



Predictable implant release: simulation, evidence, and case-based discussion

Amir A. Mahabadi, MD
University Hospital Essen/ Germany
West German Heart and Vascular Center

&

Dabit Arzamendi, MD
Hospital de la Santa Creu I Sant Pau
Barcelona, Spain



Potential conflicts of interest

Speaker's name: Amir A. Mahabadi

- ☐ I do not have any potential conflict of interest to report
- ☒ I have the following potential conflicts of interest to report:
Honoraria for lectures: Amgen, Berlin Chemie, Daiichi Sankyo,
Edwards Lifesciences Services GmbH, Novartis, Sanofi
Honoraria for advisory board activities: Amgen, Novartis, Sanofi
Research funding: Daiichi Sankyo

Expert opinions, advice and all other information expressed represent contributors' views and not necessarily those of Edwards Lifesciences.



Predictable implant release: evidence, and case-based discussion

Amir A. Mahabadi, MD

University Hospital Essen/ Germany

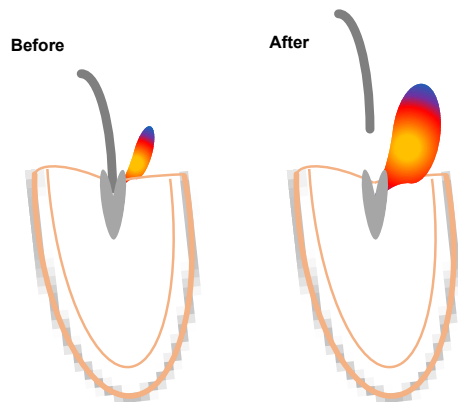
West German Heart and Vascular Center

Department of Cardiology and Vascular Medicine

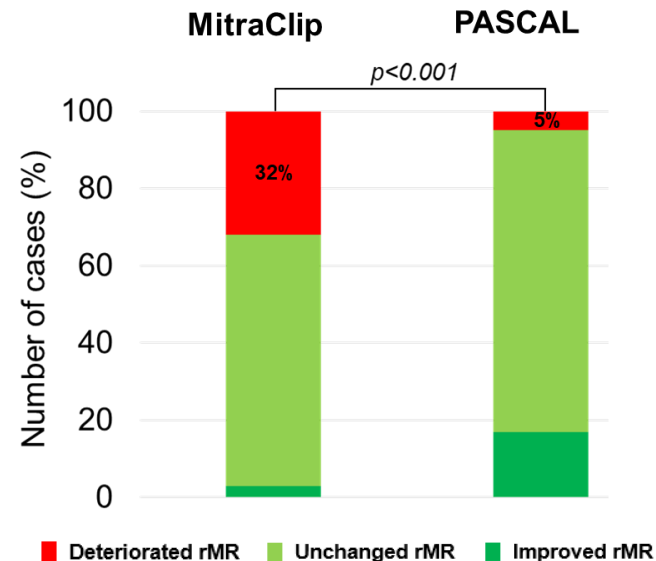


Effective MR Reduction and High Post-delivery Predictability

Retrospective, single-center study, with n=100 MitraClip* and n=100 PASCAL system**



Predictability of post-delivery residual MR (rMR)
Significantly less MR deterioration¹ in patients treated with PASCAL system



¹ MR deterioration: reoccurrence of MR due to new jet, increase of residual MR, and/or return of MR

* Number of MitraClip implanted over time: 2017: n=34; 2018: n=57; 2019: n=5; 2020: n=4; ** Number of PASCAL implants implanted over time: 2017-2018: n=0; 2019: n=40; 2020: n=60.

Luedike P. [...] Mahabadi AA. Impact of Mitral Valve Repair Technologies on Predictability of Post-Delivery Residual Mitral Regurgitation. JACC Cardiovasc Interv. 2021 Dec 13;14(23):2638-2640

PASCAL Precision System Predictability Registry

Hypothesis

- PASCAL Precision system enables predictable reduction of MR prior and post-delivery

Design

- Retrospective multi-center (Essen, Bad Oeynhausen, Tübingen) observational study

Methods

- **Patients treated with PASCAL Precision system: PASCAL (P10) implant and PASCAL Ace implant**
- Evaluation of pre- and post-delivery MR
 - Blinded assessment at central core lab
 - 3D vena contracta area
 - EROA

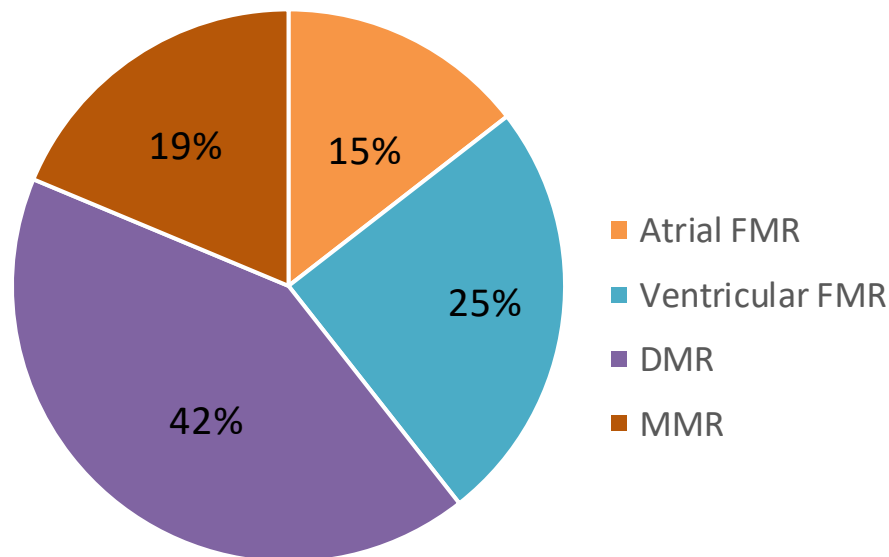
MR: mitral regurgitation; EROA: effective regurgitant orifice area

Helthammer K. [...] Mahabadi AA. Impact of MV anatomy on predictability of post-delivery MR with a new generation TEER-device. E-Poster. EuroPCR 2024

Baseline Characteristics

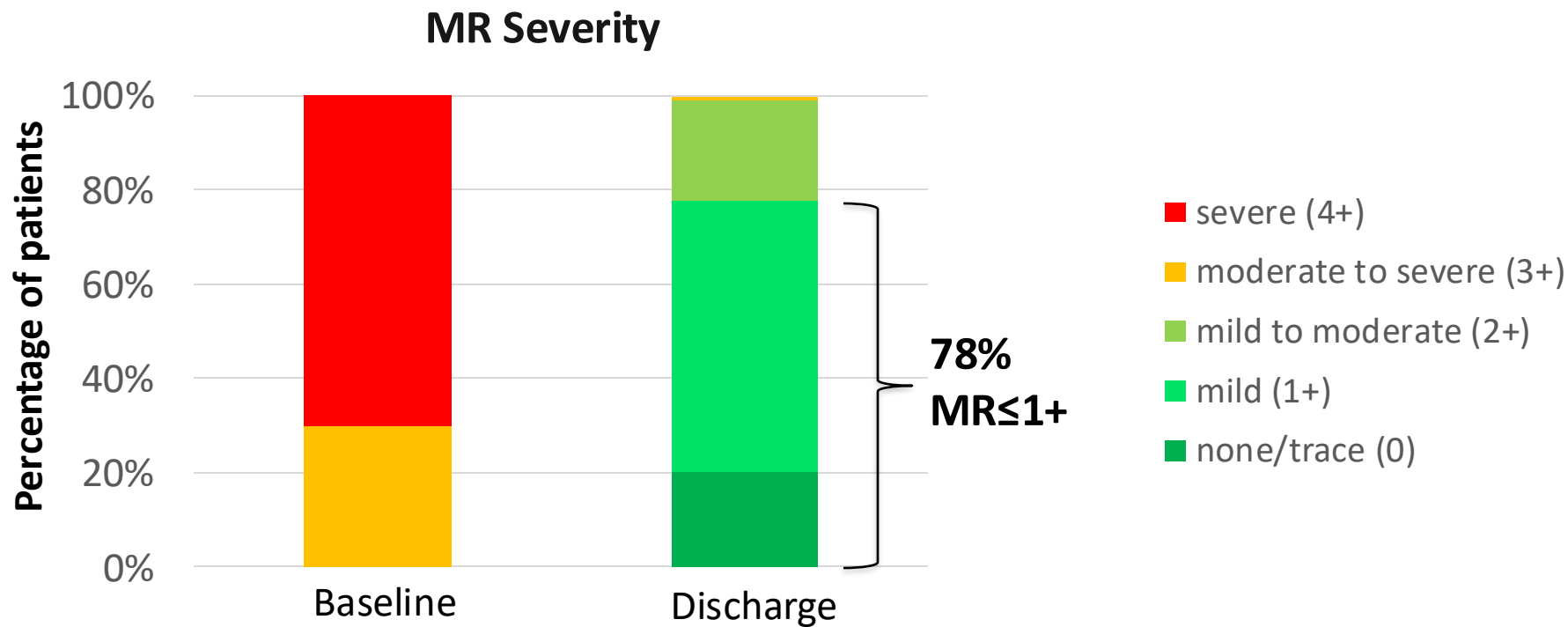
	All patients (n=141)
Male, n (%)	85 (60.3)
Age, years	78 ± 9.9
STS Score (%)	5.5 ± 5.4
CAD, n (%)	68 (48.2)
Atrial fibrillation, n (%)	94 (66.7)
COPD, n (%)	13 (9.2)
Previous valve, n (%)	4 (5.0)
NT-proBNP (pg/ml)	5047 ± 9386
GFR (ml/min)	55 ± 24
Number of implants, n	1.4 ± 0.6
Anatomical complexity*, n (%)	74 (52.5)

Aetiology



* Anatomical complexity denotes the proportion of patients who met at least one criterion for complex or very complex mitral valve anatomy as defined by Hausleiter J. et al. EuroIntervention.2023;18(12):957-976.
 STS: society of thoracic surgeons; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; NT-proBNP: N-terminal pro-B-type natriuretic peptide; GFR: glomerular filtration rate; FMR: functional mitral regurgitation; DMR: degenerative mitral regurgitation; MMR: mixed mitral regurgitation
 Hellhammer K. [...] Mahabadi AA. Impact of MV anatomy on predictability of post-delivery MR with a new generation TEER-device. E-Poster. EuroPCR 2024

Mitral Regurgitation Severity (n=141)



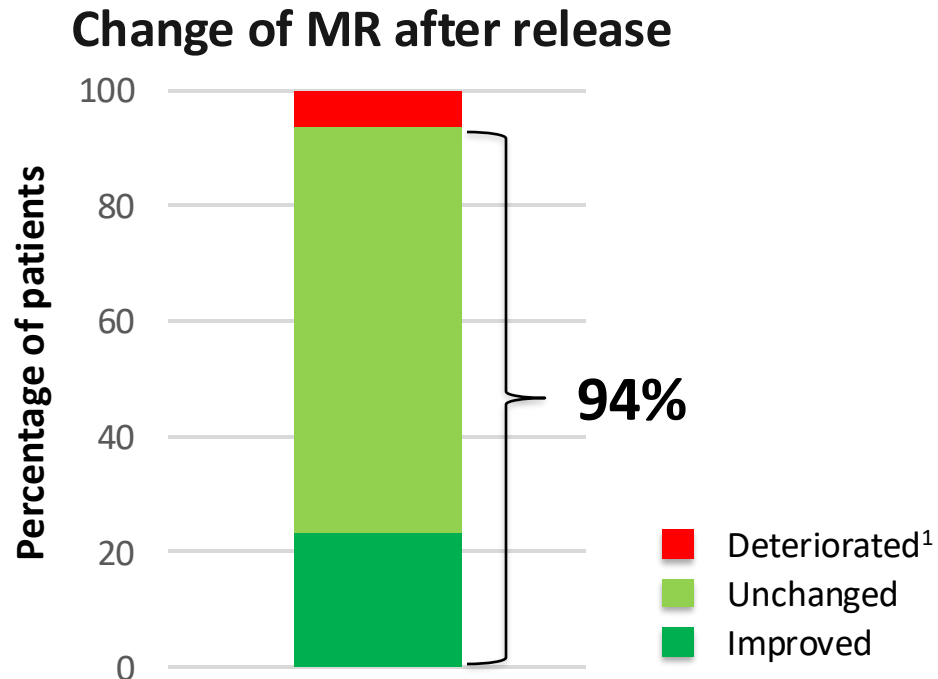
MR: mitral regurgitation

Hellhammer K. [...] Mahabadi AA. Impact of MV anatomy on predictability of post-delivery MR with a new generation TEER-device. E-Poster. EuroPCR 2024

Predictability of Post-delivery Residual MR (N=141)

94% predictability
of post-delivery resMR

23% of patients experienced
improvement in resMR from pre- to
post-delivery

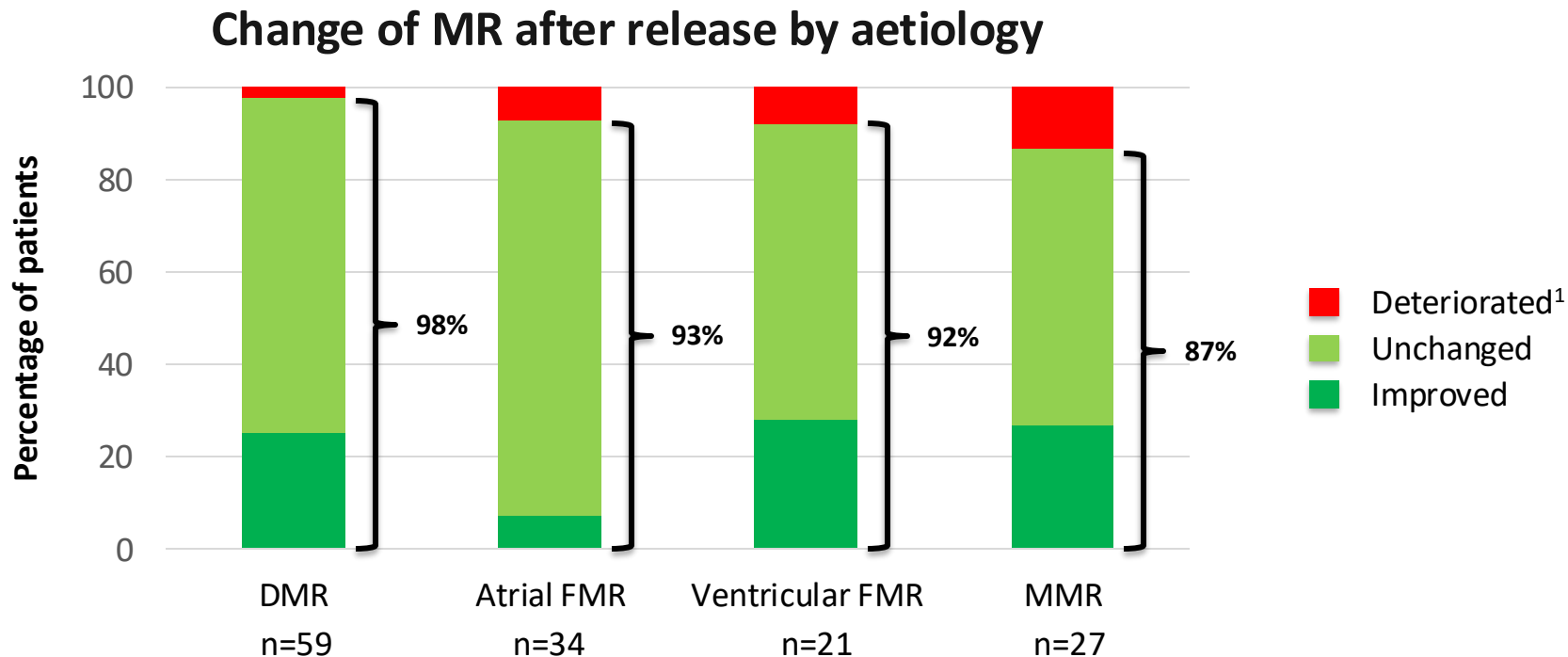


MR: mitral regurgitation; resMR: residual MR

¹Deterioration of initially documented MR reduction: reoccurrence of MR due to new jet, increase of residual MR and/or return of MR

Hellhammer K. [...] Mahabadi AA. Impact of MV anatomy on predictability of post-delivery MR with a new generation TEER-device. E-Poster. EuroPCR 2024

Predictability of Post-delivery Residual MR



MR: mitral regurgitation; FMR: functional mitral regurgitation; DMR: degenerative mitral regurgitation; MMR: mixed mitral regurgitation

¹Deterioration of initially documented MR reduction: reoccurrence of MR due to new jet, increase of residual MR and/or return of MR

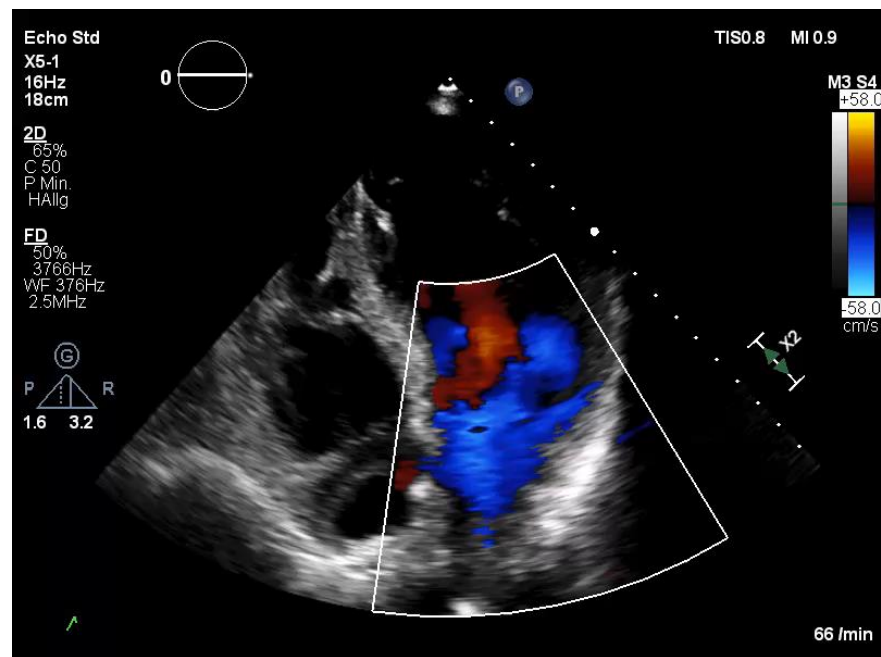
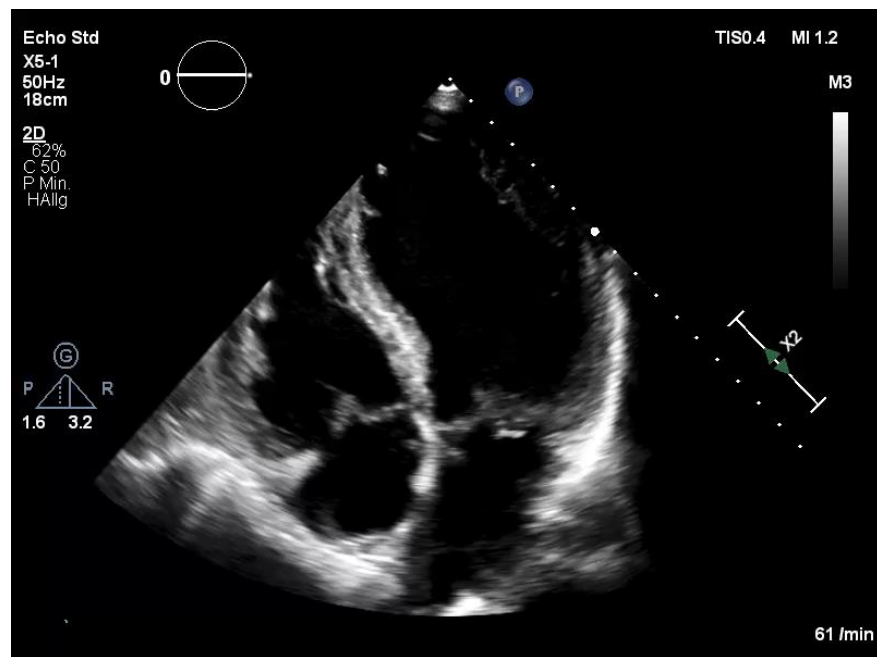
Hellhammer K. [...] Mahabadi AA. Impact of MV anatomy on predictability of post-delivery MR with a new generation TEER-device. E-Poster. EuroPCR 2024

Case Presentation– PASCAL Ace Implant

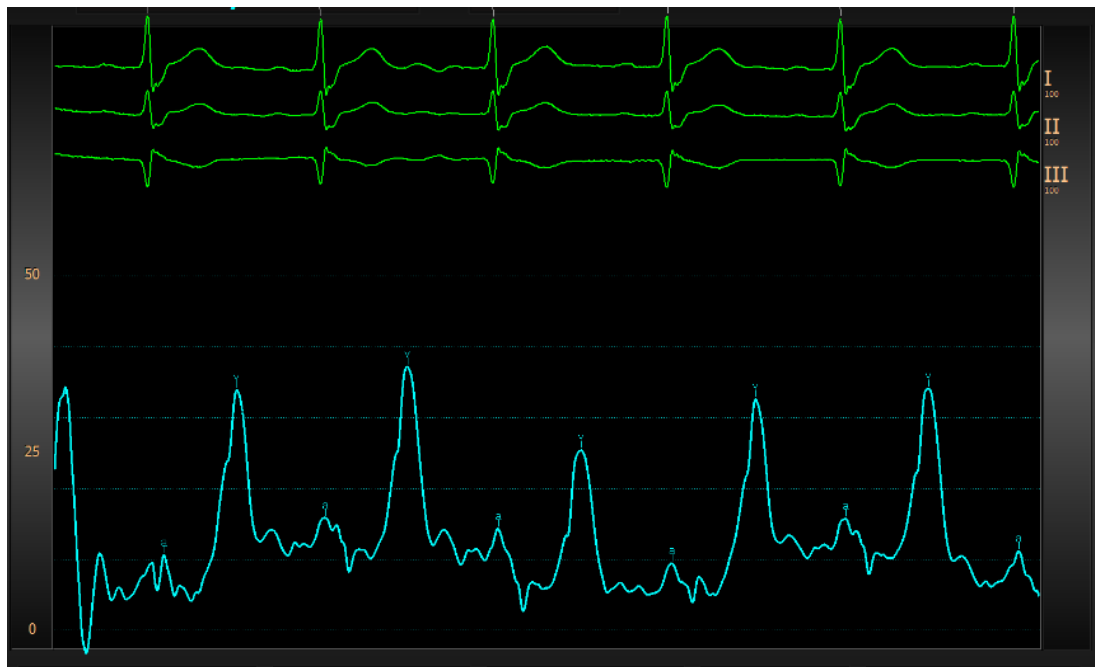
- Male patient, 77 years of age
- Dyspnea NYHA III
- Cardiovascular medical history:
 - Aortic valve stenosis with SAVR 2013
 - Coronary 1-vessel revascularization therapy with LIMA to RIVA 2013
 - Ao. asc. replacement 2013
 - Paroxysmal AF
 - Arterial hypertension
- COPD Gold II, Renal deficiency (stage III)

NYHA: New York Heart Association; SAVR: surgical aortic valve replacement; LIMA: left internal mammary artery; RIVA: ramus interventricularis anterior; AF: atrial fibrillation; COPD: chronic obstructive pulmonary disease

Transthoracic Echocardiography

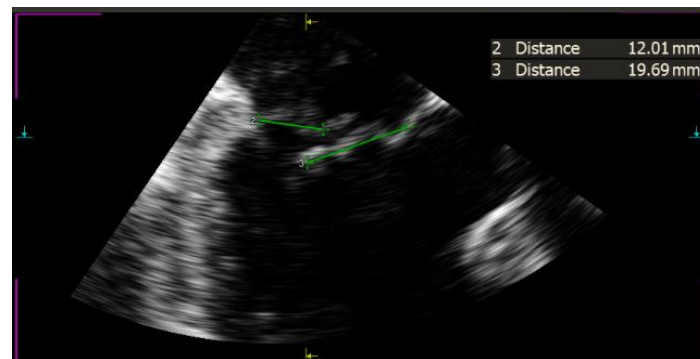
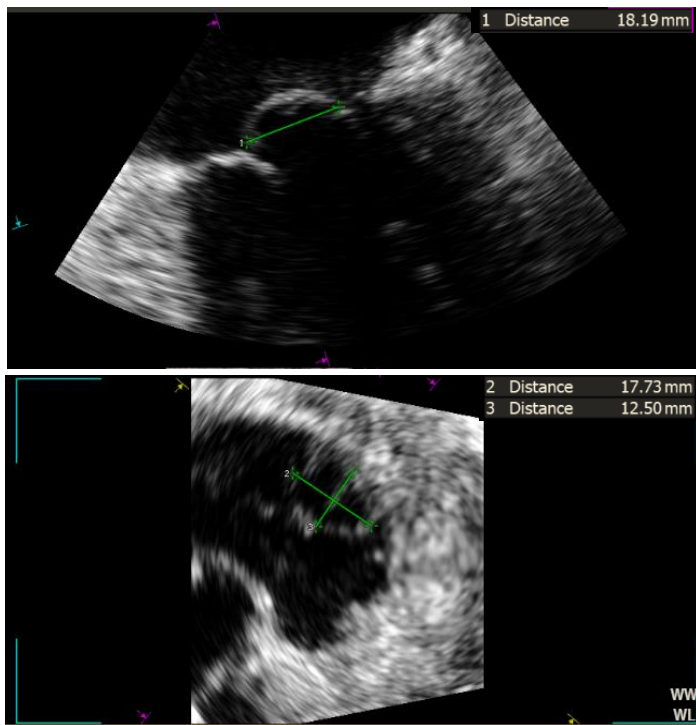


Right Heart Catheterization



PW 12/31 (12)

3D-TEE: Procedural Planning

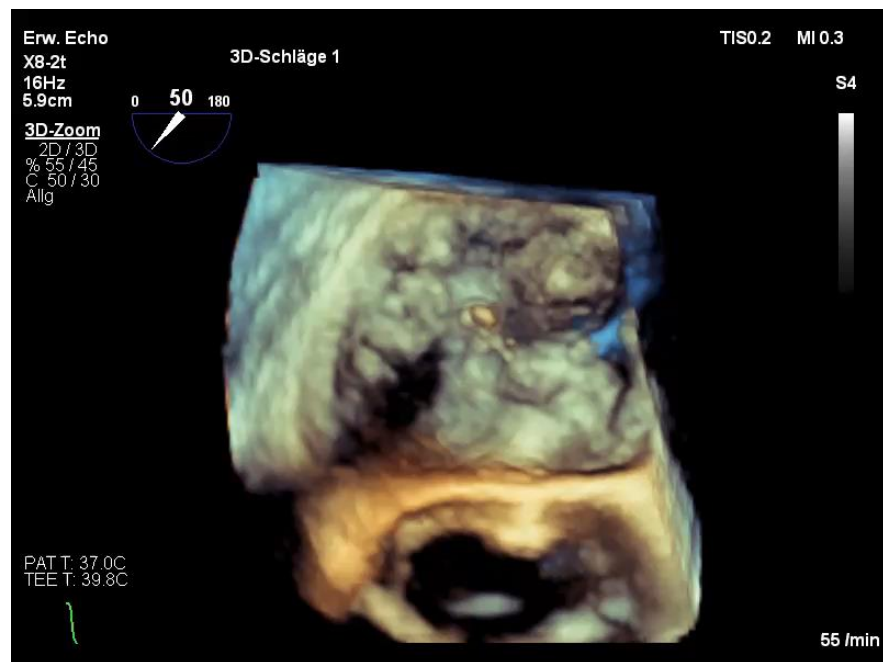


Strategy:

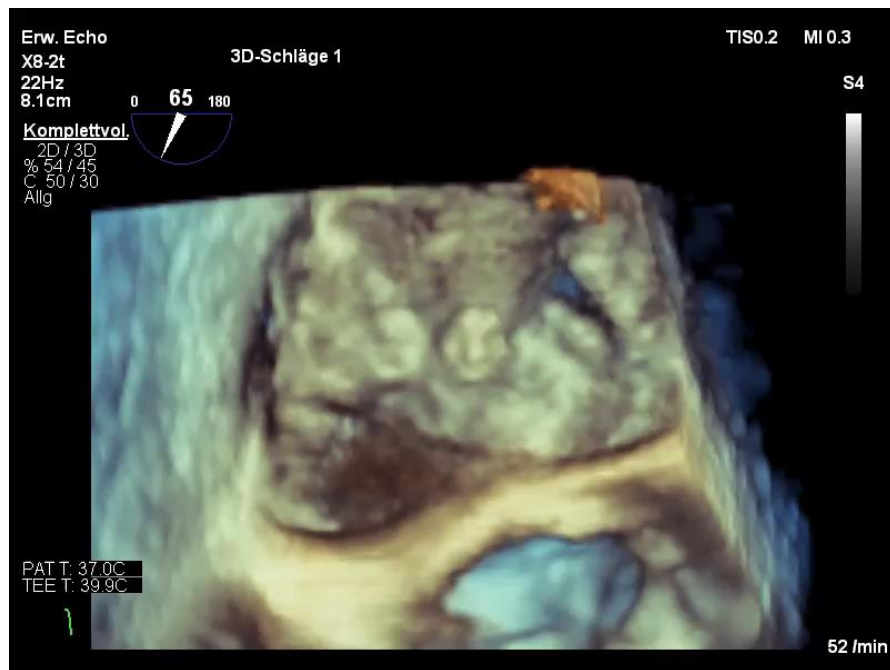
- 2-device strategy
- PASCAL Ace implant

TEE: transesophageal echocardiography

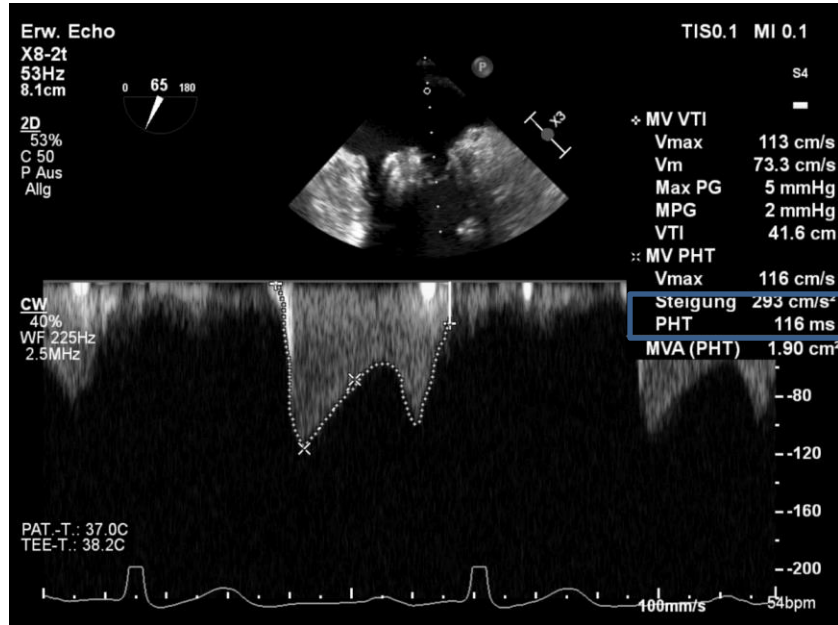
Procedure



Procedure



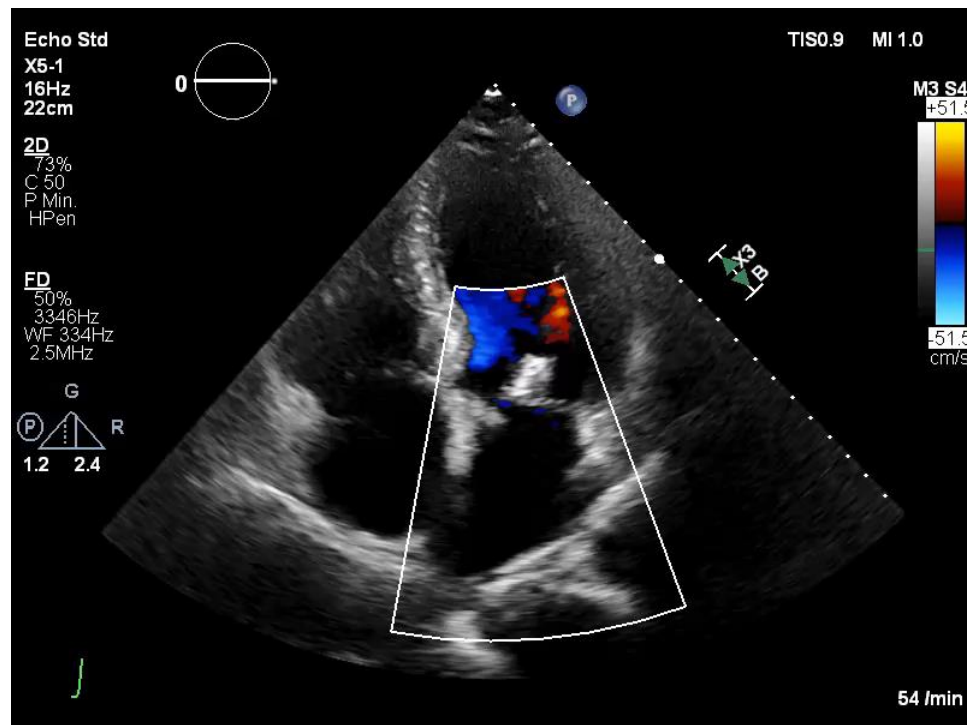
Procedure



- Duration:
 - Total: 52 minutes
 - Guide sheath in to out: 38 minutes
- Fluoroscopy-time: 10.9 minutes
- Dose area product: 1651 cGycm³
- Contrast: 15 ml
- Procedure in conscious sedation
- Discharge on 2nd post-interventional day

Follow-up at 3 Months

	Pre-procedural	3-M follow-up
Dyspnea	NYHA III	NYHA I
NT-proBNP	1273 pg/ml	682 pg/ml
6-MWD	283 m	412 m



MV-MPG: 2mmHg

NYHA: New York Heart Association; NT-proBNP: N-terminal pro-B-type natriuretic peptide; 6MWD, 6-minute walk distance; MV-MPG: mitral valve- mean pressure gradient

Conclusion

Retrospective multi-center cohort study with central core lab evaluation

- ✓ 78% no or mild MR at discharge in real-world setting
- ✓ Predictable post-delivery residual MR in 94% of procedures
- ✓ Improvement in residual MR in 23% of patients from pre- to post-delivery

MR: mitral regurgitation

Hellhammer K. [...] Mahabadi AA. Impact of MV anatomy on predictability of post-delivery MR with a new generation TEER-device. E-Poster. EuroPCR 2024

Thank you

Expert opinions, advice and all other information expressed represent contributors' views and not necessarily those of Edwards Lifesciences.

Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

Edwards, Edwards Lifesciences, PASCAL, PASCAL Ace and PASCAL Precision are trademarks or service marks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.

© 2024 Edwards Lifesciences Corporation. All rights reserved. PP-EU-8490 v1.0

Edwards Lifesciences Sàrl • Route de l'Etraz 70, 1260 Nyon, Switzerland • edwards.com

PCR

PCRONline.com