2-27-2023

CRT-700.1 Multi-Center Compassionate use Early Feasibility Evaluation of J-Valve Transcatheter Treatment for Severe Aortic Valve Regurgitation: Preliminary Results

Hanad Bashir

Michael Reardon

Sachin S. Goel

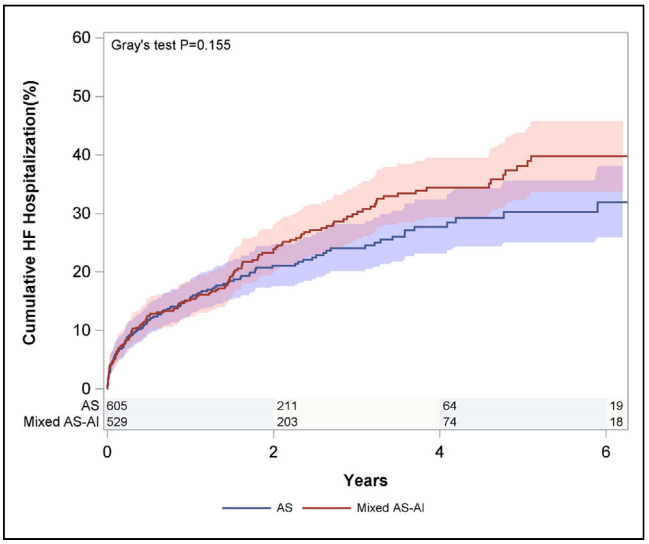
Neil Fam

Julius Jelisejevas

See next page for additional authors

Authors

Hanad Bashir, Michael Reardon, Sachin S. Goel, Neil Fam, Julius Jelisejevas, John G. Webb, Jian Ye, Tiberio M. Frisoli, Muhaimen Siddiqui, Santiago Garcia, Geoffrey A. Answini, and Dean J. Kereiakes



CRT-700.07

Outcomes Among Patients Undergoing Transcatheter Aortic Valve Replacement With Very Low Baseline Gradients

Faisal Rahman,[1] Hetal H. Mehta,[2] Jon R. Resar,[1] Rani K. Hasan,[1] Hamza Aziz,[1] Wendy Marconi,[1] Matthew J. Czarny[1]
[1]Johns Hopkins University, Baltimore, MD; [2]Doylestown Health, Doylestown, PA

BACKGROUND While there is evidence that patients with low-flow low-gradient aortic stenosis (AS) benefit from transcatheter aortic valve replacement (TAVR), data are lacking regarding outcomes of patients with a very low mean gradient (VLG).

METHODS In this retrospective, single-center study of patients with severe AS who underwent TAVR, three groups were defined using baseline mean aortic valve gradient: VLG (≤25 mmHg), low gradient (LG, 26-39 mmHg), and high gradient (HG, ≥40mmHg). The primary outcome was the composite of Kansas City Cardiomyopathy Questionnaire (KCCQ)-12 <45, decrease in KCCQ-12 ≥10 compared to baseline, or death at 1-year.

RESULTS One-thousand six patients were included; 571 HG, 353 LG, and 82 VLG. The median age was 82.1 years (interquartile range [IQR] 76.3-86.9); VLG patients had more baseline comorbidities compared to the other groups. The primary outcome was highest at 1-year in the VLG group (VLG: 46.7%, LG: 29.9%, HG: 23.1%, p=0.002), with no difference between groups after adjustment for baseline characteristics. At baseline, <30% of VLG patients had an excellent or good (50-100) KCCQ-12, whereas more than 75% and 50% had an excellent or good KCCQ-12 at 30-day and 1-year follow-up, respectively.

CONCLUSIONS Although patients with VLG undergoing TAVR have a higher rate of poor outcomes at 1-year compared to patients with LG and HG severe AS, this difference is largely attributable to baseline comorbidities. Patients with severe AS undergoing TAVR have significant improvement in health status outcomes regardless of resting mean gradient.

CRT-700.08

Implantation of Contemporary Transcatheter Valves in Patients With Extra-Small Annuli Undergoing TAVR - From TAVI-SMALL 2 Registry

Pier Pasquale Leone,[1] Damiano Regazzoli,[2] Antonio Mangieri,[3] Matteo Pagnesi,[4] Marco Barbanti,[5] Rui Teles,[6] Marianna Adamo,[4] Maurizio Taramasso,[7] Federico De Marco,[8] Francesco Giannini,[9] Yohei Ohno,[10] Francesco Saia,[11] Alfonso Ielasi,[12] Flavio Ribichini,[13] Diego Maffeo,[14] Francesco Bedogni,[15] Won-Keun Kim,[16] Francesco Maisano,[17] Corrado Tamburino,[5] Nicolas Van Mieghem,[18] Antonio Colombo,[3] Bernhard Reimers,[3] Azeem Latib[1]
[1]Montefiore Medical Center, Bronx, New York, NY; [2]IRCCS Humanitas Research Hospital, Rozzano, Italy, Italy; [3]IRCCS Humanitas Research Hospital, Rozzano, Italy; [4]Institute of Cardiology, ASST Spedali Civili, Department of Medical and Surgical specialties, Radiological sciences and Public Health, University of Brescia, Brescia, Italy, Brescia, Italy; [5]U.O.C. Cardiologia, Centro Alte Specialità e Trapianti, A.O.U. Policlinico "G. Rodolico - San Marco", Catania, Italy, Catania, Italy; [6]Hospital de Santa Cruz, Centro Hospitalar de Lisboa Ocidental, Nova Medical School, CEDOC, Lisbon, Portugal, Lisbon, Portugal; [7]HerzZentrum Hirslanden Zurich, Switzerland and University of Zurich, Switzerland, Zurich, Switzerland; [8]Centro Cardiologico Monzino, Milan, Italy; [9]GVM Care and Research, Maria Cecilia Hospital, Ravenna, Italy, Ravenna, Italy; [10]Department of Cardiology, Tokai University Hospital, Kanagawa, Japan, Tokai, Japan; [11]Cardiology Unit, St. Orsola Hospital, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy, Bologna, Italy; [12]IRCCS Ospedale Galeazzi Sant'Ambrogio, Milan, Italy; [13]Division of Cardiology, Department of Medicine, University of Verona, Verona, Italy, Verona, Italy; [14]Interventional Cardiology Unit, Cardiovascular Department, Fondazione Poliambulanza Istituto Ospedaliero, Brescia, Italy, Brescia, Italy; [15]Department of Cardiology, IRCCS Policlinico San Donato, San Donato Milanese, Milan, Italy, Milan, Italy; [16]Department of Cardiology, Kerckhoff Heart Center, Bad Nauheim, Germany, Bad Nauheim, Germany; [17]Cardio-Thoracic-Vascular Department, IRCCS Ospedale San Raffaele , Milan, Italy, Milan, Italy; [18]Department of Cardiology, Thoraxcenter, Erasmus Medical Center, Rotterdam, Netherlands

BACKGROUND Transcatheter aortic valve replacement (TAVR) in patients with extra-small annuli may result in prosthesis-patient mismatch (PPM). We sought to compare forward-flow hemodynamics and clinical outcomes of contemporary transcatheter valves in these patients.

METHODS Among 1,378 patients with severe aortic stenosis and small aortic annuli from the TAVI-SMALL 2 international retrospective registry, 299 had extra-small annuli (perimeter <62.8 mm or area <314 mm^2) and were treated with transfemoral implantation of supra-annular (SAV, n =162 [Evolut R/PRO {n=137}, Acurate Neo {n=25}]) and intra-annular valves (IAV, n =137 [Portico {n=25}, SAPIEN 3 {n=106}]) between 2011 and 2020 at 16 centers. Primary endpoints were pre-discharge mean aortic gradient and incidence of severe PPM. Secondary endpoint was incidence of all-cause mortality.

RESULTS When compared with IAV, SAV had lower pre-discharge mean aortic gradient (9.1±4.9 mmHg vs. 13.2±5.8 mmHg, p<0.001) and incidence of severe PPM (3.3% vs. 13.2%, p=0.030).No significant difference in all-cause mortality was evident between groups at a median follow-up of 378 (198-574 interquartile range) days (10.1% vs. 15.1%, p=0.198), while cardiovascular mortality tended to be lower after SAV implantation (2.6% vs. 7.6%, p=0.072). More than mild paravalvular leak was similar between groups (11.9% vs. 7.2%, p=0.196). No difference in major vascular complications (3.1% vs. 6.6%, p=0.155) or permanent pacemaker implantation (12.9% vs. 10.3%, p=0.708) was observed.

CONCLUSION SAV implantation was associated with more favorable forward hemodynamic profile than IAV implantation in patients with extra-small aortic annuli undergoing TAVR. All-cause mortality at medium-term follow-up did not significantly differ between groups.

CRT-700.1

Multi-Center Compassionate use Early Feasibility Evaluation of J-Valve Transcatheter Treatment for Severe Aortic Valve Regurgitation: Preliminary Results

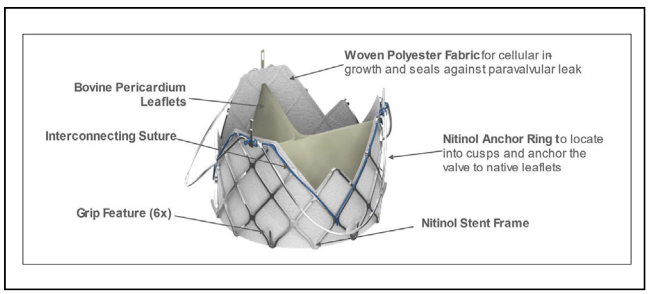
Hanad Bashir,[1] Michael Reardon,[2] Sachin S. Goel,[2] Neil Fam,[3] Julius Jelisejevas,[4] John G. Webb,[4] Jian Ye,[5] Tiberio M. Frisoli,[6] Muhaimen Siddiqui,[7] Santiago Garcia,[1] Geoffrey A. Answini,[1] Dean J. Kereiakes[1]
[1]The Christ Hospital, Cincinnati, OH; [2]Houston Methodist, Houston, TX; [3]Unity Health Toronto, Toronto, QC, Canada; [4]St. Paul's and Vancouver General Hospital University of British Columbia, Vancouver, BC, Canada; [5]Division of Cardiovascular Surgery, St. Paul's Hospital and Vancouver General Hospital, Vancouver, BC, Canada; [6]5Center for Structural Heart Disease, Division of Cardiology, Henry Ford Health System, Detroit, MI; [7]Epidemiology Department of Public Health John Hopkins University, Baltimore, MD

BACKGROUND Although transcatheter aortic valve replacement (TAVR) is accepted therapy for treatment of symptomatic severe aortic valve stenosis (AS), current devices are associated with increased procedural complications and sub-optimal outcomes when used to treat of aortic valve regurgitation (AR). Severe AR is the indication for 20-30% of surgical aortic valve replacements and is associated with increased morbidity and mortality. J-valve is a short frame, self-expanding TAVR device. (Figure) specifically designed for treatment of severe AR. Anchor rings facilitate commissural alignment and secure attachment to non-calcified native valves.

METHODS From Sept 2019 through Oct 2022, patients with symptomatic severe AR who were not surgical candidates or excluded from the ALIGN-AR trial were enrolled into a compassionate use early feasibility study at 5 North American centers. All patients signed informed consent for protocol approved by respective institutional review boards.

RESULTS Data from 13/28 patients (mean age 80 yrs; 38.5% male) with symptomatic (92.3% NYHA class III/IV; mean LVEF 48% [range 23-64%]) severe (92% grade III/IV) AR, atrial fibrillation (53.8%), and pacemaker/ICD (15.4%), had J-valve TAVR (15.4% alternative access). There were no deaths to 30 days and post-procedural AR grade was none/trivial in all patients. In follow-up (mean 333 days) there are 0 cardiac deaths (total mortality 30.7%; 3 malignancies, 1 sepsis). Serial echocardiograms demonstrate AR grade none/mild in 89%, and 100% at 30 days and 1 year respectively).

CONCLUSION Despite high risk profile, preliminary analysis of this multi-center compassionate use study suggests that J-valve is safe with durable effectiveness for the treatment of symptomatic severe AR. Full data set on all patients will be presented.



CRT-700.11

Peak Areal Stretch Location as a Variable to Predict Aortic Root Rupture Risk Using Pre-Procedural Computational Modeling

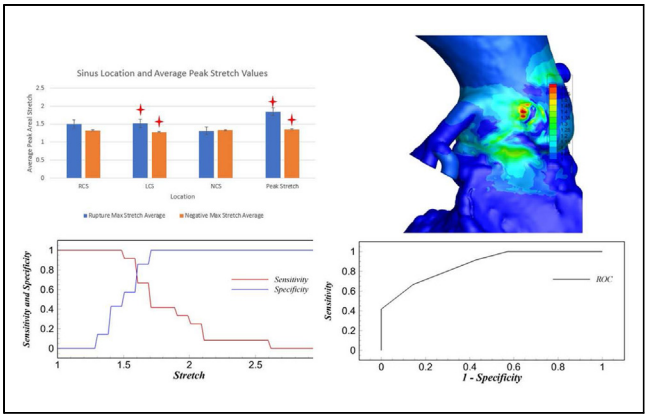
Taylor Nicole Sirset,[1] Breandan Yeats,[2] Sri Krishna Sivakumar,[2] Aniket Venkatesh,[2] Janar Sathananthan,[3] Scott Lilly,[1] Karim Al-Azizi,[4] Molly Szerlip,[4] Venkateshwar Polsani,[5] Pradeep Yadav,[5] Vinod Thourani,[5] Lakshmi Prasad Dasi[2]
[1]The Ohio State University, Columbus, OH; [2]Georgia Institute of Technology, Atlanta, GA; [3]University of British Columbia, Vancouver, BC, Canada; [4]Baylor Scott & White the Heart Hospital, Plano, TX; [5]Piedmont Hospital, Atlanta, GA

BACKGROUND Although aortic root rupture occurs in less than 1% of Transcatheter Aortic Valve Replacement (TAVR) procedures, it can be a lethal complication. There is a higher occurrence of rupture (4-5%) in the bicuspid aortic valve patient population. The objective of this paper is to further understand the risk of aortic root rupture during TAVR using a pre-procedural computationally derived biomarker.

METHODS Pre - TAVR computed tomography (CT) angiograms from patients who suffered an aortic root rupture (n=12) and from patients who did not have any complications during their procedure (n=14) were segmented into a virtual 3D model where a balloon-expandable valve was implanted using a validated computational simulation model. The segmentations and simulations were blinded to patient outcome. Quantitative measurements of local areal stretch were obtained in the right coronary sinus, left coronary sinus, and non-coronary sinus (LCS, RCS, NCS). Areal stretch, $\lambda=1+\varepsilon$, where ε is the areal strain, was calculated to quantify tissue deformation.

RESULTS We identified a statistically significant relationship between the mean LCS stretch and aortic annular rupture incidence ($p = 0.050$) and a statistically significant relationship between the maximum areal stretch found in the aortic sinuses / annulus and incidence of aortic root rupture ($p = 0.0011$). Sensitivity and Specificity plots demonstrated an Area Under the Curve of 0.86 (Figure 1) for a maximum stretch threshold of 1.6 (i.e. 60% areal stretch).

CONCLUSION There is a potential relationship between the location of peak areal stretch in the aortic valve (specifically the LCS) and the occurrence of an aortic root rupture. Different sinuses within the aorta may have differing areal stretch tolerances.



CRT-700.12

New Adverse Coronary Events in Valve-in-Valve TAVR and Native TAVR – A Two-Year Matched Cohort

Ofir Koren,[1] Vivek Patel,[1] Robert Naami,[2] Edmund Naami,[3] Takashi Nagasaka,[1] Alon Shechter,[1] Sharon Natanzon,[1] Siamak Kohan,[4] Zev Allison,[1] Addee Lerner,[5] Daniel Eugene Cheng,[1] Tarun Chakravarty,[1] Mamoo Nakamura,[1] Hasan Jilaihawi,[6] Raj R. Makkar[1]
[1]Cedars-Sinai Medical Center, Los Angeles, CA; [2]University Hospitals Cleveland Medical Center, Case Western Reserve University School of Medicine, Cleveland, OH; [3]School of Medicine, University of Illinois, Illinois, IL; [4]Kaiser Permanente Medical Center, Los Angeles, CA; [5]University of California (UCLA), Los Angeles, CA; [6]NYU Langone Health, New York, NY

OBJECTIVE To assess the incidence of new adverse coronary events (NACE) following transcatheter aortic valve replacement (TAVR) and valve-in-valve TAVR.

BACKGROUND ViV-TAVR is an accepted treatment for degenerative prostheses. TAVR studies have suggested an increased risk of coronary artery (CA) obstruction and CA flow stasis influencing thrombus formations. Whether contemporary ViV-TAVR is associated with higher NACE than TAVR is unknown.

METHODS We used data from 1224 TAVR patients between 2016 and 2021. We propensity-matched patients following VIV-TAVR and TAVR by significant predictors to overcome confounders in patients' baseline characteristics and procedural factors.

RESULTS The matched population included 129 patients in each group. In line with prior reports, there was a higher in-hospital CA obstruction trend with VIV-TAVR (3.1 vs. 1.6%; p=0.23). Despite this, two-year cumulative NACE was similar between groups (4.7% vs. 6.2% respectively, p=0.79), with no difference between its components: myocardial infarction (MI) (p=.210), unplanned coronary catheterization (p=.477), or CA bypass graft (CABG)(p=.998). Moreover, hypoattenuated leaflets thickening (HALT) at 30-day CT was observed in nearly a quarter of the patients with no difference between groups (23.9 vs. 23.1%, HR 1.02, 95% CI 0.50-1.28, p=.872). There was no difference in the progression rate of the CA calcium score (CACS) (p-log-rank=0.468, 95% CI 0.12-1.24). In both groups, low CA height was an unfavorable predictor for in-hospital coronary obstruction and NACE (HR 1.20 and HR 1.25, p=.001 and p<.0001, respectively).

CONCLUSION At a 2-year follow-up, ViV-TAVR was not associated with a higher rate of MI, unplanned catheterization, CABG, CACS progression, or HALT.