Results of the study demonstrate that mitral incompetence reduction with MitraClip treatment is effective, low risk, and leads to significant improvement in NYHA functional class in approximately 90% of patients with heart failure.

**TCTAP A-118**

12 Months Results from a CE Mark Trial of a 2nd Generation, Self-Expanding, Transfemoral Aortic Bioprosthesis for the Treatment of Patients with Severe Aortic Stenosis

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**BACKGROUND** A novel and innovative transfoemral aortic valve implantation (TF-AVI) system was used to treat 89 patients with severe aortic stenosis in a CE mark trial. This single-arm registry was performed at 6 clinical sites in Brazil, Germany and Japan. The first patient was implanted in January 2012 and the last study implant procedure took place in early October 2013.

**METHODS** These 89 high-risk patients afflicted with severe aortic stenosis were treated in single-arm trials conducted at 6 centers in Brazil, Germany and Japan. Treated patients have a mean age of 83.7 ± 4.4 years, an STS Score of 7.5 ± 2.2%, and a logistic EuroSCORE of 26.6 ± 7.7%. Baseline mean aortic gradient was 43.6 ± 17.1 mmHg and mean AVA was 0.7 ± 0.2 cm². Nearly all patients presented in NYHA Class III/IV at screening (n = 84) and 65.2% were female. All patients provided EC-approved written informed consent.

**RESULTS** Procedure success rate was 94.4% (n = 84) with 3 valve-in-valve procedures and 2 failed implantations due to one instance of annular rupture and one case of bioprosthesis leaflet tear. Both failed procedures occurred during post-dilatation. The implant procedures were performed using small, medium and large valves covering an annular range of 21 mm to 27 mm. At 30 days there were 3 deaths, 2 strokes and no MI reported. Only 8 new pacemaker implants were required for a rate of 9.0%. Freedom from VARC II combined safety at 30 days was 84.3% (n = 75). Echocardiography at 30 days revealed only 4 patients (4.9%) with moderate or severe paravalvular leak - there were no patients with a paravalvular leak above grade 2. The mean gradient was reduced to 8.0 ± 2.9 mmHg and the aortic valve area was 1.8 ± 0.3 cm². At 12 months, all-cause mortality was 28.5% (n = 20) with 3 additional strokes and one myocardial infarction reported.

**CONCLUSION** Outcomes from treatment with this new 2ndGeneration TF-AVI system confirm its feasibility of use and safety out to one year. In September 2014 this device received CE mark approval, and further postmarket data may be expected in the near future.

**TCTAP A-119**

Incidence and Procedural Outcome of Bicuspid Aortic Valve in 684 Patients Undergoing Transcatheter Aortic Valve Implantation

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**BACKGROUND** Data on transcatheter aortic valve implantation (TAVI) in bicuspid aortic valve (BAV) is rare and inconsistent, particularly concerning incidence and outcome. In part this might be attributed to an inadequate recognition of this condition and/or a relatively low sensitivity of echocardiography. However, multislice computed tomography (MSCT) is thought to have a better diagnostic accuracy.

The aim of this retrospective analysis was to review MSCTs for detection and classification of BAVs and verify the impact on procedural outcome.

**RESULTS** The mean age was 67 years (53-86), 58.3% (n = 14) was male with a mean logistic EuroSCORE of 21%. At baseline, 90% of patients were in New York Heart Association (NYHA) functional class III or IV and 75% (n = 66) had a left ventricular ejection fraction (LVEF) ≤50%. 45.8% (n = 11) patients presented with functional mitral regurgitation (FMR) and 54.2% (n = 13) patients presented with degenerative mitral regurgitation (DMR). Procedural success was achieved in 96% of patients. Severity of MR was reduced in all successfully treated patients, 18 (75%) were discharged with MR ≤2+. There was improvement in the severity of MI at 6 months, compared with baseline (p < 0.0001). Thirty-day mortality was 6%. At 6 months, approximately 90% of patients had New York Heart Association functional class II or class I (p < 0.0001).

**CONCLUSION** Results of the study demonstrate that mitral incompetence reduction with MitaClip treatment is effective, low risk, and leads to significant improvement in NYHA functional class in approximately 90% of patients with heart failure.

**TCTAP A-117**

Improvement of New York Heart Association (NYHA) Status in High Risk Patients with Severe Mitral Incompetence Following Percutaneous MitraClip Procedure

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**BACKGROUND** MitraClip has been increasingly performed in Asian countries since 2011. Our study is to evaluate the effectiveness of improvement of heart failure symptoms and functional status in heart failure patients with percutaneous method of reduction of mitral incompetence (MI) with the MitraClip system.

**METHODS** Patients were selected for the MitraClip procedure based on the consensus of the Heart Team in our center. Between February 2012 and December 2013, 24 patients considered high risk as surgical candidates underwent percutaneous therapy for severe MI using the MitraClip system. Clinical and echocardiographic evaluation at baseline, and at 6-month follow-up. Mortality data, including cause of death, were collected.

**RESULTS** The mean age was 67 years (53-86), 58.3% (n = 14) was male with a mean logistic EuroSCORE of 21%. At baseline, 90% of patients were in New York Heart Association (NYHA) functional class III or IV and 75% (n = 66) had a left ventricular ejection fraction (LVEF) ≤50%. 45.8% (n = 11) patients presented with functional mitral regurgitation (FMR) and 54.2% (n = 13) patients presented with degenerative mitral regurgitation (DMR). Procedural success was achieved in 96% of patients. Severity of MR was reduced in all successfully treated patients, 18 (75%) were discharged with MR ≤2+. There was improvement in the severity of MI at 6 months, compared with baseline (p < 0.0001). Thirty-day mortality was 6%. At 6 months, approximately 90% of patients had New York Heart Association functional class II or class I (p < 0.0001).

**CONCLUSION** Results of the study demonstrate that mitral incompetence reduction with MitaClip treatment is effective, low risk, and leads to significant improvement in NYHA functional class in approximately 90% of patients with heart failure.