ECOCARDIOGRAFIA 2015
XVII Congresso Nazionale SIEC
Hotel Royal Continental
Napoli, 16-18 Aprile 2015

Controversie sulla TAVI:

La TAVI NON è una procedura soprautilizzata. Anzi…

Flavio Ribichini
Università di Verona

La TAVI NON è una procedura soprautilizzata. Anzi…

Sia da un punto di vista

Epidemiologico

Economico

Tecnico-prognostico

Prevalenza della Stenosi Aortica Severa in Italia

Prevalenza della stenosi aortica degenerativa negli anziani: risultati di uno studio epidemiologico di comunità

Barbara Bordoni[1], Francesco Saia[1], Cristina Ciuca[1], Cinzia Marrozzini[1], Marianna Santoro[1], Gianni Dall'Ara[1], Laura Anderlucci[2], Michela Montefiori[1], Carolina Moretti[1], Anna Alberti[3], Gianpaolo Bragagni[3], Claudio Montori[4], Giovanni Pollastri[4], Daniela Cocchi[2], Antonio Marzocchi[1], per i Ricercatori dello Studio ELISA (vedi Appendice)

[1]*Istituto di Cardiologia, Università di Bologna e Azienda Ospedaliera Universitaria S. Orsola-Malpighi, Bologna*
[2]*Dipartimento di Scienze Statistiche "Paolo Fortunati", Università degli Studi, Bologna*
[3]*U.O. di Medicina Interna, Ospedale di San Giovanni in Persiceto (BO)*
[4]*Medici di Medicina Generale, San Giovanni in Persiceto (BO)*

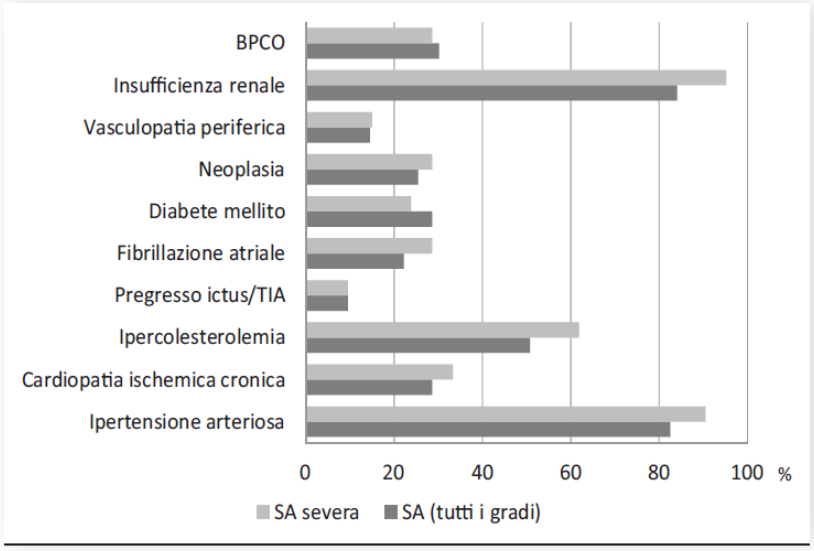


Figura 2. Comorbilità.
BPCO, broncopneumopatia cronica ostruttiva; SA, stenosi valvolare aortica; TIA, attacco ischemico transitorio.

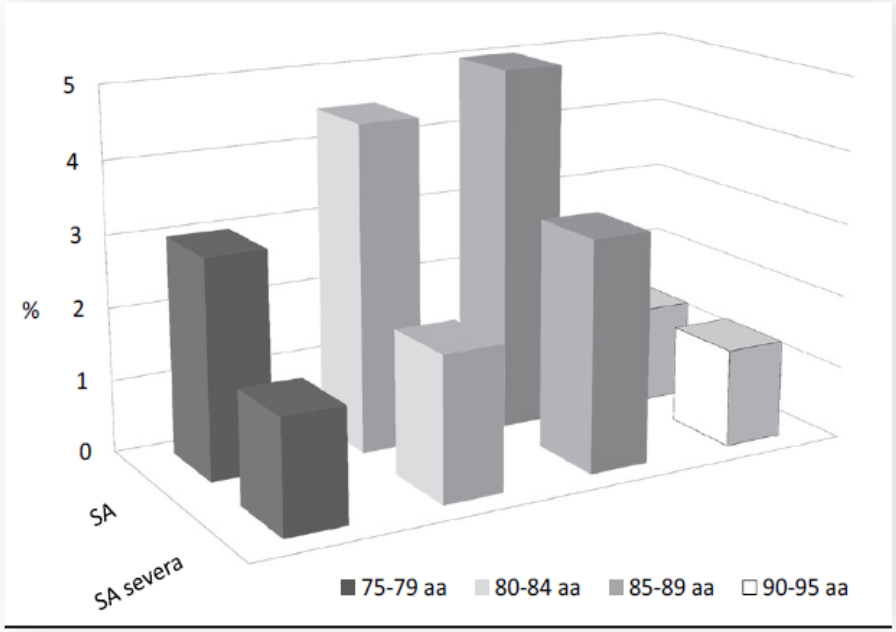
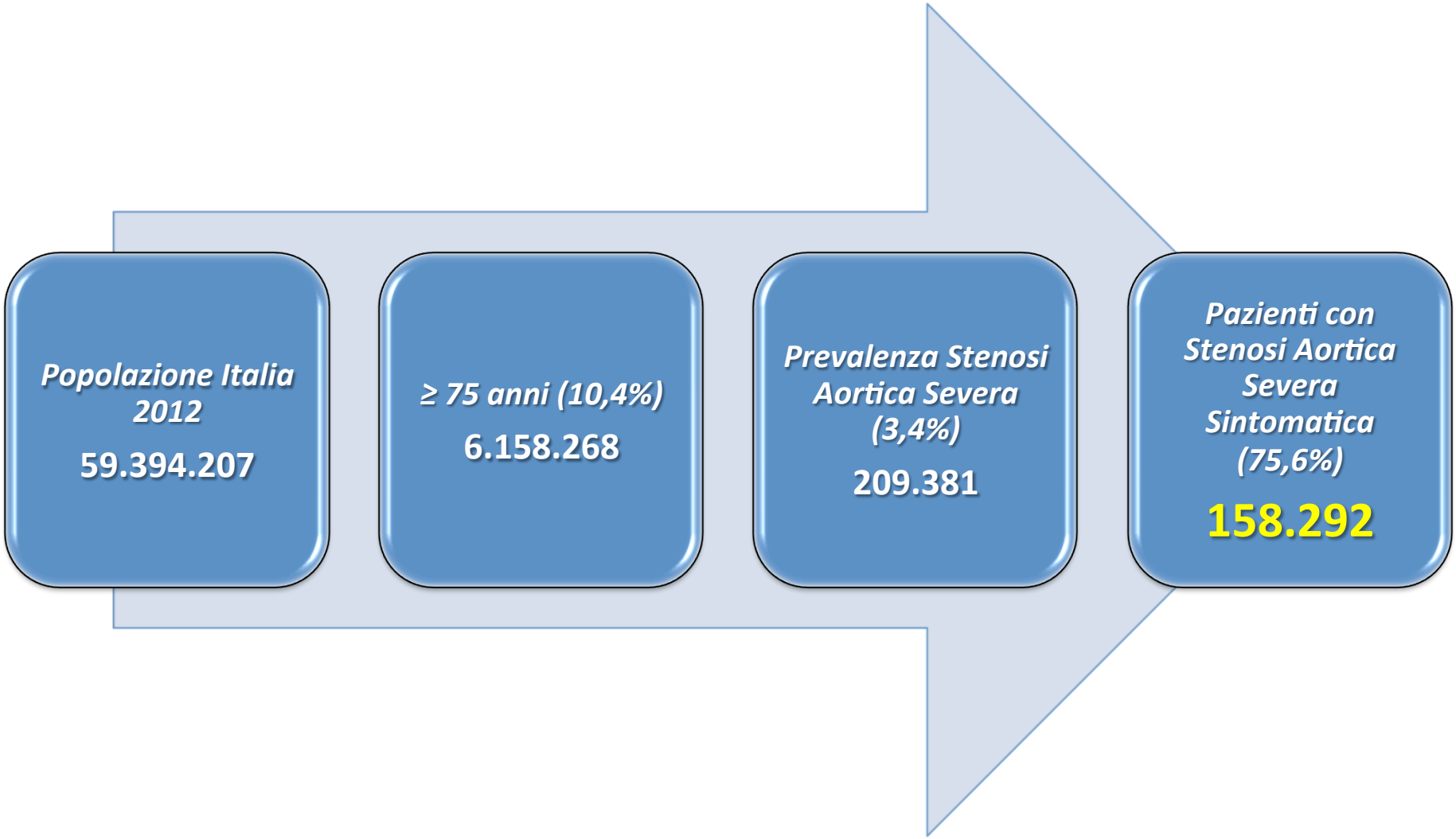


Figura 3. Prevalenza della stenosi valvolare aortica (SA) per fasce di età.

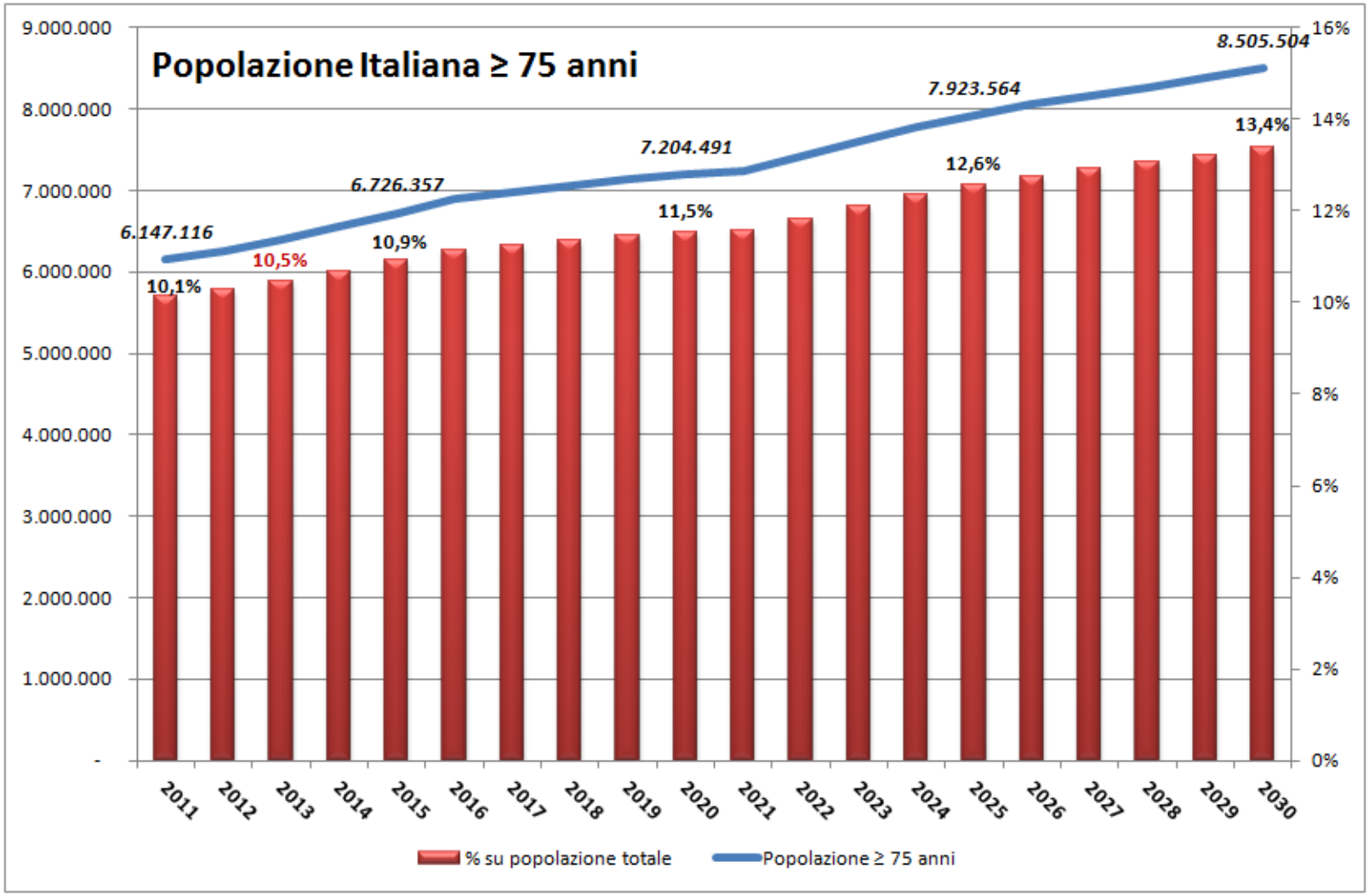
La prevalenza di SA degenerativa in pazienti di età 75-95 anni nel nostro studio è risultata del 3.8%, con possibilità di lieve sottostima legata alle metodiche di screening impiegate ed all'esclusione di pazienti estremamente compromessi. È necessaria una maggiore attenzione verso la diagnosi di SA, al pari di un attento monitoraggio della popolazione affetta anche da forme di grado lieve o moderato per prevenire il sottotrattamento o il trattamento tardivo.

Prevalenza della Stenosi Aortica Severa in Italia



Fonte: Osnabrugge et al. JACC 2013; ISTAT Population Data 2012

Invecchiamento della popolazione Italiana



Fonte: ISTAT, 2014

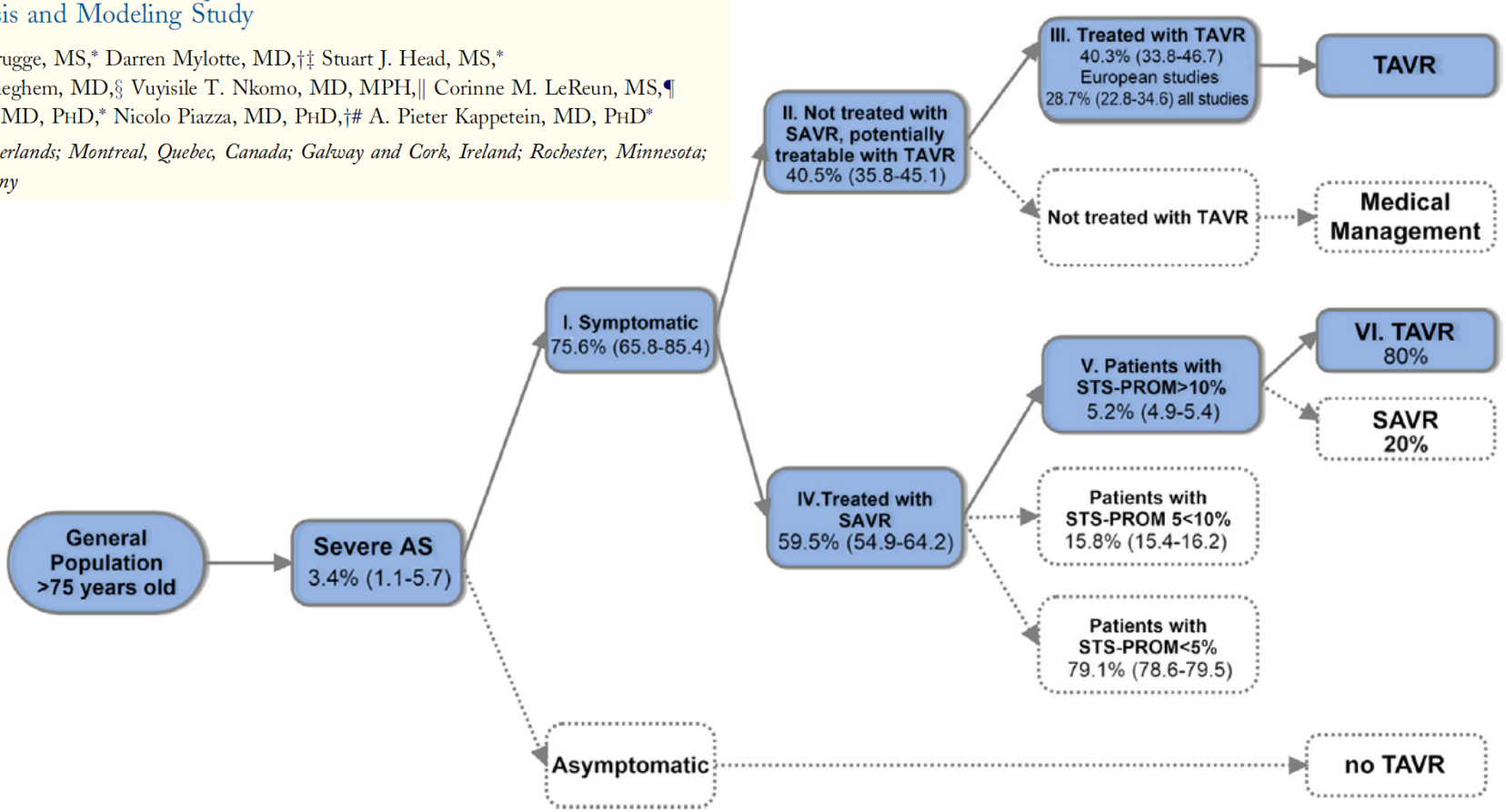
Prevalenza della SVA severa e popolazione candidata a TAVI

Aortic Stenosis in the Elderly

Disease Prevalence and Number of Candidates for Transcatheter Aortic Valve Replacement: A Meta-Analysis and Modeling Study

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*

Rotterdam, the Netherlands; Montreal, Quebec, Canada; Galway and Cork, Ireland; Rochester, Minnesota; and Munich, Germany



Prevalence of TAVI-eligible patients in Italy: 29.597 (<20%)

Candidates x million: >400

Incidence of new TAVI-eligible patients in Italy every year: 2.679

Source: *Osnabrugge et al. JACC 2013; ISTAT Population Data 2012

Popolazione eligibile a TAVI in Francia: Stima dell'HAS (Haute Authorièe de Santè)

Réévaluation des bioprothèses valvulaires implantées par voie artérielle transcutanée ou par voie transapicale

5.5. Données concernant la population cible

A partir des données du PMSI et de l'étude de Iung *et al.* (35) (31,8% des patients symptomatiques sont récusés à la chirurgie) ; la population cible, sans prendre en considération les patients à haut risque chirurgical, peut être estimée à 5 175 patients par an en France.

Il est difficile de réaliser une estimation plus précise de la population cible.

Indications for intervention

The reasons for not performing an intervention in the 31.8% of patients with severe single-valve disease who did not undergo intervention, while in NYHA class III or IV, were: regression of symptoms under medical treatment (overall 39.9%, 1.8% as the sole reason), end-stage disease (18.4%), symptoms attributed to coronary artery disease (14.9%), and recent myocardial infarction (7.9%). Besides cardiac causes, the presence of at least one extracardiac cause was considered to contraindicate surgery in 55.3% of cases. The most frequent reasons stated were: old age (27.6%, as a sole reason in 1.3%), chronic obstructive pulmonary disease (13.6%), renal failure (6.1%), and short life expectancy (19.3%).

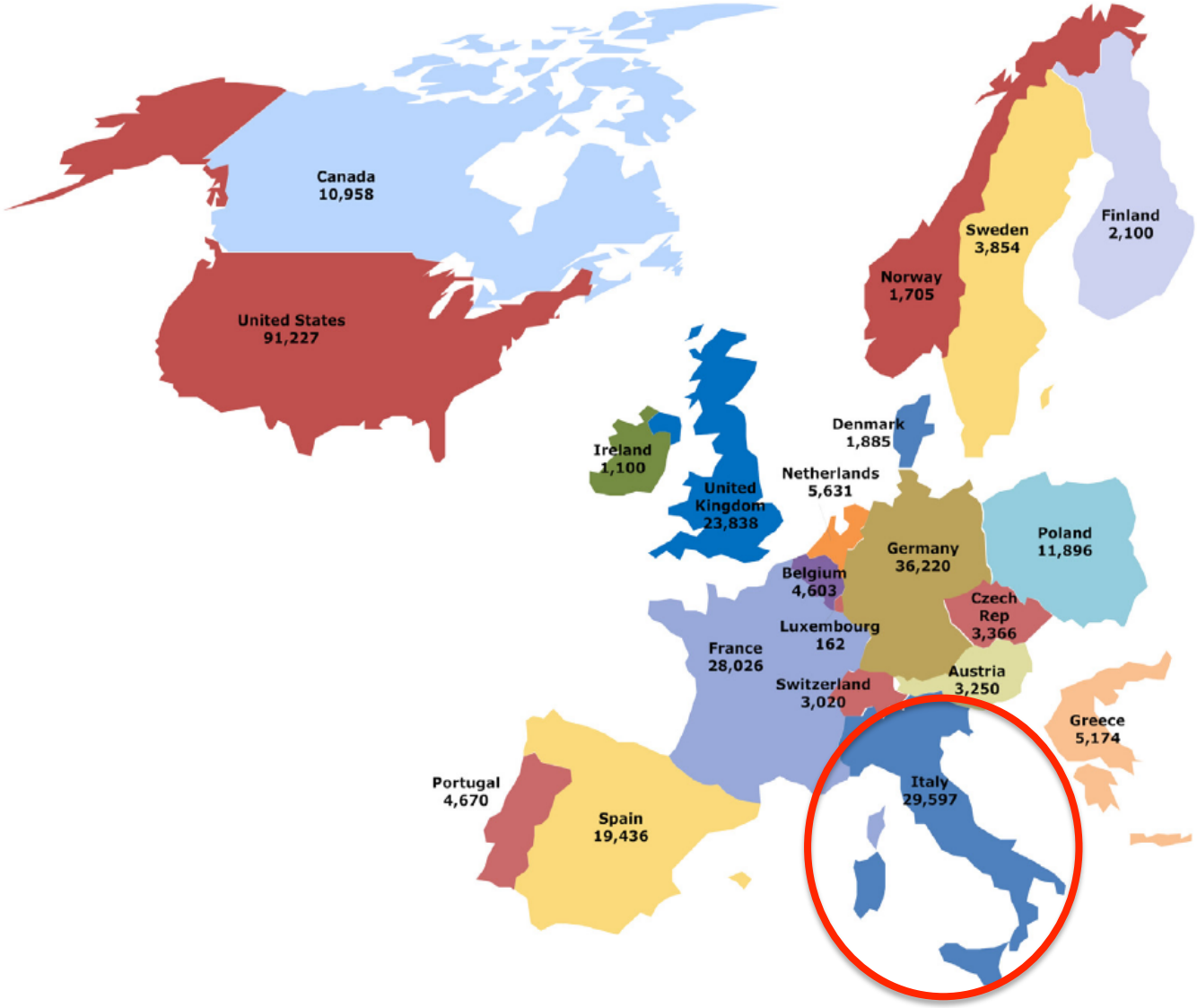
Numero di sostituzioni chirurgiche → 31,8% non trattabili → **Popolazione trattata con TAVI ≈ 80 pts/mln**

Si stà valutando un aumento a 100/mln per includere pazienti ad alto e medio rischio

Fonte: Haute Authoritè de Santè, France , 2012.; Iung et al. 2003

Pazienti candidati a TAVI nel mondo

Total number of TAVR candidates	
Country	**Candidates (95%CI)**
Austria	3,250 (1,389-5,947)
Belgium	4,603 (1,964-8,409)
Czech Republic	3,336 (1,433-6,160)
Denmark	1,885 (805-3,448)
Finland	2,100 (898-3,856)
France	28,026 (11,992-51,266)
Germany	36,220 (15,388-66,610)
Greece	5,174 (2,258-9,493)
Italy	29,597 (12,596-54,471)
Ireland	1,100 (467-2,003)
Luxembourg	162 (69-298)
Norway	1,705 (731-3,103)
Poland	11,896 (5,162-22,051)
Portugal	4,670 (1,990-8,538)
Spain	19,436 (8,265-35,713)
Sweden	3,854 (1,633-7,083)
Switzerland	3,020 (1,280-5,554)
The Netherlands	5,631 (2,379-10,379)
The United Kingdom	23,838 (10,554-43,461)
Total 19 European countries	**189,836 (80,281-347,372)***
The United States	91,227 (38,885-165,875)
Canada	10,958 (4,688-19,995)
Total North America	**102,558 (43,612-187,002)***



Source: *Osnabrugge et al. JACC 2013

Tasso di utilizzo di TAVI in Europa secondo il sistema di rimborso.

Veramente, hospital budgets…

Source: *Osnabrugge et al. JACC 2013

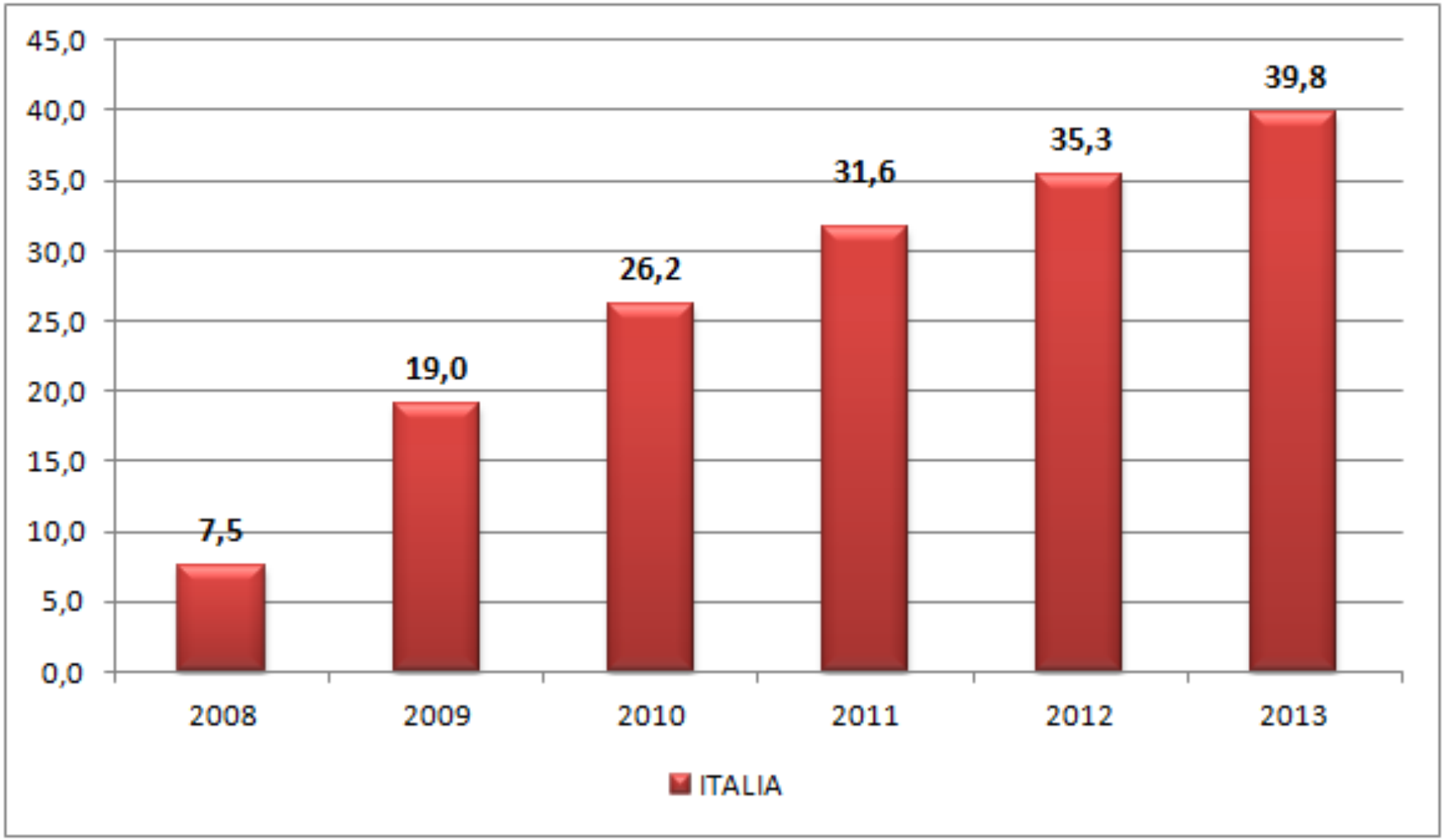
Sost. Valvolari Aortiche - Italia

REGIONE	RICOVERI PER PAZIENTI:			TOTALE RICOVERI
	RESIDENTI	FUORI REGIONE	ESTERO	
PIEMONTE	975	117	4	1.096
VALLE D'AOSTA	0	0	0	0
LOMBARDIA	1.733	616	24	2.373
P.A. BOLZANO	0	0	0	0
P.A TRENTO	98	12	1	111
VENETO	1.058	91	4	1.153
FRIULI VENEZIA GIULIA	223	8	0	231
LIGURIA	260	13	1	274
EMILIA ROMAGNA	953	321	14	1.288
TOSCANA	801	116	1	918
UMBRIA	135	16	1	152
MARCHE	242	12	0	254
LAZIO	947	118	8	1.073
ABRUZZO	205	27	0	232
MOLISE	34	38	1	73
CAMPANIA	784	27	0	811
PUGLIA	756	46	0	802
BASILICATA	59	8	0	67
CALABRIA	170	6	0	176
SICILIA	641	18	1	660
SARDEGNA	219	0	0	219
TOTALE	**10.293**	**1.610**	**60**	**11.963**

200 impianti/Mln

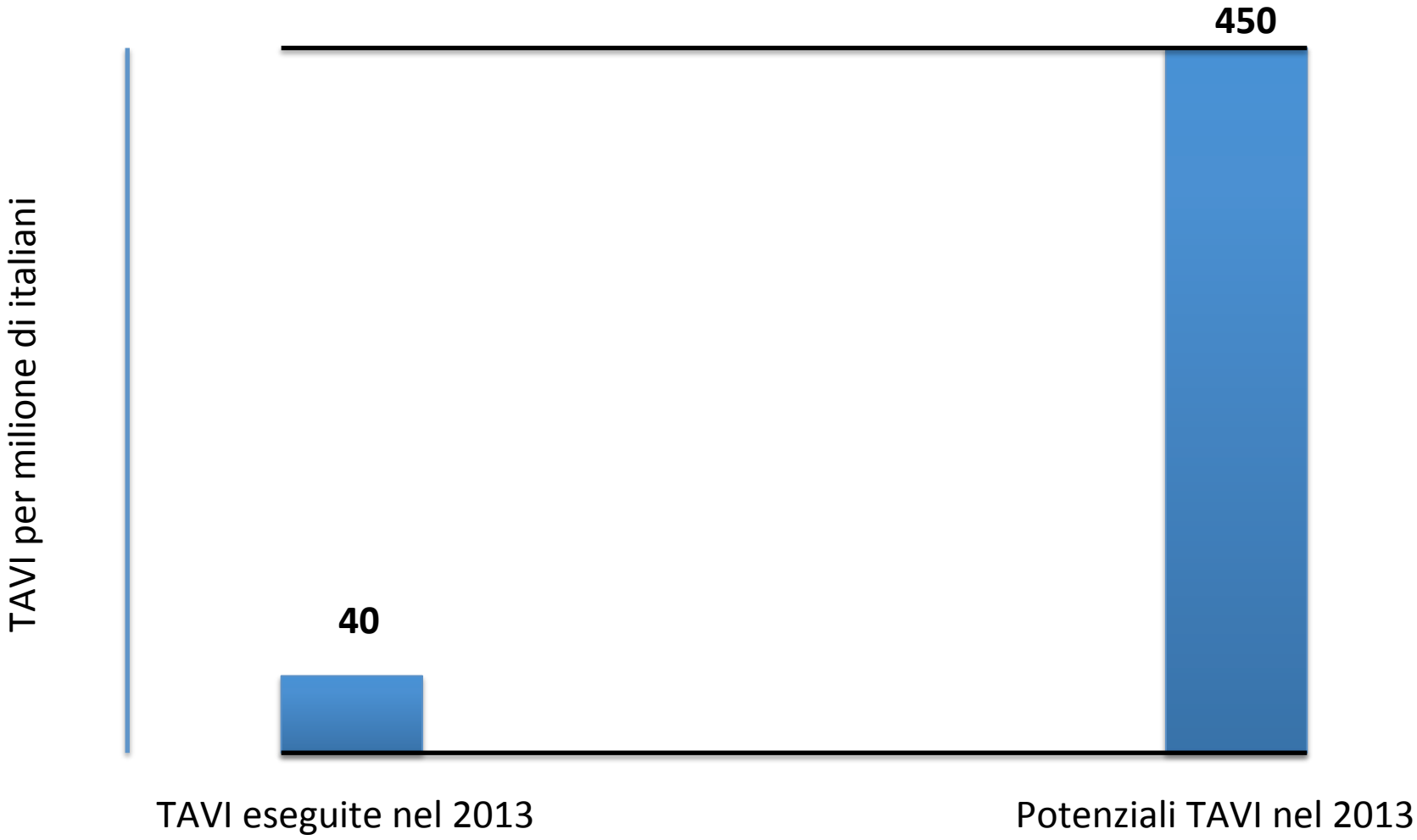
Fonte: Elaborazioni Centro Studi Assobiomedica su dati SDO 2009 del Ministero della Salute

Impianti TAVI per milione di abitanti Italia

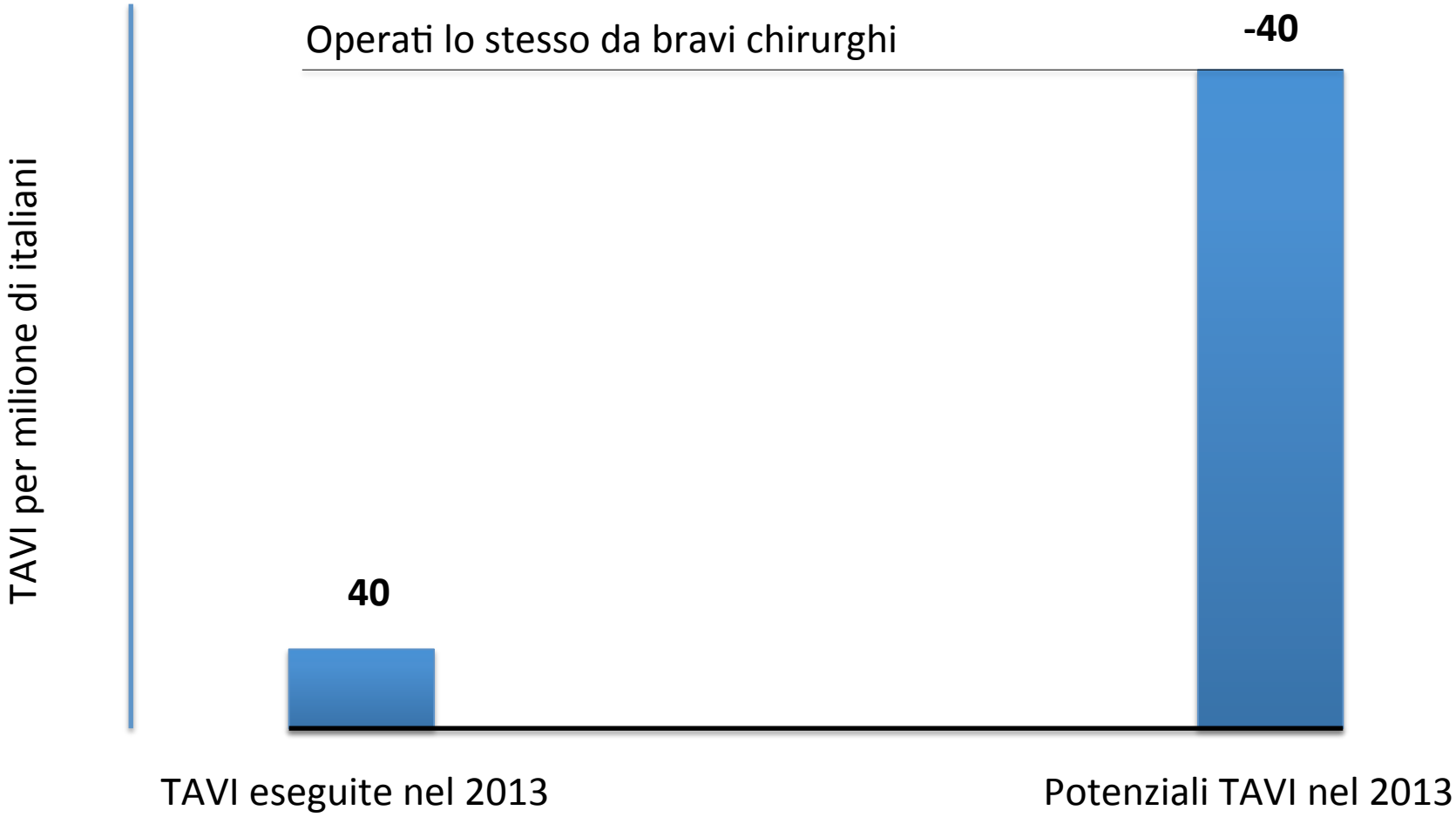


Fonte: adattato da Società Italiana di Cardiologia Invasiva - GISE

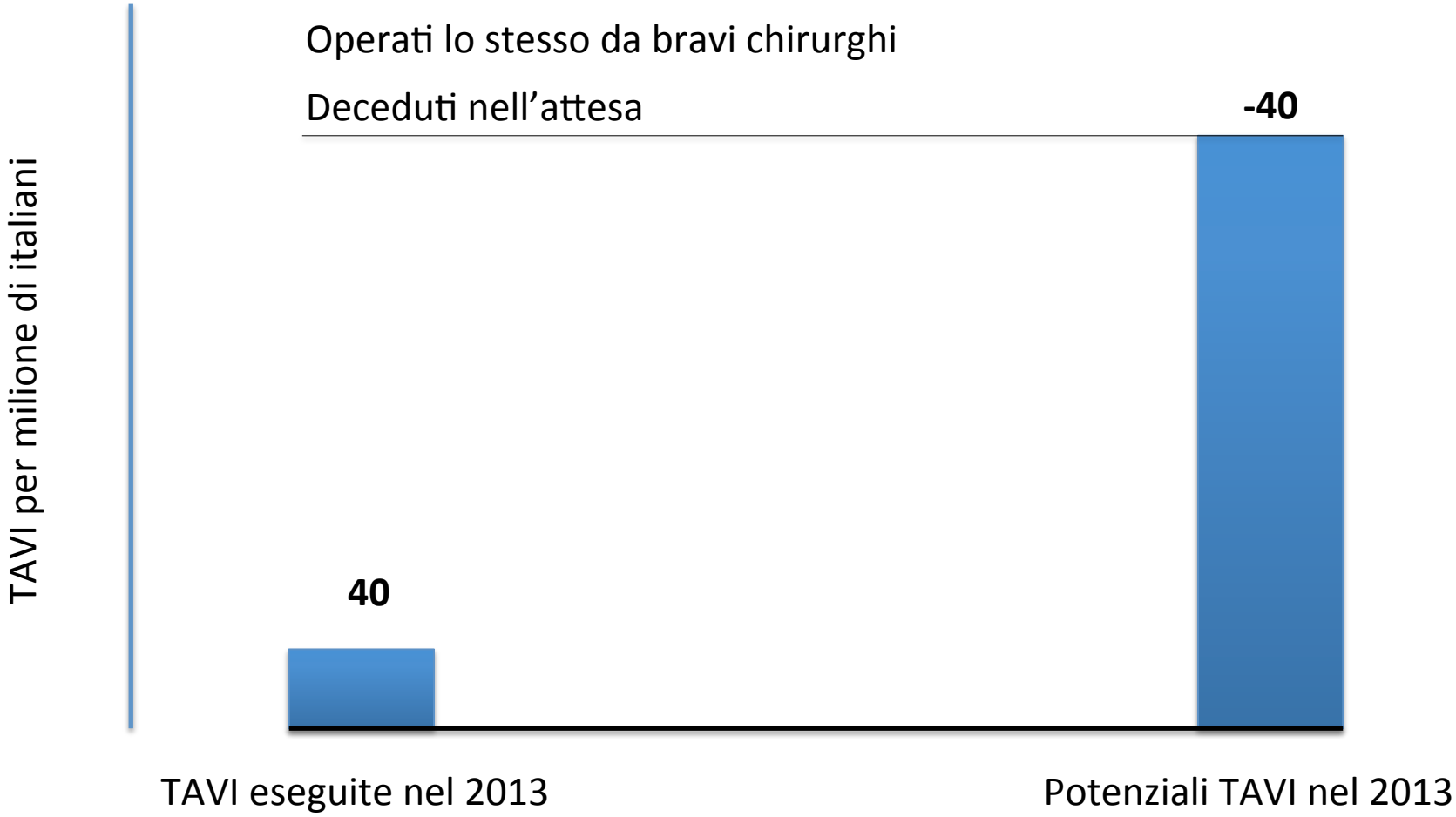
TAVI eseguite e candidati a TAVI per milione di abitanti in Italia



TAVI eseguite e candidati a TAVI per milione di abitanti in Italia



TAVI eseguite e candidati a TAVI per milione di abitanti in Italia

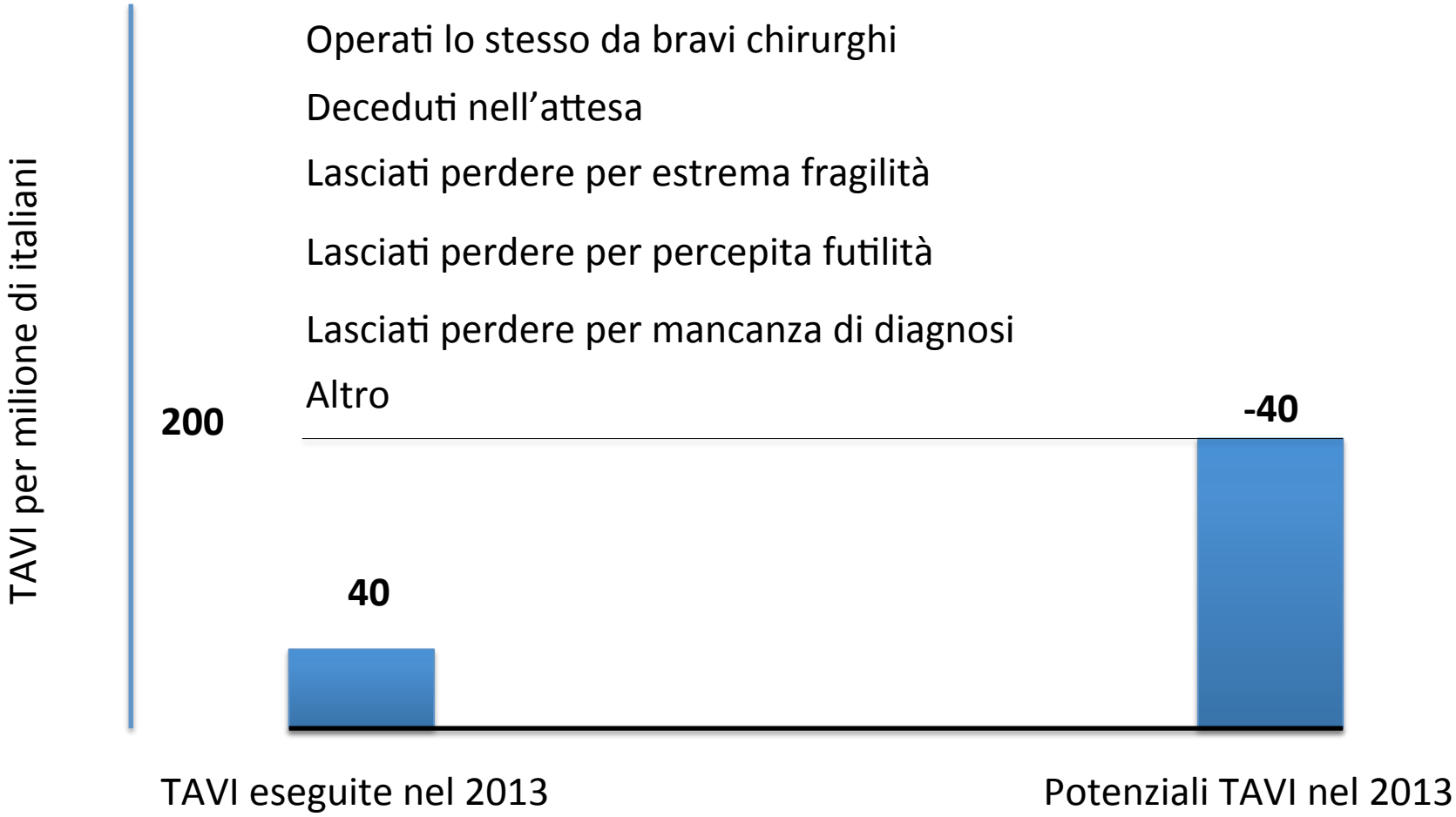


TAVI eseguite e candidati a TAVI per milione di abitanti in Italia

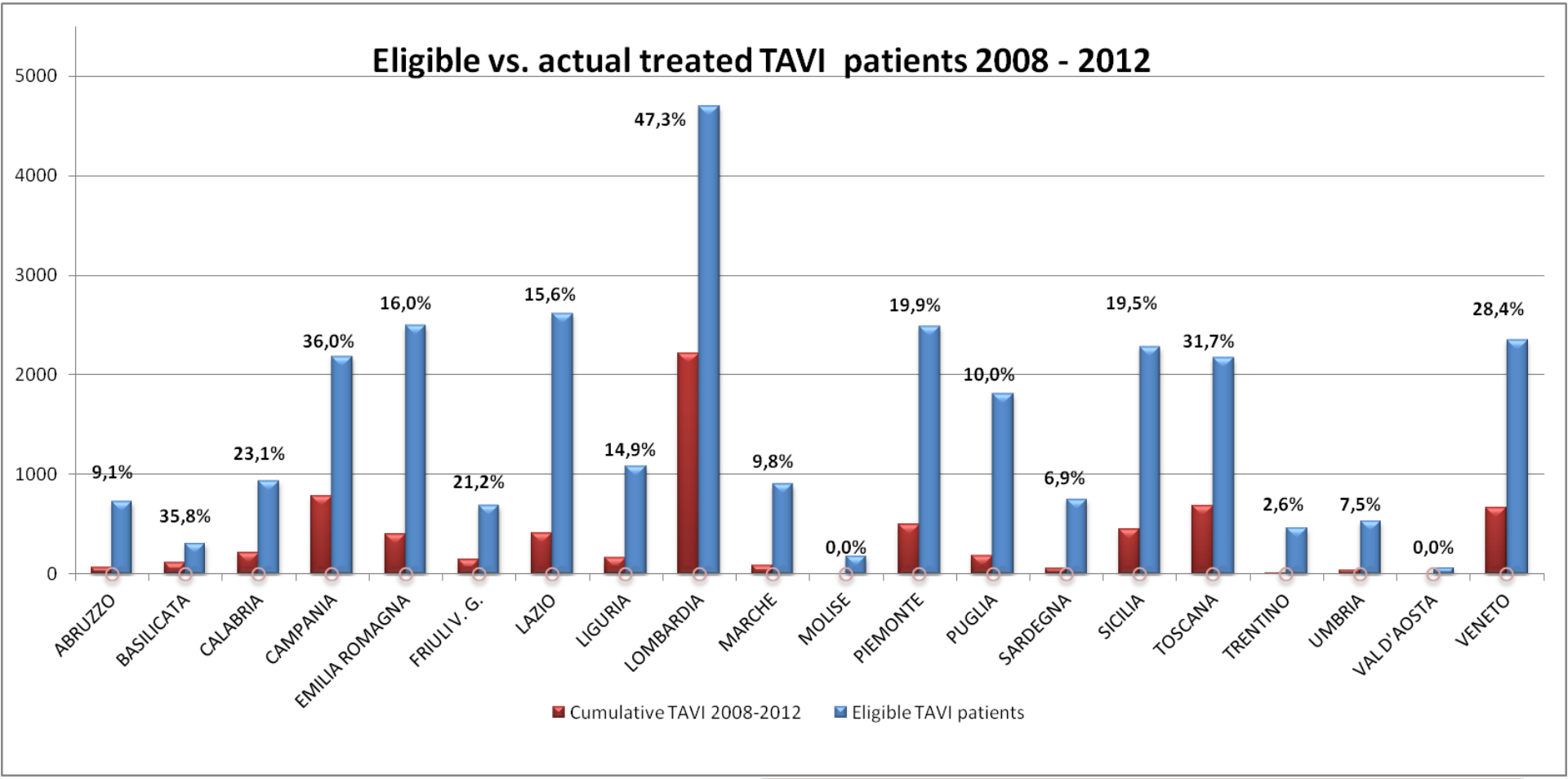
TAVI eseguite e candidati a TAVI per milione di abitanti in Italia

TAVI eseguite e candidati a TAVI per milione di abitanti in Italia

TAVI eseguite e candidati a TAVI per milione di abitanti in Italia



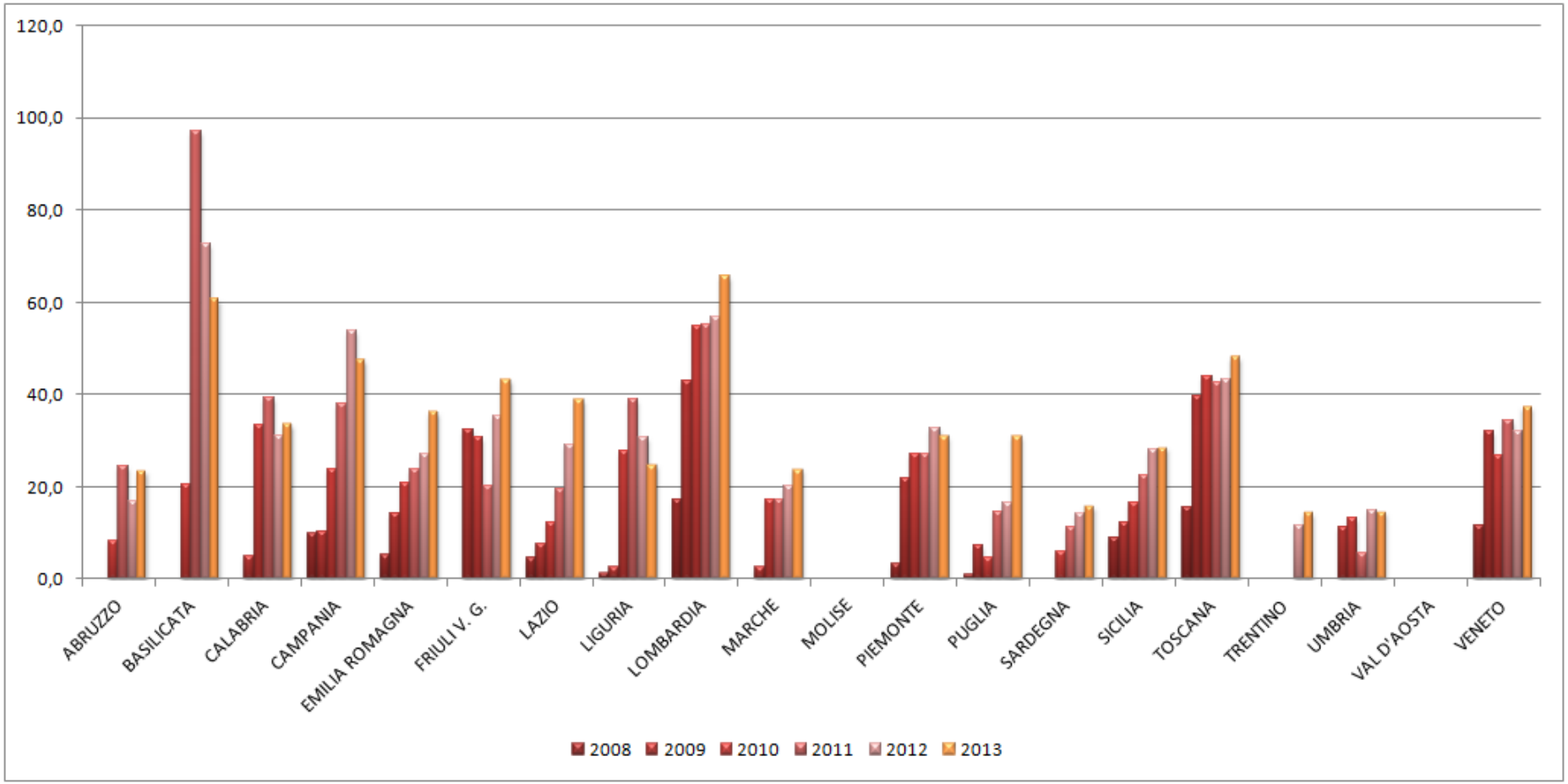
Copertura del bisogno epidemiologico TAVI a livello Regionale



24,1% of eligible Italian TAVI patients have been treated in the last 5 years.

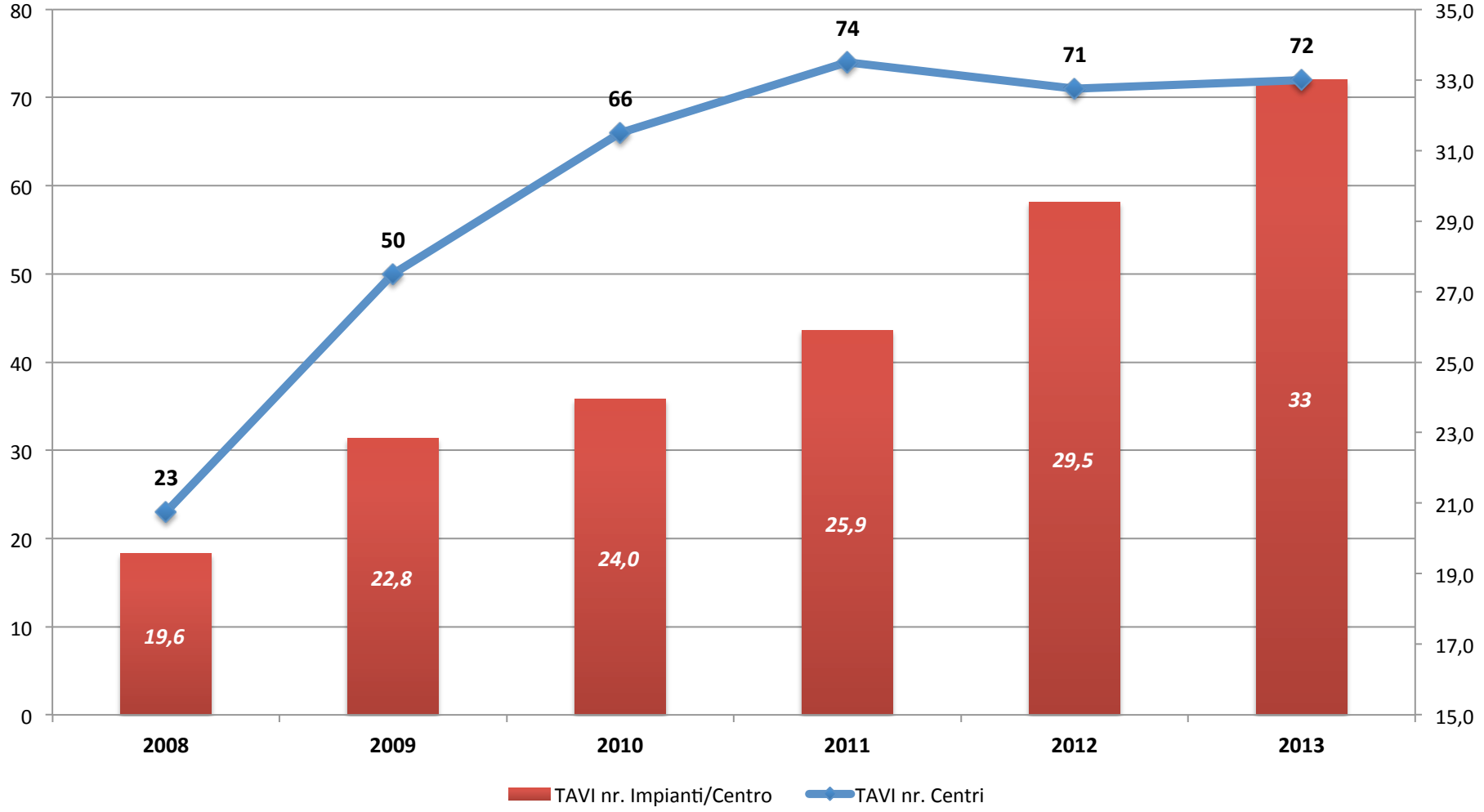
Source: GISE, ISTAT, Osnabrugge et al. JACC 2013

Impianti TAVI per milione di abitanti per Regioni



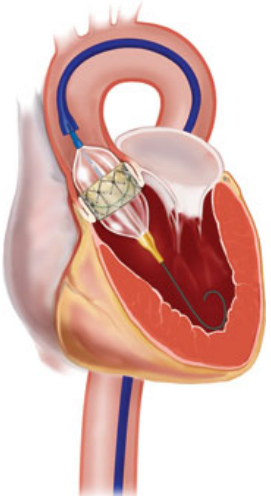
Fonte: adattato da Società Italiana di Cardiologia Invasiva - GISE

Evoluzione dei Centri TAVI in Italia



Fonte: adattato da Società Italiana di Cardiologia Invasiva - GISE

LA SVA SEVERA NEL ANZIANO: UTILITA vs FUTILITA



- Prevalence of Severe Aortic Stenosis > 75 yrs = 4.3%
  > 80 yrs = 4.9%

- Frailty status impacts prognosis in older adults with heart disease

- TAVR has become an alternative treatment option for patients with severe symptomatic aortic stenosis considered to be at high or prohibitive surgical risk

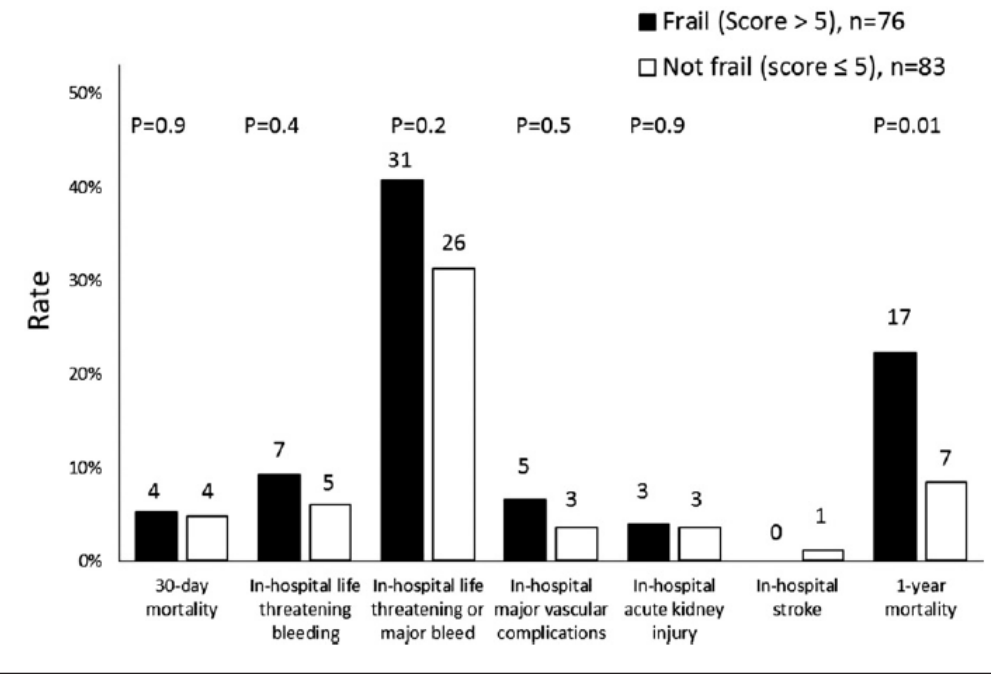
- Cardiac risk scores, however, do not take into account some important factors such as frailty, likely to be prevalent among elderly persons and high-risk profile patients undergoing TAVR

The Impact of Frailty Status on Survival After TAVR in elderly patients

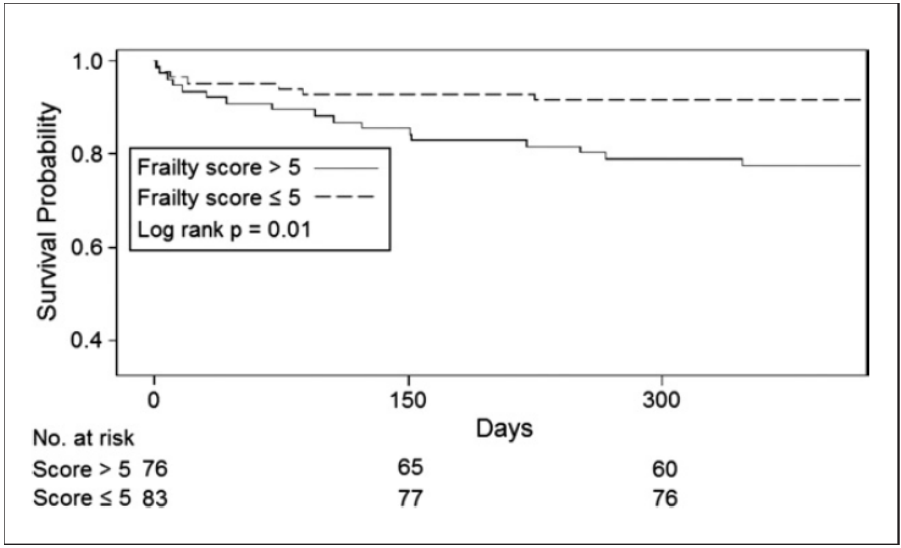
(patients from PARTNER)

FRAILTY SCORE →

Frailty Domain	Measure	Frailty Score
Slowness	15-ft walk gait speed (m/s)	Quartiles (0–3)
Weakness	Grip strength (kg)	Sex-based quartiles (0–3)
Wasting and malnutrition	Serum albumin (g/dl)	Quartiles (0–3)
Inactivity	Katz activities of daily living	Any dependence = 3, Independent = 0

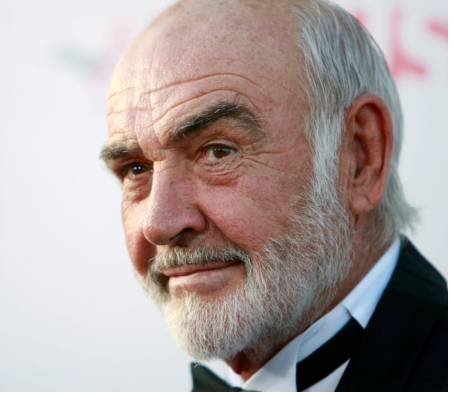


Procedural and 30-day outcomes.



Long-term survival

Green, JACC 2012



S.C 84 yo

P.R. 74 yo

In medicina non esiste una età anagrafica, ma una età biologica.

I vecchi di oggi sono stati giovani, e molti lo sono fino alla morte.

I giovani di oggi sono i vecchi di domani, e un buon medico deve aiutare i pazienti a rimanere giovani.

Dobbiamo prepararci a capire che avremmo pazienti anagraficamente sempre più anziani ma biologicamente più giovani.

La medicina endovascolare offre un enorme potenziale terapeutico per la "fragile" popolazione di età avanzata.

La TAVI NON è una procedura soprautilizzata. Anzi…

Sia da un punto di vista

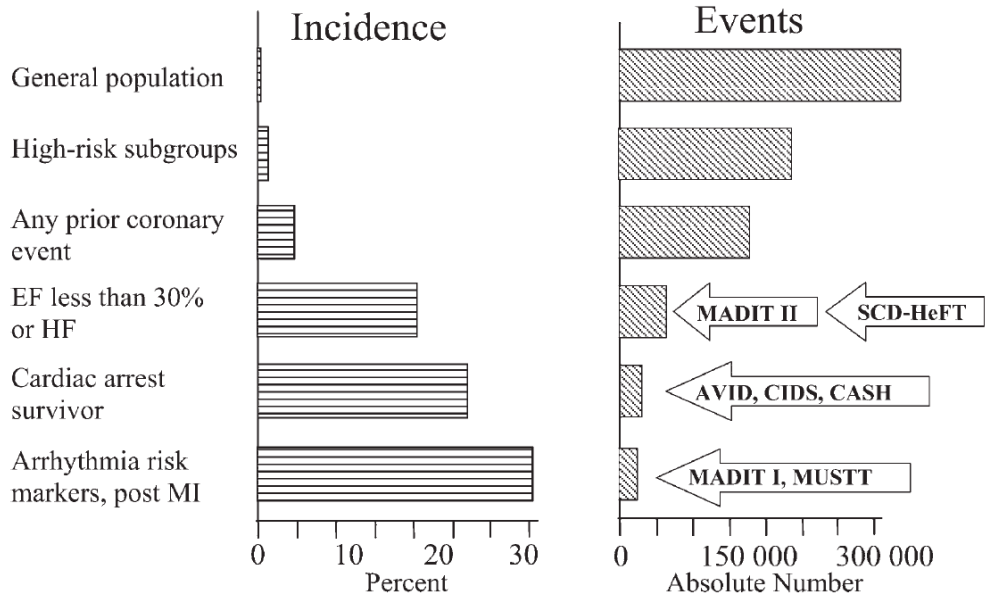
Economico

Epidemiologia della MCI in Italia

La morte cardiaca improvvisa in Italia. Dimensioni, percezioni, politiche ed impatto economico-finanziario

Mario Del Vecchio[1], Luigi Padeletti[2]

[1]*Professore Associato di Economia Aziendale, Facoltà di Medicina e Chirurgia, Università degli Studi, Firenze,*
[2]*Cattedra di Cardiologia, Istituto di Clinica Medica e Cardiologia, Università degli Studi, Firenze*



- Incidence of Sudden Cardiac Death (SCD) ranges from 55.000 to 60.000 cases/year
- 50% of cases may be predicted, due to high risk conditions

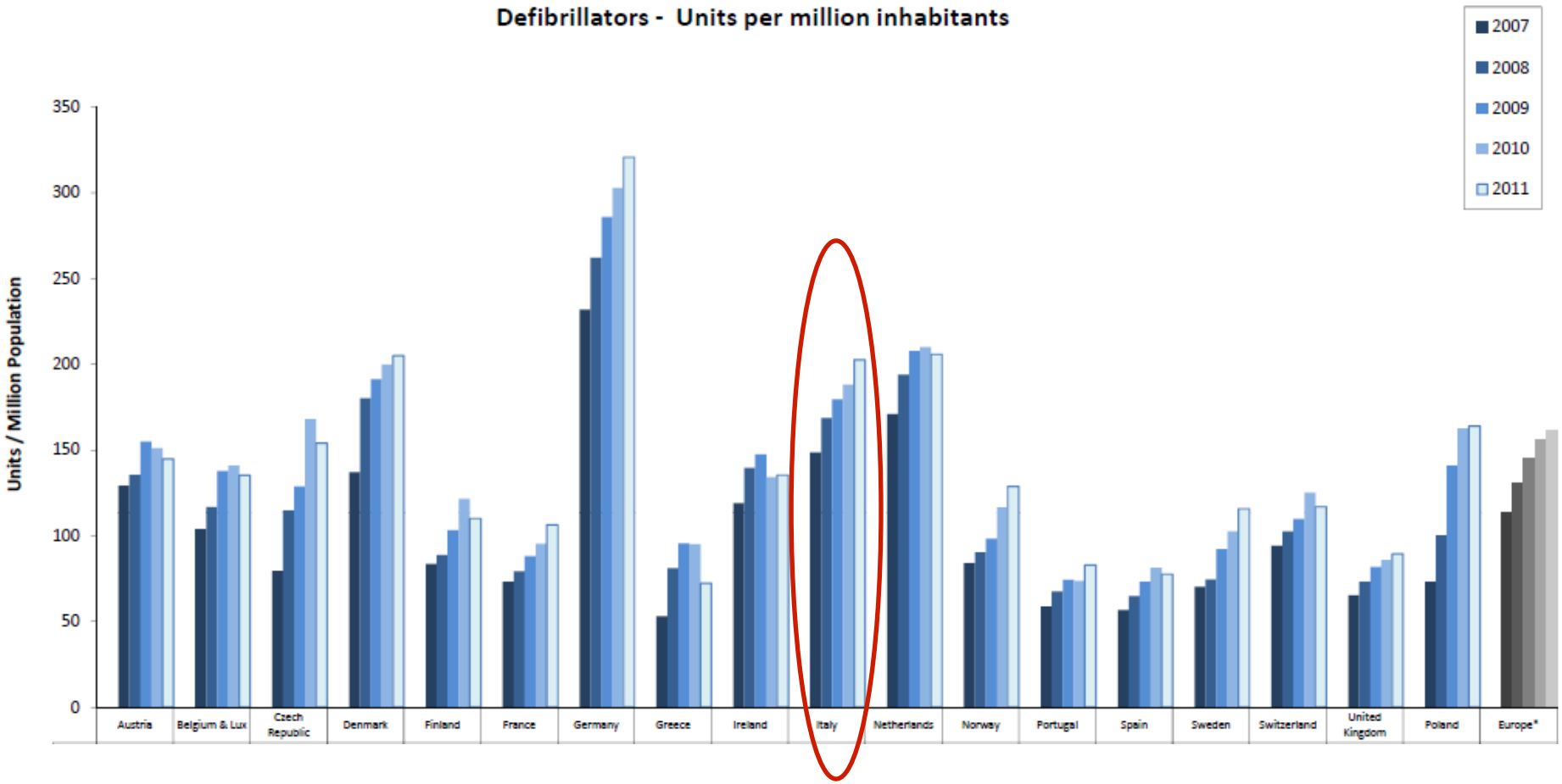
At least 27.500 patients may benefit from ICD every year

10 times more than TAVI…! (2679)

NNT for primary prevention: 18
NNT for secondary prevention: 13

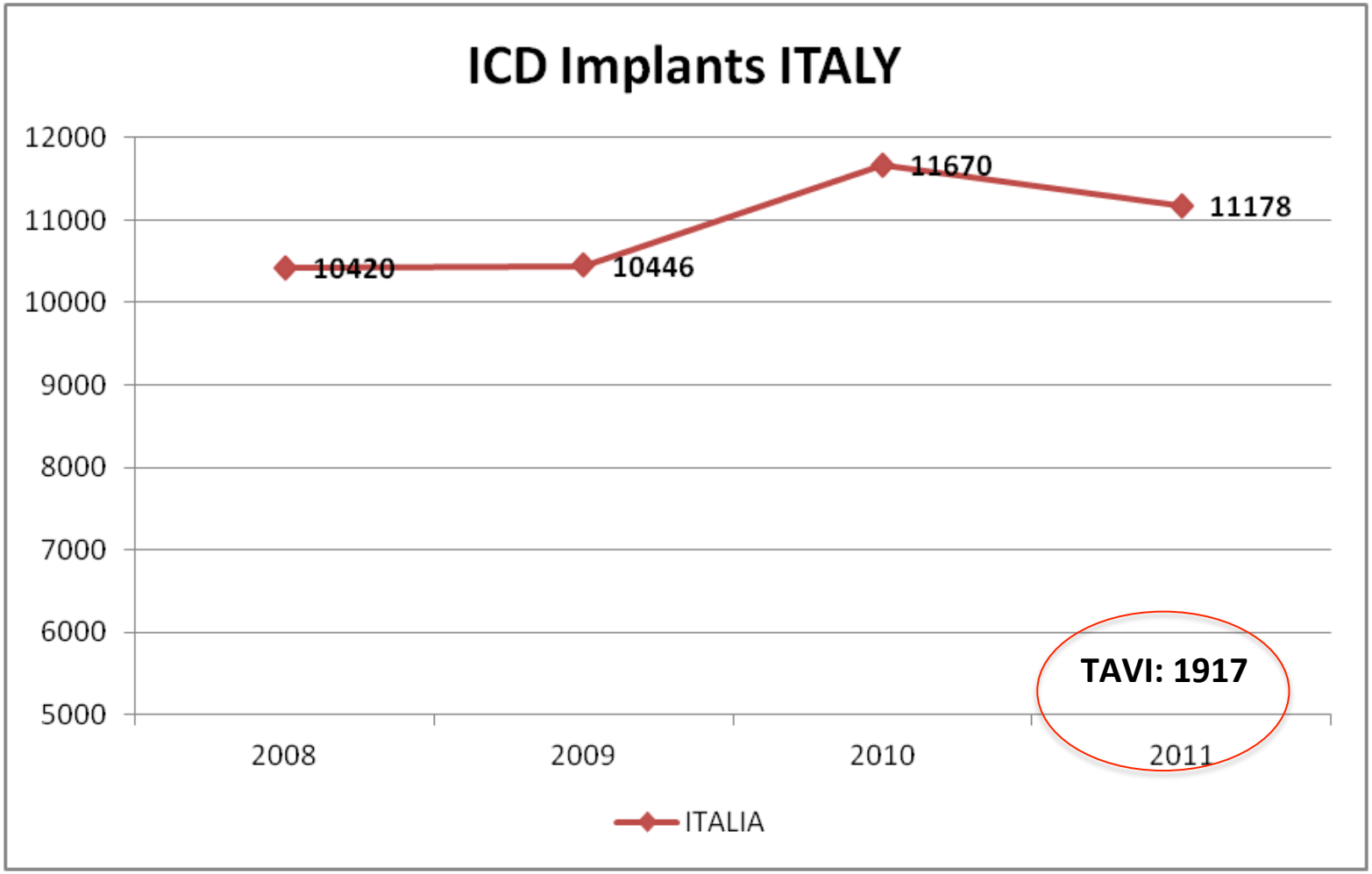
Source: Del Vecchio M, Padeletti L. G Ital Cardiol 2008, ACC/AHA/ESC Guidelines, 2006

Adozione del ICD in Europa



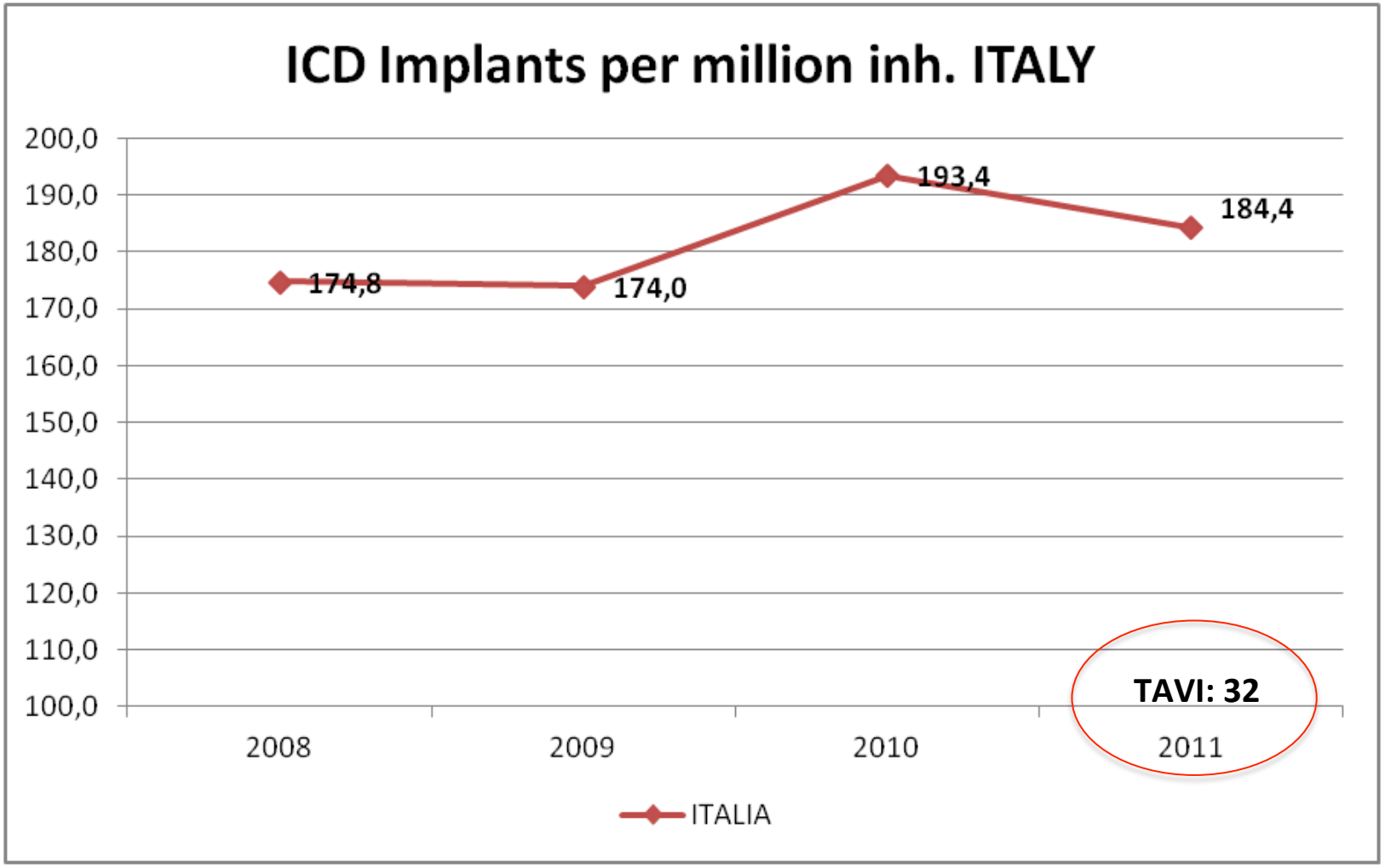
Source: Adapted from Camm A, Nisam S.Europace 2010

Totale di impianti ICD in Italia



Source: AIAC Database – only 1st Implants (no substitutions)

Impianti ICD x Mln. abitanti



Therapy appropriateness
Both TAVI and ICDs are in Class I

Table 11 Recommendations for the use of transcatheter aortic valve implantation

Recommendations	Class [a]	Level [b]	Ref [c]
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	99
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	97

Recommendations for the use of implanted cardioverter defibrillators in patients with heart failure

Recommendations	Class[a]	Level[b]	Ref[c]
Secondary prevention An ICD is recommended in a patient with a ventricular arrhythmia causing haemodynamic instability, who is expected to survive for >1 year with good functional status, to reduce the risk of sudden death.	I	A	144–147
Primary prevention An ICD is recommended in a patient with symptomatic HF (NYHA class II–III) and an EF ≤35% despite ≥3 months of treatment with optimal pharmacological therapy, who is expected to survive for >1 year with good functional status, to reduce the risk of sudden death			
(i) Ischaemic aetiology and >40 days after acute myocardial infarction	I	A	148, 149
(ii) Non-ischaemic aetiology	I	B	149

Source: ESC. Vahanian et al. 2012; Mc Murray et al. 2012

EuroIntervention The Official Journal of EuroPCR and the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

résumè online abstract submission

EuroIntervention 2013;9:175-177

Numbers needed to treat (lives!) and numbers needed to save (money)

Flavio Ribichini[1]*, MD; David Taggart[2], MD; Corrado Vassanelli[1], MD

	TAVI	ICD	Source
- NNT	5	13	Leon et al. 2010, AVID study 1997
- procedures/year	2.097	11.178	GISE 2012, AIAC 2011
- Hospital Perspect. - device cost	€ 20.800,00	€ 13.168,26	Reg. Lombardia - DDG 11264/2012
- H. System Perspect. - Avg. Reimbursed	€ 24.401,00	€ 16.573,00	TAVI avg. Reimbursement in 2012; DRG 515
- Impact on Italy Medical Device Budget	0,84%	2,84%	Medical Device Budget = 4,8% of Nat. Health Fund
- Hospital Cost per life saved	€ 104.000,00	€ 171.187,38	=NNT x Hosp. Cost
- Health System Cost per life saved	€ 122.005,00	€ 215.449,00	=NNT x Sys. Cost

While costs per patients are comparable between the two technologies, Hospital and Health System costs per life saved are favorable to TAVI option.

La TAVI NON è una procedura soprautilizzata. Anzi…

Sia da un punto di vista

Tecnico-prognostico

Five-Year Outcomes after Randomization to Transcatheter or Surgical Aortic Valve Replacement: Final Results of The PARTNER 1 Trial

Michael J. Mack, MD
on behalf of The PARTNER Trial Investigators

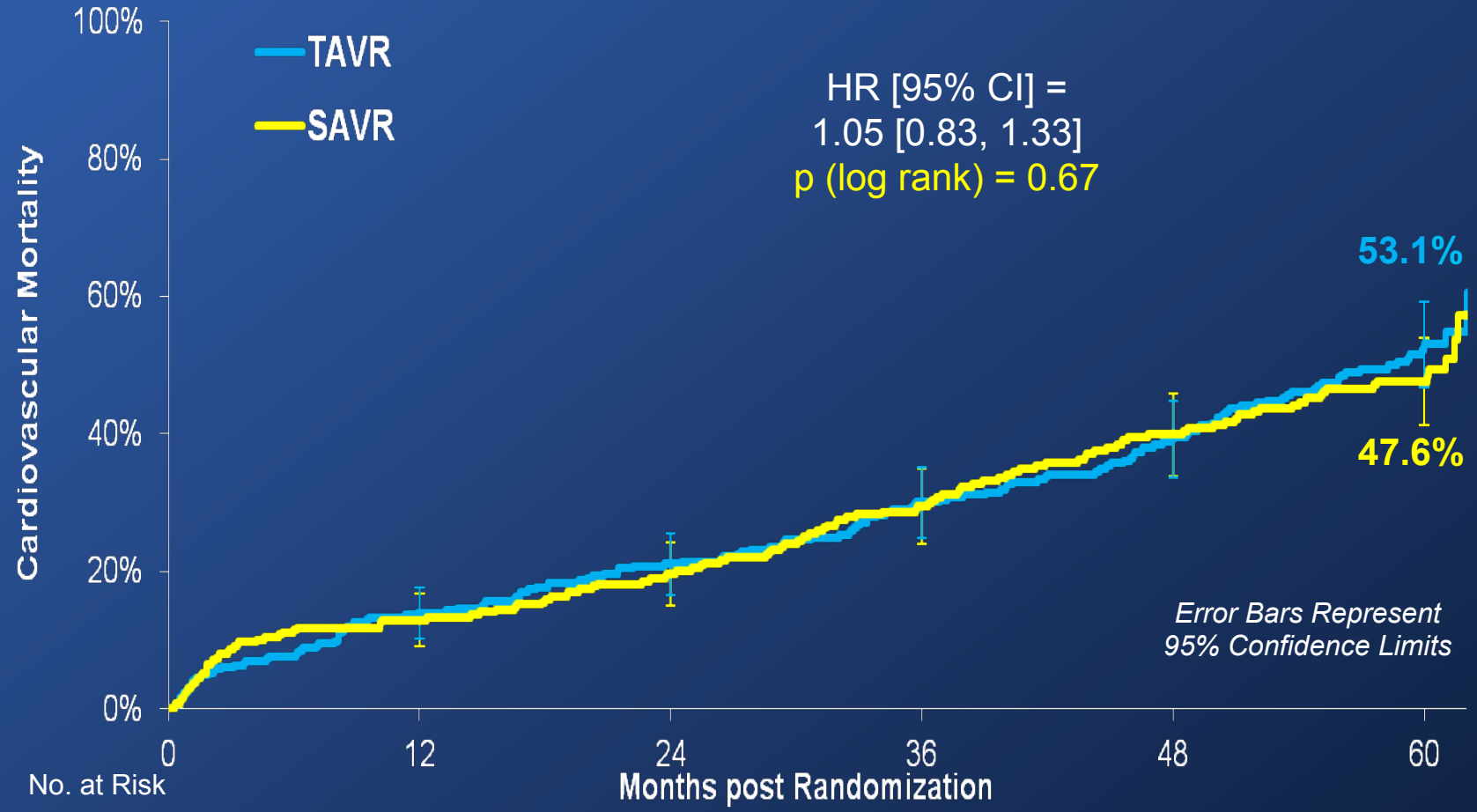
ACC 2015 | San Diego | March 15, 2015

THE PARTNER TRIAL

Cardiovascular Mortality (ITT)

All Patients

THE PARTNER TRIAL

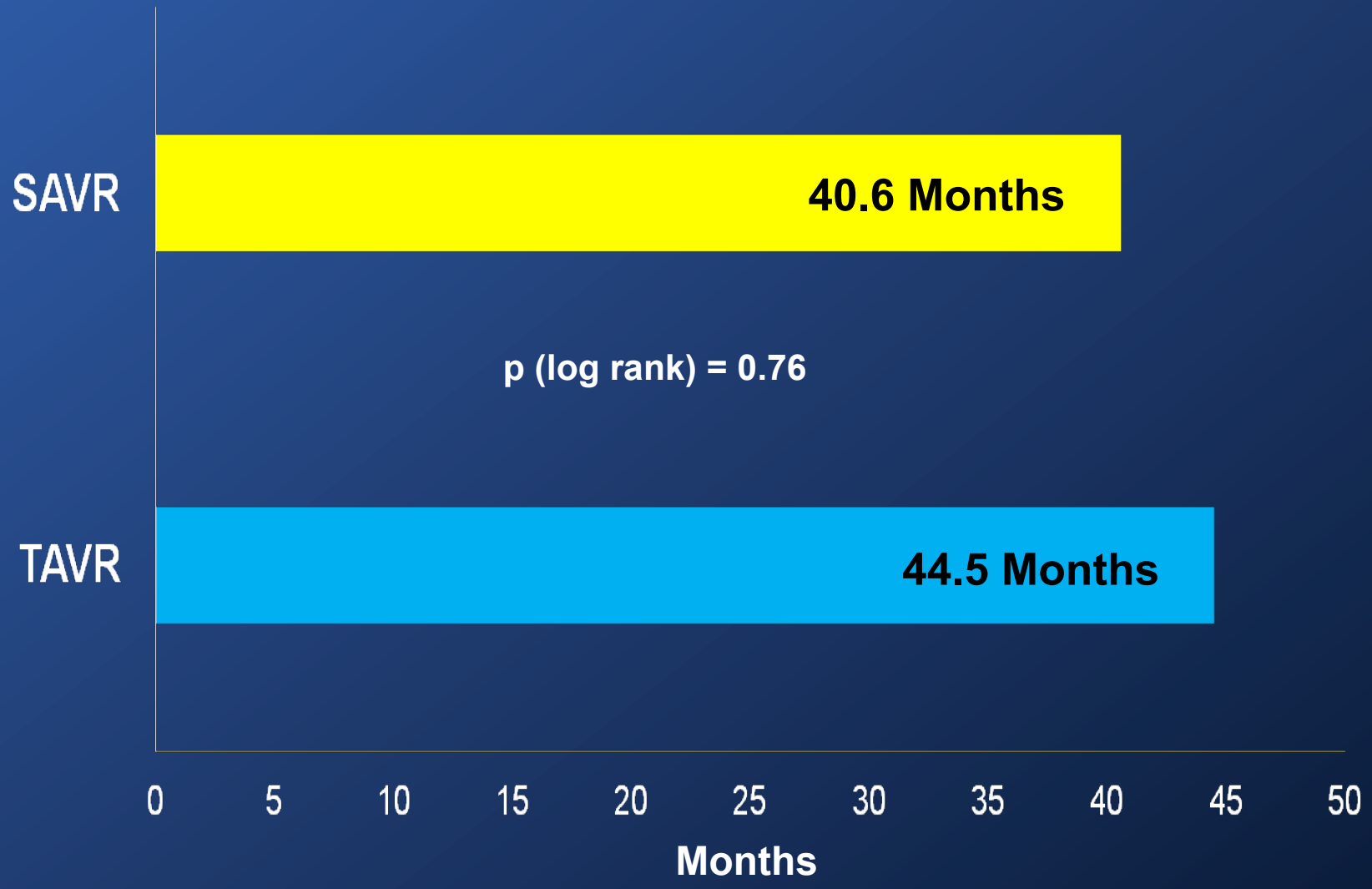


No. at Risk

TAVR	348	262	228	191	154	61
SAVR	351	236	210	174	131	64

Median Survival

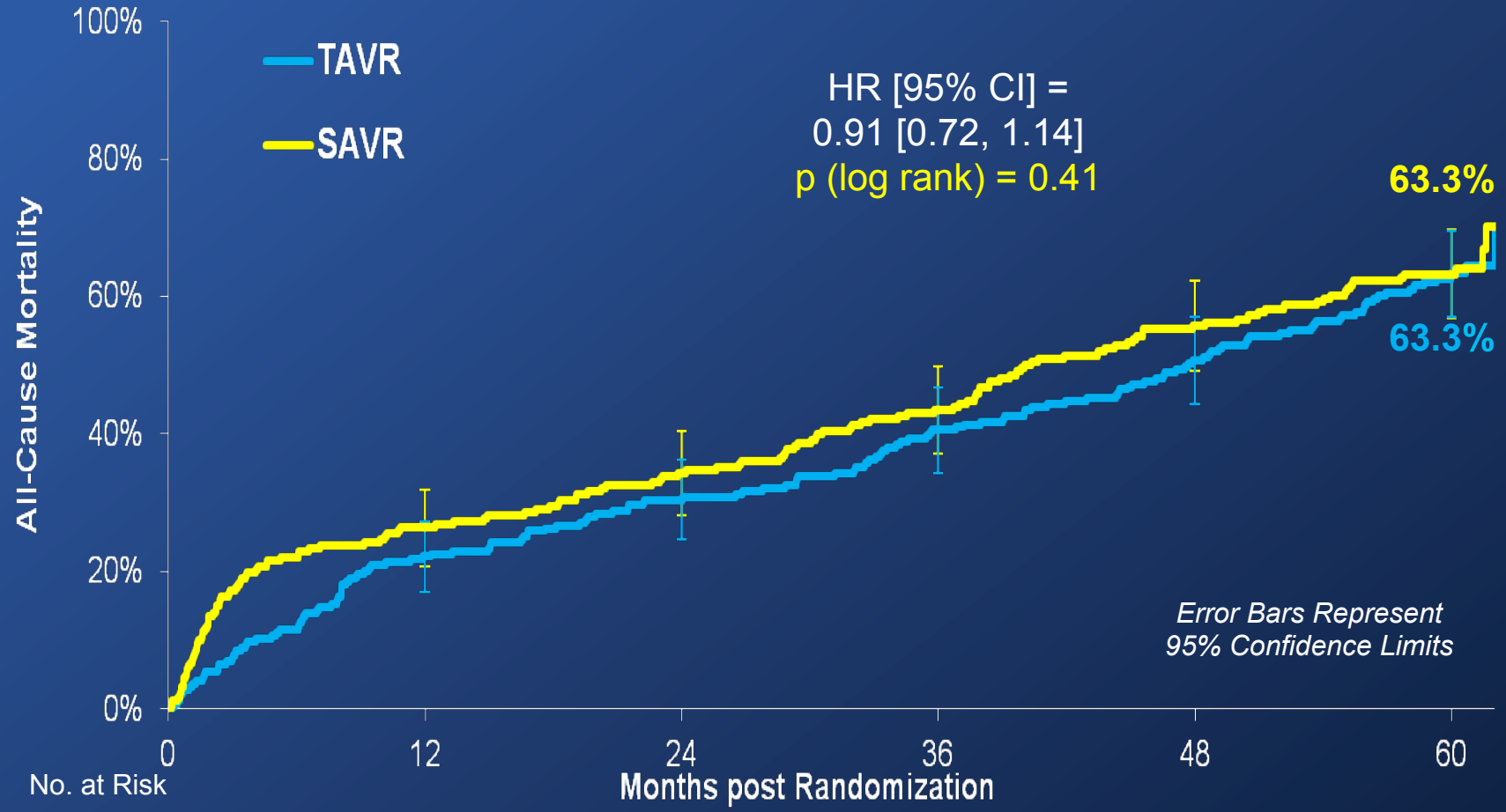
All Patients



All-Cause Mortality (ITT)

Transfemoral Patients

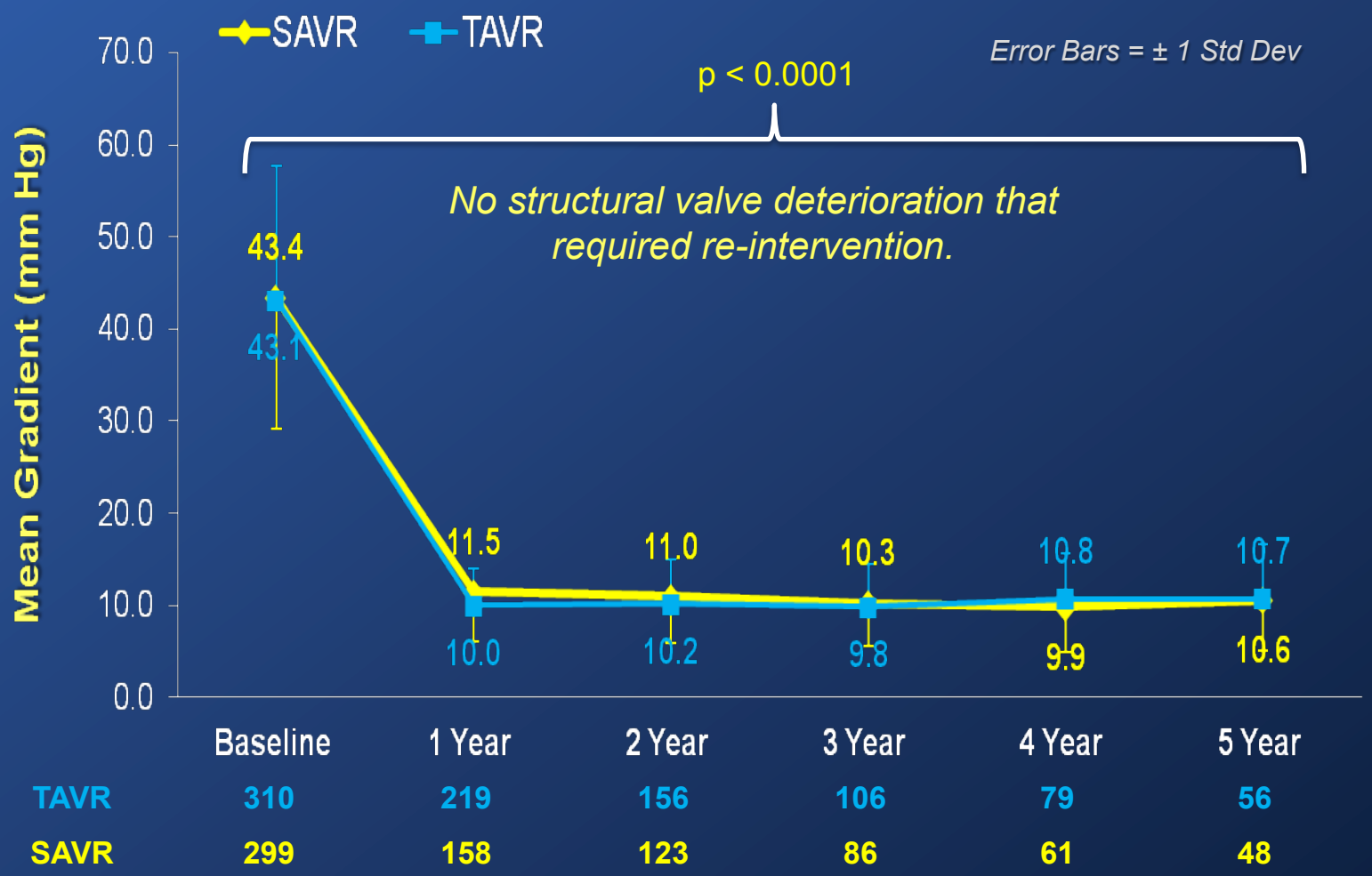
THE PARTNER TRIAL



No. at Risk

TAVR	244	189	167	141	115	50
SAVR	248	168	150	125	93	46

Aortic Valve Mean Gradient



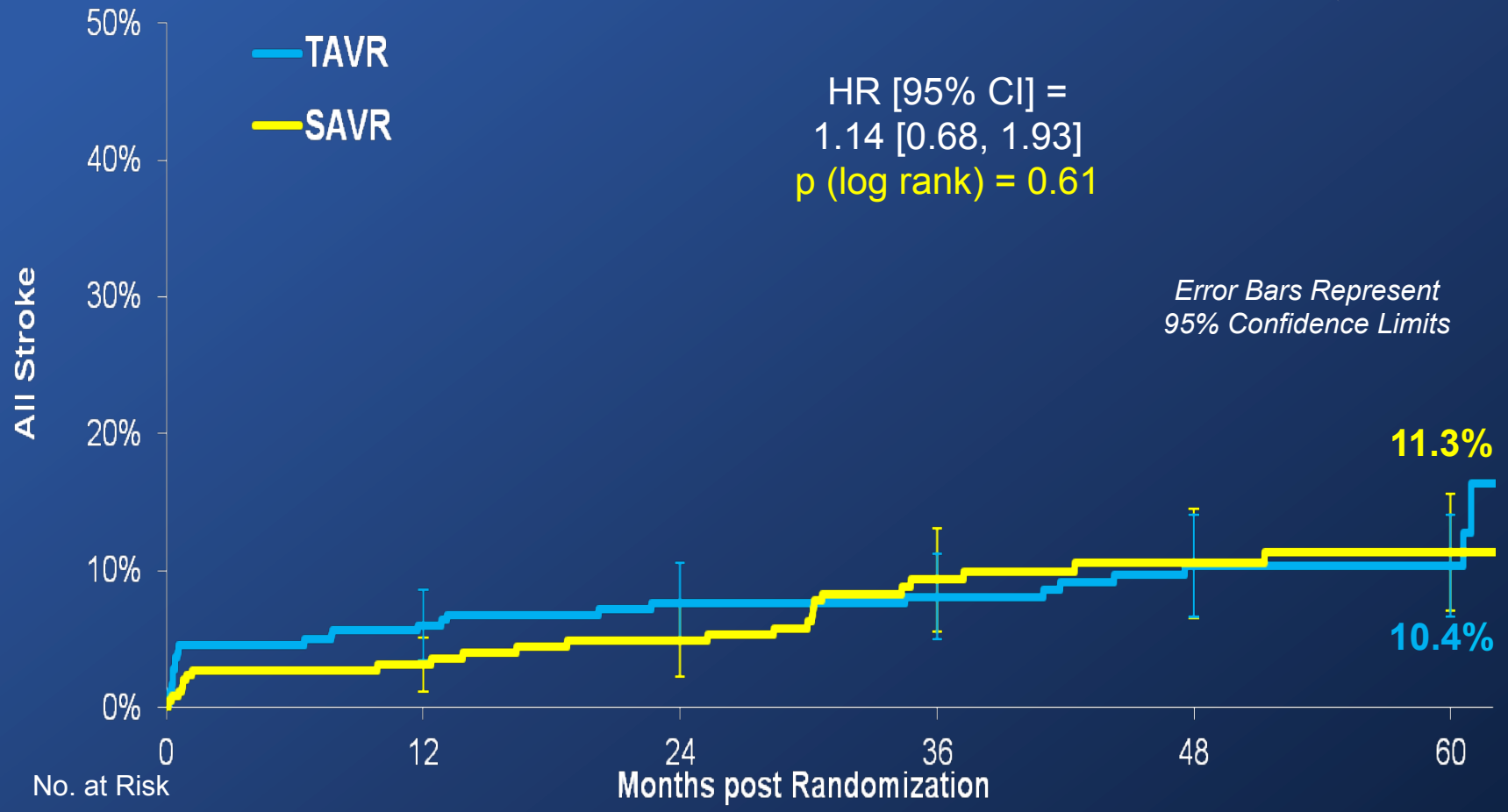
Aortic Valve Area

	Baseline	1 Year	2 Year	3 Year	4 Year	5 Year
TAVR	304	211	151	106	79	53
SAVR	294	154	121	84	60	46

LV Mass Index

All Stroke (ITT)
All Patients

THE PARTNER TRIAL



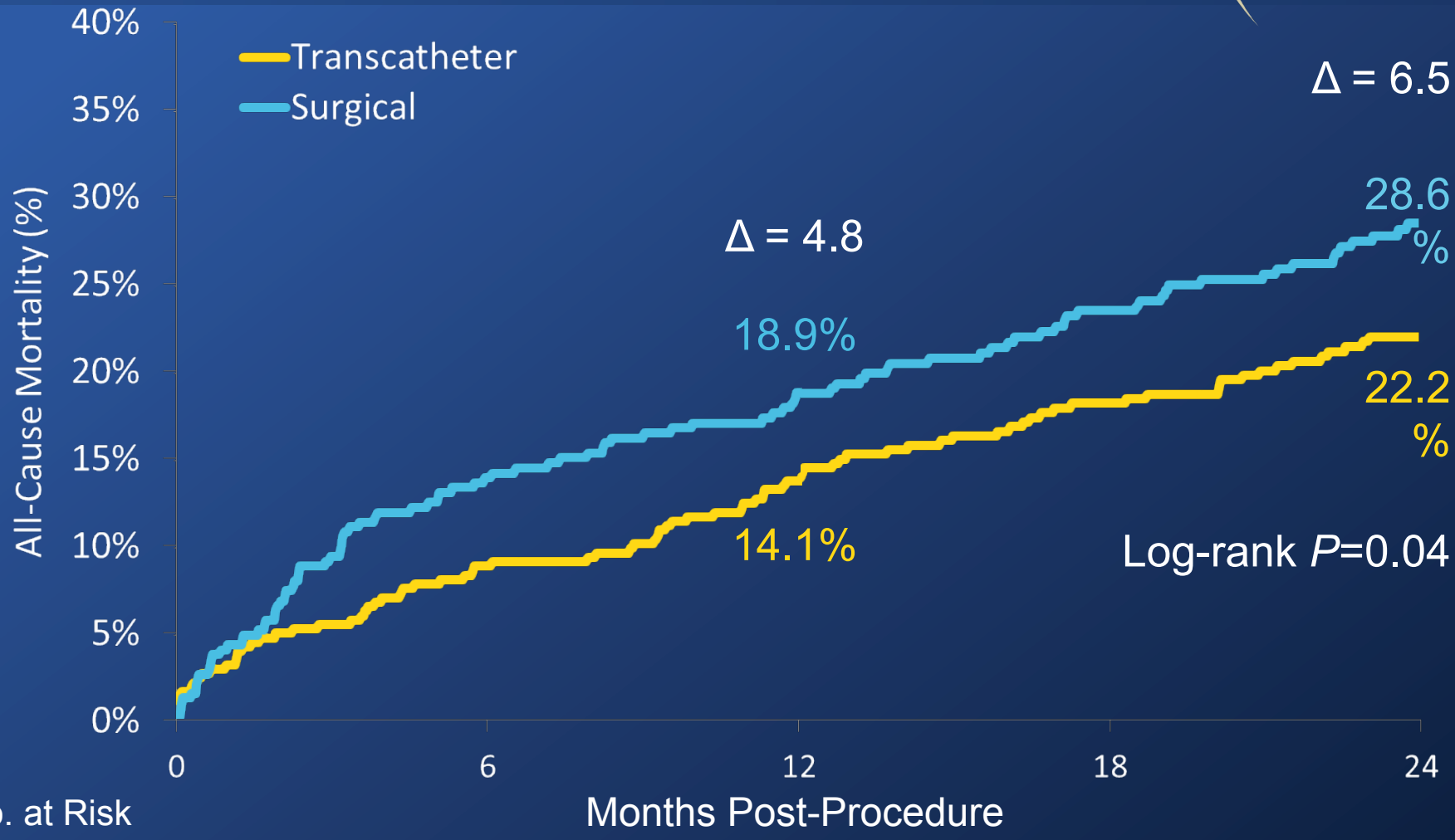
No. at Risk

TAVR	348	251	217	181	144	57
SAVR	351	230	205	169	128	64

CoreValve US Pivotal Trial
High Risk 2-Year Results

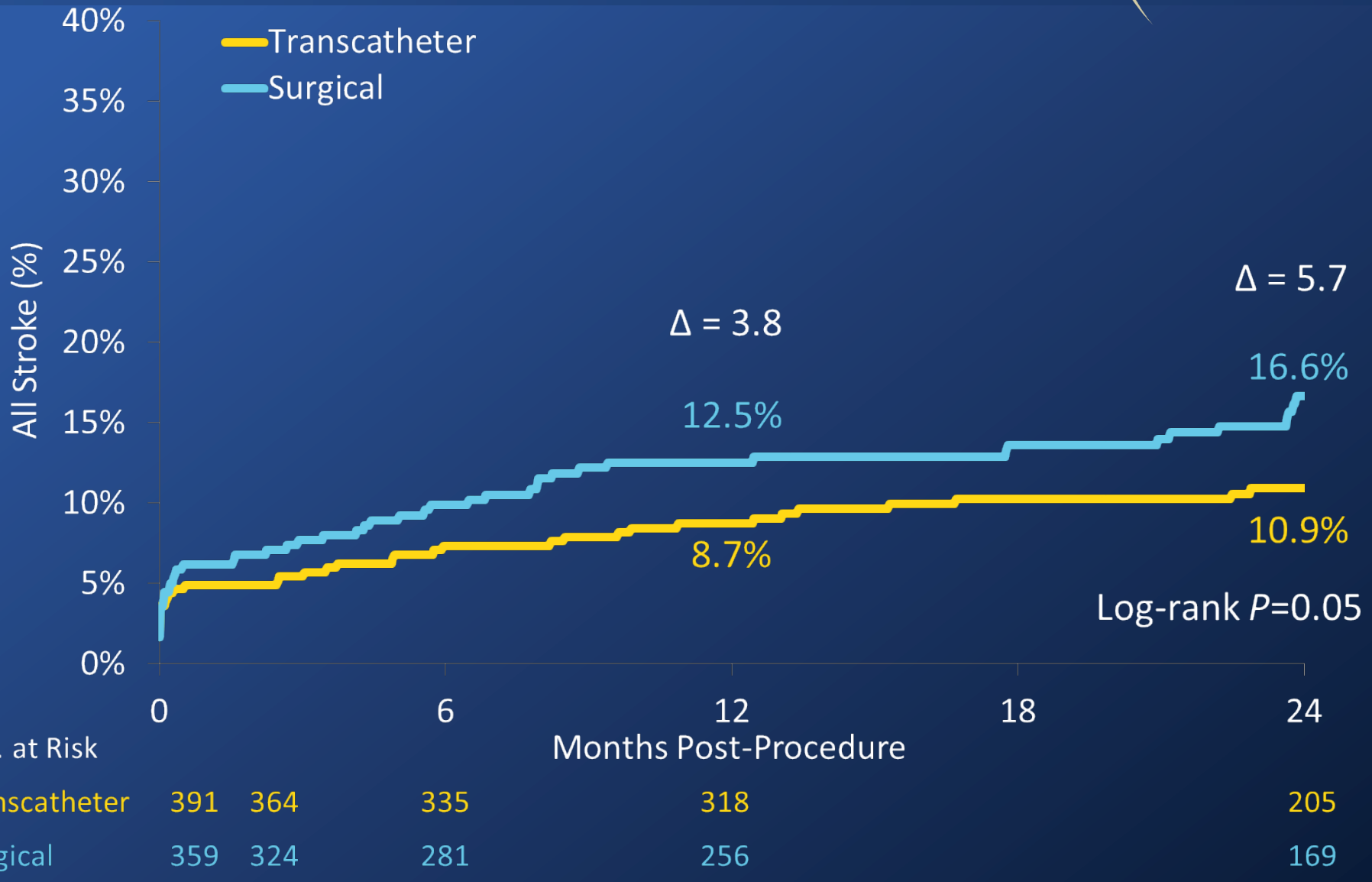
A Randomized Comparison of Self-expanding Transcatheter and Surgical Aortic Valve Replacement in Patients with Severe Aortic Stenosis Deemed at Increased Risk for Surgery 2-Year Outcomes

All-Cause Mortality



No. at Risk					
Transcatheter	391	378	354	334	219
Surgical	351	343	304	282	191

All Stroke


Transcatheter
Surgical
All Stroke (%)
40%
35%
30%
25%
20%
15%
10%
5%
0%
Δ = 3.8
Δ = 5.7
16.6%
12.5%
10.9%
8.7%
Log-rank P=0.05
0
6
12
18
24
Months Post-Procedure
No. at Risk
Transcatheter 391 364 335 318 205
Surgical 359 324 281 256 169

Echocardiographic Findings

THE PARTNER TRIAL

TAVR had significantly better valve performance over SAVR at all follow-up visits

(*P*<0.001)

Cosa succederà nel prossimo futuro?

1: La ridotta invasività della TAVI
2: l buoni risultati a 5 anni delle prime valvole Edwards
3: I migliori risultati della TAVI rispetto alla AVR in pazienti ad alto rischio (CoreValve)
4: La possibilità di trattare pazienti a rischio intermedio (studi in corso con valvole Edwards e CoreValve)

Un forte ridimensionamento della chirurgia della SVA con un aumento delle TAVI.

Case Presentation

A 87y old woman was referred to the Division of Cardiovascular Surgery because of a known diagnosis of severe aortic valve stenosis (AVS) and a rapid progression of symptoms. The patient had a 2-year history of effort angina, (CCS II) with recent worsening into class III and onset of effort dispnea (NYHA II) in the last 3 months. One week before admission she also had an episode of syncope during a housekeeping activity.

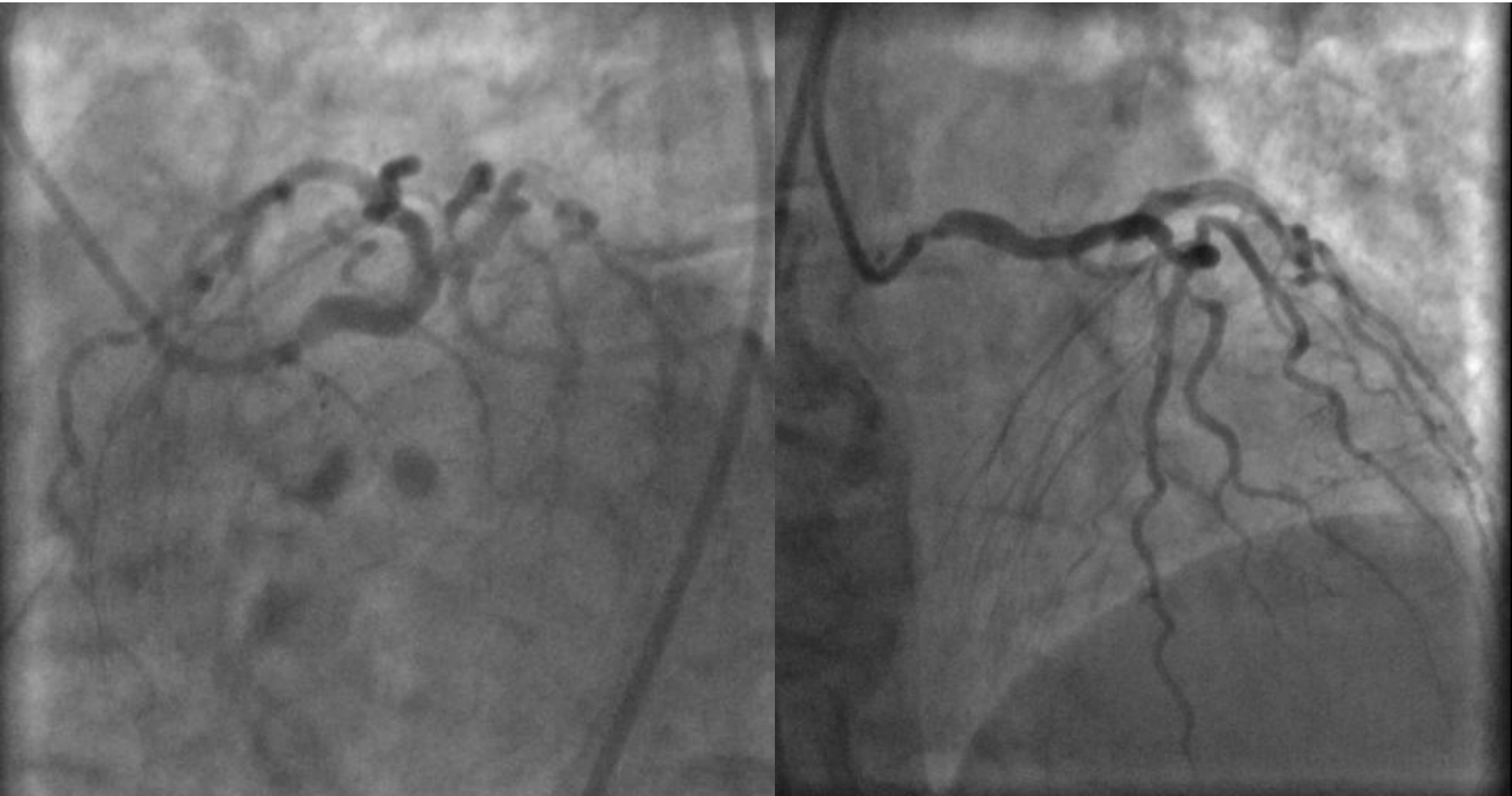
The patient had antecedents of hypertension, mild dyslipidemia, mild to moderate chronic renal failure (SC Cl ranging from 45 to 55ml/h/ 1.73m2) and a previous TIA.

ECG had signs of LV hypertrophy.

Echocardiography revealed a well preserved LV function (EF 52%) and a severe AVS with a peak gradient of 114mmHg and 0.38cm2/m2 valve area.

She was referred to the Division of Cardiology for cardiac catheterization and coronary angiography

Coronary angiography revealed a severe ostial stenosis of the LM and non significant atherosclerotic disease of the RCA.
Moderate pulmonary hypertension (PAP= 38mmHg).



Right ICA: 80% stenosis
Left ICA: 70% stenosis

After discussion with the Heart Team

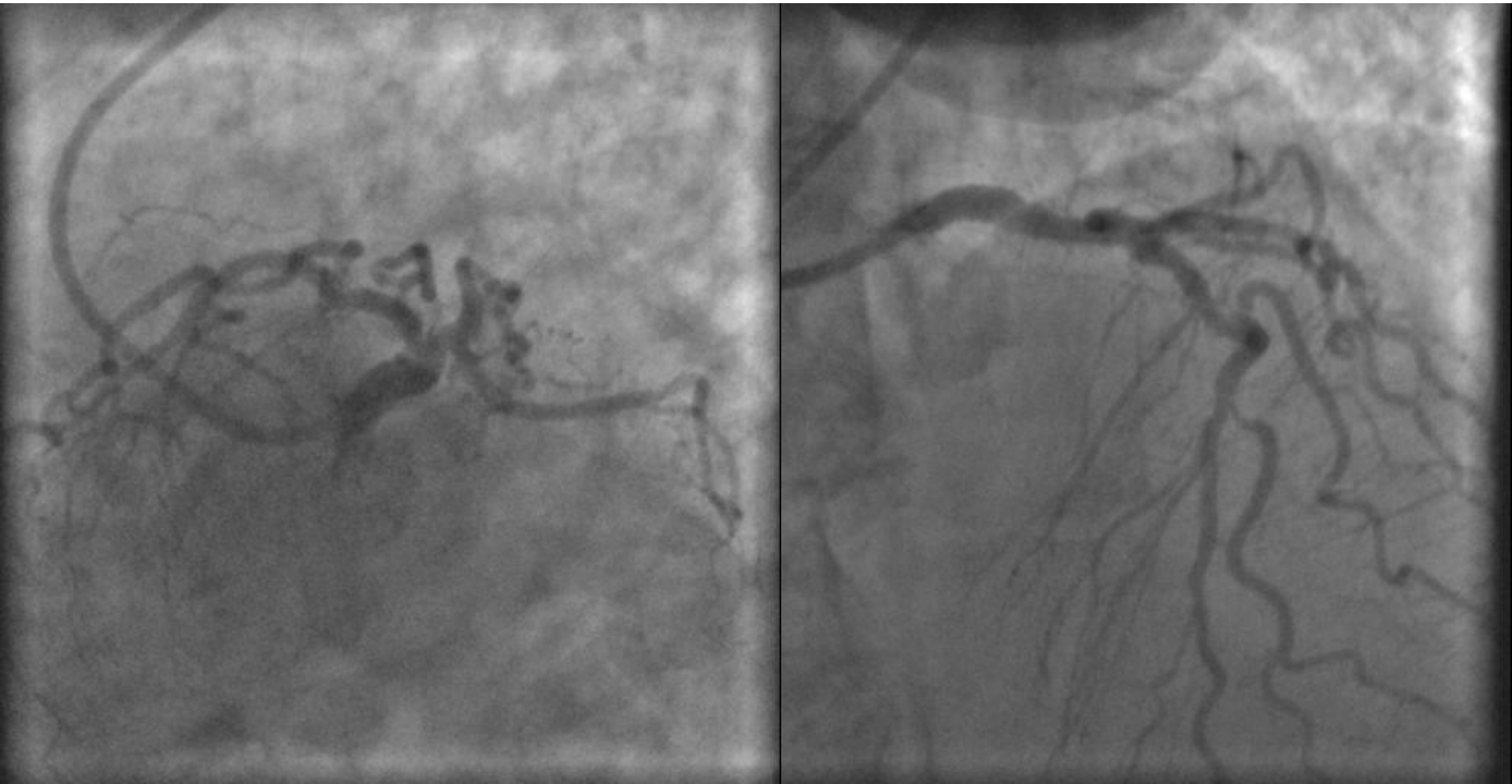
Due to the good mental conditions of the patient despite her general fragility a totally percutaneous strategy was proposed in 4 steps:

Step 1. Percutaneous treatment of the ULM by the right radial artery (Low SYNTAX score= 14).

Step 1. Percutaneous treatment of the LM.

Percutaneous implantation of a Xience V 4.0x12mm in the ostial ULM under IVUS guidance and post-expansion of the stent with a 4.5x10mm non compliant balloon.

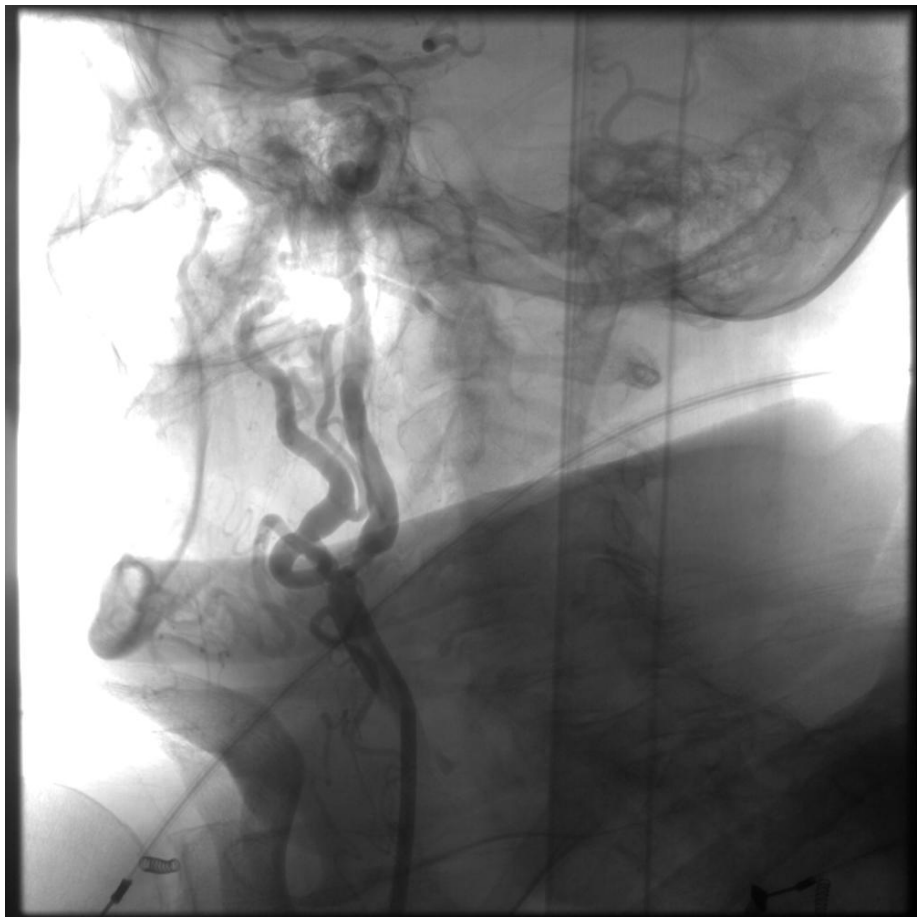
The patient was pre-treated with dual anti platelet therapy and this was advised to be continued for 6 months

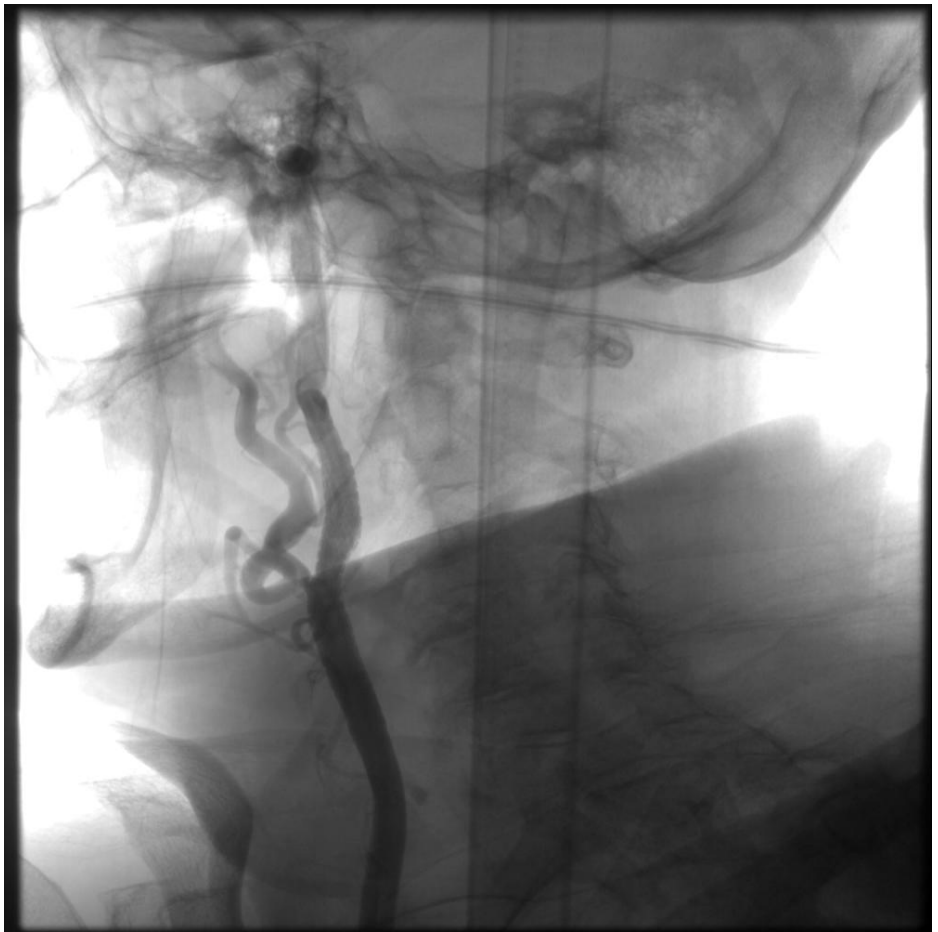


Step 2. Percutaneous treatment of the right ICA by the right femoral artery.

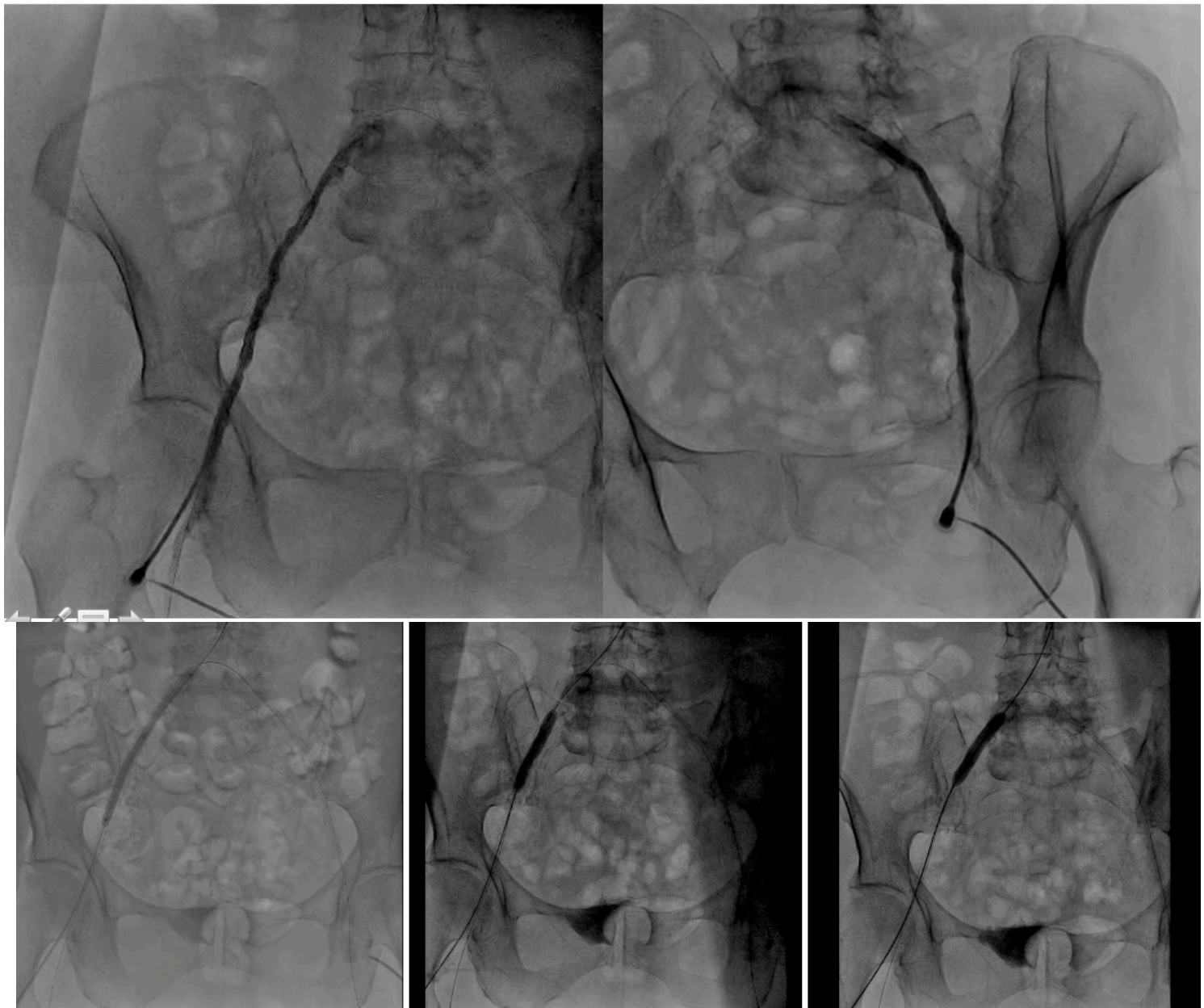
The patient had a complete release form angina during her daily activities immediately after the PCI. One week after the PCI of the LM the patient was readmitted for the treatment of the carotid artery disease.

A 7.0x40mm carotid Precise stent was positioned and post-dilated with a 5.5mm balloon. The procedure was un-eventful and the patient was discharged 3 days later.





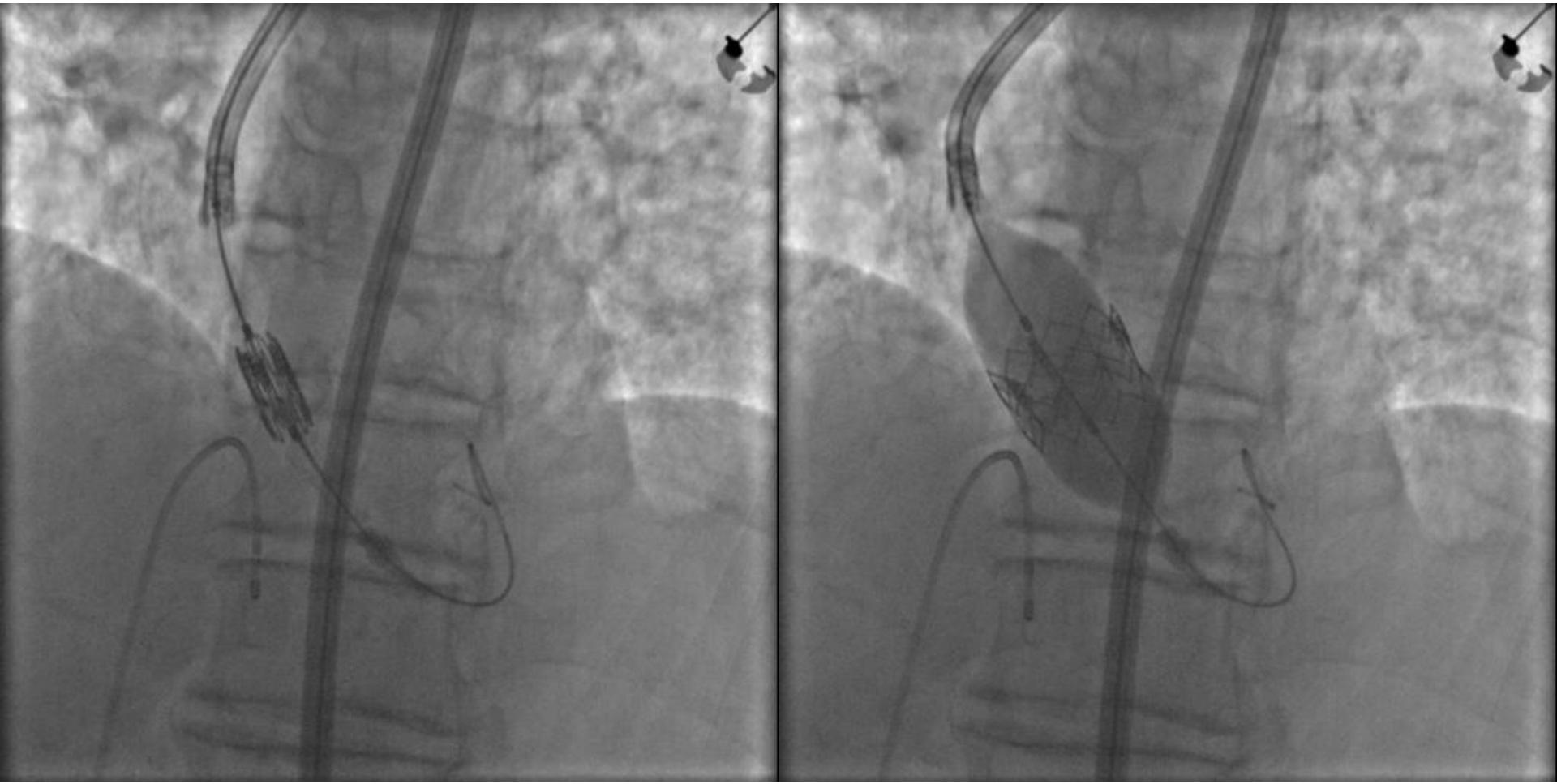
Step 3. PTA of the iliac-femoral vascular access



Step 4. Percutaneous treatment of the AVS.

A 23mm Edwards Sapien Novaflex valve was implanted with success and without complication.

The femoral vascular access was managed percutaneously



Aortic
angiography after
trans-catheter
aortic valve
implantation
(TAVI).
No aortic regurgitation
is observed and the two
coronary arteries are
well perfused.

The patients was discharged
8 days later.

At present: 4 years follow-up
without clinical events.

She is now 91 years old.

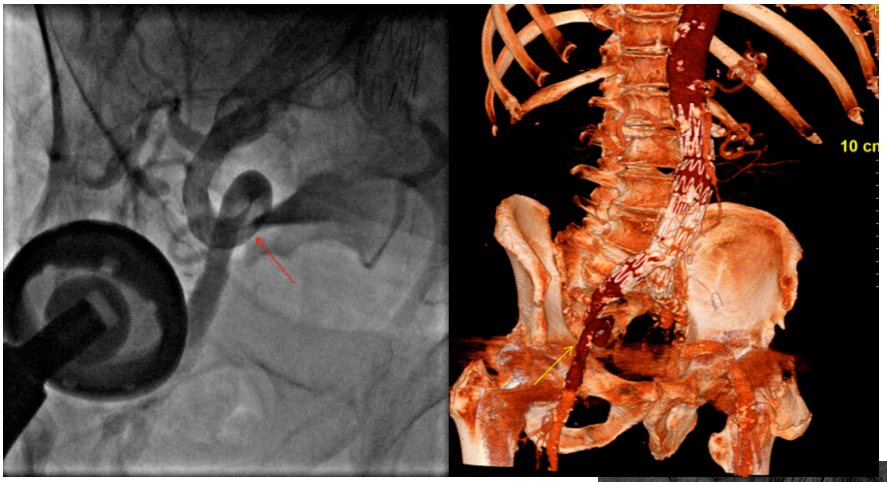
Contents lists available at SciVerse ScienceDirect

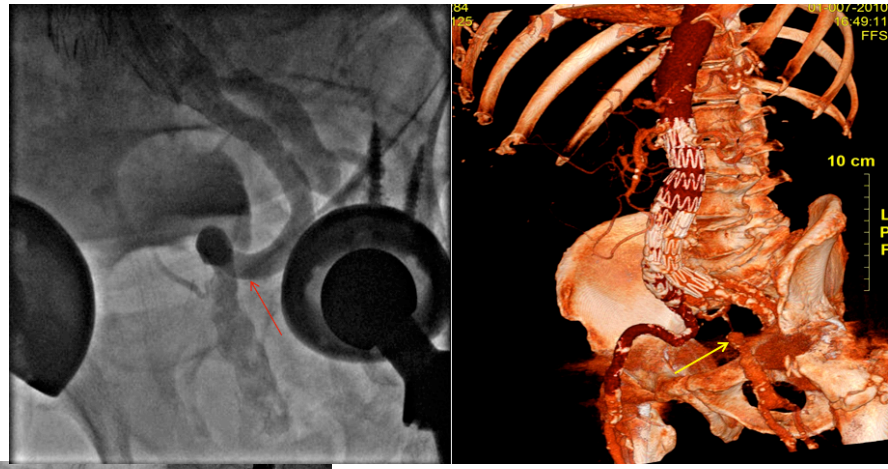
Cardiovascular Revascularization Medicine

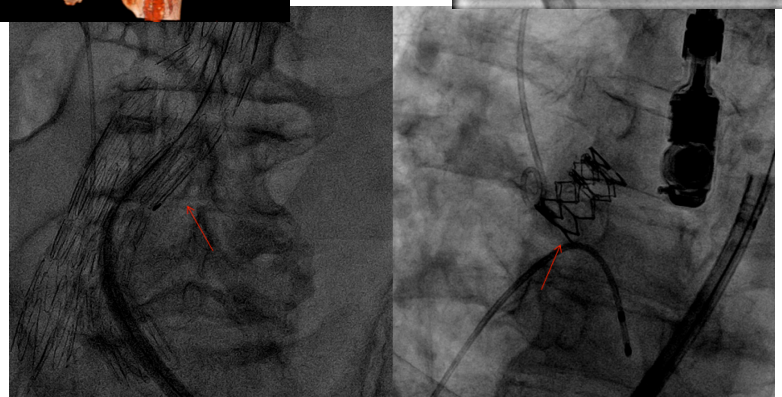
Transfemoral Edwards-Nova ex valve implantation in a patient with aorto-iliac endoprosthesis and severely tortuous bilateral external iliac arteries-"Railing track"

Rajesh M. Dandale, Gabriele Pesarini, Francesco Santini, Gionata Molinari, Andrea Rossi, Aldo Milano, Giuseppe Faggian, Corrado Vassanelli, Flavio Ribichini *

The Department of Medicine, University of Verona, 37126 Verona, Italy







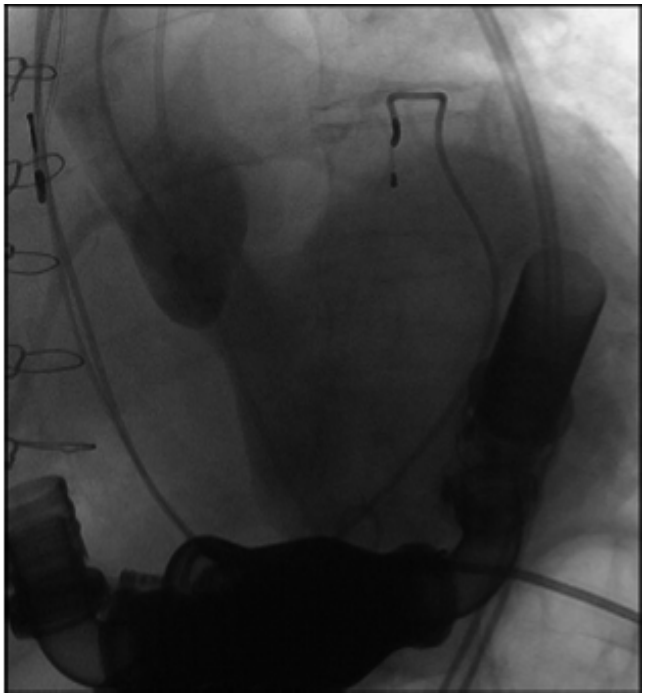
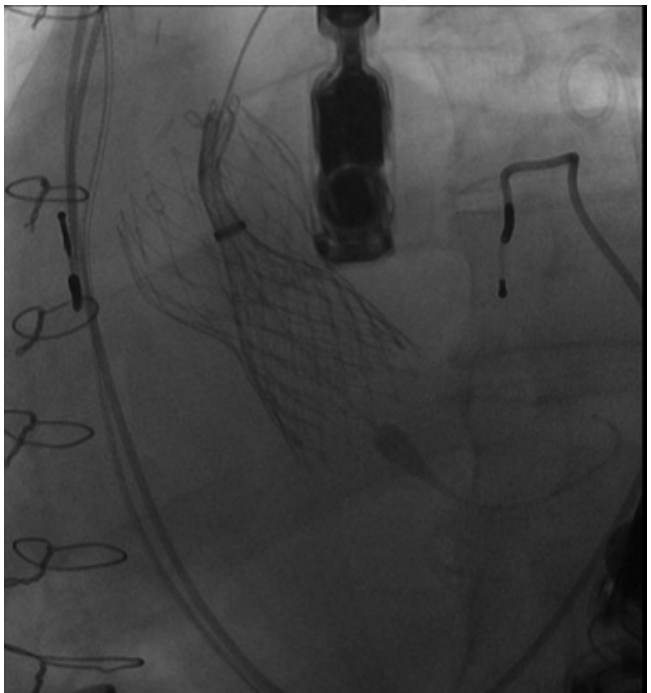
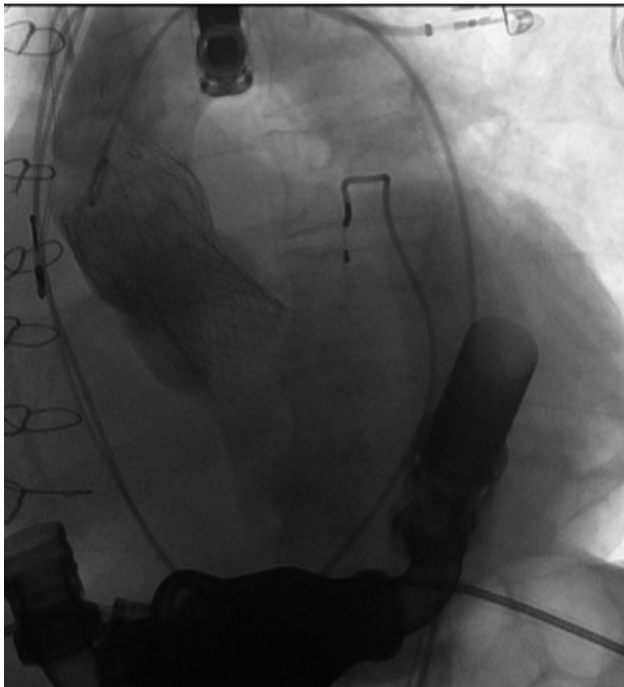
JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 5, NO. 1, 2012

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC.
DOI: 10.1016/j.jcin.2011.10.009

First Successful Management of Aortic Valve Insufficiency Associated With HeartMate II Left Ventricular Assist Device Support by Transfemoral CoreValve Implantation

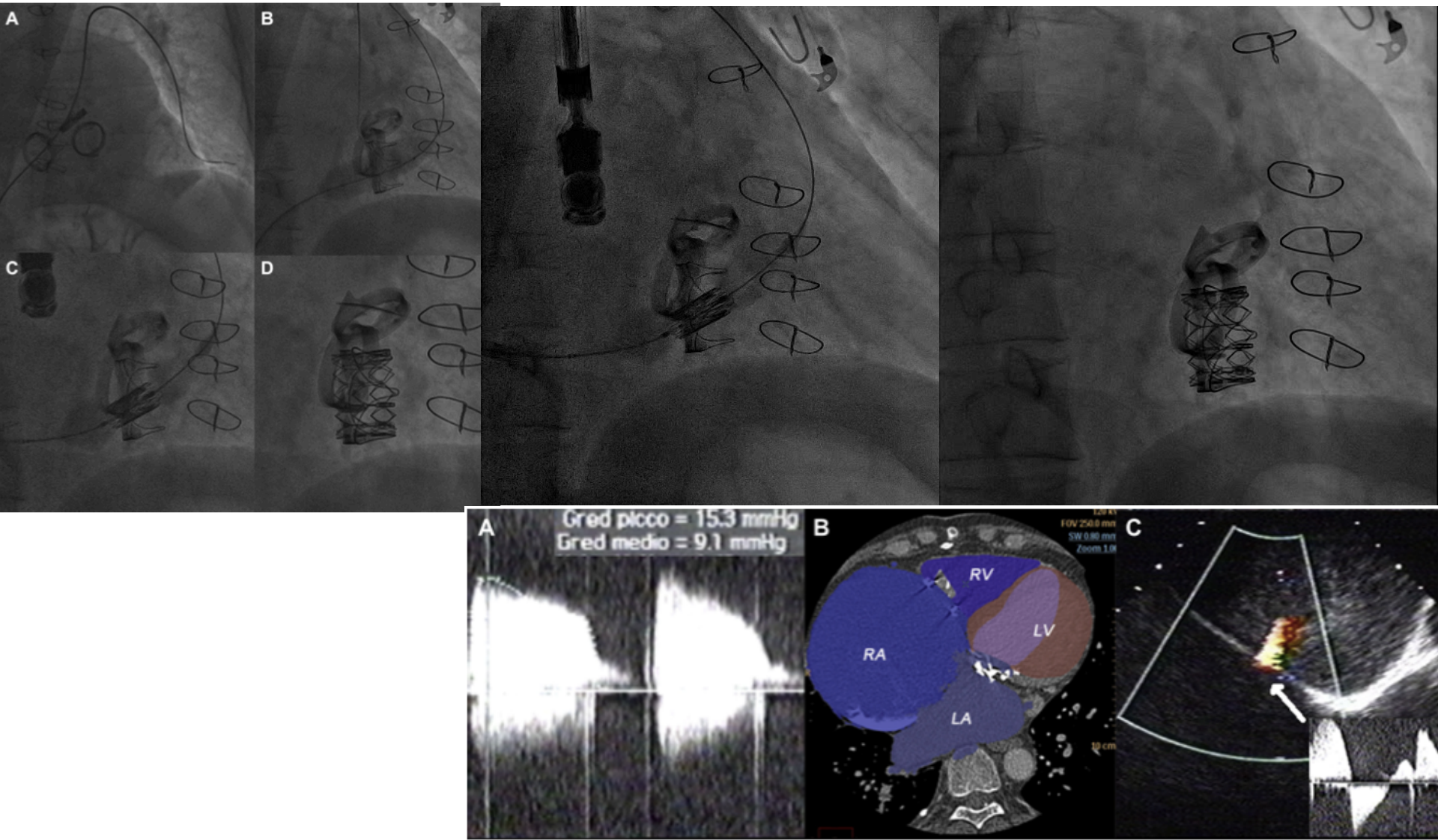
The Columbus's Egg?

Francesco Santini, MD,* Alberto Forni, MD,* Rajesh Dandale, MD,* Flavio Ribichini, MD,† Andrea Rossi, MD,† Gianluigi Franchi, MD,‡ Francesco Onorati, MD,* Corrado Vassanelli, MD,† Alessandro Mazzucco, MD,* Giuseppe Faggian, MD*

Transcatheter Tricuspid Valve Implantation by Femoral Approach in Trivalvular Heart Disease

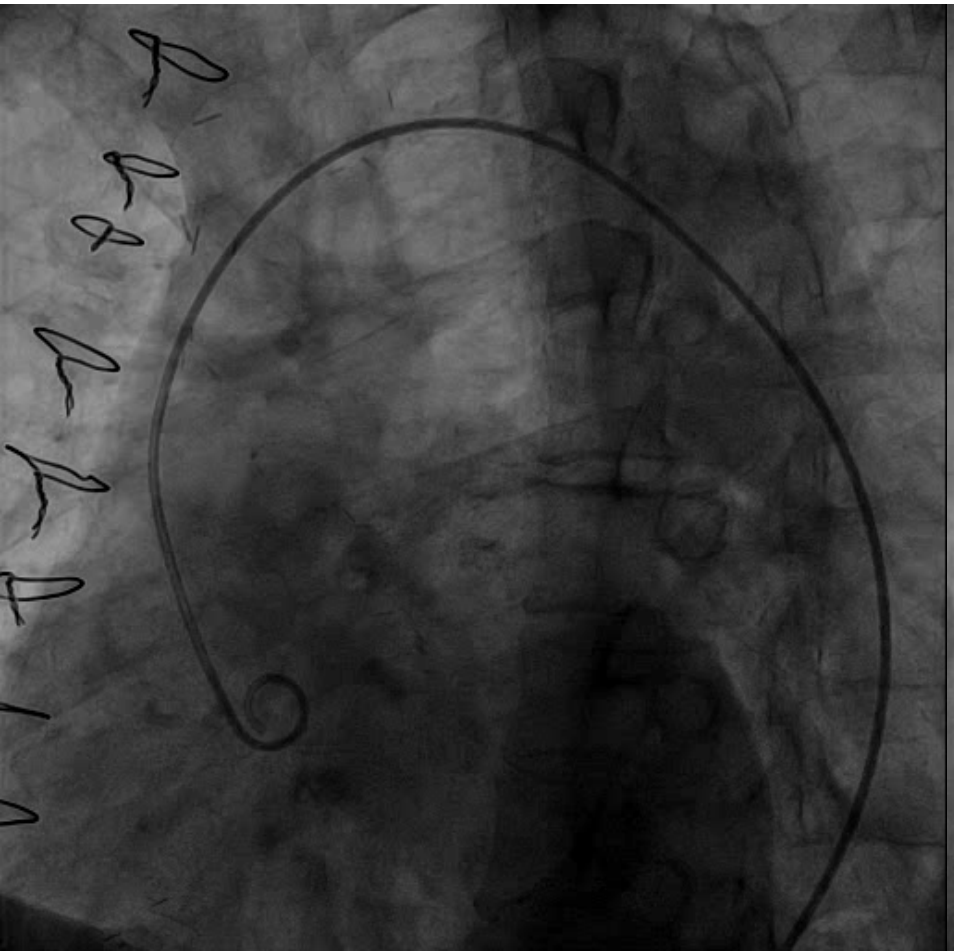
Flavio Ribichini, MD[a,*], Gabriele Pesarini, MD, PhD[a], Mauro Feola, MD[a], Marco Agostini, MD[a], Gionata Molinari, MD[a], Andrea Rossi, MD[a], Giuseppe Faggian, MD[b], and Corrado Vassanelli, MD[a]



"Valve in Valve" Implantation of Two Self-Expandable Transcatheter Aortic Valves in a Patient With Aortic Root Aneurysm and Massive Aortic Regurgitation: "A New TAVI Option"

Gabriele Pesarini,[1] **MD, PHD, Francesco Bedogni,**[1] **MD, and Flavio Ribichini,**[1*] **MD**

Catheter-based treatment of aortic regurgitation (AR) often proves challenging especially due to associated anatomical difficulties. Here, we present a case of CoreValve implantation with a novel use of the valve-in-valve technique to effectively treat severe AR in a patient with repeated cardiac surgery and aneurismatic prosthetic ascending aorta.



La strada per le TAVI è spianata…
e di TAVI se ne faranno sempre di più…

Pazienti con rischio intermedio

Libera scelta del paziente a favore della TAVI

Possibilità di trattare anche pazienti complessi con insufficienza aortica

SVR per giovani candidati a protesi meccaniche o per pazienti con associata CAD complessa o giovani con valvolopatia multiple

Malattie dell'aorta ascendente e dell'arco aortico

Salar de Uyuni, Jujuy, Argentina


TAVI oggi
VITA...
Lago Nahuel Huapi, Bariloche, Argentina

TAVI domani

“Intervento di routine in Day Surgery”

Eulogio Garcia

GRAZIE

Le Odle, Val di Funes, Alto Adige