The annuloplasty option - Why is Cardioband tricuspid system an essential tool to have in your tricuspid regurgitation program?

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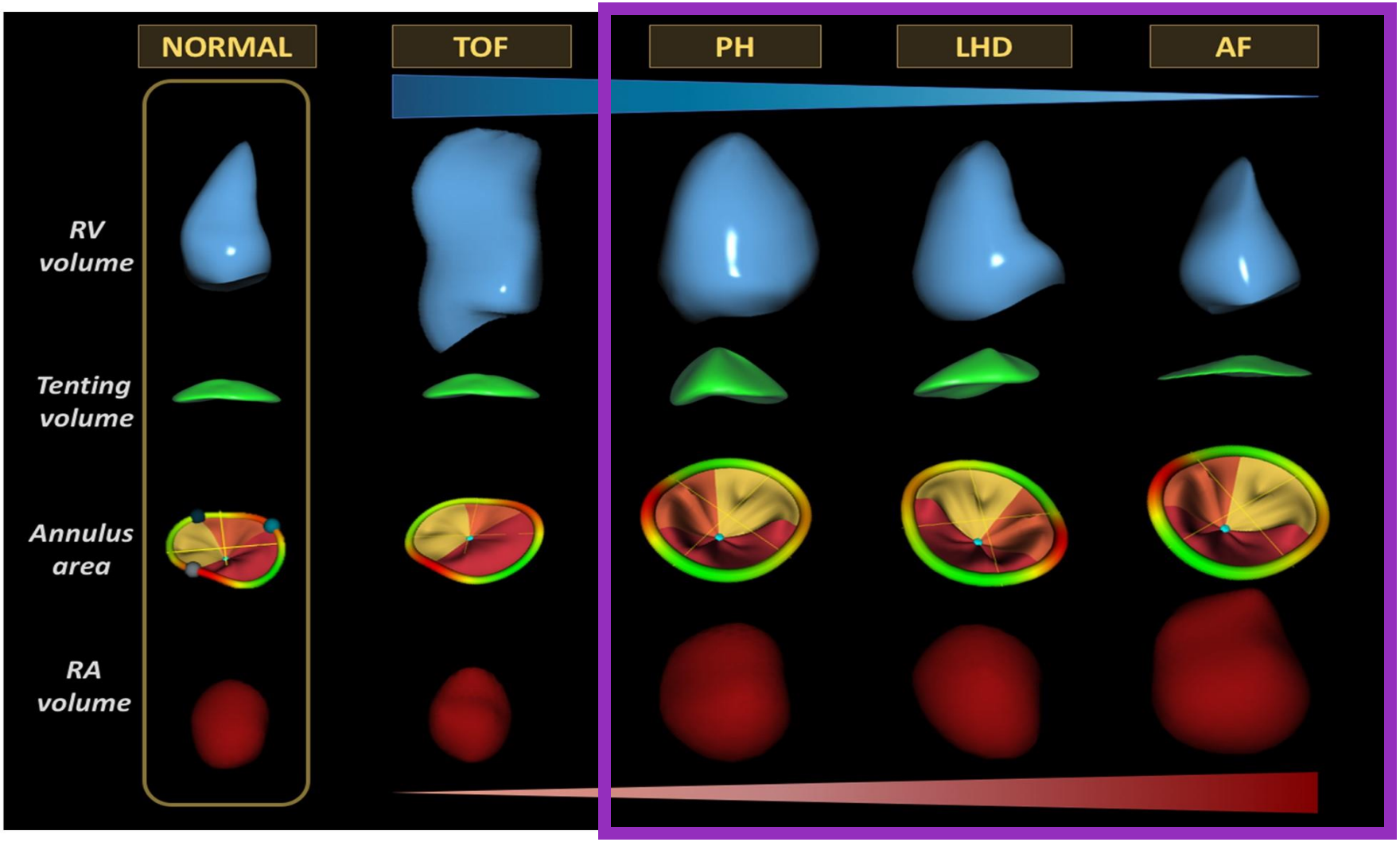
Potential conflicts of interest

Speaker's name: Volker Rudolph

☑ I have the following potential conflicts of interest to report:

- Research grants: Edwards Lifesciences, Abbott Vascular, Boston Scientific

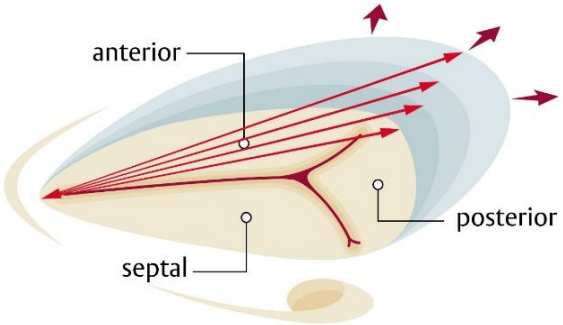
Pathophysiology of Functional Tricuspid Regurgitation: An Annular Disease



Muraru et al. EHJ CV Imag 2020

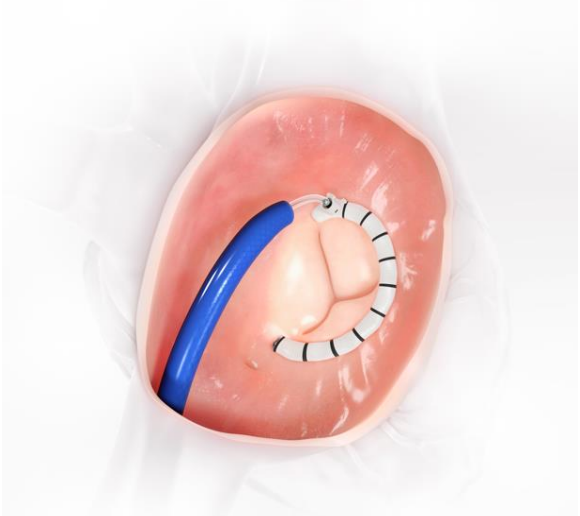
Cardioband Tricuspid Valve Reconstruction System

Addresses the main problem



Reduction of **septo-lateral diameter** and right ventricular free wall dilation

No barrier for future therapies



Restores valve to a more functional state – facilitating **leaflet coaptation**

Standardized implantation

Enables **annular reduction** through a standardised procedure based on each **patient's anatomy**

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Nickenig G. et al. EuroIntervention 2021;16:e1264-e1271. DOI: 10.4244/EIJ-D-20-01107

Pathophysiology of Functional Tricuspid Regurgitation

Table 1. Proposed new integrated classification of TR.

	Leaflet structure	Pathophysiology	Aetiology	Imaging
Secondary (functional)				
A. Atrial	Normal	RA enlargement and dysfunction leading to significant isolated annular dilation; RV often normal*	Carpentier I: Atrial fibrillation/flutter[101] Age[102] Heart failure with preserved ejection fraction[103,104]	Marked **TV annular dilation** is the dominant mechanism TV leaflet tethering is absent or minimal (except for late stages with secondary RV dysfunction) TV leaflet mobility is typically normal (Carpentier type I) RA is significantly dilated
A. Atrial	Normal	RA enlargement and dysfunction leading to significant isolated annular dilation; RV often normal*	Carpentier I: Atrial fibrillation/flutter[101] Age[102] Heart failure with preserved ejection fraction[103,104]	Marked **TV annular dilation** is the dominant mechanism TV leaflet tethering is absent or minimal (except for late stages with secondary RV dysfunction) TV leaflet mobility is typically normal (Carpentier type I) RA is significantly dilated RV volume is typically normal (except in late stages)
Primary (organic)	Abnormal	Lack of leaflet coaptation due to intrinsic changes leading to restricted or excessive leaflet mobility or leaflet perforation	Carpentier I: Congenital Endocarditis Carpentier II: Myxomatous disease Traumatic Post biopsy Carpentier IIIA: Carcinoid[109] Rheumatic Radiotherapy Tumours	**TV leaflet structural abnormalities** characteristic of each primary aetiology are the dominant mechanisms TV leaflet mobility is variable (all Carpentier types) TV annulus, RV and RA are typically dilated (except in acute TR)

Praz F et al. EuroIntervention 2021;17:791-808. DOI: 10.4244/EIJ-D-21-00695
RA - right atrium, TV - tricuspid valve, RV - right ventricle
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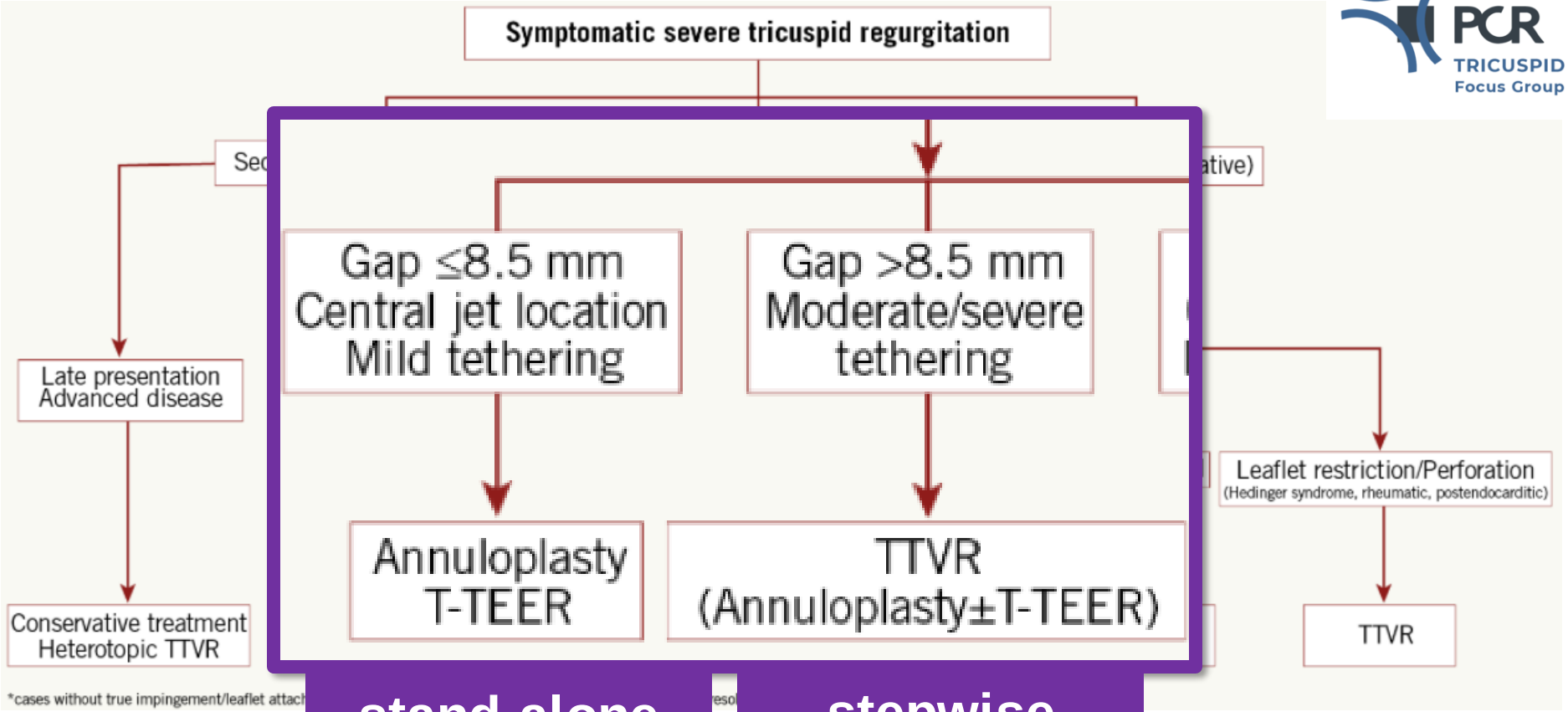
Proposed algorithm for the selection of TTVI systems



Praz F et al. EuroIntervention 2021;17:791-808. DOI: 10.4244/EIJ-D-21-00695
CIED - cardiac implantable electronic device, TR – tricuspid regurgitation, TTVR - transcatheter tricuspid valve replacement, T-TEER - tricuspid transcatheter edge-to-edge repair
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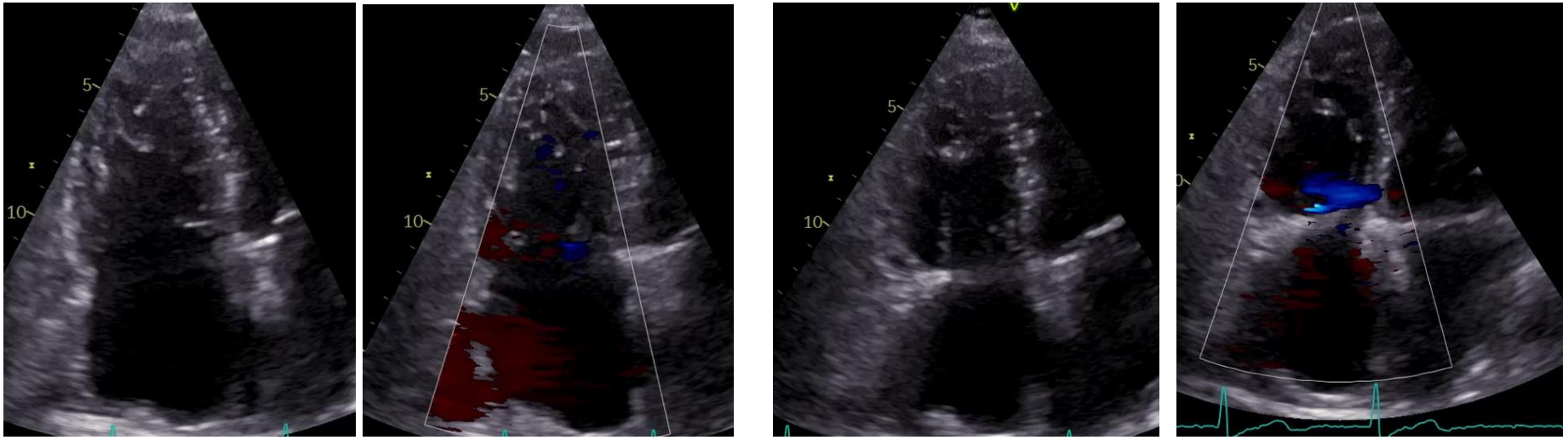
2 patient cases: stand-alone annuloplasty

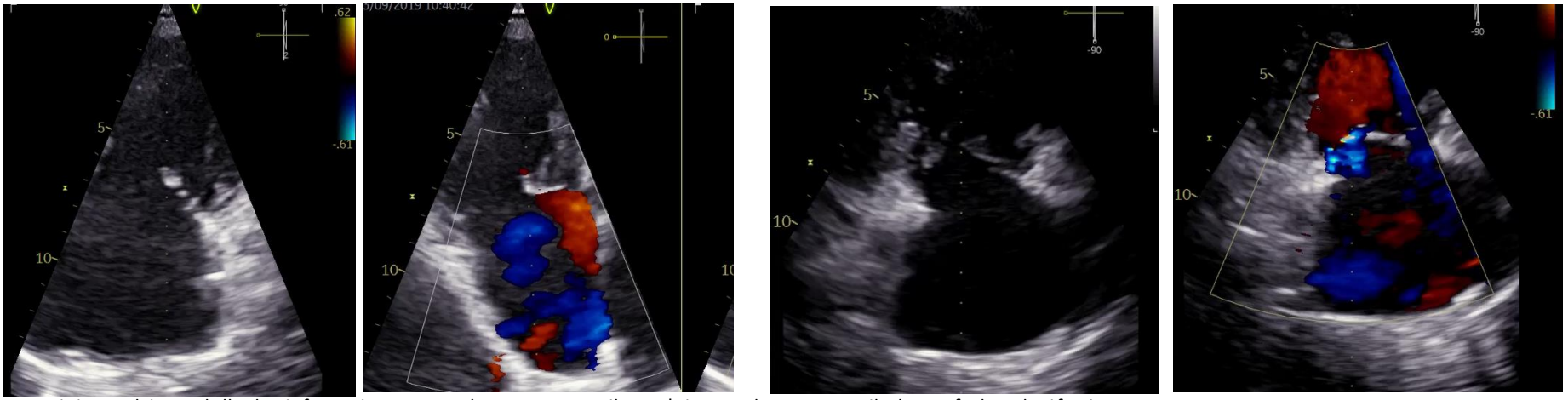
atrial TR – predominant annular dilation

discharge echo

#1



#2



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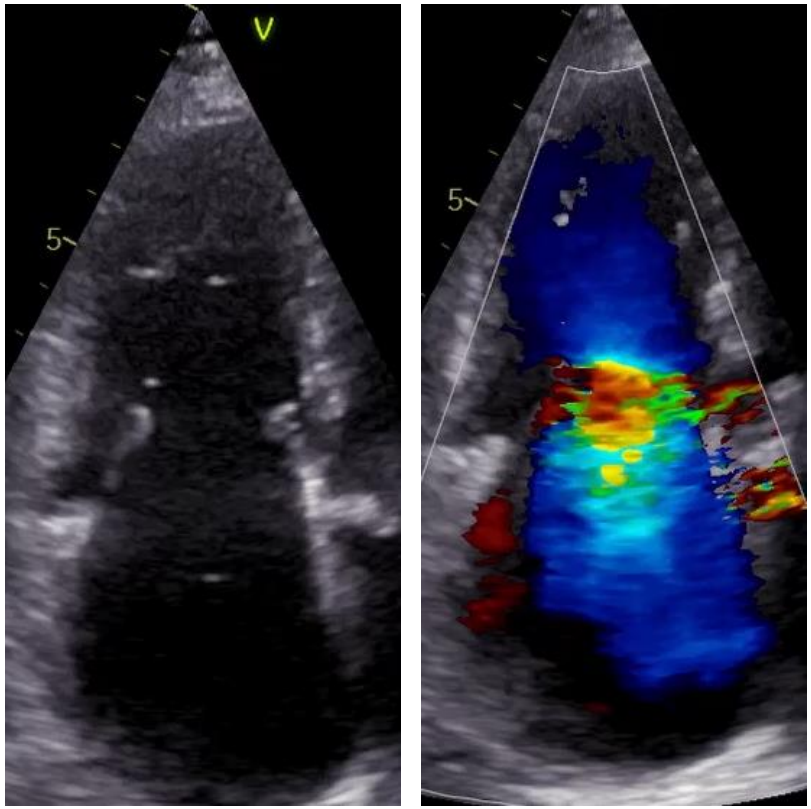
Patient case #2: sequential strategy
Baseline

atrial TR – extensive annular dilation, 15 mm coaptation gap, leaflet tethering

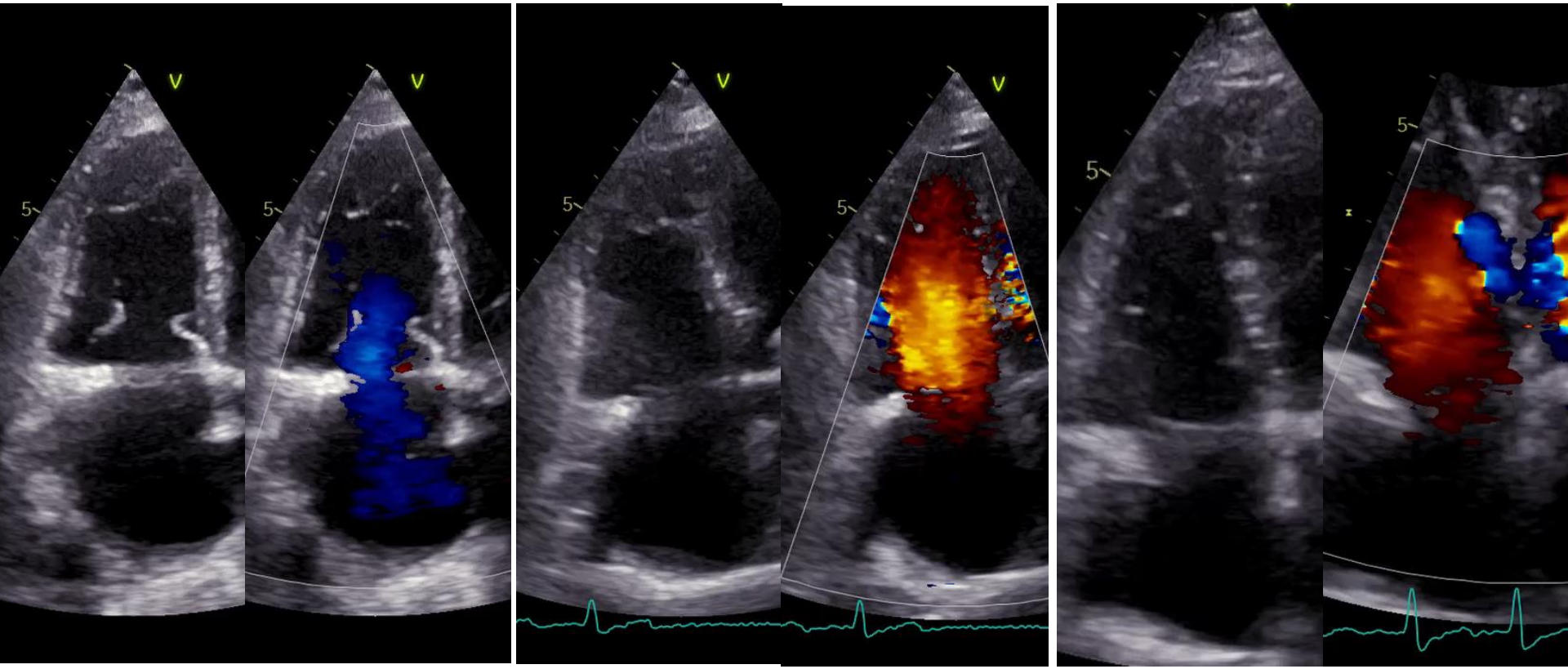


Patient case #2

Sequential strategy

...or just watch and wait

Discharge | **1 month** | **1 year**



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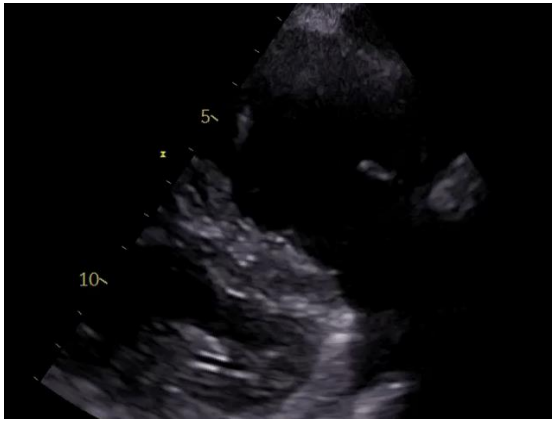
Patient screening - Echo

Atrial TR

Ventricular TR

Restricted septal leaflet



Freely moving lead

Lead impingement

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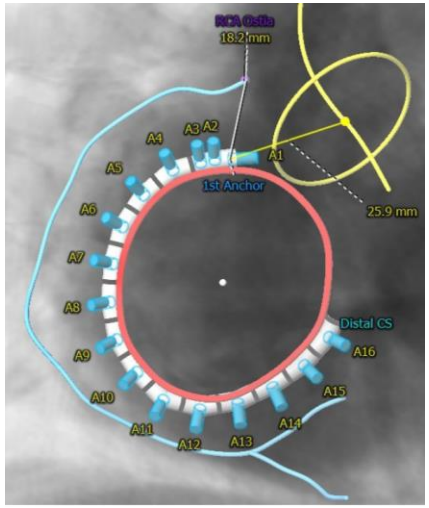
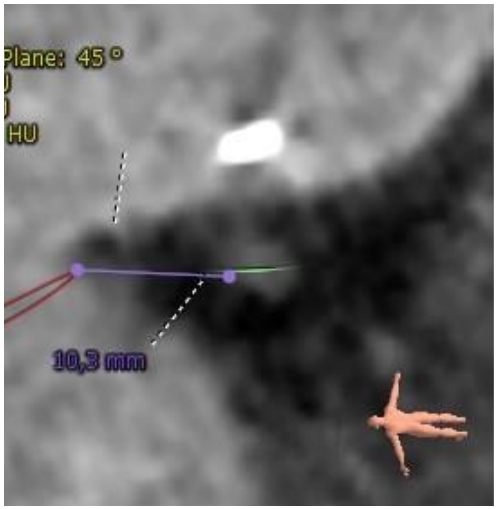
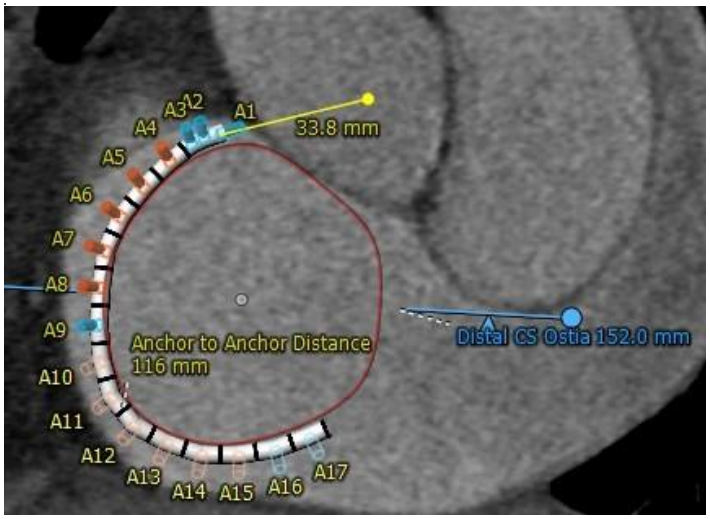
Patient screening - CT

Optimal annular size – optimal landing zone

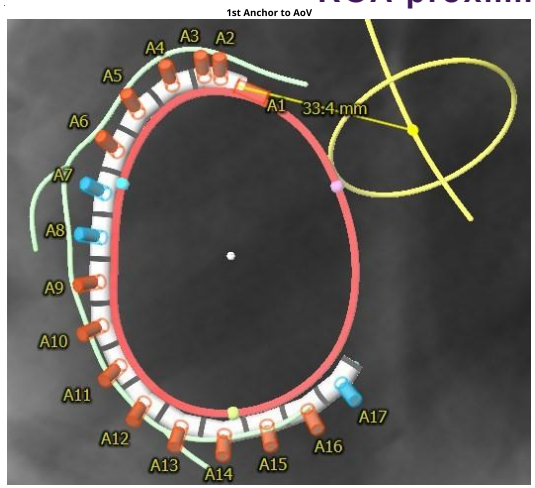


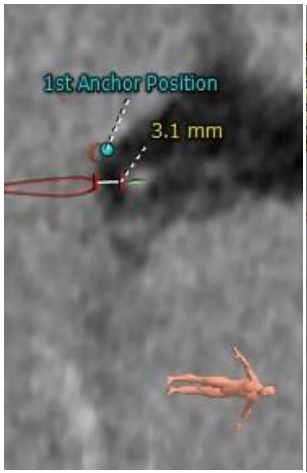


Annular size too large



RCA proximity – no landing zone





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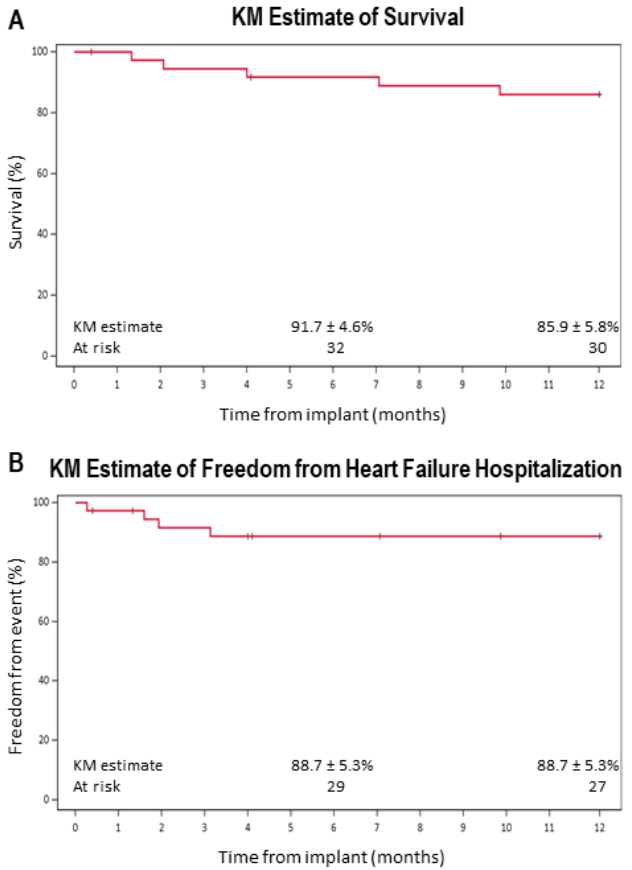
CEC-adjudicated major adverse events

Major adverse events	30 days (N=37) % (n)	1 year (N=37) % (n)
Cardiovascular mortality	0	8.1% (3)
Myocardial infarction	0	0
Stroke	0	5.4% (2)
Right coronary artery perforation	0	0
Arrhythmia and conduction disorders requiring permanent pacing	0	0
New need for renal replacement therapy	0	0
Reintervention on previously implanted study device	0	5.4% (2)
Severe bleeding*	21.6% (8)	35.1% (13)
Life-threatening	2¶	1§
Fatal	0	3‡
Major access site and vascular complications requiring intervention	8.1% (3)	8.1% (3)
Tamponade	2.7% (1)	2.7% (1)
Other events		
All-cause mortality	0	13.5% (5)
Heart failure rehospitalization	2.7% (1)	10.8% (4)



* Severe bleeding defined as major, extensive, life threatening, or fatal per Mitral Valve Academic Research Consortium

¶ Pericardial effusion/tamponade (related to device and procedure), subdural haematoma (possibly related to procedure)

§ Haemothorax (related to device at reintervention)

‡ Erosive oesophagitis (unrelated), GI haemorrhage (unrelated), cerebrovascular accident (unrelated)

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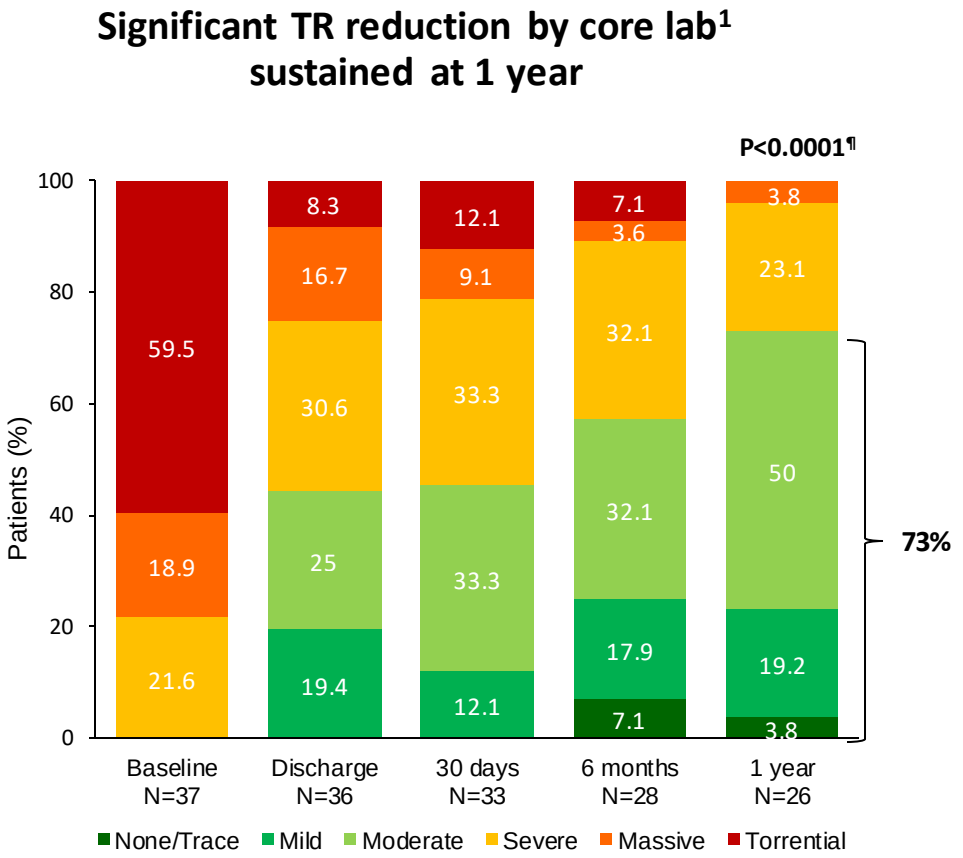
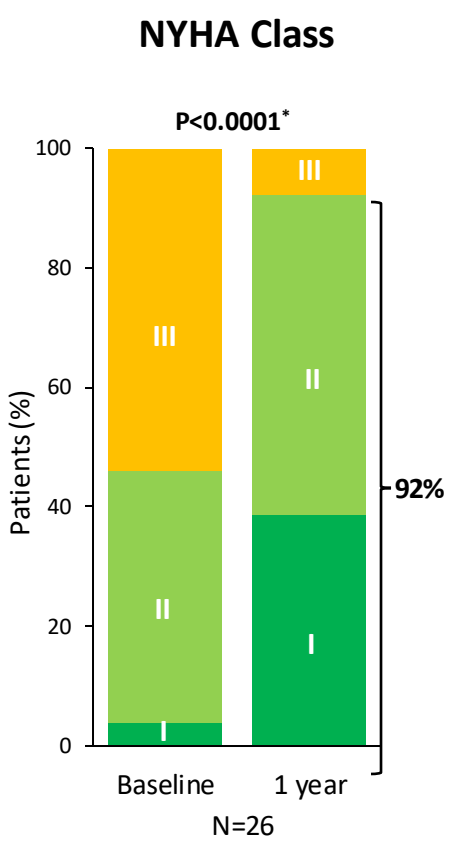
TR reduction and functional status





At one year, 100% improved by at least one TR grade and 73% by at least two grades 73% achieved moderate or lower TR

At one year, 92% of patients were in NYHA class I or II

[1]Cardiovascular Research Foundation ¶Wilcoxon signed-rank test for tricuspid regurgitation (TR) grade at baseline and discharge and baseline and 1 year. N=26, Baseline tricuspid regurgitation (TR) grades by transthoracic echocardiography (TTE; n=26), 30.8% severe, 11.5% massive, 57.7% torrential. One year TR grades: 3.8% none/trace, 19.2% mild, 50.0% moderate, 23.1% severe, 3.8% massive. *Wilcoxon signed-rank test; *NYHA*, New York Heart Association.

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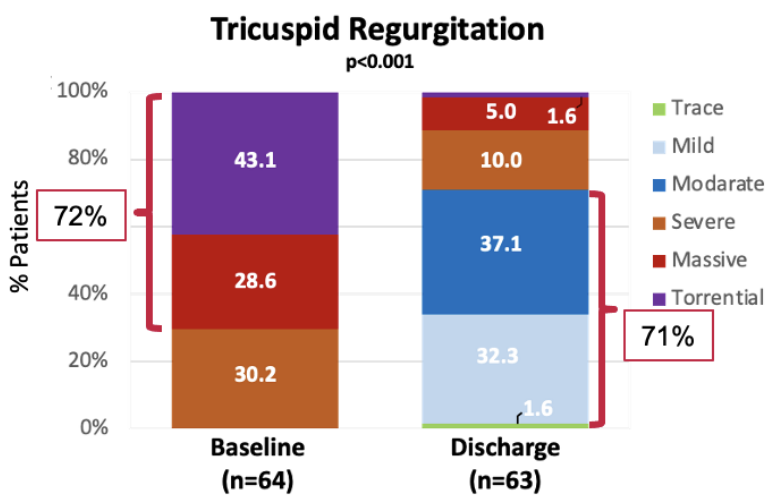
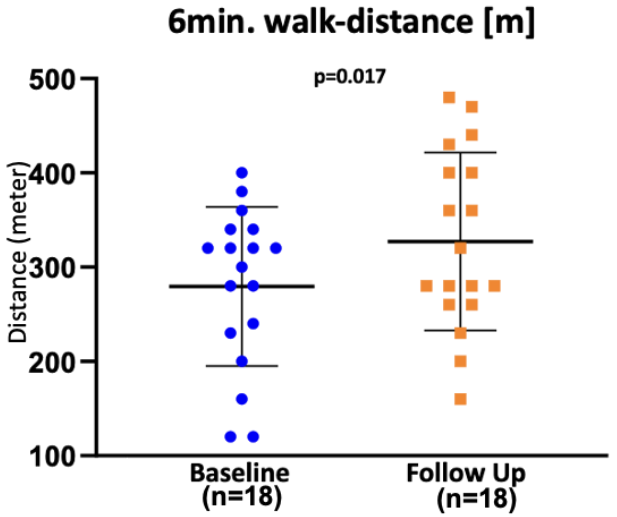
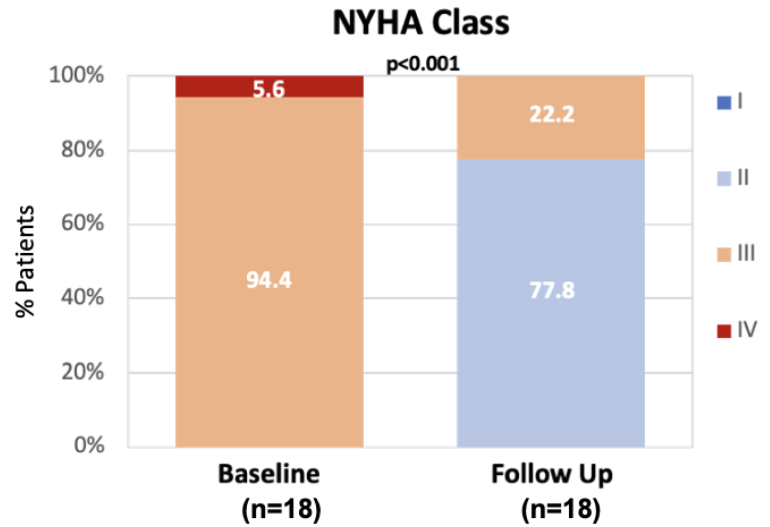
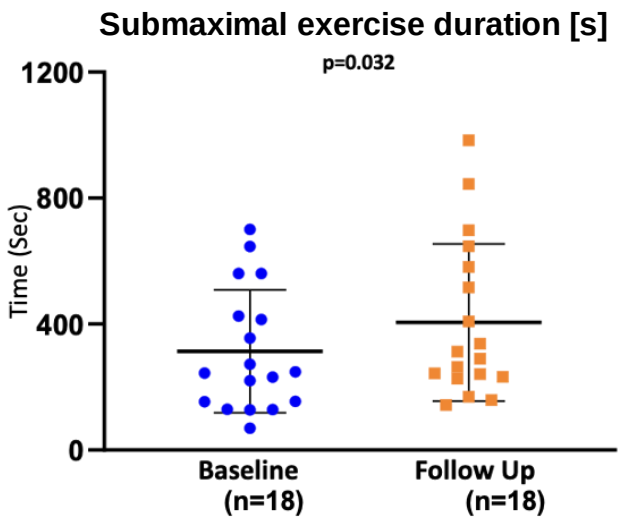
Bad Oeynhausen Experience









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Conclusion

- Cardioband TR EFS showed favourable outcomes at one-year:
  - Significant and sustained decrease in TR with 100% improving by at least one grade and 73% by at least two grades
    - 73% of patients had ≤ moderate TR at one year
  - Significant TV annular reduction of 21%
  - 92% of patients in NYHA class ≤ II and 19-point improvement in overall KCCQ score
  - One-year 13.5% all-cause mortality and 10.8% HF rehospitalization in an elderly patient population with high comorbidities
    - No 30-day mortality
- "One size fits all" does not work for TR treatment
- Preferred choice in extensive annular dilatation/ large gap size
- Annuloplasty addresses the primary pathology in secondary TR and leaves further interventional options

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Thank You

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Thank You

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