

BIELLA CUORE

2025



**12-13
SETTEMBRE 2025**

Agorà Palace Hotel - Biella



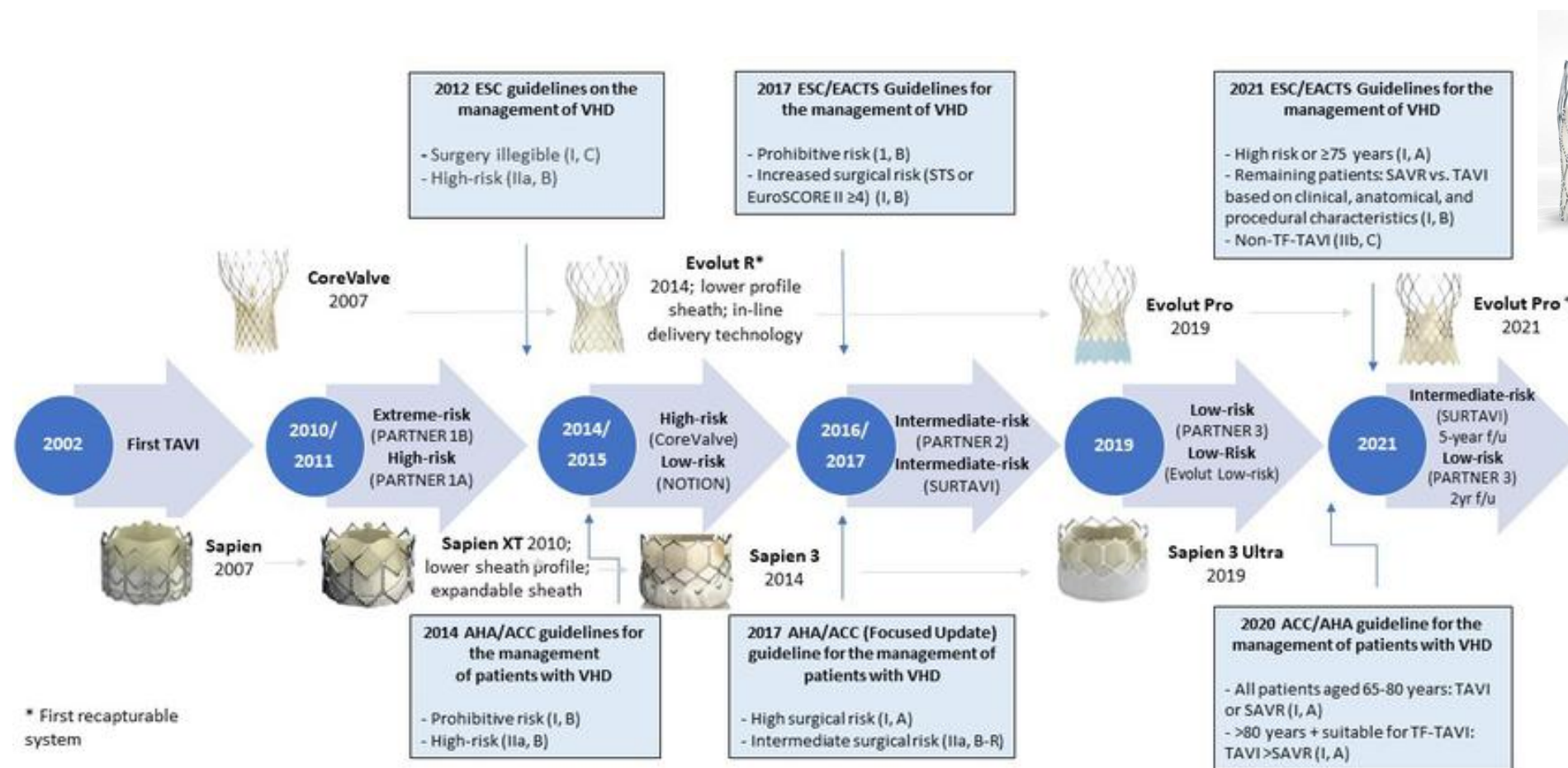
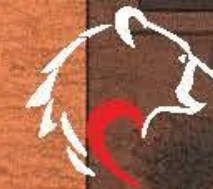
TAVI: Prospettive Future

**Vincenzo A. Galiffa
AOU Maggiore della Carità Novara**



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Navitor

2025 ESC/EACTS Guidelines for the management of valvular heart disease

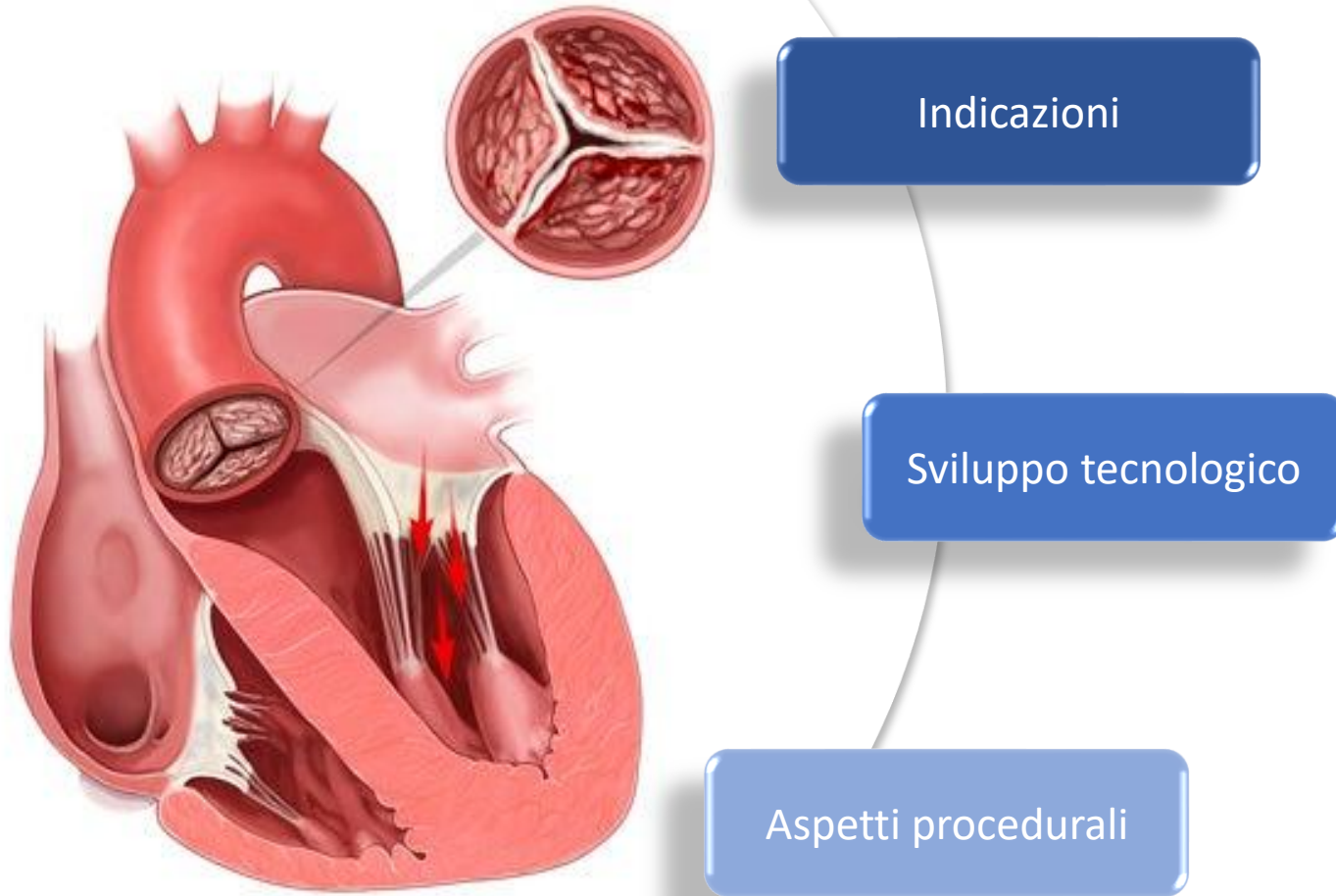
Developed by the task force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)



Myval

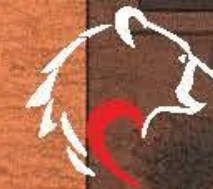
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Indicazioni

2025 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)

Mode of intervention

It is recommended that AV interventions are performed in Heart Valve Centres that report their local expertise and outcome data, have on-site interventional cardiology and cardiac surgical programmes, and a structured collaborative Heart Team.

I

C

It is recommended that the mode of intervention is based on Heart Team assessment of individual clinical, anatomical, and procedural characteristics, incorporating lifetime management considerations and estimated life expectancy.

I

C

TAVI is recommended in patients ≥ 70 years of age with tricuspid AV stenosis, if the anatomy is suitable.^{d 1–4,389–397,465,485,486}

I

A

SAVR is recommended in patients < 70 years of age, if the surgical risk is low.^{e 413,429,487}

I

B

SAVR or TAVI are recommended for all remaining candidates for an aortic BHV according to Heart Team assessment.^{2,4,396,397,429,488–490}

I

B

Non-transfemoral TAVI should be considered in patients who are unsuitable for surgery and transfemoral access.^{417–423,491–498}

IIa

B

TAVI may be considered for the treatment of severe BAV stenosis in patients at increased surgical risk, if the anatomy is suitable.^{430–432,434,499–502}

IIb

B

Balloon aortic valvotomy may be considered as a bridge to SAVR or TAVI in haemodynamically unstable patients, and (if feasible) in those with severe AS who require urgent high-risk NCS.

IIb

C

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Original Investigation

Self-expanding Transcatheter vs Surgical Aortic Valve Replacement in Intermediate-Risk Patients 5-Year Outcomes of the SURTAVI Randomized Clinical Trial

Nicolas M. Van Mieghem, MD, PhD¹; G. Michael Deeb, MD^{2,3}; Lars Søndergaard, MD, PhD^{4,5}; [et al](#)

» [Author Affiliations](#) | [Article Information](#)

2025 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)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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

Jeffrey J. Popma, M.D., G. Michael Deeb, M.D., Steven J. Yakubov, M.D., Mubashir Mumtaz, M.D., Hemal Gada, M.D., Daniel O'Hair, M.D., Tanvir Bajwa, M.D., John C. Heiser, M.D., William Merhi, D.O., Neal S. Kleiman, M.D., Judah Askew, M.D., Paul Sorajja, M.D., Joshua Rovin, M.D., Stanley J. Chetcuti, M.D., David H. Adams, M.D., Paul S. Teirstein, M.D., George L. Zorn III, M.D., John K. Forrest, M.D., Didier Tchétché, M.D., Jon Resar, M.D., Antony Walton, M.D., Nicolo Piazza, M.D., Ph.D., Basel Ramlawi, M.D., Newell Robinson, M.D., George Petrossian, M.D., Thomas G. Gleason, M.D., Jae K. Oh, M.D., Michael J. Boulware, Ph.D., Hongyan Qiao, Ph.D., Andrew S. Mugglin, Ph.D., and Michael J. Reardon, M.D., for the Evolut Low Risk Trial Investigators*

Heart Valve Cent
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surgical risk is low
s for an aortic B
to are unsuitable
stenosis in patient
AVR or TAVI in f

The NEW ENGLAND JOURNAL of MEDICINE

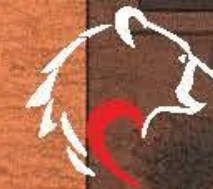
ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years

M.J. Mack, M.B. Leon, V.H. Thourani, P. Pibarot, R.T. Hahn, P. Genereux, S.K. Kodali, S.R. Kapadia, D.J. Cohen, S.J. Pocock, M. Lu, R. White, M. Szerlip, J. Ternacle, S.C. Malaisrie, H.C. Herrmann, W.Y. Szeto, M.J. Russo, V. Babaliaros, C.R. Smith, P. Blanke, J.G. Webb, and R. Makkar, for the PARTNER 3 Investigators*

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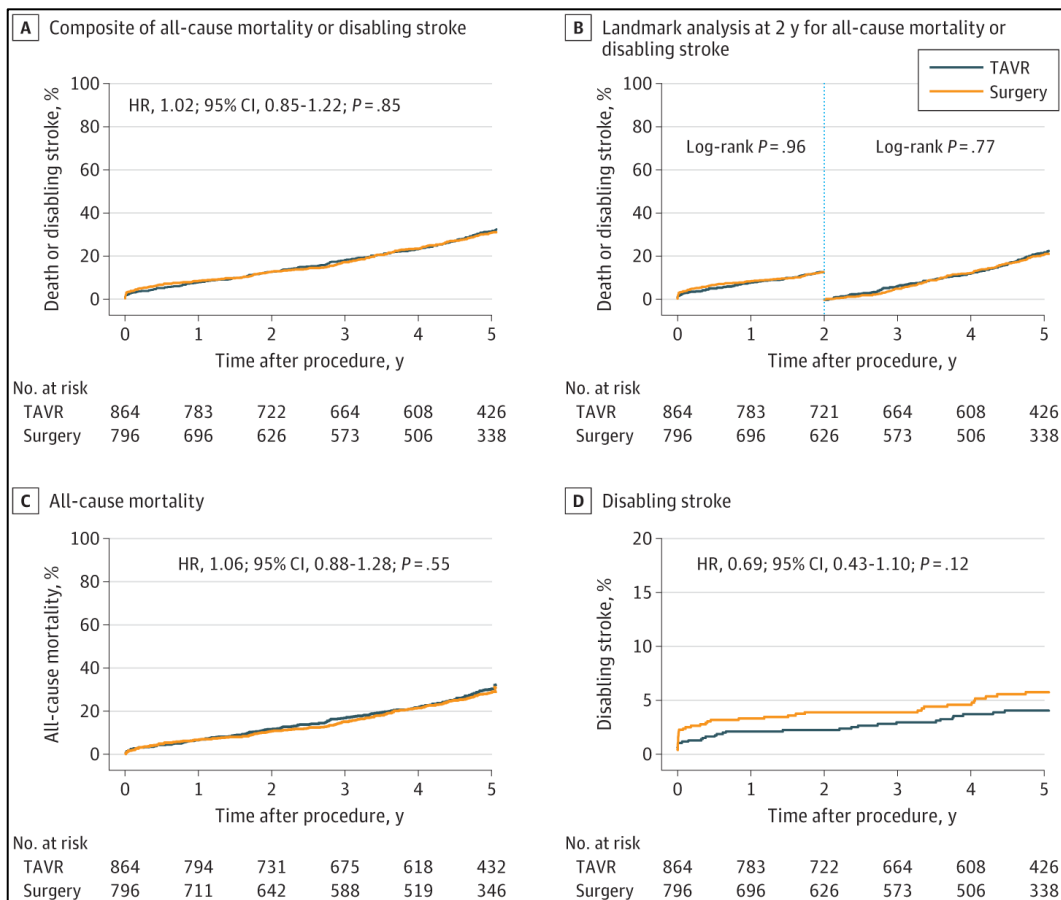
Original Investigation

Self-expanding Transcatheter vs Surgical Aortic Valve Replacement in Intermediate-Risk Patients

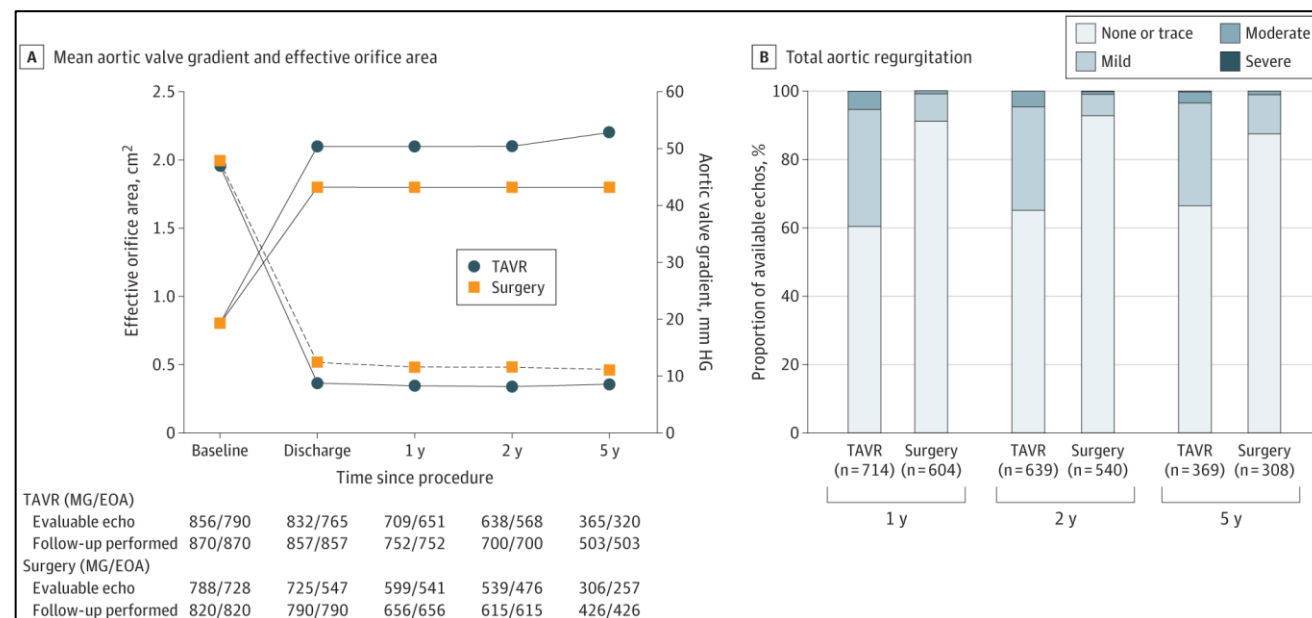
5-Year Outcomes of the SURTAVI Randomized Clinical Trial

Nicolas M. Van Mieghem, MD, PhD¹; G. Michael Deeb, MD^{2,3}; Lars Søndergaard, MD, PhD^{4,5}; et al

► Author Affiliations | Article Information



- 1660 pz con stenosi aortica a rischio intermedio (STS-PROM) randomizzati a TAVI vs SAVR
- TAVI con valvole autoespandibili sopranulari



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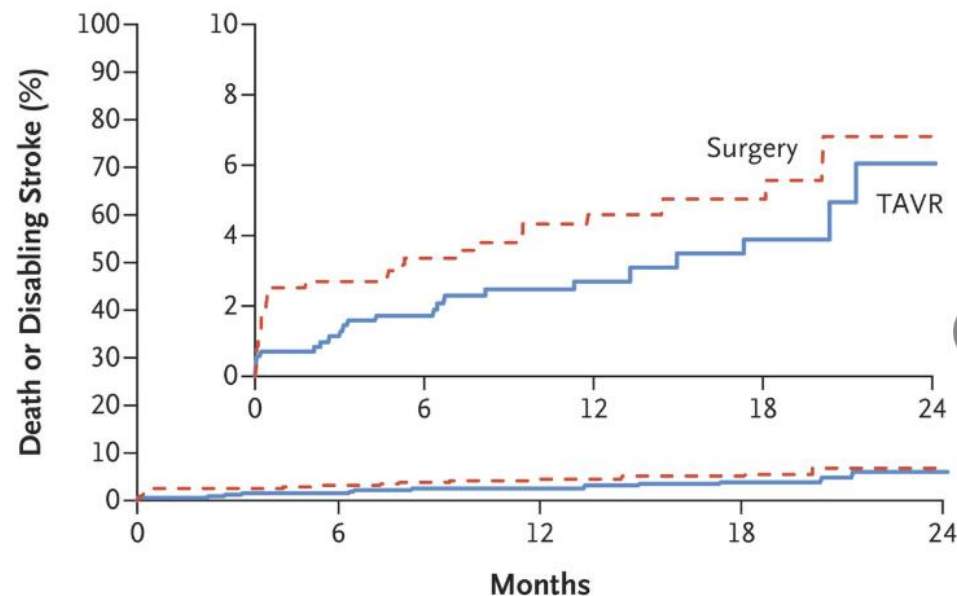
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Tanvir Bajwa, M.D., John C. Heiser, M.D., William Merhi, D.O.,

- 1468 pz con stenosi aortica a basso rischio randomizzati a TAVI vs SAVR
- TAVI con valvole espandibili sopranulari
- Età media 74 anni
- Endpoint composito: morte per tutte le cause e stroke disabilitante

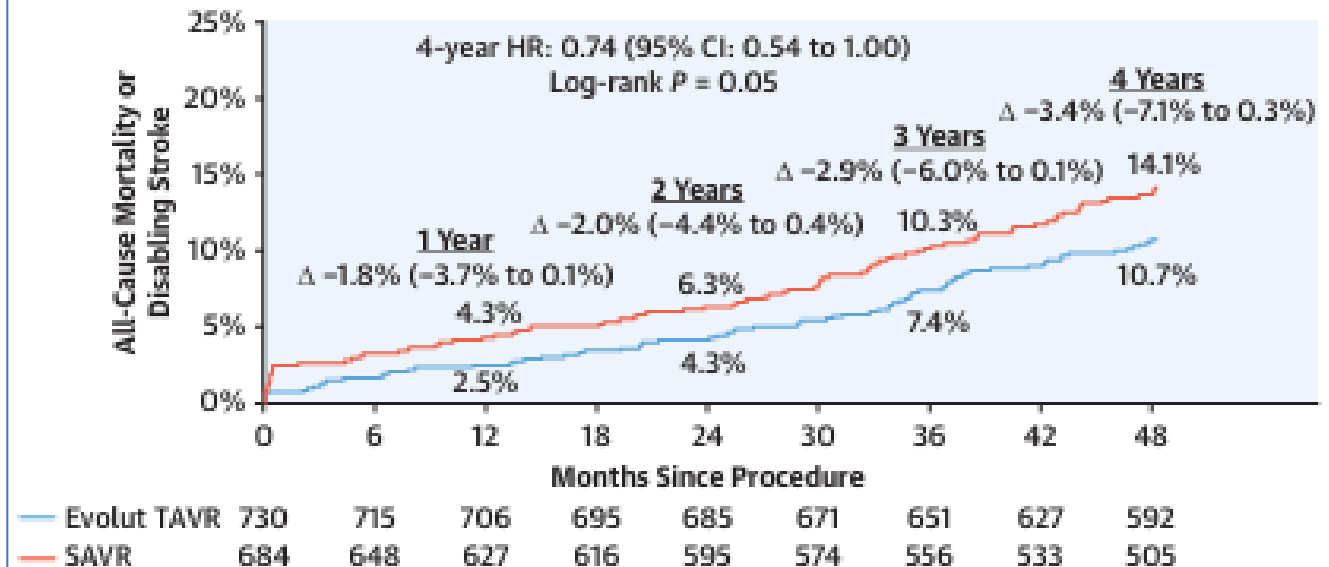
B Incidence of Primary End Point



No. at Risk

Surgery	678	576	366	195	69
TAVR	725	648	435	233	80

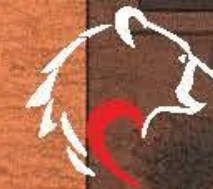
FIGURE 1 Primary Endpoint of All-Cause Mortality or Disabling Stroke Through 4 Years



Kaplan-Meier estimates for all-cause mortality or disabling stroke through 4 years. At 4 years, there was a 26% relative reduction in the hazard ($P = 0.05$) for death or disabling stroke with transcatheter (TAVR) compared with surgical (SAVR) aortic valve replacement, and the curves continued to separate over time. Deltas represent the difference in Kaplan-Meier rates (95% CI) for TAVR vs SAVR.

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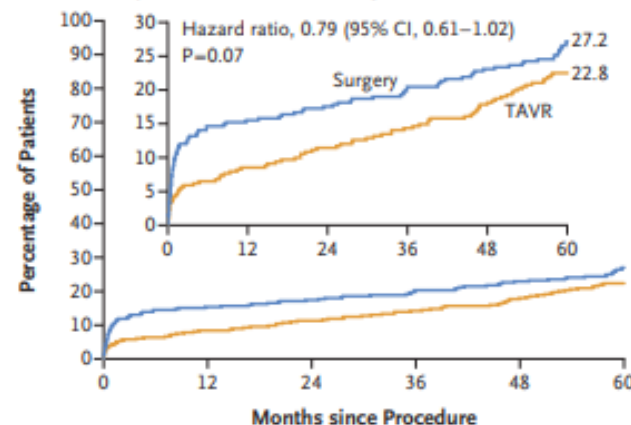
ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years

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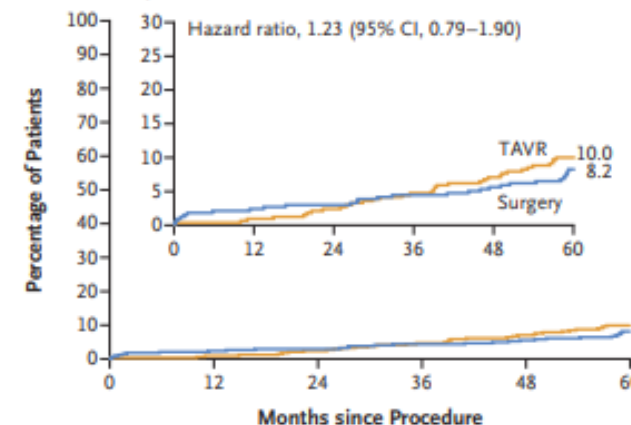
- 1000 pz con stenosi aortica a basso rischio randomizzati a TAVI vs SAVR
- TAVI con valvole balloon-expandable
- Età media 74 anni
- Endpoint composito: morte per tutte le cause, stroke, reospedalizzazione legata all'intervento

A Death from Any Cause, Stroke, or Rehospitalization



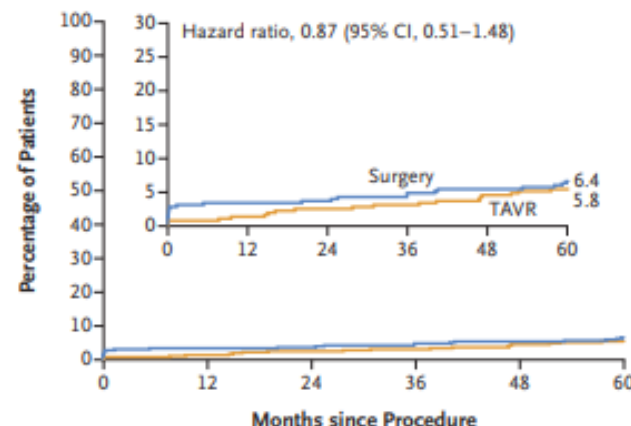
No. at Risk						
Surgery	454	372	349	328	309	276
TAVR	496	453	434	415	391	353

B Death from Any Cause



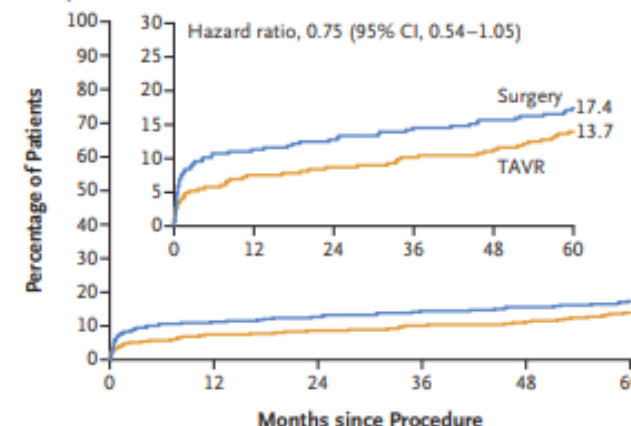
No. at Risk						
Surgery	454	427	409	394	379	346
TAVR	496	490	478	460	438	405

C Stroke



No. at Risk						
Surgery	454	416	397	378	361	329
TAVR	496	486	468	450	428	391

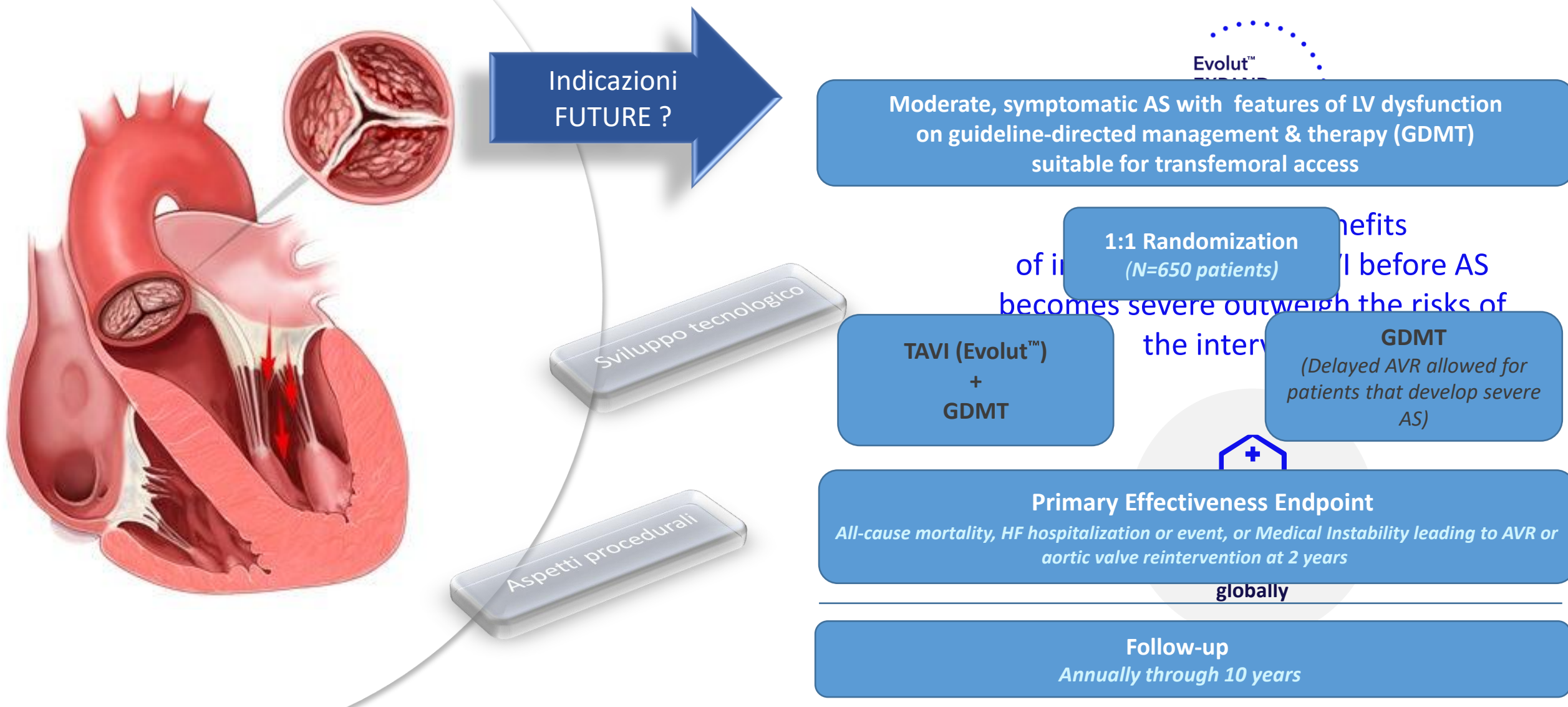
D Rehospitalization



No. at Risk						
Surgery	454	381	359	339	321	289
TAVR	496	455	439	419	396	361

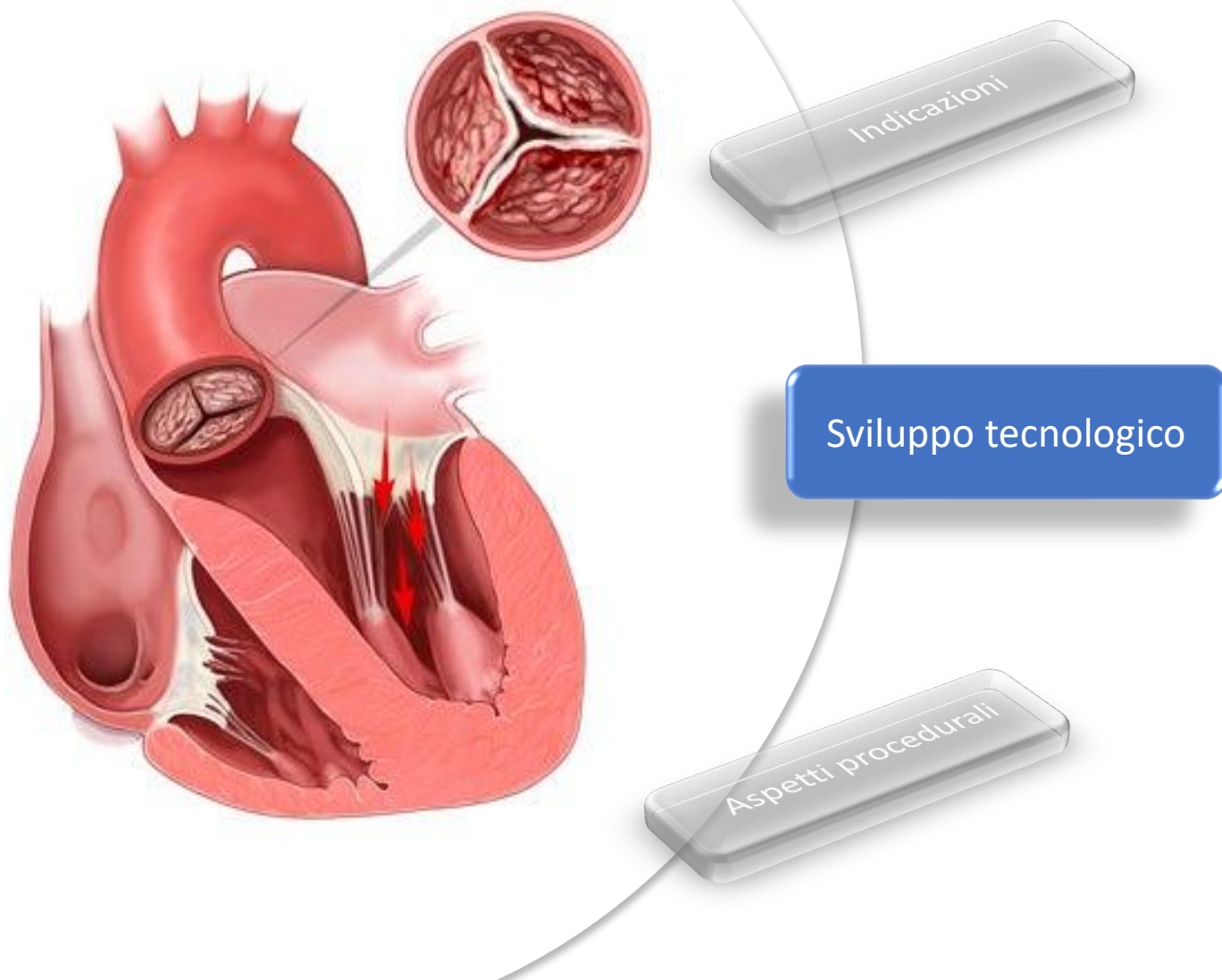
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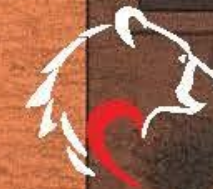
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Miglioramento valvole
attualmente in uso

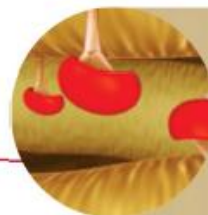
Nuovi dispositivi



SAPIEN 3 Ultra RESILIA valve

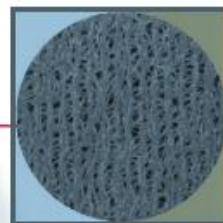
Riduzione progressione
calcificazione

Effectively addressing calcification, a leading cause of tissue valve failure



Advanced calcium-blocking tissue technology^{1,2}

Potential to improve valve longevity and reduce
risk of reintervention



Taller*, textured outer skirt extended to 29mm valve¹

Delivering the PVL results you demand
impacting immediate and long-term outcomes^{3,4}



Only THV with dry tissue storage¹

Mitigates calcium-attracting
glutaraldehyde residuals

PVL, paravalvular leak, *Compared to the SAPIEN 3 transcatheter valve.

1. Data on file
2. De la Fuente et al. Advanced Integrity Preservation Technology Reduces Bioprosthesis Calcification While Preserving Performance and Safety. *Journal of Heart Valve Disease*. 2015.
3. Kodali S et al. Paravalvular regurgitation after transcatheter aortic valve replacement with the Edwards SAPIEN valve in the PARTNER trial: characterizing patients and impact on outcomes. *Eur Heart J*. 2015
4. Makkar R et al. Five-Year Outcomes of Transcatheter or Surgical Aortic-Valve Replacement. *N Engl J Med*. 2020



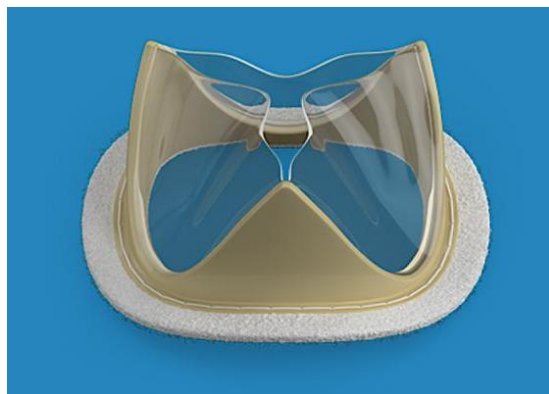
DurAVR



Nuove tecnologie per i foglietti

Valvola composta da un **monoblocco** di pericardio bovino trattato con tecnologia per ridurre le calcificazioni

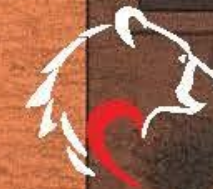
Foldax TRIA



- Costituita da un **polimero sintetico** disegnato per resistere alle calcificazioni e alla formazione di trombi
- Possibile durata per tutta la vita
- Produzione robotizzata
- Telaio con architettura aperta senza montanti tra le commissure, preservando accesso coronarico
- Disponibile sia per chirurgia che per rilascio transcateretere

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Siegel Valve



- Valvola balloon-expandable
- Rilascio transfemorale utilizzando un introduttore espandibile con basso profilo **da 8 Fr**
- Dimensioni 19-27 mm
- Struttura cilindrica in Renio senza accorciamento durante il rilascio
- Nickel-free dry porcine leaflets, rivestimento con ossido nitrico per ridurre le calcificazioni
- Gonnellina per ridurre PVL e marker commissurali per orientamento

Optimum



- Valvola self-espandibile
- Minore altezza tra le self per migliore riaccesso coronarico
- Geometria ottimizzata, disegnata per migliorare durata e dinamica dell'apertura delle cuspidi
- Marker per allineamento commissurale
- Ricatturabile e riposizionabile

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Nuove tecnologie per il trattamento dell'insufficienza aortica severa

TAVI may be considered for the treatment of severe AR in symptomatic patients ineligible for surgery according to the Heart Team, if the anatomy is suitable. ^{264,265,268,269}

IIb

B

- L'uso di valvole transcateretere non dedicate attualmente è **off-label**:
 - rischio di malposizionamento della protesi
 - insufficienza residua
 - necessità di impianto di una seconda valvola o conversione chirurgica)
- **Device dedicati** sembrano minimizzare il rischio di migrazione della valvola e insufficienza residua
- Insufficienza aortica spesso associata a **dilatazione annulus e radice aortica**, minima presenza di calcificazioni che compromettono ancoraggio e stabilità della valvola



Jena Valve Trilogy



J- Valve



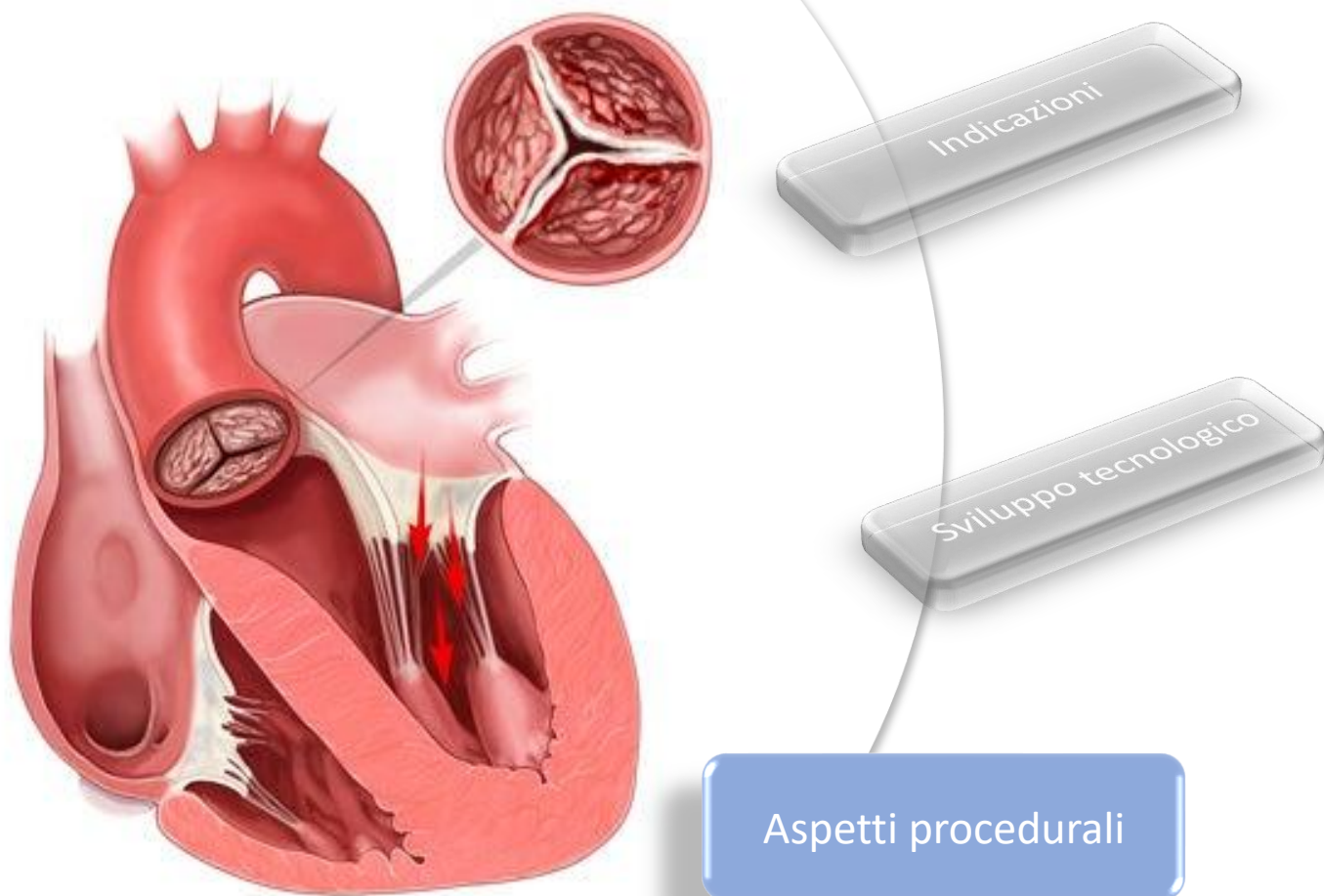
Hancor Valve



Cusper

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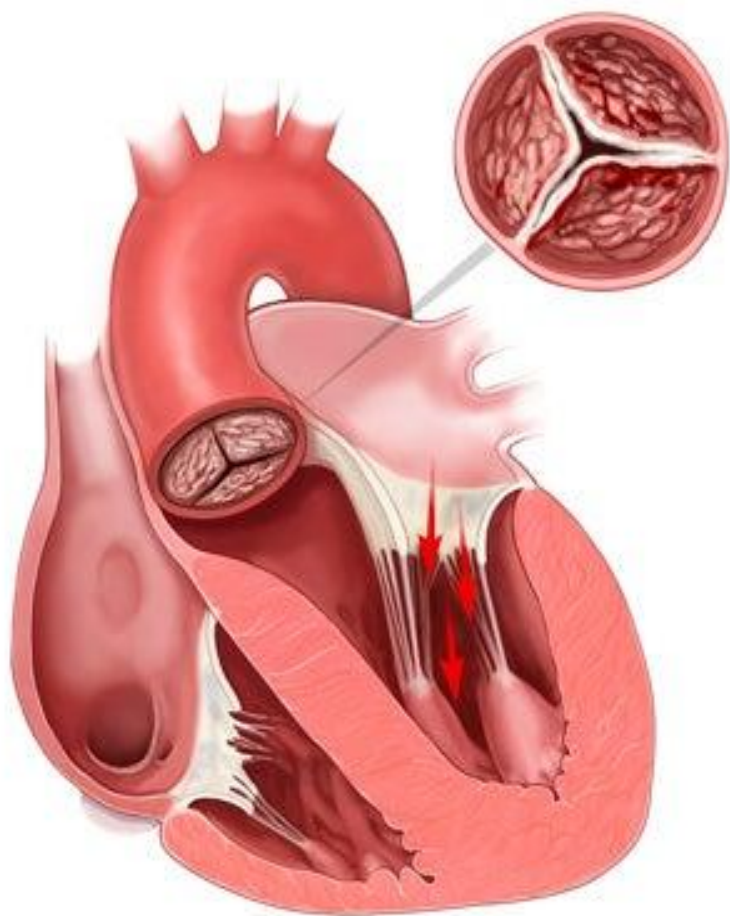
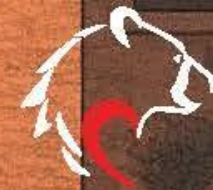
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**Ottimizzazione procedurale e
post-procedurale**



Sfide organizzative



Ottimizzazione procedurale e post-procedurale

Planning preprocedurale

Intervento in sedazione senza anestesia generale

Accesso vascolare ecoguidato

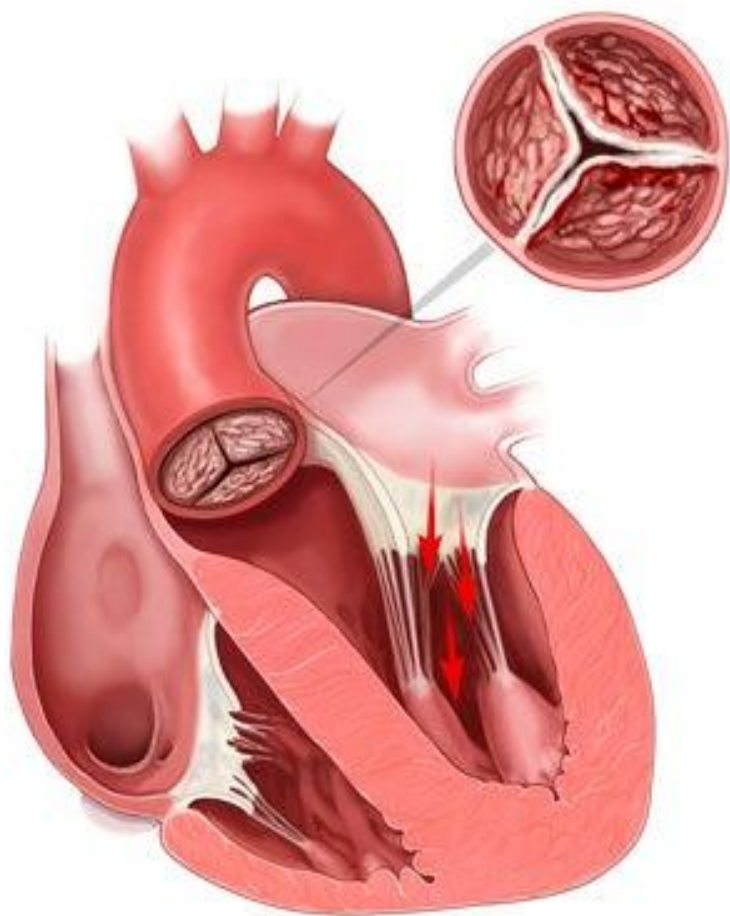
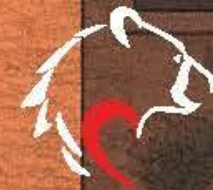
Marker per posizionamento valvolare

Allineamento commissurale per riaccesso coronarico

Riduzione rischio occlusione coronarica nelle ViV

Riduzione tasso di impianto di PM e predittori di BAV postoperatorio

Dimissione precoce



Ottimizzazione procedurale e post-procedurale

Planning preprocedurale

Intervento in sedazione senza anestesia generale

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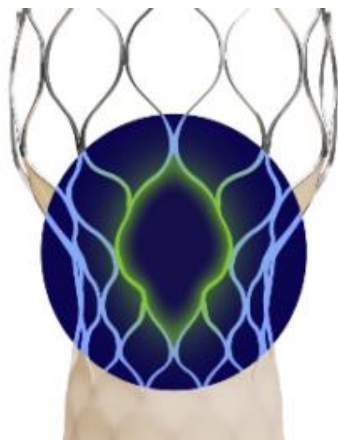
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Allineamento commissurale e riaccesso coronarico

Ampliamento
delle maglie
in corrispondenza
degli osti coronarici



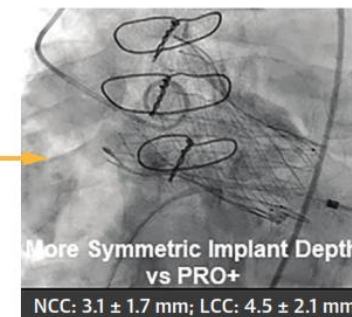
Transfemoral TAVR With Evolut FX, N = 226 U.S. Centers June 27, 2022-September 16, 2022

- Age 80 ± 9 years, 51.8% Female
- 34.1% Low Surgical Risk
- 4.0% Bicuspid Aortic Valve
- 10.6% Valve-in-Valve

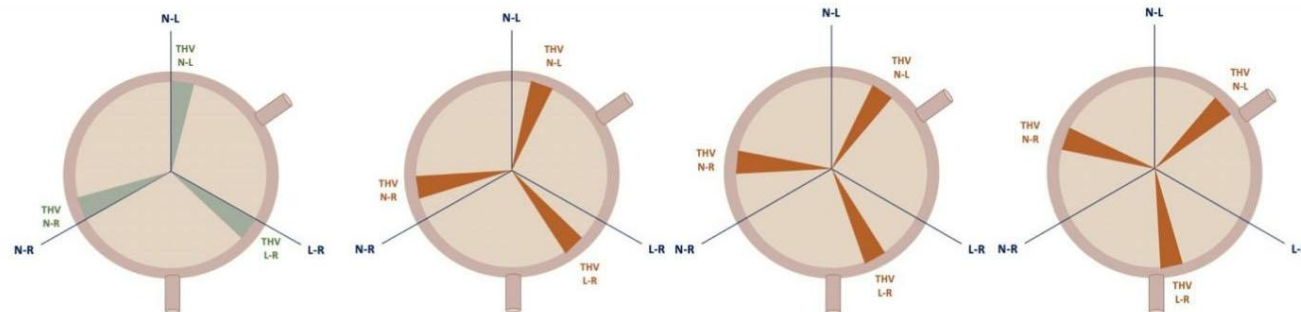
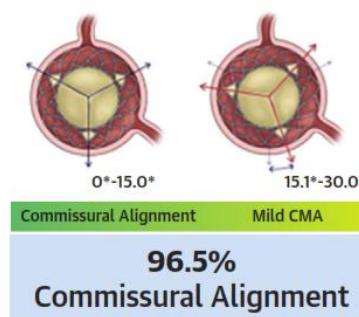
- 94.2% Conscious Sedation
- 67.6% Direct Inline Sheath
- 35.4% Lundquist Stiff Wire Use
- 98.4% "Hat" Marker at Optimal Orientation During Deployment



Technical Success: 99.1%



More Symmetric Implant Depth
vs PRO+
NCC: 3.1 ± 1.7 mm; LCC: 4.5 ± 2.1 mm



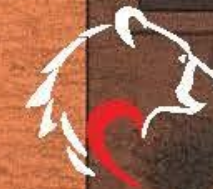
Commissural Alignment
0-15°

Commissural Misalignment
Mild 15-30°

Commissural Misalignment
Moderate 30-45°

Commissural Misalignment
Severe 30-45°

Sviluppo di tecniche di allineamento commissurale



Riduzione rischio occlusione coronarica nelle ViV

Occlusione coronarica rappresenta una delle possibili problematiche degli interventi ViV o TAVI-in-TAV.

È fondamentale una corretta pianificazione dell'intervento con studio della TAC; tipo e dimensioni della protesi disfunzionante, ampiezza dei seni di Valsalva, altezza delle coronarie sono i principali fattori di rischio.

In casi a rischio elevato di occlusione sono state utilizzate diverse tecniche:

- Chimney technique
- BASILICA (Bioprosthetic or Native Aortic Scallop Intentional Laceration to Prevent Iatrogenic Coronary Artery Obstruction)

BASILICA Procedure

Bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic Coronary Artery obstruction (BASILICA) is a procedure to prevent coronary obstruction.

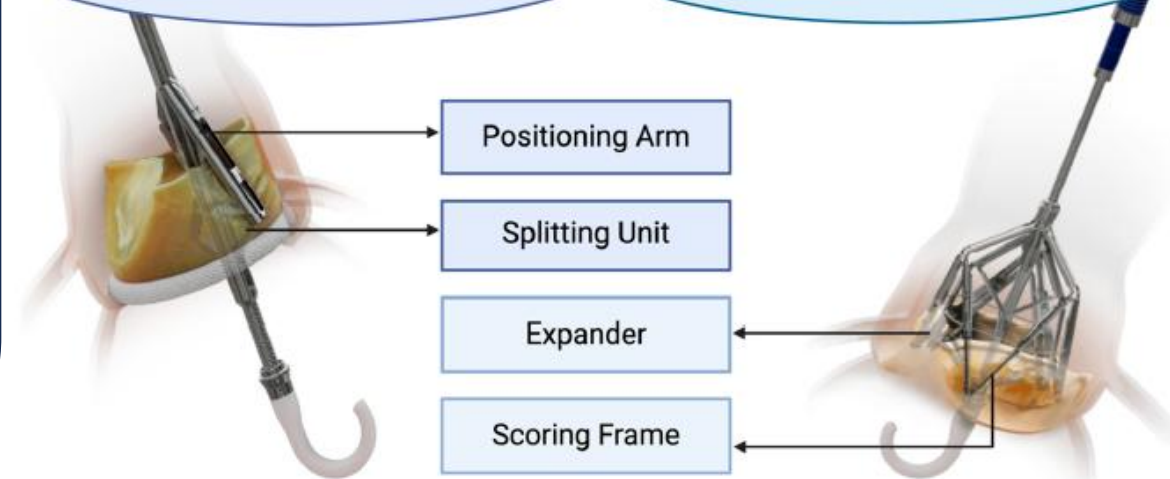
Leaflet Modification Devices

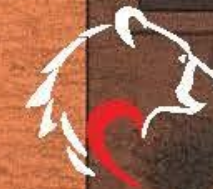
ShortCut™

Leaflet splitting to reduce coronary ostial obstruction

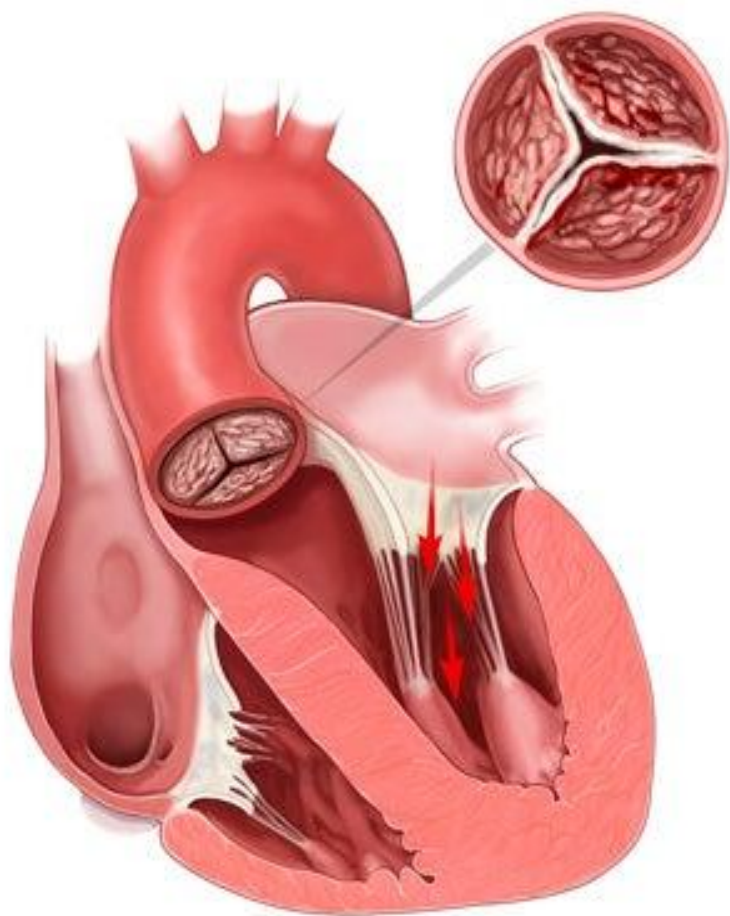
Leaflex™

Scoring of calcium deposits to restore valvular mobility





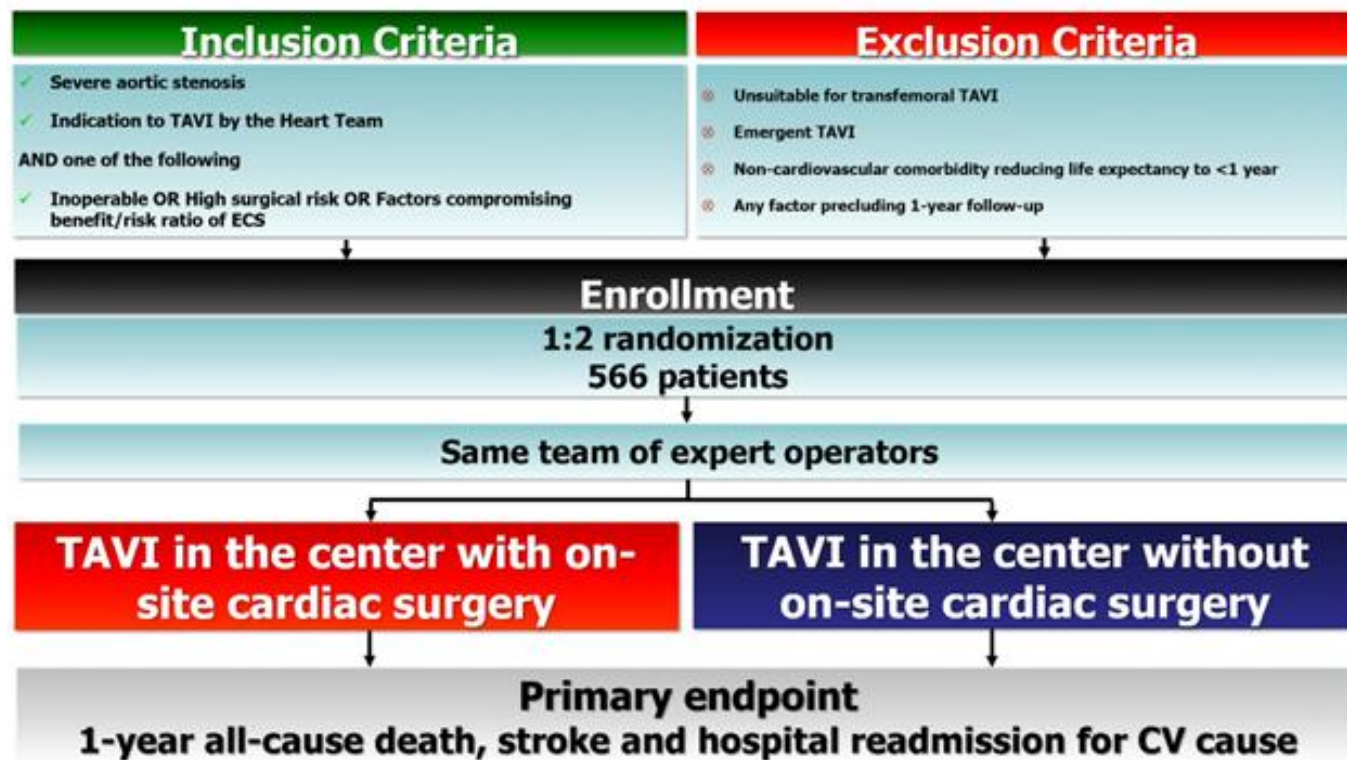
Sfide organizzative

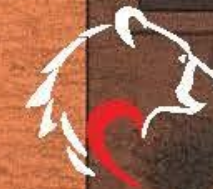


Transcatheter aortic-valve implantation with or without on-site cardiac surgery: The TRACS trial

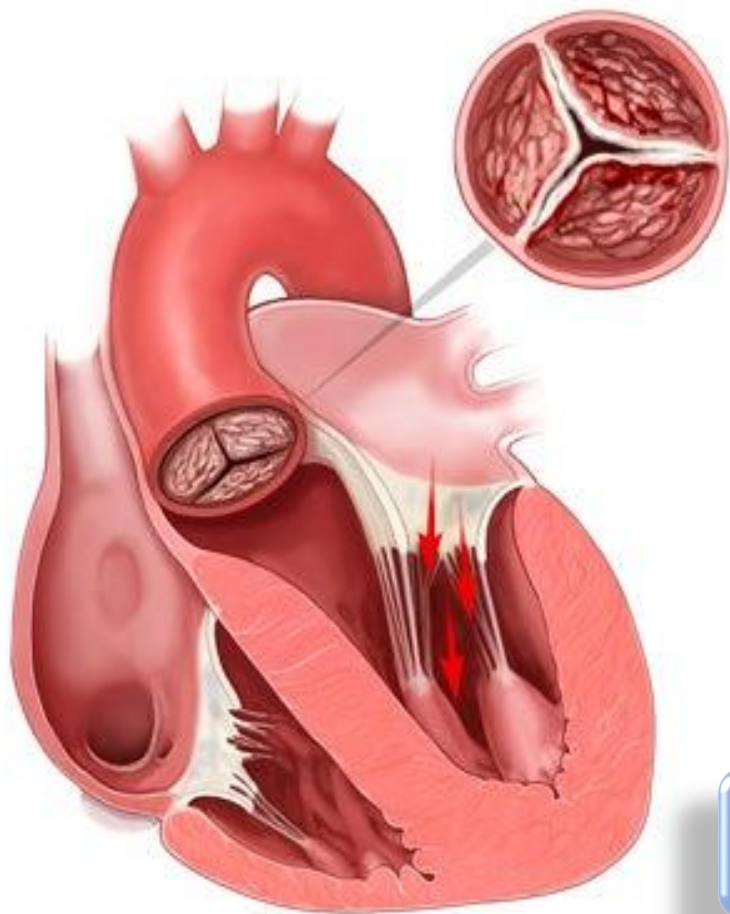


Gianmarco Iannopolo, MD^a, Marta Cocco, MD^b, Alessandro Leone, MD^c, Salvatore Saccà, MD^d, Domenico Mangino, MD^e, Andrea Picchi, MD^f, Matteo Rocco Reccia, MD^g, Massimo Fineschi, MD^h, Emanuele Meliga, MDⁱ, Andrea Audo, MD^j, Giampiero Nobile, MD^a, Carlo Tumscitz, MD^b, Carlo Penzo, MD^b, Francesco Saia, MD^k, Andrea Rubboli, MD^l, Carolina Moretti, MD^l, Luigi Vignali, MD^m, Giampaolo Niccoli, MD^m, Paolo Cimaglia, MD^b, Andrea Rognoni, MDⁿ, Daniela Aschieri, MD^o, Daniele Iaccarino, MD^p, Filippo Ottani, MD^q, Caterina Cavazza, MD^q, Ferdinando Varbella, MD^r, Gioel Gabrio Secco, MD^s, Leonardo Bolognese, MD^s, Ugo Limbruno, MD^f, Vincenzo Guiducci, MD^t, Gianluca Campo, MD^b, and Gianni Casella, MD^a





CONCLUSIONI



Nei prossimi anni sicuramente il numero di procedure TAVI sarà superiore a quello attuale

Lo sviluppo dei dispositivi è in continua evoluzione; solo il tempo, l'utilizzo e gli studi clinici ci permetteranno di capire quali device sopravviveranno e quali no

Dovremo confrontarci con necessità crescenti (invecchiamento della popolazione, espansione delle indicazioni) cercando di essere costo-efficaci

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ONCE, NOKIA CEO ENDED HIS LAST
SPEECH BY SAYING,



Grazie per
l'attenzione

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2025



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Agorà Palace Hotel - Biella



TAVI: Prospettive Future

**Vincenzo A. Galiffa
AOU Maggiore della Carità Novara**

