Surgical and interventional treatment of Tricuspid Regurgitation

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Disclosures

Maurizio Taramasso received consultant or speaker fees from:

- Abbott Vascular, Boston Scientific, Edwards Lifesciences, 4tech, CoreMedic, Simulands, Occlufit, MTEx, Shenqi Medical, Medira

Institutional Educational Grant from:

- Edwards Lifesciences

Advisory Board:

- Abbott Vascular, Medira

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Tricuspid Valve Surgery

- Concomitant tricuspid surgery at the time of left-side valve surgery
- Isolated tricuspid valve surgery:
  - **late TR after left-side surgery**
  - **«Atrial» TR due to annular dilatation**
  - organic or iatrogenic TR
  - endocarditis

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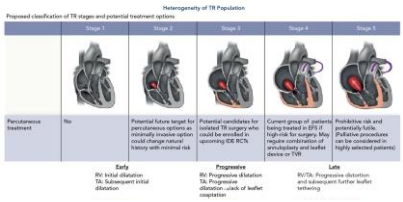
TR is a progressive condition



Courtesy of A. Latib

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Stage 1

Suture annuloplasty

Ring annuloplasty

Cinching annuloplasty

Edge-to-edge (Clover)

Leaflet augmentation

Replacement

Stage 5

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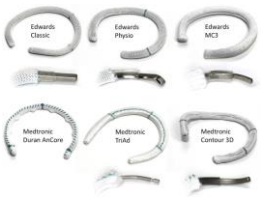
Improved surgical techniques



Disease specific rings, adjunctive procedures, **beating heart, minimally invasive approach**

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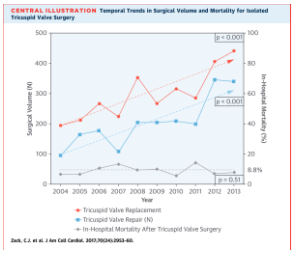
Isolated tricuspid valve surgery



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High surgical risk

Why is Isolated TV Surgery High Risk?

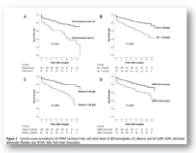
449 consecutive patients who underwent TV surgery (397 repairs and 52 replacements) due to severe TR between 1997 and 2010.

Cox-regression analysis revealed independent determinants of mortality:

- Age (HR=1.03; 95% CI 1.01 to 1.05)
- Male gender (HR=1.96; 95% CI 1.29 to 2.99)
- NYHA functional class IV (HR=2.08; 95% CI 1.31 to 3.30)
- Liver cirrhosis (HR=2.51; 95% CI 1.11 to 5.68)
- Preoperative levels of hemoglobin (HR=0.89; 95% CI 0.80 to 0.99)
- Albumin (HR=0.52; 95% CI 0.33 to 0.81)
- GFR (HR=0.86; 95% CI 0.78 to 0.95)

WE OPERATE TOO LATE!!

Kim JB, Jung S-H, Choo SJ, et al. Heart 2013;99:181–187.



Procedural type was not predictive of mortality (p=0.58) or causes of TR (p=0.97)

Courtesy of R. Hahn

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Early indication

Recommendations for Intervention on Secondary Tricuspid Regurgitation ESC/EACTS 2017
CLASS I (Level of Evidence C)
1. Surgery is indicated in patients with severe secondary tricuspid regurgitation undergoing left-sided valve surgery
CLASS IIa (Level of Evidence C)
1. Surgery should be considered in patients with mild or moderate secondary tricuspid regurgitation with a dilated annulus (≥ 40mm or > 21 mm/m² by 2D echocardiography) undergoing left-sided valve surgery
2. After previous left-sided surgery and in absence of recurrent left-sided valve dysfunction, surgery should be considered in patients with severe tricuspid regurgitation who are symptomatic or have progressive RV dilatation/ dysfunction, in the absence of severe RV or LV dysfunction and severe pulmonary vascular disease/hypertension
CLASS IIb (Level of Evidence C)
1. Surgery may be considered in patients undergoing left-sided valve surgery with mild or moderate secondary tricuspid regurgitation even in the absence of annular dilatation when previous recent right-heart failure has been documented.

DO NOT WAIT FOR RV FAILURE SYMPTOMS!!!

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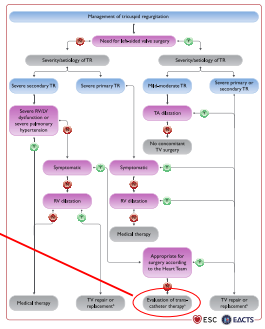
2021 ESC/EACTS Guidelines for the management of valvular heart disease

Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Transcatheter treatment of symptomatic secondary severe tricuspid regurgitation may be considered in inoperable patients at a Heart Valve Centre with expertise in the treatment of tricuspid valve disease.[1]

IIb | C



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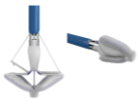
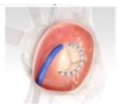
3 Devices are CE-Approved

- Triclip
- Pascal
- Cardioband





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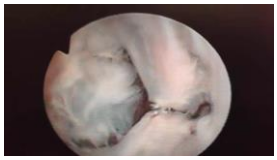
TRICLIP™ SYSTEM CONCEPTS

- TriClip System facilitates the reconstruction of an insufficient tricuspid valve through tissue approximation
- Repair creates a tissue bridge



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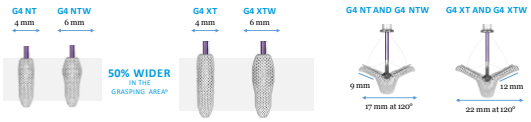
TriClip™ G4 TVRS | Two Additional Sizes

FOUR IMPLANT SIZES

Tailors therapy to individual patients rather than tailoring the patient to the device

WIDER IMPLANT SIZES

To further reduce TR with a single implant[9]



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Percutaneous Edge-to-edge Repair for Tricuspid Regurgitation: 2-year Outcomes from the TRILUMINATE™ Trial

Ralph Stephan von Bardeleben MD, Philipp Lurz MD PhD, Marta Sitges MD, Paul Sorajja MD, Jörg Hausleiter MD, Shih-Wa Ying MSc, Megan Heitkemper PhD, Gilbert H. L. Tang MD MSc MBA, Rebecca T. Hahn MD and Georg Nickenig MD

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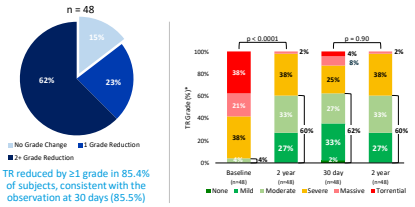
Sustained TR Reduction



TR reduced to moderate or less at 30-days **(62%)** was sustained through 2 years follow-up **(60%)**.

*Dropout due to death, withdrawal, missed visits, and unreadable echo.

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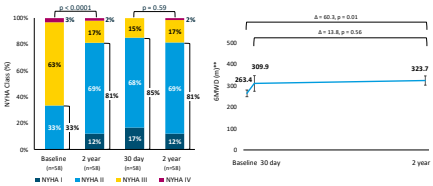
Functional Status Improvement



Sustained improvements in NYHA class and 6MWD were evident over the course of 2 years*

*Dropout due to death, withdrawal, missed visits.
**Six Minute Walk Test (6MWT) distance is not required at 30-day follow-up visit per protocol.

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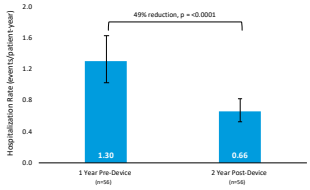
Reduction in Hospitalizations



A significant reduction in hospitalization rate was seen at 2 years **(49%)**.*

*Dropout due to death, withdrawal, missed visits

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Real-world Outcomes for Tricuspid Edge-to-Edge Repair: Initial 30-Day Results from the TriClip™ bRIGHT Study

Philipp Lurz, Robert Schueler, Bjoern Goebel, Helge Moellmann, Georg Nickenig, Raffi Bekeredjian, Rodrigo Estevez, Iskandar Atmowihardjo, Alexander Schmeisser, Erwan Donal

TriClip™ bRIGHT Study is sponsored by Abbott

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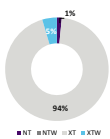
PRIMARY ENDPOINT
Acute procedural success was achieved in 90% of subjects, successfully meeting the primary endpoint performance goal of 75% (p < 0.0001).

PROCEDURAL OUTCOMES

METRIC	N=200
Implant Success	98%
Acute Procedural Success	90%
Device Time (min)	78 ± 42
Total Procedure Time (min)	106 ± 52
Average Clips per Subject	2.0 ± 0.8

CLIP USAGE*



*TriClip™ G4 recently integrated into bRIGHT, only available for 7% (14/200) of cases.

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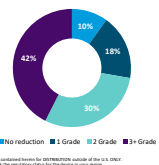
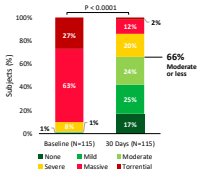
90% of subjects had TR reduced by at least 1 grade at 30 days with the majority (66%) reduced to moderate or less.

TR GRADE REDUCTION AT 30 DAYS (paired, N=115)



TR GRADE (CORE LAB)



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Strong Safety Profile

Only 1% of subjects experienced a major adverse event through 30 days, confirming the safety of the TriClip™ procedure.

EVENT	N=200
Major Adverse Event (MAE) through 30 Days	1.0% (2)
Cardiovascular Mortality	0.5% (1)
Myocardial Infarction	0% (0)
Stroke	0.5% (1)
New Onset Renal Failure	0% (0)
Non-elective CV Surgery, TVRS Device-related AE	0.5% (1)

EVENT	N=200
Other Clinical Safety Endpoints through 30 Days	
All-cause Mortality	0.5% (1)
Tricuspid Valve Re-intervention or Re-operation	1.5% (3)
Major Bleeding	7.0% (14)
New Onset Liver Failure	0% (0)
New Onset Atrial Fibrillation	0.5% (1)
Single Leaflet Device Attachment*	7.6% (10)
Embolization*	0% (0)
Tricuspid Valve Mean Gradient ≥ 5 mmHg*	1.7% (2)

*In subjects with a 30-day echo read by the core lab prior to data snapshot.

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MAT-2115318 v2.0 | Item approved for Global DUA use only.

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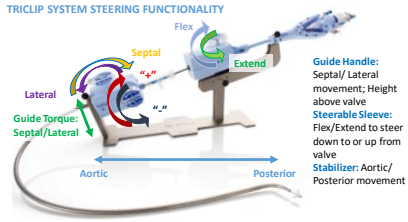
STEERING AND POSITIONING THE TRICLIP™



Note: TriClip System movements may vary based on patient anatomy, due to variations in the non-planar Tricuspid Valve annulus and varying leaflet anatomy/orientation.

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9-EH-0-11188-01 19-2021

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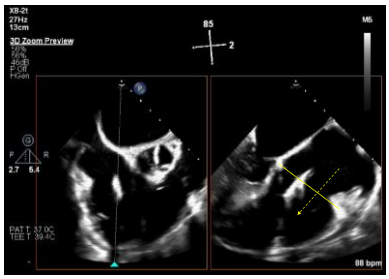
Key point 1: Trajectory perpendicular to the TV plane → use F/E and S/L



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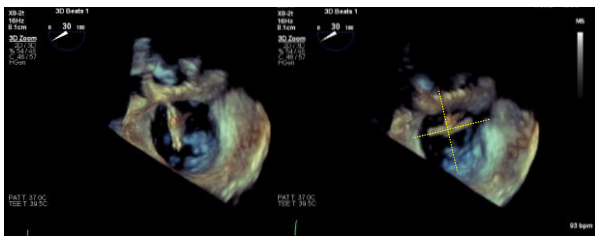
Key point 2: check the perpendicularity with the coaptation line at the «target»



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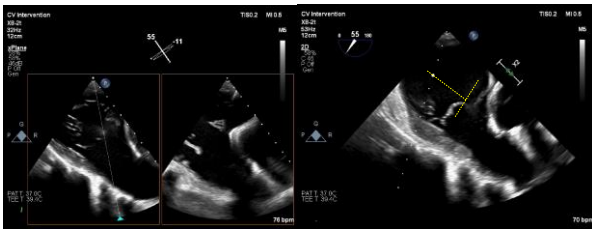

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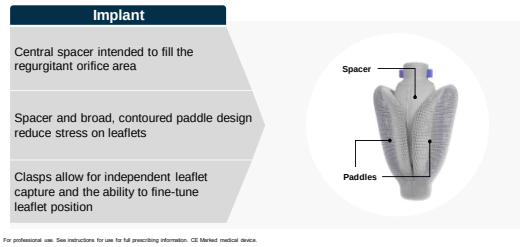
Edwards PASCAL Transcatheter Valve Repair System



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First commercial multicenter experience
with the
PASCAL transcatheter valve repair system
for tricuspid regurgitation

Jörg Hausleiter

Ludwig-Maximilians-University Munich, Germany

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Baseline Clinical Characteristics

Baseline clinical characteristics (n=181), %	
Female	51
Age, yrs	78 ± 8
EuroSCORE II, %	5.5 ± 5.6
STS-PROM, %	7.7 ± 6.7
Coronary artery disease	42
Atrial fibrillation	93
CIED with transvalvular lead	32
Renal failure (GFR < 60 ml/min)	39
NYHA functional class III / IV	91
6MWD, m	241 ± 123
NT-proBNP, pg/ml	4398 ± 7460

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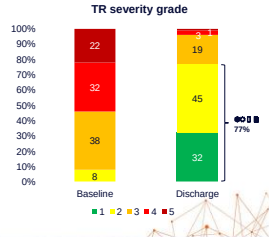
Procedural & In-Hospital Outcomes

Procedural outcome, %	
Technical success	98.4
Number of devices, n	1.7 ± 0.6
Procedure time, min	94 ± 43
Concomitant mitral TEER	9
SLDA (n=5)	2
Access site compl.* (n=2)	1
Other adverse event	0

* one case of bleeding and one AV-fistula, both requiring intervention



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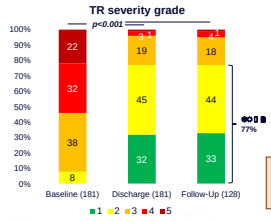
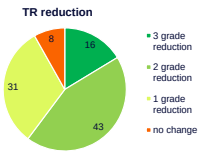
Follow-Up Outcome: TR reduction





- Sustained **TR reduction** to 2+ at follow-up **(77%)**
- TR **reduced by** [illegible] in **92%**

Median 147, IQR 46 – 271 days

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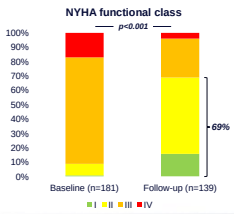
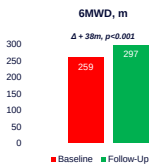
Follow-Up Outcome: functional status





Functional improvement according to **NYHA class** and **6MWD**

Median 147, IQR 46 – 271 days

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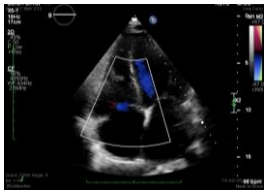
M. M.
female, 78 yo
NYHA III, AFib

- Severe ("massive") functional Tricuspid Regurgitation
- Annular dilatation (47 mm antero-septal)
- LV-EF 70%,
- Mild Pulmonary Hypertension (sPAP 30 mmHg)
- Preserved RV Function, mild MR
- Severe Renal Failure (eGFR 22 ml/min)
- Long-standing Afib
- Previous Hospitalizations for right heart decompensation (3x) in 9 months
- Peripheral Artery Disease
- **TRI-Score: 22%**



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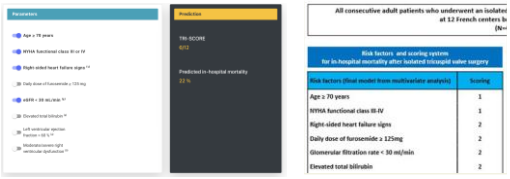

All consecutive adult patients who underwent an isolated at 12 French centers b (N=

Risk factors and scoring system for in-hospital mortality after isolated tricuspid valve surgery

Risk factors (final model from multivariate analysis)	Scoring
Age ≥ 70 years	1
NYHA functional class III-IV	1
Right-sided heart failure signs	2
Daily dose of furosemide ≥ 125mg	2
Glomerular filtration rate < 30 ml/min	2
Elevated total bilirubin	2

European Heart Journal (2022) **43**, 654–662

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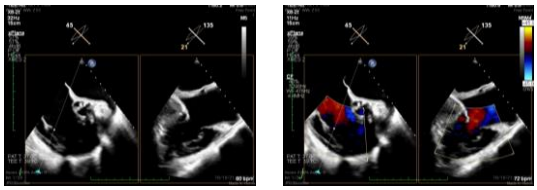
Pascal Tricuspid



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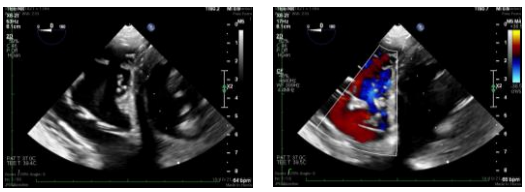
TEE: transgastric short axis



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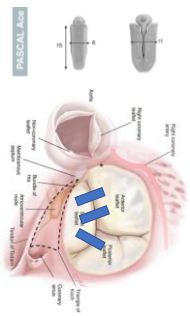
Procedural plan

- Massive functional isolated tricuspid regurgitation
- TEE-Guided transcatheter tricuspid Edge-to-Edge Repair
- PASCAL ACE in AS line of coaptation, 1 or 2 further devices more central
- Preclosure of venous access



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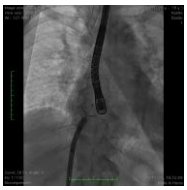
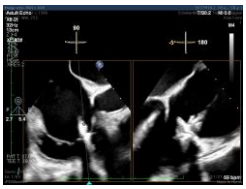
Insertion and trajectory

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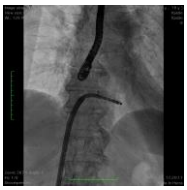
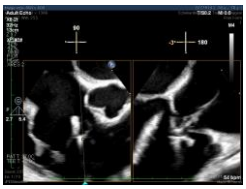
1st Pascal ACE A-S

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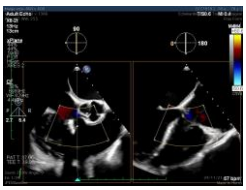
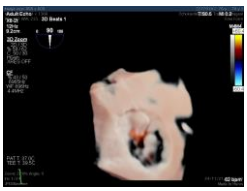
Residual central jet

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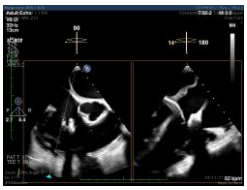
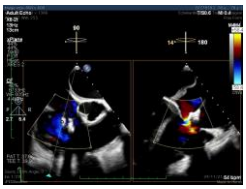
2nd Pascal ACE A-S, more central

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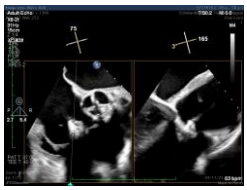
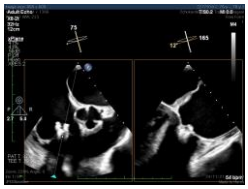
Clasping of AS leaflets

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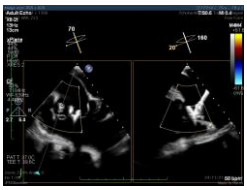
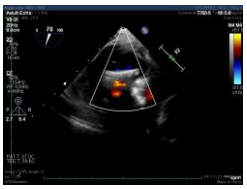
3rd Pascal ACE P-S

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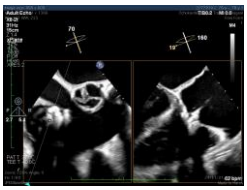
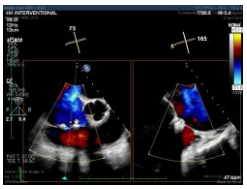
Independent clasping used

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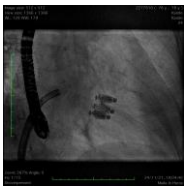
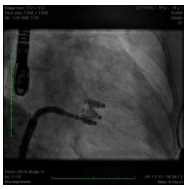
Final release

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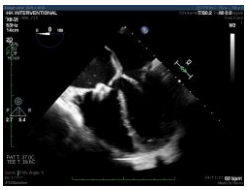
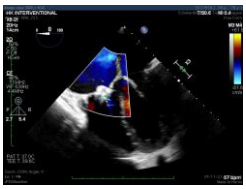
Final result, Gradient 2 mmHg





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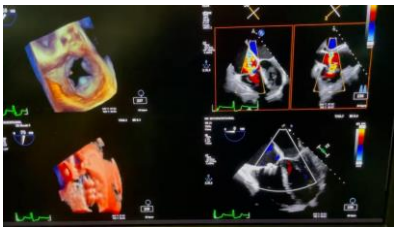
Pre- and post-



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Selection assistance for Tricuspid TEER

	Ideal TR for edge-to-edge repair	Edge-to-edge repair to be considered	Edge-to-edge repair not recommended or only in exceptional cases
Anatomy	Secondary TR with structurally normal leaflets	Secondary TR with normal leaflets or primary TR with leaflet prolapse	Severe leaflet (rheumatic) thickening or shortening or destruction or very large leaflet prolapse
Clinic	Severe TR based on the 5-grade scale	Massive TR based on the 5-grade scale	Torrential TR based on the 5-grade scale
Imaging	Good transesophageal & transgastric echocardiographic windows	Sufficient transesophageal & transgastric echocardiographic windows	Insufficient echocardiographic windows
Anatomy	Coaptation deficit < 8 – 9 mm measured at the location of planned Clip placement and good leaflet mobility	Coaptation deficit 8 – 9 mm measured at the location of planned Clip placement, reduced leaflet mobility	Coaptation deficit > 9 mm measured at the location of planned Clip placement or/and severe leaflet tethering
	Central TR jet extending in the antero-septal commissure	Central TR jet extending in the postero-septal or antero-posterior commissure	Non-central or very eccentric jets or jets originating from antero-posterior commissure
Clinic	No PM/ICD lead	Presence of PM/ICD lead, no significant leaflet interaction and no potential interaction with clip	PM/ICD lead-induced TR
	Normal to moderately reduced RV function, normal to moderate RV/annular dilatation	Moderately reduced RV function, moderate RV/annular dilatation	Severely reduced RV function or severe RV/annular dilatation
	No pulmonary hypertension	Post-capillary pulmonary hypertension	Pre-capillary pulmonary hypertension

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Cardioband Tricuspid System Procedure

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TRI-REPAIR Study

Technical Success

• Successful access, deployment and positioning of the Cardioband device • Septolateral reduction at intra-procedure and discharge	100% (30/30)

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TRI-REPAIR Study

30-Day Safety Profile and Adverse Events Up to 2 Years

CEC Adjudicated Events	Cumulative Event Rates n (%)		
	30 Days	1 Year	2 Years
Death	2 (6.7)	5 (16.7)[a]	8 (26.7)[a]
Stroke	1 (3.3)	1 (3.3)	2 (6.7)
Myocardial infarction	0	0	0
Device related secondary intervention	0	1 (3.3)[b]	2 (6.7)
Device related cardiac surgery	0	0	0
Bleeding complications[c]	4 (13.3)	6 (20.0)[a]	7 (23.3)
Fatal	1 (3.3)	1 (3.3)	2 (6.7)
Life-threatening	1 (3.3)	1 (3.3)	1 (3.3)
Extensive	2 (6.7)	4 (13.3)[a]	4 (13.3)
Coronary complications	3 (10.0)	3 (10.0)	3 (10.0)
Renal failure	1 (3.3)	1 (3.3)	1 (3.3)
Conduction system disturbance	1 (3.3)	1 (3.3)	2 (6.7)
Ventricular arrhythmia	2 (6.7)	3 (10.0)	3 (10.0)

23/30 patients (77%) had none of the above events at 30 days

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TRI-REPAIR Study

Sustained TR Reduction at 2 Years[1]

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TRI-REPAIR Study

Sustained Functional Status Improvement at 2 Years

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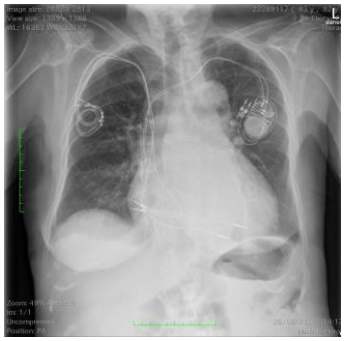

Repair is not always feasible…

Female, 83 yo
NYHA III, AFib

- Torrential Tricuspid Regurgitation
- Previous PM implantation; by failing leads without possibility to extract, both leads implanted twice
- LV-EF 50%, mildly depressed RV function
- Mild Pulmonary Hypertension (sPAP 35 mmHg)
- Severe renal failure
- Hepatic congestion, Oedema +++
- Previous Hospitalisations for Right Heart Failure
- Prohibitive surgical risk

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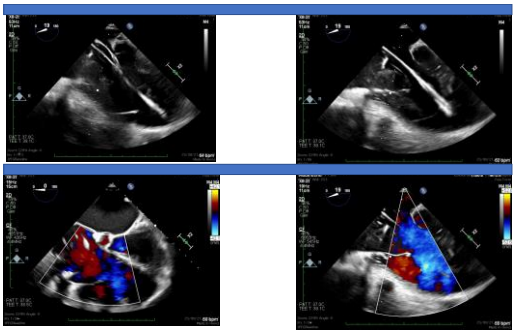

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Heterotopic Tricuspid Valve Implantation (TRICENTO)

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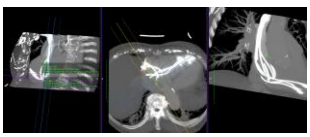

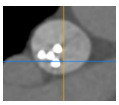

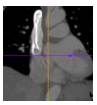

CT-planning

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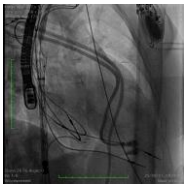
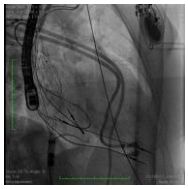
TRICENTO Implantation

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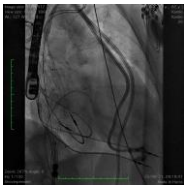
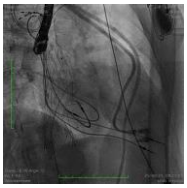
Final release and angiogram

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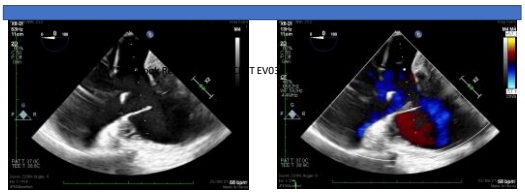
2 tricuspid valve “in a series”



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EVOQUE Tricuspid Valve

Unique valve design engages leaflets, chords, and annulus to achieve secure placement

Atraumatic anchors
compatible with pre-existing leads and respect the native anatomy

Conforming frame
designed to achieve optimal retention force

Multiple sizes
offer treatment for a broad range of tricuspid pathologies and anatomies

Courtesy of Dr. J. Webb

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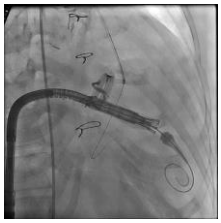
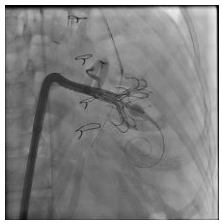
Anchors opened and pulled back to valve





Courtesy of Dr. J. Webb

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CEC Adjudicated Major Adverse Events at 30 Days

Major Adverse Events	N=124[a] N (%)
Cardiovascular mortality	3 (2.4%)
Myocardial infarction	0 (0%)
Stroke	0 (0%)
Renal complications requiring unplanned dialysis or renal replacement therapy	1 (0.8%)
Severe bleeding[b]	22 (17.7%)
Major access site and vascular complications	2 (1.6%)
Non-elective tricuspid valve re-intervention, percutaneous or surgical	2 (1.6%)
Major cardiac structural complications	1 (0.8%)
Device-related pulmonary embolism	0 (0%)
Composite MAE Rate	**23 (18.5%)**
Other Events	**N=124[a] N (%)**
All cause mortality	4 (3.2%)
Site-Reported Events	**N=76[a] N (%)**
New permanent pacemaker	8 (10.5%)

81.5% of patients had no MAEs at 30 days

[a]Denominator for % calculation includes all patients who reached 30-day follow-up as well as any patients who experienced an MAE prior to follow-up. [b]Severe bleeding is defined as major, extensive, life-threatening, or fatal bleeding per Mitral Valve Academic Research Consortium (MVARC).

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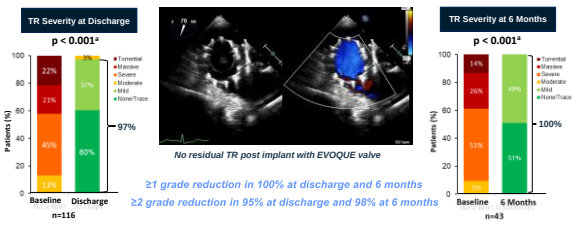
Significant Reduction in TR Severity by Core Lab[1] at 6 Months



[1]Core lab: Baylor, Scott and White Research Institute; [a]Wilcoxon signed-rank test. TR, tricuspid regurgitation

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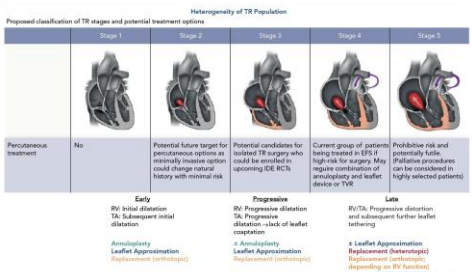

Courtesy of A. Latib

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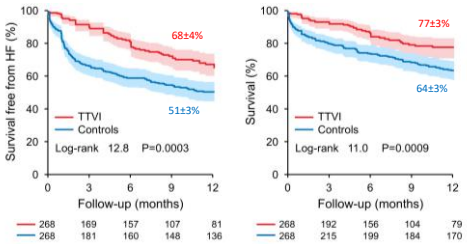
Does TTVI improve survival?



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Conclusions

- TTVI is feasible with different technologies, with a reasonable overall procedural success rate and it is associated with low mortality and significant clinical improvement
- TTVI is associated with greater survival and reduced HR hospitalisation compared to medical treatment alone
- Interventional timing is crucial to achieve prognostic benefit
- Need for better definitions and risk stratification →TVARC

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