

How Do We Interpret Tricuspid TEER Trials and Registries?

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Disclosures

- **Consulting or Advisory Board:** 4C Medical, Abbott Structural, Adona, Boston Scientific, Edwards Lifesciences, Foldax, GE Medical, HighLife, Laza, Medtronic, Philips, VDyne, WL Gore
- **Institutional Research:** Abbott Structural, Boston Scientific, Edwards Lifesciences, Medtronic
- **National P.I.:** EXPAND II, HighLife (US), SOAR EFS, SUMMIT-MAC, TRILUMINATE Pivotal, VDyne



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Study Patient Enrollment

TRILUMINATE™ Pivotal

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?

Yes

TRILUMINATE Pivotal RCT
Randomized 1:1,
Device:vs. GDMT alone

No, but at least 1
grade TR reduction

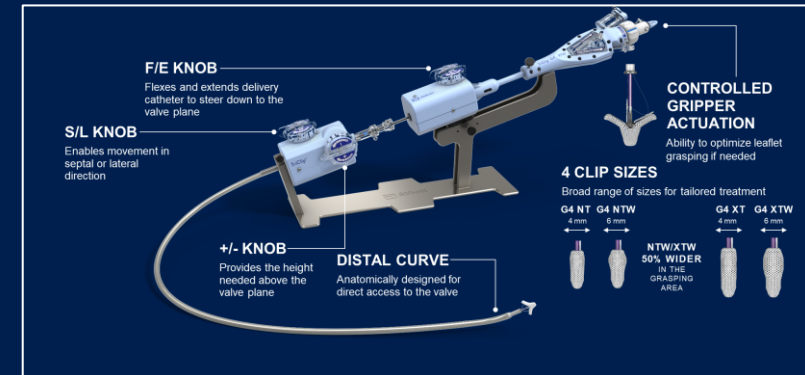
TRILUMINATE Pivotal
Single Arm

bRIGHT

Per Site Assessment,
Subjects Meeting Instructions for Use

Yes

bRIGHT Real-World Registry



Interpretation #1

Excellent and Safe TR reduction with TriClip



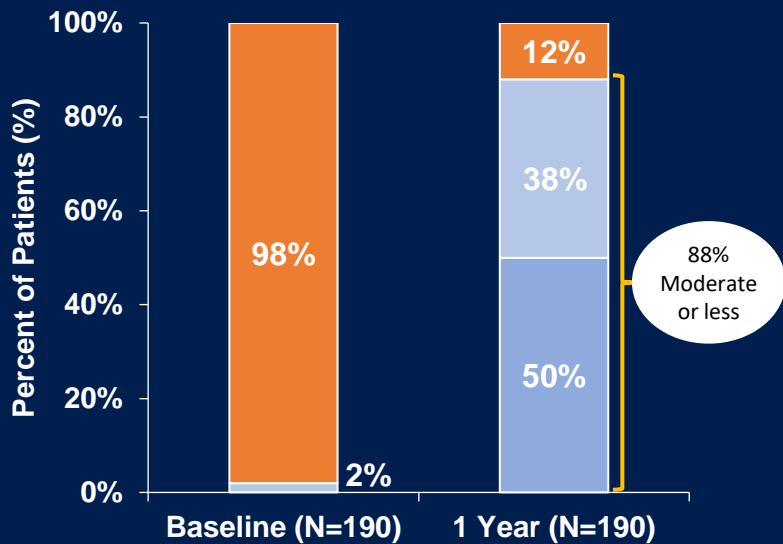
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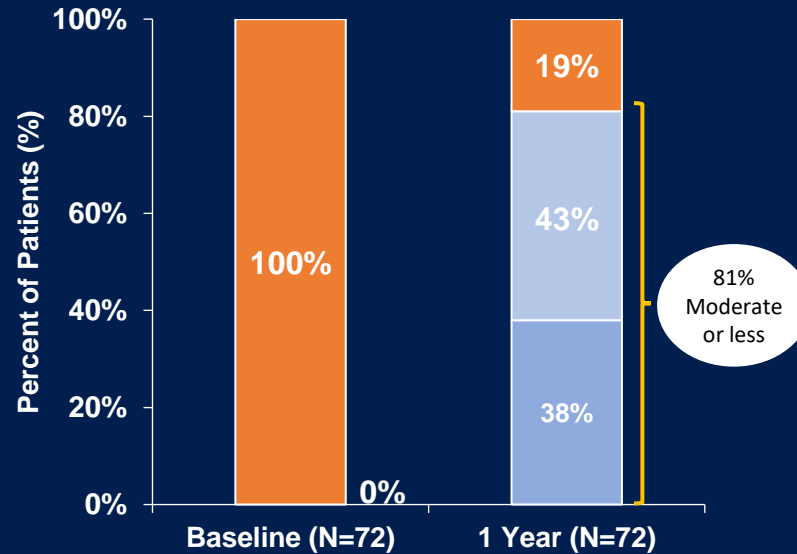
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TR Reduction at 1 Year

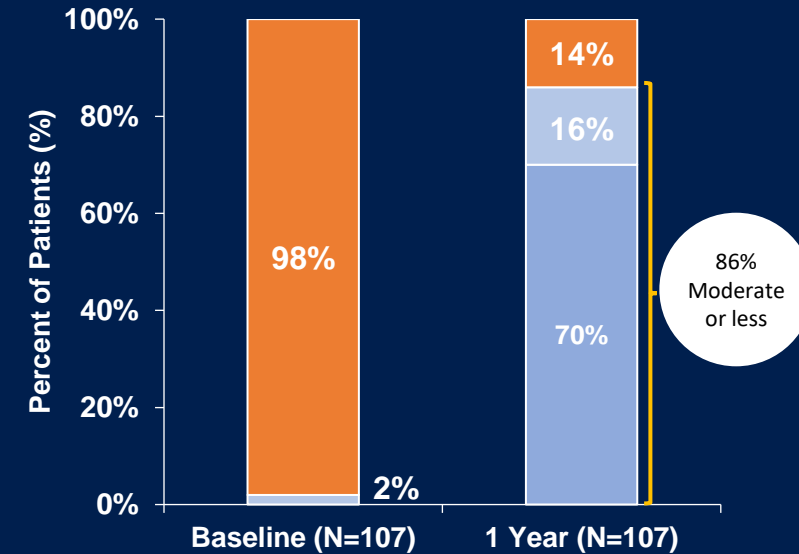
**TRILUMINATE™ Pivotal
Randomized Device Arm**



**TRILUMINATE™ Pivotal
Single Arm**



**bRIGHT
Real-world Registry**



■ Severe/Massive/Torrential ■ Moderate ■ Trace/Mild

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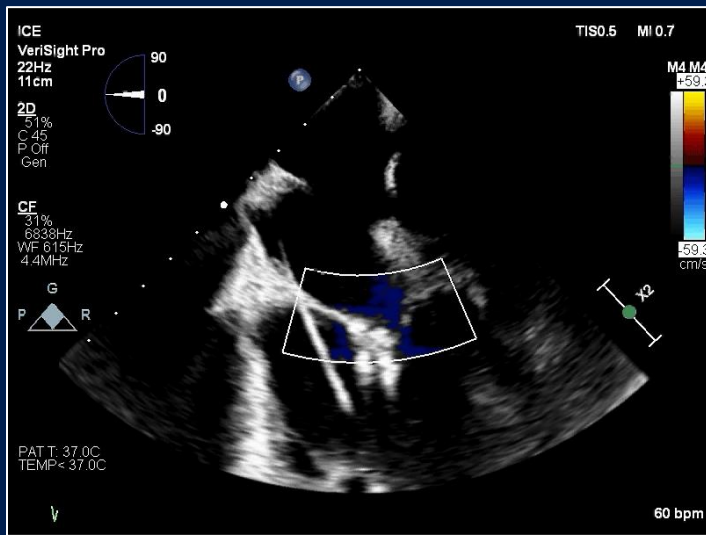
Torrential TR, 50%
CIED leads, 16%

Torrential TR, 74%
CIED leads, 35%

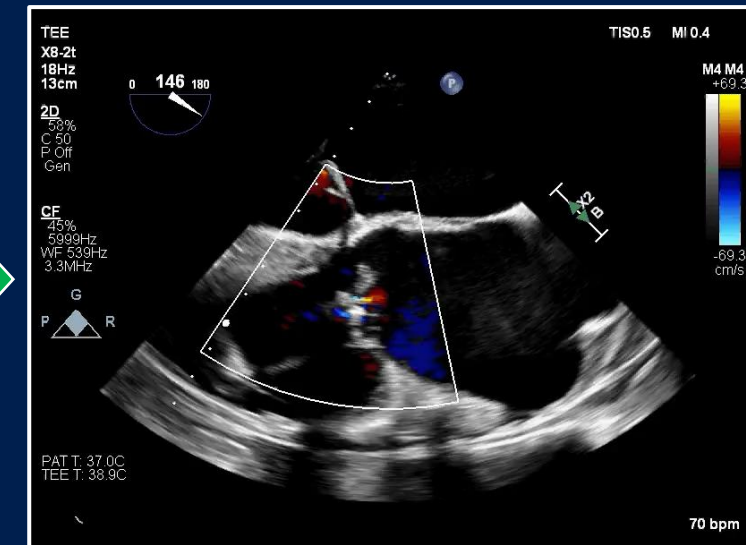
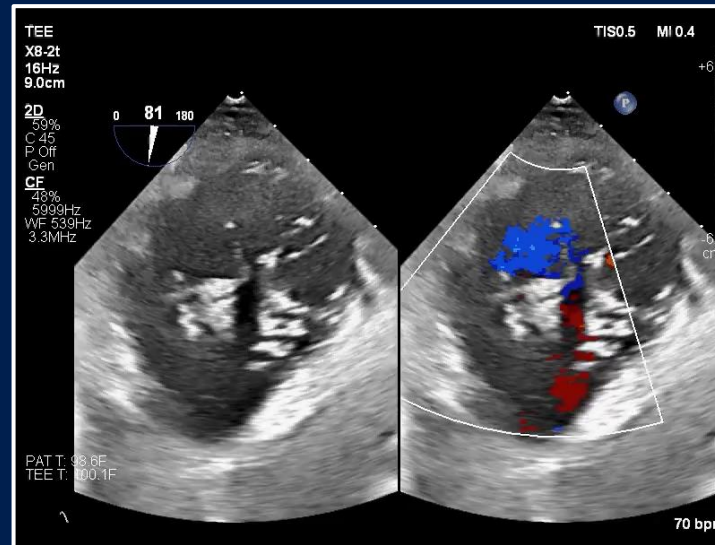
Torrential TR, 27%
CIED leads, 23%

Challenging Anatomy Treated with Early Experience

Case example



Another case example



Median no. enrolled cases per site in RCT = 2

30-day Adverse Events

Variable	TRILUMINATE™ Pivotal RCT (Device Arm) N=172	TRILUMINATE™ Pivotal SA N=99	bRIGHT N=511
All-cause Mortality	0.6%	0%	1.0%
Cardiovascular Mortality	0.6%	0%	0.8%
Endocarditis Requiring Surgery	0%	0%	0%
New-onset Renal Failure	1.2%	0%	1.4%
Non-elective CV Surgery, TVRS For Device-related AE	0%	0%	0.2%
Major Bleeding*	5.1%	5%	7.2%
Single Leaflet Device Attachment (SLDA)	7.0%	7.5%	3.8%
Stroke	0.6%	0%	0.4%
Myocardial Infarction	0%	0%	0%
Device Embolization	0%	0%	0%
Device Thrombosis	0%	0%	0%
New CRT/CRT-D/ICD/Permanent Pacemaker	0.6%	0%	0%

*Defined as bleeding ≥ Type 3 based on a modified Bleeding Academic Research Consortium (BARC) definition

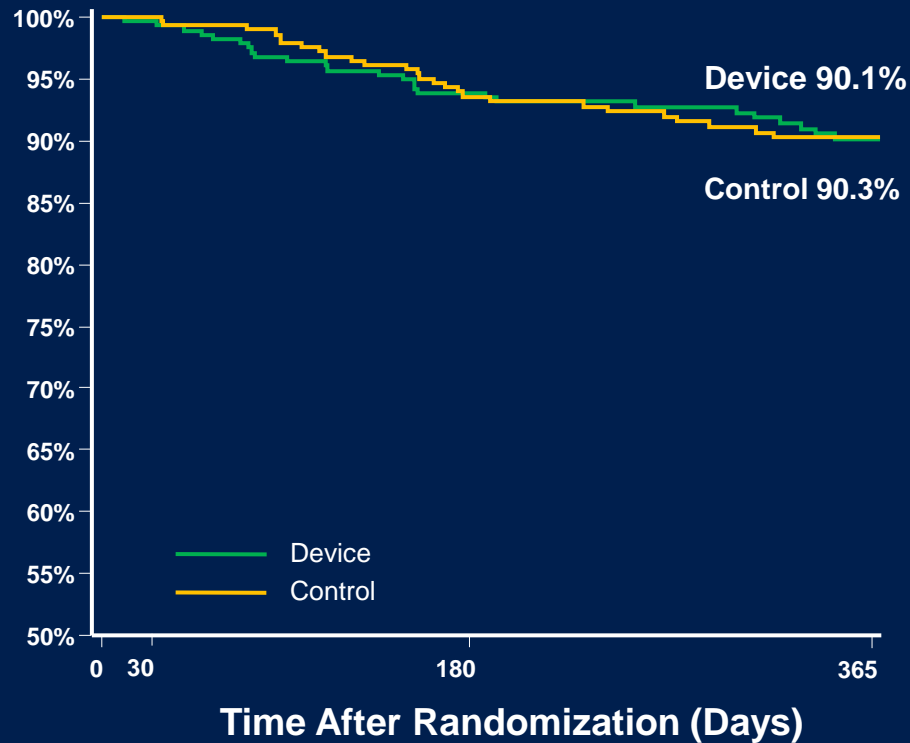
Interpretation #2

No Effect on Early Survival

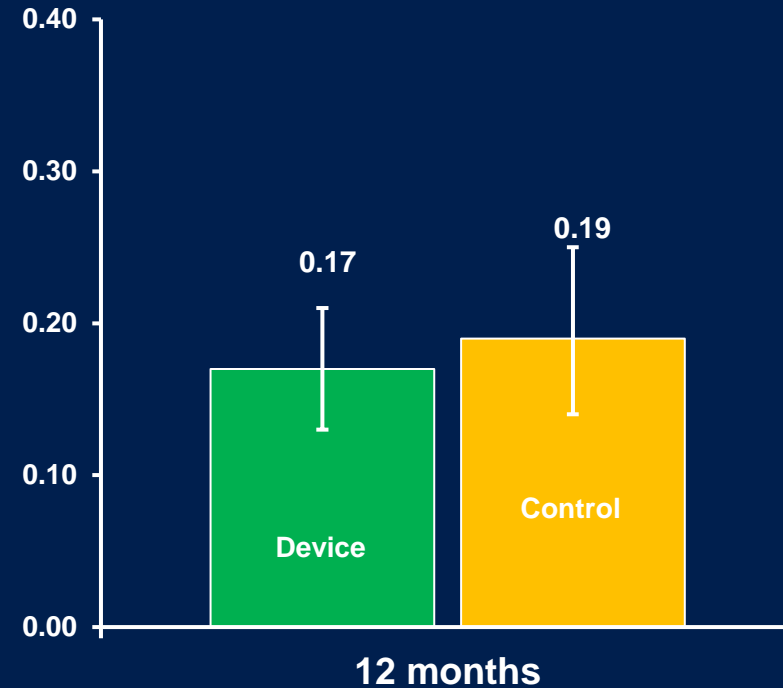
(and we shouldn't have been surprised)

TRILUMINATE RCT at One-year (n=572)

Survival free of death, TV surgery

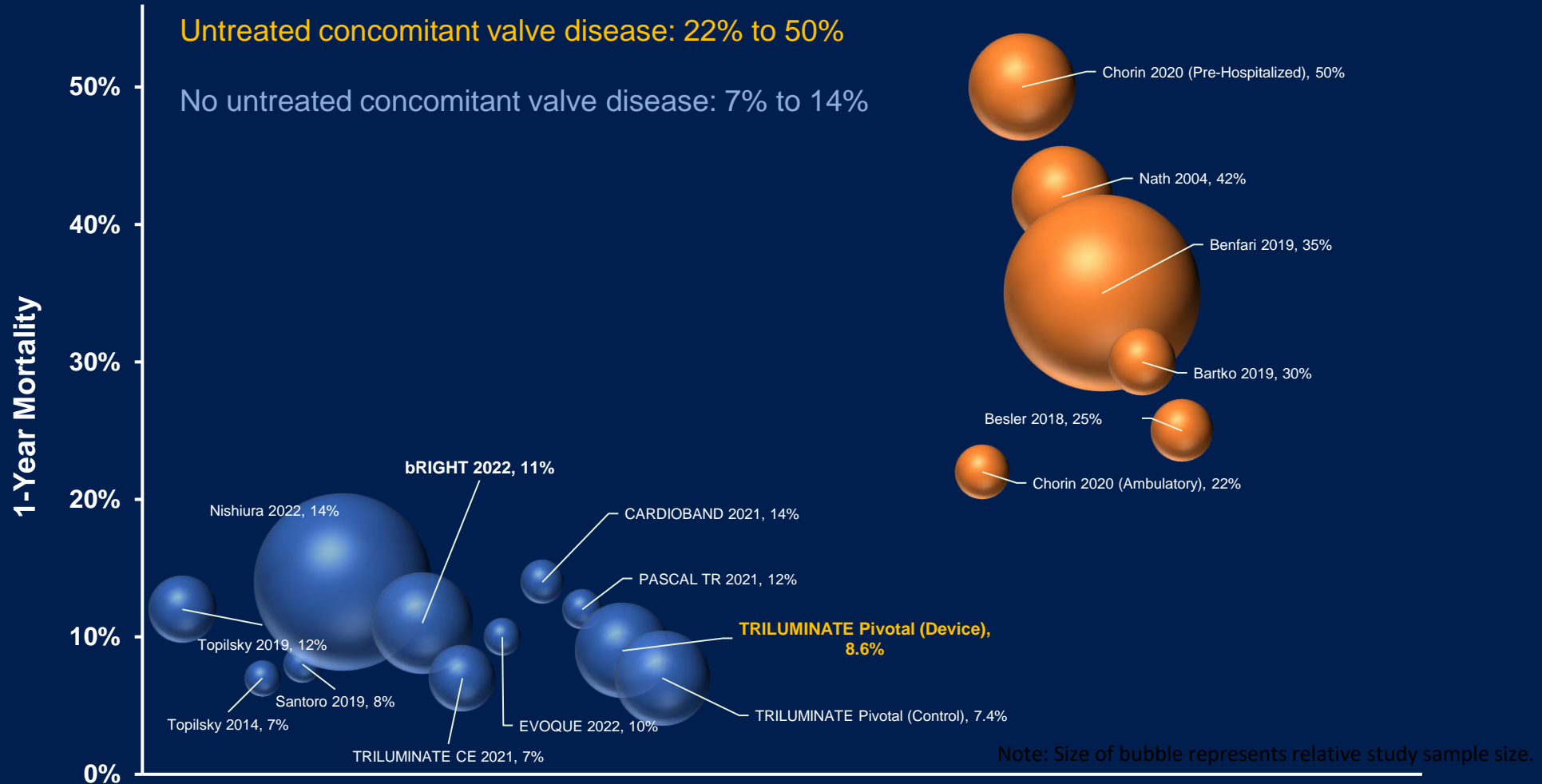


Annualized HF hospitalization



Mortality, 8.6%; HFH, 14.9%

One-Year Mortality for Patients with Severe TR



Interpretation #3

Quality-of-life Benefit is Meaningful



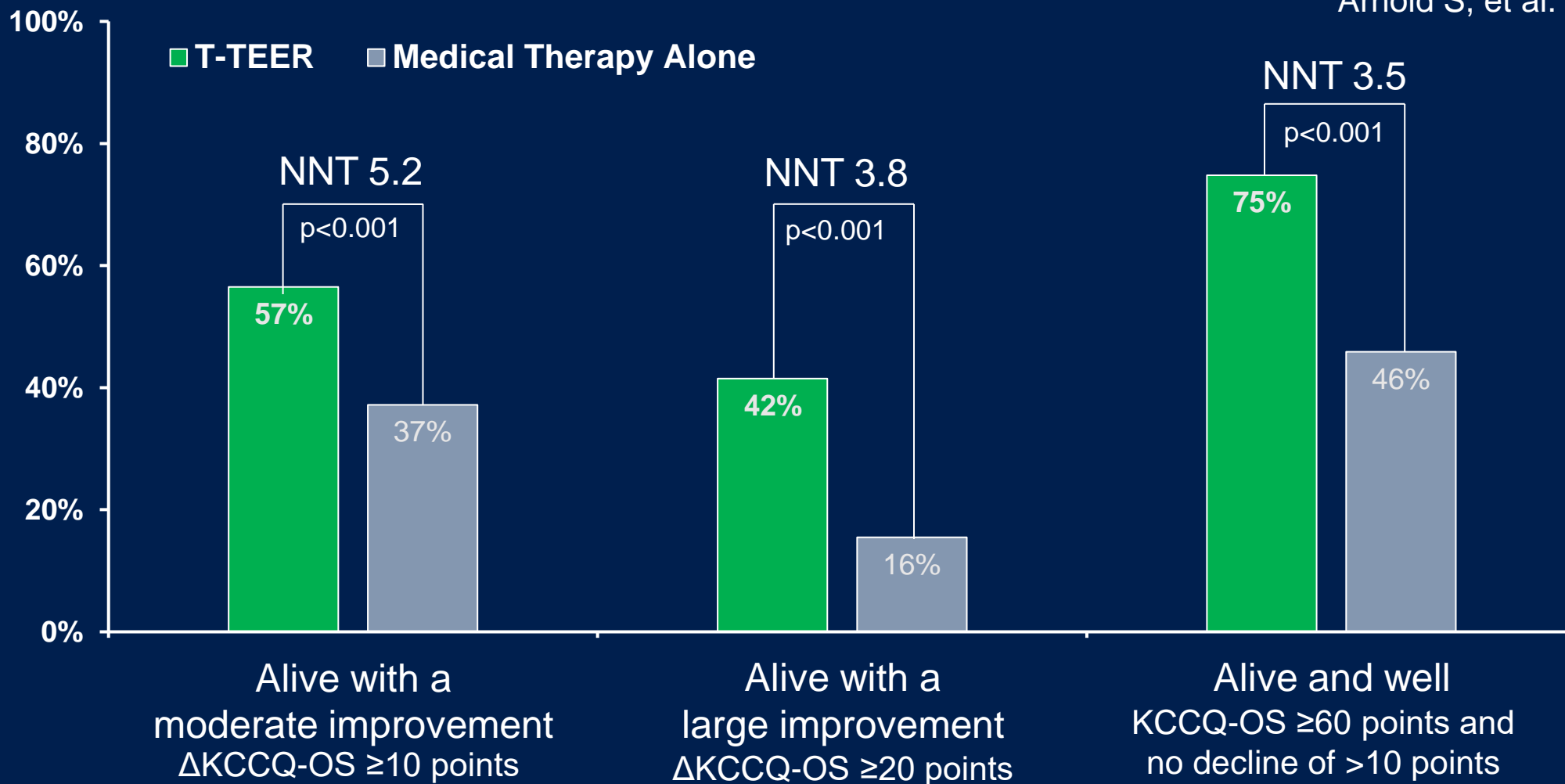
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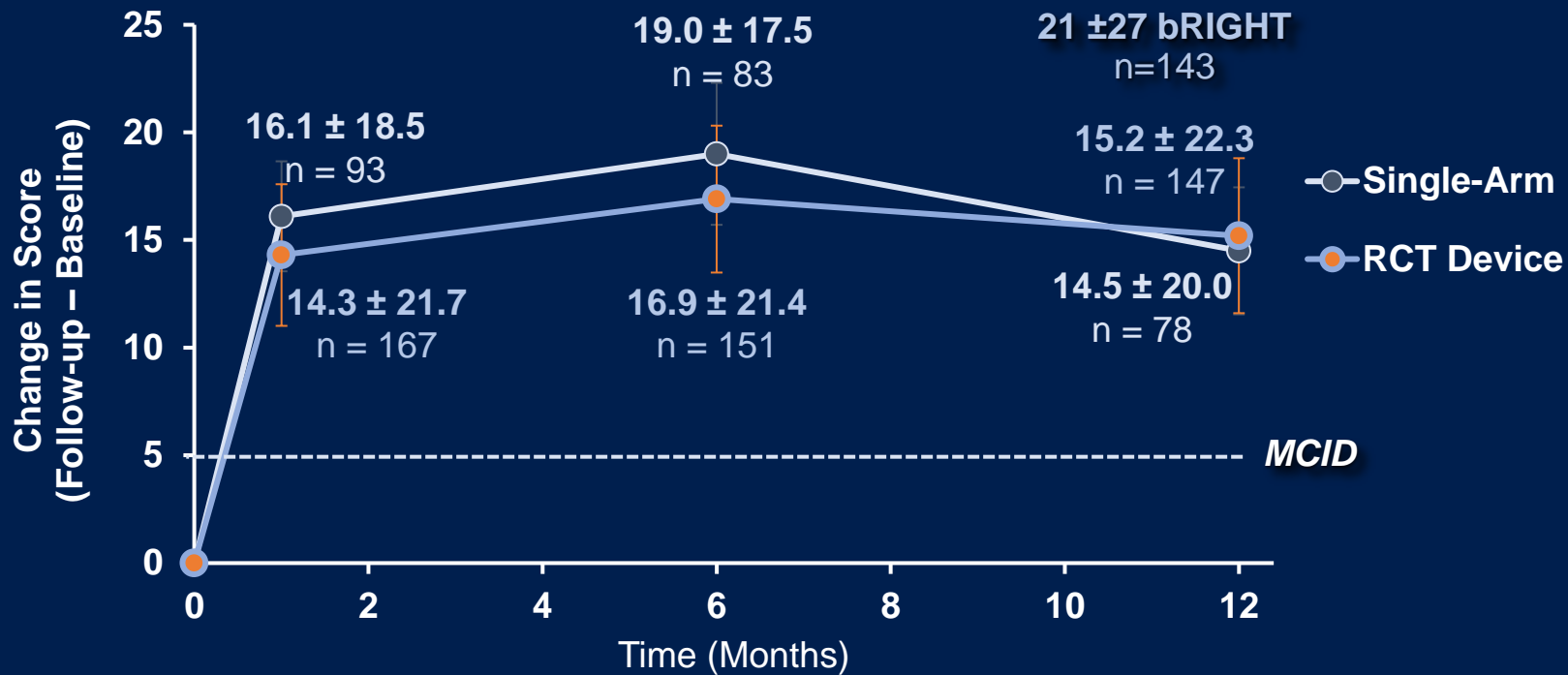
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Categorical Outcomes at 1 Year

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QOL Improvement with TriClip Therapy



High threshold chosen
No waning of effect

Exploratory Analyses Among T-TEER Patients*

Association of KCCQ-OS change with change in TR grade (baseline to 1 year)

	Estimate (95% CI)	P-value
Change in KCCQ-OS per 1 grade improvement in TR severity	4.1 (1.8 to 6.5)	0.001

Association of KCCQ-OS change at 1 month with subsequent events

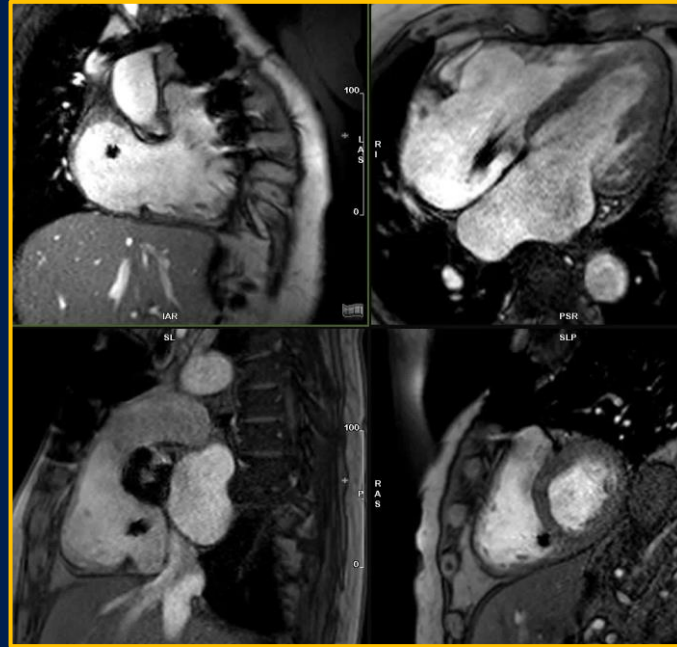
	Hazard Ratio (95% CI) per 10-point increase in KCCQ-OS	P-value
Death	0.77 (0.64-0.93)	0.007
Heart failure hospitalization	0.70 (0.58-0.84)	<0.001
Death or heart failure hospitalization	0.74 (0.65-0.84)	<0.001

* Including randomized arm, roll-in patients, and those in single-arm trial (n=396)

Arnold S, et al. TCT 2023

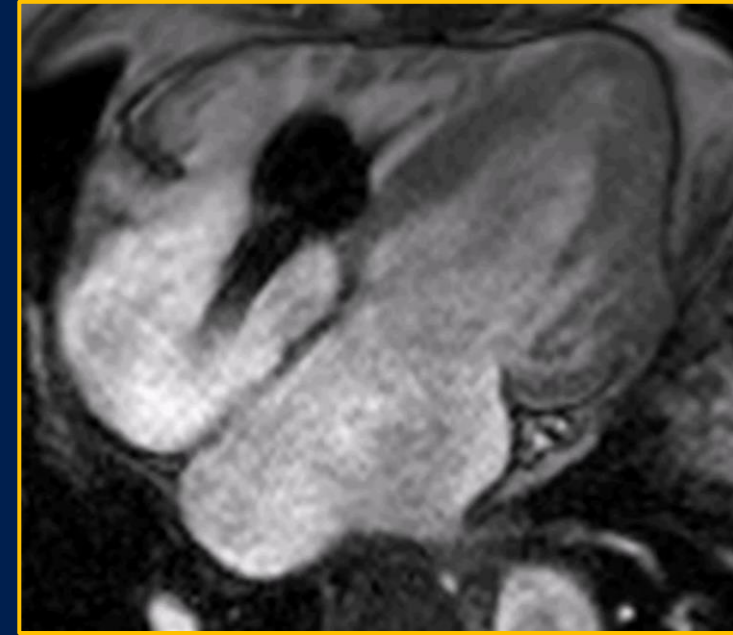
TriClip Case

Baseline



Regurgitant Vol = 86 ml
RVEDV = 237 ml
RV Diameter = 50.1 mm

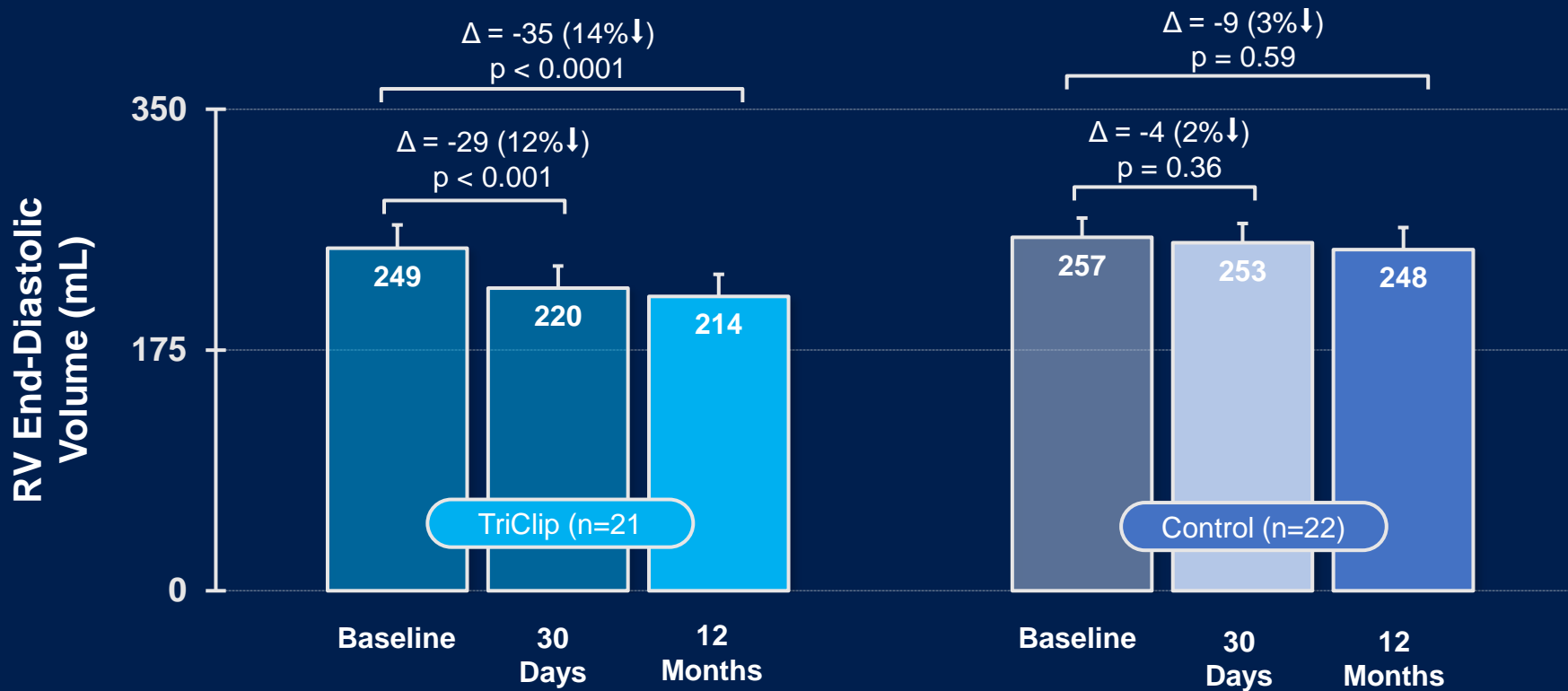
30-days after TriClip



Regurgitant Vol = 2 ml
RVEDV = 166 ml
RV Diameter = 43.8 mm

Images courtesy of Dr. João Cavalcante

RV Volume Reduction (CT) Paired Analysis

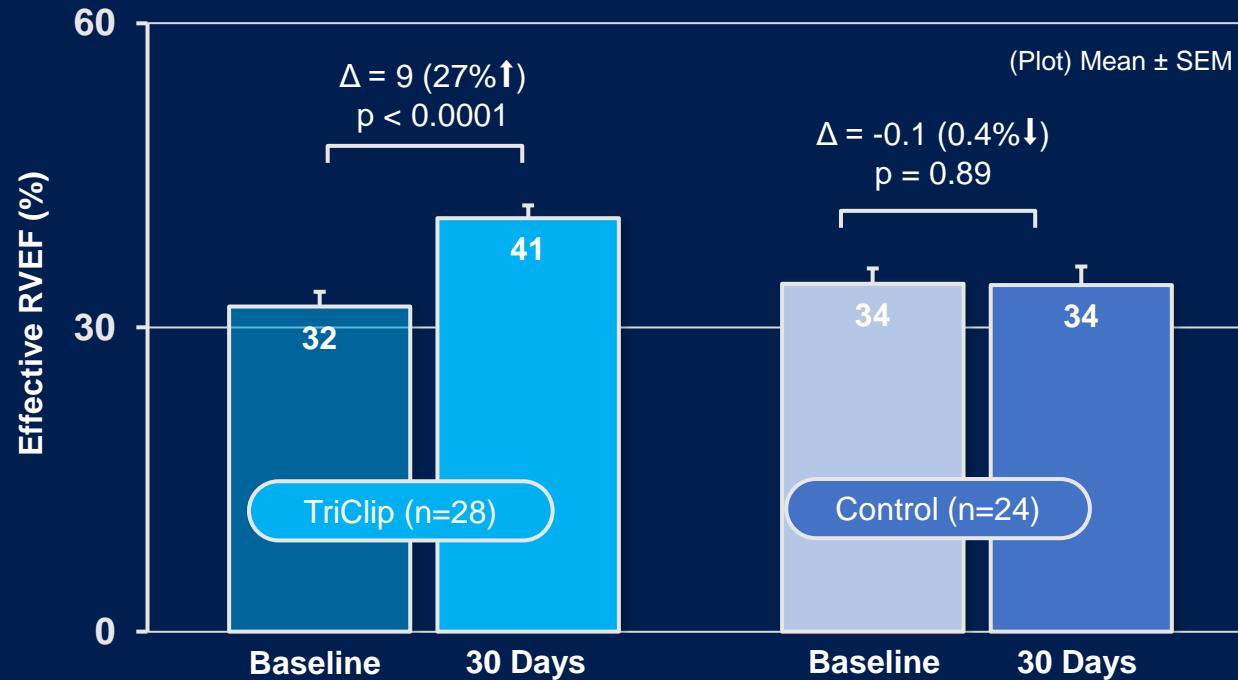


(Plot) Mean ± SEM

Cavalcante J, et al. TCT 2023

Effective RV Ejection Fraction (MRI) Paired Analysis

Effective RV EF =
Forward Stroke
Volume / RVEDV



Cavalcante J, et al. TCT 2023

Summary of TriClip Trials and Registries

- High degree of sustained TR reduction (81-89% moderate or less at 1 year) in RCT, single arm, and real-world
- Low MAE, ~1% at 30 days (death and PPM)
- Survival >90% at 1-yr of isolated TR
- Significant sustained QOL improvement, related to adverse events in post hoc analyses
- Favorable RV remodeling seen in device treated patients

Thank you!

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