ORIGINAL ARTICLE

Tricuspid-Valve Intervention in Heart Failure

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ABSTRACT

BACKGROUND

The effect of transcatheter tricuspid-valve repair on clinical outcomes, including death and hospitalization for heart failure, in patients with severe tricuspid regurgitation remains uncertain.

METHODS

We randomly assigned patients with symptomatic severe tricuspid regurgitation and an increased risk of future heart-failure events in a 2:1 ratio to tricuspid-valve repair plus medical therapy (tricuspid-repair group) or medical therapy alone (medical-therapy group). The first primary end point was a hierarchical composite of death from any cause, hospitalization for heart failure, and quality-of-life improvement at 1 year, assessed by win ratio. If the between-group difference was significant, a second primary end point would be tested: a composite of death from any cause or hospitalization for heart failure through 3 years.

RESULTS

A total of 360 patients underwent randomization (237 patients were assigned to the tricuspid-repair group and 123 to the medical-therapy group). The mean (±SD) age of the patients was 80.3±6.4 years, and 56.4% were women. The win ratio for the first primary end point was 2.42 (95% confidence interval [CI], 1.76 to 3.33; P<0.001), favoring tricuspid-valve repair. The Kaplan–Meier estimate for freedom from death from any cause or hospitalization for heart failure (second primary end point) through 3 years was 52.4% (95% CI, 43.2 to 63.6) in the tricuspid-repair group and 21.0% (95% CI, 12.7 to 34.6) in the medical-therapy group (hazard ratio for death from any cause or hospitalization for heart failure, 0.40; 95% CI, 0.29 to 0.55; P<0.001). Major adverse events within 30 days occurred in 14 patients (5.9%) in the tricuspid-repair group.

CONCLUSIONS

Among patients with symptomatic severe tricuspid regurgitation, transcatheter tricuspid-valve repair plus medical therapy was superior to medical therapy alone with respect to a hierarchical composite of death from any cause, hospitalization for heart failure, and quality-of-life improvement at 1 year and was also associated with a lower risk of a composite of death from any cause or hospitalization for heart failure through 3 years. (Funded by the German Center for Cardiovascular Research and others; TRIC-I-HF ClinicalTrials.gov number, NCT04634266.)

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Tricuspid regurgitation is associated with increased morbidity and mortality.[1,2] Options for medical therapy remain limited, and isolated tricuspid-valve surgery is rarely performed owing to increased operative risk.[3,4] Transcatheter tricuspid-valve interventions have emerged as an alternative to surgery. Among these, tricuspid edge-to-edge repair is the most widely adopted and is associated with high procedural success and a favorable safety profile.[5,6]

To date, two randomized, controlled trials have compared transcatheter tricuspid-valve repair with medical therapy alone and shown improvements in quality of life but no apparent reductions in hospitalization for heart failure or in mortality at 1 year.[7,8] In a recent analysis, 2-year outcome data suggested reductions in hospitalization for heart failure.[9] However, the low event rates observed in both trials limited the ability to determine the benefits of transcatheter valve repair. Consequently, the effect of transcatheter tricuspid-valve repair in patients at increased risk for heart-failure events remains uncertain.

The Tricuspid Intervention in Heart Failure (TRIC-I-HF) trial was designed to evaluate whether a strategy of transcatheter tricuspid-valve repair plus medical therapy would result in a lower risk of death and hospitalization for heart failure than medical therapy alone among patients with severe tricuspid regurgitation who are at increased risk for future heart-failure events.

Methods

Trial Design

TRIC-I-HF is an investigator-initiated, prospective, multicenter, open-label, randomized, controlled strategy trial testing the superiority of transcatheter tricuspid-valve repair plus medical therapy (tricuspid-repair group) over medical therapy alone (medical-therapy group). The trial was conducted at 29 high-volume heart-valve centers in Germany. A full list of participating sites is provided in Table S1 in the Supplementary Appendix, available with the full text of this article at NEJM.org.

The trial design and rationale have been described previously, and the trial protocol and statistical analytical plan are available at NEJM.org.[10] All the participants provided written informed consent. The trial was approved by the responsible ethics committees. Hospitalizations were adjudicated by an independent clinical-events committee. Echocardiographic data were analyzed by an independent core laboratory.

The trial was conducted in accordance with the principles of the Declaration of Helsinki. Trial oversight and author responsibilities are described in the Supplementary Appendix. The authors had unrestricted access to the data, prepared all drafts of the manuscript, and vouch for the completeness and accuracy of the data and for the fidelity of the trial to the protocol.

Patient Selection

Patient selection and enrollment was at the discretion of the local heart team, without need for approval by a central eligibility committee or screening for baseline medical treatment. Patients who were eligible for enrollment had at least severe tricuspid regurgitation on a five-grade scale (mild, moderate, severe, massive, and torrential), despite medical therapy including diuretic therapy adjusted to the individual optimal dose for at least 30 days. Patients were considered to be at advanced risk for future heart-failure events as defined by either a history of decompensation in the previous 12 months or the presence of a cardiorenal or cardiohepatic syndrome. In these patients with heart failure, a cardiorenal syndrome was defined as chronic kidney disease (estimated glomerular filtration rate, <60 ml per minute per 1.73 m^2 of body-surface area), and a cardiohepatic syndrome was defined by elevated levels of at least two of three laboratory markers of cholestasis: bilirubin, alkaline phosphatase, and γ-glutamyltransferase.[10]

The presence of advanced risk of future heart-failure events was added to the protocol as an additional inclusion criterion in July 2023. All the patients underwent preprocedural right heart catheterization to allow comprehensive hemodynamic characterization and selection on the basis of previously identified cutoff values.[11] Detailed inclusion and exclusion criteria are listed in Table S2.

Randomization and Follow-up

Patients were randomly assigned in a 2:1 ratio to the tricuspid-repair group or the medical-therapy group through a secure Web-based system. Randomization was conducted in permuted blocks, with stratification according to trial site and severity of tricuspid regurgitation. Transcatheter

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valve repair was recommended to be performed within 14 days after randomization. Clinical follow-up in both groups was conducted at 1 and 12 months, followed by annual visits up to 3 years (with a window of ±6 weeks). For this analysis, follow-up was completed, with the last randomly assigned patient reaching the 12-month follow-up visit.

STRATEGY FOR TRANSCATHETER TRICUSPID-VALVE REPAIR

The local heart-valve team selected from devices that have received a European Certificate of Conformity (known as the CE mark) for transcatheter tricuspid-valve repair suitable for the individual patient. The commercially available CE-marked devices included the PASCAL system and the Cardioband system (both Edwards Lifesciences) and the TriClip system (Abbott Cardiovascular).

END POINTS

The first primary end point was a hierarchical composite of death from any cause, hospitalization for heart failure, and quality-of-life improvement at 12 months, as assessed by means of the Kansas City Cardiomyopathy Questionnaire (KCCQ), with a clinically meaningful improvement defined as an increase of at least 15 points; scores on the KCCQ range from 0 to 100, with higher scores indicating better health status. The second primary end point was a composite of death from any cause or hospitalization for heart failure, assessed in a time-to-event analysis at a minimum follow-up of 12 months. Crossover from medical therapy to transcatheter tricuspid-valve repair 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 intravenous diuretic therapy was administered during that hospitalization. Accordingly, crossover was allowed only after a patient had had a primary end-point event, and any subsequent hospitalization for the crossover procedure was not counted as an additional end-point event. Secondary end points included the individual components of the composite end point, echocardiographic variables, and patient-reported outcome measures. A list of all prespecified secondary end points is provided in Table S3.

STATISTICAL ANALYSIS

For the first primary end point, we calculated that a sample size of 224 patients in the tricuspid-repair group and 112 patients in the medical-therapy group (a total of 336 patients) would provide 85% power, assuming a win ratio of 1.818 and a significance level of 5% for a two-sided test. This calculation also assumes that the proportion of wins is 0.4, the proportion of losses is 0.22, and the proportion of ties is 0.38. For the sample-size calculation for the second coprimary end point, we assumed an incidence of 45% in the medical-therapy group and 30% in the tricuspid-repair group. Assuming a two-sided significance level of 5%, a power of 90%, and a 2:1 randomization ratio, we calculated that 324 patients would be required. To account for anticipated dropouts, the target sample size was increased to 360 patients.

All analyses were conducted according to the intention-to-treat principle in the full analysis population, which included all the patients who underwent randomization. Baseline and follow-up demographic and clinical characteristics are summarized with standard descriptive statistics. The two primary end points were tested in a hierarchical manner in a closed testing procedure. The first primary end point was evaluated by means of the Finkelstein–Schoenfeld method and summarized as a win ratio with corresponding 95% confidence intervals across all possible pairwise comparisons between the trial groups. If the difference in the win-ratio analysis was significant, the second coprimary end point would be analyzed with the use of a two-sided log-rank test to compare event-free survival between trial groups. Kaplan–Meier methods and stratified Cox proportional-hazards models were used to estimate event-free survival and hazard ratios with 95% confidence intervals. Both tests were two-sided at a significance level of 0.05 and stratified according to the severity of tricuspid regurgitation for the main analysis.

There were no interim efficacy analyses. No adjustments for multiplicity were performed for secondary end points, and the widths of the confidence intervals should not be used to infer definitive treatment effects. Detailed statistical methods have been published[10] and are described in further detail, including handling of missing data, in the Supplementary Appendix.

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RESULTS

TRIAL POPULATION

From March 2022 through June 2025, a total of 360 patients underwent randomization, with 237 patients assigned to the tricuspid-repair group and 123 patients to the medical-therapy group (Fig. S1). Participating German heart-valve centers had substantial experience in transcatheter tricuspid-valve repair, with a total mean (±SD) of 176±163 procedures before trial-site initiation. The mean age of the patients was 80.3±6.4 years (range, 53 to 92), and 56.4% were women (Table 1). Baseline characteristics were well balanced between the two groups and reflect a trial population at increased risk for future heart-failure events, with 75.0% having New York Heart Association (NYHA) class III or IV heart failure, 55.0% hospitalized for heart failure in the previous year, 81.7% having cardiorenal syndrome, and 46.2% having cardiohepatic syndrome. Medical therapy for right heart failure included loop diuretics (in

Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Tricuspid Repair (N=237)	Medical Therapy (N=123)
Age — yr	80.6±5.9	80.2±6.6
Female sex — no. (%)	134 (56.5)	69 (56.1)
Race or ethnic group — no. (%)†		
White	195 (82.3)	101 (82.1)
Other	13 (5.5)	6 (4.9)
Missing data	29 (12.2)	16 (13.0)
Body-mass index‡	26.1±5.3	25.9±5.0
Median EuroSCORE II score (IQR) — %§	4.3 (2.9–6.2)	4.2 (2.8–7.9)
Median TRI-SCORE (IQR) — points¶	4.0 (3.0–6.0)	5.0 (4.0–6.0)
NYHA class III or IV heart failure — no. (%)	181 (76.4)	89 (72.4)
Atrial fibrillation or flutter — no. (%)	218 (92.0)	120 (97.6)
Diabetes mellitus — no. (%)	60 (25.3)	32 (26.0)
Arterial hypertension — no. (%)	188 (79.3)	101 (82.1)
Dyslipidemia — no. (%)	100 (42.2)	54 (43.9)
Coronary artery disease — no. (%)	110 (46.4)	68 (55.3)
Previous myocardial infarction — no. (%)	14 (5.9)	16 (13.0)
Previous CABG — no. (%)	18 (7.6)	14 (11.4)
Previous stroke or TIA — no. (%)	22 (9.3)	17 (13.8)
COPD — no. (%)	23 (9.7)	15 (12.2)
CIED with right ventricular lead — no. (%)	49 (20.7)	25 (20.3)
Hospitalization for heart failure in previous 12 mo — no. (%)	135 (57.0)	63 (51.2)
Cardiorenal syndrome — no. (%)‖	194 (81.9)	100 (81.3)
Estimated GFR — ml/min/1.73 m^2	46.0±17.5	43.7±16.3
Cardiohepatic syndrome — no./total no. (%)**	80/181 (44.2)	46/92 (50.0)
Bilirubin — mg/dl	0.9±0.5	0.9±0.5
Median γ-glutamyltransferase (IQR) — U/liter	84 (41–155)	79 (43–138)
Alkaline phosphatase — U/liter	113.5±54.4	115.7±53.0
Hemoglobin — mg/dl	12.3±2.3	12.4±2.3
Median NT-proBNP (IQR) — pg/ml	2022 (1229–3283)	2076 (1195–4066)
KCCQ score††	51.9±22.3	52.4±23.5
6-Min walk distance — m‡‡	240.1±128.4	233.4±117.8

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Table 1. (Continued.)

Characteristic	Tricuspid Repair (N=237)	Medical Therapy (N=123)
Tricuspid regurgitation at baseline — no. (%)		
Moderate	12 (5.1)	5 (4.1)
Severe	119 (50.2)	64 (52.0)
Massive	81 (34.2)	42 (34.1)
Torrential	25 (10.5)	12 (9.8)
Median tricuspid annular plane systolic excursion (IQR) — mm§§	19.1 (16.5–22.0)	18.0 (15.2–20.8)
Median right ventricular fractional area change (IQR) — %¶¶	37.1 (31.6–44.3)	36.4 (31.2–40.7)

* Plus–minus values are means ±SD. CABG denotes coronary-artery bypass grafting, CIED cardiac implantable electronic device, COPD chronic obstructive pulmonary disease, GFR glomerular filtration rate, IQR interquartile range, NT-proBNP N-terminal pro–B-type natriuretic peptide, NYHA New York Heart Association, and TIA transient ischemic attack.
† Race and ethnic group were reported by the patient.
‡ The body-mass index is the weight in kilograms divided by the square of the height in meters.
§ Scores on the European System for Cardiac Operative Risk Evaluation II (EuroSCORE II) range from 1 to 100%, with higher scores indicating a greater risk of in-hospital death after cardiac surgery.
¶ The TRI-SCORE ranges from 0 to 12, with higher scores indicating a greater risk of in-hospital death after isolated tricuspid-valve surgery.
‖ Cardiorenal syndrome was defined by a persistent estimated GFR of less than 60 ml per minute per 1.73 m^2 of body-surface area.
** Cardiohepatic syndrome was defined by elevation of at least two of three laboratory markers of cholestasis (bilirubin, γ-glutamyltransferase, and alkaline phosphatase) above the upper limit of the normal range.
†† Scores on the Kansas City Cardiomyopathy Questionnaire (KCCQ) range from 0 to 100, with higher scores indicating better quality of life. Data were available for 224 patients in the tricuspid-repair group and 121 patients in the medical-therapy group.
‡‡ Data were available for 197 patients in the tricuspid-repair group and 105 patients in the medical-therapy group.
§§ Data were available for 187 patients in the tricuspid-repair group and 97 patients in the medical-therapy group.
¶¶ Data were available for 171 patients in the tricuspid-repair group and 96 patients in the medical-therapy group.

94.2% of the patients; median daily dose, 80 mg), sodium–glucose cotransporter 2 inhibitors (in 52.2%), and mineralocorticoid receptor antagonists (in 43.1%) (Table S4). At baseline, tricuspid regurgitation was graded as severe in 50.8% of the patients, massive in 34.2%, and torrential in 10.3%. The mean left ventricular ejection fraction was 54.3±8.6%. Data on additional echocardiographic variables are provided in Table S5. Hemodynamic characteristics obtained from right heart catheterization at baseline are shown in Table S6. The representativeness of the trial population is described in Table S7.

PROCEDURAL CHARACTERISTICS

Among the 231 patients who underwent transcatheter tricuspid therapy, 3 (1.3%) underwent transcatheter annuloplasty, 227 (98.3%) were scheduled to undergo transcatheter edge-to-edge repair, and 1 (0.4%) underwent transcatheter tricuspid-valve replacement in a deviation from the trial protocol (Table S8). Of those undergoing edge-to-edge repair, 149 (65.6%) received the PASCAL system and 75 (33.0%) the TriClip system, with implantation of at least one device. The number of devices implanted was one in 28.6% of patients, two in 62.1%, and three or more in 9.4%.

PRIMARY END POINTS

Follow-up was completed in 93.5%, 58.3%, and 20.5% of eligible patients at 1, 2, and 3 years, respectively (Table S9). The mean follow-up interval was 594±323 days in the tricuspid-repair group and 567±351 days in the medical-therapy group. For the first primary hierarchical end point at 1 year after randomization, 16,909 wins were observed in the tricuspid-repair group and 6966 in the medical-therapy group, with 5276 ties, which corresponded to a win ratio of 2.42 (95% confidence interval [CI], 1.76 to 3.33; P<0.001) in favor of tricuspid repair. The interventional strategy showed consistently more wins across all components of the primary end point, including death from any cause (wins, 4366 vs. 3166), hospitaliza-

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tion for heart failure (wins, 9280 vs. 2871), and improvement of at least 15 points in the KCCQ score (wins, 3263 vs. 929) (Fig. 1, Table 2, and Tables S10 and S11). The win-ratio analysis stratified according to severity of baseline tricuspid regurgitation is shown in Figure S2.

Given the significant difference observed in the win-ratio analysis, the second primary end point was analyzed. Kaplan–Meier estimates for event-free survival for the composite of death from any cause or hospitalization for heart failure were 73.9% in the tricuspid-repair group and 48.4% in the medical-therapy group at 1 year; these values decreased to 52.4% and 21.0%, respectively, at 3 years, which corresponded to a hazard ratio of 0.40 (95% CI, 0.29 to 0.55, P<0.001) (Fig. 2A and Table 2). In a post hoc analysis, the number needed to treat to prevent one death or hospitalization for heart failure with tricuspid-valve repair in 1 year was 4 (95% CI, 3 to 6). With respect to the individual components of the primary end point, the Kaplan–Meier estimates for death from any cause were 86.5% in the tricuspid-repair group and 82.5% in the medical therapy group at 1 year and 72.3% and 53.9%, respectively, at 3 years (hazard ratio, 0.62; 95% CI, 0.40 to 0.96) (Fig. 2B). The estimated percentage of patients who were alive and free from hospitalization for heart failure was 79.6% in the tricuspid-repair group and 51.3% in the medical-therapy group at 1 year (hazard ratio for hospitalization for heart failure, 0.35; 95% CI, 0.25 to 0.50) and 62.4% and 31.0%, respectively, at 3 years (hazard ratio, 0.35; 95% CI, 0.25 to 0.51) (Fig. 2C). Tricuspid repair was also associated with a lower cumulative incidence of hospitalization for heart failure when we accounted for the competing risk of death (Fig. S3). There was no evidence of a violation of the proportional-hazards assumption (Table S11).

SAFETY ANALYSIS AND CROSSOVER PROCEDURES

Major adverse events occurred in 14 patients (5.9%) within 30 days after tricuspid transcatheter-valve repair. One death occurred 17 days after tricuspid edge-to-edge repair owing to noncardiac reasons. Single-leaflet device attachment within 30 days was reported in 4 patients (1.7%). The safety analysis is reported in Table S12. All serious adverse events during the course of the trial are listed in Table S13.

In the medical-therapy group, crossover to transcatheter tricuspid intervention was permitted after a primary end-point event involving hospitalization for severe heart failure resulting in intravenous diuretic therapy. The cumulative incidence of crossover is shown in Figure S4. In 28 of 48 crossovers (58%), the valve-repair procedure was performed during the hospitalization that constituted the primary end-point event, whereas the remaining crossover procedures were performed during subsequent hospitalizations. Table S14 lists the baseline characteristics of patients with crossover procedures and those without such procedures.

SECONDARY END POINTS

The severity of tricuspid regurgitation at 30 days was moderate or less in 135 of 192 patients (70.3%) in the tricuspid-repair group, as compared with 29 of 98 patients (29.6%) in the medical-therapy group. The corresponding percentages for mild tricuspid regurgitation or less at 1 year were 56.3% and 19.2% (Fig. 3A and Fig. S5). Tricuspid repair was associated with substantial improvement in NYHA functional class at 1 year; NYHA class I or II heart failure was reported in 138 of 187 patients (73.8%) in the tricuspid-repair group and in 49 of 86 patients (57.0%) in the medical-therapy group (Fig. 3B and Fig. S5). The mean change in the KCCQ score from baseline to 1-year follow-up was 11.2±21.9 points (95% CI, 8.0 to 14.5) in the tricuspid-repair group and 4.3±24.9 points (95% CI, –1.1 to 9.6) in the medical-therapy group (Fig. S6). Results for other secondary end points are listed in Table 2.

DISCUSSION

In this investigator-initiated trial, an interventional strategy of transcatheter tricuspid-valve repair in addition to medical therapy was superior to medical therapy alone with respect to a hierarchical composite of death from any cause, hospitalization for heart failure, and quality-of-life improvement at 1 year in patients with severe tricuspid regurgitation who were at increased risk for future heart-failure events. In addition, the interventional strategy was associated with a lower incidence of a composite of death from any cause or hospitalization for heart failure through 3 years of follow-up; this benefit was driven by a lower incidence of each component (death from any cause and hospitalization for heart failure) during

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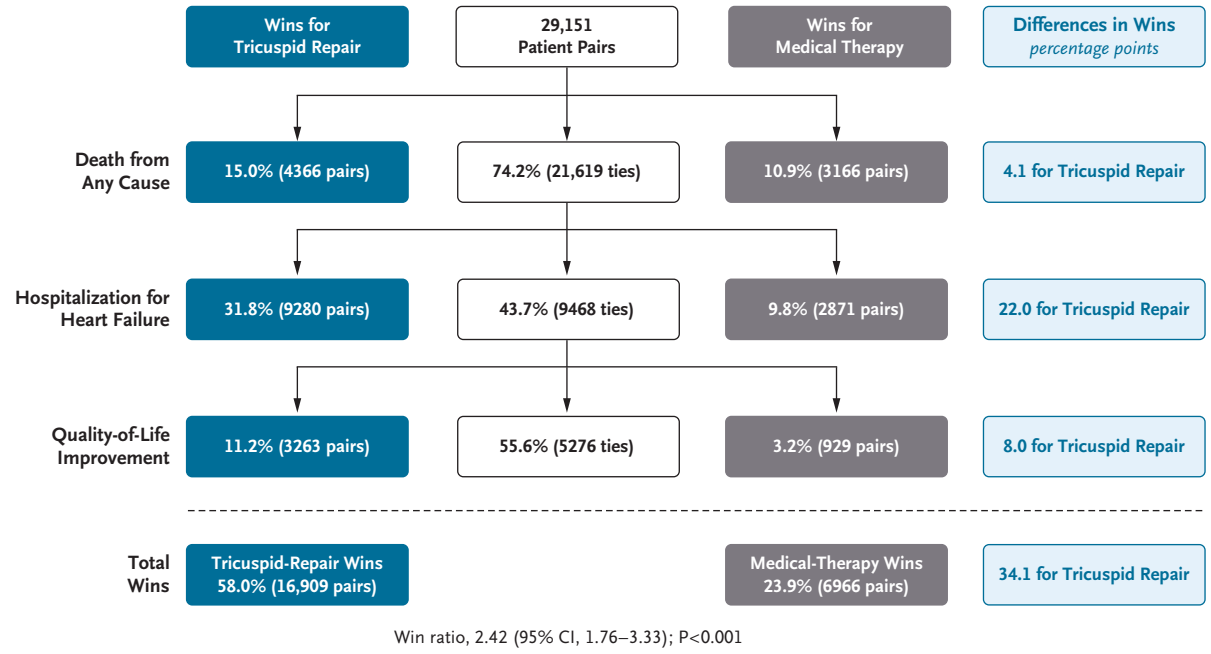

Figure 1. Win-Ratio Analysis for Death, Hospitalization for Heart Failure, and Quality-of-Life Improvement (First Coprimary End Point).
Shown are the components of the win-ratio calculation in the tricuspid-repair group as compared with the medical-therapy group. The win ratio was determined from the analysis of the hierarchical composite primary end point by systematically comparing all possible patient pairs, starting with the first event in the hierarchy. The win ratio was calculated by dividing the number of wins in the tricuspid-repair group by the number of wins in the medical-therapy group. Values are reported as percentages and numbers of pairs. The results for this composite primary end point were calculated after the last patient had reached the 12-month follow-up. Included in the medical-therapy group are patients who crossed over to receive tricuspid repair within the 1-year visit window. Quality-of-life improvement was assessed by the Kansas City Cardiomyopathy Questionnaire (KCCQ), with a clinically meaningful improvement defined as an increase of at least 15 points; scores on the KCCQ range from 0 to 100, with higher scores indicating better health status. Details on the imputation strategy for missing KCCQ data are provided in the Supplementary Appendix, including Table S15.

follow-up. The findings also showed the procedural safety as well as the sustained reduction in the severity of tricuspid regurgitation when transcatheter tricuspid-valve repair is performed at experienced heart-valve centers.

These findings extend previous evidence from randomized trials by showing that the benefits of an interventional strategy were not confined to improvements in quality of life but also translated into meaningful differences in hard clinical outcomes. In the primary analyses of earlier randomized trials, treatment effects were largely driven by quality-of-life improvements, without effects on hospitalization for heart failure or death within the first year after intervention.[7,8] Subsequent analyses suggested an association between tricuspid transcatheter edge-to-edge repair and a decreased incidence of hospitalization for heart failure with longer follow-up.[9] In contrast, this trial showed a consistent and clinically relevant reduction in hospitalization for heart failure that emerged early and was sustained over time, together with a reduction in mortality as observed during a mean follow-up of 1.6 years. The early and pronounced separation of event curves in patients with advanced heart failure underscores the immediate benefit of tricuspid-valve repair when added to optimized, stable medical therapy. This benefit is further reflected in a post hoc analysis that showed a number needed to treat of four to prevent one death or hospitalization for heart failure in 1 year, a magnitude that compares favorably with established interventional strategies, such as in patients with secondary mitral regurgitation.[12,13]

A key explanation for these findings probably lies in the characteristics of the trial population, which differed from those in previous trials. In

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Table 2. Primary and Secondary End Points.

End Point	Tricuspid Repair (N=237)	Medical Therapy (N=123)	Effect Size (95% CI)
Primary			
Win-ratio analysis for death from any cause, hospitalization for heart failure, and quality-of-life improvement at 1 yr — wins/pairs (%)*	16,909/29,151 (58.0)	6966/29,151 (23.9)	2.42 (1.76 to 3.33)†
Kaplan–Meier estimate of freedom from death or hospitalization for heart failure at 3 yr (95% CI) — % of patients	52.4 (43.2 to 63.6)	21.0 (12.7 to 34.6)	0.40 (0.29 to 0.55)‡
No. of deaths or hospitalizations for heart failure (% of patients)	79 (33.3)	76 (61.8)	
Secondary§			
Kaplan–Meier estimate of survival at 1 yr (95% CI) — % of patients	86.5 (82.3 to 91.1)	82.5 (75.8 to 89.8)	0.74 (0.42 to 1.29)‡
No. of deaths (% of patients)	31 (13.1)	20 (16.3)	
Kaplan–Meier estimate of survival at 3 yr (95% CI) — % of patients	72.3 (64.1 to 81.6)	53.9 (41.5 to 70.0)	0.62 (0.40 to 0.96)‡
No. of deaths (% of patients)	45 (19.0)	34 (27.6)	
Kaplan–Meier estimate of freedom from hospitalization for heart failure at 1 yr (95% CI) — % of patients	79.6 (74.5 to 85.1)	51.3 (42.7 to 61.5)	0.35 (0.25 to 0.51)‡
No. of hospitalizations for heart failure (% of patients)	46 (19.4)	54 (43.9)	
Kaplan–Meier estimate of freedom from hospitalization for heart failure at 3 yr (95% CI) — % of patients	62.4 (52.8 to 73.6)	31.0 (21.4 to 44.8)	0.35 (0.25 to 0.50)‡
No. of hospitalizations for heart failure (% of patients)	59 (24.9)	66 (53.7)	
Mean change in KCCQ score from baseline to 1 yr — points	11.20±21.93	4.31±24.94	6.89 (1.76 to 12.02)¶
NYHA functional class of I or II heart failure at 1 yr — no./total no. (%)	138/187 (73.8)	49/86 (57.0)	2.13 (1.24 to 3.64)‖
Mean change in distance on 6-min walk test from baseline to 1 yr — m	40±90	20±95	20 (–0.1 to 40.1)¶
Mean change in body weight from baseline to 1 yr — kg	0.13±5.59	–0.65±6.93	0.78 (–0.79 to 2.35)¶
Peripheral edema of grade 2+ or higher at 1 yr — no./total no. (%)	21/175 (12.0)	14/80 (17.5)	0.64 (0.31 to 1.34)‖

* Quality-of-life improvement was assessed by means of the KCCQ, with a clinically meaningful improvement defined as an increase of at least 15 points.
† Shown is the win ratio.
‡ Shown are hazard ratios that were calculated for the composite end point of time to death from any cause or hospitalization for heart failure, the end point of time to death from any cause, or the end point of time to hospitalization for heart failure.
§ For secondary end points, the widths of the confidence intervals have not been adjusted for multiplicity and should not be used to infer treatment effects.
¶ Shown is the mean difference.
‖ Shown is the odds ratio.

contrast to previous randomized trials, the TRICI-HF trial enrolled patients with more advanced heart failure. This fact is reflected by a higher percentage of patients with a history of hospitalization for heart failure in the preceding year (55.0%, vs. 23.8% in TRILUMINATE Pivotal [Trial to Evaluate Cardiovascular Outcomes in Patients Treated with the Tricuspid Valve Repair System Pivotal] and 40.3% in the Tri.Fr trial) and a higher percentage with NYHA class III or IV heart fail-

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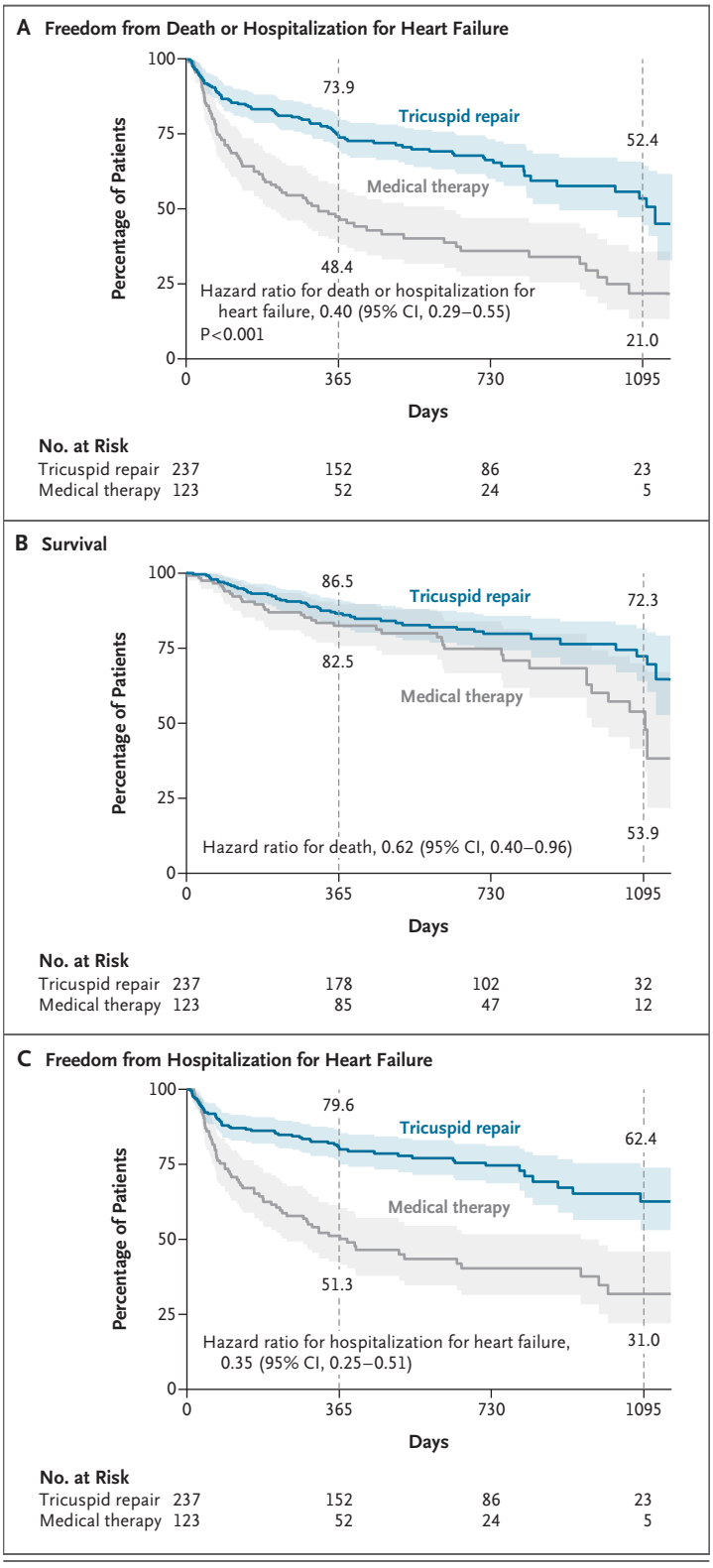
Figure 2. Kaplan–Meier Estimates of Adjudicated Clinical Events at 3 Years.

Shown are Kaplan–Meier estimates for prespecified events as adjudicated by the clinical-events committee at 3 years. Panel A shows freedom from death from any cause or hospitalization for heart failure (second coprimary end point), Panel B survival, and Panel C freedom from hospitalization for heart failure. Shaded areas indicate 95% confidence intervals. For the individual end points of survival and freedom from hospitalization for heart failure, the widths of the confidence intervals have not been adjusted for multiplicity and should not be used to infer treatment effects.



ure (75.0%, vs. 55.1% and 42.3%, respectively), which resulted in a substantially higher 1-year mortality in the medical-therapy group (17.5%, vs. 8% and 5.4%, respectively).[7,8,14] Accordingly, the TRIC-I-HF trial represents a population with a high symptomatic burden of systemic congestion and an increased risk of adverse clinical outcomes.[15,16]

Increased operator experience in transcatheter tricuspid-valve repair may provide an additional explanation for the better outcomes observed in this trial than in previous randomized trials. Owing to the marked anatomic variability of the tricuspid valve, the challenges of grasping thin leaflets in the presence of large coaptation gaps, and the complexity of intraprocedural echocardiographic imaging, transcatheter tricuspid-valve repair remains a technically demanding procedure with a pronounced volume–outcome relationship. In line with this, data from the PASTE (PASCAL for Tricuspid Regurgitation — a European Registry) study indicate that success rates after tricuspid edge-to-edge repair are higher at experienced heart-valve centers.[6] Moreover, recent advances in patient selection as well as management of patient care before and after interventional therapy may have contributed to the trial findings.

This trial has several limitations. Patients were assigned to the medical-therapy group despite the availability and reimbursement of transcatheter tricuspid-valve repair in Germany. Crossovers were permitted by protocol only after the occurrence of a primary end-point event, defined as severe heart-failure decompensation resulting in hospitalization and intravenous diuretic therapy. This design feature, together with the 2:1 randomiza-

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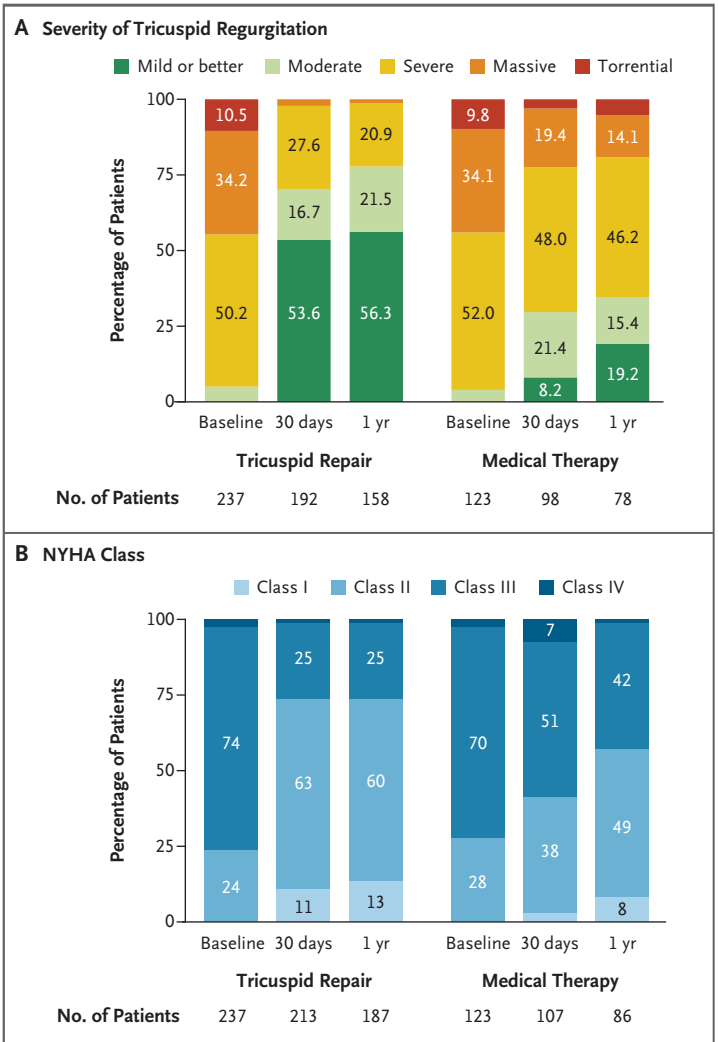

Figure 3. Severity of Tricuspid Regurgitation and NYHA Class.

The bar graphs summarize the severity of tricuspid regurgitation as adjudicated by the echocardiographic core laboratory (Panel A) and the severity of heart failure as defined by the New York Heart Association (NYHA) functional class (Panel B) at baseline, 30 days, and 1 year in both trial groups.

tion scheme, was necessary to support recruitment in a setting in which tricuspid interventions are commercially available. Crossovers did not affect the analysis of the primary end point because they were permitted only after a patient had had a hospitalization for heart failure that met the end-point definition. However, crossovers complicate the interpretation of secondary end points and limit direct comparisons with other randomized clinical trials. Accordingly, changes in functional status, quality of life, and echocardiographic variables in the medical-therapy group should be interpreted with caution. Of note, although crossover may have attenuated the estimated treatment effect, all-cause mortality remained lower in the tricuspid-repair group than in the medical-therapy group, which supports the robustness of an early interventional strategy. The open-label design may have influenced quality-of-life assessments, although the concordant effects on clinical end points mitigate this concern. The national trial design may limit the generalizability of the findings to other countries. In addition, the use of different devices precludes conclusions regarding the relative efficacy of specific tricuspid-valve repair systems. Finally, follow-up was complete through 1 year after randomization, whereas 3-year follow-up remains ongoing for patients enrolled later in the trial. Accordingly, longer-term outcomes are subject to greater uncertainty and should be interpreted with caution.

In this trial involving patients with heart failure and severe tricuspid regurgitation, an interventional strategy of transcatheter tricuspid-valve repair and medical therapy resulted in significantly better outcomes than medical therapy alone with respect to a hierarchical composite of death from any cause, hospitalization for heart failure, and quality-of-life improvement at 1 year. This strategy also led to a lower incidence of a composite of death from any cause or hospitalization for heart failure at 3 years.

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