

TAVI – Summit 2012
Seoul, September 9, 2012

TAVI Implantation: Rapid Pacing, Pre- and Post Dilatation

Eberhard Grube, MD, FACC, FSCAI

Medizinische Klinik und Poliklinik II, University Hospital Bonn, Germany

Hospital Alemão Oswaldo Cruz, São Paulo, Brazil

Stanford University, School of Medicine, Palo Alto, CA

Potential conflicts of interest

Speaker's name: Eberhard GRUBE, MD

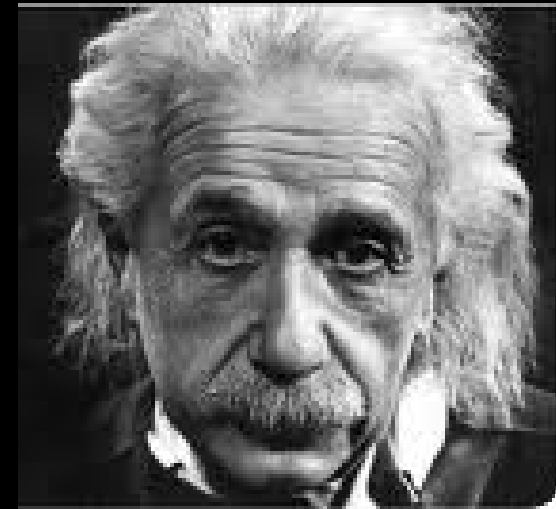
X I have the following potential conflicts of interest to report:

- Research contracts
- Consulting (BSC, J&J Cordis, Abbott, Biosensors, Medtronic Symetis, Direct Flow, InSeal, Valtech, Mitralign, Claret)
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s): Proctor for CoreValve (Medtronic).

I do not have any potential conflict of interest

TAVI: Rapid Pacing, Predilatation...

"Make everything as simple as possible,
but not simpler"



Albert Einstein

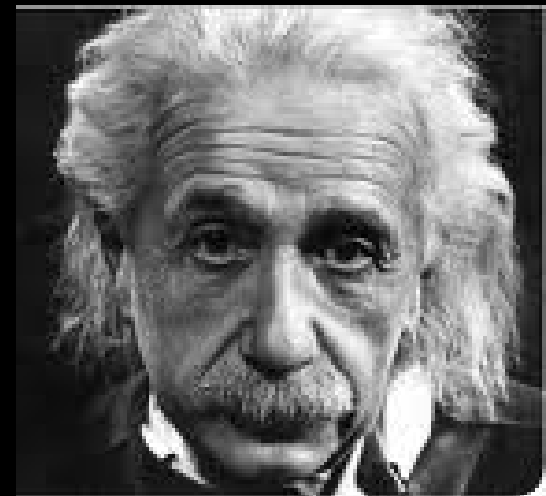
TAVI: Rapid Pacing, Predilatation...

In TAVI try to be

- as simple (with regards to procedural steps),
 - as quick (with regards to procedure time) and
 - as least traumatic (with regards to material)
- to the heart as possible in order to protect the chronically ill myocardium and to reduce procedural complications.

Therefore minimize the use of

- Wires
- Balloons
- Pacemakers
- Drugs and
- Contrast



TAVI: Rapid Pacing, Predilatation...

Rapid Pacing (180-200/sec):

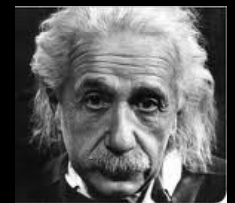
...to initiate "Cardiac Stand-Still" with temporary suppression of the circulation to "stabilize" the aortic ring (less motion) for safer and more precise positioning and deployment of the THV.

Pacing (80/sec):

...to avoid arrhythmias (PVC's) in patients with slow heart rates during deployment without compromising circulation and lowering the BP.

In Balloon expandable Valves the former is a must....

In Core Valve the former is a matter of personal preference while the latter is advisable...



BAV of the aortic valve – The Beginning

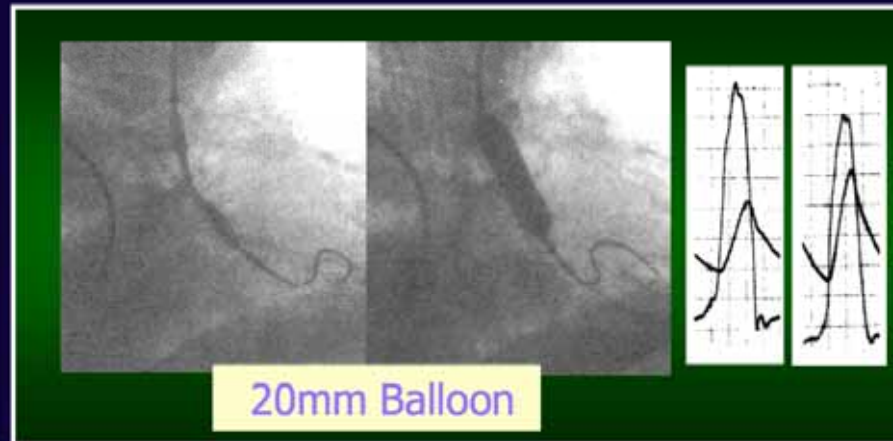
ROUEN: Sept 1985 **F.I.M. BALLOON VALVULOPLASTY**

72 y-old female,
AS + CAD
Severely symptomatic:

- Daily syncopal attacks
- NYHA grade 3
- Angina

Declined by surgeons

Uneventful procedure
Total relief of symptoms
Return to normal life
Death at 2 years (AMI)



PERCUTANEOUS TRANSLUMINAL VALVULOPLASTY OF ACQUIRED AORTIC STENOSIS IN ELDERLY PATIENTS: AN ALTERNATIVE TO VALVE REPLACEMENT?

ALAIN CRIBIER
NADIR SAOUDI
JACQUES BERLAND

THIERRY SAVIN
PAULO ROCHA
BRICE LETAC

*Service des Soins Intensifs Cardiologiques et des Explorations
Hémodynamiques Cardiovasculaires, Centre Hospitalier et
Universitaire, Hôpital Charles Nicolle, Rouen, France*

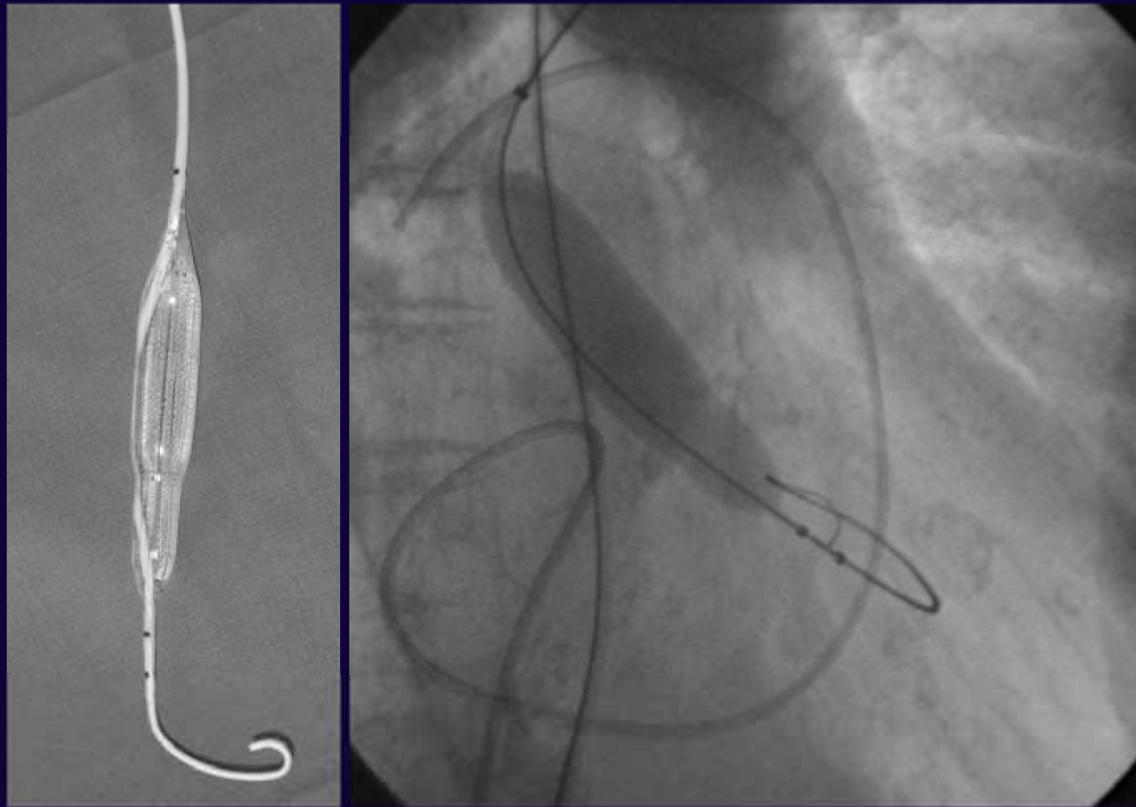
THE LANCET, JANUARY 11, 1986

THE LANCET, Jan 11, 1986



BAV of the aortic valve – The Beginning

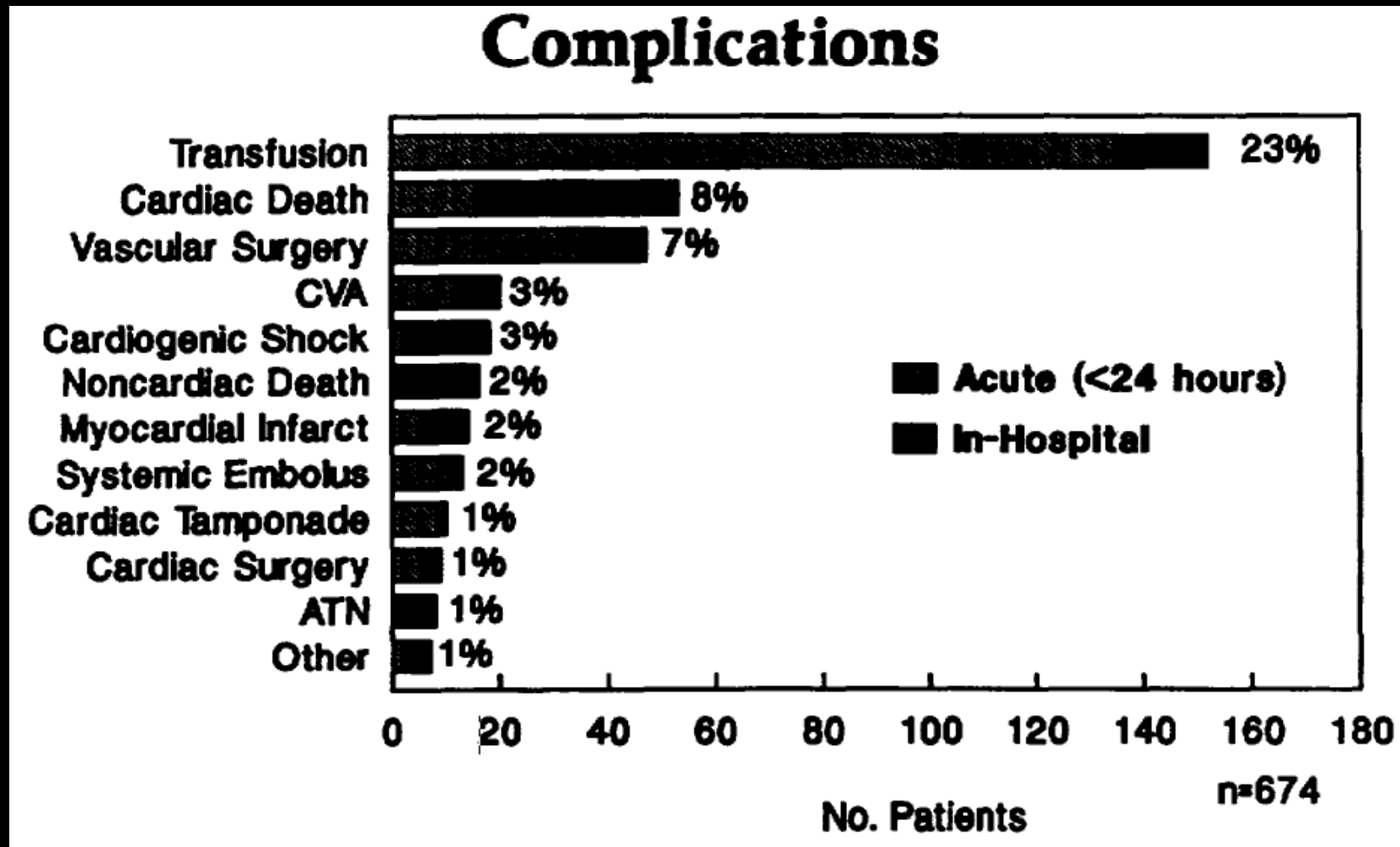
Specific balloon catheter for BAV
developed with Mansfield / Boston Scientific



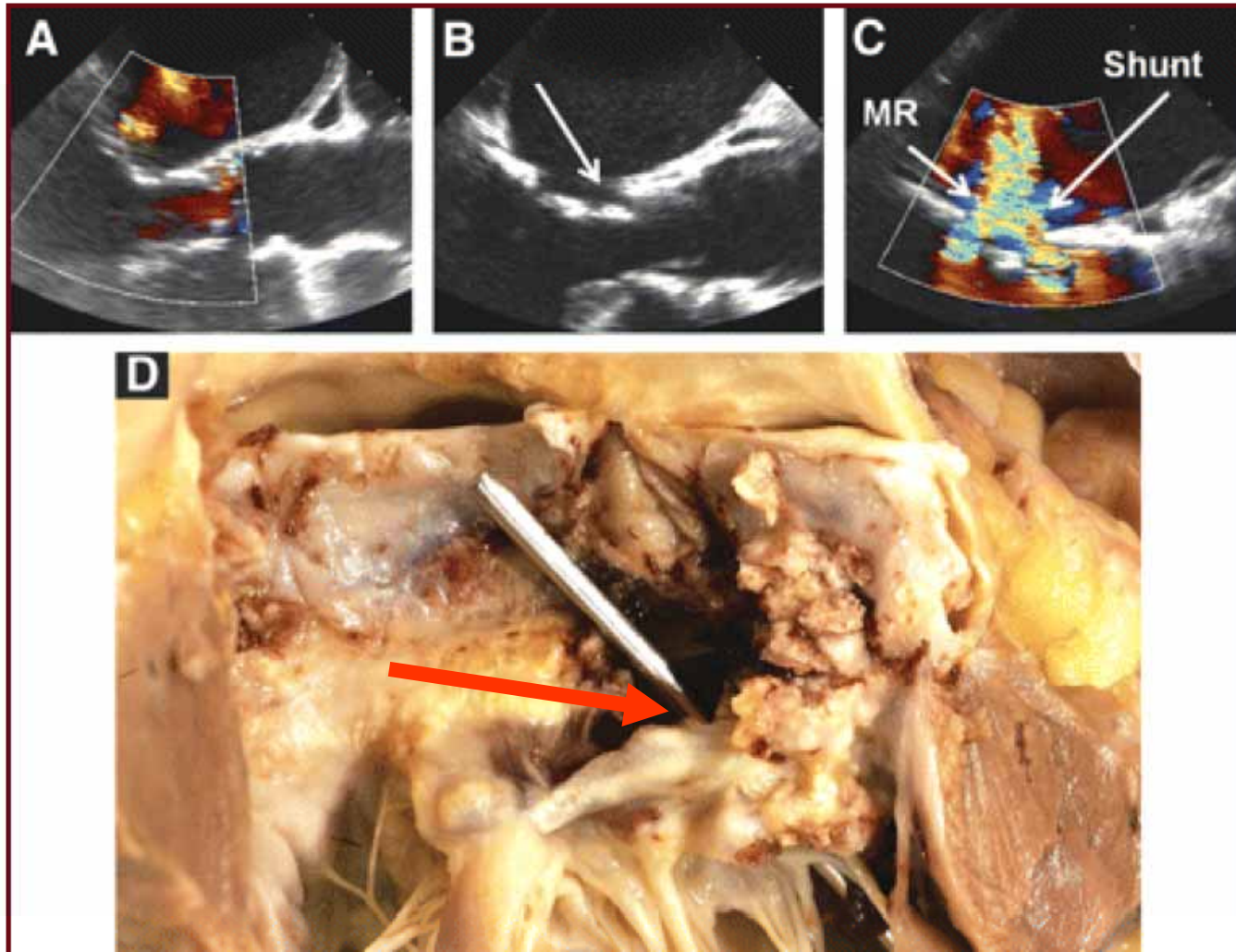
The « Cribier-Letac Balloon Catheter »

Courtesy of A. Cribier

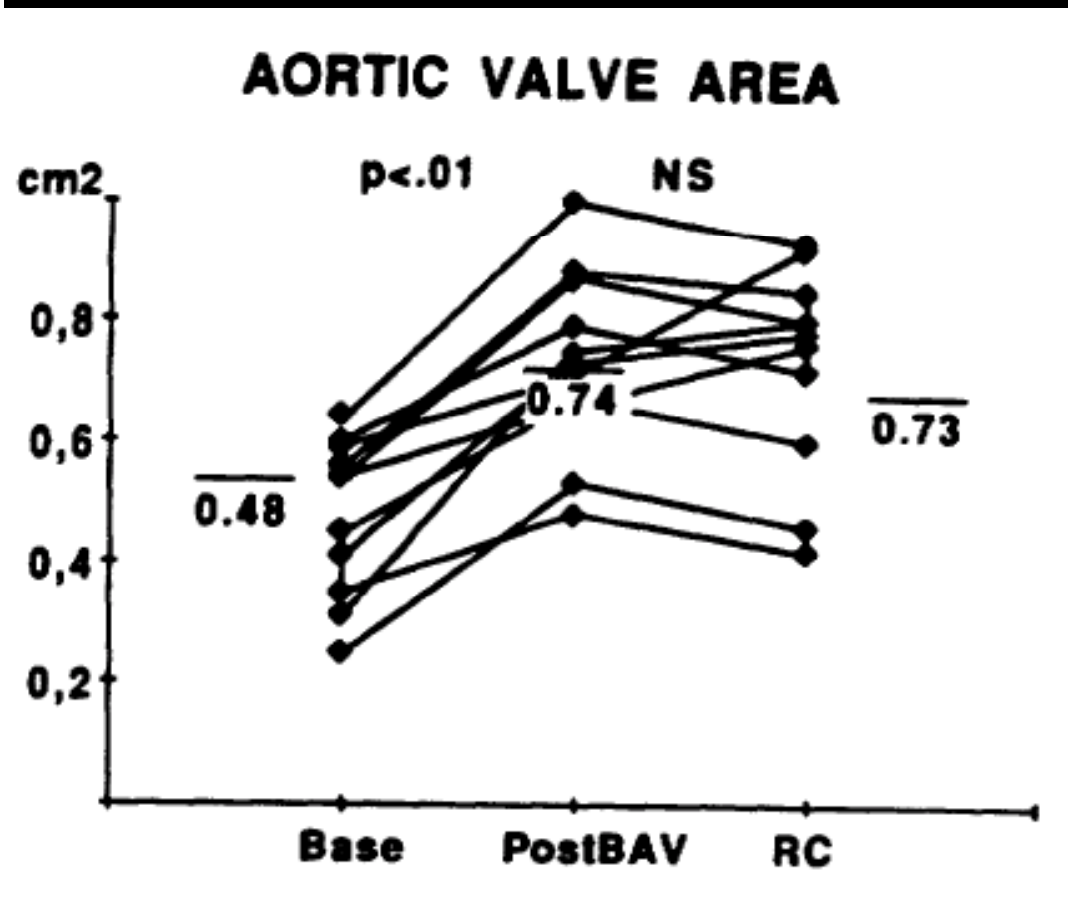
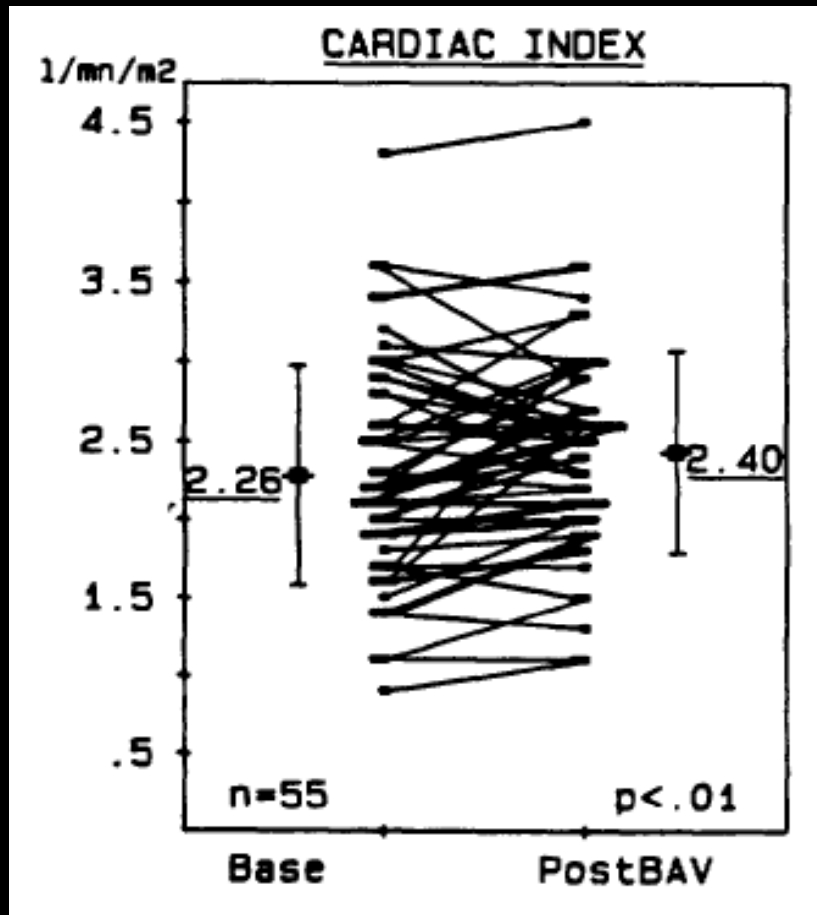
Acute follow-up (<24 hrs) in 674 patients of the NHLBI BAV registry



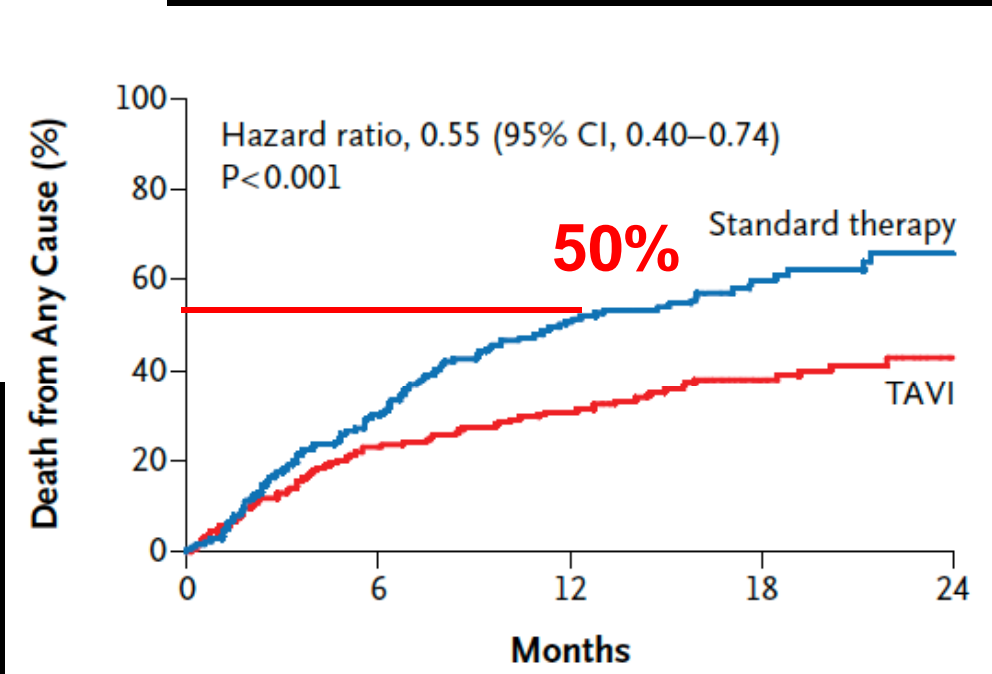
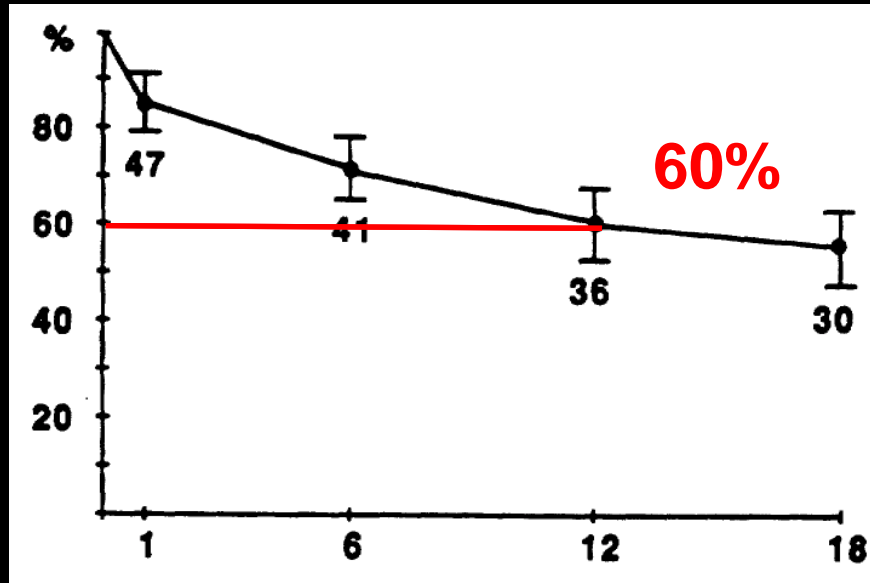
Annular rupture with tear of anterior mitral curtain



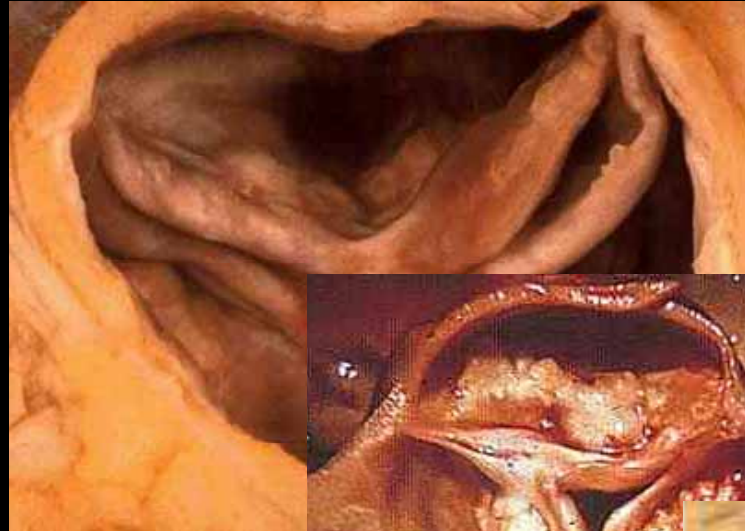
BAV of the aortic valve – Sustained success...?



BAV of the aortic valve – An old story continues...?

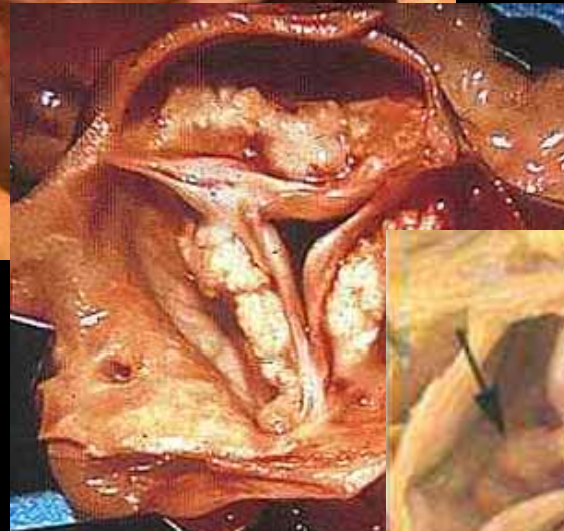


Calcific Aortic Stenosis



Deformed
Eccentric
Calcified
Nodular
Rigid

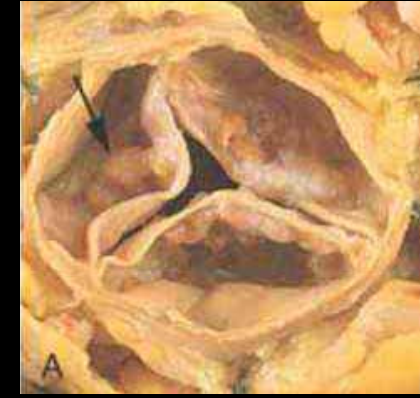
**HOSTILE
TARGET**



- *difficult to displace*
- *prone to fragmentation and embolization*

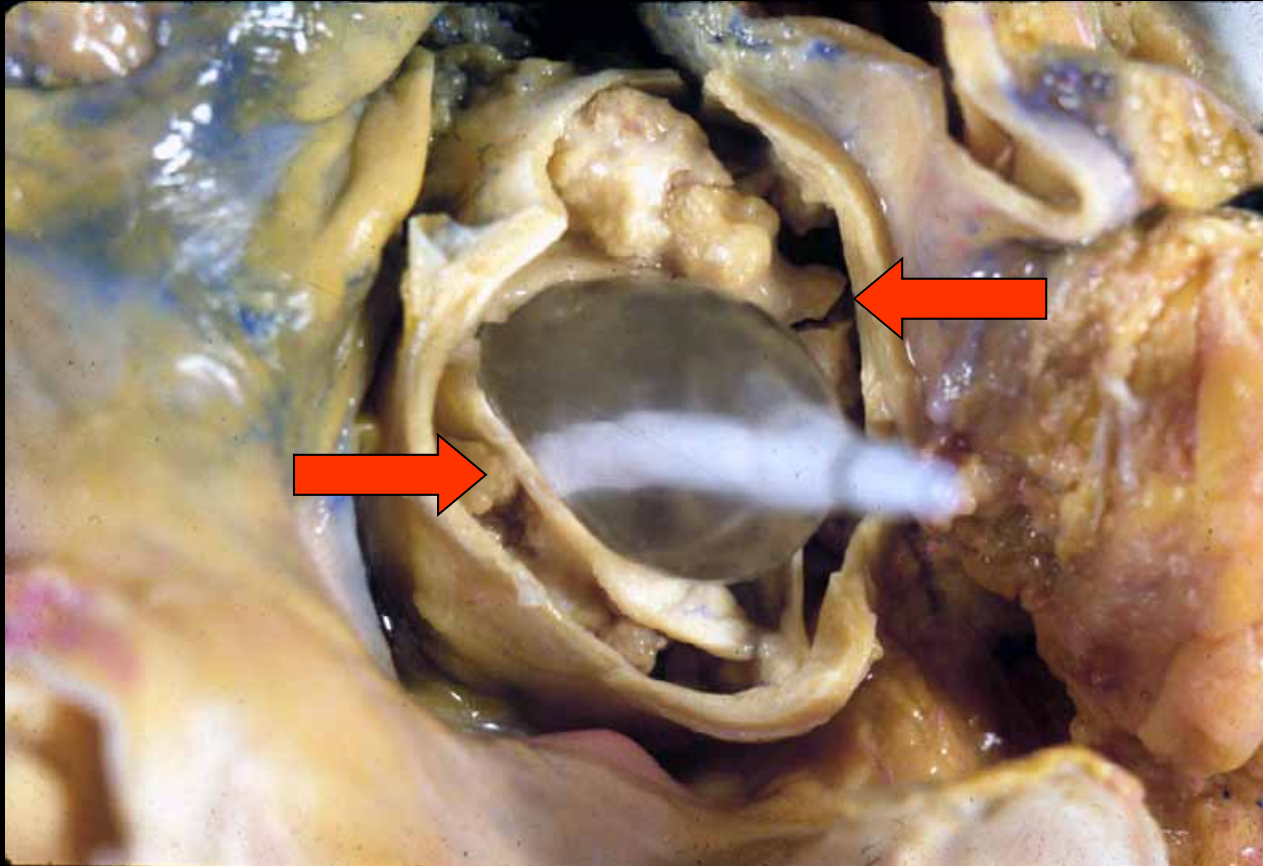
Disadvantages of BAV

- Rapid pacing
 - Hemodynamic deterioration
- Balloon/Annular rupture
- Aortic regurgitation
- Cerebral Hypoxemia
- Conduction disturbances
- Embolization into
 - Cerebral circulation (stroke, silent cerebral embolism)
 - Coronary arteries (cardiogenic shock)
- Radiation exposure
- Procedure time and Contrast

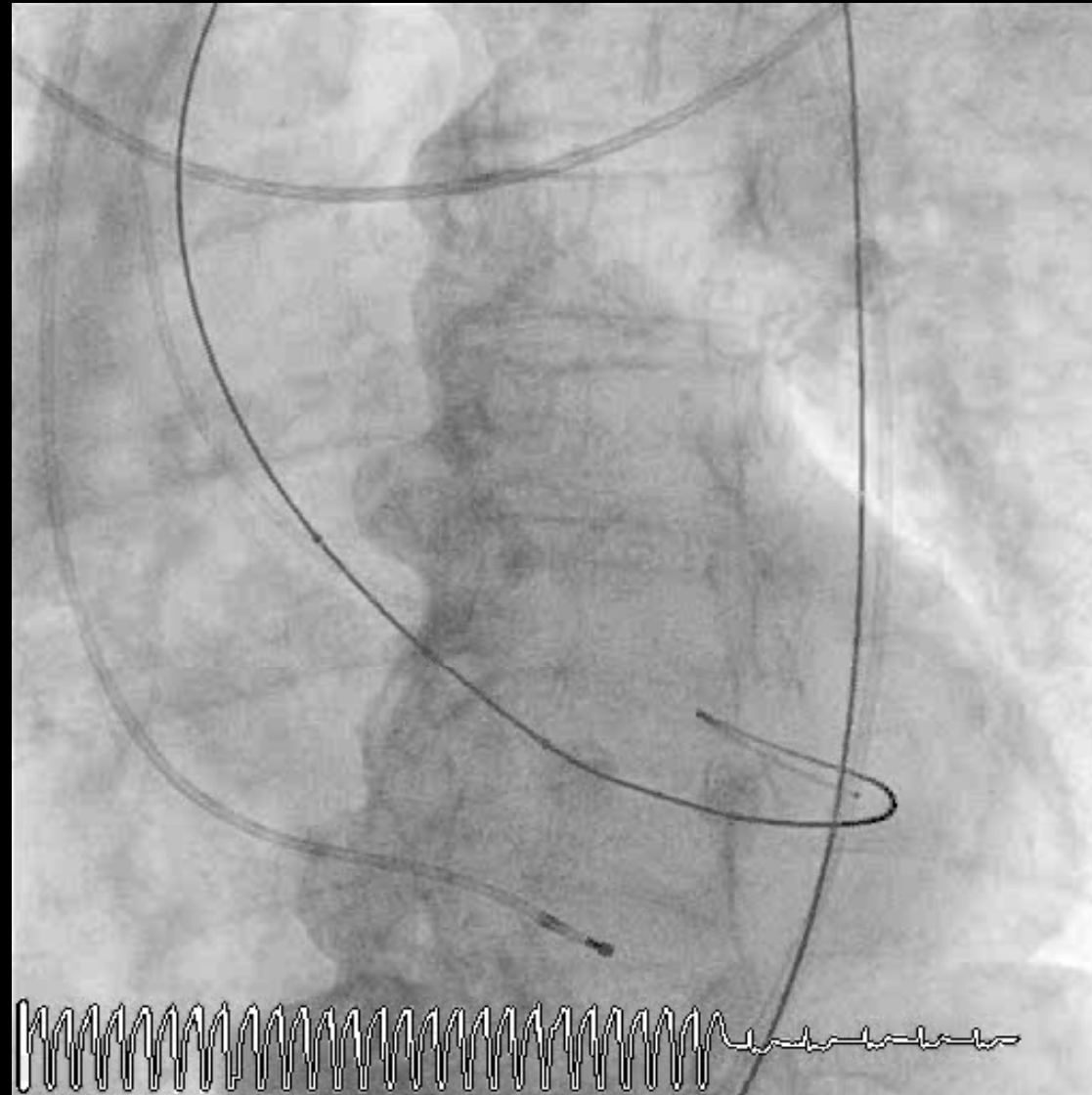


Despite disadvantages of BAV it was believed that Balloon Predilatation was necessary to create "room" for the easy passage and complete delivery of the THV

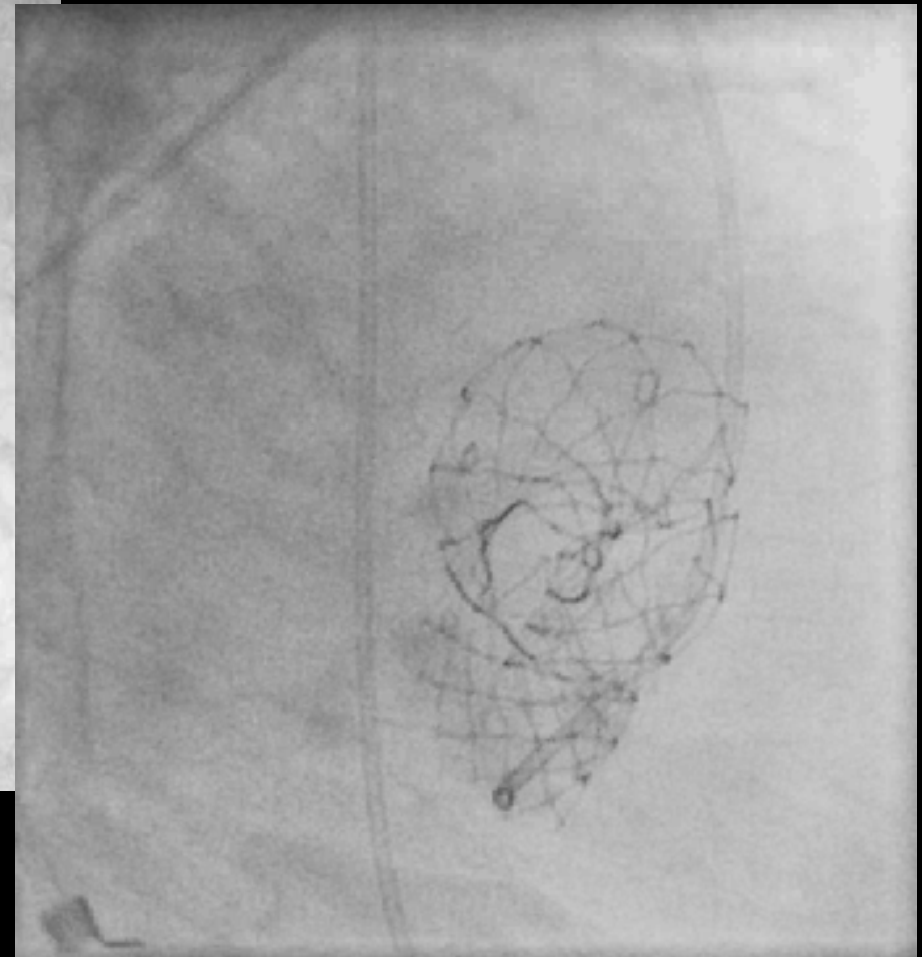
Balloon valvuloplasty in heavily calcified aortic valve



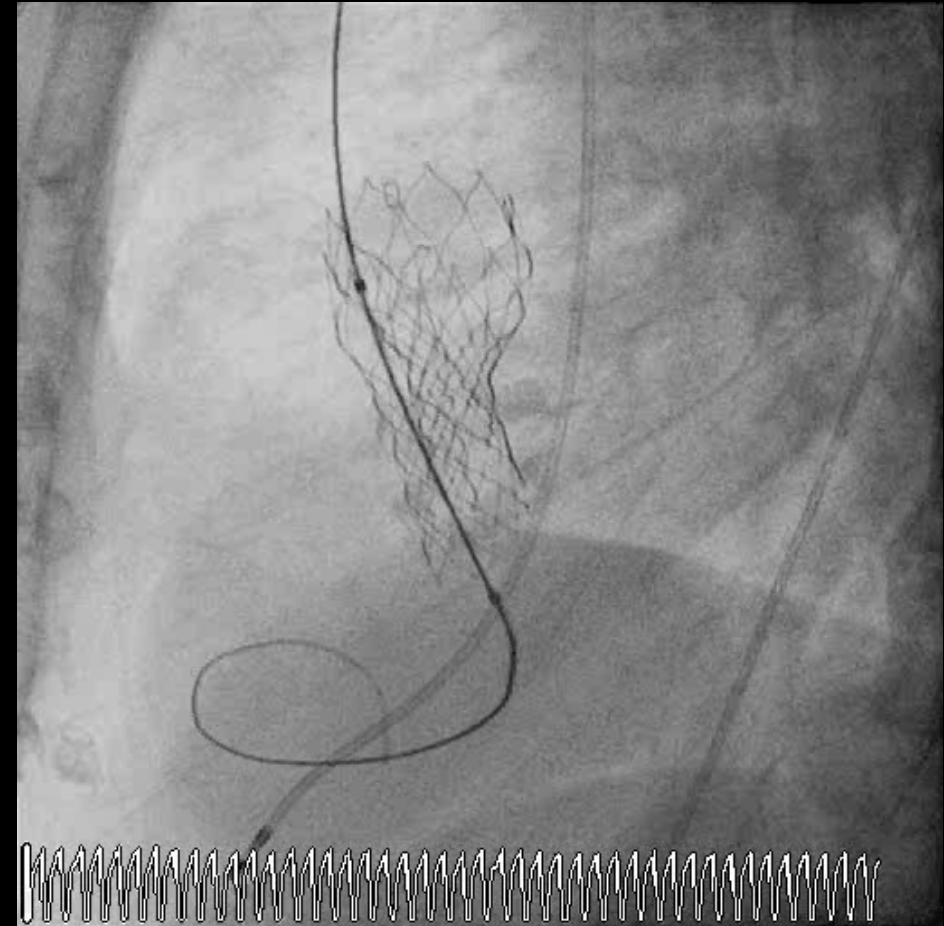
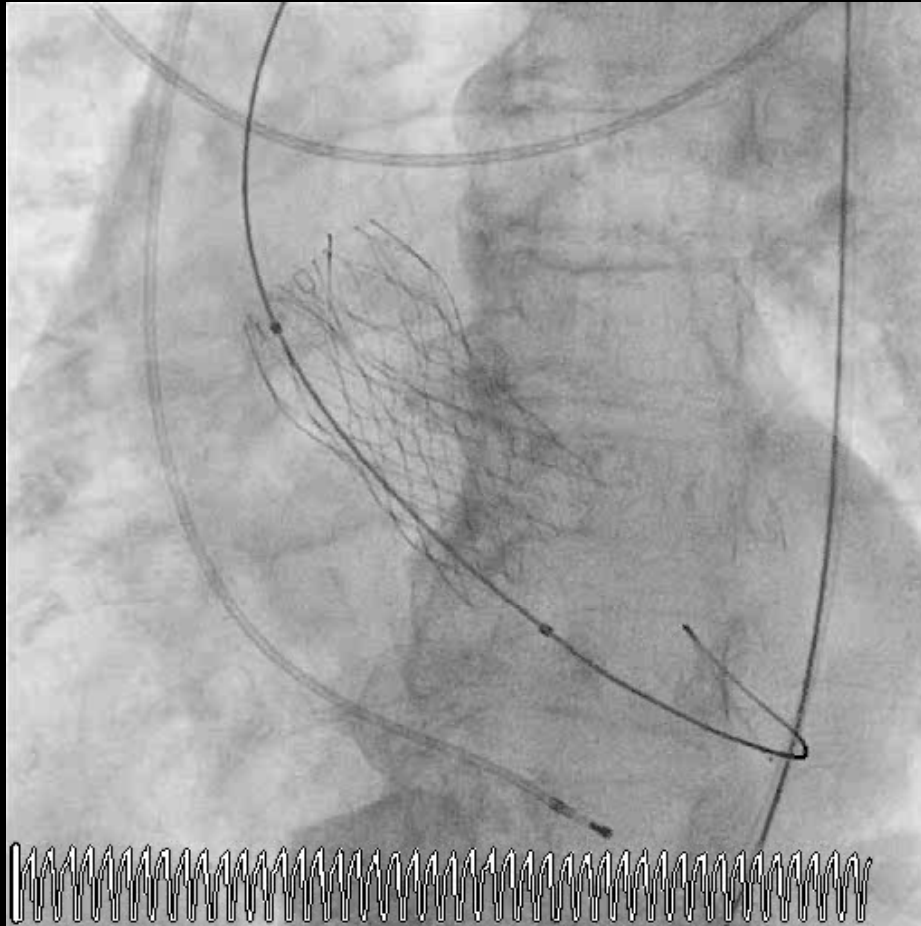
Frame underexpansion despite Predilation



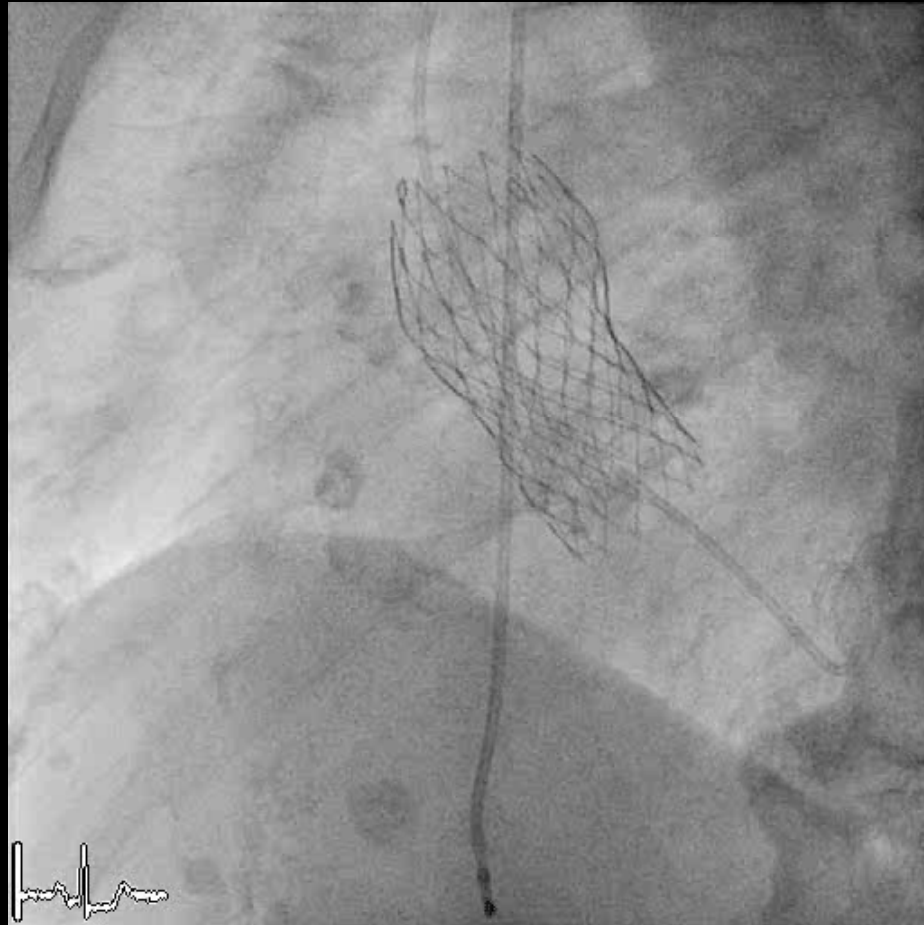
Frame underexpansion despite Predilation



Frame underexpansion despite Predilation



Frame underexpansion despite Predilation



Frame underexpansion despite Predilation



TAVI without BAV favors patients...

- At high risk for ischemic stroke
 - Calcified aortic cusps
- With low cardiac output
 - Severely impaired LV function
 - No/low contractile reserve
 - Highly dilated LV

TAVI without Predilation

Symptomatic, aortic valve stenosis qualifying for TAVI
Medtronic CoreValve prosthesis 26 and 29mm
Transfemoral

International, multi-center

**TAVI without
Predilation**
N=60

versus

**TAVI
18F CoreValve S&E study***
N=126

Follow-Up

Postprocedural

30 d

12 mo

Primary Endpoint: Safety at 30 days

Secondary Endpoints: Procedural Success, valve gradient, paravalvular regurgitation, symmetry.

PI: Eberhard Grube MD

Feasibility of Transcatheter Aortic Valve Implantation Without Balloon Pre-Dilation

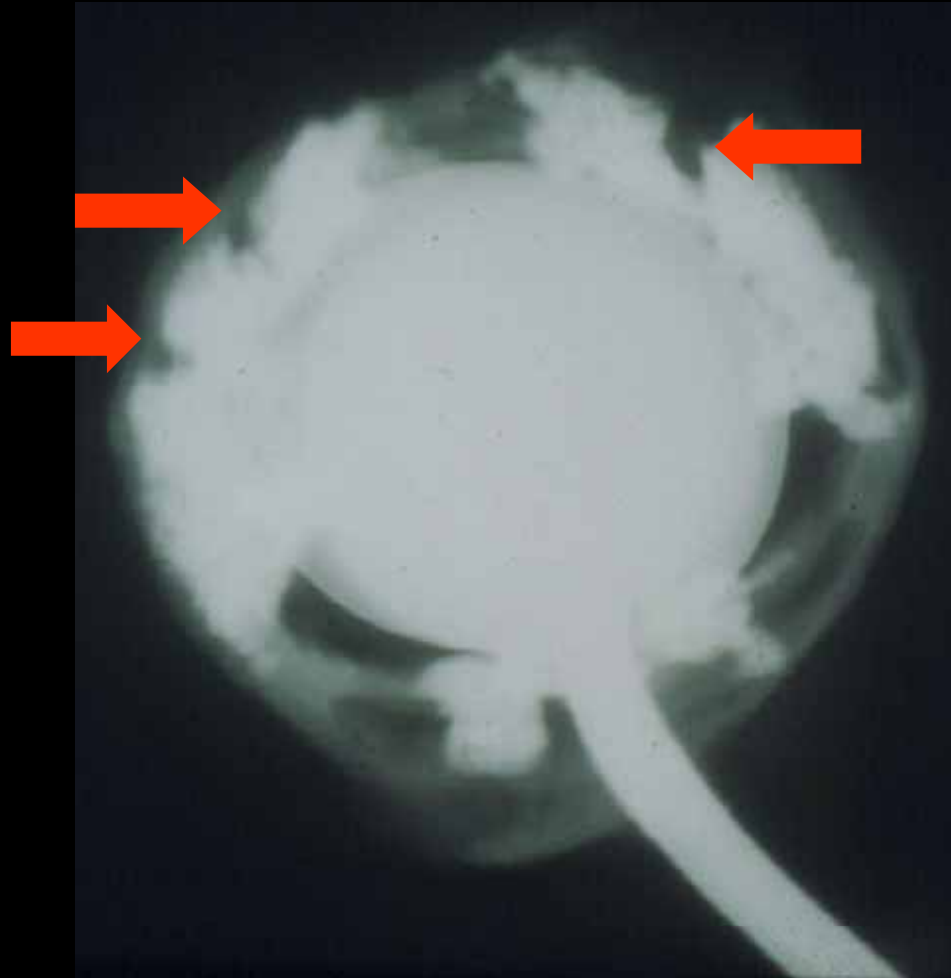
A Pilot Study

Eberhard Grube, MD,* Christoph Naber, MD,† Alexandre Abizaid, MD,‡
Eduardo Sousa, MD,‡ Oscar Mendiz, MD,§ Pedro Lemos, MD,|| Roberto Kalil Filho, MD,||
Jose Mangione, MD,¶ Lutz Buellesfeld, MD#

Bonn and Essen, Germany; Sao Paulo, Brazil; Buenos Aires, Argentina; and Bern, Switzerland

*Grube E et al. J Am Coll Cardiol. 2011;

X-ray of BAV in autopsied heart
(note splits in Ca⁺⁺ nodules)



Procedural Results

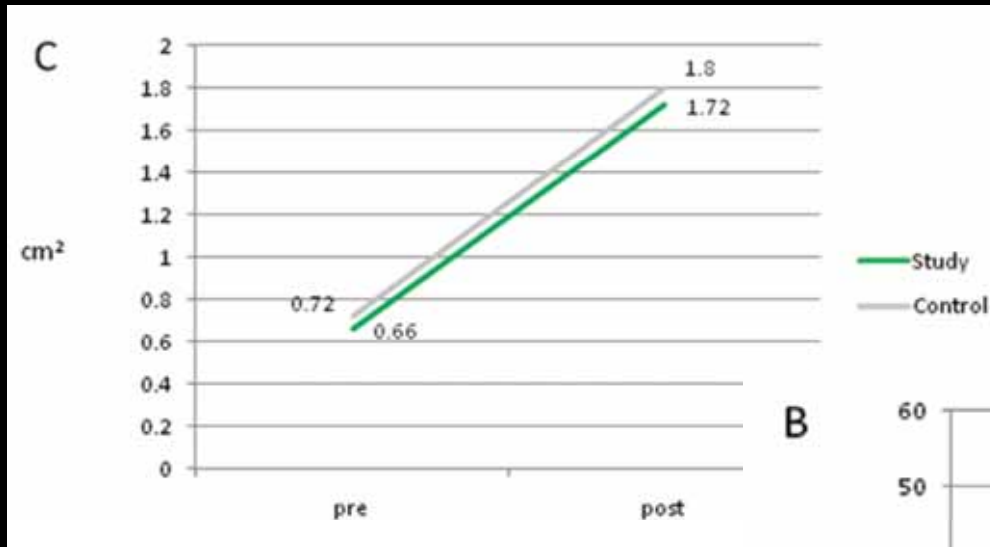
	Study Group n=60	Control Group n=126
Technical Success Rate	96.7% (58)	81.7% (103)
Valve embolization	0	0
Conversion to surgery	1.7% (1)	5.6% (7)
Postdilation	16.7% (10)	n.a.

Clinical Outcome at 30days

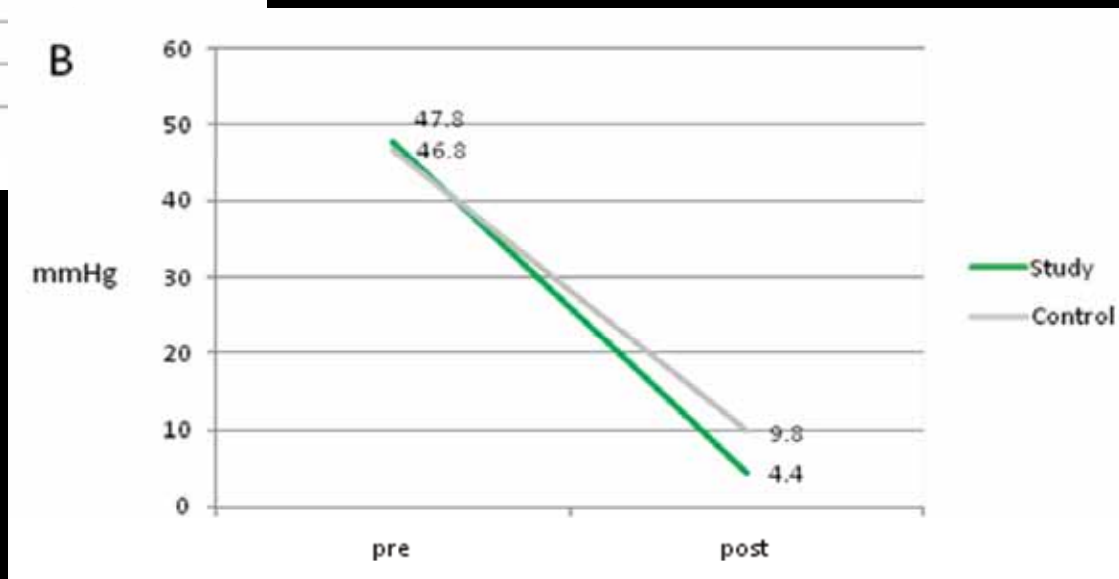
	Study Group n=60	Control Group n=126
All-cause Mortality	6.7% (4)	14.3% (18)
Myocardial infarction	0	5.6% (7)
Stroke/TIA	5.0% (3)	11.9% (15)
Need for pacemaker implantation	11.7% (7)	27.8% (35)
Vascular Access Complication	10.0% (6)	9.5% (12)

“Direct” TAVI without balloon predilation

Effective orifice area



Mean pressure gradients



Direct TAVI in “*real life*”

	Grube et al. ¹⁰ (n=60)	UKB Bonn (n=140) <u>With</u> Pre-dilatation	UKB Bonn (n=54) <u>Without</u> Pre-dilatation	P-Value*
Technical success, n (%)	58 (96.7)	137 (97.8)	53 (98.1)	0.97
Post-dilatation, n (%)	10 (16.7)	41 (29.3)	16 (29.6)	0.96
Mean gradient (mmHg)	4.4 ± 2.0	7.1 ± 6.4	9.2 ± 9.4	0.11
30-day mortality, n (%)	4 (6.7)	10 (7.1)	3 (5.6)	0.40
Pacemaker implantation, n (%)	7 (11.7)	35 (25.0)	7 (13.0)	0.011
Stroke, n (%)	3 (5.0)	8 (5.7)	0 (0)	0.073
Myocardial infarction, n (%)	0 (0)	4 (2.9)	0 (0)	0.21
Acute kidney injury, n (%)	n.a.	36 (26.3)	9 (16.7)	0.22
Moderate/severe periAR, n (%)	7 (11.7)	23 (16.4)	2 (3.7)	0.018

Sinning/Grube, *unpublished data*

Multicenter randomized clinical trial evaluating balloon valvuloplasty before valve implantation

SIMPLIFY TAVI Study

TITLE OF STUDY	Use of the Self-Expandable CoreValve Prosthesis without Predilatation in Patients with Severely IMPaired Left-Ventricular Ejection Fraction for Transcatheter Aortic Valve Implantation Study. The SIMPLIFY TAVI Study
CONDITION	Aortic stenosis, left-ventricular ejection fraction $\leq 35\%$, transcatheter aortic valve implantation (TAVI)
OBJECTIVE(S)	To demonstrate that the avoidance of balloon valvuloplasty of the native aortic valve with use of a self-expandable transcatheter heart valve is associated with a reduction of the composite primary endpoint in TAVI patients with severely impaired left-ventricular ejection fraction (EF $\leq 35\%$)
INTERVENTION(S)	Control intervention: TAVI procedure including balloon valvuloplasty before valve deployment (Group A). Experimental intervention: TAVI <u>without</u> balloon valvuloplasty before valve deployment (Group B). Follow-up per patient: All patients will be followed up for 30 days, 6 months, and 1 year after TAVI.