INDICATIONS FOR TAVI: PATIENTS TO IMPLANT AND PATIENTS TO AVOID

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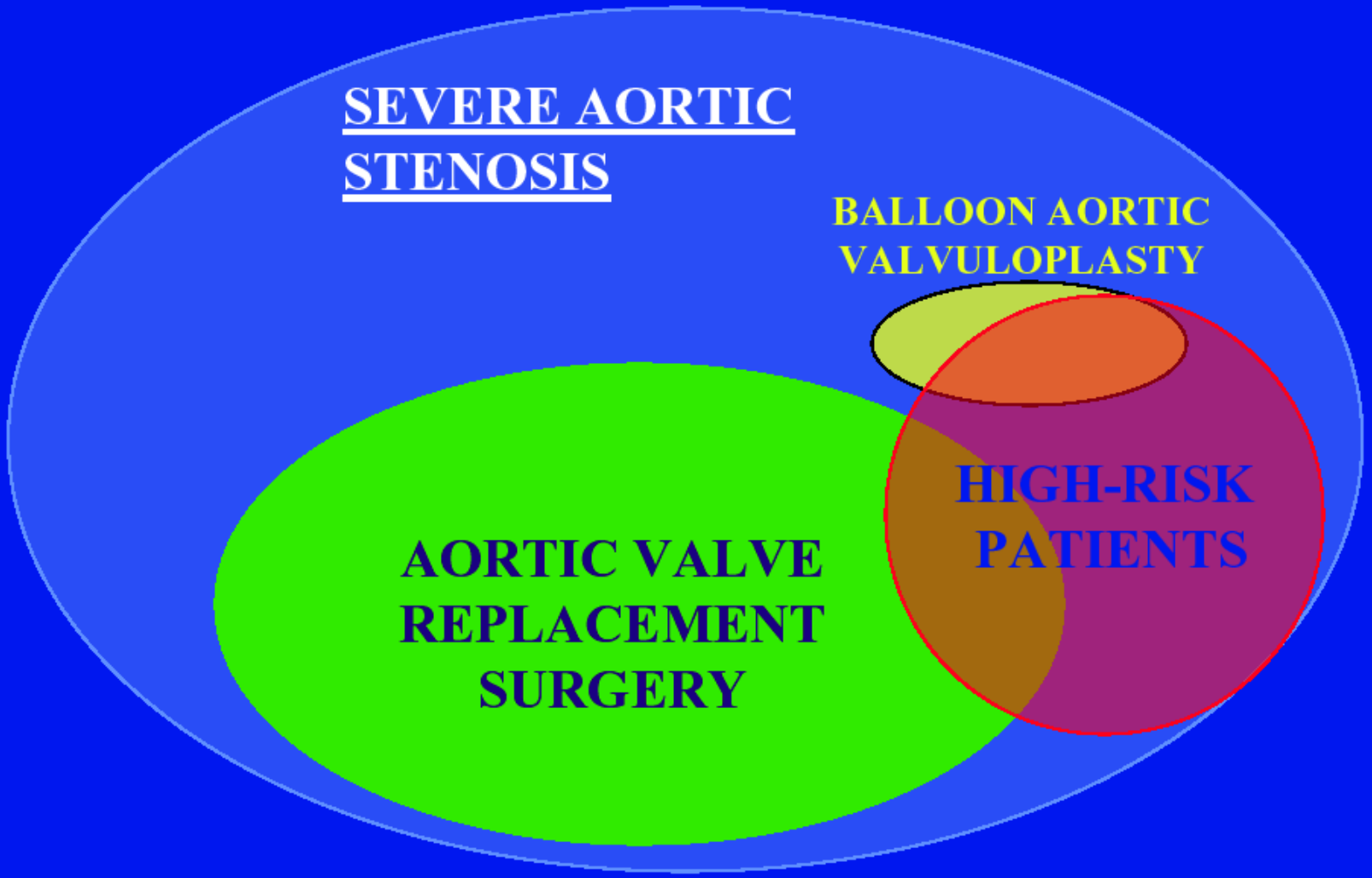
"Città della Salute e della scienza", Torino

Severe Aortic Stenosis: Therapy



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.	I	C
TAVI should only be performed in hospitals with cardiac surgery on-site.	I	C
TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a " heart team" and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities.	I	B
TAVI should be considered in high risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a "heart team" based on the individual risk profile and anatomic suitability.	IIa	B

« 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).

EACTS
EUROPEAN SOCIETY OF CARDIOLOGY®

European Heart Journal (2012) **33**, 969–976
doi:10.1093/eurheartj/ehr491

181 pts from June 2007 and August 2008 eligible for 3 years f.u

MORTALITY RATE 34,8%

CARDIOVASCULAR MORTALITY RATE 12,5%

MACCE

Conclusions

This multicentre study demonstrates that TAVI with the 18-Fr CoreValve ReValving System is associated with sustained clinical and functional cardiovascular benefits in high-risk patients with symptomatic AS up to 3-year follow-up. Non-cardiac causes accounted for the majority of deaths at follow-up.

European Heart Journal (2012) 33, 969–976

Catheter Cardiovasc Interv. 2012 Aug 6. doi: 10.1002/ccd.24597. [Epub ahead of print]

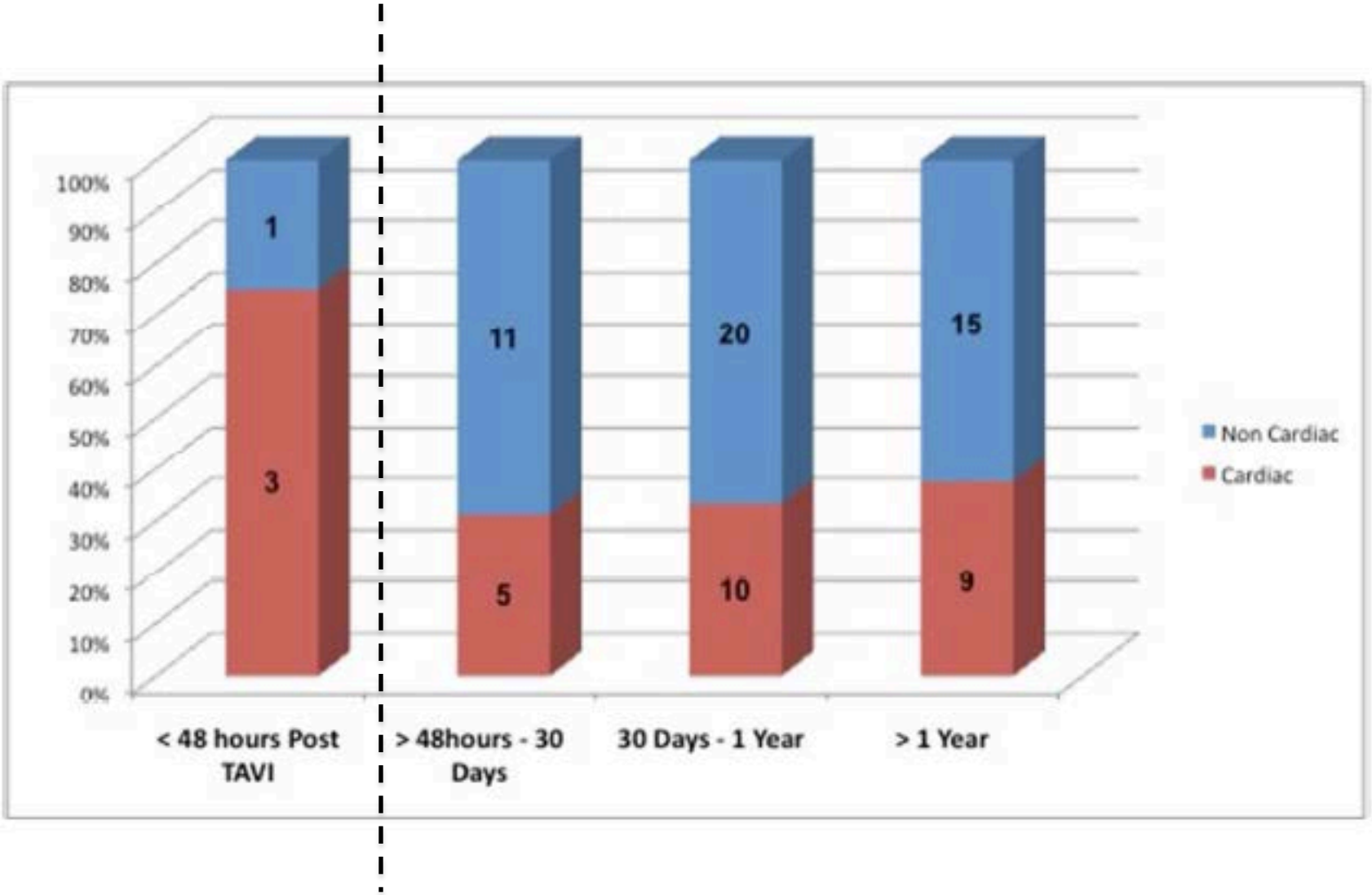
Cause of death after transcatheter aortic valve implantation.

Van Mieghem NM, van der Boon RM, Nuis RJ, Schultz C, van Geuns RJ, Serruys PW, Kappetein AP, van Domburg RT, de Jaegere PP.
Department of Interventional Cardiology, Thoraxcenter, Erasmus Medical Center, Rotterdam, the Netherlands. n.vanmieghem@erasmusmc.nl.

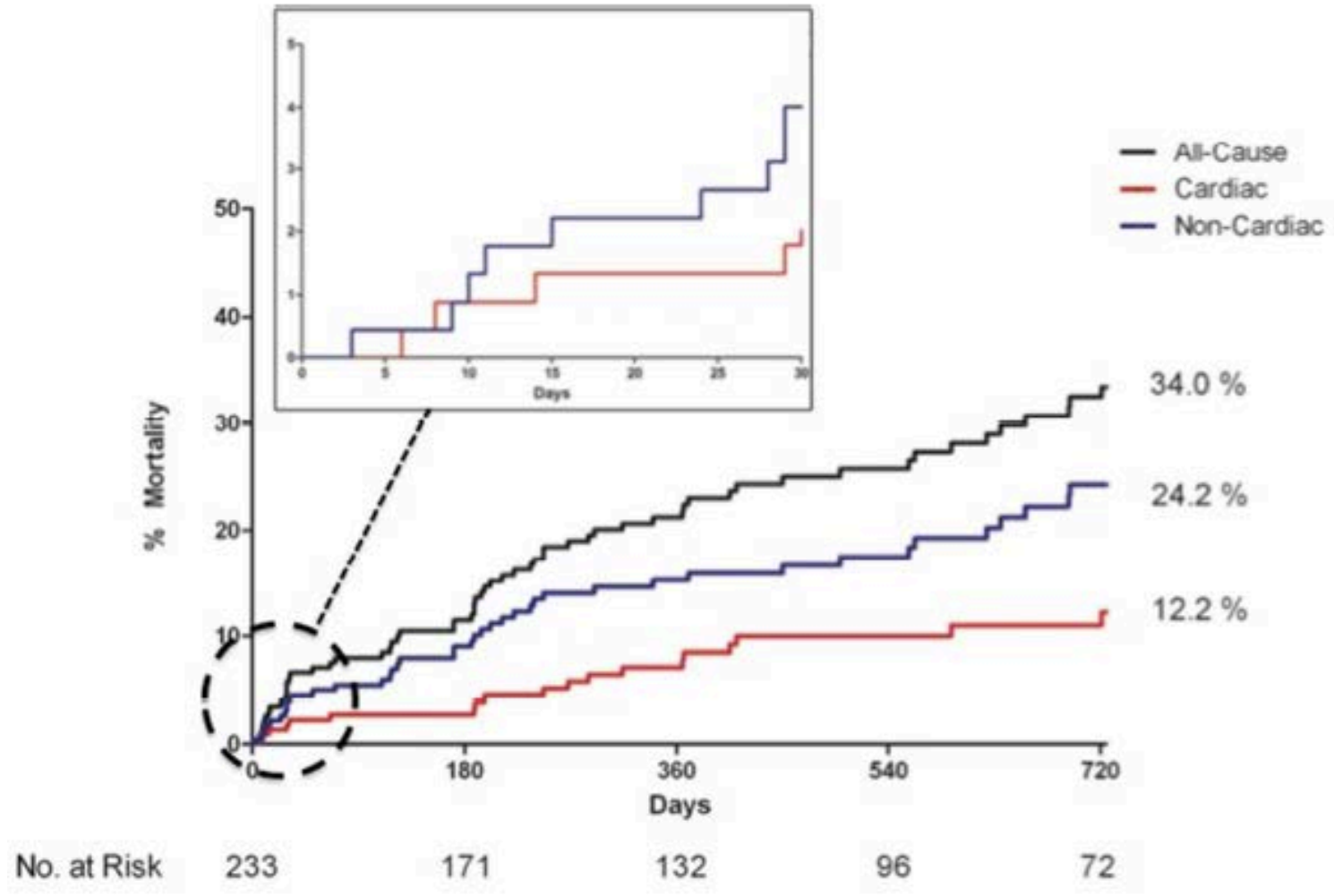
- **237 pts between November 2005 and December 2011**
- **Median follow up 13 months**

→ **31% Overall mortality at median f.u**

Catheter Cardiovasc Interv. 2012 Aug 6



Catheter Cardiovasc Interv. 2012 Aug 6



Catheter Cardiovasc Interv. 2012 Aug 6

SHOULD WE RELY ON TRADITIONAL SURGICAL RISK SCORES?

Table 6 Multivariate analysis for mid-term all-cause mortality

	HR	LCI	UCI	*P*
Age (years)	1.3	0.5	2.1	0.10
Renal clearance less than 30 ml/min/m^2	4	1.3	8	0.001
Ejection fraction (as continuous variable)	0.9	0.5	1.2	0.60
Life-threatening and major bleeding	2.1	0.6	11	0.60
Logistic Euroscore	1.3	0.8	1.6	0.30
STS mortality score	1.01	0.9	1.05	0.40
ACEF score	1.7	0.8	2.8	0.06

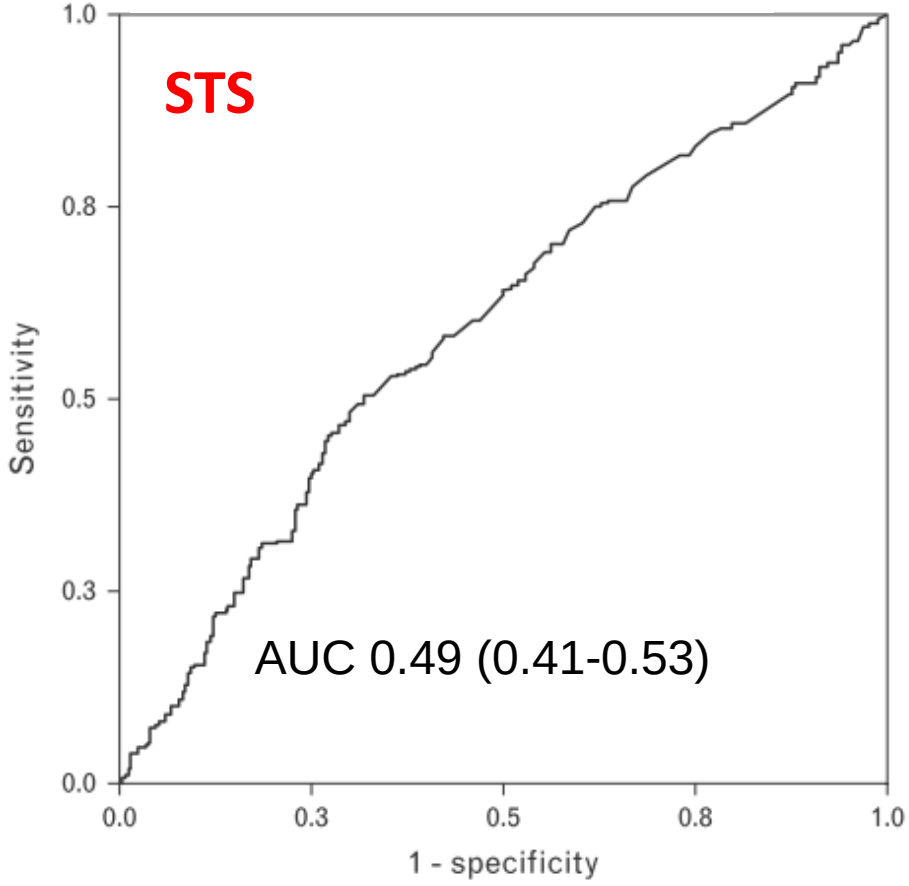
ACEF, the Age, Creatinine, and Ejection Fraction score; HR, hazard ratio; LCI, lower confidence interval; STS, the Society of Thoracic Surgeons; UCI, upper confidence interval.

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]

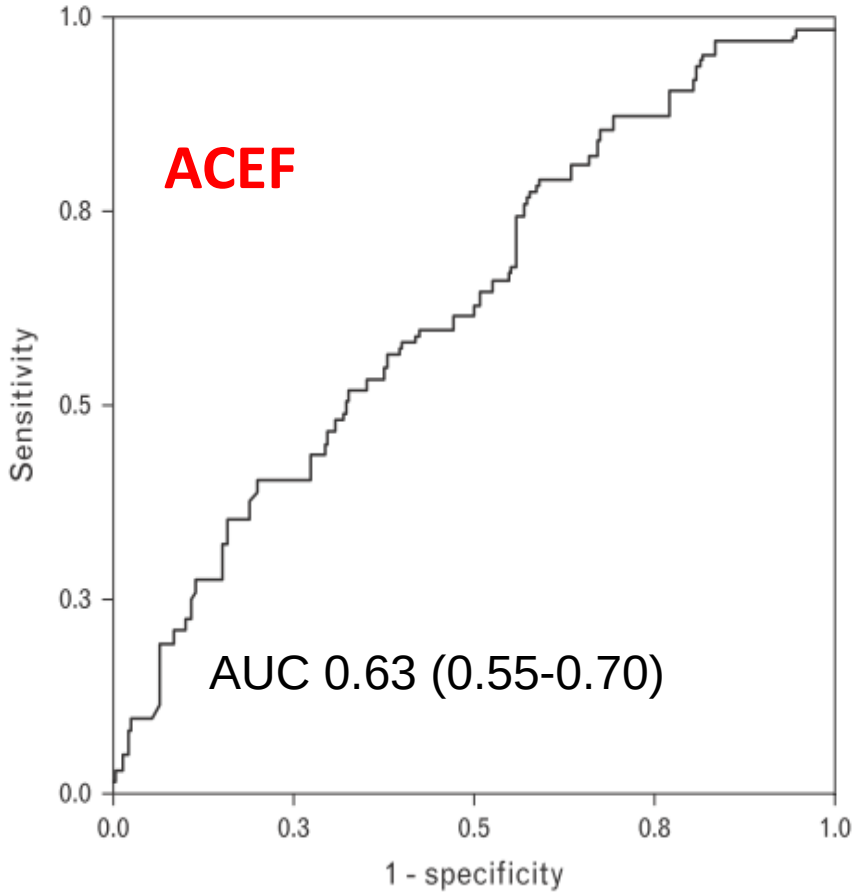
Journal of Cardiovascular Medicine 2013

IN HOSPITAL COMPLICATIONS



Area under the curve for the Society of Thoracic Surgeons mortality score and in-hospital complications.

MID TERM ALL CAUSE MORTALITY



Area under the curve for Age, Creatinine, and Ejection Fraction score for mid-term death.

Journal of Cardiovascular Medicine 2013

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HOW TO CLASSIFY RISK IN THESE PATIENTS?

We have focused on:

- Baseline features: GENDER

- Well know risk factors for intervention procedures
  - DIABETES MELLITUS
  - RENAL DISEASE
  - PREVIOUS CAD

- Echocardiographic data

- Access choice

- In Hospital complications

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GENDER DIFFERENCES

	Female patients (216)	Male patients (161)	*p*-value
Age	82.9±5.45	81.65±5.32	0.027
BSA (body surface area) m^2	1.65±0.19	1.82±0.14	<0.0001
Diabetes, insulin-dependent	8.3%	2.1%	0.046
Previous myocardial infarction	13.3%	28.6%	<0.0001
Previous percutaneous coronary intervention	29.2%	44.1%	0.018
Previous coronary artery bypass graft	5.1%	20.5%	<0.0001
Abdominal aortic aneurysm	1.1%	1.5%	0.952
Carotid artery disease[a]	22.2%	27.6%	0.018
Peripheral artery disease[a]	13.9%	33.0%	<0.0001
Previous stroke	7.8%	6.2%	0.771
Chronic obstructive pulmonary disease[b]	19.8%	38.7%	<0.0001
Last creatinine value before intervention (mg/dl)	1.21±0.54	1.47±1.0	0.002

Gender differences in patients undergoing TAVI: a multicentre study

EuroIntervention 2013;9:367-372

GENDER DIFFERENCES

	Female patients (216)	Male patients (161)	*p*-value
Pre-TAVI echo data			
Ejection fraction	54.7±11.3	49.22±13.5	<0.001
Aortic valve area, cm^2	0.60±0.19	0.64±0.189	0.119
Mean aortic gradient, mmHg	56.4±18.2	48.64±13.9	<0.001
Aortic valve insufficiency (mild, moderate and severe)	36.6%	29.8%	0.168
Aortic valve insufficiency			0.04
mild	27.8%	23.6%	
moderate	6.9%	2.5%	
severe	0.5%	3.7%	
Pulmonary hypertension	19.3%	19.1%	0.954
Severe mitral valve insufficiency	9.1%	5%	0.675
Transfemoral approach	86.1%	84.3%	0.906
Transapical approach	6.0%	9.3%	0.889
Transsubclavian approach	7.9%	9.9%	0.954
Prosthesis diameter			<0.001

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EuroIntervention 2013;9:367-372

GENDER DIFFERENCES

Table 3. 30-day events.

	Female patients (216)	Male patients (161)	*p*-value
Death from any cause*	7.4%	8.7%	0.648
Cardiovascular death*	6.0%	8.1%	0.443
Transient ischaemic attack*	1.4%	2.5%	0.611
Stroke*	3.1%	1.9%	0.492
Bleeding*	44%	25%	0.024**
life-threatening	21.1%	12.7%	0.004**
major	13.5%	9.7%	0.638
minor	9.8%	2.4%	0.068
Patients requiring transfusions	64%	35%	0.007
Major vascular complications*	12.9%	9.8%	0.449
Minor vascular complications*	11.7%	5.1%	0.073
Combined safety endpoint	31%	26%	0.318
Patients prescribed			0.694

Table 4. Long-term follow-up events.

	Female patients (216)	Male patients (161)	*p*-value
Length of follow-up (days)	502±342	481±368	0.646
Death from any cause*	22.8%	30.8%	0.143
Cardiovascular death*	10.8%	18.8%	0.071
Myocardial infarction	0%	1.5%	0.466
Transient ischaemic attack*	1.9%	3.1%	0.410
Stroke*	4.2%	1.9%	0.211

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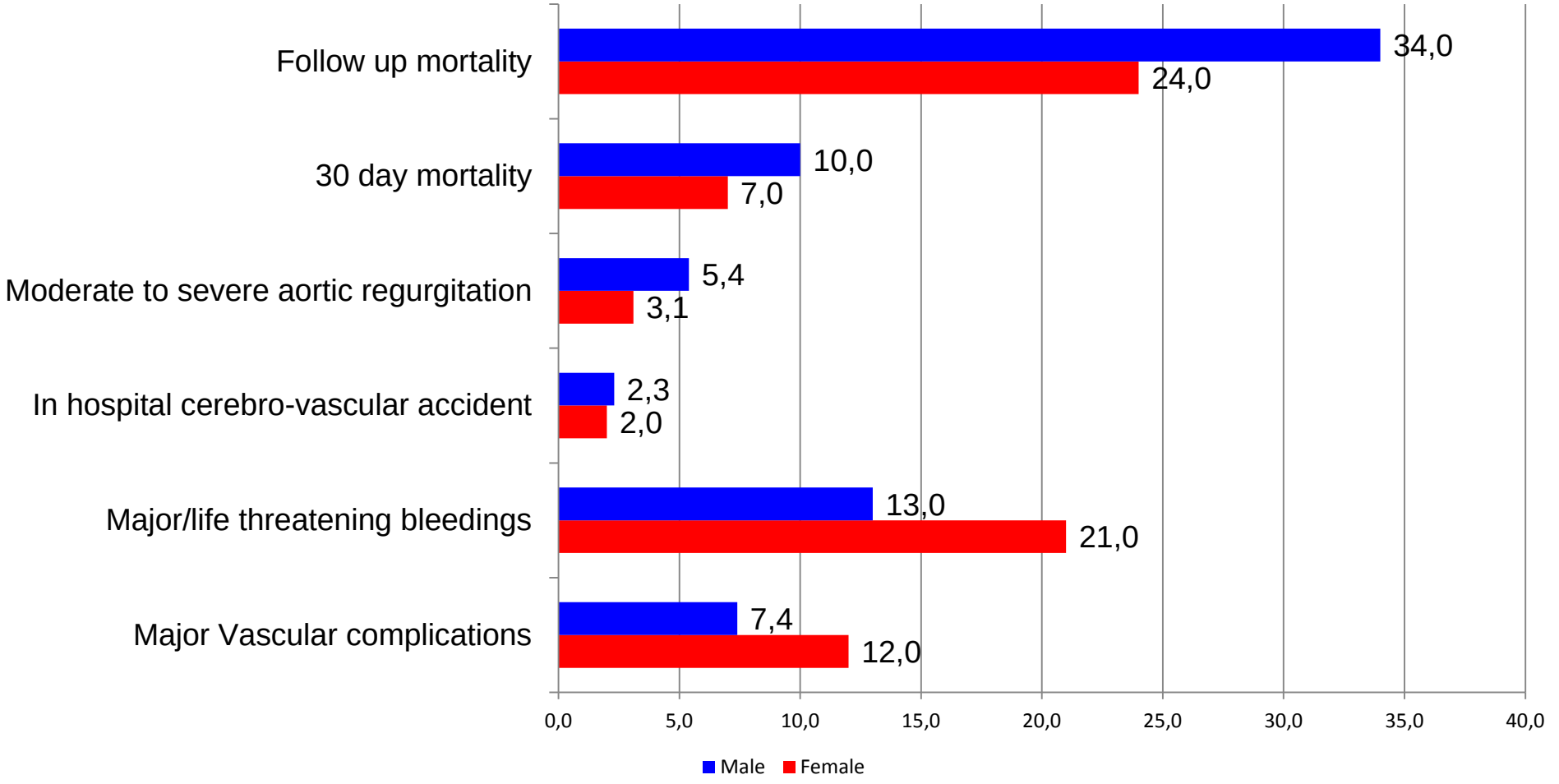
GENDER DIFFERENCES: POOLED DATA



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

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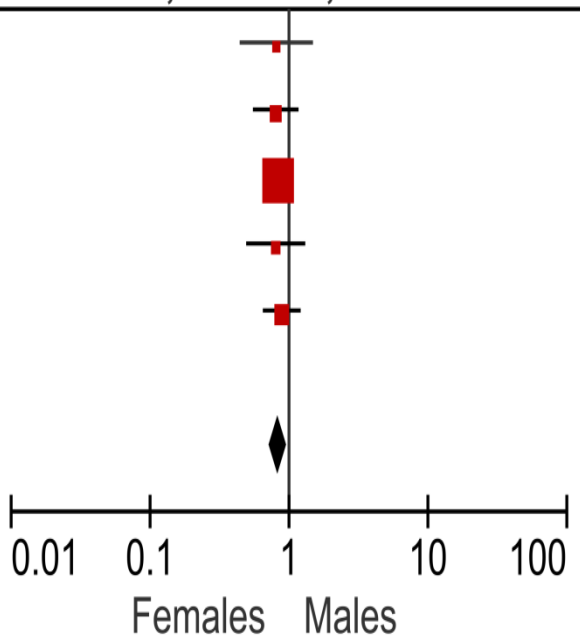
GENDER DIFFERENCES: POOLED DATA

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Random, 95% CI
Hayashida 2012	-0.21	0.31	5.1%	0.81 [0.44, 1.49]
Humpries 2012	-0.22	0.193	13.1%	0.80 [0.55, 1.17]
Partner trial	-0.18	0.094	55.1%	0.84 [0.69, 1.00]
Turin 2013	-0.22	0.25	7.8%	0.80 [0.49, 1.31]
Zahn 2013	-0.12	0.16	19.0%	0.89 [0.65, 1.21]
Total (95% CI)			**100.0%**	**0.84 [0.73, 0.96]**

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.22$, df = 4 (P = 0.99); $I^2 = 0\%$

Test for overall effect: Z = 2.56 (P = 0.01)



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GENDER DIFFERENCES: OUTCOME PREDICTORS

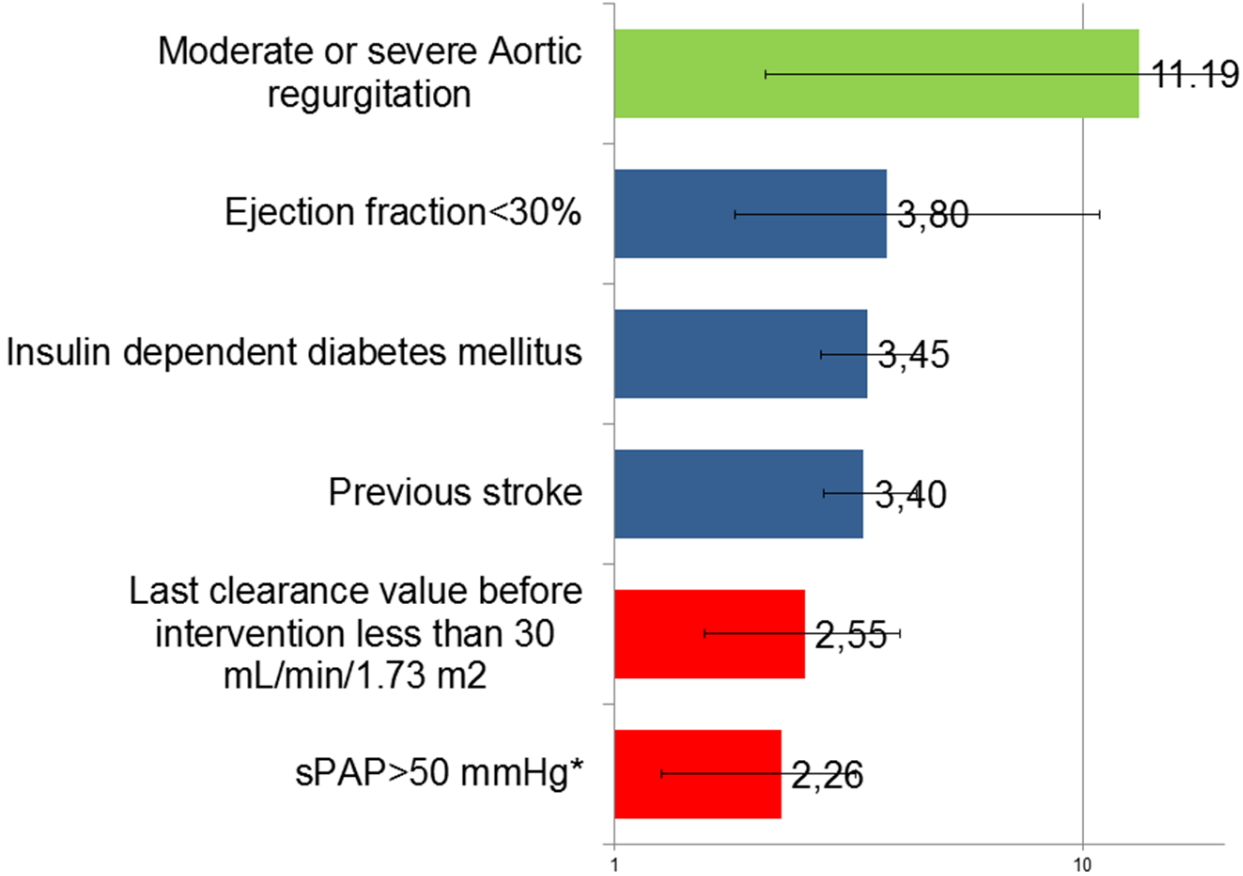

Figure 2. Independent predictors of adverse events at mid term follow up according to gender (red: female patients; blu; male; green both)

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DIABETES MELLITUS

	No-Diabetes n=361 (%)	**Orally Treated Diabetes n=78 (%)**	**Insulin Treated Diabetes n=72 (%)**	***P***
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*
TIA	4 (1.1)	0	1 (1.4)	*0.91*
Myocardial infarction	5 (1.4)	0	6 (8.3)	*0.002*
Re-intervention	3 (0.8)	0	0	*0.29*

DIABETES MELLITUS

Covariates	HR	LCI	UCI	P
Insulin Treated Diabetes	1.7526	1.1008	2.7904	0.018
Glomerular Filtration Rate <30 ml/min/1.73m2	2.1849	1.4219	3.3572	0.0004
Ejection Fraction <30%	1.7774	0.9658	3.2711	0.06
Pulmonary Artery Pressure >50mmHg	2.2199	1.4816	3.3260	0.0001
Prior Myocardial Infarction	1.3241	0.8603	2.0380	0.20
Prior stroke	1.4140	0.8712	2.2951	0.16
Age	0.9798	0.9516	1.0088	0.17

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RENAL DISEASE

Table 1 **BASELINE FEATURE**
Baseline features.

	Patients with preserved renal function N = 72	Patients with moderate CKD N = 219	Patients with severe CKD N = 73	p
Age (years)	79 ± 5.7	83 ± 4.8	84 ± 5.1	0.001
Male gender	44.4	42.9	38.4	0.728
Diabetes	39	27	36	0.098
Insulin dependent diabetes	7	3.4	8.2	0.391
Hypertension	89	84	92	0.207
Hyperlipidemia	55	54	52	0.977
Prior myocardial infarction	13	22	18	0.175
Surgical revascularization	9	13	14	0.550
Cerebrovascular disease[a]	13%	24%	30%	0.063
Peripheral artery disease[a]	17	24	29	0.222
Last creatinine value before intervention	0.86 ± 0.18	1.16 ± 0.29	1.89 ± 0.51	<0.001
Clearance[b]	79.50 ± 20.10	43 ± 8	24.0 ± 4.00	<0.001
NYHA	2.83 ± 0.605	2.84 ± 0.627	2.92 ± 0.662	0.625
Logistic euro score[c]	17 ± 11	23 ± 13	30 ± 17	<0.001
STS score mortality[a]	5 ± 4	6 ± 3	10 ± 7	<0.001

International Journal of Cardiology 167 (2013) 1514–1518

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,*]

RENAL DISEASE

IN HOSPITAL EVENTS

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RENAL DISEASE

LONG TERM FOLLW-UP EVENTS

Table 4
Long term follow-up events.

	Patients with preserved renal function N = 72 (%)	Patients with moderate CKD N = 219 (%)	Patients with severe CKD N = 73	p
Length of follow-up (days)	540 ± 342	472 ± 368	489 ± 210	0.677
Death for any cause[a]	10%	19%	21%	0.154
Cardiovascular death[a]	7%	8%	19%	0.041 0.300 after multivariable adjustment
Clearance[b]	74 ± 22	43 ± 14	30 ± 8	<0.001
Clearance variation	−4.7 ± 18	0.4 ± 12	4.9 ± 7.4	<0.001
Shifting in CKD class				<0.001
Patients with preserved renal function	79.6%	8%	0%	
Pts with moderate CKD	18.4%	76%	47.1%	
Patients with severe CKD	0%	13.6%	51%	
Pts with kidney failure or replacement therapy	2%	2.5%	2%	
Myocardial infarction	3.4%	0%	0%	0.67
Transient ischemic attach[a]	1.4%	3.2%	1.4%	0.550
Stroke[a]	2.8%	2.8%	4.1%	0.834

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RENAL DISEASE

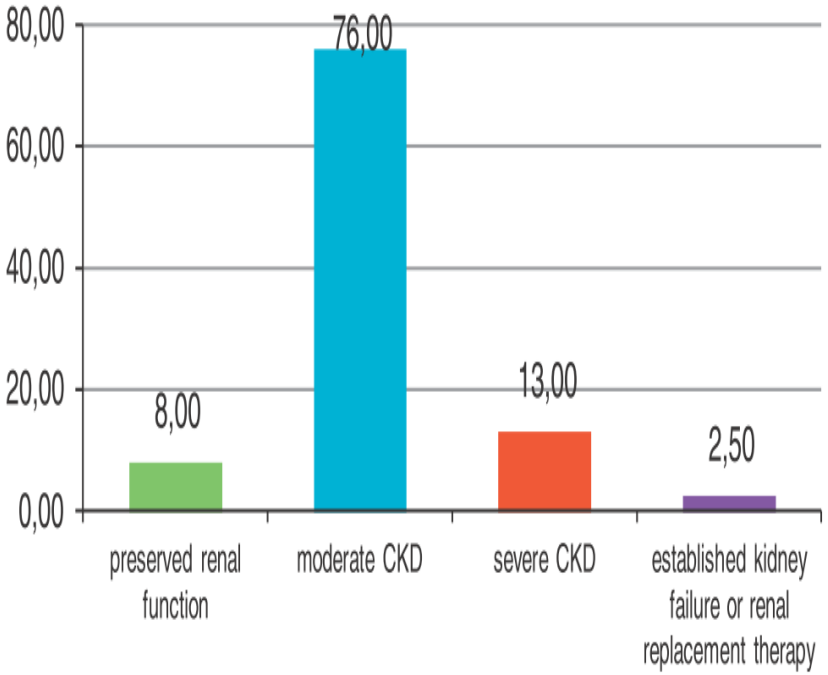

Fig. 2. Renal function after TAVI in patients with moderate CKD.

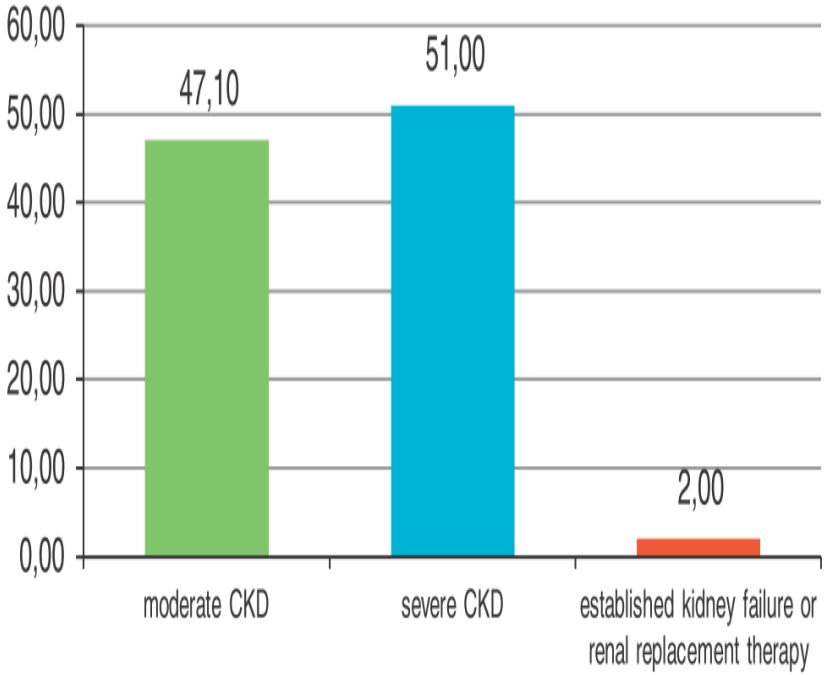

Fig. 3. Renal function after TAVI in patients with severe CKD.

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PREVIOUS CAD

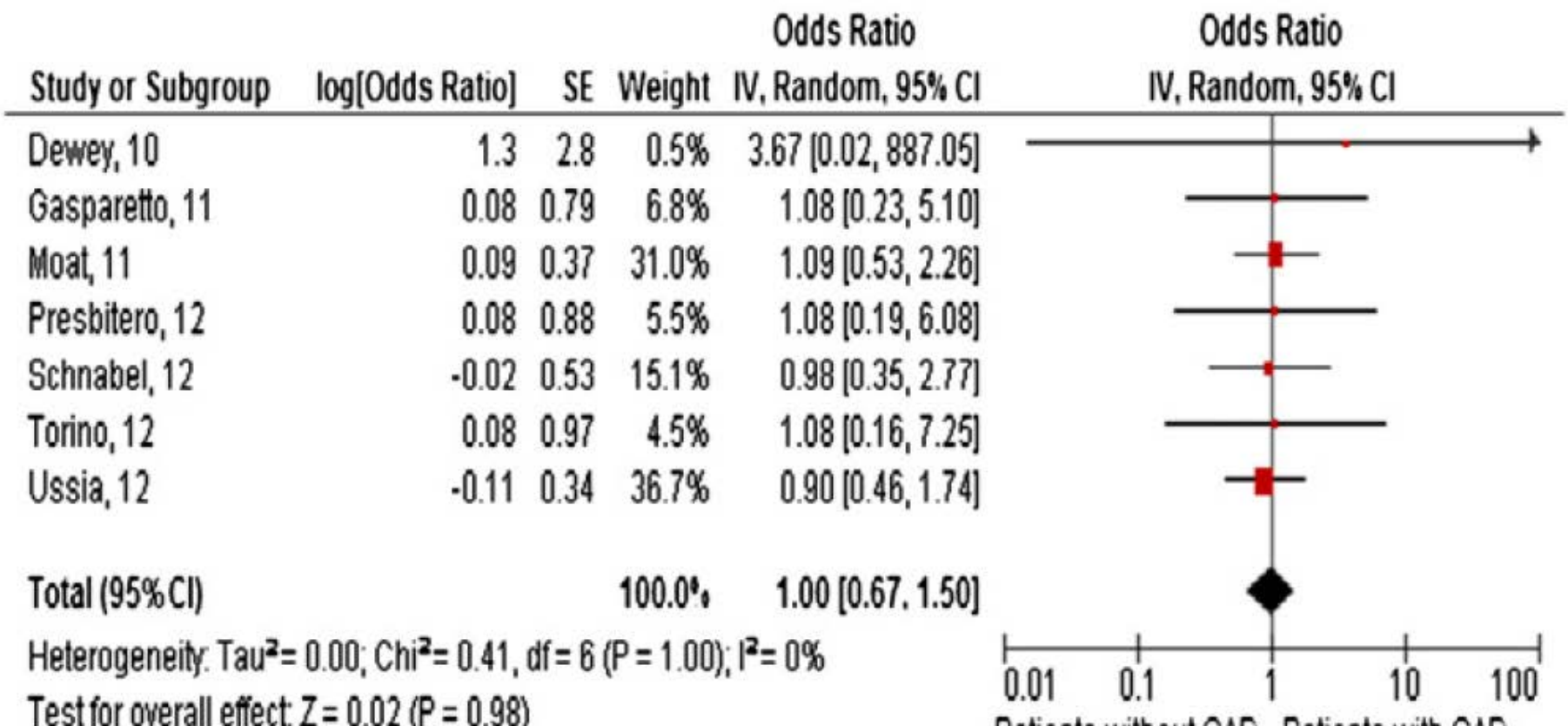

Fig. 2. Pooled adjusted OR for all cause death.

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

F. D'Ascenzo [i,l,1,*], F. Conrotto [i,1], F. Giordana [i], C. Moretti [i,l], M. D'Amico [i], S. Salizzoni [j], P. Om
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G. Tarantini [f], P. Presbitero [g], M. Mennuni [g], M.L. Rossi [g], M. Gasparini [m], G. Biondi Zoccai [h,l], M
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HOW TO CLASSIFY RISK IN THESE PATIENTS?

We have focused on:

- Baseline features: GENDER

- Well know risk factors for intervention procedures
  - DIABETES MELLITUS
  - RENAL DISEASE
  - PREVIOUS CAD)

- Pulmonary Hypertension

- Access choice

- In Hospital complications

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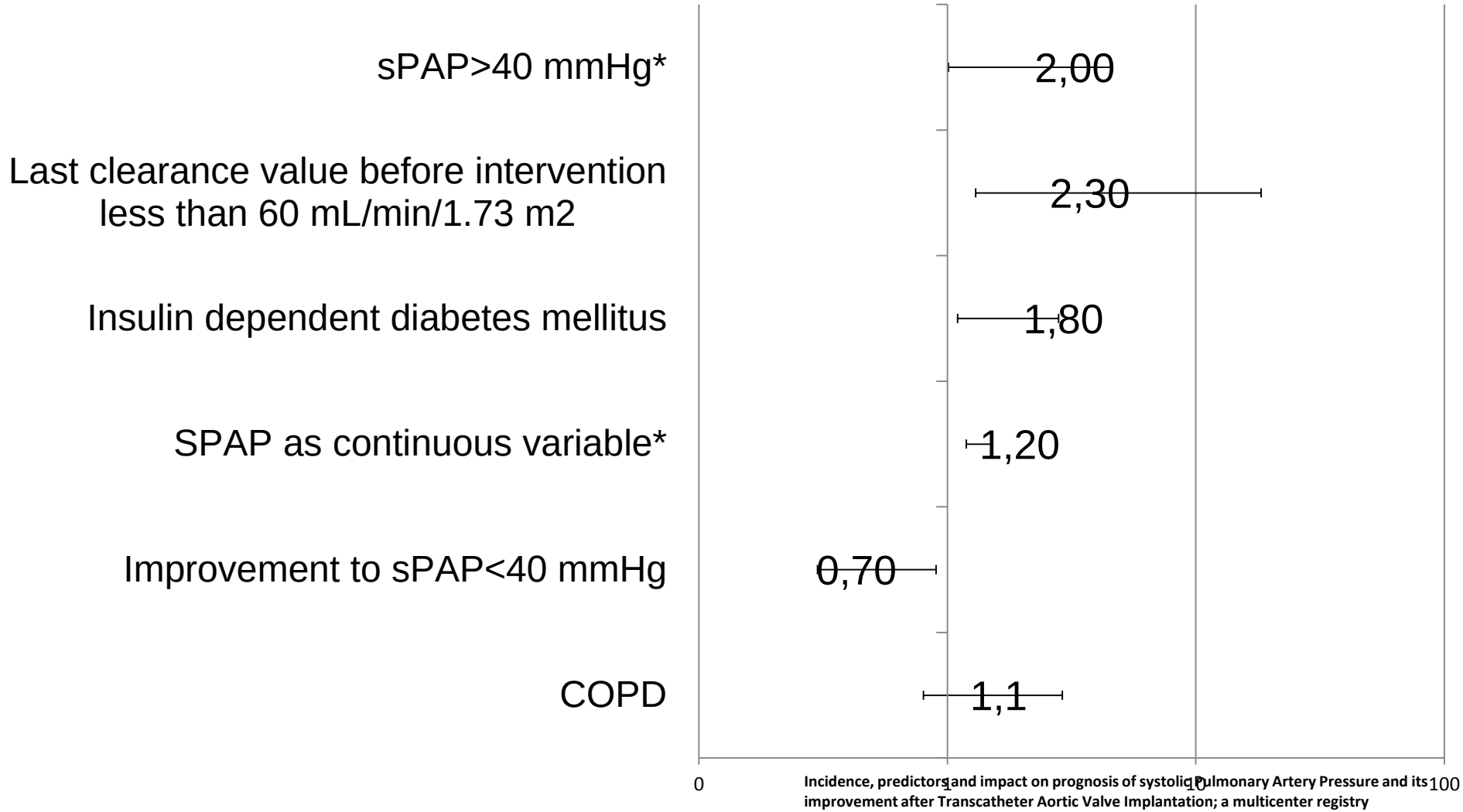
PULMONARY HYPERTENSION: PROGNOSTIC IMPACT



Incidence, predictors and impact on prognosis of systolic Pulmonary Artery Pressure and its improvement after Transcatheter Aortic Valve Implantation; a multicenter registry

Fabrizio D'Ascenzo MD, Federico Conrotto MD, Stefano Salizzoni MD, Marco Luciano Rossi MD, Freek Nijhoff MD, Valeria Gasparetto MD, Marco Barbanti MD, Marco Mennuni MD, Pierluigi Omedè MD, Walter Grosso Marra MD, Giorgio Quadri MD, Francesca Giordana MD, Corrado Tamburino MD, Giuseppe Tarantini MD, Patrizia Presbitero MD, Massimo Napodanno MD, Pieter Stella MD, PhD, Giuseppe Biondi Zoccai, MD, Piefrancesco Agostoni MD, PhD, Maurizio D'Amico MD, Claudio Moretti MD Mauro Rinaldi MD, Sebastiano Marra MD,Fiorenzo Gaita MD

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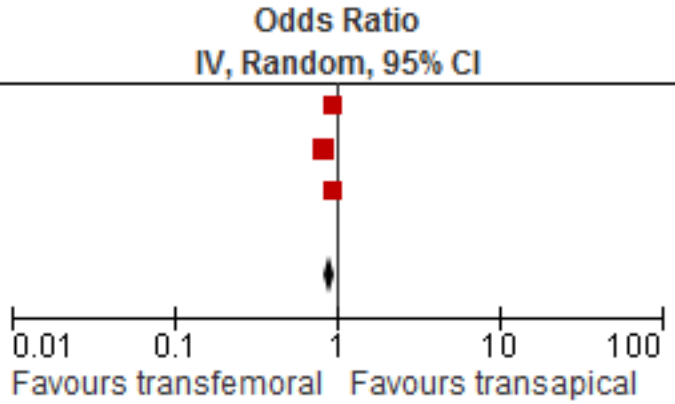
IMPACT OF ACCESS CHOICE

Risk of stroke

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Random, 95% CI
Pilgrim, 12	-0.06	0.04	29.9%	0.94 [0.87, 1.02]
Source, 13	-0.17	0.018	36.8%	0.84 [0.81, 0.87]
Torino, 12	-0.05	0.03	33.3%	0.95 [0.90, 1.01]
Total (95% CI)			**100.0%**	**0.91 [0.83, 0.99]**

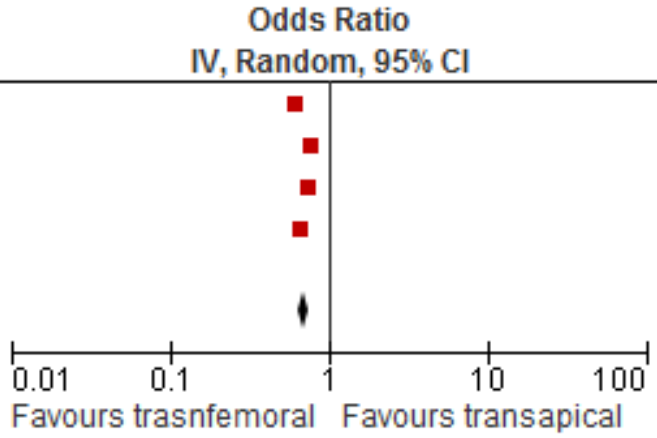
Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 15.09$, df = 2 (P = 0.0005); $I^2 = 87\%$
Test for overall effect: Z = 2.15 (P = 0.03)



Risk of in hospital bleeding

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Random, 95% CI
Amabile, 12	-0.48	0.043	22.1%	0.62 [0.57, 0.67]
Pilgrim,12	-0.25	0.04	22.8%	0.78 [0.72, 0.84]
Source, 13	-0.3	0.015	27.9%	0.74 [0.72, 0.76]
Torino, 12	-0.4	0.02	27.1%	0.67 [0.64, 0.70]
Total (95% CI)			**100.0%**	**0.70 [0.65, 0.76]**

Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 31.77$, df = 3 (P < 0.00001); $I^2 = 91\%$
Test for overall effect: Z = 8.55 (P < 0.00001)

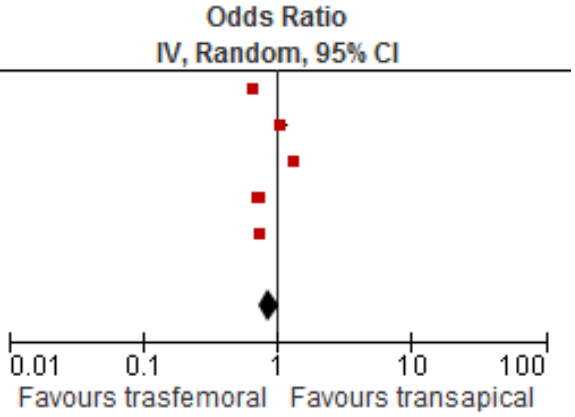


IMPACT OF ACCESS CHOICE

30 days mortality

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Random, 95% CI
Hemmann, 12	-0.42	0.024	20.2%	0.66 [0.63, 0.69]
Pilgrim, 12	0.06	0.05	19.4%	1.06 [0.96, 1.17]
Schymik, 12	0.29	0.04	19.8%	1.34 [1.24, 1.45]
Source, 13	-0.32	0.015	20.4%	0.73 [0.71, 0.75]
Torino, 12	-0.29	0.022	20.3%	0.75 [0.72, 0.78]
Total (95% CI)			**100.0%**	**0.87 [0.72, 1.05]**

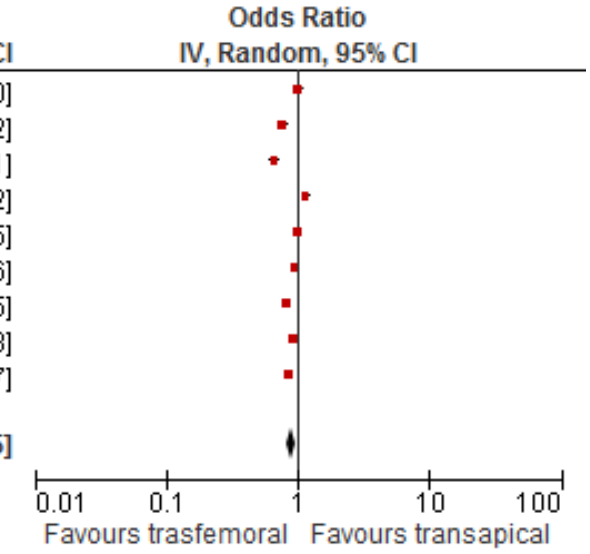
Heterogeneity: Tau² = 0.05; Chi² = 290.37, df = 4 (P < 0.00001); I² = 99%
Test for overall effect: Z = 1.45 (P = 0.15)



1 year mortality

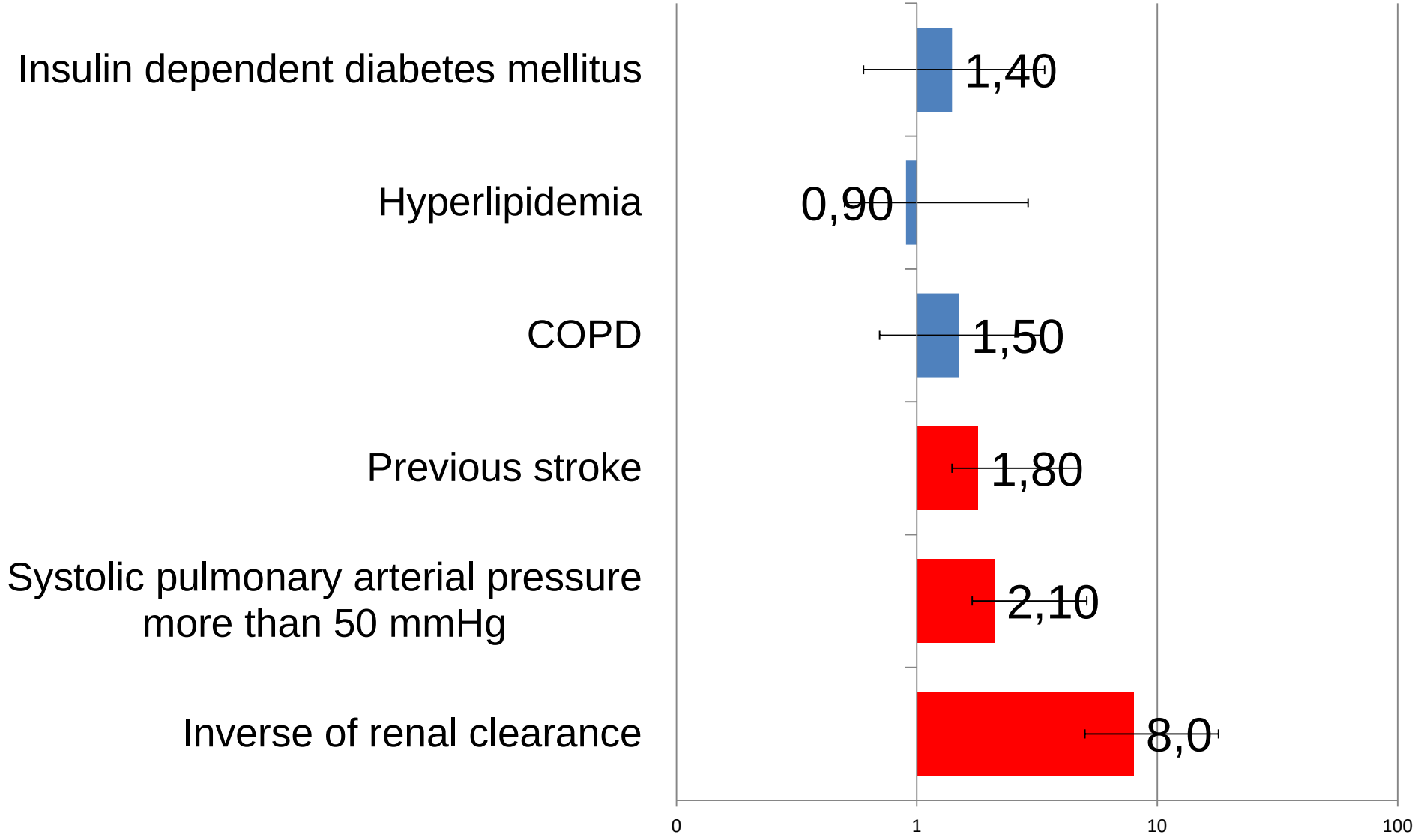
Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Random, 95% CI
Smith, PARTNER 11	0	0.047	9.8%	1.00 [0.91, 1.10]
Webb, 09	-0.27	0.039	10.4%	0.76 [0.71, 0.82]
Himbert, 09	-0.42	0.038	10.5%	0.66 [0.61, 0.71]
Schymik, 12	0.13	0.034	10.8%	1.14 [1.07, 1.22]
Torino, 12	0	0.025	11.3%	1.00 [0.95, 1.05]
Hemmann, 12	-0.07	0.017	11.7%	0.93 [0.90, 0.96]
Source, 13	-0.2	0.017	11.7%	0.82 [0.79, 0.85]
Moat, 11	-0.1	0.015	11.8%	0.90 [0.88, 0.93]
Gilard, 12	-0.16	0.008	12.0%	0.85 [0.84, 0.87]
Total (95% CI)			**100.0%**	**0.89 [0.83, 0.95]**

Heterogeneity: Tau² = 0.01; Chi² = 210.83, df = 8 (P < 0.00001); I² = 96%
Test for overall effect: Z = 3.61 (P = 0.0003)



THE STT SCORE: Survival posT TAVI score

http://www.emounito.org/taviscore/index.php?cat=home



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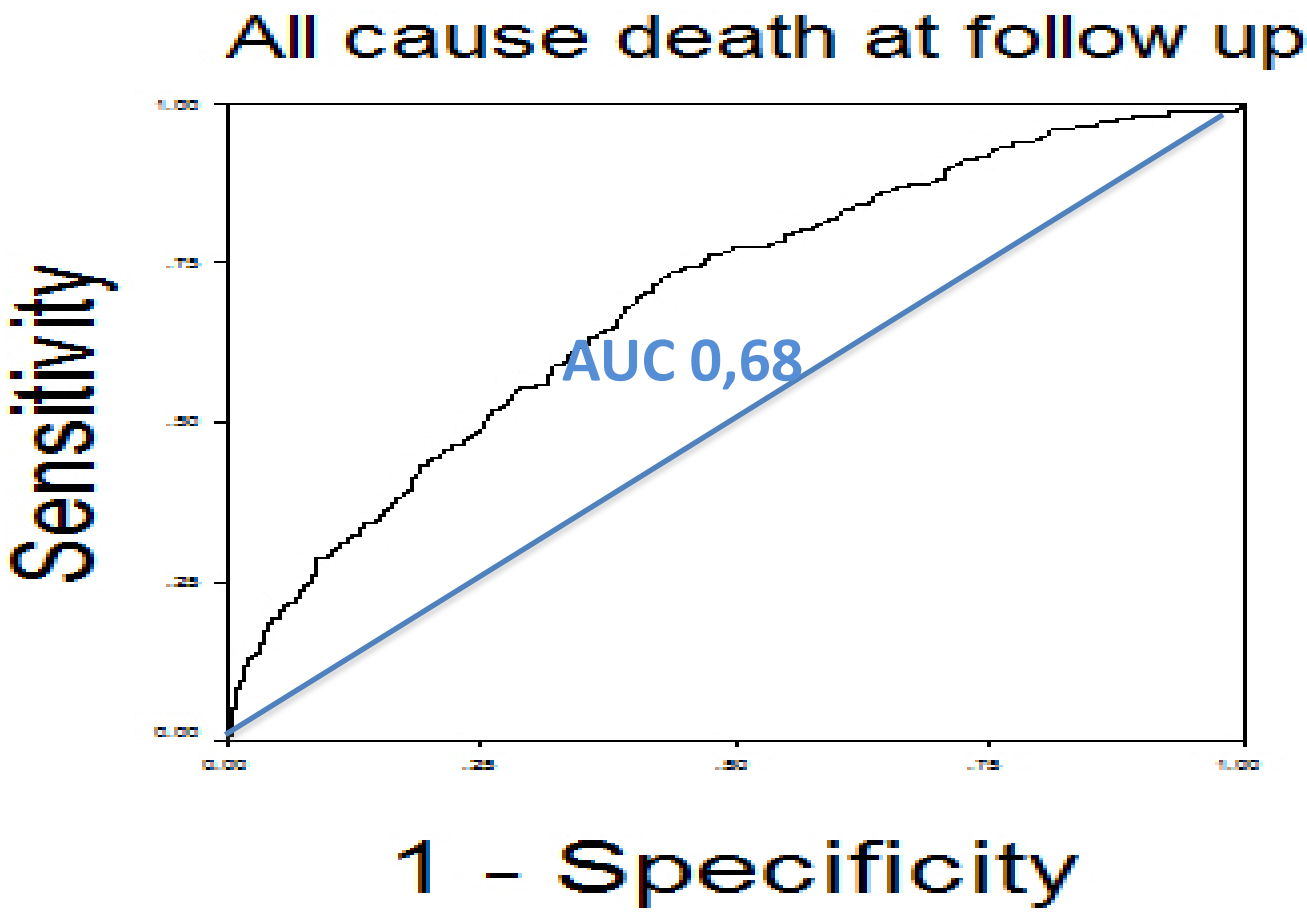

Figure n 3. Receiver-operating characteristics of STT for all cause death at one year on derivation cohort (ROC 0.68: 0.62-0.71)

THE STT SCORE: Survival posT TAVI score

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Model with STT score		Model with STS score		NRI
	<5%	5-10%	>10%	
Patients with all cause death at follow up				
<12%	2 (50)	4 (8)	0 (0)	
12-17%	2 (150)	26 (48)	15 (27)	
>17%	4 (30)	24 (44)	50 (73)	
Total Number	15	54	65	11 patients (8%)
Patients who did not die from all cause death				
<12%	61 (56)	50 (19)	20 (16)	
12-17%	40 (46)	164 (74)	65 (53)	
>17%	10 (8)	54 (11)	36 (31)	
Total Number	120	268	121	31 patients (6%)

Failure in reclassification
Improvement in reclassification
No variation in reclassification

Figure n 8.
NRI for STT compared to STS for patients who died at follow up was of 8%, and for those who survived of 6%, with a global gain in reclassification of 14% ($p<0.001$)