



70TH ESCVS CONGRESS & 7TH IMAD MEETING

20 | 23 JUNE 2022



TAVI vs Mini Invasive Aortic Valve Replacement ?



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Statement of Financial Interest

No disclosures

Recommendations

2017 ESC/EACTS Guidelines for the management of valvular heart disease

	Favours TAVI	Favours SAVR
Clinical characteristics		
STS/EuroSCORE II <4% (logistic EuroSCORE I <10%) ^a		+
STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%) ^a	+	
Presence of severe comorbidity (not adequately reflected by scores)	+	
Age <75 years		+
Age ≥75 years	+	
Previous cardiac surgery	+	
Frailty ^b	+	
Restricted mobility and conditions that may affect the rehabilitation process after the procedure	+	
Suspicion of endocarditis		+
Anatomical and technical aspects		
Favourable access for transfemoral TAVI	+	
Unfavourable access (any) for TAVI		+
Sequelae of chest radiation	+	
Porcelain aorta	+	
Presence of intact coronary bypass grafts at risk when sternotomy is performed	+	
Expected patient–prosthesis mismatch	+	
Severe chest deformation or scoliosis	+	
Short distance between coronary ostia and aortic valve annulus		+
Size of aortic valve annulus out of range for TAVI		+
Aortic root morphology unfavourable for TAVI		+
Valve morphology (bicuspid, degree of calcification, calcification pattern) unfavourable for TAVI		+
Presence of thrombi in aorta or LV		+
Cardiac conditions in addition to aortic stenosis that require consideration for concomitant intervention		
Severe CAD requiring revascularization by CABG		+
Severe primary mitral valve disease, which could be treated surgically		+
Severe tricuspid valve disease		+
Aneurysm of the ascending aorta		+
Septal hypertrophy requiring myectomy		+

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease

COR	LOE	RECOMMENDATIONS
1	A	1. For symptomatic and asymptomatic patients with severe AS and any indication for AVR who are <65 years of age or have a life expectancy >20 years, SAVR is recommended (1-3).
1	A	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).
1	A	3. For symptomatic patients with severe AS who are >80 years of age or for younger patients with a life expectancy <10 years and no anatomic contraindication to transfemoral TAVI, transfemoral TAVI is recommended in preference to SAVR (1,4-10).
1	B-NR	4. In asymptomatic patients with severe AS and an LVEF <50% who are ≤80 years of age and have no anatomic contraindication to transfemoral TAVI, the decision between TAVI and SAVR should follow the same recommendations as for symptomatic patients in Recommendations 1, 2, and 3 above (1,2,4-10).
1	B-NR	5. For asymptomatic patients with severe AS and an abnormal exercise test, very severe AS, rapid progression, or an elevated BNP (COR 2a indications for AVR), SAVR is recommended in preference to TAVI (1-3,11).
1	A	6. For patients with an indication for AVR for whom a bioprosthetic valve is preferred but valve or vascular anatomy or other factors are not suitable for transfemoral TAVI, SAVR is recommended (1-3,11).
1	A	7. For symptomatic patients of any age with severe AS and a high or prohibitive surgical risk, TAVI is recommended if predicted post-TAVI survival is >12 months with an acceptable quality of life (12,13,14,15).
1	C-EO	8. For symptomatic patients with severe AS for whom predicted post-TAVI or post-SAVR survival is <12 months or for whom minimal improvement in quality of life is expected, palliative care is recommended after shared decision-making, including discussion of patient preferences and values.
2b	C-EO	9. In critically ill patients with severe AS, percutaneous aortic balloon dilation may be considered as a bridge to SAVR or TAVI.

AVIS DE LA CNEDiMT

7 avril 2024

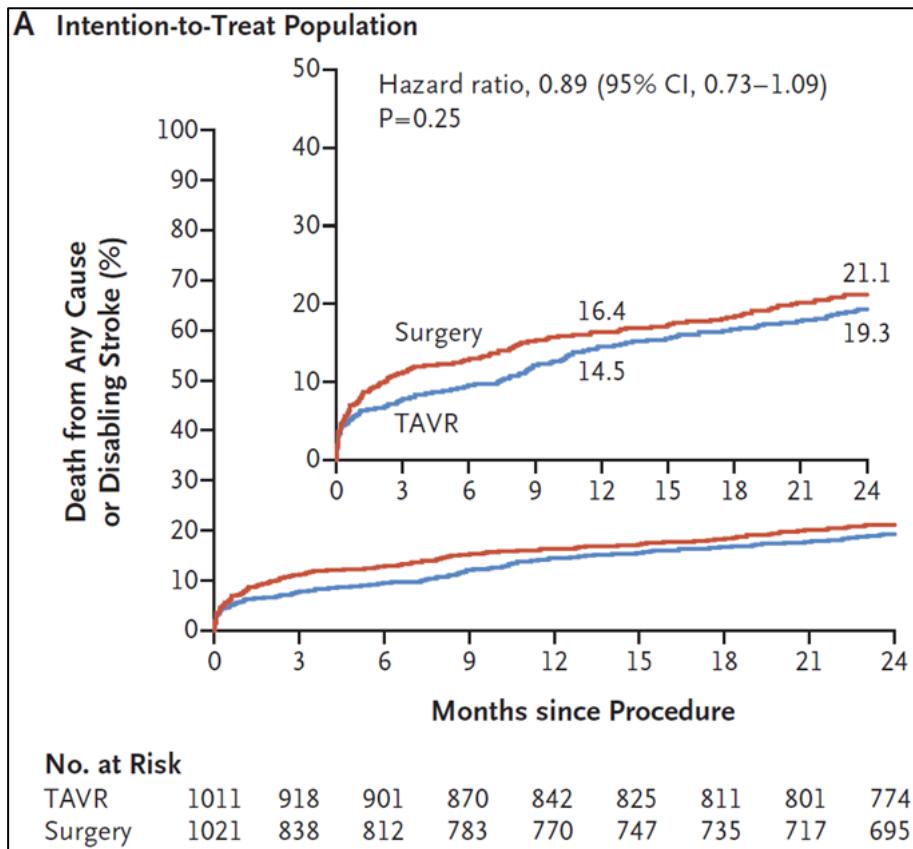
Faisant suite à l'examen du 24/03/2020, la CNEDiMTS a adopté le projet d'avancement le 07/04/2020.

Indications retenues :	<p>Patients âgés de plus de 65 ans à bas risques (STS < 4%) ayant une stenose artérielle sévère symptomatique (SVAn > 0,6 cm⁻² m⁻¹) sur une artérite tricuspidale sans indication chirurgicale valvulaire mitrale ou coronaire (tricuspid commun et/ou SYNTAX > 32) associée et avec une anatomie favorable à la voie transfémorale. L'indication doit être posée lors d'une réunion multidisciplinaire en prenant en compte les scores de risque et les comorbidités associées.</p>
Les patients ayant une espérance de vie inférieure à 1 an compte tenu de facteurs extracardiaques (comorbidités) ou ayant des calcifications importantes dans la chambre de chasse sous aortique ne sont pas éligibles à la technique (non-indication). Il est rappelé la nécessité du respect des contre-indications figurant au marquage CE du dispositif EDWARDS SAPIEN 3.	
Service Attendu (SA) :	Suffisant.
Comparateurs référents	Chirurgie de remplacement valvulaire aortique.
Amélioration du SA :	ASA de niveau III.
Type d'inscription :	Nom de marque.
Durée d'inscription :	Jusqu'à la date de fin de prise en charge de la bioprothèse valvulaire aortique EDWARDS SAPIEN 3 implantée par voie transfémorale avec le système DEPLOYMENT MEDICAL®.

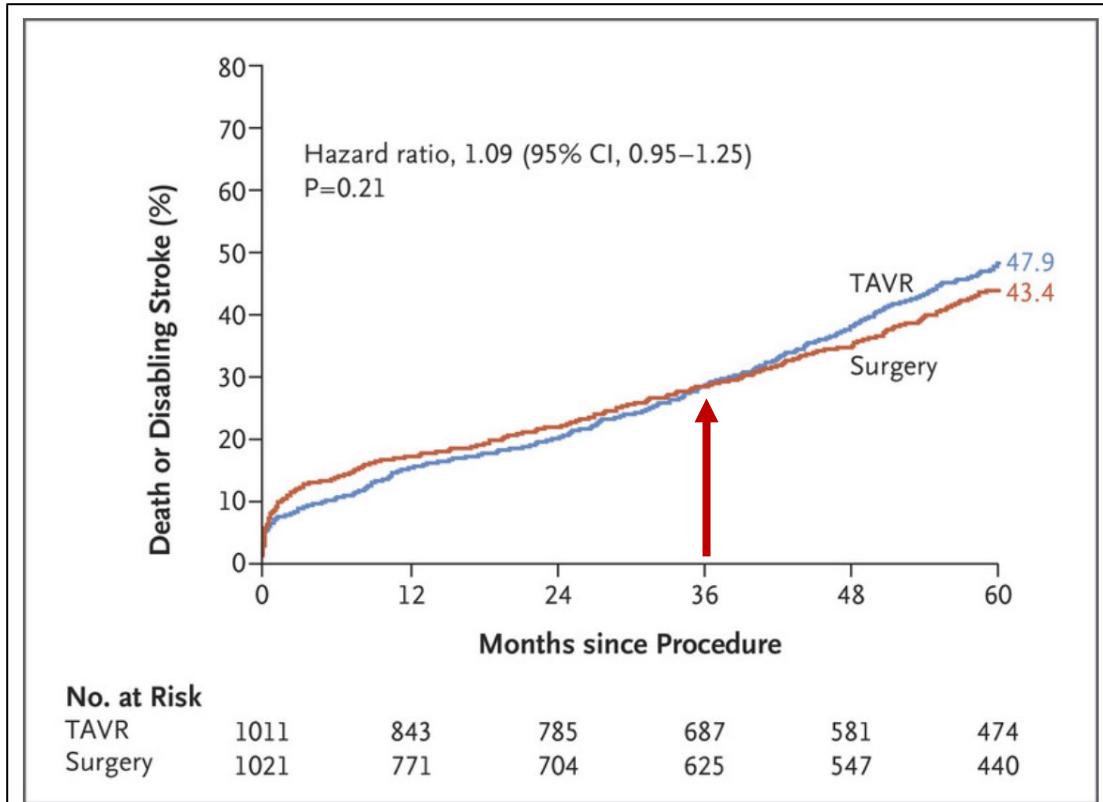
TAVI vs AVR

Life expectancy

PARTNER 2 Trial – 2 Years



PARTNER 2 Trial – 5 Years



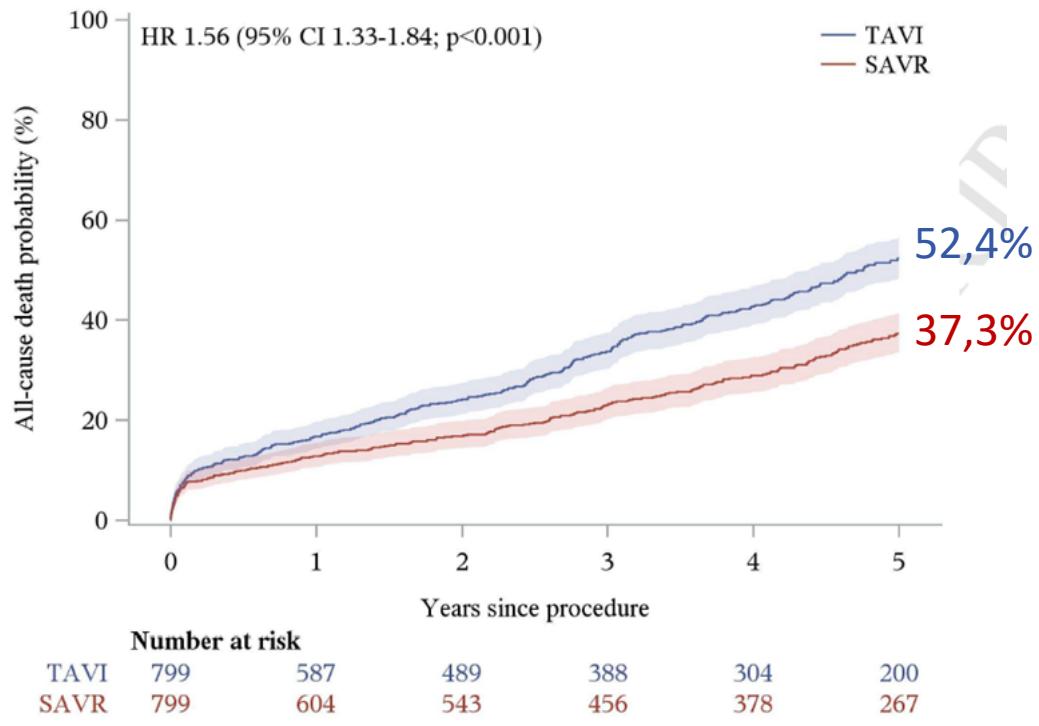
Leon MB et al. NEJM 2016;374:1609-1620

Makkar R et al. NEJM 2020;382:799-809

TAVI vs AVR

Life expectancy

Comparison of transcatheter to surgical aortic valve implantation in high risk patients:
A nationwide study in France



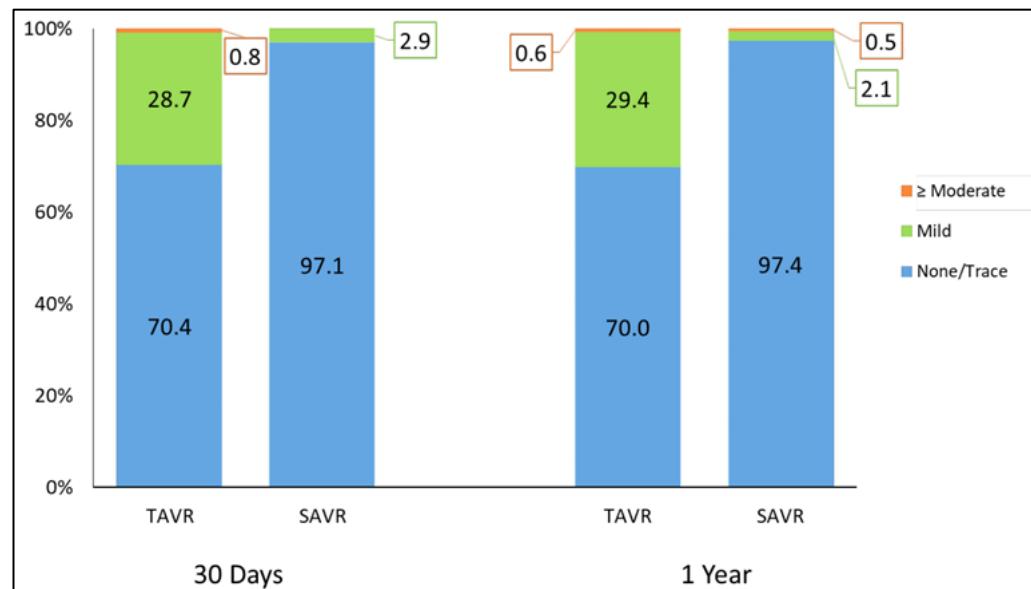
TAVI vs AVR

Risk of paravalvular leak

**Evolut LR - TAVR 39.4% vs.
SAVR 3.4%**

	30 Days		
	TAVR	Surgery	95% BCI for difference
Paravalvular leak	N=703	N=608	
None – no. (%)	146 (20.8)	544 (89.5)	(-71.9, -64.2)
Trace – no. (%)	280 (39.8)	44 (7.2)	(28.2, 36.5)
Mild – no. (%)	253 (36.0)	18 (3.0)	(29.0, 36.6)
Moderate – no. (%)	22 (3.1)	1 (0.2)	(1.6, 4.4)
Severe – no. (%)	2 (0.3)	1 (0.2)	(-0.6, 0.8)

**Partner 3 – TAVR 29.6% vs.
SAVR 2.9%**



TAVI vs AVR

Risk of pace maker and LBBB

Evolut LR –

TAVR 17.4% vs. SAVR 6.1%

Table 2. Clinical End Points at 30 Days and at 12 Months.⁹

End Point	30 Days				12 Months			
			Difference, TAVR–Surgery (95% BCI)				Difference, TAVR–Surgery (95% BCI)	
	% of patients	percentage points	% of patients	percentage points	% of patients	percentage points	% of patients	percentage points
Death from any cause or disabling stroke	0.8	2.6	–1.8 (–3.2 to –0.5)		2.9	4.6	–1.8 (–4.0 to 0.4)	
Death from any cause	0.5	1.3	–0.8 (–1.9 to 0.2)		2.4	3.0	–0.6 (–2.6 to 1.3)	
Death from cardiovascular cause	0.5	1.3	–0.8 (–1.9 to 0.2)		1.7	2.6	–0.9 (–2.7 to 0.7)	
All stroke	3.4	3.4	0.0 (–1.9 to 1.9)		4.1	4.3	–0.2 (–2.4 to 1.9)	
Disabling	0.5	1.7	–1.2 (–2.4 to –0.2)		0.8	2.4	–1.6 (–3.1 to –0.3)	
Nondisabling	3.0	1.7	1.2 (–0.3 to 2.9)		3.4	2.2	1.1 (–0.6 to 2.9)	
Transient ischemic attack	0.6	0.8	–0.2 (–1.2 to 0.7)		1.7	1.8	–0.2 (–1.6 to 1.3)	
30-Day composite safety end point†	5.3	10.7	–5.4 (–8.3 to –2.6)		NA	NA	NA	
Life-threatening or disabling bleeding	2.4	7.5	–5.1 (–7.5 to –2.9)		3.2	8.9	–5.7 (–8.4 to –3.1)	
Major vascular complication	3.8	3.2	0.6 (–1.4 to 2.5)		3.8	3.5	0.3 (–1.7 to 2.3)	
Acute kidney injury stage 2 or 3	0.9	2.8	–1.8 (–3.4 to –0.5)		0.9	2.8	–1.8 (–3.4 to –0.5)	
Atrial fibrillation	7.7	35.4	–27.7 (–31.8 to –23.6)		9.8	38.3	–28.5 (–32.8 to –24.1)	
Permanent pacemaker implantation	17.4	6.1	11.3 (8.0 to 14.7)		19.4	6.7	12.6 (9.2 to 16.2)	
Myocardial infarction	0.9	1.3	–0.4 (–1.5 to 0.7)		1.7	1.6	0.1 (–1.3 to 1.5)	
Coronary-artery obstruction	0.9	0.4	0.5 (–0.3 to 1.4)		0.9	0.4	0.5 (–0.3 to 1.4)	
Endocarditis	0.1	0.2	–0.1 (–0.7 to 0.3)		0.2	0.4	–0.2 (–0.9 to 0.5)	
Valve thrombosis	0.1	0.1	0.0 (–0.4 to 0.4)		0.2	0.3	–0.1 (–0.9 to 0.5)	
Aortic reintervention	0.4	0.4	0.0 (–0.8 to 0.7)		0.7	0.6	0.0 (–1.0 to 0.9)	
Hospitalization for heart failure	1.2	2.5	–1.3 (–2.8 to 0.1)		3.2	6.5	–3.4 (–5.9 to –1.0)	

Partner 3 –

PMP: TAVR 6.5% vs. SAVR 4%

LBBB: TAVR 22% vs. SAVR 8%

30 Days			
	TAVR (N = 496)	Surgery (N = 454)	Treatment Effect [95% CI]
New permanent pacemaker	6.5% (32)	4.0% (18)	1.66 [0.93, 2.96]
New permanent pacemaker (Baseline pacemaker excluded)	6.6% (32)	4.1% (18)	1.65 [0.92, 2.95]
New LBBB	22.0% (106)	8.0% (35)	3.17 [2.13, 4.72]

France TAVI 2018: 13,5 % Pace maker (HAS 2020)

TAVI vs MIAVR

Minimally-invasive versus transcatheter aortic valve implantation: systematic review with meta-analysis of propensity-matched studies

Mathew P. Doyle^{1,2,3}, Kei Woldendorp^{1,2,4}, Martin Ng^{1,4}, Michael P. Vallely⁵, Michael K. Wilson⁶, Tristan D. Yan^{1,6,7}, Paul G. Bannon^{1,2,4}

J Thorac Dis 2021;13(3):1671-1683 | <http://dx.doi.org/10.21037/jtd-202233>

Open access

Valvular heart disease

openheart Minimally invasive surgery versus transcatheter aortic valve replacement: a systematic review and meta-analysis

Ahmed Sayed ,¹ Salma Almotawally ,¹ Karim Wilson ,¹ Malak Munir ,¹ Ahmed Bendary ,² Ahmed Ramzy ,² Sameer Hirji ,³ Abdelrahman Ibrahim Abushouk ,⁴

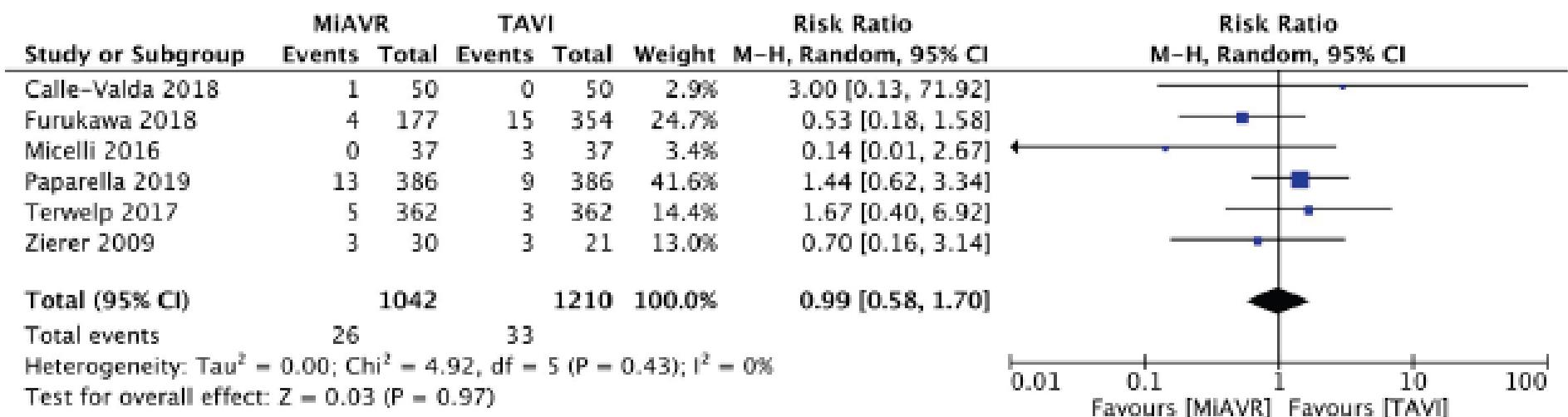
Open Heart 2021;8:e001535. doi:10.1136/openhrt-2020-001535

TAVI vs MIAVR

Mortality

Short term

Doyle et al. Journal of Thoracic Disease, 2021

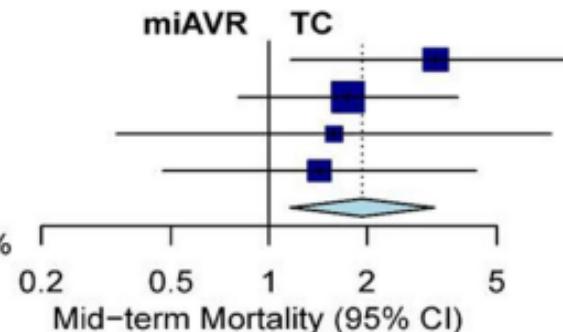


Mid term

Sayed A, et al. Open Heart 2021

B Source	RR (95% CI)
Miceli2015	3.25 [1.17; 9.05]
Calle-Valda2017	1.75 [0.81; 3.80]
Bruno2017	1.58 [0.34; 7.35]
Zierer2009	1.43 [0.47; 4.32]
Total	1.93 [1.16; 3.22]

Heterogeneity: $\chi^2 = 1.41$ ($P = .70$), $I^2 = 0\%$



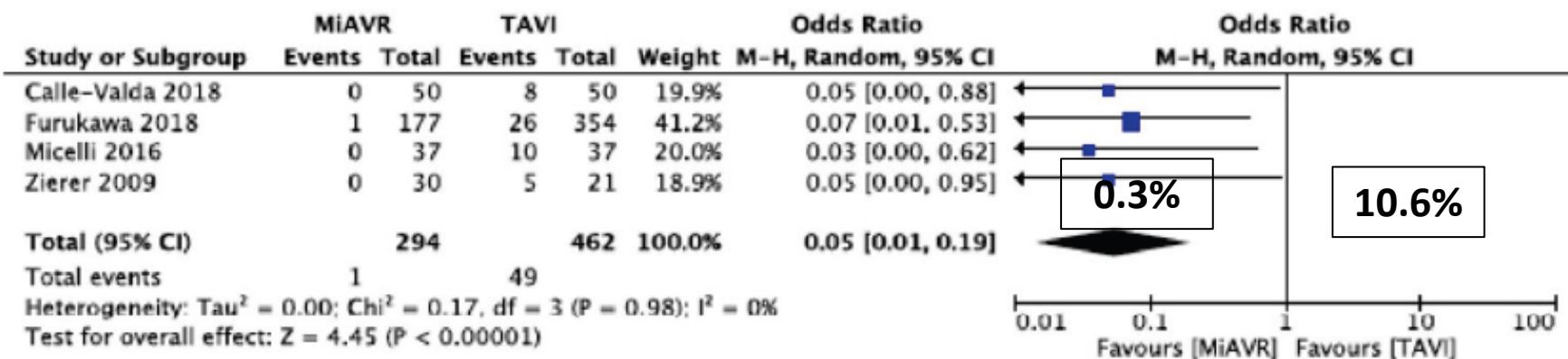
TAVI vs MiAVR

Paravalvular leak

Sayed A, et al. Open Heart 2021

Doyle et al. Journal of Thoracic Disease, 2021

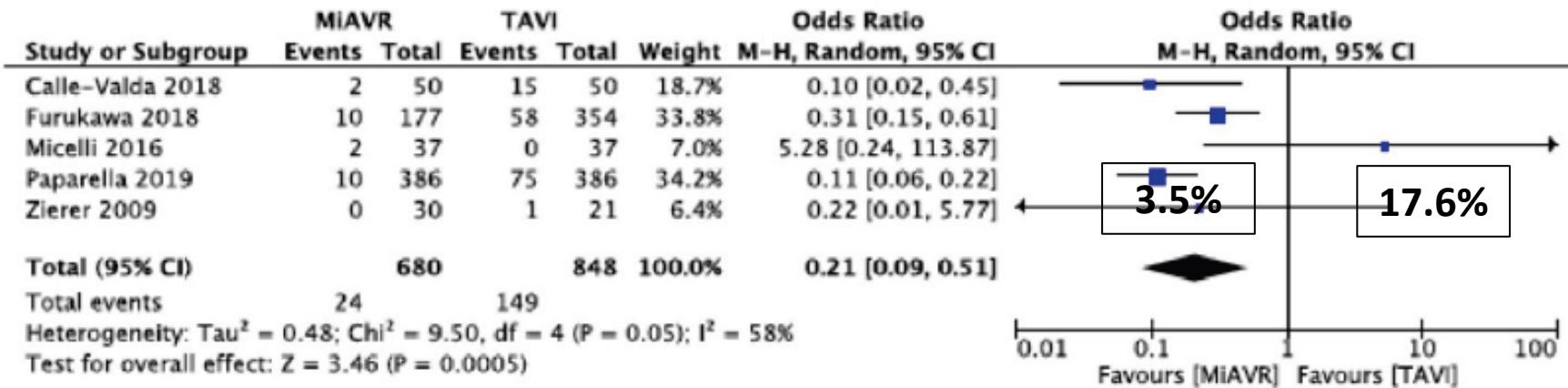
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Permanent Pace Maker

Doyle et al. Journal of Thoracic Disease, 2021

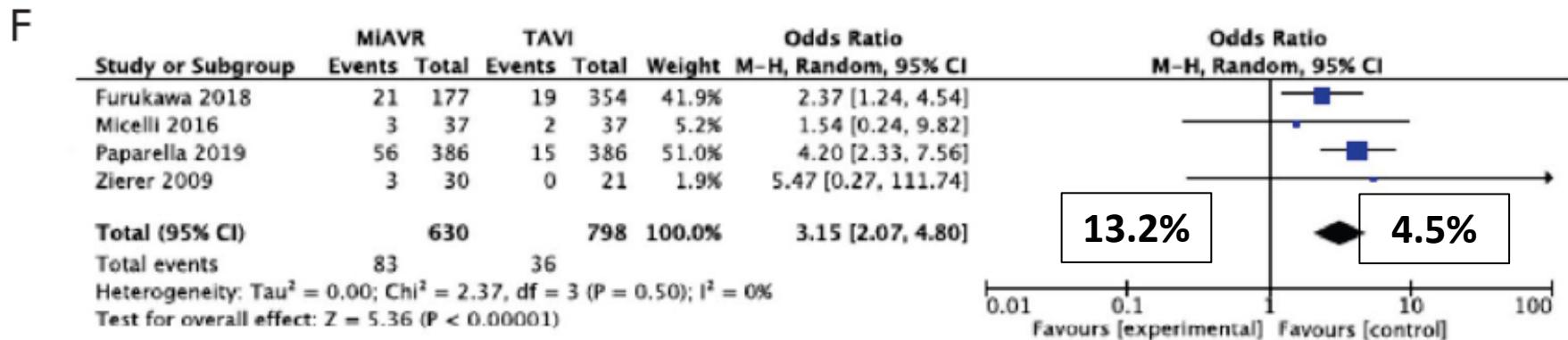
B



TAVI vs MIAVR

AKI

Doyle et al. Journal of Thoracic Disease, 2021



Lenght hospital

TAVI better MIAVR

Doyle et al. Journal of Thoracic Disease, 2021

Sayed A, et al. Open Heart 2021

NOAF

TAVI better MIAVR

Sayed A, et al. Open Heart 2021

CVA

TAVI = MIAVR

Doyle et al. Journal of Thoracic Disease, 2021

Sayed A, et al. Open Heart 2021

Conclusions

- **MIAVR / TAVI**
 - Less pace maker
 - Less paravalvular leak
 - Equivalent short term survival , but lower mid term survival (*long term?*)
 - Equivalent stroke
 - More renal failure
- **Questions**
 - Durability of TAVI valve / durability surgical valve
 - Result TAVI /Bicuspid?

Conclusions

- **Message for surgeon :**
 - learn and perform MIAVR (RAT) because the grey zone isn't defined and could change with the new generation of synthetic valve



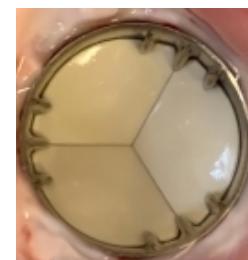
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artificial heart valves
designed to be:

- Low Thrombogenic
- Lifelong Durable
- Inaudible for the Patients

Caution: Novostia technology is an investigational device not yet approved for sale



Triflo , Novostia

Thanks you for your attention

Bicuspid Aortic Valve

Bicuspid Aortic Valve Morphology and Outcomes After Transcatheter Aortic Valve Replacement



Sung-Han Yoon, MD,^a Won-Keun Kim, MD,^b Abhijeet Dhole, MD,^c Stephan Milhorini Pio, MD,^d Vasilis Babaliaros, MD,^e Hasan Jilaihawi, MD,^f Thomas Pilgrim, MD,^g Ole De Backer, MD,^h Sabine Bleiziffer, MD,ⁱ Flavien Vincent, MD,^j Tobias Shmidt, MD,^k Christian Butter, MD,^l Norihiko Kamioka, MD,^e Lena Eschenbach, MD,^m Matthias Renker, MD,^b Masahiko Asami, MD,^g Mohamad Lazkani, MD,ⁿ Buntaro Fujita, MD,^{o,p} Antoinette Birs, MD,^q Marco Barbanti, MD,^r Ashish Pershad, MD,^s Uri Landes, MD,^t Brad Oldemeyer, MD,ⁿ Mitusnobu Kitamura, MD,^k Luke Oakley, MD,^a Tomoki Ochiai, MD,^a Tarun Chakravarty, MD,^a Mamoo Nakamura, MD,^a Philip Ruile, MD,^u Florian Deuschl, MD,^v Daniel Berman, MD,^a Thomas Modine, MD,^{j,w} Stephan Ensminger, MD,^{o,p} Ran Kornowski, MD,^t Rudiger Lange, MD,^m James M. McCabe, MD,^q Mathew R. Williams, MD,^f Brian Whisenant, MD,^x Victoria Delgado, MD,^d Stephan Windecker, MD,^g Eric Van Belle, MD,^j Lars Sondergaard, MD,^h Bernard Chevalier, MD,^y Michael Mack, MD,^z Jeroen J. Bax, MD,^d Martin B. Leon, MD,^{aa} Raj R. Makkar, MD,^a for the Bicuspid Aortic Valve Stenosis Transcatheter Aortic Valve Replacement Registry Investigators

- 1034 consecutive carefully selected BAV TAVR – 11 centers
- Mean age: 75 years - STS Score 3.7%
- Sapien 3: 72%; Evolut R/Pro: 18%

Bicuspid Aortic Valve

TABLE 3 Procedural and Clinical Outcomes According to Valve Morphology

	Overall (N = 1,034)	Morphological Features			p Value
		None (n = 324)	Calcified Raphe or Excess Leaflet Calc (n = 441)	Calcified Raphe Plus Excess Leaflet Calc (n = 269)	
Procedural outcomes					
Conversion to surgery	9 (0.9)	1 (0.3)	2 (0.5)	6 (2.2)	0.028
Coronary obstruction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	—
Aortic root injury	18 (1.7)	3 (0.9)	3 (0.7)	12 (4.5)	<0.001
Implantation of second valve	14 (1.4)	4 (1.2)	3 (0.7)	7 (2.6)	0.10
Echocardiographic findings					
Aortic valve gradient, mm Hg	10.6 ± 5.0	10.8 ± 5.4	10.4 ± 4.3	10.9 ± 5.6	0.37
Effective orifice area, cm ²	1.7 ± 0.5	1.7 ± 0.4	1.7 ± 0.5	1.8 ± 0.5	0.053
LVEF, %	56.3 ± 14.0	59.0 ± 13.3	55.3 ± 14.1	54.5 ± 14.4	<0.001
Paravalvular regurgitation ≥mild*	291 (28.6)	63 (19.8)	130 (29.7)	98 (37.3)	<0.001
Paravalvular regurgitation ≥moderate*	33 (3.2)	5 (1.6)	11 (2.5)	17 (6.5)	0.002
Clinical outcomes					
Death at 30 days					
From any cause	21 (2.0)	5 (1.5)	5 (1.1)	11 (4.1)	0.016
From cardiac cause	17 (1.6)	4 (1.2)	3 (0.7)	10 (3.7)	0.009
Death at 1 yr					
From any cause	55 (6.7)	10 (3.8)	16 (4.6)	29 (13.6)	<0.001
From cardiac cause	33 (3.9)	6 (2.2)	6 (2.7)	21 (9.6)	<0.001
Death at 2 yrs					
From any cause	74 (12.5)	12 (5.9)	24 (9.5)	38 (25.7)	<0.001
From cardiac cause	40 (5.9)	6 (2.2)	9 (3.6)	25 (14.4)	<0.001
Stroke	28 (2.7)	9 (2.8)	12 (2.7)	7 (2.6)	>0.99
Major vascular complication	34 (3.3)	8 (2.5)	12 (2.7)	14 (5.2)	0.12
Bleeding (life-threatening or major)	37 (3.6)	10 (3.1)	14 (3.2)	13 (4.9)	0.46
Acute kidney injury (stage 2 or 3)	20 (1.9)	7 (2.2)	6 (1.4)	7 (2.6)	0.43
Composite endpoint	86 (8.3)	20 (6.2)	28 (6.3)	38 (14.1)	<0.001
Aortic valve reintervention	5 (0.7)	2 (0.9)	2 (0.6)	1 (0.4)	0.91
New permanent pacemaker†	118 (12.2)	31 (10.3)	50 (11.9)	37 (15.1)	0.23

Bicuspid Aortic Valve

