

as compared to circular TAV expanded to 23, 21, and 19mm, respectively. In addition, in the presence of 0.75 eccentricity, the maximum principal stress value in the commissures was increased by 173%, 213% and 149%, as compared to circular TAV expanded to 23, 21, and 19mm, respectively.

CONCLUSIONS Computational models were developed to study the synergistic impact of incomplete and eccentric TAV stent expansion on leaflet stress distributions. Eccentric and incomplete stent deployment induce localized high stress regions within the TAV leaflets. Increased mechanical stress on TAV leaflets may lead to accelerated tissue degeneration and diminished long-term valve durability.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Durability, Leaflet damage, Transcatheter aortic valve replacement

TCT-622

Is there a therapeutic limit to sequential aortic valve-in-valve? Hydrodynamic analysis of sequential valve-in-valve using the novel Inovare prosthesis in surgical aortic bioprosthesis

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BACKGROUND The sequential implantation of a transcatheter heart valve (THV) within a similar device, also known as valve-in-valve-in-valve, will be an important concept in the future, considering patients with elevated surgical risk and failed THVs within surgical aortic valves (SAV). However, this procedure has not been studied in depth, especially considering the reduction of effective orifice area (EOA) and the elevation of transvalvular gradients (ΔP). Our objective was to evaluate the hydrodynamic performance of valve-in-valve-in-valve, determining the therapeutic limits.

METHODS Using a pulse duplicator, three sets of valve-in-valve-in-valve were tested. FDA specifications for cardiac output, mean arterial pressure and heart rate variation were used. EOA and ΔP were measured. First set was a 23mm surgical valve with two sequential THV implants of 22mm and 20mm. Second set was a 25mm surgical valve with two sequential THV implants of 24mm and 22mm. The last set was a 25mm surgical valve with three sequential implants of 24mm, 22mm and 20mm.

RESULTS The results obtained from the three sets are represented on Table 1.

	EOA (cm2)	ΔP (mmHg)
20mm THV within 22mm THV within 23mm SAV	0.97	12.8
22mm THV within 24mm THV within 25mm SAV	0.97	13.46
20mm THV within 22mm THV within 24mm THV within 25mm SAV	0.86	15.32

CONCLUSIONS The use of multiple THVs as an alternative to repeated conventional aortic valve replacement can be considered feasible after hydrodynamic testing. Satisfactory results can be obtained with up to 22mm THVs. When a 20mm THV was needed, results were borderline to prohibitive, depending on whether it was the 2nd or 3rd implantation. The less-than-optimal results might be due to device underexpansion.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Transapical, Transcatheter aortic valve replacement, Valve-in-valve

TCT-623

Transcatheter Aortic Valve Replacement In Women Versus Men: An Analysis of the CoreValve US Pivotal and Continued Access Trials

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BACKGROUND There is limited data, especially from the US, on sex-related differences with regards to patient characteristics and outcomes with the CoreValve prosthesis. The objective of this study is to compare the baseline characteristics and clinical outcomes in women and men undergoing transcatheter aortic valve replacement with the CoreValve prosthesis in the United States.

METHODS Patients used for this analysis include all patients who underwent TAVR in any one of the 4 CoreValve US trials- the CoreValve Pivotal extreme and high risk trials as well as the CoreValve Continued Access extreme and high risk trials. Data from 3687 patients including 1708 women and 1979 men undergoing TAVR were included for analysis.

RESULTS Women comprised 46% of the final cohort and at baseline had a higher STS score (9.6% vs. 8.3%). While there was no difference in baseline NYHA classification, women tended to have fewer cardiac comorbidities and a lower rate of coronary artery disease including fewer MIs, CABGs, and PCIs. Women were also less likely to have peripheral vascular disease, a pre-existing pacemaker, or a prior stroke. Conversely, women had increased frailty indices as measured by KATZ ADL deficits, walk times, and grip strength. At baseline women had a higher mean gradient across the aortic valve (51.5 vs 44.3mmHg) and smaller EOA (0.66 vs. 0.79cm²). From a procedural standpoint, women were slightly more likely to require alternative access (21% vs 18.35%) and tended to receive smaller sized valves. The 30-day and 1-year outcomes are summarized in the table below.

CONCLUSIONS Women, who account for nearly half of the population undergoing TAVR within the CoreValve US trials, tend to have fewer cardiac comorbidities and increased frailty as compared to men. While differences exist in procedural risks between men and women undergoing TAVR with the CoreValve prosthesis, there was no difference in 30-day or 1-year mortality.

	30 -days			1 year		
	Male (N=1979)	Female (N=1708)	P-value	Male (N=1979)	Female (N=1708)	P-value
All-Cause Mortality, %	114 (5.8)	100 (5.9)	0.87	406 (24.1)	315 (21.3)	0.08
Cardiovascular, %	109 (5.6)	98 (5.8)	0.74	305 (18.1)	242 (16.4)	0.23
Stroke, %	79 (4.0)	95 (5.7)	0.02	129 (7.7)	141 (9.3)	0.05
Major, %	42 (2.1)	60 (3.6)	0.01	72 (4.5)	86 (5.6)	0.04
All-Cause Mortality or Major Stroke, %	142 (7.2)	140 (8.2)	0.22	434 (25.6)	353 (23.4)	0.32
Bleed, %	615 (31.2)	728 (42.7)	<0.0001	694 (36.7)	781 (46.8)	<0.0001
Life-Threatening/ disabling, %	200 (10.2)	244 (14.3)	0.0001	261 (14.3)	290 (17.9)	0.002
Major Vascular Complication, %	96 (4.9)	165 (9.7)	<0.0001	103 (5.3)	168 (9.9)	<0.0001
Acute Kidney Injury, %	222 (11.3)	175 (10.4)	0.38	222 (11.3)	175 (10.4)	0.38
Myocardial Infarction, %	16 (0.8)	18 (1.1)	0.43	33 (2.1)	34 (2.4)	0.52
Cardiac Tamponade, %	11 (0.6)	42 (2.5)	<0.0001	15 (0.8)	43 (2.5)	<0.0001
New Permanent Pacemaker Implant, %	453 (23.2)	311 (18.6)	0.0007	508 (27.0)	346 (21.4)	0.0001
KCCQ Overall Summary Score Change from Baseline	22.4 ± 27.4	22.4 ± 27.2	0.96	28.0 ± 28.1	28.9 ± 26.4	0.53