

## TAVR in the Elderly: Futility Versus Utility

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## Disclosure

- Lecture fees from Medtronic and Edwards
- Proctor Medtronic











## **Establishing the value of a procedure**

#### UTILITY/FUTILITY

#### **COST/EFFECTIVE**



# Degenerative aortic valve stenosis: the new pandemic





<sup>30</sup> TCTAP2025



CVRF

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



Ϊςταρ2025

Leon et al; NEJM 2010

NNT= 5







Subgroup	TAVI	Standard Therapy		I	Relative Risk (95% CI)		NNT	P Value for Interaction
	no. of events,	/total no. (%)						
Overall	55/179 (30.7)	89/179 (49.7)			-	0.62 (0.47-0.81)	5	
Age								0.54
≤85 yr	28/96 (29.2)	46/90 (51.1)			-	0.57 (0.39-0.83)	5	
>85 yr	27/83 (32.5)	43/89 (48.3)			-	0.67 (0.46-0.96)	6	
Sex								0.80
Female	30/97 (30.9)	46/95 (48.4)			-	0.64 (0.44-0.92)	6	
Male	25/82 (30.5)	43/84 (51.2)			-	0.60 (0.40-0.88)	5	
Body-mass index								0.20
≤25	32/83 (38.6)	46/87 (52.9)			Н	0.73 (0.52-1.02)	7	
>25	23/96 (24.0)	43/92 (46.7)				0.51 (0.34-0.78)	4	
STS score								0.44
≤ll	22/93 (23.7)	32/76 (42.1)			-	0.56 (0.36-0.88)	5	
>11	33/86 (38.4)	56/102 (54.9)			-	0.70 (0.51-0.96)	6	
LV ejection fraction								0.50
≤55%	30/82 (36.6)	58/95 (61.1)			-	0.60 (0.43-0.83)	4	
>55%	24/91 (26.4)	28/77 (36.4)			<b>⊢</b>	0.73 (0.46-1.14)	10	
Pulmonary hypertension								0.47
No	18/69 (26.1)	30/66 (45.5)			_	0.57 (0.36-0.92)	5	
Yes	29/82 (35.4)	42/85 (49.4)			+	0.72 (0.50-1.03)	7	
Moderate or severe mitral regurgitation								0.09
No	43/133 (32.3)	59/127 (46.5)			-	0.70 (0.51-0.95)	7	
Yes	9/38 (23.7)	23/38 (60.5)				0.39 (0.21-0.73)	3	
COPD (oxygen-dependent)								0.70
No	41/141 (29.1)	64/133 (48.1)		-8-	-	0.60 (0.44-0.83)	5	
Yes	14/38 (36.8)	25/46 (54.3)			+	0.68 (0.41-1.11)	6	
Prior CABG or PCI								0.60
No	20/72 (27.8)	32/68 (47.1)			-	0.59 (0.38-0.93)	5	
Yes	23/84 (27.4)	50/92 (54.3)				0.50 (0.34-0.75)	4	
Peripheral vascular disease								0.10
No	35/124 (28.2)	70/134 (52.2)				0.54 (0.39-0.75)	4	
Yes	20/54 (37.0)	19/45 (42.2)				0.88 (0.54-1.43)	19	
			0.1		1.0 10.	0		
				TAVI Better	Standard Therapy Better			



### The dark side of the moon





<sup>30</sup> TCTAP2025









## 20% of patients did not improve quality of life



Leon et al; NEJM 2010





#### Can we identify these patients



**ŤCTAP2025** 



## 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





## Risk models to assess the risk of 1-year death

	Poor Outcome (Definition	e at 6 mo No. 1)	Poor Outcome at 1 y (Definition No. 2)	
Predictor	OR (95% Cl)	<i>P</i> Value	OR (95% CI)	<i>P</i> Value
Male sex				0.097
Diabetes mellitus	1-1		CE	N/A
Major arrhythmia	TIST			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 <sup>2</sup> )	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





Renal disease

disease





#### Limited predictive capacity with traditional statistics

#### Poor Outcome at 6 mo (Definition No. 1) Predictor OR (95% CI) **P** Value Male sex 0.097 1.23 (0.96-1.57) Diabetes mellitus 0.82 (0.63-1.06) 0.130 0.036 Major arrhythmia 1.29 (1.02-1.63) 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/m<sup>2</sup>) 0.98 (0.96-1.00) 0.104 Oxygen-dependent lung disease 0.002 1.77 (1.23-2.54) < 0.001 Mean aortic valve gradient (per 10 mm Hg) 0.82 (0.75-0.89) Mini-Mental Status Examination (per 1 point) 0.036 0.96 (0.92-1.00) 6-Min Walk Test distance (per 10 m) 0.97 (0.96-0.98) < 0.001

#### **Artificial Intelligence**







Anemia

Active cancer



#### **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%
- Al algorithms to predict 1-year mortality compared to traditional statistic





## **Synthetic data generation**



10 -

10 20 30 40 50 60

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real dataset. Baseline characteristics are simi as the original population.



External validation in a real dataset

### 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

