Impianto transcatetere di protesi valvolari aortiche
Approccio transfemorale

Rules of Engagement

Dr. A. Agostinelli

Dr. L. Vignali

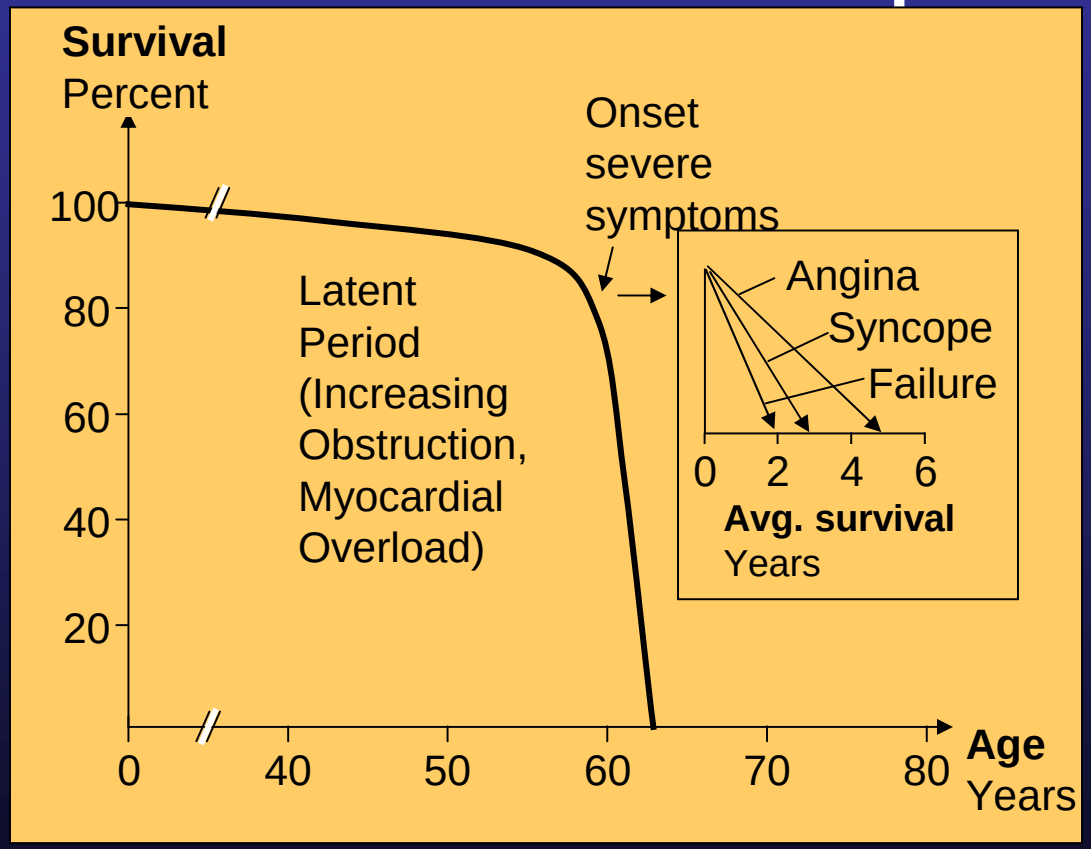
Cardiac Surgery

Parma
2012

Interventional Cardiology

Aortic stenosis is life-threatening and progresses rapidly

The Problem Is Serious
Treatment Options and Timing Matter



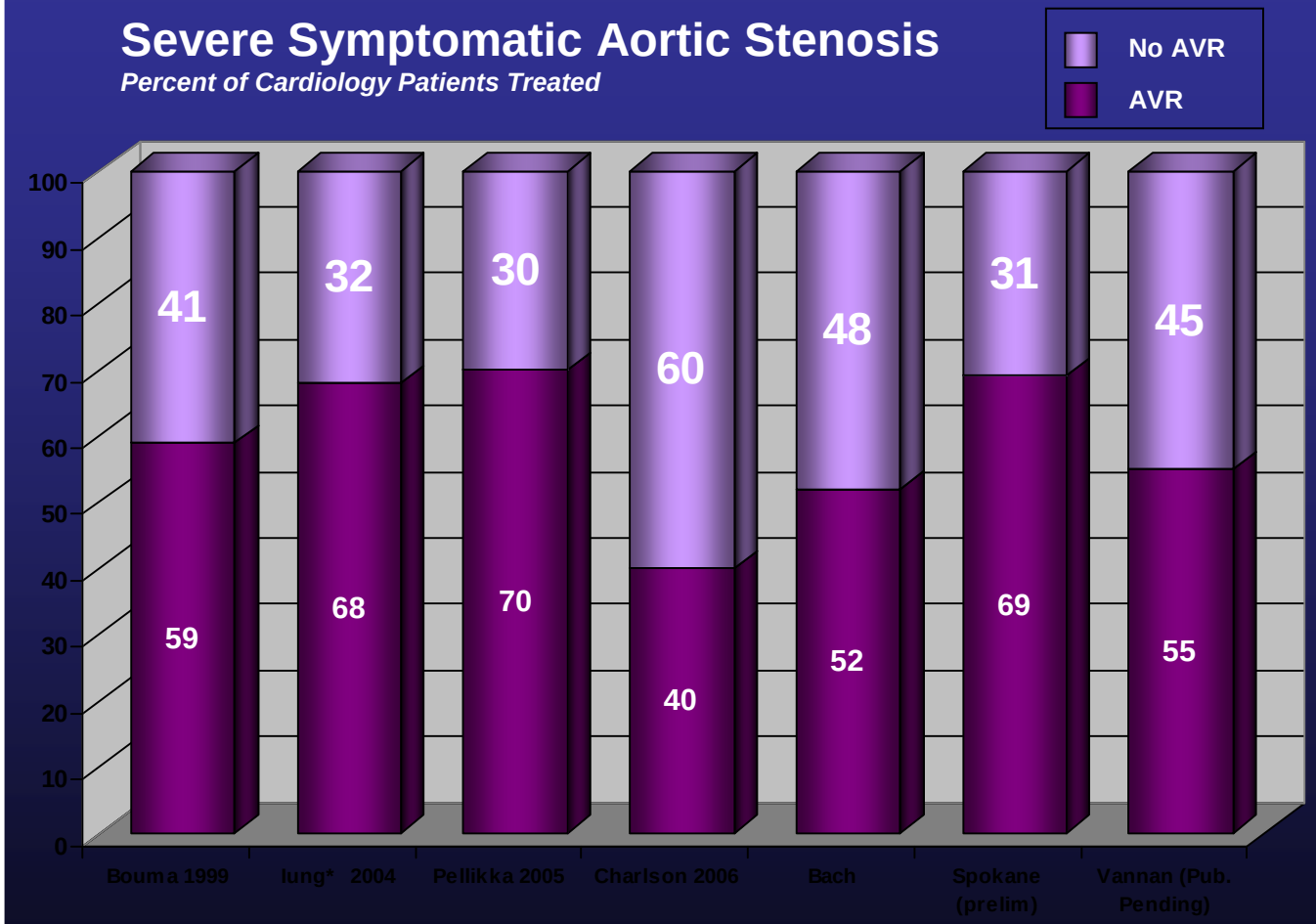
"Survival after onset of symptoms is 50% at two years and 20% at five years."[1]

"Surgical intervention [for severe AS] should be performed promptly once even … minor symptoms occur."[2]

Sources: [1] S.J. Lester et al., "The Natural History and Rate of Progression of Aortic Stenosis," *Chest* 1998

[2] C.M. Otto, "Valve Disease: Timing of Aortic Valve Surgery," *Heart* 2000

At least 30-40% of Cardiologists' AS Patients Go Untreated



Under-treatment especially prevalent among patients managed by *Primary Care* physicians

1. Bouma B J et al. To operate or not on elderly patients with aortic stenosis: the decision and its consequences. Heart 1999;82:143-148
2. Iung B et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. European Heart Journal 2003;24:1231-1243 (includes both Aortic Stenosis and Mitral Regurgitation patients)
3. Pellikka, Sarano et al. Outcome of 622 Adults with Asymptomatic, Hemodynamically Significant Aortic Stenosis During Prolonged Follow-Up. Circulation 2005
4.

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 LELAC

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

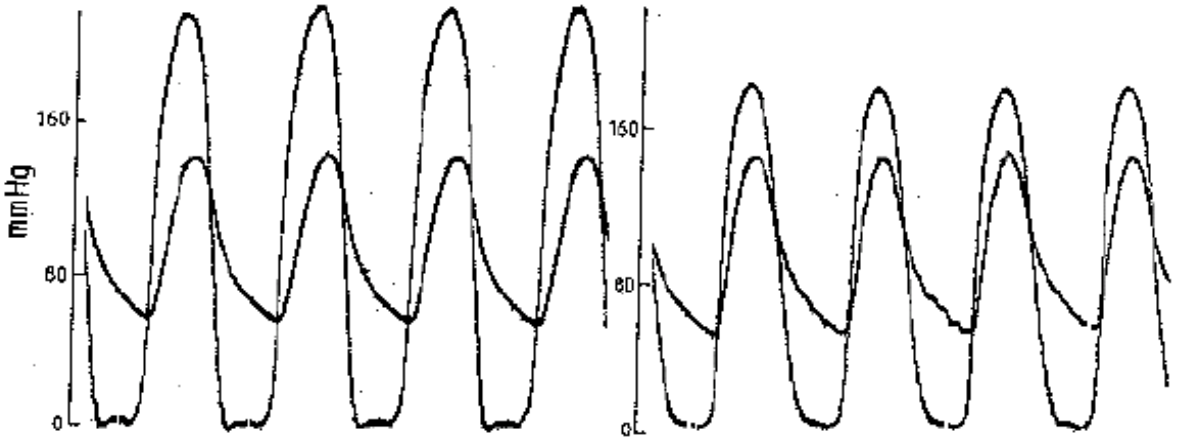


Fig 3—Simultaneous recording of left ventricular and aortic pressures before (left) and at the end of PTAV (right) in case 1.

Transvalvular systolic gradient decreased from 90 to 40 mm Hg

Lancet, January 11, 1986

Dr. Alain Cribier

First-in-Man PIONEER

Circulation — American Heart Association. Learn and Live.

Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis

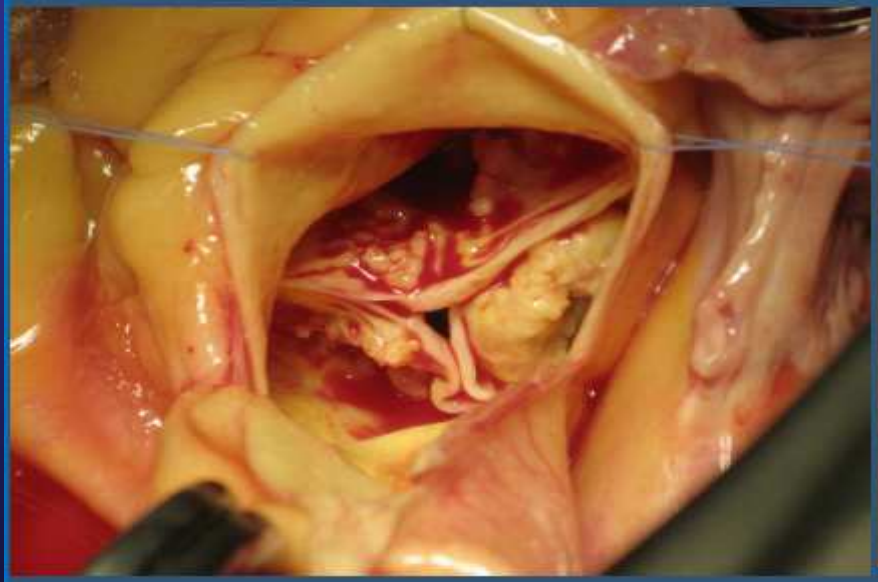
First Human Case Description

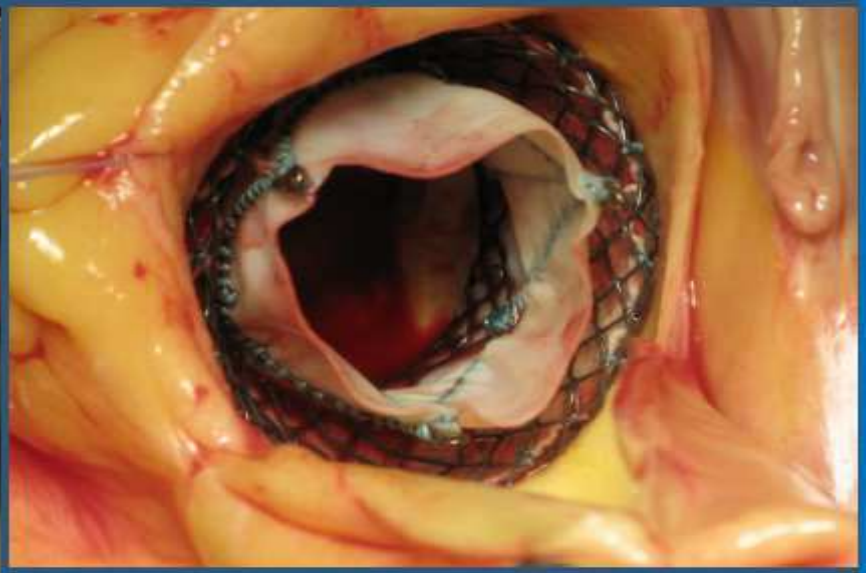
Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derumeaux, MD; Frederic Anselme, MD; François Laborde, MD; Martin B. Leon, MD

Conclusions— Nonsurgical implantation of a prosthetic heart valve can be successfully achieved with immediate and midterm hemodynamic and clinical improvement.

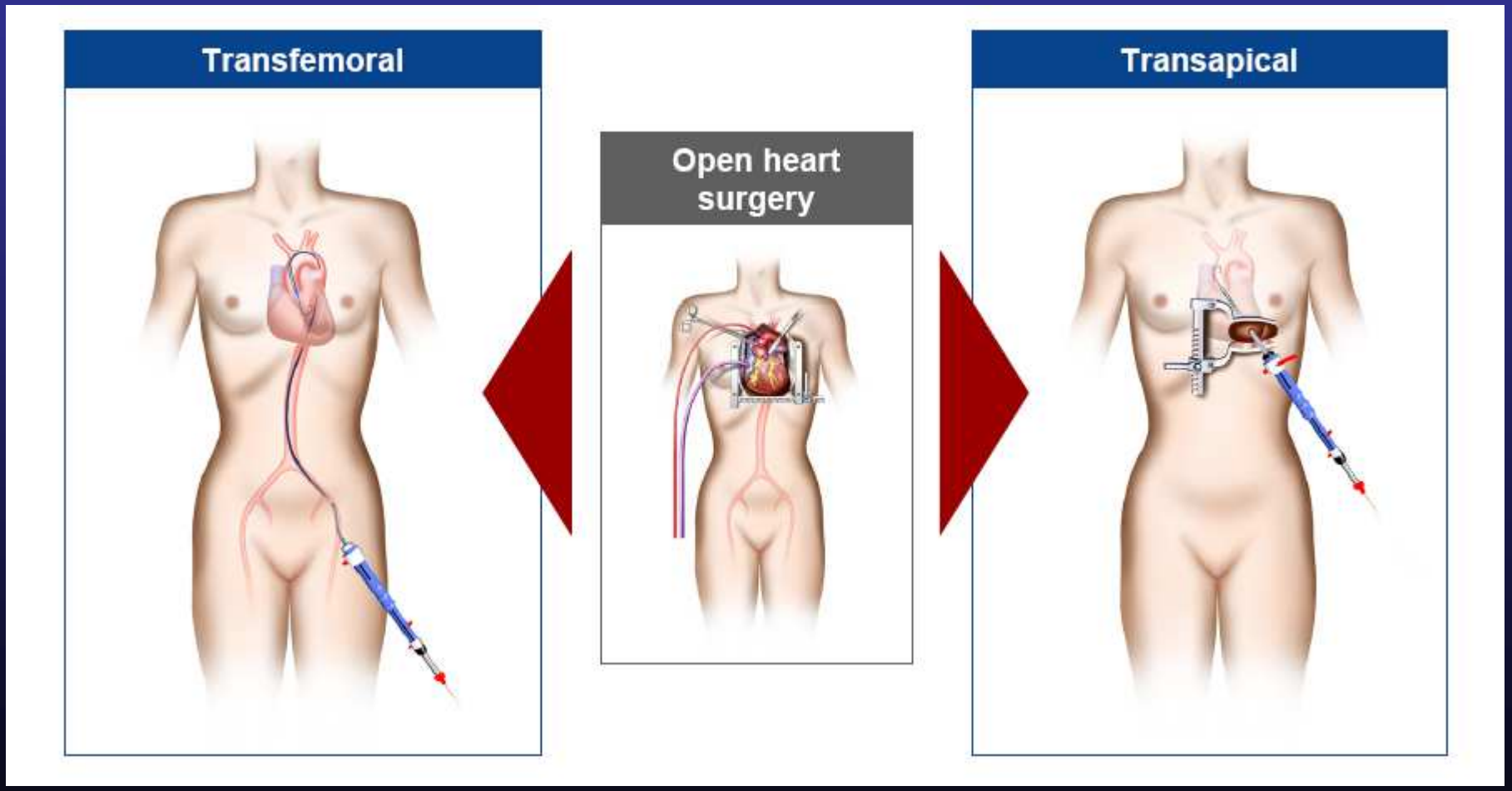
April 16, 2002

Acute Implant Study



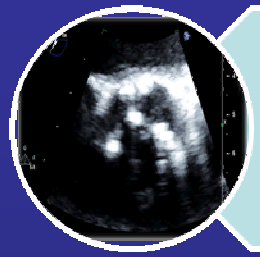


Tecniche di impianto di protesi valvolari Aortiche



PATIENT INDICATIONS

AVA < 0.8 cm^2

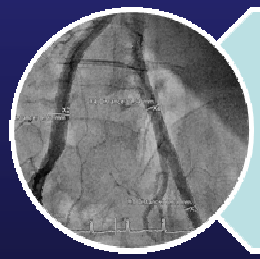


Symptomatic Aortic Stenosis

STS > 10 %
Euroscore > 20 %

Risk Evaluation

26 mm > 8 mm
23 mm > 7 mm



Femoral Minimal Diameter

18 to 24 mm

Annulus by TEE

CONTRA INDICATIONS

1. Non-valvular aortic stenosis
2. Congenital aortic stenosis, unicuspid or bicuspid aortic valve
3. Non-calcified aortic stenosis
4. Evidence of intracardiac mass, thrombus or vegetation
5. Active bacterial endocarditis or other active infections
6. Untreated clinically significant coronary artery disease requiring revascularization
7. Severe ventricular dysfunction with ejection fraction < 20%
8. Unstable angina during index procedure
9. Myocardial infarction within 1 month
10. Cerebrovascular accident (CVA)
11. Severe coagulation problems
12. Hypertrophic cardiomyopathy with or without obstruction (HOCM)
13. Presence of mitral bioprosthesis
14. Recent pulmonary emboli
15. Significant atheroma of femoral and iliac vessels
16. Severe deformities of the chest
17. Severe tortuosities of the femoro-iliac vessels
18. Patients with bilateral iliofemoral bypasses
19. Severe calcifications or femoro-iliac vessels < 7mm

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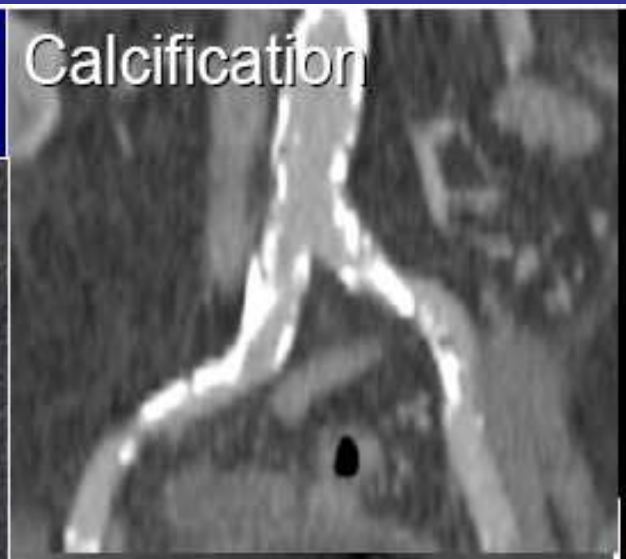
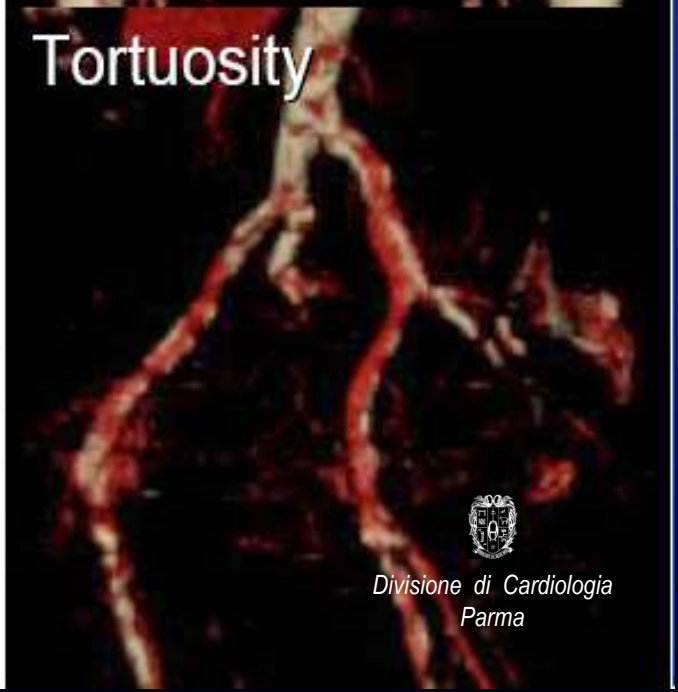
Parma

Access





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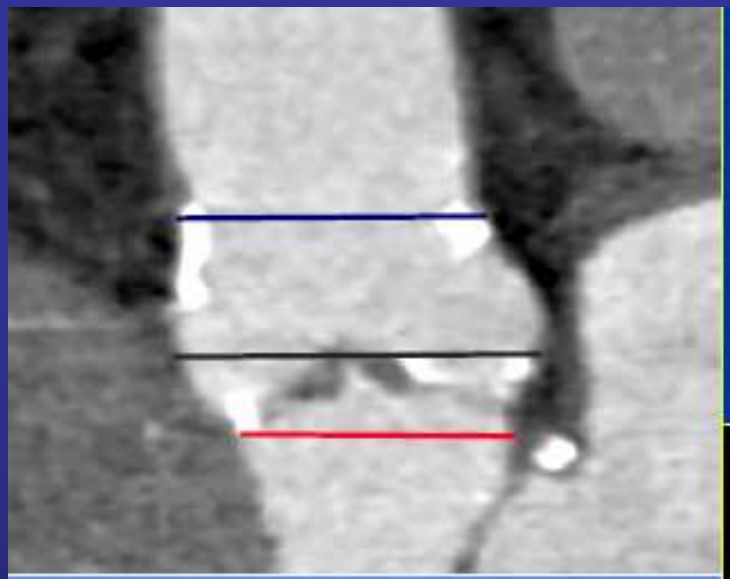
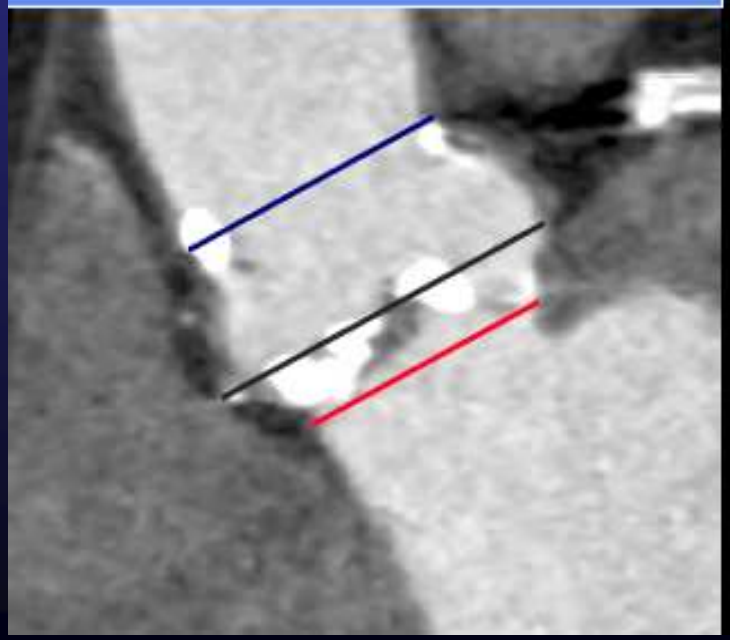
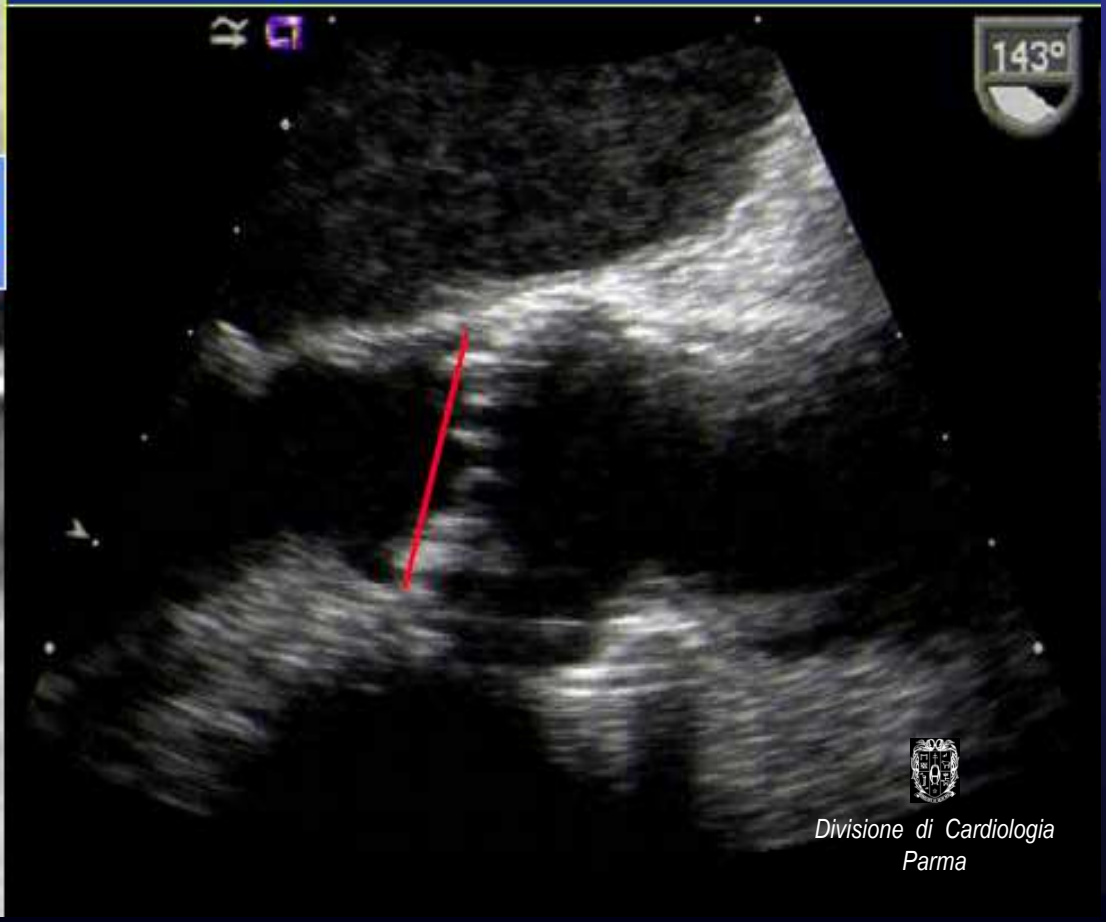
Annulus Size by CT and TEE



ST Junction Annulus Valve





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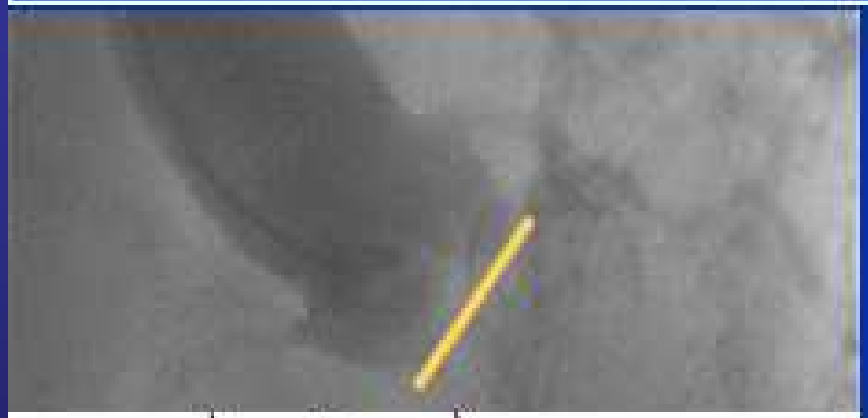
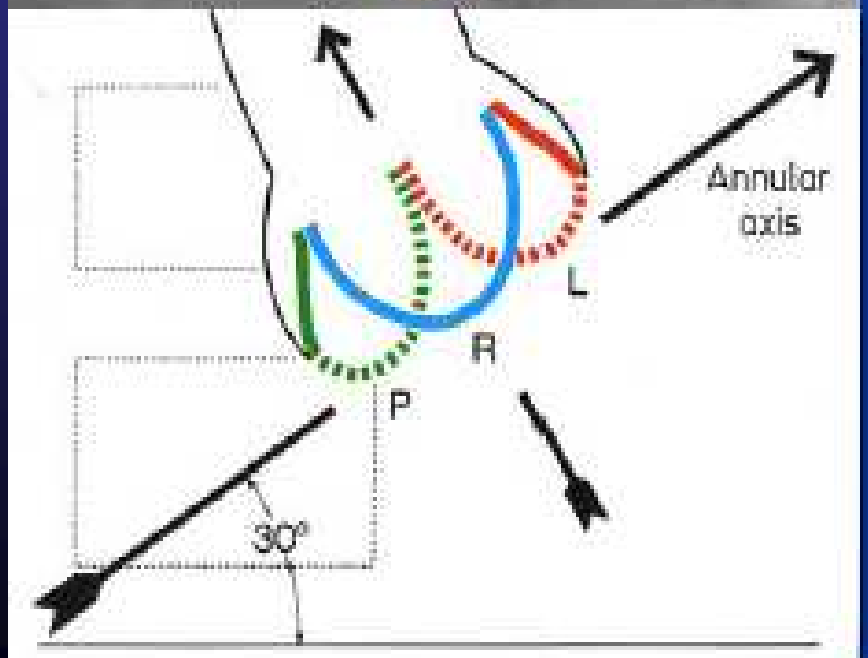
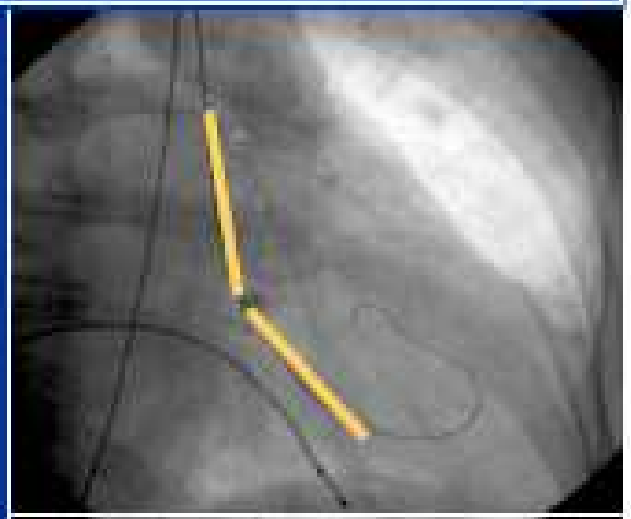
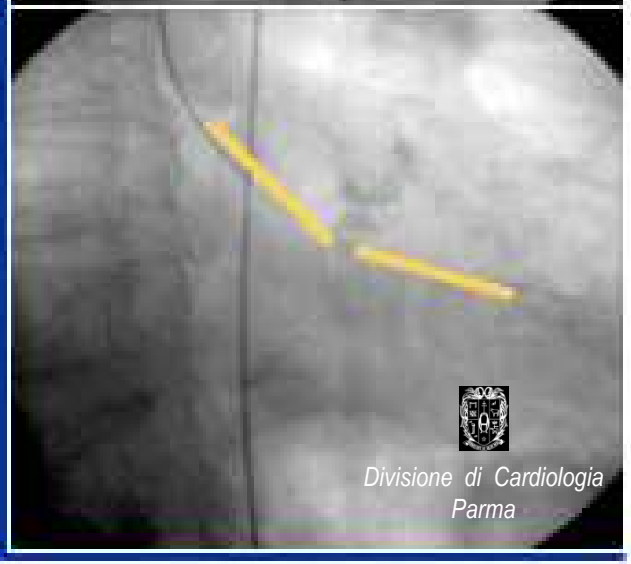
Angiographic Landmarks for Valve Implantation

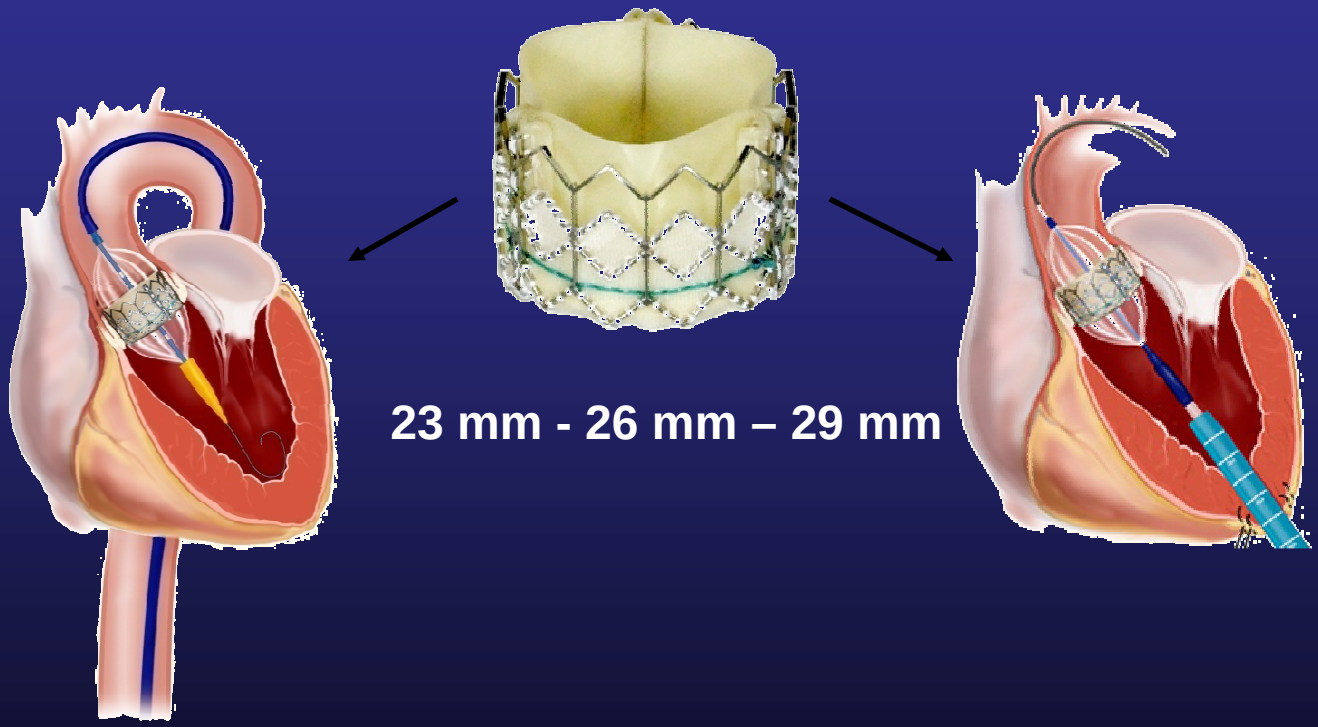








Edwards SAPIEN™ Transcatheter Heart Valve: **Two Delivery Options**



23 mm - 26 mm – 29 mm

TRANSFEMORAL

TRANSAPICAL

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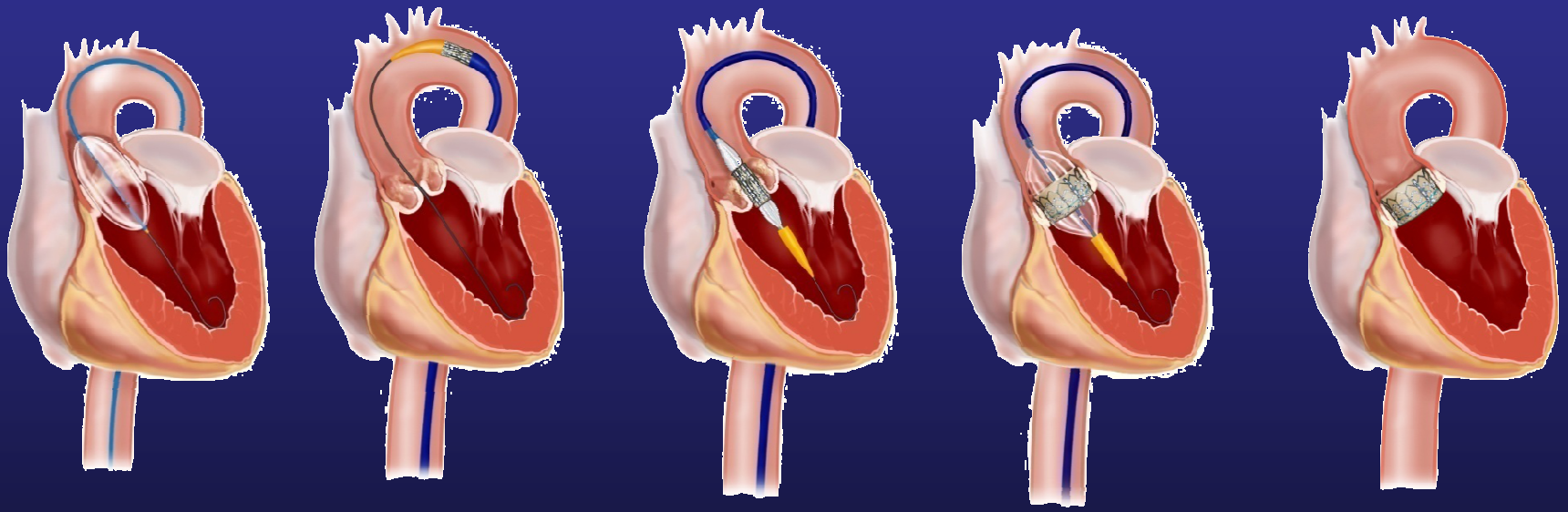
Edwards SAPIEN™ Transcatheter Heart Valve:
The Transfemoral Approach



Balloon Aortic Valvuloplasty

RetroFlex™ II Advancement

Valve Positioning

Valve Deployment

Final Result

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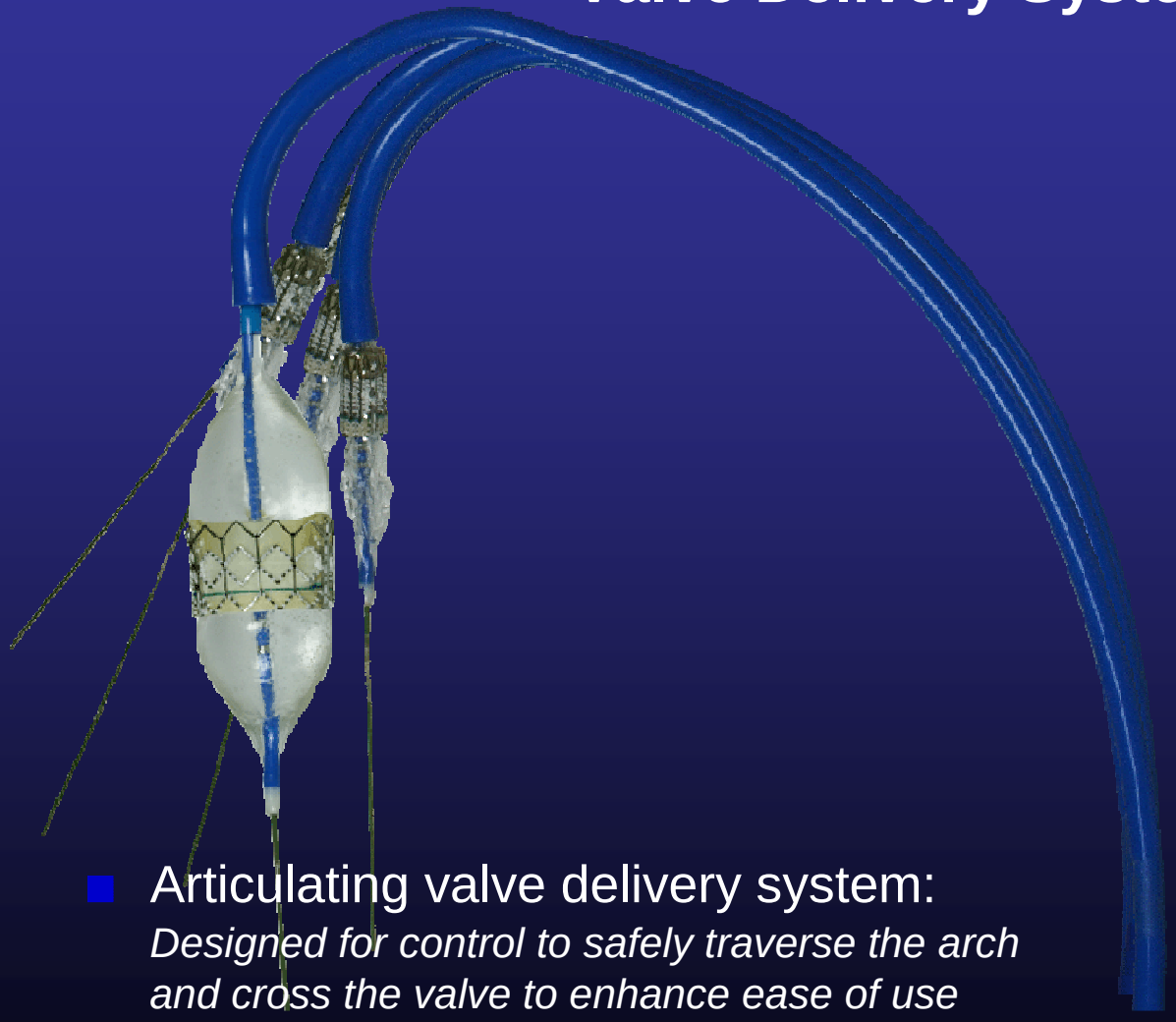
RetroFlex™ Transfemoral
Valve Delivery System



- Articulating valve delivery system:
  Designed for control to safely traverse the arch and cross the valve to enhance ease of use

Evolution of Aortic Valve Implant

2002 2004 2006

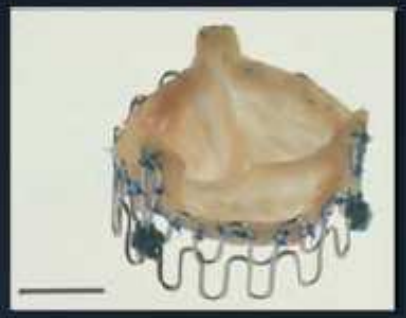
First aortic transcatheter Implant via antegrade Approach
A. Cribier

First aortic Implant of the CoreValve via retrograde Approach
JC.Laborde, E. Grube

First percutaneous CoreValve Implant without Circ.Support
E. Grube, U. Gerckens

20 YEARS OF INNOVATION
TCT 2008

Edwards Transcatheter Valve Evolution



Andersen hand-made
Percutaneous Aortic Valve
First pig implant, May '89

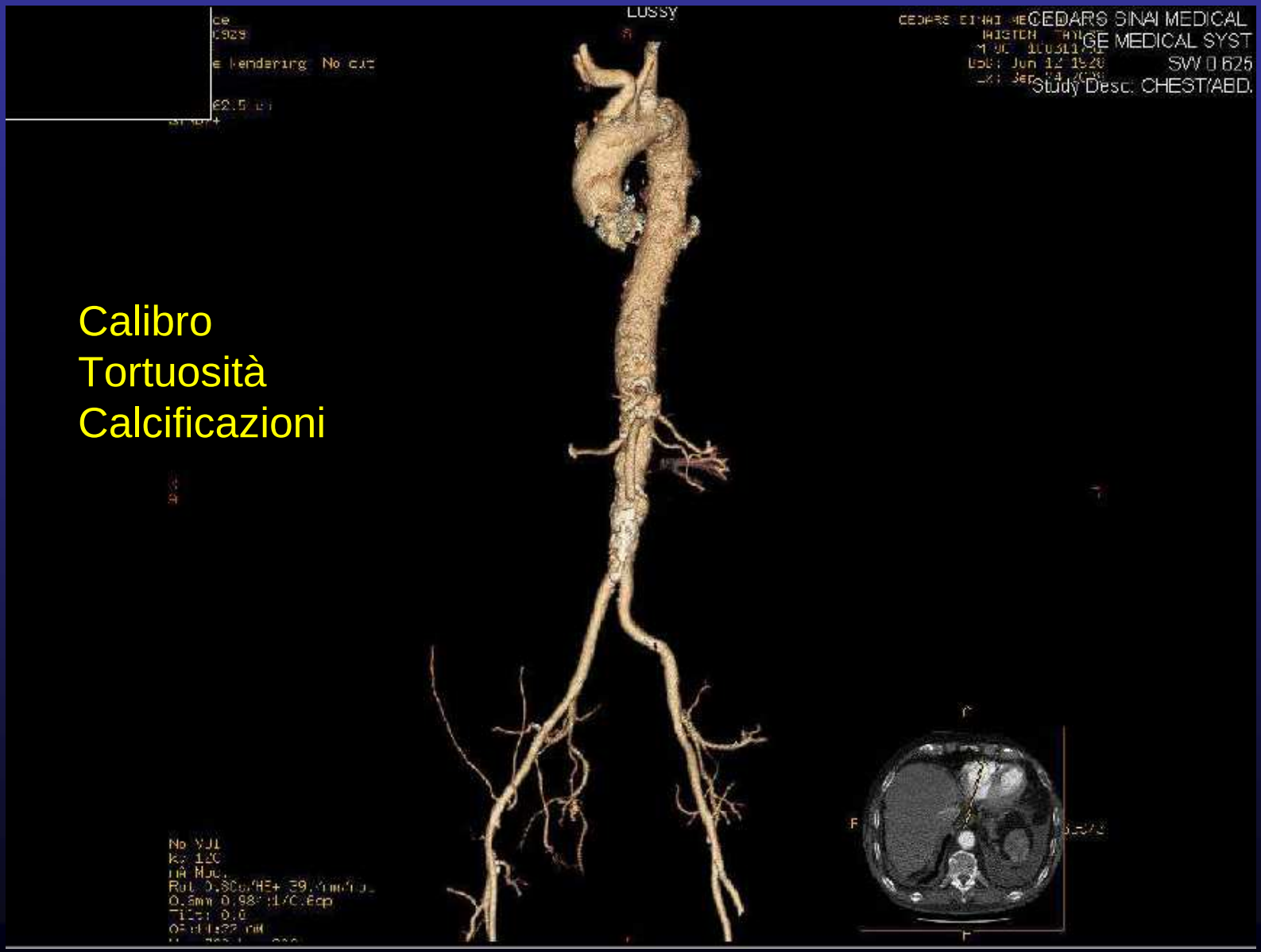
Untreated Equine Tissue

Cribier-Edwards™ THV
23mm FIM, April 2002

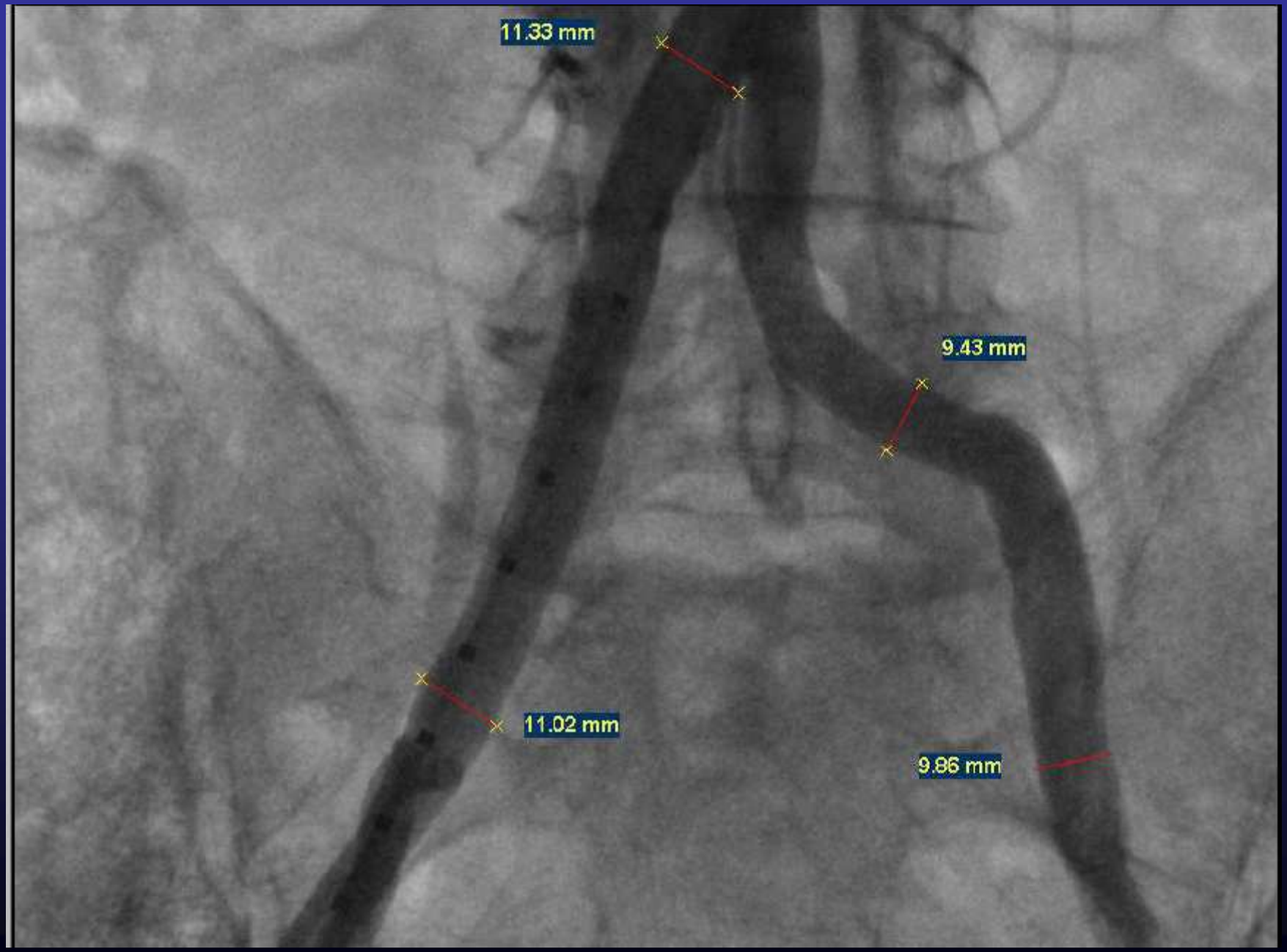
Treated Bovine Tissue

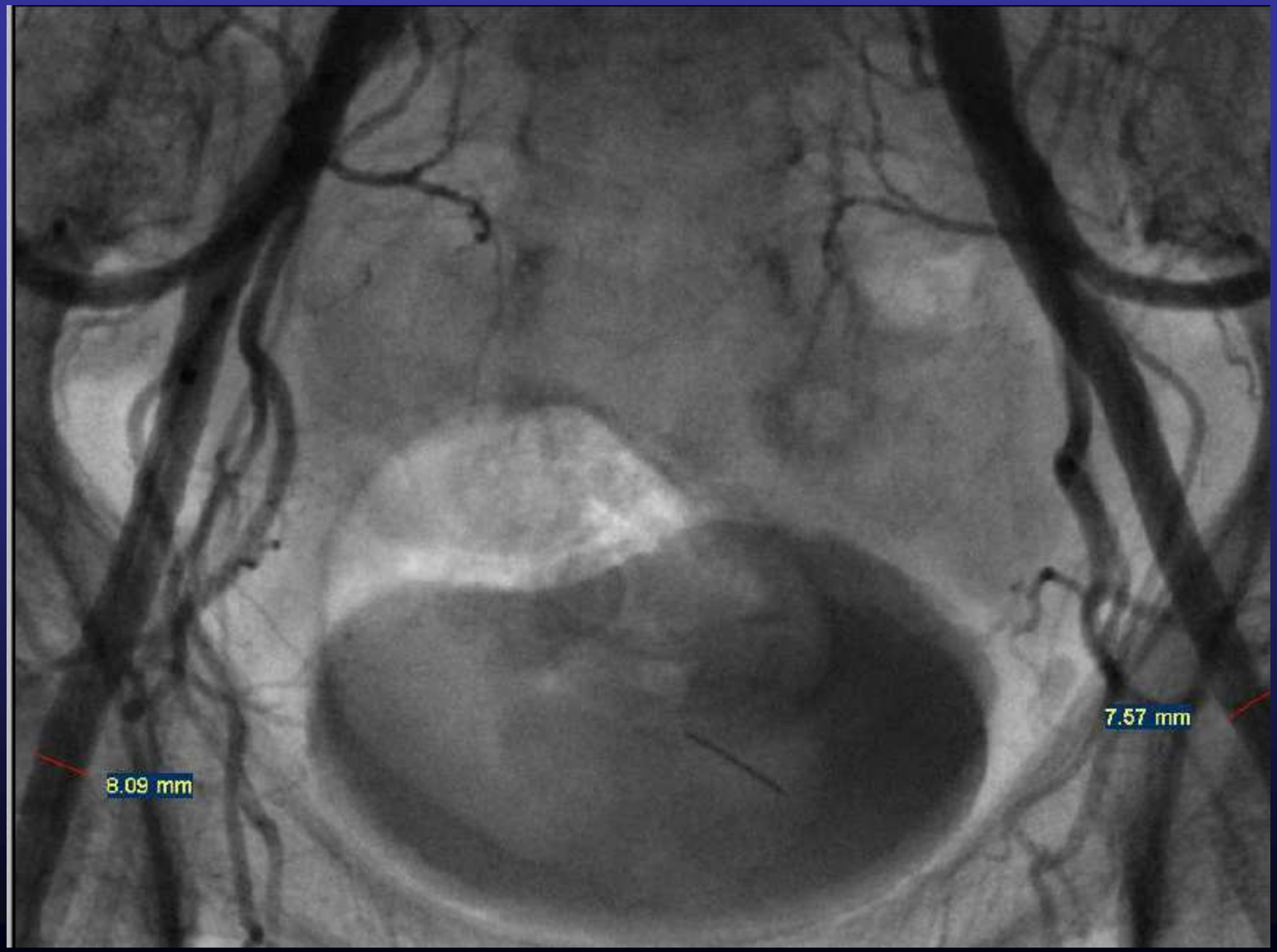
Edwards SAPIEN™ THV
23mm, 26mm
August, 2007

APPROCCIO RETROGRADO

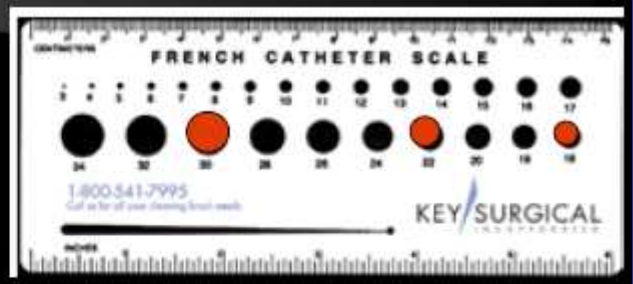


Calibro
Tortuosità
Calcificazioni


11.33 mm
9.43 mm
11.02 mm
9.86 mm


8.09 mm
7.57 mm

Catheter Size Reduction



Generation 1
25F
Transcatheter

Generation 2
21F
Transcatheter

Generation 3
18F
Percutaneous

2004-2005

N=10

2005-2006

N=24

Oct 2006

N=237

Siegburg Total
N=271

Siegburg

20 YEARS OF INNOVATION
TCT 2008

CoreValve PAVR *ReValving* System

Delivery Catheter Evolution

GEN1
8mm

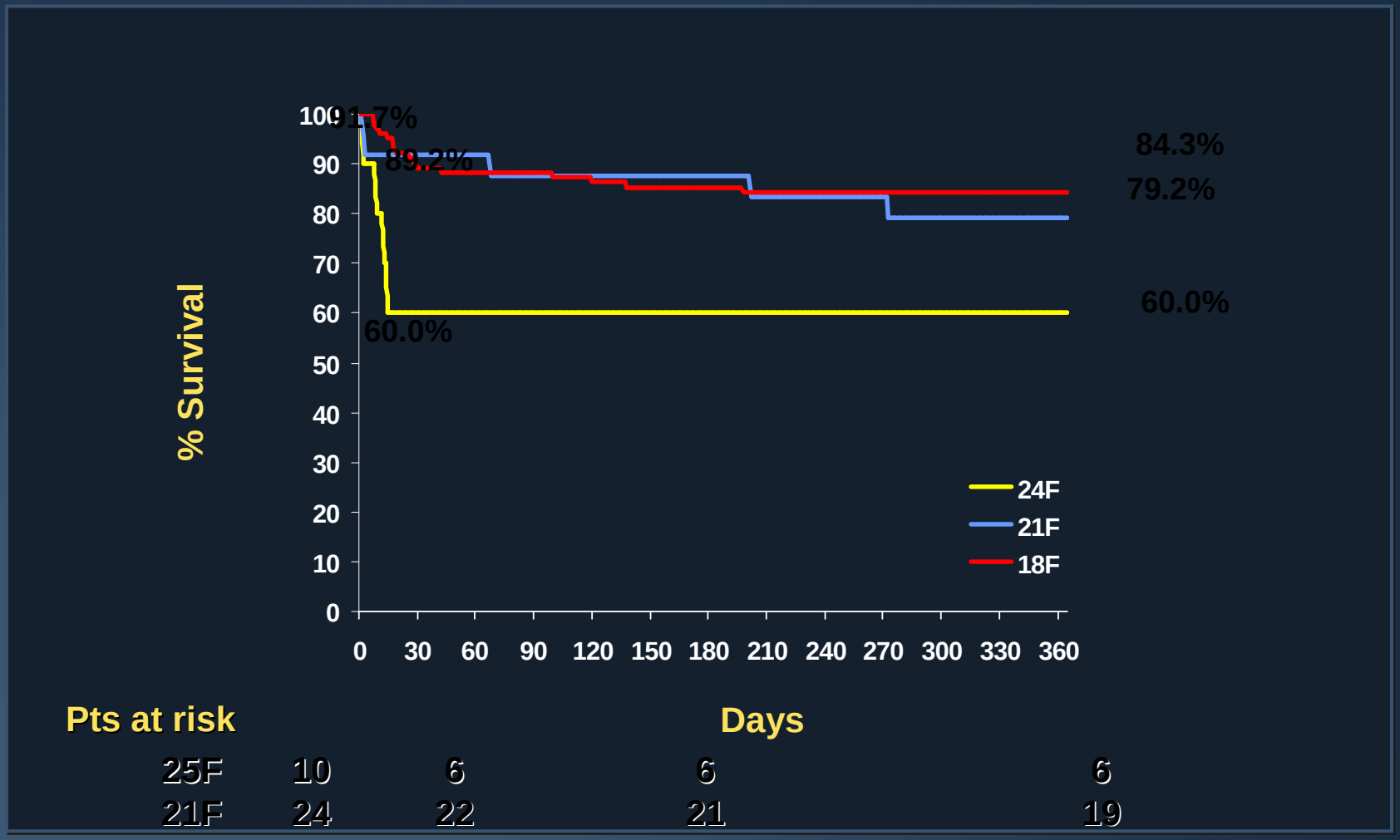
GEN2
7mm

GEN3
6mm = 18 Fr

CARDIOVASCULAR RESEARCH FOUNDATION

CoreValve Siegburg Experience

One-year Survival



Pts at risk			Days	
25F	10	6	6	6
21F	24	22	21	19
18F	102	91	66	51

Grube E, et al. *Circ Cardiovasc Intervent* 2008;1:167-75.

TCT 2009 TRANSCATHETER CARDIOVASCULAR THERAPEUTICS

Columbia University Medical Center

NewYork-Presbyterian

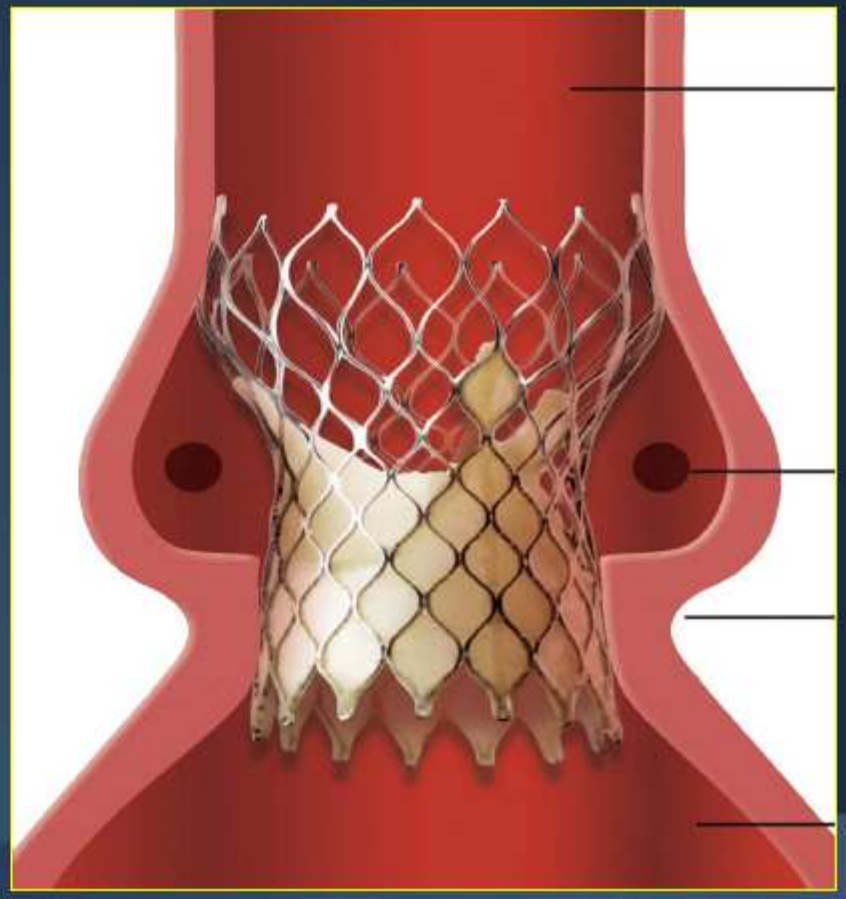
The University Hospital of Columbia and Cornell


CoreValve 2008
Anesthesiologist
Cardiologist

20 YEARS OF INNOVATION TCT 2008

CoreValve PAVR *ReValving* System
Frame and Valve

- ***Self Expandable Nitinol Frame***
  - ***no recoil***
  - ***radiopaque***
- ***Porcine Pericardium Tissue Valve***
- ***Size: 26 and 29 mm***

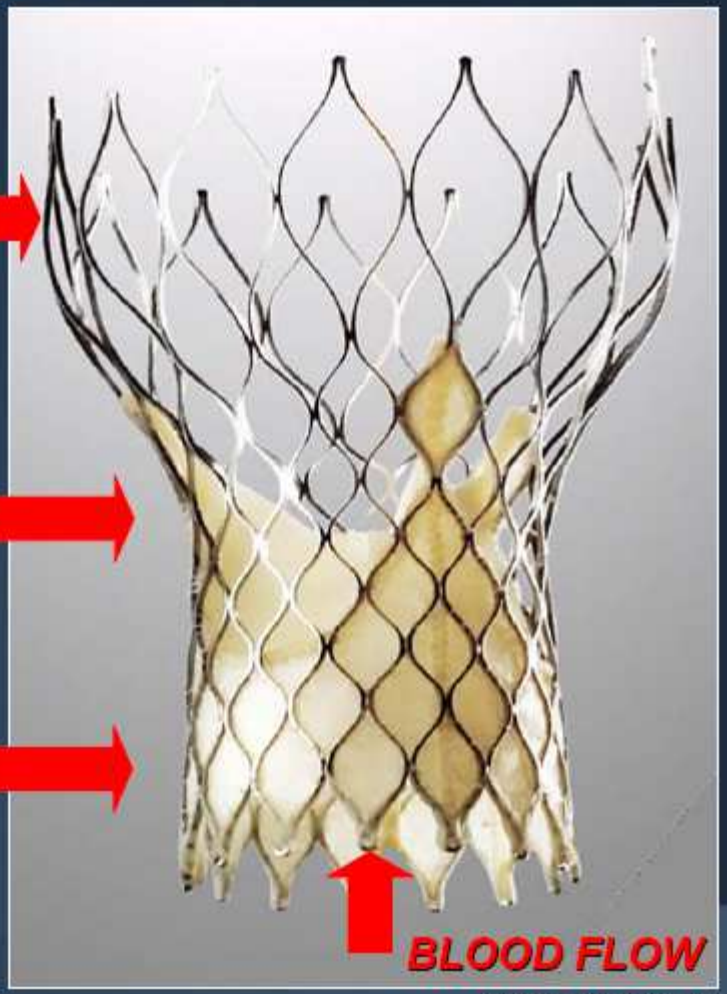


CARDIOVASCULAR RESEARCH FOUNDATION

20 YEARS OF INNOVATION TCT 2008

CoreValve PAVR *ReValving* System
Frame and Valve

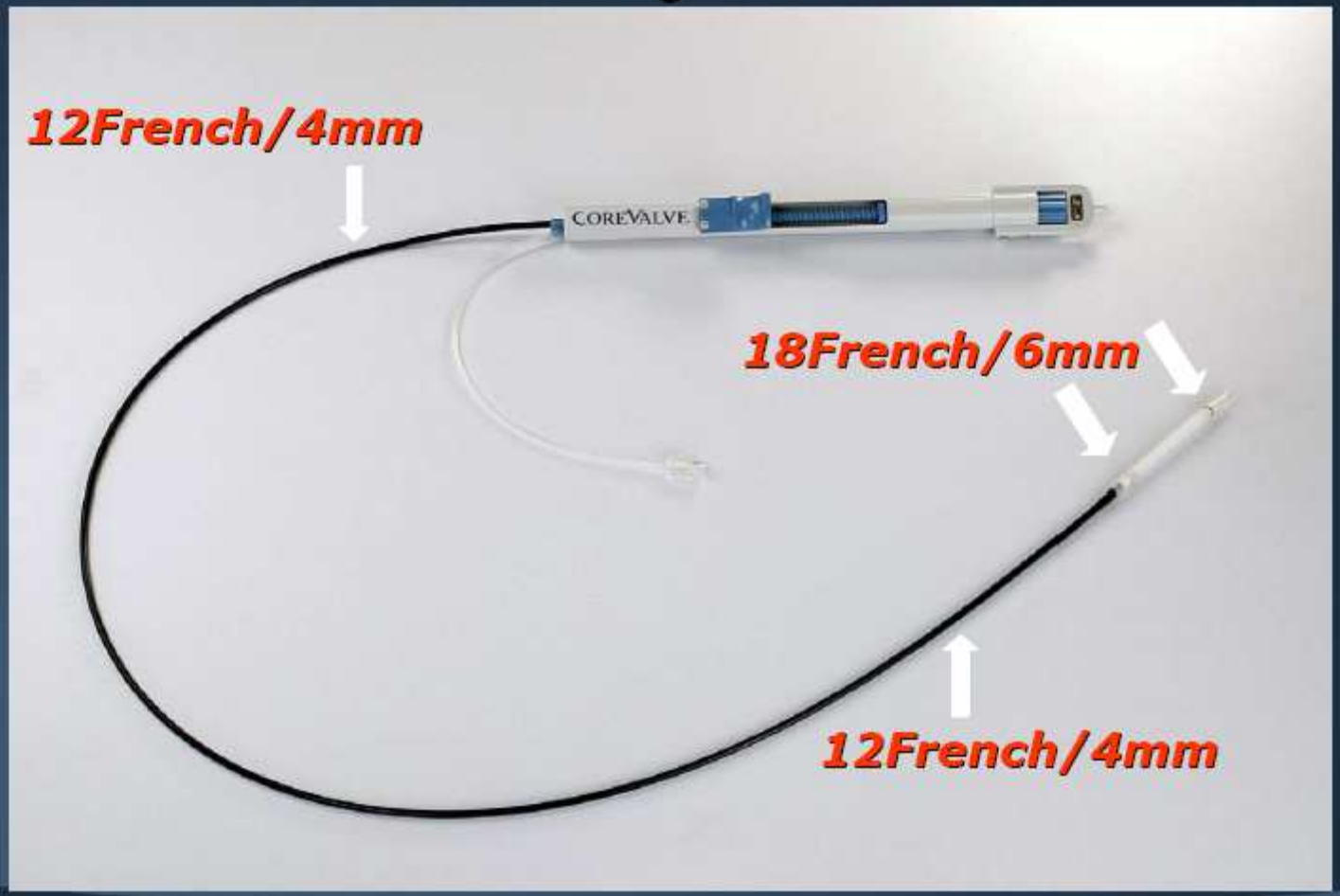
- ***Low radial force area***
  = orients the system
- ***Constrained area***
  = avoids coronaries
  = hosts supra-annular valve leaflets
- ***High radial force***
  = secure anchoring
  = mitigates paravalvular leak



CARDIOVASCULAR RESEARCH FOUNDATION

20 YEARS OF INNOVATION
TCT 2008

CoreValve PAVR *ReValving* System
Delivery Catheter



CARDIOVASCULAR RESEARCH FOUNDATION

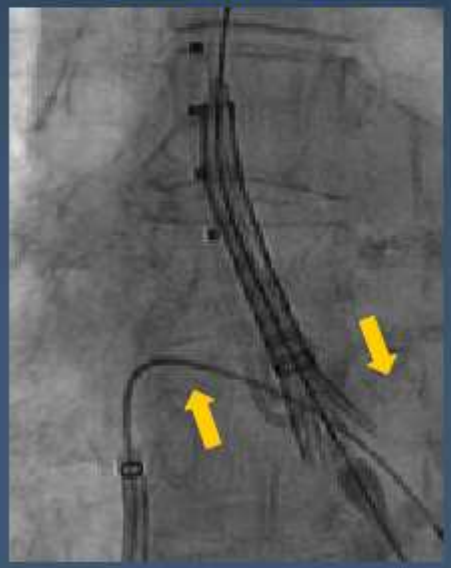
20 YEARS OF INNOVATION TCT 2008

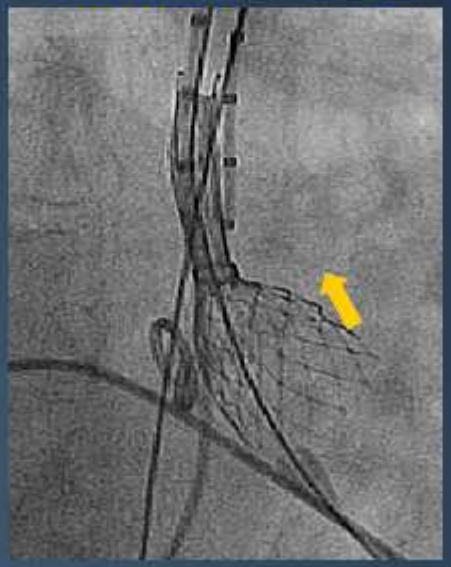
Lesson Learned
Slow and Stepwise Deployment Allows Repositionability

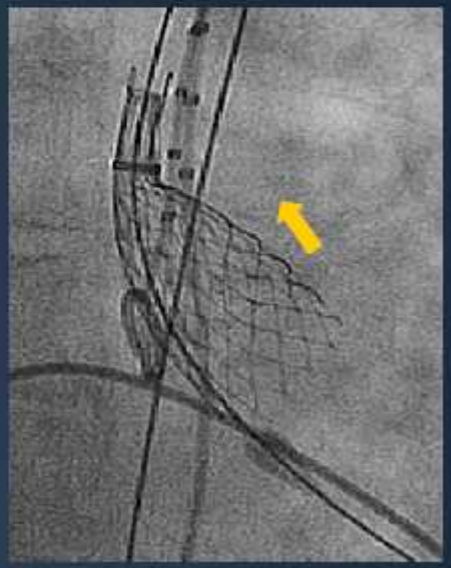
Before annular contact

After annular contact

Before device release

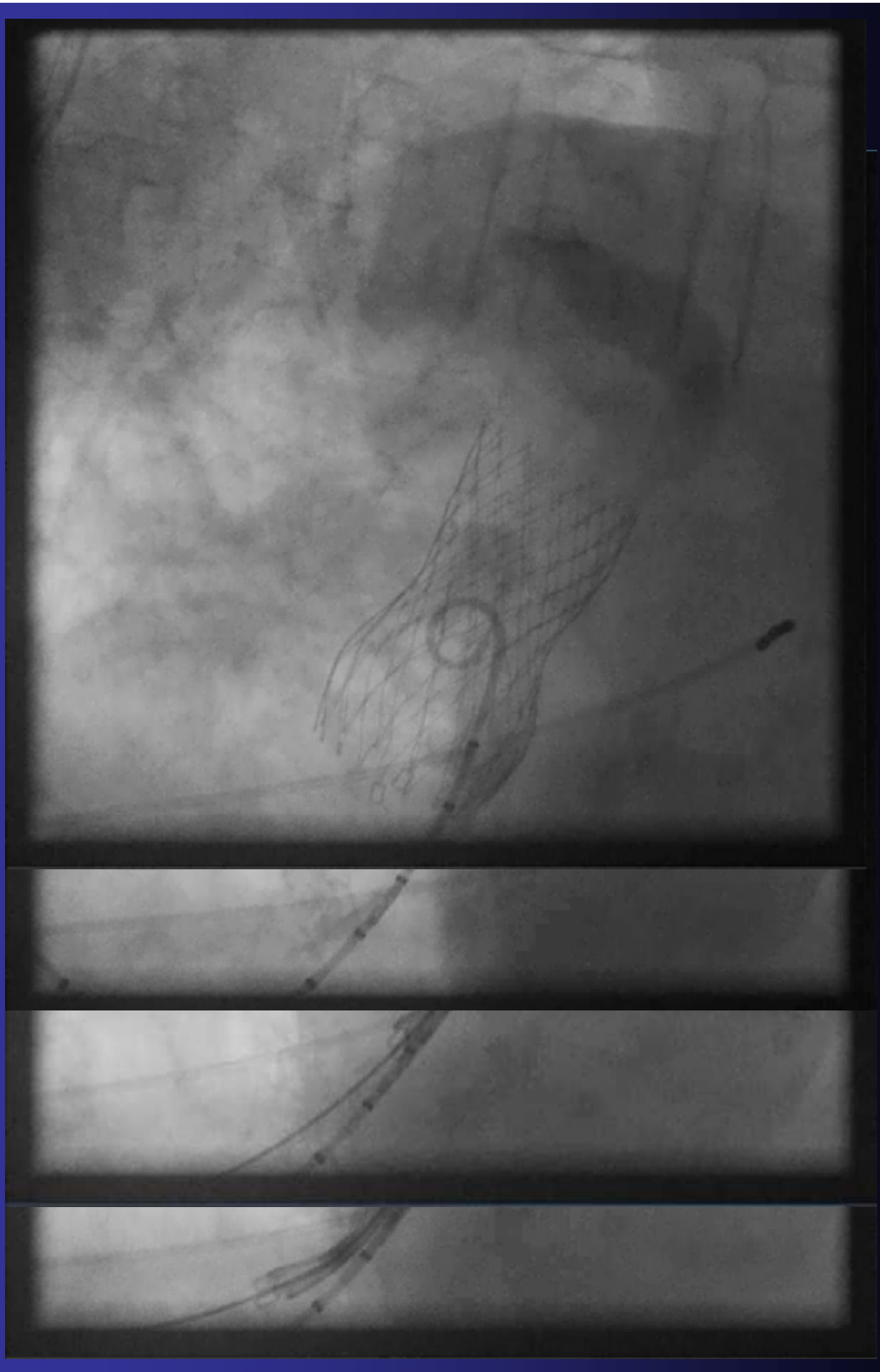


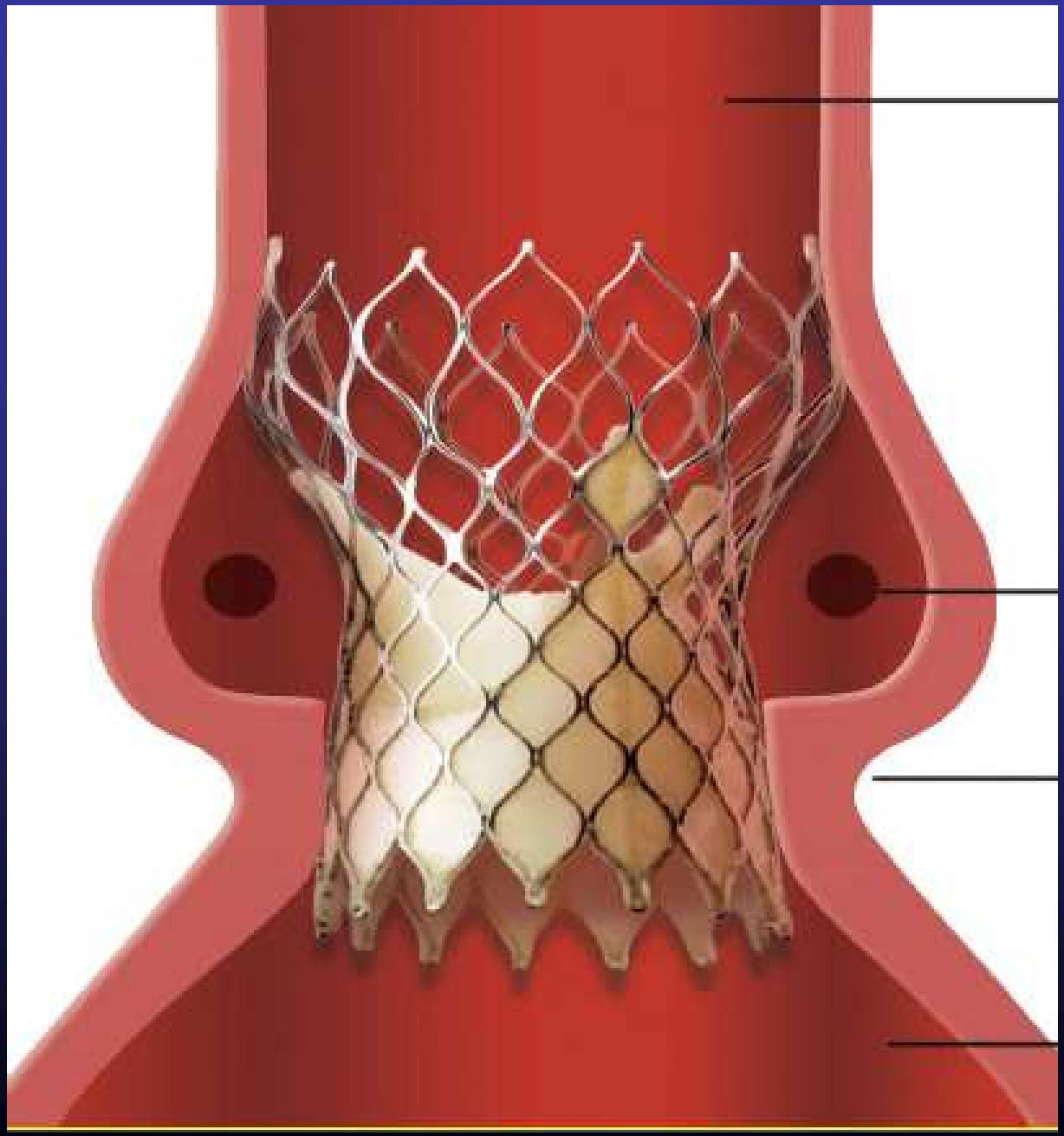




No need to "rush" since…

CARDIOVASCULAR RESEARCH




Aorta Ascendente
Ostio Coronarico
Anulus aortico
Cavità ventricolare

ACCESSI E PM TEMPORANEO

PREPARAZIONE CRIMPAGGIO VALVOLA

VALVULOPLASTICA 2

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NOVAFLEX E VALVOLA

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INSERIMENTO VALVOLA

NOVAFLEX IN ARCO

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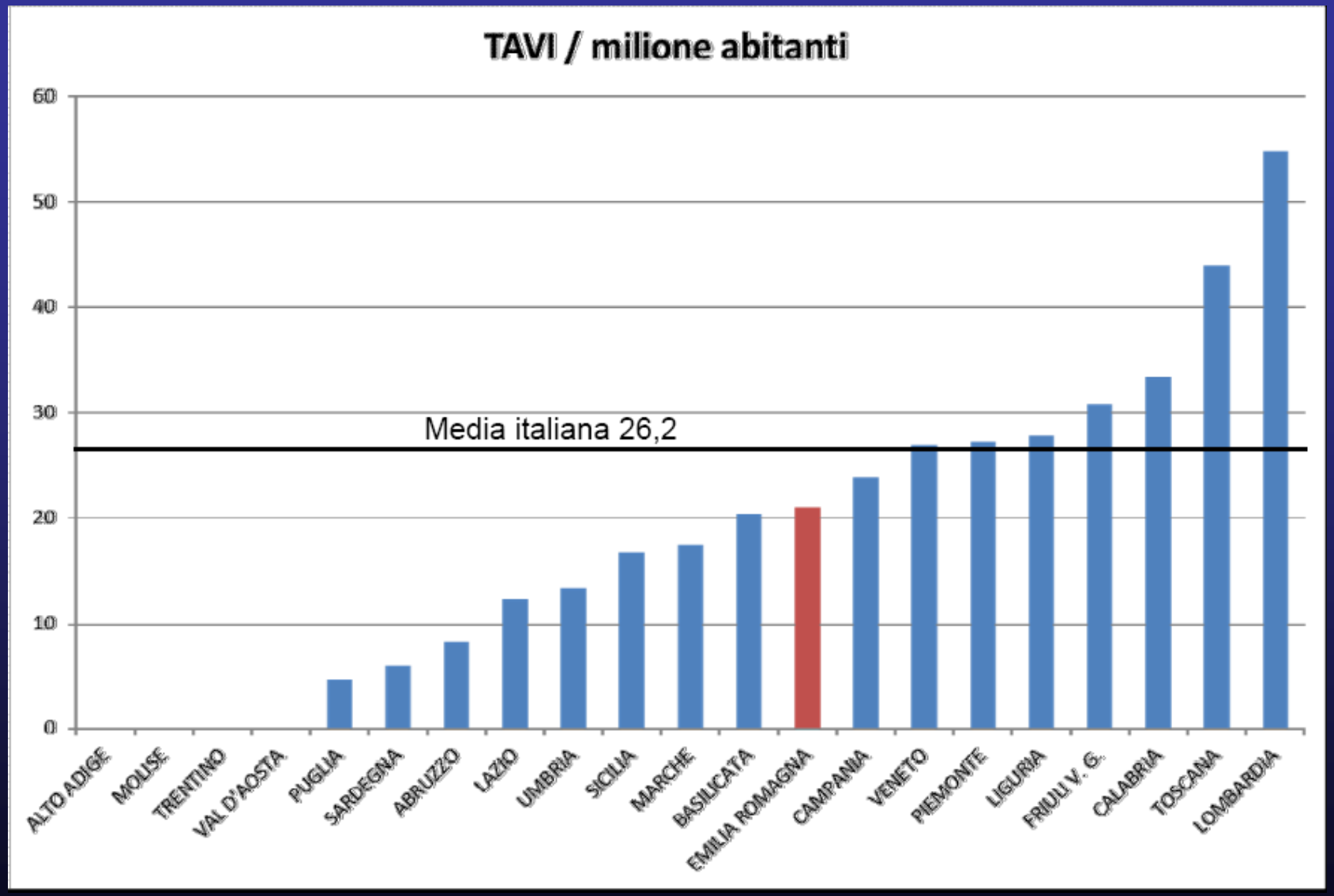
VALVOLA IN POSIZIONE

Divisione di Cardiologia
Parma

APERTURA VALVOLA

RIMOZIONE INTRODUTTORE


TAVI / milione abitanti
60
50
40
30
20
10
0
Media italiana 26,2
ALTO ADIGE
MOLISE
TRENTINO
VAL D'AOSTA
PUGLIA
SARDEGNA
ABRUZZO
LAZIO
UMBRIA
SICILIA
MARCHE
BASILICATA
EMILIA ROMAGNA
CAMPANIA
VENETO
PIEMONTE
LIGURIA
FRIULI V. G.
CALABRIA
TOSCANA
LOMBARDIA

RegioneEmilia-Romagna

Agenzia sanitaria e sociale regionale

AGENZIA SANITARIA E SOCIALE REGIONALE
COMMISSIONE CARDIOLOGICA CARDIOCHIRURGICA REGIONALE

DOCUMENTO DI INDIRIZZO PER L'IMPIANTO CLINICAMENTE APPROPRIATO DELLE PROTESI VALVOLARI AORTICHE PER VIA PERCUTANEA E TRANSAPICALE

Indicazioni di utilizzo appropriato

Sulla base della documentazione scientifica sopra citata, la Commissione Cardiologica e Cardiochirurgica Regionale ritiene che l'impianto di protesi valvolare aortica per via percutanea o transapicale sia oggi applicabile ai pazienti con le seguenti caratteristiche cliniche concomitanti:

- **stenosi valvolare aortica di grado severo (gradiente medio superiore a 40 mmHg e/o una velocità superiore a 4 m/sec e/o una superficie valvolare iniziale inferiore a 1cm2 e/o indice IAVA $\leqslant$ 0.6 cm2/m2);**

- **sintomi legati al restringimento aortico (classe funzionale NYHA superiore a 2 oppure 1 con frazione di eiezione ventricolare < 40%)**

Regione Emilia-Romagna

Agenzia sanitaria e sociale regionale

Programma di ricerca Regione-Università 2007-2009
Area 2 - "Ricerca per il Governo clinico"

PROGETTO TAVI

Transcatheter Aortic Valve Implantation

IMPIANTO DI PROTESI VALVOLARI AORTICHE
PER VIA ARTERIOSA E TRANSAPICALE:
STUDIO DI SICUREZZA ED EFFICACIA PER DEFINIRE UN MODELLO
REGIONALE DI UTILIZZO OTTIMALE DELLA NUOVA TECNICA

Coordinatore Scientifico

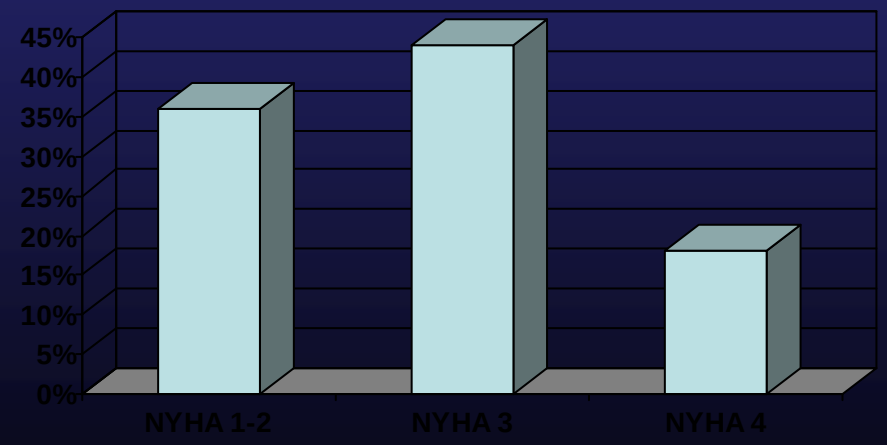
Antonio Marzocchi

TAVI PR-RE

TAVI (TF e TA)	N° 47
Età media	83,6 +/- 5,6
Euroscore Logistico	21,9 +/- 11
Mortalità 30 gg	8,5%
Mortalità 1 anno	17%

PRESENTAZIONE CLINICA

- CLASSE NYHA 1-2 NEL 36%
- CLASSE NYHA 3 NEL 44%
- CLASSE NYHA 4 NEL 18%



COMORBIDITA’

- Pregressa CCH nel 23% (11 pazienti)
- Pregressa PTCA nel 23% (11 pazienti)
- Insufficienza renale cronica nel 34% (16 pazienti)

- Nel 14% FE < o = 40%
- Nel 86% FE > 40%

MORTALITA’ 30 GIORNI

- 3 decessi intraprocedurali in fase di apprendimento con tutor
- 1 decesso intraospedaliero

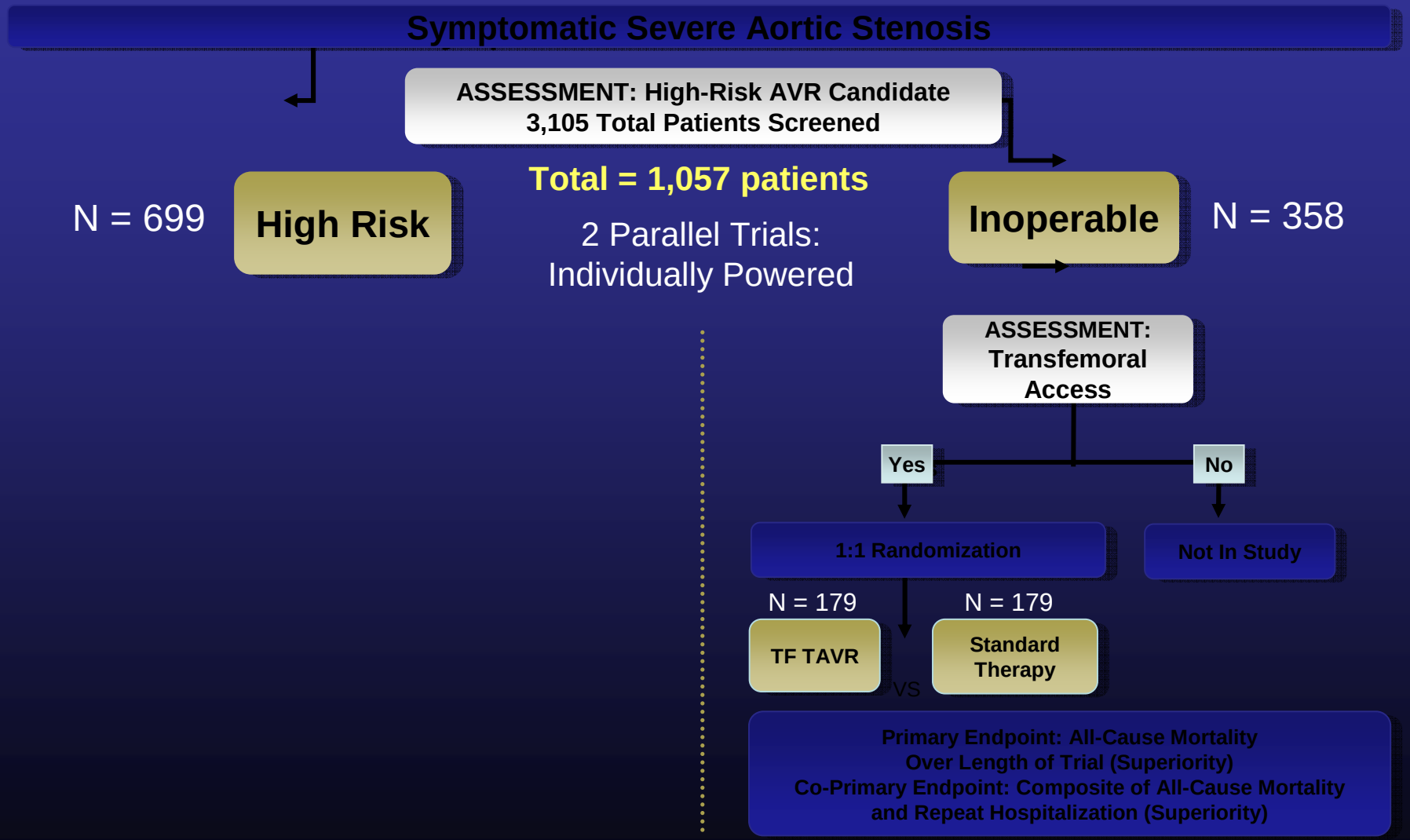
MORTALITA’ 1 ANNO

- 5 decessi di cui 3 per causa cardiaca e 2 per causa non cardiaca (?)

Confronto TAVI con Partner B e registro Italiano Core Valve

	TAVI PR-RE (n° 47)	Partner B (n° 179) **(TF)**	Reg. Ital. Core Valve (n° 663) (TF,TS)
Età media	**83,6 +/- 5,6**	83,1+/- 8,6	80,9+/- 6,1
Euroscore Logistico	**21,9 +/- 11**	26,4+/-17,2	24+/-13,5
Mortalità 30 gg	**8,5%**	5%	7,9%
Mortalità 1 anno	**17%**	30,7%	15%

PARTNER Study Design



Inoperable PARTNER Cohort
Primary Endpoint: All-Cause Mortality

The NEW ENGLAND JOURNAL of MEDICINE

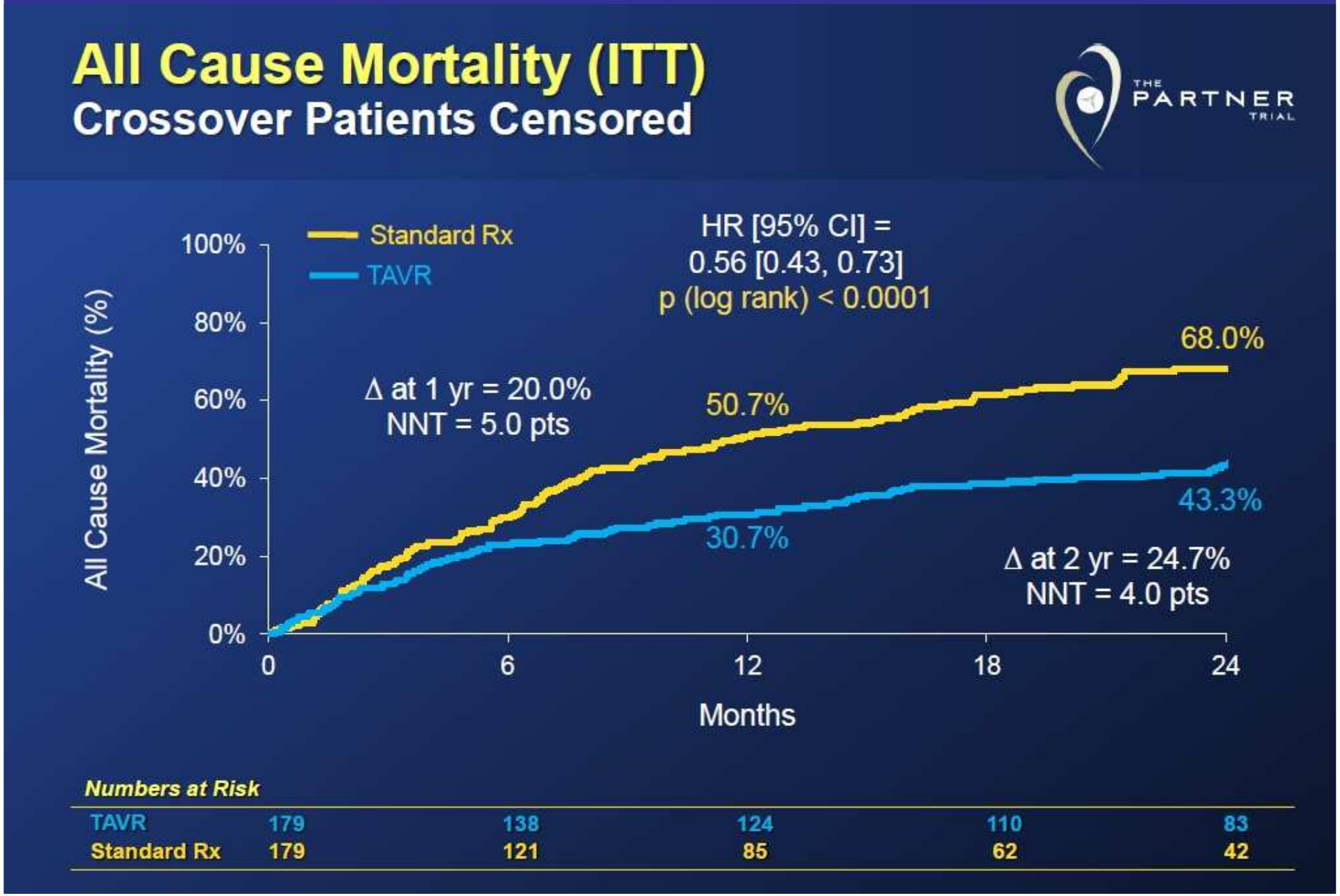
Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

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 C. 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*

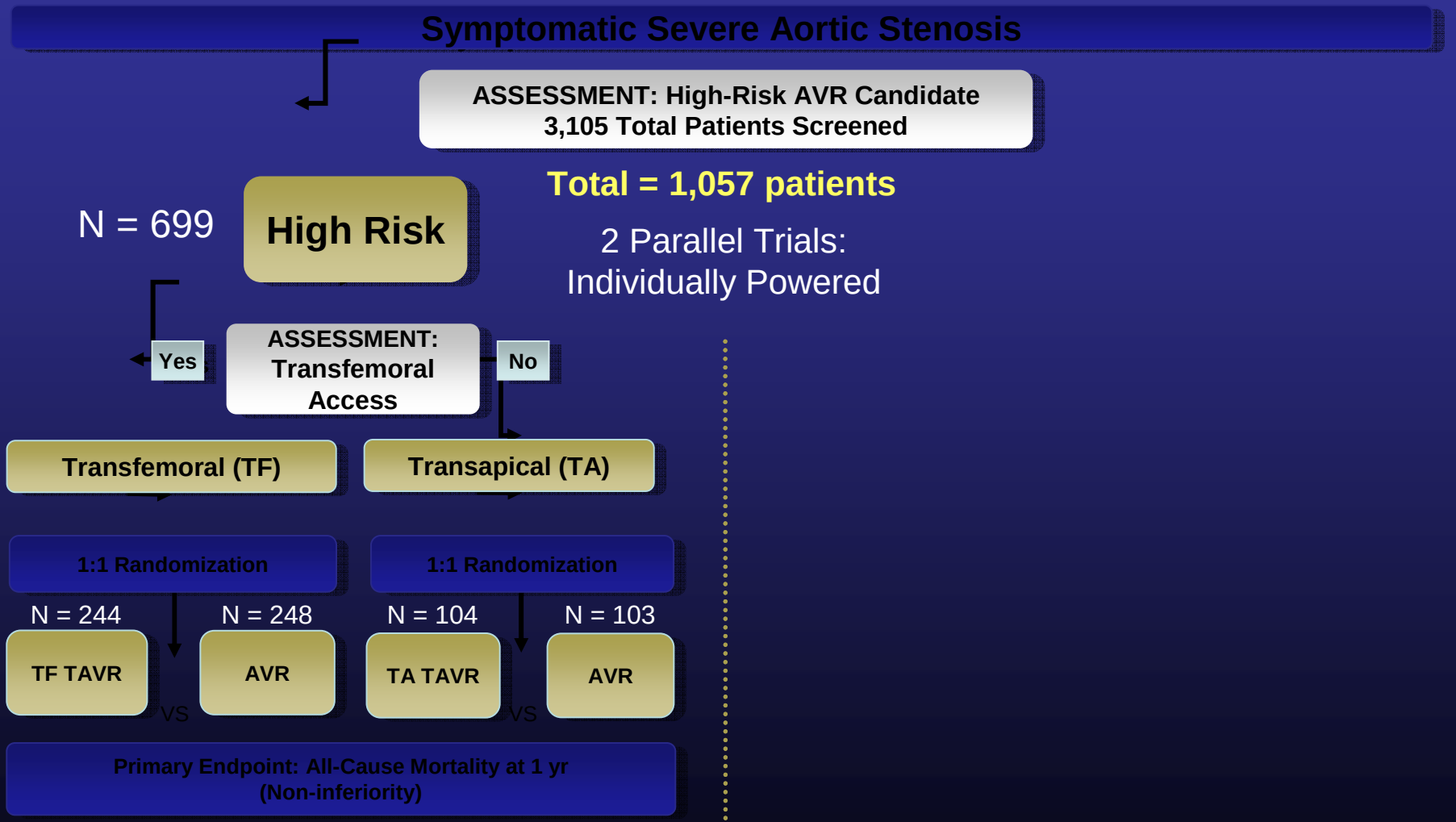
Months

Numbers at Risk					
TAVI	179	138	122	67	26
Standard Rx	179	121	83	41	12

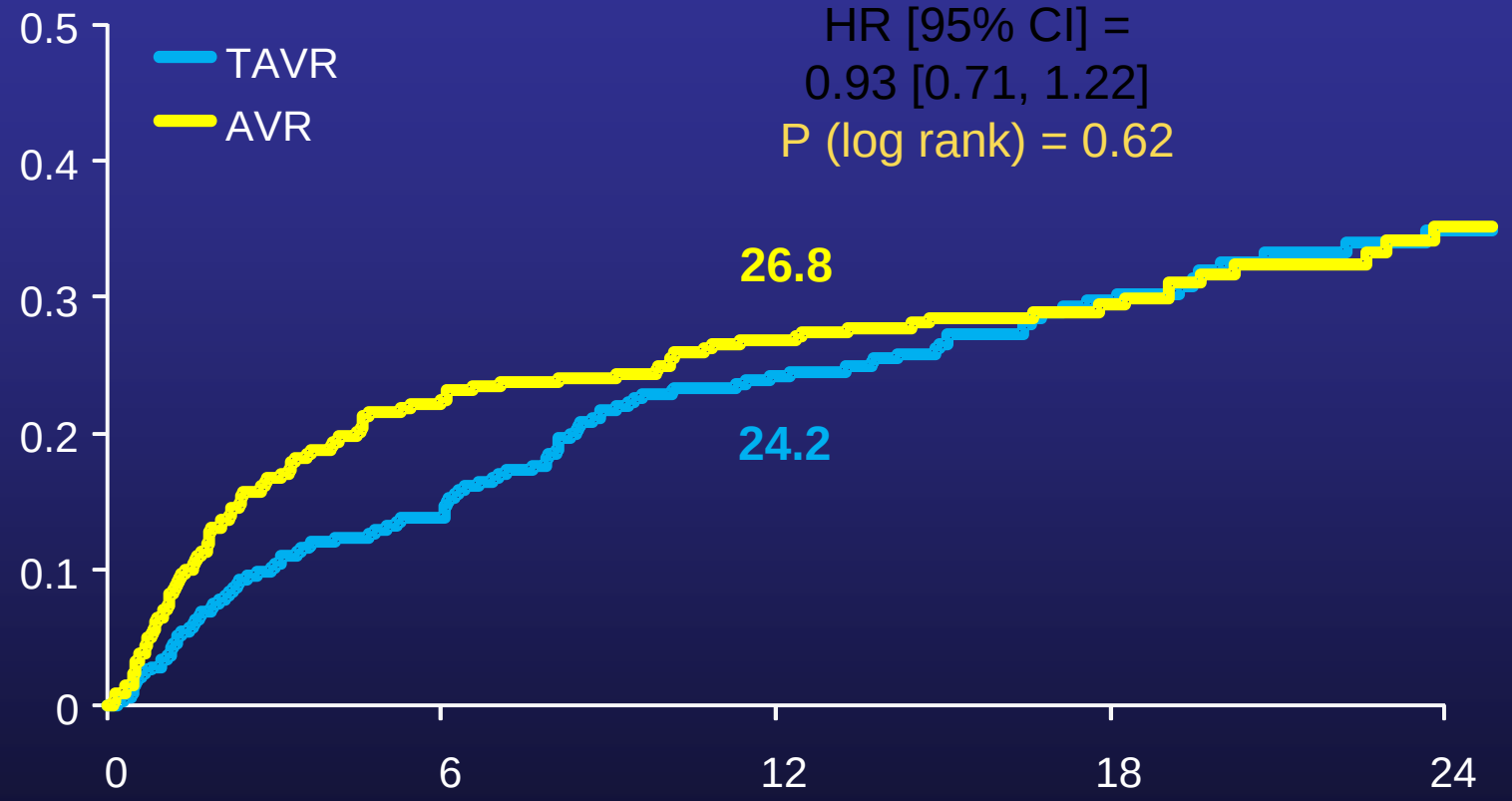
Partner Cohort B – 2y



PARTNER Study Design



Primary Endpoint: All-Cause Mortality at 1 Year



No. at Risk

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

Conclusioni

- Al momento la TAVI non deve essere considerata una alternativa per pazienti a basso rischio chirurgico;
- La volontà del paziente, di per se, non è considerata una indicazione condivisibile;
- E’ mandatorio che l’indicazione derivi dal giudizio condiviso di un team multidisciplinare (cardiologo clinico, cardiologo interventista e cardiochirurgo), di “alto rischio operatorio”.

La proposta di criteri di indicazione alla sostituzione valvolare aortica transcatetere prevede:

- Giudizio clinico congiunto e condiviso fra cardiologo e cardiochirurugo di alto rischio cardiochirurgico:
  - In pazienti con età < 75 anni ed EUROSCORE logistico > 20
  - In tutti i pazienti con età > 85 anni con EUROSCORE logistico > 10
  - Disfunzione di protesi valvolare aortica biologica nei pazienti con indicazione a reintervento ad elevato rischio

Impianto transcatetere di protesi valvolari aortiche
Approccio transfemorale

Rules of Engagement

Dr. A. Agostinelli

Dr. L. Vignali

Cardiac Surgery

Parma

Interventional Cardiology