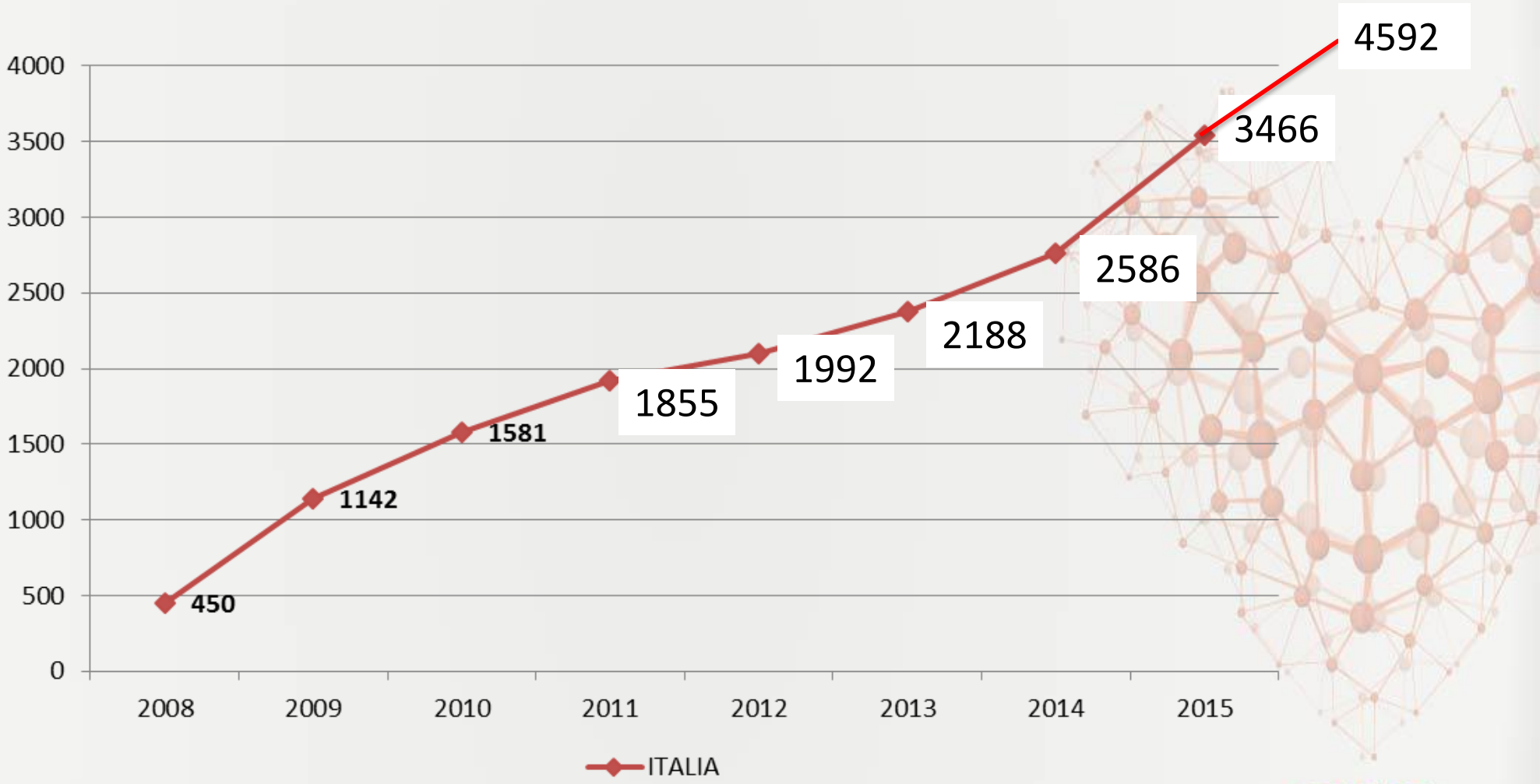
La TAVI è una metodica oramai consolidata con costi crescenti. Analizziamo i risultati immediati e a distanza: la stiamo usando nei pazienti “giusti”?”

Giuseppe Musumeci

SC Cardiologia

Ospedale Santa Croce e Carle, Cuneo

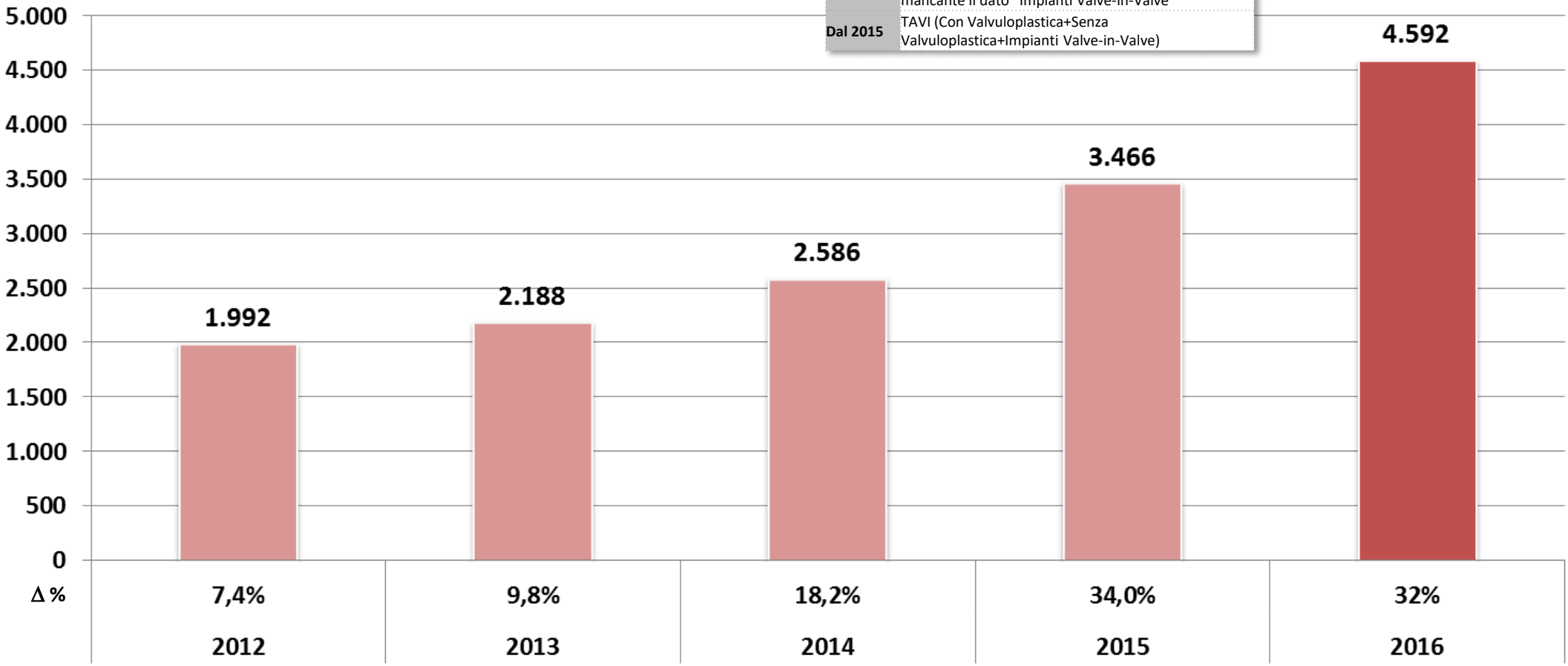
Numero impianti TAVI - Italia



Fonte: adattato da Società Italiana di Cardiologia Invasiva – GISE

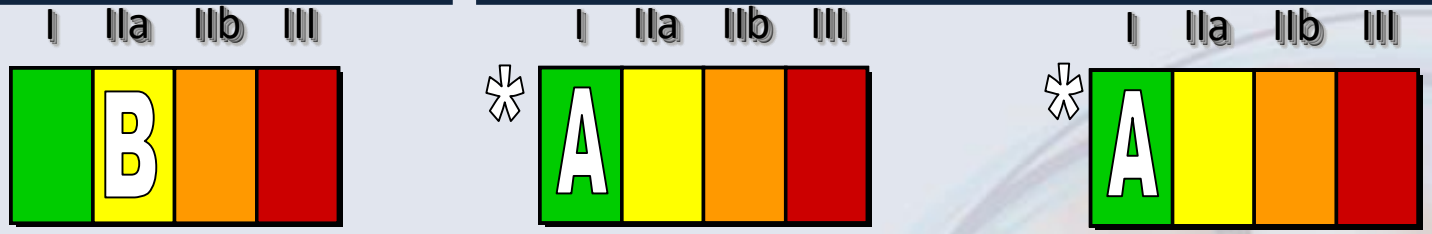
TAVI
SERIE STORICA

	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)

* upgraded

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

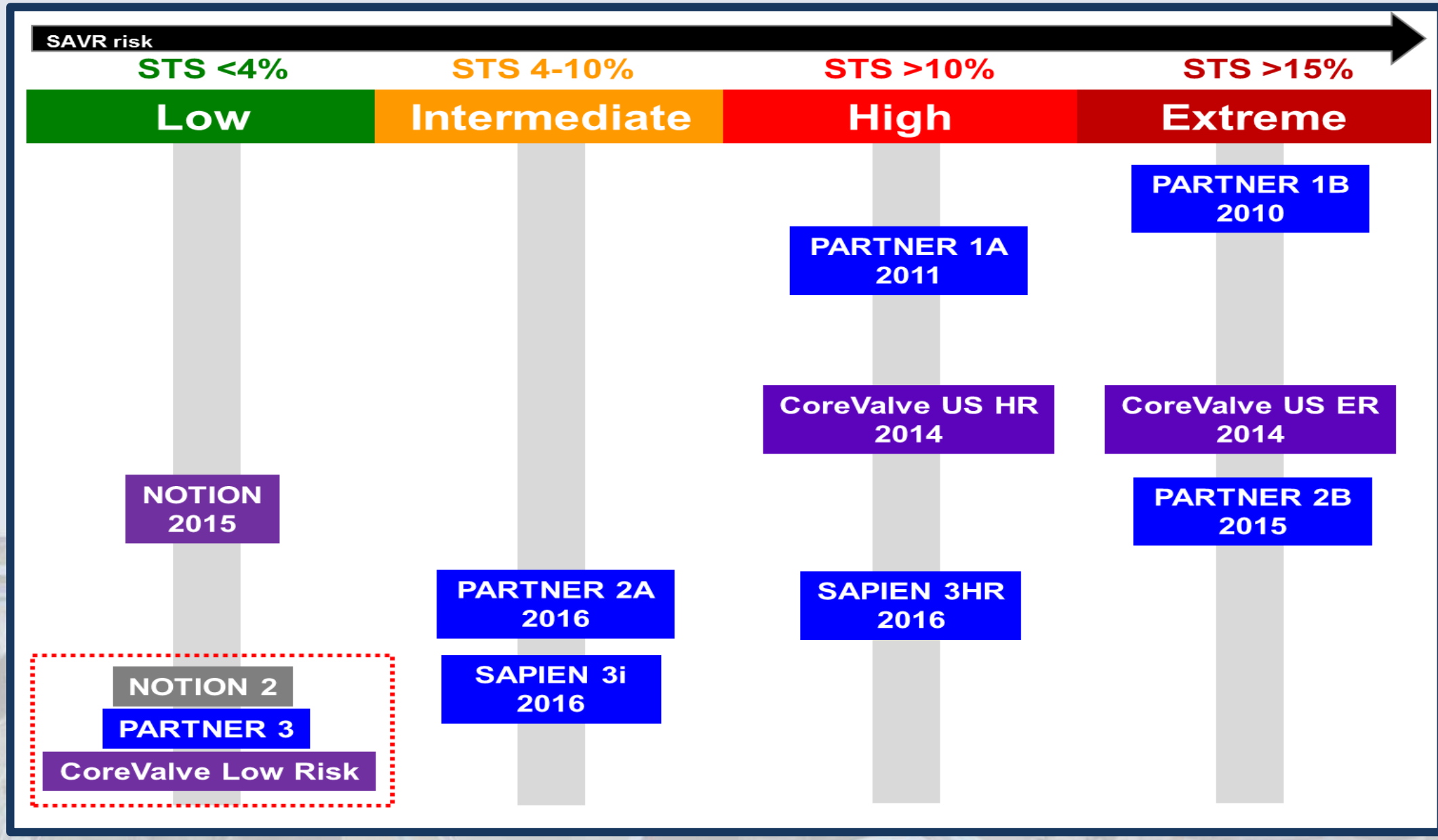
2017 ESC/EACTS Guidelines for the management of valvular heart disease

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



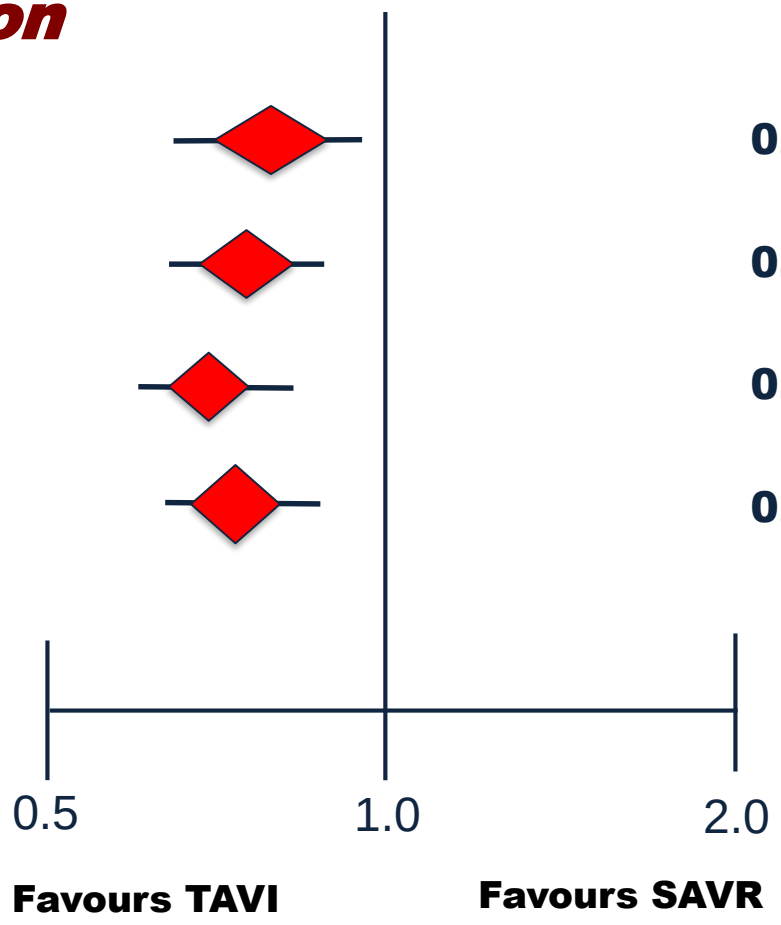
TAVI vs SAVR: Meta-Analysis Of 4 Randomized Trials

	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

Study Design

Symptomatic Severe Aortic Stenosis

ASSESSMENT by Heart Valve Team

Operable (STS ≥ 4%) – **5.8**

Age – 82

Randomized Patients n = 2032

Yes

ASSESSMENT:
Transfemoral Access

Transfemoral (TF)

Transapical

1:1 Randomization (n = 1550)

1:1 Rand

TF TAVR
(n = 775)

vs.

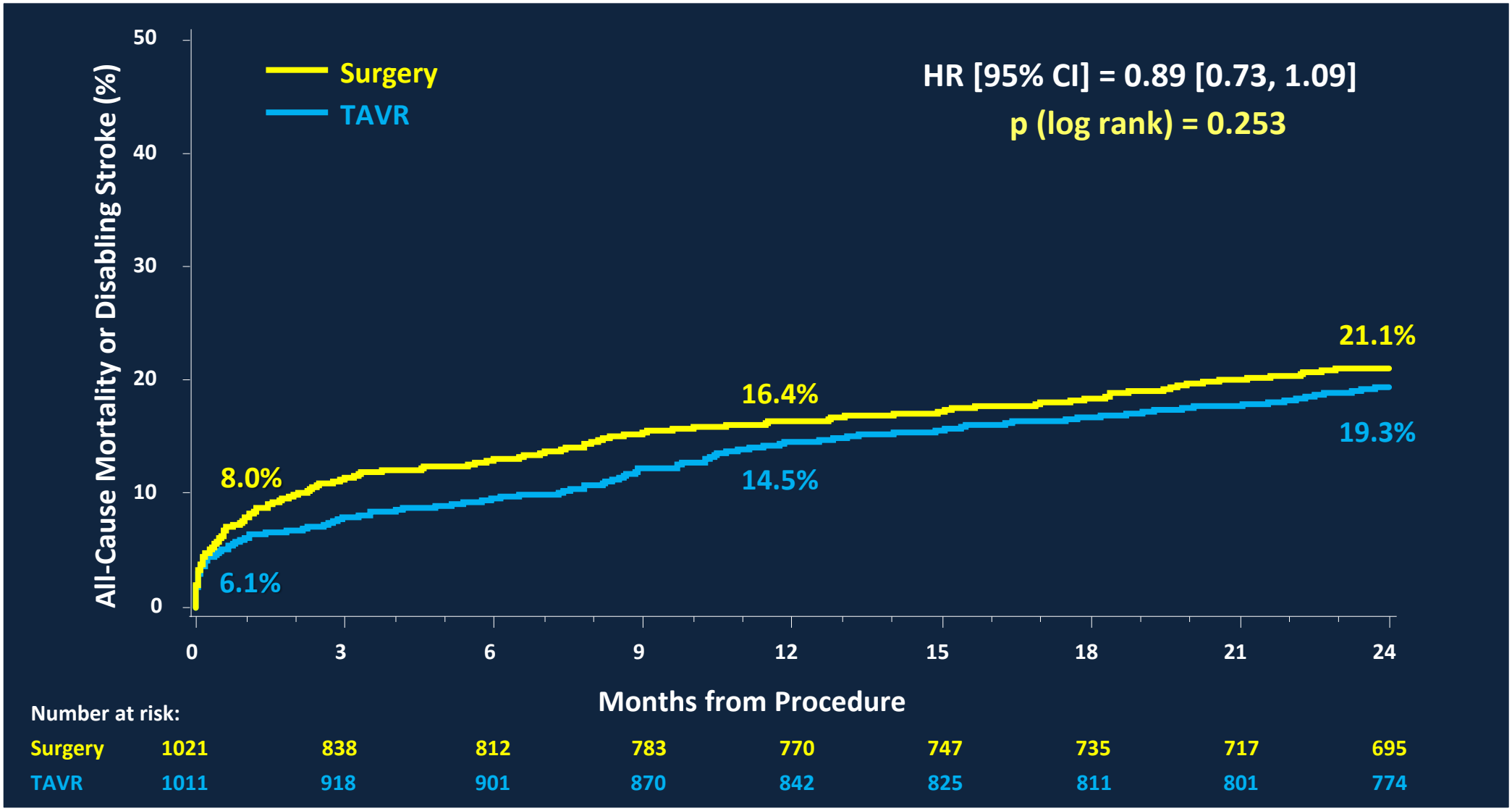
Surgical AVR
(n = 775)

TA/TAo TAVR
(n = 236)

I° EP: All-Cause Mortality or Disabling Stroke at

Leon M, et al. NEJM 2016

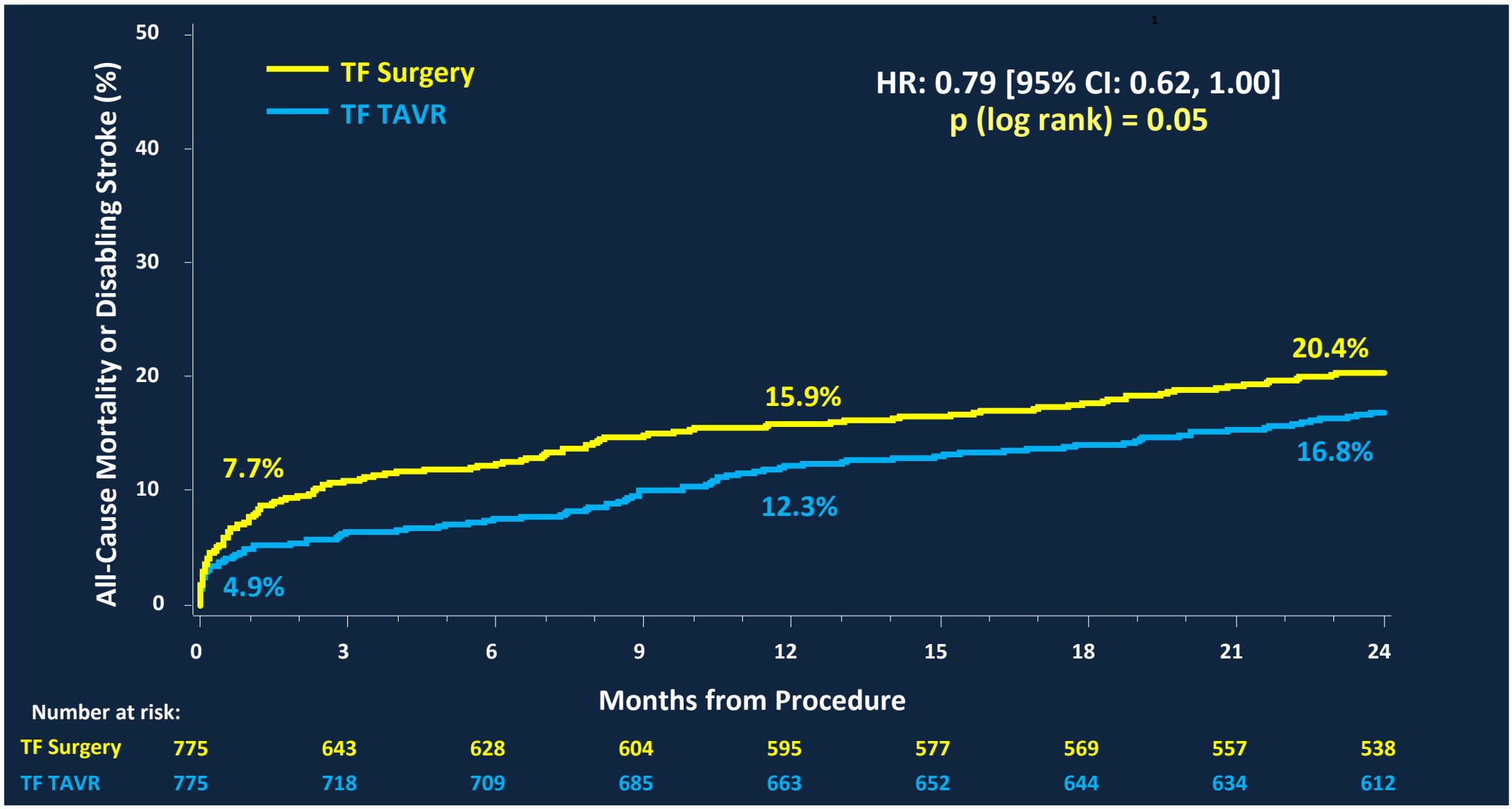
I° EP (ITT):
All-Cause Mortality or Disabling Stroke



Leon M, et al. NEJM 2016

I° EP (ITT) - TF

All-Cause Mortality or Disabling Stroke



Leon M, et al. NEJM 2016

European Heart Journal
doi:10.1093/eurheartj/ehw112

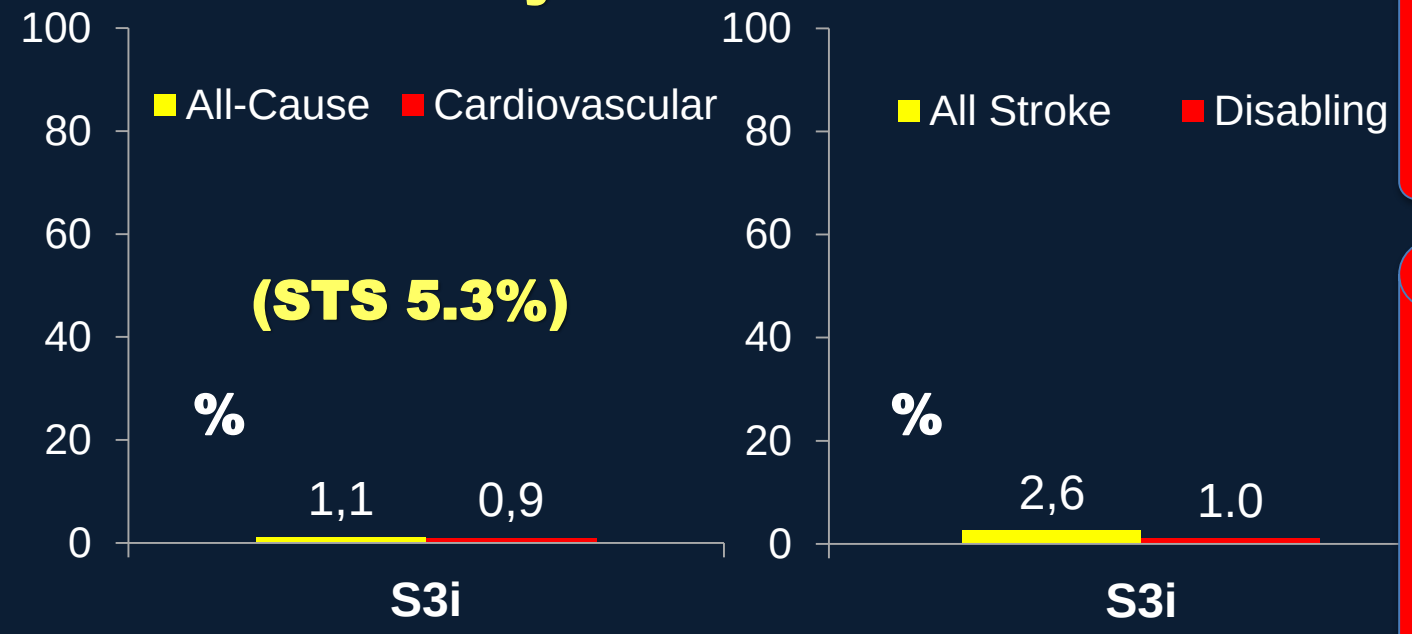
SEARCH
TAVI

Large registry # 1

Early clinical and echocardiographic outcomes after SAPIEN 3 transcatheter aort

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 Craig Miller, Craig R Smith, Maria C Alu, Rupa Pappiatapeni, Ralph R D'Agostino Jr, Martin B Leon

Propensity *"SCORE"* 1-year results

STS – 5.3

Sapien 3 Intermediate Risk Registry

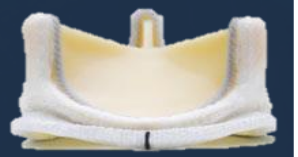
AGE 82

N=1077

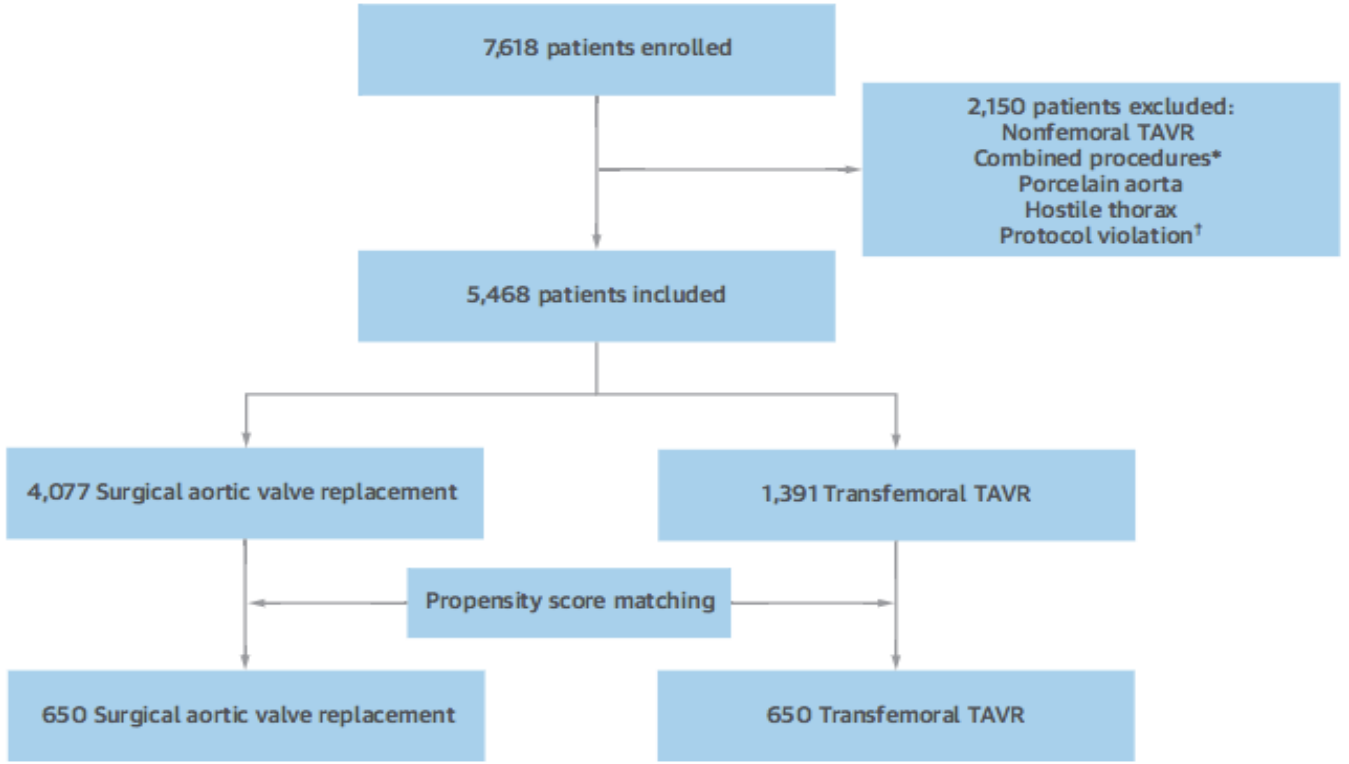
Surgical AVR arm Partner 2A trial

AGE 82

N=944



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



registry # 3

http://dx.doi.org/10.1016/j.jacc.2015.06.013

CrossMark

ent

ucci, MD,§ Francesco Onorati, MD,‖
aro Santoro, MD,**
RVANT Research Group

- ❑ **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
Study Design

Symptomatic Severe Aortic Stenosis

Intermediate Surgical Risk
STS PROM ≥3% and <15%

Heart Team Evaluation
Assess inclusion/exclusion
Risk classification

Screening Committee
Confirmed eligibility

Randomization n=1,746
Stratified by need for revascularization

Baseline neurological assessments

94% TF

TAVR N=864
age 79.9 – mean STS 4.4%

TAVR only

TAVR + PCI

SAVR N=796
age 79.6 – mean STS 4.5%

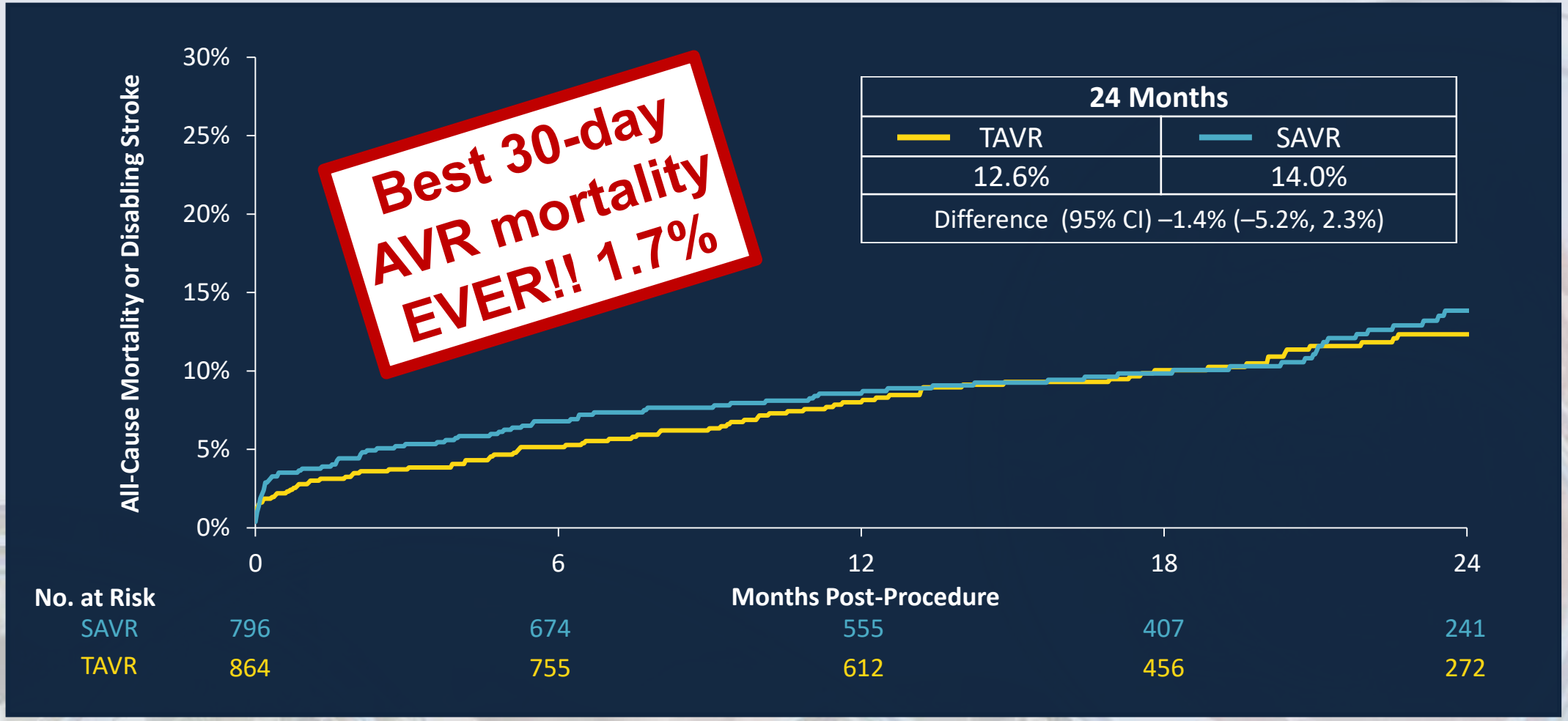
SAVR only

SAVR + CABG

I° EP: All-Cause Death or Disabling Stroke at 2 Years (non-inferiority)

Reardon M, ACC 2017

All-Cause Mortality or Disabling Stroke



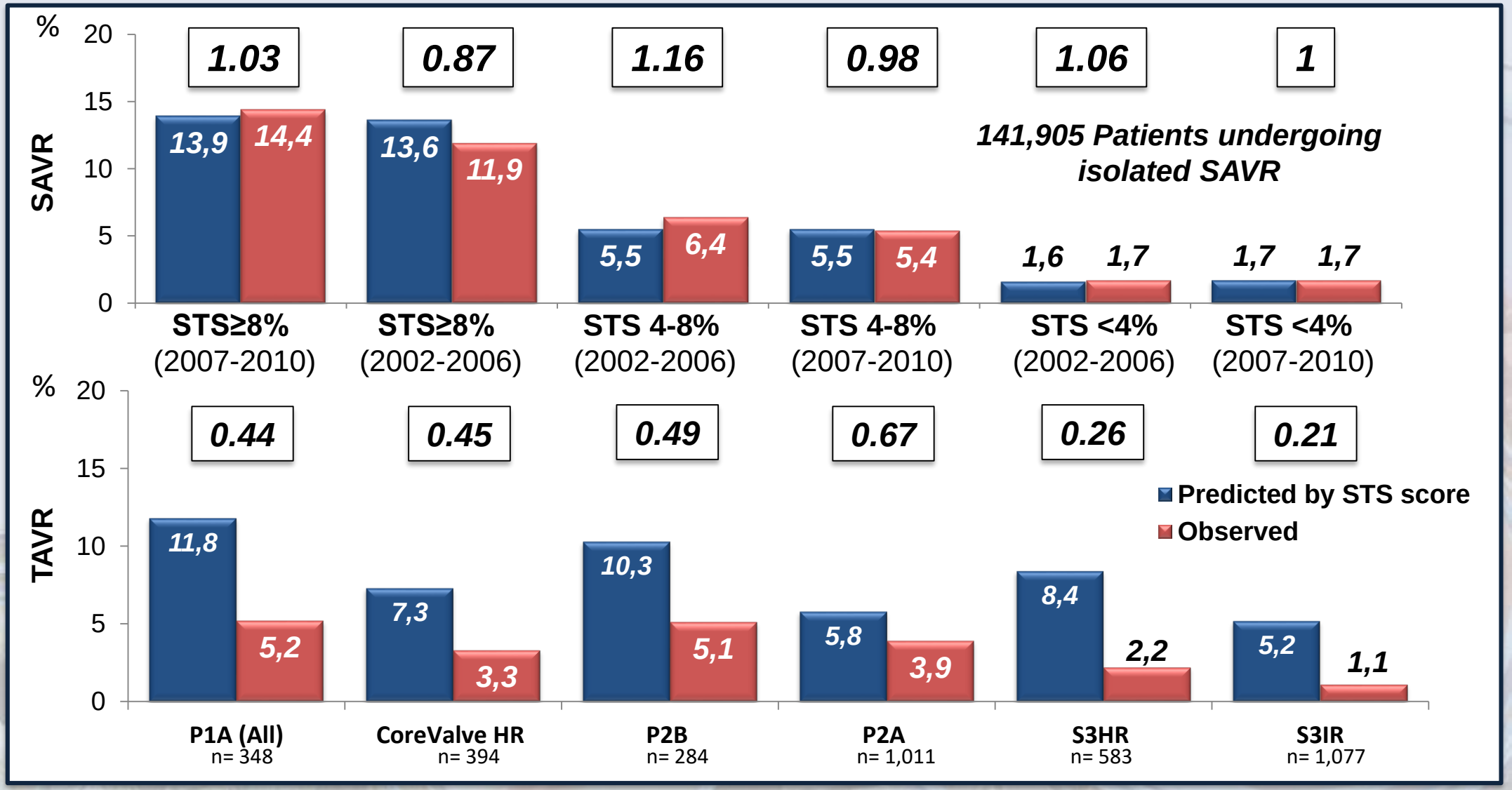
Reardon M, ACC 2017

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

Observed vs. predicted mortality at 30 days after SAVR or TAVI

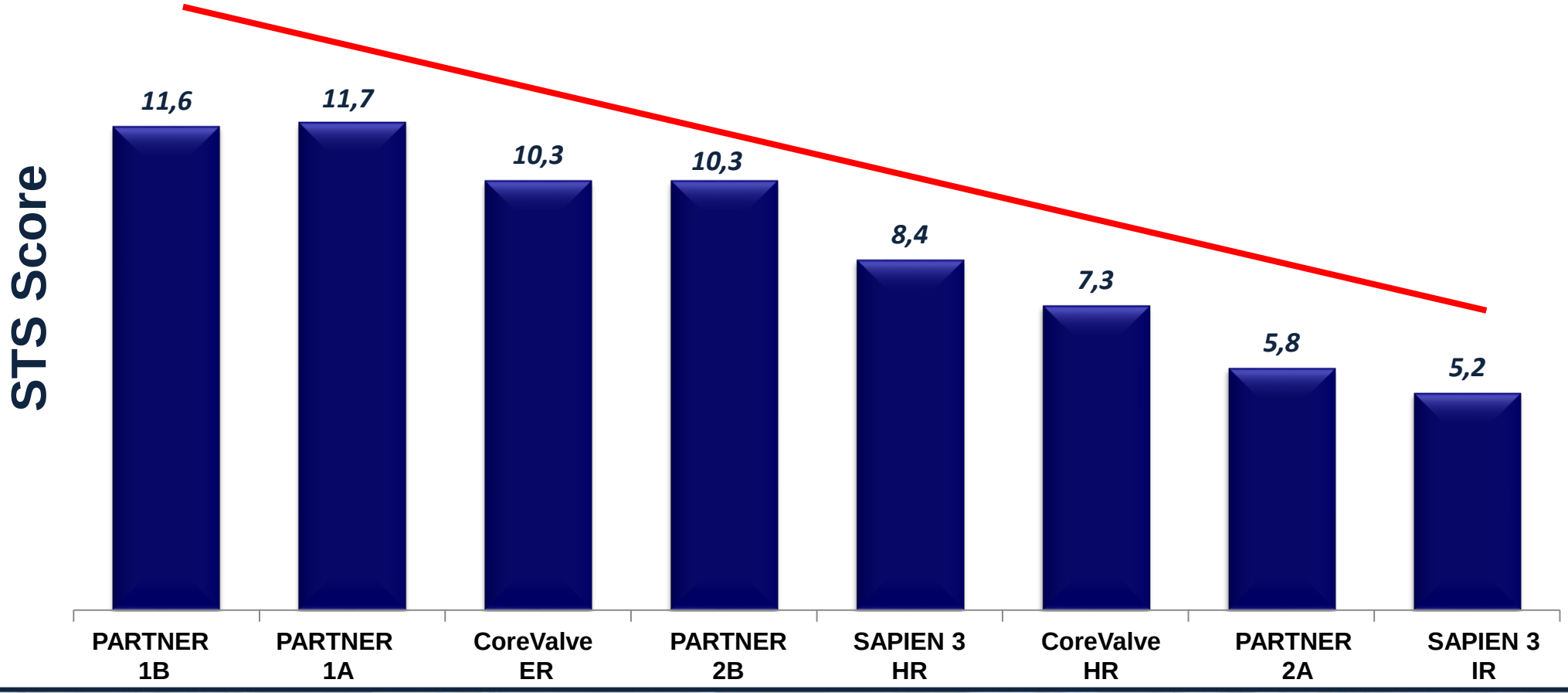


Thourani et al, Ann Thorac Surgery 2015
Pilgrim et al, JACC 2015

SURGICAL RISK AND AGE

Mean Age across studies:

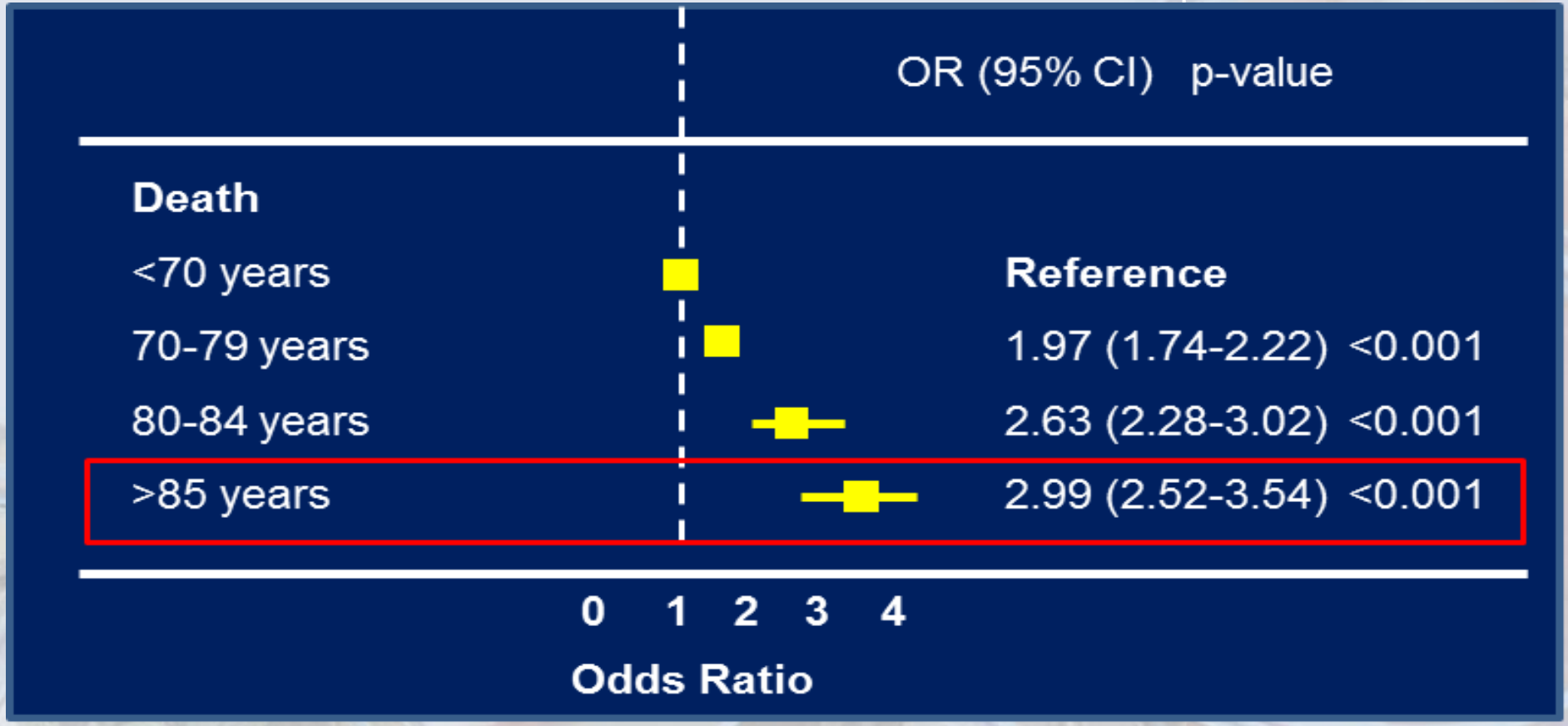
PARTNER 1B	PARTNER 1A	CoreValve ER	PARTNER 2B	SAPIEN 3 HR	CoreValve HR	PARTNER 2A	SAPIEN 3 IR
83	84	83	83	84	82	83	82



FACTORS FAVORING TAVR VS. SAVR

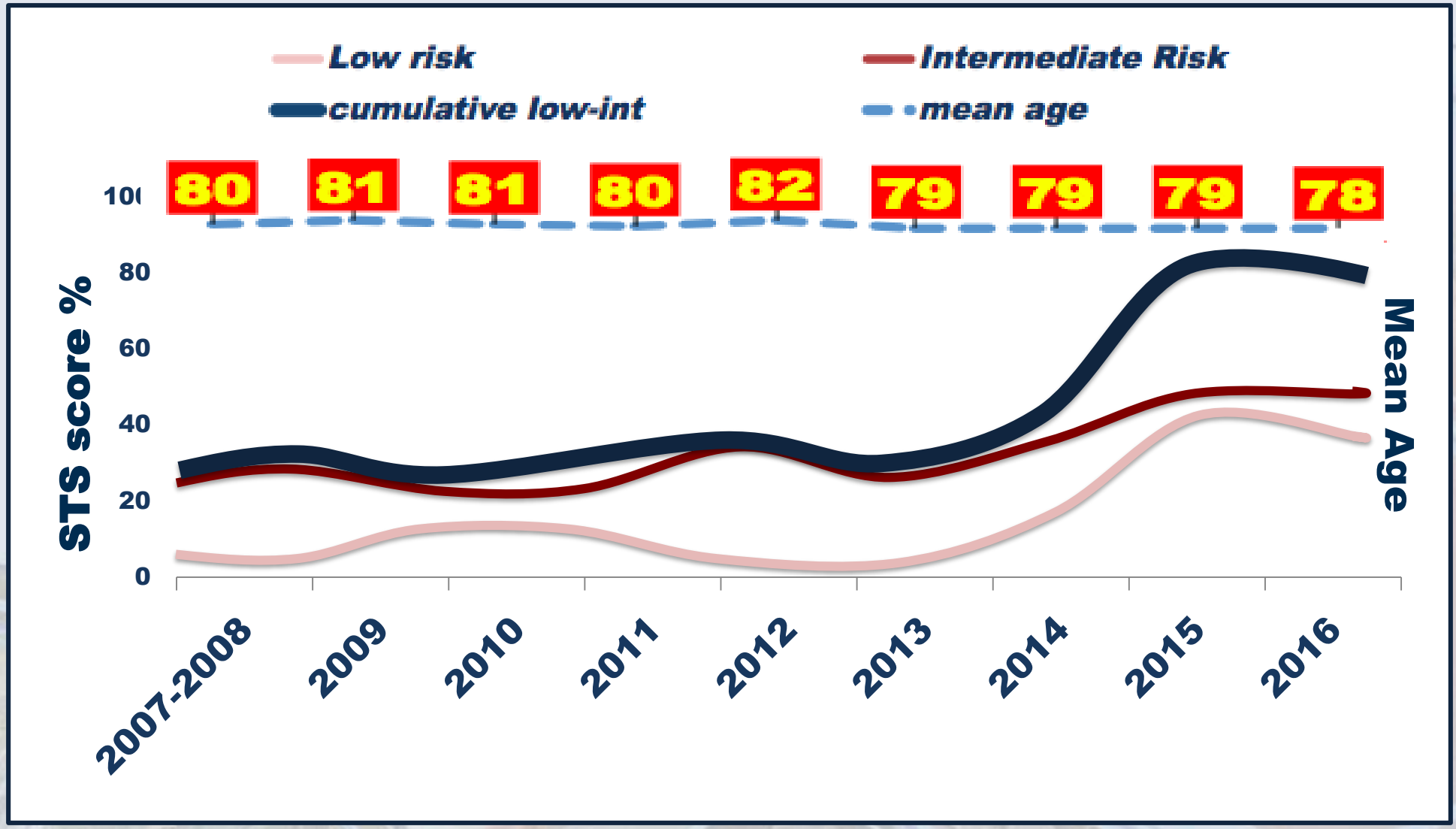
SAVR – US Registry - 104,699 pts

Mean age 70 yrs



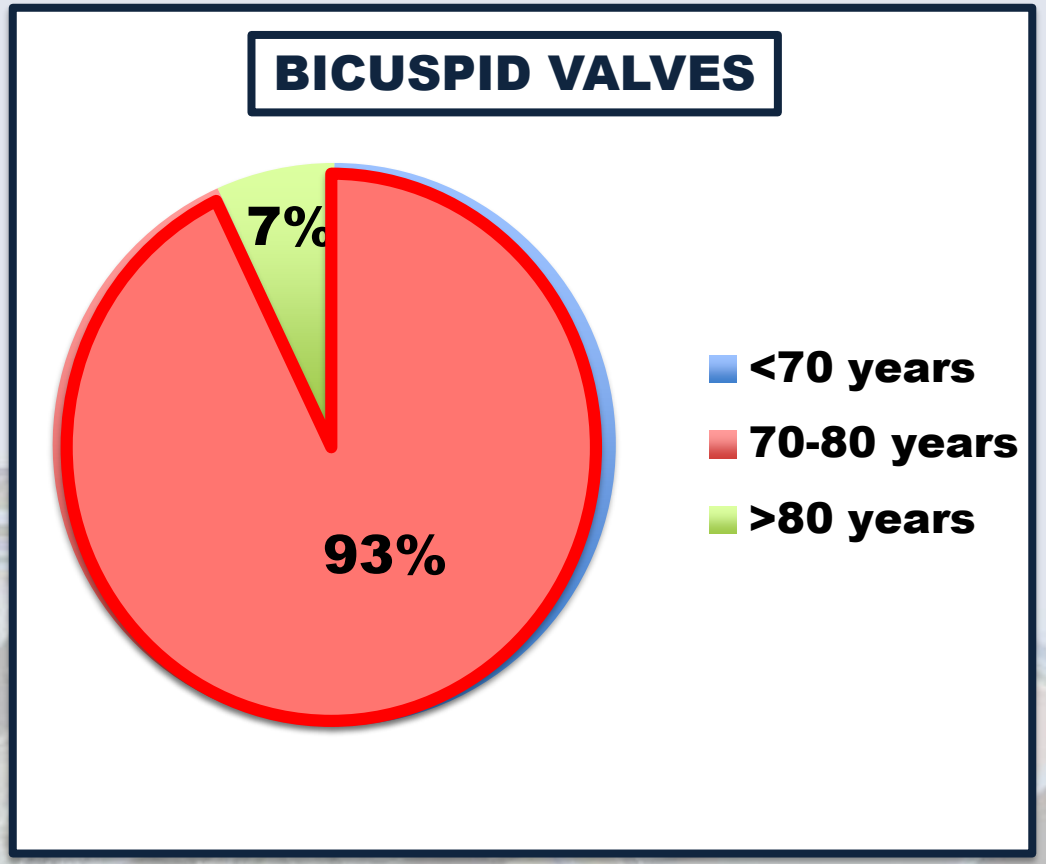
Agarwal et al. J Thorac Cardiovasc Surg 2015

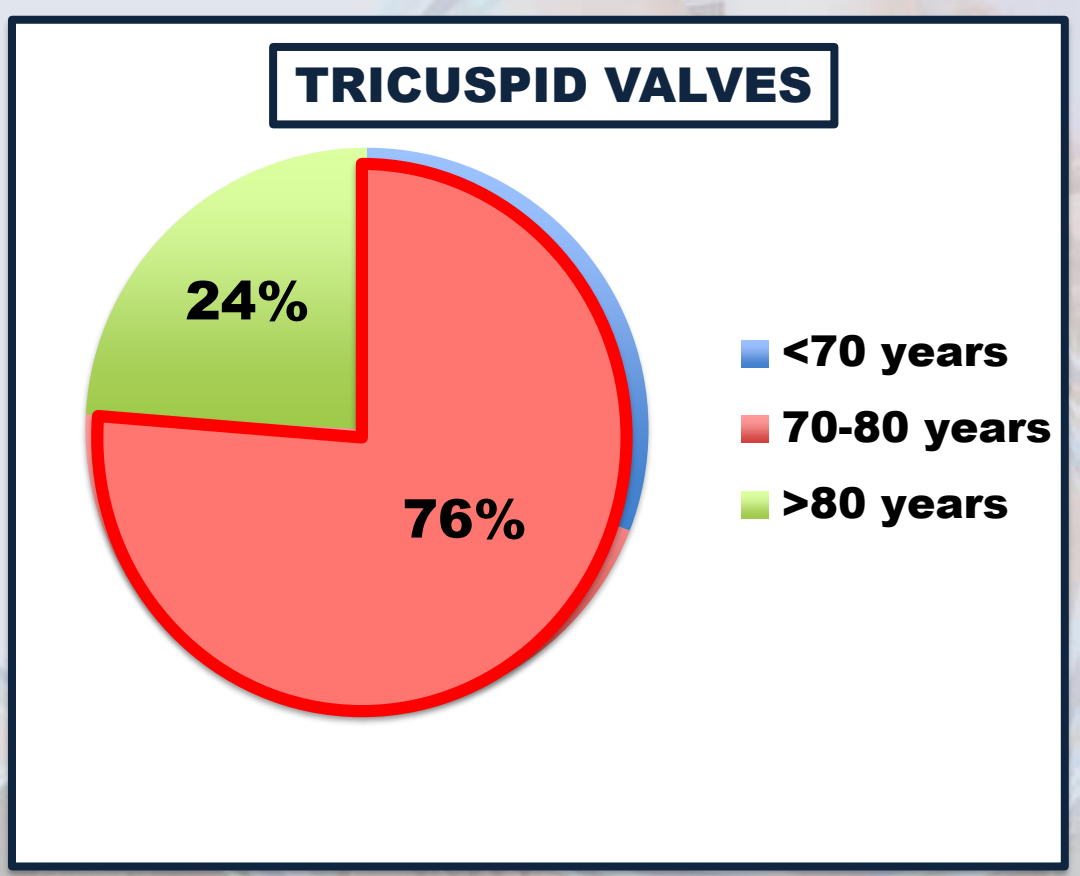
PURE VALVE Registry 2007-2015 – 752 TAVR pts



Severe aortic stenosis: age distribution

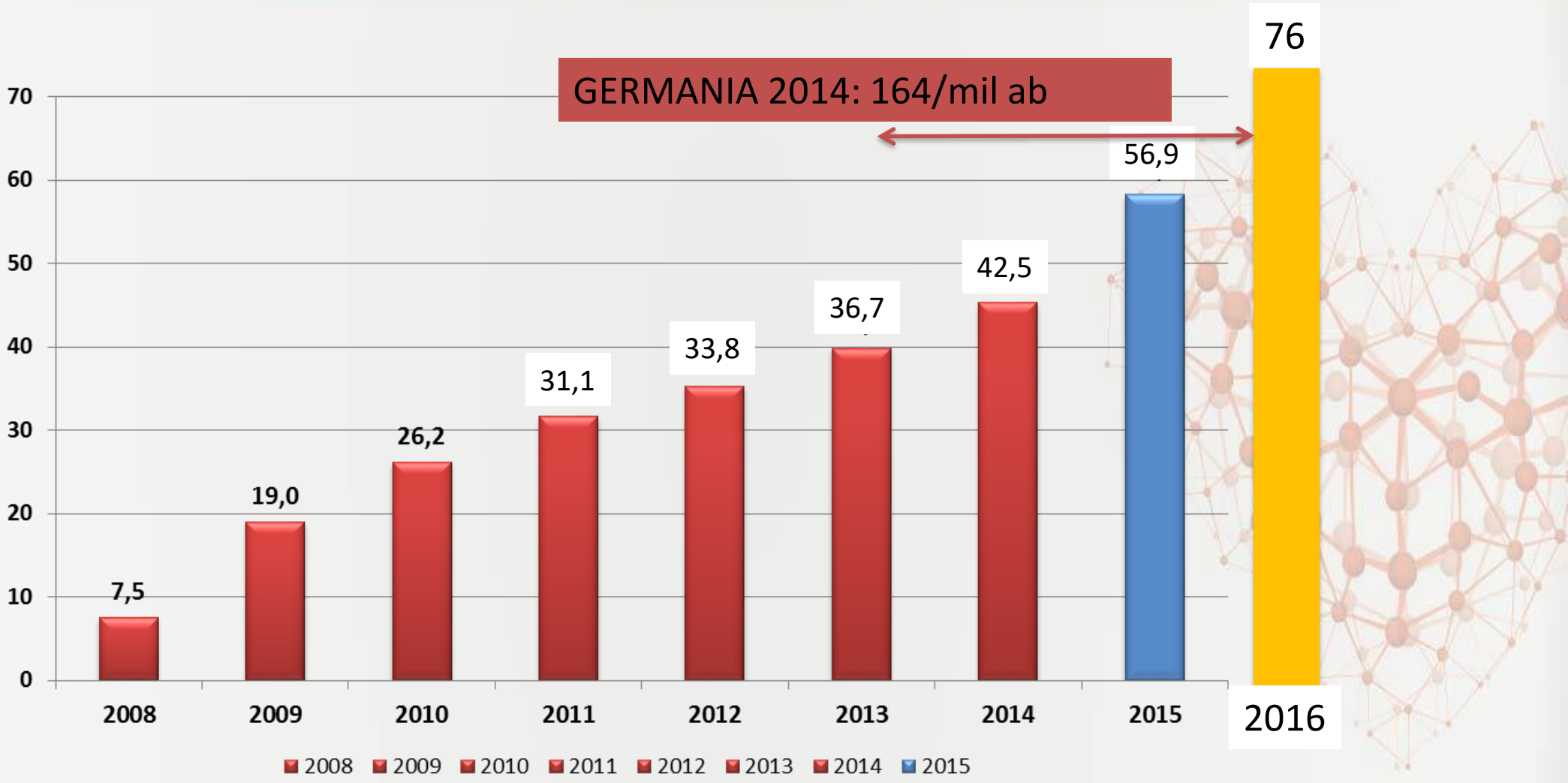
Severe aortic stenosis in patients undergoing AVR
n=932 pts





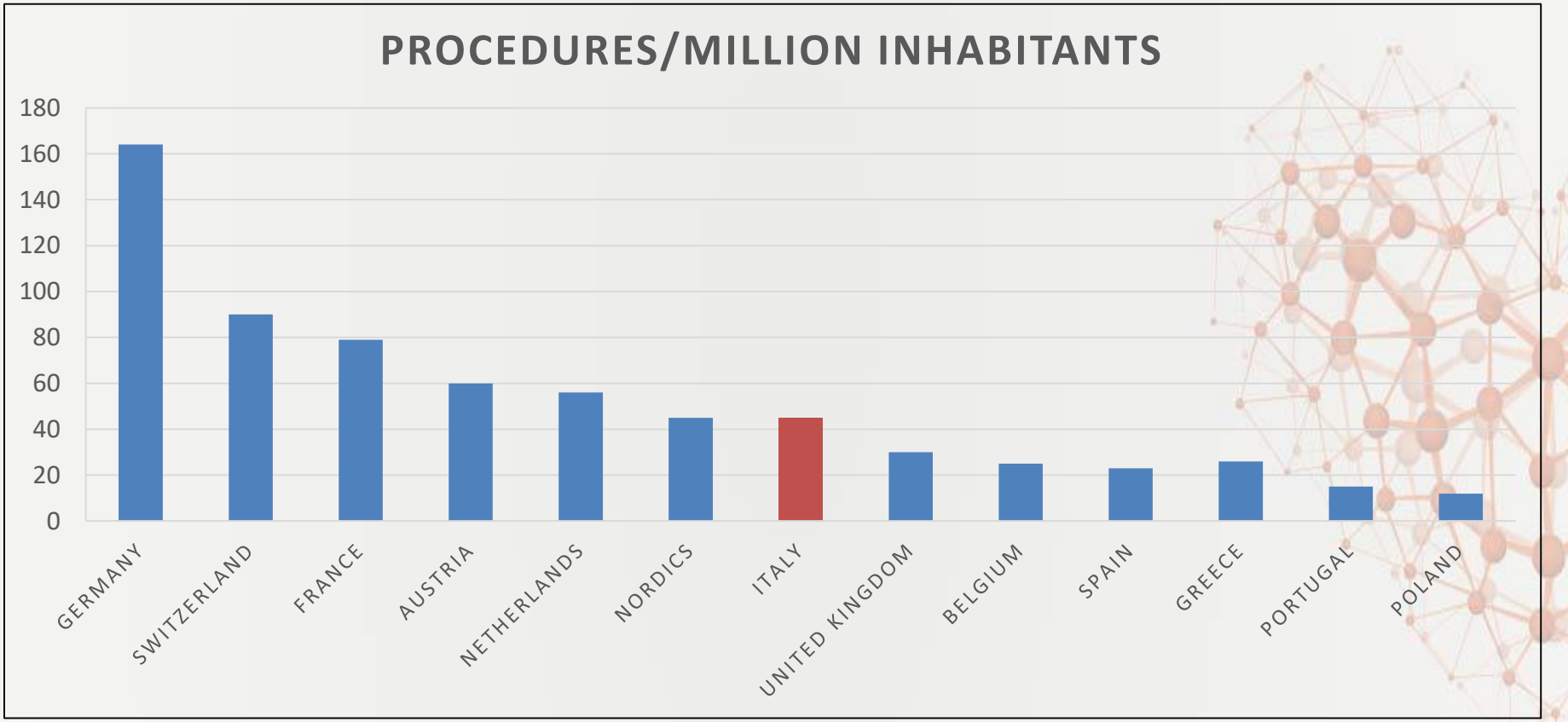
Roberts W, Circulation 2005

TAVI per milione di abitanti - Italia



Fonte: adattato da Società Italiana di Cardiologia Invasiva - GISE

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)

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

Interventional Cardiology

Our Message:

ADAPT

and

EVOLVE !

GISE
Società Italiana di Cardiologia Interventistica

PROCESSO AI GRANDI TRIAL

Lo studio SURTAVI

Giorgio Baralis[1], Giuseppe Musumeci[1], Francesco Musumeci[2]

[1]S.C. Cardiologia, A.O. Santa Croce e Carle, Cuneo

[2]U.O.C. Cardiochirurgia e Centro Trapianti di Cuore, Dipartimento Cardiovascolare, A.O. San Camillo-Forlanini, Roma

degenza estremamente limitati. 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.


NBC
“Non mi preoccupo mai del futuro, arriva sempre abbastanza presto”
ALBERT EINSTEIN