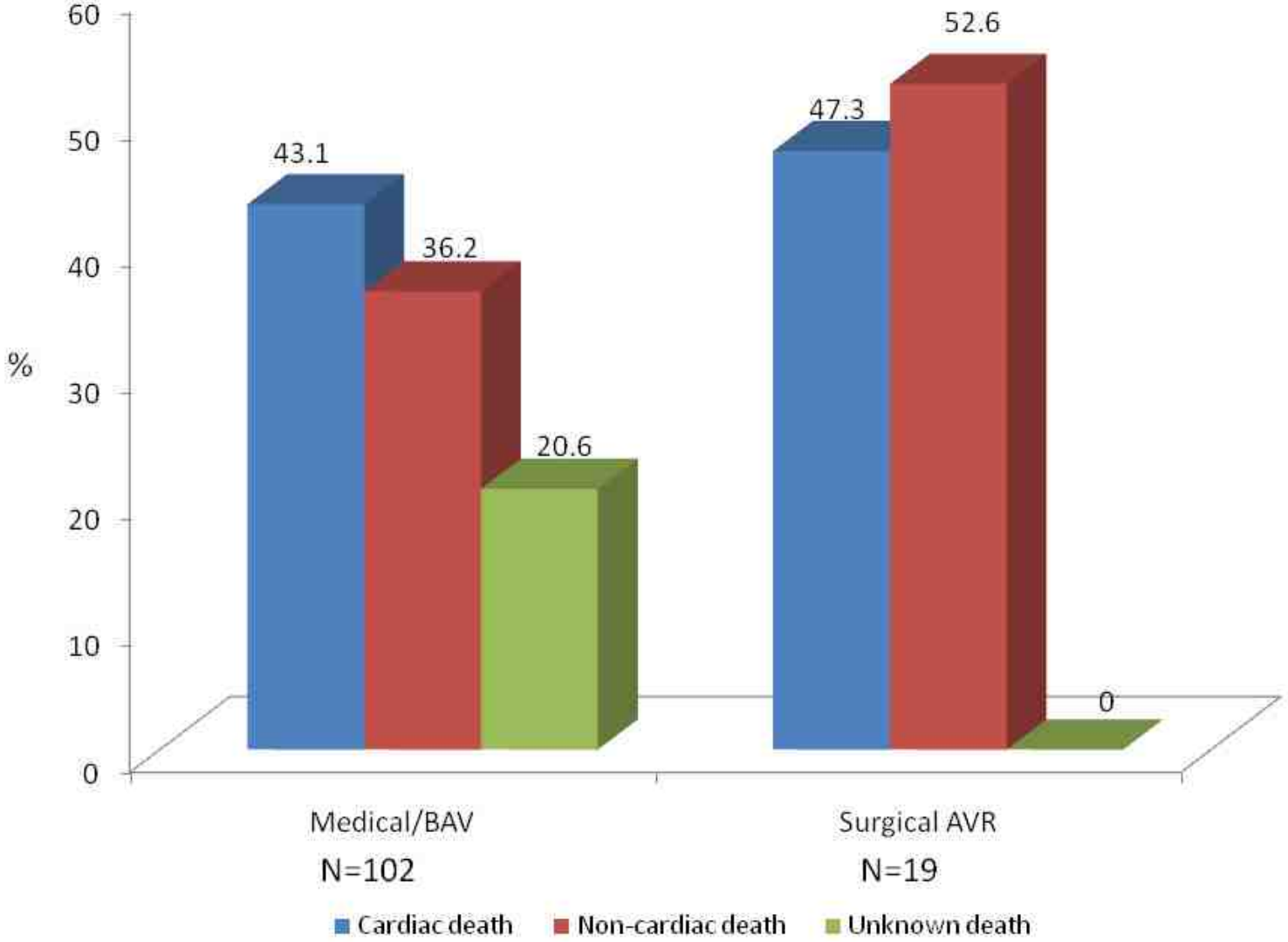
WHC: Ben-Dor et al. ACC 09

255 patients excluded from the Partner Trial at WHC



<u>Medical group</u>: higher STS 12.8±7.0 vs. 8.5±5.1, p<0.001 and logistic Euroscore 42.4±22.8 vs. 24.4,
<u>Surgical Group:</u> surgical mortality 3.4%, in hospital mortality 17.04%, and 17.8% discharged to nursing care facilities due to debilitation.

Cause of Death



Clinical Benefit of BAV

- **Temporary improvement in:**
  - **CHF**
  - **syncope**
  - **angina.**

- **Hypothesis: "repeated BAV could decrease the rate of death"**
  - **should we recommend BAV q 3-6 months until definitive therapy is performed ?**

Diagnostic Benefits of BAV

90 year old

Recurrent pulmonary edema.

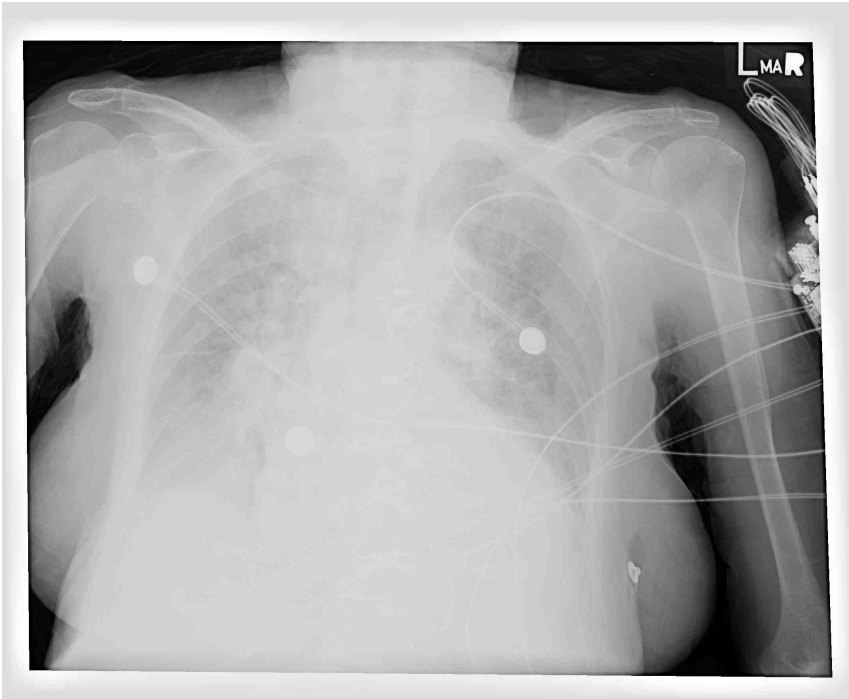
EF 20%, 4+ MR, BNP 5,000.

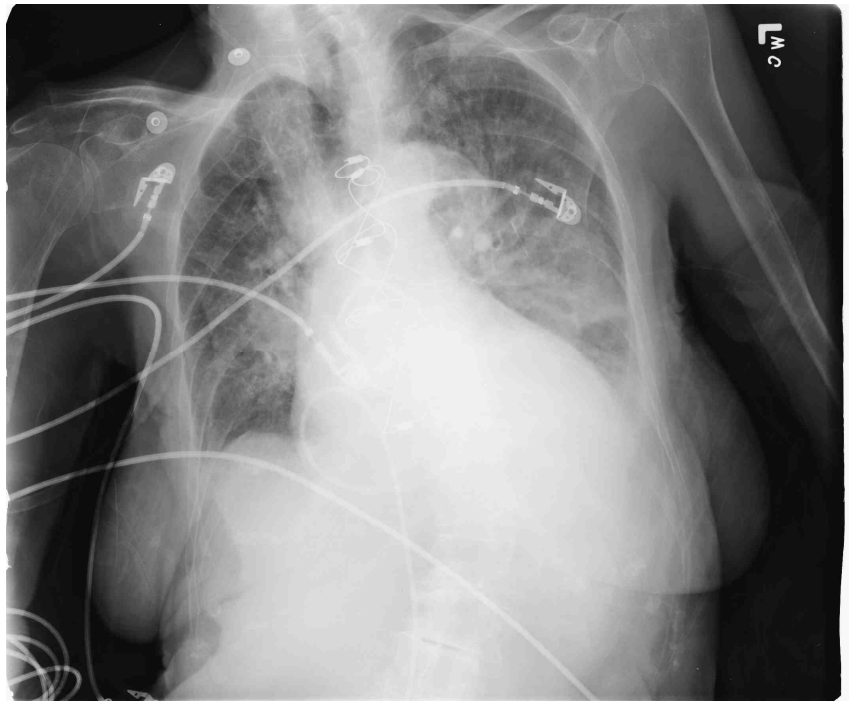
AVA 0.29 cm2. STS 22

<u>After PTAV</u>

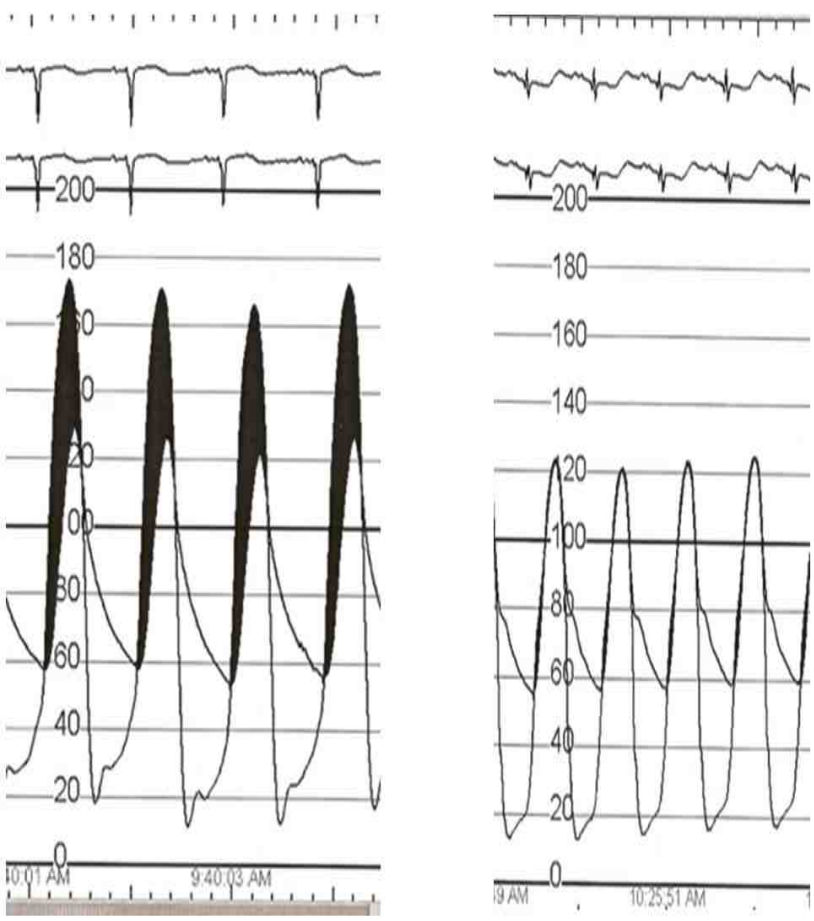
EF improved to 50%

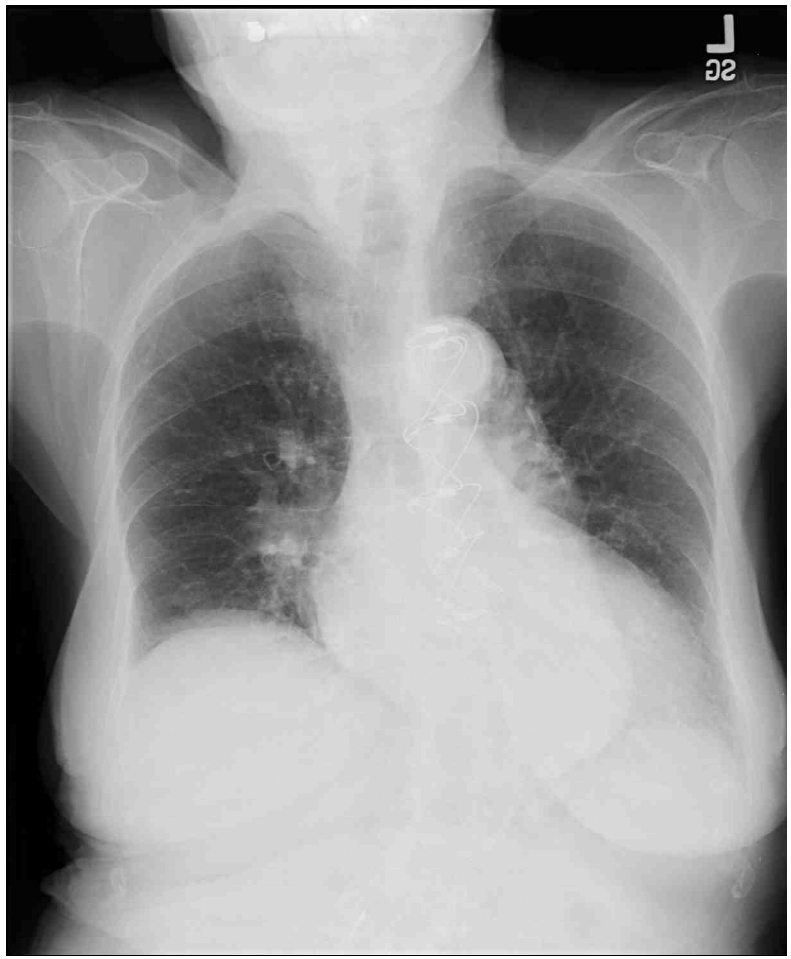
MR decreasedto 1-2+





Patient became eligible for TAVI





Diagnostic Benefit of BAV

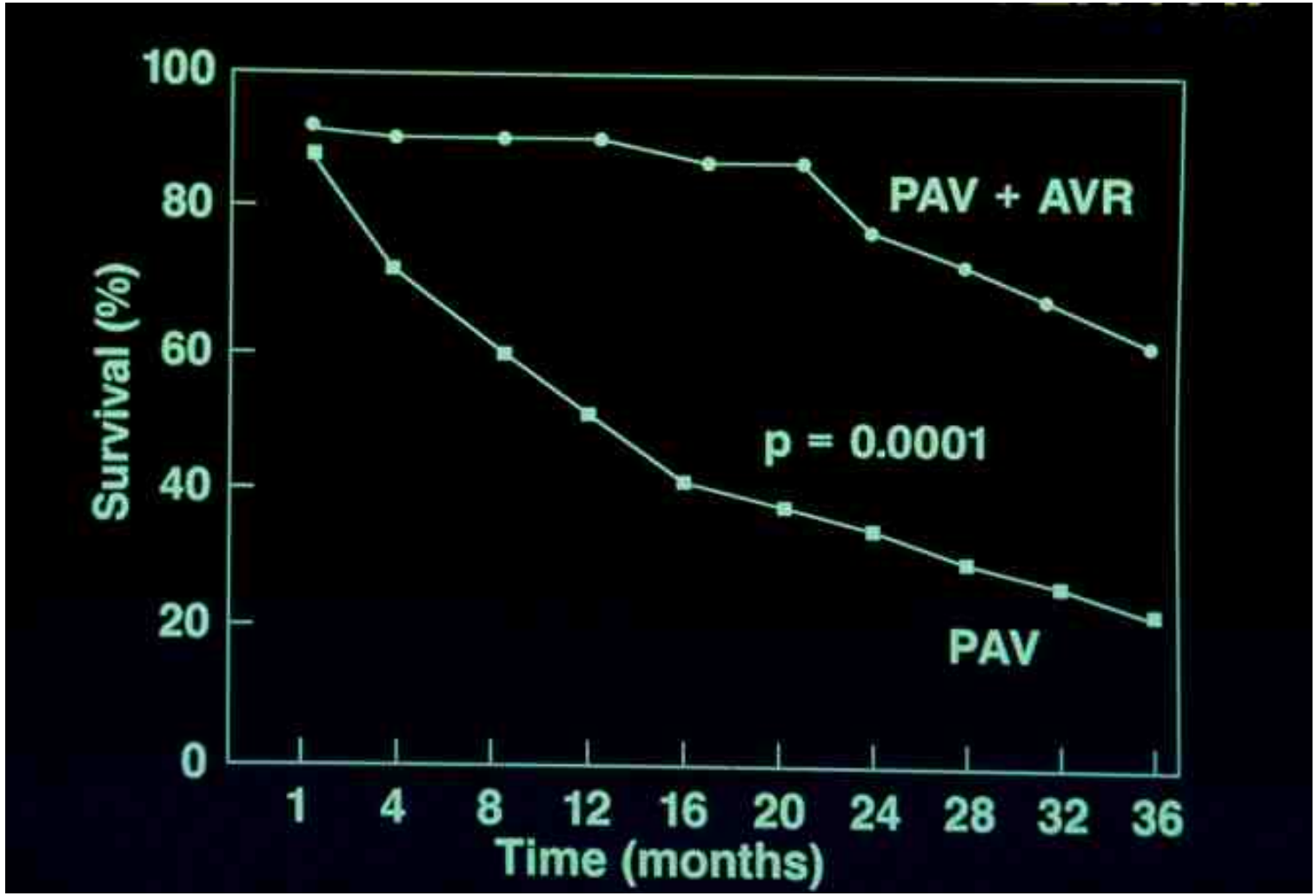
Excellent tool to evaluate reversibility of

- **LV dysfunction**
- **MR**
- **Pulmonary hypertension**

WHC.

Milner et al. Clin Res 36: 302A, 1988.
Milner et al. Clin Res 3:302A, 1988.
Milner et al. Clin Res 37:6A, 1989.

BAV as a Bridge to AVR



Indications for BAV

- **Best Indications:**
  - Bridge to AVR.
  - Evaluate for reversibility of severe LV dysfunction and severe MR.
- **Other Indications:**
  - Palliative symptom alleviation.
  - Temporizing for percutaneous AVR.
  - Urgent therapy for patients is severe CHF/shock due to critical AS.

AHA/ACC 2008 Update for BAV Guidelines.
J Am Coll Cardiol 2008; 52:e1-142

Operative Risk	AVA	Other	Class
High	~~≤0.7~~ 1.0 cm²	Bridge to AVR *	~~IIab~~
–	~~≤0.7~~ 1.0 cm²	Severe Comorbidity	IIb
–	≤0.7 cm²	Prior to urgent noncardiac surgery	~~IIb~~
Not high	~~≤0.7~~ 1.0 cm²		III

- **The valve area threshold increased from 0.7 cm2 to 1.0 cm2.**
- **"Prior to urgent noncardiac surgery" has been eliminated as an indication.**
- **Most importantly, unless operative risk is high, BAV is never indicated**

ESC Guidelines for Aortic Balloon Valvuloplasty 2007

Indication	Class
	I
A bridge to surgery in hemodynamically unstable patients who are at high risk for AVR	IIb (level of evidence: C)
Palliation in patients with serious comorbid conditions	IIb (level of evidence: C)
Patients who require urgent noncardiac surgery	IIb (level of evidence: C)

Additional palliative indications:

Expected survival <3 years.
Age >80 , AVR refused
Cardiogenic shock (due to AS)

BAV not helpful in:

- Extreme LV dysfunction, particularly when unrelated to AS (e.g., scar due to large MI's).
- Terminal CHF with multiple system failure.
- Severe arch atheroma with high risk of Cerebral embolization.
- Aortic insufficiency $\geq$2+ at baseline.
- Life-limiting non cardiac illness.

Summary

A. Clinical Benefits of BAV

- Not a permanent cure
- Safe procedure
- Good initial clinical improvement

B. Diagnostic Benefits

- LV dysfunction reversibility
- MR and PH reversibility

C. Bridging for AVR: excellent strategy

D. Therapeutic Benefit:

- Occasionally used for palliative care.

CONCLUSIONS

- BAV will play a central role in the treatment of all nonsurgical AS patients who are candidates for transcatheter therapy.
- Long term survival after BAV is poor.
- A successful valvuloplasty appears to be a final AVA at least 1cm^2 , which is associated with lower mortality rate.
- Trans catheter or surgical aortic valve replacement should be pursued aggressively if final AVA>1cm^2 is not met.
- This may be especially true in patients who developed restenosis after the first BAV since the second BAV is seldom as successful in reaching that end point.