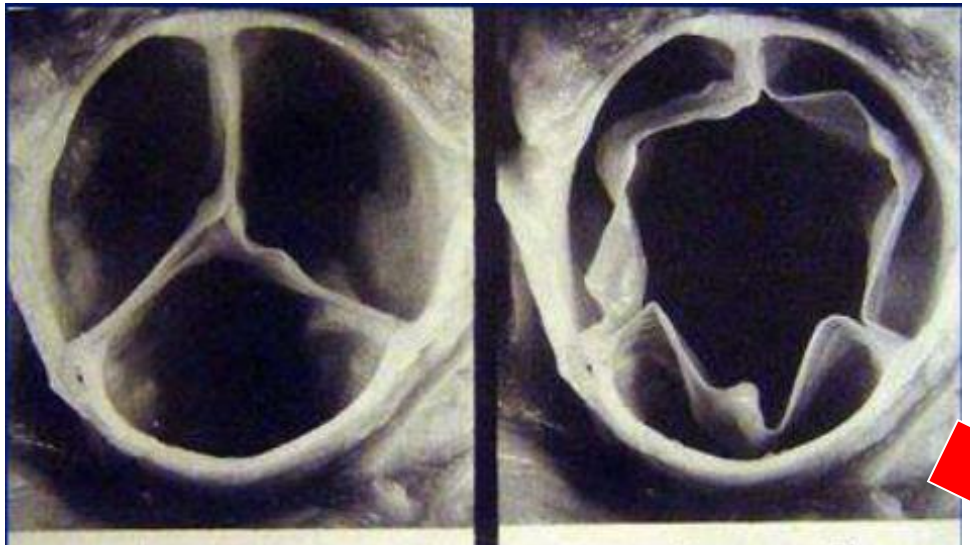
Trattamento percutaneo della patologia valvolare aortica

Giacomo Boccuzzi, MD, FESC

S.C Cardiologia
Ospedale San Giovanni Bosco, Torino, Italy

STENOSI VALVOLARE AORTICA DEGENERATIVA



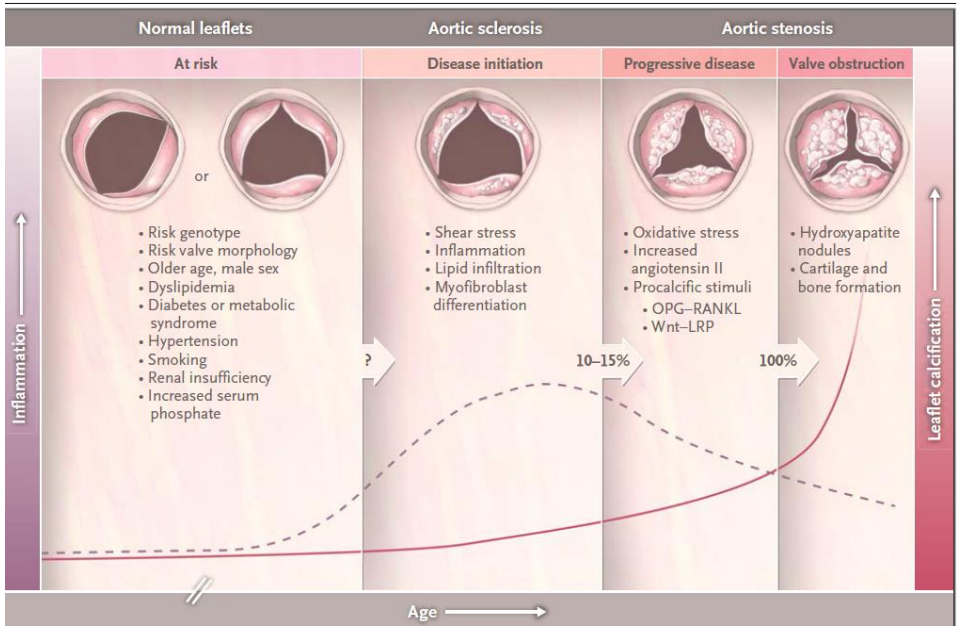
The NEW ENGLAND JOURNAL of MEDICINE

REVIEW ARTICLE

John A. Jarcho, M.D., *Editor*

Aortic-Valve Stenosis — From Patients at Risk to Severe Valve Obstruction

Catherine M. Otto, M.D., and Bernard Prendergast, D.M.



TERAPIA MEDICA della STENOSI AORTICA SEVERA SINTOMATICA ?

PERCHE' UNA SOSTITUZIONE VALVOLARE AORTICA PERCUTANEA ?

- **Offrire un'opzione ai pazienti considerati "inoperabili" o ad alto rischio chirurgico (mortalità > 10%)**

- **Fisiologica evoluzione verso procedure meno invasive (gradimento del paziente, riduzione tempi di degenza e di riabilitazione, riduzione costi)**

ROUEN: 1985
BALLOON VALVULOPLASTY PROPOSED AS A PALLIATIVE PROCEDURE FOR THESE PATIENTS

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

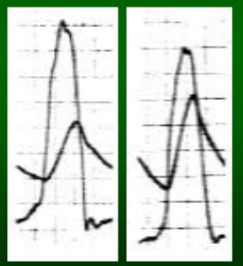
Service des Soins Intensifs Cardiologiques et des Explorations Hémodynamiques Cardiovasculaires, Centre Hospitalier et Universitaire, Hôpital Charles Nicolle, Rouen, France

THE LANCET, JANUARY 11, 1986

THE LANCET, JANUARY 11, 1986

Rouen Sept 1985

72 y-old female, AS + CAD
Severely symptomatic
Declined for surgery



F.I.M.: 20mm Balloon

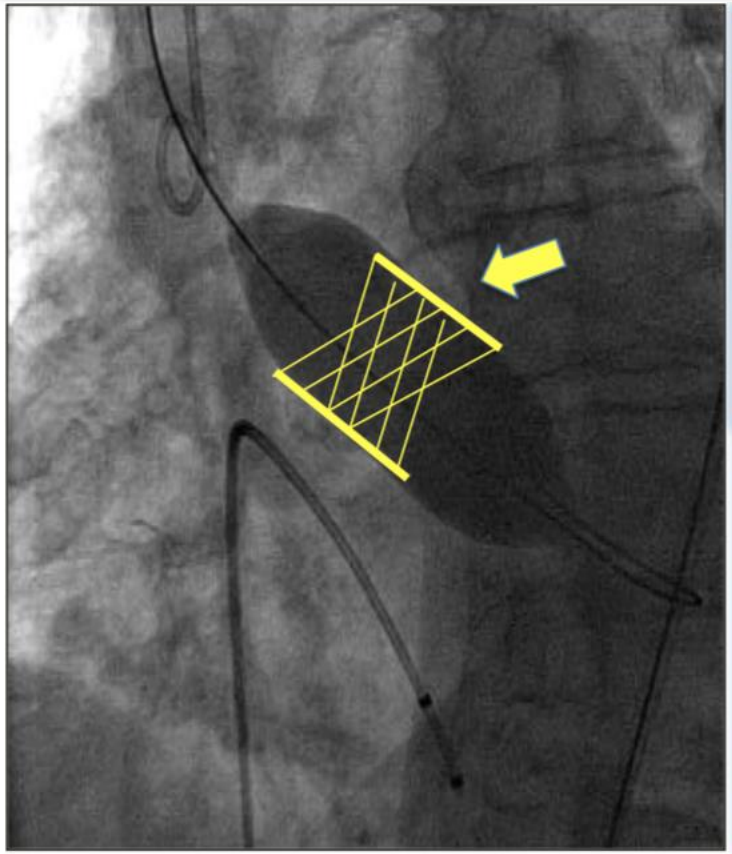
Thousand of cases performed worldwide

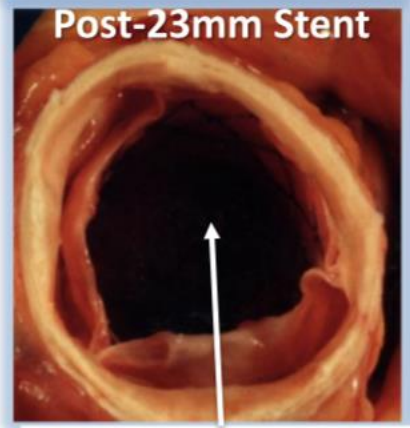
Hemodynamic / symptomatic improvement

ONE MAIN LIMITATION

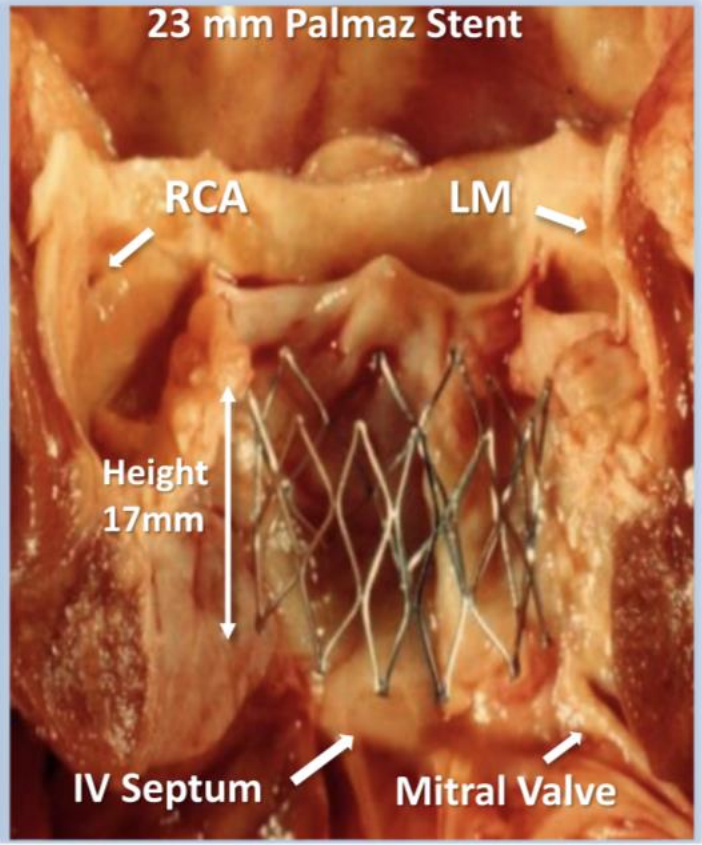
Early valve restenosis: 80% at one year

FROM 1987 BIRTH OF THE IDEA OF "STENTED-VALVE"





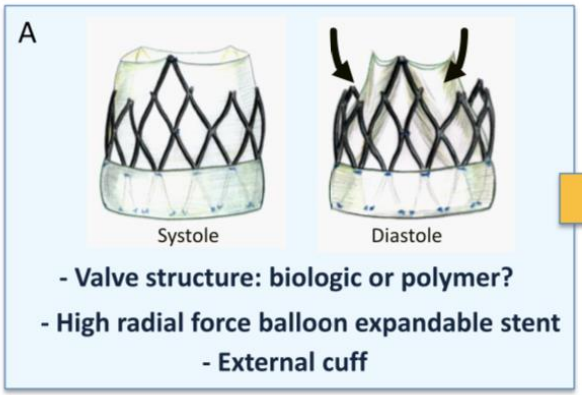
Circular opening

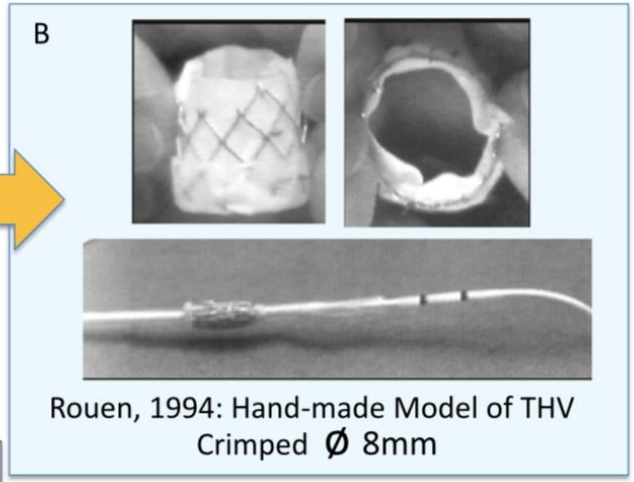


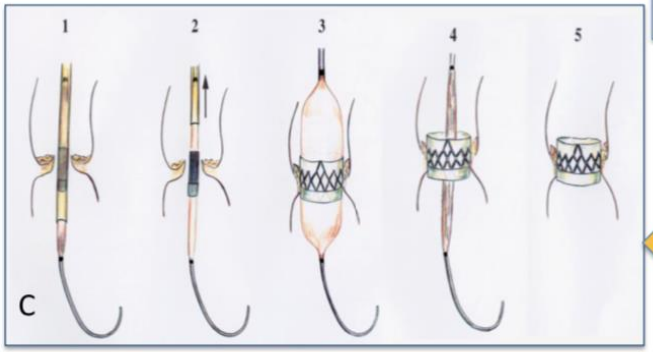
Respect of adjoining structures

1994 Autopsy study. 12 case of calcific AS. A balloon-expandable peripheral artery stent of 23 mm in diametre (palmaz stent) was able to maintain a circular opening in all calcified aortic valves

1994 first EUROPEAN PATENT







Transfemoral approach conceivable

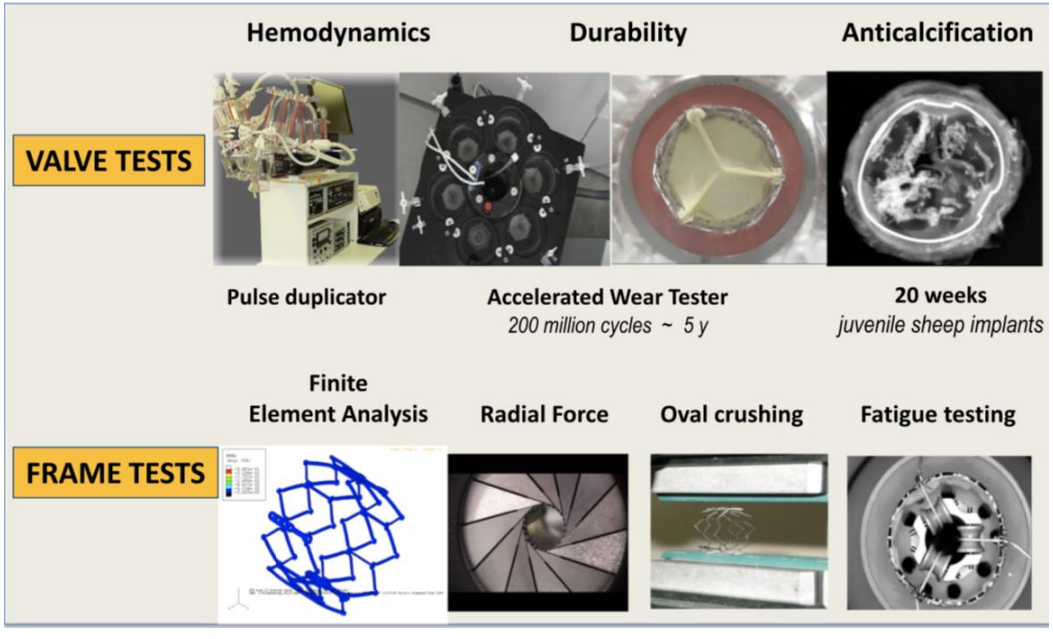
Unanimously unfavorable opinions from all experts with regard to the design of the prosthesis, the potential risks of the procedure---------

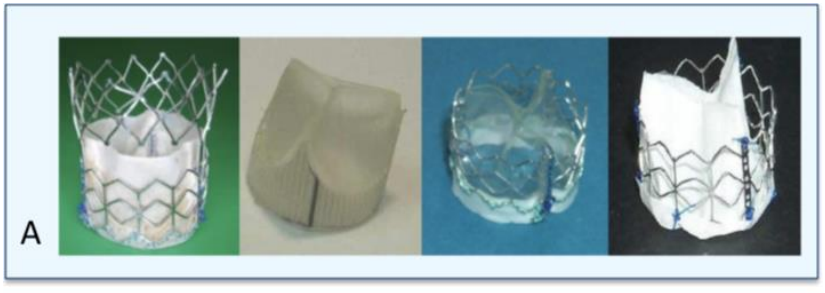
The project was looking like ”**the most stupid ever proposed**”

PRECLINICAL ENGINEERING OUTPUT: FROM CONCEPT TO FINALIZED PROTOTYPE

MANY DIFFERENT VALVE CONFIGURATIONS WERE INVESTIGATED.

1. FRAME MATERIAL AND DESIGN (profile, dimensions, skirt, crimping process and expansion, fatigue, resistance)
2. LEAFTLETS DESIGN (material, stress distribution, leak, fatigue and durability, calcification)
3. LOADING and DELIVERY CATHTER SYSTEM





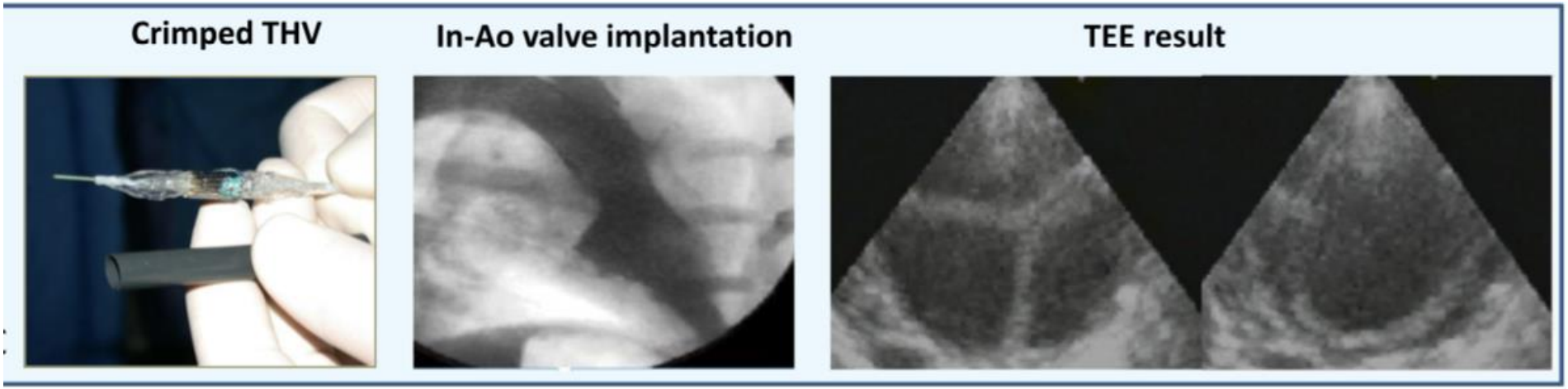
Finalized device

Tri-leaflet valve (polymer, then bovine pericardium)
Stainless steel stent, single Ø23mm

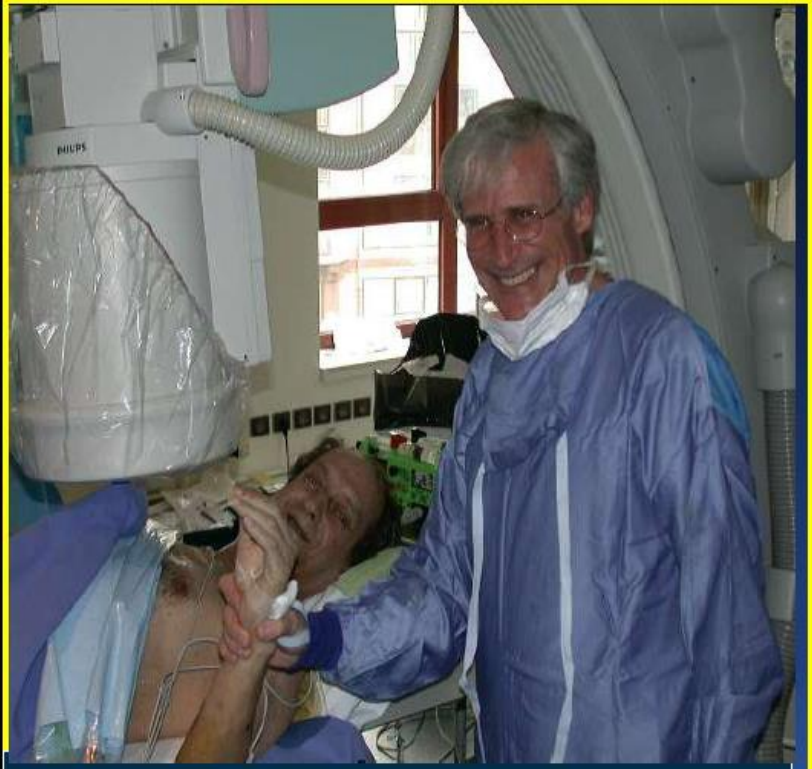
FROM PROTOTYPES TO ANIMAL MODEL

IN THE YEAR 2000, THE ANIMAL EXPERIMENTATION STARTED ON THE SHEEP MODEL.

OVER 100 THV IMPLATATIONS WERE PERFORMED



Rouen, April 16, 2002: F.I.M THV implantation Trans-septal approach



30 min post-implantation

8 days post-implantation

STORIA DELLA SOSTITUZIONE VALVOLARE AORTICA

Homograft – 1962

Mechanical heart valve – 1962

Porcine valve – 1965

Pericardial tissue valve – 1969

First PVT animal implantation
A. Cribier

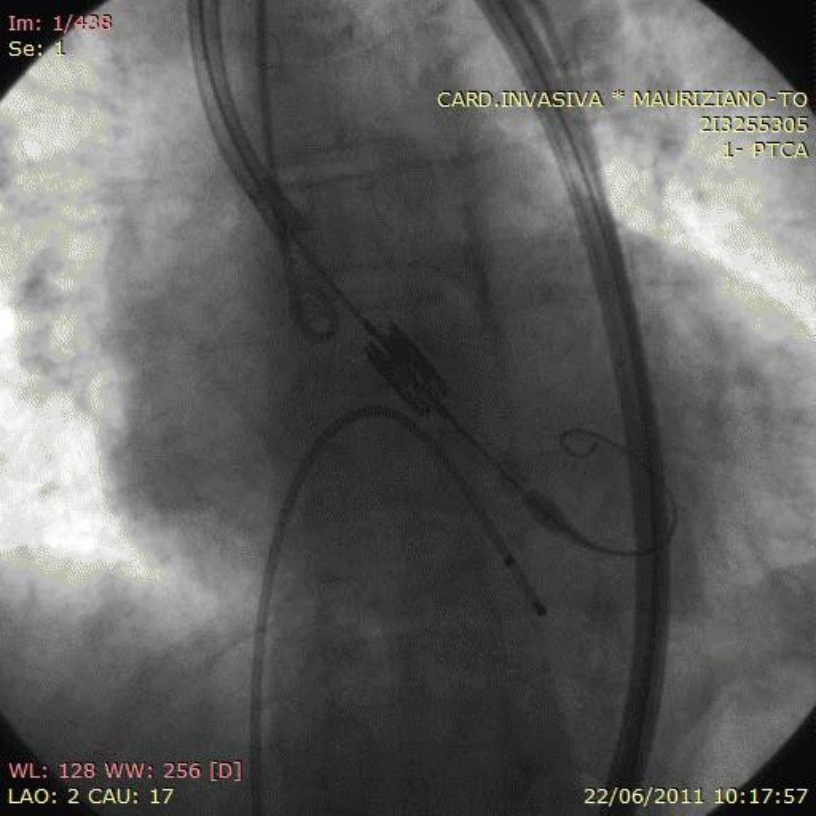
First Corevalve animal implantation
JC. Laborde

First Edwards/PVT Transapical Beating Heart AVR
Webb, Lichtenstein – Nov 29, 2005

1960 1970 2000 2001 2002 2004 2006

First PVT Transcatheter AVR
by Antegrade Approach
Alain Cribier - 2002

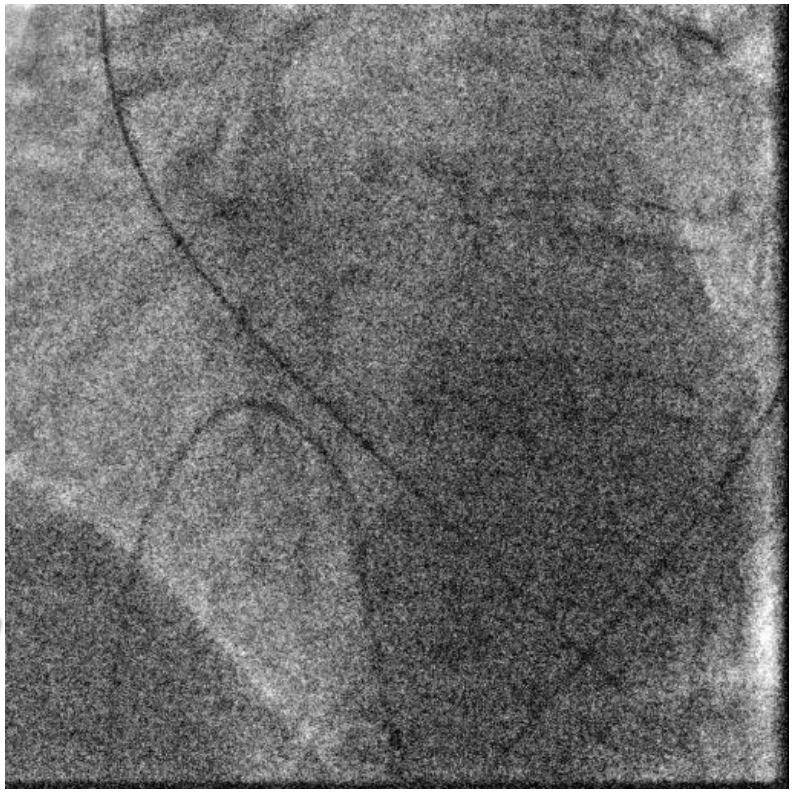
First CoreValve PERCUTANEOUS AVR
by Retrograde Approach – Oct 12, 2006
Serruys, DeJaegere, Laborde



2002 Impianto di valvola aortica percutanea (TAVI)

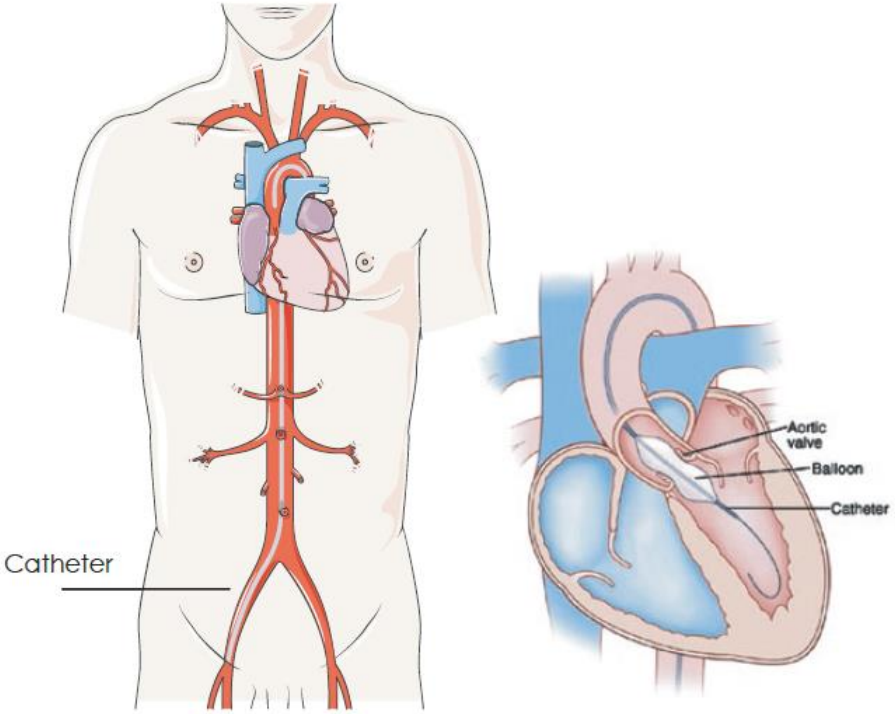
≠

20 anni



1985 Valvuloplastica aortica pallone (BAV Balloon aortic valvuloplasty)

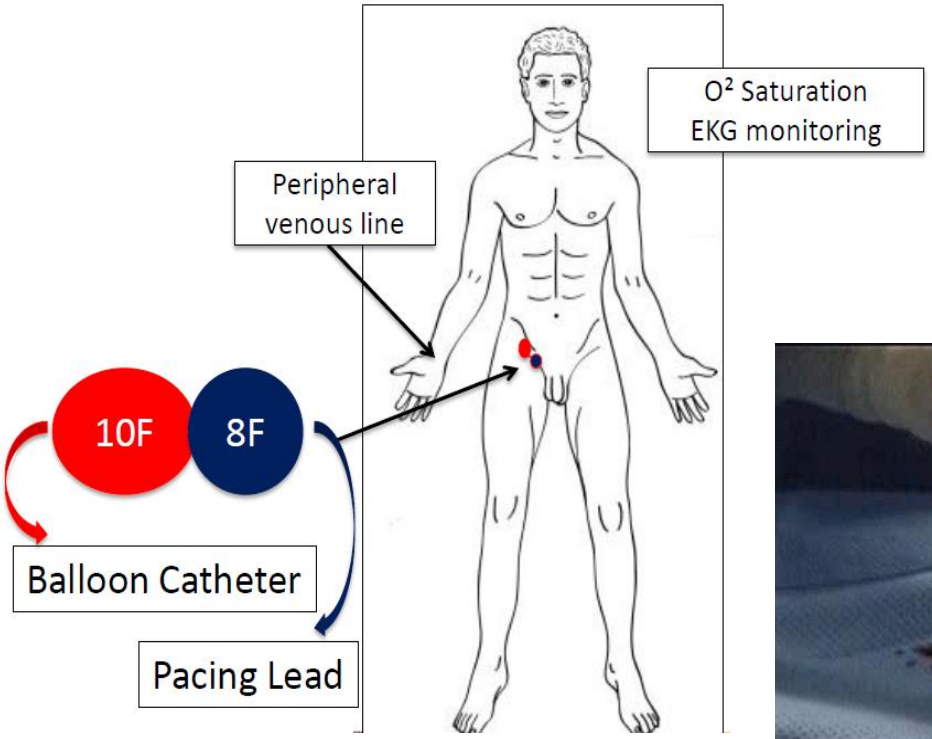
VALVULOPLASTICA AORTICA (BAV): Aspetti tecnici



- Vascular access
- Pacing lead placement
- Aortic valve crossing
- Balloon dilatation
- Arterial closure

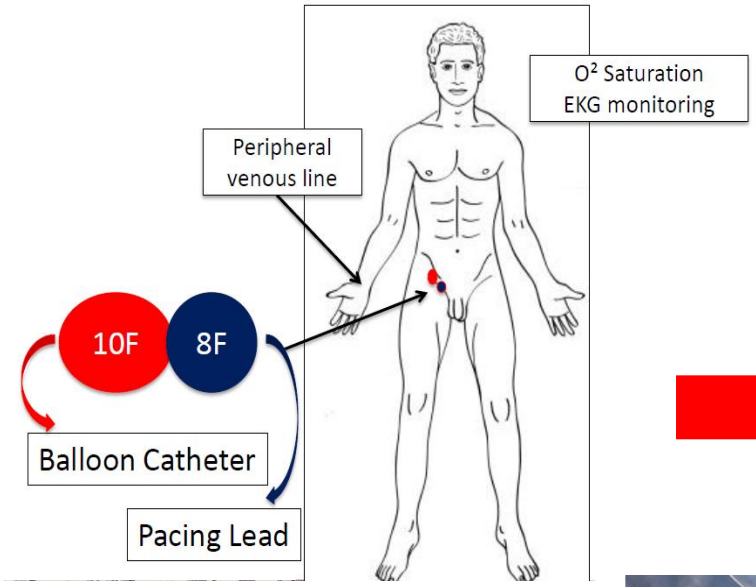
Anestesia locale. Tempo procedura circa 45 min

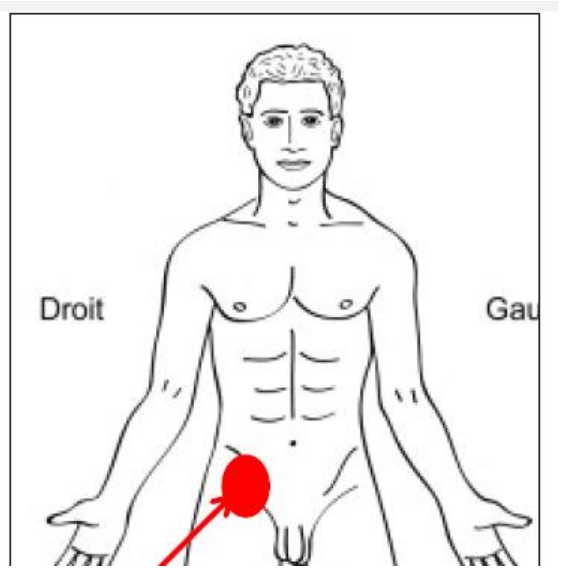
VALVULOPLASTICA AORTICA (BAV): accessi vascolari



Accesso arterioso

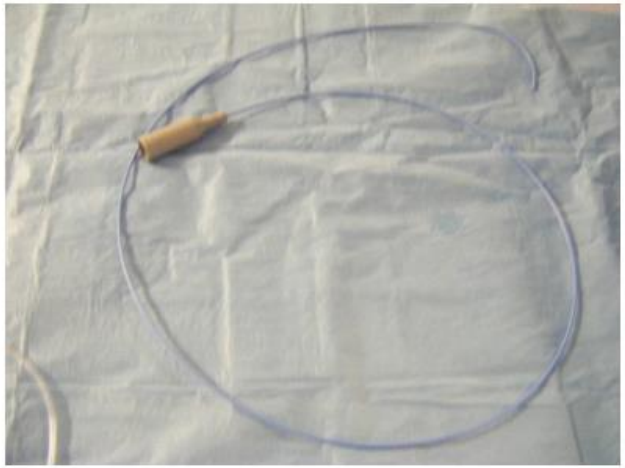
VALVULOPLASTICA AORTICA (BAV): accessi vascolari



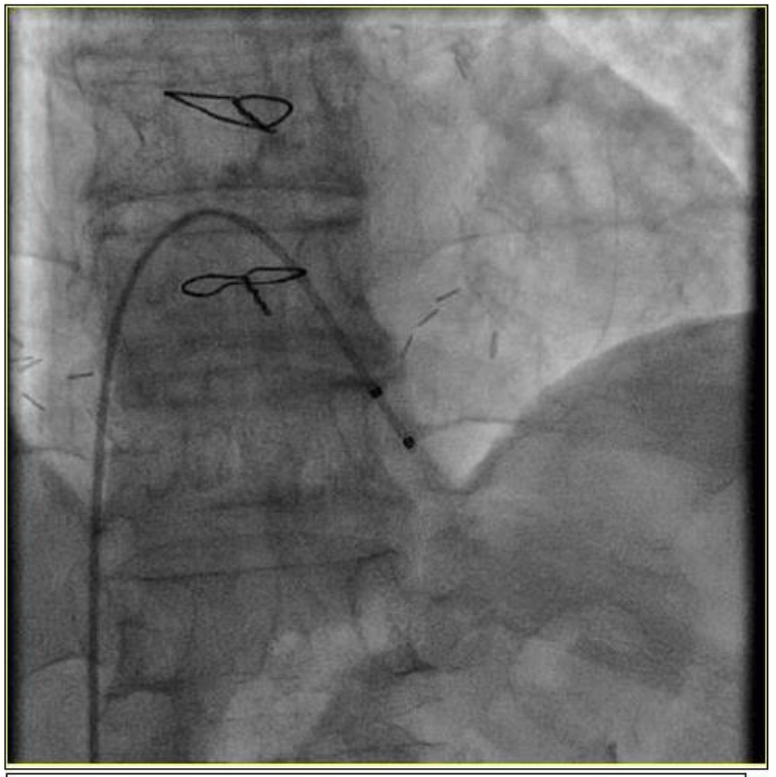


8 F

BAV: posizionamento PM e test rapid pacing

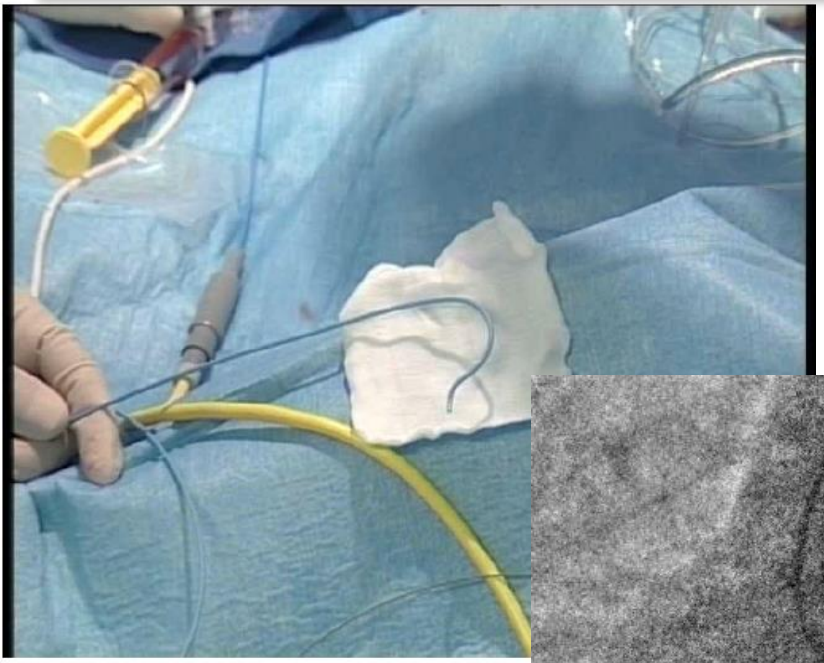


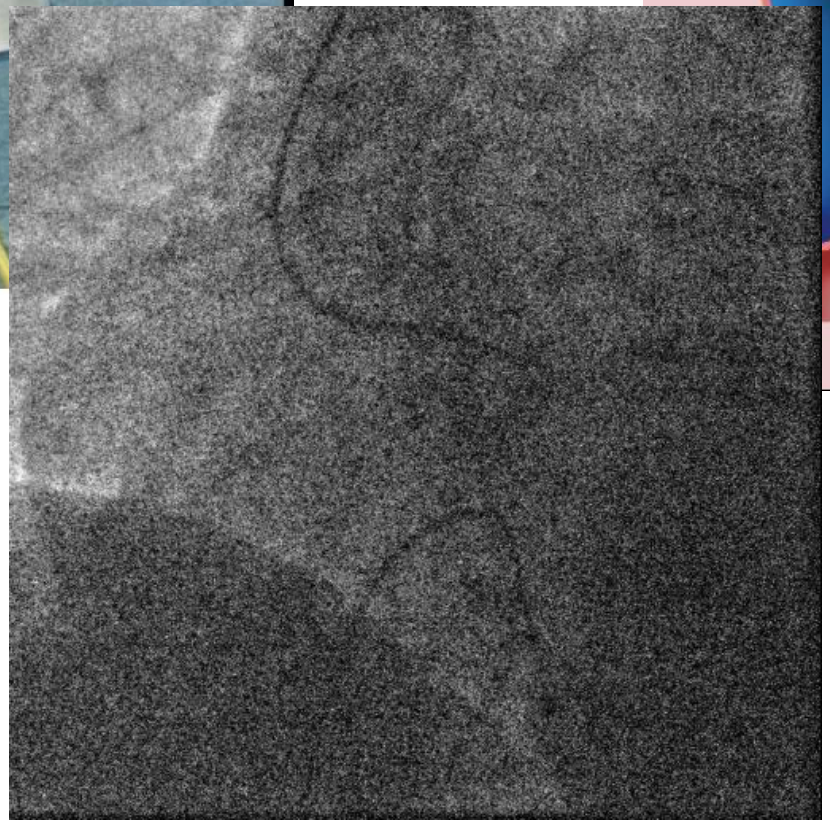
Test of Rapid Ventricular pacing
(180 b/min)

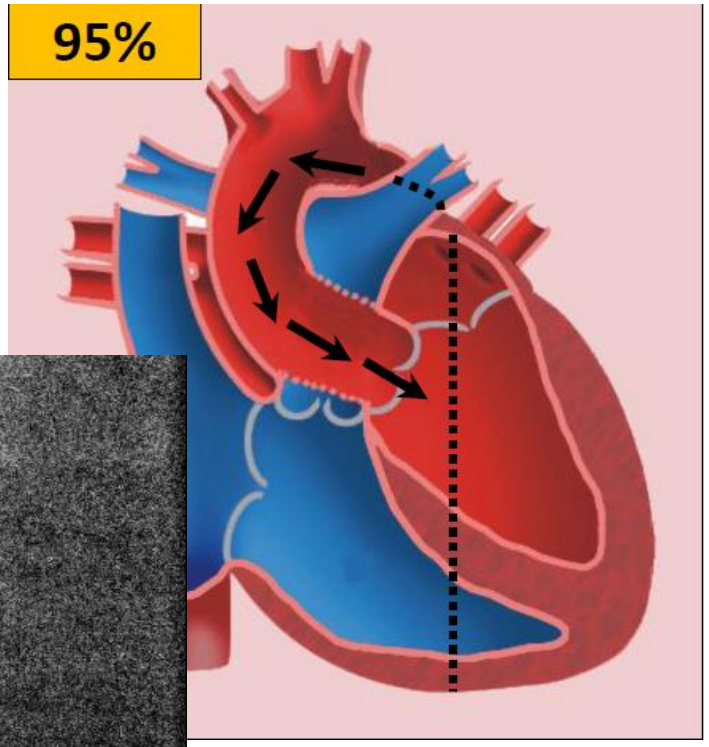


Tip of pacing lead placed at
mid-part of the RV posterior wall

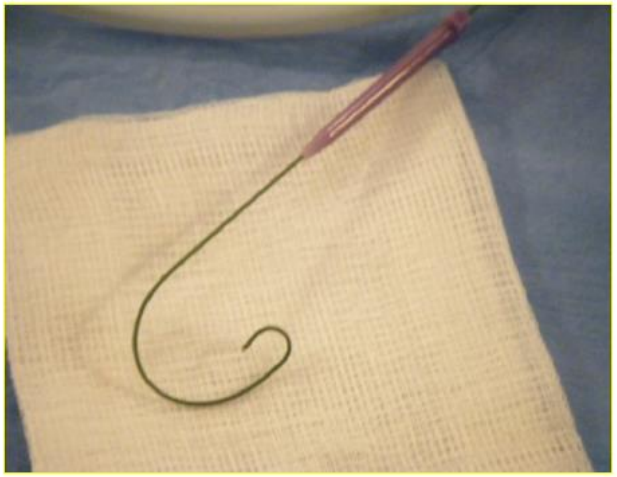
BAV: Crossing della stenosi aortica

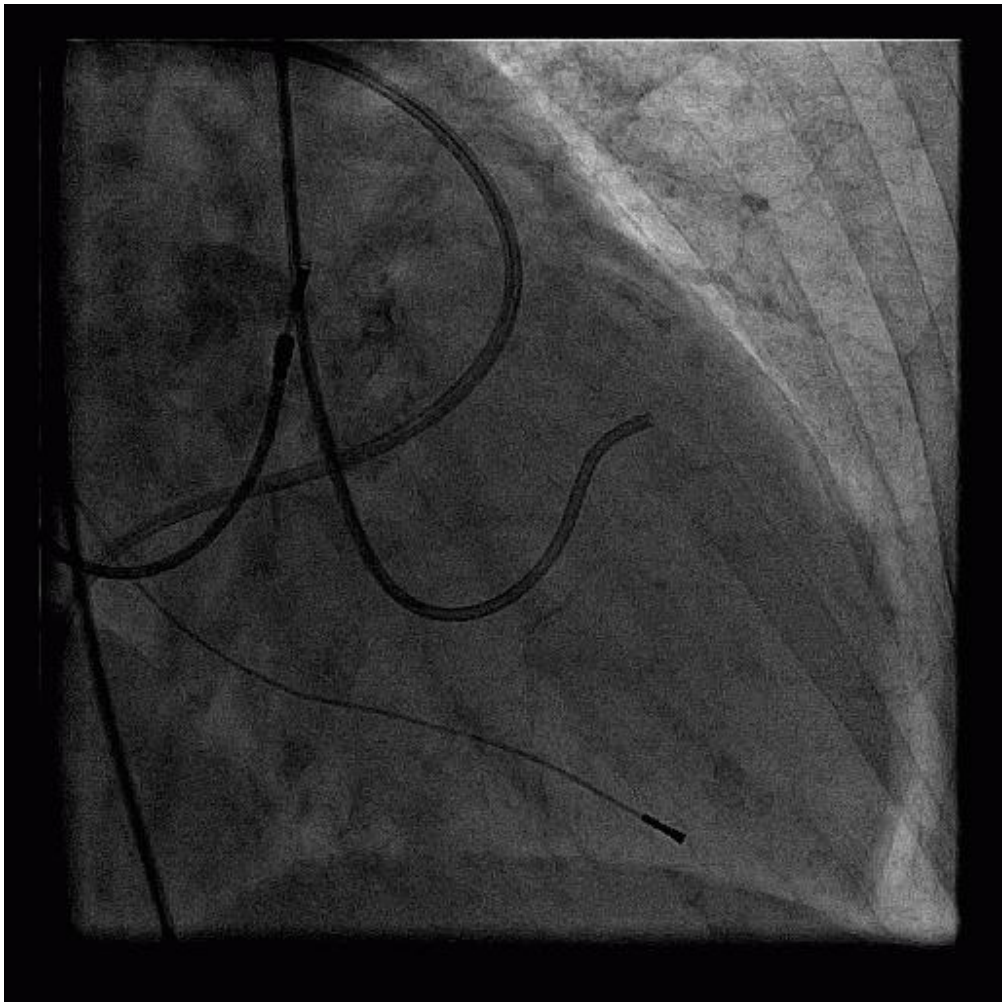






BAV: Posizionamento della guida ad alto supporto





BAV:scelta del pallone

BALT
10 F Compatible

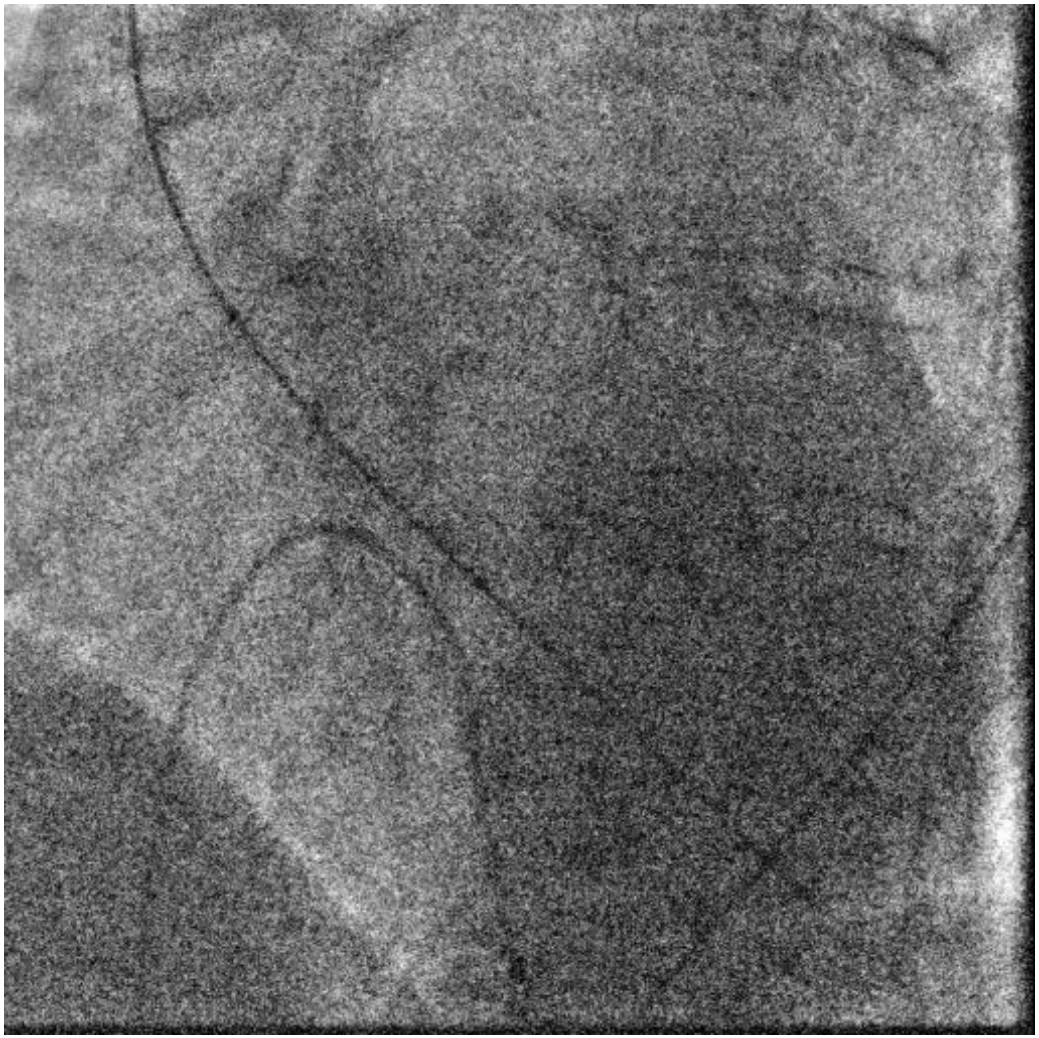
Z-MED
12-14F Compatible

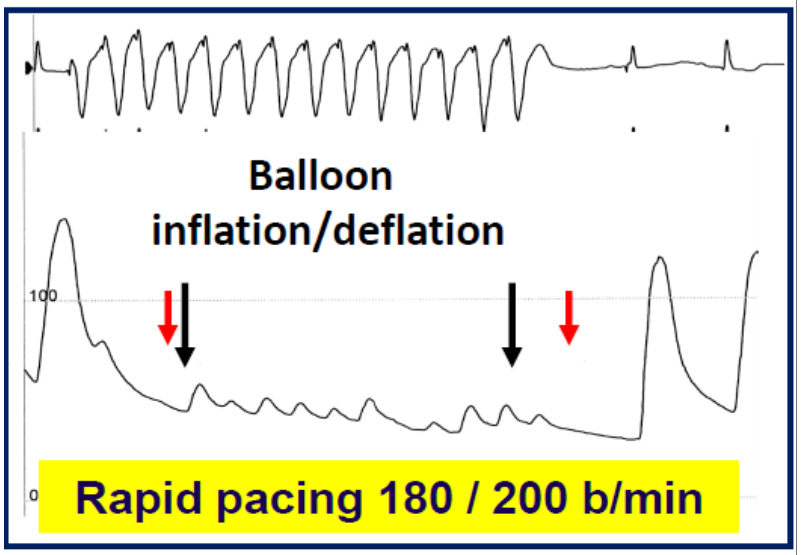
NUCLEUS
10F Compatible

Sizes from 18 to 28 mm

Women: 20/23 **Men: 23/25**

BAV: rapid pacing e dilatazione





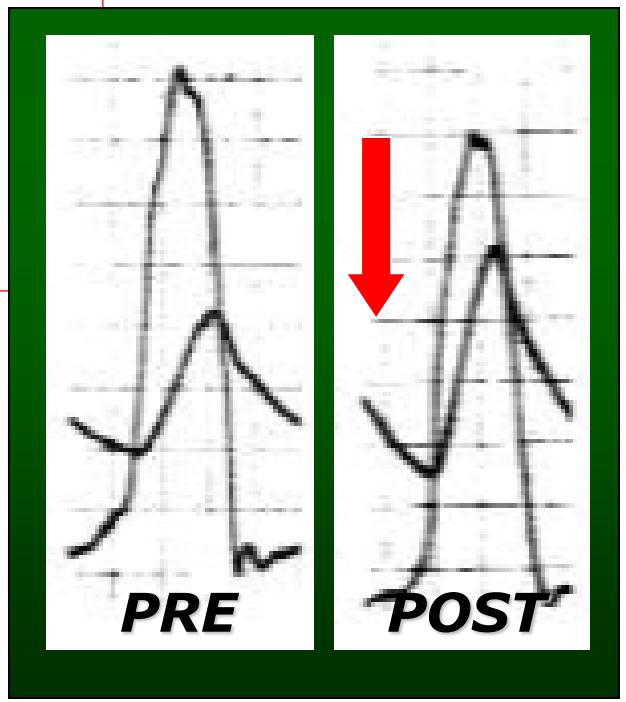
Contrast (15% dilution)

2-3 inflations per size

BAV: scopo della dilatazione

- 2 to 3 inflations per balloon size (20, 23, 25mm)
- 1st size: 20 or 23mm depending on sex (smaller in female), annulus size and amount of calcification
- Increase size if unsatisfactory result

Objective:
- mean gradient < 20 mm Hg
- AVA ↗ by 80% to 100%
- without AR > grade 2



BAV: COMPLICAZIONI

Variables, n (%)	Overall population N = 323
Overall major complication	22 (6.8)
Death	8 (2.5)
Stroke	6 (1.8)
Vascular complications	8 (2.5)
Major	5 (1.5)
Minor	3 (1.0)
Stroke	6 (1.8)
Annulus rupture	1 (0.3)
Myocardial infarction	0 (0)
Severe aortic regurgitation	5 (1.5)
Pacemaker	2 (0.6)

Balloon aortic valvuloplasty in the era of transcatheter aortic valve replacement: Acute and long-term outcomes

Am Heart J 2014;167:235-40

Hélène Eltchaninoff, MD,[a,c] Eric Durand, MD, PhD,[a,c] Bogdan Borz, MD,[a] Akira Furuta, MD,[a] Karim Bejar, MD,[a] Alexandre Canville, MD,[a] Ali Farhat, MD,[a] Chiara Fraccaro, MD,[a] Matthieu Godin, MD,[a] Christophe Tron, MD,[a] Rahul Sakhuja, MD,[b] and Alain Cribier, MD[a] *Rouen, France; and Kingsport, TN*

BAV: INDICAZIONI

European Heart Journal (2012) 33, 2451–2496
doi:10.1093/eurheartj/ehs109

ESC/EACTS GUIDELINES

Guidelines on the management of valvular heart disease (version 2012)

The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: Alec Vahanian (Chairperson) (France)*, Ottavio Alfieri (Chairperson)* (Italy), Felicita Andreotti (Italy), Manuel J. Antunes (Portugal), Gonzalo Barón-Esquivias (Spain), Helmut Baumgartner (Germany), Michael Andrew Borger (Germany), Thierry P. Carrel (Switzerland), Michele De Bonis (Italy), Arturo Evangelista (Spain), Volkmar Falk (Switzerland), Bernard Iung (France), Patrizio Lancellotti (Belgium), Luc Pierard (Belgium), Susanna Price (UK), Hans-Joachim Schäfers (Germany), Gerhard Schuler (Germany), Janina Stepinska (Poland), Karl Swedberg (Sweden), Johanna Takkenberg (The Netherlands), Ulrich Otto Von Oppell (UK), Stephan Windecker (Switzerland), Jose Luis Zamorano (Spain), Marian Zembala (Poland)

Vahanian et al; Eur Heart J 2012

BAV: INDICAZIONI

Balloon valvuloplasty may be considered :

- As a bridge to surgery or TAVI in haemodynamically unstable patients who are at high risk for surgery
- In patients with symptomatic severe AS who require urgent major non-cardiac surgery
- As a palliative measure in selected individual cases when surgery is contraindicated because of severe comorbidities and TAVI is not an option

Recommendation class IIb, level of evidence C

BAV: INDICAZIONI

But also, as a bridge to TAVR/SAVR
in difficult decisions:

- Alteration of cognitive functions
- Association to pulmonary disease
- Depressed LV function
- Low gradient

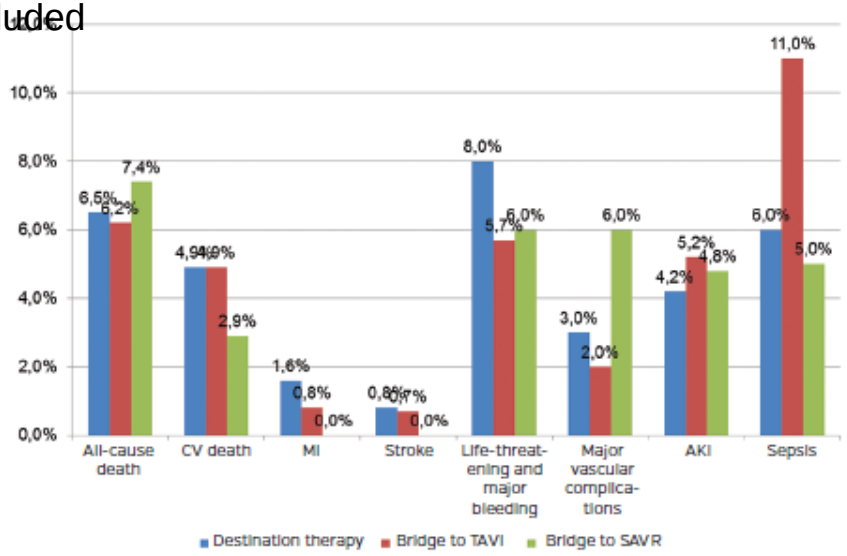
J INVASIVE CARDIOL 2015;27(12):547-553

Outcomes of Patients Undergoing Balloon Aortic Valvuloplasty in the TAVI Era: A Multicenter Registry

Claudio Moretti, MD[1]; Sujay Chandran, MD[2]; Paul-Louis Vervueren, MD[3]; Fabrizio D'Ascenzo, MD[1]; Marco Barbanti, MD[4]; Roshan Weerackody, MD[2]; Giacomo Boccuzzi, MD[5]; Dae-Hyun Lee, MD[6]; Jose de la Torre Hernandez, MD[6]; Pierluigi Omedè, MD[1]; Vincent Nijenhuis, MD[7]; Norris Igbineweka, MD[8]; Patrick Lim, MD[9]; Ten Berg, Prof[7]; Didier Carrié, Prof[3]; David Hildick-Smith, MD[8]; Simona Gulino, MD[10]; Stefano Cannata, MD[4], Giuseppe Gargiulo, MD[4]; Corrado Tamburino, MD[4]; Federico Conrotto, MD[1]; Ilaria Meynet, MD[1]; Giorgio Quadri, MD[1]; Ludovica Marangoni, MD[1]; Salma Taha, MD[1,11]; Giuseppe Biondi Zoccai, MD[12]; Stefano Salizzoni, MD[1]; Sebastiano Marra, MD[1]; Fiorenzo Gaita, Prof[1]

BAV Outcomes in the TAVI Era

A total of 811 patients aged 82 ± 9 years were included



Esperienza Ospedale San Giovanni Bosco (tot. 70 pz)

Età	**81± 5**
Donne	**67 %**
Euroscore	**22,4±9**
Ipertensione	**79 %**
Diabete	**32 %**
CAD	**57 %**
CCH pregresso	**23 %**
IRC	**25 %**
FA	**19 %**
BPCO	**31 %**
Vasculopatia cerebrale	**15 %**
Aorta a porcellana	**5,8 %**

CASO CLINICO

Uomo di 75 anni, fumatore.

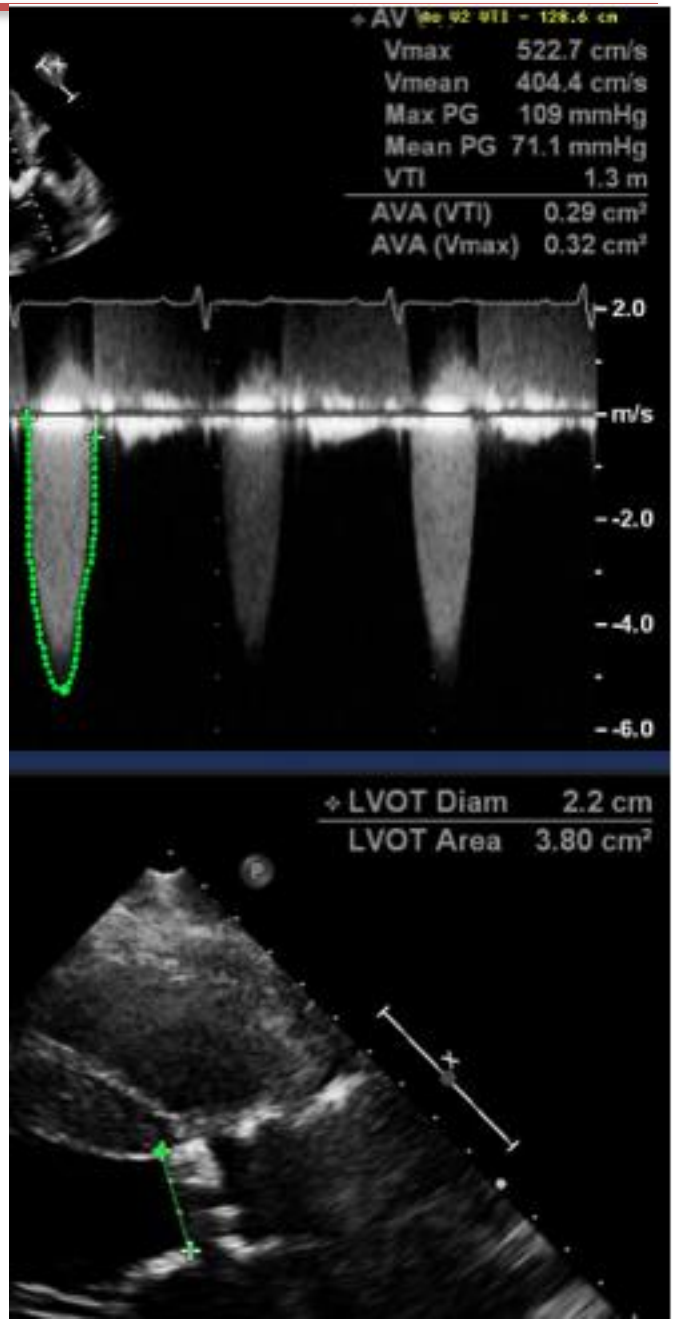
Recente diagnosi di K polmone (infiltrante bronco sx)

Riferisce dispnea progressiva da circa 2 mesi. Alcuni episodi di dispnea parossistica notturna. Non angina. Non sincopi. Alcuni episodi di emottisi di breve durata

All'esame obiettivo: presenza di soffio sistolico 3/6 alla base

Ematochimici nella norma. RX e CT scan (conferma K polmone)

ECOTT: EF 50-55%, AVA 0.3 cm2, gradiente medio: 71 mmHg



IL PAZIENTE DEVE ESSERE SOTTOPOSTO AD INTERVENTO CHIRURGICO DI LOBECTOMIA: Qual è il trattamento indicato prima dell'intervento ?

1. ***INIZIARE TERAPIA DIURETICA e PROCEDERE ALL'INTERVENTO CHIRURGICO***

2. ***INIZIARE TERAPIA CON BETABLOCCANTI e PROCEDRE ALL'INTERVENTO CHIRURGICO***

3. ***INTERVENTO COMBINATO DI SOSTITUZIONE AORTICA E LOBECTOMIA***

4. ***VALVULOPLASTICA AORTICA SEGUITA DA LOBECTOMIA***

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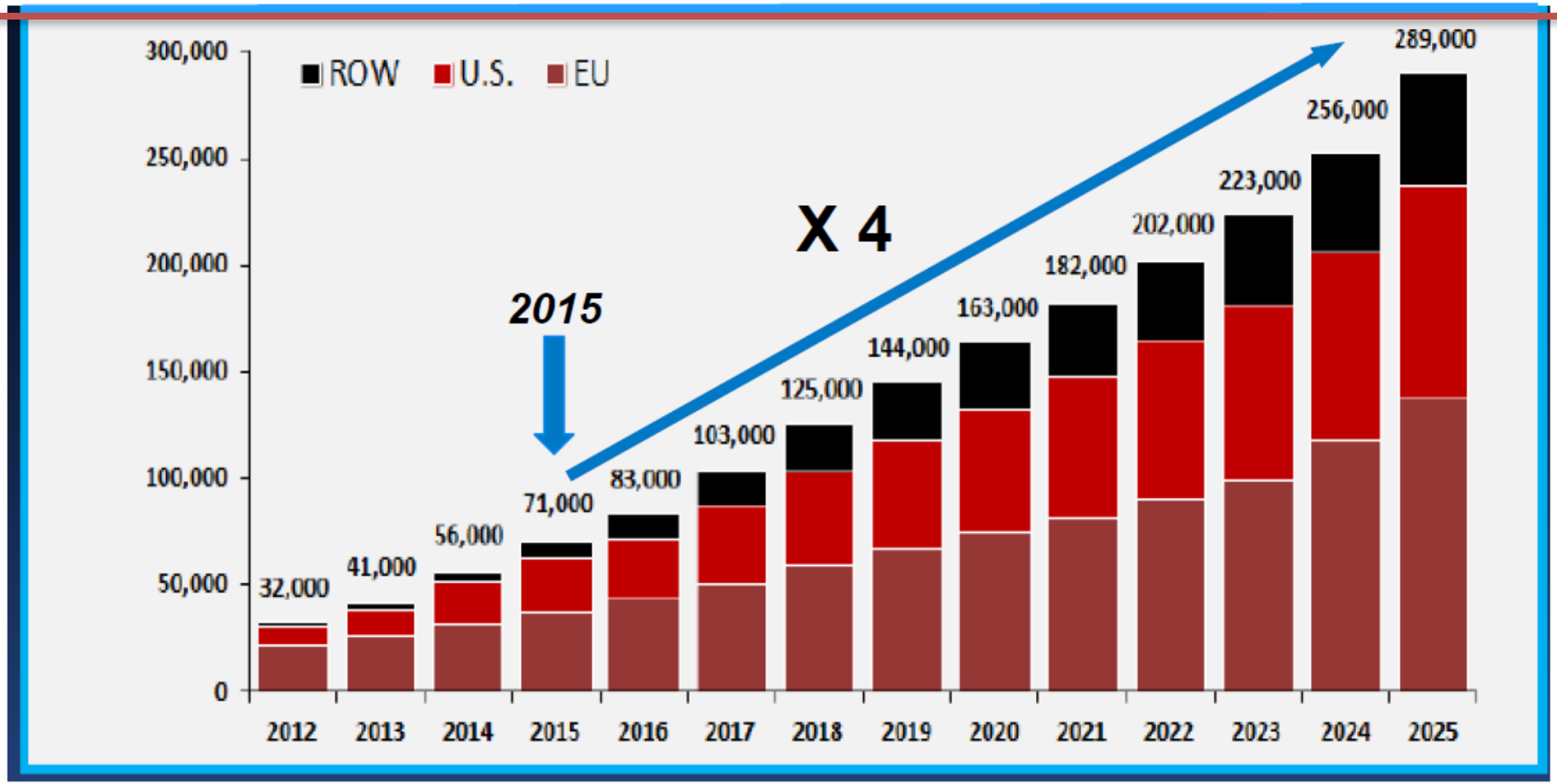
4. ***VALVULOPLASTICA AORTICA SEGUITA DA LOBECTOMIA***

research article

Balloon aortic valvuloplasty (BAV) as a bridge to aortic valve replacement in cancer patients who require urgent non-cardiac surgery

Radiol Oncol 2014; 48(1): 62-66.

SOSTITUZIONE VALVOLARE AOTICA PERCUTANEA TAVI. PREVISIONI DI IMPIANTI



An increase x 4 within the next 10 years

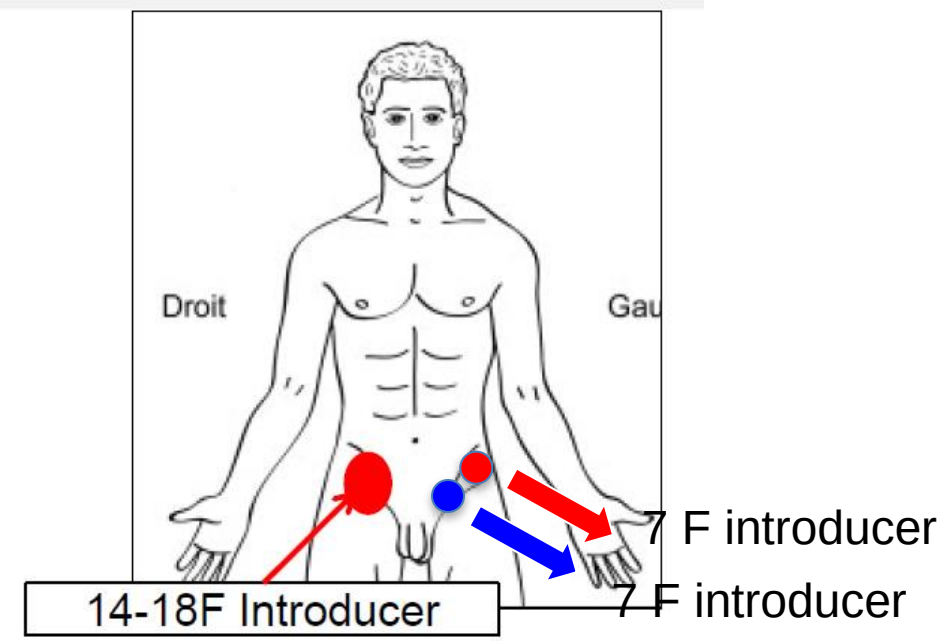
SOSTITUZIONE TRANS CATETERE VALVOLA AORTICA (TAVI): Aspetti tecnici

ACCESSI VASCOLARI:

introduttore arterioso 14-18 F

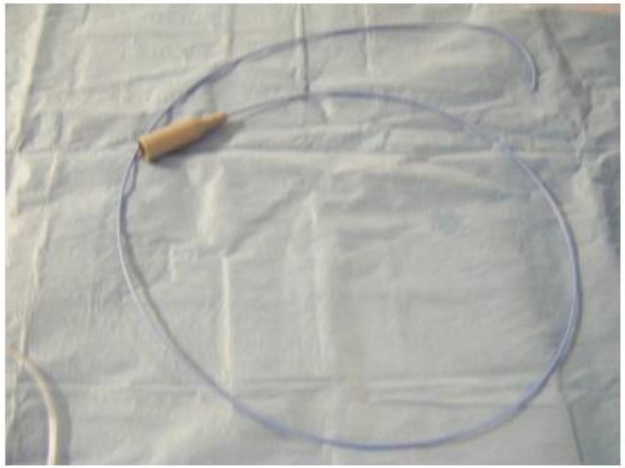
introduttore venoso 7 F

introduttore arterioso 7 f

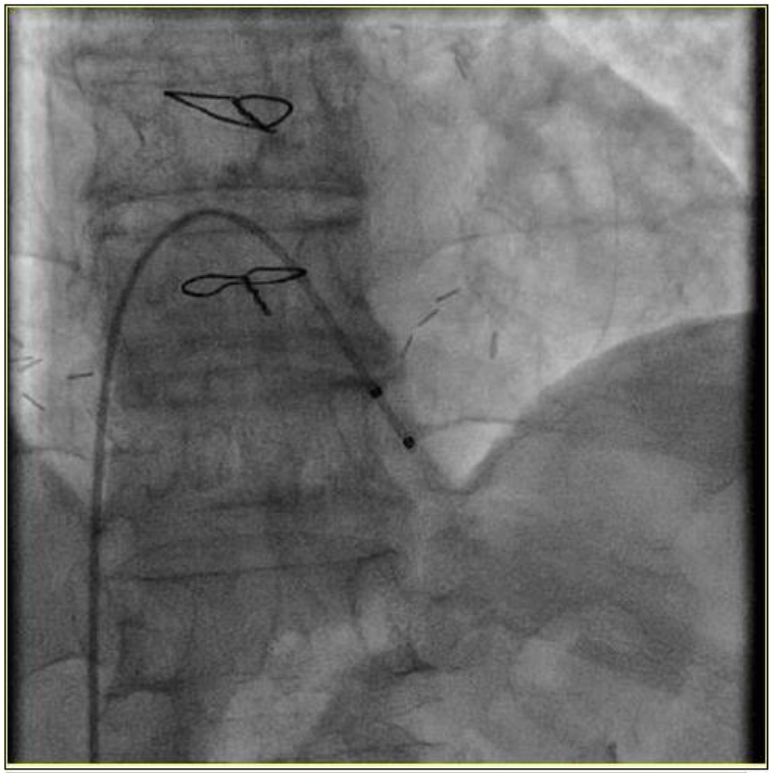


Anestesia locale. Tempo procedura circa 45 min

TAVI: posizionamento PM e test rapid pacing

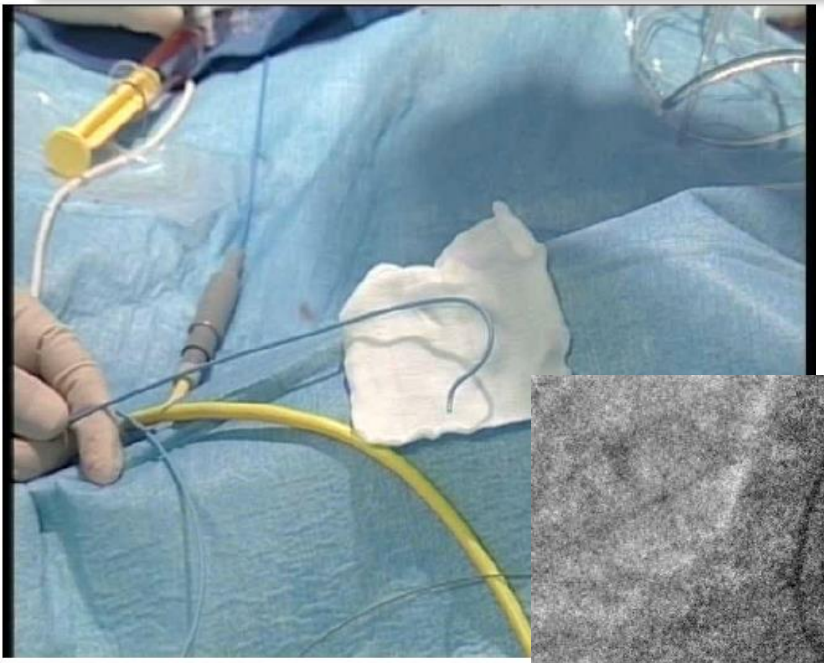


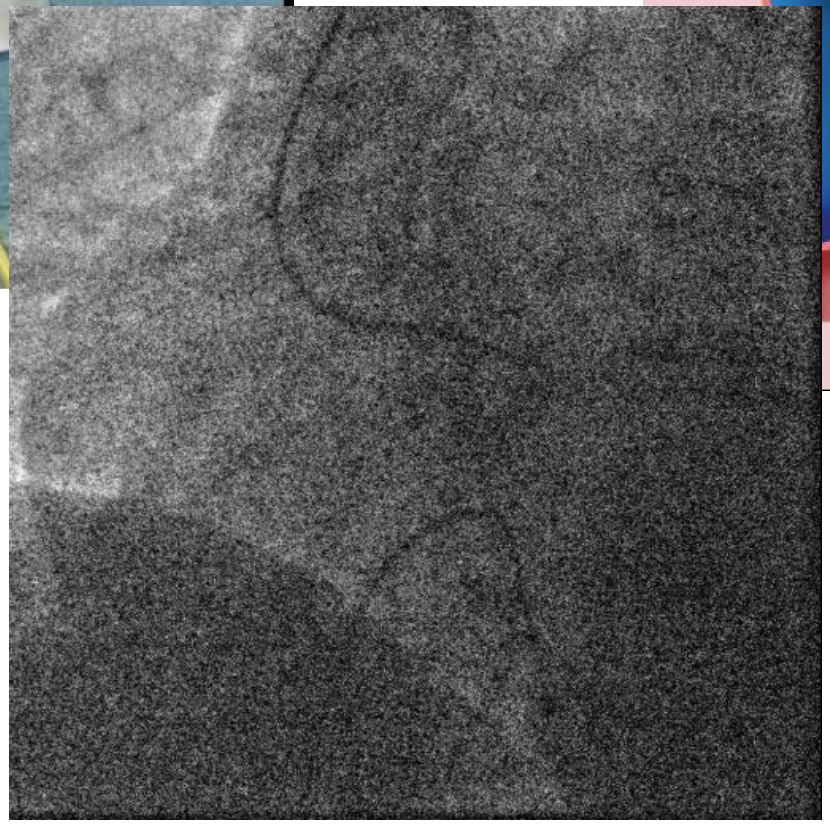
Test of Rapid Ventricular pacing
(180 b/min)

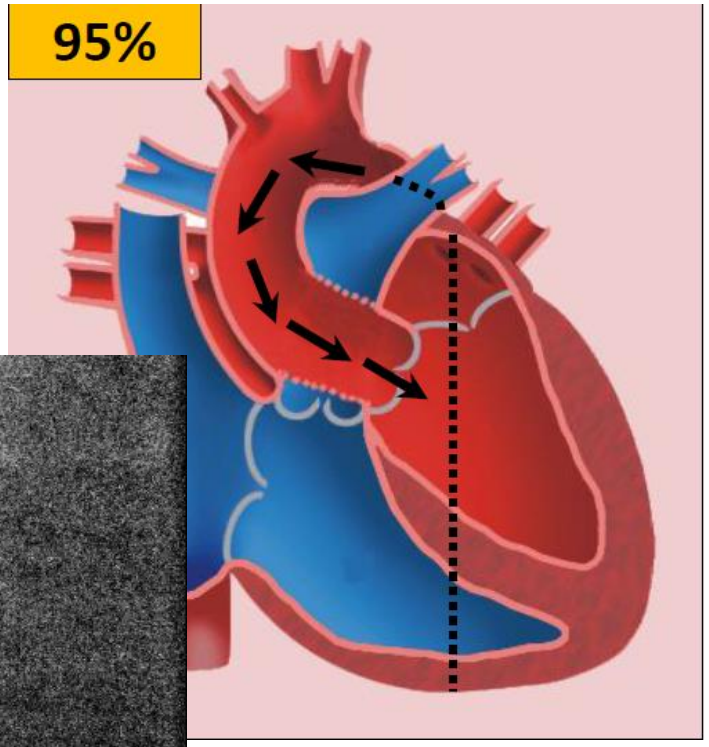


Tip of pacing lead placed at
mid-part of the RV posterior wall

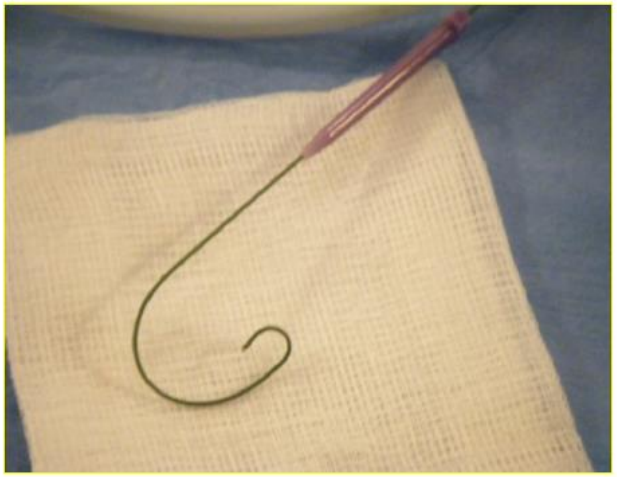
TAVI femorale: Crossing della stenosi aortica

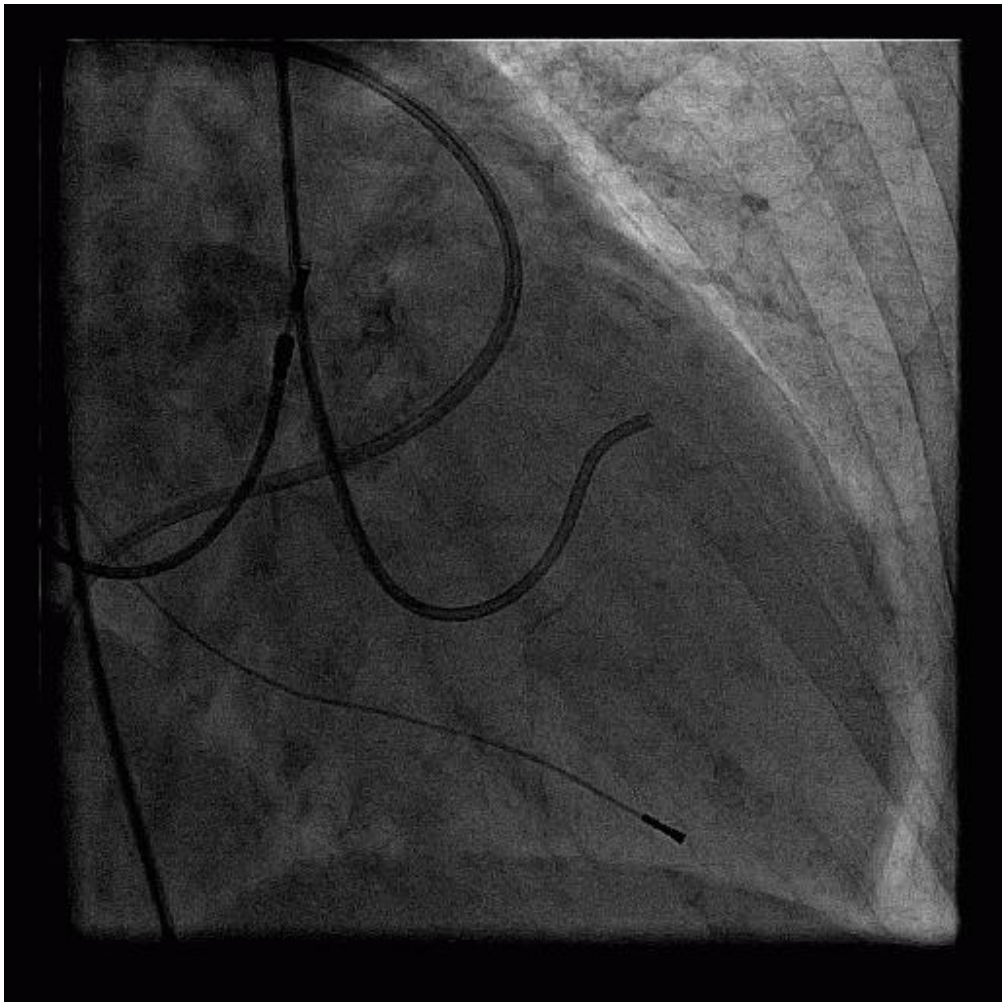




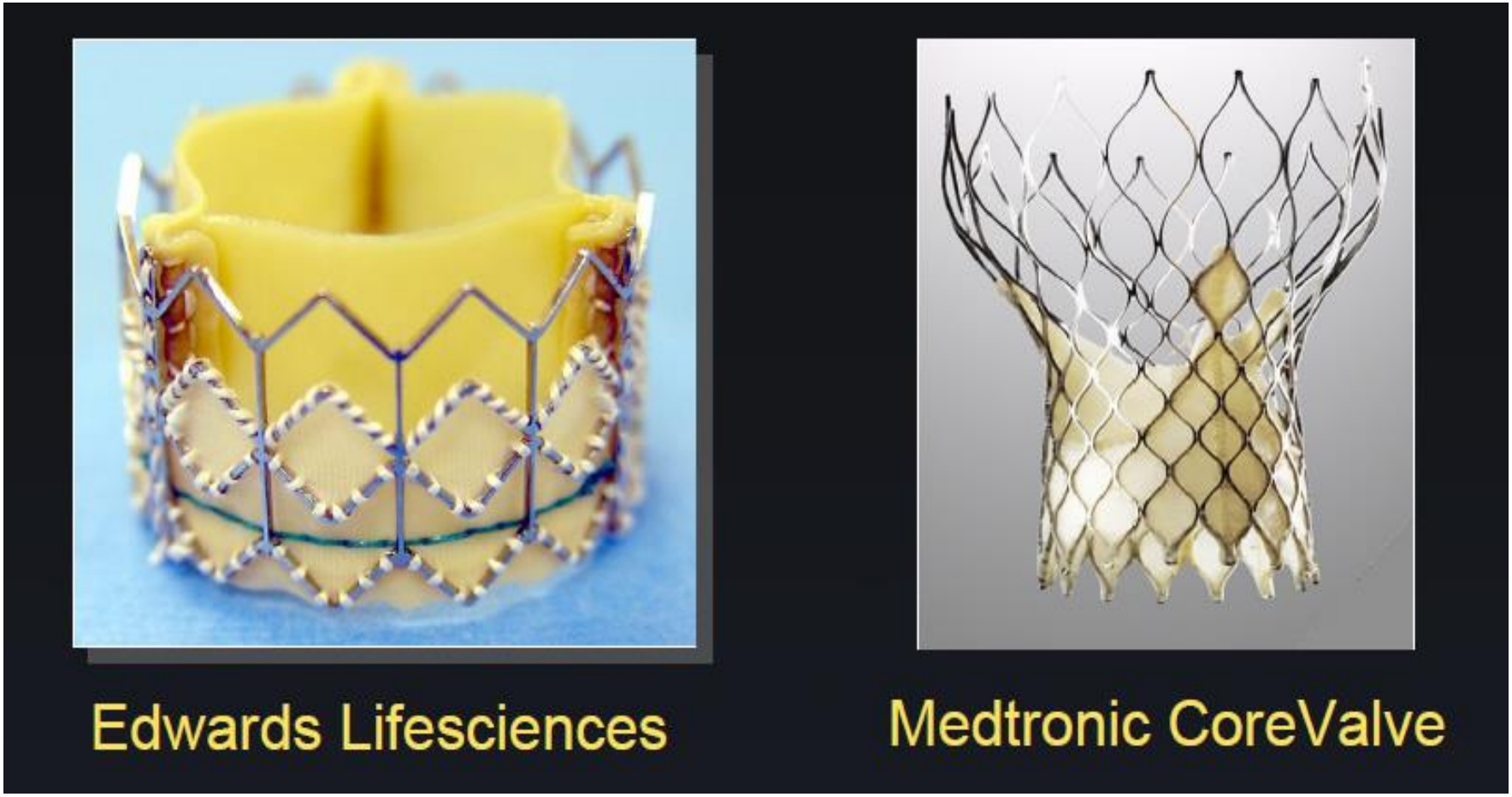


TAVI: Posizionamento della guida ad alto supporto





TAVI:scelta della valvola



TAVI:scelta della valvola

Direct Flow
Direct Flow Medical

Lotus
Boston Scentific

Jena Valve
Jena Valve Technologies

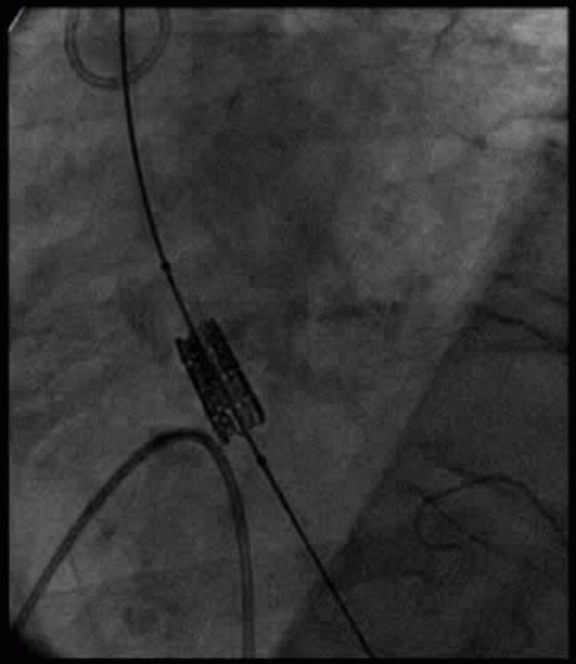
Portico
St. Jude Medical

Acurate
Symetis

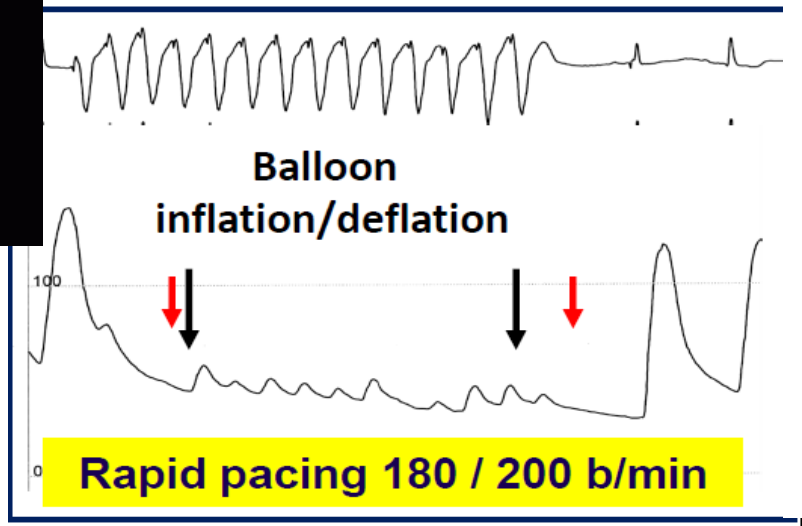
Engager
Medtronic

Centera
Edwards Lifesciences

TAVI: impianto di valvola balloon expandable



PHV delivery under rapid pacing (200 b/min)



TAVI: impianto di valvola auto expandable

INIZIO ESPERIENZA SAN GIOVANNI BOSCO

CERTIFICATE OF ACHIEVEMENT

Presented to

Dr. Giacomo Boccuzzi

in recognition of the successful completion of

Edwards SAPIEN™ THV Training Program

covering the technical and clinical aspects of Transcatheter Heart Valve procedure

CERTIFICATE OF ACHIEVEMENT

Presented to

Dr. Roberto Garbo

in recognition of the successful completion of

Edwards SAPIEN™ THV Training Program

covering the technical and clinical aspects of Transcatheter Heart Valve procedure

[redacted]

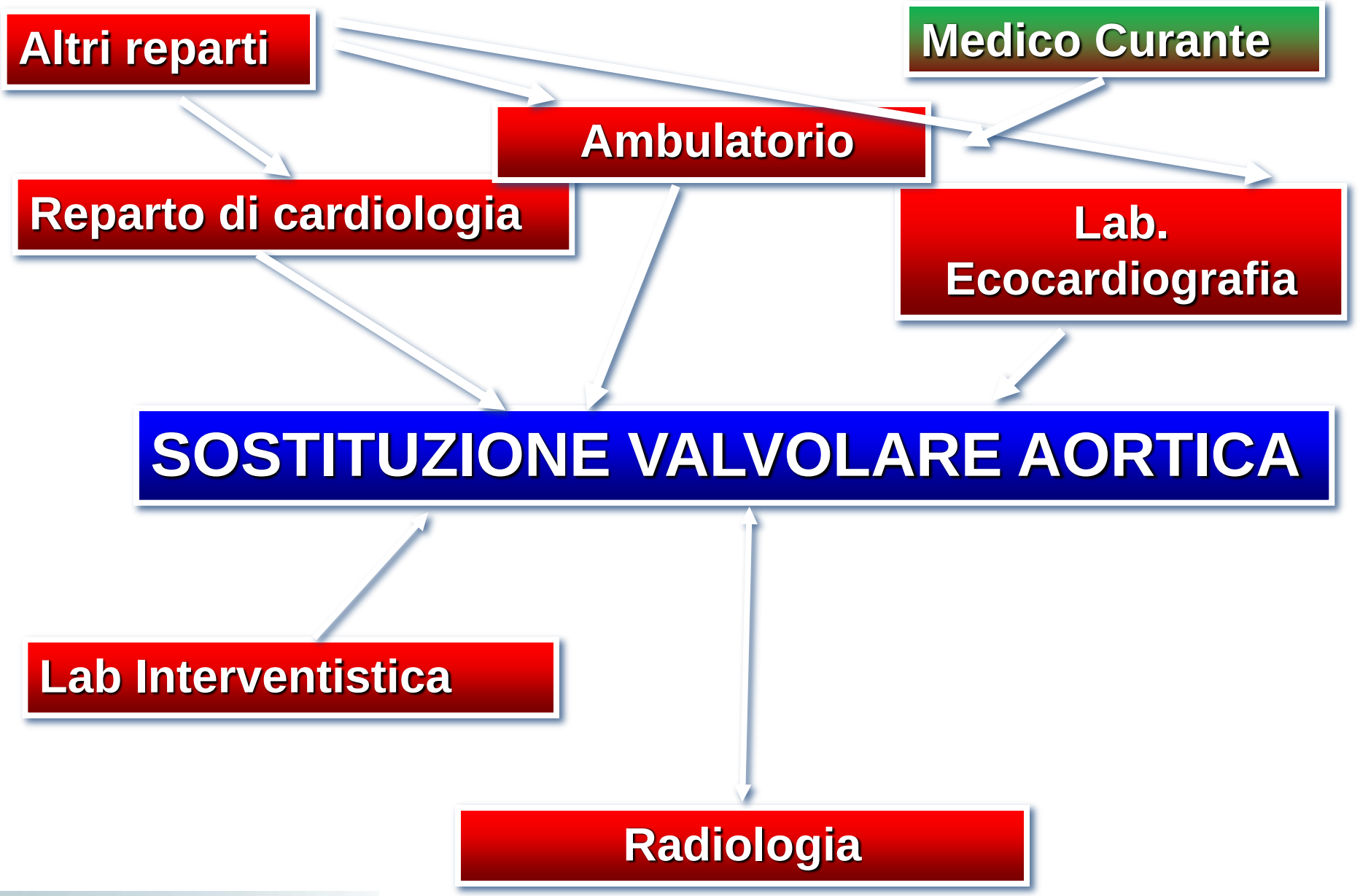
Faculté de Médecine et de Pharmacie, Rouen

on September 8th & September 9th 2009

life is now

Edwards

Nathalie Freysz

Senior Training and Education Manager

'Team Approach' per lo screening dei pazienti