# Potential conflicts of interest

Speaker's name: Victor Mauri, MD

❑ I have the following potential conflicts of interest to declare
   - Speaker honoraria and travel compensation by Edwards Lifesciences
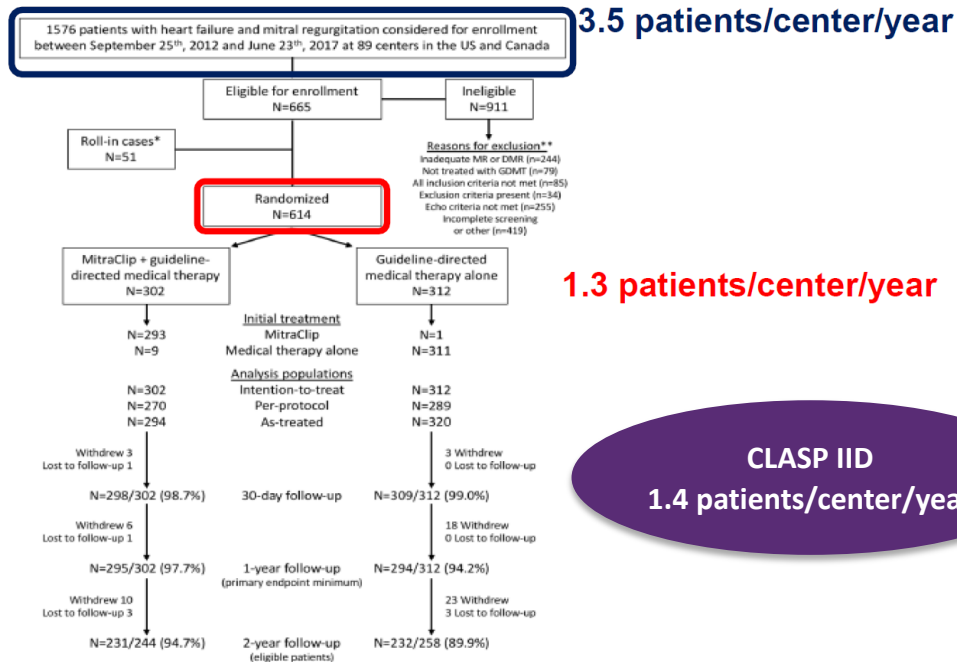
# Expert opinion disclaimer

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# COAPT Trial

- **78 centers**

- **42 inclusion/exclusion criteria**

- 1576 patients screened

- 614   patients randomized

**38% pts included**



**3.5 patients/center/year**

**1.3 patients/center/year**

**CLASP IID
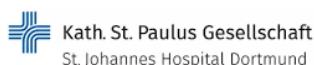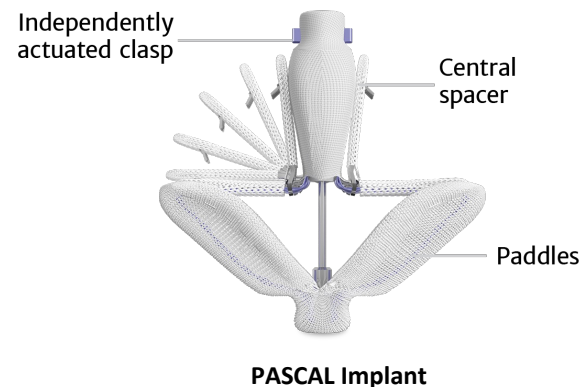1.4 patients/center/year**

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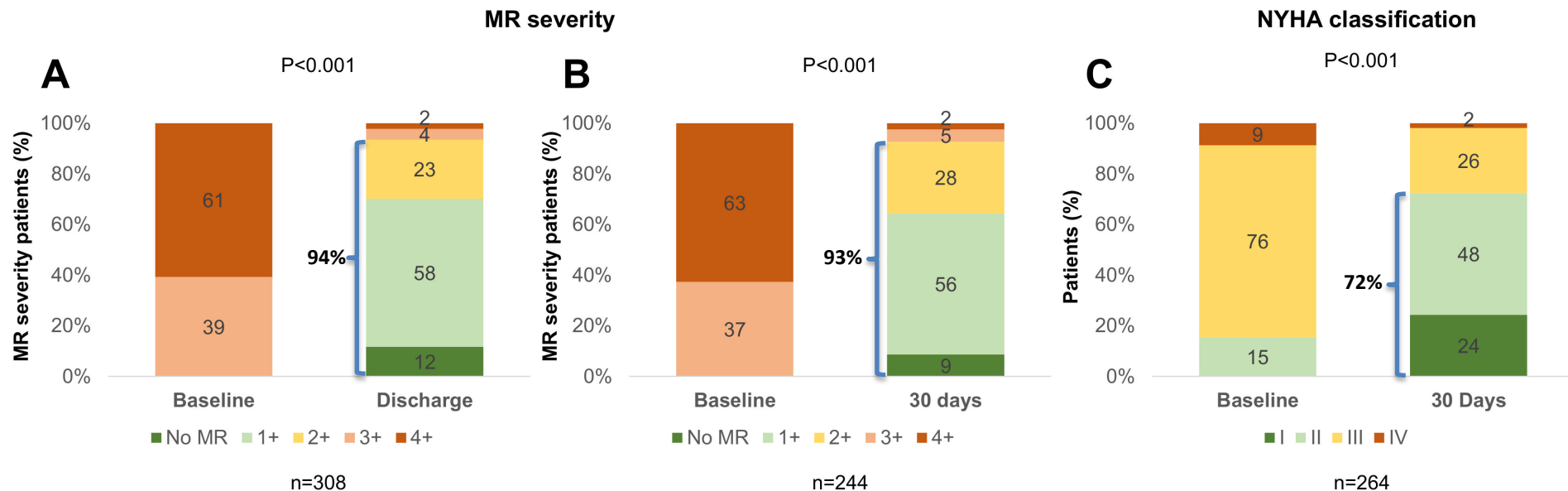Based on: G.W. Stone et al. NEJM 2018

Patients       First 309 patients treated post-approval

Location       10 high volume centers in Germany

Time period    02/2019 – 12/2019

               No inclusion-/exclusion criteria

               PASCAL implant (P10) only

Independently actuated clasp

Central spacer

Paddles

**PASCAL Implant**

HDZ NRW
UKRUB UNIVERSITÄTSKLINIKUM DER RUHR-UNIVERSITÄT BOCHUM

ukb universitäts klinikumbonn

Kath. St. Paulus Gesellschaft
St. Johannes Hospital Dortmund

UKD Universitätsklinikum Düsseldorf

Universitätsmedizin Essen
Universitätsklinikum

UKGM UNIKLINIKUM GIESSEN UND MARBURG

UNIKLINIK KÖLN

HERZZENTRUM LEIPZIG
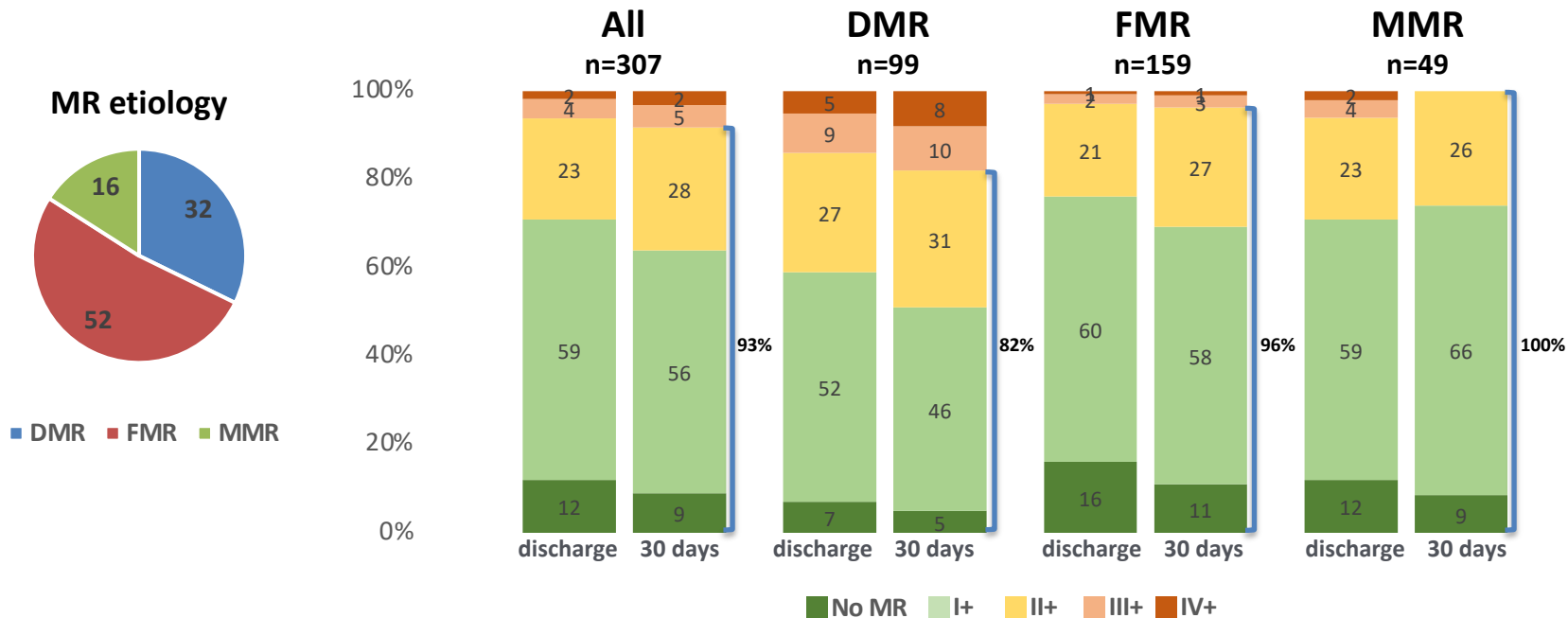
UNIVERSITÄTSmedizin. MAINZ

LMU KLINIKUM

Mauri V et al., German Multicenter Experience With a New Leaflet-Based Transcatheter Mitral Valve Repair System for Mitral Regurgitation. JACC Cardiovasc Interv. 2020 14;13(23):2769-2778.
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# Key results initial cohort



**MR severity**

**NYHA classification**

**A**     P<0.001

**B**     P<0.001

**C**     P<0.001

Panel A (MR severity patients %), Baseline vs Discharge:
- Baseline: 61 (4+), 39 (3+)
- Discharge: 2, 4, 23, 58, 12 — 94%

Panel B (MR severity patients %), Baseline vs 30 days:
- Baseline: 63 (4+), 37 (3+)
- 30 days: 2, 5, 28, 56, 9 — 93%

Panel C (Patients %), Baseline vs 30 Days:
- Baseline: 9 (IV), 76 (III), 15 (II)
- 30 Days: 2, 26, 48, 24 — 72%

Legend A/B: ■ No MR ■ 1+ ■ 2+ ■ 3+ ■ 4+
Legend C: ■ I ■ II ■ III ■ IV

n=308     n=244     n=264

Mauri V et al., German Multicenter Experience With a New Leaflet-Based Transcatheter Mitral Valve Repair System for Mitral Regurgitation. JACC Cardiovasc Interv. 2020 14;13(23):2769-2778.
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# Degree of MR by etiology

**MR etiology**

- DMR
- FMR
- MMR

DMR: 32, FMR: 52, MMR: 16

| | All n=307 | DMR n=99 | FMR n=159 | MMR n=49 |
|---|---|---|---|---|

Legend: No MR, I+, II+, III+, IV+

93% (All), 82% (DMR), 96% (FMR), 100% (MMR)
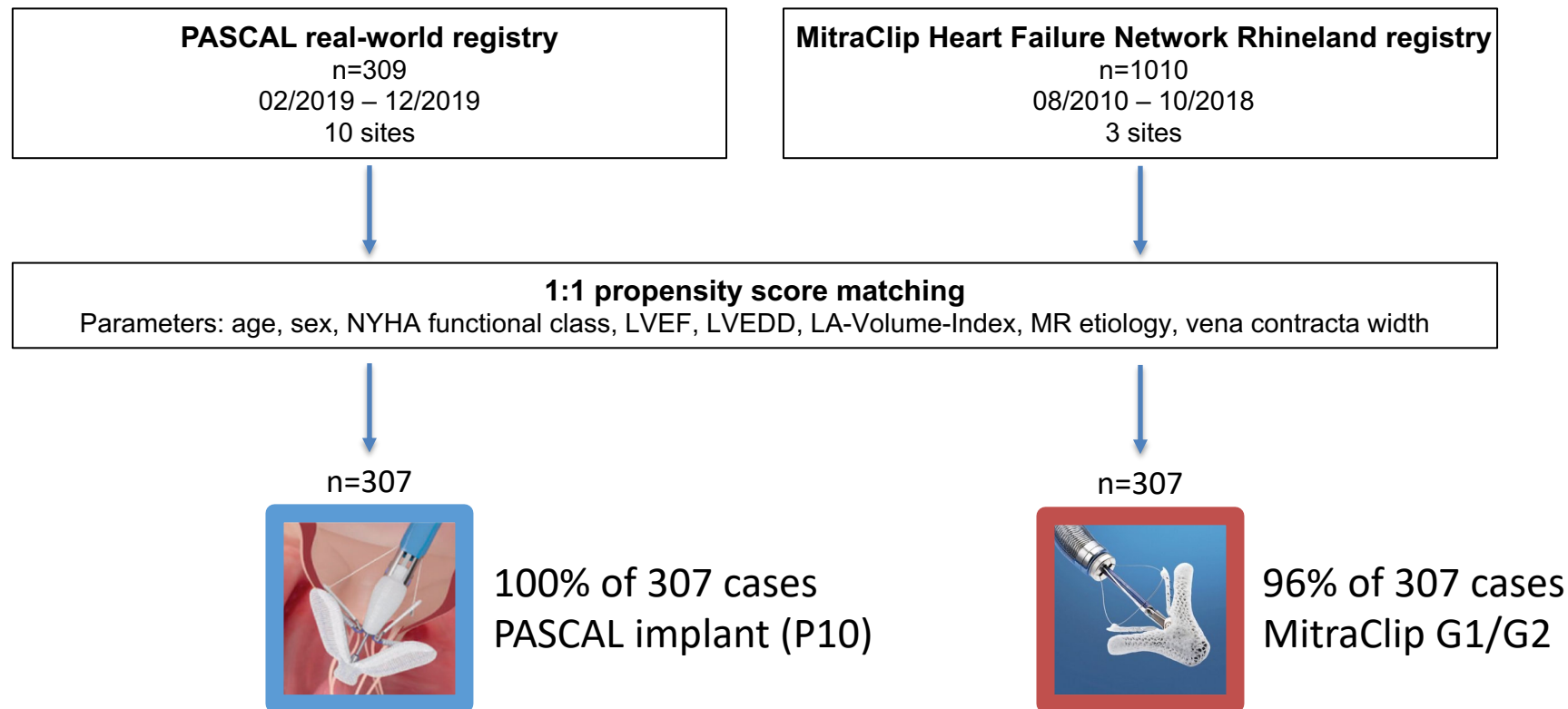
**Clinical success at 30 days**   86.9%   75.3%   92.0%   94.6%   P<0.001

Clinical success (CLASP trial definition): successful device implantation, MR ≤2+, and freedom from mortality, stroke, unplanned surgical or interventional procedures and device failure at 30 days

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Unpublished data

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**PASCAL real-world registry**
n=309
02/2019 – 12/2019
10 sites

**MitraClip Heart Failure Network Rhineland registry**
n=1010
08/2010 – 10/2018
3 sites

**1:1 propensity score matching**
Parameters: age, sex, NYHA functional class, LVEF, LVEDD, LA-Volume-Index, MR etiology, vena contracta width

n=307

n=307

100% of 307 cases
PASCAL implant (P10)

96% of 307 cases
MitraClip G1/G2

NYHA: New York Heart Association; LVEF: left ventricular ejection fraction, LVEDD: left ventricular end-diastolic diameter
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Mauri V et al., accepted at JACC Cardiovasc Interv. 2022

# Baseline characteristics matched cohort

| Clinical characteristics | PASCAL | MitraClip | P |
|---|---|---|---|
| Age (yrs) | 77.0±9.6 | 77.1±8.5 | 0.424 |
| Female | 42.3% | 42.0% | 0.935 |
| NYHA functional class III/IV | 86.0% | 83.1% | 0.245 |
| Coronary artery disease | 56.4% | 61.6% | 0.218 |
| Previous cardiac surgery | 20.5% | 36.8% | <0.001 |
| ICD/CRT | 22.5% | 19.9% | 0.489 |
| Atrial fibrillation | 70.7% | 63.5% | 0.071 |
| Chronic lung disease | 22.1% | 20.5% | 0.694 |
| Renal disease | 62.5% | 67.1% | 0.237 |
| EuroSCORE II (%) | 5.8±4.5 | 6.9±4.9 | 0.002 |

| Echo characteristics | PASCAL | MitraClip | P |
|---|---|---|---|
| MR etiology | | | 0.932 |
| Functional/mixed MR | 67.1% | 66.4% | |
| Degenerative MR | 32.9% | 33.6% | |
| Vena contracta width (mm) | 7.3±2.1 | 7.1±2.0 | 0.400 |
| EROA (cm²) | 0.39±0.22 | 0.34±0.13 | 0.267 |
| LVEF (%) | 47±15 | 47±15 | 0.657 |
| LVEDD (mm) | 57±10 | 57±10 | 0.773 |
| Transmitral gradient (mmHg) | 1.9±1.1 | 2.2±1.1 | 0.001 |
| LA Volume index (ml/m²) | 68±29 | 65±30 | 0.088 |
| sPAP (mmHg) | 45±14 | 49±16 | <0.001 |

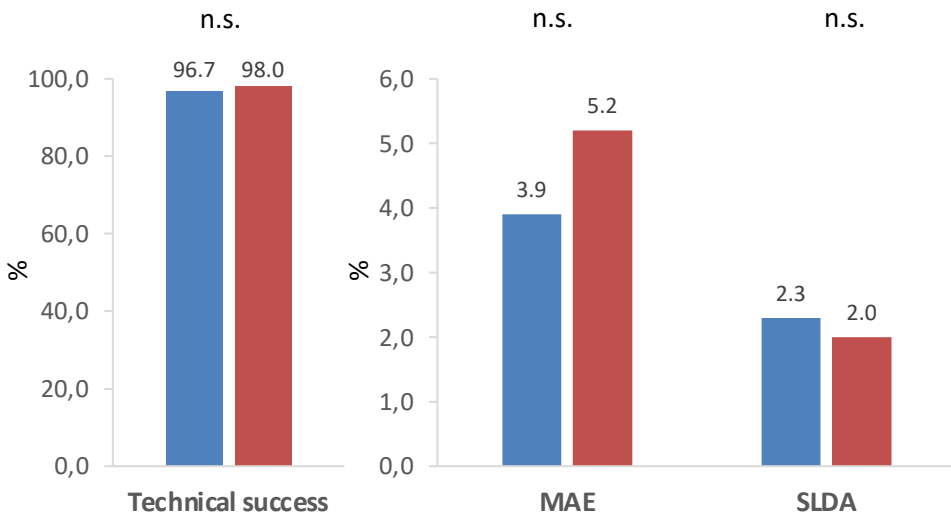Exact Fisher Test or Mann-Whitney U test

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# Clinical outcomes and transmitral gradient

**Clinical outcomes**

**Mean transmitral gradient**

Exact Fisher Test. * p<0.05; n.s.: not significant
Gradients: Values are adjusted for baseline gradients ±SEM
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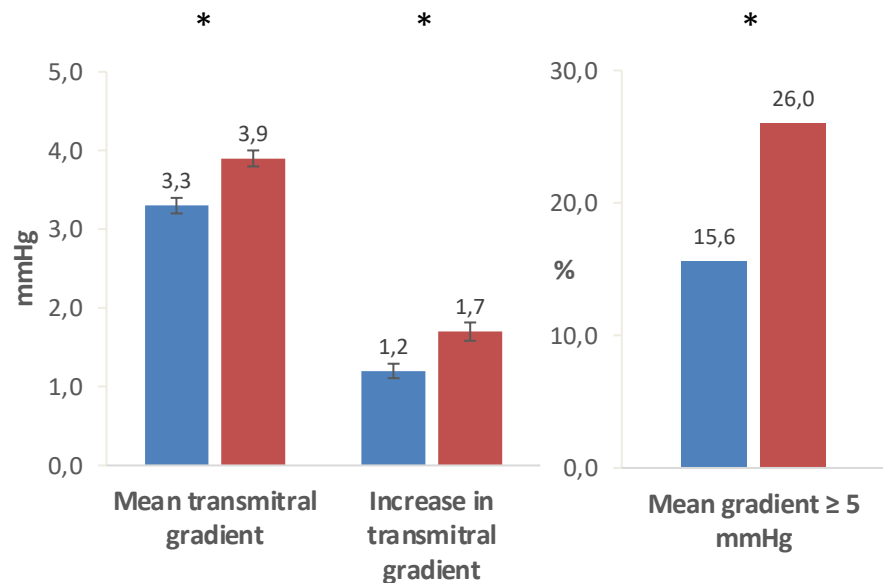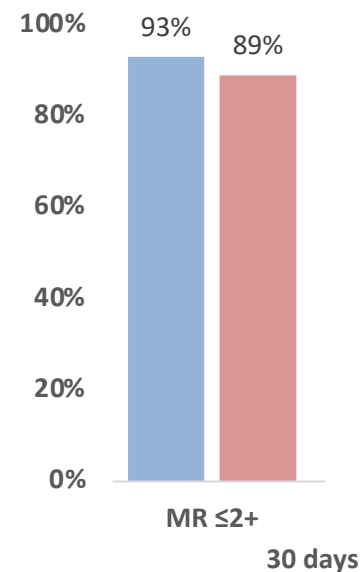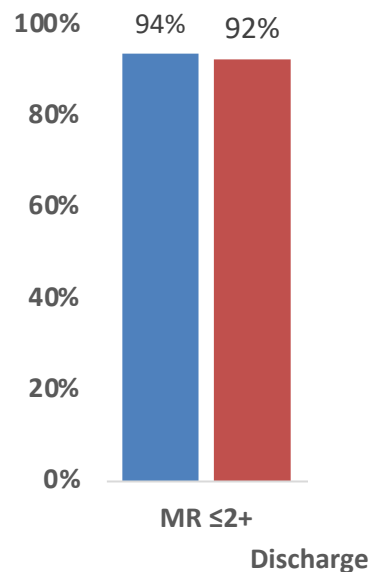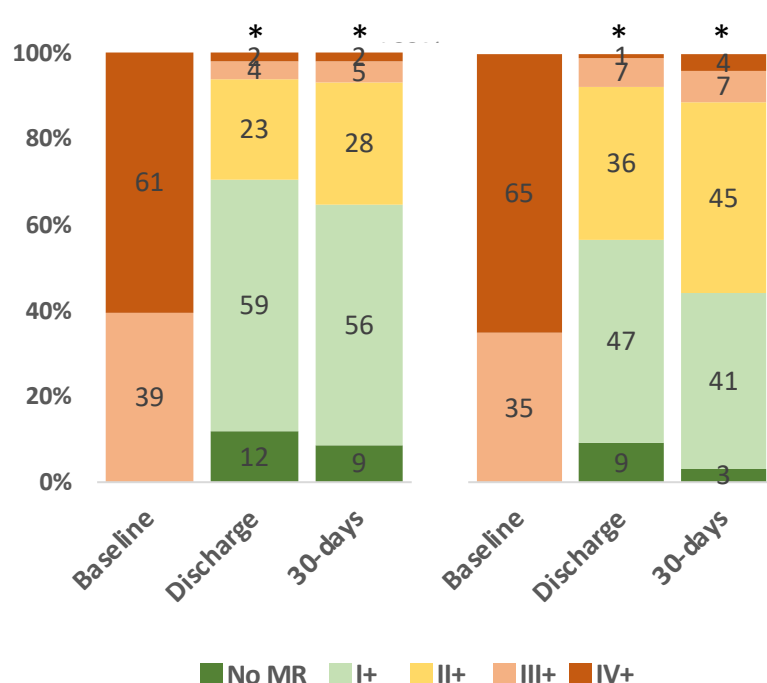Mauri V et al., accepted at JACC Cardiovasc Interv. 2022

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# Degree of MR at discharge and 30 days



PASCAL

MitraClip

No MR | I+ | II+ | III+ | IV+

MR ≤2+ Discharge: PASCAL 94%, MitraClip 92%

MR ≤2+ 30 days: PASCAL 93%, MitraClip 89%

PASCAL | MitraClip

Exact Fisher Test  * p<0.05; left panel: comparison to baseline
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# Thank you!



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