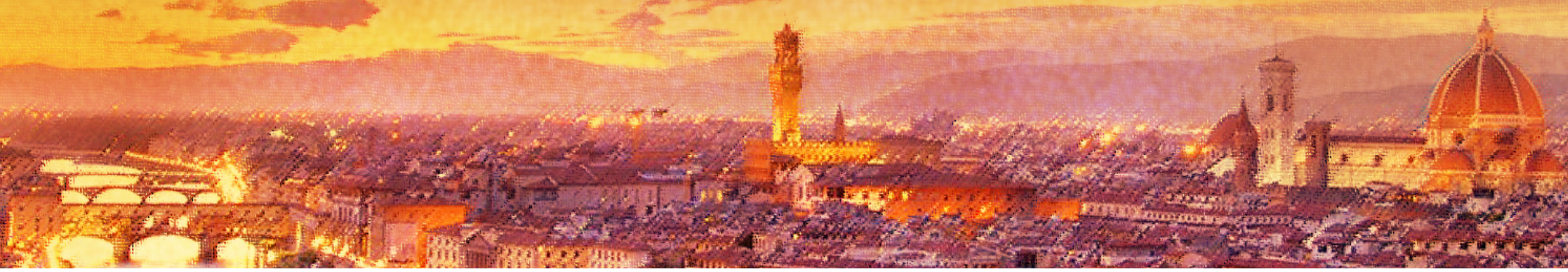
Conoscere e Curare il Cuore 2019

VENERDI' 1 MARZO

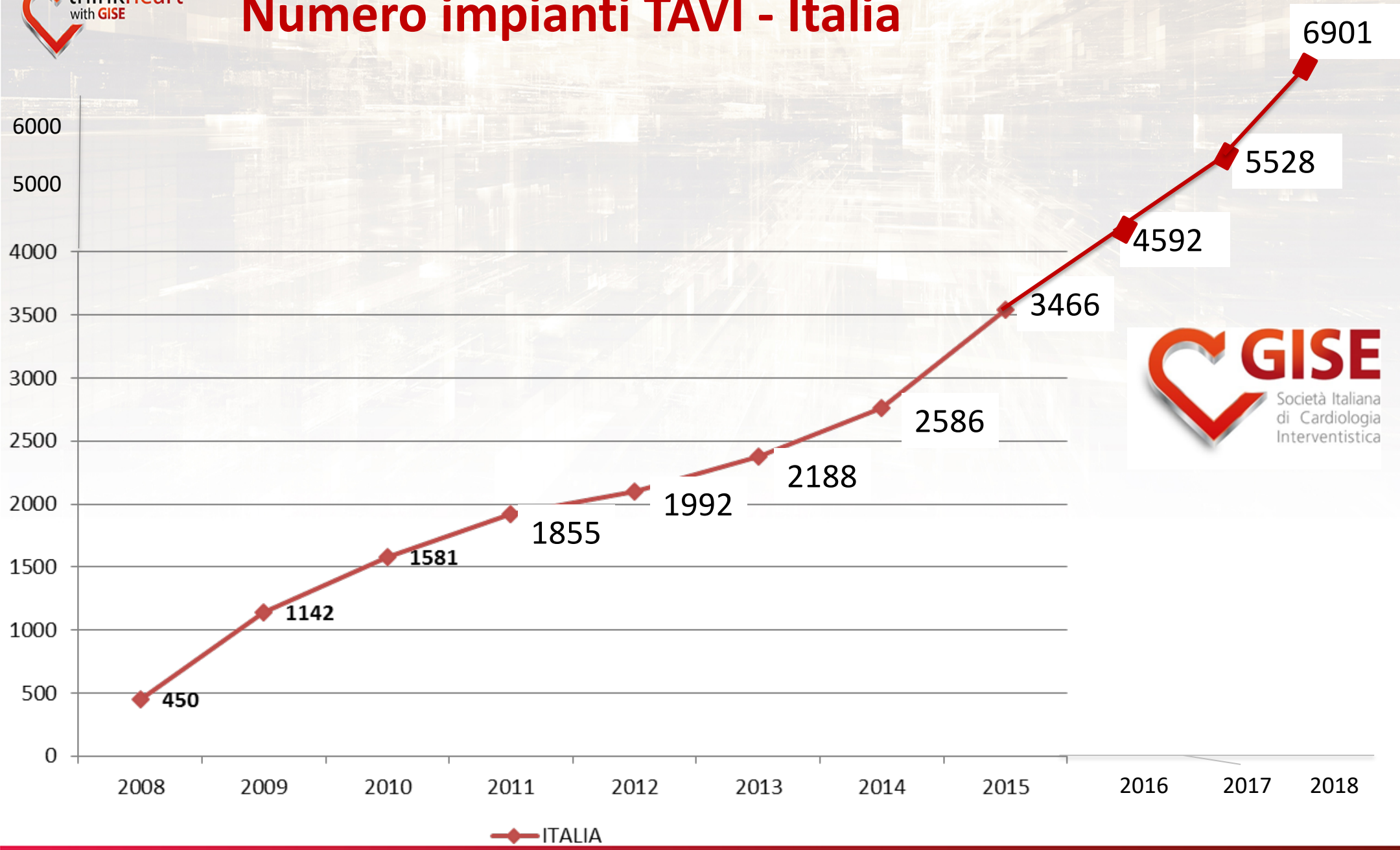
LE TAVI IN ITALIA: UNA CRESCITA DISOMOGENEA

Giuseppe Musumeci

USC Cardiologia
Ospedale S. Croce e Carle, Cuneo

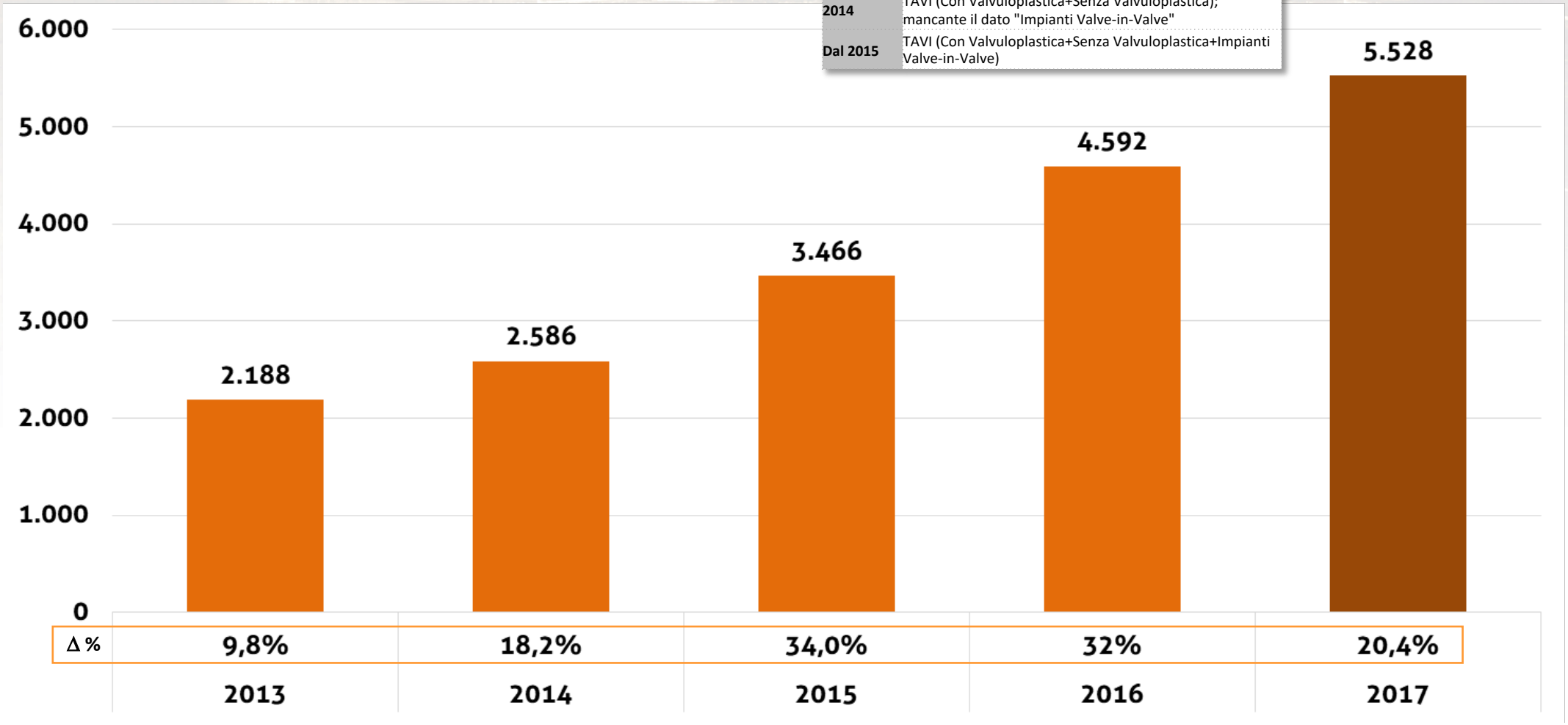


Numero impianti TAVI - Italia



TAVI
ITALIA SERIE STORICA

	EVOLUZIONE RACCOLTA DATI TAVI NEGLI ANNI
2011	Impianto Protesi Percutanee Aortiche
2012	Protesi Valvolari aortiche
2013	Protesi Valvolari aortiche
2014	TAVI (Con Valvuloplastica+Senza Valvuloplastica); mancante il dato "Impianti Valve-in-Valve"
Dal 2015	TAVI (Con Valvuloplastica+Senza Valvuloplastica+Impianti Valve-in-Valve)



Pre-existing market (SAVR)

New market

Low Risk (Must Meet ALL Criteria in This Column)	Intermediate Risk (Any 1 Criterion in This Column)	High Risk (Any 1 Criterion in This Column)	Prohibitive Risk (Any 1 Criterion in This Column)

ESC European Society of Cardiology

European Heart Journal (2017) **38**, 2739–2786
doi:10.1093/eurheartj/ehx391

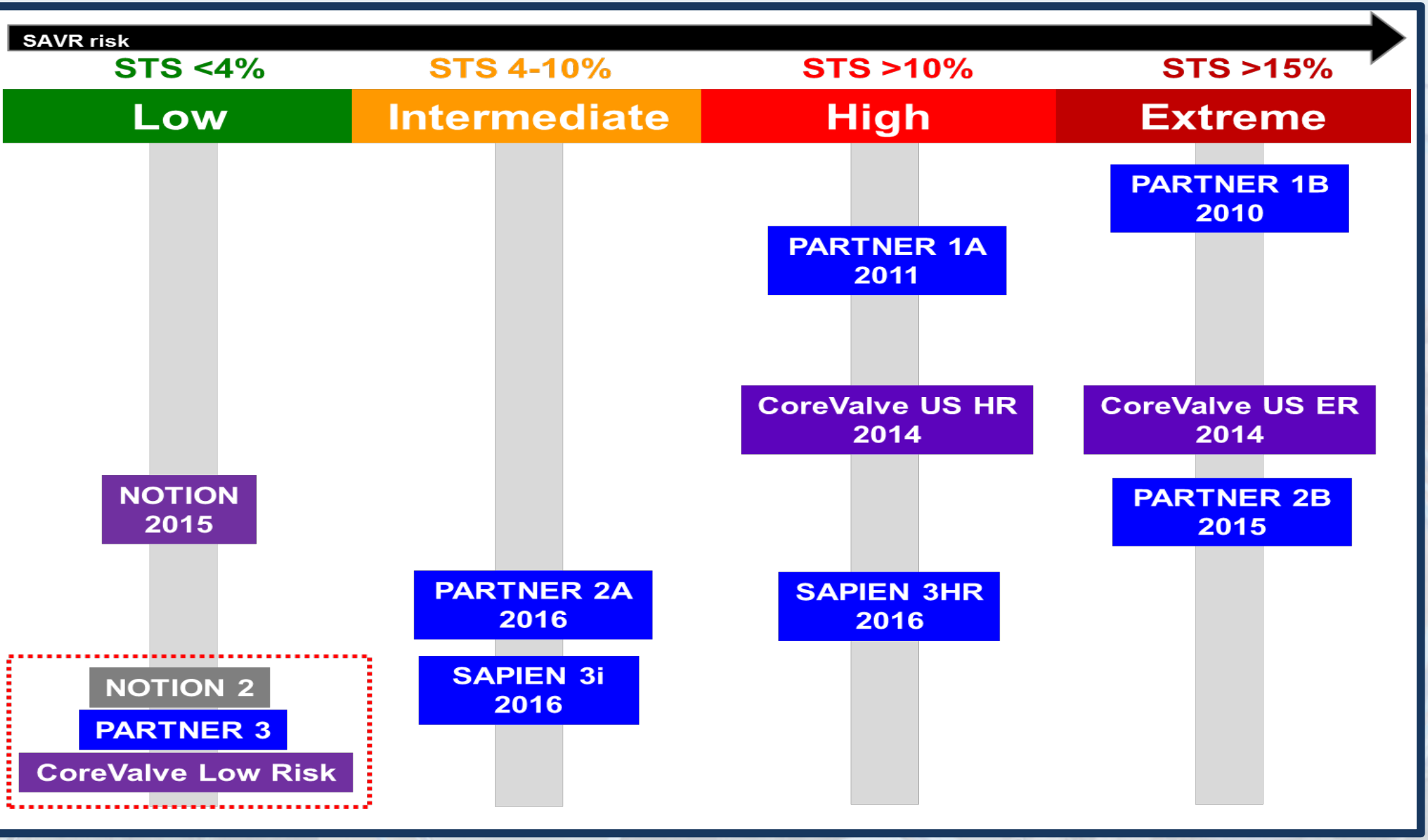
2017 ESC/EACTS Guidelines for the management of valvular heart disease

The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

B) Choice of intervention in symptomatic aortic stenosis		
Aortic valve interventions should only be performed in centres with both departments of cardiology and cardiac surgery on site and with structured collaboration between the two, including a Heart Team (heart valve centres).	I	C
The choice for intervention must be based on careful individual evaluation of technical suitability and weighing of risks and benefits of each modality (aspects to be considered are listed in *Table 7*). In addition, the local expertise and outcomes data for the given intervention must be taken into account.	I	C
SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II < 4% or logistic EuroSCORE I < 10%[d] and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation).[93]	I	B
TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.[91,94]	I	B
In patients who are at increased surgical risk (STS or EuroSCORE II ≥ 4% or logistic EuroSCORE I ≥ 10%[d] or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics (see *Table 7*), with TAVI being favoured in elderly patients suitable for transfemoral access.[91,94–102]	I	B

	Favours TAVI	Favours SAVR
Clinical characteristics		
STS/EuroSCORE II <4% (logistic EuroSCORE I <10%)[a]		+
STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%)[a]	+	
Presence of severe comorbidity (not adequately reflected by scores)	+	
Age <75 years		+
Age ≥75 years	+	
Previous cardiac surgery	+	
Frailty[b]	+	
Restricted mobility and conditions that may affect the rehabilitation process after the procedure	+	
Suspicion of endocarditis		+
Anatomical and technical aspects		
Favourable access for transfemoral TAVI	+	
Unfavourable access (any) for TAVI		+
Sequelae of chest radiation	+	
Porcelain aorta	+	
Presence of intact coronary bypass grafts at risk when sternotomy is performed	+	
Expected patient–prosthesis mismatch	+	
Severe chest deformation or scoliosis	+	
Short distance between coronary ostia and aortic valve annulus		+
Size of aortic valve annulus out of range for TAVI		+
Aortic root morphology unfavourable for TAVI		+
Valve morphology (bicuspid, degree of calcification, calcification pattern) unfavourable for TAVI		+
Presence of thrombi in aorta or LV		+
Cardiac conditions in addition to aortic stenosis that require consideration for concomitant intervention		
Severe CAD requiring revascularization by CABG		+
Severe primary mitral valve disease, which could be treated surgically		+
Severe tricuspid valve disease		+
Aneurysm of the ascending aorta		+

The TAVR Path through Risk Categories



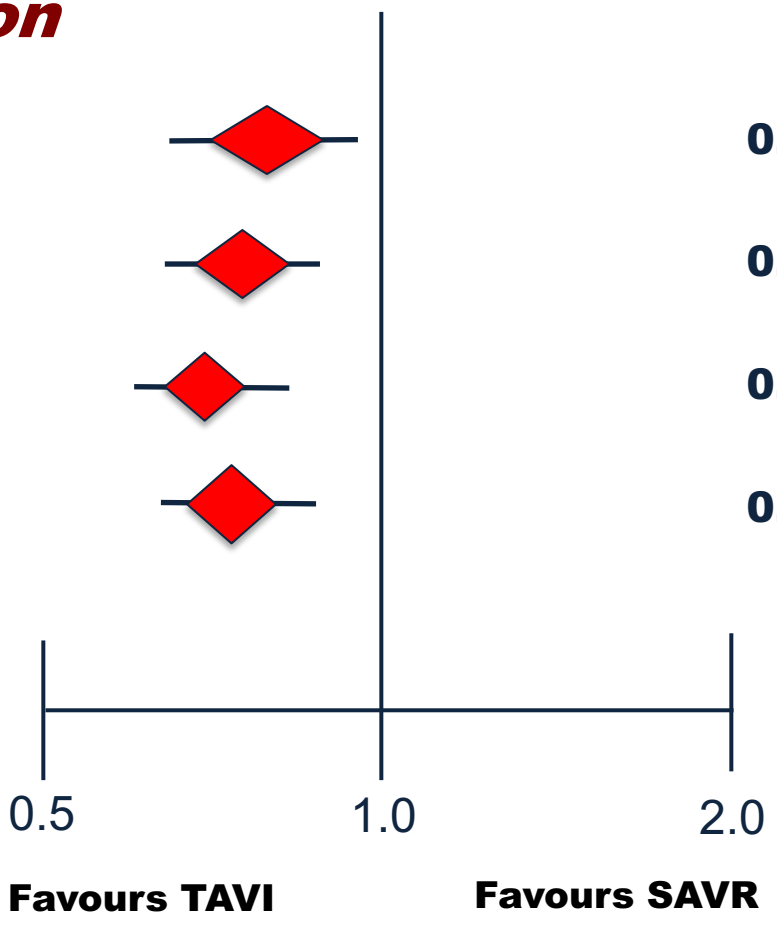
TAVI vs SAVR: Meta-Analysis Of 4 Randomized Trials

	PARTNER 1A[1–3]		US CoreValve High Risk[5–7]		NOTION[8]		PARTNER 2A[9]	
	TAVI	SAVR	TAVI	SAVR	TAVI	SAVR	TAVI	SAVR
Number of centres	25		45		3		57	
Recruitment period	2007–09		2011–12		2009–13		2011–13	
Longest follow-up, year	5		3		2		2	
Design	Non-inferiority		Non-inferiority		Superiority		Non-inferiority	
ITT patients, *n*	348	351	394	401	145	135	1011	1021
As-treated patients, *n*	344	313	391	359	142	134	994	944
STS, mean (SD)	11.8 ± 3.3	11.7 ± 3.5	7.3 ± 3.0	7.5 ± 3.2	2.9 ± 1.6	3.1 ± 1.7	5.8 ± 2.1	5.8 ± 1.9
Intervention's characteristics								
TAVI valve system	Edwards SAPIEN	na	Medtronic CoreValve	na	Medtronic CoreValve	na	Edwards SAPIEN XT	na
Access site, *n*								
Transfemoral	244	na	394	na	145	na	775	na
Transthoracic	104	na	0	na	0	na	236	na

Siontis et al. Eur Heart J 2016

TAVI vs SAVR: Meta-Analysis Of 4 Randomized Trials

Overall population



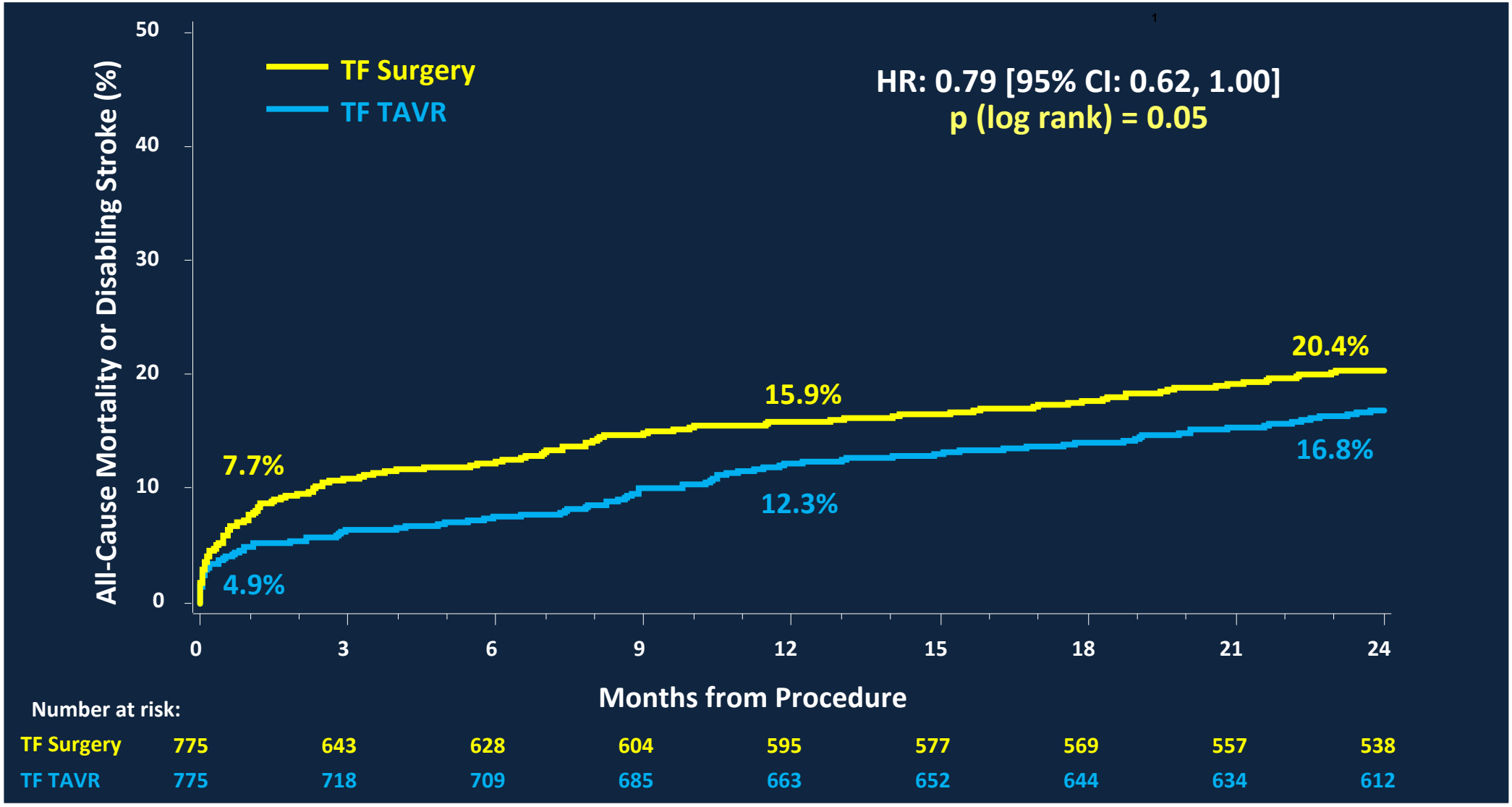
	HR (95% CI)	p	p_{het}
Death	**0.87** (0.77-0.97)	0.038	0.76
Kidney Injury	**0.61** (0.41-0.90)	0.013	0.16
New-onset AFib	**0.46** (0.34-0.63)	<0.001	.004
Major bleeding	**0.57** (0.35-0.92)	0.020	<.001

Siontis et al. Eur Heart J 2016

The PARTNER 2A Trial

I° EP (ITT) - TF

All-Cause Mortality or Disabling Stroke



Leon M, et al. NEJM 2016

European Heart Journal
doi:10.1093/eurheartj/ehw112

SEARCH
TAVI

Large registry # 1

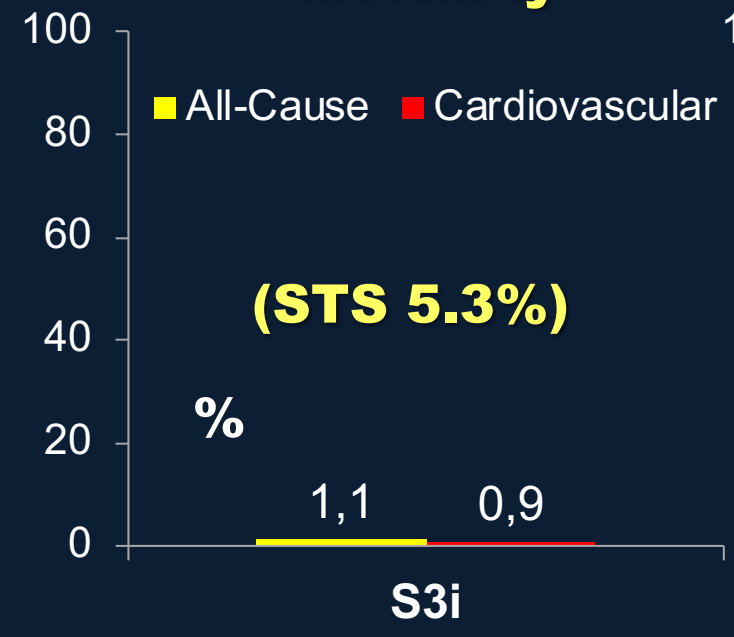
Early clinical and echocardiographic outcomes after SAPIEN 3 transcatheter aort

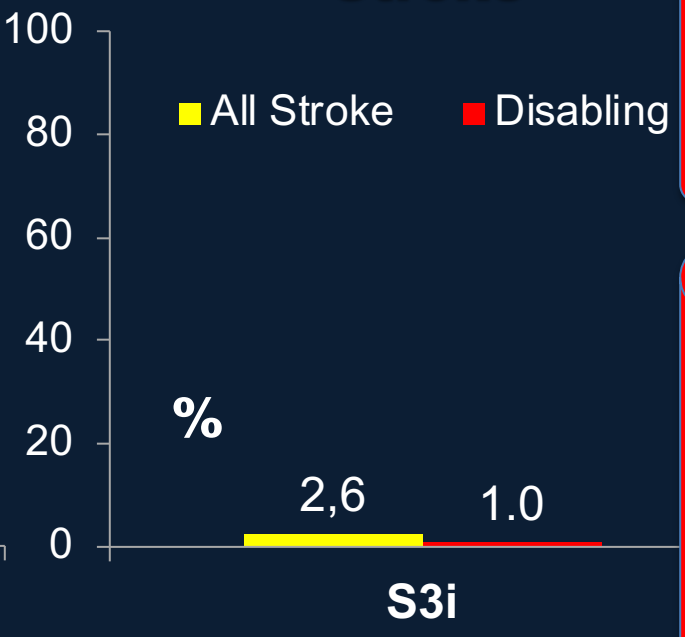
stenosis

asilis Babaliaros[2]
Meissman[14]

Mortality and Stroke: S3i

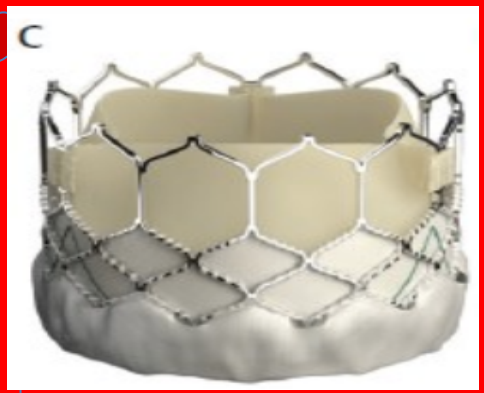
At 30 Days (As Treated Patients)





Age – 82

STS – 5.3



Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis

Vinc
S Ch
Jond
John G Webb, Jeffrey W Moses, Michael J Mack, D J Craig Muller, Craig R Smith, Maria C Alu, Rupa Ramjatanepi, Ralph B D'Agostino Jr, Martin B Leon

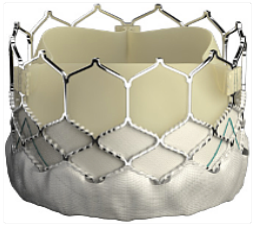
Propensity *"SCORE"* 1-year results

STS – 5.3

Sapien 3 Intermediate Risk Registry

AGE 82

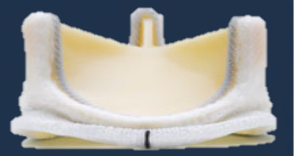
N=1077



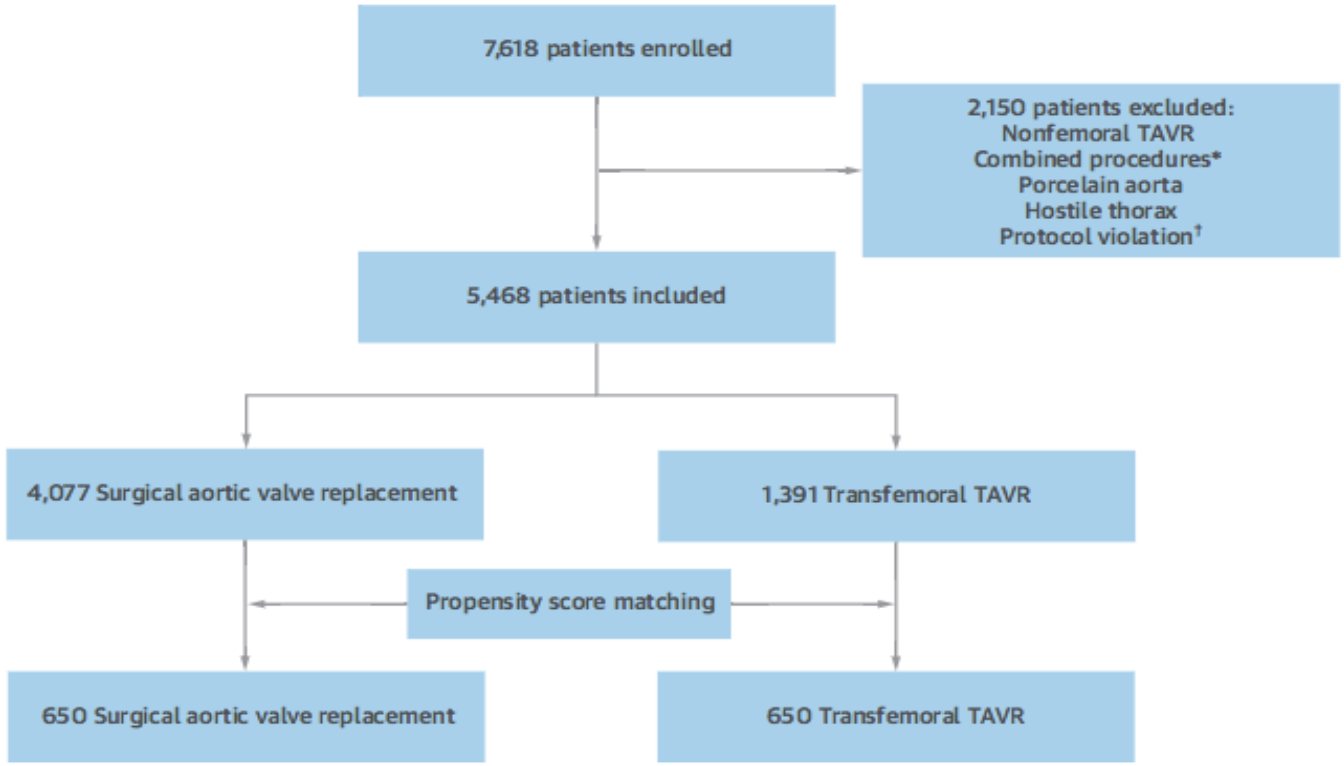
Surgical AVR arm Partner 2A trial

AGE 82

N=944



	SAPIEN 3 TAVR	*SAVR*
Cardiac death	4.5%	8.1%
Any stroke	4.6%	8.2%



registry # 3

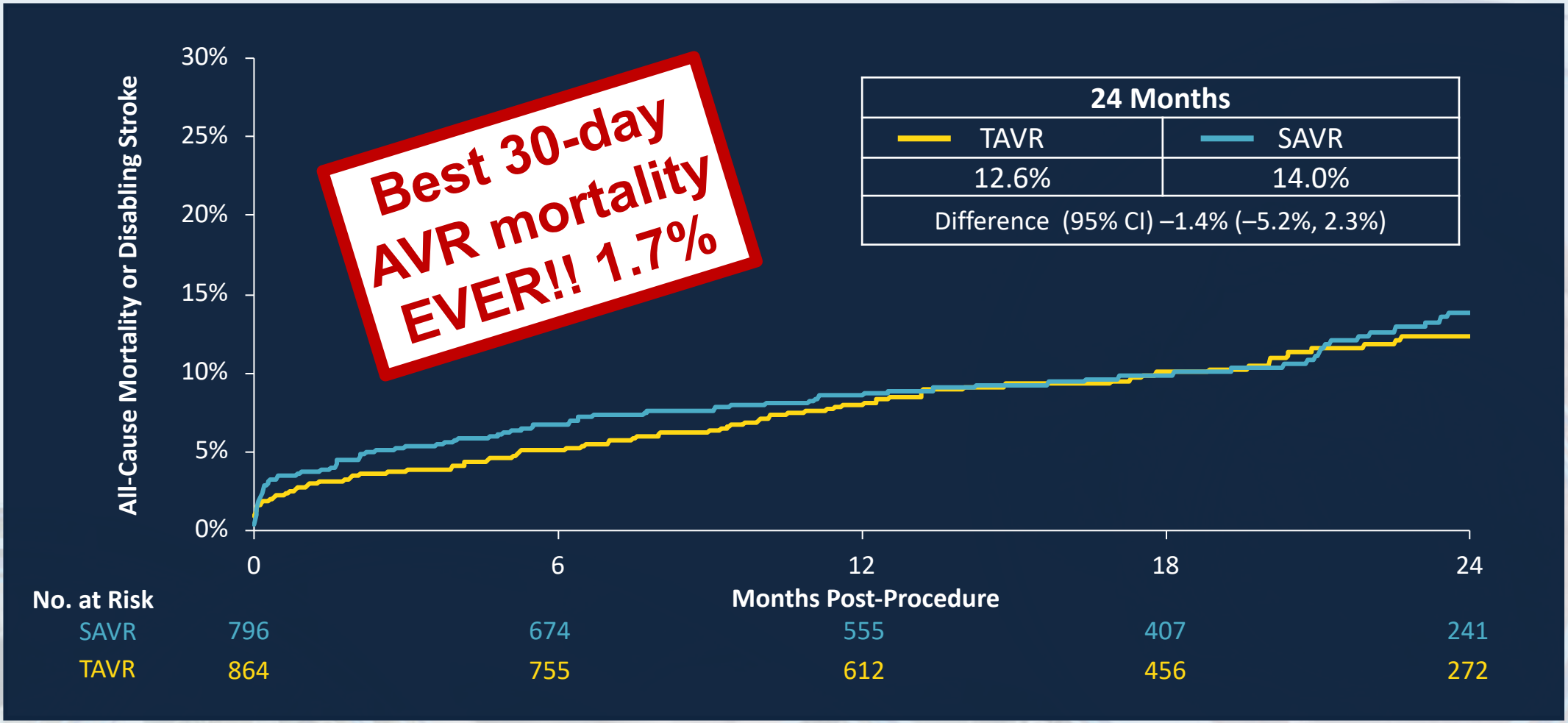
- **Enrollment: Dec 2010-June 2012**
- **Country: Italy**
- **93 hospitals: 34 cath lab, 59 Surgery**
- **THV: ES XT, CV**
- **Follow up: 3 years**

Age 80 Log€score 9.5

EARLY CLINICAL OUTCOMES OF MATCHED OF PAIRS OF PATIENTS

	SAVR	TAVR
Stroke	2.2%	1.3% 
Acute renal failure	10.9%	6.1% 
Blood transf. unit	3.6±3.6	2.3±2.2 
Major vascular complications	0.5% 	7.9%
PM implantation	3.6% 	15.5%

SURTAVI Trial All-Cause Mortality or Disabling Stroke



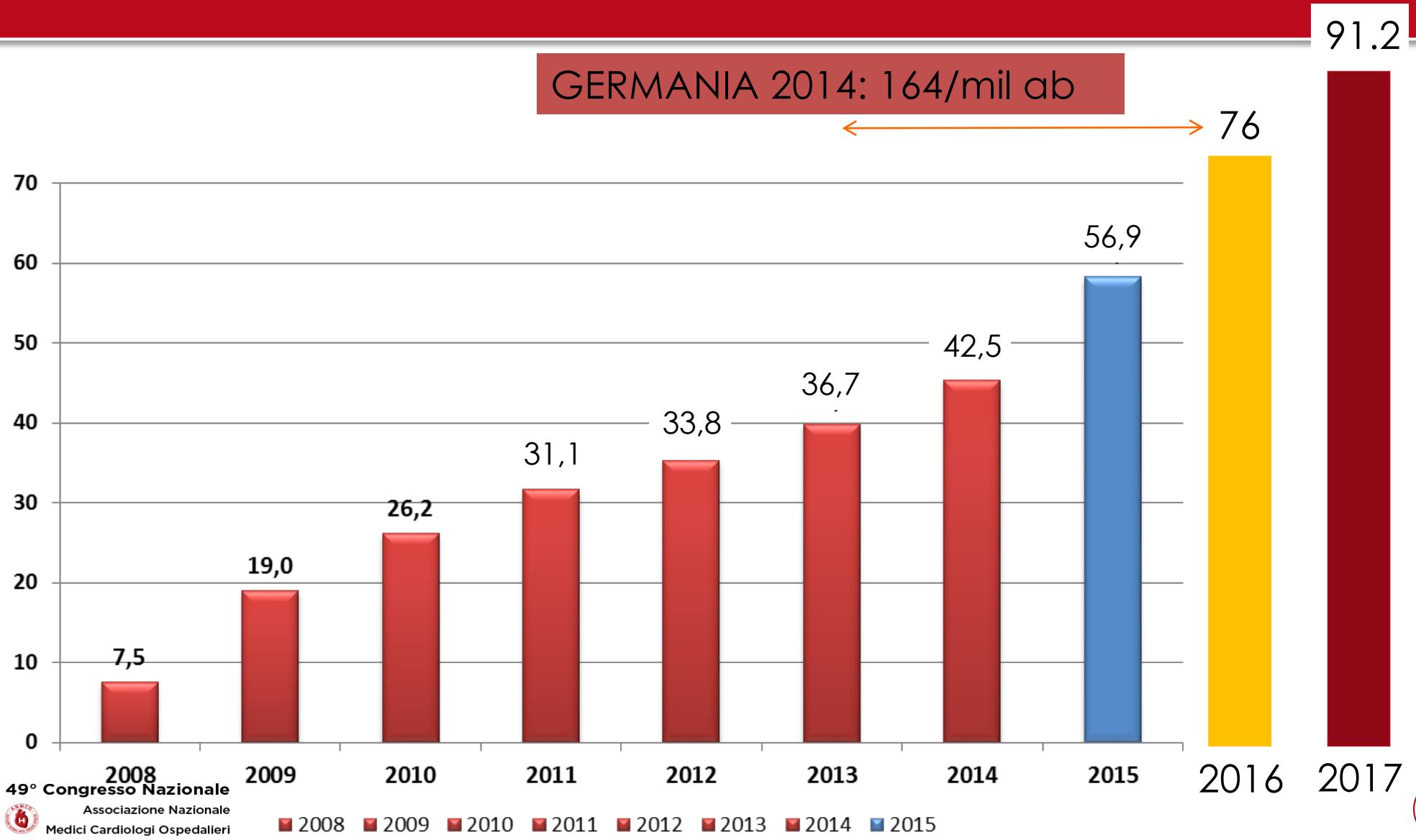
Reardon M, ACC 2017

30-Day Safety and Procedure-related Complications

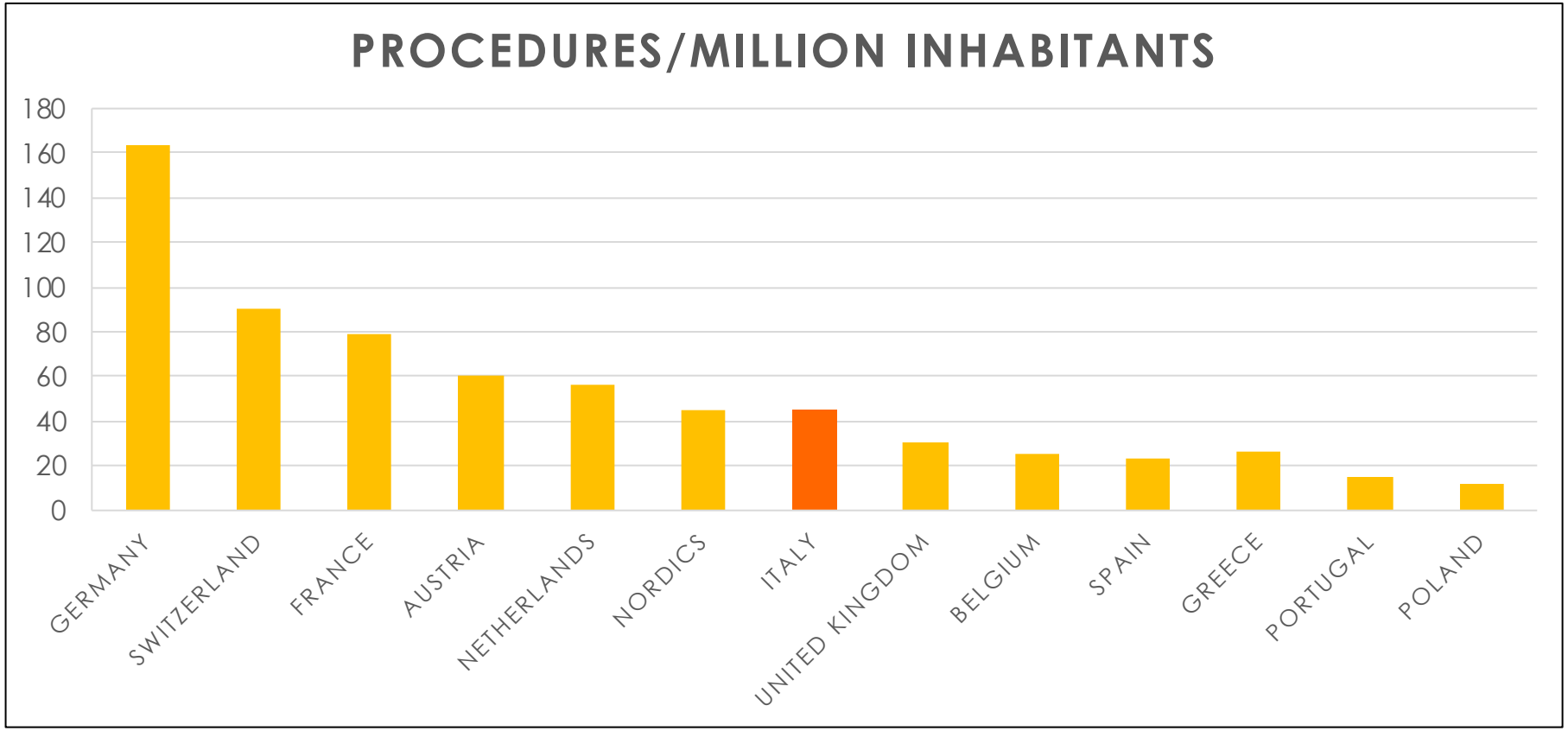
	SAVR	TAVR
Stroke	5.6 %	3.4% 
Shock	3.8%	1.1% 
Acute renal failure (stg 2-3)	4.4%	1.7% 
> 2 U blood transfusions	29.8%	9.2% 
Major vascular complications	1.1% 	6.0%
PM implantation	6.6% 	25.9%

Reardon M, ACC 2017

TAVI per milione di abitanti - Italia

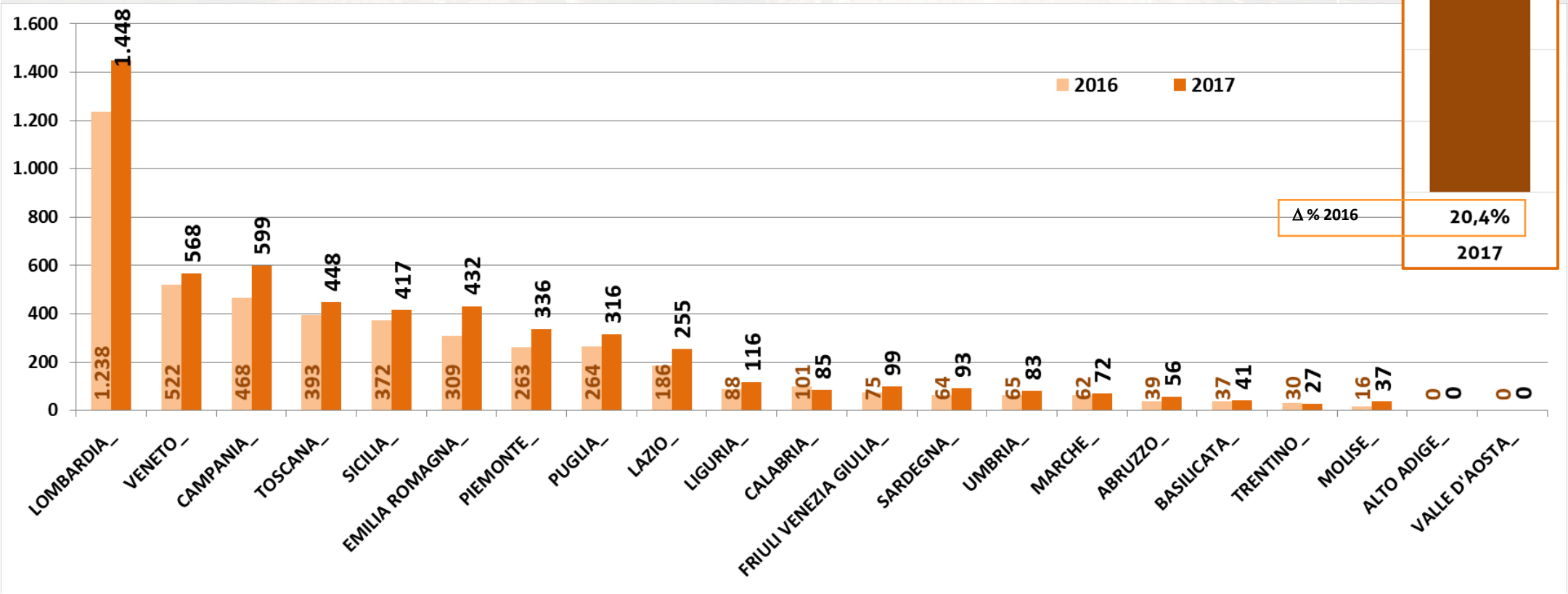


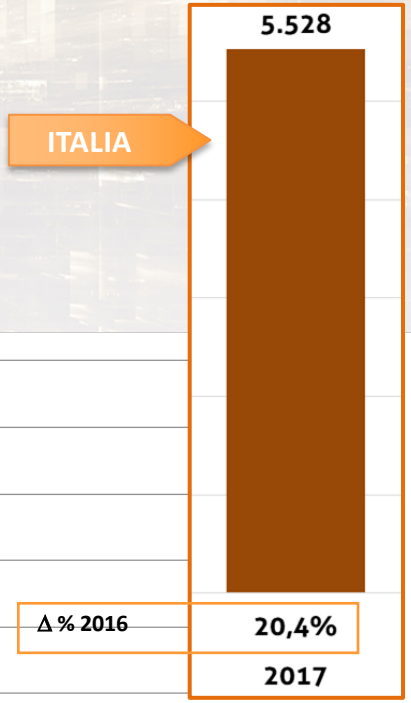
Diffusione TAVI in Europa - Dati 2014



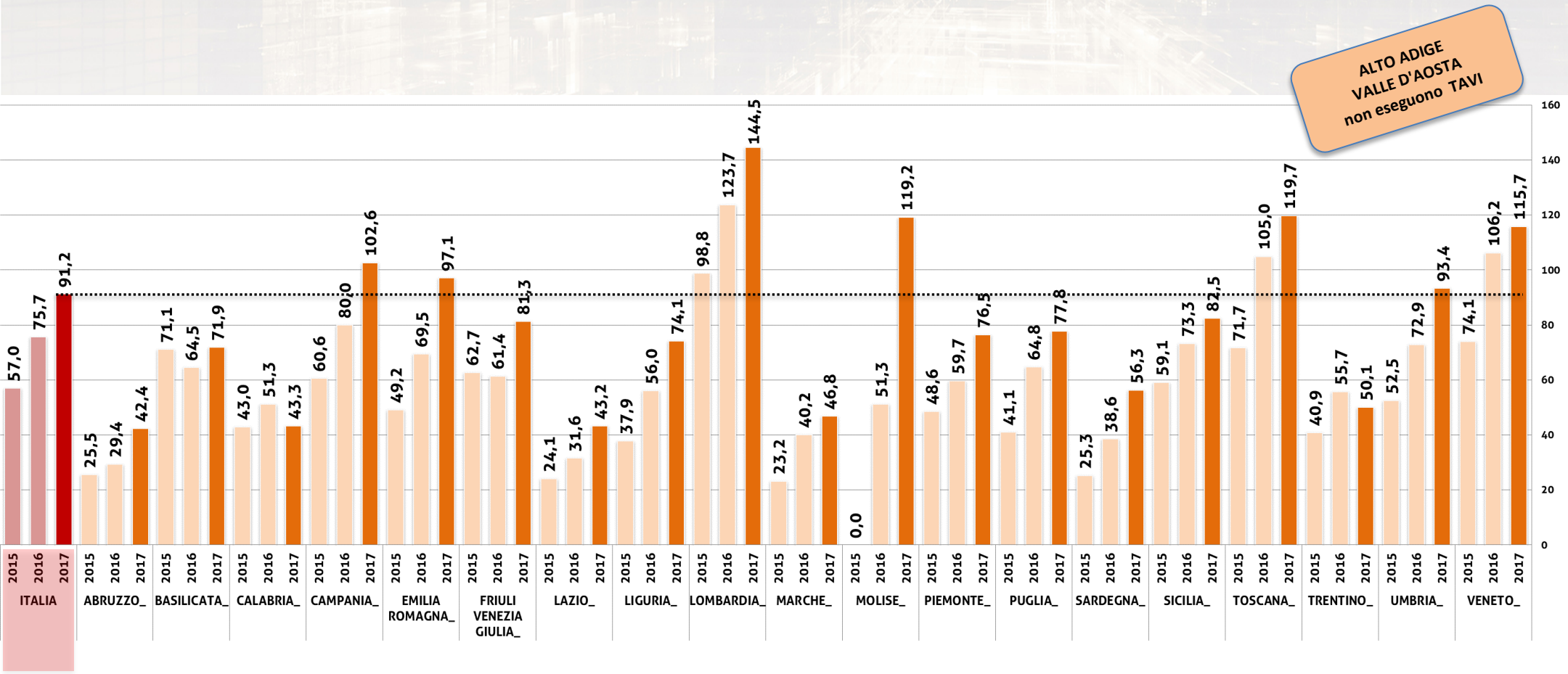
Fonte: European population: EUROSTAT database. TAVI 2014 procedures: Germany: AQUA report, France: PMSI, Poland: TAVI registry. TAVI 2014 procedures: Switzerland, Austria, Netherlands, Nordics, Italy, UK, Belgium, Spain, Greece, Portugal, Spain: BIBA medical (Independent third party data)

TAVI, VALORI ASSOLUTI
REGIONI 2016 E 2017



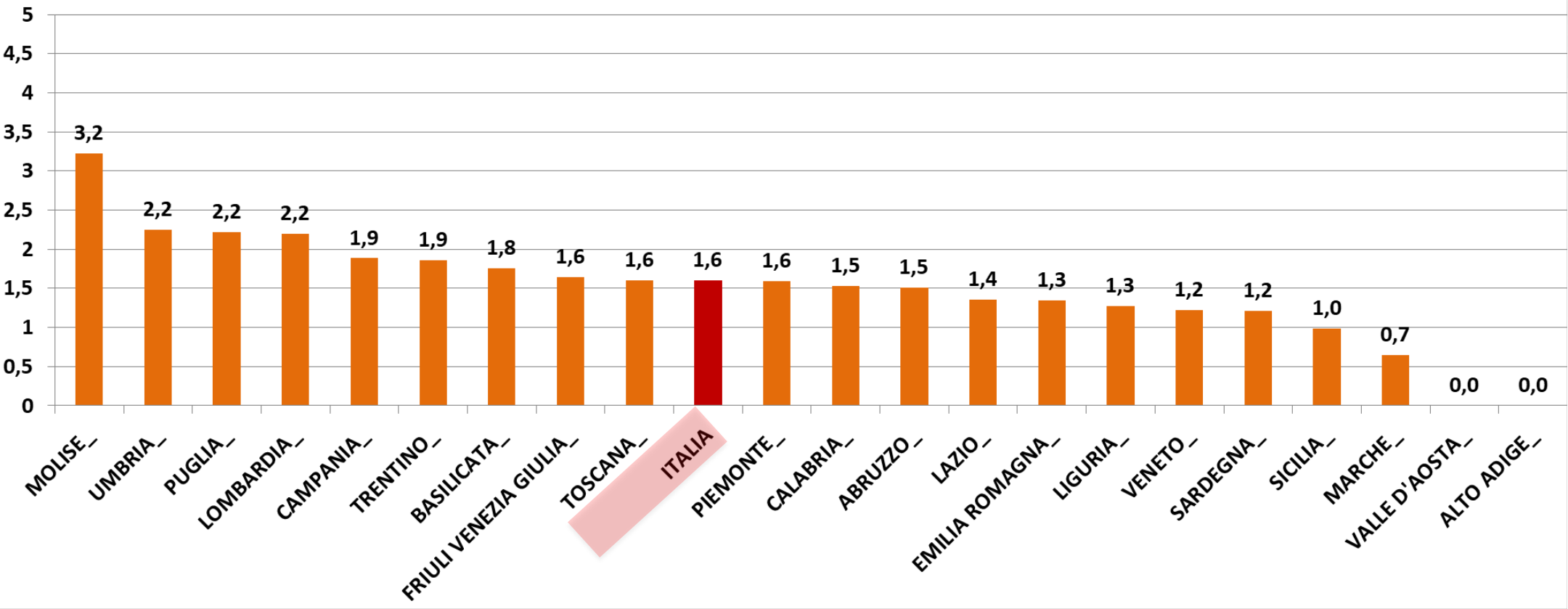


TAVI/1.000.000 ABITANTI
ITALIA E REGIONI 2015-2017



LABORATORI TAVI/1.000.000 ABITANTI REGIONE
ITALIA E REGIONI 2017

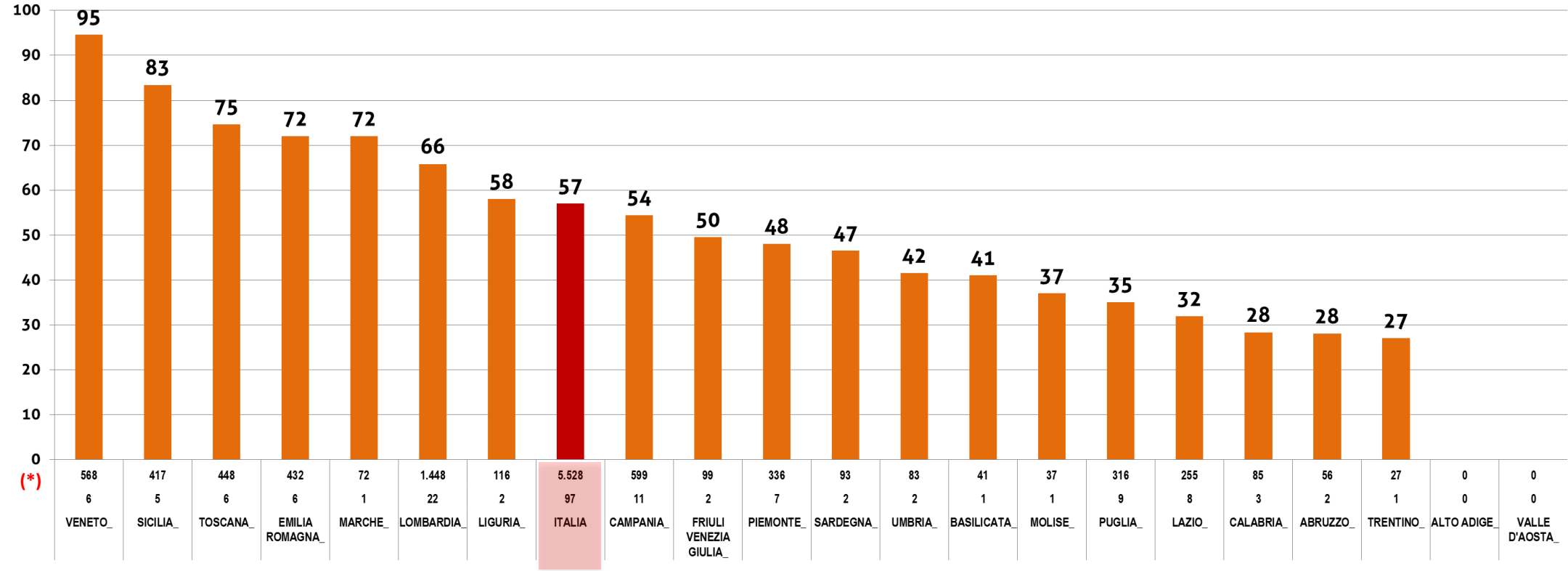
(LABORATORI A DISPOSIZIONE OGNI MILIONE DI ABITANTI REGIONE)



MEDIA NUMERO TAVI PER OGNI LABORATORIO

(TAVI/LABORATORI CHE ESEGUONO TAVI)

ITALIA E REGIONI 2017



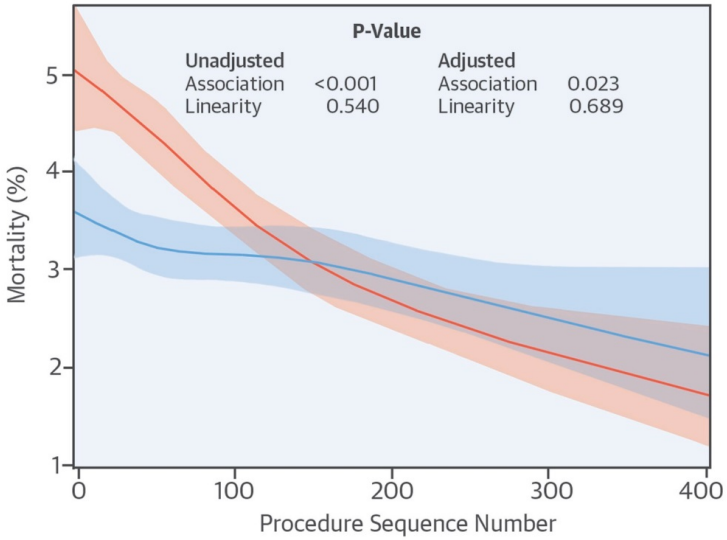
(*) NUMERO TAVI
NUMERO LABORATORI CHE ESEGUONO TAVI

Procedural Experience and Relation to Outcomes

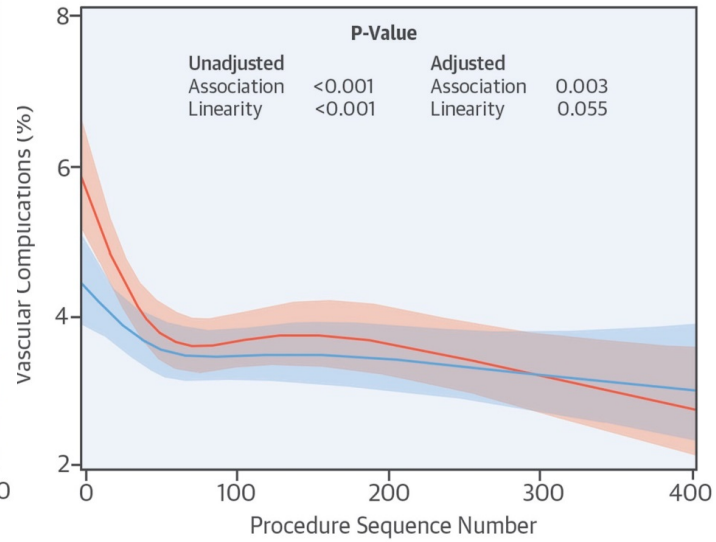
Carroll et al, *J Am Coll Cardiol*. 2017 Jul 4;70(1):29-41

Data from 42,988 commercial procedures conducted at 395 hospitals submitting to the Transcatheter Valve Therapy Registry from 2011 through 2015

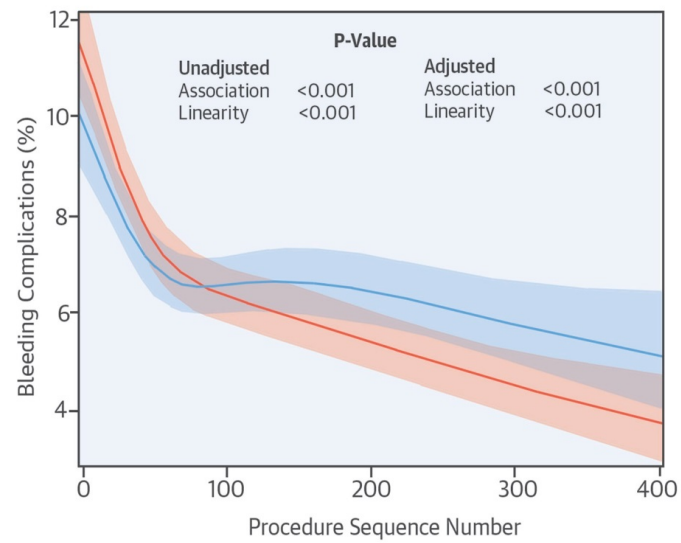
In-Hospital Mortality 4%



Vascular Complications 7.1%



Bleeding Complications 8.6%

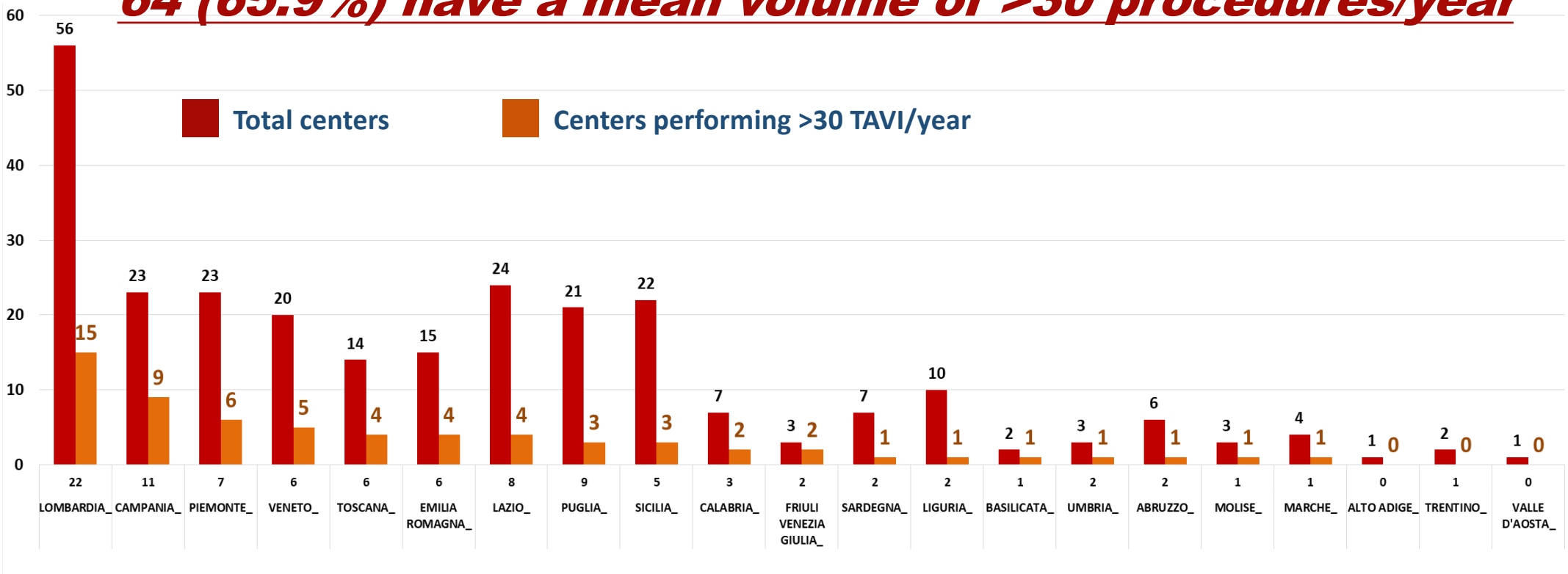


Unadjusted Adjusted

Proportion of Centers Performing TAVI by Region

Out of 97 centers performing TAVI in Italy,

64 (65.9%) have a mean volume of >30 procedures/year



SOURCE: GISE Think Heart 2018

National Societies Position Papers

Journal of the American College of Cardiology
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Vol. 59, No. 13, 2012
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doi:10.1016/j.jacc.2012.01.001

EXPERT CONSENSUS DOCUMENT

2012 ACCF/AATS/SCAI/STS Expert Consensus Document on Transcatheter Aortic Valve Replacement

Developed in collaboration with the American Heart Association, American Society of Echocardiography, European Association for Cardio-Thoracic Surgery, Heart Failure Society of America, Mended Hearts, Society of Cardiovascular Anesthesiologists, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance

ELSEVIER

Canadian Journal of Cardiology 28 (2012) 520–528

Society Position Statement

Transcatheter Aortic Valve Implantation: A Canadian Cardiovascular Society Position Statement

John Webb, MD, FRCPC,[a] Josep Rodés-Cabau, MD, FRCPC,[b] Stephen Fremes, MD, FRCSC,[c] Philippe Pibarot, DVM, PhD,[b] Marc Ruel, MD, FRCSC,[d] Reda Ibrahim, MD, FRCPC,[e] Robert Welsh, MD, FRCPC,[f] Christopher Feindel, MD, FRCSC,[g] and Samuel Lichtenstein, MD, FRCSC[a]

Qualitätskriterien zur Durchführung der kathetergestützten Aortenklappenimplantation (TAVI)

Aktualisierung des Positionspapiers der Deutschen Gesellschaft für Kardiologie

Dutch Guidelines For Competencies For Transcatheter Heart Valve Intervention

Nederlandse Vereniging voor Thoraxchirurgie

Nederlandse Vereniging voor Cardiologie

Journal of the American College of Cardiology
© 2012 by the Society for Cardiovascular Angiography and Interventions, the American Association for Thoracic Surgery, the American College of Cardiology Foundation, and the Society of Thoracic Surgeons
Published by Elsevier Inc.
Vol. 59, No. 22, 2012
ISSN 0735-1097/12/$36.00
doi:10.1016/j.jacc.2012.02.016

COMPETENCE STATEMENT

Multisociety (AATS, ACCF, SCAI, and STS) Expert Consensus Statement: Operator and Institutional Requirements for Transcatheter Valve Repair and Replacement, Part 1: Transcatheter Aortic Valve Replacement

Transcatheter aortic valve implantation. Expert Consensus of the Association of Cardiovascular Interventions of the Polish Cardiac Society and the Polish Society of Cardio-Thoracic Surgeons, approved by the Board of the Polish Cardiac Society and National Consultants in Cardiology and Cardiac Surgery

Rev Port Cardiol. 2013;32(10):801–805

ELSEVIER DOYMA

Revista Portuguesa de **Cardiologia**
Portuguese Journal of **Cardiology**
www.revportcardiol.org

POSITION STATEMENT

Position statement on transcatheter aortic valve implantation in Portugal☆

Rui Campante Teles[a,*], Vasco Gama Ribeiro[b], Lino Patrício[c], José Pedro Neves[d], Luís Vouga[e], José Fragata[f], Manuel Almeida[a], Pedro Braga[b], Duarte Cacela[c], Miguel Abecasis[d], Pedro Canas da Silva[g], Hélder Pereira[h]

POSITION PAPER

Documento di posizione della Società Italiana di Cardiologia Invasiva (SICI-GISE) sui requisiti minimi per ospedali ed operatori che eseguono procedure di impianto transcatetere di protesi valvolare aortica in pazienti con stenosi valvolare severa sintomatica

Gennaro Santoro[1], Francesco Bedogni[2], Vittorio Ambrosini[3], Sergio Berti[4], Anna Sonia Petronio[5], Angelo Ramondo[6], Alessandro Salvi[7], Giovanni Sorropago[3], Gian Paolo Ussia[8], Alberto Cremonesi[9]

Heart, Lung and Circulation (2015) **24**, 219–223
1443-9506/04/$36.00
http://dx.doi.org/10.1016/j.hlc.2014.09.009

POSITION STATEMENT

Position Statement for the Operator and Institutional Requirements for a Transcatheter Aortic Valve Implantation (TAVI) Program

Darren L. Walters[a,*], Mark Webster[b], Sanjeevan Pasupati[c], Antony Walton[d], David Muller[e], Jim Stewart[b], Michael Williams[f], Andrew MacIsaac[g], Greg Scalia[a,h], Michael Wilson[i], Adam El Gamel[c], Andrew Clarke[j], Jayme Bennetts[k], Paul Bannon[i]

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[g]St Vincent's Hospital, Victoria 3065, Australia
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[i]Cardiothoracic Surgery, RPAH Medical Centre and The Heart Care Centre, Sydney, New South Wales, Australia
[j]Department of Cardiothoracic Surgery, Prince Charles Hospital, Queensland 4032, Australia
[k]Flinders Medical Centre, South Australia 5042, Australia

The SICI-GISE Position Paper

POSITION PAPER

Documento di posizione della Società Italiana di Cardiologia Invasiva (SICI-GISE) sui requisiti minimi per ospedali ed operatori che eseguono procedure di impianto transcatetere di protesi valvolare aortica in pazienti con stenosi valvolare severa sintomatica

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[1]*Azienda Ospedaliero-Universitaria Careggi, Firenze*
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[3]*Clinica Montevergine, Mercogliano (AV)*
[4]*Ospedale "G. Pasquinucci", Fondazione "G. Monasterio", Massa*
[5]*Azienda Ospedaliero-Universitaria Pisana, Pisa*
[6]*Ospedale San Bassiano, Bassano del Grappa (VI)*
[7]*Azienda Ospedaliero-Universitaria, Ospedali Riuniti, Trieste*
[8]*Policlinico Ferrarotto, Catania*
[9]*Sansavini Foundation, Cotignola (RA)*

At present, transcatheter aortic valve implantation (TAVI) is a proven treatment option for patients with symptomatic degenerative aortic stenosis at high risk for conventional surgery. In countries where TAVI is currently performed, the number of procedures and centers involved has been continuously increasing. The present document from the Italian Society of Interventional Cardiology (SICI-GISE) aims to improve the available evidence and current consensus on this topic through the definition of training needs and knowledge base for both operators and centers.

Key words. Operators; Training programs; Transcatheter aortic valve implantation.

G Ital Cardiol 2011;13(11):772-776

2011 Position Paper Objectives

- **Define structural and organizational requirements of TAVI center**
- **Establish training programs for proctors and operators**

THE SICI-GISE POSITION PAPER

POSITION PAPER

Update del documento di posizione della Società Italiana di Cardiologia Interventistica (SICI-GISE) sui requisiti minimi per ospedali ed operatori che eseguono procedure di impianto transcatetere di protesi valvolare aortica

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NEW POSITION PAPER OBJECTIVES

- **Re-define structural and organizational requirements of TAVI center**
- **Re- Establish training programs for proctors and operators - *revised***
- **Periprocedural set-up**


Institutional
requirements

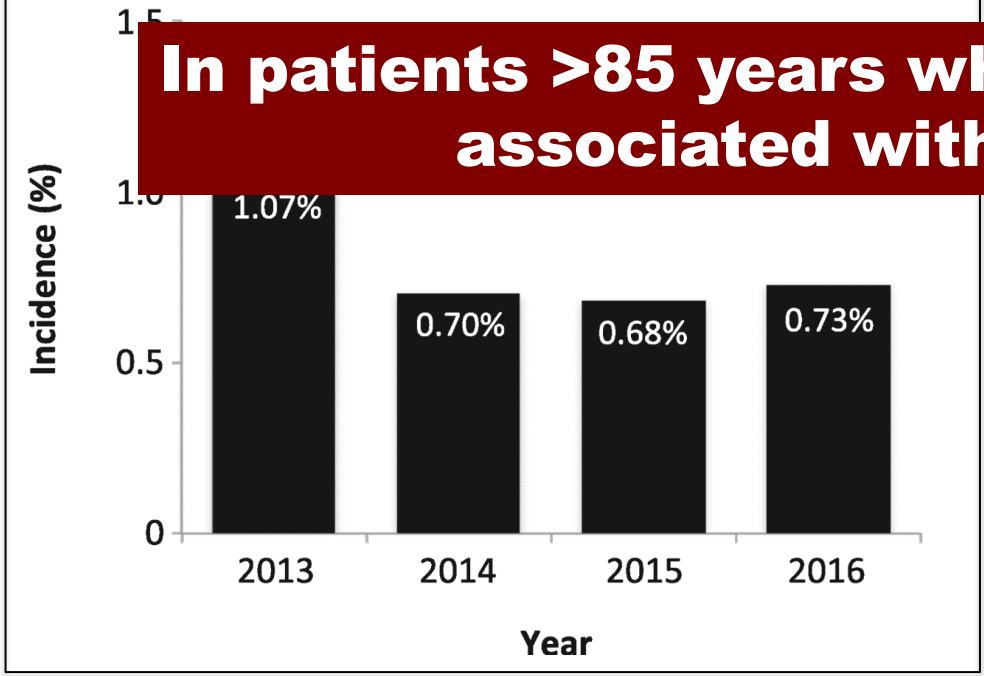
INSTITUTIONAL REQUIREMENTS- *ESSENTIALS*

1. CENTRES WITH BOTH DEPARTMENTS OF CARDIOLOGY AND CARDIAC SURGERY ON SITE

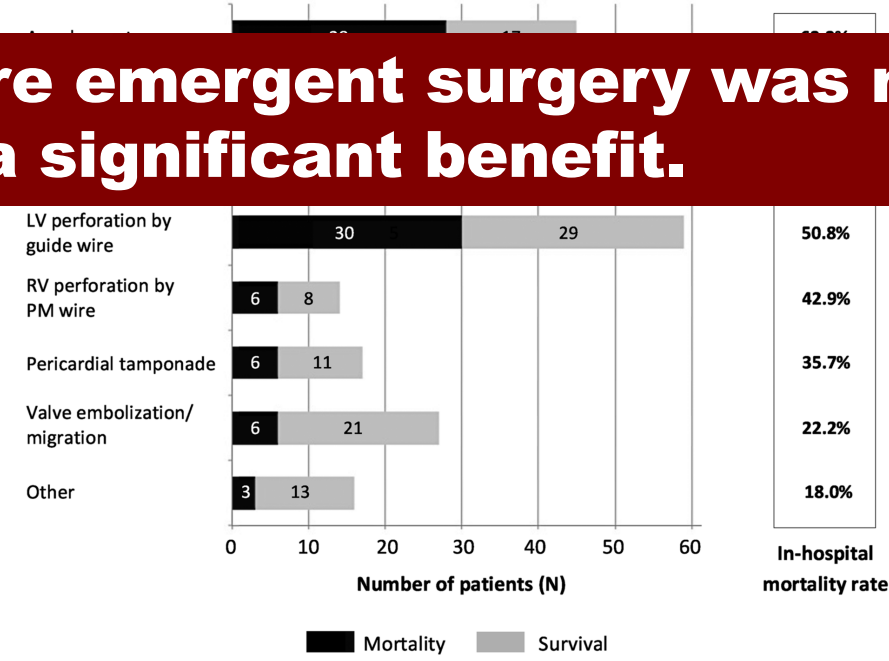
European Registry on Emergent Cardiac Surgery during TAVI (EuRECS-TAVI)
including 27,760 TF-TAVI procedures between 2013 and 2016

In patients >85 years where emergent surgery was not associated with a significant benefit.

EMERGENT CARDIAC SURGERY AND TAVI



COMPLICATIONS AND MORTALITY



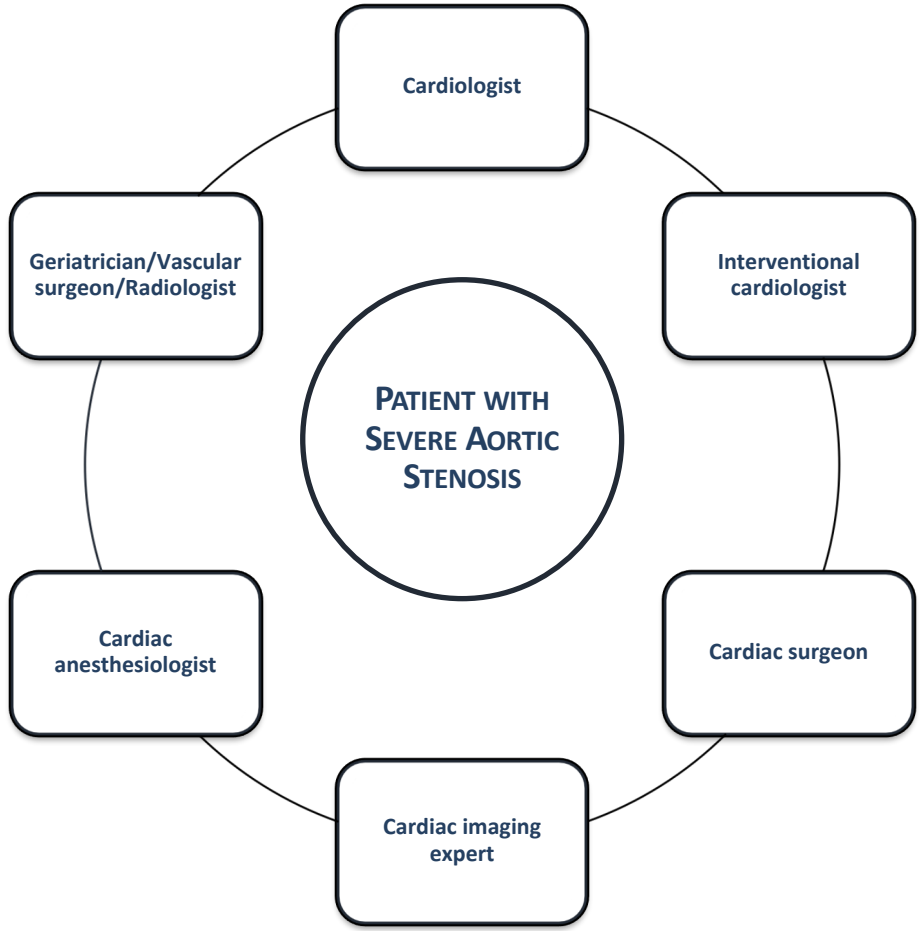
Eggebrecht H et al, *Eur Heart J.* 2018 Feb 21;39(8):676-684

INSTITUTIONAL REQUIREMENTS- *FACILITIES*

1. Minimum activity level of 3 (preferably 5)/monthTAVI/month
2. On site cardiac surgery performing SAVR
    - Annual mortality rate <6%
3. At least 2 Cath-lab laboratories (or one cath lab and one hybrid room)
    - 1000 coronary angiographies/year
    - 400 PCI/year
4. Post-procedure intensive care facility
5. Electrophysiology laboratory
6. Anesthesia unit with cardiac anesthesiologists
7. Vascular surgery
8. Cardiology unit with telemetry
9. Radiologic imaging: cardiac CT capabilities
10. Staffing specialities: neurology, nephrology, geriatry and/or internal medicine
11. Participation in national registries collecting data on all patients undergoing TAVI

INSTITUTIONAL REQUIREMENTS- *ESSENTIALS*

2. Multidisciplinary Heart Team



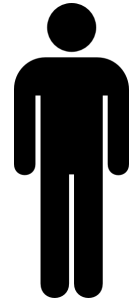
CATHETERIZATION LAB OR HYBRID ROOM

1. Surgical instruments
2. Wires, catheters, and balloons for valvuloplasty and prosthesis implantation
3. Temporary pacemaker with pacing ability
4. Instruments for emergency pericardiocentesis
5. Material for endovascular procedures: aortic occlusion balloon catheters, wires and balloon for peripheral arteries, covered stents, long sheats of at least 20 F
6. Retrieval instruments (snare) of different sizes
7. Wires, catheters and balloons for percutaneous coronary procedures

INSTITUTIONAL REQUIREMENTS - *TEAM LEADER*

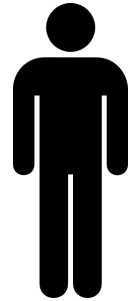
FIRST operator = TEAM LEADER

TRANSFEMORAL AND TRANSSUBCLAVIAN TAVI



***Skills*: Perform valve implantation**
Manage complications with a transcatheter approach

TRANSAPICAL AND TRANSAORTIC TAVI



***Skills*: Perform valve implantation**
Manage complications requiring surgical intervention

OPERATORS REQUIREMENTS

1. To be TF/TS first operator, since at least 5 years, for coronary angiography, PCI, cardiac catheterization, temporary pacemaker implantation
2. To perform more than 75 procedures/year (in a center with a total number of more than 400 PCI/year)
3. To perform diagnostic and interventional procedures through radial and femoral access and to use retrieval systems
4. To have performed as first operator:
   - Aortic valvuloplasty
   - Pericardiocentesis (elective or urgent)
   - Angiography and percutaneous interventions on peripheral vessels

"OLD-FASHION" WORK-UP SAS

PRE-PROCEDURAL PHASE

Referring Physician
Detection of AS

Referring Cardiologist: ECHO
Confirmation of AS, severity, clinical/psychocosial status, comorbidities
Which possible therapeutic option?
Discussion with patient and relatives

CARDIAC SURGEON (refusal)

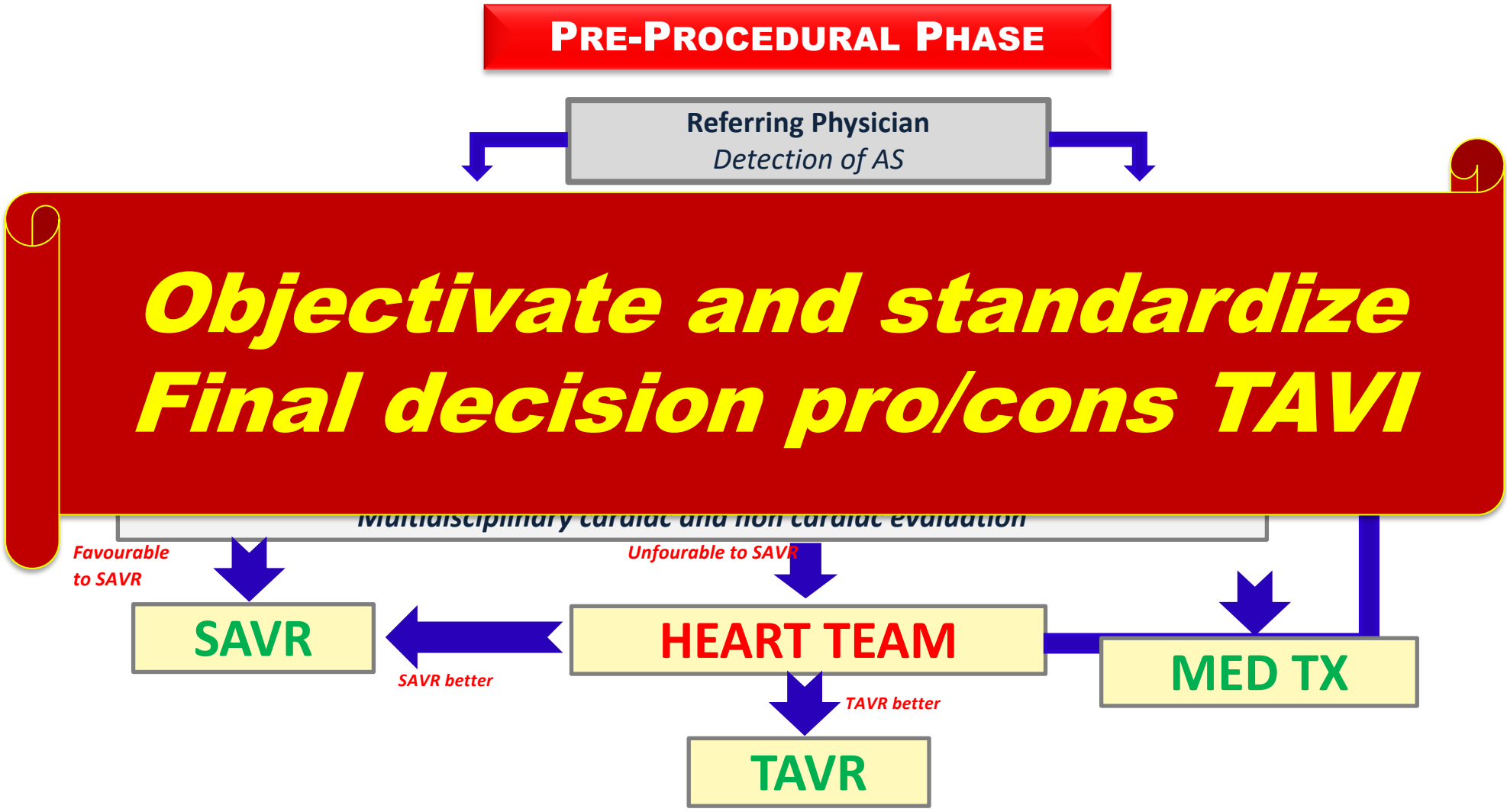
Multidisciplinary cardiac and non cardiac evaluation

HEART TEAM

TAVR

MED TX

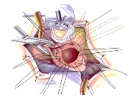
"UPDATED" WORK-UP SAS



GISE
Società Italiana di Cardiologia Interventistica

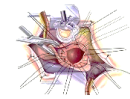
Check List for the Choice of TAVI or SAVR

Clinical Characteristics

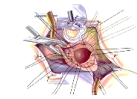
	Favours TAVI	Favours SAVR
STS/EuroSCORE II<4%		+
STS/EuroSCORE II≥4%	+	
Severe comorbidity	+	
Age < 75 years		+
Age ≥ 75 years	+	
Previous cardiac surgery	+	
Frailty	+	
Restricted mobility and conditions that may affect the rehabilitation process	+	
Suspicion of endocarditis		+

Anatomic Characteristics

	Favours TAVI	Favours SAVR
Favourable for TF access	+	
Sequelae of chest radiation	+	
Porcelain aorta	+	
Intact bypass at risk in case of sternotomy	+	
Expected patient-prosthesis mismatch	+	
Severe chest deformation	+	
Short distance between coronary ostia and aortic annulus	+	
Annulus out of range for TAVI		+
Aortic root unfavourable for TAVI		+
Thrombi in aorta or LV		+
Valve morphology (bicuspid, calcification)		+

Other Cardiac Conditions

	Favours TAVI	Favours SAVR
Severe CAD requiring CABG		+
Severe primary mitral disease which could be treated surgically		+
Severe tricuspid valve disease		+
Aneurysm of the ascending aorta		+
Septal hypertrophy requiring myectomy		+

Prospettive future

- INTERMEDIATE RISK POPULATION C.ca 10.000 TAVI/anno = 166 TAVI/milione ab.
- Garantire numeri minimi (100 laboratori TAVI, 10.000 procedure/anno = 100 TAVI/anno)
- Accordi interaziendali trasversali per la strutturale
- Rimodulazione CCH, spostamento budget
- Incremento procedure = riduzione costi
- Ruolo aziende di device

Corrado Tamburino TH GISE Milano Aprile 2017

PROCESSO AI GRANDI TRIAL

Lo studio SURTAVI

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Chiaramente sono state eseguite in centri con cardiochirurgia on-site attraverso una indispensabile collaborazione e confronto con il cardiochirurgo e il cardioanestesista nell'ambito dell'Heart Team. La procedura TAVI però rende ancora più centrale rispetto al passato la figura del cardiologo che in questo momento è in grado di eseguire diagnosi della patologia, stratificare la prognosi, indicare il tipo e il momento del trattamento e adesso eseguire in prima persona il trattamento stesso per via transcatetere.