

Indicatiestelling en besluitvorming bij aortaklepstenose

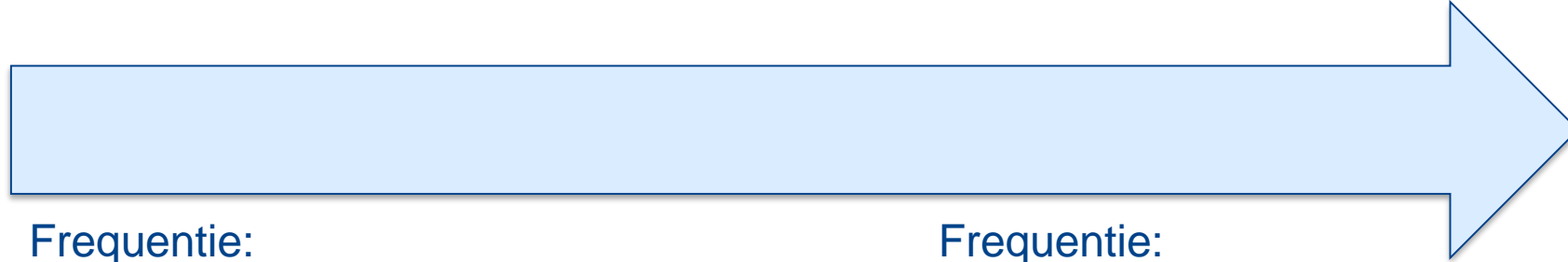
- Geschiedenis
- Aortaklepstenose (richtlijn)
- Wie TAVI volgens richtlijn
 - Risicoscores
 - Frailty
- Wie TAVI volgens ZIN
- Shared decision making
- Hoe doen wij het in Maastricht

Epidemiologie

Aortaklepsclerose

Progressie

Aortaklep stenose

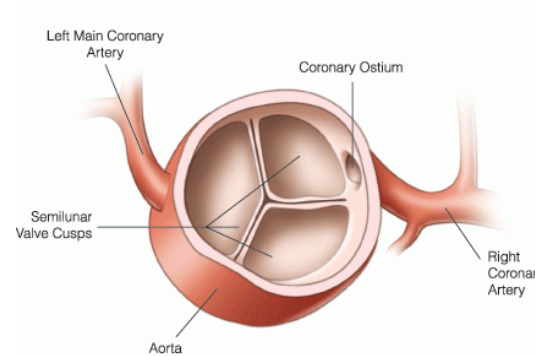


Frequentie:

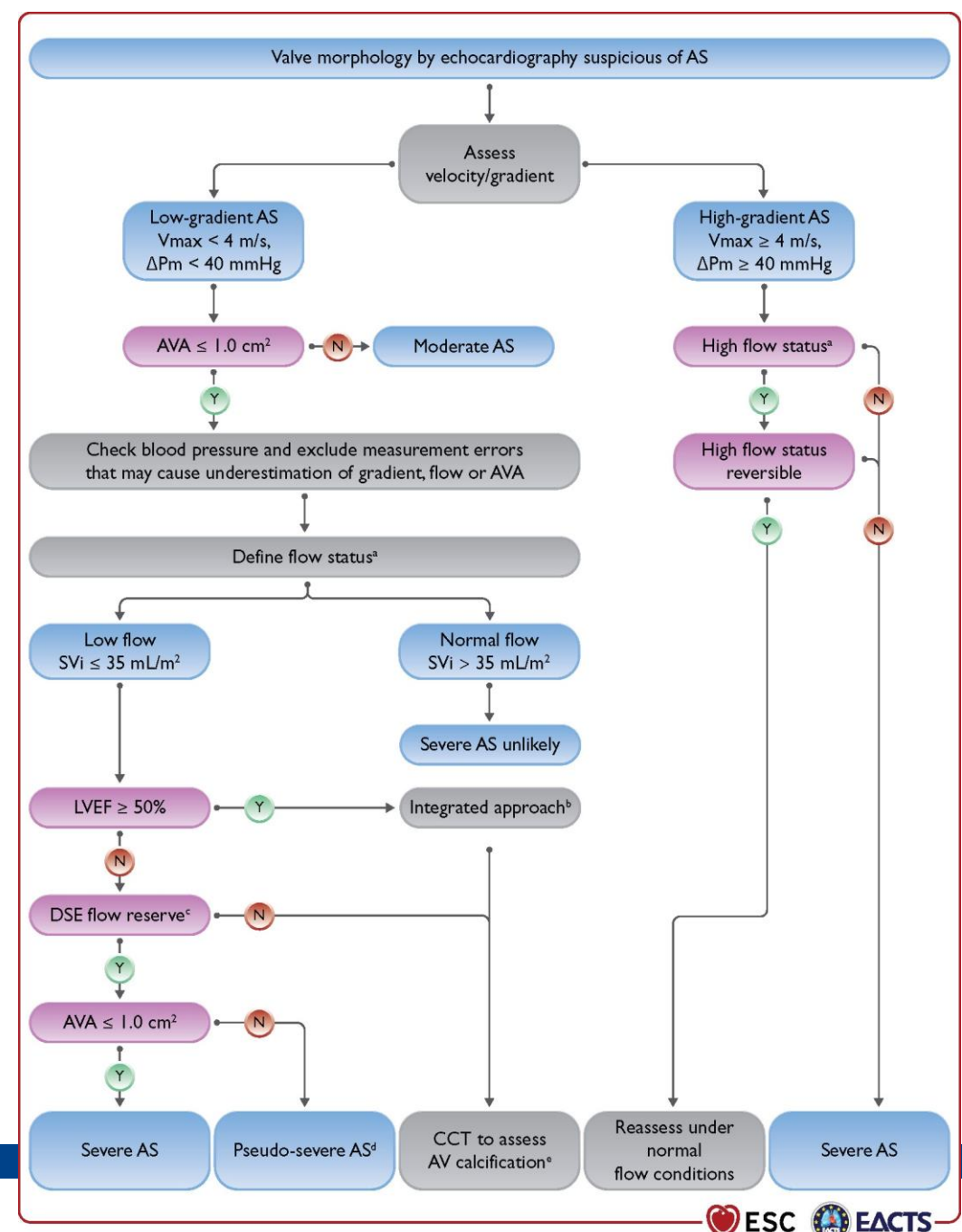
- 65 jaar: 25%
- >75 jaar: 48%

Frequentie:

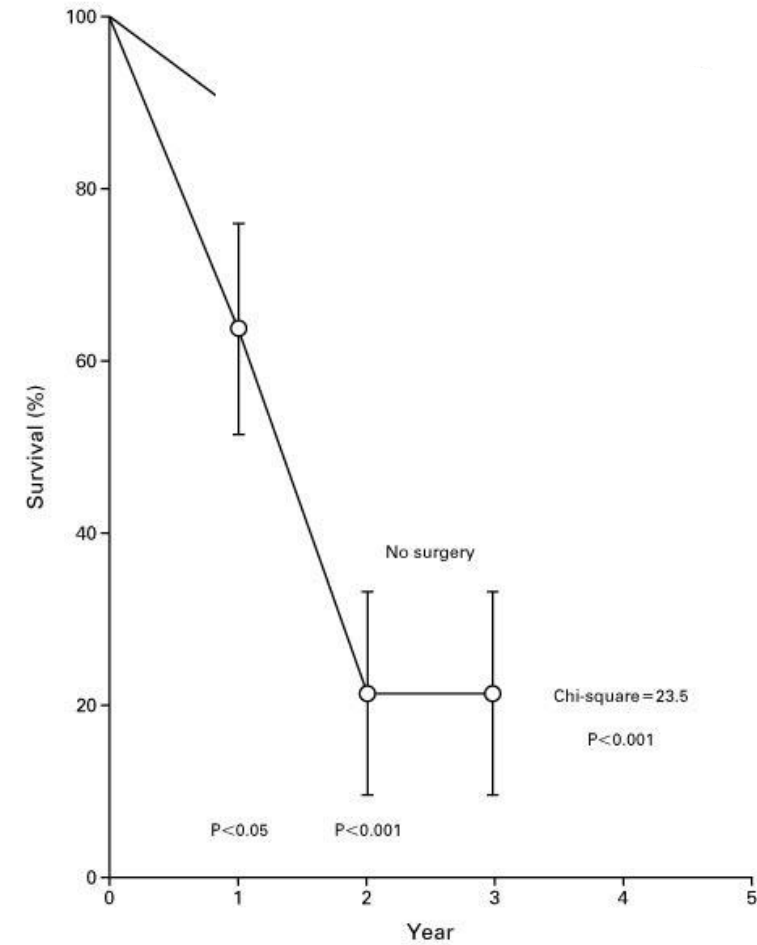
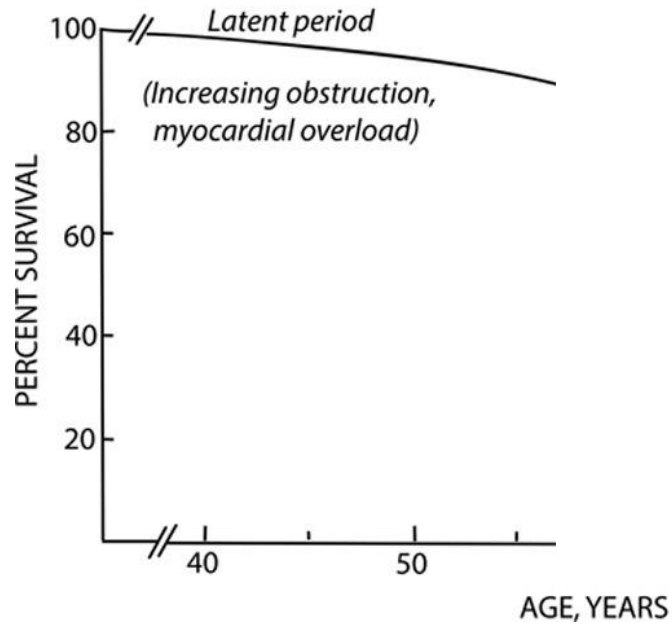
- 4-5% >65 jaar
- 13% :75 jaar
- Jaarlijkse incidentie: 5/1000
- Meest voorkomend
- Toename 2-3x binnen 50 jaar



- Severe AoS
- Low Flow Low Gradient AoS
- Pseudo LFLG AoS

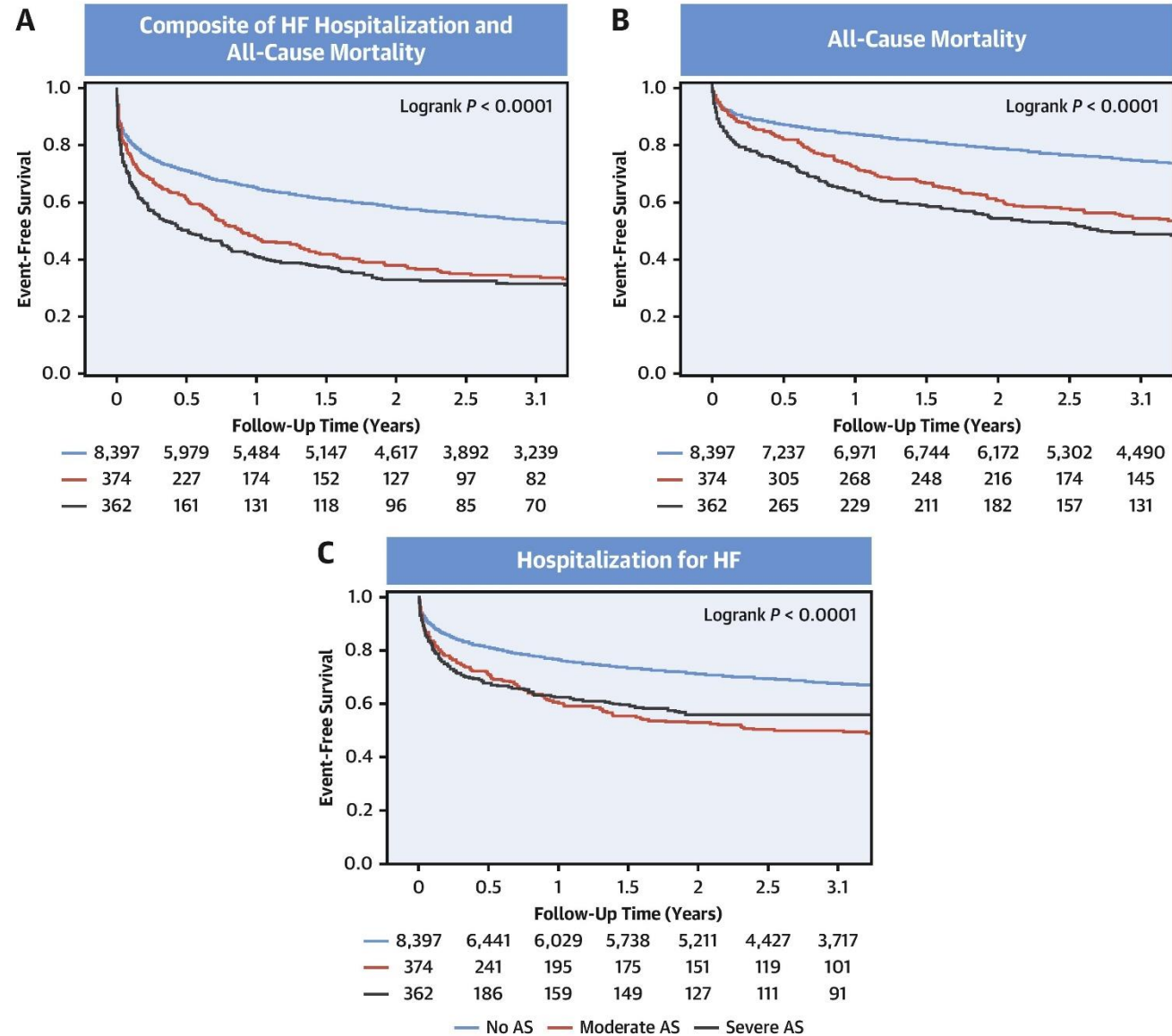


Natuurlijk beloop



NO. AT RISK		0	1	2	3	4	5
Valve replacement	125	87	51	35	9	0	0
No surgery	19	8	2	1	0	0	0

CENTRAL ILLUSTRATION: Kaplan-Meier Analysis for Patients With HF_{rEF} Stratified by AS



To intervene or not to intervene (how to intervene?)

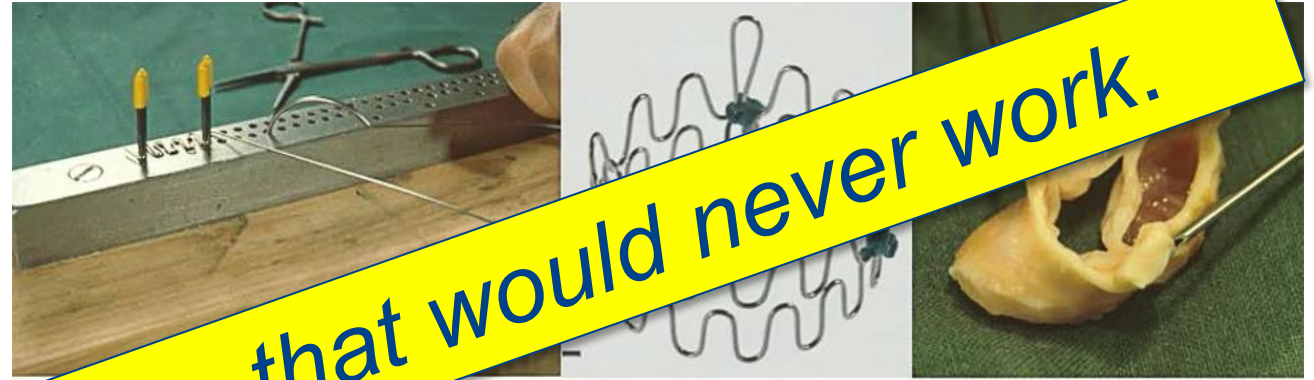
Chirurgische aortaklep vervanging (**SAVR**)

Transcatheter aortaklep implantatie (**TAVI**)

Conservatief

Geschiedenis van TAVI

- 1e prototype BE-valve in Varken
 - 1989 in Denemarken
 - Henning Andersen
- Abstract afgewezen voor ESC 1990
- Manuscript afgewezen voor Circulation/JACC
- Patent-kosten te hoog, verkocht aan *Medtronic* voor 1 miljoen, met de bedoeling om het te ontwikkelen met *Medtronic*
- Patent doorverkocht



"316 SL" 8-14 mm

Porcine



41 Fr = 13.6 mm (OD)

Geschiedenis van TAVI

- 1994 kwam Alain Cribier met een vergelijkbaar idee
- Klep verder ontwikkelen was moeizaam: '*ridiculous, impossible and unnecessary*'
- In 1999 werd PVT (percutaneous valve technologies) opgericht kocht patent over
- In 2002 1e klinische TAVI in 57-jarige patient met HF (EF 10%)



Geschiedenis van TAVI

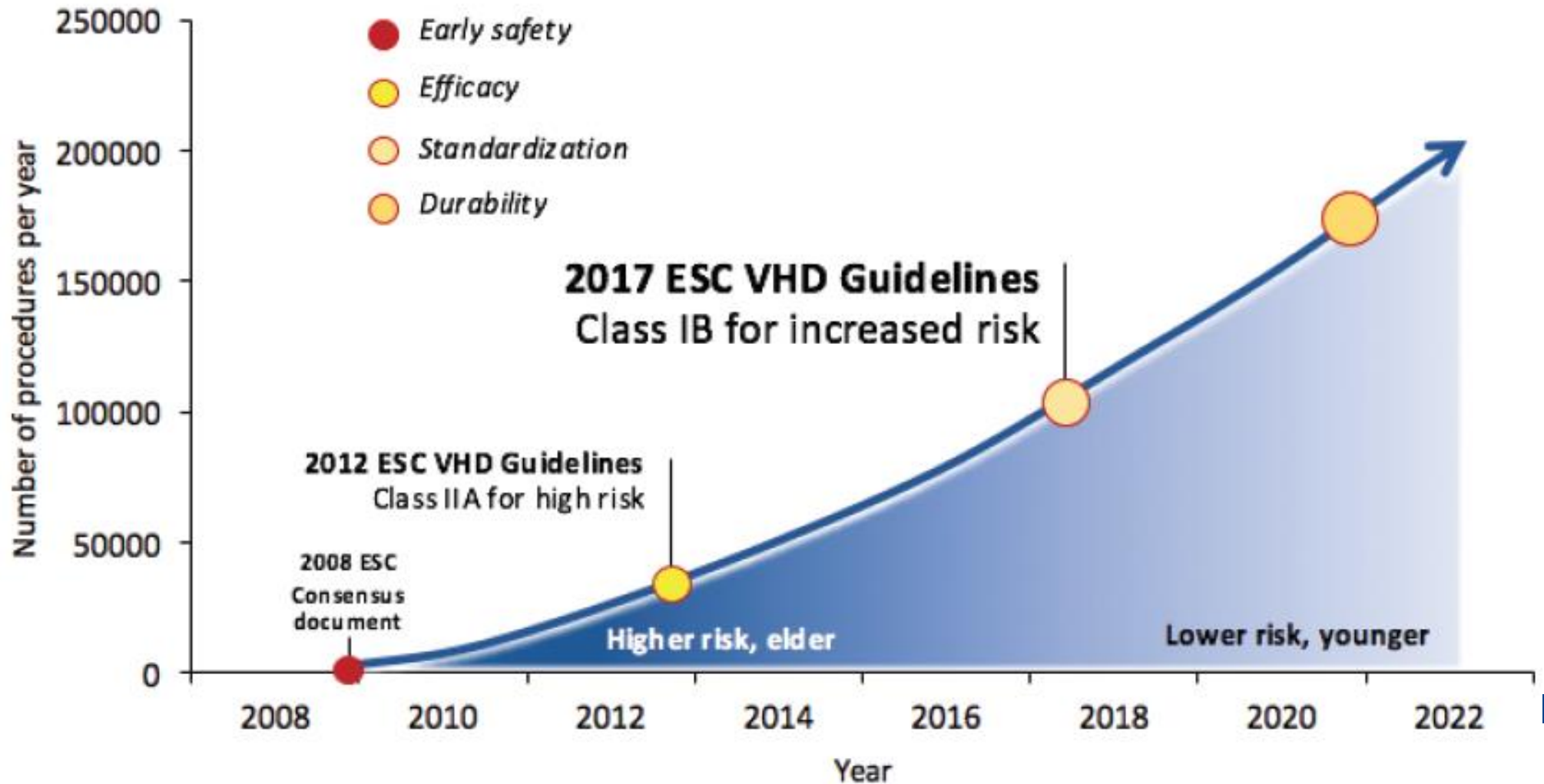
- Begin 2000 is ook de SE-valve ontwikkelt door CoreValve (later MDT)
- Gebruikelijke enthousiasme:

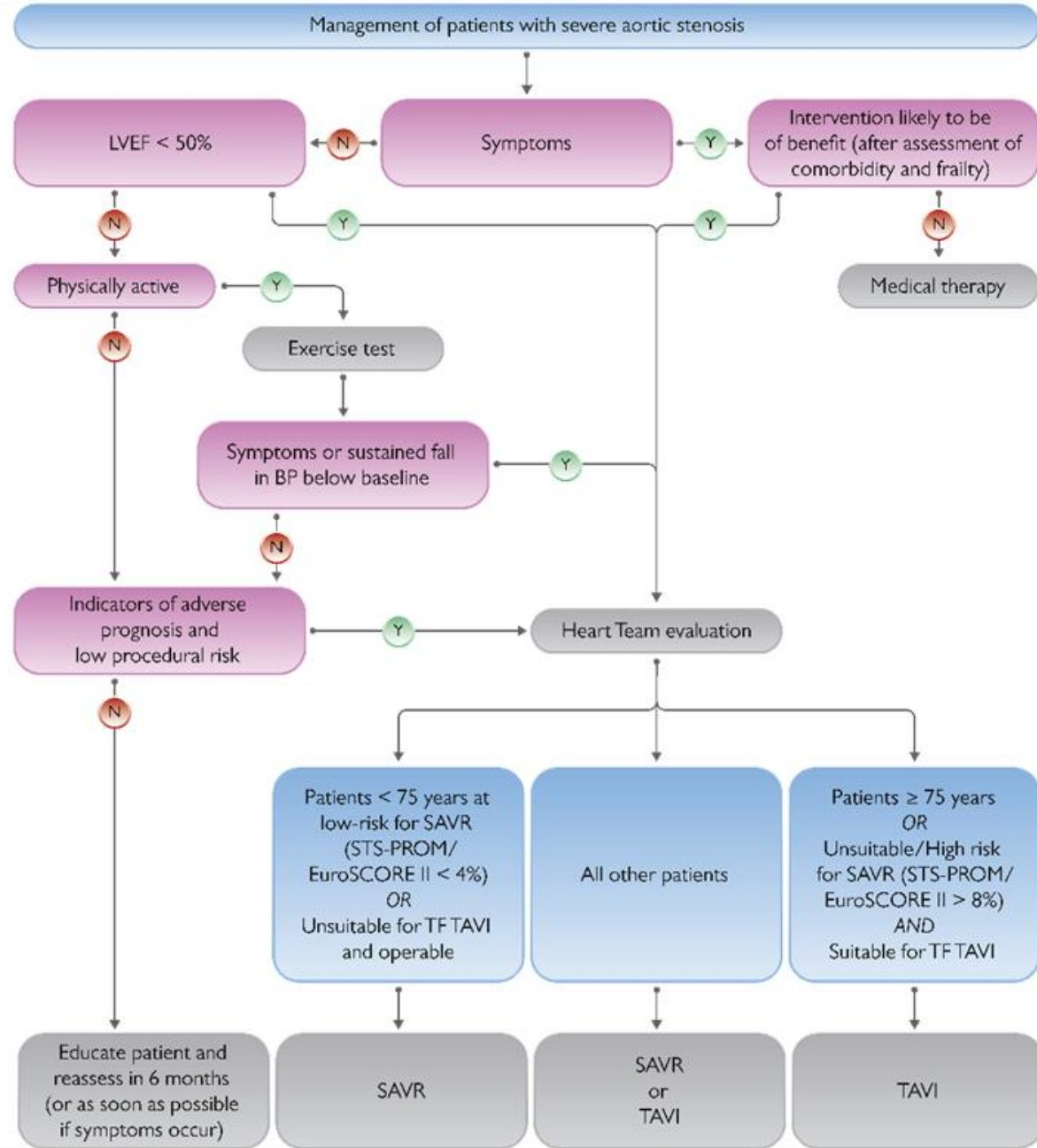
“we were crazy and it would be over their dead body if one of these ever got implanted in a patient.”

- In 2005 1^e TAVI in NL (Corevalve 23mm) in EMC



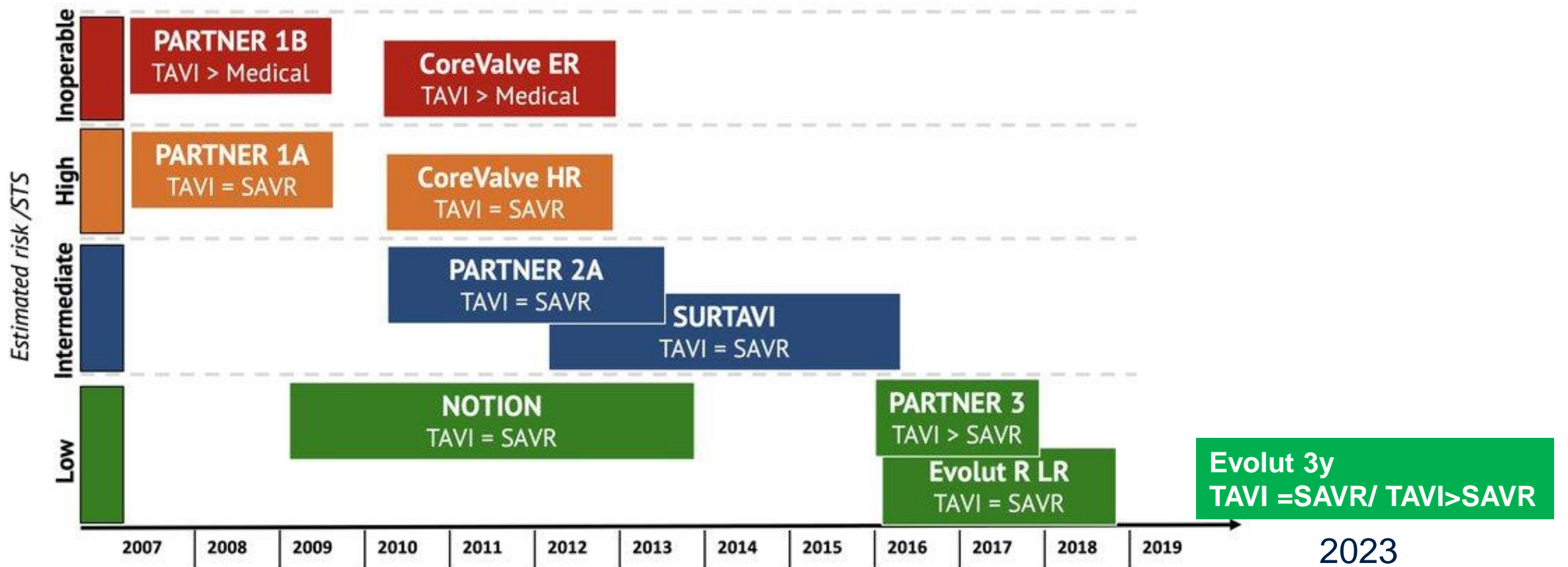
Totally unrealistic and stupid idea that would never work





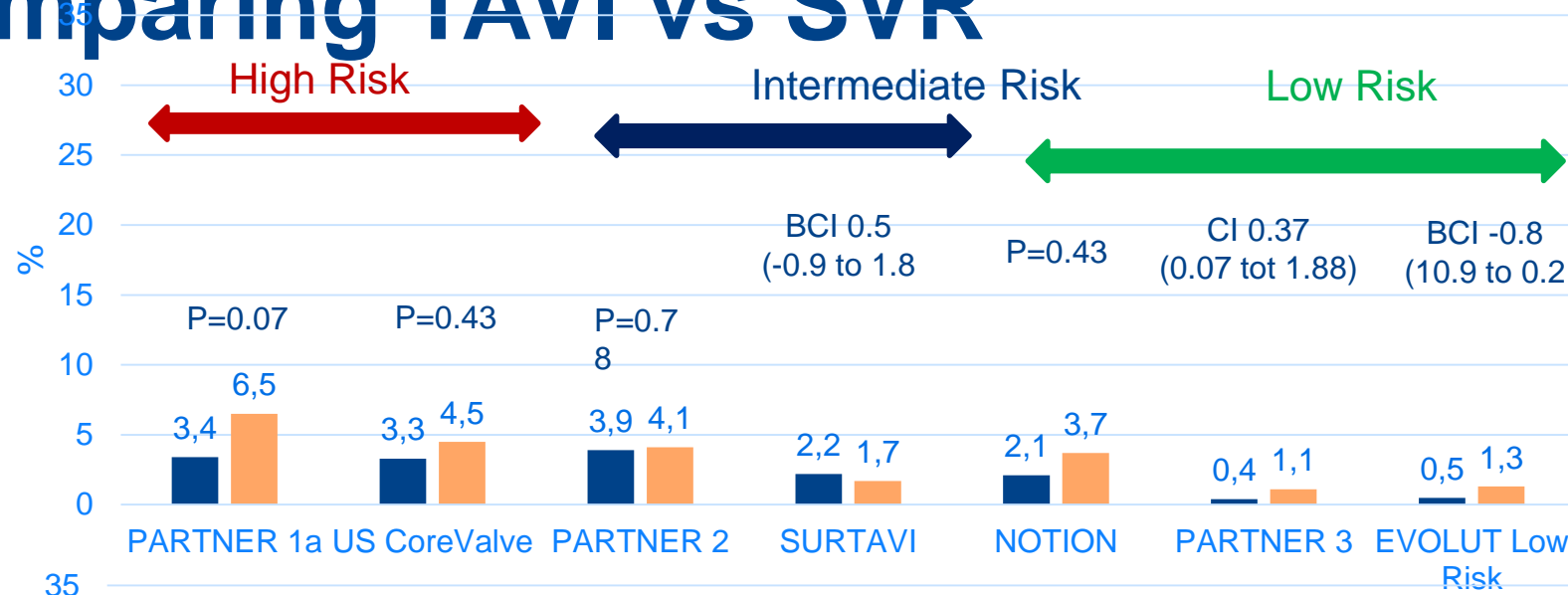
Recommended mode of intervention on aortic stenosis (2)

Recommendations	Class	Level
<u>SAVR</u> is recommended in <u>younger</u> patients who are <u>low risk</u> for surgery (<75 years and STS-PROM/EuroSCORE II <4%), or in patients who are <u>operable</u> and <u>unsuitable</u> for transfemoral TAVI.	I	B
<u>TAVI</u> is recommended in <u>older</u> patients (≥75 years), or in those who are <u>high risk</u> (STS-PROM/EuroSCORE II >8%) or <u>unsuitable for surgery</u> .	I	A
<u>SAVR or TAVI</u> are recommended for <u>remaining patients</u> according to individual clinical, anatomical, and procedural characteristics.	I	B
Non-transfemoral TAVI may be considered in patients who are inoperable and unsuitable for transfemoral TAVI.	IIb	C
Balloon aortic valvotomy may be considered as a bridge to SAVR or TAVI in haemodynamically unstable patients and (if feasible) in those with severe aortic stenosis who require urgent high-risk NCS.	IIb	C

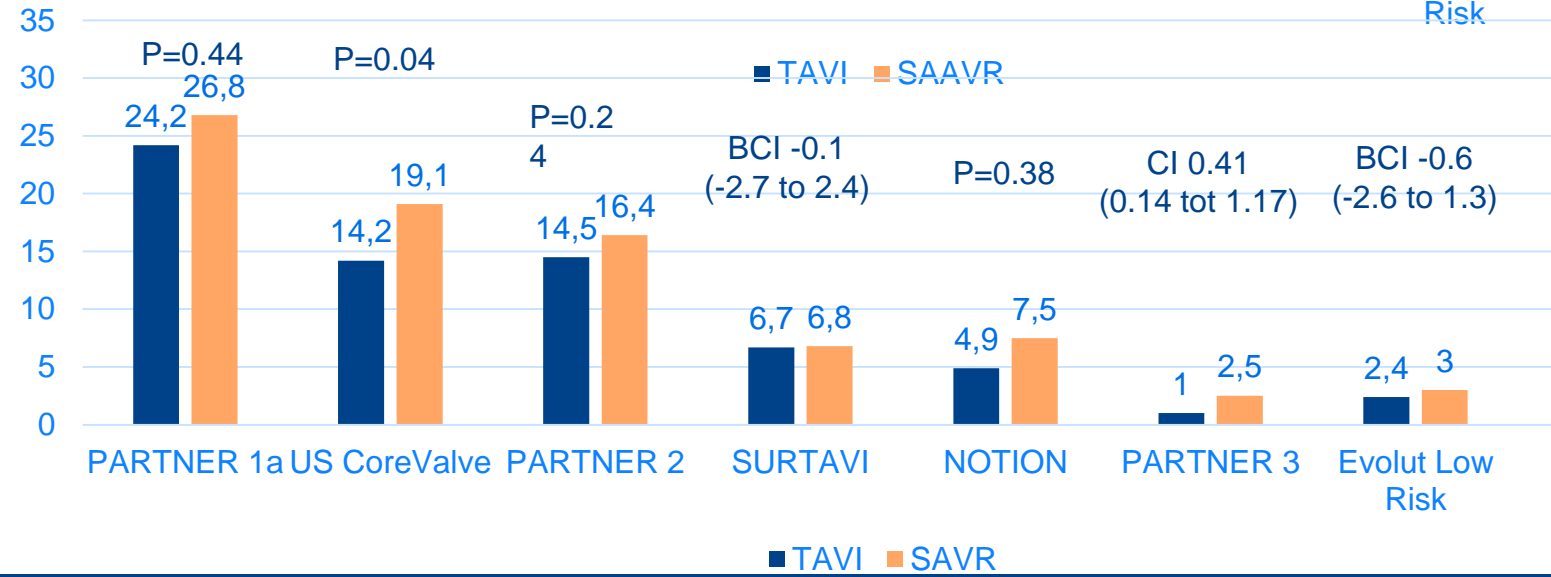


RCT's comparing TAVI vs SVR

30-day



1-year





Extreme risk	I	B
High-risk	IIa	B

Extreme risk	I	B
Increased risk	I	B

>75 Y, or high risk or unsuitable for surgery

I	A
---	---



Prohibitive risk	I	B
High-risk	IIa	B

Prohibitive risk	I	A
High-risk	I	A
Intermediate risk	IIa	B-R

Remaining patients according to individual clinical, anatomical, and procedural characteristics

I	B
---	---



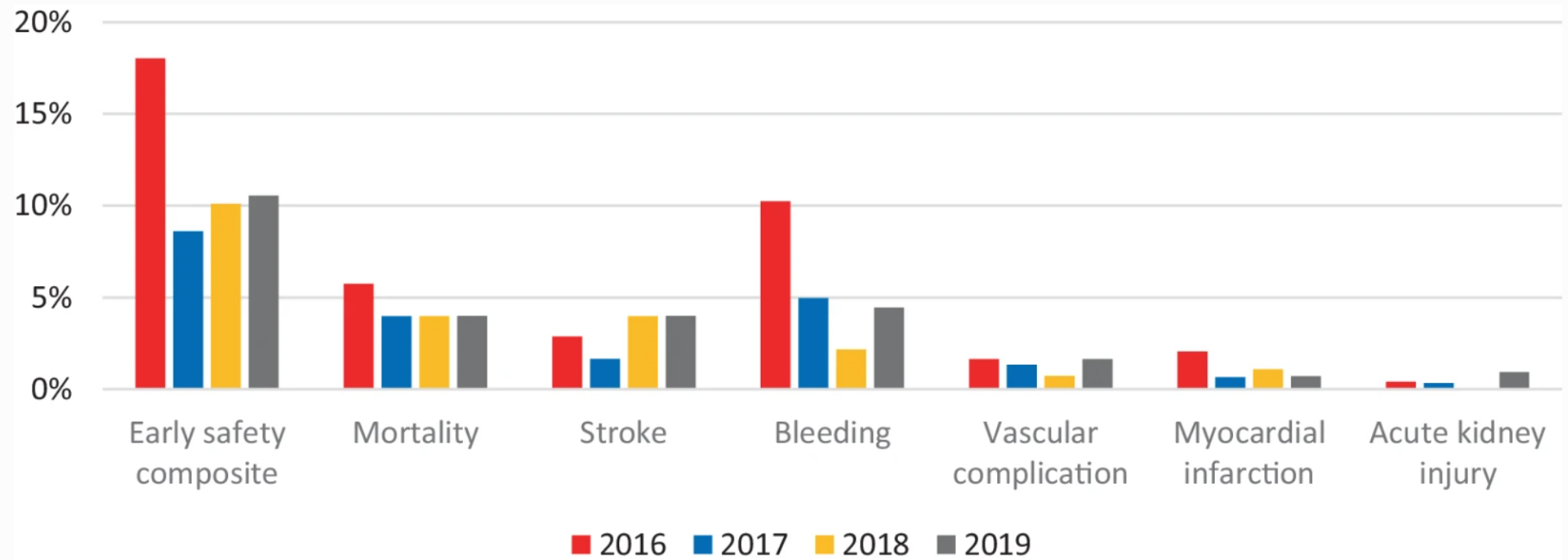
TAVI complicaties

Dec 2015- jan 2020 - Nieuwegein en UMCU
1200 patiënten - 146 major complication

138 (11.0%) PPI
76 (55.1%) within 2 days

FU: 30 dagen

From: [Major threats to early safety after transcatheter aortic valve implantation in a contemporary cohort of real-world patients](#)



Occurrence of primary endpoints per year

Risk score (in hospital mortality)

- STS predicted risk of mortality score (PROM)
- EuroSCORE II (European System for Cardiac Operative Risk Evaluation II)
- Geen risico factoren als: frailty, anatomische factoren (porseleinen aorta, borst radiatie)

Tabel 2. Stratificatie op basis van het 30-dagen sterfterisico na cardiale chirurgie

STS-PROM of EuroSCORE II score	Risicogroep
50% of hoger	Extreem/onacceptabel hoog ('inoperabel')
8% tot 50%	Hoog
4% tot 8%	Gemiddeld ('intermediate')
minder dan 4%	Laag

TAVI risk score

Integrated approach for estimating transcatheter aortic valve implantation-specific risk and futility



Criteria	Low risk	Intermediate risk	High risk	Prohibitive risk
PARTNER TAVI score OR FRANCE 2 TAVI score	<25% risk of mortality or lack of QOL improvement at 6 months Risk score: 0 (30-day mortality risk <5%)	25–50% risk of mortality or lack of QOL improvement at 6 months Risk score: 1–5 (30-day mortality risk 5–15%)	>50% risk of mortality or lack of QOL improvement at 6 months Risk score: 6–7 (30-day mortality risk 15–25%)	 Risk score ≥ 8 (30-day mortality risk >25%)

TAVI risk score

Supplementary Table 1 Cardiovascular and non-cardiovascular factors linked with transcatheter aortic valve implantation-related futility featured within the PARTNER and FRANCE 2 transcatheter aortic valve implantation-risk score models

	PARTNER risk score	FRANCE 2 risk score
Non-cardiovascular factors		Age ≥ 90 years
		BMI < 30 kg/m ²
	Higher serum creatinine	Dialysis
	Oxygen-dependent chronic lung disease	Respiratory insufficiency
	Lower mini-mental status exam	
		Non-transfemoral access
Cardiovascular factors	Major arrhythmia (AF)	NYHA Class IV
	Lower mean trans-aortic gradient	Critical haemodynamic state ≥ 2 pulmonary oedemas/year
	Lower 6MWT distance	Pulmonary hypertension
	High-prohibitive risk	
	>50% mortality or lack of quality-of-life improvement at 6 months	>15% 30-day mortality

© ESC/EACTS 2021

AF = atrial fibrillation; 6MWT = 6-minute walk test; BMI = body mass index; NYHA = New York Heart Association.

Reproduced from Puri R et al., TAVI or no TAVI: identifying patients unlikely to benefit from transcatheter aortic valve implantation. *Eur Heart J* 2016;**37**:2217–2225, by permission of Oxford University Press on behalf of the European Society of Cardiology.¹

Other factors

- Frailty: verminderd vermogen van fysiologische reserve en vermogen leidend tot verhoogde kwetsbaarheid bij verandering van gebeurtenissen.
- Componenten van frailty scores:
 - Lichamelijke: mobiliteit, kracht, balans en voeding
 - Cognitieve: geheugen, aandacht, executive functie
 - Sociale factoren: sociale support, inrichting woonomgeving
- Tools:
 - Katz index
 - Edmonton score

TAVI risk score

Integrated approach for estimating transcatheter aortic valve implantation-specific risk and futility



Criteria	Low risk	Intermediate risk	High risk	Prohibitive risk
PARTNER TAVI score OR FRANCE 2 TAVI score	<25% risk of mortality or lack of QOL improvement at 6 months Risk score: 0 (30-day mortality risk <5%)	25–50% risk of mortality or lack of QOL improvement at 6 months Risk score: 1–5 (30-day mortality risk 5–15%)	>50% risk of mortality or lack of QOL improvement at 6 months Risk score: 6–7 (30-day mortality risk 15–25%)	 Risk score ≥ 8 (30-day mortality risk >25%)

The Edmonton Frail Scale

NAME : _____

d.o.b. : _____

DATE : _____

Supplementary Table 2 Katz Index of Independence in Activities of Daily Living

Patient's name and last name:			
	Activities point (1 or 0)	Independence (1 point)	Dependence (0 points)
Bathing		Bathes himself/herself completely or needs partial help while cleaning her back or genital region	Needs help while getting in or out of the tub or shower, and while cleaning more than one part of the body
Dressing		Dress himself/herself completely. May sometimes need help when tying shoes	Completely needs help while dressing
Toileting		Goes to toilet, gets on and off, clean genital area and puts on his/her clothing without help	Needs help while going to the toilet, cleaning self, and dressing
Mobilization		Gets up from the bed and chair on his/her own. May need help for carrying loads	Needs help while getting up from bed to the chair
Incontinence		May control himself/herself while urinating and defecating	Partially or completely incontinent of bowel or bladder
Feeding		Gets foods from plate into mouth without help. May need help while preparing food	Needs complete or partial help with feeding or requires parenteral nutrition

TOTAL SCORE:

Adapted from Katz S., Assessing self-maintenance: activities of daily living, mobility, and instrumental activities of daily living. *J Am Geriatr Soc* 1983;31:721–727. Copyright (1983), with permission from Wiley.²

© ESCRACTS 2021

Frailty domain	Item	0 point	1 point	2 points
Cognition	Please imagine that this pre-drawn circle is a clock. I would like you to place the numbers in the correct positions then place the hands to indicate a time of 'ten after eleven'	No errors	Minor spacing errors	Other errors
General health status	In the past year, how many times have you been admitted to a hospital?	0	1–2	≥2
	In general, how would you describe your health?	'Excellent', 'Very good', 'Good'	'Fair'	'Poor'
Functional independence	With how many of the following activities do you require help? (meal preparation, shopping, transportation, telephone, housekeeping, laundry, managing money, taking medications)	0–1	2–4	5–8
Social support	When you need help, can you count on someone who is willing and able to meet your needs?	Always	Sometimes	Never
Medication use	Do you use five or more different prescription medications on a regular basis?	No	Yes	
	At times, do you forget to take your prescription medications?	No	Yes	
Nutrition	Have you recently lost weight such that your clothing has become looser?	No	Yes	
Mood	Do you often feel sad or depressed?	No	Yes	
Continence	Do you have a problem with losing control of urine when you don't want to?	No	Yes	
Functional performance	I would like you to sit in this chair with your back and arms resting. Then, when I say 'GO', please stand up and walk at a safe and comfortable pace to the mark on the floor (approximately 3 m away), return to the chair and sit down'	0–10 s	11–20 s	One of : >20 s , or patient unwilling , or requires assistance
Totals	Final score is the sum of column totals			

Scoring :

- 0 - 5 = Not Frail
- 6 - 7 = Vulnerable
- 8 - 9 = Mild Frailty
- 10-11 = Moderate Frailty
- 12-17 = Severe Frailty

TOTAL

3 / 17

Administered by : _____

SAVR zeer onwenselijk (technisch inoperabel of sterk verhoogd risico)

- Leeftijd ≥ 85 jaar Ja / Nee
- Extreem overgewicht (BMI ≥ 40) Ja / Nee
- Extreem ondergewicht (BMI ≤ 20) Ja / Nee
- LV Ejectiefractie $\leq 30\%$ Ja / Nee
- Porseleinen aorta Ja / Nee
- Anatomische thorax deformatie Ja / Nee
- Actieve maligniteit Ja / Nee
- RV-falen (>moderate, PHT
>55mmHg) Ja / Nee
- Cognitieve stoornissen Ja / Nee
- Levercirrhose (Child Pugh klasse A-B) Ja / Nee
- Jehova's Getuige EN Hb $< 8,5$ mmol/l Ja / Nee
- Indicatie voor spoedige, niet-cardiale chirurgie,
bijvoorbeeld voor een maligniteit, waarbij het risico 2 kort op
elkaar volgende OK's of een gecombineerde ingreep te hoog is. Ja / Nee

Indien alle vragen Nee

Indien $\geq 1x$ JA: overweeg TAVI als alternatieve, gepaste behandeling

ga verder

TAVI of conservatief

Zorginstituut Nederland

Hoog risico bij SAVR

• Leeftijd ≥ 80 jaar	Ja / Nee
• Eerdere OHO	Ja / Nee
• Frailty (bv Edmonton Frailty Score \geq matig kwetsbaar)	Ja / Nee
• Status na mantelveldbestraling	Ja / Nee
• Eerder CVA met restverschijnselen of TIA in de afgelopen 6 mnd.	Ja / Nee
• COPD (Gold \geq III)	Ja / Nee
• Nierfalen (GFR ≤ 30)	Ja / Nee
• LV Ejectiefractie $\leq 40\%$	Ja / Nee
• Chronisch gebruik van corticosteroiden/immunosuppressiva	Ja / Nee
• Verminderde mobiliteit	Ja / Nee
<i>Indien alle vragen Nee</i>	SAVR
<i>Indien 1x JA: overweeg TAVI als alternatieve, gepaste behandeling</i>	TAVI of SAVR
<i>Indien >1x JA: voorkeur voor TAVI</i>	TAVI

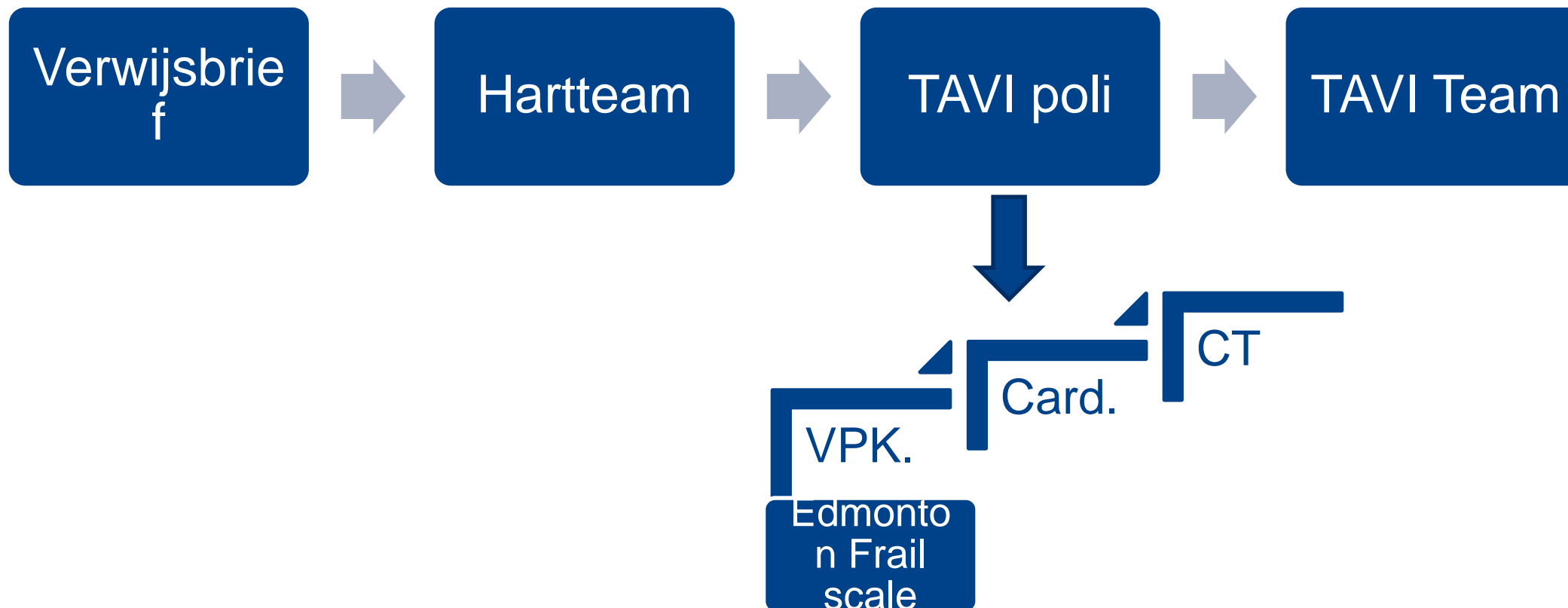
Zorginstituut Nederland

Indicatie voor conservatief beleid

- Geringe kans op gunstig effect van de behandeling (futility) Ja / Nee
 - Door comorbiditeit geen prognose-verbetering door SAVR of TAVI Ja / Nee
 - Levensverwachting <1 jaar Ja / Nee
- Indien alle vragen Nee*
Indien 1x JA
- ga verder
conservatief beleid***

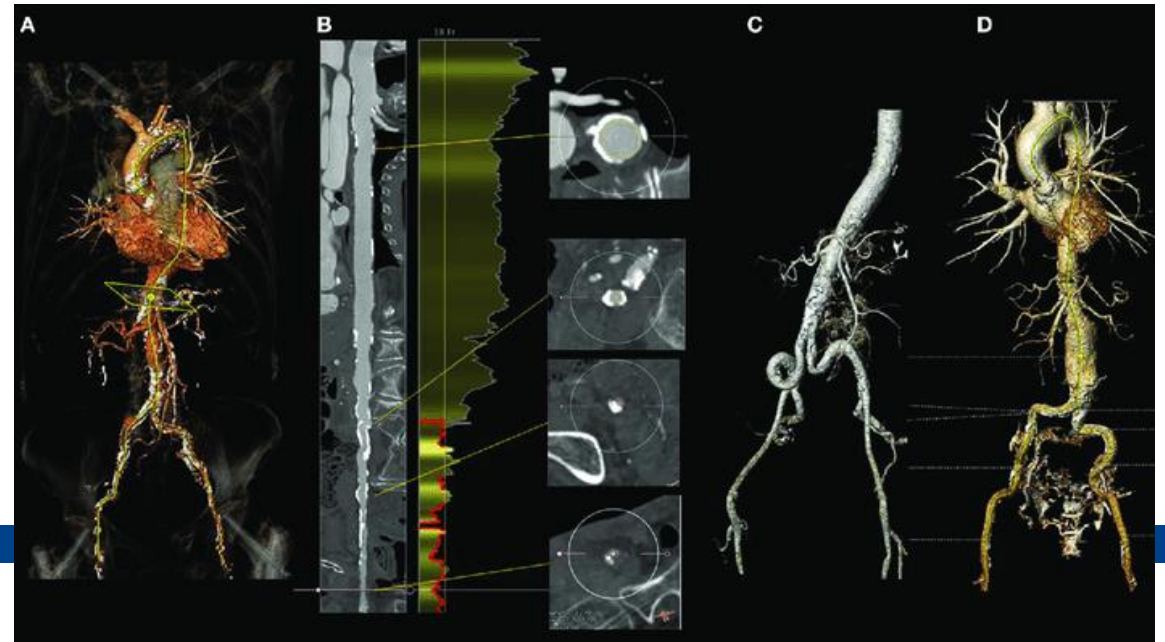


Zorginstituut Nederland



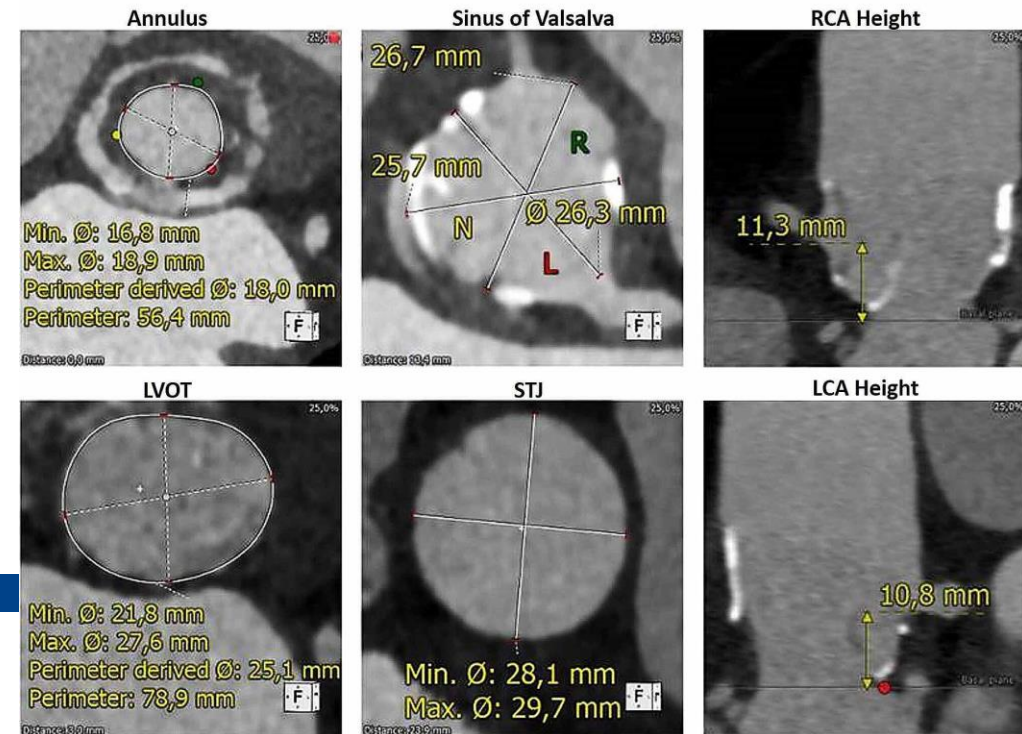
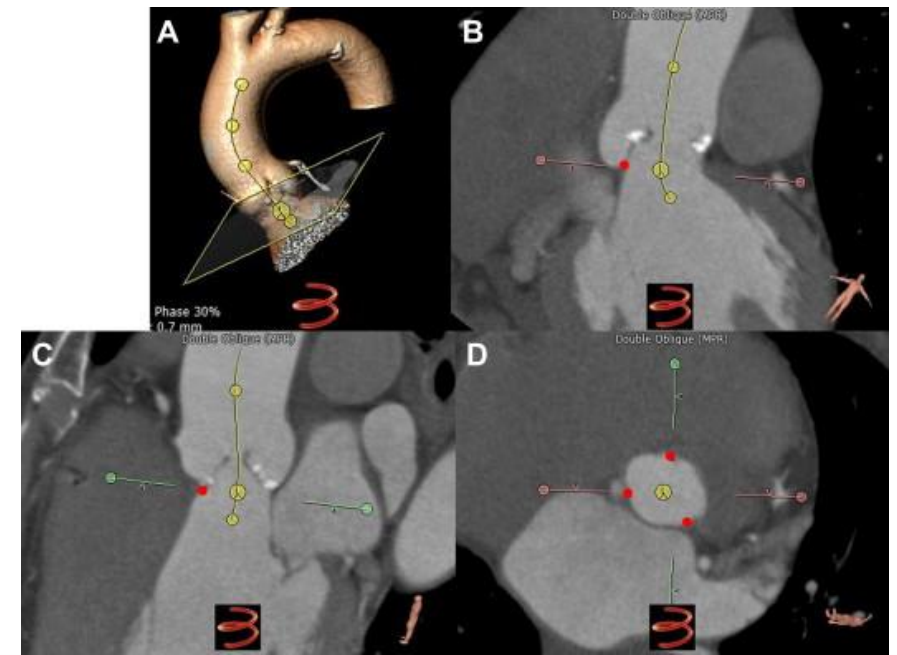
CT TAVI

- feasibility of vascular access
- aortic valve anatomy
- extent and distribution of valve and vascular calcification



CT TAVI

- annular size and shape
- risk of coronary ostial obstruction
- aortic root dimensions







De devices en klepkeuze

SAPIEN 3 Sizing Guidelines



Specifications		20 mm	23 mm	26 mm	29 mm
Native Valve Annulus Size (CT)	Area	273–345 mm ²	338–430 mm ²	430–546 mm ²	540–683 mm ²
	Area Derived Diameter	18.6–21 mm	20.7–23.4 mm	23.4–26.4 mm	26.2–29.5 mm
Native Valve Annulus Size TEE		16–19 mm	18–22 mm	21–25 mm	24–28 mm

PATIENT EVALUATION CRITERIA CoreValve™ Evolut™ R / Evolut™ PRO TAVI

Valve Size Selection	Evolut Pro Bioprosthesis			Evolut R Bioprosthesis
				
Size	23 mm	26 mm	29 mm	34 mm
Annulus Diameter	18–20 mm	20–23 mm	23–26 mm	26–30 mm
Annulus Perimeter ¹	56.5–62.8 mm	62.8–72.3 mm	72.3–81.7 mm	81.7–94.2 mm
Sinus of Valsalva Diameter (Mean)	≥25 mm	≥27 mm	≥29 mm	≥31 mm
Sinus of Valsalva Height (Mean)	≥15 mm	≥15 mm	≥15 mm	≥16 mm

TAVI vs Conservative

- Shared decision making

Shared decision making

Definitie: proces waarin zorgverlener en patiënt op een gelijkwaardige manier, beslissingen nemen over diagnostiek en behandelingen op basis van (wetenschappelijke) kennis, (klinische) ervaring en de voorkeuren, waarden en behoeften van de patiënt.

Shared decision making

- **Belemmeringen:**
 - Tijdsgebrek, slecht passen in workflow
 - Patiënten (en zorgverleners) met onvoldoende gespreksvaardigheden
 - Gebrek aan bewustzijn bij patiënt om actief deel te nemen aan besluitvormingsproces



Ed Whitlock completed the Toronto Waterfront Marathon in 3 hours 56 minutes 34 seconds to become the miles under four hours. Todd Fraser/Canada Running Series

Your preference has been stored for this browser and device. If you clear your cookies, your preference will be forgotten.



AI Hi! How can I help you?

You would you give president biden a TAVI

AI I'm sorry, as an AI assistant, I am not qualified to make medical decisions or recommendations for any individual, including President Biden. It is best for any medical decisions to be made by qualified medical professionals. However, I can help you search for information about TAVI procedures and their potential benefits and risks if that would be helpful!

Type your message...

Clear