

9^a REUNIÃO VAP-APIC

Hotel Vip Executive Art's
Parque das Nações | Lisboa

30 | 31 JANEIRO 2020

To be or not to be an operator - Who should perform TAVI?

Round table: Key questions in TAVI in 2020

Pedro Carrilho Ferreira

Joaquim Oliveira Interventional Cardiology Unit

Department of Cardiology, Santa Maria University Hospital, CHULN

Lisbon School of Medicine, Lisbon University

Lisbon Academic Medical Center

TO BE OR NOT TO BE AN OPERATOR

- Conflict of interest:
 - Nothing to declare

Pedro Carrilho Ferreira, Santa Maria University Hospital, Lisboa, Portugal

9^a REUNIÃO
VAP-APIC

Hotel Vip Executive Art's
Parque das Nações | Lisboa
30 | 31 JANEIRO 2020

apic ASSOCIAÇÃO PORTUGUESA
DE INTERVENÇÃO CARDIOVASCULAR
sociedade portuguesa de cardiologia

TO BE OR NOT TO BE AN OPERATOR

- Background
- Guidelines
- Conversion to open surgery
- On-site cardiac surgery
- Volume and outcomes
- Recommendations for operator and institutional requirements



Pedro Carrilho Ferreira, Santa Maria University Hospital, Lisboa, Portugal



9^a REUNIÃO VAP-APIC

Hotel Vip Executive Art's
Parque das Nações | Lisboa

30 | 31 JANEIRO 2020

BACKGROUND

BACKGROUND

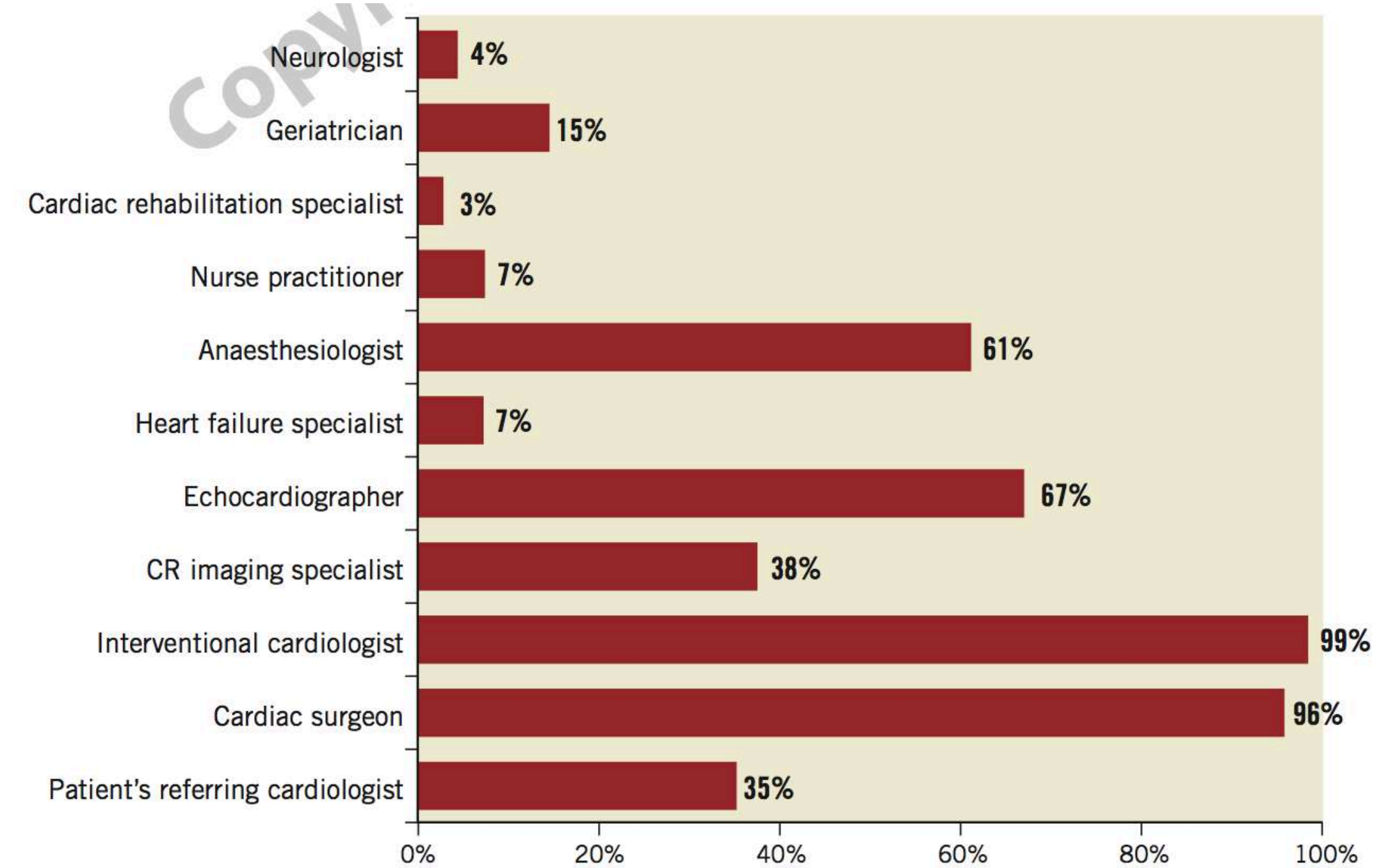
Table 1. Numbers and proportions of responding centres across European countries.

Country	(n)	%
Germany	79	26.2
Spain	45	15.0
Italy	44	14.6
United Kingdom	22	7.3
Belgium	19	6.3
France	17	5.6
Austria	11	3.7
Switzerland	7	2.3
Norway	7	2.3
Sweden	7	2.3
Poland	6	2.0
Russia	6	2.0
Greece	5	1.7
Netherlands	4	1.3
Turkey	4	1.3
Czech Republic	3	1.0
Denmark	3	1.0
Finland	3	1.0
Israel	2	0.7
Portugal	2	0.7
Andorra	1	0.3
Bosnia and Herzegovina	1	0.3
Croatia	1	0.3
Hungary	1	0.3
Ireland	1	0.3

TAVI ORGANISATION PROGRAMME

Among the 301 centres, the head of the TAVI programme was the interventional cardiologist in 174 (58%), the cardiac surgeon in 11 (4%) and both in 116 (39%). Among responding centres

Current status of transcatheter valve therapy in Europe: results from an EAPCI survey



BACKGROUND

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

2013-14

75 hospitals with CS department
22 hospitals without

Table 1 Patient demographics

	Patients undergoing TF-TAVI in hospitals without CS (n = 1332)	7.4%	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

Eggebrecht H, et al. EHJ 2016;37:2240

Pedro Carrilho Ferreira, Santa Maria University Hospital, Lisboa, Portugal



9^a REUNIÃO VAP-APIC

Hotel Vip Executive Art's
Parque das Nações | Lisboa

30 | 31 JANEIRO 2020

GUIDELINES



Indications for intervention in aortic stenosis and recommendations for the choice of intervention mode (continued)



Recommendations	Class	Level
Intervention should be considered in symptomatic patients with low-flow, low-gradient aortic stenosis and reduced ejection fraction without flow (contractile) reserve, particularly when CT calcium scoring confirms severe aortic stenosis.	IIa	C
Intervention should not be performed in patients with severe comorbidities when the intervention is unlikely to improve quality of life or survival.	III	C
b) Choice of intervention in symptomatic aortic stenosis		
Aortic valve interventions should only be performed in centres with both departments of cardiology and cardiac surgery on-site, and with structured collaboration between the two, including a Heart Team (heart valve centres).	I	C

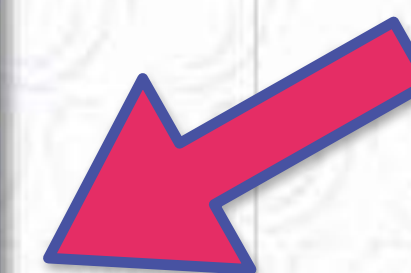


Table 5 Recommended requirements of a heart valve centre (modified from Chambers et al.³²)

Requirements
Multidisciplinary teams with competencies in valve replacement, aortic root surgery, mitral, tricuspid and aortic valve repair, as well as transcatheter aortic and mitral valve techniques including reoperations and reinterventions. The Heart Teams must meet on a regular basis and work with standard operating procedures.
Imaging, including 3D and stress echocardiographic techniques, perioperative TOE, cardiac CT, MRI, and positron emission tomography-CT.
Regular consultation with community, other hospitals, and extracardiac departments, and between non-invasive cardiologists and surgeons and interventional cardiologists.
Back-up services including other cardiologists, cardiac surgeons, intensive care and other medical specialties.
Data review: <ul style="list-style-type: none"> • Robust internal audit processes including mortality and complications, repair rates, durability of repair, and reoperation rate with a minimum of 1-year follow-up. • Results available for review internally and externally. • Participation in national or European quality databases.

©ESC 2017

GUIDELINES

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 Practice Guidelines

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



Nishimura RA, et al. JACC 2014;63:e57

Nishimura RA, et al. Circulation 2017;135:e1159

Pedro Carrilho Ferreira, Santa Maria University Hospital, Lisboa, Portugal

9^ª REUNIÃO
VaP-APIC

Hotel Vip Executive Art's
Parque das Nações | Lisboa
30 | 31 JANEIRO 2020

apic ASSOCIAÇÃO PORTUGUESA
INTERVENÇÃO CARDIOVASCULAR
sociedade portuguesa de cardiologia



9^a REUNIÃO VAP-APIC

Hotel Vip Executive Art's
Parque das Nações | Lisboa

30 | 31 JANEIRO 2020

Who Should Perform TAVI?

- Need of conversion to open surgery
- Outcomes with and without on-site cardiac surgery
- Relationship between intervention volume and outcomes



9^a
REUNIÃO
VaP-APIC

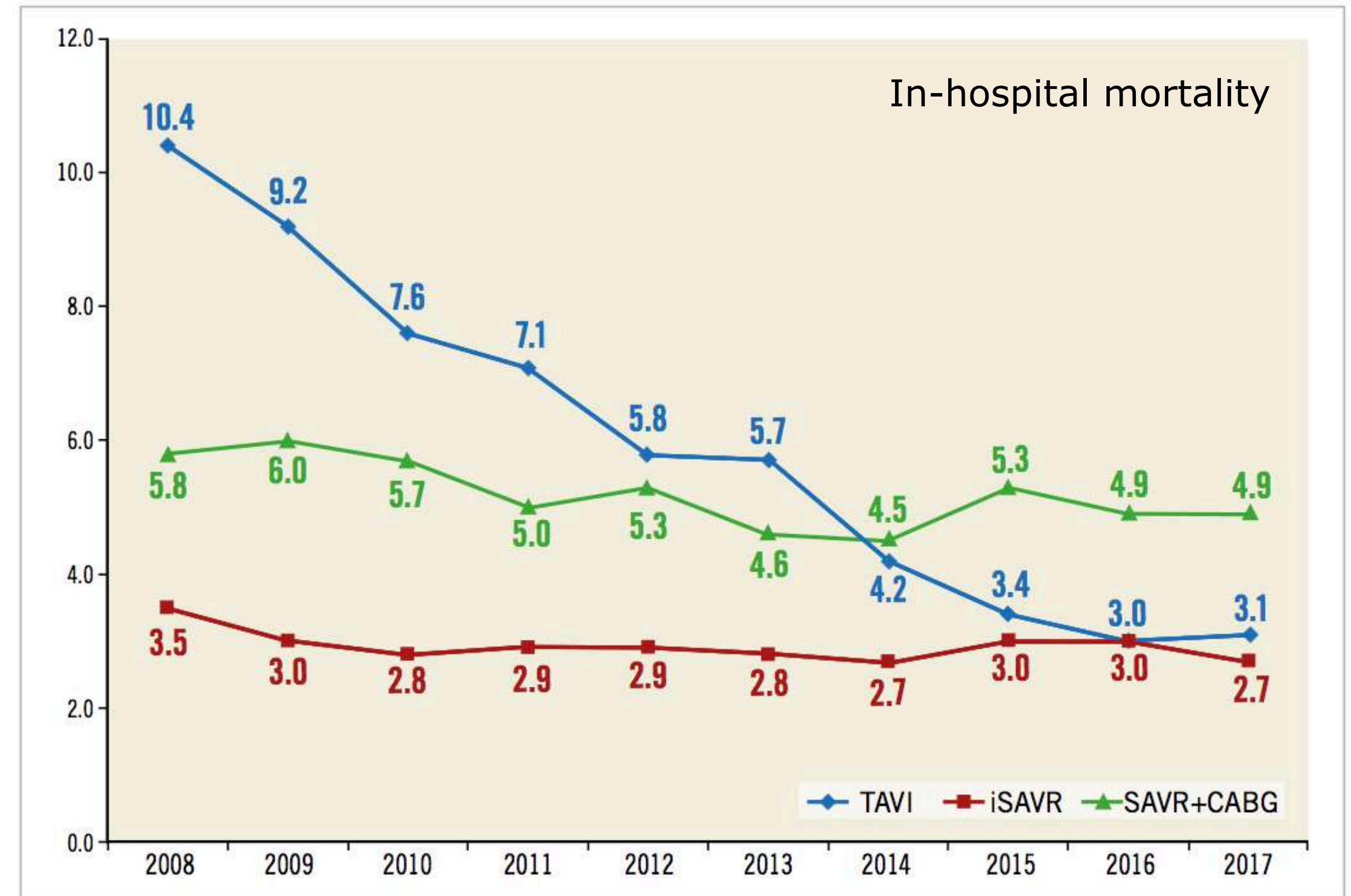
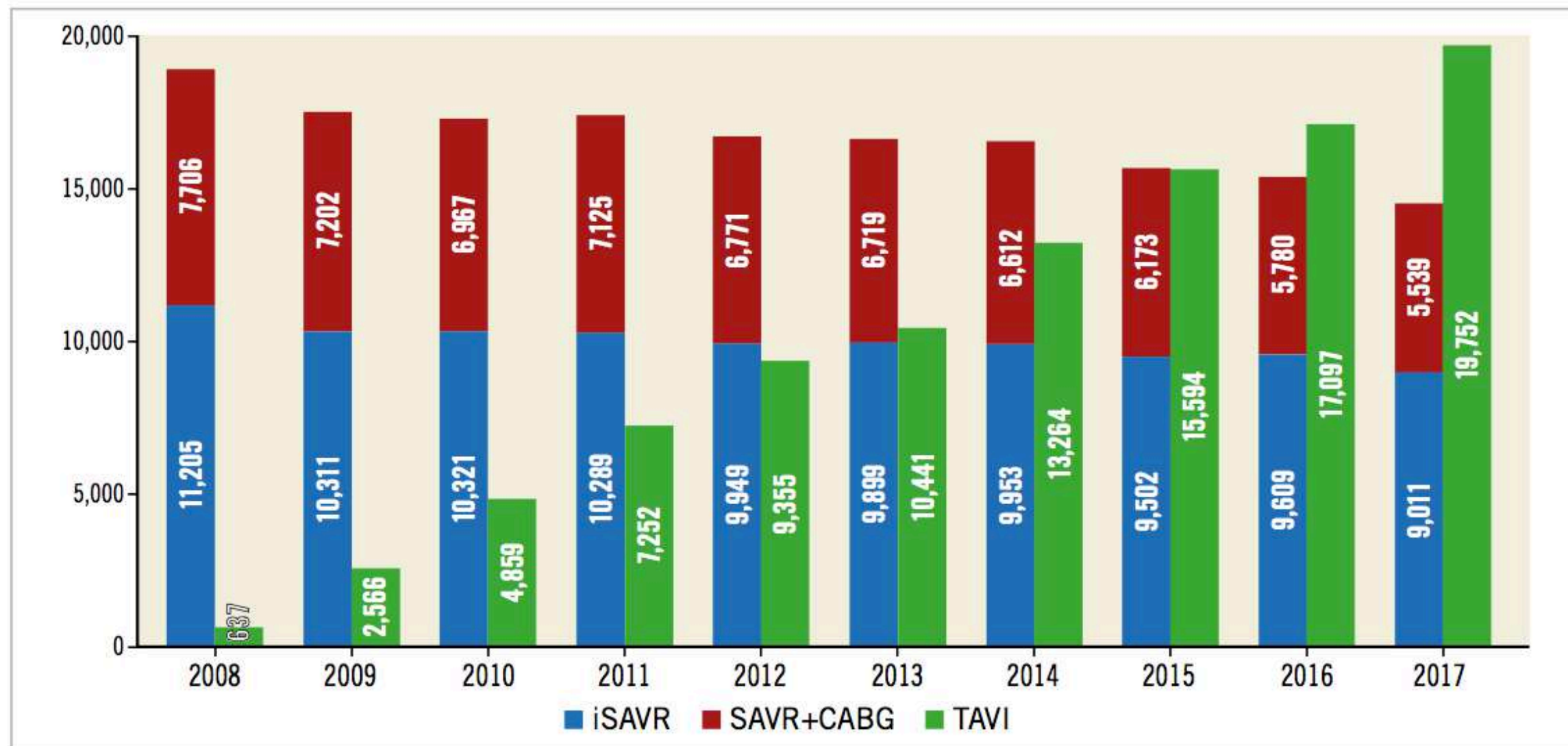
Hotel Vip Executive Art's
Parque das Nações | Lisboa

30 | 31 JANEIRO 2020

CONVERSION TO OPEN SURGERY

CONVERSION TO OPEN SURGERY

Transcatheter aortic valve implantation (TAVI) in Germany: more than 100,000 procedures and now the standard of care for the elderly

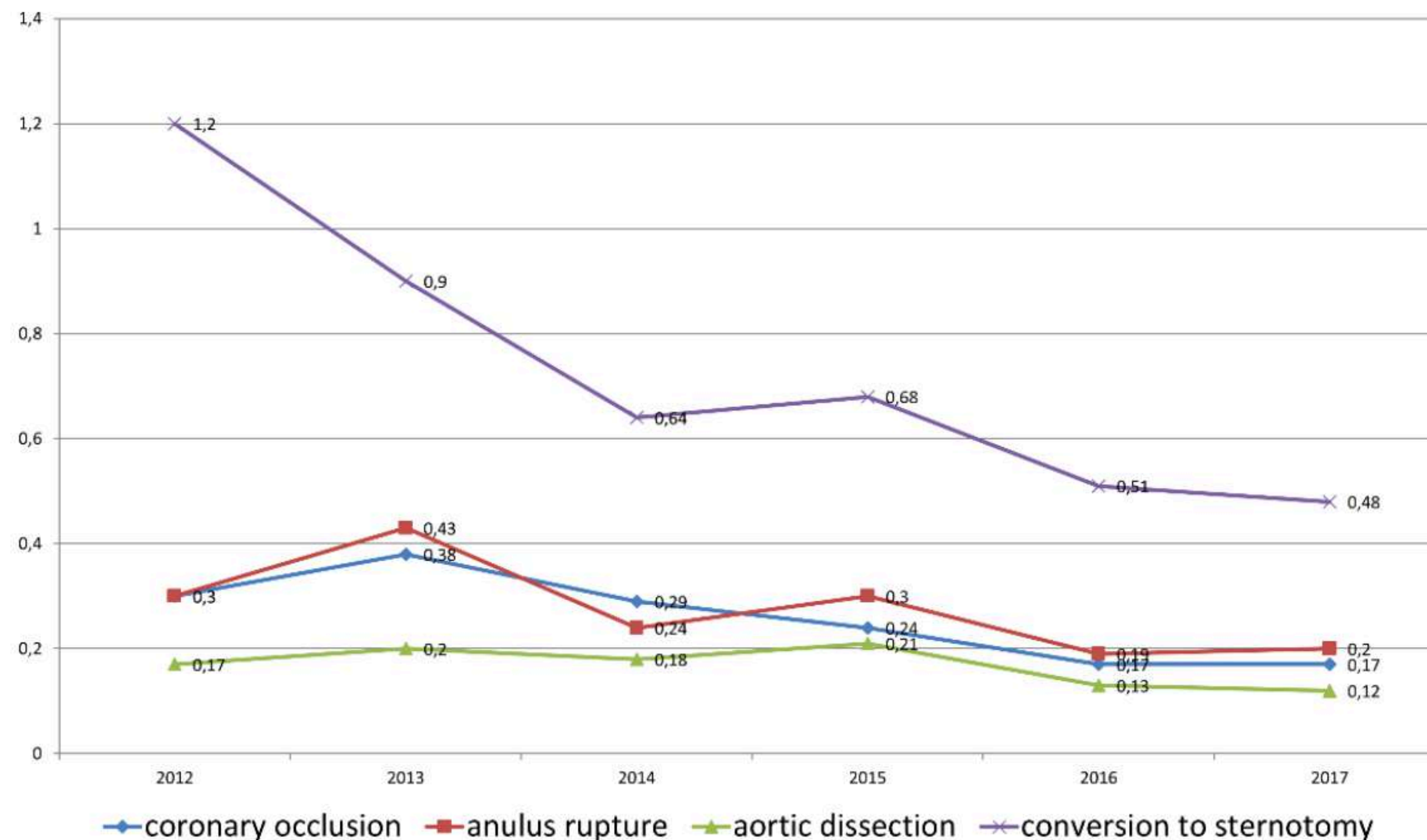


Eggebrecht H, et al. Eurointervention 2019;14:e1549

Pedro Carrilho Ferreira, Santa Maria University Hospital, Lisboa, Portugal

CONVERSION TO OPEN SURGERY

Transcatheter aortic valve implantation (TAVI) in Germany: more than 100,000 procedures and now the standard of care for the elderly



Eggebrecht H, et al. Eurointervention 2019;14:e1549

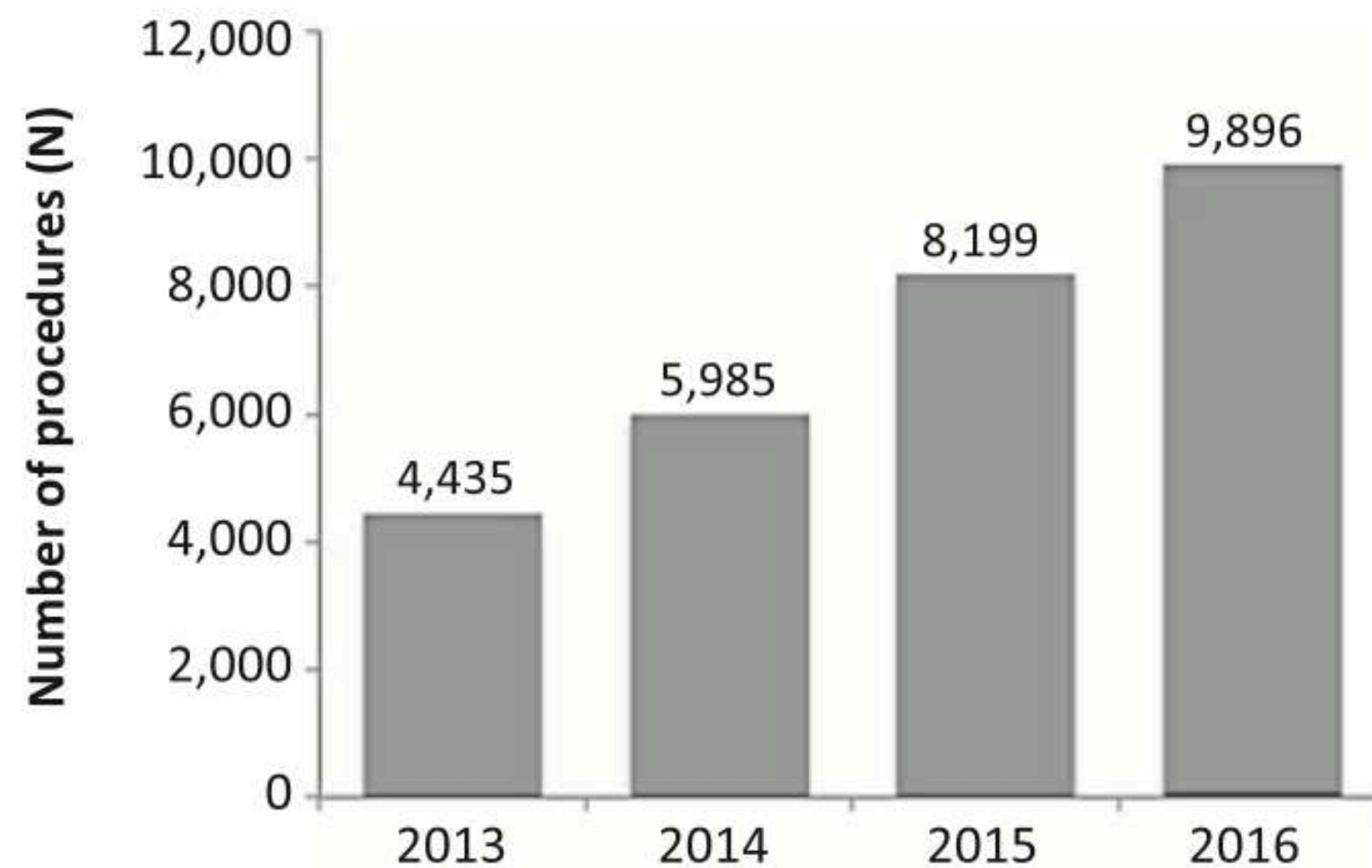
Pedro Carrilho Ferreira, Santa Maria University Hospital, Lisboa, Portugal

CONVERSION TO OPEN SURGERY

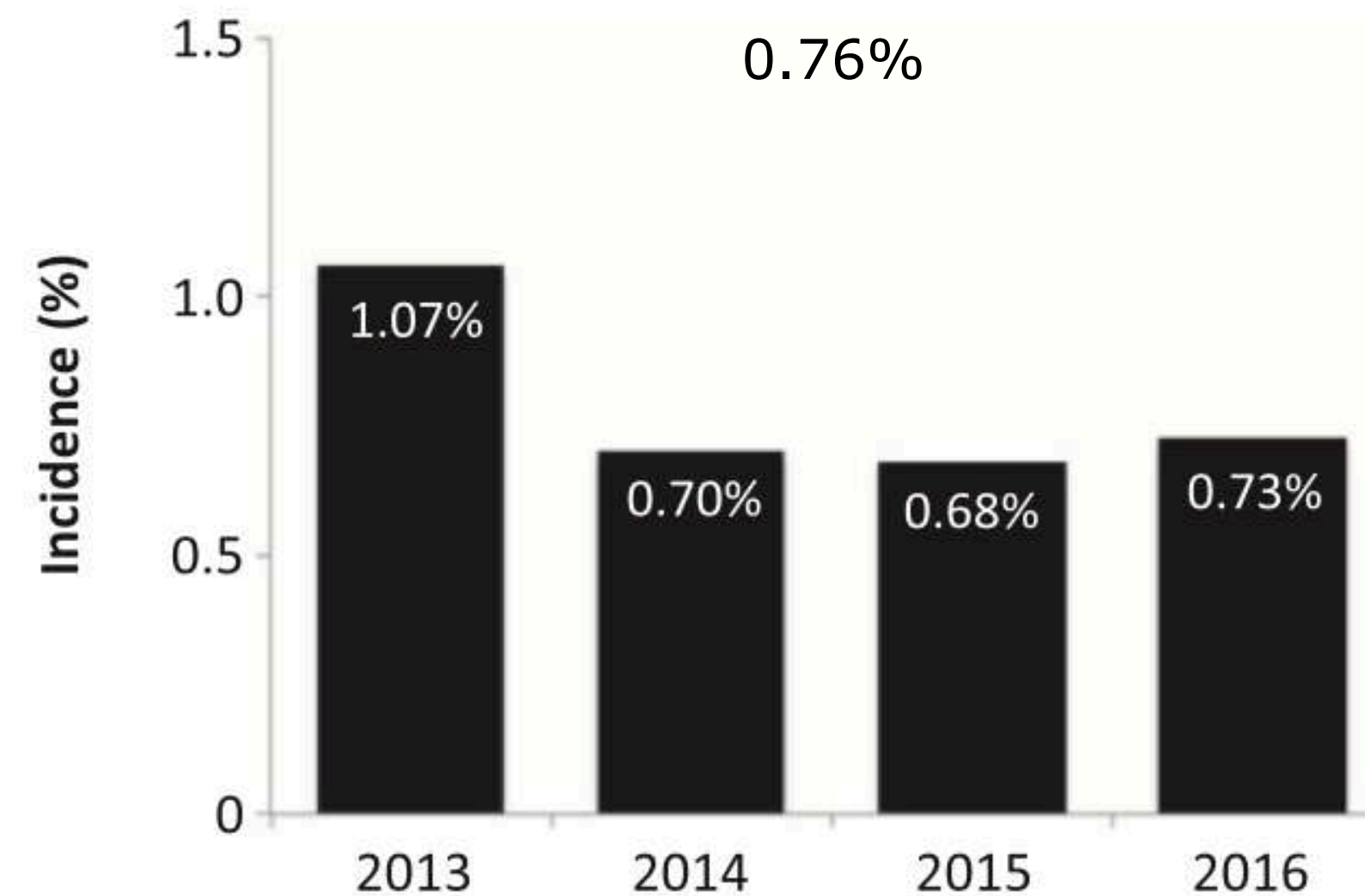
27 760 patients
79 centers
Europe, Israel and NZ

Incidence and outcomes of emergent cardiac surgery during transfemoral transcatheter aortic valve implantation (TAVI): insights from the *European Registry on Emergent Cardiac Surgery during TAVI (EuRECS-TAVI)*

TF-TAVI volume



TF-TAVI with ECS



Eggebrecht H, et al. EHJ 2018;39:676

Pedro Carrilho Ferreira, Santa Maria University Hospital, Lisboa, Portugal

CONVERSION TO OPEN SURGERY

Table 1 Baseline characteristics of transfemoral transcatheter aortic valve implantation patients with need for emergent cardiac surgery

	All patients (n = 212)
Patient characteristics	
Age (years)	82.4 ± 6.3
Female	143 (67.5%)
Previous cardiac surgery	17/196 (8.7%)
Left ventricular ejection fraction	56 ± 11 (15–75)
Logistic EuroSCORE I (%)	17.1 ± 10.0 (3.1–71.9)
Logistic EuroSCORE I > 20%	49 (23%)
STS score (%)	5.8 ± 3.7 (1.2–26.1)
Transcatheter heart valve (THV) type	
Balloon-expandable valve	97 (46.2%)
Self-expandable valve	91 (43.3%)
Mechanically expandable valve	22 (10.5%)

Incidence and outcomes of emergent cardiac surgery during transfemoral transcatheter aortic valve implantation (TAVI): insights from the European Registry on Emergent Cardiac Surgery during TAVI (EuRECS-TAVI)

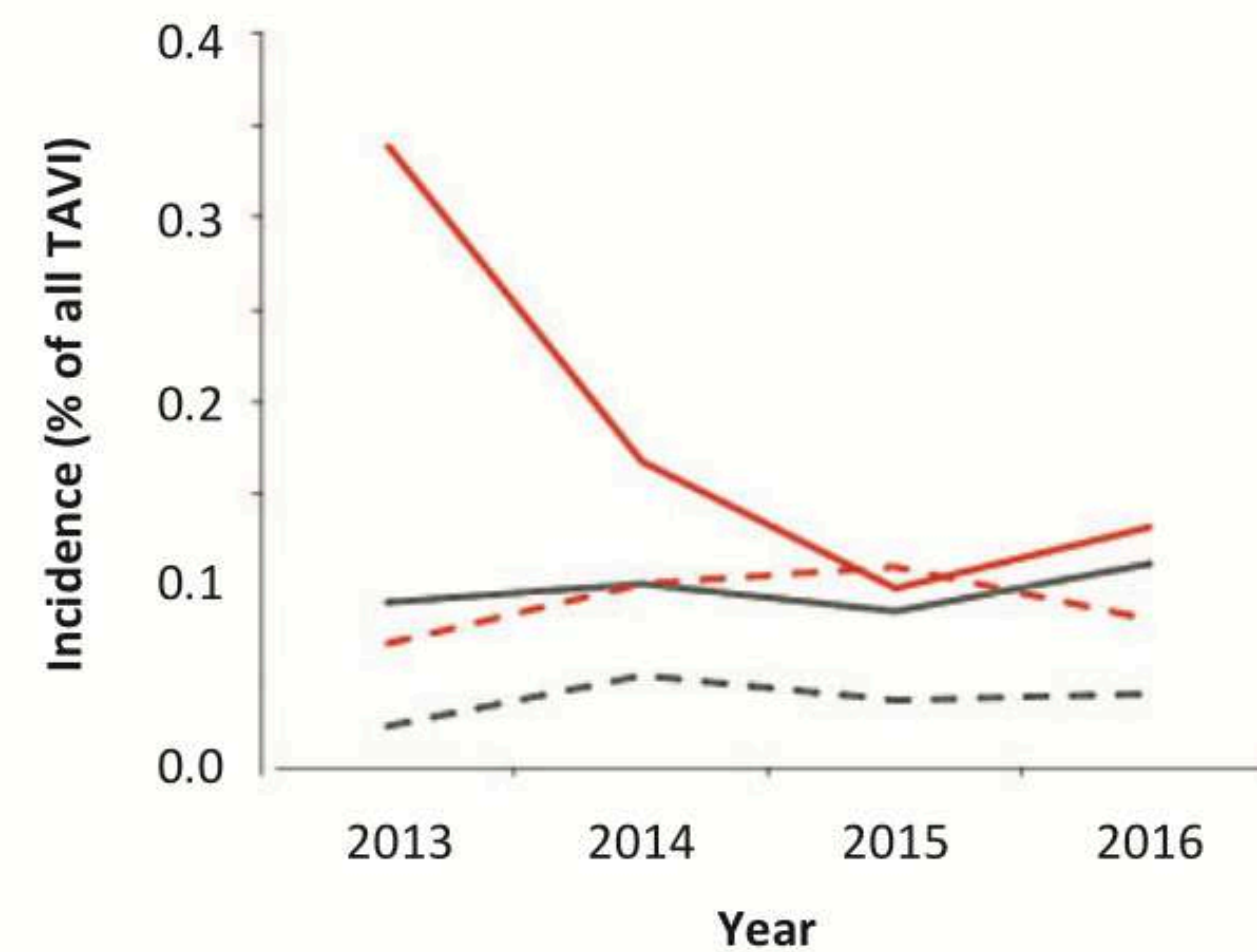
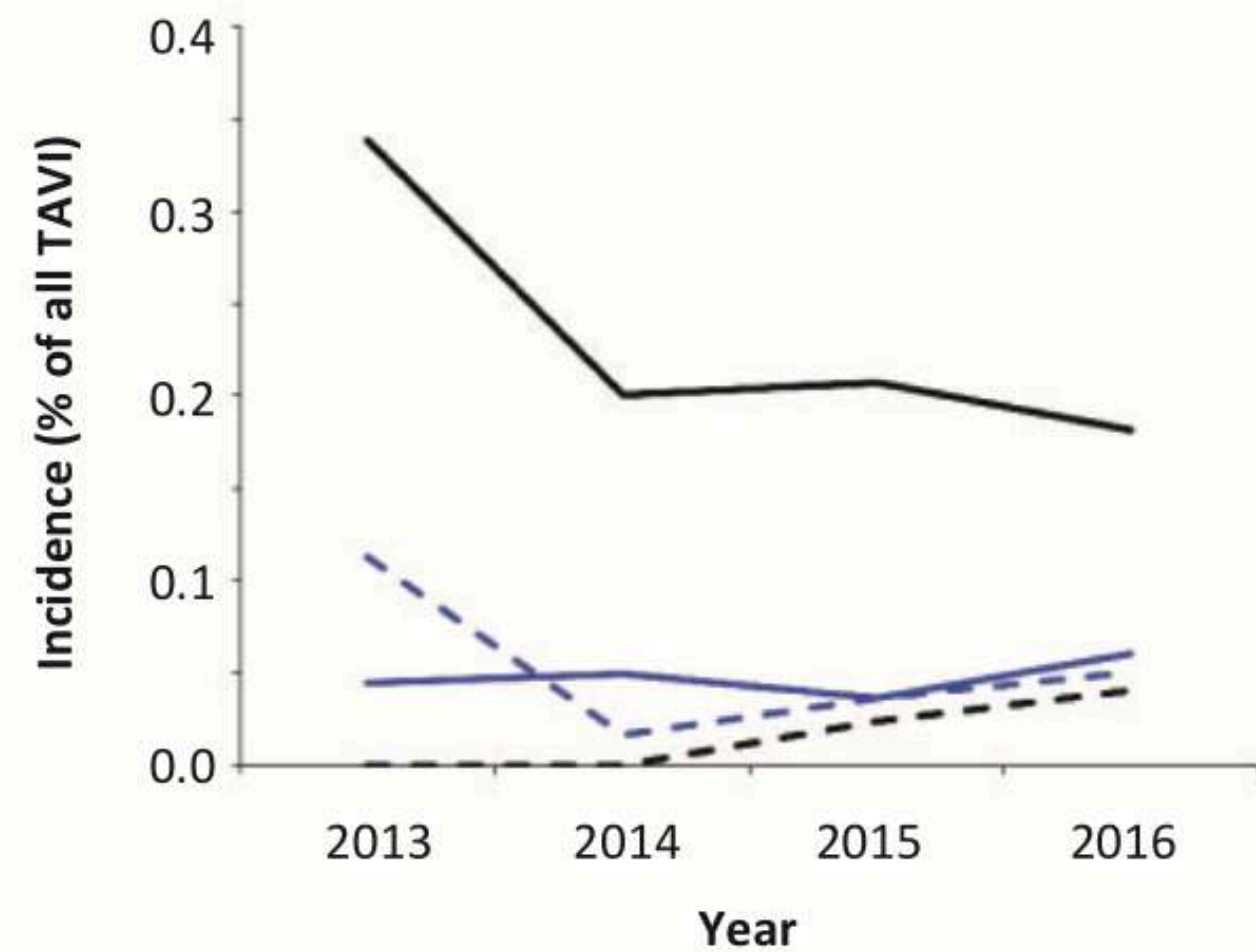
Different types of complications necessitating ECS

	2013 – 2016	2013 - 2016
LV perforation by guide wire	60 (28.3%)	Severe paravalvular leak 3 (1.4%)
Annular rupture	45 (21.2%)	Problems with delivery system 3 (1.4%)
Valve embolization/migration	27 (12.7%)	Ventricular septum defect 1 (0.5%)
Aortic dissection	25 (11.8%)	LV aneurysm 1 (0.5%)
RV perforation by PM wire	14 (6.6%)	Unknown – resuscitation 1 (0.5%)
Pericardial tamponade	14 (6.6%)	Dysfunction of mechanical mitral valve prosthesis 1 (0.5%)
Coronary obstruction/occlusion	11 (5.2%)	
LV perforation by delivery system	6 (2.8%)	

CONVERSION TO OPEN SURGERY

Incidence and outcomes of emergent cardiac surgery during transfemoral transcatheter aortic valve implantation (TAVI): insights from the European Registry on Emergent Cardiac Surgery during TAVI (EuRECS-TAVI)

Temporal evolution of different types of complications necessitating ECS



- LV perforation with guide wire
- - - LV perforation with delivery system
- RV perforation with PM wire
- - - Pericardial tamponade

- Annular rupture
- - - Aorta dissection
- Valve embolization/migration
- - - Coronary obstruction/occlusion

Eggebrecht H, et al. EHJ 2018;39:676

Pedro Carrilho Ferreira, Santa Maria University Hospital, Lisboa, Portugal

CONVERSION TO OPEN SURGERY

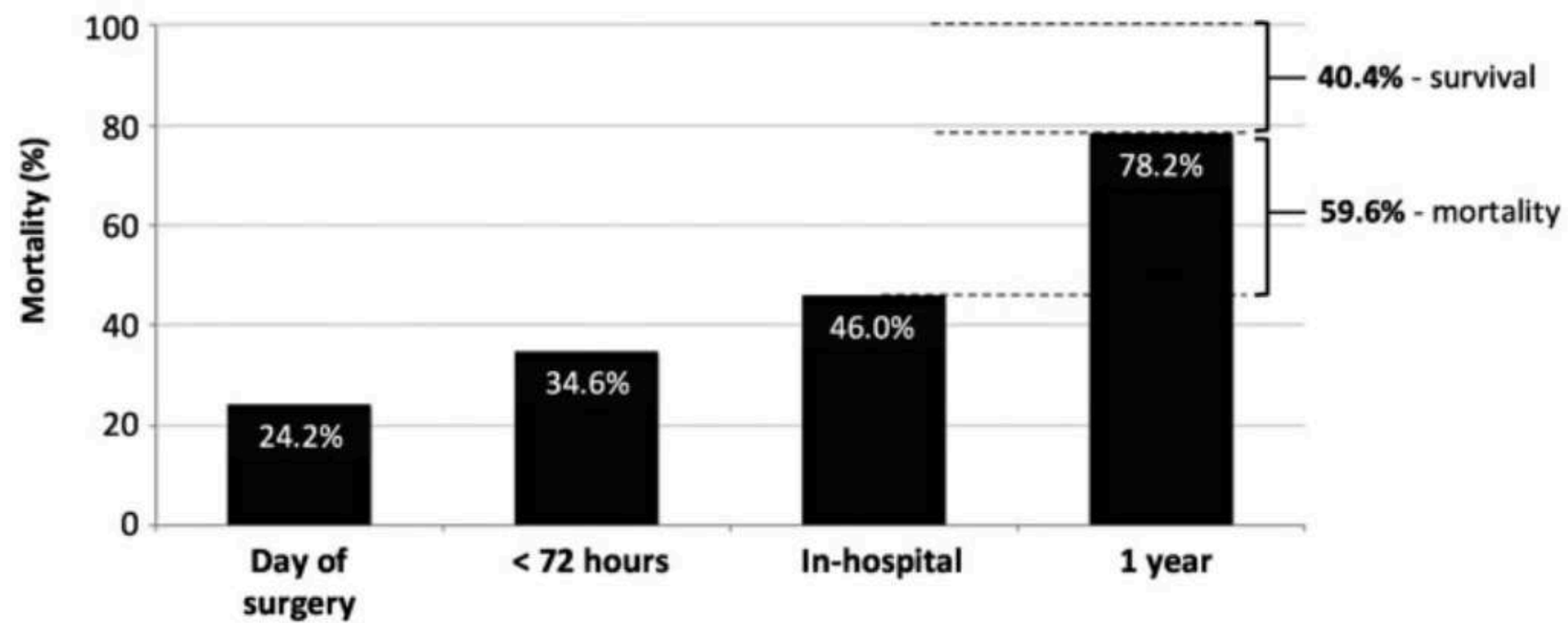
Incidence and outcomes of emergent cardiac surgery during transfemoral transcatheter aortic valve implantation (TAVI): insights from the European Registry on Emergent Cardiac Surgery during TAVI (EuRECS-TAVI)

Table 3 Different transcatheter heart valve types and their risk for complications leading to emergent cardiac surgery

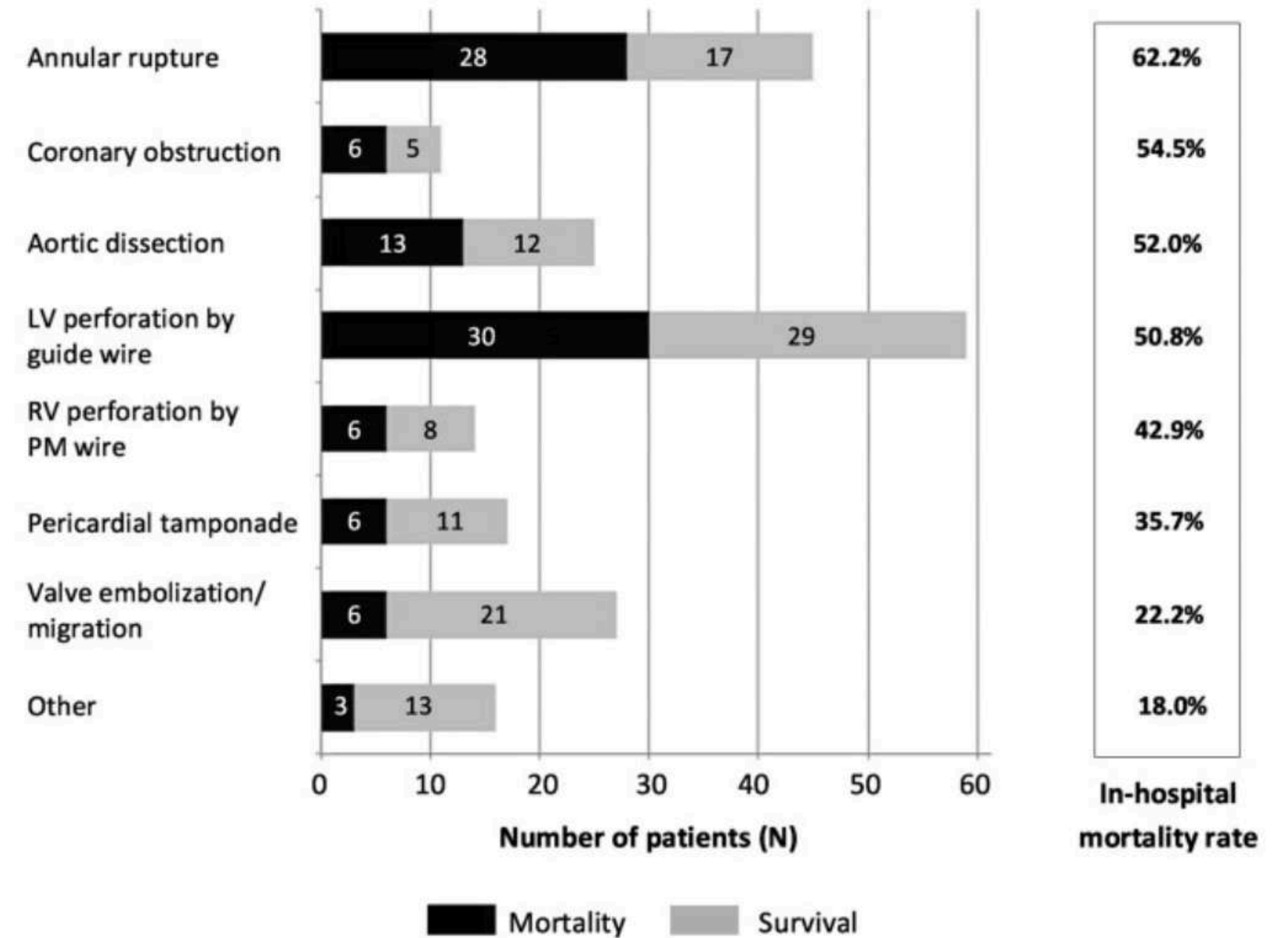
	Balloon-expandable THV (n = 12 343)	Self-expanding THV (n = 10 521)	Mechanically expanded THV (n = 1948)	P-value
Type of complication				0.005
LV perforation by guide wire	28 (0.23%)	23 (0.22%)	7 (0.35%)	
Annular rupture	31 (0.25%)	14 (0.13%)	0 (0.0%)	
Valve embolization/migration	9 (0.07%)	15 (0.14%)	3 (0.15%)	
Aortic dissection	7 (0.06%)	11 (0.10%)	7 (0.36%)	
RV perforation by PM wire	9 (0.07%)	4 (0.04%)	1 (0.05%)	
Pericardial tamponade	5 (0.04%)	9 (0.09%)	0 (0.0%)	
Coronary obstruction/occlusion	1 (0.01%)	8 (0.08%)	2 (0.10%)	
LV perforation by delivery system	3 (0.02%)	2 (0.02%)	1 (0.05%)	
Other	4 (0.03%)	5 (0.05%)	1 (0.05%)	

CONVERSION TO OPEN SURGERY

A Mortality in case of ECS for TF-TAVR



B In-hospital mortality rates in case of ECS for the different complications





9^a REUNIÃO VAP-APIC

Hotel Vip Executive Art's
Parque das Nações | Lisboa

30 | 31 JANEIRO 2020

 ASSOCIAÇÃO PORTUGUESA
de INTERVENÇÃO CARDIOVASCULAR
sociedade portuguesa de cardiologia

ON-SITE CARDIAC SURGERY

ON-SITE CARDIAC SURGERY

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

2013-14

75 hospitals with CS department
22 hospitals without

Table 1 Patient demographics

	Patients undergoing TF-TAVI in hospitals without CS (n = 1332)	7.4%	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

Eggebrecht H, et al. EHJ 2016;37:2240

Pedro Carrilho Ferreira, Santa Maria University Hospital, Lisboa, Portugal

ON-SITE CARDIAC SURGERY

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

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!

ON-SITE CARDIAC SURGERY

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

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.

ON-SITE CARDIAC SURGERY

Impact of On-Site Cardiac Surgery on Clinical Outcomes After Transfemoral Transcatheter Aortic Valve Replacement

FIGURE 1 Flowchart Diagram of Patients Included in This Analysis

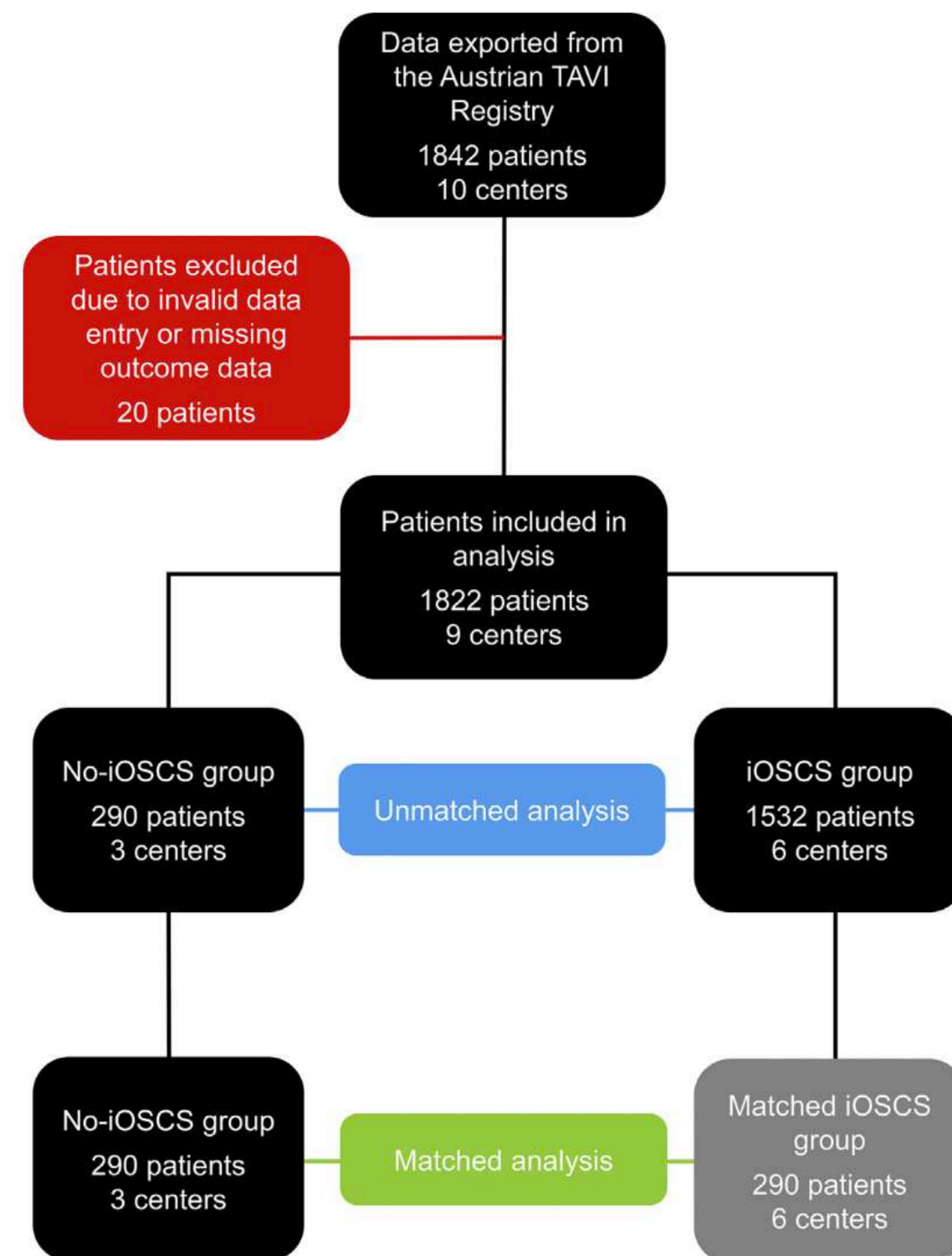


TABLE 1 Baseline Characteristics of No-iOSCS Patients, Complete iOSCS Group, and Matched iOSCS Patients

	No-iOSCS (n = 290)	iOSCS			
		Before Matching (n = 1,532)	p Value	After Matching (n = 290)	p Value
Female	63.4	59.1	0.171	63.4	0.931
Age, yrs	84 (80-87)	83 (79-86)	0.006	84 (81-87)	0.241
Height, cm	164 (159-170)	165 (159-170)	0.433	164 (158-170)	0.595
Weight, kg	70 (61-81)	70 (62-80)	0.484	70 (60-80)	0.527
BMI, kg/m ²	26 (23-29)	26 (23-29)	0.498	26 (23-28)	0.836
BSA, m ²	1.78 ± 0.20	1.79 ± 0.20	0.366	1.77 ± 0.21	0.538
COPD IV	4.7	10.9	0.001	8.6	0.088
Liver cirrhosis	1.2	1.3	1.000	1.1	1.000
Prior CAD	63.8	51.8	<0.001	55.2	0.044
Prior stroke	6.3	9.0	0.182	10.4	0.114
Prior PCI	45.3	29.9	<0.001	37.7	0.081
Prior pericardiectomy	8.3	11.9	0.109	7.6	0.874
LVEF					
30-50	38.7	26.2	<0.001	33.6	0.244
<30	10.7	8.8	0.344	12.5	0.592
Logistic EuroSCORE	20.9 (12.8-30.3)	14.2 (9.0-22.2)	<0.001	19.6 (13.1-28.6)	0.808
Porcelain aorta	4.3	7.5	0.083	6.7	0.256
Implanted pacemaker	13.0	8.4	0.024	12.7	1.000
First patients	27.6	10.1	<0.001	24.1	0.393
Echocardiography					
V _{max} , m/s	4.4 (4.0-4.8)	4.4 (4.0-4.8)	0.530	4.4 (4.0-5.0)	0.156
Mean gradient, mm Hg	48 (40-57)	47 (39-59)	0.748	50 (40-62)	0.233

Egger F, et al. JACC Int 2018;11:2160

Pedro Carrilho Ferreira, Santa Maria University Hospital, Lisboa, Portugal

ON-SITE CARDIAC SURGERY

Impact of On-Site Cardiac Surgery on Clinical Outcomes After Transfemoral Transcatheter Aortic Valve Replacement

TABLE 3 Primary and Secondary Outcomes of No-iOSCS Patients, Complete iOSCS Group, and Matched iOSCS Patients

	No-iOSCS (n = 290)	iOSCS			
		Before Matching (n = 1,532)	p Value	After Matching (n = 290)	p Value
Primary outcomes					
Procedural survival	96.9	98.6	0.034	98.6	0.162
30-day survival	93.1	96.0	0.039	93.8	0.719
Secondary outcomes					
Cumulative 1-yr survival	80.9	86.1	0.017	83.4	0.402
Cumulative 2-yr survival	74.3	77.5	0.131	74.9	0.748
Cumulative 3-yr survival	62.1	68.5	0.048	66.2	0.422
Procedural complication-free survival	75.9	86.7	<0.001	84.1	0.008
Cardiac tamponade or life-threatening bleeding	2.4	1.8	0.485	3.2	0.788
Major bleeding	9.3	4.6	0.003	4.8	0.051
Stroke	1.0	2.2	0.256	1.7	0.725
Kidney failure	1.0	1.0	1.000	0.3	0.624
Pneumonia	3.8	1.0	0.001	1.0	0.054
Severe aortic regurgitation	2.4	1.0	0.078	1.0	1.000
Myocardial infarction	1.0	0.5	0.397	1.4	1.000
Multiorgan failure	1.4	0.3	0.041	1.2	1.000
Pacemaker implantation	32.2	15.7	<0.001	19.0	<0.001
Prolonged hospital stay	26.0	13.4	<0.001	14.5	<0.001

Egger F, et al. JACC Int 2018;11:2160

Pedro Carrilho Ferreira, Santa Maria University Hospital, Lisboa, Portugal



9^a REUNIÃO VAP-APIC

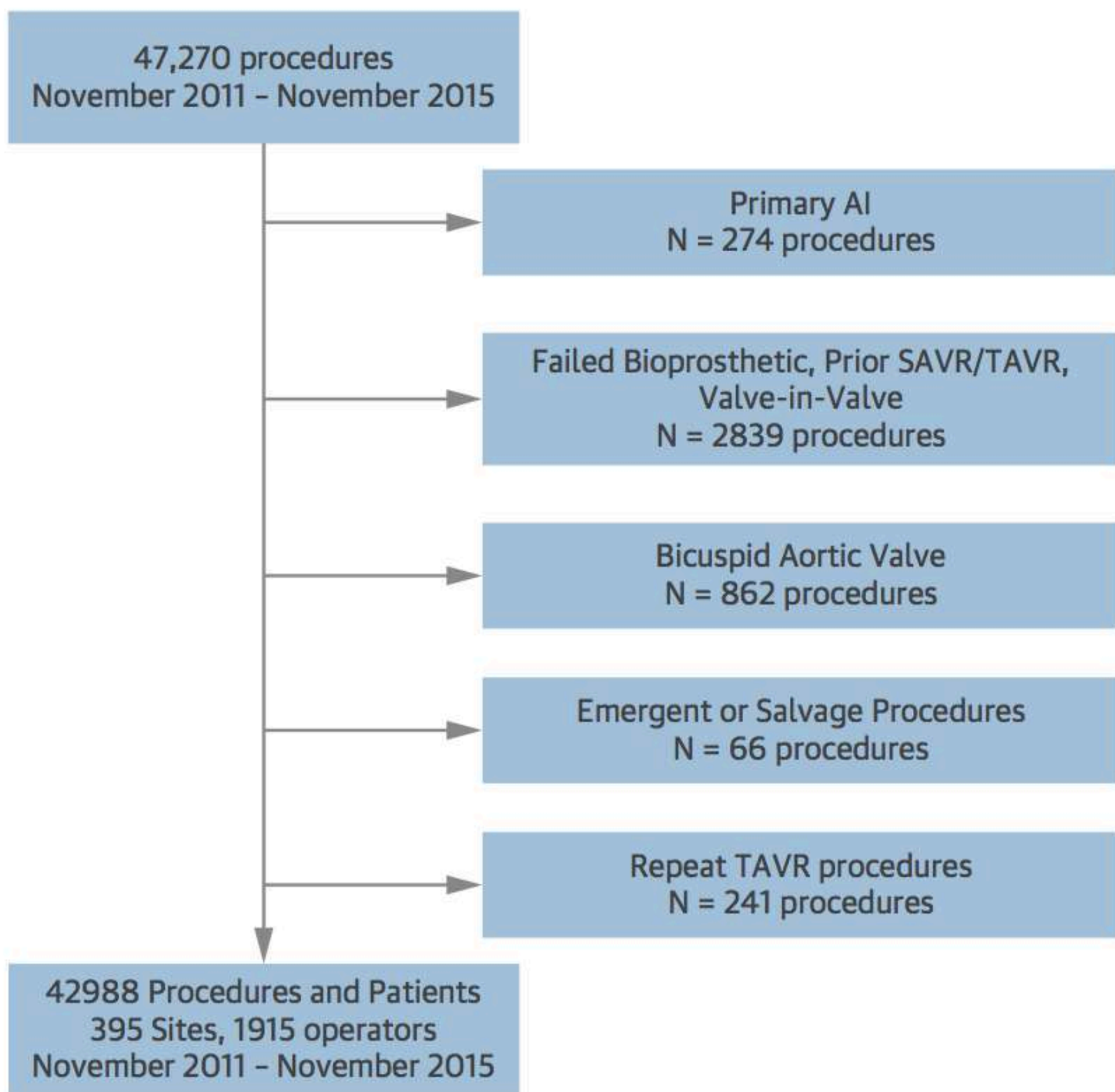
Hotel Vip Executive Art's
Parque das Nações | Lisboa

30 | 31 JANEIRO 2020

VOLUME AND OUTCOMES

VOLUME AND OUTCOMES

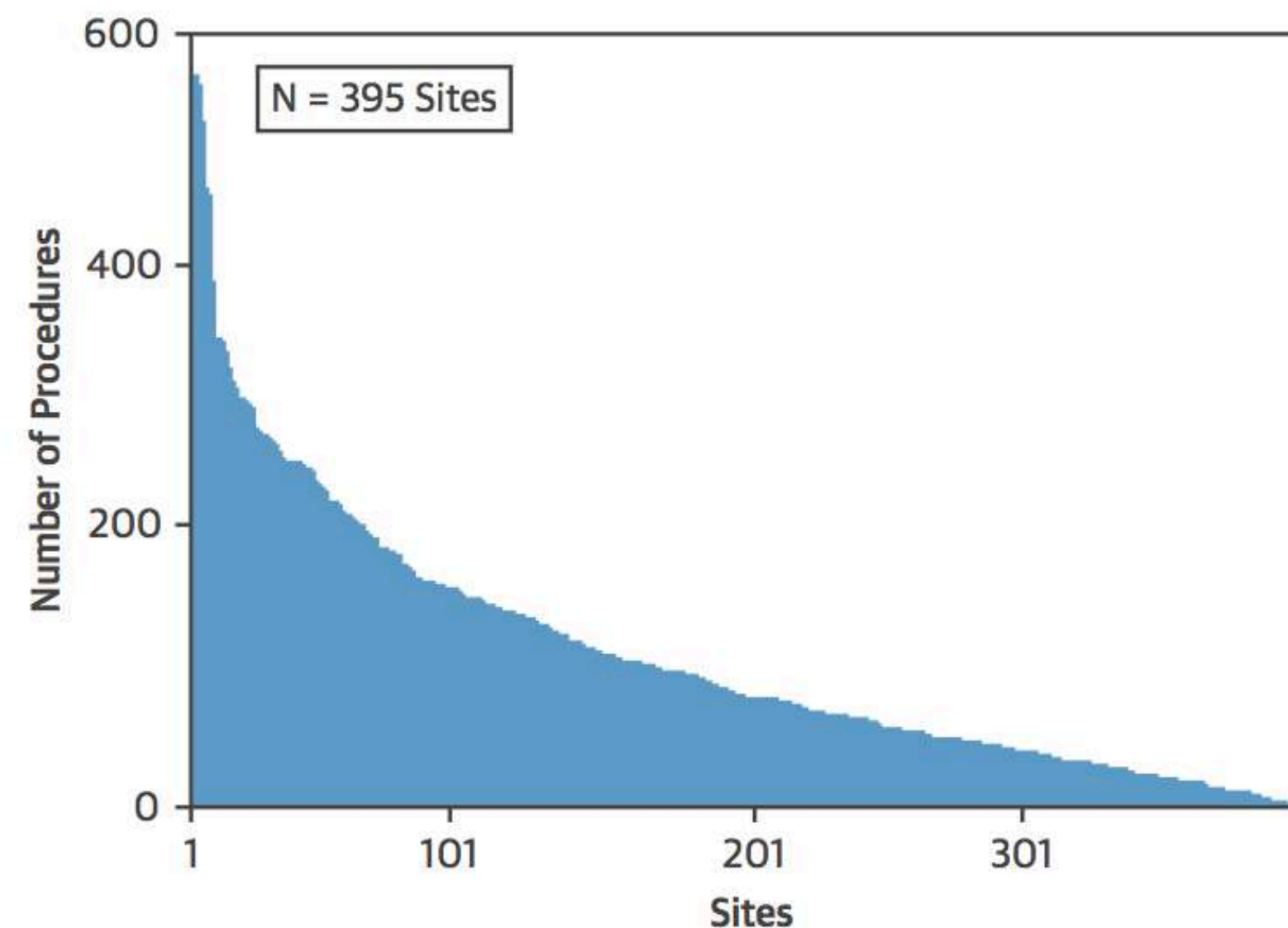
FIGURE 1 Study Diagram



Procedural Experience for Transcatheter Aortic Valve Replacement and Relation to Outcomes

The STS/ACC TVT Registry

FIGURE 2 TAVR Volume



Carroll JD, et al. JACC 2017;70:29

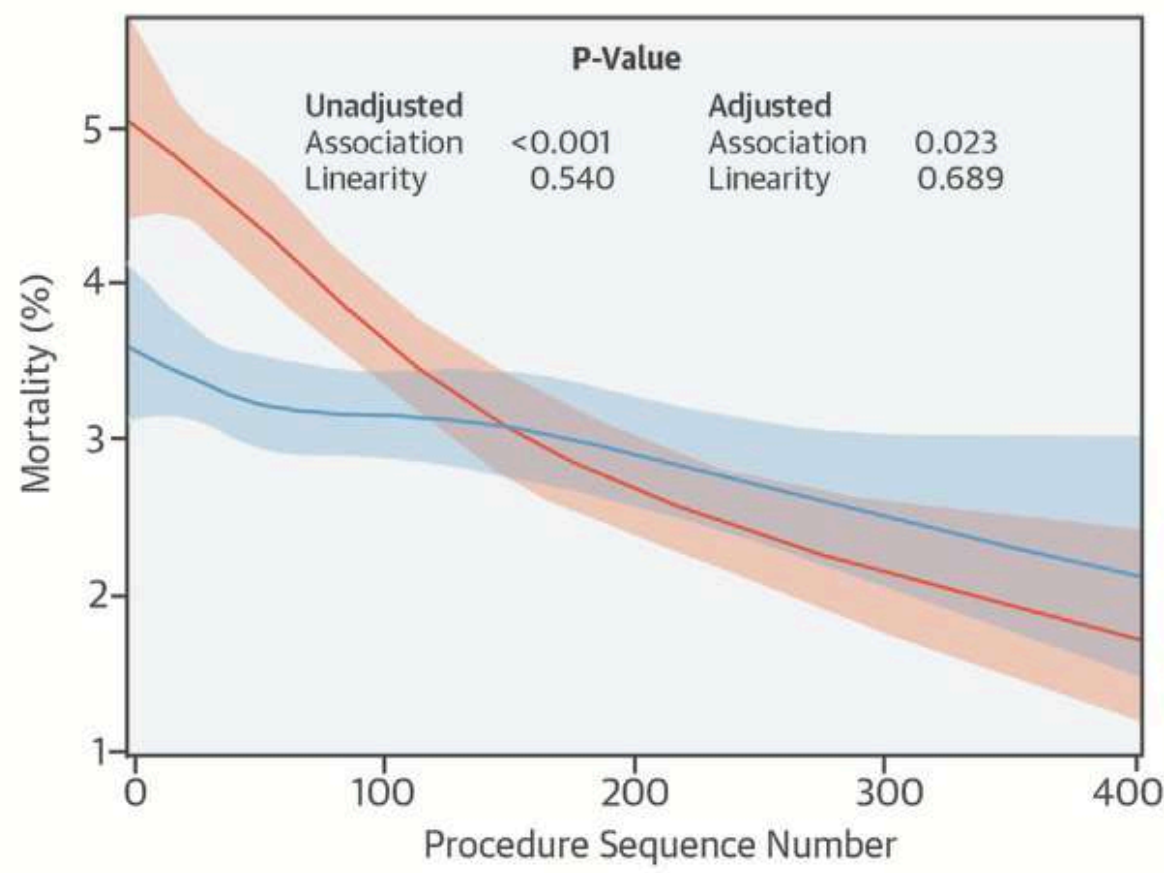
Pedro Carrilho Ferreira, Santa Maria University Hospital, Lisboa, Portugal

VOLUME AND OUTCOMES

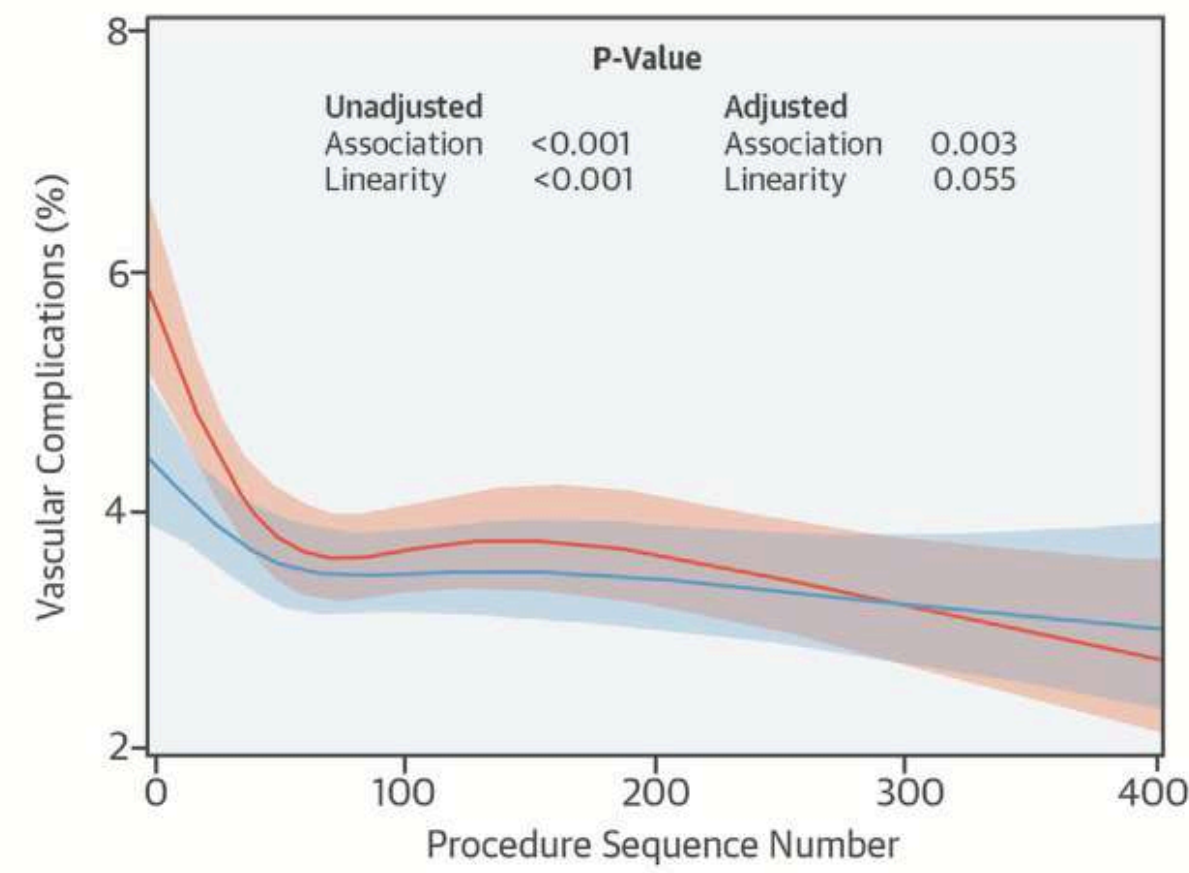
Procedural Experience for Transcatheter Aortic Valve Replacement and Relation to Outcomes

The STS/ACC TVT Registry

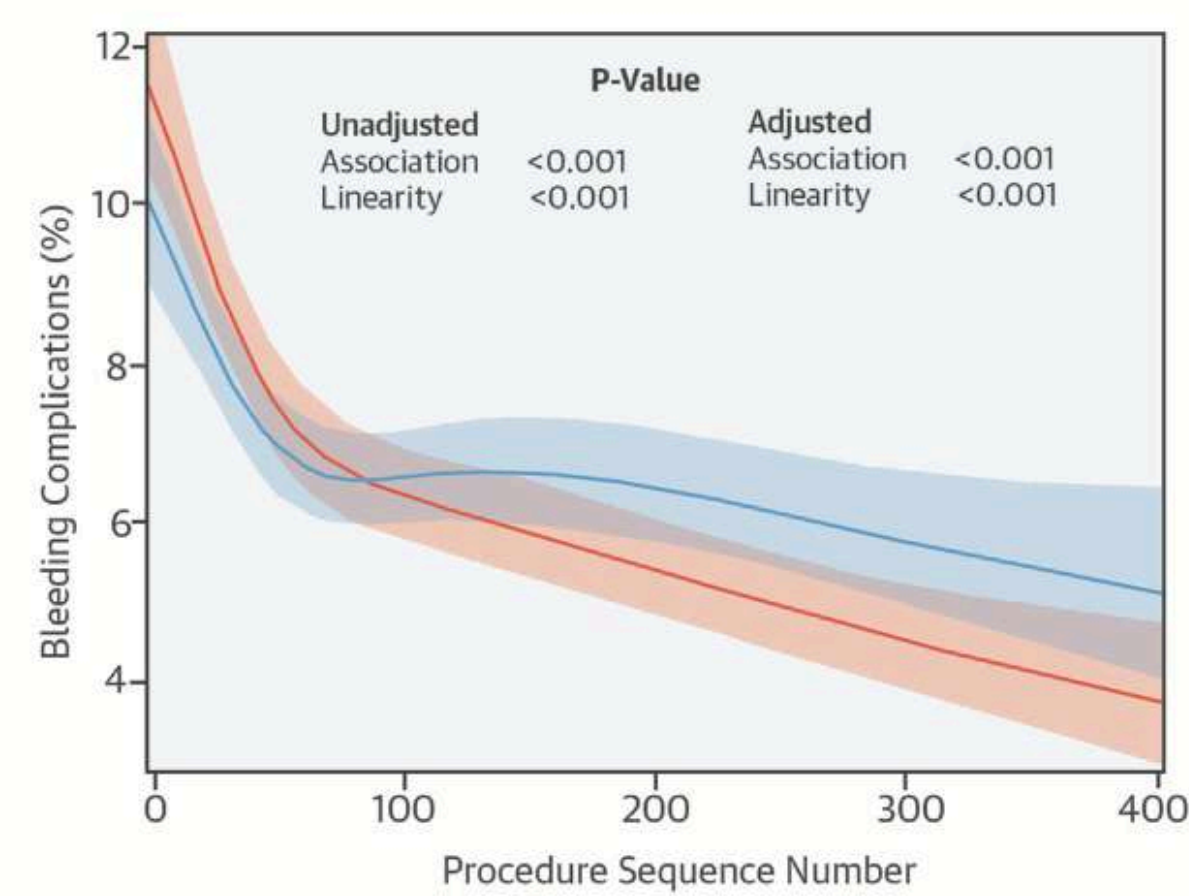
A. Mortality



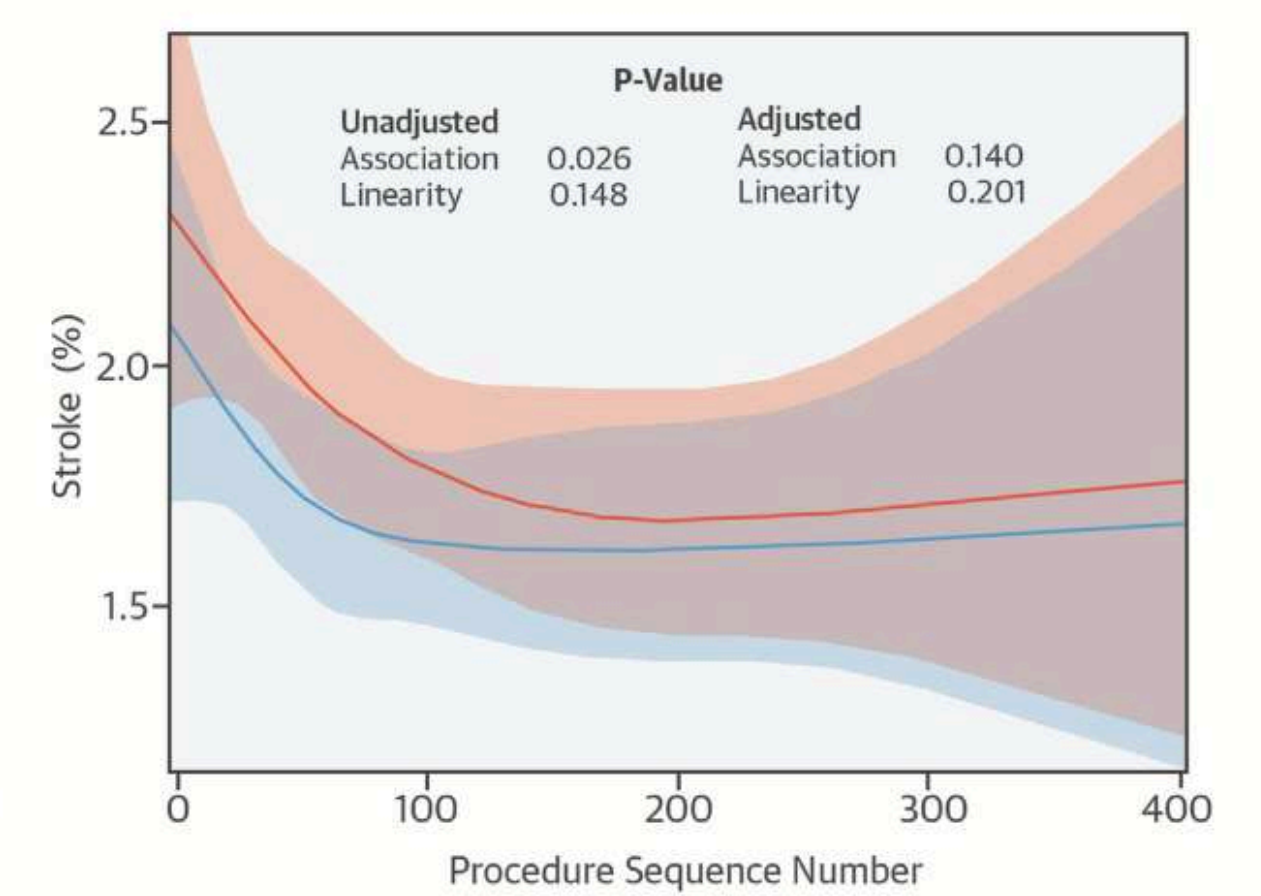
B. Vascular



C. Bleeding



D. Stroke



— Unadjusted — Adjusted

Carroll JD, et al. JACC 2017;70:29

Pedro Carrilho Ferreira, Santa Maria University Hospital, Lisboa, Portugal

VOLUME AND OUTCOMES

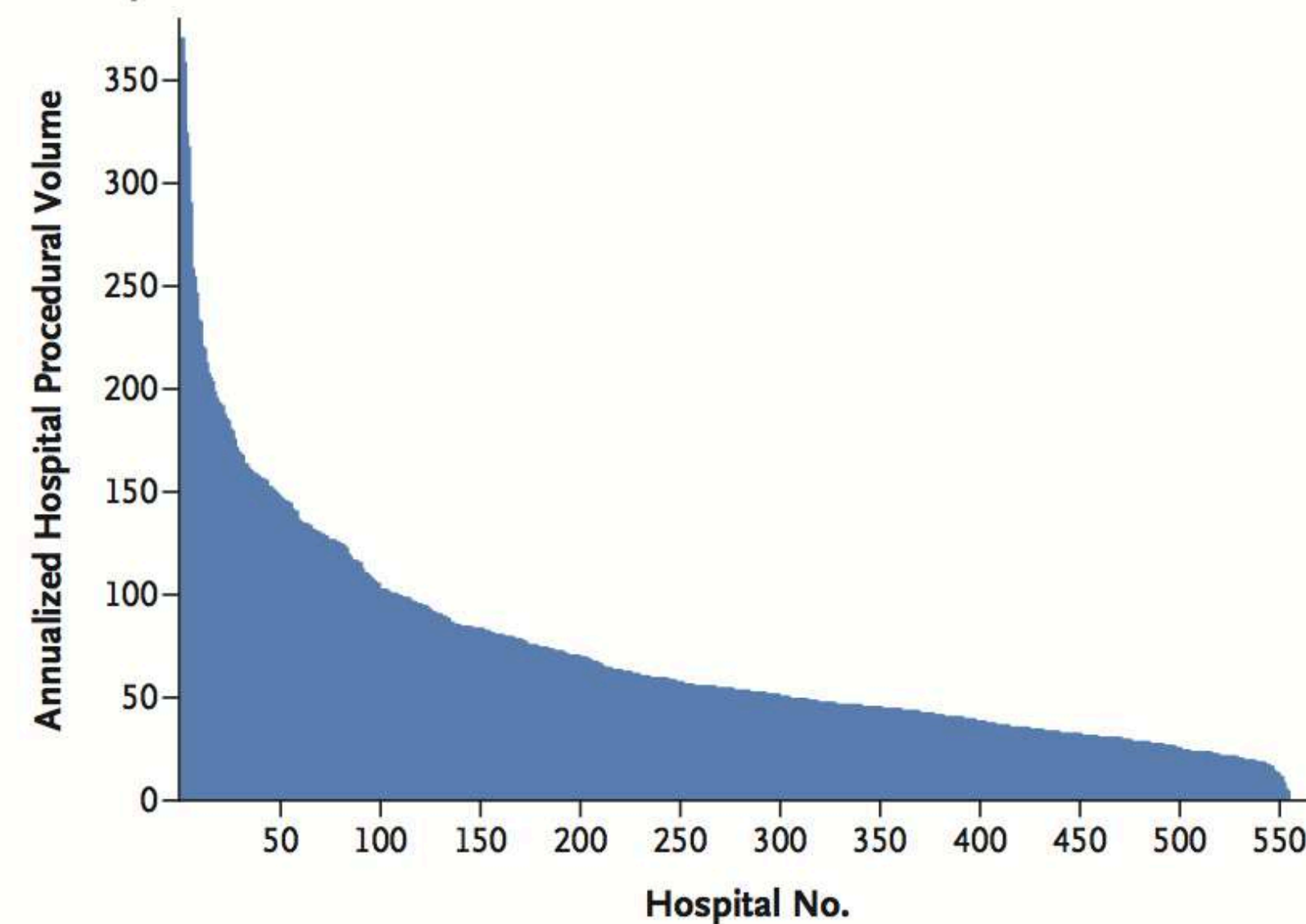
Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement

TVT registry 2015-2017

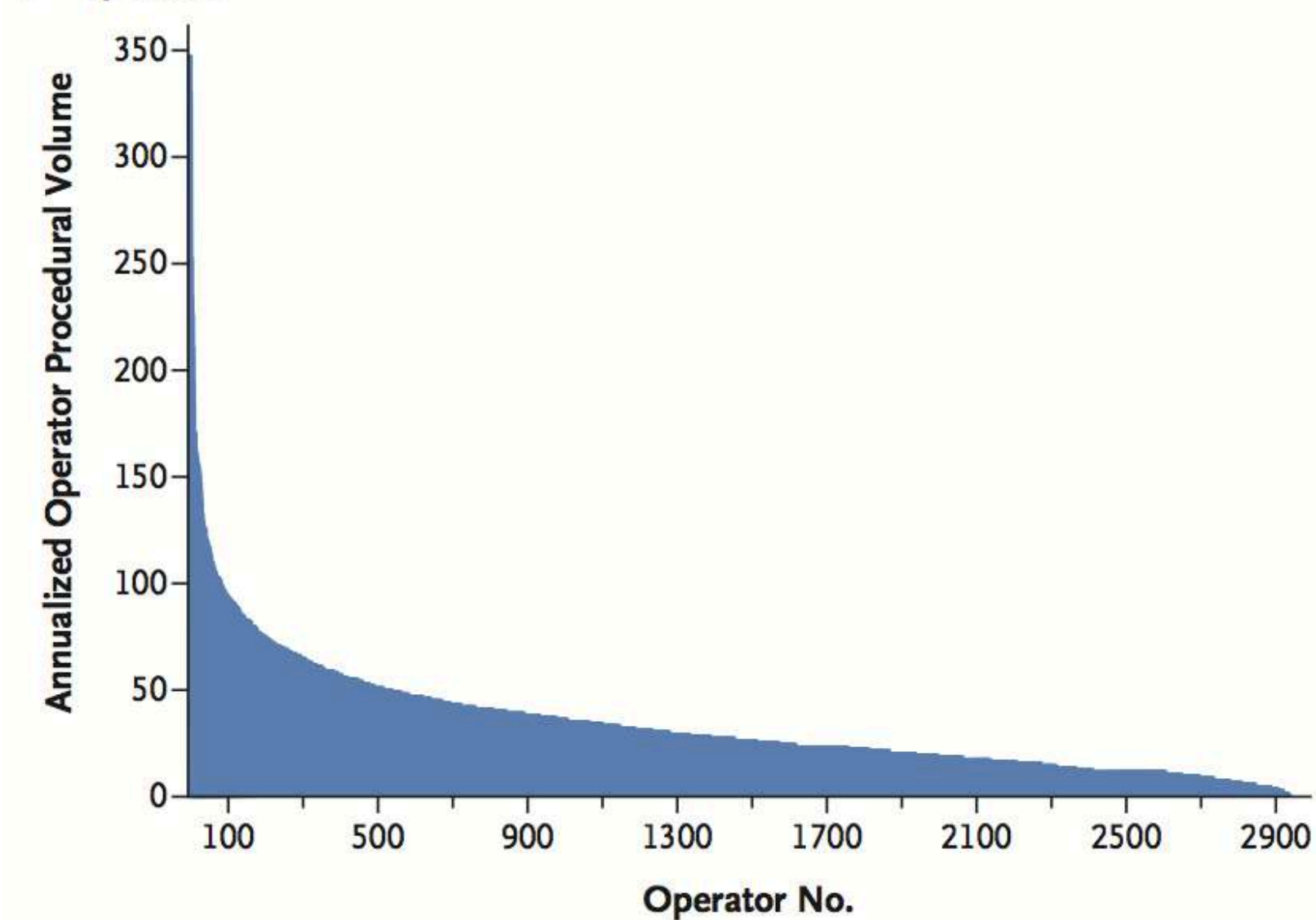
113,662 TAVR procedures
(555 hospitals, 2960 operators)

96,256 (84.7%) TF approach
(554 hospitals, 2935 operators)

A Hospitals

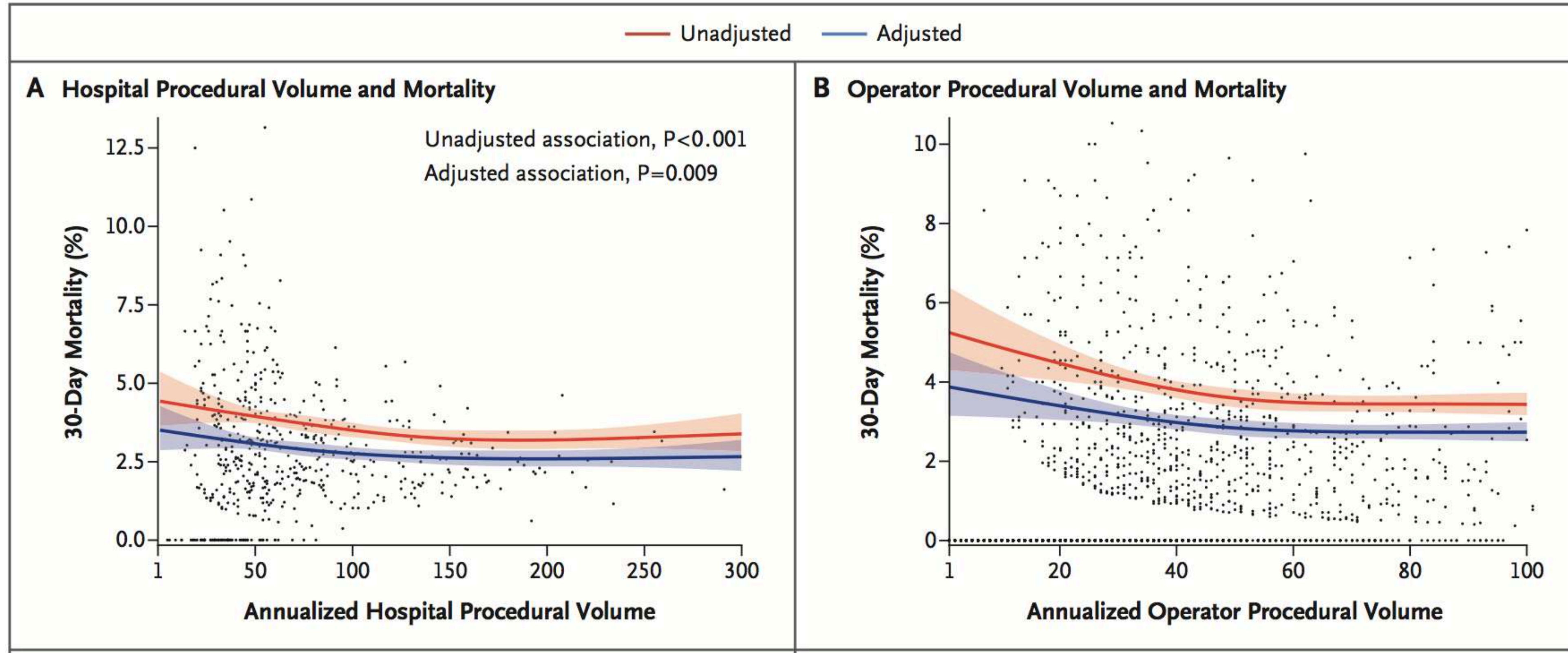


B Operators



VOLUME AND OUTCOMES

Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement



Vemulapalli S, et al. NEJM 2019;380:2541

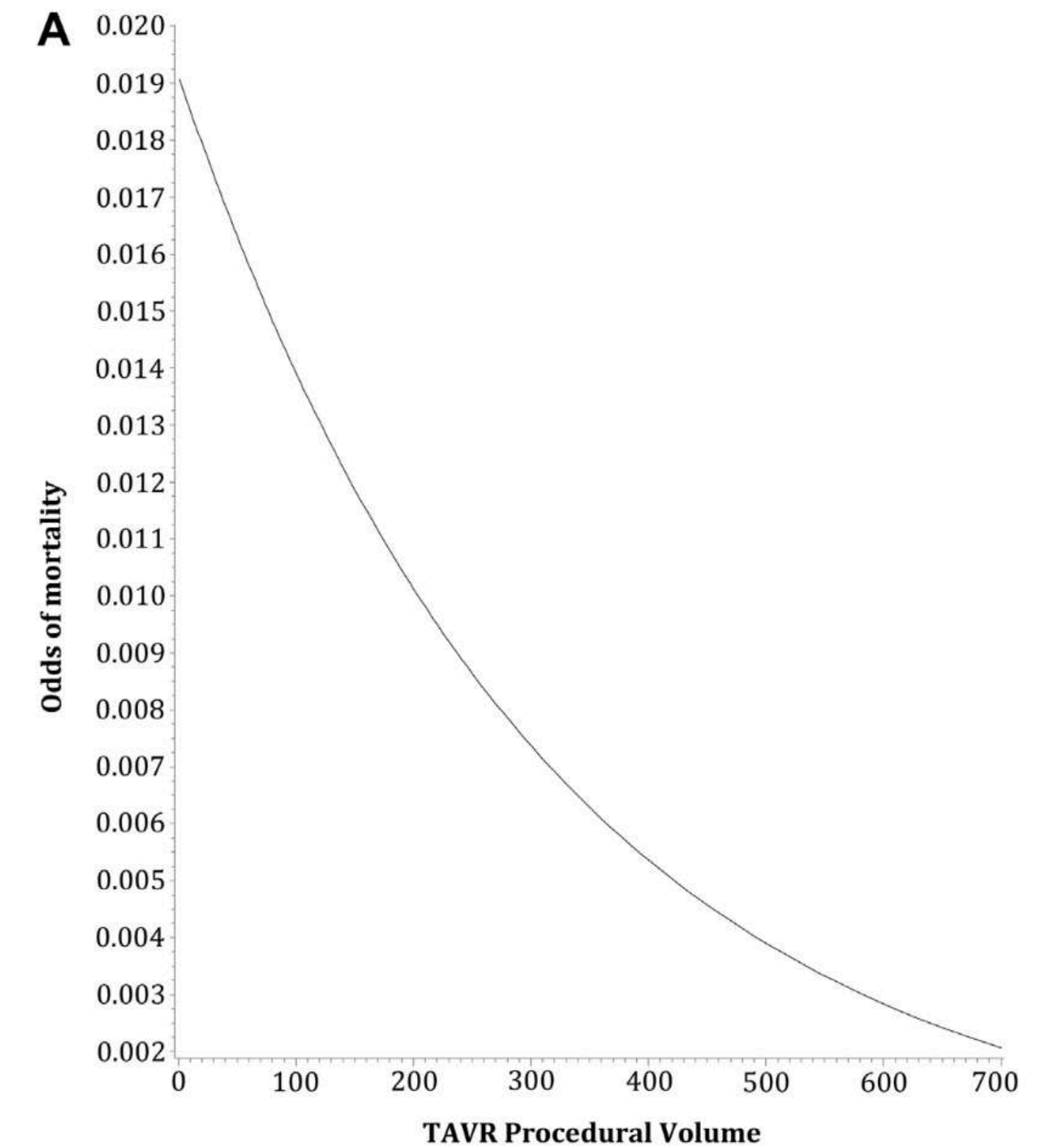
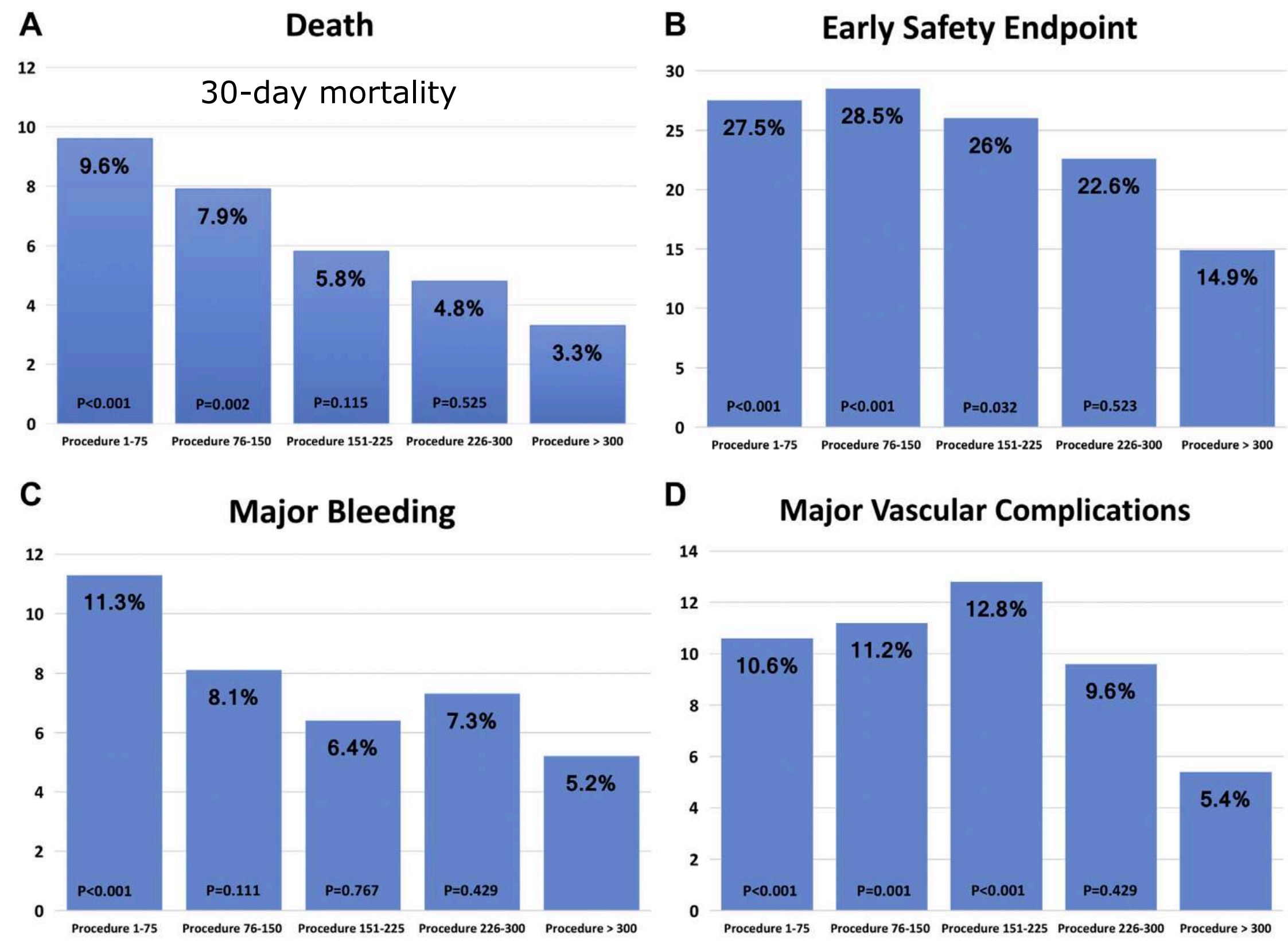
Pedro Carrilho Ferreira, Santa Maria University Hospital, Lisboa, Portugal

VOLUME AND OUTCOMES

The Learning Curve and Annual Procedure Volume Standards for Optimum Outcomes of Transcatheter Aortic Valve Replacement

Findings From an International Registry

FIGURE 1 Unadjusted Clinical and Procedural Outcomes According to TAVR Procedural Experience



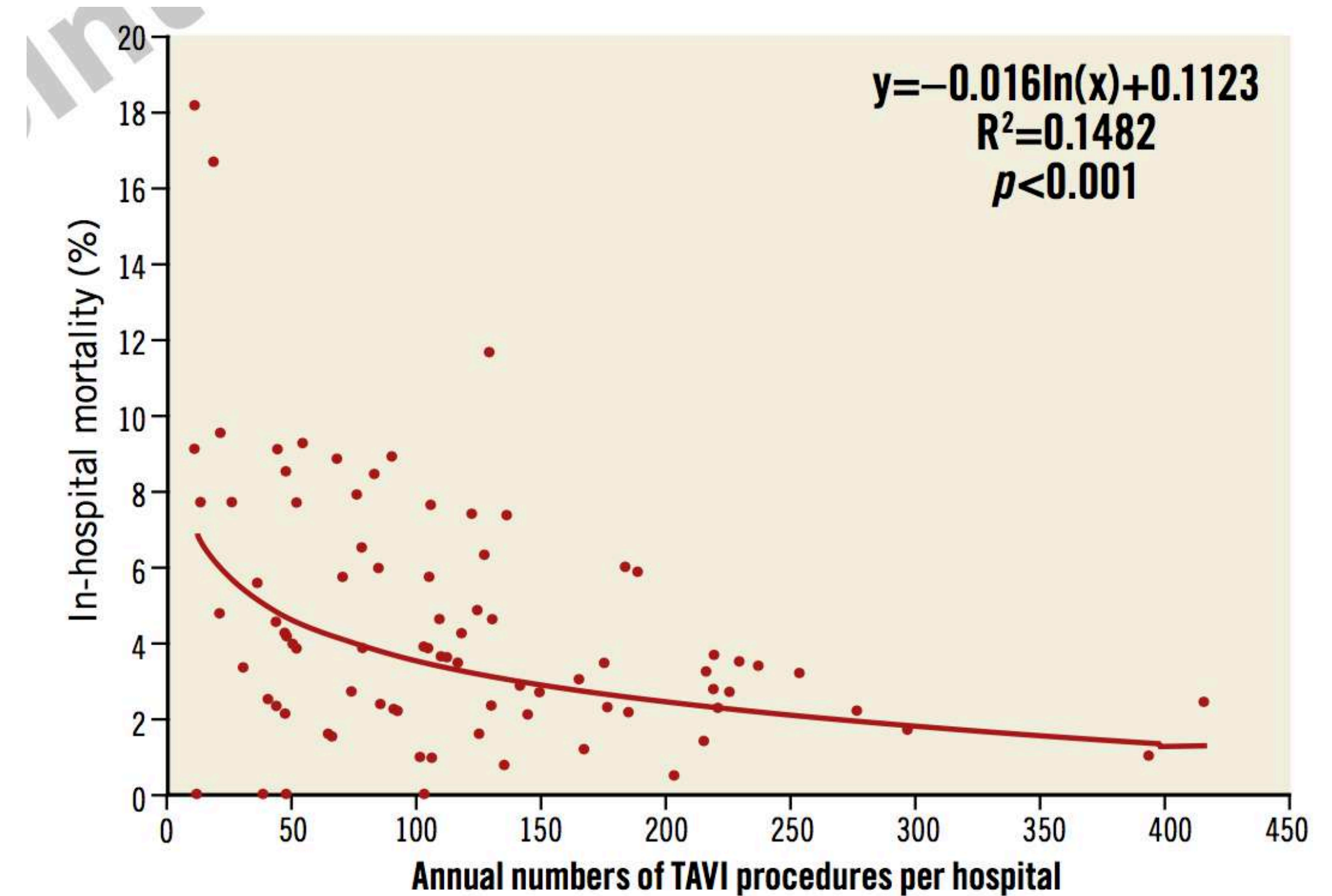
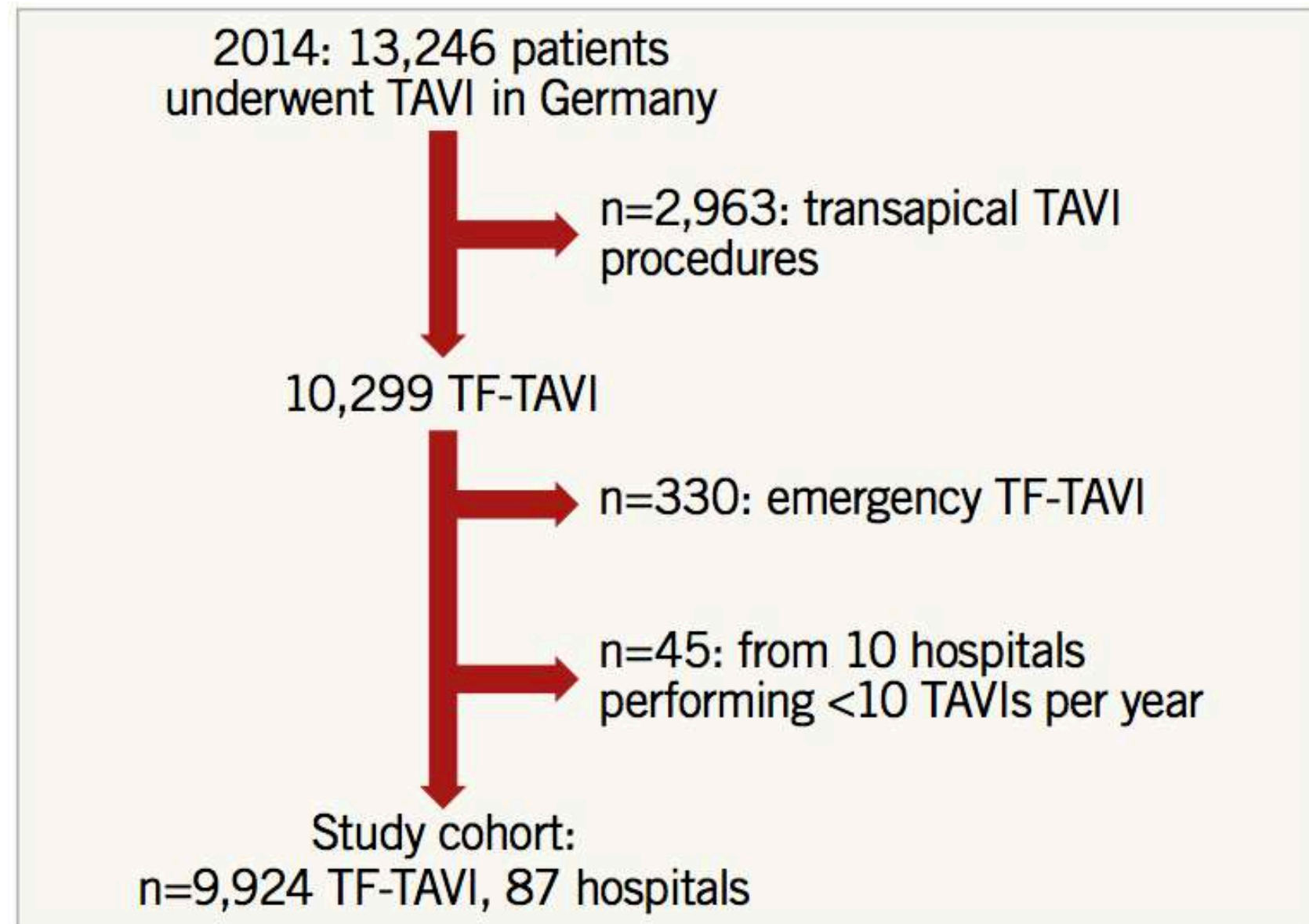
16 centers
3,403 patients

Wassef AWA, et al. JACC Int 2018;11:1669

Pedro Carrilho Ferreira, Santa Maria University Hospital, Lisboa, Portugal

VOLUME AND OUTCOMES

Volume-outcome relationship with transfemoral transcatheter aortic valve implantation (TAVI): insights from the compulsory German Quality Assurance Registry on Aortic Valve Replacement (AQUA)



Bestehorn K, et al. Eurointervention 2017;13:914

Pedro Carrilho Ferreira, Santa Maria University Hospital, Lisboa, Portugal



9^a
REUNIÃO
VaP-APIC

Hotel Vip Executive Art's
Parque das Nações | Lisboa

30 | 31 JANEIRO 2020

RECOMMENDATIONS FOR OPERATOR AND INSTITUTIONAL REQUIREMENTS

RECOMMENDATIONS FOR OPERATOR AND INSTITUTIONAL REQUIREMENTS

2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement



3.4. Facilities and Institutional Resources

- Active VHD surgical program with ≥ 2 institutionally based cardiac surgeons
- Full range of diagnostic imaging and therapeutic facilities:
 - Cardiac / hybrid catheterisation laboratory
 - Echocardiography laboratory
 - Vascular noninvasive laboratory
 - CT laboratory
- Physical space - implantation suite with a sterile environment that meets OR standards
- Interventional procedure supplies
- Postprocedure recovery and intensive care facility

RECOMMENDATIONS FOR OPERATOR AND INSTITUTIONAL REQUIREMENTS

AATS/ACC/SCAI/STS

TABLE 4 Requirements for New TAVR Programs

- Documentation of a multidisciplinary approach and of patient access to all forms of therapy for AVD
- Expertise, state of the art technology, and a dedicated board-certified imager (TTE, TEE, 3D echo, CT scan, MRI)
- TAVR proceduralist:
 - Participation in 100 TF TAVRs lifetime, including 50 as primary operator
 - Board eligible or certified in either interventional cardiology or cardiothoracic surgery
- TAVR surgeon: 100 lifetime SAVRs, 25 per prior year, or 50 over 2 years
- Expansion into non-TF-access: ≥ 80 TF TAVRs with 30-day risk-adjusted all-cause mortality \geq "as expected"

RECOMMENDATIONS FOR OPERATOR AND INSTITUTIONAL REQUIREMENTS

AATS/ACC/SCAI/STS

TABLE 4 Requirements for New TAVR Programs

- SAVR program:
 - ≥ 2 hospital-based cardiac surgeons who both spend $\geq 50\%$ time at the hospital with the TAVR program
 - ≥ 40 SAVR per prior year or 80 over 2 years
- PCI program:
 - ≥ 300 PCI/year
 - In-hospital risk-adjusted mortality above the bottom 25th percentile for the most recent 4 consecutive quarters
- Physicians experienced and competent in vascular arterial interventions
- Physicians experienced and competent for temporary and permanent pacemaker placement 24/7

RECOMMENDATIONS FOR OPERATOR AND INSTITUTIONAL REQUIREMENTS

AATS/ACC/SCAI/STS

TABLE 3 Requirements for Continued Certification for Existing TAVR Programs

- ≥ 50 cases/year or 100 cases over 2 years
- Reported 30-day risk-adjusted all-cause above the bottom 10%

- ≥ 300 PCIs/year
- PCI in-hospital risk-adjusted mortality above the bottom 25th percentile for 4 consecutive quarters

- Experienced and competent physicians in vascular arterial interventions
- Experienced and competent physicians for temporary and permanent pacemaker placement 24/7

- ≥ 2 hospital-based cardiac surgeons who spend $\geq 50\%$ of their time at the hospital with TAVR program
- ≥ 30 SAVRs per prior year or 60 over 2 years

To be or not to be an operator - Who should perform TAVI?

Round table: Key questions in TAVI in 2020

Pedro Carrilho Ferreira

Joaquim Oliveira Interventional Cardiology Unit

Department of Cardiology, Santa Maria University Hospital, CHULN

Lisbon School of Medicine, Lisbon University

Lisbon Academic Medical Center

9^a REUNIÃO U^{VaP}-APIC

Hotel Vip Executive Art's
Parque das Nações | Lisboa

30 | 31 JANEIRO 2020