

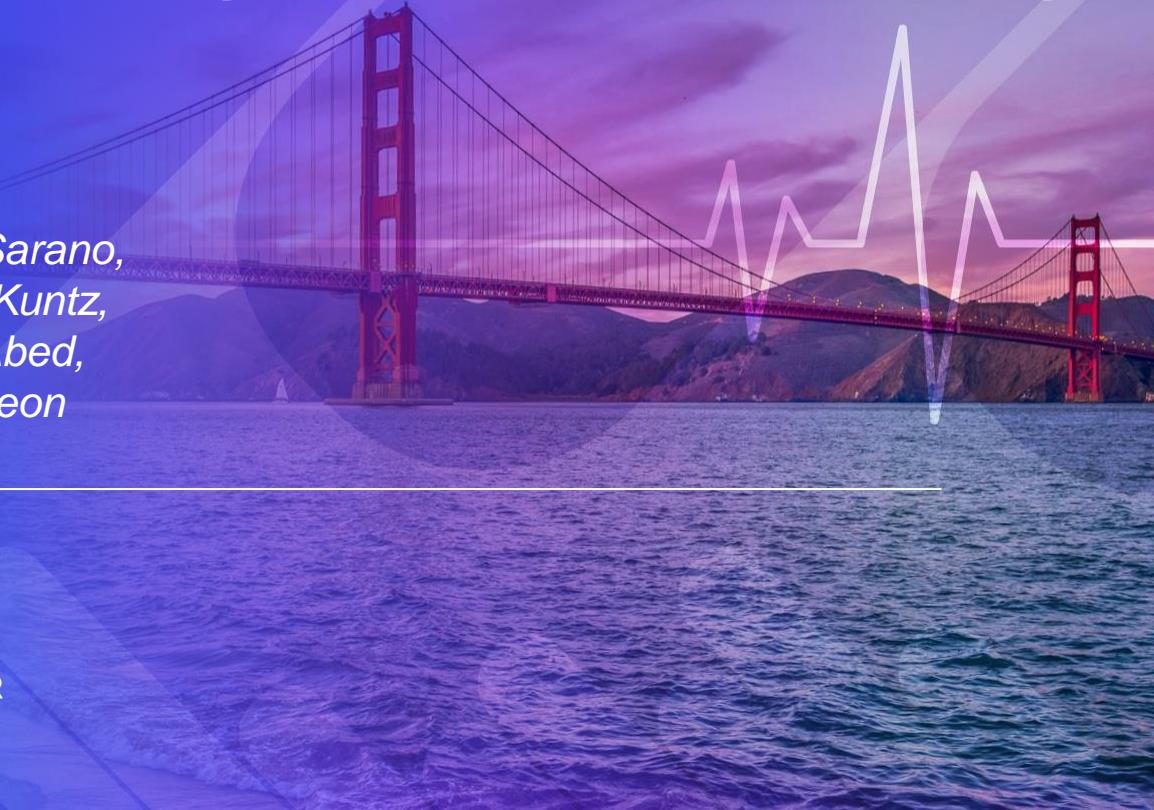
Aortic Valve Area Reduction

A Novel Concept to Quantify Aortic Stenosis Severity

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CARDIOVASCULAR
THERAPEUTICS®



Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship

Grant/Research Support

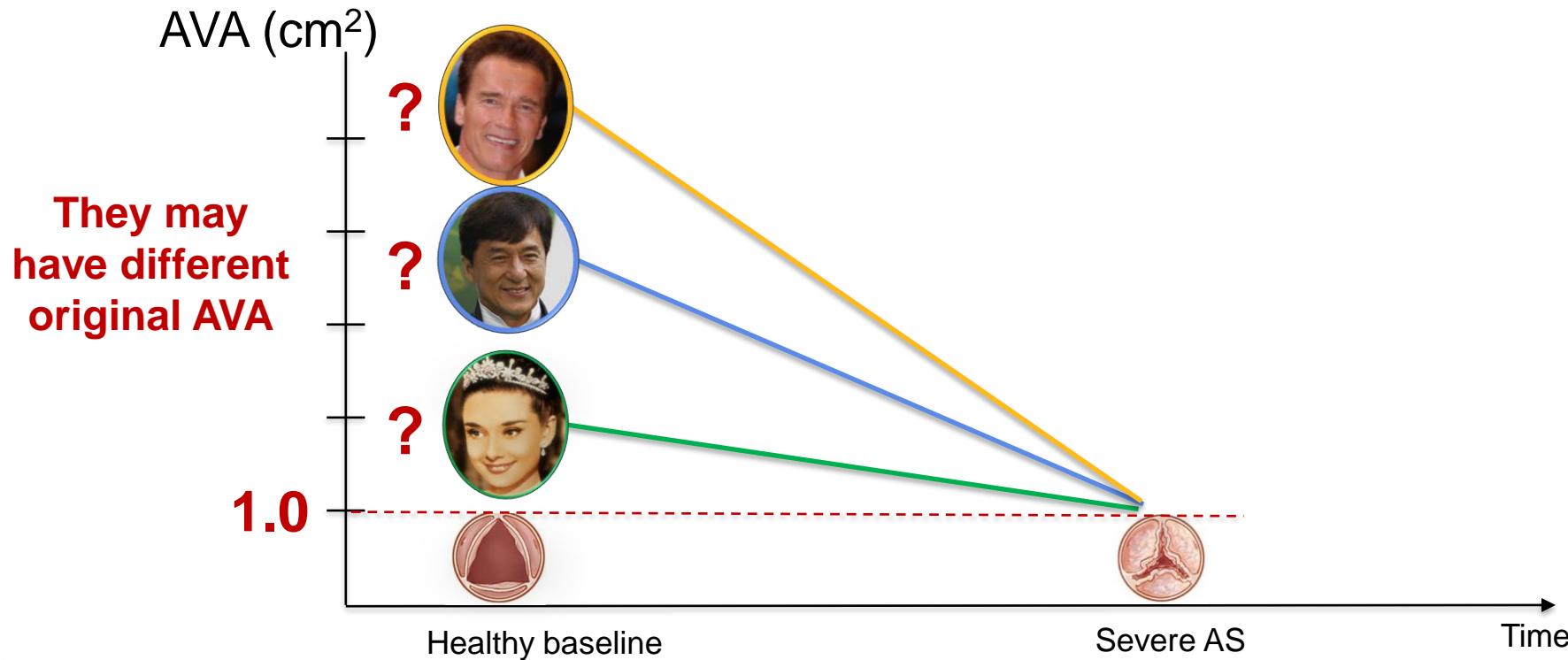
Consultant Fees/Honoraria

Ineligible Company

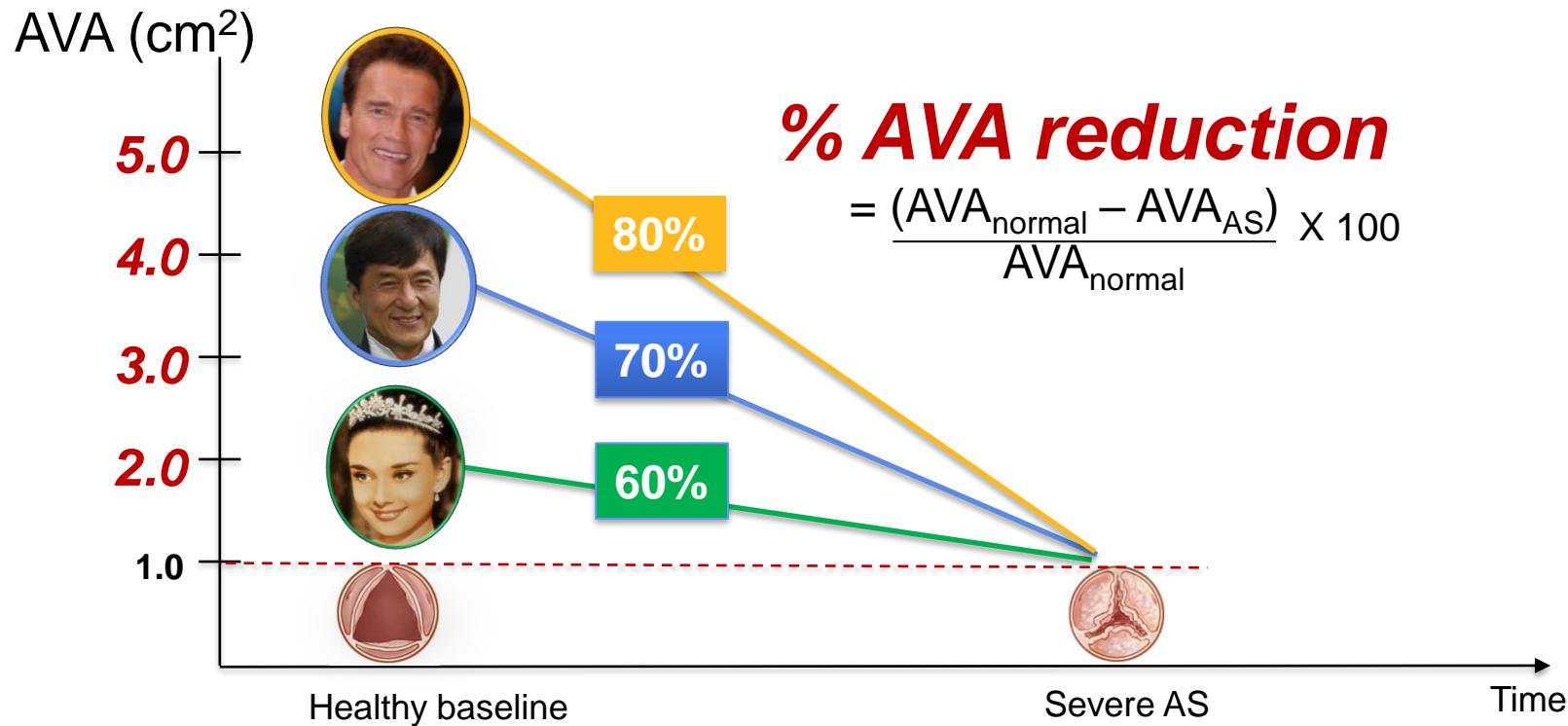
ANTERIS technologies

ANTERIS, Medtronic, Edwards,

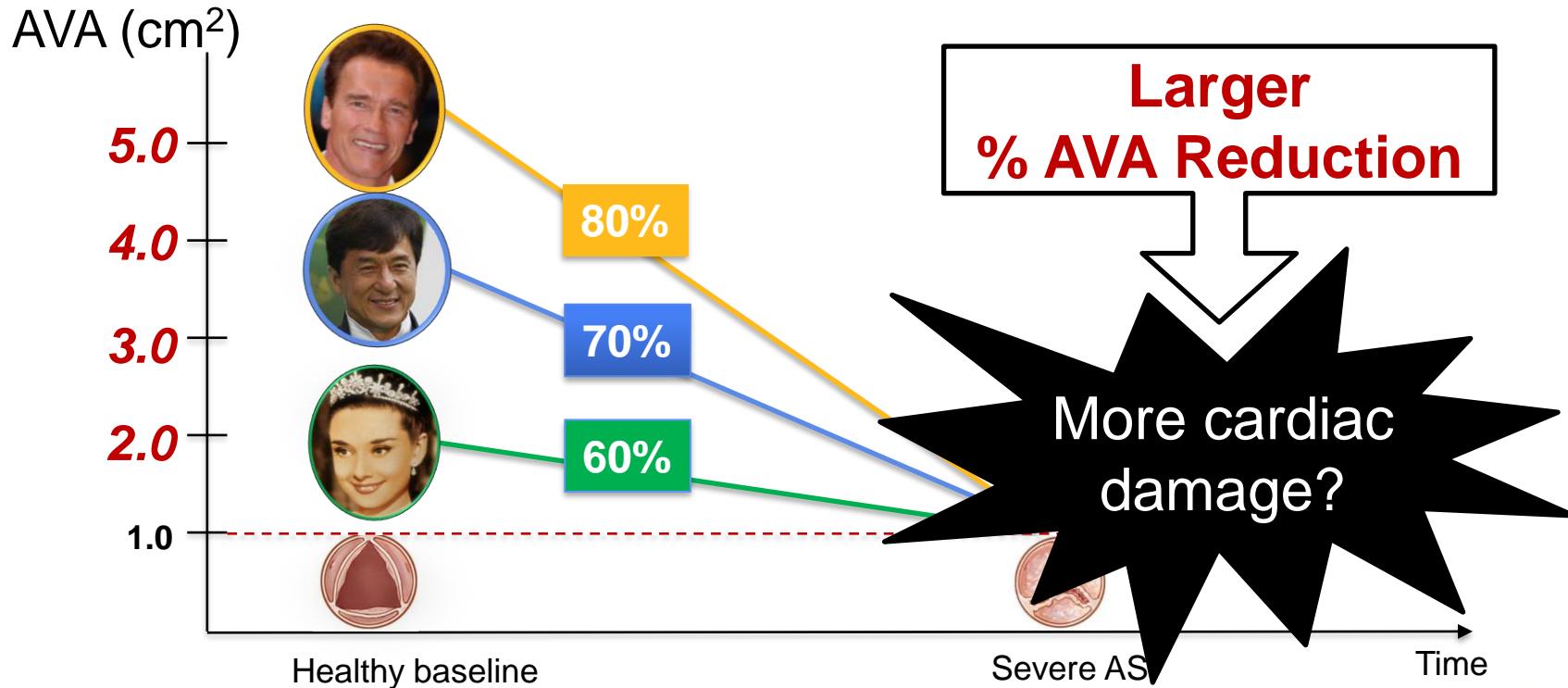
Is AVA < 1cm² Cutoff Appropriate for Everyone?



What If We Knew the Original Healthy AVA?

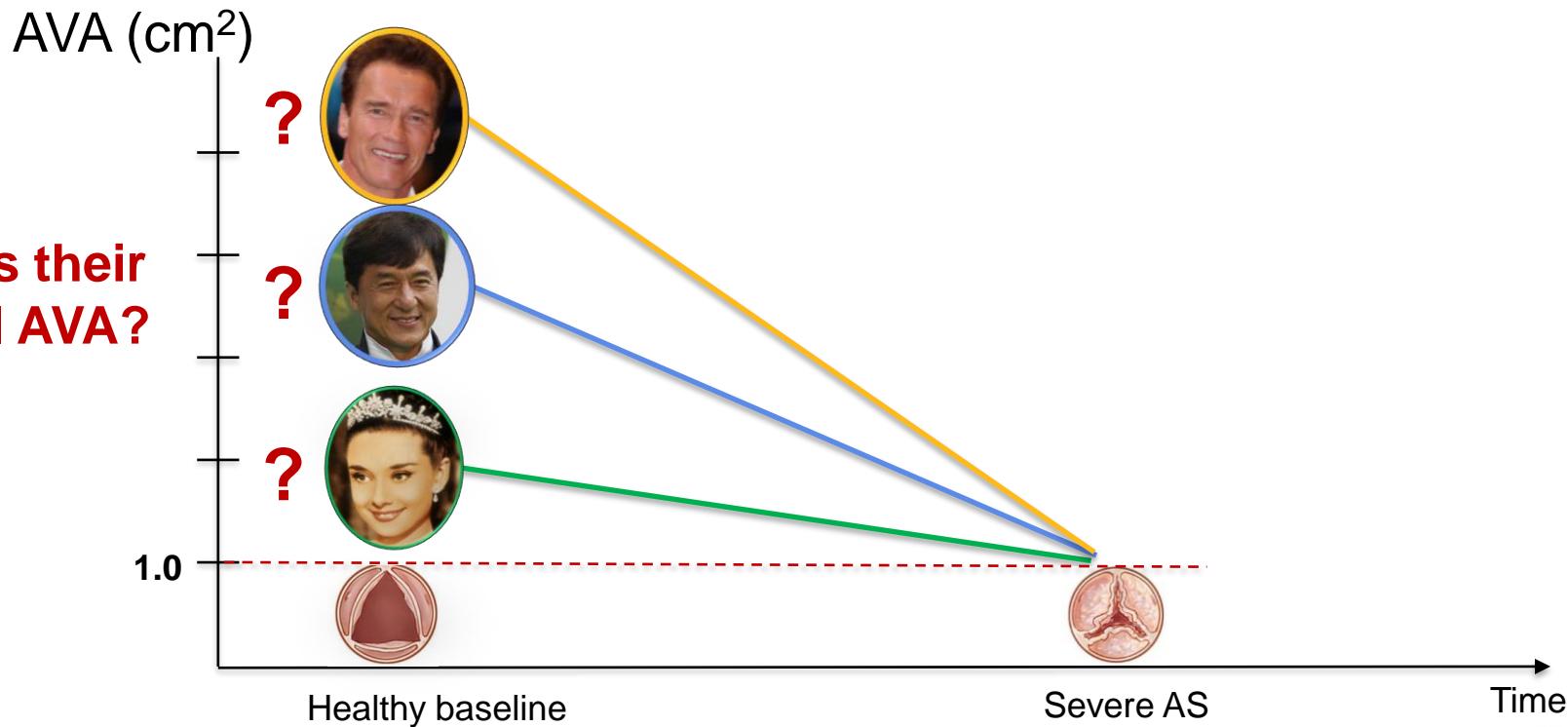


Treating Some Patients Too Late?



What Is the Original Healthy AVA?

What is their
normal AVA?



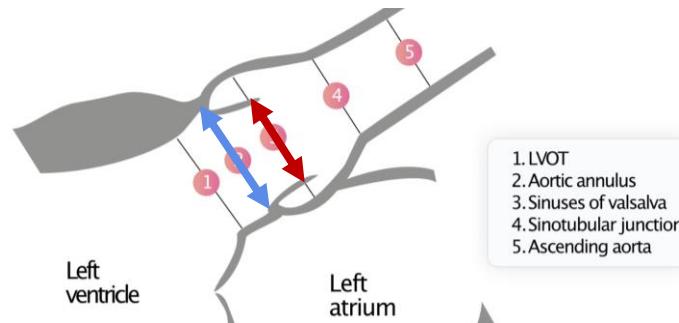
Study aims

- 1. Estimate the normal AVA**
- 2. Calculate personalized % AVA reduction**
- 3. Study if the % AVA reduction is meaningful**

Study design

Part 1: Develop a formula for estimating normal AVA

- Cohort: Subjects with normal aortic valve



Part 2: Assess distribution of AVA reduction in TAVR cohort

- Cohort: TAVR cohort (Symptomatic Severe AS)

Part 1: Study cohort of normal aortic valve

Patients who underwent CABG \pm SMVR/r at ANW between 2021/01 & 2024/04
N=1391

<Inclusion criteria>

Patients received

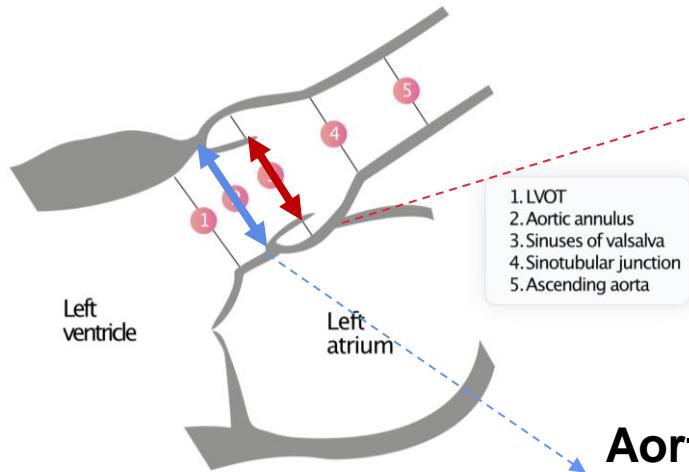
- ECG-gated contrast-enhanced CT
- Intraprocedure TEE

<Exclusion criteria>

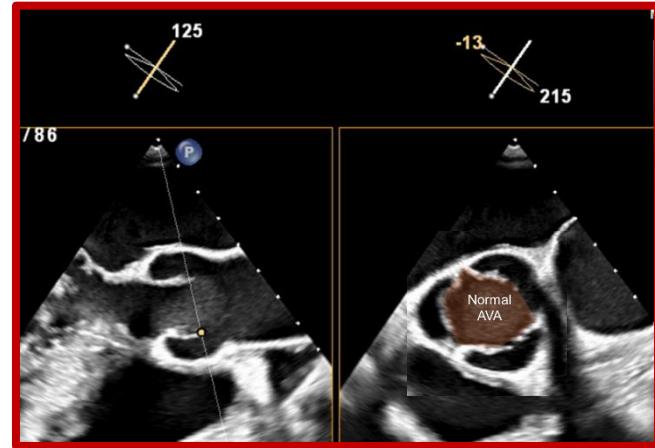
- Any aortic valve abnormality
- Non-tricuspid leaflets

N=347

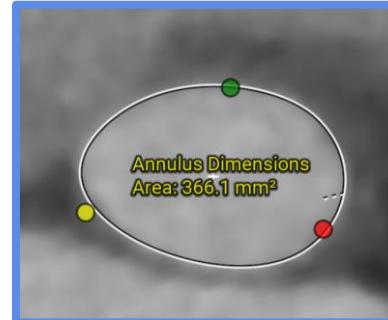
Normal AVA by TEE planimetry, Anulus area by CT



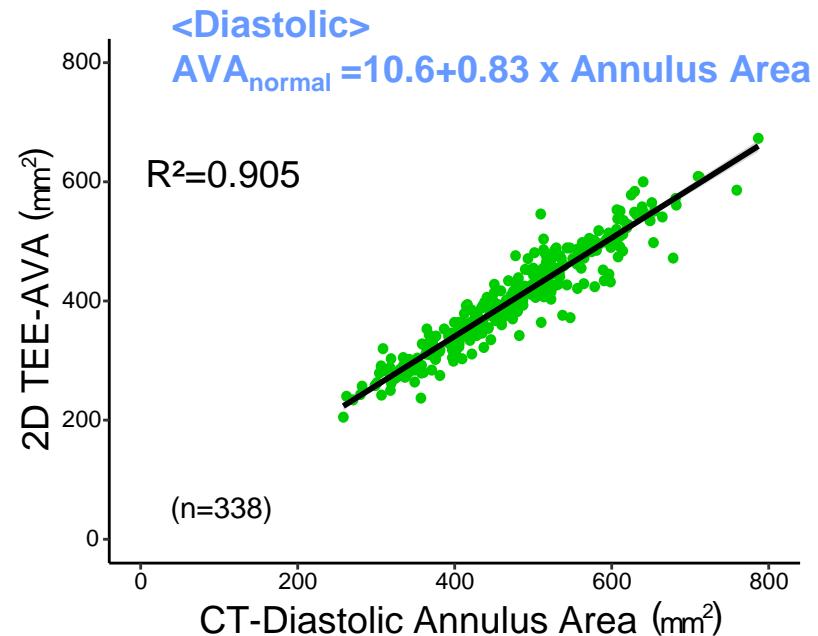
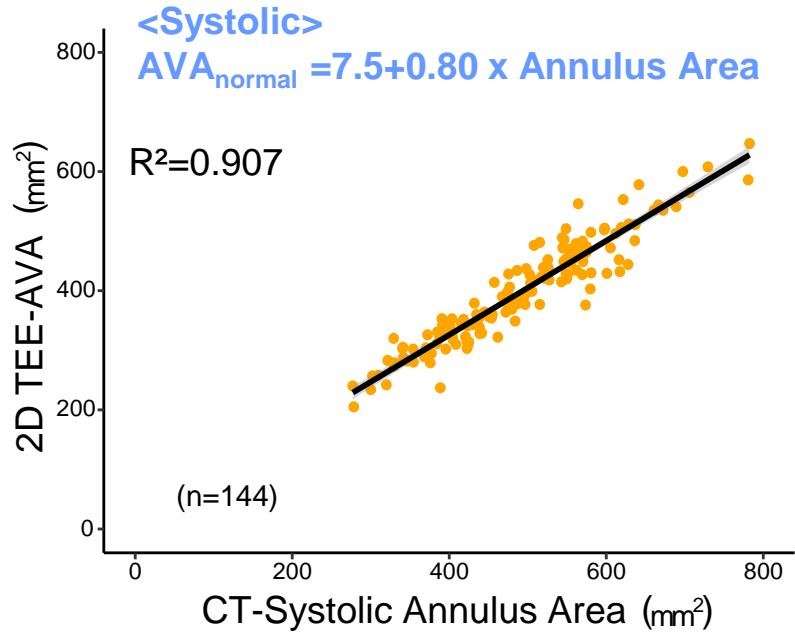
AVA by
2D TEE



Aortic Annulus Area
by pre-surgery CT

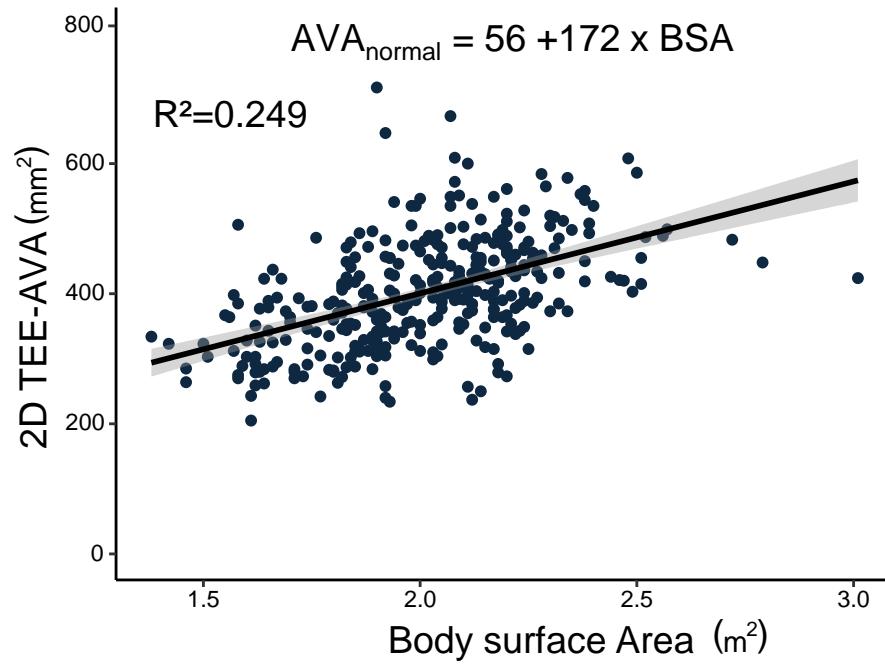
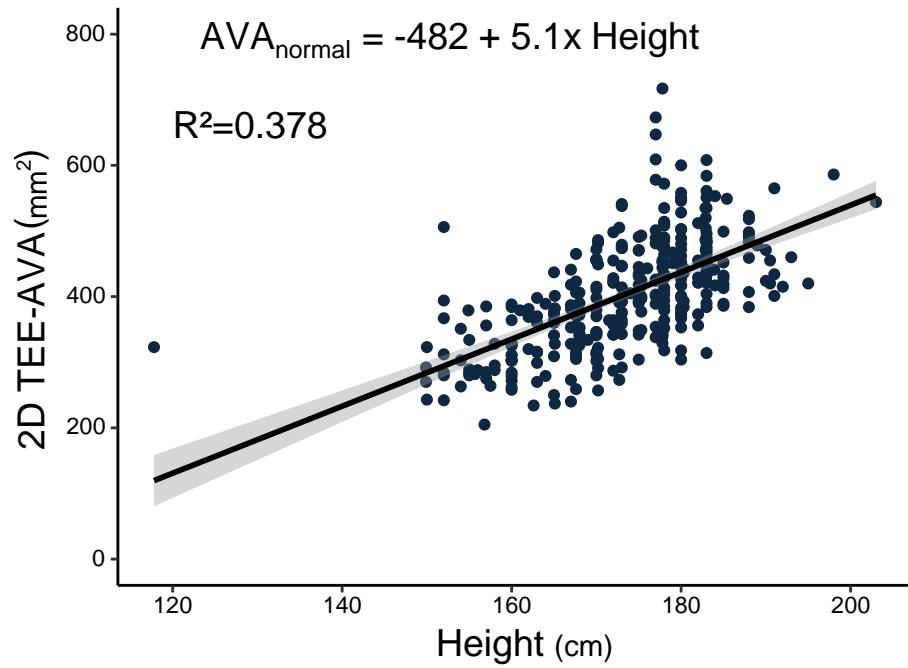


Strong correlation between AVA and Annulus Area



Normal AVA can be estimated by Annulus Area

Height or BSA is not a good reference



Study cohort of TAVR to assess impact of %AVA reduction

TAVR @ Abbott Northwestern Hospital
Jul 2015 – Dec 2021
N=1471

Exclusion

- Bicuspid
- Valve-in-Valve
- Previous aortic valve repair
- No pre-TAVR CT performed

Study population
N=1212

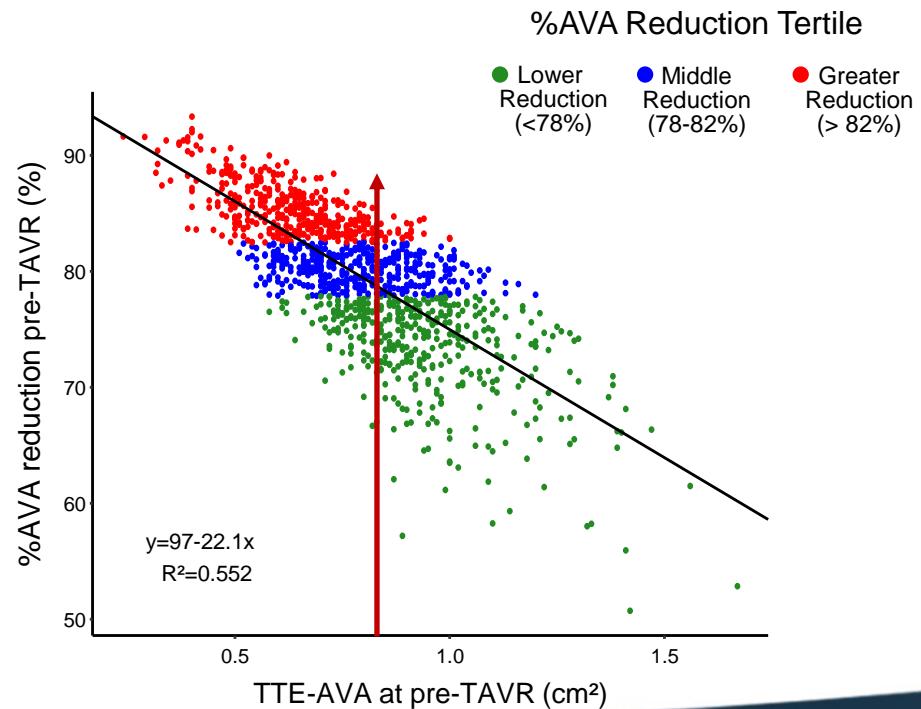
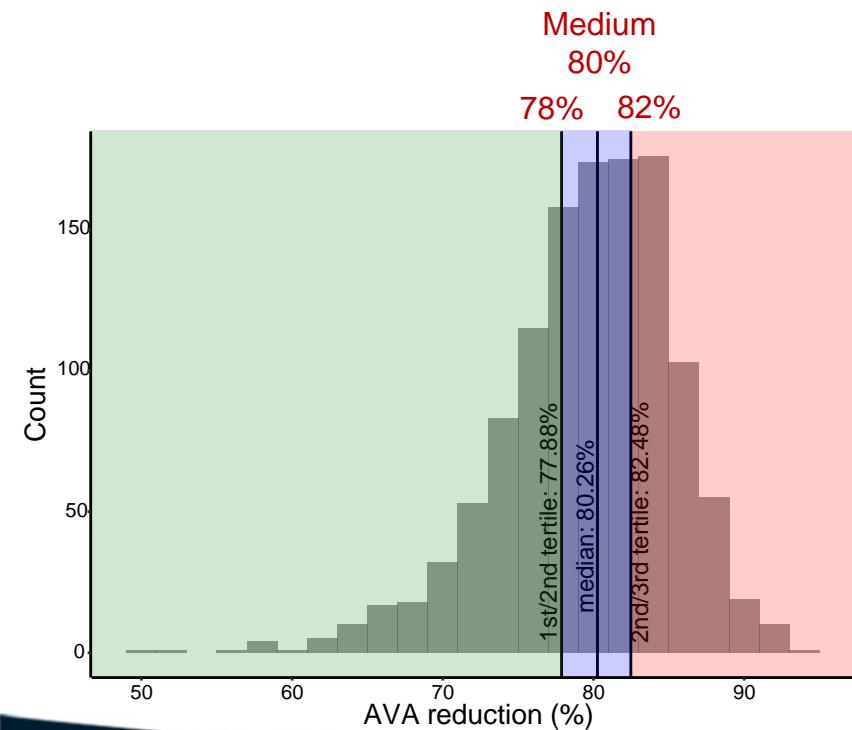
$$1. \text{ AVA}_{\text{normal}} = 7.5 + 0.795 \times \text{AA}_{\text{systolic}}$$

Pre-TAVR CT

$$2. \text{ AVA reduction (\%)} = \frac{(\text{AVA}_{\text{normal}} - \text{AVA}_{\text{AS}})}{\text{AVA}_{\text{normal}}} \times 100$$

Pre-TAVR TTE

Wide Variability in %AVA Reduction Compared to Traditional AVA



Results: Part 2

Patient characteristics

	Overall, N = 1,212	AVA reduction < 77.9% N = 404	AVA reduction 77.9 – 82.5% N = 404	AVA reduction >82.5% N = 404	p
Age (years)	82 (76, 87)	80 (74, 86)	83 (77, 87)	82 (77, 87)	<0.001
Male, n (%)	705 (58%)	182 (45%)	239 (59%)	284 (70%)	<0.001
DM, n (%)	422 (35%)	144 (36%)	140 (35%)	138 (34%)	>0.9
HT, n (%)	1,055 (87%)	354 (88%)	356 (88%)	345 (85%)	0.5
CAD, n (%)	617 (51%)	189 (47%)	207 (51%)	221 (55%)	0.08
Prior MI, n (%)	230 (19%)	70 (17%)	75 (19%)	85 (21%)	0.4
Prior CABG, n (%)	204 (17%)	47 (12%)	75 (19%)	82 (20%)	0.002
Prior PCI, n (%)	409 (34%)	140 (35%)	123 (30%)	146 (36%)	0.2
Afib, n (%)	487 (40%)	133 (33%)	157 (39%)	197 (49%)	<0.001
STS-PROM score (%)	3.37 (2.20, 5.30)	3.20 (2.14, 5.14)	3.40 (2.18, 5.03)	3.49 (2.30, 5.68)	0.12
NYHA ≥ III, n (%)	636 (81%)	199 (80%)	191 (76%)	246 (86%)	0.008

Greater AVA reduction, More Cardiac Damage

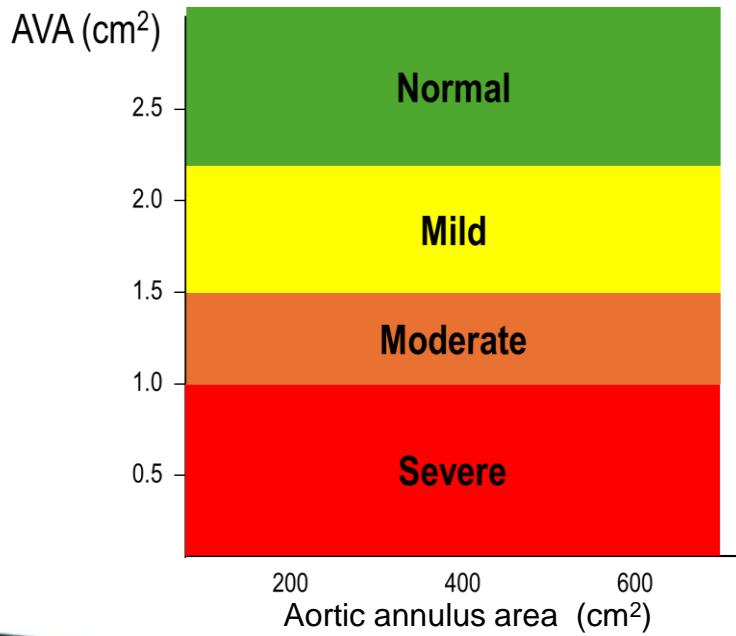
Pre-TAVR TTE	Overall, N = 1,212	AVA reduction < 77.9% N = 404	AVA reduction 77.9 – 82.5% N = 404	AVA reduction >82.5% N = 404	p
LVEF (%)	60 (53, 65)	63 (58, 68)	60 (55, 65)	58 (45, 63)	<0.001
LV mass index (g/m ²)	113 (94, 136)	105 (88, 127)	117 (96, 140)	122 (101, 144)	<0.001
E/e'	16 (12, 21)	16 (12, 21)	16 (12, 21)	15 (11, 20)	0.035
LAV index (ml/m ²)	41 (32, 53)	38 (29, 49)	41 (33, 53)	46 (35, 60)	<0.001
MR ≥ moderate, n (%)	199 (16%)	50 (12%)	64 (16%)	85 (21%)	0.004
TR ≥ moderate, n (%)	173 (14%)	40 (9.9%)	54 (13%)	79 (20%)	<0.001
PASP (mmHg)	37 (29, 48)	35 (28, 45)	36 (29, 47)	39 (31, 51)	<0.001
TAPSE, cm	2.00 (1.70, 2.40)	2.10 (1.80, 2.40)	2.00 (1.70, 2.40)	1.90 (1.50, 2.21)	<0.001
SVi (ml/m ²)	37 (30, 44)	44 (37, 51)	38 (33, 43)	31 (25, 36)	<0.001
Cardiac damage* Stage 3 or 4	388 (32%)	103 (25%)	114 (28%)	171 (42%)	<0.001

Next steps

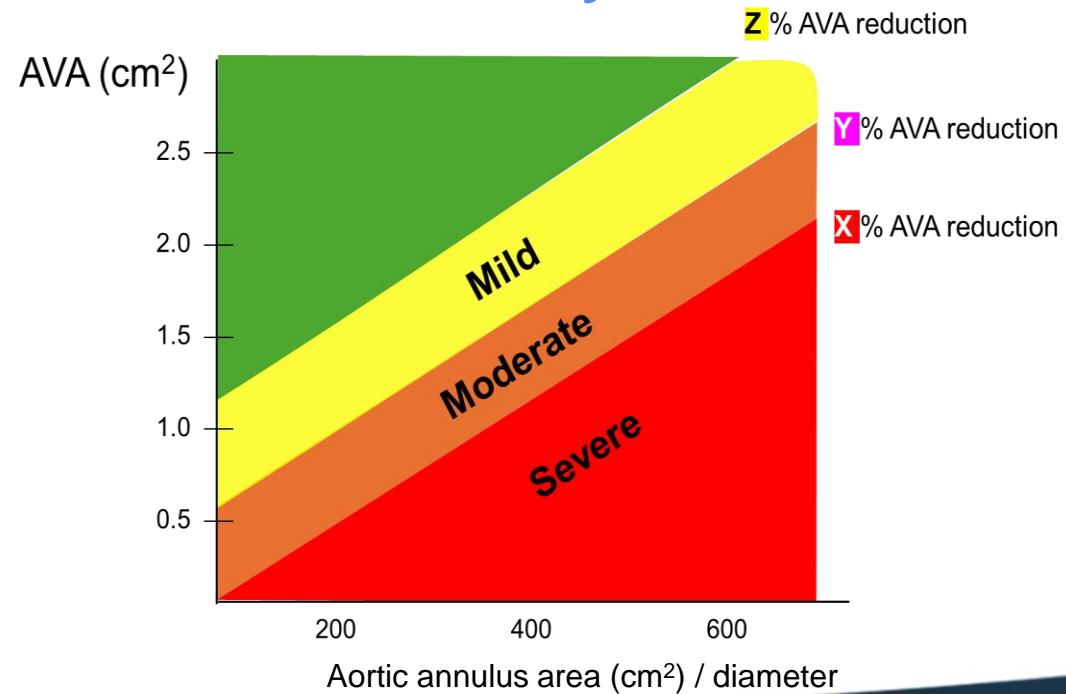
- Evaluate the incremental value of %AVA reduction beyond conventional TTE parameters for AS severity
→ *will be presented at London Valves*
- Validate the applicability of %AVA reduction using TTE-measured LVOT or annulus diameter instead of CT-derived annulus area
- Determine the optimal cut-off value of %AVA reduction across the entire AS severity spectrum, with focus on moderate and severe AS

Fukui-Sarano-Bapat Definition

Current definition



New definition by AVA reduction



Conclusion

- Developed a formula to estimate normal AVA from annulus area
- %AVA reduction introduced as a novel, personalized metric for AS severity
- This metric improves the quantification of AS severity and risk stratification
- May help optimize timing of aortic valve intervention