



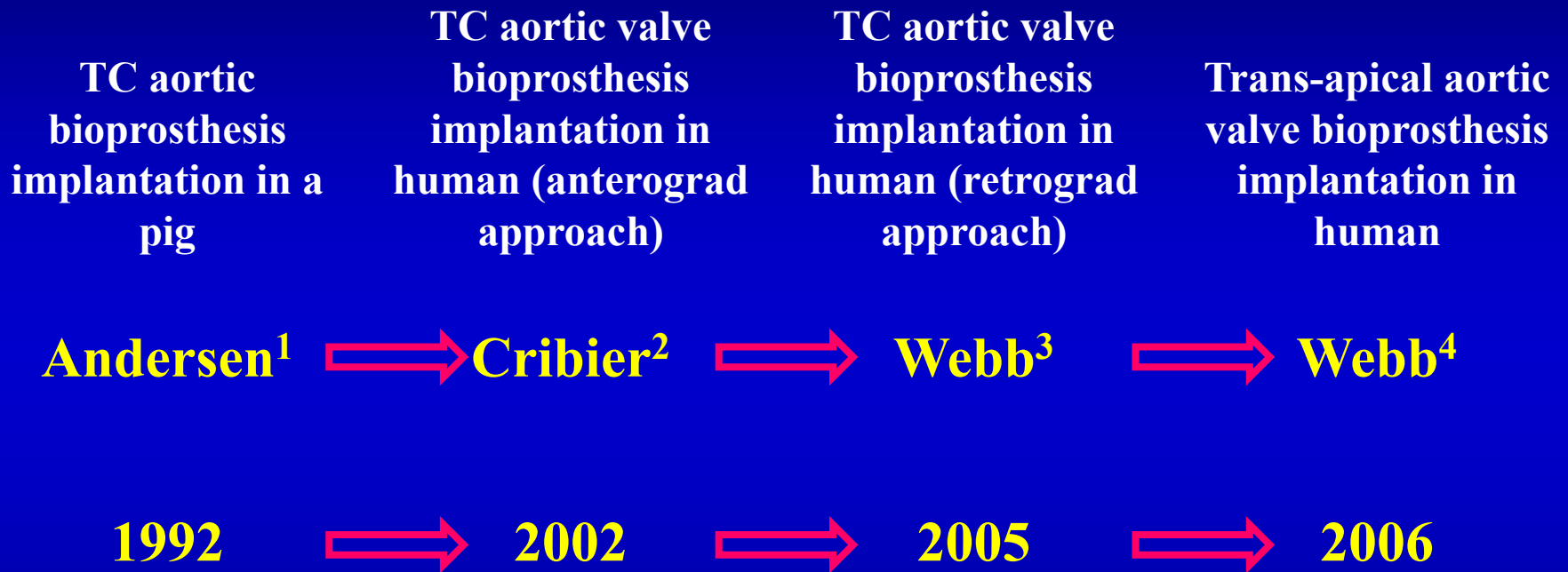
Cardiologia Universitaria
Città della Salute e della Scienza, Torino
UNIVERSITÀ degli STUDI di TORINO



TAVI: 8 years of experience in Piemonte

*Dott. M. D'Amico
Head of the Cath Lab
Department of Cardiology
Città della salute e della Scienza Hospital
Turin*

Hystory of TAVI



¹Andersen HR, Knudsen LL, Hasenkam JM. Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs. *Eur Heart J.* 1992 May;13(5):704-8

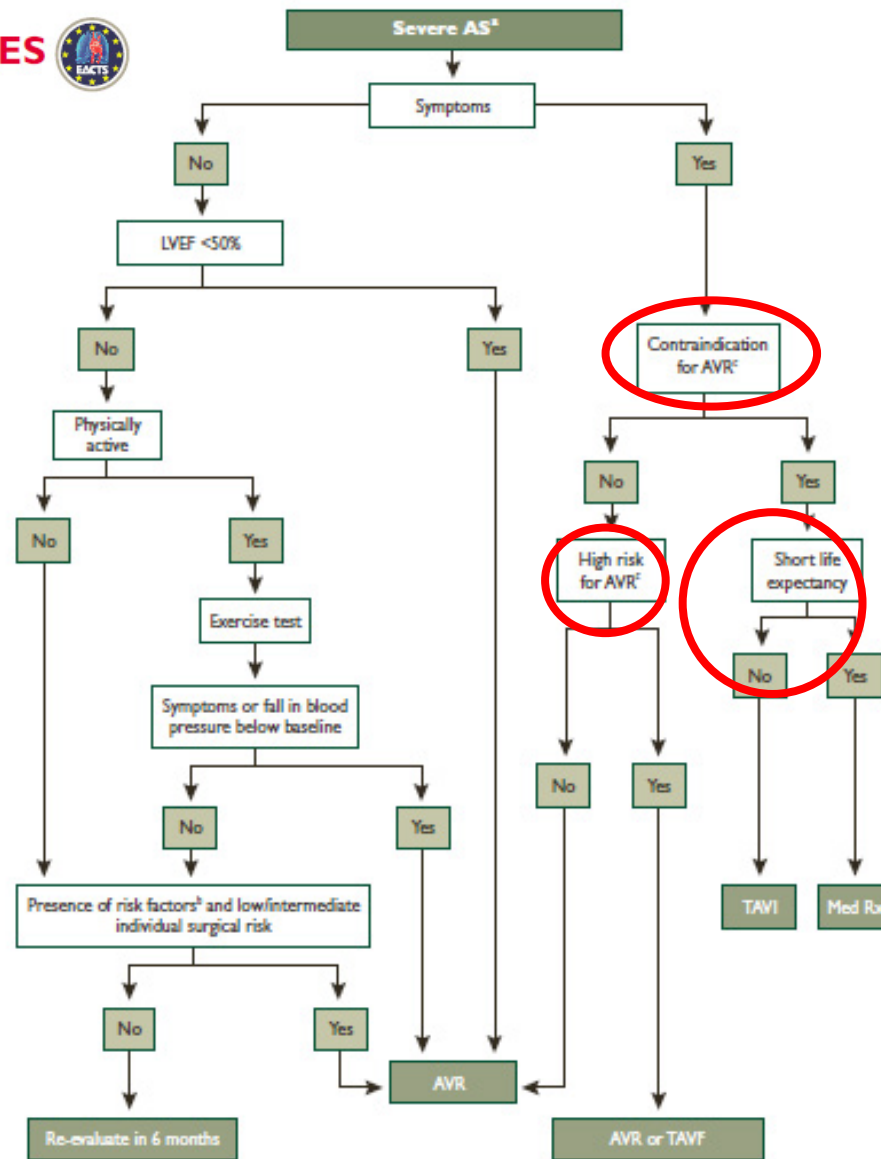
²Cribier A, Eltchaninoff H, Bash A, Borenstein N, Tron C, Bauer F, Derumeaux G, Anselme F, Laborde F, Leon MB. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. *Circulation.* 2002 Dec 10;106(24):3006-8.

³Webb JG, Chandavimol M, Thompson CR, Ricci DR, Carere RG, Munt BI, Buller CE, Pasupati S, Lichtenstein S. Percutaneous aortic valve implantation retrograde from the femoral artery. *Circulation.* 2006 Feb 14;113(6):842-50.

⁴Ye J, Cheung A, Lichtenstein SV, Carere RG, Thompson CR, Pasupati S, Webb JG. Transapical aortic valve implantation in humans. *J Thorac Cardiovasc Surg.* 2006 May;131(5):1194-6.

Indication to TAVI

ESC/EACTS GUIDELINES

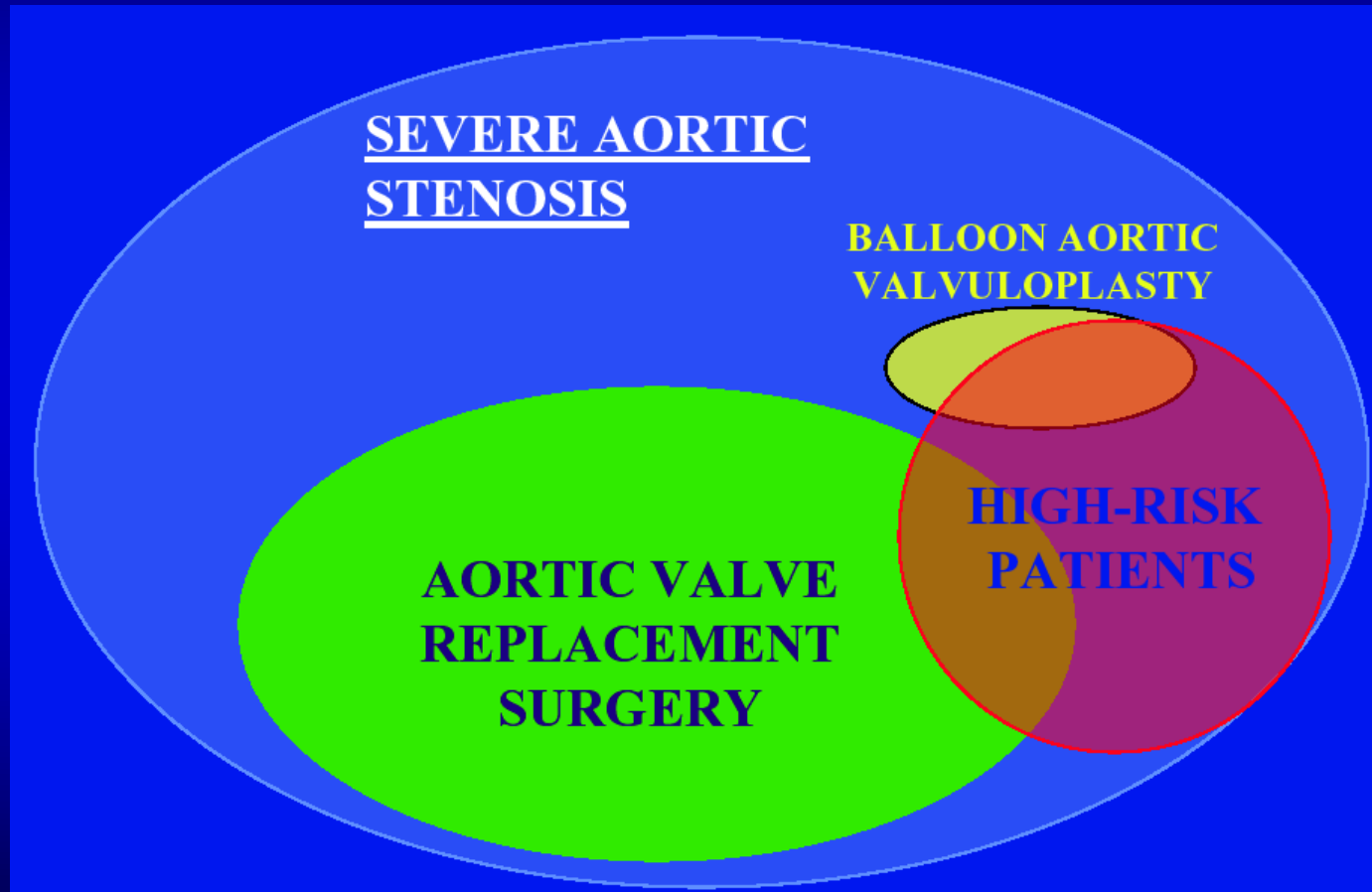


TAVI guideline in Piedmont

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, cardiocirurgo, anestesista rianimatore
5. Presenza di unità operativa di cardiocirurgia
6. Parere del paziente (l'esplicita richiesta del pz non può essere considerata un'indicazione al trattamento)
7. Consenso informato scritto

Patients' selection



TAVI Centers in Piemonte



*Azienda Ospedaliera Nazionale
SS. Antonio e Biagio e Cesare Arrigo
Alessandria*



*Azienda Ospedaliera
S.Croce e Carle Cuneo*

AZIENDA OSPEDALIERO UNIVERSITARIA DI RILIEVO NAZIONALE ED ALTA SPECIALIZZAZIONE
MAGGIORE DELLA CARITA' NOVARA

2008-2016 TAVI procedures

1190 procedures



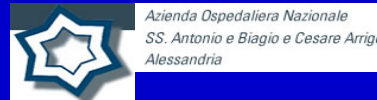
Osp. Molinette, Torino 316



Osp. Mauriziano, Torino 373



Cl. Villa Maria Pia, Torino 66



Osp. Civile, Alessandria 111



Città di Alessandria 51



Azienda Ospedaliera
S. Croce e Carle, Cuneo 146



Osp. Maggiore, Novara 57

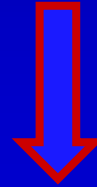


Cl. San Gaudenzio, Novara 70

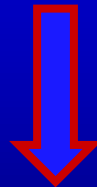
2015: TAVI Observed...



215 TAVI in Piedmont



~ 4.500.000 ab.



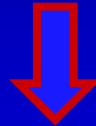
48 TAVI/million/2015

...TAVI Expected

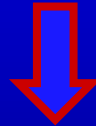
70/million/year*



315/year in Piedmont



33/million/year TAVI implanted
in Piedmont

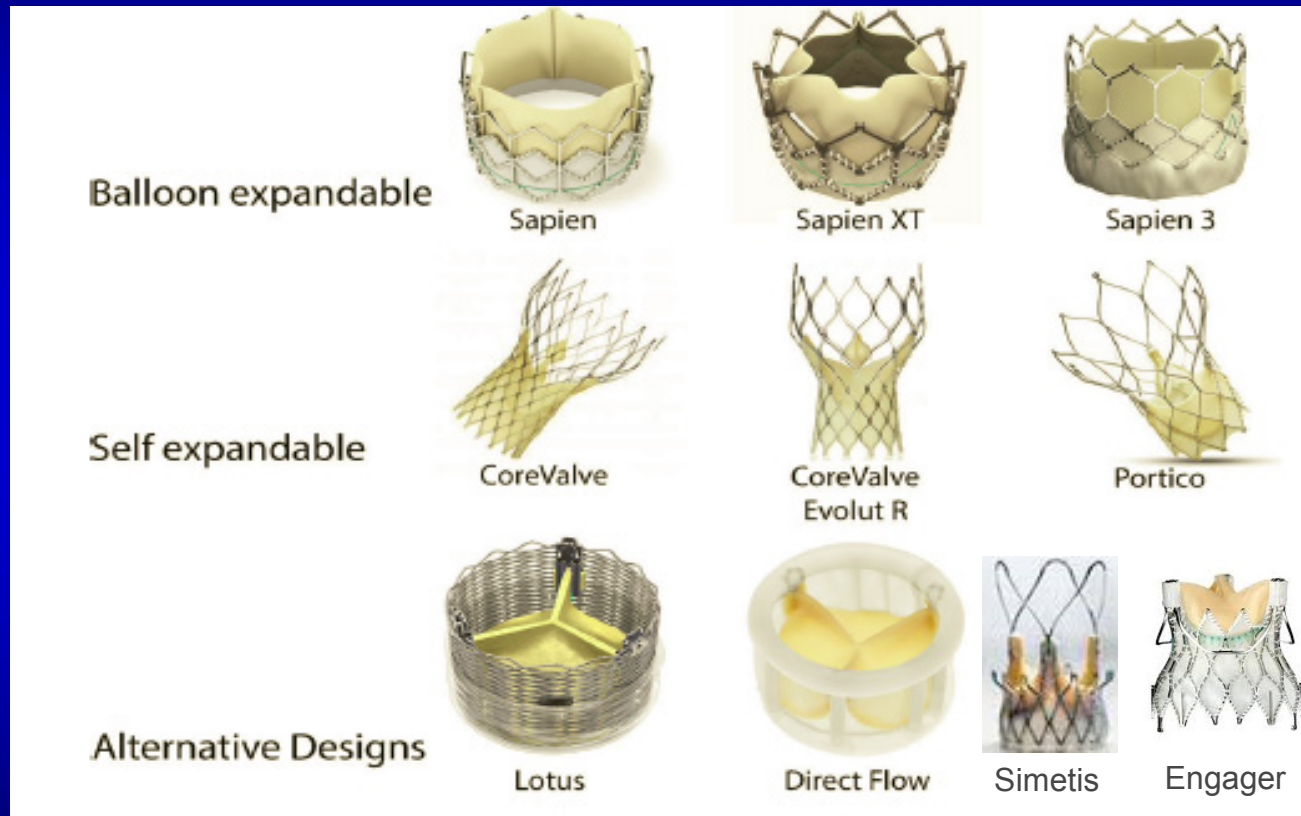


37/million/year of patients not treated

*Ruben L. J. Osnabrugge, MS; Darren Mylotte, MD; Stuart J. Head, MS; Nicolas M. Van Mieghem, MD; Vuyisile T. Nkomo, MD, MPH; Corinne M. LeReun, MS; Ad J. J. C. Bogers, MD, PHD; Nicolo Piazza, MD, PHD; A. Pieter Kappetein, MD, PHD. **Disease Prevalence and Number of Candidates for Transcatheter Aortic Valve Replacement. A Meta-analysis and Modeling Study.** J Am Coll Cardiol. 2013;62(11):1002-1012.

*Mylotte DI, Osnabrugge RL, Windecker S, Lefèvre T, de Jaegere P, Jeger R, Wenaweser P, Maisano F, Moat N, Søndergaard L, Bosmans J, Teles RC, Martucci G, Manoharan G, Garcia E, Van Mieghem NM, Kappetein AP, Serruys PW, Lange R, Piazza N. Transcatheter aortic valve replacement in Europe: adoption trends and factors influencing device utilization. J Am Coll Cardiol 2013 Jul 16;62(3):210-9. Epub 2013 May 15.

Type of Valve implanted







Adapted from Weiss, Curr Atheroscler Rep, 2015

Type of valve implanted

	Core Valve	CV-Evolute	Engager	ES I gen	ES-XT	ES-3	Lotus	Other valves -Portico -Direct Flow -Simetis	
TF	375	157	0	35	161	125	11	43	907
TA	0	0	10	31	158	56	0	3	258
TS	10	7	0	0	0	0	0	0	17
TAo	1	1	0	0	3	1	0	0	6
	386	165	10	66	322	182	11	46	

TAVI «OFF LABEL»

Mitral V-in-V	Tricuspid V-in-V	Tricuspid valve-in-ring	TAVI for aortic regurgitation
20	5	2	12
			
20 ES-XT	3 ES-XT 2 ES 3	2 ES-XT	6 CV+ CV-E 3 Portico 2 Engager 1 Lotus

30-days VARC mortality

Patients' selection

**Technology
improvement**

4->9%

Single center expertise



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TAVI 2010-2016

Molinette experience: what we learned

Trans-catheter Valve Implantation (TVI) 2010-2016

283 TVI patients

15 TVI «off-label»

2 Aortic Regurgitation

3 Mitral V-in-V

1 Mitral V-in-V+TAVI

5 Tricuspid V-in-V

2 Tricuspid valve in ring

2 Pulmonary stenosis

2 Engager
10 ES XT
3 ES 3

268 TAVI ⇒ 10 Aortic V-in-V

9 Edwards Sapien I generation

50 Edwards Sapien XT

37 Edwards Sapien 3

117 CoreValve I generation

41 CoreValve-Evolute

10 Engager

4 Lotus

60 ES-TF

151 CV-TF

7 CV-TS

4 Lotus-TF

36 ES-TA

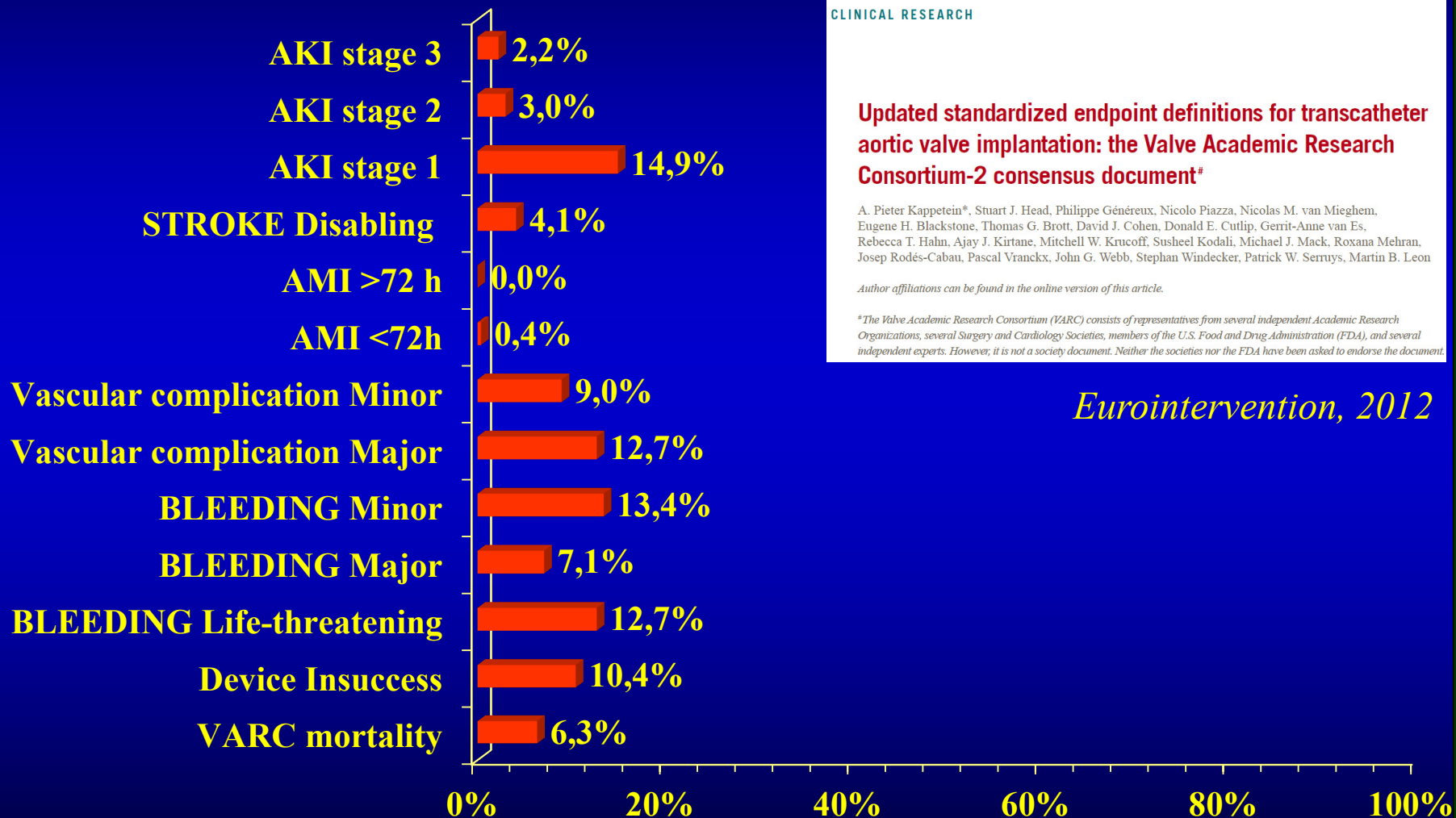
10 Engager-TA

268 TAVI

Population

	N (%), mean±SD
Age, yo	81.9±6.5
Female	157 (59)
Diabetes	79 (29)
Log EUROSCORE I, %	21±12
STS score, %	8±6
AF permanent	56 (21)
AF parossistic	29 (11)
Coronaropathy	142 (53)
PCI pre-TAVI	37 (14)
PCI during TAVI	9 (3)
EF, %	55±14
Moderate MR	64 (24)
Severe MR	9 (3)
Hospitalization lenght, days	
pre-TAVI	8±13, median 4
post-TAVI	11±25, median 8

VARC II complications



CLINICAL RESEARCH

Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document[#]

A. Pieter Kappetein*, Stuart J. Head, Philippe Généreux, Nicolo Piazza, Nicolas M. van Mieghem, Eugene H. Blackstone, Thomas G. Brott, David J. Cohen, Donald E. Cutlip, Gerrit-Anne van Es, Rebecca T. Hahn, Ajay J. Kirtane, Mitchell W. Krucoff, Susheel Kodali, Michael J. Mack, Roxana Mehran, Josep Rodés-Cabau, Pascal Vranckx, John G. Webb, Stephan Windecker, Patrick W. Serruys, Martin B. Leon

Author affiliations can be found in the online version of this article.

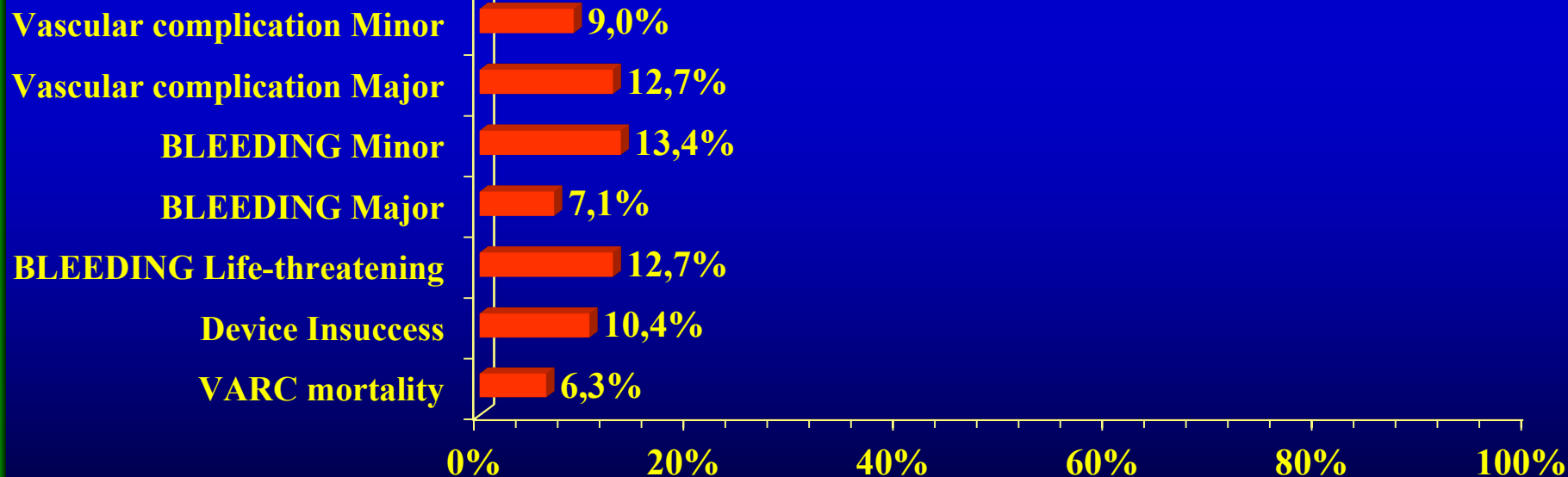
[#]The Valve Academic Research Consortium (VARC) consists of representatives from several independent Academic Research Organizations, several Surgery and Cardiology Societies, members of the U.S. Food and Drug Administration (FDA), and several independent experts. However, it is not a society document. Neither the societies nor the FDA have been asked to endorse the document.

Eurointervention, 2012

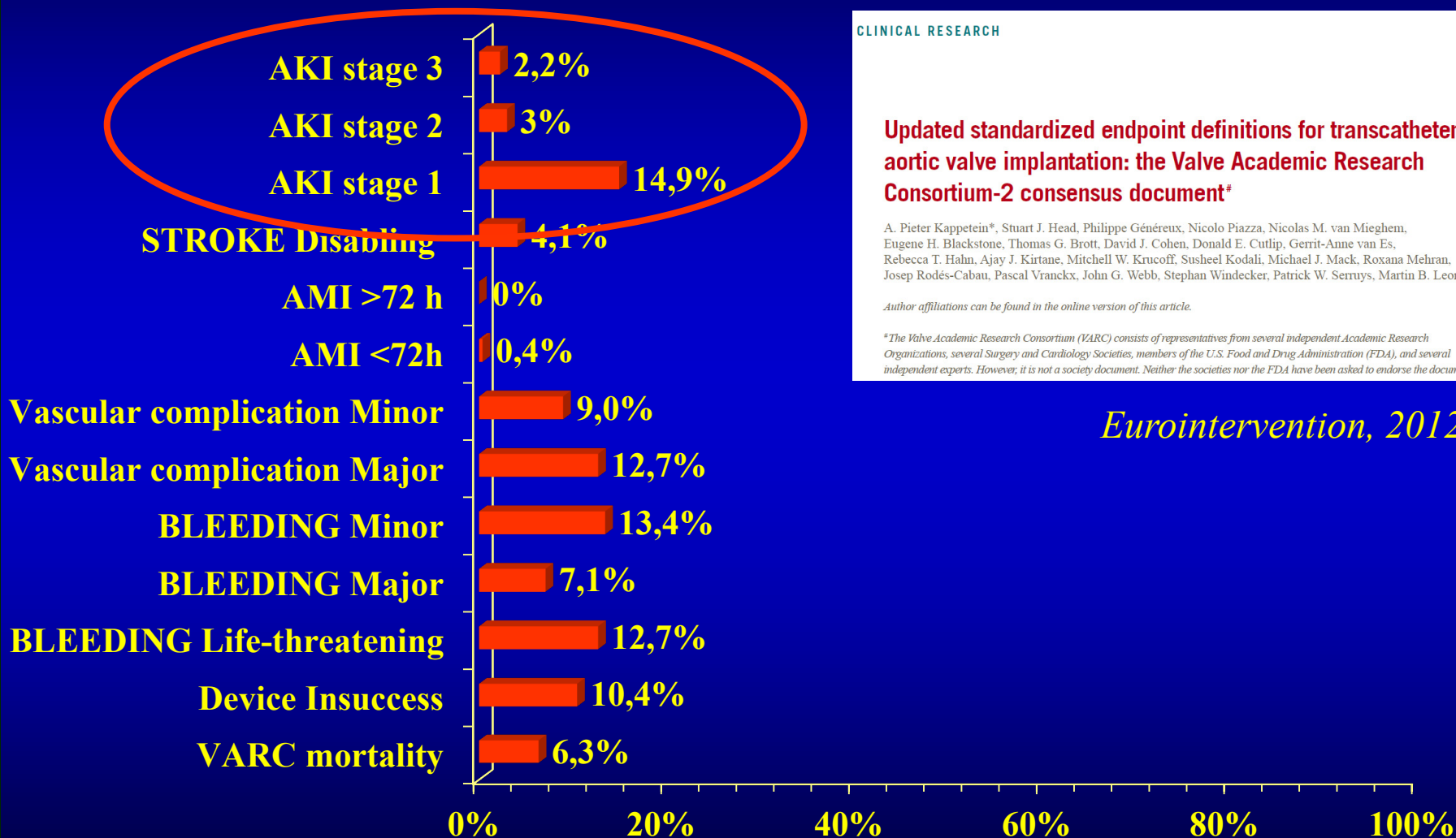
VARC II complications

Vascular complications rate in relation to the implanted valve

	CoreValve	CV-Evolute	ES 1° gen	Sapien XT	Sapien 3
Major vascular complication, %	12%	10%	22%	18%	16%
Sheath Introducer, French	22 F	18 F	23->26 F	21->23 F	19 F



VARC II complications



CLINICAL RESEARCH

Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document[#]

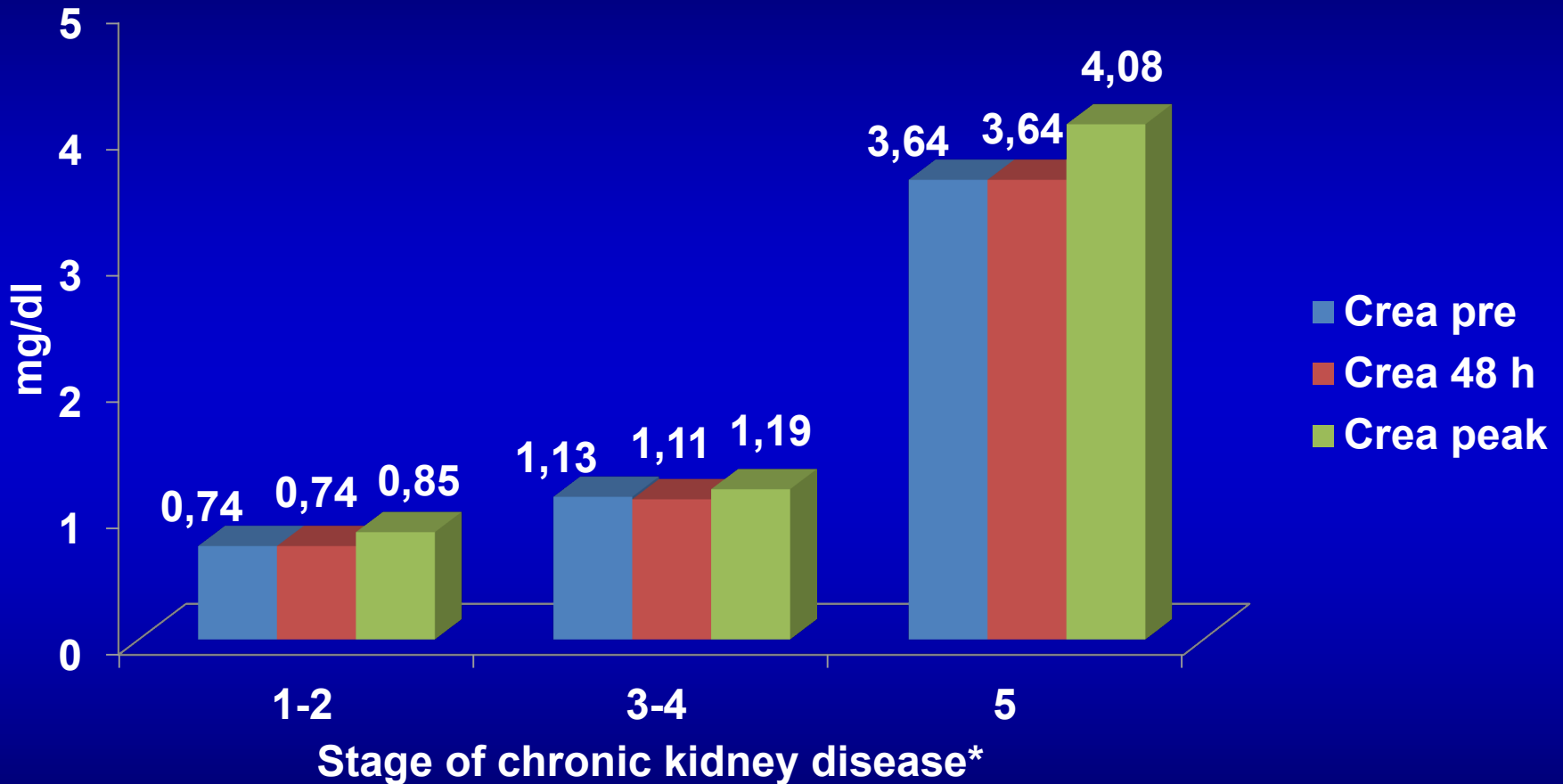
A. Pieter Kappetein*, Stuart J. Head, Philippe Généreux, Nicolo Piazza, Nicolas M. van Mieghem, Eugene H. Blackstone, Thomas G. Brott, David J. Cohen, Donald E. Cutlip, Gerrit-Anne van Es, Rebecca T. Hahn, Ajay J. Kirtane, Mitchell W. Krucoff, Susheel Kodali, Michael J. Mack, Roxana Mehran, Josep Rodés-Cabau, Pascal Vranckx, John G. Webb, Stephan Windecker, Patrick W. Serruys, Martin B. Leon

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Eurointervention, 2012

Focus on Acute Kidney Injury



6 patients underwent dialysis->2 chronic dialysis

*KDOQI CKD classification

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,*}

Int. J Cardiol 2013

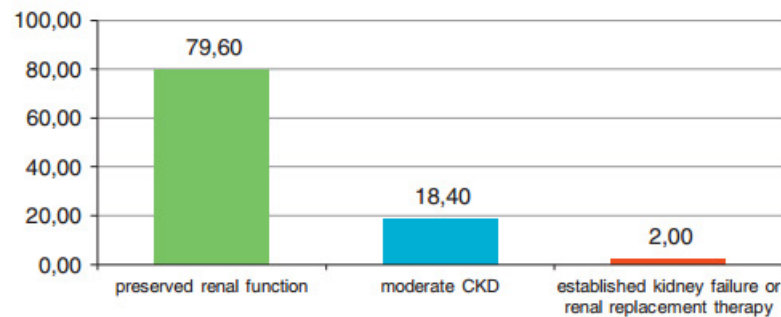


Fig. 1. Renal function after TAVI in patients with preserved renal clearance.

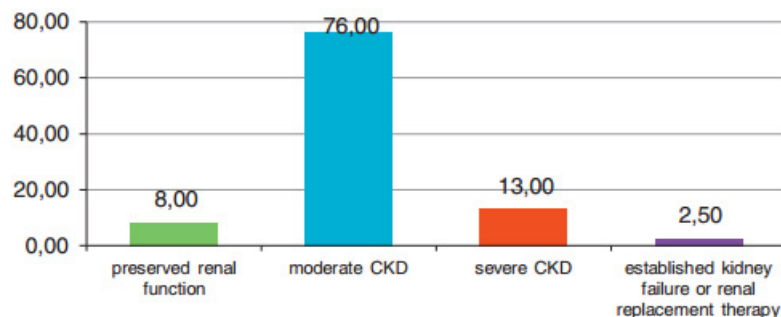


Fig. 2. Renal function after TAVI in patients with moderate CKD.

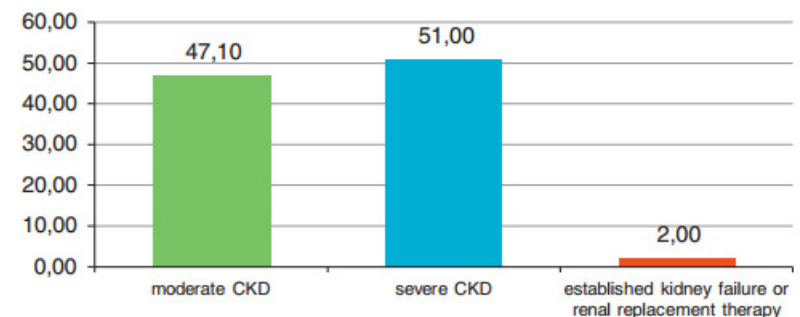
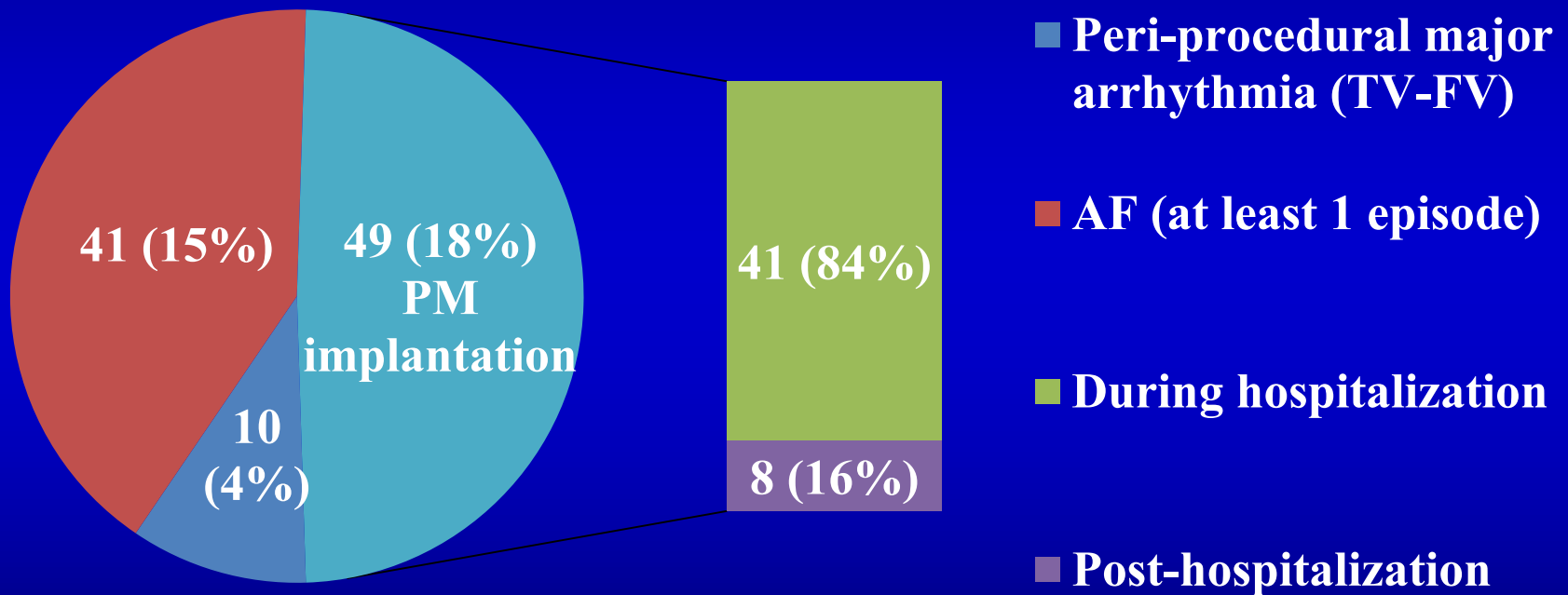


Fig. 3. Renal function after TAVI in patients with severe CKD.

Rhythm and conduction disturbances



Incidence of PM implantation related to the implanted valve

<i>Type of implanted valve</i>	<i>n°PM/tot</i>	<i>%</i>
Edwards Sapien I generation	0/9	0%
Edwards Sapien XT	10/50	20%
Edwards Sapien 3	2/37	5%
CoreValve I generation	29/117	25%
CoreValve-Evolute	7/41	17%
Engager	0/10	0%
Lotus	2/4	50%

P<0.001

Original Investigation

Comparison of Balloon-Expandable vs Self-expandable Valves in Patients Undergoing Transcatheter Aortic Valve Replacement

The CHOICE Randomized Clinical Trial

Mohamed Abdel-Wahab, MD; Julinda Mehilli, MD; Christian Frerker, MD; Franz-Josef Neumann, MD; Thomas Kurz, MD; Ralph Tölg, MD; Dirk Zachow, MD; Elena Guerra, MD; Steffen Massberg, MD; Ulrich Schäfer, MD; Mohamed El-Mawardy, MD; Gert Richardt, MD; for the CHOICE investigators

Variable	No./Total No. (%)		Relative Risk (95% CI)	P Value
	Balloon-Expandable Valve (n = 121)	Self-expandable Valve (n = 117)		
Death				
Any cause	5/121 (4.1)	6/117 (5.1)	0.81 (0.25-2.57)	.77
Cardiovascular causes	5/121 (4.1)	5/117 (4.3)	0.97 (0.29-3.25)	.99
Stroke	7/121 (5.8)	3/117 (2.6)	2.26 (0.60-8.52)	.33
Myocardial infarction	1/121 (0.8)	0/117 (0.0)		.99
Bleeding				
Life threatening	10/121 (8.3)	14/117 (12.0)	0.69 (0.32-1.49)	.35
Major	23/121 (19.0)	17/117 (14.5)	1.31 (0.74-2.32)	.36
Minor	11/121 (9.1)	9/117 (7.7)	1.18 (0.51-2.74)	.70
Major or minor	34/121 (28.1)	26/117 (22.2)	1.26 (0.81-1.97)	.30
Vascular complications				
All	17/121 (14.0)	15/117 (12.8)	1.10 (0.57-2.09)	.78
Major	12/121 (9.9)	13/117 (11.1)	0.89 (0.42-1.88)	.76
Minor	5/121 (4.1)	2/117 (1.7)	2.42 (0.48-12.21)	.28
Acute kidney injury	5/121 (4.1)	11/117 (9.4)	0.44 (0.16-1.23)	.13
Repeat procedure for valve-related dysfunction	1/121 (0.8)	2/117 (1.7)	0.48 (0.04-5.26)	.62
Combined safety end point ^a	22/121 (18.2)	27/117 (23.1)	0.79 (0.48-1.30)	.42
Major adverse cardiovascular and cerebrovascular events ^b	8/121 (6.6)	4/117 (3.4)	1.93 (0.60-6.25)	.38
Rehospitalization for heart failure	0/110 (0.0)	5/117 (4.3)		.02
NYHA class improvement			1.09 (1.00-1.19)	.06
Quality of life				
Score, mean (95% CI)	71.0 (68.2-73.9)	65.9 (62.4-69.5)		.02
Score change, median (IQR)	12.5 (0-20)	10 (0-20)		.19
New permanent pacemaker	19/110 (17.3)	38/101 (37.6)	0.46 (0.28-0.74)	.001

ES XT e CV I gen

JAMA, 2014

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 Tchetché, MD^h, Israel M. Barbash, MDⁱ, Ron Waksman, MD^j,
Augusto D'Onofrio, MD^j, Thierry Lefevre, MD^k, Thomas Pilgrim, MD^l, 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

25 studies, 8874 patients

Am J Cardiol, 2014

30 days-mortality 7.5% ↔ **6.3%**

AKI 8% ↔ **6.7%**

Lifethreatening and major bleeding 13.8% ↔ **20%**

Major vascular complications 8.8% ↔ **12.7%**

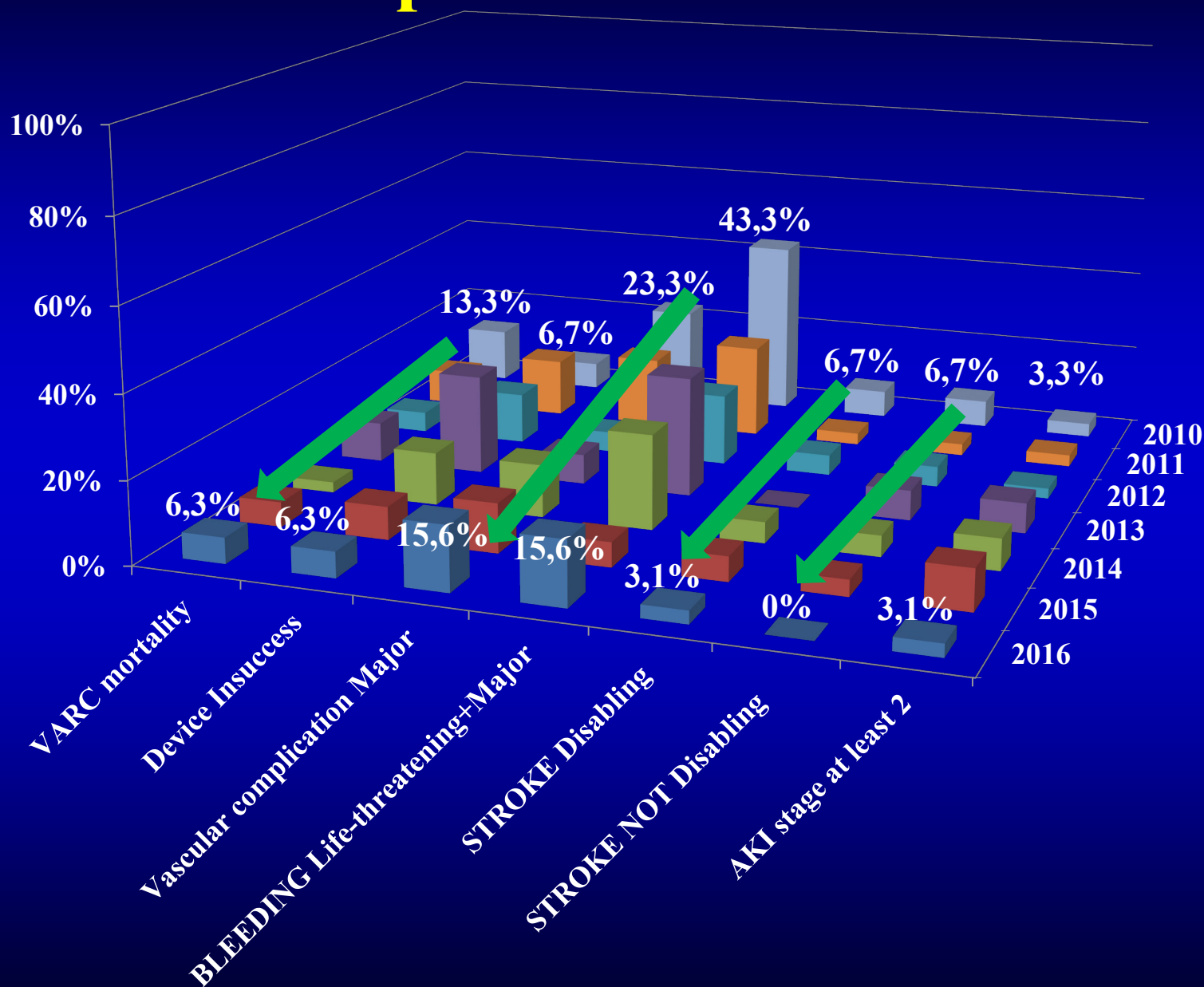
Peri-procedural AMI 0.6% ↔ **0.4%**

PM implantation 12.5% ↔ **18%**

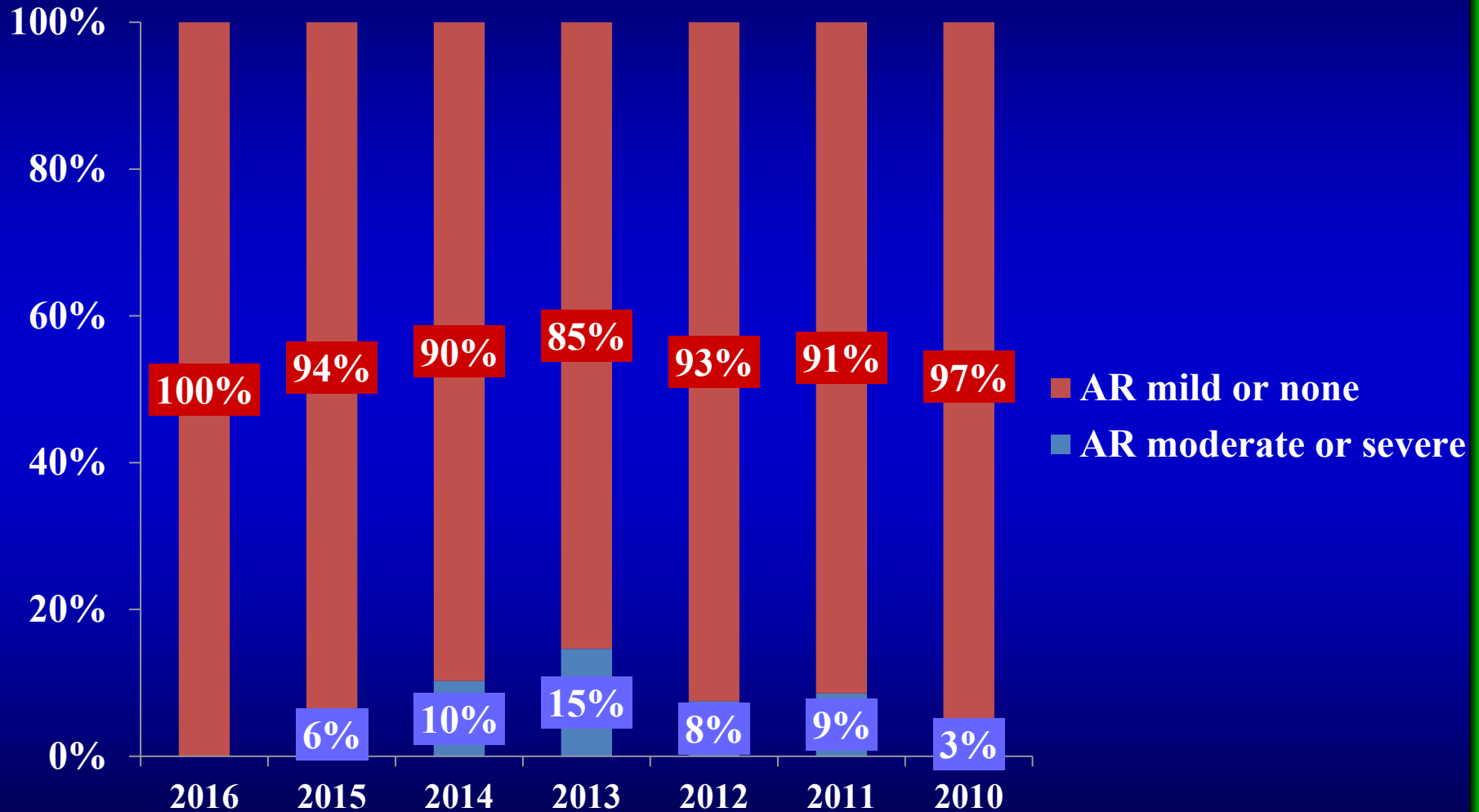
Short-term outcomes

	VARC Mortality	Bleeding (Major+LT)	Stroke	Vascular Complications	AR>2	AMI	PM implantation
UK, JACC 2015, 3980 pts, CV-ES	6.3%	-	4.1 %	8.4%	13.6 %	1.3%	16.3 %
EUR, EuroInt 2013, 4571 pts, CV-ES/XT	7.4 %	16.8%	1.8 %	3.1 %	7.7%	0.9%	13.2 %
FRANCE2, NEJM 2011, 3195 pts, CV-ES	9.7%	5.7%	4.1%	4.7%	16.5%	1.2%	15.6%
Molinette, 268 pts, CV, CV evolute, Sapien, S XT, Engager, Lotus	6.3%	20%	4.1%	12.7%	7.4%	0.4%	18%

VARC II complications-Landmark analysis



Aortic regurgitation-Landmark analysis



2 severe AR (ES XT, TF)

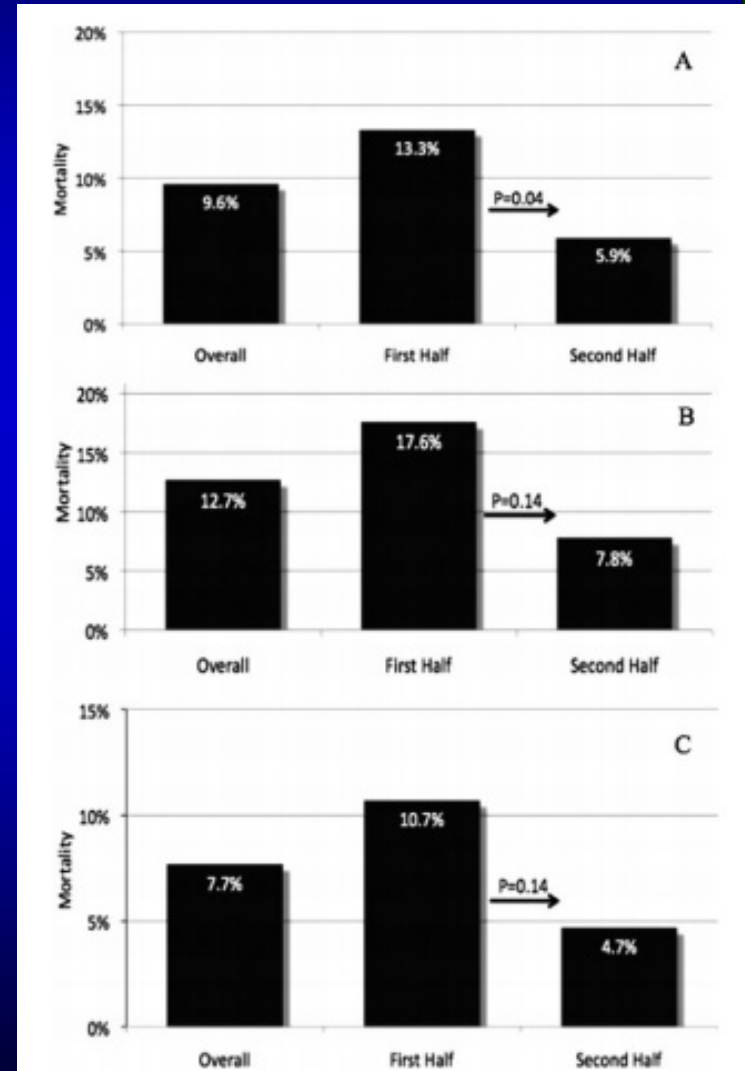
Transcatheter Aortic Valve Implantation: Lessons From the Learning Curve of the First 270 High-Risk Patients

Ronen Gurvitch, MBBS, Edgar L. Tay, MBBS, Namal Wijesinghe, MD, J. Ye, MD, Fabian Nietlispach, MD, David A. Wood, MD, Samuel Lichtenstein, MD, Anson Cheung, MD, and John G. Webb,^{*} MD

CCI, 2011

Combined complications	Overall	First half	Second half	P value
Major vascular injury, <i>n</i> (%)	18 (6.7)	11 (8.1)	7 (5.2)	0.33
Transfusion > 4 units PRBC, <i>n</i> (%)	23 (8.6)	15 (11.1)	8 (5.9)	0.13
Cardiac tamponade, <i>n</i> (%)	6 (2.2)	3 (2.2)	3 (2.2)	1
Acute renal failure, <i>n</i> (%)	18 (6.7)	8 (5.9)	10 (7.4)	0.63
Temporary hemodialysis, <i>n</i> (%)	7 (2.6)	2 (1.5)	5 (3.7)	0.25
Atrial fibrillation (new), <i>n</i> (%)	12 (4.4)	7 (5.2)	5 (3.7)	0.56
Stroke, <i>n</i> (%)	9 (3.3)	5 (3.7)	4 (2.9)	0.74
New permanent pacemaker, <i>n</i> (%)	16 (5.9)	8 (5.9)	8 (5.9)	1
Prolonged ventilation, <i>n</i> (%)	9 (3.3)	2 (1.5)	7 (5.2)	0.09
Pulmonary embolism, <i>n</i> (%)	2 (0.7)	2 (1.5)	0 (0)	0.16
Pneumonia, <i>n</i> (%)	12 (4.4)	7 (5.2)	5 (3.7)	0.56
Coronary vessel obstruction, <i>n</i> (%)	3 (1.1)	2 (1.5)	1 (0.7)	0.56
Valve embolization, <i>n</i> (%)	7 (2.6)	5 (3.7)	2 (1.5)	0.25
Failure to deliver THV device, <i>n</i> (%)	6 (2.2)	6 (4.4)	0	0.01

CONCLUSIONS TAVI operator experience results in improved procedural success and 30-day mortality. This is likely a **combination of improved technical skill, better patient selection, and technological advances**. Although overall complication rates are low, scope remains to further reduce procedural adverse events such as vascular injury, pacemaker needs, and stroke. Future technological and procedural advances may continue to further improve patient outcomes.



Meta-Analysis of the Impact of Mitral Regurgitation on Outcomes After Transcatheter Aortic Valve Implantation



Tarun Chakravarty, MD^a, Eric Van Belle, MD^b, Hasan Jilaihawi, MD^a, Amit Noheria, MBBS, SM^c, Luca Testa, MD^d, Francesco Bedogni, MD^d, Andreas Rück, MD^e, Marco Barbanti, MD^{f,g}, Stefan Toggweiler, MD^h, Martyn Thomas, MDⁱ, Muhammed Zeeshan Khawaja, MBBS, MRCPⁱ, Andrea Hutter, MD^j, Yigal Abramowitz, MD^a, Robert J. Siegel, MD^a, Wen Cheng, MD^a, John Webb, MD^g, Martin B. Leon, MD^k, and Raj R. Makkar, MD^{a,*}

A 30-day mortality

Study or subgroup	Moderate-severe MR		None-mild MR		Weight	Risk ratio M-H, Random, 95% CI
	Events	Total	Events	Total		
Barbanti et al.	4	103	24	396	2.5%	0.64 [0.23, 1.81]
Baumgartner et al.	36	519	123	2096	20.8%	1.18 [0.83, 1.69]
Bedogni et al.	31	337	34	670	12.2%	1.81 [1.13, 2.90]
Hutter et al.	8	60	20	208	4.5%	1.39 [0.64, 2.99]
Khawaja et al.	6	60	16	256	3.3%	1.60 [0.65, 3.92]
Ruck et al.	12	113	29	463	6.5%	1.70 [0.89, 3.22]
Toggweiler et al.	19	132	26	319	8.7%	1.77 [1.01, 3.08]
Van Belle et al.	71	661	220	2534	41.6%	1.24 [0.96, 1.59]
Total (95% CI)		1985		6942	100.0%	1.35 [1.14, 1.59]

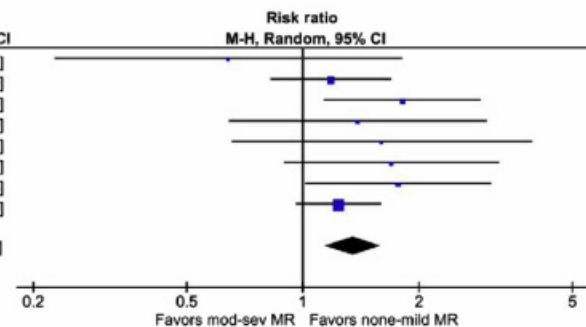
Total events

187

492

Heterogeneity: Tau² = 0.00; Chi² = 6.02, df = 7 (P = 0.54); I² = 0%

Test for overall effect: Z = 3.58 (P = 0.0003)



B 1-year mortality

Study or subgroup	Moderate-severe MR		None-mild MR		Weight	Risk ratio M-H, Random, 95% CI
	Events	Total	Events	Total		
Barbanti et al.	24	103	106	396	6.4%	0.87 [0.59, 1.28]
Baumgartner et al.	120	519	386	2096	29.3%	1.26 [1.05, 1.50]
Bedogni et al.	72	337	101	670	12.9%	1.42 [1.08, 1.86]
Hutter et al.	18	60	44	208	4.4%	1.42 [0.89, 2.26]
Khawaja et al.	17	60	52	256	4.3%	1.39 [0.87, 2.23]
Ruck et al.	21	113	79	463	5.1%	1.09 [0.70, 1.68]
Toggweiler et al.	36	132	67	319	7.8%	1.30 [0.91, 1.84]
Van Belle et al.	128	661	401	2534	29.7%	1.22 [1.02, 1.46]
Total (95% CI)		1985		6942	100.0%	1.24 [1.13, 1.37]

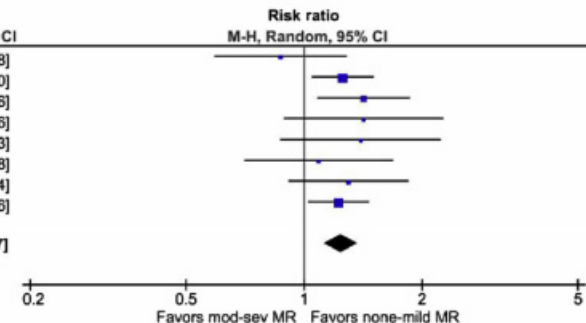
Total events

436

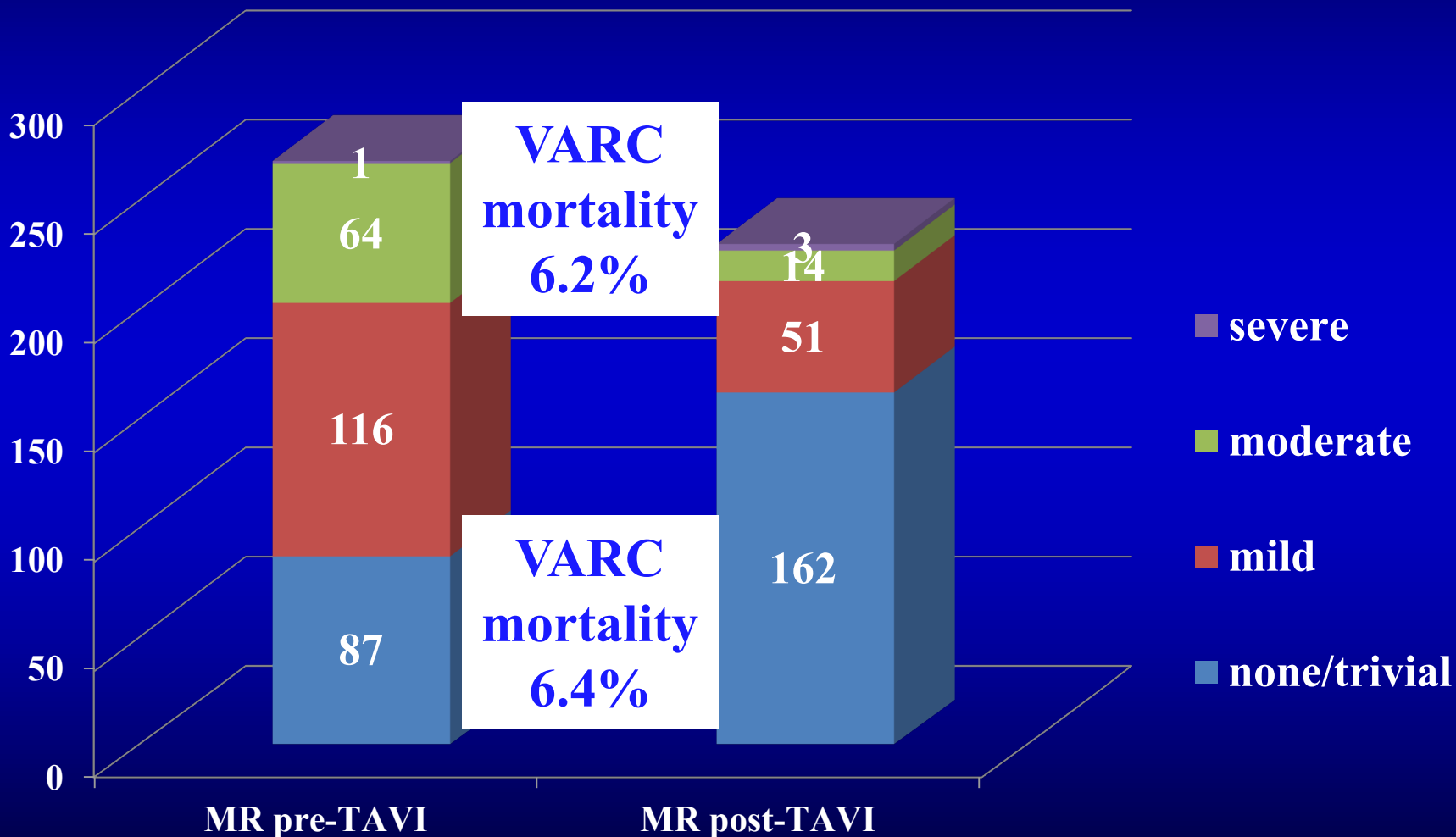
1236

Heterogeneity: Tau² = 0.00; Chi² = 5.15, df = 7 (P = 0.64); I² = 0%

Test for overall effect: Z = 4.35 (P < 0.0001)



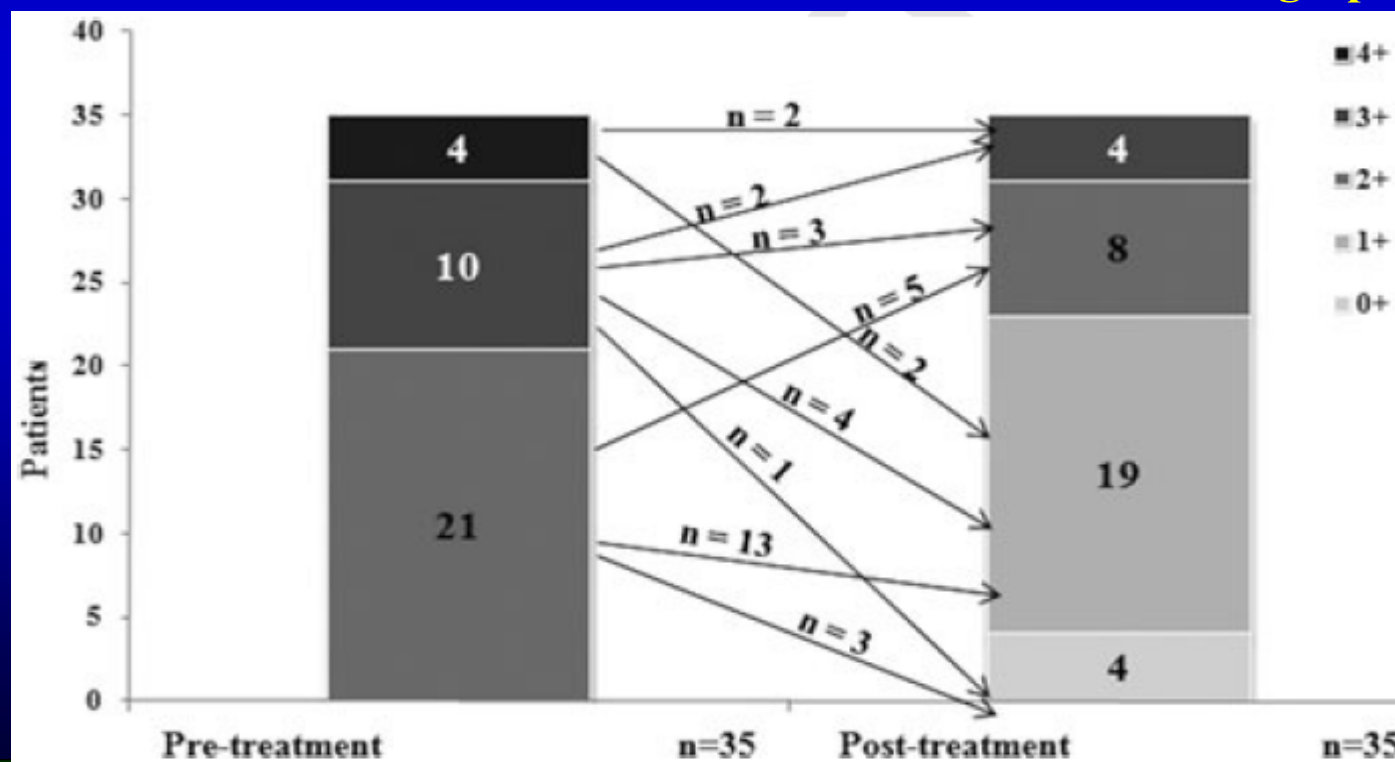
Focus on Mitral Regurgitation



6 Impact of TAVI on Mitral Regurgitation: A Prospective Echocardiographic Study

Francesca Giordana, M.D.,* Michele Capriolo, M.D.,* Simone Frea, M.D.,* Walter Grosso Marra, M.D.,* Mauro Giorgi, M.D.,* Laura Bergamasco, Ph.D.,† Pier Luigi Omedè, M.D.,* Imad Sheiban, M.D.,* Maurizio D'Amico, M.D.,* Virginia Bovolò, M.D.,* Stefano Salizzoni, M.D.,‡ Michele La Torre, M.D.,‡ Mauro Rinaldi, M.D.,‡ Sebastiano Marra, M.D.,* Fiorenzo Gaita, M.D.* and Mara Morello, M.D.*

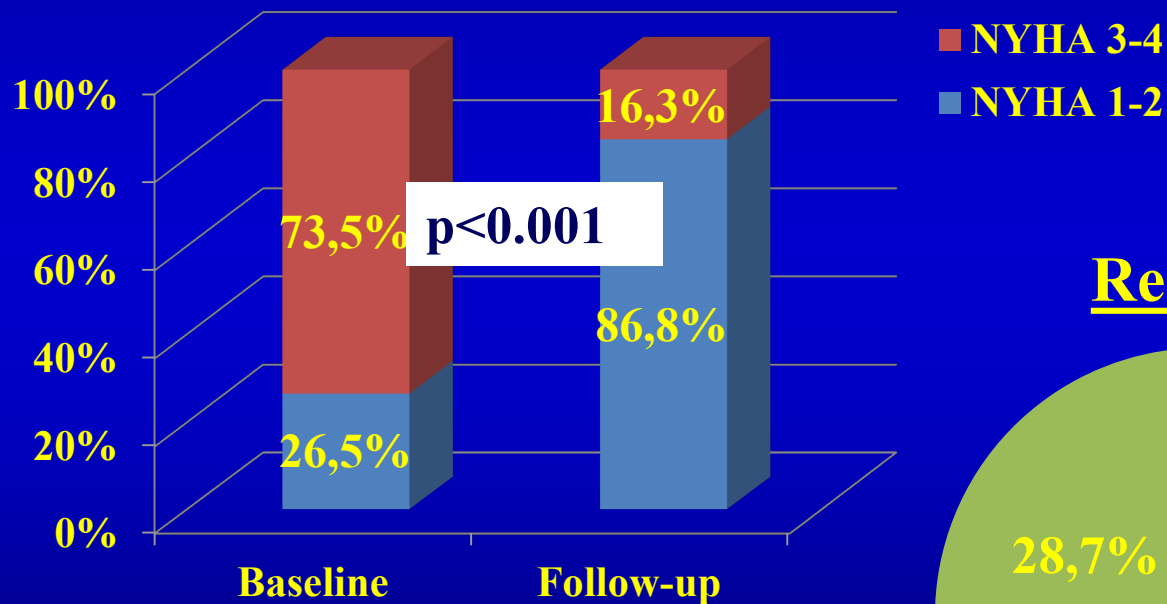
Echocardiography, 2012



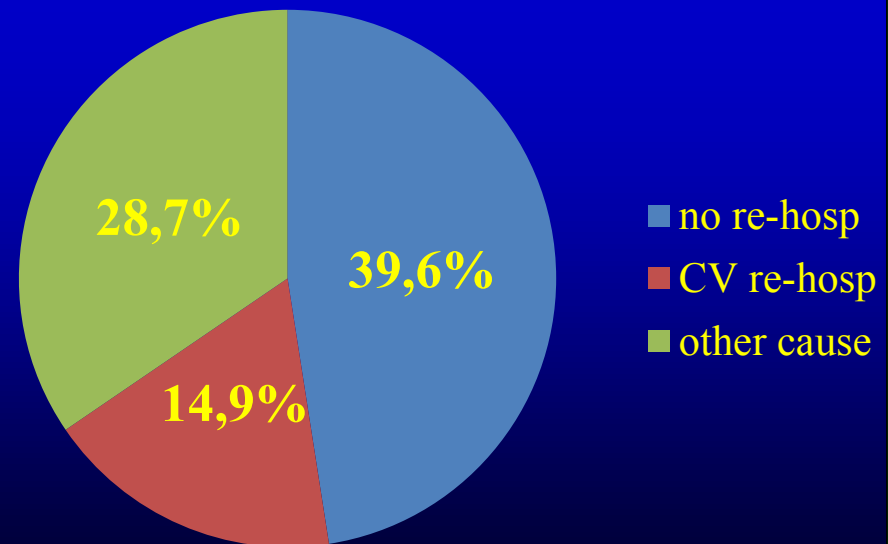
Follow-up: clinical evaluation

Mean FU 681±583 days, median 553 days

NYHA class



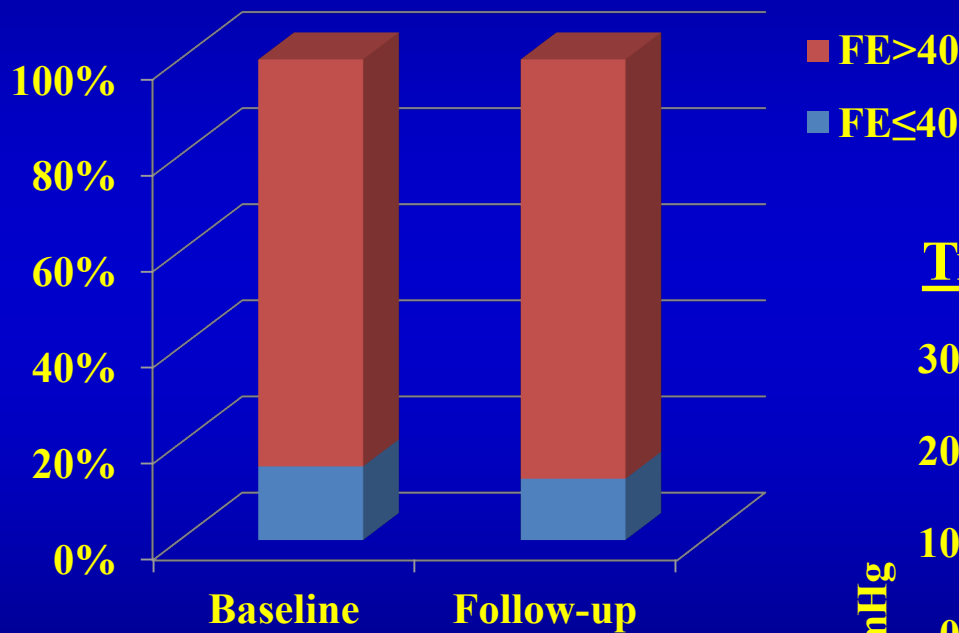
Re-hospitalization



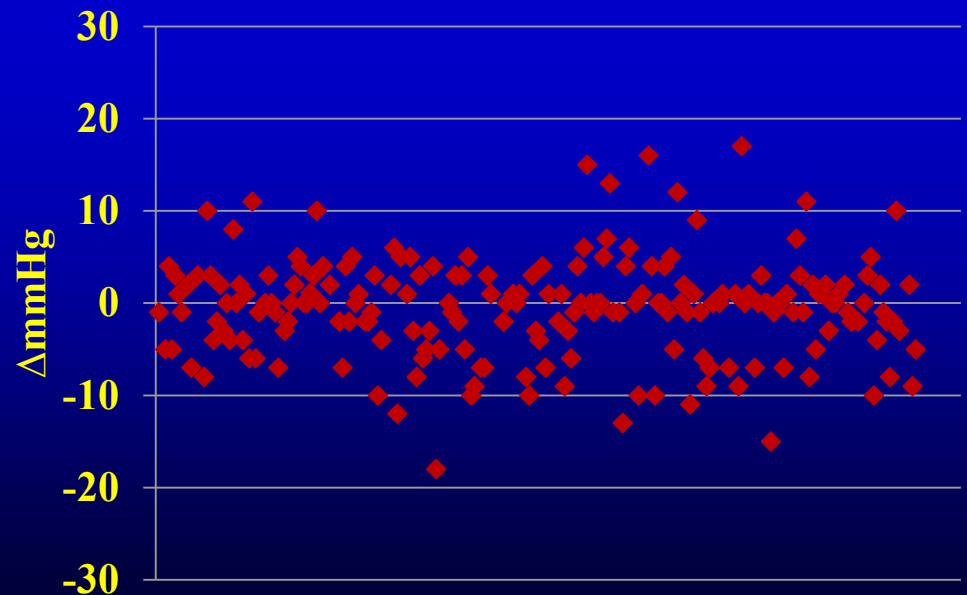
Follow-up: echo evaluation

→ At least one echo: 212 (80%) patients

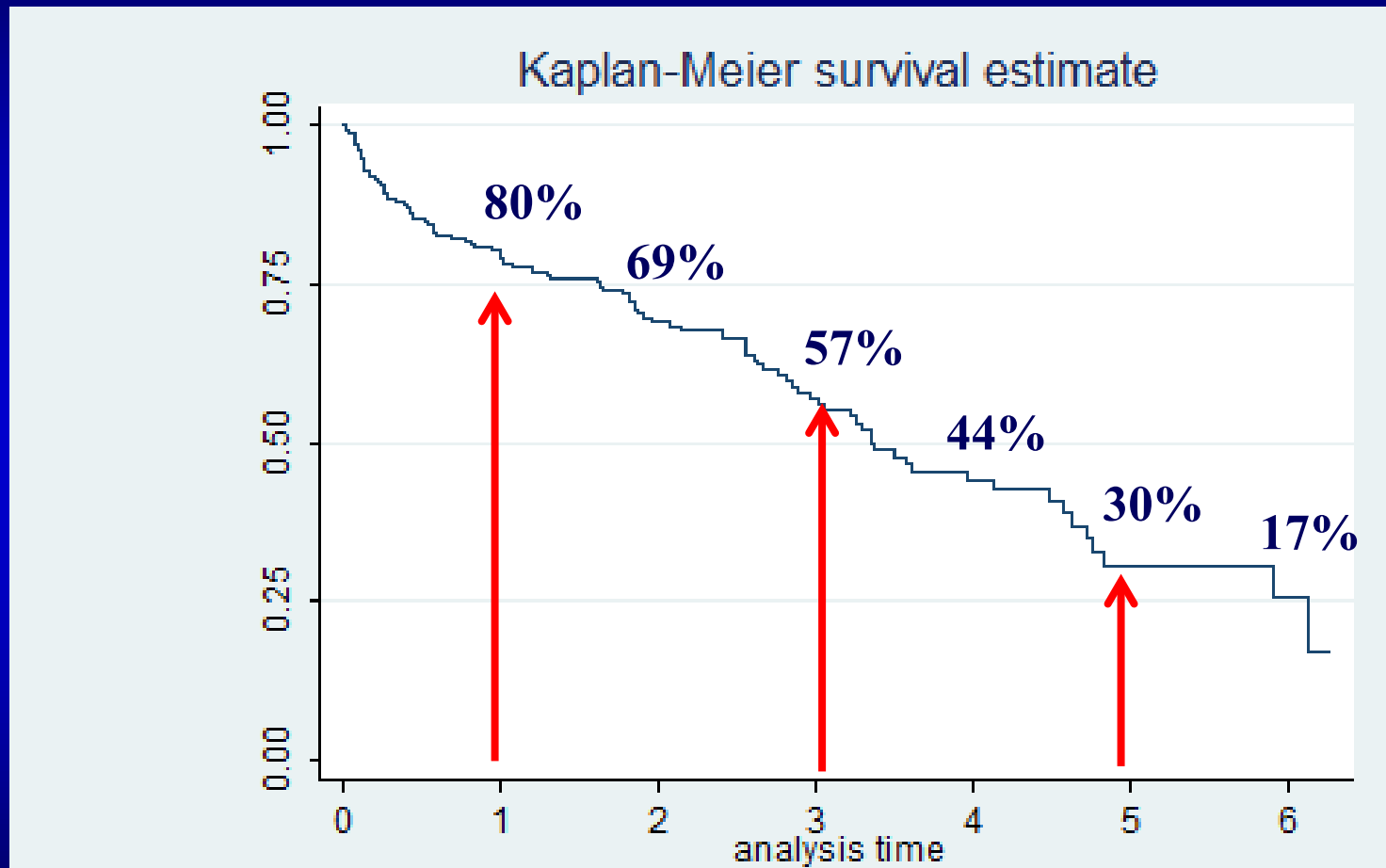
LVEF



Transprosthesis gradients variation

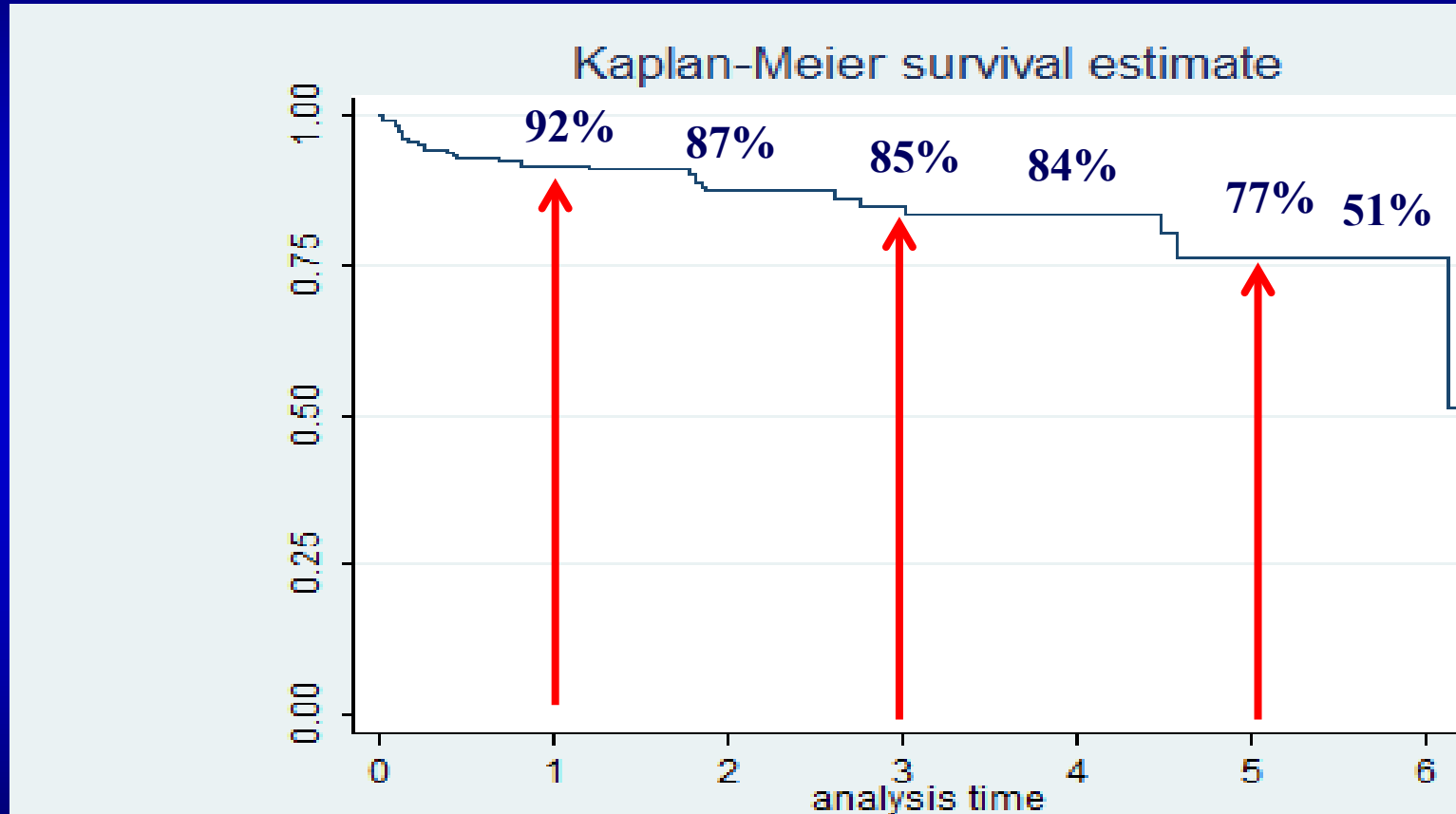


Overall Survival



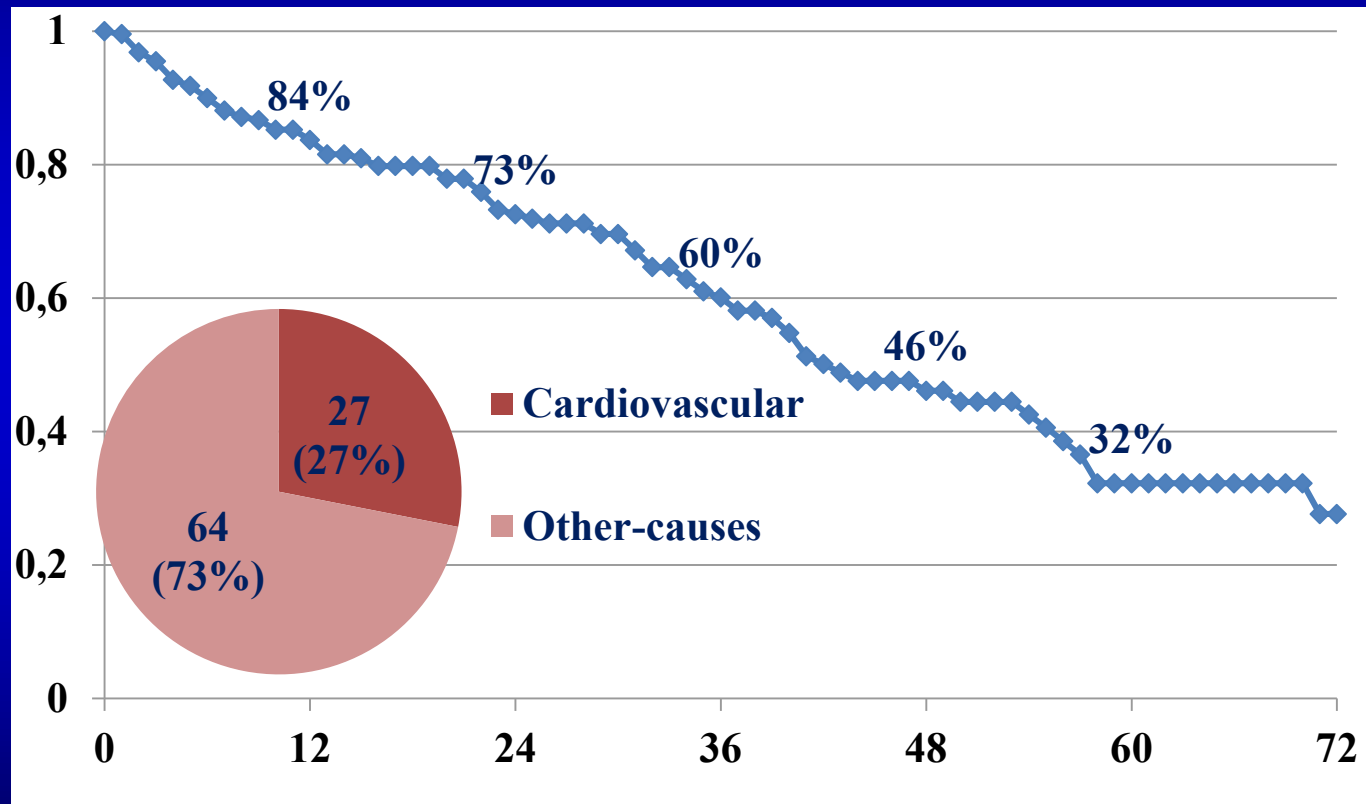
N. at risk 268 167 110 62 29 13 4

Survival-Cardiovascular Mortality



N. at risk 268 167 110 62 29 13 4

Overall Survival-without VARC mortality



N. at risk

268

167

110

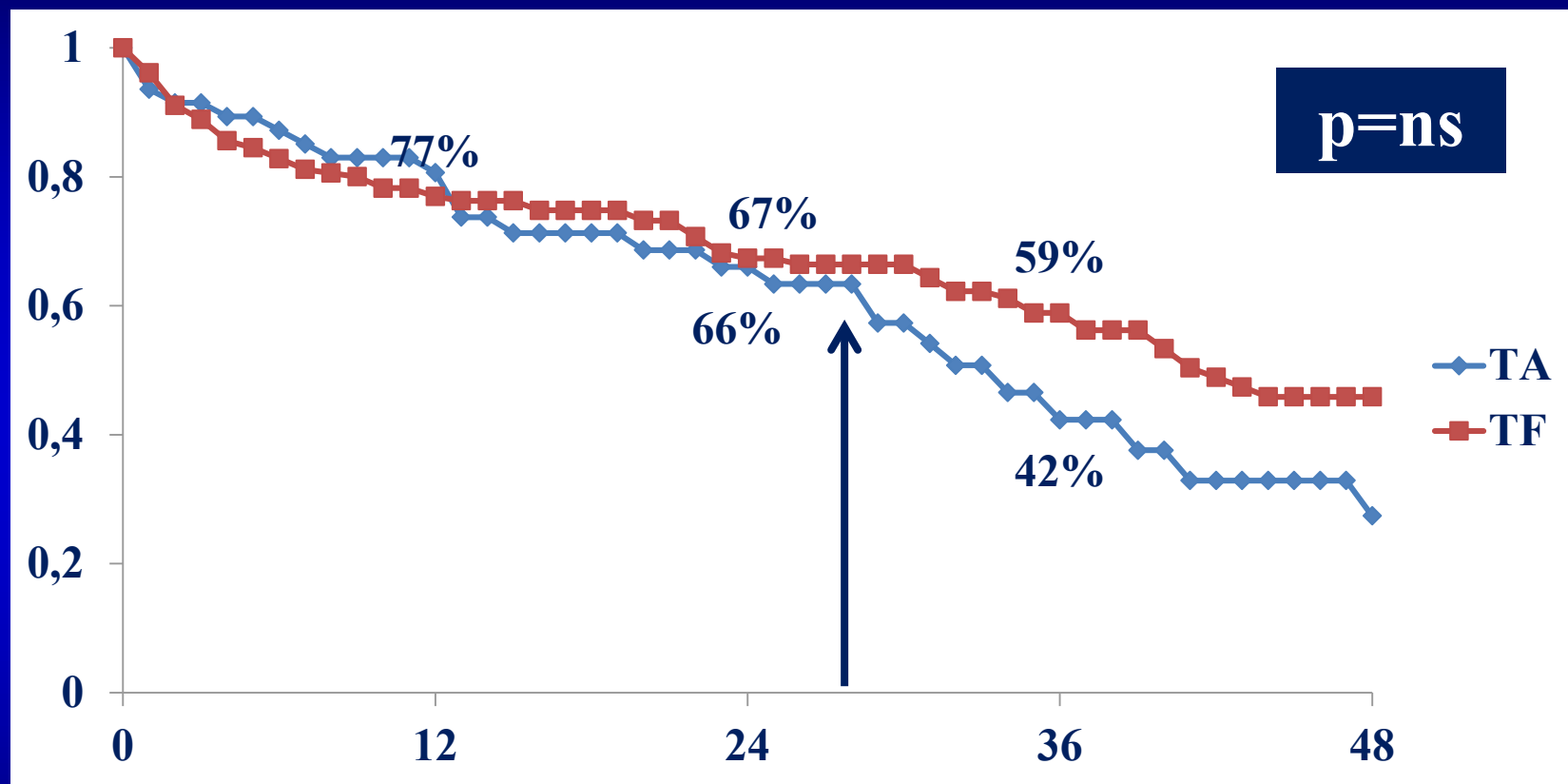
62

29

13

4

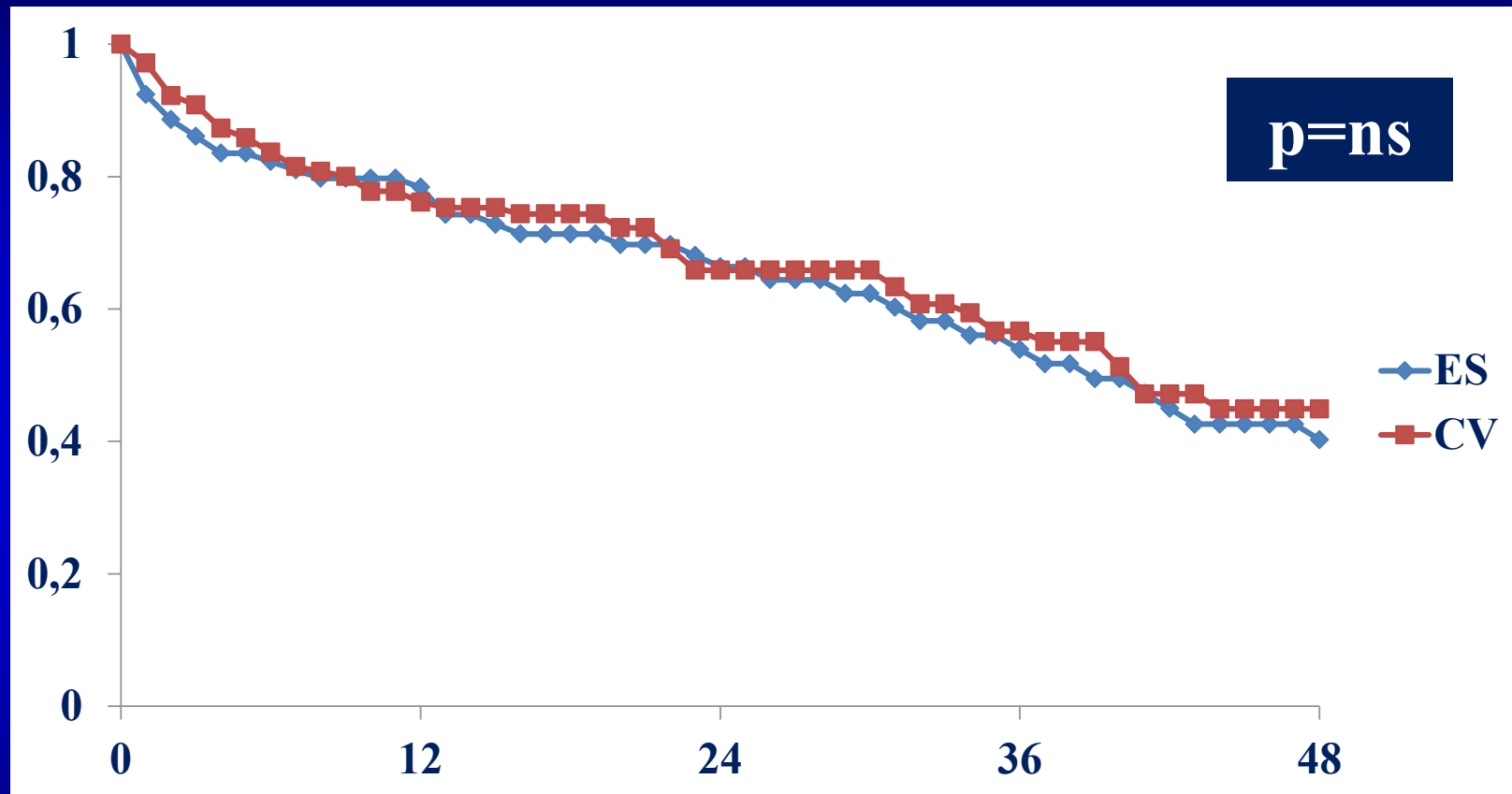
Survival-Access



N. at risk

TA	49	37	25	11	4
TF	219	130	85	51	25

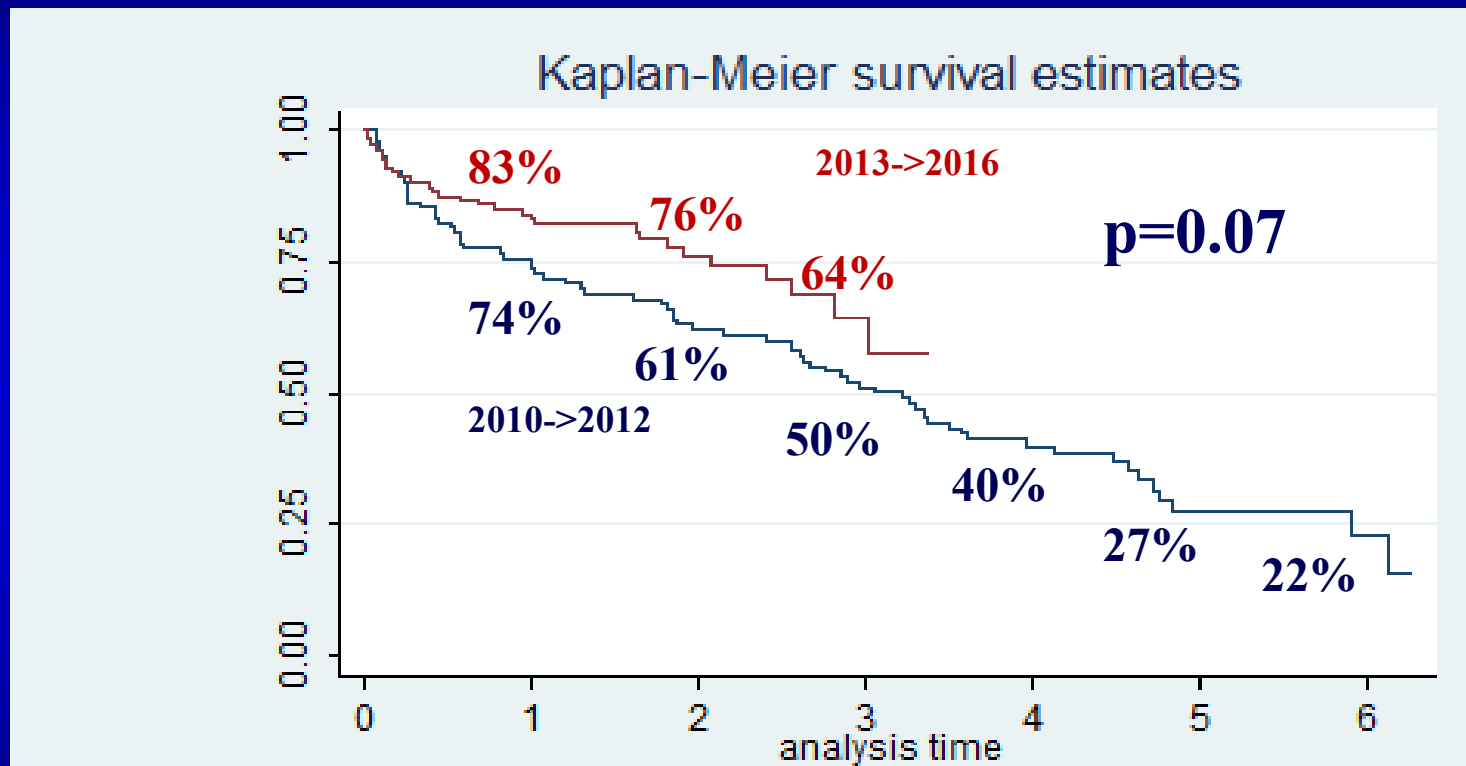
Survival-Type of valve



N. at risk

ES	96	58	43	28	16
CV	172	109	67	34	13

Survival-Landmark analysis 2010->2012 vs 2013->2016



N. at risk

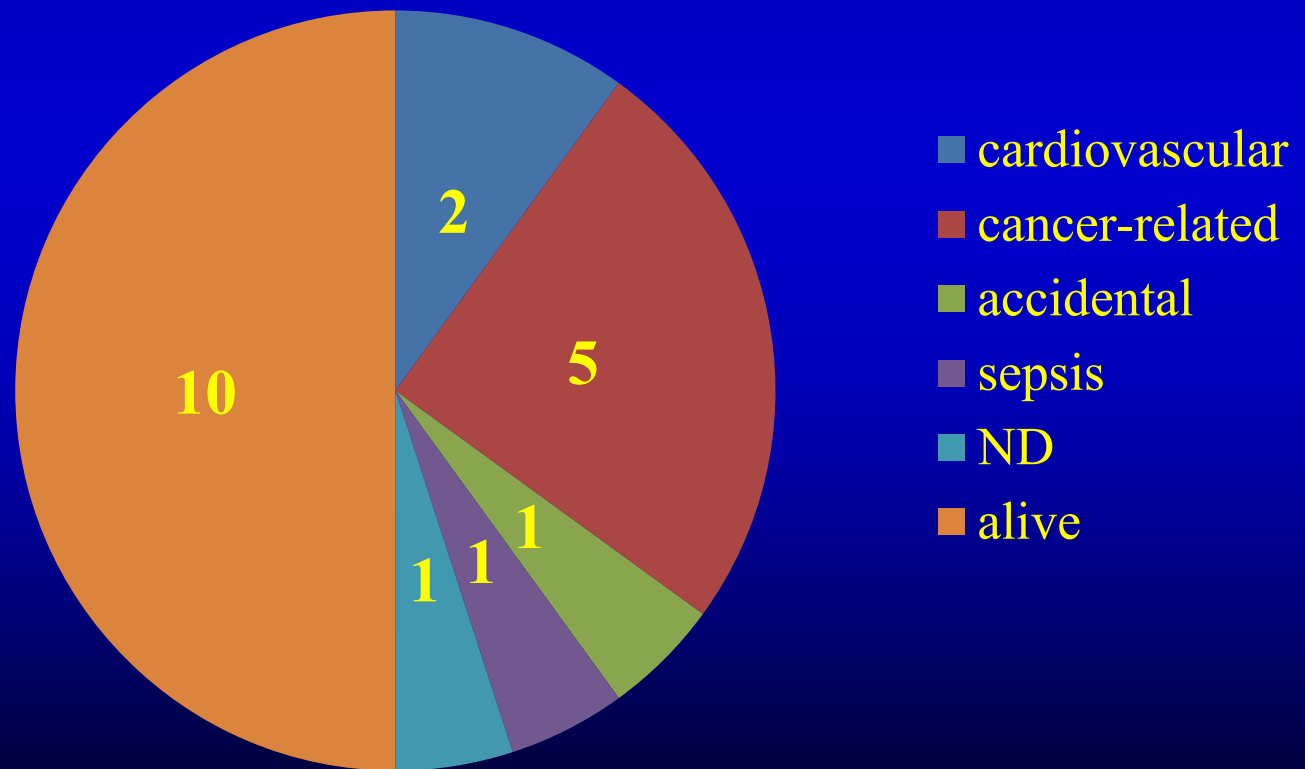
2013->2016	161	90	47	18	0	0	0
2010->2012	105	77	63	55	29	13	3

Cancer and Mortality

21 (7.8%) patients

Mean FU 681±583 days, median 553 days

OR=0.38, IC 0.13-1.11, p=0.11



**"Good
enough"
isn't
enough...**

ORIGINAL ARTICLE

Early discharge after transfemoral transcatheter aortic valve implantation

Marco Barbanti,¹ Piera Capranzano,¹ Yohei Ohno,¹ Guilherme F Attizzani,¹ Simona Gulino,¹ Sebastiano Immè,¹ Stefano Cannata,¹ Patrizia Aruta,¹ Vera Bottari,¹ Martina Patanè,¹ Claudia Tamburino,¹ Daniele Di Stefano,¹ Wanda Deste,¹ Daniela Giannazzo,¹ Giuseppe Gargiulo,¹ Giuseppe Caruso,¹ Carmelo Sgroi,¹ Denise Todaro,¹ Emanuela di Simone,¹ Davide Capodanno,¹ Corrado Tamburino^{1,2}

Heart, 2015

	Before matching			After matching		
	Early discharge (n=107)	Late discharge (n=358)	p Value	Early discharge (n=89)	Late discharge (n=178)	p Value
Death	2 (1.9)*	6 (1.7)	0.583	2 (2.2)*	3 (1.7)	0.540
New PPM	0 (0.0)	2 (0.6)	0.592	0 (0.0)	2 (1.1)	0.444
Any bleeding	1 (0.9)	0 (0.0)	0.230	1 (1.1)	0 (0.0)	0.333
Re-hospitalisation	1 (0.9)	3 (0.8)	0.650	1 (1.1)	2 (1.1)	1.000
Composite safety endpoint†	3 (2.8)	8 (2.2)	0.483	3 (3.4)	5 (2.8)	0.533
Acute kidney injury‡						
Stage 1	5 (4.6)	–	–	4 (4.5)	–	–
Stage 2	1 (0.9)	–	–	1 (1.1)	–	–
Stage 3	0 (0.0)	–	–	0 (0.0)	–	–

Values are n (%). Categorical variables were compared using the McNemar's exact test.

*Patient #1 (CoreValve 29 mm, no conduction disturbances at discharge) died at day 11 due to haemorrhagic stroke. Patient #2 (CoreValve 29 mm and PPM implanted at day 1) died at day 9 due to myocardial infarction.

†Defined as the composite of death, bleeding, PPM implantation, and re-hospitalisation for any cause.

‡Available in patients discharged within 3 days after TAVI. Outcome defined according to blood work prescribed at days 5–7 after discharge. PPM, permanent pacemaker; TAVI, transcatheter aortic valve implantation.

Editor's Choice

Rationale, Development, Implementation, and Initial Results of a Fast Track Protocol for Transfemoral Transcatheter Aortic Valve Replacement (TAVR)

Rebecca Marcantuono, MSN, CRNP, Jacob Gutsche, MD, Maureen Burke-Julien, MSN, CRNP, Saif Anwaruddin, MD, FSCAI, John G. Augoustides, MD, David Jones, MSN, CRNP, Lisa Mangino – Blanchard, MSN, CRNP, Nicole Hoke, MSN, RN, Stephanie Houseman, RN, Robert Li, MD, FSCAI, Prakash Patel, MD, Robert Stetson, MHA, Elizabeth Walsh, RN, Wilson Y. Szeto, MD, and Howard C. Herrmann,* MD, FSCAI

CCI 2015

Table 1. Fast Track Initiation vs Standard Care: Costs and Length of Stays

	Fast Track (n = 39)	Standard Care (n = 60)	P Value
Direct Costs	\$44,923 ± \$14,187	\$56,339 ± \$17,808	< .0001
ICU Stay, hours	28.4 ± 102.8	44.8 ± 45.9	< .0001
Postoperative Stay, days	4.3 ± 4.4	7.2 ± 5.3	< .0001

Protocol “GISE-Piemonte” for early discharge

CRITERI DI POTENZIALE ELEGIBILITA’:

- FE > 40%
- eGFR > 45
- Ricovero elettivo (NHYA < 4)
- Indipendenza nelle attività quotidiane

GIORNATA 0 (TAVI)

- Sala
- Accesso femorale percutaneo
- Sedazione conscia

- No BAV/BBSx durante della procedura
- No PV Leak > 1+
- No versamento pericardico
- No complicanze vascolari in sede d'accesso
- Rimozione di tutti gli sheath arteriosi al termine della procedura

- **TRASFERIMENTO IN UTIC**

GIORNATA 1 (Rivalutazione e trasferimento in reparto)

- Rimozione catetere vescicale
- Accessi vascolari in ordine
- TTE
- Mobilizzazione protetta
- NYHA I-II
- NO aritmie maggiori (incl. FA new onset)
- NO IRC tipo 3 (VARC-2) o eGFR < 25
- NO riduzione Hb > 2 mg/dl in 2 prelievi consecutivi
- NO trasfusioni
- NO BAV/BBSx di nuova insorgenza
- NO segni clinici o lab di infezione (febbre?)
- **Trasferimento in reparto**
- **Proseguimento mobilizzazione (telemetria)**

GIORNATA 2 (Mobilizzazione completa)

- Progressiva ripresa delle abitudini quotidiane in assenza di sintomi

GIORNATA 3 (Verifica criteri per dimissione «precoce»)

- ✓ **Data dimissione**
 - ✓ NYHA I-II
 - ✓ NO aritmie maggiori (incl. FA new onset)
 - ✓ NO IRC tipo 3 (VARC-2) o eGFR < 25
 - ✓ NO riduzione Hb > 2 g/dl in 2 prelievi consecutivi
 - ✓ NO trasfusioni
 - ✓ NO BAV/BBSx di nuova insorgenza
 - ✓ NO segni clinici o lab di infezione (febbre?)
-
- **Dimissione con richiesta emocromo completo, creat, eGFR, elettroliti dopo 5-7 gg**

FU telefonico a 7 gg e 30 gg

- Data FU
- NYHA
- Riospedalizzazione
- Decesso
- IMA
- Trasfusione
- PM
- IRA



Featured Case Reports

Same Day Discharge after Transcatheter Aortic Valve Replacement: Are We There yet?

Philippe Généreux,^{1,2*} MD, Philippe Demers,¹ MD, and Frédéric Poulin,¹ MD

TABLE I. Proposed Requirements for Early Discharge After TAVR

Procedure level

The absence of any major intraprocedural complication

- Neurological events (stroke, transient ischemic attack, delirium) requiring in-hospital treatment or additional investigation
- Temporary or persistent new arrhythmia (AV block, atrial fibrillation, left or right bundle branch block, etc.) requiring in-hospital therapy or additional investigation
- Major bleeding or vascular complications with risk for recurrence (access related, cardiac structure, other)
- Unsatisfactory intraprocedural hemostasis
- Implantation of a second (or more) valve for any reason (paravalvular leak, embolization, malpositioning, etc.)
- Moderate or severe aortic regurgitation with potential for patient's intolerance on instability, with need for further treatment (medical, percutaneous, or surgical)
- Suboptimal valve positioning with risk to develop further complications (AV block, coronary compromise, etc.)
- Significant contrast load with risk of development of acute kidney injury or the presence of GFR <60 cc/min at baseline
- Significant blood product transfusions or volume with potential risk for delayed volume overload owing to redistribution
- Use of safe transcatheter valve system not associated with the occurrence of late complications (i.e., AV block)

Patient level

- Sustained stable vital signs
- Normal or adequate cognition
- Ability to mobilize safely
- Ability to eat properly
- Stable hemoglobin
- Stable renal function
- No new arrhythmias (AV block, atrial fibrillation, left or right bundle branch block, etc.) or the presence of a prior pace-maker
- No clinical or EKG signs of cardiac ischemia
- Patient's willingness for early discharge

Environment/milieu level

- Adequate family and network support
- Proximity of living and capacity for an early (next day) phone follow-up

What's going on? PARTNER II TRIAL

The NEW ENGLAND JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

APRIL 28, 2016

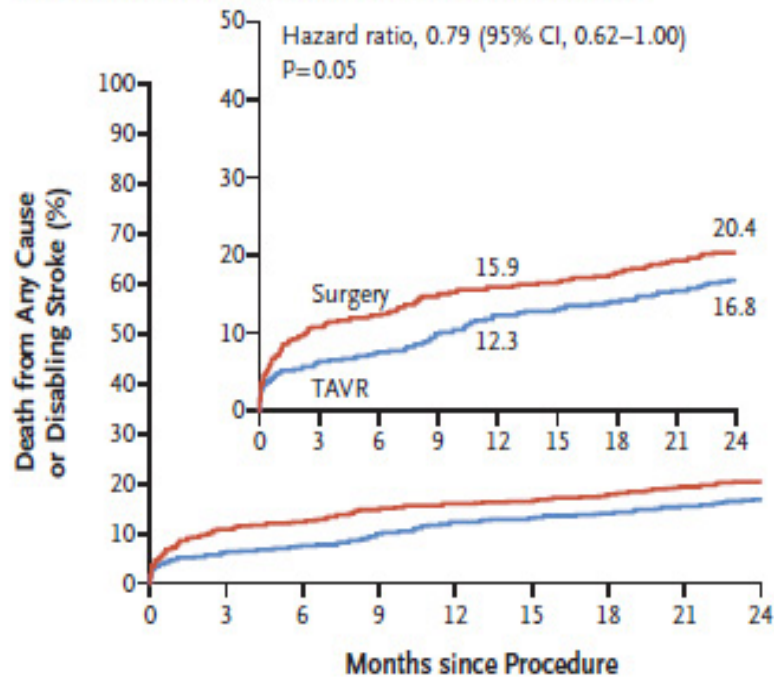
VOL. 374 NO. 17

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

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D., Raj R. Makkar, M.D.,
Lars G. Svensson, M.D., Ph.D., Susheel K. Kodali, M.D., Vinod H. Thourani, M.D., E. Murat Tuzcu, M.D.,
D. Craig Miller, M.D., Howard C. Herrmann, M.D., Darshan Doshi, M.D., David J. Cohen, M.D.,
Augusto D. Pichard, M.D., Samir Kapadia, M.D., Todd Dewey, M.D., Vasilis Babaliaros, M.D.,
Wilson Y. Szeto, M.D., Mathew R. Williams, M.D., Dean Kereiakes, M.D., Alan Zajarias, M.D.,
Kevin L. Greason, M.D., Brian K. Whisenant, M.D., Robert W. Hodson, M.D., Jeffrey W. Moses, M.D.,
Alfredo Trento, M.D., David L. Brown, M.D., William F. Fearon, M.D., Philippe Pibarot, D.V.M., Ph.D.,
Rebecca T. Hahn, M.D., Wael A. Jaber, M.D., William N. Anderson, Ph.D., Maria C. Alu, M.M.,
and John G. Webb, M.D., for the PARTNER 2 Investigators*

Major outcomes: Death and Stroke

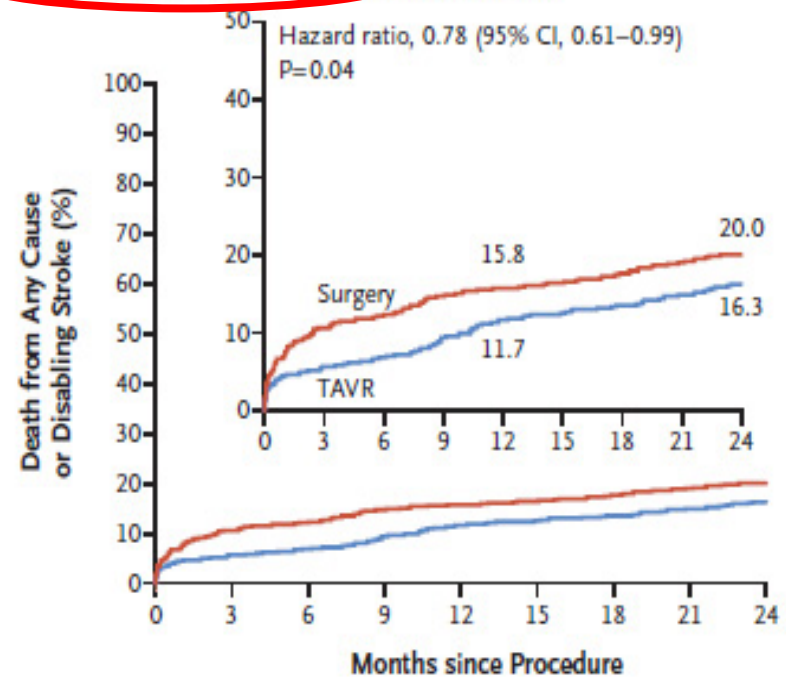
C Transfemoral-Access Cohort, Intention-to-Treat Analysis



No. at Risk

TAVR	775	718	709	685	663	652	644	634	612
Surgery	775	643	628	604	595	577	569	557	538

D Transfemoral-Access Cohort, As-Treated Analysis



No. at Risk

TAVR	762	717	708	685	663	652	644	634	612
Surgery	722	636	624	600	591	573	565	555	537

Final Remarks-what we learned

- Patients' selection: don't treat «futility»
- Imaging for complications' reduction
- Operator skillness. Minimum procedures' number/year.
- The right device for the right patient
- Improvement of out of cath lab standard of care.
If possible early discharge.