



Transcatheter Repair in Severe TR

Data suggest repair in selected patients only

Nir Flint

Division of Cardiology
Tel Aviv Sourasky Medical Center

TRILUMINATE Pivotal

- N=350, 65 centers
- Severe, Symptomatic (NYHA II-IV) Isolated TR
- Intermediate/High Surgical risk

• Main Exclusion Criteria:

- SPAP > 70mmHG or Precapillary PHTN by RHC
- LVEF < 20%

• Anatomical Exclusion:

- Calcification at grasping area
- Coaptation defect > 2cm
- Pacemaker lead that would prevent clipping

Subjects Approved by Eligibility Committees for

- Suitable anatomy
- Adequate management (assessed via RHC)
- No fixed pre-cap PHTN (assessed via RHC)

Yes

Predicted to achieve TR of moderate or less?

N=350

Yes

TRILUMINATE Pivotal RCT
Randomized 1:1,
Device:Medical Therapy alone

N=100

No, but at least 1
grade TR reduction

TRILUMINATE Pivotal
Single Arm

TRILUMINATE

Eligible patients:

Severe symptomatic TR
SPAP<70mmHg
GDMT for 30 days

Informed Consent
N=1573

```
graph TD; A[Informed Consent N=1573] --> B[ ]
```

TRILUMINATE

Eligible patients:

Severe symptomatic TR
SPAP < 70 mmHg
GDMT for 30 days

Informed Consent
N=1573

Echo Core Lab and
Eligibility Committee:

Predicted to achieve TR of
moderate or less?

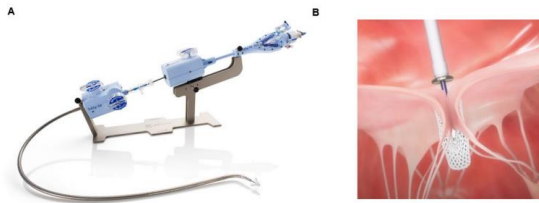
Screen failure
(or single arm)
N= 911

Randomized
N=350

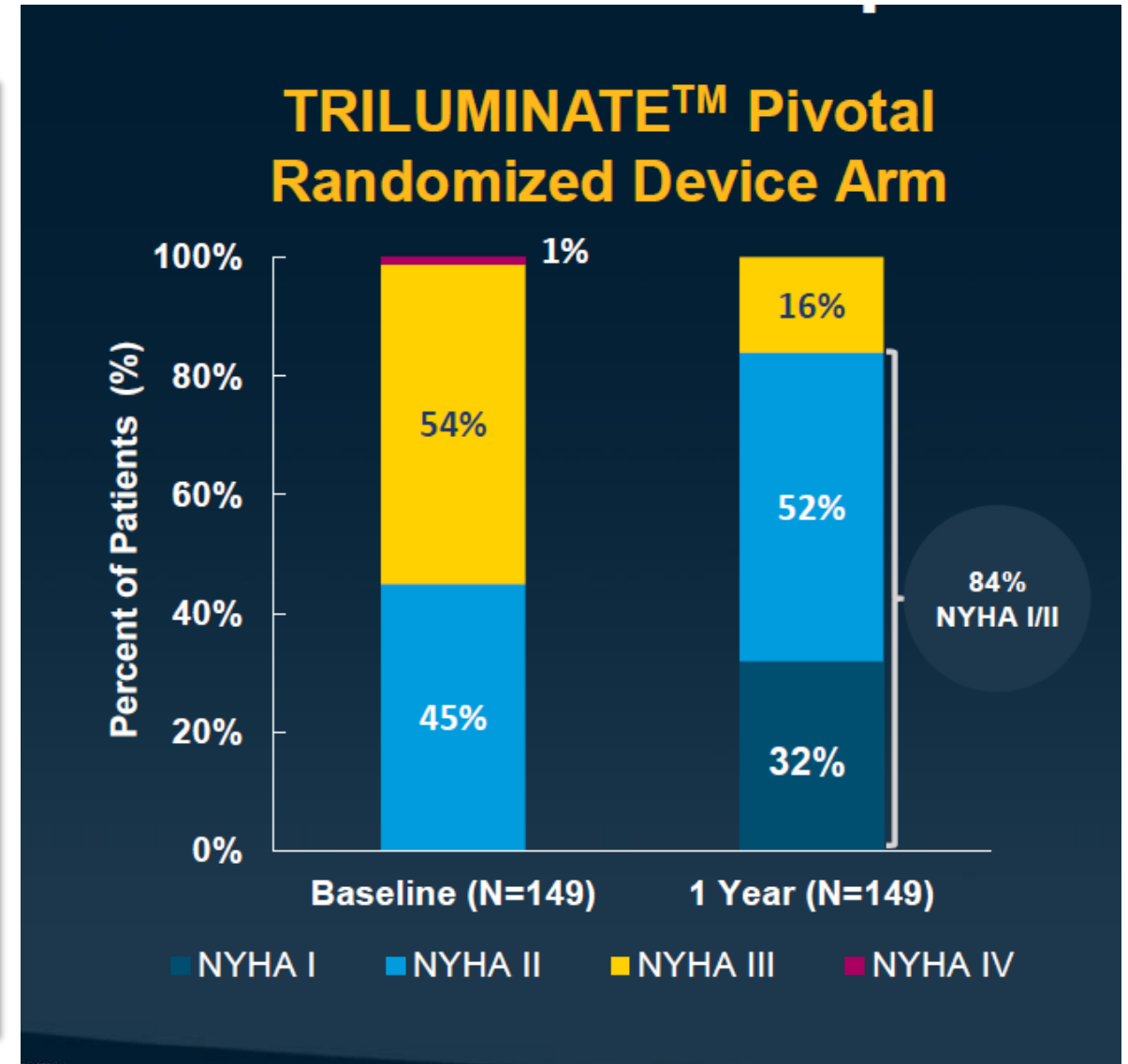
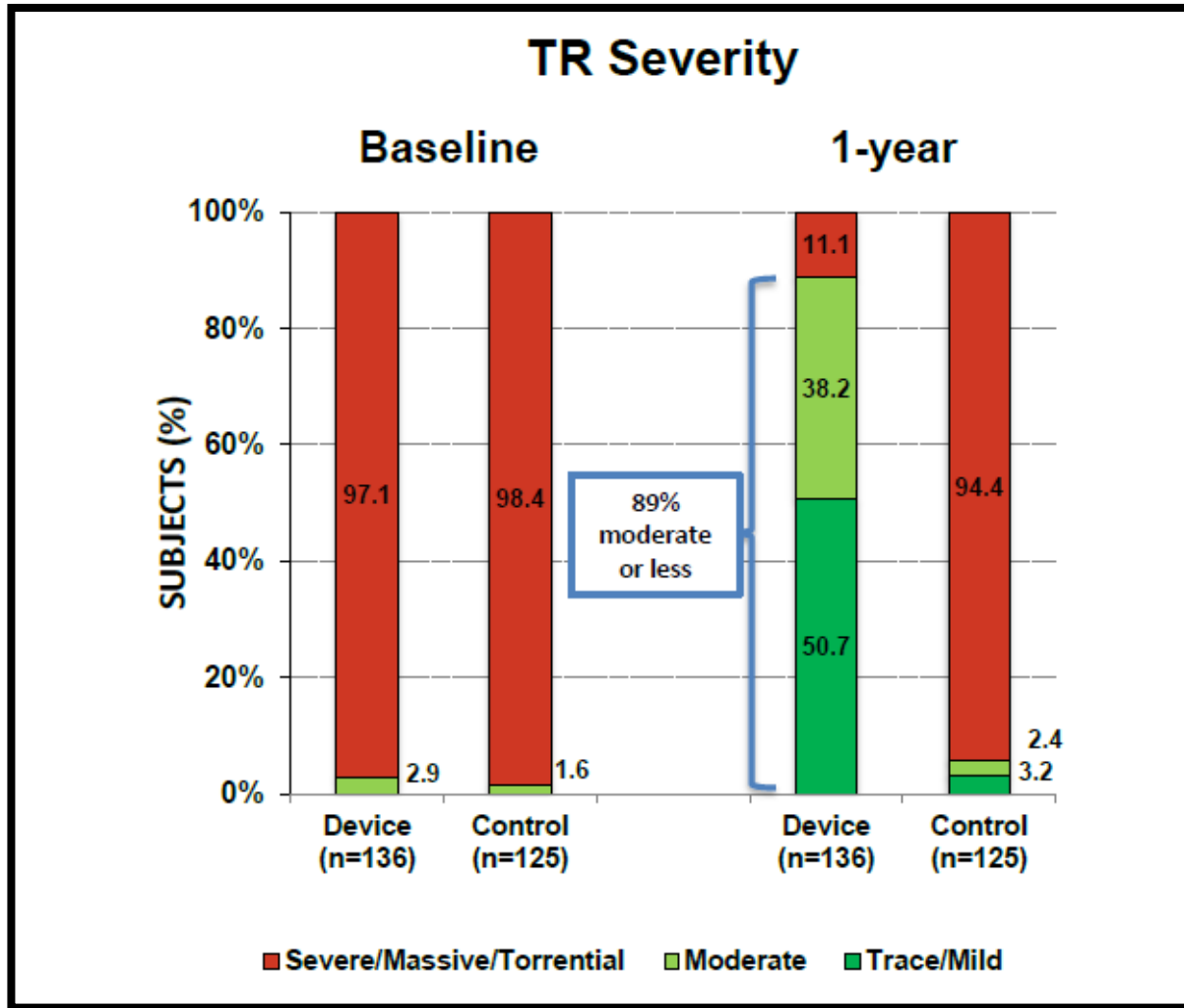
Randomized 1:1

TriClip
(N=175)

Medical Therapy
(N=175)

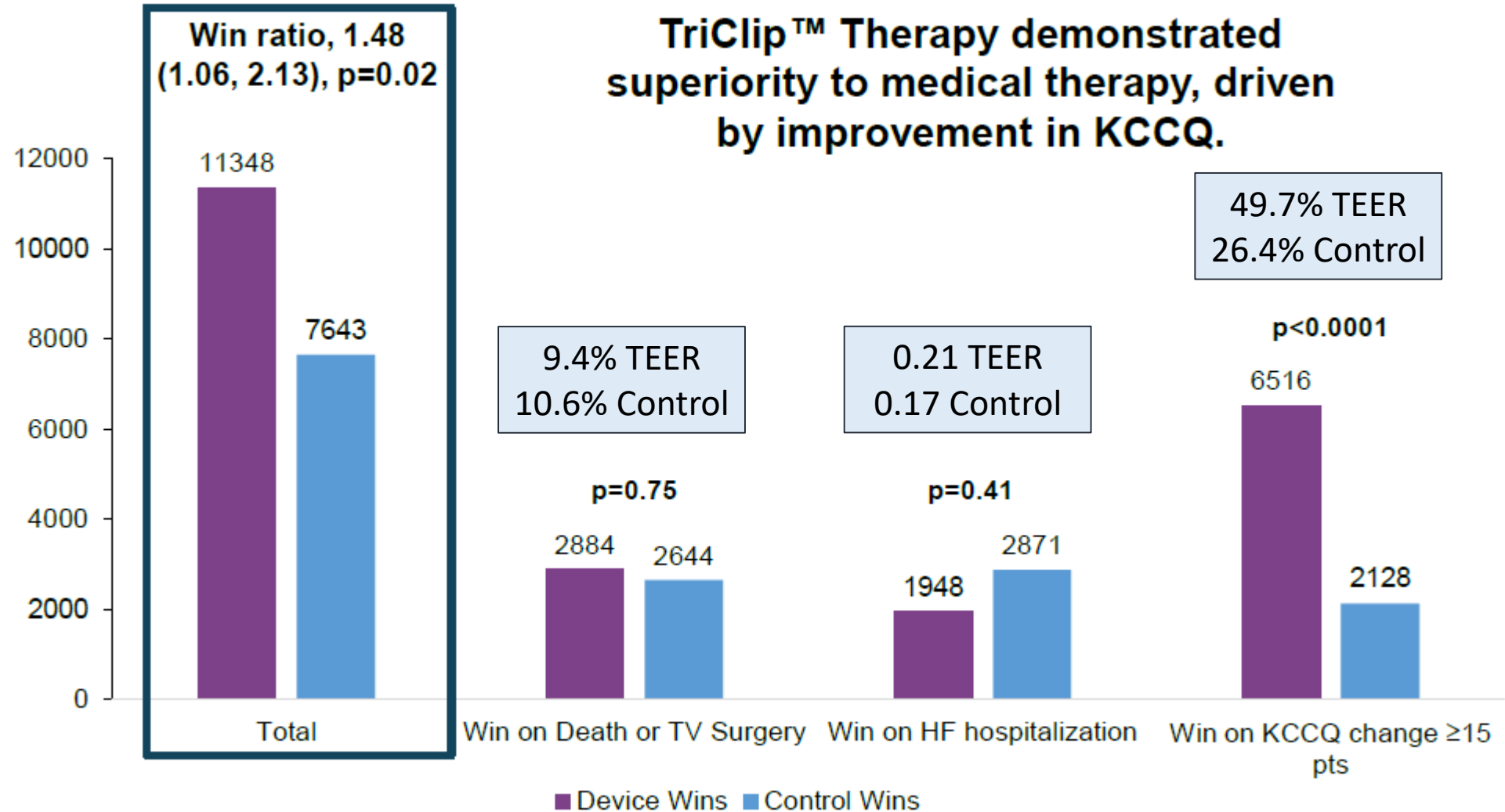


TRILUMINATE Pivotal



TRILUMINATE Pivotal

PRIMARY ENDPOINT



Triluminate Vs. Real World

	TRILUMINATE N=350	bRIGHT (TriClip) N=511	PASTE (PASCAL) N=603
Massive/Torrential TR	71%	88%	56%
Prior HF Hosp. 1y pre procedure	25%	40%	--
NYHA III/IV	55%	80%	89%
Prior PM/ICD/CRT	15%	23%	28%
KCCQ Score	55	44	--

TRILUMINATE

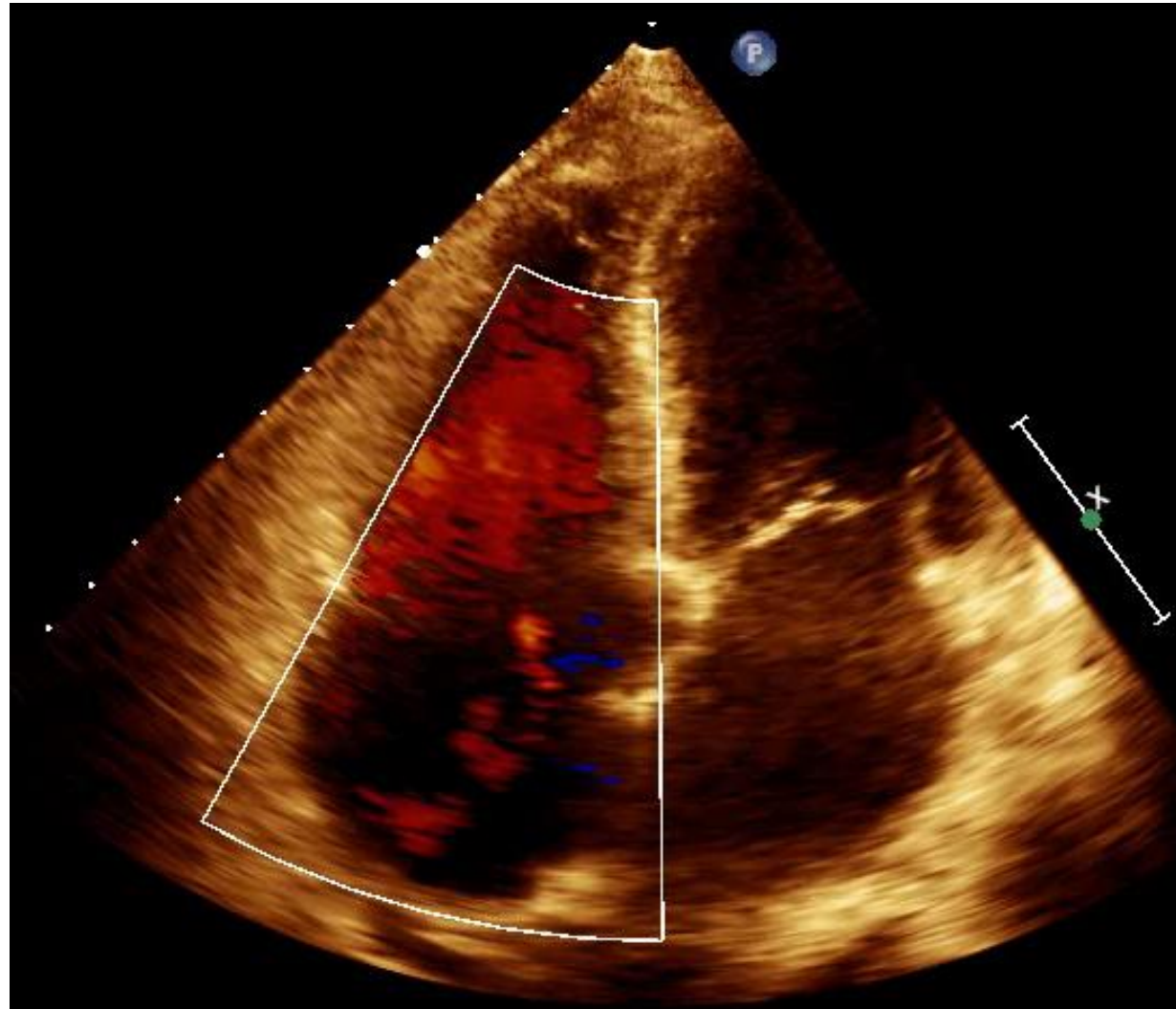


- First RCT
- 87% Procedural success
- Met the primary outcome
- Overall safe procedure
- 5-year follow-up



- Open-label trial, no sham
- QoL benefit only
- No change in 6mW (-8m)
- Highly selective population
- 50% with moderate or more residual TR
- 5% major bleeding, 7% SLDA @ 30-day

To TEER or Not to TEER?

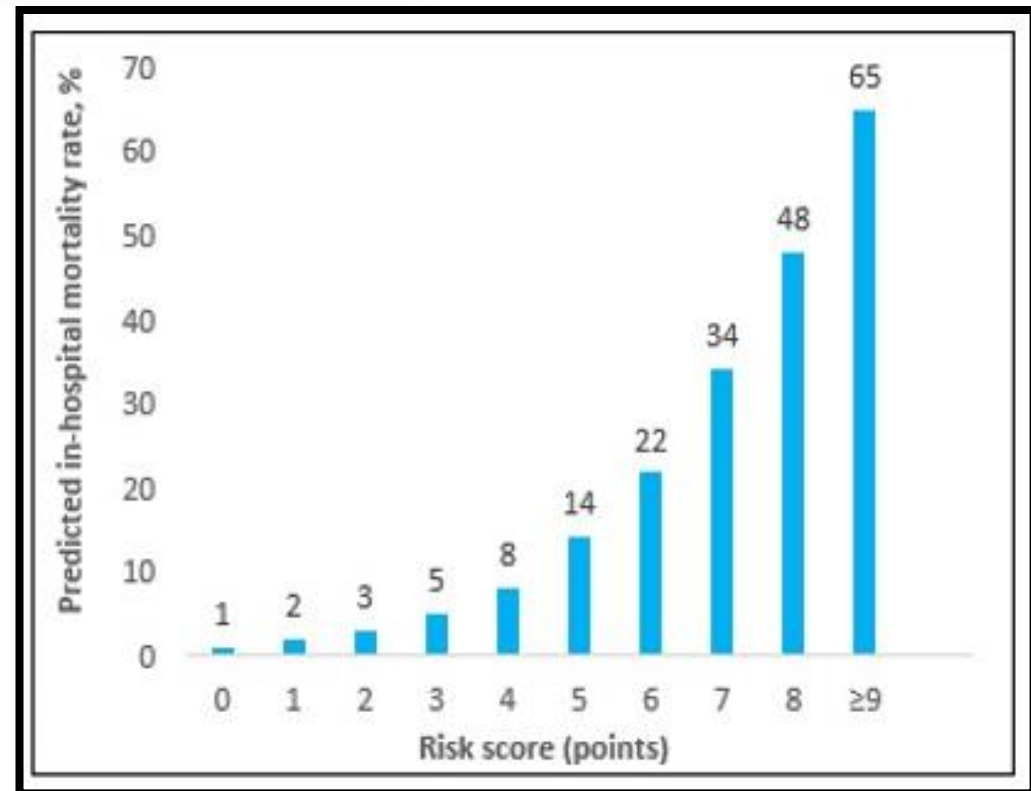


TRI-SCORE

TRI-SCORE: a new risk score for in-hospital mortality prediction after isolated tricuspid valve surgery

Julien Dreyfus ^{1,*†}, Etienne Audureau ^{2,3,†}, Yannick Mbaki ¹⁵, Damien Eyharts ⁸,
Augustin Coisne ^{6,7}, Yoan Lavie-Badie ⁸, Maxime Bouchery ⁹,
Michele Flagiello ¹⁰, Baptiste Bazire ¹¹, Florian Eggensteiner ¹²,
Florence Viau ¹³, Elisabeth Riant ^{1,14}, Yannick Mbaki ¹⁵, Damien Eyharts ⁸,
Thomas Senage ¹⁶, Thomas Modine ⁶, Martin Nicol ¹, Fabien Doguet ^{17,18},
Virginia Nguyen ¹, Thierry Le Tourneau ¹⁹, Christophe Tribouilloy ^{4,5},
Erwan Donal ¹⁵, Jacques Tomasi ²⁰, Gilbert Habib ^{13,21},
Christine Selton-Suty ¹², Richard Raffoul ²², Bernard Jung ²³,
Jean-François Obadia ¹⁰, and David Messika-Zeitoun ^{24*}

Risk factors (final model from multivariate analysis)	Scoring
Age \geq 70 years	1
NYHA functional class III-IV	1
Right-sided heart failure signs	2
Daily dose of furosemide \geq 125mg	2
Glomerular filtration rate $<$ 30 ml/min	2
Elevated total bilirubin	2
Left ventricular ejection fraction $<$ 60%	1
Moderate/severe right ventricular dysfunction	1
Total	12



TRI-SCORE: Predicts Mortality post T-TEER



ESC

European Society of Cardiology

European Heart Journal (2023) 00, 1–12
<https://doi.org/10.1093/eurheartj/ehad585>

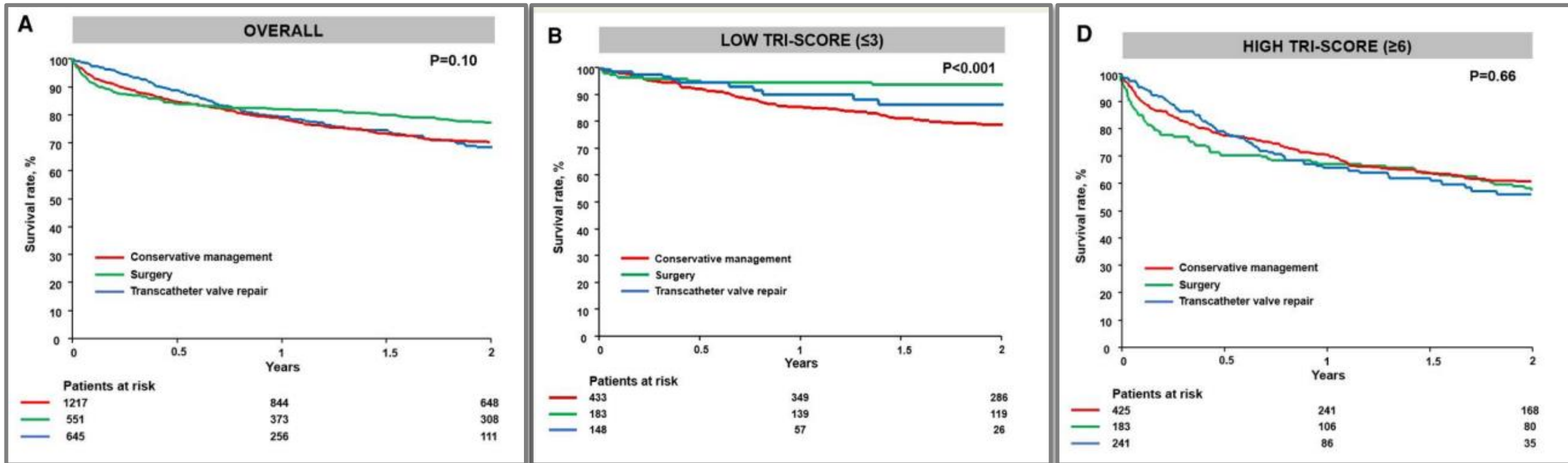
FASTTRACK CLINICAL RESEARCH

Valvular heart disease

Isolated TR International Registry (N=2413)

- Conservative (n=1217)
- Transcatheter (n=551)
- Surgery (n=645)

TRI-SCORE and benefit of intervention in patients with severe tricuspid regurgitation



Adjusted for age, sex, comorbidities (P=0.23)

TRI-SCORE: Predicts Mortality post T-TEER

TRI-SCORE and benefit of intervention in patients with severe tricuspid regurgitation

Isolated TR International Registry (N=2413)

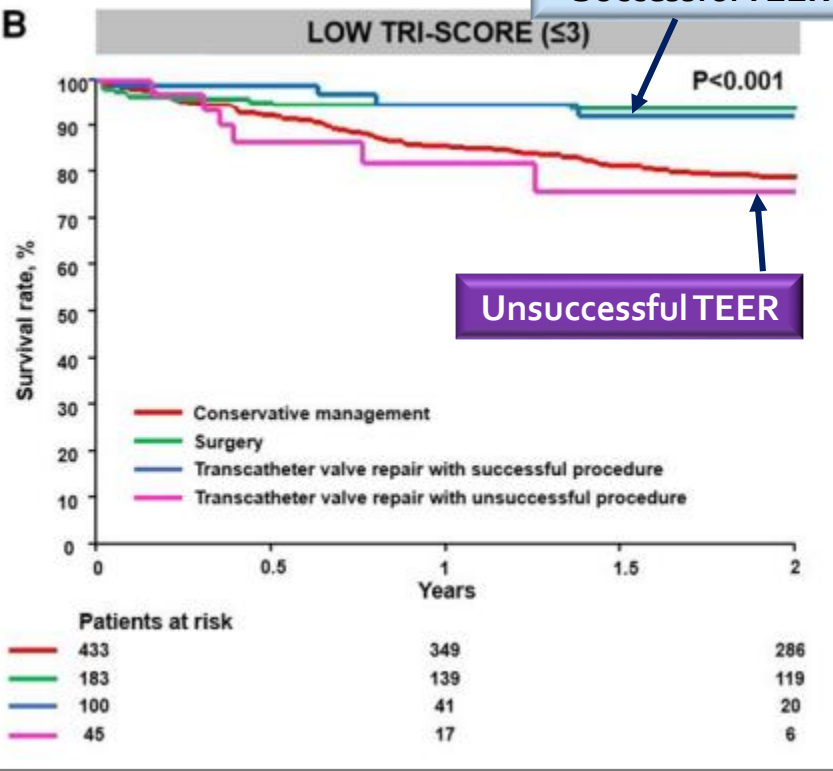
- Conservative (n=1217)
- Transcatheter (n=551)
- Surgery (n=645)

Successful TEER

LOW TRI-SCORE (≤ 3)

P<0.001

Unsuccessful TEER

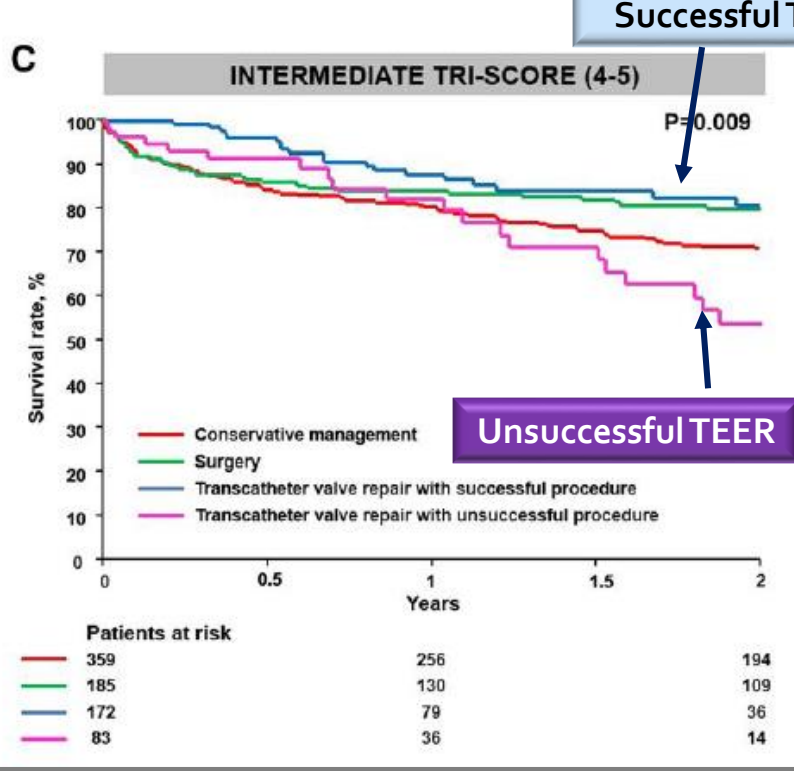


Successful TEER

INTERMEDIATE TRI-SCORE (4-5)

P=0.009

Unsuccessful TEER

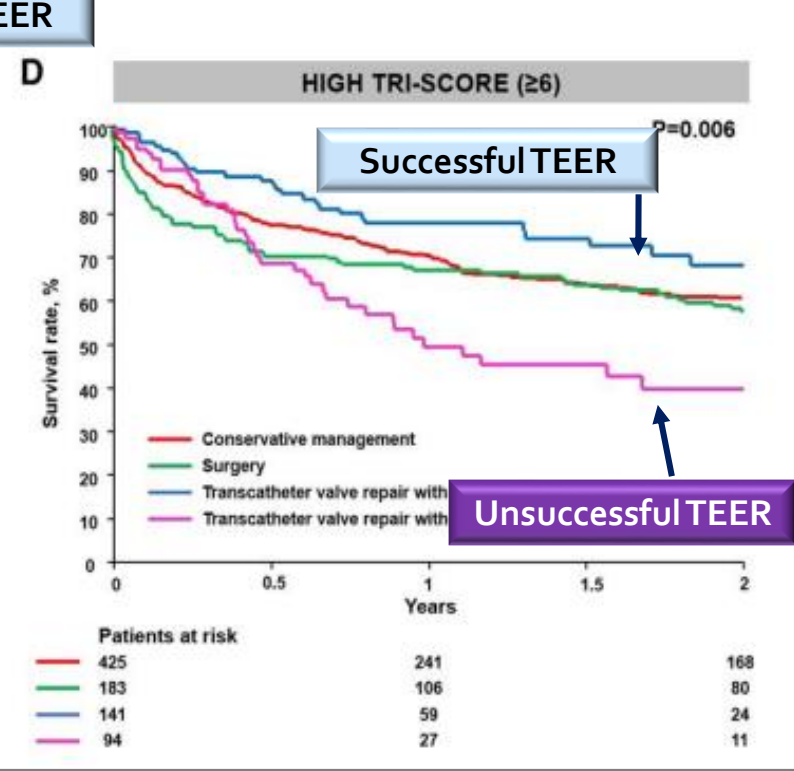


Successful TEER

HIGH TRI-SCORE (≥ 6)

P=0.006

Unsuccessful TEER

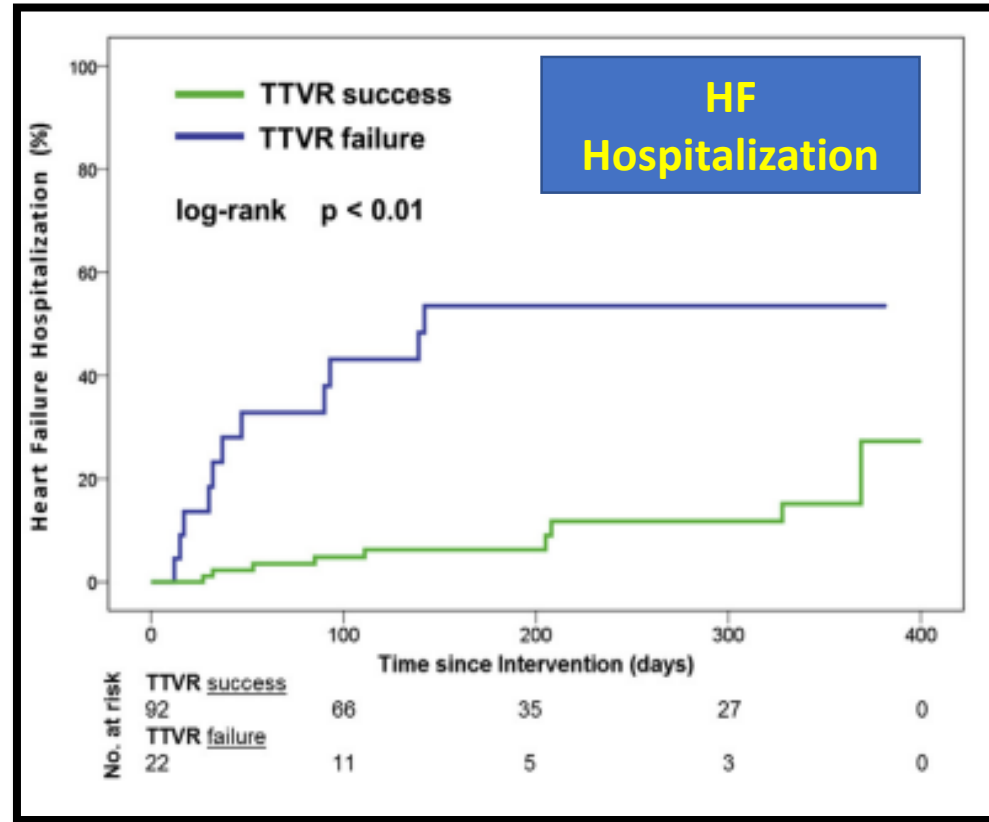
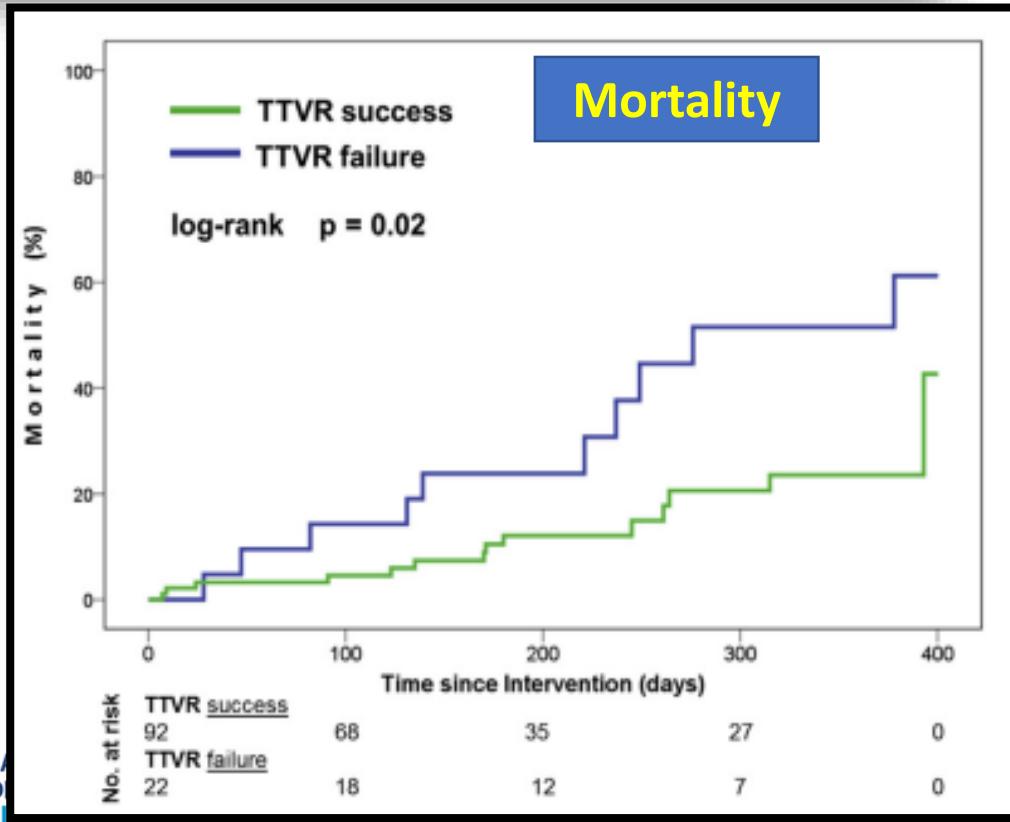


T-TEER Procedural Success

Predictors of Procedural and Clinical Outcomes in Patients With Symptomatic Tricuspid Regurgitation Undergoing Transcatheter Edge-to-Edge Repair



Christian Besler, MD,^{a,*} Mathias Orban, MD,^{b,c,*} Karl-Philipp Rommel, MD,^{a,*} Daniel Braun, MD,^b Mehul Patel, MD,^d Christian Hagl, MD,^e Michael Borger, MD, PhD,^f Michael Nabauer, MD,^b Steffen Massberg, MD,^{b,c} Holger Thiele, MD,^a Jörg Hausleiter, MD,^{b,c,†} Philipp Lurz, MD, PhD^{a,†}



T-TEER Procedural Success

1-Year Outcomes After Edge-to-Edge Valve Repair for Symptomatic Tricuspid Regurgitation

Results From the TriValve Registry

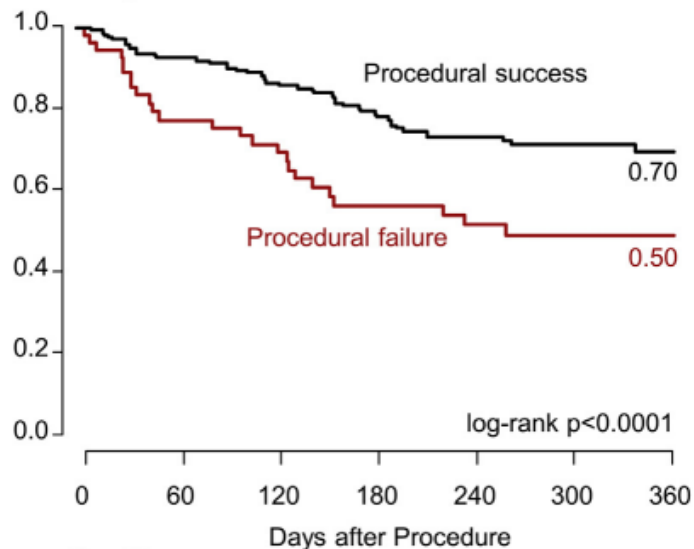
Michael Mehr, MD,^{a,b,*} Maurizio Taramasso, MD,^{c,*} Christian Besler, MD,^d Tobias Ruf, MD,^e Kim A. Conne Marcel Weber, MD,^g Ermela Yzeiraj, MD,^h Davide Schiavi, MD,ⁱ Antonio Mangieri, MD,^j Laura Vaskelyte, M Hannes Alessandrini, MD,^k Florian Deuschl, MD,^l Nicolas Brugger, MD,^m Hasan Ahmad, MD,ⁿ Luigi Biasco Mathias Orban, MD,^{a,b} Simon Deseive, MD,^{a,b} Daniel Braun, MD,^{a,b} Karl-Philipp Rommel, MD,^d Alberto Pozzo Christian Frerker, MD,^k Michael Nábauer, MD,^{a,b} Steffen Massberg, MD,^{a,b} Giovanni Pedrazzini, MD,^o Gilbert H.L. Tang, MD,^{n,p} Stephan Windecker, MD,^m Ulrich Schäfer, MD,^j Karl-Heinz Kuck, MD,^h Horst Siev Paolo Denti, MD,^l Azeem Latib, MD,^l Joachim Schofer, MD,^h Georg Nickenig, MD,^g Neil Fam, MD,^f Stephan von Bardeleben, MD,^c Philipp Lurz, MD,^d Francesco Maisano, MD,^{c,i} Jörg Hausleiter, MD,^{a,b,i}

Leaflet-to-annulus index and residual tricuspid regurgitation following tricuspid transcatheter edge-to-edge repair

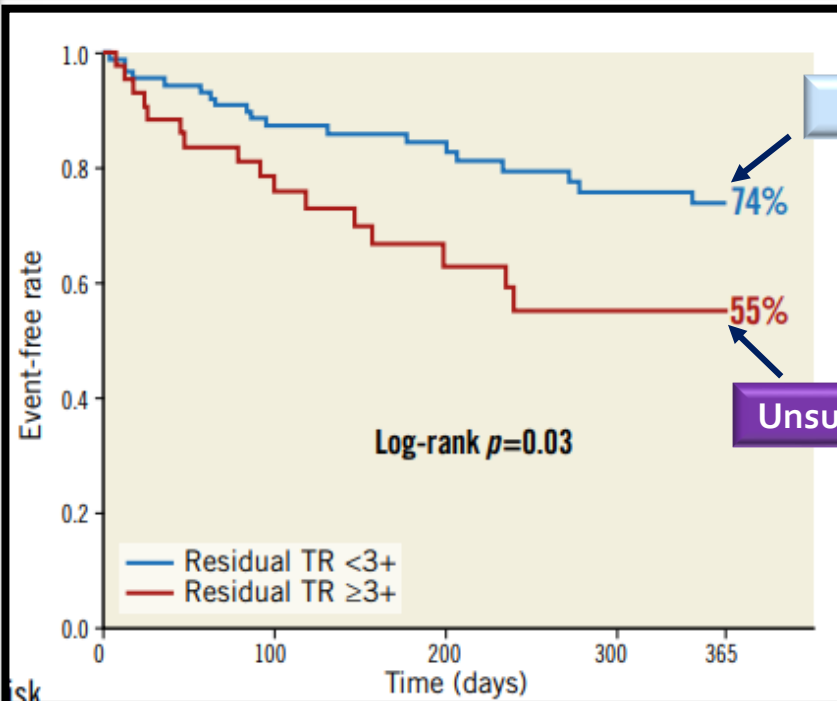
Tetsu Tanaka, MD; Atsushi Sugiura*, MD, PhD; Refik Kavsar, MD; Johanna Vogelhuber, MD; Can Öztürk, MD; Marc Ulrich Becher, MD; Sebastian Zimmer, MD; Georg Nickenig, MD; Marcel Weber, MD

Medizinische Klinik und Poliklinik II, Universitätsklinikum Bonn, Bonn, Germany

Mortality or unplanned hospitalization for HF according to Procedural Success



No at risk						
192	157	140	119	95	82	68
57	39	34	26	21	18	15



Successful TEER

Unsuccessful TEER

T-TEER Procedural Success

1-Year Outcomes After Edge-to-Edge Valve Repair for Symptomatic Tricuspid Regurgitation

Results From the TriValve Registry

Michael Mehr, MD,^{a,b,*} Maurizio Taramasso, MD,^{c,*} Christian Besler, MD,^d Tobias Ruf, MD,^e Kim A. Conne Marcel Weber, MD,^f Ermela Yzeiraj, MD,^b Davide Schiavi, MD,^g Antonio Mangieri, MD,^h Laura Vaskelyte, M Hannes Alessandrini, MD,^b Florian Deuschl, MD,ⁱ Nicolas Brugger, MD,^m Hasan Ahmad, MD,ⁿ Luigi Biasco Mathias Orban, MD,^{a,b} Simon Deseive, MD,^{a,b} Daniel Braun, MD,^{a,b} Karl-Philipp Rommel, MD,^g Alberto Pozz Christian Frerker, MD,^k Michael Nábauer, MD,^{a,b} Steffen Massberg, MD,^{a,b} Giovanni Pedrazzini, MD,^o Gilbert H.L. Tang, MD,^{n,p} Stephan Windecker, MD,^m Ulrich Schäfer, MD,^g Karl-Heinz Kuck, MD,^h Horst Siev Paolo Denti, MD,^g Azeem Latib, MD,^g Joachim Schofer, MD,^h Georg Nickenig, MD,^g Neil Fam, MD,^f Stephan von Bardeleben, MD,^e Philipp Lurz, MD,^g Francesco Maisano, MD,^{g,i} Jörg Hausleiter, MD,^{a,b,i}

Leaflet-to-annulus index and residual tricuspid regurgitation following tricuspid transcatheter edge-to-edge repair

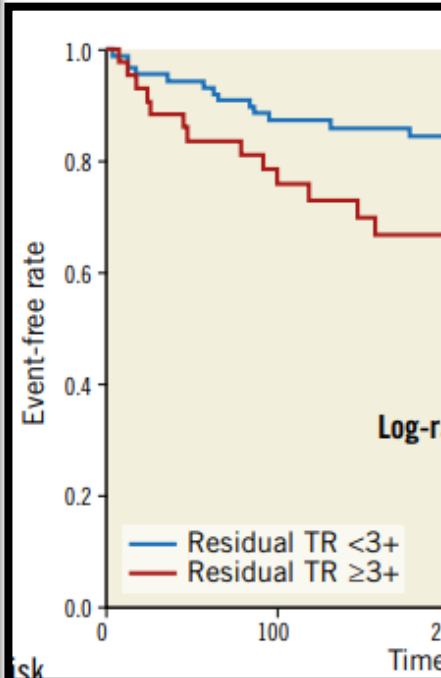
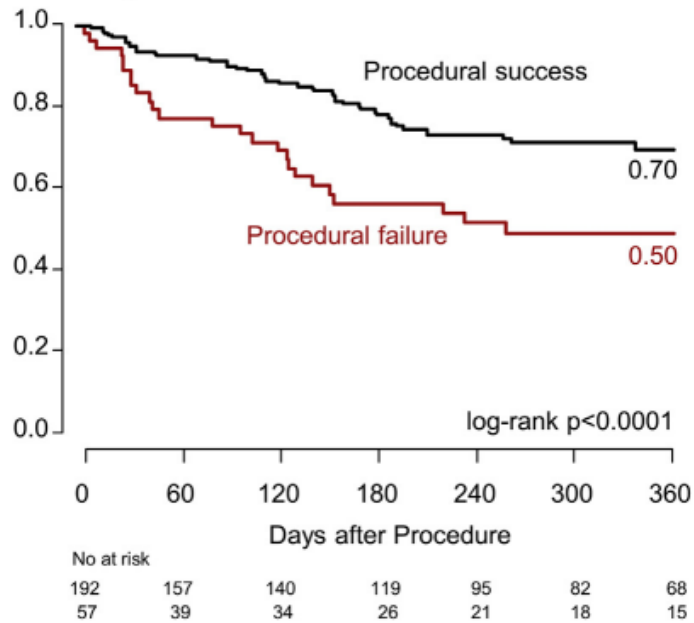
Tetsu Tanaka, MD; Atsushi Sugiura*, MD, PhD; Refik Kovacur, MD; Johanna Vogelhuber, MD; Can Öztürk, MD; Marc Ulrich Becher, MD; Sebast

Medizinische Klinik und Poliklinik II, Universitätsklinikum

Clinical and Echocardiographic Outcomes of Transcatheter Tricuspid Valve Interventions: A Systematic Review and Meta-Analysis

Anna Sannino^{1,2*}, Federica Ilardi^{2,3}, Rebecca T. Hahn⁴, Patrizio Lancellotti^{5,6}, Philipp Lurz⁷, Robert L. Smith¹, Giovanni Esposito² and Paul A. Grayburn¹

Mortality or unplanned hospitalization for HF according to Procedural Success



Study	Odds Rate, Random, 95% CI	Sig.	N	1-year mortality
Besler et al. 2018	0.47 (0.18, 1.20)	0.114	114	
Mehr et al. 2019	0.45 (0.23, 0.88)	0.020	249	
Orban et al. 2020	0.42 (0.15, 1.14)	0.089	119	
TRILUMINATE 2019-21	0.29 (0.08, 1.05)	0.060	85	
Overall (random-effects model)	0.42 (0.27, 0.66)	0.000	567	Procedural Success

Heterogeneity: $\tau^2 = 0.00$; $df=3$ ($P=0.938$); $I^2=0.00$.

Predictors of T-TEER Procedural Success

Predictors of Procedural Success

Predictors of Procedural and Clinical Outcomes in Patients With Symptomatic Tricuspid Regurgitation Undergoing Transcatheter Edge-to-Edge Repair



Christian Besler, MD,^{a,*} Mathias Orban, MD,^{b,c,*} Karl-Philipp Rommel, MD,^{a,*} Daniel Braun, MD,^b Mehul Patel, MD,^d Christian Hagl, MD,^e Michael Borger, MD, PhD,^f Michael Nabauer, MD,^b Steffen Massberg, MD,^{b,c} Holger Thiele, MD,^a Jörg Hausleiter, MD,^{b,c,†} Philipp Lurz, MD, PhD^{a,†}

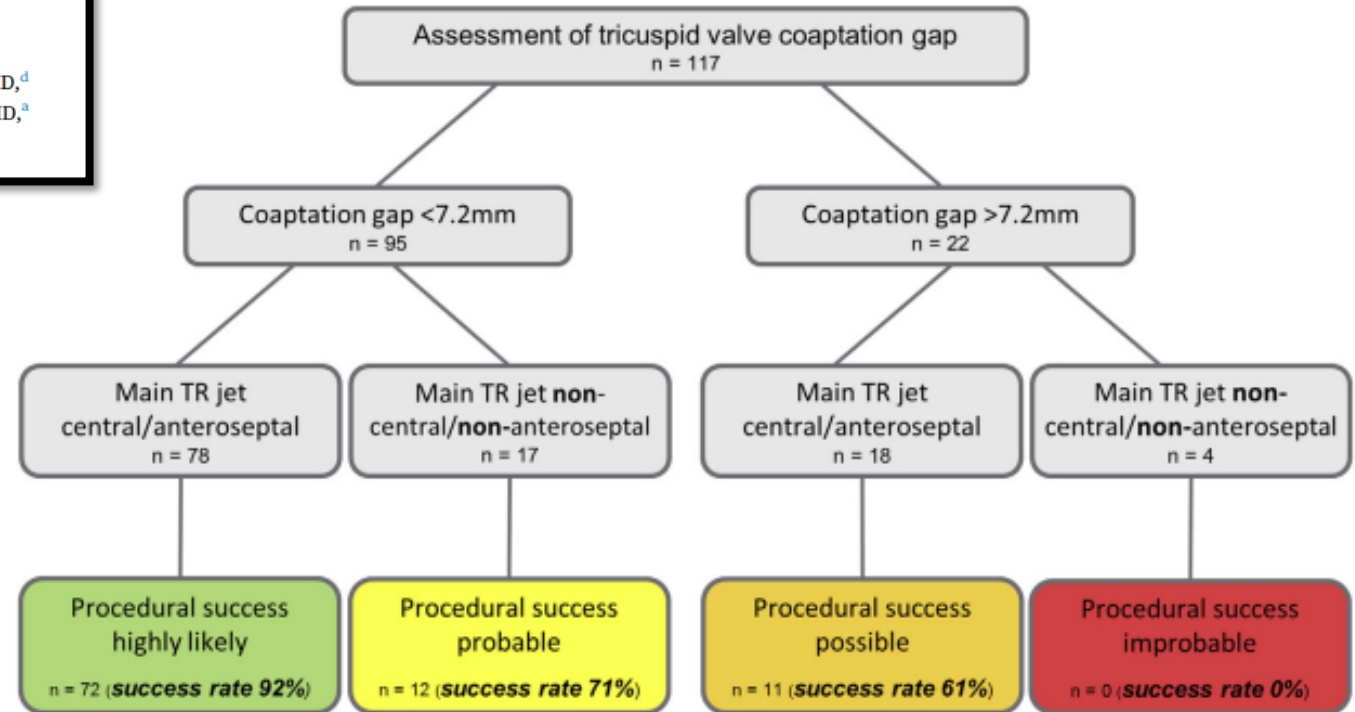
TABLE 4 Predictors of Procedural Transcatheter TV Repair Success

	Univariate		Multivariate	
	Odds Ratio	p Value	Odds Ratio	p Value
TR EROA (PISA)	0.21 (0.06-0.73)	0.01	—	—
TV tenting area	0.65 (0.45-0.94)	0.02	—	—
TR vena contracta	0.87 (0.77-0.99)	0.04	—	—
TV coaptation gap	0.74 (0.63-0.87)	<0.01	0.73 (0.62-0.88)	<0.01
TR jet non-central/non-anteroseptal	0.22 (0.08-0.62)	<0.01	0.18 (0.06-0.56)	<0.01

Univariate and multivariate logistic regression for procedural TTVR success, displaying only significant univariate predictors. Univariate predictors were subsequently tested in a multivariate stepwise model.

Abbreviations as in Tables 1, 2, and 3.

Patient Stratification According to Procedural Success

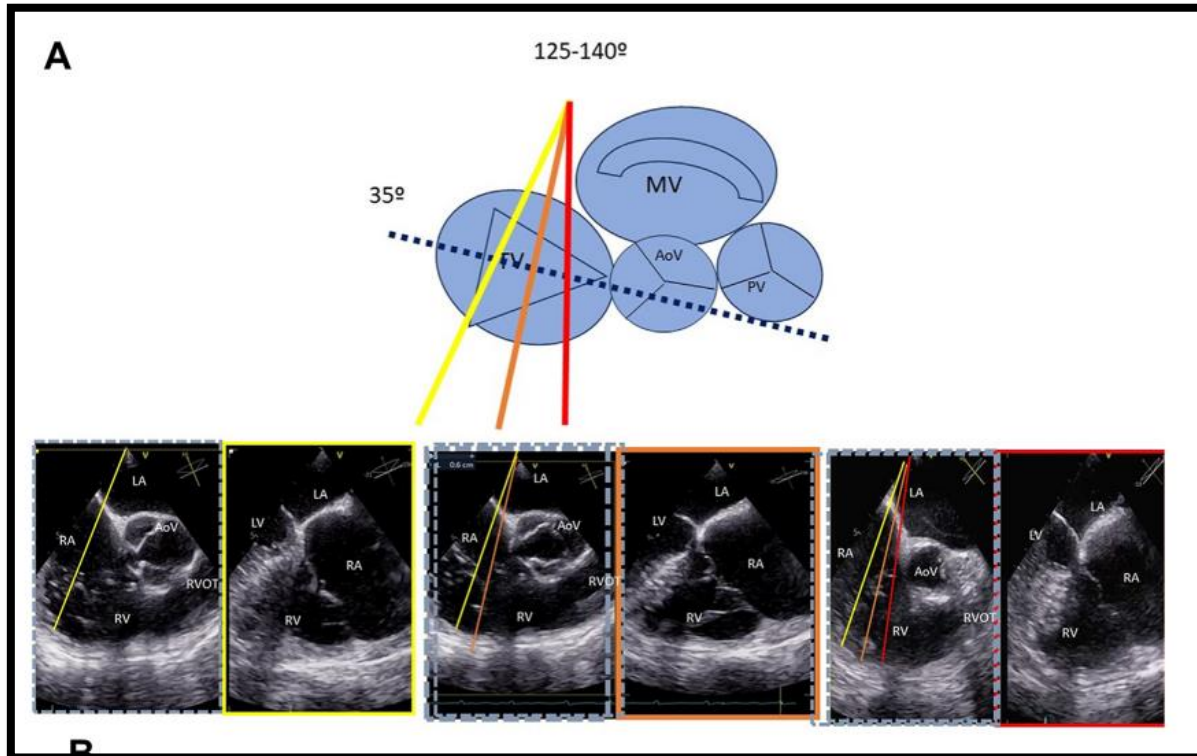


Proposed scheme for patient stratification for transcatheter tricuspid valve edge-to-edge repair according to the determined cut-off value of 7.2 mm for tricuspid valve coaptation gap and main tricuspid regurgitant jet orientation. TR = tricuspid regurgitation.

Measuring TV Coaptation Gap

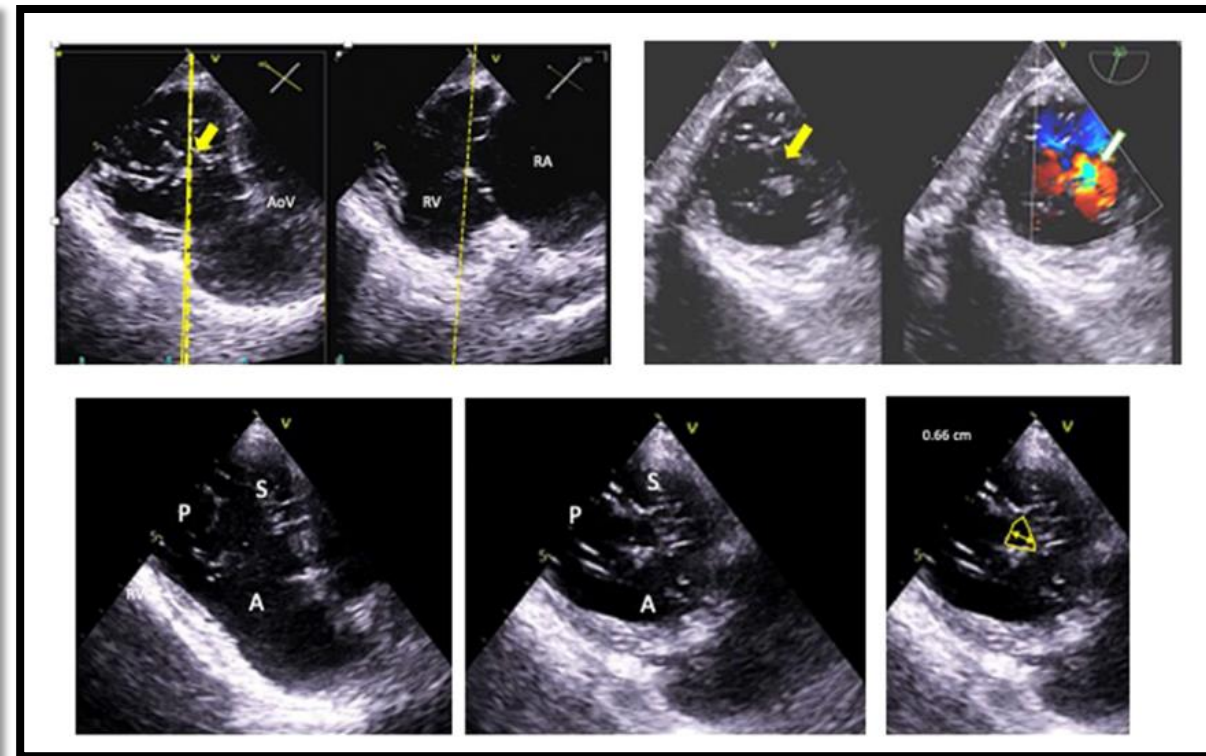
How and where to measure coaptation gap:

RV inflow/outflow



Complete scan of the TV from the anterior to posterior aspect

Transgastric SAX

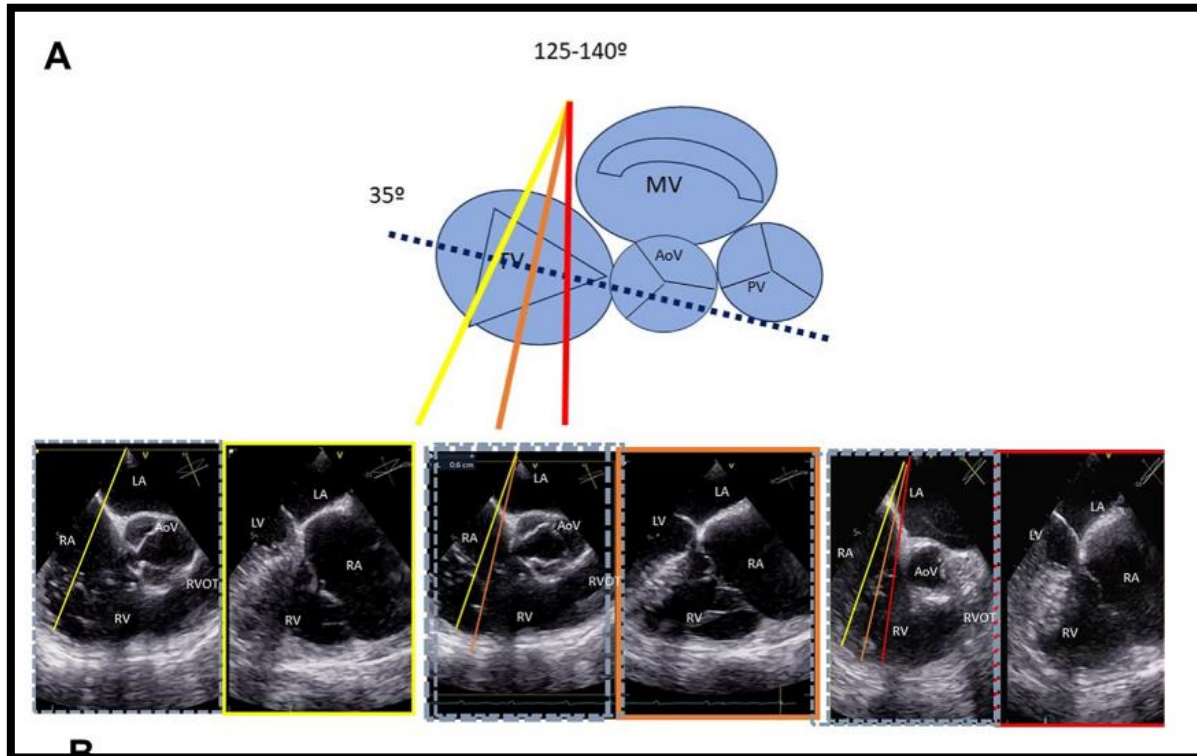


Ensure measurements are taken at the tips of each leaflet and in a plane parallel to the annulus to ensure all leaflet tips are included

Measuring TV Coaptation Gap

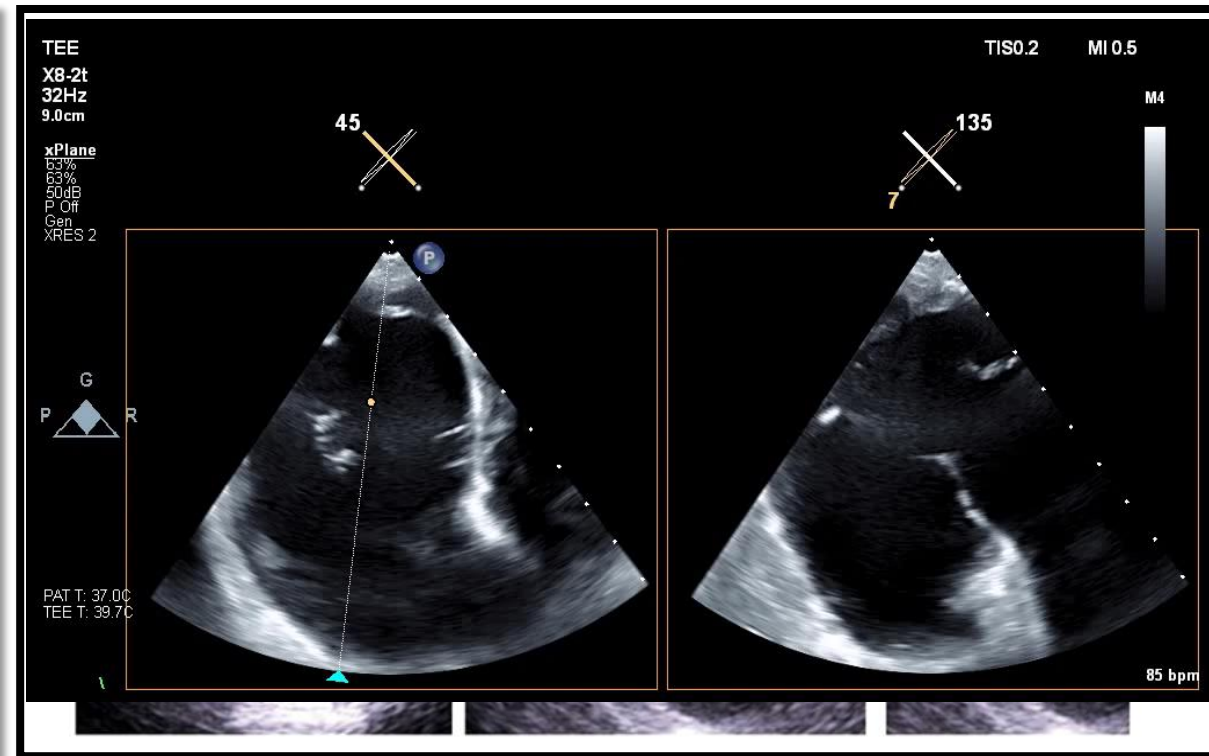
How and where to measure coaptation gap:

RV inflow/outflow



Complete scan of the TV from the anterior to posterior aspect

Transgastric SAX



Ensure measurements are taken at the tips of each leaflet and in a plane parallel to the annulus to ensure all leaflet tips are included

Predictors of Procedural Success

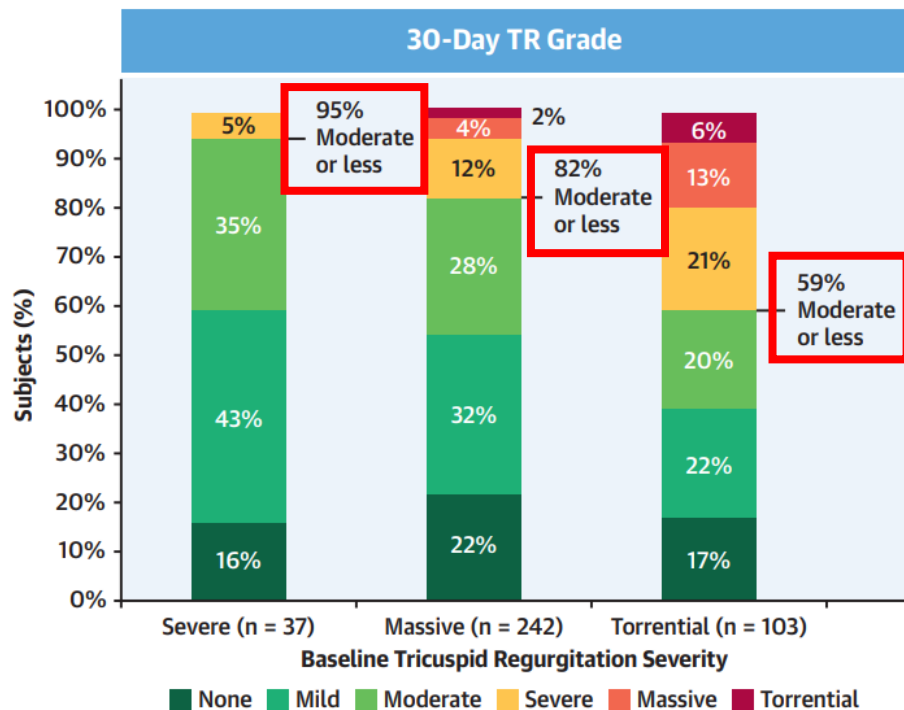
ORIGINAL INVESTIGATIONS

Short-Term Outcomes of Tricuspid Edge-to-Edge Repair in Clinical Practice



Philipp Lurz, MD, PhD,^a Christian Besler, MD,^a Thomas Schmitz, MD,^b Raffi Bekeredjian, MD,^c Georg Nickenig, MD,^d Helge Möllmann, MD,^e Ralph Stephan von Bardeleben, MD,^f Alexander Schmeisser, MD,^g Iskandar Atmowihardjo, MD,^h Rodrigo Estevez-Loureiro, PhD, MD,ⁱ Edith Lubos, MD,^j Megan Heitkemper, PhD,^k Dina Huang, PhD,^k Harald Lapp, MD,^l Erwan Donal, MD,^m on behalf of the bRIGHT PAS Principal Investigators

bRIGHT – TriClip post-approval study (N= 511)



Predictors of Procedural Success

ORIGINAL INVESTIGATIONS

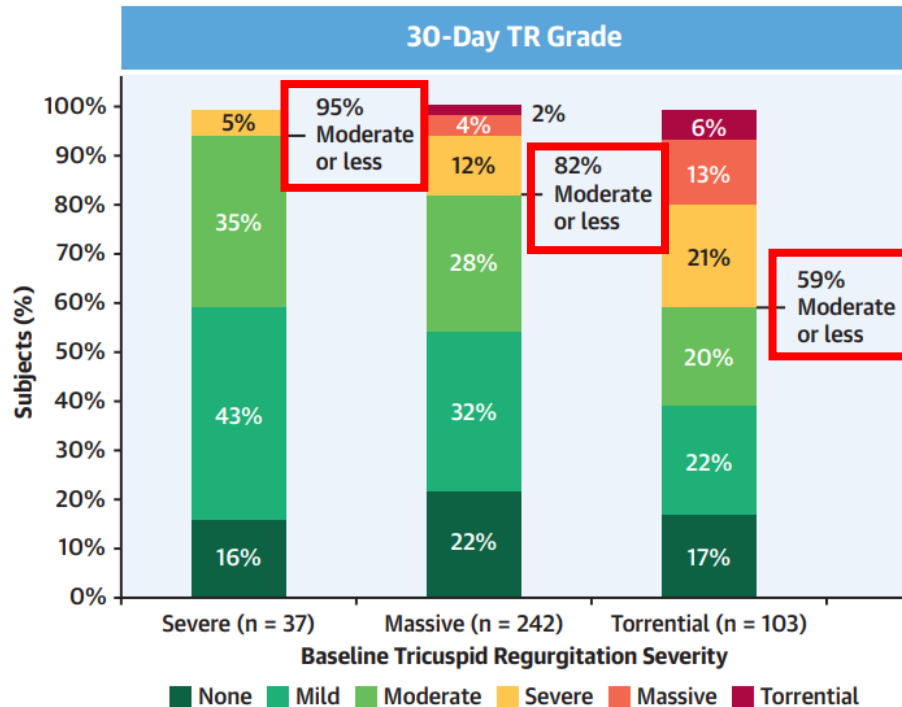
Short-Term Outcomes of Tricuspid Edge-to-Edge Repair in Clinical Practice



Philipp Lurz, MD, PhD,^a Christian Besler, MD,^a Thomas Schmitz, MD,^b Raffi Bekeredjian, MD,^c Georg Nickenig, MD,^d Helge Möllmann, MD,^e Ralph Stephan von Bardeleben, MD,^f Alexander Schmeisser, MD,^g Iskandar Atmowihardjo, MD,^h Rodrigo Estevez-Loureiro, PhD, MD,ⁱ Edith Lubos, MD,^j Megan Heitkemper, PhD,^k Dina Huang, PhD,^k Harald Lapp, MD,^l Erwan Donal, MD,^m on behalf of the bRIGHT PAS Principal Investigators

bRIGHT – TriClip post-approval study (N= 511)

Predictors of Achieving Moderate or Less TR at Discharge (Univariate)



Variable	OR (95% CI)	OR (95% CI)	P Value
Presence of Pacemaker Lead	0.67 (0.40-1.11)		0.1188
Tricuspid Regurgitation*	0.31 (0.19-0.50)		<0.0001
Gap Size (cm)	0.79 (0.63-0.99)		0.0428
Tethering Distance (cm)	0.67 (0.53-0.86)		0.0013
Right Ventricular End-Diastolic Dimension (cm)	0.62 (0.49-0.78)		<0.0001
Right Atrial Volume (mL)	0.64 (0.51-0.80)		<0.0001
Tricuspid Annular Diameter (cm)	0.72 (0.57-0.91)		0.0068

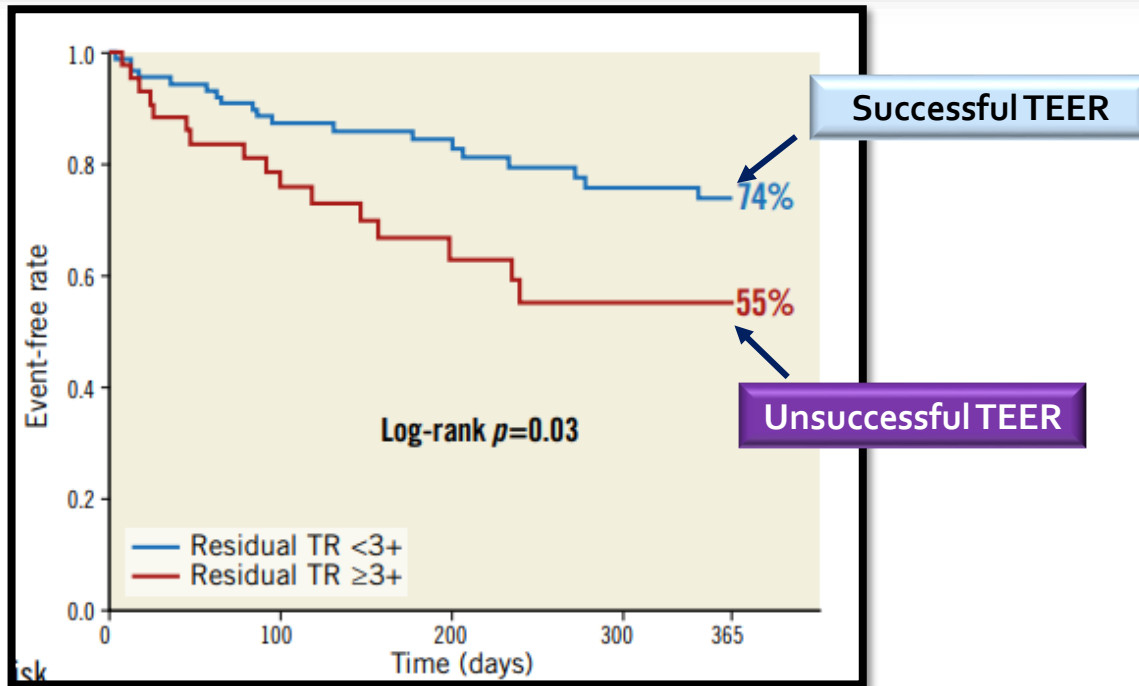
Predictors of Procedural Success

Leaflet-to-annulus index and residual tricuspid regurgitation following tricuspid transcatheter edge-to-edge repair

Tetsu Tanaka, MD; Atsushi Sugiura*, MD, PhD; Refik Kavsar, MD; Johanna Vogelhuber, MD; Can Öztürk, MD; Marc Ulrich Becher, MD; Sebastian Zimmer, MD; Georg Nickenig, MD; Marcel Weber, MD

Medizinische Klinik und Poliklinik II, Universitätsklinikum Bonn, Bonn, Germany

Consecutive T-TEER (n=140)
Procedural Success (TR≤2+):69%



Residual TR ≥3: independent predictor of mortality and HFH (HR=2.04, P=0.04)

Predictors of Procedural Success

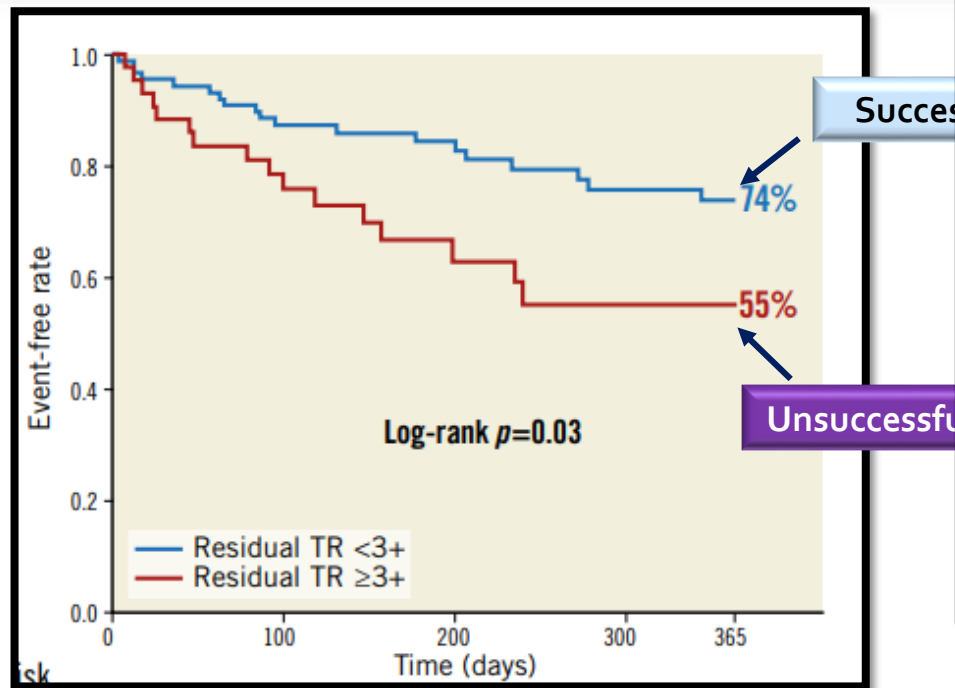
Leaflet-to-annulus index and residual tricuspid regurgitation following tricuspid transcatheter edge-to-edge

Consecutive T-TEER (n=140)

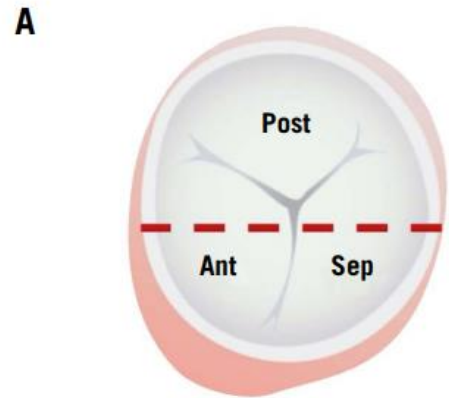
Procedural Success (TR≤2+):69%

Tetsu Tanaka, MD; Atsushi Sugiura*, MD, PhD; Refik Kavsar, MD; Johanna Vogt, MD; Can Öztürk, MD; Marc Ulrich Becher, MD; Sebastian Zimmer, MD; Georg Nicken

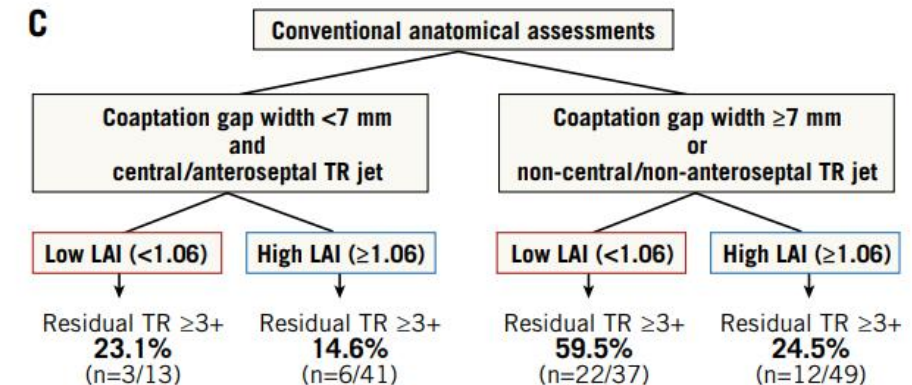
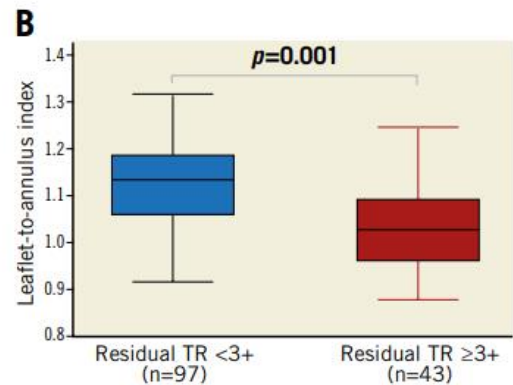
Medizinische Klinik und Poliklinik II, Universitätsklinikum Bonn, Bonn, Germany



Residual TR ≥3: independent predictor of mortality and HFH (HR=2.04, P=0.04)



$$\text{Leaflet-to-annulus index} = \frac{\text{Anterior leaflet length} + \text{Septal leaflet length}}{\text{Septolateral tricuspid annulus diameter}}$$



Lower Leaflet-to-annulus index was associated with residual TR ≥3+ after TEER (independent of the baseline TR grade and anatomical parameters)

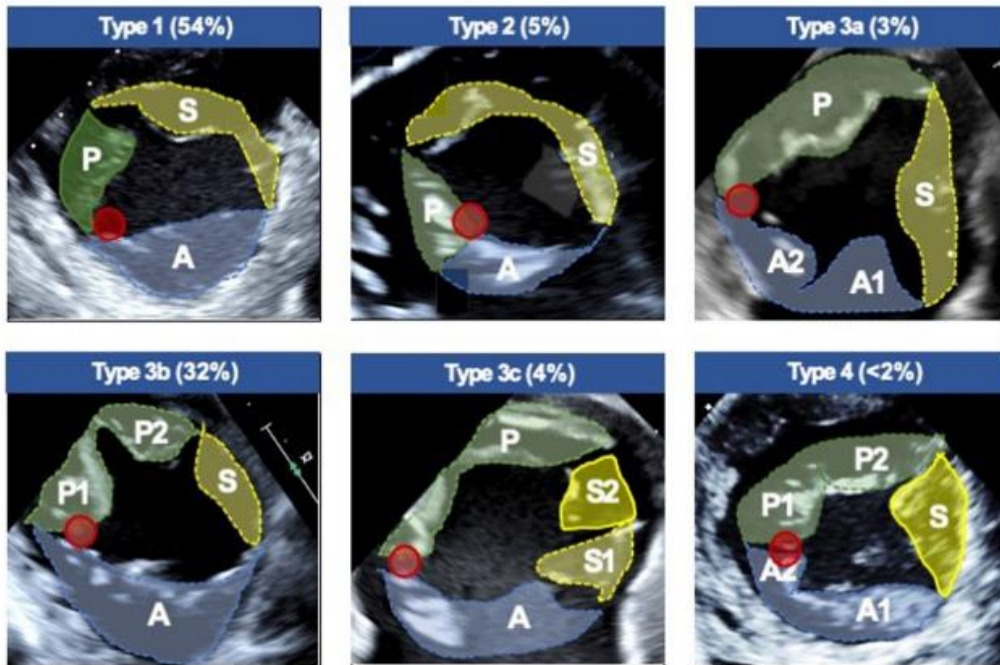
Predictors of T-TEER Success

Leaflet Configuration and Residual Tricuspid Regurgitation After Transcatheter Edge-to-Edge Tricuspid Repair



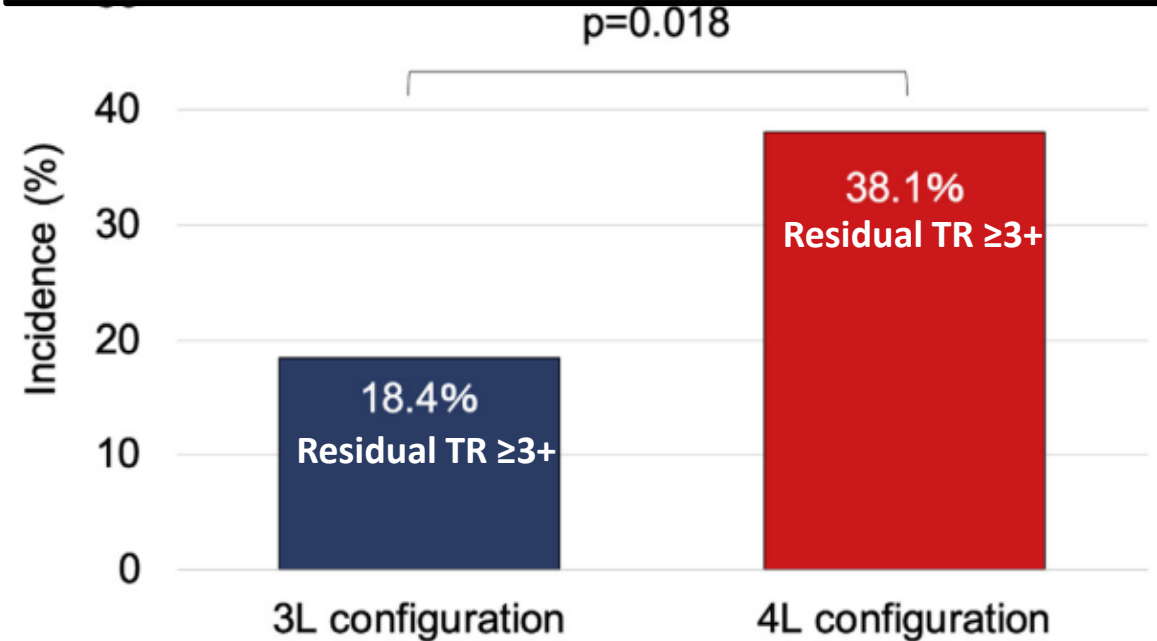
Atsushi Sugiura, MD,* Tetsu Tanaka, MD,* Refik Kavsar, MD, Can Öztürk, MD, Johanna Vogelhuber, MD, Nihal Wilde, MD, Marc Ulrich Becher, MD, Sebastian Zimmer, MD, Georg Nickenig, MD, Marcel Weber, MD

Classification of Tricuspid Valve Leaflet Morphology



39% with 4 leaflet configuration

4 Leaflet TV Configuration is associated with worse residual TR



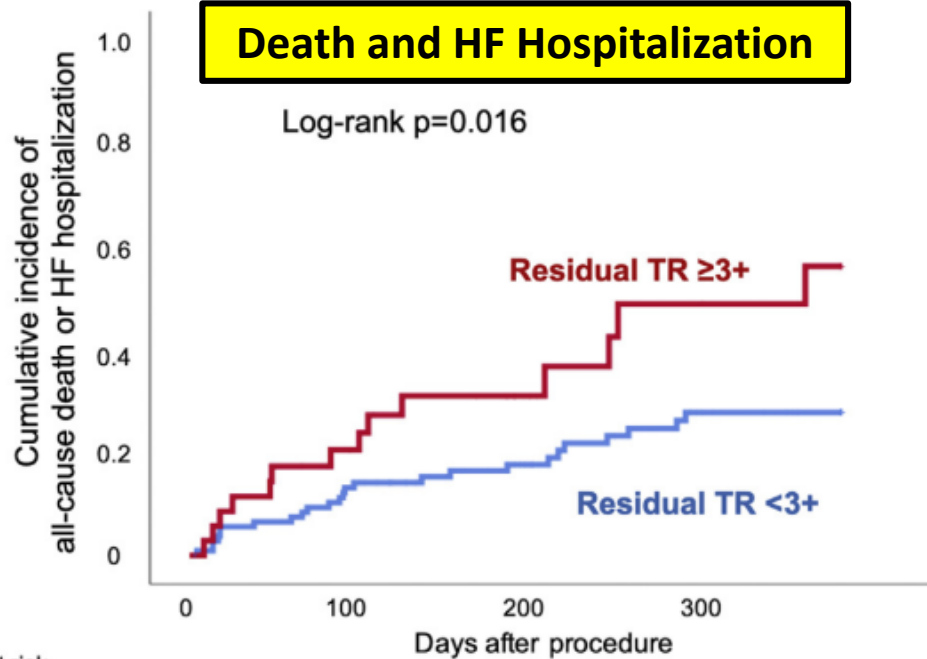
Predictors of T-TEER Success

Leaflet Configuration and Residual Tricuspid Regurgitation After Transcatheter Edge-to-Edge Tricuspid Repair

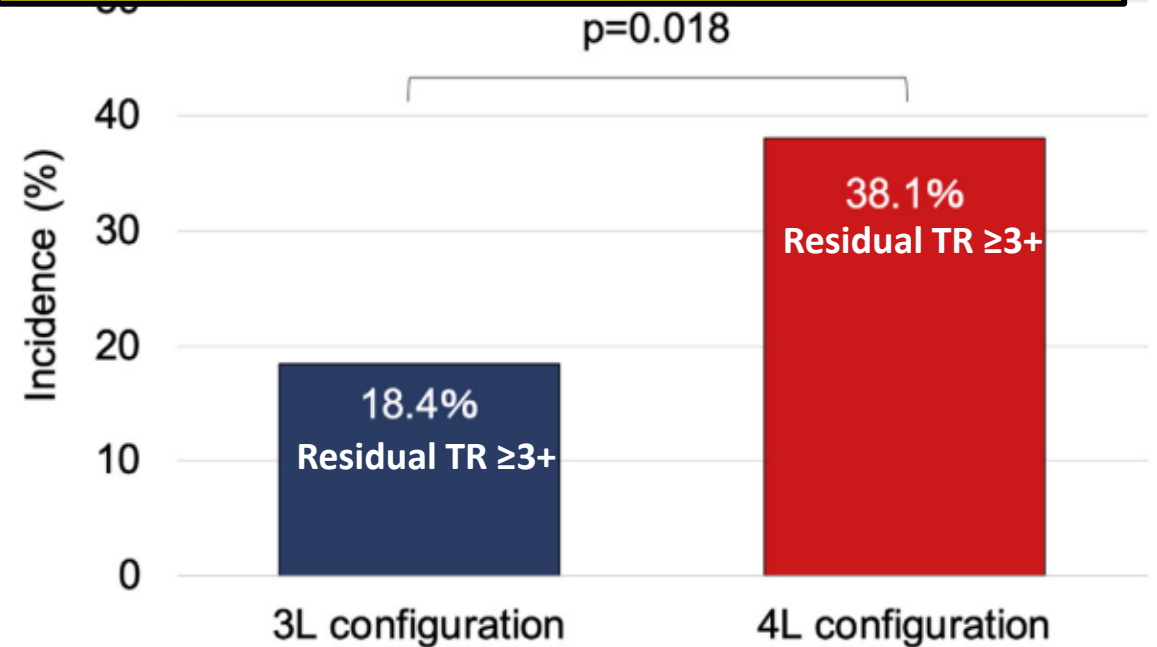


Atsushi Sugiura, MD,* Tetsu Tanaka, MD,* Refik Kavsar, MD, Can Öztürk, MD, Johanna Vogelhuber, MD, Nihal Wilde, MD, Marc Ulrich Becher, MD, Sebastian Zimmer, MD, Georg Nickenig, MD, Marcel Weber, MD

Death and HF Hospitalization



4 Leaflet TV Configuration is associated with worse residual TR



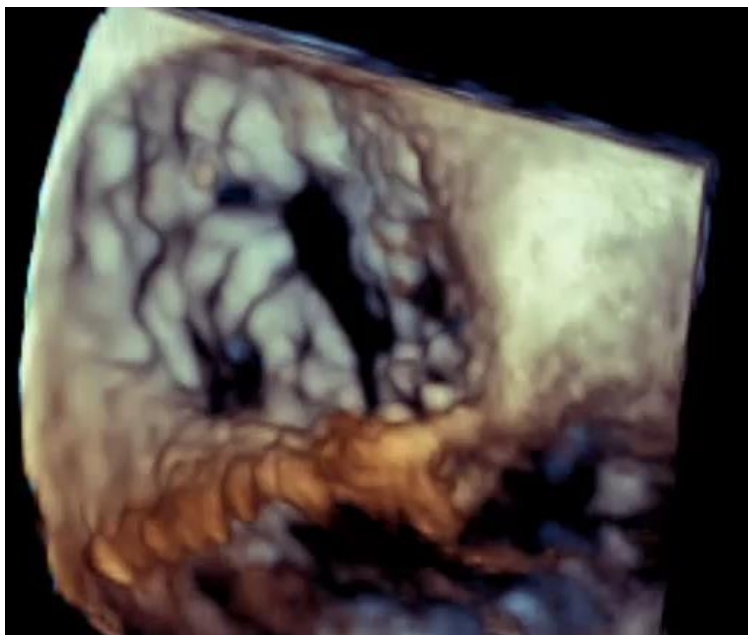
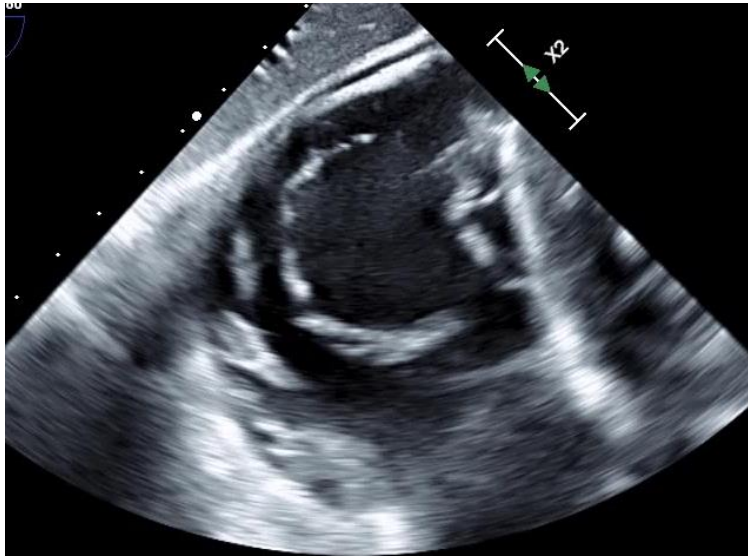
Predictors of T-TEER Success

Table 2 Key considerations indicating low feasibility for TEER

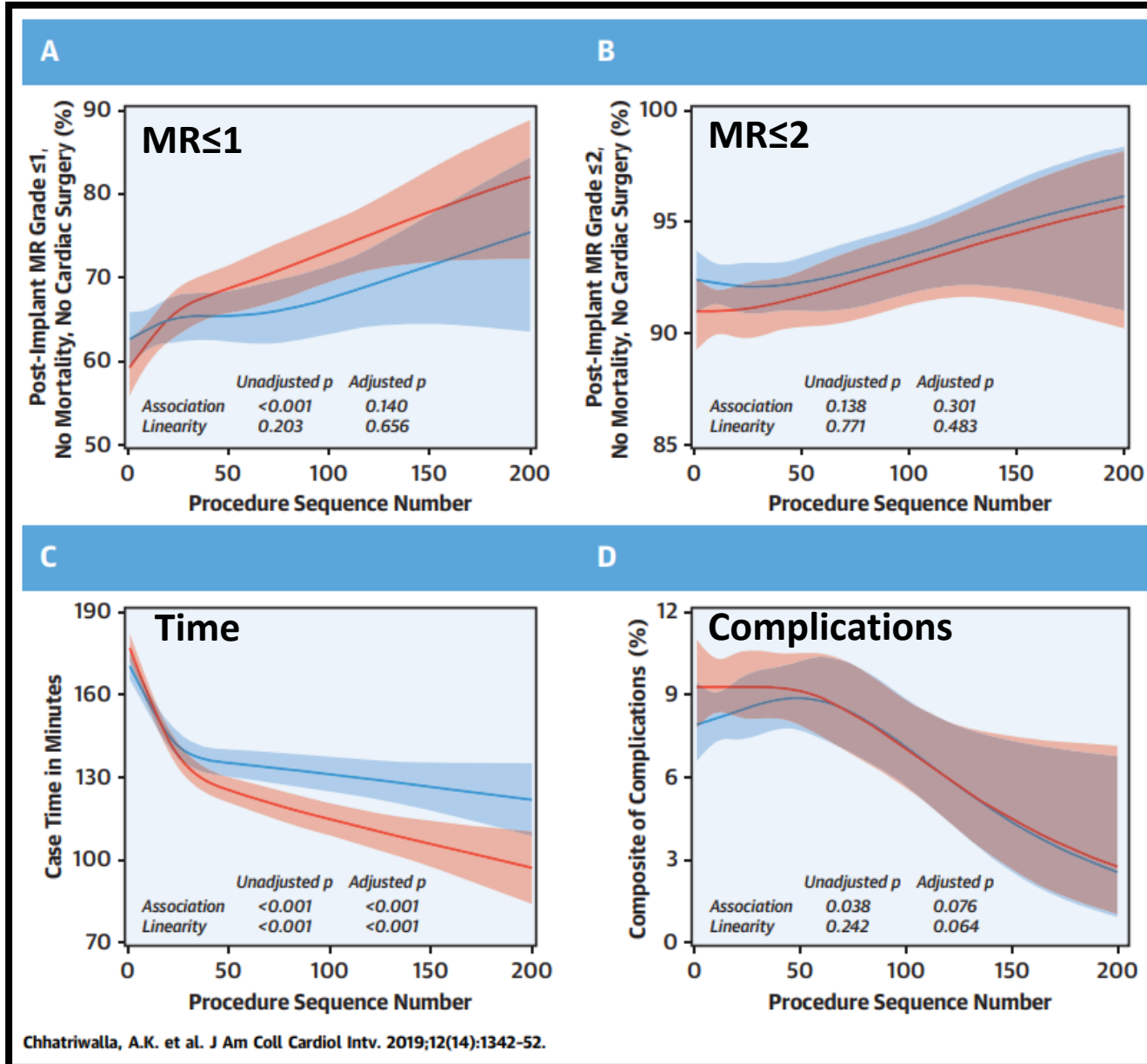
	Favorable	Feasible	Unfavorable
Morphology	Trileaflet valve	Nontrileaflet valve	Nontrileaflet valve with dense chordae
Coaptation gap	<7 mm	>7 to 8.5 mm	≥8.5 mm
Leaflets	Normal leaflet length (≥7 mm) and mobility without flail or tethering	Primary TR with small flail gap (<10 mm), secondary TR with tethering height <9 mm	Primary TR with large flail gap (≥10 mm), short or thickened leaflets (length <7 mm), leaflet perforation, secondary TR with tethering height ≥9 mm or tenting area >2.1 cm ²
Jet location	Central TR within anteroseptal commissure	Central TR within nonanteroseptal commissure	Massive/torrential TR with either highly eccentric or multicommissural jets
CIED Leads	No leads	Lead without interaction	Lead causing impingement
Imaging	Good TEE windows	Adequate TEE ± ICE	Inadequate windows
RV remodeling	Normal to mildly dilated and/or impaired	Moderately dilated and/or impaired	Severely dilated and/or impaired (CMR or 3D TEE RVEF <45%)
Pulmonary hemodynamics	Normal peak + mean PAP, TPG and TAPSE/PASP >.41	PASP ≤ 60-65 mm Hg, pulmonary resistance ≤ 4 WU, mean PAP ≤ 30 mm Hg, TPG ≤ 17 mm Hg	PASP > 60-65 mm Hg, pulmonary resistance >4 WU, mean PAP > 30 mm Hg, and TPG >17 mm Hg, TAPSE/PASP ≤ .41
End-organ manifestations	Normal liver and renal function	Liver function test derangement/ Child-Pugh A cirrhosis moderate CKD	Child Pugh B/C cirrhosis severe CKD/dialysis dependent

CKD, Chronic kidney disease; PAP, PA pressure; TPG, transpulmonary gradient; WU, Wood units.

Good Imaging is Imperative



TEER Outcome and Operator Experience



Is Moderate Residual TR a Procedural Success?

Moderate TR is Progressive

Tricuspid Regurgitation Progression A Natural History Cohort Study

Gary Ma MD, Ajit Raisinghani MD, Ehtisham Mahmud MD, Ori Ben-Yehuda MD

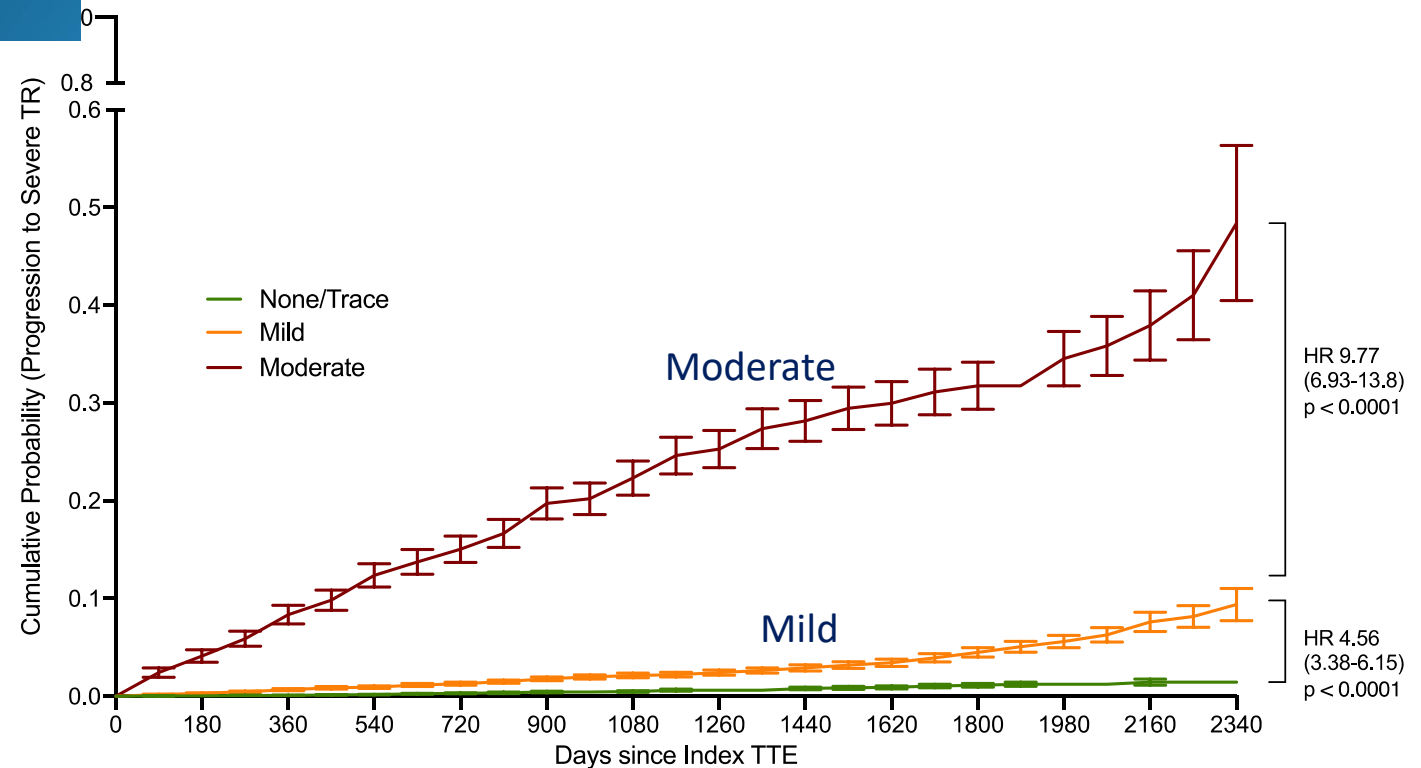
121,066 Transthoracic Echocardiograms (TTE) reviewed among 69,133 unique patients

underlying congenital heart disease

139 Patients excluded for pre-existing tricuspid valve intervention/replacement

48,830 Patients excluded due to

19,144 patients with serial TTEs included for analysis



No. at Risk

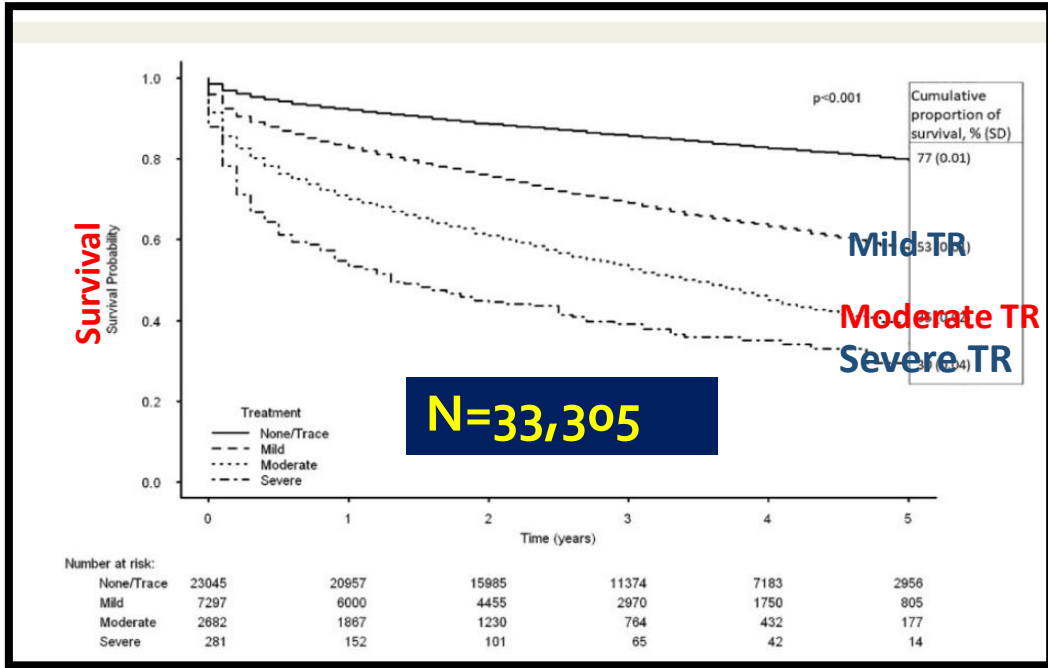
None/Trace TR	11090	9765	8183	6610	5559	4641	3792	3072	2422	1793	1306	831	428	94
Mild TR	6707	5842	4927	4103	3479	2927	2415	1936	1534	1167	835	540	283	75
Moderate TR	1030	865	689	568	465	380	302	233	187	140	106	74	31	8

Moderate TR is Progressive

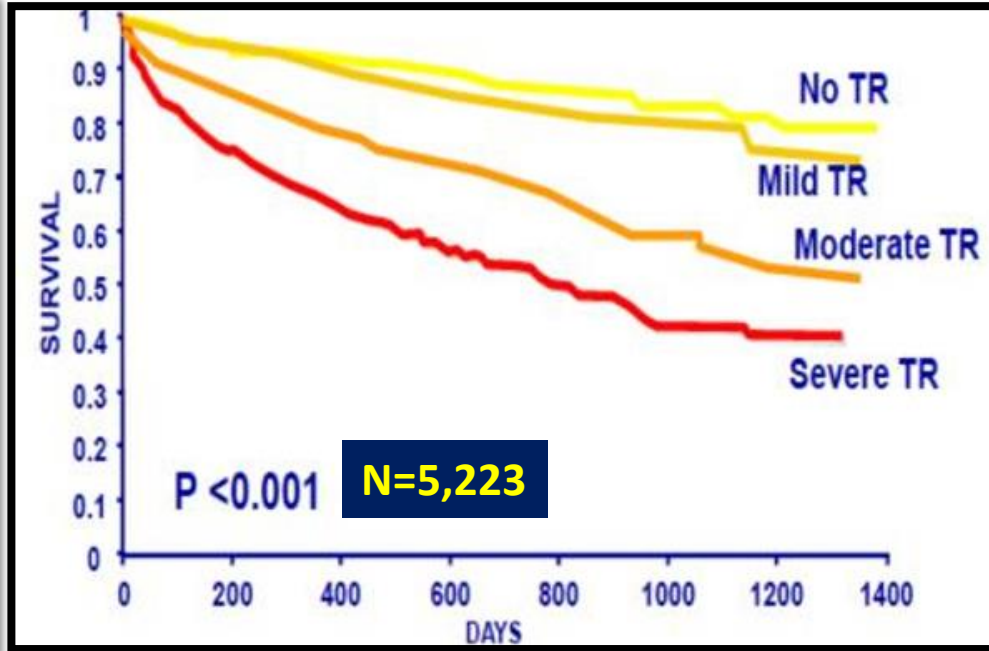
Table 2 Multivariate Cox Regression of Risk Factors for Progression to Severe TR

	None/Trace		Mild		Moderate	
	Adjusted HR	P-value	Adjusted HR	P-value	Adjusted HR	P-value
Male	0.72 (0.35-1.46)	0.356	0.63 (0.42-0.96)	0.03	0.86 (0.56-1.31)	0.478
Age	0.97 (0.94-0.99)	0.002	1.0 (0.98-1.01)	0.702	1.01 (0.1.0-1.02)	0.2
Body Mass Index	0.94 (0.90-0.99)	0.022	1.00 (0.98-1.03)	0.793	1.01 (0.99-1.03)	0.293
AF/AFL	8.53 (3.42-21.29)	<.001	2.58 (1.56-4.24)	<.001	1.06 (0.59-1.90)	0.852
LV Ejection Fraction <50%	1.38 (0.51-3.71)	0.527	2.40 (1.52-3.79)	<.001	1.3 (0.83-2.05)	0.256
RV Systolic Pressure >40mmHg	3.44 (1.17-10.15)	0.025	3.09 (1.99-4.79)	<.001	0.87 (0.53-1.43)	0.573
TAPSE <18mm	1.09 (0.49-2.44)	0.833	1.2 (0.75-1.92)	0.446	1.01 (0.62-1.62)	0.982
TAPSE/RVSP <0.31	1.46 (0.27-7.88)	0.663	0.81 (0.45-1.47)	0.487	1.29 (0.77-2.16)	0.328
Lateral E/e' \geq 10	1.81 (0.85-3.83)	0.122	1.32 (0.87-1.99)	0.195	1.34 (0.88-2.03)	0.178
Severe Aortic Stenosis	3.20 (0.43-24.02)	0.259	1.88 (0.59-6.044)	0.284	0.396 (0.05-2.88)	0.36
Severe Aortic Regurgitation	N/A		0 (0-7.47)	0.972	N/A	
Severe Mitral Stenosis	N/A		0 (0-5.57)	0.968	0 (0-7.72)	0.963
Severe Mitral Regurgitation	N/A		1.33 (0.473-3.751)	0.587	1.08 (0.46-2.53)	0.868

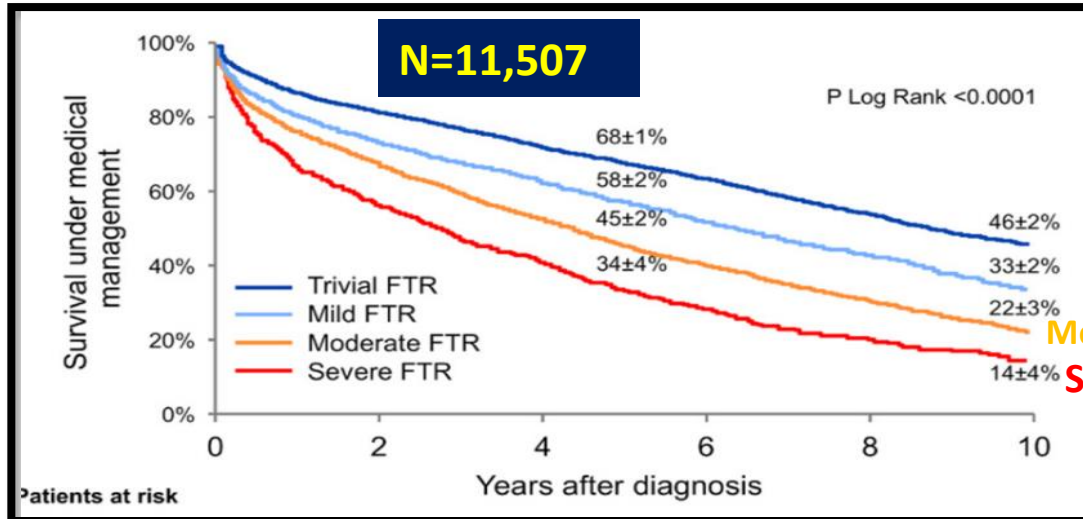
Moderate TR



Chorin E. EHJ CVI 2020



Nath J, JACC 2004



Tricuspid VARC Definitions

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
© 2023 THE AUTHORS. PUBLISHED BY ELSEVIER INC ON BEHALF OF THE AMERICAN COLLEGE OF
CARDIOLOGY AND THE SOCIETY OF THORACIC SURGEONS AND BY OXFORD UNIVERSITY PRESS
ON BEHALF OF THE EUROPEAN SOCIETY OF CARDIOLOGY. THIS IS AN OPEN ACCESS ARTICLE
UNDER THE CC BY-NC-ND LICENSE (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

VOL. 82, NO. 17, 2023

THE PRESENT AND FUTURE

JACC STATE-OF-THE-ART REVIEW

Tricuspid Valve Academic Research Consortium Definitions for Tricuspid Regurgitation and Trial Endpoints

Rebecca T. Hahn, MD,^{a,b} Matthew K. Lawlor, MD, MS,^a Charles J. Davidson,^a
Anna Sannino, MD, PhD,^{e,f} Ernest Spitzer, MD,^{g,h} Philipp Lurz, MD, PhD,ⁱ B
Yan Topilsky, MD,^k Suzanne J. Baron, MD, MSc,^{l,m} Scott Chadderdon, MD,ⁿ
Gilbert H.L. Tang, MD, MSc, MBA,^p Maurizio Taramasso, MD, PhD,^{q,r} Paul A
Luigi Badano, MD, PhD,^{t,u} Jonathon Leipsic, MD,^v JoAnn Lindenfeld, MD,^w
Sreekanth Vemulapalli, MD,^{y,z} Bjorn Redfors, MD, PhD,^{b,aa} Maria C. Alu, MS,
Josep Rodés-Cabau, MD, PhD,^{bb} Gorav Ailawadi, MD, MBA,^{cc} Michael Mack
Martin B. Leon, MD,^{a,b} Jörg Hausleiter, MD,^{ff,gg} on behalf of the TVARC Ste

ABSTRACT

Interest in the pathophysiology, etiology, management, and outcomes of patie
grown in the wake of multiple natural history studies showing progressively wor
TR severity, even after adjusting for multiple comorbidities. Historically, isolate
associated with high in-hospital mortality rates, leading to the development of tr
of this first Tricuspid Valve Academic Research Consortium document is to standardize definitions of disease etiology and
severity, as well as endpoints for trials that aim to address the gaps in our kn
management of patients with TR. Standardizing endpoints for trials should pro
ingful comparisons between clinical trials. A second Tricuspid Valve Academic
focus on further defining trial endpoints and will discuss trial design options. (

© 2023 The Authors. Published by Elsevier Inc on behalf of the American Coll
Thoracic Surgeons and by Oxford University Press on behalf of the European S
access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

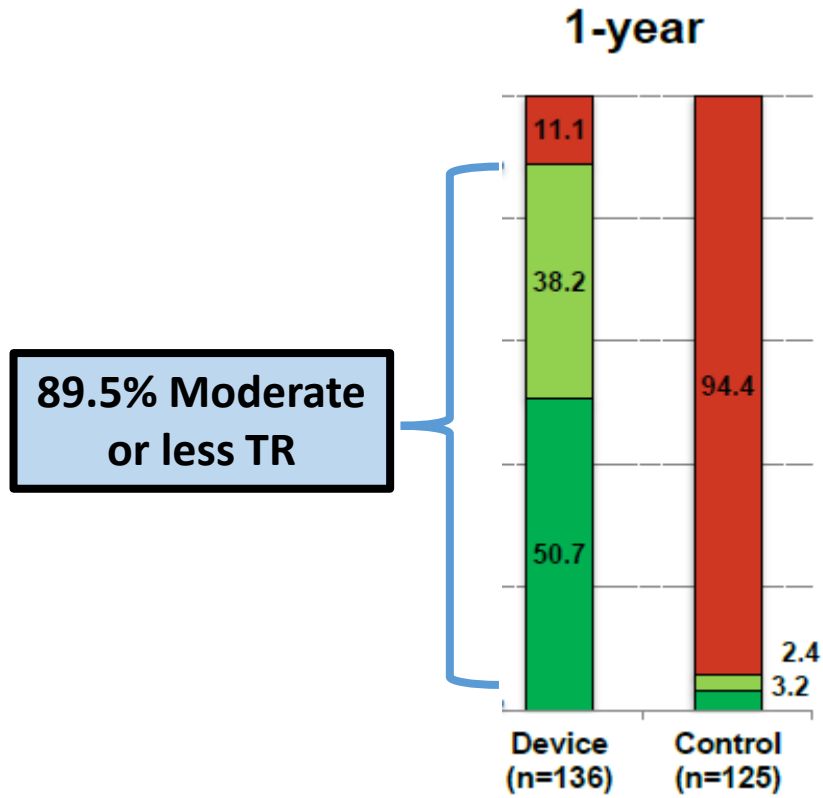
I. Intraprocedural success

All of the following must be present:

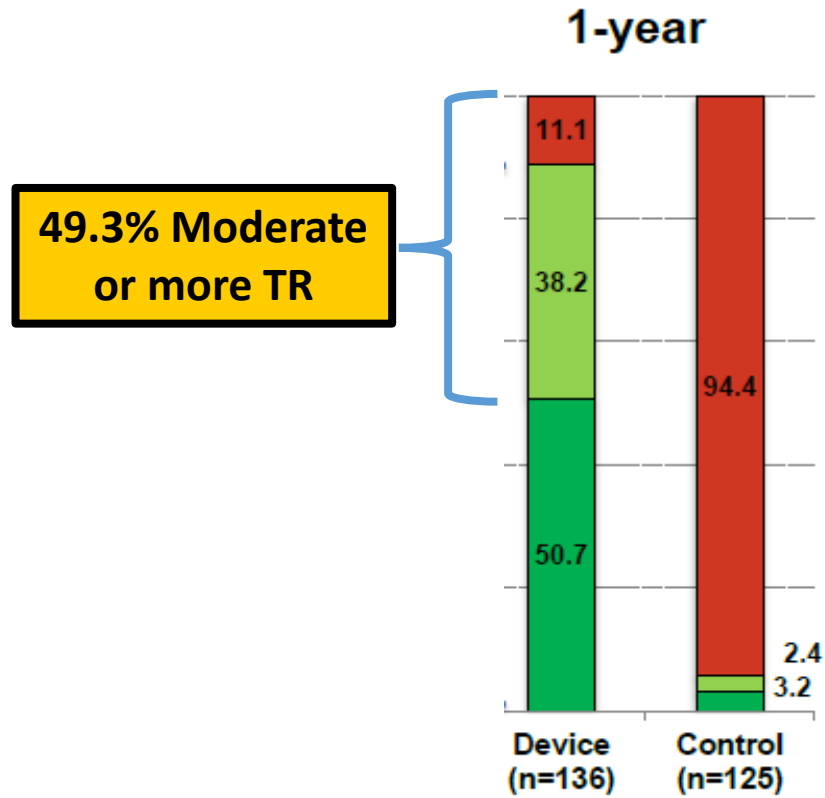
1. Absence of intraprocedural mortality or stroke; and
2. Successful access, delivery, and retrieval of the device delivery system; and
3. Successful deployment and correct positioning of the intended device(s) without requiring implantation of unplanned additional de-
vices; and
4. Adequate performance of the transcatheter device. Performance of devices whose purpose is a reduction in TR, should include the
absence of tricuspid stenosis (TVA ≥ 1.5 cm² or TVAi ≥ 0.9 cm²/m² [≥ 0.75 if BMI > 30 kg/m²], DVI < 2.2 , mean gradient < 5 mm Hg);
reduction of total tricuspid regurgitation to optimal (\leq mild [1+]) or acceptable (\leq moderate [2+]).
5. Absence of device-related obstruction of forward flow
6. Absence of device-related pulmonary embolism
7. Freedom from emergency surgery or reintervention during the first 24 h related to the device or access procedure.

quantitative measures of severity.⁹⁴ Nonetheless,
moderate or more ($\geq 2+$) residual TR following device
therapy is associated with adverse outcomes.^{39,95}

What is Procedural Success in T-TEER?

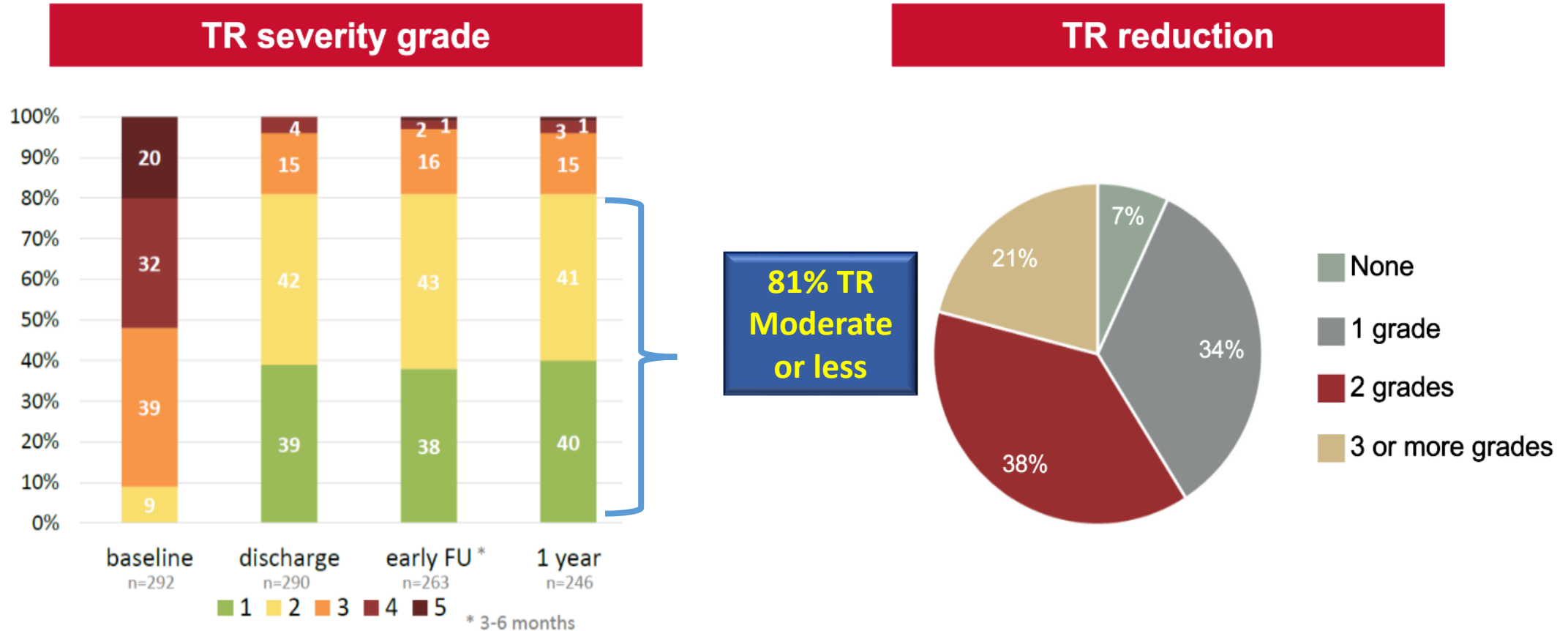


What is Procedural Success in T-TEER?



PASTE: PASCAL for Tricuspid Regurgitation, a European registry

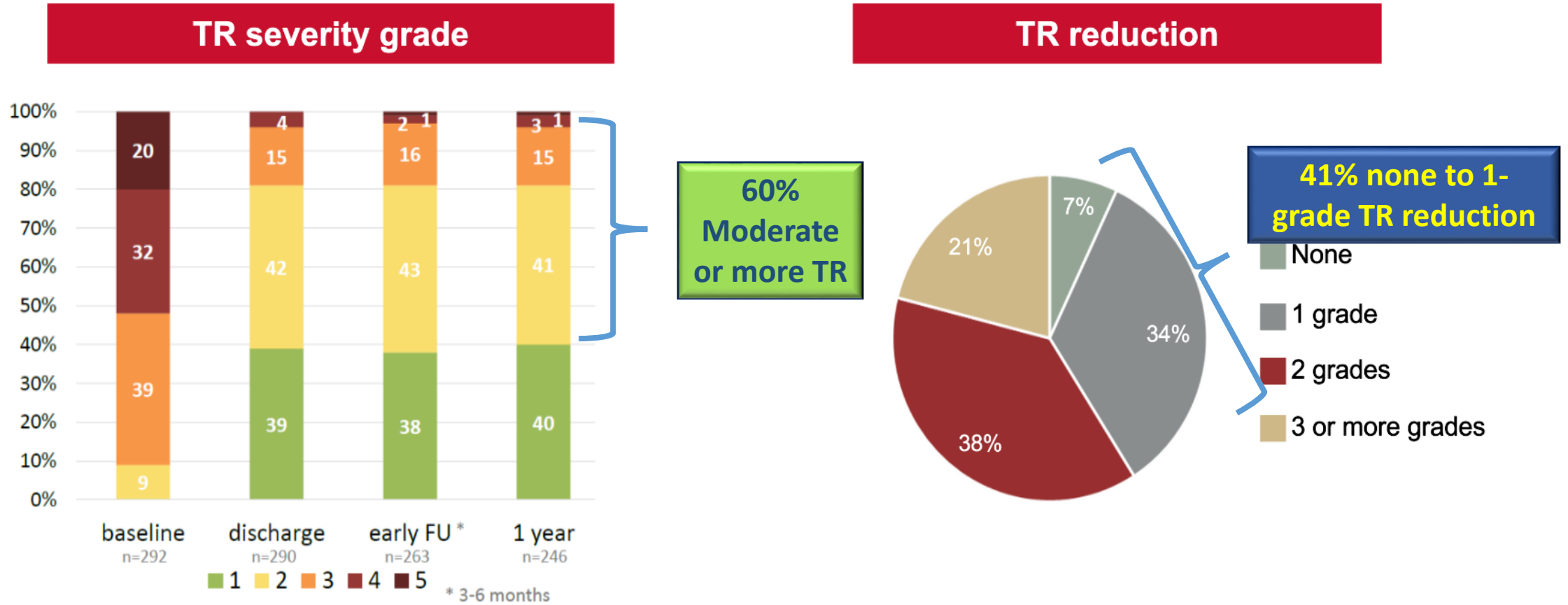
Reduction of TR at 1-year



81% TR Moderate or less

PASTE: PASCAL for Tricuspid Regurgitation, a European registry

Reduction of TR at 1-year



T-TEER and Residual TR



Study	<u>Moderate or more residual TR</u> at 1-year
TRILUMINATE Pivotal	49.3%
bRIGHT	49%*
PASTE	60%
TRICLASP	41%

* 30-day F/U

T-TEER and Residual TR


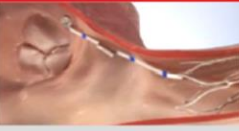



















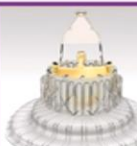


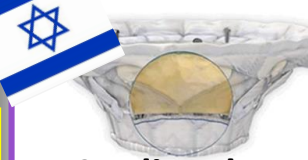



Study	<u>Moderate or more residual TR</u> at 1-year
TRILUMINATE Pivotal	49.3%
bRIGHT	49%*
PASTE	60%
TRICLASP	41%
TRISCEND Single arm	2.4% (0.0% severe)
TRISCEND II Pivotal	4.9%**

* 30-day F/U

** First 150 patients @ 6-month F/U

Transcatheter Tricuspid Valve Technologies

Anchor/ Mechanism	Historical and New Technologies															
Annuloplasty (Direct and Indirect) Device	 TriAlign		 4Tech		 Millepede		 Pasta		 Cardiac Implants		 MIA PolyCor		 Cardioband ☆			
Leaflet Device/ Spacers	 Mistral		 TriClip ☆		 PASCAL ☆		 FORMA		 CroiValve		 TV Occluder		 Coramaze			
Heterotopic Valve (in IVC/SVC)	 TriCentro		 SAPIEN in IVC		 TricValve ☆											
Orthotopic Valve Replacement	 Navigate		 Trisol		 V-dyne		 Tri-Cares		 LUX		 Intrepid		 EVOQUE ☆		 Cardiovalve	
													 Innovalve			

 = Not Available for Clinical Use = Randomized Controlled Trial
 = Early Human Use ☆ = CE Mark Approval in Europe
 = Early Feasibility Trial



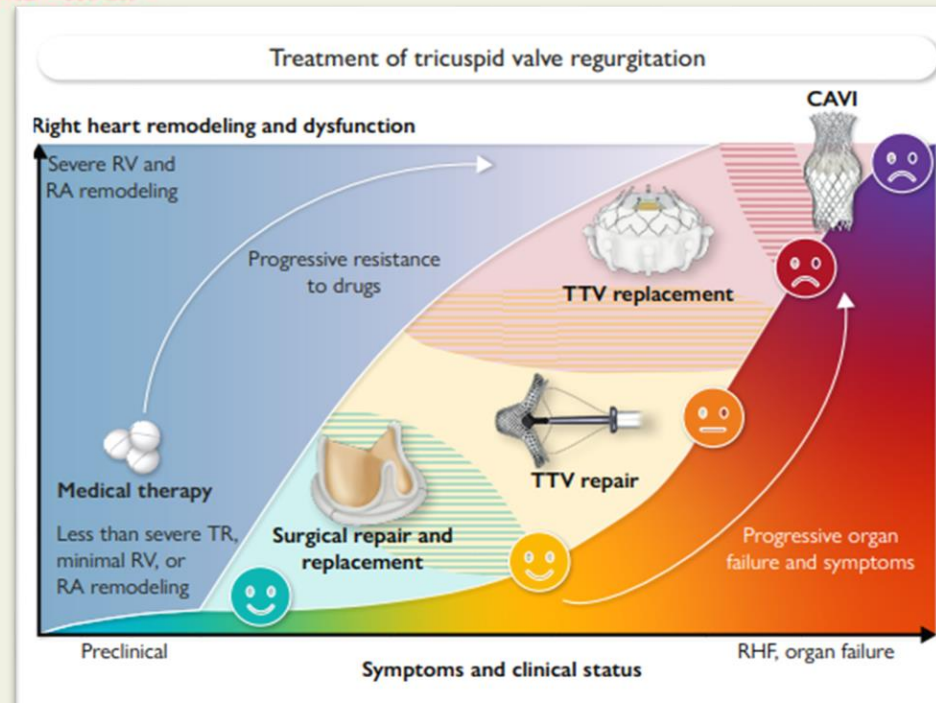
Transcatheter treatment of the tricuspid valve: current status and perspectives

Francesco Maisano ^{1*}, Rebecca Hahn ², Paul Sorajja ³, Fabien Praz ⁴, and Philipp Lurz ⁵

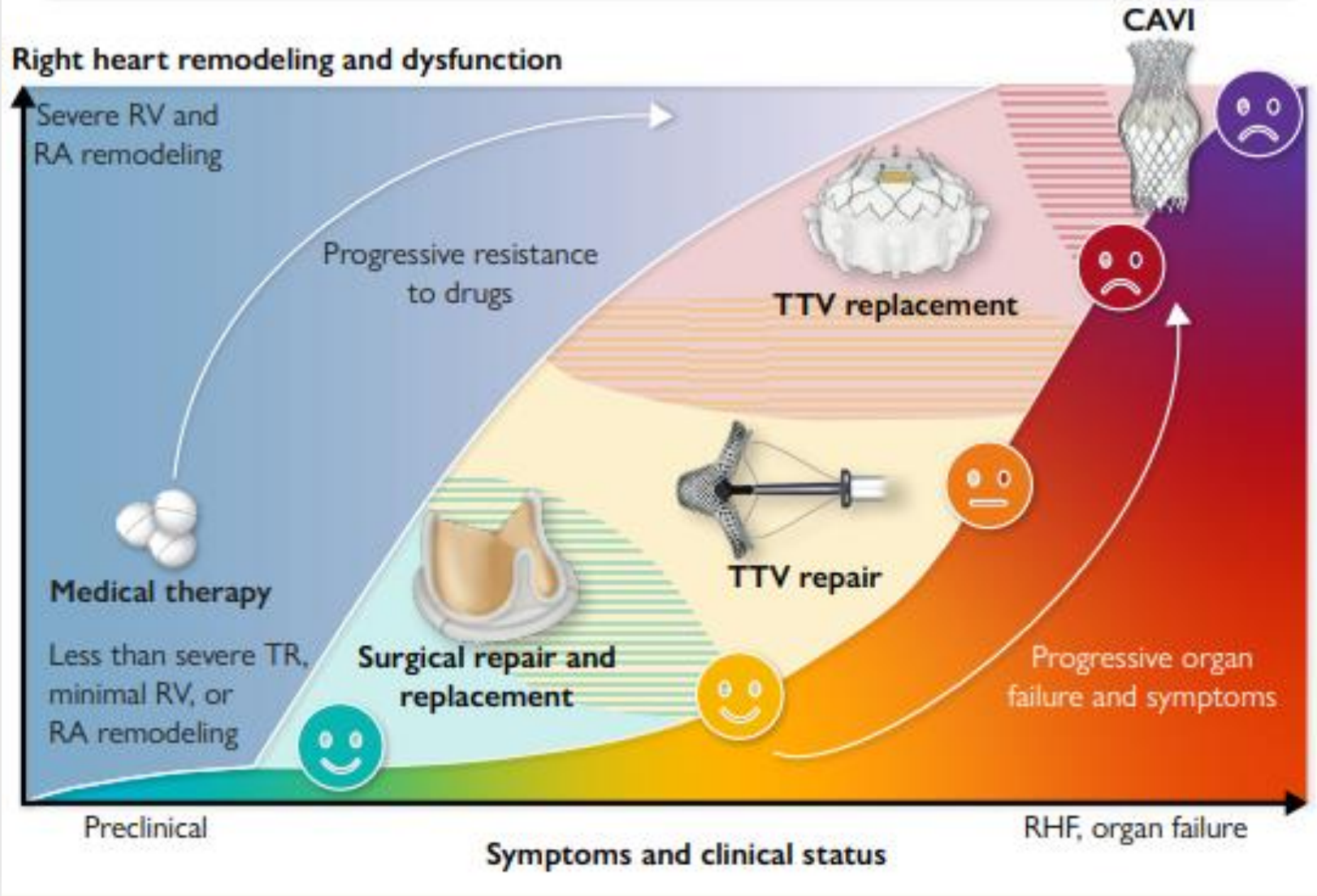
¹Division of Cardiac Surgery and Valve Center, IRCCS Ospedale San Raffaele, Università Vita Salute, Via Olgettina 60, 20132 Milano, Italy; ²Department of Medicine, Columbia University Irving Medical Center, New York, 161 Fort Washington Avenue, 10032 New York, NY, USA; ³Minneapolis Heart Institute at Abbott Northwestern Hospital, 920 East 28th Street, Suite 100, 55407 Minneapolis, MN, USA; ⁴Bern University Hospital, University of Bern, Anna-Seiler-Haus Freiburgstrasse 20, 3010 Bern, Switzerland; and ⁵Department of Cardiology, Universitätsmedizin Johannes Gutenberg-University, Langenbeckstraße 1, 55131 Mainz, Germany

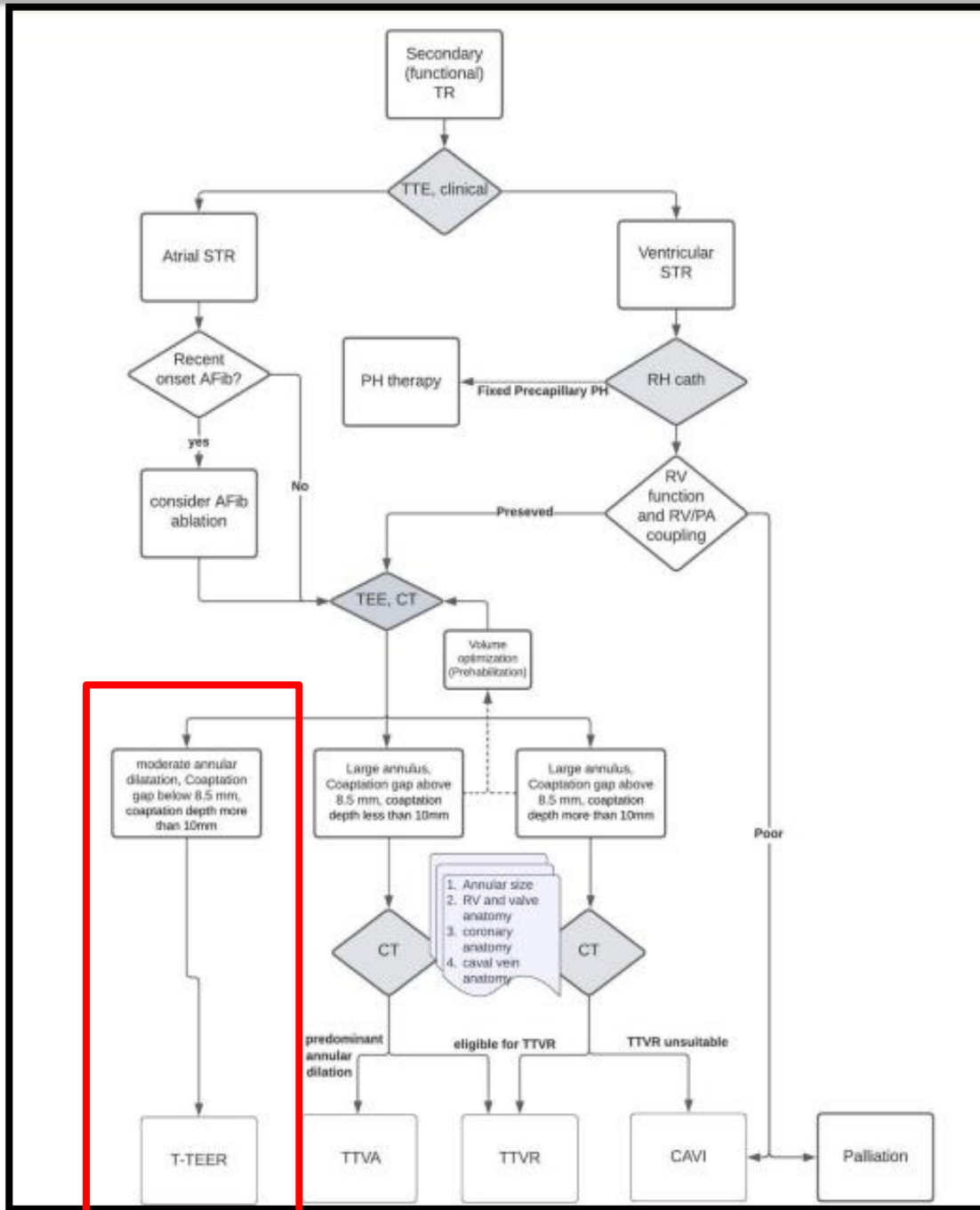
Received 2 August 2023; revised 13 January 2024; accepted 29 January 2024; online publish-ahead-of-print 1 March 2024

Graphical Abstract



Treatment of tricuspid valve regurgitation





Summary

- Decision to proceed with T-TEER, wait for replacement technologies or continue with medical therapy is challenging.
- For most patients, **T-TEER is the first and last Tricuspid Intervention.**
- T-TEER should be pursued early in low and intermediate risk patients with **high likelihood of procedural success – preferably mild or less TR, as moderate TR has prognostic implications.**
- Assessing **feasibility for T-TEER** is important:
 - **Good Imaging is imperative.**
 - **Anatomy:** Coaptation gap, # of leaflets, leaflet tethering, TR severity, pacemaker.
 - **Experienced institutions, operators and imagers.**
- **We need more studies** on patient & device selection, and effects of T-TEER on outcomes (awaiting CLASP-TR, TRI-FR, TRISCEND II).

Thank You

nirf@tlvmc.gov.il