Aortic Valve Disease and TAVR

Hall D

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TCT-800

Transcatheter Aortic Valve Replacement with a New Self-expanding Percutaneous Heart Valve and Motorized Delivery System

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Background: Refining transcatheter aortic valve replacement with newly designed bioprostheses and delivery systems is anticipated to reduce the risk of complications and enhance ease of prosthesis implantation. We report the first-in-human experience and short- and mid-term clinical outcomes with a new self-expanding transcatheter heart valve and motorized delivery system.

Methods: The CENTERA valve (Edwards Lifesciences Inc., CA, USA) was implanted in 15 patients with symptomatic severe aortic stenosis via percutaneous femoral or axillary arterial access. Patients underwent transthoracic echocardiography and multidetector computed tomography before and after valve implantation. Clinical and echocardiographic follow-up was obtained at 30 days and for the initial 10 patients after one year. Outcomes were reported according to the Valve Academic Research Consortium guidelines.

Results: All 15 device implants were successful. Aortic valve area increased from 0.7 ± 0.1 cm2 to 1.6 ± 0.2 cm2 post procedure (p < 0.01) and 1.8 ± 0.3 cm2 at one-year follow-up. Mean trans-aortic gradient decreased from 36.3 ± 14.2 mmHg to 10.6 ± 5.4 mmHg post-procedure (p < 0.001) and to 10.8 ± 4.1 mmHg at one year follow-up. All patients were in NYHA class I (25%) or II (75%) at one-year follow-up and only one patient had more than mild paravalvular regurgitation at one-year follow-up. Four patients (27%) received a new permanent pacemaker. Survival was 87% at 30 days and 80% at one year. None of the deaths were valve related.

Conclusions: Transcatheter aortic valve replacement with the CENTERA transcatheter heart valve and motorized delivery system is feasible and leads to excellent short- and mid-term clinical and hemodynamic outcomes.

TCT-801

Outcome after a TAVI procedure with self-expanding bioprosthesis using CoreValve or Accucath delivery device: France 2 Registry results

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Background: Permanent pacemaker implantation (PP) following high degree aorticventricular block is a frequent complication after Transcatheter Aortic Valve Implantation (TAVI) by using self-expanding bioprostheses (SEB) system. Recent improvements of SEB from CoreValve Device (CD) to Accucath CoreValve Device (ACD) have aimed to allow easier delivery and also expected to reduce the PP rate. However, the clinical outcome of PP occurrence and differences of PP rate between MCD and ACD after TAVI remains unclear.

Methods: A total of 958 patients (82+7 years; female: 49%) with severe symptomatic aortic stenosis were selected SEB between January 2010 and October 2011 in 33 centers of the FRANCE 2 Registry. The current study investigated 1) the incidence of PP rate according to the differences of 2 devices and 2) the midterm clinical outcome of PP occurrence after TAVI.

Results: Procedural success rate was 96.9% and PP rate was 22.4% in overall population. CD and ACD were implanted in 54.5% (n=522) and 41.5% (n=436) of patients, respectively. There was no significant differences of PP rate between CD and ACD (21.6% vs. 23.4%, p=0.52). During the mean follow-up of 242+179 days, the PP occurrence was not associated with increasing all cause mortality when compared with non PP occurrence 14.4% Vs 13.2 % (p=0.13).

Conclusions: PP remains frequent after TAVI with SEB and device improvement failed to show an impact on PP implantation rate. Overall mortality was not impacted by PP.

TCT-802

Impact of experience on TAVI outcome a propensity matched analysis from the PRAGMATIC Plus Initiative

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Background: Not much is known about the impact of the mounting clinical experience and technological refinements on clinical endpoints after TAVI.

Methods: We retrospectively analyzed 793 consecutive TF-TAVI patients from 4 European centers and evaluated experience in three propensity score matched cohorts subcategorized based on enrollment date.

Results: Three propensity score matched cohorts of 214 TF-TAVI patients were identified. With mounting experience and moving from the initial to the last cohort, all-cause 30-day mortality trended to be lower (7.0% in T1 vs. 3.7% in T3, p=0.16) but with no significant 1-year survival (79.9% vs. 86.0%, p=0.016). Over time there were significantly less major vascular complications (15% vs. 7.9%, p = 0.023), life threatening (17.8% vs. 7.9%, p=0.003) and major bleedings (22.4% vs. 12.1%, p=0.007). Major vascular complications and life-threatening bleedings due to closure device failure decreased significantly (9.2% vs. 3.1%, p = 0.01 and 5.7% vs. 1 %, p = 0.01 respectively).The combined safety endpoint dropped from 31.3% in T1 to 17.8% in T3 (p < 0.001). By multivariable analysis (including adjustment for arterial sheath size) the last cohort as compared to the initial cohort was associated with significant reductions in 30-day mortality (OR 0.35, 95% CI 0.12 – 0.96), stage 3 AKI (OR 0.12, 95% CI 0.29 – 0.93) and the combined safety endpoint (OR 0.52, 95% CI 0.29 – 0.93).

Conclusions: Growing TAVI experience results in significant reductions in major vascular complications, life threatening bleedings and the combined clinical safety endpoint and improved 1-year survival.

TCT-803

Emergency and prophylactic use of miniaturized veno-arterial extracorporeal membrane oxygenation (vaECMO) in transcatheter aortic valve implantation (TAVI)

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Background: In transcatheter aortic valve implantation (TAVI), short term mortality closely relates to life threatening procedural complications. Veno-arterial extracorporeal membrane oxygenation (vaECMO) can be used to stabilize the patient in emergency situations. However, for the prophylactic use of ECMO in very high risk patients undergoing TAVI there is no experience. We report our center’s experience using vaECMO in TAVI.

Methods: From January 2009 to August 2011, we performed 131 TAVI. Emergency vaECMO was required in 8 cases (7%): ventricular perforation (n=3), hemodynamic instability/ cardiogenic shock (n=4), hemodynamic deterioration due to ventricular tachycardia (n=1). From August 2011 on, during 83 procedures, prophylactic vaECMO was systematically used in very high risk patients (n=9, 11%) and emergency vaECMO in one case (1%) due to ventricular perforation.

Results: Median logistic EuroScore in prophylactic vaECMO patients was considerably higher compared to the remaining TAVI population (30% vs. 15%, p=0.003) while median logistic EuroScore of patients with emergency vaECMO was comparable (18% vs. 15%, p=0.08). Comparing prophylactic to emergency vaECMO, procedural success, procedural related death, and 30-day mortality were 78% vs. 100% (p=0.5), 33% vs. 0% (p=0.2) and 44% vs. 0% (p=0.08), respectively. Major vascular complications and rate of life threatening bleeding did not differ in both groups (11% vs. 11%, p=0.09 and 11% vs. 33%, p=0.6) and were not vaECMO related.

Conclusions: Life-threatening complications during TAVI can be managed using emergency vaECMO but mortality remains high. Systematic use of prophylactic vaECMO in very high risk patients is safe and might be advocated in selected high risk patients.

TCT-804

Safety and Efficacy of 14Fr Balloon Expandable Sheath for Trans-catheter Aortic Valve Implantation (TAVI)

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Background: The aim of this study is to show access site complication and success rate in trans-catheter aortic valve implantation (TAVI) with 14Fr balloon expandable sheath which is expanded to 19Fr in artery by comparing to those with standard 18Fr sheath.

Methods: From January 2009 to August 2011, we performed 131 TAVI. In 106 consecutive patients who underwent TAVI, patients who had subclavian (n=18) balloon catheter and technological refinements on clinical endpoints after TAVI.

Results: No significant differences of PP rate between CD and ACD (21.6% vs. 23.4%, p=0.52). During the mean follow-up of 242+179 days, the PP occurrence was not associated with increasing all cause mortality when compared with non PP occurrence 14.4% Vs 13.2 % (p=0.13).

Conclusions: PP remains frequent after TAVI with SEB and device improvement failed to show an impact on PP implantation rate. Overall mortality was not impacted by PP.