

# Edwards Cardioband Tricuspid Valve Reconstruction System Early Feasibility Study: One-Year Outcomes

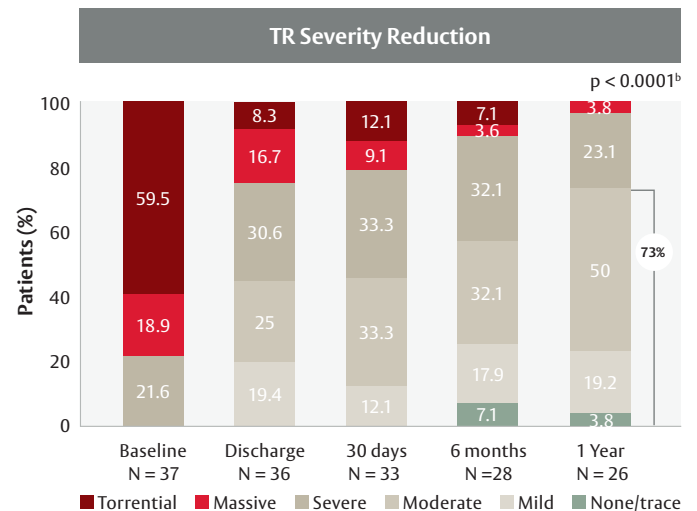
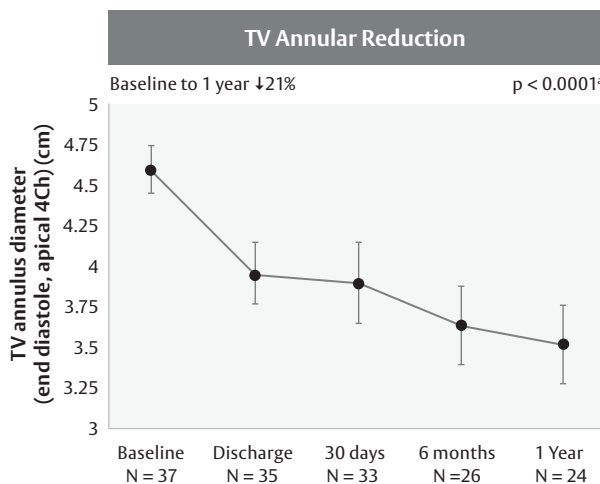


During the late-breaking trial session, Dr. William Gray reported the one-year outcomes from the U.S. multicentre, prospective, single-arm early feasibility study in 37 patients with symptomatic,  $\geq$  severe chronic functional tricuspid regurgitation.

## Study design & baseline parameters

Study Design: Single-arm, multicentre, prospective study	
Enrolled patients: 37	Female: 76%
NYHA functional class III or IV: 65%	Tricuspid regurgitation ( $\geq$ severe) <sup>1</sup> : 100%
Age, years: $78 \pm 7.5$	LVEF (%): $57.6 \pm 5.7^*$

## Key results



<sup>1</sup> Cardiovascular Research Foundation. \* n=33 .

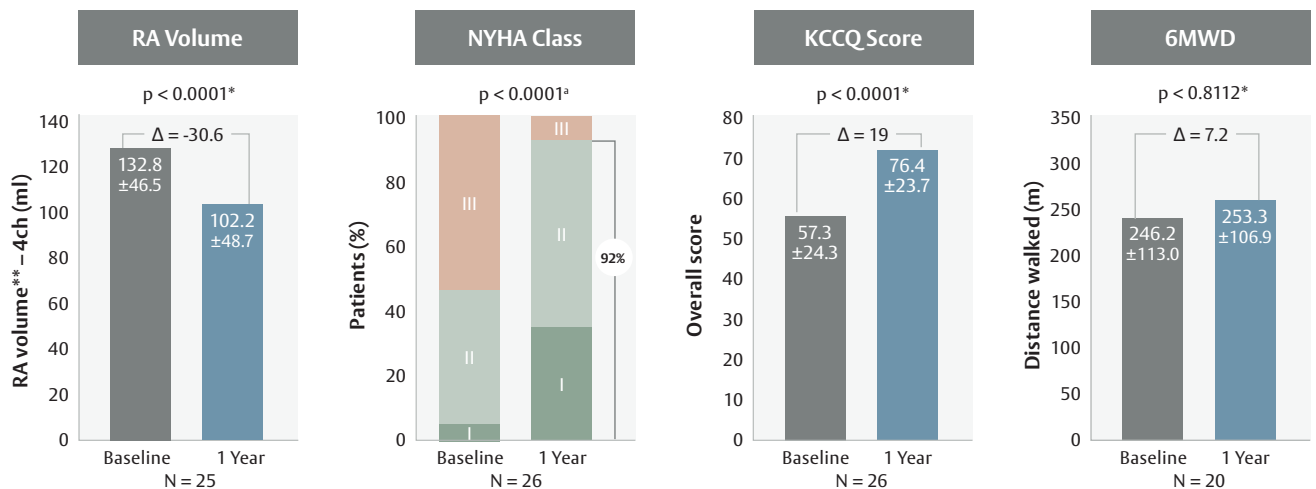
<sup>a</sup> Paired t-test for mean tricuspid valve (TV) annulus diameter (end diastole, apical 4ch) baseline to 1 year. N=24, baseline=44.6mm, one year=35.1mm. Bars represent 95% CI.

<sup>b</sup> Wilcoxon signed-rank test for tricuspid regurgitation (TR) grade at baseline and discharge and baseline and 1 year. N=26, Baseline tricuspid regurgitation (TR) grades by transthoracic echocardiography (TTE; N=26), 30.8% severe, 11.5% massive, 57.7% torrential. One-year TR grades: 3.8% none/trace, 19.2% mild, 50.0% moderate, 23.1% severe, 3.8% massive. NYHA, New York Heart Association; LVEF, left ventricular ejection fraction.



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- Significant tricuspid valve annular reduction of 21%
- Significant TR reduction of at least one-grade reduction in all patients and two-grade reduction in 73%
- 73% of patients had  $\leq$  moderate TR at one year
- 92% of patients were in NYHA  $\leq$  II with a 19-point improvement in the overall KCCQ score
- One-year 13.5% all-cause mortality and 10.8% HF rehospitalization in an elderly patient population with high comorbidities



\*Paired t-test. \*\*Single plane Simpson's. <sup>a</sup>Wilcoxon signed-rank test. RA, right atrium; NYHA, New York Heart Association; KCCQ, Kansas City Cardiomyopathy Questionnaire; 6MWD, 6-minute walk distance.

## Conclusion

- Tricuspid valve repair with the Cardioband tricuspid system demonstrated high survival and low heart failure rehospitalization rates at one year
- Significant reduction in TR severity and improvements in echocardiographic, clinical, and quality of life outcomes were sustained and durable at one year in a patient population with majority torrential TR at baseline

Visit [Edwards.com/CardiobandTR](https://www.edwards.com/CardiobandTR) for more information

TR: tricuspid regurgitation.  
Grey W. Cardioband TR early feasibility study one-year results. LBT EuroPCR 2022

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