# Cambio en las nuevas guías 2025 ESC / EACTS

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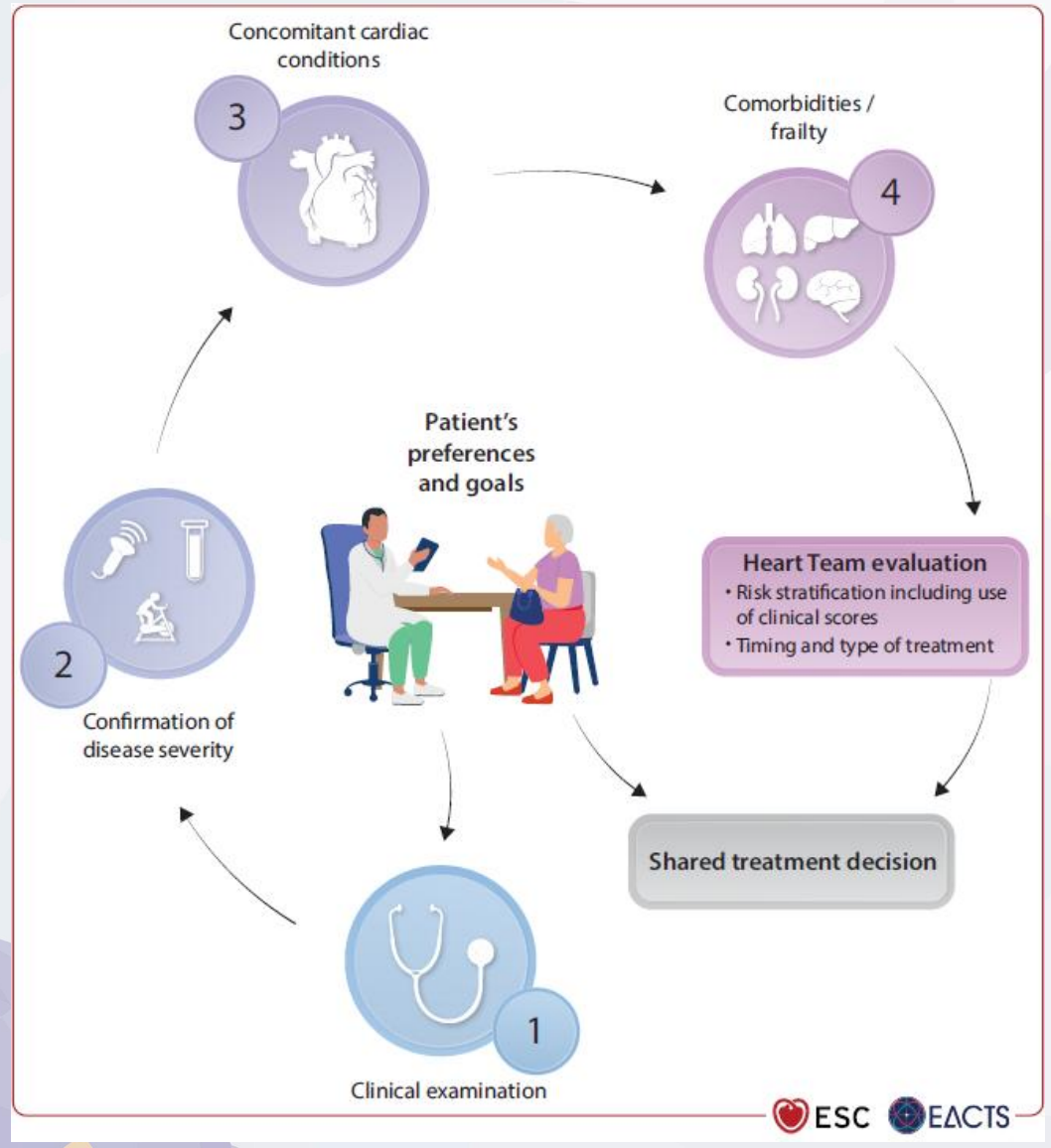
*Hospital Universitario Ramón y Cajal*

# Patients central role of the Heart Team




## The Heart Team meeting facilitates balanced presentation of all appropriate options

"The value of the Heart Team approach has become increasingly apparent as options for the treatment of VHD have extended to include high-risk and inoperable patients (most of whom now undergo transcatheter interventions), and low-risk and asymptomatic patients (who derive prognostic benefit from increasingly safe procedures)."[1]

**"The patient's preference plays a central role in this process."**

Praz F, *et al.* 2025 ESC/EACTS Guidelines for the management of valvular heart disease. *Eur Heart J.* 2025. doi:10.1093/eurheartj/ehaf194

# CAD and TAVI

| | | |
|---|---|---|
| Omission of invasive coronary angiography should be considered in TAVI candidates, if procedural planning CT angiography is of sufficient quality to rule out significant CAD. | IIa | B |
| PCI should be considered in patients with a primary indication to undergo TAVI and ≥90% coronary artery stenosis in segments with a reference diameter ≥2.5 mm. | IIa | B |

| Study (Journal, Year) | Design / Population | Intervention (PCI Strategy) | Main Results | Clinical Implications |
|---|---|---|---|---|
| ACTIVATION Trial (JACC Intv 2021) | Randomized, 235 pts with severe AS + significant CAD, planned for TAVI | Pre-TAVI PCI vs No PCI | 1-yr death/rehospitalization: 41.5% (PCI) vs 44.0% (No PCI); non-inferiority not met; ↑ bleeding with PCI | Routine PCI before TAVI does not improve outcomes; UNDERPOWERED due to slow recruitment |
| **NOTION-3 (NEJM 2024**, n=455 randomized / 452 mITT) | Open-label RCT; severe AS + significant CAD (FFR ≤0.80 or ≥90% stenosis) | PCI + TAVI vs TAVI alone | MACE reduced by ≈29% at ~2 yrs; no excess bleeding; benefit from fewer MI and unplanned PCI | **First RCT showing benefit of selective PCI in anatomically/physiologically significant CAD** |
| REVASC-TAVI Registry (EuroIntervention 2023) | Multicentre registry, 1,603 TAVI pts with stable CAD | PCI before vs concomitant vs after TAVI | 2-yr mortality: PCI after TAVI 6.8% vs before 20.1% vs concomitant 20.6% (p<0.001) | Timing matters: **post-TAVI PCI may be safest; observational evidence only** |
| Meta-analyses 2023–24 (ICR J Review 2024) | Pooled data (~15,000–60,000 TAVI pts with CAD) | Mixed PCI vs conservative approaches | No mortality benefit for routine PCI; ↑ bleeding/AKI when done pre-TAVI or concomitant | Supports individualized CT-guided approach and ≥90% stenosis threshold (ESC 2025) |

# Ongoing and Upcoming RCT on PCI in TAVI



| | | |
|---|---|---|
| Omission of invasive coronary angiography should be considered in TAVI candidates, if procedural planning CT angiography is of sufficient quality to rule out significant CAD. | IIa | B |
| PCI should be considered in patients with a primary indication to undergo TAVI and ≥90% coronary artery stenosis in segments with a reference diameter ≥2.5 mm. | IIa | B |

| Trial | Design / Population | Intervention | Primary Endpoint / Status | Estimated Completion |
|---|---|---|---|---|
| PRO-TAVI (NCT05252964) | Randomized, multicentre; severe AS + stable CAD | **Deferred vs routine PCI before TAVI** | Non-inferiority for death/MI/stroke at 1 yr | Expected 2026 |
| OPTIMAL-TAVI (NCT04310046) | Randomized; severe AS + CAD (any risk) | **PCI before vs after TAVI** | Composite of death, MI, or HF rehospitalization | Ongoing – Results 2025–26 |
| EASY-TAVI PCI Timing Study (planned) | Pragmatic RCT; moderate CAD TAVI candidates | **Concomitant vs staged PCI** | Procedural complications and 1-yr MACE | Recruiting 2025 |
| NOTION-3 Extension | Extension of NOTION-3 (455 pts) | **PCI + TAVI vs TAVI alone** | Long-term MACE, 5-yr durability data | Expected 2027 |

# Management of asymptomatic severe aortic stenosis

| Asymptomatic patients with severe aortic stenosis | | |
|---|---|---|
| Intervention is recommended in asymptomatic patients with severe AS and LVEF <50% without another cause.[14,354–359] | I | B |
| Intervention should be considered in asymptomatic patients (confirmed by a normal exercise test, if feasible) with severe, high-gradient AS and LVEF ≥50% as an alternative to close active surveillance, if the procedural risk is low.[360–363,367,368] *New* | IIa | A |
| Intervention should be considered in asymptomatic patients with severe AS and LVEF ≥50% if the procedural risk is low and one of the following parameters is present:<br>• Very severe AS (mean gradient ≥60 mmHg or $V_{max}$ >5.0 m/s).[14,362,363,482–484]<br>• Severe valve calcification (ideally assessed by CCT) and $V_{max}$ progression ≥0.3 m/s/year.[303,353,364]<br>• Markedly elevated BNP/NT-proBNP levels (more than three times age- and sex-corrected normal range, confirmed on repeated measurement without other explanation).[97,365]<br>• LVEF <55% without another cause.[14,354,356–359] | IIa | B |
| Intervention should be considered in asymptomatic patients with severe AS and a sustained fall in BP (>20 mmHg) during exercise testing. | IIa | C |

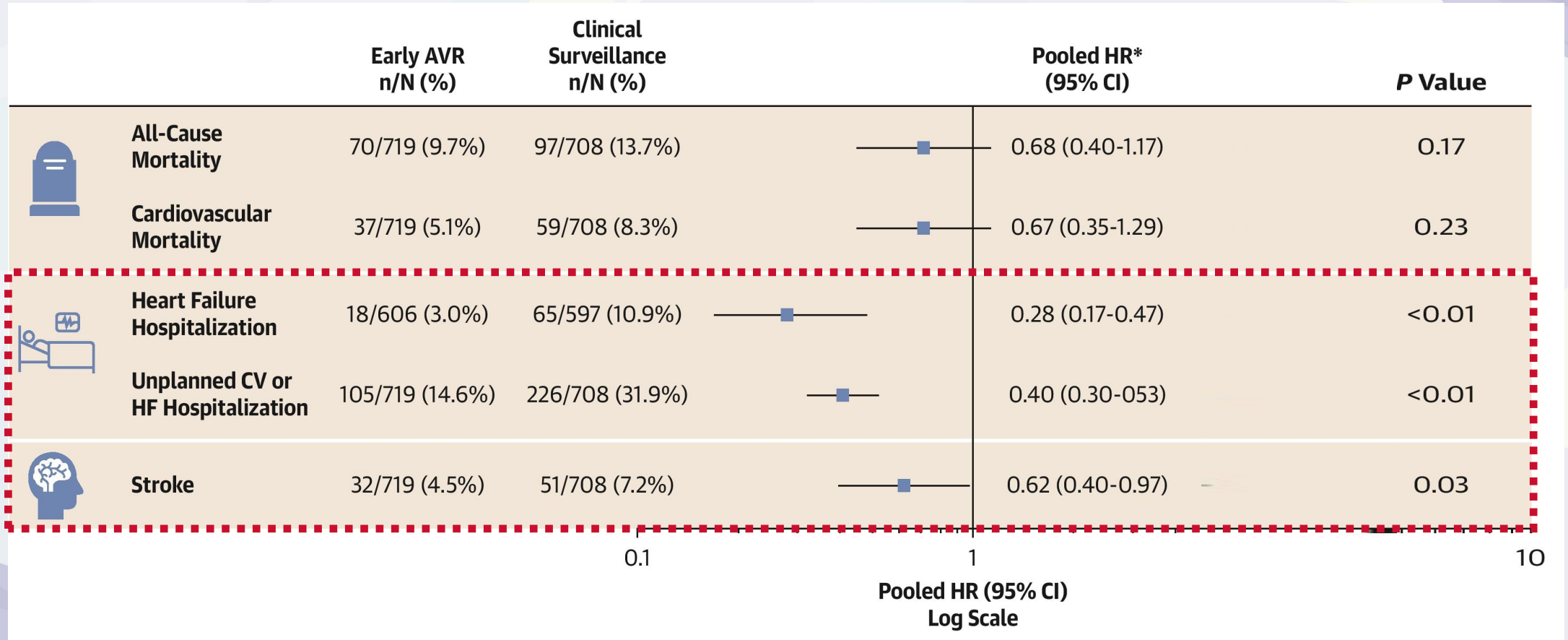
**New Class II A recommendation for AVR in asymptomatic patients with high-gradient AS and normal LVEF**

Praz F, *et al.* 2025 ESC/EACTS Guidelines for the management of valvular heart disease. *Eur Heart J.* 2025. doi:10.1093/eurheartj/ehaf194

| Study | Design / Population | Intervention | Main Results (Asymptomatic only) | Implications |
|---|---|---|---|---|
| **EARLY TAVR (NEJM 2024)** | Multicenter RCT; n=901; asymptomatic severe AS | TAVR vs Clinical Surveillance | Primary endpoint (mortality,stroke,hospitalization: 12.1% vs 33.2% (HR 0.35); 25 % of patients crossed over to TAVR within 1 year. | Reduces CV events; no difference in strokes and all-cause mortality |
| EVOLVED (Lancet 2024) | RCT; n=224; asymptomatic severe AS with biomarkers or MRI fibrosis | Early AVR (mostly surgical) vs Watchful Waiting | No reduction in death/AS hospitalization (HR 0.92, NS) | Biomarkers alone insufficient for early intervention**. Study was underpowered** |
| RECOVERY (NEJM 2020) | Single-center RCT; n=145; asymptomatic very severe AS | Early Surgical AVR vs Watchful Waiting | 8-year mortality: 10% vs 32% (HR 0.33). Mean follow-up 6 years | Supports early surgery in very severe AS |
| AVATAR (Circulation 2021) | Multicenter RCT; n=157; asymptomatic severe AS; negative exercise test | Early Surgical AVR vs Conservative | Composite: 15.2% vs 34.7% (HR 0.46). Mean follow-up 2.5 years | Benefit of early surgery with significant reduction of mortality and HF hospitalizations |

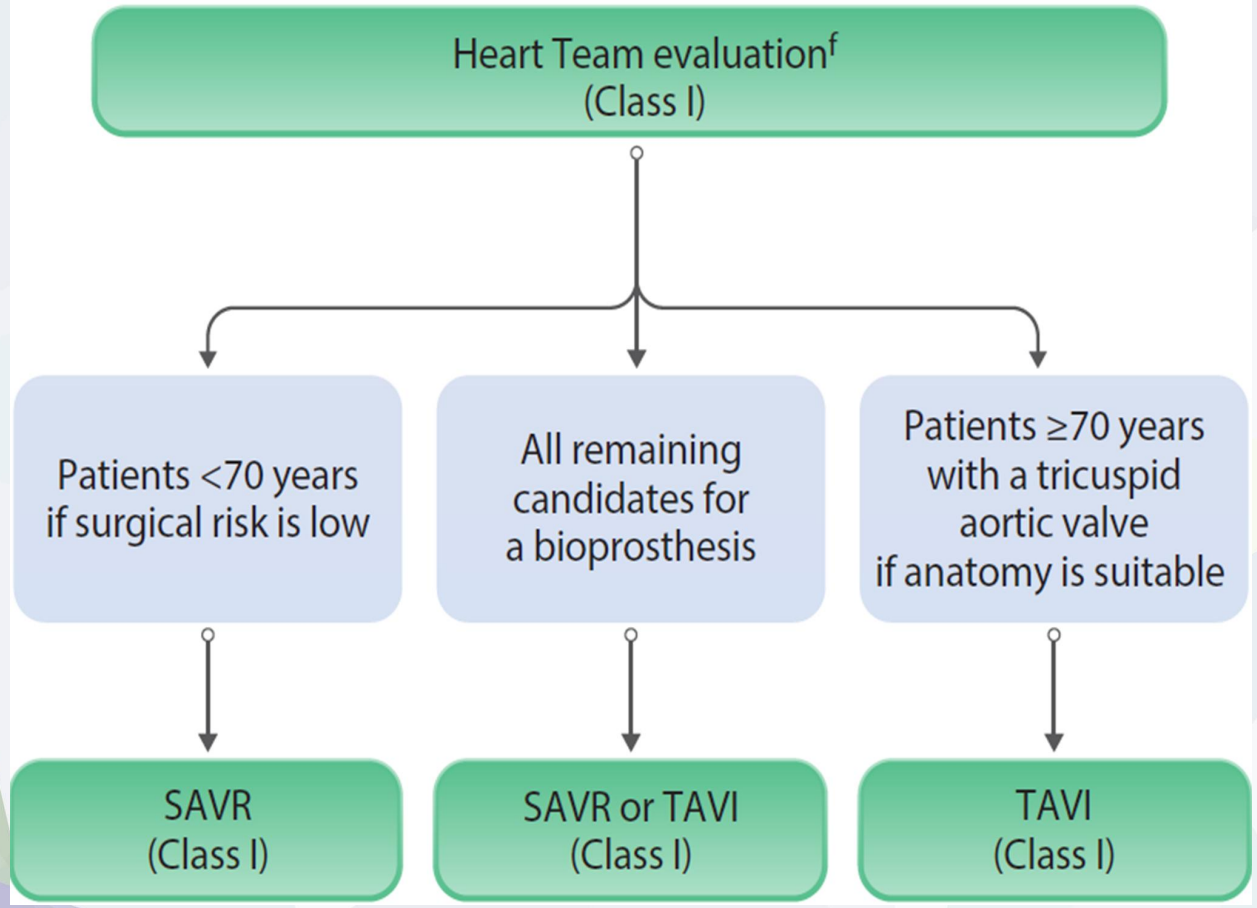
# Evidence behind the new asymptomatic AS recommendation

## Meta-analysis of the EARLY TAVR, EVOLVED, RECOVERY, and AVATAR trials




1. Généreux P, *et al*. Aortic valve replacement vs clinical surveillance in asymptomatic severe aortic stenosis: A systematic review and meta-analysis. *J Am Coll Cardiol*. 2025;85(9):912-922.

# New age cut-off to determine treatment strategy




**TAVI recommended for patients ≥70 years-old regardless of surgical risk**

- "TAVI is recommended as the primary treatment modality in elderly patients ≥70 years of age with a tricuspid aortic valve, if anatomy is suitable and transfemoral access is feasible."[1]
- "SAVR remains the preferred treatment in patients <70 years of age if surgical risk is low."[1]
- "SAVR or TAVI are recommended for all remaining candidates… according to Heart Team assessment." [1]

**TAVI is standard of care for patients ≥70 years with tricuspid AV stenosis (Class IA), and <70 years at increased risk for surgery.**

| | | |
|---|---|---|
| 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 |

# Evidence behind the new age cut-off

## DEDICATE trial[1]

The NEW ENGLAND JOURNAL of MEDICINE

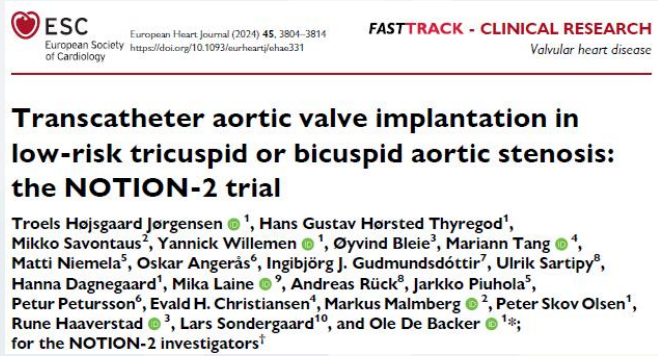
ORIGINAL ARTICLE

Transcatheter or Surgical Treatment of Aortic-Valve Stenosis

S. Blankenberg, M. Seiffert, R. Vonthein, H. Baumgartner, S. Bleiziffer, M.A. Borger, Y.-H. Choi, P. Clemmensen, J. Cremer, M. Czerny, N. Diercks, I. Eitel, S. Ensminger, D. Frank, N. Frey, A. Hagendorff, C. Hagl, C. Hamm, U. Kappert, M. Karck, W.-K. Kim, I.R. König, M. Krane, U. Landmesser, A. Linke, L.S. Maier, S. Massberg, F.-J. Neumann, H. Reichenspurner, T.K. Rudolph, C. Schmid, H. Thiele, R. Twerenbold, T. Walther, D. Westermann, E. Xhepa, A. Ziegler, and V. Falk, for the DEDICATE-DZHK6 Trial Investigators*

- Mean age **74 years**
- **TAVI noninferior to surgery** for the primary endpoint of death or stroke at 1 year

## NOTION-2 trial[2]



ESC European Society of Cardiology

European Heart Journal (2024) 45, 3804–3814
https://doi.org/10.1093/eurheartj/ehae331

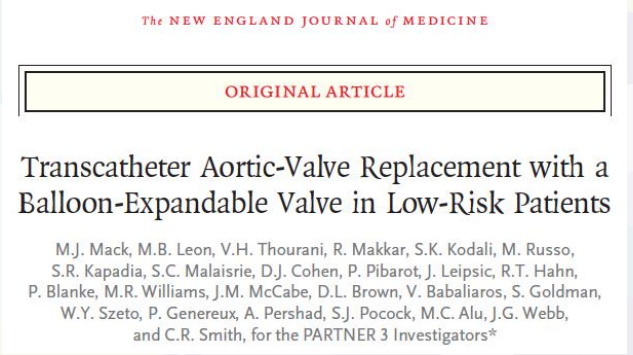
FASTTRACK - CLINICAL RESEARCH
*Valvular heart disease*

**Transcatheter aortic valve implantation in low-risk tricuspid or bicuspid aortic stenosis: the NOTION-2 trial**

Troels Højsgaard Jørgensen[1], Hans Gustav Hørsted Thyregod[1], Mikko Savontaus[2], Yannick Willemen[1], Øyvind Bleie[3], Mariann Tang[4], Matti Niemela[5], Oskar Angerås[6], Ingibjörg J. Gudmundsdóttir[7], Ulrik Sartipy[8], Hanna Dagnegaard[1], Mika Laine[9], Andreas Rück[8], Jarkko Piuhola[5], Petur Petursson[6], Evald H. Christiansen[4], Markus Malmberg[2], Peter Skov Olsen[1], Rune Haaverstad[3], Lars Sondergaard[10], and Ole De Backer[1]*; for the NOTION-2 investigators†

- Mean age **71 years**
- **Similar rate** of the primary endpoint of **death, stroke, or rehospitalization** at 1 year with **TAVI vs. surgery**

## PARTNER 3 trial[3]



The NEW ENGLAND JOURNAL of MEDICINE

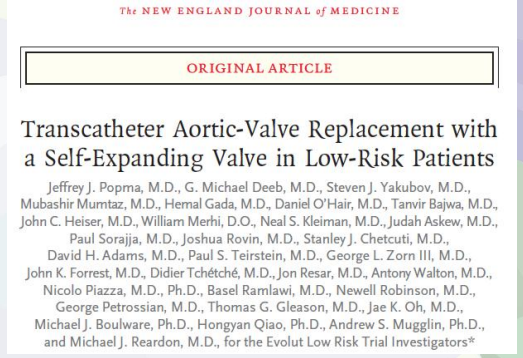
ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

M.J. Mack, M.B. Leon, V.H. Thourani, R. Makkar, S.K. Kodali, M. Russo, S.R. Kapadia, S.C. Malaisrie, D.J. Cohen, P. Pibarot, J. Leipsic, R.T. Hahn, P. Blanke, M.R. Williams, J.M. McCabe, D.L. Brown, V. Babaliaros, S. Goldman, W.Y. Szeto, P. Genereux, A. Pershad, S.J. Pocock, M.C. Alu, J.G. Webb, and C.R. Smith, for the PARTNER 3 Investigators*

- Mean age **73 years**
- **TAVI superior to surgery** for the primary endpoint of death, stroke, or rehospitalization at 1 year

## Evolut Low Risk trial[4]



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*

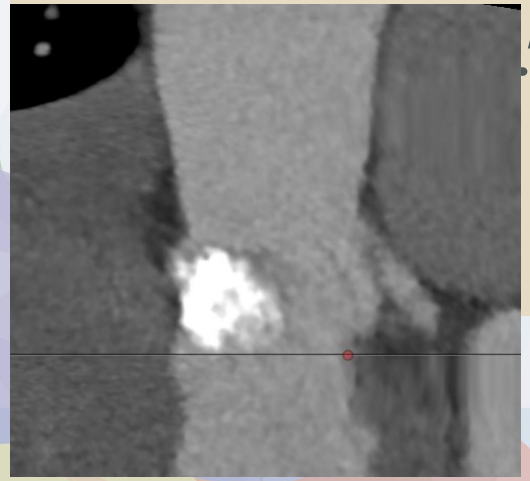
- Mean age **74 years**
- **TAVI noninferior to surgery** for the primary endpoint of death and disabling stroke at 2 years

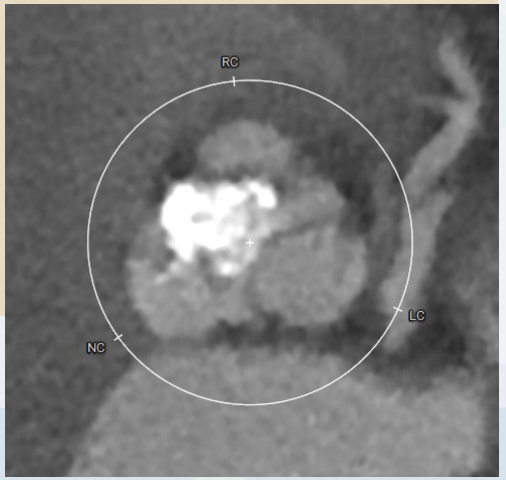
1. Blankenberg S, *et al*. Transcatheter or surgical treatment of aortic valve stenosis. *N Engl J Med*. 2024;390(17):1572–1583.
2. Jørgensen TH, *et al*. Transcatheter aortic valve implantation in low-risk tricuspid or bicuspid aortic stenosis: the NOTION-2 trial. *Eur Heart J*. 2024;45(37):3804–3814.
3. Mack, MJ. *et al.* Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med.* 2019;380(18):1695-1705.
4. Popma, JJ. *et al.* Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med.* 2019;380(18):1706-1715

# New recommendation for bicuspid patients

| | | |
|---|---|---|
| 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 |

**"SAVR remains the primary mode of treatment for stenotic BAV, particularly if patients are young or have coexistent aortopathy or unfavourable valve morphology. TAVI may be considered in patients at increased surgical risk, if [redacted]."[1]**






## Anatomical challenges and importance of correct sizing are highlighted

- "BAV anatomy adds complexity to TAVI because of asymmetric AV calcification and elliptical annular shape, as well as the lack of standardization of valve sizing." [1]
- "Heavy cusp calcification, particularly in conjunction with a calcified raphe, is associated with increased risk of aortic root injury, PVL, and mortality after TAVI. Data on TAVI in two-sinus BAV (Sievers type 0) are scarce."[1]

# Evidence behind TAVI in BAV

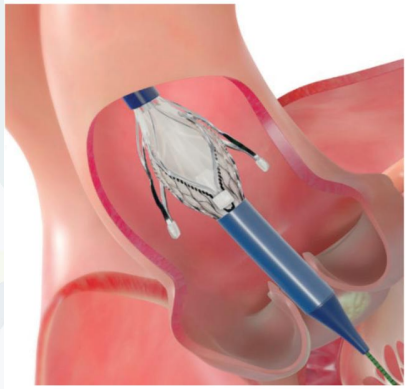
| Study | Design / Population | Intervention | Main Results (BAV only) | Implications |
|---|---|---|---|---|
| NOTION-2 (NEJM 2024) | RCT, low-risk ≤75 yrs (tricuspid + bicuspid subset ≈ 100 pts) | TAVI vs SAVR (mixed valves) | In BAV: primary composite 14.3% (TAVI) vs 3.9% (SAVR); HR≈3.8 (wide CI) | First RCT including BAV; small subgroup, TAVI inferior in low-risk BAV |
| PARTNER 3 Bicuspid Registry (JACC 2022) | Prospective registry, low-risk BAV, matched to tricuspid cohort | Balloon-expandable (SAPIEN 3) | 1-yr composite death/stroke/rehosp 10.9% vs 10.2% (NS); death 0.7%; stroke 2.1% | Low-risk BAV outcomes comparable to tricuspid AS in selected anatomy |
| Evolut Low-Risk BAV Study (JACC:CI 2024) | Prospective, single-arm, low-risk BAV | Self-expanding (Evolut R/PRO) | 3-yr death/disabling stroke 4.1%; no mod/sev PVL; PPI 19% | Durable mid-term outcomes; supports feasibility in anatomically suitable BAV |
| STS/ACC TVT Registry (2021–23) | Large registry, real-world BAV vs tricuspid | Mixed platforms (mainly Evolut & SAPIEN 3) | 30d death 0.9% vs 0.8%; 1y death 4.6% vs 6.6%; ↑ PVL and PPI in BAV | Confirms acceptable outcomes; slightly ↑ PVL/PPI risk vs tricuspid |
| Meta-analyses (2023–24) | Systematic reviews >60 000 BAV cases | Mixed TAVI devices | No diff. mortality/stroke vs SAVR; ↓ major bleeding; ↑ PPI (~18%) | Aggregated evidence → supports Class IIb B recommendation in ESC 2025 |

# New recommendation for aortic regurgitation

| 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. | IIb | B |
|---|---|---|

| Study | Design / Population | Intervention | Main Results | Implications |
|---|---|---|---|---|
| ALIGN-AR (Lancet 2024) | Prospective, multicentre, single-arm; high-risk symptomatic native AR | Dedicated JenaValve Trilogy system | Device success 95–96%; 30 d composite safety 26.7%; 1 yr mortality 7.8% | First pivotal evidence supporting TAVI in pure AR using dedicated valve |
| ALIGN-AR Continued Access (2024–25) | Real-world expansion (~500 pts) | Same device (JenaValve Trilogy) | 30 d mortality 1.6%; 1 yr ~8%; low PVL rates | Confirms feasibility and safety in larger population |
| Meta-analyses & Registries (2023–24) | 22 studies, ~6,700 patients with native AR | Mixed TAVI platforms (non-dedicated and dedicated) | 30 d mortality ≈8%; 1 yr ≈15%; PVL and embolization main issues | Support Class IIb B recommendation for high-risk AR patients |

A



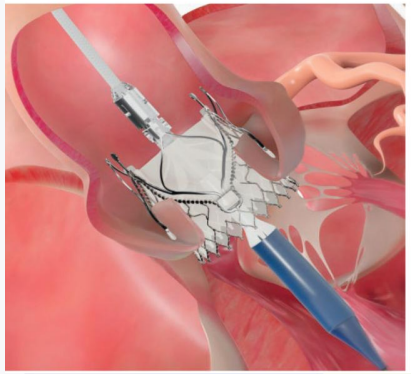
Alignment and positioning

B

Sizing recommendations (CT scan)

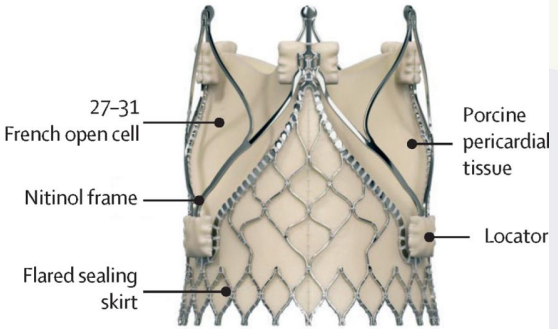
| Perimeter-derived annulus diameter range (mm) | Annulus perimeter range (mm) | Maximum LVOT perimeter at 2 mm, 4 mm, and 6 mm below the annulus | | |
|---|---|---|---|---|
| | | 2 mm | 4 mm | 6 mm |
| 21·0–24·2 | 66–76 | 78 | 80 | 82 |
| 23·2–26·4 | 73–83 | 85 | 87 | 89 |
| 25·5–28·6 | 80–90 | 92 | 94 | 96 |

C



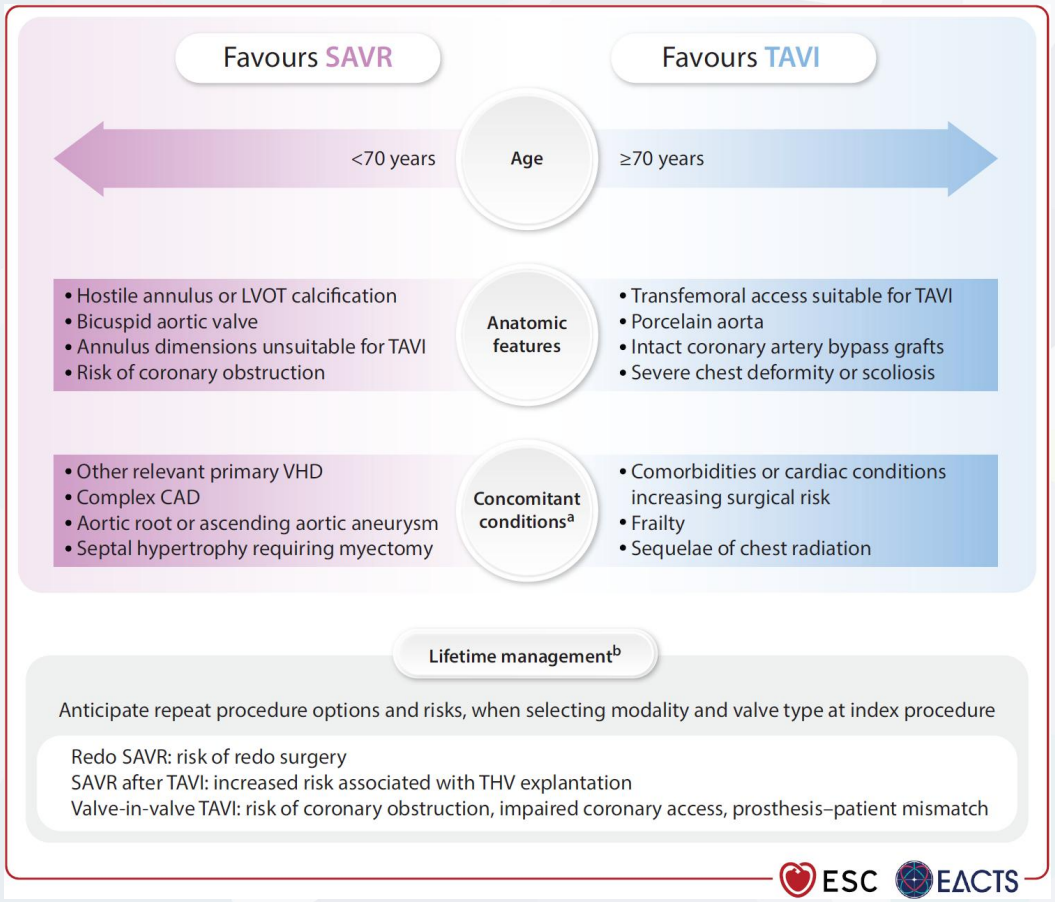
D

**Pacemaker 24%**



# Lifetime management is a deciding factor






## Lifetime management is now an important factor when deciding the therapy and prosthesis

- "Selection of the most appropriate mode of intervention should take into account clinical characteristics (age and estimated life expectancy, concomitant conditions), access and valve anatomy, and surgical risk, as well as repeat procedure options and risks (lifetime management)."[1]
- **"Decision-making concerning the mode of intervention and type of prosthesis needs to integrate expected valve durability, and the potential risks of future reinterventions."**[1]

| | | |
|---|---|---|
| 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 |

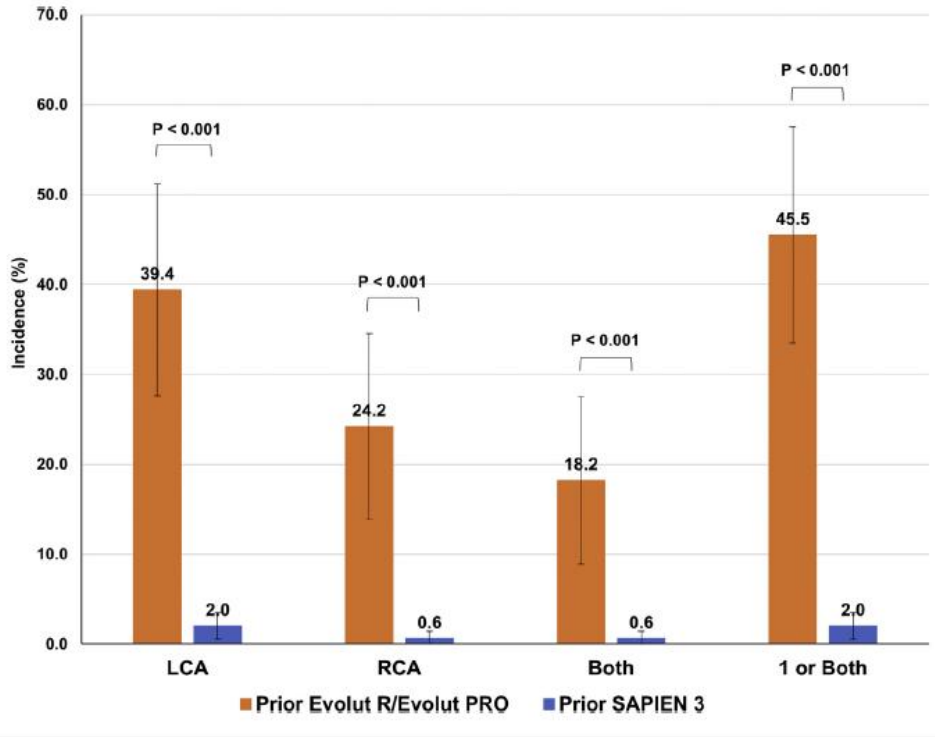
Praz F, *et al. Eur Heart J.* 2025. doi:10.1093/eurheartj/ehaf194

# Evidence behind lifetime management

## Higher risk of sinus sequestration during TAV- in-TAV with supra-annular valves with a high neo-skirt

**RESOLVE registry**

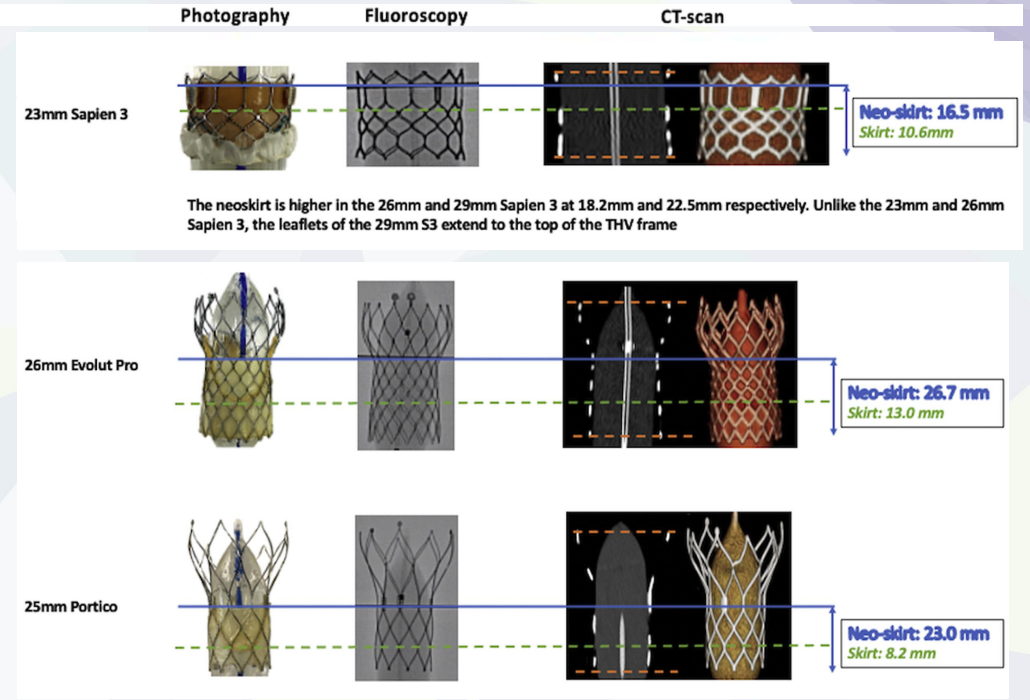
FIGURE 3 CT-Identified Risk of Sinus Sequestration in Redo TAVR in Evolut R/Evolut PRO and SAPIEN 3




CT-identified risk of sinus sequestration in redo TAVR in prior Evolut R/Evolut PRO and prior SAPIEN 3 are shown. Abbreviations as in Figure 1.

- Risk of sinus sequestration at 1 or both coronary arteries: 45.5% with Evolut R/Evolut PRO vs. 2.0% with the SAPIEN 3 platform (p<0.001)

*Ochiai T, et al. JACC Cardiovasc Interv. 2020;13(22):2617-2627.*




- "The risk of sinus sequestration at the time of TAV-in-TAV implantation is particularly increased in supra-annular valves with a high neo-skirt

*Akodad M, et al. JACC Cardiovasc Interv. 2021;14(20):2298-2300.*

# Antithrombotic therapy



## Transcatheter aortic valve implantation without indication for oral anticoagulation

DAPT is not recommended to prevent thrombosis after TAVI, unless there is a clear indication. **III** **B**

| Study | Design / Population | Intervention | Main Findings | Limitations | Implications |
|---|---|---|---|---|---|
| POPular-TAVI Cohort A (NEJM 2020) | RCT; 331 TAVI patients without OAC indication | SAPT (aspirin) vs DAPT (aspirin + clopidogrel) | Bleeding 15.1% vs 26.6%; no difference in death/MI/stroke | Moderate sample; 12-month follow-up; selected low-risk population | SAPT safer; no ischemic advantage of DAPT |
| ARTE Trial (JACC CI 2017) | RCT; 222 post-TAVI patients | Aspirin vs Aspirin + Clopidogrel | More bleeding with DAPT; no ischemic benefit | Single-center; older valve platforms; limited generalizability | Supports avoiding routine DAPT |
| Meta-analysis (Sanz-Sánchez 2021) | 4 RCTs; 1,086 TAVI patients without OAC | SAPT vs DAPT | Major bleeding ↓ (OR 0.44); no diff. in death/MI/stroke | Heterogeneous RCTs; study-level data; bleeding-driven outcomes | Strong pooled evidence for SAPT |

# Conclusions

- **Heart Teams** have a central role in decision-making and the **patient's preference** is at the center.
- **CAD strategy simplified** (CT-first – **Class IIa**, selective PCI, **Class IIa**)
- AVR is recommended in **asymptomatic patients** with high-gradient AS and normal LVEF **(Class IIa)**
- TAVI is standard of care for patients **≥70 years** with tricuspid AV stenosis (**Class IA**)
- **Lifetime management** is now an important factor when deciding the therapy and prosthesis
- TAVI may be considered for **bicuspid patients** at increased surgical risk (**Class IIb**)
- TAVI may be considered for severe aortic regurgitation in symptomatic patients ineligible for surgery if the anatomy is suitable (**Class IIb**)
- SAPT standard after TAVI; **no routine DAPT/OAC (Class IIIb)**