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 V2R 2 criteria at 2 days, 1 and 2 years.

Results: Overall, of 558 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%), atrioventricular block (n = 1/18; 5.5%) and cardiac tamponade (n = 1/18; 5.5%). Causes of HI after VI included atrioventricular 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 that developed HI after PBAV had greater 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) 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.

The Predictive Value of Vascular Complications Following Transcatheter Aortic Valve Implantation Reevaluated by V2R-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 sole percutaneous trans-femoral approach and their predictive value for survival, using both the updated Valve Academic Research Consortium-2 (VARC-2) criteria and the former V2R-1 criteria.

Methods: Between March 2009 and September 2013, 403 consecutive patients at a mean age (±SD) of 83±6 underwent percutaneous trans-femoral TAVI. All procedures were performed using an 18/19 Fr sheath. Vascular complications were defined by both V2R-1 and VARC-2 criteria and analyzed separately.

Results: V2R-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 V2R 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; 95% 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 Transapical and Transfemoral Accesses for Transcatheter Aortic Valve Replacement with Edwards SAPIEN valve: PARTNER Trial vs Worldwide Studies and Registries

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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 Transcatheter 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 (24.8±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.