

TAVI. CCH still on site?

Gianmarco Iannopolo

UOC Cardiologia

Ospedale Maggiore Carlo Alberto Pizzardi, Bologna





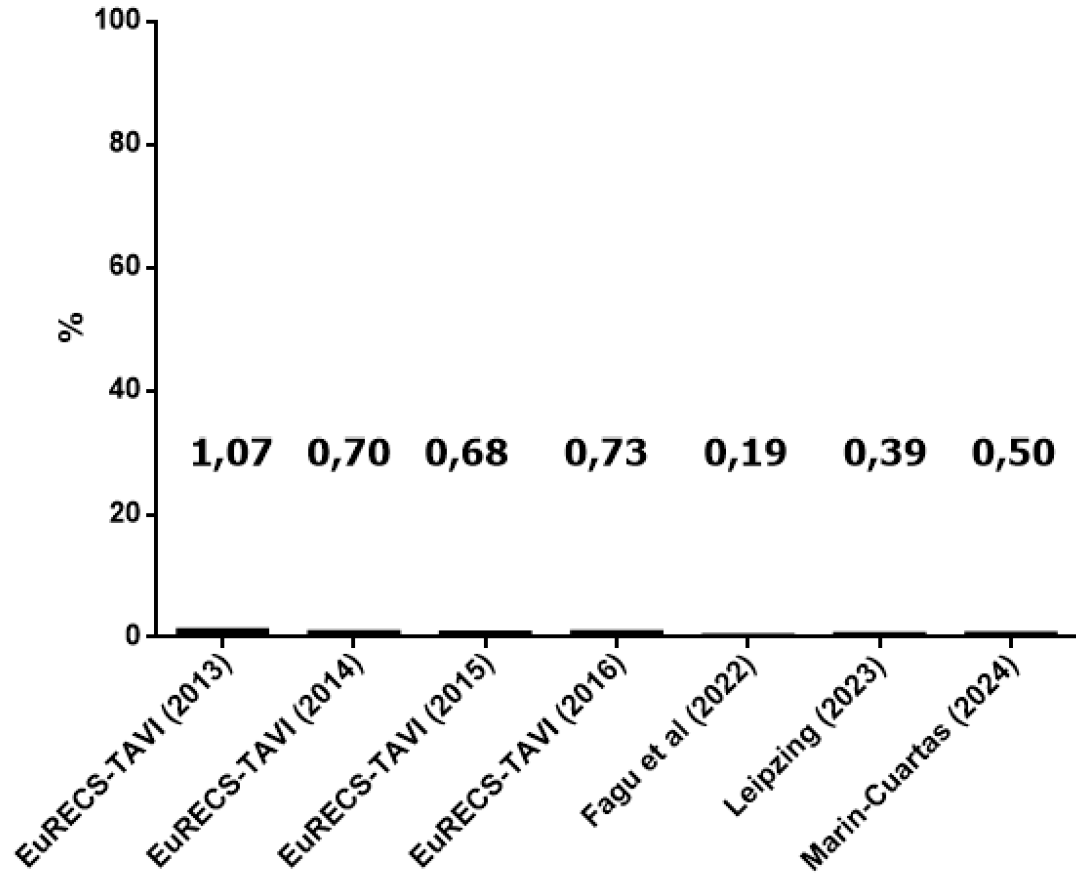
Why should on-site cardiac surgery be needed?



Heart Team Discussion



Emergent Cardiac Surgery



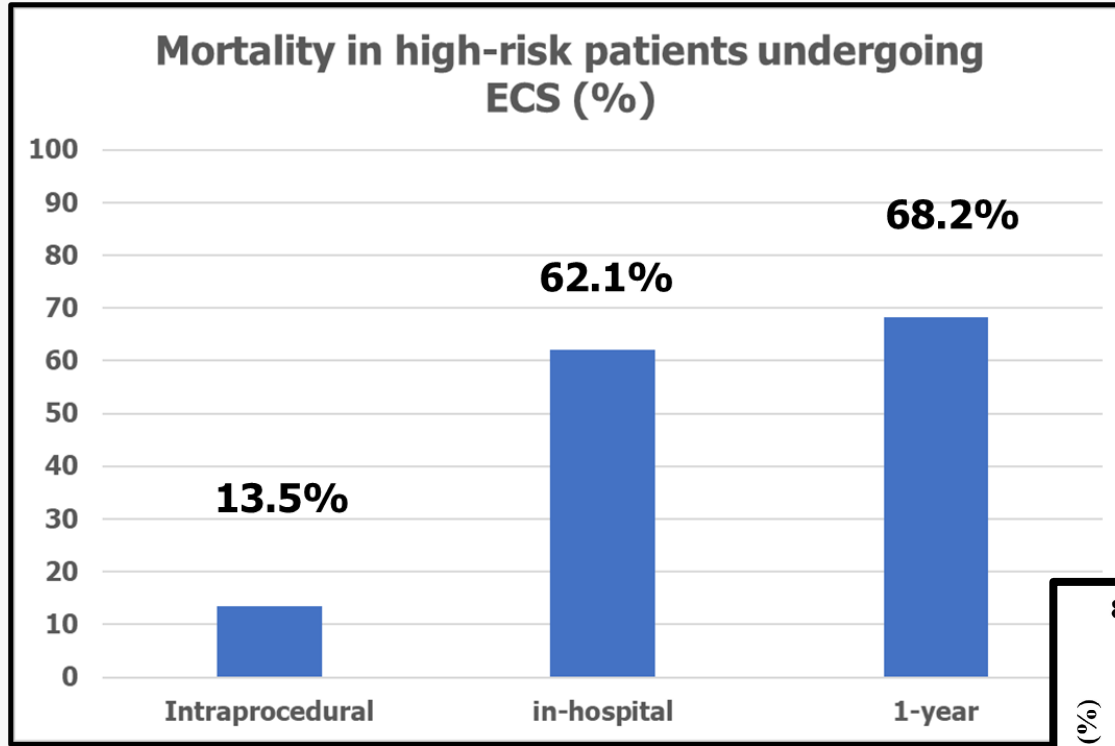
Aarts et al JACC CVI 2025



Mas-Peiro et al Circulation CVI 2026

The contemporary incidence of ECS is extremely low ($\approx 0.5\%$)

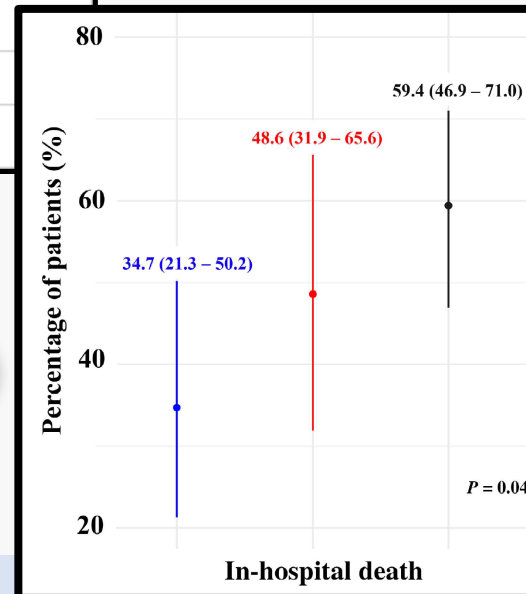
Leipzig



Even when performed, ECS
is associated with extremely
high mortality

USA

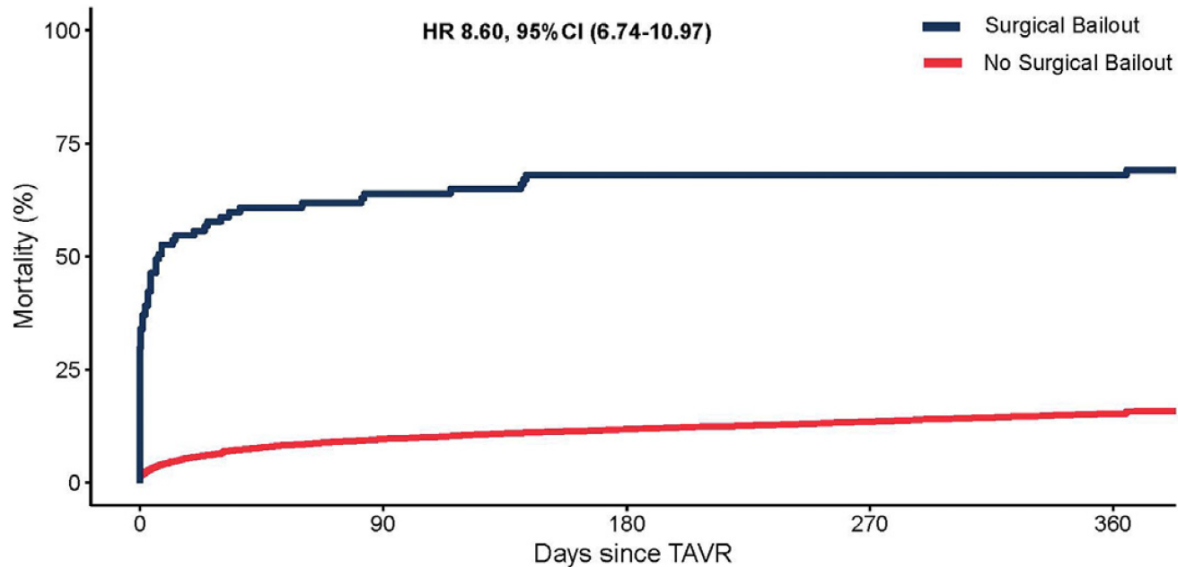
Intraprocedural death was 12.5% (n=19), and in-hospital death was 49.3% (n=75). The most common postoperative complications were acute kidney failure requiring dialysis (24.3% [n=37]), major bleeding (24.3% [n=37]), and low cardiac output syndrome (18.4% [n=28]). The incidence of stroke was 13.2% (n=20). Extracorporeal life support was required in 11 (7.2%) patients, all of whom died during the index hospitalization. Early death according to risk group is displayed



The NNT is 580*

*System-level NNT estimate

CENTER2 study

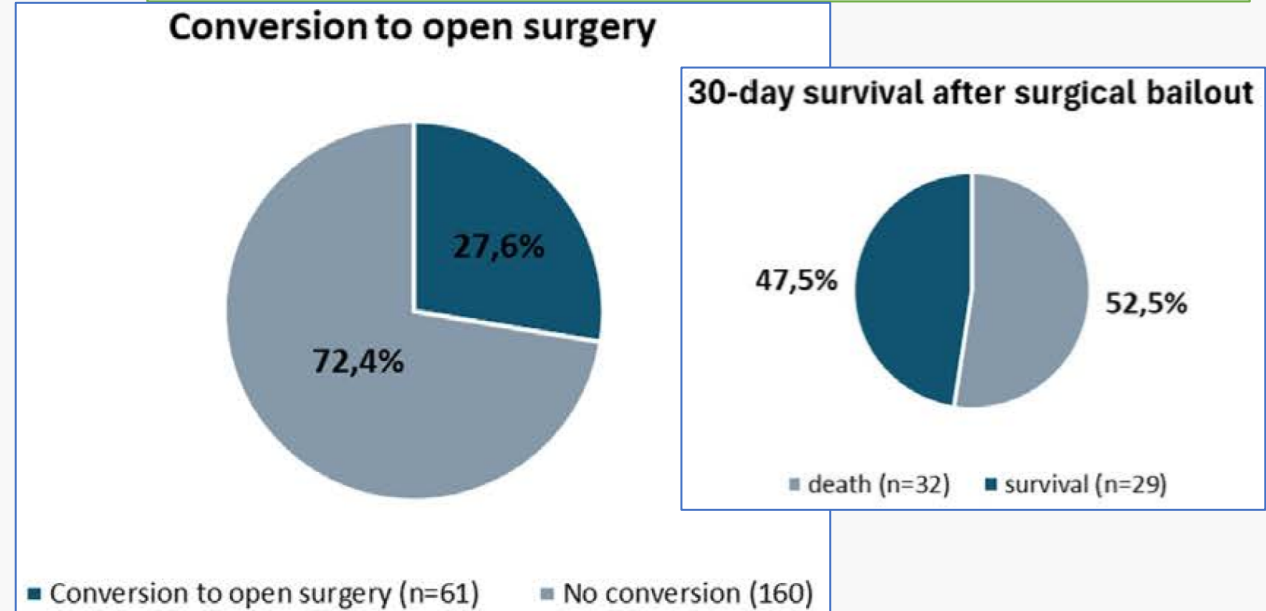


Ventricular perforation prevalent reason

1-year mortality 68.3%

NNT 620*

18 EU/Canada study



Annulus rupture prevalent reason

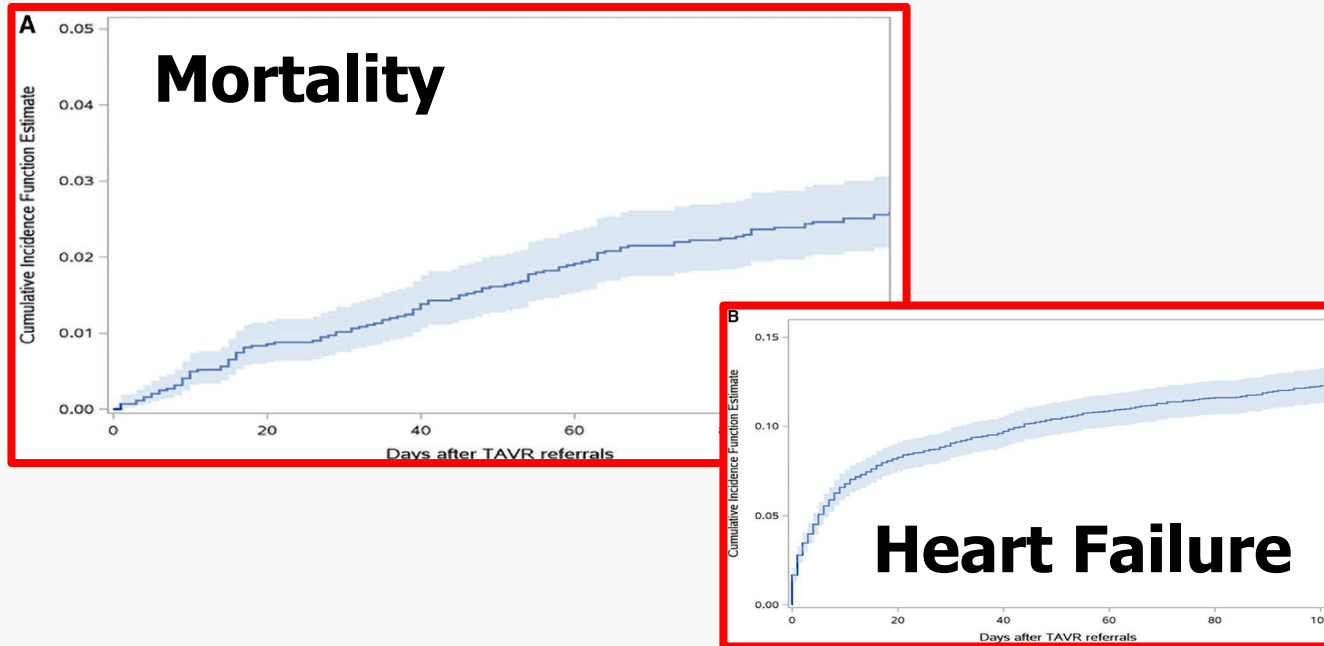
30-day mortality 52.8% NNT 370*

1-year mortality 71.3% NNT 585*

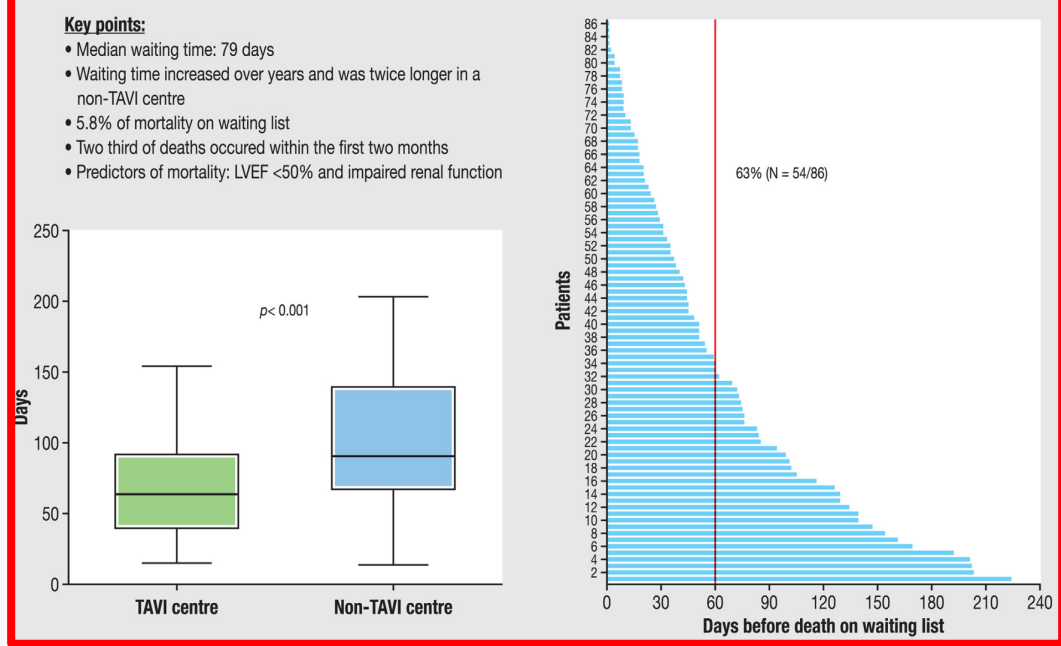


How important is the waiting time for TAVI?

Canada



France



- The number of TAVI is exploding
 - Waiting time is associated with death
 - A timely intervention maximizes the benefit of the procedure
- The NNH is 17-50**

*System-level NNH estimate

Elbaz-Greener et al Circulation 2018, Poinson et al Archives of CVD 2025

How important is the waiting time for TAVI?

WAIT-TIMES BENCHMARKS FOR TAVI

Simulation models

- Based on population data from Ontario, Canada
- Explore impact of different risk groups definitions and wait-times on clinical outcomes

REDUCTIONS IN ADVERSE EVENTS

(compared to no prioritization)

Up to	
29%	Deaths
23%	Hospitalizations
38%	Urgent procedures

WAIT-TIMES BENCHMARKS

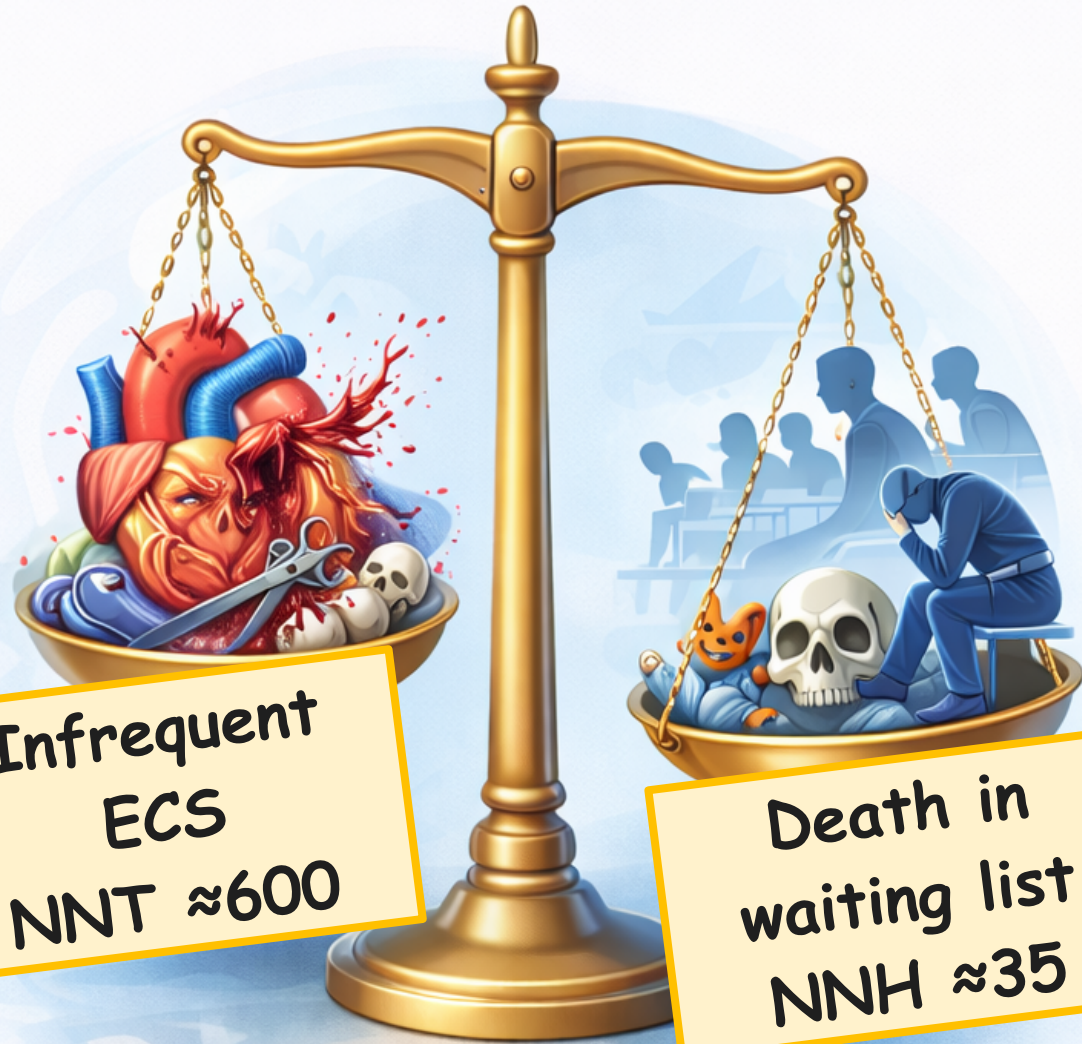
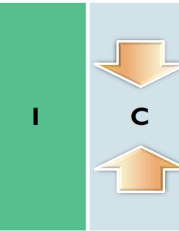
	High-risk 20% of population	3 weeks*
	Medium-risk 10% of population	7 weeks*
	Low-risk 70% of population	16 weeks*

*from referral

Prioritizing higher-risk patients, reduces events but results in unacceptably long wait-times for the other groups

Give things their proper weight

Aortic valve interventions must be performed in Heart Valve Centres that declare their local expertise and outcomes data, have active interventional cardiology and cardiac surgical programmes on site, and a structured collaborative Heart Team approach.



Infrequent
ECS
NNT ≈ 600

Death in
waiting list
NNH ≈ 35



Opinion

Scientific
Data

Rare catastrophic events must be balanced against frequent preventable deaths

*System-level estimates



Hypothesis

- **A shared indication by experienced Heart Team plus planning and intervention performed by experienced operators are the most effective strategies to minimize complications, independently by the presence or not of on-site cardiac surgery**
- **Shifting patients from hub to spoke centers could reduce waiting times to TAVI and events while on the waiting list**



Transcatheter Aortic-Valve Implantation with or without on-site Cardiac Surgery (TRACS) trial

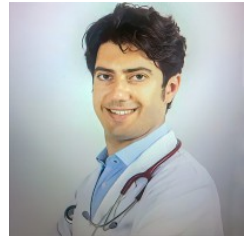
The TRACS trial was an investigator-initiated, multicenter, prospective, non-inferiority, randomized trial.

Country: Italy



13 centers

Study PI: Gianmarco Iannopollo



Study Chair:

Gianni Casella

Vincenzo Guiducci



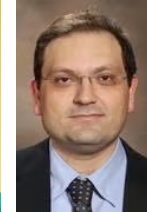
Executive Committee: Gianmarco

Iannopollo, Gianni Casella, Salvatore Saccà,
Filippo Ottani, Caterina Cavazza, Vincenzo
Guiducci

CEC:

Paolo Cimaglia

Giampaolo Niccoli



DSMB: Gianluca Campo

Aldo Maggioni, Francesco Saia, Emanuele
Barbato, Luigi Vignali, Davide Pacini, Francesco
Nicolini, Giovanni Melina

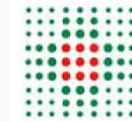


ARO: Veronica Lodolini, Alice Santoni

Stats: Donato Martella, Nicola Pesenti



Sponsor



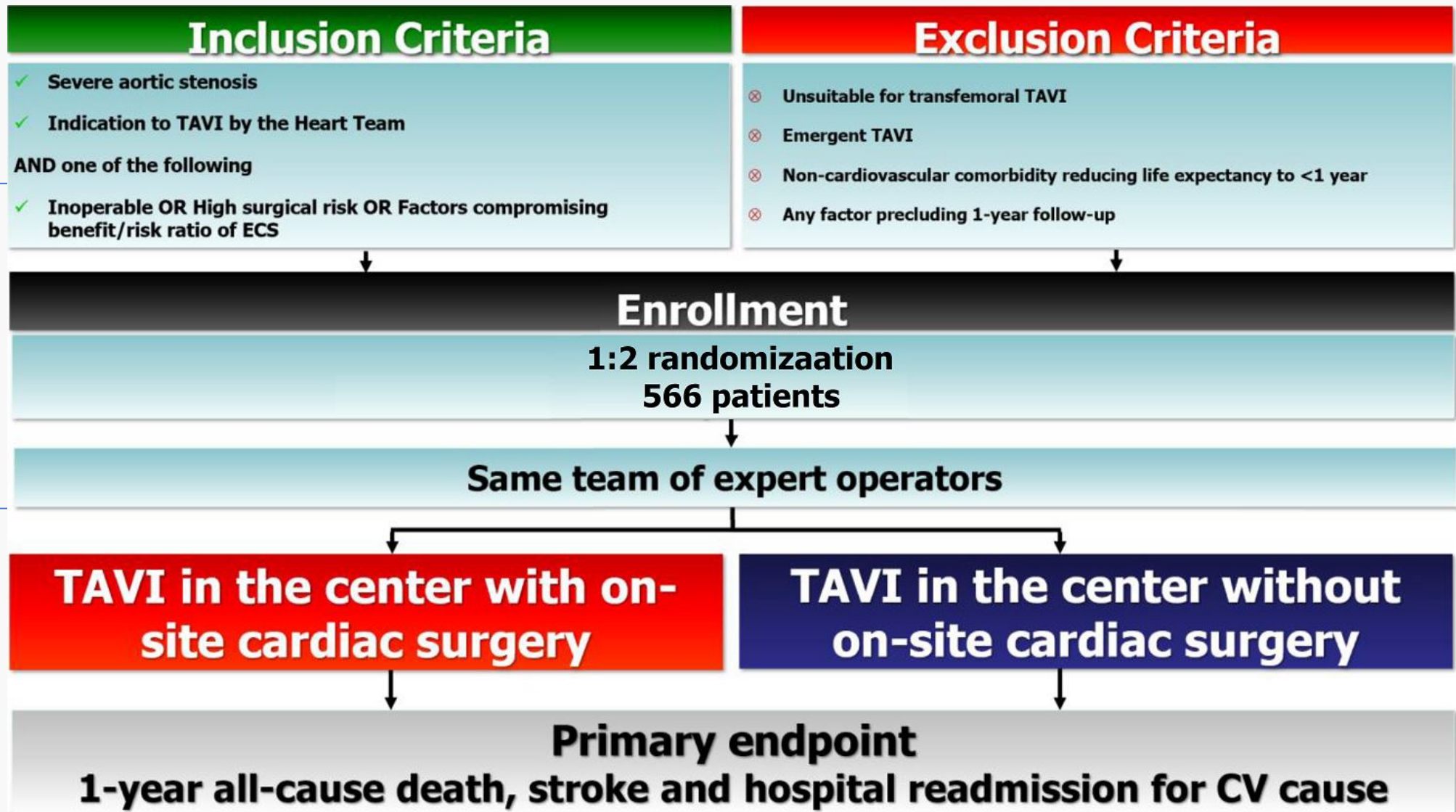
Azienda Unità Sanitaria Locale
Bologna

Supporter



Università
degli Studi
di Ferrara

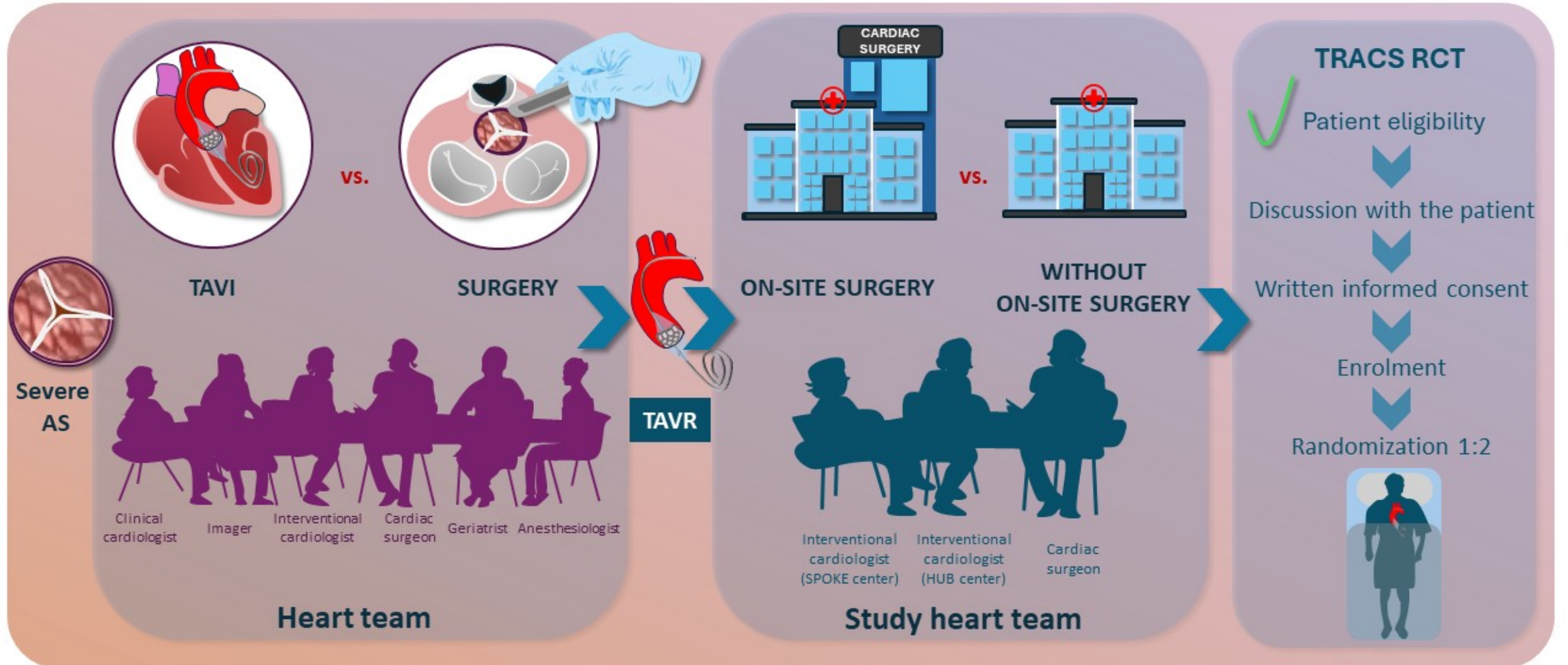
Study Flow



Porcelain aorta
 Frailty
 Severe liver disease
 Hostile chest
 Severe PH
 Severe RV dysfunction
 Age ≥85 years
 Severe COPD



Heart Team matters!





July 2

657 randomized pts

611 have undergone TAVI

(413 TAVI in centers w/o CS)

No ECS required so far

No safety concerns from DSMB

Waiting time from randomization:

Without CS 21 ± 21 days

With CS 75 ± 44 days

	PARTNER Inoperable	PARTNER High-Risk	TRACS
Characteristic	(n=179)	(n=348)	(n=657)
Age - years	83 $\pm$ 9	84 $\pm$ 7	85 (84-88)
Male sex - no. (%)	82 (46)	201 (58)	323 (49)
STS score	11 $\pm$ 6	11 $\pm$ 3	8 $\pm$ 3.2
Medical history			
Prior MI - no. (%)	33 (19)	92 (27)	121 (18.8)
Prior BAV - no. (%)	25 (16)	46 (13)	122 (18)
CVA - no. (%)	48 (27)	95 (29)	47 (8.3)
PAD - no. (%)	54 (30)	148 (43)	104 (16.1)
COPD - no. (%)	74 (41)	151 (44)	72 (11)
Creatinine >2 mg/dl - no. (%)	10 (5.6)	38 (11)	33 (5)
History of AF - no. (%)	28 (33)	80 (41)	204 (31)
Additional data			
Frailty - no. (%)	21 (12)	46 (13)	250 (38)
Extensively calcified aorta - no. (%)	34 (19)	2 (1)	28 (4.2)
Study specific data			
Inoperable	179 (100)		207 (32)
High-risk		348 (100)	203 (31.3)
At least 1 factor compromising ECS			616 (94.3)
Criterion age $\geq$ 85 years			449 (68)



The future must be evidence-driven!



ESC Congress 2027

Milan, Italy

27 to 30 August

See you in Milan
for the TRACS
presentation



Transcatheter Aortic-Valve Implantation
without on-site Cardiac Surgery Broadened
Access: the TRACS-PRIME trial

Inclusion Criteria

- ✓ Severe aortic stenosis
- ✓ Indication for TAVI by Heart Team
- ✓ Enrichment criteria (limited benefit from ECS)

Exclusion Criteria

- ✗ Unsuitable for transfemoral TAVI
- ✗ Emergent TAVI
- ✗ Non-cardiovascular comorbidity reducing life expectancy to <1 year
- ✗ Any factor precluding 1-year follow-up

Enrollment

1:3 randomization
1612 patients

Same team of expert operators

On-site cardiac surgery center

No on-site cardiac surgery
center

1-year Clinical Efficacy Endpoint

All-cause death, all stroke or procedure-related or valve-related hospitalization



Conclusions

- **Aortic stenosis should be considered a time-dependent disease (aortic stenosis network = STEMI network)**
- **Access and waiting list for TAVI are major issues**
- **Expanding access through spoke centers deserves rigorous evaluation (RCTs).**



GRAZIE PER L'ATTENZIONE

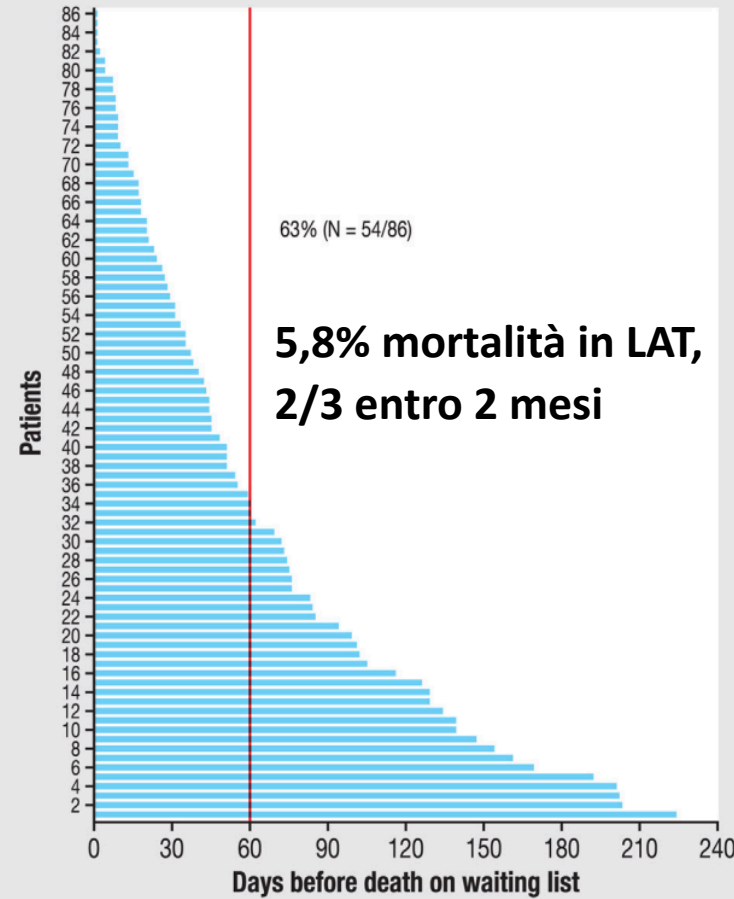
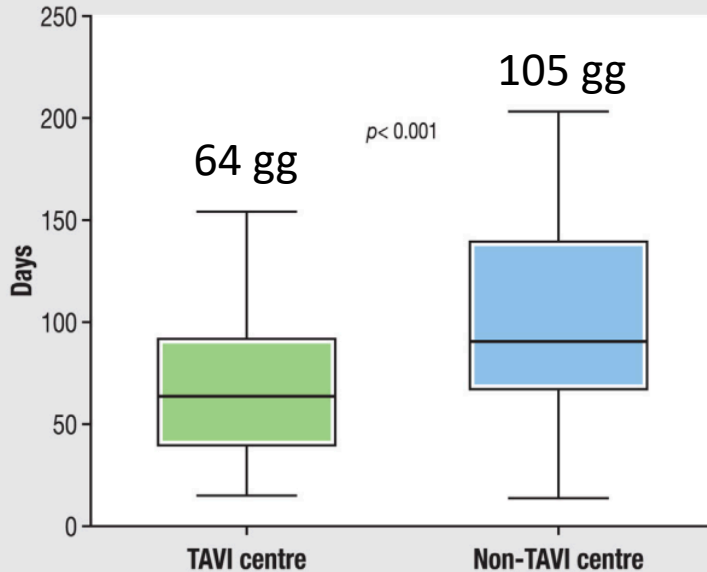


BACK UP SLIDES

Waiting time (2)

Key points:

- Median waiting time: 79 days
- Waiting time increased over years and was twice longer in a non-TAVI centre
- 5.8% of mortality on waiting list
- Two third of deaths occurred within the first two months
- Predictors of mortality: LVEF <50% and impaired renal function



- Tempo di attesa mediano **di 79 giorni**
- **Lista di attesa è aumentata negli anni in maniera lineare.**
- **Maggiore attesa nel centro senza TAVI in sede** (105 giorni vs 64 giorni; $P < 0.001$)
- **5.8% di mortalità in lista di attesa**, principalmente per cause CV
- 63% delle morti **entro i primi 2 mesi**
- Fattori predittivi di morte: **FE < 50% e eGFR < 60 ml/min**



Hypothesis

- **A shared indication by experienced Heart Team plus planning and intervention performed by experienced operators are the most effective strategies to minimize complications, independently by the presence or not of on-site cardiac surgery**
- **Shifting patients from hub to spoke centers could reduce waiting times to TAVI and events while on the waiting list**