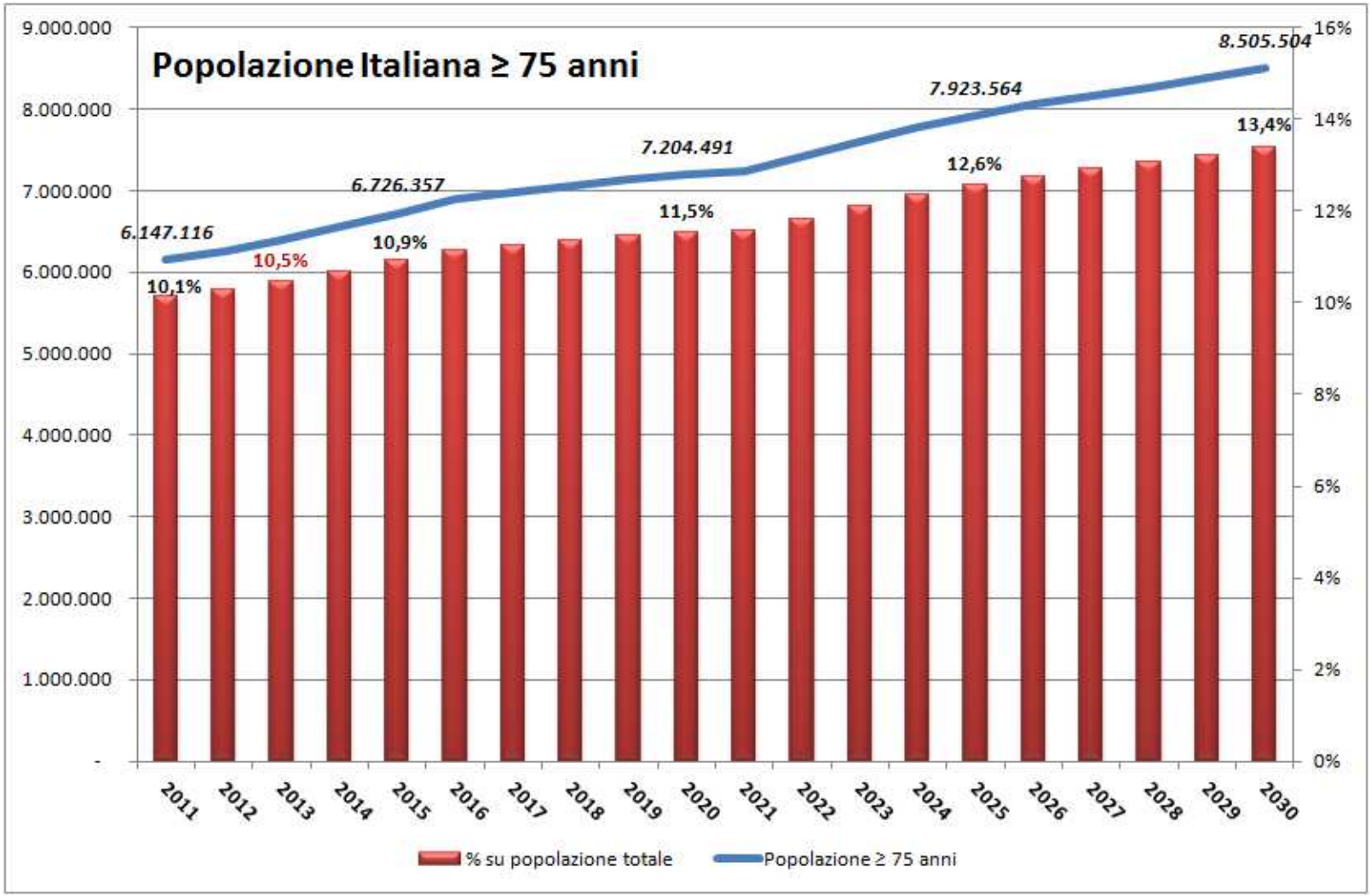
Invecchiamento della popolazione Italiana



Fonte: ISTAT, 2014

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Severe aortic stenosis 3.4% >80y

1.000.000 pts in Europe

Aortic Stenosis in the Elderly

Disease Prevalence and Number of Candidates for Transcatheter Aortic Valve Replacement: A Meta-Analysis and Modeling Study

Ruben L. J. Osnabrugge, MS,* Darren Mylotte, MD,†‡ Stuart J. Head, MS,* Nicolas M. Van Mieghem, MD,§ Vuyisile T. Nkomo, MD, MPH,‖ Corinne M. LeReun, MS,¶ Ad J. J. C. Bogers, MD, PHD,* Nicolo Piazza, MD, PHD,†# A. Pieter Kappetein, MD, PHD*

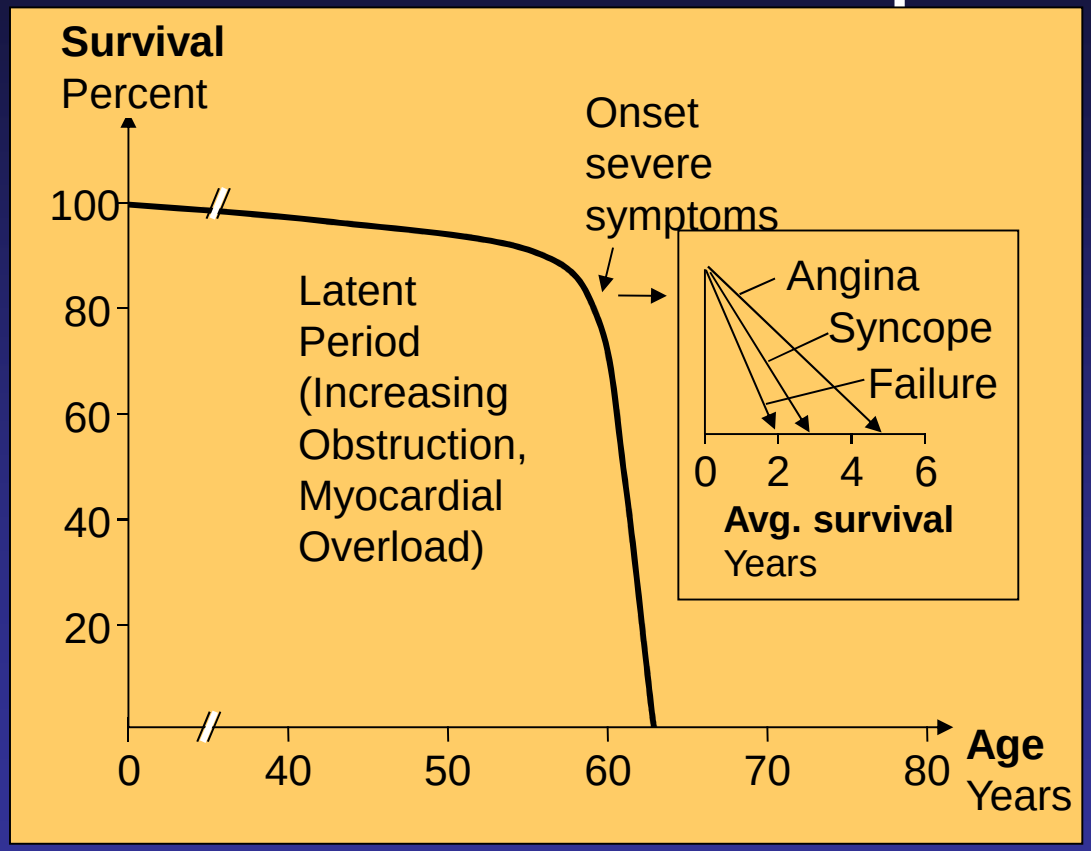
Rotterdam, the Netherlands; Montreal, Quebec, Canada; Galway and Cork, Ireland; Rochester, Minnesota; and Munich, Germany

Total number of TAVR candidates	
Country	**Candidates (95%CI)**
Austria	3,250 (1,389-5,947)
Belgium	4,603 (1,964-8,409)
Czech Republic	3,336 (1,433-6,160)
Denmark	1,885 (805-3,448)
Finland	2,100 (898-3,856)
France	28,026 (11,992-51,266)
Germany	36,220 (15,388-66,610)
Greece	5,174 (2,258-9,493)
Italy	29,597 (12,598-54,471)
Ireland	1,100 (467-2,002)
Luxembourg	162 (69-298)
Norway	1,705 (731-3,103)
Poland	11,896 (5,162-22,051)
Portugal	4,670 (1,990-8,538)
Spain	19,436 (8,265-35,713)
Sweden	3,854 (1,633-7,093)
Switzerland	3,020 (1,280-5,554)
The Netherlands	5,631 (2,379-10,379)
The United Kingdom	23,930 (10,554-43,461)
Total 19 European countries	**189,836 (80,281-347,372)***
The United States	91,227 (38,885-165,875)
Canada	10,958 (4,688-19,995)
Total North America	**102,558 (43,612-187,002)***

Number of potential TAVI candidates/nation following the current Indications : Inoperable, HR STS > 10

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]

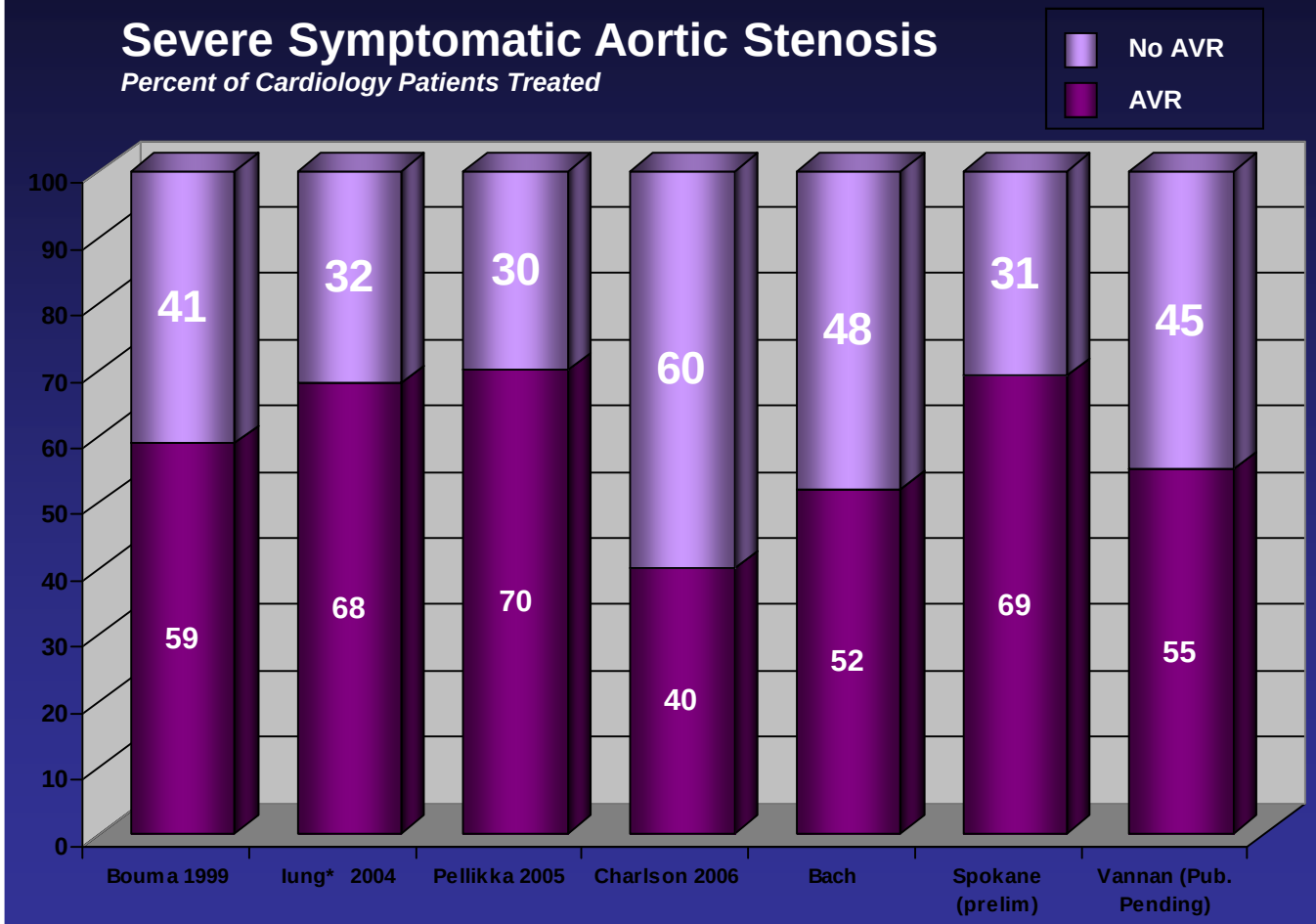
Sources:

[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

Chart:: Ross J Jr, Braunwald E. Aortic stenosis. *Circulation*. 1968;38 (Suppl 1):61-7.

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. Charlson E et al. Decision-making and outcomes in severe symptomatic aortic stenosis. J Heart Valve Dis2006;15:312-321

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 LELIAC

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

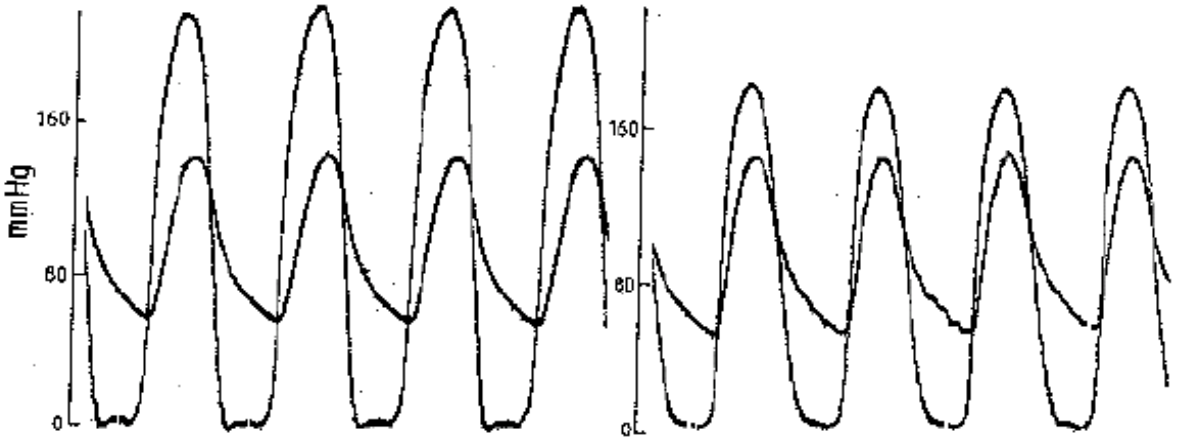
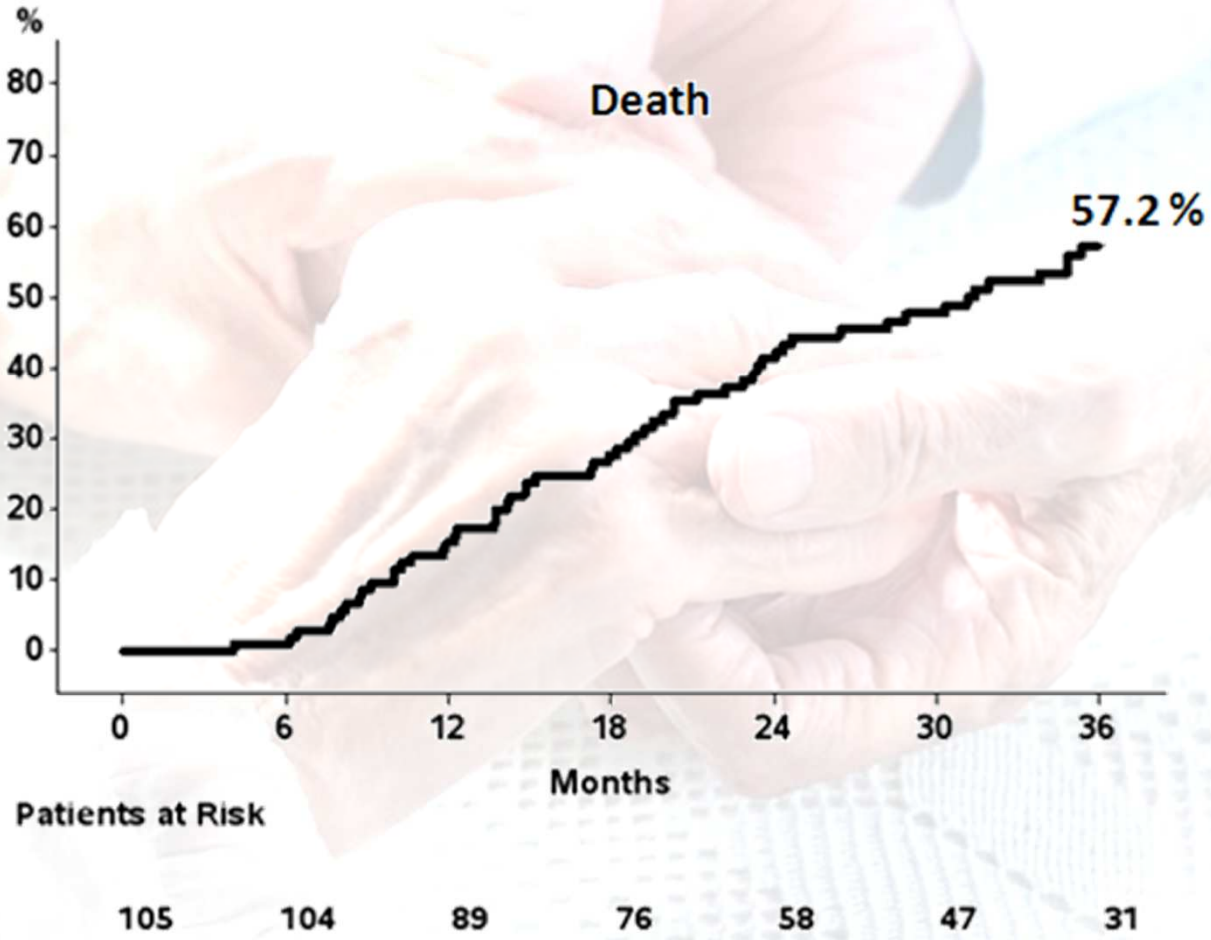


Fig 3—Simultaneous recording of left ventricular and aortic pressures before (left) and at the end of PTAV (right) in case 1.

Transvalvular systolic gradient decreased from 90 to 40 mm Hg

Lancet, January 11, 1986

Long-term mortality with repeated BAV



Bordoni B, et al. J Inv Cardiol 2015; *in press*

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

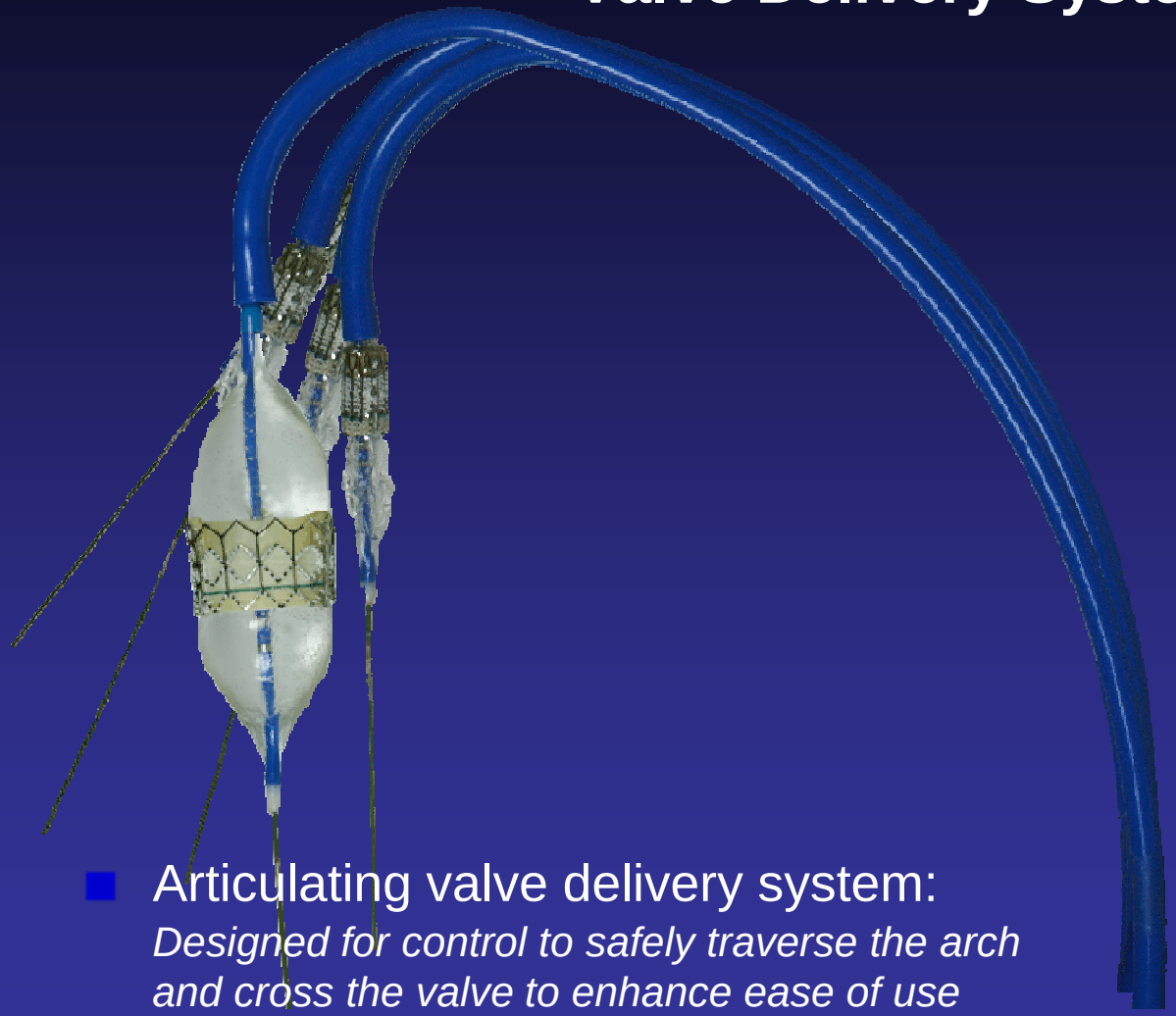
First Human Case Description

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

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

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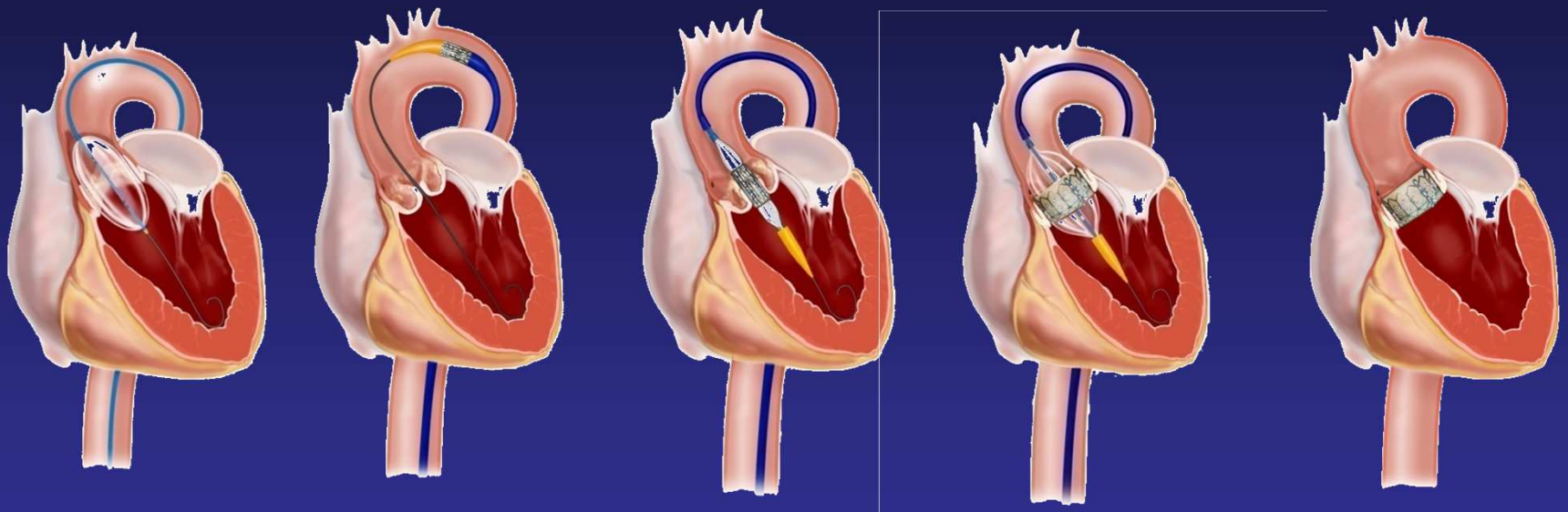
Edwards SAPIEN™ Transcatheter Heart Valve: **The Transfemoral Approach**



Balloon Aortic Valvuloplasty

RetroFlex™ II Advancement

Valve Positioning

Valve Deployment

Final Result

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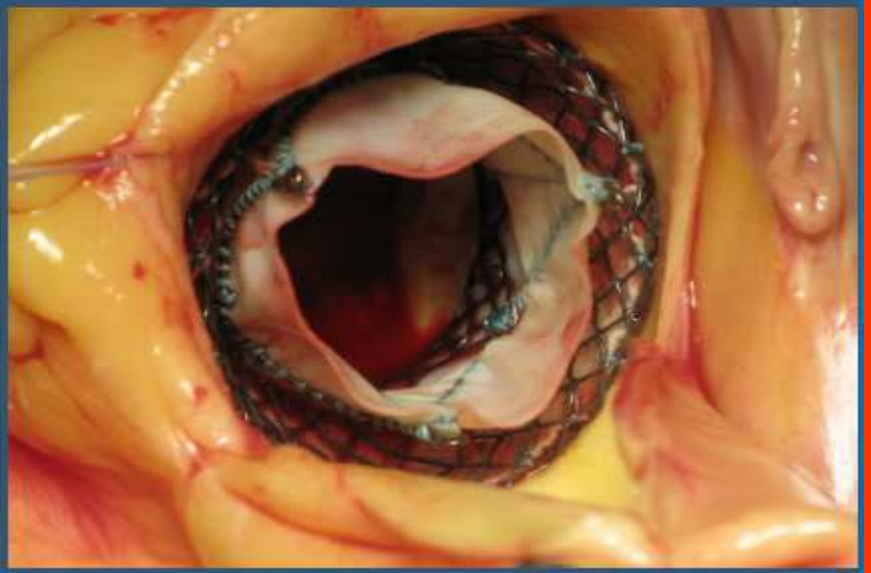
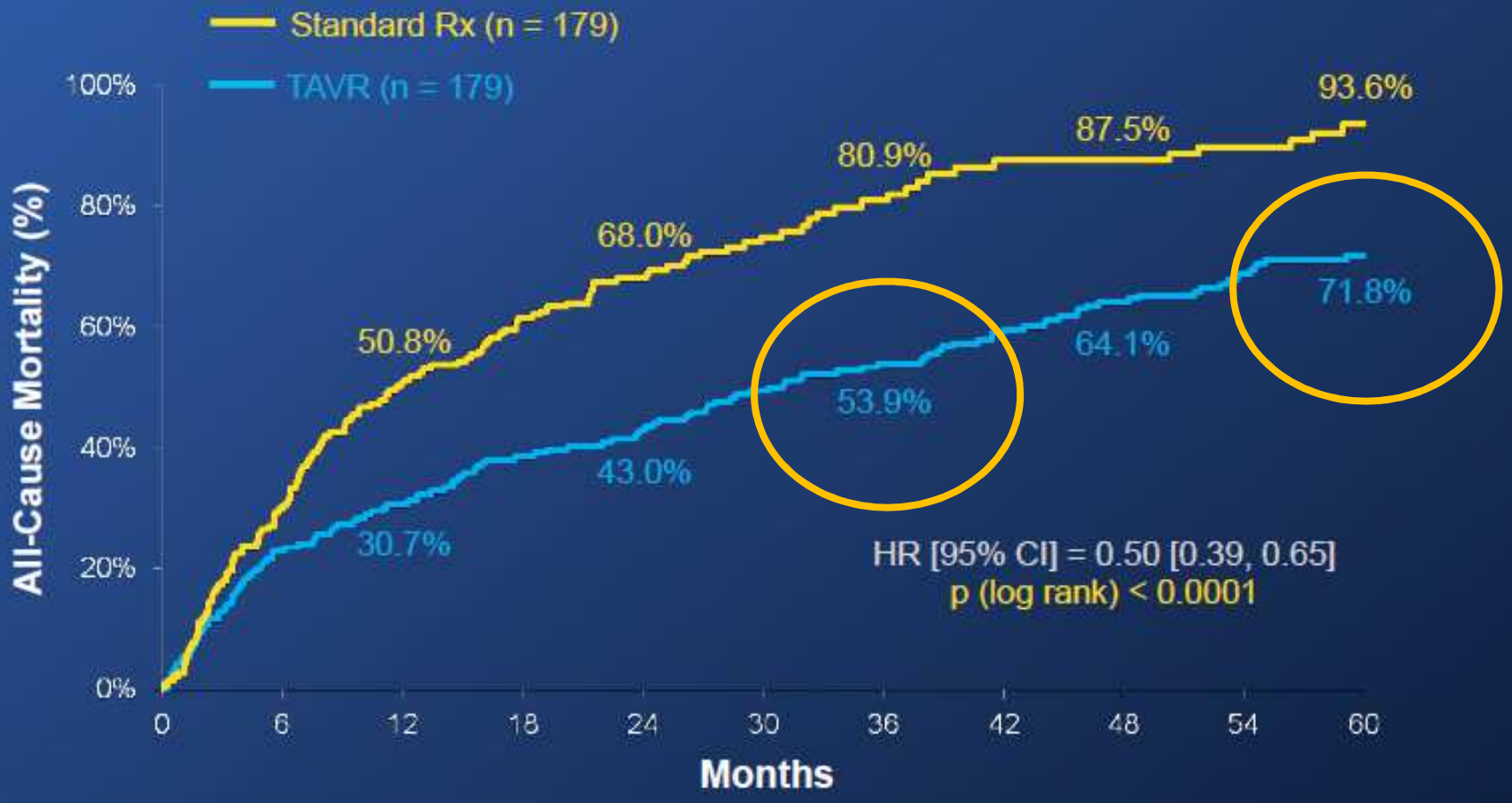
Acute Implant Study



All-Cause Mortality (ITT)

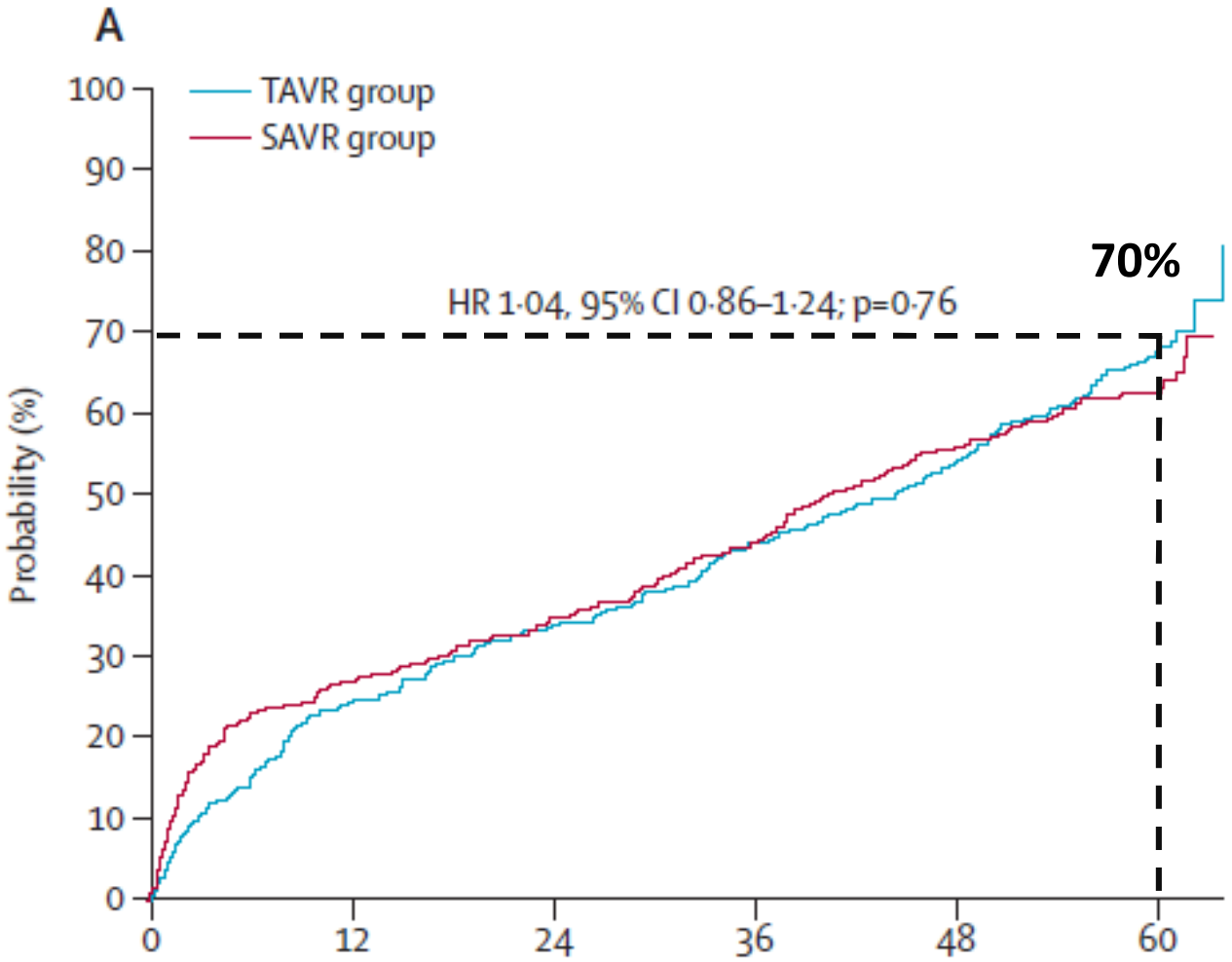
Crossover Patients Censored at Crossover



Sopravvivenza mediana:

11 mesi terapia standard - 30 mesi TAVI

PARTNER Cohort A (High risk)



Mack MJ et al. *Lancet* 2015; *in press*

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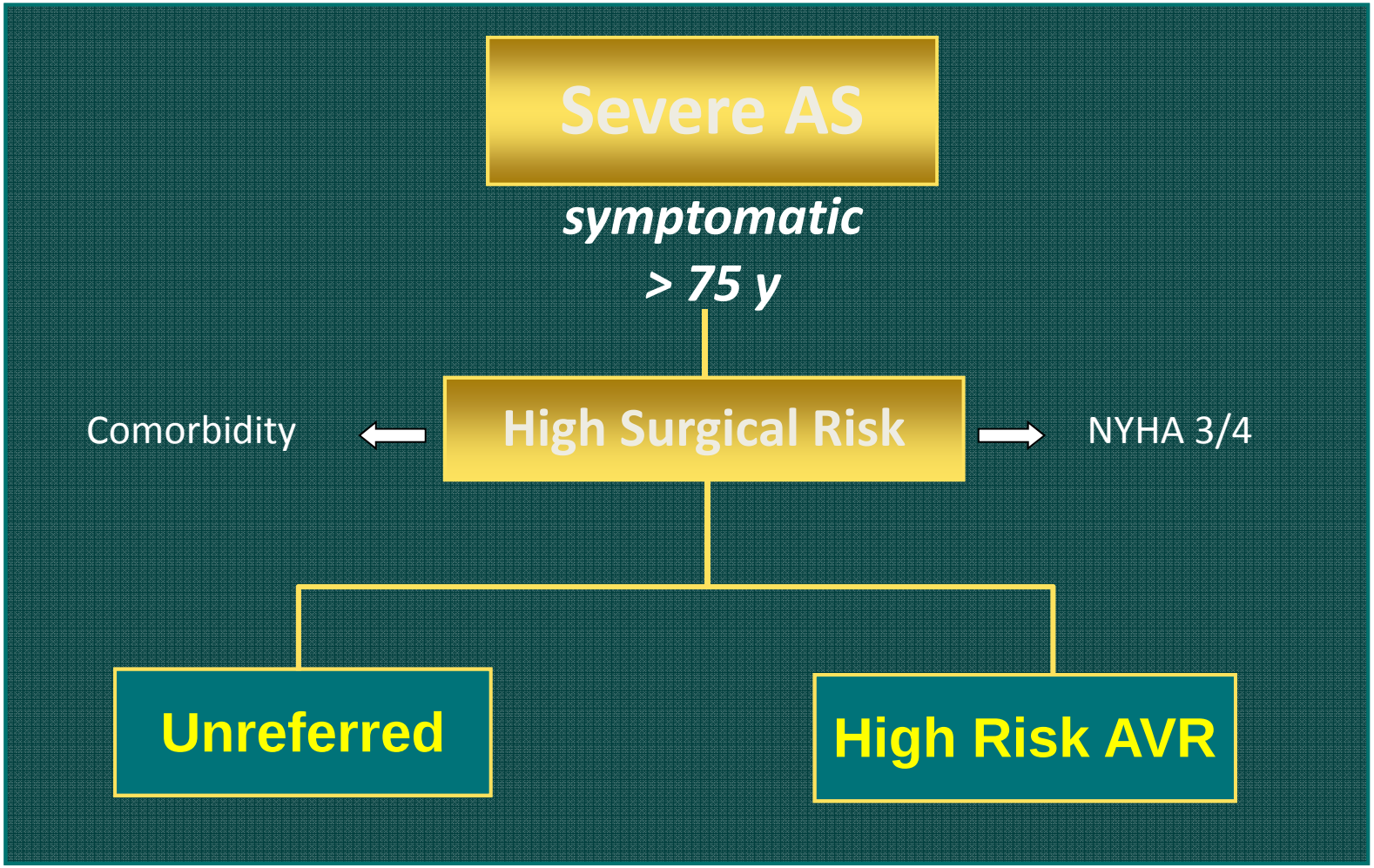
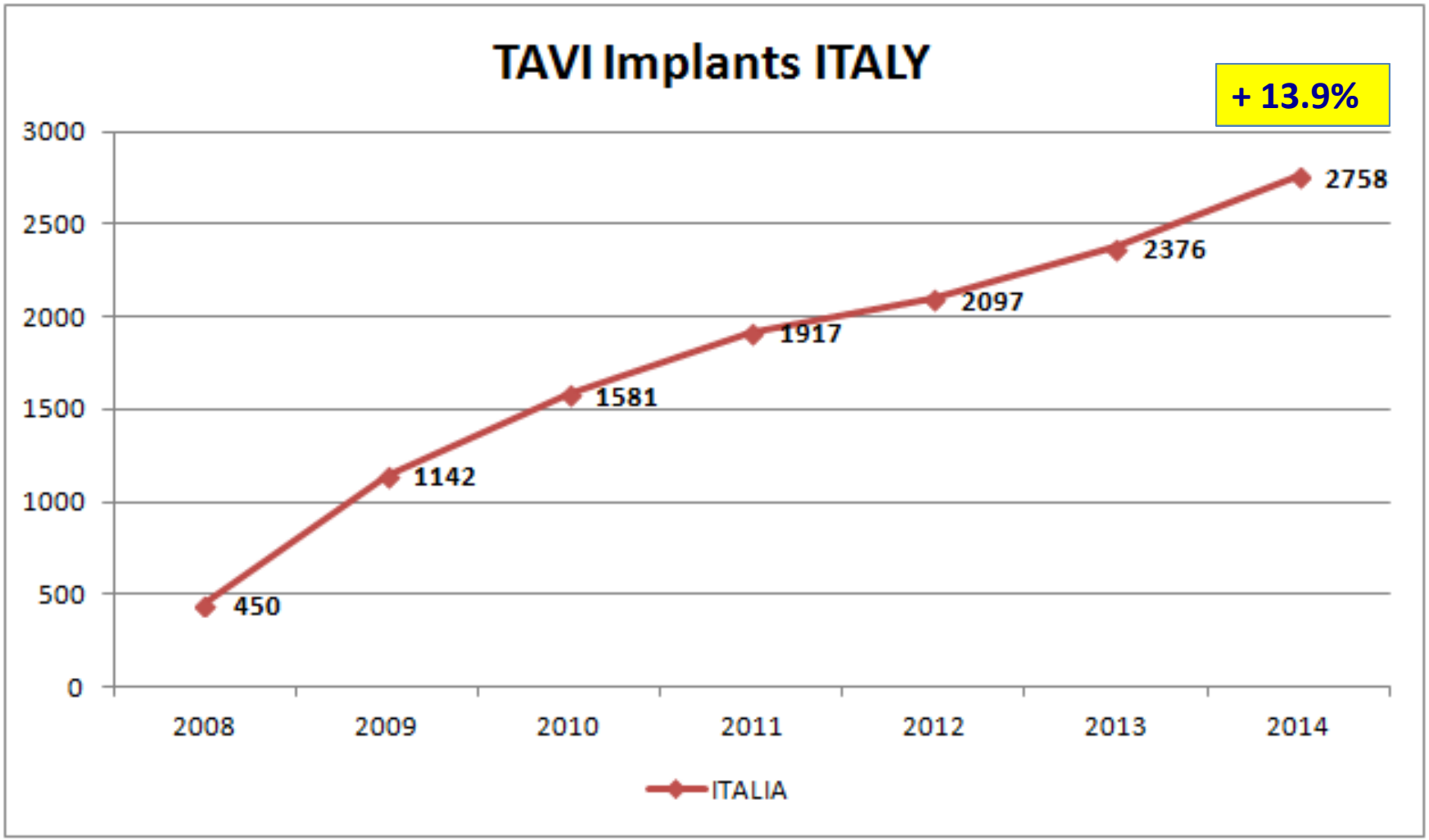
Candidates for Transcatheter AVR

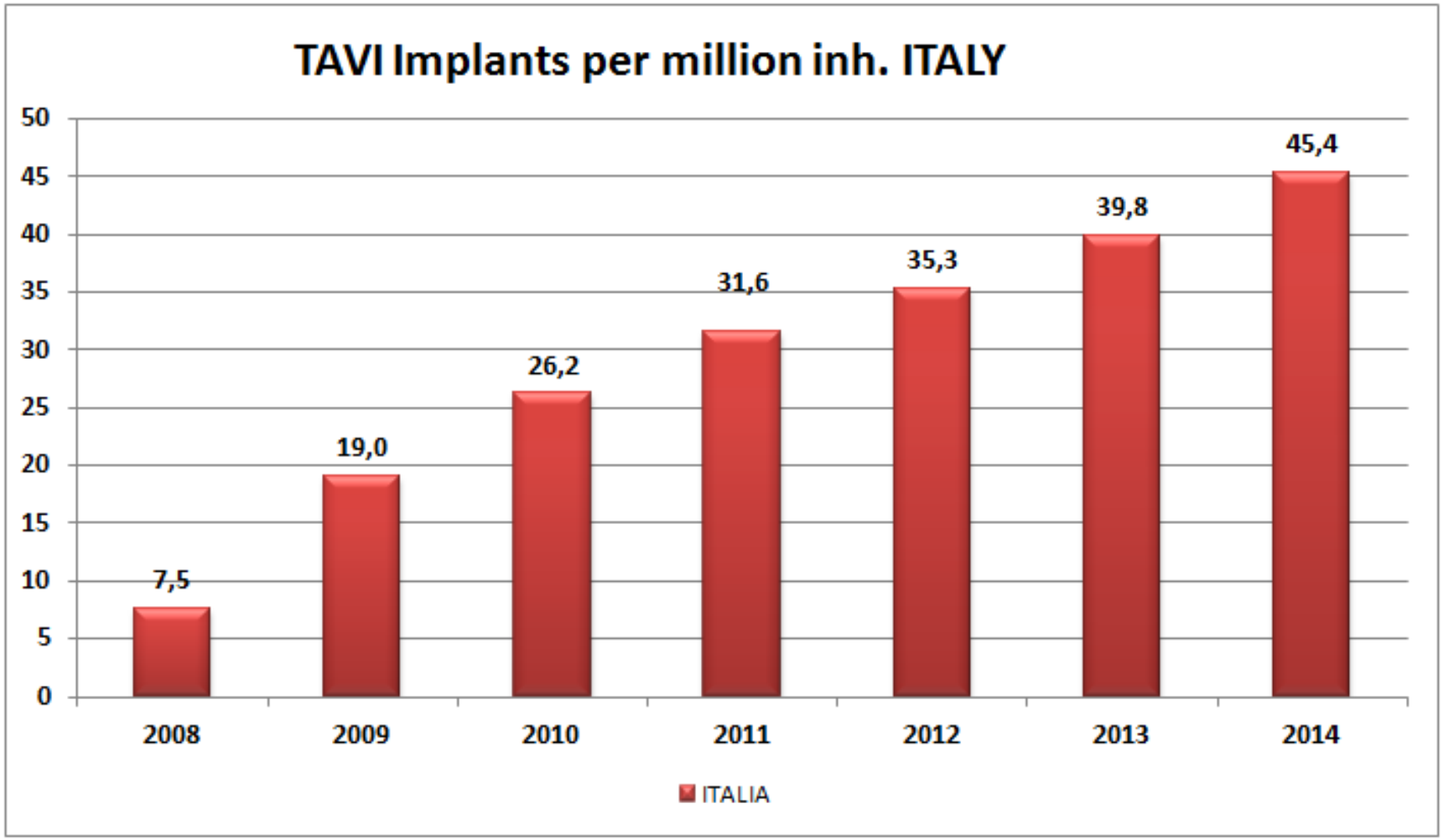


Numero impianti TAVI - Italia



Fonte: adattato da Società Italiana di Cardiologia Invasiva – GISE

Impianti TAVI per milione di abitanti Italia



Fonte: adattato da Società Italiana di Cardiologia Invasiva - GISE

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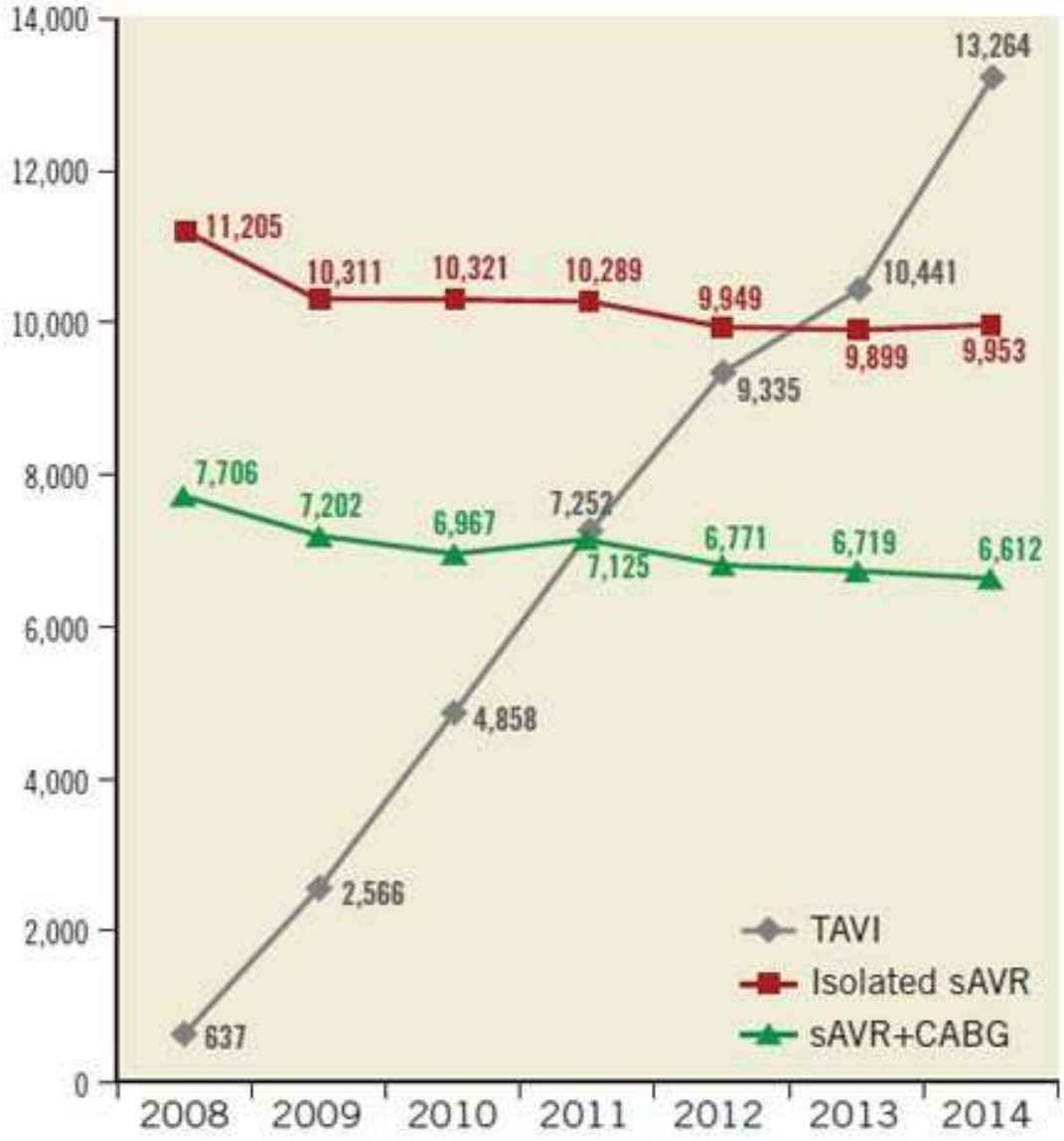
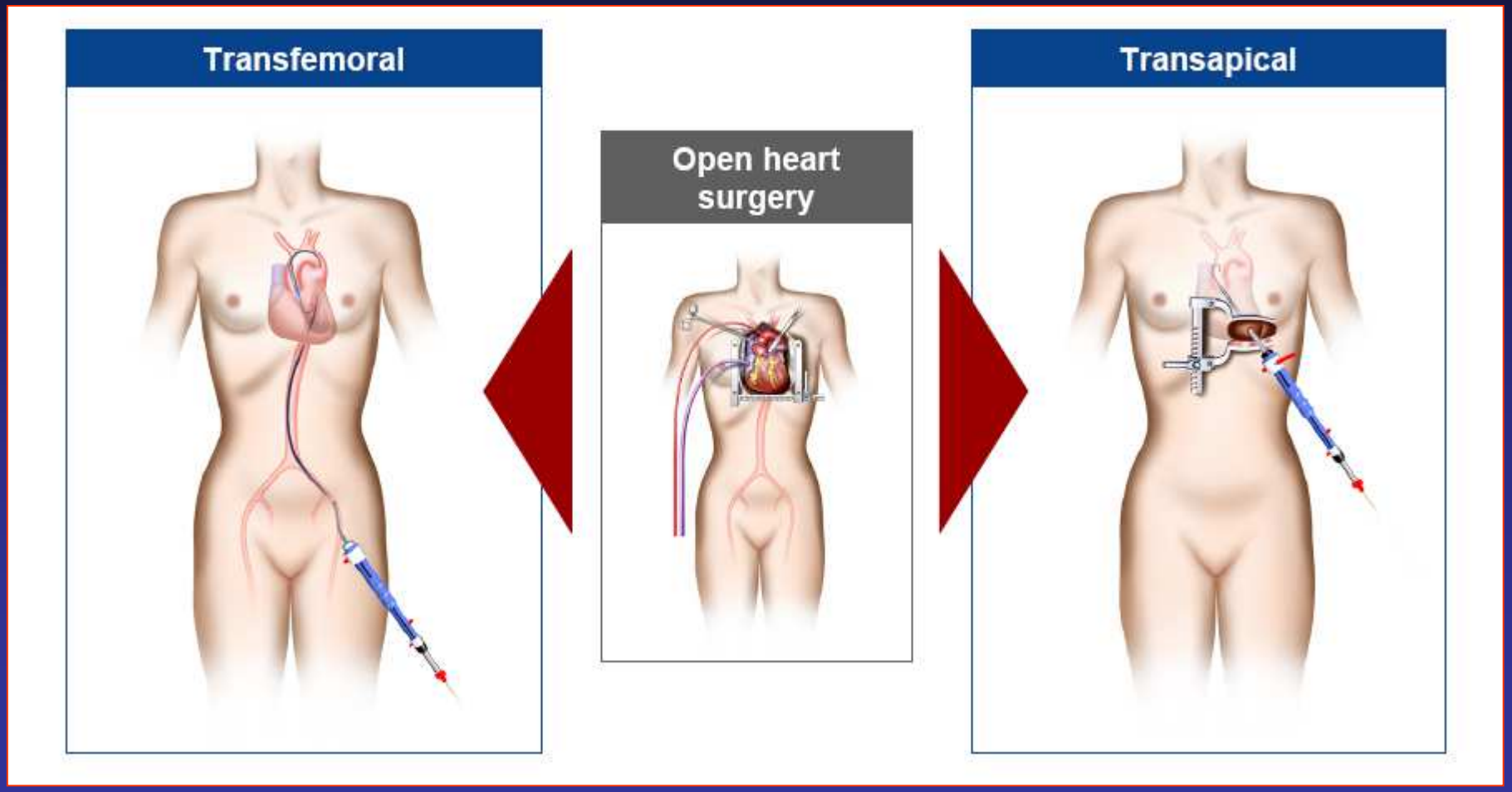
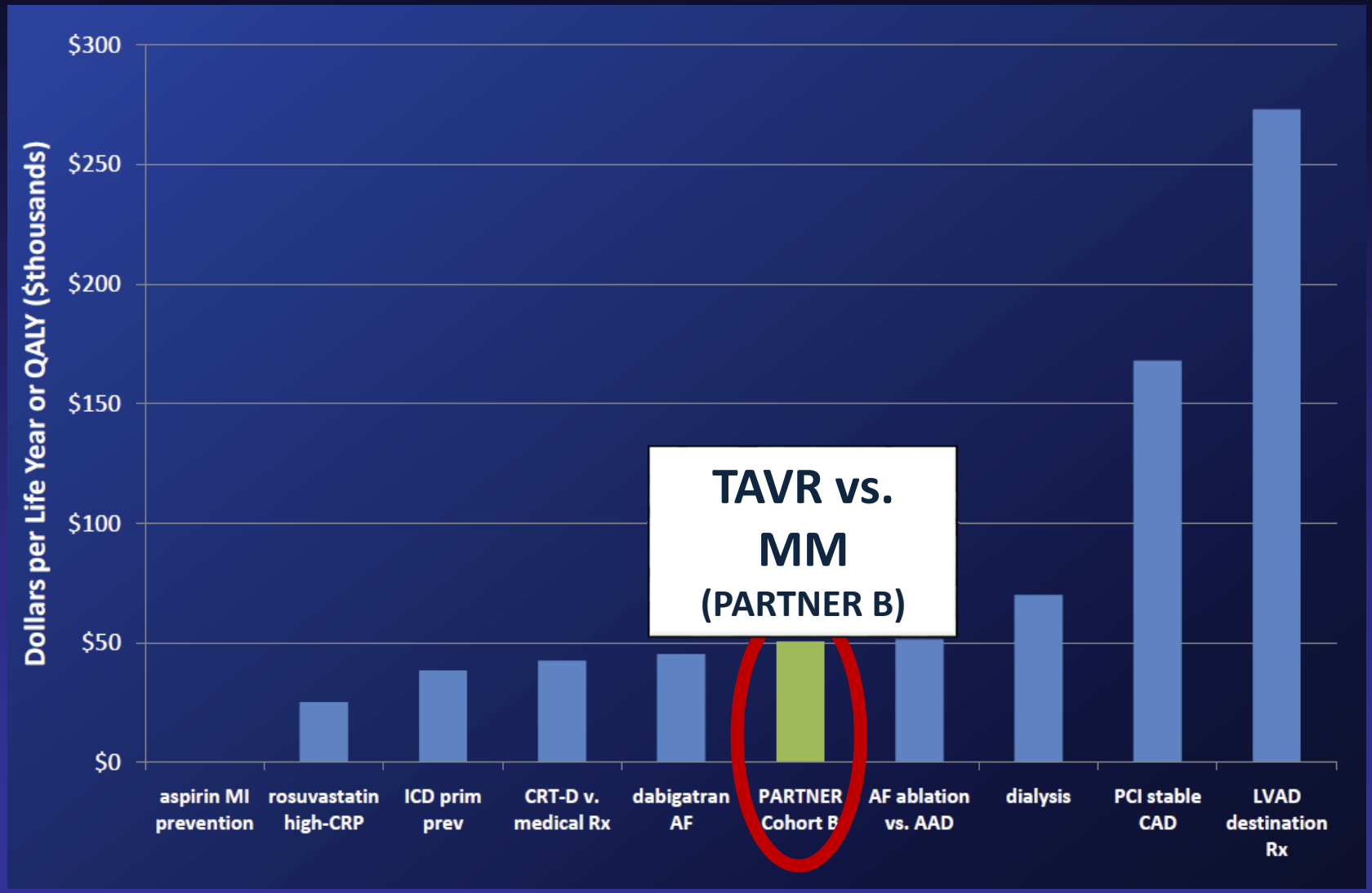
TAVI in Germania



Tecniche di impianto di protesi valvolari Aortiche



PARTNER B Cost-Effectiveness Analysis



Reynolds MR, et al. Circulation 2012; 125:1102-9
Mark DB. Circulation 2002; 106: 626

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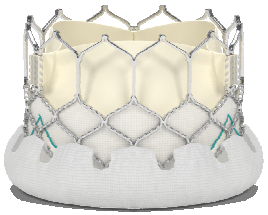
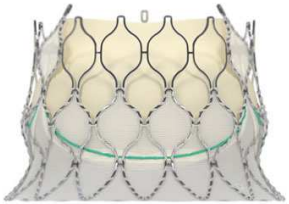
New Transfemoral Valves

Medtronic Evolut

Edwards Sapien 3



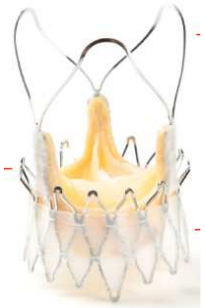
Centera



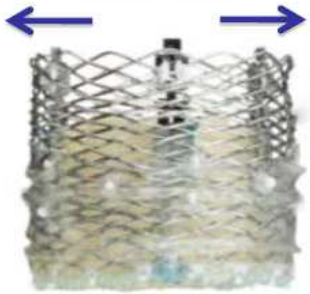
Direct Flow

St Jude Portico

Simetys



Boston Lotus



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Big Five

- Durability
- Cardiac rythm disturbances
- Access site complications
- Stroke
- Residual aortic regurgitation

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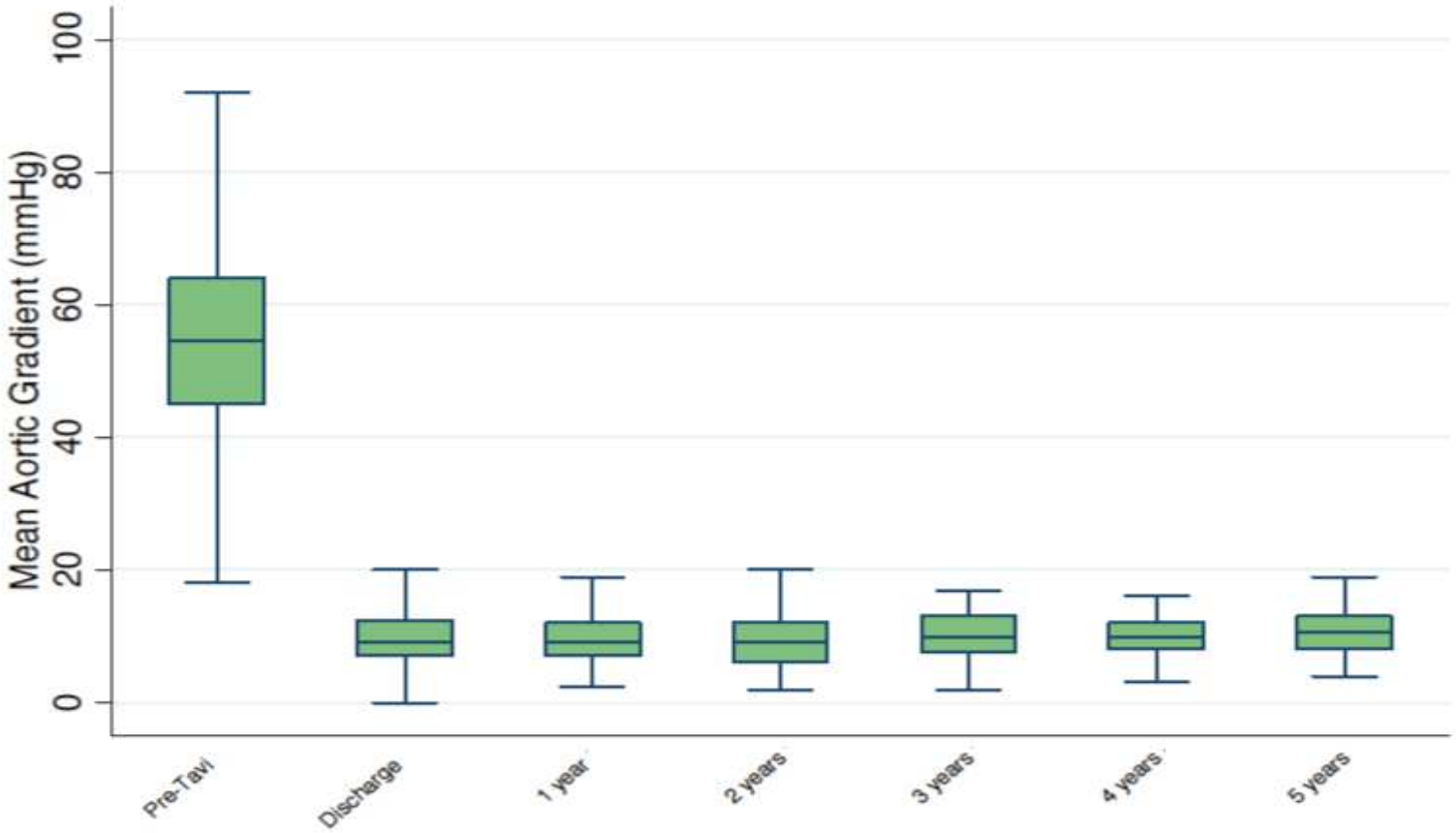
Durability

Corevalve italian Registry 5 years Follow up



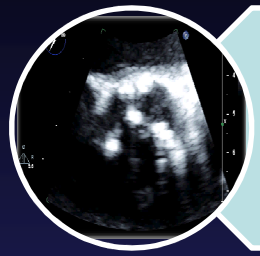
. **Time trends in transaortic mean gradient.**

Barbanti et al JACC Cardiovasc Intv 2015

Can age be considered a contraindication?

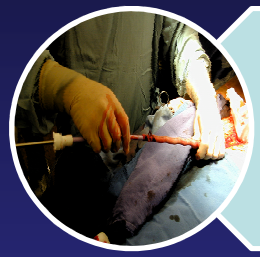
PATIENT INDICATIONS

AVA < 0.8 cm^2



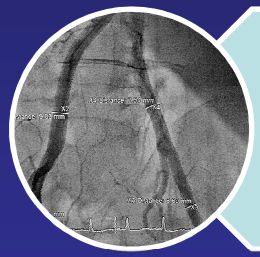
Symptomatic Aortic Stenosis

STS > 10 %
Euroscore > 20 %



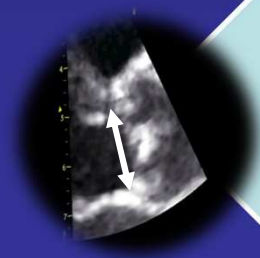
Risk Evaluation

26 mm > 8 mm
23 mm > 7 mm



Femoral Minimal Diameter

18 to 24 mm



Annulus by TEE

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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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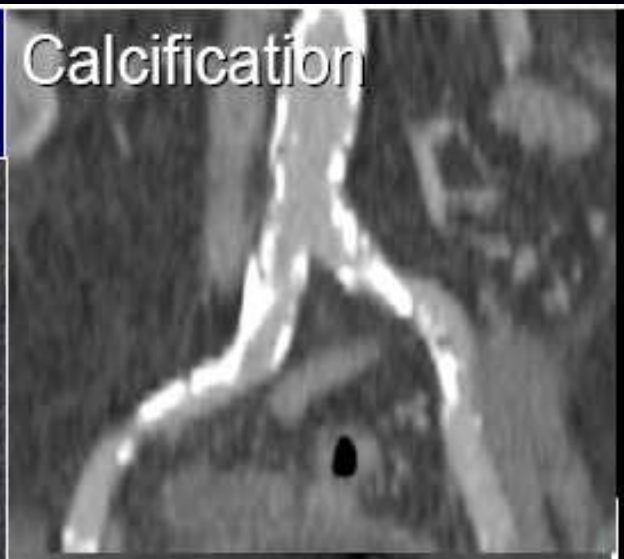
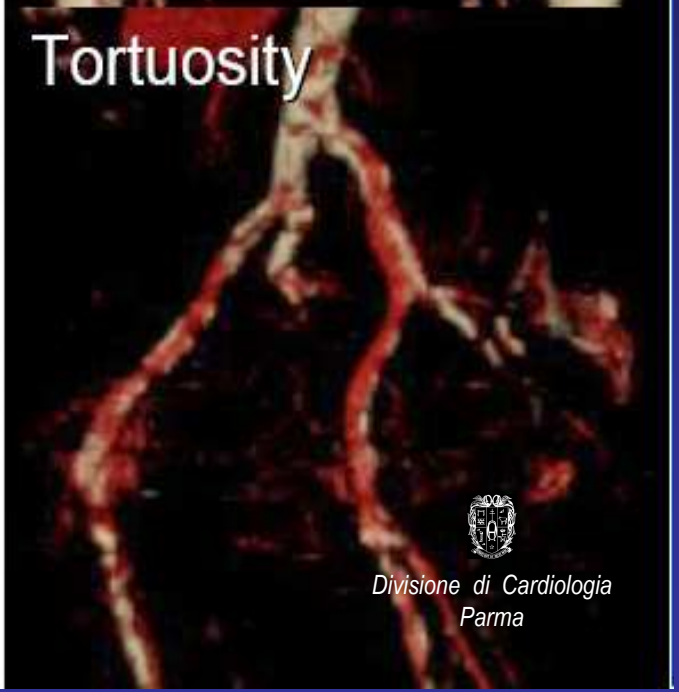
Parma

Access





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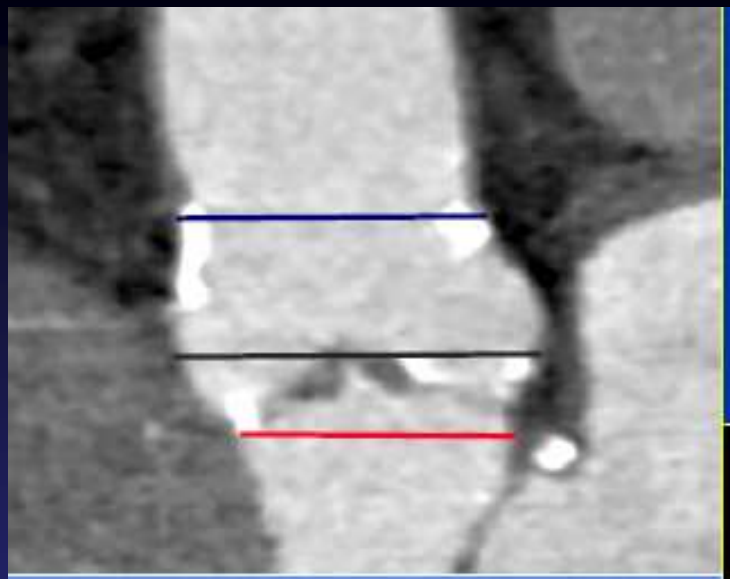
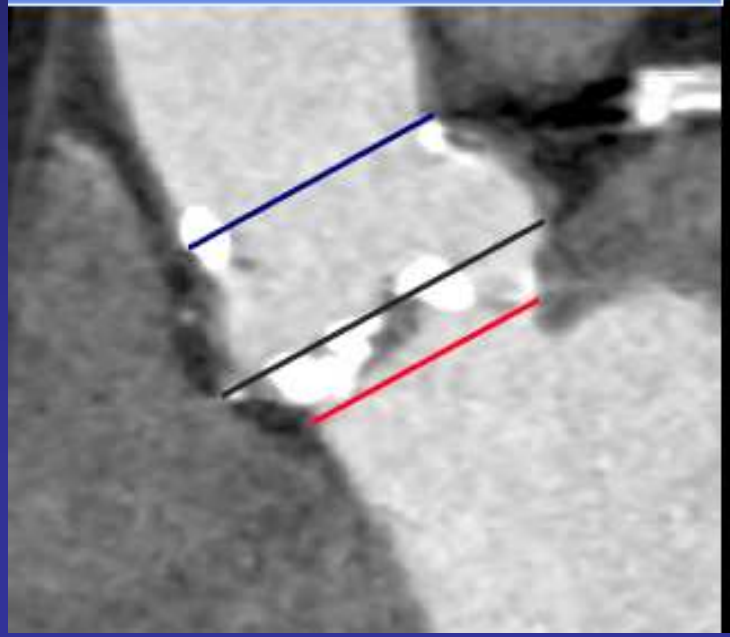
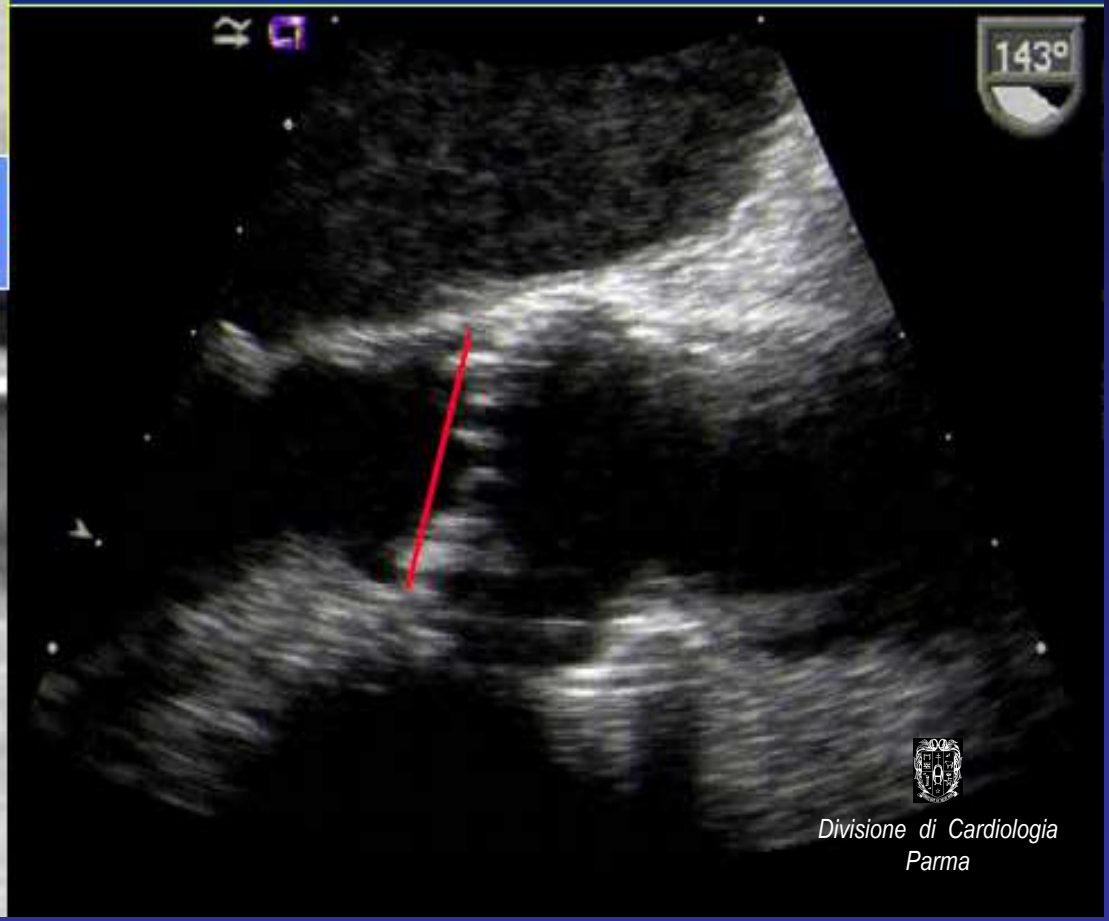
Annulus Size by CT and TEE



ST Junction Annulus Valve





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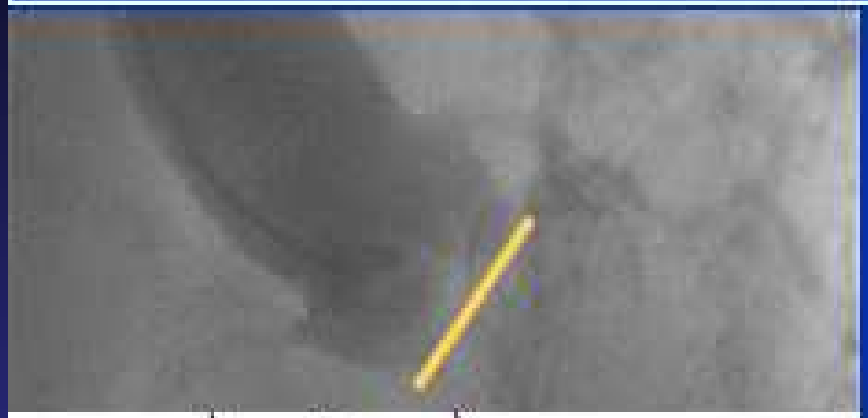
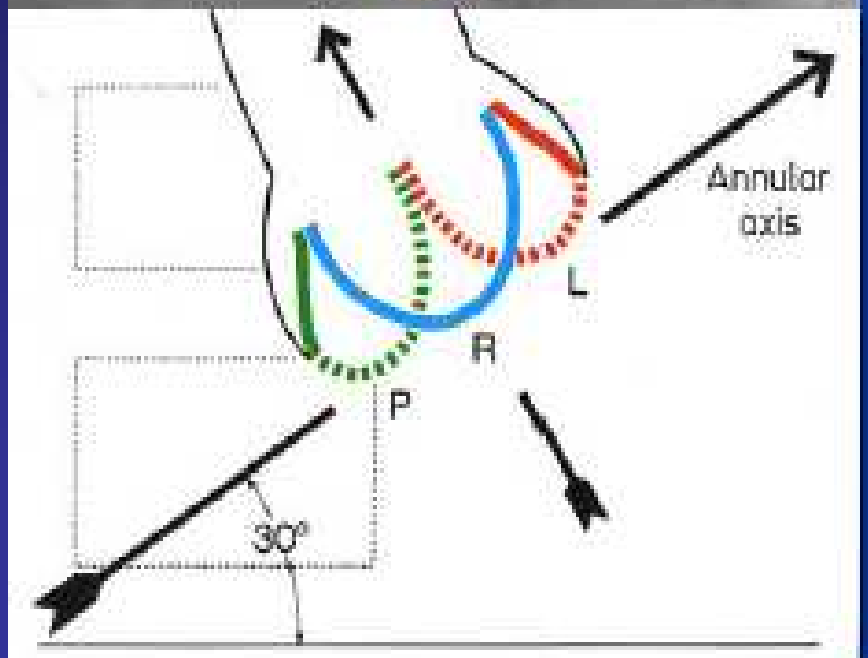
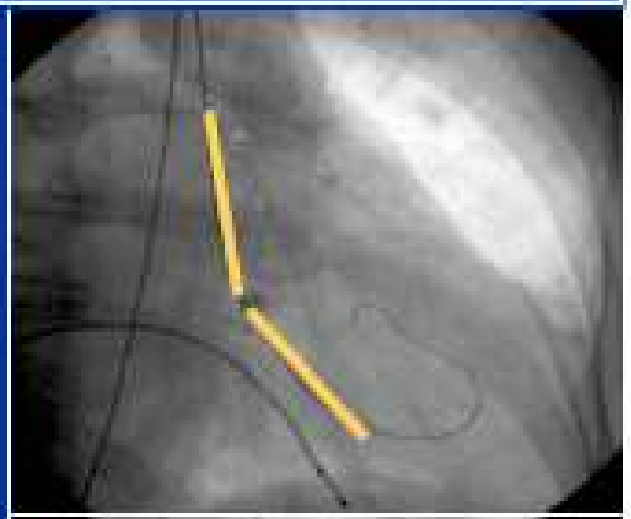
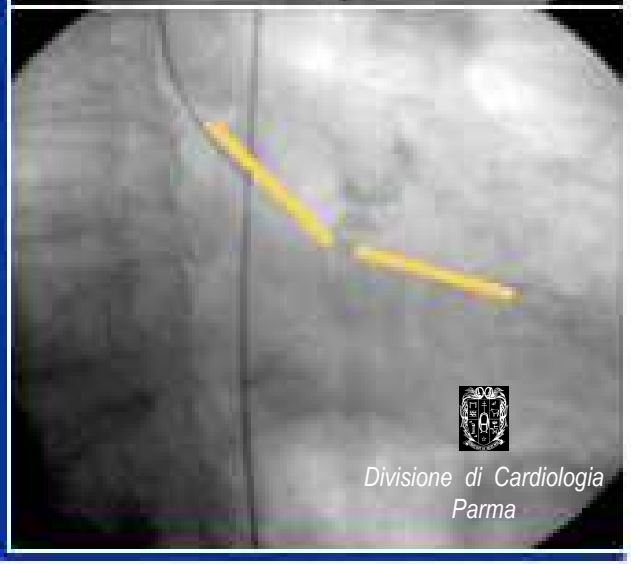
Angiographic Landmarks for Valve Implantation

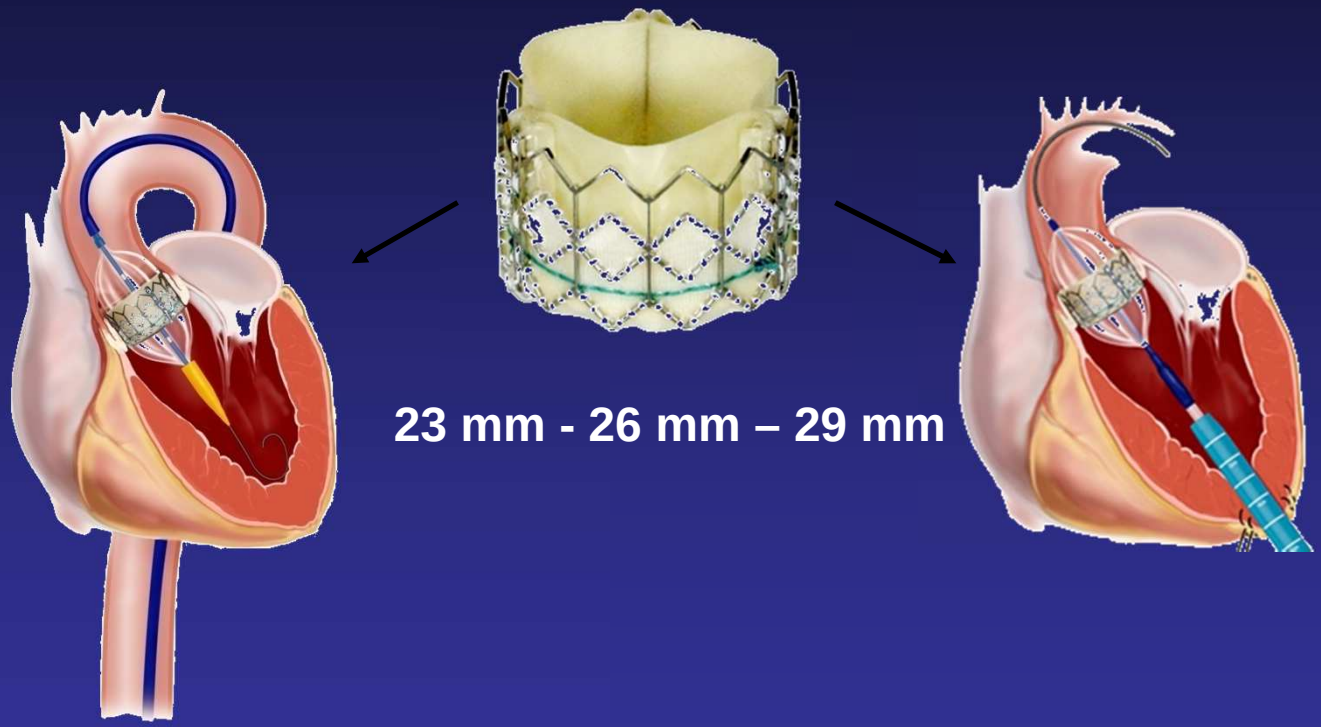








Edwards SAPIEN™ Transcatheter Heart Valve: **Two Delivery Options**



23 mm - 26 mm – 29 mm

TRANSFEMORAL

TRANSAPICAL

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Evolution of Aortic Valve Implant

2002 — 2004 — 2006

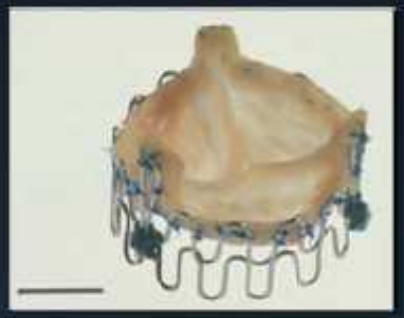
First aortic transcatheter Implant via antegrade Approach
A. Cribier

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

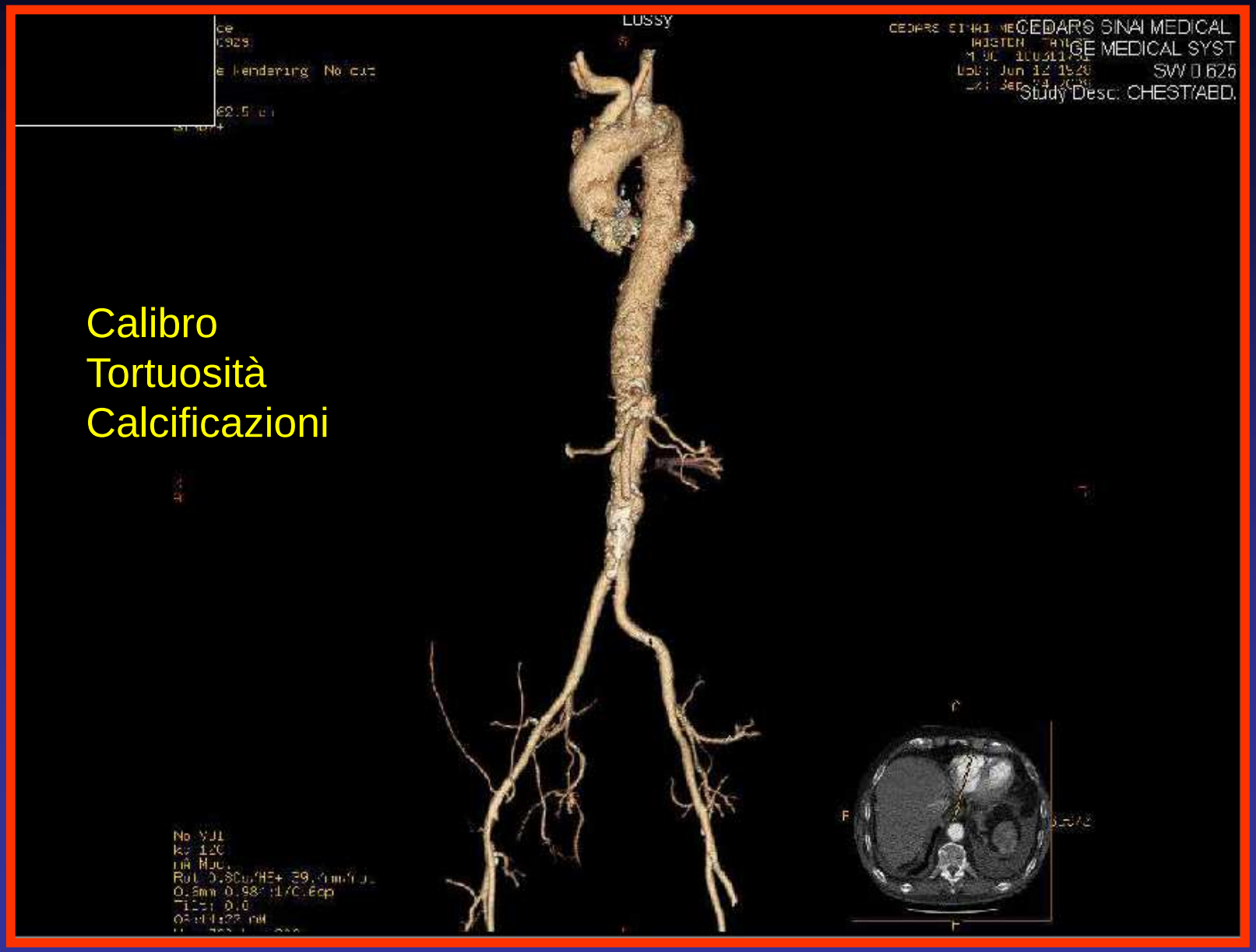
Untreated Equine Tissue

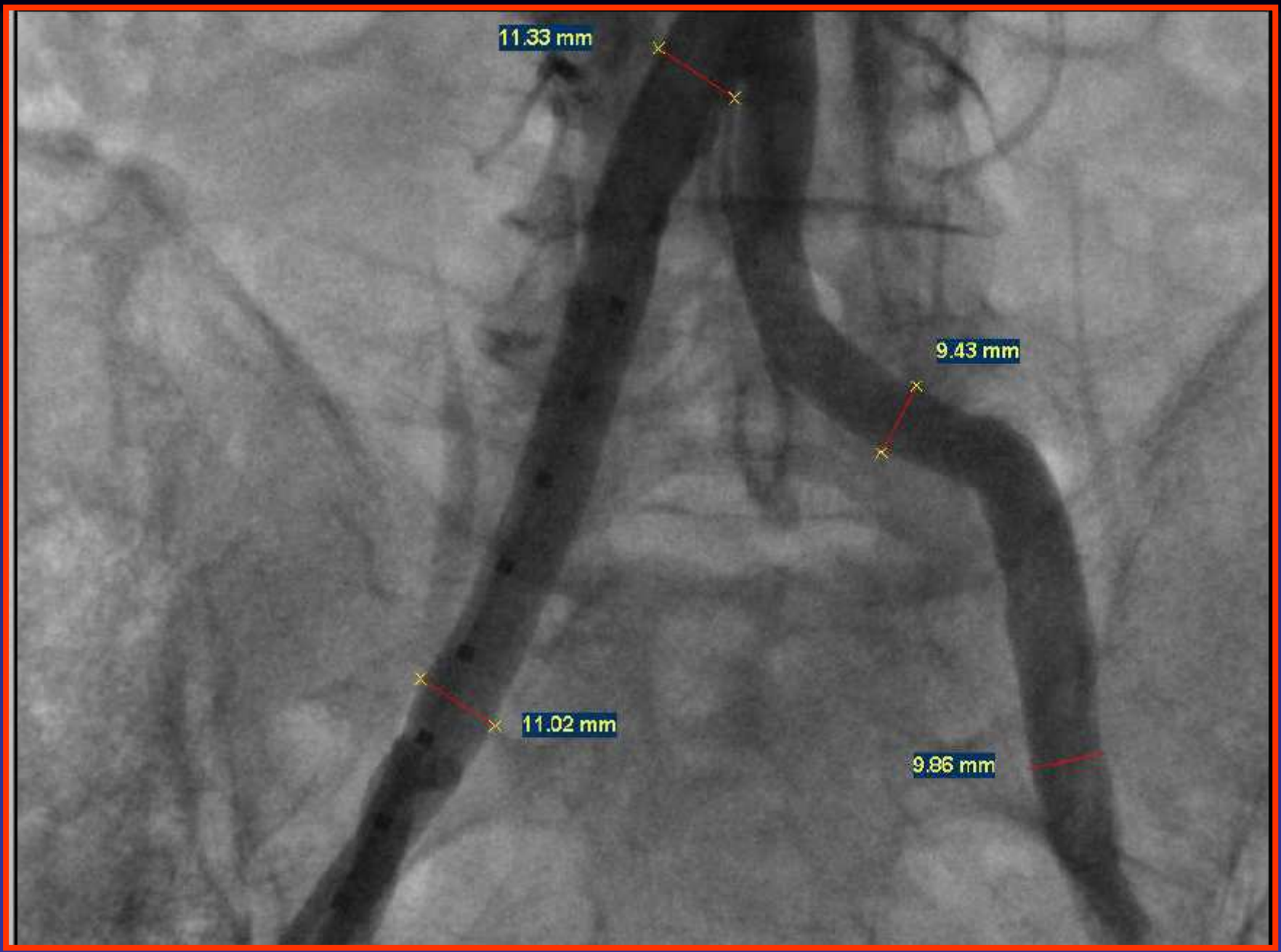
Cribier-Edwards™ THV
23mm FIM, April 2002

Treated Bovine Tissue

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

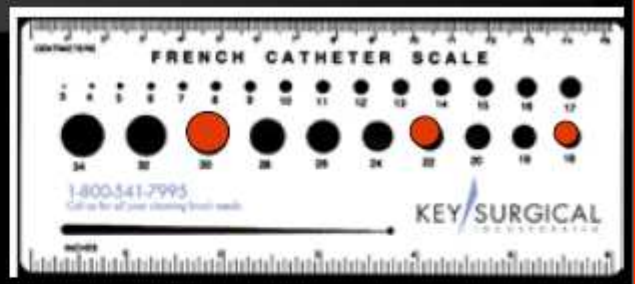
APPROCCIO RETROGRADO




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

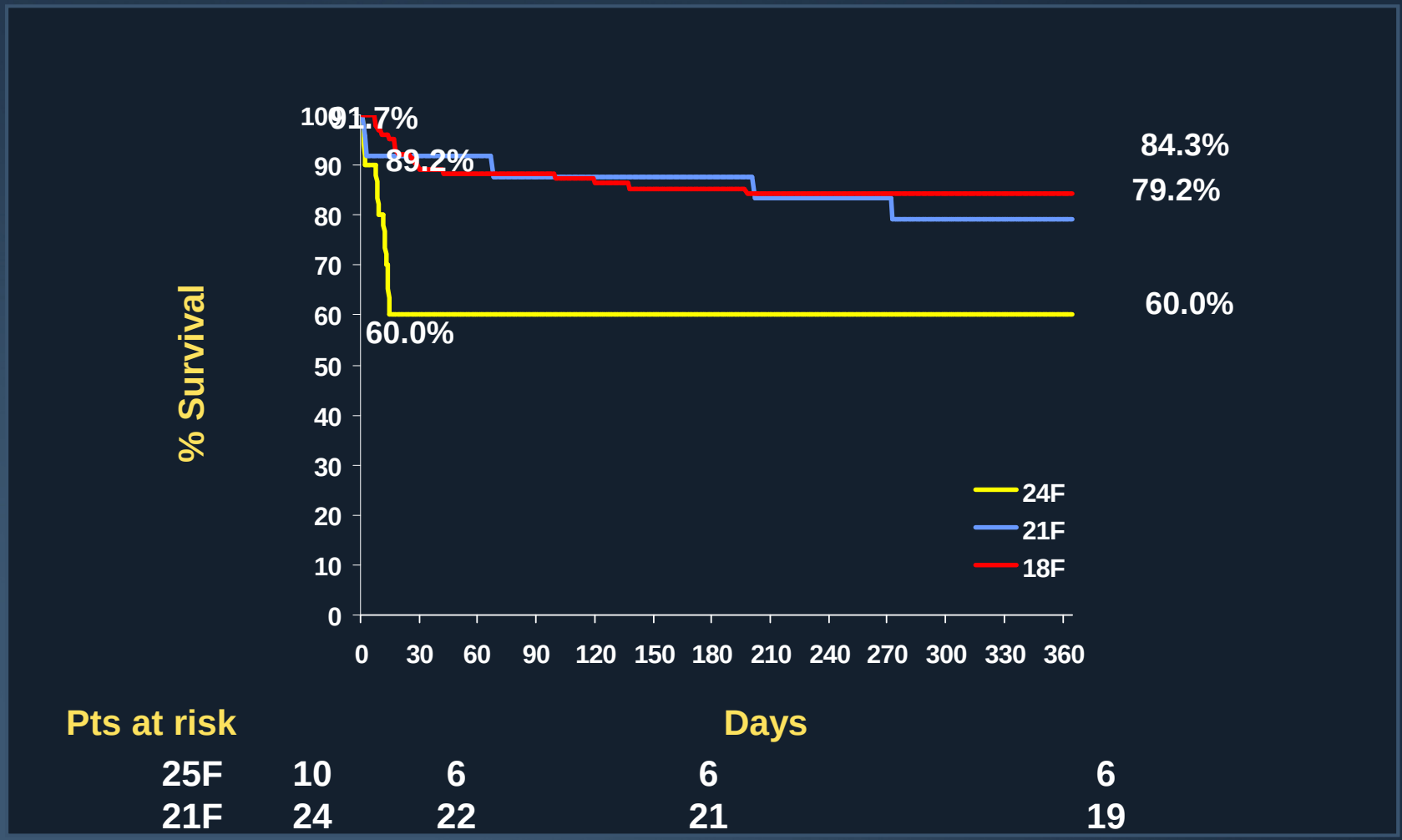
GEN2
7mm

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

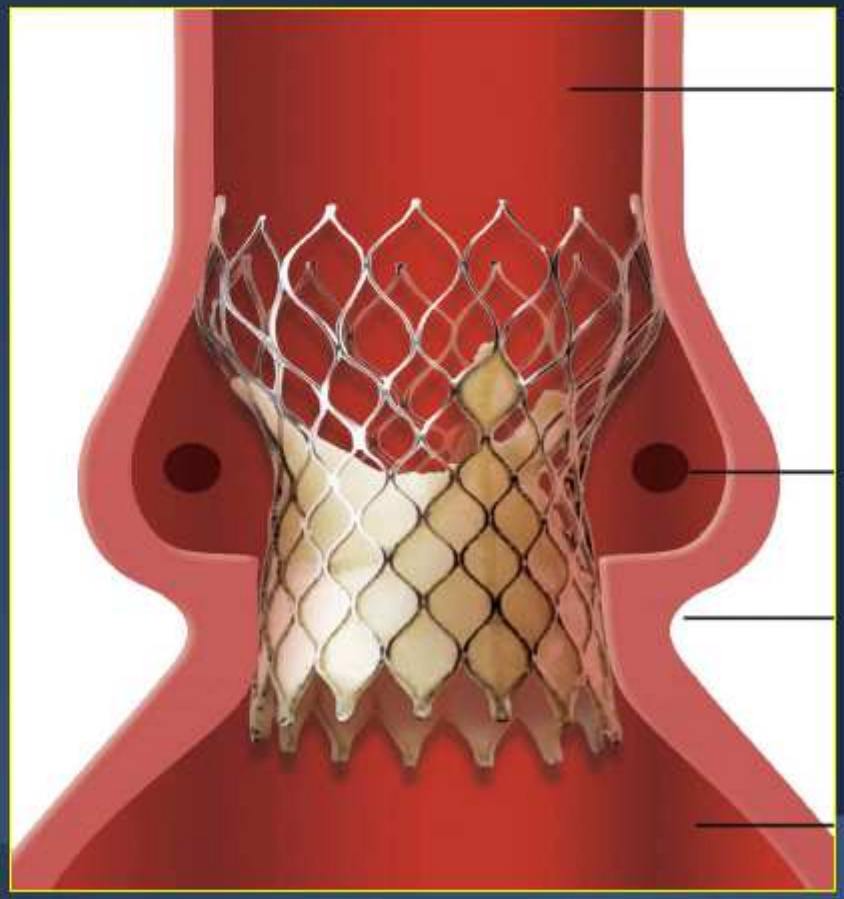
Columbia University Medical Center
NewYork-Presbyterian
The University Hospital of Columbia and Cornell


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

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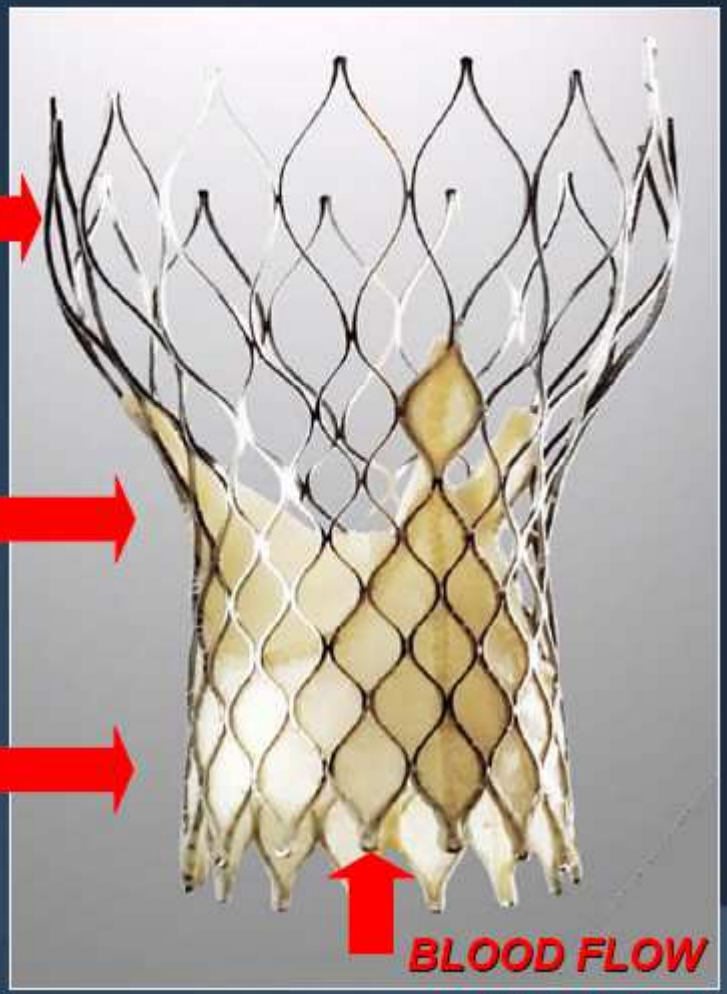
CoreValve PAVR *ReValving* System
Frame and Valve

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



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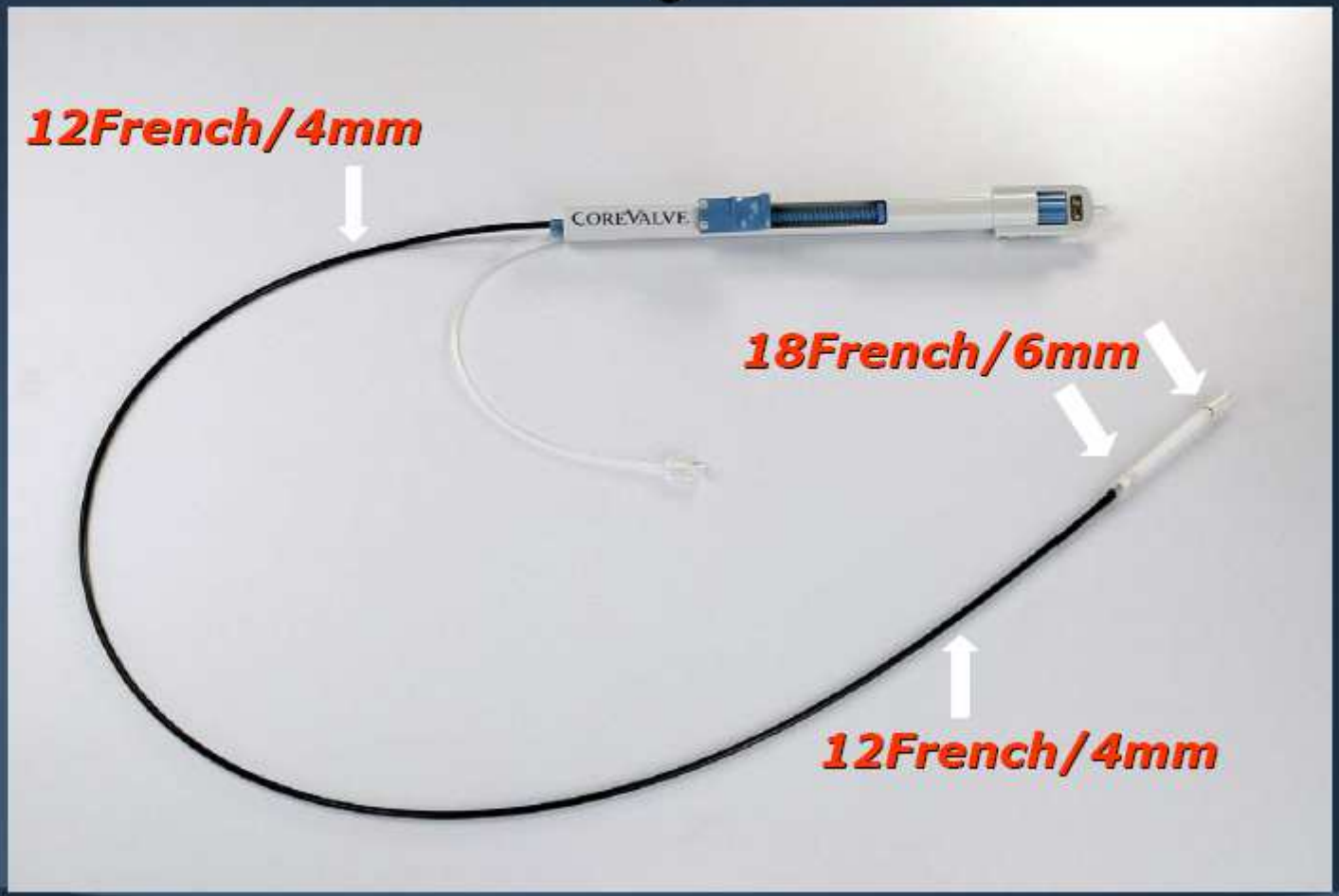
CoreValve PAVR *ReValving* System
Delivery Catheter



CARDIOVASCULAR RESEARCH FOUNDATION

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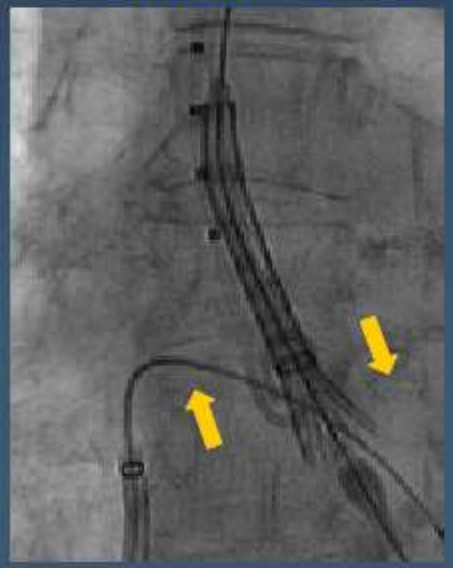
TCT 2008

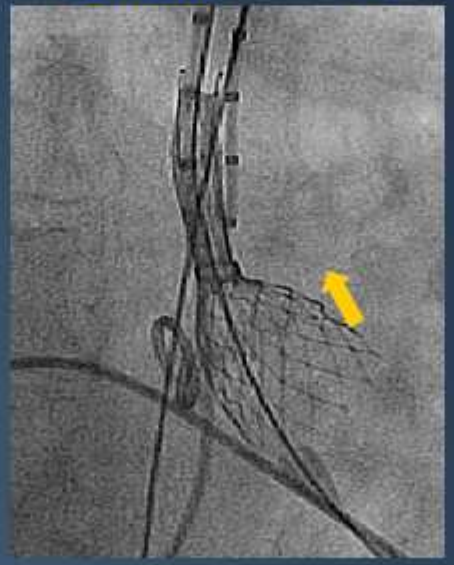
Lesson Learned
Slow and Stepwise Deployment Allows Repositionability

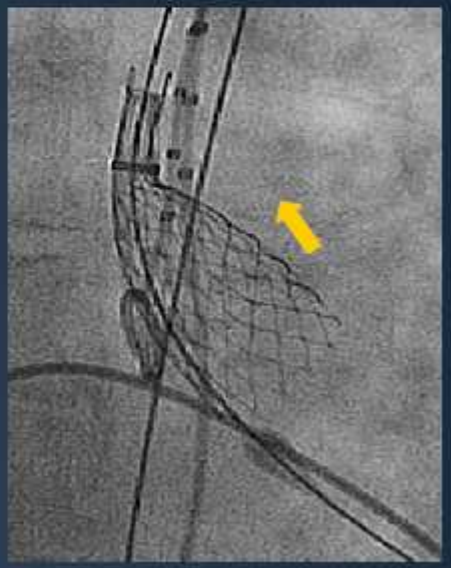
Before annular contact

After annular contact

Before device release

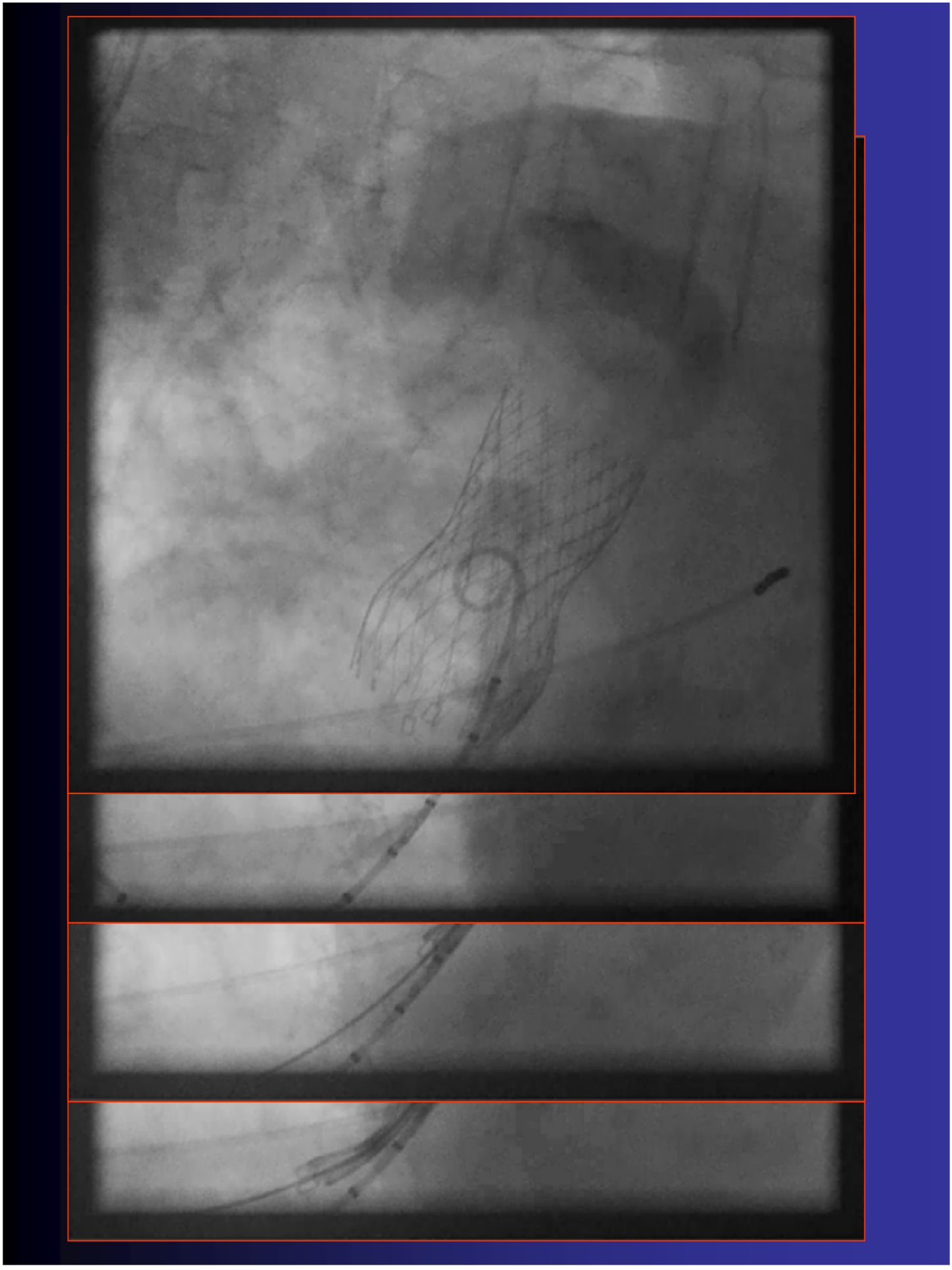


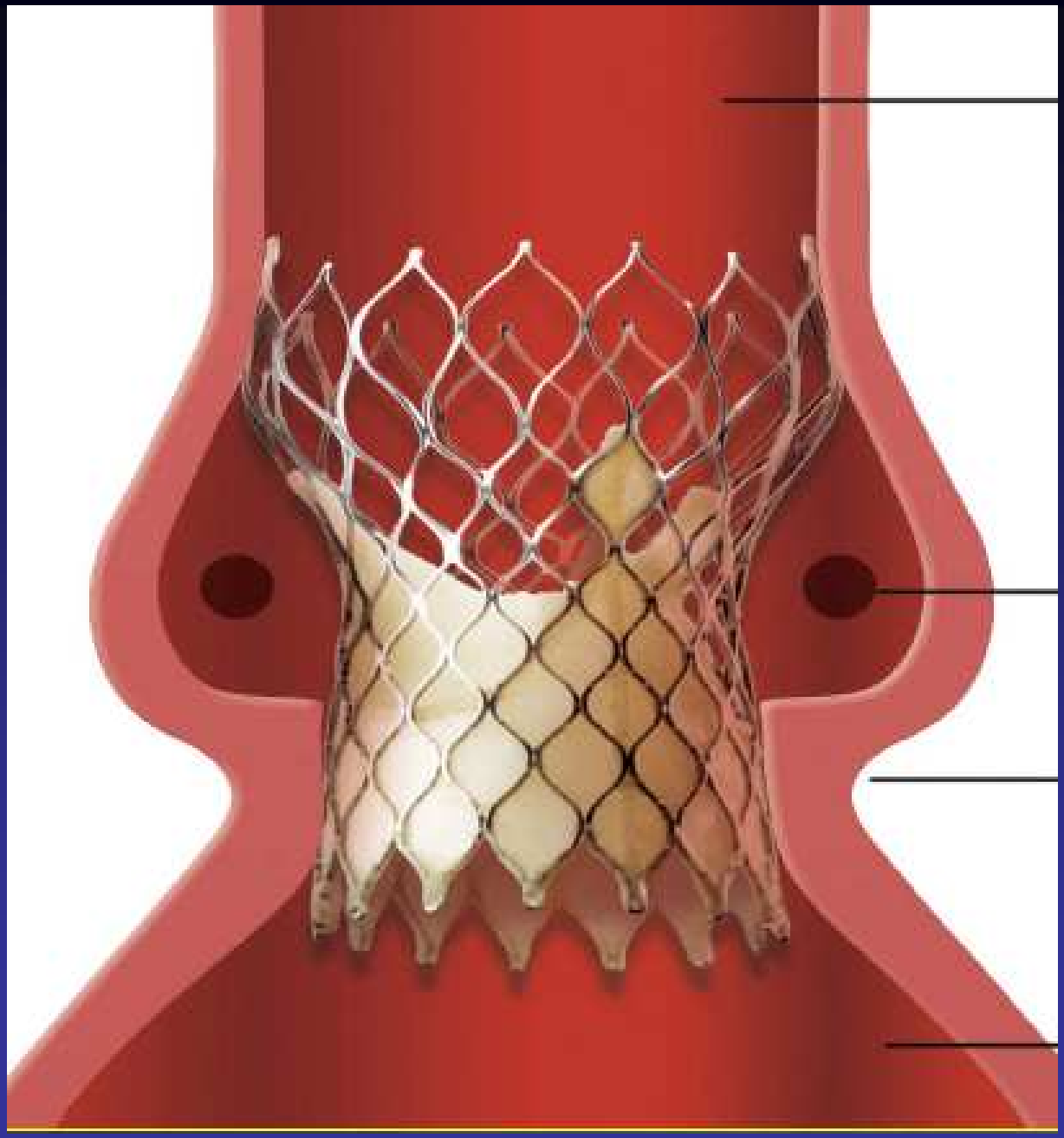




No need to "rush" since…

CARDIOVASCULAR RESEARCH




Aorta Ascendente
Ostio Coronarico
Anulus aortico
Cavità ventricolare

Impianto transcatetere di protesi valvolari aortiche
Approccio transfemorale

Rules of Engagement

Cardiac Surgery

Interventional Cardiology