Transcatheter Echo Guided Mitral Valve Repair with NeoChord Implantation: Results from NeoChord Independent International Registry

A. Colli, E. Bizzotto, E. Manzan, L. Besola, F. Zucchetta, D.Pittarello, K. Rucinskas, A. Aidietis, V. Janusauskas, D. Zakarkaite, A, Drasutiene, B. Danner, H.Sievert, K. Kurnicka, K. Wrobel, S.Salizzoni, M.Rinaldi, C. Savini, D. Pacini, M.Cefarelli G. Gerosa

Padua, Italy; Vilnius, Lithuania, Gottingen, Germany, Frankfurt Germany, Warsaw, Poland, Turin, Italy, Bolonia, Italy

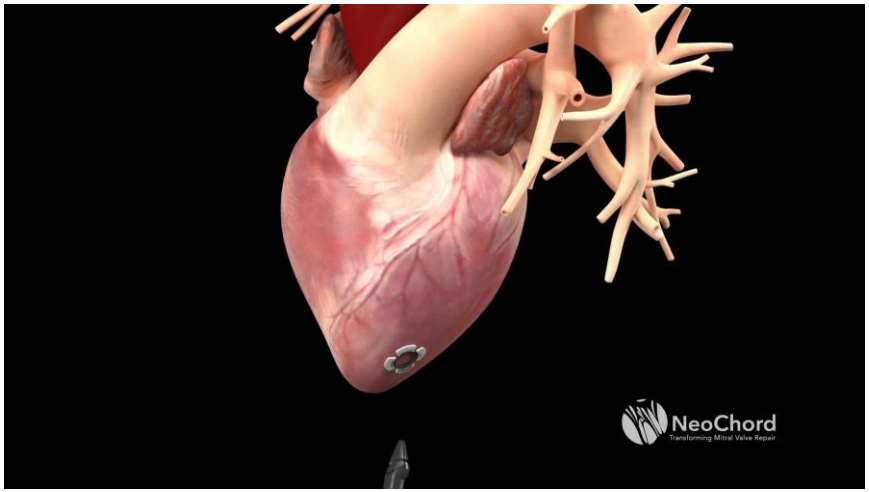
Disclosure Statement of Financial Interest

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

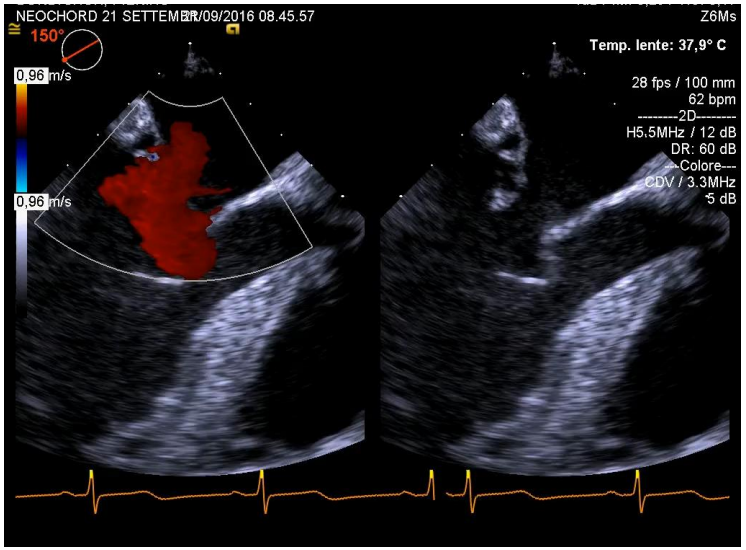
Affiliation/Financial Relationship	Company
• Major Stock Shareholder/Equity	• NeoChord Inc

Background

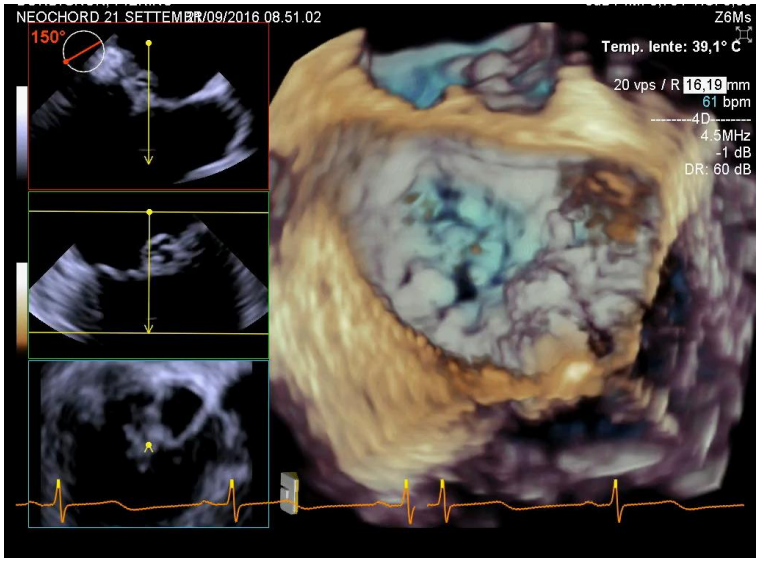
Transapical off-pump mitral valve repair with neochordae implantation (TOP-MINI), also know as NeoChord procedure, is a novel transcatheter procedure to treat patient suffering severe symptomatic degenerative MR



Pre-operative TEE

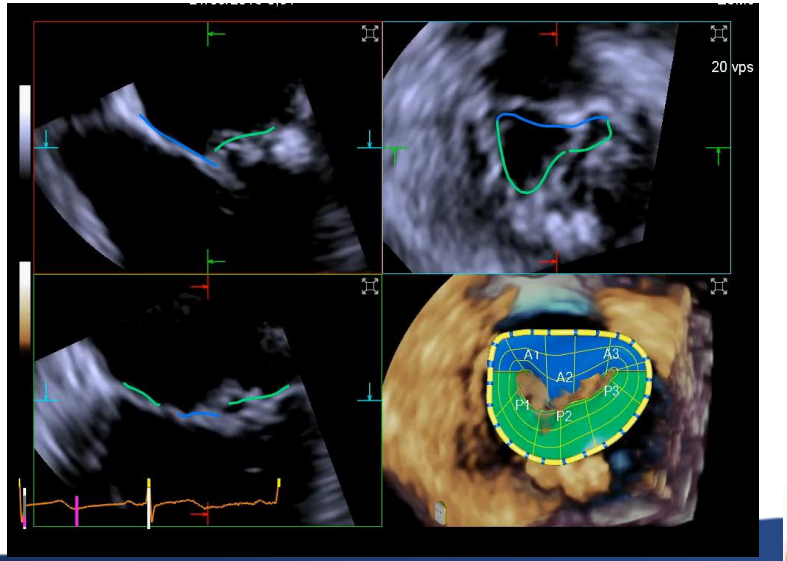


2 D



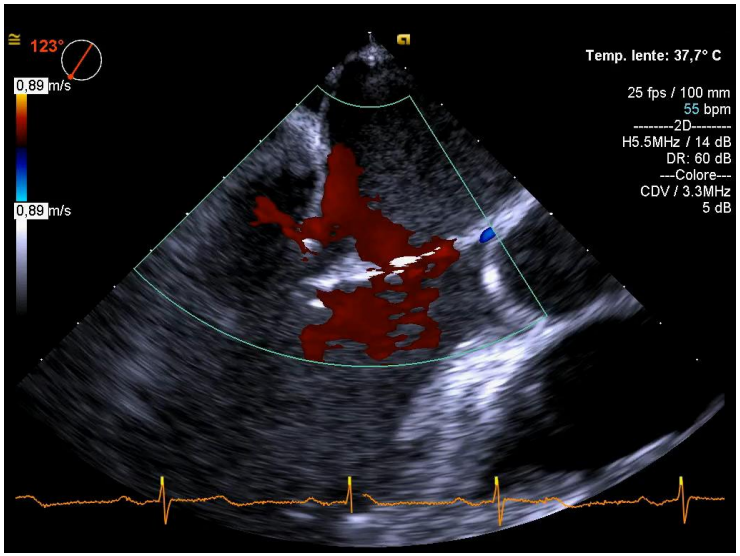
3 D

3 D colour

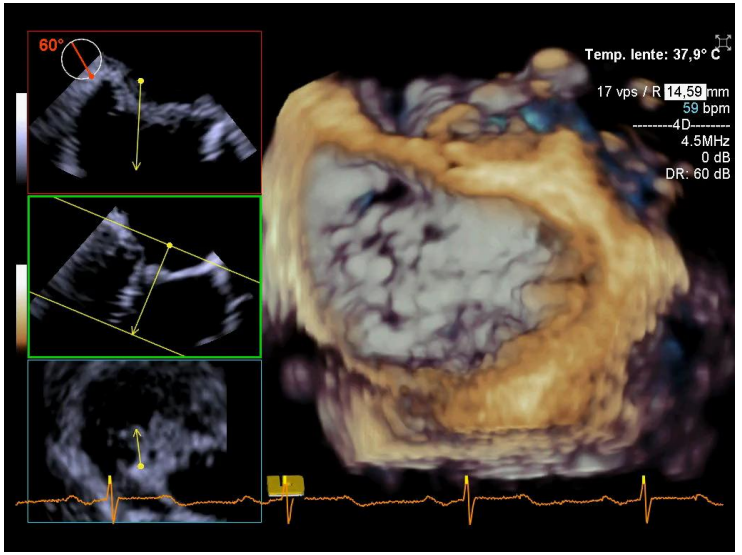


Valve Modelling

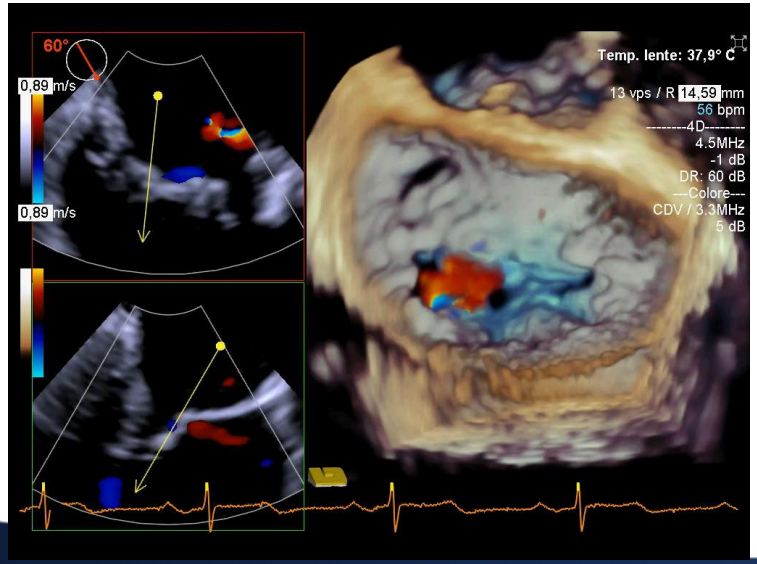
Post-Operative TEE



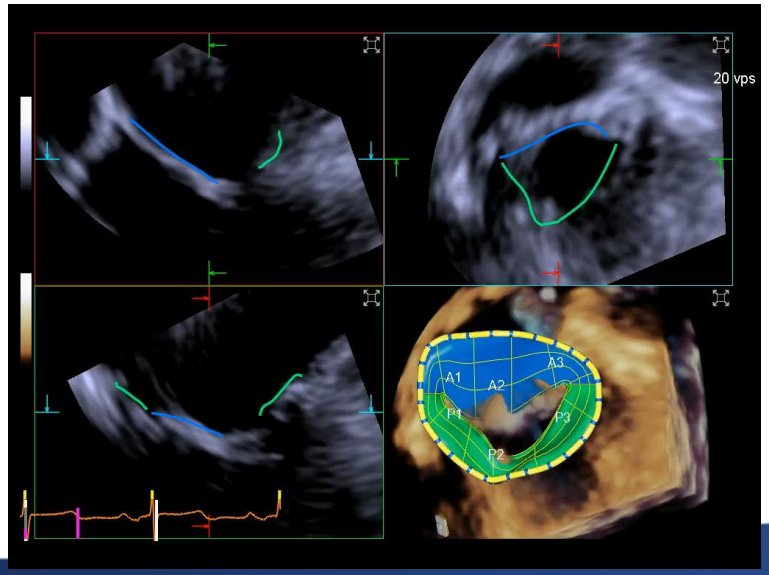
2 D



3 D



3 D colour



Valve Modelling

NeoChord International Registry

Design

Retrospective, multi-center, Independent clinical evaluation of the NeoChord Mitral Valve Repair Procedure

Objective

To evaluate the early clinical efficacy of the NeoChord procedure on patients with Posterior Leaflet Disease

NeoChord International Registry

232 patients enrolled between 11/13 and 9/16 in 7 European Centers

↓

192 patients presented Posterior leaflet disease

↓

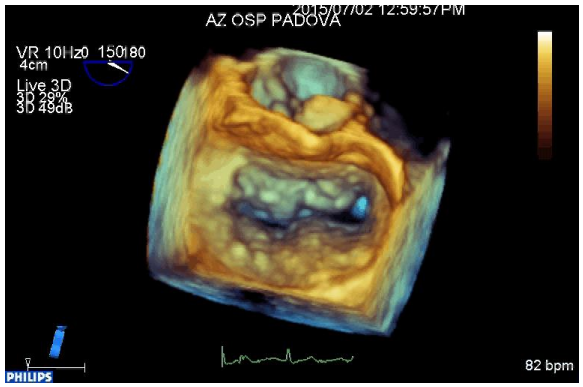
Clinical follow-up at 1 months in **96.3**% (N=185)

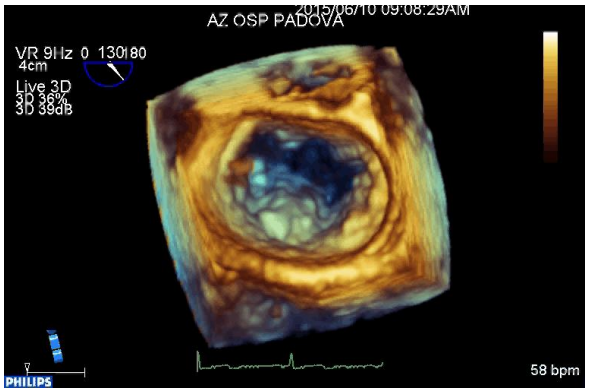
↓

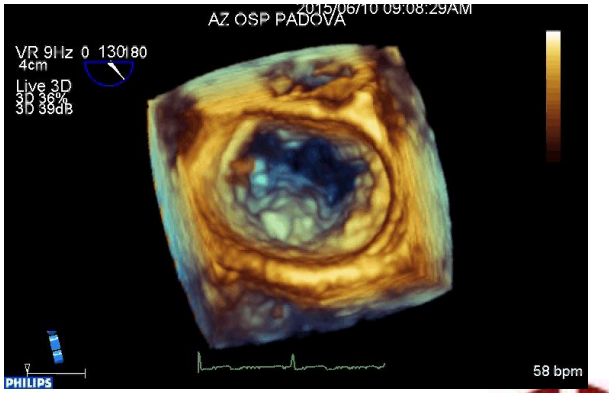
Clinical follow-up at 12 months in **61**% (N=117)

3D-TEE assessment of MV morphology

- **TYPE A: Isolated central posterior leaflet prolapse/flail (P2)**
- **TYPE B: Posterior multisegment prolapse/flail**
- **TYPE C: anterior, bileaflet disease, presence of annular/leaflet calcifications and/or paracommissural disease**







Colli et al, Interact Cardiovasc Thorac Surg 2015

Methods

- For the present cohort analysis:

- Inclusion criteria: Type A and Type B anatomy
- Exclusion criteria: Type C anatomy

Methods

- Outcomes were defined according to MVARC guidelines
- Primary endpoint was defined as PATIENT SUCCESS composite of:

  - Procedure success = placement of at least 2 neochordae and residual MR≤mild at the end of the procedure

  - Freedom from Major Adverse Events (MAE) = death, stroke, MR > moderate, structural or functional failure and/or unplanned interventions related to the procedure or device

  - decreased in NYHA functional classification (≥1 class)

Methods

- **MR severity was graded as:**
  - **Absent**
  - **Mild:** VC<3mm, pulmonary vein flow=systolic dominance, RV<30ml
  - **Moderate:** VC=3-6mm, pulmonary vein flow=systolic blunting, RV<45 ml
  - **Severe:** VC>6mm, systolic flow reversal, RV≥45ml

Baseline Characteristics

	Median (I-III Quartile) or N (%)
Age (years)	66 (55-76)
Male	138 (71.9%)
Euroscore-II (%)	1 (0.7-1.7)
STS-PROM MV repair score (%)	0.8 (0.3-1.6)
Arterial hypertension	114 (59.4%)
COPD	19 (9.9%)
Diabetes mellitus type II	10 (5.2%)
Associated ischemic CAD	35 (18.2%)
Previous Cardiac Surgery	8 (4.2%)
Previous PCI	18 (9.4%)
Previous stroke	1 (0.5%)
Malignancy	22 (11.5%)
Glomerular filtration rate (ml/min)	75.7 (55.2-99.5)

Baseline Characteristics

	Median (I-III Quartile) or N (%)
NYHA functional class	
- **I**	12 (6.2%)
- **II**	90 (46.9%)
- **III**	87 (45.3%)
- **IV**	3 (1.6%)
MR grade	
- **Absent/trace**	0 (0%)
- **Mild**	0 (0%)
- **Moderate**	2 (1%)
- **Severe**	190 (99%)

Baseline Characteristics

Leaflet prolapse	71 (37%)
Leaflet flail	121 (63%)
Anatomic MV type	
- **A**	79 (41.1%)
- **B**	113 (58.9%)
EF (%)	60 (55-66)
- **≤ 30**	0 (0%)
- **31-55**	28 (14.6%)
- **> 55**	164 (85.4%)
LVEDV (ml/m²)	78 (66-91)
- **< 70**	38 (19.8%)
- **70-100**	141 (73.4%)
- **> 100**	13 (6.8%)
PAPs (mmHg)	35 (28-43)
- **≤ 25**	65 (33.8%)
- **26 – 35**	56 (29.2%)
- **36 – 45**	38 (19.8%)
> 45	33 (17.2%)

Operative Characteristics

	Median (I-III Quartile) or N (%)
Neochordae in place (n)	4 (3-4)
- **2**	10 (5.2%)
- **3**	67 (34.9%)
- **4**	76 (39.6%)
- **5**	28 (14.6%)
- **6**	8 (4.2%)
- **7**	3 (1.5%)
Conversion to conventional surgery	2 (1%)
- **MV Repair**	1 (0.5%)
- **MV Replacement**	1 (0.5%)
Procedural ECMO support	4 (2.1%)
Procedural IABP support	1 (0.5%)
Access site complications	4 (2.1%)
Ventricular fibrillation	3 (1.6%)
Operative time (min)	133 (120-155)

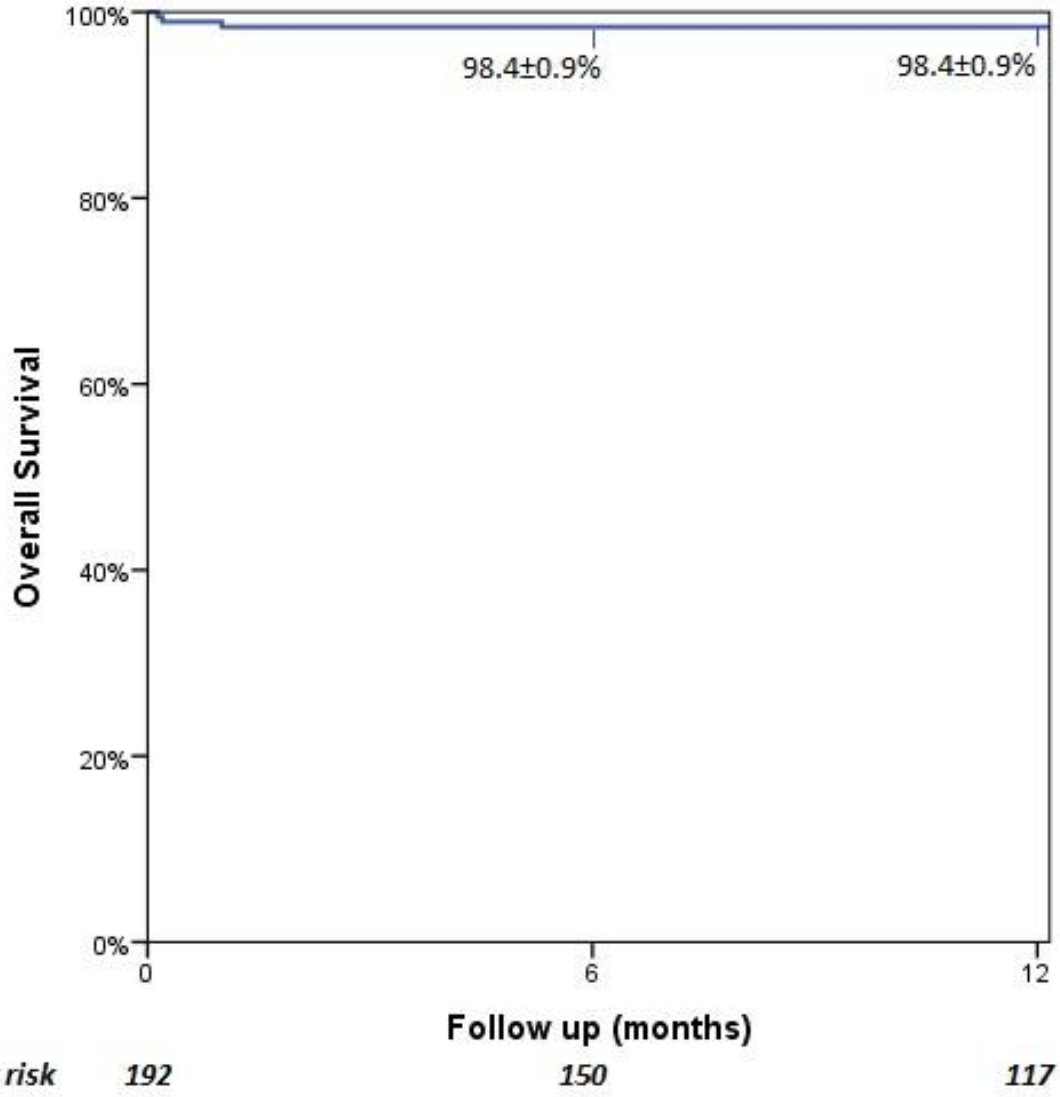
Postoperative Characteristics

	Median (I-III Quartile) or N (%)
Mechanical ventilation time (hours)	3 (1-4)
- 0 (OR extubation)	33 (17.4%)
- ≤ 3	72 (37.9%)
- 4-6	63 (33.2%)
- > 6	22 (11.5%)
Total Hospital Length of stay (days)	7 (7-9)
Discharge	
- Home	97 (51%)
- Rehabilitation center	90 (47.4%)
- In hospital death	3 (1.6%)
Procedure success	187 (97.4%)
Transient ischemic attack	1 (0.5%)
Stroke	0 (0.0%)

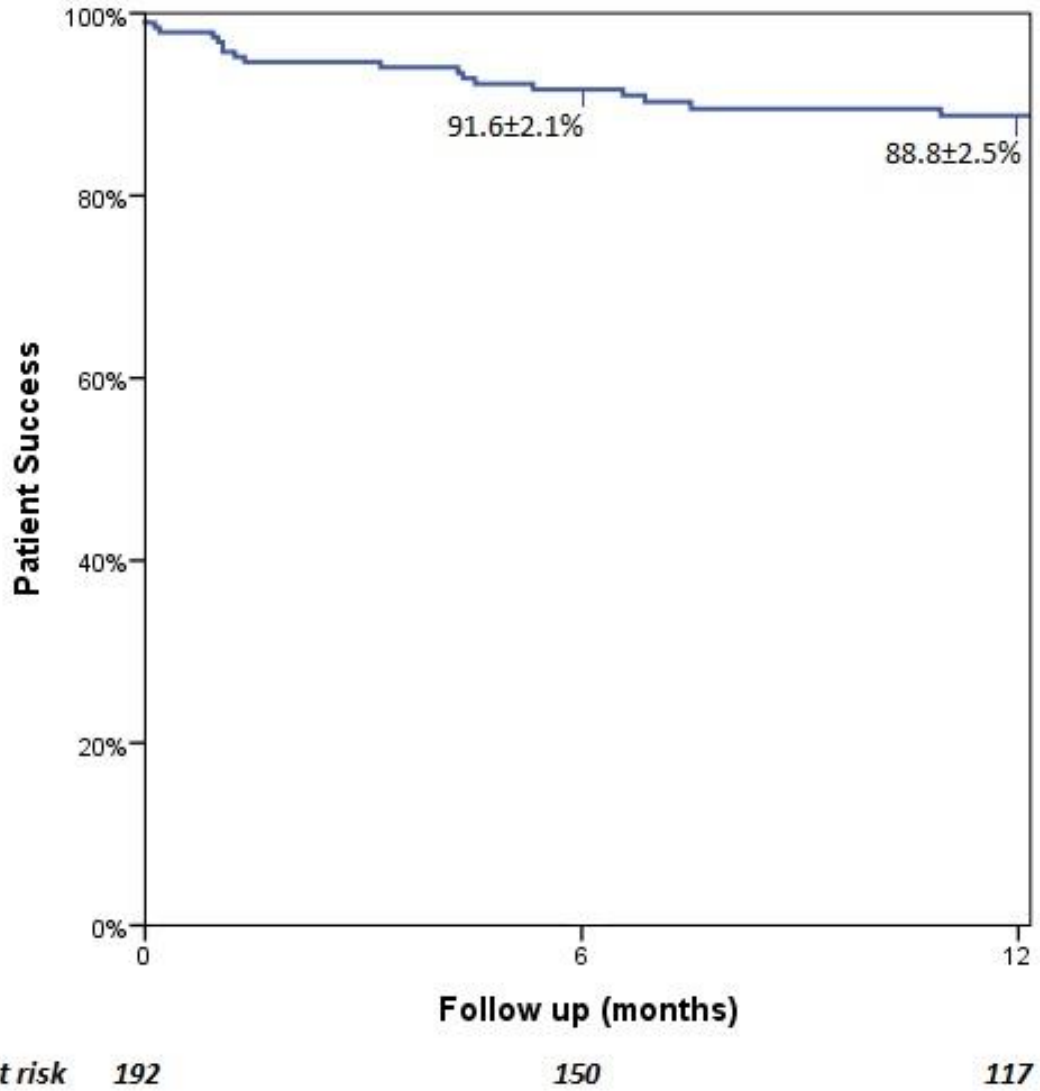
Postperative Characteristics

Acute myocardial infarction	2 (1%)
Vascular complications	2 (1%)
Acute kidney injury	
- **Stage I (creatinine increase > 150-199%)**	6 (3.2%)
- **Stage II (creatinine increase > 200-299%)**	2 (1%)
- **Stage III (creatinine increase > 300%)**	2 (1%)
- **Need of CVVH**	2 (1%)
Bleeding	
- **Minor**	8 (4.2%)
- **Major**	2 (1%)
- **Extensive**	4 (2.1%)
Conduction disturbances	
- **Transient**	11 (5.8%)
- **Permanent**	0 (0.0%)
New onset AF	
- **Paroxysmal**	34 (17.9%)
- **Persistent**	5 (2.6%)

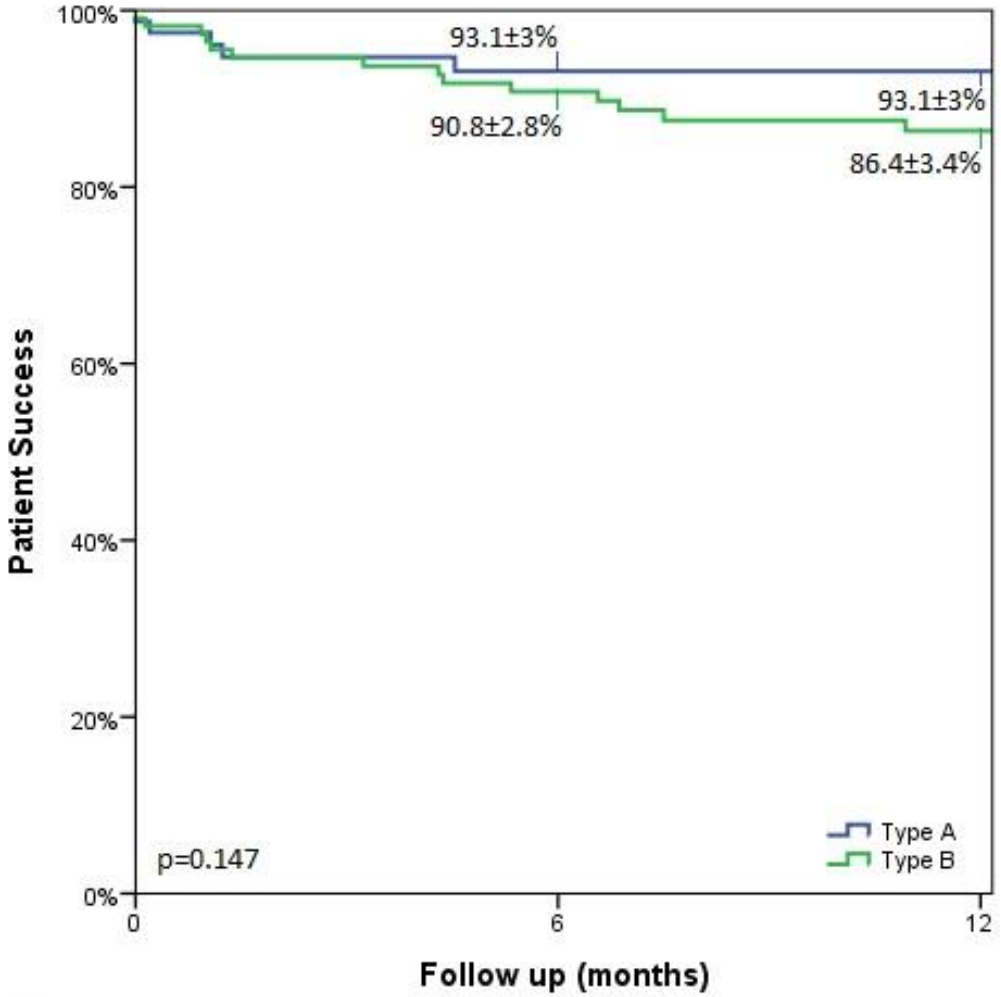
Overall Survival



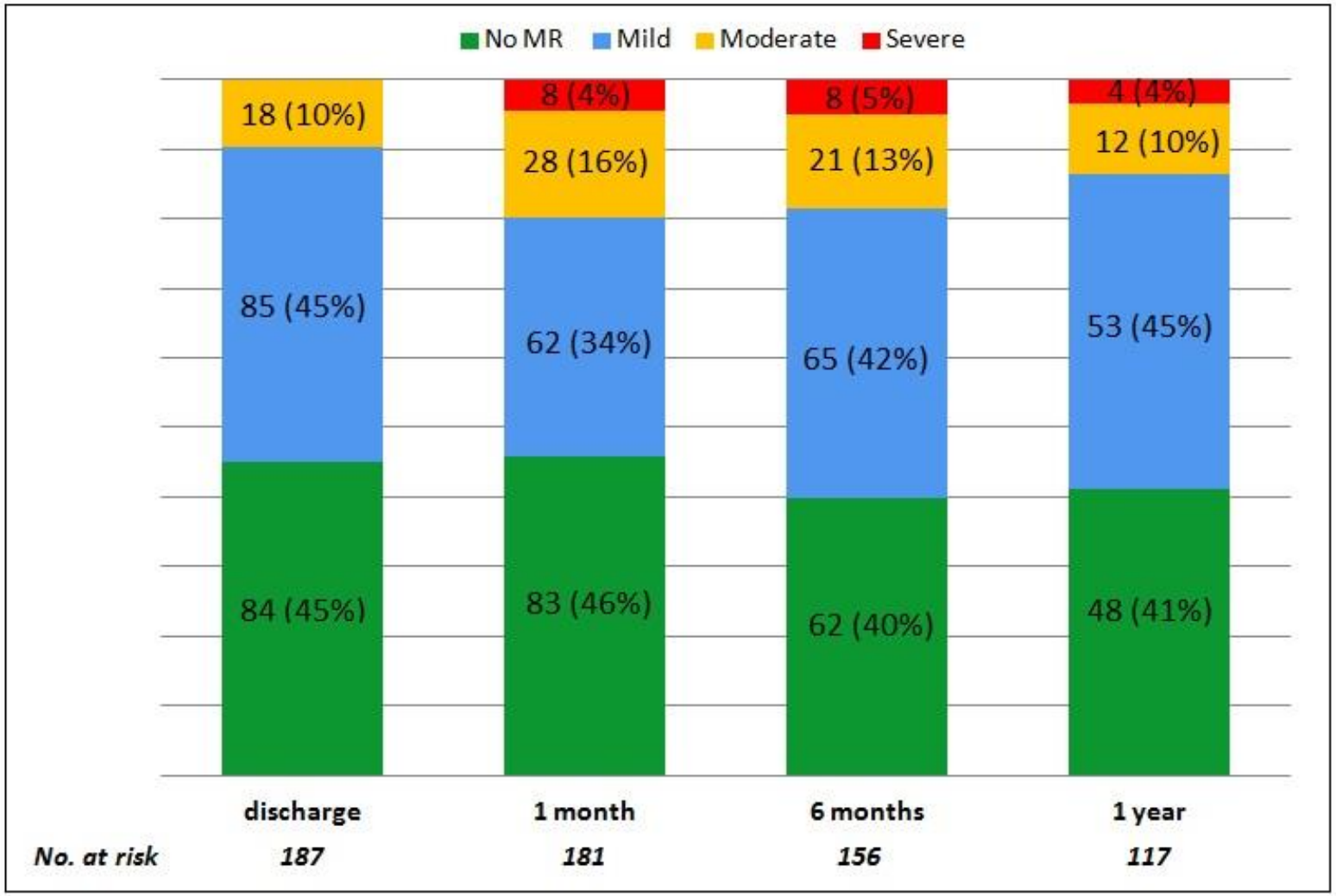
Overall Patient Success



Patient Success for anatomic type

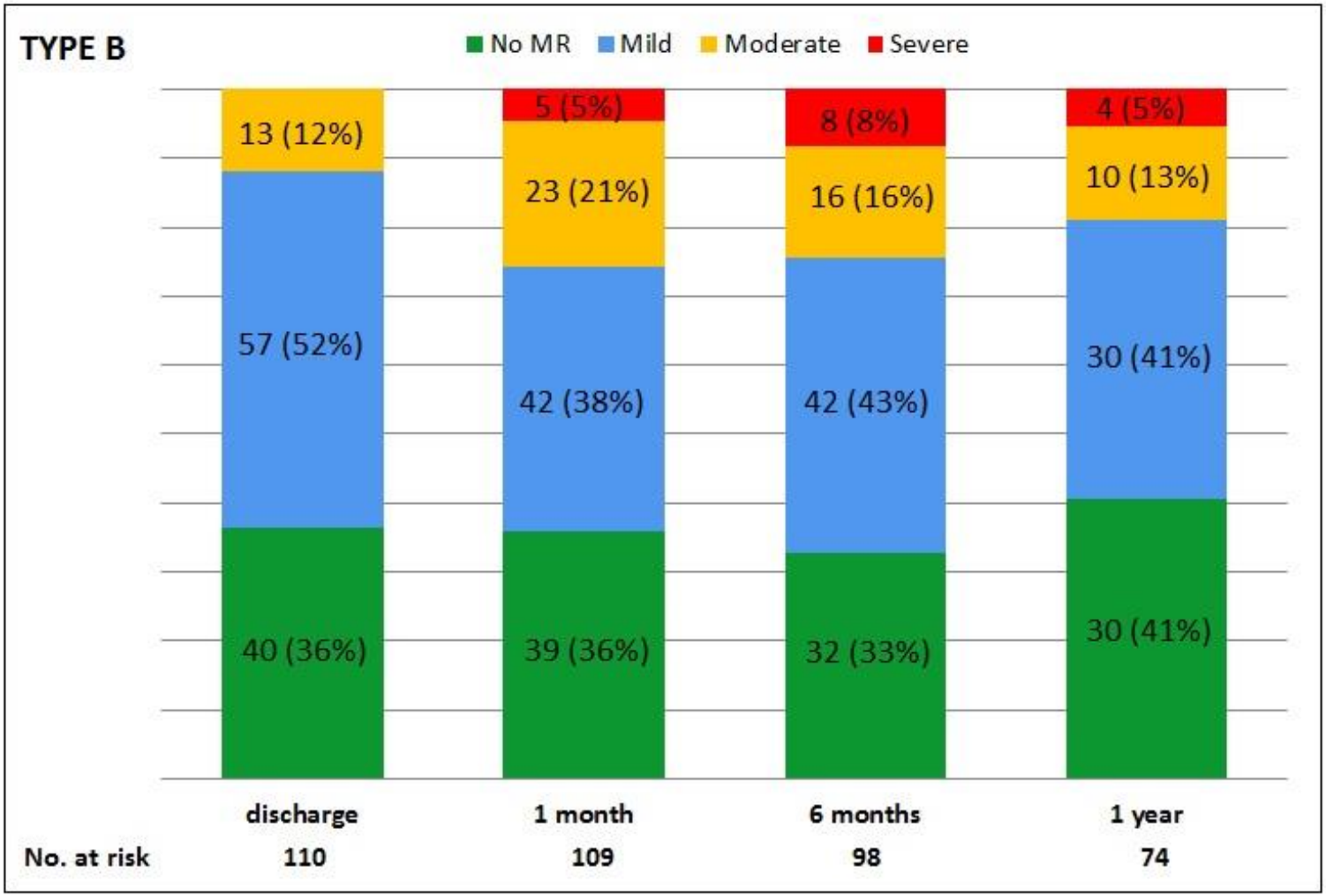


Overall Mitral Regurgitation



Mitral Regurgitation for Type A

Mitral Regurgitation for Type B



Echo Results

TTE PARAMETERS	PRE-OP *(Mean±SD)*	2 YEARS FU *(Mean±SD)*	Δ *(Mean±SD)*	p value
AP diameter *(mm)* Systolic Diastolic	34.9 ± 5.9 39.8 ± 5.6	35.1 ± 3.8 39.4 ± 4.3	↓ 0.2 ± 5.8 ↓ 0.4 ± 6.1	0.862 0.741
LL diameter (mm) Systolic Diastolic	36.3 ± 5.1 39.7 ± 4.4	34.9 ± 4.9 39.6 ± 5.8	↑ 1.5 ± 5.3 ↑ 0.2 ± 6.7	0.191 0.904
LVEDVi (mL/m^2)	80 ± 19.6	63.8 ± 19.8	↑ 16.2 ± 21.1	0.001
LVESVi (mL/m^2)	35.8 ± 14.2	26 ± 8.9	↑ 9.7 ± 16.1	0.008
LAVi (mL/m^2)	52.9 ± 21	45.5 ± 20	↑ 7.3 ± 16.7	0.057
LAD (mm)	58.5 ± 10.1	48.7 ± 9.7	↑ 9.8 ± 12.1	0.001
sPAP (mmHg)	39.5 ± 14.3	23.1 ± 8.5	↑ 16.4 ± 13.3	<0.001

Conclusions

The NeoChord procedure is now technically standardized and reproducibile

- **Patient Selection Criteria: Leaflet-to-Annulus Index, MV Morphology classification**
- **Access site: Postero-Lateral, modifications based on Leaflet-to-Annulus Index evaluation**
- **Echocardiographic guidance protocol**
- **Tensioning protocol: Tourniquets, Overtensioninig, 3D-Color Doppler Real Time**

Conclusions

- **NeoChord procedure showed good early and 1-year clinical results for patients with MR due to posterior leaflet disease**

- **Despite the absence of annuloplasty the results appeared stable up to 1-year suggesting that concomitant annuloplasty might not always be mandatory in MV Repair**

Conclusions

- **Early referral of patients with MR is the key for future evolution of MV repair surgery**

- **The long term analysis of the present NeoChord Independent International Registry will be of an extreme value for the future transcatheter MV repair clinical practice**

andrea.colli@unipd.it