TRI-REPAIR: 30-Day Outcomes of Transcatheter TV Repair in Patients With Severe Secondary Tricuspid Regurgitation

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support	• DFG, BMBF, EU, Abbott, AGA, AstraZeneca, Bayer, Berlin Chemei, Biosensus, Biotronic, BMS, Boehringer Ingelheim, Daiichi Sankyo, Edwards, Medtronic, Mitratech, Novartis, Pfizer, Sanofi Aventis, St. Jude
• Consulting Fees/Honoraria	• Abbott, AGA, AstraZeneca, Bayer, Berlin Chemei, Biosensus, Biotronic, BMS, Boehringer Ingelheim, Daiichi Sankyo, Edwards, Medtronic, Mitratech, Novartis, Pfizer, Sanofi Aventis, St. Jude
• Other Financial Benefit (participating in clinical study)	• Abbott, AGA, AstraZeneca, Bayer, Berlin Chemei, Biosensus, Biotronic, BMS, Boehringer Ingelheim, Daiichi Sankyo, Edwards, Medtronic, Mitratech, Novartis, Pfizer, Sanofi Aventis, St. Jude

Only ~0.6% of tricuspid regurgitation patients are treated today

1.6M

TR prevalence

<10,000

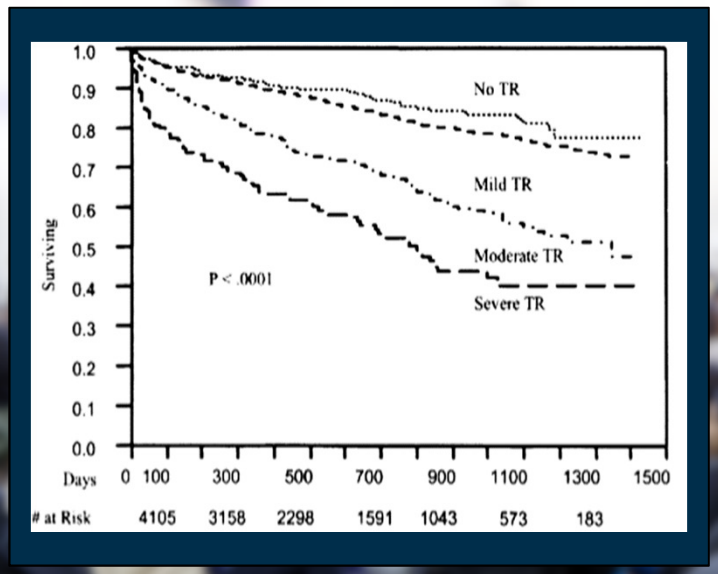
Surgical procedures annually

1. Singh JP, et.al. Prevalence and Clinical determinants of mitral, tricuspid, and aortic regurgitation, Am J Cardiol. 1999;83:897-902
2. McCarthy P.M, Sales V.L , Evolving Indications for Tricuspid Valve Surgery. Curr Treat Options Cardiovasc Med. 2010 Dec; 12(6): 587–597.

>25% mortality at year 1 for severe TR

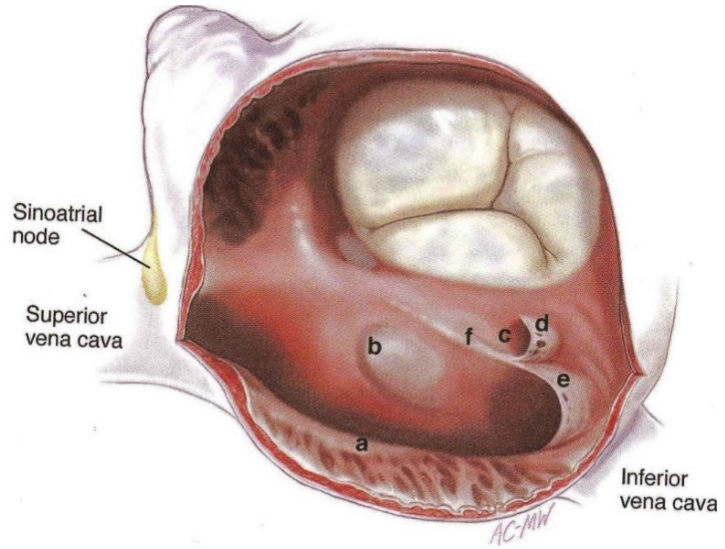
5,223 patients

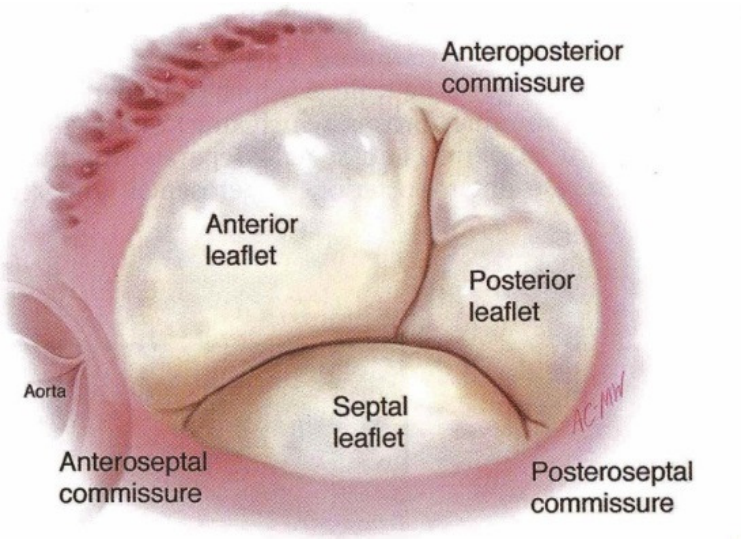
Study shows that moderate to severe TR increases mortality*



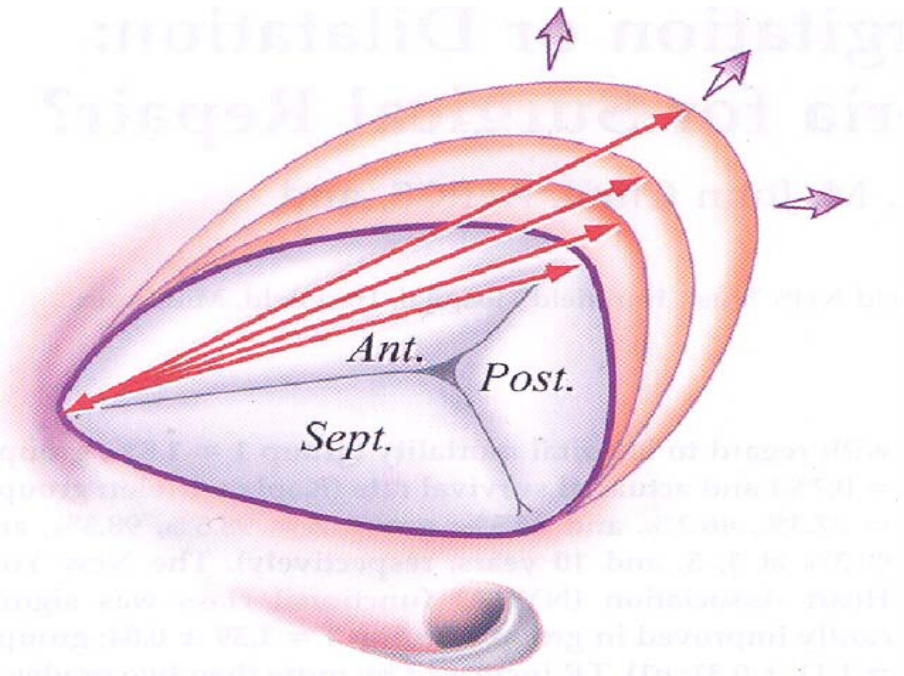
* Independent of PASP, LVEF, IVC size, RV size/function. Nath. JACC 2004;43:405

Tricuspid valve anatomy





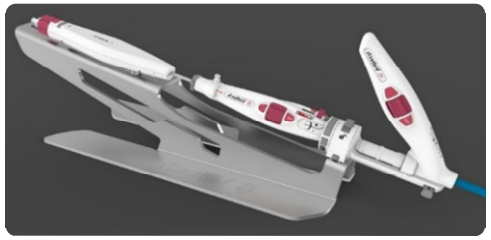
Functional TR - an outcome of annular dilatation

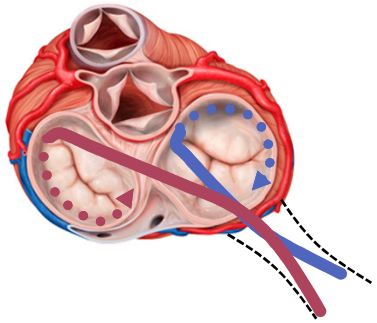


Edwards Cardioband Tricuspid Repair System

- Tricuspid annular reduction via transfemoral access
  - Dedicated technology to treat tricuspid regurgitation
  - Same concept and similar implant technique used with the Edwards Cardioband Mitral Repair System
- Short learning curve for Edwards Cardioband Mitral System users

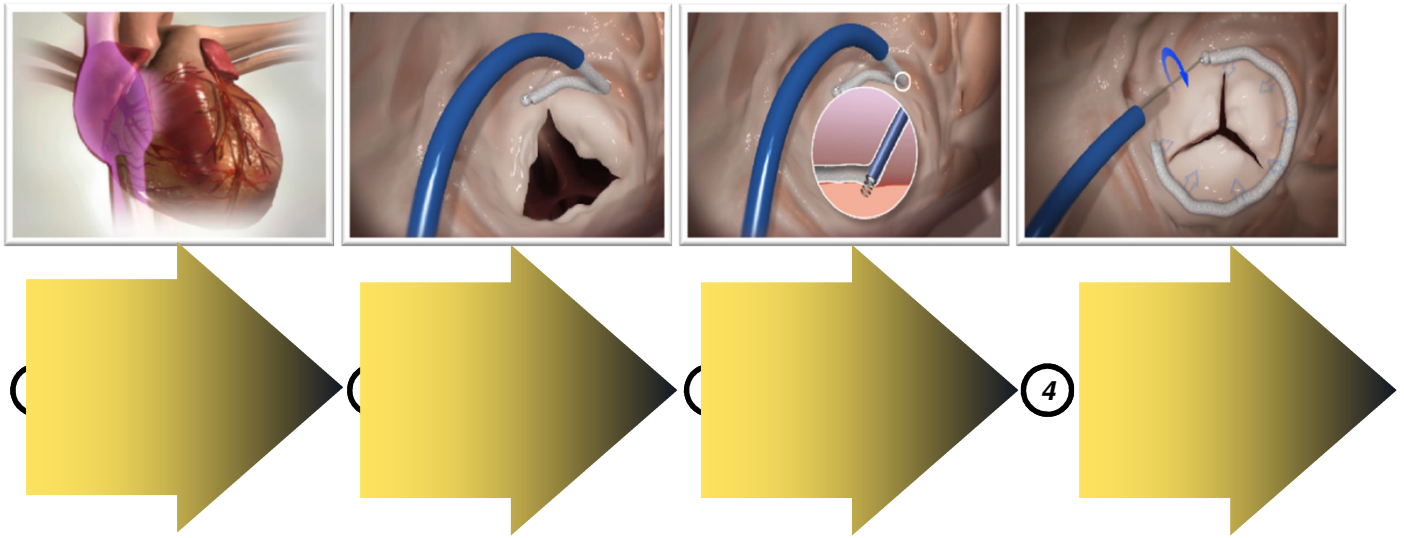
MR





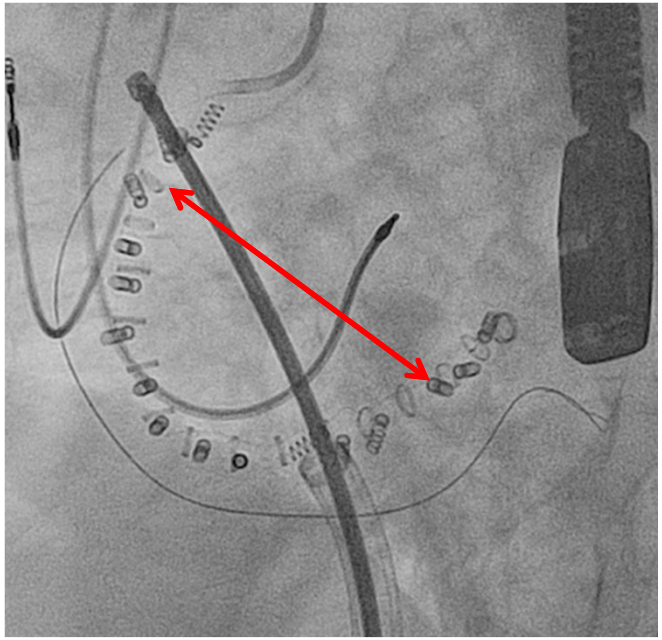
TR

Edwards Cardioband Tricuspid Repair Procedure

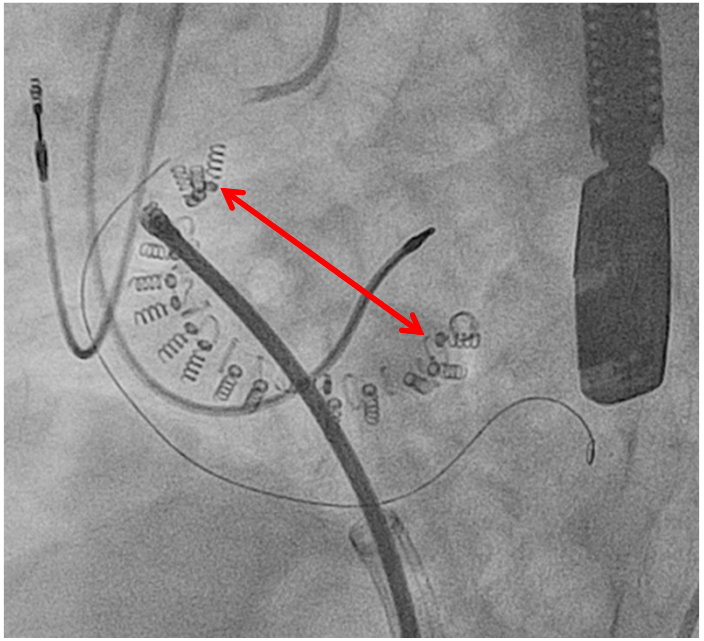


Edwards Cardioband Tricuspid Repair System
Transcatheter Tricuspid Valve Repair Fluoroscopic View

Pre-Reduction



Post-Reduction



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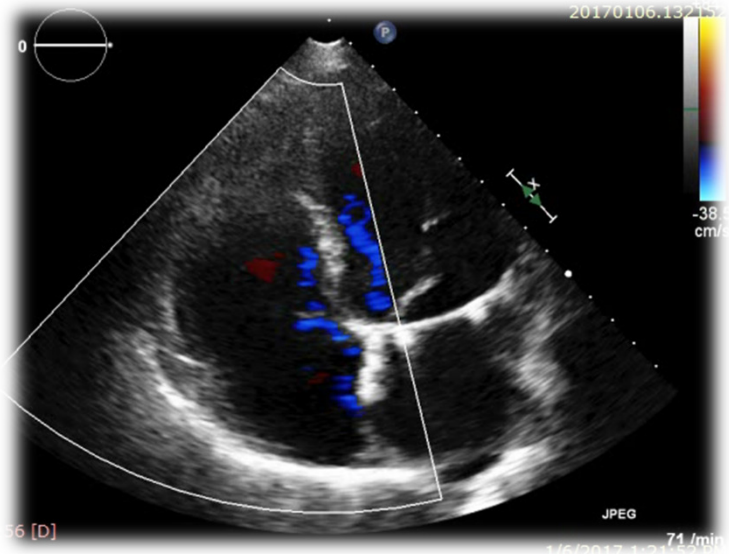
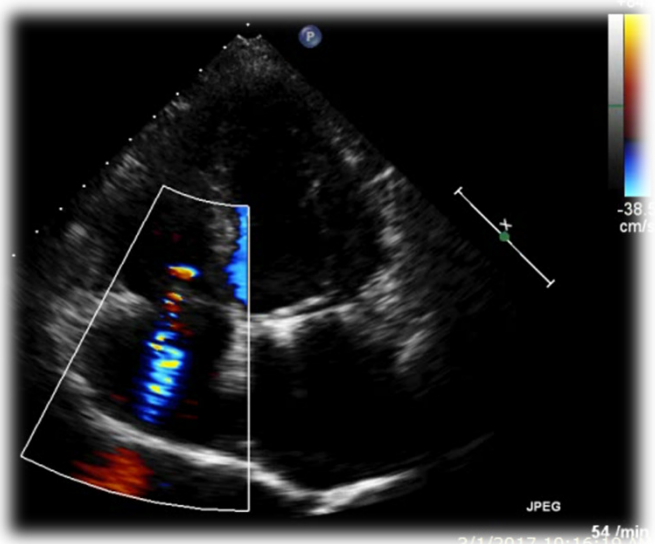
Edwards Cardioband Tricuspid Repair System Transthoracic Echocardiogram Result

Baseline



Discharge



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Edwards Cardioband Tricuspid Repair System
FIH Study (TRI-REPAIR)

Single arm, multi-center, prospective study to evaluate the performance and safety of the Edwards Cardioband System for repair of tricuspid regurgitation

Edwards TRI-REPAIR Study
Major Inclusion Criteria

- Chronic functional tricuspid regurgitation (FTR) 2+ to 4+ on a scale of 4+ (moderate to severe) with annular diameter ≥ 40 mm with valve systolic pulmonary pressure (sPAP) ≤ 60mmHg
- New York Heart Association (NYHA) Class II-IVa
- Symptomatic despite Guideline Directed Medical Therapy (GDMT); at minimum patient on diuretic regimen
- LVEF ≥ 30%
- The local site Heart Team concur that surgery will not be offered as a treatment option

Edwards TRI-REPAIR Study
Major Exclusion Criteria

- Aortic, mitral and/or pulmonic valve stenosis and/or regurgitation ≥ moderate
- Previous tricuspid valve repair or replacement
- Presence of trans-tricuspid pacemaker or defibrillator leads which cause impingement of the tricuspid valve leaflet as evaluated by echocardiography
- MI or known unstable angina within the 30 days prior to the index procedure
- Any PCI or transcatheter valvular intervention within 30 days prior to the index procedure or planned 3 months post the index procedure
- Cerebrovascular accident (CVA) within the past 6 months
- Subject is on chronic dialysis and/or anemia (Hb < 9 g/L)
- Life expectancy of less than 12 months
- Patients with cardiac cachexia

Edwards TRI-REPAIR Study
Endpoints

Primary

Safety

- Overall rate of Major Serious Adverse Events (MSAEs)* and serious adverse device effects (SADE) until hospital discharge and at post-operative 30 days

Technical

- Successful access, deployment and positioning of the Cardioband device
- Septolateral reduction at intra-procedure and discharge

Secondary

- TR grade, EROA and Regurgitant Volume (by echocardigraphy)
- Tricuspid annular plane systolic excursion (TAPSE)
- Technical success
- Functional tests: NYHA, 6MWD and KCCQ
- LVEF
- LVEDVI
- LVESVI
- Blood tests results for: NT-pro BNP, GOT, GGT, Bilirubin and BUN creatinine clearance
- Diuretic therapy
- Activity by wearable device (selected sites only)

Edwards TRI-REPAIR Study
Participating Sites

Principal Investigator	Location	Country
Georg Nickenig, MD	Universitätsklinikum Bonn, Bonn	Germany
R. S. von Bardeleben, MD	Universitätsmedizin der Johannes Gutenberg Universität Mainz, Mainz	Germany
Karl-Heinz Kuck, MD	Asklepios, St. Georg, Hamburg	Germany
Ulrich Schäfer, MD	Universitäres Herzzentrum Hamburg GmbH (UHZ), Hamburg	Germany
Jörg Hausleiter, MD	LMU Klinikum der Universität München, Campus Großhadern, München	Germany
Stephan Baldus, MD	Heart Center University of Köln, Köln	Germany
Alec Vahanian, MD	Hôpital Bichat-Claude Bernard, Paris	France
Azeem M. Latib, MD	Ospedale San Raffaele, Milano	Italy
Francesco Maisano, MD	University Hospital, Zurich	Switzerland

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Demographics

Variable	Mean (Range) or % N=30*
Age (years)	75.6 ± 6
Gender	Female - 74%
EuroSCORE II (%)	4.2%
Elevated Pulmonary Pressure (>35mmHg by Echo)	46%
Mean Systolic Pulmonary Arterial Pressure (mm Hg)	36 ± 11
LVEF (%)	57 ± 11
Baseline NYHA Class of III or IV (%)	86%
Diabetes	26%
Atrial Fibrillation	93%
Previous Heart Surgery	36%
CABG	23%
Valve Surgery (1x Mitral, 1x Aortic, 1x Aortic & Mitral)	13%
Previous Transcatheter Valve Repair/Replacement	10%
Moderate to Severe Renal Failure	53%
Prior Stroke	13%
Systemic Hypertension	80%
Electrodes in RV	13%

* Study is ongoing. Study demographics are based on available data.

Edwards TRI-REPAIR Study
Procedural outcomes

Successful access, deployment and positioning of the Cardioband device	100% (30/30)

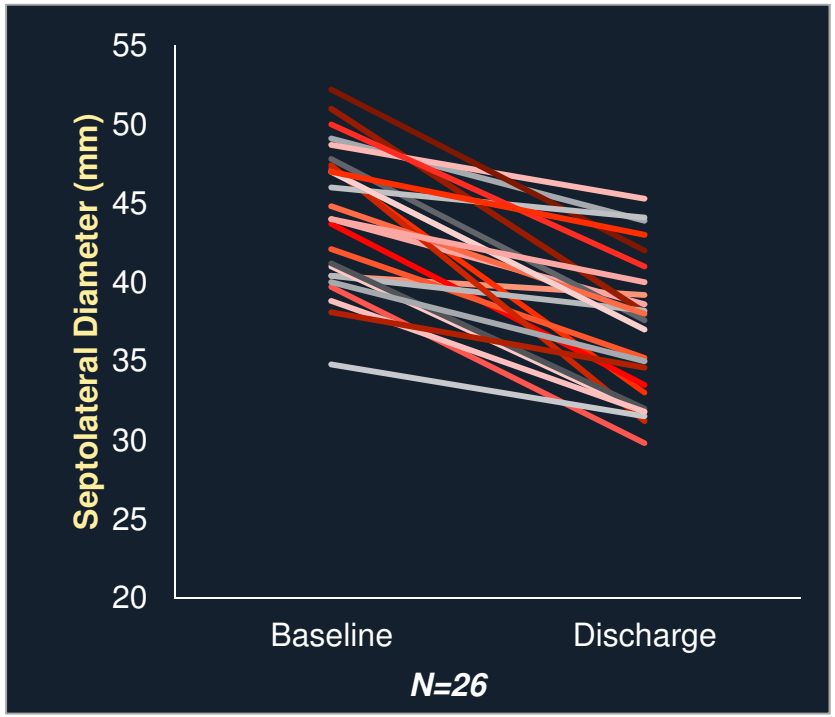
Edwards TRI-REPAIR Study
Adjudicated major safety events at 30 days

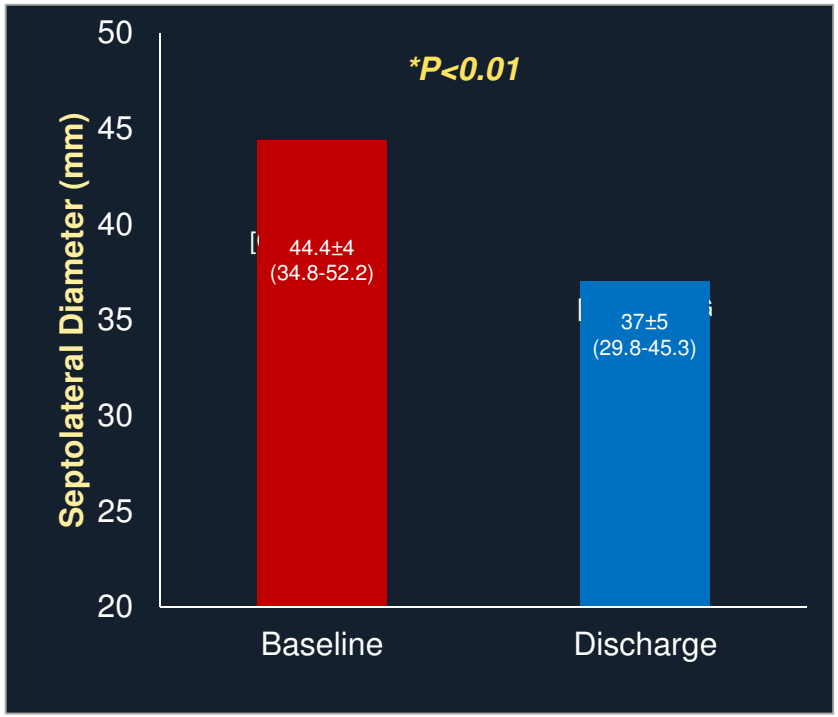
Adjudicated peri-procedural events	n
Death	2
Right ventricular failure	1
Bleeding unrelated to the device†	1
Stroke	1
Bleeding Complications*	3
Life-threatening†	2
Extensive	1
Device Related Cardiac Surgery	0
Renal Failure	0

* MVARC Guidelines (Stone et al, 2015)
† One patient had two life-threatening bleeding complications (cardiac tamponade, intracranial hemorrhage) and died

Edwards TRI-REPAIR Study

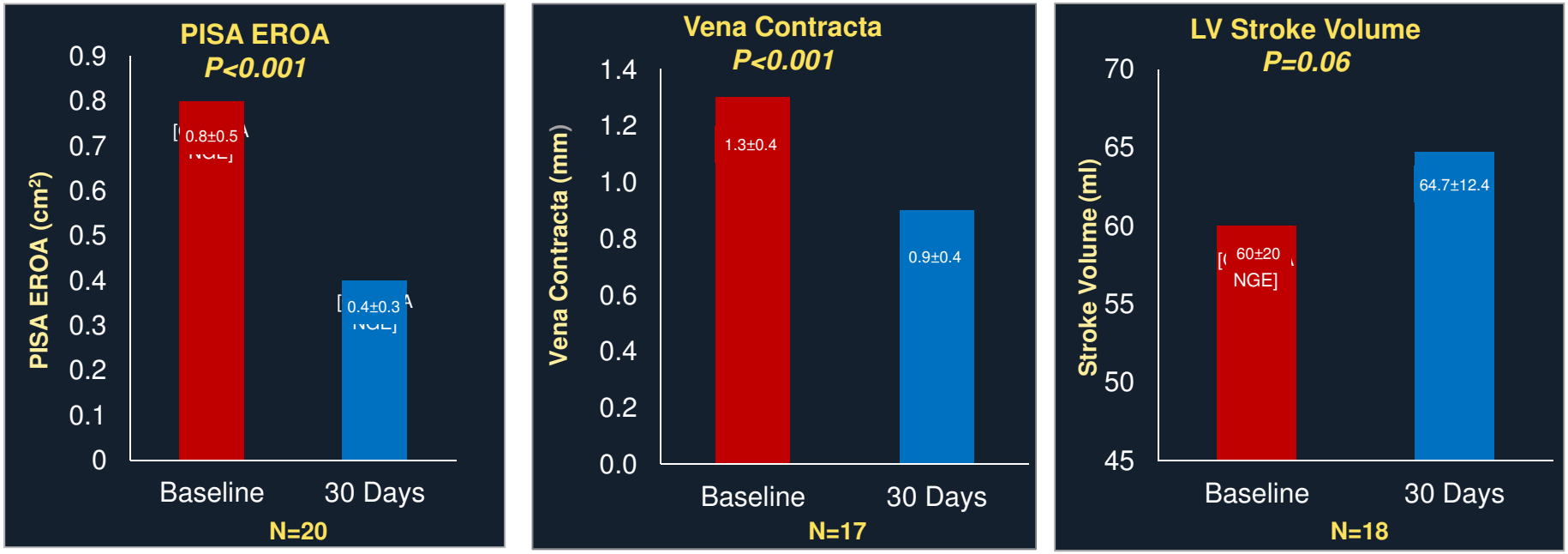
17% average reduction in septolateral diameter by core lab





Data not fully monitored, subject to change

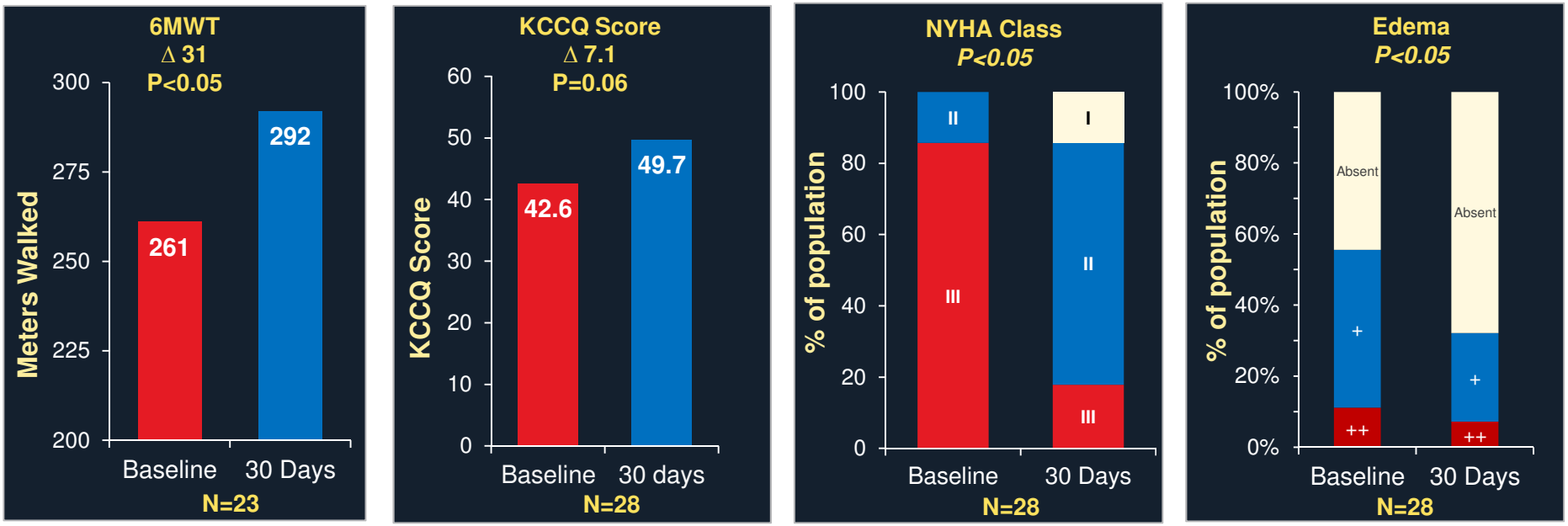
Edwards TRI-REPAIR Study
50% reduction in PISA EROA, 31% reduction in vena contracta, and 7% improvement in stroke volume by core lab at 30 days



- Large proportion of patients treated with “torrential TR”
- Improvements resulted in most patients achieving lower severity or moderate TR at 30 days.

Data not fully monitored, subject to change

Edwards TRI-REPAIR Study
Functional improvement at 30 days



- NYHA functional status and KCCQ QoL scores are left-sided Heart failure clinical endpoints
- Further study needed to understand clinically important endpoints for patients with right-sided heart dysfunction

6MWT - 6 Min Walk Test, KCCQ - Kansas City Cardiomyopathy Questionnaire, NYHA Class - New York Heart Association (NYHA) Functional Classification

Data not fully monitored, subject to change

Edwards TRI-REPAIR Study

Conclusions

- Use of Edwards Cardioband System for tricuspid regurgitation is feasible and safe
- Significant annular reduction
- Reduced TR, despite treating a large proportion of patients with “torrential” TR at baseline
- Improvements in functional status

Thank You