Up to 6-year performance and clinical outcomes of balloon expandable transcatheter aortic valve according to the implantation strategy: insight from the DIRECTAVI trial

F. Leclercq¹, N. Jammoul¹, V. Dupasquier¹, M. Akodad¹, P.A. Meunier¹, S. Soltani¹, L. Mouliš¹, J.C. Macia¹, P. Robert¹, L. Schmutz¹, C. Piot², F. Targosz³, H. Benkemoun⁴, F. Roubille¹, G. Cayla⁵

¹University Hospital Arnaud de Villeneuve, Montpellier, France
²Clinic du Millenaire, Montpellier, France
³Perpignan Hospital Centre, Perpignan, France
⁴Clinic St Pierre, Perpignan, France
⁵University Hospital of Nimes, cardiology, Nimes, France

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Background: The randomized DIRECTAVI trial demonstrated safety and feasibility of transcatheter aortic valve implantation (TAVI) without balloon aortic valvuloplasty (BAV) using SAPIEN 3 balloon-expandable devices.

Purpose: To evaluate long-term clinical and hemodynamic results according to the implant strategy (direct TAVI versus BAV) with the SAPIEN 3 balloon-expandable device in patients included in the DIRECTAVI trial.

Methods: All patients included in the DIRECTAVI trial since 2016 were offered a clinical and echocardiographic follow-up until January 2023. We applied Valve Academic Research Consortium (VARC-3) criteria to define moderate/severe hemodynamic valve deterioration (HVD) as an increase in mean gradient ≥10 mm Hg resulting with a final mean gradient ≥20 mm Hg, or new/worsening aortic regurgitation (AR) of 1 grade resulting in ≥moderate AR. Survival until moderate/severe HVD between the 2 groups was the primary end-point and overall survival between direct TAVI and BAV were compared using logrank tests. Major clinical outcomes at latest follow-up were also assessed using Chi² or Fisher’s tests.

Results: Among 250 patients included in DIRECTAVI, 228 patients were followed-up during 4.5 ± 1.1 years. Mean age at follow-up was 87 ± 6.7 years. Incidence rates of moderate/severe HVD were similar in the 2 groups (1.45 versus 1.97 per 100 person-years, p=0.6) (Figure). Incidence rates for death were similar between groups (9.19 and 7.34 events per 100 persons-years for BAV and direct TAVI, respectively, p=0.4). No clinically significant differences in outcomes were observed at the latest follow-up, including major stroke (4.4% for BAV versus 2.6% for direct TAVI, p=0.7), hospitalizations for heart failure (15.8% for BAV group and 11.4% for direct TAVI group, p=0.3), permanent pacemaker implantation (37.7% for BAV and 31.6% for direct TAVI, p=0.3). Moderate/severe patient-prosthesis mismatch was also similar between groups (p=0.6).

Conclusion: Compared to systematic BAV, direct implantation of the SAPIEN 3 device was not associated with an increased risk of moderate/severe valve deterioration or adverse clinical events up to 6-year follow-up. These results encourage wide use of this simplified strategy with balloon-expandable devices, when possible.
Survival without valve deterioration

Kaplan-Meier curves on incidence of moderate/severe HVD estimates to 6 years.

BAV = Balloon Aortic Valvuloplasty; HVD = Hemodynamic Valve Deterioration; TAVI = Transcatheter Aortic Valve Implantation.