Risk Factors and Clinical Significance Of Intra-Procedural Haemodynamic Instability In Patients Undergoing Transcatheter Aortic Valve Implantation

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Background: Haemodynamic instability (HI) represent the most important intra-operative manifestation of major complications occurring during TAVI. The aim of this study was to investigate the causes, risk factors and clinical significance of HI during TAVI.

Methods: From November 2007 to September 2013 all patients consecutively treated in our center were included. HI was defined as a drop of mean arterial pressure ≥ 20 mmHg with a heart rate ≥ 100 or ≤ 50 beats/min for ≥ 1 min. Causes of HI were classified in those occurring post-preparatory balloon aortic valvuloplasty (PBAV) and post-valve implantation (VI).

Each group was compared with a control group where HI did not occur. Outcomes were assessed according to VARC-2 criteria at 2 days, 1 and 2 years.

Results: Overall, of 538 patients that underwent TAVI, 35 (7.4%) developed HI. Of these 18/453 (3.9%) developed HI after PBAV, while 19/538 (3.5%) developed HI after VI. Causes of HI after PBAV included severe aortic regurgitation (AR; n = 12/18, 66.7%), new-onset tachy- or brady-arrhythmia (n = 4/18; 22.2%), aortic annular rupture (n = 1/18; 5.5%) and cardiac tamponade (n = 1/18; 5.5%). Causes of HI after VI included aortic dissection (n = 2/19; 10.5%), cardiac tamponade (n = 14/19; 73.6%), coronary obstruction (n = 2/19; 10.5%) and severe AR (n = 1/19; 5.2%). Patients who developed HI after PBAV had greater all-cause and cardiovascular mortality at 30 days (respectively, 11.1% vs. 3%, p = 0.002; and 11.1% vs. 1.8%, p = 0.009) while no differences were found in all-cause and cardiovascular mortality at 2 years of follow-up. Conversely patients that developed HI after implantation had higher rates of all-cause and cardiovascular mortality at 30 days (respectively, 26.3% vs. 2.7%, p < 0.001; and 21.1% vs. 1.9%, p < 0.001) and at 2-year follow-up (respectively, 36.8% vs. 16.9%, p = 0.025; and 26.3% vs. 9.3%; p = 0.015).

Conclusions: HI can occur after both PBAV and VI. The most common cause of HI after PBAV were severe AR. Conversely, the most common after VI was cardiac tamponade. HI after PBAV was associated with a higher 30-day mortality but did not affect long-term survival.

Predictive Value of Vascular Complications Following Transcatheter Aortic Valve Implantation Reevaluated by VARC-1 and 2 Definitions

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Background: Vascular complications (VC) during transcatheter aortic valve implantation (TAVI) are reported using various criteria and several access site approaches. We aimed to describe the prevalence of VC associated with TAVI via a single and standardized access site approach and their predictive value for survival, using both the updated Valve Academic Research Consortium-2 (VARC-2) criteria and the former VARC-1 criteria.

Methods: Between March 2009 and September 2013, 403 consecutive patients at a median age (±SD) of 83±6 underwent transcatheter aortic valve implantation (TAVI). All procedures were performed using an 18/19 Fr sheath. Vascular complications were defined by both VARC-1 and VARC-2 criteria and analyzed separately.

Results: VARC-1 and VARC-2 defined VC occurred in 71 (18%) and 78 (19%) patients, respectively, with 15 (4%) and 33 (8%) defined as major VC. The difference in frequency of major and minor VC was mainly driven by VARC-2 implementation of major bleeding events. With either VARC definition, patients with minor VC had similar mortality and complications rates as those patients without VC. In multivariate analyses, referenced to patients with minor or no VC, only VARC-1 defined major VC were significantly associated with increased mortality (HR 3.52; 95% CI 1.5-8.4; p=0.005), whereas VARC-2 defined major VC were found to be only marginally significant (HR 1.9; CI 0.9-3.9; p=0.08).

Conclusions: The VARC-2 VC criteria increase the observed rate of major VC following TAVI mainly by the inclusion of major bleeding events, and by doing so decrease their predictive usefulness on patient outcomes.

A Comparison of the Complications and Mortality between the Transcatheter and Transfemoral Accesses for Transcatheter Aortic Valve Replacement with Edwards SAPIEN valve: PARTNER Trial vs Worldwide Studies and Registreries

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Background: The Placement of Aortic Transcatheter Valves (PARTNER) study was the first randomized controlled study involving the Edwards SAPIEN valve. We intended to compare outcomes of transfemoral(TF) vs transapical(TA) access for Transcutaneous Aortic Valve Replacement (TAVR) between the rigorous PARTNER trial environment and real-world patient registries.

Methods: We searched databases for Edwards SAPIEN TAVR studies comparing the TF and TA approaches regarding the following outcomes: 30-day and 1-year mortality; 30-day stroke; 30-day permanent pacemaker implantation; and 30-day vascular complications. The outcomes were then compared between the PARTNER trial and the pooled data from remaining studies.

Results: The PARTNER trial had 244 TF and 104 TA patients. In the pooled data from 17 studies, TA patients had a significantly higher EuroSCORE as compared to TF patients (24.6±12.9 vs 21.3±12.0; p<0.001). In the intention-to-treat analysis of the PARTNER study the EuroSCORE was not significantly different between the TA and TF groups (29.8±15.9 vs 29.1±16.1; p=0.61). As shown in Table 1, 30-day and 1-year mortality were similar between the two approaches in the PARTNER trial; conversely, pooled results showed a significantly decreased risk with the TF approach. The PARTNER trial and remaining studies showed an increased incidence of 30-day vascular complications in the TF arm and a similar risk of 30-day stroke incidence and new pacemaker insertion between accesses.
Conclusions: In patients undergoing TAVI, the majority of patients with MR at baseline showed improvement in severity of regurgitation. Patients with moderate MR or above demonstrated the greatest improvement.

TCT-780
Clinical Outcomes of Asian Patients with Low to Intermediate Risk Undergoing Transcatheter Aortic Valve Implantation
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Background: Transcatheter aortic valve implantation (TAVI) is an established treatment alternative to surgical aortic valve replacement in high-risk and inoperable patients and outcomes among patients with intermediate risk remain to be determined. The aim of this study was to assess clinical outcomes among Asian patients with low to intermediate risk undergoing TAVI.

Methods: Data from Asian TAVI multicenter registry were pooled and analyzed. In total, 185 patients with severe symptomatic aortic stenosis undergoing TAVI were categorized according to the Society of Thoracic Surgeons (STS) score into low (STS < 3%; N = 82, 44.3%), intermediate (STS 3% and ≤ 8%; N = 77, 41.6%), and high risk (STS > 8%; N = 26, 14.1%) groups.

Results: Significant differences were found between the groups (low risk vs. intermediate-risk vs. high-risk) for age (75.6 ± 5.5 vs. 80.5 ± 5.2 vs. 80.1 ± 6.7, p < 0.001), body mass index (25.5 ± 3.1 vs. 23.6 ± 3.7 vs. 22.3 ± 3.1, p = 0.0001), diabetes (21.3% vs. 46.7% vs. 68.4%, p < 0.001), previous coronary artery bypass surgery (1.3% vs. 6.7% vs. 21.1%, p = 0.0004), and peripheral artery disease (4.0% vs. 8.3% vs. 42.1%, p < 0.001). No differences were observed with regards to major cardiovascular complication, postoperative aortic regurgitation > moderate, new permanent pacemaker, device success and all-cause mortality at 30 days, however significant difference was found for all-cause mortality at 1-year (2.5% vs. 11.3% vs. 17.9%, p = 0.043).

Conclusions: Compared with patients at high risk, patients with low or intermediate risk have favorable clinical outcomes after TAVI in the Asian population.

TCT-781
Impact of Smaller and Expandable Sheath During TAVR: Results From a Single-Center Registry
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Background: Vascular and bleeding complications are common following transcatheter aortic valve replacement (TAVR). The impact of the expandable sheath (e-sheath) for trans-femoral Edwards aortic valve replacement is unclear. Our objective was to compare the incidence of procedural complication when using 18Fr fixed size sheath vs. 16 to 18Fr e-sheath during TAVR.

Methods: We enrolled 90 consecutive patients who underwent TAVR with Edwards valve at our center. Since June 2011 e-sheath has been routinely employed to obtain femoral access. Prostar System for vascular hemostasis, and intraprocedural heparin monitored by activated clotting time were used in all cases. We compared baseline and procedural outcomes according to the use of e-sheath. Vascular and bleeding complications were defined using the VARC-2 definitions.

Results: Patients receiving e-sheath (n=54, 60%) matched for age, sex, body mass index, rate of peripheral artery disease, diabetes, and chronic kidney disease compared to those treated with fixed size sheath. E-sheath use was associated with reductions in major or life-threatening bleeding (5.6% vs. 39%, p< 0.001) and minor vascular complication (24% vs. 39%, p=0.31), while major vascular complication (7.4% vs. 5.6%, p=0.73), and procedural mortality (0.0% vs. 2.7%, p=0.21) resulted not significantly different (Figure 1).

Conclusions: The use of e-sheath is associated with substantial reductions in bleeding and minor vascular bleeding, during trans-femoral TAVR, while an advantage in term of major vascular complication was not readily apparent.

TCT-782
Abstract Withdrawn

TCT-783
Less access-site related vascular complications with double versus single Prostar closure device in patients with transfemoral Transcatheter Aortic Valve Implantation
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Background: Serious vascular complications have been reported to occur in 6% of the transfemoral TAVI patients. The aim was to report access site related complications using Single (SP) versus Double (DP) Prostar XL for closure of 18F femoral arterial access in TAVI.

Methods: 134 patients included in our prospective TAVI database at Karolinska University Hospital (Nov 2012- Feb 2014), transfemoral-TAVI was performed in 126 patients using 18F sheath. The first 63 consecutive patients were treated with SP and the last 63 patients with DP closure. Primary endpoint was defined as access-site related vascular complication (femoral hematoma >4 cm in diameter, external femoral bleeding, retroperitoneal hematoma or blood transfusion within 1 week after the procedure). Secondary endpoint was defined as post-procedure hemoglobin (Hb)-fall.

Conclusions: In patients undergoing TAVI, the majority of patients with MR at baseline showed improvement in severity of regurgitation. Patients with moderate MR or above demonstrated the greatest improvement.