RESILIA Tissue in Surgical Aortic Valve Replacement for Patients with Bicuspid Aortic Valves:

Findings from a 7-year IDE study

Edwards

Study Introduction

Patients with bicuspid aortic valves (BAV) may require aortic valve replacement at a younger age than patients with tricuspid aortic valves (TAV). To avoid anticoagulation, younger patients are increasingly opting for bioprosthetic aortic valves. This study investigates the safety and effectiveness of valves with RESILIA tissue over a period of 7 years after aortic valve replacement (AVR) in BAV patients.

Aim

- Compare outcomes between BAV and TAV patients after AVR with RESILIA tissue
- Assess mortality over a period of 7 years (primary outcome)
- Assess stroke, valve thrombosis, endocarditis, structural valve deterioration, need for reoperation, and echocardiographic parameters to 7 years (secondary outcomes)

Study Methods & Patient Demographics

Methods

This sub-analysis of the COMMENCE IDE trial is focused on BAV patients over a period of 7 years.

Trial methodology

- **A prospective, international IDE trial**
- **27 clinical sites**
  Study subjects enrolled in U.S., Canada, and Europe
- **Patient re-consent at 5 years**
  For extended follow up (years 6-10)
- **Extended follow-up**
  10 sites participating

Safety endpoints

- **All potential safety endpoints**
  Adjudicated by an independent Clinical Events Committee
- **SVD and other safety outcomes**
  Defined per "Guidelines for reporting morbidity and mortality after cardiac valve interventions" (Akins et al. 2008)

Effectiveness endpoints

- **Independent echocardiographic core laboratory**
  Evaluated hemodynamic performance
- **New York Heart Association (NYHA) functional class**

Patient Demographics

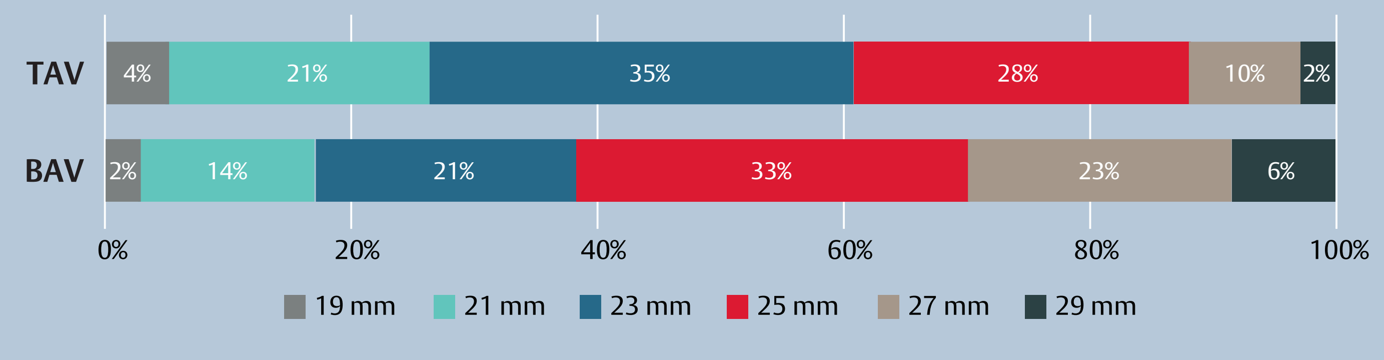
BAV

214 patients | **1.2±1.0** STS risk score | **59.8±12.4** years mean age

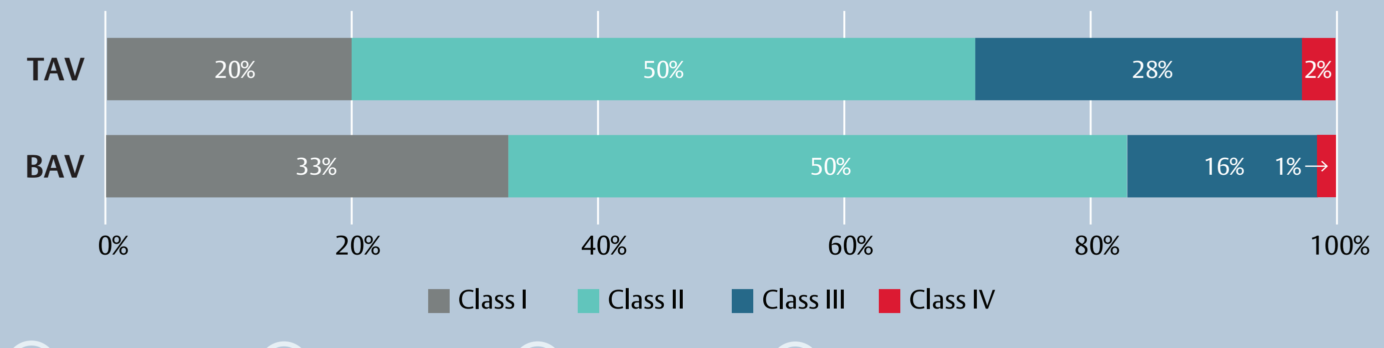
TAV

458 patients | **2.3±2.0** STS risk score | **70.2±9.5** years mean age

Valve-size distribution



NYHA classification



Results

PS-IPTW and age-adjusted freedom from events at 7 years (%)

Endpoint	Bicuspid (N = 213)	Tricuspid (N = 451)	p
Mortality	**91.9 (88.2, 95.8)**	**88.1 (82.0, 94.6)**	**.35**
Valve-related mortality	98.1 (96.4, 99.8)	96.1 (93.9, 98.4)	.23
Reoperation	**98.3 (96.9, 99.8)**	**97.0 (94.7, 99.3)**	**.36**
Study valve explant	98.5 (97.3, 99.8)	98.3 (96.6, 100.0)	.84
Stroke	92.6 (89.5, 95.8)	95.1 (92.6, 97.7)	.28
Valve thrombosis*	N/A	N/A	N/A
Endocarditis	98.9 (97.6, 100.0)	96.1 (93.7, 98.4)	.07
Structural Valve Deterioration**	N/A	N/A	N/A
Major PVL***	N/A	N/A	N/A
PPI	92.1 (88.9, 95.4)	91.9 (88.4, 95.5)	.94
Valve-related PPI	98.9 (98.0, 99.9)	99.8 (99.4, 100.0)	.16

*N/A for analyses due to small event numbers (i.e., two events in BAV and zero events in TAV)
**N/A for analyses due to small event numbers (i.e., zero events in BAV and two events in TAV)
***N/A for analyses due to small event numbers (i.e., zero events in BAV and three events in TAV) Variables in PS model: age, sex, BSA, NYHA, concomitant surgery, endocarditis, heart failure, renal failure, previous surgery, coronary disease, peripheral vascular disease, chronic obstructive pulmonary disease, diabetes, pulmonary hypertension, liver disease, valve size

Outcomes at 7 years

Outcome #1

At 7 years, majority of BAV patients had no or trace paravalvular leak (98.6%) and had no or trace transvalvular regurgitation (97.3%)

Outcome #2

A sub-analysis for patients ≤65 years demonstrated clinically stable hemodynamics and no significant difference between valve types (all p valves > .05)

Outcome #3

PS-IPTW and age-adjusted rates of freedom from all-cause mortality at 7 years were 99.2% for BAV and 96.7% for TAV for patients ≤65 years

Conclusions

In this IDE trial, in a BAV cohort of N=214 patients of average age 59.8 years, mortality was low through 7 years (7-year freedom from all-cause mortality of 91.9%)

No SVD was reported in the BAV cohort through 7 years, which is encouraging

- 97.3% had no or trace transvalvular regurgitation, an early marker of SVD

The BAV group exhibited similar clinically stable mean gradients and low levels of transvalvular regurgitation as TAV patients (7-year mean gradients: 9.09 mmHg in BAV vs. 8.97 mmHg in TAV)

- This was further reaffirmed in the even younger BAV ≤65 years sub-cohort

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.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.
See instructions for use for full prescribing information.

Reference:

Takayama H, Bavaria JE, Heimansohn DA, et al. RESILIA Tissue in Surgical Aortic Valve Replacement for Patients with Bicuspid Aortic Valves: Findings from a 7-year IDE study. Presented at the 60th Society of Thoracic Surgeons Annual Meeting, January 2024

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