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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 worldwire 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 cm^2, p=0.2265; post-MBV mean MVA (Gorlin) were 2.00 ± 0.52 and 2.02±0.37 cm^2, p=0.9554; MBV dilatation área 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 cm^2, 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 cm^2 (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 cm^2.

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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 perfomed, 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 cm^2. FU was 156 ± 144 months. Multivariate Cox analisys 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 cm^2. Mean pre and post-MVA (Gorlin): 0.90±0.20 and 2.02±0.37 cm^2, respectively (p<0.001). Success (MVA ≥1.5 cm^2): 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 funcional 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 cm^2 (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 cm^2.

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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-dilation, 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.

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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