

**TURIN,
October
25th-27th
2018
Starhotels
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GIORNATE CARDIOLOGICHE **TORINESI**



TAVI lower risk 2018 **Is it a business for Interventional Cardiology?**

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Professor and Director of Interventional
Cardiology, University of Padua
GISE president



The motion:



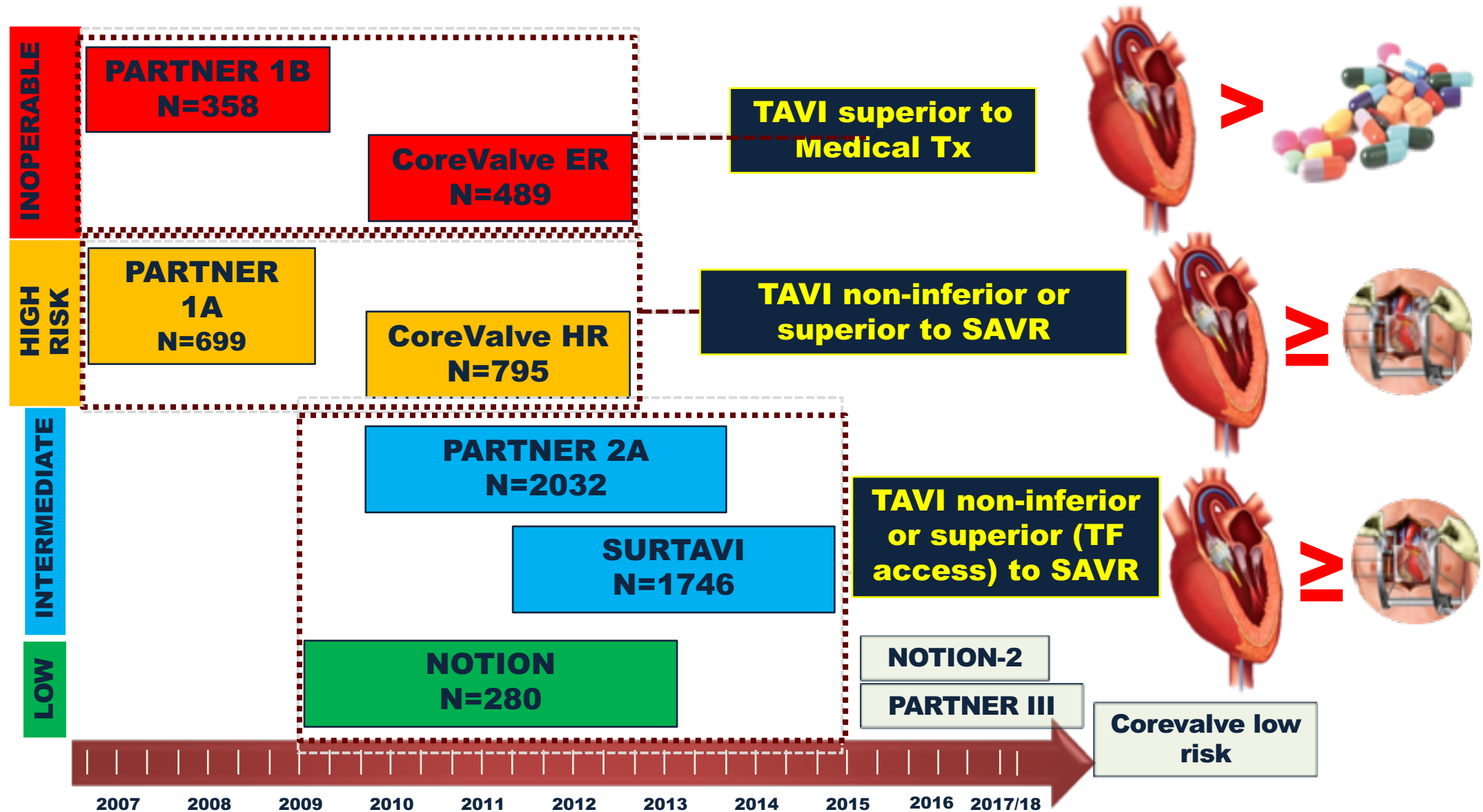
***TAVI (in lower risk pts) is a business for
Interventional Cardiology ?***

The motion:



***TAVI (in **lower risk pts**) is a business for
Interventional Cardiology ?***

EVIDENCE BASE DERIVED FROM CLINICAL TRIALS



Valvular heart disease

Transcatheter aortic valve implantation in lower-risk patients: what is the perspective?

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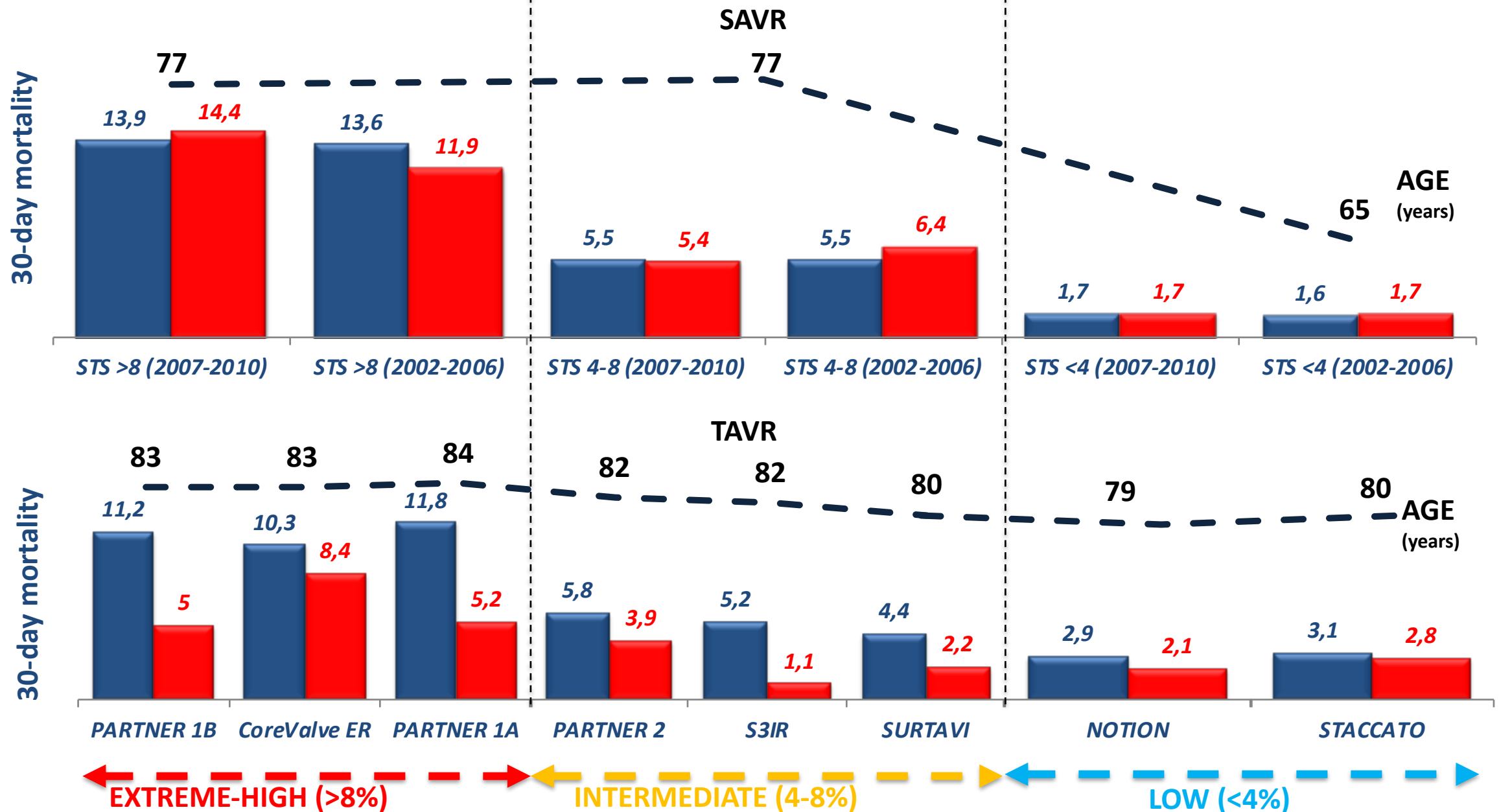
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In the last decade, transcatheter aortic valve implantation (TAVI), a disruptive technology, has revolutionized the therapy of symptomatic severe aortic stenosis, and current guidelines state that the recommendations for TAVI and surgical aortic valve replacement (SAVR) are equivalent in patients at high-risk. Increased operator experience, technical advances in the new generation of transcatheter heart valves (THV) and excellent TAVI results in recently published randomized controlled trials have led to the expansion of TAVI indication as an alternative to SAVR in intermediate-risk subjects, given appropriate patient selection. The time is opportune to examine the role of TAVI in low-risk patients, currently the objective of on-going randomized trials. This review aims to summarize the available knowledge on TAVI in low- to intermediate-risk patients and to discuss the potential advantages and pitfalls TAVI will face in this clinical setting.

Keywords

TAVI • Low risk • Intermediate risk • Aortic stenosis

INTERACTION BETWEEN RISK AND AGE



PRACTICE AHEAD OF GUIDELINES: “**LOWER RISK**”

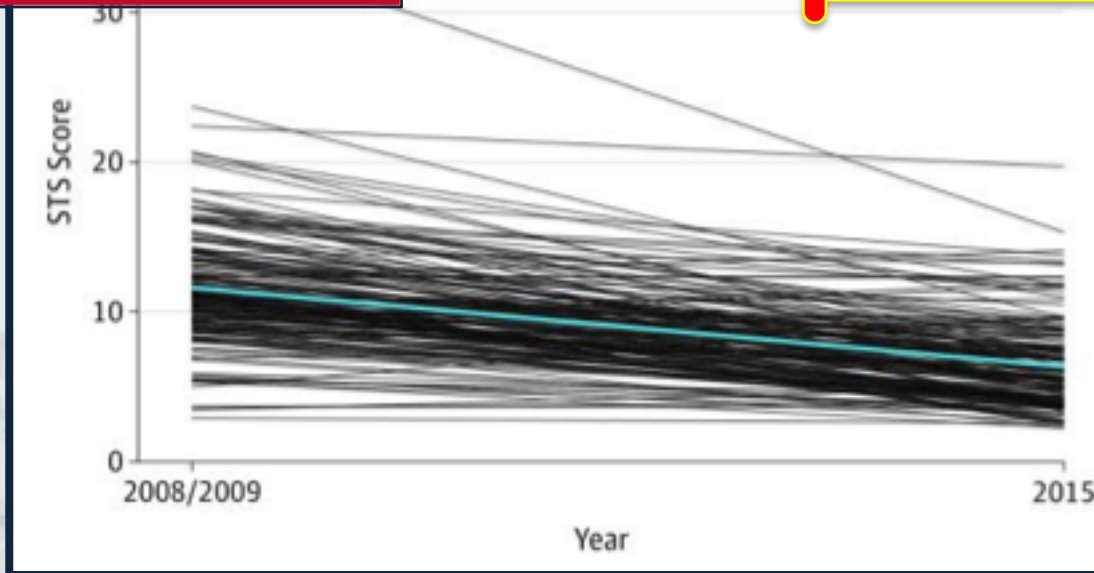
Discount in risk over time

Sensitive risk scores work bidirectionally and are regularly updated by the most recent outcome data

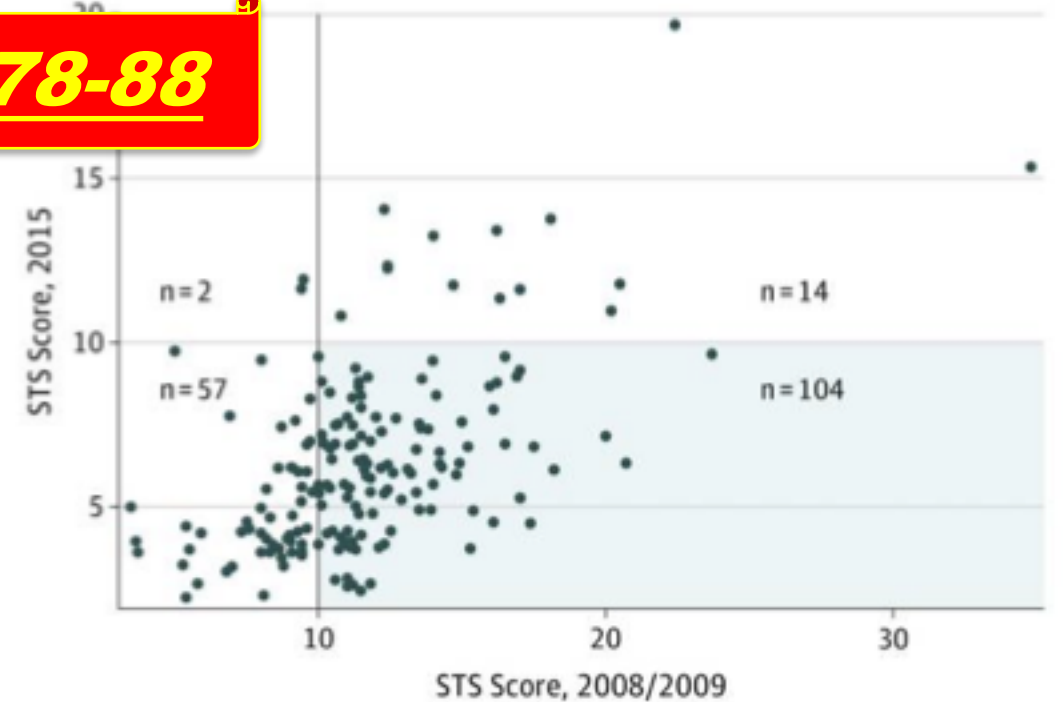
Single-center study (N=177)



Age – 78-88



**Per Patient Change in STS Score
Between 2008/2009 and 2015**



**Scatterplot of STS Scores in 2008/2009
Compared with 2015**

PRACTICE AHEAD OF GUIDELINES: “*SOURCE 3*”



n = 1945

SURGICAL RISK

Age – 78

29.0%

HIGH
32.2%

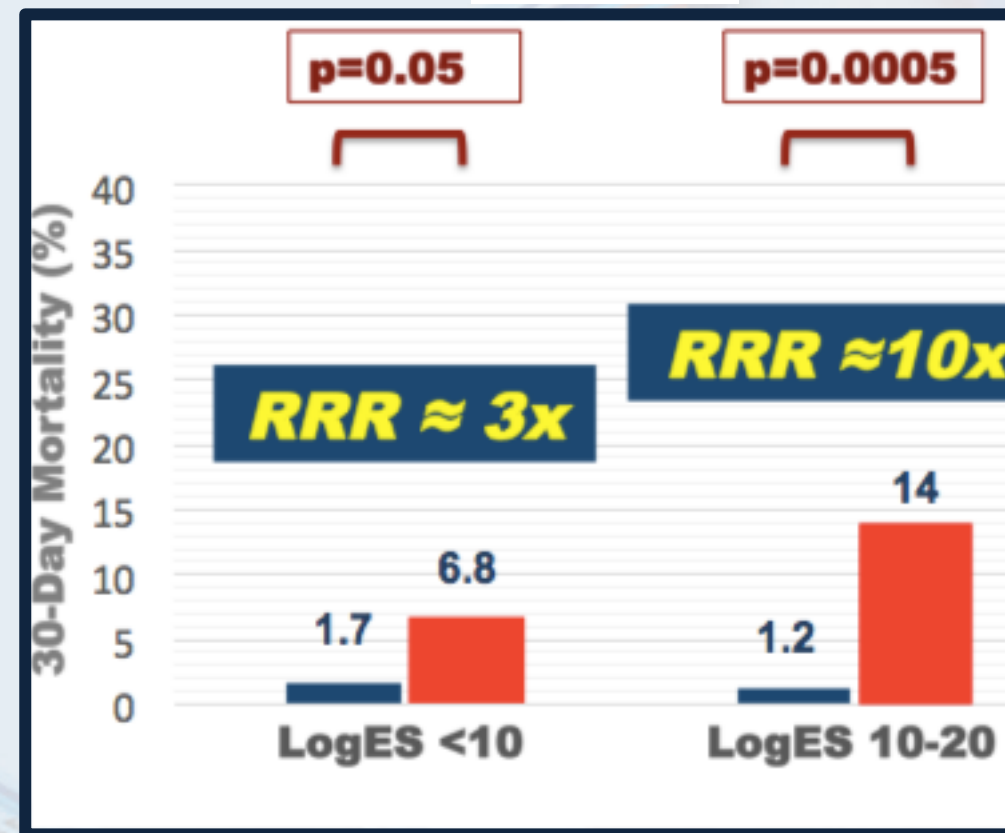
Age – 82

INTERMEDIATE
38.7%

❑ **MORE THAN 2/3 INTERMEDIATE OR LOW RISK**

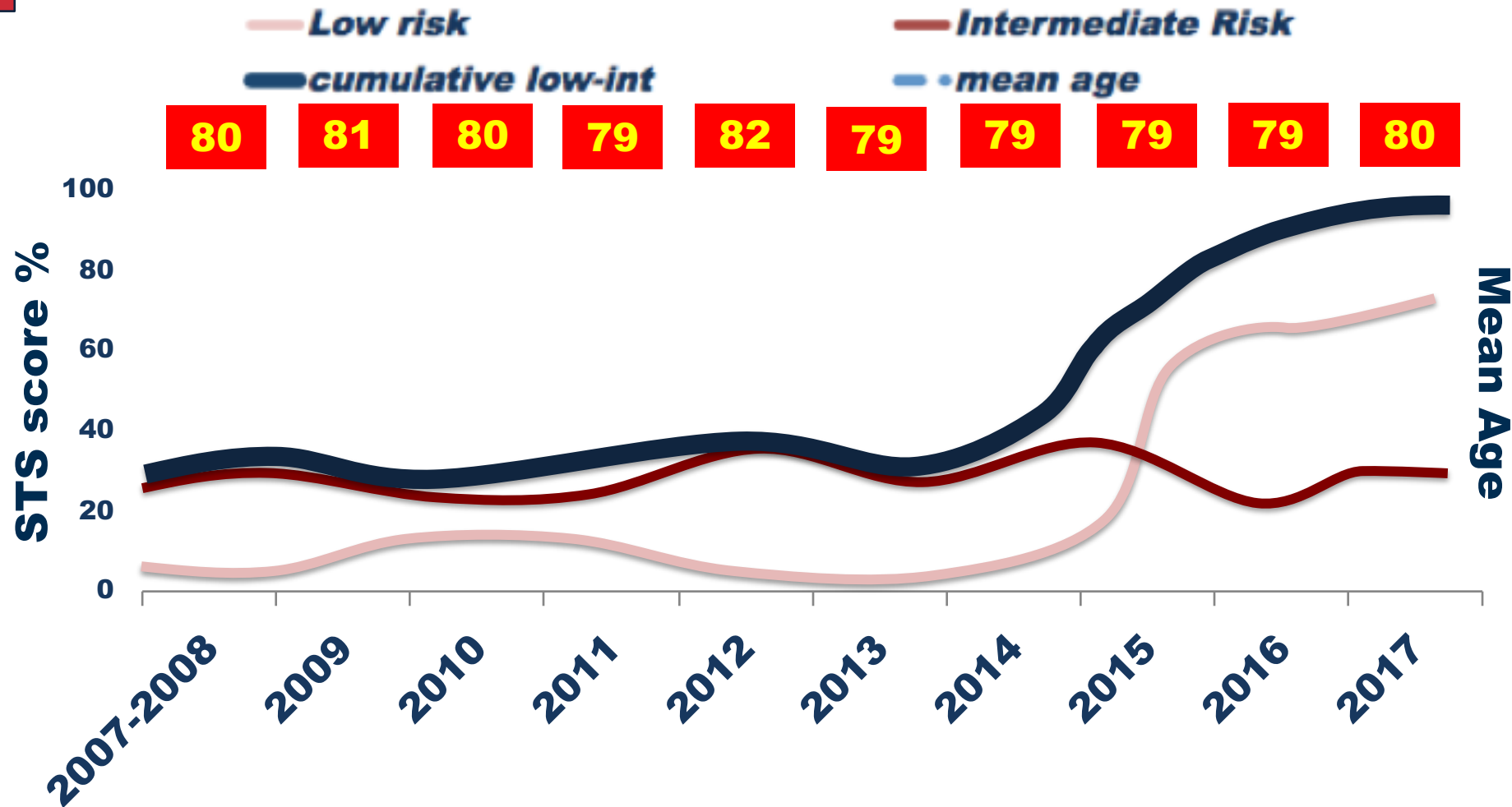
❑ **IR/LR 70% IN *TF* vs. 60% IN *NON-TF* (p <0.01)**

■ Observed
■ Expected



PRACTICE AHEAD OF GUIDELINES: “*PD registry*”

2007-2017 – 900 TAVI pts

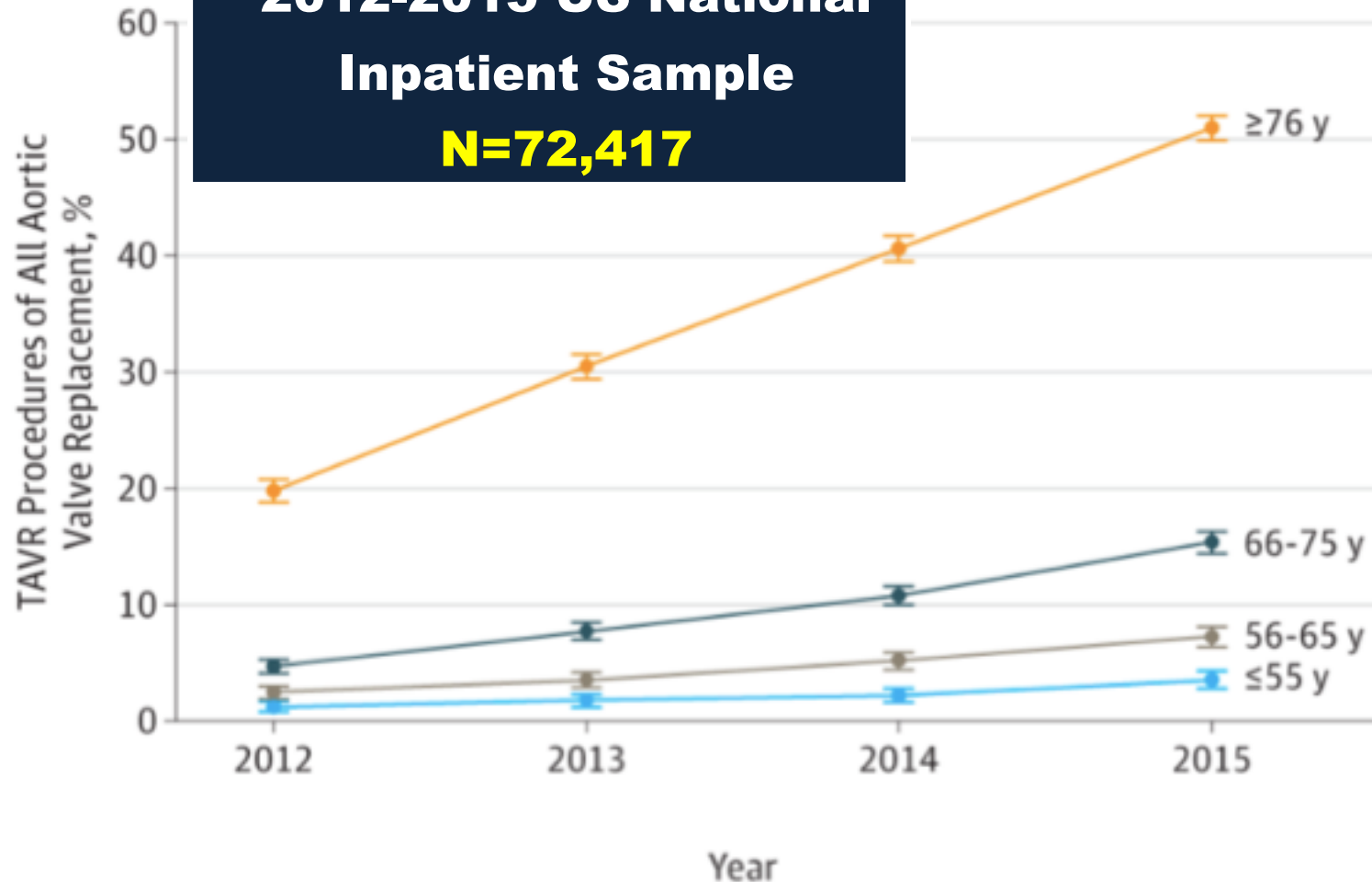


Proportion of pts <65 years treated with TAVI is increasing



**2012-2015 US National
Inpatient Sample**

N=72,417



Sedrakyian A et al, JAMA 2018

OBSERVANT



OBSERVANT < 65 yrs (n 7618 SAS pts undergoing TAVI o SAVR) 93 Italian Centers

Tarantini, Seccareccia et al., submitted

OBSERVANT population

7618

2634 ≥80 years of age
102 missing by age

Patients <80 years of age

4882

81 excluded because
TAVI with transthoracic

Study population

4801

SAVR

4318

0,3%

<65 yrs

969

65-74 yrs

1867

65-74 yrs

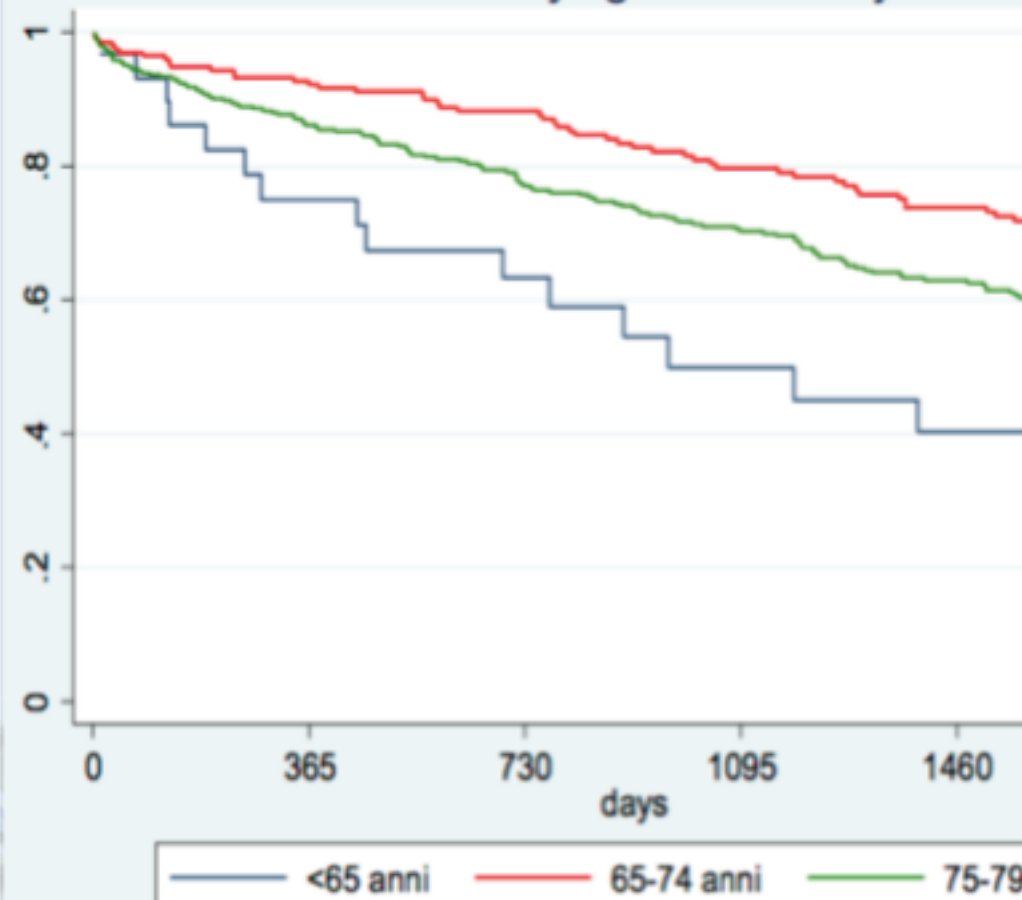
1482

<65 yrs

23

	OR	P_value
Age, yrs (SD)	1.08	0.000
Female	1.31	0.253
Smoking history	0.52	0.027
Creatinine, mg/dl (SD)	1.18	0.044
Previous IMA	0.38	0.011
Unstable angina	0.75	0.088
Oxygen dependency	4.19	0.005
COPD	3.86	0.000
Neurologic dysfunction	5.89	0.000
Chronic liver disease	6.54	0.000
Active neoplastic disease	16.92	0.000
Peripheral arteriopathy	1.86	0.027
Previous cardiac surgery	10.89	0.000
Frailty score, moderate-severe	2.01	0.041
Previous PCI	6.58	0.000
Previous BAV	5.15	0.006
Porcelain aorta	25.54	0.000
Difficult thoracic approach	2.00	0.060
NYHA functional class		
II	2.40	0.134
III	4.27	0.012
IV	9.08	0.000
Left ventricular ejection fraction		
30-50%	1.32	0.296
<30%	4.20	0.003
Coronary artery disease		
1 vessel	0.76	0.404
2 vessels	0.44	0.117
3 vessels	0.45	0.076

TAVI-Death by age classes-adjusted



The motion:



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TAVI vs SAVR: META-ANALYSIS OF 4 RANDOMIZED TRIALS

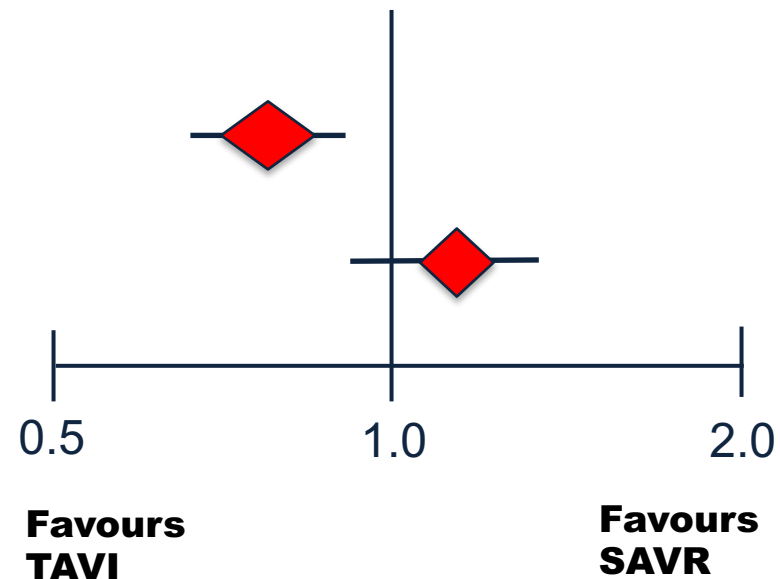
SIONTIS ET AL. EUR HEART J 2016

Death from any cause

Access Route

Transfemoral

Transthoracic





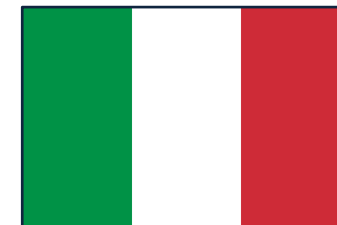
OBSERVANT (n 7618 pts) – 1718 TAVI TF

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

OBSERVANT



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



TF TAVI by Interventional Cardiologist

- 1558 (91%) in Cath lab**
- 161 (9%) in Cardiosurgery (Hybrid room) – 92 (57%
surgical femoral approach)**



OBSERVANT II - *Ongoing*

OBservational Study of Effectiveness of TAVI with new geneRation deVices for severe Aortic steNosis Treatment II

OBSERVANT II

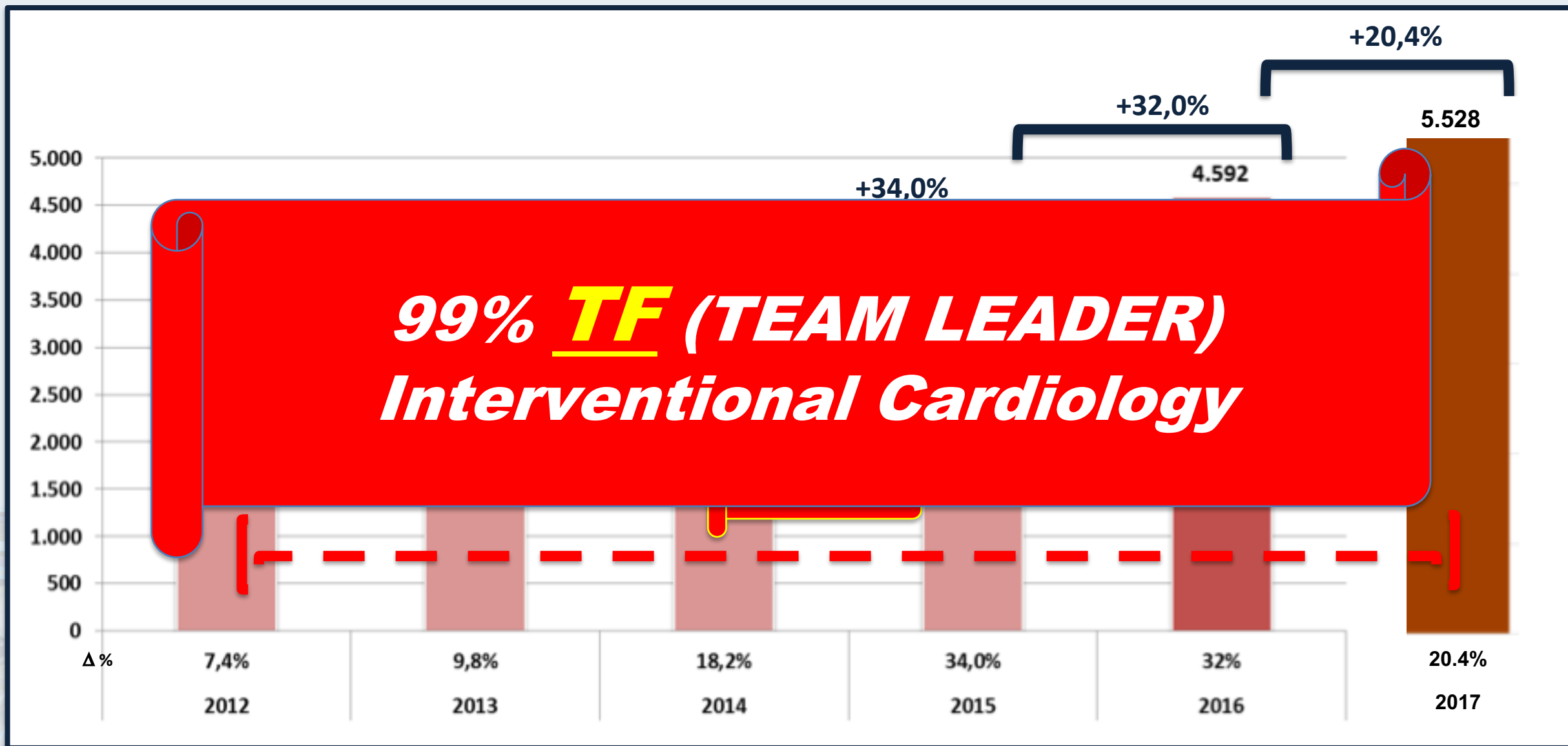


METODI

Lo studio osservazionale per il monitoraggio delle procedure TAVI da parte dei cardiologi interventisti prevede la raccolta di un limitato numero di informazioni cliniche che consentirà di stimare il rischio individuale nella popolazione eleggibile ad una procedura valvolare. Il dataset proposto in OBSERVANT II si ispira in larga parte al dataset proposto e adottato nello studio OBSERVANT, salvo

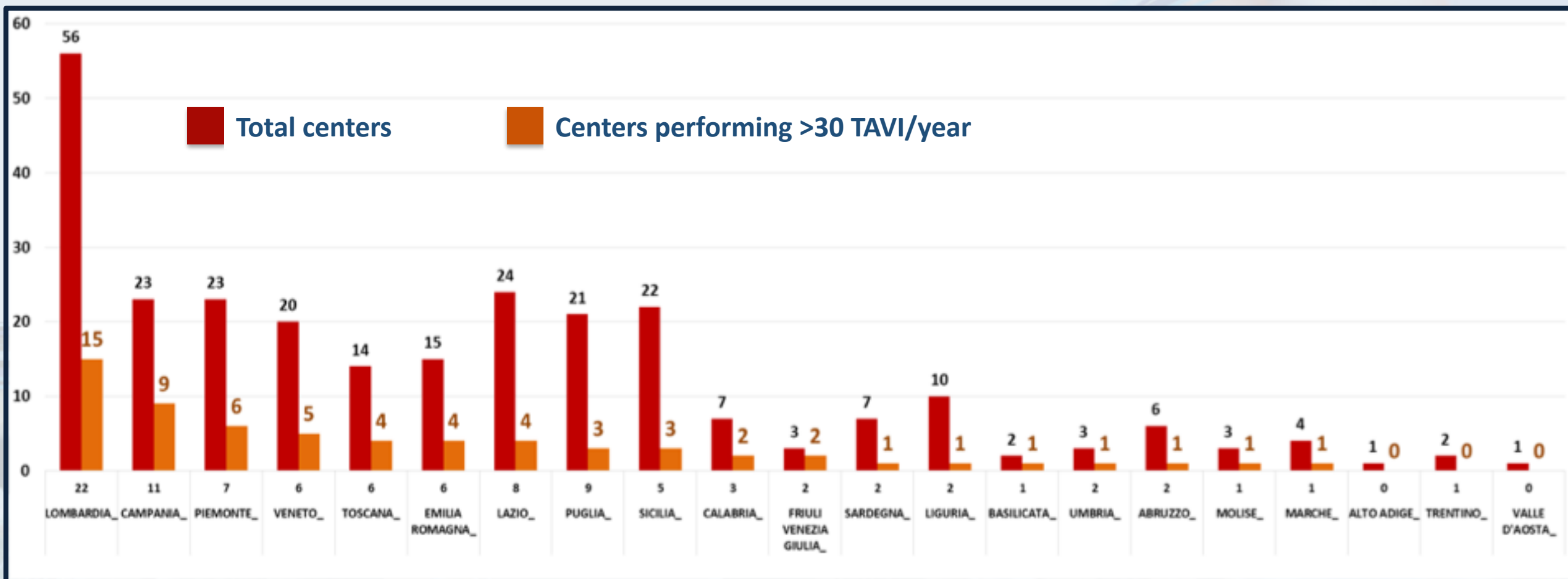
TF (percutaneous) TAVI only

TAVI implants - ITALY



CENTERS PERFORMING TAVI BY REGION

***Out of 97 centers performing TAVI in Italy,
64 (65.9%) have a mean volume of >30 procedures/year***

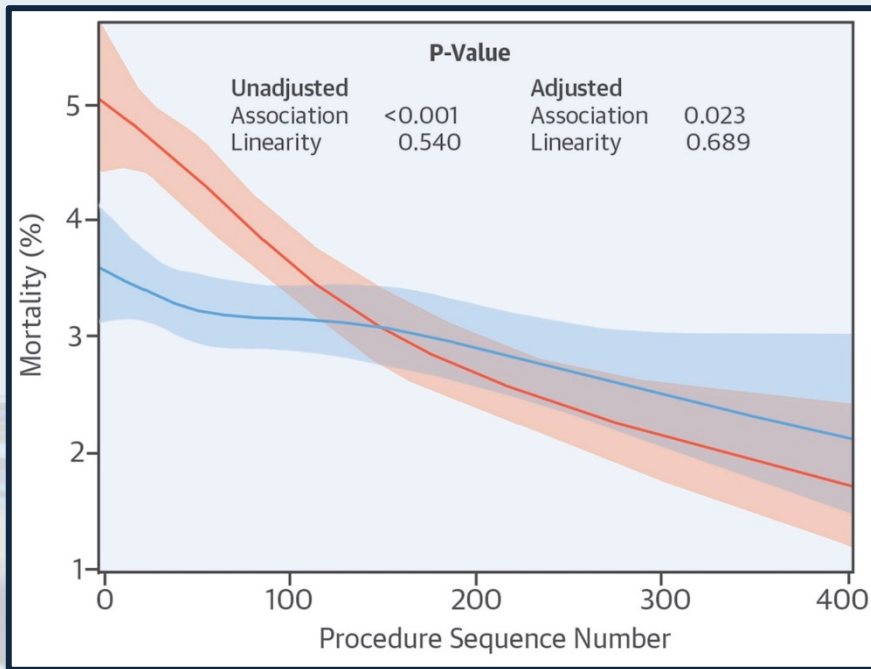


PROCEDURAL EXPERIENCE AND RELATION TO OUTCOMES

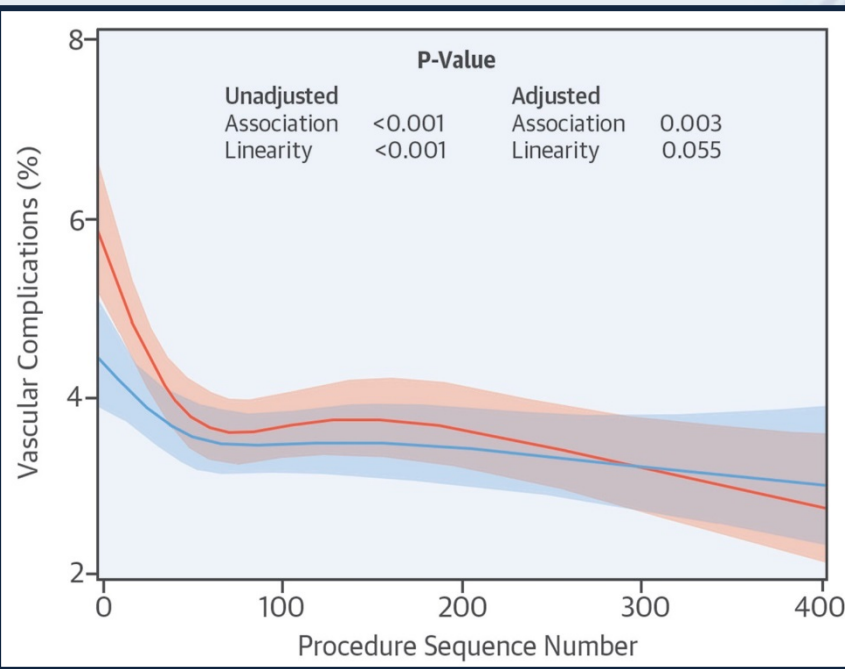
Carroll et al, *JACC*. 2017;70:29-41

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

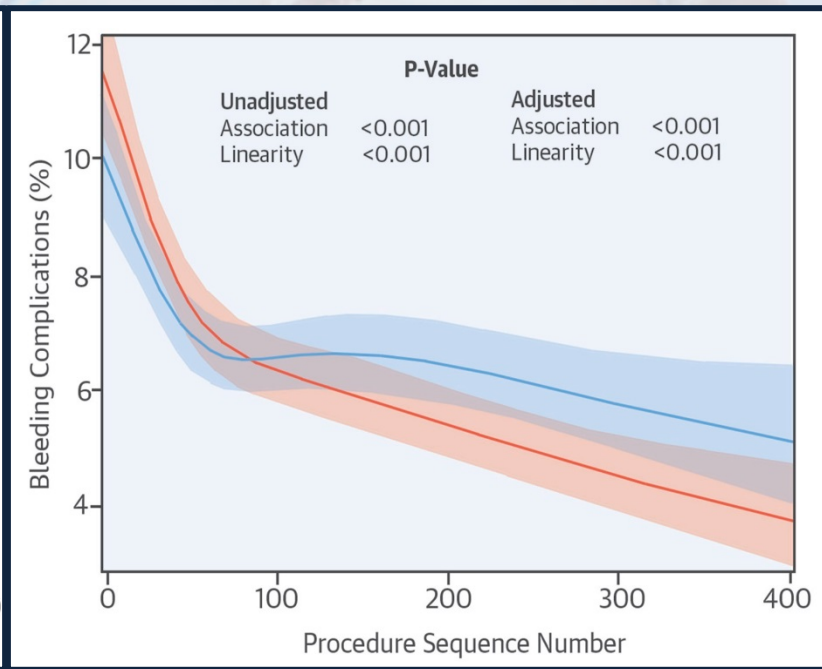
IN-HOSPITAL MORTALITY 4%



VASCULAR COMPLICATIONS 7.1%



BLEEDING COMPLICATIONS 8.6%



— Unadjusted — Adjusted

2018 AATS/ACC/SCAI/STS OPERATOR AND INSTITUTIONAL RECOMMENDATIONS AND REQUIREMENTS FOR *NEW TAVR PROGRAM*

Proposed TAVR proceduralist

- 1) Prior experience at an active TAVR site, at least **100 TF TAVR** with at least **50 cases** as **primary operator****
- 2) Certification of device-specific training on device(s) to be used**

Proposed TAVR surgeon

- 1) At least **100 SAVRs/lifetime** or **50 SAVRs over 2 y** with at least **20 SAVRs** in the past 1y prior to initiation of the TAVR program**

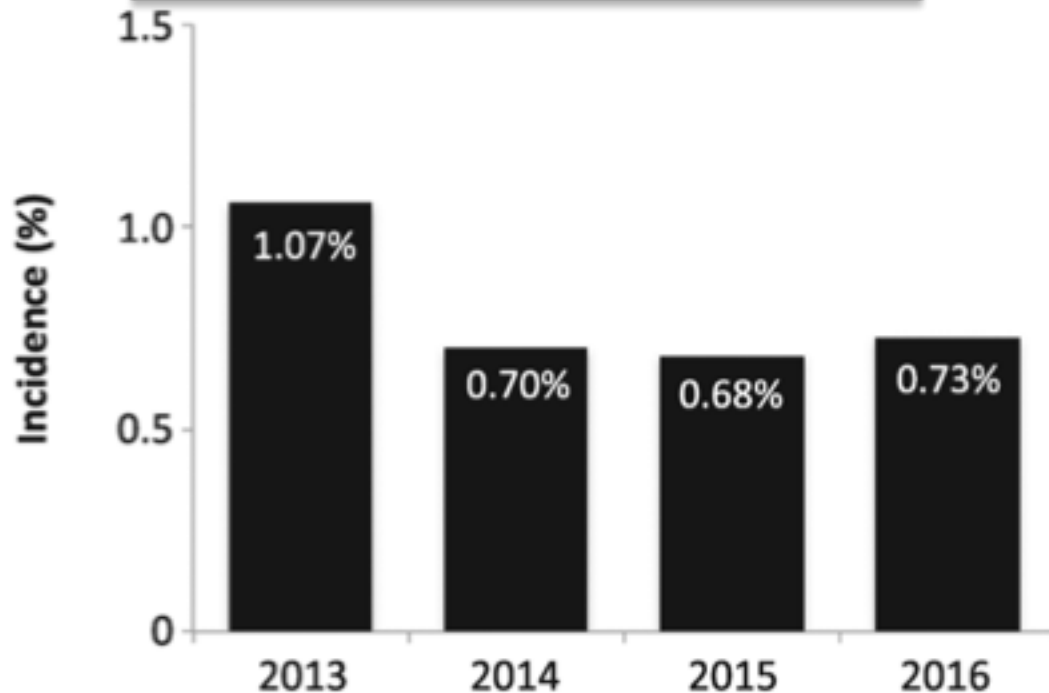
Prior to expanding into alternative-access TAVR

Completion of 80 TF TAVR with an STS/ACC TVT Registry 30-d risk-adjusted TAVR all-cause death “*AS EXPECTED*” or “*BETTER THAN EXPECTED*”

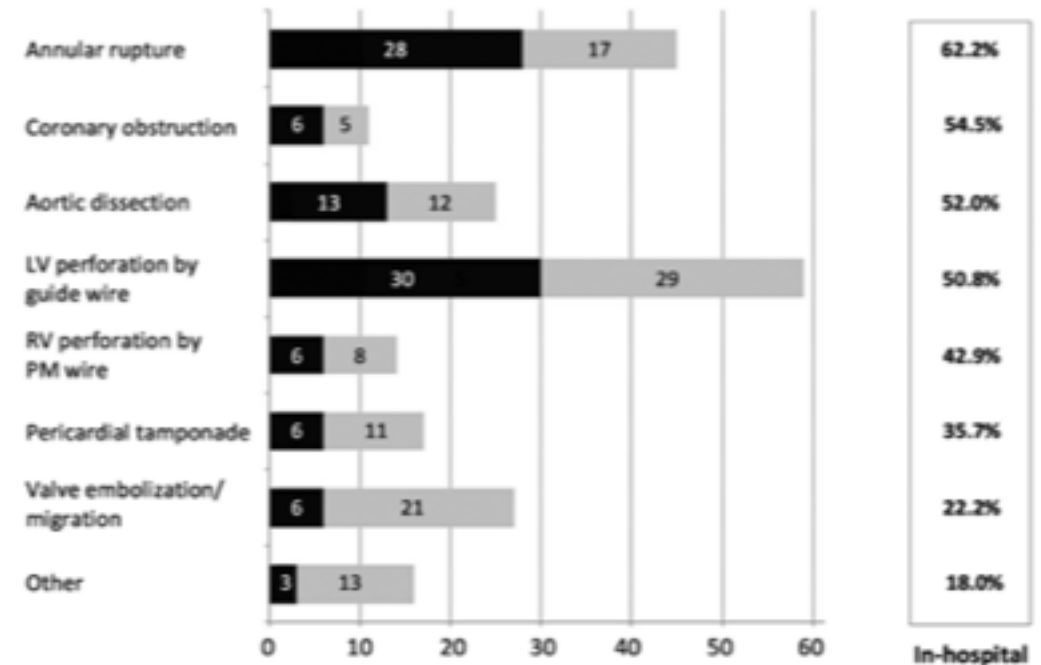
European Registry on Emergent Cardiac Surgery during TAVI (EuRECS-TAVI)

27,760 TF-TAVI procedures between 2013 and 2016

EMERGENT CARDIAC SURGERY AND TAVI



COMPLICATIONS AND MORTALITY



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

TAVI ACCESSORY DEVICES

(*lower risk pts*)

- ☐ ***Cerebral embolic* protection devices**
- ☐ **New balloon *aortic valvuloplasty* systems**
- ☐ ***Aortic valve remodeling* technologies**
- ☐ **Safer temporary pacemakers**
- ☐ **Vascular access *closure devices***

RIEDIZIONE DEL DOCUMENTO DI CONSENSO TAVI

Rieditato dopo sette anni dalla prima edizione



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 transcateretere di protesi valvolare aortica

NEW POSITION PAPER OBJECTIVES

- **Re-define Institutional (structural and organizational) requirements of TAVI center**
- **Re- Establish proctors and operators requirements**
- **Periprocedural set-up**

Massimo Siviglia, Leonardo Spedicato, Amerigo Stabile, Corrado Tamburino, Tullio Nicola Maria Tesorio, Salvatore Tolaro, Fabrizio Tomai, Carlo Trani, Renato Valenti, Orazio Valsecchi, Giuseppe Valva, Ferdinando Varbella, Carlo Vigna, Luigi Vignali, Sergio Berti



INSTITUTIONAL REQUIREMENTS- **TEAM LEADER**

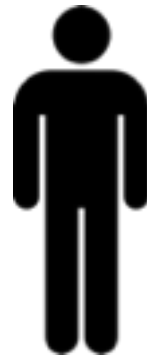
FIRST operator = TEAM LEADER

**TRANSFEMORAL AND
TRANSSUBCLAVIAN TAVI**



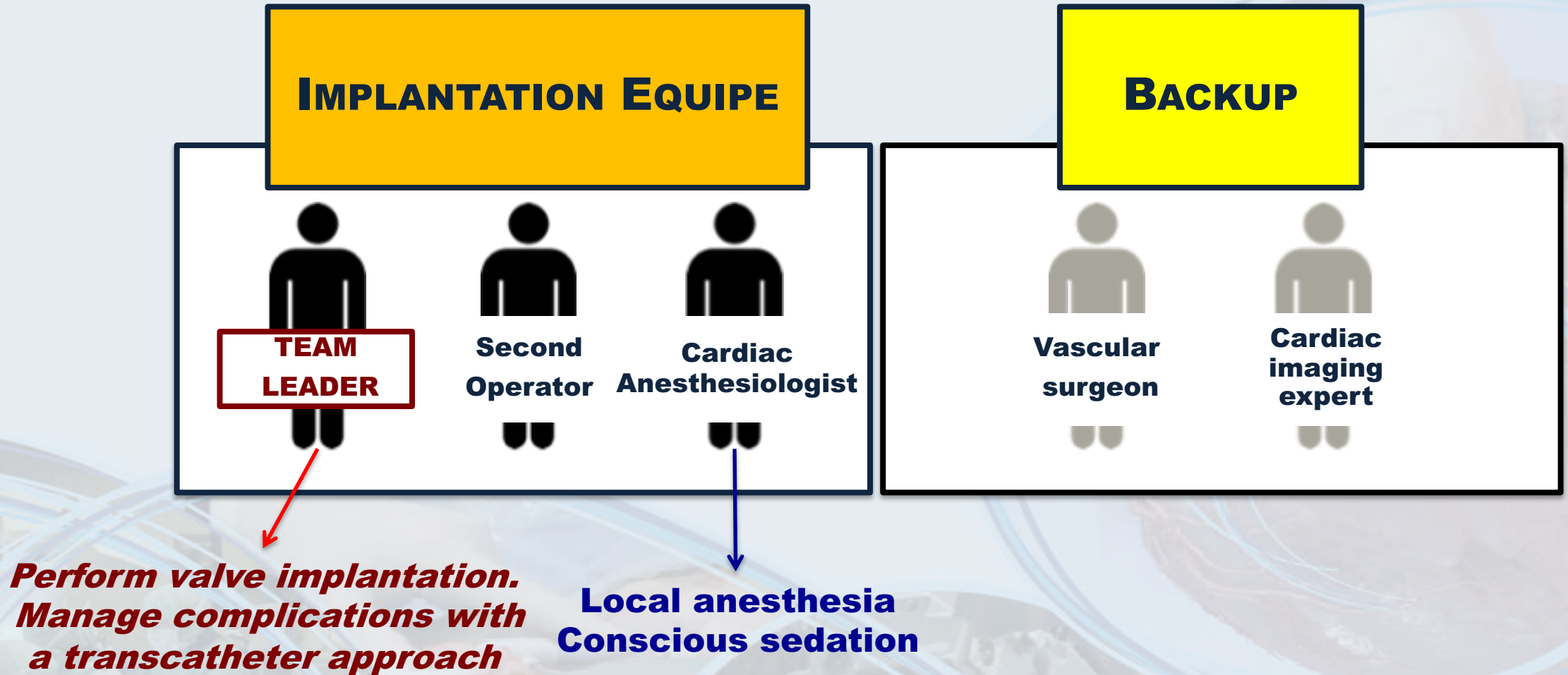
Skills: Perform valve implantation
Manage complications with a
transcatheter approach

**TRANSAPICAL AND
TRANSAORTIC TAVI**

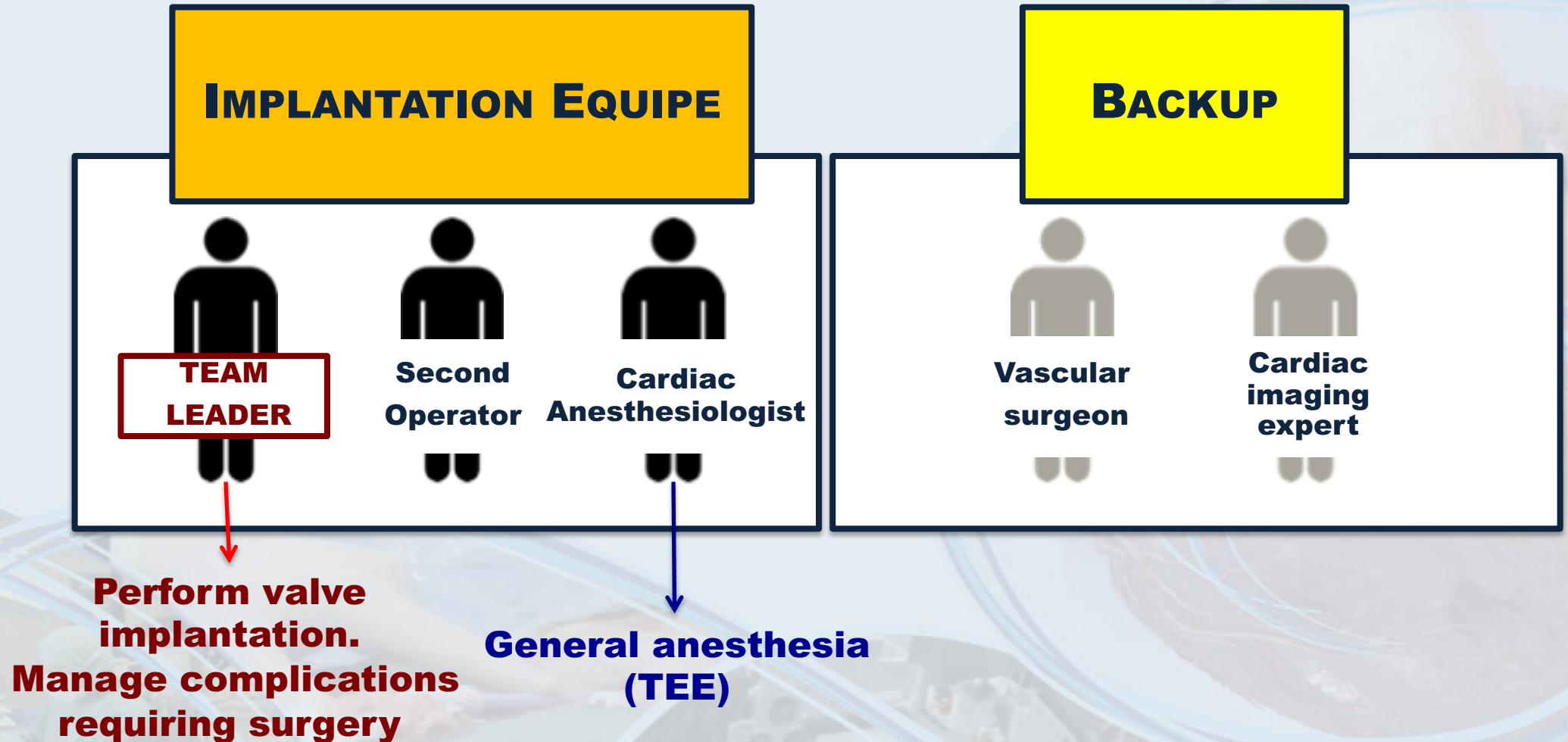


Skills: Perform valve implantation
Manage complications
requiring surgical intervention

PERI-PROCEDURAL PHASE TRANSFEMORAL/TRANS-SUBCLAVIAN TAVI



PERI-PROCEDURAL PHASE TRANSAPICAL/TRANSAORTIC TAVI



The motion:



MOTION APPROVED

**TF TAVI (in lower risk pts) is a business for
Interventional Cardiology ?**



**Nobel Memorial Prize in
Economic Sciences**

$$U_i(s_1^e, s_2^e, \dots, s_i^e, \dots, s_N^e) \geq U_i(s_1, s_2, \dots, s_i, \dots, s_N)$$



Everyone (Patients and doctors) wins in any configuration of strategies when "one (goes) for the blonde", the others for a brunette.