Mitral Annular Calcification (MAC)

ICD Codes Proposal

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[Revised / updated for Sec. 508 accessibility]

Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

- Research Grant Support

Company

- Edwards Lifesciences

Research engagements

- Sponsor and Global PI
- Sponsor and National PI
- Steering Committee
- DSMB member
- National Co-PI
- National Co-PI
- National Co-PI

Clinical Trial

- TMVR in MAC Global Registry
- MITRAL EFS and MITRAL II Pivotal Trial
- SUMMIT Pivotal trial (Tendyne)
- SITRAL
- PARTNER 3 MViV
- ENCIRCLE Pivotal trial (SAPIEN M3)
- CardioMech

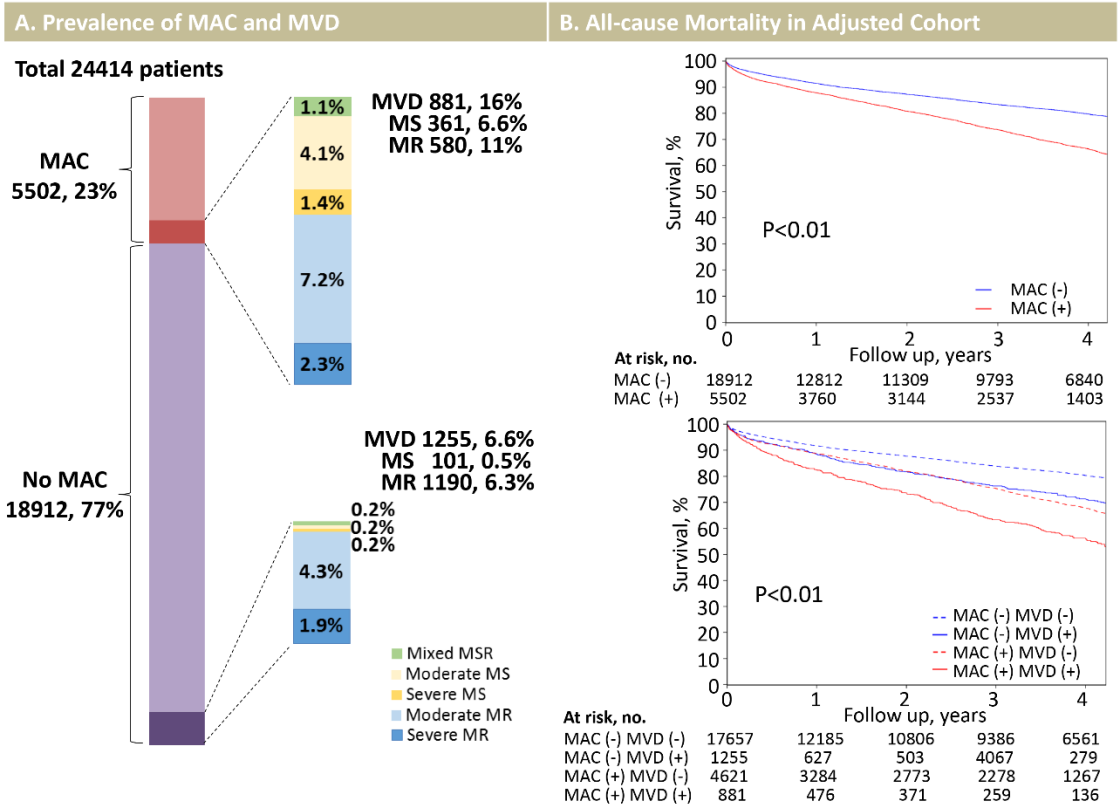
Learning Objectives

- To review prevalence and natural history of MAC.
- To describe early outcomes of TMVR in patients with MAC.
- To delineate ongoing clinical trials and the importance of ICD codes for MAC.

Prevalence of MAC

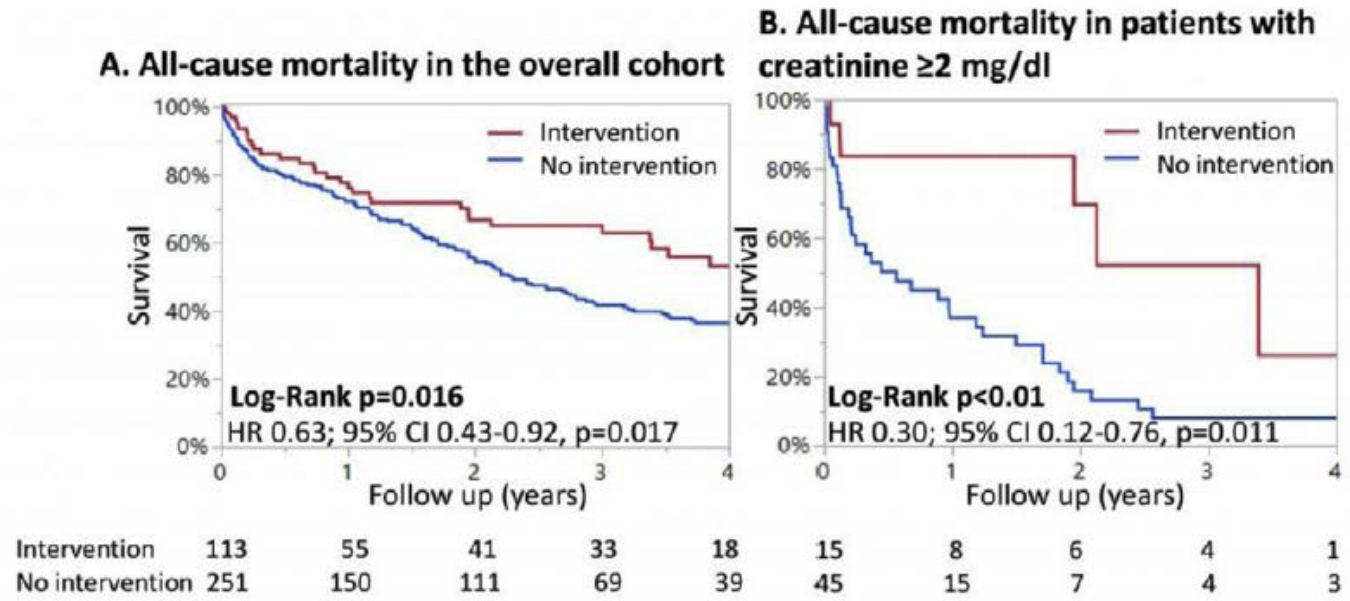
24,414 patients who had transthoracic echo at Mayo Clinic (Jan-Dec 2015)

23% had MAC



Impact of MV Intervention in MAC

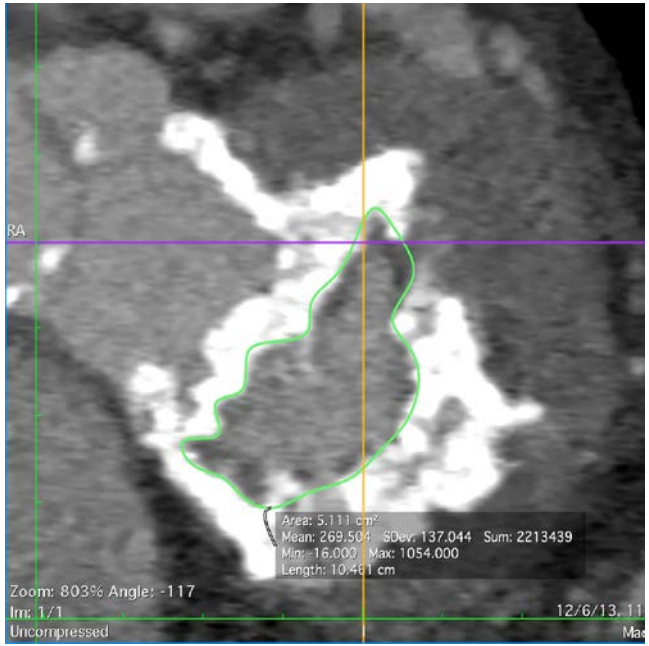
5,502 MAC patients, 364 had severe MV dysfunction.
MV intervention=113 (surgery-91, Transcatheter=22), Med Rx= 251)



HR: unadjusted hazard ratio (intervention vs. no intervention), CI: confidence interval

Mitral Annular Calcification (MAC)

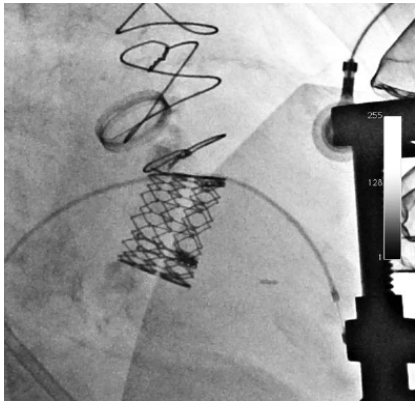
High Surgical Risk



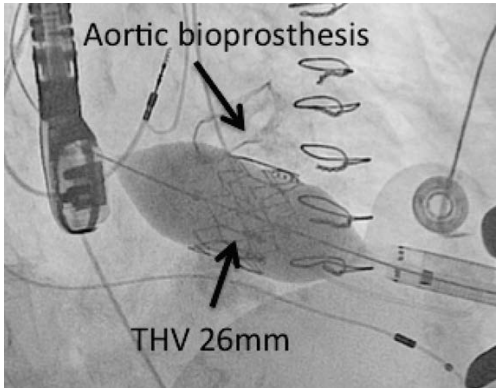
- Comorbidities increase risk
- Technically challenging
- Rupture of posterior wall of LV
- >20% mortality
- Many pts untreated due to risk

Casarotto et al, G Ital Cardiol 1977;7(4):387-94.
Goodney et al, *Ann Thorac Surg* 2003;76:1131-1136.
Vohra et al, *J Heart Valve Dis* 2011;20(6):624-6.

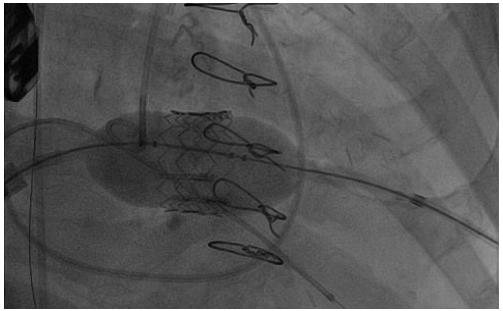
First Isolated Reports of SAPIEN in MAC



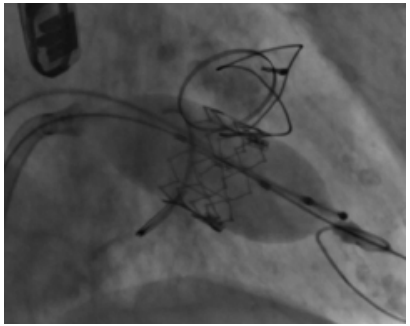
Hassan et al, *Circulation* 2013;128:e74-e76.



Sinning et al, *Eur Heart J* 2013.

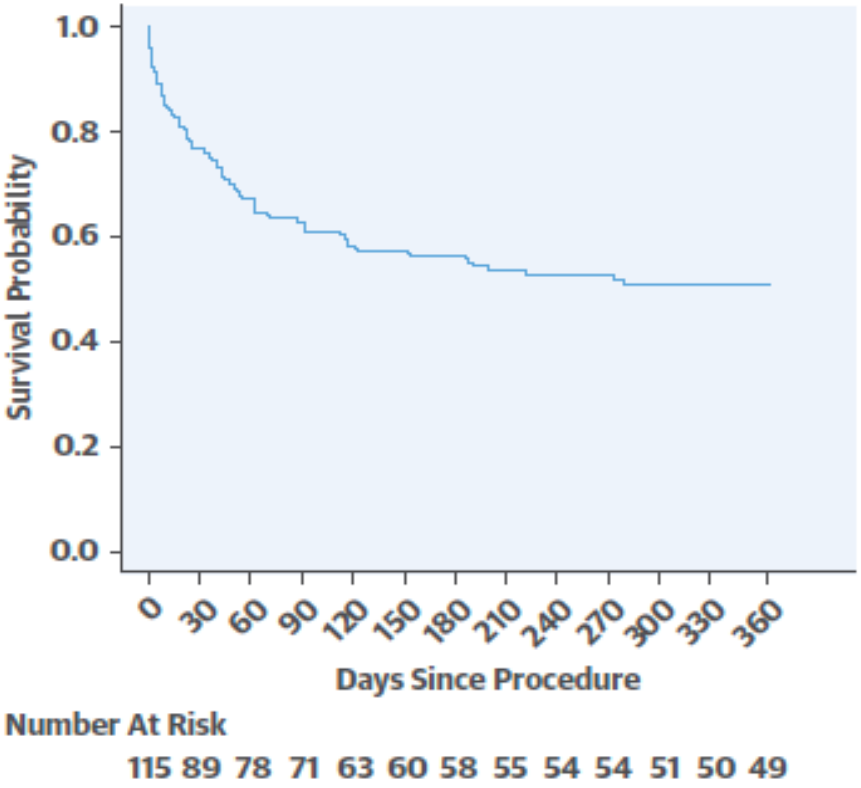


Guerrero et al, *CCI 2014*;83:E287-291.



Fassa et al, *JACC Cardiovasc Interv* 2014;7:696-7.

TMVR in MAC Global Registry



1 year mortality
TMVR in MAC Global Registry
STS 15.3%

Guerrero, Urena et al. JACC 2018; 71:1841-53.

TMVR in MAC Global Registry, cont.

Multivariate Cox Regression Analysis

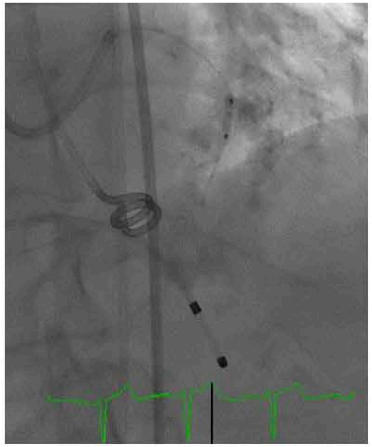
Independent Predictors of 1-Year Mortality

	HR	95% CI	p
Technical success (yes vs no)	0.22	0.09-0.51	**0.0005**
LVOT obstruction	2.63	1.14-6.06	**0.0227**

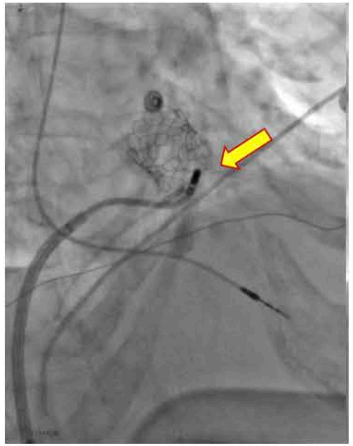
Guerrero, Urena et al, *JACC* May 1st. 2018;71:1841-53.

Preventing LVOT Obstruction

Septal Reduction Strategies

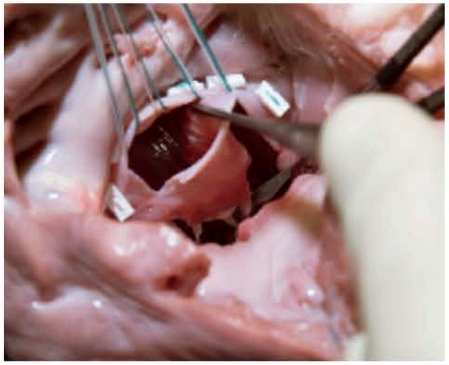


Alcohol
Septal Ablation*
Concept generated in MITRAL trial

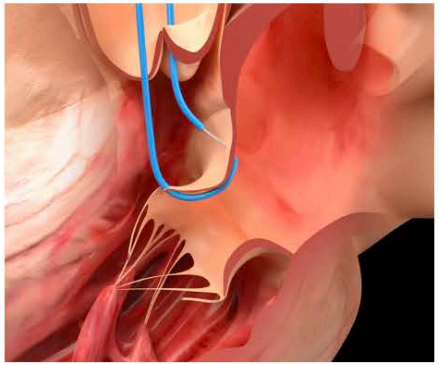


Radiofrequency
Septal Ablation

Anterior Leaflet Strategies



Surgical resection
(MITRAL and SITRAL trials)



Percutaneous laceration
(LAMPOON trial)

*Guerrero et al, *CCI* 2017 Dec 1;90(7):1220-1226.
*Wang, Guerrero et al, *JACC Intv 2019;*12:1268-79.

MITRAL Trial

Mitral Implantation of TRAnscatheter vaLves

91 patients extremely high surgical risk (STS PROM >15% or M&M >50%)

SAPIEN XT

SAPIEN 3

Inclusion Criteria

NYHA II or greater

Valve-in-Valve
n=30

Severe MS (MVA ≤1.5 cm2)

At least Moderate-Severe MR

100% Transseptal

Valve-in-Ring
n=30

Severe MS (MVA ≤1.5 cm2)

At least Moderate-Severe MR

100% Transseptal

Native MV (MAC)
n=31*

Severe MS (MVA ≤1.5 cm2)

Severe MR + Moderate MS

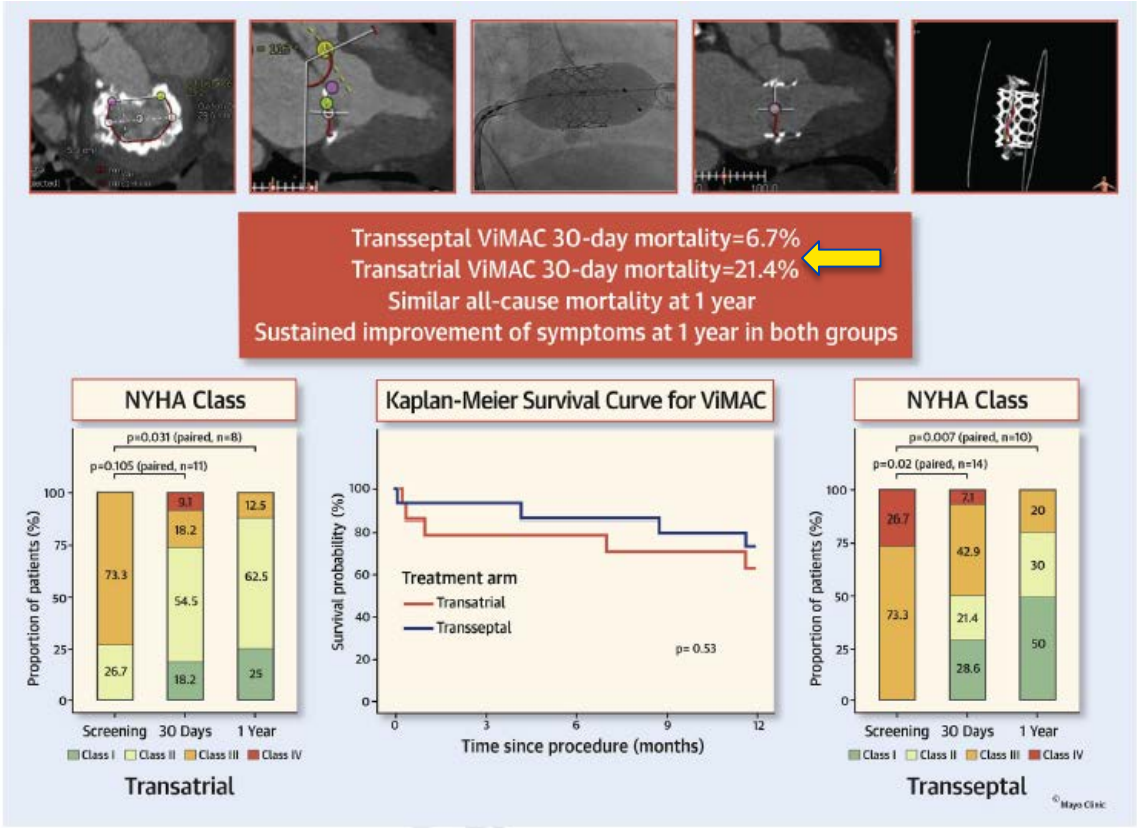
15 Transseptal
15 Transatrial
1 Transapical

MAYO CLINIC

First 2 patients in MAC arm were treated with SAPIEN XT, al subsequent patients were treated with SAPIEN 3 valves

* 1 withdrew consent 3 weeks post TMVR

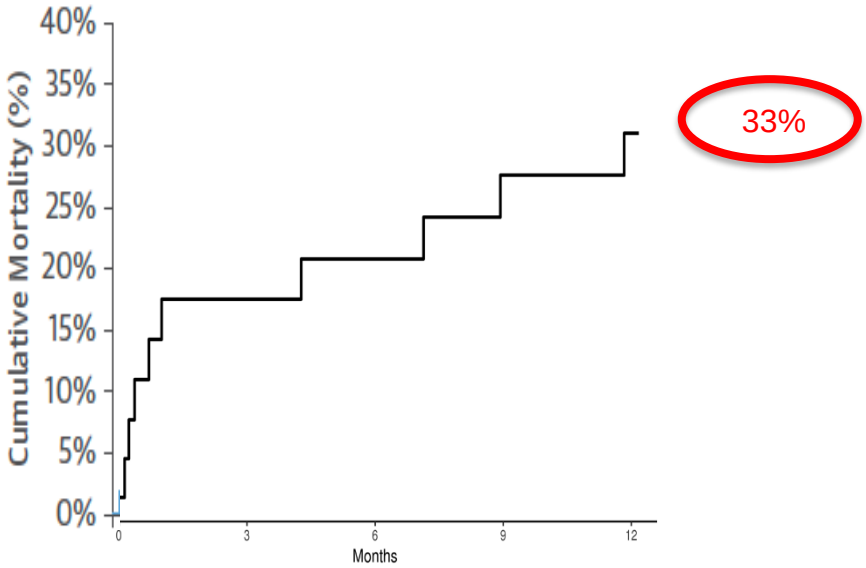
Thirty-Day and 1-Year Outcomes of Valve-in-Mitral Annular Calcification in the Mitral Implantation of TRAnscatheter VaLves Trial (Central Illustration*)



*From Guerrero et al, *JACC Intv April 19,* 2021;14:830-45.

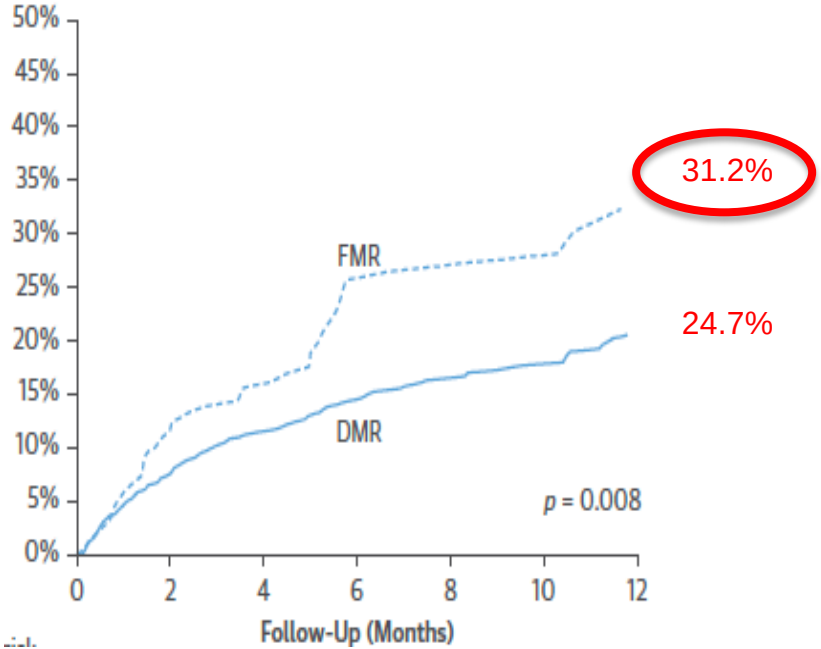
1-year Mortality

Mitral Implantation of TRAnscatheter VaLves Trial



33%

MITRAL Trial MAC arm, n=30 eligible for follow-up (STS 8.6%)



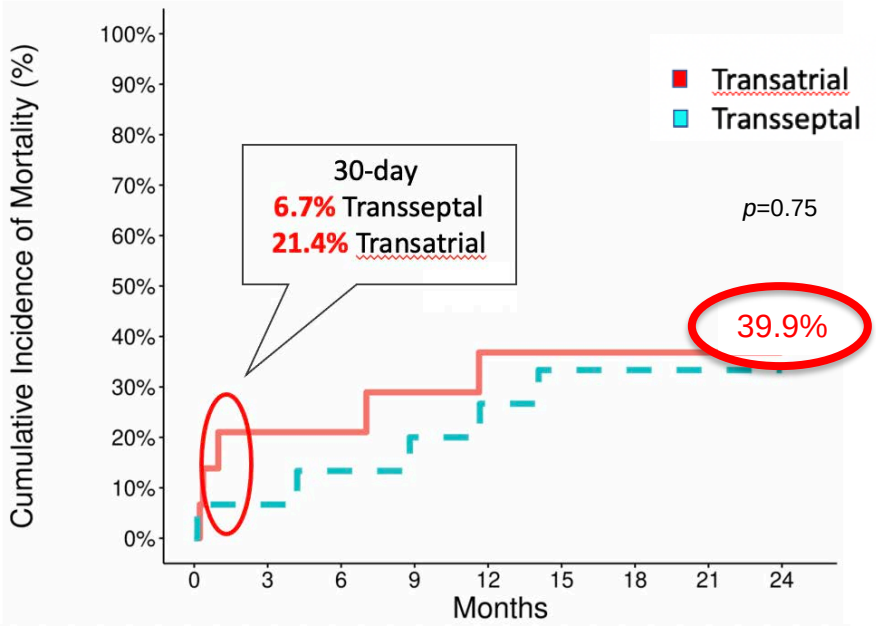
31.2%

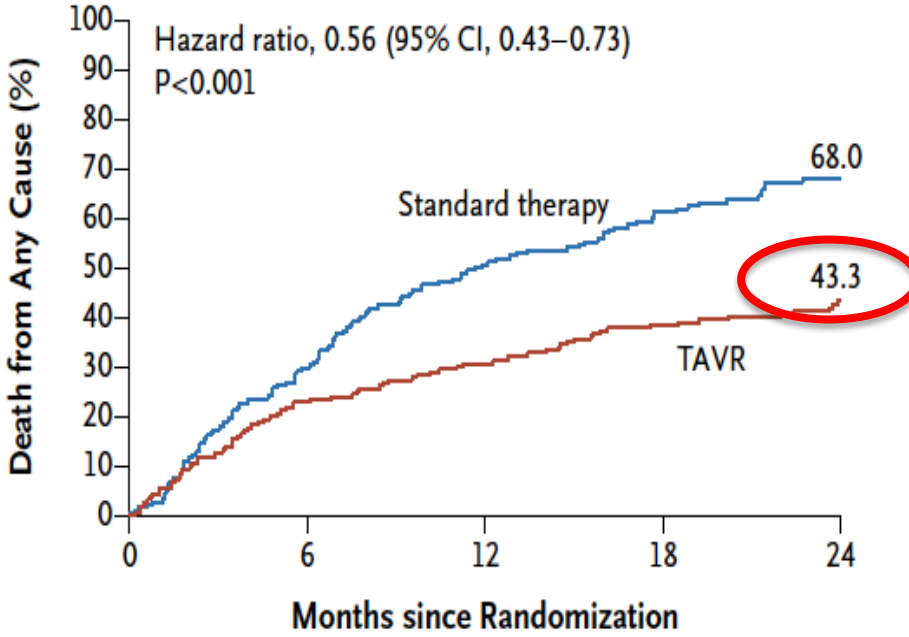
24.7%

MitraClip TVT Registry (STS MVr 6.1%, MVR 9.2%)

Guerrero, et al. JACC Interv 2021
Sorajja, et al JACC 2017

MITRAL Trial MViMAC 2-Year Mortality





MITRAL Trial ViMAC arm, n=31 (mean STS 8.6%)

*Makkar et al. NEJM 2012;366(18):1696-1704.

SAPIEN 3

MITRAL II Pivotal Trial

Mitral Implantation of TRAnscatheter vaLves

SAPIEN 3 Ultra

High surgical risk patients

Inclusion criteria

Severe MAC with Severe MS (MVA ≤1.5 cm2) or ≥3+ MR

NYHA II or greater

Valve-in-MAC
n=110

100% Transseptal

Alcohol Septal ablation
RF Ablation or LAMPOON
allowed

Not Randomized

Primary Endpoint

All-cause death and Hospitalization for HF at 1 year

NCT 04408430
IDE G200074
CMS approved 12-10-20
Trial launched March 8, 2021

Natural History
n=100

Patients
not candidates
for MV intervention

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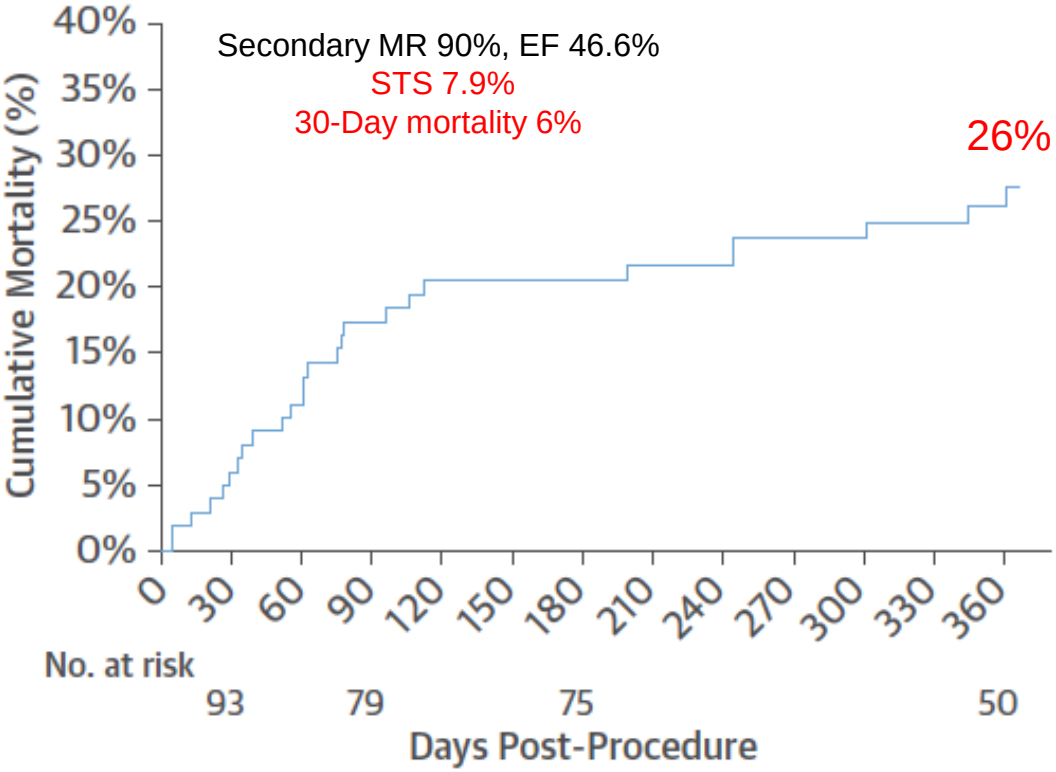
12 patients treated

Tendyne Global Feasibility Study

1 Year Outcomes



1-Year mortality

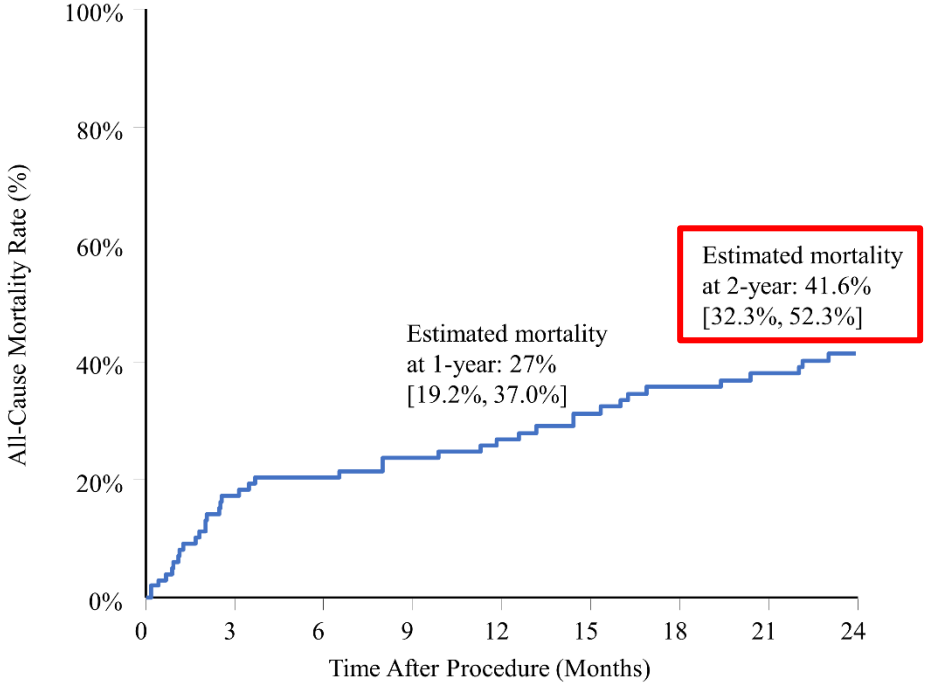
TAVR in PARTNER IA STS 11.7%: 24%

MitraClip TVT Registry STS 6.1%:
DMR= 24.7%
FMR= 31%

Note: Tendyne CE Mark Approval, Jan 30, 2020

Tendyne Global Feasibility Study, slide 2

2-Year Outcomes

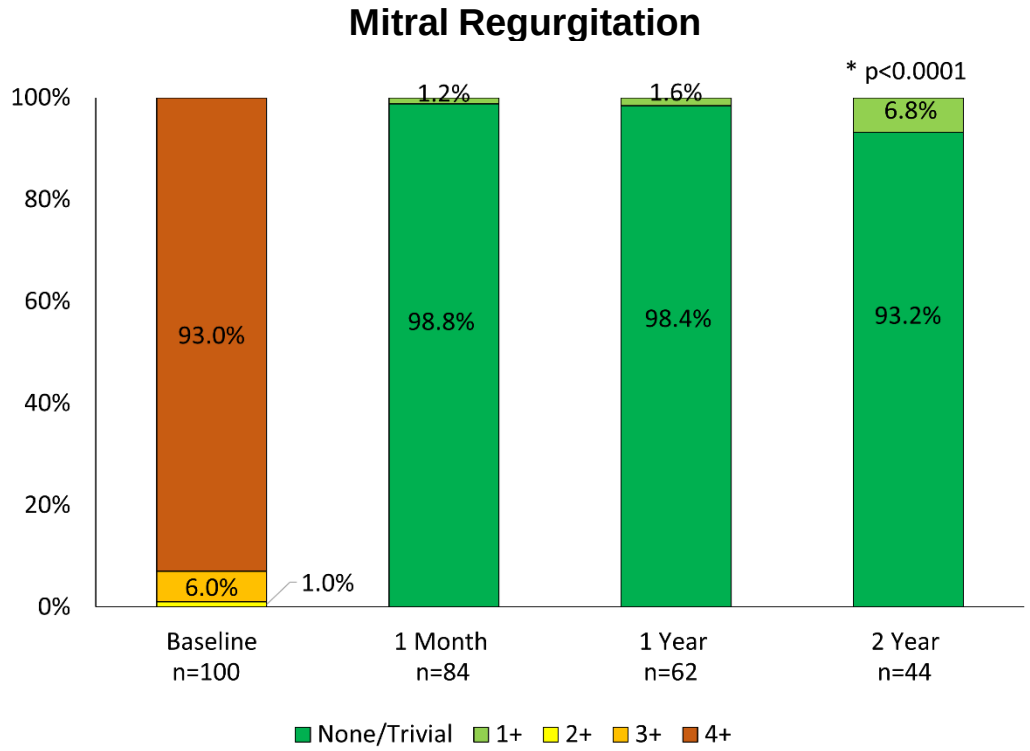


Mortality at 2-yr	N (%)
All-Cause Death	39.0% (39/100)
Cardiovascular Death	34.0% (34/100)
Refractory Heart Failure	14.0% (14/100)
Arrythmia/Cardiac Arrest	8.0% (8/100)
Myocardial Infarction	2.0% (2/100)
Stroke	1.0% (1/100)
Blood Loss Requiring Transfusion	2.0% (2/100)
Cardiac Perforation	1.0% (1/100)
Device Migration or Malposition	1.0% (1/100)
Endocarditis	1.0% (1/100)
Shock	1.0% (1/100)
Other	3.0% (3/100)

Mueller et al, *In Press JACC* 2021.

Tendyne Global Feasibility Study, slide 3

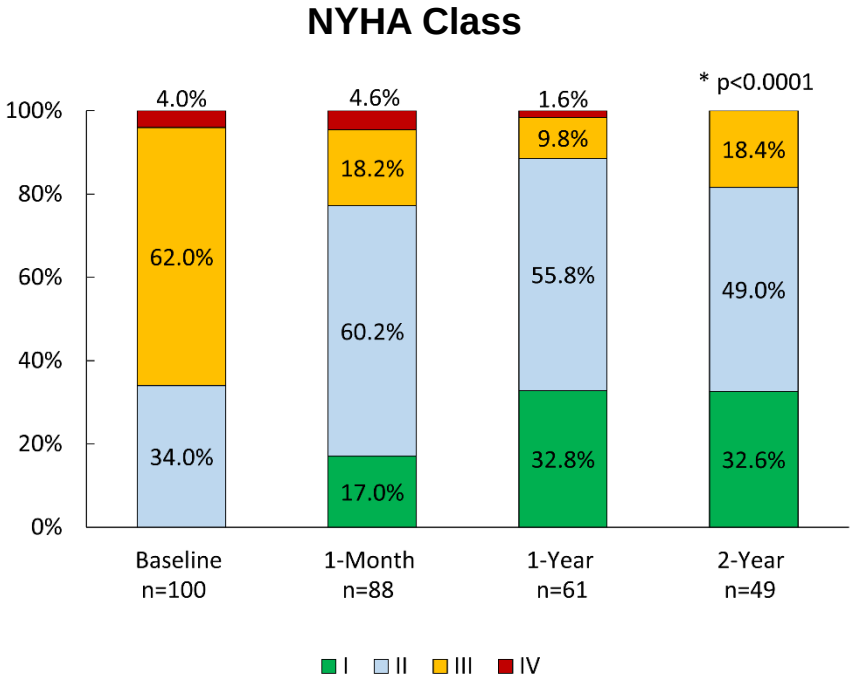
2 Year Outcomes

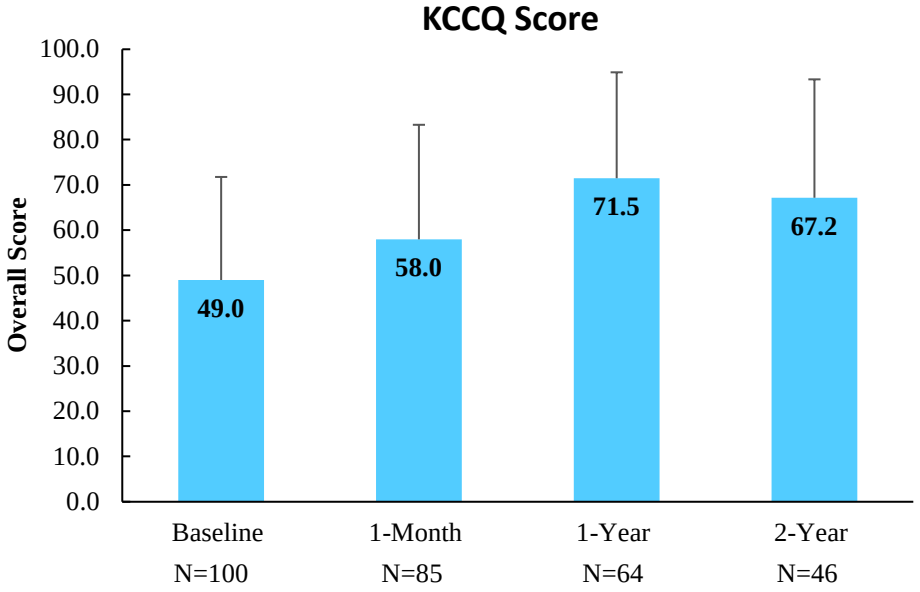


Mueller et al, *In Press JACC* 2021.

Tendyne Global Feasibility Study, slide 4

2 Year Outcomes





At 2 years, KCCQ score improved 19.1 points from baseline (paired comparison).

Early Experience Tendyne in MAC*

9 patients, **STS 7.4%**

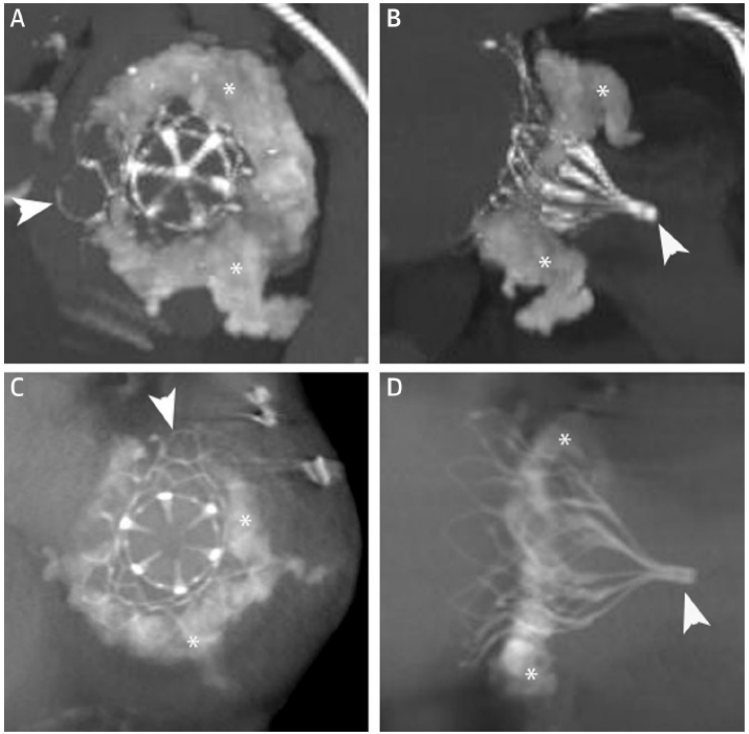


TABLE 4 Clinical Events in Follow-Up

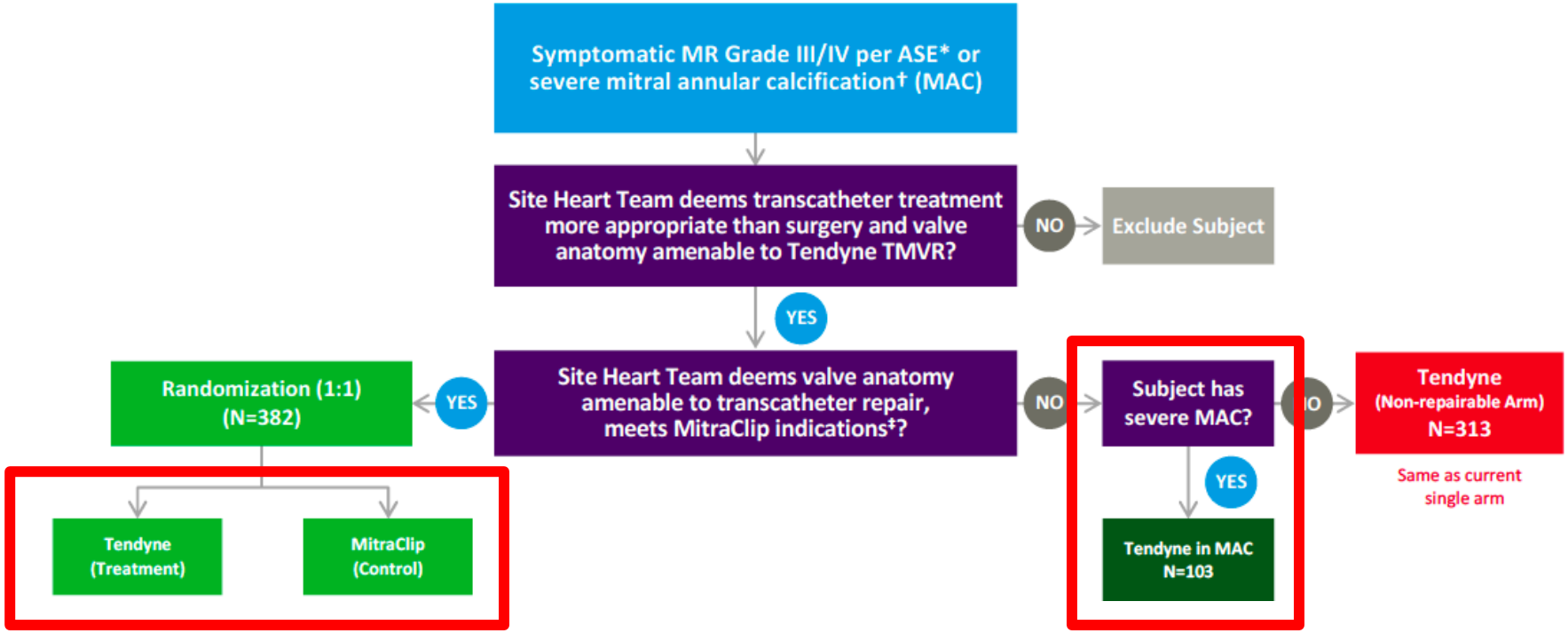
Treated Population (N = 9)	30 Days	Last Follow-Up
Any mortality	0	1
Cardiovascular mortality	0	0
Stroke or TIA	0	0
Myocardial infarction	0	0
Heart failure hospitalization	0	2
Re-intervention for MV	0	0
BARC 2, 3, or 5 bleeding	1	1
Device-specific adverse events		
Bioprosthetic valve dysfunction	0	0
Hemolysis	0	0
Embolization	0	0
Thrombosis	0	0
Erosion, migration, malposition	0	0
Fracture	0	0
Endocarditis	0	0
New-onset atrial fibrillation	0	0
New permanent pacemaker	0	0

Sorajja et al, *JACC* 2019;74:1431-40.

*EFS Prospective trial ongoing and MAC arm under SUMMIT pivotal Trial

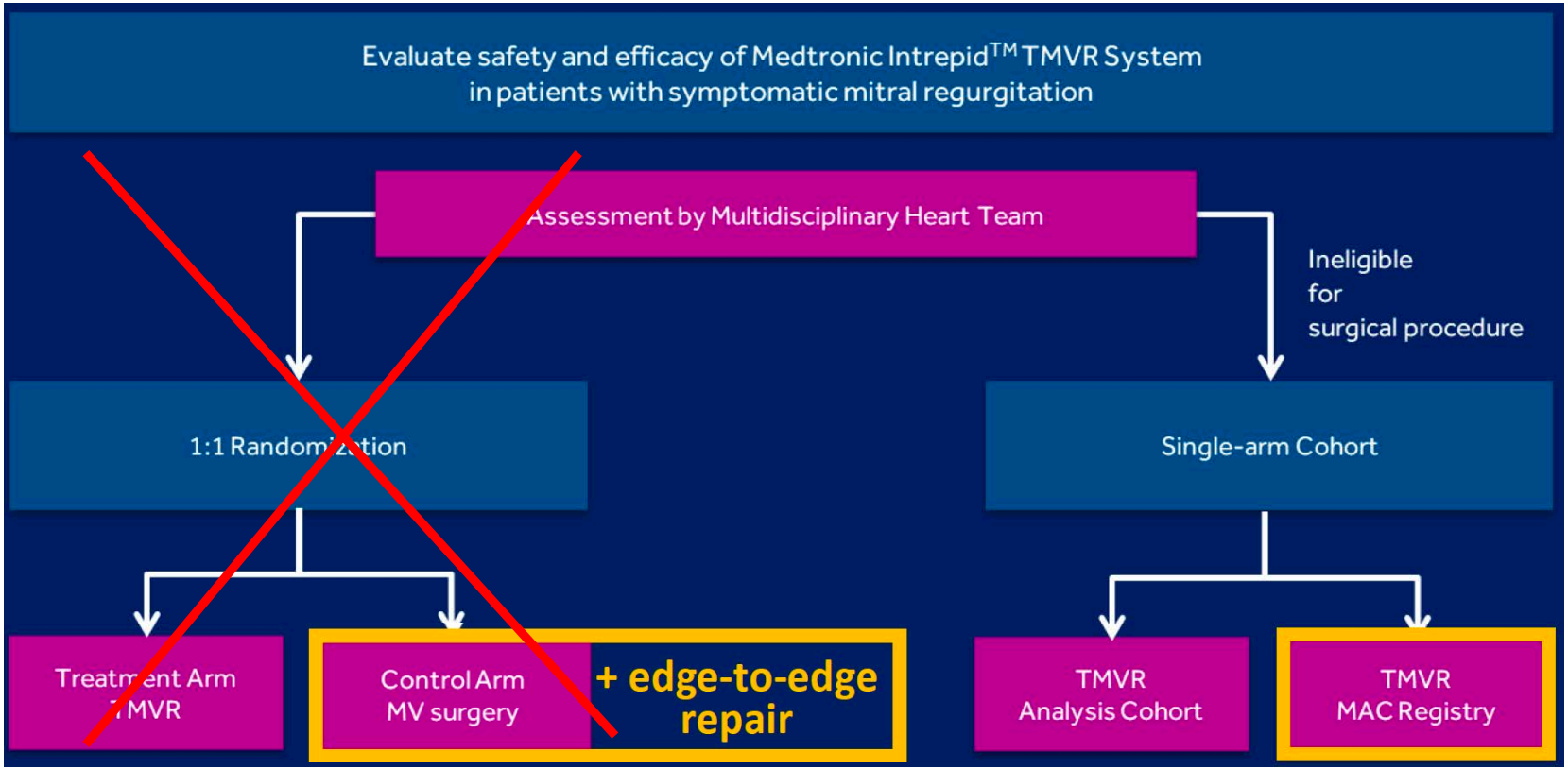
Clinical Trial to Evaluate the Safety and Effectiveness of Using the Tendyne Mitral Valve System for the Treatment of Sympotamic MITral Regurgitation

SUMMIT Trial: New design approved by FDA 8-2-19



Rogers et al, *TCT* 2019.

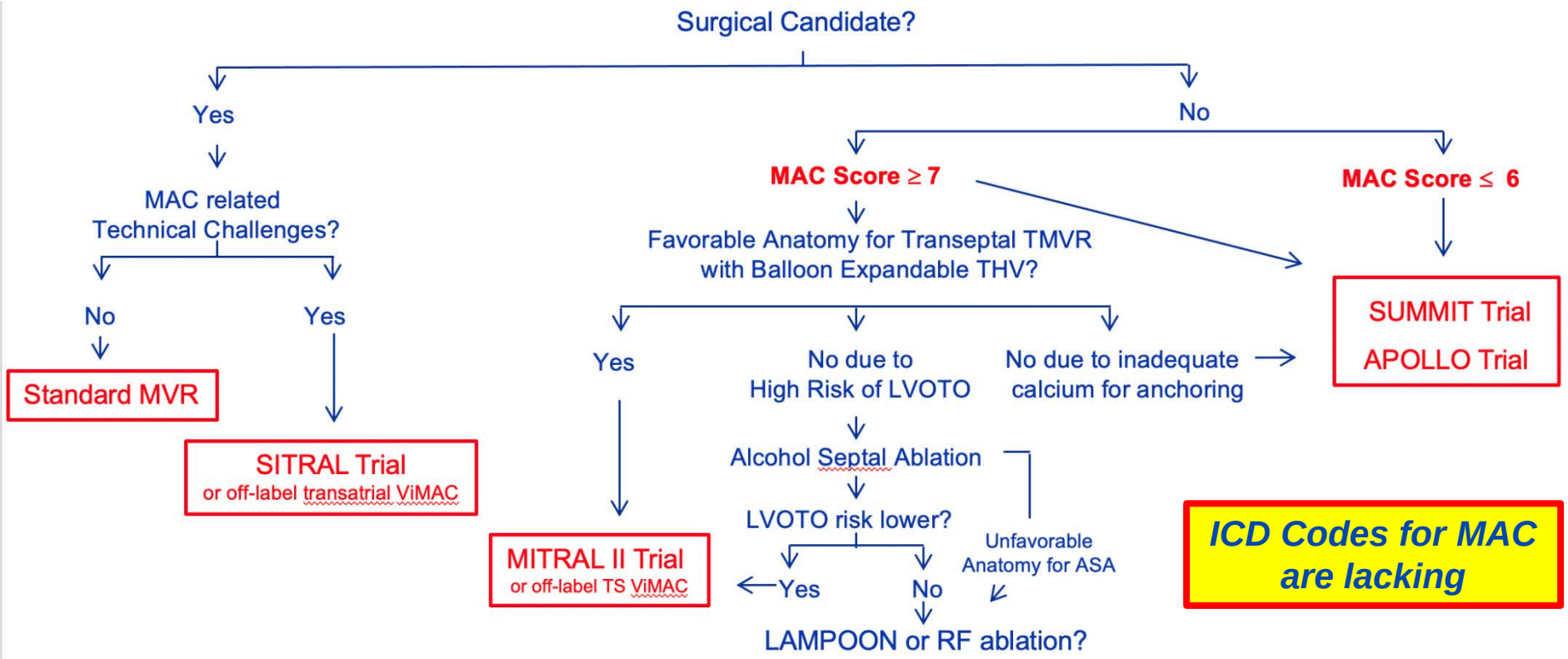
Changes in APOLLO Trial



Leon et al, *TCT* 2019.

Evolving Algorithm…..

Severe MV Disease and Severe MAC
Symptomatic Patient Despite Medical Treatment



Conclusions

- MAC is a common condition which is associated with increased CV and all-cause mortality as well as limited treatment options.
- TMVR is emerging as a treatment option for patients with severe MAC.
- ICD codes are needed for accurate documentation of MAC and MAC-related outcomes in research and clinical practice.

Thank You

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