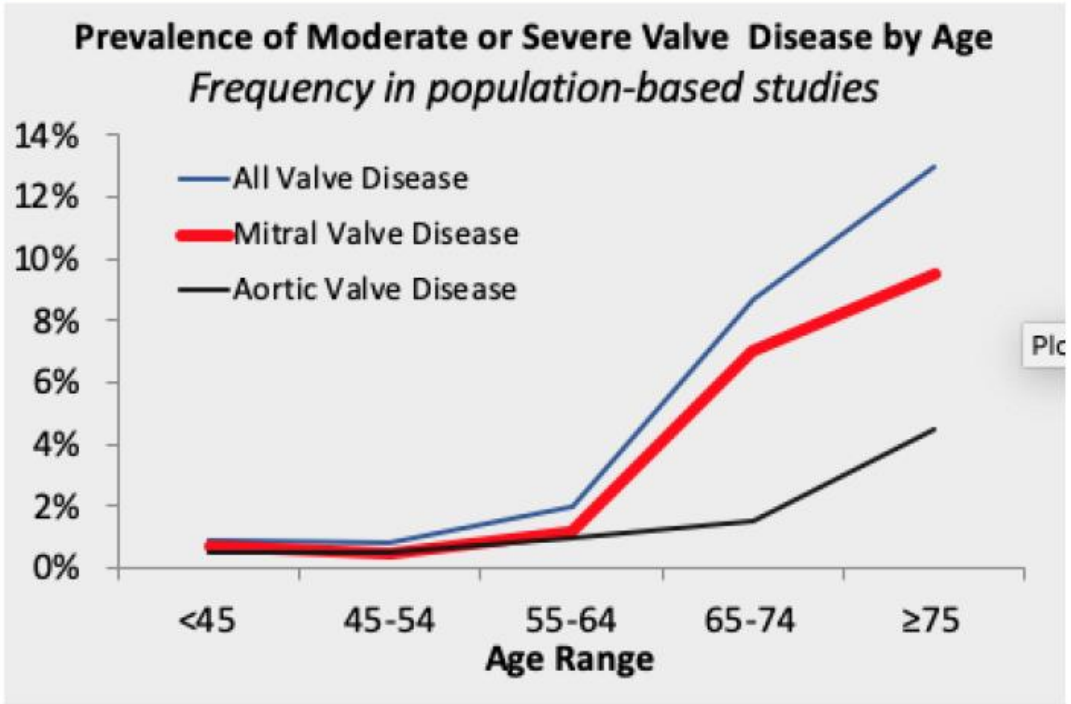
Traitement percutané des Valves Mitrales
Remplacer ou réparer

Emmanuel TEIGER

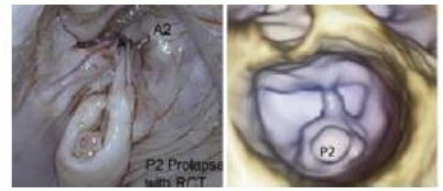
CardioConnect 15 Octobre 2022

Management of Mitral Regurgitation
MR is Highly Prevalent and Heterogeneous Disease

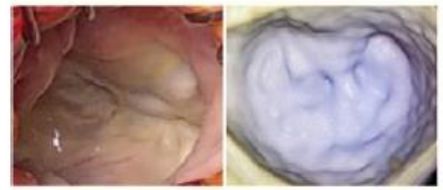
Prevalence of MR[1]



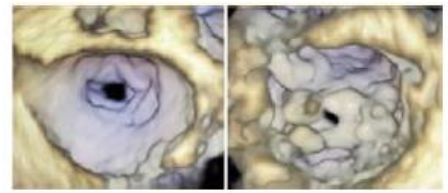
Examples of Mitral Valve Pathoanatomic Heterogeneity[2]



P2 prolapse with RCT (Type II)

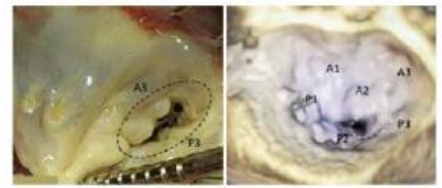


Annular dilation (Type I)

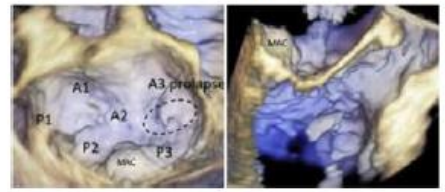


Rheumatic MS (Type IIIA)

Commissural prolapse



Restricted Posterior Leaflet (Type IIIB)

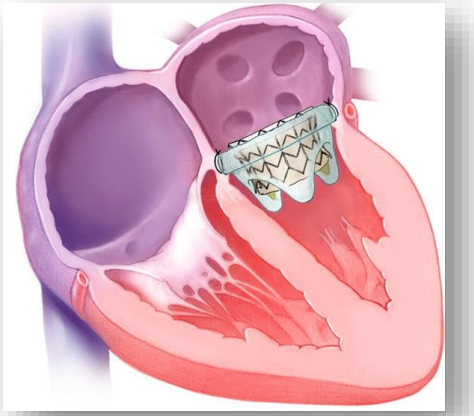


Mixed (A3 prolapse + MAC + restricted posterior leaflet)

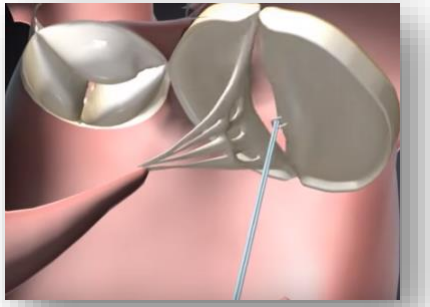
CRF TVT

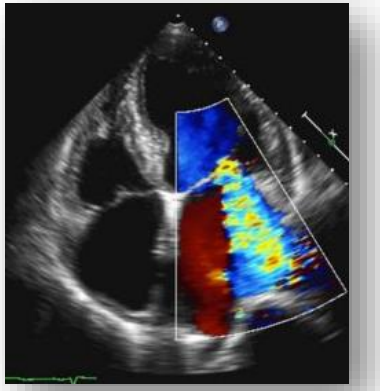
[1]Nkomo, et. al. , Lancet 2006; 368: 1005-11.
[2]Gheorghe, et al., JACC Card. Imag. 2021; 14: 112-127

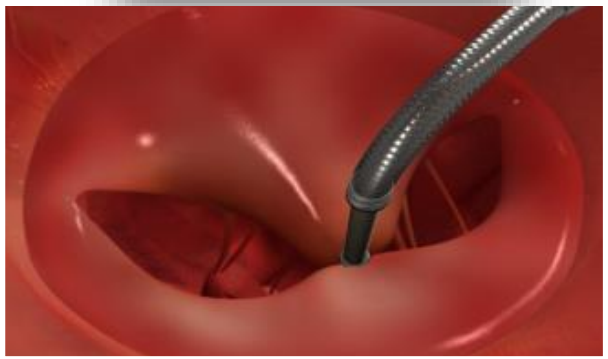
Les stratégies



ViR
Valve in MAC
ViV
Prothèse dédiée
directe
indirecte
Annuloplastie
TMVI
Fuite mitrale
Néocordage
clip

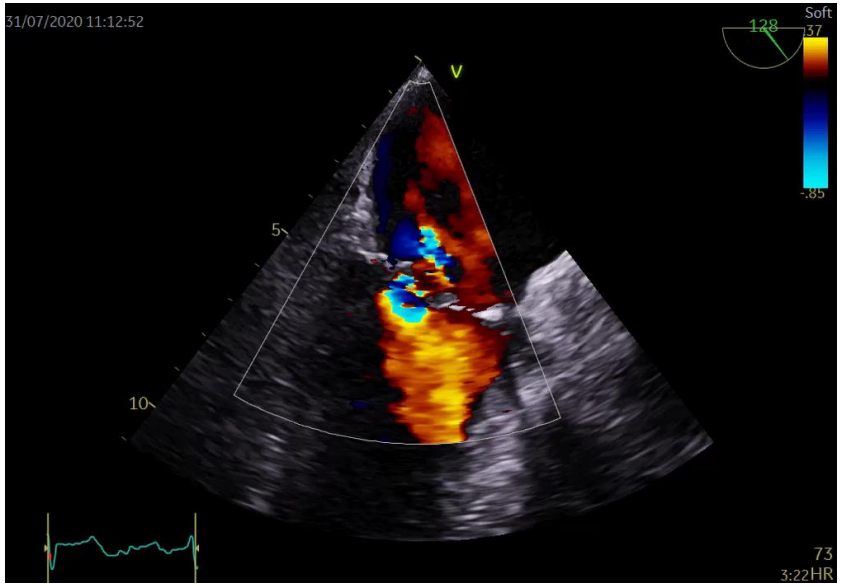


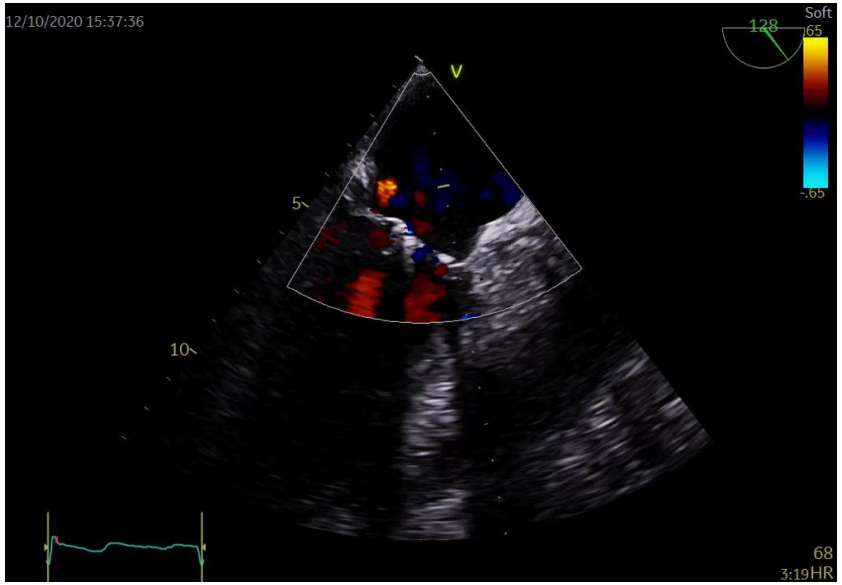




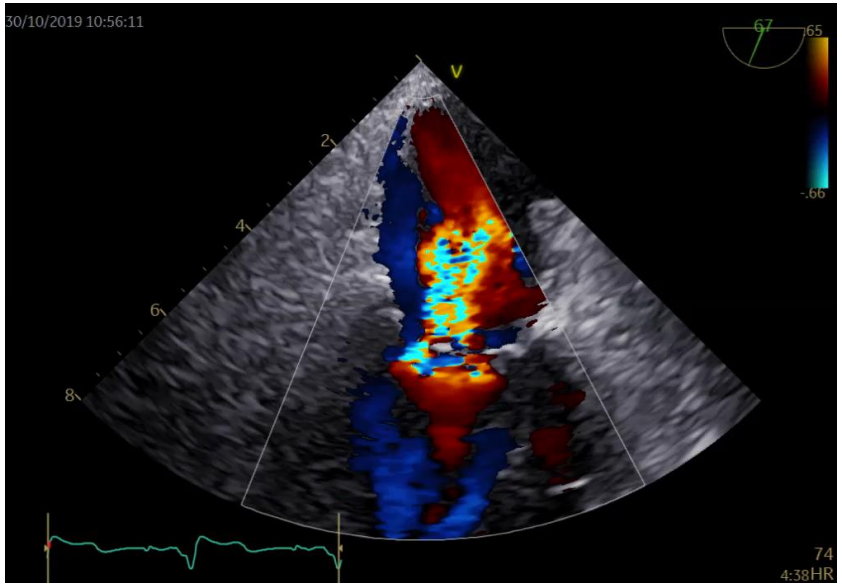
Exemples

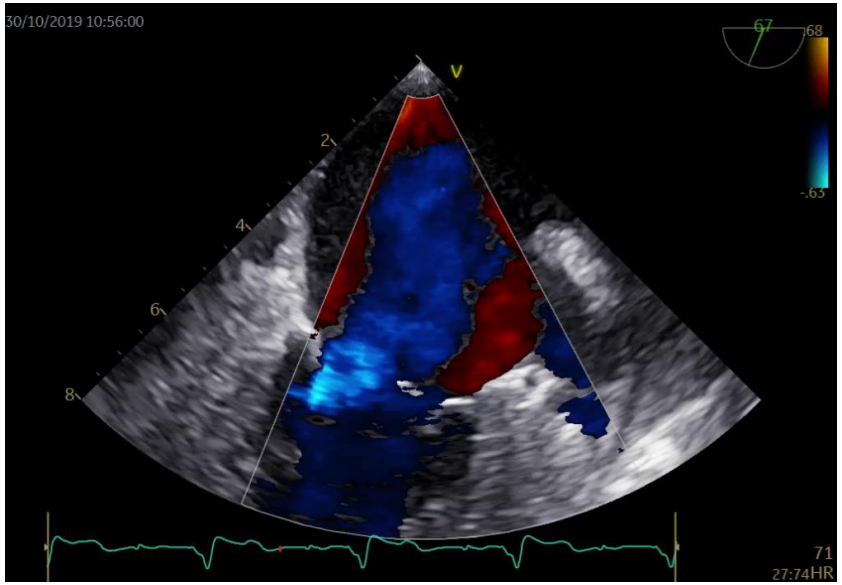
IM organique





IM secondaire





HAUTE AUTORITÉ DE SANTÉ

Patients avec insuffisance mitrale sévère, d'origine dégénérative, symptomatique malgré une prise en charge médicale optimale, non éligibles à la chirurgie de réparation ou de remplacement valvulaire et répondant aux critères échocardiographiques d'éligibilité. Tous ces critères et en particulier la contre-indication chirurgicale doivent être validés par une équipe multidisciplinaire *ad hoc*.

ESC European Society of Cardiology

European Heart Journal (2017) **38**, 2739–2791
doi:10.1093/eurheartj/ehx391

Indications for intervention in severe primary mitral regurgitation

Percutaneous edge-to-edge procedure may be considered in patients with symptomatic severe primary mitral regurgitation who fulfil the echocardiographic criteria of eligibility and are judged inoperable or at high surgical risk by the Heart Team, avoiding futility.	IIb

Indications for mitral valve intervention in chronic secondary mitral regurgitation[a]

When revascularization is not indicated and surgical risk is not low, a percutaneous edge-to-edge procedure may be considered in patients with severe secondary mitral regurgitation and LVEF >30% who remain symptomatic despite optimal medical management (including CRT if indicated) and who have a suitable valve morphology by echocardiography, avoiding futility.	IIb

HAUTE AUTORITÉ DE SANTÉ

Patients avec une insuffisance mitrale secondaire de grade 3+/4+ symptomatique malgré une prise en charge médicale optimale et remplissant les critères suivants :

- non éligibles à la chirurgie de réparation ou de remplacement valvulaire,
- ayant eu une hospitalisation pour insuffisance cardiaque dans les 12 mois précédant l'intervention,
- ayant une fraction d'éjection ventriculaire gauche comprise entre 20 et 50%,
- et une surface de l'orifice régurgitant > 0,3 cm² et un volume télédiastolique indexé du ventricule gauche ≤ 96 mL/m².

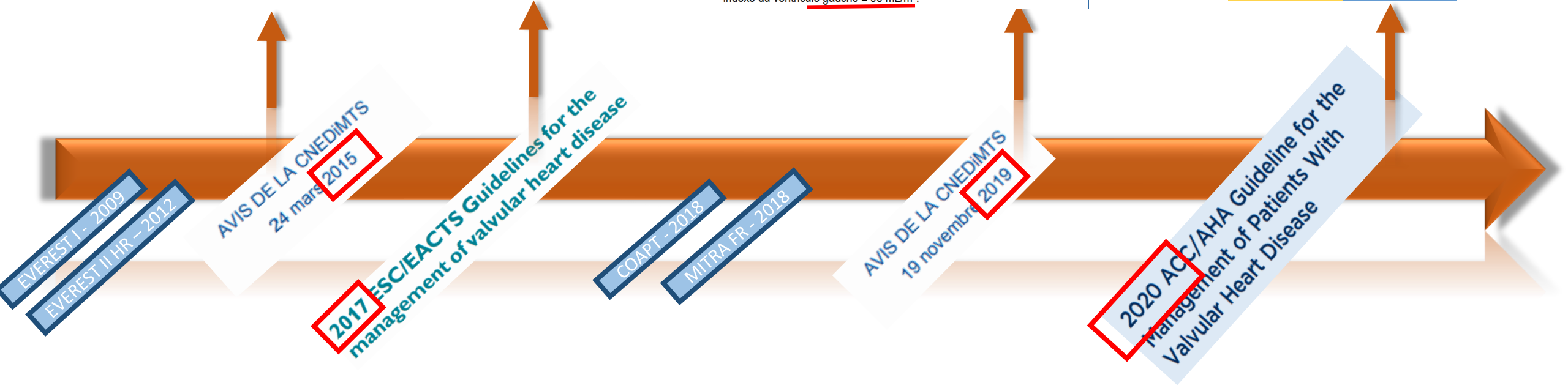
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY

PUBLISHED BY ELSEVIER

6. In severely symptomatic patients (NYHA class III or IV) with primary severe MR and high or prohibitive surgical risk, transcatheter edge-to-edge repair (TEER) is reasonable if mitral valve anatomy is favorable for the repair procedure and patient life expectancy is at least 1 year (17,18).

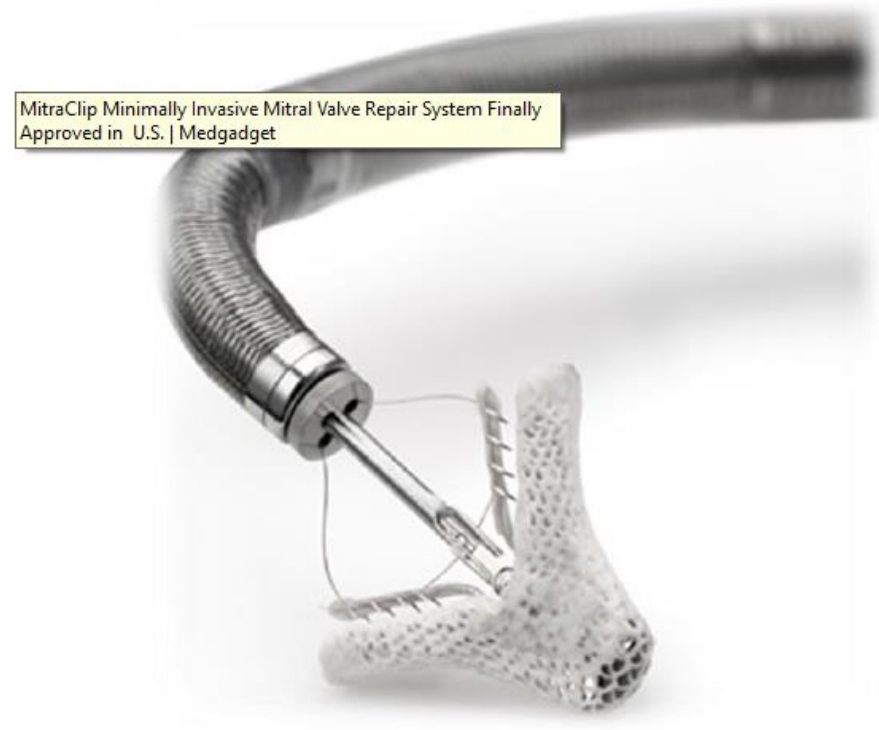
1. In patients with chronic severe secondary MR related to LV systolic dysfunction (LVEF <50%) who have persistent symptoms (NYHA class II, III, or IV) while on optimal GDMT for HF (Stage D), TEER is reasonable in patients with appropriate anatomy as defined on TEE and with LVEF between 20% and 50%, LVESD ≤70 mm, and pulmonary artery systolic pressure ≤70 mm Hg (1-8).

2a	B-NR



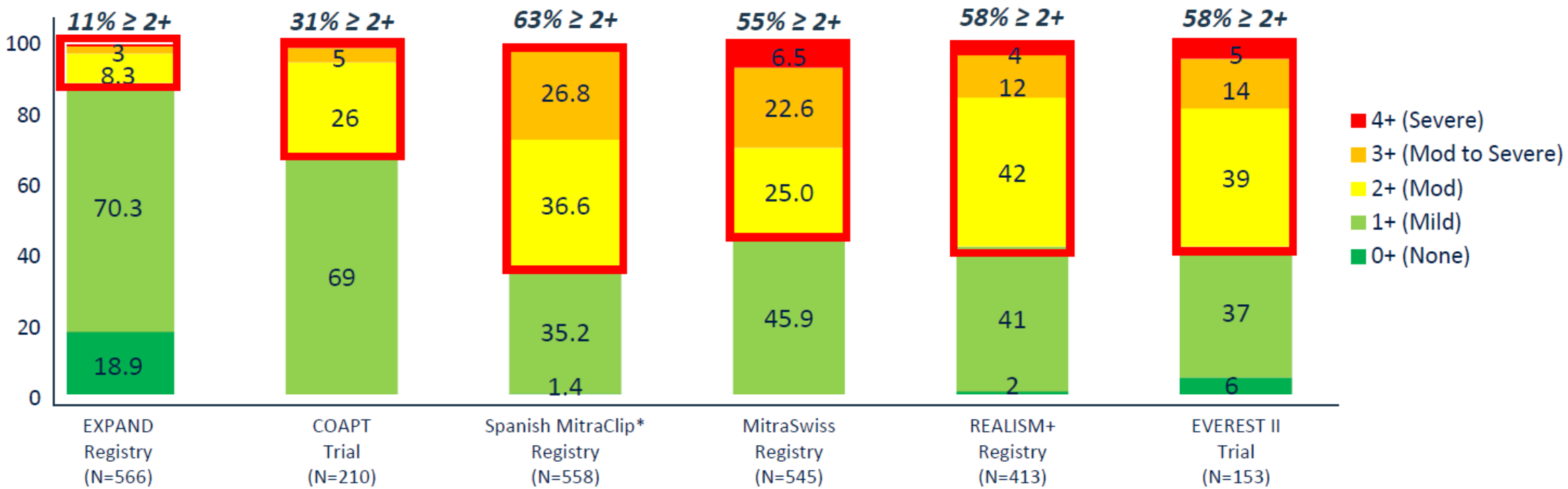
Challenges with the MitraClip

- Anatomic Challenges
  - Leaflet pathology – calcium, clefts
  - Small valve area
  - Leaflet tethering
  - Broad jets
- Residual MR
- Residual Stenosis
- Recurrent MR
- Durability



Many TEER patients do not achieve MR grade ≤ 1+ [1-5]

Mitral Regurgitation at 1 Year



Results are from different studies and are shown for illustrative purposes only. Results may differ in a head-to-head study.

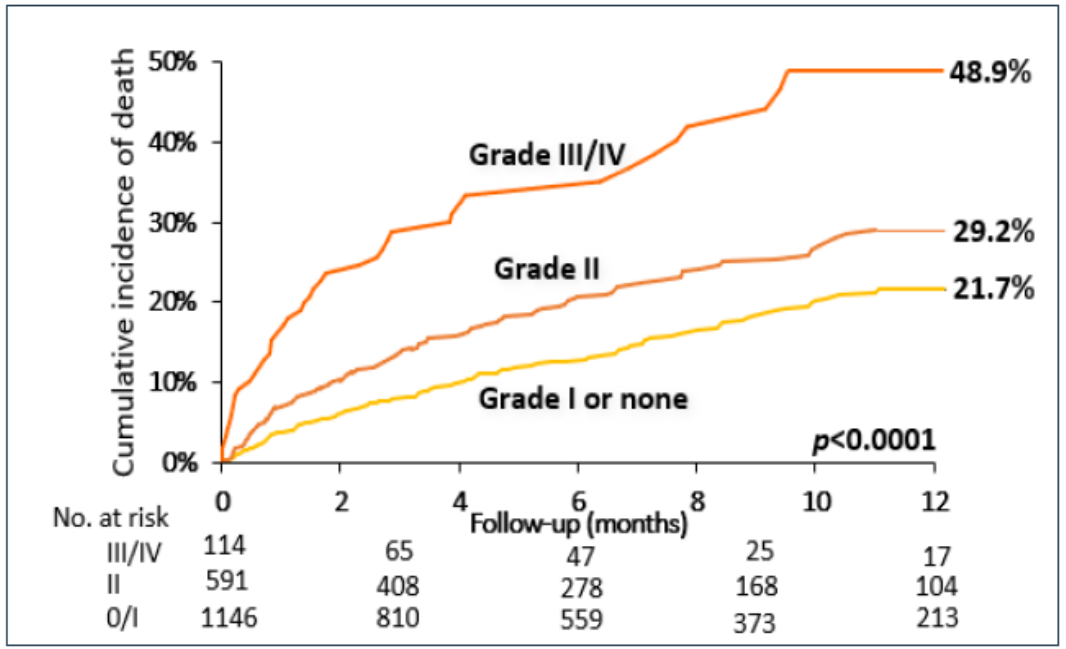
CRF TVT

[1]Kar, TCT 2020; [2]Lim EuroPCR 2020; [3]Pascual, et. al. Rev Esp Cardiol. 2020;73(8):643–651; [4]Surder, et. al. EuroIntervention. 2020;16(2):e112-e120; [4]Ailwadi, et. al. Circulation. 2019;139(1):37-47; [5]Feldman, et. al. J Am Coll Cardiol 2015;66: 2844-54 ; * Baseline patient numbers used for 1 year data.

Residual MR is Associated with Increased Risk of Mortality and Heart Failure Hospitalization

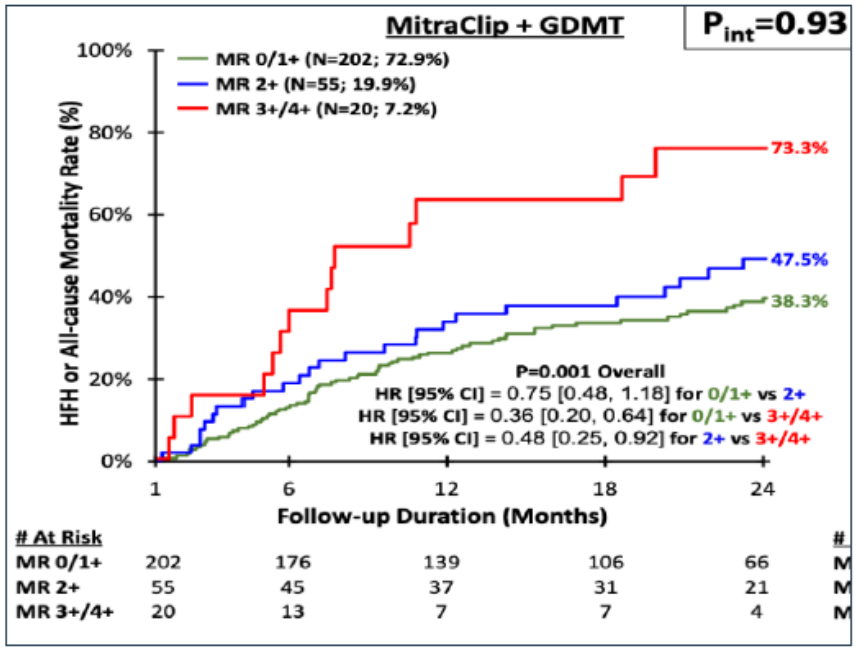
Primary MR

STS / ACC TVT Registry (US)[1]



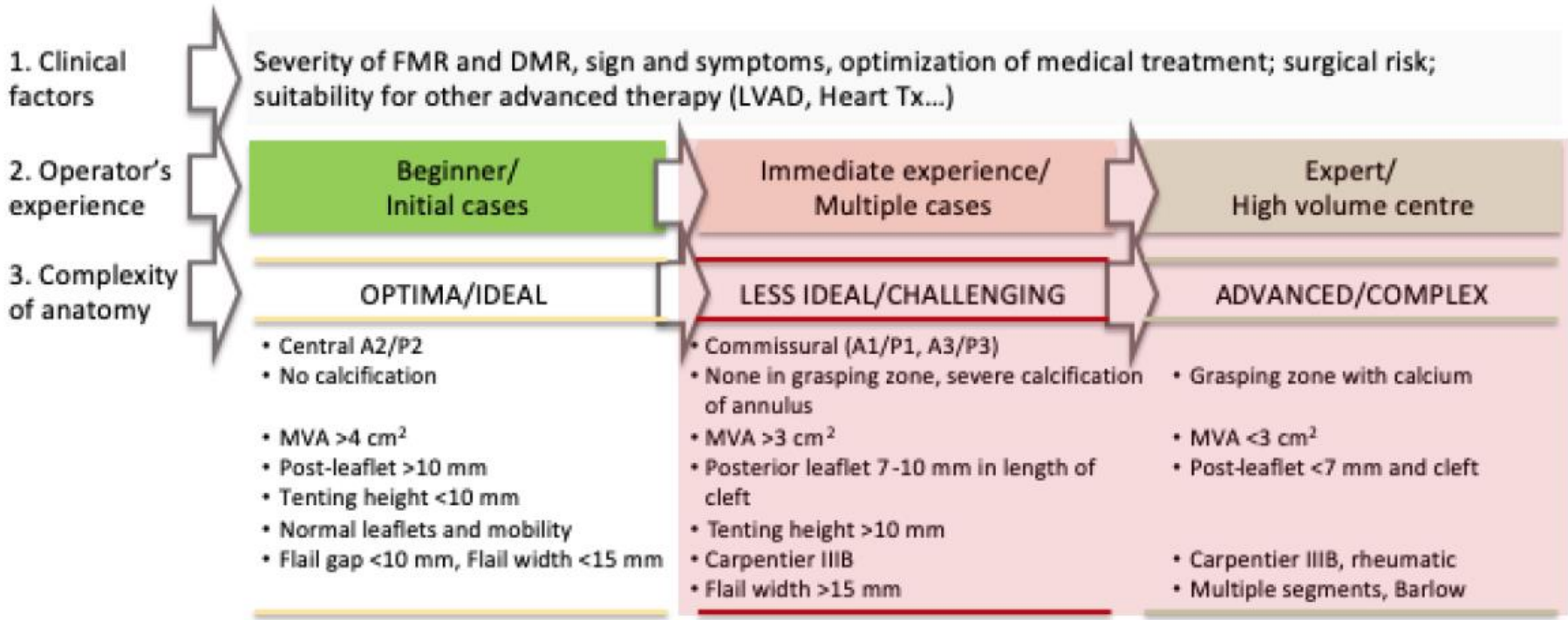
Secondary MR

COAPT Clinical Trial (Device Arm)[2]



[1] Sorajja et. al. J Am Coll Cardiol. 2017; 70(19):2315-27
[2] Presented by Saibal Kar, Relationship between Residual Mitral Regurgitation and Clinical and Functional Outcomes in the COAPT Trial, EuroPCR 2019

Patient Selection
Anatomical Suitability for TEER

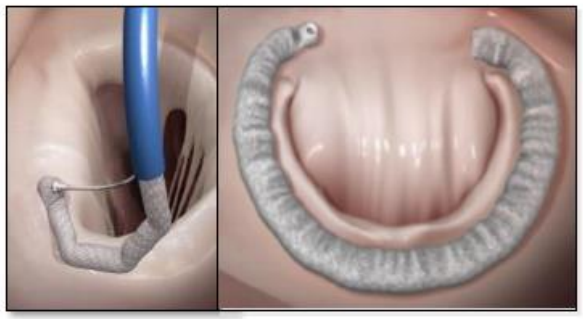


Reproduced from Gavazzoni et al., Eur Heart J Cardiovasc Imaging (2020). DOI: 10.1093/ehjci/jeaa062.

Expanding portfolio of transcatheter mitral repair and replacement

NeoChord

Harpoon



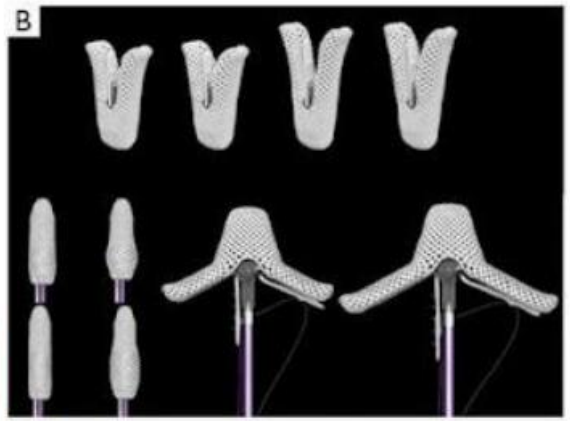
Cardioband

Chordal Replacement
NeoChord
Harpoon

Leaflet Repair
MitraClip
PASCAL

Combo procedures

Annuloplasty
Cardioband
Carillon

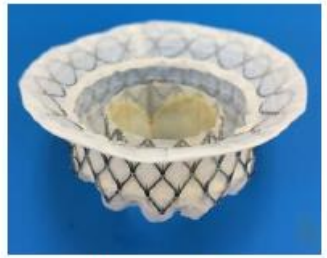


MitraClip XTR/W & NTR/W

PASCAL

Replacement
Tendyne, Intrepid, Tiara, Cardiovalve, HighLife, etc.

Tendyne

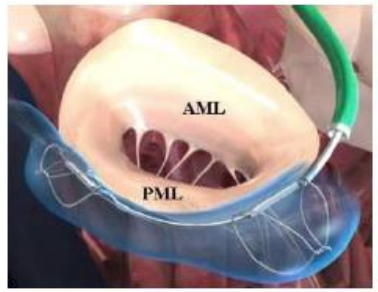


Intrepid

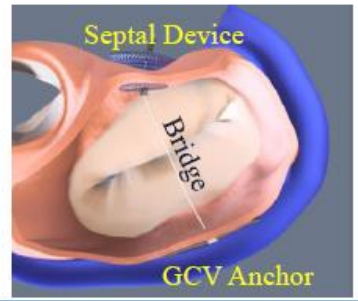
Annuloplasty Devices

* CE mark

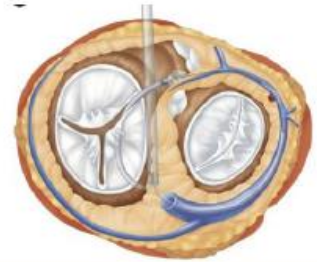
INDIRECT ANNULOPLASTY



Carillon*

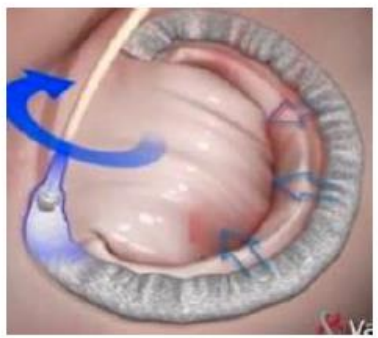


MVRx ARTO



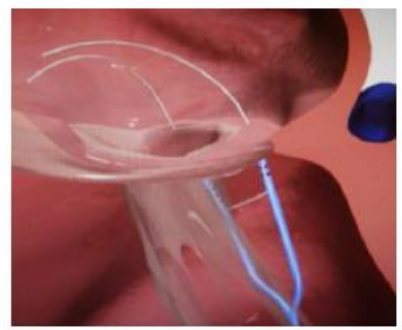
Mitral Loop Cerclage

DIRECT ANNULOPLASTY



Cardioband*

Millipede



Mitralign*

Valcare

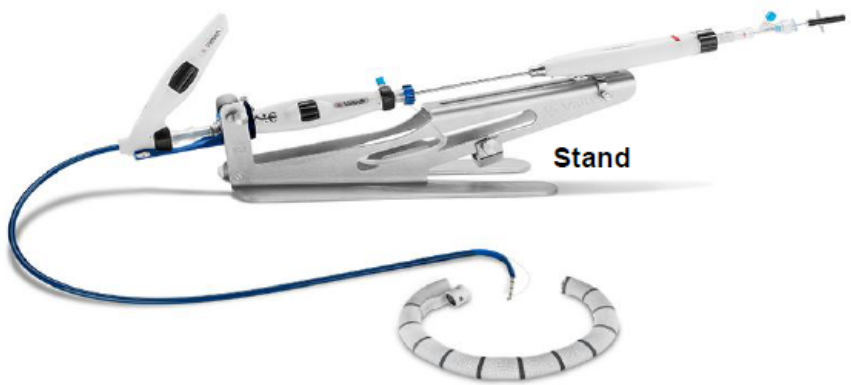
Valfix

AccuCinch

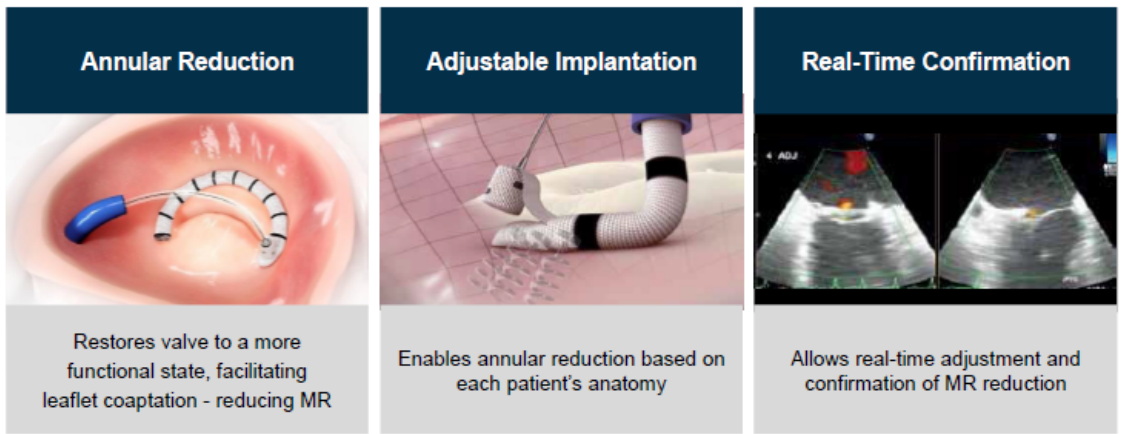
Edwards Cardioband

Semi-rigid posterior partial fully adjustable direct annuloplasty band with anchor cinching

Cardioband mitral delivery system



Cardioband mitral system implant



Points to Remember

- Transfemoral-transeptal delivery
- Posterior band that avoids aorto-mitral continuity
- CB sized based on anatomy
- Stepwise deployment & fully adjustable
- Preserves future treatment options
- Risk of coronary injury

Clinical Programme

Cardioband CE-mark Trial

- Prospective single-arm 60-pt study

MiBAND Trial

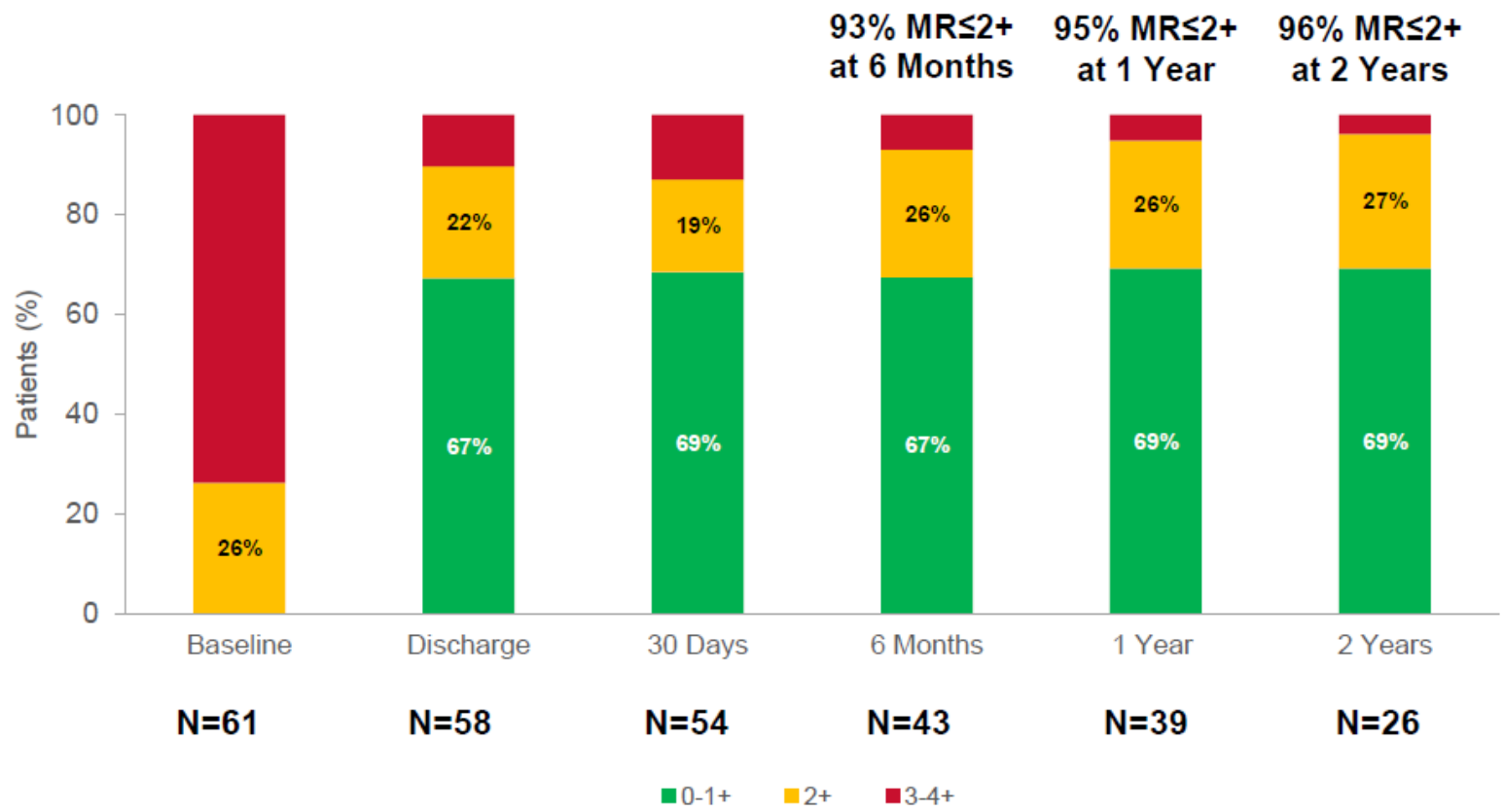
- Prospective multi-center single-arm post-market study

ACTIVE Trial

- Randomized 2:1 against medical Rx

EINSTEIN Albert Einstein College of Medicine | Montefiore

MR Reduction Sustained at 2 Years[1]



[1]Core Lab - Dr. Paul Gravburn – Baylor University

A Toolbox or surgical-type approach to MR

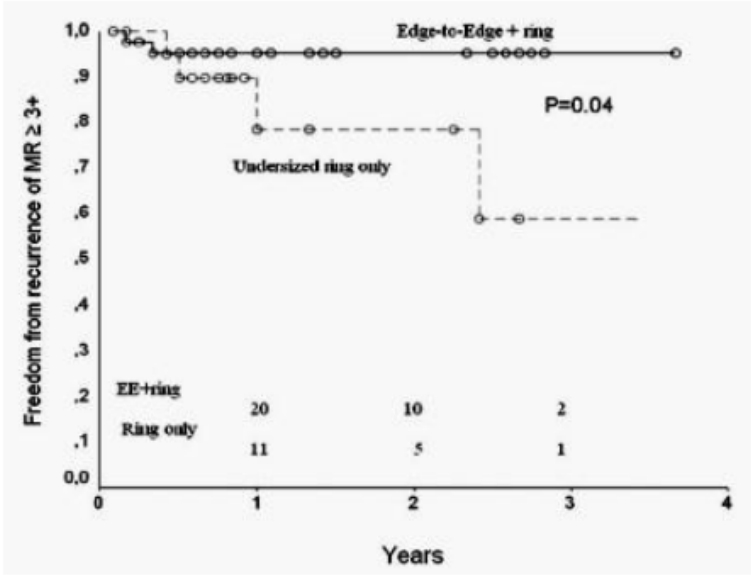
Combination of transcatheter Leaflet repair & Annnuloplasty

- Improve long term durability
- Improve MR reduction in FMR and DMR

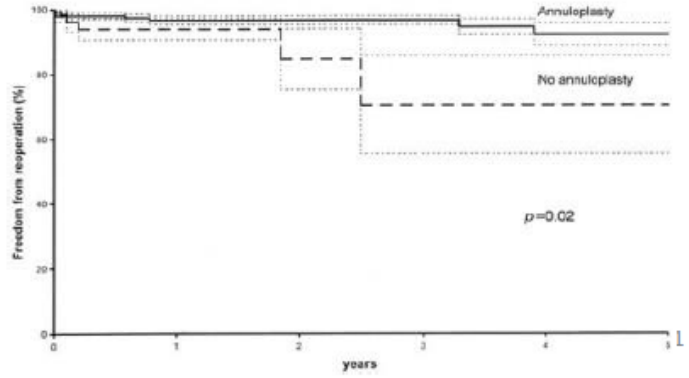
Table 4 Unfavourable anatomical conditions for percutaneous edge-to-edge repair

Commissural lesions
Short posterior leaflet
Severe asymmetric tethering
Calcification in the grasping area
Severe annular calcification
Cleft
Severe annular dilatation
Severe left ventricular remodelling
Large (>50%) inter-commissural extension of regurgitant jet
Severe myxomatous degeneration with multi-scallop prolapse

De Bonis et al. Eur Heart J. 2016;37:133-139



De Bonis et al. Circulation 2005;112[suppl I]:I 402-I408

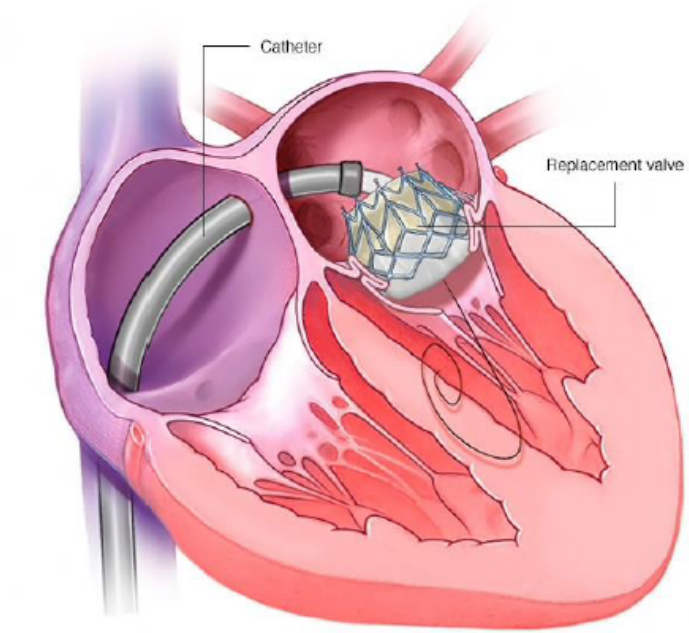


Maisano et al JTCVS 2003

EINSTEIN | Montefior

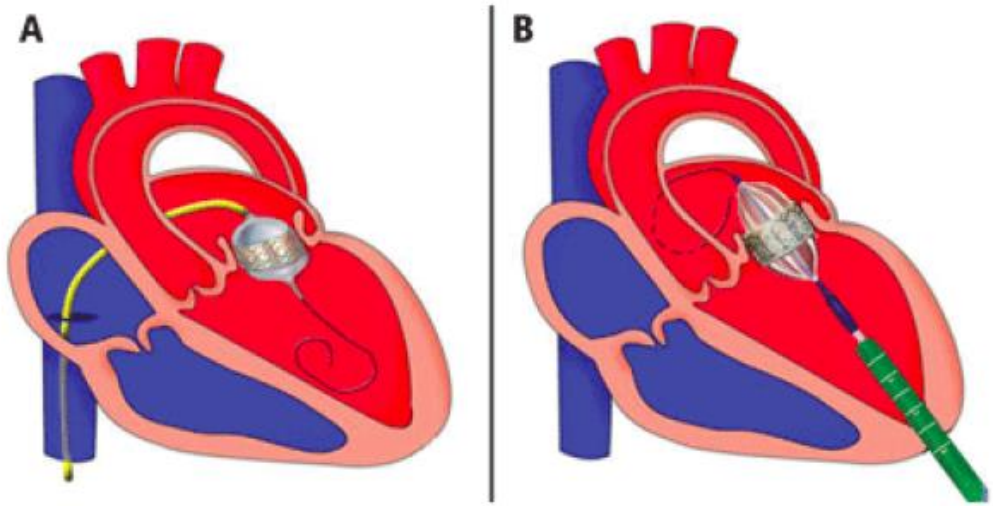
Transcatheter mitral replacement vs repair?

- **More durable reduction in MR**
  - Residual MR following therapy affects survival
  - Residual MR in MitraFR: 17% had ≥3+ MR at 12 mos
  - Residual MR in COAPT: 31% had ≥2+ MR at 12 mos
- **Fewer anatomic and clinical exclusions**
  - Able to treat small valves, MAC, multiple jets and perforations
  - Some devices able to treat mitral stenosis
  - Exclusions of those considered for COAPT ~ 58%
- **Reproducible procedural success**
  - Encouraging data with regards to feasibility and safety with a variety of devices



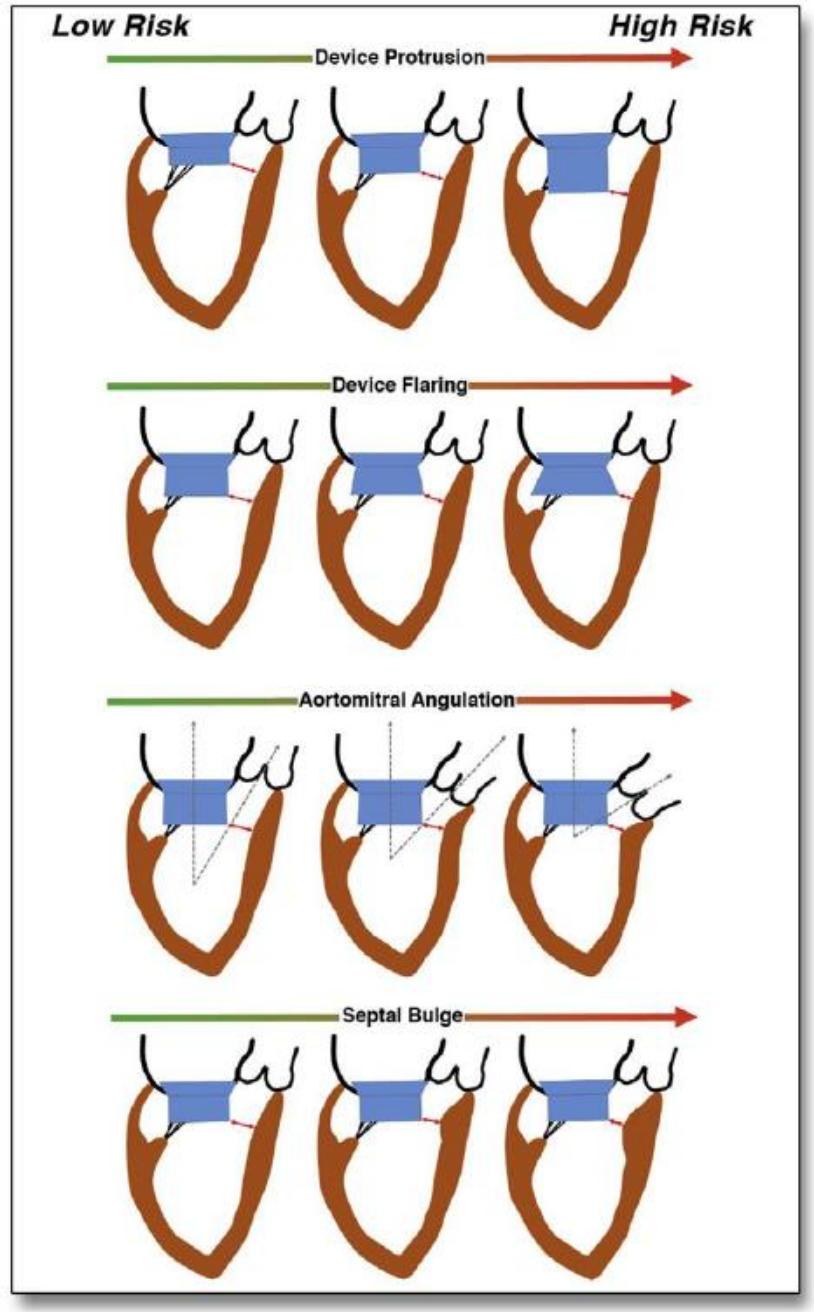
Transcatheter Mitral Valve Challenges

- Transapical
  - Large sheaths
  - Direct injury to myocardium
  - Bleeding complications
  - Respiratory compromise from thoracotomy
- Trans-septal
  - Large device & sheath
  - Risk of venous injury
  - Large iASD
  - Septal crossing and turning can be challenging
  - Left ventricular size
  - Coaxial position for deployment
  - Does the iatrogenic ASD need to be closed?
- Orientation of the valve
  - Mimic D shape of native annulus



Risk Factors for LVOT Obstruction

- Small LVOT-diameter
- Septal bulge
- Larger Aorto-mitral angle
- Device protrusion into LV
- Device flaring
- Remaining systolic function

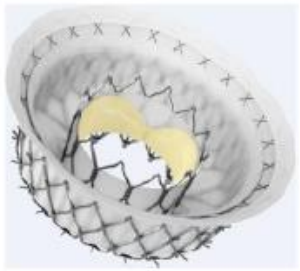


Blanke P et al JACC: Cardiovascular Imaging 2016

TMVR Devices

EVOQUE
Edwards

Sapien M3
Edwards



Intrepid
Medtronic

CardioValve
Venus Medtech

Tendyne
Abbott

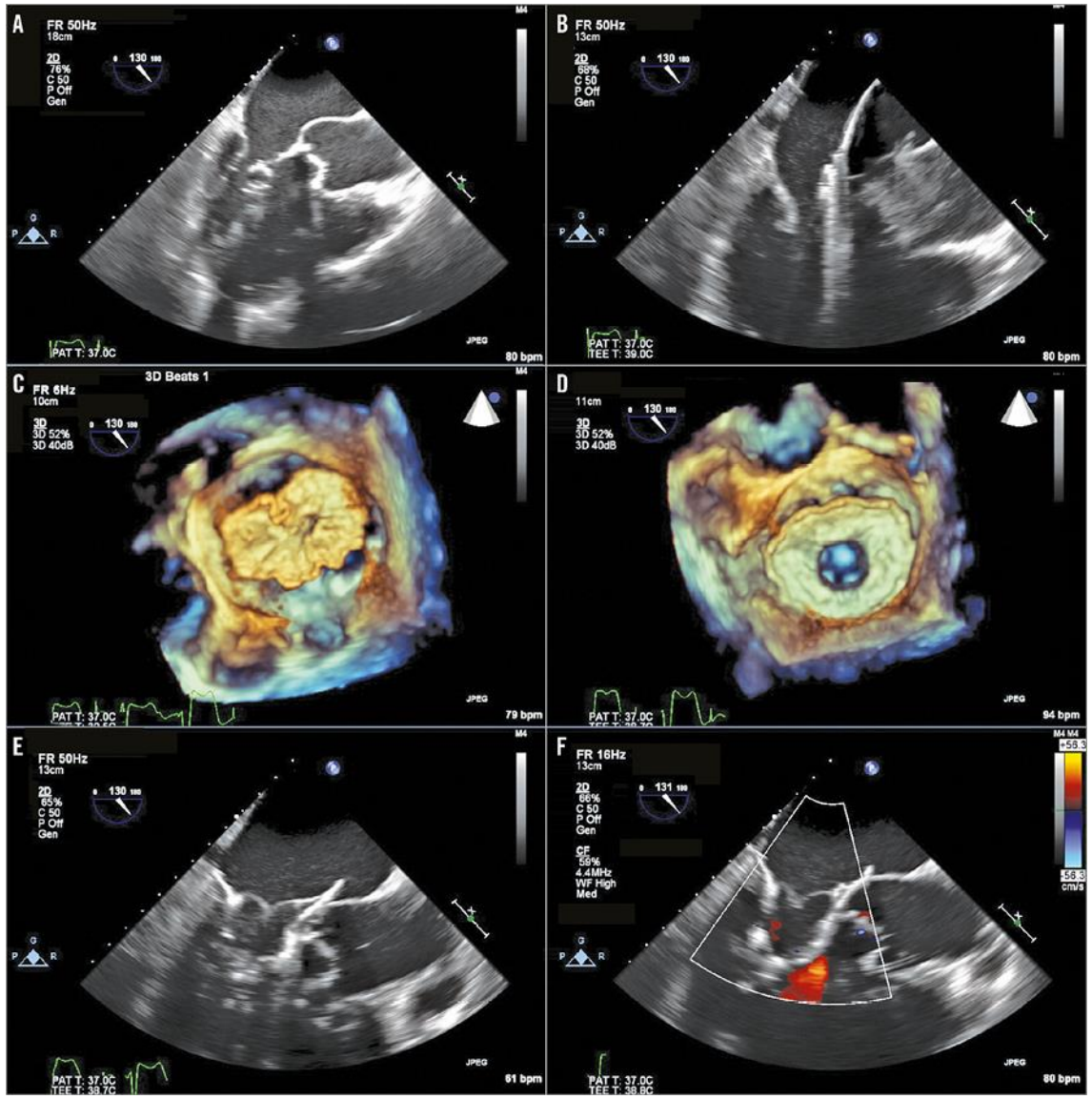
CEPHEA
Abbott

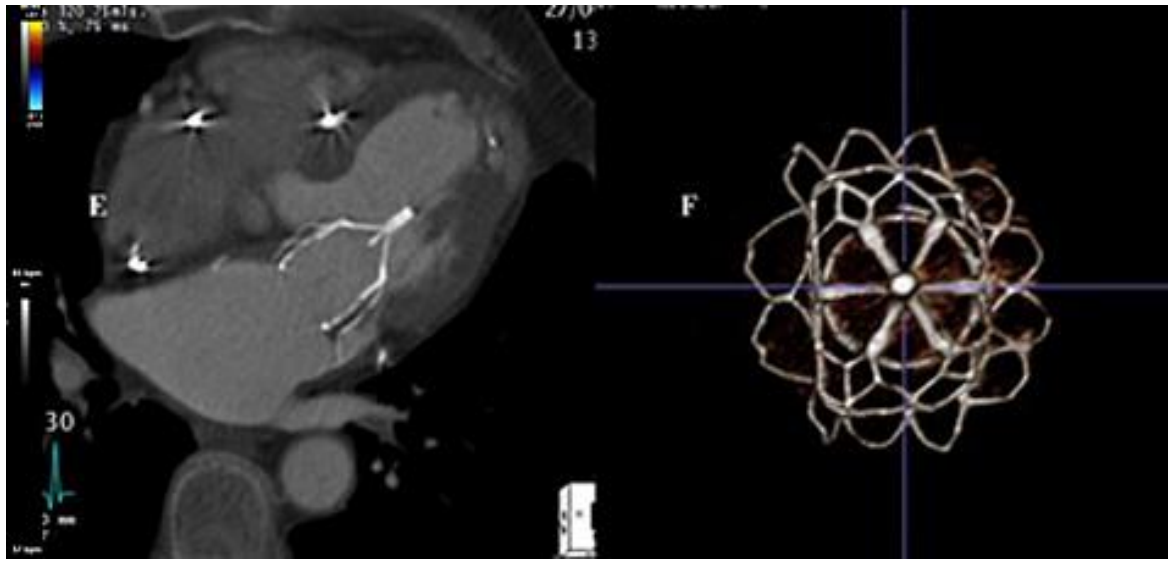
AltaValve
4C Medical

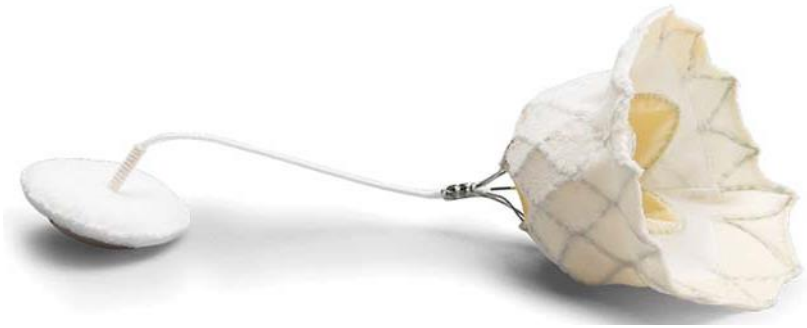
HighLife
HighLife Medical

Tiara
Neovasc

Remplacement: Tendyne



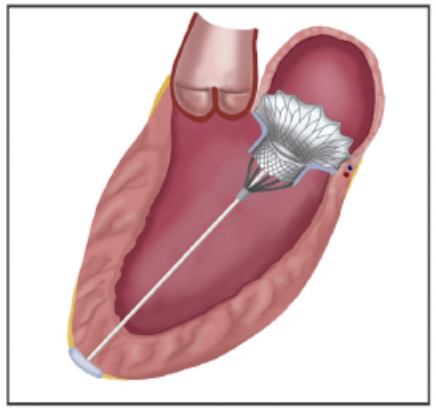




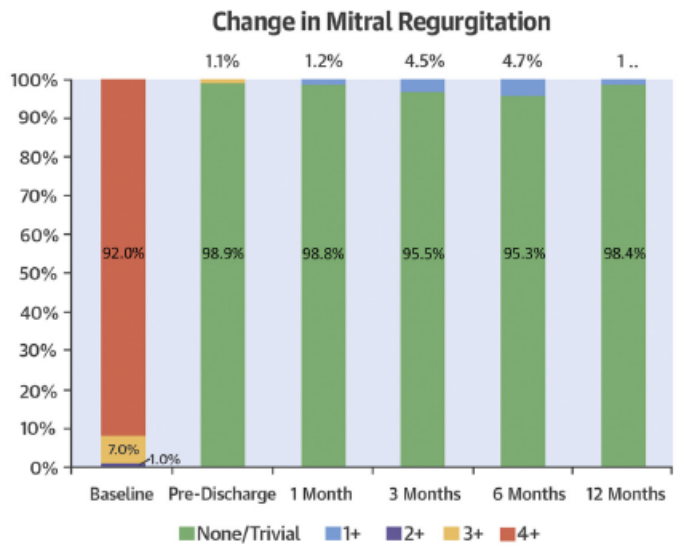
Remplacement: Tendyne

CENTRAL ILLUSTRATION Clinical Outcomes With Transcatheter Mitral Valve Replacement With the Prosthesis

First 100 Patients Treated

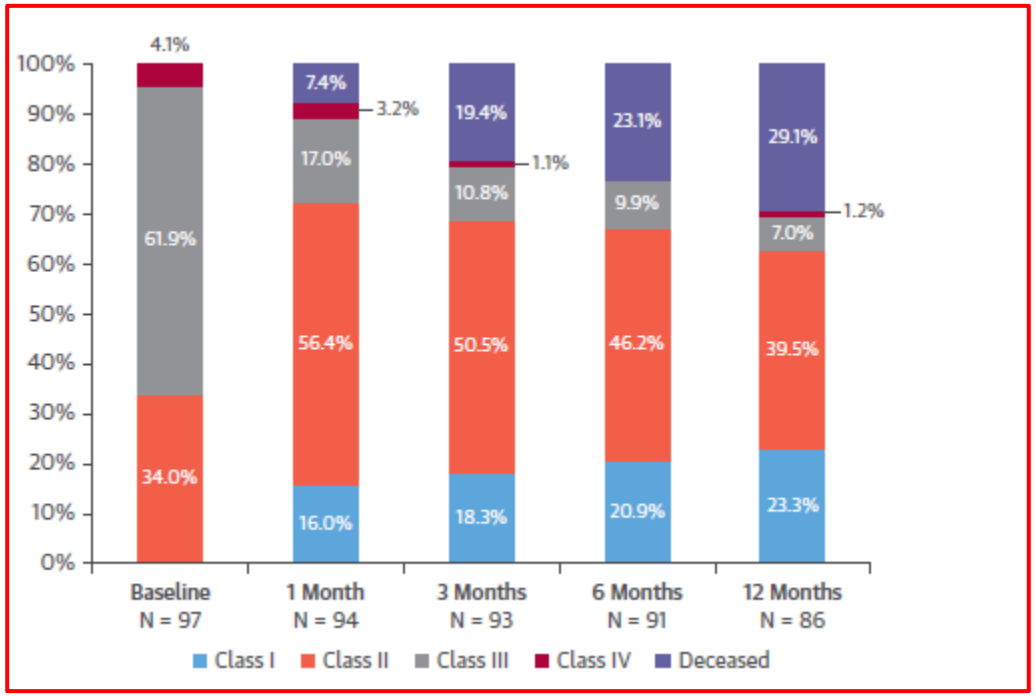


- No intra-procedural deaths
- Technical success in 96%
- 30-day death, 6%; 1-year mortality, 26%
- Among survivors at 1 year, 88.5% with mild or no symptoms



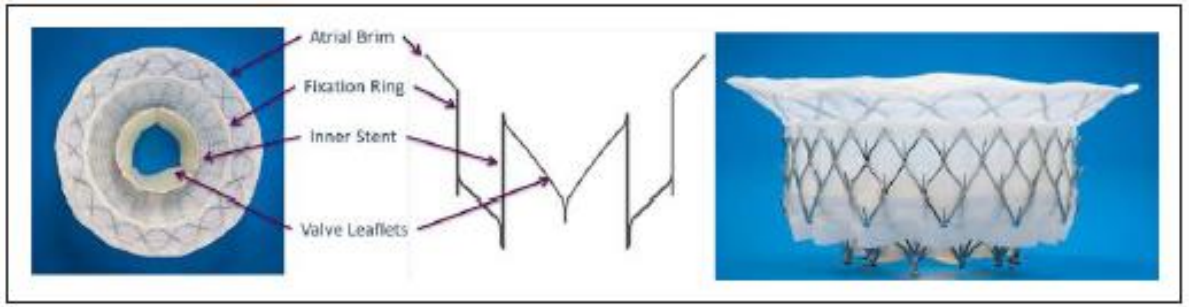
Sorajja, P. et al. J Am Coll Cardiol. 2019;73(11):1250-60.

(Left) The Tendyne prosthesis. **(Right)** Changes in mitral regurgitation at baseline and after treatment with the prosthesis. Severity of mitral regurgitation was determined in a core echocardiography laboratory at baseline and through 12-month follow-up for survivors.



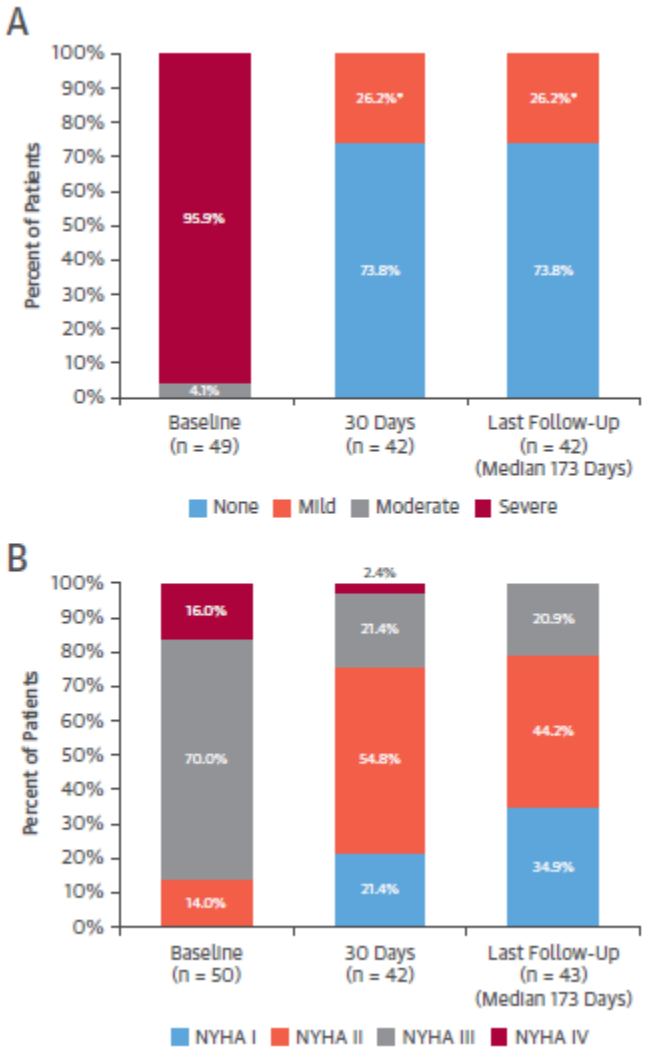
Tendyne: 100 cas Transapical

Remplacement: Intrepid



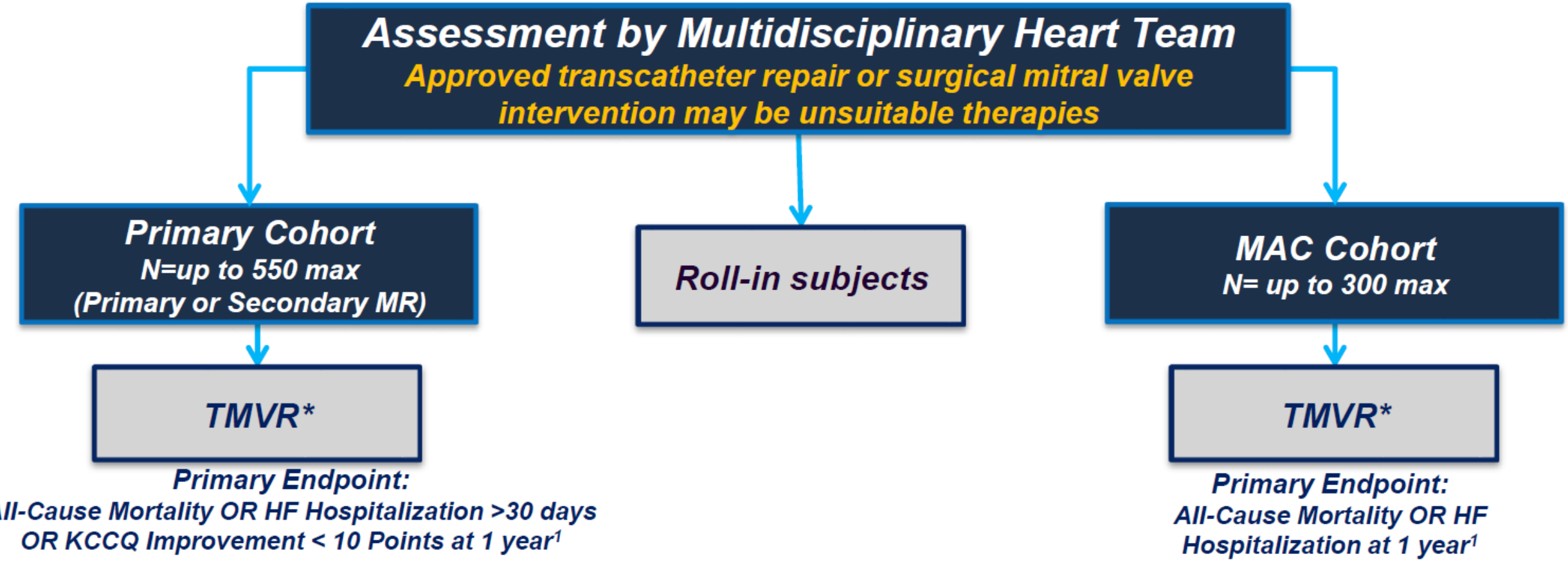
STS predicted risk of mortality for mitral replacement, %	6.4 ± 5.5
EuroSCORE II, %	7.9 ± 6.2

Intrepid: 50 cas. Transapical



APOLLO Pivotal Trial

Investigating Both Transfemoral and Transapical Approaches

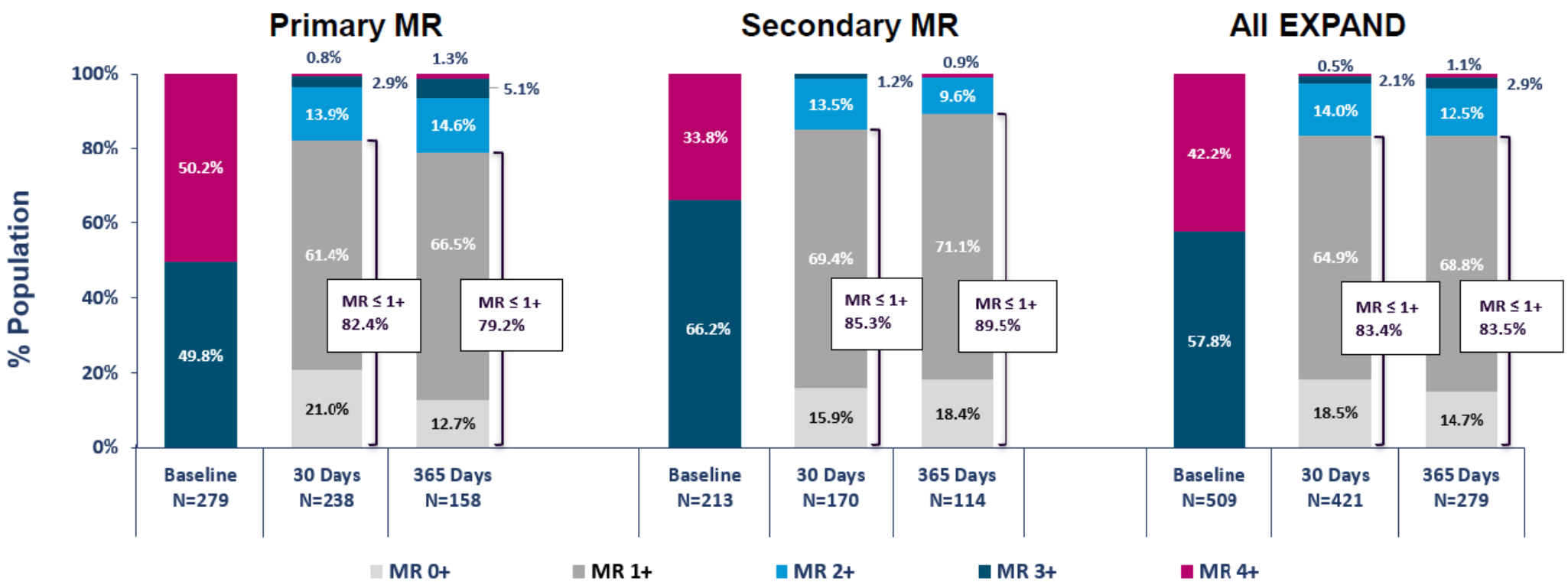


[1] Performance goal based on comparative literature

HIGHEST MR REDUCTION ACHIEVED WITH TMVr*

83.5% MR ≤ 1+ AT 1 YEAR IN SUBJECTS WITH BASELINE MR ≥ 3+

ECL Adjudicated MR Severity by Etiology



*Reported to date

Kar S. Core-Lab Adjudicated Contemporary Clinical Outcomes at 1 Year with MitraClip™ (NTR/XTR) System from Global EXPAND Study. Data presented at TCT 2020.

TRANSFEMORAL APOLLO

Expanding Patient Access with a Less Invasive Therapy

Intrepid Transfemoral System APOLLO Launch

>50% Sites Trained, Training Complete by June

APOLLO Study

Assessment by Multidisciplinary Heart Team

Approved transcatheter repair or surgical mitral valve interventions may be unsuitable therapies

- ***MR Cohort*** *(Primary or Secondary MR) N=250-550*
- ***Roll-in subjects***
- ***MAC Cohort*** *N = up to 300 max.*

35 Fr Intrepid Transfemoral System

CONCLUSION

- Les outils disponibles pour le traitement de la Mitrale sont en plein développement
- Nécessité de prise en charge dans des centres experts
- Le Mitraclip dans les bonnes formes donne de bons résultats
- Les formes plus complexes doivent donner lieu à des analyses fines
- Les valves percutanées utilisables par voie transeptale semblent prometteuses
- Les études d’évaluation des différentes stratégies sont en cours