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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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Background: The objectives of this study were to determine the impact of the degree of residual aortic regurgitation (AR) and acuteness of presentation of AR following transcatheter aortic valve replacement (TAVR) on outcomes.
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 transthoracic echocardiography; acute AR was defined as an increase in AR severity of ≥1 degree compared to pre-procedural echocardiography.
Results: Residual AR was classified as mild in 761 (43.9%) patients and moderate-severe in 247 (14.2%) patients. The presence of moderate-severe AR was an independent predictor of mortality at a mean follow-up of 21±17 months when compared to none-trace (adjusted HR [95%CI]: 1.88 [1.37-2.58], p < 0.001) and mild AR (adjusted HR [95%CI]: 1.69 [1.27-2.25], 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 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 [1.17-4.30], 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 acute 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.

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

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Background: Transcutaneous 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 resheathable 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 post procedure at 30, 90, 180 days and 1 year. 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=6.0). Resheathing (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 30 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 through 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.

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Influence of Body-Mass-Index on Survival of Aortic Stenosis Patients Treated by Transcatheter Aortic Valve Replacement: Insights on Obesity-Paradox from The PARTNER Trial

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Background: We sought to evaluate possible influence of body mass index (BMI) on survival of patients with severe aortic stenosis (AS) in different treatment strategies.
Methods: Patients who underwent transcatheter aortic valve replacement (TAVR) in the PARTNER trial were evaluated according to their BMI (n=2,519): underweight (< 18.5 kg/m2, n=109), normal weight (18.5-25 kg/m2, n=1,029), overweight (25-30 kg/m2, n=800), obese (30-40 kg/m2, n=484), and morbidly obese (≥40 kg/m2, n=97).
Results: In the total group of patients that underwent TAVR: obese patients were younger, had lower STS score and worse 6-minute walk performance at baseline (table). Patients that were underweight and those with morbid obesity had the highest 30-day mortality. After propensity matching, adjusting for dissimilarity between the normal weight, overweight and obese groups, obese patients had lower 1-year mortality than patients with normal body weight (18.7% vs. 29.4%, p=0.002). Multivariate analysis revealed that obesity was a strong independent predictor for 1-year survival after TAVR: obesity vs. normal weight, odds ratio 1.37 (CI, 1.05-1.78, p=0.02); obesity vs. underweight, odds ratio 2.13 (CI 1.4-3.22, p< 0.001).
Conclusions: In patients with severe AS undergoing TAVR, those having obesity had better survival than those with normal body weight, after adjustment for differences in baseline characteristics. The "obesity-paradox" was evident in high-risk AS patients.

Table. Baseline characteristics and clinical outcomes of patients that underwent TAVR

	Underweight (n=109)	Normal weight (n=1,029)	Overweight (n=800)	Obese (n=484)	Morbidly obese (n=97)	p-value
Age (yrs)	85.9 ± 6.3	86.5 ± 6	84.9 ± 6.4	80.7 ± 8	76.8 ± 7.8	<0.001
STS score (%)	12.9 ± 3.9	11.9 ± 4.5	11.1 ± 3.6	10.8 ± 3.7	10.8 ± 3.9	<0.001
6-minute walk test (m)	96 ± 103	116 ± 117	110 ± 117	86 ± 103	58 ± 89	<0.001
30-day mortality	9.2%	7.7%	4.6%	4.1%	9.3%	0.007
1-year mortality	33.2%	25.6%	21%	17.1%	17.6%	<0.001