Update on procedural outcomes after TAVI

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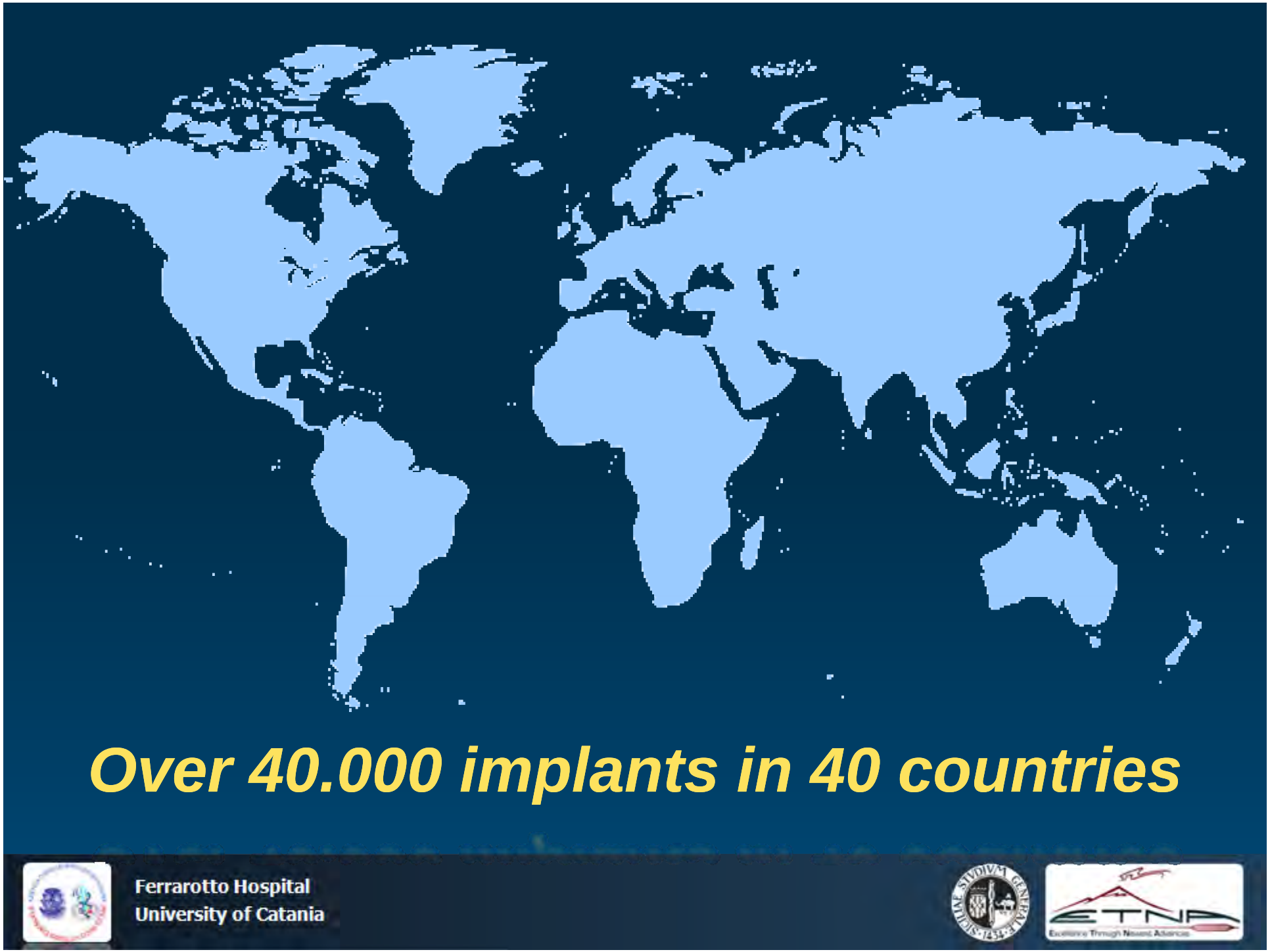
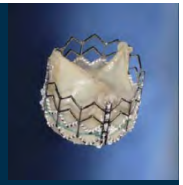
ETNA Foundation

Clinical Results from the WorldWide Transfemoral and Transapical TAVI Experience

What has been done?...


Over 40.000 implants in 40 countries
Ferrarotto Hospital
University of Catania
ETNA

PARTNER IDE Trial



Population: High Risk/Non-Operable Symptomatic, Critical Calcific Aortic Stenosis

ASSESSMENT: Operability

Total n= 1040

Yes

n= up to 690 pts

Cohort A

ASSESSMENT: Transfemoral Access

Yes

Cohort A TF Powered Independently

1:1 Randomization

Trans femoral vs **AVR Control**

No

Cohort A TA Powered to be Pooled with TF

1:1 Randomization

Trans apical vs **AVR Control**

Primary Endpoint: All Cause Mortality (Non-inferiority)

No

Cohort B

n=350 pts

ASSESSMENT: Transfemoral Access

Yes

358 pts

1:1 Randomization

Trans femoral vs **Medical Management Control**

No

Not in Study

Primary Endpoint: All Cause Mortality (Superiority)

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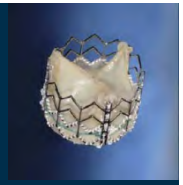
PARTNER IDE Trial



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1:1 Randomization

Trans femoral vs **AVR Control**

No

Cohort Powered Pooled w

1:1 Randomization

Trans apical vs **AVR Control**

Primary Endpoint: All Cause Mortality (Non-inferiority)

Two Trials: Individually Powered Cohorts (Cohorts A & B)

No

Cohort B

n=350 pts

ASSESSMENT: Transfemoral Access

Yes

1:1 Randomization

Trans femoral vs **Medical Management Control**

No

Not in Study

Primary Endpoint: All Cause Mortality (Superiority)

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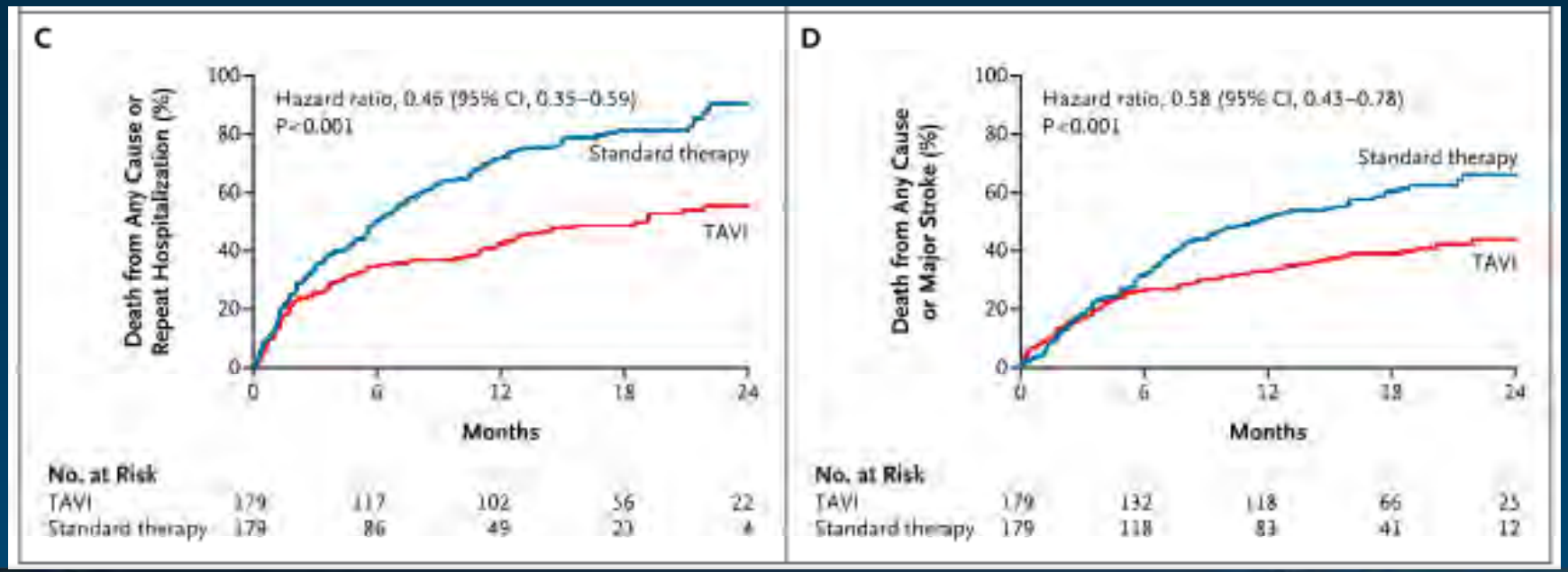
The NEW ENGLAND JOURNAL of MEDICINE

Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela C. Douglas, M.D., John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators*

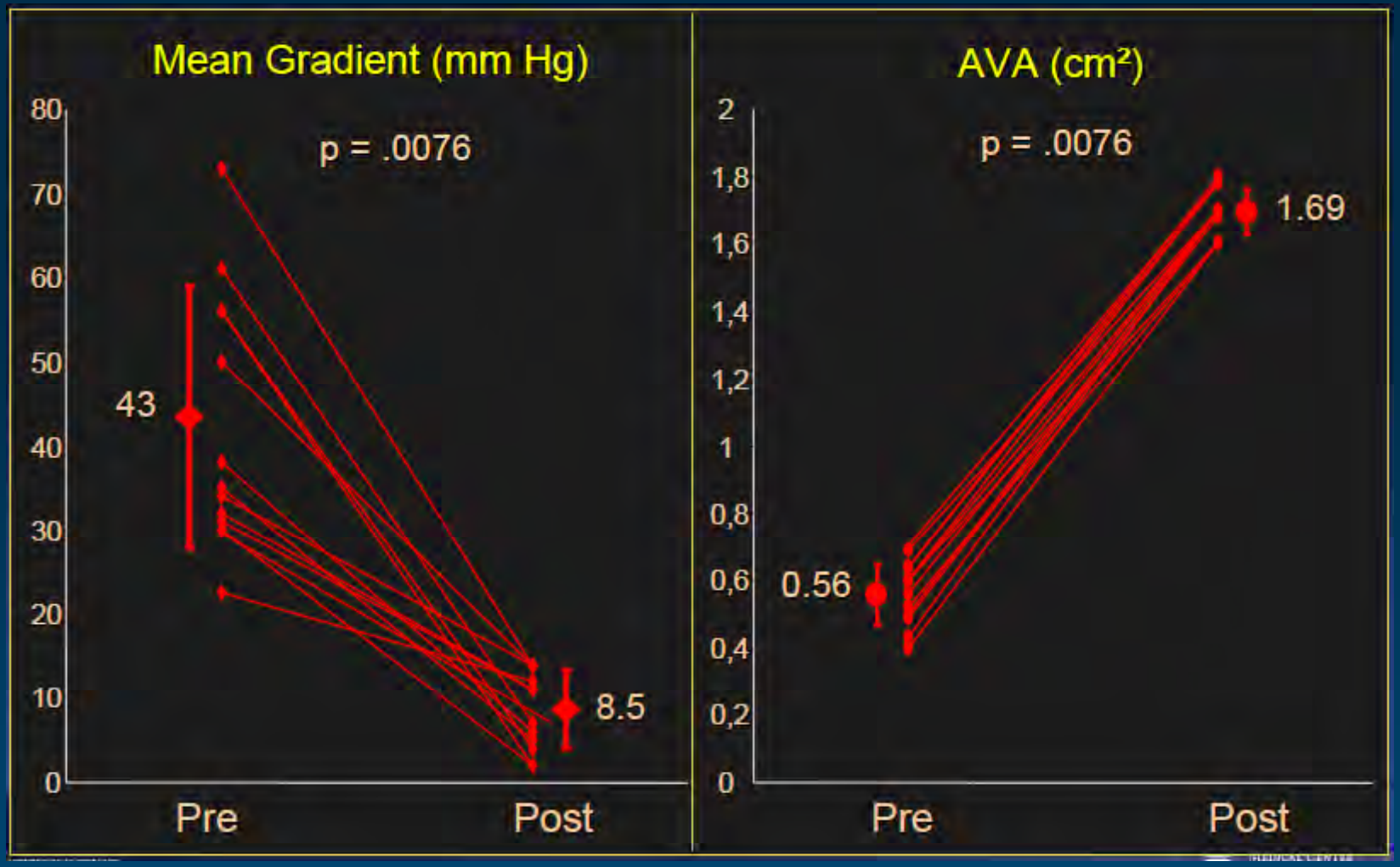


Death from any cause @ 24 mos
50.7% std therapy vs 30.7% TAVI
Δ at 1y 20% NNT 5

Cardiovascular Death @ 24 mos
44.6% std therapy vs 20.5% TAVI
Δ at 1y 24.1% NNT 4.1

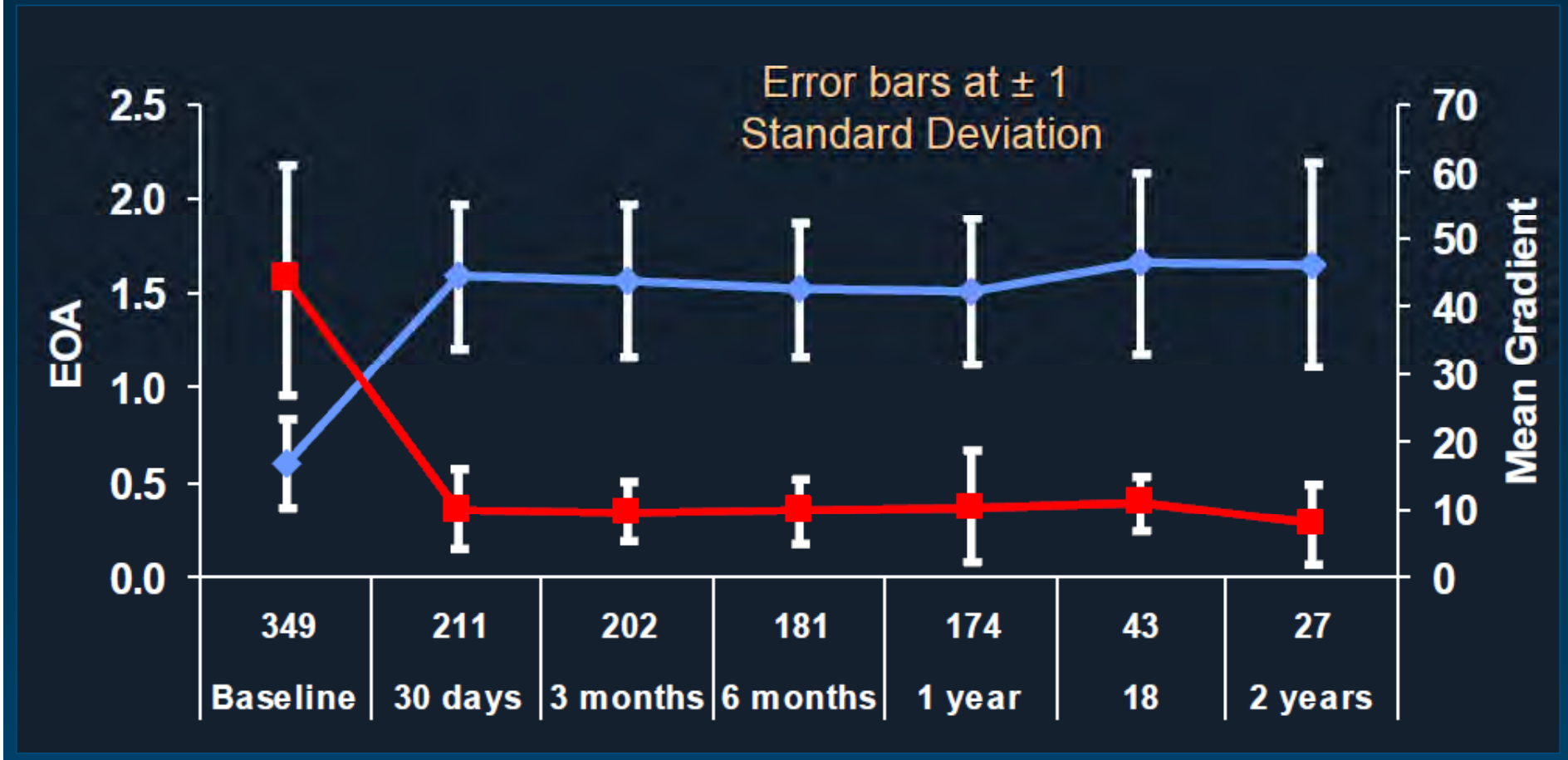
Cribier – Early TAVI Experience

Procedural Results (n=16)



POOLED* Monitored Edwards TAVI

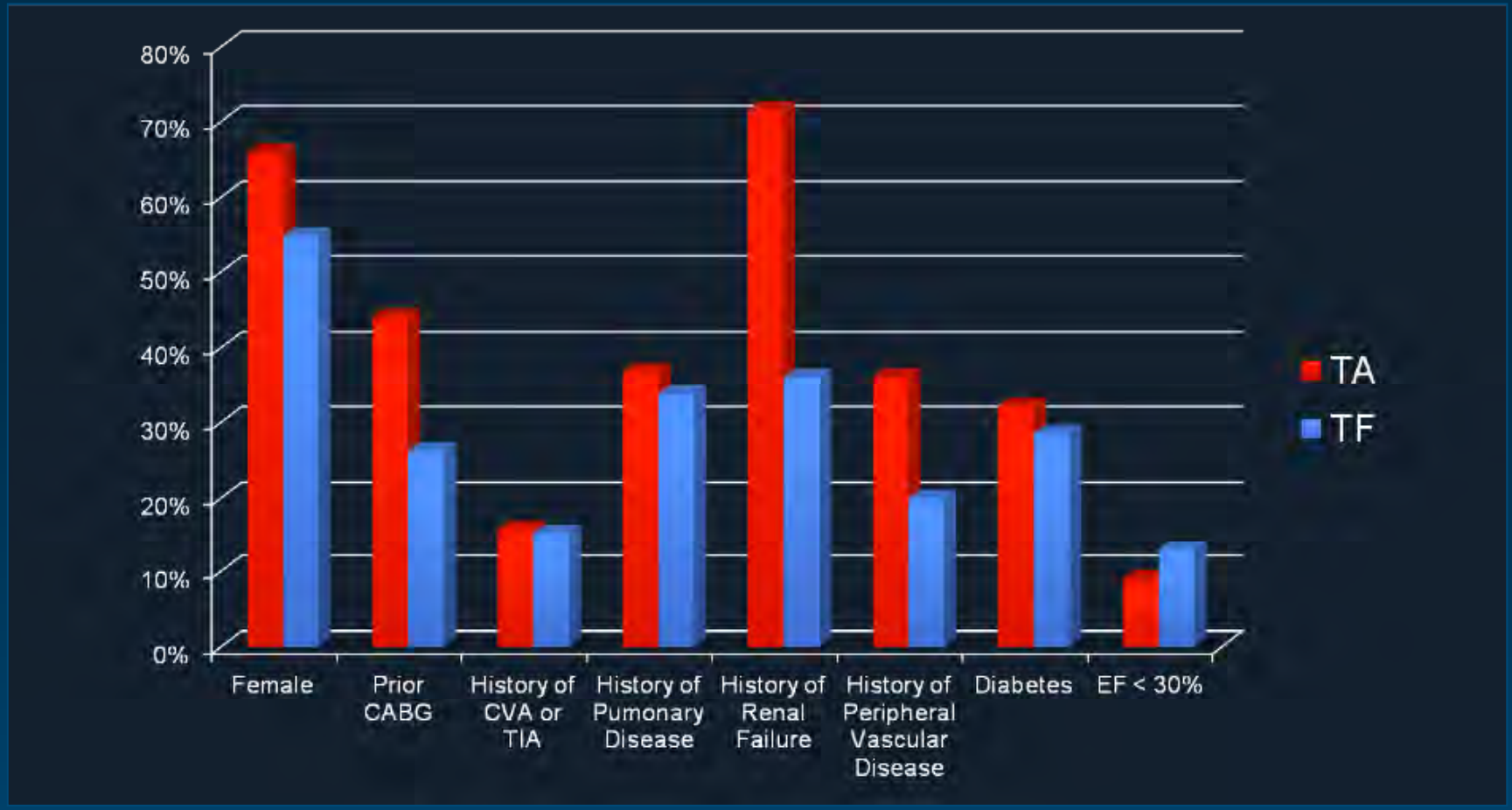
Mean Gradients and EOA (Echo)



*** REVIVE, REVIVAL, TRAVERCE and PARTNER EU**

POOLED* Monitored Edwards TAVI

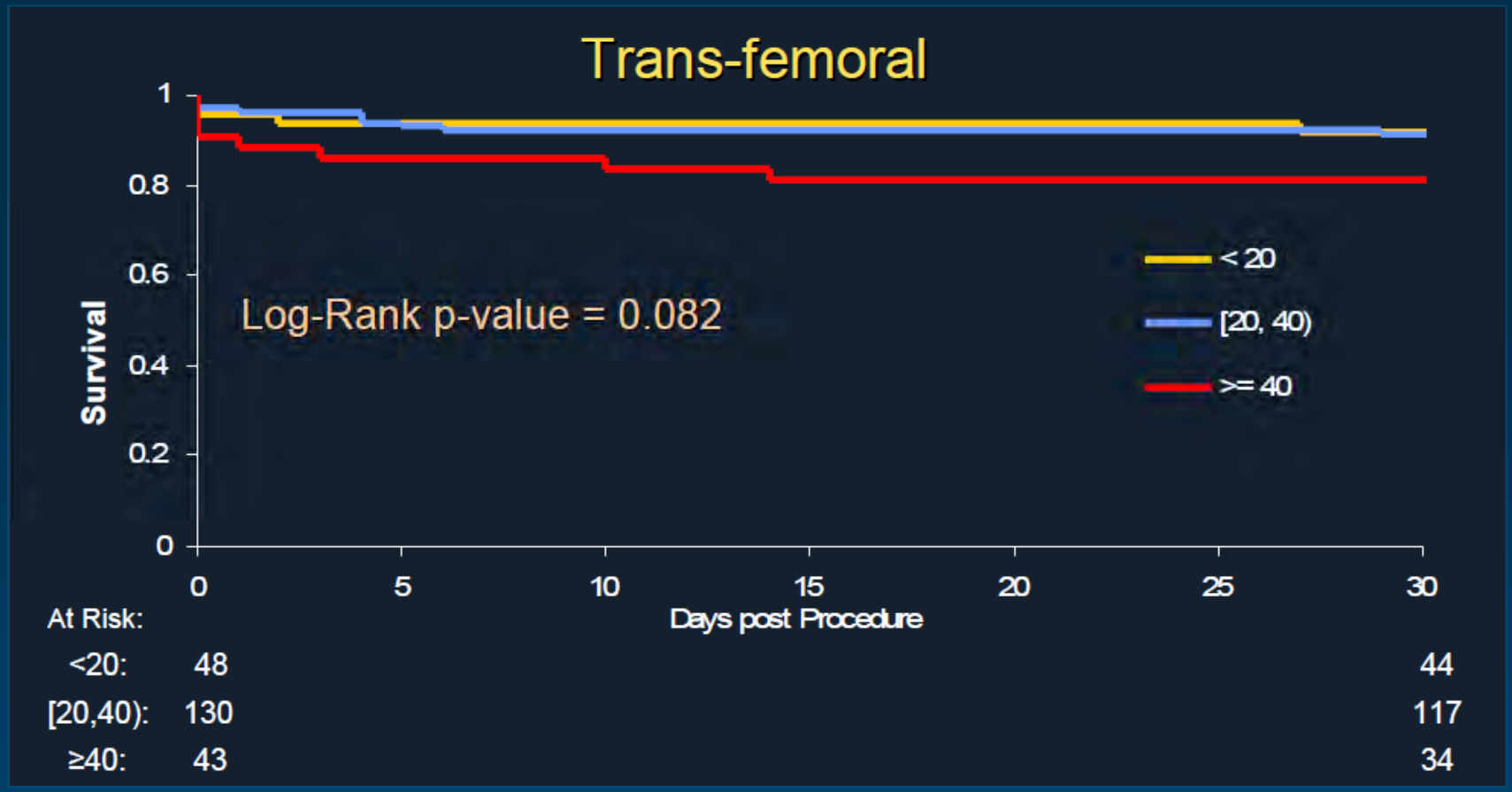
Patient Characteristics (TA vs. TF)



*** REVIVE, REVIVAL, TRAVERCE and PARTNER EU**

POOLED* Monitored Edwards TAVI

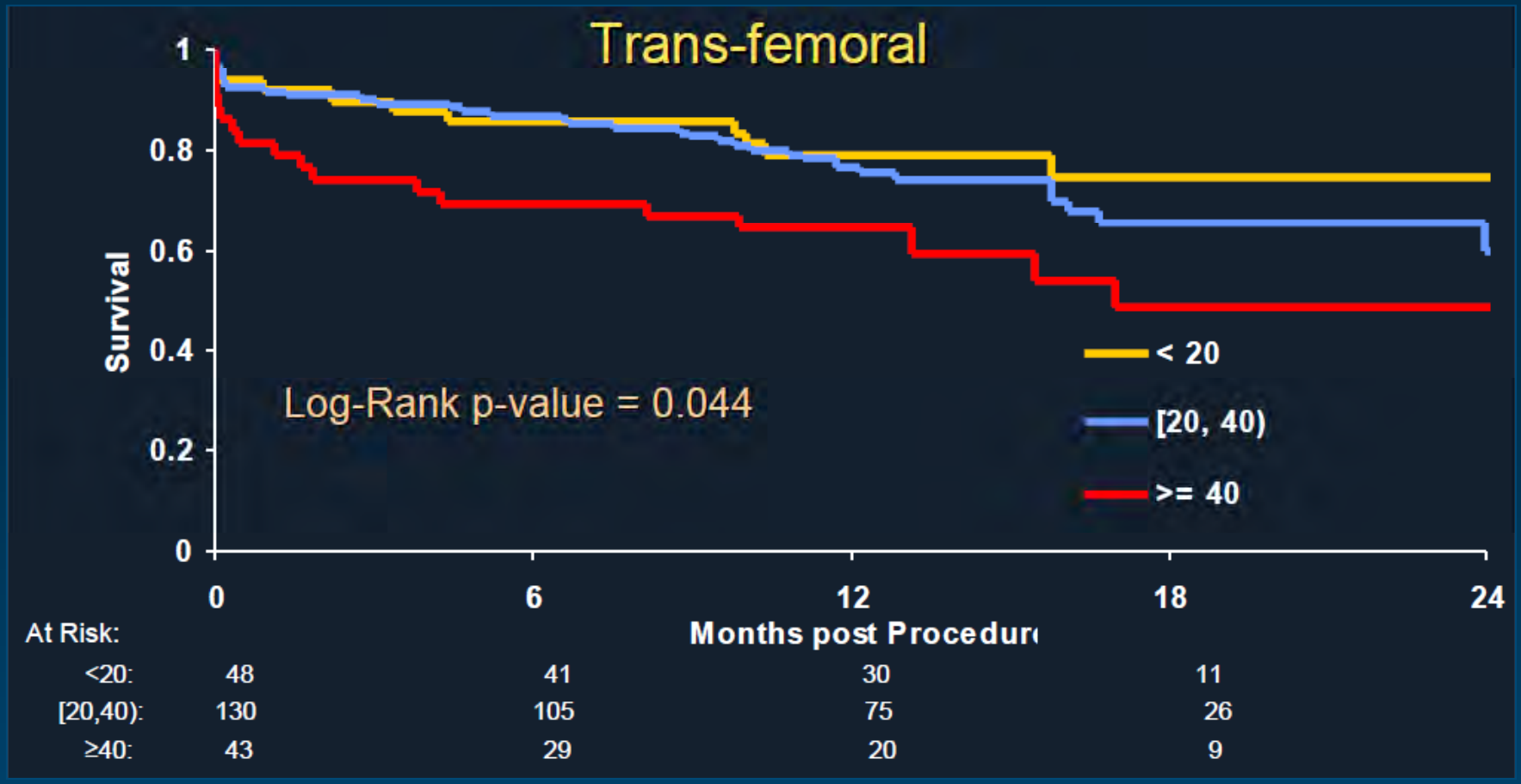
30-Day Mortality (vs. EuroSCORE)



*** REVIVE, REVIVAL, TRAVERCE and PARTNER EU**

POOLED* Monitored Edwards TAVI

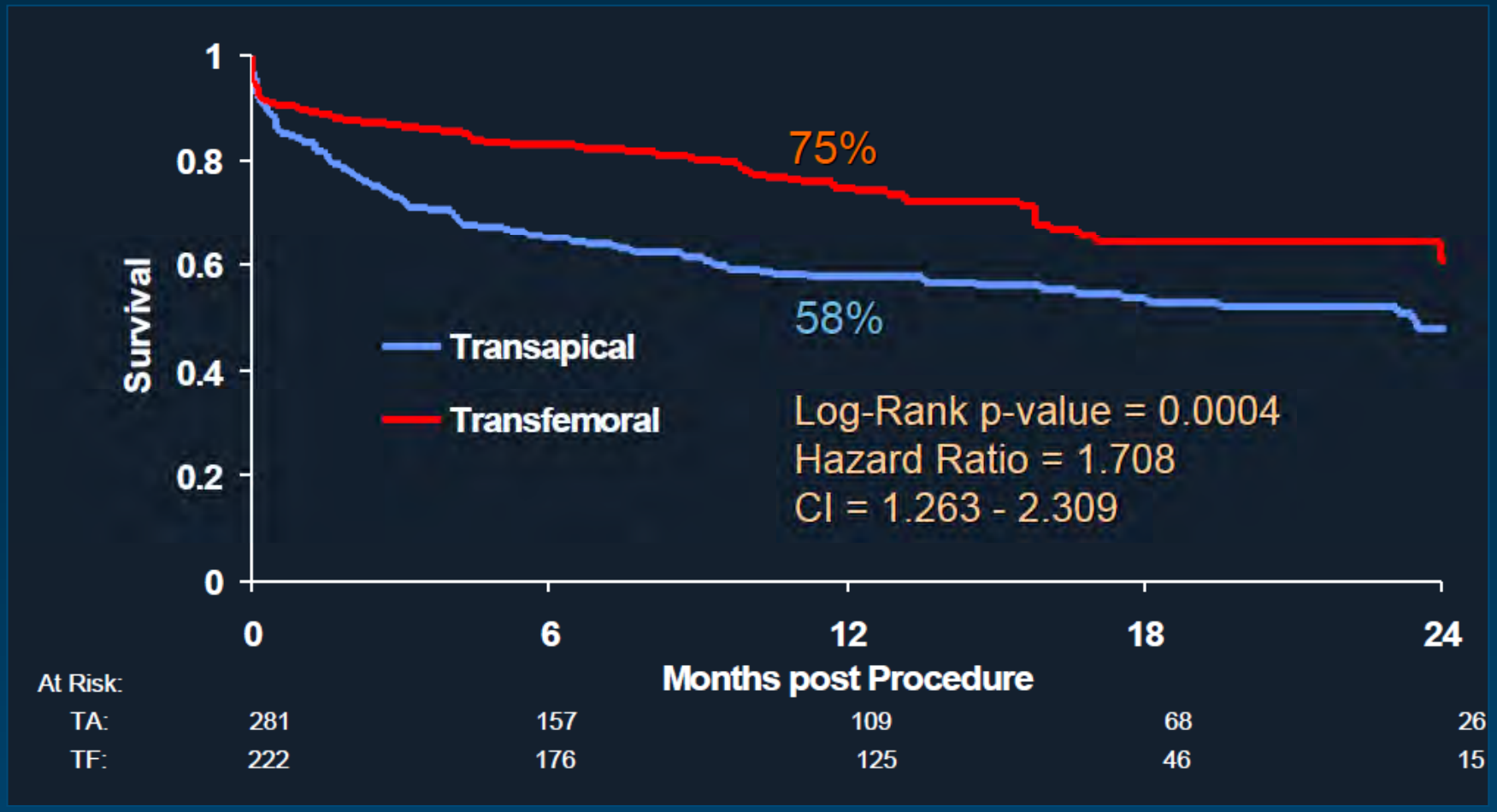
24-Months Mortality (vs. EuroSCORE)



*** REVIVE, REVIVAL, TRAVERCE and PARTNER EU**

POOLED* Monitored Edwards TAVI

2-Yr Mortality



*** REVIVE, REVIVAL, TRAVERCE and PARTNER EU**

SOURCE Registry Methods

34 Centres Initially Participating in Commercial Launch
1123 patients

Excluded:
2 Centres / 85 patients

- Unable to obtain Ethic Cte approval
- Unable to secure administrative support
- One missing patient due to admin. error

Included:
32 centres
1038 patients

AND

98% complete follow-up

100% procedure data
All consecutively enrolled

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SOURCE Registry

Preliminary data

	TF (n=463)	TA (n=575)	P-value
Age (yrs)	81.7	80.7	NS
Female	55.2%	56%	NS
Pulmonary Disease	25.4%	29.4%	NS
Renal Failure	26.3%	32.9%	0.024
Logistic EuroSCORE	25.7	29.2	<0.005
Peripheral Vascular Disease	10.9%	27.5%	<0.001
Carotid Artery Stenosis (>50%)	7.6%	17.1%	<0.001
Incidence of CAD	47.4%	56.0%	<0.006
Porcelain Aorta	4.6%	11.5%	<0.001
Prior CABG	17.6%	26.9%	<0.001
Mitral Valve Disease	16.1%	32.8%	<0.001

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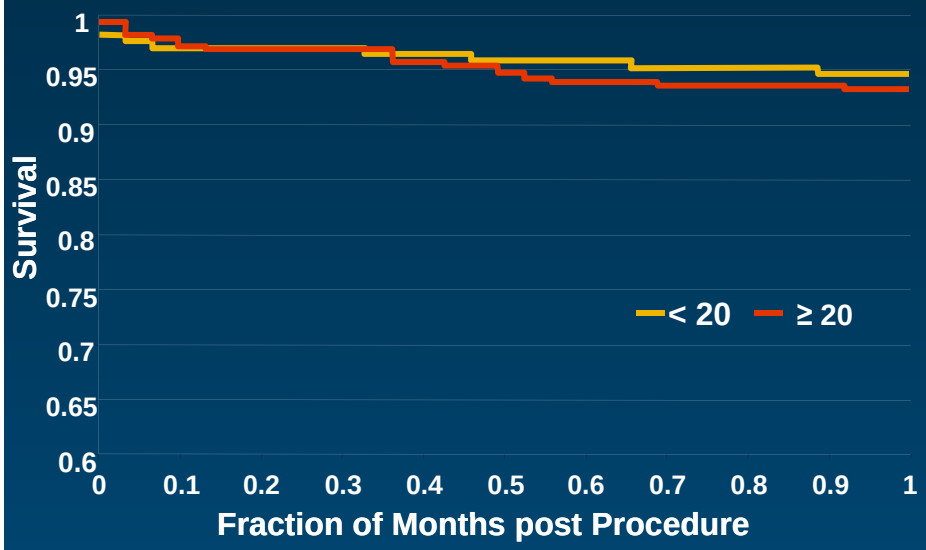
Courtesy of Edwards Lifesciences Inc.

SOURCE Registry

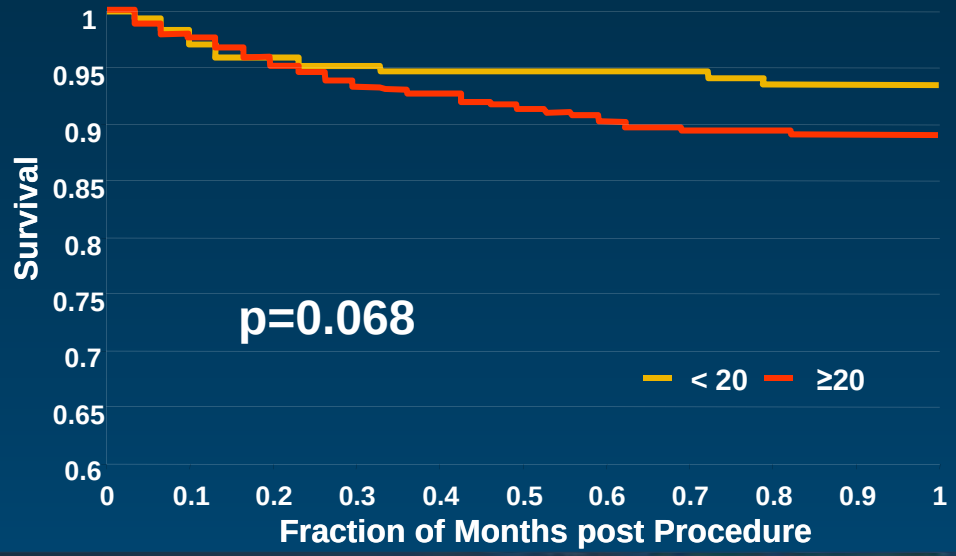
Preliminary data

	TF (n=459)	TA (n=571)
30 day	93.7%	89.7%
EuroSCORE <20	94.6% (Mean 12.5)	93.4% (Mean 12.4)
EuroSCORE >20	93.3% (Mean 33.7)	88.1% (Mean 36.3)

30 Day All Cause Mortality - TF Approach
Stratified by Logistic EuroSCORE



30 Day All Cause Mortality - TA Approach
Stratified by Logistic EuroSCORE



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Courtesy of Edwards Lifesciences Inc.

SOURCE Registry

Preliminary data – Procedure Complications <30 day

	TF (n=463)	TA (n=575)	Total (n=1038)
Acute procedure success	436/95.6% n=456	523/92.9% n=563	959/94.1% n=1019
Device Success*	428/92.4%	522/90.8%	950/91.5%
Conversion to sAVR	8/1.7%	20/3.5%	28/2.7%
AR >+2	15 (3.2%)	34 (5.9%)	49 (4.7%)
Valve Migration	0 (0.0%)	3(0.5%)	3(0.3%)
Valve Malposition	8 (1.7%)	8 (1.4%)	16(1.5%)
Coronary Obstruction	3 (0.7%)	3 (0.5%)	6 (0.6%)

**Device success is a composite including AR <2+ and only 1 valve*

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Courtesy of Edwards Lifesciences Inc.

SOURCE Registry

Preliminary data – Major Complications <30 day

	TF (n=463)	TA (n=575)	Total (n=1038)
Death	29 (6.3%)	59 (10.3%)	88 (8.5%)
Stroke	11 (2.4%)	16 (2.6%)	27 (2.5%)
Renal Failure Requiring Dialysis	23 (5.0%)	69 (11.7%)	92 (8.7%)
Permanent Pacemaker	31 (6.7%)	42 (7.3%)	73 (7.0%)

TAVI Experience up to 2010

30 day results of The SOURCE Registry: A European Registry of Transcatheter Aortic Valve Implantation using the Edwards SAPIEN™ Transcatheter Heart Valve

Martyn Thomas, MD , Gerhard Schymik, MD, Thomas Walther, MD, Dominique Himbert, MD, Thierry Lefèvre, MD, Hendrik Treede, MD, Holger Eggebrecht, MD, Paolo Rubino, MD, Iassen Michev, MD, Rüdiger Lange, MD and Olaf Wendler, MD on behalf of the SOURCE investigators

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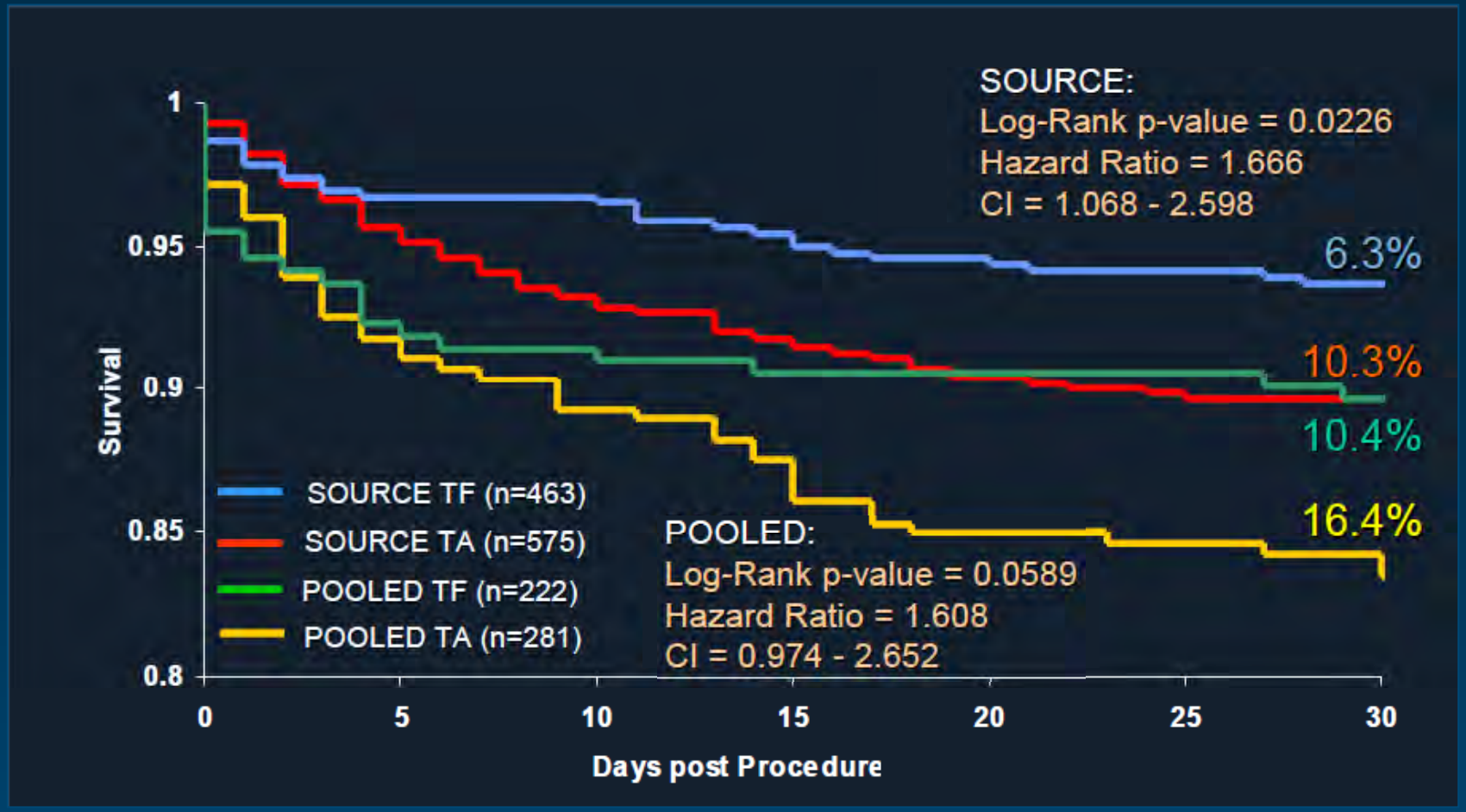
Thomas M et al. Circulation 2010;122:00-00

Inside the SOURCE Registry

- Consecutive case multi-center registry (no core labs,
- MD event adjudication)
- Cohort 1 = 32 centers, 1,038 pts; TA 575 pts (55%), TF 463 pts (45%)
- Baseline risks greater for TA pts; Logistic EuroSCORE 29.1% TA vs. 25.7% TF (P<0.001); TA pts with more PVD, CAD, carotid disease, prior CABG, porcelain Ao, mitral valve disease, and renal dysfunction
- 30-day mortality 6.3% TF and 10.3% TA
- 30-day stroke 2.5% and similar for TF and TA
- Vascular complications (all) was not a predictor of 30-day mortality

Thomas M et al. Circulation 2010;122:00-00

POOLED* Monitored Edwards TAVI vs. SOURCE: *30-day Mortality*



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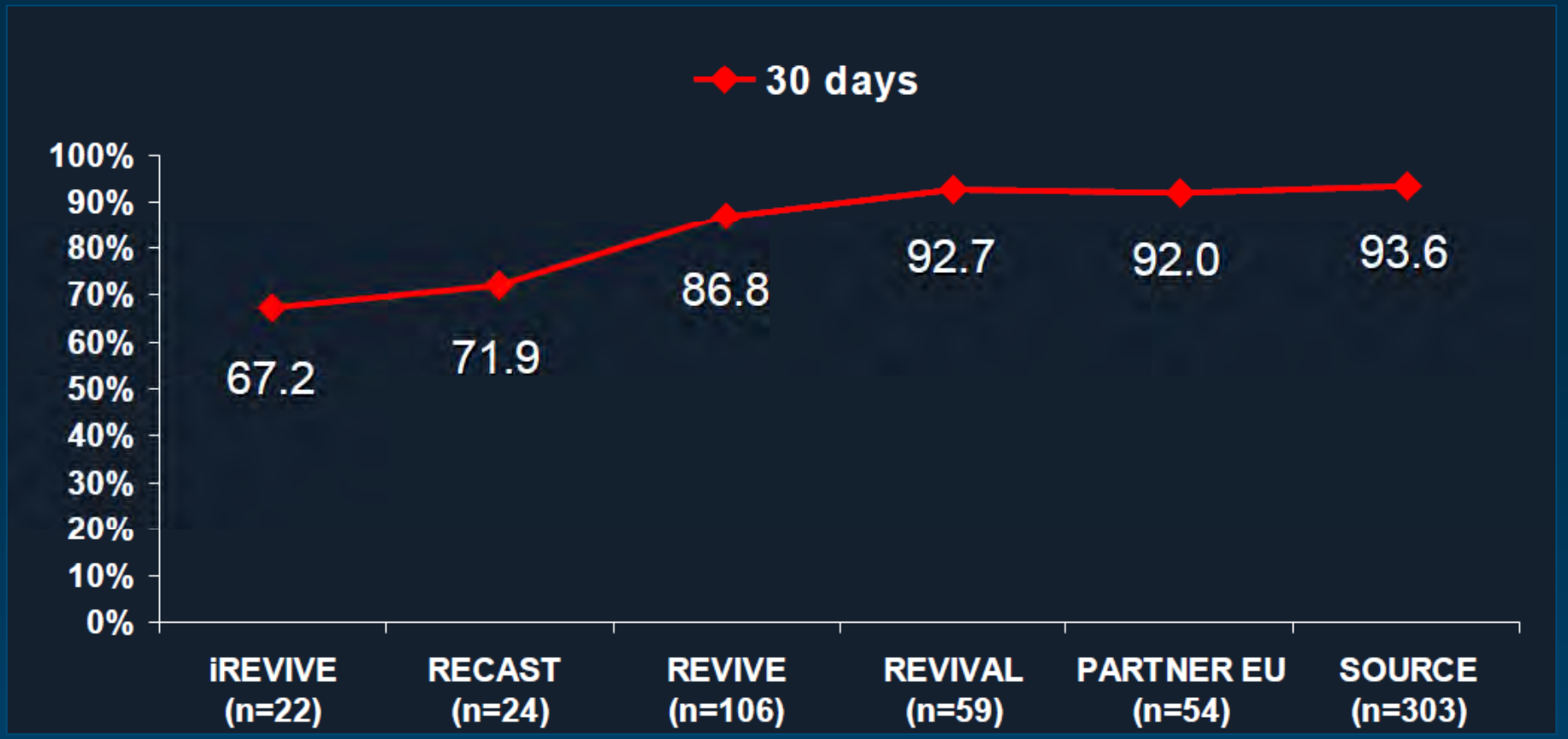
Transfemoral AVR

Survival at 1 month



Early "evolution", then "stabilization"

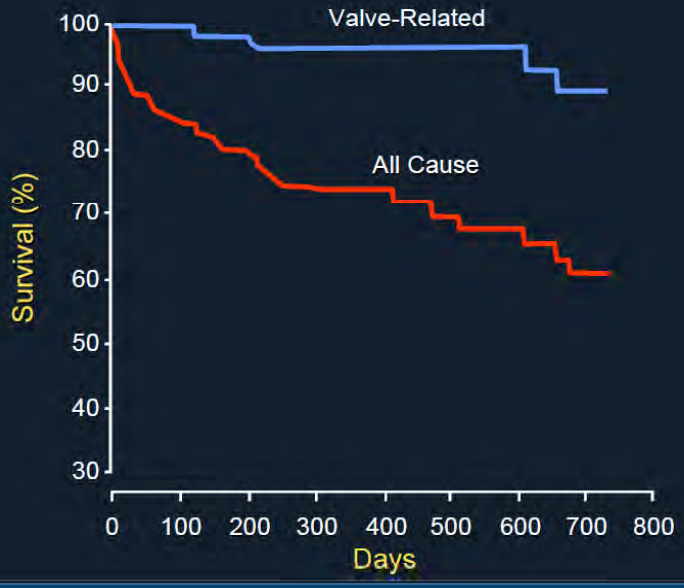
Vancouver TAVI Experience

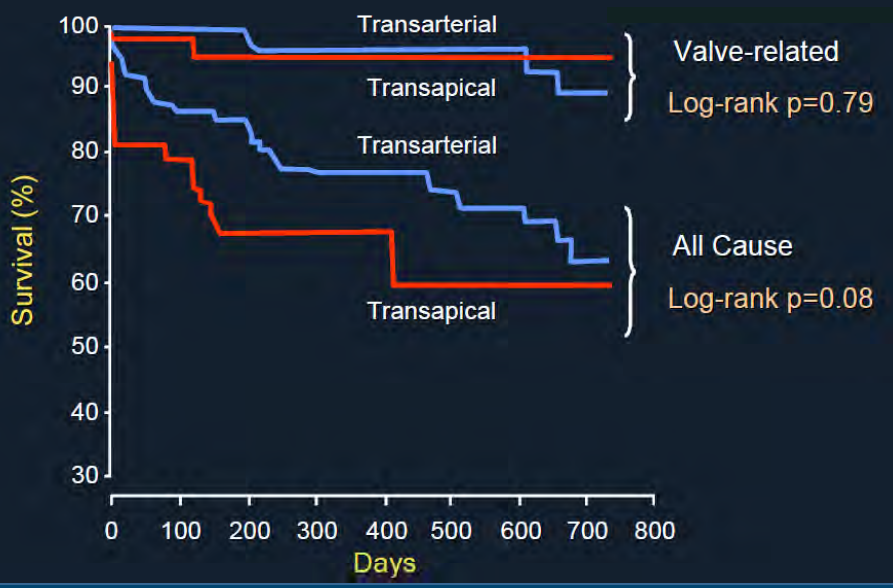
Survival at 1 year

Transcatheter Aortic Valve Implantation

Impact on Clinical and Valve-Related Outcomes

John G. Webb, MD*; Lukas Altwegg, MD*; Robert H. Boone, MD; Anson Cheung, MD; Jian Ye, MD; Samuel Lichtenstein, MD, PhD; May Lee, MSc; Jean Bernard Masson, MD; Christopher Thompson, MD; Robert Moss, MD; Ron Carere, MD; Brad Munt, MD; Fabian Nietlispach, MD; Karin Humphries, PhD





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Webb JG, et al. Circulation 2009;119:3009-3016

Clinical experience

CoreValve ReValving® Experience

Post-CE Mark Results of Percutaneous Aortic Valve Replacement (PAVR) Procedures through 30-April-2009 with Data Collected through 12-May-2009

Presented at TCT 2009

Expanded Evaluation Registry

Mean ± SD or %	Total EER N = 1483
Age (years)	81.2 ± 6.4
Logistic EuroSCORE (%)	22.6 ± 13.7
Female	55.4%
NYHA	I-II: 16.1% III-IV: 83.9%
Aortic Valve Area (cm^2)	0.64 ± 0.18
Peak gradient (mm Hg)	79.5 ± 26.1
Mean gradient (mm Hg)	49.2 ± 16.3
LVEF(%)	52.3 ± 13.8

Expanded Evaluation Registry

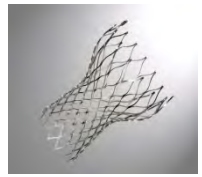
	Total EER
Angina	15.8%
Aortic Aneurysm	3.0%
Atrial Fib	28.3%
Carotid AD	13.4%
CAD	59.9%
COPD	24.7%
CHF	16.4%
Cardiomyopathy	6.1%
Diabetes Mellitus	25.9%
Hyperlipidemia	50.0%
Hypertension	68.6%
Pulmonary Hypertension	28.3%

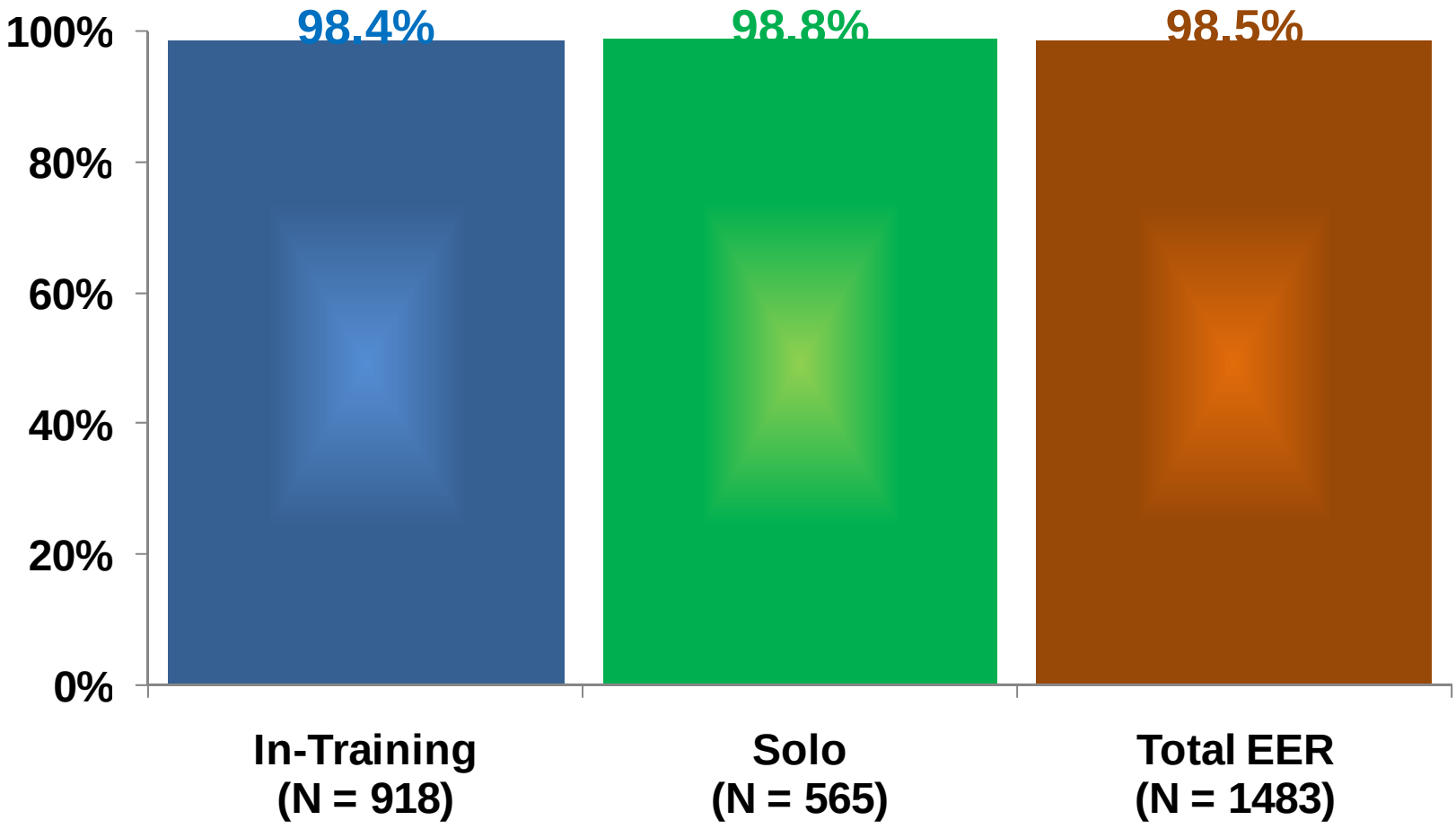
Expanded Evaluation Registry

	Total EER
Mediastinal Radiation	2.5%
MI	11.3%
PVD	24.1%
Porcelain Aorta	7.7%
Renal Failure	26.6%
Stroke or TIA	9.4%
Pacemaker	12.2%
Defibrillator	1.2%
CABG	21.4%
Valvular Surgery	3.9%
PCI	28.6%

Procedural Success

Expanded Evaluation Registry

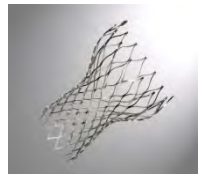


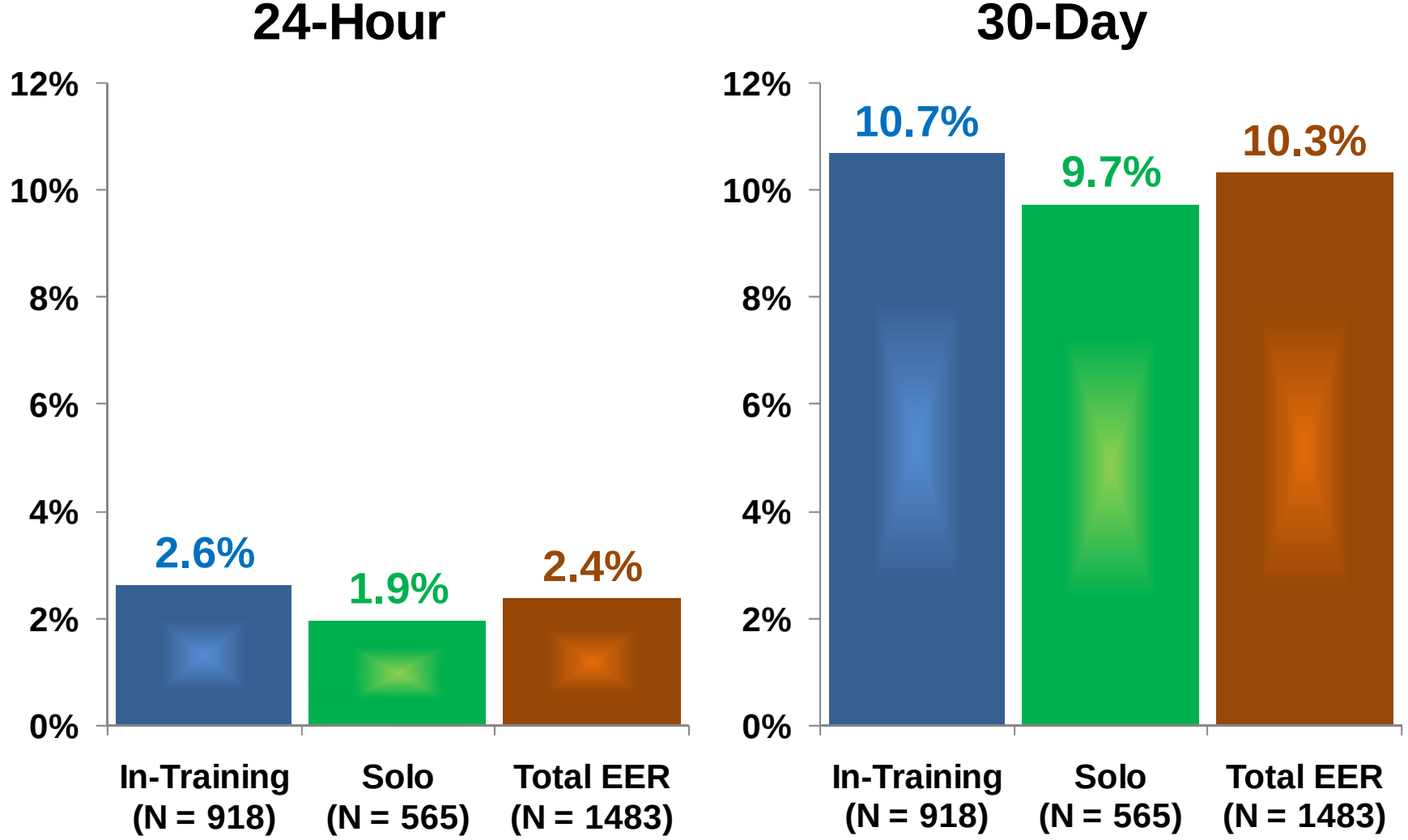


Schuler, TCT 2009

Mortality Rate

Expanded Evaluation Registry





Schuler, TCT 2009

24-hours Adverse Events*

	Total EER
CARDIAC Deaths†	1.8%
Aortic Dissection	0.7%
Cardiac Tamponade	3.0%
Cardiac Perforation	2.3%
Access Site Complication	2.6%
Major Bleeding	5.0%
Conversion to Surgery	0.4%
Myocardial Infarction	0.7%
Major Arrhythmia	5.6%
Permanent Pacemaker	7.2%
Renal Failure	0.7%
Stroke	1.1%
TIA	0.3%

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* Multiple events in same patients = data not cumulative

† Includes deaths where cause is not known

Other ≤30-Day Adverse Events*

	Total EER
CARDIAC Deaths†	6.7%
Aortic Dissection	0.9%
Cardiac Tamponade	3.6%
Cardiac Perforation	2.7%
Access Site Complication	2.9%
Major Bleeding	6.9%
Conversion to Surgery	0.8%
Myocardial Infarction	0.9%
Major Arrhythmia	15.7%
Permanent Pacemaker	25.0%
Renal Failure	2.2%
Stroke	2.2%
TIA	0.4%

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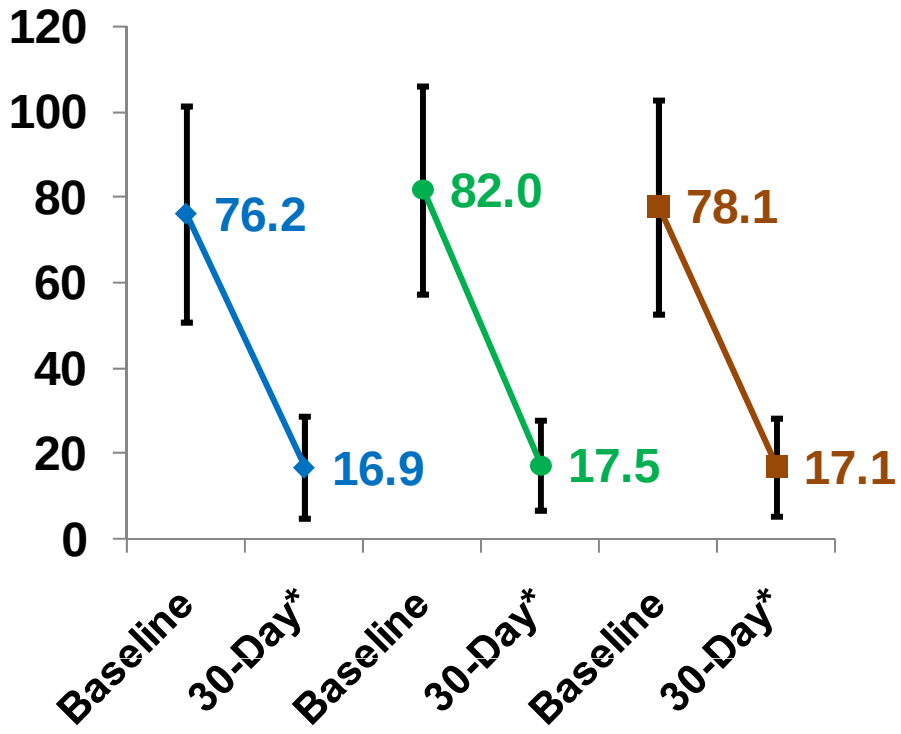
* Multiple events in same patients = data not cumulative

† Includes deaths where cause is not known

30-Day Paired Gradient Comparison

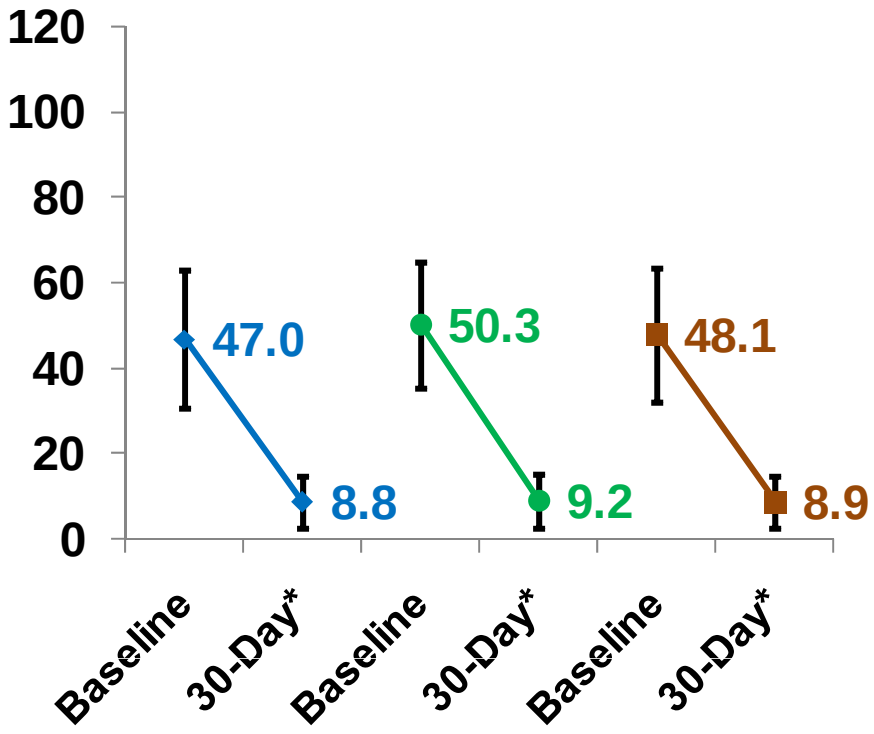
Expanded Evaluation Registry

Peak Gradient (mm Hg)
Mean ± SD



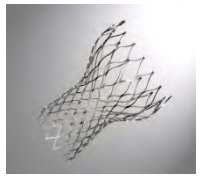
In-Training (N =362) **Solo (N = 188)** **Total EER (N = 550)**

Mean Gradient (mm Hg)
Mean ± SD

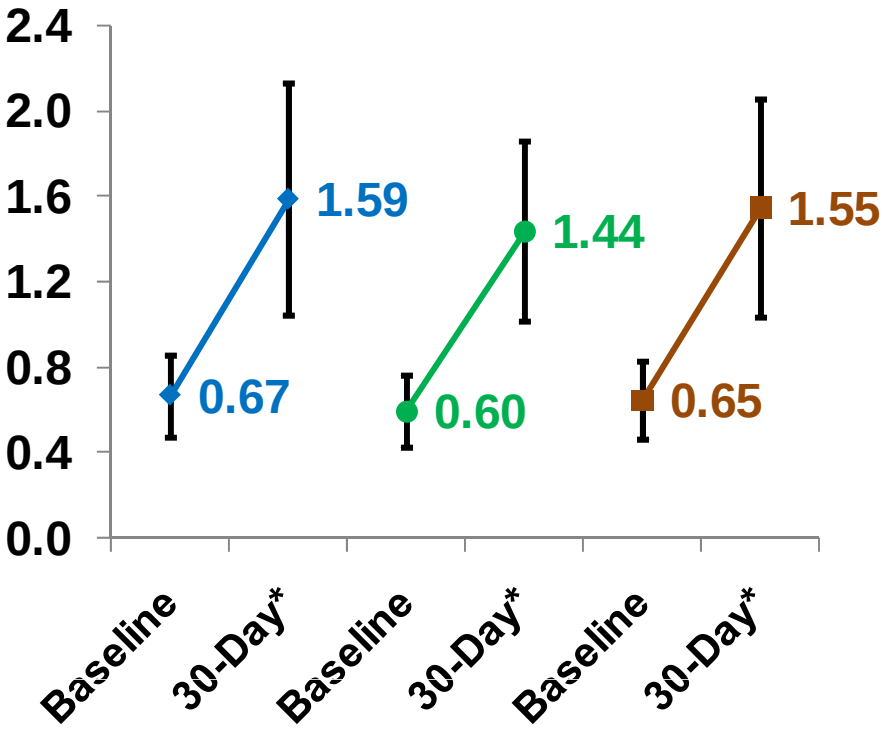


In-Training (N = 320) **Solo (N = 162)** **Total EER (N = 482)**

30-Day Paired Echo Data Comparison
Expanded Evaluation Registry

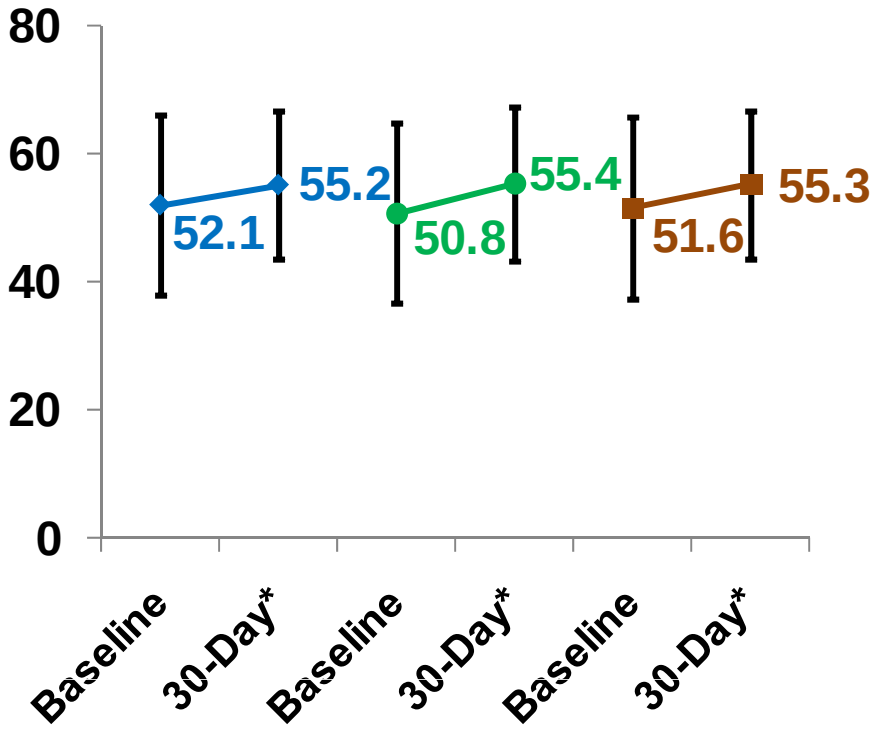


Effective Orifice Area (cm^2)
Mean ± SD



In-Training (N = 202)	Solo (N = 79)	Total EER (N = 281)

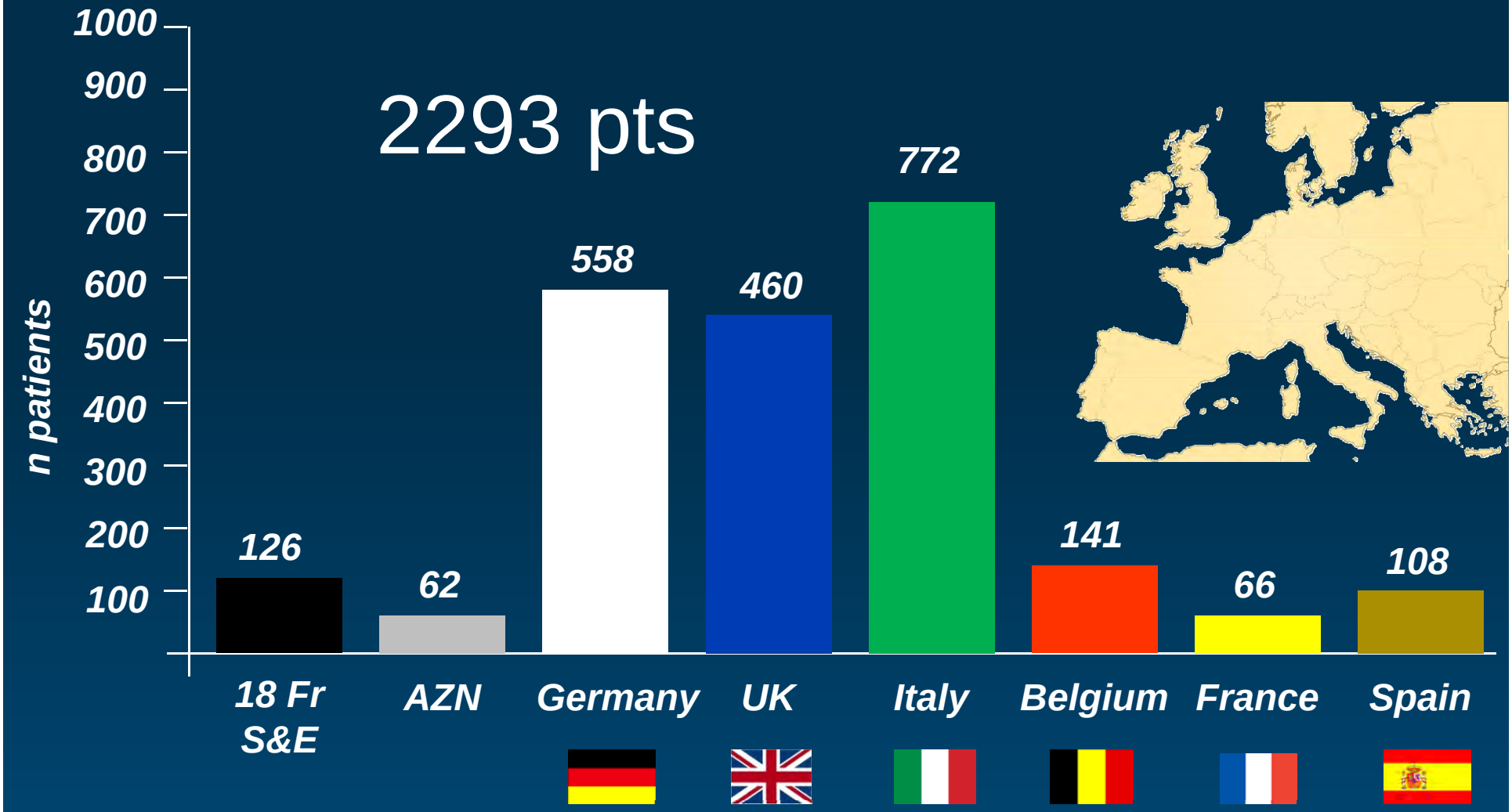
LVEF (%)
Mean ± SD



In-Training (N = 461)	Solo (N = 252)	Total EER (N = 713)

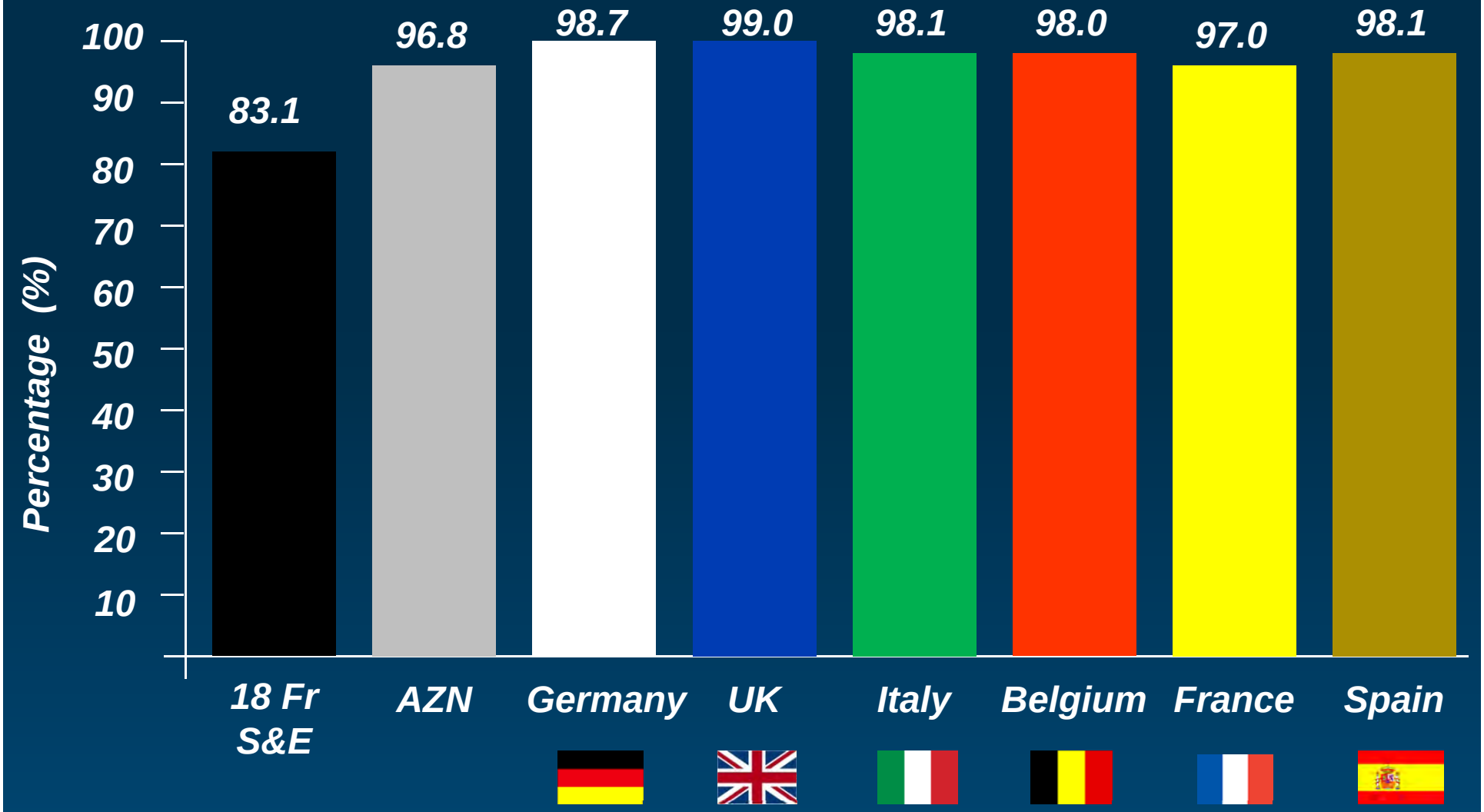
European CRS Registries Results

Patient Enrollment



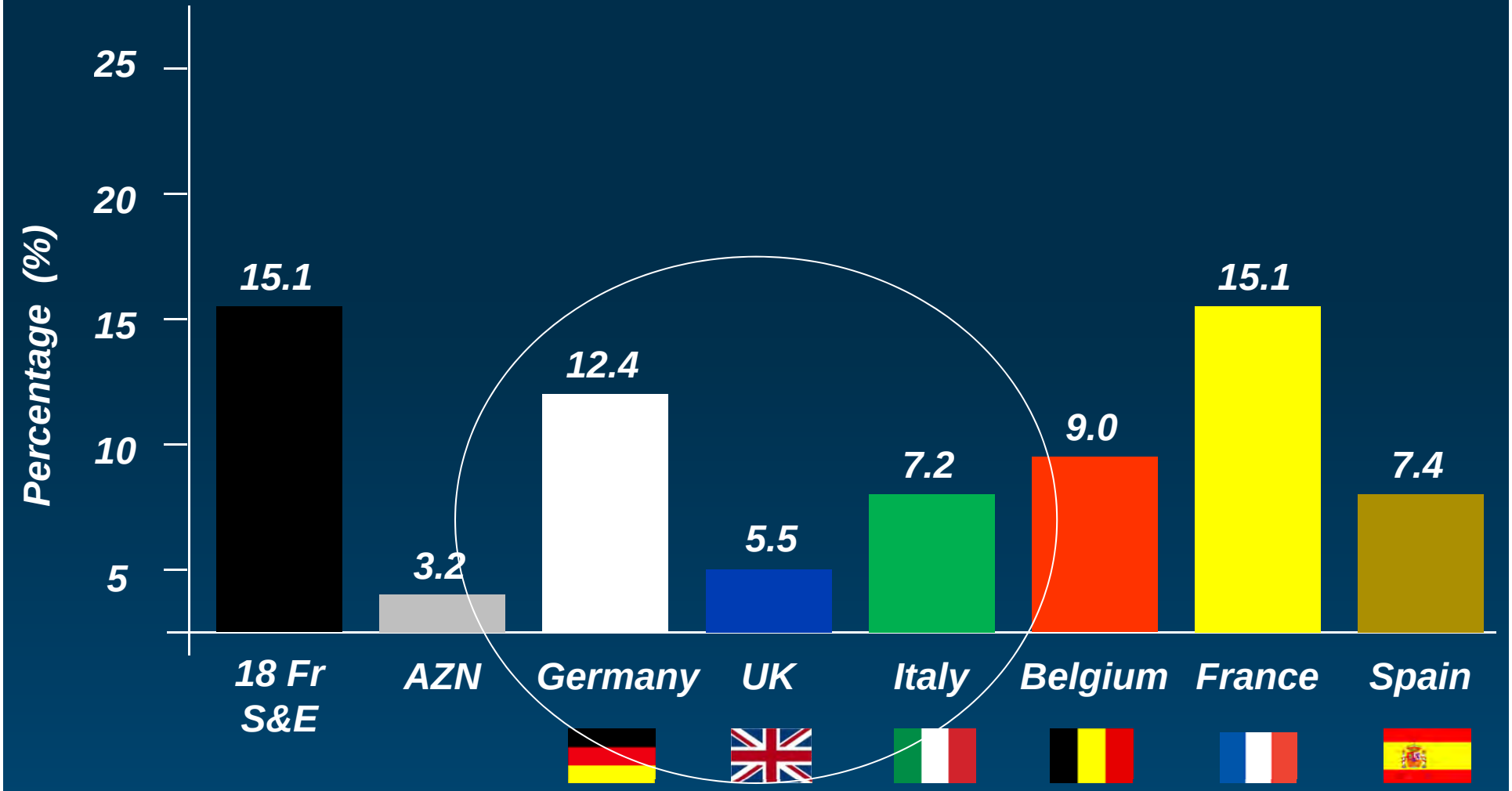
European CRS Registries Results

Procedural Success



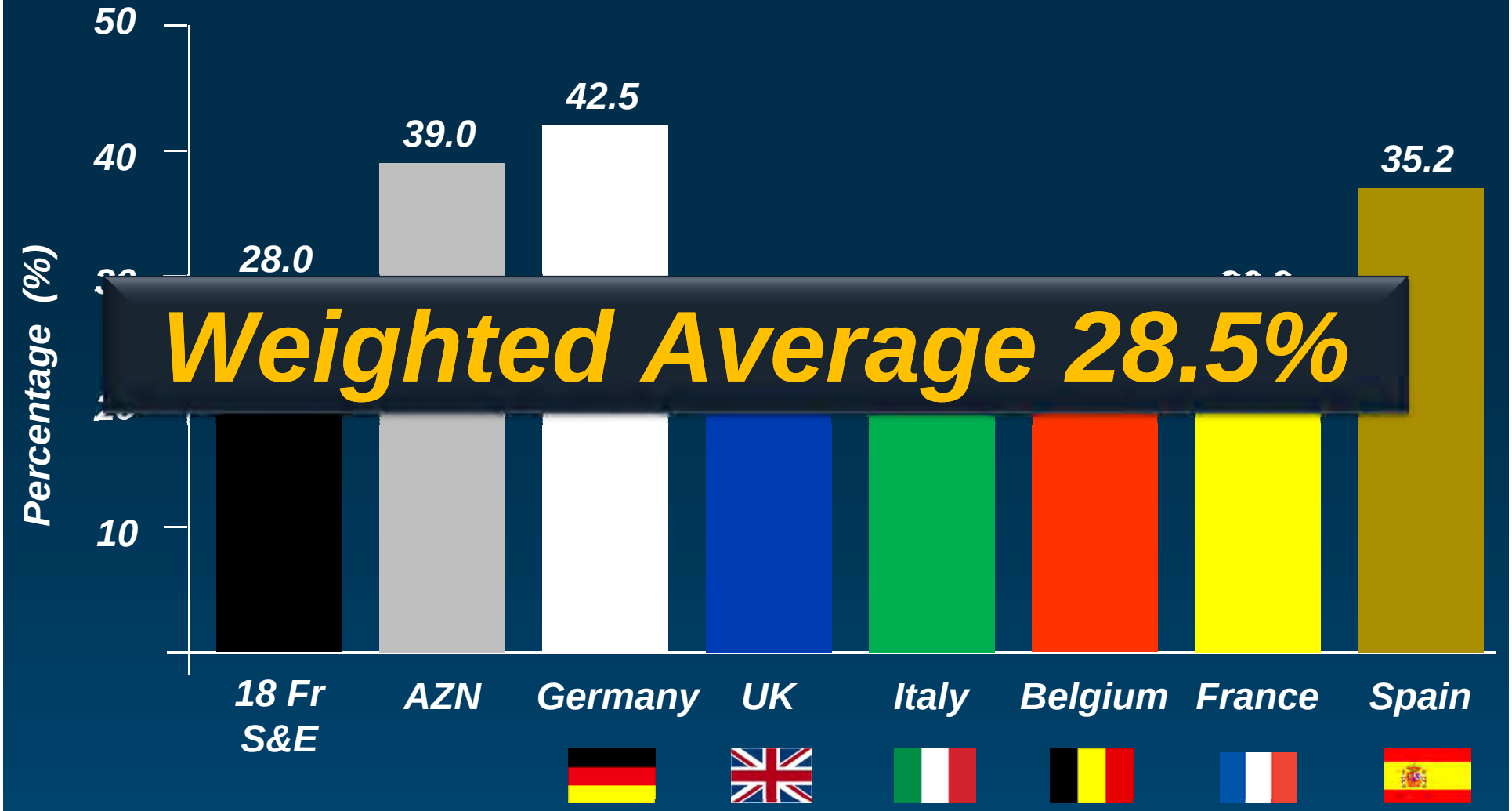
European CRS Registries Results

30-day all-cause mortality



European CRS Registries Results

30-day PM implantation



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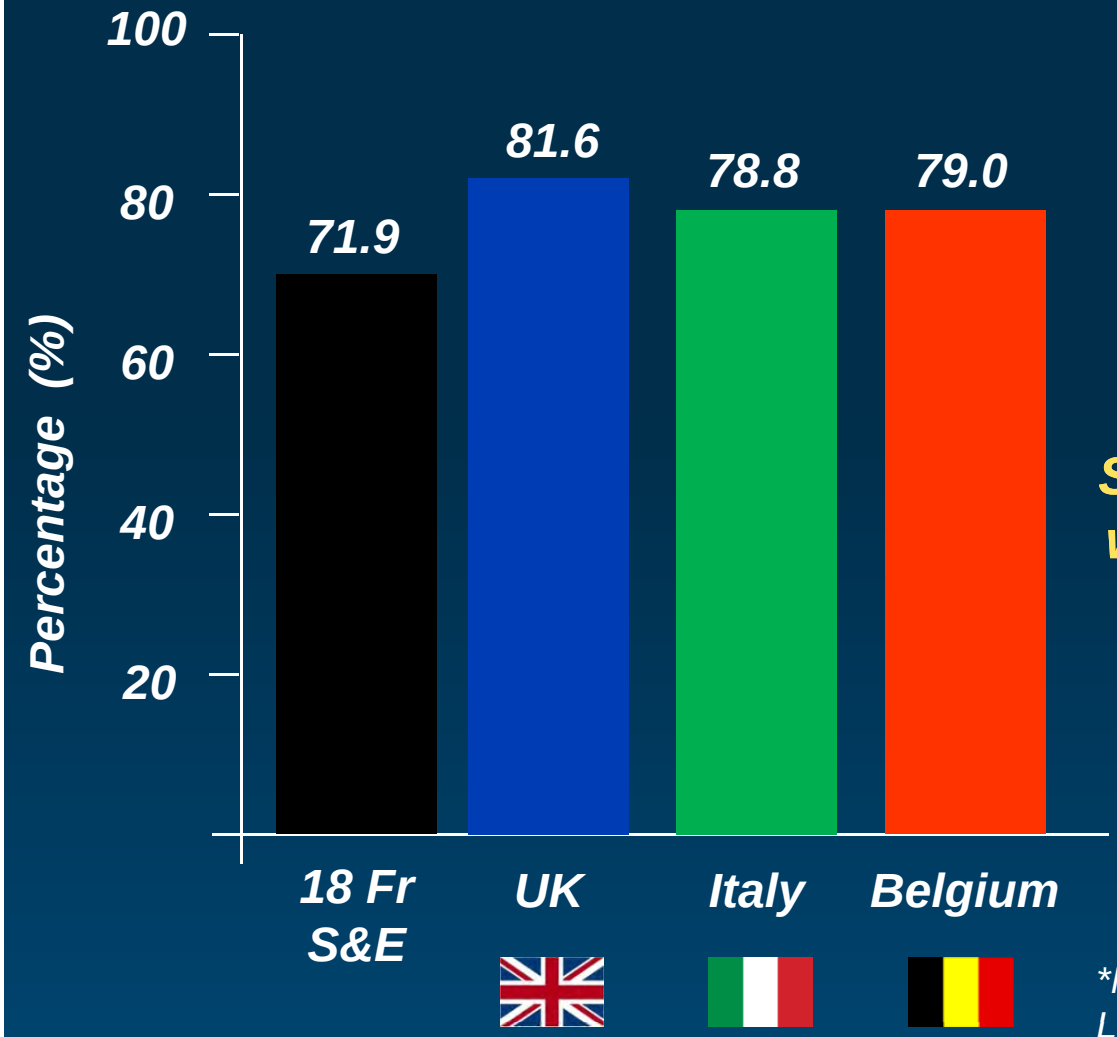
European CRS Registries Results

1-year Survival



Survival rates are comparable with octogenarians who have had sAVR or sAVR+CABG*

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**Moat, Neal. UK TAVI Registry, TAVI Mid and Long-term Clinical Outcomes. EuroPCR 2010.*

European Experience

National Registries

European Heart Journal Advance Access published September 23, 2010

European Heart Journal
doi:10.1093/eurheartj/ehq3

Imaging

Transcatheter
results from a

Ralf Zahn[1]*, Ulrich Ge
Holger Eggebrecht[5], R
Gert Richardt[9], Hans-R
Transcatheter Aortic V

[1]Abteilung für Kardiologie, Herzzentrum, Ludwig
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European Heart Journal
doi:10.1093/eurheartj/ehq261

CLINICAL PAPER

Transcatheter aortic valve implantation: early results of the FRANCE (FRench Aortic National CoreValve and Edwards) registry

Hélène Eltchaninoff[1]*, Alain Prat[2], Martine Gilard[3], Alain Leguerrier[4], Didier Blanchard[5], Gérard Fournial[6], Bernard Iung[7], Patrick Donzeau-Gouge[8], Christophe Tribouilloy[9], Jean-Louis Debrux[10], Alain Pavie[11], and Pascal Gueret[12], on behalf of the FRANCE Registry Investigators

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European Heart Journal (2010) **31**, 984–991
doi:10.1093/eurheartj/ehp570

CLINICAL RESEARCH
Valvular heart disease

Transcatheter aortic valve implantation: predictors of procedural success—the Siegburg–Bern experience

Lutz Buellesfeld[1]*, Peter Wenaweser[2], Ulrich Gerckens[1], Ralf Mueller[1], Barthel Sauren[3], Georg Latsios[1], Bernfried Zickmann[3], Gerrit Hellige[2], Stephan Windecker[2], and Eberhard Grube[1]

[1]Dep
Switz

Aims The purpose of the present analysis was to identify predictors of procedural success of percutaneous transcatheter aortic valve implantation (TAVI).

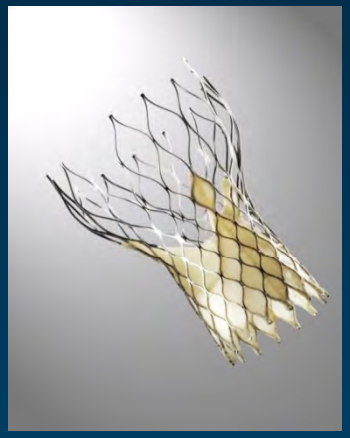
Methods and results We prospectively assessed in-hospital outcome of patients undergoing TAVI at two institutions. We analysed clinical, morphological, and procedural parameters using univariate and multivariate regression models. Between 2005 and 2008, a total of 168 consecutive patients with symptomatic aortic valve stenosis underwent TAVI using the self-expanding CoreValve Revalving prosthesis. Patients (93%) were highly symptomatic with a New York Heart Association grade III/IV and a mean aortic valve area of 0.66 ± 0.21 cm^2. Acute and in-hospital procedural success rates were 90.5 and 83.9%, respectively, with an in-hospital mortality, myocardial infarction, and stroke rate of 11.9, 1.8, and 3.6%, respectively. Predictors of in-hospital procedural success were type of access (OR 0.33, 95% CI 0.13–0.82, $P = 0.017$), prior coronary intervention (OR 5.3, 95% CI 1.20–23.41, $P = 0.028$) and pre-procedural Karnofsky index using univariate regression. Pre-procedural Karnofsky index emerged as the only independent predictor (OR 1.04, 95% CI 1.00–1.08, $P = 0.032$) in the multivariate analysis.

Conclusion Pre-procedural functional performance status predicts the in-hospital outcome after TAVI. Patients with a good functional status are likely to benefit more from TAVI than previously reported high-risk patients.

Keywords Percutaneous aortic valve implantation • Aortic stenosis • Predictors

Italian CoreValve Registry

First patient
June 2007



- Since June 2007 a web-based registry was started
- 14 participating sites

Catania, University
Pisa, University
Brescia, H. Civile
Padova, University
Milano, S.Ambrogio
Milano, Niguarda
Firenze, Careggi
Milano, S.Raffaele
Bologna, University
Roma, S. Camillo
Legnano

Firenze, Careggi
Bari, University
Mirano

Ferrarotto Hospital
University of Catania

Italian CoreValve Registry

Transcatheter Aortic Valve Implantation in 663 Patients with Severe Aortic Stenosis

Data collected from 663 patients

Tamburino C. et al. on behalf of CRS Italian Registry Investigators

Ferrarotto Hospital
University of Catania

Under review Circulation

Italian CoreValve Registry

Baseline Characteristics 663 pts

	Mean±SD/n (%)	
Age (years)	81±7.3	
NYHA class III/IV	434	(71.5)
Prior MI	143	(21.6)
Prior CABG	104	(15.7)
Prior AVR	10	(1.5)
Logistic EuroScore	23±14	

Italian CoreValve Registry

Procedural Data

Vascular Approach		
Transfemoral, n (%)	**599**	**(90.3)**
Subclavian, n (%)	**64**	**(9.7)**
Prosthesis		
CRS 26-mm, n (%)	**409**	**(61.6)**
CRS 29-mm, n (%)	**254**	**(38.4)**
Procedural time (minutes)	**79±34**	
Procedural success, n (%)	**650**	**(98.0)**
Two CoreValve implantation, n (%)	**24**	**(3.6)**
Procedural death, n (%)	**6**	**(0.9)**

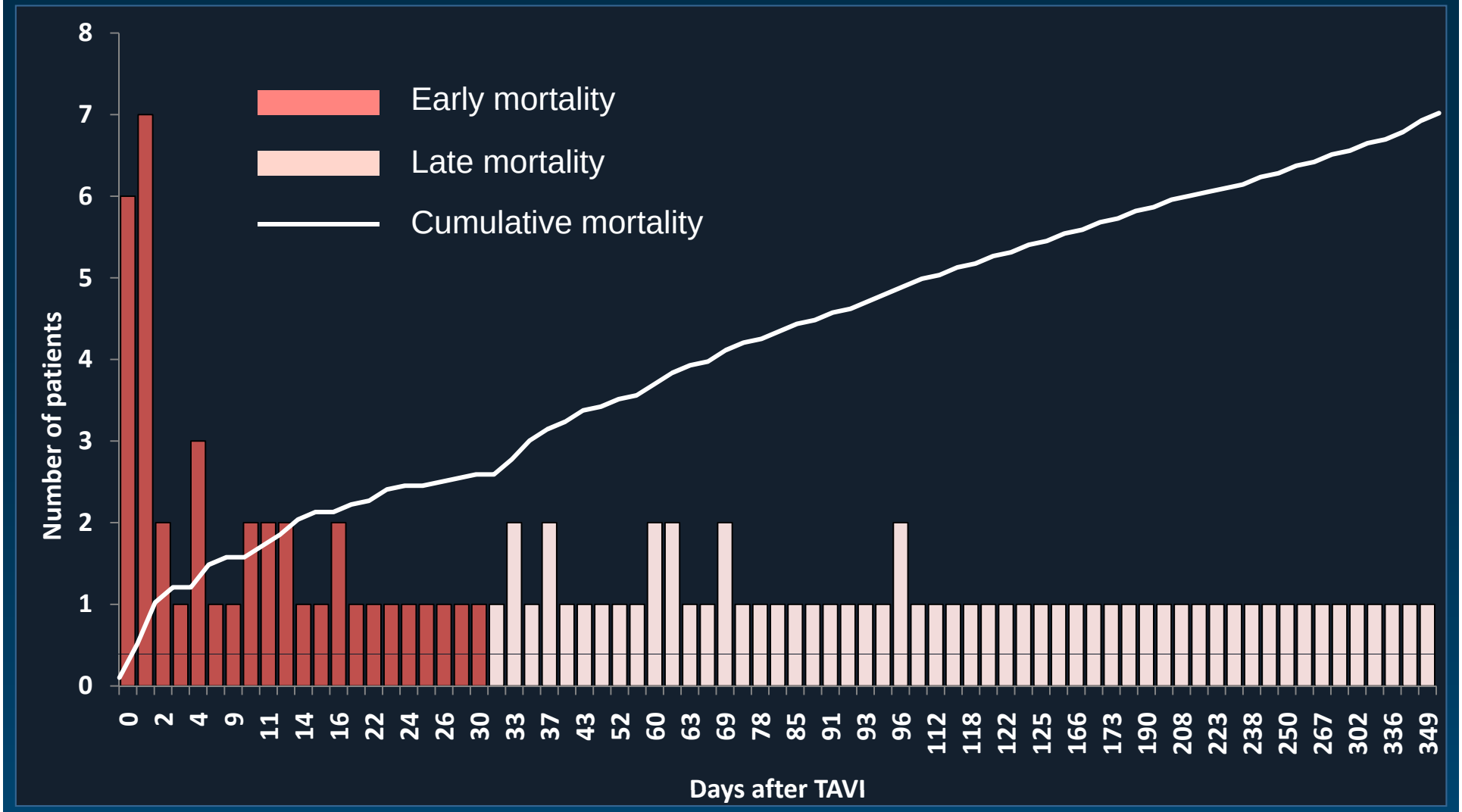
Italian CoreValve Registry

One-year clinical results

Endpoint	Cumulative incidence
MACCE	**16.6%**
Death	15.0%
Myocardial infarction	1.2%
Stroke	2.5%
CHF requiring hospitalization	8.2%
Major bleeding	3.2%
Pacemaker implantation	19.1%
Prosthesis dysfunction	0.2%

Italian CoreValve Registry

Distribution of mortality over time



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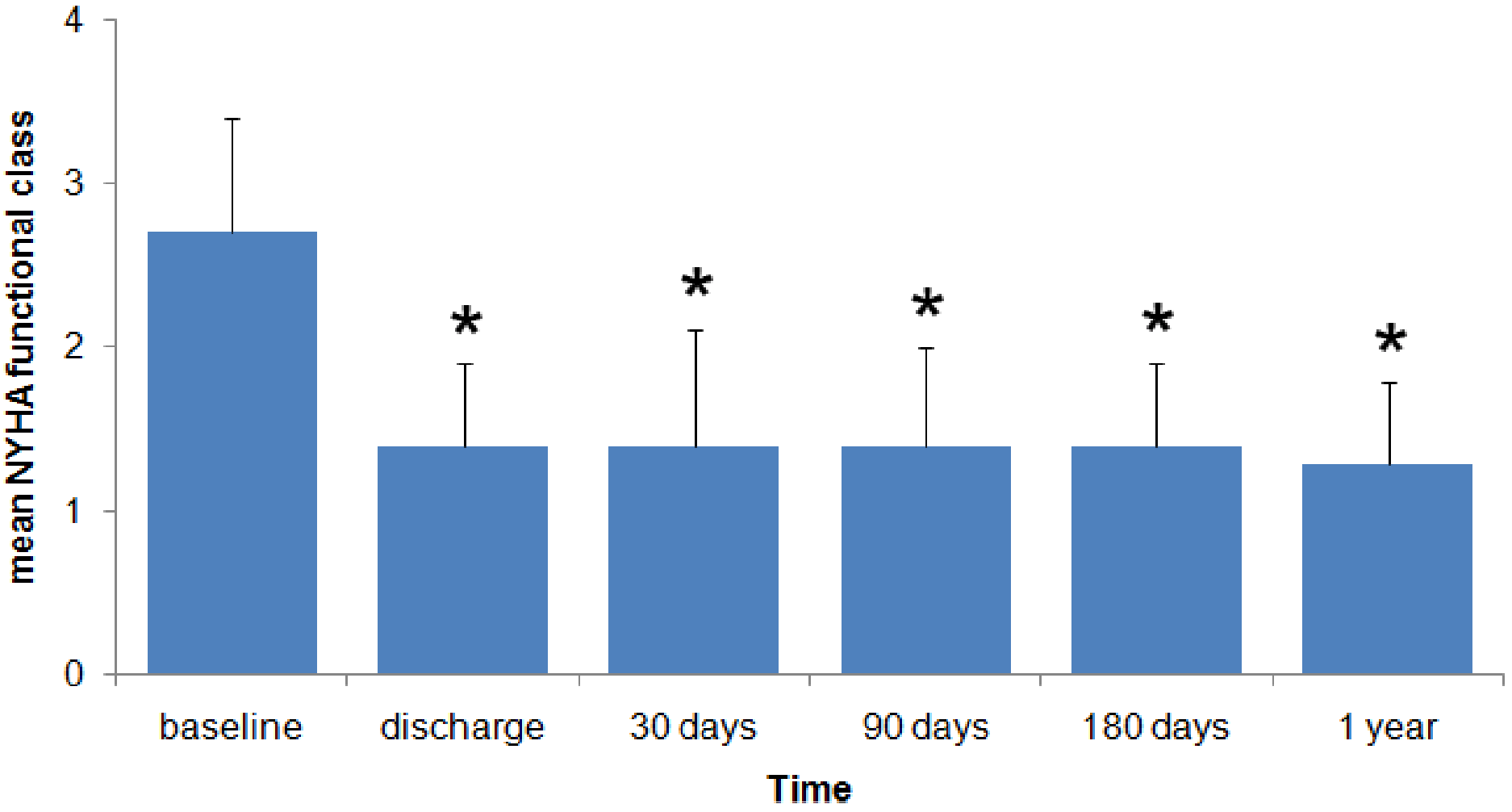
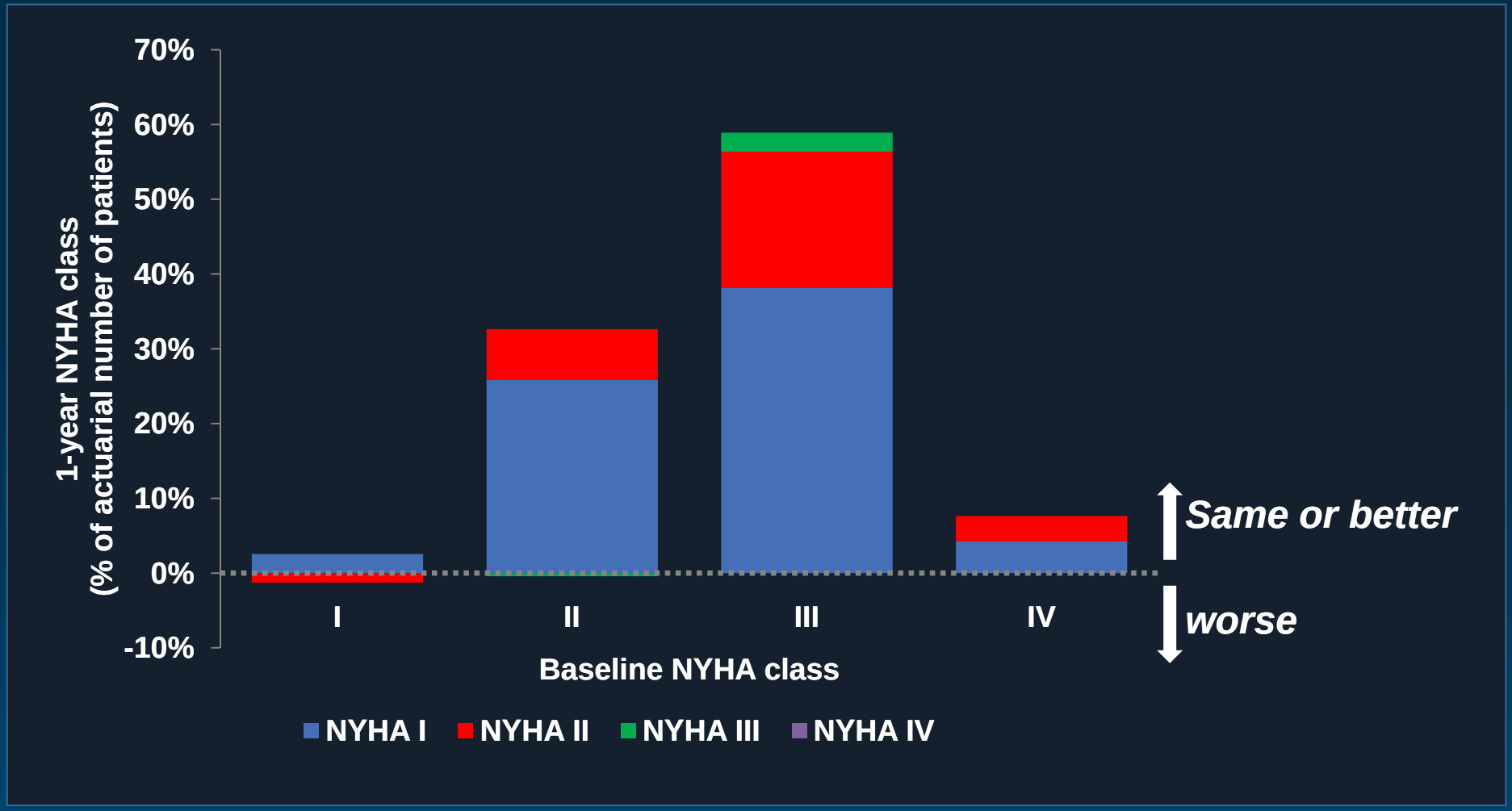
Italian CoreValve Registry

NYHA Functional Class



Italian CoreValve Registry

Paravalvular leak



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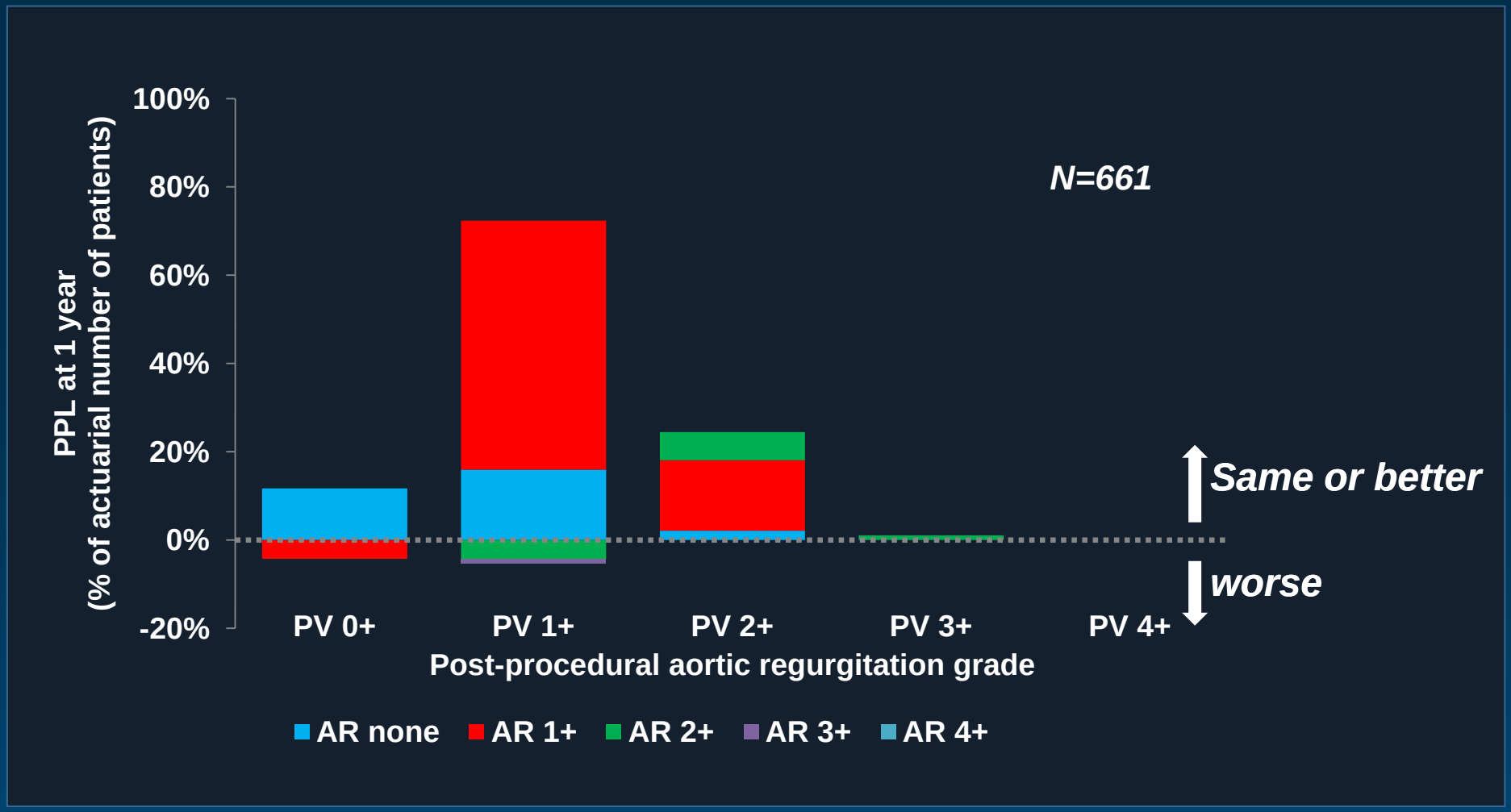
Italian CoreValve Registry

Paravalvular leak



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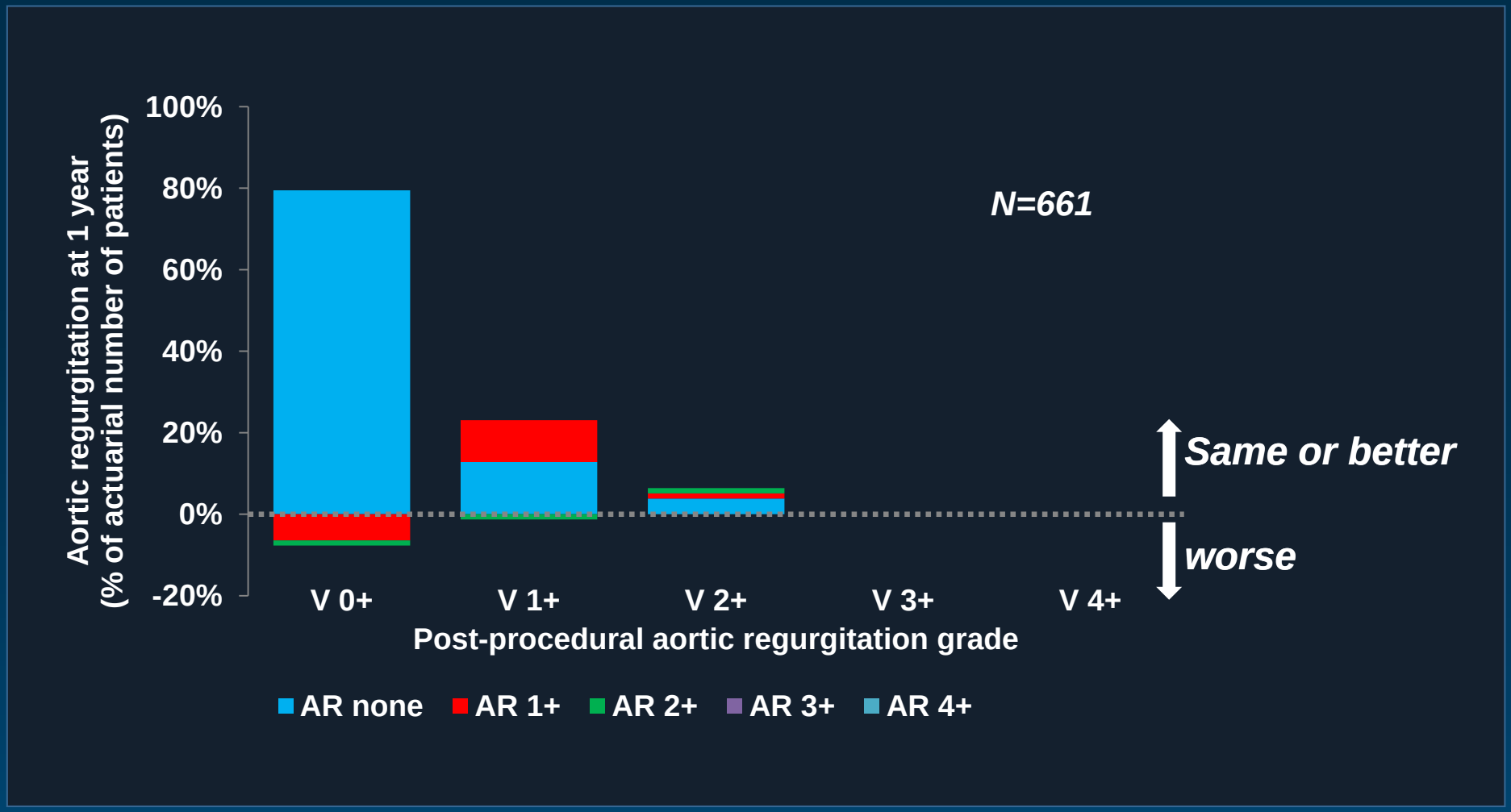
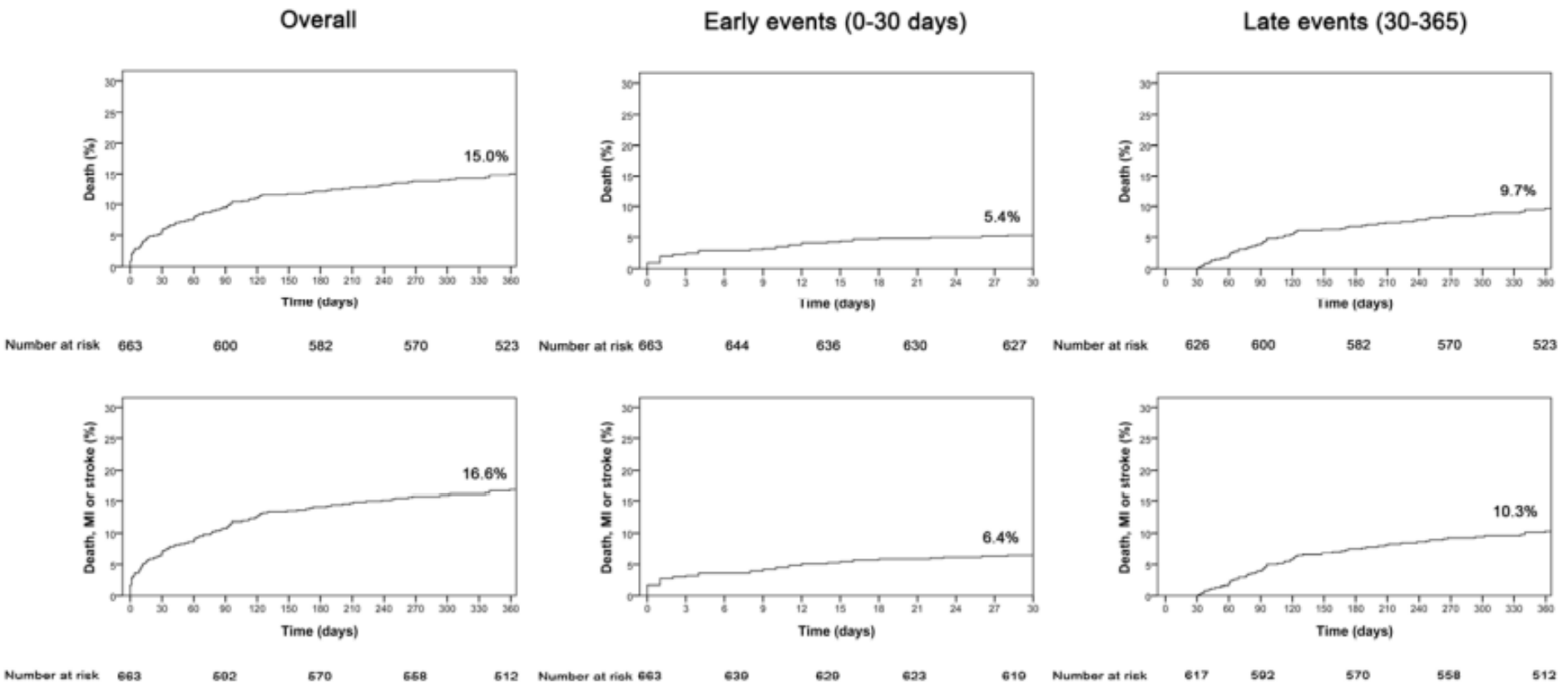
Italian CoreValve Registry

Aortic Regurgitation



Italian CoreValve Registry

Mortality and MACCE incidence



Data of total study population and subdivided into early and late events.

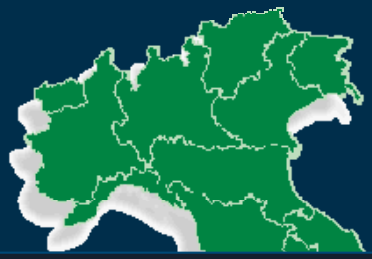
Italian CoreValve Experience

	Overall population (n = 663)	Patients who died (n = 81)	Survivors (n = 582)	p value
Cardiovascular risk factors				
Diabetes mellitus, n (%)	175 (26.4)	33 (40.7)	142 (24.4)	0.002
Clinical history				
Acute pulmonary edema, n (%)	213 (32.1)	39 (48.1)	174 (29.9)	0.001
Renal insufficiency, n (%)	154 (23.2)	29 (35.8)	125 (21.5)	0.004
Clinical presentation				
NYHA class III and IV, n (%)	434 (71.5)	65 (80.2)	409 (70.3)	0.063
Logistic EuroSCORE, %±SD	23.0±13.7	27.4±15.9	22.4±13.3	0.005
Baseline echocardiographic parameters				
Left ventricular ejection fraction < 40%, n (%)	135 (20.4)	23 (28.4)	112 (19.2)	0.055
Systolic Pulmonary Artery Pressure > 60 mmHg, n (%)	76 (11.5)	19 (23.5)	57 (9.8)	< 0.001
Peak pressure gradient, mmHg±SD	83.7±25.1	76.8±25.8	84.7±24.9	0.010
Mean pressure gradient, mmHg±SD	51.8±17.0	47.2±18.3	52.5±16.8	0.011
Annulus diameter, mm±SD	22.2±2.2	22.8±2.1	22.1±2.2	0.007

Italian CoreValve Experience	Overall population n = 663	Patients who died (n = 81)	Survivors (n = 582)	p value
Procedural variables				
Anesthesia				0.002
General, n (%)	183 (27.6)	34 (42.0)	149 (25.6)	
Local, n (%)	480 (72.4)	47 (58.0)	433 (74.4)	
Procedural success, n (%)	650 (98.0)	75 (92.6)	575 (98.8)	< 0.001
Procedural death, n (%)	6 (0.9)	6 (7.4)	-	-
Stroke, n (%)	8 (1.2)	3 (3.7)	5 (0.9)	0.062
Combined procedure related death, stroke and MI (%)	14 (2.1)	9 (11.1)	-	-
Conversion to open heart surgery, n (%)	5 (0.8)	4 (4.9)	1 (0.2)	0.001
Sepsis, n (%)	2 (0.3)	2 (2.5)	0 (0)	0.015
Life-threatening arrhytmias, n (%)	13 (2.0)	5 (6.2)	8 (1.4)	0.014
Cardiac tamponade, n (%)	8 (1.2)	4 (4.9)	4 (0.7)	0.010

Italian CoreValve Registry

First patient June 2007



Catania, University

Pisa, University

Brescia, H. Civile

Padova, University

663 patients treated with TAVI

24 Valve-in-Valve procedures

3.6%

Legnano

Firenze, Careggi

Bari, University

Mirano

- Since June 2007 a web-based registry was started
- 14 participating sites

Ferrarotto Hospital
University of Catania

The Valve-in-Valve technique For Treatment of Aortic Bioprosthesis Malposition:

An analysis of incidence and 1 year clinical outcomes from the Italian CoreValve Registry

Marco Barbanti, Gian Paolo Ussia, Angelo Ramondo, Anna Sonia Petronio, Federica Ettori, Gennaro Santoro, Silvio Klugmann, Francesco Bedogni, Francesco Maisano, Antonio Marzocchi, Arnaldo Poli, Massimo Napodano and Corrado Tamburino

Ferrarotto Hospital
University of Catania

Submitted JACC, pending minor revisions

CRS Italy: Valve-in-Valve

Baseline Clinical Characteristics

	Overall population (n = 663)	No-ViV group (n = 639)	ViV group (n = 24)	p value
Age, years±SD	81.0±7.3	81.0±7.3	80.3±6.2	0.656
Female gender, n (%)	371 (56.0)	358 (56.0)	13 (54.1)	0.857
Diabetes mellitus, n (%)	175 (26.4)	171 (26.7)	4 (16.6)	0.271
Prior acute pulmonary edema, n (%)	213 (32.1)	203 (31.8)	10 (41.7)	0.308
Prior balloon valvuloplasty, n (%)	113 (17.0)	111 (17.4)	2 (8.3)	0.193
Prior myocardial infarction, n (%)	143 (21.6)	138 (21.6)	5 (20.9)	0.929
Prior stroke, n (%)	48 (7.2)	45 (7.0)	3 (12.5)	0.248
Prior bypass graft surgery, n (%)	104 (15.7)	100 (15.6)	4 (16.7)	0.535
Prior PCI, n (%)	189 (28.5)	181 (28.3)	8 (33.3)	0.594
Peripheral vascular disease, n (%)	127 (19.2)	123 (19.2)	4 (16.7)	0.500
COPD, n (%)	141 (21.3)	136 (21.3)	5 (20.8)	0.958
Renal insufficiency†, n (%)	154 (23.2)	149 (23.3)	5 (20.8)	0.777
Porcelain aorta, n (%)	72 (10.9)	72 (11.3)	0 (0.0)	0.060
NYHA class III and IV, n (%)	434 (71.5)	415 (64.9)	19 (79.2)	0.486
Logistic Euroscore, % SD	23.0 13.7	22.9 13.7	23.6 14.3	0.803

CRS Italy: Valve-in-Valve

Baseline Echo characteristics

	Overall population (n = 663)	No-ViV group (n = 639)	ViV group (n = 24)	p value
Left ventricular ejection fraction, %±SD	52.1±25.5	52.2±25.9	49.3±15.1	0.581
Peak pressure gradient, mmHg±SD	83.7±25.2	83.9±25.2	79.0±22.4	0.359
Mean pressure gradient, mmHg±SD	51.8±17.0	52.0±17.1	45.4±14.8	0.062
Annulus diameter, mm±SD	22.2±2.2	22.1±2.1	23.6±2.7	0.010*
Aortic regurgitation 3+ or 4+, n (%)	35 (5.3)	33 (5.1)	2 (8.3)	0.365

CRS Italy: Valve-in-Valve

Procedural variables

	Overall population (n = 663)	No-ViV group (n = 639)	ViV group (n = 24)	p value
Procedure time, minutes±SD	79.1±33.6	78.0±33.4	101.3±30.8	0.001*
Fluoroscopy time, minutes±SD	21.3±13.3	20.6±12.2	35.9±25.5	<0.001*
Approach				0.306
Trans-femoral, n (%)	599 (90.3)	576 (90.1)	23 (90.4)	
Trans-subclavian, n (%)	64 (9.7)	63 (9.9)	1 (9.6)	
Device†				0.898
CRS 26-mm	394 (59.4)	379 (59.3)	15 (62.5)	
CRS 29-mm	269 (40.6)	260 (40.7)	9 (37.5)	
Post dilatation, n (%)	68 (10.2)	56 (8.8)	12 (50)	<0.001*
Procedural success, n (%)	650 (98.0)	626 (97.9)	24 (100)	0.616

CRS Italy: Valve-in-Valve

Procedural Outcomes

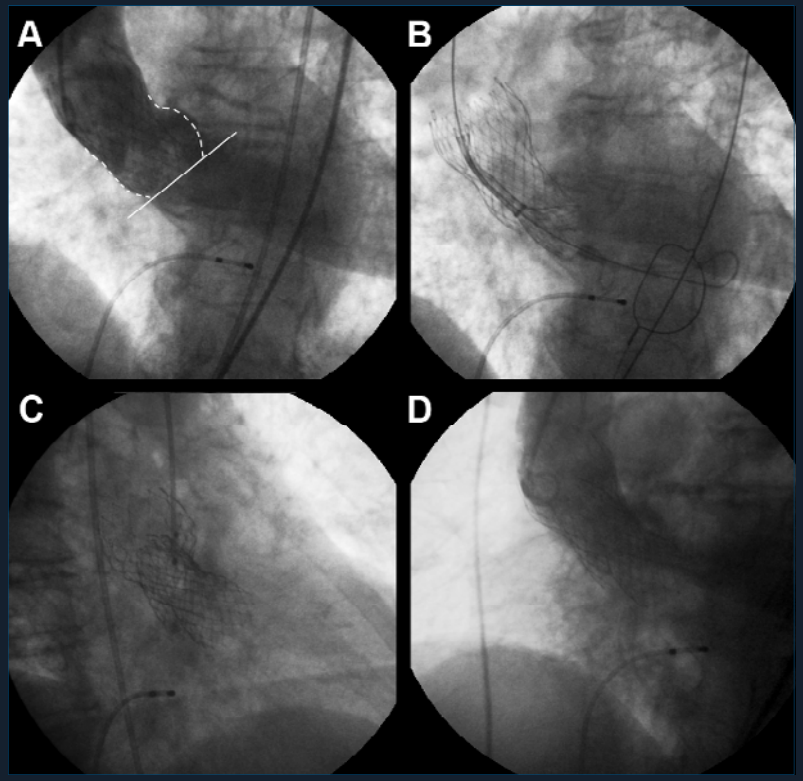
	Overall population (n = 663)	No-ViV group (n = 639)	ViV group (n = 24)	p value
Valve embolization, n (%)	4 (0.6)	4 (0.6)	0 (0.0)	0.831
Death, n (%)	6 (0.9)	6 (0.9)	0 (0.0)	0.801
Myocardial infarction, n (%)	0 (0)	0 (0)	0 (0.0)	1.000
Stroke, n (%)	8 (1.2)	8 (1.2)	0 (0.0)	0.743
Conversion to open heart surgery, n (%)	5 (0.8)	5 (0.8)	0 (0.0)	0.831
MACCEs, n (%)	18 (2.7)	18 (2.8)	0 (0.0)	0.510
Major access site complications, n (%)	13 (2.0)	12 (3.7)	1 (4.2)	0.384
Cardiac tamponade, n (%)	8 (1.2)	8 (1.2)	0 (0.0)	0.743

CRS Italy: Valve-in-Valve

Causes of PPL

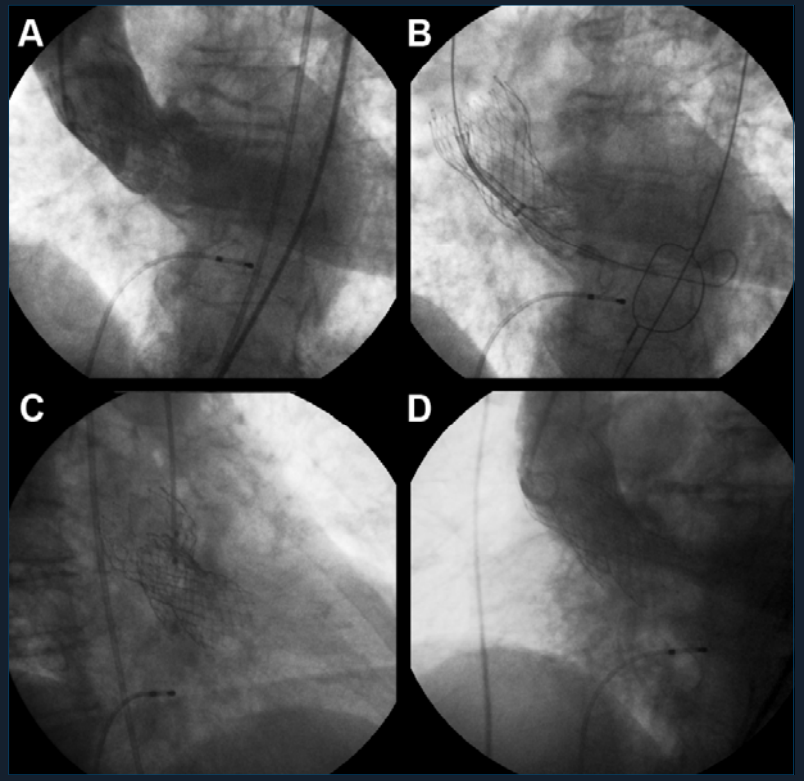
lower deployment

75.0% (N=18)



higher deployment

25.0% (N=6)



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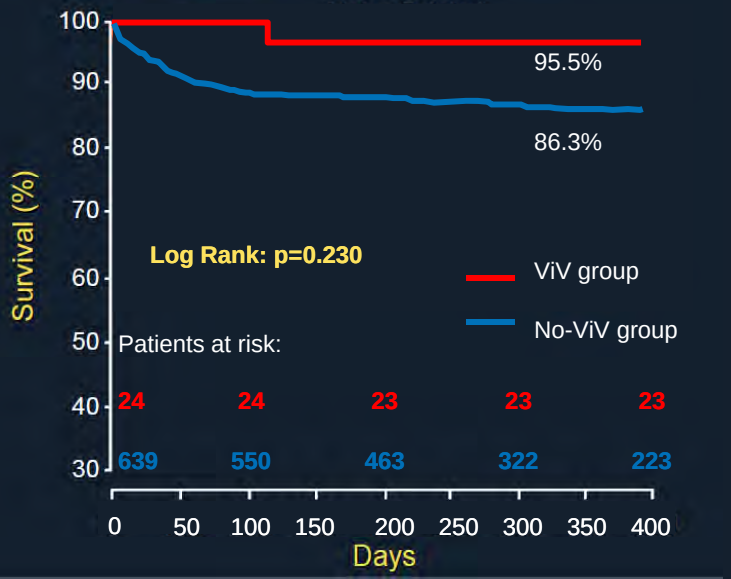
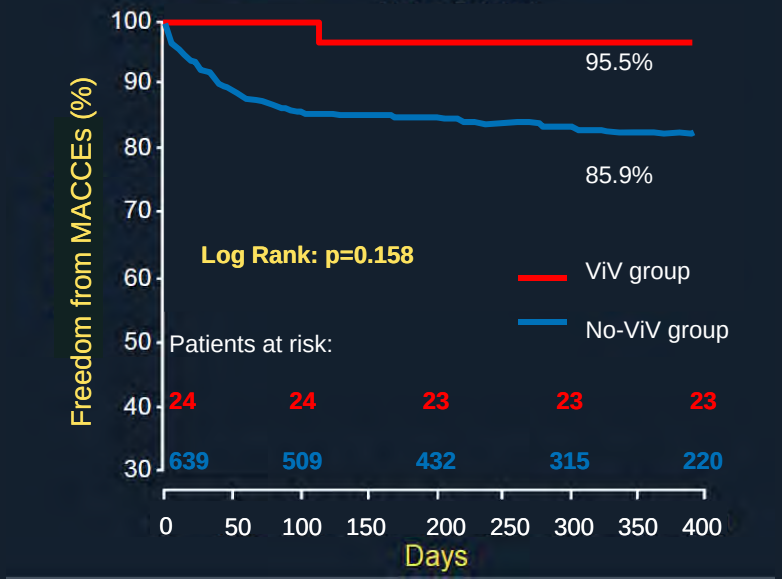
CRS Italy: Valve-in-Valve

1-year outcomes





- *NYHA class comparable in the two groups*
- *No differences between two groups in terms of echo data*
- *No structural valve deterioration, valve thrombosis, new PPL or tromb events*
- *At 30-days higher incidence of PM implantation in the ViV group*

Quality of Life Assessment After TAVI
SF-12v2 Health Survey Quality Metric

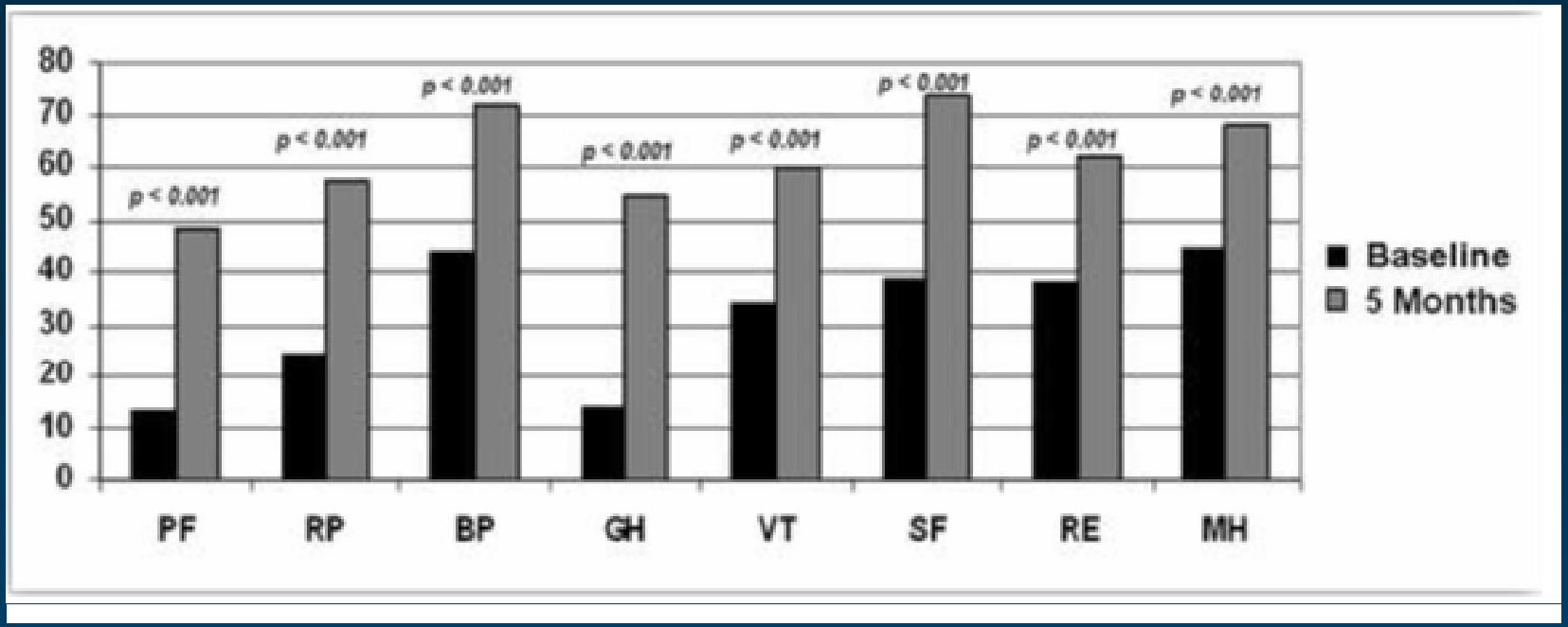
GP Ussia, M Mulè, M Barbanti, V Cammalleri, M Scarabelli, S Immè, D Capodanno, S. Ciriminna, C Tamburino

- **physical functioning (PF):** represents levels and kinds of limitation in lifting, climbing stairbending, knellingor wolking moderate distances
- **role physical (RP):** the degree in physical health for which a person performs activities typical for a specific age and social responsibility, such as a job, community activities and volunteer work
- **bodily pain (BP):** the intensity , frequency and duration of bodily pain and limitations in usual activities due to pain
- **general health (GH):** the belief and evaluation of person's overall health including current and prior health, outlook, resistance to illness
- **vitality (VH):** measure of feeling of energy, pep, fatigue and tiredness
- **social functioning (SF):** ability to develop, maintain and nurture mature social relationship, including family, friends, and marital relationship
- **Role-emotional (RE):** represent personal feeling of job performance on work or other activities
- **mental health (MH):** a person's emotional, cognitive and intellectual status

Ussia GP et al. Eur Heart Journal, 2009

Quality of Life Assessment After Transcatheter Aortic Valve Implantation

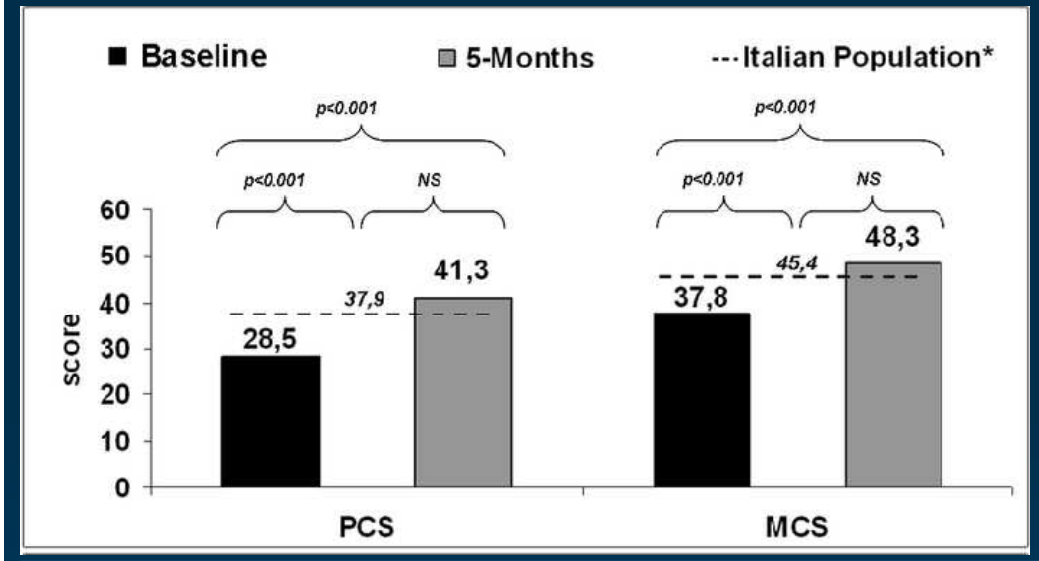
GP Ussia, M Mulè, M Barbanti, V Cammalleri, M Scarabelli, S Immè,
D Capodanno, S Ciriminna, C Tamburino



Results of 8 health concepts derived from MOS SF-12v2® questionnaire compared before undergoing TAVI and 5 months after the procedure

Ussia GP et al. Eur Heart Journal, 2009

Quality of Life Assessment After Transcatheter Aortic Valve Implantation



***PCS and MCS scores in a representative sample of Italian population > 75 years old (5283 adults)**

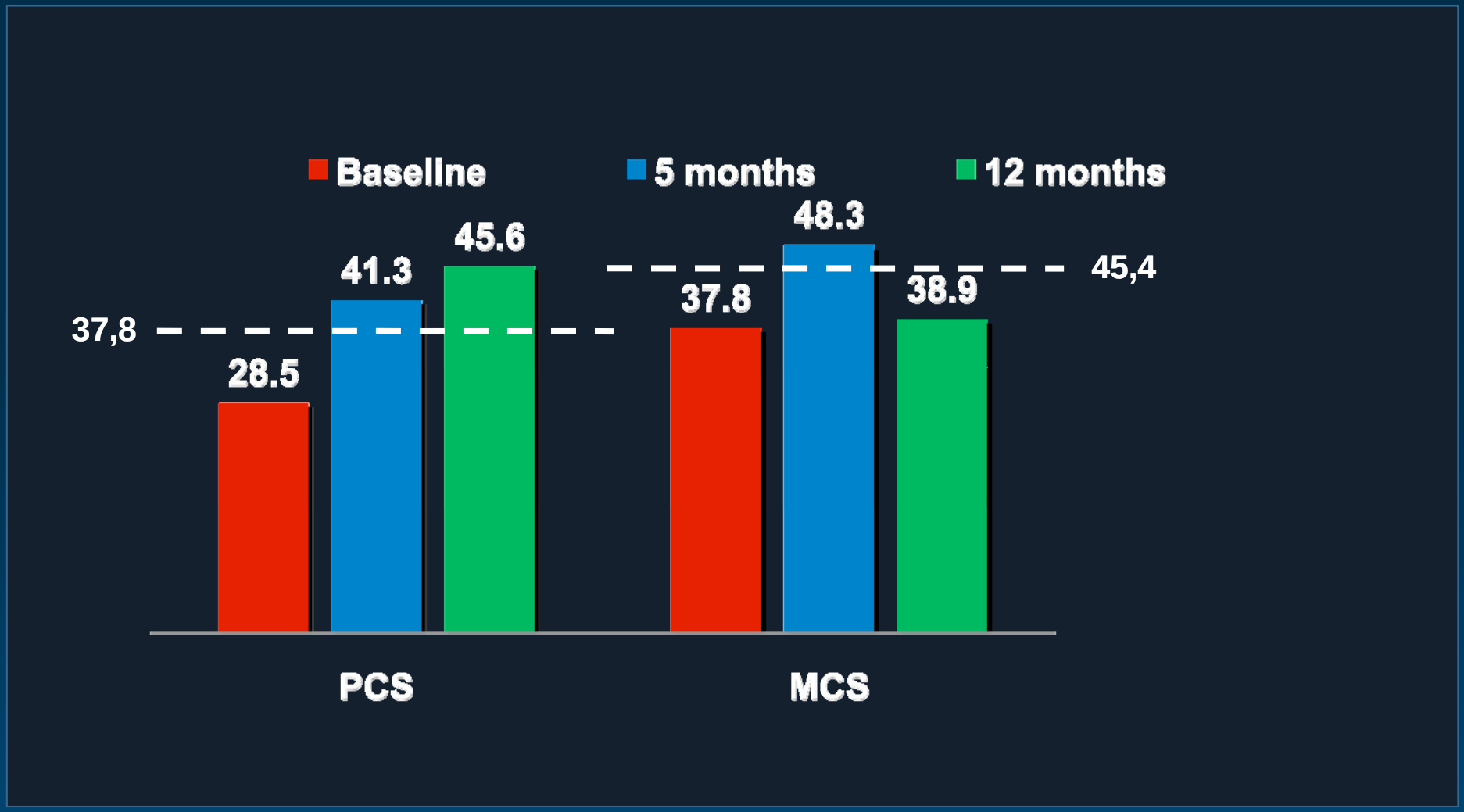
Results of Physical Component Status (PCS) and Mental Component Status (MCS) scores before and at 5 months after TAVI compared with general Italian population.

Data obtained show that patients have a significant improvement in physical and mental status after TAVI (p<0,001)

Ferrarotto Hospital
University of Catania

Ussia GP et al. Eur Heart Journal, 2009

Catania Experience, QoL at 1 year
(preliminary data)



Ferrarotto Hospital
University of Catania

"Off-label" Indications in Transcatheter Aortic Valve Implantation

Corrado Tamburino MD, Phd, FESC, FSCAI

Cardiovascular Department and Division of Cardiology
Ferrarotto Hospital - University of Catania - Italy

rarotto Hospital
University of Catania

Selection Criteria for CRS

Elements below reflect Indications for Use according to the CE Mark

Diagnostic Findings	Non-Invasive		Angiography				Selection Criteria	
	Echo	CT/MRI	LV	Ao Root	CAG	Vascular	Recommended	Not Recommended
Atrial or Ventricular Thrombus	X						Not Present	Present
Sub Aortic Stenosis	X	X	X				Not Present	Present
LV Ejection Fraction	X		X				≥20%	<20% Without contractile reserve
Mitral Regurgitation	X						≤Grade 2	>Grade 2 Organic Reason
Vascular Access Diameter		X				X	≥6 mm Diameter	<6 mm Diameter
Aortic and Vascular Disease		X				X	None to Moderate	Severe Vascular Disease
Indications for 26 mm CoreValve Device								
Annulus Diameter	X	X					20-23 mm	<20 mm or >23 mm
Ascending Aorta Diameter		X		X			≤40 mm	>40 mm
Indications for 29 mm CoreValve Device								
Annulus Diameter	X	X					24-27 mm	<24 mm or >27 mm
Ascending Aorta Diameter		X		X			≤43 mm	>43 mm

General medical guidance for use CoreValve*

Diagnostic Findings	Non-Invasive		Angiography				Selection Criteria	
	Echo	CT/MRI	LV	Ao Root	CAG	Vascular	Recommended	Moderate-High Risk
LV Hypertrophy	X	X					Normal to Moderate (0,6 - 1,6 cm	Severe ≥ 1.7 cm
Coronary Artery Disease		X			X		None, Mid or Distal >70%	Proximal Lesions >70%
Aortic Arch Angulation		X				X	Large Radial Turn	Sharp Turn
Aortic Root Angulation		X				X	<30 degrees	30-45 degrees
Aortic and Vascular Disease		X				X	No or Light Vascular Disease	Moderate Vascular Disease
Vascular Access Diameter		X				X	>6 mm	Calcified and elongated >7 mm
Anatomic Considerations for 26 mm CoreValve Device								
Sinus of Valsalva Width	X	X		X			≥27 mm	<27 mm
Sinus of Valsalva Height	X	X		X			≥15 mm	<15 mm
Anatomic Considerations for 29 mm CoreValve Device								
Sinus of Valsalva Width	X	X		X			≥29 mm	<29 mm
Sinus of Valsalva Height	X	X		X			≥15 mm	<15 mm

*-General medical guidance reflects the experience to date with the product, but final judgment remains with the implanting physicians(s).

Consult with a certified proctor to determine if your patient is Moderate-High Risk

INTERNATIONAL

CAUTION: The CoreValve System is not currently available in the USA for clinical trials for sale.

"Off-label" Indications

- Indication out of the selection matrix
- Assess the feasibility of the procedure
- Predict the result
- Assess risk benefit ratio for the patient
- Experience in the standard procedure and managing complications

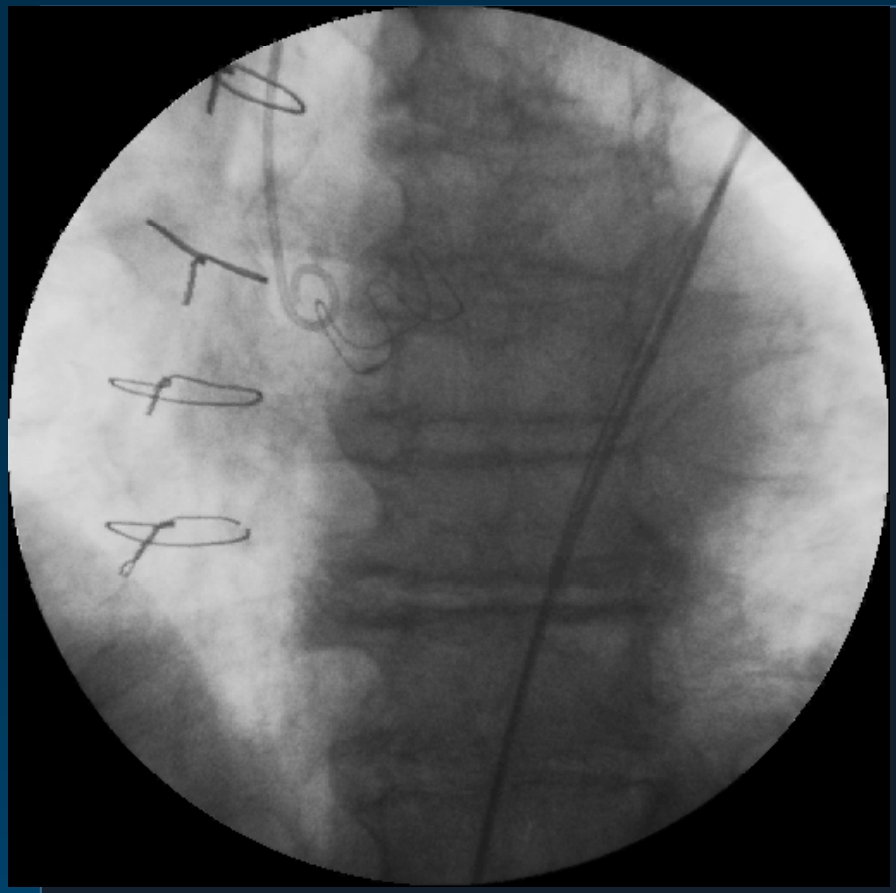
"Off-label" Indications

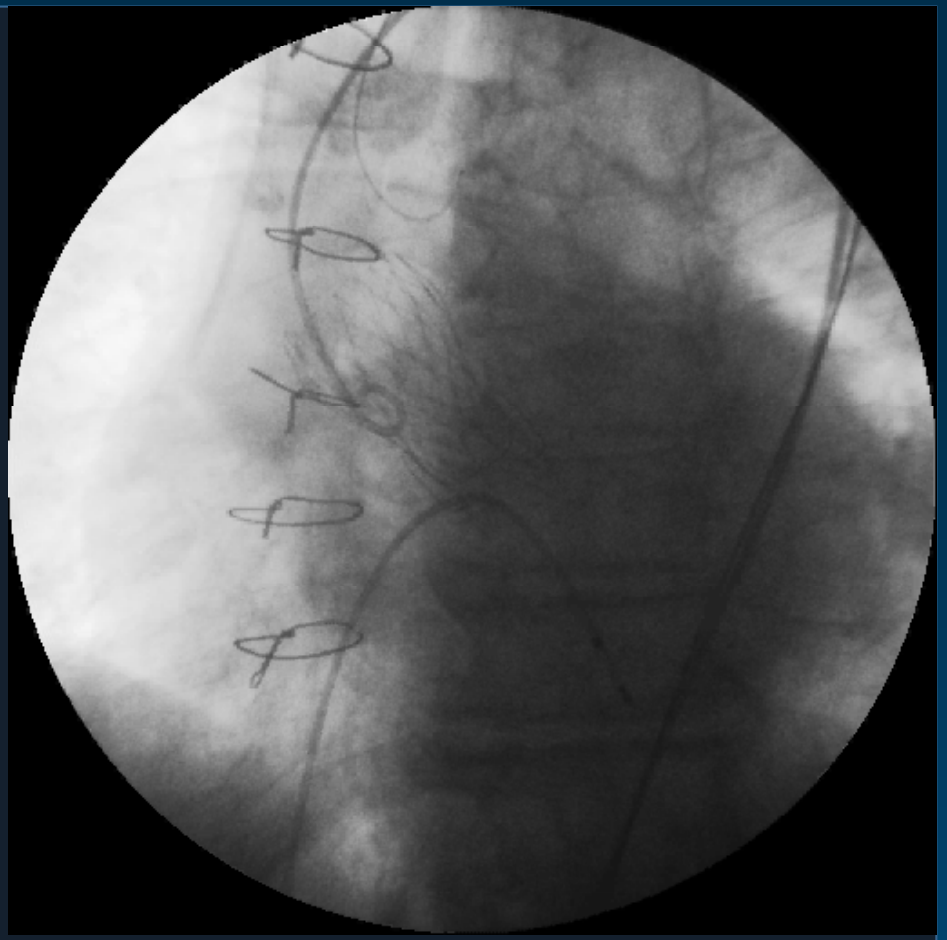
- **Aortic Bioprosthesis degeneration**
- **Bicuspid Aortic Valve**
- **Severe Isolated Aortic Valve Regurgitation**
- **Severe Mitral Regurgitation**
- **Large Aortic Annulus**
- **Femoral artery < 6 mm**

Stented Bioprosthesis degeneration

- **83 yo male, severe BPCO, NYHA III stenosis biological prosthesis, aneurysm of the left sinus of valsalva, paraprosthtetic leak**
- **issues:**
  - **Prosthesis diameter**
  - **Paraprosthetic leak**
  - **Risk of leaflet fracture during prevalvuloplasty**
- **Solutions**
  - **Avoid if possible valvuoplasty, or use undersized balloon**
  - **Post dilate**

Stented Bioprosthesis degeneration





Stentless Bioprosthesis degeneration

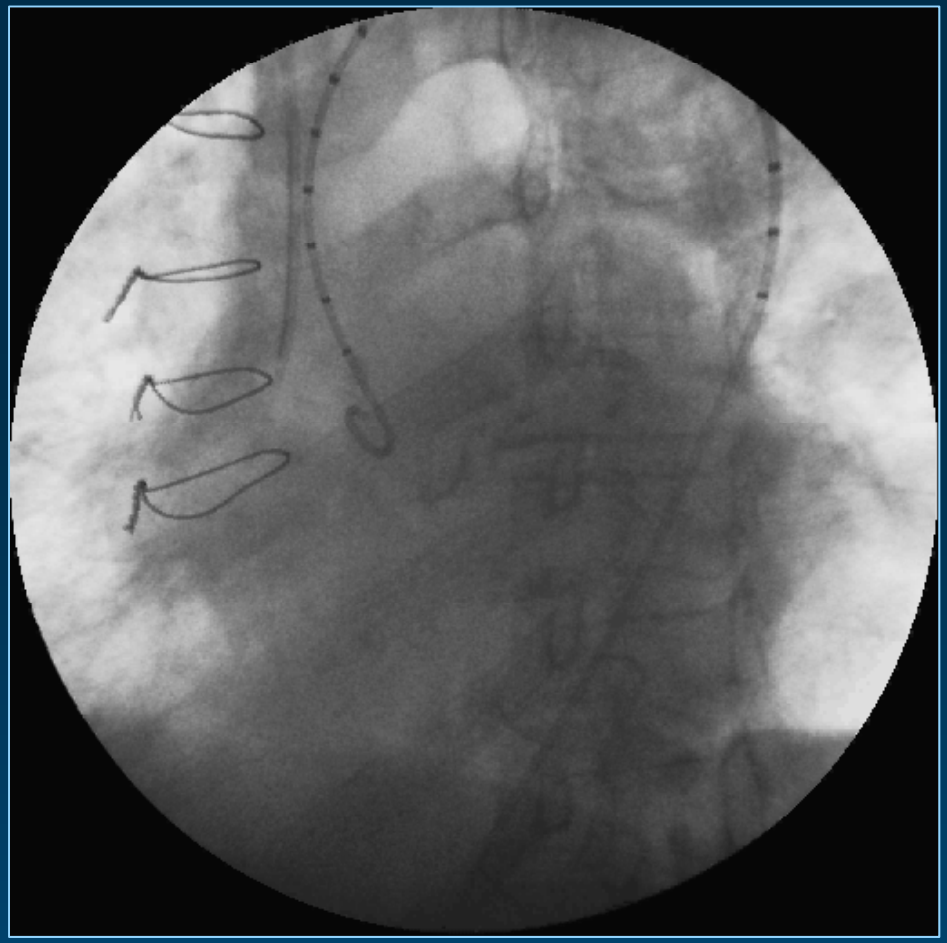
- **84 yo female, NYHA III, stentless valve malfunction secondary to endocarditis, MR 3+, LAD stenosis**
- **issues:**
  - **Low radiopacity of the valve/Low calcifications**
  - **Coesistence of severe regurgitation**
  - **LAD stenosis**
- **Solutions**
  - **No pre implant BAV**
  - **LAD PCI**
  - **Pig tail as marker**
  - **Right ventricular pacing during implantation**

Stentless Bioprosthesis degeneration

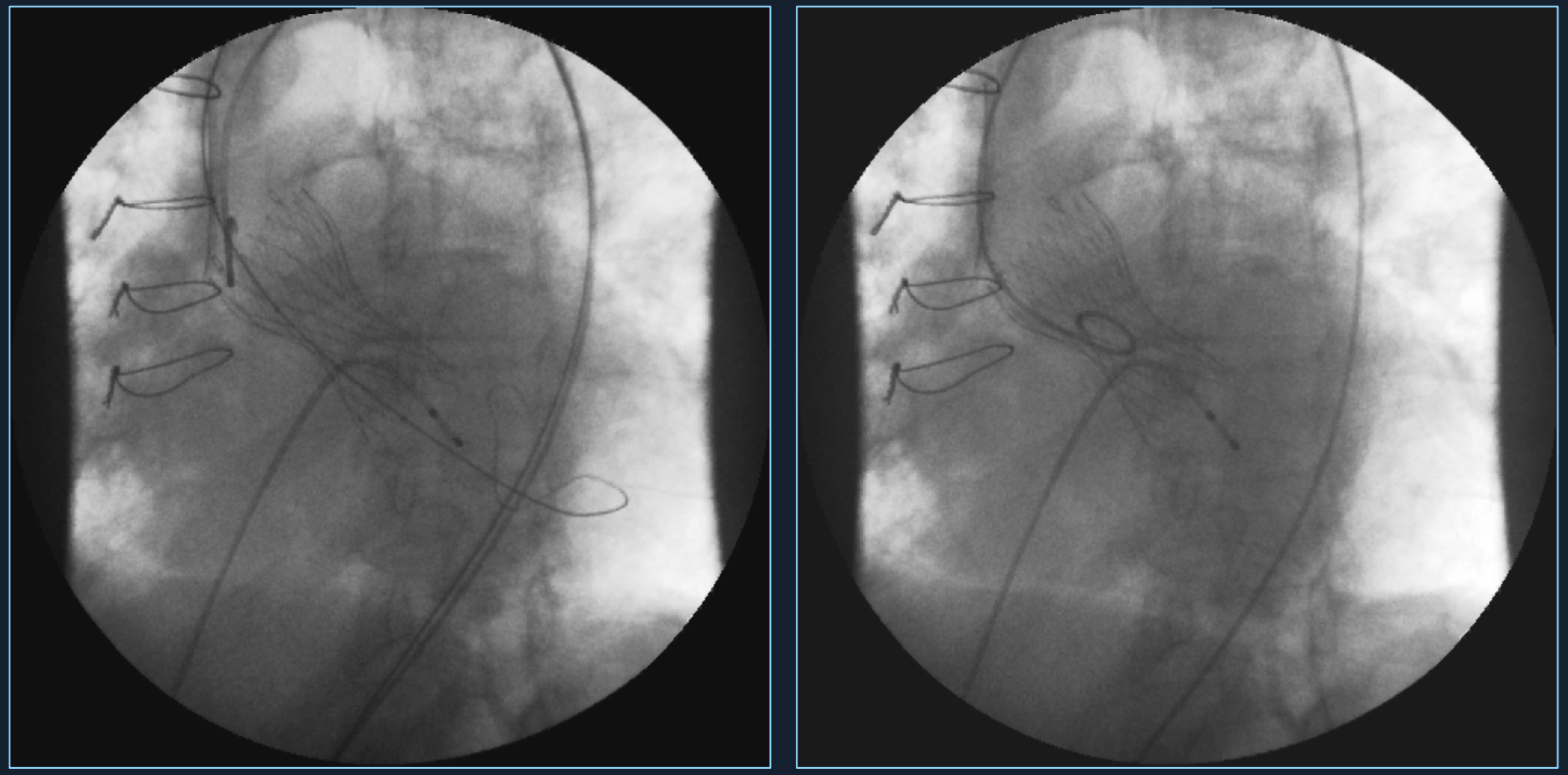
Case Report

Treatment of Severe Regurgitation of Stentless Aortic Valve Prosthesis with a Self-Expandable Biological Valve

Gian Paolo Ussia, MD, FSCAI, Marco Barbanti, MD, Corrado Tamburino, MD, PhD, FESC, FSCAI



Aortic Bioprosthesis degeneration



Aortic Bioprosthesis degeneration

Case Report

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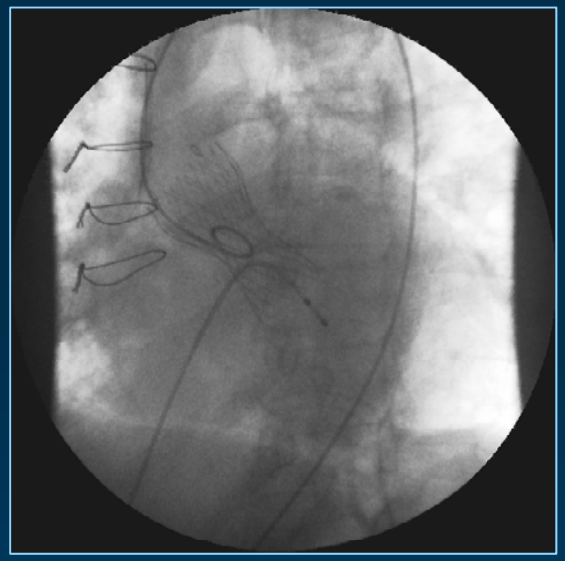


At 2 years:

- ✓ **NYHA I, CCS 0**
- ✓ **Mean transvalvular gradient 15 mmHg**
- ✓ **Para-prosthetic leak 2+**

"Off-label" Indications

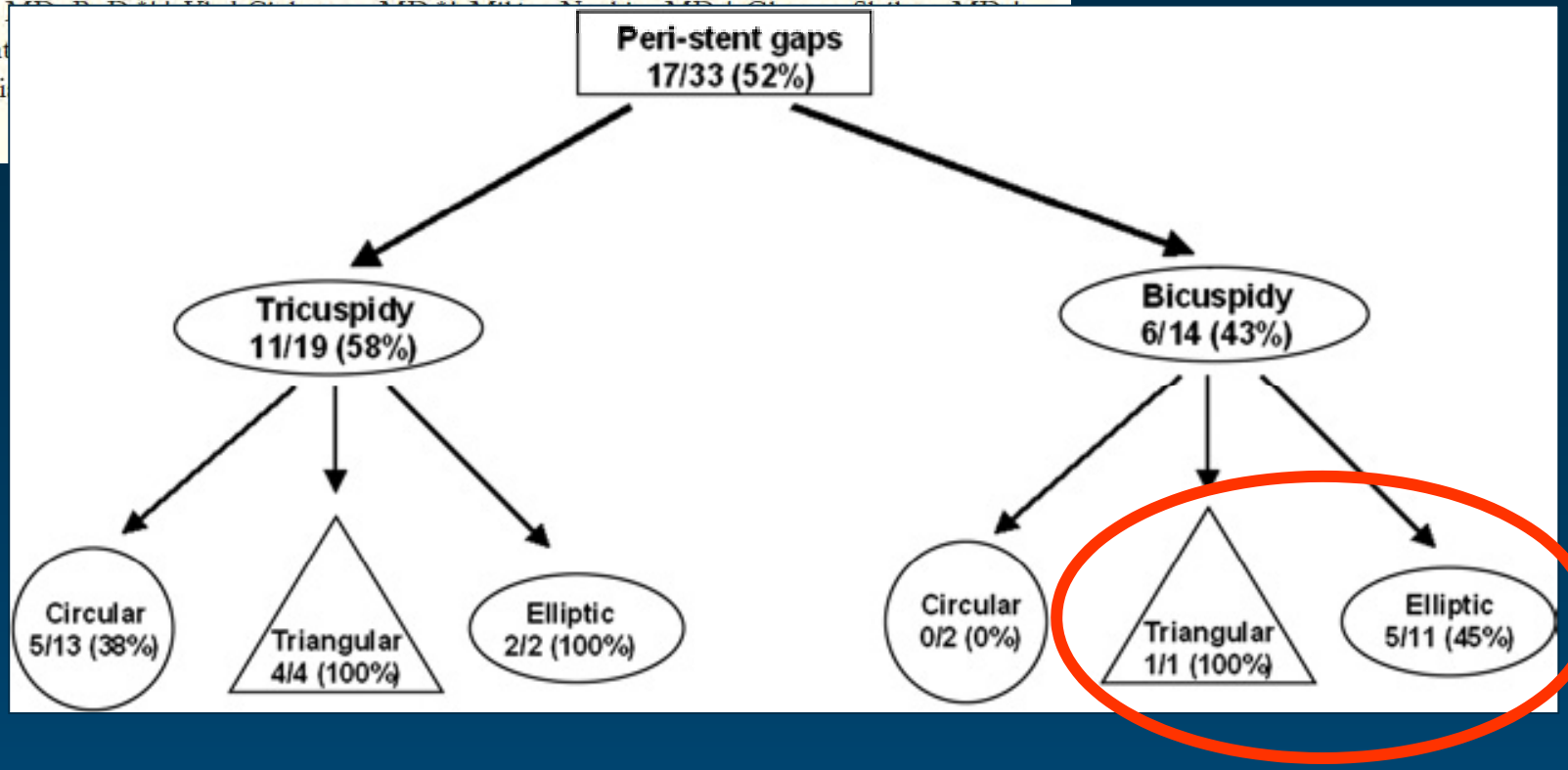
- Aortic Bioprosthesis degeneration
- **Bicuspid Aortic Valve**
- Severe Isolated Aortic Valve Regurgitation
- Severe Mitral Regurgitation
- Large Aortic Annulus

Bicuspid Aortic Valve

Is It Reasonable to Treat All Calcified Stenotic Aortic Valves With a Valved Stent?

Results From a Human Anatomic Study in Adults

Rachid Zegdi,
Antoine Lafont
Jean-Noël Fabi
Paris, France



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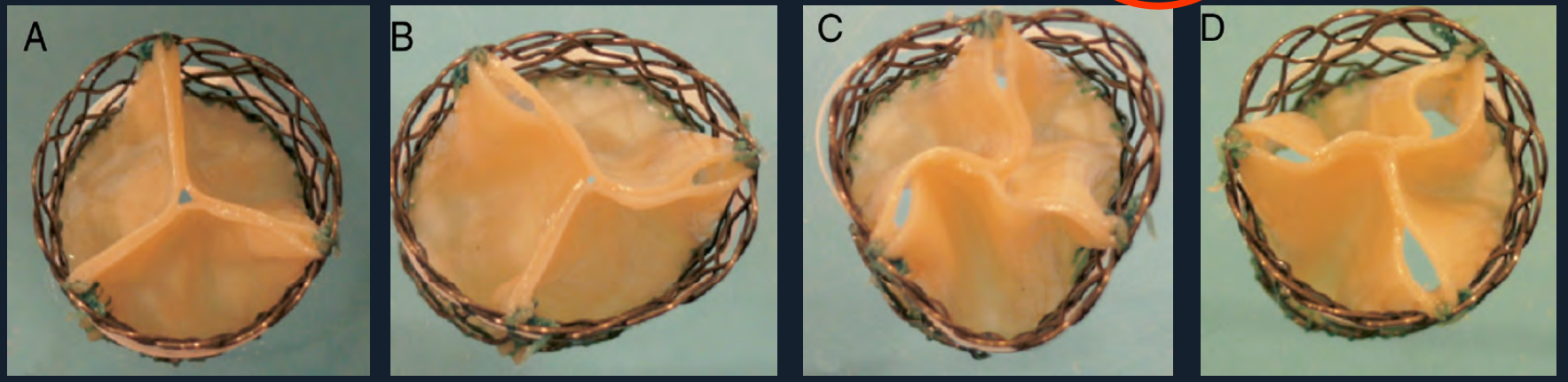
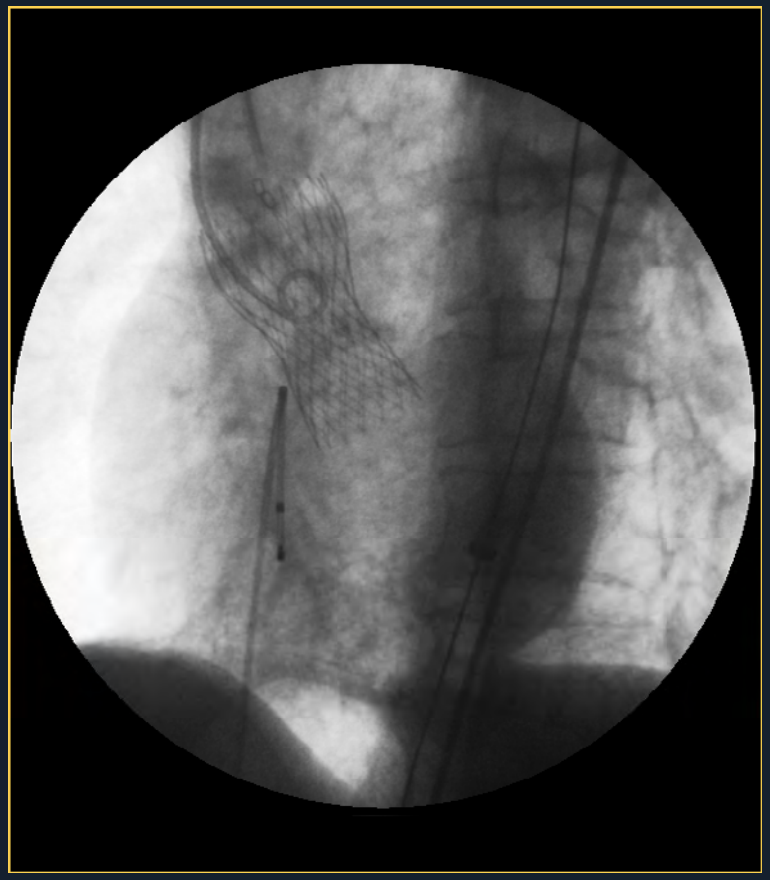
J Am Coll Cardiol 2008;51:579-84)

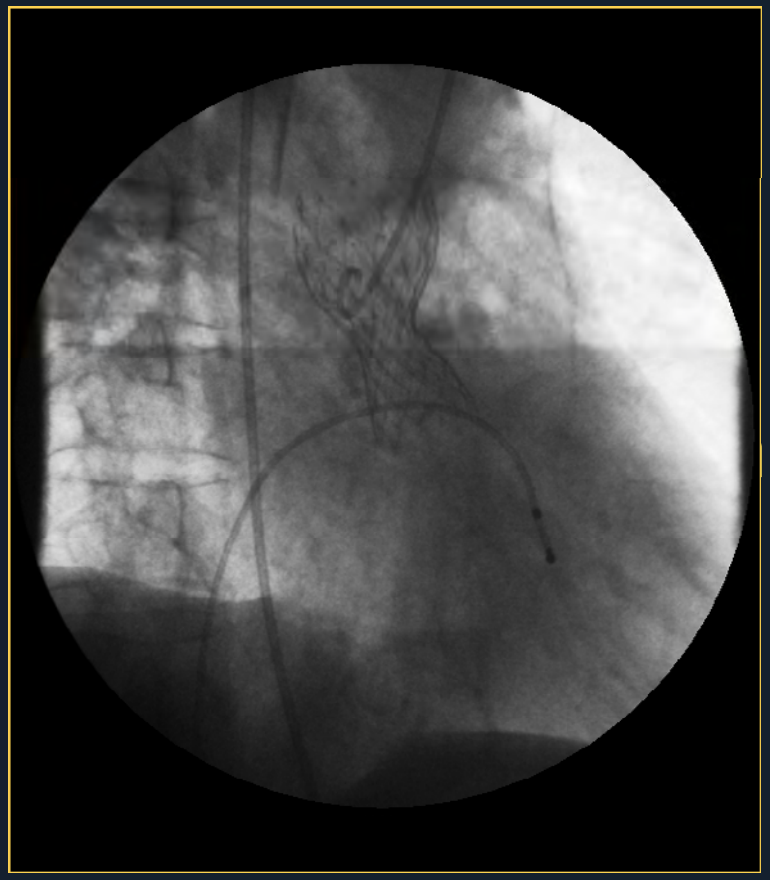
Bicuspid Aortic Valve

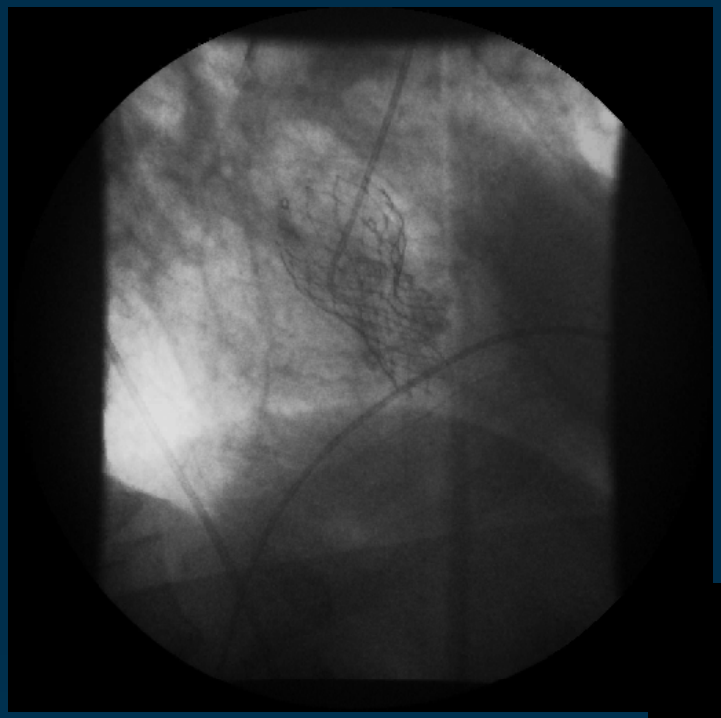
Stent Shape	Tricuspidy (n 19)	Bicuspidy (n 14)
Circular, n (%)	13 (68)	2 (14)
Elliptic, n (%)	2 (11)	11 (79)
Triangular, n (%)	4 (21)	1 (7)

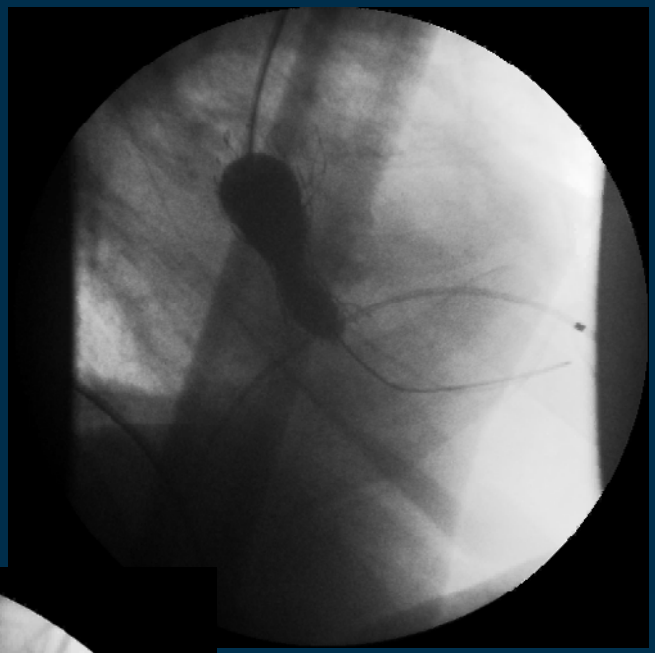


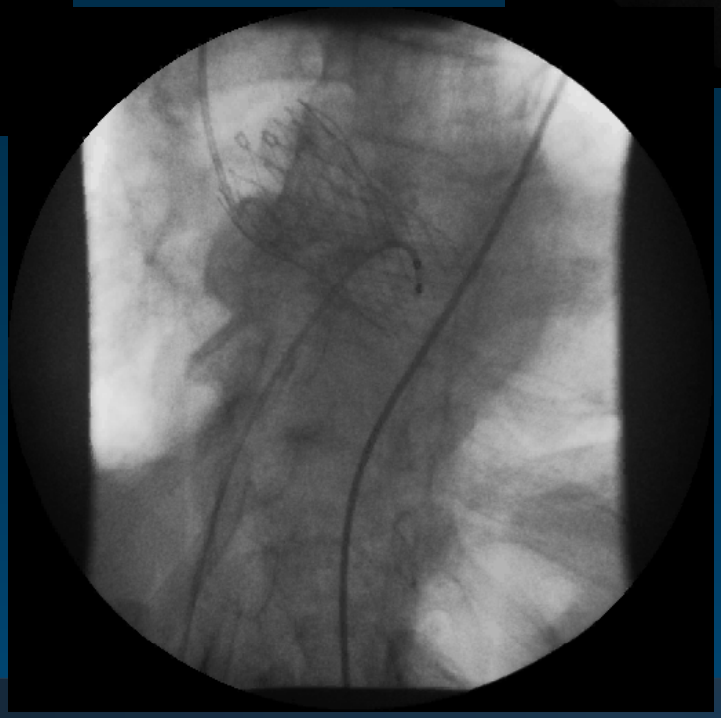
Bicuspid Aortic Valve











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It works !!!


FERRARI LUIGI
358475
Age:82 years
M
26 Feb 2009
16:43:40
A
OSP. VITT. EMANUELE CT
CT
SEGMENT 740ms 0.00s Cardiac 0.5 CE 740m
S
I
2 cm
kVP:120
mA:450
msec:400
mAs:114
Thk:0.5 mm
Aquilion
Vitrea®
W/L:1272/394
Oblique
LAD
P


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Thk:0.5 mm
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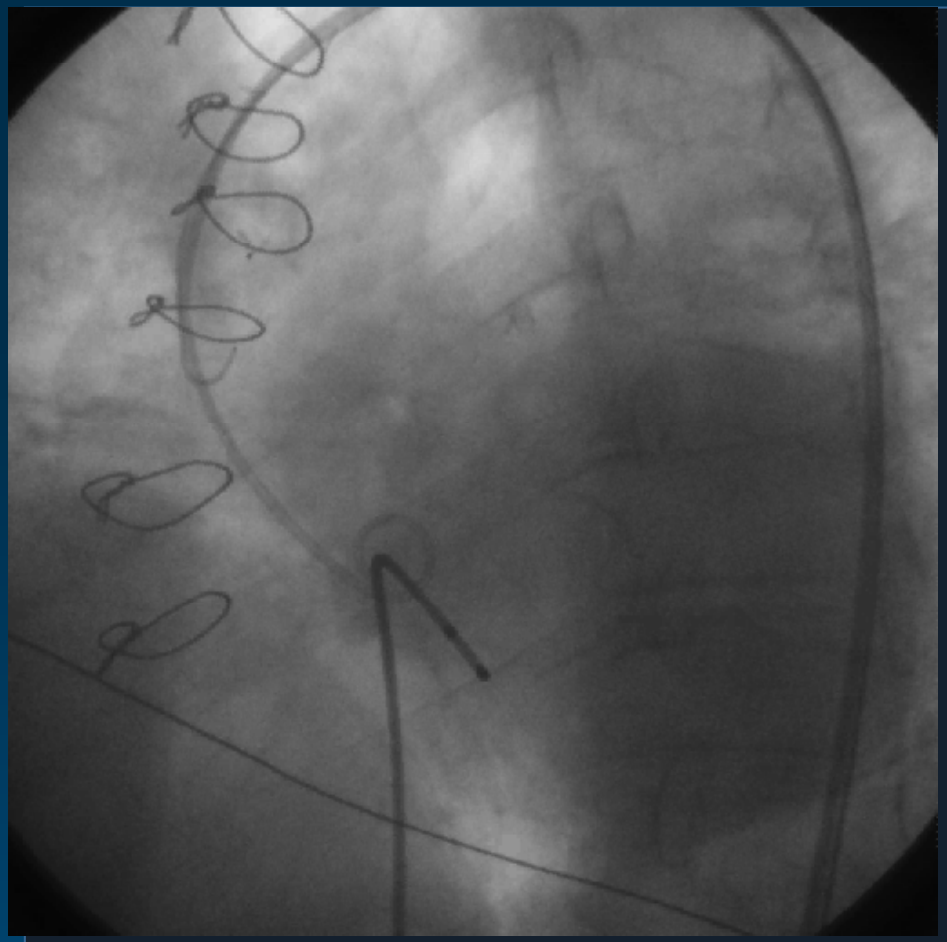
Vitrea®
W/L:1272/394
Oblique
LAD
R

Bicuspid Aortic Valve

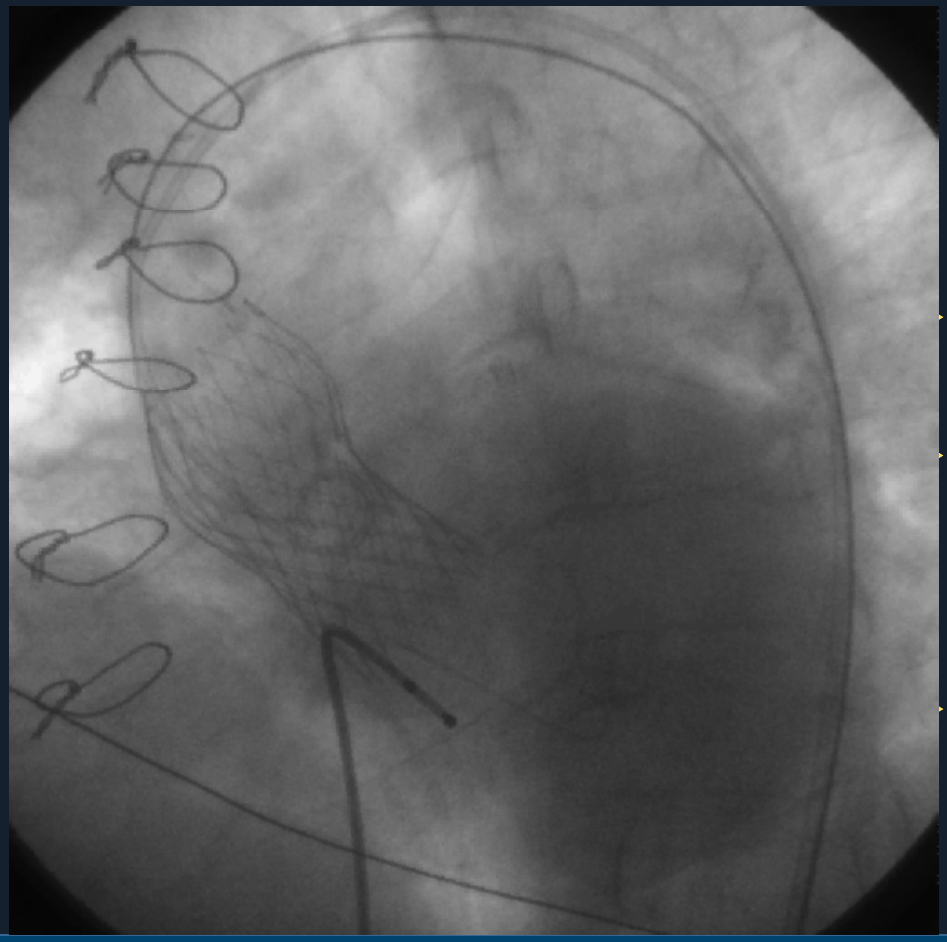
- **Bicuspid Aortic Valve can be treated**
- **There is possibility of oval expansion**
- **The self expandable valve can continue to expand after implantation and gain circular shape**
- **Even if underexpanded the valve fuction and the frame sustain the stress**

Severe Isolated Aortic Valve Regurgitation



- No Calcifications
- No anatomic markers
- Challenging anchoring

Severe Isolated Aortic Valve Regurgitation

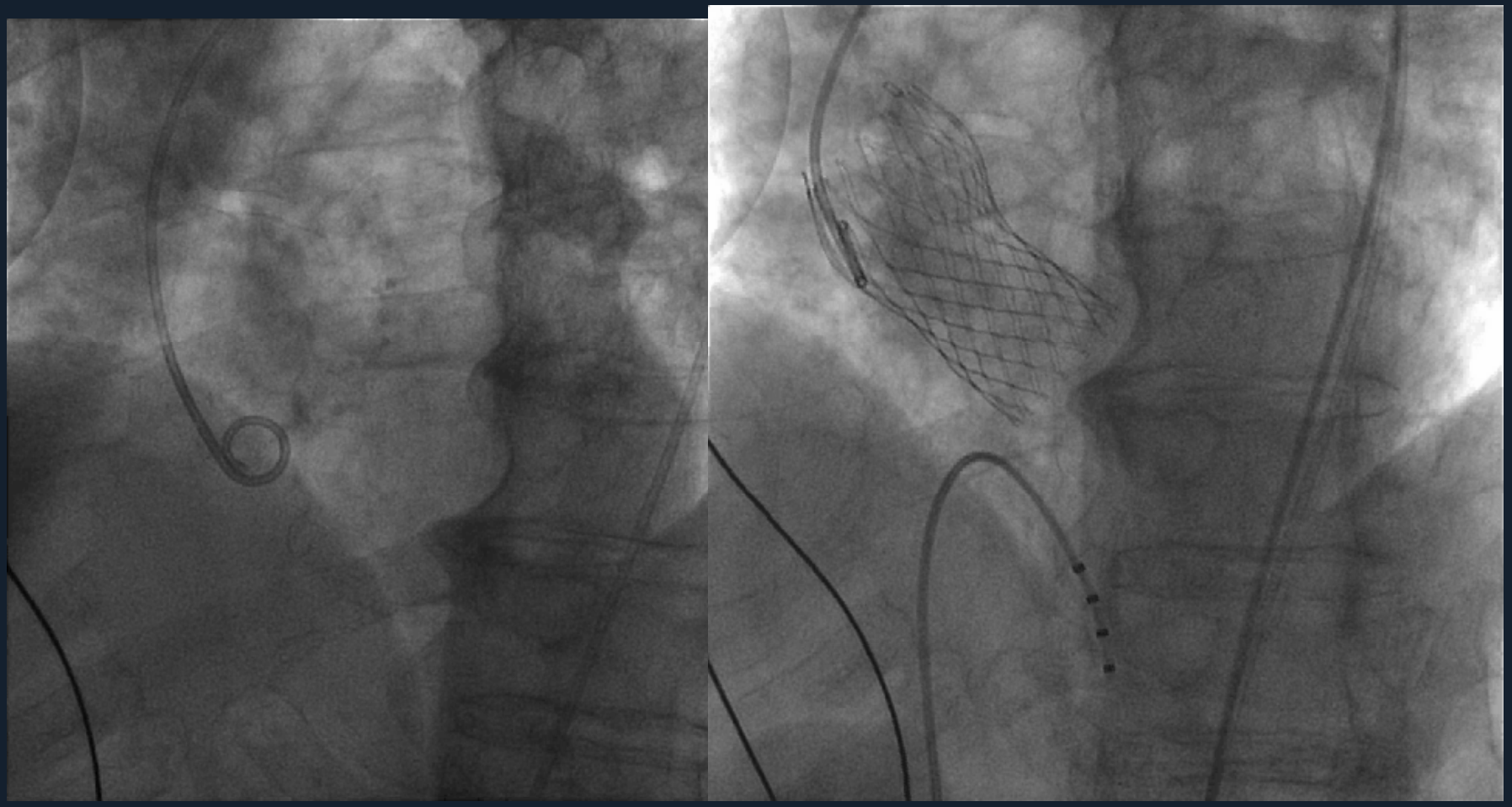


- **Optimal sealing**
- **Absence of Perivalvular leak**
- **No embolization**

Large Aortic Annulus

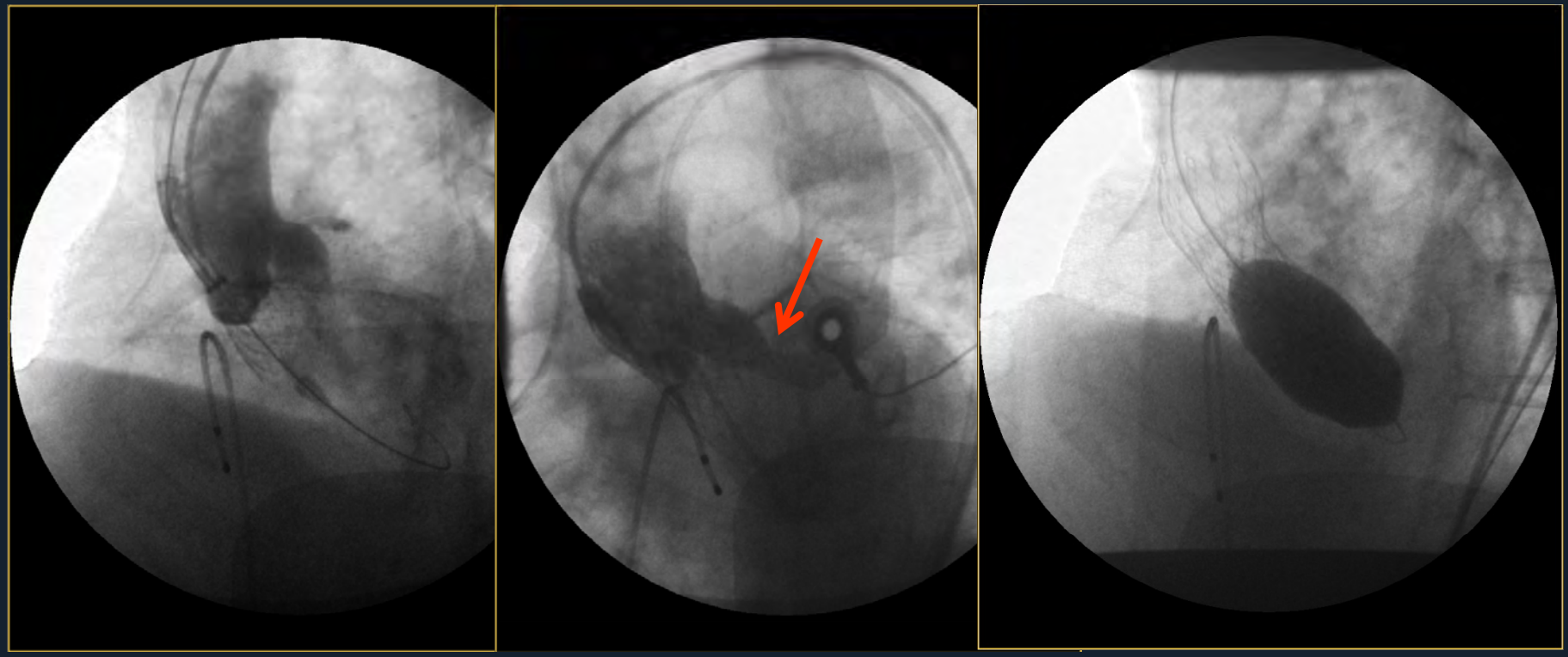
- 79 years ol, s\p CABG, lymphoma, chemio-therapy
- Issue: large aortic valve annulus = 28 mm
- Solution
  - Predilate with small balloon (Ø22 mm)
  - High implantion for using the largest part of the valve (29 mm)
  - Post-dilate the lower part with a 28 mm Baloon with perfect RV pacing
- Results:
  - Good implant,
  - Mild paravalvular leak

Large Aortic Annulus

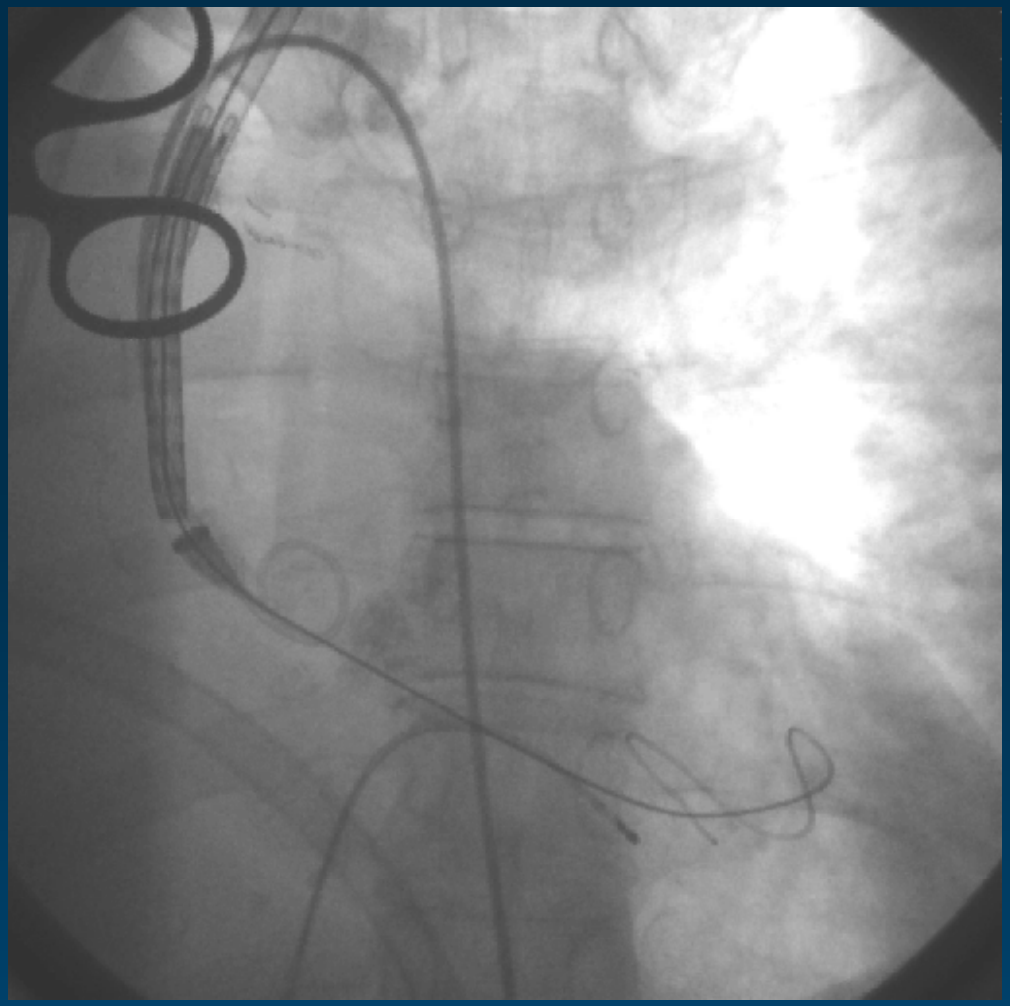


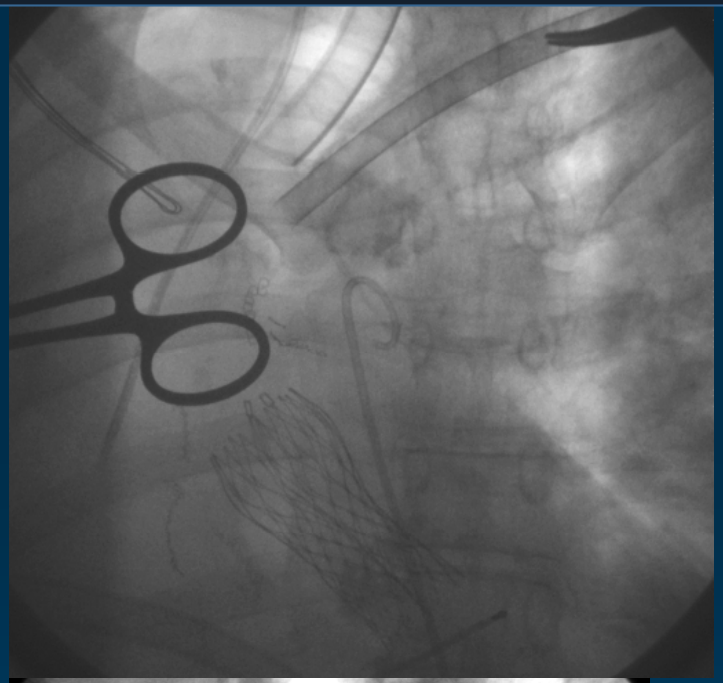
Large Aortic Annulus

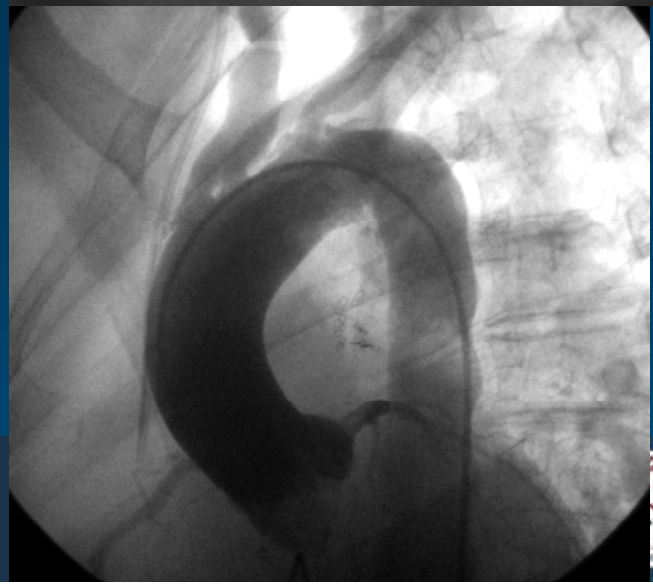
Post implant balloon valvuloplasty RV pace 180 bpm,



Subclavian Artery







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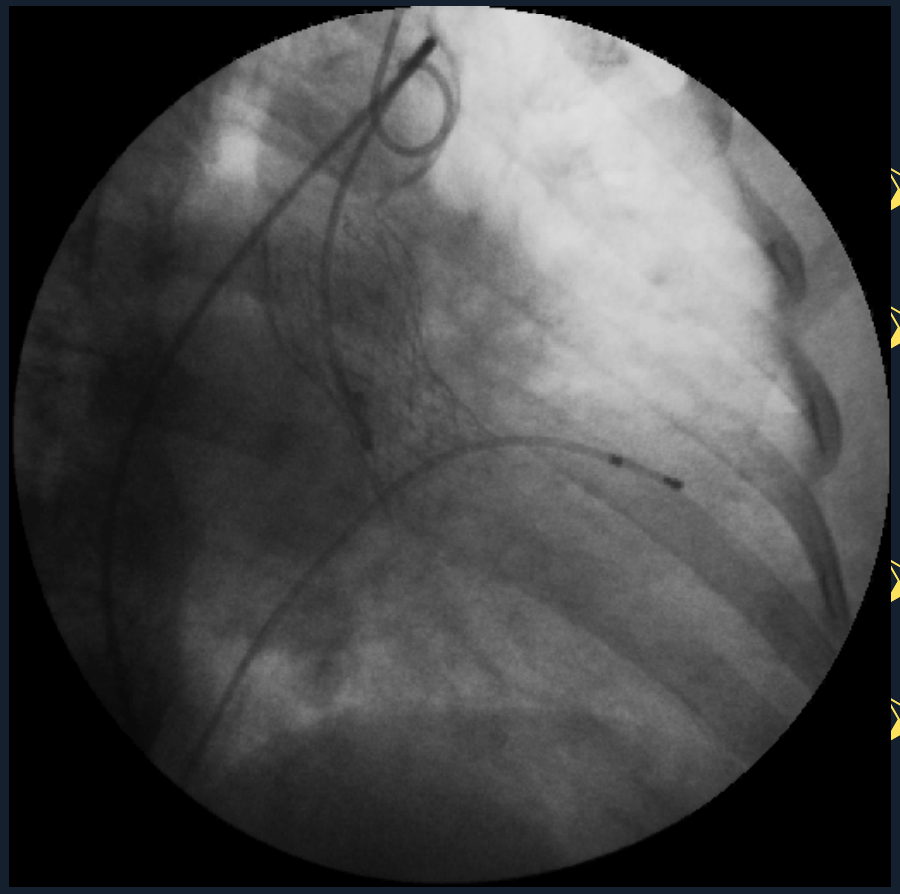
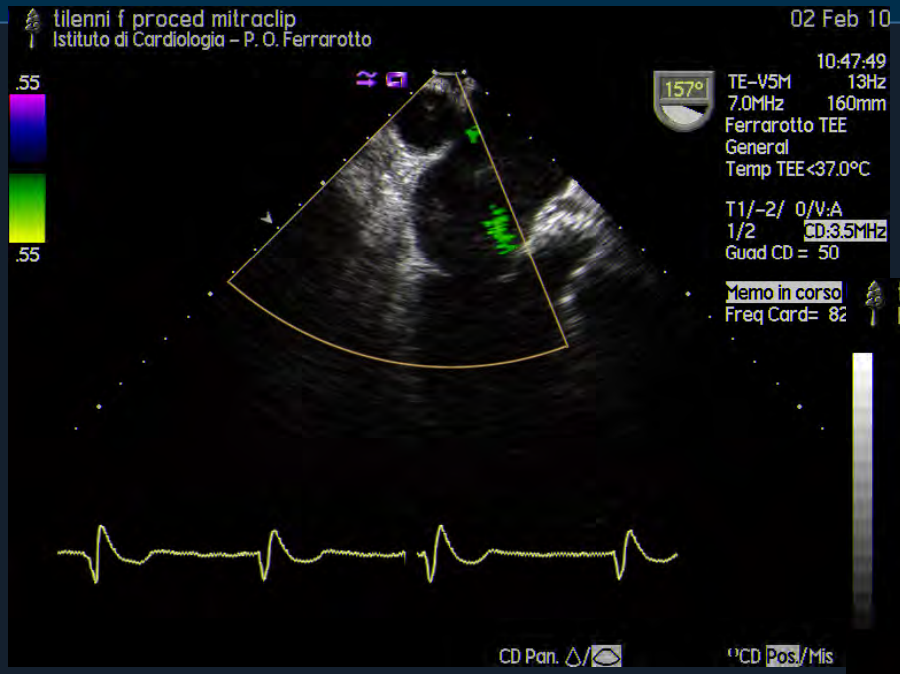
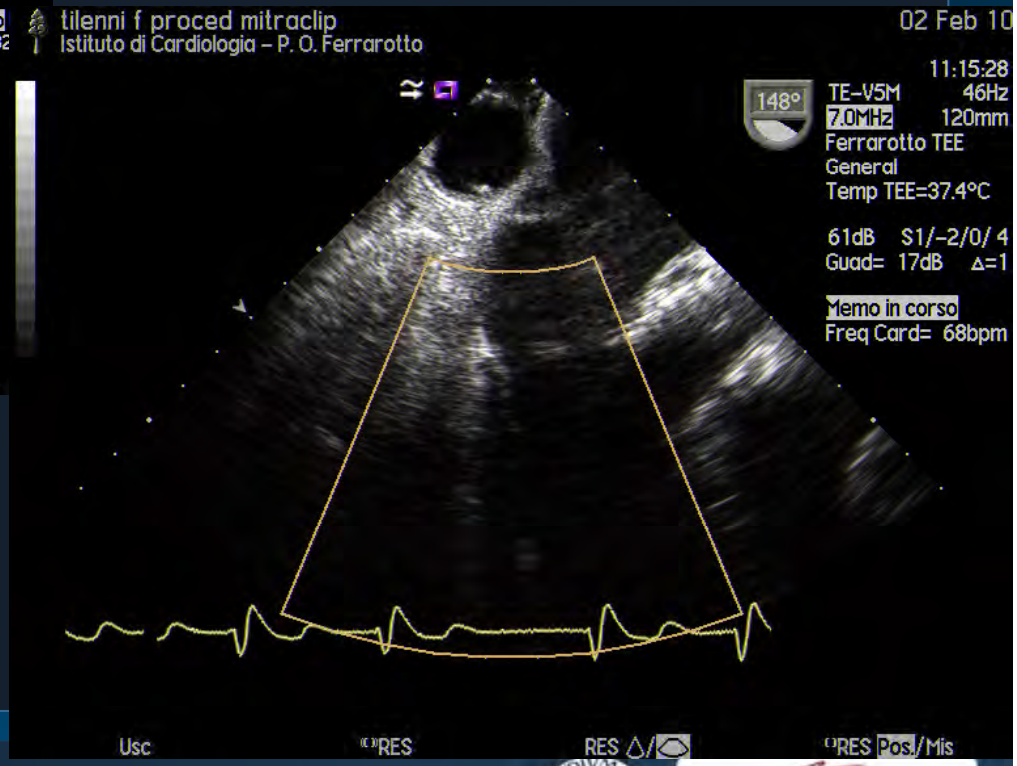
Severe Mitral Regurgitation



- 80 yo female, NYHA 3
- Severe AVS , MR 3 + for chordal rupture
- 26-mm CRS
- No improvement in MR after TAVI

Severe Mitral Regurgitation





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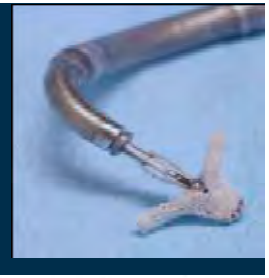
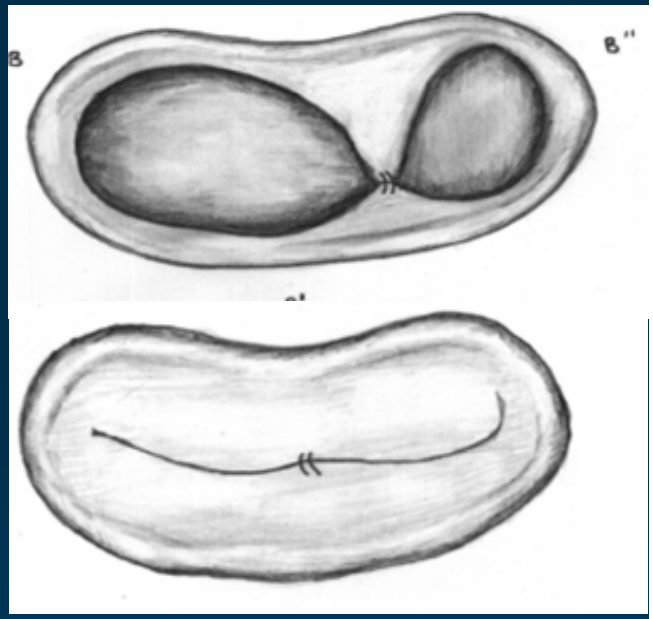
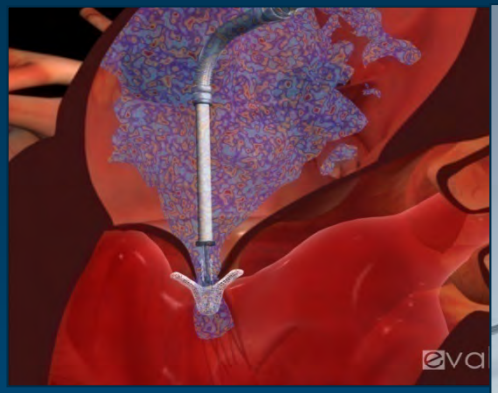
MitraClip™



- ✓ Edge-to-Edge Technique
- ✓ Permanent leaflet approximation using a sutures + clip
- ✓ Trans-septal approach
- ✓ Echocardiographic and fluoroscopy guidance on a beating heart





Catheter Delivery System

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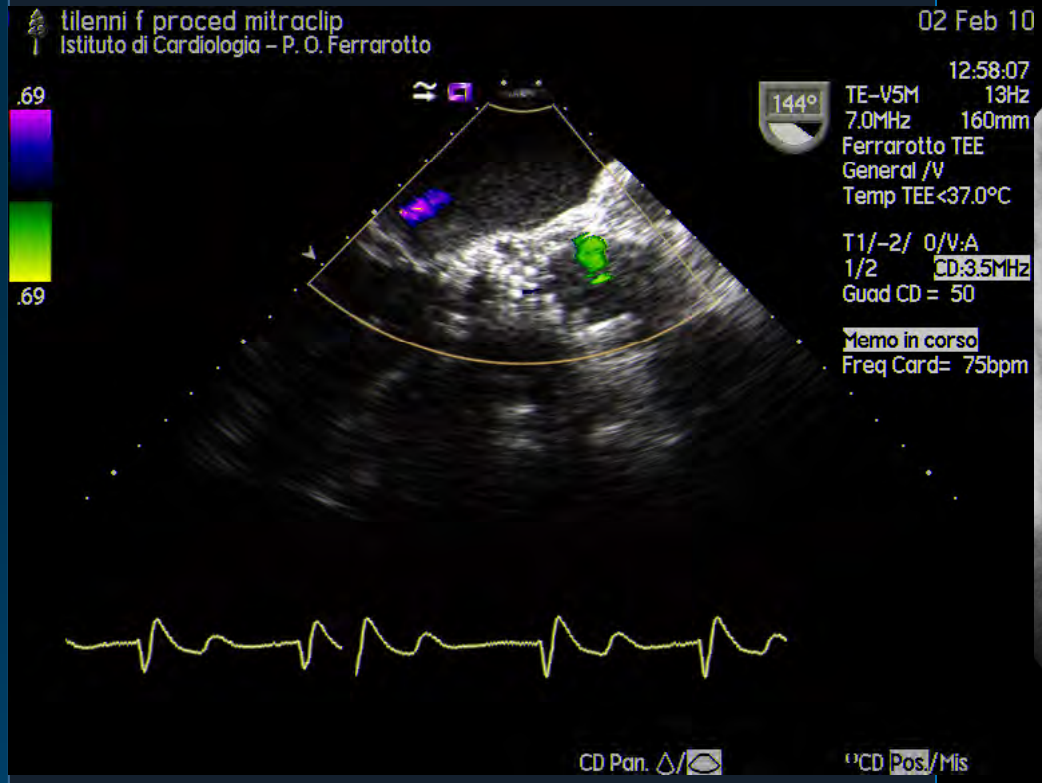
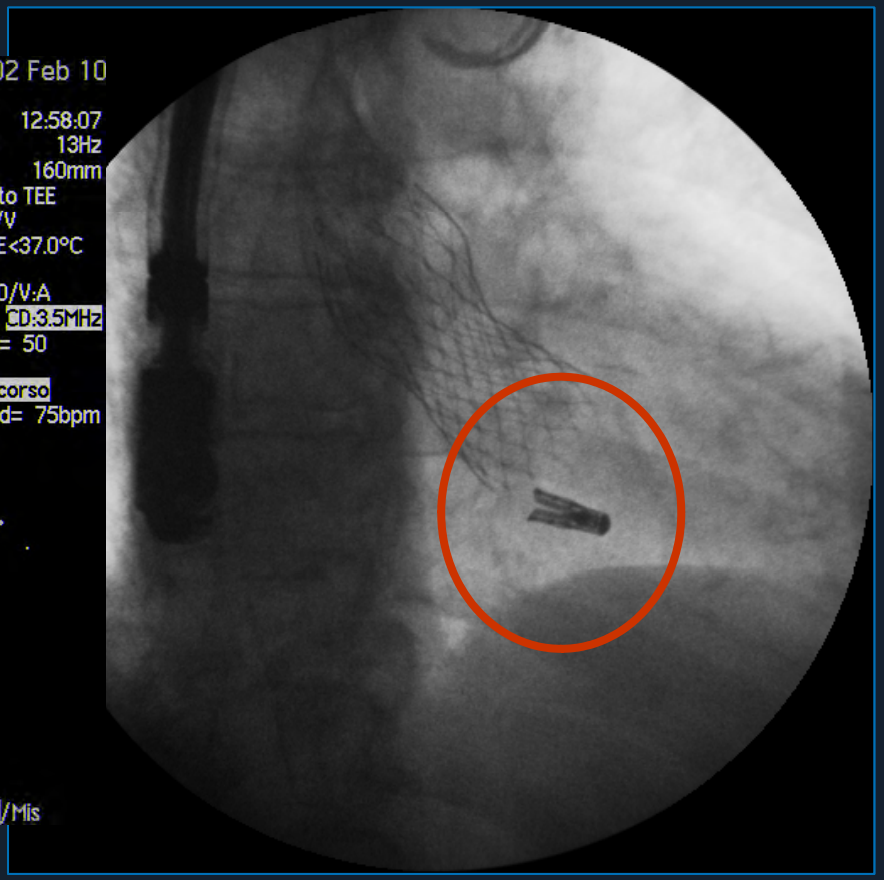
Severe Mitral Regurgitation





Gruppo di Lavoro

Dott. Fabio Tiecco (Commissione Unica dei Dispositivi medici del Ministero della Salute)

Dott. Danilo Fusco (Dipartimento di Epidemiologia del SSR)

Dott.ssa Rossana De Palma (Regione Emilia Romagna)

Ing .Carlo Zocchetti (Regione Lombardia)

Dott. Salvatore Scondotto (Regione Sicilia)

Dott. Piero Borgia (Regione Lazio)

Dott. Egidio Celentano (Regione Campania)

Ing. Aldo Mauro (Regione Calabria)

Dott.ssa Anna Orlando (Regione Piemonte)

OBSERVANT

OBservational Study of Effectiveness of AVR-TAVI procedures for severe Aortic steNosis Treatment

Endorsed by:

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Conclusions

- ***The TAVI is a safe and effective procedure***
- ***More experience is gained better results are obtained***
- ***Off label TAVI can be performed in very selected case assessing the risk benefit ratio of the procedure***
- ***Probably the “off label” procedure of the 2010 will be “in label” procedure in the next future***