Clinical Summary:

Five-year outcomes following bicuspid aortic valve replacement with a novel tissue bioprosthesis

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Inspiring Results

Background

- The COMMENCE trial is an FDA IDE trial investigating the novel RESILIA tissue in aortic valve replacement (AVR)
- AVR outcomes through 5 years from this trial have been reported and reveal good safety and hemodynamics[1]
  - Zero events of structural valve deterioration (SVD)*, clinically stable hemodynamics, and low rates of transvalvular regurgitation

Key Points

- In this IDE trial, in a BAV cohort of N=214 patients of average age 59.8 years, the morbidity and mortality were very low through 5 years
- The BAV group exhibited similarly stable mean gradients and low levels of transvalvular regurgitation as tricuspid aortic valve patients (TAV), despite being a full decade younger

Methods

- In the COMMENCE aortic trial, N = 689 patients underwent AVR with a valve with RESILIA tissue. Annual follow-up occurred through 5 years, during which various safety and annual echo outcomes were collected
- In this COMMENCE aortic trial sub-analysis, the authors sought to investigate the outcomes of BAV patients
  - The authors evaluated safety outcomes, paravalvular and transvalvular regurgitation, and summary hemodynamics
  - They also constructed longitudinal models to estimate the change in mean gradient and the change in effective orifice area separately over 5 years postoperatively

Patient Population

- Of the N = 689 total implanted patients, there were N = 214 patients with BAV and N = 458 patients with TAV
- Patient age at implant: BAV: 59.8 ± 12.4 yrs; TAV: 70.2 ± 9.5 yrs
- Patient study valve size: BAV: 24.6 ± 2.4 mm; TAV: 23.5 ± 2.1 mm

Results

- Safety endpoints, probability event-free at 5 years (Table 1):
  - All-cause mortality: 95.9% (BAV), 86.3% (TAV)
  - Endocarditis: 98.5% (BAV), 97.4% (TAV)
  - SVD: 100% (BAV), 100% (TAV)*
- BAV hemodynamics: mean gradient was 10.3 mmHg at 1 year, 10.1 mmHg at 2 years, 11.1 mmHg at 3 years, 11.3 mmHg at 4 years, and 11.5 mmHg at 5 years
- In the hemodynamic modeling, there was no difference in change in mean gradient or in effective orifice area over 5 years between the BAV and TAV groups
  - This was the case in the unadjusted model as well as the model adjusted for valve size, body surface area, and age
- At each annual follow-up, there was between 97% - 99% none/trivial paravalvular leak (PVL) in the BAV cohort. There was no significant difference in mild or greater PVL over time between BAV and TAV patients
- Transvalvular regurgitation (see Figure 1). At each annual follow-up, there was between 95% - 99% none/trivial transvalvular regurgitation in the BAV cohort. There was no significant difference in mild or greater transvalvular regurgitation over time between BAV and TAV patients

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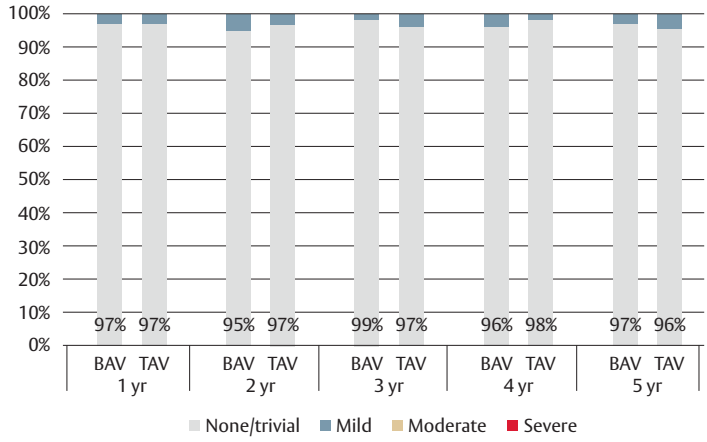
Table 1. Safety endpoints

	BAV cohort (N = 214)		TAV cohort (N = 458)		Log-rank test
	Early (≤30 d) event rate	Freedom from @ 5 yrs	Early (≤30 d) event rate	Freedom from @ 5 yrs	P-value
Mortality	2 (0.9%)	95.9% (93.0 - 98.7)	6 (1.3%)	86.3% (83.0 - 89.7)	0.0004
Valve-related mortality	1 (0.5%)	97.8% (95.7 - 99.9)	2 (0.4%)	96.2% (94.4 - 98.1)	0.26
Reoperation	0 (0%)	98.5% (96.8 - 100.0)	1 (0.2%)	98.8% (97.7 - 99.8)	0.78
Study valve explant	0 (0%)	98.5% (96.8 - 100.0)	0 (0%)	99.2% (98.4 - 100.0)	0.37
Stroke	3 (1.4%)	94.6% (91.5 - 97.7)	8 (1.7%)	94.5% (92.2 - 96.7)	0.98
Valve thrombosis	0 (0%)	100% (100.0 - 100.0)	0 (0%)	100% (100.0 - 100.0)	NA
Endocarditis	0 (0%)	98.5% (96.8 - 100.0)	0 (0%)	97.4% (95.7 - 99.0)	0.45
SVD	0 (0%)	100% (100.0 - 100.0)	0 (0%)	100% (100.0 - 100.0)*	NA

**1 SVD diagnosed at postoperative day 1,848.*

All event definitions per CW Akins et al. J Thorac Cardiovasc Surg 2008;135:732-8 and adjudicated by Clinical Events Committee.

Figure 1. Transvalvular regurgitation results



Conclusions

- The SVD rate in the BAV cohort was zero at 5 years, which is encouraging
  - Transvalvular regurgitation, an early marker of SVD, also remained exceedingly low
- The BAV group exhibited similar clinically stable mean gradients and low levels of transvalvular regurgitation as TAV patients, despite being a full decade younger
- The 5-year BAV results in this trial should serve as a benchmark for future SAVR or TAVR outcomes in BAV patients
- RESILIA tissue continues to show promise, even in younger patients
  - A subgroup of COMMENCE aortic trial patients is being followed through 10 years, and other trials are investigating RESILIA tissue in the postmarket setting

Reference

1. JE Bavaria, et al. Ann Thorac Surg 2022; doi.org/10.1016/j.athoracsur.2021.12.058

Important Safety Information: INSPIRIS RESILIA Aortic Valve

Indications: For use in replacement of native or prosthetic aortic heart valves. **Contraindications:** There are no known contraindications with the use of the INSPIRIS RESILIA aortic valve. **Complications and Side Effects:** Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, any of which could lead to reoperation, explantation, permanent disability, and death. **Warnings:** DO NOT ADJUST THE VALVE DIAMETER BY EXPANDING THE BAND PRIOR TO OR DURING IMPLANTATION OF THE SURGICAL VALVE. The expandable band is not designed to allow for compression or expansion during implantation of the surgical valve. This will cause damage to the valve and may result in aortic incompetence. DO NOT PERFORM STAND-ALONE BALLOON AORTIC VALVULOPLASTY PROCEDURES ON THIS VALVE FOR THE SIZES 19 – 25 mm as this may expand the valve causing aortic incompetence, coronary embolism or annular rupture. Valve-in-valve sizing in the INSPIRIS valve has only been tested with specific Edwards transcatheter heart valves. Use of other transcatheter valves may result in embolization of transcatheter devices anchored within or result in annular rupture.

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