Clinical Impact of the Presence of Aortic Regurgitation Following Transcatheter Aortic Valve Replacement:Insights into the Degree and Acuteness of Presentation

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Methods: A total of 1735 patients undergoing TAVR with balloon- or self-expanding valves were included. The presence and the degree of AR were evaluated by trans-thoracic echocardiography. Moderate-severe AR was defined as an increase in AR severity of ≥1 degree compared to pre-procedural echocardiography.

Results: AR severity was mild in 761 (43.9%) patients and moderate-severe in 747 (42.7%) patients. The presence of moderate-severe AR was an independent predictor of mortality at a mean follow-up of 21.1±17 months when compared to none-trace AR (adjusted HR [95%CI]: 1.88 [1.37-2.58], p < 0.001) and mild AR (adjusted HR [95%CI]: 1.69 [1.27-2.23], p < 0.001) groups. There was no increased risk in patients with mild AR compared to those with none-trace AR (p = 0.393). In patients with moderate-severe AR, acute cardiac AR was observed in 161 (65%) patients and chronic AR in 86 (35%) patients. Acute moderate-severe AR was independently associated with increased risk of mortality when compared to none-trace-mild AR (adjusted HR [95%CI]: 2.37 [1.53-3.66], p < 0.001) and chronic moderate-severe AR (adjusted HR [95%CI]: 2.24 [1.17-4.3], p < 0.015). No differences in survival rate were observed between patients with chronic moderate-severe and none-trace-mild AR (p > 0.50).

Conclusions: In conclusion, residual AR is a frequent complication of TAVR. The clinical impact (increased acute and late overall and cardiovascular mortality) of this complication was mainly limited to those patients with moderate-severe AR of AR origin (significant increase vs. baseline), suggesting that early additional measures for the treatment of paravalvular leaks leading to a decrease in the severity of AR in such patients are probably of major clinical importance. The final risk/benefit ratio of such a strategy will have to be determined in future studies.

Multicentre clinical study evaluating a novel resectable self-expanding transcatheter aortic valve system

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Background: Transcatheter aortic valve replacement (TAVR) significantly improves the prognosis of patients; however limitations with repositioning and optimization of placement can result in complications. This investigation evaluates the resorbable and repositionable St Jude Medical Portico self-expanding TAVR system.

Methods: This prospective, single arm, multicenter study evaluated the safety and efficacy of the Portico System. Between March 2012 and April 2014, 120 TAVR patients were enrolled and treated at 10 sites in the UK, Germany, Netherlands and Australia using the 18F and 19F Portico system (23mm, 25mm, 27mm or 29mm valve). Patients were followed for a procedure time of 24 months. All adverse events were categorized by VARC definitions and adjudicated by an independent events committee. Echocardiography was evaluated by an independent laboratory.

Results: The Portico TAVR system was successfully implanted in 118 patients (94% Female; Mean Age=84; STS=0.0). Reshaping (27%) was successful in all instances. Paravalvular Leak at 30 days (n=59), as assessed by core lab 15.3 absent/trace, 72.9% mild, 3.4% moderate and 0% severe. Average implant depth was 7.8mm (n=89). There was significant HF improvement over time with no remaining Class IV HF patients at 3 months, and 80% of patients achieving Class I or II status at 1 year. Hemodynamic performance significantly improved post TAVI and maintained at follow-ups. Mean Aortic Valve Area improved from 0.6 cm2 to 1.7, 1.6, 1.5 and 1.5 cm2 at days 3, 6 and 12 months, respectively. Mean gradient improved from 45.8 mmHg to 8.7, 9.2, 9.5, 9.9 mmHg over the same follow-up intervals. Mortality at 30 days was 3.0%, all due to cardiovascular causes. Mortality increased to 8.0% through all follow-up, with 5.0% due to cardiovascular causes. Disabling stroke was observed in 3.0% of patients over 30 days, and 3.3% through follow-up. Eleven patients (9.2%) had new pacemaker implantation.

Conclusions: The novel Portico TAVR system allows for safe repositioning and optimization of the device position. The functional and symptomatic outcomes appear to support the efficacy and safety of the device.