

CRT-400.23**Long-term follow-up of Percutaneous Mitral Valvuloplasty With Inoue Versus Balt Single Balloon in Mitral Stenosis**

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OBJECTIVE This study aimed to demonstrate that mitral balloon valvuloplasty (MBV) with the Balt single balloon (BSB) has similar outcome and long-term follow-up (FU) than MBV performed with the Inoue worldwide accepted technique.

METHODS From 1987 to 2013 a total of 526 procedures were performed, being 312 with a FU, 56 (17.9%) with Inoue balloon (IB) and 256 (82.1%) with BSB. The mean FU in IB group was 33 ± 27 (2 to 118) and 55 ± 33 (1 to 198) months, $p < 0.0001$. Univariate analysis (UA) and multivariate Cox analysis (MVA) were utilized to determine independent predict variables of survival and event free survival (EFS) in both techniques groups. The major events (ME) were death, cardiac surgery and new MBV.

RESULTS In IB and BSB groups there were, respectively: female 42 (75.0%) and 222 (86.7%); mean age 37.3 ± 10.0 (19 to 63) and 38.0 ± 12.6 (13 to 83) years, $p = 0.7138$; sinus rhythm 51 (91.1%) and 215 (84.0%), $p = 0.1754$; echo score (ES) 7.6 ± 1.3 (5 to 10) and 7.2 ± 1.5 (4 to 14) points, $p = 0.0528$; echo mitral valve area (MVA) pre-MBV 0.96 ± 0.18 and 0.93 ± 0.21 cm², $p = 0.2265$; post-MBV mean MVA (Gorlin) were 2.00 ± 0.52 and 2.02 ± 0.37 cm², $p = 0.9554$; MBV dilatation area 6.09 ± 0.27 and 7.02 ± 0.30 , $p < 0.0001$. At the end of the FU, there were in IB and BSB groups, respectively: echo MVA 1.71 ± 0.41 and 1.54 ± 0.51 cm², $p = 0.0552$; new severe mitral regurgitation in 5 (8.9%) and 17 (6.6%) patients, $p = 0.5633$; new MBV in 1 (1.8%) and 13 (5.1%), $p = 0.4779$; mitral valve surgery in 3 (5.4%) and 27 (10.4%), $p = 0.3456$; deaths 2 (3.6%) and 11 (4.3%), $p = 1.000$; cardiac deaths 1 (1.8%) and 9 (3.5%), $p = 1.000$; ME 5 (8.9%) and 46 (18.0%), $p = 0.1449$. In UA and MCA the BSB or IB technique do not predict survival or EFS. The independent risk factors to survival (MCA with 2 models with 5 and 6 variables) were: age < 50 years ($p = 0.016$, HR=0.233, 95% IC 0.071-0.764), ES ≤ 8 ($p < 0.001$, HR=0.105, 95% IC 0.34 - 0.327), MBV dilatation area ($p < 0.001$, HR 16.838, 95% IC 3.353 - 84.580) and no mitral valve surgery in the FU ($p = 0.001$, HR0.152, 95% IC 0.050 - 0.459). Independent risk factors to EFS: no prior commissurotomy ($p = 0.012$, HR=0.390, 95% IC 0.187 - 0.813) and post-MBV MVA ≥ 1.50 cm² ($p = 0.001$, HR=7.969, 95% IC 3.413-18.608).

CONCLUSION MBV with BSB and IB were equally efficient, there were similar survival and EFS in the FU. Independent predictors of survival were: age < 50 years, ES ≤ 8 points, MBV dilatation area > 7 mm² and no mitral valve surgery in the FU. Independent risk factors of EFS were no prior commissurotomy and post-MBV MVA ≥ 1.50 cm².

CRT-400.24**Percutaneous Mitral Valvuloplasty With Balt Single Balloon. Long-term Follow-up**

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OBJECTIVE To evaluate the long-term follow-up (FU) of mitral balloon valvuloplasty (MBV) with Balt single balloon (BSB) technique and to determine independent predictors of survival and event-free survival (EFS).

METHOD From 1987 to 12-31-2013, 526 procedures of MBV were performed, 404 (77.1%) with BSB. There were 256 procedures with long-term FU. Balloon diameter: 25 mm in 5 procedures, 30 mm in 251; mean dilatation area: 7.02 ± 0.30 cm². FU was 156 ± 144 months. Multivariate Cox analysis to determine IPS and EFS.

RESULTS Mean age: 38.0 ± 12.6 (13 to 83) years, 222 (86.7%) female gender, 215 (84.0%) sinus rhythm, echo score (ES) 7.2 ± 1.5 (4 to 14) points and echo mitral valve area (MVA) pre-MBV 0.93 ± 0.21 cm². Mean pre and post-MVA (Gorlin): 0.90 ± 0.20 and 2.02 ± 0.37 cm², respectively ($p < 0.001$). Success (MVA ≥ 1.5 cm²): 241 (94.1%) procedures. Mean pulmonary artery pressure pre and post-MBV: 27 ± 10 and 20 ± 7 mmHg, respectively. Three (1.2%) patients began the FU with severe mitral regurgitation (SMR). At the end of FU 119 (46.5%) patients were in NYHA functional class (FC) I; 70 (27.3%) in FC II; 53

(20.7%) in FC III; 3 (1.2%) in FC IV; 11 (4.3%) deaths; 17 (8.2%) patients with SMR; 20 (4.7%) were submitted to a new MBV; 27 (10.5%) to mitral valve surgery and 70 (26.3%) without any medicine. Independent predictors of survival were: ES ≤ 8 points ($p < 0.001$, HR0.116, 95% IC 0.035-0.384), age ≤ 50 years old ($p = 0.011$, HR 0.203, 95% IC 0.059-0.693) and absence of mitral valve surgery in the FU ($p = 0.004$, HR 0.170, 95% IC 0.050-0.571). Independents of EFS were: absence of prior commissurotomy ($p < 0.002$, HR 0.318, 95% IC 0.151-0.667), female gender ($p = 0.036$, HR 0.466, 95% IC 0.229-0.951) and MVA post-MBV ≥ 1.50 cm² ($p < 0.001$, HR 0.466, 95% IC 4.884-28.457).

CONCLUSIONS Success in 94% of procedures. At the end of follow-up (25 years) only 4.3% of mortality. The independent predictors of survival were: ES ≤ 8 points, age ≤ 50 years old and absence of mitral valve surgery in the FU. Independent predictors of EFS were: absence of prior commissurotomy, female gender and MVA post-MBV ≥ 1.50 cm².

CRT-400.25**Abstract Withdrawn****CRT-400.26****Transfemoral Aortic Valve Implantation in Patients With Symptomatic Severe Aortic Stenosis With the Repositionable Lotus Valve: Results From a High Volume Center**

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AIMS The Lotus valve (Boston Scientific Corporation) is designed to reduce the risk for residual paravalvular aortic regurgitation and can be easily repositioned. The study evaluates the procedural and 30-day results for the 23, 25 and 27mm Lotus valve in patients undergoing transfemoral aortic valve implantation (TAVI).

METHODS AND RESULTS We prospectively enrolled 110 patients with severe symptomatic aortic stenosis in a high-volume center. Procedures were performed without general anesthesia by transfemoral approach. Patients presented with diabetes in 23%, atrial fibrillation 38%, a mean STS score of 7 logistic EuroScore of 16. Patients were followed for 30 days. Events were adjudicated according to the VARC-2 criteria. Patients received the 23 mm (N=20), 25 mm (N=43) or 27 mm (N=47) Lotus device based on pre-procedural 256 multislice computed tomography. Mean oversizing in relation to annulus (8.7%) or left ventricular outflow tract (LVOT; 10.1%) did not differ between the three valve sizes. After valve release (including re-positioning) there was no residual moderate or severe aortic regurgitation. Rate of mild aortic regurgitation (9.1%; N=10/110) did not differ between groups. There was no valve embolization or need for a second valve. Rate of major vascular complication was 4.5% with no difference between valve and delivery sheath sizes. Device success according to VARC-2 was high with 96%. Patients without device success had a mean aortic gradient of more than 20mmHg assessed by echocardiography one day after valve implantation. There was no need for post-dilatation, no annular rupture and no conversion to surgery. Contrast amount was mean 99mL. Need for pacemaker implantation due to grade II (type II)/III atrioventricular block was 18%. There was a significant higher need for pacemaker implantation in patients with LVOT calcification compared to patients without LVOT calcification (34.5% versus 14.1%, $p < 0.01$). Within 30 days all cause mortality (0.9%) and stroke (disabling 2.7%, non-disabling 0.9%) were low with no difference between groups. NCT02162069

CONCLUSION In patients with severe symptomatic aortic stenosis transfemoral TAVI with the repositionable Lotus valve was associated with a high rate of device success, no moderate or severe residual aortic regurgitation, and low rates of major vascular complication, mortality and stroke within 30 days.

CRT-400.27**Implications of New-Onset Atrial Fibrillation After Transcatheter and Surgical Aortic Valve Replacements**

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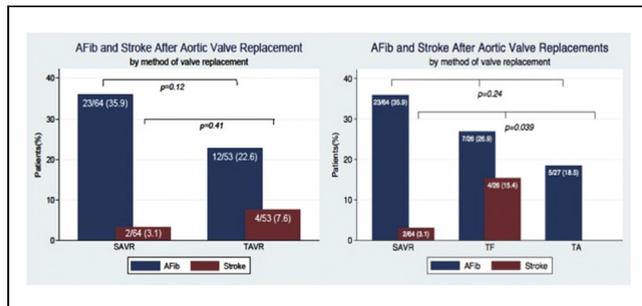
BACKGROUND The relative incidences of new-onset AF post-TAVR and their effects on post-operative ischemic stroke versus SAVR have

not been well described. We sought to compare the incidences of new-onset AF after TAVR and to determine their potential relationship to post-interventional stroke versus SAVR.

METHODS Retrospective-cohort study examining 117 patients with AVR for aortic stenosis and free of pre-existing AF between January 2011 and June 2014 utilizing clinical histories from procedure until 6-month follow-up. New-onset AF defined as transient AF episodes during the first 72 hours or any diagnosis of paroxysmal, chronic, or persistent AF after the 72 hour window. Continuous variables analyzed using a t-test or Wilcoxon rank sum test, and categorical variables analyzed using chi-squared or Fisher's exact test.

RESULTS 117 AVR cases occurred consisting of 53 TAVRs and 64 SAVRs. 27 TAVR patients underwent TA and 26 TF. Overall, 29.9% of patients developed AF. 22.6% of TAVR patients and 35.9% of SAVR patients developed new-onset AF. 18.5% of TA-TAVR and 26.9% of TF-TAVR patients developed AF. 24 AF episodes occurred within 72 hours; 29.2% within 24 hours, 20.8% between 24-48 hours, and 50.0% between 48-72 hours. Six patients had strokes; 4 post-TAVR (7.6%) and 2 post-SAVR (3.2%) [p=0.41].

CONCLUSION We found no difference in AF incidence between the three approaches. TA-TAVR has a statistically significant CVA reduction versus TF-TAVR and SAVR (p=0.039). TF-TAVR has the highest AF and CVA incidence. Delivery technique and the presence of aortic arch atheroma may contribute to higher CVA rates. We found no definite relationship between new-onset AF and CVA.



CRT-400.28

Correlation Between Left Ventricular Outflow Tract Area by CCTA and TTE

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BACKGROUND Trans thoracic echocardiographic (TTE) assessment of aortic stenosis (AS) severity and cardiac output measurements are affected by the left ventricular outflow tract (LVOT) area typically calculated based on a single diameter measured in the parasternal long axis view.

OBJECTIVE To evaluate the correlation between the left ventricular outflow tract (LVOT) area measured by coronary CT angiogram (CCTA) and the LVOT area computed from TTE using the LVOT diameter in subjects with severe AS.

METHODS Retrospective analysis of 34 patients with severe AS. CCTA and TTE were performed within a period of 60 days in subjects evaluated for transcatheter aortic valve replacement (TAVR). The LVOT area by CCTA was obtained by direct planimetry and is compared to LVOT area computed by TTE using the LVOT diameter.

RESULTS The mean LVOT area by TTE and CCTA was 4.06 cm² (range 2.48 -5.63 cm²) and 4.73 cm² (range 3.34 -7.40 cm²) respectively. LVOT area obtained by CCTA was consistently higher by 0.67 ± 0.35 cm² or 22 ± 20% than the TTE derived LVOT area (Fig 1). The diameter to derive the LVOT area by CCTA varies with TTE by 1.8 ± 2.4 mm with 95% C.I. The discrepancy between these two modalities increases with higher BSA with a correlation coefficient of 0.59.

CONCLUSION TTE-based LVOT consistently underestimates the actual 3-dimensional LVOT area based on CCTA. The difference in the diameter is driven by the elliptical shape of LVOT with larger lateral diameter that is not measured by the TTE. Consequently TTE systematically underestimates cardiac output and index and overestimates aortic valve area.

CRT-400.29

Right Ventricular Function Association With Long-Term Mortality Among Transcatheter Aortic Valve Replacement Patients

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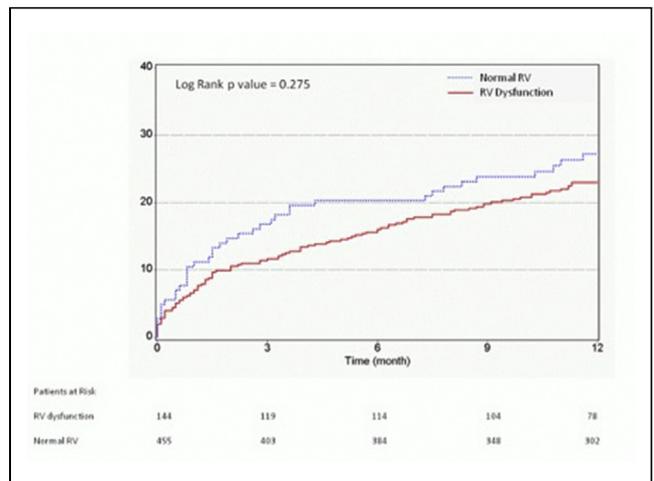
BACKGROUND Right ventricular (RV) function was shown to be associated with adverse outcomes in a variety of cardiac patients and is considered a risk factor for adverse outcome according the updated Valve Academic Consortium Criteria.

OBJECTIVE Our goal was to assess the impact of RV function at baseline on 1-year mortality among severe aortic stenosis (AS) patients undergoing transcatheter aortic valve replacement (TAVR).

METHODS All severe AS patients treated with TAVR from 5/2007 to 11/2014 at our center, were included in the present study, and baseline and procedural characteristics were recorded for each patient. The patients were categorized according to RV function as assessed by current guidelines, and 1-year comparison of mortality rates was performed.

RESULTS Among 599 patients, 144 (24%) had RV dysfunction. There were significant differences between the 2 groups, as patients with RV dysfunction were younger (81±9 vs. 84±8, p=0.003) and were more likely to be male (64% vs. 43%, p<0.001). In addition, patients with RV dysfunction had higher rates of prior myocardial infarction (29% vs. 16%, p<0.001) and atrial fibrillation (54% vs. 39%, p=0.001). Echocardiographic parameters demonstrated higher rates of ejection fraction <40% (37% vs. 20%, p=0.001), tricuspid regurgitation above moderate (16% vs. 9%, p=0.03) and higher pulmonary artery systolic pressure (50±17 vs. 44±16, p=0.001) among severe AS patients with RV dysfunction compared to patients with normal RV function. Despite the unfavorable cardiac function, severe AS patients undergoing TAVR has similar mortality rates at 1-year (27% vs. 23%, p=0.27).

CONCLUSION Severe AS patients with RV dysfunction have similar benefit from TAVR as patients with normal RV function. The presence of RV dysfunction does not correlate with outcome in patients with severe.



CRT-400.30

Hemodynamic Assessment of Paradoxical Low Flow, Low Gradient Severe Aortic Stenosis

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BACKGROUND Current guidelines discourage aortic stenosis (AS) evaluation by direct pressure measurement if echocardiography (echo) is adequate. However several studies show sizable differences between echo and catheterization (cath) lab measurements. Low flow/