# Transcatheter mitral valve repair Devices and Data

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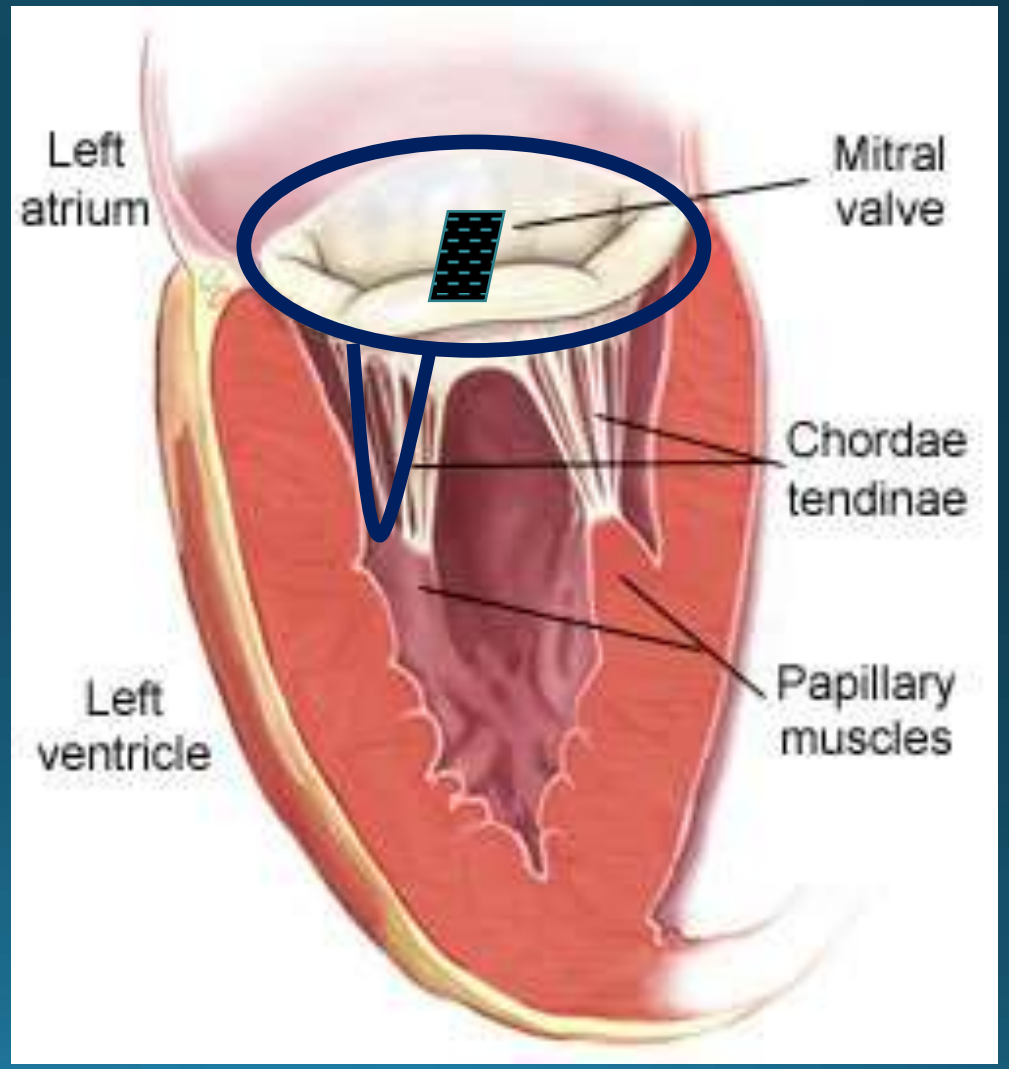
# Transcatheter mitral valve repairs

- Edge to Edge leaflet repair
- Percutaneous annuloplasty
- Chordal replacement



# Edge to Edge repair

- Mitraclip ( Abbott Vascular) ( Most data to date)
- Pascal ( Edwards Lifesciences)

# Mitraclip

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# Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation

## 5-Year Results of EVEREST II

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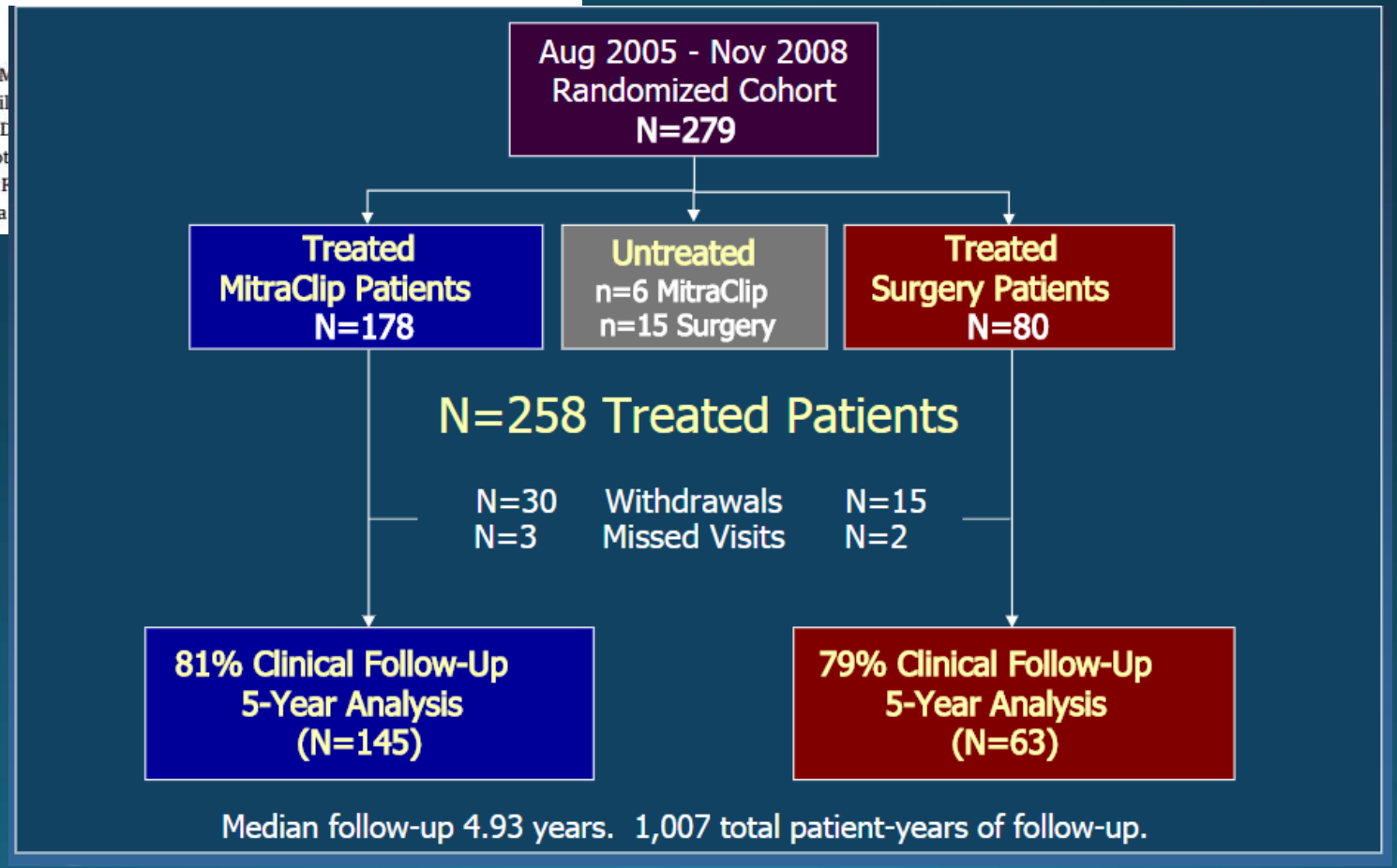
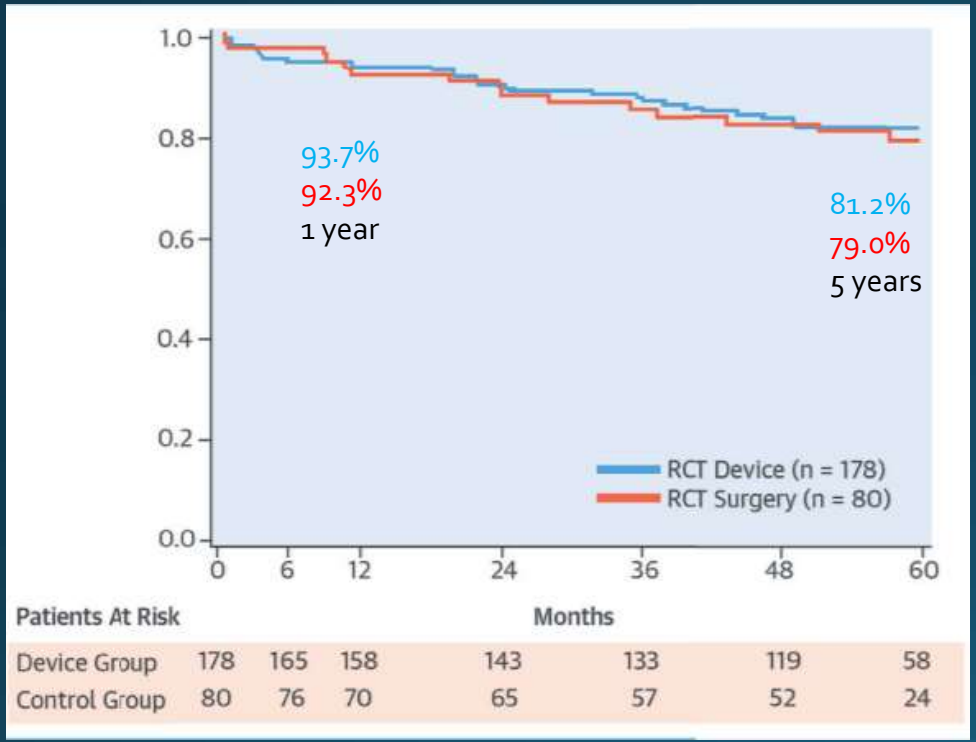
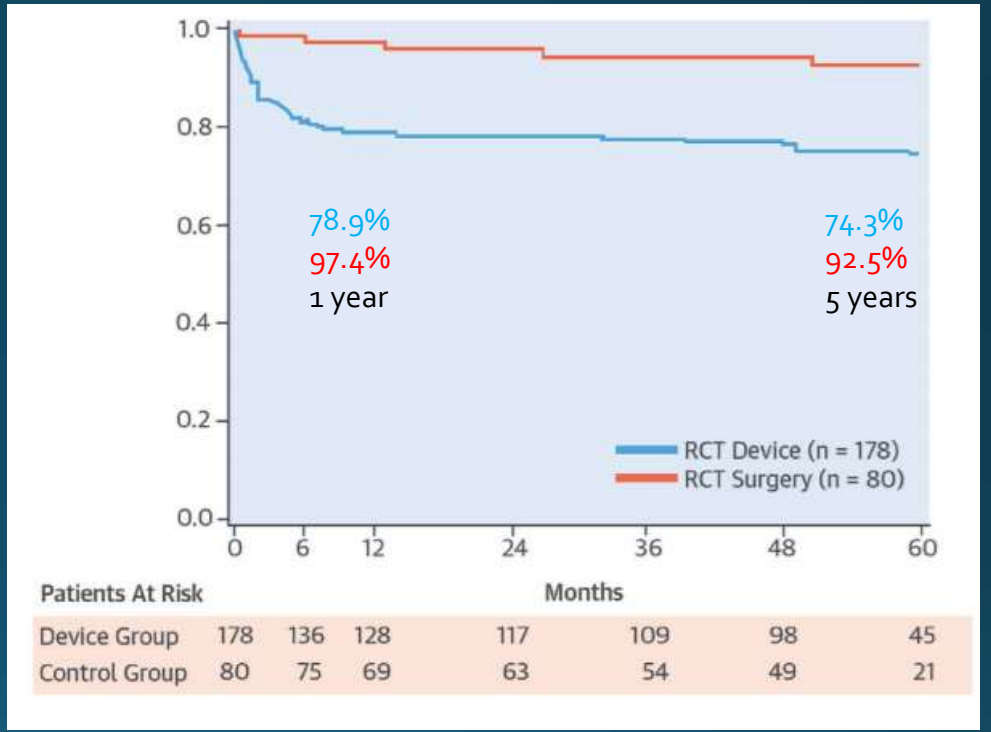


## Freedom from Mortality




## Freedom from MV surgery or reoperation




Feldman et al. JACC 2015

# Ongoing trials

- COAPT trial (610)
- RESHAPE HF2 trial (380)
- MATTERHORN (288)
- MITRA-FR ( ISS) (210)

- 5 trials randomizing ~1656 patients with heart failure and secondary (functional) MR to MitraClip vs. GDMT or MV Surgery
- As of Oct. 24th, 2016, ~876 patients have been randomized:
  - COAPT – 482/610 (79%)
  - MITRA-FR – 231/288 (80%)
  - RESHAPE-HF-2 – 132/380 (35%)
  - MATTERHORN – 31/210 (15%)
  - EVOLVE-HF – 0/168 (0%)

# COAPT Trial: Design

## ~610 patients enrolled at up to 100 sites

Symptomatic HF treated with maximally tolerated guideline directed medical therapy
Significant FMR (≥3+ by echo core lab);
Not appropriate for MV surgery as determined by site's local heart team
Valve anatomy eligible for MitraClip treatment
Up to 3 roll-in procedures per site for investigators without prior MitraClip experience or no MitraClip procedures in the prior 12 months

Randomize 1:1

| MitraClip<br>N~305 | Control group<br>Standard of care<br>N~305 |
|---|---|

Clinical and TTE follow-up: Baseline, treatment, 1-week (phone), 1, 6, 12, 18, 24, 36, 48, 60 months

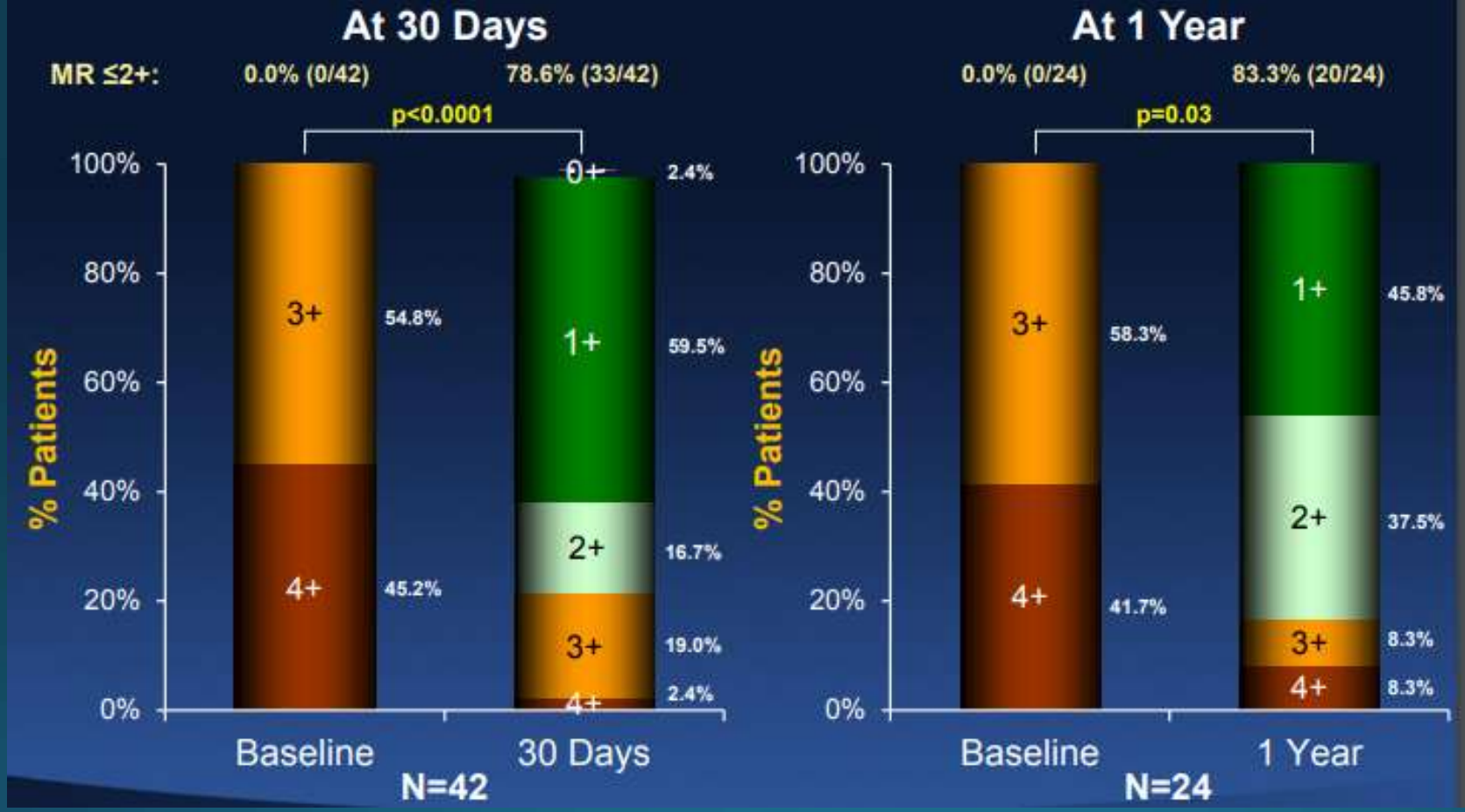
**Primary endpoint:** Hospitalization for heart failure within 2 years

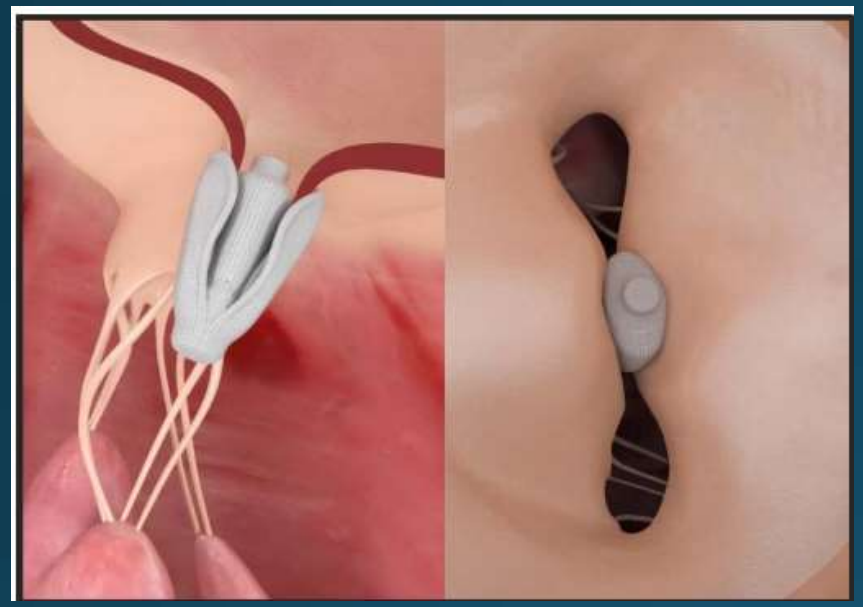
**Principal Investigators:** Gregg Stone, Michael Mack

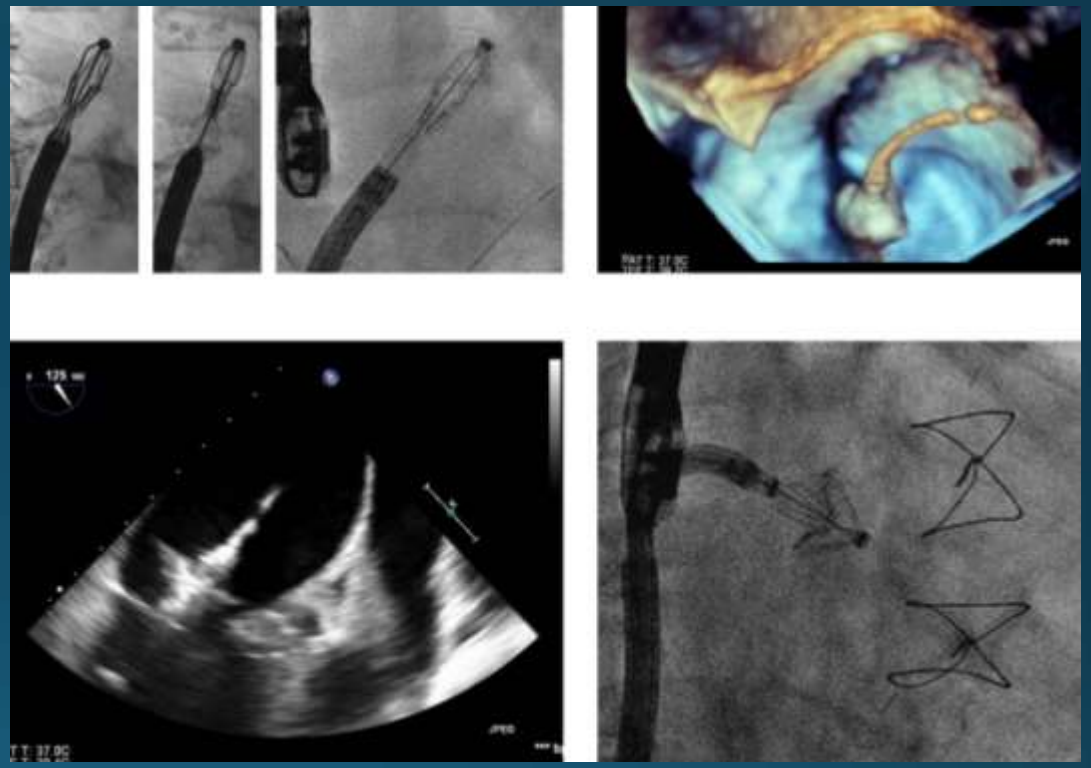
| Event | 30 days (n=50) | 1 year (n=47) |
|---|---|---|
| **Death** | 0% (0) | 15.5% (7)* |
| **Hospitalization, any** | 14.0% (10) | 54.9% (51) |
| Heart failure hospitalization (1˚ effectiveness endpoint) | 12.0% (7) | 29.1% (26) |
| Other CV Hospitalization | 2.0% (1) | 11.5% (8) |
| Non-CV Hospitalization | 4.0% (2) | 32.8% (17) |
| **Adverse event, any** | 8.0% (5) | 10.6% (7) |
| 1˚ safety endpoint composite | 4.0% (2) | 4.0% (2) |
| Stroke | 0% (0) | 2.5% (1) |
| MV replacement due to MitraClip device or procedure | 0% (0) | 0% (0) |
| Endocarditis requiring surgery | 0% (0) | 0% (0) |
| Echo core lab confirmed MS requiring surgery | 0% (0) | 0% (0) |
| Non-elective CV surgery for device-related complication | 4.0% (2) | 4.0% (2) |
| Single leaflet device attachment (SLDA) | 0% (0) | 0% (0) |
| Device embolization | 0% (0) | 0% (0) |
| Myocardial infarction† | 2.0% (1) | 4.6% (2) |
| Major bleeding† | 4.0% (2) | 10.4% (15) |

# Mitral Regurgitation Severity

## Echo Core Lab Assessed (paired measures)





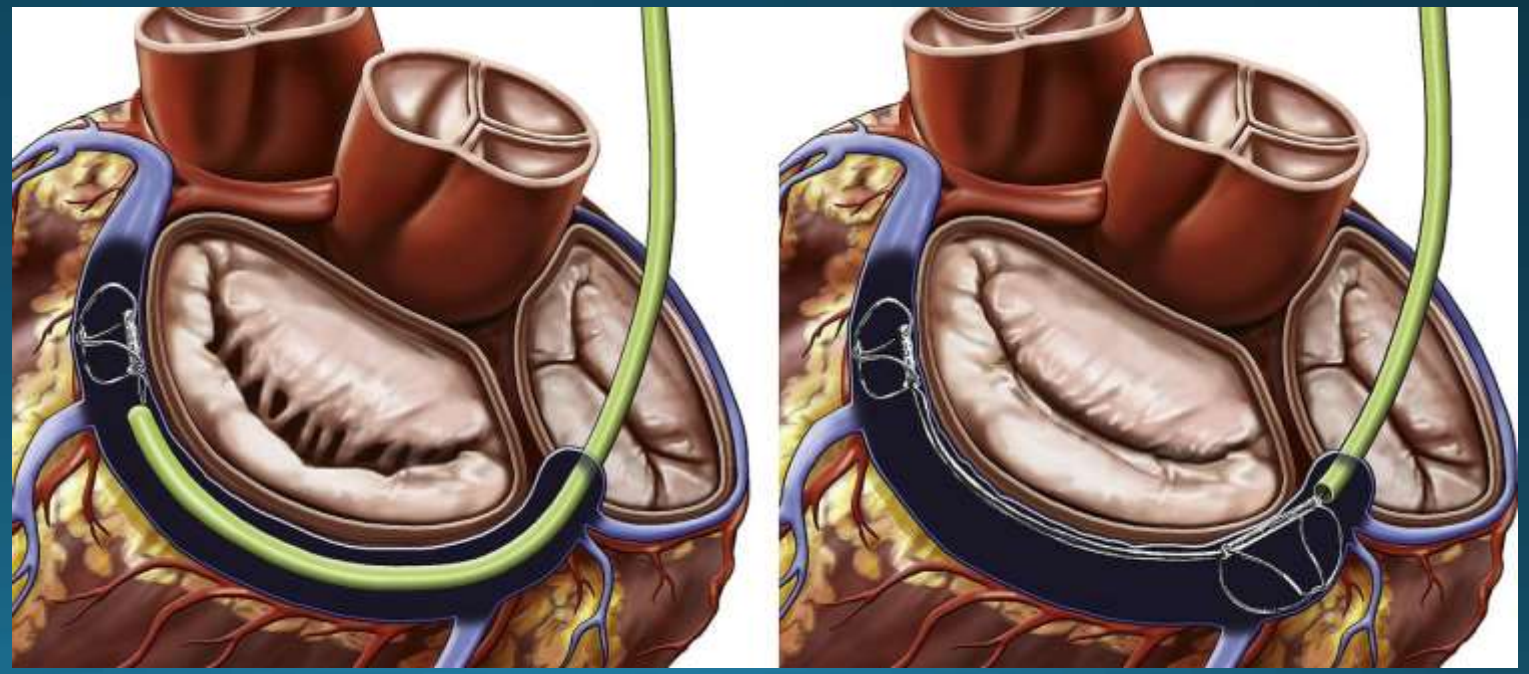


# Percutaneous Annuloplasty

- Coronary sinus annuloplasty
- Direct Annuloplasty
- Basal ventriculoplasty

# Coronary sinus annuloplasty

- Carillon device ( Cardiac dimensions)



# Direct annuloplasty

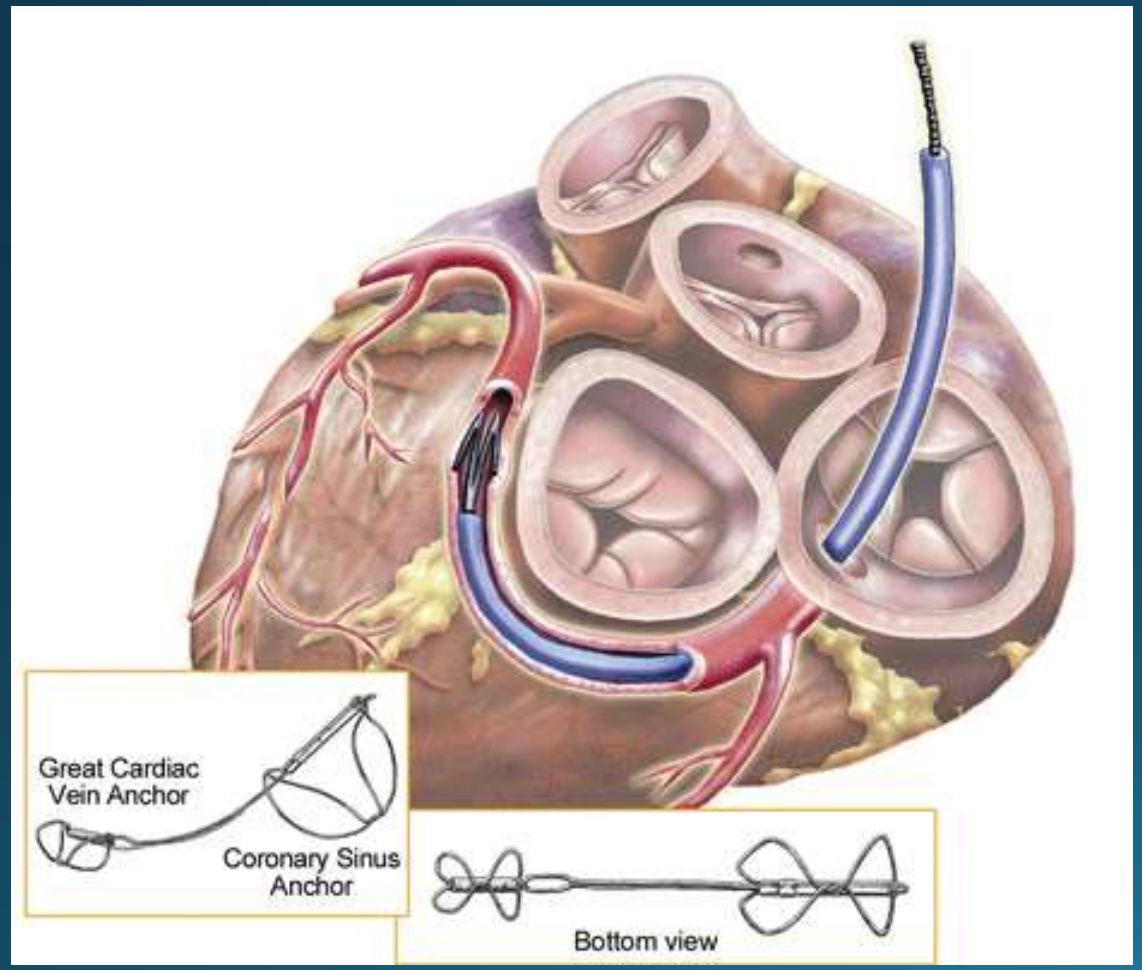
- Cardioband ( Edwards Lifesciences)
- CE Mark obtained 2015
- Mitralign ( CE Mark study completed)
- Millipede
- MVRx Arto systems

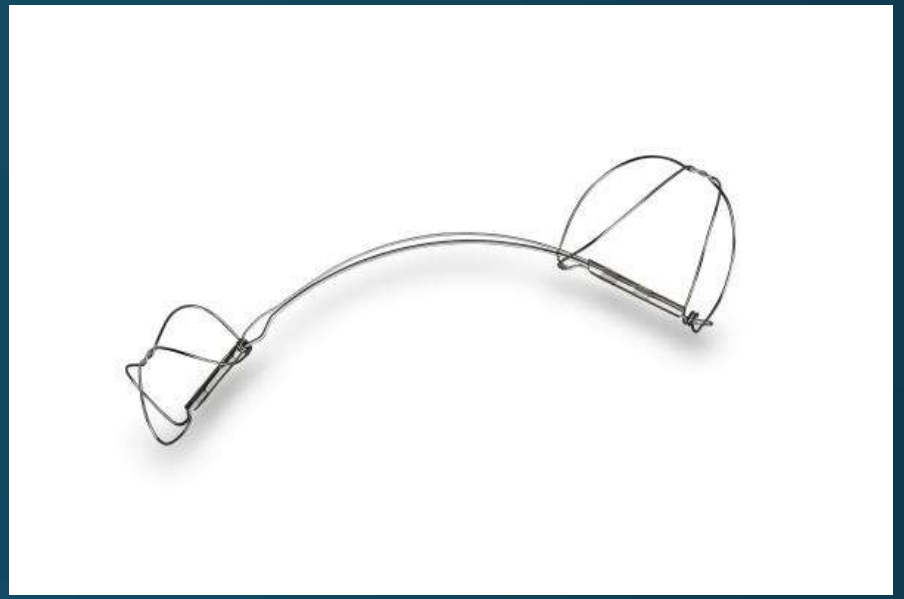
# Chordal placement

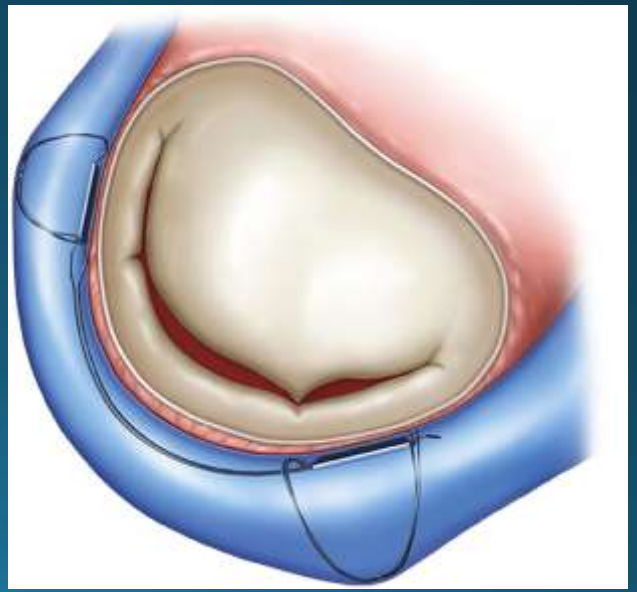
- Neochord
- Harpoon

# Carillon Device

Jugular
venous access



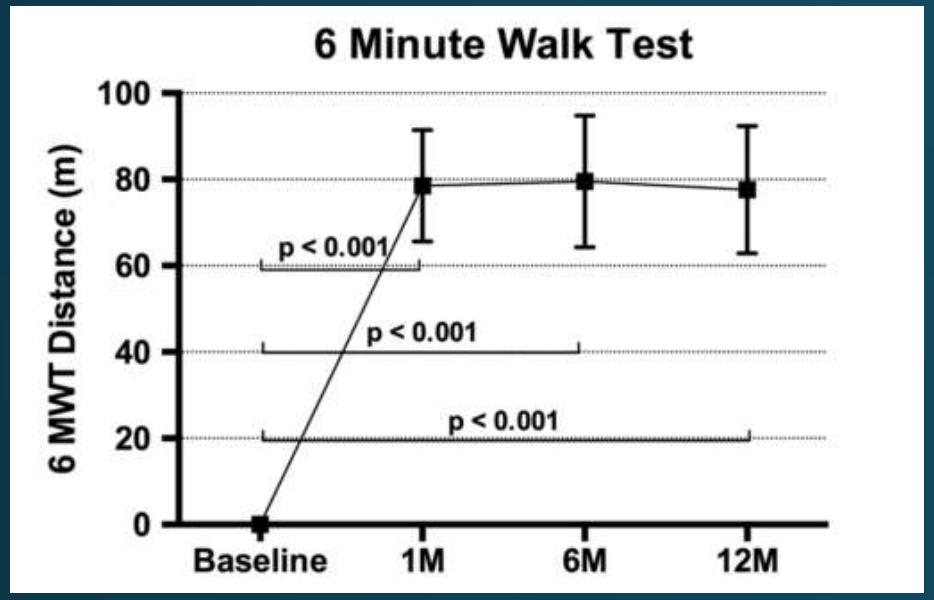



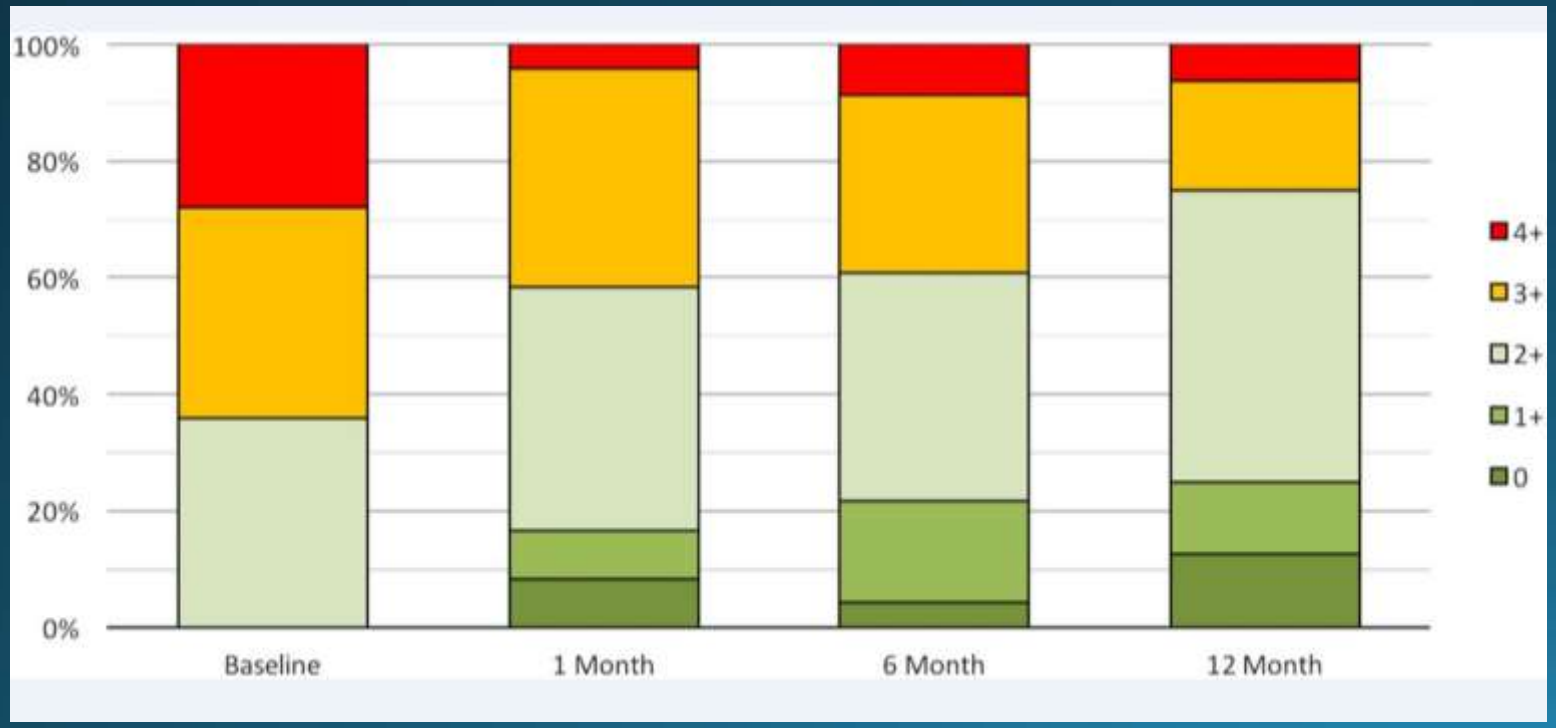


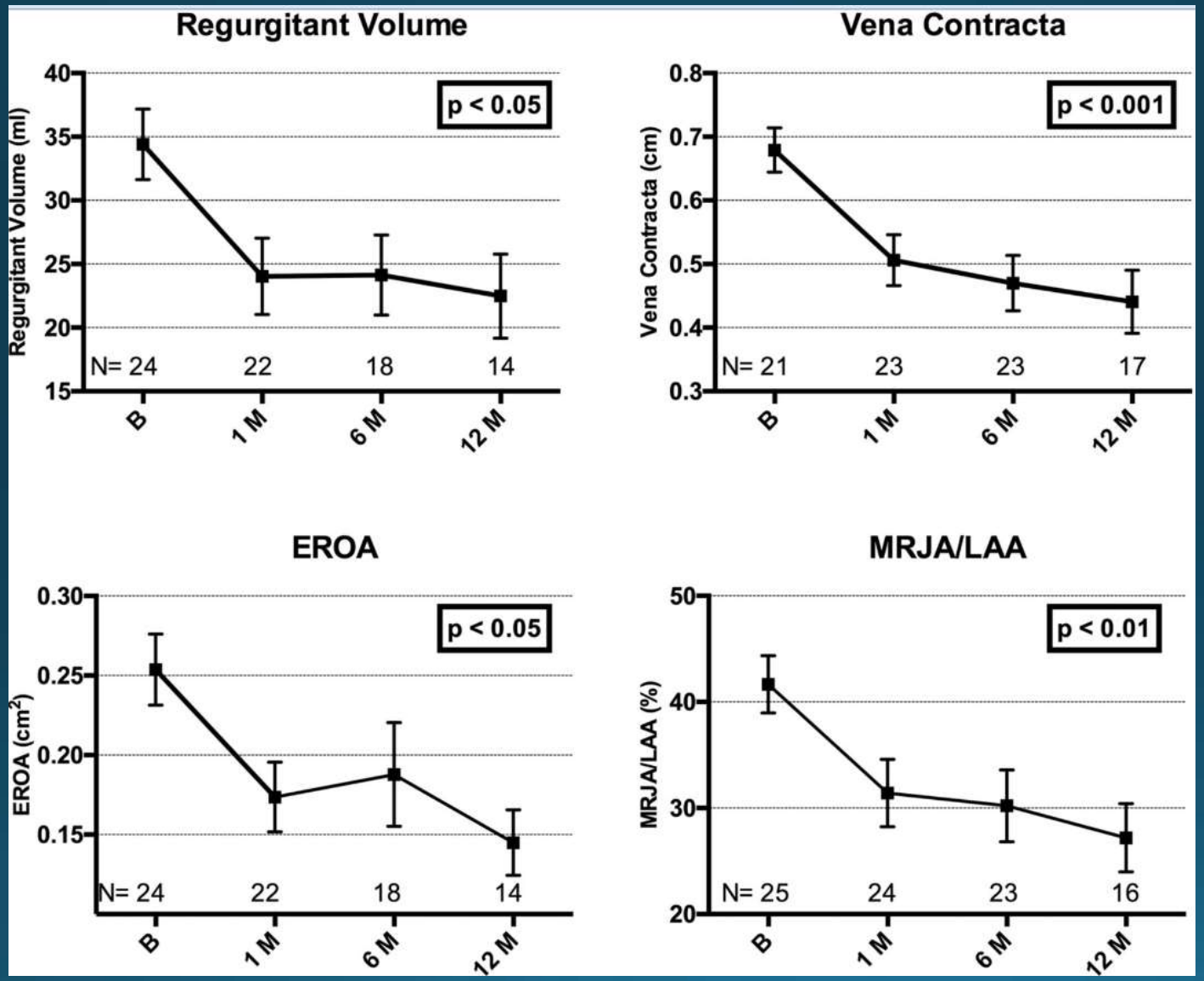
# Clinical trials

| Trial | No of Pats |
|---|---|
| AMADEUS | 30 |
| TITAN | 53 |
| TITAN II | 30 |

Titan II ( 36 patients enrolled)
Implanted 30/36
6/36, not successful due to coronary compromise
No device related major events ( 1 unrelated death)


6 Minute Walk Test
6 MWT Distance (m)
100
80
60
40
20
0
p < 0.001
p < 0.001
p < 0.001
Baseline
1M
6M
12M


100%
80%
60%
40%
20%
0%
Baseline
1 Month
6 Month
12 Month
4+
3+
2+
1+
0




Lipiecki et al. Openheart 2016

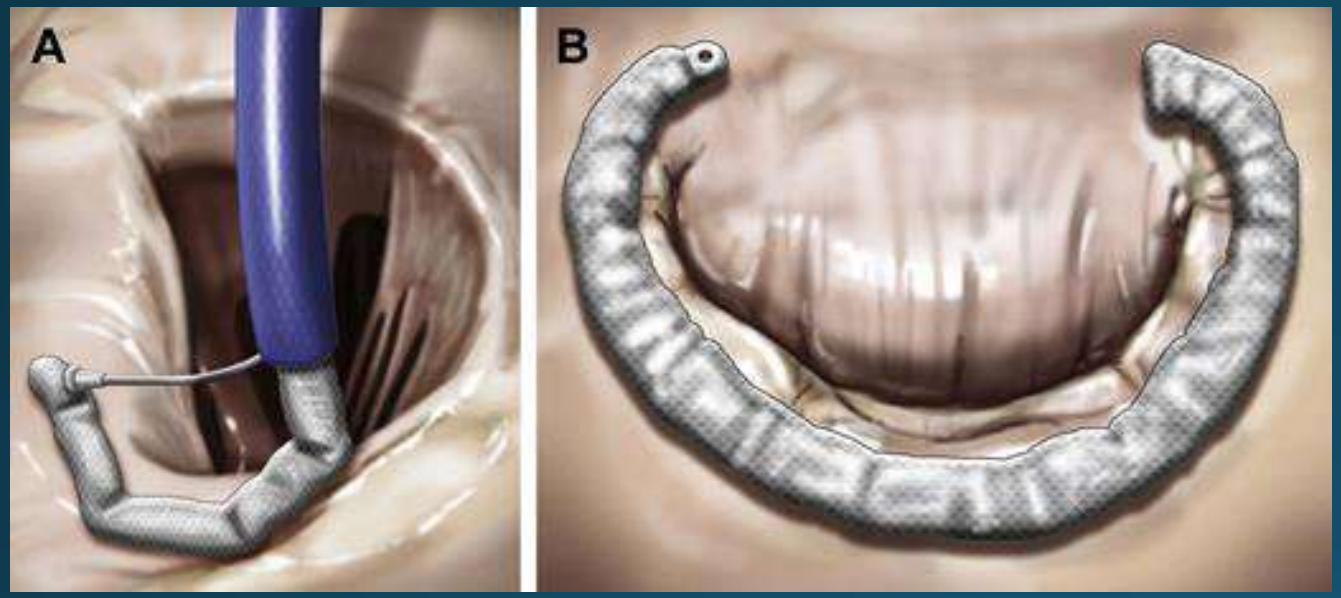
# Ongoing trials for Carillon device

- REDUCE FMR RCT

( Carillon Mitral Contour System for reducing functional mitral regurgitation)

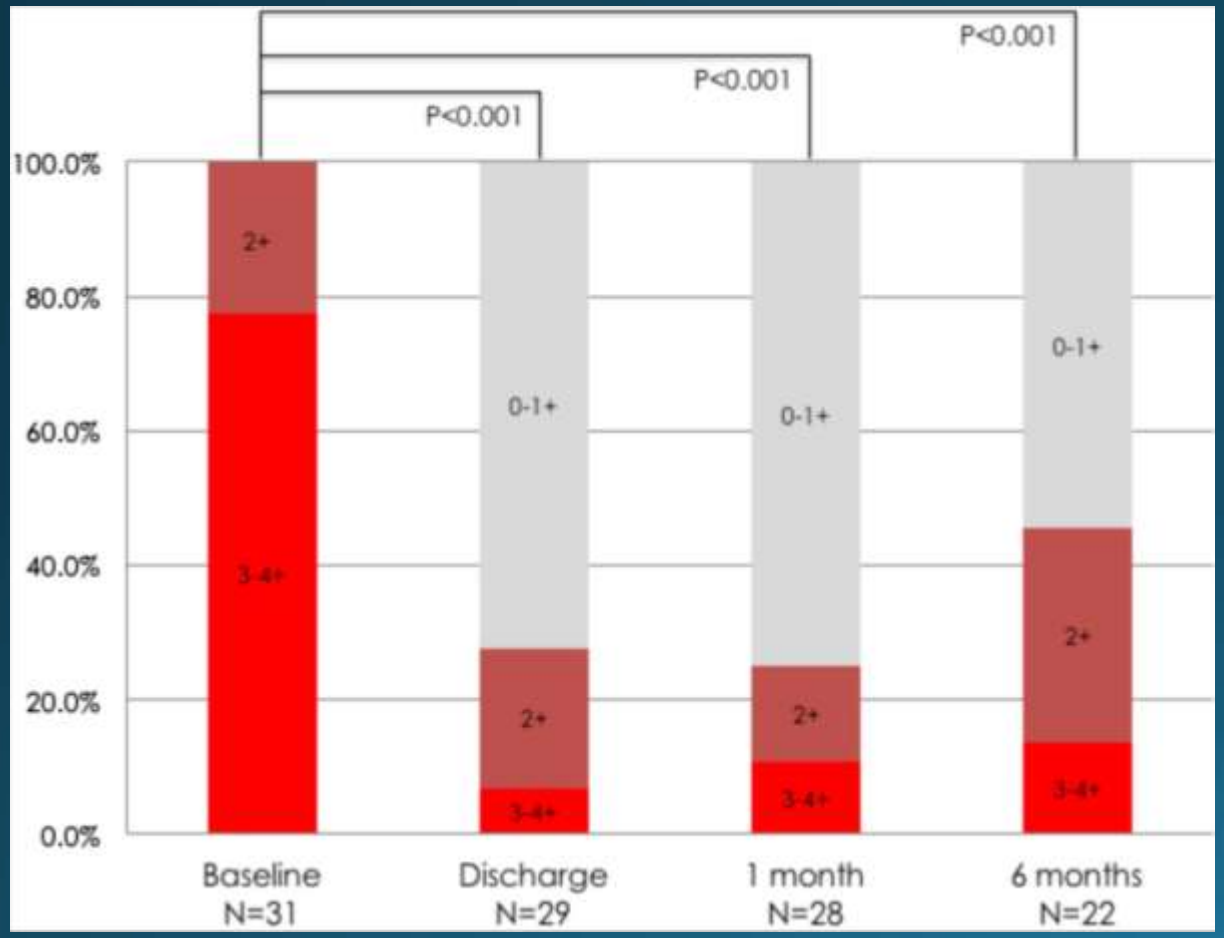
- Carillon US IDE trial

# Cardioband



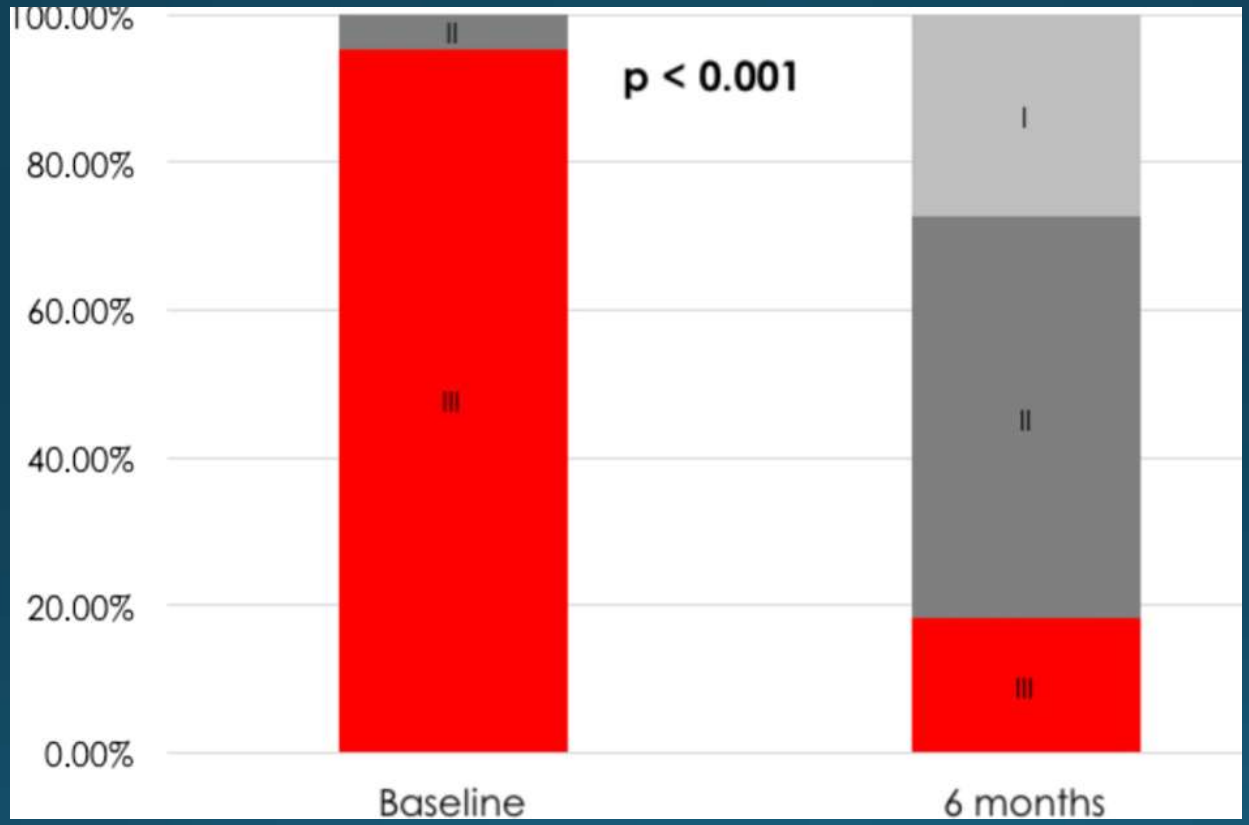


# Cardioband data




Reductions of regurgitant volume 36.8mls to 24.5ml
ERO 0.26 to 0.15
PISA radius 0.84 to 0.64

Nickenig et al. JACC Interv 2016

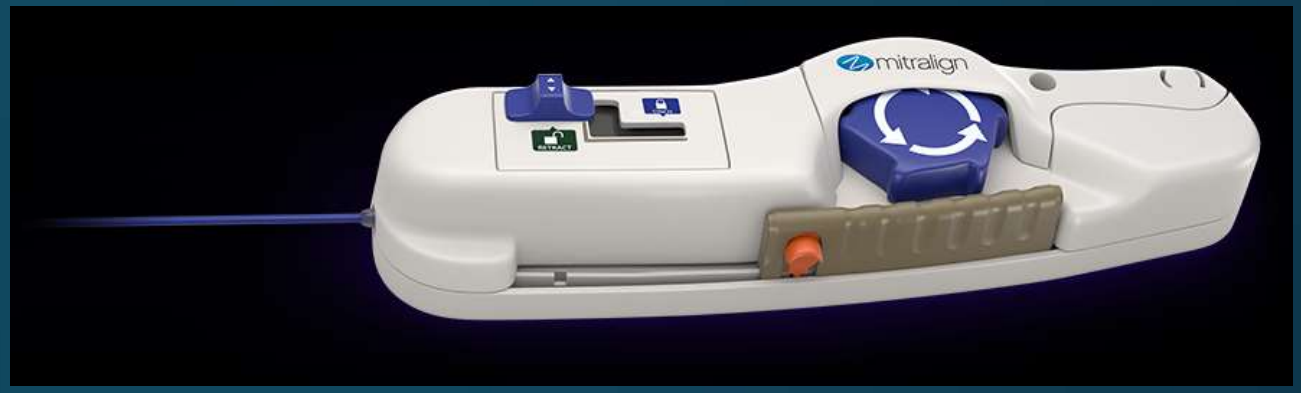


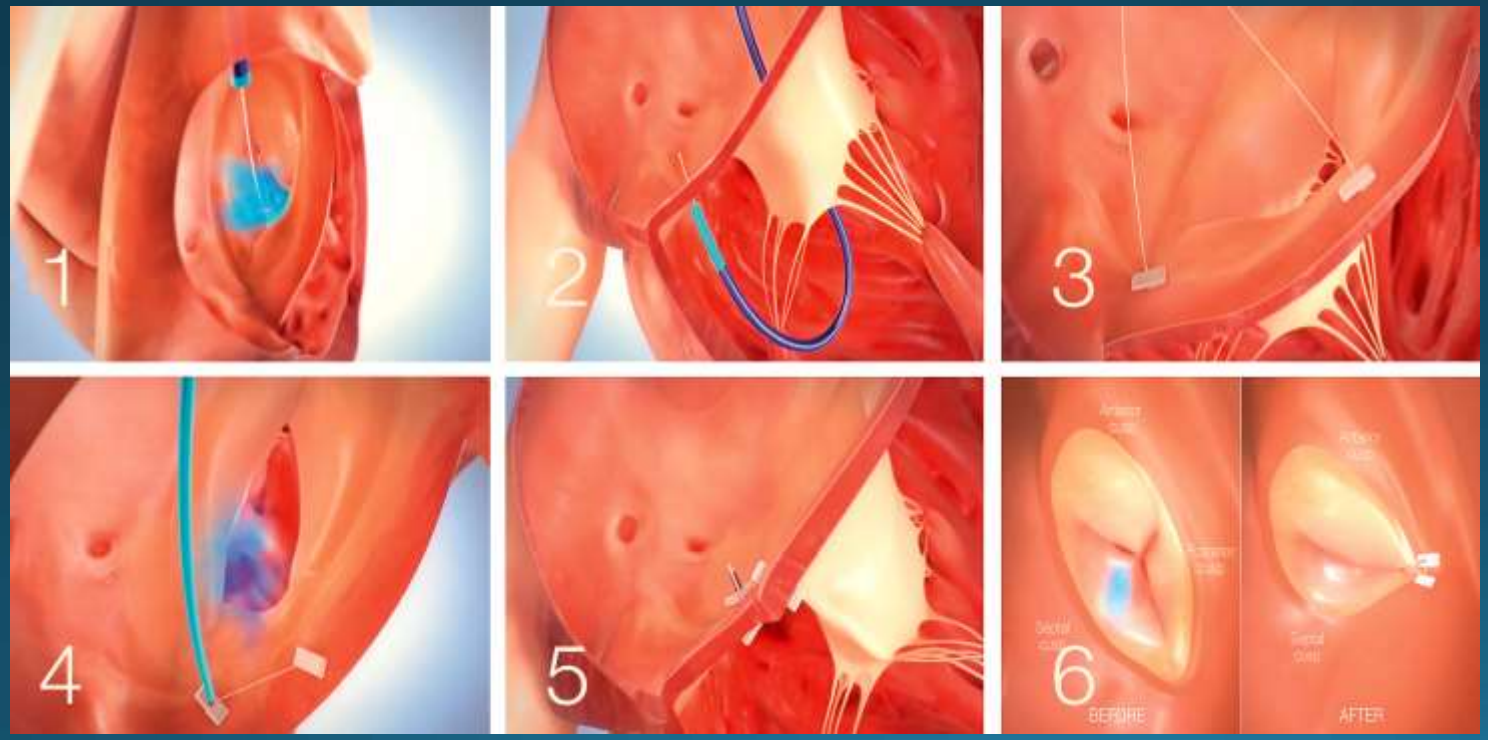

NYHA III/IV from 95 to 18%

# Ongoing trial for Cardioband

- REPAIR registry – transcatheter repair of mitral insufficiency with cardioband system)

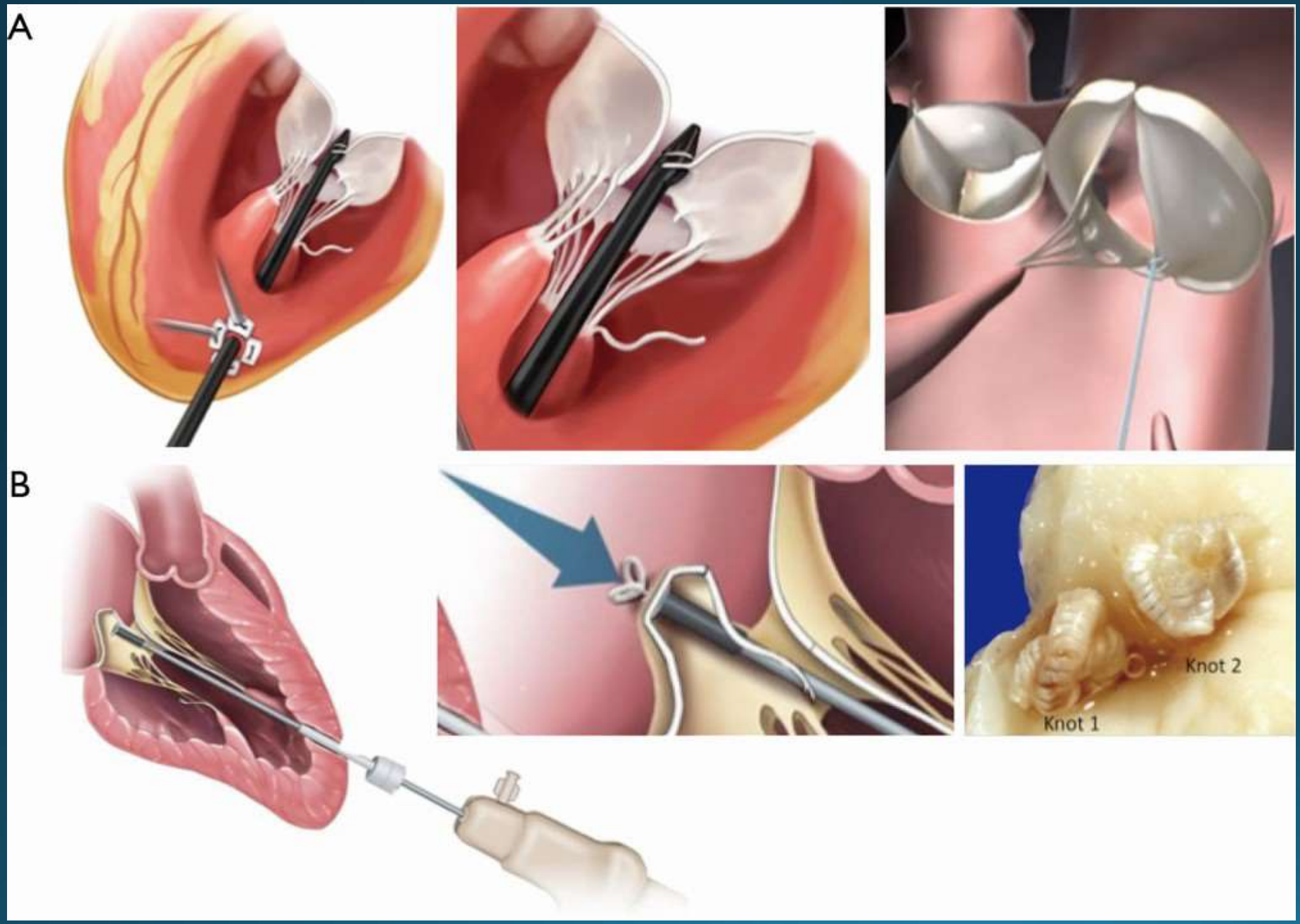
# Mitralign



# Mitralign data

- Completed CE Mark study
- For functional MR cases
- Not commercializing in Europe currently with focus on tricuspid repair


A
B
Knot 2
Knot 1

# TACT ( transapical artificial chordae tedninae) trial

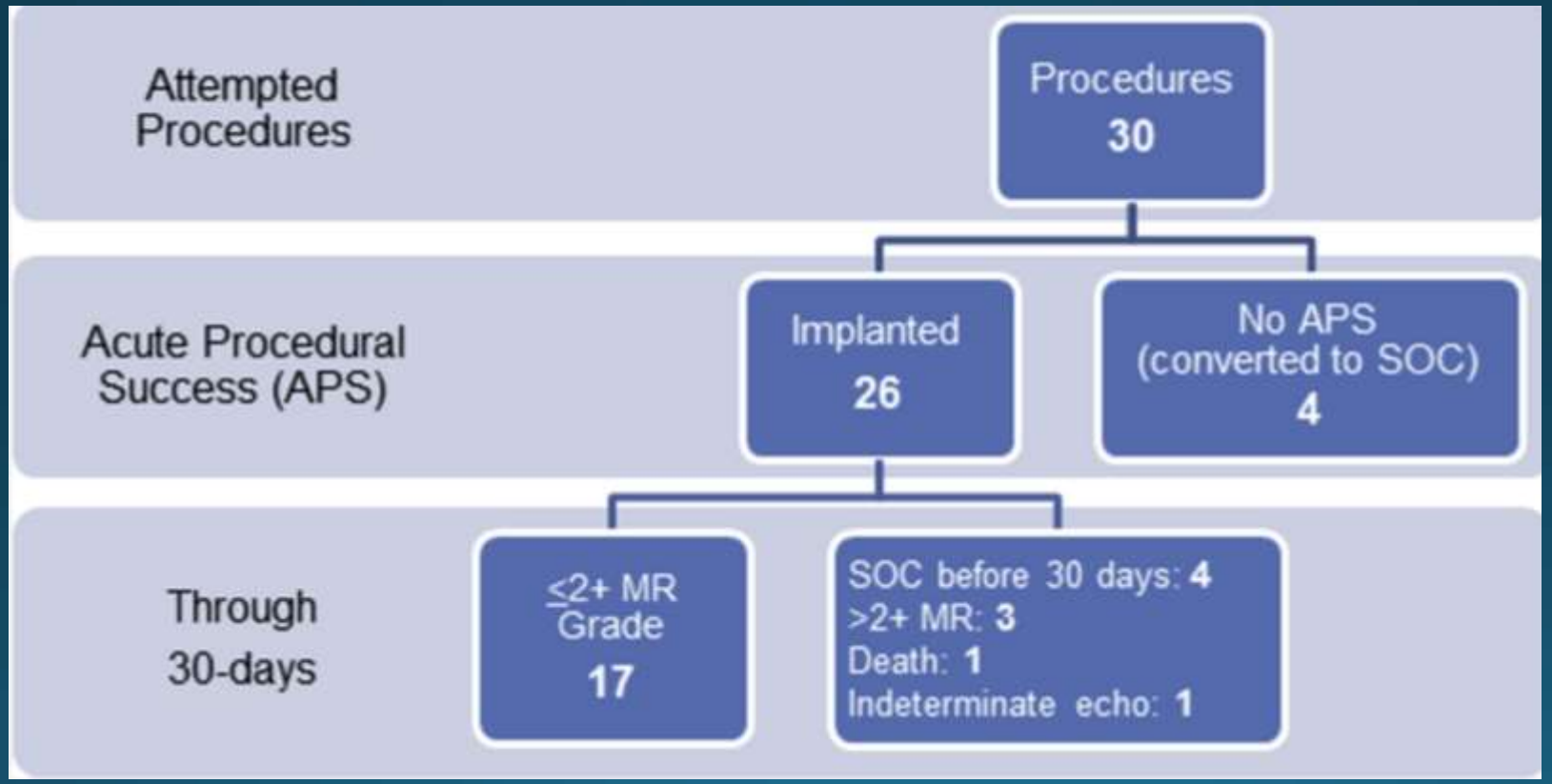


Table 3.
MAEs in the Entire Patient Cohort as Well as in the Latter 15 Patients Who Underwent Implantation Through a Posterolateral Approach

| | Entire Cohort (n = 30) | Posterolateral Approach (n = 15; Patients #16 to #30) |
|---|---|---|
| Any MAE | 8 (26.7) | 1 (6.7) |
| Death (post-cardiotomy syndrome with subsequent sepsis) | 1 (3.3) | 0 (0.0) |
| Reoperation for failed repair* | 6 (20.0) | 1 (6.7) |
| Procedure-related transfusion >2 U of blood | 5 (16.7) | 1 (6.7) |
| Procedural ventilation >48 h | 1 (3.3) | 0 (0.0) |
| Stroke (transient) | 1 (3.3) | 0 (0.0) |
| Myocardial infarction | 0 (0.0) | 0 (0.0) |
| Nonelective cardiovascular surgery | 0 (0.0) | 0 (0.0) |
| Renal failure | 0 (0.0) | 0 (0.0) |
| Deep wound infection | 0 (0.0) | 0 (0.0) |
| New onset of permanent atrial fibrillation | 0 (0.0) | 0 (0.0) |
| Septicemia | 0 (0.0) | 0 (0.0) |

Values are n (%).

* One patient was intraoperatively converted to standard of care, but adjudicated as a major adverse event (MAE) because the standard of care procedure required a modification. Numbers are not mutually exclusive because 1 patient can experience more than 1 MAE.

# Conclusion

- There are an increasing number of transcatheter platforms that can be used to treat severe MR
- It is possible that a combination of these therapies may be needed to optimize treatment of a heterogenous pathology