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 be 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 Pritchard[1]
[1]FDA Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, Laboratory of Cardiovascular and Interventional Therapeutics, Laurel, MD; [2]Medtronic Cardiovascular, Mounds View, MN; [3]Massachusetts General Hospital, Harvard Medical School, Boston, MA; [4]Medtronic 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 (MATLAB). 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 comparted 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 Maisano[6]
[1]Bichat Hospital, Paris, France; [2]Asklepios St Georg, Hamburg, Germany; [3]San Raffaele Hospital, Milano, Italy; [4]University Hospital Köln, Köln, Germany; [5]University Hospital Bonn, Bonn, Germany; [6]University Hospital Zurich, Zurich, Switzerland

OBJECTIVE Cardioband system enables percutaneous implantation of an adjustable "surgical-like" device for mitral reconstruction and MR reduction using a transseptal 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 Transseptal 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 Waksman[2]
[1]NHLBI, National Institutes of Health, Bethesda, MD; [2]MedStar 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

	Small aortic annulus			Medium aortic annulus			Large aortic annulus		
n=193	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 (23.5)	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

Baseline characteristics, valve hemodynamics by echocardiography and clinical outcomes were compared.

RESULTS Patients with SAA were more likely to be female (87.4 vs. 16.2%, p<0.001, SAA vs. LAA) and had lower body surface area (1.7 vs. 2.0m2, p<0.001, SAA vs. LAA). Dimensionless index was higher (0.64 vs. 0.53; P=0.02) and peak velocity was lower (1.8 vs. 2.4m/sec, p<0.001) for SEV vs. BEV in patients with SAA, but there was no difference in patients with LAA. There was a trend towards more paravalvular leak with SEV in SAA, but only mild-moderate in severity. Annulus size did not impact mortality at 1 year (11.1 vs. 13.0%, p=0.94, SAA vs. LAA).

CONCLUSION In patients with aortic stenosis undergoing TAVR, annulus size does not impact outcomes. Valve hemodynamics are more favorable with SEV than with BEV in patients with SAA. This can be attributed to the supra-annular location of the valve leaflets and may influence valve type selection in patients with SAA.

CRT-400.18

Use of a Self Expandable Nitinol Stent Graft as Treatment for Pre Closure Device Failure During Transcatheter Aortic Valve Replacement

Arie Steinvil, Nelson Bernardo, Hector M. Garcia-Garcia, Toby Rogers, Sarkis Kiramijyan, Eddie Koifman, Smita Negi, Sang Yeub Lee, Michael Lipinski, Michael A. Gaglia, Rebecca Torguson, Lowell F. Satler, Itsik Ben-Dor, Ron Waksman
Washington hospital center, Rockville, MD

BACKGROUND Access site related vascular complications (VC) following sheath removal related to pre-closure device failure during transcatheter aortic valve replacement (TAVR) are common and treatment options may vary.

METHODS We describe our experience with the use of a self-expandable nitinol stent graft (GORE® VIABAHN® Endoprosthesis; Gore Medical; USA) in a series of consecutive patients who underwent TAVR between the years 2013-2015, for whom failure of the pre-closer device was the indication for common femoral artery stenting.

RESULTS Included were 22 TAVR patients at a mean (±SD) age of 82±8. Most of the patients were males (14, 63%), Caucasian (19, 86%), had a previous history of coronary artery disease (13, 59%) and heart failure (21, 95%). The access site was the right common femoral artery in the majority of cases (19, 86%). Most vessels had only mild calcifications and tourtuisty. The minimal luminal diameter was 7.6±1.3 mm. Overall 24 covered stents were deployed using a cross over technique from the contralateral femoral artery. The stent diameters ranged between 8-11 mm and their length was mostly 50 mm (21,87%). All deployments were successful regaining normal flow, and non of the patients required surgery. The mean HB drop was 2.8 ± 1.1 and 14 patients needed blood transfusions during hospitalization. Acute kidney injury occurred in 5 patients. Length of hospital stay was 9 ± 4 days. All patients survived during a 30 day follow up period.

CONCLUSION The use of a self-expandable nitinol stent graft is a feasible and safe treatment option for access site related VC following TAVR.

CRT-400.19

Geometry and Motion of the Aortic Valve Across Species: Implications for Transcatheter Aortic Valve Replacement Device Evaluation and Development

Shelby A. Leonard,[1] Alex Hill,[2] Rajiv Gupta,[3] Srinivasan Varahoor,[4] William F. Pritchard,[1] John W. Karanian[1]
[1]FDA Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, Laboratory of Cardiovascular and Interventional Therapeutics, Laurel, MD; [2]Medtronic Cardiovascular, Mounds View, MN; [3]Massachusettes General Hospital, Harvard Medical School, Boston, MA; [4]Medtronic Cardiovascular, Minneapolis, MN

BACKGROUND Modeling of aortic valve safety and performance for TAVR is challenging due to a lack of understanding of aortic valve anatomy and geometry over the cardiac cycle and the limitations of preclinical animal models. The geometry and motion-induced changes of the aortic valve over the cardiac cycle in animal models was compared to human.

METHODS Gated cardiac CT angiograms from six normal adults and eight swine and sheep were segmented and the aortic valve analyzed (Mimics, Materialise, Leuven, Belgium). Measurements included aortic valve volume, length and angle, and for each valve plane, ellipticity, area and perimeter. Differences between species and over the cardiac cycle (end systole vs end diastole) are reported.

RESULTS The normal human aortic valve area, volume, perimeter, and length are greater than that of the swine and sheep (p<0.05, Figure 1). Significant changes in these characteristics were generally observed for all species over the cardiac cycle with no change in area or perimeter noted in the human (Table 1). However a significant increase in ellipticity was observed for the human valve ring plane and midpoint of the valve over the cardiac cycle. The angle between the sinotubular junction and valve ring plane was greatest in the swine valve although the change in angle over the cardia cycle was significant in the human (Table 1).

CONCLUSION The data show normal human aortic valves although larger than swine or sheep have different motion-induced geometric changes in valve size over the cardiac cycle compared to swine and sheep. These include changes in valve length, ellipticity and angle. Basic geometric differences between animal models compared to human combined with the impact of cardiac motion present modeling challenges. This data should inform the design and evaluation of aortic valve replacement technology.

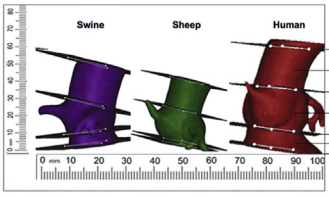

Figure 1. 3D segmentations of swine, sheep and human aortic valve. LVOT-P: left ventricular outflow tract plane; LVOT: left ventricular outflow tract; VR-P: valve ring plane; AV: aortic valve; StJ-P: sinotubular junction plane; AAr: ascending arch; AAr-P; ascending arch plane.

Table 1. Changes in aortic valve geometry over the cardiac cycle (m± SE)

	Species	ES vs ED	% Δ	ES vs ED	% Δ	ES vs ED	% Δ
		Length (mm)		Volume (mm^3)		Angle °	
Valve (VR-P to StJ-P)	Swine	19.7±0.7,18.1±0.5	-8.8**	8841±785, 7911.3±760	-11.8***	23.3±0.8, 26.7±2.6	12.9
	Sheep	19.5±0.4, 17.9±0.3	-3.85*	9899±454, 9284±425	-6.6*	4.0±0.5, 3.3±0.8	-22.1
	Human	23.6±0.6, 22.0±0.6	-7.3*	15963±818, 15376±728	-3.8*	8.2±1.6, 11.7±1.9	30.1*
Plane		Ellipticity		Area (mm^2)		Perimeter (mm)	
Sinotubular Junction	Swine	0.37±0.05, 0.39±1.04	-5.1	383±27, 347±29	-10.3	71.2±53.7, 67.6±2.8	-5.4*
	Sheep	0.31±0.03, 0.37±0.03	16.2*	410±17, 370±20	-10.8**	72.9±1.4, 69.4±1.9	-5.0**
	Human	0.39±0.02, 0.34±0.04	-14.7	607±30, 589±43	-3.3	88.8±2.4, 87.6±3.3	-1.4
Midpoint of Valve	Swine	0.44±0.04, 0.42±0.03	-3.0	542±40, 513±42	-5.5***	95.1±3.2, 91.9±3.2	-3.5*
	Sheep	0.44±0.02, 0.46±0.02	4.1	612±25, 588±27	-4.0**	100.6±2.3, 97.4.7±2.7	-3.4*
	Human	0.32±0.02, 0.42±0.02	24.8**	805±35, 768±29	-4.8	117.3±2.2, 113.5±2.2	-3.3
Valve Ring	Swine	0.67±0.04, 0.67±0.03	0.8	351±22, 412±16	14.7**	66.9±2.1, 75.5±1.3	7.3**
	Sheep	0.69±0.02, 0.67±0.03	-2.8	370±15, 474±25	21.8***	70.9±1.5, 80.2±2.2	11.5***
	Human	0.58±0.02, 0.62±0.02	6.5*	449±24, 451±25	0.6	77.4±1.9, 78.0±2.0	0.8

*Denotes significance at p<.05; **p<.005; ***p<.0005

CRT-400.20

Episode of Care Costs for Transcatheter Aortic Valve Replacement in the United States

Daniel D'Attilio, Seth Clancy
Edwards Lifesciences, Irvine, CA

BACKGROUND Bundled payments, also known as episode of care payments, have received increased attention from payers as a mechanism to control healthcare costs and promote quality. Hospitals are increasingly in need of metrics to understand resource utilization beyond the index hospitalization, extending out 30, 60 and 90 days post-discharge. The purpose of this analysis was to identify "episode of care" costs for Transcatheter Aortic Valve Replacement (TAVR) patients including the index hospitalization and all post-discharge care through 30, 60 and 90 day time periods.

METHODS We retrospectively evaluated 6,352 patients receiving TAVR in 2013 from Medicare claims. Using Medicare Cost Reports, we calculated the total episode of care costs for the index TAVR hospitalization and defined periods of post-discharge care including 30, 60 and 90 days. Episodic costs included the index admission, physician fees, subsequent inpatient admissions (readmissions), skilled nursing facility (SNF), hospital outpatient and home health (HH). Inpatient rehabilitation and long term care were excluded as cost information were not available for these services. Rates of post-discharge care use and length of stay were calculated where available.

RESULTS The average index hospitalization cost for TAVR in 2013 was $65,701 as shown in Table 1. The average episode of care costs were $74,629, $78,438 and $80,860 at 30, 60 and 90 days, respectively. Readmissions were the largest driver of post-discharge resource utilization followed by physician costs, SNF, HH and hospital outpatient. Readmission rates were 18.9%, 27.8%, and 35.3% at 30, 60, and 90 days, respectively. Among TAVR patients with readmissions, the average length of stay for the readmissions were 5.8, 5.7 and 5.7 days for the three time points, respectively.