



VI Edizione

**IL PAZIENTE
FRAGILE IN
CARDIOLOGIA**

Sabato
25 Marzo 2023

HOTEL CASCINA FOSSATA
Via Ala di Stura 5 - Torino

evento ECM

Trattamento
percutaneo (TAVI):
Indicazioni e
modalità

DR. FRANCESCO COLOMBO
SC CARDIOLOGIA 2, OSPEDALE SAN GIOVANNI BOSCO

TAVI

=

transcatheter aortic valve
implantation

Case History

57 year-old man

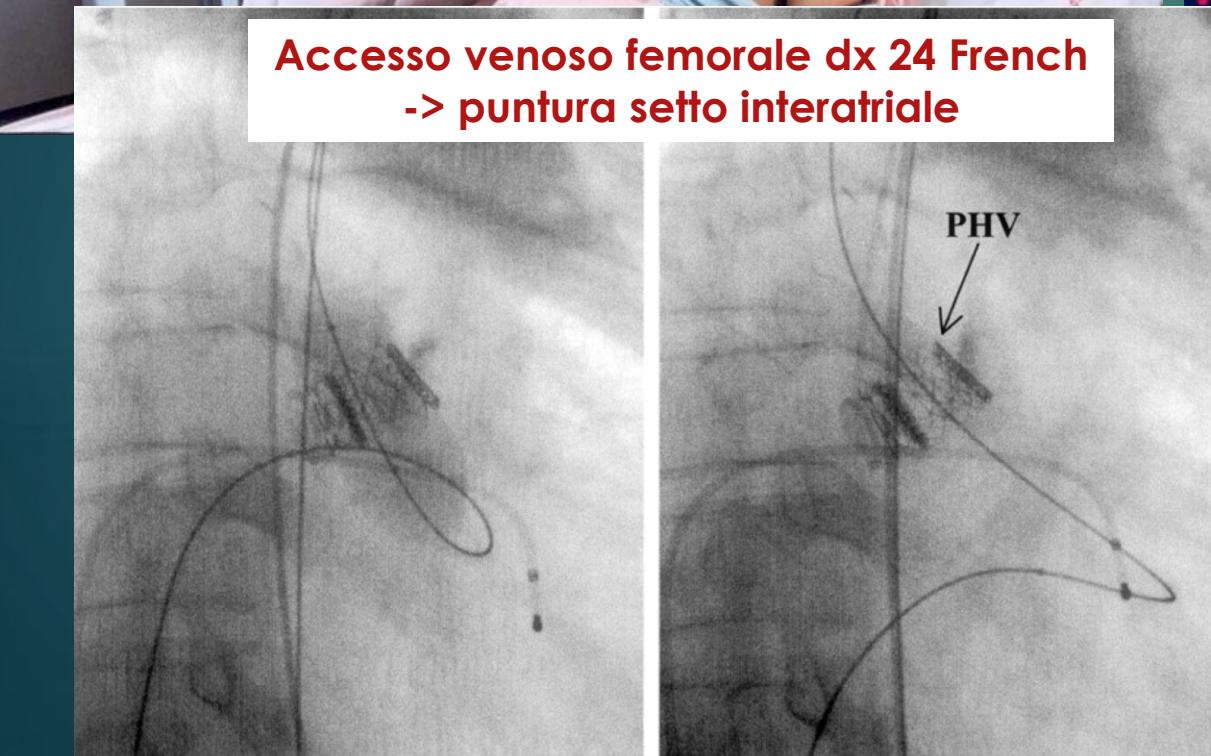
Severe calcific aortic stenosis in cardiogenic shock

LVEF 12%

Valve replacement declined by three surgical teams
due to hemodynamic instability and comorbidities:

- Severe peripheral vascular disease with subacute ischemia of the right leg (occlusion of aorto bifemoral bypass)
- Silicosis and lung cancer (lobectomy in 1999)

Accesso venoso femorale dx 24 French
-> puntura setto interatriale



Sept 1985: F-I-M Balloon Aortic Valvuloplasty

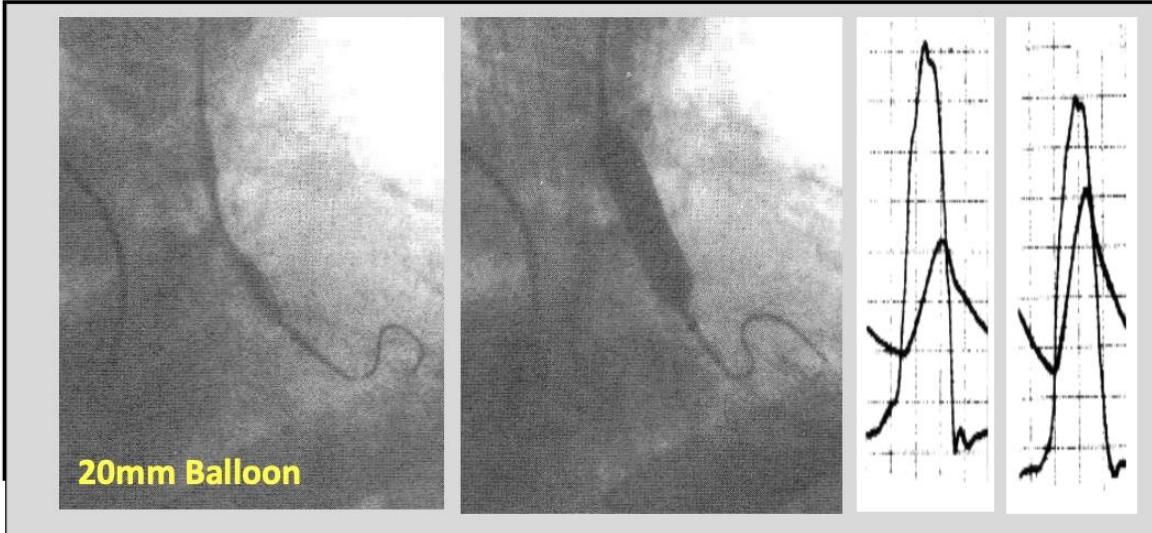


PERCUTANEOUS TRANSLUMINAL
VALVULOPLASTY OF ACQUIRED AORTIC
STENOSIS IN ELDERLY PATIENTS: AN
ALTERNATIVE TO VALVE REPLACEMENT?

A. Cribier et al,

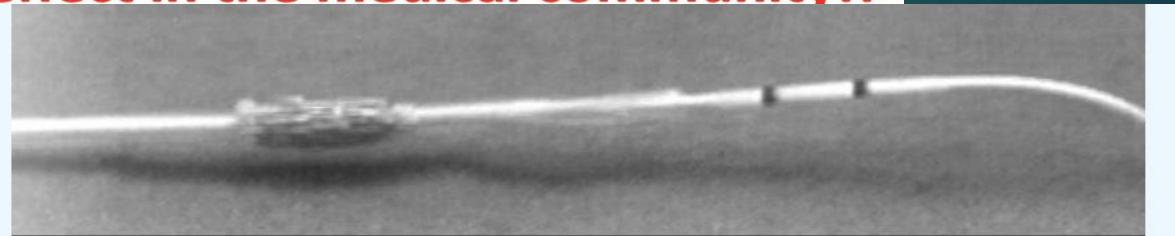
THE LANCET, JANUARY 11, 1986

"Resolving the issue of restenosis became a obsession for me"



- Two years without symptom !
- Return to normal life

A bomb effect in the medical community!!



Rouen, 1994: Hand-made Model of THV
Crimped Ø 8mm

1. MAJ 1989



0 1 2 3 4 5 6 7 8

1. MAJ 1989

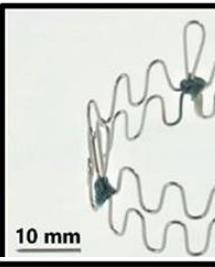
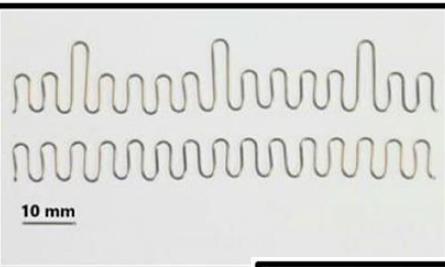
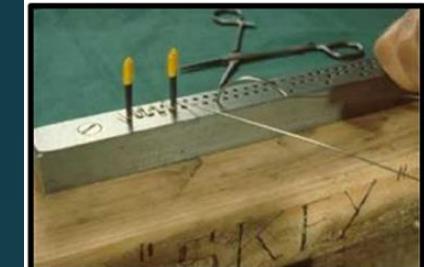


0 1 2 3 4 5 6 7 8

1. MAJ 1989



0 1 2 3 4 5 6 7 8



JACC
Journal of the American College of Cardiology

Simon Dack, MD, Editor-in-Chief
655 Avenue of the Americas, New York, NY 10010 (212) 633-3930 Telecopier 212 633-3913



July 26, 1990

FEB 06 1991 REC 14152 (14152)

TEL 1C1615-540931

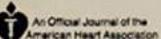
E341 F02

Circulation

University of California San Diego School of Medicine and UCSD Medical Center

Editorial Office
2225 Avenue de la Playa
Suite 202
La Jolla, CA 92037
(619)454-9734
(619)454-0931

February 5, 1991



An Official Journal of the

American Heart Association

Editor-in-Chief

John Ross, Jr.

Associate Editors

Kenneth R. Chien

James W. Covell

Michael H. Criqui

Robert L. Engler

Gregory K. Friedman

Pascal Nicod

David J. Sahn

Managing Editor

Kevin Brennan

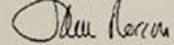
Henning Rud Andersen, M.D.
Department of Cardiology
Skejby University Hospital
Bredstrandsgade
DK - 8200 Aarhus N

RE: CR901049, "Implantation of Artificial Heart Valves"

Dear Dr. Andersen:

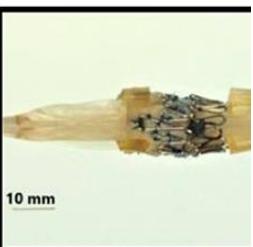
Your revised manuscript has been reviewed by the original reviewers and by an additional referee. While it has been improved, I'm afraid that the consensus of the editors and the referees is that its priority remains too low for publication in Circulation. Comments are enclosed for your information, which we hope will be useful in preparing for resubmission elsewhere.

A number of considerations in addition to the referees' comments were taken into account by the editors in reaching this decision. Because of the large number of manuscripts submitted to Circulation, some worthwhile papers cannot be published. Thank you for submitting your manuscript to the journal, and I hope you will consider submitting other manuscripts to us again in the future.

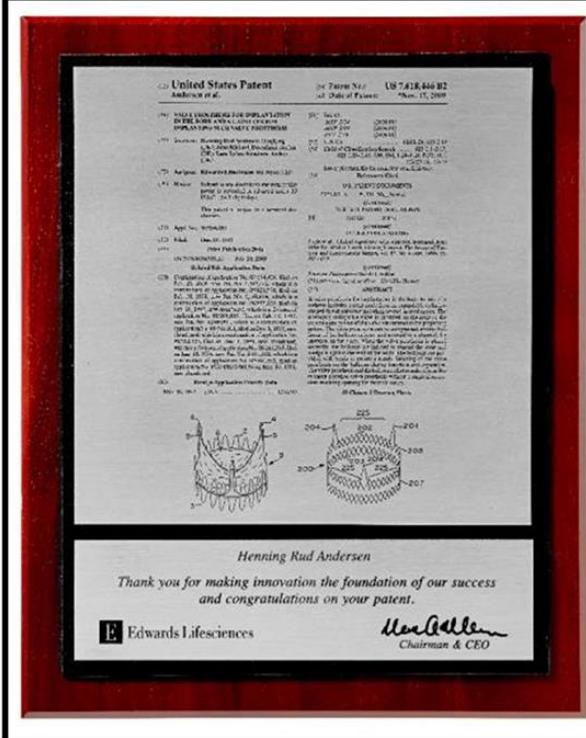
Sincerely yours,


John Ross, Jr., M.D.
Editor

JR/J
Enclosure



10 mm

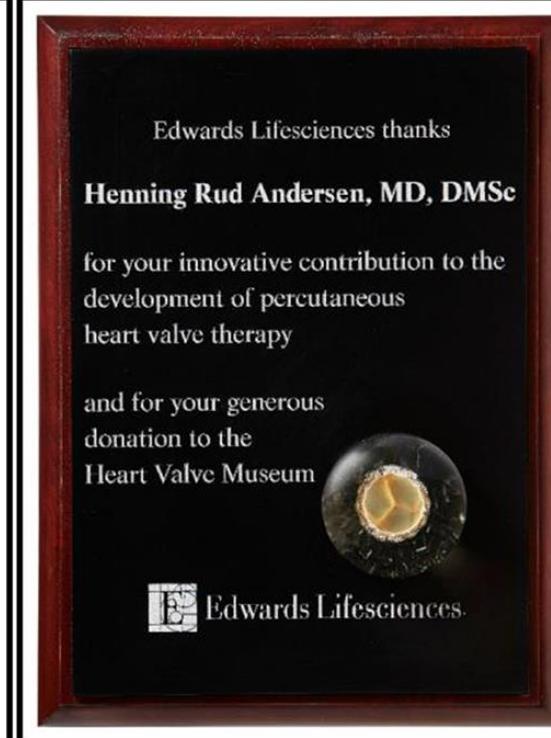


Henning Rud Andersen

Thank you for making innovation the foundation of our success
and congratulations on your patent.

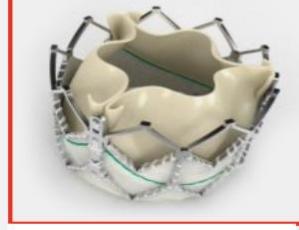
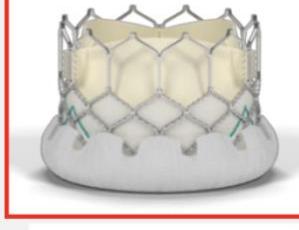
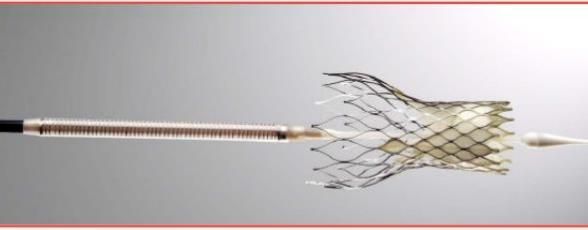
Edwards Lifesciences

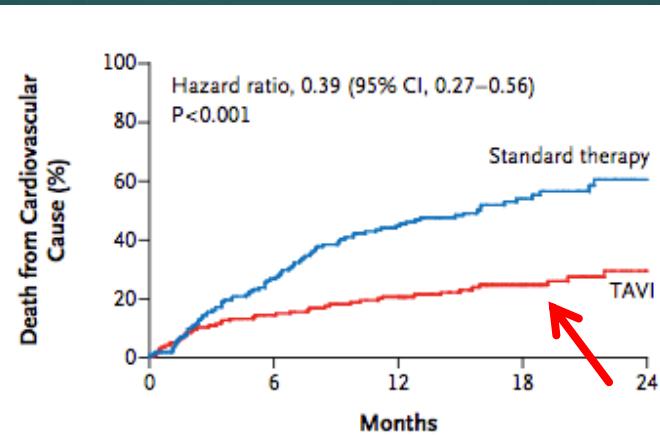
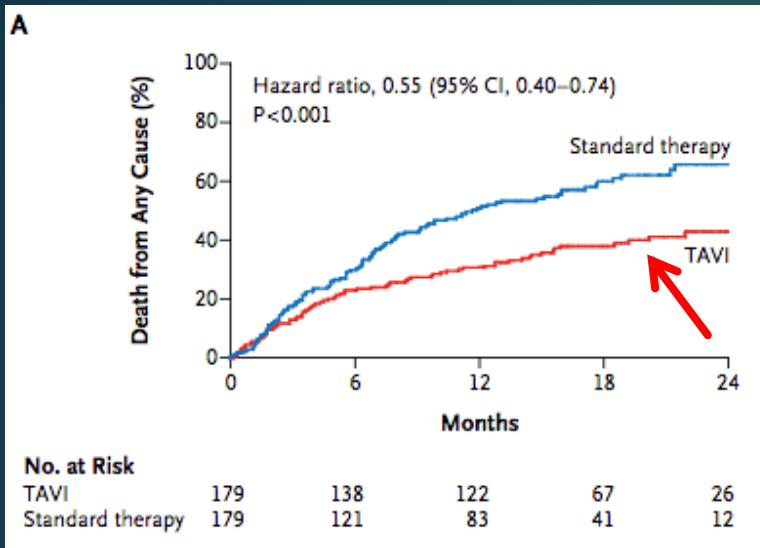

Steve Gallo
Chairman & CEO



Henning Rud Andersen. Front Cardiovasc Med 2021 Sep 29;8:7221693.

Evoluzione dei materiali

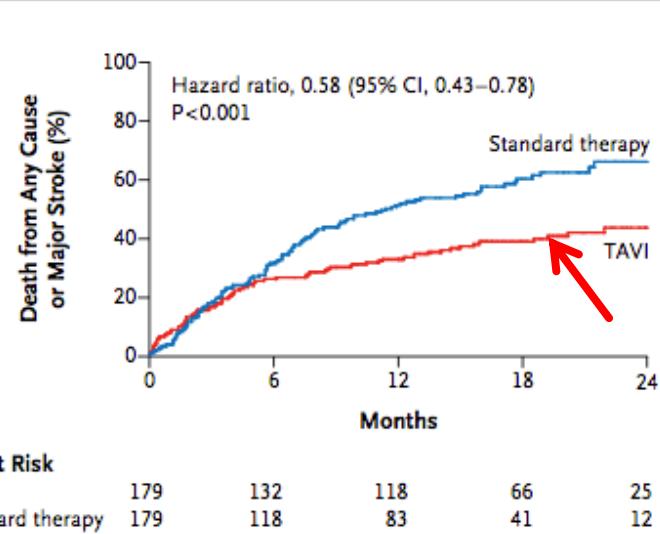
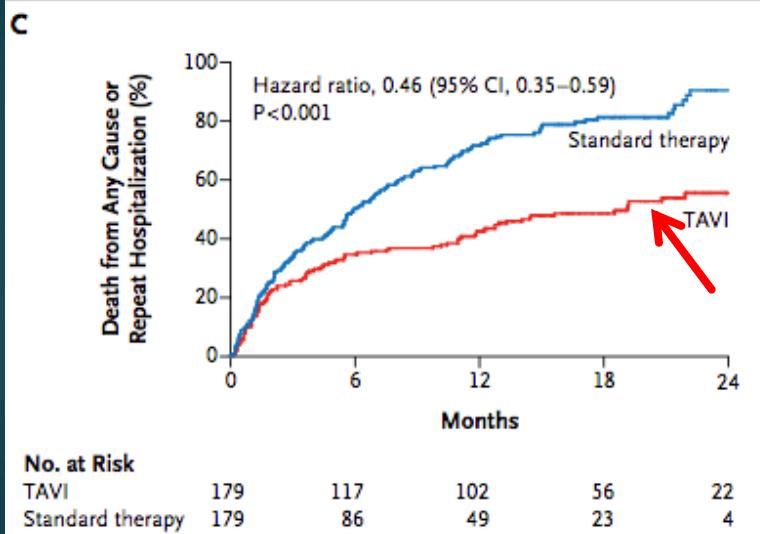
	2005 Edwards SAPIEN	2009 SAPIEN XT	2012 SAPIEN 3
Edwards			
Sheath size	24F	18-20F	14-16F
Valve sizes	23, 26mm	23, 26, 29mm	20, 23, 26, 29mm
CoreValve	2006		2012 Evolut R 
Sheath size	21F → 18F		14F
Valve sizes	26, 29mm		23, 26, 29, 31mm



The NEW ENGLAND JOURNAL of MEDICINE

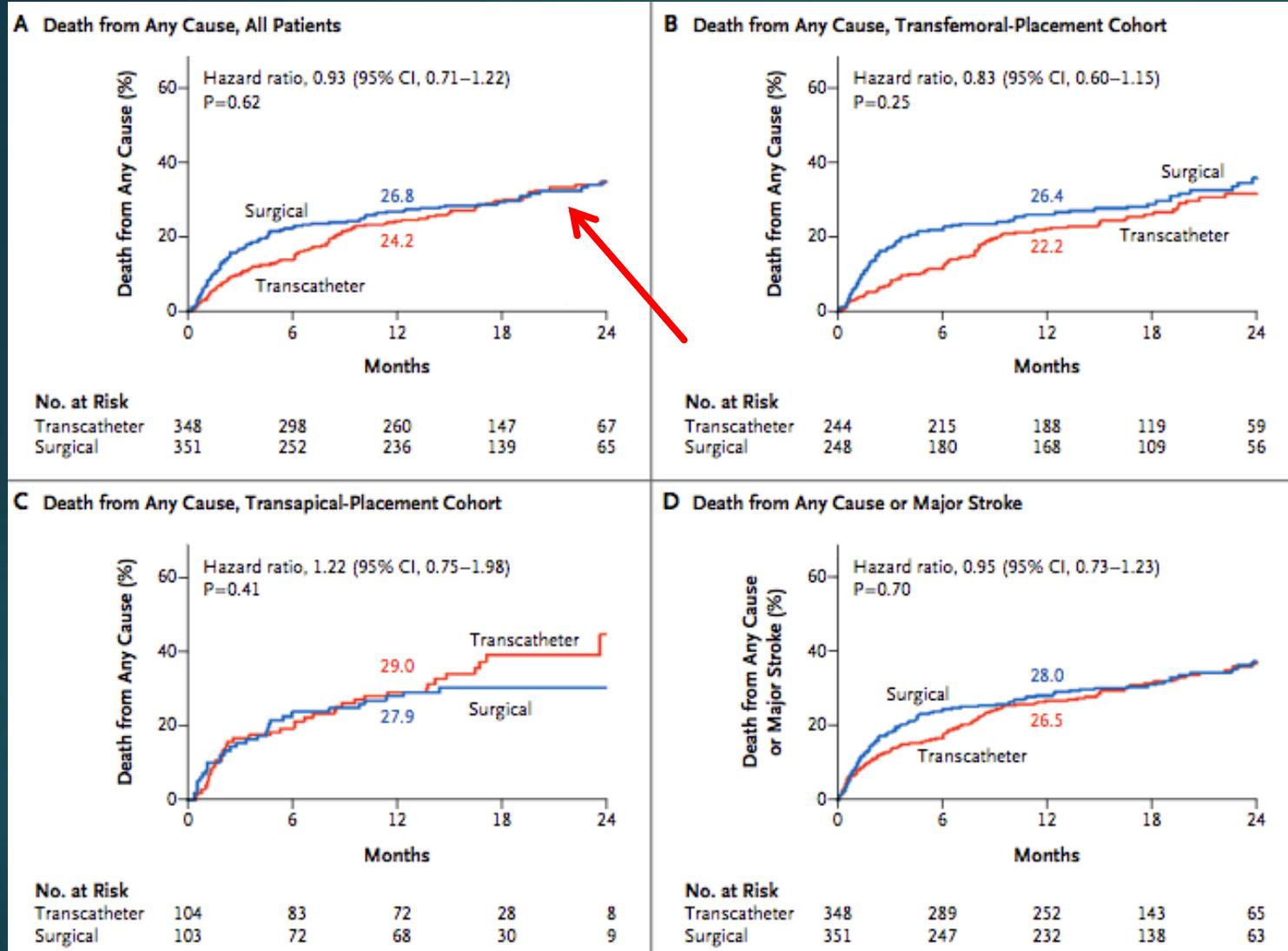
ESTABLISHED IN 1812 OCTOBER 21, 2010 VOL. 363 NO. 17

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



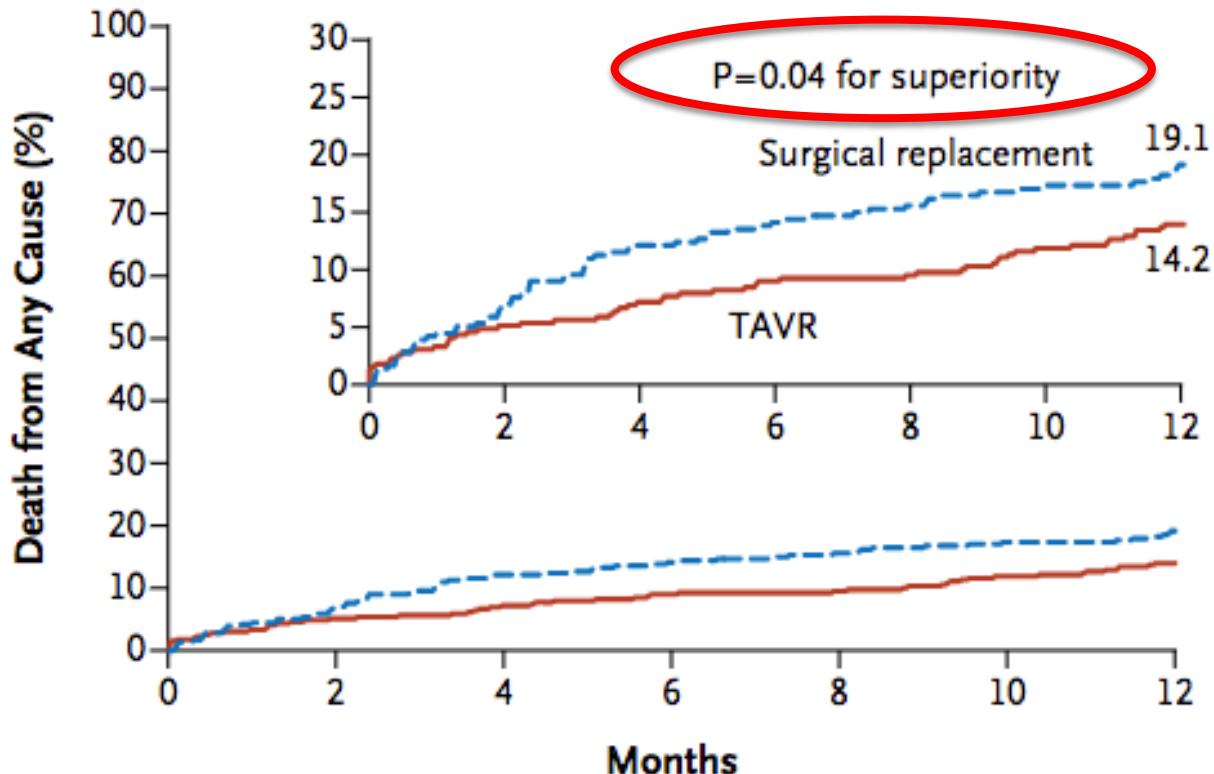
PARTNER Trial Coorte B

TAVI superiore nei pazienti che non possono andare incontro a chirurgia



PARTNER Trial Coorte A

TAVI non inferiore nei pazienti ad alto rischio chirurgico



No. at Risk

	0	3	6	9	12
TAVR	390	377	353	329	
Surgical replacement	357	341	297	274	

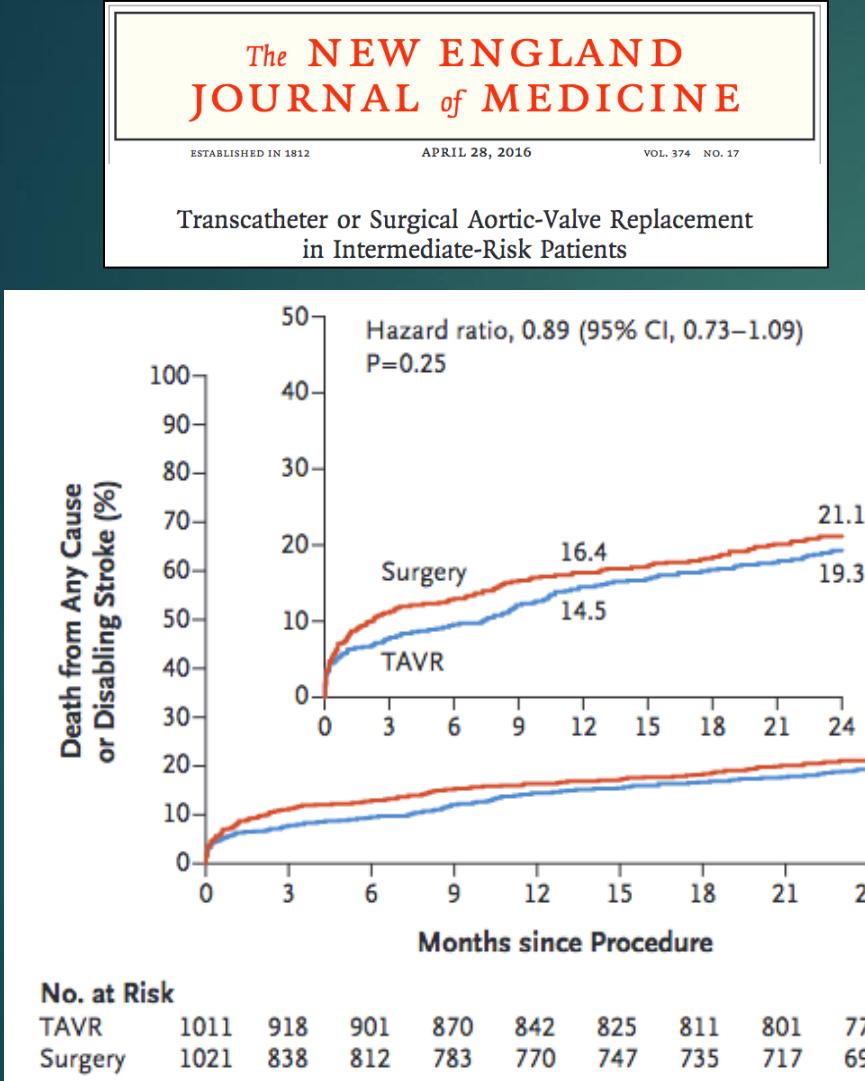
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis

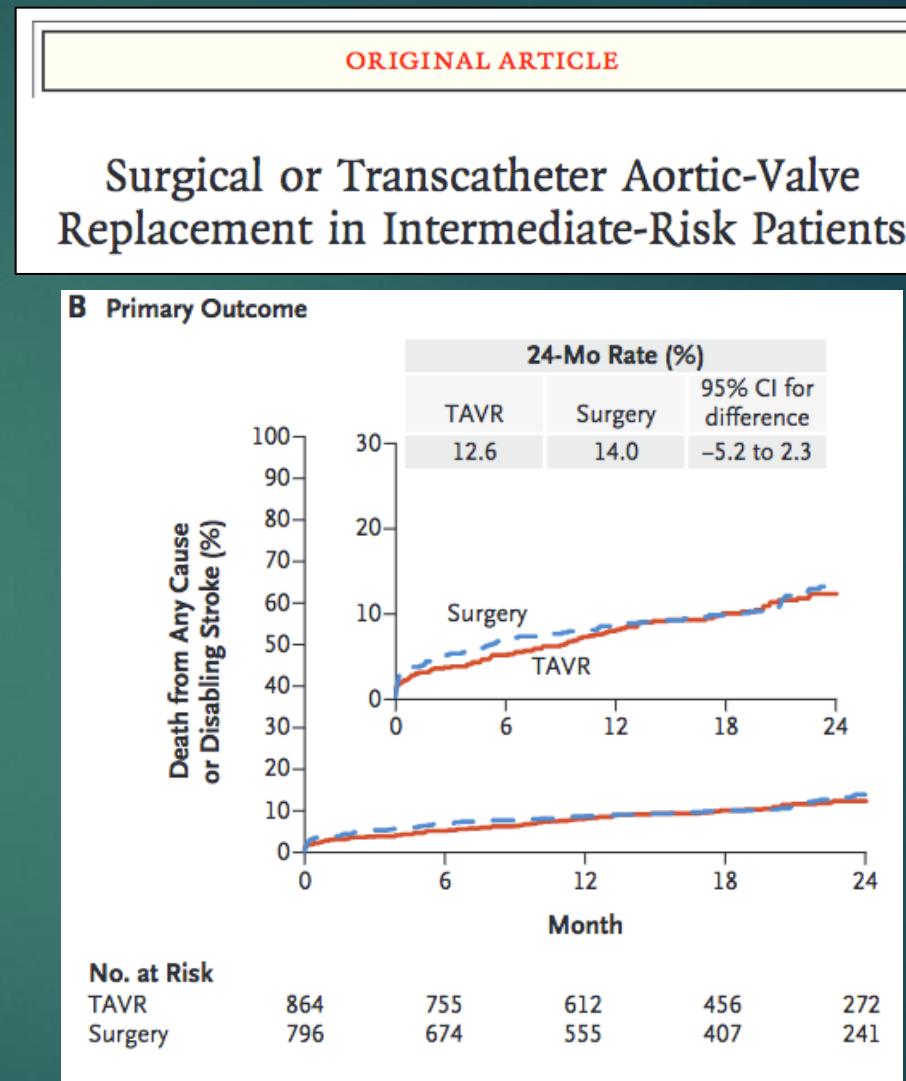
TAVI superiore nei pazienti ad elevato rischio chirurgico

PARTNER 2A



Leon MB et al. NEJM 2016; 374:1609-1620.

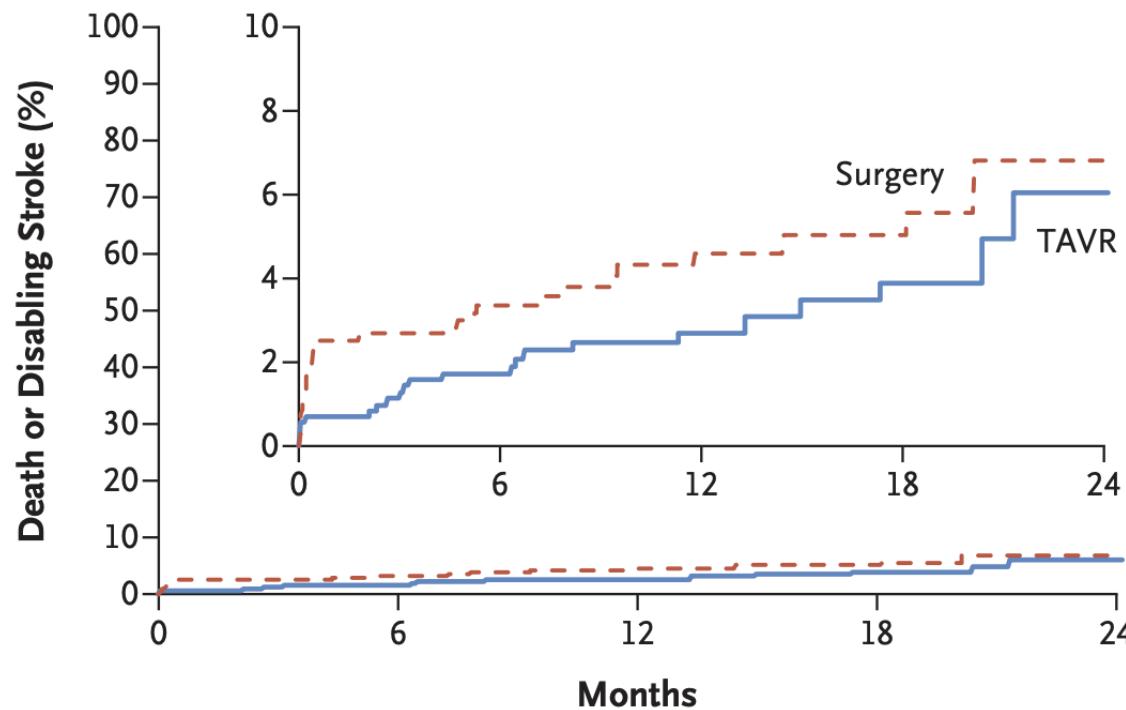
SURTAVI Trial



Reardon MJ et al. NEJM 2017; 376:1321-31.

TAVI non inferiore nei pazienti a rischio chirurgico INTERMEDIO

B Incidence of Primary End Point



The NEW ENGLAND JOURNAL of MEDICINE

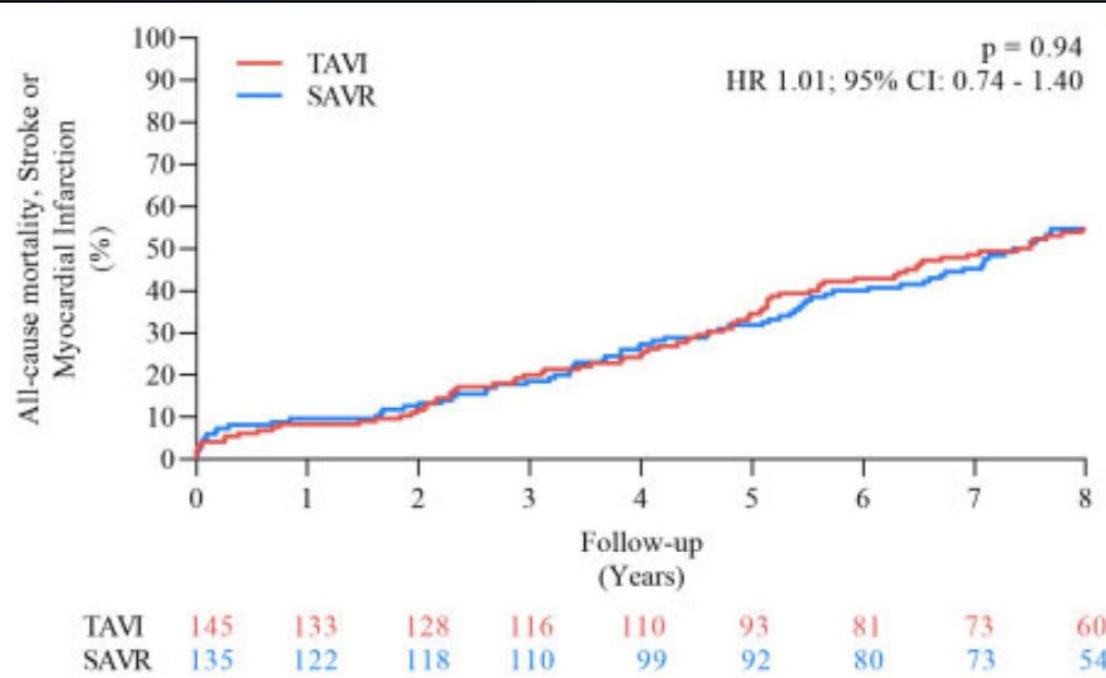
ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with
a Self-Expanding Valve in Low-Risk Patients

Evolut Low Risk Trial

STS mortality <3% (media 2%), età media 74 anni

TAVI non inferiore nei pazienti a rischio chirurgico BASSO



ESC

European Society
of Cardiology

European Heart Journal (2021) 42, 2912–2919
doi:10.1093/eurheartj/ehab375

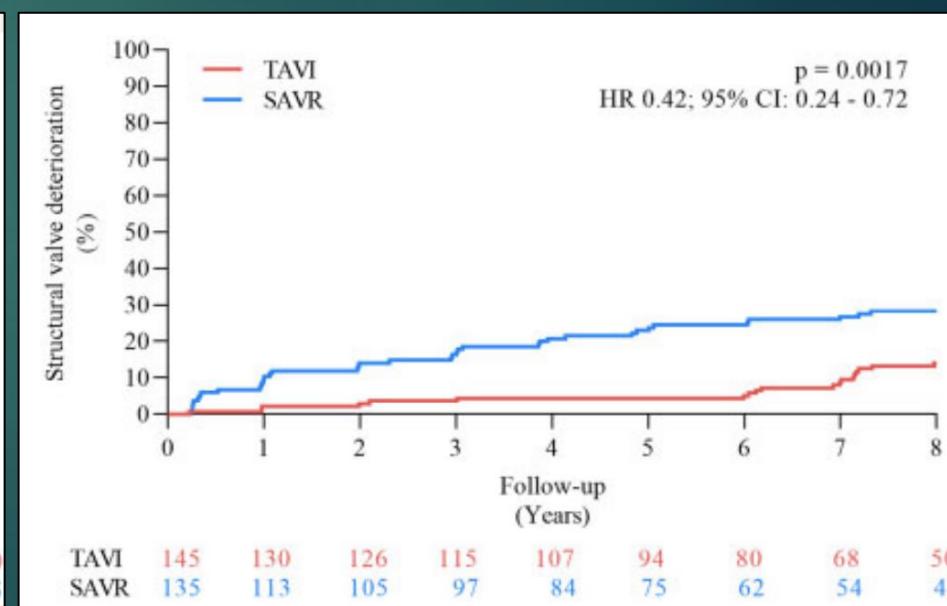
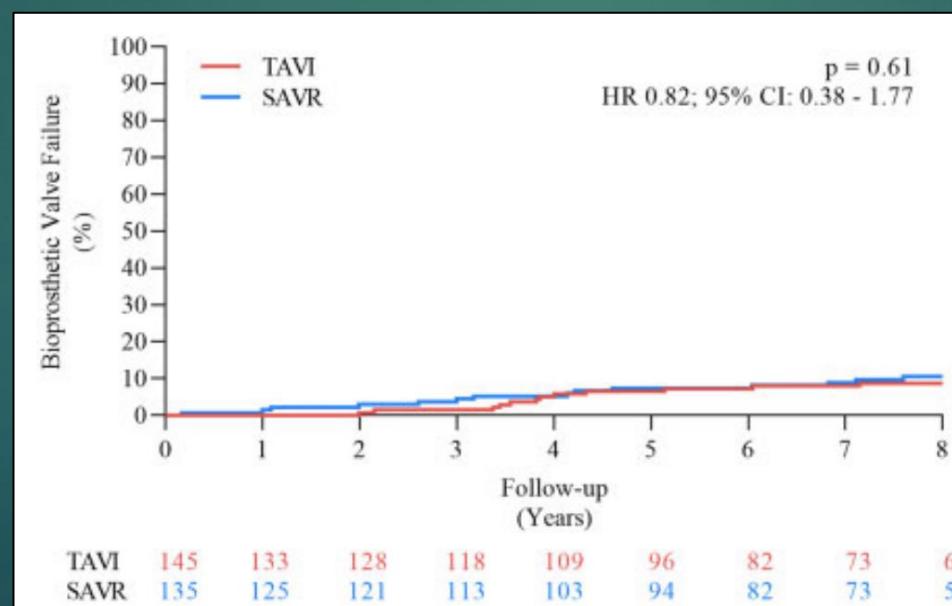
CLINICAL RESEARCH

Valvular heart disease

Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement

NOTION Trial 8 years

STS ca. 3%
età media 79 anni

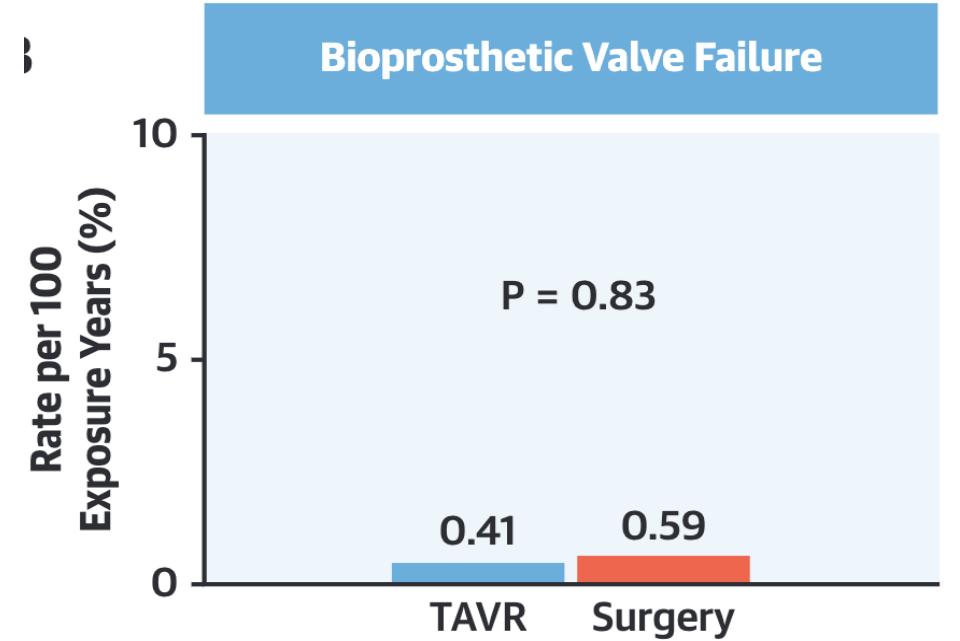
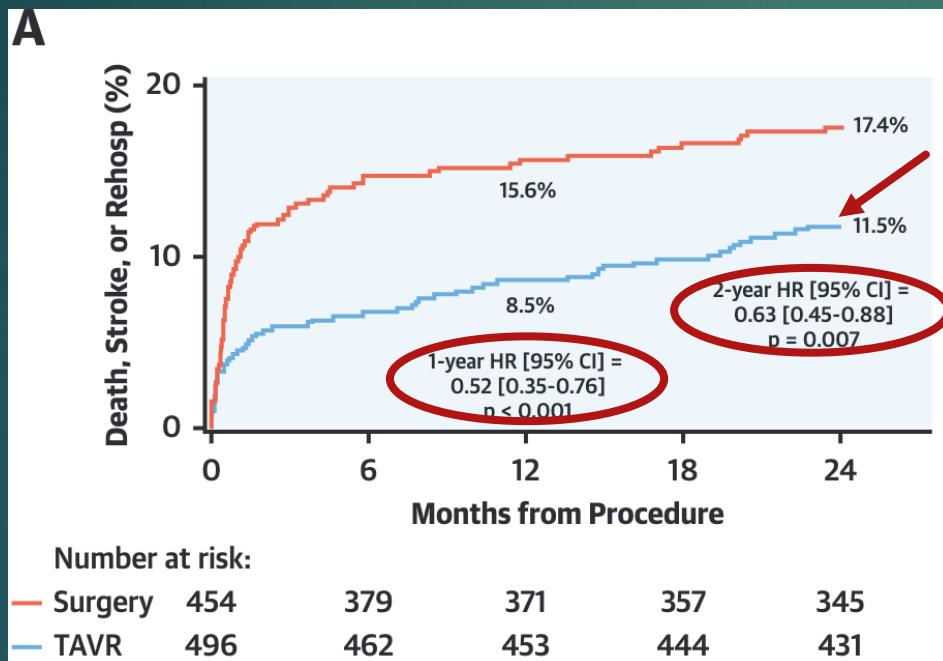


Outcomes 2 Years After Transcatheter Aortic Valve Replacement in Patients at Low Surgical Risk



PARTNER 3

STS mortality <4% (media 1.9%), età media 73 anni



TAVI superiore nei pazienti a rischio chirurgico BASSO

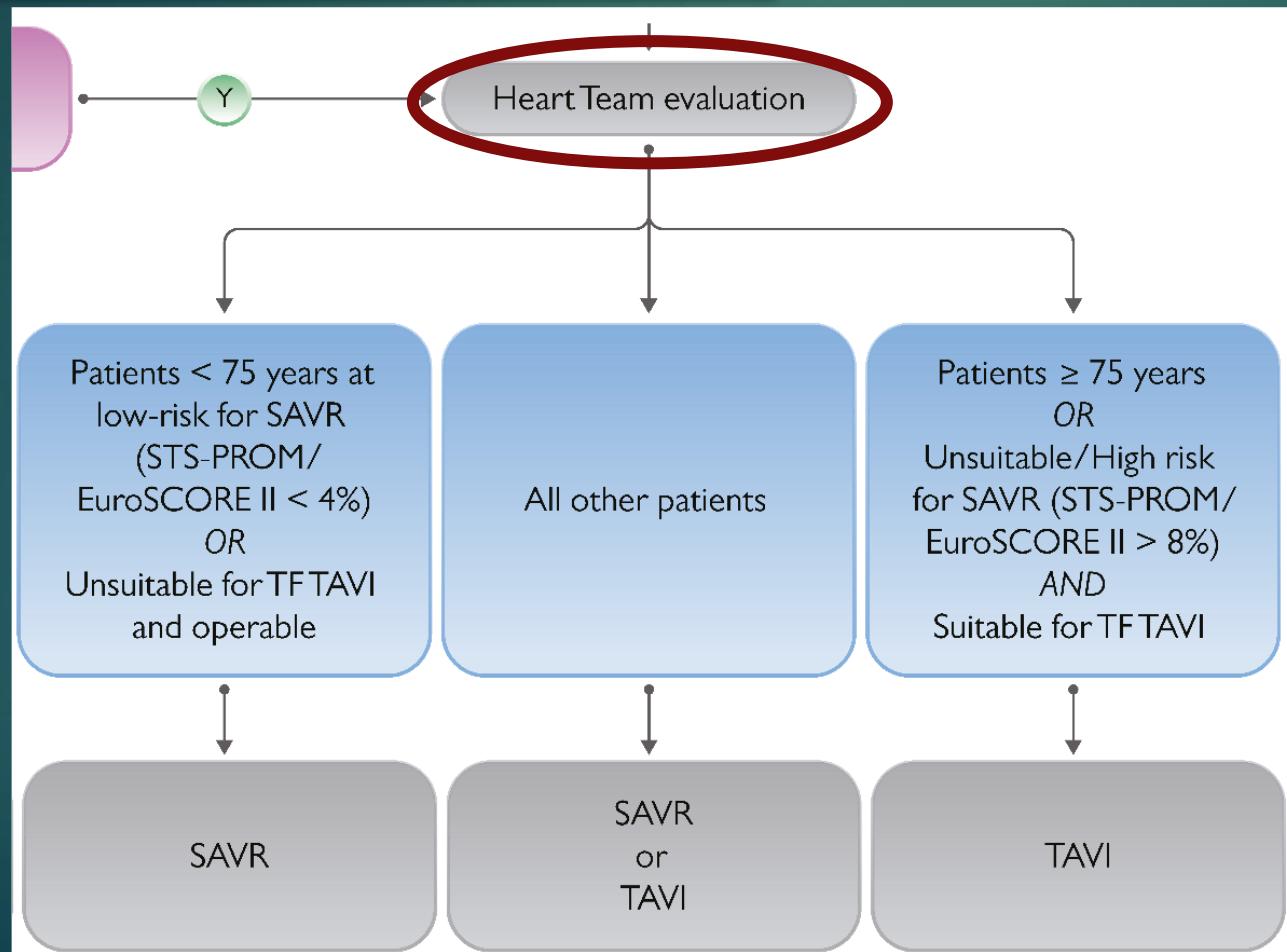
2021 ESC/EACTS Guidelines for the management of valvular heart disease

Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

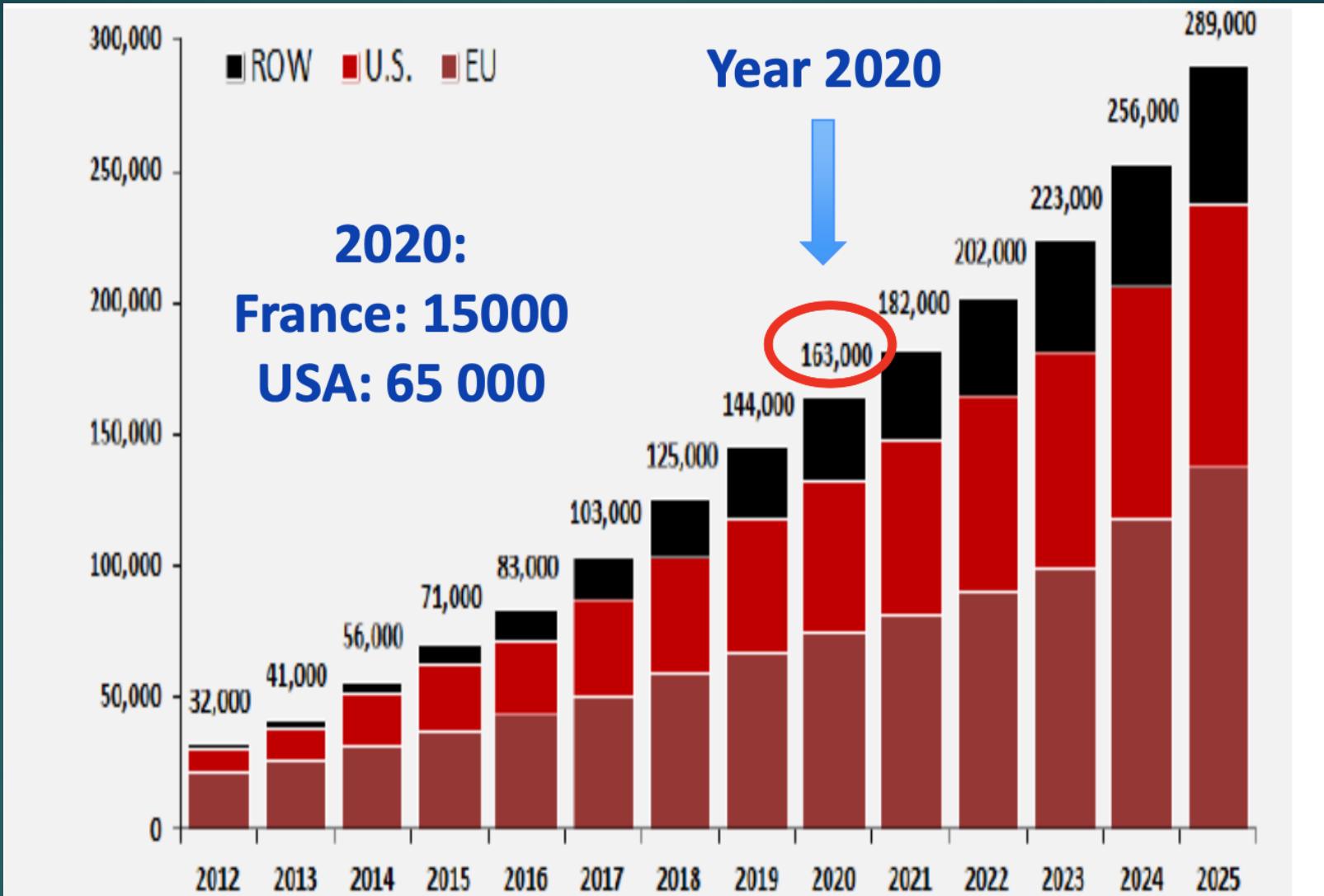
Recommendations	Class	Level
Intervention is recommended in <u>symptomatic patients</u> with severe, high-gradient aortic stenosis [mean gradient ≥ 40 mmHg, peak velocity ≥ 4.0 m/s, and valve area ≤ 1.0 cm 2 (or ≤ 0.6 cm 2 /m 2)].	I	B
Intervention is recommended in symptomatic patients with severe low-flow (SVI ≤ 35 mL/m 2), low-gradient (<40 mmHg) aortic stenosis with reduced ejection fraction ($<50\%$), and evidence of flow (contractile) reserve.	I	B
SAVR is recommended in younger patients who are low risk for surgery (<75 years and STS-PROM/EuroSCORE II $<4\%$), or in patients who are operable and unsuitable for transfemoral TAVI.	I	B
TAVI is recommended in older patients (≥ 75 years), or in those who are high risk (STS-PROM/EuroSCORE II $>8\%$) or unsuitable for surgery.	I	A
SAVR is recommended in patients with severe aortic stenosis undergoing CABG or surgical intervention on the ascending aorta or another valve.	I	C

2021 ESC/EACTS Guidelines for the management of valvular heart disease

Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

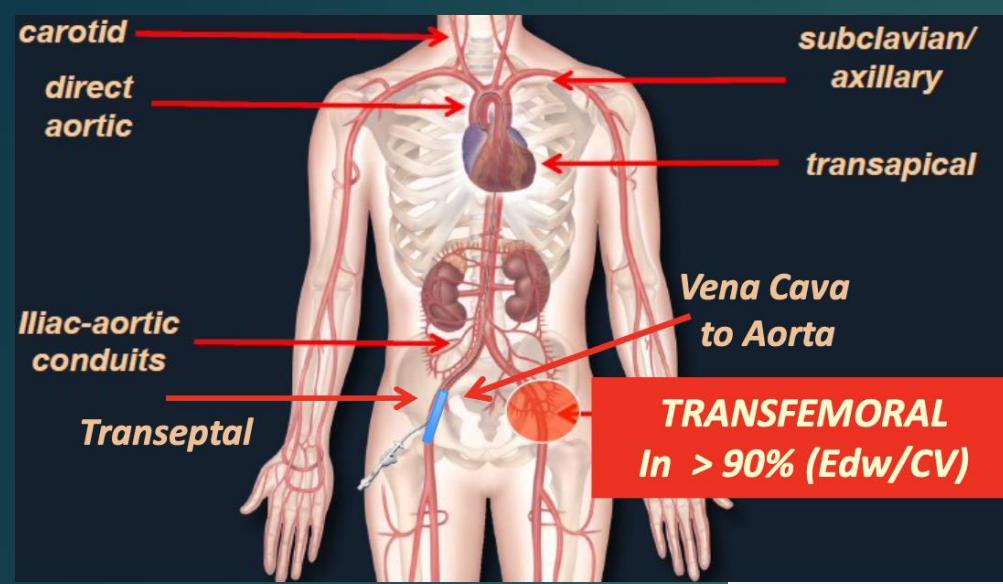


	Favours TAVI	Favours SAVR
Clinical characteristics		
Lower surgical risk	-	+
Higher surgical risk	+	-
Younger age ^a	-	+
Older age ^a	+	-
Previous cardiac surgery (particularly intact coronary artery bypass grafts at risk of injury during repeat sternotomy)	+	-
Severe frailty ^b	+	-
Active or suspected endocarditis	-	+
Anatomical and procedural factors		
TAVI feasible via transfemoral approach	+	-
Transfemoral access challenging or impossible and SAVR feasible	-	+
Transfemoral access challenging or impossible and SAVR inadvisable	+ ^c	-
Sequelae of chest radiation	+	-
Porcelain aorta	+	-
High likelihood of severe patient–prosthesis mismatch (AVA <0.65 cm ² /m ² BSA)	+	-
Severe chest deformation or scoliosis	+	-
Aortic annular dimensions unsuitable for available TAVI devices	-	+
Bicuspid aortic valve	-	+
Valve morphology unfavourable for TAVI (e.g. high risk of coronary obstruction due to low coronary ostia or heavy leaflet/LVOT calcification)	-	+
Thrombus in aorta or LV	-	+
Concomitant cardiac conditions requiring intervention		
Significant multi-vessel CAD requiring surgical revascularization ^d	-	+
Severe primary mitral valve disease	-	+
Severe tricuspid valve disease	-	+
Significant dilatation/aneurysm of the aortic root and/or ascending aorta	-	+
Septal hypertrophy requiring myectomy	-	+

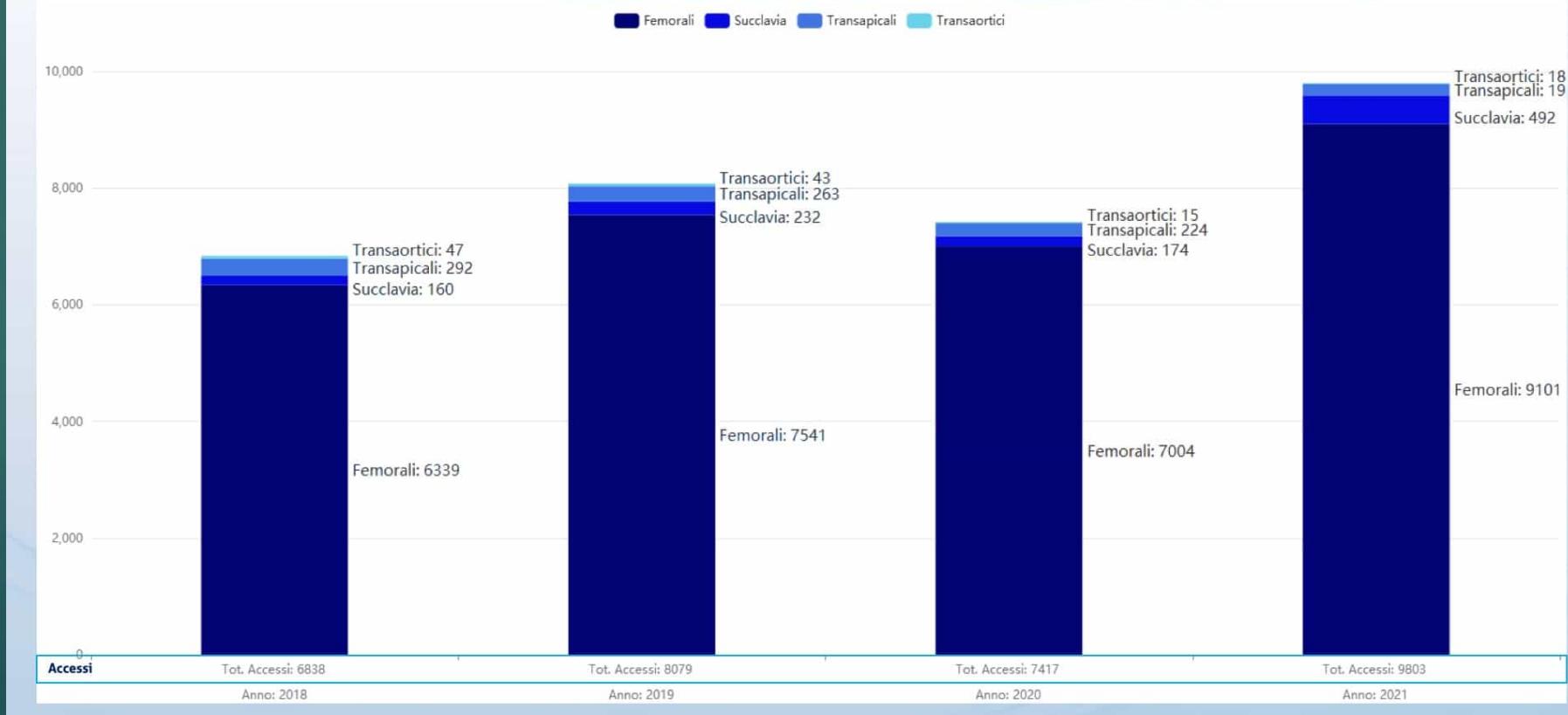


A spectacular worldwide expansion

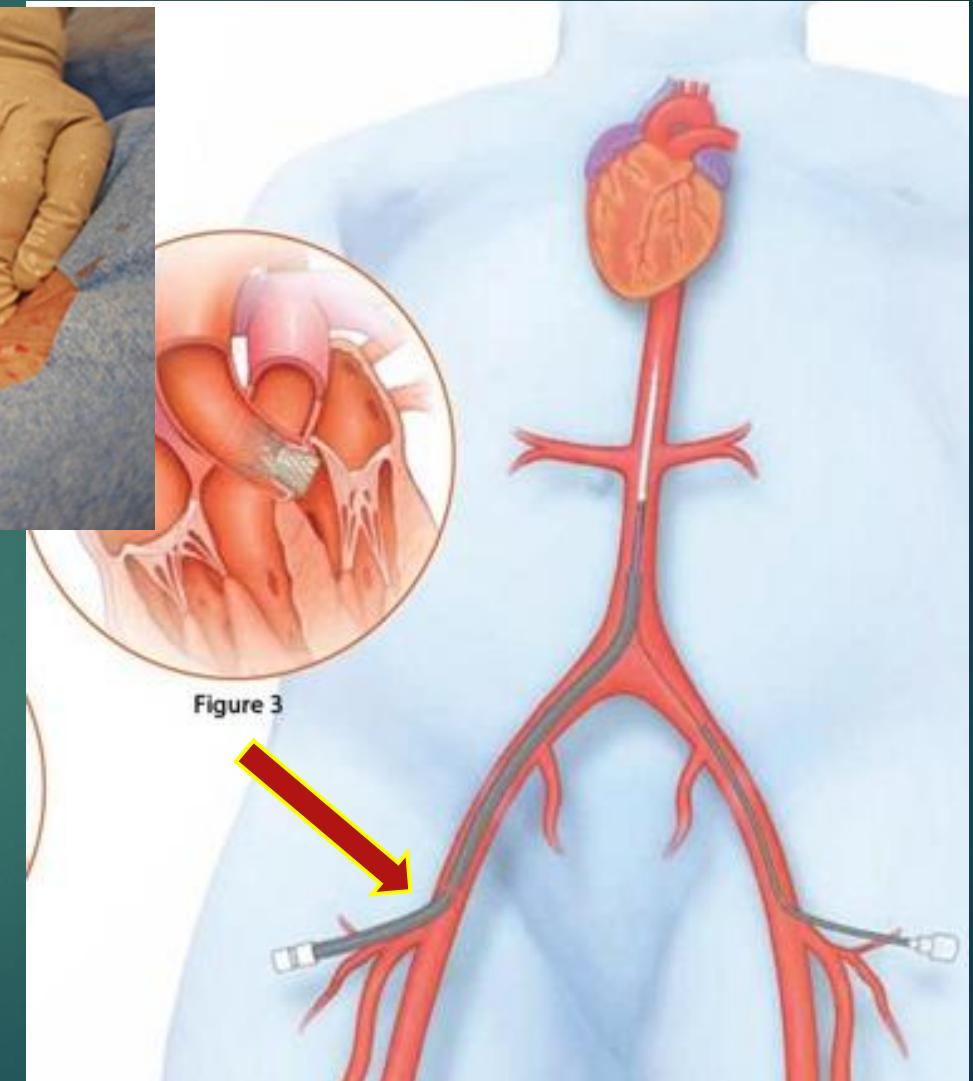
A predicted X 4 TAVI growth within 10 years



(Femorale, Succlavia,Transapicale, Transaortico) Italia



Accesso arterioso femorale



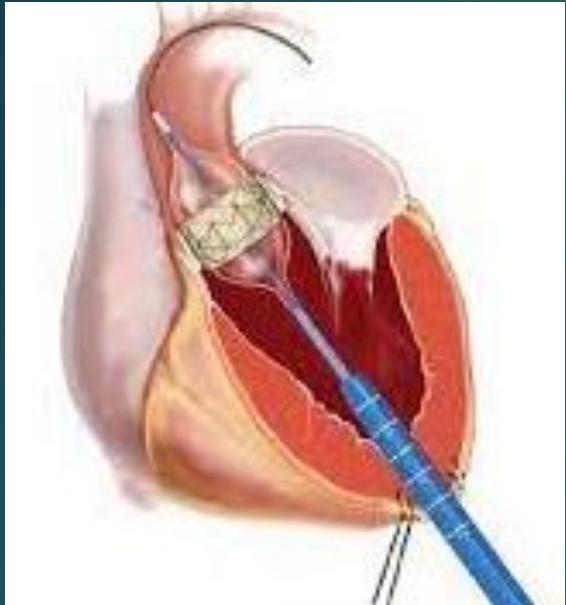
- Procedura interamente percutanea
- Anestesia locale
- Durata ca. 1 ora
- 75% dimesso in 3 giorni

AngioTC

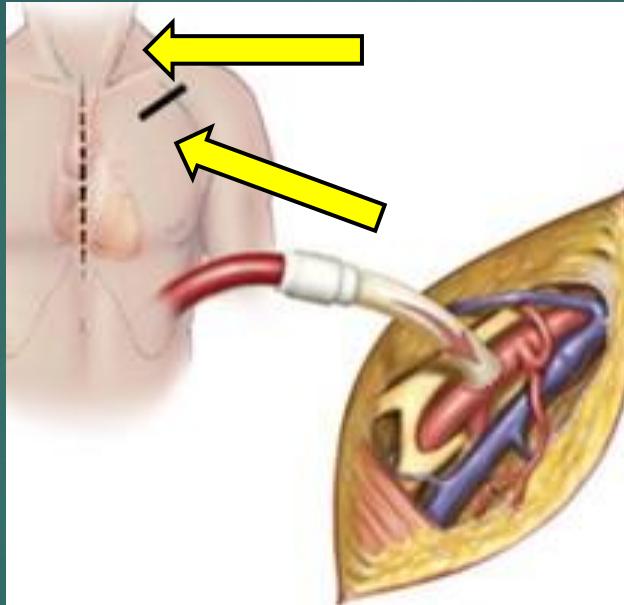
- ▶ Calibri e percorribilità dell'accesso femorale
- ▶ Caratteristiche dell'aorta
- ▶ Dimensioni dell'anulus valvolare (=sizing della protesi)
- ▶ Proiezione d'impianto
- ▶ Entità delle calcificazioni valvolari
- ▶ Altezza delle coronarie



Accessi alternativi



Transapicale

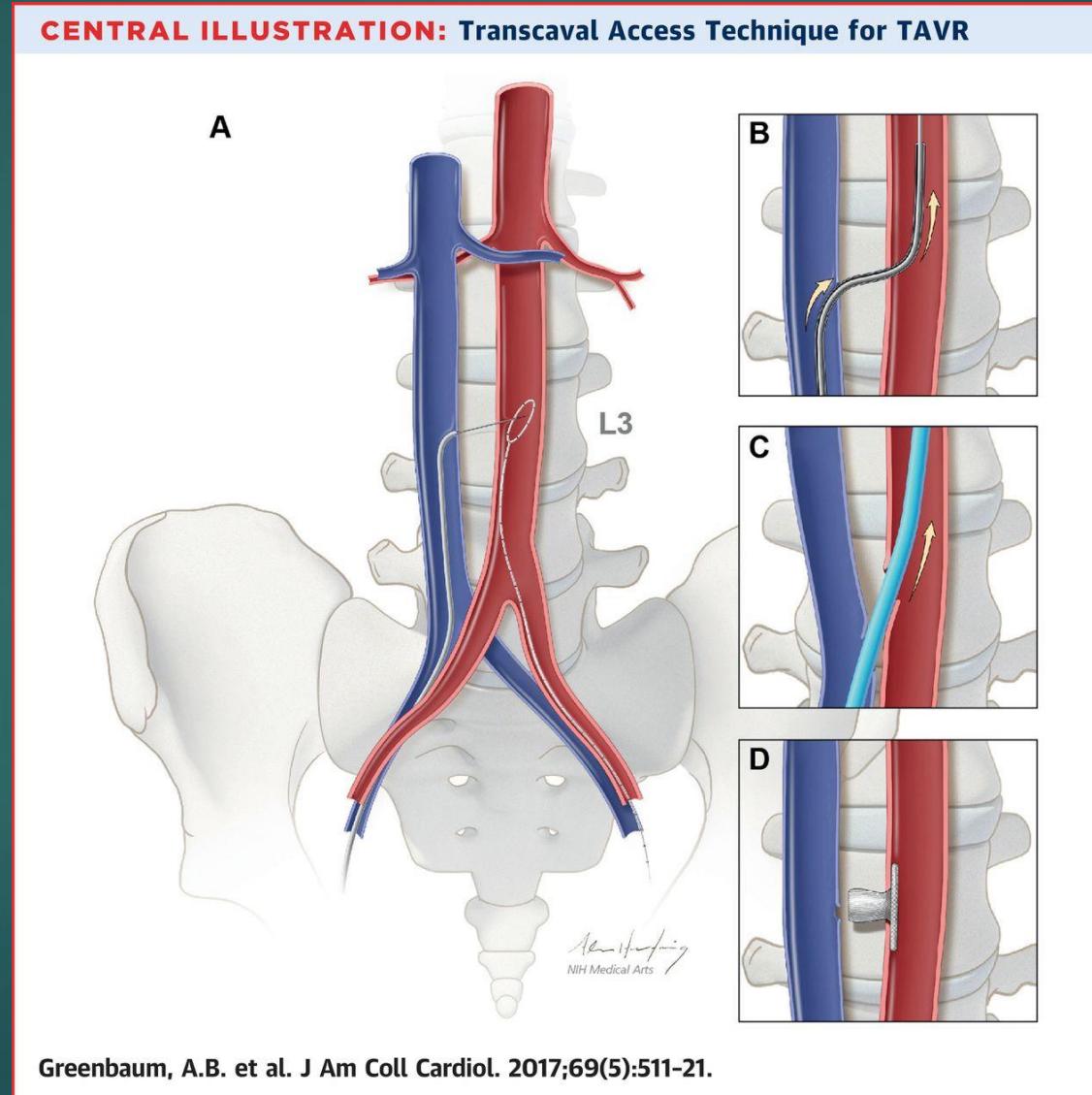


Transucclavia /
Transcarotidea



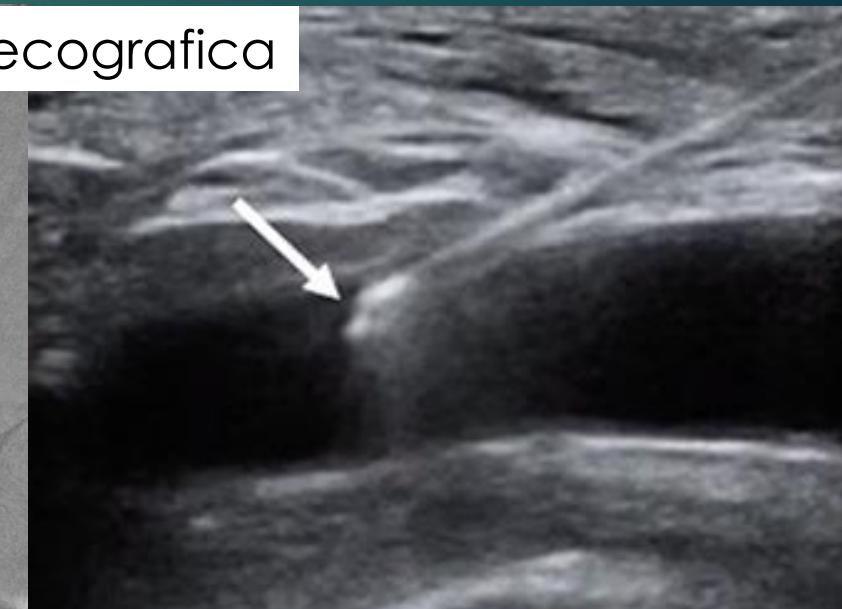
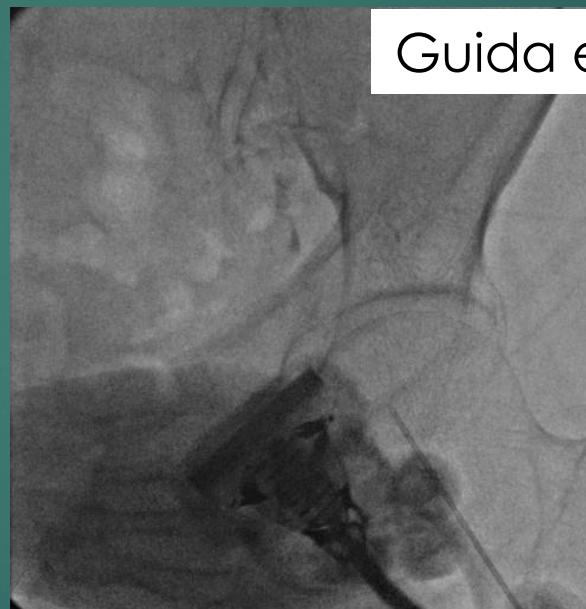
Transaortico

Accessi alternativi

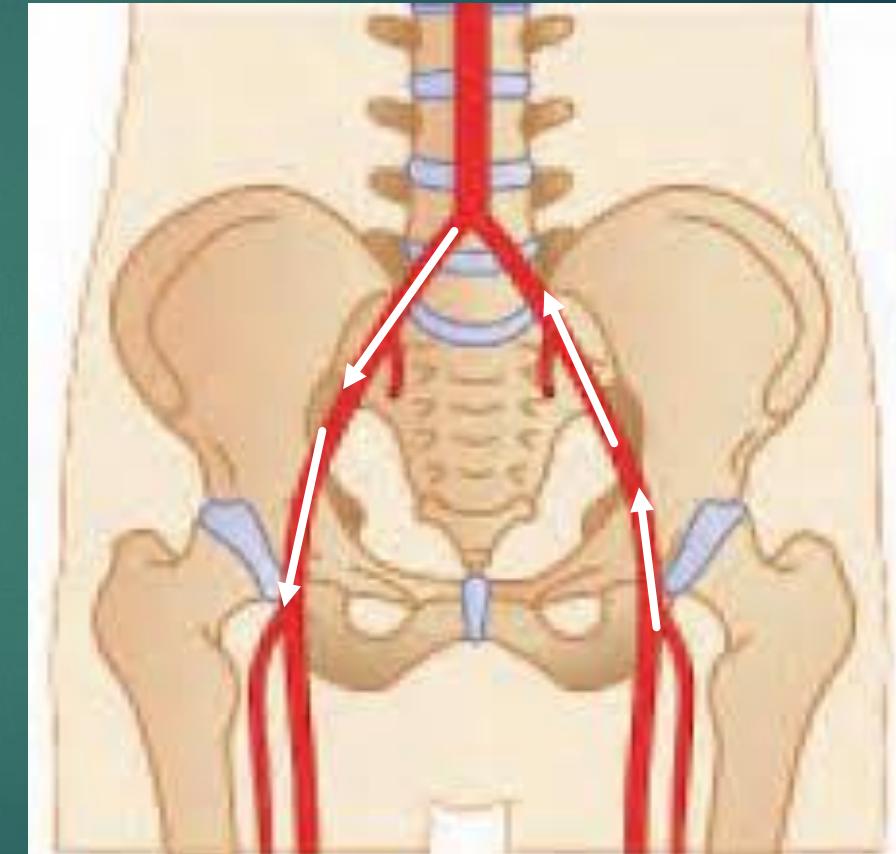
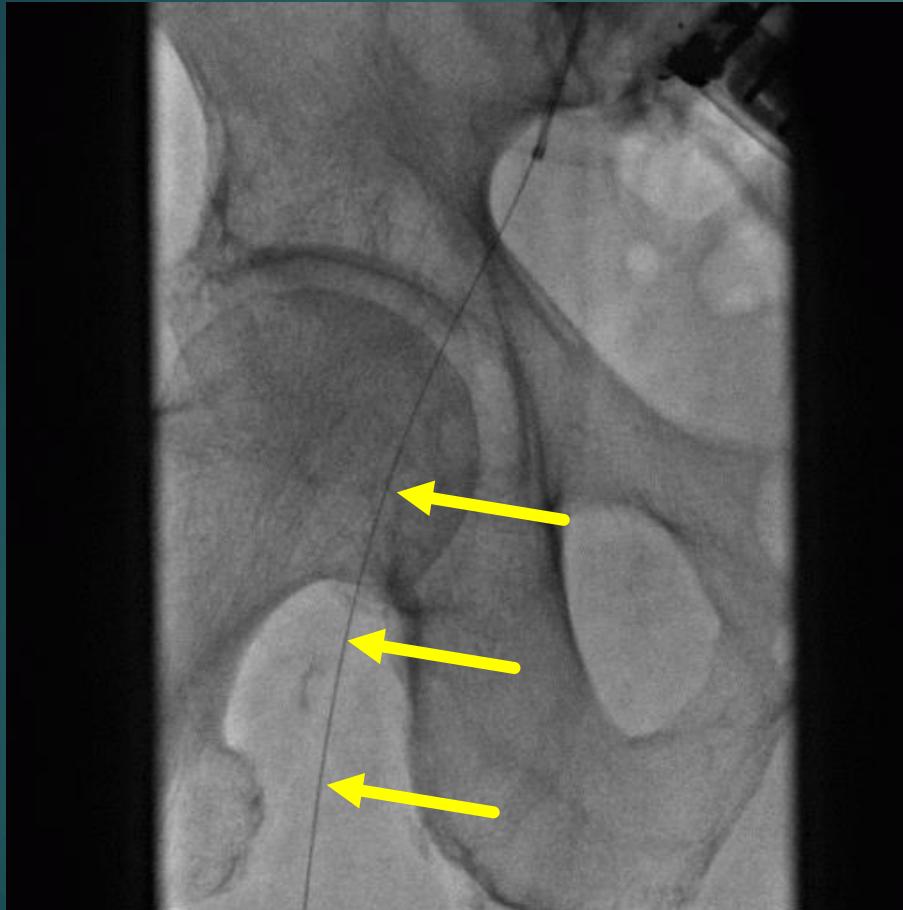


Transcavale

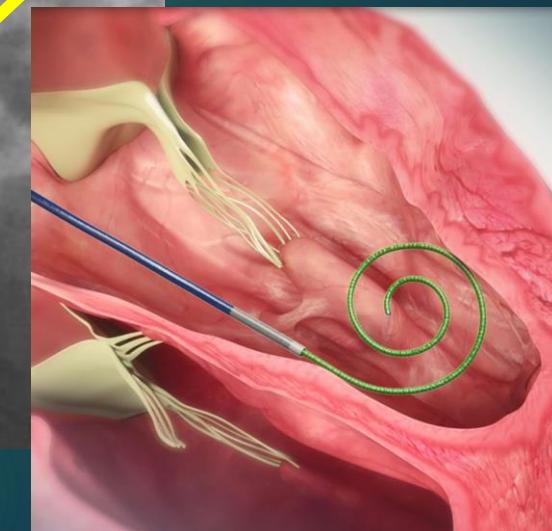
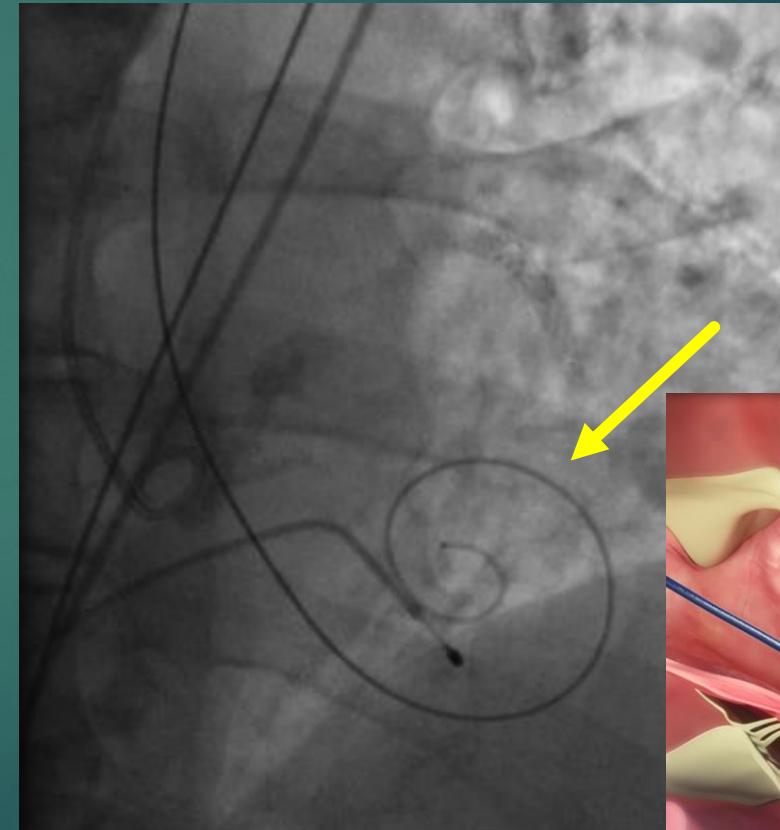
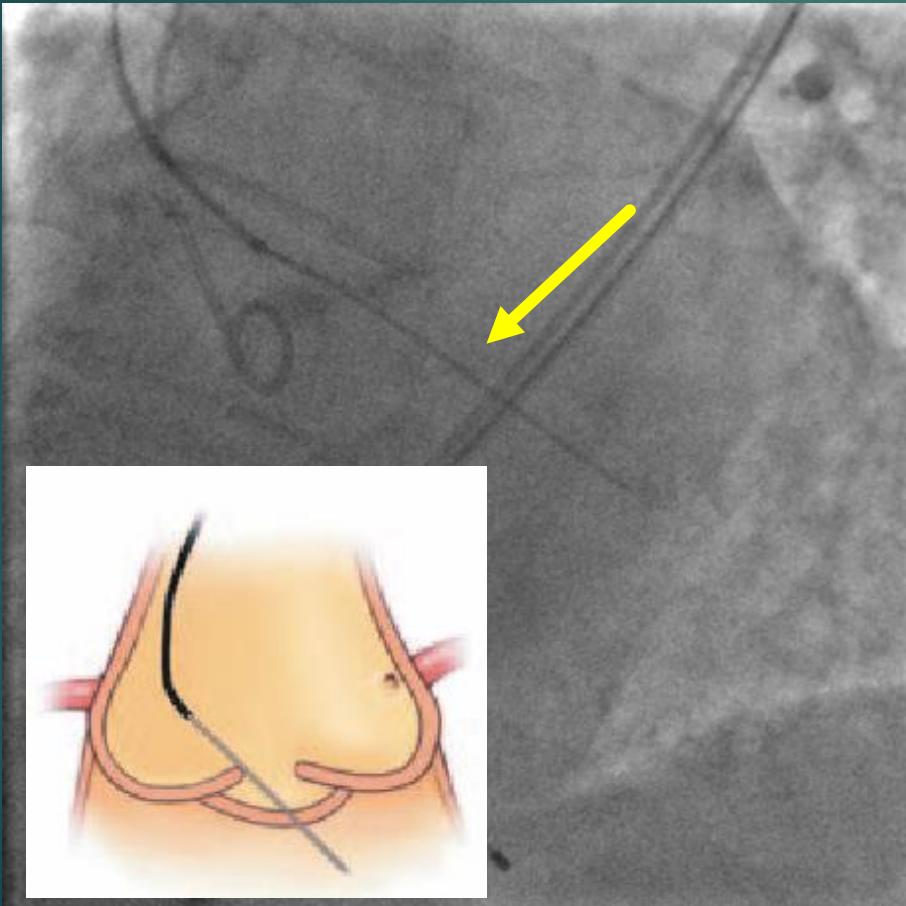
Puntura arteriosa femorale



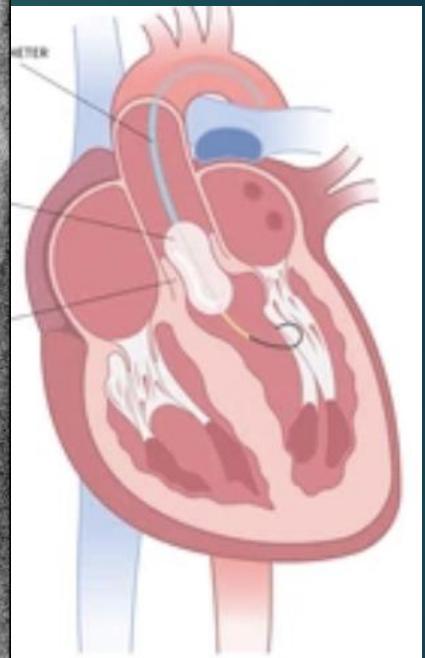
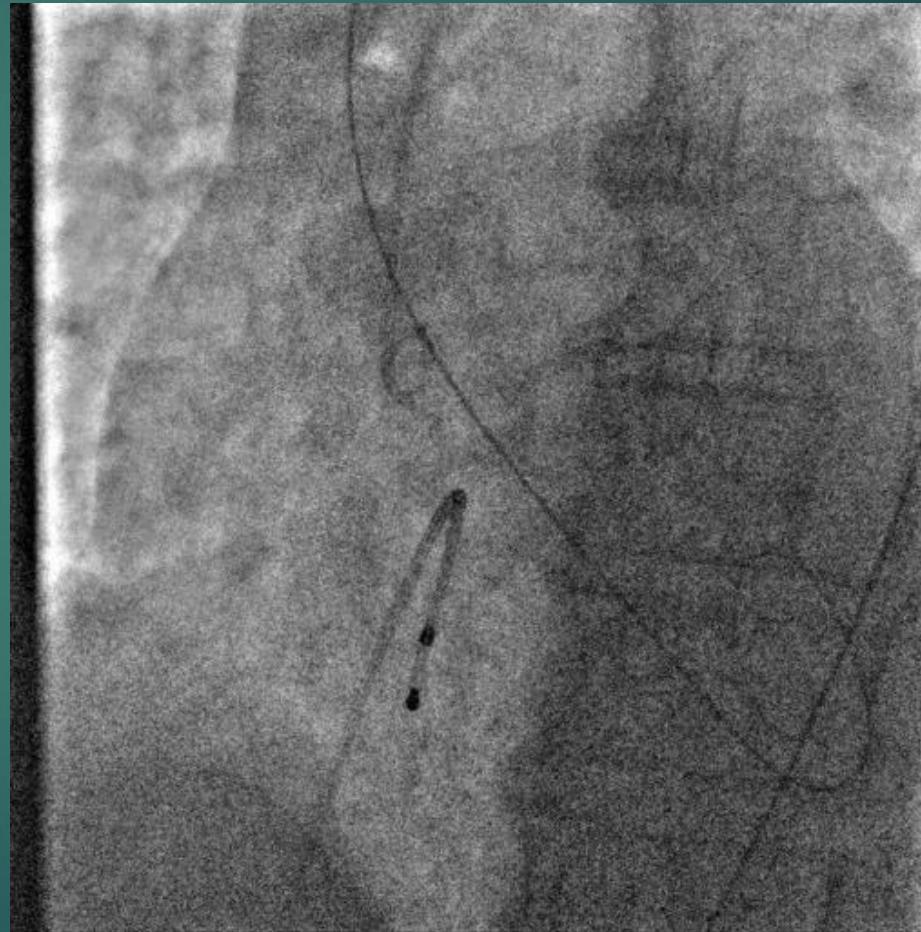
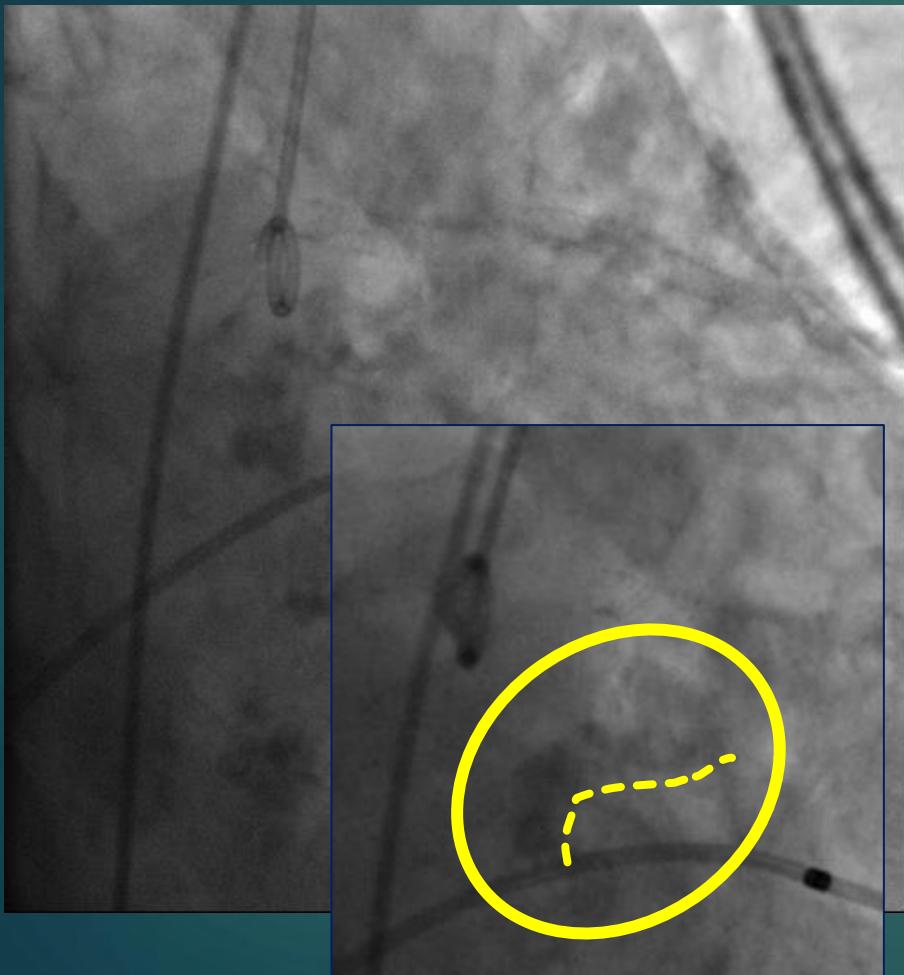
Protezione d'arto



Crossing della valvola aortica e posizionamento di filo guida supportivo in ventricolo sinistro



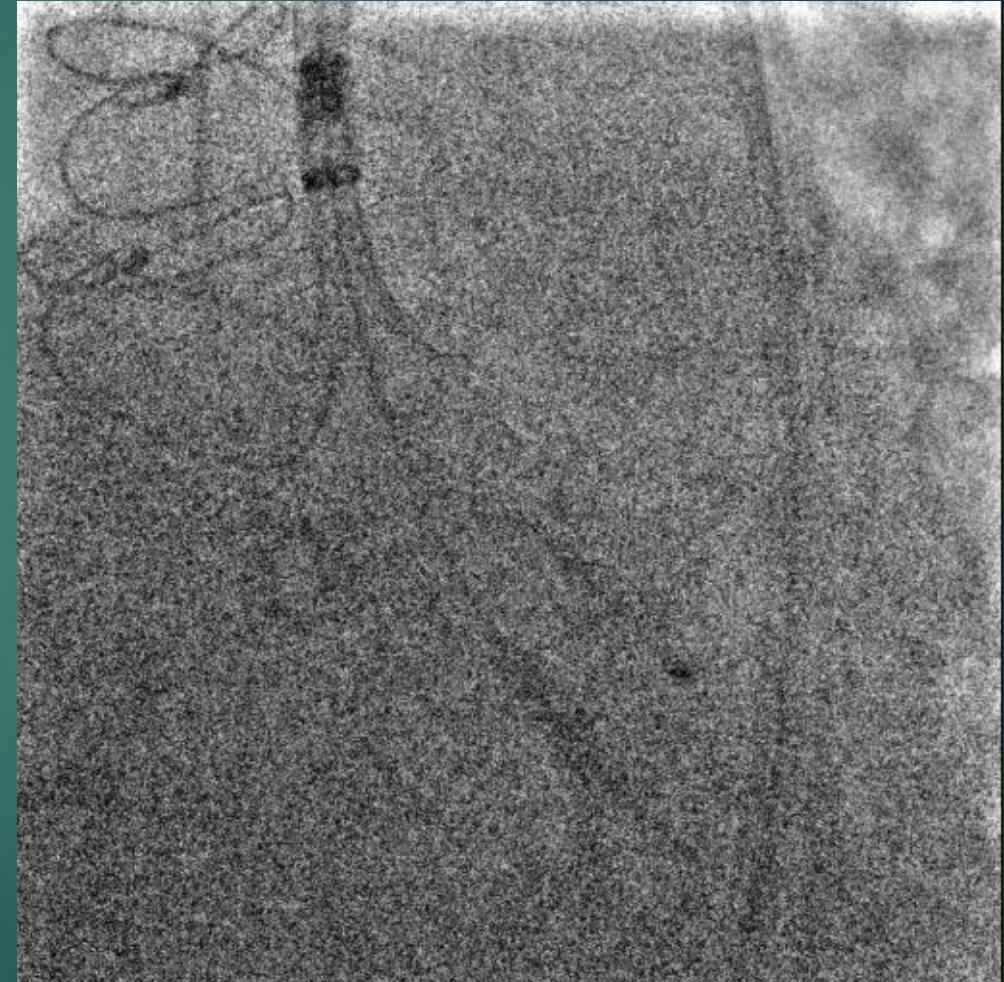
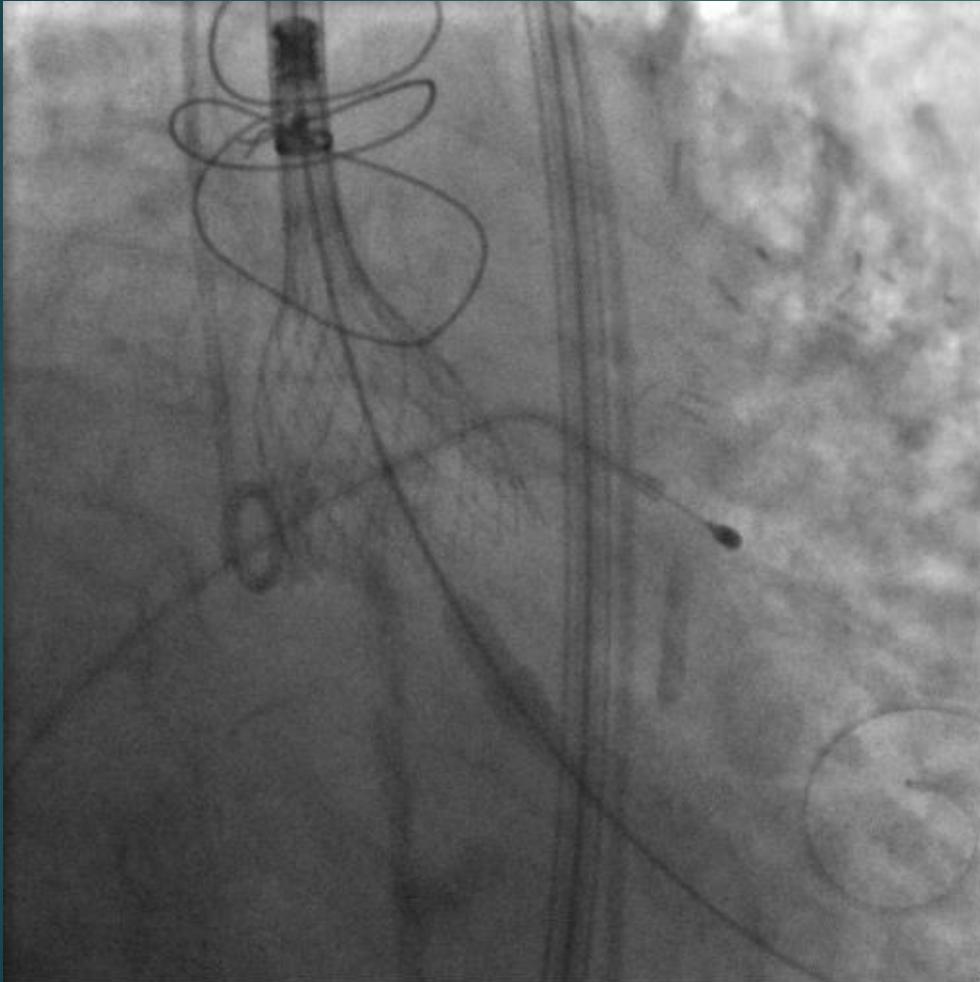
Eventuale valvuloplastica aortica



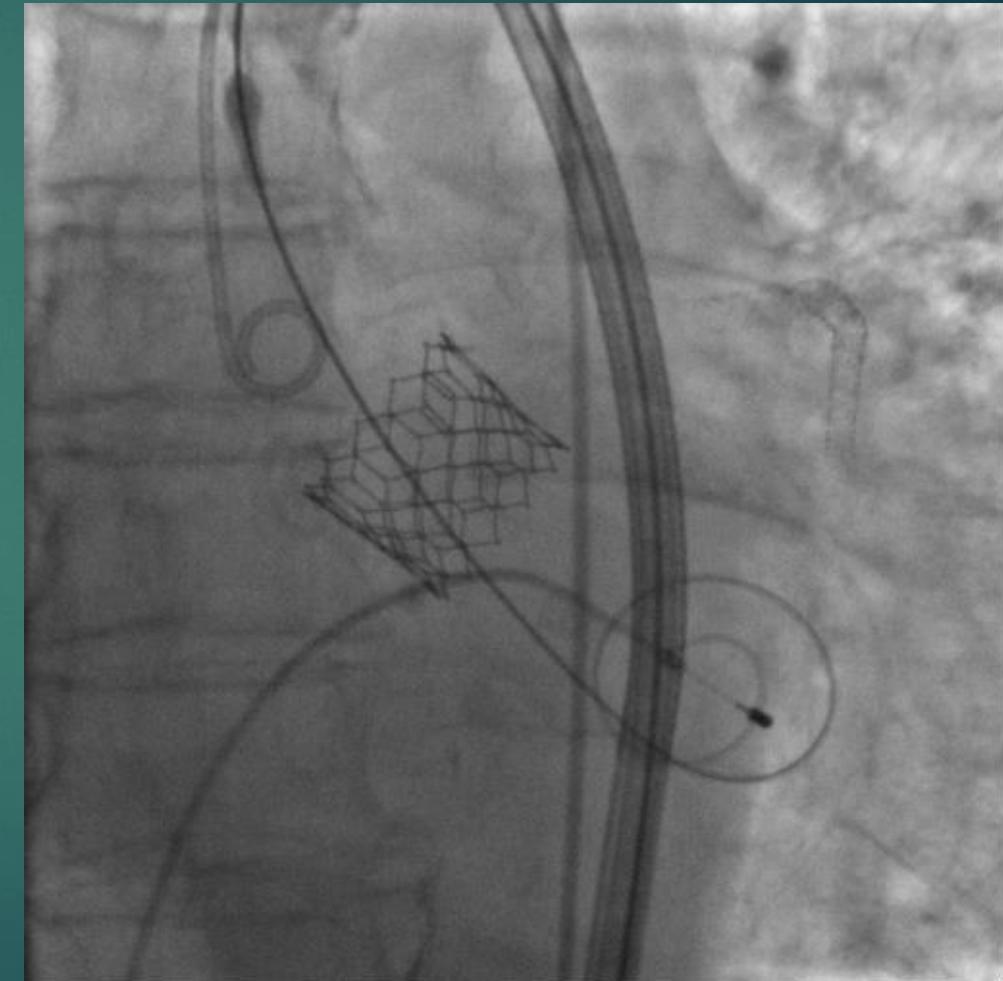
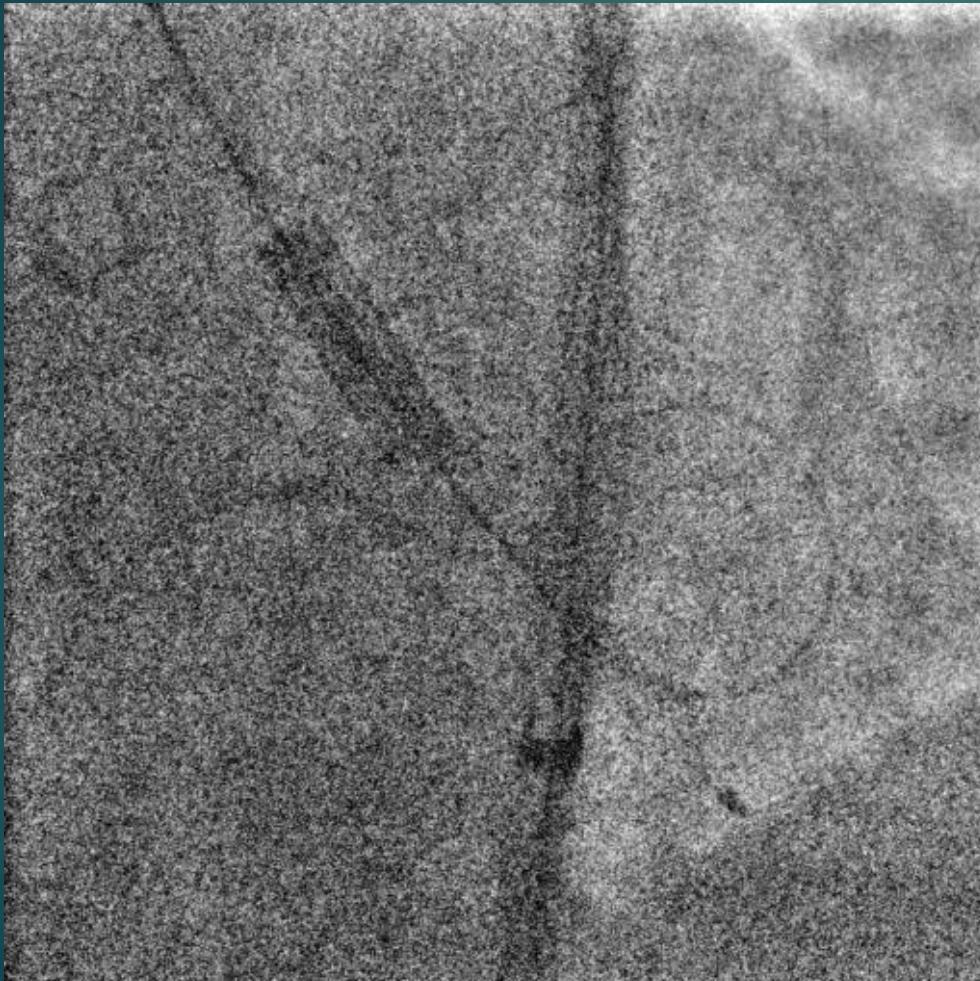
Commercially available THVs

	Self-expanding THVs			Balloon-expandable THVs	
	Evolute PRO+	Acurate Neo2	Navitor	Myval	Sapien Ultra 3
					
Frame	Nitinol	Nitinol	Nitinol	Cobalt-Nickel	Cobalt-Chromium
Valve tissue	Porcine Pericardial	Porcine Pericardial	Bovine pericardial	Bovine pericardial	Bovine pericardial
Valve sizes (mm)	23, 26, 29, 34	23, 25, 27	23, 25, 27, 29	20, 21.5, 23, 24.5, 26, 27.5, 29, 30.5, 32	20, 23, 26, 29
Sheath sizes (Fr)	14 (23, 26, 29 mm) 18 (34 mm)	14	14 (23, 25 mm) 15 (27, 29 mm)	14	14 (20, 23, 26 mm) 16 (29 mm)
Design	Supra-annular	Supra-annular	Intra-annular	Intra-annular	Intra-annular
Repositioning	Yes	No	Yes	No	No

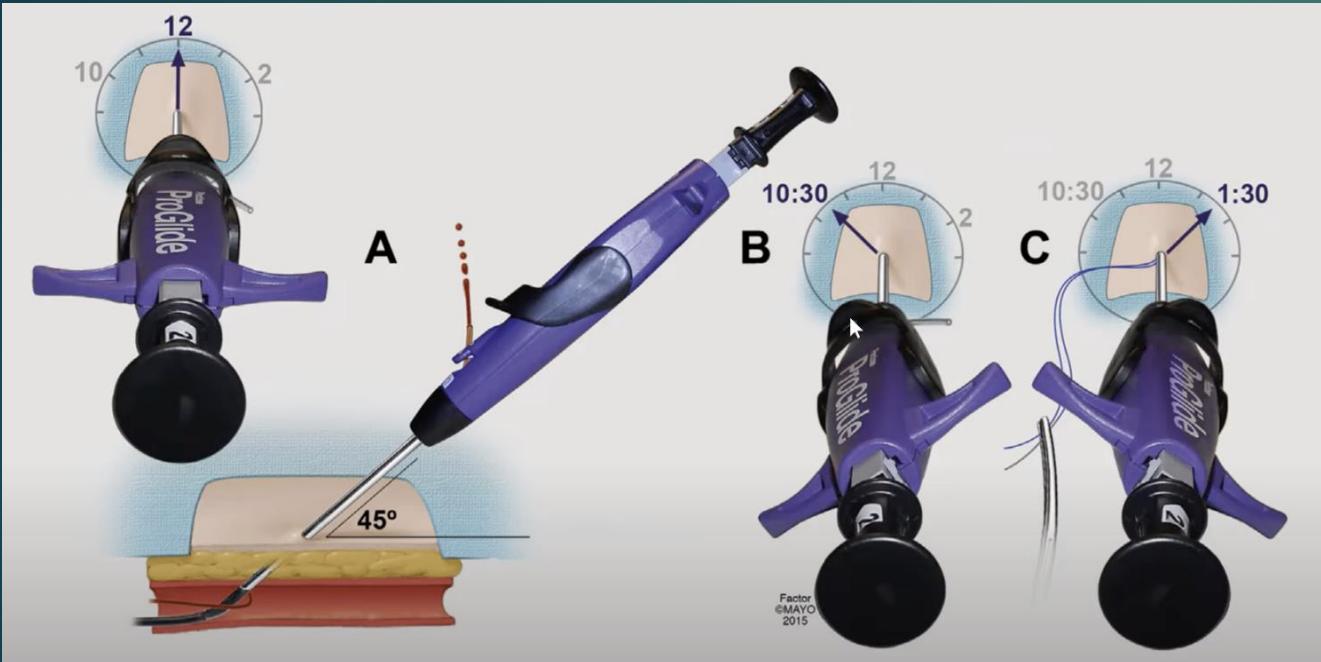
Impianto della valvola



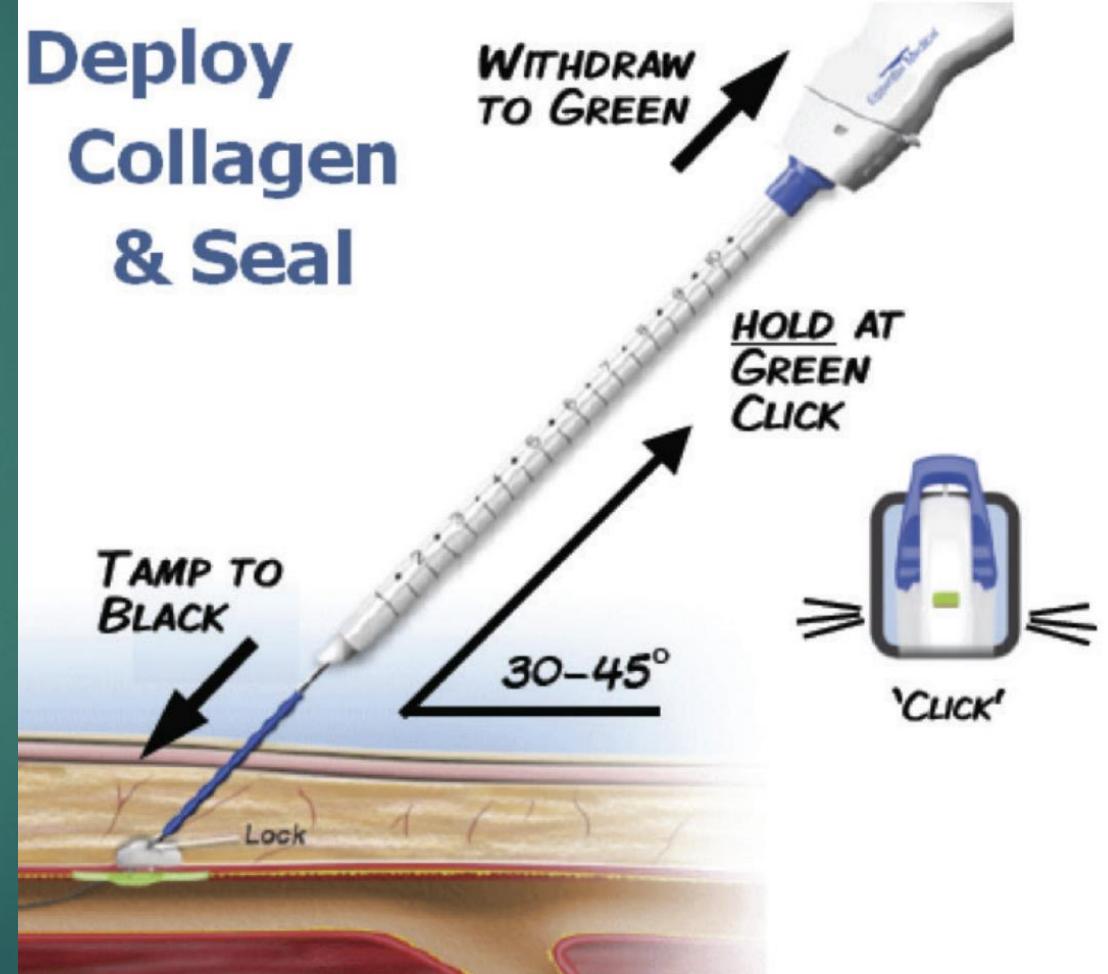
Impianto della valvola



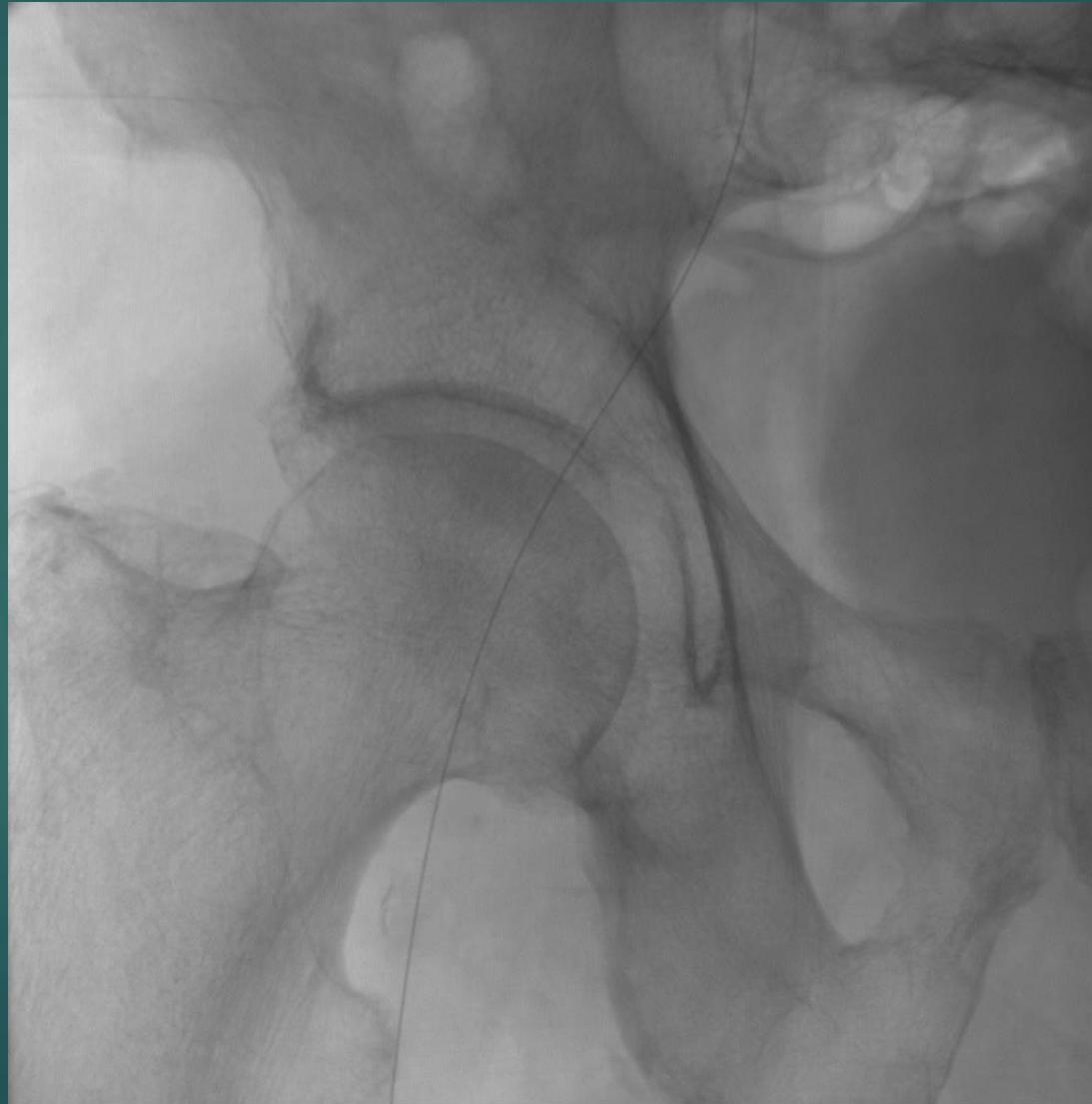
Emostasi



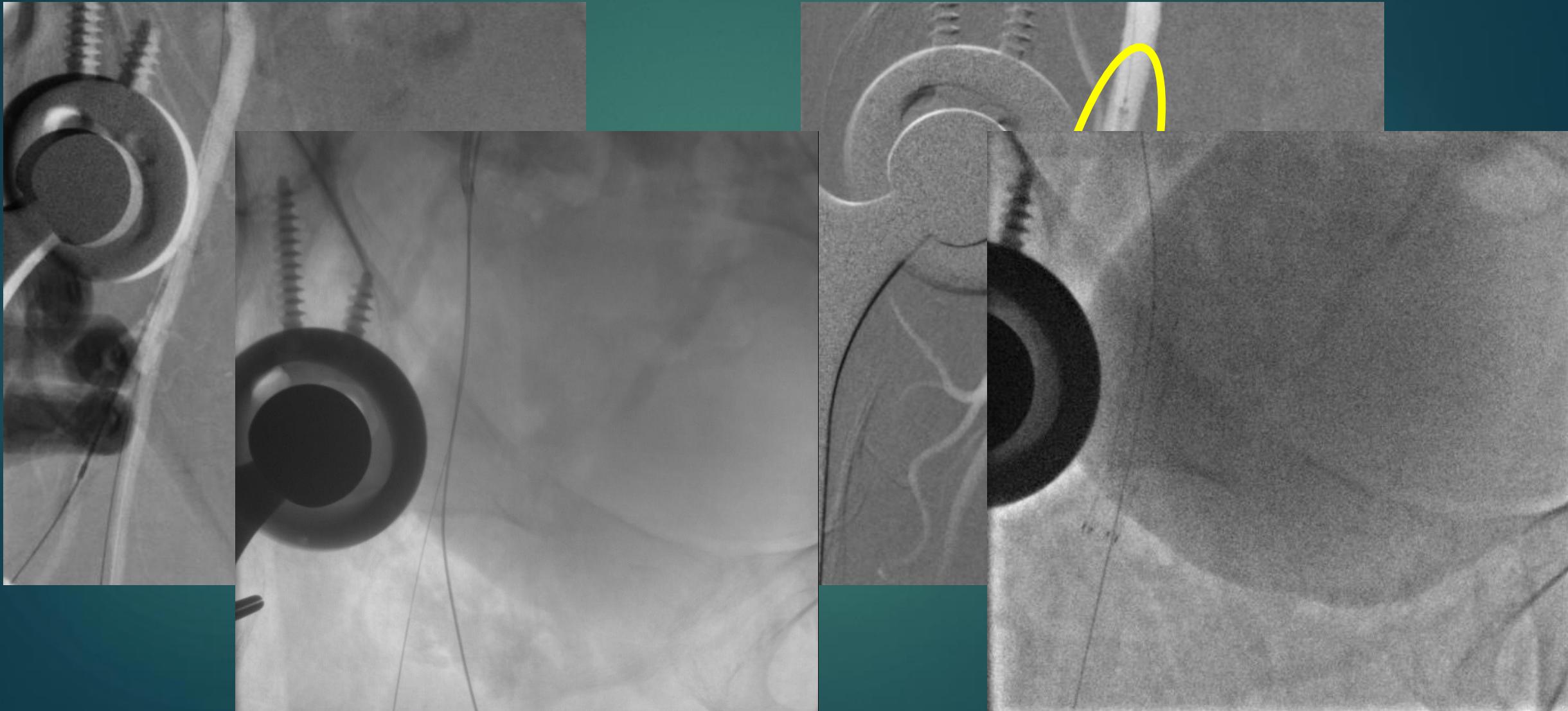
Deploy Collagen & Seal



Verifica dell' emostasi



Verifica dell'emostasi



Conclusioni

- ▶ Nell'arco di 20 anni l'evoluzione dei materiali, l'esperienza degli operatori e la ricerca scientifica hanno reso la TAVI una procedura efficace, «snella» e con un buon profilo di sicurezza.
- ▶ E' lecito attendersi in futuro un ulteriore perfezionamento di questa tecnica e quindi un sempre maggior impiego.



Grazie per l'attenzione