

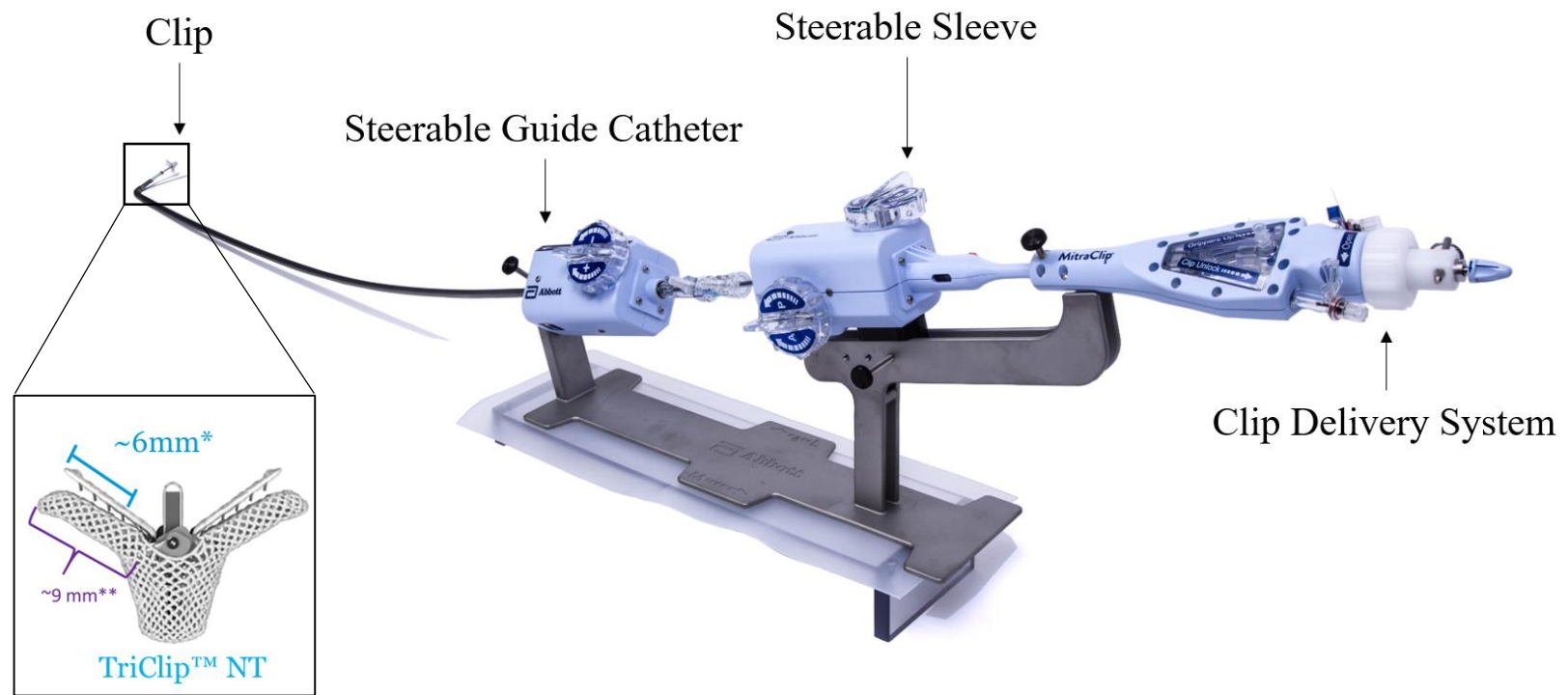
Percutaneous Edge-to-Edge Repair for Tricuspid Regurgitation: Primary Outcomes from the TRILUMINATE clinical trial

Nickenig G, Lurz P, von Bardeleben S, Sitges M, Sorajja P, Hausleiter J, Denti P, Weber M and Hahn R

The speaker reports the following disclosures:

Honoraria for lectures/advisory boards/clinical trials/research funding:
Abbott, AGA, AstraZeneca, Bayer, Berlin Cardiovalve, Chemie,
Biosensus, Biotronic, BMS, Boehringer Ingelheim, Daiichi Sankyo,
Edwards, Medtronic, Novartis, Pfizer, SanofiAventis, St. Jude

- Significant tricuspid regurgitation is a progressive condition with poor prognosis
- Treatment for TR is currently limited to the use of diuretics and high-risk surgical procedures
- Minimally invasive catheter-based procedures could potentially reduce TR with low procedural risk
- Prior retrospective analyses have indicated that percutaneous edge-to-edge repair on the tricuspid valve may be a promising option for treatment of clinically-significant TR¹



OBJECTIVE

Evaluate safety and performance of the TriClip™ in patients with symptomatic moderate or greater tricuspid regurgitation.

DESIGN

Prospective, single arm, multi-center study, conducted at 21 sites in United States and Europe.

**PRIMARY
ENDPOINTS**

Effectiveness: TR reduction of at least 1 grade at 30 days post-procedure.
Safety: A composite of major adverse events at 6-months.

ELIGIBILITY

Inclusion: (1) Symptomatic with moderate or greater TR.
(2) No indication for left-sided/pulmonary valve correction.
Exclusion: (1) severe hypertension or pulmonary artery pressure
(2) LVEF \leq 20%

Variable	All Patients (n=85)
Age, mean (years)	77.8 ± 7.9
Male / Female (%)	34% / 66%
Hypertension	86%
Prior MI	17.6%
A-fib	92%
Prior Aortic Intervention	11%
Prior Mitral Intervention	33%
Replacement – Surgery	25%
Replacement – Percutaneous	7.1%
Repair – Surgery	28.6%
Repair – Percutaneous	32.1%
Other	14.3%
CRT/ICD/PPM	14%
Renal Disease	46%
Diabetes	22%

Variable	All Patients (n)
RV End Diastolic Dimension (cm)	5.27 ± 0.67 (81)
NYHA FC III/IV	75%
EuroSCORE II	8.6 ± 10.9%
LVEF	59.39 ± 8.09% (73)
TAPSE	1.44 ± 0.31 (79)
PA Pressure, systolic (mmHg)	38.9 ± 16.0
6MWT (m)	277.47 ± 137.20 (76)
BNP	534.13 ± 353.84
NT-proBNP	3626.78 ± 13579.21
Tricuspid Regurgitation Grade	
Moderate	6% (5)
Severe	29% (24)
Massive	29% (24)
Torrential	37% (31)

Procedural Data

Parameter	TVRS
Implant Success Rate ¹	100%
Acute Device Success ² (n)	100%
Acute Procedural Success (APS) ³	91.6%
Device Time, min (n)	75.2±49.4
Total Procedure Time ⁴ , min (n)	152.7±57.8
Fluoroscopy Duration, min (n)	23.3±17.8

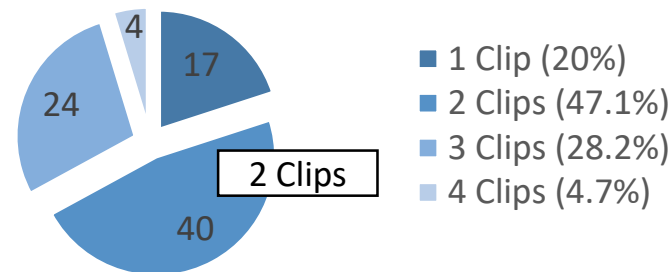
¹ Successful delivery and deployment of the Clip(s) with achievement of leaflet approximation(s) and retrieval of the delivery catheter

² Successful access, delivery of the Clip and removal of device delivery system, with no additional unplanned surgery or re-intervention.

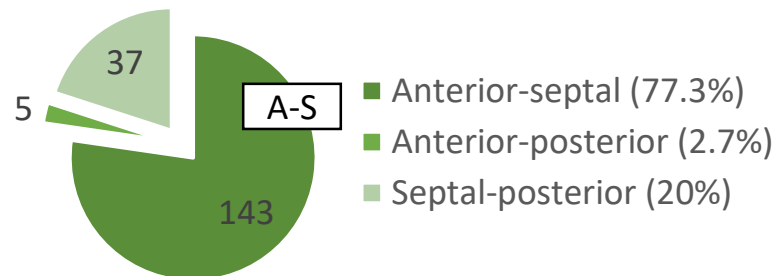
³ Successful implantation of the TVRS Clip with at least 1 grade reduction in TR severity as determined by the Echocardiography Core Laboratory (ECL) assessment of a discharge echocardiogram.

⁴ The time elapsed from the first of any of the following: intravascular catheter placement or trans-esophageal echocardiogram (TEE), to the removal of the last catheter and TEE.

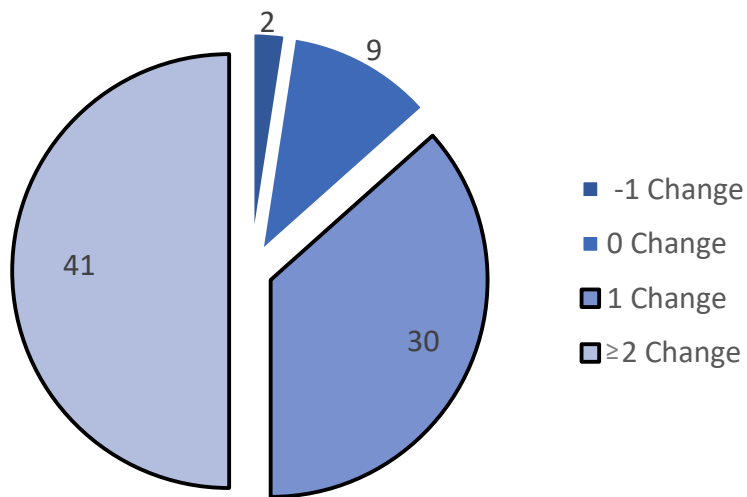
Number of Clips Implanted per Subject (n=85)



Leaflet Attachment Location (n=185)

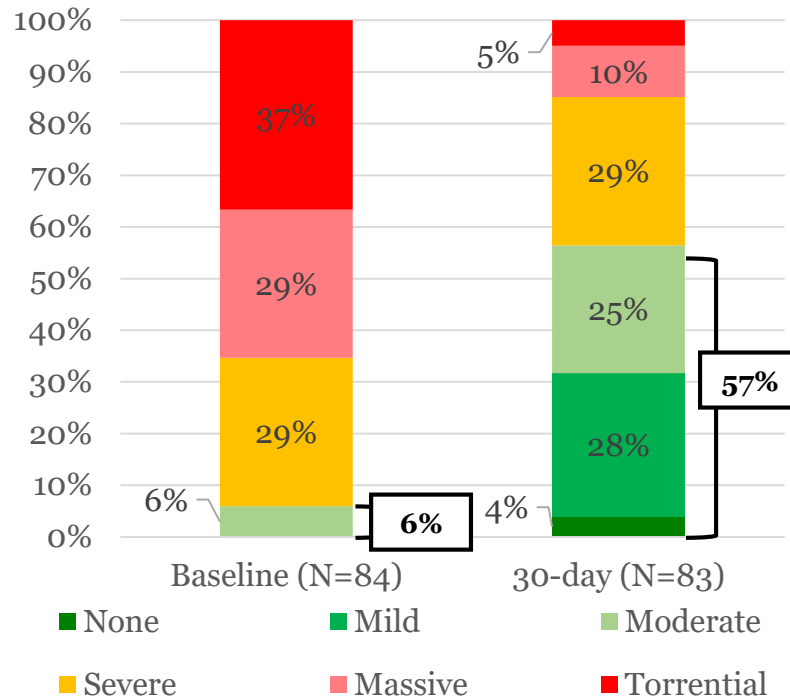


TR Change at 30 Days (N=82)



86.6% showed at least 1 grade improvement at 30 days. The 97.5% lower confidence limit was 77.3%, which is greater than the performance goal of 35%, thus the primary effectiveness endpoint is met.

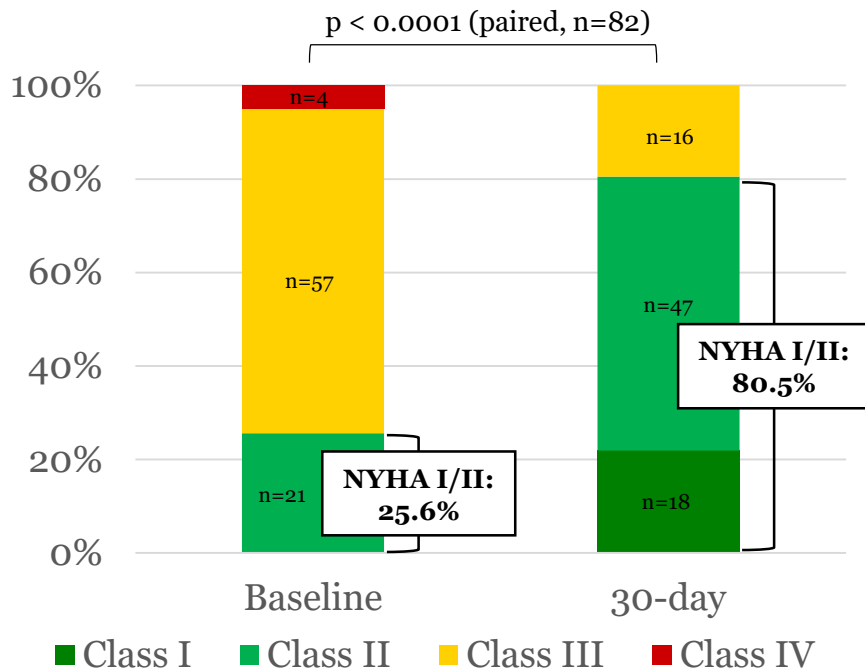
TR Grade



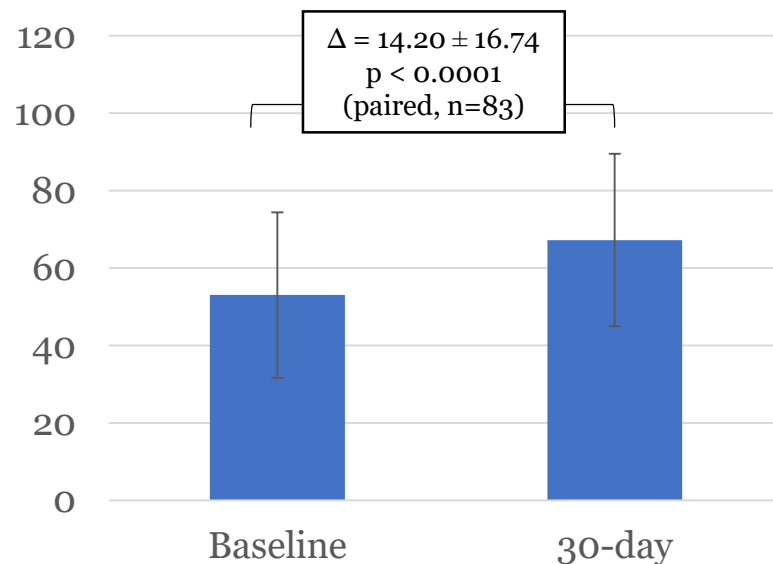
Results – Echocardiographic Parameters

Tricuspid Valve Characteristics	Baseline (n)	30 Days (n)	P value
EROA (cm²)	0.68 ± 0.31 (42)	0.43 ± 0.30 (42)	<0.0001
Regurgitant Volume (mL/beat)	54.87 ± 20.78 (41)	36.25 ± 21.29 (41)	<0.0001
Regurgitation Jet Area (cm ²)	14.62 ± 6.13 (65)	9.48 ± 5.79 (65)	<0.0001
Vena Contracta Width (cm)	1.73 ± 0.64 (82)	0.99 ± 0.59 (82)	<0.0001
PISA Radius (cm)	0.94 ± 0.22 (45)	0.70 ± 0.26 (45)	<0.0001
Inferior Vena Cava Diameter (cm)	2.30 ± 0.57 (54)	2.24 ± 0.58 (54)	0.4810
Tricuspid Annular Diameters, A-P and S-L (cm)	4.30 ± 0.55 (77)	4.05 ± 0.53 (77)	<0.0001
Mean Tricuspid Valve Gradient (mmHg)	1.21 ± 0.65 (72)	2.15 ± 1.26 (72)	<0.0001
Cardiac Output (L/min)	4.25 ± 0.91 (50)	4.82 ± 1.29 (50)	0.0009
Left Ventricle Characteristics	Baseline (n)	30 Days (n)	P value
Forward LV Stroke Volume (mL)	62.47 ± 13.97 (50)	64.63 ± 12.99 (50)	0.2241
LV Ejection Fraction (%)	59.19 ± 8.28 (69)	60.07 ± 7.79 (69)	0.0964

NYHA Functional Class



KCCQ Score*



*5 pt improvement is considered clinically meaningful
MVARC recommends 10 point improvement for MR
61% of patients experienced >10 point improvement

Event	(n)
Major Adverse Event (MAE) through 30-day	1
Cardiovascular Mortality	0
Myocardial Infarction	0
Stroke	0
New Onset Renal Failure	1
Non-elective CV surgery, TVRS	0
Device-related AE	0
Other Clinical Safety Endpoints	
All-cause Mortality	0
Major Bleeding ¹	6
Pulmonary Thromboembolism	0
New Onset Liver Failure	0
New Onset Atrial Fibrillation	1
Single Leaflet Device Attachment²	5
Embolization	0
Tricuspid Valve Mean Gradient \geq 5mmHg ³	4

30-day data demonstrate no risk for death, stroke, myocardial infarction, endocarditis requiring surgery, or non-elective cardiovascular surgery, therefore there is no safety concern.

¹ Subjects were reported drop in hemoglobin of 3-5 g/dl (BARC Type 3a)

² Subjects TR severity and clinical symptoms did not worsen, as compared to baseline. No additional intervention was needed.

³ Subjects did not present with clinical symptoms. No additional intervention was needed.

- High implant and acute procedural success rates (100% and 91.6%)
- TR reduction of at least 1 grade was achieved in 86.6% of subjects
- Significant increase in proportion of patients categorized as NYHA class I/II (25.6% to 80.5%)
- Significant improvement in KCCQ score
- Safe procedure with low complication rates

- The TriClip™ effectively reduced TR by at least 1 grade at 30 days with a low complication rate
- Subjects experienced a significant improvement in quality of life and NYHA functional class
- **The TRILUMINATE study found edge-to-edge repair with the TriClip™ device to be a promising treatment option for patients with symptomatic severe TR**