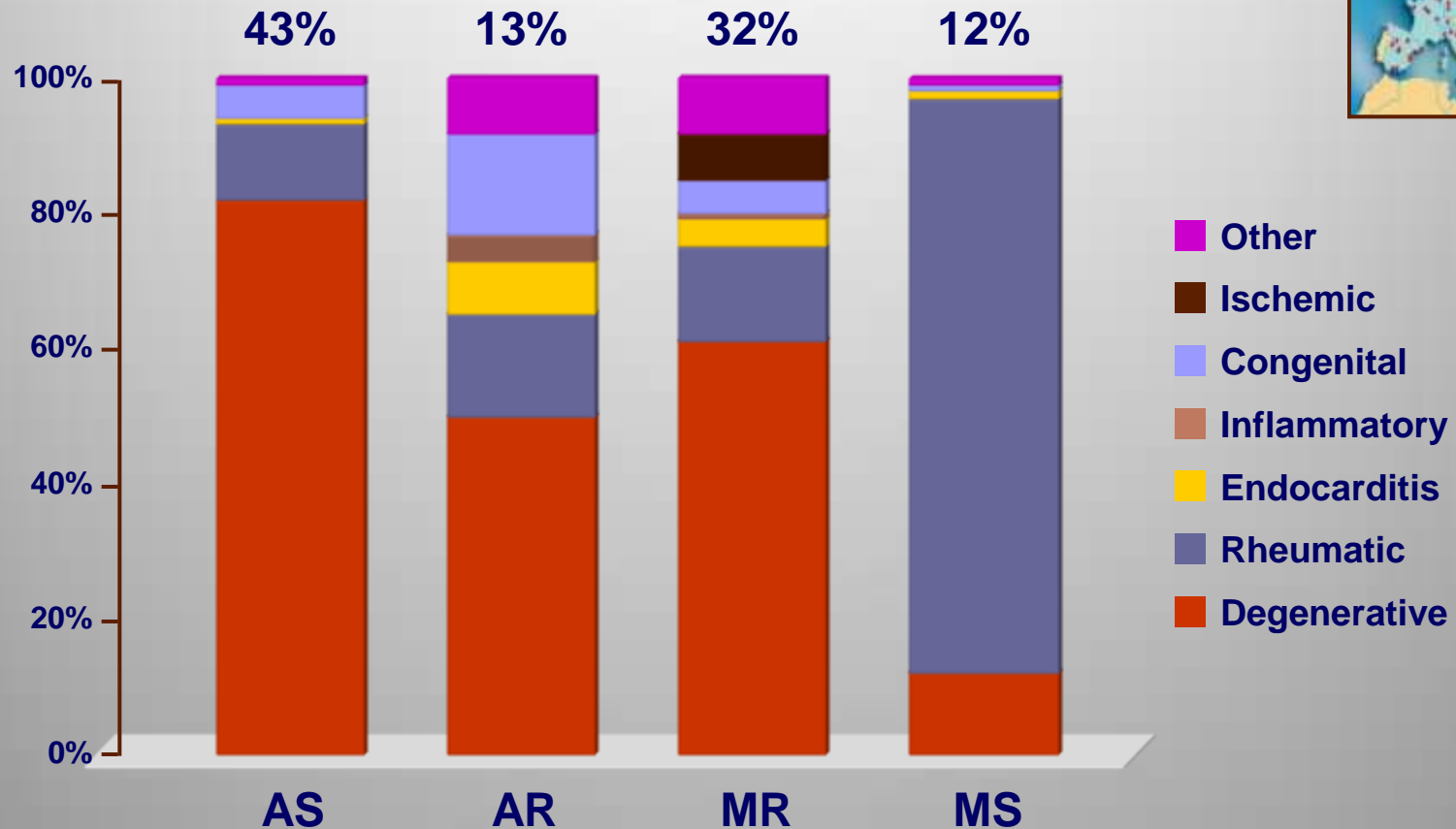


# VALVOLA AORTICA SENZA SUTURE

**Ottavio Alfieri**

Istituto Scientifico San Raffaele  
Milano

# Aetiologies of Single Valvular Heart Diseases in the Euro Heart Survey



lung et al. *Eur Heart J* 2003;24:1244-53

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &  
European Journal of Cardio-Thoracic Surgery 2012 -  
doi:10.1093/ejcts/ezs455).

# Patient Characteristics in the Euro Heart Survey

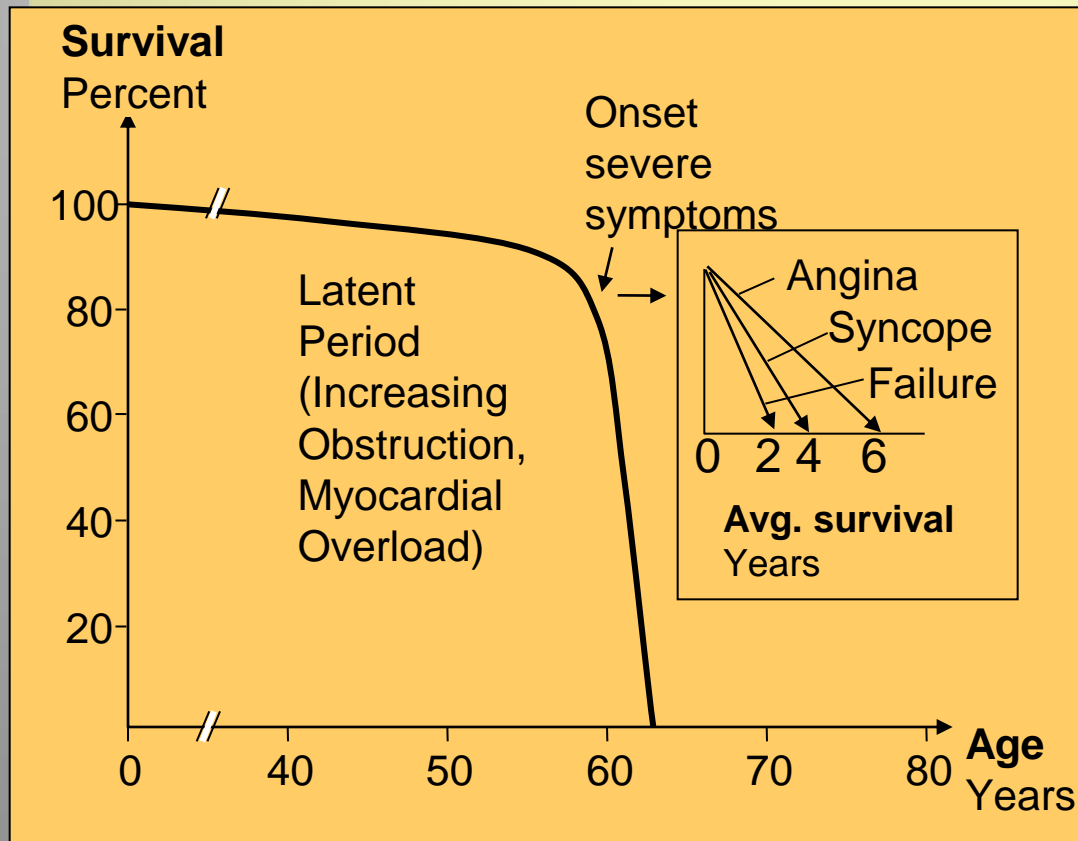


	Age (years)	≥ 70 years (%)	≥ 1 comorbidity (%)
<b>AS</b>	69 ± 12	56	36
<b>AR</b>	58 ± 16	25	26
<b>MS</b>	58 ± 13	18	22
<b>MR</b>	65 ± 14	44	42

lung et al. *Eur Heart J* 2003;24:1244-53

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &  
European Journal of Cardio-Thoracic Surgery 2012 -  
doi:10.1093/ejcts/ezs455).

# ...Aortic stenosis is life-threatening and progresses rapidly...

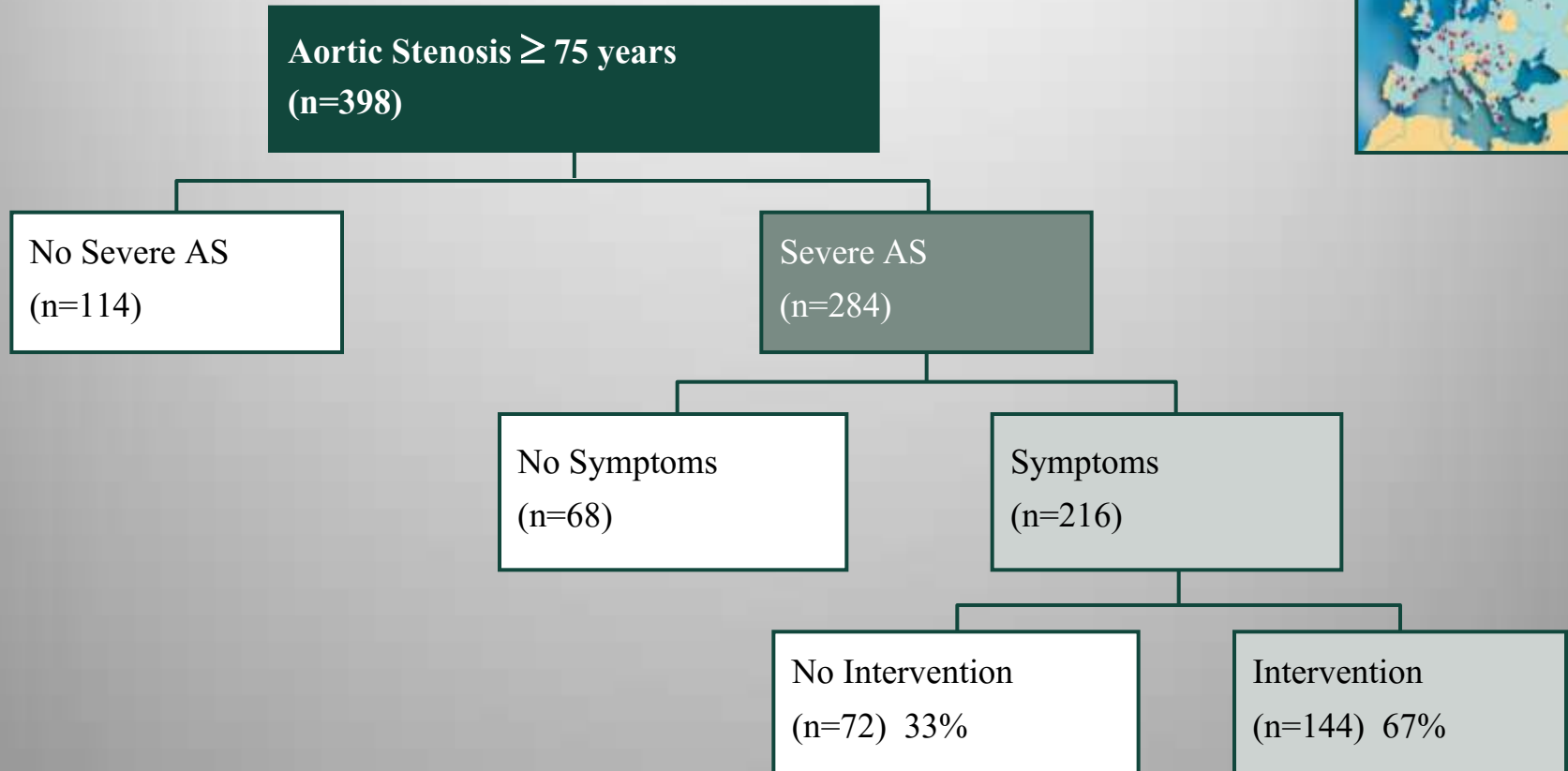


Sources: <sup>1</sup> S.J. Lester et al., "The Natural History and Rate of Progression of Aortic Stenosis," *Chest* 1998

<sup>2</sup> C.M. Otto, "Valve Disease: Timing of Aortic Valve Surgery," *Heart* 2000

Chart: Ross J Jr, Braunwald E. Aortic stenosis. *Circulation*. 1968;38 (Suppl 1):61-7.

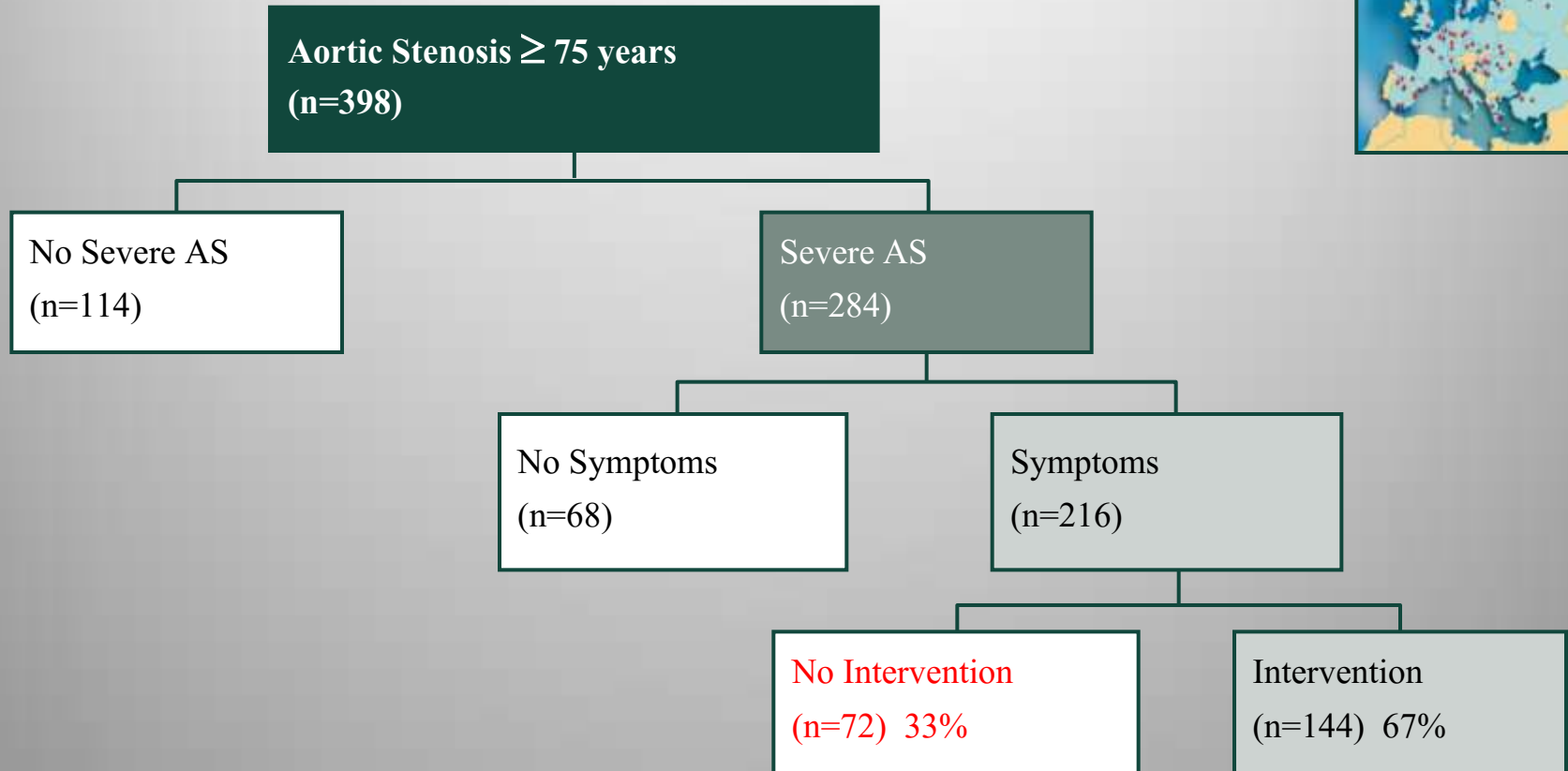
# Management of Severe Symptomatic AS in the Elderly



lung et al. *Eur Heart J* 2005;26:2714-2720

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# Management of Severe Symptomatic AS in the Elderly

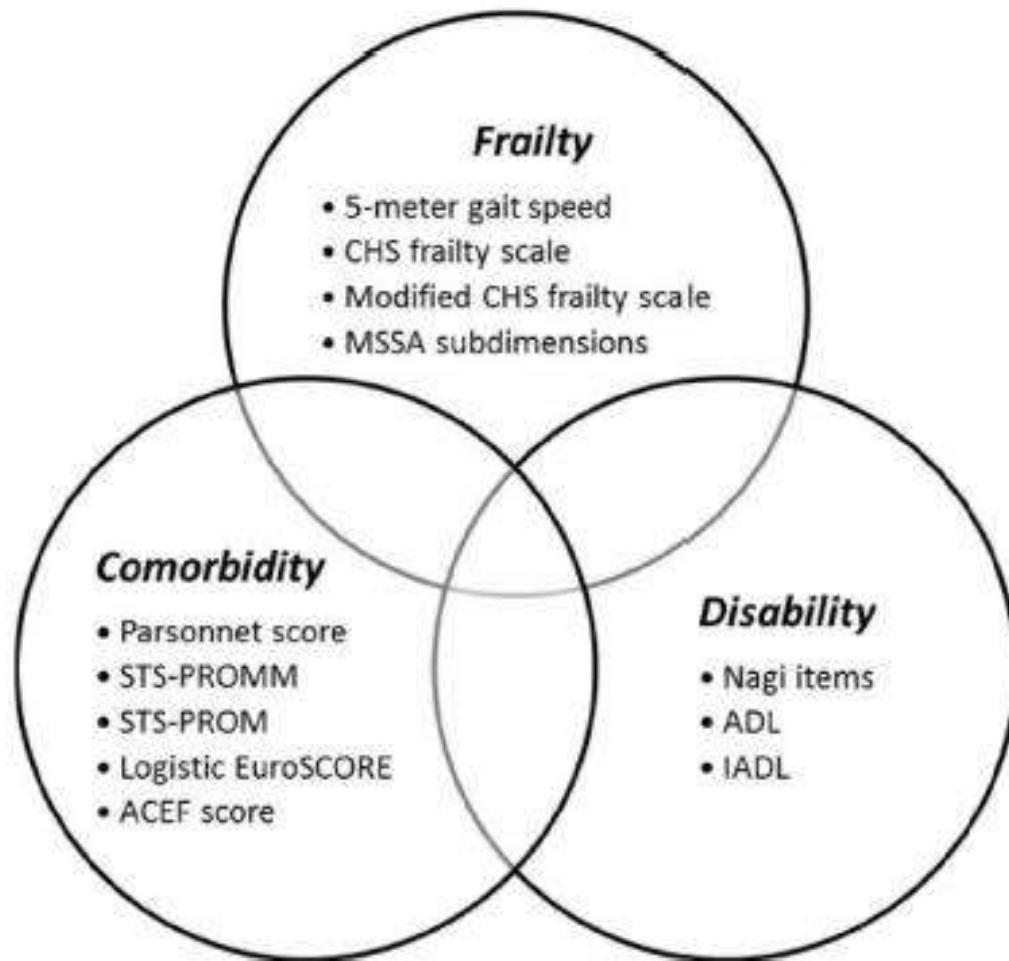


lung et al. *Eur Heart J* 2005;26:2714-2720

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &  
European Journal of Cardio-Thoracic Surgery 2012 -  
doi:10.1093/ejcts/ezs455).

# Addition of Frailty and Disability to Cardiac Surgery Risk Scores Identifies Elderly Patients at High Risk of Mortality or Major Morbidity

Jonathan Afilalo, MD, MSc; Salvatore Mottillo, MD; Mark J. Eisenberg, MD, MPH;  
Karen P. Alexander, MD; Nicolas Noiseux, MD; Louis P. Perrault, MD, PhD;  
Jean-Francois Morin, MD; Yves Langlois, MD; Samuel M. Ohayon, BSc; Johanne Monette, MD, MSc;  
Jean-Francois Boivin, MD, ScD; David M. Shahian, MD; Howard Bergman, MD



Circ Cardiovasc  
Qual Outcomes.  
2012;5:222-228



# Aortic Valve Implantation

## The Evolving Process

Invasiveness

Conventional through midline sternotomy

Surgical through minimal incision

On pump, arrested heart sutureless valve replacement

Transaortic delivery

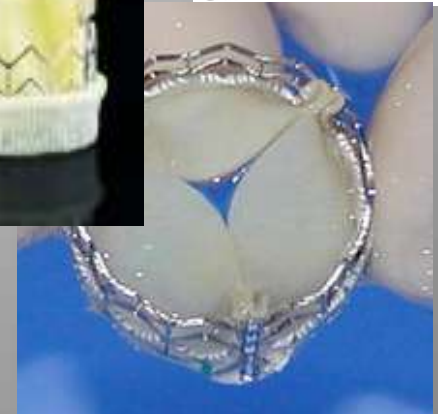
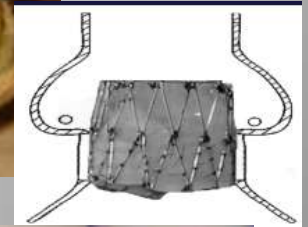
Transapical delivery

Transaxillary delivery

Transcarotid delivery

Percutaneous transfemoral

**TAVI**



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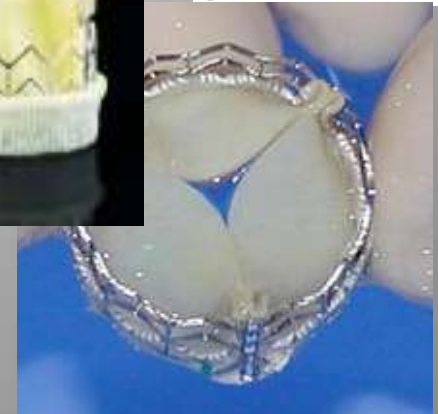
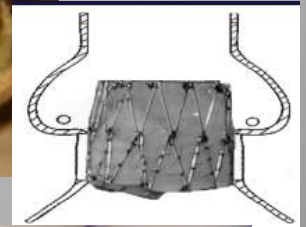
Transapical delivery

Transaxillary delivery

Transcarotid delivery

Percutaneous transfemoral

**TAVI**



# Sutureless aortic prosthesis



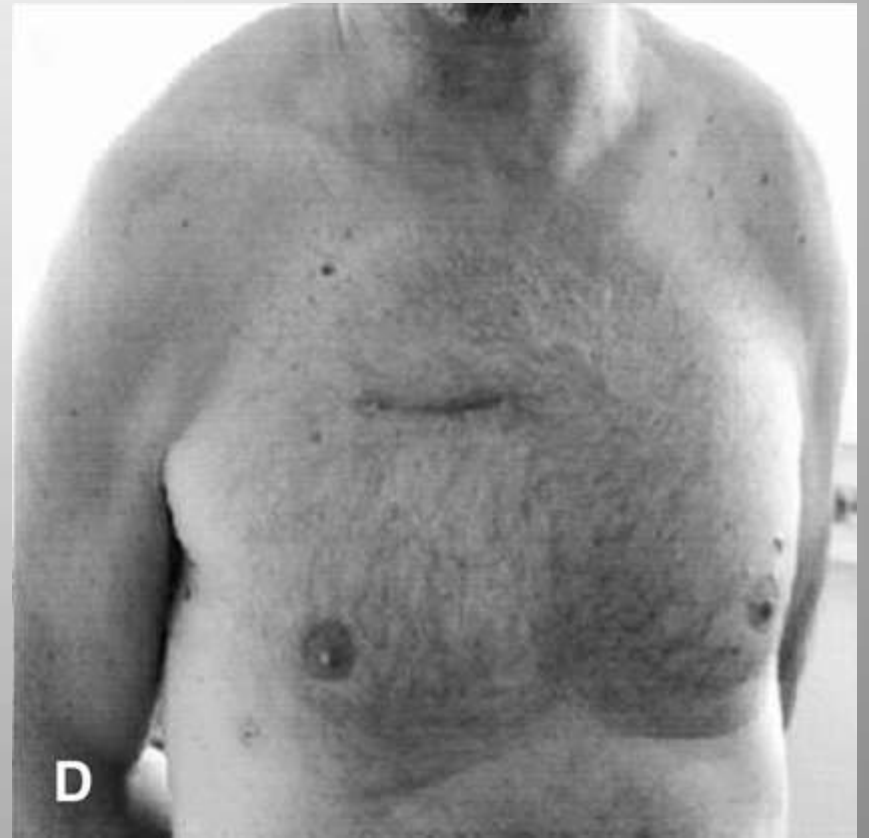
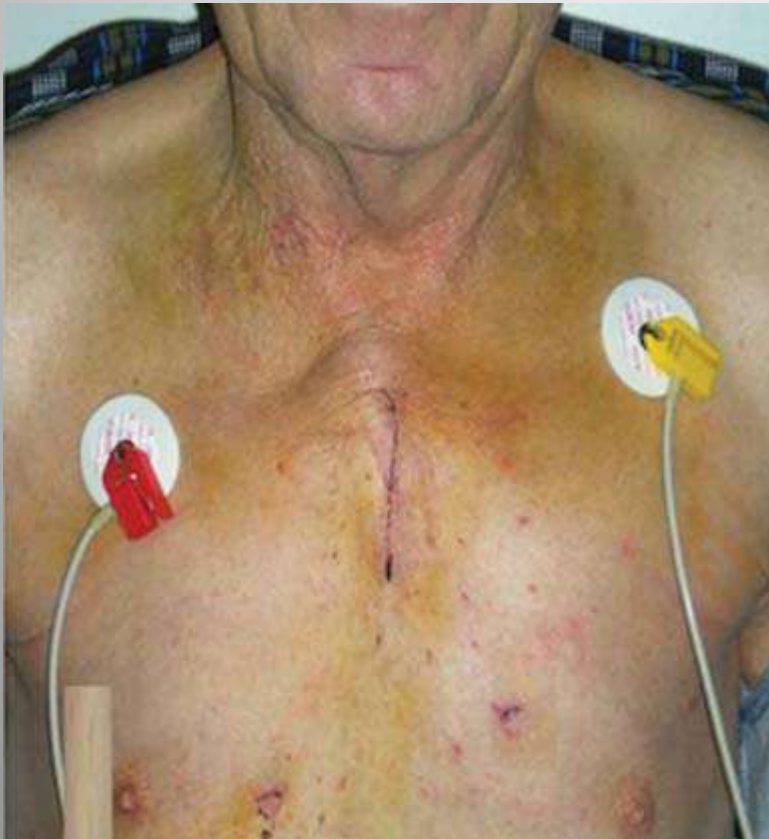
Medtronic 3f Enable



Sorin Perceval S



Edwards Intuity



# Does Ministernotomy Improve Postoperative Outcome in Aortic Valve Operation? A Prospective Randomized Study

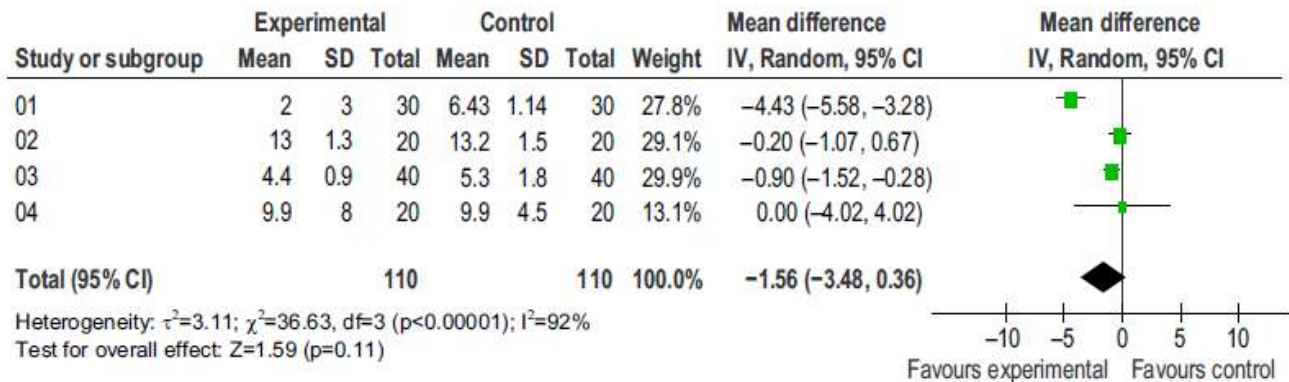
Variable	Min	Full	<i>p</i>
In-hospital death	1	2	1.0
Reexploration for bleeding	0	3	0.24
Mean mediastinal drainage (mL/m <sup>2</sup> )	183 ± 89	280 ± 189	0.004
Bleeding > 800 mL	0	7	0.012
Mean blood transfused (mL/m <sup>2</sup> )	157 ± 98	293 ± 172	< 0.001

40 minimally invasive AVR randomized vs. 40 full sternotomy AVR:

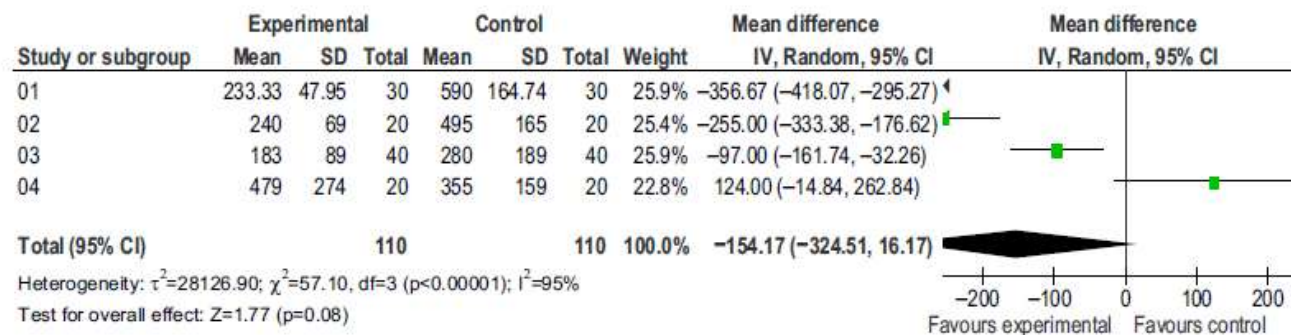
- Reduced blood loss and transfusion
- Reduced postoperative pain
- Improved recovery of respiratory function
- Earlier extubation, shorter LOS

FEV <sub>1</sub>	80.8 ± 18.6	81.7 ± 21.5	0.84
MIP	54 ± 12 <sup>a</sup>	46.6 ± 17.7 <sup>a</sup>	0.007
MEP	62 ± 11.4 <sup>a</sup>	53 ± 10.5 <sup>a</sup>	< 0.001
RV	84 ± 16.3	85 ± 17.4	0.6
Postoperative spirometric data at 1–2 months (% expected)			
TLC	92 ± 13 <sup>b</sup>	88.6 ± 19 <sup>b</sup>	0.35
FEV <sub>1</sub>	80.5 ± 22	79.6 ± 20	0.93
MIP	72 ± 25 <sup>b</sup>	67 ± 21 <sup>b</sup>	0.34
MEP	68.8 ± 14.7 <sup>b</sup>	64.7 ± 10.6 <sup>b</sup>	0.155
RV	91 ± 25.5	86 ± 18.4	0.32

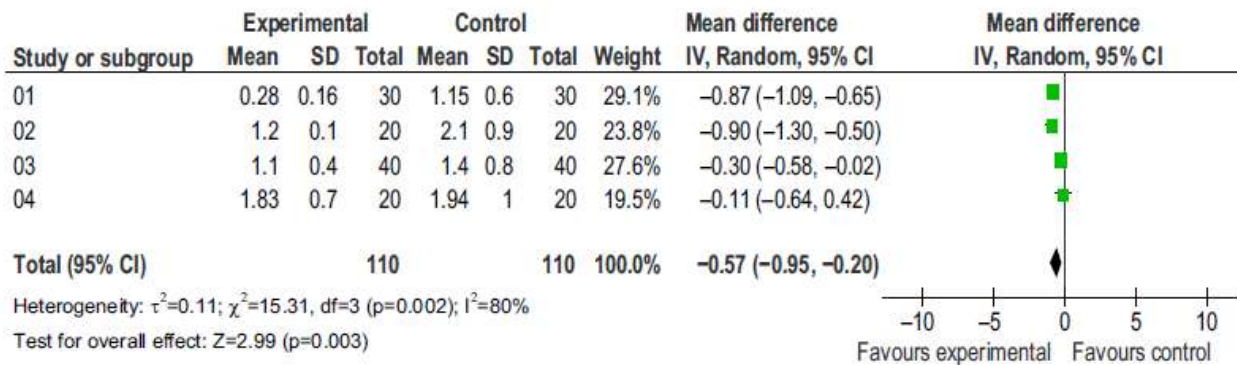
# Mini-sternotomy for aortic valve replacement reduces the length of stay in the cardiac intensive care unit: meta-analysis of randomised controlled trials



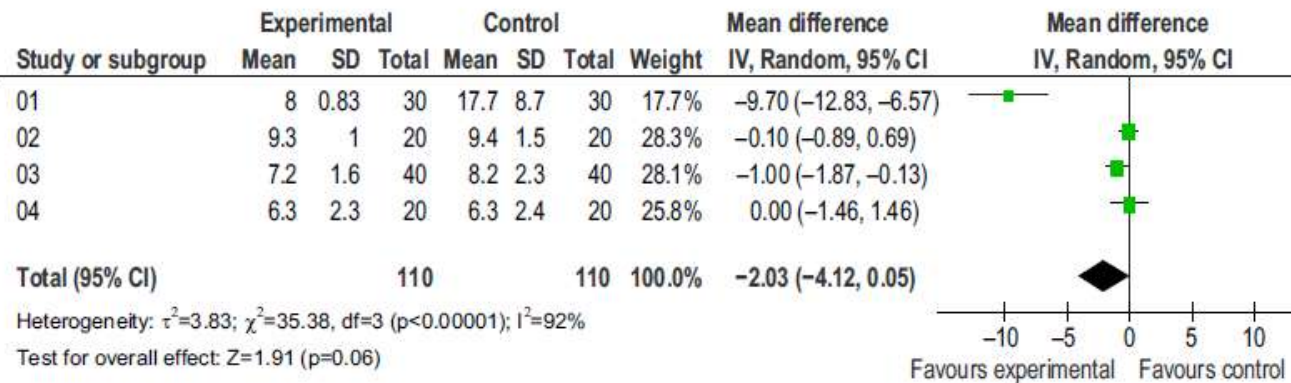
**Figure 2** Duration of ventilation in hours.



**Figure 3** Postoperative bleeding in the first 24 h measured in millilitres.



**Figure 4** Length of intensive care unit stay in days.



**Figure 5** Length of hospital stay in days.

# Aortic Valve Implantation

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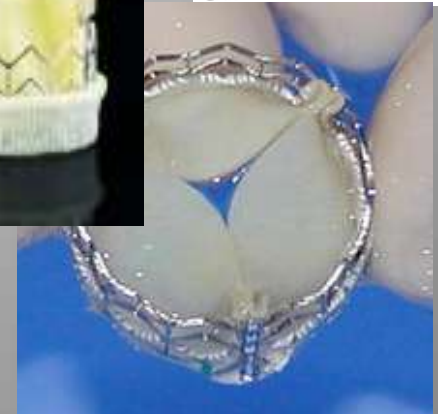
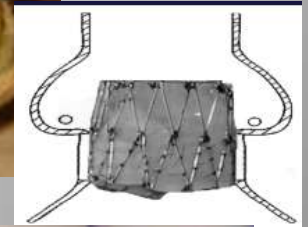
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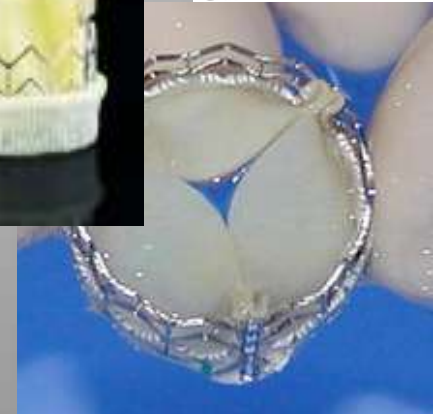
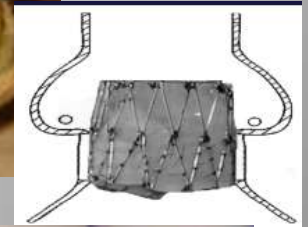
Transapical delivery

Transaxillary delivery

Transcarotid delivery

Percutaneous transfemoral

**TAVI**



# **Dr. Alain Cribier**

## **First-in-Man PIONEER**



**April 16, 2002**



### ***Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis***

#### ***First Human Case Description***

*Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derumeaux, MD; Frederic Anselme, MD; François Laborde, MD; Martin B. Leon, MD*

**AHA; Nov, 2002**

# TAVI Technologies

## Current Generation Devices



Edwards Lifesciences



Medtronic CoreValve

# Next Generation TAVR System

## New Self-Expanding TAVI Systems



PORTICO  
(St. Jude)



ENGAGER  
(Medtronic)



ACURATE  
(Symetis)



EVOLUT R  
(Medtronic)

# Next Generation TAVR Systems

## Not All New TAVI Systems are Self-Expanding Designs



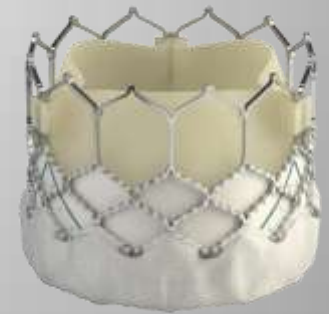
**Direct Flow:**  
Polyester fabric cuff with two inflatable rings; positioning wires for placement; bovine tissue valve



**Lotus:**  
Nitinol wire frame, bovine tissue valve; outer PU skirt; mechanical expansion and locking



**Jena Valve:**  
Nitinol-based, positioning feelers and clipping mechanism; porcine aortic root valve



**SAPIEN 3:**  
balloon exp (4 sizes), cobalt frame; bovine tissue valve; outer skirt; precise positioning

# AHA/ACC TAVR Guidelines - 2014

## Class I:

- Heart Valve Team should collaborate on decisions
- Pts not suitable for AVR and survival > 12 mos

## Class IIa:

- Reasonable alternative to surgical AVR in high surgical risk pts

Recommendations	COR	LOE
Surgical AVR is recommended in patients who meet an indication for AVR (Section 3.4) with low or intermediate surgical risk (Section 2.5 in the full-text guideline)	I	A
For patients in whom TAVR or high-risk surgical AVR is being considered, members of a Heart Valve Team should collaborate to provide optimal patient care	I	C
TAVR is recommended in patients who meet an indication for AVR for AS who have a prohibitive surgical risk and a predicted post-TAVR survival >12 mo	I	B
TAVR is a reasonable alternative to surgical AVR in patients who meet an indication for AVR (Section 3.4) and who have high surgical risk (Section 2.5 in the full-text guideline)	IIa	B
Percutaneous aortic balloon dilation may be considered as a bridge to surgical or transcatheter AVR in severely symptomatic patients with severe AS	IIb	C
TAVR is not recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of AS	III/No Benefit	B

# PARTNER Study Design



## Symptomatic Severe Aortic Stenosis

**ASSESSMENT: High-Risk AVR Candidate**  
3,105 Total Patients Screened

n = 699

**High-Risk**

**Total = 1,057 patients**  
2 Parallel Trials:  
Individually Powered

**ASSESSMENT:  
Transfemoral  
Access**

**High-Risk TF**

**High-Risk TA**

1:1 Randomization

1:1 Randomization

TF TAVR

VS

AVR

TA TAVR

VS

AVR

Primary Endpoint: All-Cause Mortality (1 yr)  
(Non-Inferiority)

**Inoperable**

n = 358

**ASSESSMENT:  
Transfemoral  
Access**

1:1 Randomization

TF TAVR  
n = 179

VS

Standard  
Therapy  
n = 179

Primary Endpoint: All-Cause Mortality  
Over Length of Trial (Superiority)

THE NEW ENGLAND JOURNAL OF MEDICINE

***Published April 2012***

ORIGINAL ARTICLE

## Transcatheter Aortic-Valve Replacement for Inoperable Severe Aortic Stenosis

Raj R. Makkar, M.D., Gregory P. Fontana, M.D., Hasan Jilaihawi, M.D., Samir Kapadia, M.D., Augusto D. Pichard, M.D., Pamela S. Douglas, M.D., Vinod H. Thourani, M.D., Vasilis C. Babaliaros, M.D., John G. Webb, M.D., Howard C. Herrmann, M.D., Joseph E. Bavaria, M.D., Susheel Kodali, M.D., David L. Brown, M.D., Bruce Bowers, M.D., Todd M. Dewey, M.D., Lars G. Svensson, M.D., Ph.D., Murat Tuzcu, M.D., Jeffrey W. Moses, M.D., Matthew R. Williams, M.D., Robert J. Siegel, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Stuart Pocock, Ph.D., Craig R. Smith, M.D., and Martin B. Leon, M.D., for the PARTNER Trial Investigators\*

# All Cause Mortality (ITT) Crossover Patients Followed



## Numbers at Risk

	0	6	12	18	24
TAVR	179	138	124	110	83
Standard Rx	179	121	85	67	51

ORIGINAL ARTICLE

***Published April 2012***

## Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement

Susheel K. Kodali, M.D., Mathew R. Williams, M.D., Craig R. Smith, M.D.,  
Lars G. Svensson, M.D., Ph.D., John G. Webb, M.D., Raj R. Makkar, M.D.,  
Gregory P. Fontana, M.D., Todd M. Dewey, M.D., Vinod H. Thourani, M.D.,  
Augusto D. Pichard, M.D., Michael Fischbein, M.D., Ph.D., Wilson Y. Szeto, M.D.,  
Scott Lim, M.D., Kevin L. Greason, M.D., Paul S. Teirstein, M.D.,  
S. Chris Malaisrie, M.D., Pamela S. Douglas, M.D., Rebecca T. Hahn, M.D.,  
Brian Whisenant, M.D., Alan Zajarias, M.D., Duolao Wang, Ph.D.,  
Jodi J. Akin, M.S., William N. Anderson, Ph.D., and Martin B. Leon, M.D.,  
for the PARTNER Trial Investigators\*

# All-Cause Mortality (ITT)



## Numbers at Risk

	0	6	12	18	24	30	36
TAVR	348	296	260	234	172	70	31
AVR	351	252	236	217	165	65	32

# Contraindications for transcatheter aortic valve implantation

## Absolute contraindications

Absence of a “heart team” and no cardiac surgery on the site.  
Appropriateness of TAVI, as an alternative to AVR, not confirmed by a “heart team”.

### *Clinical*

- Estimated life expectancy < 1 year.
- Improvement of quality of life by TAVI unlikely because of comorbidities.
- Severe primary associated disease of other valves with major contribution to the patient’s symptoms that can be treated only by surgery.

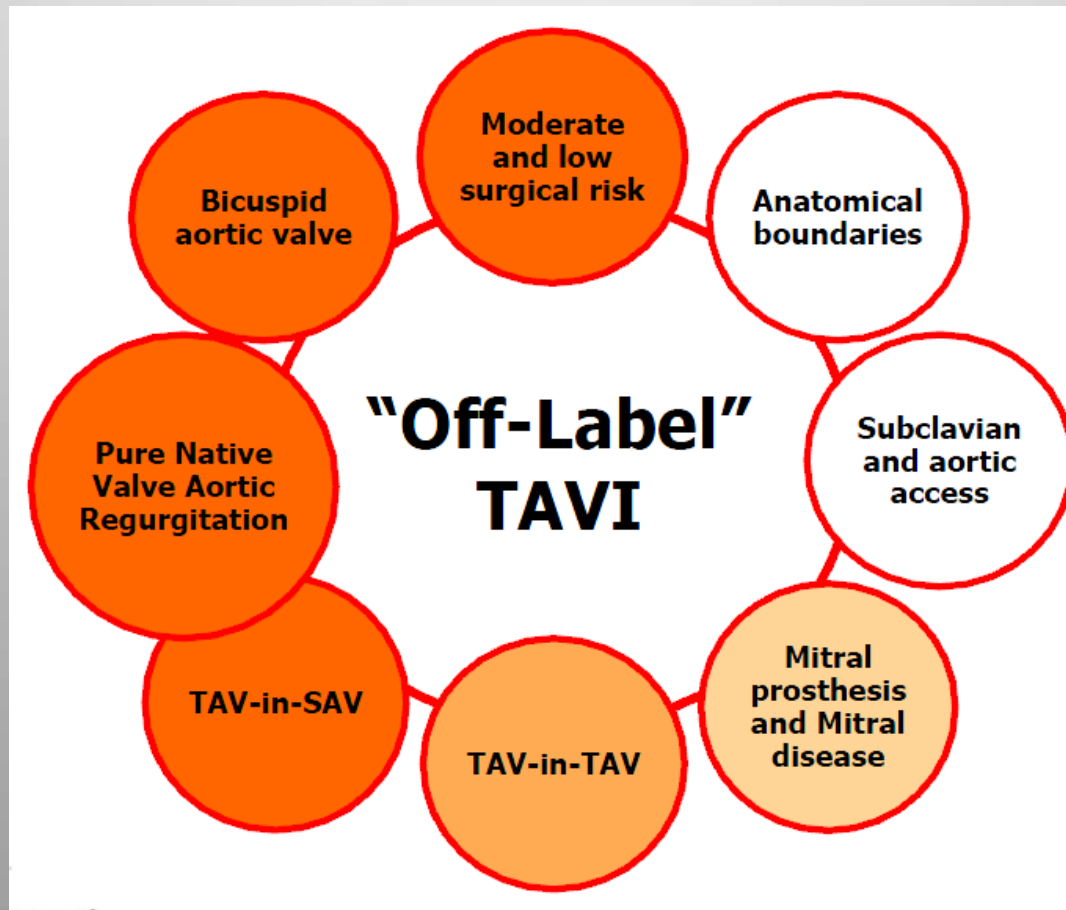
### *Anatomical*

- Inadequate annulus size (< 18 mm, > 29 mm).
- Thrombus in the left ventricle.
- Active endocarditis.
- Elevated risk of coronary ostium obstruction (asymmetric valve calcification, short distance between annulus and coronary ostia, small aortic sinuses).
- Plaques with mobile thrombi in the ascending aorta, or arch.
- For transfemoral/subclavian approach: inadequate vascular access (vessel size, calcification, tortuosity).

## Relative contraindications

- Bicuspid or non-calcified valves.
- Untreated coronary artery disease requiring revascularization.
- Haemodynamic instability.
- LVEF < 20%.
- For transapical approach: severe pulmonary disease, LV apex not accessible.

# ...Expanding TAVI...

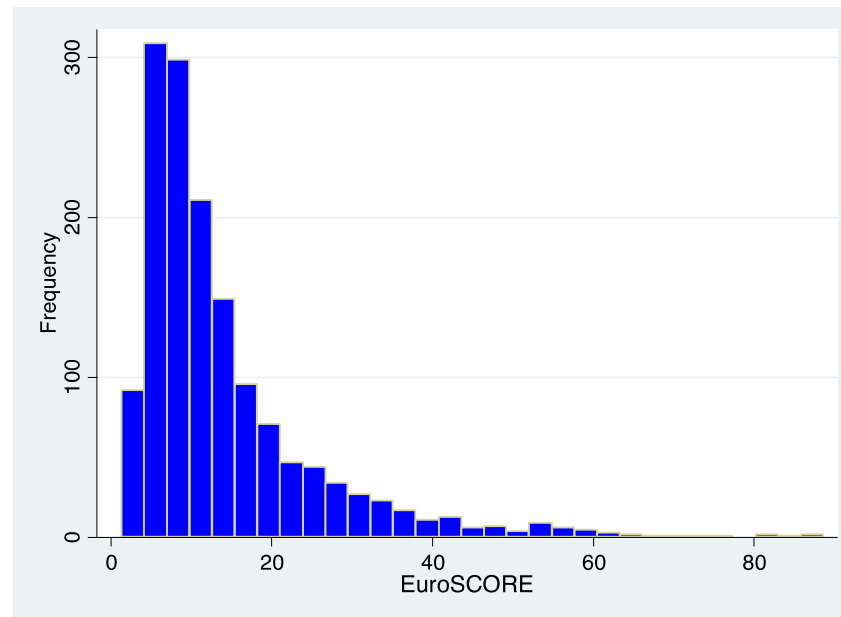




# Log-EuroSCORE

## Patients undergoing TAVI procedure (N = 1544)

Patients reporting difficult thoracic approach, porcelain aorta or severe frailty score are excluded



<b>Log - EuroSCORE :</b>	<b>Mean=</b>	<b>14.1 <u>+11.8</u></b>
	<b>Median=</b>	<b>10.3</b>
	<b>75° percentile =</b>	<b>16.9</b>

# FINAL CONSIDERATIONS

- TAVI is the standard of care for inoperable pts ( cave futile interven
- TAVI is an alternative to AVR in high risk pts (the cost of the proce
- Stroke rate, vascular complications , residual AR ,PM requirement rem
- Extension of TAVI to intermediate risk pts is presently not justified  
( PARTNER II, SURTAVI , UK TAVI and other studies are exploring the  
To note that the risk of TAVI is lower in lower risk pts.