Tavi vs Savr.
Δίπτυχη Αορτική Βαλβίδα

ΓΕΩΡΓΙΟΣ Δ. ΚΑΤΣΙΜΑΓΚΛΗΣ
ΔΙΕΥΘΥΝΤΗΣ Α' ΚΑΡΔΙΟΛΟΓΙΚΗΣ ΚΛΙΝΙΚΗΣ &
ΑΙΜΟΔΥΝΑΜΙΚΟΥ ΕΡΓΑΣΤΗΡΙΟΥ
ΝΑΥΤΙΚΟΥ ΝΟΣΟΚΟΜΕΙΟΥ ΑΘΗΝΩΝ

Conflict of interest

- Proctor fees from Boston Scientific and Abbott

- In the past decade, the U.S. has seen a 25-fold increase in the use of TAVR, with more than 100,000 performed annually. This technique is now employed in approximately 85% of all isolated aortic valve replacements.
- Around 10% of TAVR procedures are performed on patients with bicuspid aortic valves.
- The younger the patient with severe aortic stenosis (AS), the more likely it is that they'll have a bicuspid aortic valve.
- In the low-risk trials of TAVR vs. SAVR, no patients were under the age of 65, and only about 9% were below 70.

Ταξινόμηση

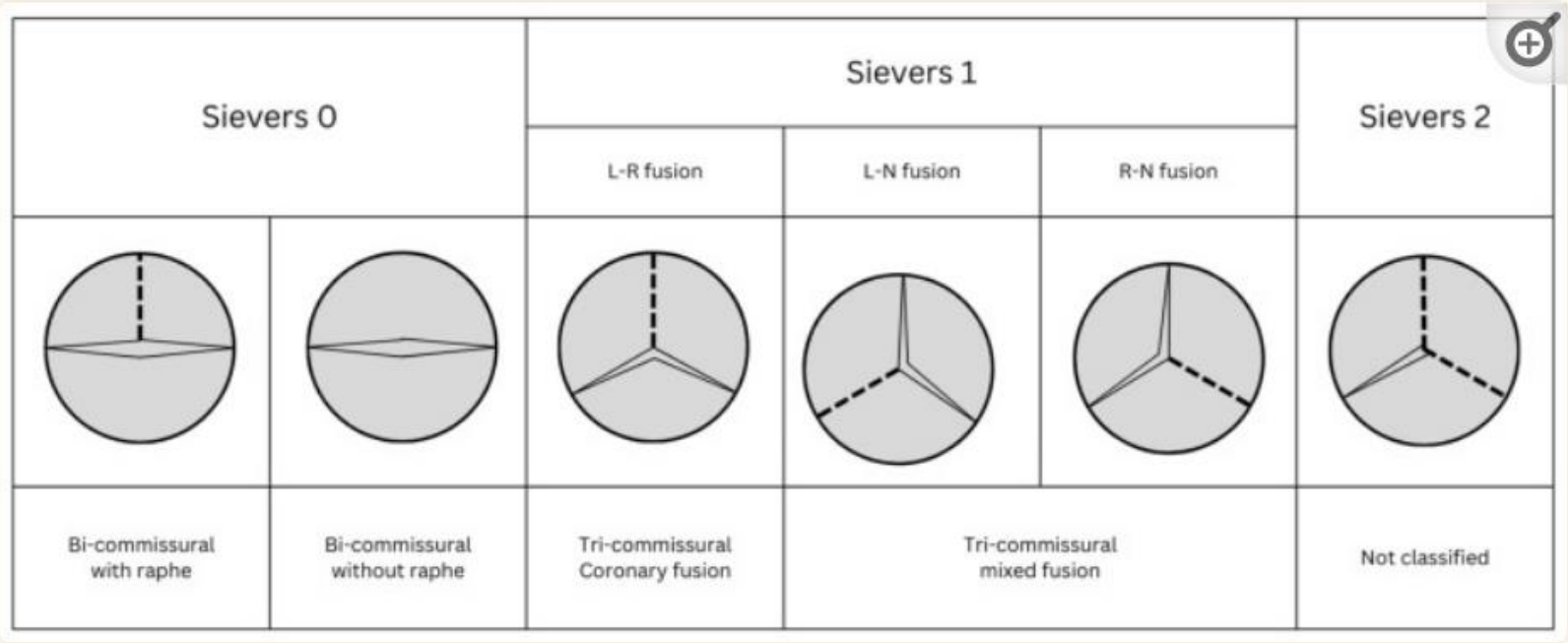


Figure 1

Morphological classification of bicuspid aortic valve. Bicuspid aortic valve (BAV) morphological classification systems as adapted from Sievers (top headings) and Jilahaiwi (bottom headings).

AORTIC STENOSIS-TAVI /ACC/AHA RECOMMENDATIONS-2020

	Favors SAVR	Favors TAVI
Age/life expectancy*	Younger age/longer life expectancy	Older age/fewer expected remaining years of life
Valve anatomy	BAV Subaortic (LV outflow tract) calcification Rheumatic valve disease Small or large aortic annulus†	Calcific AS of a trileaflet valve
Prosthetic valve preference	Mechanical or surgical bioprosthetic valve preferred Concern for patient–prosthesis mismatch (annular enlargement might be considered)	Bioprosthetic valve preferred Favorable ratio of life expectancy to valve durability TAVI provides larger valve area than same size SAVR
Concurrent cardiac conditions	Aortic dilation‡ Severe primary MR Severe CAD requiring bypass grafting Septal hypertrophy requiring myectomy AF	Severe calcification of the ascending aorta ("porcelain" aorta)
Noncardiac conditions		Severe lung, liver, or renal disease Mobility issues (high procedural risk with sternotomy)

AORTIC STENOSIS/ESC/RECOMMENDATIONS 2021

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	–	+

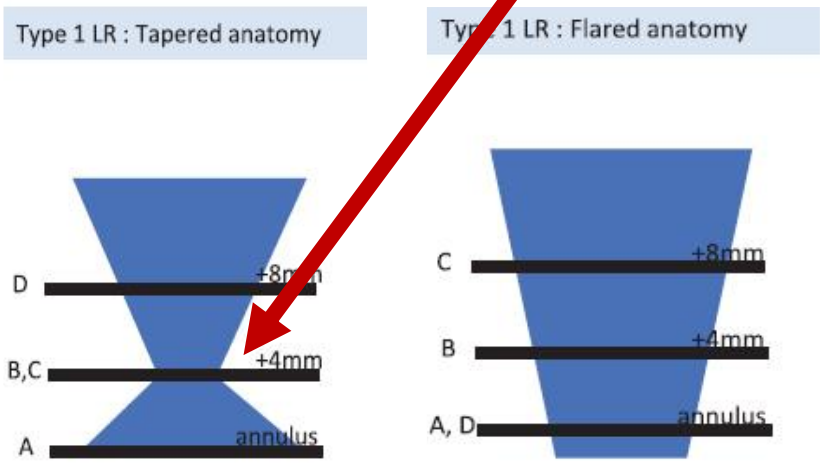
Τεχνικές προκλήσεις της δίπτυχης ανατομίας στην TAVI

1. ↑ πιθανότητα μεγάλου αορτικού δακτυλίου (± ανιούσας αορτής), εκτός των ορίων που καλύπτονται από τις διαθέσιμες

2. Περισσότερο ελλειπτική η γεωμετρία στο επ στα 2/3 των ασθενών μη κυλινδρικό σχήμα (tapered ή flared) του συμπλέγματος της AV [2,3]

Περιοχή υψηλής αντίστασης στις κομισσούρες

- **Υποέκπτυξη της πρόθεσης**
- **Κίνδυνος για ρήξη του δακτυλίου σε επιθετική μεταδιάταση**



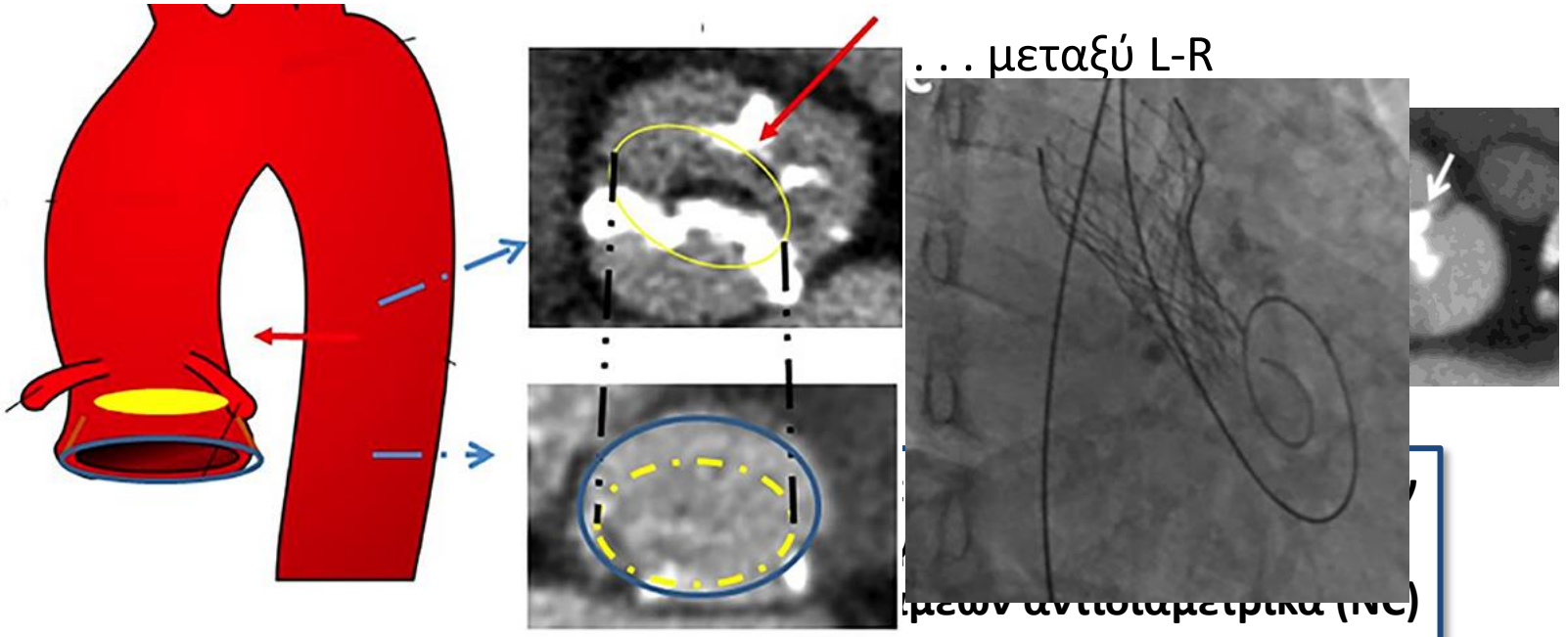
Vincent et al, *Circulation* 2021

[1] Shibayama et al, *J Am Soc Echocardiogr* 2014
[2] Tchetche et al, *Circ Cardiovasc Interv* 2019
[3] Kim et al, *EuroIntervention* 2019

Τεχνικές προκλήσεις της δίπτυχης ανατομίας στην TAVI

3. Μεγαλύτερο φορτίο ασβεστίου, κατανεμημένο πιο έκκεντρα και ασύμμετρα[1,2]

4. Ύπ



. . . μεταξύ L-R

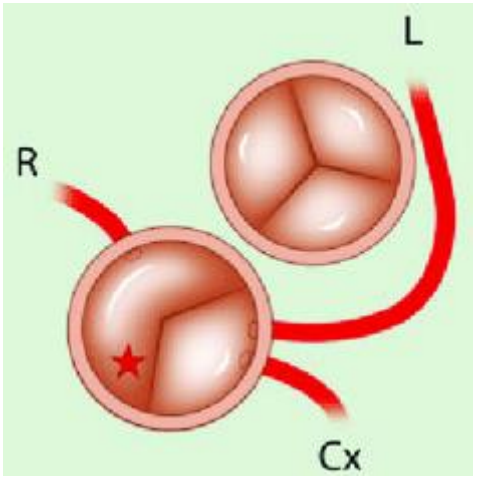
(κοντά στο δ. His)

Costa et al, *Cardiovasc Med* 2022

[1] Roberts et al, *Am J Cardiol* 2012
[2] Tchetche et al, *Circ Cardiovasc Interv* 2019

Τεχνικές προκλήσεις της δίπτυχης ανατομίας στην TAVI

5. Συχνότερες οι ανωμαλίες των στεφανιαίων αγγείων[1,2,3]
(διακριτές εκφύσεις LAD και LCx, εκφύσεις κοντά στις κομισσούρες)



Koppel et al, *Eur Heart J Cardiovasc Imaging* 2022

→ ▪ **Κίνδυνος απόφραξης**

(…ωστόσο, το ύψος έκφυσης ≥ TAV)

[1] van Rosendael et al, *Am J Cardiol* 2016
[2] Philip et al, *Catheter Cardiovasc Interv* 2015
[3] Kong et al, *Circ Cardiovasc Imaging* 2017

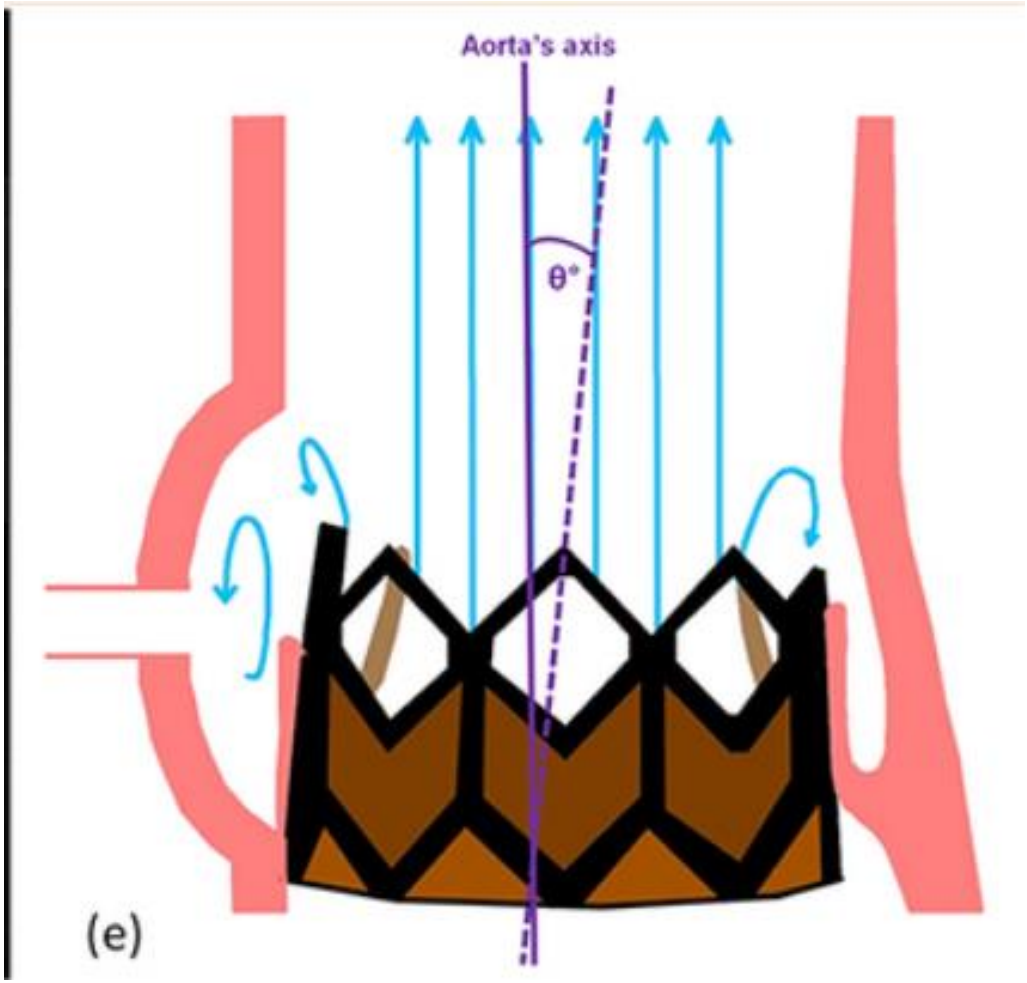
Τεχνικές προκλήσεις της δίπτυχης ανατομίας στην TAVI

6. Περισσότερο οριζόντια η θέση της αορτής → δυσχερέστερη η ακριβής τοποθέτηση της πρόθεσης .

7. Συχνή συνύπαρξη αορτοπάθειας, που δεν αντιμετωπίζεται με TAVI. Διαφορετικοί τύποι BAVσυσχετίζονται με διαφορετικά εμβρυολογικά χαρακτηριστικά και διαφορετικό shear stress στο τοίχωμα της αορτής.
(συσχέτιση της περιοχής της προσβεβλημένης αορτής με τον τύπο της BAV)

[1] Jilaihawi et al, *Catheter Cardiovasc Interv* 2015
[2] Shen et al, *Eur Heart J Cardiovasc Imaging* 2020

Thrombosis



Primary Results From the Evolut Low Risk Bicuspid Study

Basel Ramlawi, MD, FACC
Valley Health System, Winchester, Virginia
For the Evolut Low Risk Bicuspid Investigators

Key Exclusion Criteria

Evolut™ Low Risk Bicuspid Study

- Age < 60 years
- Multivessel coronary artery disease (SYNTAX score >22)
- Ascending aorta diameter > 4.5 cm
- Aortopathy requiring surgical intervention
- Prohibitive LVOT calcification
- Anatomic dimensions outside recommended range
  - SOV (≥ 25 mm)
  - Annulus (18 to 30 mm)
  - Trileaflet aortic valve on MSCT

Summary

Evolut™ Low Risk Bicuspid Study

- TAVR with Evolut supra-annular self-expanding valve in low-risk bicuspid patients achieved excellent early results:
  - Annular sizing achieved 95.3% device success
  - Low mortality and stroke at 30 days (1.3%)
  - Low rates of PVL (no moderate/severe)
  - Consistent hemodynamics across Sievers Classification
- Patients will be followed for 10 years

25

Clinical Implications

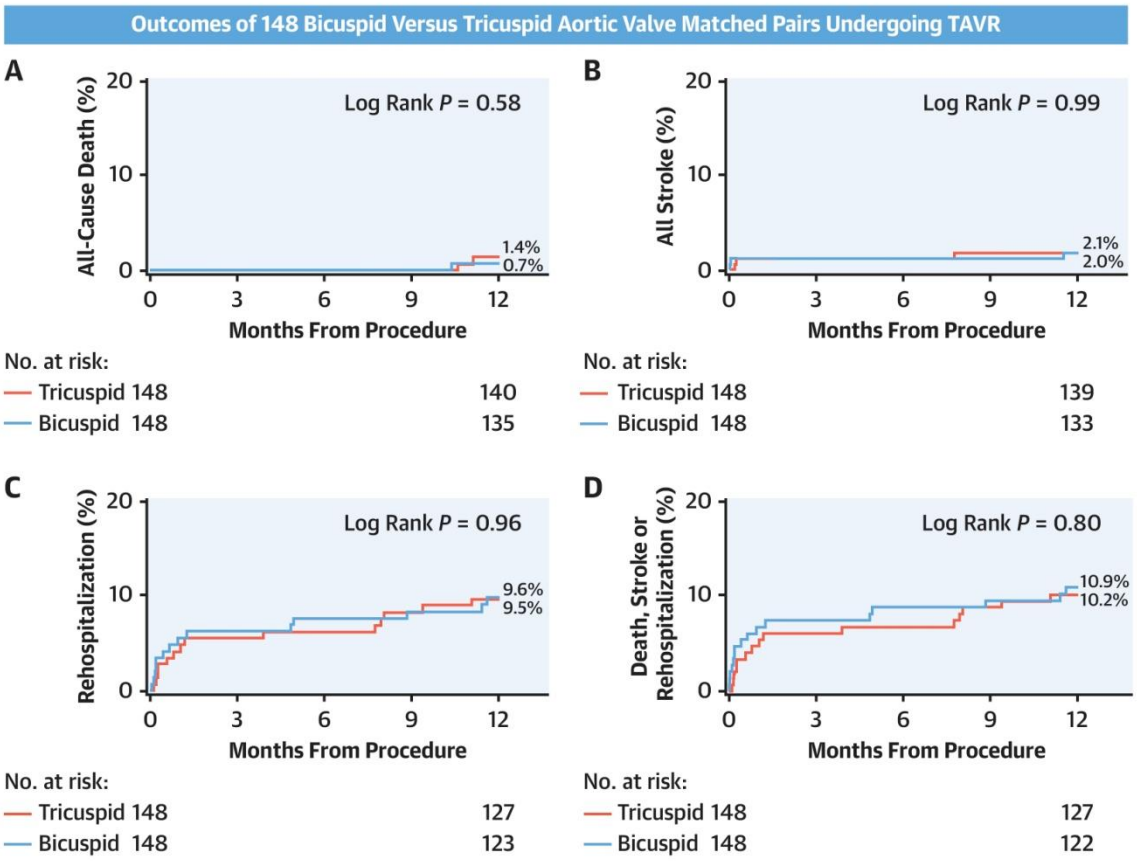
Evolut™ Low Risk Bicuspid Study

- In low-risk AS patients with bicuspid morphology, TAVR with Evolut can be considered a viable alternative to SAVR… after considering anatomic, clinical and patient social factors.

- Data is based on short-term results and needs to be confirmed long-term in this low-risk cohort.

Partner 3 bicuspid cohort

CENTRAL ILLUSTRATION: Time-to Event Curves for Propensity-Matched Tricuspid and Bicuspid Patients Through 1 Year



Williams, M.R. et al. J Am Coll Cardiol Intv. 2022;15(5):523-532.

Among highly select bicuspid aortic stenosis low-surgical-risk patients without extensive raphe or subannular calcification, TAVR with the SAPIEN 3 valve demonstrated similar outcomes to a matched cohort of patients with tricuspid aortic stenosis.

TAVI σε BAV: επιλογή ασθενών

Favorable for transcatheter aortic valve replacement	Favorable for surgical aortic valve replacement
Tricommissural bicuspid aortic valve with incomplete raphe (Incomplete or acquired Type 1 Sievers)	Sievers type 1 with heavily calcified raphe and excess leaflet calcification
Sievers type 1 with noncalcified raphe or incomplete raphe	Sievers type 2
Sievers type 0 (if circularity preserved)	Extreme elliptic shape
Annulus dimensions within transcatheter heart valve sizing range	highly calcified leaflet
Homogenous and moderate calcified leaflets	Circumferential calcifications
Absence of aortopathy or aorta dimension <45 mm (50 mm in high-risk patients)	Highly calcified left ventricular outflow tract
	Low calcium burden and large annulus (mixed aortic regurgitation and aortic stenosis)
	Shallow/effaced sinus and long calcified leaflet or low coronary takeoff
	Anomaly of coronary implantation

Vincent et al, *Circulation* 2021

TAVR in Bicuspid Aortic Valve

What we know

- Feasible and safe
- One-year mortality similar to surgery and TAV
- Better results with newest generation of THV
- A CT Scan is mandatory for procedure planning
- Calcified raphe + highly calcified leaflets associated with poor outcomes

Warning

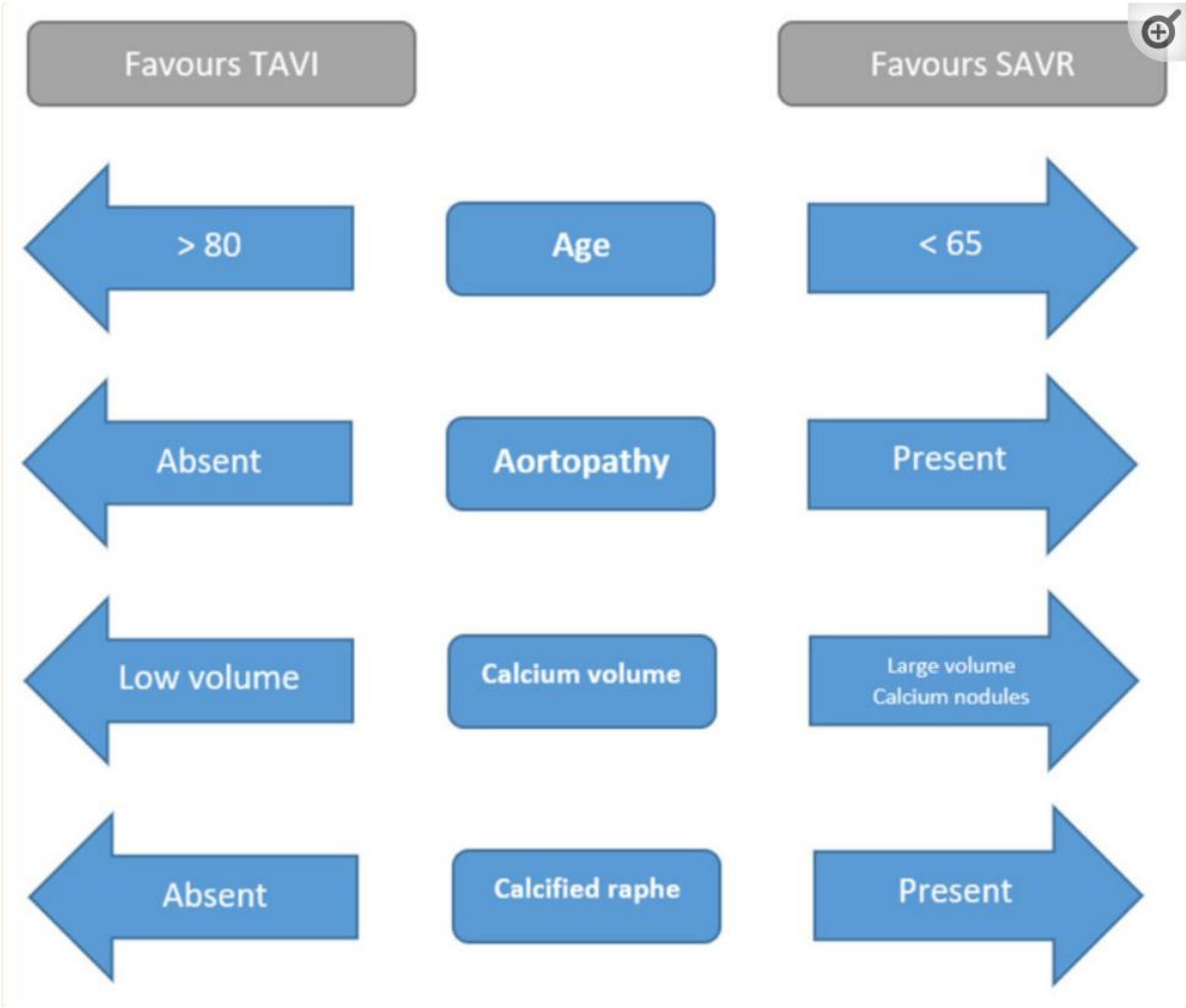
- Low but higher risk of stroke than TAV
- Higher risk of pacemaker implantation than surgery
- Low but higher risk of annulus rupture than TAV (BE-valve)
- Higher risk of ≥mild PVR than TAV or surgery

Remaining questions

- Anatomical features favorable/unfavorable for TAVR
- Optimal CT scan sizing methods for THV selection
- Type of valve based on anatomy
- Prosthetic valve durability
- Prosthetic valve thrombosis
- Evolution of the aortopathy after TAVR

Need for randomized trial of TAVR vs. SAVR and larger cohorts with long-term follow-up in patients with BAV after TAVR

Vincent et al, *Circulation* 2021


Favours TAVI
Favours SAVR
> 80
Age
< 65
Absent
Aortopathy
Present
Low volume
Calcium volume
Large volume
Calcium nodules
Absent
Calcified raphe
Present

Valve Selection

- Retrospective data in BAV-TAVI have shown BEV to be associated with a small numerical increase in the risk of annular rupture (1.7% vs. 0.0%, $p = 0.173$), whereas SEVs are associated with a significantly increased rate of moderate or severe PVR (10.8% vs. 0.8%, $p < 0.001$).

- The balloon-expandable (Sapien 3™, Edwards Lifesciences, CA, USA) and self-expandable (Evolut R/PRO™, Medtronic, MN, USA) THV have received US Food and Drug Administration and European Conformity approval for all categories of surgical risk regardless of anatomy

BAV Randomized Trials in the Works

- The **NAVIGATE** trial (chaired by Windecker and Matthias Siepe, MD).
- The **BELIEVERS** trial (chaired by Raj R. Makkar, MD, FACC, and Vinod H. Thourani, MD, FACC).
- The **YOUNG TAVR** (chaired by Mayra E. Guerrero, MD, FACC, and Thourani).
- These trials will assess the primary safety endpoint of death, stroke and moderate or more paravalvular regurgitation at **one year**, as well as the primary efficacy endpoint of death, stroke and procedure- and valve-related hospitalizations at **five** years, with pre-specified follow-up at **10** years. Patients will be asked for lifelong follow-up.

BAV Randomized Trials in the Works

- 2 scenarios.

  1)People who are on the higher end of the surgical risk spectrum where they're likely to get TAVR.

  2)Patients who are lower risk and have anatomy not suitable for TAVR who are sent for surgery.

Ross procedure.

- The Ross procedure is emerging as the optimal surgical treatment for younger adults with aortic valve disease, with a growing number of studies now showing it is the only surgical option that restores normal life expectancy to a patient

- Observational studies to date indicate that TAVR in selected patients with bicuspid valve disease performs very well perhaps better than SAVR, but validation in a randomized clinical trial against the current gold standard SAVR is missing.
- Mainly SEV. Be careful the coronaries for future TAVI in TAVI for young patients.


ΝΑΥΤΙΚΟ
ΝΟΣΟΚΟΜΕΙΟ
ΑΘΗΝΩΝ