TCT-786

The Effect of Post-dilatation on Outcome in the PARTNER 2B Trial

Rebecca Hahn1, Philippe Pibarot2, Leonardo Rodriguez2, John Webb4, Lars Svensson3, William N. Anderson3, Martin Leon3, Wael Jaber4

1Columbia/University, New York, United States, 2Quebec Lung & Heart Institute, Laval University, Quebec, Quebec, 3Cleveland Clinic Foundation, Cleveland, OH, 4University of British Columbia, Vancouver, BC, 5Cleveland Clinic Clinic, Cleveland, USA, 6Edwards Lifesciences, Irvine, CA, 7Cardiovascular Research Foundation, New York, NY

Background: Paravalvular regurgitation (PVR) following transcatheter aortic valve replacement (TAVR) is associated with increased mortality. The purpose of the study is to evaluate the effect of post-dilatation (PD) on PVR and clinical outcomes.

Methods: Inoperable patients with severe, symptomatic aortic stenosis were randomized to transfemoral SAPIEN or SAPIEN XT and evaluable 30 day echocardiograms (n = 434) were analyzed. PVR and total AR was assessed by an independent Echocardiography Core Lab as none/trace, mild, moderate and severe according to American Society of Echocardiography guidelines. The rate of PD was determined for each enrolling site and grouped by frequency: Group 1: PD performed in < 10% of the patients in the given site; Group 2: 10% and < 25%; Group 3: ≥25%.

Results: There were significant between PD group differences in the incidence of PVR and total AR (Figure 1A) with the lowest PVR severity in Group 3 (p < 0.05). There was no difference in 30day mortality or stroke rate between PD groups (Figure 1B).

Conclusions: Sites that perform PD on ≥25% of cases have less moderate and severe PVR. There is no apparent association between higher rates of PD and early post-procedural mortality or stroke in this cohort of the PARTNER 2 trial. Further analysis in a larger patient population should be performed.

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Preliminary Clinical Experience using the SAPIEN 3 device

Danny Dvir1, Marco Barbanti1, Robert De Larochellière1, Daniel Doyle4, Melanie Freeman1, Henriquê R. Ribeiro2, Josep Rodés-Cabau1, John Tan1, David A. Wood3

1St. Paul's Hospital, Vancouver, British Columbia, 2St. Paul's Hospital - University of British Columbia, Vancouver, British Columbia, 3Quebec Lung and Heart Institute, Laval University, Quebec, Quebec, 4Cleveland Clinic Clinic, Cleveland, USA

Background: The SAPIEN 3 transcatheter heart valve with the low profile Commander transfemoral and Certitude transcatheter delivery systems (Edwards Lifesciences, CA) incorporate features intended to facilitate accurate positioning and improve paravalvular sealing. We review the initial clinical experience with this device.

Methods: SAPIEN 3 valves were implanted in 26 patients (age 79.2±9.3 years, 88.5% male, STS score 6.1±3.6).

Results: Device size was 25mm in 88.5%, 29mm in 11.5%. Valve positioning was accurate in all cases, with no moderate or severe paravalvular leaks. Mean aortic valve gradient decreased from 39.6±15.7mmHg to 12.4±4.7mmHg and mean aortic valve area increased from 0.67±0.16cm2 to 1.62±0.35cm2 (p<0.001). Major vascular complications occurred in 3.8%, major/life-threatening bleeding rate in 7.7%, and there were no stroke events. Hospital discharge was a median of 3 days after the procedure. Survival at 30 days was 96.2% with 92.3% of survivors in NYHA functional class I or II.

Conclusions: Early outcomes with the SAPIEN 3 THV were excellent with improved device positioning and reduced post procedural regurgitation. Longer follow-up of a larger group of patients is needed to validate these findings.

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Balloon Aortic Valvuloplasty in Severe Aortic Stenosis Patients Has Potential For Improving In Renal Insufficiency

Christopher Pedersen2, William J. Druzler2, Irvin Goldenberg1, Michael Mooney2, Stephanie Butten-Ramos2, Robert S. Schwartz2

1Minnesota Heart Institute Foundation, Minneapolis, MN, 2Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, Minneapolis, MN

Background: Balloon aortic valvuloplasty (BAV) is occasionally a bridge for optimizing transcatheter aortic valve replacement outcomes. This study examined whether BAV improves renal insufficiency in these high-risk patients.

Methods: Our 320 pt BAV database was queried for pts with stage-4 chronic kidney disease (CKD4, CrCl <30 ml/min) and stage-3 (CKD3, CrCl 30-59 ml/min). CrCl was determined using the Cockcroft-Gault equation. Demographics including risk factors, intraprocedural hemodynamics, pre and post BAV echocardiographic findings, periprocedural fluids, medication regimens, and pre and post BAV GcCr (ΔGcCr) were compared for differences between the two groups (g). Successful BAV was defined as ≥30% increase in echocardiographic AVA.

Results: 81 pts were identified, 15 in the CKD4 gp (age 85±6.2), and 66 in the CKD3 gp (83.7±7.5). Baseline CrCl in CKD4 was 24.4±4.3 ml/min, and in CKD3 pts was 46.3±9.0 ml/min. The mean post BAV improvement in CrCl for the CKD4 pts was 9.6±13.9 ml/min and CKD3 pts was -1.8±11.2 ml/min (p=0.0011) respectively. There was a significant association between age and CrCl improvement across all pts. The odds ratio of significant improvement in CKD4 pts was age dependent up to 82 years of age. The mean follow-up time was 83.9±7.2 days.

Conclusions: Pts with CKD and aortic stenosis undergoing BAV experience a modest improvement in CrCl. Improvement was associated with more advanced CKD and younger age.

TCT-789

Intentionally Underexpanding Balloon-expandable Transcatheter Aortic Valves: Proof of concept and clinical implications

Marco Barbanti1

1St. Paul’s Hospital - University of British Columbia, Vancouver, British Columbia

Background: Oversizing of balloon-expandable transcatheter heart valves (THVs) during transcatheter aortic valve replacement (TAVR) is recommended to reduce paravalvular regurgitation. However excessive oversizing may be associated with a risk of annular injury.

Methods: Patients (n=43) who underwent TAVR with an intentionally under-expanded balloon expandable THV were enrolled in this study. In patients where the nominal THV transvalvular area exceeded the CT annular area by >20% (or >15% with adverse root features) the deployment balloon was intentionally underfilled by 5-15%. Study patients were compared to consecutive control patients, who had nominally filled THV deployment balloons (n=87). All patients underwent pre and post procedural CT imaging as well as transthoracic and transesophageal echocardiography to assess THV stent geometry, expansion, eccentricity and hemodynamics.

Results: Among the study group, the THV balloon was underfilled by 1, 2, 3, and 4 ml in 7(16.3%), 24(55.8%), 10(23.3%), and 2(4.7%) patients, respectively. On transthoracic echocardiogram, post procedure THV area was 1.62±0.38 cm2 in the study group and 1.66±0.41 cm2 in the control group (p=0.602). Mean gradient across the THV was 11.2±4.0 mmHg and 10.6±3.9 mmHg in study and control groups, respectively (p=0.411). Paravalvular regurgitation was >mild in 1 patient (3%) in the study group and 6(6.9%) patients in the control group (p=0.261). Transvalvular regurgitation was not observed in either group. In-hospital complication rates were similar. THV expansion at the inflow was 85.2±7.2% versus 102.5±6.2% (p<0.001), at the mid-portion 88.1±7.3% versus 102.4±6.3% (p<0.001) and at the outflow 91.5±7.2% versus 102.8±6.0% (p<0.001), in study versus control groups respectively.

Conclusions: Intentionally underexpanding balloon-expandable THVs as part of a strategy intended to reduce paravalvular regurgitation and annular injury did not appear to adversely affect procedural clinical outcomes. THV gradients, or THV areas. The impact of underexpansion of THVs on durability and late outcomes remains to be determined.