TAVI BEST CANDIDATE AND OPTIMIZED LONG TERM FOLLOW-UP

Maurizio D'Amico M.D.



Dipartimento Cardiovascolare e Toracico Città della Salute e della Scienza, Turin Ital

ADVANCES IN CARDIAC ARRHYTHMIAS and **GREAT INNOVATIONS** IN CARDIOLOGY XXVII GIORNATE CARDIOLOGICHE TORINE

PRELIMINARY PROGRAM



JMC

Fiorenzo Gaita Sebastiano Marra

October 23-24

urin



Davide Castagno //

Indications for transcatheter aortic valve implantation

	Class	Level
TAVI should only be undertaken with a multidisciplinary "heart team" including cardiologists and cardiac surgeons and other specialists if necessary.	Т	С
TAVI should only be performed in hospitals with cardiac surgery on-site.	1	С
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.	ų.	в
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.	lla	в

« At the present stage, TAVI should not be performed in patients at intermediate risk for surgery and trials are required in this population. »

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 & European Journal of Cardio-Thoracic Surgery 2012 doi:10.1093/ejcts/ezs455).



www.escardio.org/guidelines

Contraindications for transcatheteter 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).
- 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.

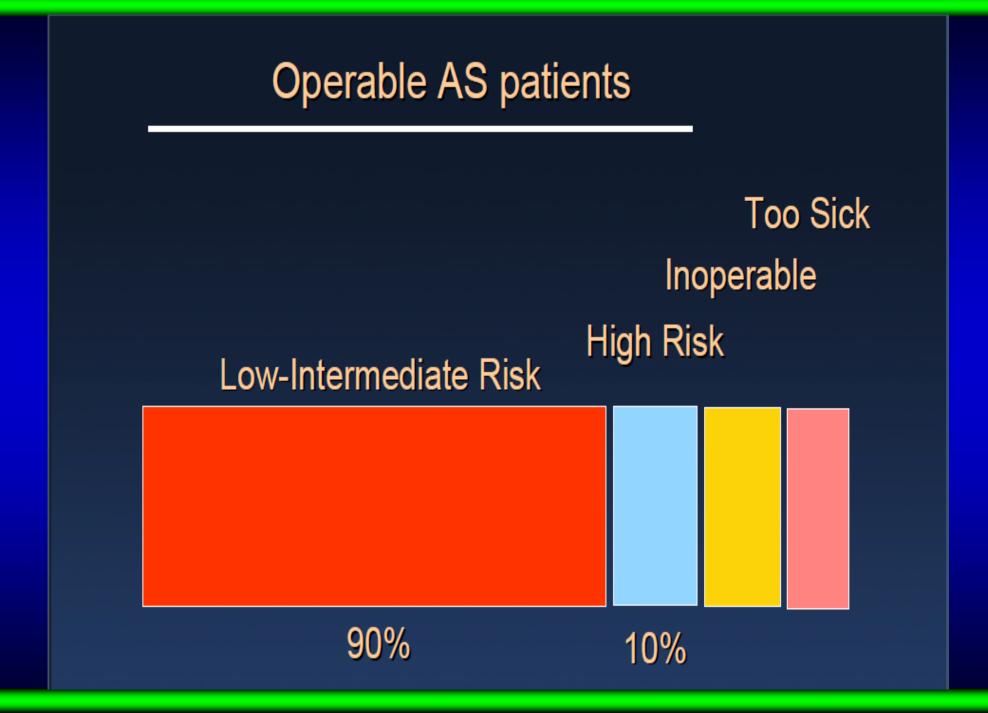
European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 & European Journal of Cardio-Thoracic Surgery 2012 doi:10.1093/ejcts/ezs455).

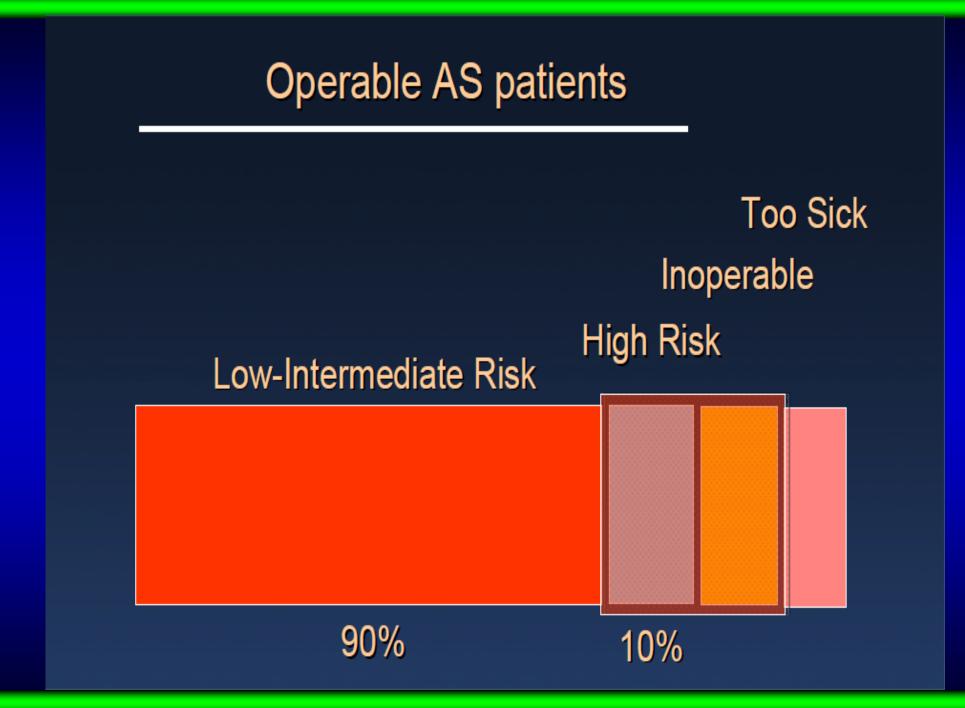


Regional Guidelines for TAVI implantation

Indicazioni all'impianto di protesi aortiche trans-catetere (Percutanee e Transapicali) D.G.R. n° 16 – 11109 del 30/03/2009

- 1. Stenosi aortica valvolare severa
- 2. Elevato/proibitivo rischio chirurgico: Euroscore additivo > 10
- 3. Parere multidisciplinare di non operabilità
- 4. Parere combinato cardiologo interventista, cardiochirurgo, anestesista rianimatore
- 5. Presenza di unità operativa di cardiochirurgia
- 6. Parere del paziente (l'esplicita richiesta del pz non può essere considerata un'indicazione al trattamento)
- 7. Consenso informato scritto





RISK SCORE

✓ EUROSCORE Logistic
 ✓ EUROSCORE Standard
 ✓ EUROSCORE II
 ✓ STS score

PROCEDURAL SUCCESS

- LEE score
- ADL score
- 15 feets walking test
- Prension test

FRAILTY

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. Zoccai^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

J Cardiovasc Med 2013, 14:894–898

In TAVI patients, ACEF score, STS score and Logistic Euroscore provided <u>only a moderate correlation</u> <u>and a low accuracy</u> both for 30-day and medium-term outcomes.

<u>Dedicated scores</u> are needed to properly tailor time and kind of approach.

PREDICTORS

• BASELINE

• PROCEDURAL

• PERI-PROCEDURAL COMPLICATION

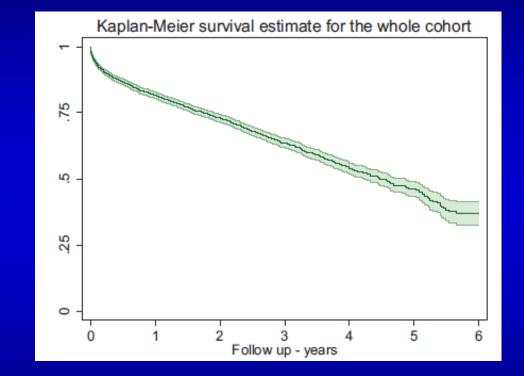
Transcatheter Aortic Valve Implantation in the United Kingdom

Temporal Trends, Predictors of Outcome, and 6-Year Follow-Up: A Report From the UK Transcatheter Aortic Valve Implantation (TAVI) Registry, 2007 to 2012

Ludman et al. Circulation. 2015;131:1181-1190. DOI: 10.1161

- moderately impaired left ventricular function (left ventricular ejection fraction, 30%–49%)
- peripheral vascular disease
- COPD
- creatinine >200 μmol/L
- Logistic EuroSCORE, ≥40

At multivariate analysis only <u>Logistic EuroSCORE, \geq 40 was independent predictor of 30-days mortality.</u>



The 30-day mortality: 9.7% in in 2007 and 2008 and 5.8% in 2012(*P*=0.089).

30-day mortality

Predictors of mortality at 3 and 5 years

Long-Term Outcomes After Transcatheter
Aortic Valve Replacement in High-Risk
Patients With Severe Aortic Stenosis

The U.K. Transcatheter Aortic Valve Implantation Registry

					5 ye	ars
Renal dysfunction	LOW EF	atrial fibrillation,	logistic EuroSCORE > 18.5	chronic obstructive pulmonary disease	Age	CAD
					Duncan et al, J Am Co	ll Cardiol Intv 2015;8:645–53

Original Investigation

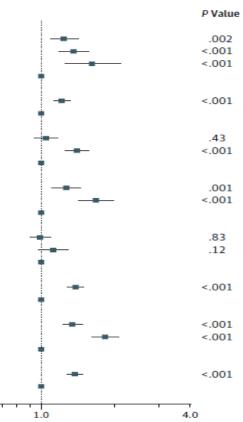
Clinical Outcomes at 1 Year Following Transcatheter Aortic Valve Replacement

David R. Holmes Jr, MD; J. Matthew Brennan, MD, MPH; John S. Rumsfeld, MD, PhD; David Dai, PhD; Sean M. O'Brien, PhD; Sreekanth Vemulapalli, MD; Fred H. Edwards, MD; John Carroll, MD; David Shahian, MD; Fred Grover, MD; E. Murat Tuzcu, MD; Eric D. Peterson, MD, MPH; Ralph G. Brindis, MD, MPH; Michael J. Mack, MD; for the STS/ACC TVT Registry

JAMA. 2015;313(10):1019-1028. doi:10.1001/jama.2015.1474

Figure 2. Multivariate Risk-Adjusted Outcome of Mortality

	Mo	Hazard Ratio		
	No./Total	% (95% CI)	(95% CI)	
Age, y				
75-84	934/4652	23.8 (22.4-25.2)	1.23 (1.08-1.41)	
85-94	1203/5726	24.5 (23.2-25.7)	1.35 (1.18-1.55)	
≥95	72/258	31.4 (25.3-37.7)	1.61 (1.24-2.09)	
<75	241/1546	18.9 (16.8-21.2)	1 [Reference]	
Sex				
Male	1273/5848	25.8 (24.6-27.1)	1.21 (1.12-1.31)	
Female	1176/6316	21.7 (20.6-22.8)	1 [Reference]	
COPD				
Moderate	376/1709	25.9 (23.6-28.3)	1.04 (0.94-1.17)	
Severe	457/1640	33.1 (30.5-35.7)	1.39 (1.25-1.55)	
None/mild	1597/8694	21.6 (20.6-22.5)	1 [Reference]	
Renal function				
Creatinine ≥2 mg/dL without dialysis	221/798	31.5 (28.0-35.1)	1.26 (1.10-1.44)	
Dialysis	163/474	41.0 (35.9-46.0)	1.66 (1.41-1.95)	
Creatinine <2 mg/dL without dialysis	2056/10861	22.3 (21.4-23.2)	1 [Reference]	
LVEF, %				
30-45	476/2177	25.7 (23.7-27.8)	0.99 (0.90-1.09)	
<30	215/836	30.4 (26.9-34.0)	1.11 (0.97-1.28)	
>45	1689/8803	22.6 (21.6-23.6)	1 [Reference]	
Access site				
Other	1200/5256	26.6 (25.2-27.9)	1.37 (1.27-1.48)	
Transfemoral	1211/6807	21.2 (20.1-22.3)	1 [Reference]	
STS PROM score, %				
8-15	868/3748	27.1 (25.5-28.7)	1.33 (1.21-1.46)	
>15	503/1444	39.5 (36.7-42.2)	1.82 (1.60-2.06)	
<8	1078/6988	18.6 (17.5-19.6)	1 [Reference]	
Preoperative atrial fibrillation				
Yes	1252/5086	29.0 (27.6-30.4)	1.37 (1.27-1.48)	
No	1193/7058	19.9 (18.9-21.0)	1 [Reference]	



Hazard Ratio (95% CI)

0.5

Registry of Transcatheter Aortic-Valve Implantation in High-Risk Patients

Martine Gilard et al, for the FRANCE 2 investigators, NEJM

Outcomes	All Patients (N=3195)	Transfemoral Approach (N=2361)	Transapical Approach (N=567)	Subclavian Approach (N=184)	P Value†	Edwards SAPIEN (N=2107)	Medtronic CoreValve (N=1043)	
Periprosthetic regurgitation at 30 da — no./total no. (%)	ays				0.09			
Grade 0	724/1915 (37.8)	483/1418 (34.1)	173/334 (51.8)	37/112 (33.0)		515/1256 (41.0)	203/642 (31.6)	- 8
Grade 1	875/1915 (45.7)	671/1418 (47.3)	131/334 (39.2)	58/112 (51.8)		567/1256 (45.1)	301/642 (46.9)	- 1
Grade 2	301/1915 (15.7)	251/1418 (17.7)	30/334 (9.0)	15/112 (13.4)		169/1256 (13.5)	128/642 (19.9)	X
Grade 3	15/1915 (0.8)	13/1418 (0.9)	0	2/112 (1.8)		5/1256 (0.4)	10/642 (1.6)	4
Complications at 1 yr — no. (%)								- I
Stroke								t
Major	72 (2.3)	51 (2.2)	12 (2.1)	5 (2.7)	0.88	41 (1.9)	27 (2.6)	- 1
Minor	59 (1.8)	36 (1.5)	13 (2.3)	8 (4.3)	0.07	41 (1.9)	18 (1.7)	
Myocardial infarction	37 (1.2)	20 (0.8)	10 (1.8)	6 (3.3)	0.004	16 (0.8)	20 (1.9)	4
Bleeding								t
Life-threatening	39 (1.2)	29 (1.2)	8 (1.4)	1 (0.5)	0.76	32 (1.5)	6 (0.6)	
Major	144 (4.5)	36 (1.5)	19 (3.4)	6 (3.3)	< 0.001	42 (2.0)	16 (1.5)	
Minor	236 (7.4)	161 (6.8)	54 (9.5)	13 (7.1)	0.08	166 (7.9)	70 (6.7)	
Vascular complication								
Major	150 (4.7)	129 (5.5)	11 (1.9)	8 (4.3)	0.002	57 (2.7)	47 (4.5)	
Minor	160 (5.0)	139 (5.9)	9 (1.6)	12 (6.5)	<0.001	60 (2.8)	49 (4.7)	
New pacemaker	497 (15.6)	359 (15.2)	77 (13.6)	47 (25.5)	<0.001	243 (11.5)	252 (24.2)	
Valve migration	40 (1.3)	28 (1.2)	8 (1.4)	2 (1.1)	0.91	23 (1.1)	17 (1.6)	

- an increased logistic EuroSCORE
- NYHA functional class III or IV versus class I or II
- transapical approach versus transfemoral approach
- periprosthetic regurgitation grade of 2 or higher versus a grade of less than 2

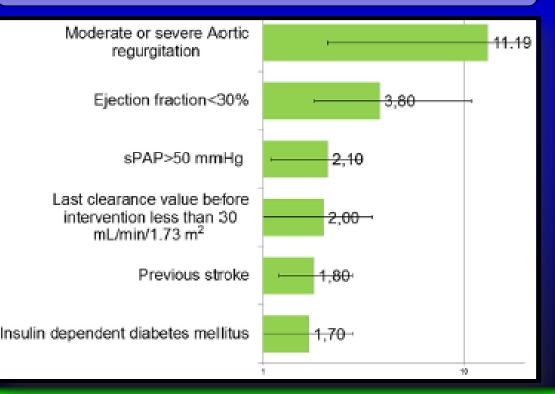
A Gender Based Analysis of Predictors of All Cause Death After Transcatheter Aortic Valve Implantation

Federico Conrotto, MD^{a,*}, Fabrizio D'Ascenzo, MD^b, Stefano Salizzoni, MD^c, Patrizia Presbitero, MD^d, Pierfrancesco Agostoni, MD, PhD^e, Corrado Tamburino, MD, PhD^f, Giuseppe Tarantini, MD, PhD^g, Francesco Bedogni, MD^h, Freek Nijhoff, MD^e, Valeria Gasparetto, MD^g, Massimo Napodano, MD^g, Giuseppe Ferrante, MD^d, Marco Luciano Rossi, MD^d, Pieter Stella, MD, PhD^e, Nedy Brambilla, MD^h, Marco Barbanti, MD^f, Francesca Giordana, MD^b, Costanza Grasso, MD^a, Giuseppe Biondi Zoccai, MDⁱ, Claudio Moretti, MD^b, Maurizio D'Amico, MD^a, Mauro Rinaldi, MD^c, Fiorenzo Gaita, MD^b,

and Sebastiano Marra, MD^a

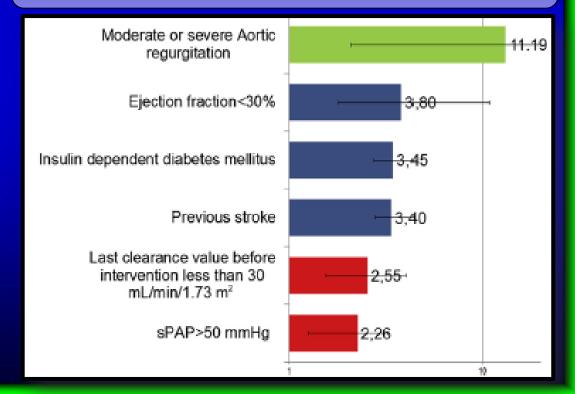
Am J Cardiol 2014;114:1269e1274

Independent predictors of adverse events at midterm follow-up in the overall population.



TAVI patients from June 2007 to December 2012 at 6 institutions 464 female and 372 male

Independent predictors of adverse events at midterm follow-up according to gender (red, female patients; blue, male patients; green, all patients).



BASELINE PREDICTORS

Effect of Gender After Transcatheter Aortic Valve Implantation: A Meta-Analysis

Federico Conrotto, MD, Fabrizio D'Ascenzo, MD, Patrizia Presbitero, MD, Karin H. Humphries, DS, John G. Webb, MD, Stephen A. O'Connor, MD, Marie-Claude Morice, MD, Thierry Lefèvre, MD, Costanza Grasso, MD, Pierluigi Sbarra, MD, Salma Taha, MD, Pierluigi Omedè, MD, Walter Grosso Marra, MD, Stefano Salizzoni, MD, Claudio Moretti, MD, Maurizio D'Amico, MD, Giuseppe Biondi-Zoccai, MD, Fiorenzo Gaita, MD, and Sebastiano Marra, MD

Ann Thorac Surg 2015;99:809–16

Six studies

6,645 patients were included 50% women EuroSCORE 26.2 vs 22.4 women vs men

30-days mortality

50 days mortanty							
	rema	le	Mak	9		Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl
Hayashida 2012	16	131	23	129	18.9%	0.64 [0.32, 1.28]	
Humpries 2012	20	306	31	278	23.3%	0.56 [0.31, 1.00]	
Partner trial	79	1212	79	1332	40.6%	1.11 [0.80, 1.53]	+
Turin 2013	16	216	15	161	17.3%	0.78 [0.37, 1.63]	
Total (95% CI)		1865		1900	100.0%	0.80 [0.56, 1.15]	•
Total events	131		148				
Heterogeneity: Tau ² = 0.06; Chi ² = 5.17, df = 3 (P = 0.16)					6); I² = 42	%	0.01 0.1 1 10 100
Test for overall effect: Z = 1.20 (P = 0.23)							Favours Female Favours Maõe

Mid-term mortality

Significantly higher risk of major bleeding, vascular complications and a lower rate of postprocedural moderate to severe aortic regurgitation in women compared with men

Chucks on Cuck many	la al Odda Datial	er.	Mainht	Odds Ratio	Odds Ratio
Study or Subgroup	log[Odds Ratio]	SE	Weight	IV, Random, 95% Cl	IV, Random, 95% Cl
Abdel-Wahab 2014	-0.27	0.132	21.8%	0.76 [0.59, 0.99]	+
Hayashida 2012	-0.21	0.31	4.0%	0.81 [0.44, 1.49]	
Humpries 2012	-0.22	0.193	10.2%	0.80 [0.55, 1.17]	
Partner trial	-0.18	0.094	43.1%	0.84 [0.69, 1.00]	
Turin 2013	-0.22	0.25	6.1%	0.80 [0.49, 1.31]	-+
Zahn 2013	-0.12	0.16	14.9%	0.89 [0.65, 1.21]	+
Total (95% CI)			100.0%	0.82 [0.73, 0.93]	•
Heterogeneity: Tau ² =	0.00 Chi ² = 0.59				
Test for overall effect:		0.01 0.1 1 10 100 Favors Females Favors Males			

Impact of Diabetes Mellitus on Early and Midterm Outcomes After Transcatheter Aortic Valve Implantation (from a Multicenter Registry)

Conrotto et al Am J Cardiol 2014;113:529e534

Variable	Diabetes Mellitus							
	None	Orally Treated	Insulin Treated	Value				
	(n = 361),	(n = 78),	(n = 72),					
	n (%)	n (%)	n (%)					
Valve				0.38				
Core valve	190 (52.6)	53 (67.9)	29 (40.3)					
Edwards SAPIEN	171 (47.4)	25 (32.1)	43 (59.7)					
Approach				0.38				
Transapical	87 (24.1)	13 (16.7)	19 (26.4)					
Transfemoral	206 (57.1)	46 (59)	43 (59.7)					
Trans-subclavian	68 (18.8)	19 (24.3)	10 (13.9)					
In-hospital outcomes								
Death (any cause)	17 (4.7)	5 (6.4)	7 (9.7)	0.09				
Cardiovascular	16 (4.4)	5 (6.4)	6 (8.3)	0.15				
death								
TIA	2 (0.5)	1 (1.2)	0	0.81				
Stroke	5 (1.4)	1 (1.2)	3 (4.1)	0.1				
Bleeding (major	158 (43.8)	33 (42.3)	29 (40.3)	0.57				
and life								
threatening)								
Major vascular	25 (6.9)	3 (3.8)	8 (11.1)	0.42				
complication								
Periprocedural	3 (0.85)	0	2 (2.8)	0.25				
myocardial								
infarction								
Myocardial	0	0	1 (1.4)	0.05				
infarction >72 h								
Acute kidney injury	74 (20.5)	19 (24.3)	15 (20.1)	0.76				

Procedural characteristics and in-hospital outcomes

Diabetes does <u>not significantly affect rates of</u> <u>procedural complications</u> in TAVI patients, but a trend of higher short-term mortality in diabetic patients was recorded Impact of Diabetes Mellitus on Early and Midterm Outcomes After Transcatheter Aortic Valve Implantation (from a Multicenter Registry)

Mid-term follow-up

Am J Cardiol 2014;113:529e534

Midterm follow-up events									
Variable	Diabetes Mellitus								
	None (n = 361), n (%)	•	Insulin Treated (n = 72), n (%)	p Value					
Death	67 (18.6)	13 (16.6)	24 (33.3)	0.01*					
Cardiovascular death	42 (11.6)	8 (10.2)	11 (15.3)	0.51					
Stroke	9 (2.4)	1 (1.3)	4 (5.5)	0.27					
Transient ischemic attack	4 (1.1)	0	1 (1.4)	0.91					
Myocardial infarction	5 (1.4)	0	6 (8 3)	0.002*					
Reintervention	3 (0.8)	0	0	0.29					

After multivariable adjustment, insulin-treated DM was independently correlated with death and myocardial infarction

Mid-term prognostic value of coronary artery disease in patients undergoing transcatheter aortic valve implantation: A meta-analysis of adjusted observational results

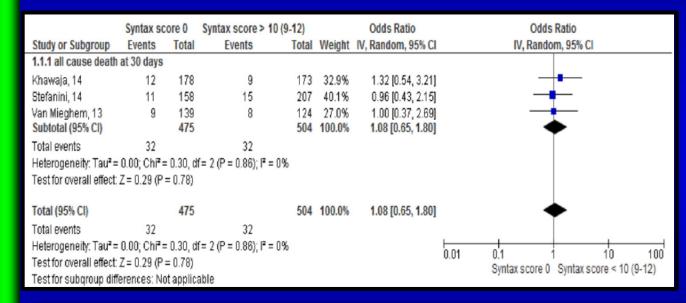
F. D'Ascenzo^{I, I,} ▲ ^{1,} ▲ F. Conrotto^{I,}, F. Giordana^I, C. Moretti^{I, I}, M. D'Amico^I, S. Salizzoni^J, P. Omedè^I, M. La Torre^J, M. Thomas^a, Z. Khawaja^a, D. Hildick-Smith^b, Gp. Ussia^c, M. Barbanti^{c, d}, C. Tamburino^c, John Webb^d, R.B. Schnabel^e, M. Seiffert^e, S. Wilde^e, H. Treede^e, V. Gasparetto^f, M. Napodano^f, G. Tarantini^f, P. Presbitero^g, M. Mennuni^g, M.L. Rossi^g, M. Gasparini^m, G. Biondi Zoccai^{h, I}, M. Lupo^k, M. Rinaldi^J, F. Gaita^I, S. Marra^I

Odds Ratio Odds Ratio SE Weight IV, Random, 95% Cl Study or Subgroup log[Odds Ratio] IV, Random, 95% Cl Dewey, 10 3.67 [0.02, 887.05] 1.3 2.8 0.5% 2472 patients Gasparetto, 11 0.08 0.79 6.8% 1.08 [0.23, 5.10] mean follow-up 452 d Moat, 11 0.09 0.37 31.0% 1.09 [0.53, 2.26] Presbitero, 12 0.08 0.88 5.5% 1.08 [0.19, 6.08] (357 - 585)Schnabel, 12 -0.02 0.53 15.1% 0.98 [0.35, 2.77] Torino, 12 0.08 0.97 4.5% 1.08 [0.16, 7.25] -0.11 0.34 36.7% Ussia, 12 0.90 [0.46, 1.74] Total (95%CI) 100.0% 1.00 [0.67, 1.50] Heterogeneity: Tau² = 0.00; Chi² = 0.41, df = 6 (P = 1.00); l² = 0% 0.1 0.01 100 Test for overall effect: Z = 0.02 (P = 0.98) Patients without CAD Patients with CAD

Int J Cardiol. 2013 Oct 3;168(3):2528-32.

Impact of residual coronary artery disease on patients undergoing TAVI: A meta-analysis of adjusted observational studies

Salma Taha ^{a,c,*,1}, Claudio Moretti ^a, Fabrizio D'Ascenzo ^a, Nicolas M. Van Mieghem ^d, Pierluigi Omedè ^a, Antonio Montefusco ^a, Mohamed Abdel Ghany ^c, Doaa Fouaad ^c, Salwa Demitry ^c, Giuseppe Biondi Zoccai ^b, Fiorenzo Gaita ^a



Impact of residual Syntax less than 10 (9–12) on all cause death at 30 days

International Journal of Cardiology 181 (2015) 77-80

No impact of residual Syntax less than 10 (9–12) on acute myocardial infarction, stroke and AKI at 30 days

Patients with a Syntax score≤10 seem to undergo TAVI procedure without additional risk

30 days and midterm outcomes of patients undergoing percutaneous replacement of aortic valve according to their renal function: A multicenter study

Fabrizio D'Ascenzo ^a, Claudio Moretti ^a, Stefano Salizzoni ^b, Mario Bollati ^a, Maurizio D'Amico ^a, Flavia Ballocca ^a, Francesca Giordana ^a, Marco Barbanti ^d, Gian Paolo Ussia ^d, Nedy Brambilla ^c, Francesco Bedogni ^c, Giuseppe Biondi Zoccai ^e, Corrado Tamburino ^a, Fiorenzo Gaita ^d, Imad Sheiban ^{a,*}

International Journal of Cardiology 167 (2013) 1514–1518

- 72 patients with a preserved renal function 219 with moderate CKD 73 with severe CKD
- Period: January 2007 to December 2011
- Median follow-up of 540±250 days

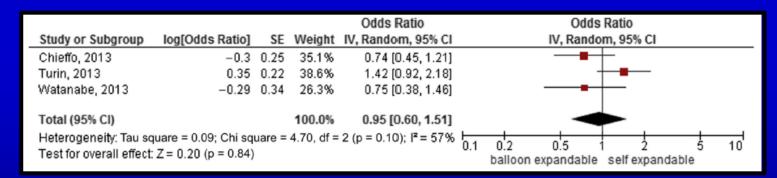
Patients with severe renal disease showed a trend toward a high risk of complications, bleeding and stroke, and of death

After TAVI implantation especially patients with severe kidney impairment showed an improvement in renal function

PROCEDURAL and POST-PROCEDURAL PREDICTORS

Meta-Analysis of Comparison Between Self-Expandable and Balloon-Expandable Valves for Patients Having Transcatheter Aortic Valve Implantation

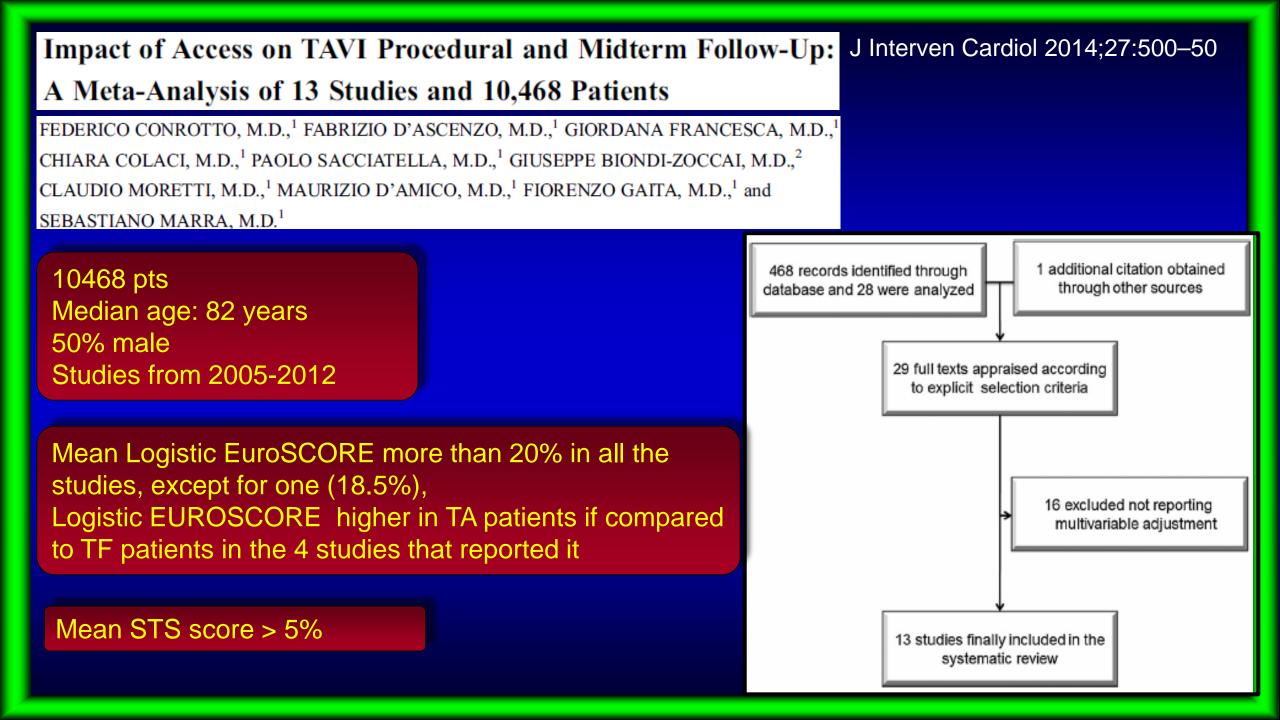
Claudio Moretti, PhD^a, Fabrizio D'Ascenzo, MD^a, Marco Mennuni, MD^b, Salma Taha, MD^{a,c,*}, Nedy Brambilla, MD^d, Freek Nijhoff, MD^e, Chiara Fraccaro, MD^f, Marco Barbanti, MD^g,
 Corrado Tamburino, MD^g, Giuseppe Tarantini, MD^f, Marco L. Rossi, MD^b, Patrizia Presbitero, MD^b,
 Massimo Napodanno, MD^f, Pieter Stella, PhD^e, Francesco Bedogni, MD^d, Pierluigi Omedè, MD^a,
 Federico Conrotto, MD^h, Antonio Montefusco, MD^a, Francesca Giordana, MD^a,
 Giuseppe Biondi Zoccai, MDⁱ, Piefrancesco Agostoni, PhD^e, Maurizio D'Amico, MD^h,
 Mauro Rinaldi, MD^j, Sebastiano Marra, MD^h, and Fiorenzo Gaita, MD^a



Mortalità a lungo termine

Am J Cardiol 2015;115:1720e1725

Risks of moderate or severe AR and pacemaker implantation were lower with the balloon-expandable devices



A Meta-Analysis of 13 Studies and 10,468 Patients

J Interven Cardiol 2014;27:500–50

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Random, 95% C	Odds Ratio I IV, Random, 95% CI
Amabile, 25	-0.48	0.04	19.2%	0.62 [0.57, 0.67]	•
Pilgrim, 24	-0.25	0.04	19.2%	0.78 [0.72, 0.84]	-
SOURCE, 20	-0.3	0.02	20.7%	0.74 [0.71, 0.77]	•
Turin, 21	-0.4	0.02	20.7%	0.67 [0.64, 0.70]	-
Van der Boon, 26	-0.11	0.03	20.1%	0.90 [0.84, 0.95]	
Total (95% CI)			100.0%	0.74 [0.66, 0.82]	•
Heterogeneity: Tau ² = 0	.02; Chi ² = 84.96, d				
Test for overall effect: Z	= 5.44 (P < 0.0000	0.01 0.1 1 10 100 Favors Transfemoral Favors Transapical			

Pooled adjusted odds ratio for peri-procedural bleedings

A Meta-Analysis of 13 Studies and 10,468 Patients

J Interven Cardiol 2014;27:500-50

Study or Subgroup	log[Odds Ratio] S	E Weight	Odds Ratio IV, Random, 95% C	Odds Ratio IV, Random, 95% Cl			
Pilgrim, 24	-0.06 0.0	4 29.9%	0.94 [0.87, 1.02]	•			
SOURCE, 20	-0.17 0.0	2 36.6%	0.84 [0.81, 0.88]	•			
Turin, 21	-0.05 0.0	3 33.5%	0.95 [0.90, 1.01]	•			
Total (95% Cl)		100.0%	0.91 [0.83, 0.99]	•			
Heterogeneity: Tau ² = 0.01; Chi ² = 13.92, df = 2 (P = 0.0009); l ² = 86% Test for overall effect: Z = 2.18 (P = 0.03) Image: Constraint of the second							

Pooled adjusted odds ratio for peri-procedural stroke

A Meta-Analysis of 13 Studies and 10,468 Patients

J Interven Cardiol 2014;27:500–50

				Odds Ratio	Odds	Ratio
Study or Subgroup	log[Odds Ratio]	SE	Weight	IV, Random, 95% C	I IV, Rando	m, 95% Cl
Hemman, 15	-0.42	0.02	16.8%	0.66 [0.63, 0.68]		
Schymik, 18	0.29	0.04	16.4%	1.34 [1.24, 1.45]		•
SOURCE, 20	-0.32	0.02	16.8%	0.73 [0.70, 0.76]		
Turin, 21	-0.29	0.02	16.8%	0.75 [0.72, 0.78]	•	
Van der Boon, 26	-0.49	0.03	16.6%	0.61 [0.58, 0.65]		
Wenaweser, 22	0	0.03	16.6%	1.00 [0.94, 1.06]		•
Total (95% CI)			100.0%	0.81 [0.68, 0.97]	*	
Heterogeneity: Tau ² = 0	0.05; Chi ² = 392.26,		10 100			
Test for overall effect: 2	Z = 2.32 (P = 0.02)				0.01 0.1 favors Transfemoral	10 100 Favors Transapical

Pooled adjusted odds ratio for 30-days mortality

A Meta-Analysis of 13 Studies and 10,468 Patients

J Interven Cardiol 2014;27:500-50

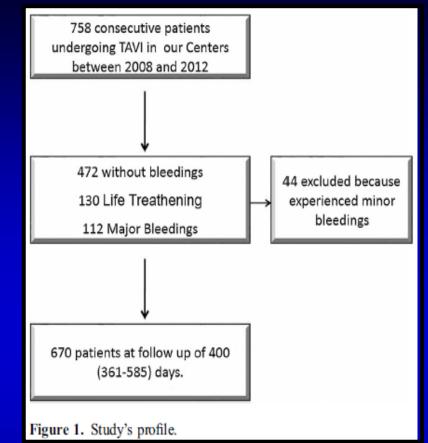
				Odds Ratio	Odds Ratio	
Study or Subgroup	log[Odds Ratio]	SE	Weight	IV, Random, 95% Cl	IV, Random, 95% CI	
Gilard, 14	-0.16	0.08	6.4%	0.85 [0.73, 1.00]	-	
Hemman, 15	-0.07	0.02	10.7%	0.93 [0.90, 0.97]	-	
Himbert, 16	-0.42	0.04	9.4%	0.66 [0.61, 0.71]	-	
Moat, 17	-0.14	0.024	10.5%	0.87 [0.83, 0.91]	-	
Schymik, 18	0.13	0.03	10.1%	1.14 [1.07, 1.21]	-	
Smith, PARTNER,19	-0.12	0.02	10.7%	0.89 [0.85, 0.92]	-	
SOURCE, 20	-0.15	0.01	11.1%	0.86 [0.84, 0.88]	-	
Turin, 21	-0.2	0.01	11.1%	0.82 [0.80, 0.83]	-	
Van der Boon, 26	-0.28	0.02	10.7%	0.76 [0.73, 0.79]	-	
Webb, 23	-0.27	0.04	9.4%	0.76 [0.71, 0.83]	•	
Total (95% CI)			100.0%	0.85 [0.80, 0.90]	•	
Heterogeneity: Tau ² = 0.01; Chi ² = 220.50, df = 9 (P < 0.00001); l ² = 96%						
Test for overall effect: Z		0.01 0.1 1 10 100 FavorsTransfemoral Favors Transapical				

Pooled adjusted odds ratio for mid-term mortality (1 y)

Impact on Prognosis of Periprocedural Bleeding after TAVI: Mid-Term Follow-Up of a Multicenter Prospective Study

CLAUDIO MORETTI, M.D.,^{1,2} MAURIZIO D'AMICO, M.D.,³ FABRIZIO D'ASCENZO, M.D.,¹ CHIARA COLACI, M.D.,¹ STEFANO SALIZZONI, M.D.,⁴ CORRADO TAMBURINO, M.D.,⁵ PATRIZIA PRESBITERO, M.D.,³ SEBASTIANO MARRA, M.D.,⁴ IMAD SHEIBAN,² and FIORENZO GAITA¹

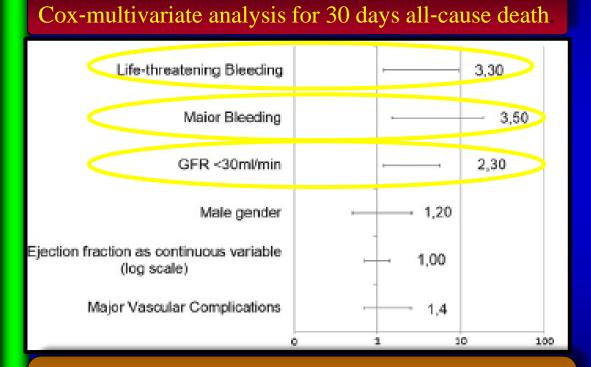
J Interven Cardiol 2014;27:293-299



At 30 days and mid-term follow-up all-cause and cardiovascular deaths were higher in patients with bleeding compared to the "no bleeding" group

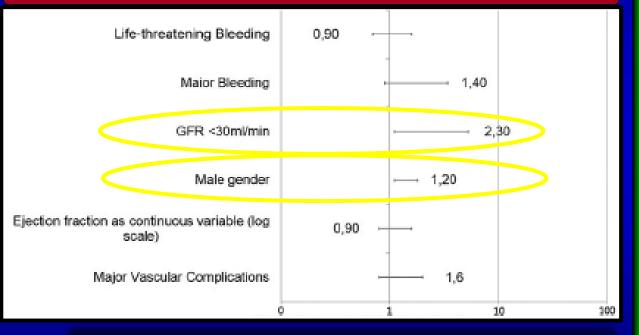
Impact on Prognosis of Periprocedural Bleeding after TAVI: Mid-Term Follow-Up of a Multicenter Prospective Study

J Interven Cardiol 2014;27:293–299



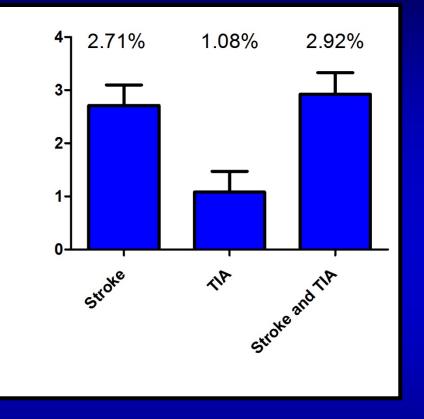
<u>Life-threatening</u> and <u>major bleedings</u>, <u>procedural GFR<30 ml/min</u> were independent predictors of death.

Cox-multivariate analysis for mid-term all-cause death

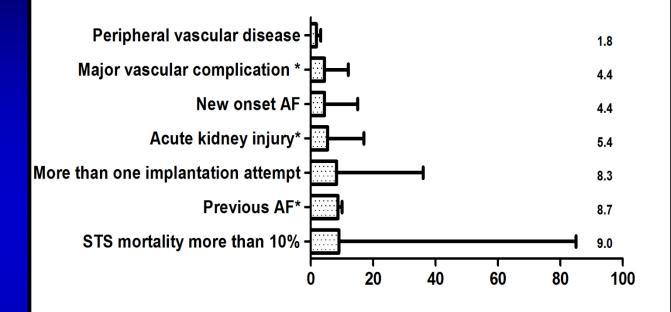


Procedural GFR<30 ml/min and male gender were independent predictors of death

STROKE and TAVI - METANALISYS



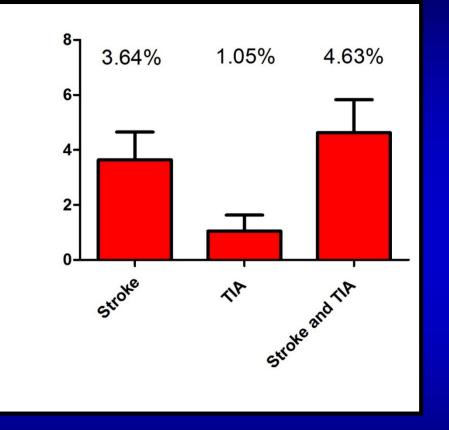
Incidence of stroke, of TIA and of stroke or TIA at 30 days.

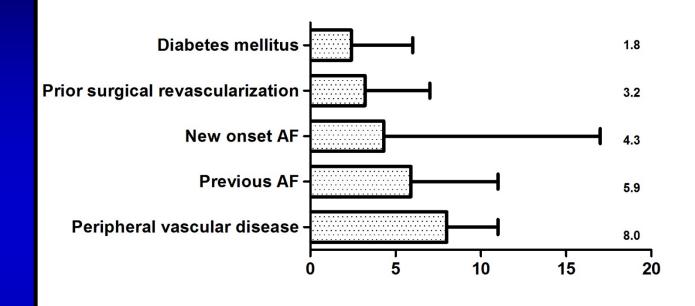


Independent predictors of stroke at 30 days (variables with * have been reported in at least two studies)

> Work in progress, Turin 2015

STROKE and TAVI - META-ANALYSIS





Independent predictors of stroke at follow up

Incidence of stroke, of TIA and of stroke or TIA after a follow up of 14 (11-17) months.

Work in progress, Turin 2015

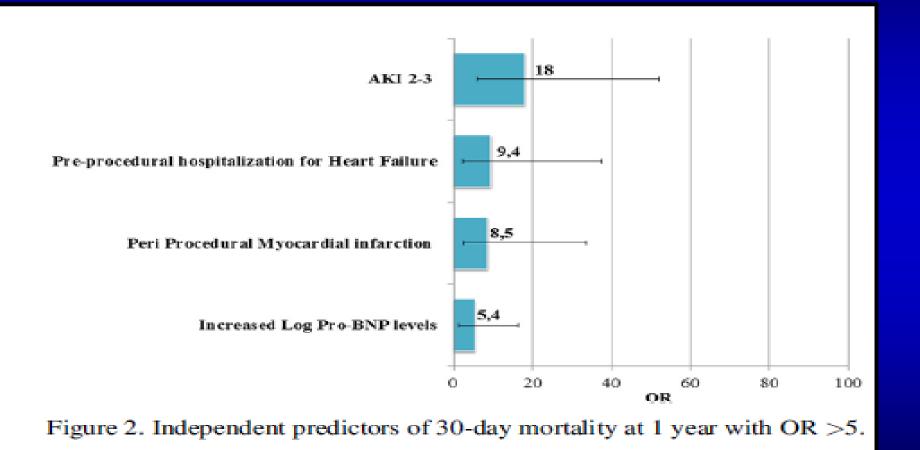
Meta-Analysis of Predictors of All-Cause Mortality After Transcatheter Aortic Valve Implantation



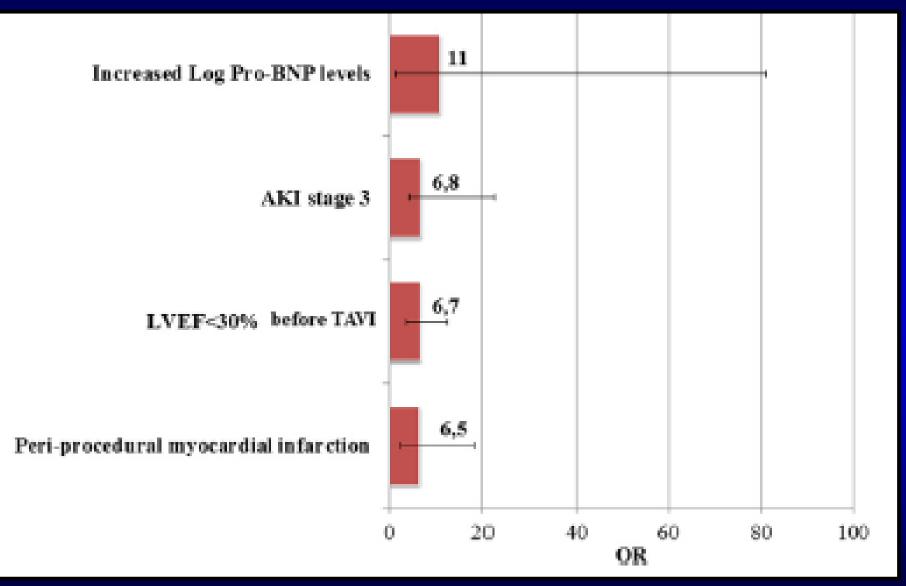
Francesca Giordana, MD^{a,*}, Fabrizio D'Ascenzo, MD^a, Freek Nijhoff, MD^b, Claudio Moretti, MD^a, Maurizio D'Amico, MD^a, Giuseppe Biondi Zoccai, MD^c, Jan Malte Sinning, MD^d, George Nickenig, MD^d, Nicolas M. Van Mieghem, MD^e, Adelaide Chieffo, MD^f, Nicolas Dumonteil, MD^g, Didier Tchetche, MD^h, Israel M. Barbash, MDⁱ, Ron Waksman, MDⁱ, Augusto D'Onofrio, MD^j, Thierry Lefevre, MD^k, Thomas Pilgrim, MD¹, Nicolas Amabile, MD^m, Pablo Codner, MD^{n,o}, Ran Kornowski, MD^{n,o}, Ze Yie Yong, MD^p, Jan Baan, MD^p, Antonio Colombo, MD^q, Azeem Latib, MD^q, Stefano Salizzoni, MD^r, Pierluigi Omedè, MD^a, Federico Conrotto, MD^a, Michele La Torre, MD^r, Sebastiano Marra, MD^a, Mauro Rinaldi, MD^r, and Fiorenzo Gaita, MD^a

Am J Cardiol 2014;114:1447–1455)

Predictors of 30-days mortality



Predictors of 1 year mortality



Usefulness and Validation of the Survival posT 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^e, 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, MD^j,
Fiorenzo Gaita, MD^a, Maurizio D'Amico, MD^h, and Claudio Moretti, MD, PhD^{a,h}

Am J Cardiol 2014;114:1867e1874

1,064 patients from 6 institution Period: January 2007- December 2012

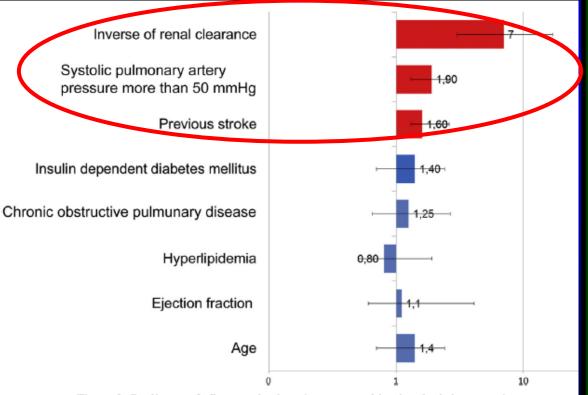


Figure 2. Predictors of all-cause death at 1 year at multivariate logistic regression.



Cardlo Group.org

TAVI STT SCORE: INSERT DATA TO COMPUTE SCORE

PAPs > 50mmHg (estin *

Previous TIA or STROF V

Clereance value estimated with MDRD...

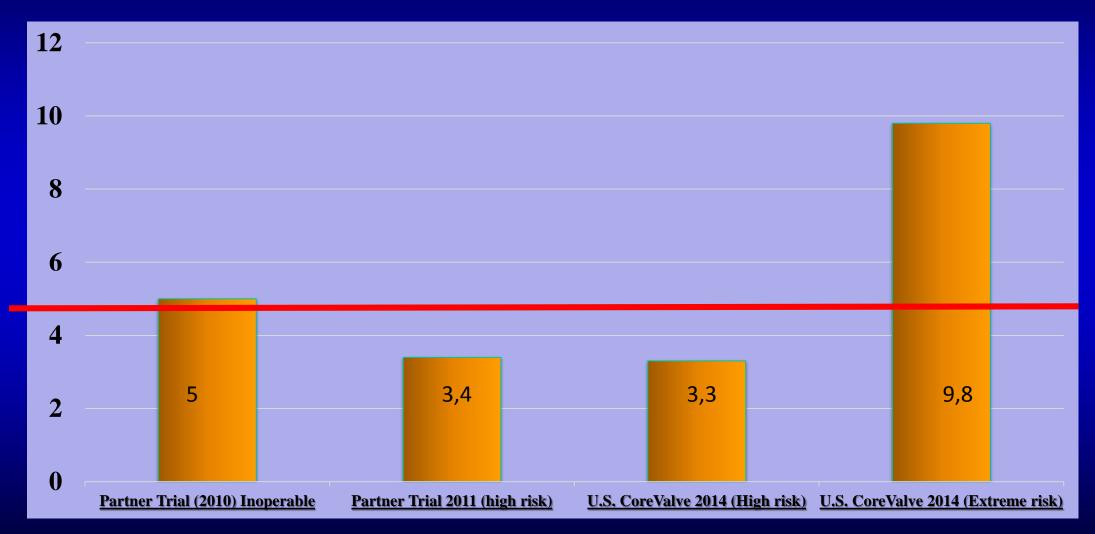
Internal ID or patient s name (optional)...

CENTRE or City (optional)...

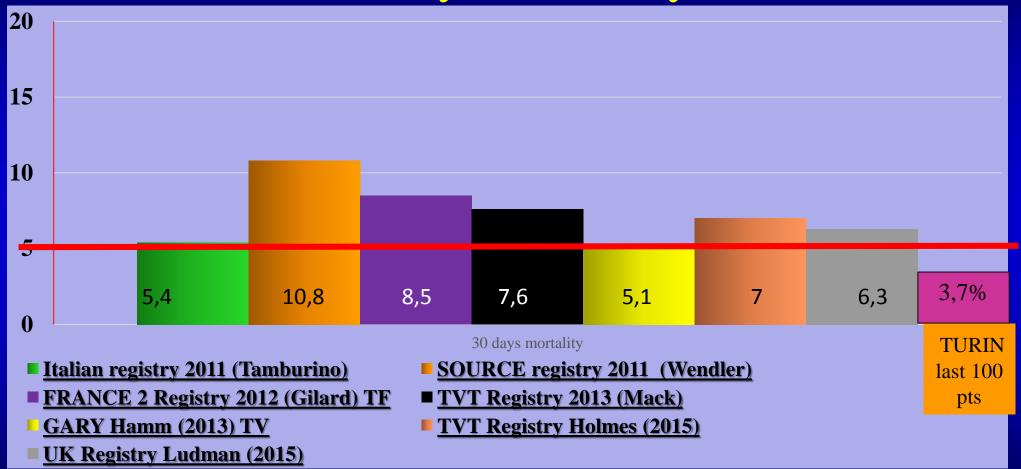
Reference: Am J Cardiol. 2014 Sep 28;114(12):1867-1874

CALCULATE

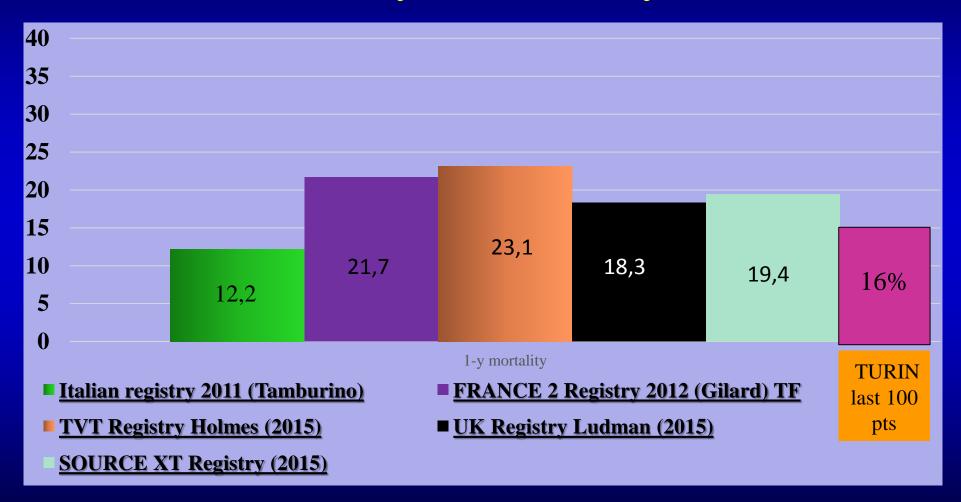
Main outcome of trials 30 days mortality



Main outcomes of principal registries 30 days mortality

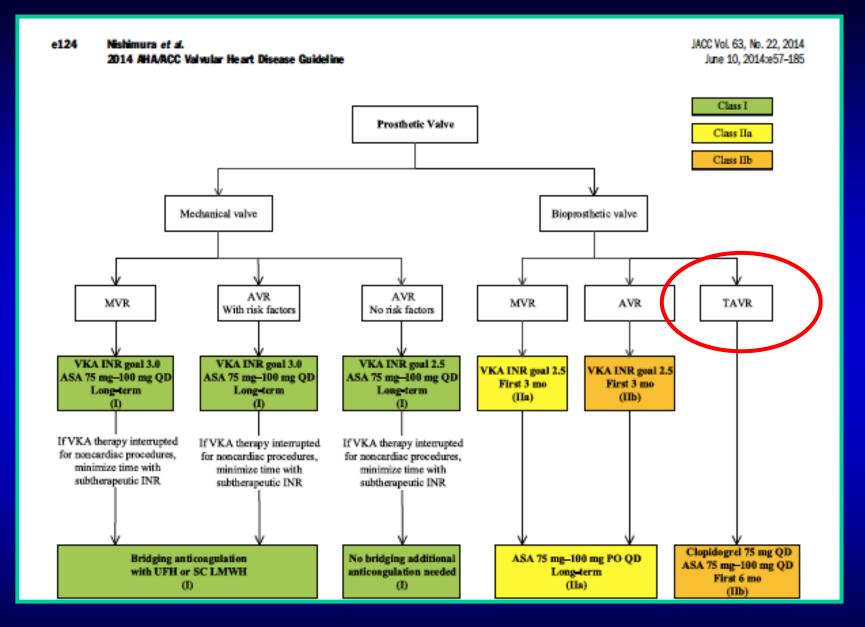


Main outcomes of principal registries 1 year mortality



ANTI-PLATELETS THERAPY





2014 AHA/ACC Valvular Heart Disease Guideline

	PARTNER Trial (17,18)	ACC/STS Recommendations (58)
Pre-procedural	Aspirin 80 mg	-
	Clopidogrel 300 mg	
Procedural	Unfractionated heparin	Unfractionated heparin
	Goal ACT: 250 s	Goal ACT: 300 s
	Reversal with protamine optional	Reversal with protamine recommended
	Bivalirudin not allowed?	Bivalirudin -not mentioned
Post-procedural (first 30 day	ys) Aspirin 81 mg/day indefinitely +	Aspirin 81 mg/day indefinitely +
	Clopidogrel 75 mg/day × 90 days	Clopidogrel 75 mg/day × 3-6 months
		If warfarin indicated (AF), then no
		clepidogrel
	CCS Statement (59)	
	000 Statement (05)	
	_	
	-	
Indefinite low-d	ose aspirin generally recommended +	
Thienopyridine	× 1-3 months	
If oral anticoas	ulant indicated (AF), avoid triple	
	ss definite indication exists	JACC Vol. 62, No. 25, 2013:2349–59





Canadian Journal of Cardiology 31 (2015) 775-784

Systematic Review/Meta-analysis

Comparison of Dual-antiplatelet Therapy to Mono-antiplatelet Therapy After Transcatheter Aortic Valve Implantation: Systematic Review and Meta-analysis

Sumeet Gandhi, MD,^a Jon-David R. Schwalm, MD, MSc,^b James L. Velianou, MD,^b Madhu K. Natarajan, MD, MSc,^b and Michael E. Farkouh, MD, MSc^c

^a Department of Medicine, Division of Cardiology, McMaster University, Hamilton, Ontario, Canada ^b Department of Medicine, Division of Cardiology, and Population Health Research Institute, McMaster University, Hamilton, Ontario, Canada ^c Peter Munk Cardiac Centre and Heart and Stroke Richard Lewar Centre of Excellence, University of Toronto, Toronto, Ontario, Canada

Conclusions: DAPT in patients who have undergone TAVI demonstrated no benefit over MAPT in reduction of ischemic events, with a trend toward increased harm because of bleeding. Future considerations should be given to MAPT with clopidogrel alone, as well as the omission of clopidogrel loading before the procedure.

Canadian Journal of Cardiology Volume 31 2015

CONCLUSIONS

• According to Guidelines only high risk patients should be treated

• Surgical risk scores fail to accurately predict mortality after transcatheter aortic valve implantation: dedicated scores are needed

• Heart Team still remain foundamental in patient's selection

• Promising performance of second generation devices

Thanks for attention