



## Valve-in-MAC

# MITRAL I and MITRAL II trials: What Have we learned?

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# 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

- Institutional Research Grant Support.

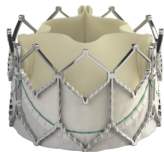
## Company

- Edwards Lifesciences

*Off label use of products and investigational devices  
will be discussed in this presentation*

# Learning Objectives

- To review short and long-term clinical outcomes of ViMAC in MITRAL I EFS.
- To identify the strategies that resulted in those outcomes.
- To describe strategies in the MITRAL II trial and enrollment update.

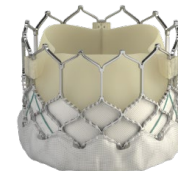


SAPIEN XT

# MITRAL Trial

## Mitral Impplantation of TRAnscatheter vaLves

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



SAPIEN 3

### Inclusion Criteria

NYHA II or greater

**Valve-in-Valve**  
**n=30**

Severe MS (MVA  $\leq 1.5$  cm<sup>2</sup>)  
At least Moderate-Severe MR

**100% Transseptal**

**Valve-in-Ring**  
**n=30**

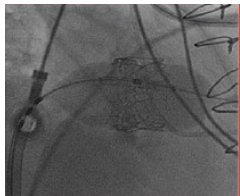
Severe MS (MVA  $\leq 1.5$  cm<sup>2</sup>)  
At least Moderate-Severe MR

**100% Transseptal**

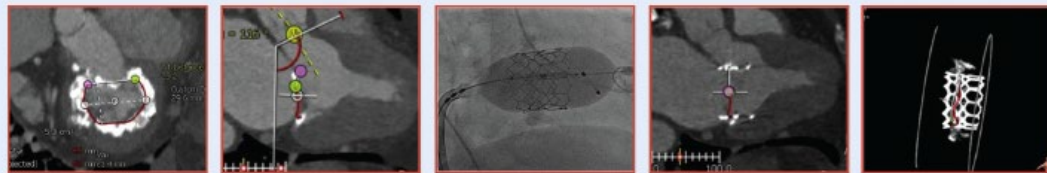
**Native MV (MAC)**  
**n=31\***

Severe MS (MVA  $\leq 1.5$  cm<sup>2</sup>)  
Severe MR + Moderate MS

**15 (48.4%) Transseptal**  
**15 (48.4%) Transatrial**  
**1 (3.2%) Transapical**



## MITRAL Trial Mitral Implantation of TRANscatheter vaLVes

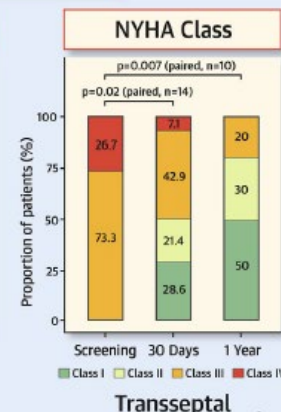
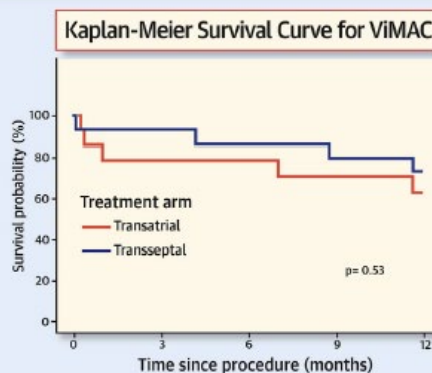
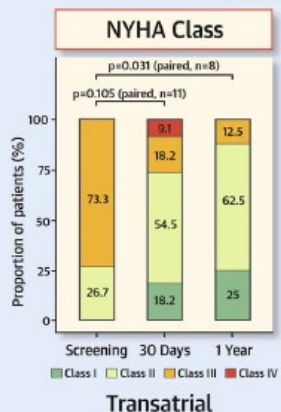


**Transatrial**  
30-day mortality= 21.4%  
1 year= 38.5%

Transseptal ViMAC 30-day mortality=6.7%  
Transatrial ViMAC 30-day mortality=21.4%  
*Similar 30-day mortality at 1 year*  
Sustained improvement of symptoms at 1 year in both groups

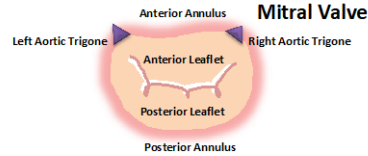
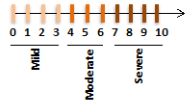
STS 8.6± 8.2%

**Transseptal**  
30-day mortality= 6.7%  
1 year= 26.7%

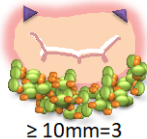
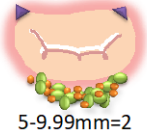


# Cardiac CT MAC Score

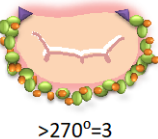
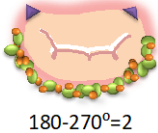
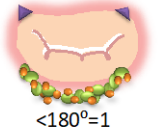
## CT-Based MAC Score



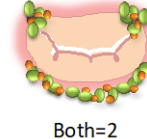
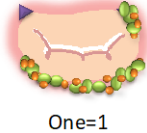
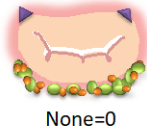
### I. Calcium Thickness



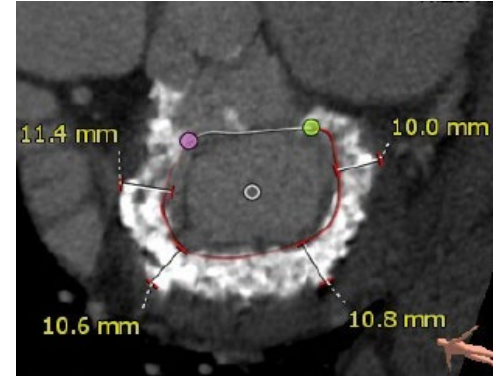
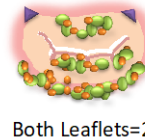
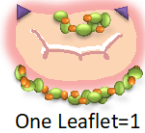
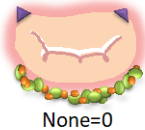
### II. Calcium Distribution



### III. Trigone Involvement



### IV. Leaflet Involvement



Mean Cardiac CT MAC Score  $6.8 \pm 1.64$

**Zero THV embolizations!**

# TMVR in MAC Global Registry

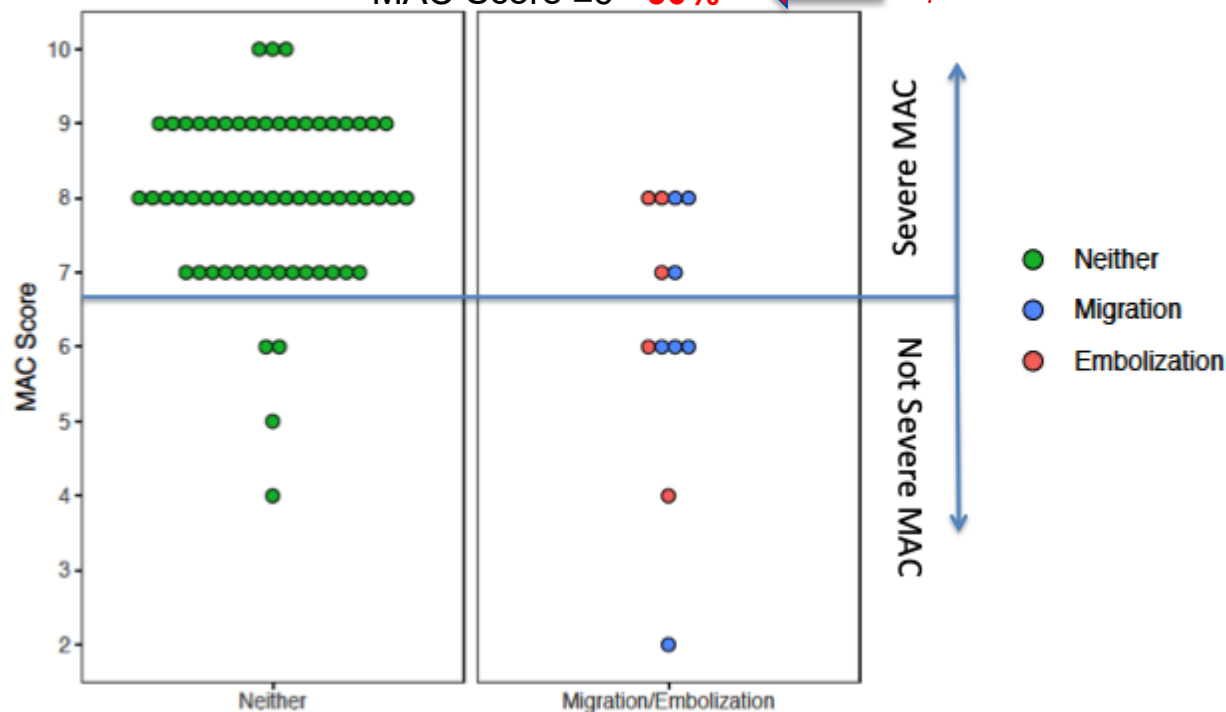
Valve embolization or migration (entire cohort n=72)

5 embolizations and 7 migrations=12/72 (16.7%)

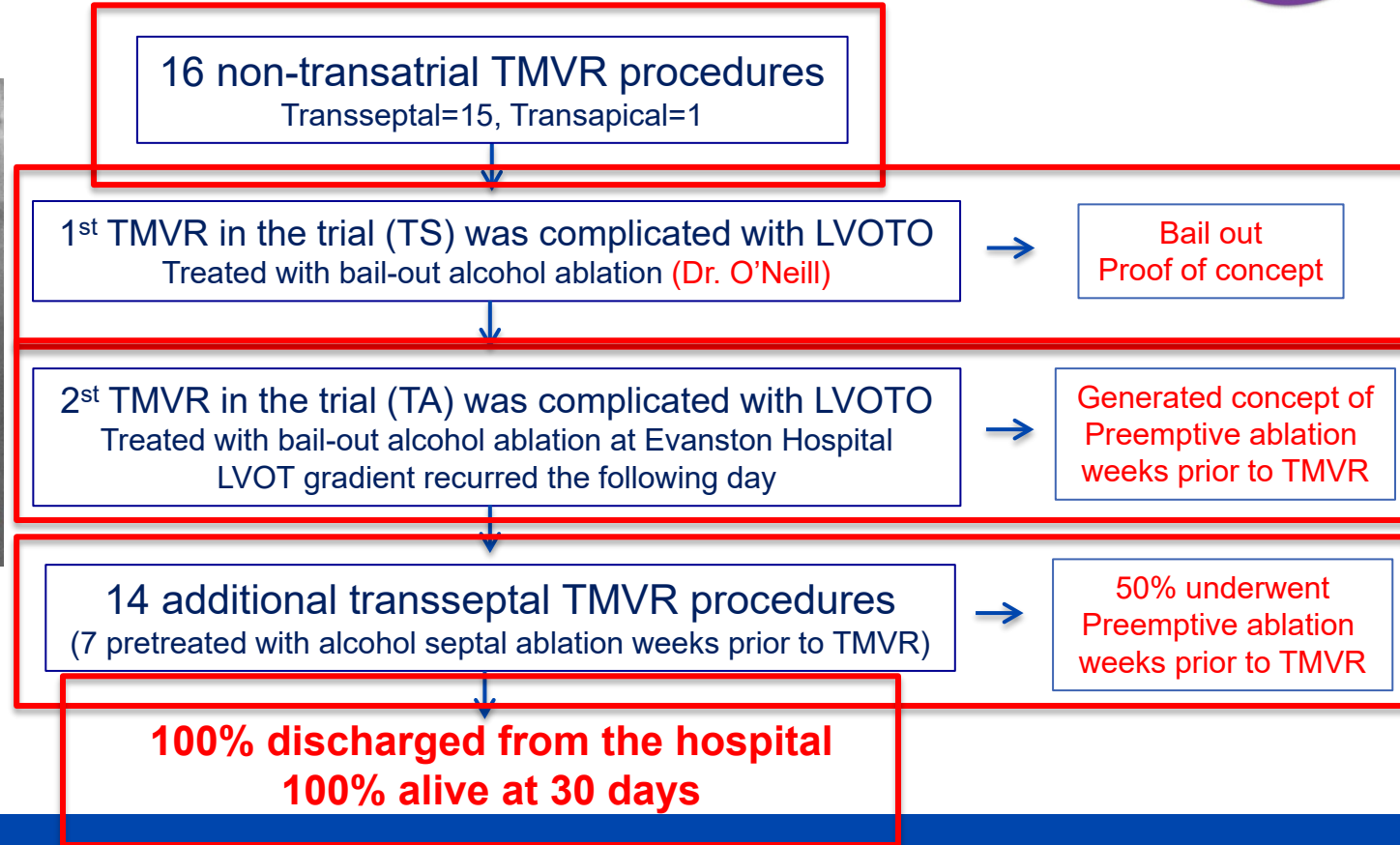
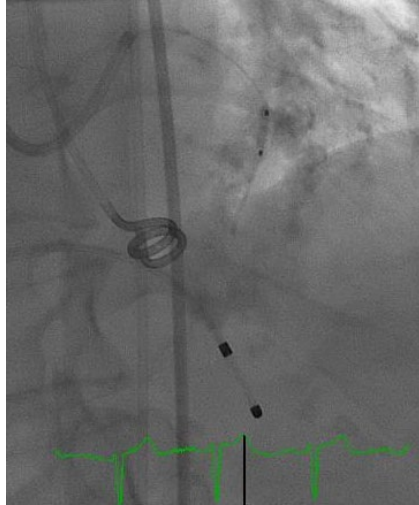
MAC score  $\geq 7 = 9.7\%$

MAC Score  $\leq 6 = 60\%$

$p < 0.001$



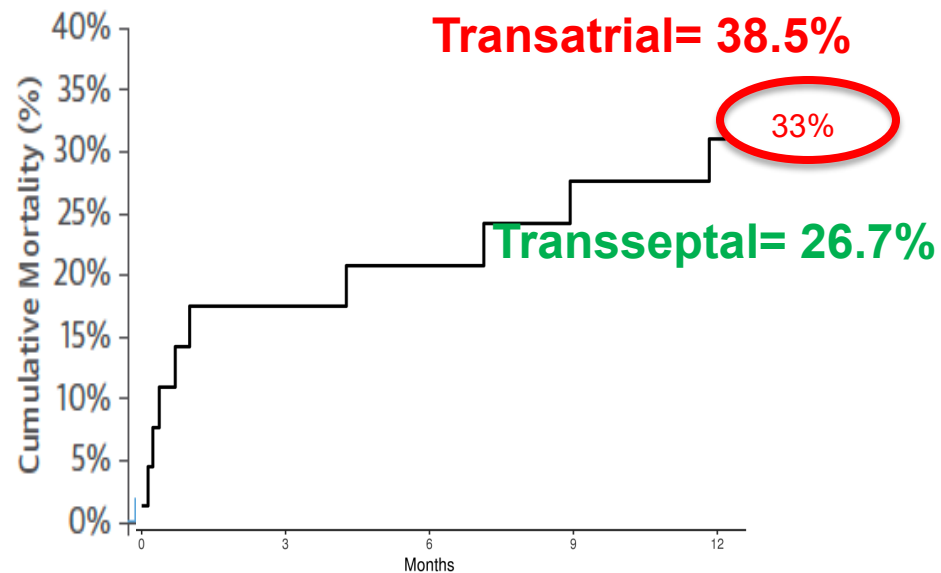
## Role of Alcohol Septal Ablation





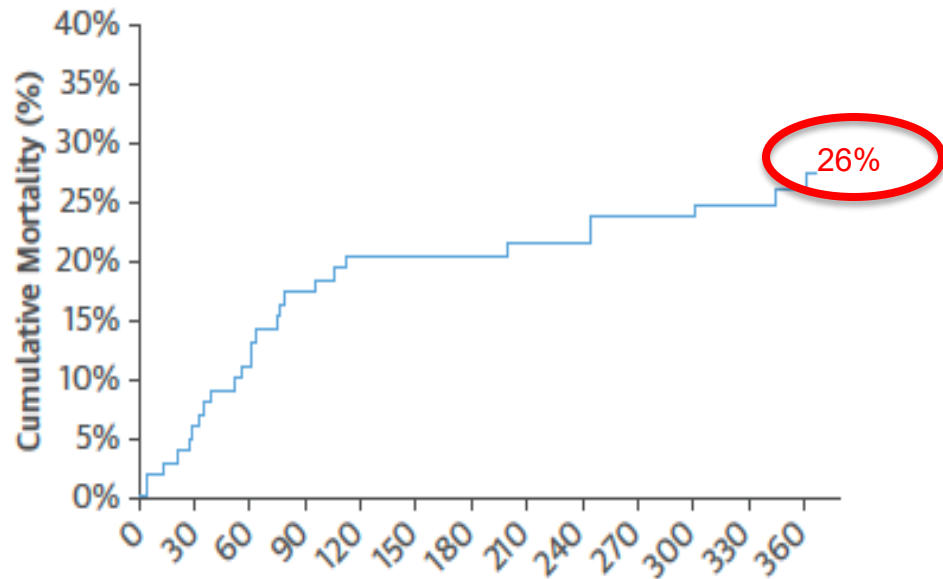


# 1-year Mortality



**MITRAL Trial MAC arm, n=30 eligible for follow-up (STS  $8.6 \pm 8.2\%$ )**

Guerrero et al, *JACC Cardiovasc Inter* 2021 Apr 26;14(8):830-845.

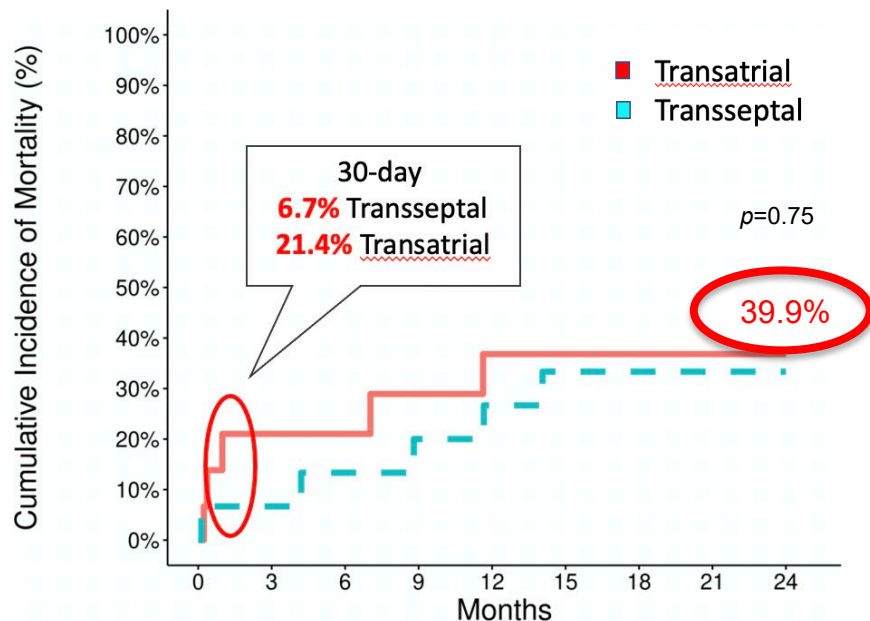


**Tendyne Global EFS, n=100 (STS  $7.8 \pm 8.7\%$ )**

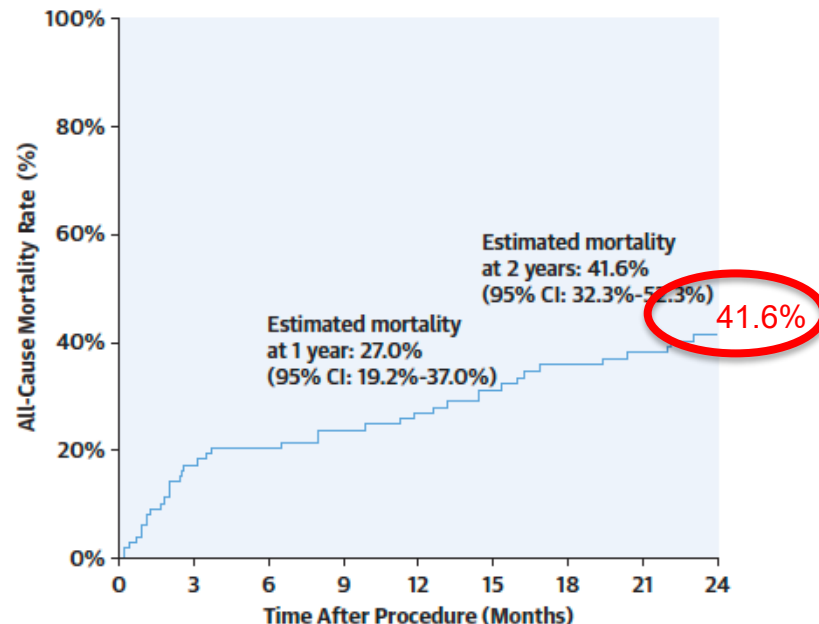
Sorajja, et al *JACC* 2019;73:1250-60.



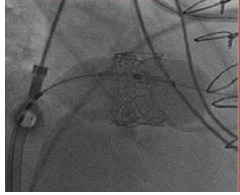
# MITRAL Trial MViMAC 2-Year Mortality



MITRAL Trial ViMAC arm, n=31 (mean STS  $8.6\% \pm 8.2\%$ )

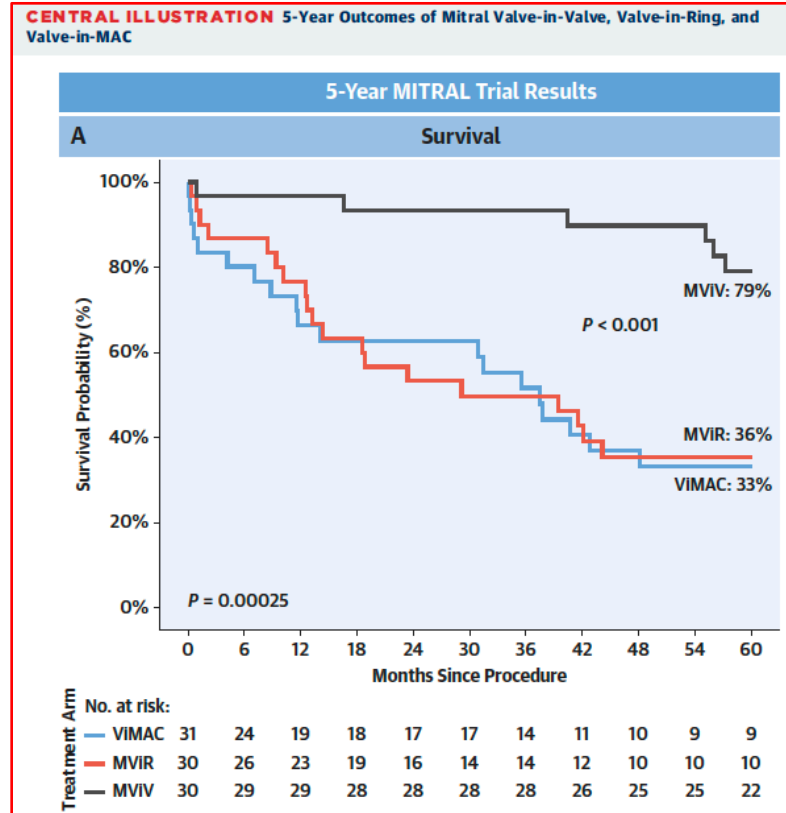


Tendyne Global EFS n=100 (mean STS  $7.8 \pm 8.7\%$ )



# MITRAL Trial

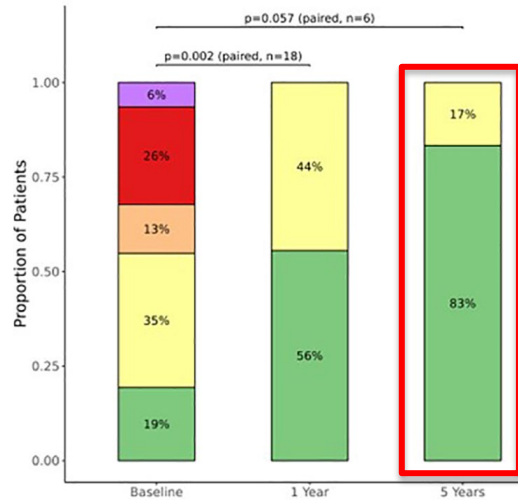
## Mitral Implantation of TRANscatheter vaLves



← Old patients with multiple comorbidities

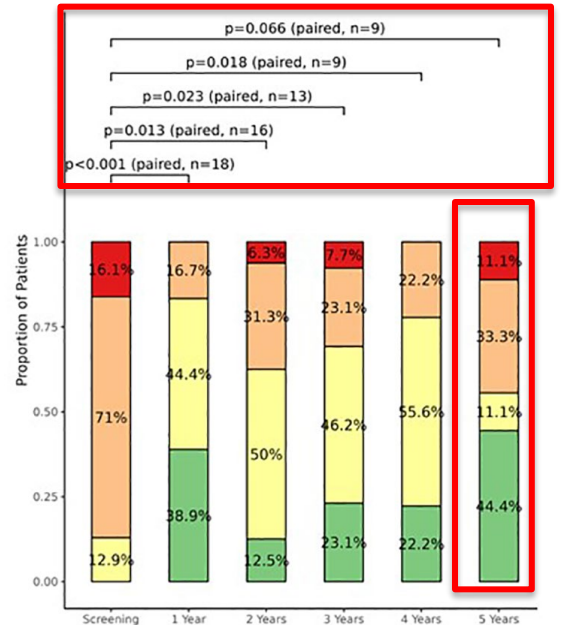
# 5-Year Outcomes

## MR Reduction



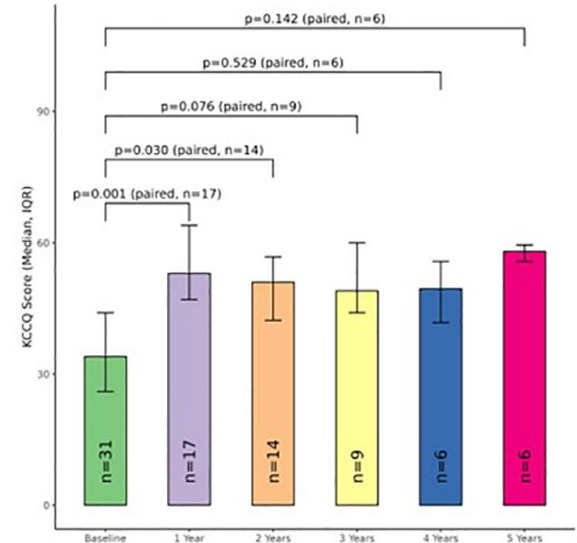
■ None/Trace ■ 1+ ■ 2+ ■ 3+ ■ 4+

## NYHA Class



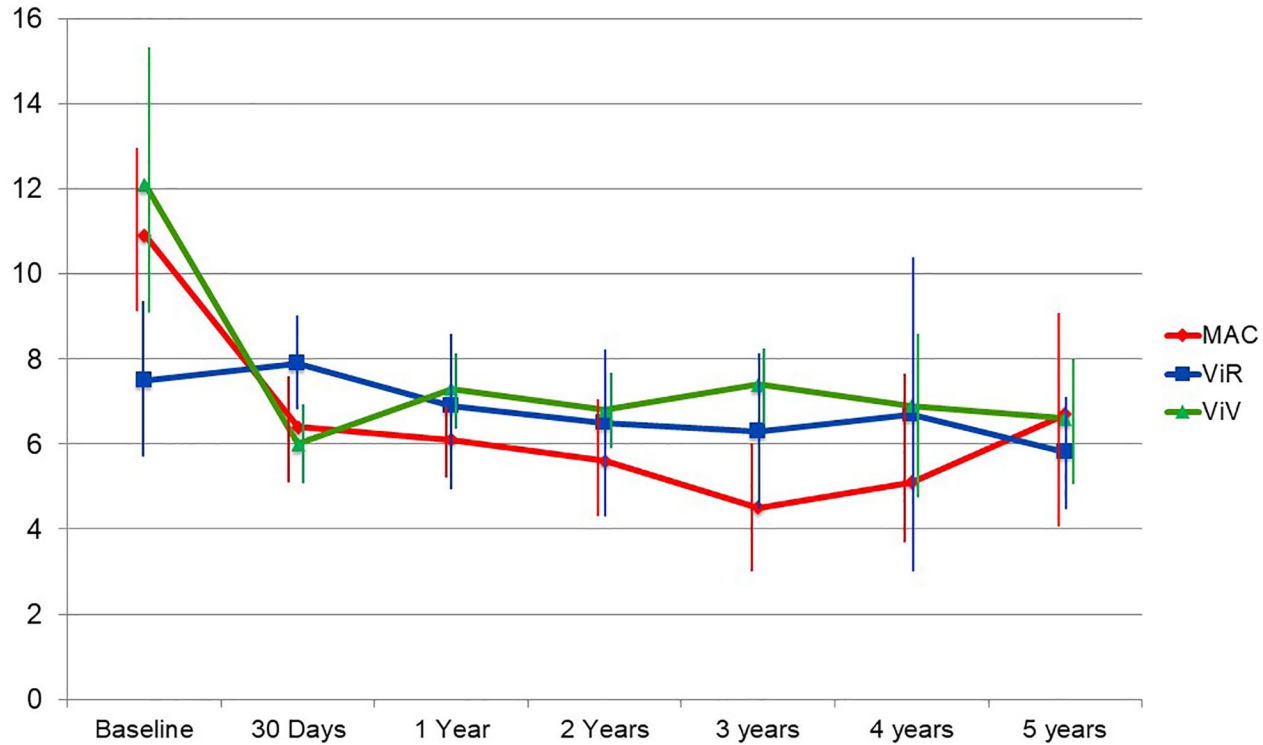
■ Class I ■ Class II ■ Class III ■ Class IV

## KCCQ Scores



# 5-Year Outcomes

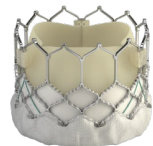
## Mitral Valve Gradient at 5 Years



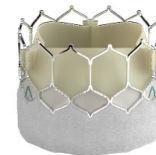
# MITRAL II Pivotal Trial

## Mitral Impplantation of TRAnscatheter vaLves

High surgical risk patients



SAPIEN 3



SAPIEN 3 Ultra

Severe MAC with Severe MS (MVA

NYHA

MR

**Valve-in-MAC**  
**n=110**

**100% Transseptal**  
**CT MAC score  $\geq 7$**

*Alcohol Septal ablation*  
*RF Ablation*  
*or LAMPOON*

*Allowed if Neo-LVOT  $< 200 \text{mm}^2$*

**Enrollment >90% completed**

**Natural History**  
**n=100**

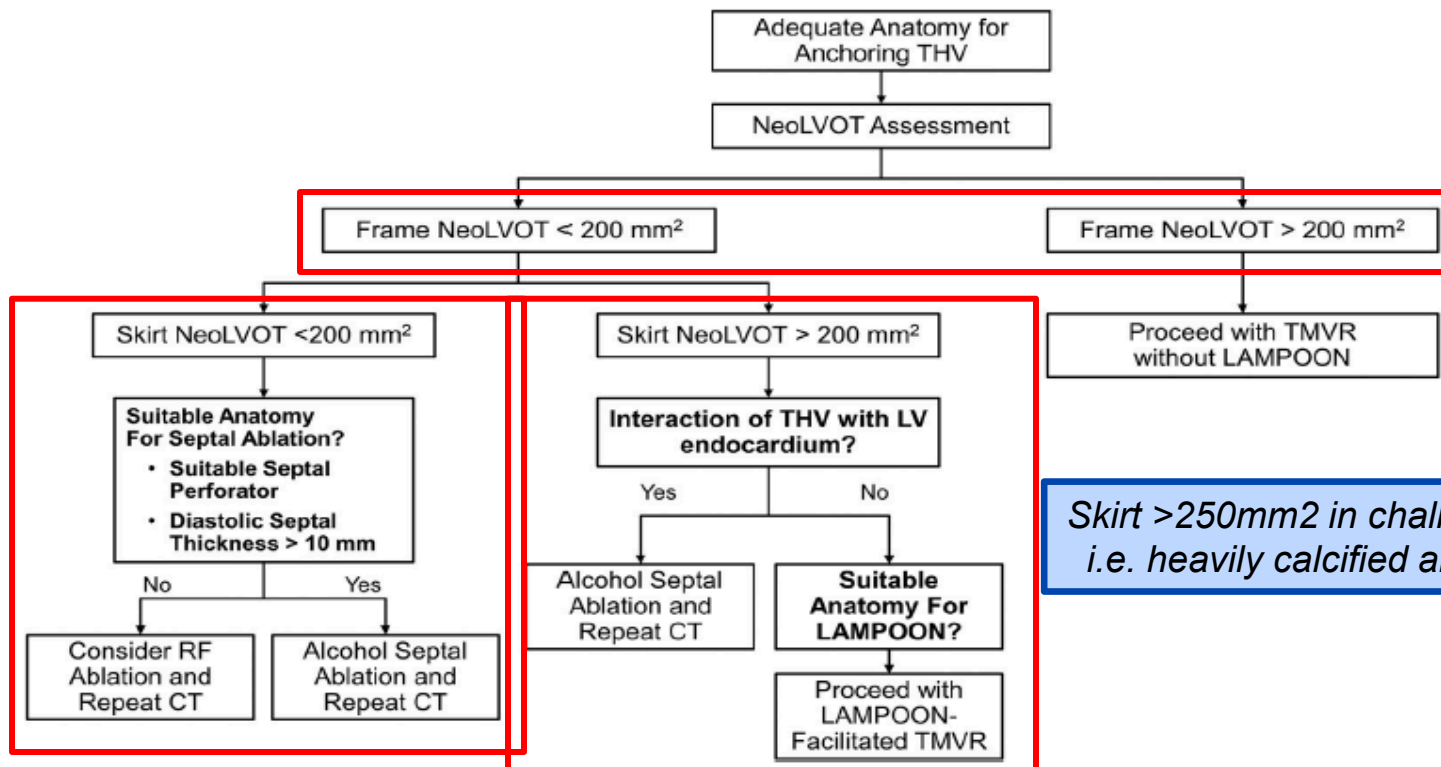
point  
hospitalization for HF at 1 year

NCT 04408430  
IDE G200074

*Patients not candidates*  
*for MV intervention*  
*or not interested in intervention*

# How to Prevent LVOT Obstruction

**FIGURE 7** Algorithm for Management of LVOT Obstruction Risk Before TMVR



*Skirt >250mm² in challenging cases?  
i.e. heavily calcified anterior leaflet?*

# Summary

## ● **MITRAL EFS findings:**

- In carefully selected patients, Transseptal ViMAC was associated with:
- A 30-day mortality lower than predicted by the STS score
- 1 and 2-year mortality similar to Tendyne and early TEER experience.
- Low 33% survival at 5 years
- Survivors experienced sustained improvement of symptoms and Quality of Life & stable THV performance at 5 years

## ● **The MITRAL II trial:**

- Evaluates transseptal ViMAC in high-risk patients with a MAC score of 7
- Expanded strategy to decrease the risk of LVOTO:
- Allows septal modification (alcohol and/or RF) & leaflet modification (LAMPOON)
- Enrollment ongoing, >90% complete.





# Thank You

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