

TAVR in the Elderly: Futility Versus Utility

Tullio Palmerini, MD
University of Bologna, Italy

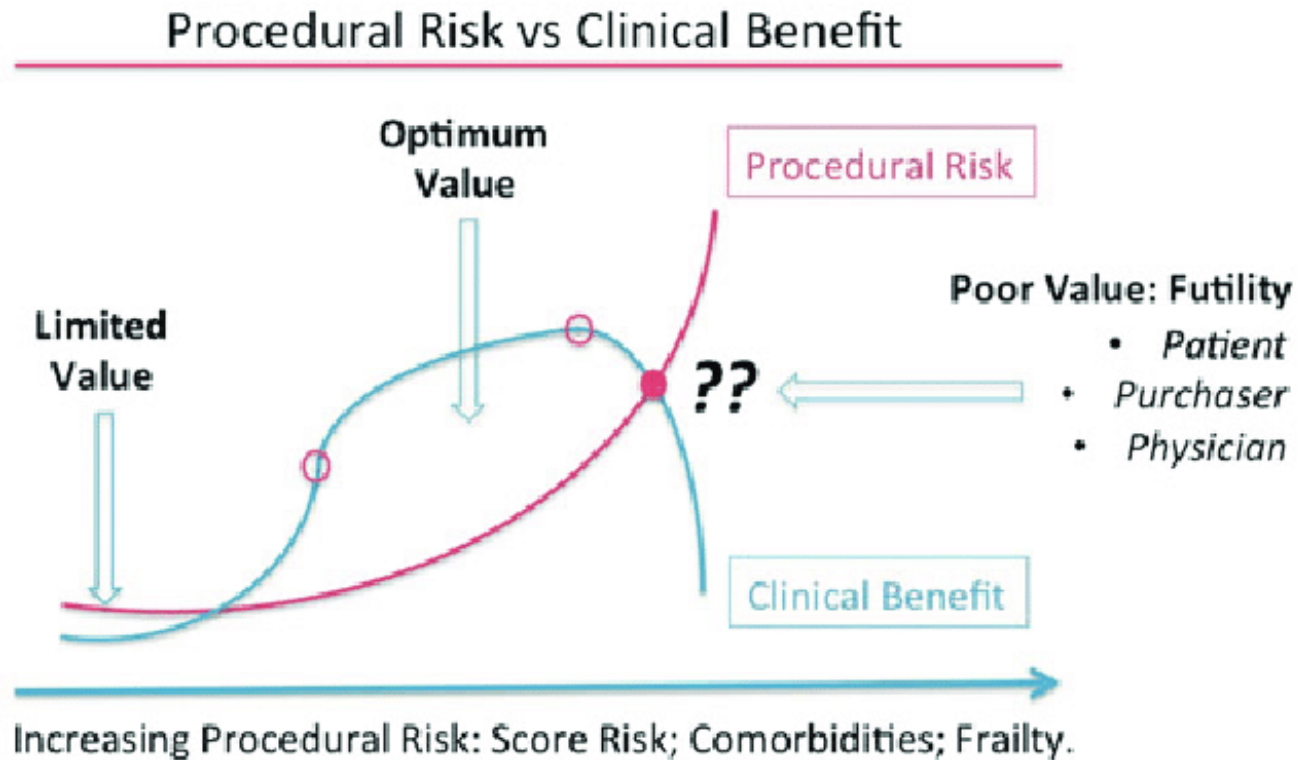
Disclosure

- Lecture fees from Medtronic and Edwards
- Proctor Medtronic



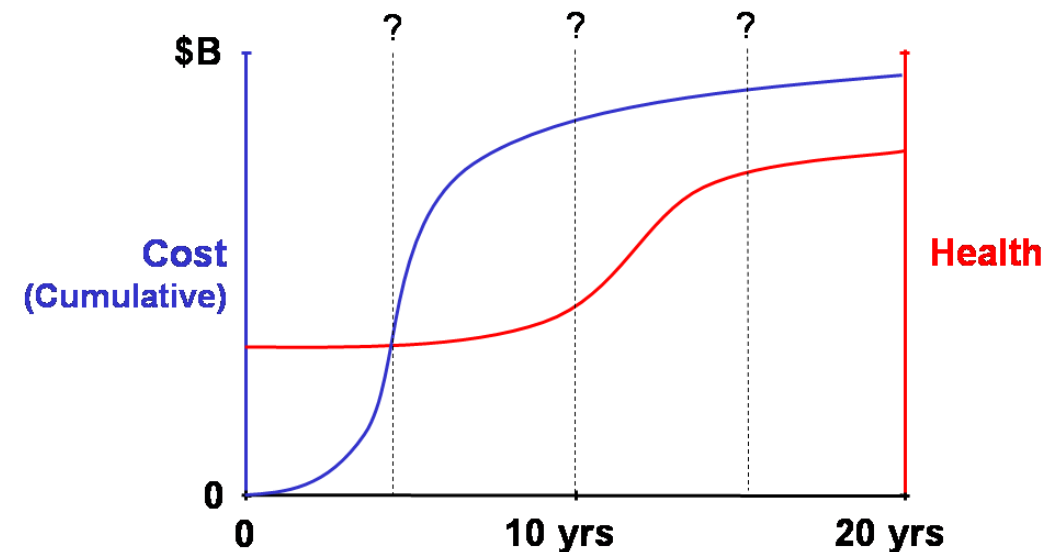
Establishing the value of a procedure

UTILITY/FUTILITY

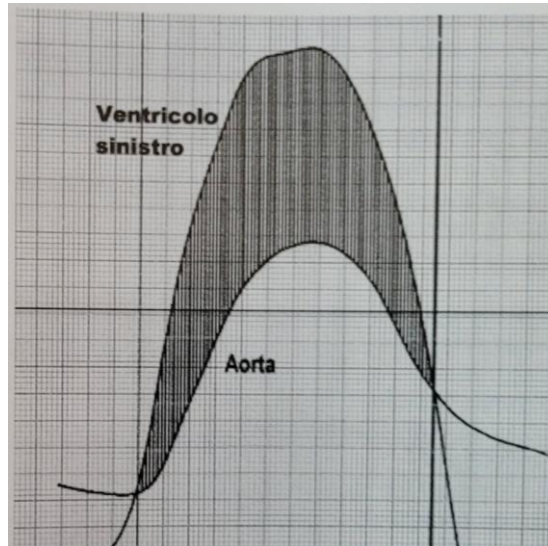


COST/EFFECTIVE

The economic burden of treatment



Degenerative aortic valve stenosis: the new pandemic



Renal
disease



Liver
disease



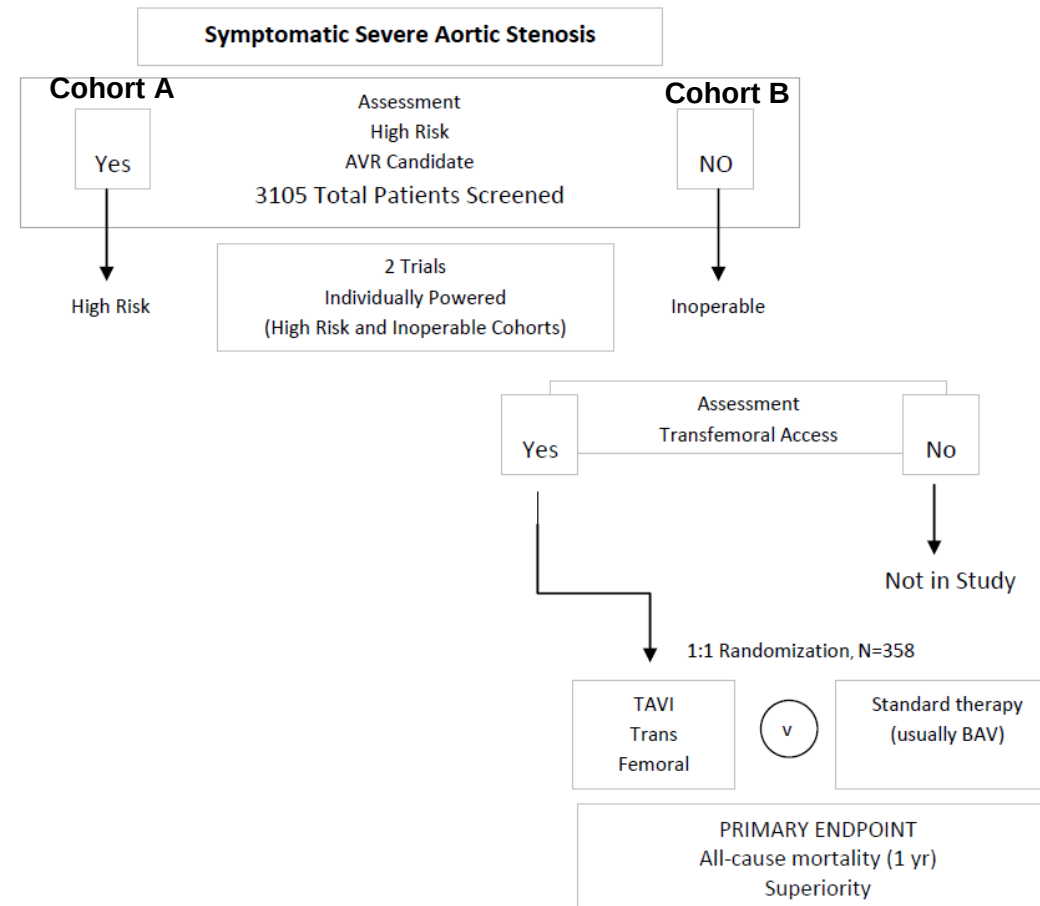
Active
cancer



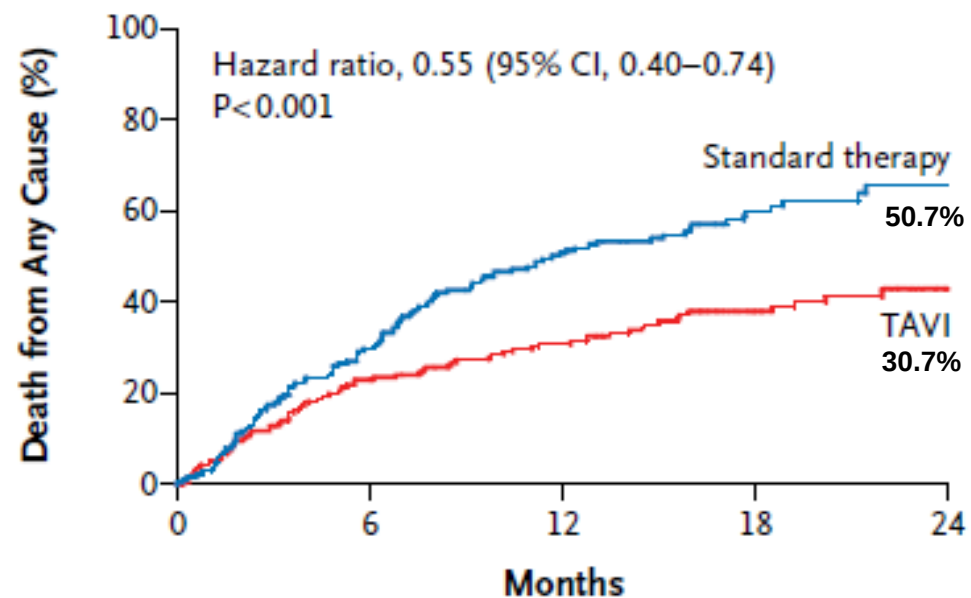
Anemia



Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

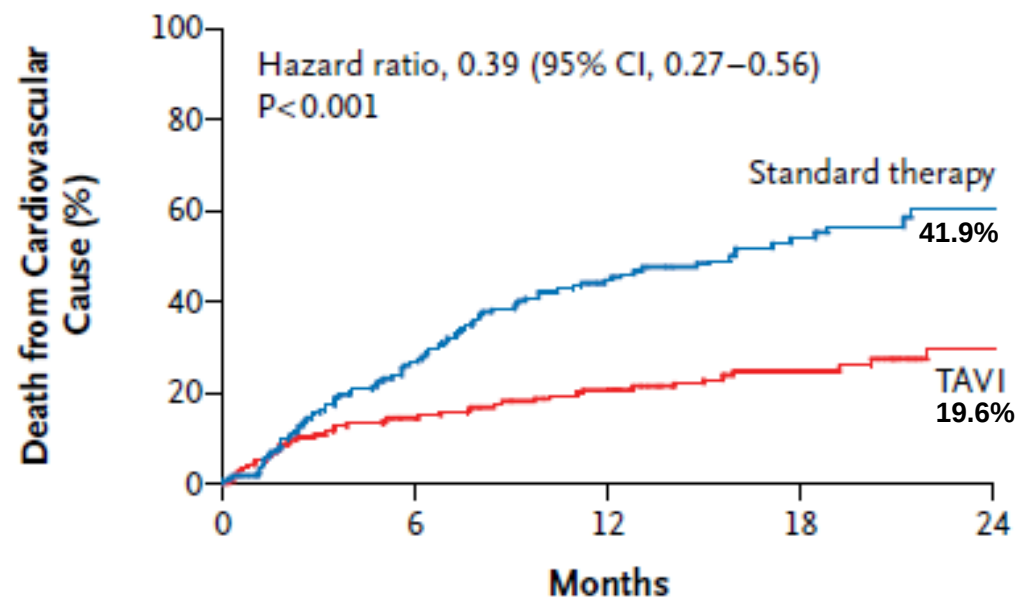


NNT= 5

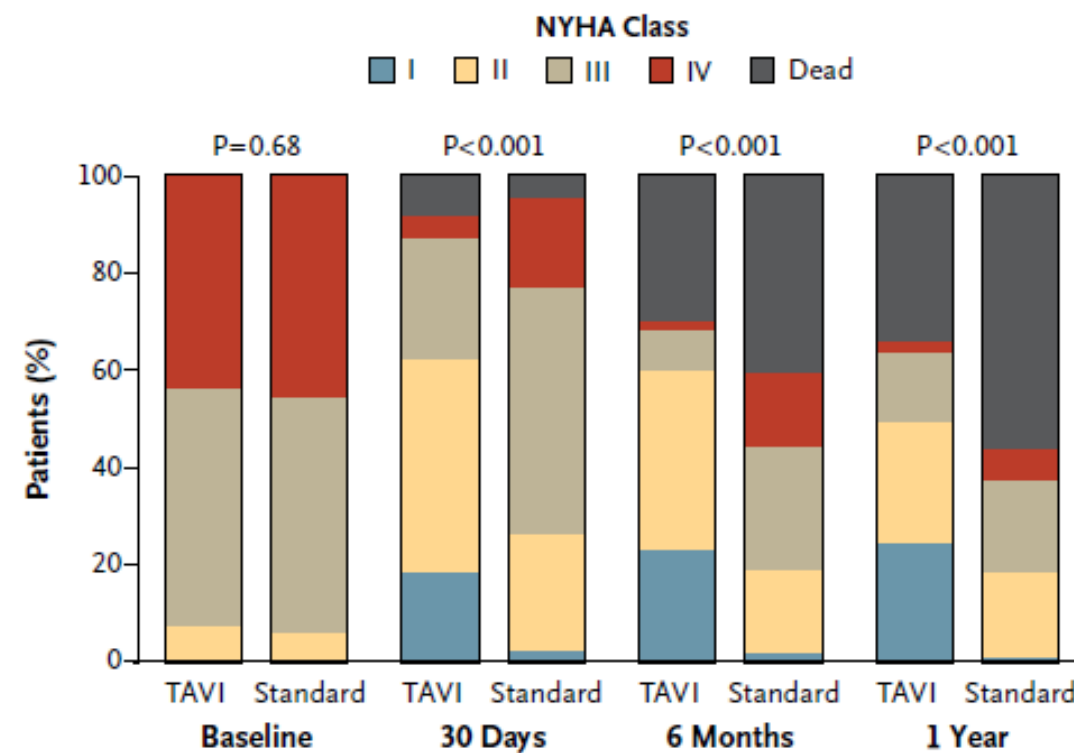
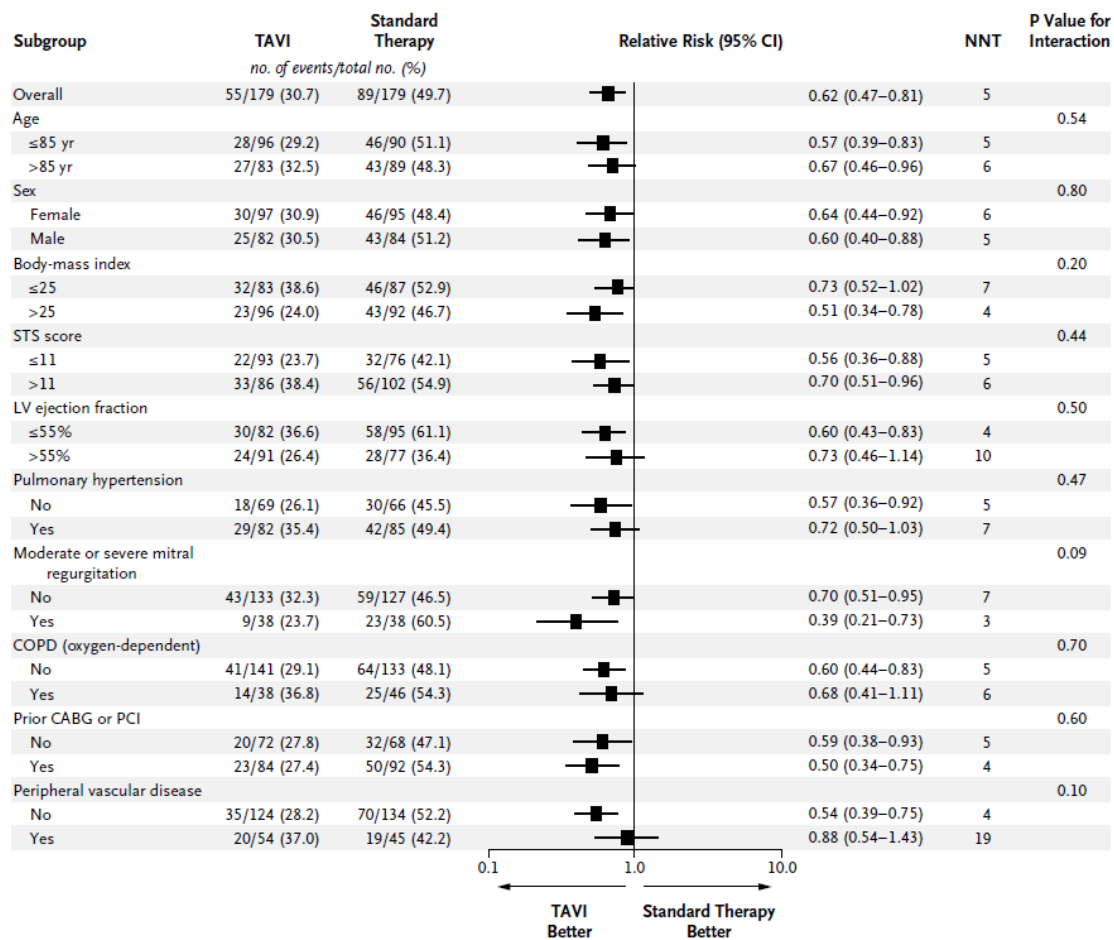


No. at Risk					
TAVI	179	138	122	67	26
Standard therapy	179	121	83	41	12

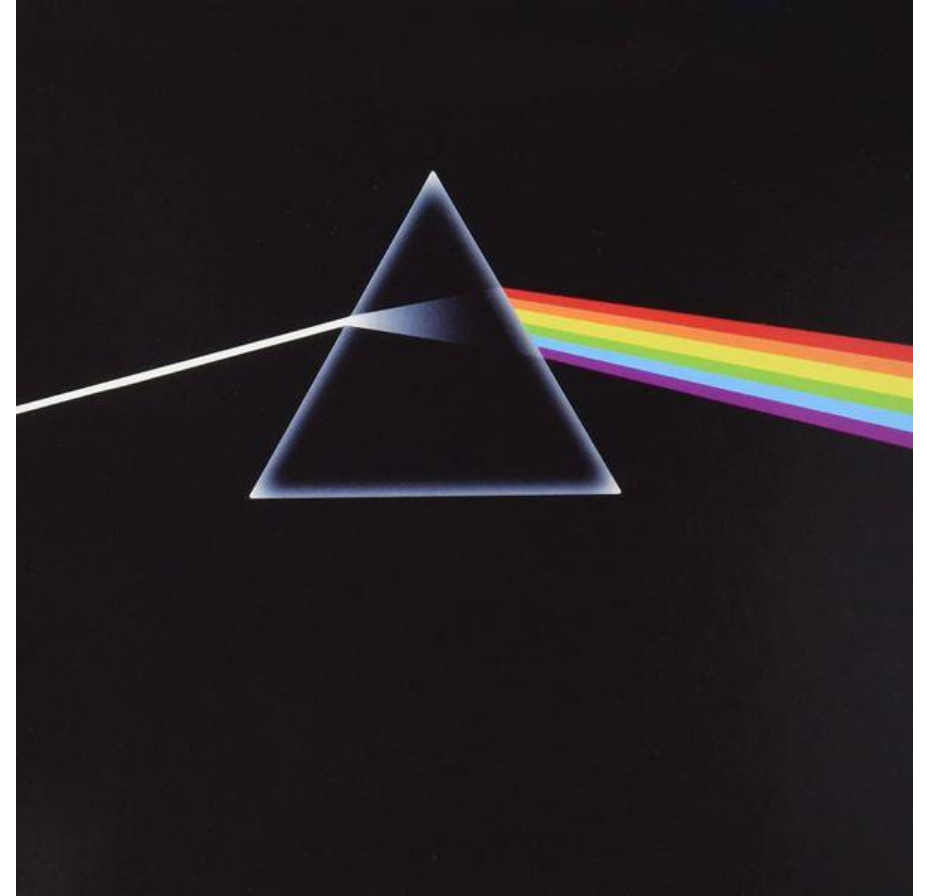
NNT= 4

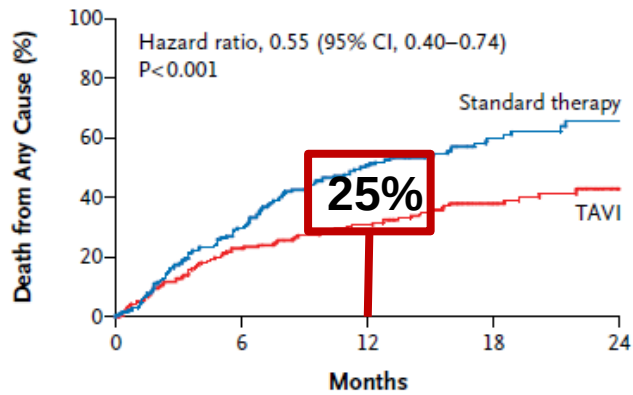


No. at Risk					
TAVI	179	138	122	67	26
Standard therapy	179	121	83	41	12



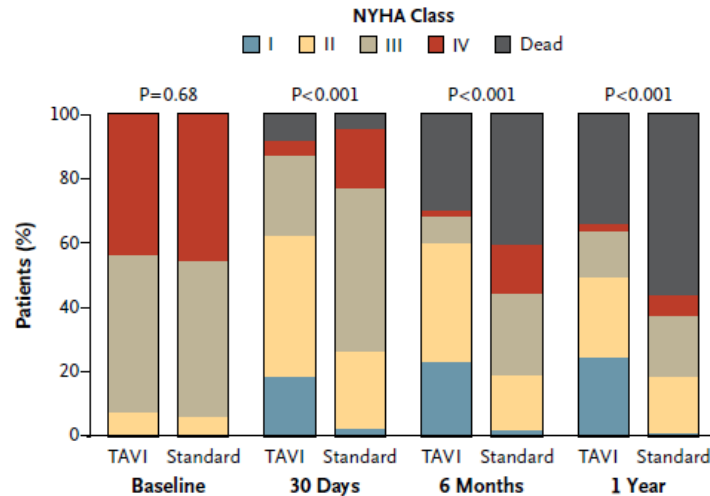
The dark side of the moon





No. at Risk					
TAVI	179	138	122	67	26
Standard therapy	179	121	83	41	12

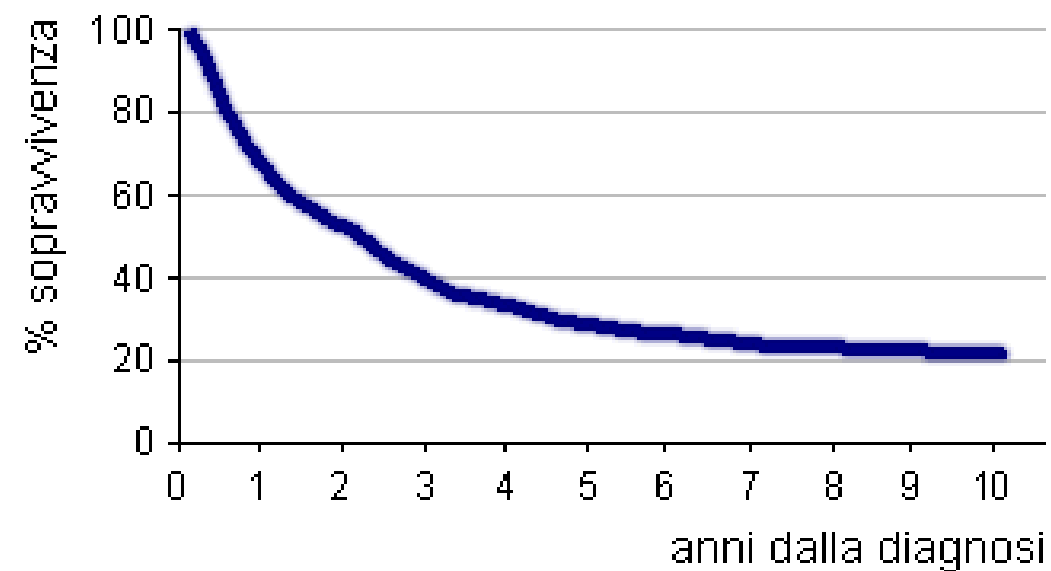
1 in 4 patients undergoing TAVR were dead at 1 year



20% of patients did not improve quality of life



Can we identify these patients



Predicting outcomes after intervention: how we identify futility?

Eyeball test



**“In God we trust.
All others must bring data.”**

- Dr. W. Edwards Deming



Cognitive limits for clinical prediction and decision making in uncertain situations

- Cognitive load

Episode based medicine

- Representability bias
- Availability bias

Risk models to assess the risk of 1-year death

Predictor	Poor Outcome at 6 mo (Definition No. 1)		Poor Outcome at 1 y (Definition No. 2)	
	OR (95% CI)	P Value	OR (95% CI)	P Value
Male sex	C statistic 0.65			0.097
Diabetes mellitus				N/A
Major arrhythmia				0.280
Serum creatinine (per				0.005
Mean arterial pressure (per 1 mm Hg)	1.01 (1.00–1.02)	0.209	N/A	N/A
Body mass index (per 1 kg/m ²)	0.98 (0.96–1.00)	0.104	1.00 (0.98–1.02)	0.791
Oxygen-dependent lung disease	1.77 (1.23–2.54)	0.002	1.80 (1.25–2.61)	0.002
Mean aortic valve gradient (per 10 mm Hg)	0.82 (0.75–0.89)	<0.001	0.84 (0.77–0.90)	<0.001
Mini-Mental Status Examination (per 1 point)	0.96 (0.92–1.00)	0.036	0.94 (0.90–0.97)	0.001
6-Min Walk Test distance (per 10 m)	0.97 (0.96–0.98)	<0.001	0.97 (0.96–0.98)	<0.001

Complex biological system

Uncertainty in clinical prediction

Limited predictive capacity with traditional statistics

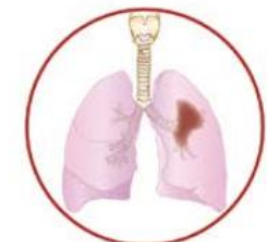
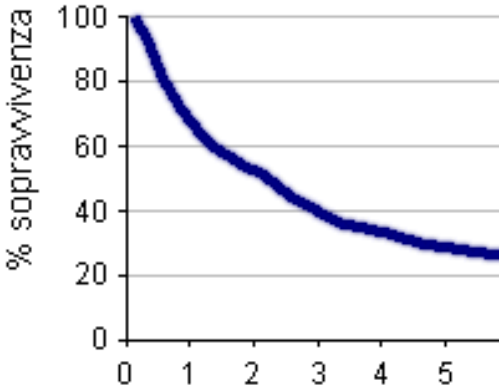
Artificial Intelligence



Renal disease



Liver disease



Active cancer



Anemia

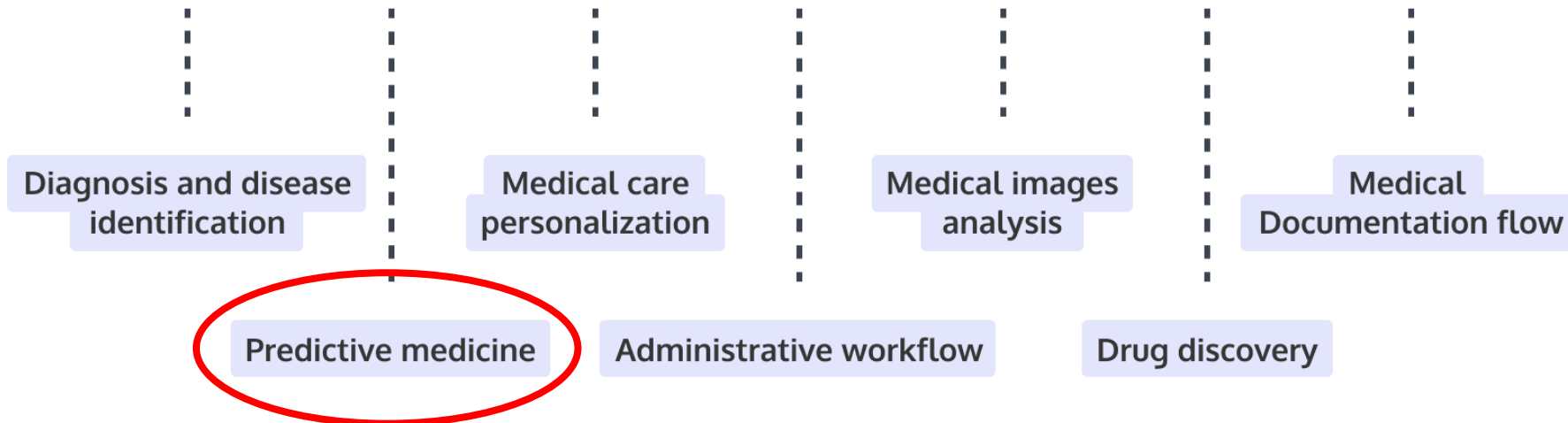
Predictor	Poor Outcome at 6 mo (Definition No. 1)	
	OR (95% CI)	P Value
Male sex	1.23 (0.96–1.57)	0.097
Diabetes mellitus	0.82 (0.63–1.06)	0.130
Major arrhythmia	1.29 (1.02–1.63)	0.036
Serum creatinine (per 1 mg/dL)	1.32 (1.03–1.70)	0.028
Mean arterial pressure (per 1 mm Hg)	1.01 (1.00–1.02)	0.209
Body mass index (per 1 kg/m²)	0.98 (0.96–1.00)	0.104
Oxygen-dependent lung disease	1.77 (1.23–2.54)	0.002
Mean aortic valve gradient (per 10 mm Hg)	0.82 (0.75–0.89)	<0.001
Mini-Mental Status Examination (per 1 point)	0.96 (0.92–1.00)	0.036
6-Min Walk Test distance (per 10 m)	0.97 (0.96–0.98)	<0.001



Artificial Intelligence in medicine



ML algorithms in healthcare: app fields



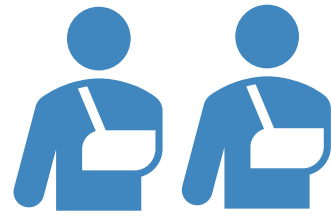
Artificial intelligence to predict 1-year mortality in elderly patients undergoing TAVR

- **Dataset from 18 Italian centers with 3856 patients undergoing TAVR**
- **1-year mortality: 13.8%**
- **AI algorithms to predict 1-year mortality compared to traditional statistic**

Synthetic data generation

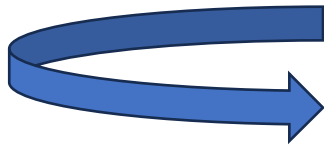


Real patients in
the dataset

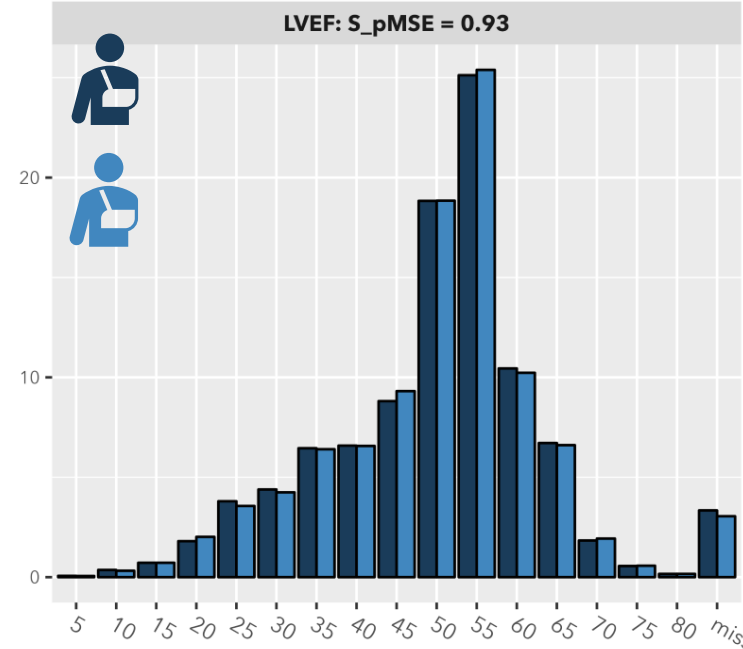


Synthetic
patients

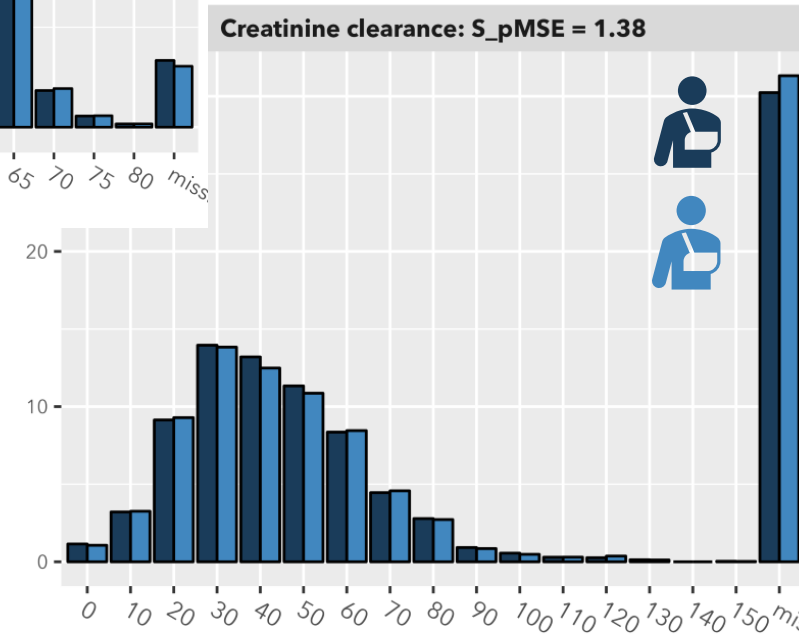
Boosting of the dataset creating new patients
using a statistical algorithm generated from a
real dataset. Baseline characteristics are similar
as the original population.



External validation in a real
dataset



44 baseline variables



Conclusions

- **Futility is a looming issue in patients undergoing TAVI**
- **Identifying patients who are truly benefiting from TAVI is an issue of paramount importance for saving cost and a better allocation of economic resources**
- **Artificial intelligence has the potential to develop decision algorithms with high specificity to select patients who are truly going to benefit from TAVI**