PASCAL Repair System Tricuspid Regurgitation Clinical Evidence

Edith Lubos, M.D.

Marienkrankenhaus, Hamburg, Germany

Potential Conflicts of Interest

Speaker's name: Edith Lubos

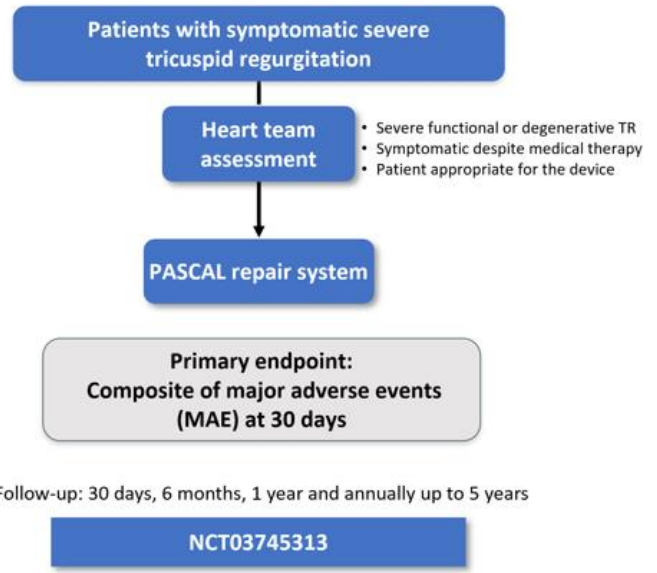
I have the following potential conflicts of interest to report:

Affiliation/Financial Relationship	Company
Honoraria for lectures	Edwards Lifesciences
Grant support	Edwards Lifesciences

Study Design

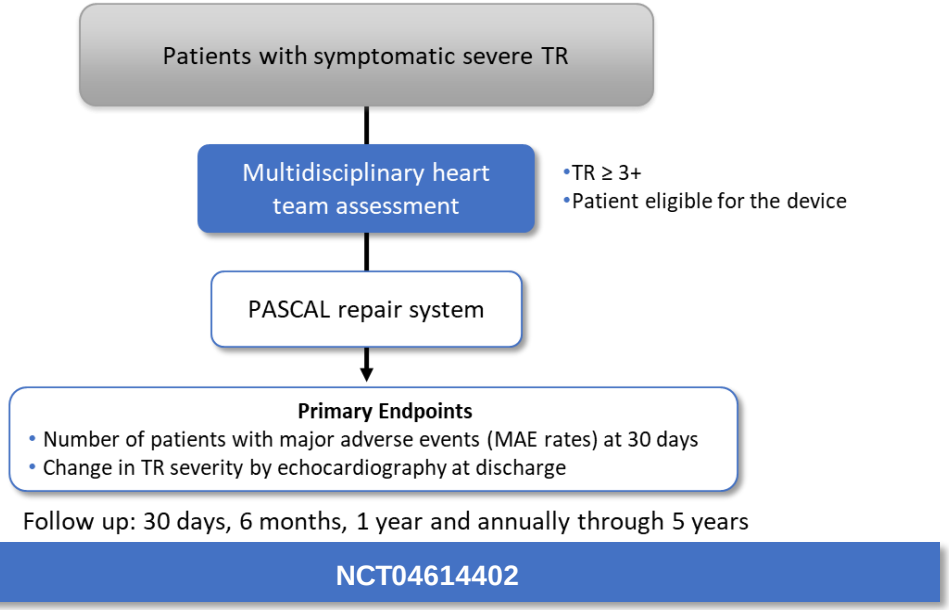
THE CLASP TR STUDY

Prospective, multicenter, single-arm study to evaluate the safety and performance of the Edwards PASCAL Transcatheter Valve Repair System in TR[1]
Principal Investigator:
Susheel K. Kodali, MD



THE TriCLASP STUDY

Prospective, multicentre, single arm, post-market clinical follow-up study[2]
Principal Investigator:
Stephan Baldus, MD



https://clinicaltrials.gov; NCT03745313, NCT04614402

[1]Hahn R. Transcatheter tricuspid valve repair: CLASP TR study one-year results. LBT EuroPCR 2022

[2]Baldus S. 30-Day outcomes for transcatheter tricuspid repair: TriCLASP post-market study. LBT EuroPCR 2022

Baseline Characteristics

THE CLASP TR STUDY

Baseline Characteristics	% or Mean ± SD (n=65)
Age, years	77 ± 9
Female	55%
STS mortality score, MV repair	7.7% ± 5.5*
EuroSCORE II	5.0 ± 4.7¶
NYHA functional class III or IV	71%
Tricuspid regurgitation ≥ severe[1]	97%*[a]
Atrial fibrillation/flutter	89%
Systemic hypertension	92%
Prior CABG	31%
Prior aortic valve surgery/intervention	17%
Prior mitral valve surgery/intervention	20%
Pacemaker lead crossing TV annulus	14%
Ascites	28%
Renal insufficiency or failure	43%

THE TriCLASP STUDY

Baseline Characteristics	% or Mean ± SD (n=74)
Age, years	80 ± 6
Female	58%
STS score, MV Repair	9.0 ± 6.9
NYHA functional class III or IV	77%
Tricuspid regurgitation ≥ severe[2]	83%[b]
Systemic hypertension (treated)	91%
Pulmonary hypertension (PASP ≥ 30 mmHg)	39%
Atrial fibrillation	96%
Pacemaker or ICD	23%
Prior surgery/intervention, any valve	36%
Renal insufficiency or failure	55%
Diabetes	30%

[1]Core Laboratory, Cardiovascular Research Foundation
[2]Core laboratory: Cardialysis
[a]TR severity for one patient was deemed inconclusive after core laboratory adjudication. *N=64. ¶N=62. [b]TR severity for 10 patients was reclassified to moderate or less after core lab adjudication. PASP, pulmonary arterial systolic pressure. *CABG*, coronary artery bypass graft; *ICD*, implantable cardioverter defibrillator; *NYHA*, New York Heart Association; *STS*, Society for Thoracic Surgeons

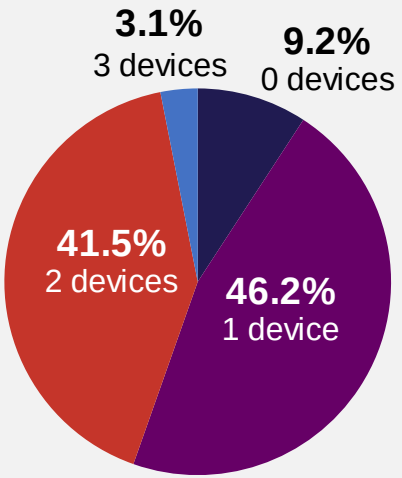
Hahn R. Transcatheter tricuspid valve repair: CLASP TR study one-year results. LBT EuroPCR 2022
Baldus S. 30-Day outcomes for transcatheter tricuspid repair: TriCLASP post-market study. LBT EuroPCR 2022

Device and Procedural Success

THE CLASP TR STUDY

	%, Mean ± SD or Median (Q1, Q3)
Successful implant rate[1,2]	91%*
Procedural success[3]	88%¶
Clinical success[4]	77%¶
Discharged to home	95%‡
Device time, minutes (implant insertion to release)	147 ± 89^
First 34 patients	154 ± 81#
Last 31 patients	140 ± 97#
Length of hospital stay (procedure to discharge), days	2.6 ± 3.5‡ 1.0 (1.0, 3.0)

Number of Devices
Per patient



[1]Implant deployed and delivery system retrieved as intended at exit from the cardiac catheterization laboratory.
[2]Implants were successfully retrieved in six patients whose leaflets were unable to be captured due to complex anatomy with no adverse sequelae.
[3]Implant success with at least one grade reduction in TR at the end of the procedure without surgical or percutaneous intervention prior to hospital discharge. TR grade availability dependent on data entry timing and imaging readability.
[4]Procedural success without major adverse events at 30 days.
*N=65. ¶N=56. ^N=58. ‡N=62. #N=29
Hahn R. Transcatheter tricuspid valve repair: CLASP TR study one-year results. LBT EuroPCR 2022

Procedural Characteristics

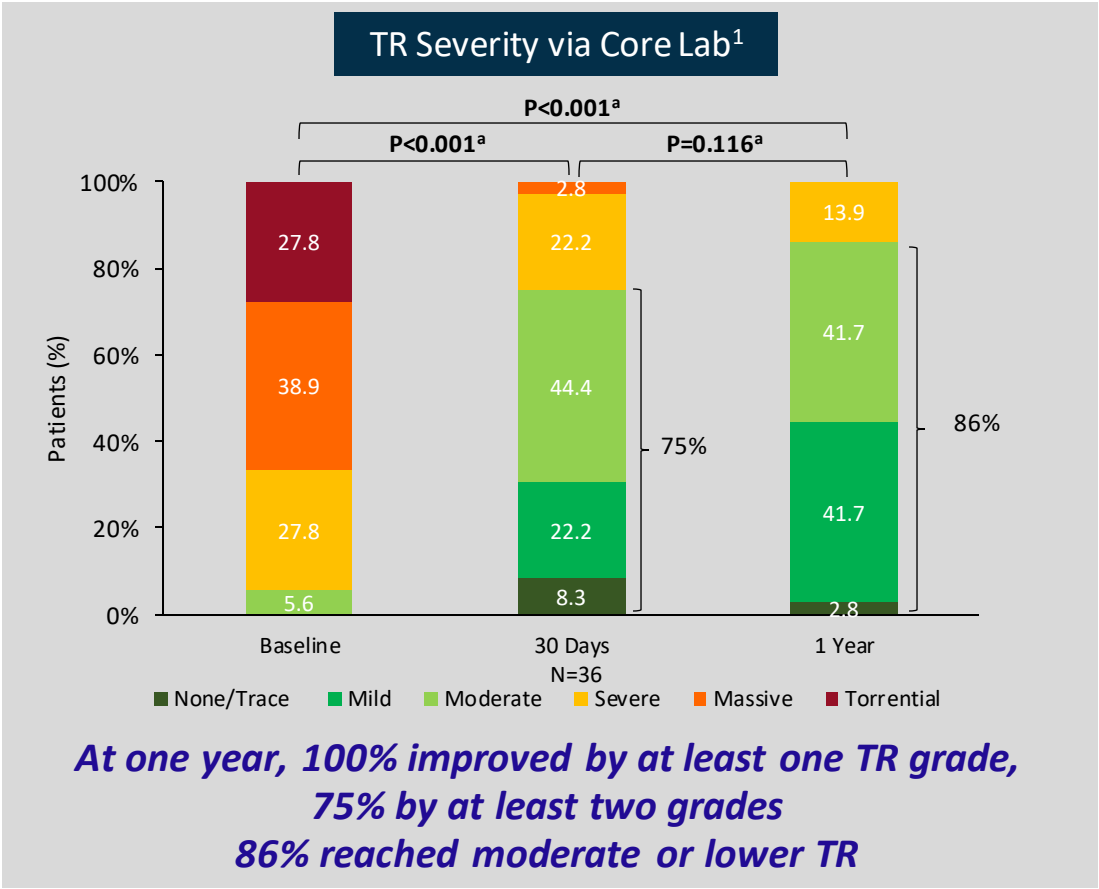
THE TriCLASP STUDY

	% (n/N) or Mean ± SD (N)
Successful implant rate[1]	97% (70/72)
Procedural success[2]	78% (42/54)
Clinical success[3]	78% (42/54)
Mean number of devices implanted	1.8 ± 0.6 (72)
PASCAL Ace	100% (73)
Device time (implant insertion to release), mins	84.2 ± 48.5 (58)
Length of hospital stay (procedure to discharge), days	5.1 ± 3.9 (72)
Discharged to home	92% (66/72)

[1]Implant deployed and delivery system retrieved as intended at exit from the cardiac catheterisation laboratory
[2]Implant success with at least one grade reduction in TR at discharge without surgical or percutaneous intervention prior to hospital discharge. TR grade availability dependent on data entry timing and imaging readability
[3]Procedural success without major adverse events at 30 days
Baldus S. 30-Day outcomes for transcatheter tricuspid repair: TriCLASP post-market study. LBT EuroPCR 2022

TR Reduction at One Year

THE CLASP TR STUDY



At one year, 100% improved by at least one TR grade,
75% by at least two grades
86% reached moderate or lower TR

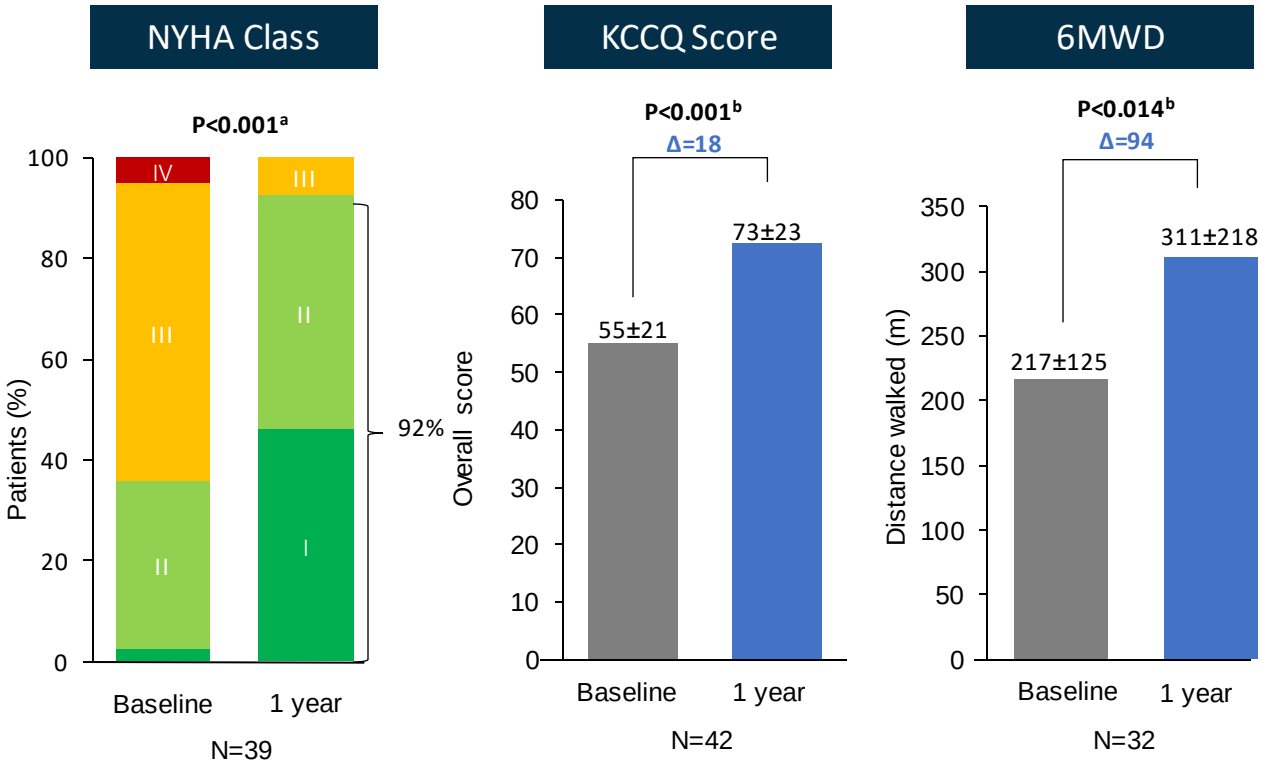
[1]Cardiovascular Research Foundation. Graphs show paired data. Two patients initially considered to have severe TR at baseline by transoesophageal echocardiography were reclassified as moderate TR by transthoracic echocardiography. [a]Wilcoxon signed-rank test.

TR, tricuspid regurgitation

Hahn R. Transcatheter tricuspid valve repair: CLASP TR study one-year results. LBT EuroPCR 2022

Clinical, Functional, and Quality of Life at One Year

THE CLASP TR STUDY

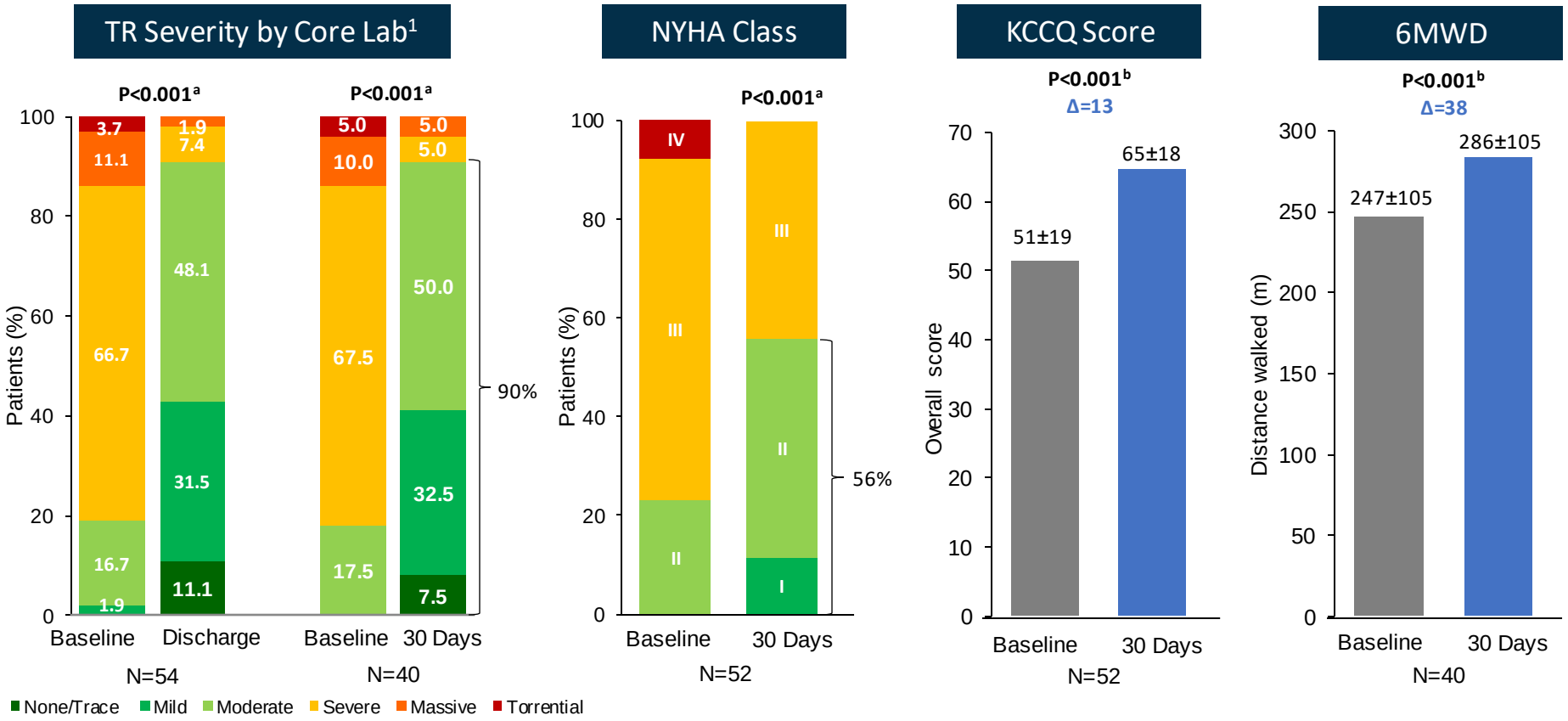


[a]Wilcoxon signed-rank test. [b]Paired t-test. *NYHA*, New York Heart Association; *KCCQ*, Kansas City Cardiomyopathy Questionnaire; *6MWD*, 6-minute walk distance.

Hahn R. Transcatheter tricuspid valve repair: CLASP TR study one-year results. LBT EuroPCR 2022

Improved TR Grade and Clinical, Functional, and Quality-of-Life Outcomes at 30 days

THE TriCLASP STUDY



88% achieved ≥ 1 TR grade reduction and 90% had ≤ moderate TR at 30 days

Graphs show paired data. [1]Core laboratory: Cardialysis. [a]Wilcoxon signed-rank test. [b]Paired t-test for mean ± SD.
NYHA, New York Heart Association; *KCCQ,* Kansas City Cardiomyopathy Questionnaire; *6MWD*, 6-minute walk distance

Baldus S. 30-Day outcomes for transcatheter tricuspid repair: TriCLASP post-market study. LBT EuroPCR 2022

Major Adverse Events (30 Days, 1 Year)

THE CLASP TR STUDY

CEC Adjudicated Major Adverse Events	30 days N=65 % (n)	1 year N=65 % (n)
Cardiovascular mortality	3.1% (2)	7.7% (5)
Myocardial infarction	0	0
Stroke	1.5% (1)	4.6% (3)
New need for dialysis or renal replacement therapy	0	0
Reintervention related to the device	0	1.5% (1)[a]
Severe bleeding*	7.7% (5)	9.2% (6)
Major access site and vascular complications requiring intervention	3.1% (2)	3.1% (2)
Composite MAE rate	**9.2% (6)**	**16.9% (11)**
Other events		
All-cause mortality	3.1% (2)	10.8% (7)
Heart failure rehospitalization	0	18.5% (12)
SLDA (core lab)¶	4.6% (3)	4.6% (3)

[a]Surgical explant of study device and successful tricuspid repair with a surgical ring.
*Severe bleeding is major, extensive, life-threatening or fatal bleeding, as defined by Mitral Valve Academic Research Consortium.
¶Core Laboratory, Cardiovascular Research Foundation. No new SLDA cases occurred after 30 days
MAE, major adverse events; SLDA, single-leaflet device attachment
Hahn R. Transcatheter tricuspid valve repair: CLASP TR study one-year results. LBT EuroPCR 2022

Adverse Events (30 Days)

THE TriCLASP STUDY

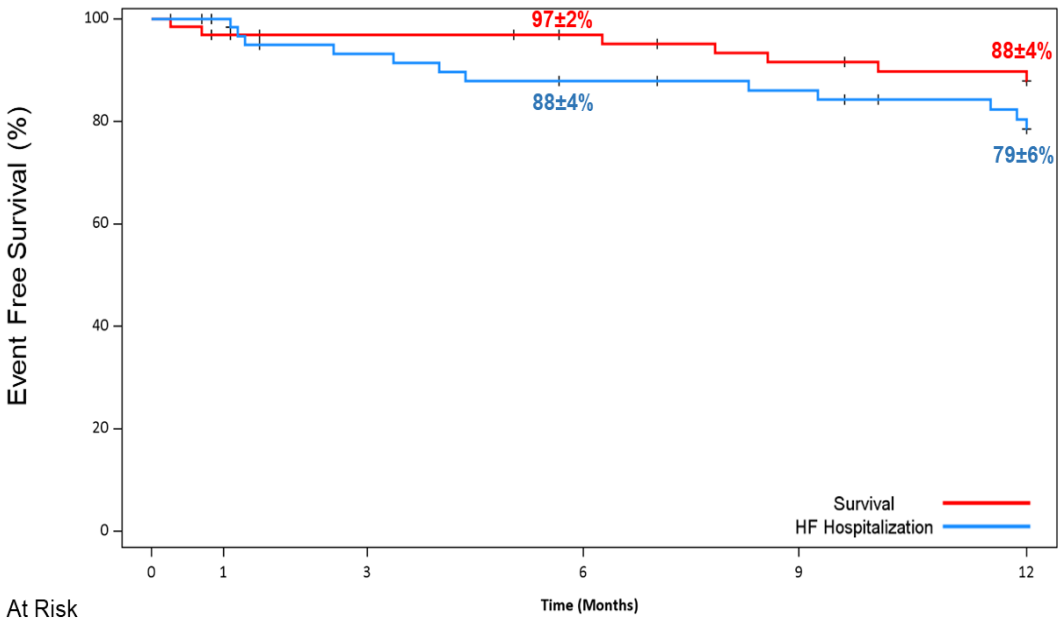
CEC-adjudicated major adverse events	30 days N=67[a] % (n)
Cardiovascular mortality	1.5% (1)
Myocardial infarction	0
Stroke	1.5% (1)
New need for dialysis or renal replacement therapy	1.5% (1)
Major cardiac structural complications	0
Device embolism¶	0
Nonelective tricuspid valve reintervention	0
Severe bleeding*	1.5% (1)
Major access site and vascular complications	0
Composite MAE rate	**3.0% (2)**
Other events	% (n/N)[a]
All-cause mortality	2.9% (2/68)
Heart failure rehospitalization	4.5% (3/66)

[a]Denominator for % calculation includes all patients who reached 30-day follow-up as well as any patients who experienced an event prior to follow-up
¶Adjudicated by the echocardiographic core laboratory
*Severe bleeding is major, extensive, life threatening or fatal as defined by Mitral Valve Academic Research Consortium
MAEs, major adverse events
Baldus S. 30-Day outcomes for transcatheter tricuspid repair: TriCLASP post-market study. LBT EuroPCR 2022

Survival and Heart Failure Hospitalization rates

THE CLASP TR STUDY

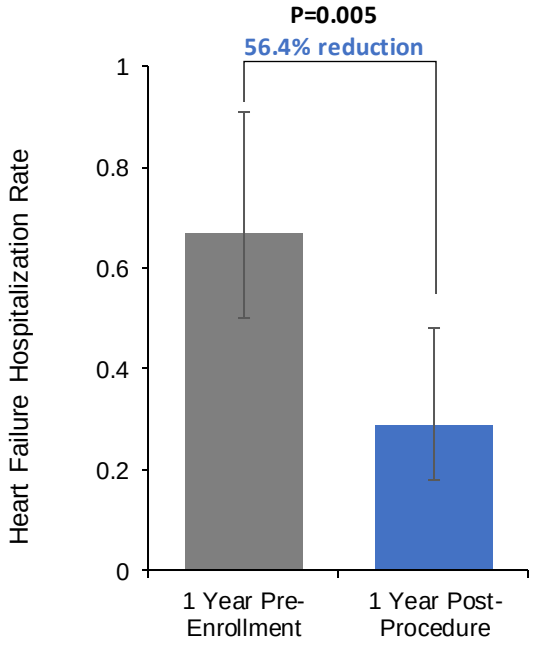
CEC-adjudicated survival and freedom from HFH[1]



At Risk		
Survival	55	49
Freedom from heart failure hospitalization	49	42

[1]Kaplan-Meier analysis estimate ± std error.
HFH, heart failure hospitalization; *CEC*, clinical events committee

Annualized HFH*



Days alive and not hospitalized for heart failure at one year: 363.1

*Pre-enrollment HFH data collected via site-reported medical history. Post-procedure HFH data was CEC adjudicated. Error bars represent 95% confidence interval. P value derived from two sample z test for incidence rate ratio on natural log scale.

Hahn R. Transcatheter tricuspid valve repair: CLASP TR study one-year results. LBT EuroPCR 2022

PASCAL Repair System TR Clinical Evidence:

- **CLASP TR study one-year results demonstrated:**
  - Significant TR reduction was sustained, with 86% achieving moderate or less TR, 100% had ≥ 1 grade reduction, and 75% had ≥ 2 grade reduction
  - Significant reduction in rate of annualized heart failure hospitalization
  - Significant improvements in NYHA class, KCCQ score, and 6MWD
  - Learnings in patient selection and device procedure contributed to overall success

- **TriCLASP study showed favourable 30-day results:**
  - 97% freedom from MAEs
  - TR reduction, with 88% of patients achieving ≥ 1 TR grade reduction, and 90% had moderate or less TR
  - Improvements in NYHA class, KCCQ score, and 6MWD

Thank You

Expert Opinions, advice and all other information expressed represent contributors' views and not necessarily those of Edwards Lifesciences.

For professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

Edwards devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

Edwards Lifesciences • Route de l'Etraz 70, 1260 Nyon, Switzerland • edwards.com

PCR

PCRonline.com