

Aortic Valvuloplasty in 2014

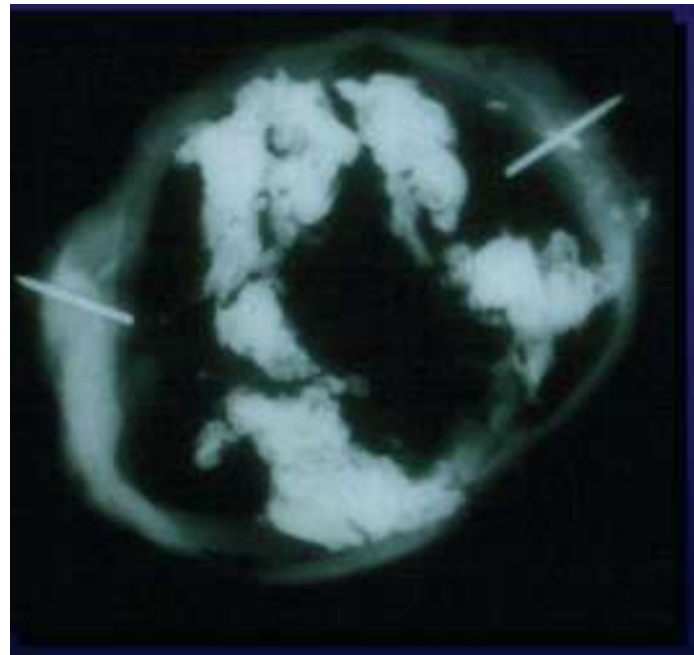
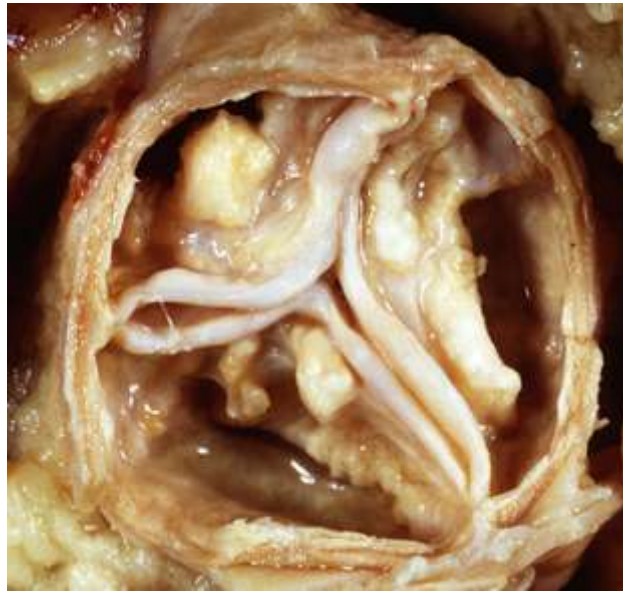
Augusto Pichard, M.D.

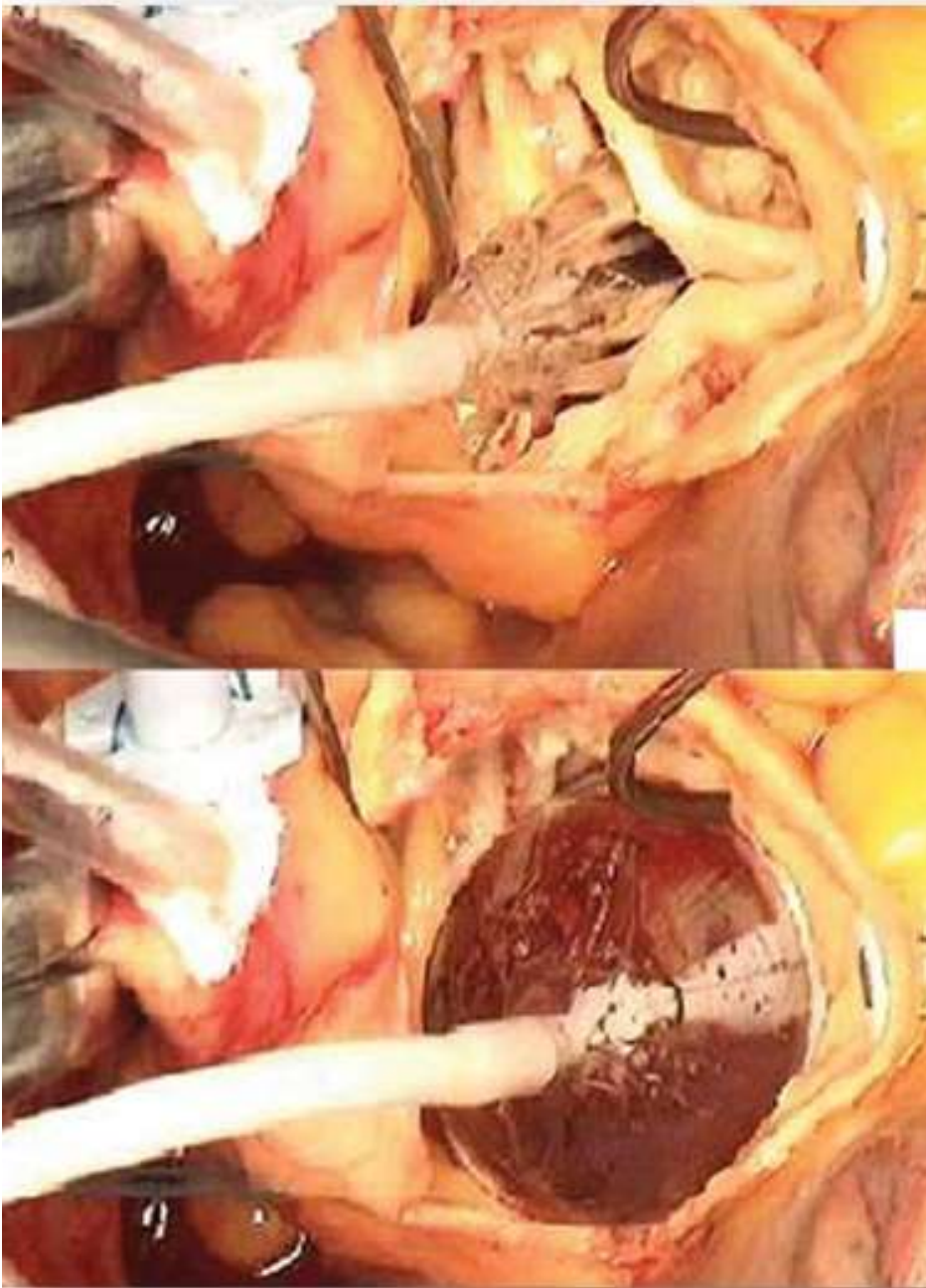
**Director Innovation and Structural Heart Disease,
Vice Chair, Medstar Heart Institute,
Medstar Washington Hospital Center.
Professor of Medicine (Cardiology),
Georgetown University Medical School.**

Washington, DC



Mechanism of Valvuloplasty





**26 patients with BAV
at the time of AVR**

**No Debris
Embolization**

**Wendt et al., Essen.
Min Inv Ther 2011**

Aortic Valvuloplasty Course

Washington Hospital Center 1987.



BAV Technique at WHC

Access:

- Arterial Micropuncture → 6F dilator → preclose with 1 Proglide.
- 8-9-10 F sheath for 20, 22 or 25 Maxi Balloon (Cordis)

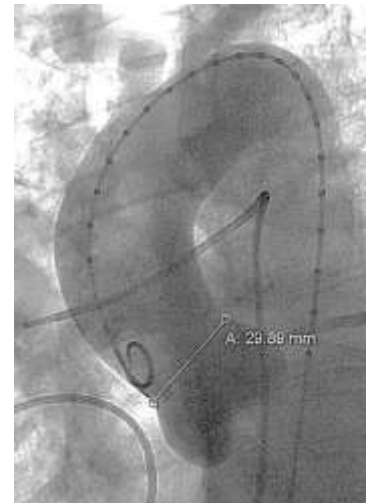
Balloon Sizing

- Measure Sinutubular junction (aortogram with 5F marker pigtail; 10-15 cc contrast) and downsize balloon by 3-5 mm
- Use CT measurements

Inflations

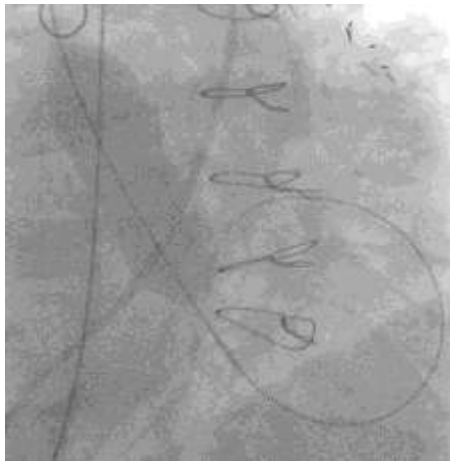
- 20,22 and 25 cc's for 20,22 and 25 mm balloons
- Usually 2 inflations.

Heparin ?

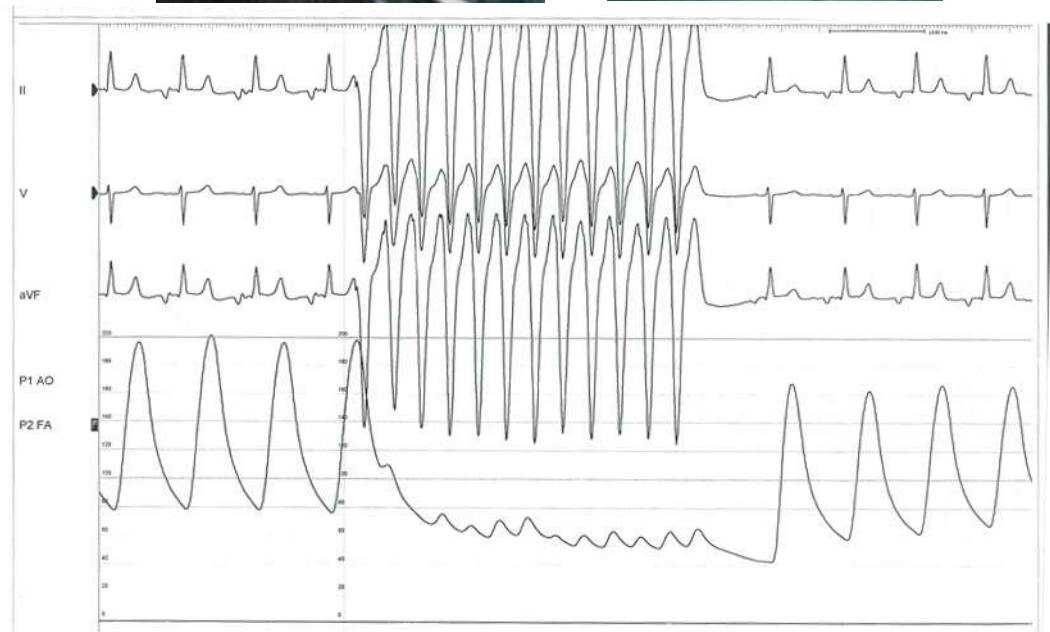


Rapid LV Pacing with Amplatz Super Stiff ST-1 Wire

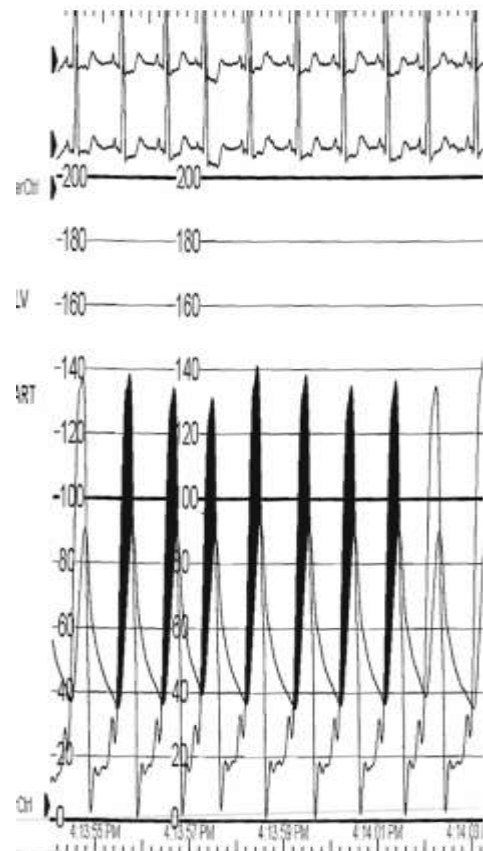
Large, stable loop



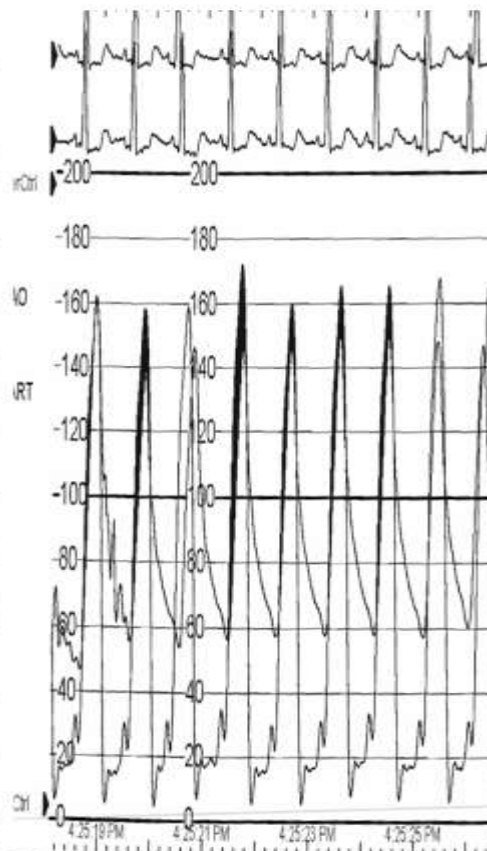
Rapid LV pacing with ST-1 wire



Good Results

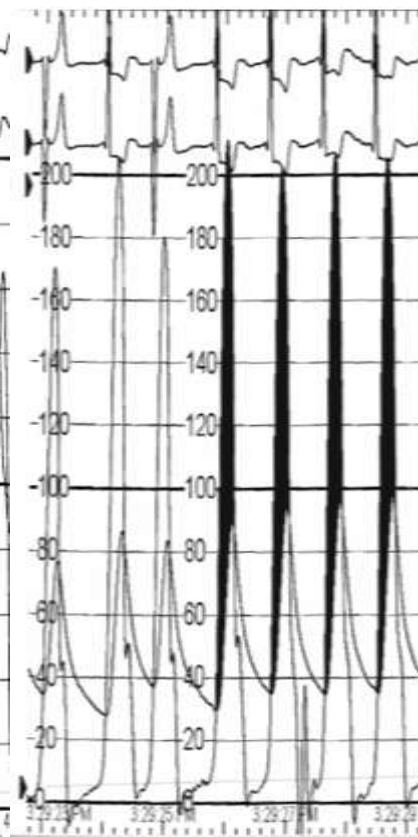


CO 3.4, Mean Grad 57, AVA .54

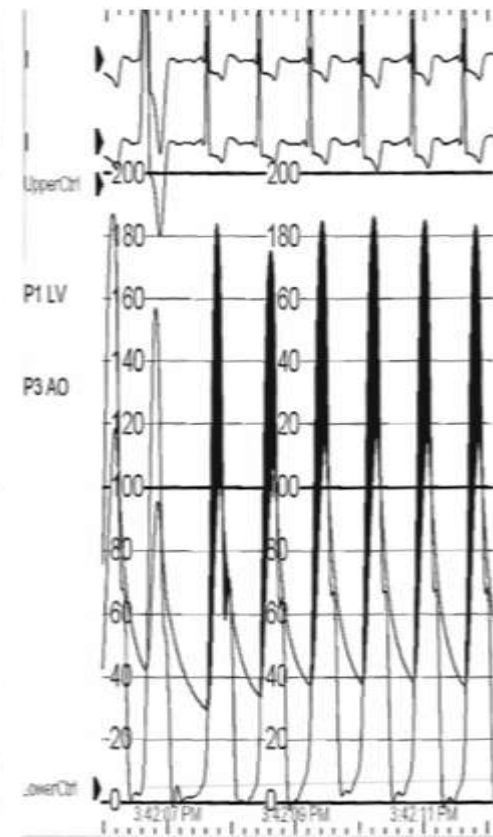


CO 3.6, Mean Grad 17, AVA 1.2

Sub Optimal Result



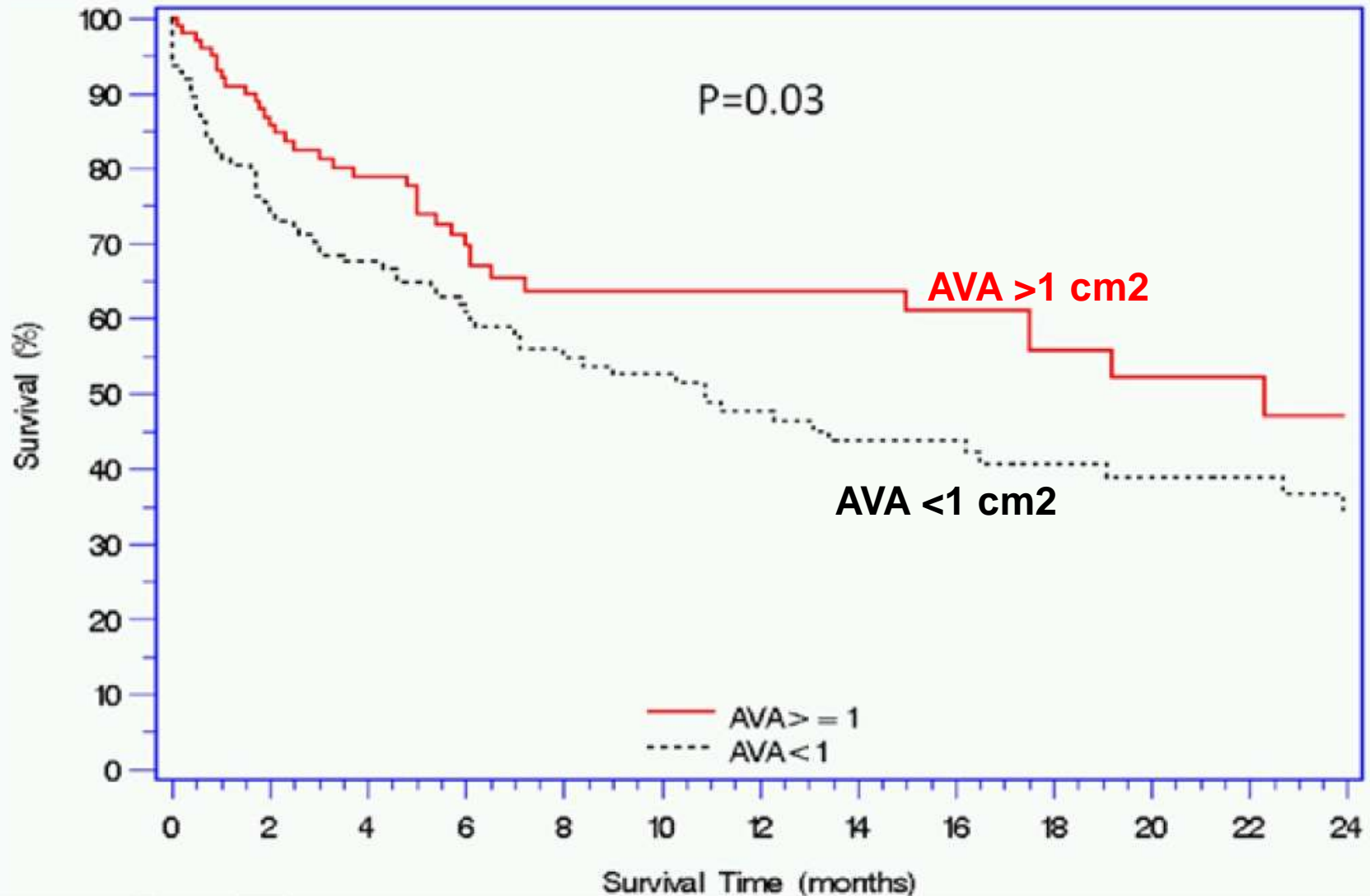
CO 6.2, Mean Grad 100, AVA .62



CO 6.2, Mean Grad 54, AVA .94

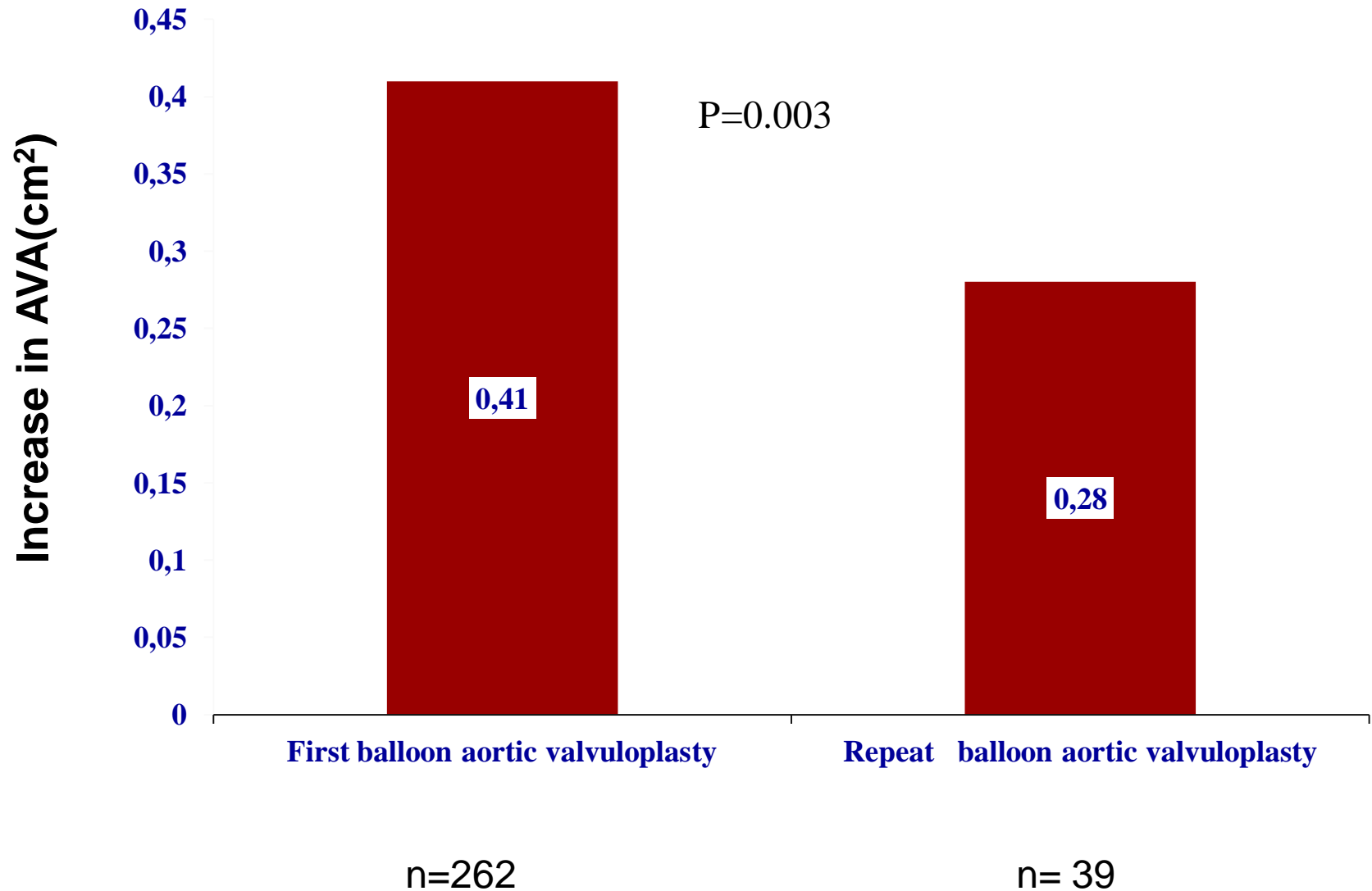
Survival and Final AVA

WHC: Ben-Dor et al. JACC Interv 2010;3:1150-6



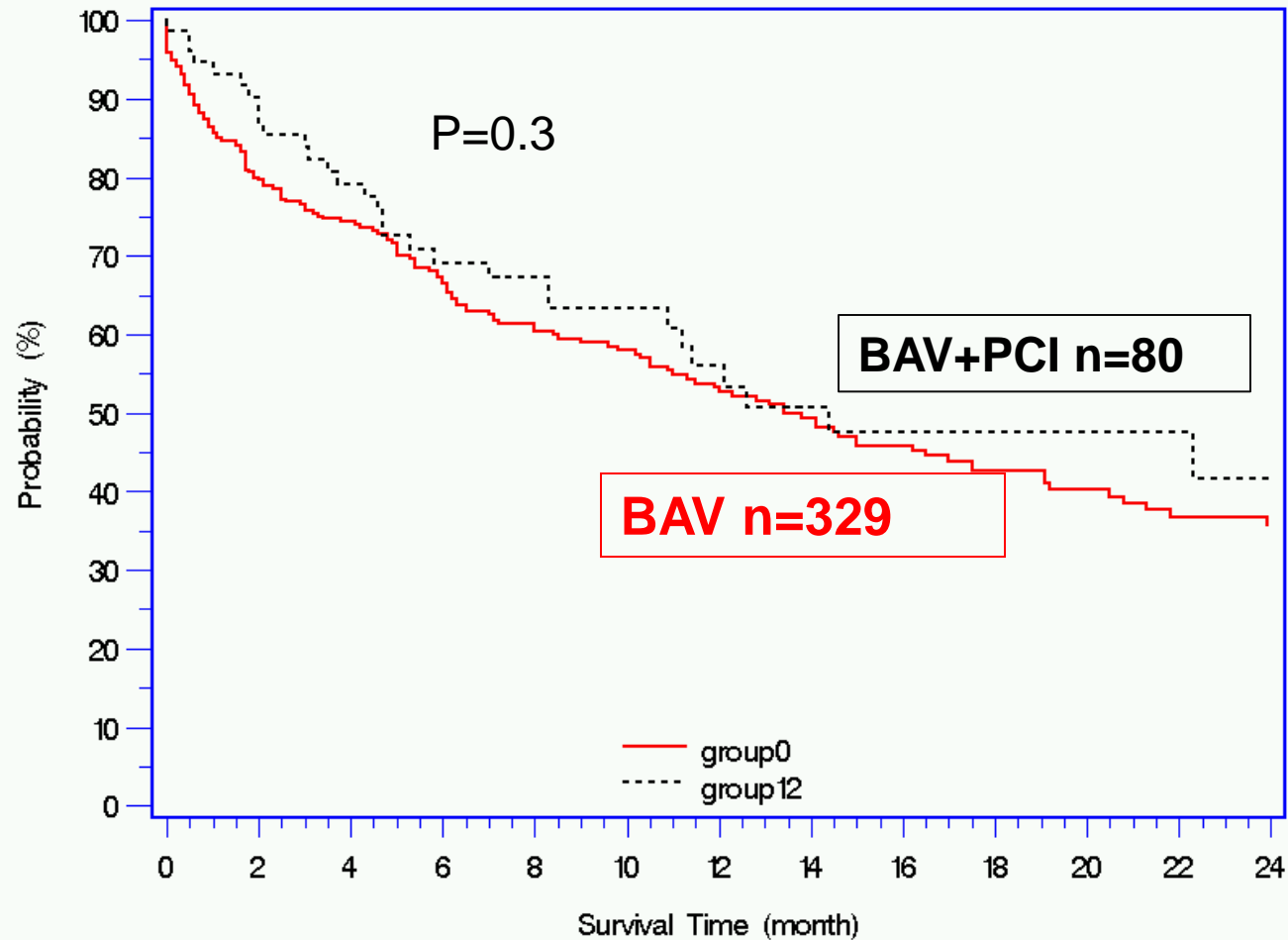
First vs Repeat BAV

WHC. Ben-Dor et al. 2010



BAV with and without PCI

WHC: Ben-Dor et al. CCI 82:E835-41



PCI was done before BAV in 66 (82.5%) and after in 14 (17.5%).

Appropriate Use of BAV.

- 1. For Palliative Relief of Symptoms (temporary benefit).**

2. To Evaluate Reversibility of Advanced CHF

90 year old.

Admitted 5 times with APE.

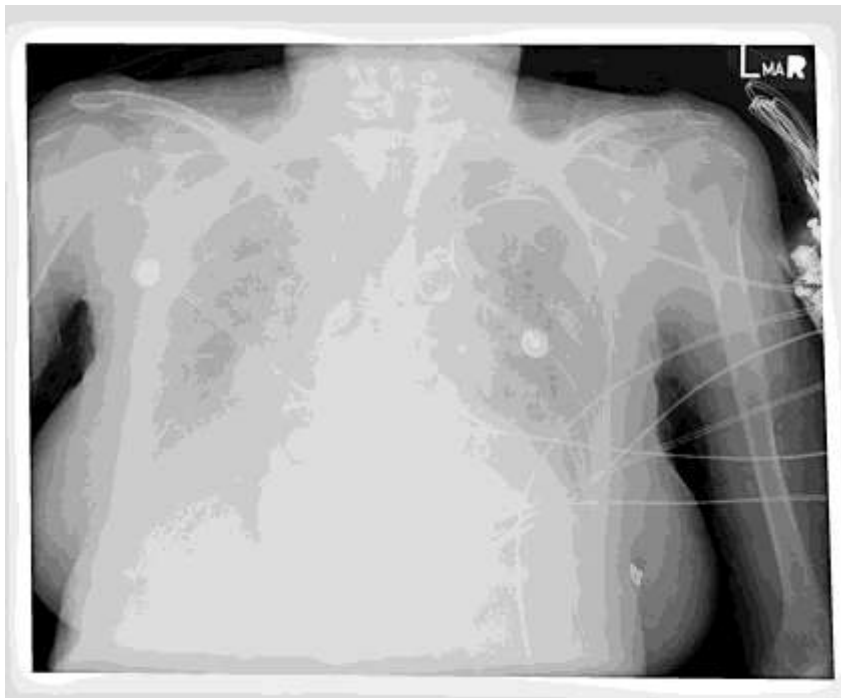
EF 20%, 4+ MR, BNP 5,000.

AVA 0.29 cm². STS 22

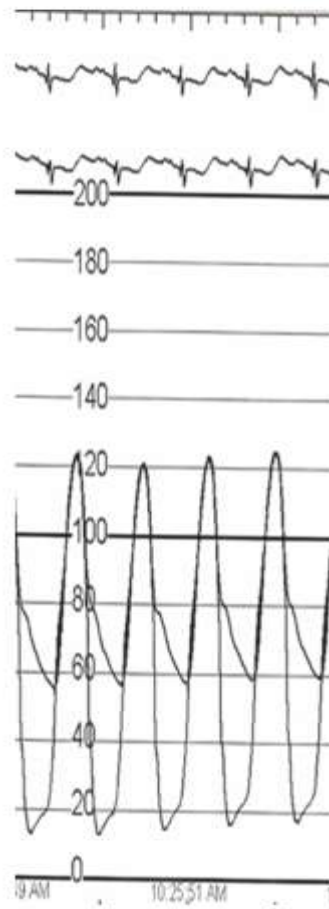
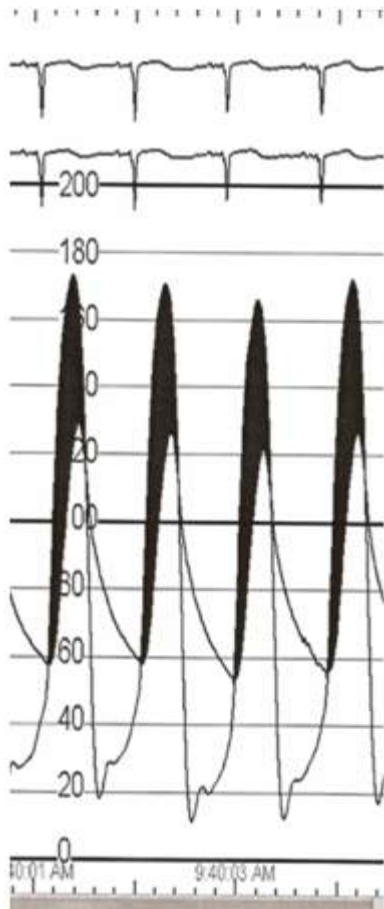
After PTAV

EF improved to 50%

MR now 1-2+

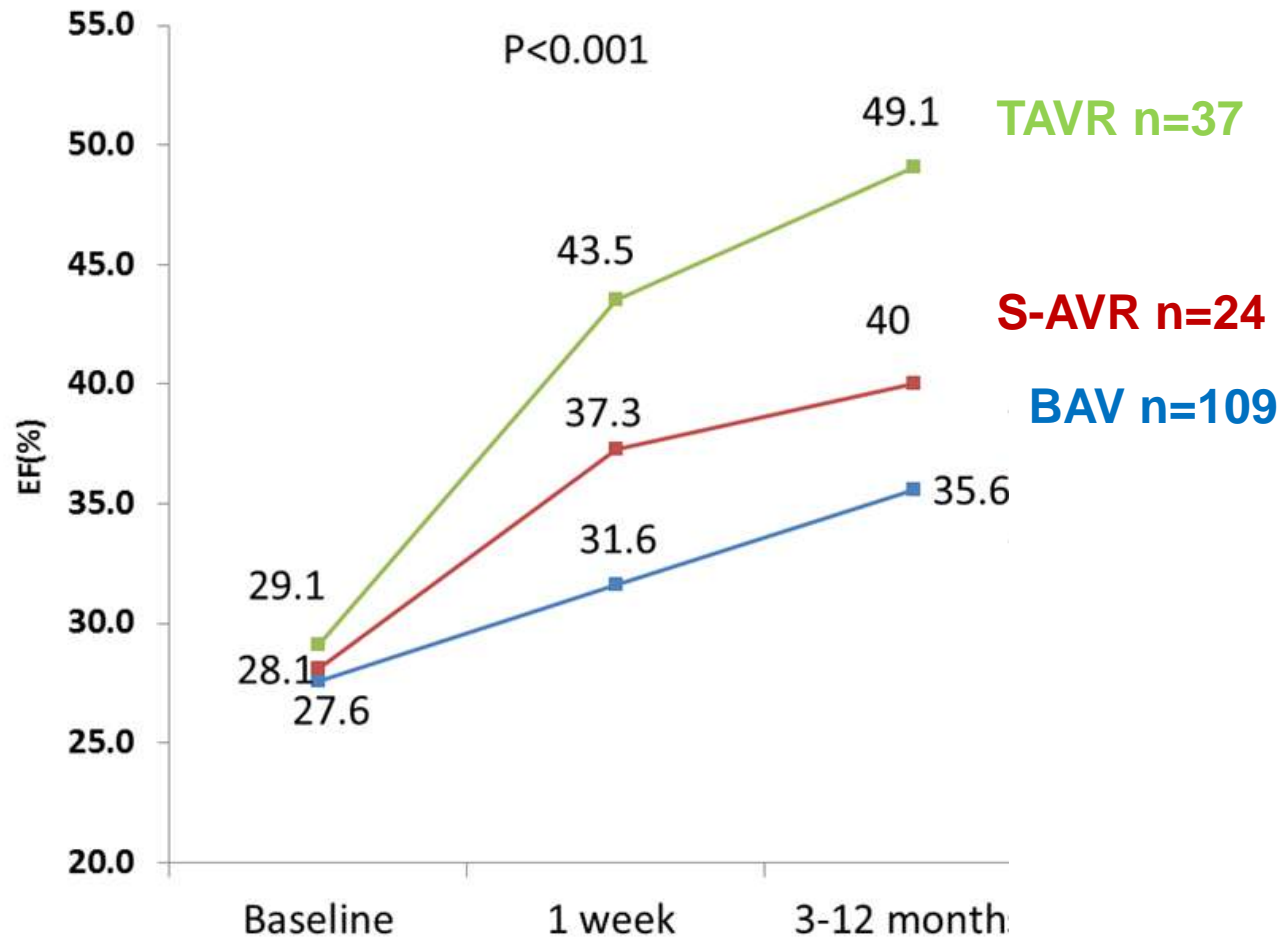


Patient became eligible for TAVI



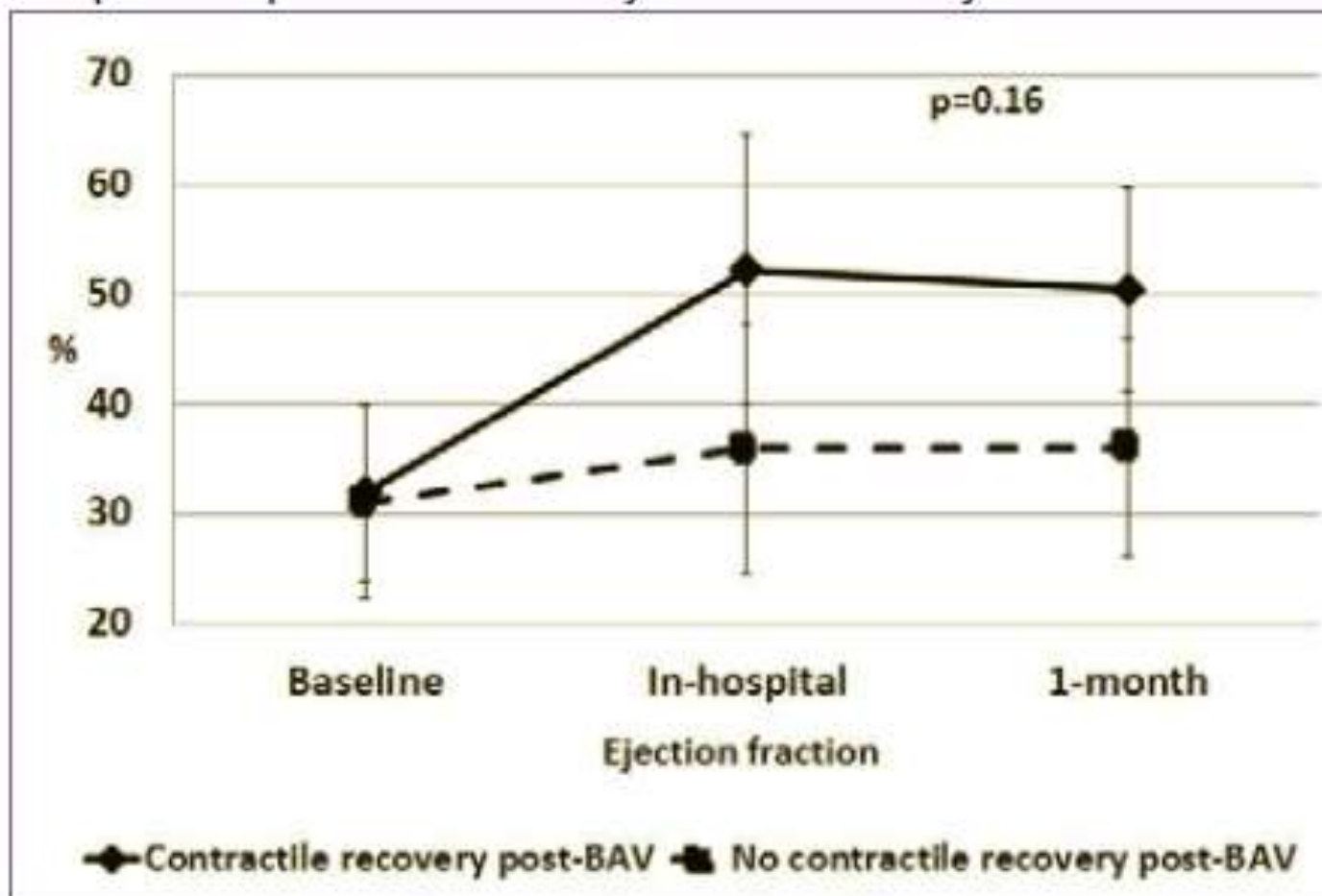
3. To Evaluate Reversibility of LV Dysfunction.

WHC: Ben-Dor et al. 2011



LV Recovery after BAV, then TAVR.

WHC: Barbash et al. ACC 2014

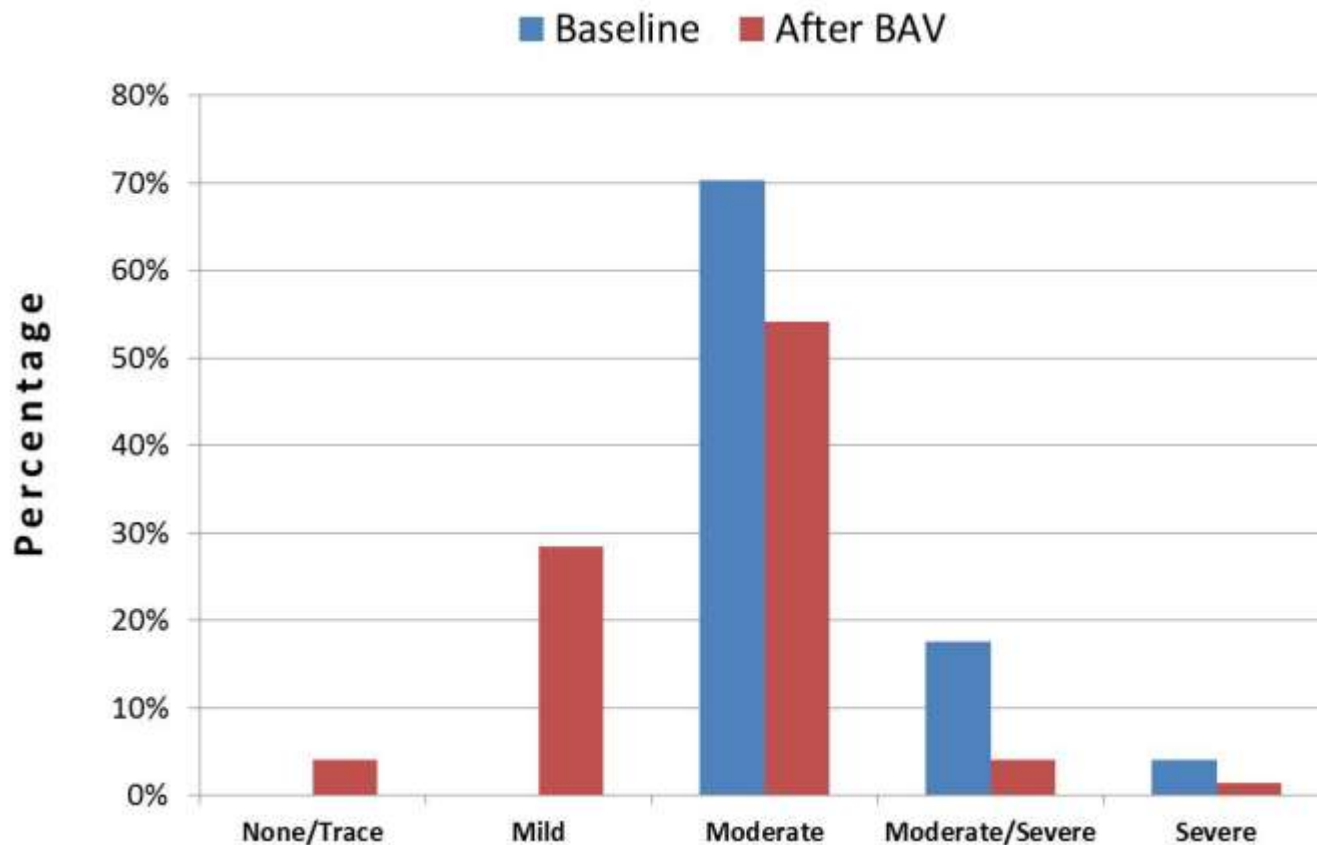


1 year survival was similar for those with and without LV recovery

4. To Evaluate MR Reversibility.

WHC: Maluenda et al. AJC 2011;108:1777-82

74 patients with mod-severe MR. Mean STS score 15. Mean Age 84



46% improved; 54% did not improve

5. To Decrease the Risk of AVR or TAVR

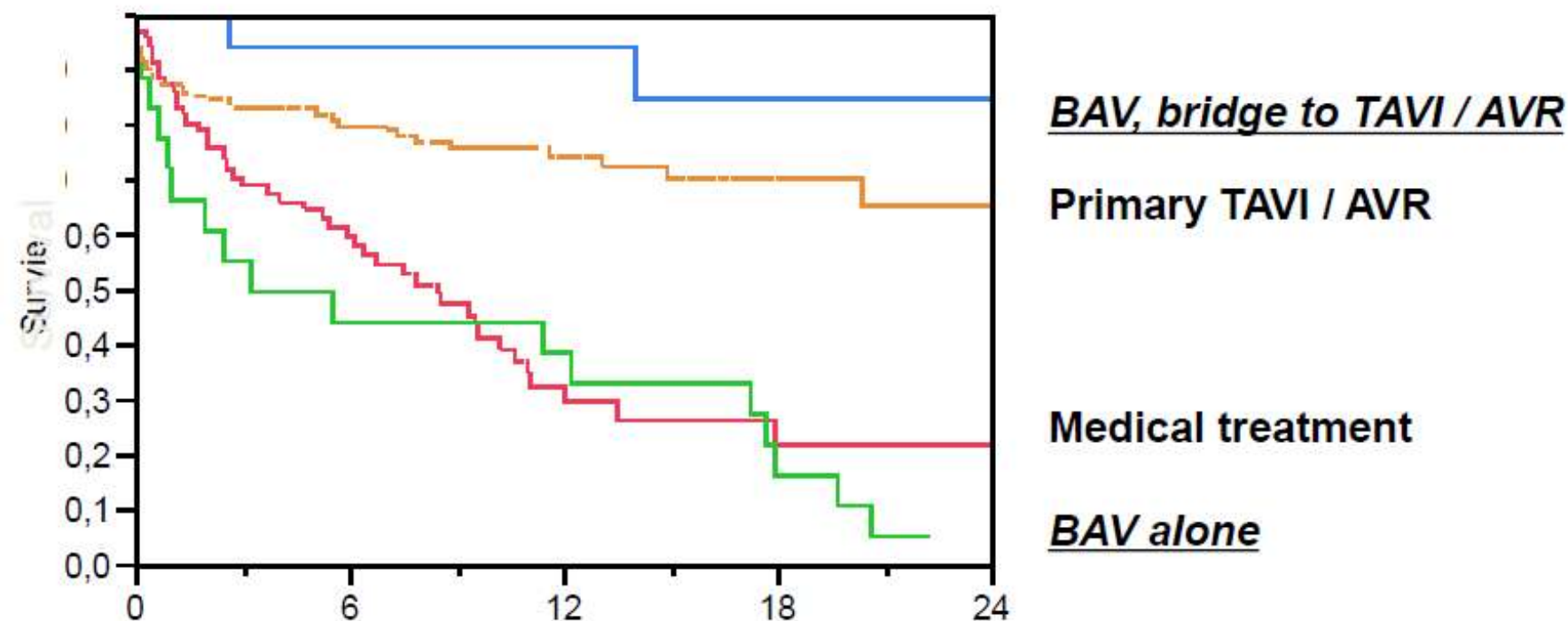
For the patient with severe CHF and:

- ✓ **severe pulmonary hypertension,**
- ✓ **severe LV dysfunction**
- ✓ **significant MR**

Results of BAV

Balloon Aortic Valvuloplasty

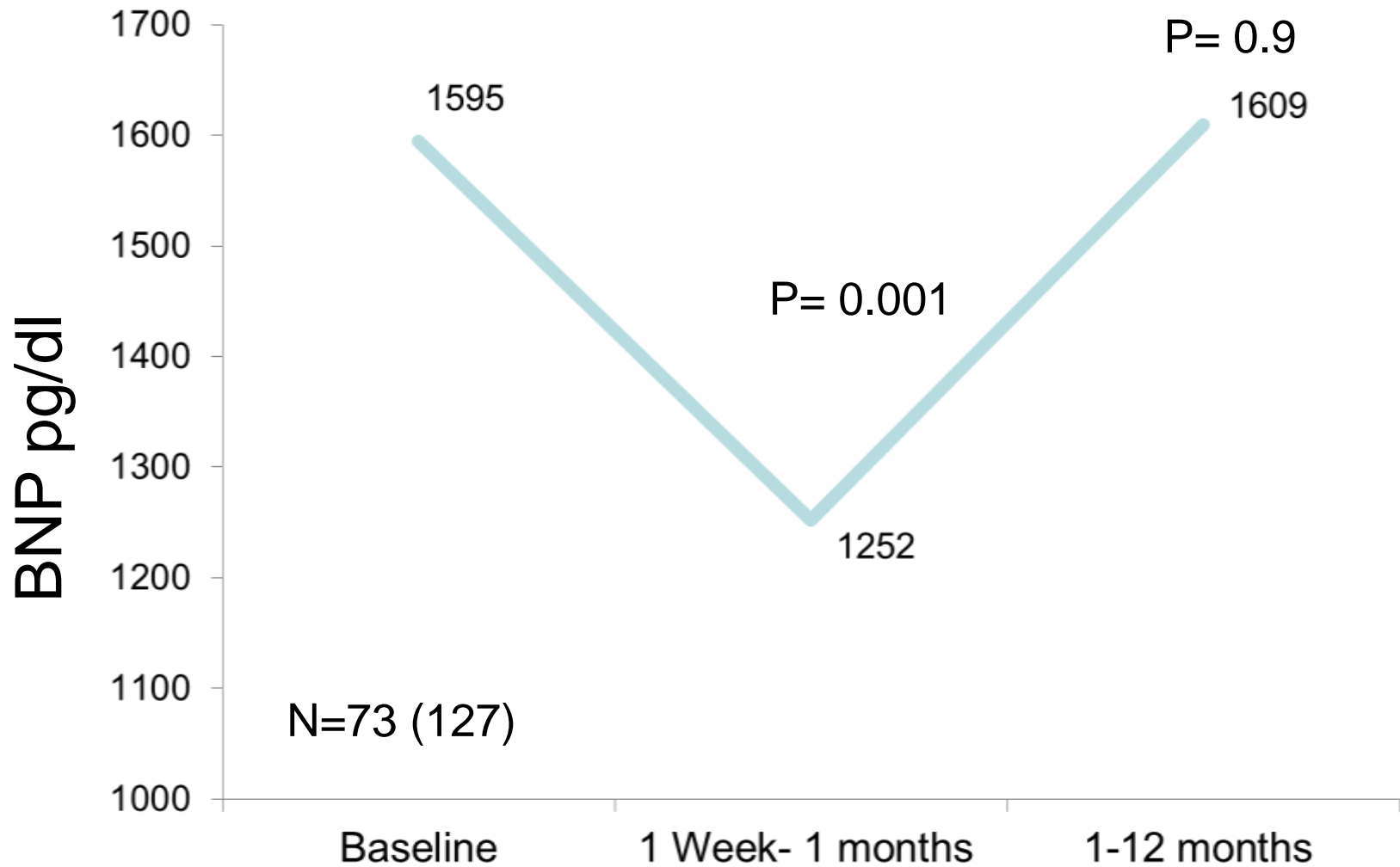
Long-term Results



(Tissot, EuroInterv 2011;7:49-56.)

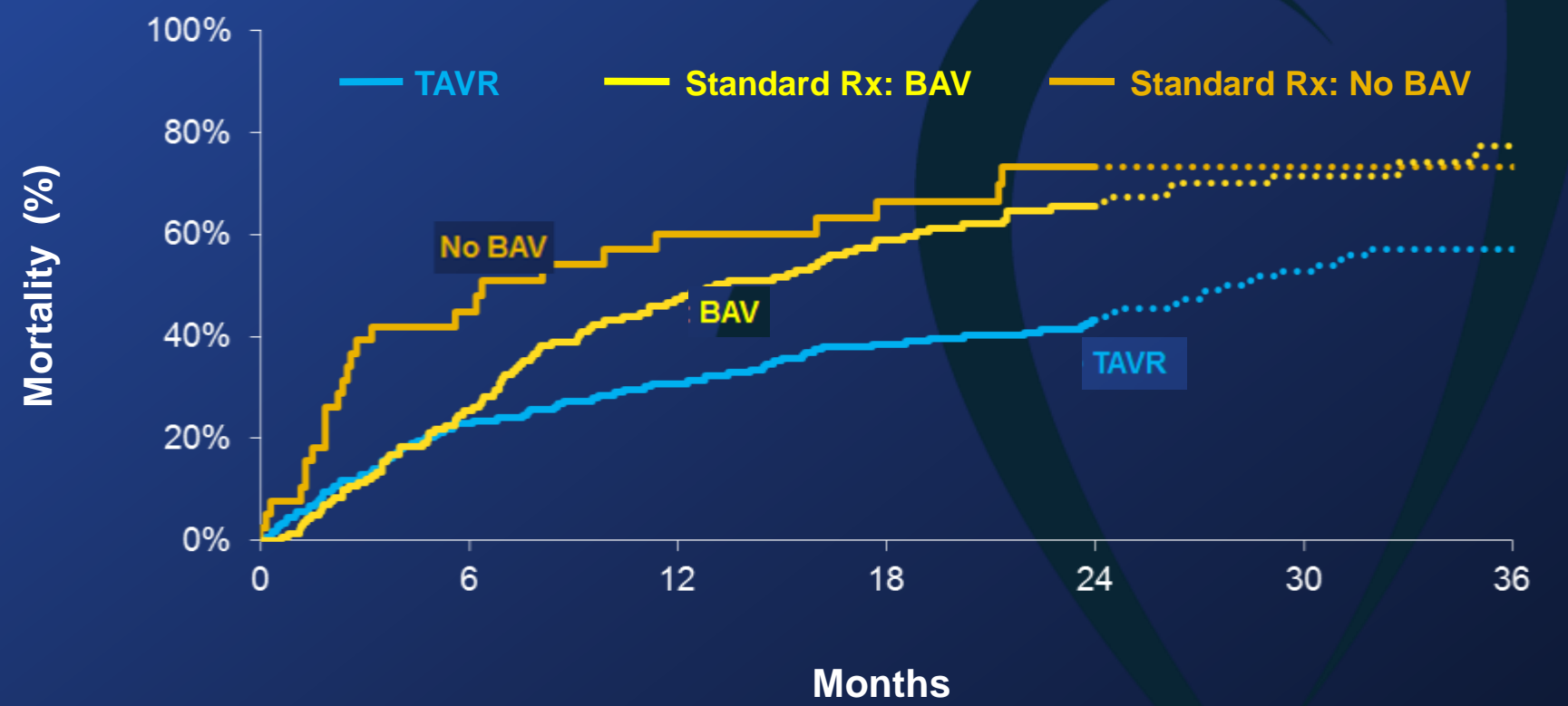
BNP after BAV.

WHC: Ben-Dor et al. AHA 2011



All Cause Mortality vs BAV

Partner 1B

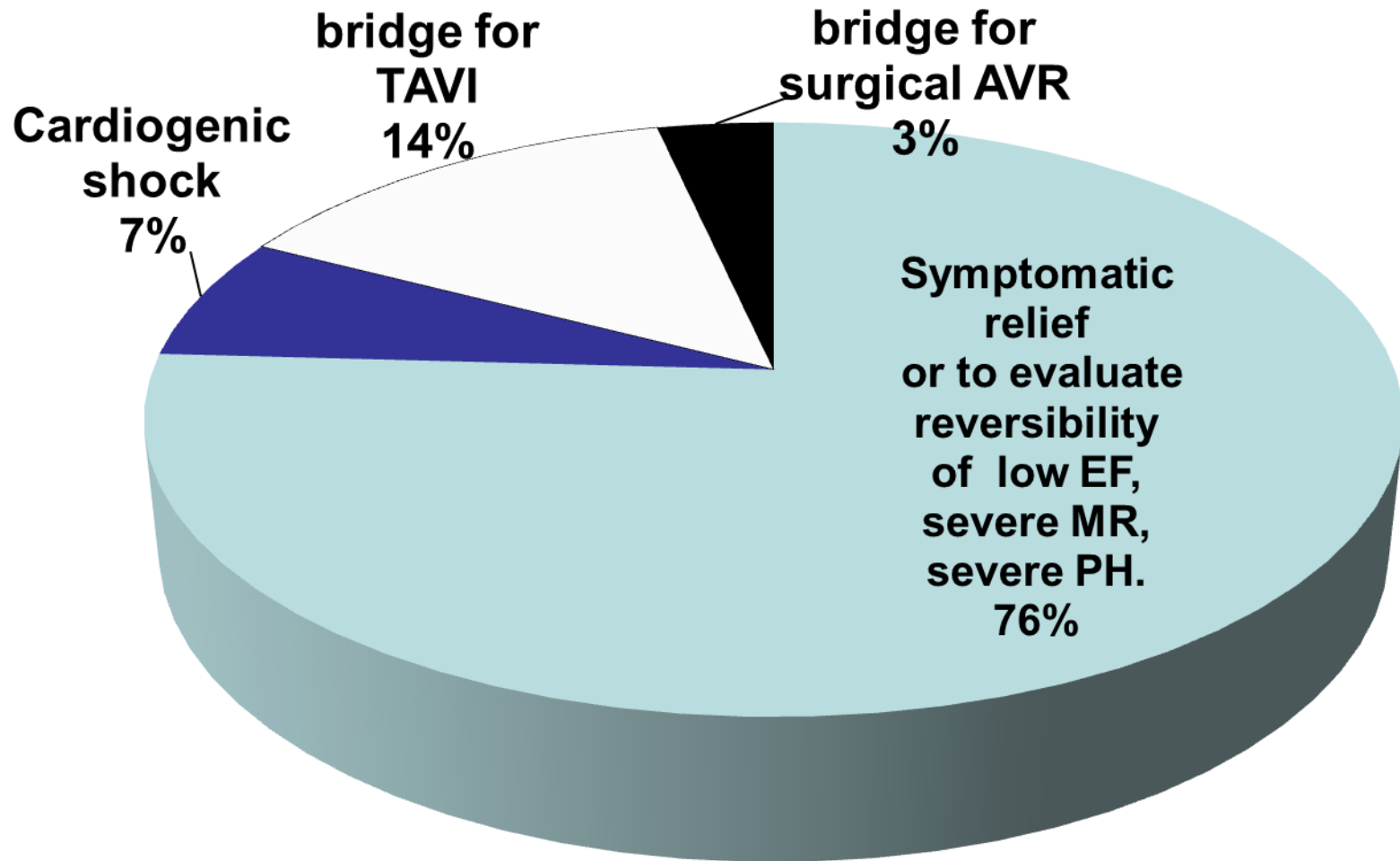


Numbers at Risk

TAVR	179	138	124	110	83	47	14
Standard Rx: BAV	142	105	74	54	37	18	5
Standard RX: No BAV	39	18	13	10	7	2	1

Reasons for BAV at WHC.

Washington Hospital Center. Ben-Dor et al. JACC Interv 2010;3:1150-6



n=505 procedures

BAV corrects von Willebrand Factor Abnormalities

Bander, Sharma et al. 2010

110 patients with BAV (60) or AVR (50).

- GI bleed in 4% AVR patients and 13% BAV patients.**
- vWF-Ristocetin cofactors/vWF:Ag ratio and the large vWF multimers increased 64% with AVR and 48% with BAV.**
- BAV improves the vWF abnormality associated with critical AS.**

Complications

WHC: Ben-Dor et al. CRT 2012

	2006-9 n=282	2010-11 n=242	
Intra procedural death (%)	6(2.0)	5(2.0)	0.97
Stroke	7(2.3)	4(1.6)	0.56
Tamponade	1(0.33)	3(1.2)	0.22
Coronary occlusion	2(0.67)	0	0.20
Severe aortic regurgitation	4(1.3)	2(0.8)	0.56
Profound hypotension	5(1.7)	3(1.2)	0.66
Permanent pacemaker	4 (1.3)	3(1.2)	0.90
Hemodialysis	2 (0.67)	1(0.6)	0.68
Vascular complication	24(8.1)	10(4.1)	0.05

Aortic Valvuloplasty

Rouen. Eltchaninof 2010

1985 first case by Cribier.

n=461 patients

AVA .66 to 1.10

Vasc complications: 2.9% (1.6% required surgery).

CVA 1.4%

Severe AR 1.2%

Tamponade 1.1%

AV avulsion 0.8%

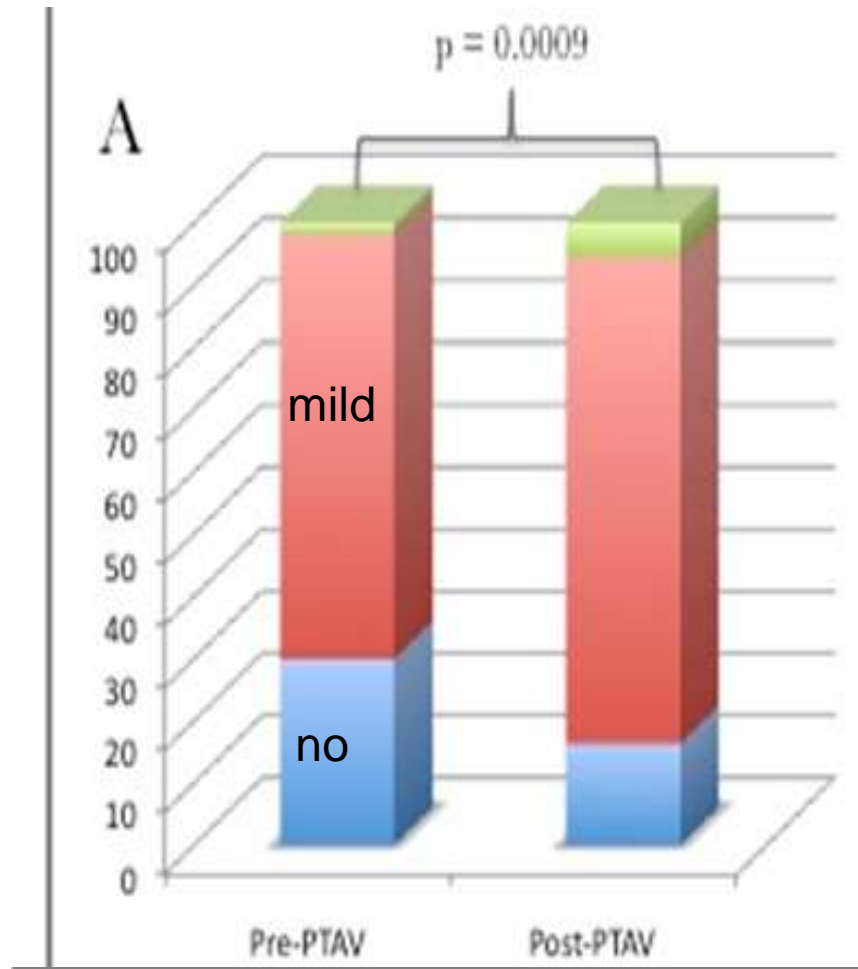
Death: 1.7%

Death at 1 week 3.5%

Death 1986-88: 4.9%, 2002-5: 2.1%, 2007-8: 0.94%

AR post PTAV

WHC: Gonzalez et al. 2011



BAV in patients with AR

Saia et al. CCI 2012;79:315-21

416 patients with BAV: 73 with moderate or severe AR.

AR improved or did not change: 89% patients.

Acute AR: 7 patients.

- 5 resolved by mobilizing a “stuck” leaflet with a pigtail catheter.**

Conduction Abnormalities after BAV

WHC: Laynez et al. AJC 2012;110:1164-8

329 patients with BAV.

PR interval did not change.

New LBBB 0.6%

New RBBB 0

PPM 0.9%

AF 0.9%

ACC/AHA Guidelines (2008 Update) and Evolving Indications

Class IIb

- Aortic balloon valvotomy might be reasonable as a **bridge to surgery in hemodynamically unstable** adult patients with AS who are at high risk for AVR.
- BAV might be reasonable **for palliation** in adult patients with AS in whom AVR cannot be performed because of serious comorbid conditions.
- For patients in need of **urgent non cardiac surgery**.

Evolving Indications

- **BAV as a bridge to T-AVR (TAVI)**
- **Diagnostic intervention on low output/ low gradient AS to predict response to transcatheter AVI, (afterload mismatch vs. intrinsic contractility depression)**

ESC Guidelines for Aortic Balloon Valvuloplasty 2007

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

Additional palliative indications:

Expected survival <3 years.

Age >80 , AVR refused

Cardiogenic shock (due to AS)

Indications for BAV

- **Therapeutic:**
 - Bridge to other procedures
 - Palliative symptom relief
- **Diagnostic:**
 - Reversibility of severe LV dysfunction
 - Reversibility of severe MR
 - Low flow, low gradient AS, to help determine response to T-AVR or S-AVR.

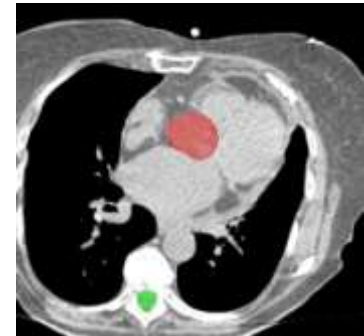
BAV not helpful in:

- 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.**

Valvuloplasty “Plus”

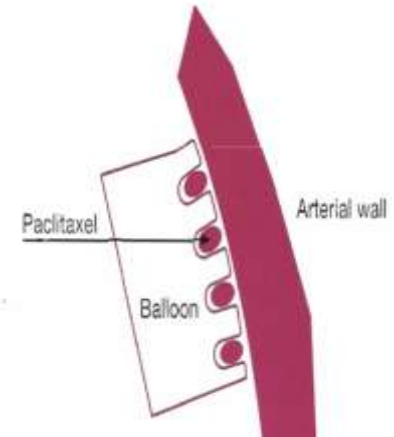
1. BAV followed by localized radiotherapy

- ARAVA Trial at WHC
- RADAR Trial at MHI



2. Balloon coated with Paclitaxel

- Animal data
- Few patients in Greece and Vienna



New Balloons

Loma Vista TRUE Balloon



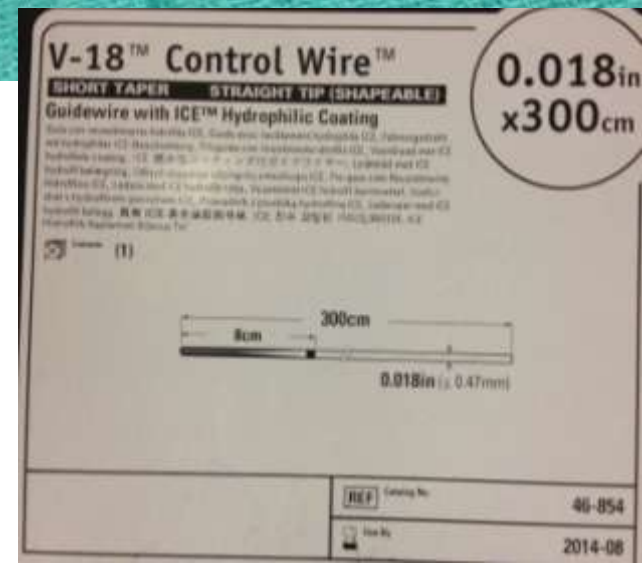
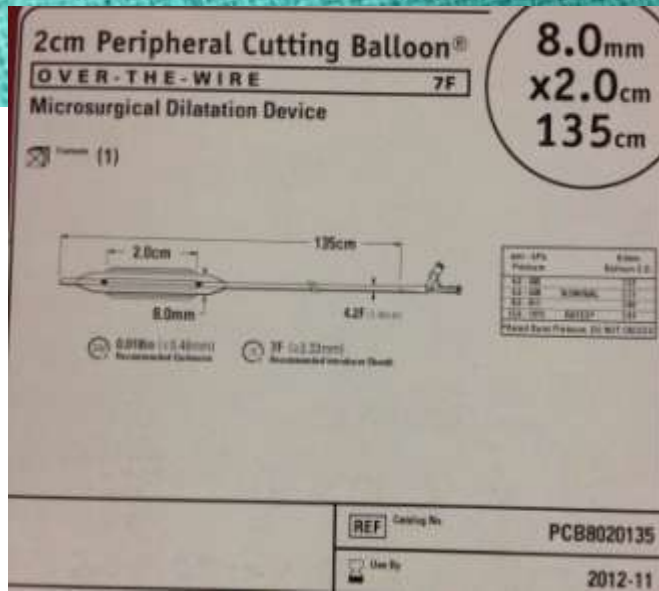
- Kevlar composite balloon material
- Precise size and shape (<1% growth)
- Fast inflation and deflation (2-3X faster)
- Exceptional puncture resistance
(no balloon ruptures in >1,500 cases)
- Excellent re-wrap

Valvuloplasty Scoring Balloon Design



- 18, 20, 22, 24 mm diameter x 4.0 cm length balloons, atraumatic soft tip
- Laser cut nitinol scoring element with 4 rings and 12 rectangular wires/struts
- 12 French sheath compatible (0.035" guidewire)
- RBP 5-8 atm with scoring element force amplification ~18x
- Rapid deflation time ~5 seconds

BAV with Two 8 mm Cutting Balloons



Leaflex AVRT

(Aortic Valve Remodeling Therapy)

- Mechanical shock waves to fracture calcium within valve
- Increased leaflet compliance: significant, true increase in AVA
- Trans-femoral 13Fr catheter
- Non-occlusive: no rapid pacing
- Device can be used as:
 - Stand-alone therapy
 - Bridge to TAVR or SAVR
 - Preparation for TAVR



Conclusion

Aortic Valvuloplasty:

- Provides effective improvement in AVA in most patients.
- Benefit is temporary (average 6 months: 2 months to 2 years).
- Excellent tool as bridge to definitive AVR (surgical or percutaneous).
- Excellent tool to evaluate reversibility of severe LV dysfunction, severe MR, severe CHF.

The end