# the right patient at the right time, who is the patient who benefits from M-TEER

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#### Disclosure Statement of Financial Interest and Potential for Conflicts of Interest

I, Francesco Maisano, have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation

Grant and/or Research Support Abbott (Steering Committee of EXPAND G4

and CoPI EXPAND); Medtronic; Edwards Lifesciences; Biotronik; Boston Scientific Corporation, NVT, Terumo, Roche, Valgen, Venus

Abbott; Medtronic; Edwards Lifesciences; Swissvortex; Perifect; Xeltis; Transseptal s Consulting fees, Honoraria:

solutions; Cardiovalve, Magenta, Croivalve

Royalty Income/IP Rights Edwards Lifesciences (FMR surgical

annuloplasty)

shareholder of

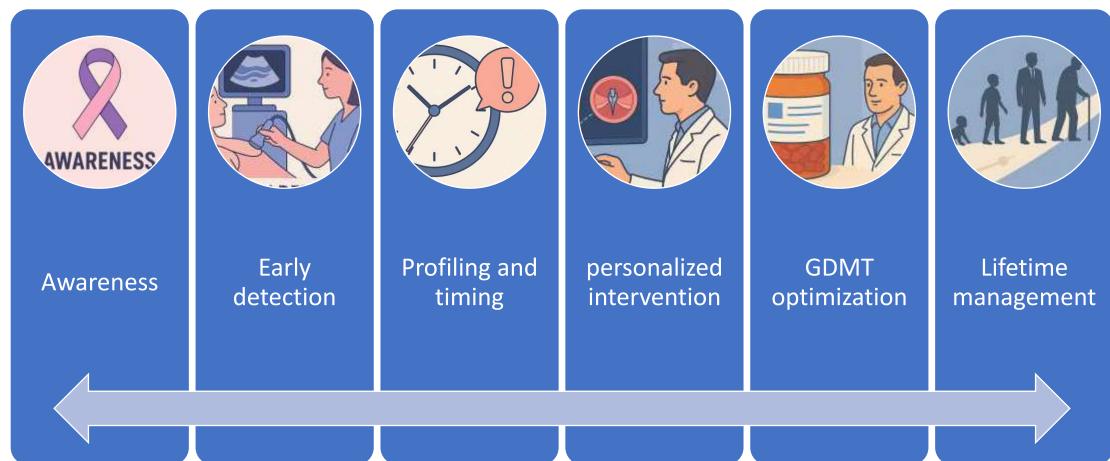
Cardiovalve, Magenta, SwissVortex, Transseptalsolutions, Occlufit, 4Tech, Perifect







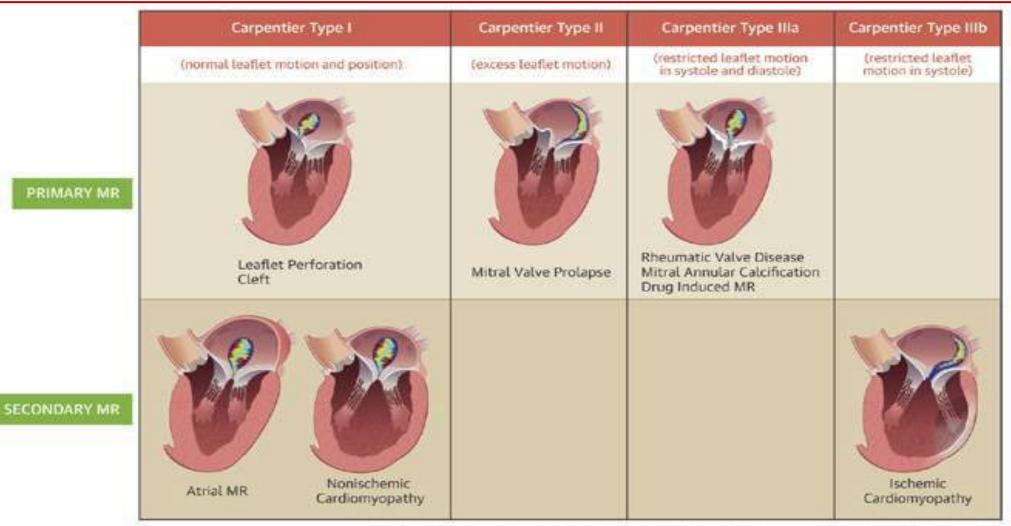
# Benefit is obtained if: diagnosis is made, early, TEER is performed in a timely manner, in the right patient, by a good operator and the patient are properly followed-up







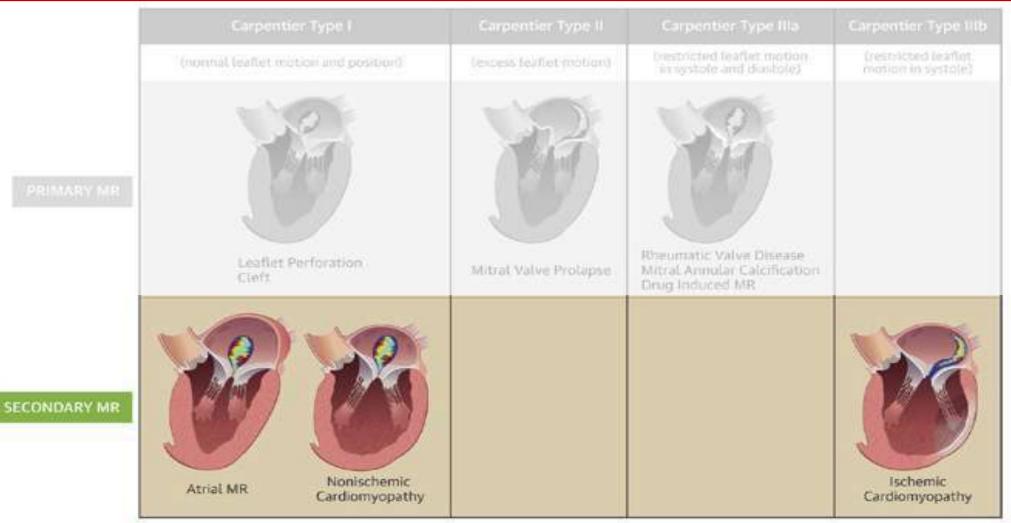
## MR: a spectrum of phenotypes







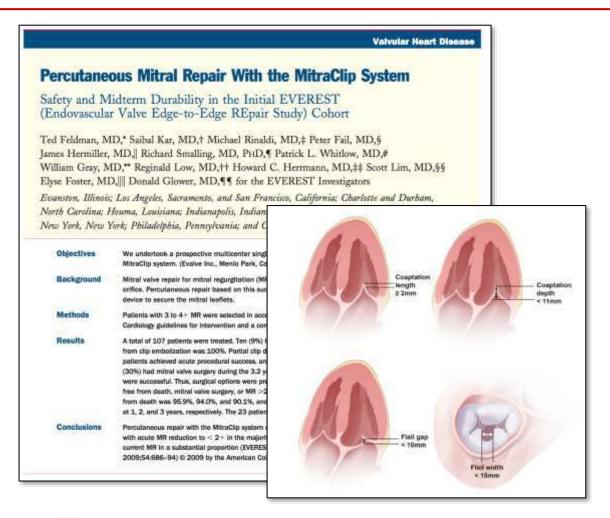
## MR: a spectrum of phenotypes





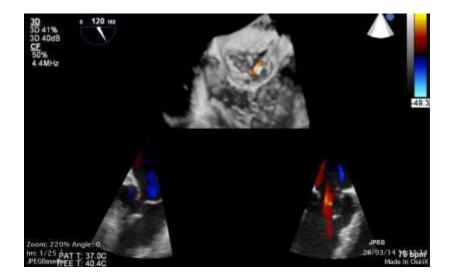


### SMR: Anatomical ideal candidates



### **AVOID** (if beginner)

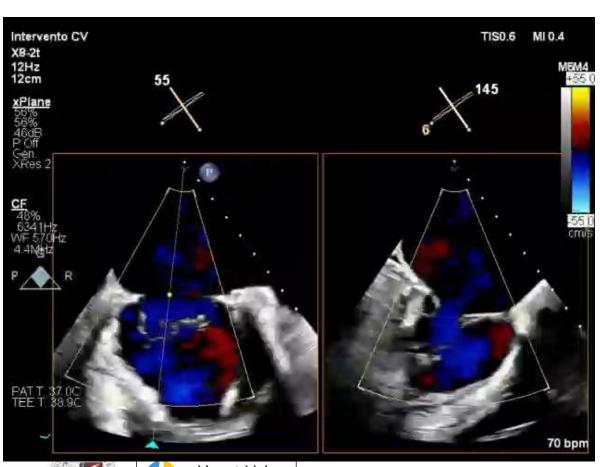
- Severely dynsfunctioning LV
- Severe leaflet tethering
- Calcified leaflets (and annulus)
- Non central MR
- Complex Jet morphology







## A good way to start..atriogenic FMR

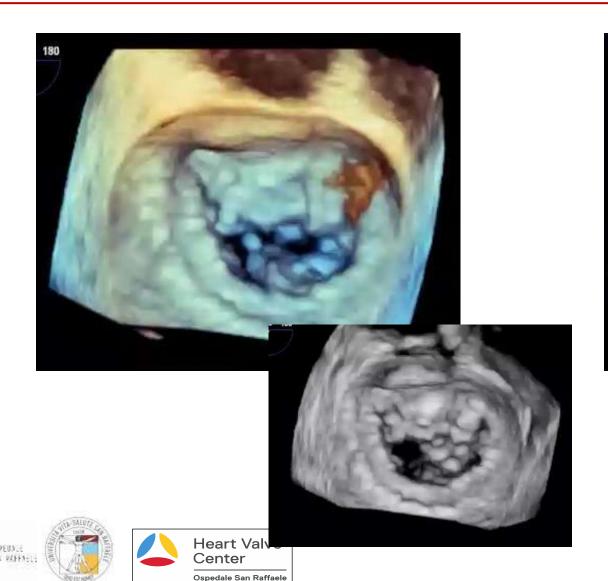






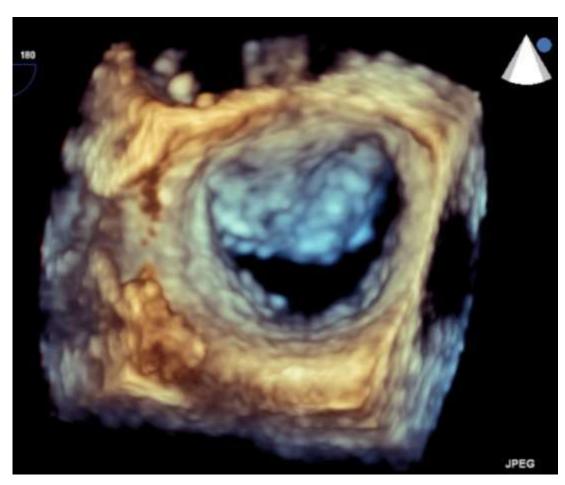


## TEER for atrial SMR: indirect annular reduction in addition to leaflet coaptation





## More than anatomy... timing

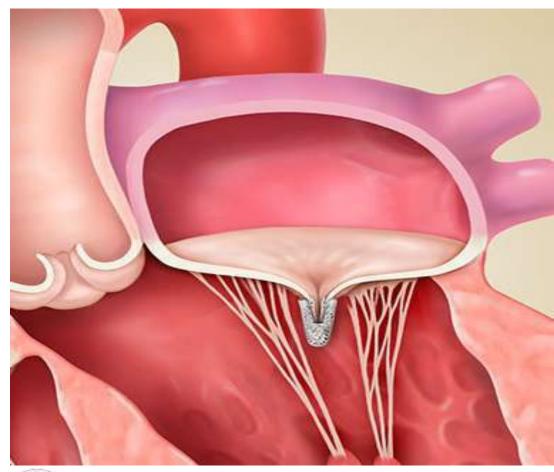


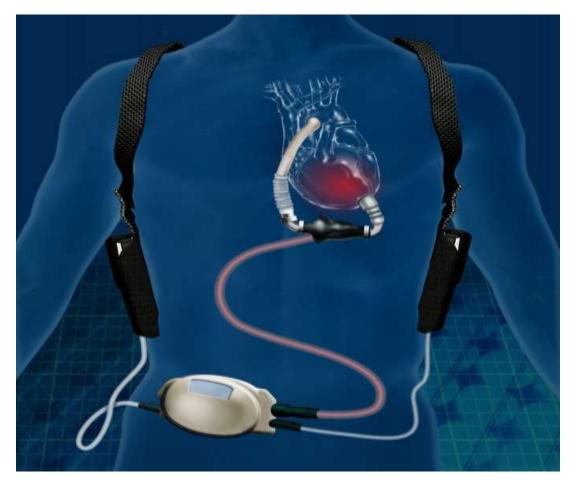






## MitraClip therapy is not an alternative to ECMO, VAD or HTx



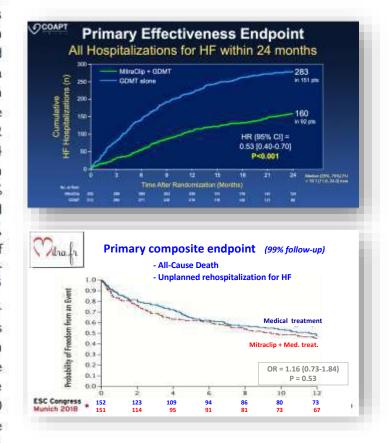






## COAPT vs Mitra-FR phenotype

Two randomized trials, MITRA-FR and COAPIT, evaluated the effectiveness of percutaneous edge-to-edge mitral valve repair plus OMT compared to OMT alone, in symptomatic patients with reduced LVEF (15-40% in MITRA-FR and 20-50% in COAPT) and moderate-to-severe or severe SMR [effective regurgitant orifice area (EROA) ≥ 20 mm2 in MITRA-FR and EROA ≥ 30 mm2 in COAPTI.610-612 MITRA-FR failed to show any benefit from the intervention on all-cause mortality or HF hospitalization at 12 months (primary endpoint; HR 1.16, 95% CI 0.73-1.84) and at 24 months. 610,611 In contrast, COAPT showed a significant reduction in hospitalization for HF at 24 months (primary endpoint; HR 0.53, 95% CI 0.40-0.70) and mortality (secondary endpoint; HR 0.62, 95% CI 0.46-0.82).612 Differences in patient selection, concomitant MT, echocardiographic assessment, procedural issues and severity of SMR in relation to the degree of LV dilatation may be responsible for the diverging results of the MITRA-FR and COAPT trials. 613-615 Thus, percutaneous edge-to-edge mitral valve repair should be considered for outcome improvement only in carefully selected patients who remain symptomatic (NYHA class II-IV) despite OMT, with moderate-to-severe or severe SMR (EROA ≥30 mm<sup>2</sup>), favourable anatomical conditions, and fulfilling the inclusion criteria of the COAPT study (i.e. LVEF 20-50%, LV end-systolic diameter <70 mm, systolic pulmonary pressure <70 mmHg, absence of moderate or severe RV dysfunction, absence of severe TR, absence of haemodynamic instability) (Figure 17).615,616



TEER should be considered in selected symptomatic patients, not eligible for surgery and fulfilling criteria suggesting an increased chance of responding to the therapy.

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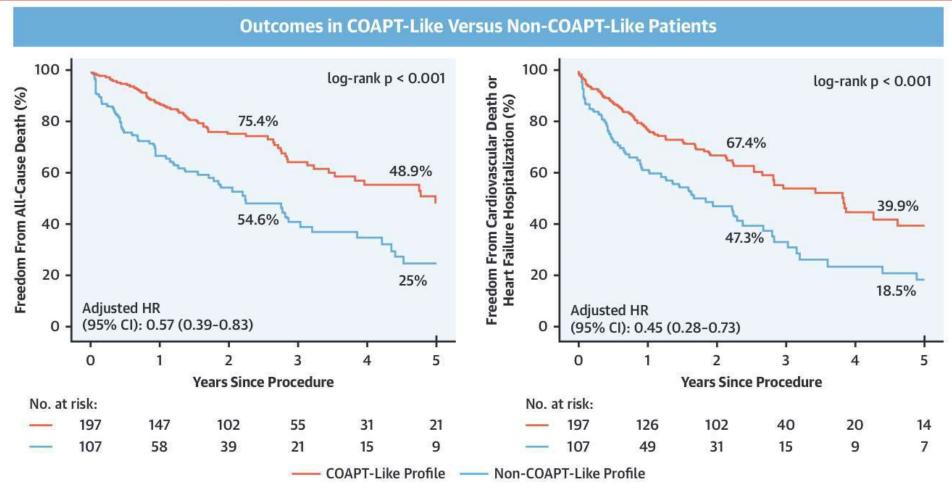
In high-risk symptomatic patients not eligible for surgery and not fulfilling the criteria suggesting an increased chance of responding to TEER, the Heart Team may consider in selected cases a TEER procedure or other trans-catheter valve therapy if applicable, after careful evaluation for ventricular assist device or heart transplant.

ШЬ





## COAPT phenotype predicts survival and freedom from HF hospitalizations



Adamo, M. et al. J Am Coll Cardiol Intv. 2021;14(1):15-25.





## who are the COAPT like patients: LV function, LV size, Right ventricle, clinical presentation

Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients
With Functional Mitral Regurgitation (COAPT)-Like Profile Definition

#### All of the 3 following criteria should be fulfilled to define a COAPT-like profile:

#### Absence of Severe Left Ventricular Impairment

- ✓ Left ventricular ejection fraction ≥20%. and
- ✓ Left ventricular end-systolic diameter ≤70 mm

### Absence of Right Ventricular Impairment and/or Severe Pulmonary Hypertension

- √ TAPSE ≥15 mm or peak systolic velocity by tissue Doppler imaging ≥8 cm/s, and
- Less than severe tricuspid regurgitation, and
- ✓ Systolic pulmonary artery pressure ≤70 mm Hg

#### Absence of Hemodynamic Instability

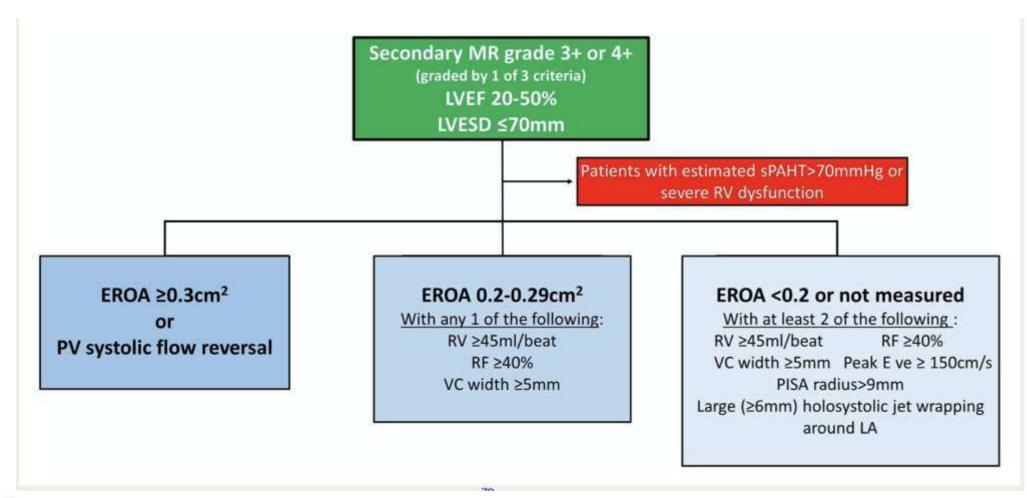
- No advanced heart failure refractory to medical therapy, and
- No need for intravenous drugs or mechanical circulatory support

The lack of at least 1 of these 3 criteria defines a non-COAPT-like profile





## who are the COAPT like patients: severe MR







### RESHAPE II

The NEW ENGLAND JOURNAL of MEDICINE

#### ORIGINAL ARTICLE

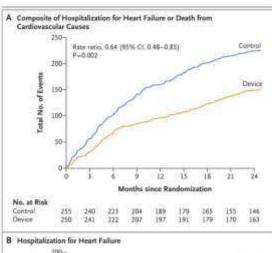
## Transcatheter Valve Repair in Heart Failure with Moderate to Severe Mitral Regurgitation

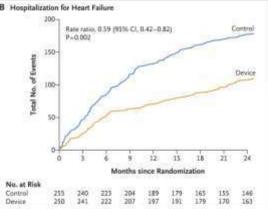
S.D. Anker, T. Friede, R.-S. von Bardeleben, J. Butler, M.-S. Khan, M. Diek, J. Heinrich, M. Geyer, M. Placzek, R. Ferrari, W.T. Abraham, O. Alfieri, A. Auricchio,
A. Bayes-Genis, J.G.F. Cleland, G. Filippatos, F. Gustafsson, W. Haverkamp, M. Kelm, K.-H. Kuck, U. Landmesser, A.P. Maggioni, M. Metra, V. Ninios, M.C. Petrie, T. Rassaf, F. Ruschitzka, U. Schäfer, P.C. Schulze, K. Spargias, A. Vahanian, J.L. Zamorano, A. Zeiher, M. Karakas, F. Koehler, M. Lainscak, A. Öner, N. Mezilis, E.K. Theofilogiannakos, I. Ninios, M. Chrissoheris, P. Kourkoveli, K. Papadopoulos, G. Smolka, W. Wojakowski, K. Reczuch, F.J. Pinto, Ł. Wiewiórka, Z. Kalarus, M. Adamo, E. Santiago-Vacas, T.F. Ruf, M. Gross, J. Tongers, G. Hasenfuss, W. Schillinger, and P. Ponikowski, for the RESHAPE-HF2 Investigators\*

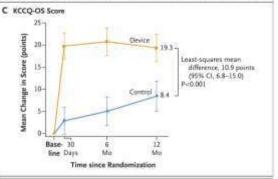
#### ABSTRACT

#### BACKGROUND

Whether transcatheter mitral-valve repair improves outcomes in patients with heart failure and functional mitral regurgitation is uncertain.







#### TABLE 1 Baseline Characteristics and 2-Year Outcomes in 3 Randomized Trials of M-TEER in FMR

	<b>COAPT (n = 614)</b>	$\mathbf{MITRA\text{-}FR}\;(\mathbf{n}=304)$	RESHAPE-HF2 (n = 505)
Mean age, y	72	70	70
Male	72	75	80
Etiology			
Ischemic	61	59	65
Nonischemic	39	41	35
NYHA functional class III/IV	61	67	75
HFH within prior 12 months	57	100 <sup>a</sup>	66
Mean LVEF, %	31	33	31
Mean LVEDV, mL	193	250	211
Mean EROA, cm <sup>2</sup>	0.40	0.31	0.25
Baseline HF medical therapy	Maximally tolerated, independent committee confirmed	Community management per EU guidelines	Optimally managed (investigator assessed)
Follow-up HF medical therapy	Few changes	Not collected	Not collected
2-y mortality, control group	46.1	34.2	29.6
Reduction with M-TEER <sup>b</sup>	0.62 (0.46-0.82)	1.02 (0.70-1.50)	0.73 (0.51-1.05)
2-y all HFHs, control group, per 100 patient-y	67.9	106.9	46.6
Reduction with M-TEER <sup>b</sup>	0.53 (0.40-0.70)	0.87 (0.56-1.35)	0.62 (0.46-0.83)

### Expanded registry, FMR cohort,

Significant Left Ventricular Remodeling in Subjects With SMR and Baseline MR 2+ Through 1 Year

JACC HEAT FALSEE FELSEE OF SHIP OF SHIP OF SHIP OF SHIP AND SHIP OF SHIP AND SHIP OF S

#### Evaluating Mitral TEER in the Management of Moderate Secondary Mitral Regurgitation Among Heart Failure Patients

Anita W. Aogar, MD, Gilbert H.L. Tang, MD, Jason H. Rogers, MD, Wolfgang Rotthauer, MD, H. Andrew Morse, MD, Poole Denti, MD, Paul Mahmery, MD, Bokhael J. Risadit, MD, Pederico M, Aoch, MD, Jose L. Zamonno, MD, Melody Dong, FaQ, Rong Buang, MS, Josen Lindenfeld, MD, Francisco Manano, MD, Balph Stephan von Barbeleben, MD, Sabal Kar, MD, Evelar Redignose, MD

#### ABSTRACT

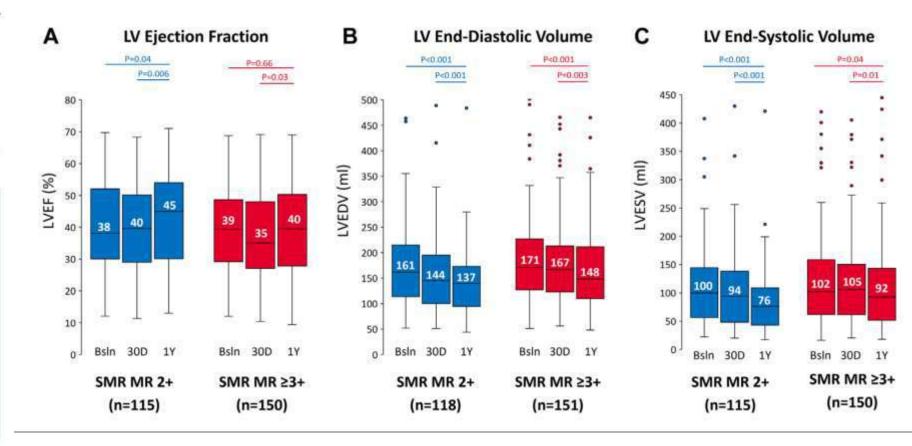
BACKGROUND Moderate secondary intrial regulgitation (SMR) impresents a subgroup of heart failure (HF) patients with resourcer restricted to medical therapy. Outcomes in patients with moderate SMR treated with mitral transcatheter edge-to-edge organi (M-TERI) are less well known.

OBJECTIVES The aim of this study was to excess the safety and effectiveness of M-TEER in subjects with moderate SMR using the EXPANDed studies.

METHODIS One-year curcomes in subjects from the EXPANDed studies (EXPAND & Comemporary, Prospective Study Evaluating Real-world Experience of Performance and Safety for the Next Generation of MitraClip Devices] and EXPAND G4 [A Post-Nariest Study Assessment of the Safety and Performance of the MitraClip G4 System) MitraClip studies) with buseline moderate SMR (2-1), per echocatillographic core laboratory (ECL) assessment, were compared with subjects with buseline server SWR ((3-1).)

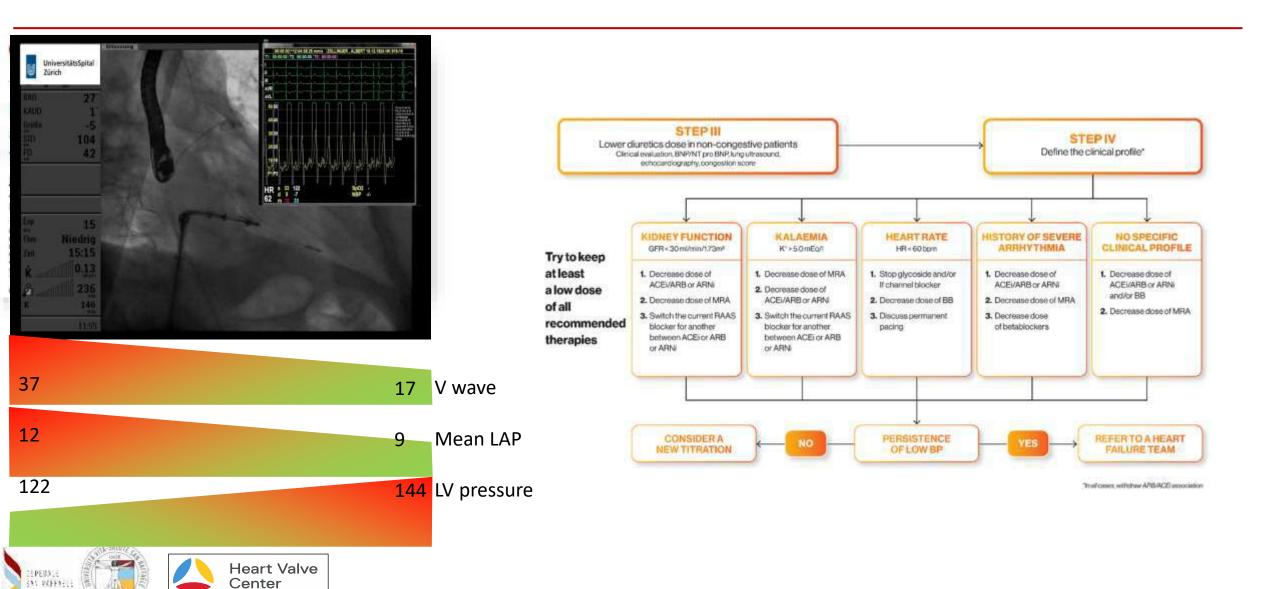
RESULTS. There were 35% subjects with moderate SMR and 525 with source SMR at baseline per ECL review. Studies characteristics were similar between the 2 subgroups. After treatment with M-TEER, significant MR reduction was achieved is both groups. Significant full ventscolar (LV) meeter immediately was observed through 1 year, with a 120 ms. decrease in LV and distributed and and special ventscolar (LV) meeter immediate SMR group. Significant 1 year improvements in NPHA functional class (1-78% MYHA functional class to 10 and quality of life (1-20 points on the Kersas City, Cardiornyopathy Questionners Overall Summary) were observed in subjects with moderate SMR. Similarly, low rates of major adverse events, all clause mortality, and HF hospitalizations were observed between the 2 subgroups through 1 year.

CONCLUSIONS in the EXPANDed studies, subjects with moderate SMR treated with M-TERR fluid improvements similar to subjects with severe SMR in quality of life and positive LY remodeling at 1 year. Future studies are needed to evaluate if M-TEER would be beenfould for HF patients with moderate SMR. (JACC Heart Fall, 2024; m m m) 0, 2024 The Authors. Published by Elevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY Leenes through continuous conflictments (M-N/A).



## A modern target: to improve compliance

Ospedale San Raffaele



## Uptitration

JACC: CARDIDVASCULAR INTERVENTIONS
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PUBLISHED BY ELSEVIER

VOL. 16. NO. 8. 2023

#### **NEW RESEARCH PAPER**

STRUCTURAL

#### Impact of Transcatheter Edge-to-Edge Mitral Valve Repair on Guideline-Directed Medical Therapy Uptitration

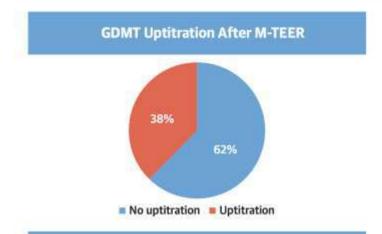


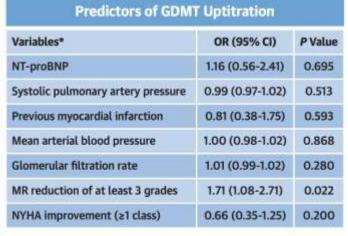
Marianna Adamo, MD, <sup>a.e.</sup> Daniela Tomasoni, MD, <sup>a.e.</sup> Lukas Stolz, MD, <sup>b.</sup> Thomas J. Stocker, MD, <sup>b.</sup> Edoardo Pancaldi, MD, <sup>e.</sup> Benedikt Koell, MD, <sup>e.</sup> Nicole Karam, MD, <sup>e.</sup> Christian Besler, MD, <sup>e.</sup> Cristina Giannini, MD, <sup>e.</sup> Francisco Sampaio, MD, <sup>e.</sup> Fabien Praz, MD, <sup>e.</sup> Tobias Ruf, MD, <sup>e.</sup> Louis Pechmajou, MD, <sup>e.</sup> Michael Neuss, MD, <sup>e.</sup> Christos Iliadis, MD, <sup>e.</sup> Stephan Baldus, MD, <sup>e.</sup> Christian Butter, MD, <sup>e.</sup> Daniel Kalbacher, MD, <sup>e.</sup> Philipp Lurz, MD, <sup>e.</sup> Bruno Melica, MD, <sup>e.</sup> Anna S. Petronio, MD, <sup>e.</sup> Ralph Stephan von Bardeleben, MD, <sup>e.</sup> Stephan Windecker, MD, <sup>e.</sup> Javed Butler, MD, <sup>e.</sup> Gregg C. Fonarow, MD, <sup>e.</sup> Jörg Hausleiter, MD, <sup>e.</sup> Marco Metra, MD, <sup>e.</sup>

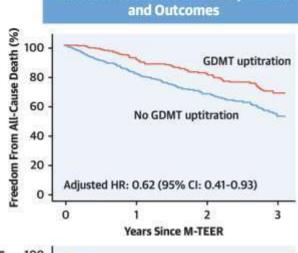
#### ABSTRACT

BACKGROUND Guideline-directed medical therapy (GDMT) optimization is mandatory before transcatheter edge-toedge mitral valve repair (M-TEER) in patients with secondary mitral regurgitation (SMR) and heart failure (HF) with reduced ejection fraction (HFrEF). However, the effect of M-TEER on GDMT is unknown.

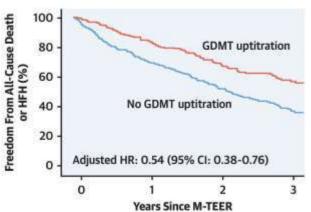
#### CENTRAL ILLUSTRATION Prevalence, Predictors, and Impact on Outcomes of Guideline-Directed Medical Therapy Uptitration After Mitral Transcatheter Edge-to-Edge Repair





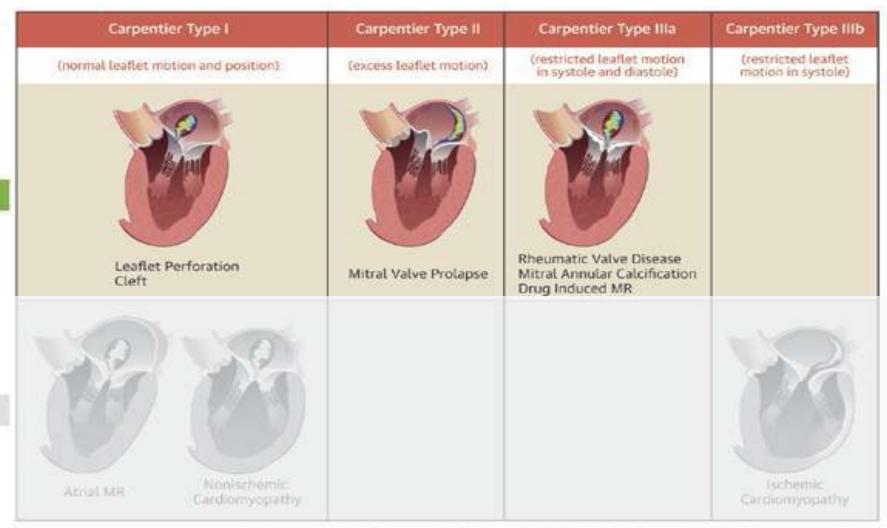


Association Between GDMT Uptitration



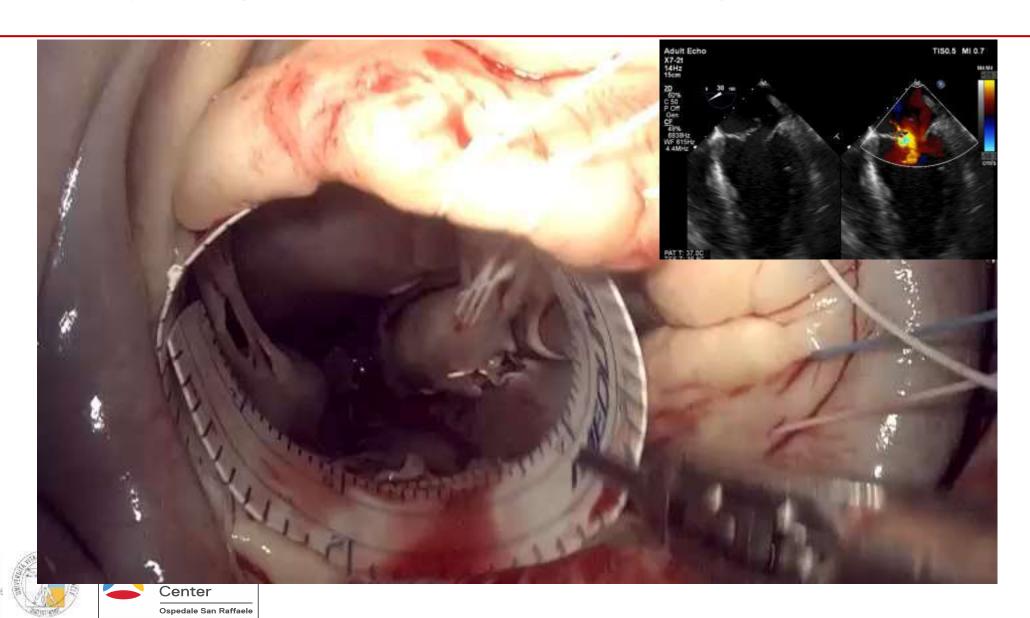
Adamo M, et al. J Am Coll Cardiol Intv. 2023;16(8):896-905.

## MR: a spectrum of phenotypes



PRIMARY MR

## Primary (Degenerative) MR is a surgical business





## Surgery is no more invasive

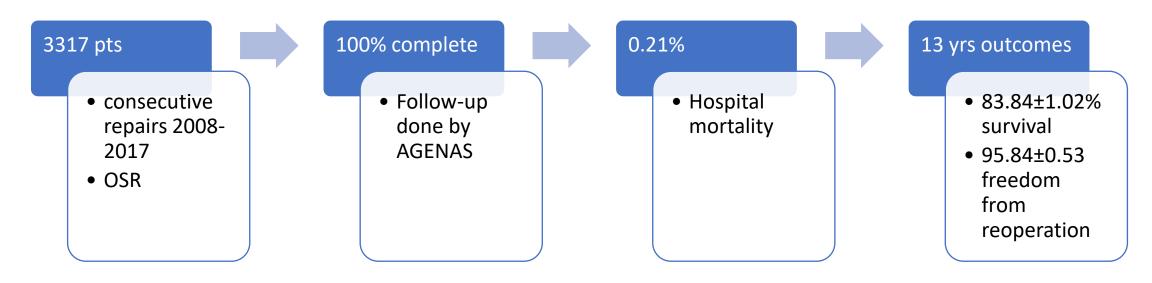






## Long-term Outcomes of Contemporary Surgical Mitral Repair for Degenerative Mitral Regurgitation: a benchmark for

### transcatheter mitral valve interventions



MR phenotype	
Barlow's disease (n, %)	611 (18.42)
• Fibro-elastic deficiency (n, %)	476 (14.35)
Myxomatous degeneration (n, %)	2115 (63.76)
REDO (n, %)	71 (2.14)

Con	Concomitant procedures (n, %)	
•	Tricuspid valve repair	491 (14.8)
•	Tricuspid valve replacement	4 (0.12)
•	AF ablation	272 (8.2)
•	Aortic valve replacement	68 (2.05)
•	Ascending aorta replacement	20 (0.6)
•	CABG	187 (5.64)

Long-term freedom from reoperation multivariable predictive analysis						
	HR	95% CI	p-value			
Mild-to-moderate MR at discharge	2.54	1.08-5.94	0.032			
Anterior leaflet disease	3.44	1.96-6.03	<0.0001			
Second CPB run	3.61	1.84-7.08	0.0002			

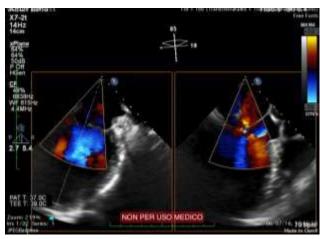
Del Forno B. JACC 2025

## However.... TEER is a great alternative for high risk and fragile patients (and elderly)

- 81 yo
- NYHA III, CCS:0
- no comorbidities
- P2 prolapse/flail
- EF: 68%
- Euroscore II: 2.07%





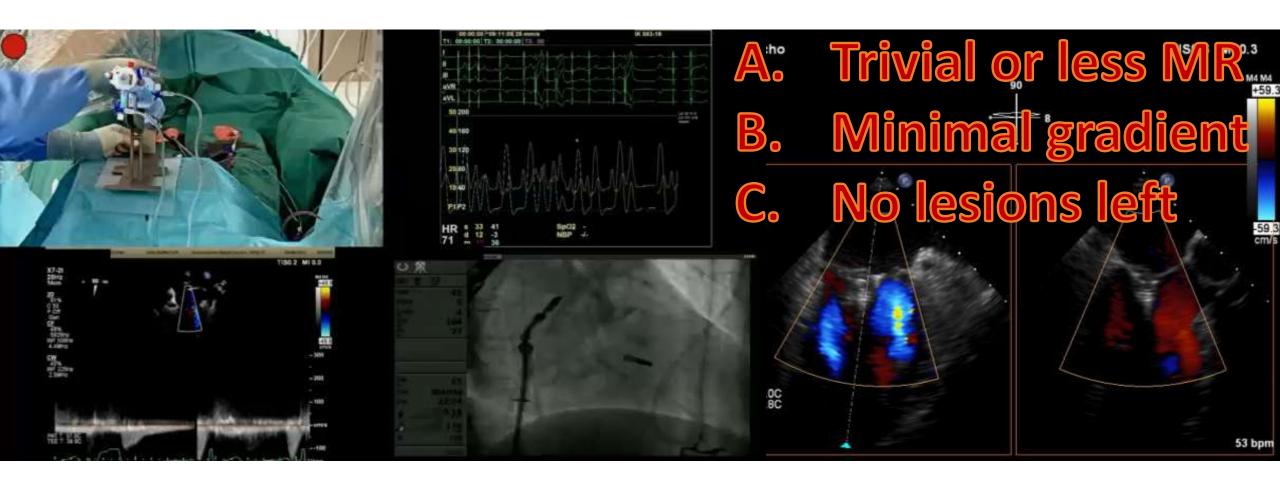








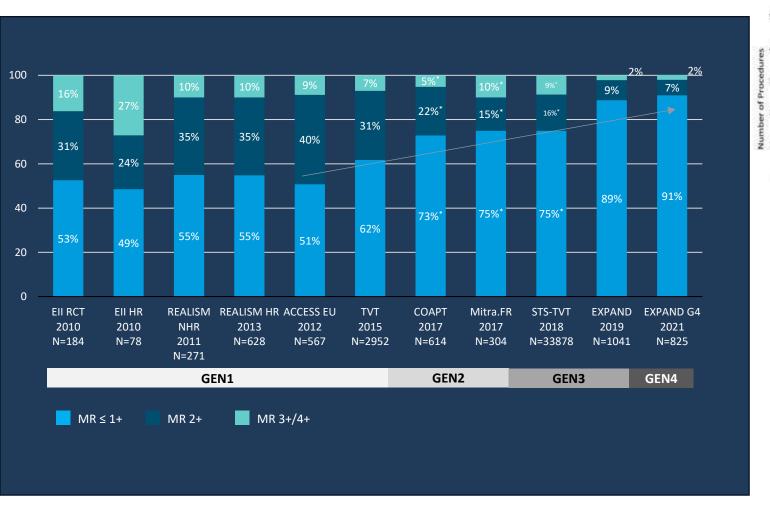
## TEER is not palliation: in intermediate risk patients, a surgical like outcome is mandatory

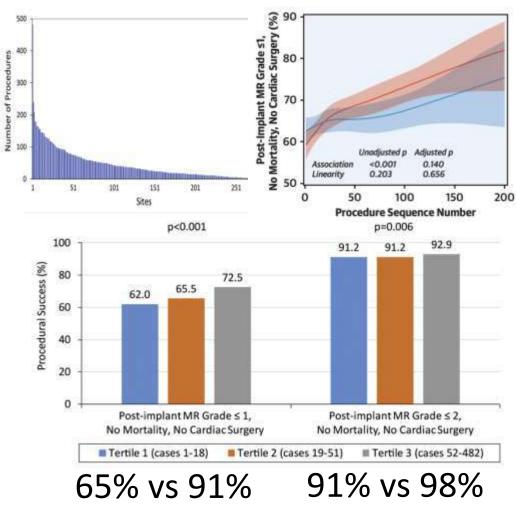






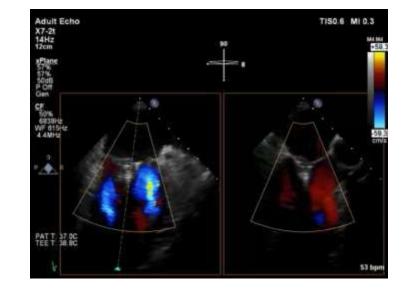
### expert centers vs overall outcomes





## how to get the best from TEER

- Patient selection
- imaging
- good (efficient) transseptal
- understand anatomy of the mitral valve
- select the device
- respect the rules of a good edge-to-edge repair
- abolish any lesion at risk of progression
- find the best compromise between MR reduction and gradients

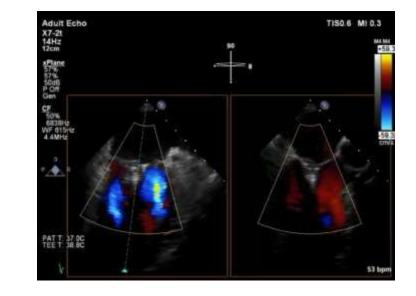






## how to get the best from TEER

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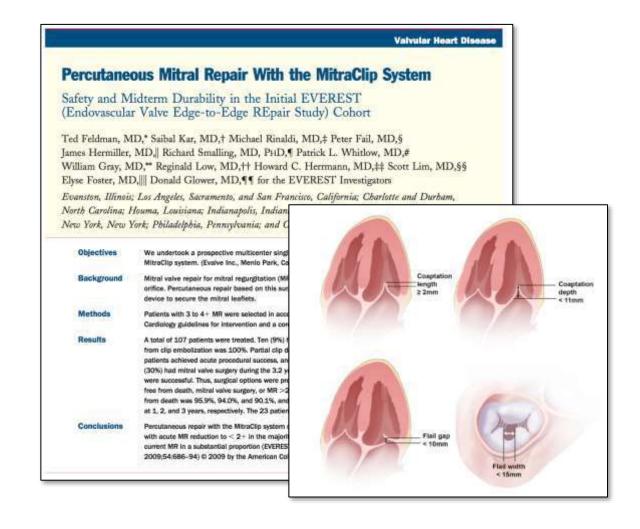






## Patient selection for DMR (for beginners)

- Narrow lesions
- Single scallop
- Anterior easier
- A2 / P2
- Avoid Bileaflet (Barlow's)
- Avoid Calcified lesions
- Avoid post-endocarditis

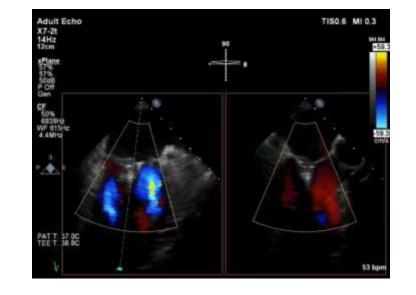






## how to get the best from TEER

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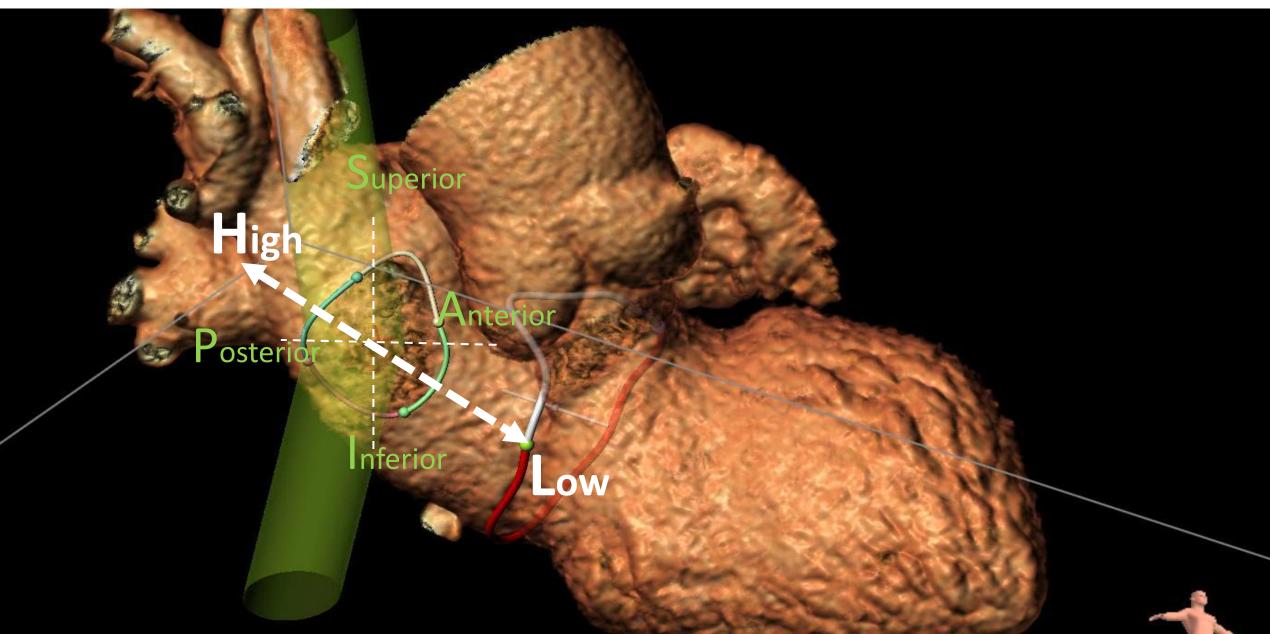
## What makes a TSP a good one..

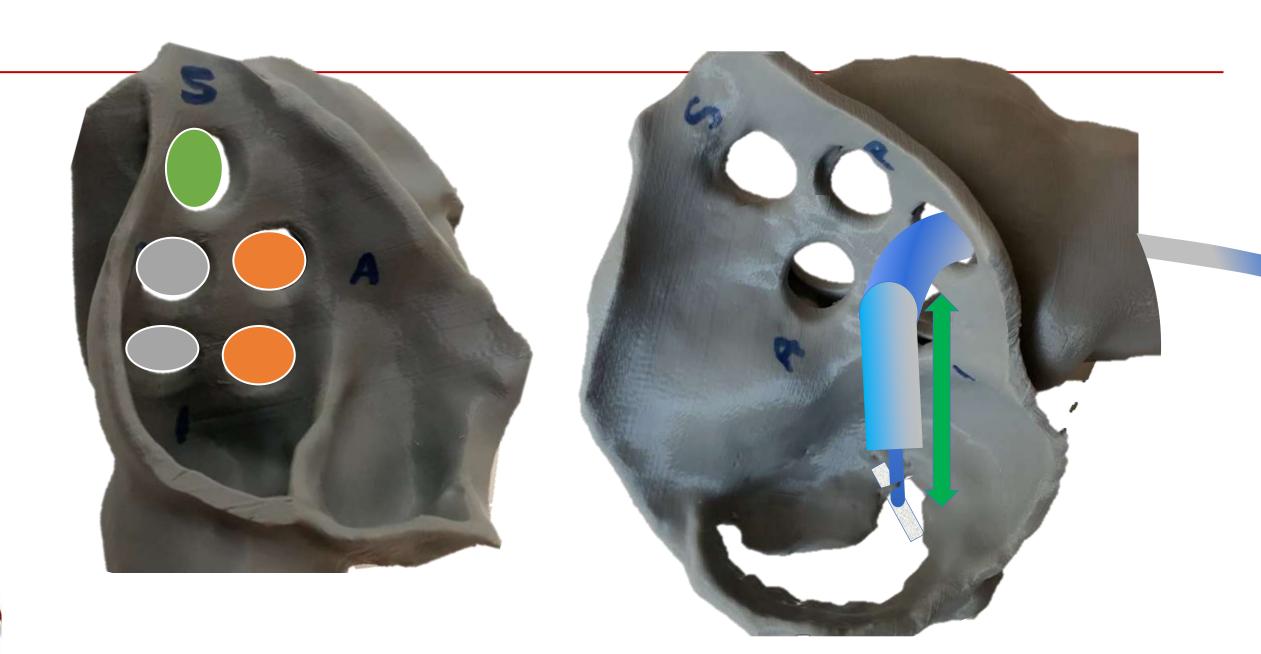
- Safe
  - Avoid complications of TSP
  - Avoid complications due to bad TSP and additional complexity to the procedure (lack of coaxiality)
- Efficient
  - Achieve coaxiality
  - Achieve smooth trajectory for delivery systems
  - Allow fast and unenventful delivery of devices

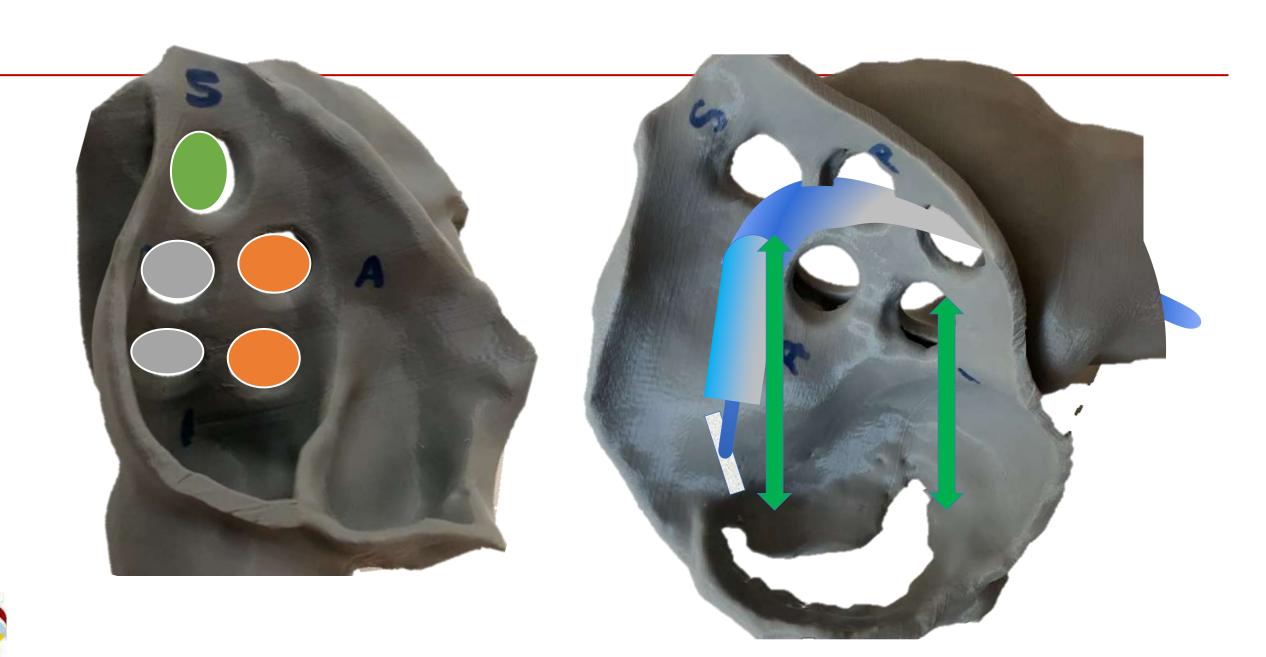




## nomenclature







## how to get the best from TEER

- Patient selection
- imaging
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- understand anatomy of the mitral valve
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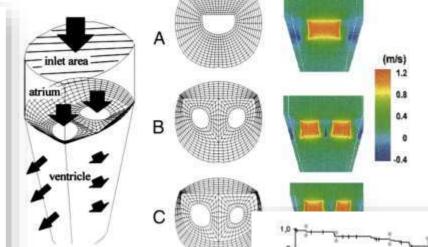
#### Surgical rules, long-term evidence, hemodynamics

#### Learning from experience Surgical rules

- The suture must incorporate the diseased segment(s) completely
- Respect symmetry
- III. Suture lenght should be kept to the minimum effective to correct MR in order to avoid stenosis
- IV. Depth of suture bites is variable according to the nature of the MR







tical Model of the Hemodynamics After the Double Or

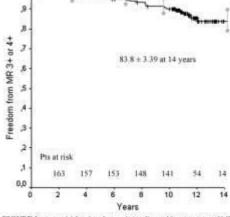


FIGURE 2. Actuarial freedom from echocardingraphic recurrence of MR ≥ 3+ (the standard error of the mean is shown as error bars). MR, Mitral regurgisation; Pts. patients. such a large variety of med ported previously by our comes were observed in p undergoing DO repair com versely, suboptimal results with rheumatic valve diseas dergo a concomitant annu years after its introduction, term results of this surgical in the right setting and w nique-namely, in degener neous prosthetic ring annul not include in this study pop ing from etiologies other th those who underwent DO with annuloplasty technique implantation). Indeed, parti experience, a ring annuloph tients with an extensively partial annuloplasties with

or the posterior reaser in the

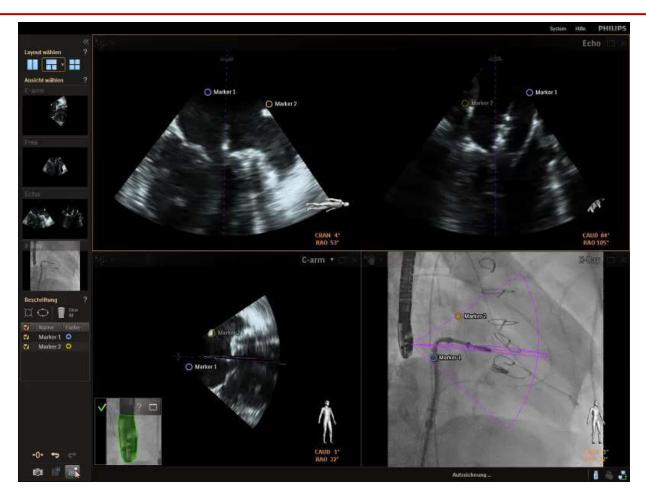
cified annulus. In addition, i MR resulting from different

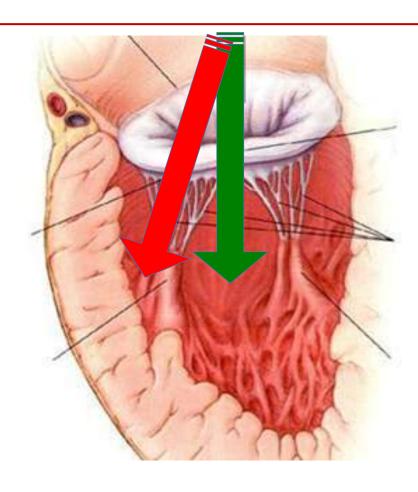
disease. 1,9,10 The 5-year re





#### CDS optimization (coaxiality and trajectory)



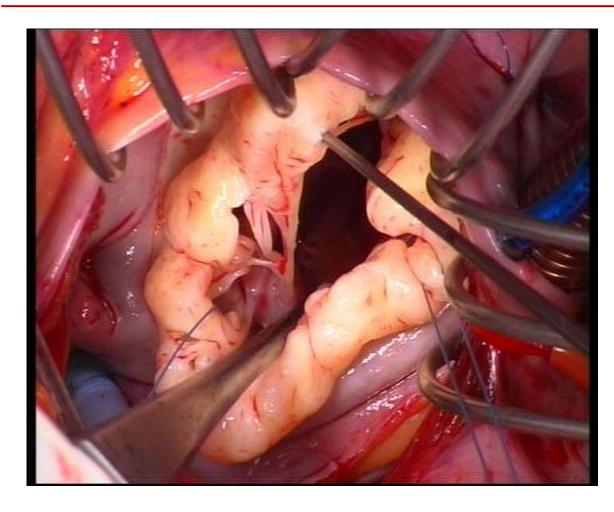


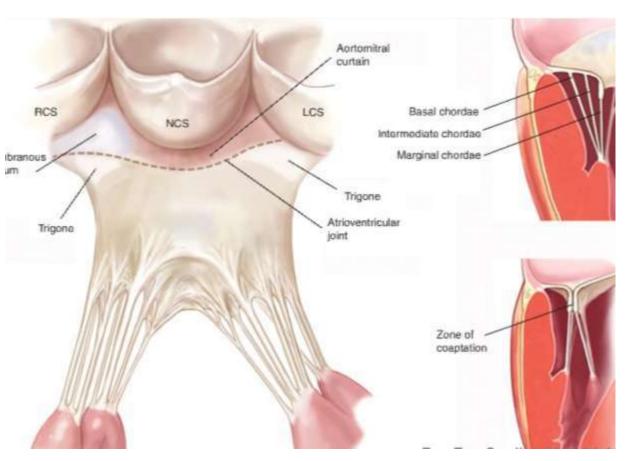
Prevent clip entanglement by checking trajectory (AP and ML) prior to enter the LV





#### A2-P2 is the chordal free zone

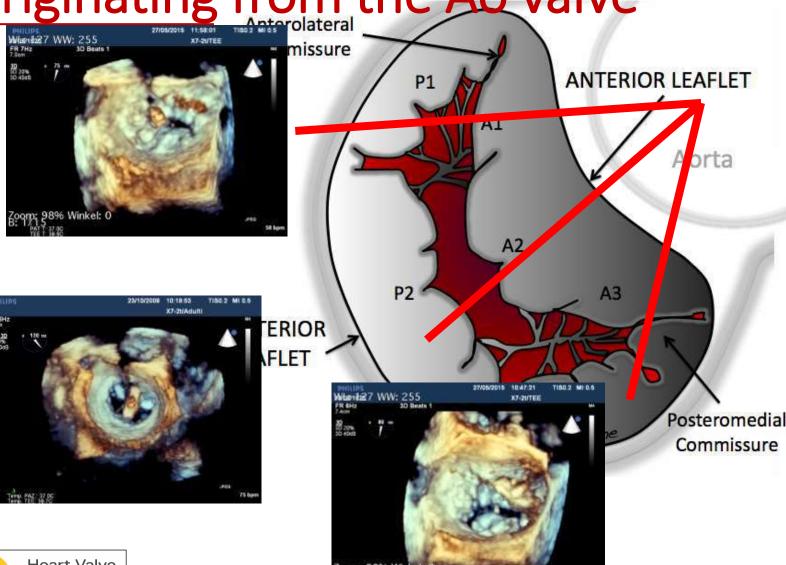






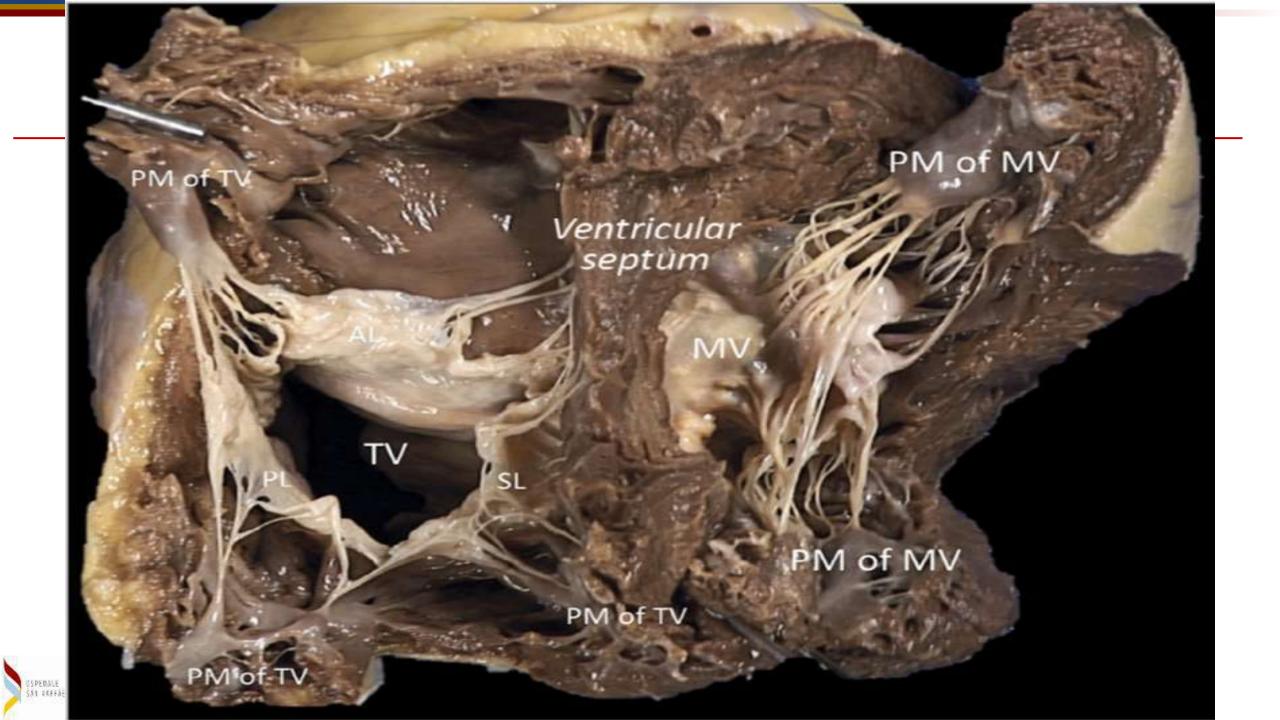


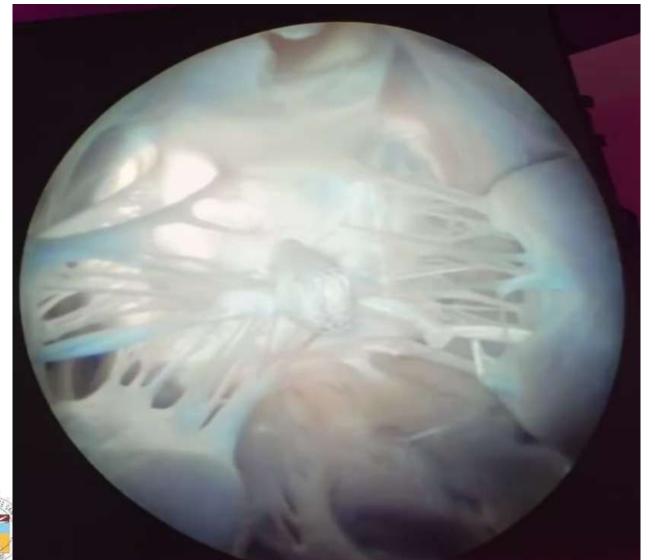
The line of coaptation is perpendicular to lines originating from the Ao valve





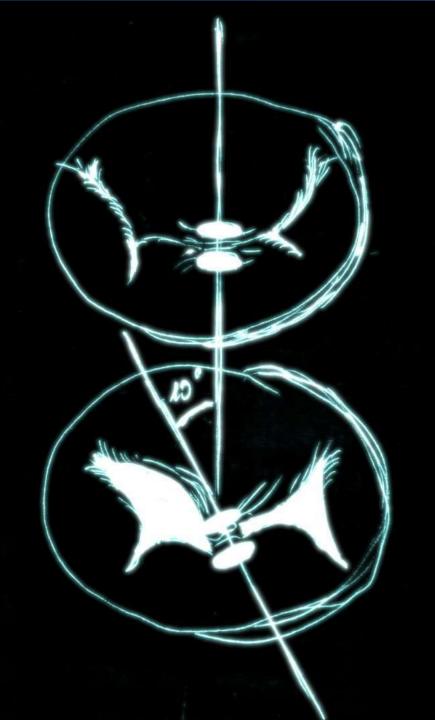








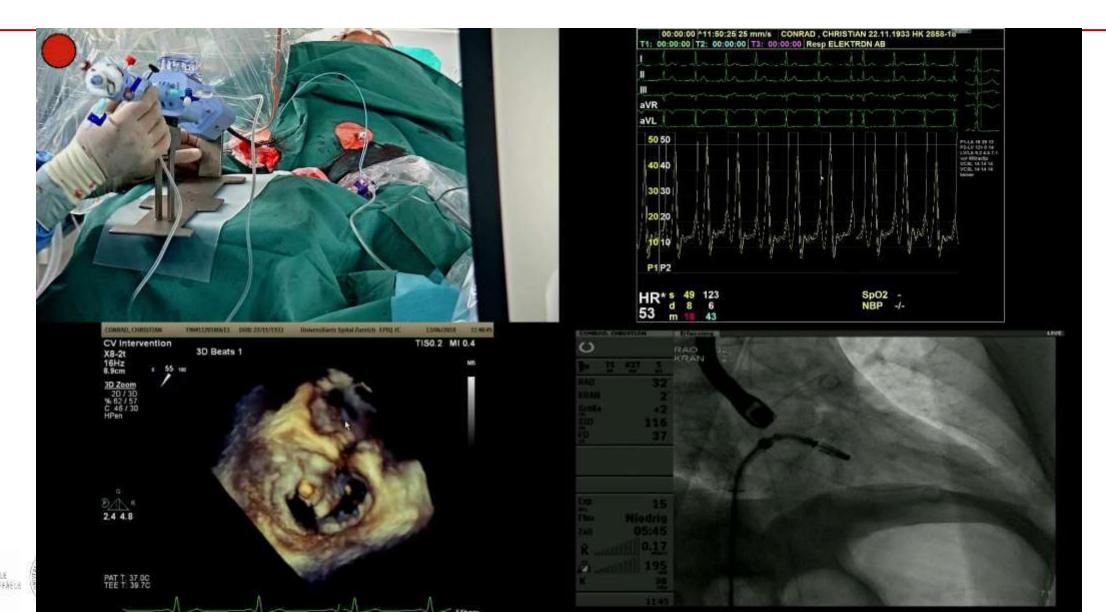




Perfect clip orientation is crucial to achieve a safe and effective MitraClip procedure.

Clip should be oriented perpendicular to the line of coaptation. This is best identified when the commissure are clearly seen on 3D Surgical view

## tip number 1: optimizing orientation

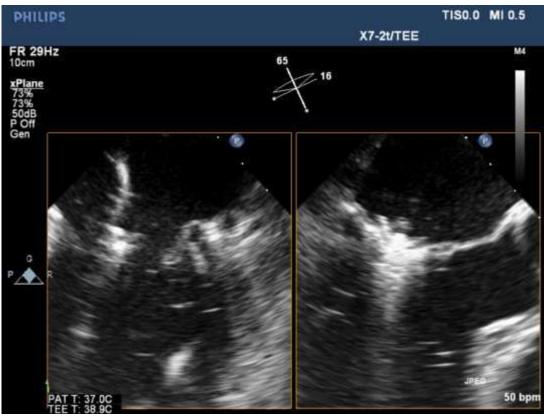


### Tip 2: cross the valve with breath hold



#### Durability assessment: leaflet insertion









#### Indipendent grasping allows more control on leaflets insertion



Improve coaptation, enhance MR reduction, improve durability

#### how to get the best from TEER

- Patient selection
- imaging
- good (efficient) transseptal
- understand anatomy of the mitral valve
- select the device
- respect the rules of a good edge-to-edge repair
- abolish any lesion at risk of progression
- find the best compromise between MR reduction and gradients









144

V wave 37

Mean LAP 12

LV pressure 122





# Alfieri Boothcamp: 3 days full immersion and networking in the Hospital where TEER was invented

PCR simulation based learning From ABC of Edge to Edge
To Master Perfection

#### Alfieri Boot Camp

Dive into the depths of valvular therapies with our innovative **3-days** masterclass organized in collaboration with **PCR** and **UniSR**.

**Join us** to unravel the complexities of **Mitral and Tricuspid** pathologies with the artfulness of a skilled operator.

This **Hands-on course** is more than just an educational journey — **it's a gateway to excellence in TEER**. Harness three decades of groundbreaking expertise as we walk you through the nuanced realms of cardiac interventions.

Whether you're an experienced surgeon, an ambitious echocardiographer or a well-trained interventional cardiologist, this program offers you the unique opportunity to EVOLVE from LEARNER to

**LEADER** in the cardiovascular community. Each day is structured to ensure

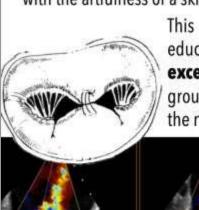
maximum interaction hands-on







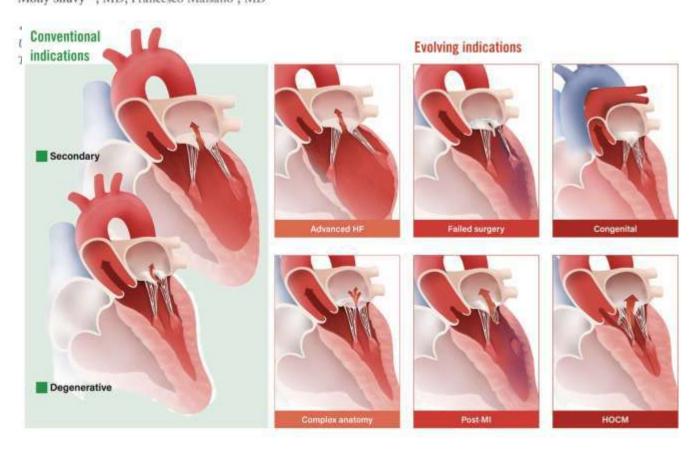


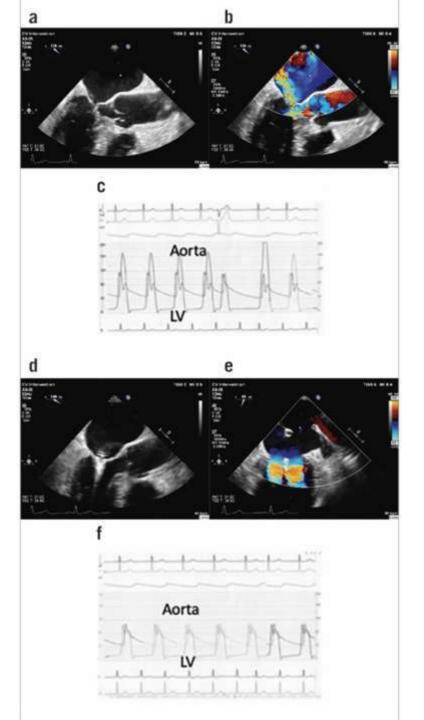


#### M-TEER, evolving indications

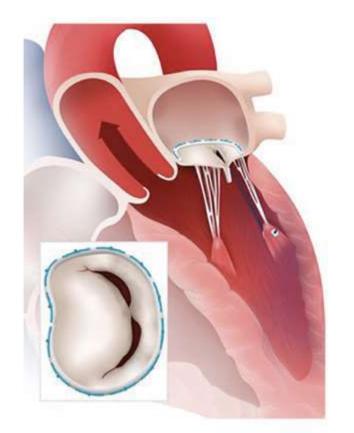
#### Evolving indications for transcatheter mitral edge-to-edge repair

Mony Shuvy1\*, MD; Francesco Maisano2, MD





## TEER for failed surgical repair



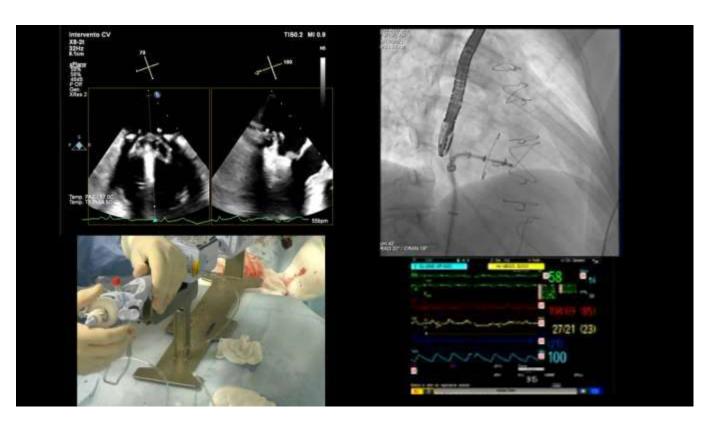


Figure 3. TEER in failed surgical mitral intervention. A ruptured chord in a previous surgical mitral ring implantation treated with TEER in a ring. TEER: transcatheter edge-to-edge repair

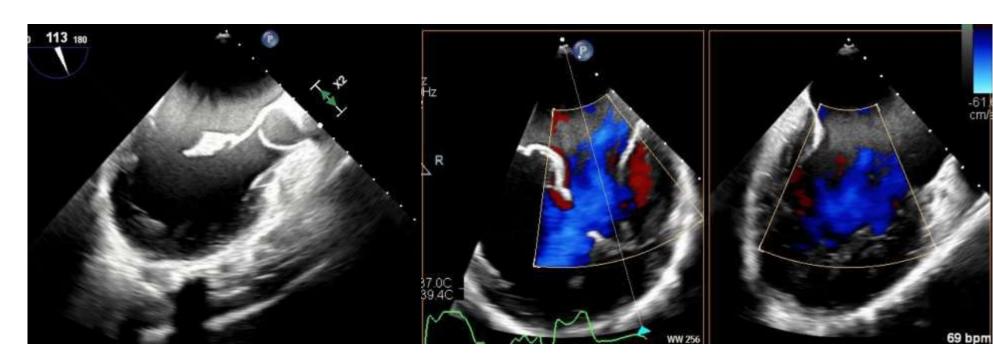




#### Congenital (Fontan physiology)

Pazient: JC

Age: 33 yo (1992)



#### **Cardiac Diagnosis**

#### Pulmonary atresia with intact septum

1992 mRBT shunt (Mr Di Donato, MR Di Carlo)

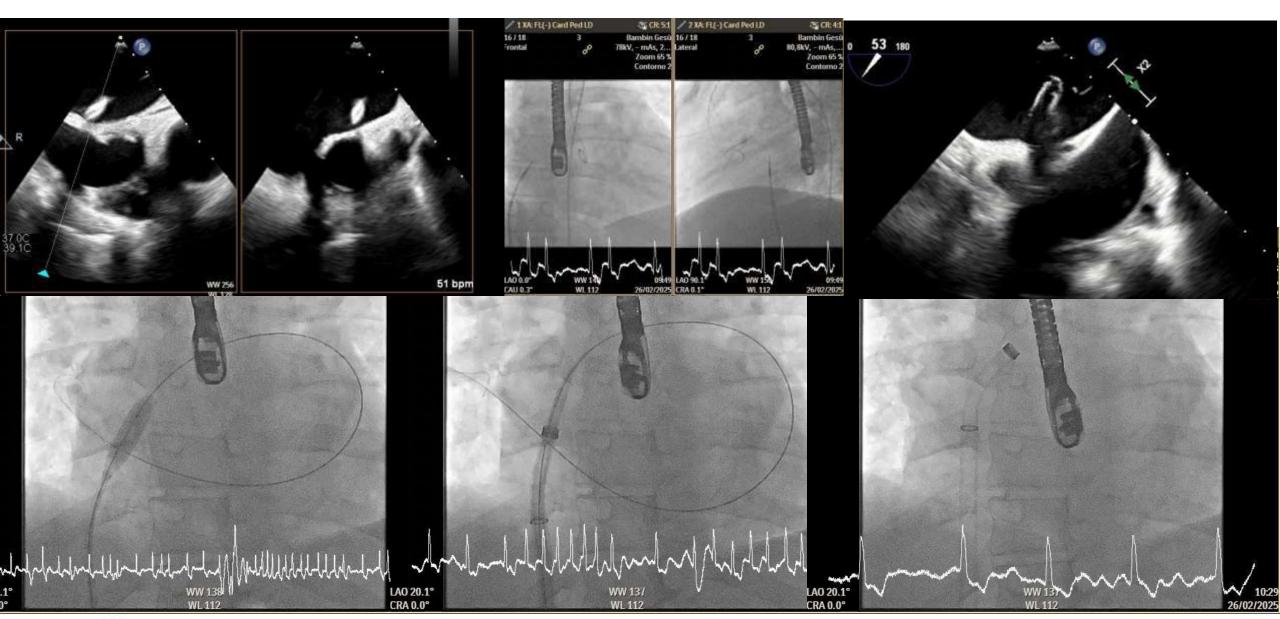
1993 bidirectional Glenn (Mr Di Carlo)

1995 intracardiac TCPC (Mr Di Carlo)

1996 redo TCPC for detachment of intra-artial patch

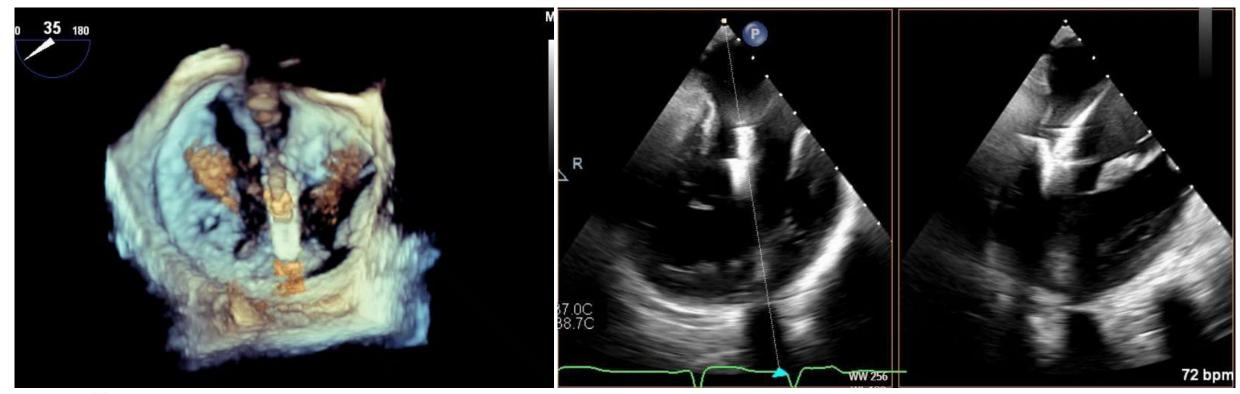






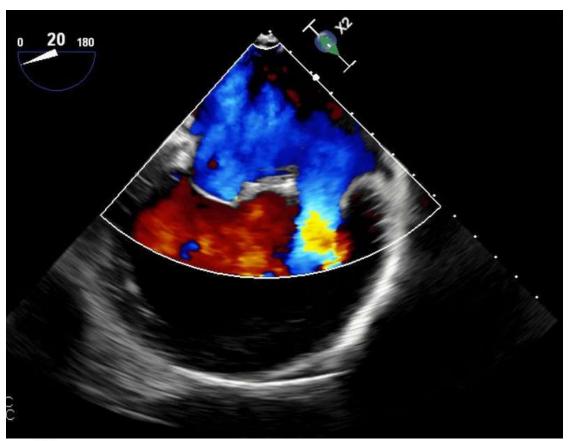


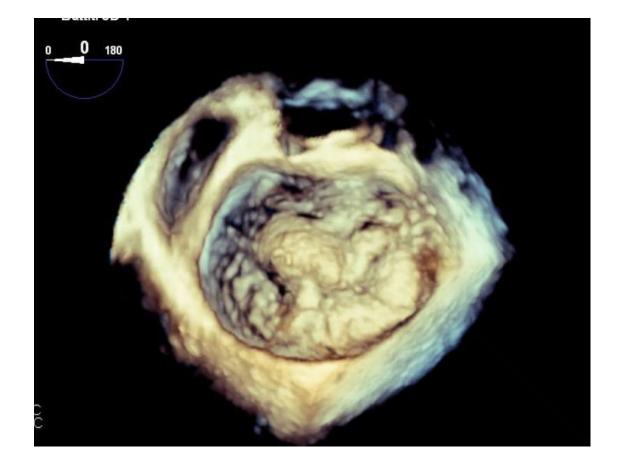






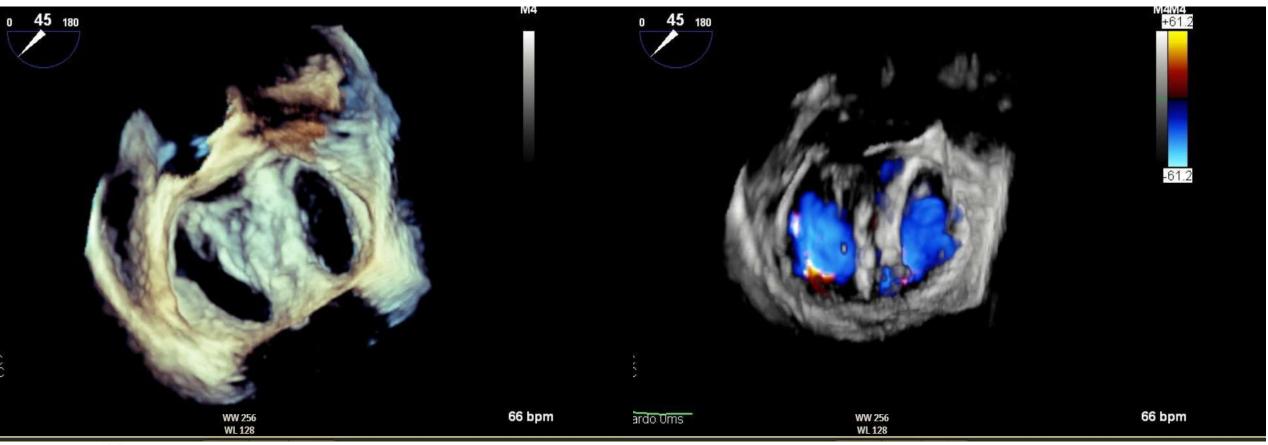










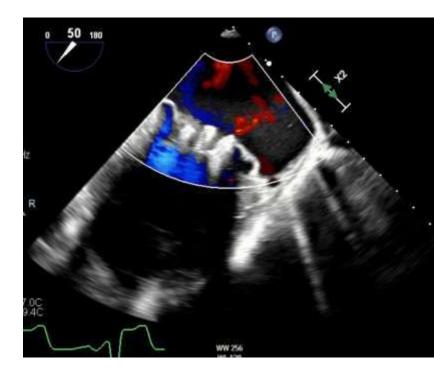






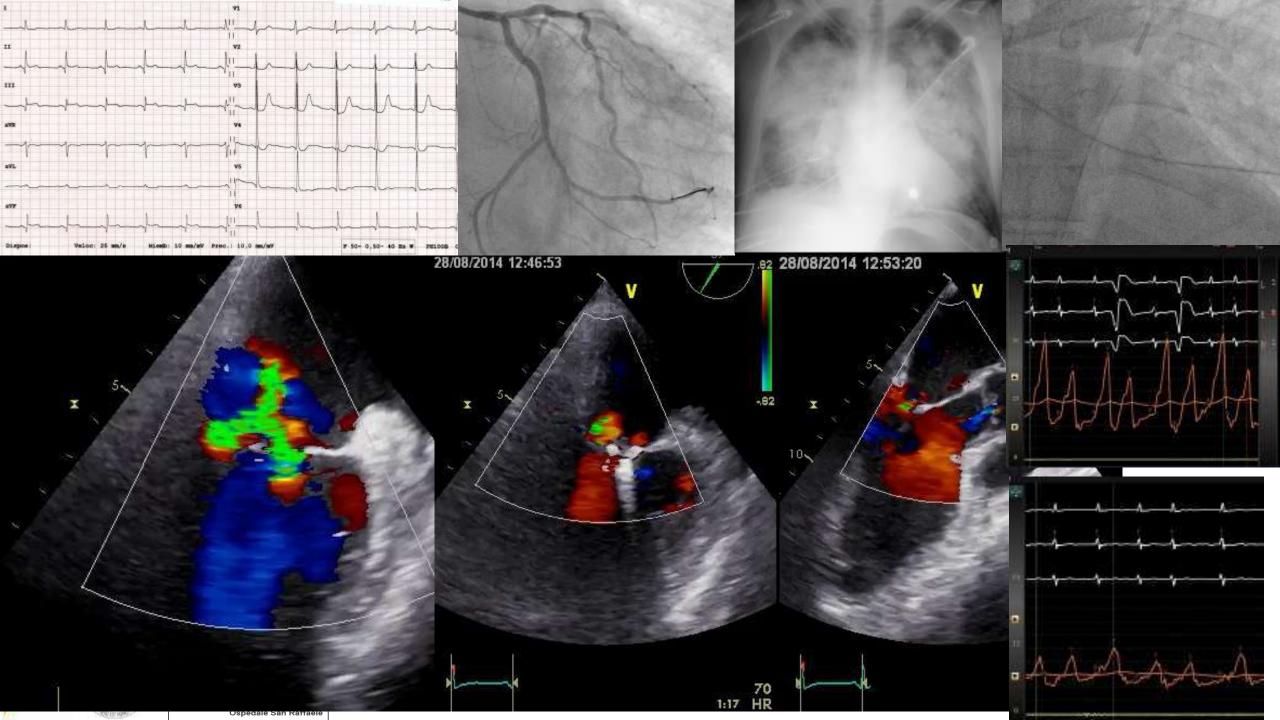












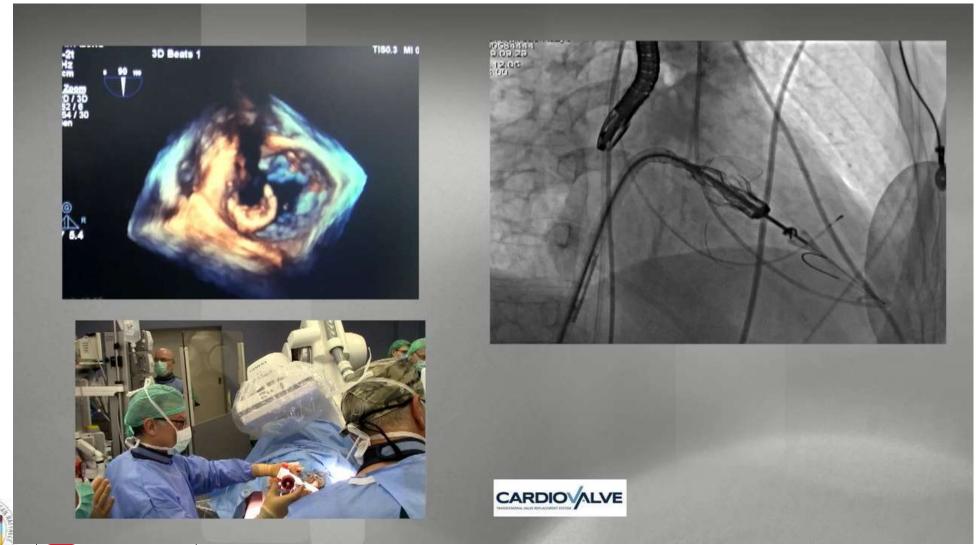
#### **EuroIntervention**

Repair! Anatomical suitability for M-TEER Centre experience Replacement? Non-complex Complex Very complex Criteria favouring replacement Suitable for M-TEER Ideal for M-TEER **Challenging for M-TEER** M-TEER hard or impossible Isolated commissural lesion - Commissural lesion with multiple - Concentric MAC with stenosis - Central pathology - No calcification (A1/P1 or A3/P3) MVA <3.0 cm<sup>2</sup> - MVA >4.0 cm<sup>2</sup> - Annular calcification without - Annular calcification with leaflet - Relevant mitral valve stenosis - Posterior leaflet >10 mm leaflet involvement involvement (mean gradient >5 mmHg) - MVA 3.5-4.0 cm<sup>2</sup> Posterior leaflet <5 mm</li> - Tenting height <10 mm - Fibrotic leaflets - Flail gap <10 mm - Posterior leaflet length 7-10 mm - Wide jet involving the whole - Calcification in the grasping zone - Flail width <15 mm - Tenting height >10 mm coaptation - Deep regurgitant cleft - Asymmetric tethering26 - MVA 3.0-3.5 cm<sup>2</sup> - Leaflet perforation - Coaptation reserve <3 mm<sup>24</sup> - Posterior leaflet length 5-7 mm Multiple/wide jets Leaflet-to-anulus index <1.2<sup>25</sup> - Rheumatic mitral stenosis - Barlow's disease - Flail width >15 mm - Cleft - Flail gap >10 mm - Failed surgical annuloplasty - Two jets from leaflet indentations



## **TMVR**

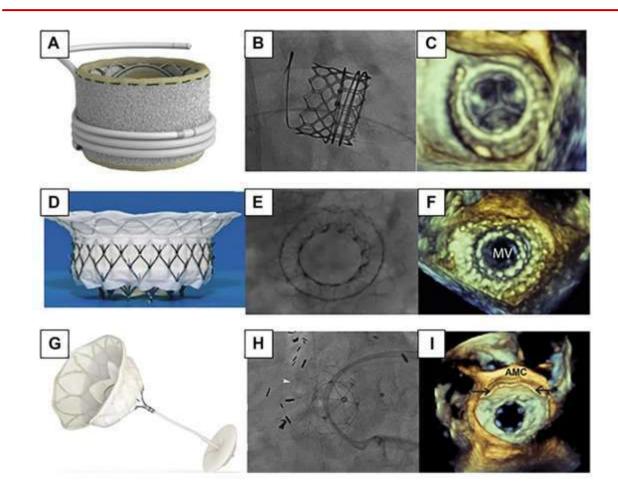
#### simpler, predictable, learnable.... The future???

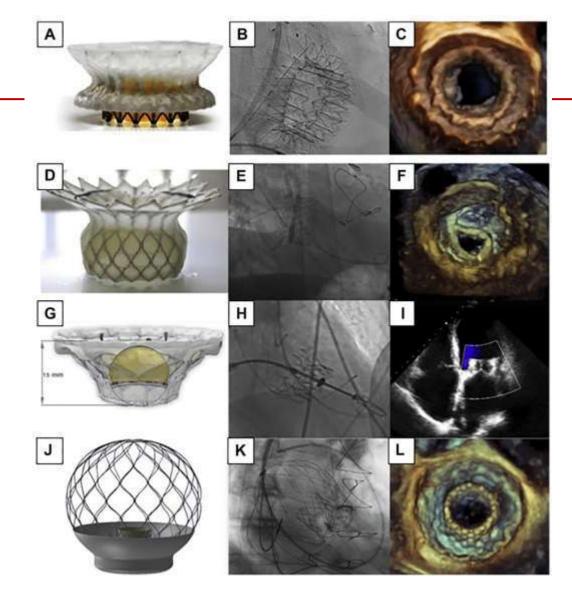




Ospedale San Raffaele

#### **TMVR**



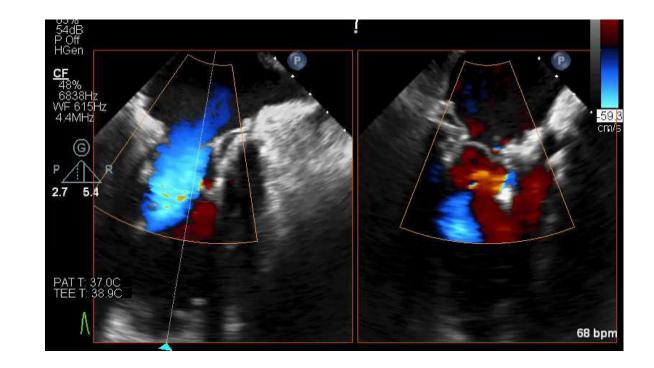






#### open issues for TMVR

- anatomical eligibility (LVOT, calcifications, size)
- timing and patient selection
- risk of the procedure
- risk of PVL, LVOTO, BAV III
- durability
- revalvability (?)
- reproducibility of results in inexperienced hands

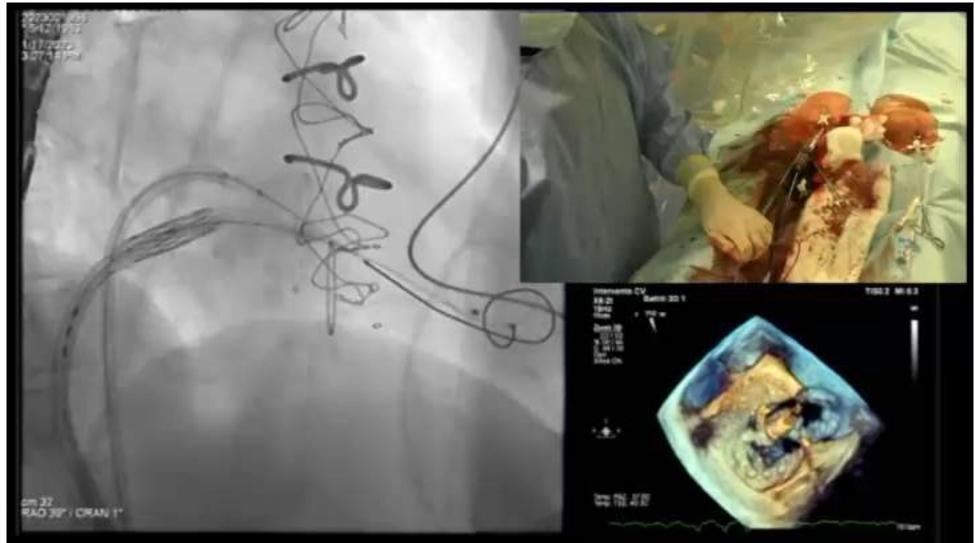






## electrosurgery a Sapien 3 ViV crossing the mitral

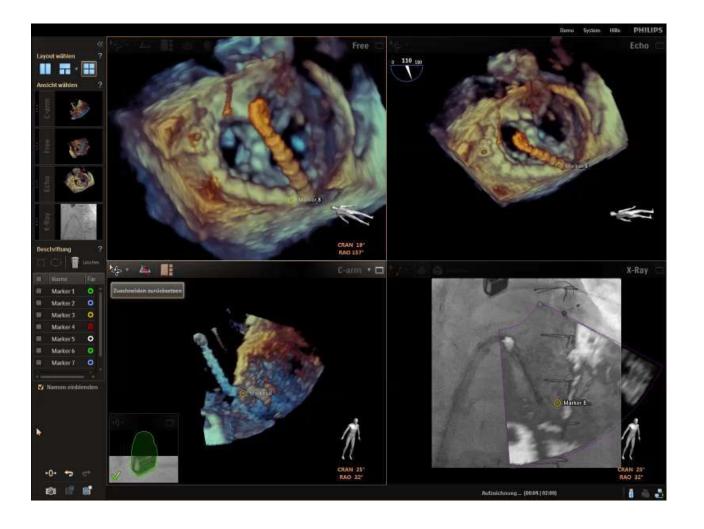
valve after anterior leaflet management (BATMAN)





# With the right instruments and the right imaging anything is possible.....











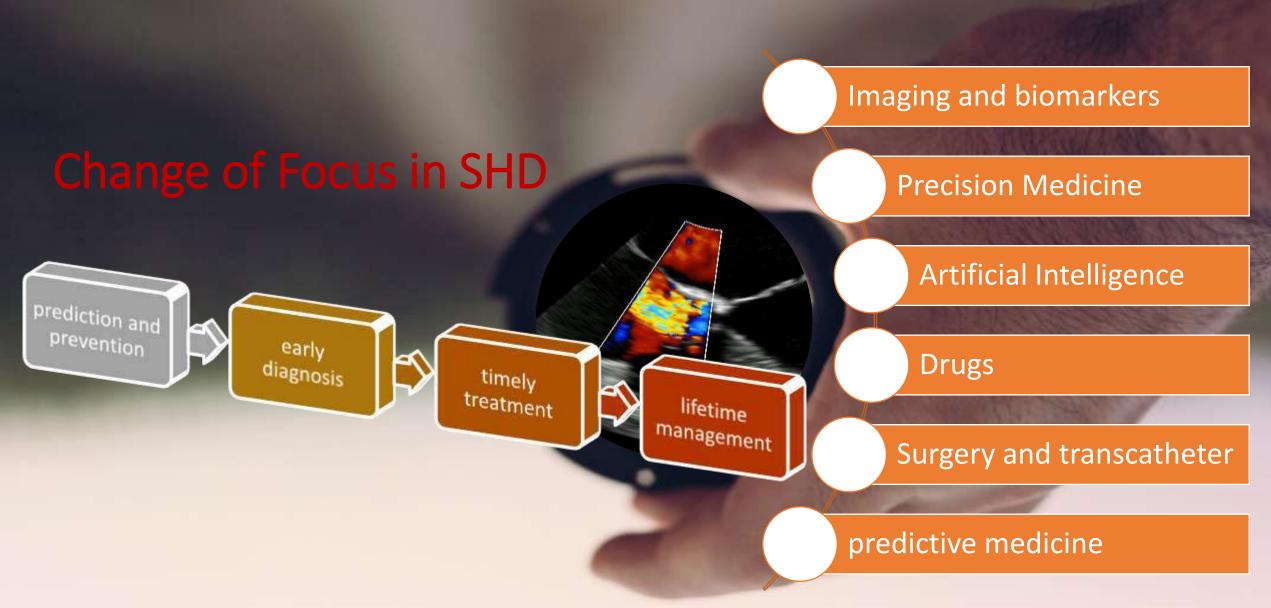
Versatile for functional and degenerative

Applicable to mitral and tricuspid

Highest safety profile in MV interventions

Available off the shelf, and requires minimal planning

Information contained herein for distribution outside the U.S. only. Check the regulatory status of the device before distribution in areas where CE marking is not the regulation in force.



from index procedure to patient-centered lifetime management