Inter-observer variability affects treatment of ascending aortic aneurysms: *Real world evidence from a prospective multi-center study on thoracic aortic aneurysms*

A TITAN:SvS Study

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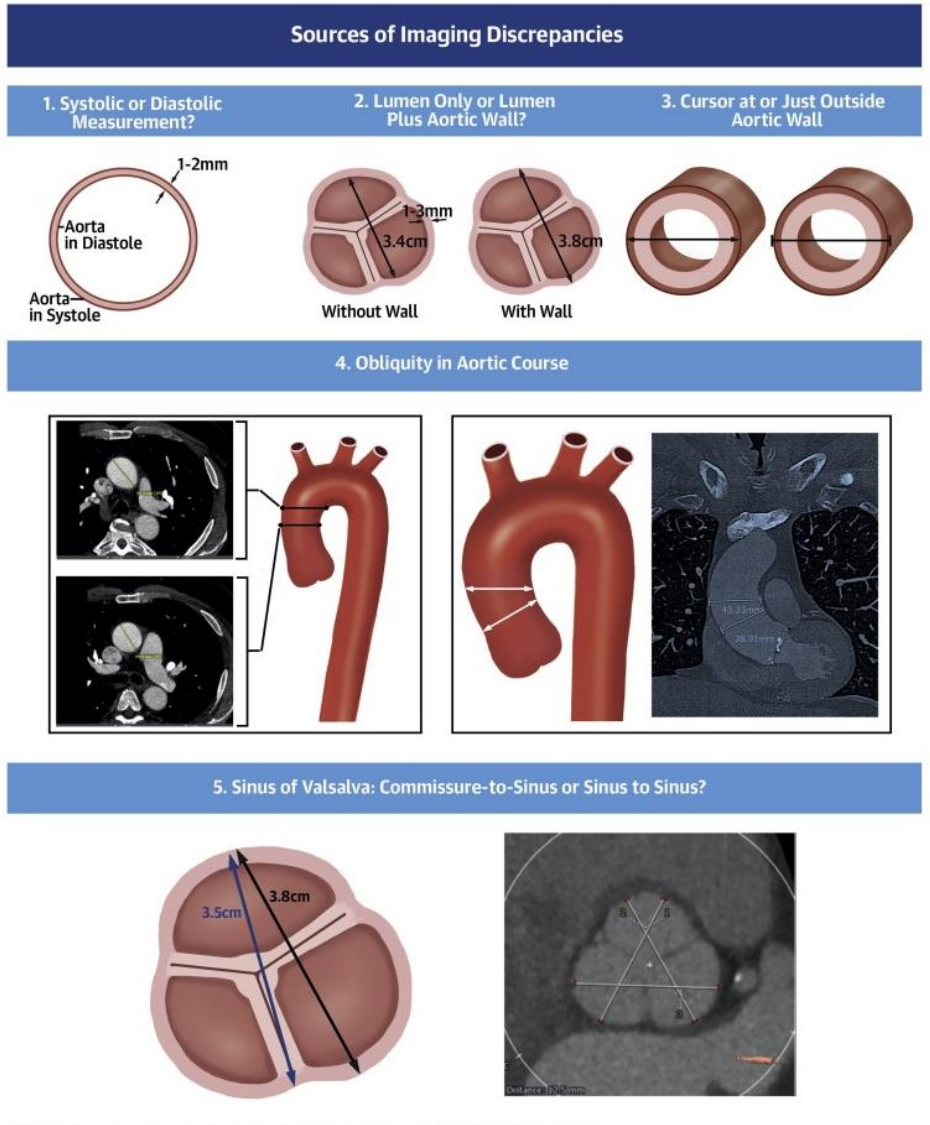
BACKGROUND

- There is a lack of prospective evidence around the risk profile of ascending thoracic aortic aneurysms (ATAA).
- Current societal guidelines rely heavily on maximal aortic diameter to guide intervention.
- Previous studies have demonstrated Inter-observer and inter-observer variabilities as high as 5mm when measuring ATAA.
- Should significant inter-observer variability be superimposed on lack of prospective evidence on intervention for ascending aortic aneurysms, then community risks making decisions based on information that is several degrees of separation from the ground truth.
- Using data from the largest ever prospective multi-center study of ATAA, we assess the degree of Inter-observer variability in assessing maximal aortic diameters as reported by 22 sites (real-world) to core lab data.



Elefteriades, J.A. et al. J Am Coll Cardiol. 2020;76(2):201-17.

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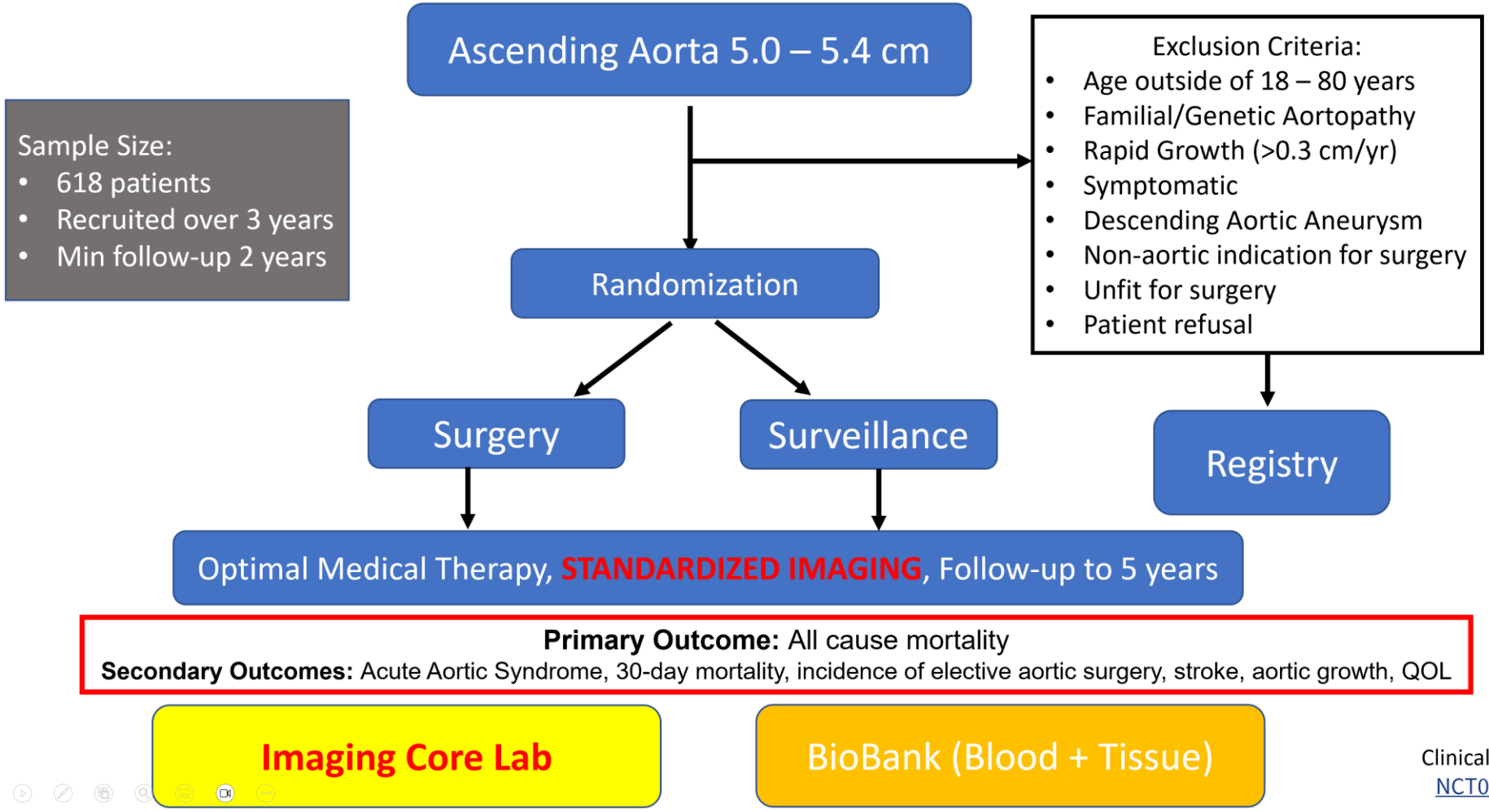
BACKGROUND

Multi-center, randomized trial of surgery vs. surveillance in ascending aortic disease
Treatment In Thoracic Aortic aNeurysm: Surgery vs. Surveillance (TITAN:SvS)



Clinical Trials.gov
NCT03536312

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METHODS

- Population derived from patients enrolled in TITAN:SvS randomized controlled trial.
- To assess accuracy and quality, aortic measurements from real world CTs were compared to the core lab reported measurements of the same CTs.
- We compared –
  - Maximal ATAA diameter
  - Sinus of Valsalva diameter
  - Sino-tubular junction diameter
  - Mid-ascending aorta diameter
  - Distal ascending aorta diameter
  - Aortic arch diameter
  - Descending thoracic aorta diameter
- Measurements which deviate by ≥2mm were noted.
- Whenever measurement differences resulted in whether patients were surgical candidates or not were also noted.
- Quality was assessed by noting whether only one measurement or two measurements were provided at different levels of the thoracic aorta.

RESULTS

DEMOGRAPHICS		
AGE	67.9 yrs	+/- 9.8
GENDER	Male 81.4%	Female 18.6%
HEIGHT	174.82 cm	+/- 15.37
WEIGHT	93.37 kg	+/- 23.73

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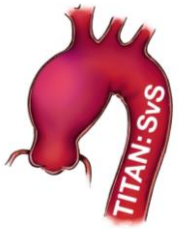

RESULTS - ACCURACY

DIAMETER COMPARISONS					
	SITE	CORE	p-value	LOWER (≥2mm)	HIGHER (≥2mm)
Max Diameter - Root to Ascending Aorta	***51.05 +/- 5.1***	***50.48 +/- 7.06***	***<0.05***	***23/264***	***74/264***
Sinus of Valsalva	43.92 +/-33	43.17 +/-28.3	0.13	39/250	95/250
Sino-Tubular Junction	42.03 +/-26.5	42.1 +/-22.7	0.89	45/238	46/238
Mid-Ascending Aorta	48.82 +/-27.2	48.62 +/-24.2	0.63	32/287	60/287
Distal Ascending Aorta	39.94 +/-26.1	39.85 +/-18.9	0.86	22/172	37/172
Aortic Arch	32.65 +/-25	39.85 +/-36.9	0.1	31/232	60/232
Descending Thoracic Aorta	29.12 +/-22.9	27.95 +/-16.1	<0.05	24/247	76/247

RESULTS – ACCURACY and QUALITY

PROPORTION of PATIENTS OUTSIDE TITAN RANGE		
SITE		
TOTAL	Under 5cm	Over 5.4cm
70/458	68/458	2/458
15.28%		
CORE		
TOTAL	Under 5cm	Over 5.4cm
93/458	92/458	1/458
20.31%		

PROPORTION of PATIENTS DID NOT MEET CRITERIA		
SITE to CORE LAB	64/264	24.24%

RESULTS - QUALITY

PROPORTION of SITE REPORTS with ONE MEASUREMENT	
Sino-Tubular Junction	94/458
Mid-Ascending Aorta	120/458
Distal Ascending Aorta	88/458
Aortic Arch	101/458
Descending Thoracic Aorta	105/458

CONCLUSION

- Based on contemporary data from the largest ever prospective study on ATAA, significant variability exists between site reported aortic diameters on CT scans compared to diameters reported by an imaging core lab.
- Due to inter-observer variability, up to 20% of patients are diagnosed as meeting a surgical threshold before they actually reach it.
- The significant difference in inter-observer variability superimposed on lack of prospective evidence on risk profile of ascending aortic aneurysms, suggests need for more nuanced reproducible risk profiling of the ascending aorta.
- When completed, the randomized arm of Titan:SvS may provide further evidence on risk profile of ATAA.