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BLEEDING AFTER TRANSCATHETER AORTIC VALVE IMPLANTATION ACCORDING TO DIFFERENT ENDPOINT DEFINITIONS AND IMPACT ON CLINICAL OUTCOMES

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Background: Although transcatheter aortic valve implantation (TAVI) is considered less invasive compared to surgical aortic valve replacement, potential life-threatening complications may occur. Bleeding complications are frequent and well respected, as they might be associated with significant impact on clinical outcomes. We investigated the association between in-hospital bleeding events after TAVI using different definitions and their respective impact on clinical outcomes.

Methods: Between August 2007 and April 2012, a total of 489 consecutive patients with symptomatic severe aortic stenosis undergoing TAVI using different access routes and devices were included into a prospective registry. Serious adverse events were retrospectively assessed and adjudicated according to standardized endpoint definitions. Bleeding complications were adjudicated according to VARC 2 and for the purpose of this analysis using the definitions of BARC, TIMI and GUSTO.

Results: Bleeding after TAVI was observed in 152 patients (31.1%) during the index procedure and was mainly due to access site injury (66.8%). Life threatening bleeding according to VARC 2 was associated with a significant increase in mortality at 30 days (HR 4.6, 95% CI 2.07-10.49) and 12 months of follow-up (HR 2.05, 95% CI 1.17-3.57) as was BARC bleeding 3 (HR 3.48, 95% CI 1.66-7.30) and HR 1.62, 95% CI 1.01-2.59, respectively. TIMI major (HR 4.52, 95% CI 1.96-10.46 and HR 2.05, 95% CI 1.16-3.62, respectively) and GUSTO severe or life-threatening bleeding (HR 13.12, 95% CI 5.29-32.55 and HR 4.66, 95% CI 2.29-9.79, respectively).

Conclusions: Bleeding after TAVI was associated with a negative impact on survival that was already present up to 12 months of follow-up, irrespective of bleeding definition. The prognostic impact of bleeding according to the VARC 2 criteria was comparable with other well-established bleeding definitions.

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TRANSCAPILLARY TRANSCATHETER AORTIC VALVE IMPLANTATION WITHOUT PRIOR BALLOON AORTIC VALVULoplastY – FEASIBLE And SAFE

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Background: Currently, pre-implant balloon aortic valvuloplasty (BAV) is considered a prerequisite for successful subsequent transcatheter aortic valve implantation (TA-AVI) using balloon-expandable devices. However, cerebral embolization has been shown to originate at least in part from BAV procedures. Omitting BAV may therefore reduce neurologic events after TA-AVI and facilitate the procedure while yielding non-inferior hemodynamic and clinical outcomes.

Methods: From May, 2011 through December, 2012 a total of 50 consecutive patients were treated by TA-AVI without pre-implant BAV (TA-AVI-BAV) using the Edwards Sapien XT device (54% male, age 77±8.4 years, log EuroSCORE I 3.3±1.0). Data were prospectively entered into a dedicated database, retrospectively analyzed and compared to a consecutive series of conventional TA-AVI using the same device (control group, n=50).

Results: A feasible and safe access route for TA-AVI was 92% (46/50) and 90% (45/50) in TA-AVI-BAV and control groups respectively. Procedure time was similar in the TA-AVI-BAV group compared to the control group (88.2±30.8 vs. 91.1±24.5 min, p=0.60), while significantly less contrast was used (137.6±67.8 vs. 182.9±78.1 ml, p=0.001). The residual paravalvular leakage in the transapical groups were 16.0±6.6 and 7.9±3.3 mmHg respectively in the TA-AVI-BAV group with similar values in the control group (18.7±8.5 and 9.3±4.7 mmHg, p=0.08 and p=0.09 respectively). Residual paravalvular leakage > grade 2 was present in 2% and 8% in TA-AVI-BAV and control groups respectively (p=0.36). Rates of 30-day mortality and peri-procedural stroke were 6% and 10% (p=0.72) and 2% and 6% (p=0.62) respectively.

Conclusions: TA-AVI-BAV is feasible and safe and has become our default technique for patients allocated to TA-AVI with balloon-expandable devices. This approach was associated in less contrast agent used and facilitated the procedure without compromising valve performance. Effects of TA-AVI-BAV on the incidence of cerebrovascular events, other periprocedural complications or hemodynamic valve performance need to be verified in larger patient numbers before general recommendations can be made.

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