The TRISCEND II Trial: Transcatheter Valve Replacement Versus Optimal Medical Therapy for Severe Tricuspid Regurgitation

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on behalf of the PIs and the **TRISCEND II** trial investigators

5 mins

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THE TRISCEND II PIVOTAL TRIAL

The TRISCEND II Trial: Transcatheter Valve Replacement Versus Optimal Medical Therapy for Severe Tricuspid Regurgitation

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Disclosure of Relevant Financial Relationships
Martin B. Leon, MD

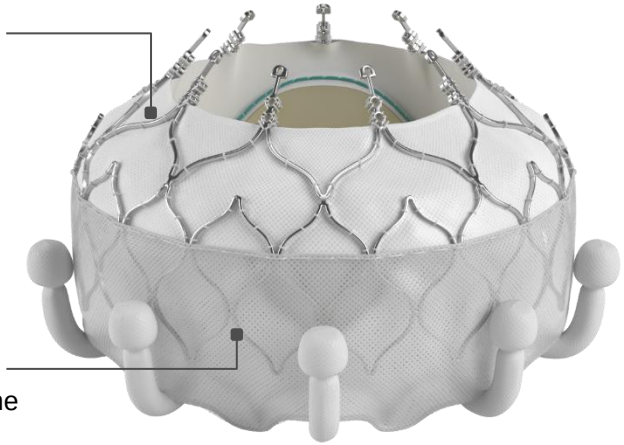
Within the prior 24 months, I have had a relevant financial relationship(s) with companies listed below.

Financial Relationship	Company
• Institutional Research Support (Columbia University)	Abbott, Boston Scientific, Edwards Lifesciences, Johnson & Johnson, Medtronic
• Consulting Fees	Anteris, Bain Capital, Foldax, Innovalve, Microport
• Equity and other interests	Ancora, Aquapass, Concept Medical, Croivalve, East End Medical, Laminar, Medinol, Microtech, Mirus, Pi-Cardia, Trajectory, SoloPace, Valve Medical, xDot, XenterMD

EVOQUE Transcatheter Tricuspid Valve Replacement System

Designed for anatomical compatibility
Self-expanding shape-memory nitinol frame designed to conform to native valve anatomy

Designed to seal within native tricuspid annulus
Intra-annular sealing skirt and frame



4 sizes treat wide range of anatomies

44mm 48mm 52mm 56mm

Delivery System

Transfemoral **28 Fr** outer diameter **3 planes of movement**

THE TRISCEND II PIVOTAL TRIAL

Purpose

Evaluate the safety and effectiveness of the EVOQUE tricuspid valve replacement system with optimal medical therapy compared with optimal medical therapy alone in patients with at least severe TR

Key Inclusion Criteria

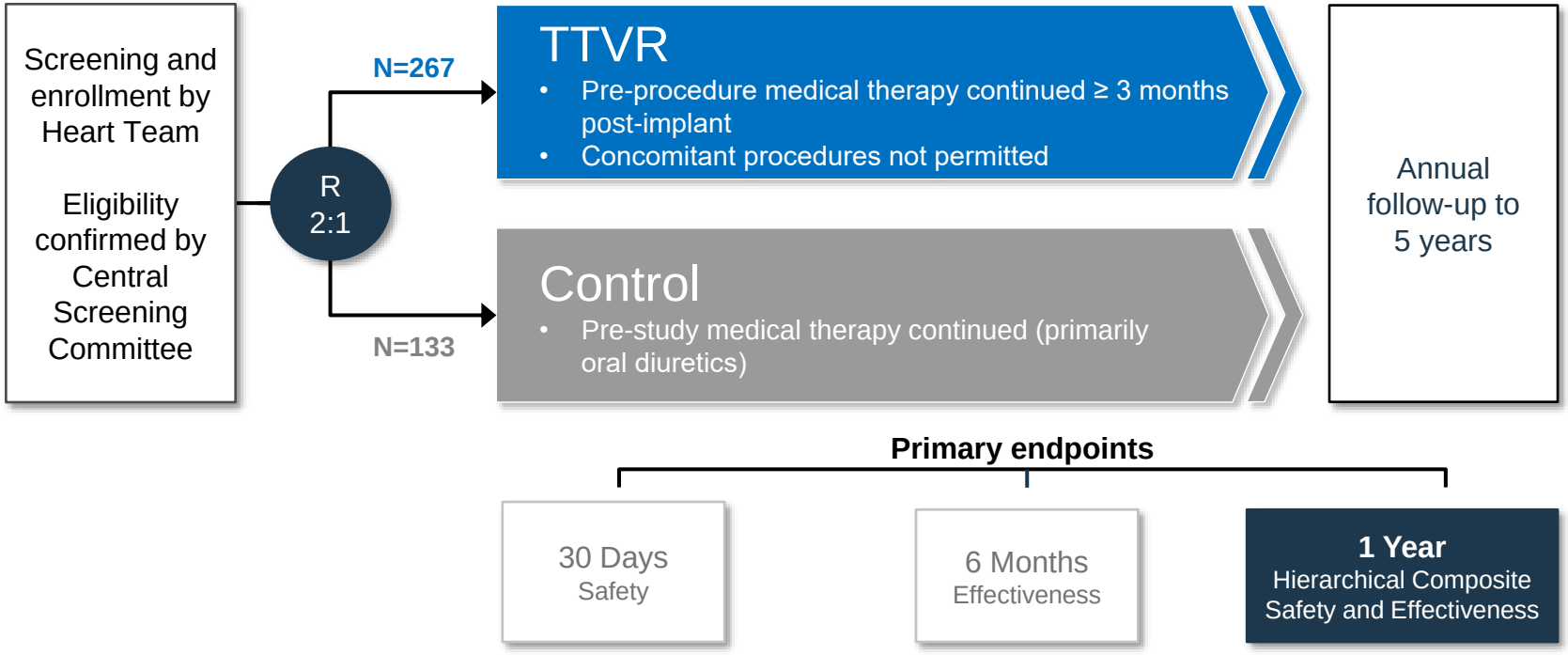
- Age ≥ 18 years
- Signs/symptoms of TR or prior heart failure hospitalization
- Medical therapy at the time of screening
- TR ≥ severe

Key Exclusion Criteria

- Anatomy precluding proper implant
- Life expectancy < 12 months
- LVEF < 25%
- Evidence of severe RV dysfunction[a]
- Severe renal insufficiency[b]
- Severe pulmonary hypertension[c]

[a]Assessed by echo core lab; Baylor Scott and White Research Institute Cardiac Imaging Core Laboratory, Plano, TX, USA. [b]Estimated glomerular filtration rate ≤25 mL/min/1.73m^2 or requiring chronic renal replacement therapy. [c]Pulmonary artery systolic pressure >60 mmHg by echo Doppler or >70 mmHg by right heart catheterization (RCH), or pulmonary vascular resistance >5 Wood units by RHC. *LVEF*, left ventricular ejection fraction; *RV*, right ventricular; *TR,* tricuspid regurgitation

THE TRISCEND II PIVOTAL TRIAL



R, randomization; *TTVR*, transcatheter tricuspid valve replacement

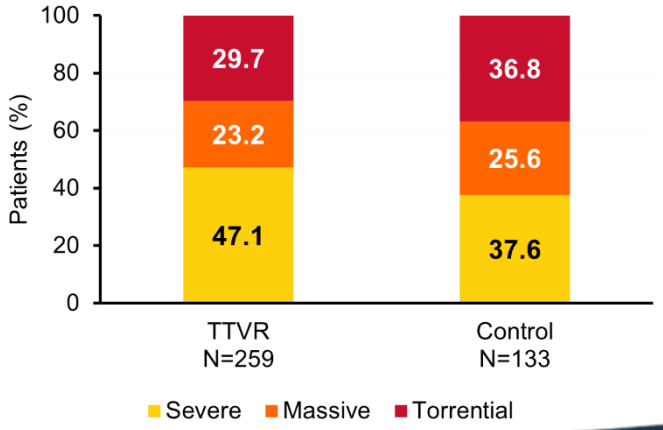
Baseline Characteristics

THE TRISCEND II PIVOTAL TRIAL

	TTVR N=259 Mean ± SD or %	Control N=133 Mean ± SD or %
Age, years	79.3 ± 7.4	79.1 ± 7.8
Female	74.9%	76.7%
NYHA class III-IV	73.0%	69.2%
KCCQ overall score, points	52.8 ± 22.0	50.6 ± 21.4
STS score, mitral valve replacement, %	9.6 ± 5.1	10.0 ± 5.2
Left ventricular ejection fraction, %	54.4 ± 9.9	54.3 ± 11.1
TAPSE, mm	16.3 ± 4.5	15.6 ± 4.2
Pulmonary artery systolic pressure, mmHg	38.6 ± 10.9	37.6 ± 11.3
Atrial fibrillation	96.1%	92.5%
Stroke	15.1%	9.0%
Chronic kidney disease	54.1%	59.4%
Ascites	18.5%	21.8%
HF hospitalization in past 12 months	34.0%	36.1%
History of pacemaker/CIED	38.2%	39.8%
Prior valve surgery/intervention	33.6%	30.8%

TR Etiology	TTVR N=259	Control N=133
Primary[a]	14.7%	14.3%
Secondary[b]	74.1%	71.4%
Mixed	9.7%	9.0%
Indeterminate	1.5%	5.3%

TR Severity by Core Lab



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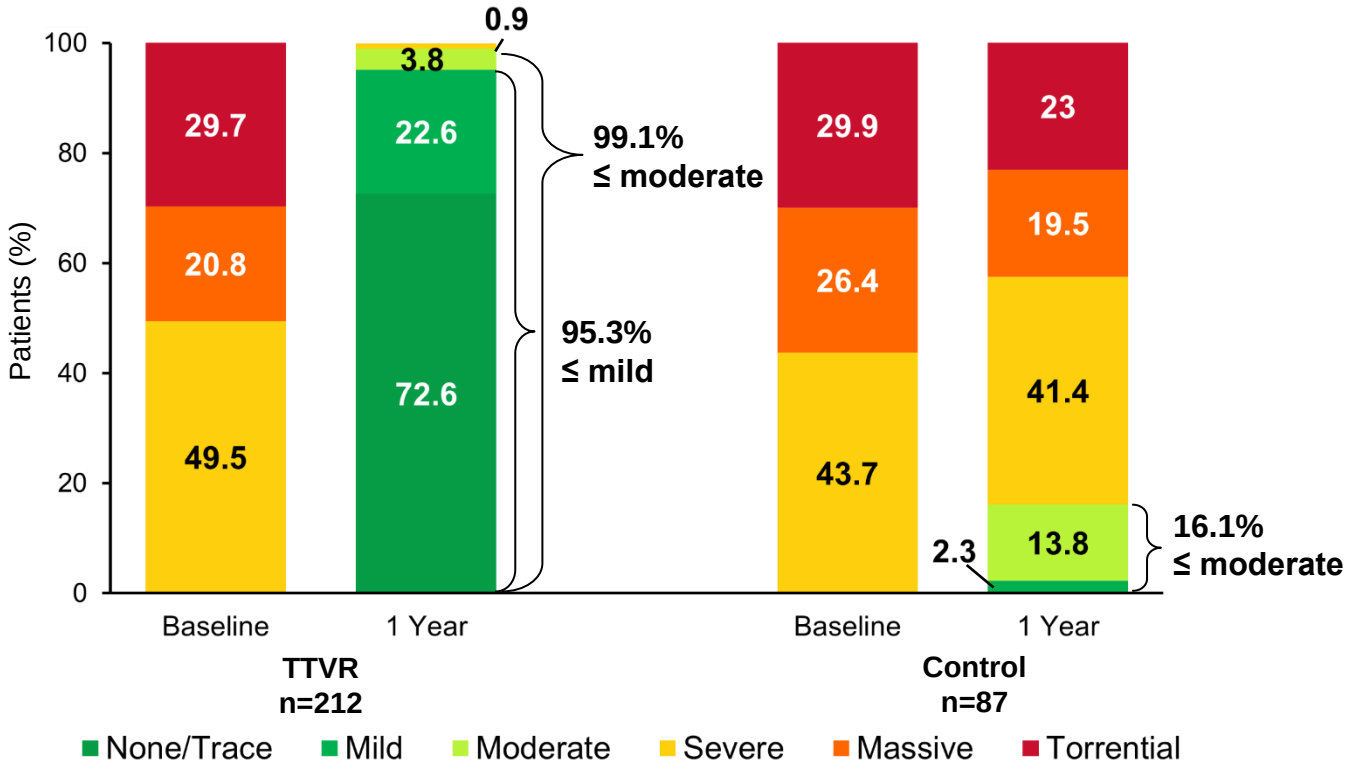
Baylor Scott and White Research Institute Cardiac Imaging Core Laboratory, Plano, TX, USA. Data from patients with available assessments. [a]Degenerative, organic, structural or pacer related. [b]Functional or nonstructural. *CIED*, cardiac implantable electronic device; *HF*, heart failure; *KCCQ*, Kansas City Cardiomyopathy Questionnaire; *NYHA*, New York Heart Association; *STS*, Society of Thoracic Surgeons; *TAPSE*, tricuspid annular plane systolic excursion; *TR*, tricuspid regurgitation; *TTVR*, transcatheter tricuspid valve replacement

Safety Outcomes

CEC-adjudicated Event	Early Events (≤ 30 Days)		Late Events (31 to 365 Days)[a]	
	TTVR N=259 % (n)	Control N=133 % (n)	TTVR N=247 % (n)	Control N=128 % (n)
Cardiovascular mortality	3.1% (8)	0.0% (0)	5.7% (14)	7.8% (10)
Myocardial infarction	0.8% (2)	0.0% (0)	1.2% (3)	0.8% (1)
Stroke	0.4% (1)	0.0% (0)	1.2% (3)	0.0% (0)
Severe bleeding[b]	10.4% (27)	1.5% (2)	5.3% (13)	4.7% (6)
Nonelective TV reintervention	0.8% (2)	0.8% (1)	0.0% (0)	2.3% (3)
New Pacemaker/CIED Implantation				
CIED implant in pacemaker-naïve patients[c]	24.7% (40/162)	0.0% (0/80)	4.2% (5/118)[d]	3.9% (3/76)[d]

[a]Patients must have at least 31 days in study to count in denominator. [b]Severe bleeding defined as fatal, life-threatening, extensive or major per the Mitral Valve Academic Research Consortium. [c]Excludes patients with pre-existing CIED. [d]Patients who had a pacemaker implanted in the first 30 days are excluded. *CEC*, clinical events committee; *CIED*, cardiac implantable electronic device; *TTVR*, transcatheter tricuspid valve replacement; *TV*, tricuspid valve

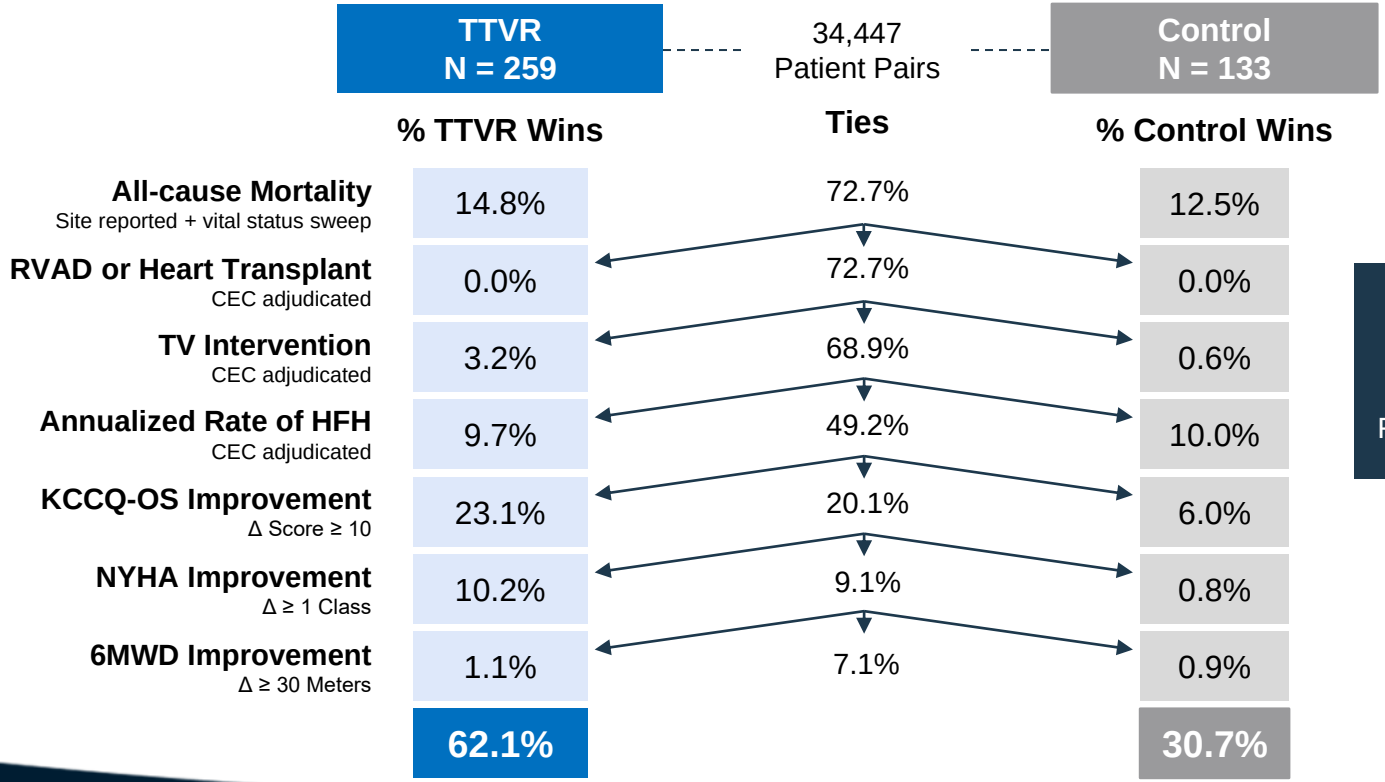
TR Grade Reduction at 1 Year with EVOQUE System



Baylor Scott and White Research Institute Cardiac Imaging Core Laboratory, Plano, TX, USA. Graphs show paired analysis. *TR,* tricuspid regurgitation; *TTVR,* transcatheter tricuspid valve replacement

Primary Safety and Effectiveness Endpoint – Percent Wins

Superior Clinical Benefits with EVOQUE System



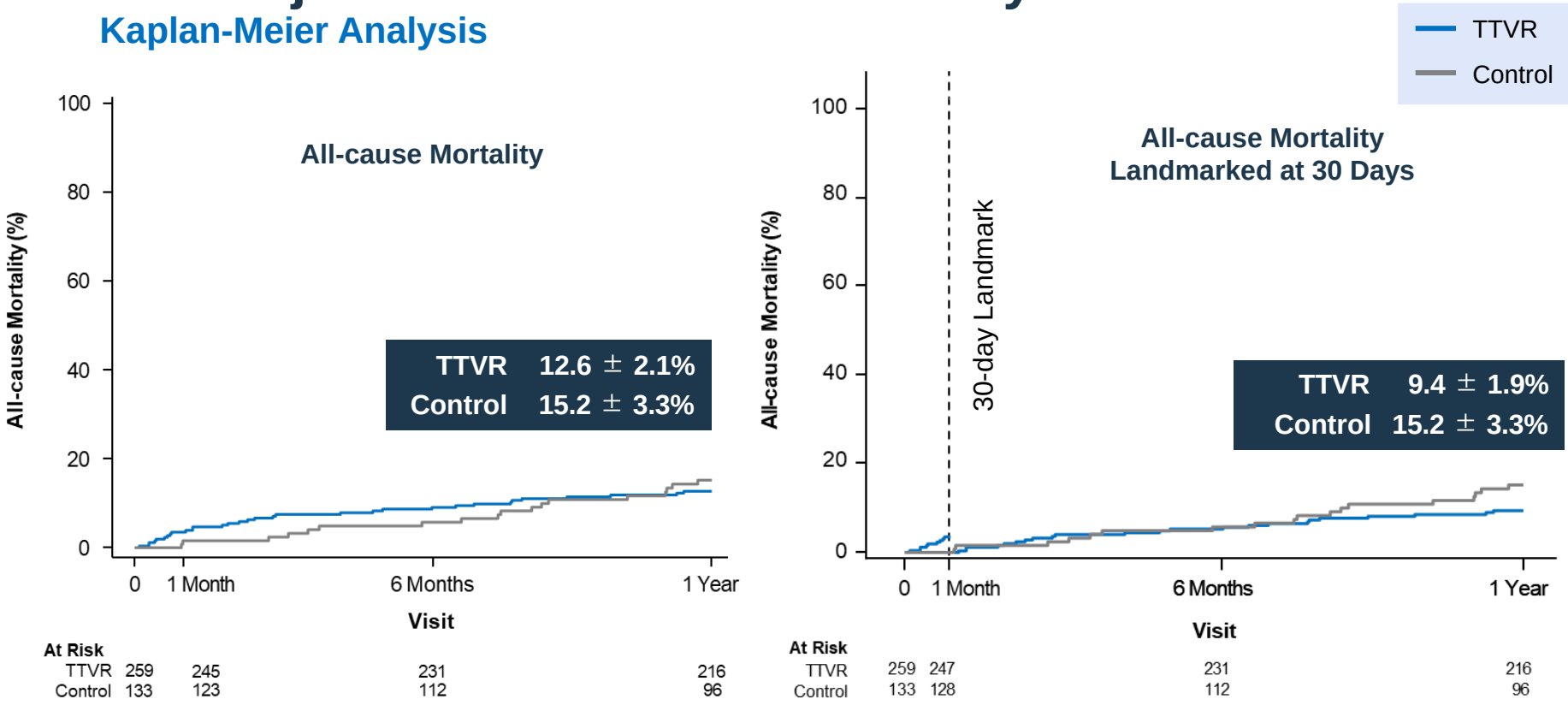
Win Ratio = 2.02
(95% CI, 1.56, 2.62)

Finkelstein-Schoenfeld: **P<0.001**

6MWD, 6-minute walk distance; *CEC*, clinical events committee; *HFH*, heart failure hospitalization, *KCCQ-OS*, Kansas City Cardiomyopathy Questionnaire Overall Summary score; *NYHA*, New York Heart Association; *RVAD*, right ventricular assist device; *TTVR,* transcatheter tricuspid valve replacement; *TV*, tricuspid valve

CEC-adjudicated All-cause Mortality to 1 Year

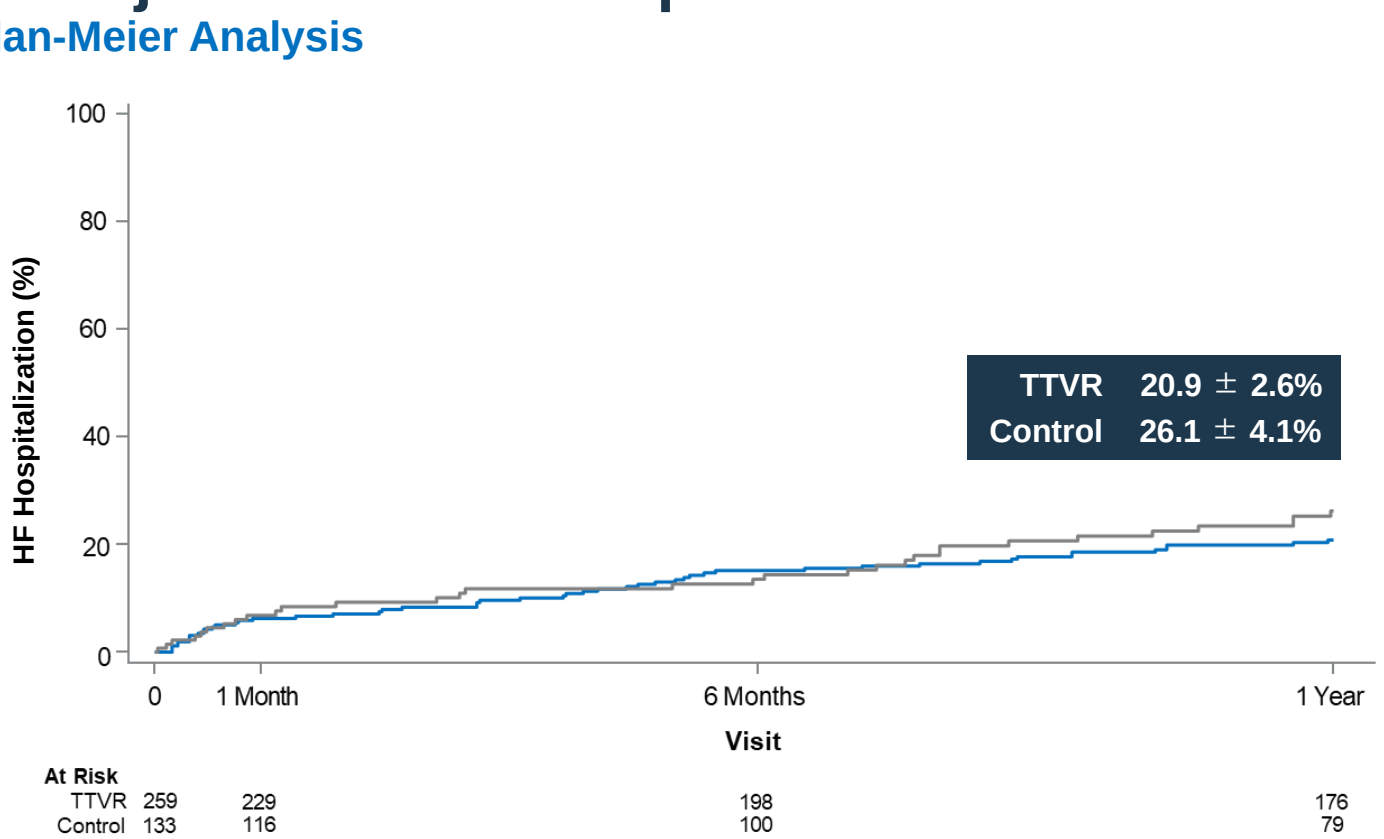
Kaplan-Meier Analysis



Kaplan-Meier estimates include standard error. *CEC*, clinical events committee; *TTVR*, transcatheter tricuspid valve replacement

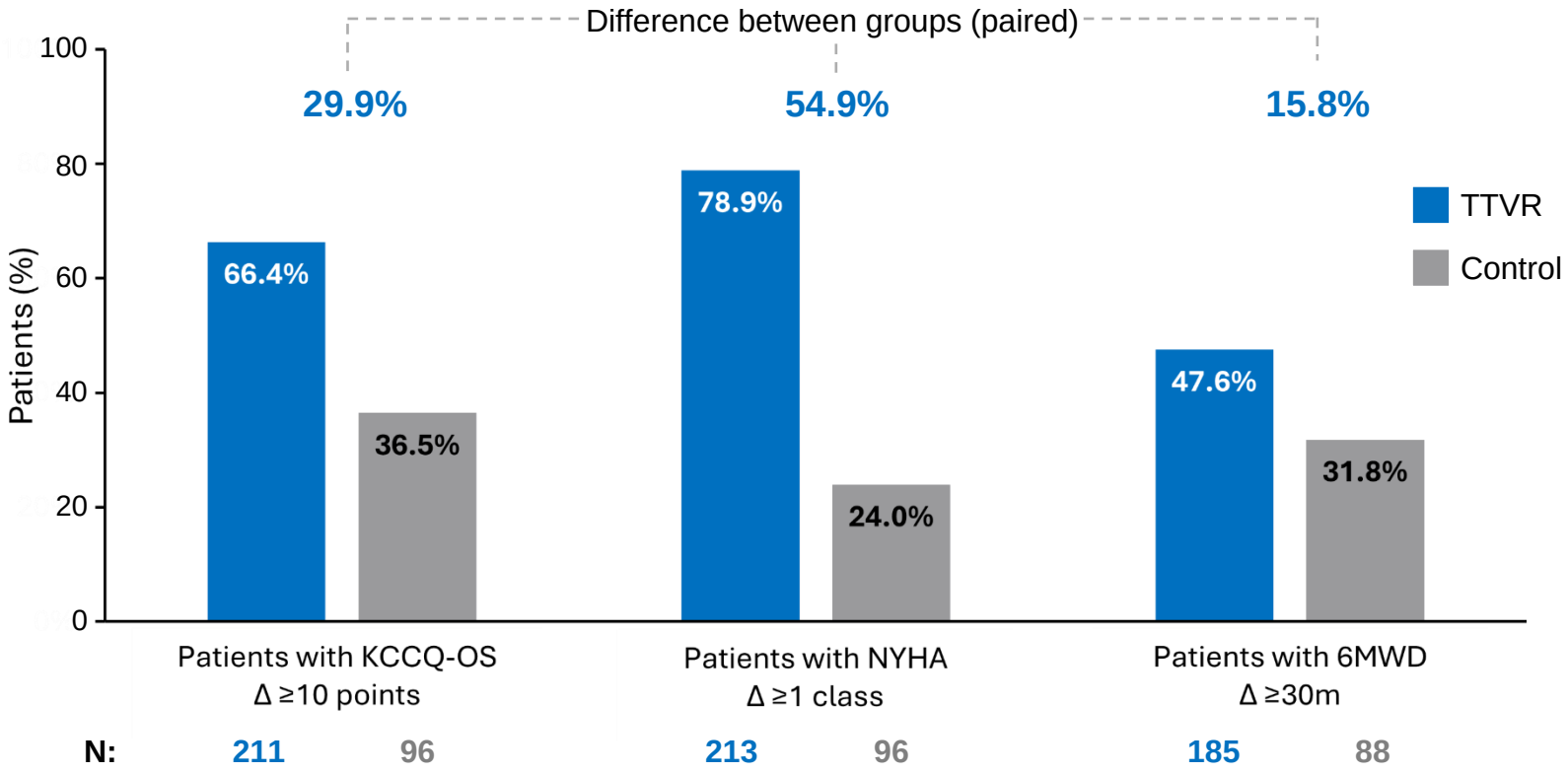
CEC-adjudicated HF Hospitalization to 1 Year

Kaplan-Meier Analysis



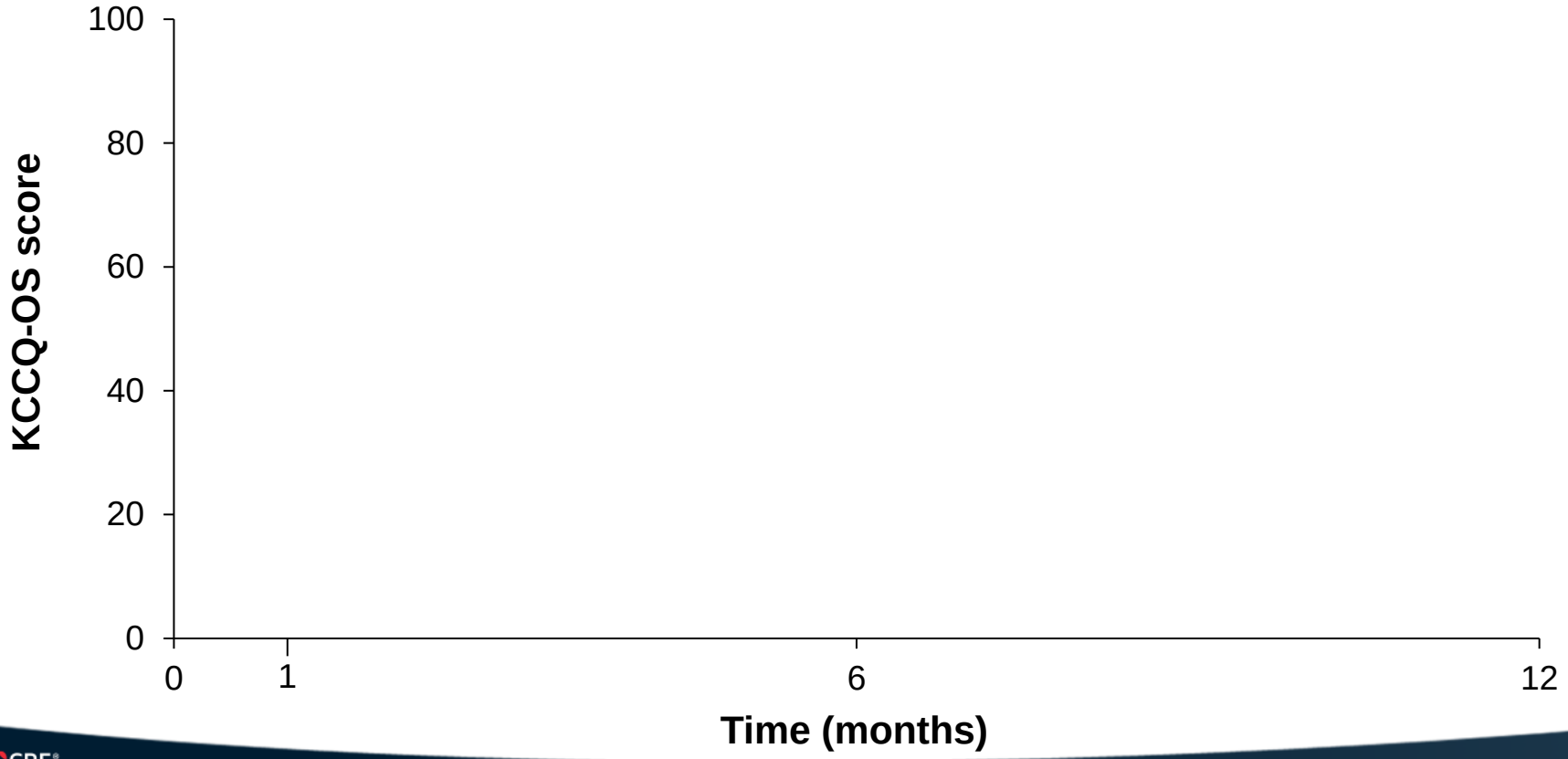
Kaplan-Meier estimates include standard error. *CEC*, clinical events committee; *HF*, heart failure; *TTVR,* transcatheter tricuspid valve replacement

Functional and Quality-of-Life Improvements at 1 Year

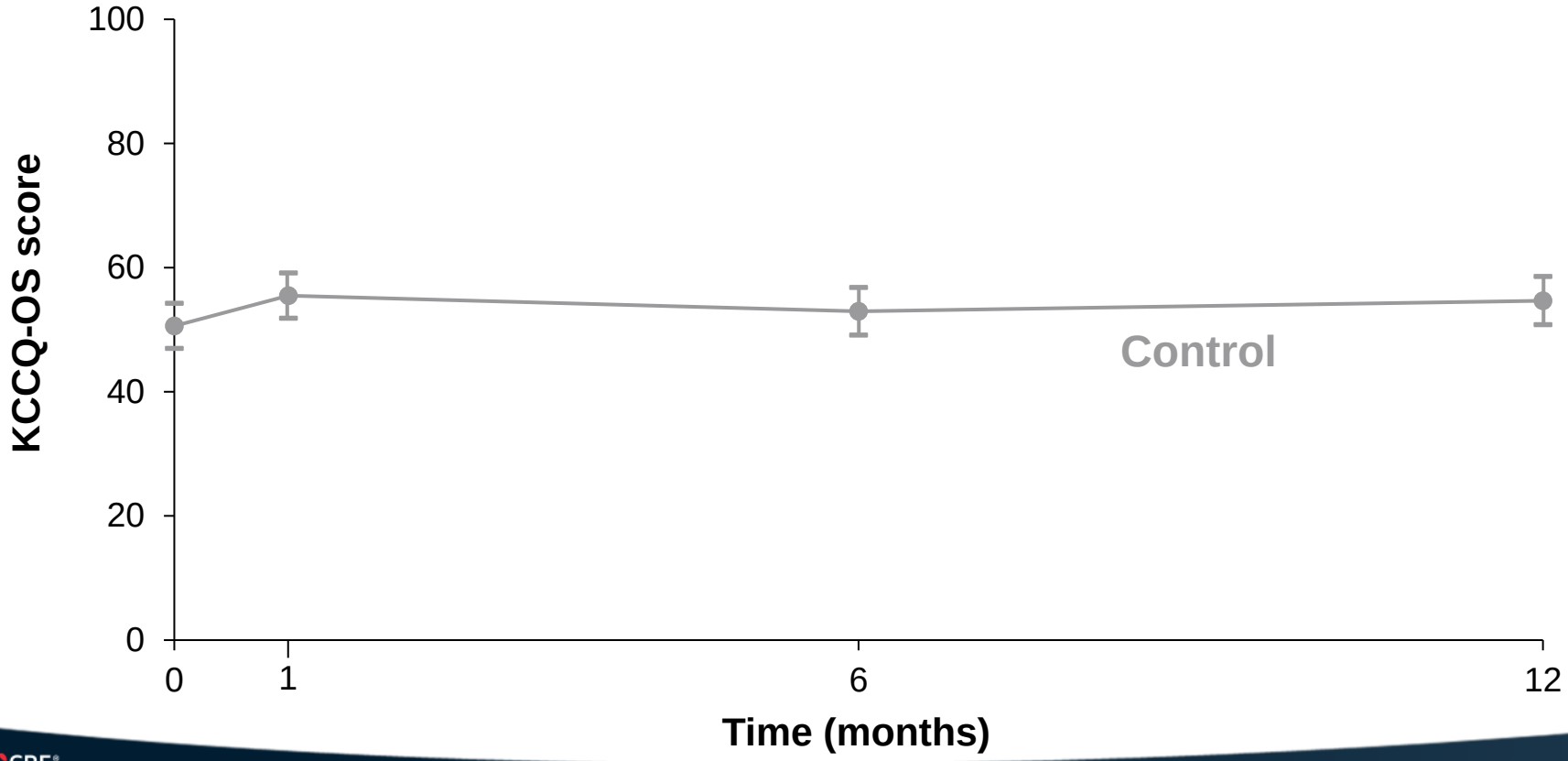


6MWD, 6-minute walk distance; *KCCQ-OS*, Kansas City Cardiomyopathy Questionnaire Overall Summary score; *NYHA*, New York Heart Association; *TTVR*, transcatheter tricuspid valve replacement

Key Health Status Outcome: KCCQ-OS

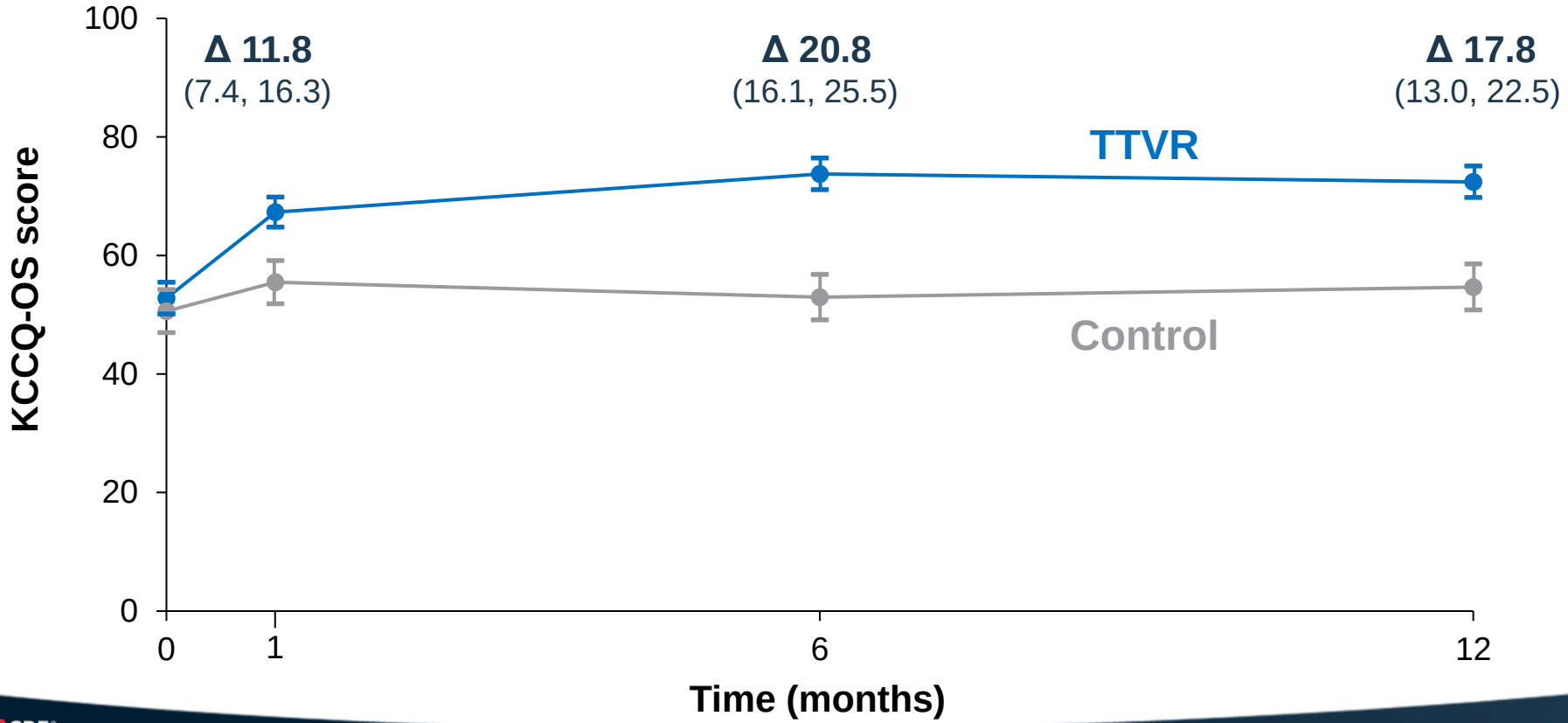


Key Health Status Outcome: KCCQ-OS



KCCQ-OS, Kansas City Cardiomyopathy Questionnaire Overall Summary score

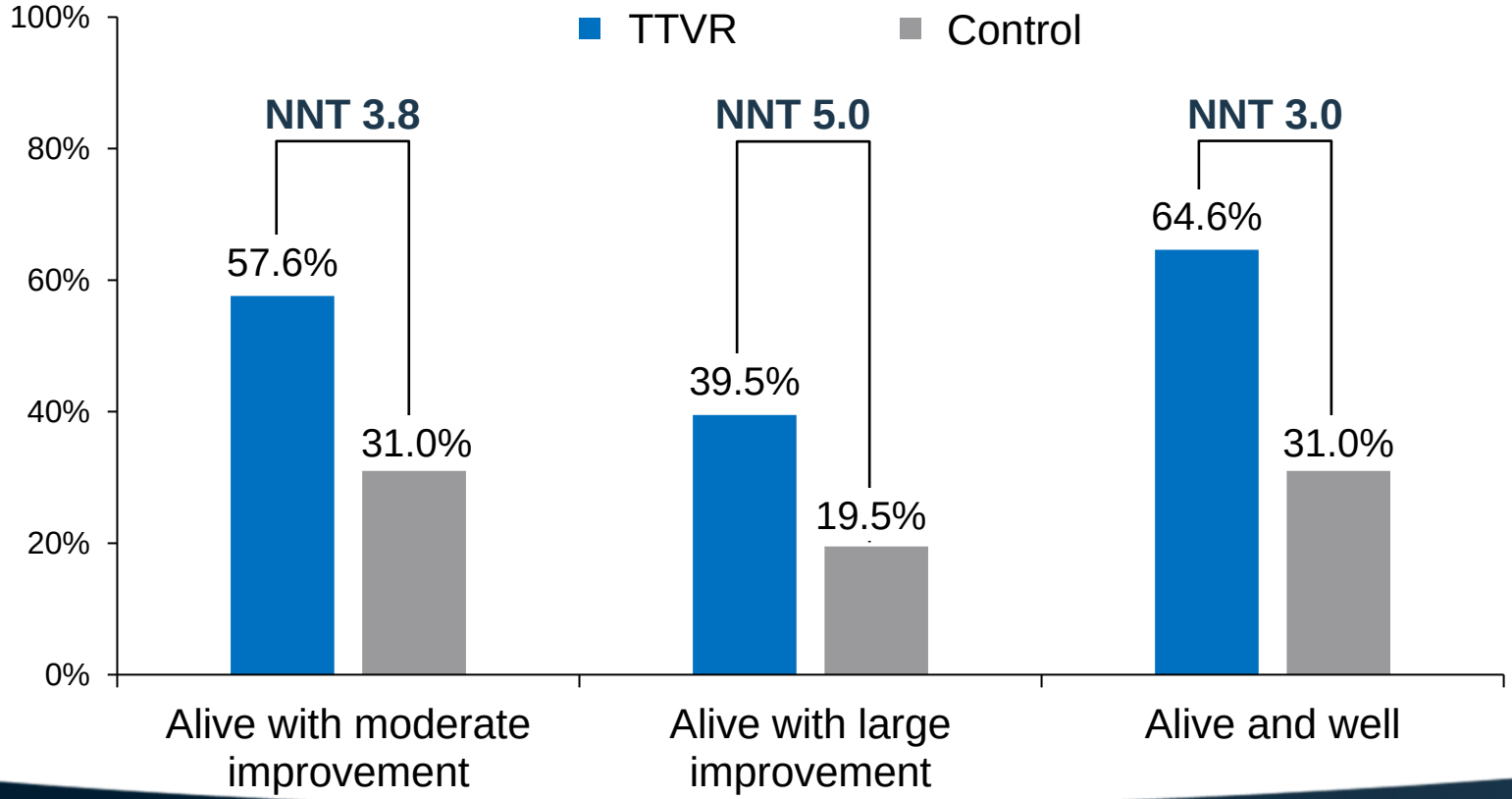
Key Health Status Outcome: KCCQ-OS



KCCQ-OS, Kansas City Cardiomyopathy Questionnaire Overall Summary score; *TTVR*, transcatheter tricuspid valve replacement

All treatment comparisons P<0.001

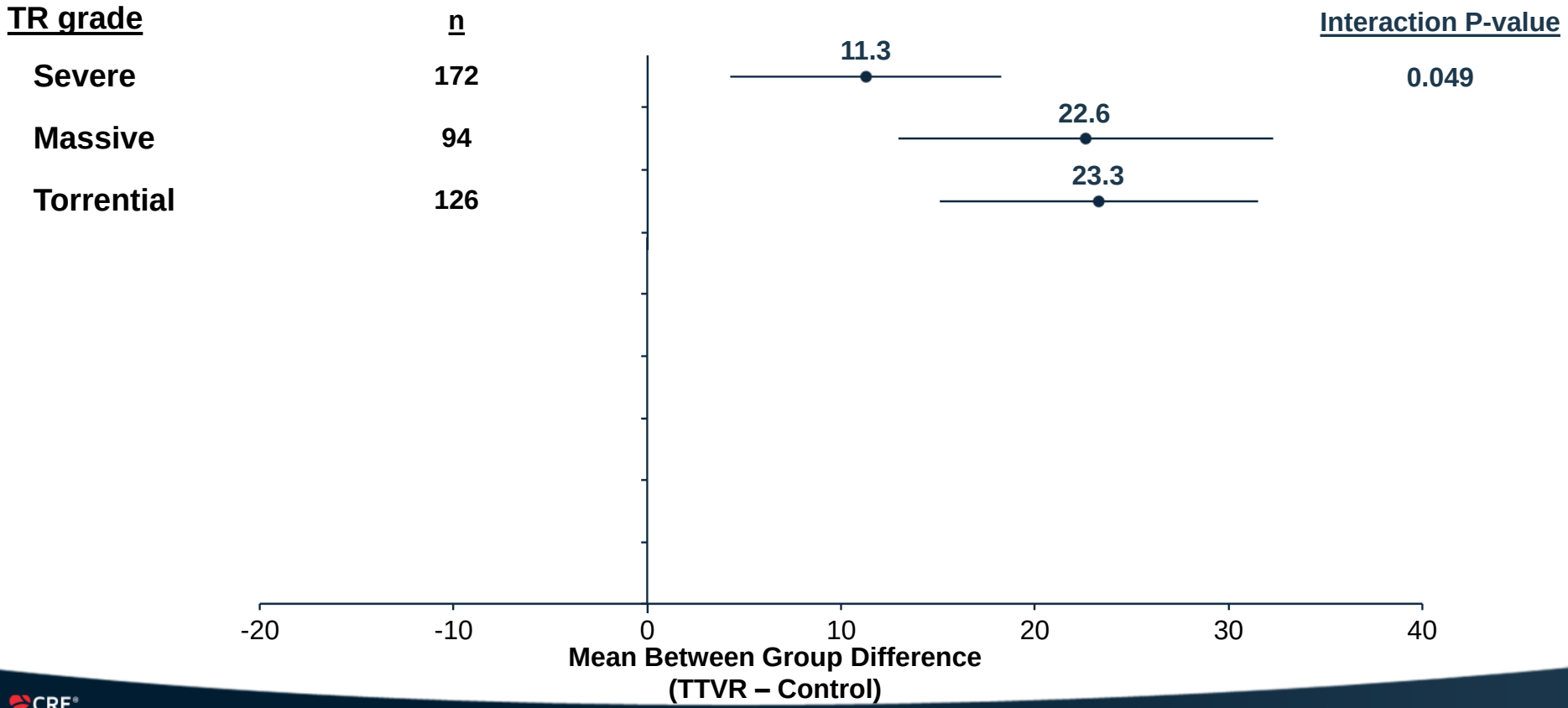
Survival and Health Status by KCCQ-OS at 1 Year



Moderate improvement: increase in KCCQ-OS ≥10; Large improvement: increase in KCCQ-OS ≥20; Alive and well: KCCQ-OS at 1 year of ≥60 and no decline from baseline of ≥10 points. *KCCQ-OS*, Kansas City Cardiomyopathy Questionnaire Overall Summary score; *NNT*, number needed to treat; *TTVR*, transcatheter tricuspid valve replacement

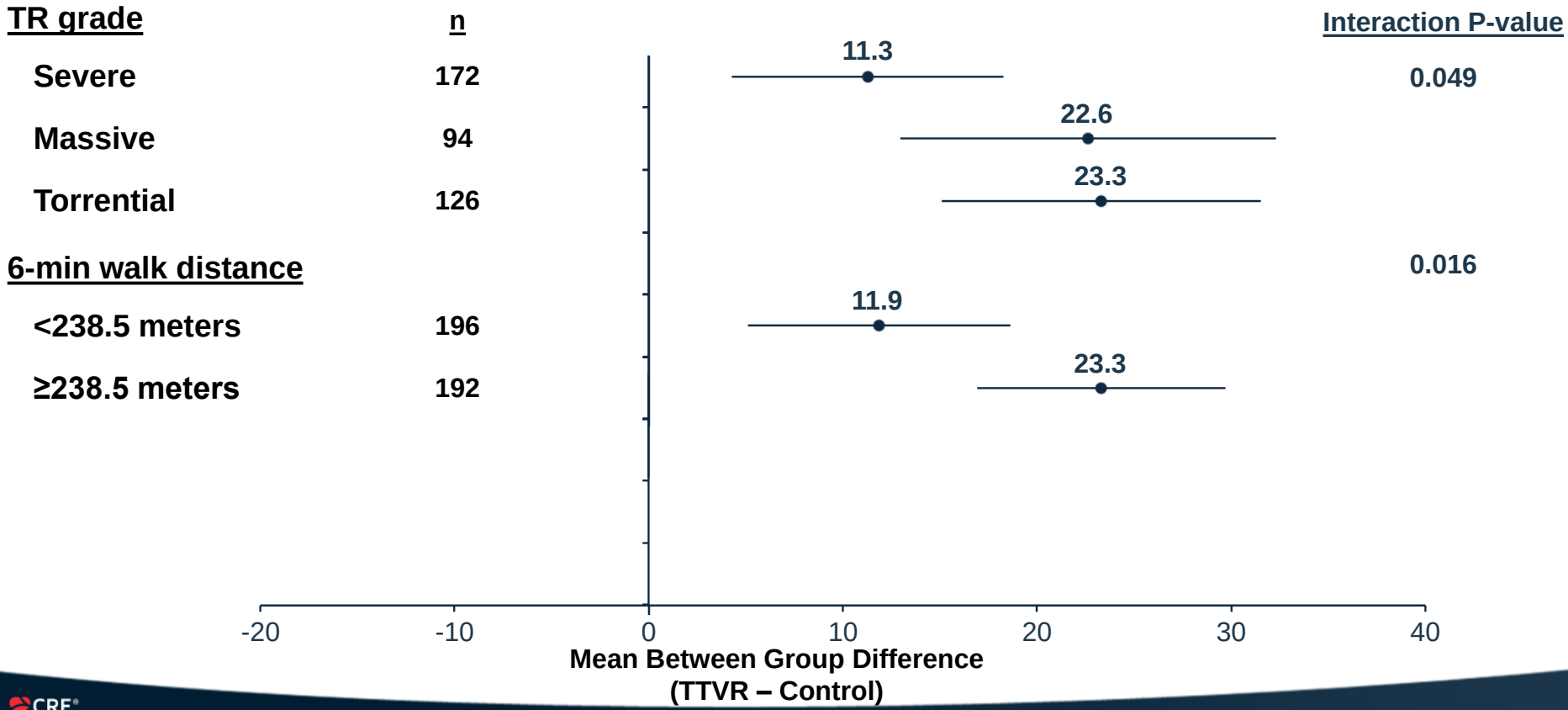
All treatment comparisons P<0.001

Baseline Subgroup Analyses at 1 Year by KCCQ-OS

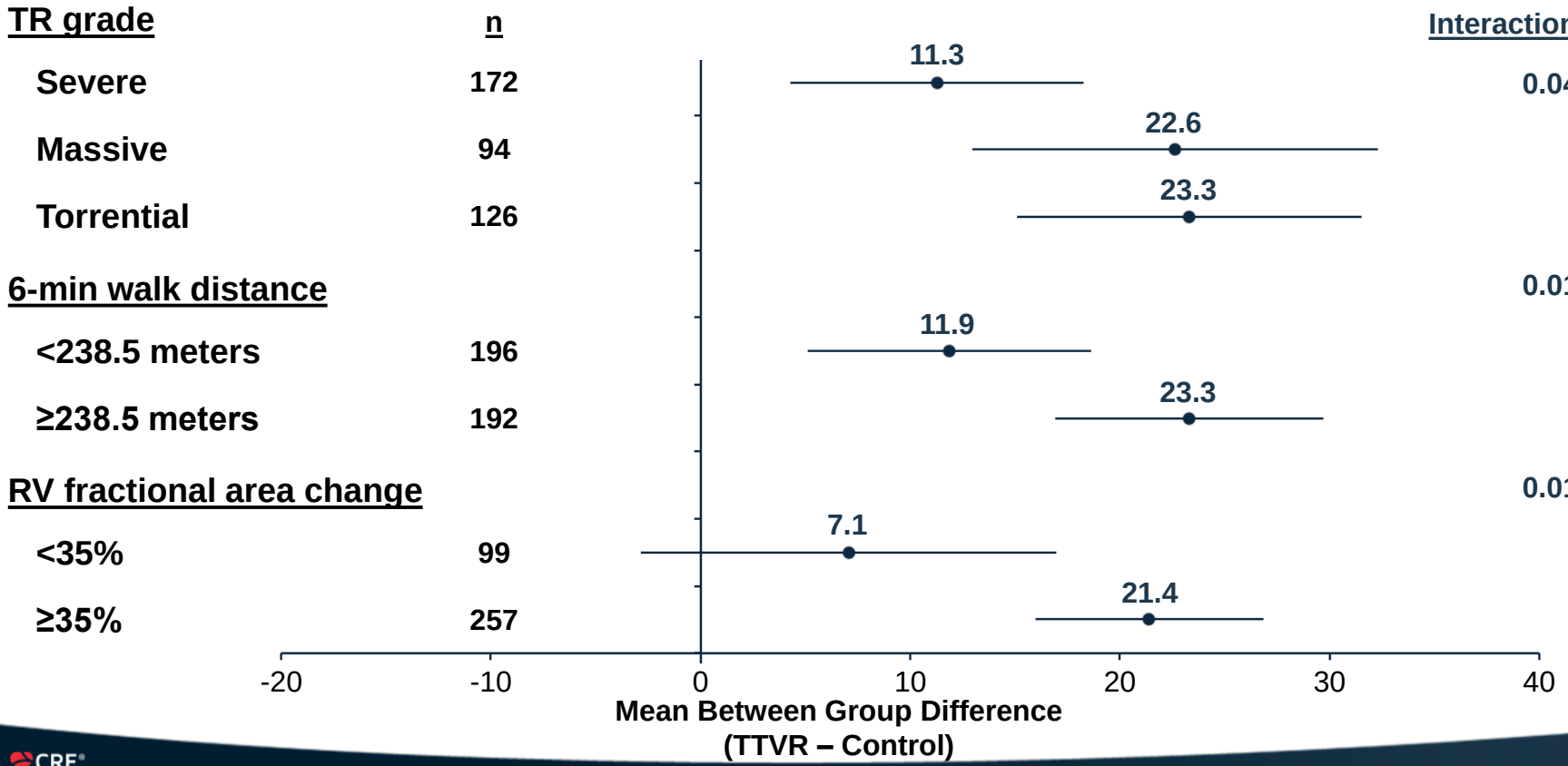


KCCQ-OS, Kansas City Cardiomyopathy Questionnaire Overall Summary score; *TR,* tricuspid regurgitation; *TTVR,* transcatheter tricuspid valve replacement

Baseline Subgroup Analyses at 1 Year by KCCQ-OS



Baseline Subgroup Analyses at 1 Year by KCCQ-OS



Additional non-significant treatment interactions: age, sex, COPD, LVEF, tricuspid annular plane systolic excursion, cardiac index, pulmonary hypertension, HF hospitalization in prior year, daily diuretic dose, baseline KCCQ-OS. *KCCQ-OS*, Kansas City Cardiomyopathy Questionnaire Overall Summary score; *RV*, right ventricle; *TTVR,* transcatheter tricuspid valve replacement

Summary and Conclusions

- At 1 year, TRISCEND II primary endpoint demonstrated superiority of EVOQUE TTVR for a patient population with limited treatment options
- TTVR with the EVOQUE system led to sustained TR reduction to ≤ mild in nearly all patients
- These TR reductions were associated with significant and marked improvement in symptoms, function, and quality of life at 1 year with favorable numerical trends in mortality and HF hospitalization
- These quality-of-life and symptomatic benefits should be balanced against periprocedural risks

The TRISCEND II trial confirms the clinical and quality-of-life benefits of the EVOQUE system for patients with ≥ severe TR

HF, heart failure; *TR,* tricuspid regurgitation; *TTVR*, transcatheter tricuspid valve replacement

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ORIGINAL ARTICLE

Transcatheter Valve Replacement in Severe Tricuspid Regurgitation

R.T. Hahn, R. Makkar, V.H. Thourani, M. Makar, R.P. Sharma, C. Haeffele, C.J. Davidson, A. Narang, B. O'Neill, J. Lee, P. Yadav, F. Zahr, S. Chadderdon, M. Eleid, S. Pislaru, R. Smith, M. Szerlip, B. Whisenant, N.K. Sekaran, S. Garcia, T. Stewart-Dehner, H. Thiele, R. Kipperman, K. Koulogiannis, D.S. Lim, D. Fowler, S. Kapadia, S. Harb, P.A. Grayburn, A. Sannino, M.J. Mack, M.B. Leon, P. Lurz, and S.K. Kodali, for the TRISCEND II Trial Investigators*

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Quality of Life After Transcatheter Tricuspid Valve Replacement

1-Year Results From TRISCEND II Pivotal Trial

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JACC