ACC.25

Two-year Outcomes Of Transcatheter Tricuspid Valve Edge-to-edge Repair For Tricuspid Regurgitation:

The TRILUMINATE Pivotal Trial

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- **Consulting fees/honoraria**: Abbott, Boston Scientific, W.L. Gore, and Medtronic
- **Steering committee member**: TRILUMINATE Pivotal study (Abbott)
- **National principal investigator**: EXPAND, REPAIR MR (Abbott)

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The TRILUMINATE Pivotal trial

- The **first randomized controlled trial** to evaluate **tricuspid TEER in subjects with symptomatic, severe TR** despite optimized medical therapy.
- The primary endpoint (evaluated at 1 year follow-up) of the TRILUMINATE Pivotal trial showed **tricuspid TEER with the TriClip device was superior to medical therapy alone**, driven by improvements in health status with no differences in mortality or heart failure hospitalization (HFH).[1]
- However, a significant reduction in HFH was seen in the later enrollment for TEER at 1 year.[2]

The TriClip device (Abbott)

[1] Sorajja P, Whisenant B, Hamid N, et al. Transcatheter Repair for Patients with Tricuspid Regurgitation. *N Engl J Med*. 2023;388(20):1833-1842.
[2] Tang GHL, Hahn RT, Whisenant BK, et al. Tricuspid Transcatheter Edge-to-Edge Repair for Severe Tricuspid Regurgitation: 1-Year Outcomes From the TRILUMINATE Randomized Cohort. *J Am Coll Cardiol*. 2025;85(3):235-246.

Study Design and Endpoints

Design

- 1:1 randomization between TriClip device and medical therapy
- Total of 572 subjects randomized
- Primary endpoint met[1]
- Crossover to device treatment allowed after 1-year follow-up if trial inclusion criteria still met

Prespecified 2-year Endpoints

1. Recurrent HF hospitalizations at 24 months
2. Freedom from all-cause mortality, tricuspid valve surgery, and tricuspid valve intervention at 24 months

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Aim: To report 2-year outcomes from the TRILUMINATE Pivotal trial

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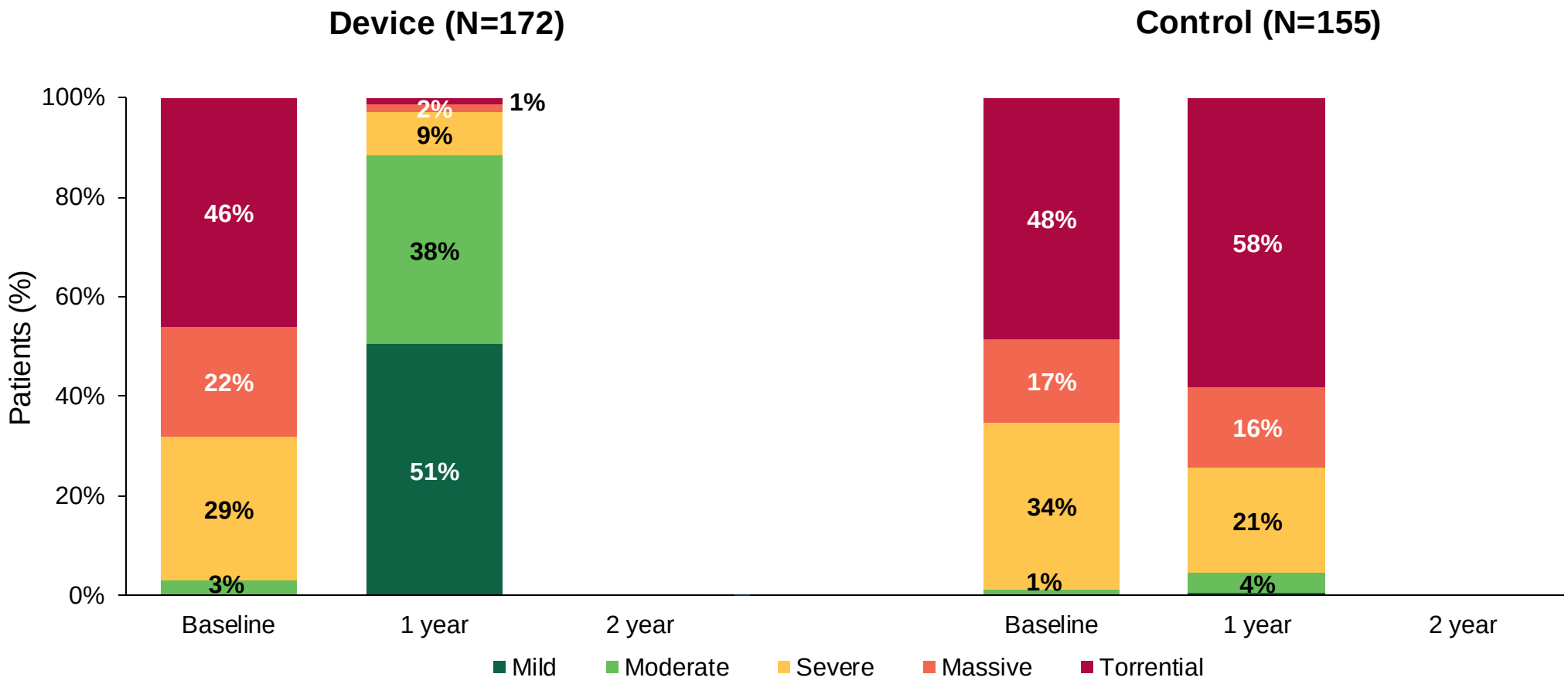
Baseline Characteristics

Characteristic	Device N=285	Control N=287
Age (years)	78.1 ± 7.9	78.1 ± 7.6
Female	58.9%	58.9%
Atrial Fibrillation	82.8%	92.7%
CRT, CRT-D, ICD, or Permanent Pacemaker	16.5%	16.4%
Previous Aortic and/or Mitral Intervention	37.9%	34.5%
HFH Within 1 Year Before Enrollment	24.9%	22.6%
NYHA Class III/IV	56.1%	54.0%
KCCQ Score	55.6 ± 22.9	54.6 ± 23.8
6-minute Walk Distance (m)	240.5 ± 116.4	249.6 ± 125.5
Functional TR Etiology	95.7%	93.9%
Torrential TR[1,2]	48.7%	51.5%
Left Ventricular Ejection Fraction (%)	59.4 ± 9.0	59.7 ± 9.2

Based on 5-grade scale from [1]Hahn RT, Badano LP, Bartko PE, et al. Tricuspid regurgitation: recent advances in understanding pathophysiology, severity grading and outcome. *Eur Heart J Cardiovasc Imaging* 2022;23:913-29. [2]Hahn RT, Zamorano JL. The need for a new tricuspid regurgitation grading scheme. *Eur Heart J Cardiovasc Imaging* 2017;18:1342-3. Data shown as % or mean±standard deviation.; *CRT*, cardiac resynchronization therapy; *CRT-D*, CRT device; *HFH*, heart failure hospitalization; *ICD*, implantable cardiac defibrillator; *KCCQ*, Kansas City Cardiomyopathy Questionnaire; *NYHA*, New York Heart Association; *TR*, tricuspid regurgitation.

INTENTION-TO-TREAT

Tricuspid Regurgitation Severity (Paired)



Paired data shown. Patients with tricuspid valve surgery are excluded.

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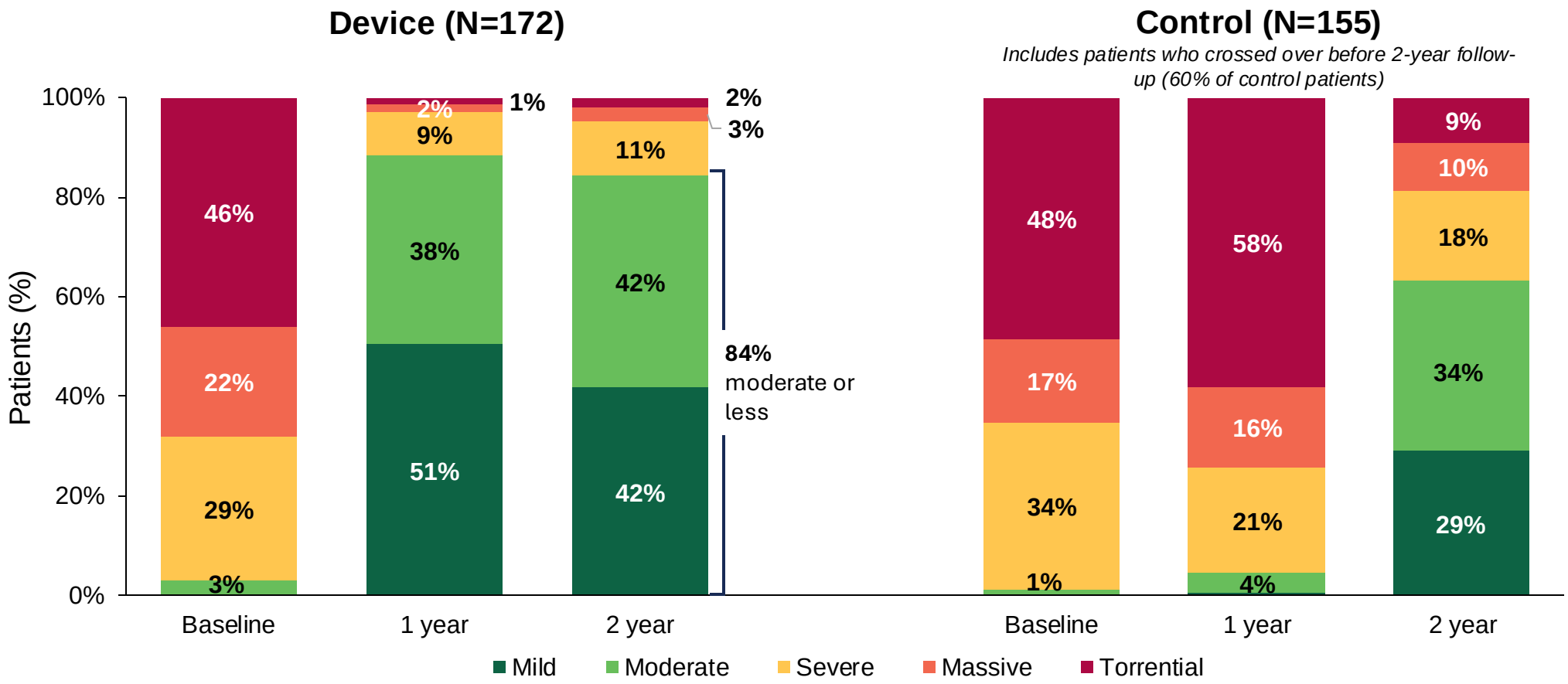
Tricuspid Regurgitation Severity (Paired)



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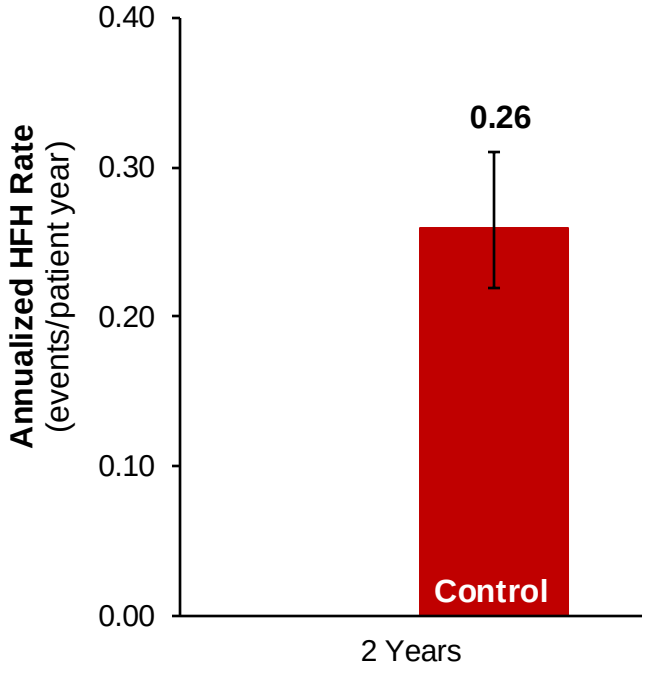
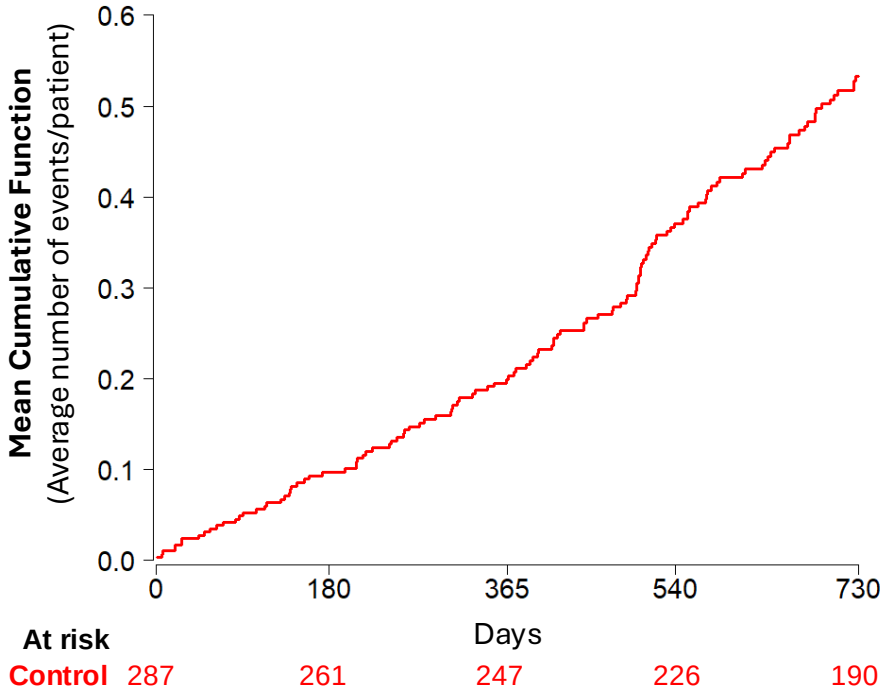
TRILUMINATE PIVOTAL TRIAL

Prespecified Endpoint: Recurrent Heart Failure Hospitalizations





Prespecified secondary endpoint from joint frailty model; intention-to-treat (ITT) analysis shown. *HFH*, heart failure hospitalization.

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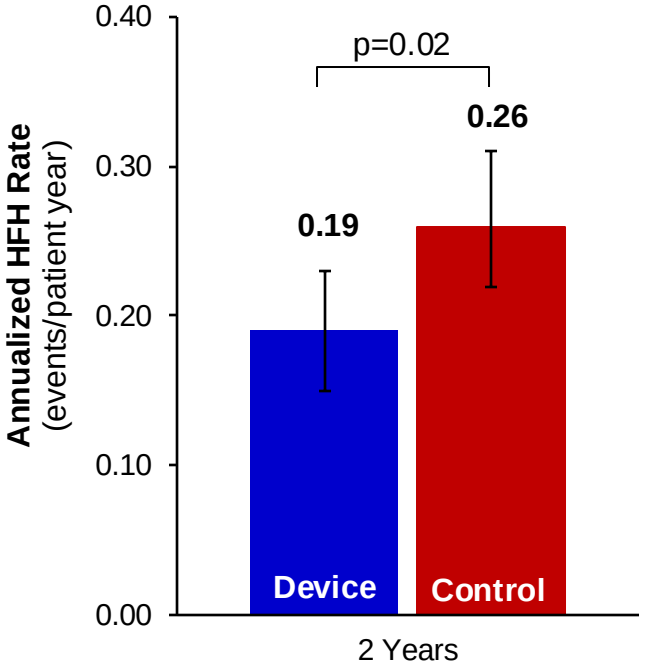
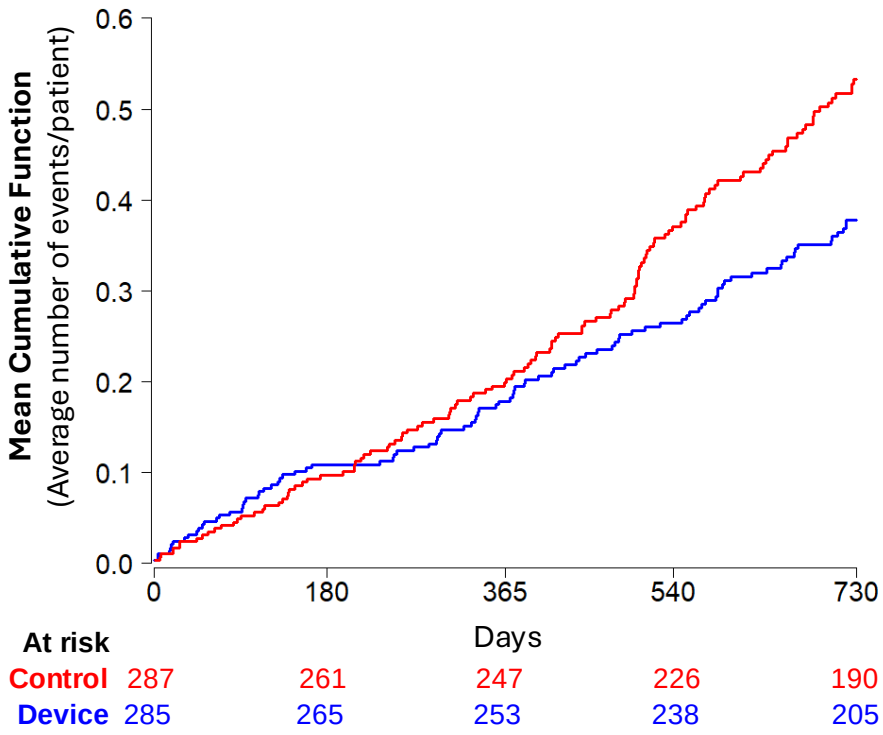


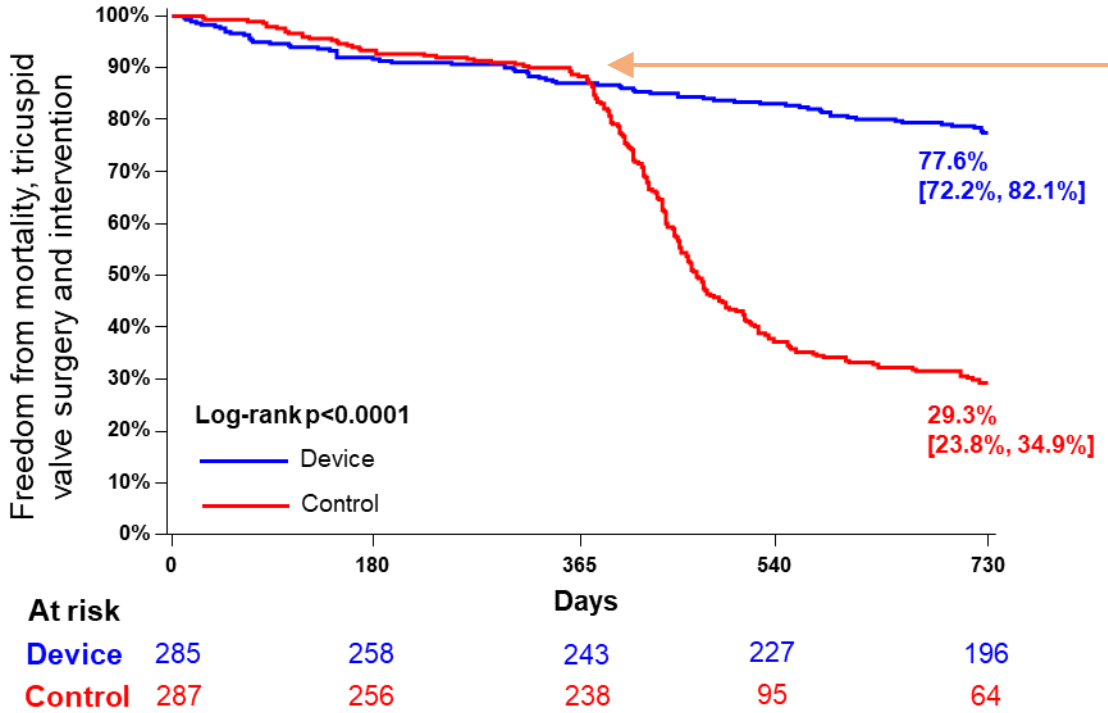


At risk					
Control	287	261	247	226	190
Device	285	265	253	238	205

Hazard ratio=0.72 (one-sided upper confidence limit of 0.93, p=0.02), indicating a **relative risk reduction of 28% with device treatment**.

Prespecified secondary endpoint from joint frailty model; intention-to-treat (ITT) analysis shown. *HFH*, heart failure hospitalization.

Prespecified Endpoint: Freedom from All-cause mortality, TV Surgery, TV Intervention



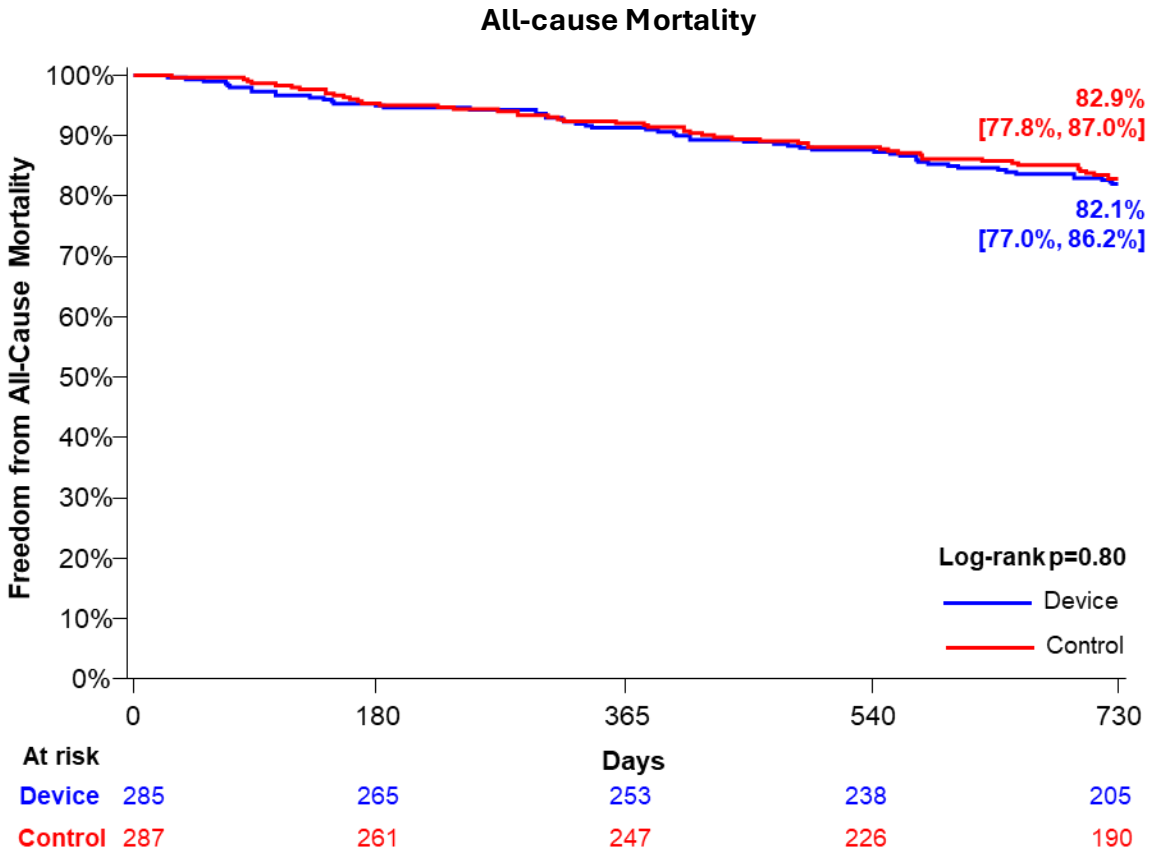
Difference driven by tricuspid valve intervention (crossover) after 1 year. Rates of all-cause mortality and tricuspid valve surgery were similar between groups.

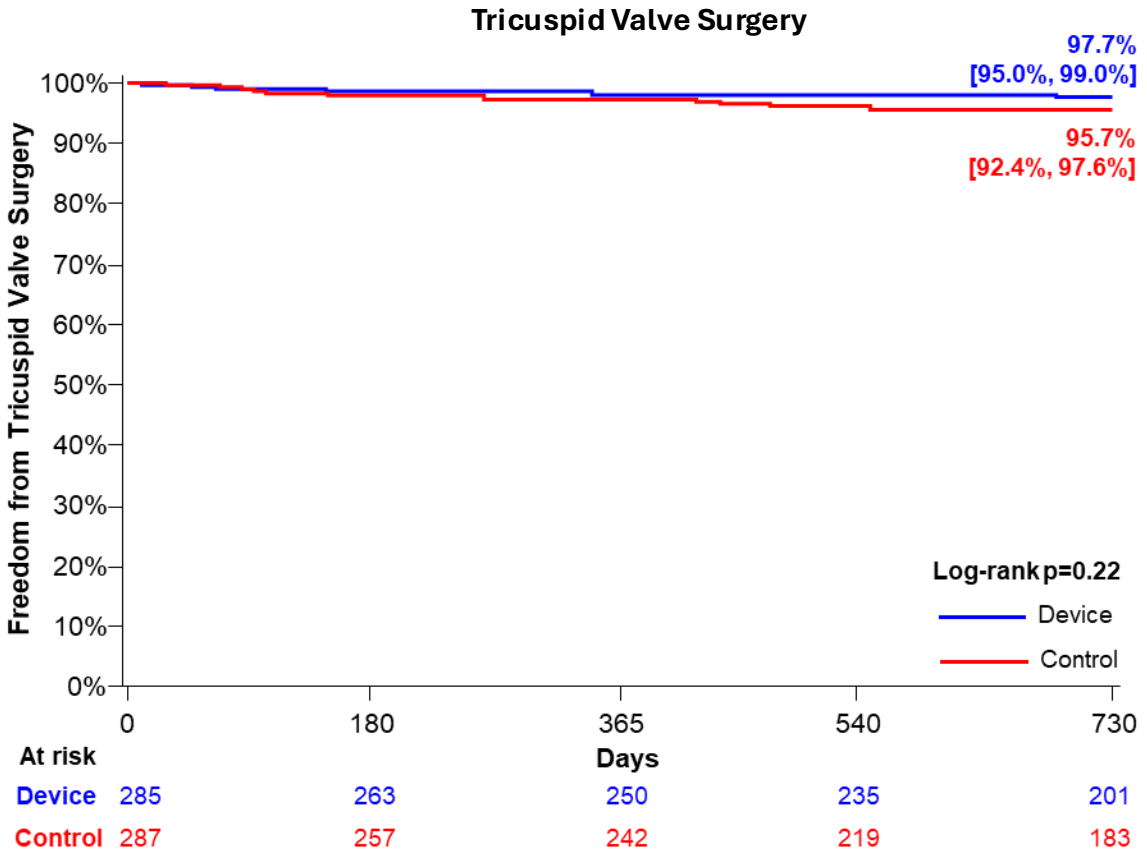
Component	Device N=285	Control N=287	p-value
Composite	**22.4% (62)**	**70.7% (185)**	**<0.0001**
All-cause mortality	17.9% (49)	17.1% (45)	
TV surgery (TVS)	2.3% (6)	4.3% (11)	
TV intervention (TVI)	3.8% (10)	61.5% (142)	

Prespecified secondary endpoint; intention-to-treat (ITT) analysis shown. *TV*, tricuspid valve; *TVS*, tricuspid valve surgery; *TVI*, tricuspid valve intervention (transcatheter).

INTENTION-TO-TREAT

All-cause Mortality and Tricuspid Valve Surgery





Prespecified secondary endpoint; intention-to-treat (ITT) analysis shown. *TVS*, tricuspid valve surgery.

INTENTION-TO-TREAT

Both 2-year Prespecified Endpoints Met

- Reduction in recurrent HF hospitalizations at 24 months in Device group ($p=0.02$).
- Higher freedom from all-cause mortality, tricuspid valve surgery, and tricuspid valve intervention at 24 months in Device group, driven by tricuspid valve intervention in the Control group ($p<0.0001$).

INTENTION-TO-TREAT

Safety Through Two Years

Adverse Event through 2 Years	Device N=285	Control N=287
Stroke	1.9%	2.5%
Transient ischemic attack	1.7%	1.0%
Tricuspid valve intervention	3.8%	61.5%
Tricuspid valve surgery	2.3%	4.3%
Cardiogenic shock	0.4%	1.3%
New conduction disturbance requiring permanent pacemaker	5.5%	4.2%
Single leaflet device attachment	6.5%	3.9%
Device embolization	0%	0%
Device thrombosis	0%	0%

Data shown as Kaplan Meier time-to-event (%). Intention-to-treat (ITT) analysis shown. All single leaflet device attachment (SLDA) events in the Device group were noted at discharge or 30-day follow-up.

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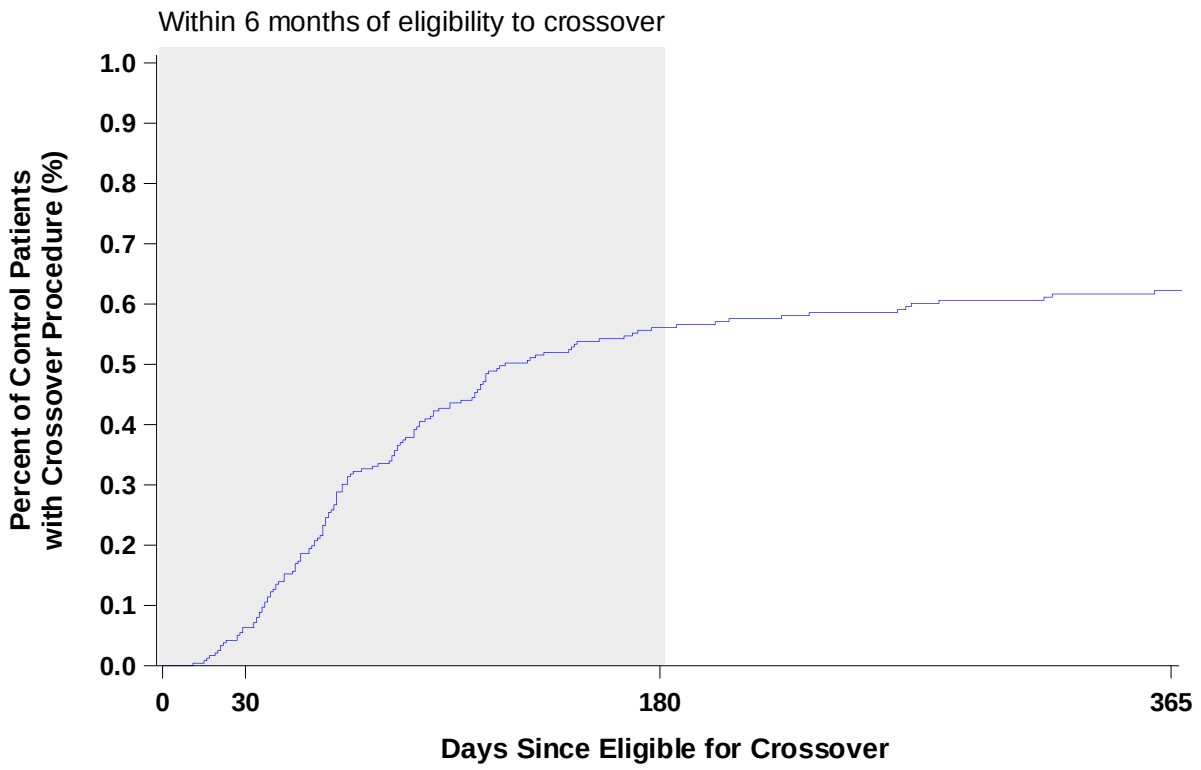
Crossover to device treatment after 1-year follow-up

Data shown as Kaplan Meier time-to-event (%). Intention-to-treat (ITT) analysis shown. All single leaflet device attachment (SLDA) events in the Device group were noted at discharge or 30-day follow-up.

Crossover Analysis

Crossover to device treatment permitted after 1-year follow-up if original inclusion criteria still met

Timing of Crossover Procedure



Of the 241 Control patients eligible for crossover after 1-year follow-up, **142 (59%) patients crossed over prior to 2-year follow-up**

92% (130/142) of crossover procedures occurred within 6 months of the 1-year visit

Characteristics Prior to Crossover

Variable at 1 Year (Prior to Crossover)	Patients who Crossed Over N=142	Patients who did not Crossover N=94
Torrential TR	65.2%	41.5%
NYHA III/IV	47.5%	30.4%
KCCQ Change (baseline to 1 year)	0 ± 18	7 ± 18
6MWD Change (baseline to 1 year)	-22 ± 103	-1 ± 90
HFH (events/patient-year)	0.17	0.07
Diuretic Dose Change (baseline to 1 year)	+22 mg	+5 mg

Patients who crossed over were **more symptomatic with a higher prevalence of torrential TR and more HFH prior to crossover.**

Includes patients eligible for crossover (completed 1-year follow-up), patients with tricuspid valve surgery are excluded. *TR*, tricuspid regurgitation; *NYHA*, New York Heart Association; *KCCQ*, Kansas City Cardiomyopathy Questionnaire; *6MWD*, 6-minute walk distance; *HFH*, heart failure hospitalization.

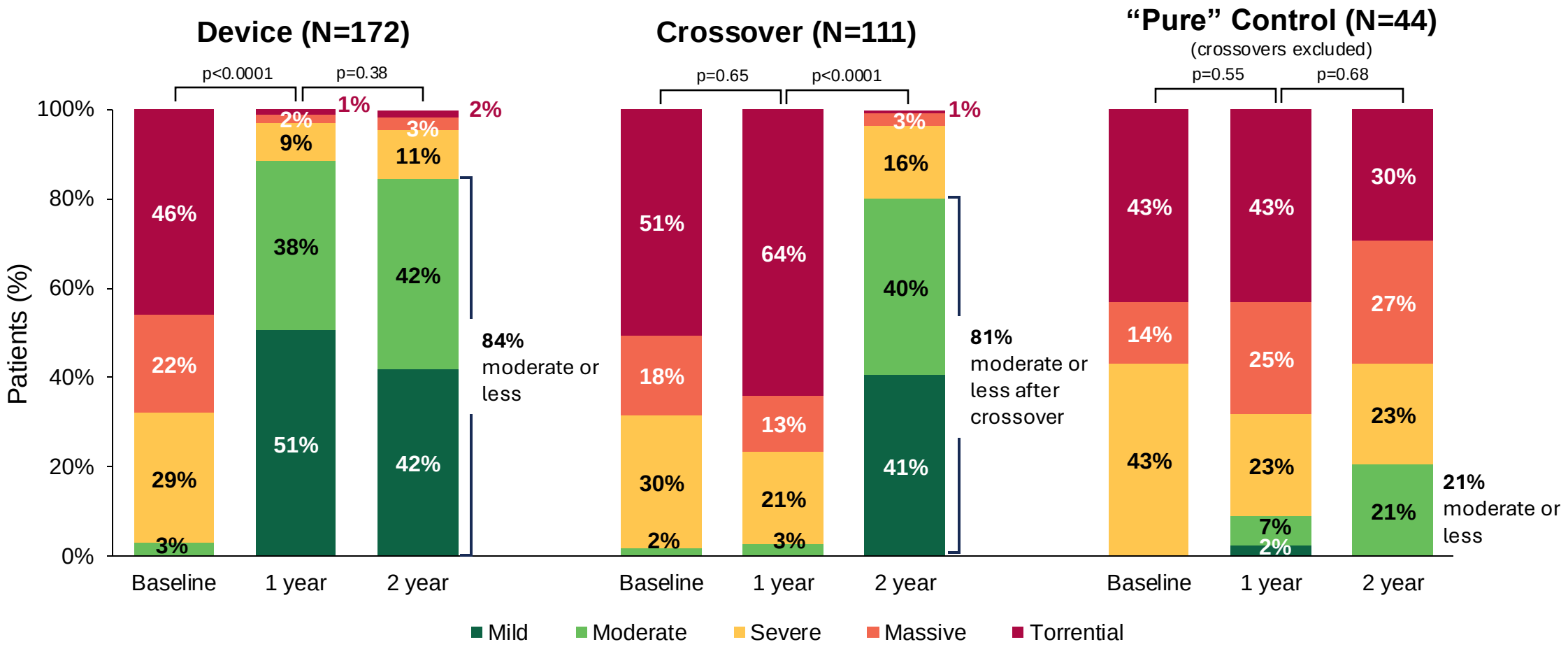
Safety of Procedure at Crossover

Adverse events through 30 days	Device Group N=281	Crossover N=142
Major Adverse Event through 30 Days		
Cardiovascular mortality	0.4%	0.7%
New-onset renal failure	0.7%	1.4%
Non-elective cardiac surgery	0%	0%
Endocarditis requiring surgery	0%	0%
Other Adverse Events through 30 Days		
Major bleeding	3.2%	2.8%
Single leaflet device attachment	5.7%	5.6%
Device embolization	0%	0%
Device thrombosis	0%	0%
Myocardial infarction	0%	0%
Stroke	0.4%	0%
New conduction disturbance requiring permanent pacemaker	0.9%	0%
Discharge to Home	97.9%	97.2%
All-cause Mortality	0.4%	1.4%
Heart Failure Hospitalization	2.5%	3.5%

Data shown as %.

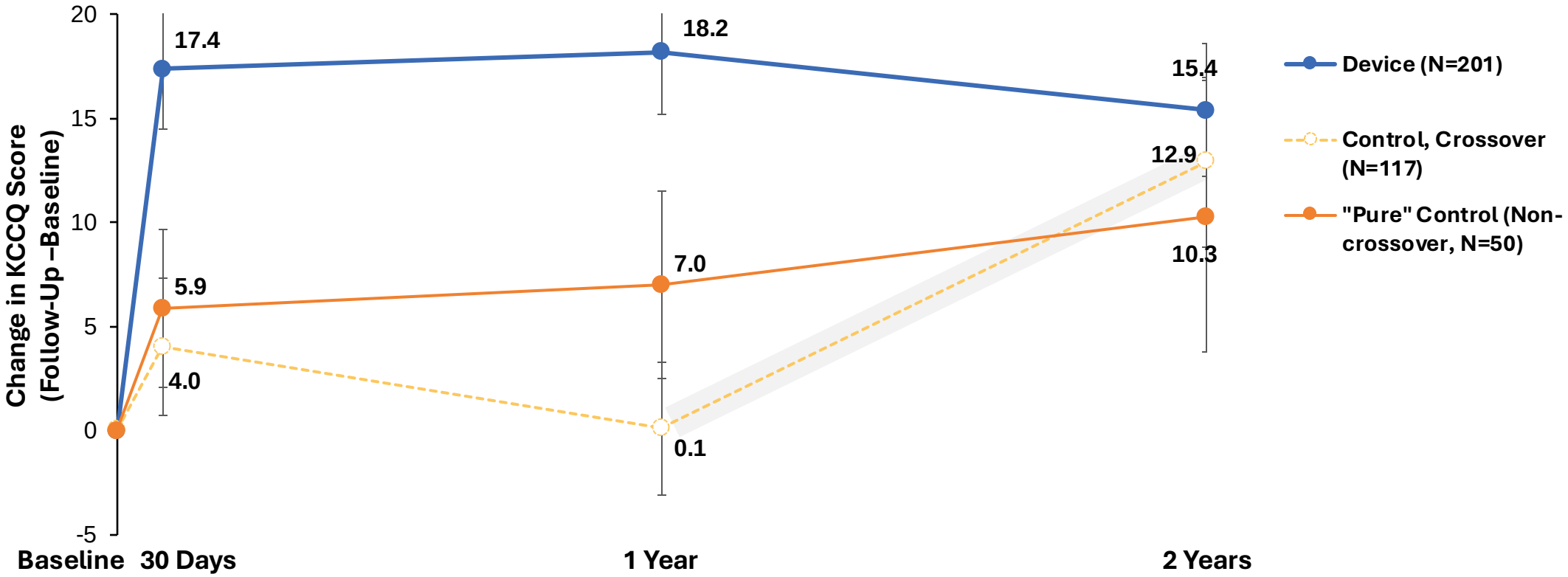
TRILUMINATE
PIVOTAL TRIAL

Tricuspid Regurgitation Grade After Crossover



Paired data shown. "Pure" control includes patients who remain on medical therapy alone. Patients with tricuspid valve surgery are excluded from all groups.

Health Status Through 2 Years



Control eligible for crossover after 1-year follow-up visit

Mean and 95%CI and paired data shown. Patients with tricuspid valve surgery are excluded.

Conclusions

- Improvements in TR severity and quality of life were sustained through 2 years in Device patients.
- Treatment with the TriClip device reduced HFH compared to medical therapy (despite crossovers in the Control group).
- TriClip continues to be safe and effective, including for Control patients who crossed over after 1-year follow-up.
- Treatment of Control patients with TriClip improved health status following crossover; however, delaying treatment resulted in symptom progression and recurrent HFH.