



# DurAVR™ TAVI novel leaflet design restores ascending aortic flow haemodynamics on cardiac MRI: First-in-human study

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# Potential conflicts of interest

**Speaker's name : Pankaj Garg**

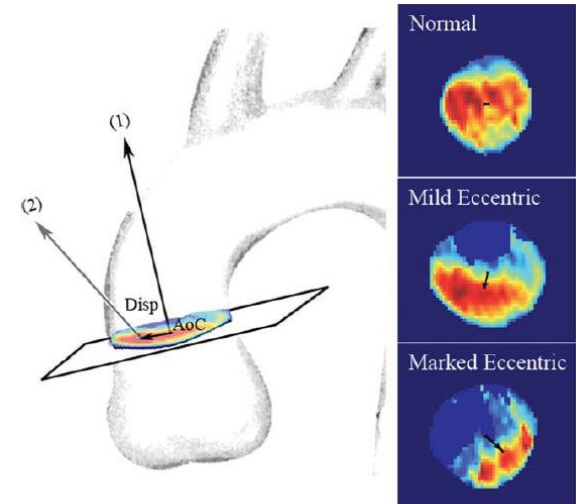
I have the following potential conflicts of interest to declare:

Receipt of grants / research support: Academy of Medical Science, MRC, NIHR, Wellcome Trust

Receipt of honoraria or consultation fees: Anteris Technologies, NAMSA

# Abnormal aortic flow may impact long-term cardiac performance

- **Abnormal aortic flow** is associated with loss of energy and makes the cardiovascular system less effective (PMID: 31535124)
- Recent studies have shown that eccentric flow in aorta, measured by aortic flow displacement can predict aortic dilatation (PMID: 28623496, 21928387, 24784460)
- It remains unclear if valvular interventions in aortic stenosis restore the normal aortic physiological flow

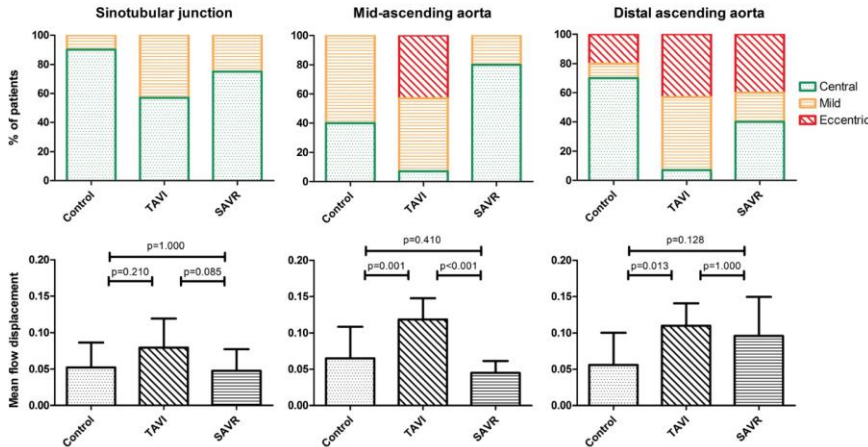
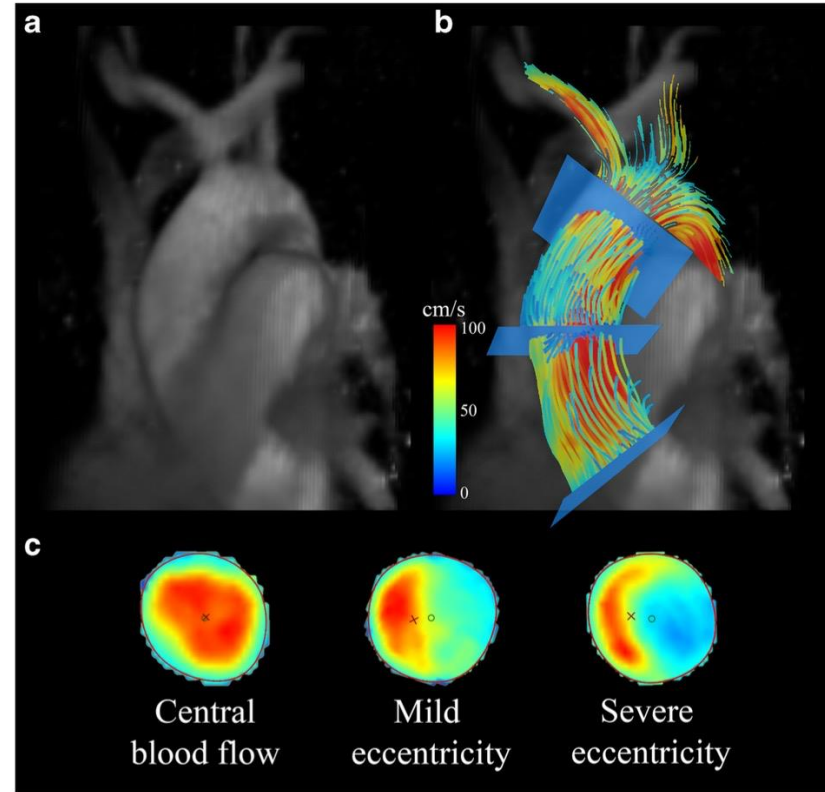


**Figure 1.** Left: Schematic representation of investigated parameters: displacement (Disp) of flow with respect to centerline (AoC), and angle of flow jet calculated between the normal to the cross-sectional plane (1) and the mean direction of peak systolic forward flow (2). Right: Cross-sectional views of the ascending aorta just distal to the sinotubular junction showing flow displacement from the center of the aorta for normal, mildly, and markedly eccentric peak systolic flow patterns. Color coding represents the velocity magnitude of forward flow.

Sigovan et al. JMIR 34:1226–1230 (2011)

# Routine TAVR/SAVR alters ascending aortic blood flow

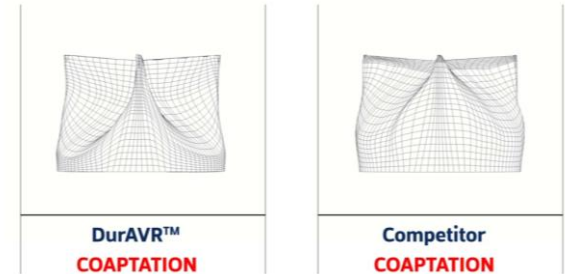
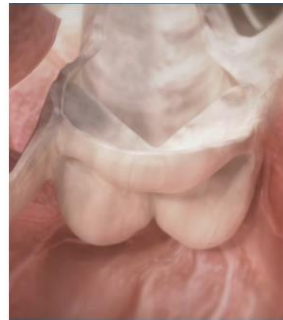
- TAVR results in increased wall shear stress in ascending aorta
- TAVR/SAVR results in **eccentric** and **displaced flow** in the ascending aorta



# DurAVR™ THV System

## DurAVR™ THV System

Single-piece aortic valve designed:  
To **restore** near-normal hemodynamic function  
For **better** coaptation and less leaflet stress



Graphical representation of the 3D single-piece geometry of DurAVR™ THV (left), and standard balloon-expandable TAVI devices (right).

**Hypothesis:** the novel leaflet design of DurAVR™ will not only restore AV pressure gradient but also normalise flow in the ascending aorta.

# Cardiac MRI study to assess aortic flow physiology

**Objective:** To investigate aortic flow physiology by cardiac MRI (cMRI) in 5 patients who received DurAVR™ transcatheter aortic valve (first-in-human) and compare results to normal age-height-weight matched controls, other transcatheter AV implants (TAVIs) and patients who had surgical AV replacement (SAVR).

- 5 DurAVR™ patients recruited in Georgia (cMRI at 6 months)
- 4 commercial TAVI and 8 SAVR valve recipients from other cMRI research registries in the UK (Sheffield/Norwich)
- 5 controls with no known aortic valve disease assessed and age-height-weight matched to reduce bias.

Parameters quantified in ascending aorta using phase contrast acquisitions:

- ✓ Aortic forward flow (AFF)
- ✓ Aortic regurgitation (AR)
- ✓ Aortic flow displacement (AFD) at peak systole
- ✓ Aortic flow reversal (AFR) at peak systole

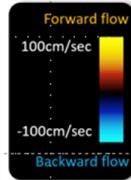
# Aortic flow of healthy AV vs post-TAVR/SAVR: is there a difference?

	Control	DurAVR	Other TAVIs	SAVR	Control vs DurAVR	Control vs other TAVIs	Control vs SAVR
	n=5	n=5	n=4	n=8	P-value	P-value	P-value
<i>Clinical characteristics</i>							
Age (years)	60 ± 15	73 ± 9	77 ± 12	73 ± 9	0.115	0.102	0.064
Height (cm)	169 ± 10	162 ± 9	160 ± 8	160 ± 9	0.315	0.198	0.156
Weight (kg)	75 ± 7	69 ± 8	80 ± 3	65 ± 13	0.220	0.215	0.141
<i>Aortic flow characteristics</i>							
AFF (ml)	66 ± 24	71 ± 26	58 ± 11	74 ± 17	0.760	0.557	0.486
AR (ml)	2 ± 2	8 ± 6	2 ± 1	6 ± 5	0.087	0.745	0.122
AFD (cm)	10 ± 5	14 ± 10	32 ± 18	24 ± 6	0.453	<b>0.033*</b>	<b>0.001**</b>
AFR (%)	1 ± 1	4 ± 6	18 ± 16	14 ± 9	0.328	<b>0.049*</b>	<b>0.008**</b>

AFF = Aortic Forward Flow; AR = Aortic Regurgitation; AFD = Aortic Flow Displacement; AFR = Aortic Flow reversal

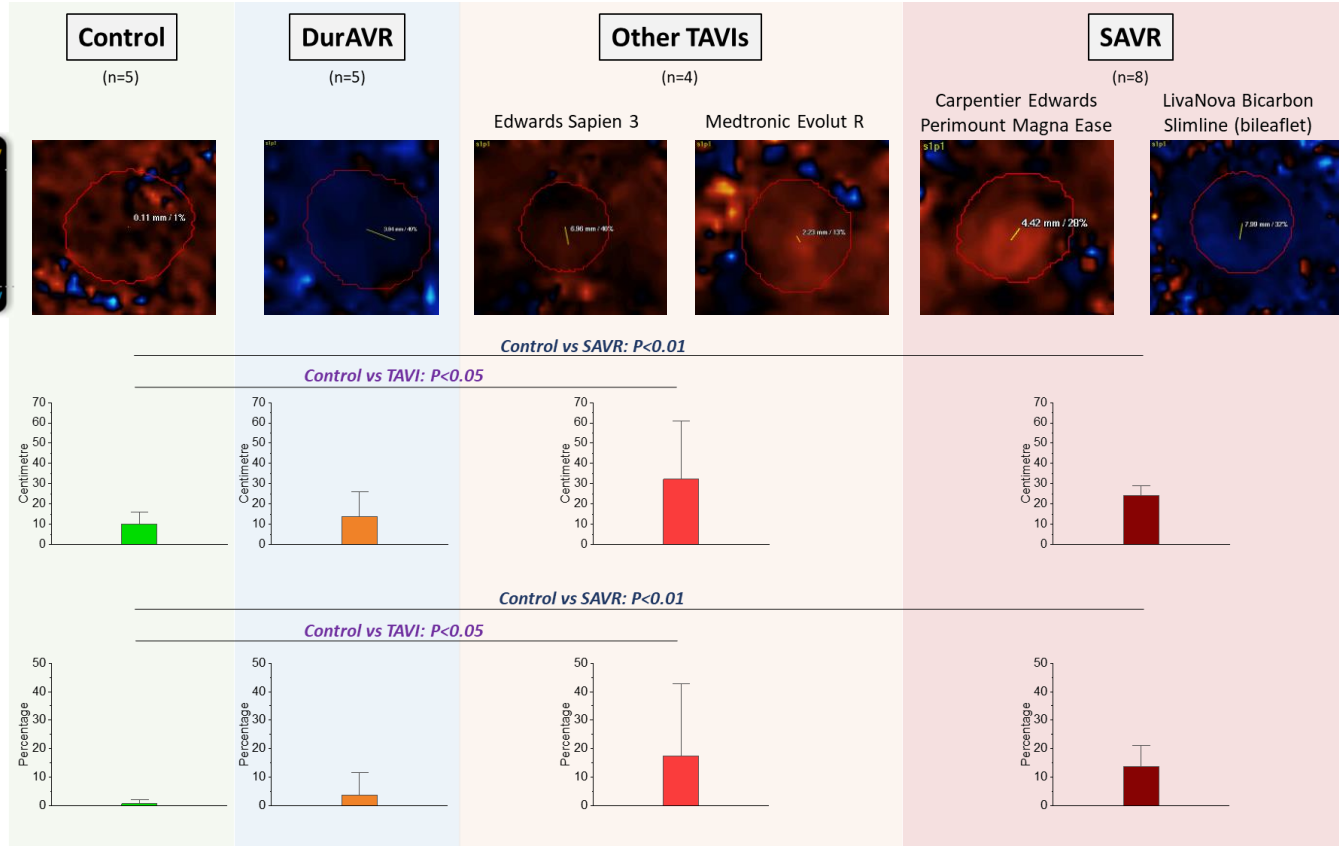
# DurAVR™ THV restores ascending aortic flow haemodynamics

The novel leaflet design of DurAVR™ restores ascending aortic flow haemodynamics whereas SAVR and other TAVI valves do not demonstrate such physiological advantage



Peak systolic aortic flow displacement (AFD)

Peak systolic aortic flow reversal (AFR)





# Why is this important?

- Restoration of normal laminal aortic flow is emerging as a novel target mainly to reduce energy loss in the cardiovascular system
- Abnormal flow, including eccentric flow, is associated with continued aortic dilatation\* which will further warrant intervention
- As TAVI is being offered to more younger cohorts, restoration of normal laminar aortic flow is an important therapeutic goal
- DurAVR™ architecture appears to restore normal aortic flow
- Future studies are warranted to investigate the prognostic importance of restoration of normal aortic flow in this patient population

\* PMID: 28623496, 21928387, 24784460

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