

groups. A sensitivity analysis was performed and confirmed the above mentioned results.

CONCLUSION TF approach has less 30-day mortality, bleeding complications, and renal failure as compared with the TA approach. One should be mindful though that the TA approach is usually saved for patient with extensive comorbidities which may contribute to these differences.

CRT-400.15

Geometry and Motion of the Mitral Valve Orifice Across Species: Implications for Development and Evaluation of Transcatheter Mitral Valve Replacement Devices

Jesse Baucom,¹ Alex Hill,² Rajiv Gupta,³ Srinivasan Varahoor,⁴ John Karanian,¹ William Pritchard¹
¹FDA Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, Laboratory of Cardiovascular and Interventional Therapeutics, Laurel, MD; ²Medtronic Cardiovascular, Mounds View, MN; ³Massachusetts General Hospital, Harvard Medical School, Boston, MA; ⁴Medtronic Cardiovascular, Minneapolis, MN

BACKGROUND Novel transcatheter mitral valve replacement devices are currently undergoing development for treatment of mitral valve disease. Although animal models are used to study safety and effectiveness of these devices, interspecies differences in the geometry and motion of the mitral valve orifice are not well characterized in the literature. The purpose of this study was to develop a quantitative characterization of geometry and motion of the mitral valve orifice over the cardiac cycle in animal models compared to human.

METHODS Gated cardiac CT angiograms over the cardiac cycle in eight swine, sheep and normal adults were analyzed (Mimics, Materialise, Leuven, Belgium). Measurements were taken at late diastole and mid-systole, corresponding to maximum and minimum mitral annular areas, respectively. Using a novel mathematical approach to define a two-dimensional outline of the mitral annulus, area, perimeter, and axial lengths were calculated (MAT-LAB). Area, perimeter, and ellipticity were measured for a left atrial plane 1.0 cm into the left atrium and parallel to the mitral annular plane.

RESULTS Mitral annular area and perimeter increased in late diastole compared to mid-systole in all three species (Table 1). Area was smaller in swine than in humans in both phases and perimeter was smaller in swine in late diastole. Area of the left atrial plane increased in swine in late diastole but decreased in sheep and humans. Area and perimeter of the atrium in this plane was larger in swine compared to humans in late diastole.

CONCLUSIONS Mitral annular area and perimeter in sheep were not different from humans, while there were differences between swine and humans. Left atrial area increased in swine in late diastole but decreased in both sheep and humans. These data should inform the design and evaluation of mitral valve replacement technology.

Table 1. Impact of motion on geometry of mitral valve orifice. Values at mid-systole (MS) and late diastole (LD) reported as mean ± standard error. Convention: LD used as reference position (100%), a positive value for percent change indicates a decrease from LD to MS.

		Species	MS	LD	% Δ
Mitral Annular Plane	Area (cm ²)	Swine	8.2 ± 0.3†	9.8 ± 0.3	16.5***
		Sheep	8.9 ± 0.2	9.4 ± 0.2	6.1***
		Human	9.8 ± 0.6	10.9 ± 0.7	10.2**
	Perimeter (mm)	Swine	104 ± 2†	113 ± 2†	7.9***
		Sheep	109 ± 1	113 ± 1	3.0**
		Human	115 ± 4	121 ± 4	5.4***
Left Atrial Plane	Area (cm ²)	Swine	14.1 ± 0.4	15.1 ± 0.6††	6.6*
		Sheep	14.0 ± 0.6	12.3 ± 0.6	-14.3**
		Human	12.8 ± 1.0	11.2 ± 0.7	-15.7*
	Perimeter (mm)	Swine	138 ± 2	142 ± 3††	2.4
		Sheep	139 ± 3	129 ± 3	-7.7**
		Human	136 ± 6	124 ± 4	-9.7

*Denotes a significance at p<0.05; ** p<0.005; *** p<0.0005.
 †Denotes a significant difference from human anatomy at p<0.05; †† p<0.005.

CRT-400.16

Transfemoral System for Mitral Valve Reconstruction - A Multicentre Experience

Alec Vahanian,¹ Karl-Heinz Kuck,² Ottavio Alfieri,³ Antonio Colombo,³ Stephan Baldus,⁴ Georg Nickenig,⁵ Francesco Maisano⁵
¹Bichat Hospital, Paris, France; ²Asklepios St Georg, Hamburg, Germany; ³San Raffaele Hospital, Milano, Italy; ⁴University Hospital Köln, Köln, Germany; ⁵University Hospital Bonn, Bonn, Germany; ⁶University Hospital Zurich, Zurich, Switzerland

OBJECTIVE Cardioband system enables percutaneous implantation of an adjustable “surgical-like” device for mitral reconstruction and MR reduction using a transeptal approach. The aim of this multi-center study was to evaluate the feasibility, safety and up to 12 month outcome of Cardioband in patients with secondary mitral regurgitation (MR).

METHODS AND FINDINGS Between February 2013 and August 2015, 45 high-risk patients with significant secondary MR were enrolled at 6 sites in Europe. All patients were screened by echocardiography and cardiac CT to assess feasibility.

Mean age was 71 years (range 49-81), thirty four patients were males (76%). Mean EuroScore II was 7.7% ± 6.7% and median STS score 7.2 % (1.0%-34.0%). At baseline 87% of patients were in NYHA class III-IV with mean left ventricular ejection fraction of 32 ± 11% (15%-59%). Device implantation was feasible in 100% patients. Procedural success (device successfully implanted with reduction of MR ≤2+ at discharge) was achieved in 95.6% of patients (43/45). After device cinching, an average ~20% reduction of the septo-lateral diameter was observed (from 39 ± 6 mm to 34 ± 7 mm; p<0.01). Thirty-day mortality was 4.4% (adjudicated as unrelated to the device). At 12 months follow up (N=20), 71% of patients presented NYHA class I-II with improvement in quality of life (MLWHFQ from 38 to 19; p<0.05 and significant improvement in 6MWT from 256 to 386 meters; p<0.05); 95% of patients (N=19) had MR≤2+.

CONCLUSIONS Transeptal mitral repair with the Cardioband device resulted in MR reduction by reconstruction of the mitral annulus. Safety profile is comparable to other transcatheter mitral procedures. MR severity reduction and clinical benefit are stable up to 12 months.

CRT-400.17

Impact Of Aortic Annulus Size and Valve Type on Valve Hemodynamics and Clinical Outcomes After Transcatheter Aortic Valve Replacement

Toby Rogers,¹ Arie Steinvil,² Edward Koifman,² Sarkis Kiramijyan,² Smita Negi,² Sang Yeub Lee,² Rebecca Torguson,² Augusto D. Pichard,² Lowell F. Satler,² Itsik Ben-Dor,² Ron Waksman²
¹NHLBI, National Institutes of Health, Bethesda, MD; ²MedStar Washington Hospital Center, Washington, DC

BACKGROUND Aortic annulus size can impact surgical prosthetic valve hemodynamics. The impact of annulus size on hemodynamics and clinical outcomes in patients undergoing transcatheter aortic valve replacement (TAVR) with balloon-expandable (BEV) vs. self-expanding valves (SEV) is not known.

METHODS 193 consecutive patients from a single center undergoing TAVR with a BEV or SEV were categorized into tertiles according to contrast-enhanced CT-derived aortic annulus perimeter (small annulus (SAA) <73mm, medium ≥73mm and <80mm, large (LAA) ≥80mm).

Data presented as n (%) for categorical or mean ± standard deviation for continuous variables

n=193	Small aortic annulus			Medium aortic annulus			Large aortic annulus		
	BEV (n=32)	SEV (n=30)	p value	BEV (n=36)	SEV (n=27)	p value	BEV (n=39)	SEV (n=29)	p value
Mean aortic valve gradient (mmHg)	10.0±1.4	7.5±1.4	0.07	16.0±8.5	6.2±1.4	0.35	10.4±5.3	9.0±2.4	0.55
Peak aortic valve velocity (m/sec)	2.4±0.4	1.8±0.4	<0.001	2.3±0.4	1.8±0.4	<0.001	2.1±0.4	2.0±0.3	0.40
Dimensionless index	0.53±0.09	0.64±0.15	0.02	0.53±0.12	0.58±0.10	0.15	0.52±0.09	0.52±0.07	0.99
Prosthesis-patient mismatch									
Moderate	8 (42.1)	4 (23.3)	0.17	14 (50.0)	5 (29.4)	0.22	15 (46.9)	1 (52.6)	0.77
Severe	0 (0.0)	0 (0.0)	—	0 (0.0)	0 (0.0)	—	0 (0.0)	0 (0.0)	—
Paravalvular leak									
Moderate/Severe	0 (0.0)	5 (20.8)	0.05	3 (9.1)	1 (3.8)	0.44	2 (6.1)	2 (8.3)	1.00