

PROSPETTIVE FUTURE  
NELL'INTERVENTISTICA VALVOLARE  
Press Review



# HOT TOPICS IN CARDIOLOGIA 2024

**27 e 28 Novembre 2024**

Villa Doria D'Angri - Via F. Petrarca 80,  
Napoli



**LIVE**  
**BREAKING**  
**NEWS**

Dott.ssa Federica Serino  
UOC Cardiologia UTIC ed Emodinamica  
AORN Cardarelli, Napoli

**Table 1. Characteristics of the Patients at Baseline.\***

Characteristic	TAVR (N=455)	Clinical Surveillance (N=446)
Age — yr	76.0±6.0	75.6±6.0
Female sex — no. (%)	131 (28.8)	147 (33.0)
Race — no. (%)†		
White	436 (95.8)	422 (94.6)
Black	9 (2.0)	11 (2.5)
Asian	7 (1.5)	9 (2.0)
Multiple or unknown	3 (0.7)	4 (0.9)
Hispanic or Latino ethnic group†	11 (2.4)	9 (2.0)
Body-mass index‡	28.4±4.6	28.6±4.8
STS-PROM score — %§	1.8±1.0	1.7±1.0
Able to perform treadmill stress test — no. (%)¶	411 (90.3)	405 (90.8)
KCCQ score	92.7±8.7	92.7±9.4
Hyperlipidemia — no. (%)	375 (82.4)	347 (77.8)
Hypertension — no. (%)	369 (81.1)	365 (81.8)
Diabetes — no. (%)	119 (26.2)	114 (25.6)
Previous myocardial infarction — no. (%)	23 (5.1)	18 (4.0)
Previous stroke — no. (%)	19 (4.2)	20 (4.5)
Peripheral vascular disease — no. (%)	33 (7.3)	21 (4.7)
Coronary artery disease — no. (%)	133 (29.2)	113 (25.3)
History of atrial fibrillation — no. (%)	71 (15.6)	59 (13.2)
Permanent pacemaker or ICD — no. (%)	21 (4.6)	9 (2.0)
Chronic obstructive pulmonary disease — no. (%)	13 (2.9)	15 (3.4)
eGFR <45 ml/min/1.73 m <sup>2</sup> — no./total no. (%)	31/455 (6.8)	20/445 (4.5)
Median NT-proBNP level (IQR) — pg/ml**	275.6 (138.8–598.9)	296.8 (147.6–607.7)
Bicuspid aortic valve on computed tomography — no./total no. (%)	37/455 (8.1)	39/444 (8.8)
Echocardiographic core laboratory variables		
Aortic-valve peak velocity — m/sec††	4.3±0.5	4.4±0.4
Mean transaortic gradient — mm Hg‡‡	46.5±10.1	47.3±10.6
Aortic-valve area — cm <sup>2</sup> §§	0.9±0.2	0.8±0.2
Left ventricular ejection fraction — %¶¶	67.4±6.5	67.4±6.7

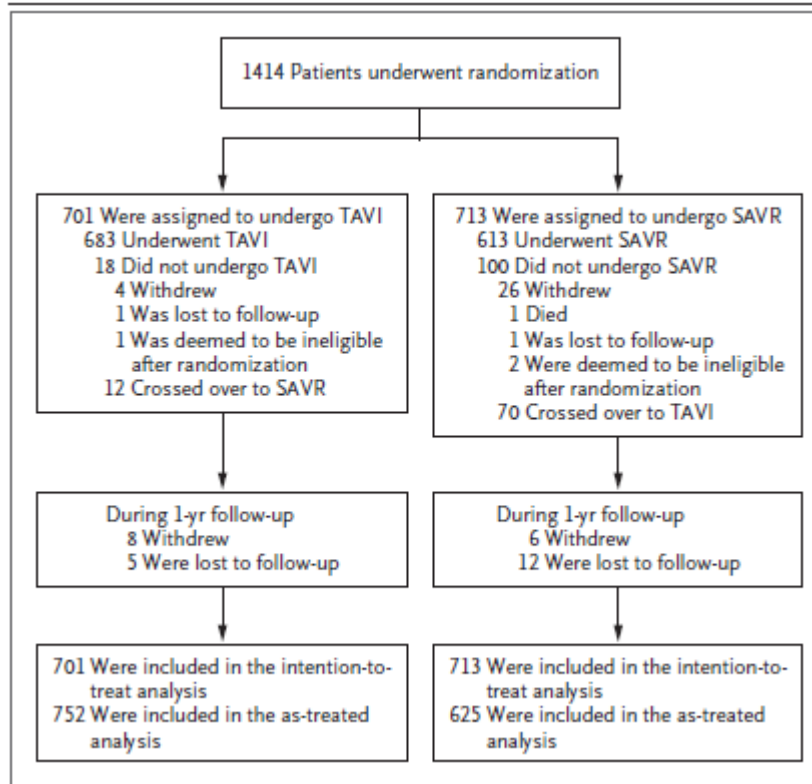
**A** Death, Stroke, or Unplanned Hospitalization for Cardiovascular

**B** Death from Any Cause

**Table 2. Primary and Secondary End Points\***

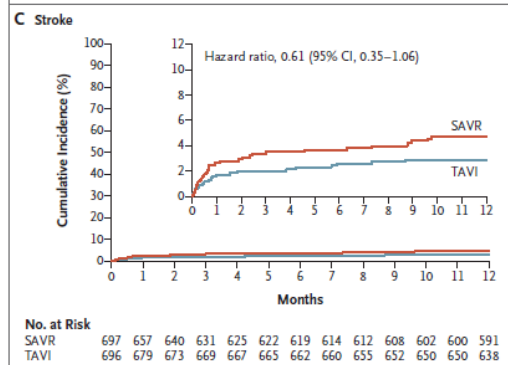
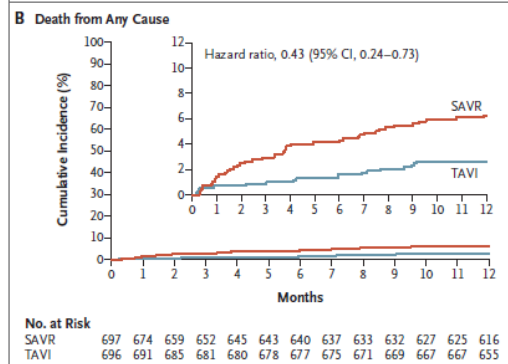
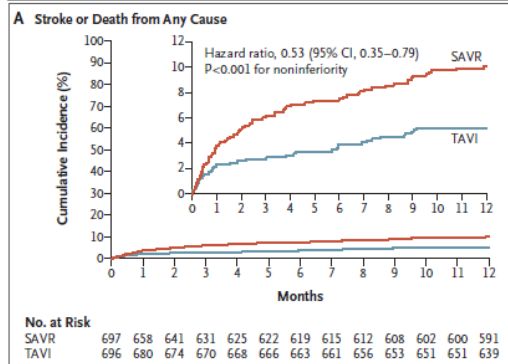
End Point	TAVR (N=455)	Clinical Surveillance (N=446)	Treatment Effect (95% CI) <sup>†</sup>	P Value <sup>‡</sup>
<b>Primary end point</b>				
Composite of death, stroke, or unplanned hospitalization for CV causes — no. (%) <sup>§</sup>	122 (26.8)	202 (45.3)	0.50 (0.40 to 0.63)	<0.001
Death	38 (8.4)	41 (9.2)	0.93 (0.60 to 1.44)	—
Stroke	19 (4.2)	30 (6.7)	0.62 (0.35 to 1.10)	—
Unplanned hospitalization for CV causes <sup>§</sup>	95 (20.9)	186 (41.7)	0.43 (0.33 to 0.55)	—
<b>Secondary end points</b>				
Favorable outcome at 2 yr — no./total no. (%) <sup>¶</sup>	354/409 (86.6)	266/391 (68.0)	18.5 (12.6 to 24.3)	<0.001
Alive	425/441 (96.4)	418/430 (97.2)	—	—
KCCQ score ≥75	373/395 (94.4)	313/390 (80.3)	—	—
KCCQ score decrease of ≤10 from baseline	356/392 (90.8)	281/387 (72.6)	—	—
Integrated measures of LV and LA health at 2 yr — no./total no. (%) <sup>  </sup>	180/374 (48.1)	121/337 (35.9)	12.2 (4.4 to 19.4)	0.001
LV global longitudinal strain ≥15%**	367/382 (96.1)	320/345 (92.8)	—	—
LV mass index <115 g/m <sup>2</sup> for men or <95 g/m <sup>2</sup> for women	319/386 (82.6)	253/351 (72.1)	—	—
LA volume index ≤34 ml/m <sup>2</sup>	214/389 (55.0)	161/353 (45.6)	—	—
Change in LV ejection fraction from baseline to 2 years — % <sup>††</sup>	-1.2±0.4	-1.3±0.4	0.1 (-0.8 to 1.3)	0.66
New-onset atrial fibrillation — no. (%) <sup>‡‡</sup>	50 (13.0)	48 (12.4)	1.08 (0.73 to 1.60)	—
Death or disabling stroke — no. (%)	44 (9.7)	50 (11.2)	0.87 (0.58 to 1.31)	—
Death	38 (8.4)	41 (9.2)	—	—
Disabling stroke	8 (1.8)	13 (2.9)	—	—

Clinical surveillance	446	429	406	295	185	87	Clinical surveillance	446	306	267	189	118	46
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**Table 1. Characteristics of the Patients at Baseline (Intention-to-Treat Population).<sup>a</sup>**

Characteristic	TAVI (N=701)	SAVR (N=713)
<b>Demographic</b>		
Age — yr	74.3±4.6	74.6±4.2
Male sex — no./total no. (%)	390/696 (56.0)	400/698 (57.3)
<b>Medical history</b>		
Median body-mass index (IQR)†	28.1 (25.3–31.9)	28.1 (25.4–31.2)
Median STS-PROM score (IQR) — %‡	1.8 (1.2–2.4)	1.9 (1.2–2.5)
Score on EuroSCORE II — %§	2.1±1.4	2.1±1.8
Median frailty score (IQR)¶	3.0 (2.0–4.0)	3.0 (2.0–3.0)
Left ventricular ejection fraction — %	57.8±9.8	57.7±9.3
<b>Cardiovascular risk factors — no./total no. (%)</b>		
Hypertension	588/694 (84.7)	605/694 (87.2)
Dyslipidemia	378/691 (54.7)	383/689 (55.6)
Diabetes mellitus	235/695 (33.8)	229/698 (32.8)
<b>Coexisting illness — no./total no. (%)</b>		
Coronary artery disease	238/694 (34.3)	266/697 (38.2)
Cerebrovascular disease	27/676 (4.0)	31/693 (4.5)
Peripheral vascular disease	34/694 (4.9)	45/697 (6.5)
Previous myocardial infarction	36/696 (5.2)	52/697 (7.5)
Previous stroke	42/692 (6.1)	42/696 (6.0)
Atrial fibrillation	201/695 (28.9)	191/697 (27.4)
COPD	101/695 (14.5)	118/697 (16.9)
Pulmonary hypertension	84/693 (12.1)	73/686 (10.6)
NYHA class ≥3	321/695 (46.2)	318/697 (45.6)
Permanent pacemaker	37/696 (5.3)	35/698 (5.0)
Left bundle-branch block	53/678 (7.8)	54/682 (7.9)
Right bundle-branch block	65/678 (9.6)	65/682 (9.5)



**Table 2. Primary and Secondary Outcomes at 1 Year (Intention-to-Treat Population).\***

Outcome	TAVI (N = 701)		SAVR (N = 713)		Hazard Ratio (95% CI)
	no. of events	% of patients	no. of events	% of patients	
<b>Primary outcome</b>					
Death from any cause or stroke†	37	5.4	68	10.0	0.53 (0.35–0.79)
<b>Secondary outcomes</b>					
Death from any cause	18	2.6	42	6.2	0.43 (0.24–0.73)
Stroke	20	2.9	32	4.7	0.61 (0.35–1.06)
Stroke or TIA	28	4.1	35	5.1	0.78 (0.47–1.27)
Disabling stroke	9	1.3	21	3.1	0.42 (0.19–0.88)
Death from any cause or disabling stroke	26	3.8	57	8.4	0.45 (0.28–0.70)
Cardiovascular death	14	2.0	30	4.4	0.47 (0.24–0.86)
Myocardial infarction	7	1.0	14	2.1	0.51 (0.20–1.19)
New-onset atrial fibrillation	86	12.4	211	30.8	0.36 (0.28–0.46)
New-onset left bundle-branch block	222	32.0	120	17.5	2.03 (1.63–2.54)
New permanent pacemaker implantation	82	11.8	47	6.7	1.81 (1.27–2.61)
Prosthetic-valve dysfunction	11	1.6	4	0.6	2.44 (0.87–8.15)
Prosthetic-valve endocarditis	4	0.6	7	0.9	0.66 (0.18–2.19)
Prosthetic-valve thrombosis	5	0.7	2	0.3	2.09 (0.50–11.64)
Aortic-valve reintervention	4	0.6	2	0.3	1.70 (0.38–9.78)
Major or life-threatening or disabling bleeding	30	4.3	119	17.2	0.24 (0.16–0.35)
Acute kidney injury of stage II or III‡	9	1.3	17	2.5	0.56 (0.24–1.21)
Vascular access-site complication	55	7.9	5	0.7	10.64 (4.84–28.94)
Rehospitalization for cardiovascular cause	84	12.2	91	13.3	0.89 (0.66–1.20)

**Table 1. Characteristics of the Patients at Baseline.\***

Conservative

**Table 2. Angiographic Findings and Characteristics of the PCI and TAVI Procedures.\***

Variable	PCI (N=227)	Conservative Treatment (N=228)
<b>Angiographic findings</b>		
Median no. of physiologically significant lesions per patient (IQR)†	1 (1–2)	1 (1–2)
No. of lesions with fractional flow reserve ≤0.80	167	155
No. of lesions with diameter stenosis ≥90%	184	162
Median largest diameter stenosis (IQR) — %	90 (80–90)	90 (71–90)
Median SYNTAX score (IQR)‡	9 (6–14)	9 (5–14)
<b>PCI procedure†</b>		
Median no. of days from randomization to PCI (IQR)	9 (1–26)	—
Timing of PCI — no./total no. (%)		
Before TAVI	163/219 (74)	—
Concomitant with TAVI	37/219 (17)	—
After TAVI	19/219 (9)	—
Complete revascularization achieved — no./total no. (%)§	194/219 (89)	—
<b>TAVI procedure</b>		
Median no. of days from randomization to TAVI (IQR)	34 (7–62)	25 (2–54)
Balloon-expandable heart valve — no. (%)	90 (40)	95 (42)
Atrial fibrillation	81 (36)	74 (32)
Peripheral artery disease	19 (8)	26 (11)

**A** Death from Any Cause, Myocardial Infarction, or Urgent Revascularization (primary end point)

**B** Death from Any Cause

Conservative

**Table 3. Primary and Secondary End Points.\***

End Point	PCI (N=227)	Conservative Treatment (N=228)	Hazard Ratio (95% CI)	P Value
	<i>number (percent)</i>			
Primary end point: MACE†	60 (26)	81 (36)	0.71 (0.51–0.99)	0.04
Secondary end points				
Death from any cause	53 (23)	62 (27)	0.85 (0.59–1.23)	
Myocardial infarction‡	17 (7)	31 (14)	0.54 (0.30–0.97)	
Urgent revascularization§	5 (2)	25 (11)	0.20 (0.08–0.51)	
Death from cardiovascular causes¶	20 (9)	30 (13)	0.67 (0.38–1.19)	
Any revascularization	6 (3)	48 (21)	0.12 (0.05–0.27)	
Stroke	23 (10)	35 (15)	0.67 (0.39–1.14)	
Safety end points				
Any bleeding event	64 (28)	45 (20)	1.51 (1.03–2.22)	
Life-threatening or disabling	23 (10)	16 (7)		
Major	26 (11)	22 (10)		
Minor	53 (23)	36 (16)		
Stent thrombosis	1 (<1)	2 (1)	—	
Acute kidney failure	12 (5)	26 (11)	0.45 (0.23–0.89)	

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# Management of coronary artery disease in patients undergoing transcatheter aortic valve implantation. A clinical consensus statement from the European Association of Percutaneous Cardiovascular Interventions in collaboration with the ESC Working Group on Cardiovascular Surgery

**Giuseppe Tarantini**<sup>1\*</sup>, MD, PhD; Gilbert Tang<sup>2</sup>, MD, MSc, MBA; Luca Nai Fovino<sup>1</sup>, MD, PhD; Daniel Blackman<sup>3</sup>, MD; Nicolas M. Van Mieghem<sup>4</sup>, MD, PhD; Won-Keun Kim<sup>5</sup>, MD; Nicole Karam<sup>6</sup>, MD, PhD; Pedro Carrilho-Ferreira<sup>7</sup>, MD; Stephane Fournier<sup>8</sup>, MD; Jerzy Pręgowski<sup>9</sup>, MD; Chiara Fraccaro<sup>1</sup>, MD, PhD; Flavien Vincent<sup>10</sup>, MD; Rui Campante Teles<sup>11</sup>, MD, PhD; Darren Mylotte<sup>12</sup>, MD; Ivan Wong<sup>13</sup>, MD; Gintautas Bieliauskas<sup>13</sup>, MD; Martin Czerny<sup>14</sup>, MD; Nikolaos Bonaros<sup>15</sup>, MD; Alessandro Parolari<sup>16</sup>, MD, PhD; Darius Dudek<sup>17,18</sup>, MD, PhD; Didier Tchétché<sup>19</sup>, MD; Hélène Eltchaninoff<sup>20</sup>, MD, PhD; Ole De Backer<sup>13</sup>, MD, PhD; Giulio Stefanini<sup>21</sup>, MD, PhD; Lars Sondergaard<sup>13</sup>, MD, PhD

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**Table 2. Advantages and disadvantages of different PCI timing in patients undergoing TAVI.**

	<b>PCI before TAVI</b>	<b>PCI after TAVI</b>	<b>Combined PCI and TAVI</b>
<b>Advantages</b>	<ul style="list-style-type: none"> <li>- Easier coronary access (especially for self-expanding THV with a supra-annular leaflet position)</li> <li>- Lower risk of ischaemia-induced haemodynamic instability (i.e., during rapid pacing)</li> <li>- Reduced contrast use compared with concomitant PCI and TAVI</li> </ul>	<ul style="list-style-type: none"> <li>- More reliable FFR/iFR of intermediate lesions</li> <li>- Lower risk of haemodynamic instability during complex PCI (i.e., with rotational atherectomy and impaired LV function)</li> <li>- Reduced contrast use compared with concomitant PCI and TAVI</li> </ul>	<ul style="list-style-type: none"> <li>- Use of the same arterial access</li> <li>- Lower cost</li> </ul>
<b>Disadvantages</b>	<ul style="list-style-type: none"> <li>- Less reliable FFR/iFR assessments of borderline lesions</li> <li>- Higher risk of haemodynamic instability due to AS</li> </ul>	<ul style="list-style-type: none"> <li>- More challenging and potentially compromised coronary access</li> <li>- Less stability and support of the coronary guiding catheter</li> <li>- Potential THV dislodgement</li> </ul>	<ul style="list-style-type: none"> <li>- Larger amount of contrast and higher risk of AKI</li> <li>- Prolonged procedure</li> <li>- Need for DAPT at the time of TAVI, hence increased bleeding risk</li> </ul>
<p>AS: aortic stenosis; AKI: acute kidney injury; DAPT: dual antiplatelet therapy; FFR: fractional flow reserve; iFR: instantaneous wave-free ratio; LV: left ventricular; PCI: percutaneous coronary intervention; TAVI: transcatheter aortic valve implantation; THV: transcatheter heart valve</p>			

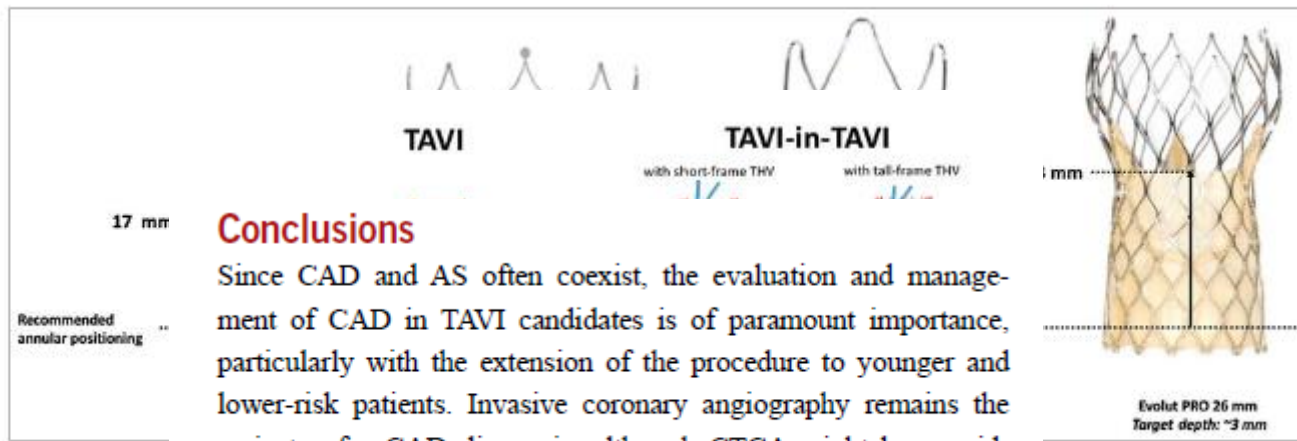
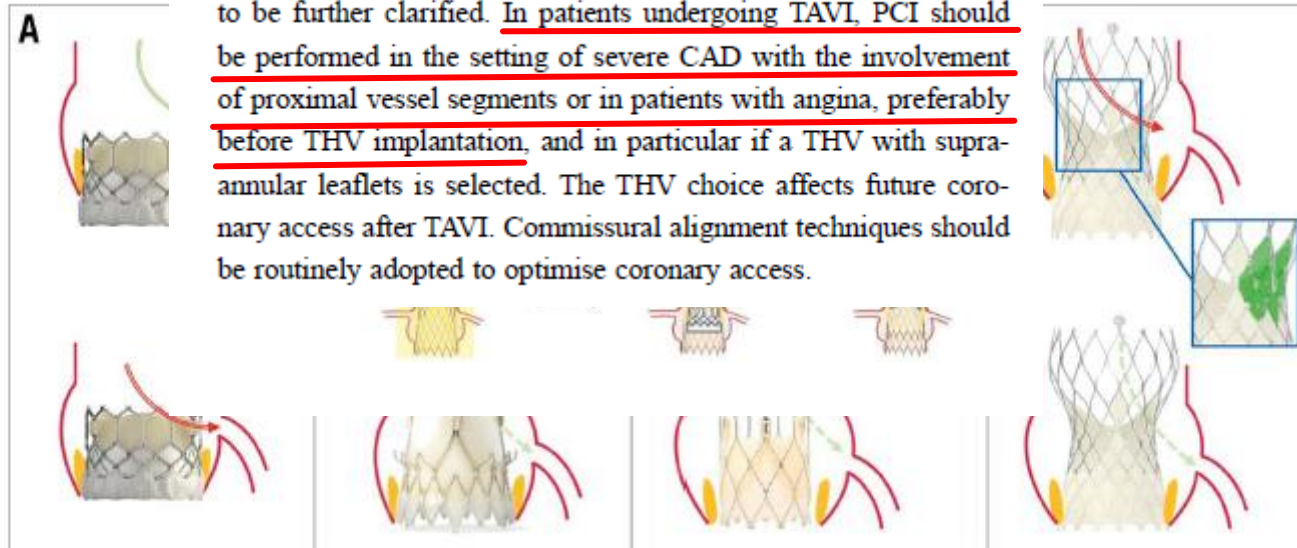


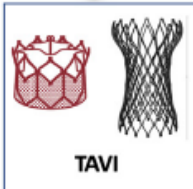
Figure 3. THV leaflet height

### Conclusions

Since CAD and AS often coexist, the evaluation and management of CAD in TAVI candidates is of paramount importance, particularly with the extension of the procedure to younger and lower-risk patients. Invasive coronary angiography remains the mainstay for CAD diagnosis, although CTCA might be considered for initial screening, particularly in patients at low risk for CAD. The role of coronary invasive physiology assessment needs to be further clarified. In patients undergoing TAVI, PCI should be performed in the setting of severe CAD with the involvement of proximal vessel segments or in patients with angina, preferably before THV implantation, and in particular if a THV with supra-annular leaflets is selected. The THV choice affects future coronary access after TAVI. Commissural alignment techniques should be routinely adopted to optimise coronary access.

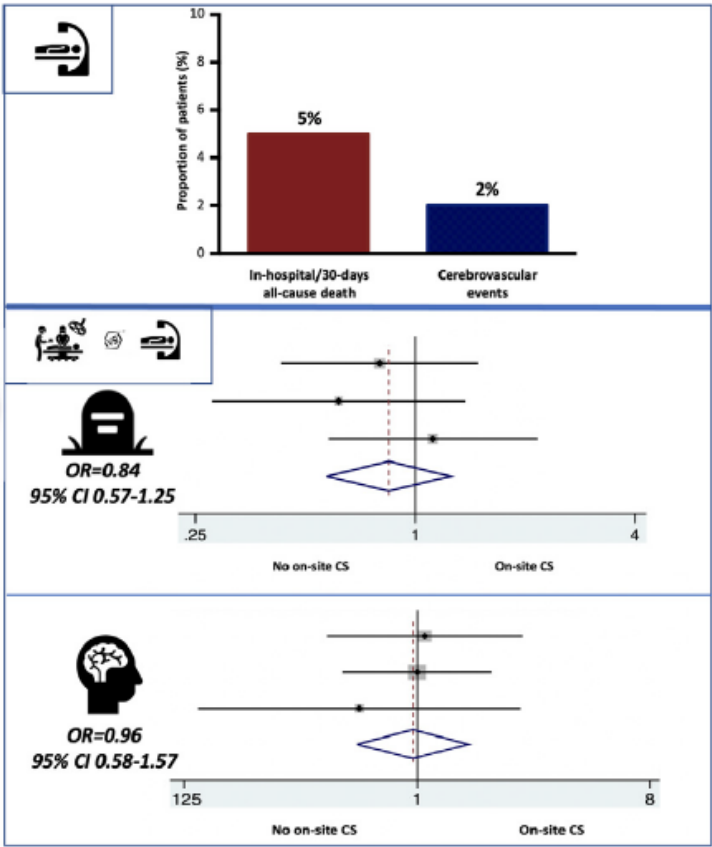


**Severe aortic stenosis patients**



**Centres with On-site vs No On-site Cardiac Surgery**

			<b>Eggebrecht et al.</b> (n=1432)	n=1254	n=178
			<b>AQUA registry</b> (n=17919)	n=16587	n=1332
			<b>Egger et al.</b> (n=1822)	n=1532	n=290
			<b>Roa Carrido et al.</b>	n=384	
			<b>Gafoor et al.</b>	n=97	



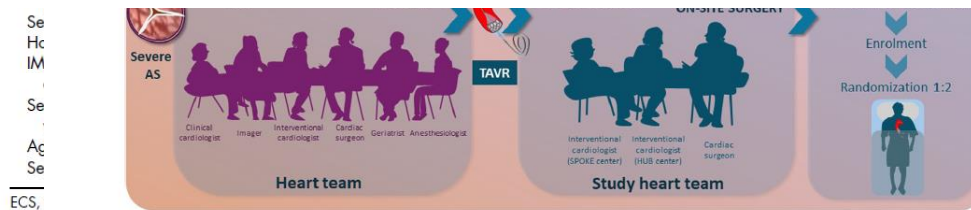
**Table 2.** Requirements for participating centers and TAVI operators

Participating centers	TAVI operators
Availability of a standard operating procedure with an external cardiac surgery department to ensure an established, weekly Heart Team discussion that includes participation from affiliated cardiac surgeons.	At least 5-year experience in coronary interventions
Availability of standard operating procedure for rapid transfer of patients with procedural complications to cardiac surgery with a	More than 75 PCIs by year

**Table 3.** Efficacy and safety endpoints

Efficacy	Safety
<p><b>Primary</b> All-cause death, stroke and hospital readmission for CV cause</p> <p><b>Secondary</b> All-cause death Cardiovascular death Myocardial infarction Hospital admission for cardiovascular cause Hospital admission for heart failure Cerebrovascular accident Ischemic stroke Hospital admission for pneumonia (<math>\pm</math> respiratory failure) Need for balloon aortic valvuloplasty for emergent condition Quality of life measured with the Eq-5D and KCCQ-12 scales Time spent on the waiting list</p>	<p><b>Primary</b> Death due periprocedural complications actionable by ECS</p> <p><b>Secondary</b> Cardiac tamponade Bleeding Kidney failure (requirement for renal replacement therapy) Severe aortic regurgitation Multiorgan failure (failure of at least two organ systems) Vascular access site and access related complications Conduction disturbances and arrhythmias Endocarditis Valve thrombosis Valve malpositioning Valve embolization Ectopic valve deployment TAV-in-TAV deployment</p>

CV, cardiovascular; KCCQ, Kansas City Cardiomyopathy Questionnaire; ECS, emergent cardiac surgery; TAV, transaortic valve.



# Grazie per l'attenzione

