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UNIVERSITÀ DEGLI STUDI DI TORINO



TAVI FOR LOW RISK PATIENT

Federico Conrotto

**Città della Salute e della
Scienza di Torino**

October, 26th 2018



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Disclosure: none



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European Journal of Cardio-Thoracic Surgery 50 (2016) 1139–1148
doi:10.1093/ejcts/ezw218 Advance Access publication 12 July 2016

ORIGINAL ARTICLE

Cite this article as: Salizzoni S, D'Onofrio A, Agrifoglio M, Colombo A, Chieffo A, Cioni M *et al.* Early and mid-term outcomes of 1904 patients undergoing transcatheter balloon-expandable valve implantation in Italy: results from the Italian Transcatheter Balloon-Expandable Valve Implantation Registry (ITER). *Eur J Cardiothorac Surg* 2016;50:1139–48.

Early and mid-term outcomes of 1904 patients undergoing transcatheter balloon-expandable valve implantation in Italy: results from the Italian Transcatheter Balloon-Expandable Valve Implantation Registry (ITER)[†]

	All patients (n = 1904)	Patients who survived (n = 1323)	Patients who died (n = 581)	HR (CI 95%)	P-value
Age (years)	81.7 (6.2)	81.7 (6.1)	81.4 (6.8)	0.998 (0.985;1.012)	0.812
Gender (male)	39.8% (757/1904)	36.8% (487/1323)	46.5% (270/581)	1.420 (1.206;1.672)	<0.001
Body mass index, kg/m ²	25.8 (4.5)	26.0 (4.6)	25.4 (4.1)	0.970 (0.951;0.988)	0.001
Underweight (BMI < 18.5 kg/m ²)	3.5% (58/1904)	3.1% (35/1323)	3.8% (22/581)	1.289 (0.842;1.973)	0.027
Overweight (25 ≤ BMI < 30 kg/m ²)	37.6% (716/1904)	38.9% (515/1323)	37.5% (219/581)	0.808 (0.672;0.970)	
Obese (BMI ≥ 30 kg/m ²)	16.2% (308/1904)	16.9% (223/1323)	18.8% (85/581)	0.800 (0.627;1.020)	
Hypertension	81.6% (1553/1904)	81.6% (1068/1323)	82.3% (478/581)	1.088 (0.879;1.346)	0.436
Diabetes mellitus	25.8% (491/1904)	25.8% (338/1323)	29.1% (169/581)	1.268 (1.060;1.517)	0.011
Insulin-dependent diabetes mellitus	9.6% (184/1904)	9.6% (126/1323)	12.7% (74/581)	1.503 (1.177;1.919)	0.002
Creatinine (mg/dl) [0.6% missing values]	1.2 (0.7)	1.2 (0.7)	1.5 (1.1)	1.285 (1.223;1.351)	<0.001
Glomerular filtration rate (ml/min/1.73 m ²) [1% missing values]	46.8 (19.7)	46.8 (19.7)	38.8 (18.8)	0.977 (0.973;0.982)	<0.001
Haemoglobin (g/dl) [11% missing values]	11.8 (1.6)	11.9 (1.6)	11.7 (1.5)	0.912 (0.861;0.966)	0.002
Log EuroSCORE (%)	21.1 (13.7)	19.6 (12.3)	24.6 (15.9)	1.021 (1.015;1.026)	<0.001
Log EuroSCORE II (%) [53% missing values]	7.3 (6.7)	6.7 (5.8)	8.6 (8.2)	1.030 (1.017;1.043)	<0.001
STS mortality score (%) [43% missing values]	9.2 (7.6)	8.8 (7.4)	10.1 (8.0)	1.018 (1.005;1.031)	0.010

STS mortality score 9.2%



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What's low risk TAVI?

How do we define the risk of a TAVI procedure?

Inaccuracy of available surgical risk scores to predict outcomes after transcatheter aortic valve replacement

Fabrizio D’Ascenzo^a, Flavia Ballocca^a, Claudio Moretti^a, Marco Barbanti^c, Valeria Gasparetto^f, Marco Mennuni^e, Maurizio D’Amico^a, Federico Conrotto^a, Stefano Salizzoni^b, Pierluigi Omedè^a, Chiara Colaci^a, Giuseppe B. Zoccali^d, Mario Lupo^b, Giuseppe Tarantini^f, Massimo Napodanno^f, Patrizia Presbitero^e, Imad Sheiban^a, Corrado Tamburino^c, Sebastiano Marra^a and Fiorenzo Gaita^a

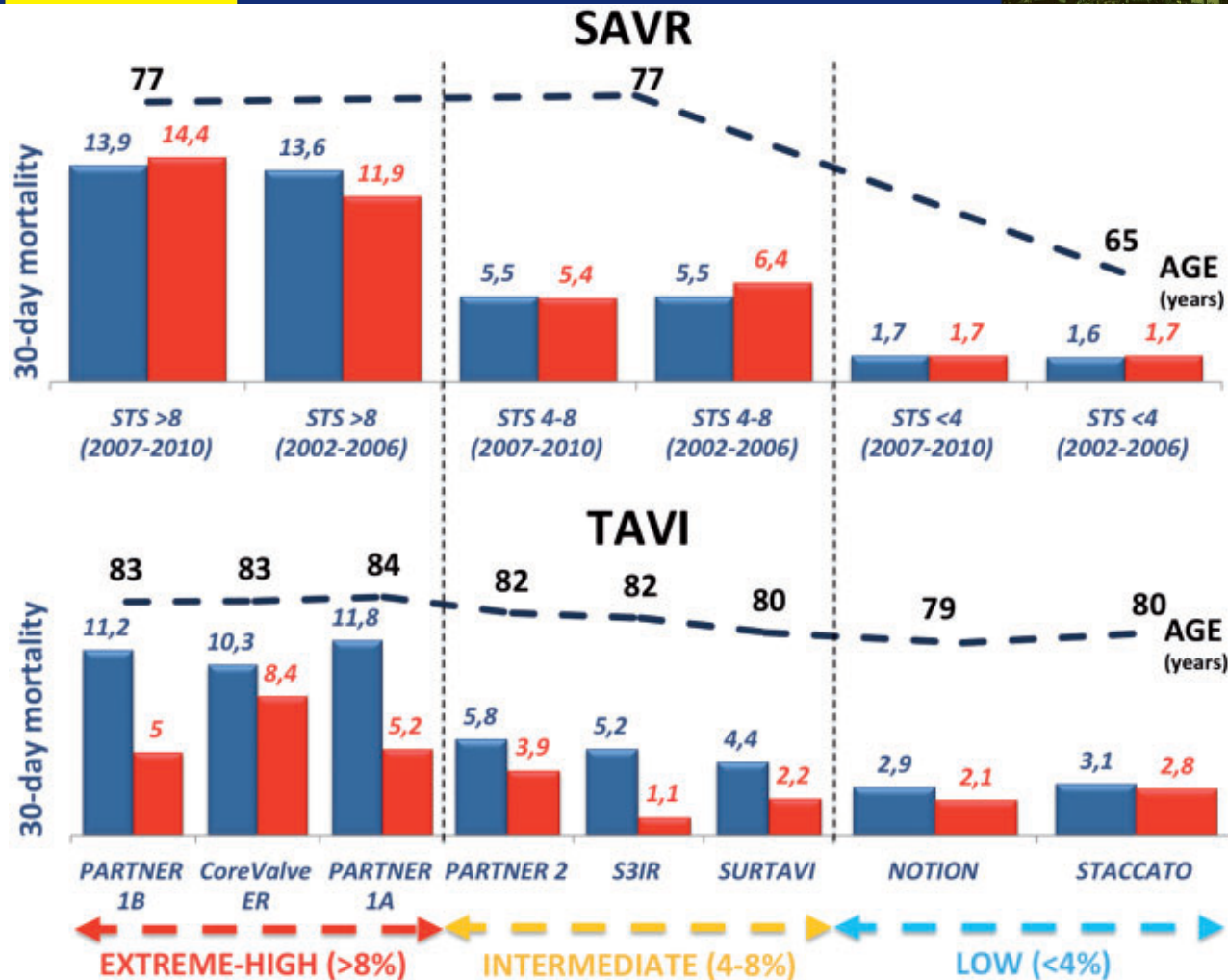
Multivariate analysis for in-hospital complications and 30-day all-cause mortality

	OR	LCI	UCI	P
Logistic regression for 30-day all-cause mortality				
Age (years)	1.4	0.8	2.4	0.09
Renal clearance less than 30 ml/min/m ²	0.61	0.10	3.53	0.58
Ejection fraction (as continuous variable)	0.8	0.7	1.5	0.56
Life-threatening and major bleeding	5.1	1.7	16	0.005
Acute kidney injury	1.9	0.4	14	0.40
Major vascular complications	1.5	0.6	2.5	0.80
Logistic Euroscore	1.03	1.01	1.05	0.027
STS mortality score	1.1	1.06	1.31	0.02
ACEF score	9.1	0.8	45	0.06
Logistic regression for in-hospital complications				
Age (years)	1.4	0.8	2.4	0.09
Renal clearance less than 30 ml/min/m ²	2.2	1.3	3.9	0.003
Ejection fraction (as continuous variable)	1.02	1.01	1.04	0.001
Previous stroke	2.5	1.4	4	0.03
Logistic Euroscore	1.03	0.98	1.05	0.13
STS mortality score	1.04	1.01	1.06	0.005
ACEF score	0.9	0.28	4	0.07

ACEF Cstat: 0.6
Euroscore Cstat: 0.53
STS score Cstat: 0.62

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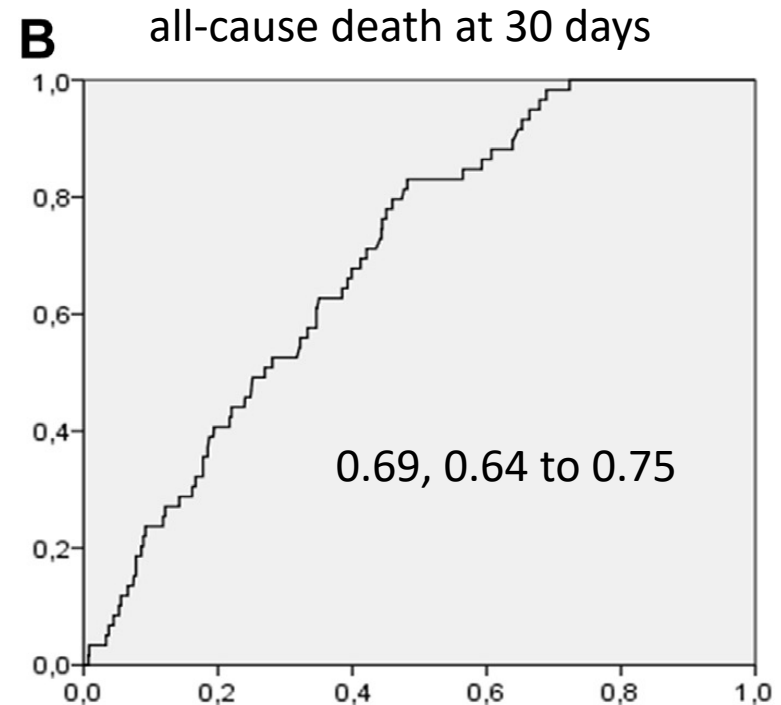
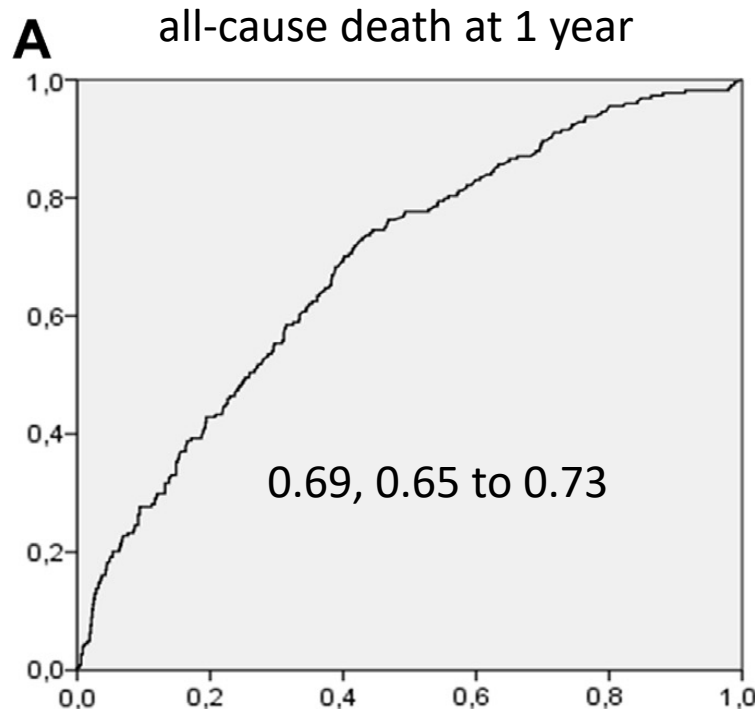


Usefulness and Validation of the Survival postT TAVI Score for Survival After Transcatheter Aortic Valve Implantation for Aortic Stenosis



Fabrizio D'Ascenzo, MD^{a,*}, Davide Capodanno, MD^b, Giuseppe Tarantini, MD, PhD^c,
Freek Nijhoff, MD^d, Cristina Ciuca, MD^e, Marco Luciano Rossi, MD^f, Nedy Brambilla, MD^g,
Marco Barbanti, MD^b, Massimo Napodano, MD^c, Pieter Stella, MD, PhD^{d,h}, Francesco Saia, MD^e,
Giuseppe Ferrante, MDⁱ, Corrado Tamburino, MD, PhD^b, Valeria Gasparetto, MD^c,
Pierfrancesco Agostoni, MD, PhD^d, Antonio Marzocchi, MD^c, Patrizia Presbitero, MD^f,
Francesco Bedogni, MD^g, Enrico Cerrato, MD^a, Pierluigi Omedè, MD^a, Federico Conrotto, MD^h,
Stefano Salizzoni, MD^j, Giuseppe Biondi Zoccai, MD^k, Sebastiano Marra, MD^h, Mauro Rinaldi, MDⁱ,
Fiorenzo Gaita, MD^a, Maurizio D'Amico, MD^h, and Claudio Moretti, MD, PhD^{a,h}

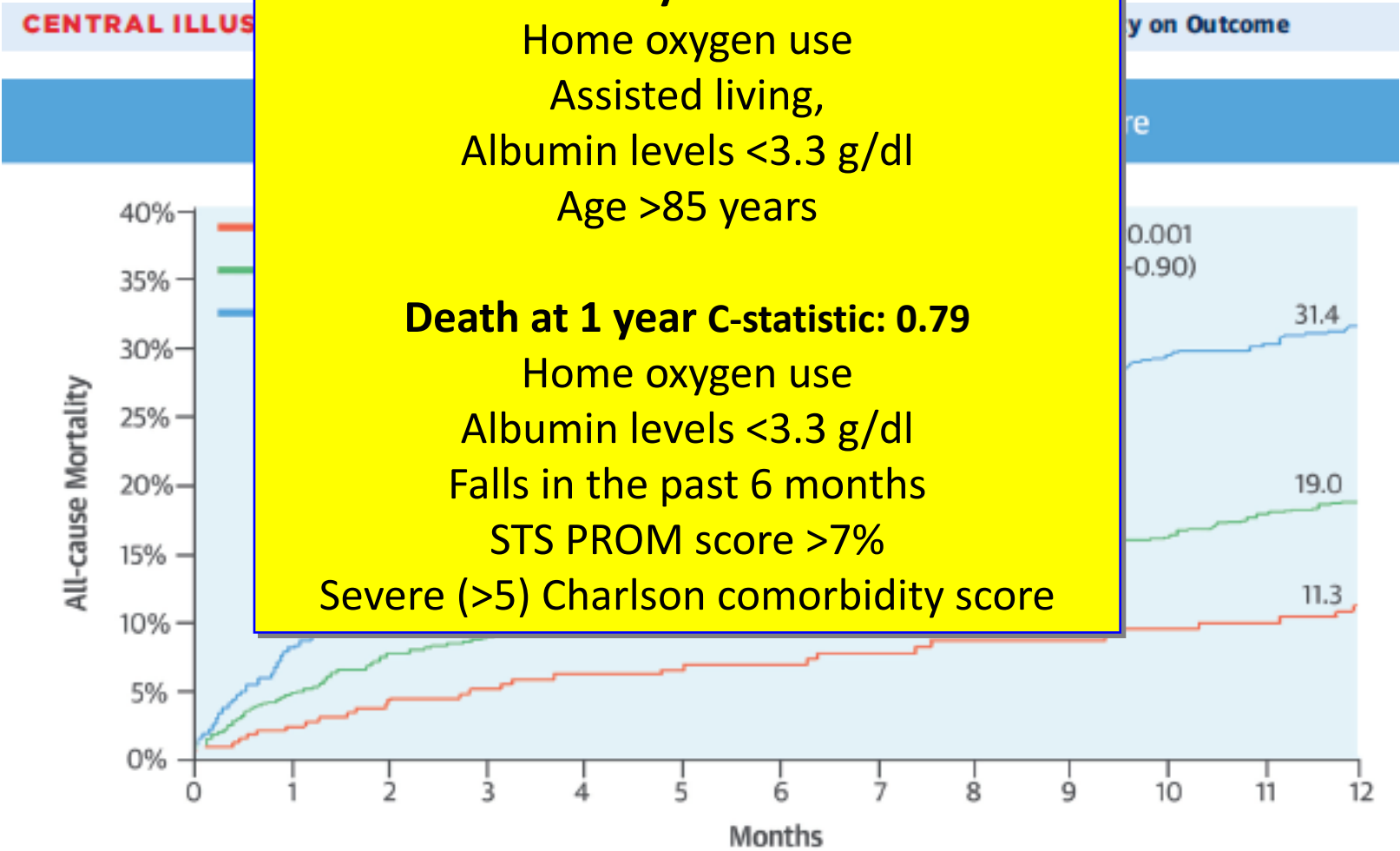
Previous stroke
Inverse of renal clearance
Systolic PAP >50 mmHg

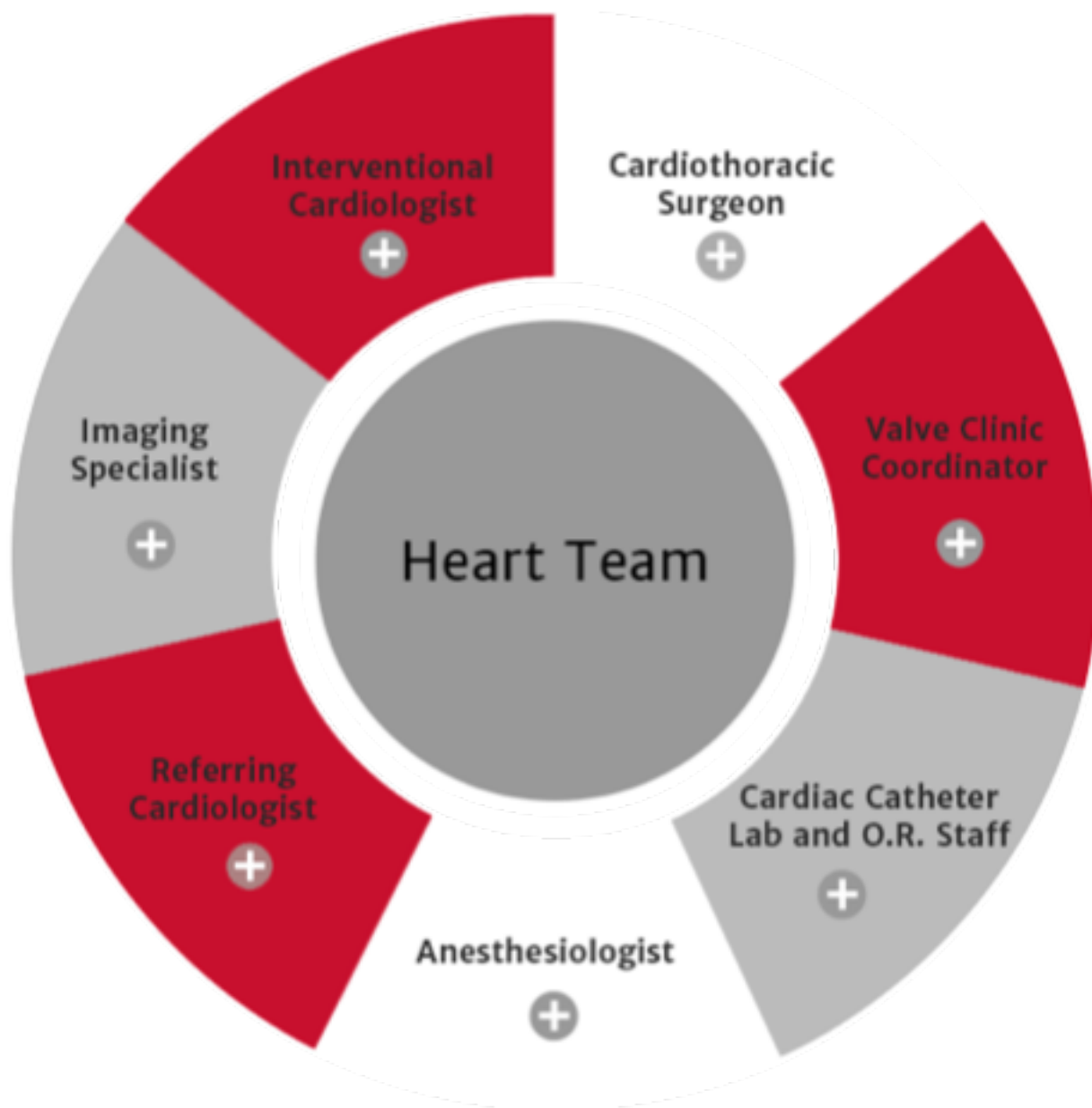


Predicting Early and Late Mortality After Transcatheter Aortic Valve Replacement



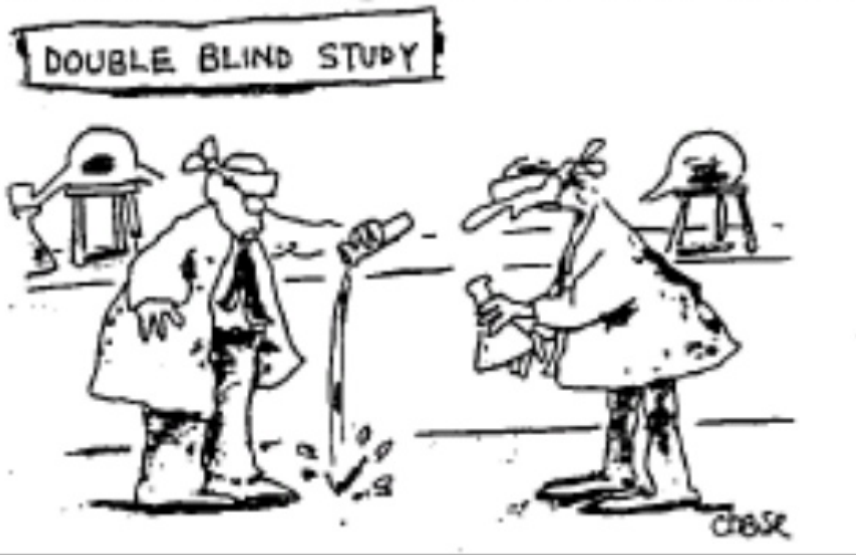
James B. Hermiller, Jr, MD,^a Steven J. Yakubov, MD,^b Michael J. Reardon, MD,^c G. Michael Deeb, MD,^d
David H. Adams, MD,^e Jonathan Afilalo, MD,^f
for the CoreValve United States Clinical Investigators





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**Randomized
trials
(Lower risk)**

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The **NEW ENGLAND**
JOURNAL of MEDICINE

ESTABLISHED IN 1812

APRIL 28, 2016

VOL. 374 NO. 17

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

2032 patients
Mean age 81.5 years
Mean STS score 5.8%

R

(with the balloon-expandable SAPIEN XT system)

TAVI

Vs

SAVR.

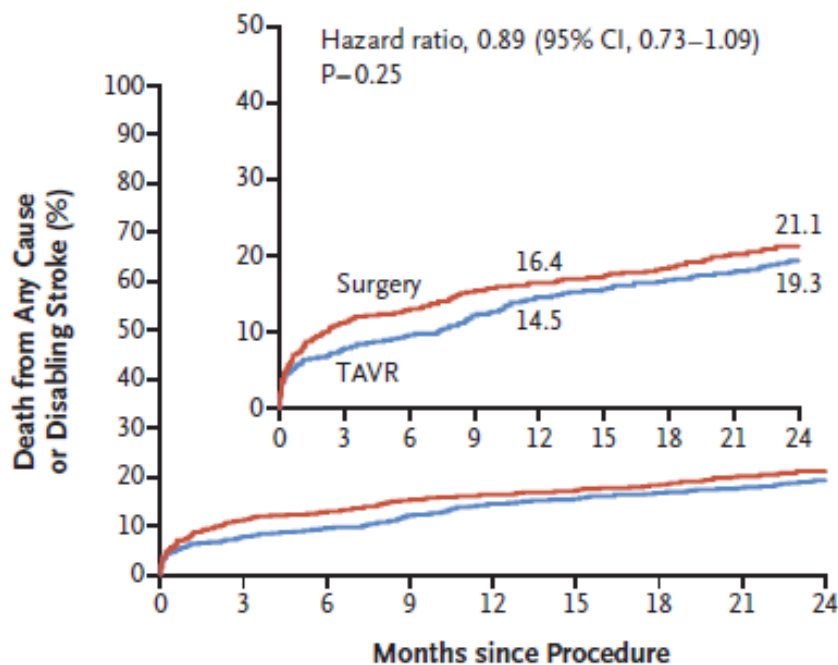
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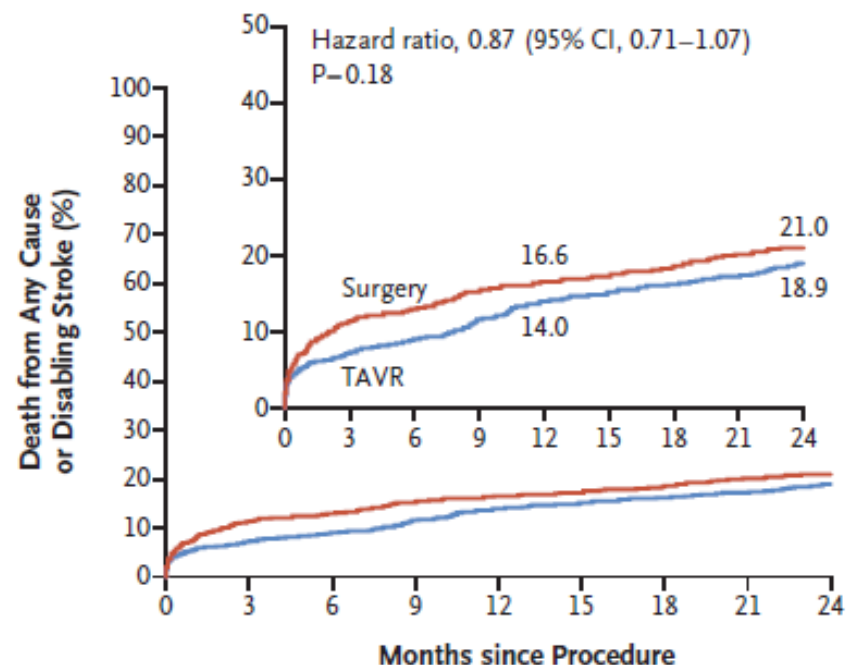
A Intention-to-Treat Population



No. at Risk

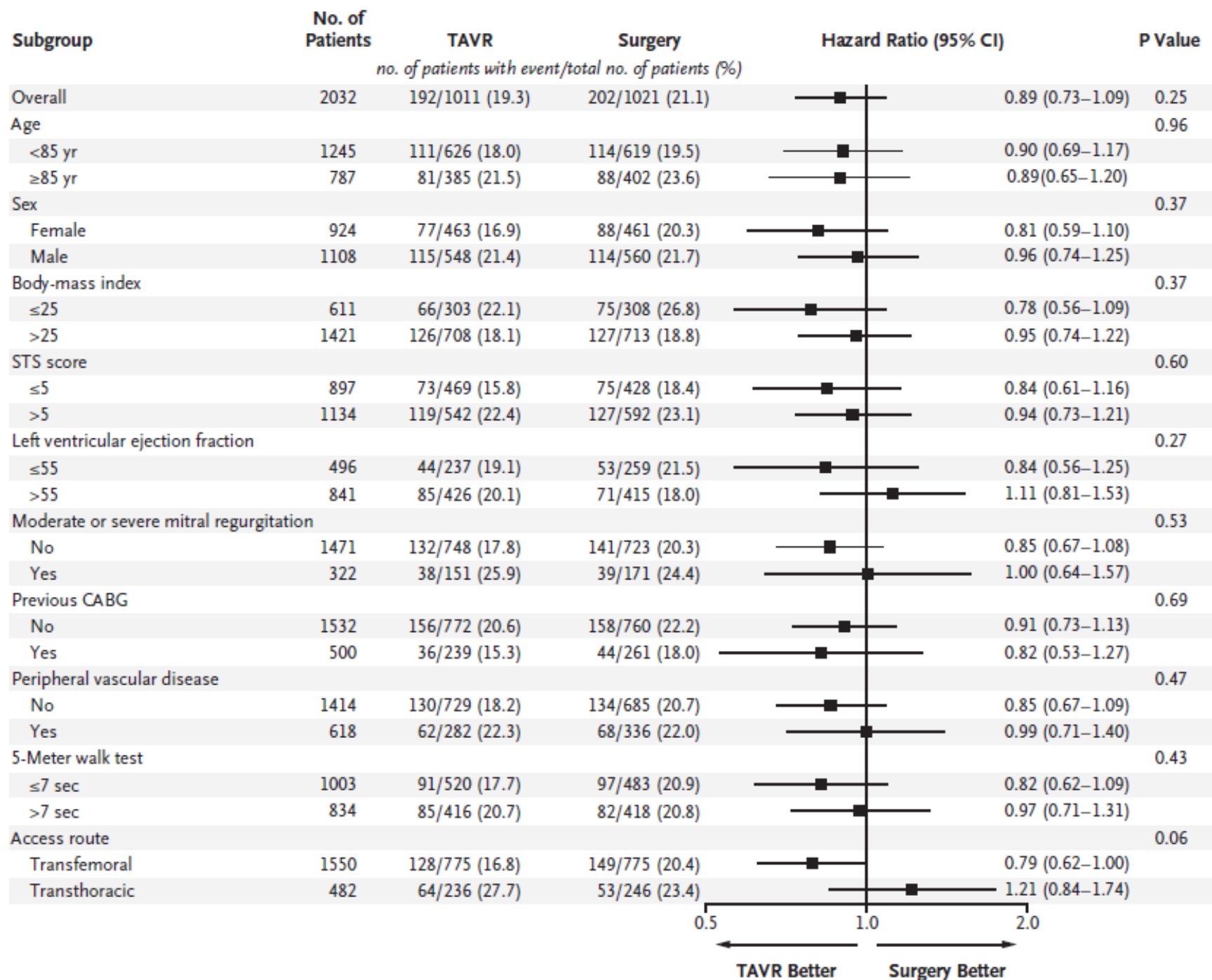
TAVR	1011	918	901	870	842	825	811	801	774
Surgery	1021	838	812	783	770	747	735	717	695

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



SURTAVI

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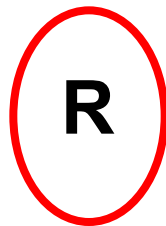


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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

1746 patients
Mean age 79.8 years
Mean STS score 4.5%



TAVI with a self expandable valve
Vs
SAVR

N Engl J Med 2017;376:1321–1331

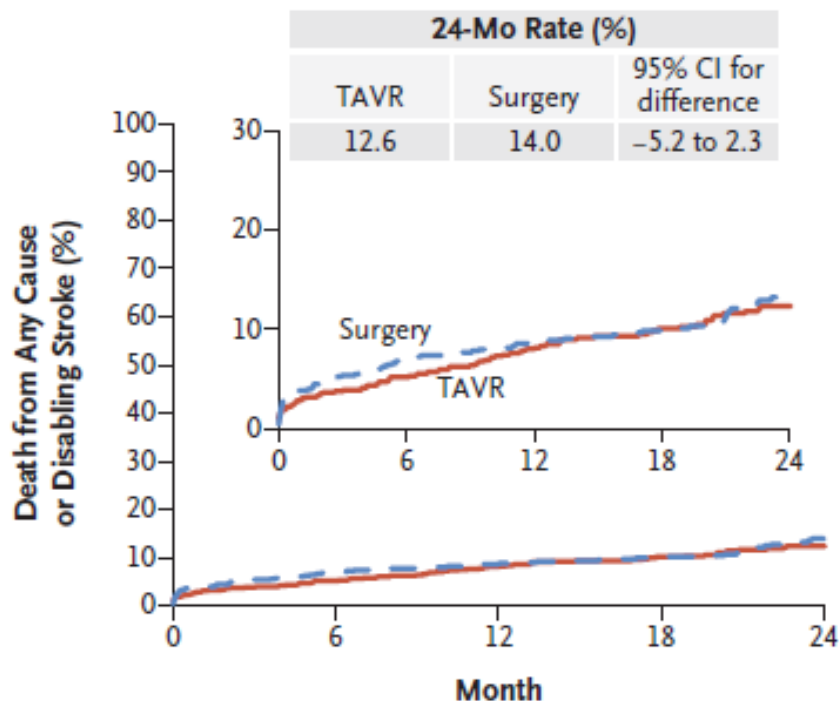
SURTA VI

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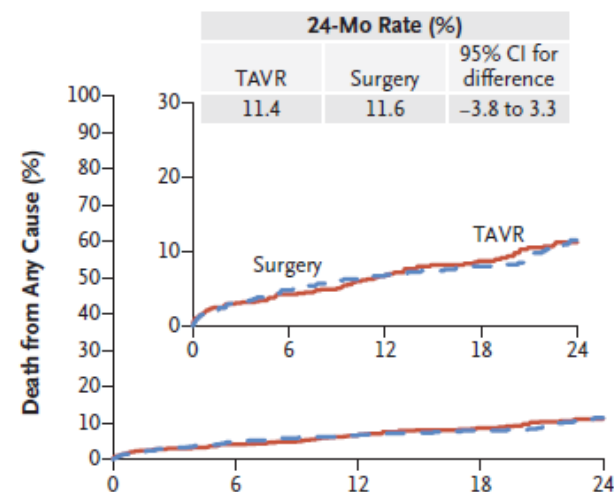
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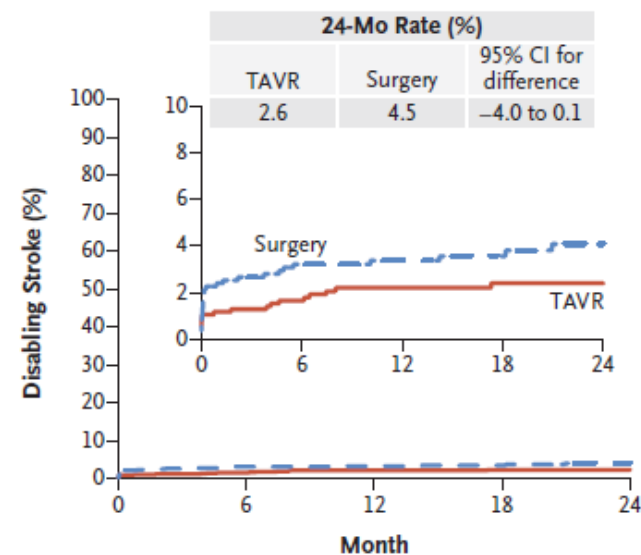
B Primary Outcome



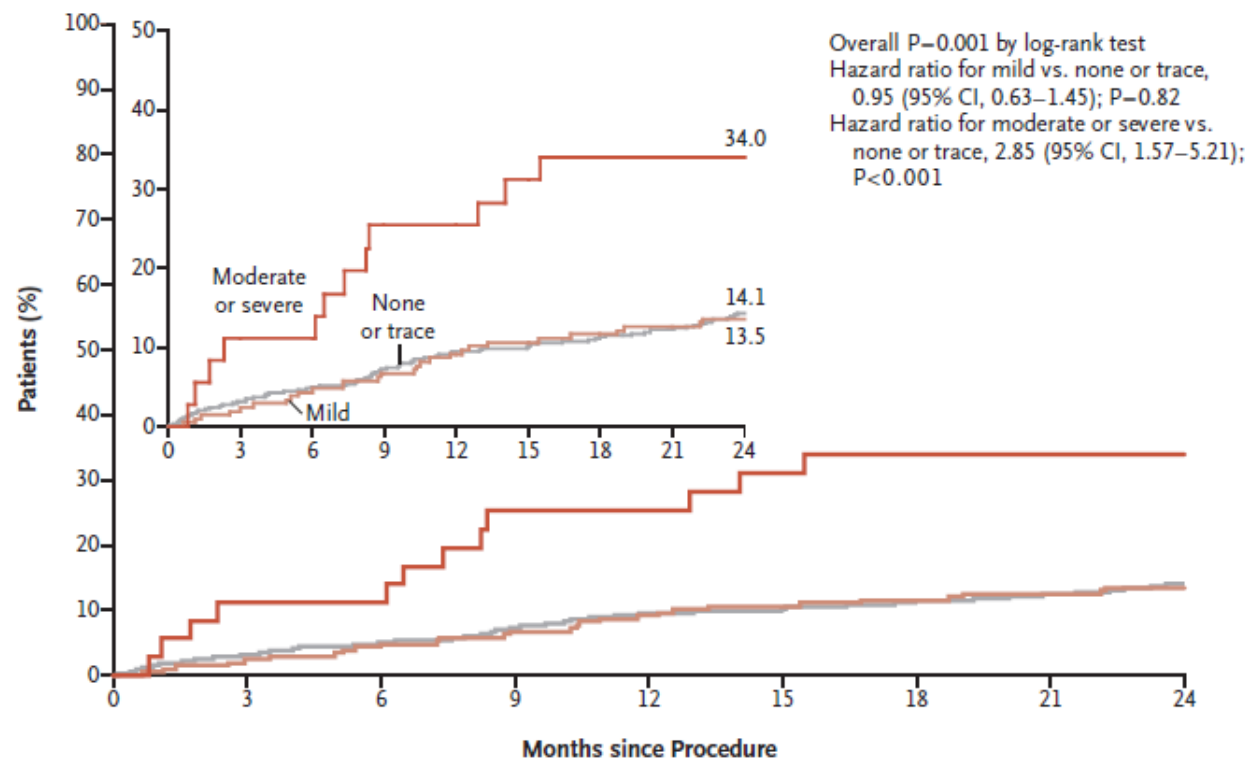
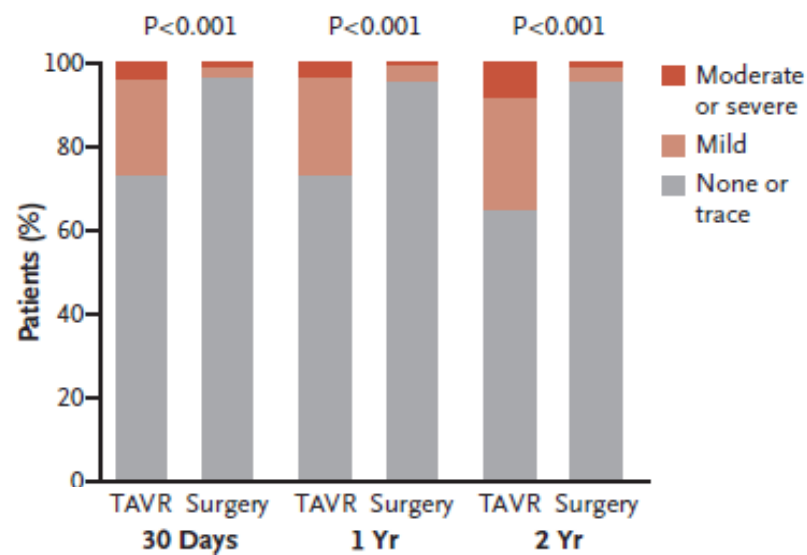
C Death from Any Cause



D Disabling Stroke



B Paravalvular Aortic Regurgitation



NOTION

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<http://dx.doi.org/10.1016/j.jacc.2015.03.014>

Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis

1-Year Results From the All-Comers NOTION
Randomized Clinical Trial



280 all-comer patients
Mean age 79.1 years
Mean STS score 3.0%

R

TAVI with a self expandable valve
Vs
SAVR

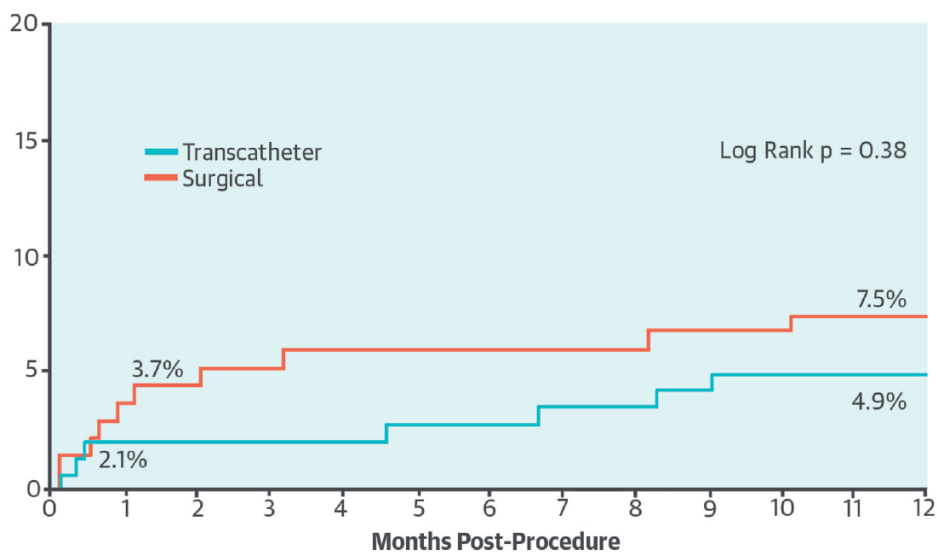
NOTION

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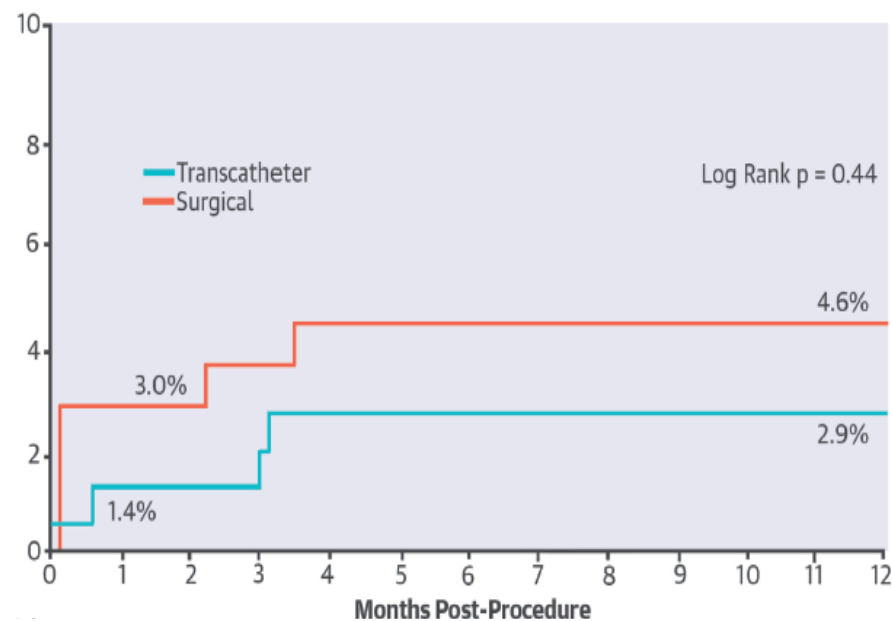
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Mortality (%)



Stroke (%)



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	Index Hospitalization* or 30 Days†			1 Year		
	TAVR	SAVR	p Value	TAVR	SAVR	p Value
Major, life threatening, or disabling bleeding*	16 (11.3)	28 (20.9)	0.03			
Cardiogenic shock*	6 (4.2)	14 (10.4)	0.05			
Major vascular complications*	8 (5.6)	2 (1.5)	0.10			
Acute kidney injury stage II or III*	1 (0.7)	9 (6.7)	0.01			
All-cause death†	3 (2.1)	5 (3.7)	0.43	7 (4.9)	10 (7.5)	0.38
Cardiovascular death†	3 (2.1)	5 (3.7)	0.43	6 (4.3)	10 (7.5)	0.25
Neurological events†	4 (2.8)	4 (3.0)	0.94	7 (5.0)	8 (6.2)	0.68
Stroke†	2 (1.4)	4 (3.0)	0.37	4 (2.9)	6 (4.6)	0.44
Transient ischemic attack†	2 (1.4)	0 (0)	0.17	3 (2.1)	2 (1.6)	0.71
MI†	4 (2.8)	8 (6.0)	0.20	5 (3.5)	8 (6.0)	0.33
Valve endocarditis†	1 (0.7)	0 (0)	0.33	4 (2.9)	2 (1.6)	0.47
New-onset or worsening AF†	24 (16.9)	77 (57.8)	<0.001	30 (21.2)	79 (59.4)	<0.001
Permanent pacemaker implantation†	46 (34.1)	2 (1.6)	<0.001	51 (38.0)	3 (2.4)	<0.001

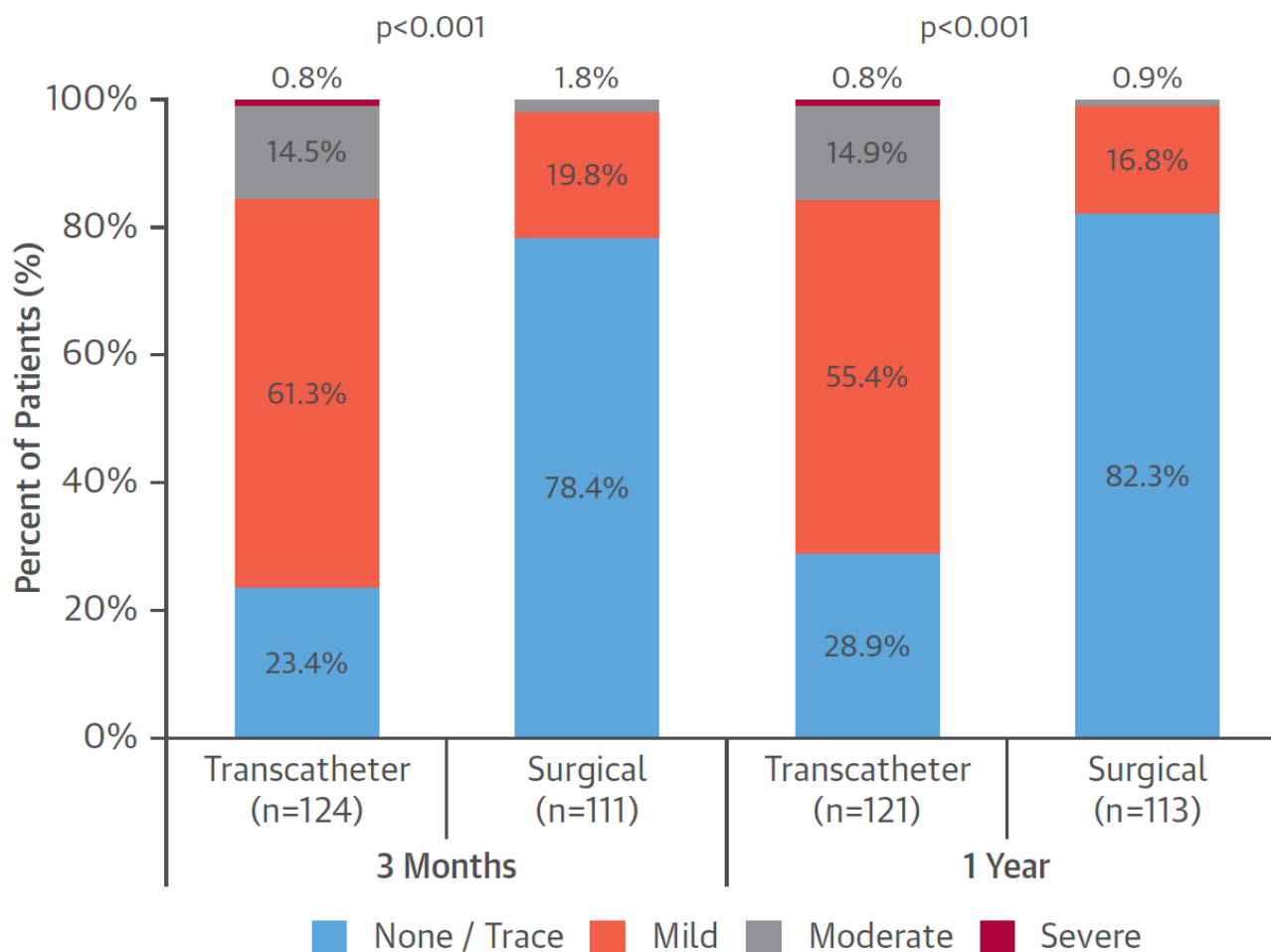
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Total Aortic Valve Regurgitation



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<http://dx.doi.org/10.1016/j.jacc.2015.06.013>

1-Year Outcomes After Transfemoral Transcatheter or Surgical Aortic Valve Replacement

Results From the Italian OBSERVANT Study



Logistic EuroSCORE 2, 5.1%



Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis

Vinod H Thourani, Susheel Kodali, Raj R Makkar, Howard C Herrmann, Mathew Williams, Vasilis Babaliaros, Richard Smalling, Scott Lim, S Chris Malaisrie, Samir Kapadia, Wilson Y Szeto, Kevin L Greason, Dean Kereiakes, Gorav Ailawadi, Brian K Whisenant, Chandan Devireddy, Jonathon Leipsic, Rebecca T Hahn, Philippe Pibarot, Neil J Weissman, Wael A Jaber, David J Cohen, Rakesh Suri, E Murat Tuzcu, Lars G Svensson, John G Webb, Jeffrey W Moses, Michael J Mack, D Craig Miller, Craig R Smith, Maria C Alu, Rupa Parvataneni, Ralph B D'Agostino Jr, Martin B Leon

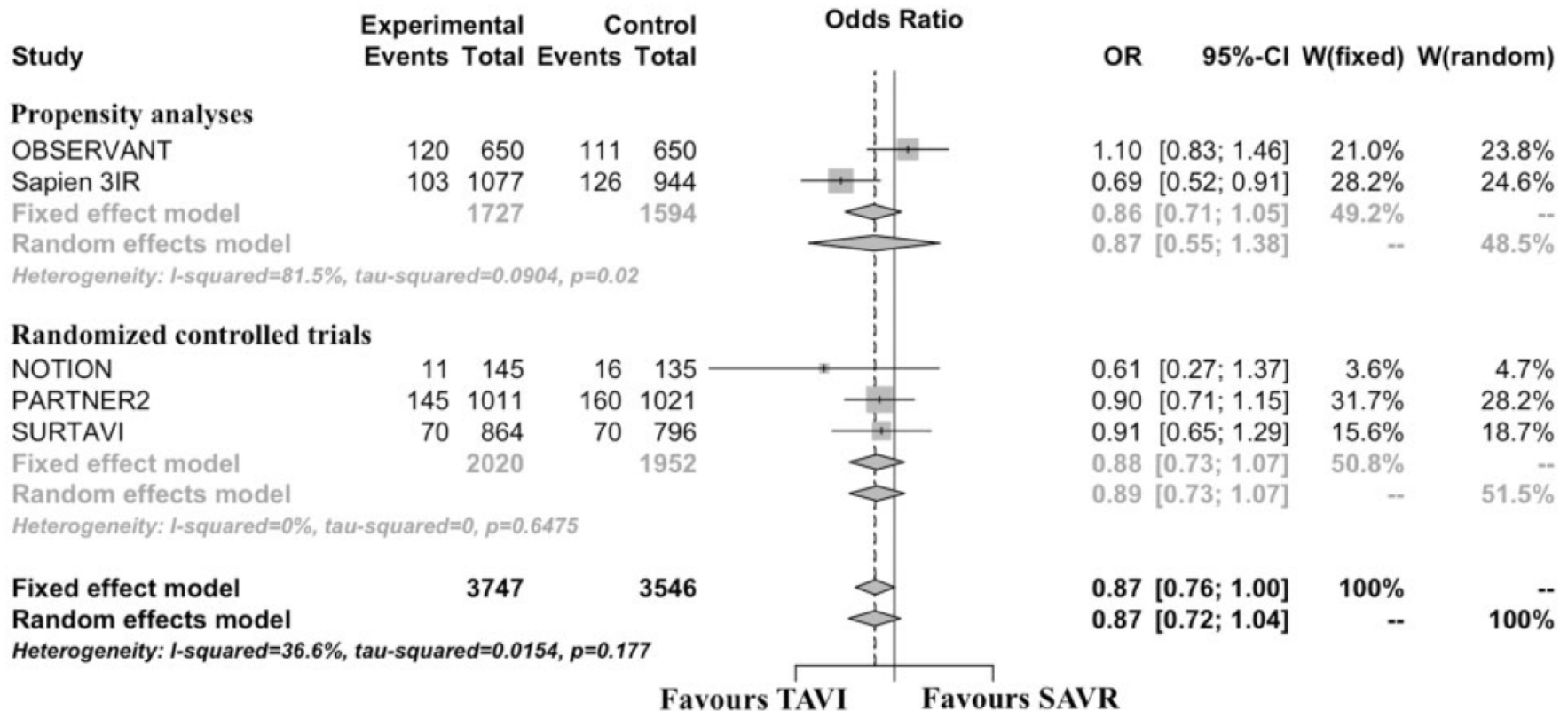
STS 5.3%

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Composite endpoint of all-cause mortality and stroke at 1-year



Tarantini et al, European Heart Journal (2018) 39, 658–666

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On-going randomized TAVI vs. SAVR trials in low-risk patients

	DEDICATE	NOTION 2	PARTNER 3	CoreValve low risk
Reference/NCT number	Clinicaltrials.gov/NCT03112980	Clinicaltrials.gov/NCT02825134	Clinicaltrials.gov/NCT02675114	Clinicaltrials.gov/NCT02701283
Study start date	2017	2016	2016	2016
Study status	Recruiting	Recruiting	Recruiting	Recruiting
Estimated study completion date	2024	2024	2027	2026
Patients' risk profile	STS-PROM 2-6%	Patient age ≤ 75 years and STS-PROM $< 4\%$	STS-PROM $< 4\%$	Operative risk $< 3\%$
Study arms	TAVI* vs. SAVR* (1:1 randomization)	TAVI* vs. SAVR* (1:1 randomization)	TAVI (SAPIEN 3) vs. SAVR* (1:1 randomization)	TAVI (CoreValve Evolut R) vs. SAVR* (1:1 randomization)
Estimated enrollment	1,600	992	1,328	1,200
Primary Outcome	- Efficacy endpoint: Overall survival at 5 years - Safety endpoint: Overall survival at 1 year and 196 deaths (event-driven)	All-cause mortality, myocardial infarction or stroke at 1 year	All-cause mortality, stroke, or re-hospitalization at 1 year	All-cause mortality or disabling stroke at 2 years
Follow up time	5 years	1 year	10 years	10 years

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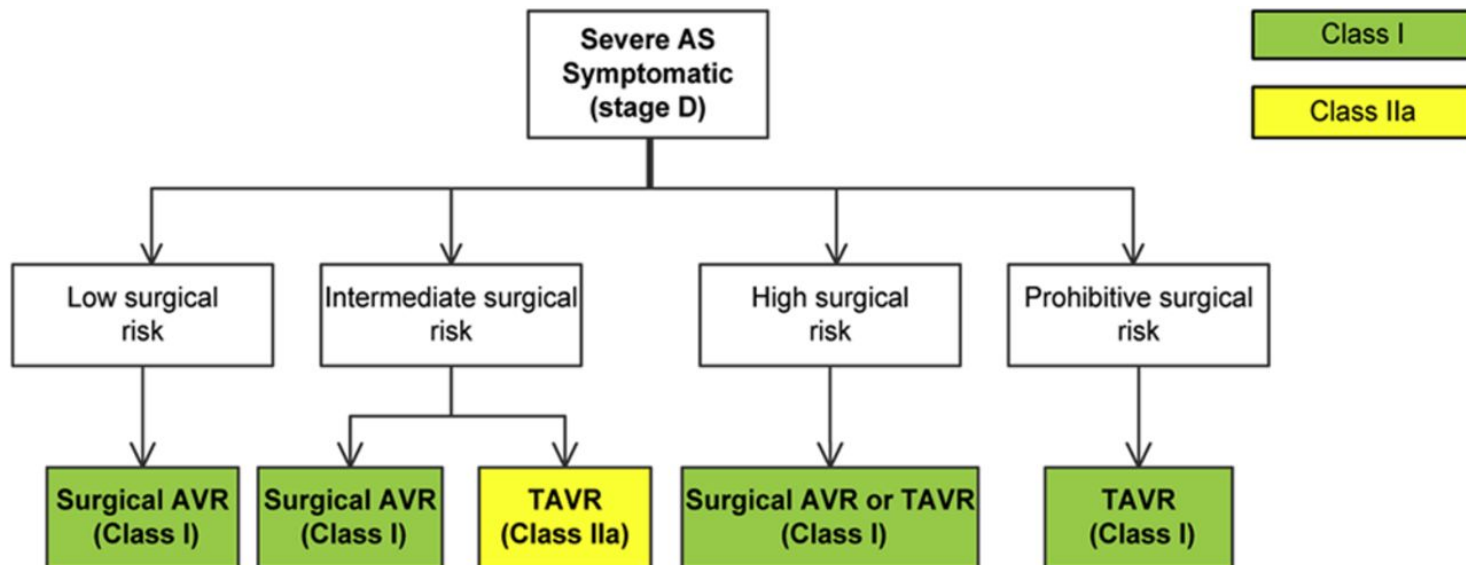
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AHA/ACC GUIDELINE

2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease

A Report of the American College of Cardiology/American Heart Association
Task Force on Clinical Practice Guidelines



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ESC

European Society
of Cardiology

European Heart Journal (2017) **38**, 2739–2791
doi:10.1093/eurheartj/ehx391

ESC/EACTS

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

TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team. ^{91,94}	I	B
In patients who are at increased surgical risk (STS or EuroSCORE II $\geq 4\%$ or logistic EuroSCORE I $\geq 10\%^d$ or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics (see <i>Table 7</i>), with TAVI being favoured in elderly patients suitable for transfemoral access. ^{91,94–102}	I	B

	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		+

	Favours TAVI	Favours SAVR
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		+

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REMAINING CHALLENGES

**Minimize Procedural
mortality, complications
and Stroke**

Paravalvular insufficiency

Valve durability

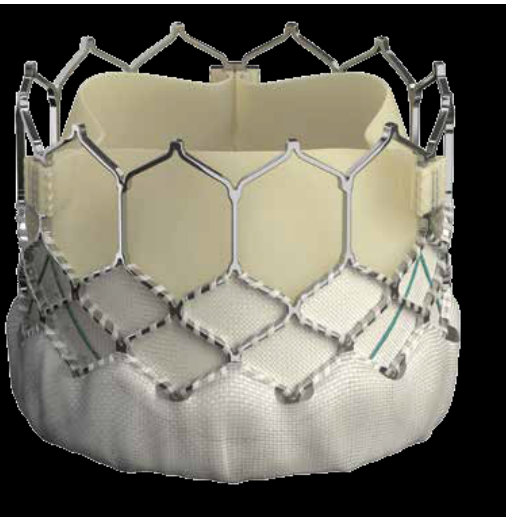


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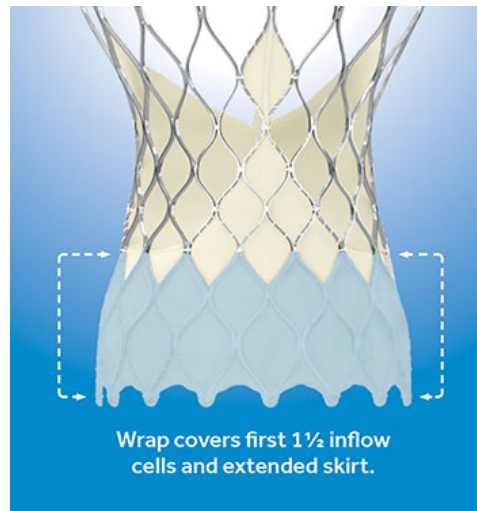
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Edwards Sapien 3



EVOLUTE Pro



**Symetis
Acurate NEO**



Lotus





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Thanks for your
attention

Minimize Procedural
mortality, complications
and Stroke

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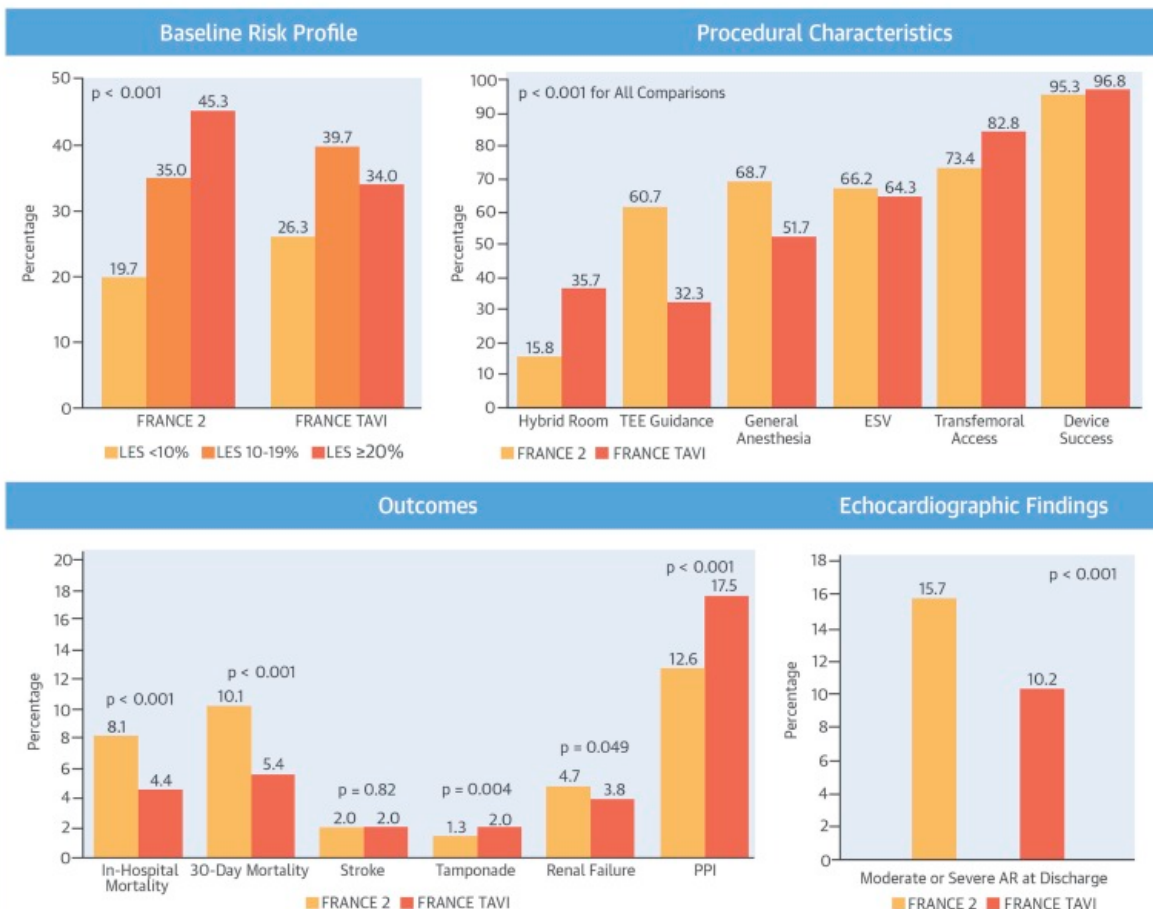
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FRANCE 2
2010-2012
4165 patients
34 Centeres

FRANCE-TAVI
2013-2015
12804 patients
48 Centeres

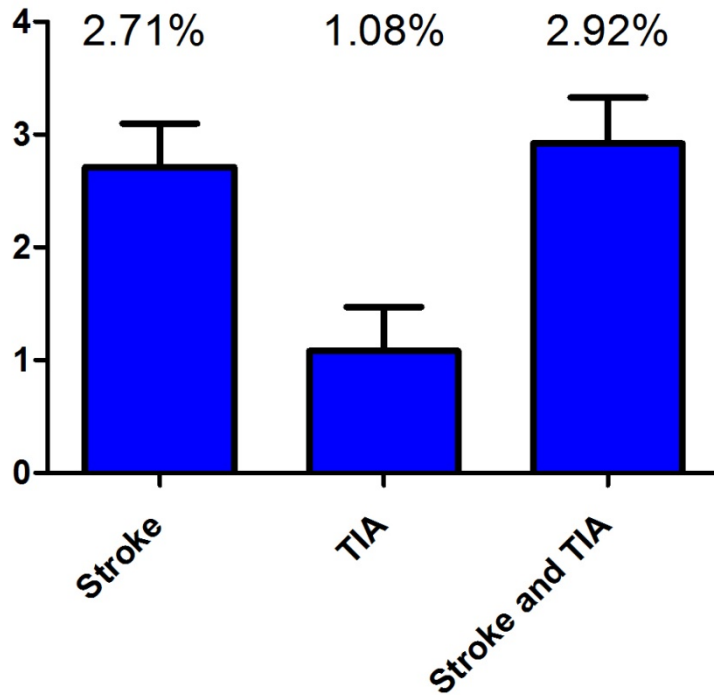
CENTRAL ILLUSTRATION: Temporal Trends in TAVR in France



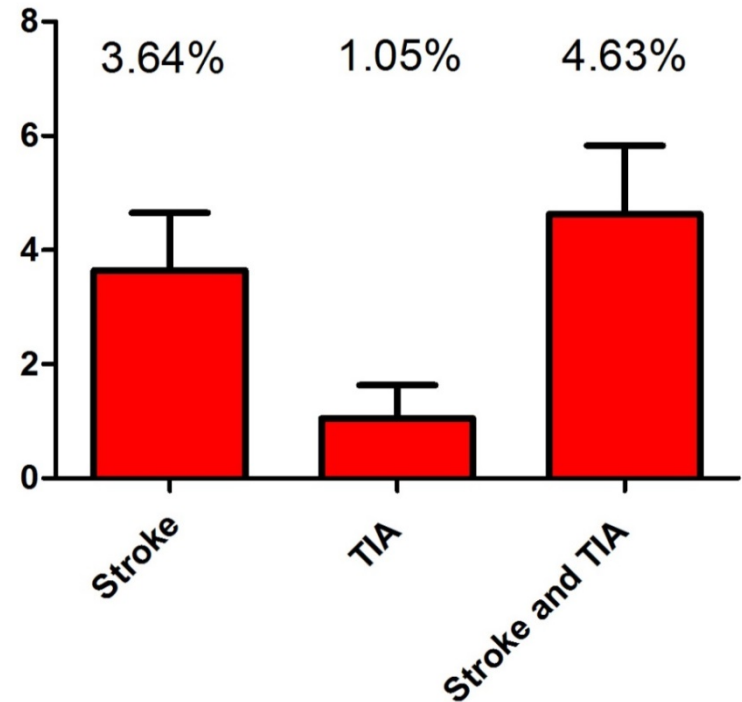
Auffret, V. et al. J Am Coll Cardiol. 2017;70(1):42-55.

Incidence and predictors of stroke at 30 days and at follow up after TAVI: a meta-analysis of 58 studies and 36775 patients.

A



B



(A) Incidence of stroke, of TIA and of stroke or TIA at 30 days.

(B) Incidence of stroke, of TIA and of stroke or TIA after a follow up of 14 (11-17) months. At 14 months rate of TIA was of 1.40% after including only studies with 30 days TIA.

Minimize Procedural
mortality, complications
and Stroke

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PARTNER II/SURTAVI 30-day Stroke

- Any stroke:
 - PARTNER II: TAVR 5.5%; SAVR 6.1% ($p=0.57$)
 - SURTAVI: TAVR: 3.4%; SAVR 5.6%
- Disabling stroke:
 - PARTNER II: TAVR 3.3%; SAVR 4.2% ($p=0.2$)
 - SURTAVI: TAVR 1.2%; SAVR: 2.5%

Paravalvular insufficiency

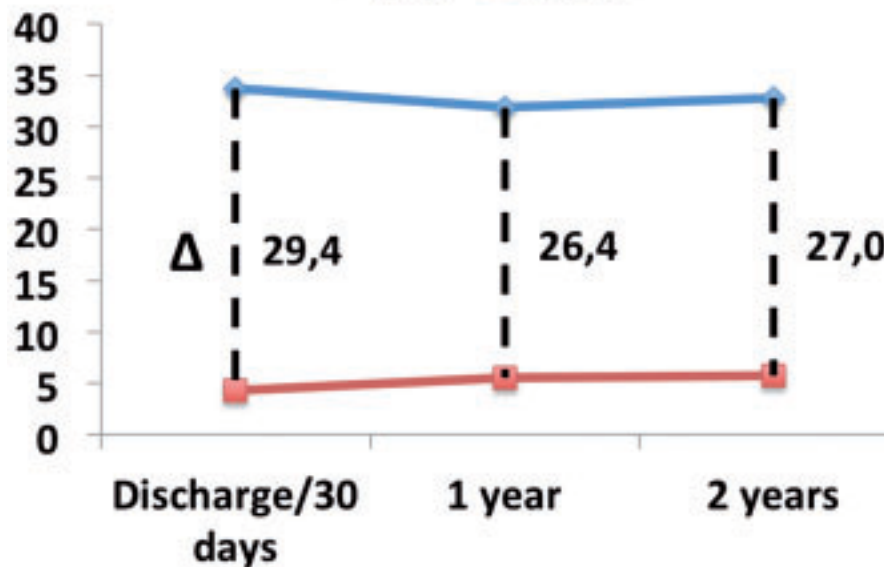
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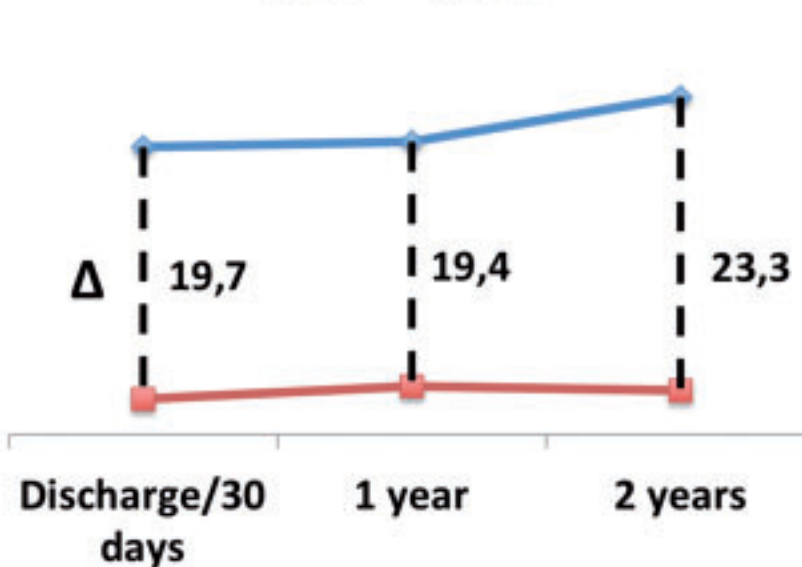
SURTAVI

— TAVI — SAVR



PARTNER 2

— TAVI — SAVR

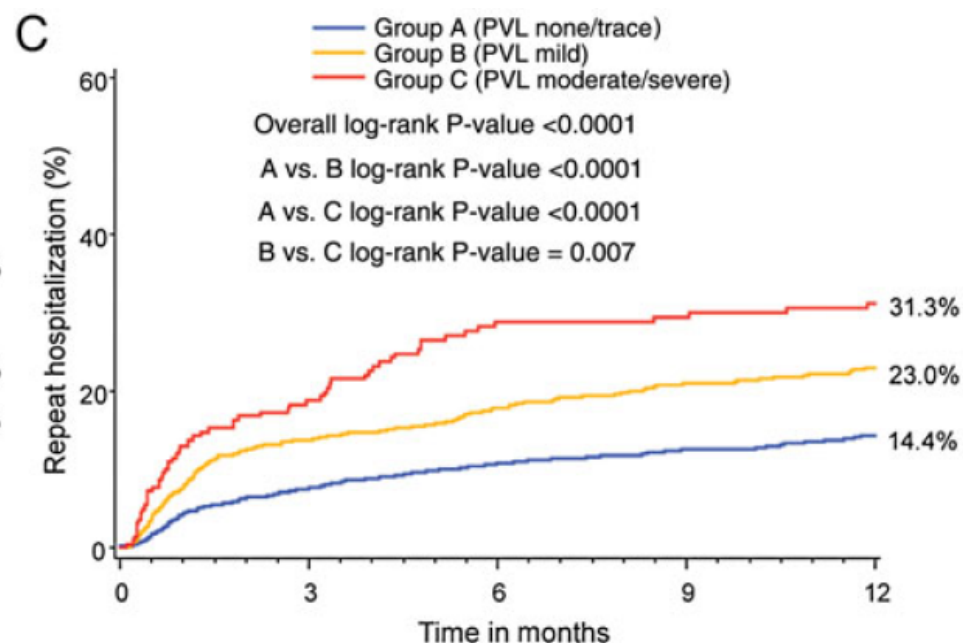
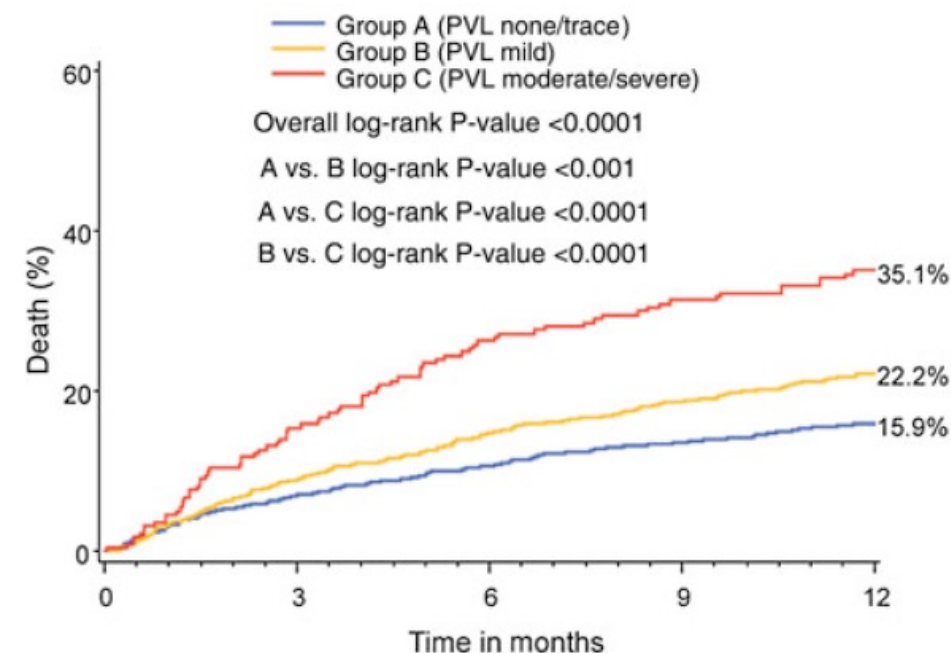




European Heart Journal (2015) 36, 449–456
 doi:10.1093/eurheartj/ehu384

CLINICAL RESEARCH
 Valvular heart disease

Paravalvular regurgitation after transcatheter aortic valve replacement with the Edwards sapien valve in the PARTNER trial: characterizing patients and impact on outcomes





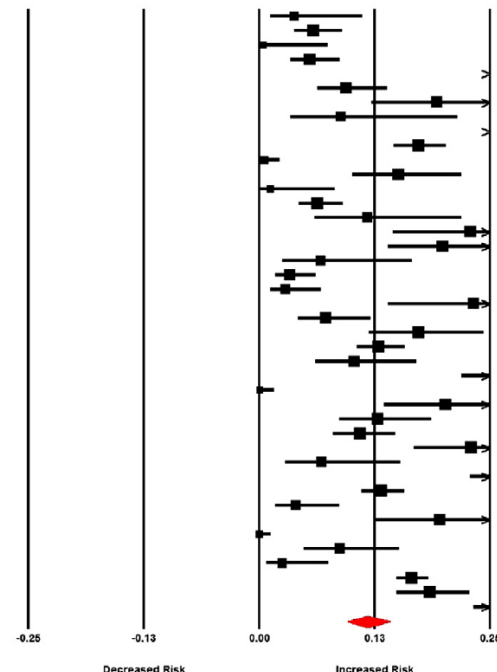
Incidence, Predictors, and Outcomes of Aortic Regurgitation After Transcatheter Aortic Valve Replacement

Meta-Analysis and Systematic Review of Literature

*The pooled estimate for
overall incidence of moderate
or severe AR was **11.7%**
95% [CI]: 9.6 to 14.1*

Study name	Statistics for each study				
	Event rate	Lower limit	Upper limit	Z-Value	Total
Lemos	0.038	0.012	0.111	-5.491	3 / 79
Cabau	0.059	0.038	0.090	-12.014	20 / 339
Bagur	0.006	0.000	0.074	-3.741	0 / 100
Gurwitsch	0.055	0.034	0.086	-11.412	17 / 310
Lefe'vre	0.469	0.385	0.555	-0.701	61 / 130
Elchaninoff	0.094	0.063	0.138	-10.327	23 / 244
Atlas	0.193	0.122	0.292	-5.147	16 / 83
Tchetché	0.089	0.034	0.214	-4.443	4 / 45
Hayashida	0.306	0.255	0.366	-6.035	80 / 260
Wahab	0.172	0.146	0.202	-15.553	119 / 590
Unbehauen	0.006	0.001	0.022	-7.308	2 / 358
Sinning	0.151	0.101	0.218	-7.475	22 / 146
Conradi	0.012	0.002	0.081	-4.368	1 / 82
Lange	0.063	0.043	0.090	-13.356	26 / 415
Leber	0.118	0.080	0.218	-5.353	8 / 68
Chorianopoulos	0.229	0.145	0.341	-4.273	16 / 70
Grube	0.199	0.140	0.274	-8.492	27 / 138
Grube E	0.067	0.025	0.165	-5.099	4 / 60
Walther	0.033	0.018	0.081	-10.458	10 / 299
Stöhr	0.029	0.012	0.067	-7.772	5 / 175
Sherif	0.232	0.140	0.360	-3.779	13 / 56
Puls	0.072	0.042	0.120	-8.866	13 / 180
Gotzmann	0.172	0.119	0.243	-7.135	25 / 145
Tamburino	0.130	0.106	0.158	-16.468	86 / 663
Amabile	0.103	0.061	0.170	-7.384	13 / 126
Buchanan	0.266	0.219	0.318	-7.846	81 / 305
D'Onofrio	0.001	0.000	0.016	-4.888	0 / 504
Ewe	0.202	0.138	0.290	-5.626	21 / 104
Makkar	0.128	0.087	0.188	-8.571	23 / 179
Kodali	0.109	0.090	0.147	-12.212	38 / 348
Garcia	0.229	0.166	0.305	-6.118	33 / 144
Goncalves	0.068	0.028	0.152	-5.667	5 / 74
VVenaweser	0.280	0.229	0.338	-6.794	72 / 257
Moat	0.132	0.111	0.156	-18.799	115 / 870
Dworakowski	0.040	0.018	0.086	-7.645	6 / 151
Jabbour	0.195	0.125	0.292	-5.234	17 / 87
Piazza	0.001	0.000	0.012	-5.064	0 / 646
Buellesfeld	0.087	0.049	0.151	-7.437	11 / 126
Wendler	0.025	0.008	0.075	-5.266	3 / 120
Girard	0.165	0.149	0.182	-26.337	316 / 1915
Fracaro	0.185	0.149	0.227	-11.286	71 / 394
REVIVAL	0.345	0.232	0.479	-2.254	19 / 55
All	0.117	0.096	0.141	-18.217	1,445/11,528

Event rate and 95% CI



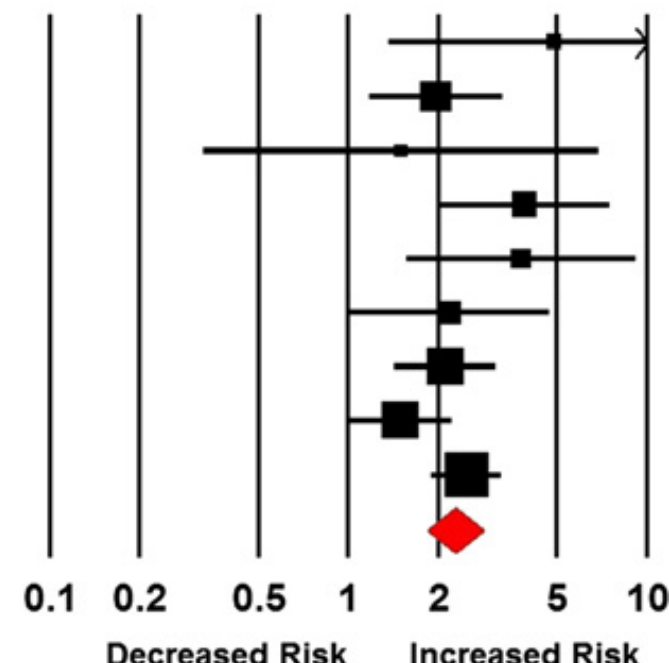


Study name

Statistics for each study

Hazard ratio and 95% CI

	Hazard ratio	Lower limit	Upper limit	Z-Value	p-Value
Lemos*	4.900	1.367	17.570	2.439	0.015
Hayashida	1.970	1.187	3.271	2.621	0.009
Amabile	1.500	0.329	6.829	0.524	0.600
Sinning	3.890	2.020	7.491	4.063	0.000
Tamburino	3.785	1.572	9.112	2.969	0.003
Fraccaro	2.190	1.023	4.686	2.020	0.043
Kodali	2.110	1.433	3.107	3.783	0.000
Moat	1.490	1.002	2.215	1.971	0.049
Gilard	2.490	1.909	3.248	6.728	0.000
All (N=4791)	2.273	1.840	2.808	7.609	0.000



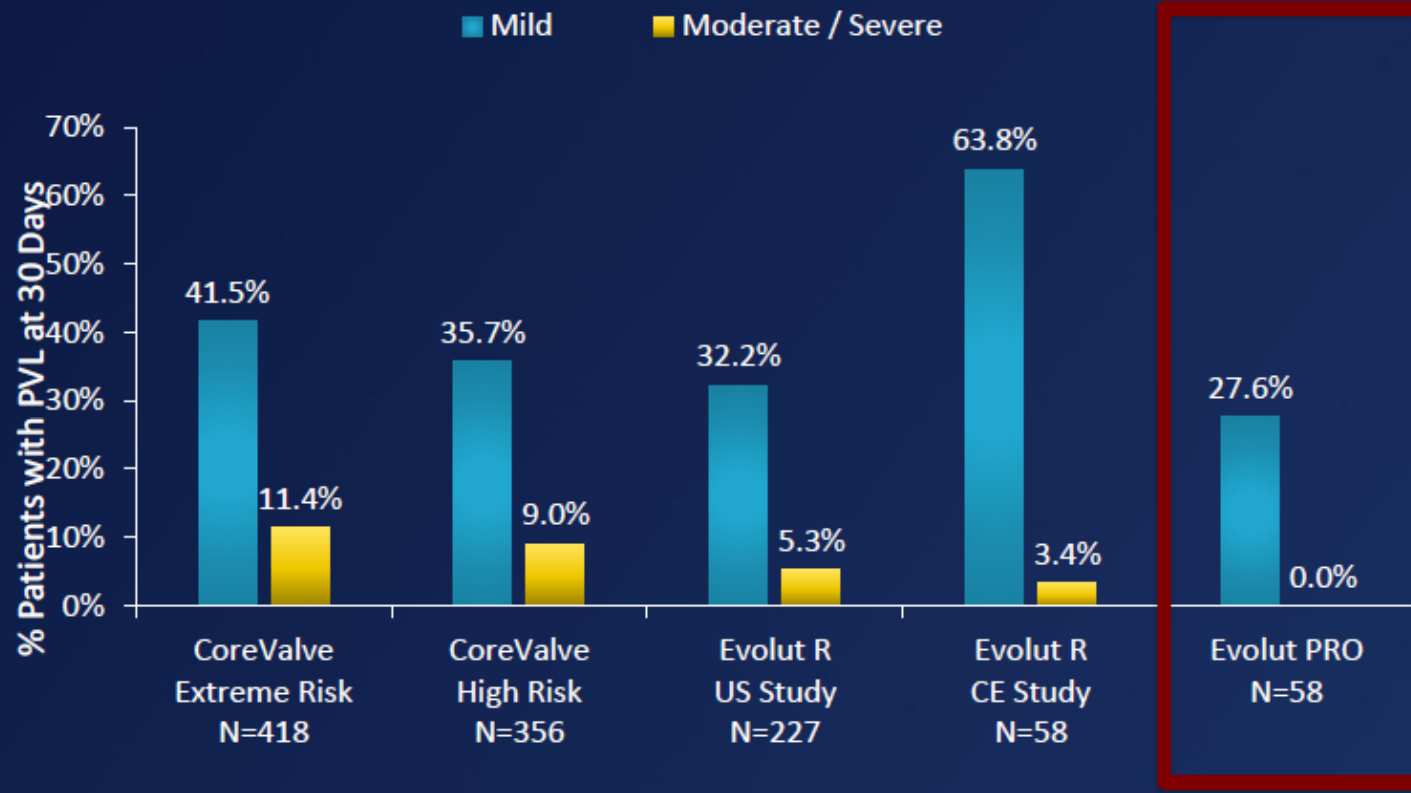
The overall 1-year mortality was unfavorable in patients with moderate or severe AR with an HR of 2.27 (95% CI: 1.84 to 2.81, p 0.001)

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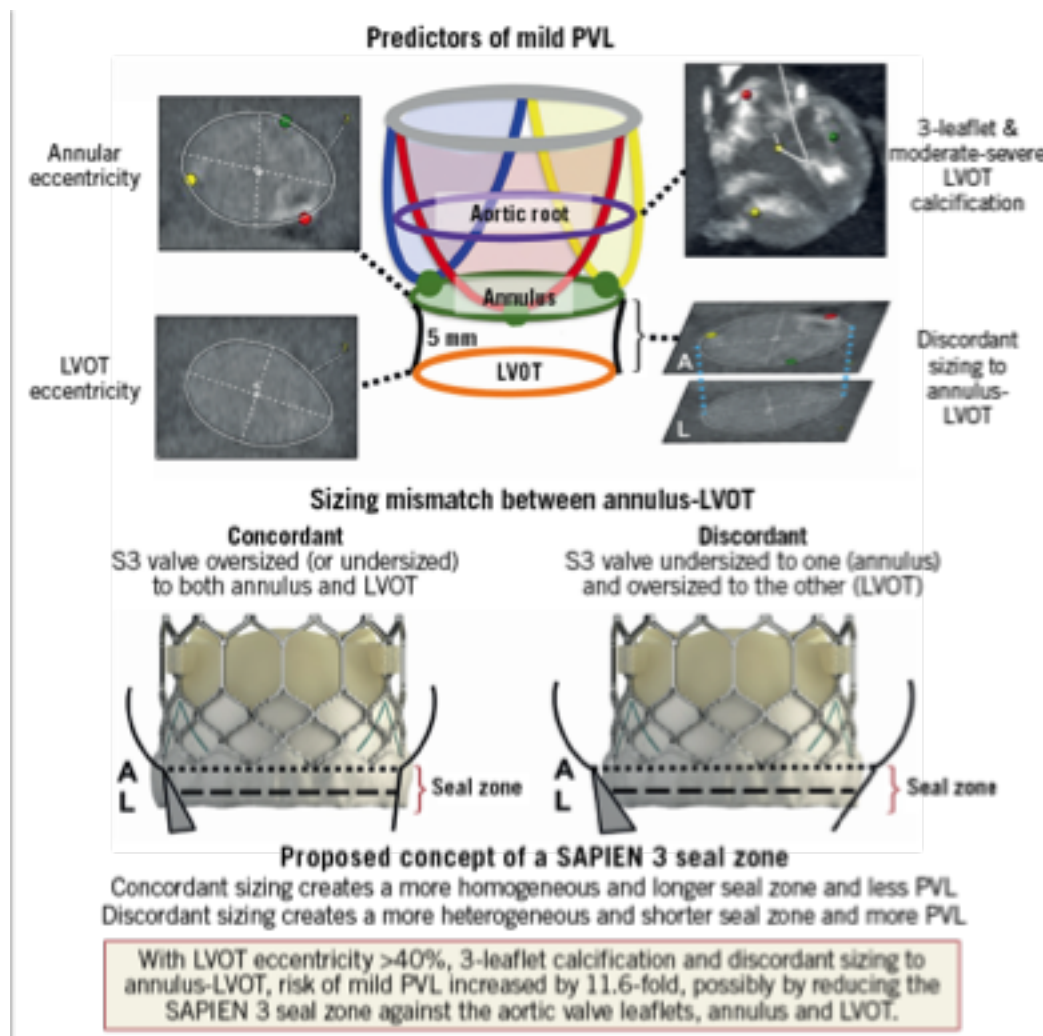
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Paravalvular Leak Rates at 30 Days



1Adams, et al., *N Engl J Med* 2014; 370: 1790-8; 2Manoharan, et al., *J Am Coll Cardiol Interv* 2015; 8: 1359-67; 3Popma et al., *JACC Cardiovasc Interv.* 2017 Feb 13;10(3):268-275; 4Popma et al., *J Am Coll Cardiol.* 2014 May 20;63(19):1972-81; 5Forrest et al., Presented at TCT 2017



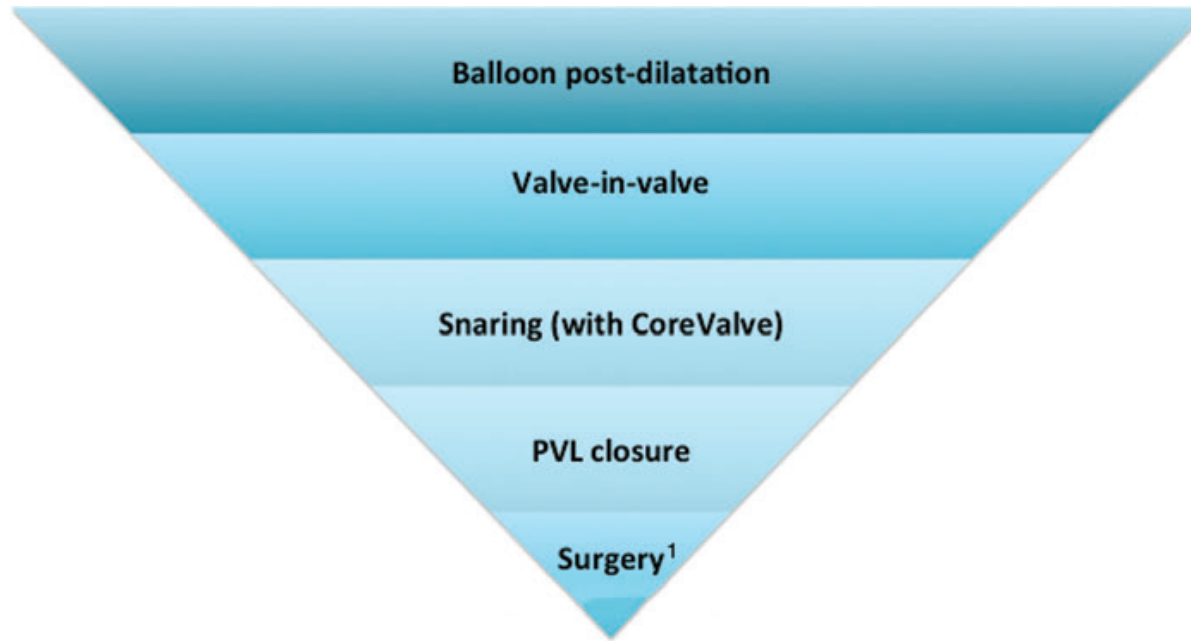
Paravalvular insufficiency

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Treatment options for significant AR after TAVI

Valve durability

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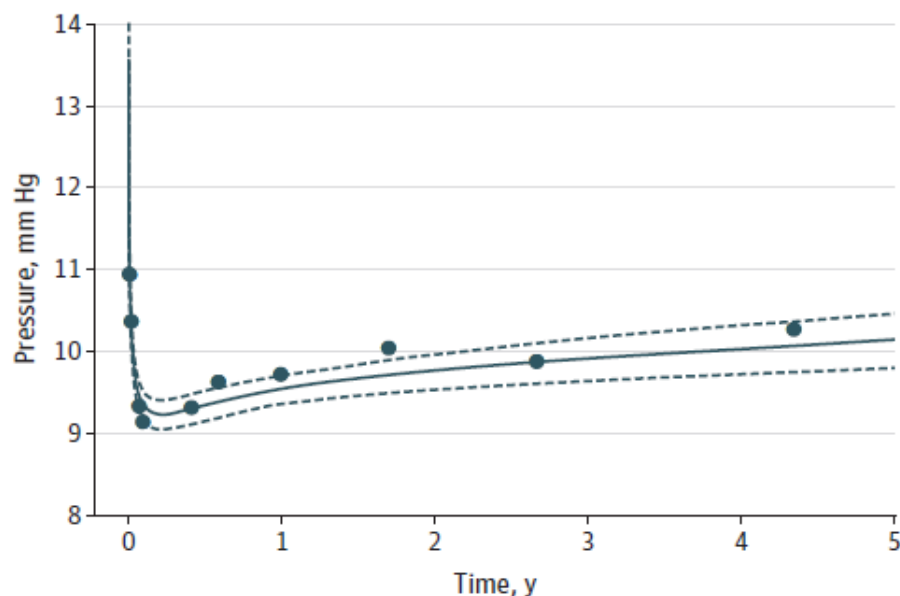
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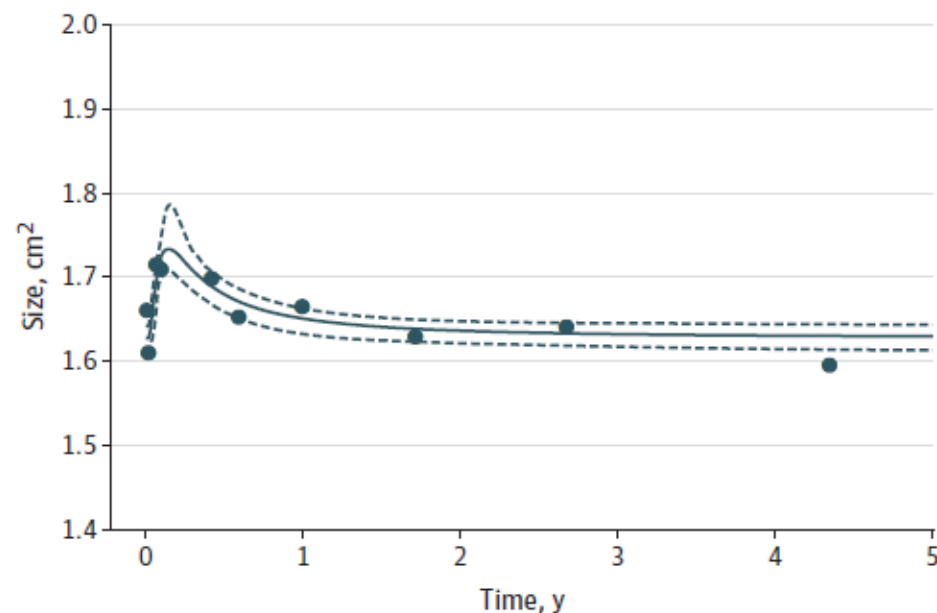
JAMA Cardiology | Original Investigation

Longitudinal Hemodynamics of Transcatheter and Surgical Aortic Valves in the PARTNER Trial

A Aortic valve mean gradient



B Effective orifice area



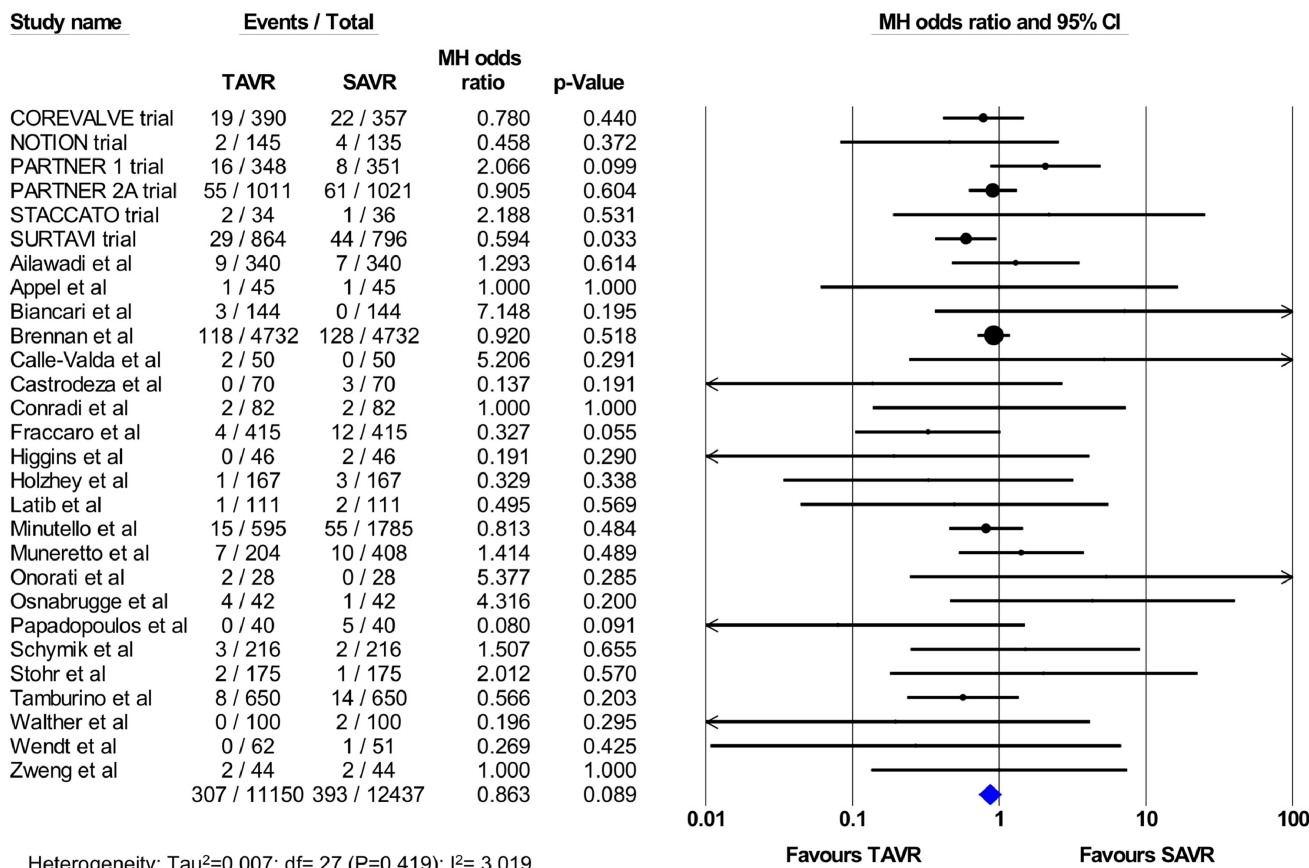
Valve durability

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Meta-Analysis Comparing the Frequency of Stroke After Transcatheter Versus Surgical Aortic Valve Replacement



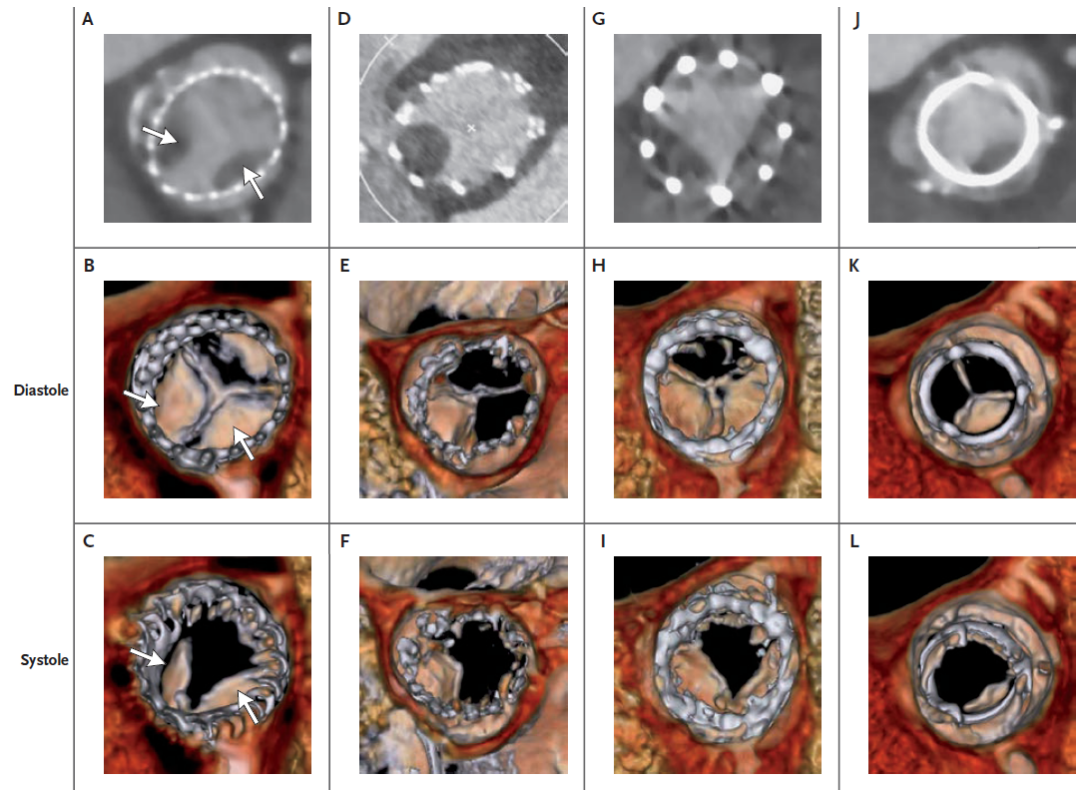
Valve durability

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Possible Subclinical Leaflet Thrombosis in Bioprosthetic Aortic Valves



Subclinical leaflet thrombosis in surgical and transcatheter bioprosthetic aortic valves: an observational study



Tarun Chakravarty, Lars Søndergaard, John Friedman, Ole De Backer, Daniel Berman, Klaus F Kofoed, Hasan Jilaihawi, Takahiro Shiota, Yigal Abramowitz, Troels H Jørgensen, Tanya Rami, Sharjeel Israr, Gregory Fontana, Martina de Knecht, Andreas Fuchs, Patrick Lyden, Alfredo Trento, Deepak L Bhatt, Martin B Leon, Raj R Makkar, on behalf of the RESOLVE and SAVORY Investigators*

	Normal leaflet motion (n=784)	Reduced leaflet motion (n=106)	p value
Age (years)	78.9 (9.0)	82.0 (8.7)	0.0009
Male sex	437 (56%)	64 (60%)	0.37
Medical condition			
Chronic kidney disease	74/727 (10%)	14/98 (14%)	0.22
Haemodialysis	8/689 (1%)	1/97 (1%)	>0.99
Hypercoagulable disorder	9/642 (1%)	0/85	0.61
Hypertension	679/783 (87%)	88 (83%)	0.30
Previous stroke	63/782 (8%)	9 (8%)	0.88
Previous transient ischaemic attack	36/782 (5%)	6 (6%)	0.63
Hyperlipidaemia	599/782 (77%)	78 (74%)	0.49
Diabetes	193/783 (25%)	22 (21%)	0.38
PCI within 3 months before AVR	84/779 (11%)	13/104 (13%)	0.60
Congestive heart failure	588/781 (75%)	84 (79%)	0.37
Syncope	47/777 (6%)	3/105 (3%)	0.26
Atrial fibrillation	233/780 (30%)	17 (16%)	0.003
Baseline echocardiogram			
Ejection fraction (%)	57.9 (12.6)	55.5 (13.2)	0.07
Mean aortic valve gradient (mm Hg)	44.2 (13.8)	44.6 (16.1)	0.83
Peak aortic valve gradient (mm Hg)	74.2 (22.1)	73.6 (26.2)	0.79
Dimensionless index	0.23 (0.09)	0.22 (0.07)	0.27

Frequency of reduced leaflet motion (n=106)	
Transcatheter valves	101/752 (13%)
Edwards	63/453 (14%)
Edwards-Sapien	1/22 (5%)
Sapien XT	12/122 (10%)
Sapien 3	50/309 (16%)
Evolut or CoreValve	9/145 (6%)
CoreValve	3/70 (4%)
Evolut	6/75 (8%)
Lotus	12/83 (14%)
Portico	15/50 (30%)
Direct flow	0/6
Centera	1/7 (14%)
Symetis	1/8 (13%)
Surgical valves	5/138 (4%)
Epic	0/16
Freestyle	0/2
Magna	4/37 (11%)
Mitroflow	0/11
Perimount	1/39 (3%)
Trifecta	0/33

Data are n (%). The p value for transcatheter versus surgical valves is 0.001.

Valve durability

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	Normal leaflet motion (n=784)	Reduced leaflet motion (n=106)	p value
Post-AVR			
Ejection fraction (%)	60.4 (13.5)	58.5 (13.1)	0.14
Mean aortic valve gradient (mm Hg)	10.9 (5.7)	9.8 (4.0)	0.20
Peak aortic valve gradient (mm Hg)	20.1 (9.6)	18.6 (7.3)	0.36
VTI ratio	0.57 (0.20)	0.56 (0.21)	0.21
At the time of the CT scan			
Ejection fraction (%)	59.3 (10.8)	56.4 (11.9)	0.03
Mean aortic valve gradient (mm Hg)	10.4 (6.3)	13.8 (10.0)	0.0004
Peak aortic valve gradient (mm Hg)	19.9 (10.4)	25.3 (15.5)	0.001
VTI ratio	0.52 (0.16)	0.43 (0.17)	<0.0001
Aortic valve gradient			
>20 mm Hg	40/714 (6%)	15/96 (16%)	0.0002
>30 mm Hg	13/714 (2%)	6/96 (6%)	0.007
>40 mm Hg	5/714 (1%)	4/96 (4%)	0.02
Change in aortic valve gradient			
>10 mm Hg	9/632 (1%)	13/88 (15%)	<0.0001
>20 mm Hg	5/632 (1%)	5/88 (6%)	0.004
>30 mm Hg	2/632 (<1%)	3/88 (3%)	0.02
Aortic valve gradient >20 mm Hg and increase in gradient >10 mm Hg	7/632 (1%)	12/88 (14%)	<0.0001
Absolute change in aortic valve gradient	-0.25 (5.0)	4.3 (9.2)	<0.0001
Relative change in aortic valve gradient	0.06 (0.61)	0.50 (0.89)	<0.0001
Absolute change in VTI ratio	-0.06 (0.22)	-0.14 (0.20)	0.001
Relative change in VTI ratio	-0.04 (0.38)	-0.21 (0.26)	0.0001

Valve durability

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	Normal leaflet motion	Reduced leaflet motion	p value
Anticoagulation vs no anticoagulation	n=784	n=106	<0.0001
Anticoagulation	216 (28%)	8 (8%)	..
No anticoagulation	568 (72%)	98 (92%)	..
Anticoagulation vs DAPT	n=393	n=39	<0.0001
Anticoagulation	216 (55%)	8 (21%)	..
DAPT	177 (45%)	31 (79%)	..
Anticoagulation vs monoantiplatelet therapy	n=558	n=71	<0.0001
Anticoagulation	216 (39%)	8 (11%)	..
Monoantiplatelet therapy	342 (61%)	63 (89%)	..
Aspirin vs ADP antagonists	n=342	n=63	0.85
Aspirin	312 (91%)	57 (90%)	..
ADP antagonists	30 (9%)	6 (10%)	..
Warfarin vs no anticoagulation	n=680	n=103	0.001
Warfarin	112 (16%)	5 (5%)	..
No anticoagulation	568 (84%)	98 (95%)	..
NOACs vs no anticoagulation	n=672	n=101	0.0002
NOACs	104 (15%)	3 (3%)	..
No anticoagulation	568 (85%)	98 (97%)	..
Monoantiplatelet vs DAPT	n=519	n=94	0.83
Monoantiplatelet therapy	342 (66%)	63 (67%)	..
DAPT	177 (34%)	31 (33%)	..

Valve durability

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	Normal leaflet motion (n=784)		Reduced leaflet motion (n=106)		Hazard ratio (95% CI)	p value
	Number of patients	Rate per 100 person-years	Number of patients	Rate per 100 person-years		
All events						
Death	34 (4%)	2.91	4 (4%)	2.66	0.96 (0.34-2.72)	0.94
Myocardial infarction	4 (1%)	0.34	1 (1%)	0.67	1.91 (0.21-17.08)	0.56
Stroke or TIA	27 (3%)	2.36	11 (10%)	7.85	3.27 (1.62-6.59)	0.001
All stroke*	22 (3%)	1.92	6 (6%)	4.12	2.13 (0.86-5.25)	0.10
Ischaemic stroke	21 (3%)	1.83	6 (6%)	4.12	2.23 (0.90-5.53)	0.08
TIA	7 (1%)	0.60	6 (6%)	4.18	7.02 (2.35-20.91)	0.0005
Non-procedural events						
Death	34 (4%)	2.91	4 (4%)	2.66	0.96 (0.34-2.72)	0.94
Myocardial infarction	4 (1%)	0.34	1 (1%)	0.67	1.91 (0.21-17.08)	0.56
Stroke or TIA	20 (3%)	1.75	8 (8%)	5.71	3.30 (1.45-7.50)	0.004
All stroke*	15 (2%)	1.31	4 (4%)	2.75	2.14 (0.71-6.44)	0.18
Ischaemic stroke	14 (2%)	1.22	4 (4%)	2.75	2.29 (0.75-6.97)	0.14
TIA	7 (1%)	0.60	5 (5%)	3.48	5.89 (1.87-18.60)	0.002
Post-CT events						
Death	34/774 (4%)	5.08	4/105 (4%)	4.61	0.92 (0.33-2.60)	0.88
Myocardial infarction	2/772 (<1%)	0.30	0/104	NA	NA	NA
Post-CT stroke or TIA	10/757 (1%)	1.53	4/98 (4%)	5.15	3.45 (1.08-11.03)	0.04
All stroke*	7/759 (1%)	1.06	2/101 (2%)	2.42	2.41 (0.50-11.61)	0.27
Ischaemic stroke	6/759 (1%)	0.91	2/101 (2%)	2.42	2.81 (0.57-13.92)	0.21
TIA*	5/772 (1%)	0.75	3/102 (3%)	3.73	5.02 (1.20-21.10)	0.03



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