

EuroValve

October 28- 29, 2021

HOTEL LIÈGE CONGRÈS, BELGIUM

COURSE DIRECTORS

Patrizio Lancellotti, Liege, Belgium
Khalil Fattouch, Palermo, Italy
Gilbert Habib, Marseille, France
José Luis Zamorano, Madrid, Spain
Philippe Pibarot, Québec, Canada
Mani Vannan, Atlanta, USA
Jeroen Bax, Leiden, The Netherlands

www.eurovalvecongress.com

Edwards EVOQUE Tricuspid Valve Replacement System*

EVOQUE Compassionate Use¹

TRISCEND Study 30-Day Outcomes²

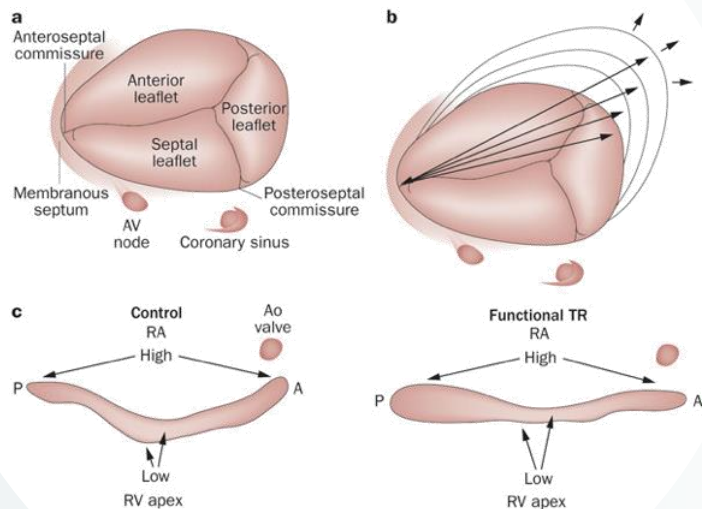
Felix Kreidel, MD,

Investigator of the EVOQUE Compassionate Use and the TRISCEND II Study

* CAUTION: Exclusively for clinical investigations. To be used by qualified investigators only. Not available for commercial use until validly CE marked or approved by in-country regulatory authority.

1. Chuang et al., Transfemoral Transcatheter Tricuspid Valve Replacement with the EVOQUE System for Severe Tricuspid Regurgitation: A Multicenter, First-in-Human 1-Year Observation, presented at TVT, July 2021
2. Kodali et al., Transfemoral Transcatheter Tricuspid Valve Replacement with the EVOQUE System for Severe Tricuspid Regurgitation: The TRISCEND Study 30-Day Outcomes 1-Year presented at euroPCR, May 2021

Current Challenges for Tricuspid Technologies

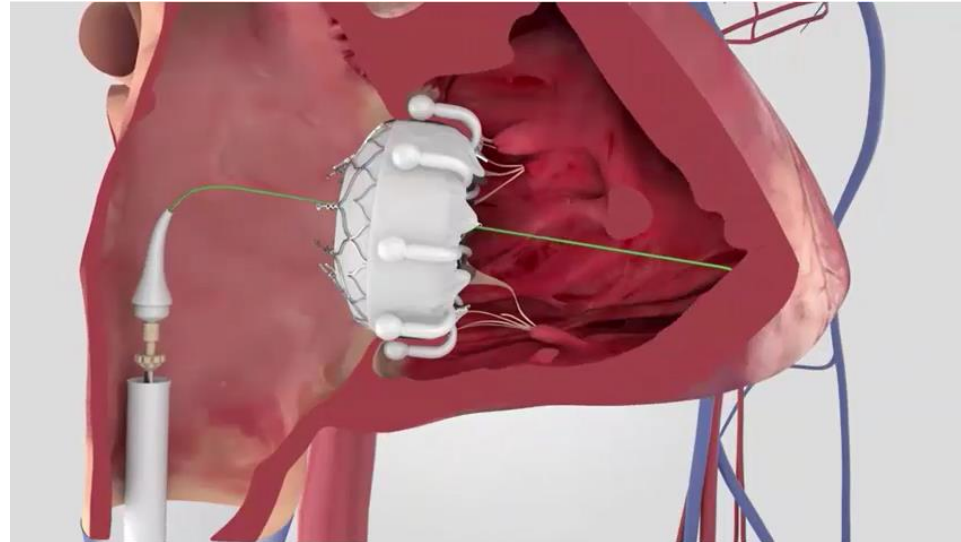
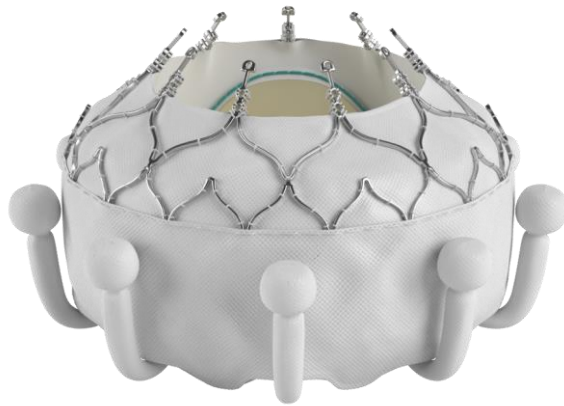


- Position/size of the **regurgitant jet**
- **Number of leaflets**
- Presence of **pacemaker leads**
- Variable shape and size of **tricuspid annulus**
- **Variable and complex leaflet anatomy**
- Difficulty capturing **tethered leaflets**
- Proximity of **RCA**
- Proximity to **AV node**

EVOQUE Tricuspid Valve Replacement System

Transfemoral replacement may address current tricuspid challenges

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



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

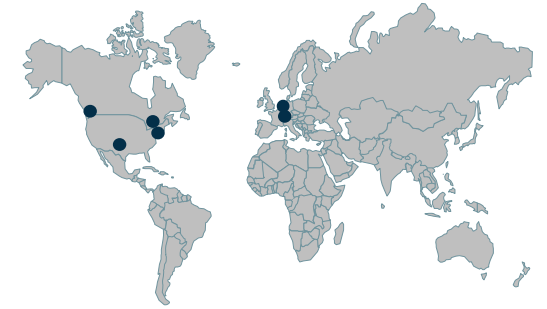
Conforming frame designed to achieve optimal retention force

Multiple sizes offer treatment for a broad range of tricuspid pathologies and anatomies (52, 48, 44 mm)

28F transfemoral delivery system compatible with all valve sizes

EVOQUE System Compassionate Use Experience: One- Year Outcomes

- Early compassionate use; Mar 2019 – July 2020
- 7 institutions
- 27 consecutive patients with symptomatic, severe+ TR, high surgical risk

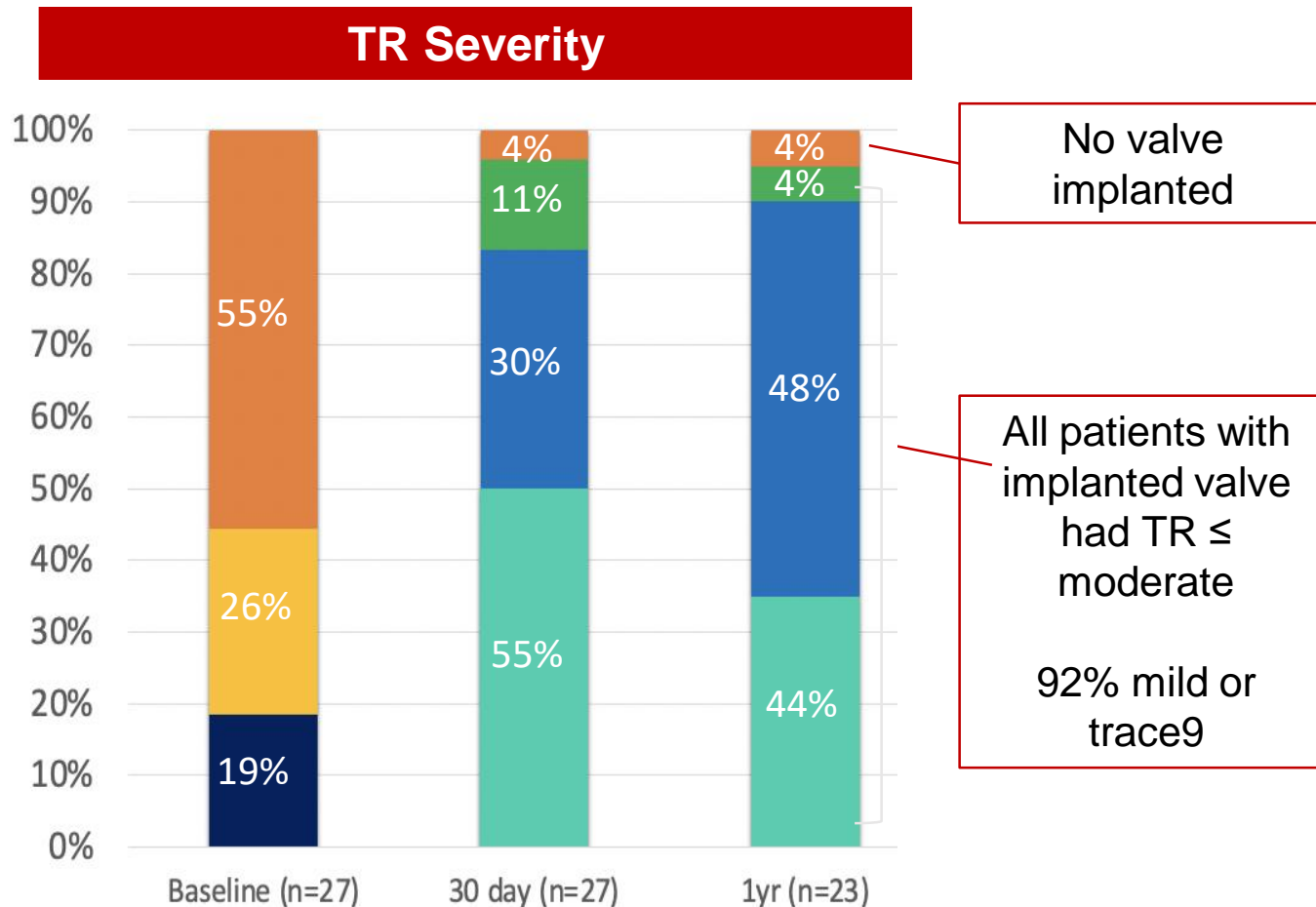


30 day Outcomes	N (%) or Mean \pm SD
Procedural success ¹	25 (93%)
Procedural time, skin to skin (mins, mean/min/max)	68 (37, 101)
Mortality	0 (0%)
Stroke	0 (0%)
Reintervention	0 (0%)
HF hospitalization	0 (0%)
Dialysis requirement	1 (4%)
Anticoagulation	25 (93%)
New PPM	2 (8%)

30 day to 1-year Outcomes	N (%) or Mean \pm SD
Mortality	2 (7%)
Valve-related mortality	0 (0%)
Stroke	0 (0%)
Re-intervention	0 (0%)
HF Hospitalization	2 (7%)
Dialysis requirement	0 (0%)
New PPM	1 (4%)
HALT	3 (12%)

¹Defined as ability to deliver and deploy the valve to the intended location with the absence of major device or procedural related serious adverse events

EVOQUE System Compassionate Use Experience: One- Year Outcomes



- The EVOQUE tricuspid valve replacement system had durable efficacy, low rates of mortality and acceptable morbidity in high surgical risk patients at one year
- All treated patients achieved TR reduction to ≤ moderate
- Patients also showed persistent significant improvement in NYHA functional class at one year, with 68% in NYHA ≤ 2
- Further studies underway: TRISCEND (NCT04221490) and TRISCEND II (NCT04482062)

EuroValve

October 28- 29 2021
HOTEL LIÈGE CONGRÈS, BELGIUM



Edwards Transcatheter Tricuspid Valve Replacement: Intervention of Safety and Clinical Efficacy Using a Novel Device

Prospective, multicenter, single arm study

Purpose:

Evaluate the safety and performance of the Edwards Transcatheter Tricuspid Valve Replacement System

Principal Investigator:
Susheel K. Kodali, MD

Patients with Symptomatic \geq Moderate Tricuspid Regurgitation

Heart Team Assessment

- Functional or degenerative TR \geq moderate
- Signs and/or symptoms or prior heart failure hospitalizations from TR despite optimal medical therapy

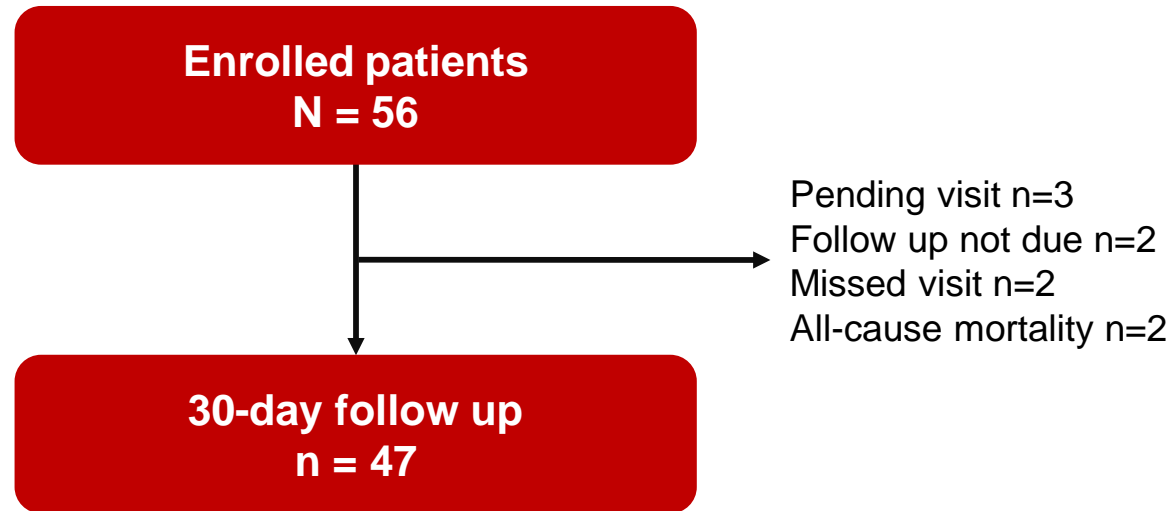
EVOQUE Valve Replacement System

Follow-up: 30 days, 6 months, 1 year and annually through 5 years

Primary Endpoints:
Freedom from device or procedure-related adverse events at 30 days

NCT04221490

Enrollment and Follow Up



Baseline Characteristics

	N = 56 % or Mean \pm SD
Age, years	79 \pm 8
Female	77%
Mean STS mortality risk score (MV Repair) (%)	7.7 \pm 5.2
NYHA functional class III or IV	84%
Tricuspid regurgitation grade \geq severe¹	92%
Atrial fibrillation	91%
Diabetes	21%
Chronic kidney disease	66%
COPD	18%
Systemic hypertension	88%
Pulmonary hypertension (sPAP \geq 30 mmHg)	79%
CABG surgery	14%
PCI intervention / stent	14%
Prior valve surgery/intervention	43%
Pacemaker or ICD	34%

¹Core lab: Baylor, Scott and White Research Institute. NYHA - New York Heart Association; sPAP - systolic pulmonary artery pressure; STS - Society for Thoracic Surgeons.

Procedural Characteristics

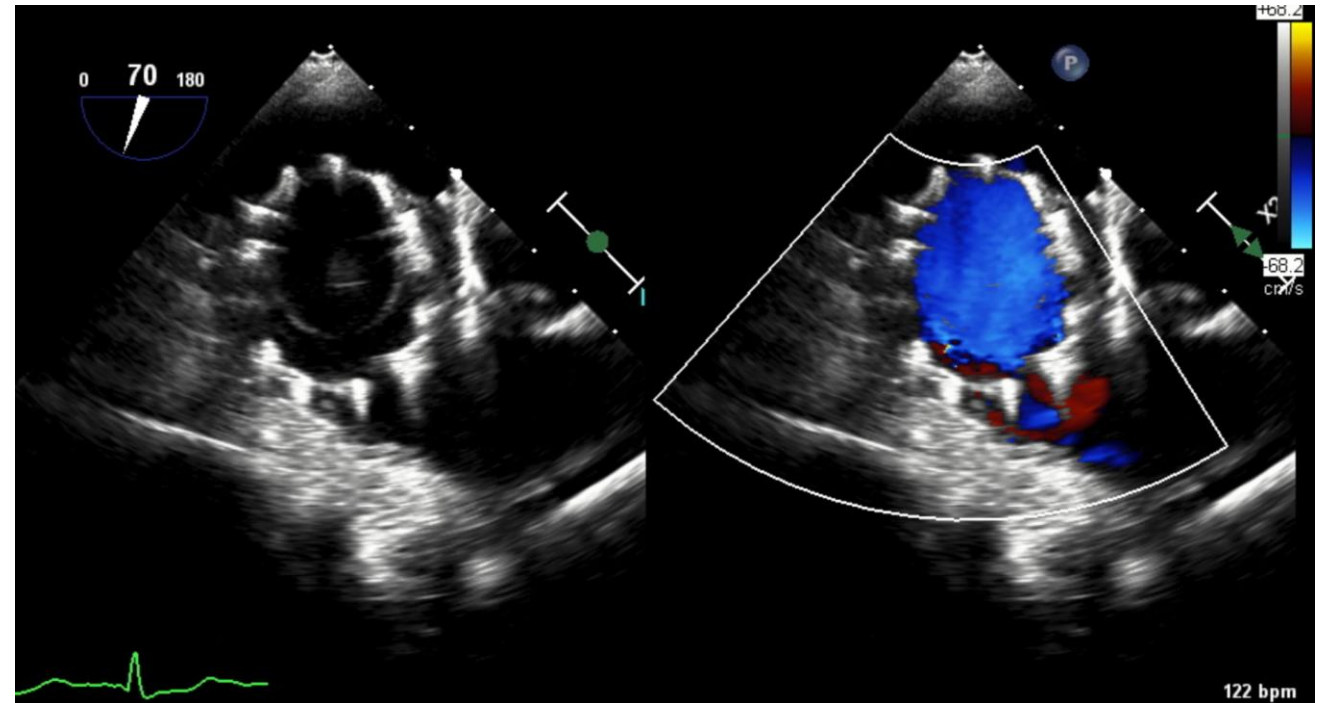
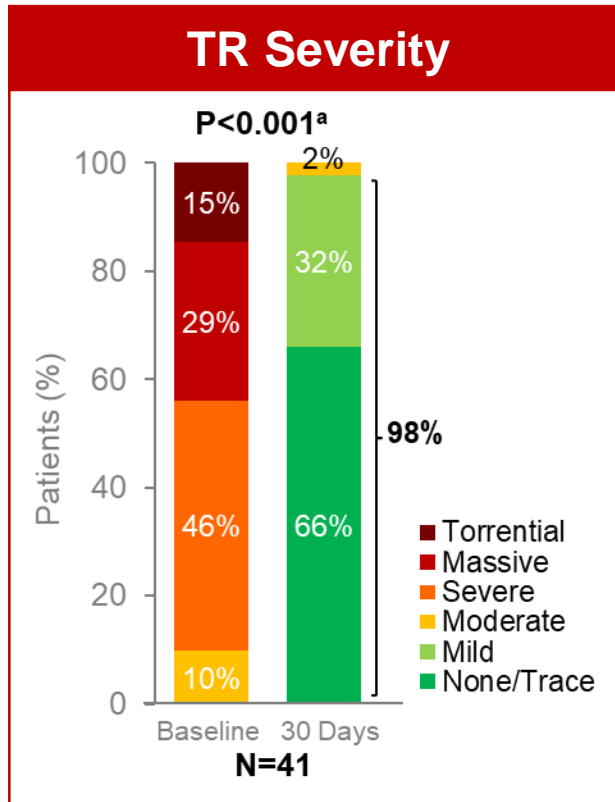
	% (n/N) or Mean \pm SD (N)
Right femoral vein access	100% (56/56)
Device success ¹	98% (55/56)
Procedural success ²	94% (50/53) ^a
Device time (implant insertion to release), mins	70 \pm 31 (56)

High device and procedural success rates

¹Device is deployed and delivery system is retrieved as intended at the time of the patient's exit from the cardiac catheterization laboratory.

²Device success without clinically significant paravalvular leak at the time of discharge. ^aParavalvular leak data not available for 3 patients.

Significant Reduction in TR Severity by Core Lab¹ at 30 Days



No residual TR post implant with EVOQUE valve

98% achieved reduction in TR severity to none/trace or mild at 30 days
100% achieved ≥ 1 grade reduction, and 95% achieved ≥ 2 grade reduction at 30 days

¹Core lab: Baylor, Scott and White Research Institute; ^aWilcoxon signed-rank test; TR - tricuspid regurgitation.

Major Adverse Events (MAEs) at 30 Days

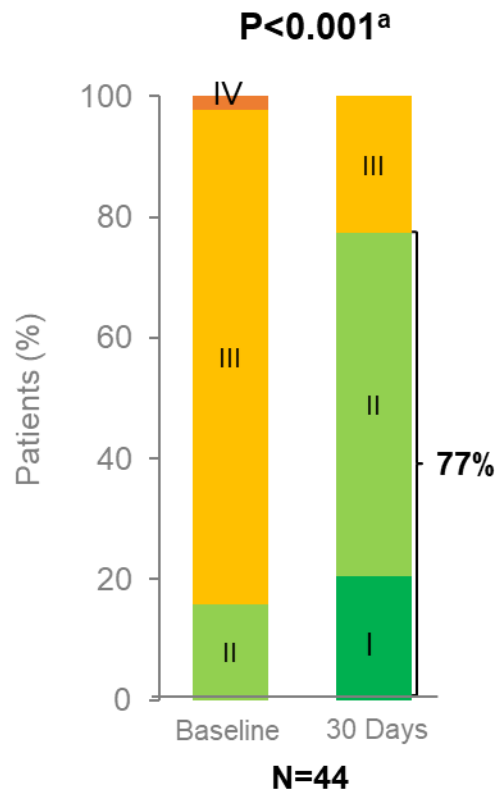
CEC Adjudicated Events	N=53 ^a % (n)
Cardiovascular mortality	1.9% (1)
Myocardial infarction	0.0% (0)
Stroke	0.0% (0)
Renal complications requiring unplanned dialysis or renal replacement therapy	0.0% (0)
Severe bleeding ^b	22.6% (12)
Non-elective tricuspid valve re-intervention, percutaneous or surgical	3.8% (2)
Major access site and vascular complications	1.9% (1)
Major cardiac structural complications	0.0% (0)
Device-related pulmonary embolism	0.0% (0)
Composite MAE Rate	22.6% (12)
Other events	
All-cause mortality	3.8% (2) ^c

41/53 of patients (77.4%) had no MAEs at 30 days

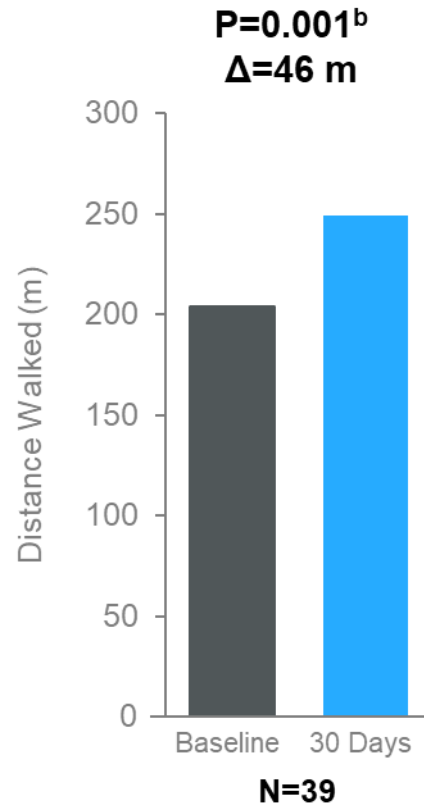
^bNone of the severe bleeding events were life-threatening or fatal

Significantly Improved Clinical, Functional, and Quality of Life Outcomes at 30 Days

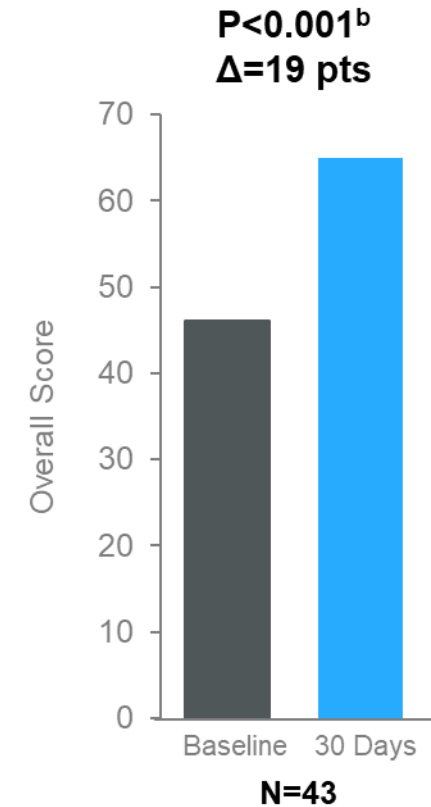
NYHA Class



6MWD



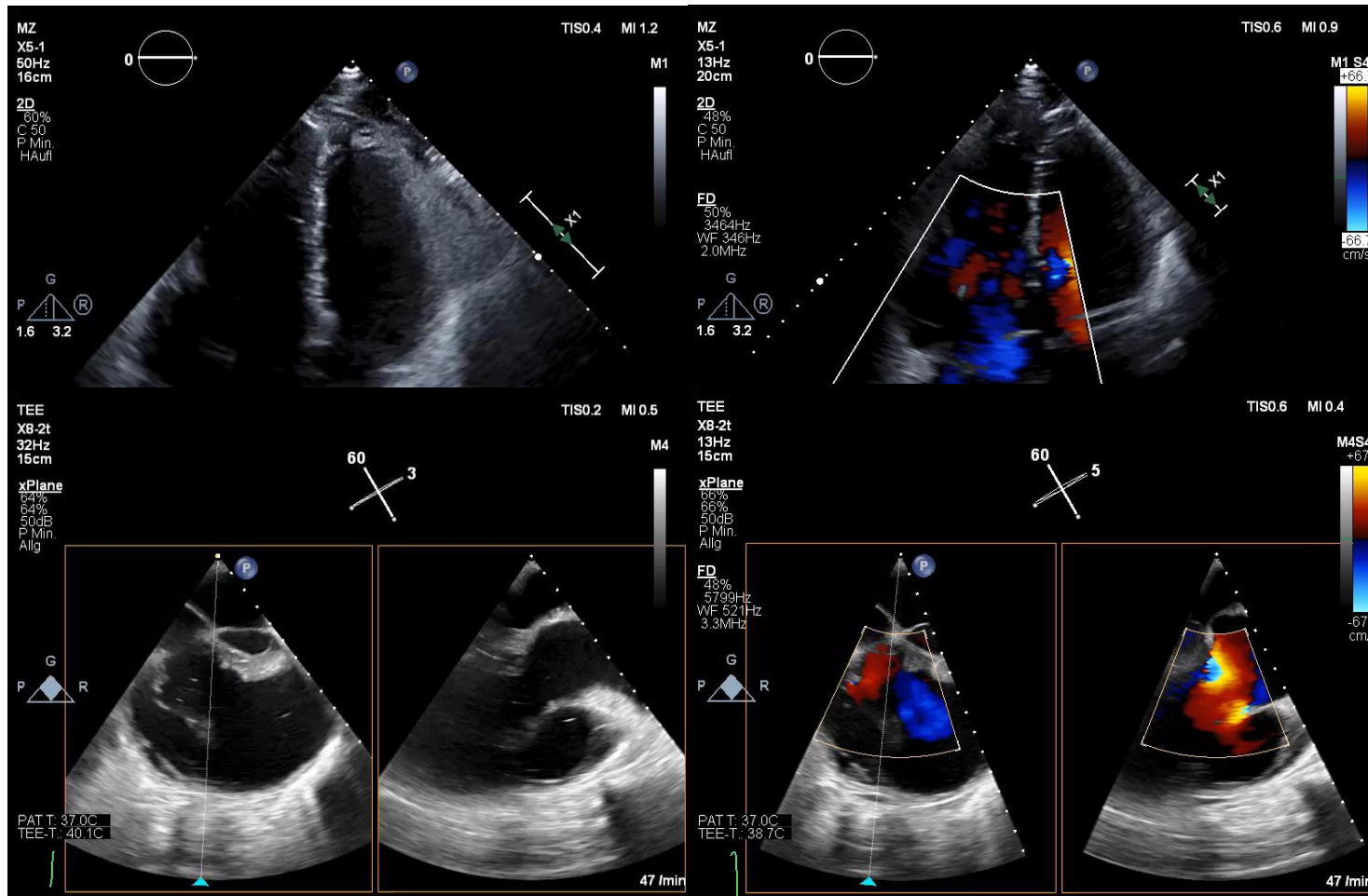
KCCQ Score



EuroValve October 28- 29 2021

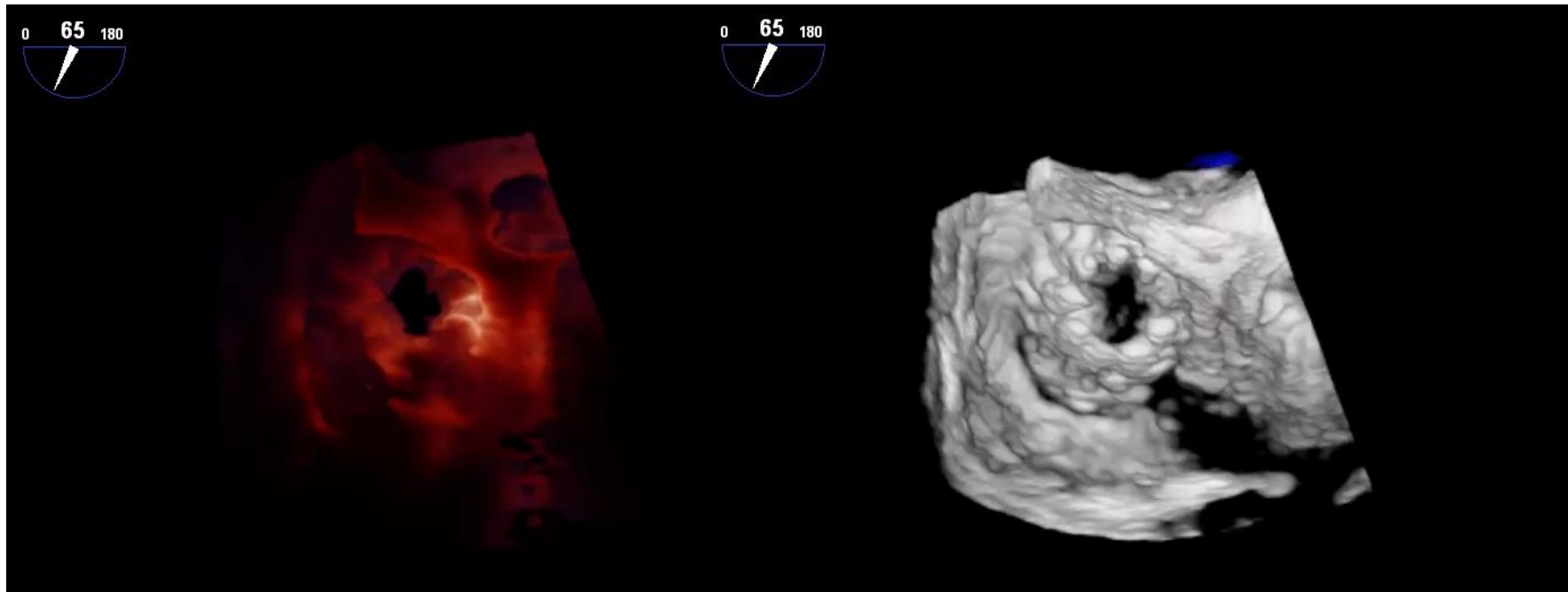
HOTEL LIÈGE CONGRÈS, BELGIUM

Compassionate use case of TTVR with EVOQUE 48 mm



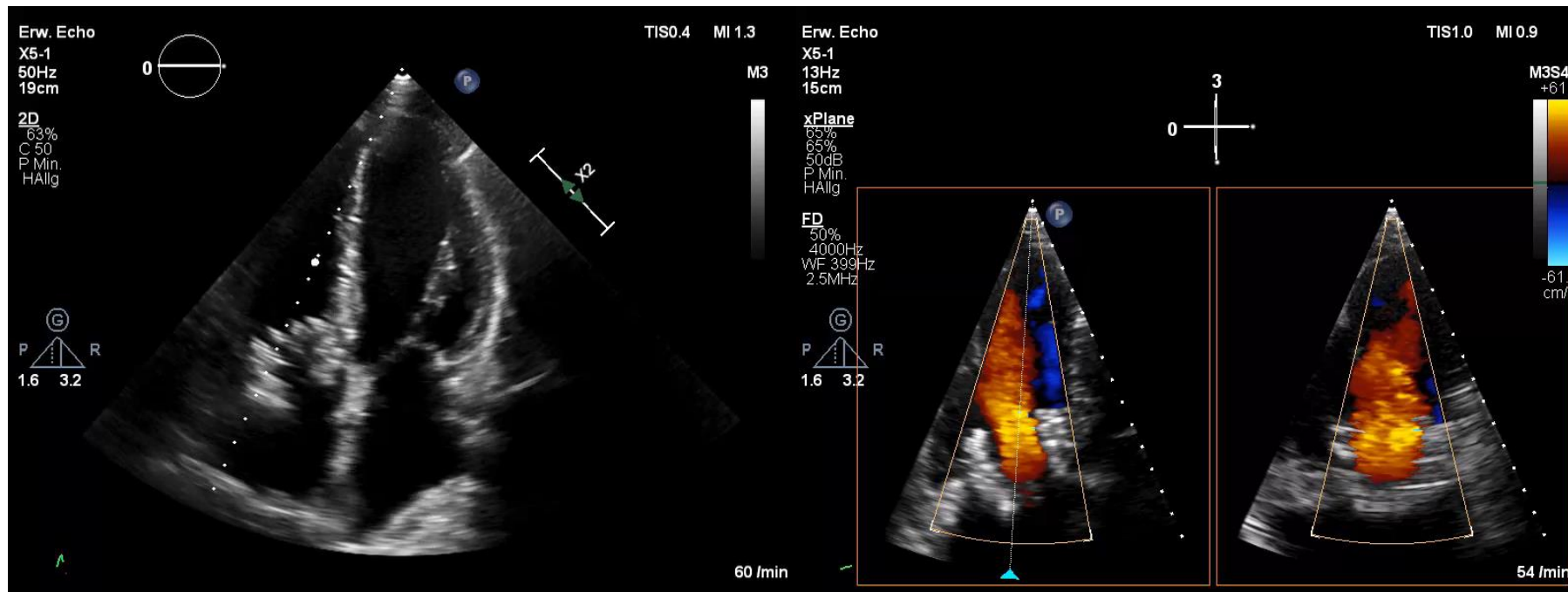
- 74yo female patient with carcinoid disease and Hedingen's syndrome
- Surgery denied due to comorbidities

Compassionate use case of TTVR with EVOQUE 48 mm



- 3D echo post implantation

TEER with PASCAL Ace - 2nd device in anteroseptal commissure

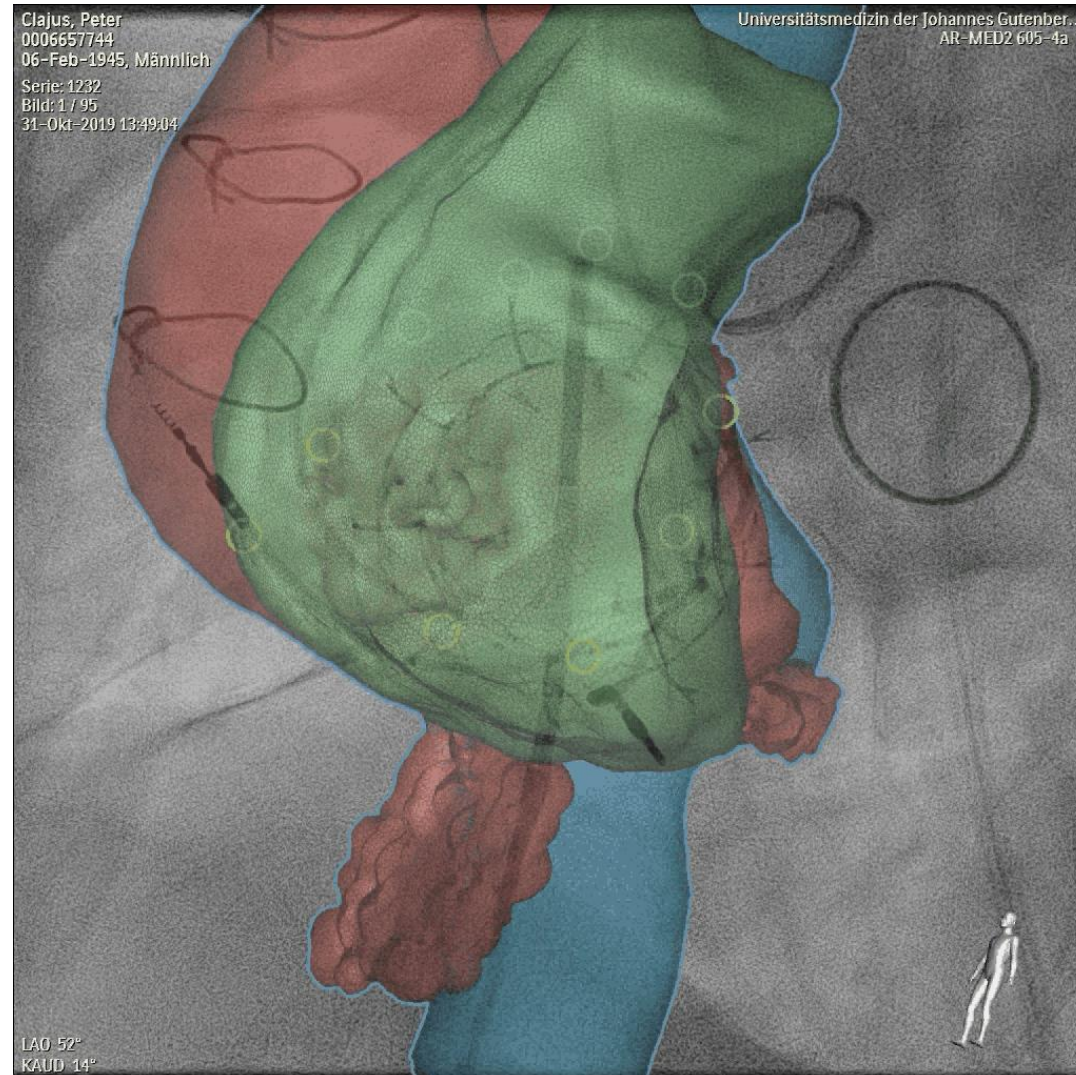


- TTE at discharge already showing reverse remodeling of the RV and RA

EuroValve

October 28- 29 2021
HOTEL LIÈGE CONGRÈS, BELGIUM

**Fusion imaging
Fluoroscopy/CT
for TTVR with
EVOQUE system**



Conclusion

- Early experience with the EVOQUE has shown
 - high technical success and very efficacious TR reduction
 - a very favorable safety profile
- Open question remain reg patient selection (PH, RV function...)
- TRISCEND II study under way (also in Europe) with 2:1 randomisation TTVR vs OMT only

Thank you

Herzklappenzentrum Mainz

Herz ■ Klappen ■ Bewegen ■ Leben ■

HeartValves@unimedizin-Mainz.de

Herzklappen@unimedizin-Mainz.de



UNIVERSITÄTSmedizin.

MAINZ

