

SUTURELESS VALVE IMPLANTATION VIA MINIMALLY INVASIVE APPROACH: RESULTS FROM THE INTERNATIONAL PROSPECTIVE MANTRA STUDY

OBJECTIVE

To report the early real-word clinical and hemodynamic performance from the MANTRA study in patients undergoing **isolated minimally invasive aortic valve replacement (MI-AVR) with the Perceval Plus sutureless bioprosthesis.**



METHODS

MANTRA is an ongoing “umbrella” prospective, multi-center, international post-market study designed to collect real-life safety and performance data on Corcym devices (Corcym S.r.l., Saluggia, Italy). Clinical and echocardiographic outcomes collected preoperatively, at discharge and at each follow up. KCCQ-12 and EQ-5D-5L questionnaires collected preoperatively and at the 30-day visit.



U. Kappert¹, HG. Je², S. Shehada³, M. Torella⁴, M. Solinas⁵, B. Meuris⁶, M. Rinaldi⁷, JW. Choi⁸, F. Pollari⁹, KY. Lam¹⁰, C. Baeza¹¹, V. Argano¹², T. Bové¹³, G.Troise¹⁴, M. Baghai¹⁵, E. Parrino¹⁶, D. Pacini¹⁷, H. Gutermann¹⁸, GS. Aldea¹⁹, S. Micovic²⁰

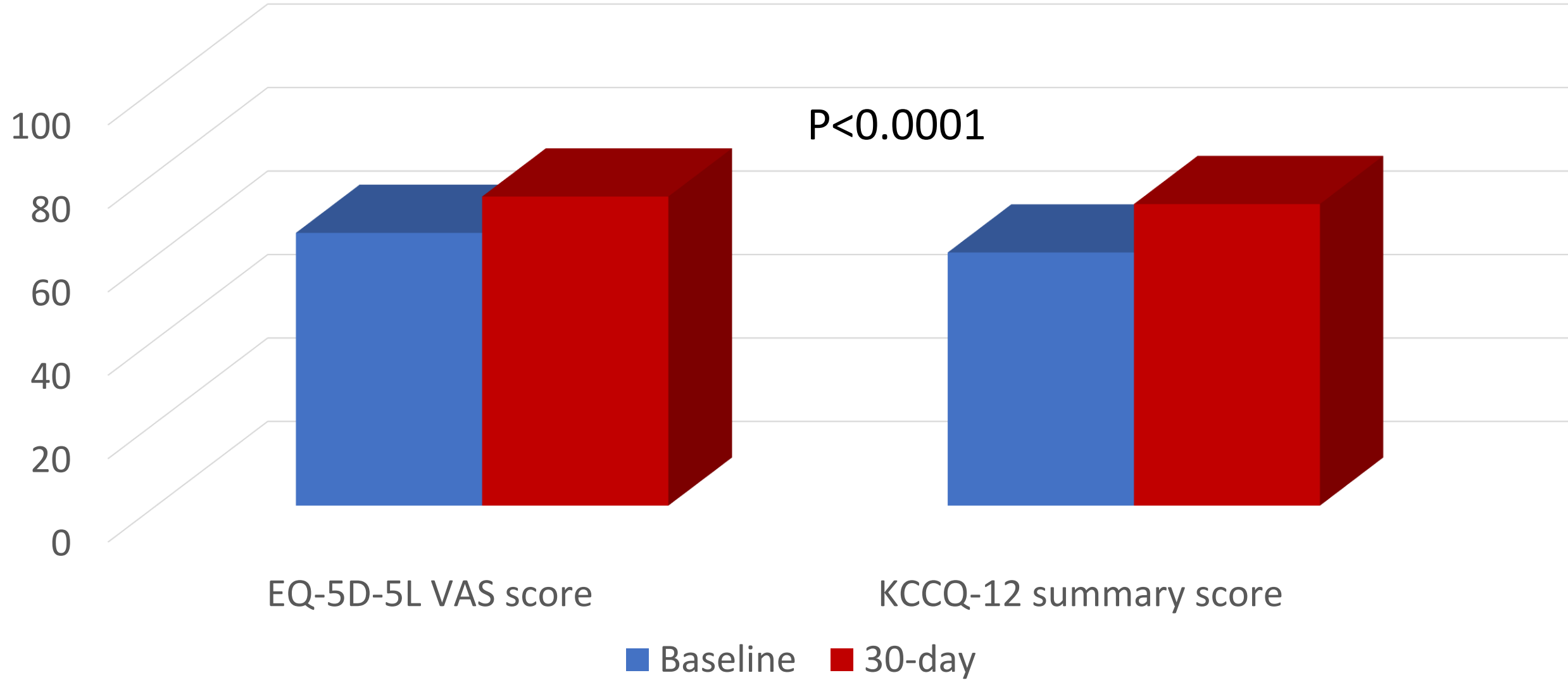
1 Herzzentrum Dresden GmbH Universitätsklinik , Dresden, Germany; 2 Pusan National University Yangsan Hospital, Yangsan, South Korea; 3 Universitätsklinikum Essen, Essen Germany; 4 University of Campania “L. Vanvitelli” - Monaldi Hospital, Napoli, Italy; 5 Ospedale del Cuore di Massa, Massa Italy; 6 UZ Leuven, Leuven, Belgium; 7 A.O.U. Città della Salute e della Scienza di Torino - Ospedale Molinette, Torino, Italy; 8 Seoul National University Hospital. Seoul, South Korea; 9 Klinikum Nürnberg-Paracelsus Medical University, Nuremberg, Germany; 10 Catharina Ziekenhuis, Eindhoven, The Netherlands; 11 University Hospitals Cleveland Medical Center, USA; 12 Policlinico Paolo Giaccone, Palermo, Italy; 13UZ Gent, Gent, Belgium; 14 Fondazione Poliambulanza Istituto Ospedaliero, Brescia, Italy; 15 King's College Hospital, London, UK, 16 Ochsner Clinic Foundation, New Orleans, USA; 17 Policlinico S.Orsola-Malpighi, Bologna, Italy; 18 Ziekenhuis Oost Limburg, Genk, Belgium; 19 University of Washington, Seattle, WA, USA; 20 Dedinje Cardiovascular Institute, Belgrade Serbia.

PATIENTS

141 patients underwent isolated MI-AVR in **19 International institutions** with implant of the **Perceval Plus valve**. Patients were enrolled from July 2021 to October 2023 and enrollment is still ongoing.

Baseline and operative data	Overall Population (N=141)
Age (year) – [mean±SD]	71.7±6.1
Female [n (%)]	76 (53.9%)
Euroscore II – [mean±SD]	1.8±1.5
Bicuspid valve [n (%)]	24 (17%)
Mini-sternotomy approach [n (%)]	69 (48.9%)
Mini-thoracotomy approach [n (%)]	72 (51.1%)
Mean cross-clamp time (min) – [mean±SD]	52.8±17.7
Mean CPB time (min) – [mean±SD]	82.5±30.5
Implant success at first attempt [n (%)]	136 (96.5%)
ICU stay (days) – [median (IQR)]	2.0 (1.0; 2.0)

RESULTS - QUALITY OF LIFE



RESULTS - SAFETY

30-day outcomes	Overall Population (N=141) N (%)
All deaths	1 (0.7%)
Re-intervention	0 (0.0%)
Stroke	2 (1.4%)
Acute Kidney Failure	1 (0.7%)
Myocardial Infarction	1 (0.7%)
Endocarditis	0 (0.0%)
Permanent pacemaker implant	4 (2.8%)
Atrial Fibrillation	5 (3.5%)

RESULTS - HEMODYNAMICS PERFORMANCE

	Baseline	30 Days
MPG [mmHg] – [mean±SD]	49.9±16.9	10.9±4.8
PPG [mmHg] – [mean±SD]	83.4±28.8	19.3±7.3
EOA [cm²] – [mean±SD]	0.76±0.20	1.67±0.51
PVL mild (%)	-	3.9%
PVL moderate-severe (%)	-	0%

CONCLUSIONS

In this prospective multicenter study, **MI-AVR with the Perceval Plus sutureless valve confirmed to be safe, reproducible and effective**, providing excellent clinical recovery at the 30-day follow-up, pacemaker implant rate aligned with standard AVR, with moderate-to-large improvements of Quality of Life and a good early hemodynamic performance.