TRICuspid **I**nterventions in **H**eart **F**ailure

Results from the TRIC-I-HF-DZHK24 trial

Jörg Hausleiter

Ludwig-Maximilians-University, Munich, Germany

On behalf of the TRIC-I-HF investigators

Rationale

The rationale of the randomized TRIC-I-HF trial was to evaluate,

if a strategy of **transcatheter tricuspid repair**
in addition to optimal medical therapy

is superior to

optimal medical therapy alone

in symptomatic patients
with at least severe tricuspid regurgitation
and an increased risk for future heart failure events.

Trial Design

- Investigator initiated, prospective, multicenter, open-label, randomized controlled strategy trial in 29 German high-volume, heart valve centers
- Patient selection and enrollment at the discretion of the local heart teams
- Tricuspid repair strategy with any CE-marked tricuspid repair device
- Clinical and echocardiographic follow-up at 30 days, 1 year, followed by annual visits
- Current analysis with completed minimum 1-year follow-up of all randomized patients

- Steering committee, data and safety monitoring board, event-adjudication committee, and echocardiographic core-lab

Main Inclusion Criteria

- Symptomatic patients with at least severe tricuspid regurgitation
- On stable medical therapy including diuretic therapy for at least 30 days
- Patients at **advanced risk for future heart failure events** (at least one of the following criteria):
  - **History of heart failure hospitalization** in previous 12 months, or
  - Presence of **cardio-renal syndrome** (eGFR < 60 ml/min/1.73 body surface area), or
  - Presence of **cardio-hepatic syndrome** (elevation of at least 2 markers for cholestasis: bilirubin, alk. phosphase, or γ-GT)

Trial Endpoints

Two hierarchical primary endpoints:

1) Win ratio of all-cause mortality, heart failure hospitalization and quality of life improvement (KCCQ ≥ 15 points) at 1 year, and – if tested positive –
2) Composite of all-cause mortality and heart failure hospitalization during follow-up up to 3 years after randomization

Secondary endpoints:

- Hospitalizations for heart failure during 3 years of follow-up
- Need for cross-overs
- All-cause mortality during 3 years of follow-up
- Reduction in TR severity by core-lab
- NYHA functional class

Factors for Enabling Patient Inclusion and Randomization in a Commercial Environment

- 2:1 randomization ratio favoring tricuspid repair
- Allowance of cross-overs from medical therapy to tricuspid repair

Cross-over

Cross-over was **only** permitted **if all of the following criteria** were met:

- at least 30 days had elapsed since randomization,
- a **heart-failure decompensation had resulted in hospitalization**, and
- IV diuretic therapy was administered during that hospitalization.

Hospitalizations for the cross-over procedure were not counted as an additional endpoint.

Power Calculations for Both Primary Endpoints

1) Win ratio

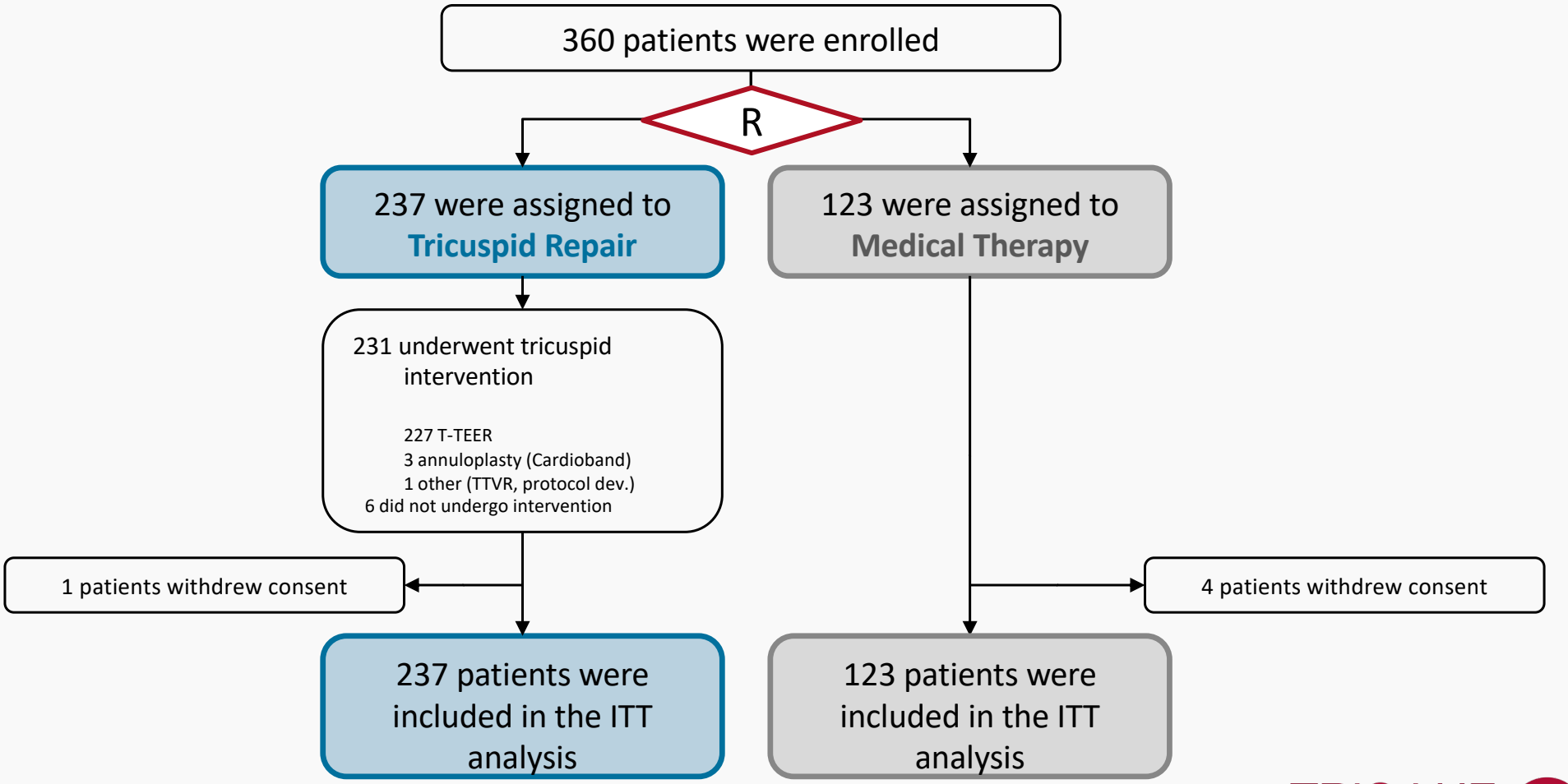
- 336 patients (224 tricuspid repair and 112 medical therapy)
- 40% wins, 22% losses, and 38% ties
- Power 85%, two-sided alpha 5%, 2:1 randomization

2) Composite of all-cause death and heart failure hospitalization

- 324 patients (216 tricuspid repair and 108 medical therapy)
- Assumed incidences of 45% (medical therapy) and 30% (tricuspid repair)
- Power 90%, two-sided alpha 5%, 2:1 randomization

→ Assuming a drop-out rate of 10%, 360 randomized patients were required.

TRIC-I-HF Flow Chart



Patient Characteristics

	Tricuspid repair (N=237)	Medical therapy (N=123)
Age (years)	80.6 ±5.9	80.2 ±6.6
Female sex (%)	56.5%	56.1%
EuroSCORE II	4.3 (2.9 – 6.2)	4.2 (2.8 – 7.9)
Tri-SCORE	4.0 (3.0 – 6.0)	5.0 (4.0-6.0)
NYHA class III or IV (%)	**76.4%**	**72.4%**
Atrial fibrillation or flutter (%)	92.0%	97.6%
Pacemaker / ICD with RV lead (%)	**20.7%**	**20.3%**
Diabetes mellitus (%)	25.3%	26.0%
Previous myocardial infarction (%)	5.9%	13.0%
Previous CABG (%)	7.6%	11.4%
Heart failure hospitalization prior 12 months (%)	**57.0%**	**51.2%**
Cardio-renal syndrome (%)	**81.9%**	**81.3%**
Cardio-hepatic syndrome (%)	**44.2%**	**50.0%**
Hemoglobin (mg/dl)	12.3 ± 2.3	12.4 ± 2.3
NTproBNP (pg/ml)	2,022 (1,229 – 3,283)	2,076 (1,195 – 4,066)

Baseline Medication Data

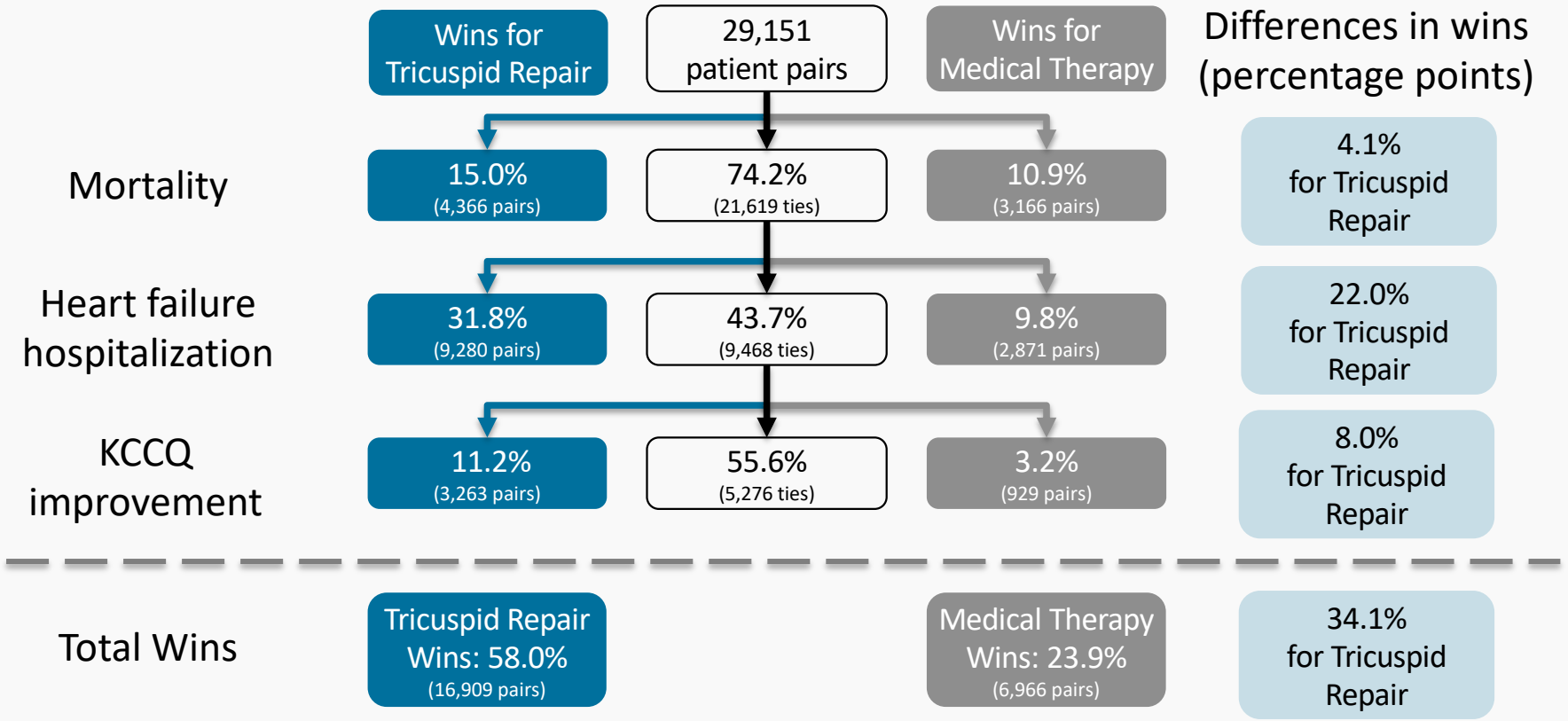
	Tricuspid repair (N=237)	Medical therapy (N=123)
Loop diuretic (%)	**93.2%**	**95.9%**
Thiazide diuretic (%)	15.2%	17.9%
Mineralocorticoid receptor antagonist (%)	**43.5%**	**42.3%**
RAS inhibitor (%)	68.8%	65.0%
Beta-blocker (%)	89.0%	86.2%
SGLT2i (%)	**52.7%**	**51.2%**

Procedural Characteristics and Safety Events @ 30 Days

	Tricuspid repair (N=237)
Underwent TTVI (%)	231 (97.5%)
Transcatheter edge-to-edge repair (T-TEER)	**98.3%**
Transcatheter annuloplasty	1.3%
Other	0.4%
T-TEER device	
PASCAL implantation	**65.6%**
TriClip implantation	33.0%
No device implantation¶	1.3%
Number of T-TEER devices / pt (%)	
1 device strategy	28.6%
2 device strategy	**62.0%**
≥3 device strategy	9.4%

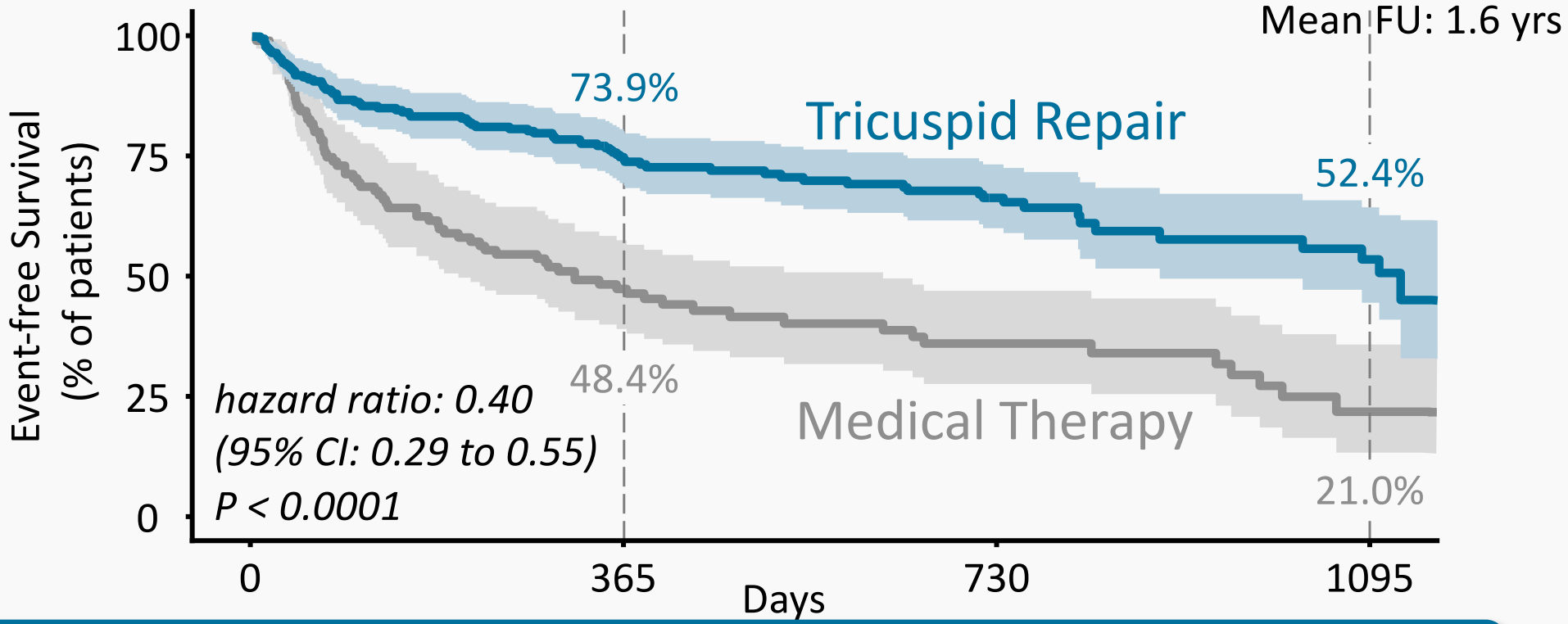
	Tricuspid repair (N=237)
All-cause mortality (%)	1 (0.4%)
Major bleeding (%)	6 (2.5%)
Mechanical circulatory support (%)	0 (0.0%)
Device embolization (%)	0 (0.0%)
Single leaflet device attachment (%)	4 (1.7%)
Tricuspid valve reintervention (%)	2 (0.8%)
Tricuspid valve surgery (%)	1 (0.4%)
New pacemaker implantation (%)	1 (0.4%)
New onset of renal failure (%)	4 (1.7%)
Any major adverse event (%)	**14 (5.9%)**

1st Primary Endpoint: Win Ratio Analysis



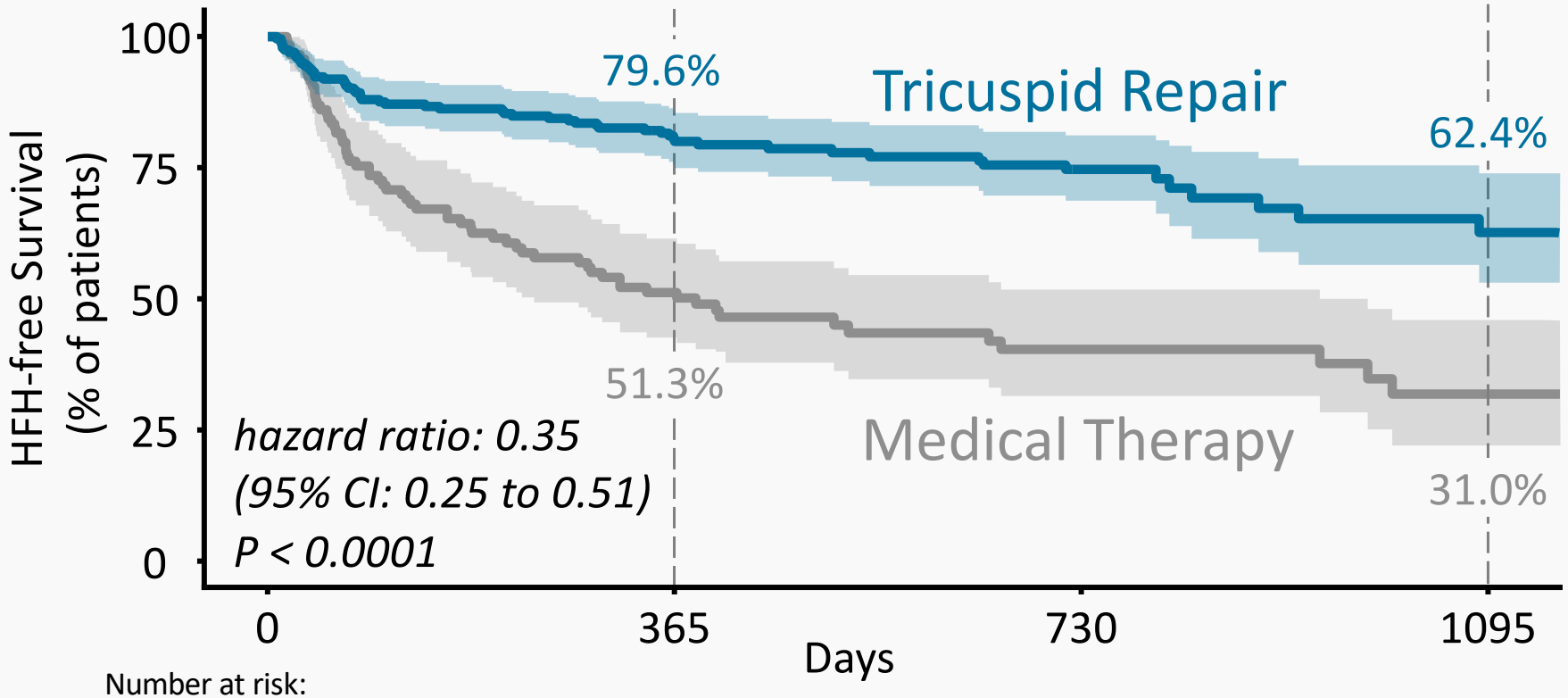
Win Ratio: 2.42 (95% CI: 1.76 – 3.33); $P < 0.0001$

2nd Primary Endpoint: Mortality or Heart Failure Hospitalization



NNT to prevent one death or HFH at 1 year: 4 (95% CI: 3-6) patients

Secondary Endpoint: Heart Failure Hospitalization During Follow-up



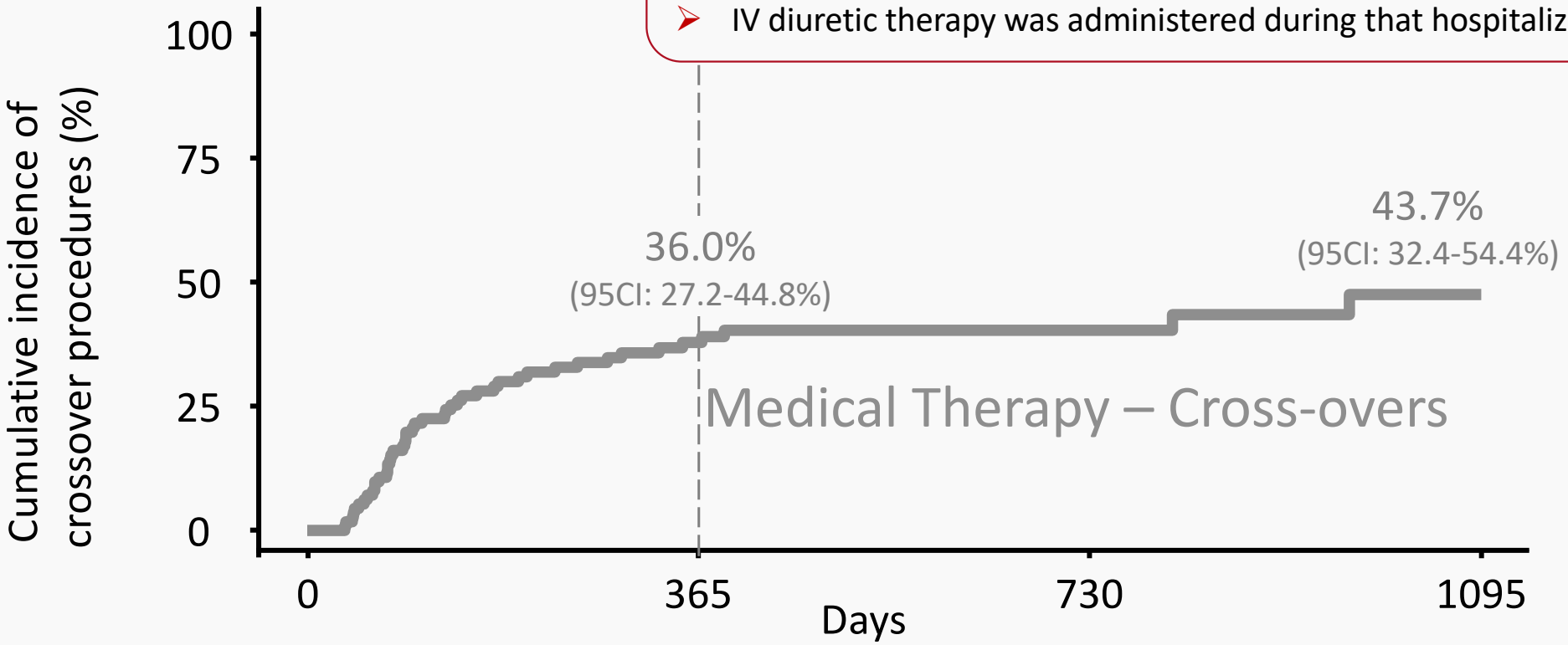
Number at risk:

Tricuspid Repair	237	152	86	23
Medical Therapy	123	52	24	5

Cumulative Cross-Overs

Cross-over was permitted **only if all of the following criteria** were met:

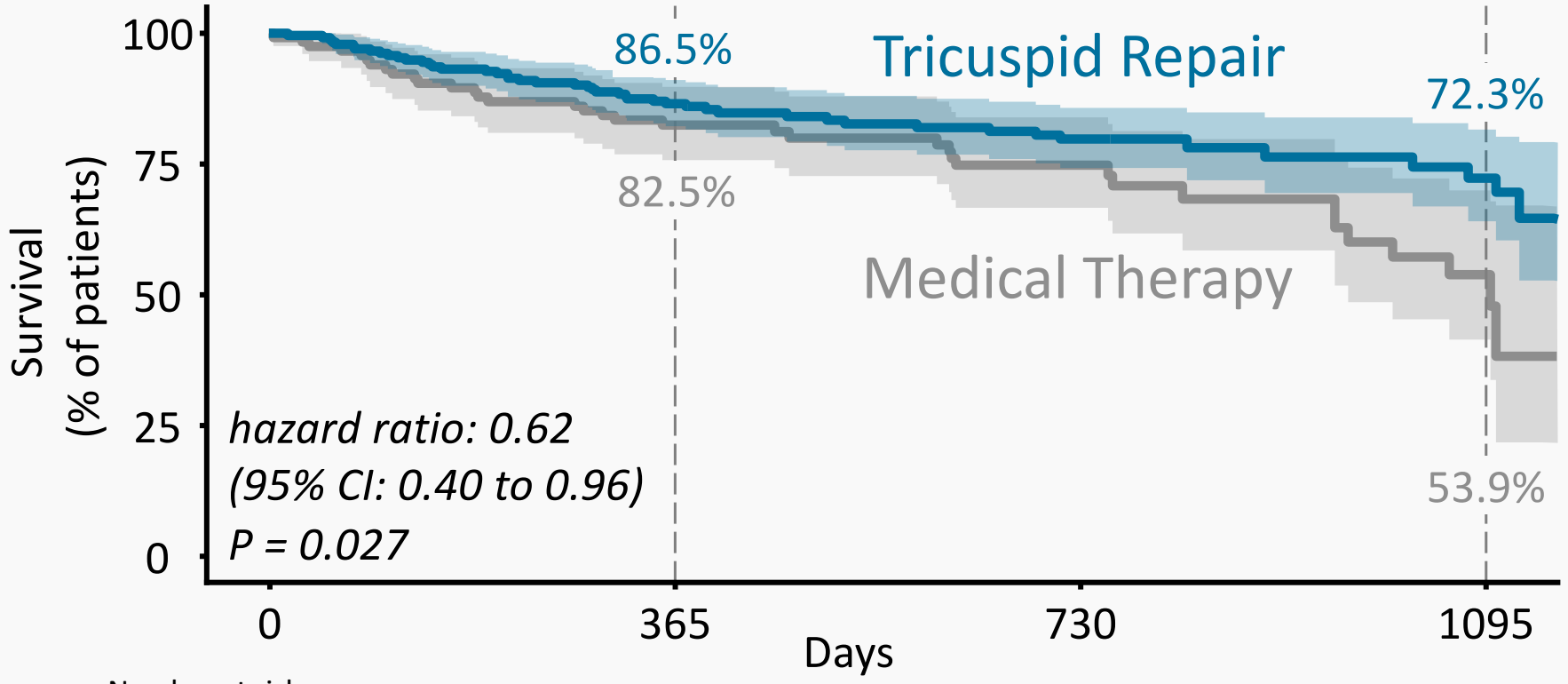
- at least 30 days had elapsed since randomization,
- a heart-failure decompensation had resulted in hospitalization, and
- IV diuretic therapy was administered during that hospitalization.



Number at risk:

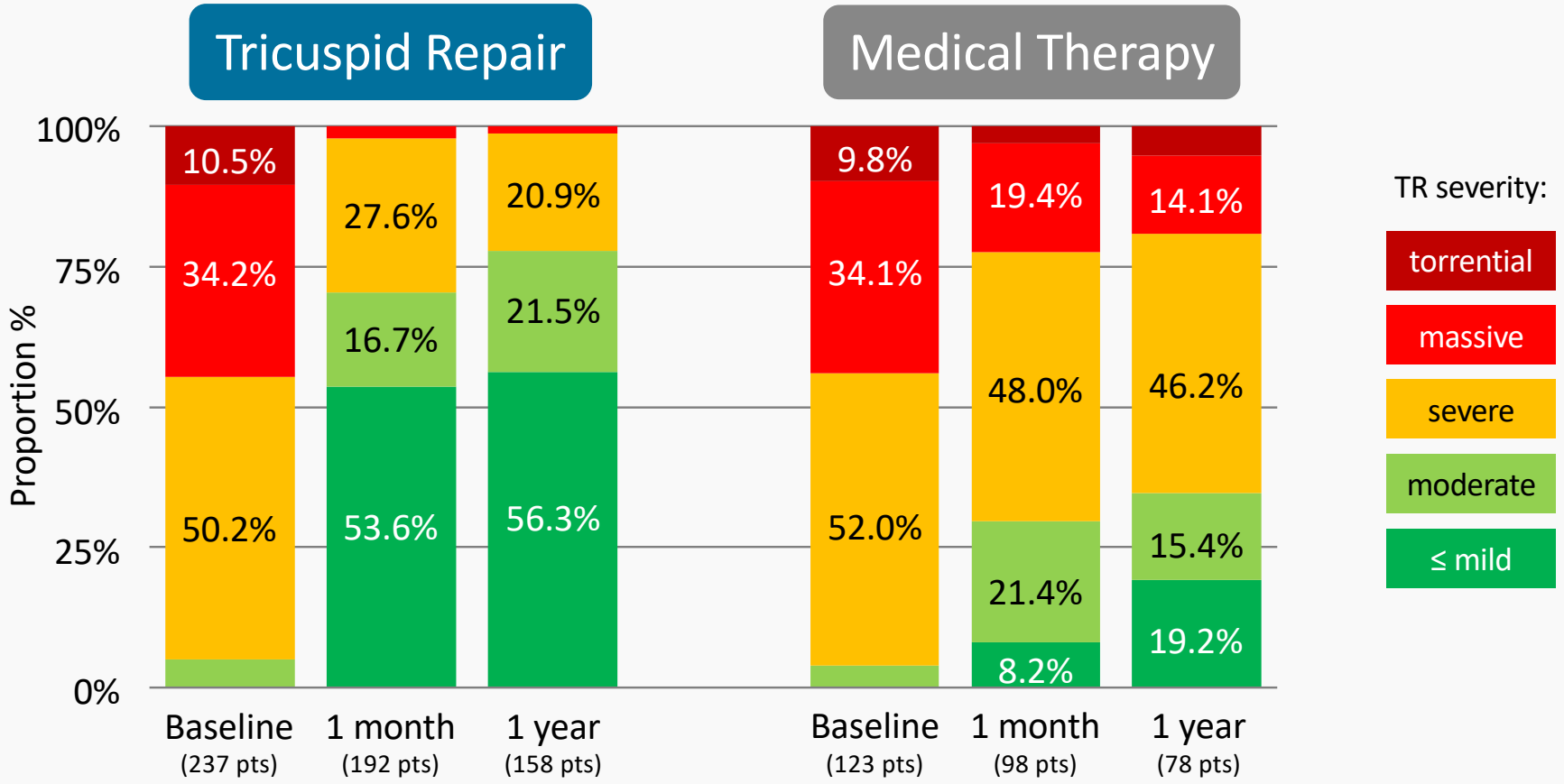
Medical Therapy	123	57	30	7

Secondary Endpoint: All-Cause Mortality During Follow-up

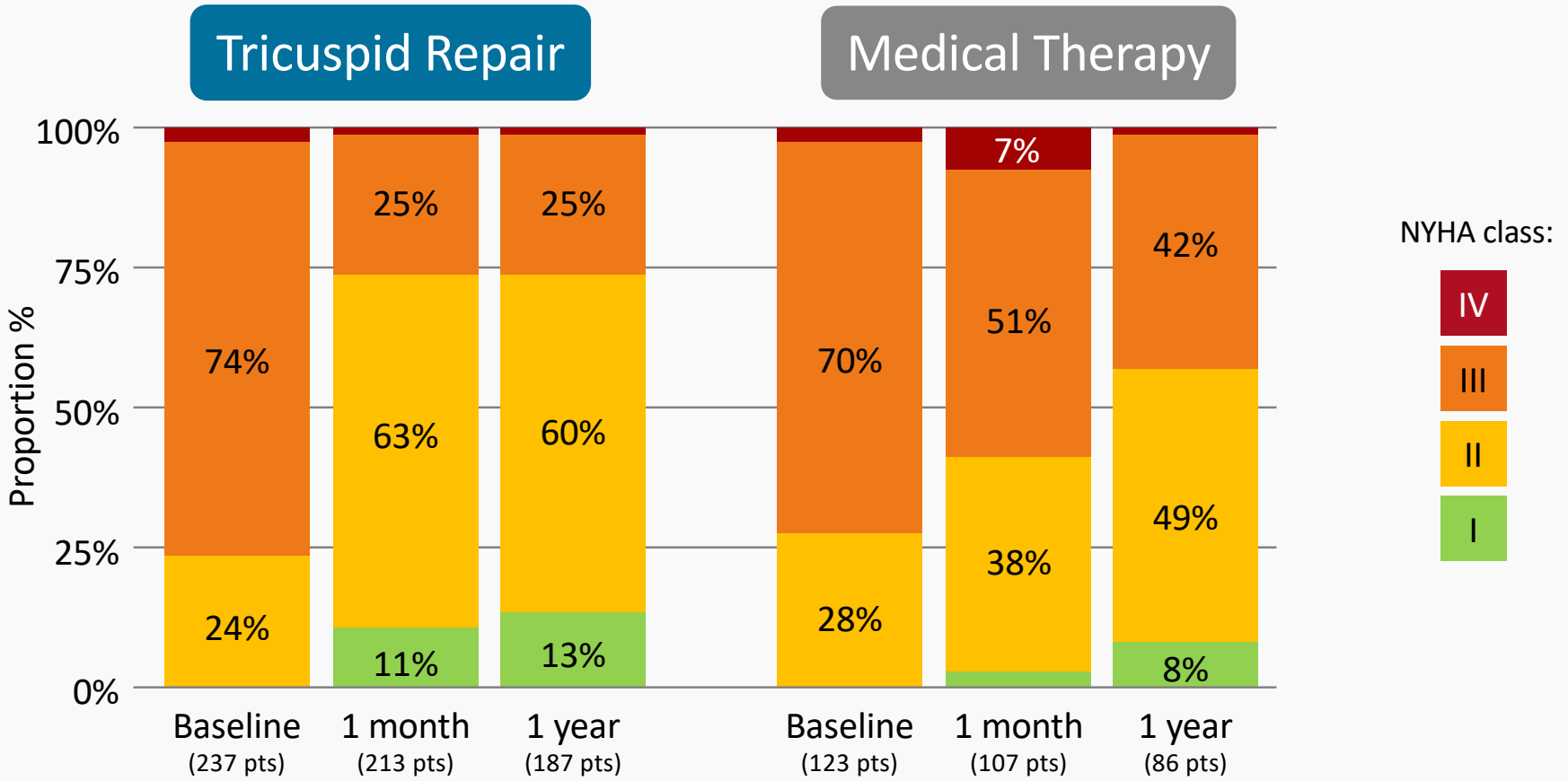


Number at risk:				
Tricuspid Repair	237	178	102	32
Medical Therapy	123	85	47	12

Secondary Endpoint: Echocardiographic TR Severity



Secondary Endpoint: NYHA Functional Class



Thank You to all Participting Patients!

Steering Committee: Prof. Dr. J. Hausleiter, Prof. Dr. S. Massberg; Prof. Dr. V. Rudolph; Prof. Dr. P. Lurz; Prof. Dr. S. Baldus; Prof. Dr. S. von Bardeleben

Event-adjudication committee: Prof. Dr. P. Hoppmann; Priv.-Doz. Dr. L. Bott-Flügel; Prof. Dr. A. Knez

Data and safety monitoring board: Prof. Dr. J. Pache; Prof. Dr. K. Tiroch; Prof. Dr. A. May

Echocardiographic Corelab: O. Soliman, MD, PhD; R. Byrne, MD, PhD; M. Ali Jawed, MD; M. Vattaparambil

Trial Statistician: Dr. V. Kehl

Clinical Research Organization: Dr. C. Blankenstein, Dr. S. Egert-Schwender, Dr. M. Grzeschniok, M. Rotter, and P. Wagner; Münchner Studienzentrum (MSZ), TUM School of Medicine and Health, Technical University of Munich, Munich, Germany

Trial investigators: Prof. Dr. T. Stocker, Prof. Dr. S. Massberg, Prof. Dr. M. Näbauer, Dr. L. Stolz, Dr. P. Doldi, Prof. Dr. L. Weckbach, Dr. J. Novotny (Department of Cardiology, LMU University Hospital, LMU Munich, Munich, Germany); Prof. Dr. T. Geisler, Prof. Dr. M. Gawaz (Department of Cardiology and Angiology, Eberhard Karls University Tübingen, Tübingen, Germany); Prof. Dr. W. Rottbauer, Prof. Dr. M. Keßler (Department of Cardiology, University Heart Center, Ulm, Germany); Prof. Dr. P. Lurz, Prof. Dr. S. von Bardeleben, PD Dr. T. Ruf (Department of Cardiology, University Medical Centre of the Johannes Gutenberg University, Mainz, Germany); Prof. Dr. E. Lubos, PD Dr. D. Schewel (Department of Internal Medicine and Cardiology, Katholisches Marienkrankenhaus, Hamburg, Germany); Prof. Dr. C. Frerker, Prof. Dr. I. Eitel (University Heart Center, Schleswig-Holstein University, Lübeck, Germany); PD Dr. N. Schofer, PD Dr. D. Kalbacher, Dr. B. Koell, Dr. L. Waldschmidt (Department of Cardiology, University Heart and Vascular Center Hamburg, University Medical Center Hamburg-Eppendorf); Dr. J. Frank, Prof. Dr. D. Frank (Department of Cardiology and Internal Intensive Medicine, University Medical Center Schleswig-Holstein Campus Kiel, Kiel, Germany); Dr. T. Kister, Prof. Dr. P. Lurz, Prof. Dr. H. Thiele (Department of Cardiology, Heart Center Leipzig at Leipzig University, Leipzig, Germany); PD Dr. R. Osteresch, Prof. Dr. R. Hambrecht, Prof. Dr. Wienbergen, Dr. U. Hanses (Bremen Institute for Heart and Circulation Research (BIHKF) at the Klinikum Links der Weser, Bremen, Germany); Prof. Dr. V. Rudolph, PD Dr. M. Gerçek, Dr. K.P. Friedrichs, Prof. Dr. T. Rudolph (Ruhr University Bochum, Heart and Diabetes Center NRW, Department of General and Interventional Cardiology/ Angiology, Bad Oeynhausen, Germany); Prof. Dr. A. Lauten (Department of General and Interventional Cardiology and Rhythmology, Helios Klinikum Erfurt, Germany); PD. Dr. E. Xhepa, Prof. Dr. M. Joner, Dr. N. Altaner, Dr. M. Kühlein-Lehr, Dr. F.M. Haug, Dr. L.-S. Scholl, Dr. L. Haimerl (Department of Cardiology, Deutsches Herzzentrum München, Munich, Germany); Dr. J. Rothe, PD Dr. C. Besler, Dr. N. Löffelhardt, Dr. M. Wild, Dr. K. Franke (Department of Cardiology and Angiology, University Heart Center Freiburg-Bad Krozingen, Bad Krozingen, and Faculty of Medicine, Freiburg University, Germany); Prof. Dr. T. Rassaf, Prof. Dr. A.A. Mahabadi, Dr. F. Schindhelm (Department of Cardiology and Vascular Medicine, West German Heart and Vascular Center, University Hospital Essen, Essen, Germany); Dr. C. Iliadis, Prof. Dr. S. Baldus, Prof. Dr. R. Pfister (Department of Cardiology, University Hospital Cologne, Cologne, Germany); Prof. Dr. G. Nickenig, Dr. J. Vogelhuber, Dr. P. Hugen (Heart Center University Hospital Bonn, Bonn, Germany); Prof. Dr. D.M. Leistner, PD Dr. P. Seppelt, PD Dr. S. Steven, Dr. K. Hemmann (Department of Cardiology and Angiology, Goethe University, Frankfurt am Main, Germany); PD Dr. E. Tigges, Dr. D.-U. Chung, Dr. T. Ubben, A. Veliqi, Dr. Y. Nejahsie, Dr. N. Geßler, Dr. A. Zahir-Akkra (Department of Cardiology and Intensive Care Medicine, Asklepios Clinic St. Georg, Hamburg, Germany); Prof. Dr. A. Polzin, Dr. F. Voß (Department of Cardiology, Pulmonology, and Vascular Medicine, Heinrich Heine University Düsseldorf, Düsseldorf, Germany); Prof. Dr. U. Landmesser, Dr. M. Reinthaler Dr. F. Barbieri (Department of Cardiology, Angiology and Intensive Care Medicine, Deutsches Herzzentrum der Charité, Berlin, Germany); Prof. Dr. C. Butter (Department of Cardiology, University Hospital Heart Centre Brandenburg, Brandenburg Medical School (MHB) Theodor Fontane, Bernau/Neuruppin, Germany); Prof. Dr. M. Konstandin, Prof. Dr. N. Frey, Dr. M. Eden, Dr. M. Krauss, Dr. I. Hörbrandt, Dr. P. Schlegel, Prof. Dr. N. Geis (Department of Cardiology, University Hospital Heidelberg, Ruprecht-Karls-University Heidelberg, Heidelberg, Germany); Dr. P. Nikolai, Prof. Dr. R. Bekeredjian (Department of Cardiology, Robert-Bosch-Hospital, Stuttgart, Germany); Dr. med. A. Wolf, Prof. M. Seyfarth und E. Ruleva (Helios Universitätsklinikum Wuppertal, Universität Witten/Herdecke, Wuppertal, Germany); Prof. Dr. M.M. Vorpahl, H. Beucher (Department of Cardiology, Helios Klinikum Siegburg, Germany); Prof. Dr. S. Möbius-Winkler, Prof. Dr. P.C. Schulze, Dr. A. Hamadanchi (Department of Internal Medicine I, Cardiology, Angiology, Intensive Medical Care, University Hospital Jena, Jena, Germany)

Funding: German Center for Cardiovascular Research, Edwards Lifesciences, LMU Munich

ESC CONGRESS 2026 MUNICH

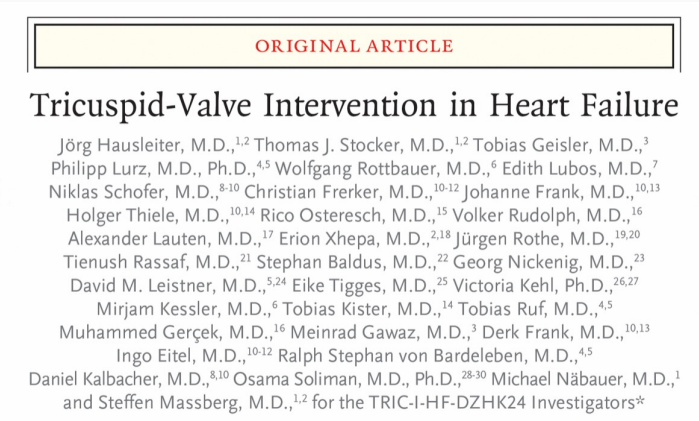
LMU KLINIKUM

TRIC-I-HF DZHK TRIAL 24

Conclusion

A strategy of **transcatheter tricuspid-valve repair** in addition to medical therapy **is superior** to medical therapy in patients with severe TR.

Tricuspid repair improves the quality of life of our patients,
but it also results in a **significant reduction in hard clinical events**,
including heart failure hospitalizations as well as all-cause mortality.



ORIGINAL ARTICLE

Tricuspid-Valve Intervention in Heart Failure

Jörg Hausleiter, M.D.,[1,2] Thomas J. Stocker, M.D.,[1,2] Tobias Geisler, M.D.,[3] Philipp Lurz, M.D., Ph.D.,[4,5] Wolfgang Rottbauer, M.D.,[6] Edith Lubos, M.D.,[7] Niklas Schofer, M.D.,[8-10] Christian Frerker, M.D.,[10-12] Johanne Frank, M.D.,[10,13] Holger Thiele, M.D.,[10,14] Rico Osteresch, M.D.,[15] Volker Rudolph, M.D.,[16] Alexander Lauten, M.D.,[17] Erion Xhepa, M.D.,[2,18] Jürgen Rothe, M.D.,[19,20] Tienush Rassaf, M.D.,[21] Stephan Baldus, M.D.,[22] Georg Nickenig, M.D.,[23] David M. Leistner, M.D.,[5,24] Eike Tigges, M.D.,[25] Victoria Kehl, Ph.D.,[26,27] Mirjam Kessler, M.D.,[6] Tobias Kister, M.D.,[14] Tobias Ruf, M.D.,[4,5] Muhammed Gerçek, M.D.,[16] Meinrad Gawaz, M.D.,[3] Derk Frank, M.D.,[10,13] Ingo Eitel, M.D.,[10-12] Ralph Stephan von Bardeleben, M.D.,[4,5] Daniel Kalbacher, M.D.,[8,10] Osama Soliman, M.D., Ph.D.,[28-30] Michael Näbauer, M.D.,[1] and Steffen Massberg, M.D.,[1,2] for the TRIC-I-HF-DZHK24 Investigators*

The NEW ENGLAND JOURNAL of MEDICINE

ESC CONGRESS 2026 MUNICH

LMU KLINIKUM

TRIC-I-HF
DZHK TRIAL 24