



ALMA MATER STUDIORUM
UNIVERSITA' DI BOLOGNA



SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Ospedaliero - Universitaria di Bologna

Policlinico S. Orsola-Malpighi

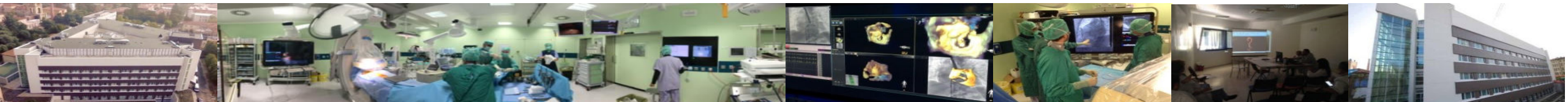
HOT TOPICS IN CARDIOLOGIA 2023

Esperienza clinica, aspettative del paziente, sviluppi tecnologici e futuro della TAVI

Francesco Saia

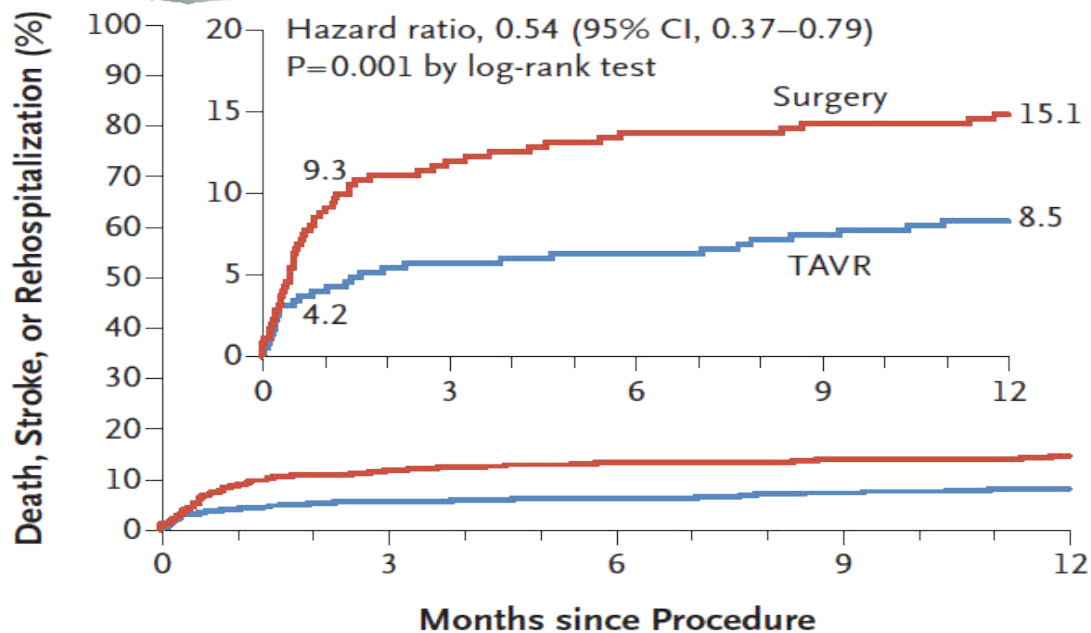
*IRCCS Azienda Ospedaliero-Universitaria di Bologna
Policlinico S. Orsola
Bologna, Italy*

Napoli, 14 Novembre 2023

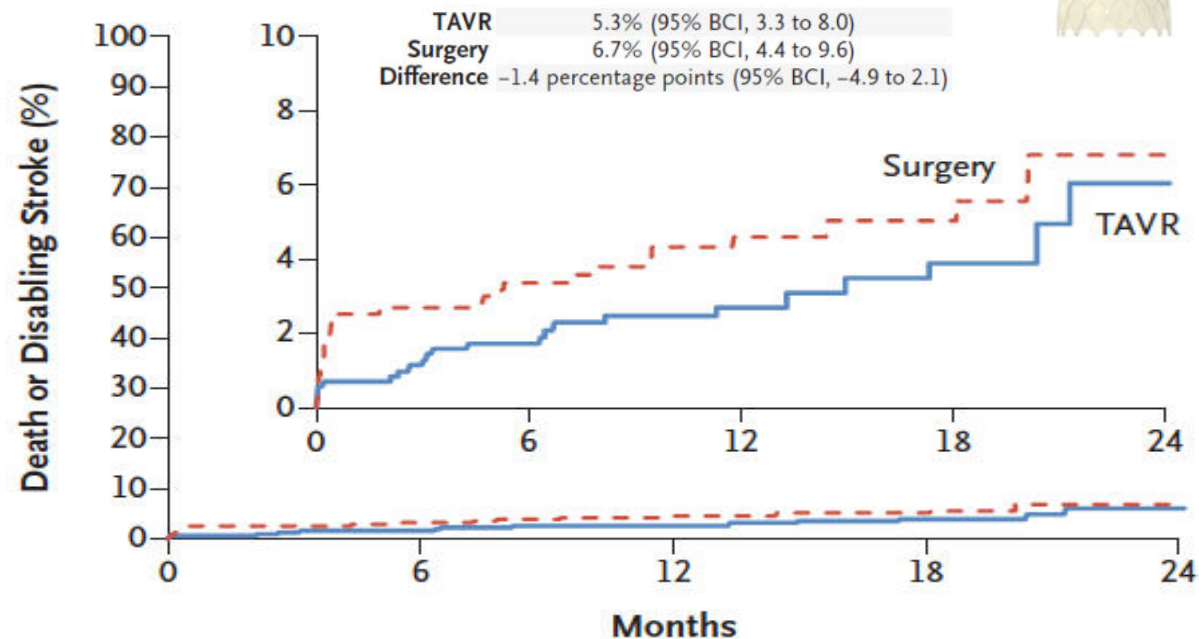


TAVI trials in low risk patients

Age 73-74 years



Mack M et al. *NEJM* 2019; 380:1695-705



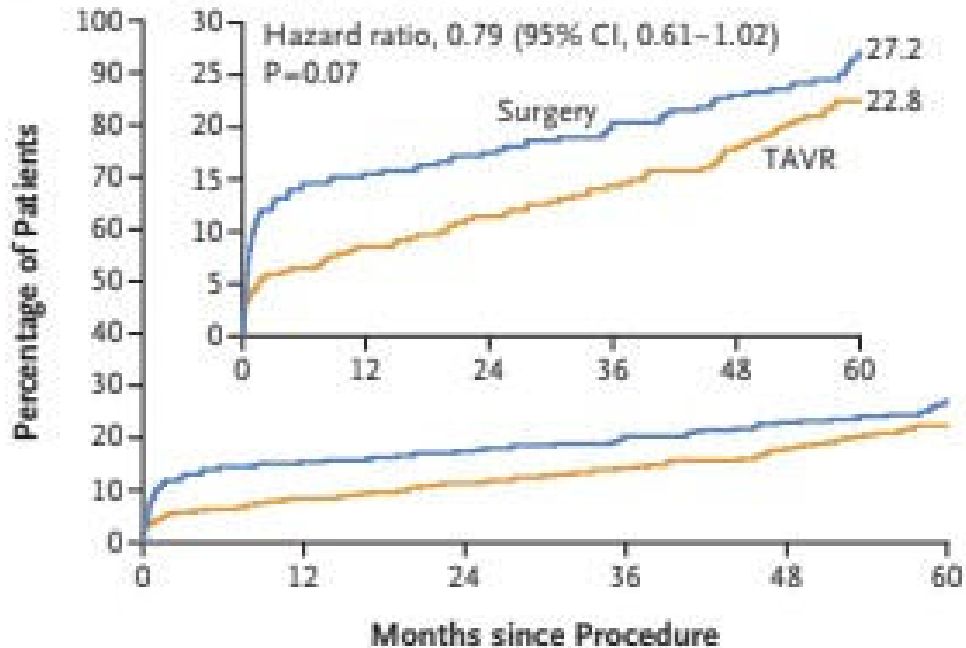
Popma J et al. *NEJM* 2019; 380:1695-705.

TAVI trials in low risk patients – Long-term follow-up



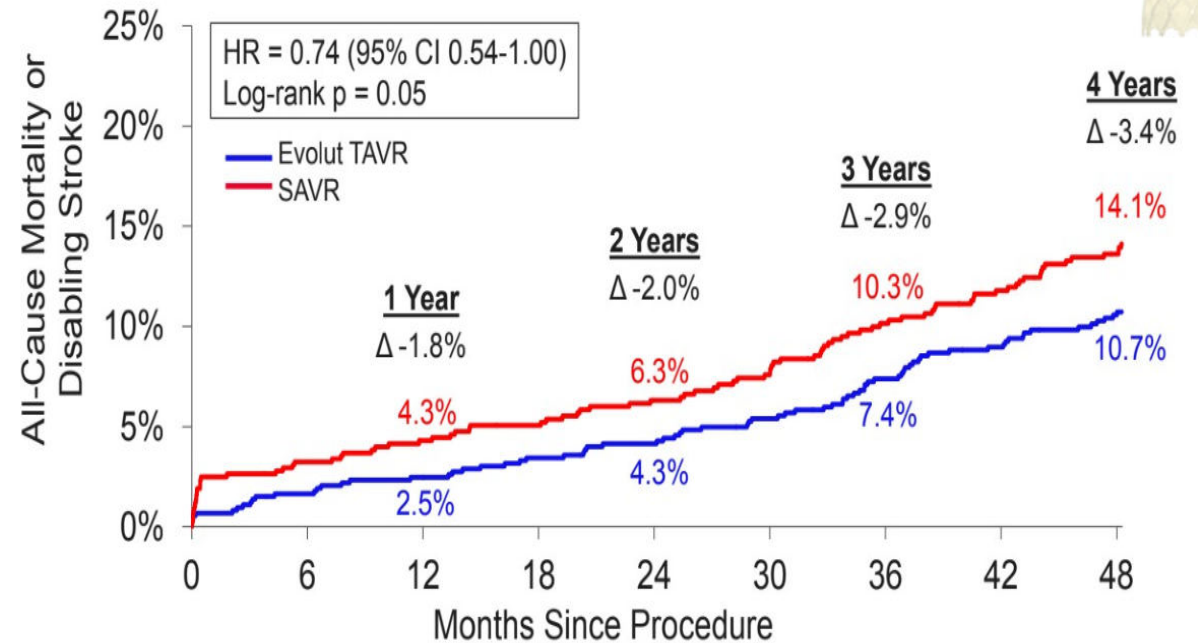
PARTNER-3 @ 5-YEAR

Death from Any Cause, Stroke, or Rehospitalization



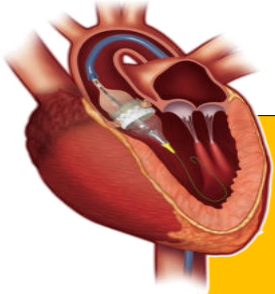
Mack MJ et al. *NEJM*. 2023;Epub ahead of print

COREVALVE LOW-RISK @ 4-YEAR



FOREST JK et al. *JAC2023*;Epub ahead of print.

Valve Heart Disease guidelines



Transfemoral TAVI is recommended in **patients ≥ 75 years**

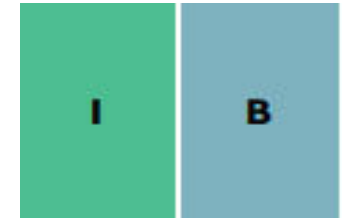
OR

in those who are **high risk** (STS/ ES II $>8\%$) or unsuitable for surgery



HEART TEAM

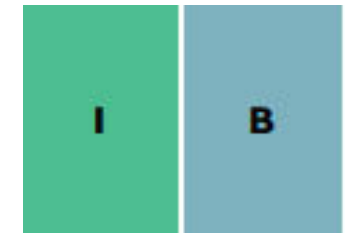
SAVR or TAVI are recommended for remaining patients according to individual clinical, anatomical, and procedural characteristics

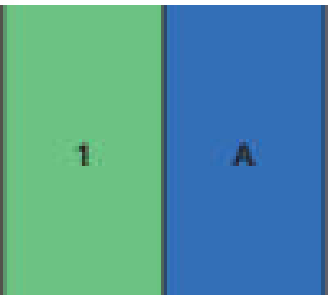


SAVR is recommended in patients **<75 years**

AND

who are **low risk** (STS/ ES II $<4\%$) for surgery

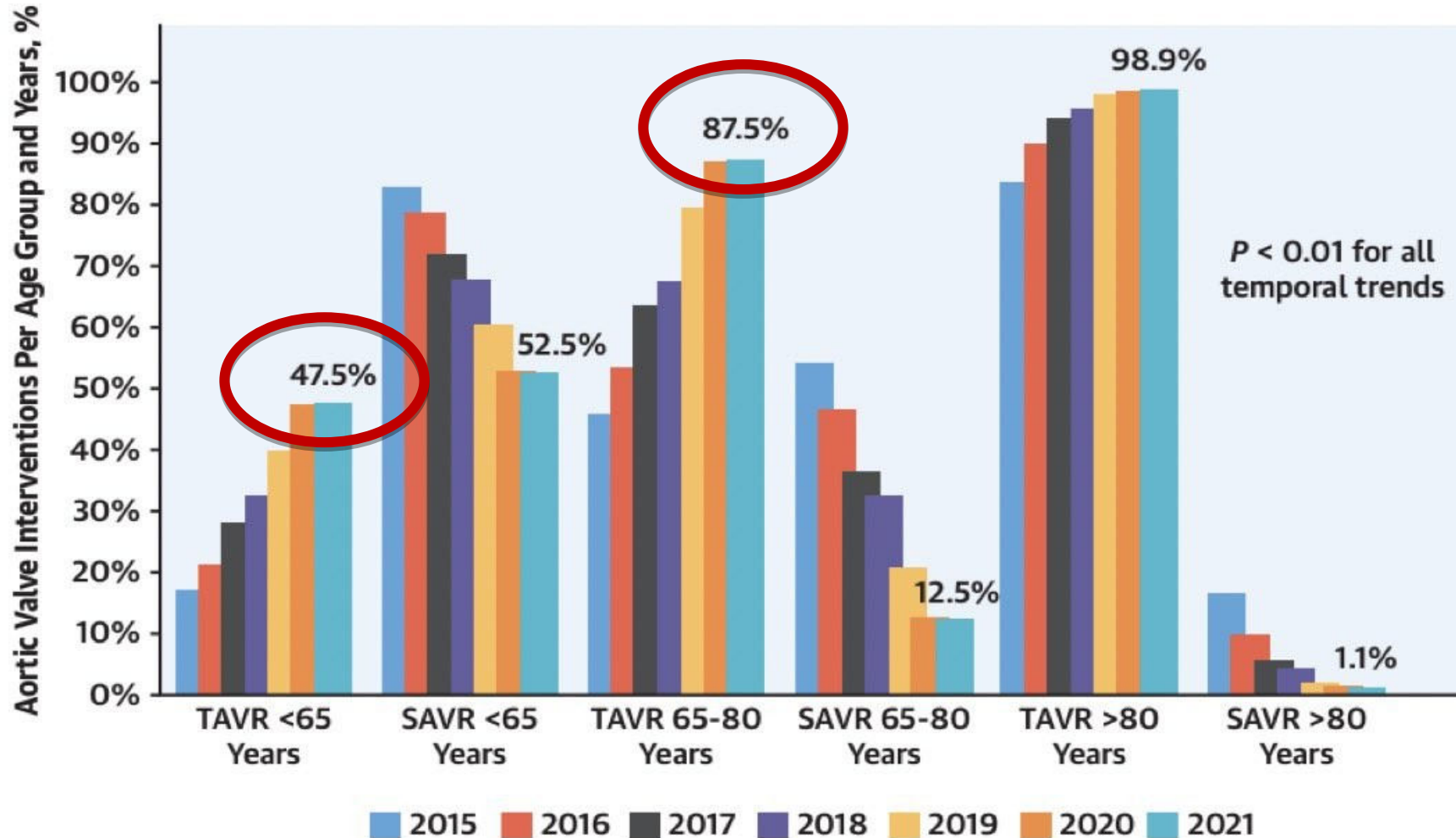




2. For symptomatic patients with severe AS who are 65 to 80 years of age and have no anatomic contraindication to transfemoral TAVI, either SAVR or transfemoral TAVI is recommended after shared decision-making about the balance between expected patient longevity and valve durability.^{1,4-8}



US trends in TAVR and SAVR



TAVI: the ideal candidate is....



VERY OLD,
FRAGILE,
INOPERABLE



HIGH-RISK



INTERMEDIATE-
RISK



LOW-RISK

YOUNGER

TAVI: therapeutic objectives



VERY OLD,
FRAGILE,
INOPERABLE



Improve QoL



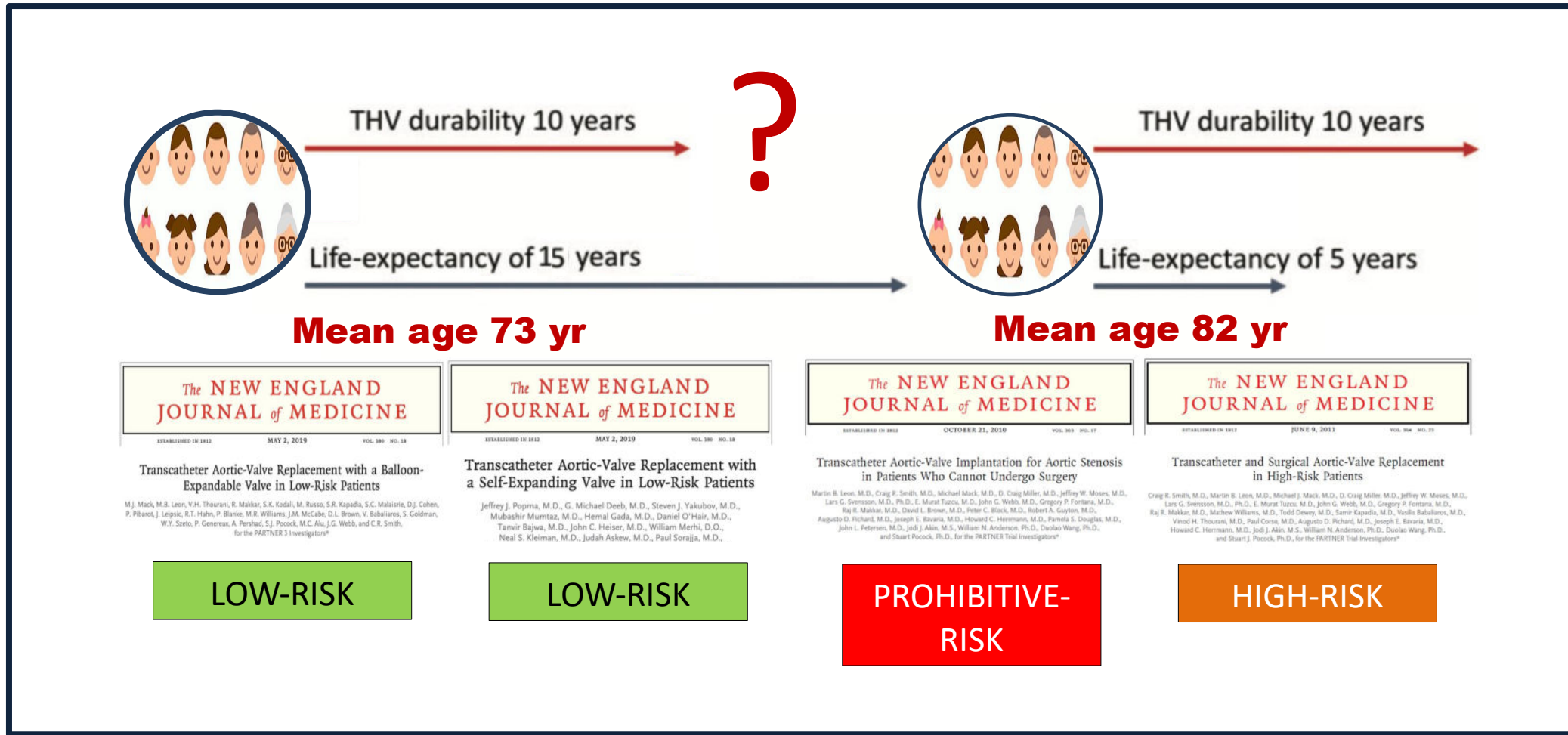
Avoid futility



Consider

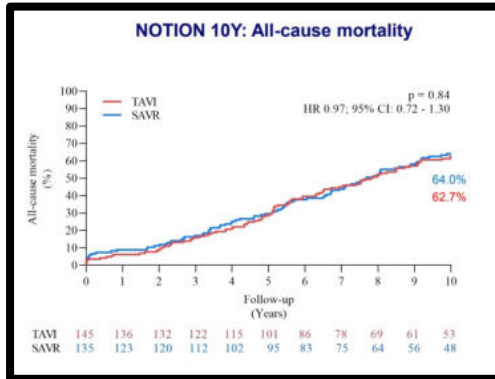
- ✓ Life expectancy
- ✓ Comorbidity
- ✓ Geriatric evaluation

TAVI durability vs. life-expectancy

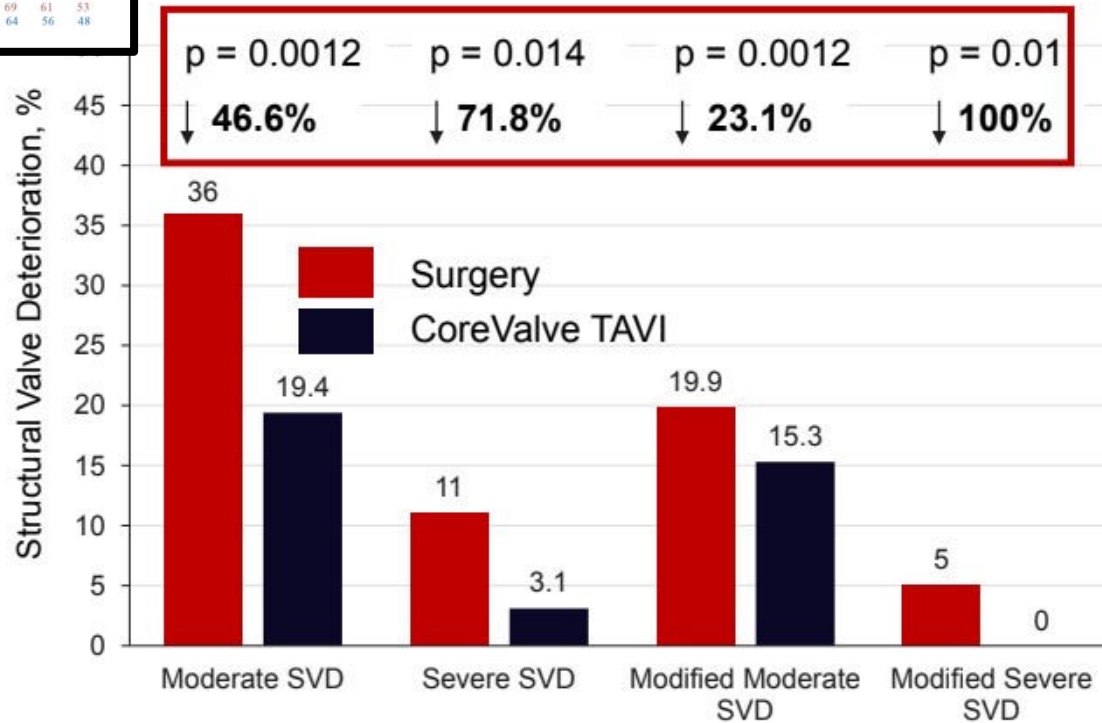


Durability: NOTION 10-year data

279 low-risk pts, 135 SAVR vs 139 CV TAVR



Structural Valve Deterioration



TRIFECTA 24%



MITROFLOW 10%



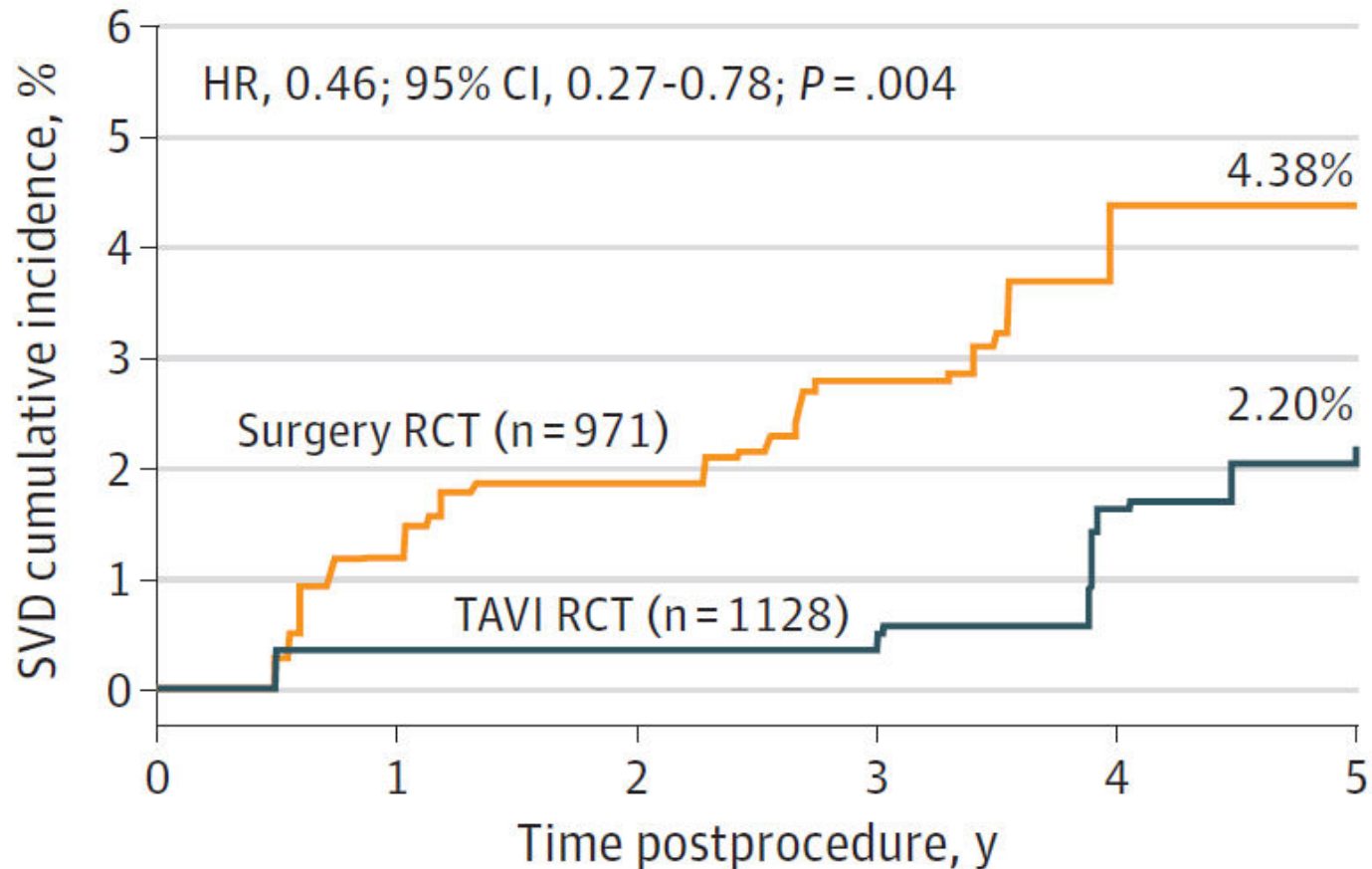
First-gen Corevalve

Jørgensen TH. et al. ESC 2023

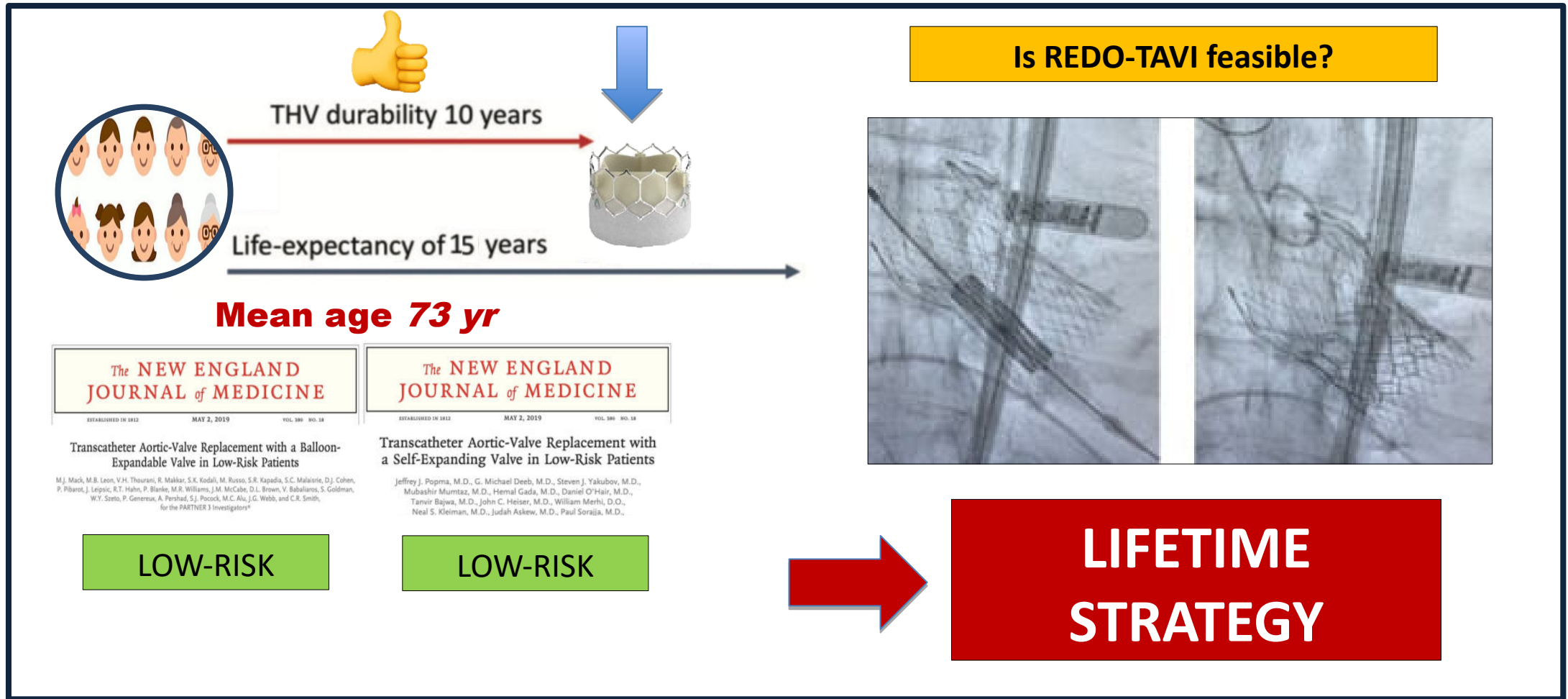
Structural Valve Deterioration: TAVI vs. SAVR

Corevalve RCTs + Registries

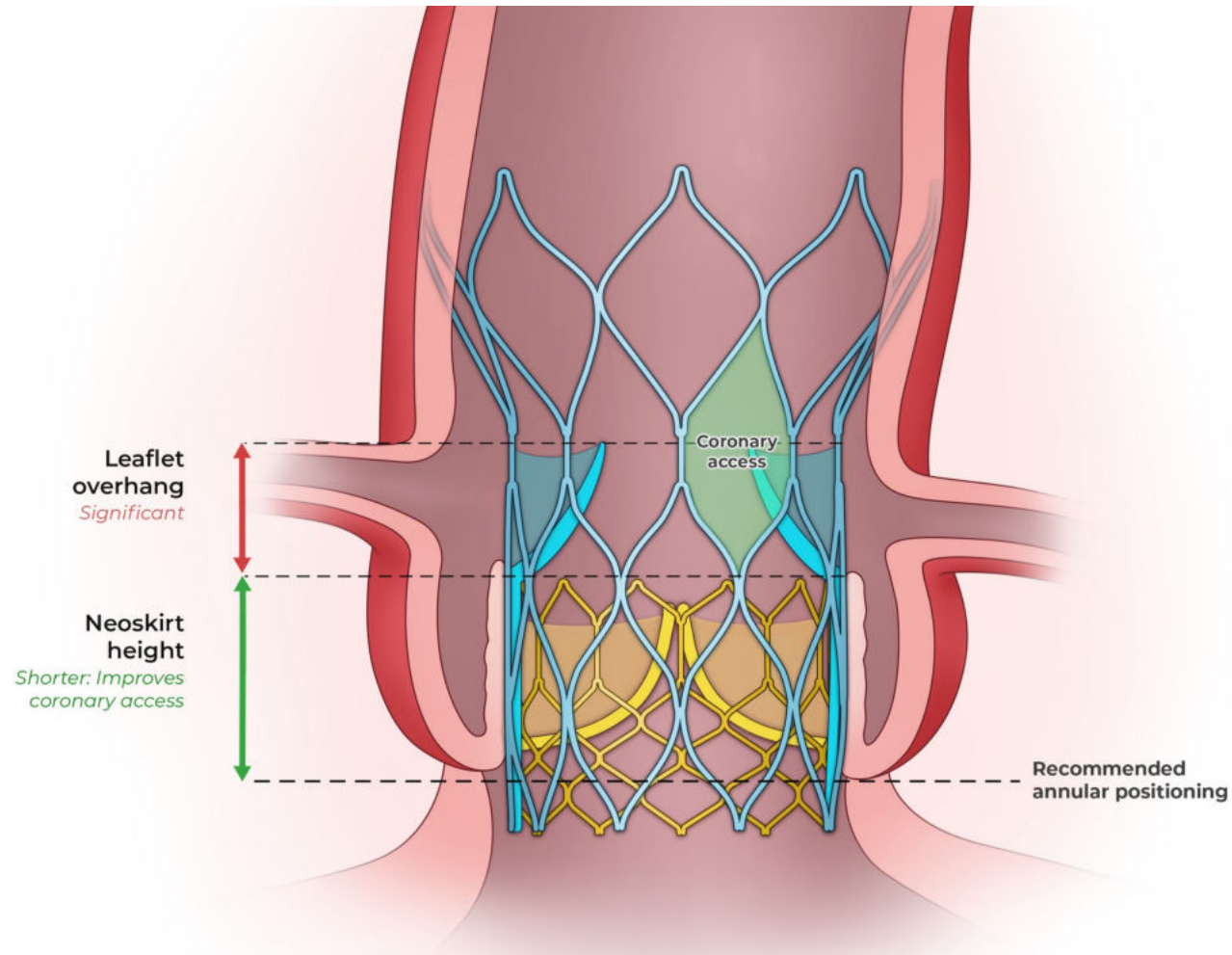
A 5-y Cumulative incidence rate of SVD



TAVI durability and **repeatability**



THV-in-THV: neoskirt and leaflet overhang



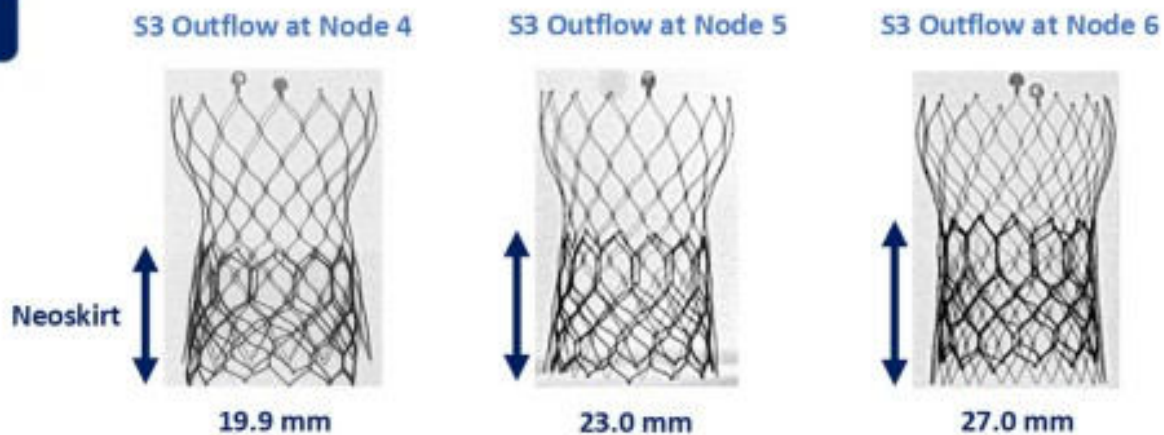
Courtesy of O. De Backer, Copenhagen



Redo-TAVI (THV-in-THV)

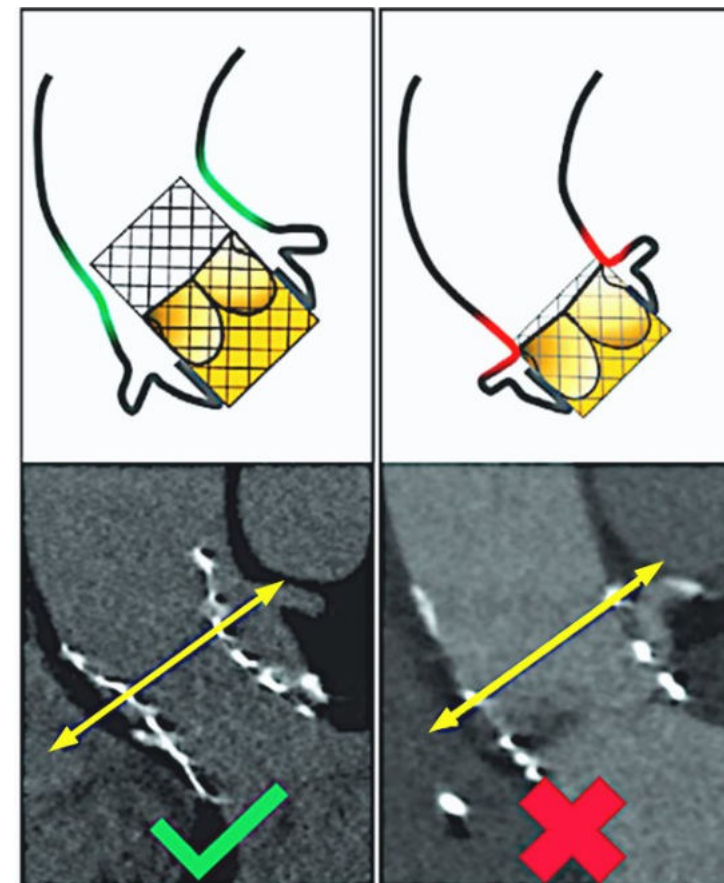
NEOSKIRT HEIGHT

29mm S3
in 34mm Evolut



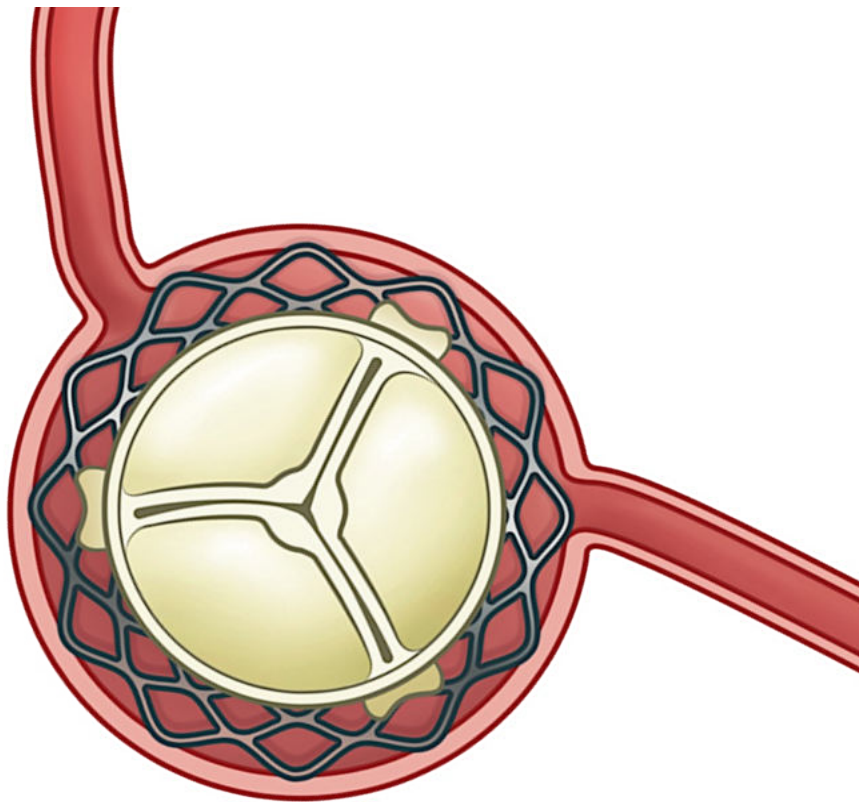
LEAFLET OVERHANG

29mm S3
in 34mm Evolut

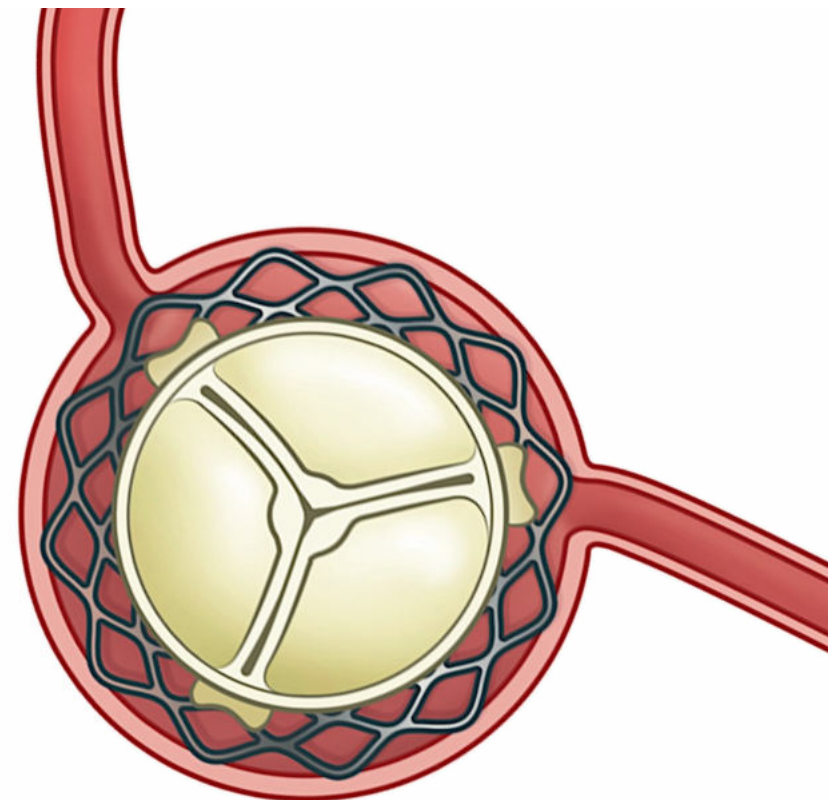


Tarantini G. et al. *Am J Cardiol.* 2023; 192:228-244

Maintaining coronary access: commissural alignment



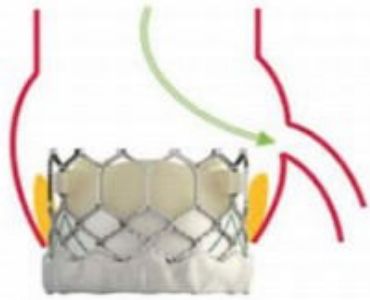
COMMISSURAL ALIGNMENT



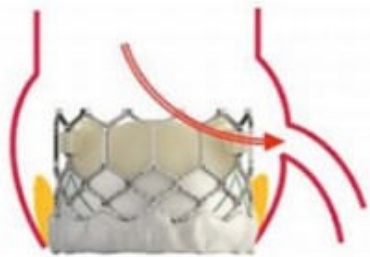
CORONARY OVERLAP

Not all THV were created equal

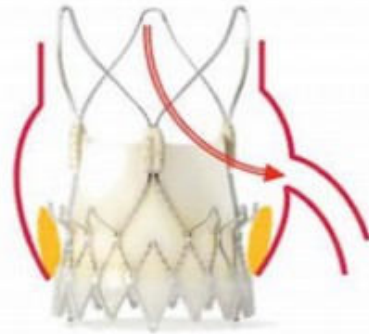
Sapien 3



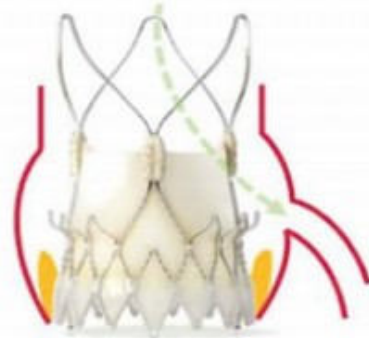
32-54 mm²



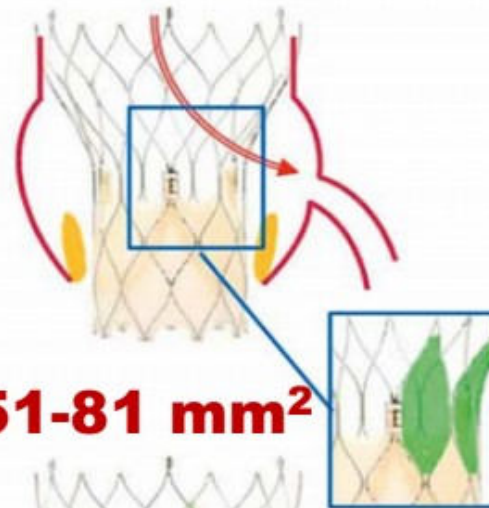
Acurate Neo



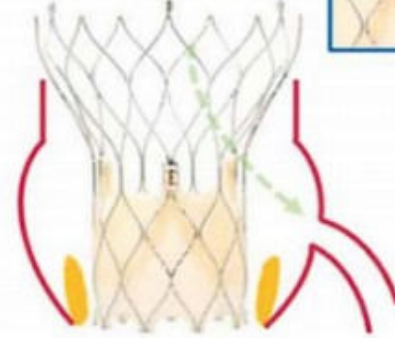
489-610 mm²



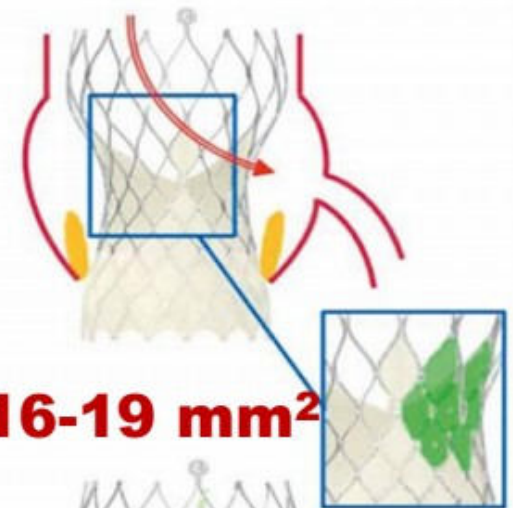
Portico



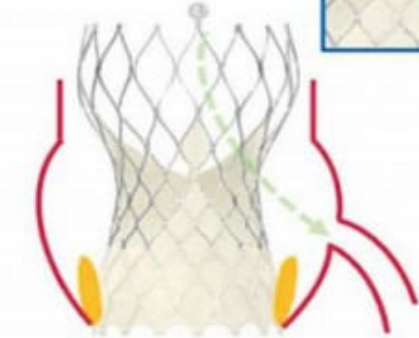
51-81 mm²



Evolut R



16-19 mm²



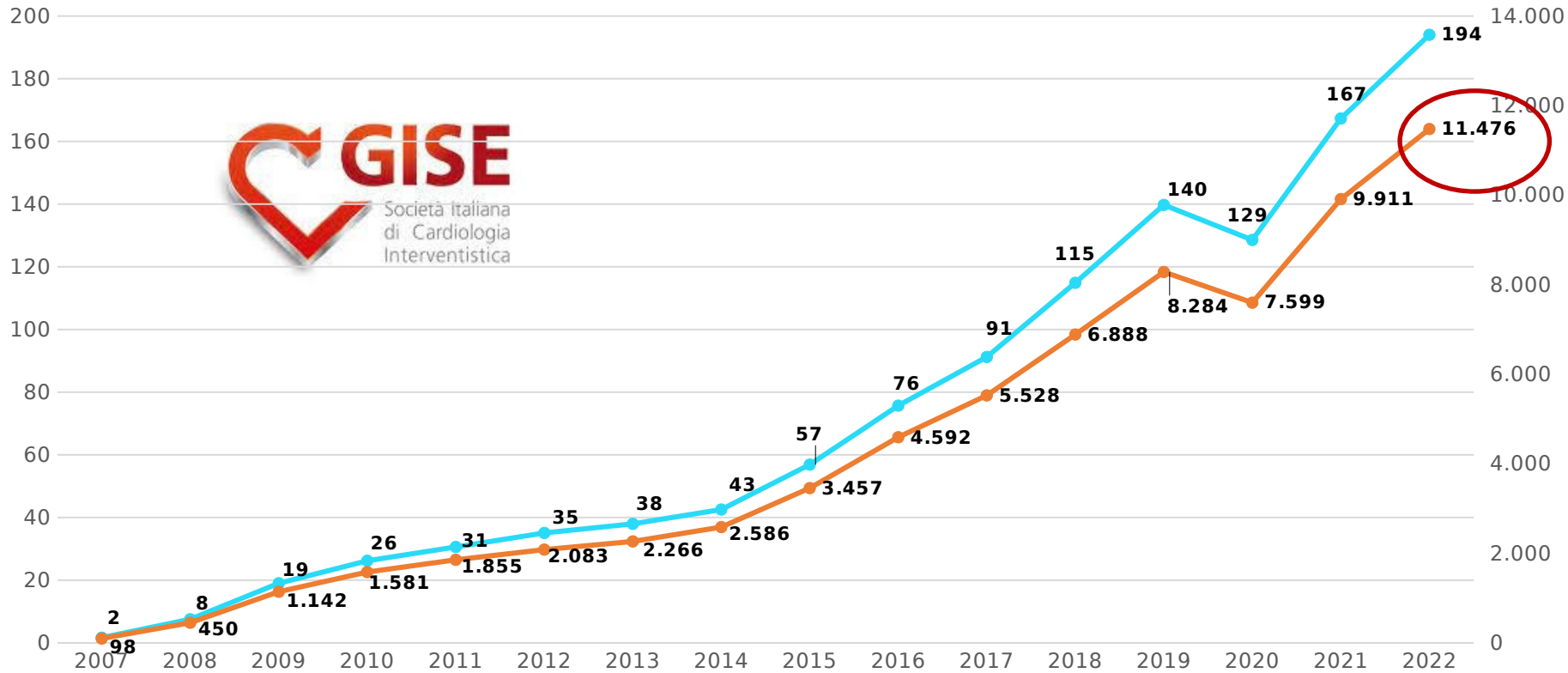
Open issues

- ❖ BICUSPID AORTIC VALVE
- ❖ SMALL ANNULUS (BEV VS. SEV)
- ❖ LVOT CALCIFICATION
- ❖ HOSTILE ACCESS (PTA-ASSISTED VS. ALTERNATIVE)
- ❖ TREATMENT OF CAD IN TAVI PTS
- ❖ BIOPROSTHESIS VALVE FRACTURE

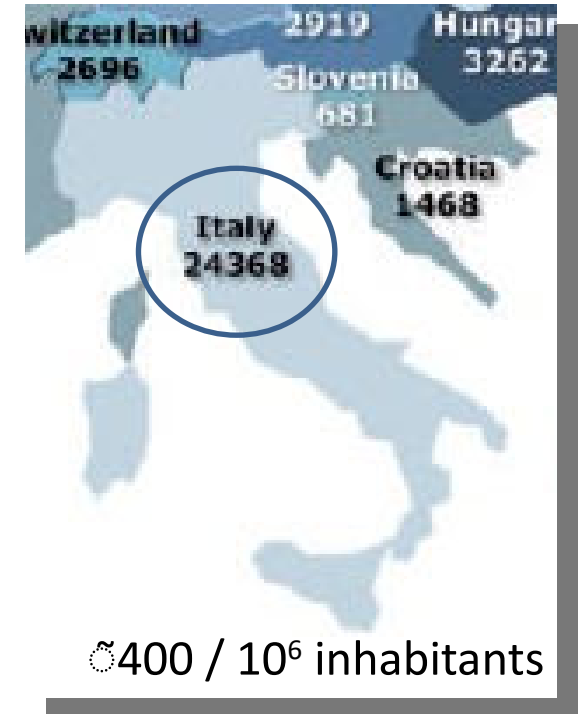
- ❖ HEART VALVE CENTER
- ❖ TAVI PATHWAY OPTIMIZATION
- ❖ TAVI WITHOUT ON SITE CARDIAC SURGERY
- ❖ FUNDING AND SUSTAINABILITY
- ❖



The Italian landscape



Present indications



400 / 10⁶ inhabitants

Durko AP. EHJ 2018

ITALIA N° IMPIANTI TAVI PER MILIONE DI ABITANTI N° IMPIANTI

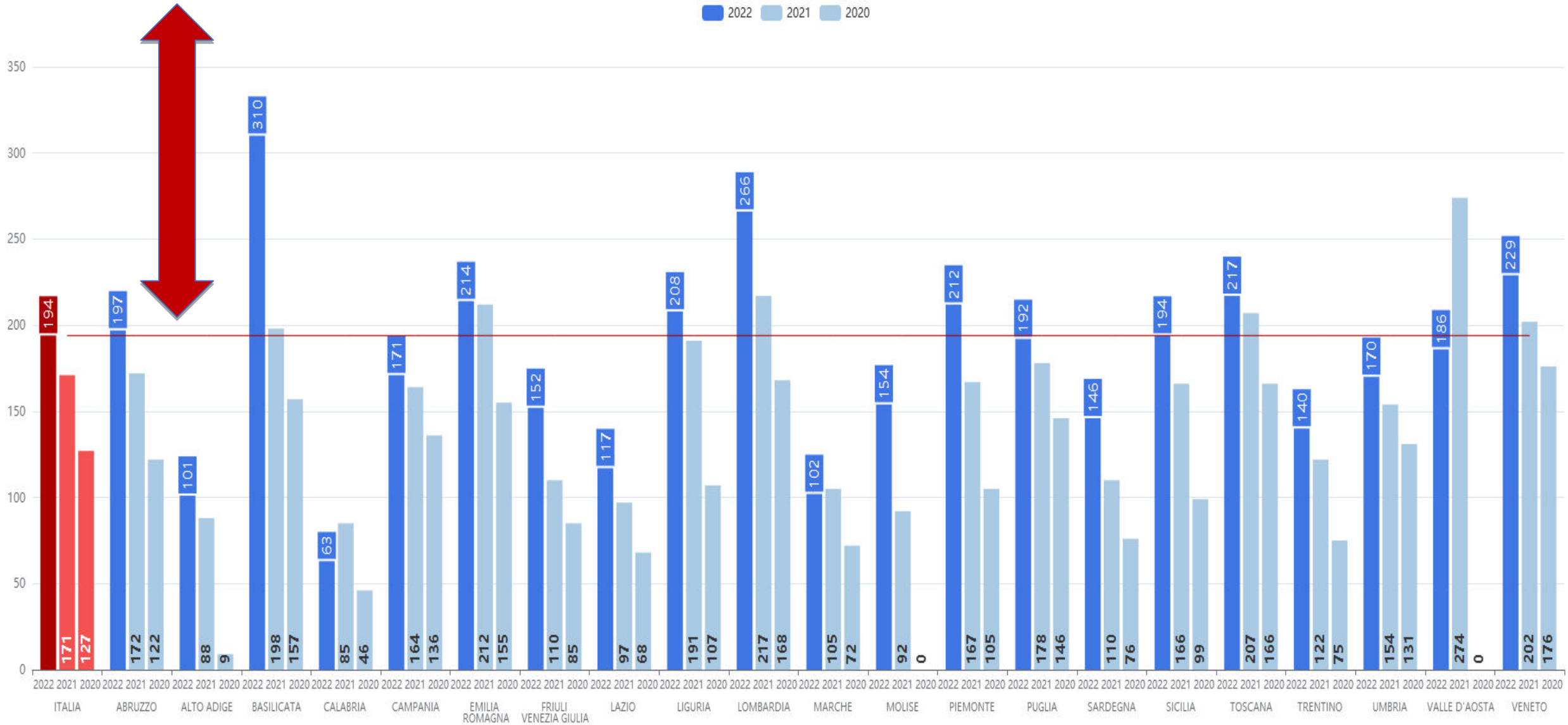
Dati attività GISE



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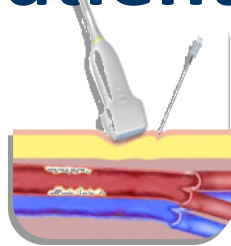
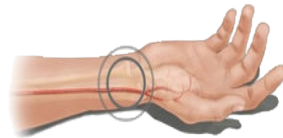

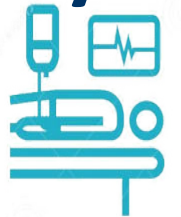


Target 400 / 10⁶ inhab. ?





- **Cardiac surgery on-site**
- Established **Heart Team**
- Entire spectrum of valve procedures available
- **High-volume** for hospital and operators
- Heart Valve clinic for outpatient and follow-up
- Continuous data review and evaluation and audits
- Education program

Optimization of in-H TAVI pathway

- Local anesthesia / sedation / patient fully awake
- Echo-guided vascular access 
- Secondary access radial 
- Early removal of temporary PM or LV wire pacing 
- No CCU after procedure  
- Early mobilization and discharge 

Benchmark for TAVI in 2023



1%

30-day
Mortality

1%

30-day
Stroke

1.5%

30-day
Major
Vascular
Complications



6-10%

30-day
Permanent
Pacemaker

<1%

Paravalvular
leak > 2+

FAST-TAVI, 3M and BENCHMARK studies

	FAST-TAVI	3M TAVR	BENCHMARK registry
Numbers	<ul style="list-style-type: none"> - 502 patients - 10 centers - 3 countries  	<ul style="list-style-type: none"> - 411 patients - 13 centers - 2 countries  	<ul style="list-style-type: none"> - 2400 pts - 28 centers - 7 countries
Study population	<ul style="list-style-type: none"> - Prospective all-commer registry - All TF TAVI patients with SAPIEN 3 - No exclusion criteria 	<ul style="list-style-type: none"> - Prospective case series - Selected TF TAVI with balloon exp. valves - 12 exclusion criteria 	<ul style="list-style-type: none"> - Prospective and retrospective registry - Implementation of 8 best practices
Study duration	<ul style="list-style-type: none"> - 12 months - Follow-up: 1-week, 30-days, 1-year 	<ul style="list-style-type: none"> - 14 months - Follow-up: 2-weeks, 30-days, 1-year 	<ul style="list-style-type: none"> - 30-day - 12-month fup to come
Results	<ul style="list-style-type: none"> - 73% of patients discharged with 72 hours - 30-day mortality: 1.1% - Rehospitalization 8.9% (early discharge cohort) 	<ul style="list-style-type: none"> - 80% selected patients discharged on day 1 	<ul style="list-style-type: none"> - LBCT EUROPCR 2023 - 2 days reduction LOS - Reduction ICU staying - Safety confirmed

Barbanti M et al. EuroIntervention. 2019; 15 :147-154

Wood DA et al. JACC Cardiovasc Interv. 2019;12:459-469

Frank D. EuroPCR 2023



Same-day discharge

 **Corrado Tamburino** · 2° [+ Segui](#)
Head of Cardio-Thoracic-Vascular and Transplant Science Department pres...
4 giorni · 🌐

My first case of same day discharge after TAVI. We started early mobilisation (4-6 hrs) few weeks ago and now are moving to very early discharge. Proud running an excellent and dynamic team. Special thanks to Carmelo Sgroi, Marco Barbanti, Giuliano Costa and all nurse and physician personnel of cathlab and wards of Policlinico University Hospital in Catania.

[Vedi traduzione](#)

 00:50

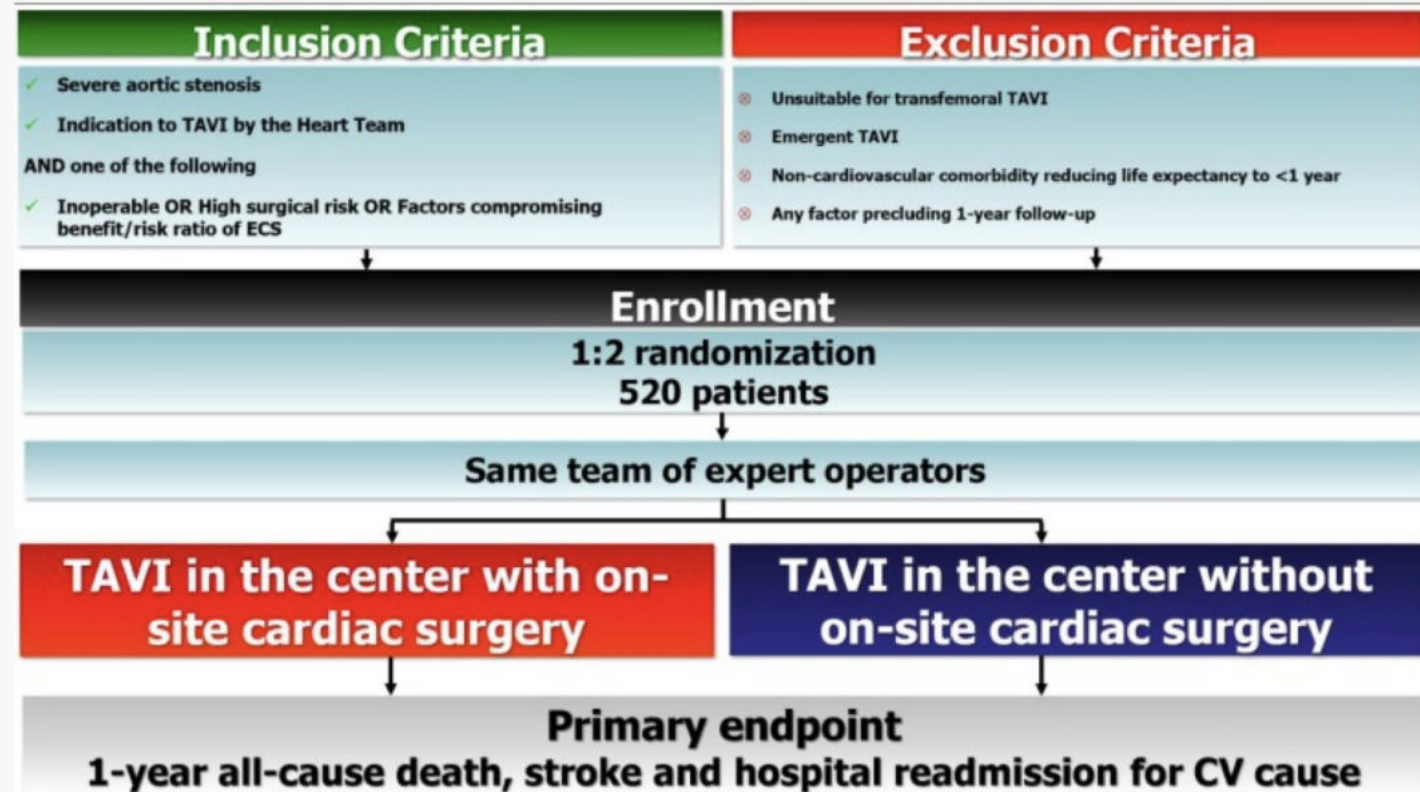
   84 2 commenti

TAVI without on-site cardiac surgery?

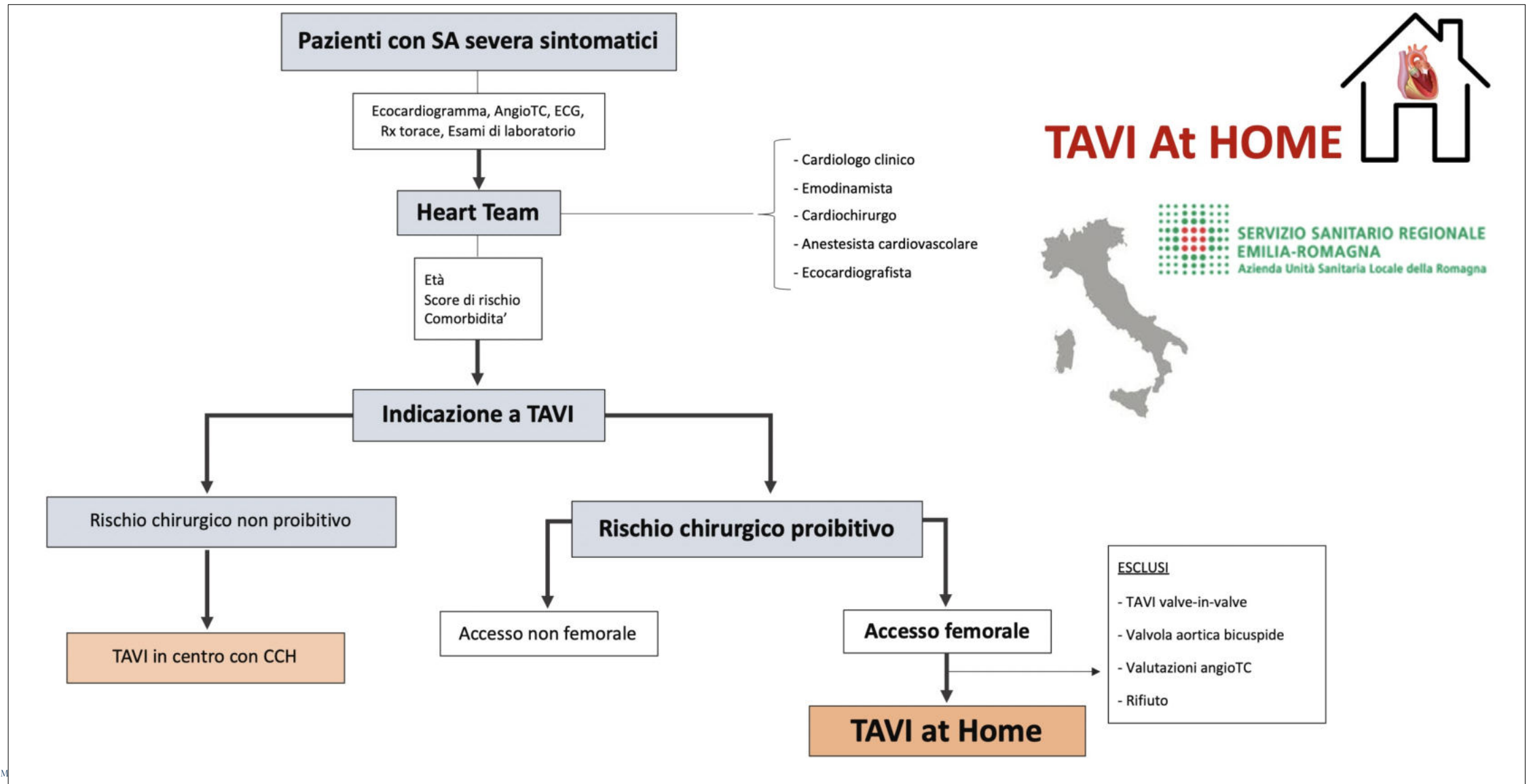


**Transcatheter Aortic-Valve
Implantation with or without on-site
Cardiac Surgery (TRACS) trial**

Study Flow



TAVI without on-site cardiac surgery?





Modelli di procurement evoluti

- Accordi di condivisione del rischio
 - Outcome-based model (pay per performance)*
- Offerte disease management comprensiva di prodotti e servizi

GARA PER LA FORNITURA DI VALVOLE CARDIACHE PER LE PUBBLICHE AMMINISTRAZIONI – II Edizione

19. Qual è il contenuto innovativo della Vostra offerta in merito alla merceologia oggetto di indagine? Vi invitiamo ad indicare la presenza di nuovi prodotti, nuove soluzioni o nuovi servizi, anche in ottica di “Value Based Procurement”, che apportino una maggiore efficacia ed efficienza, una riduzione degli impatti ambientali o benefici sociali nei confronti dei propri lavoratori, dei clienti, della società.

20. Qualora siano presenti contenuti afferenti al Value Based Procurement, descrivere una applicazione pratica per la merceologia oggetto di indagine oppure riportare degli esempi già realizzati in contesti simili.

21. In caso di implementazione di un approccio di tipo “value based” quali ritenete possano essere gli esiti clinici da considerare? E in che modo possono essere misurati?

TAVI with “hostile” access



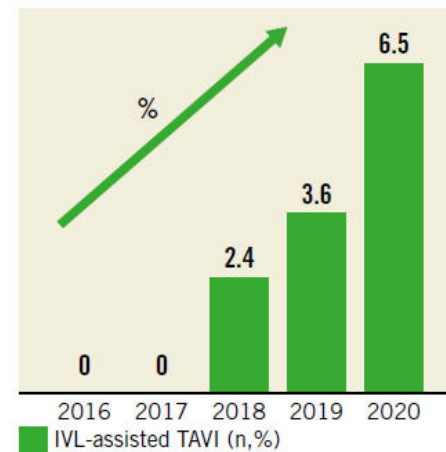
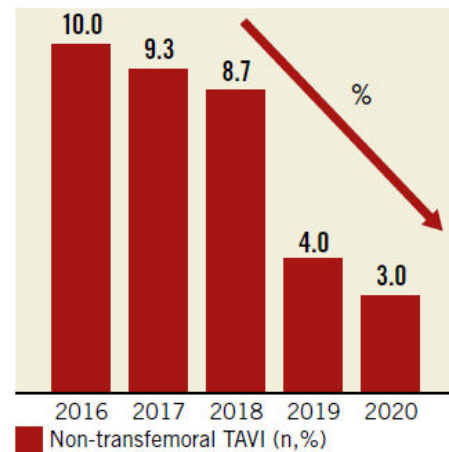
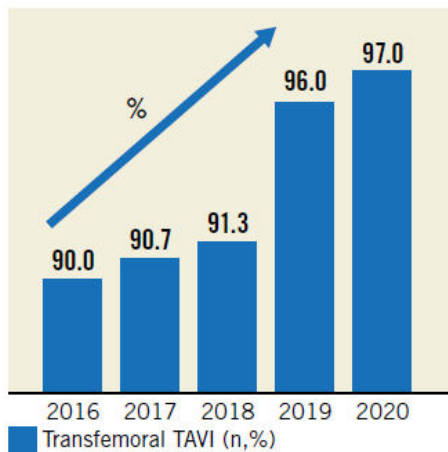
PERIPHERAL INTERVENTIONS
CLINICAL RESEARCH

■ EuroIntervention 2021;17-online-publi-sh-a

Peripheral intravascular lithotripsy of iliofemoral arteries to facilitate transfemoral TAVI: a multicentre prospective registry

Giulia Nardi¹, MD; Ole De Backer², MD, PhD, MBA, FESC; Francesco Saia³, MD, PhD; Lars Søndergaard², MD, DMSc; Francesca Ristalli¹, MD; Francesco Meucci¹, MD; Miroslava Stolcova¹, MD; Alessio Mattesini¹, MD; Pierluigi Demola¹, MD; Xi Wang^{2,4}, MD; Anees Al Jabri⁵, MD; Tullio Palmerini³, MD; Antonio Giulio Bruno³, MD, FISC; Alfonso Ielasi⁶, MD, FESC; Eric Van Belle⁷, MD, PhD, FESC, FACC; Sergio Berti⁵, MD; Carlo di Mario^{1*}, MD, PhD, FACC, FSCAI, FRCPC, FESC

- 6 high-volume European centres (2018-2020)
- 108 patients, increasing from **2.4% to 6.5%** of all TAVI from 2018 to 2020
- Transfemoral aortic valve delivery was successful in **100%** of cases
- IVL-associated **VC 3.7%**: 1 perforation and 3 major dissections requiring stent implantation (2 covered stents and 2 BMS)



3.5 x 5.9 mm

2.3 x 4.9 mm

5.1 x 6.2 mm

Coin Ø
Area

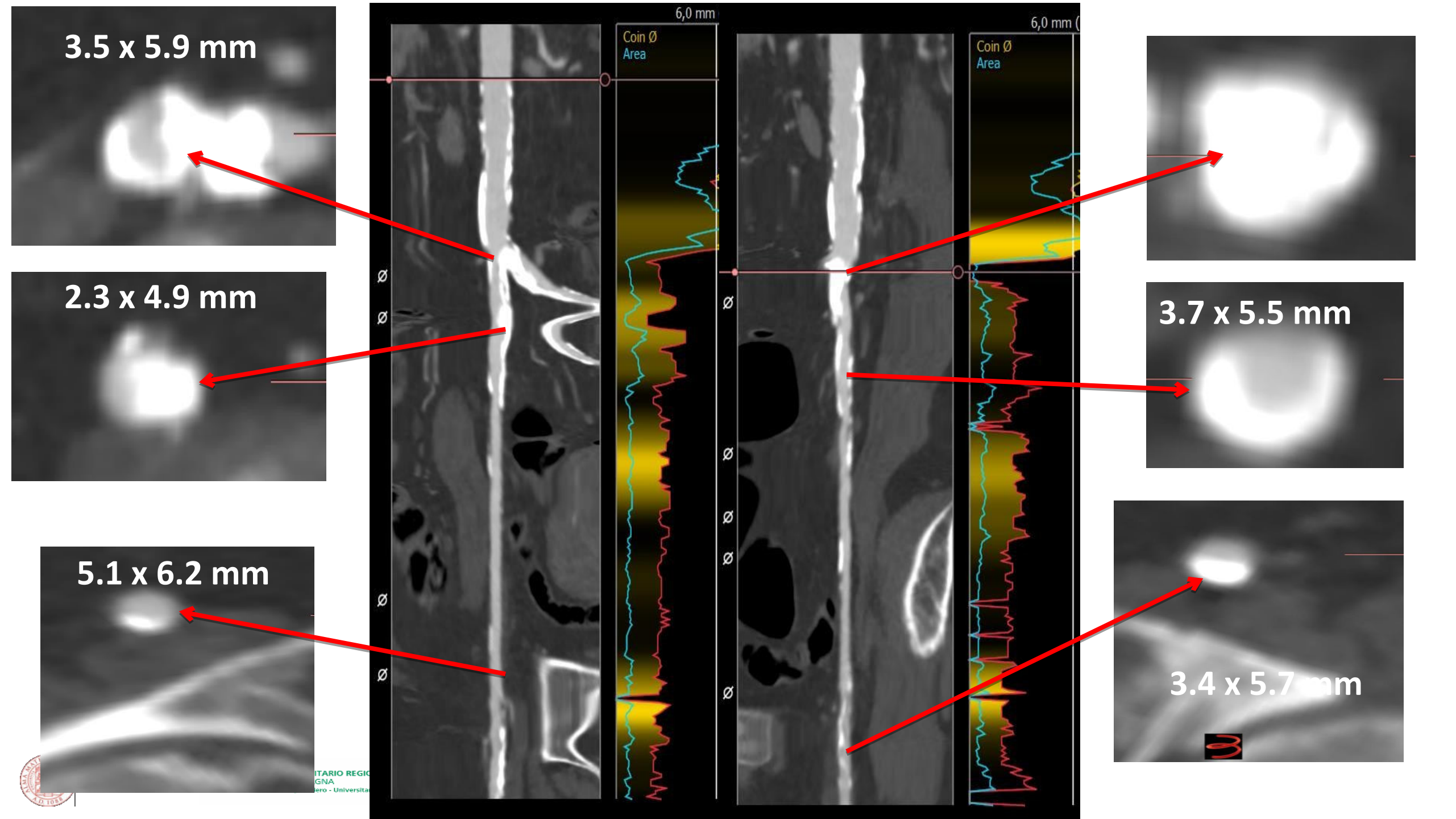
6,0 mm

Coin Ø
Area

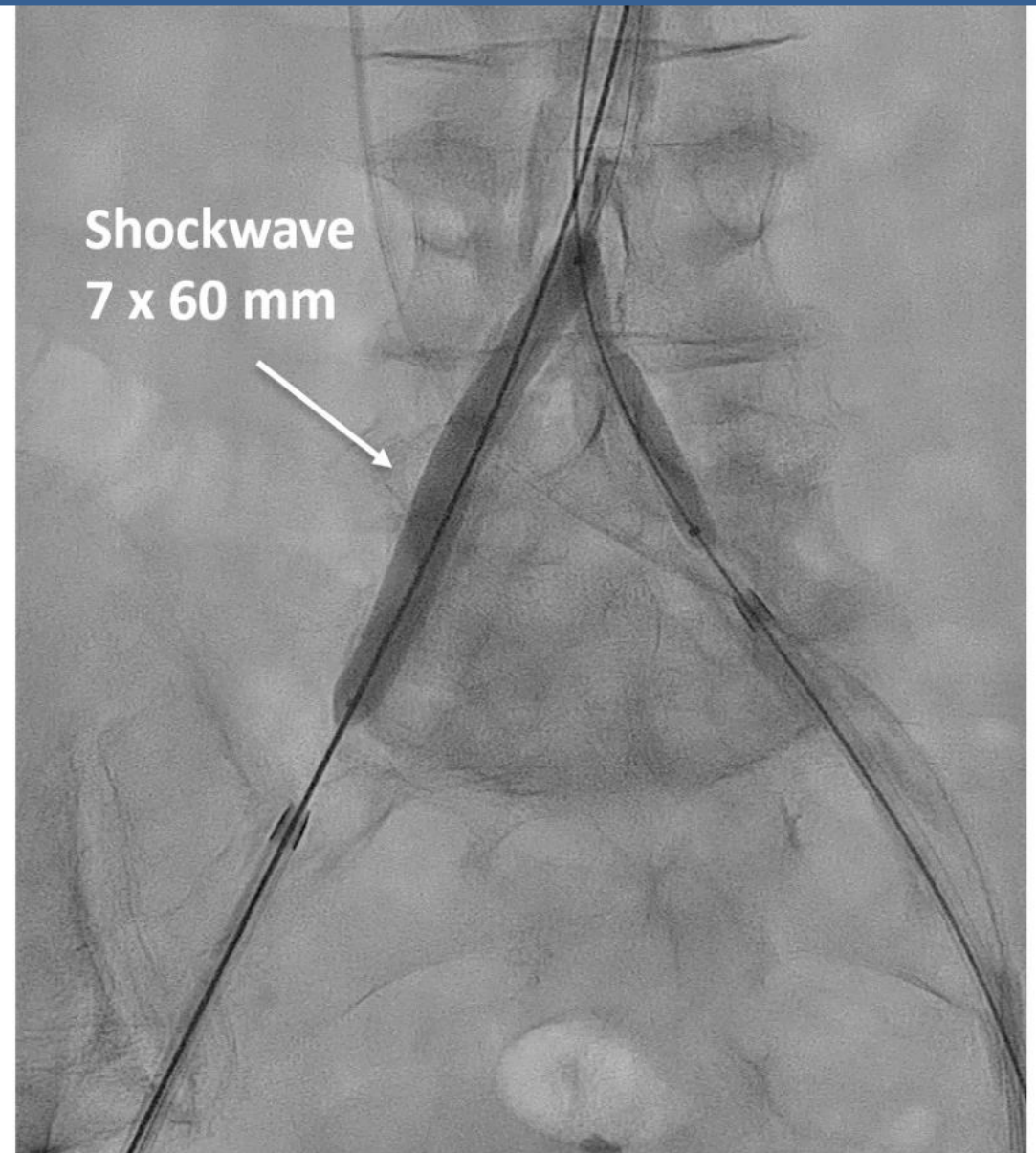
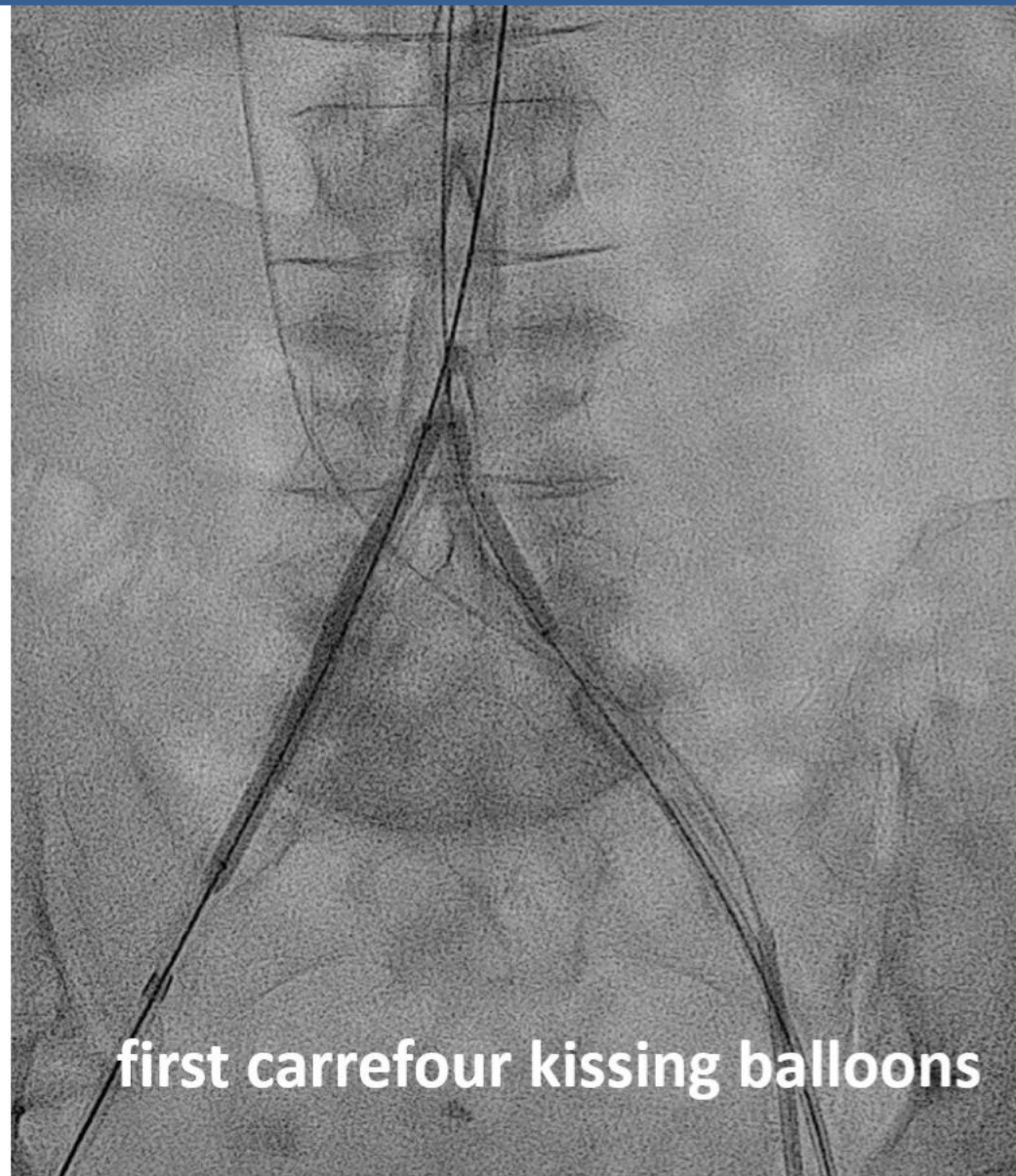
6,0 mm

3.7 x 5.5 mm

3.4 x 5.7 mm



TAVI with “hostile” access



TAVI with “hostile” access

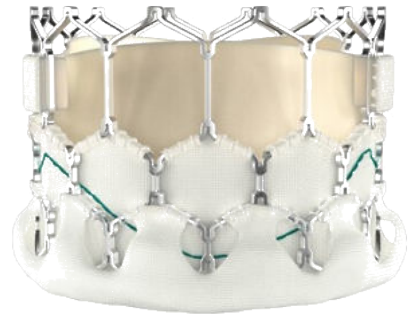


Current THV technology

BALLOON-EXPANDABLE



Sapien 3 / S3 Ultra



Myval

SELF-EXPANDING



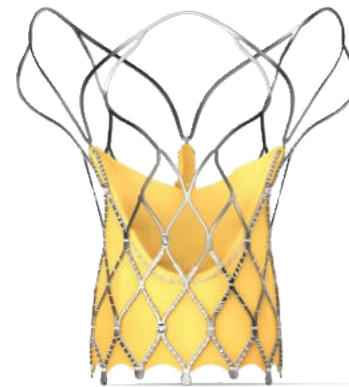
Evolut Pro / Pro+



Portico / Navitor



Acurate Neo 2



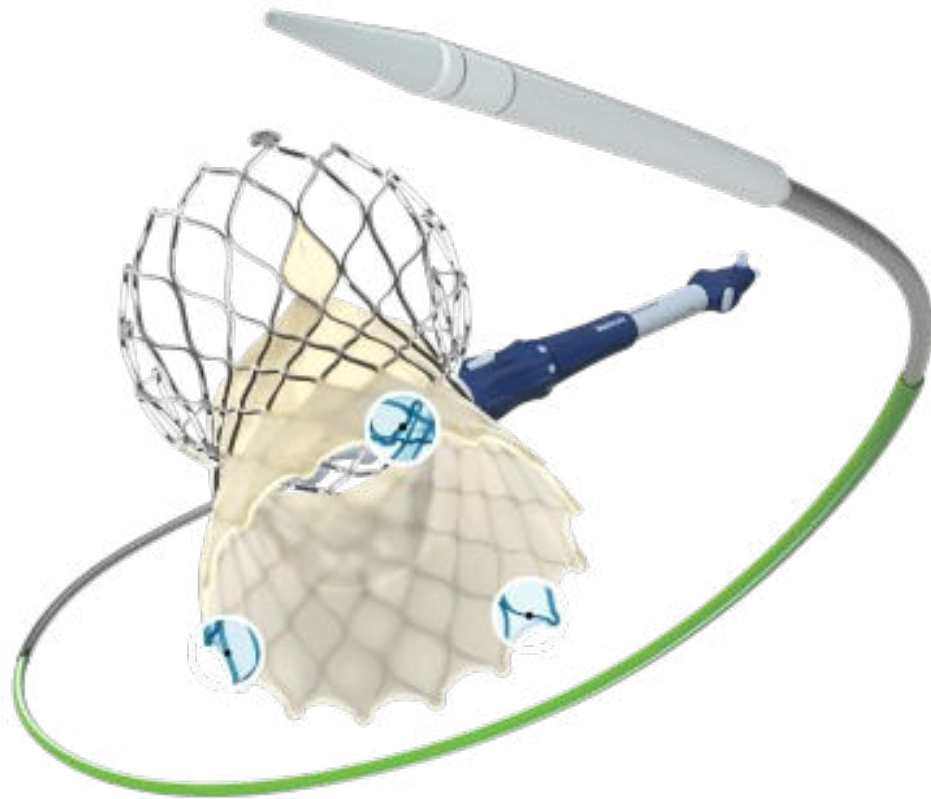
Hydra (SMT)



Allegra (NVT)

Latest-generation THVs

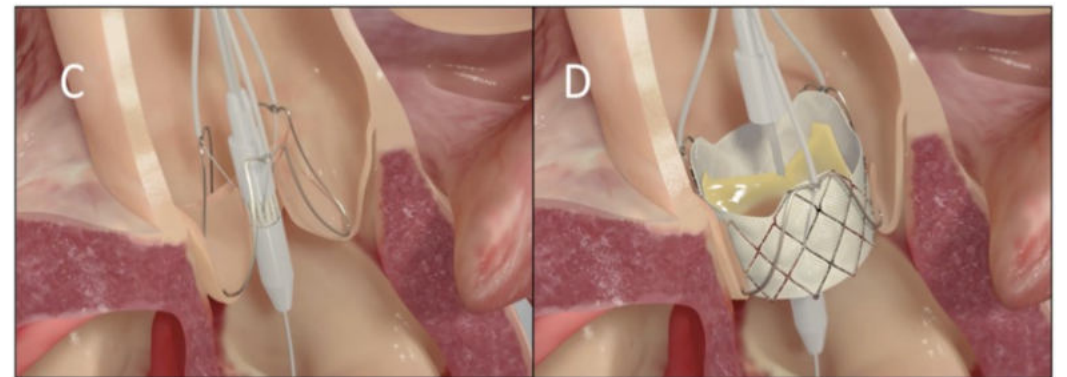
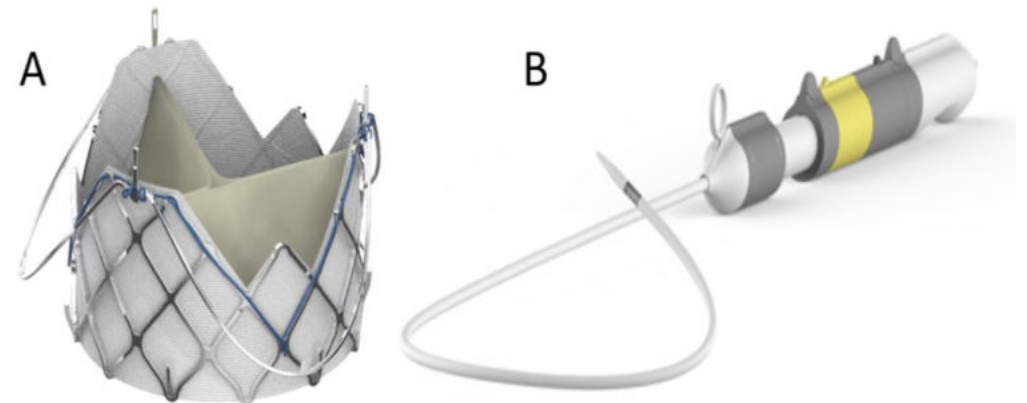
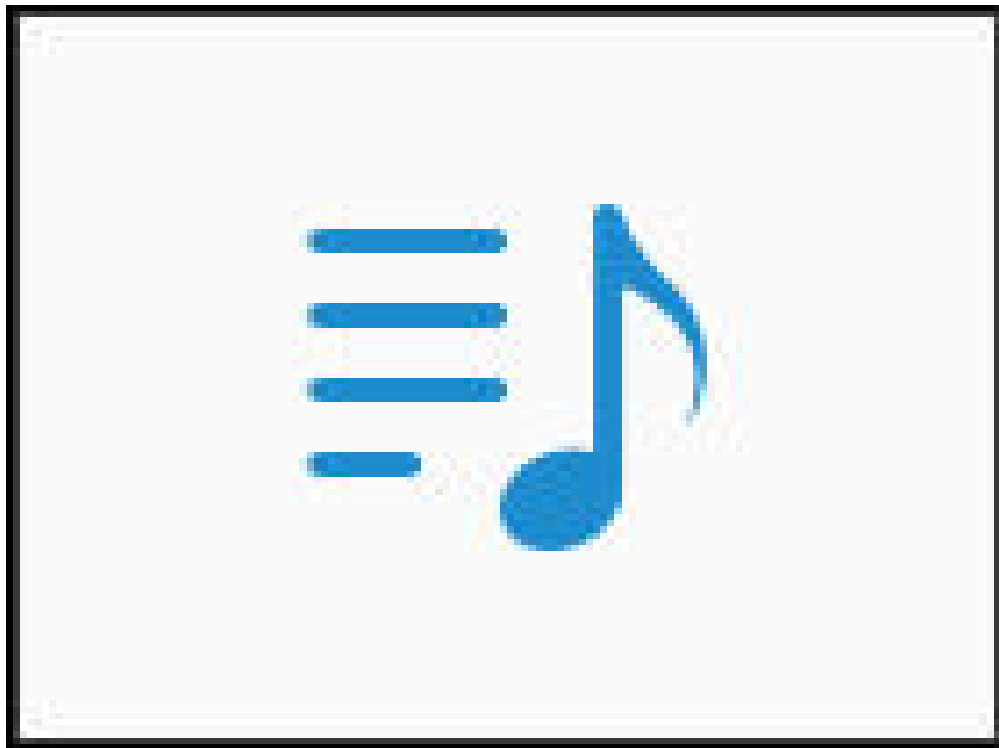
EVOLUT FX



SAPIEN X4



TAVI in pure AR: dedicated THV



DurAVR™ 3D Single-piece THV System

Designed for Lifetime Management of AS Patients

Designed to Last Longer & Work Better

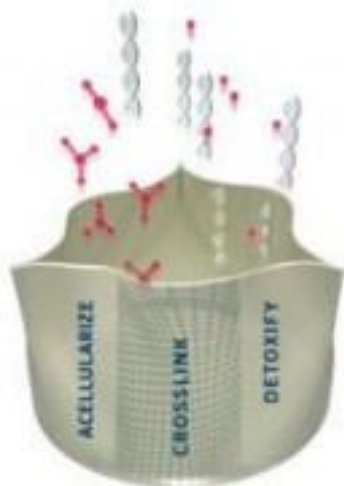
NEAR-NORMAL HEMODYNAMICS

Unique 3D single-piece valve design with large EOA,
85% greater coaptation and 35% less stress**

PROVEN TISSUE DURABILITY

Superior anti-calcification tissue process
(ADAPT®)*

- DNA and glutaraldehyde free
- 10 years of no calcification in clinical use



PARAVALULAR LEAK SOLUTION

Proven benefits of PET outer skirt

IMPROVED CORONARY ACCESS

Large, open cell geometry

ComASUR™ TF Delivery System

Ability to uniquely rotate valve at the annular level
for predictable commissural alignment



The Foldax TRIA valve



Patented polymer formulated specifically for heart valve function

Addresses ALL requirements for a high performing valve

- Biocompatible
- Biostable
- Biomechanical strength

1st New Polymeric Material in over 40 years

Surgical A + M



TAVR



TAVR uses same computer designed leaflet SAVR/SMVR

Intervention in all patients with asymptomatic severe AS

EARLY-TAVR

Patients with asymptomatic severe aortic stenosis
(age >65 years, trileaflet valve morphology)



Patient suitable for transfemoral TAVI



RANDOMISATION (n=1109)

EARLY INTERVENTION
(TAVI only)

ROUTINE CARE

2 years follow-up
All-cause mortality, all stroke and unplanned cardiovascular hospitalisation

Targeted intervention to patients with severe AS and LV decompensation

EVoLveD

Patients with asymptomatic severe aortic stenosis



Screening for LV decompensation

Elevated hs-troponin or ECG strain



CMR to confirm LV decompensation

Mid-wall fibrosis



RANDOMISATION (n=400-500)

EARLY INTERVENTION

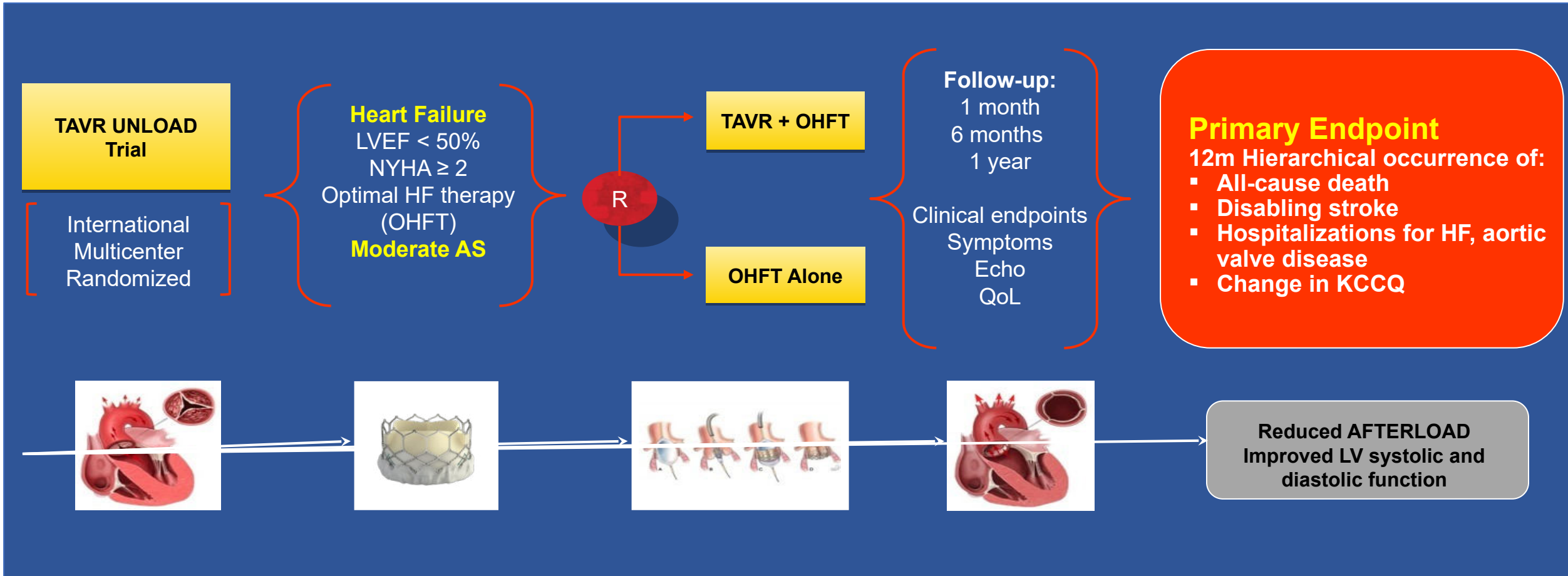
ROUTINE CARE

3 years follow-up
All-cause mortality and unplanned aortic-stenosis related hospitalisation

TAVR UNLOAD Trial

Study Design

(600 patients, 1:1 Randomized)



HOT TOPICS IN CARDIOLOGIA 2023

13 e 14 Novembre 2023

Villa Doria D'Angri
Via F. Petrarca 80, Napoli

Presidente del congresso: Dr. Ciro Mauro

Direttore UOC di Cardiologia UTIC con emodinamica
AORN Cardarelli, Napoli



GRAZIE