

# **Percutaneous Mitral Interventions & TAVI in native MV (MAC)**



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**Chair of the Board of the Institute of Cardiology  
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**Chair, Education & Training Committee**

**The European Association of Percutaneous Cardiovascular Interventions (EAPCI ESC)**

# MitraClip RCTs in Functional MR

	<b>COAPT</b>	<b>RESHAPE-HF-2</b>
N patients, sites	610 pts @ 100 NA and EU sites	380 pts @ 50 EU sites
Control arm	GDMT ± CRT	GDMT ± CRT
FMR grade	≥3+ (EROA ≥30 mm <sup>2</sup> and/or Rvol >45 mL by ECL)	≥3+ (EROA ≥30 mm <sup>2</sup> and/or Rvol >45 mL by ECL)
NYHA class	II, III, or ambulatory IV	III or ambulatory IV
Other inclusion criteria	HF hosp within 12 months or BNP ≥300 pg/ml or nT-proBNP ≥1500 pg/ml within 12 months; MV surgery is not local standard of care	HF hosp within 12 months or BNP ≥350 pg/ml or nT-proBNP ≥1400 pg/ml within 90 days; not eligible for MV surgery
LVEF	≥20% - ≤50%	≥15% - ≤40%
LV volumes	LVESD ≤70 mm	LVEDD ≥55 mm
Primary efficacy endpoint	Recurrent HF hospitalization at 24 months	Death or recurrent HF hospitalization at 12 months
Primary safety endpoint	SLDA, device embolizations, endocarditis/MS/device-related complications requiring non-elective CV surgery, LVAD, OHT at 12 mo	All-cause mortality, stroke, MI, new renal replacement therapy, non-elective CV surgery for device related complications
Total follow-up	5 years	1 year
PIs	GW Stone, M Mack	P Ponikowski, S Anker



# MitraClip RCTs in Functional MR

	<b>EVOLVE-HF</b>
N patients, sites	168 patients @ 15 global sites
Design	2x2 assignment to MitraClip vs. control, and CRT on vs. off (all pts receive CRT-D with defibrillator function on) - <b>blinded</b>
FMR grade	Severe (3-4+) by ECL
NYHA class	II - IVa
Other inclusion criteria	Patient on GDMT but without CRT; Class IIa indication for CRT (LBBB with QRS 120-149 ms or RBBB with QRS >150 ms); 6MWD >0 - <450 m
LVEF	>15% - ≤35%
LV volumes	-
Primary efficacy endpoint	Improvement in 6 minute walk test from baseline to 6 months
Primary safety endpoint	-
Total follow-up	12 months
PI	A. Asgar



# MitraClip® NT

Ready update, June 2016

Nitinol Grippers with 160° opening

Better steerability of CDS

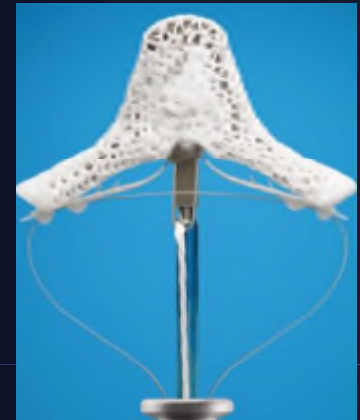
Less sleeve shortening

Less need of M Knob rotation resulting in less CDS tension

Facilitated CDS removal in case of clip not implanted



Further update

Redesign of CDS and Handle for an easy to use one-operator device





# Mitral Annuloplasty Devices

	 <b>Cardioband</b>	 <b>Carillon</b>
<b>Population</b>	<b>Symptomatic HF and FMR</b> Ischemic or non-ischemic cardiomyopathy; optimized and stable medical HF regimen	<b>Symptomatic HF and FMR</b> Ischemic or non-ischemic cardiomyopathy; optimized and stable medical HF regimen
<b>N</b>	~400	~400
<b>Randomized</b>	2:1	2:1
<b>Primary EP</b>	<b>1 year:</b> Prevalence of MR $\leq 2+$ and hierarchical comparison of all-cause mortality, # of HF hospitalizations, 6 minute walk test and KCCQ	<b>1-year efficacy:</b> Clinical endpoints and regurgitant volume <b>1-year safety:</b> Device-related major adverse events



# TMVR devices

**CardiAQ-Edwards**

**Tiara (Neovasc)**

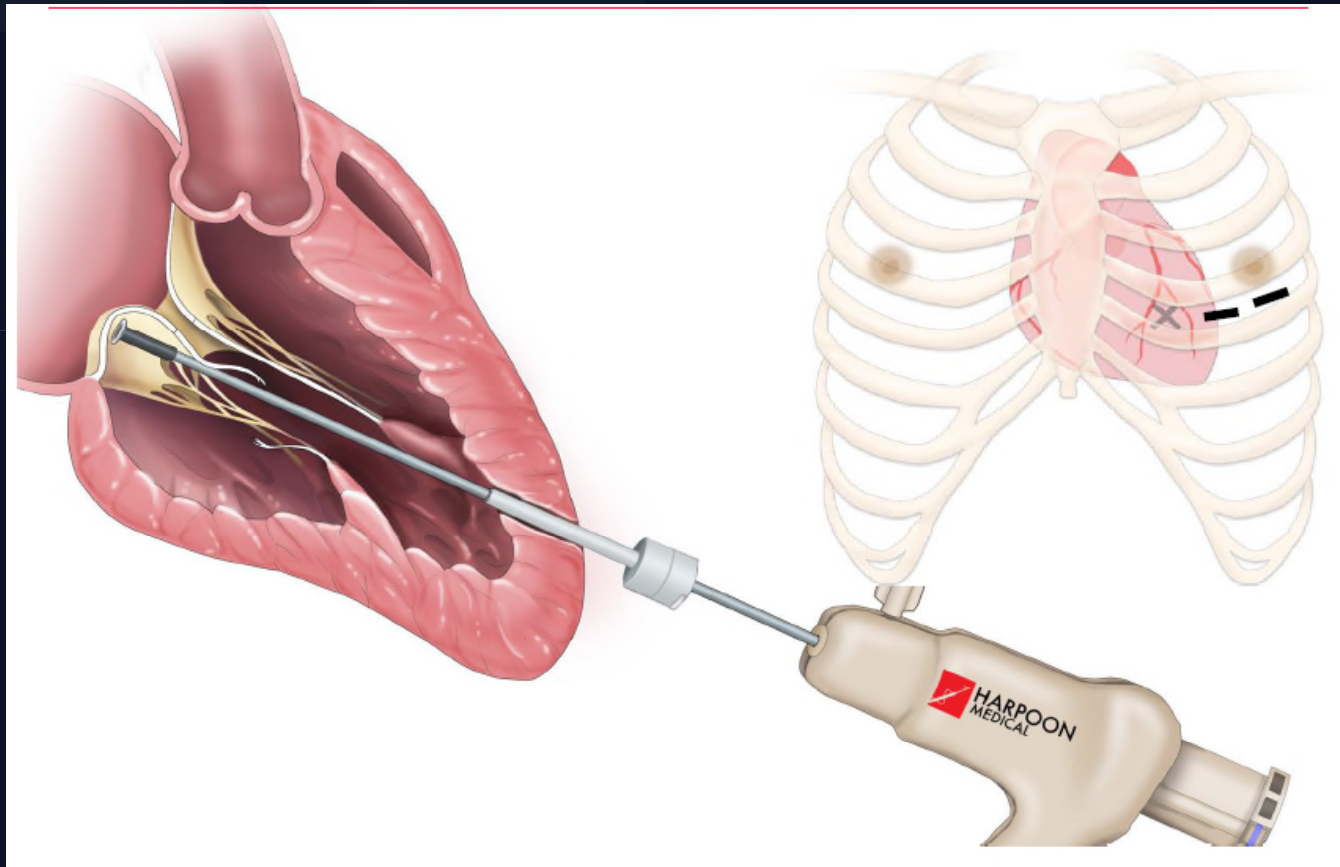


**Tendyne (Abbott)**

**Twelve (Medtronic)**



# Harpoon



# Harpoon

## Initial Human Clinical Experience

### Harpoon Artificial ePTFE Implantation:

- **100 % Procedural Success**
- **Safe – low morbidity**
- **NO: sternotomy, cross clamp, cardioplegia, or bypass**
- **Enables fine-tuning of repair with dynamic ePTFE cordal titration on the beating heart**
- **Effective MR Reduction**





# Transapical Beating-Heart Mitral Valve Repair With an Expanded Polytetrafluoroethylene Cordal Implantation Device

## Initial Clinical Experience

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Editorial, see p 198

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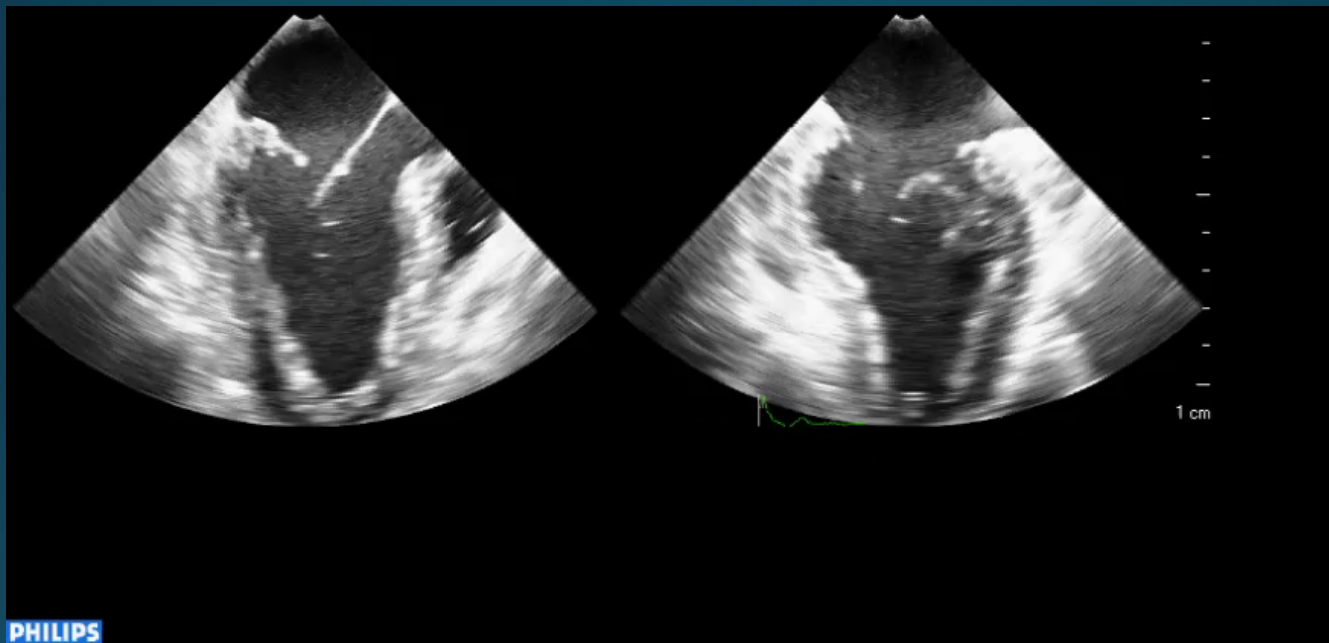
**BACKGROUND:** Degenerative mitral valve (MV) disease is a common cause of severe mitral regurgitation (MR) and accounts for the majority of MV operations. Conventional MV surgery requires cardiopulmonary bypass, aortic cross-clamping, cardioplegia, and a thoracotomy or sternotomy and, therefore, is associated with significant disability, risks, and unpredictable rates of MV repair. Transesophageal echocardiography–guided beating-heart MV repair with expanded polytetrafluoroethylene cordal insertion has the potential to significantly reduce surgical morbidity. We report the first-in-human clinical experience with a novel preformed expanded polytetrafluoroethylene knot implantation device (Harpoon TSD-5) designed to treat degenerative MR.

**METHODS:** Through a small left thoracotomy, the device was inserted into the heart and guided by transesophageal echocardiography to the ventricular surface of the prolapsed leaflet. Multiple expanded polytetrafluoroethylene cords were anchored in the leaflet and then

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James S. Gammie, MD  
Peter Wilson, BSMET  
Krzysztof Bartus, MD, PhD  
Andrzej Gackowski, MD,  
PhD  
Judy Hung, MD  
Michael N. D'Ambra, MD  
Piotr Kolsut, MD, PhD  
Gregory J. Bittle, MD  
Piotr Szymanski, MD, PhD  
Jerzy Sadowski, MD, PhD  
Bogusław Kapelak, MD,  
PhD  
Agata Bilewska, MD, PhD  
Mariusz Kusmierczyk, MD,  
PhD  
Mehrdad Ghoreishi, MD

Severe MR due to P2 prolapse



2014/11/04 1:51:11 PM  
JOHN PAUL II HOSPITAL K

VR 110 Hz 130 180  
6cm

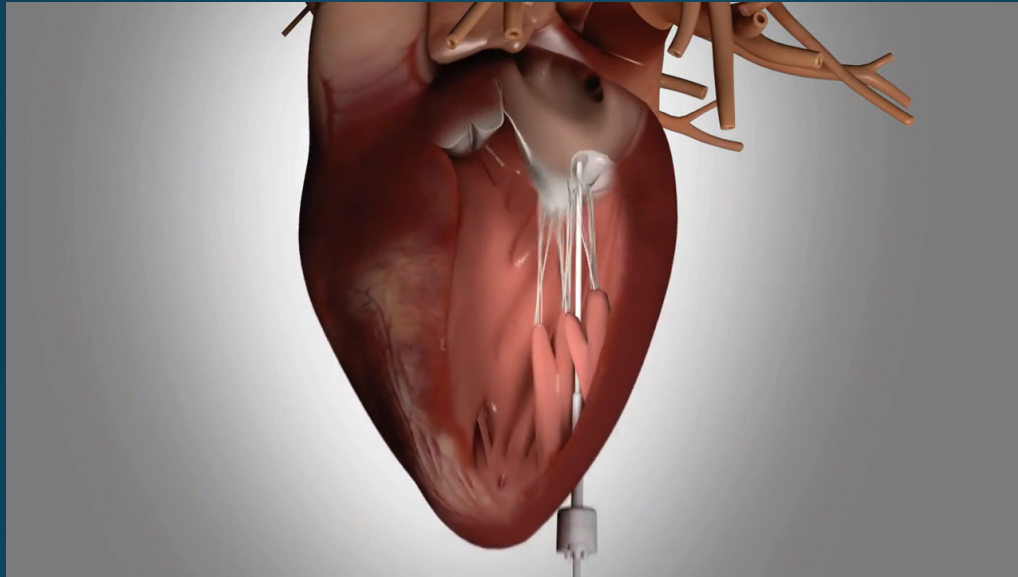
Live 3D  
3D 50%  
3D 50dB



73 bpm

PHILIPS

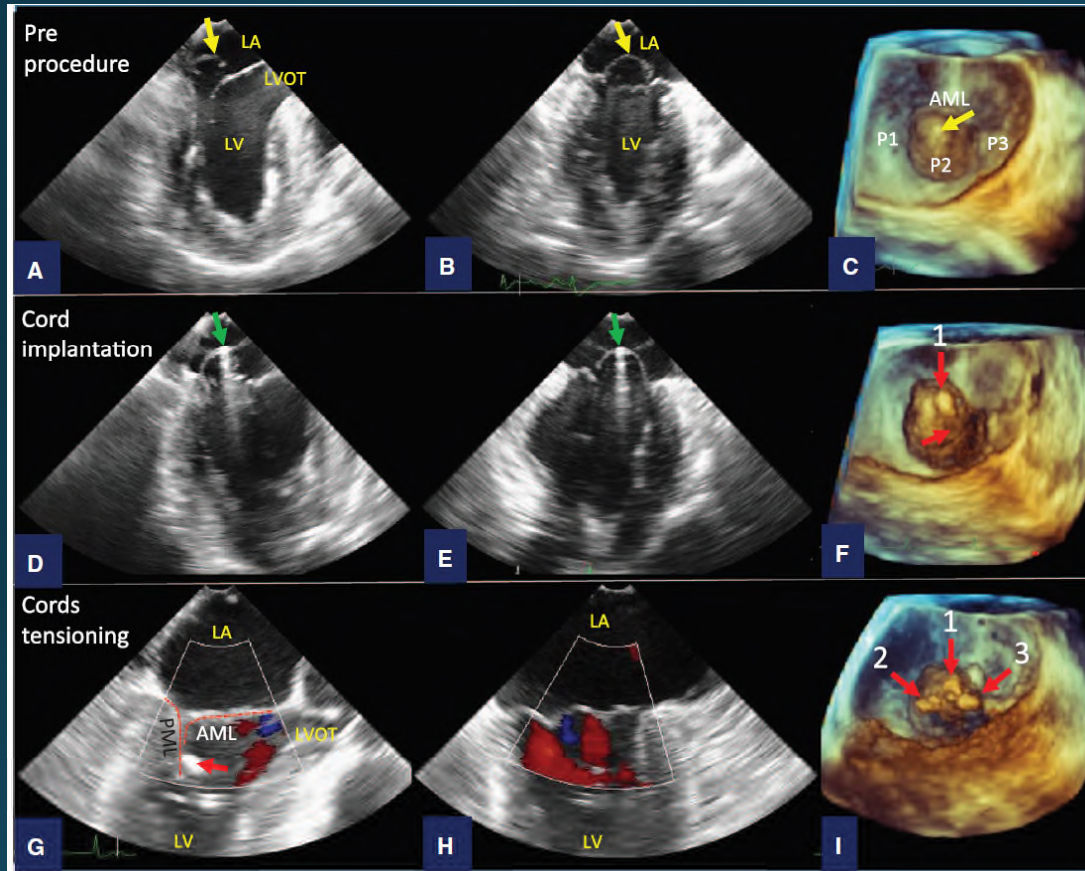




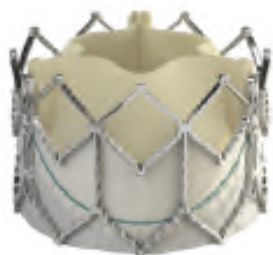
Harpoon Medical







# The MITRAL Trial



## Inclusion Criteria

### Native MV (MAC)

Calcific MS (MVA  $\leq 1.5$  cm<sup>2</sup>)  
Severe MR + Mod MS  
NYHA II or greater  
Not surgical candidate

### Valve-in-Ring

Failing surgical ring  
Severe MR or MS  
NYHA II or greater  
Not surgical candidate

### Valve-in-Valve

Failing Bioprosthesis  
Severe MR or MS  
NYHA II or greater  
Not surgical candidate

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)



# Institute of Cardiology, Krakow – ViR

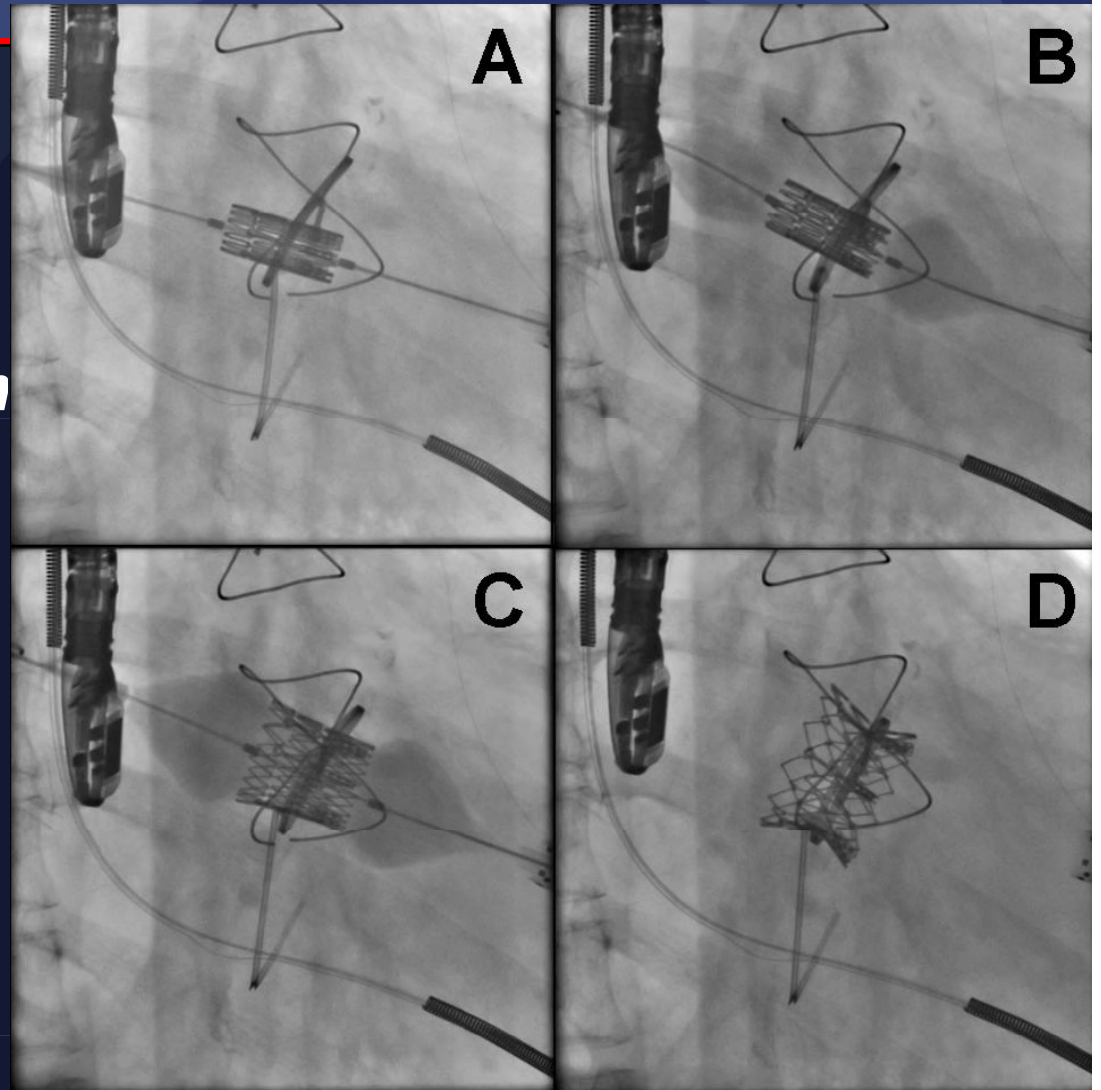
- *Initially – severe MR, Carpentier II, A2 prolapse, EROA 0.35 cm<sup>2</sup>, EF 60%*
- *Jan 2015 - MVP, **CE Physio 32**, artificial chords, mild MR*
- *Nov 2015 - severe MR, Carpentier II, bicommissural prolapse, EROA 0.57 cm<sup>2</sup>, RV 83 ml, EF 35%*





# Institute of Cardiology, Krakow – ViR

*Edwards SAPIEN XT 29mm  
in CE Physio 32*

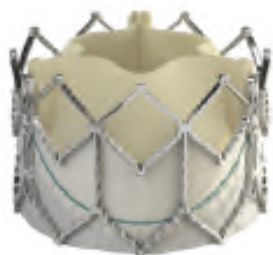


# Valve in Valve, Valve in Ring - conclusions

1. Decision on ViV, ViR procedures should be based on clinical assessment and multimodal imaging
2. ViV procedures are safe and effective procedures in appropriately selected patients with degenerated surgical bioprostheses
3. ViV is one of potential corrective measures for reducing the PVL grade after TAVI
4. ViR procedures are also recommended after failure of the surgical valve operation with rings



# The MITRAL Trial



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NYHA II or greater  
Not surgical candidate

### Valve-in-Ring

Failing surgical ring  
Severe MR or MS  
NYHA II or greater  
Not surgical candidate

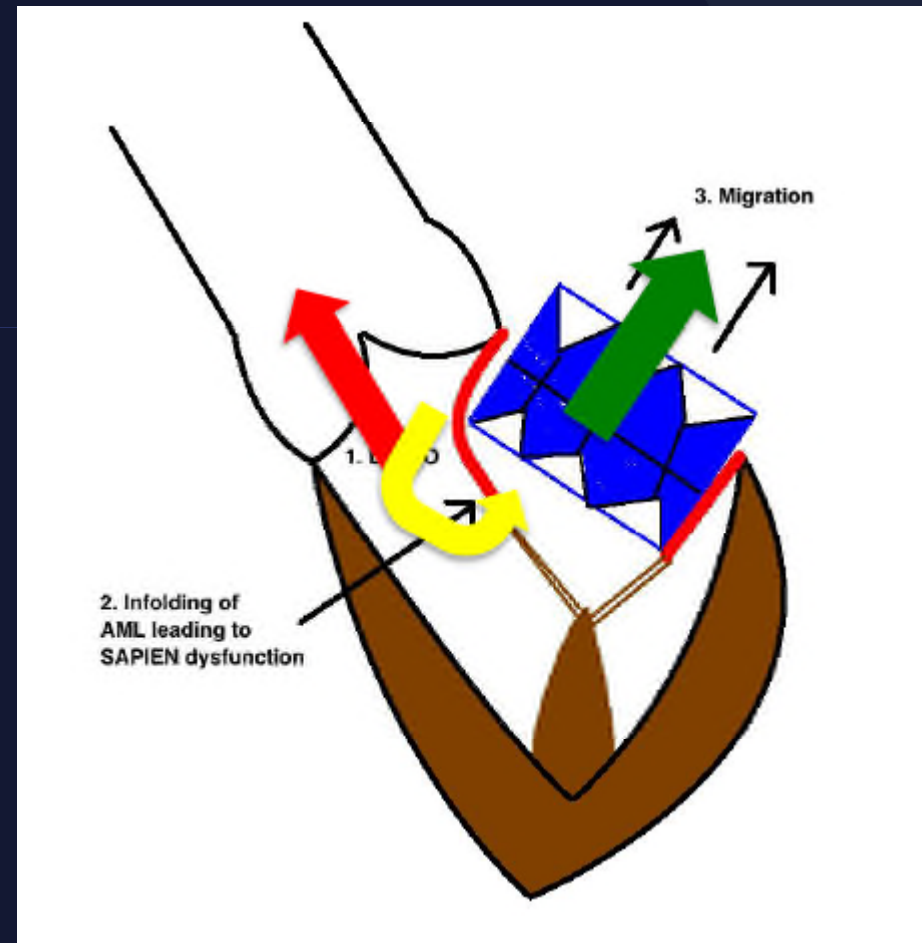
### Valve-in-Valve

Failing Bioprosthesis  
Severe MR or MS  
NYHA II or greater  
Not surgical candidate

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)

# TAVI in native MV (MAC) - possible problems

- LVOT Obstruction
- Embolisation
- Leaflet in folding





# Novel TAVI devices

## Three TAVI devices

- Small in size
- Existing delivery mechanism makes Mitral implant possible
- Implant technique is different

Sapien, Lotus and Directflow



# What we have learned and need to learn

## 1. Sizing

- CT based
- Echo based

## 2. Calcification pattern

- Close 'C'
- Open 'C'
- Commissural area

## 3. 3-D Models

## 4. Presence of Aortic prosthesis



# Current limitations

- **Largest size is 27**
- **Trans-Apical approach only**
- **Influence of the Curve of the sheath on valve angulation**



# A. W.-R.

## *Heart Team qualification (04.2016):*

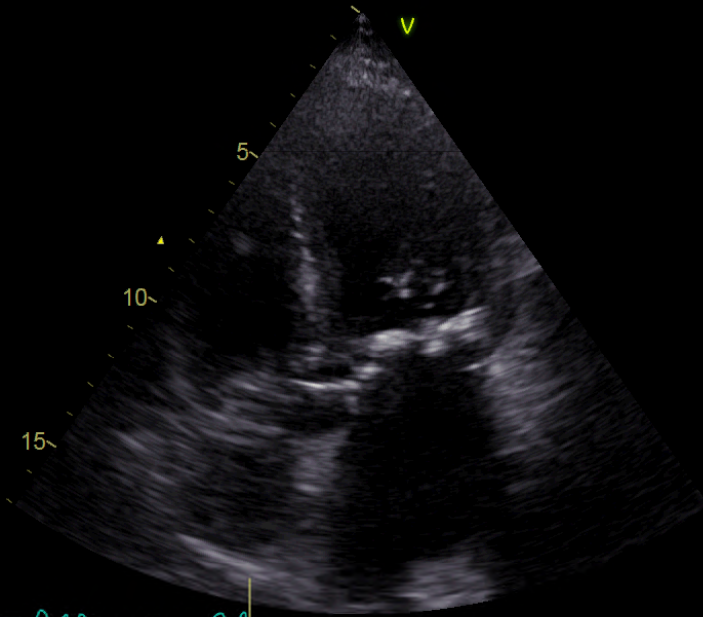
**First step: PCI RCA (performed 04.2016)**

**2nd step: angioCT – evaluation of the valvular disease**

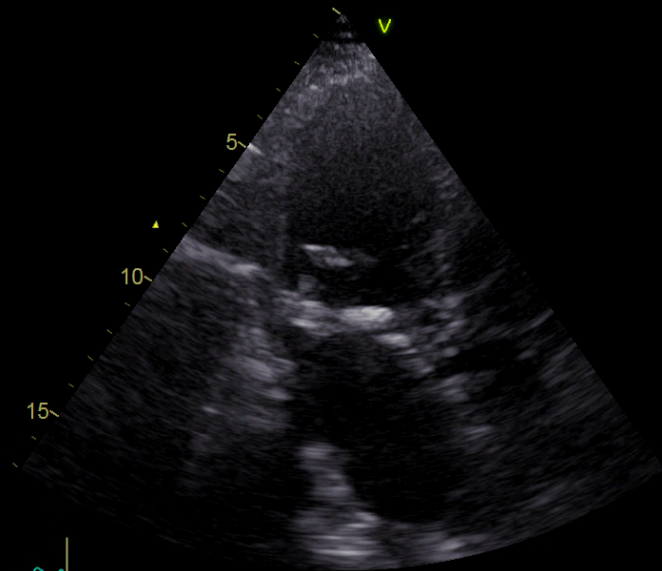
**3rd step: TAVI in mitral position (MAC)**

# A. W.-R.

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25/04/2016 13:35:30

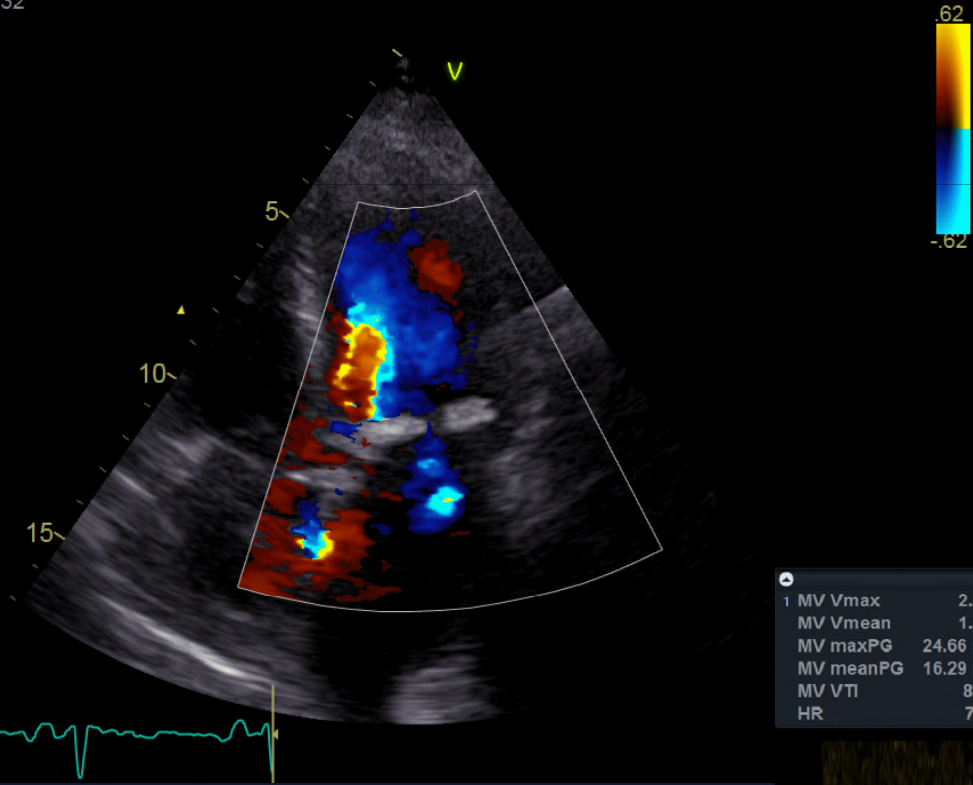


75  
2:49-1R

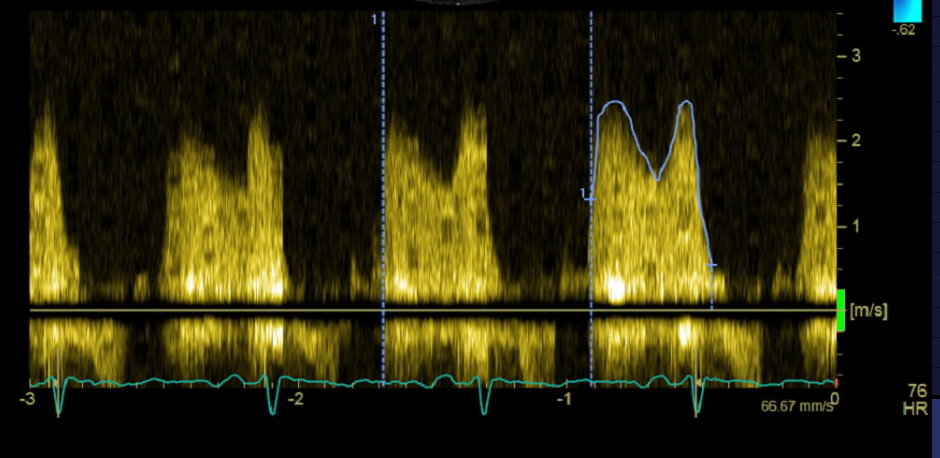
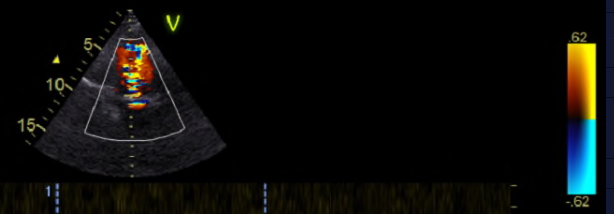


# A. W.-R.

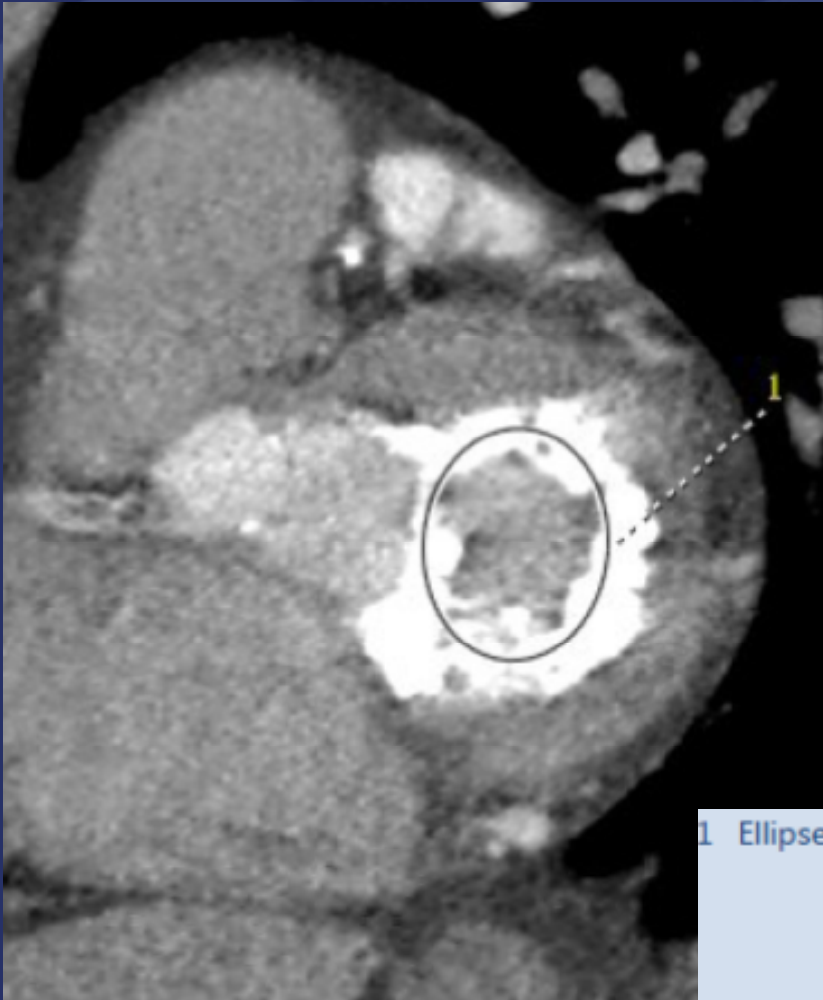
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1 MV Vmax	2.48 m/s
MV Vmean	1.96 m/s
MV maxPG	24.66 mmHg
MV meanPG	16.29 mmHg
MV VTI	88.1 cm
HR	78 BPM

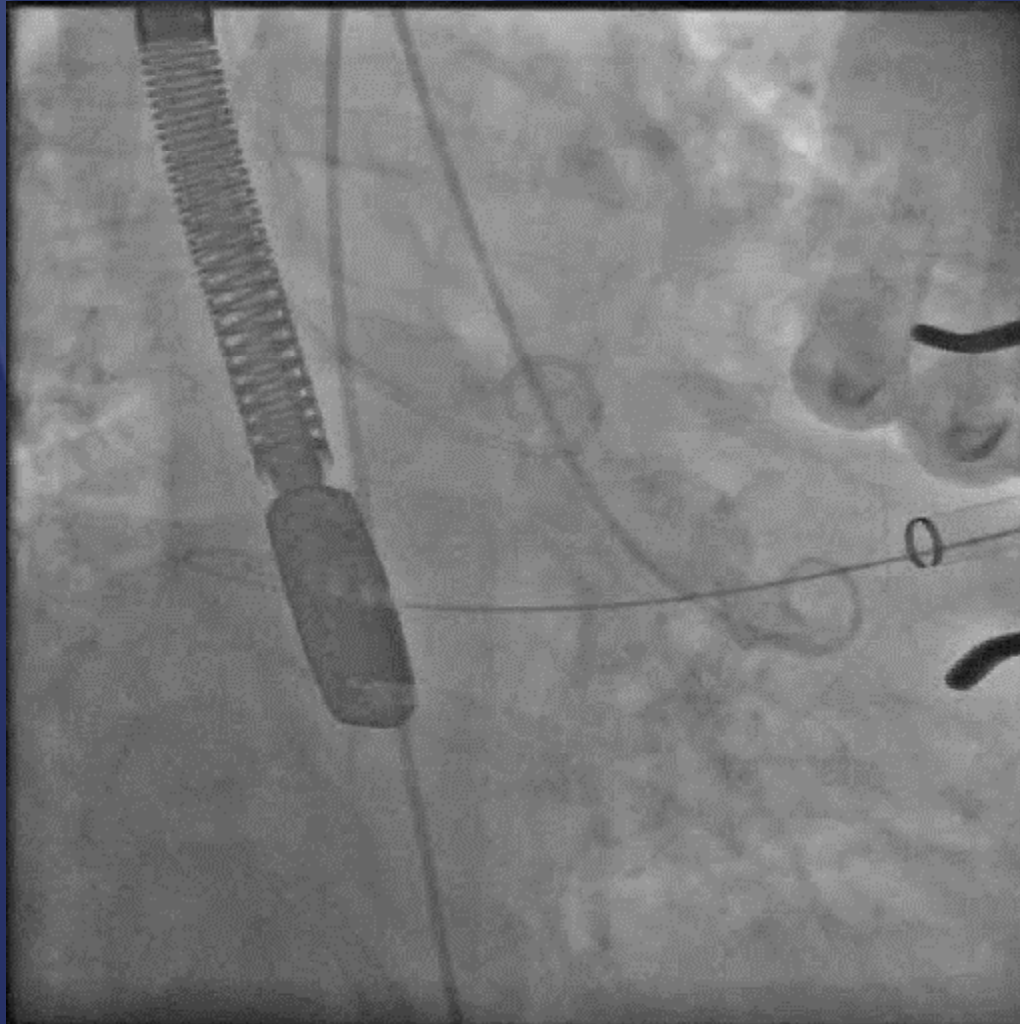


## A. W.-R.

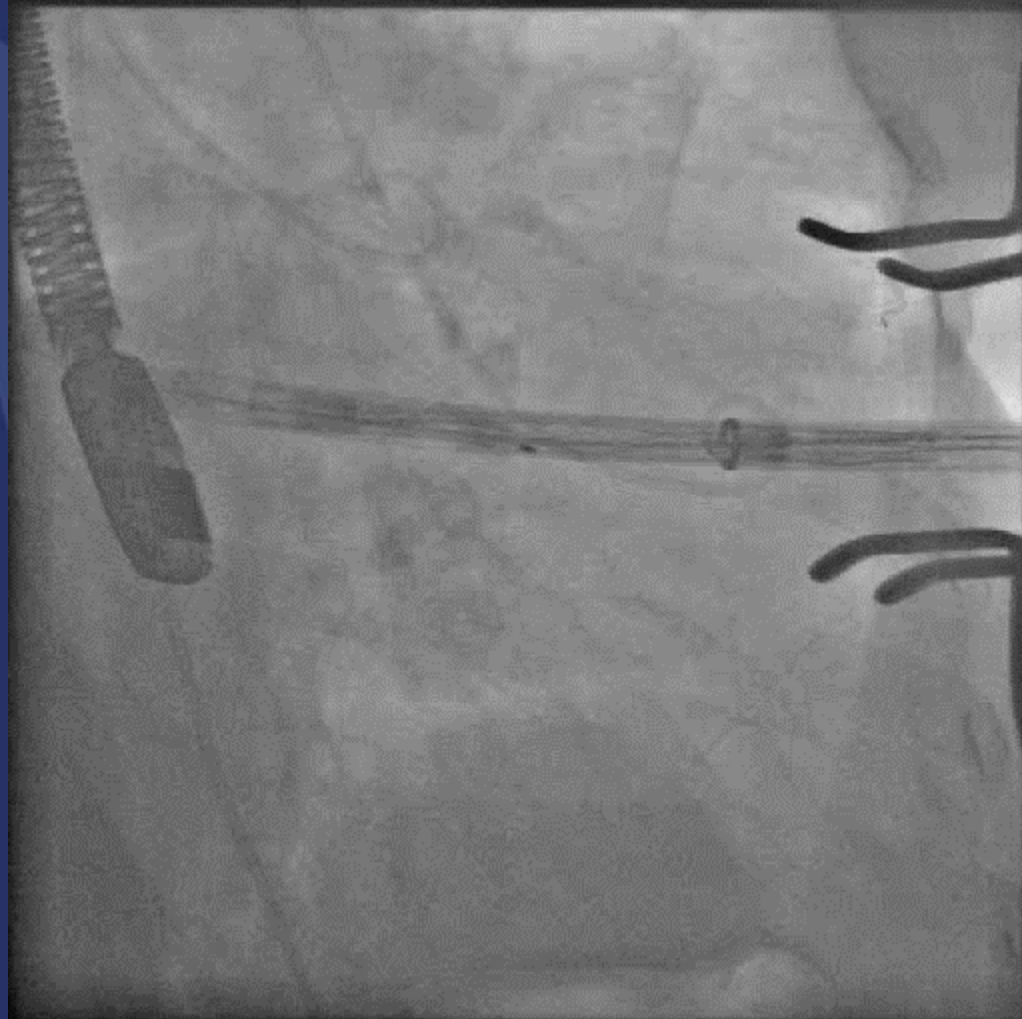


1 Ellipse Min. Ø	23.4 mm
Max. Ø	29.9 mm
Avg. Ø	26.6 mm
Area derived Ø	26.4 mm
Perimeter derived Ø	26.8 mm
Area	549.5 mm <sup>2</sup>
Perimeter	84.3 mm

**A. W.-R.**

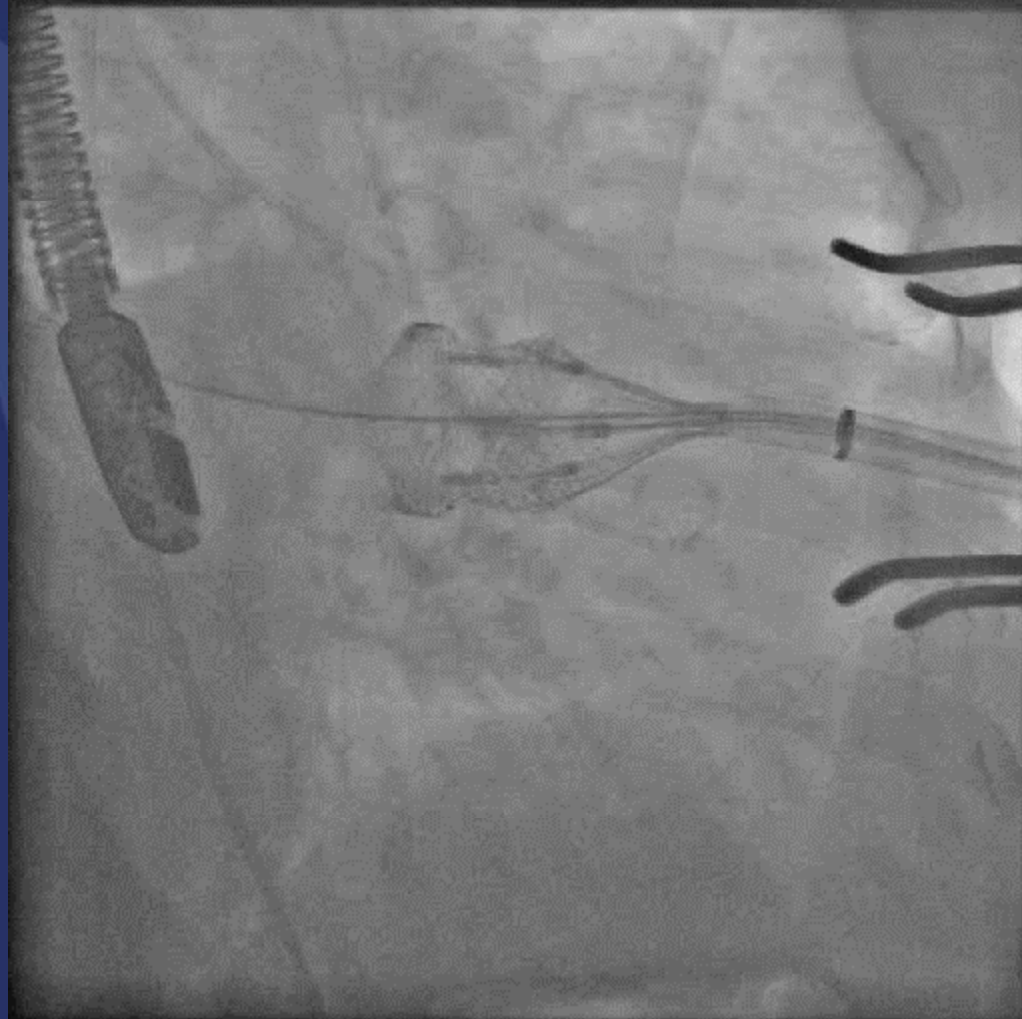


**A. W.-R.**

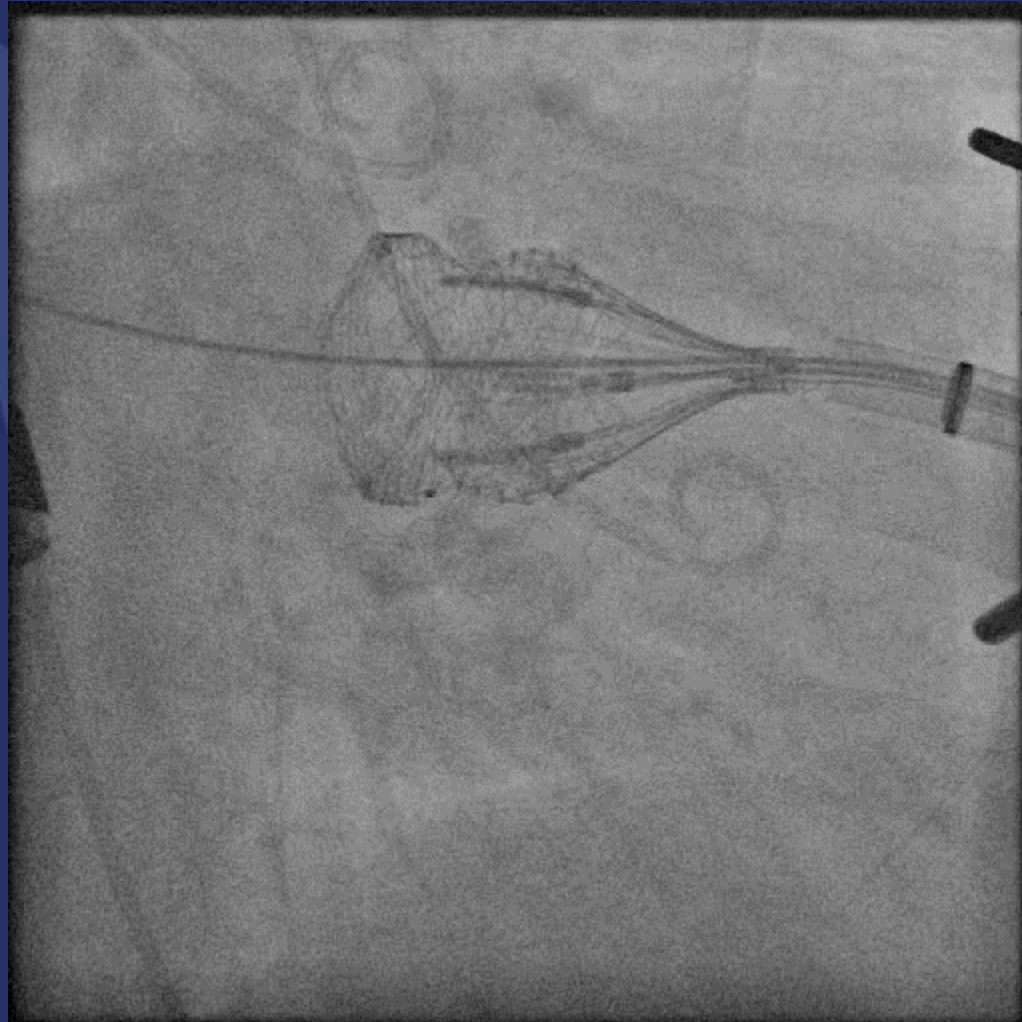




**A. W.-R.**

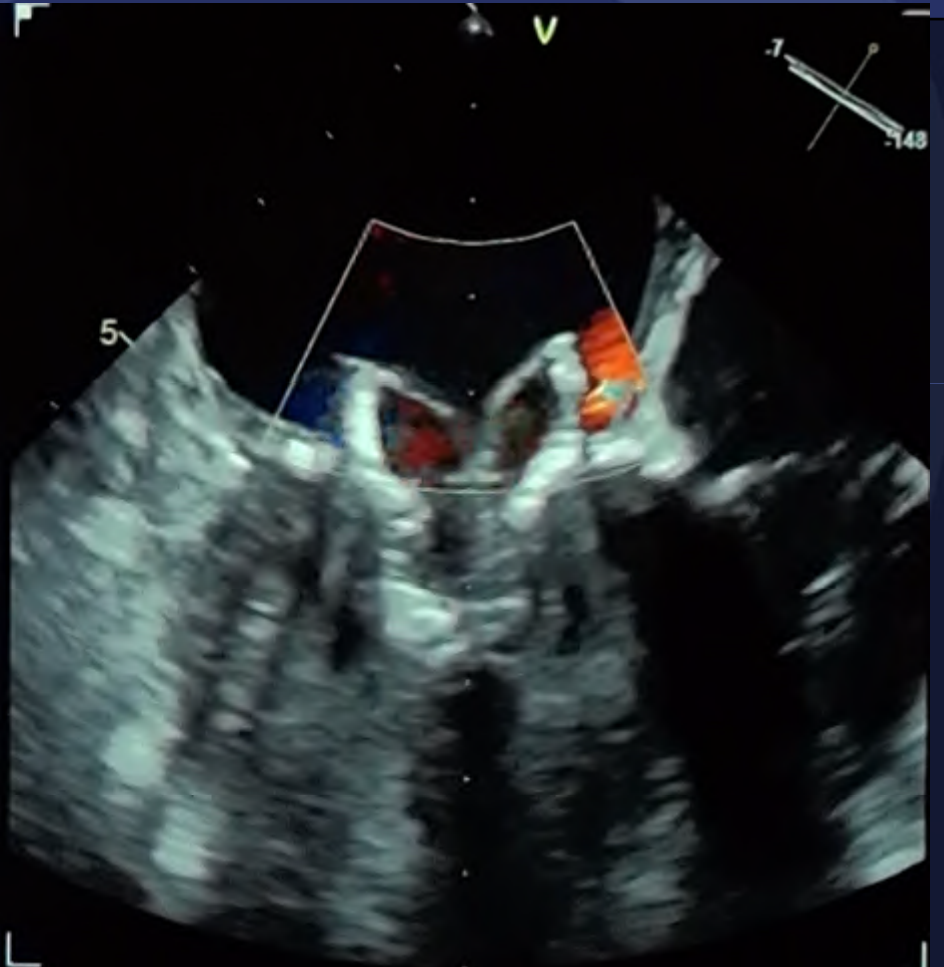
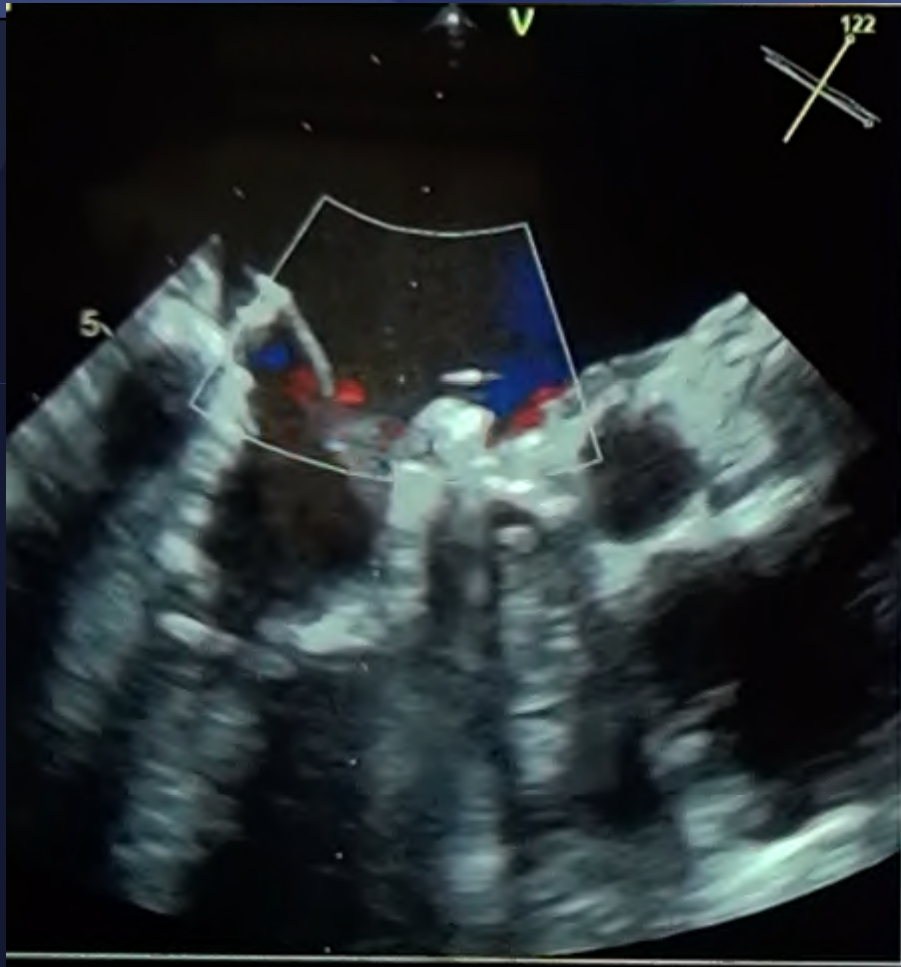


**A. W.-R.**



**A. W.-R.**







# PVL

**Given the complex nature of the mitral apparatus:**

- **PVL may be more common than with TAVI**
- **PVL may lead to higher rates of hemolysis**



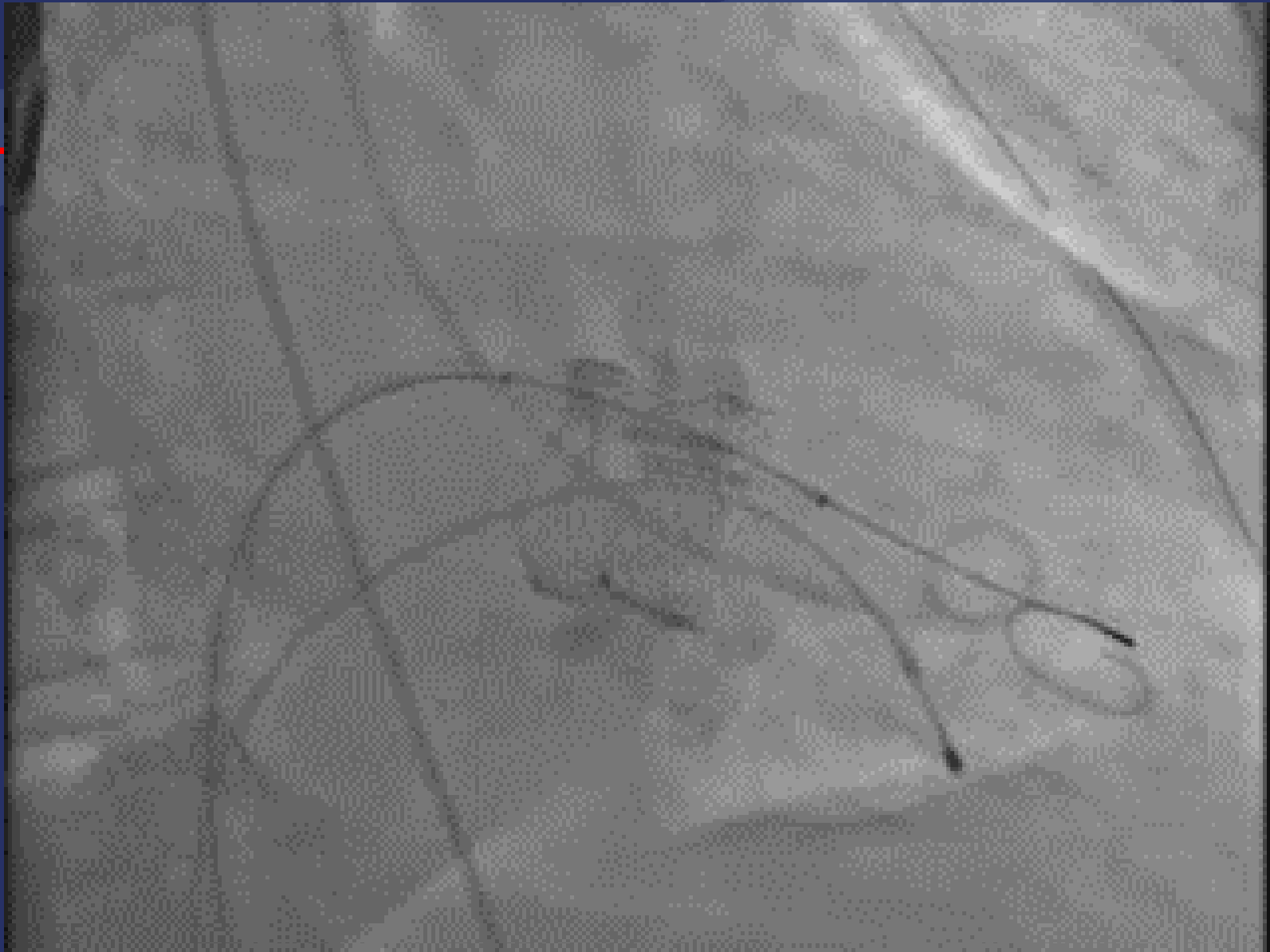
## **Solution ?**

### **Postdilatation?**

- **When indicated?**
- **How to evaluate PVL after TMVR?**
- **Size of the balloon?**
- **Which balloon?**
- **Pacing?**









# Procedural Outcomes

	<b>n (%)</b>
Technical success by MVARC criteria	78/104 (75%)
Need for second valve (migration=6, MR=7)	13/104 (12.5%)
LVOT obstruction with hemodynamic compromise	11/104 (10.5%)
Valve embolization	4/104 (3.8%)
Conversion to open surgery (embolization=2, LV perforation=1, LVOTO=1)	4/104 (3.8%)
LV perforation (surgery=1, conservative=1)	2/104 (1.9%)
Pulmonary Vein Perforation	1 (0.9%)

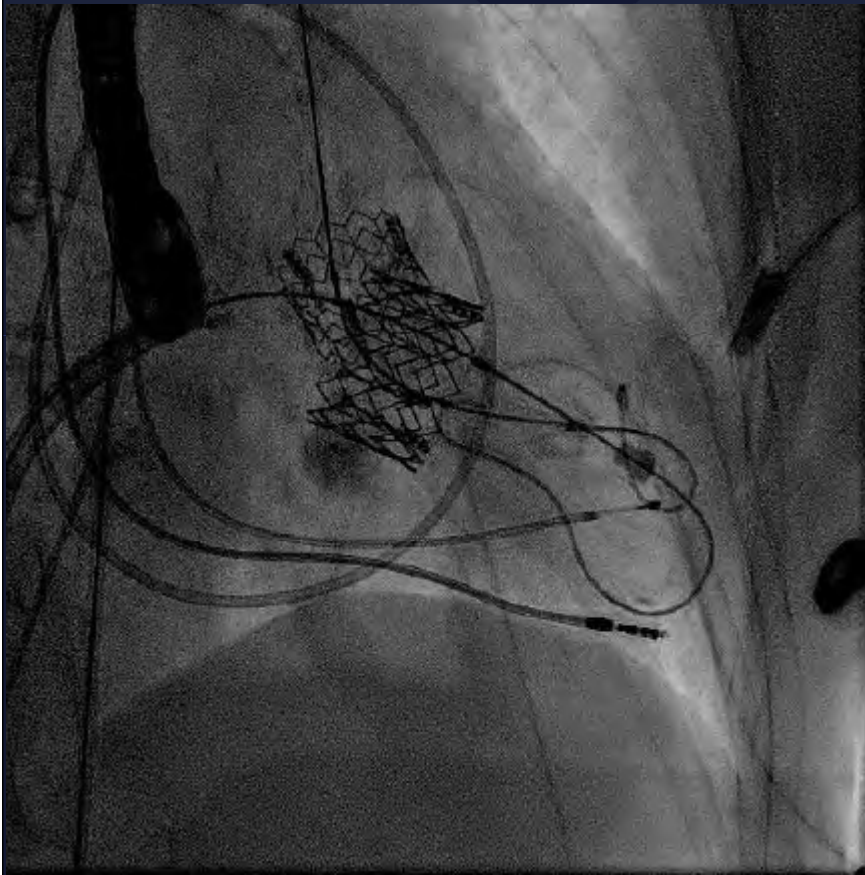
# 30 Day/Procedural Mortality

26/104 (25%)

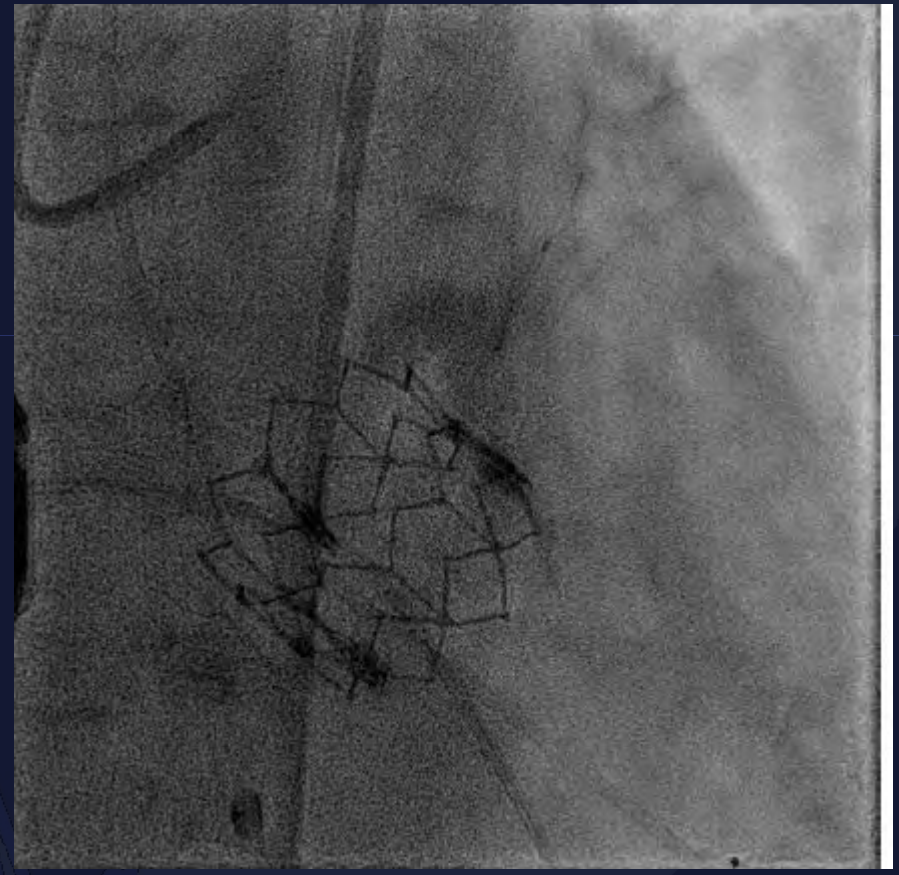
	n (%)
Cardiovascular	11/104 (10.6 %)
LVOT Obstruction	3 (2.9%)
LV Perforation	2 (1.9%)
Complete AV block	1%
MI due to air emboli / Pulmonary vein perforation	1%
Stroke	2 (1.9%)
PEA arrest	1 %
MR	1 %
Non-Cardiac	15/104 (14.4 %)
Multi-organ failure	9 (8.6%)
Pneumonia	3 (2.9%)
Thoracentesis related bleeding complication	1%
Infection	2 (1.9%)

**TMVR in MAC Global Registry**

# Techniques to treat LVOT Obstruction after TMVR



**Kissing AV and MV Valvuloplasty**



**Alcohol Septal Ablation**



# Next Steps

**CT analysis for predictors of anchoring (in progress)**

**CT analysis predictors of LVOTO (in progress)**

**Comparison valve type and approach (not enough data yet)**

**LVOT Prevention Strategies (in progress)**

**Prospective Clinical Trial (in progress)**



## Conclusions

- **TMVR is feasible in patients with MV disease with severe MAC**
- **It may be an option in carefully selected patients**
- **Important learning curve with difficulties in early experience**
- **Studies are needed to determine:**
  - **Best sizing and delivery methods**
  - **LVOT obstruction prevention strategies**
- **and improve patient selection**