Supplementary Material

Prognostic impact of guidelines-oriented age cut-off in intermediate-to-low risk patients undergoing transcatheter aortic valve implantation in a large real-world multicenter registry

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I. STUDY DEVICES

The Evolut R System (Medtronic, Inc., Minneapolis, Minnesota) comprises the Evolut R valve and the EnVeo R Delivery Catheter System (DCS) with the InLine sheath. The porcine pericardial tissue tri-leaflet valve is sutured in a supra-annular position on a compressible and self-expandable nitinol frame. The EnVeo R DCS enables the valve to be fully repositionable and recapturable before full release. The built-in InLine sheath allows for the whole system to be inserted into a patient without the need for a separate access sheath, equivalent to the outer diameter of a 14-F sheath (16). The Evolut R valve is currently available in 23, 26, 29 and 34 mm sizes. The Evolut PRO System (Medtronic, Inc., Minneapolis, Minnesota) is delivered transfemorally using a dedicated sheathless delivery system with an outer diameter of a 16-F sheath. The device has the same shape and properties of the second-generation Evolute R version except for an outer adjunctive pericardial skirt to enhance annular sealing. The Evolute PRO valve is currently available in 23, 26 and 29-mm sizes.

The Acurate NEO bioprosthesis is composed by a porcine pericardial valve leaflets mounted on a self-expanding nitinol frame in a supra-annular position, with a pericardial sealing skirt on the outer and inner surface of the stent body. The system is implanted using a dedicated transfemoral delivery system inserted through a 20-F sheath. At the top of the valve there are three flexible and repositionable stabilisation arches ensure coaxial alignment. The upper crown ensures stable positioning and anchoring of the native leaflets, which theoretically can reduce the risk of coronary obstruction and paravalvular leaks (17). The device is available in sizes small, medium, and large size.

II. PARTICIPATING CENTRES

1. Interventional Cardiology Unit, Maria Cecilia Hospital, GCM Care and Research

2. Department of Cardiology, Cardiovascular Institute, Hospital Clínico San Carlos, Madrid, Spain

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4. Department of Cardiology and Cardiac Surgery, Kerckhoff Heart and Lung Center, Bad Nauheim, Germany

5. Department of Cardiovascular Surgery, University Heart Center, Hamburg, Germany

6. Department of Cardiology, C.A.S.T. Policlinic G. Rodolico Hospital, University of Catania, Catania, Italy

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9. Department of Cardiology, IRCCS Policlinico San Donato, Milan, Italy

10. Heart Valve Clinic, University Hospital of Zürich, Zürich, Switzerland

11. Quebec Heart Institute - Laval Hospital - Quebec, Canada.

12. Department of Cardiology, Hospital of León, León, Spain

13. Department of Cardiology, Galway University Hospitals, Galway, Ireland

14. Clinic Cardiovascular Institute, University Hospital Clinic, IDIBAPS, Barcelona, Spain

15. "Evangelismos" Hospital, National and Kapodistrian University of Athens, Greece

16. Interventional Cardiology Unit, Ospedali Riuniti di Ancona, Italy

III. LIST OF COVARIATES INCLUDED IN THE INVERSE PROBABILITY WEIGHTING ANALYSIS

Age
Diabetes
Body Mass Index
Hypertension
Aortic regurgitation _moderate
Male
NYHA III or IV functional class
Aortic valve calcification _moderate
Left ventricle outflow tract calcification _moderate
Low gradient aortic stenosis
Atrial fibrillation
Chronic Obstructive Pulmonary Artery Disease
Peripheral artery disease
Porcelain aorta
Previous cardiac surgery
Previous myocardial infarction
Previous percutaneous coronary interventions
Previous pacemaker/defibrillators
Previous stroke
Ejection fraction
Transcatheter prosthesis size
Annulus perimeter size
Society of Thoracic Surgeons score

IV. SUPPLEMENTARY TABLES AND FIGURES

Supplementary table 1. In-hospital outcomes according to age quartiles

Outcome	I quartile (N=679)	II quartile (N=559)	III quartile (N=799)	IV quartile (N=648)	
Procedural death	3 (0.4)	2 (0.4)	6 (0.8)	5 (0.8)	0.726
Vascular complications					
Major	38 (5.6)	34 (6.1)	57 (7.1)	44 (6.8)	0.638
Minor	65 (9.6)	55 (9.8)	76 (9.5)	58 (9.0)	0.963
Anulus rupture	1 (0.1)	1 (0.2)	3 (0.4)	2 (0.3)	0.848
New permanent PM	64 (9.4)	56 (10)	106 (13.3)	86 (13.3)	0.036
Myocardial infarction	4 (0.6)	2 (0.4)	2 (0.3)	3 (0.5)	0.787
Tamponade	3 (0.4)	6 (1.1)	15 (1.9)	5 (0.8)	0.069
Stroke	12 (1.8)	12 (2.1)	20 (2.5)	13 (2.0)	0.815
Bleeding					
Major	23 (3.4)	20 (3.6)	37 (4.6)	28 (4.3)	0.525
Minor	72 (10.6)	54 (9.7)	70 (8.8)	57 (8.9)	0.547
AKI	32 (4.7)	28 (5.0)	55 (6.9)	34 (5.2)	0.677

Supplementary Figure 1. All-cause mortality according to age quartiles