TAVI

Dans les Centres
Sans Chirurgie Cardiaque

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Table 10 Contraindications for transcatheter aortic valve implantation

Absolute contraindications
Absence of a 'heart team' and no cardiac surgery on the site
Appropriateness of TAVI, as an alternative to AVR, not confirmed by a 'heart team'
Clinical
Estimated life expectancy <1 year Improvement of quality of life by TAVI unlikely because of comorbidities Severe primary associated disease of other valves with major contribution to the patient's symptoms, that can be treated only by surgery
Anatomical
Inadequate annulus size (<18 mm, >29 mm[a])
Thrombus in the left ventricle
Active endocarditis
Elevated risk of coronary ostium obstruction (asymmetric valve calcification, short distance between annulus and coronary ostium, small aortic sinuses)
Plaques with mobile thrombi in the ascending aorta, or arch
For transfemoral/subclavian approach: inadequate vascular access (vessel size, calcification, tortuosity)
Relative contraindications
Bicuspid or non-calcified valves
Untreated coronary artery disease requiring revascularization
Haemodynamic instability
LVEF <20%
For transapical approach: severe pulmonary disease, LV apex not accessible

AVR = aortic valve replacement; LV = left ventricle; LVEF = left ventricular ejection fraction; TAVI = transcatheter aortic valve implantation.
[a]Contraindication when using the current devices.

Table 11 Recommendations for the use of transcatheter aortic valve implantation

Recommendations	Class [a]	Level [b]	Ref [c]
TAVI should only be undertaken with a multidisciplinary 'heart team' including cardiologists and cardiac surgeons and other specialists if necessary.	I	C	
TAVI should only be performed in hospitals with cardiac surgery on-site.	I	C	
TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a 'heart team' and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities.	I	B	99
TAVI should be considered in high-risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a 'heart team' based on the individual risk profile and anatomic suitability.	IIa	B	97

AS = aortic stenosis; AVR = aortic valve replacement; TAVI = transcatheter aortic valve implantation.
[a]Class of recommendation.
[b]Level of evidence.
[c]Reference(s) supporting class I (A + B) and IIa + IIb (A + B) recommendations.

Guidelines of the management of valvular heart disease, 2012

TAVI avec CEC : Justifications

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SPECIAL ARTICLE

Transcatheter valve implantation for patients with aortic stenosis: a position statement from the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

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TAVI avec CEC : Justifications

- Equipe multidisciplinaire
- Heart Team
- Expertise valvulaire
- Opérateurs entrainés, haut volume interventionnel
- Evaluation du risque opératoire

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FASTTRACK CLINICAL RESEARCH
TAVI

Outcomes of transfemoral transcatheter aortic valve implantation at hospitals with and without on-site cardiac surgery department: insights from the prospective German aortic valve replacement quality assurance registry (AQUA) in 17 919 patients

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Aims Performing transcatheter aortic valve implantation (TAVI) at hospitals with only cardiology department but no cardiac surgery (CS) on-site is at great odds with current Guidelines.

Methods and results We analysed data from the official, prospective German Quality Assurance Registry on Aortic Valve Replacement to compare characteristics and in-hospital outcomes of patients undergoing transfemoral TAVI at hospitals with ($n = 75$) and without CS departments ($n = 22$). An interdisciplinary Heart Team was established at all centres (internal staff physicians at hospitals with on-site CS; in-house cardiologists and visiting cardiac surgical teams from collaborating hospitals at non-CS hospitals). In 2013 and 2014, 17 919 patients (81.2 $\pm$ 6.1 years, 55% females, German aortic valve (GAV) score 2.0 5.6 $\pm$ 5.8%, logistic EuroSCORE I 21.1 $\pm$ 15.4%) underwent transfemoral TAVI in Germany: 1332 (7.4%) at hospitals without on-site CS department. Patients in non-CS hospitals were older (82.1 $\pm$ 5.8 vs. 81.1 $\pm$ 6.1 years, $P < 0.001$), with more frequent co-morbidities. Predicted mortality risks per GAV-score 2.0 (6.1 + 5.5 vs. 5.5 $\pm$ 5.9%, $P < 0.001$) and logEuroSCORE I (23.2 $\pm$ 15.8 vs. 21.0 $\pm$ 15.4%, $P < 0.001$) were higher in patients at non-CS sites. Complications, including strokes (2.6 vs. 2.3%, $P = 0.452$) and in-hospital mortality (3.8 vs. 4.2%, $P = 0.396$), were similar in both groups. Matched-pair analysis of 555 patients in each group with identical GAV-score confirmed similar rates of intraprocedural complications (9.2 vs. 10.3%, $P = 0.543$), strokes (3.2% for both groups, $P = 1.00$), and in-hospital mortality (1.8 vs. 2.9%, $P = 0.234$).

Conclusion Although patients undergoing TAVI at hospitals without on-site CS department were older and at higher predicted perioperative death risk, major complications, and in-hospital mortality were not statistically different, suggesting the feasibility and safety of Heart Team-based TAVI at non-CS sites. These findings need confirmation in future randomized study.

Keywords Aortic stenosis • TAVI • TAVR • Complications • Conversion • Surgery

Table 1 **Patient demographics**

	Patients undergoing TF-TAVI in hospitals without CS (n = 1332)	Patients undergoing TF-TAVI in hospitals with CS (n = 16 587)	P-value
Age	82.1 ± 5.8 (55–97)	81.1 ± 6.1 (33–100)	<0.001
Age ≤75 years	172 (12.9%)	2529 (15.2%)	0.022
Females (%)	722 (54.2%)	9125 (55.0%)	0.568
NYHA ≥III	1204 (90.4%)	14 079 (84.9%)	<0.001
Acute decompensated heart failure (<48 h)	54 (4.1%)	518 (3.1%)	0.062
Pulmonary hypertension	633 (47,5%)	7591(45,8%)	0.001
Systolic PA pressure >55 mmHg	257 (19.3%)	2204 (13.3%)	<0.001
Atrial fibrillation	392 (29.4%)	4925 (29.7%)	0.840
Presence of permanent pacemaker	177 (13.3%)	1868 (11.3%)	0.025
Presence of implanted cardioverter defibrillator	22 (1.7%)	282 (1.7%)	0.896
ASA ≥3	1242 (93.2%)	15 221 (91.8%)	<0.001
Left ventricular ejection fraction ≤30%	148 (11.1%)	1687 (10.2%)	0.183
CAD	804 (60.4%)	8995 (54.2%)	<0.001
Left main coronary artery involvement	67 (5.0%)	639 (3.9%)	0.034
Previous myocardial infarction	183(13.7%)	2206 (13.3%)	0.650
Previous PCI	457 (34.3%)	4856 (29.3%)	<0.001
Previous open heart surgery	238 (17.9%)	2893 (17.4%)	0.693
Insulin-dependent diabetes mellitus	178 (13.4%)	2355 (14.2%)	0.400
PVD	248 (18.6%)	2504 (15.1%)	0.012
COPD with medication	222 (16.7%)	2104 (12.7%)	0.001
Previous neurologic event	186 (14.0%)	1954 (11.8%)	0.019
Chronic haemodialysis	36 (2.7%)	515 (3.1%)	0.413
LogEuroSCORE (%)	23.2 ± 15.8 (3.1–88.8)	21.0 ± 15.4 (1.5–98.3)	<0.001
LogEuroSCORE <10%	213 (16.1%)	3945 (24.1%)	<0.001
LogEuroSCORE 10–20%	520 (39.2%)	6036 (36.9%)	
LogEuroSCORE 20–30%	259 (19.5%)	2969 (18.2%)	
LogEuroSCORE >30%	333 (25.1%)	3407 (20.8%)	
GAV-Score 2.0 (%)	6.1 ± 5.5 (0.8–57)	5.5 ± 5.9 (0.6–99.9)	<0.001

ASA, American Society of Anesthesiologists; COPD, chronic obstructive lung disease; CS, cardiac surgery; NYHA, New York Heart Association; PA, pulmonary artery; PCI, percutaneous coronary intervention; TAVI, transcatheter aortic valve implantation; TF, transfemoral.

Table 3 **Procedural data**

	Patients undergoing TF-TAVI in hospitals without CS ($n = 1332$)	Patients undergoing TF-TAVI in hospitals with CS ($n = 16\,587$)	*P*-value	Odds ratio for categorical var. or stand. mean difference for continuous var.	95% CI
Elective procedure	1109 (83.3%)	13 907 (83.8%)	0.578	0.958	0.825–1.113
Procedure time (min)	110.3 ± 48.2	79.3 ± 44.8	<0.001	0.688	0.632–0.744
Fluoroscopy time (min)	18.9 ± 11.7	19.9 ± 33.1	0.273	−0.031	−0.087–0.025
Intraprocedural complications	112 (8.4%)	1817 (11.0%)	0.004	0.746	0.611–0.911
Device malpositioning	19 (1.4%)	276 (1.7%)	0.512	0.855	0.535–1.366
Device embolization	6 (0.5%)	51 (0.3%)	0.373	1.467	0.629–3.425
Coronary occlusion	4 (0.3%)	62 (0.4%)	0.671	0.806	0.293–2.218
Aortic dissection	2 (0.2%)	38 (0.2%)	0.557	0.655	0.158–2.718
Annular rupture	9 (0.7%)	55 (0.3%)	0.043/0.074**	2.045	1.008–4.147
Pericardial tamponade	6 (0.5%)	171 (1.0%)	0.039	0.434	0.192–0.982
Acute cardiac decompensation	7 (0.5%)	118 (0.7%)	0.433	0.737	0.343–1.584
Cerebral embolism	2 (0.2%)	30 (0.2%)	0.799/0.933**	0.830	0.198–3.477
Aortic regurgitation ≥2	28 (2.1%)	171 (1.0%)	<0.001	2.061	1.377–3.086
Rhythm disturbances	25 (1.9%)	489 (2.9%)	0.024	0.630	0.496–0.945
Vascular injury	33 (2.5%)	739 (4.5%)	<0.001	0.545	0.383–0.776
Composite of intraprocedural complications likely to benefit from ECS	46 (3.4%)	653 (3.9%)	0.421	0.873	0.644–1.183
Conversion to open heart surgery	4 (0.3%)	115 (0.7%)	0.088	0.431	0.159–1.171

Composite of periprocedural complications likely to benefit from ECS, device malpositioning; device embolization, annular rupture, aortic dissection, coronary obstruction, and/or pericardial tamponade.

***P*-value with Yates correction, because at least 20% of expected frequencies are <5!

Table 4 **Postprocedural outcomes**

	Patients undergoing TF-TAVI in hospitals without CS (n = 1332)	Patients undergoing TF-TAVI in hospitals with CS (n = 16 587)	P-value	Odds ratio for categorical var. or stand. mean difference for continuous var.	95% CI
In-hospital death	50 (3.8%)	703 (4.2%)	0.396	0.881	0.658–1.181
In-hospital death for the composite of intraprocedural complications likely to benefit from ECS	17/46 (37.0%)	220/653 (33.7%)	0.771	1.154	0.621–2.145
Cerebrovascular event	35 (2.6%)	378 (2.3%)	0.452	1.157	0.815–1.644
Delirium requiring treatment	47 (3.5%)	635 (3.8%)	0.582	0.919	0.680–1.242
Myocardial infarction	3 (0.2%)	60 (0.4%)	0.418	0.622	0.195–1.985
Low cardiac output	33 (2.5%)	431 (2.6%)	0.789	0.952	0.665–1.363
Resuscitation	39 (2.9%)	493 (3.0%)	0.927	0.985	0.707–1.371
Vascular complications	134 (10.1%)	1479 (8.9%)	0.161	1.217	1.010–1.466
Need for transient dialysis	15 (1.1%)	373 (2.2%)	0.007	0.500	0.295–0.832
Atrial fibrillation at discharge	315 (23.6%)	3811 (23.0%)	0.700	1.038	0.910–1.184
New pacemaker/ICD implantation	264 (19.8%)	2620 (15.8%)	<0.001	1.318	1.144–1.517
Days in hospital after TF-TAVI	11.0 ± 7.5 (0–93)	10.4 ± 7.5 (0–162)	0.005	0.080	0.024–0.136
Transfer to another hospital	142 (10.7%)	2501 (15.1%)	<0.001	0.672	0.562–0.804
Discharge to rehabilitation unit	186 (14.0%)	3074 (18.5%)	<0.001	0.714	0.608–0.837
Discharge to nursing facility	12 (0.9%)	77(0.5%)	0.029	1.949	1.058–3.591

Composite of periprocedural complications likely to benefit from ECS, device malpositioning, device embolization, annular rupture, aortic dissection, coronary obstruction, and/or pericardial tamponade.

Emergent cardiac surgery during transcatheter aortic valve implantation (TAVI): a weighted meta-analysis of 9,251 patients from 46 studies

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KEYWORDS

- aortic stenosis
- aortic valve replacement
- TAVI
- TAVR
- surgery

Abstract

Aims: Transcatheter aortic valve implantation (TAVI) is a novel treatment option for high surgical risk patients with severe symptomatic aortic valve (AV) stenosis. During TAVI, some patients may require emergent cardiac surgery (ECS). However, the incidence, reasons and outcomes of those needing ECS remain unknown.

Methods and results: We performed a search of the English medical literature using MEDLINE to identify all studies on TAVI and evaluate the incidence of ECS (i.e., within 24 hrs of TAVI) and outcomes for these patients. Forty-six studies comprising 9,251 patients undergoing transfemoral, transapical or trans-subclavian TAVI for native AV stenosis published between 01/2004 and 11/2011 were identified and included in this weighted meta-analysis. Overall, TAVI patients were old (mean=81.3±5.4 years) and had a high mean logistic EuroSCORE (24.4±5.9%). Few patients required ECS (n=102; 1.1±1.1%) and this was marginally higher among those undergoing transapical TAVI as compared to those undergoing transarterial TAVI (1.9±1.7% vs. 0.6±0.9%). Data on the reasons for ECS were available in 86% (88/102 patients) and 41% of these (36/88) were performed for embolisation/dislocation of the AV prosthesis, with aortic dissection (n=14), coronary obstruction (n=5), severe AV regurgitation (n=10), annular rupture (n=6), aortic injury (n=14), and myocardial injury including tamponade (n=12) constituting the rest. Mortality at 30 days was about 9-fold higher in patients who did need as compared with those patients who did not need ECS (67.1±37.9% vs. 7.5±4.0%).

Conclusions: Reported rates of ECS during TAVI were low with embolisation or dislocation of the prosthesis being the most common cause. ECS was associated with grave prognosis with two out of three patients dying by 30 days. Thus, refinement in TAVI technology should not only focus on miniaturisation and improving flexibility of the delivery systems and/or devices – which may have the potential for decreasing aortic dissection, annular rupture, and tamponade – but also incorporate modifications to prevent embolisation/dislocation of the valve.

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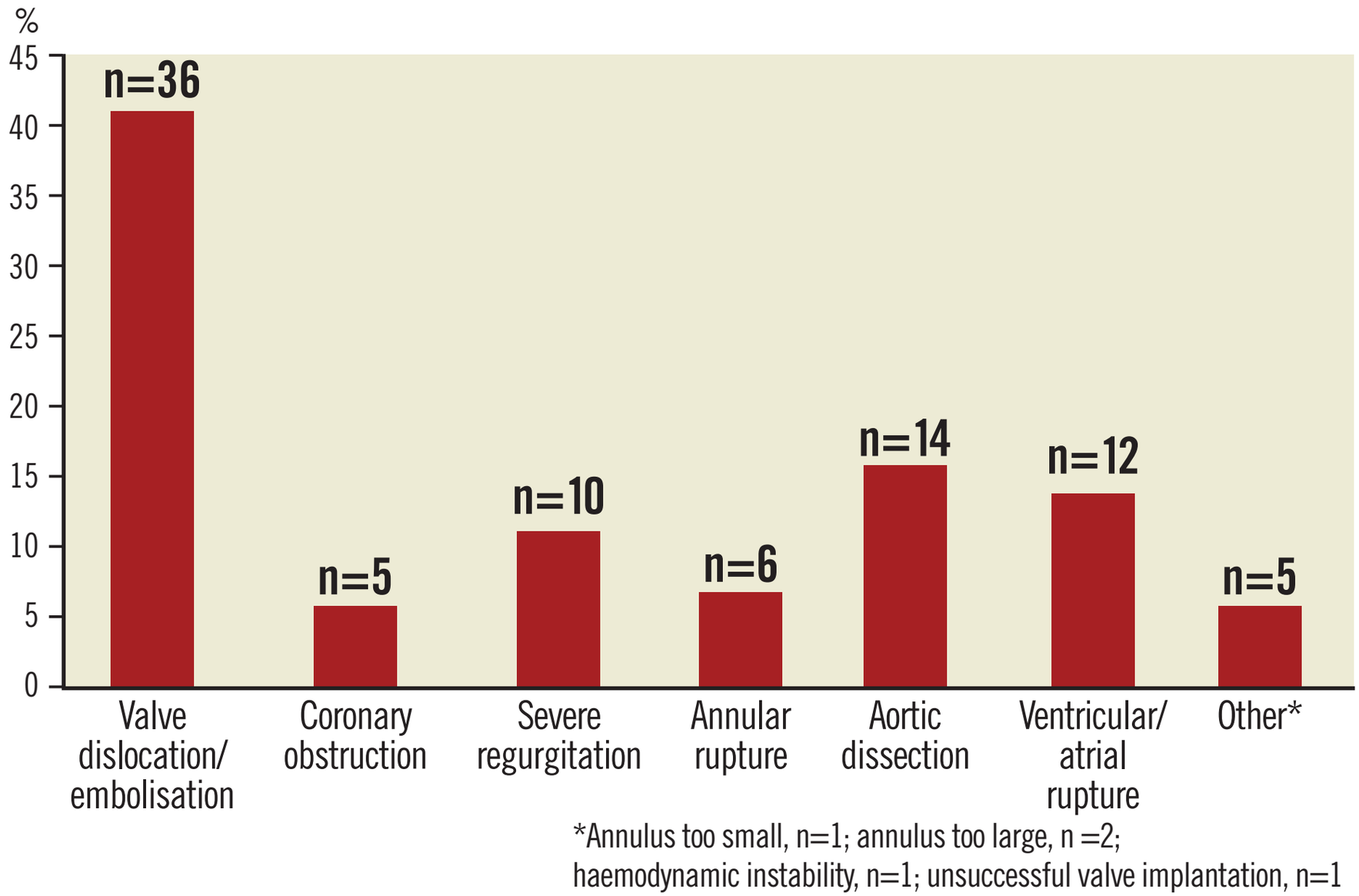

Figure 1. *Overview of reasons for ECS.*

Table 2. Patient characteristics.

	Number of publications with available data (n)	Overall number of patients with available data (n)	Number of events (n)	Weighted mean±SD
Patient age (years)	46	9,251	---	81.3±5.4
Female gender	44	8,791	4,711	53.5±8.0%
Logistic EuroSCORE (%)	42	8,561	---	24.39±5.91
STS score	26	4,391	---	11.4±4.8
Transfemoral TAVI	46	9,251	5,994	64.8±30.7%
Transaxillary TAVI	45	8,381	238	2.8±8.6%
Transapical TAVI	46	9,251	2,992	32.3±31.6%
Use of Medtronic/ CoreValve	46	9,251	3,818	41.2±42.3%
Use of Edwards SAPIEN	46	9,251	5,390	58.3±42.4%

Table 3. Need for emergent cardiac surgery and outcomes.

	Number of publications with available data (n)	Overall number of patients with available data (n)	Number of events (n)	Weighted mean±SD
Emergent cardiac surgery (%)	46	9,251	102	1.1±1.1%
30-day overall mortality	46	9,251	738	8.0±3.8%
30-day mortality in patients requiring emergent cardiac surgery	45	73	49	67.1±37.9%
30-day mortality in patients without emergent cardiac surgery	45	8,059	601	7.5±4.0%

Table 4. Need for emergent cardiac surgery with different TAVI approaches and valve prostheses.

	Medtronic/CoreValve transarterial			Edwards SAPIEN transarterial			Edwards SAPIEN transapical		
	Number of publications with available data (n)	Overall number of patients with available data (n)	Weighted mean±SD	Number of publications with available data (n)	Overall number of patients with available data (n)	Weighted mean±SD	Number of publications with available data (n)	Overall number of patients with available data (n)	Weighted mean±SD
Patient age (years)	13	2,660	81.0±1.3	16	1,300	82.0±2.5	19	2,467	80.9±1.6
Female gender	12	2,510	53.7±5.3%	16	1,300	51.1±7.1%	19	2,467	59.9±10.1%
Logistic EuroSCORE (%)	13	2,660	21.27±3.60	20	1,530	25.45±4.22	18	2,290	28.56±7.47
Need for emergent cardiac surgery (%)	13	2,660	0.6±0.9%	11	571	0.9±0.9%	21	2,531	1.9±1.7%
Overall 30-day mortality (%)	12	2,649	6.0±4.2%	16	1,289	7.1±4.3%	18	2,340	9.8±3.3%

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CLINICAL RESEARCH
TAVI

Treatment of aortic stenosis with a self-expanding transcatheter valve: the International Multi-centre ADVANCE Study

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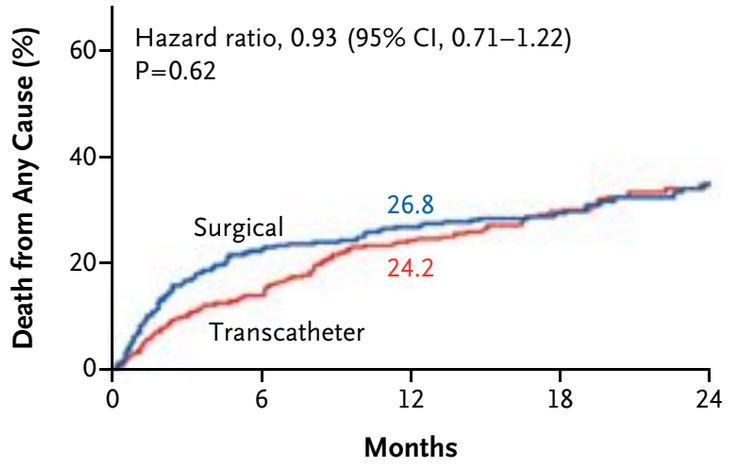
Table 2 **Procedural characteristics for all patients and by EuroSCORE[a]**

	All patients ($n = 996$)	EuroSCORE[b] ≤10% ($n = 229$)	EuroSCORE >10–20% ($n = 406$)	EuroSCORE >20% ($n = 360$)	Overall *P*-value[c]
Procedural outcomes					
Successful vascular access, delivery and deployment of device, and successful retrieval of the delivery system	971/996 (97.5) (96.5, 98.5)	223/229 (97.4)	400/406 (98.5)	347/360 (96.4)	0.185
Correct position of one device in the proper anatomical position at the end of procedure[d]	983/996 (98.7) (98.0, 99.4)	225/229 (98.3)	405/406 (99.8)	352/360 (97.8)	0.113
Mean aortic valve gradient <20 mmHg	776/807 (96.2) (94.8, 97.5)	178/186 (95.7)	315/330 (95.5)	283/291 (97.3)	0.482
No severe aortic regurgitation	871/873 (99.8) (99.5, 100)	201/201 (100)	354/355 (99.7)	315/316 (99.7)	0.923
Only one valve used[d]	956/996 (96.0) (94.8, 97.2)	220/229 (96.1)	390/406 (96.1)	345/360 (95.8)	0.984
Procedural mortality[e]	5/996 (0.5) 0.1–0.9%	0/229 (0.0)	2/406 (0.5)	3/360 (0.8)	0.579
Balloon aortic valvuloplasty (BAV)					
Pre-implant BAV	906/996 (91.0) (89.2, 92.7)	207/229 (90.4)	379/406 (93.3)	319/360 (88.6)	0.073
Post-implant BAV	235/996 (23.6) (21.0, 26.2)	55/229 (24.0)	100/406 (24.6)	80/360 (22.2)	0.726
Major complications, valve related					
Annulus rupture	0/996 (0.0) (0.0, 0.0)	0/229 (0.0)	0/406 (0.0)	0/360 (0.0)	–
Valve embolization[d]	2/996 (0.2) (0.0, 0.5)	0/229 (0.0)	2/406 (0.5)	0/360 (0.0)	0.551
Conversion to surgical aortic valve replacement[f]	1/995 (0.1) (0.0, 0.3)	1/229 (0.4)	0/406 (0.0)	0/359 (0.0)	0.460
Coronary compromised[g]	1/887 (0.1) (0.0, 0.3)	0/197 (0.0)	0/364 (0.0)	1/325 (0.3)	0.746

[a]Data are presented as *n*/total *n* (%) (95% CI).
[b]The logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) measures patient risk at the time of cardiovascular surgery and is calculated by a logistic regression equation. Scores range from 0 to 100%, with higher scores indicating greater risk.
[c]Logistic regression models were used to test for overall and group pairwise differences. Pairwise comparison *P*-values should be compared with a Bonferroni-adjusted alpha level of 0.05/3 = 0.017.
[d]Forty patients required use of a second CoreValve bioprosthesis (site-reported); 34 cases were due to malplacement of the first valve, of which 19 were due to valve insufficiency; and 6 cases were due to other reasons. In all cases the second CoreValve bioprosthesis was successfully implanted in the proper anatomical position.
[e]Two patients died from severe, diffuse haemorrhage without evidence of vascular perforation at autopsy, 1 patient died from a rupture of the aortic arch, 1 patient died of acute respiratory failure, and 1 patient died secondary to right heart failure as a result of acquired ventricular septum defect most likely due to the post-dilatation of the Medtronic CoreValve prosthesis with an oversized balloon.
[f]This patient had paravalvular regurgitation, which persisted in spite of correct transcatheter heart valve positioning and post-implant BAV. The AR did not improve, and based on the patient's clinical status, it was decided to implant a surgical valve.
[g]Patient had previous coronary artery bypass grafting; compromised flow in native vessel with good flow in grafts.

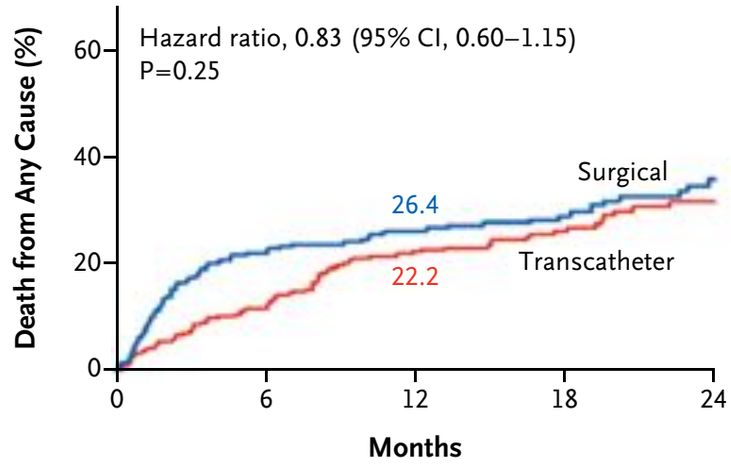
Linke et Al, Eur Heart J, 2014

A **Death from Any Cause, All Patients**



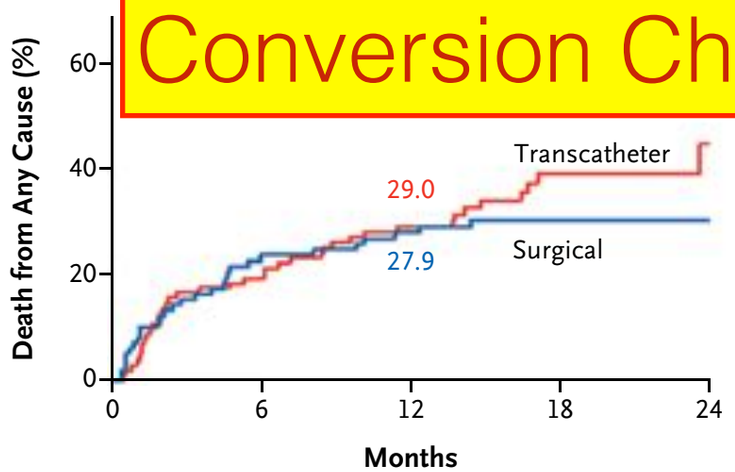
No. at Risk					
Transcatheter	348	298	260	147	67
Surgical	351	252	236	139	65

B **Death from Any Cause, Transfemoral-Placement Cohort**



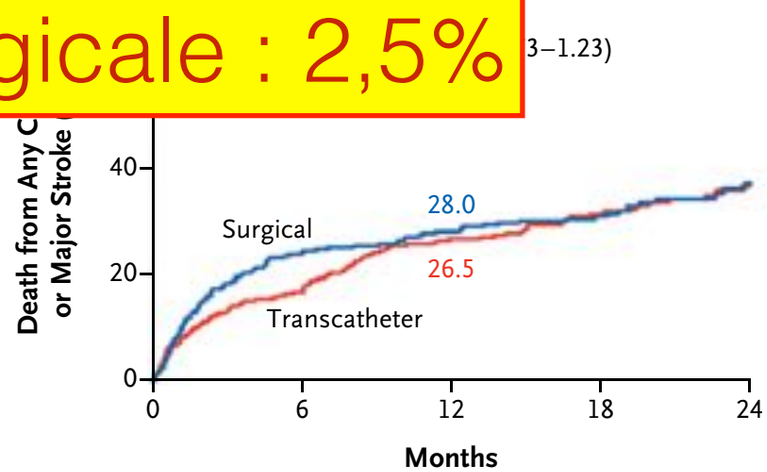
No. at Risk					
Transcatheter	244	215	188	119	59
Surgical	248	180	168	109	56

C **Death from Any Cause, Transapical-Placement Cohort**



No. at Risk					
Transcatheter	104	83	72	28	8
Surgical	103	72	68	30	9

D **Death from Any Cause or Major Stroke**



No. at Risk					
Transcatheter	348	289	252	143	65
Surgical	351	247	232	138	63

Figure 2. Time-to-Event Curves for the Primary End Point and Other Selected End Points.

Time-to-event curves are shown for death from any cause in all patients (Panel A), in the transfemoral-placement cohort (Panel B), and in the transapical-placement cohort (Panel C) and for a composite of death or major stroke (Panel D) among patients who were randomly assigned to undergo either transcatheter aortic-valve replacement (TAVR) or surgical aortic-valve replacement (AVR). The event rates were calculated with the use of Kaplan–Meier methods and compared with the use of the log-rank test.

Conversion Chirurgicale : 2,5%

Partner 1, Cohorte A

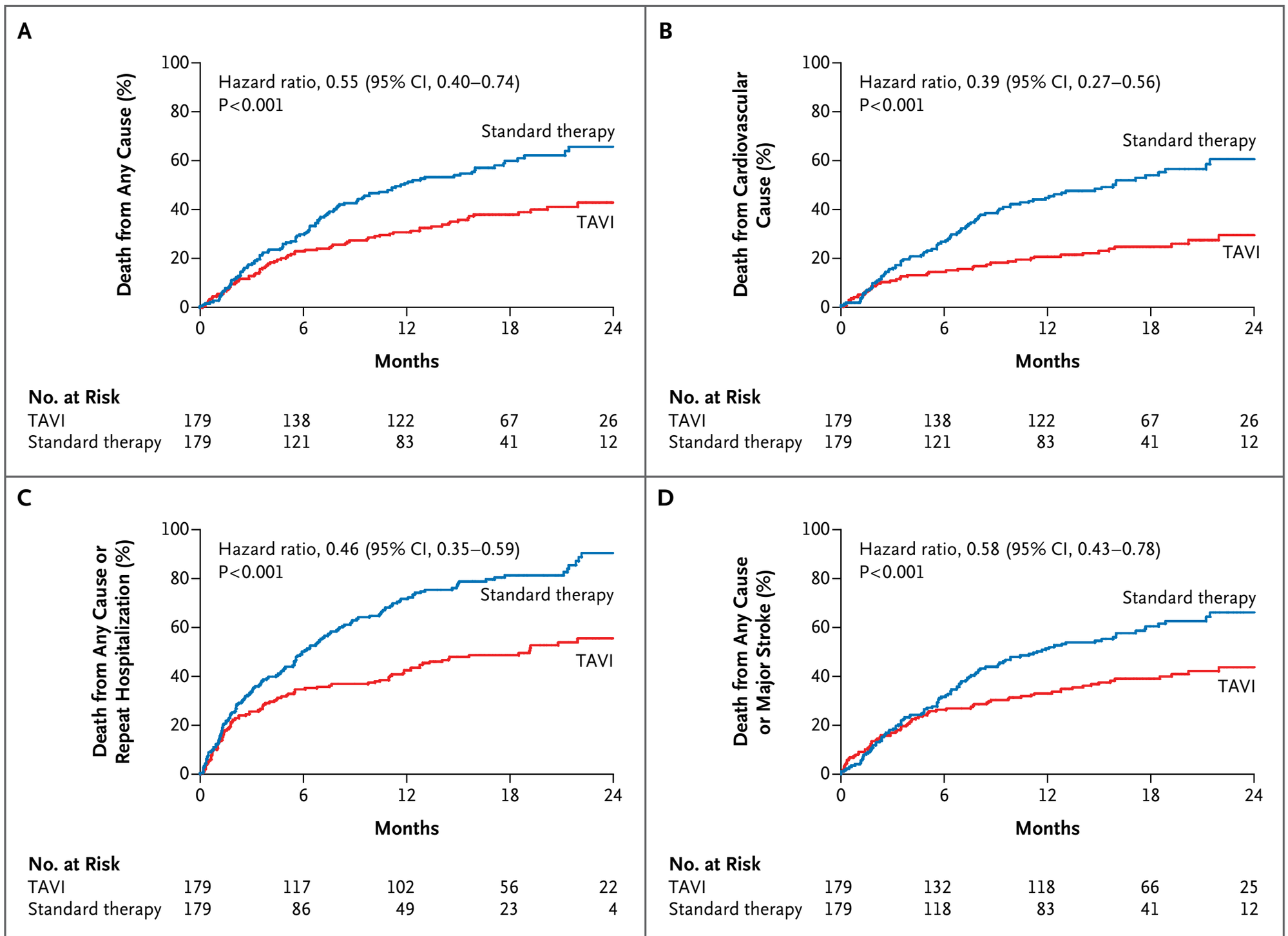


Figure 1. Time-to-Event Curves for the Primary End Point and Other Selected End Points.

Event rates were calculated with the use of Kaplan–Meier methods and compared with the use of the log-rank test. Deaths from unknown causes were assumed to be deaths from cardiovascular causes.

One-Year Clinical Outcomes With SAPIEN 3 Transcatheter Aortic Valve Replacement in High-Risk and Inoperable Patients With Severe Aortic Stenosis

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For the PARTNER Investigators

BACKGROUND: In the initial PARTNER trial (Placement of Aortic Transcatheter Valves) of transcatheter aortic valve replacement for high-risk (HR) and inoperable patients, mortality at 1 year was 24% in HR and 31% in inoperable patients. A recent report of the 30-day outcomes with the low-profile SAPIEN 3 transcatheter aortic valve replacement system demonstrated very low rates of adverse events, but little is known about the longer-term outcomes with this device.

METHODS: Between October 2013 and September 2014, 583 HR (65%) or inoperable (35%) patients were treated via the transfemoral (84%) or transapical/transaortic (16%) access route at 29 US sites. Major clinical events at 1 year were adjudicated by an independent clinical events committee, and echocardiographic results were analyzed by a core laboratory.

RESULTS: Baseline characteristics included age of 83 years, 42% female, and median Society of Thoracic Surgeons score of 8.4%. At the 1-year follow-up, survival (all-cause) was 85.6% for all patients, 87.3% in the HR subgroup, and 82.3% in the inoperable subgroup. Survival free of all-cause and cardiovascular mortality in the transfemoral patients from the HR cohort was 87.7% and 93.3%, respectively. There was no severe paravalvular leak. Moderate paravalvular leak (2.7%) was associated with an increase in mortality at 1 year, whereas mild paravalvular leak had no significant association with mortality. Symptomatic improvement as assessed by the percentage of patients in New York Heart Association class III and IV (90.1% to 7.7% at 1 year; $P<0.0001$) and by Kansas City Cardiomyopathy Questionnaire overall summary score (improved from 46.9 to 72.4; $P<0.0001$) was marked. Multivariable predictors of 1-year mortality included alternative access, Society of Thoracic Surgeons score, and disabling stroke.

CONCLUSIONS: In this large, adjudicated registry of SAPIEN 3 HR and inoperable patients, the very low rates of important complications resulted in a strikingly low mortality rate at 1 year. Between 30 and 365 days, the incidence of moderate paravalvular aortic regurgitation did not increase, and no association between mild paravalvular leak and 1-year mortality was observed, although a small increase in disabling stroke occurred. These results, which likely reflect device iteration and procedural evolution, support the use of transcatheter aortic valve replacement as the preferred therapy in HR and inoperable patients with aortic stenosis.

CLINICAL TRIAL REGISTRATION: URL: http://www.clinicaltrials.gov. Unique identifier: NCT01314313.

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Sources of Funding, see page 138

Key Words: aortic valve ■ aortic valve stenosis ■ transcatheter aortic valve replacement

Table 3. Outcomes at 1 Year (Kaplan–Meier Estimates, as Treated)

	Combined, % (n)	HR, % (n)	Inoperable, % (n)	*P* Value
All-cause mortality	14.4 (82)	12.7 (48)	17.7 (34)	0.14
TF	12.3 (59)	10.7 (34)	15.7 (25)	0.17
TA/TAo	25.3 (23)	23.7 (14)	28.4 (9)	0.54
Cardiovascular mortality	8.1 (45)	7.4 (27)	9.6 (18)	0.38
TF	6.7 (31)	6.1 (19)	7.8 (12)	0.57
TA/TAo	16.2 (14)	14.4 (8)	19.4 (6)	0.44
All stroke	4.3 (23)	5.6 (20)	1.8 (3)	0.03
Major (disabling) stroke	2.4 (13)	3.0 (11)	1.3 (2)	0.16
Repeat hospitalization	17.1 (96)	15.6 (57)	19.9 (39)	0.13
Total AR moderate or greater	2.6 (10)	1.2 (3)	5.5 (7)	0.02
All-cause mortality and stroke	17.2 (98)	16.4 (62)	18.8 (36)	0.60
All-cause mortality, stroke, AR moderate or greater	20.6 (108)	19.0 (65)	23.7 (43)	0.19
New PPM	16.8 (96)	14.5 (54)	21.3 (42)	0.02

AR indicates aortic regurgitation; HR, high risk; PPM, permanent pacemaker; TA, transapical; TAo, transaortic; and TF, transfemoral.

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Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

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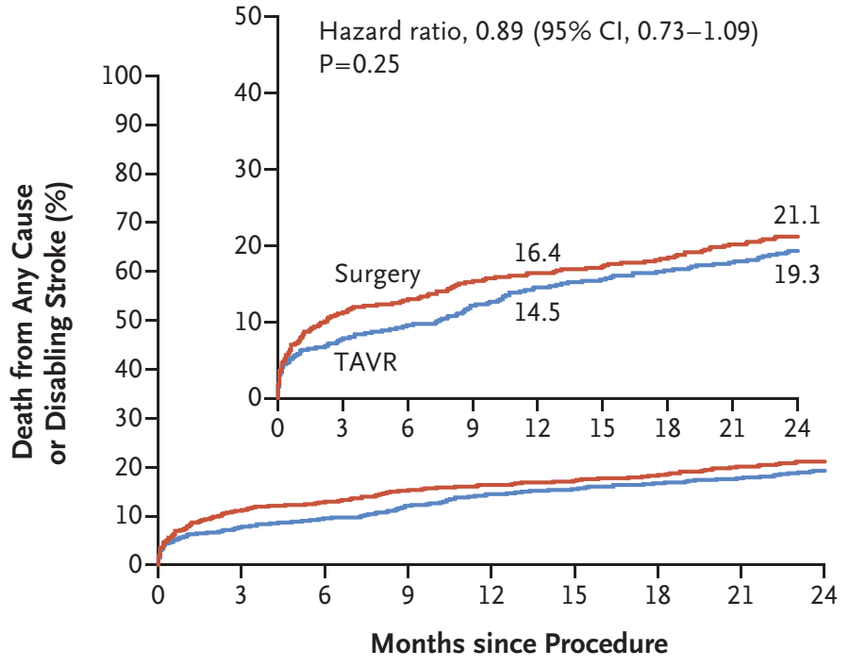
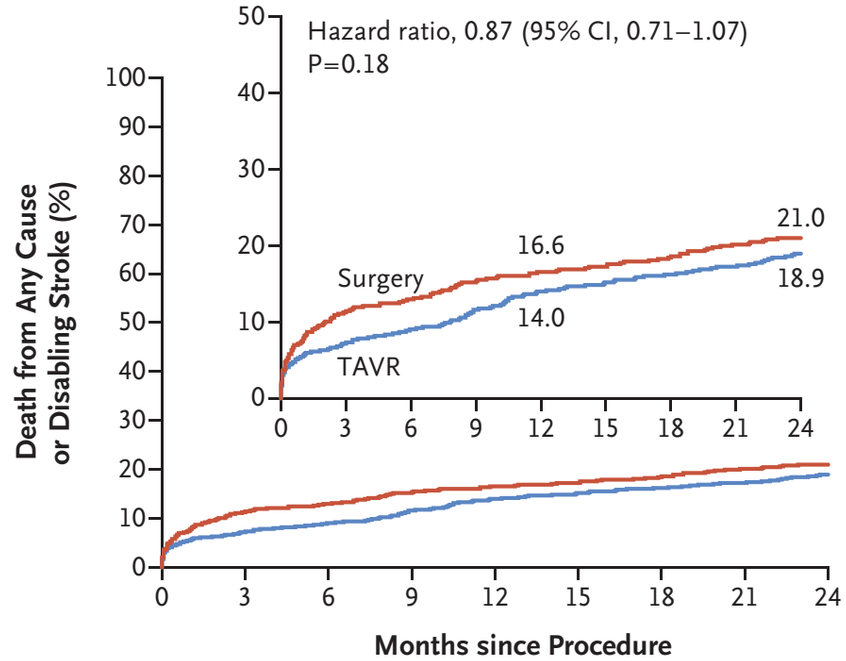
A Intention-to-Treat Population



No. at Risk									
TAVR	1011	918	901	870	842	825	811	801	774
Surgery	1021	838	812	783	770	747	735	717	695

B As-Treated Population



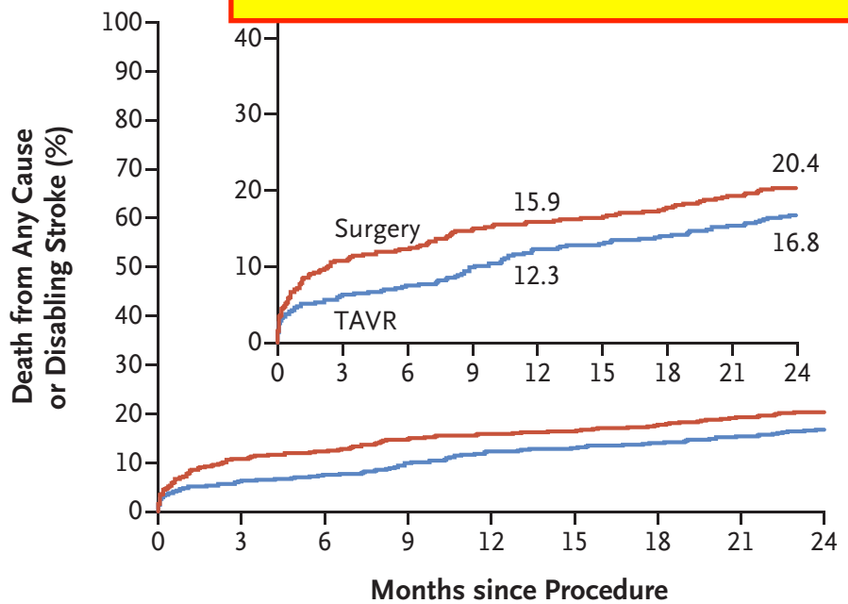
No. at Risk									
TAVR	994	917	900	870	842	825	811	801	774
Surgery	944	826	807	779	766	743	731	715	694

C Transfemoral-Acce

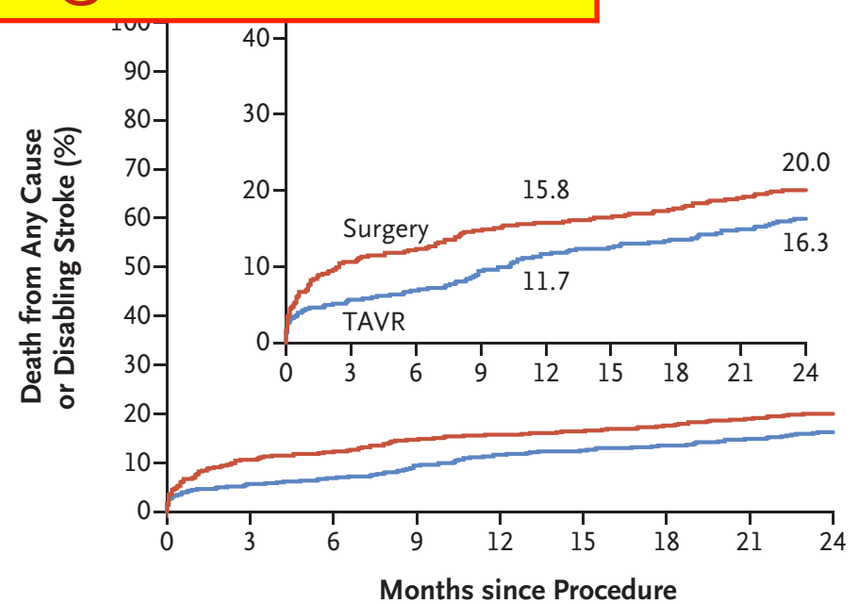
Conversion Chirurgicale : 0,3%

s

l, 0.61–0.99)



No. at Risk									
TAVR	775	718	709	685	663	652	644	634	612
Surgery	775	643	628	604	595	577	569	557	538

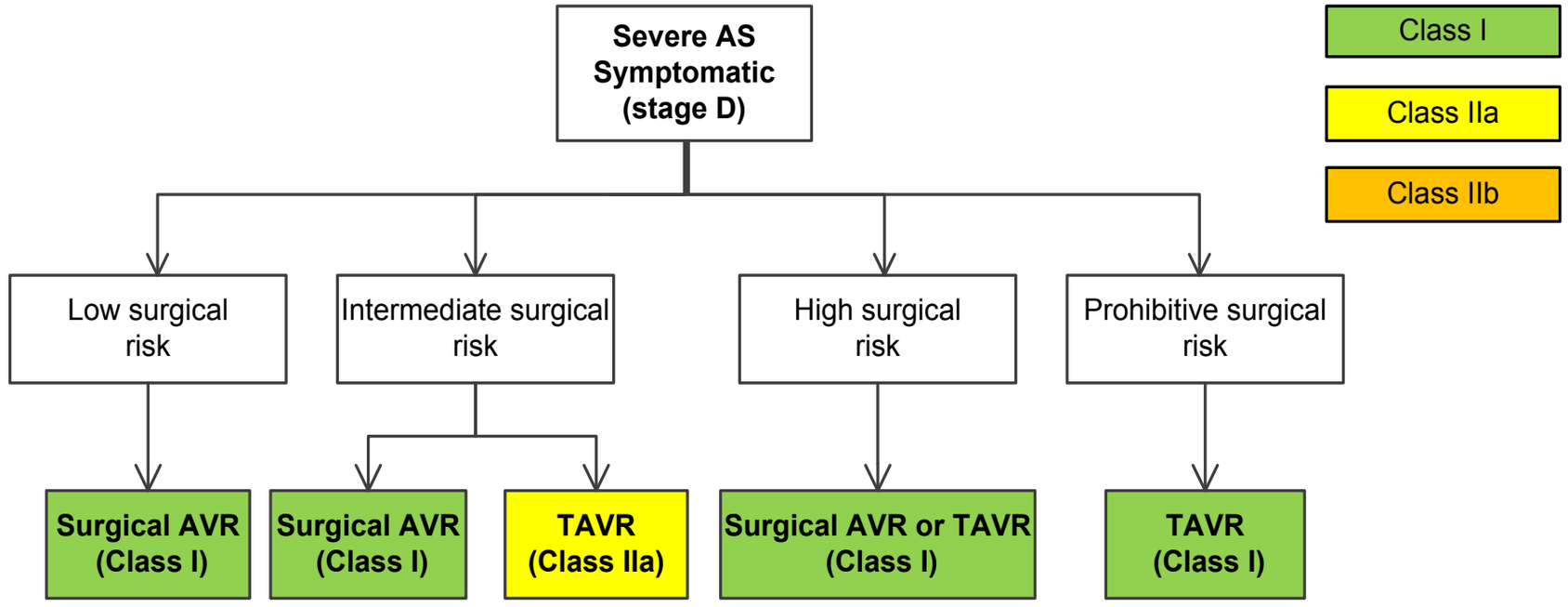


No. at Risk									
TAVR	762	717	708	685	663	652	644	634	612
Surgery	722	636	624	600	591	573	565	555	537

Figure 1. Time-to-Event Curves for the Primary Composite End Point.

The insets show the same data on an enlarged y axis. TAVR denotes transcatheter aortic-valve replacement.

Figure 1. Choice of TAVR Versus Surgical AVR in the Patient With Severe Symptomatic AS



Guidelines for Percutaneous Transluminal Coronary Angioplasty

A Report of the American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Subcommittee on Percutaneous Transluminal Coronary Angioplasty)

Subcommittee Members

Thomas J. Ryan, MD, FACC, Chairman; David P. Faxon, MD, FACC; Rolf M. Gunnar, MD, FACC; J. Ward Kennedy, MD, FACC; Spencer B. King III, MD, FACC; Floyd D. Loop, MD, FACC; Kirk L. Peterson, MD, FACC; T. Joseph Reeves, MD, FACC; David O. Williams, MD, FACC; William L. Winters Jr., MD, FACC

1. Absolute contraindications:
   a) There is no significant obstructing lesion.
   b) Multivessel disease with severe diffuse atherosclerosis is present for which an alternative form of revascularization would be unequivocally more efficacious.
   c) There is a significant obstruction (>50%) in the left main coronary artery and this main segment is not protected by at least one completely patent bypass graft to the left anterior descending or left circumflex artery.
   d) There is no formal cardiac surgical program within the institution.

E. Need for Surgical Backup

An experienced cardiovascular surgical team should be available within the institution for emergency surgery for all angioplasty procedures.* The Subcommittee feels strongly that

ACC/AHA Guidelines for Percutaneous Coronary Intervention (Revision of the 1993 PTCA Guidelines)—Executive Summary

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty)

Endorsed by the Society for Cardiac Angiography and Interventions

Committee Members

TABLE 11. Recommendations For PCI With and Without On-Site Cardiac Surgery

	With On-Site Cardiac Surgery	Without On-Site Cardiac Surgery
Elective PCI	**Class I** Patients undergoing elective PCI in facilities with on-site cardiac surgery. *(Level of Evidence: B)*	**Class III** Patients undergoing elective PCI in facilities without on-site cardiac surgery. *(Level of Evidence: C)*
Primary PCI	**Class I** Patients undergoing primary PCI in facilities with on-site cardiac surgery. *(Level of Evidence: B)*	**Class IIb** Patients undergoing primary PCI in facilities without on-site cardiac surgery, but *with* a proven plan for rapid access (within 1 h) to a cardiac surgery operating room in a nearby facility with appropriate hemodynamic support capability for transfer. The procedure should be limited to patients with ST-segment elevation MI or new LBBB on ECG, and done in a timely fashion (balloon inflation within 90 ± 30 min of admission) by persons skilled in the procedure (≥75 PCIs/year) and only at facilities performing a minimum of 36 primary PCI procedures per year. *(Level of Evidence: B)* **Class III** Patients undergoing primary PCI in facilities without on-site cardiac surgery and *without* a proven plan for rapid access (within 1 h) to a cardiac surgery operating room in a nearby facility with appropriate hemodynamic support capability for transfer. *(Level of Evidence: C)*

ACC/AHA/SCAI Practice Guideline

ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention—Summary Article

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention)

WRITING COMMITTEE MEMBERS

4.3. Role of On-Site Cardiac Surgical Back-up

Class I	**Class I**	
1. Patients undergoing elective PCI in facilities with on-site cardiac surgery. *(Level of Evidence: B)*	1. Elective PCI should be performed by operators with acceptable annual volume (at least 75 procedures per year) at high-volume centers (more than 400 procedures annually) that provide immediately available on-site emergency cardiac surgical services. *(Level of Evidence: B)*	Phrasing has been changed to reflect current terminology and volume criteria; otherwise, no significant changes.
2. Patients undergoing primary PCI in facilities with on-site cardiac surgery. *(Level of Evidence: B)*	2. Primary PCI for patients with STEMI should be performed in facilities with on-site cardiac surgery. *(Level of Evidence: B)*	Phrasing has been changed to reflect current terminology and to be consistent with the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction.
Class III	**Class III**	
Patients undergoing elective PCI in facilities without on-site cardiac surgery. *(Level of Evidence: C)*	Elective PCI should not be performed at institutions that do not provide on-site cardiac surgery.* *(Level of Evidence: C)* *Several centers have reported satisfactory results based on careful case selection with well-defined arrangements for immediate transfer to a surgical program (18–28). A small, but real fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with the immediate on-site availability of cardiac surgical support but cannot be managed effectively by urgent transfer. Wennberg et al. found higher mortality in the Medicare database for patients undergoing elective PCI in institutions without onsite cardiac surgery (29). These recommendations may be subject to revision as clinical data and experience increase.	Phrasing has been changed to reflect current terminology. As with many dynamic areas in interventional cardiology, these recommendations may be subject to revision as clinical data and experience increase.

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PRACTICE GUIDELINE

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

A Report of the American College of Cardiology Foundation/American Heart Association
Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

4.8. PCI in Hospitals Without On-Site Surgical Backup: Recommendations

CLASS IIa

1. Primary PCI is reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished (351,352). *(Level of Evidence: B)*

CLASS IIb

1. Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection (352–354). *(Level of Evidence: B)*

CLASS III: HARM

1. Primary or elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer. *(Level of Evidence: C)*

TAVI sans CEC : Pistes

- Equipe multidisciplinaire
- Heart Team
- Expertise valvulaire
- Opérateurs entrainés, haut volume interventionnel
- Evaluation du risque opératoire
- Evaluation du risque de conversion chirurgical

TAVI sans CEC

- Patients avec une contre indication chirurgicale
- Patients avec un risque faible d'embolisation de prothèse
- Patients avec un risque faible de fuite aortique post implantation
- Patients avec un risque faible d'occlusion coronaire
- Réduction du risque de perforation du VD :
  Stimulation VG : Easy TAVI

TAVI

Dans les Centres
Sans Chirurgie Cardiaque

Dr Mohamed Abdellaoui
GHM de GRENOBLE
8 juin 2017