

Mitral valve repair with a new generation annuloplasty ring via Minimally Invasive Approach: results from the international prospective MANTRA study

I. Hysi¹, M. Di Eusanio², YH. Choi³, N. Bonaros⁴, J. Kempfert⁵, C. Baeza⁶, G. Troise⁷, D. Pacini⁸, F. Pollari⁹, G. Santarpino¹⁰, V. Argano¹¹, L. Badano^{12,13}, O. Dzemaļi^{14,15}

1 Lens Hospital and Bois Bernard Private Hospital, Lens, France; 2 Ospedali Riuniti Ancona, Ancona, Italy; 3 Kerckhoff Klinik, Bad Nauheim, Germany; 4 Innsbruck Medical University, Innsbruck, Austria; 5 Klinik für Herz-, Thorax- und Gefäßchirurgie Deutsches Herzzentrum der Charité, Berlin, Germany; 6 University Hospitals Cleveland Medical Center, Cleveland, USA; 7 Poliambulanza Foundation Hospital, Brescia, Italy; 10 Policlinico S.Orsola-Malpighi, Bologna, Italy; 9 Klinikum Nürnberg-Paracelsus Medical University, Nuremberg, Germany; 10 Città di Lecce Hospital. Lecce, Italy; 11 Policlinico Paolo Giaccone, Palermo, Italy; 12 Department of Cardiology, Istituto Auxologico Italiano, IRCCS, Milano, Italy,13 Department of Medicine and Surgery, University of Milano-Bicocca Milan, Italy; 14 University Hospital of Zurich, Clinic for Cardiac Surgery, Zurich, Switzerland; 15 City Hospital of Zurich—Triemli, Clinic for Cardiac Surgery, Zurich Switzerland.Serbia.

Objective

To report the preliminary real-word clinical and hemodynamic performance from the MANTRA study in patients undergoing minimally invasive mitral valve repair (MI-MVr) with the new generation MEMO 4D semi-rigid annuloplasty ring (Figure 1).



Methods

MANTRA is a prospective, multi-center, international post-market study to collect real-life safety and performance data on Corcym devices (Corcym S.r.l, Saluggia, Italy). Interim analysis of patients enrolled between July 2021 and October 2023 (enrolment is still ongoing). Clinical and echocardiographic outcomes were collected preoperatively, at discharge and at each follow-up. KCCQ-12 questionnaires were collected preoperatively and at 30-days. Echocardiographic studies were assessed by an independent core-lab.

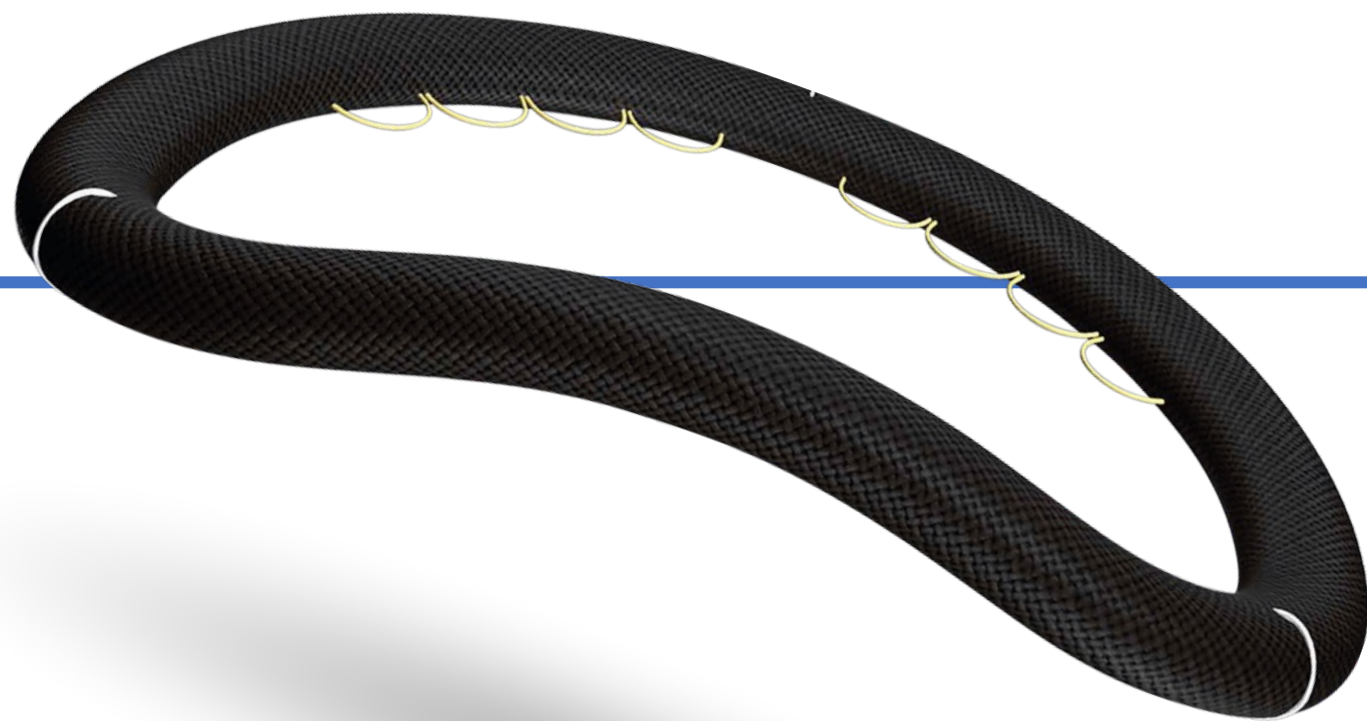


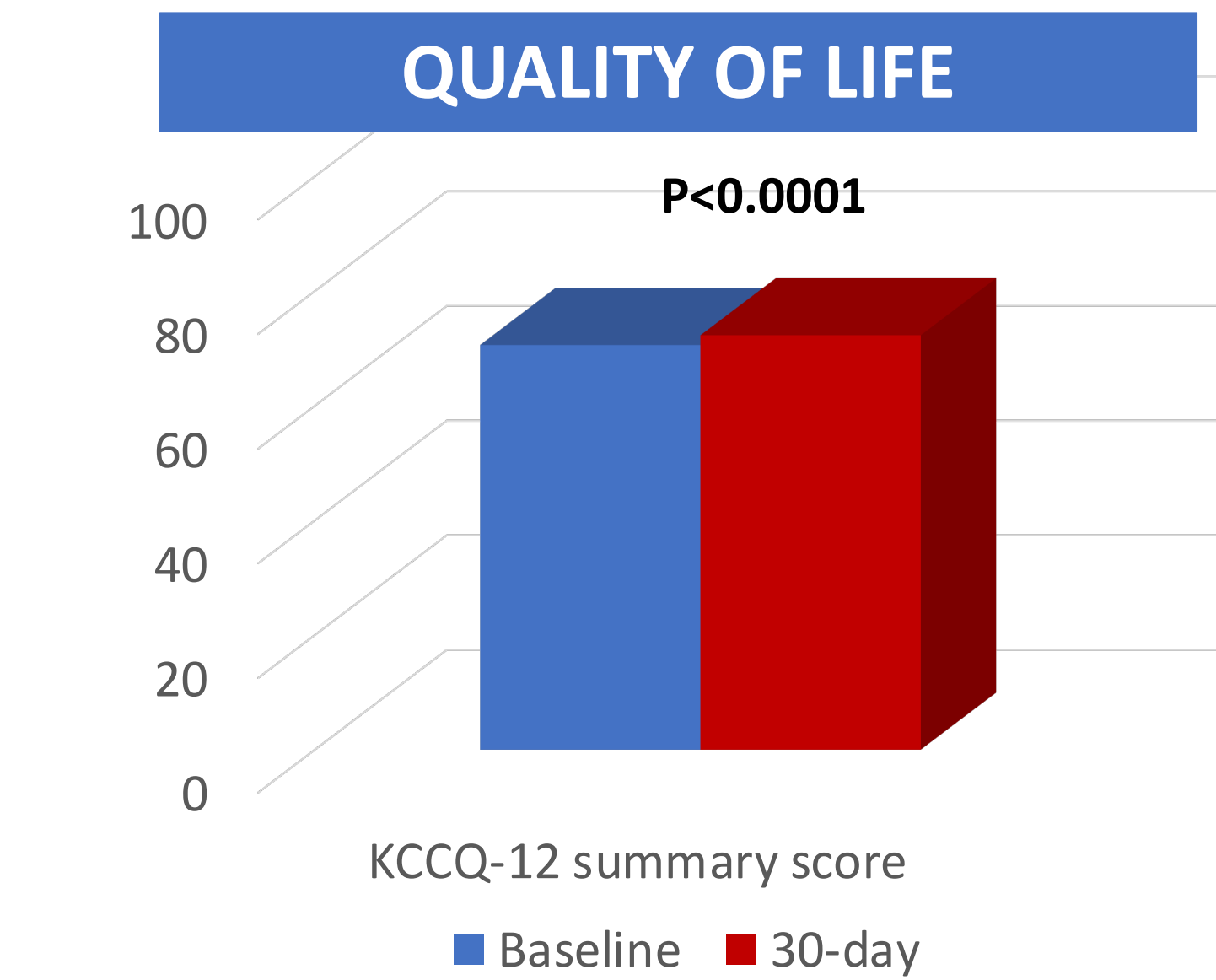
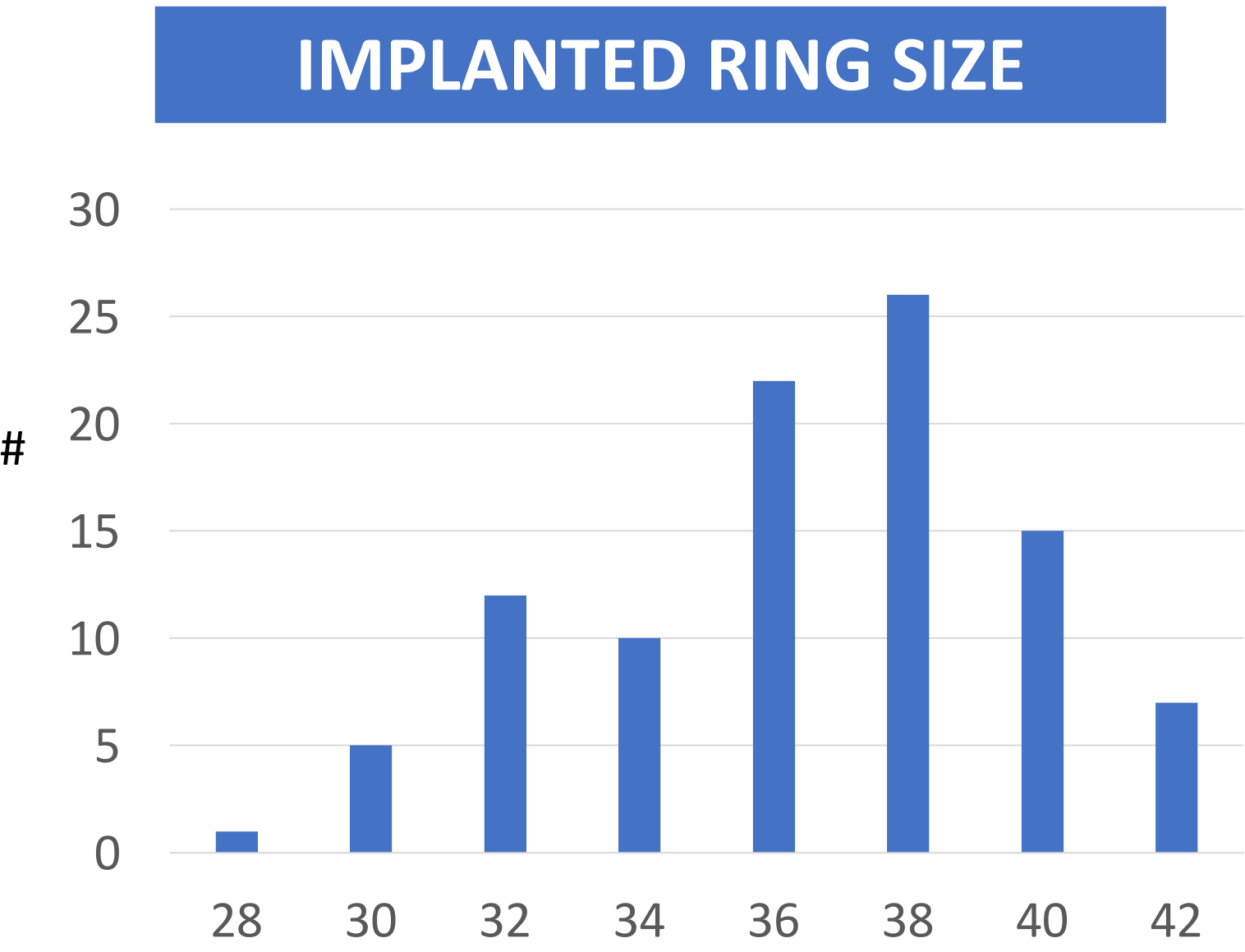
Figure 1. Memo 4D semirigid annuloplasty ring

Results

Among the 170 subjects undergoing MVr with MEMO 4D ring, **97 underwent MI-MVr in 12 International institutions through mini-thoracotomy approach.**

Baseline and operative data	Overall Population (N=97)
Age (year) – [mean±SD]	59.1±11.9
Euroscore II – [mean±SD]	1.3±1.3
Mitral regurgitation etiology [n (%)]	
Primary	90 (92.8%)
Barlow	17 (17.5%)
Secondary	4 (4.1%)
Other	3 (3.1%)
Surgical approach [n (%)]	
Direct vision	42 (43.3%)
Video assisted	25 (25.8%)
Fully endoscopic	30 (30.9%)
Concomitant procedures [n (%)]	
Tricuspid repair	14 (14.4%)
Atrial septal defect repair	21 (21.6%)
Atrial fibrillation treatment	10 (10.3%)

Echocardiographic findings – Core Lab assessed	Baseline	30 days
Left Ventricular End-Diastolic Diameter (mm) – [mean±SD]	55.06±6.86	50.13±6.47
Left Ventricular End-Diastolic Volume (ml) – [mean±SD]	167.28±53.95	126.15±38.75
Left Atrial Volume (ml) – [mean±SD]	130.96±50.04	89.32±39.65
Mean Mitral Pressure Gradient (mmHg) - [mean±SD]	-	3.16±1.41
Mitral regurgitation (%)		
Severe	-	1.4%



30-day outcomes	Overall Population (N=97) N (%)
All Deaths	0 (0.0%)
Re-intervention on mitral valve	2 (1.4%)
Stroke	0 (0.0%)
Acute Kidney Failure	1 (0.7%)
Endocarditis	0 (0.0%)
AV-block III	4 (4.1%)
Myocardial Infarction	1 (0.7%)

Conclusions

In this prospective multicenter study, MI-MVr with MEMO 4D semi-rigid annuloplasty ring confirmed to be safe and effective, providing:

- good clinical outcomes
- moderate-to-large improvement of the patient’s Quality of Life at 30 days
- good early hemodynamic performance
- optimal reduction of the severity of MR
- preservation of the left ventricular function