Three-year outcomes following transcatheter versus surgical aortic valve replacement in low surgical risk patients under 75 years of age

Thomas Modine MD[1], Didier Tchétché MD[2], Nicolas M. Van Mieghem, MD, PhD[3], Jian Huang, MD, MSc[4]; John K. Forrest MD[5], Michael J. Reardon MD[6]

[1]Université de Bordeaux, Bordeaux, France; [2]Clinique Pasteur, Toulouse, France; [3]Erasmus Medical Center Rotterdam, Rotterdam, The Netherlands; [4]Medtronic, Mounds View, USA; [5]Yale University School of Medicine, New Haven, US; [6]Methodist DeBakey Heart and Vascular Center, Houston, USA

Evolut™ Low Risk Trial

BACKGROUND

- American and European societal guidelines differ at the cut-off age for TAVI treatment of low-surgical risk patients with severe aortic stenosis.
- European guidelines propose TAVI for symptomatic patients ≥ 75 years.
- Trials have shown comparable 3-year outcomes after TAVI or surgery for low-surgical risk patients with severe aortic stenosis.
- Data for the intermediate-term outcomes of TAVI interventions in low-risk patients < 75 years is limited.

METHODS

- The 3-year outcomes after TAVI vs. surgery in patients <75 years of age were compared using eligible patients from the Evolut Low Risk trial.
- In total 703 patients were included for analysis (352 TAVI and 351 surgery).
- The primary endpoint of all-cause mortality or disabling stroke at 3 years was adjudicated by Clinical Events Committee.
- Valve performance assessed by serial Doppler echocardiography, evaluated by Echocardiography Core Lab.
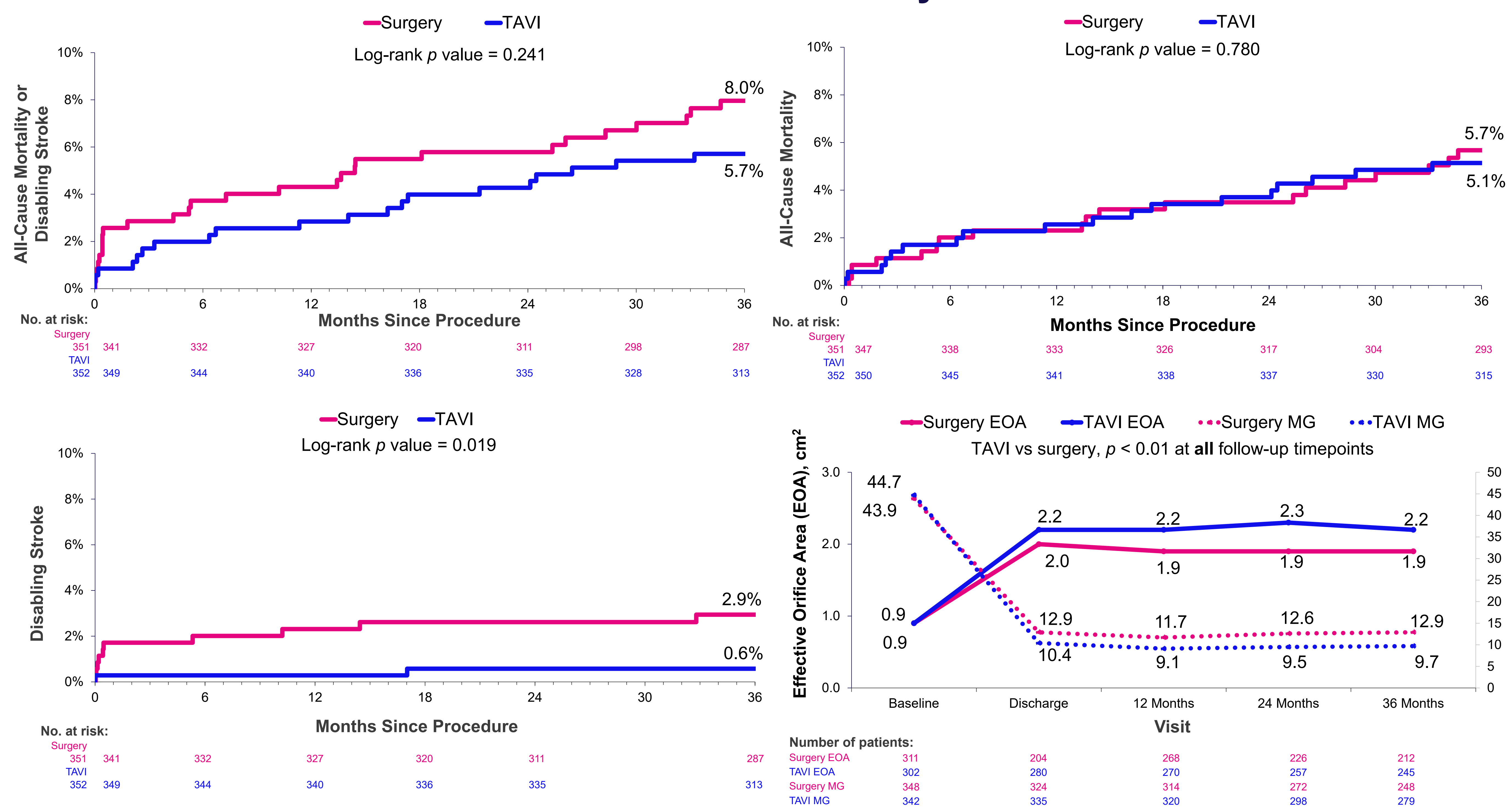
RESULTS

Table 1. Baseline Characteristics

Mean ± SD or %	Evolut TAVI (N=352)	Surgery (N=351)
Age, years	69.2 ± 4.0	69.1 ± 4.1
Female	36.9	32.8
LVEF by visual estimate	61.3 ± 8.7	61.4 ± 8.1
STS-PROM	1.7 ± 0.6	1.6 ± 0.6
NYHA class		
I	8.8	10.0
II	67.3	62.1
III	23.9	27.1
IV	0.0	0.9
Hypertension	86.1	84.3
Chronic lung disease (COPD)	18.7	21.1
Previous CABG	4.0	1.4
Previous PCI	17.0	12.8
Atrial fibrillation/Atrial flutter	13.5	10.9
Prior permanent pacemaker/defibrillator	3.1	2.0
Body surface area, m²	2.1 ± 0.2	2.1 ± 0.2
Diabetes	38.1	34.8
Peripheral arterial disease	7.2	8.6
Cerebrovascular disease	9.9	10.0
Previous myocardial infarction (MI)	7.7	4.6
SYNTAX score	1.9 ± 3.7	2.1 ± 4.0

No significant differences (p < 0.05) in baseline characteristics between treatment groups except for "Previous CABG" (p = 0.037).

Clinical Outcomes and Valve Haemodynamics At 3 Years

Clinical Outcomes and Valve Haemodynamics At 3 Years

RESULTS

Table 2. Clinical Outcomes at 3 Years

Kaplan-Meier estimate % (N)	Evolut TAVI	Surgery	P-value
All-cause mortality or disabling stroke	5.7% (20)	8.0% (27)	0.241
All-cause mortality	5.1% (18)	5.7% (19)	0.780
Cardiovascular death	4.3% (15)	3.6% (12)	0.623
All stroke	4.9% (17)	6.2% (21)	0.479
Disabling stroke	0.6% (2)	2.9% (10)	0.019
Non-disabling stroke	4.3% (15)	3.3% (11)	0.453
Aortic valve hospitalisation	7.3% (25)	8.0% (27)	0.670
All-cause mortality, disabling stroke, or aortic valve rehospitalization	11.7% (41)	14.6% (50)	0.232
Life threatening or disabling bleeding	3.7% (13)	6.9% (24)	0.056
Major vascular complication	4.3% (15)	2.6% (9)	0.220
Acute kidney injury	2.8% (10)	9.7% (34)	<0.001
Myocardial infarction	4.7% (16)	2.9% (10)	0.265
Permanent pacemaker implant[a]	21.0% (71)	7.1% (24)	<0.001
Permanent pacemaker implant[b]	20.3% (71)	7.0% (24)	<0.001
Atrial fibrillation	13.3% (46)	36.4% (127)	<0.001
Reintervention	1.5% (5)	1.5% (5)	0.962

P values for all clinical outcomes were based on the log-rank test
[a]Patients with pacemaker of implantable cardioverter defibrillator at baseline are not included.
[b]Patients with pacemaker or ICD at baseline are included.

Table 3. Bioprosthetic Valve Performance at 3 Years

% (N)	Evolut TAVI	Surgery	P-value
Paravalvular aortic regurgitation (PVR)*			<0.001
None/trace	81.3% (221)	98.4% (240)	
Mild	17.6% (48)	1.2% (3)	
Moderate	1.1% (3)	0.4% (1)	
Severe	0.0% (0)	0.0% (0)	NA
≥ Moderate	1.1% (3)	0.4% (1)	0.626
Prosthesis-patient mismatch (PPM)*a			<0.001
None	88.5% (215)	70.0% (147)	
Moderate	10.3% (25)	22.4% (47)	
Severe	1.2% (3)	7.6% (16)	<0.001
Structural valve deterioration (SVD)*			
Mean gradient ≥ 20 mm Hg	1.8% (5)	9.7% (24)	<0.001
≥ 10 mm Hg increase from 1 month/Discharge[b]	1.8% (5)	5.3% (13)	0.028
Non-structural valve dysfunction*			
Severe PVR	0.0% (0)	0.0% (0)	NA
Severe PPM	1.2% (3)	7.6% (16)	<0.001
Valve thrombosis, clinical[c]	0.3% (1)	0.3% (1)	0.989
Infectious endocarditis[c]	0.6% (2)	1.5% (5)	0.233

*Non-cumulative data are reported as proportion % (n) and compared by the chi-square test.
[a]PPM classification is according to VARC-3 criteria:
  Severe PPM: (BMI<30 and EOAI≤0.65) OR (BMI≥30 and EOAI≤0.55).
  Moderate PPM: (BMI<30 and 0.65<EOAI≤0.85) OR (BMI≥30 and 0.55<EOAI≤0.70).
  No PPM: (BMI<30 and EOAI>0.85) OR (BMI≥30 and EOAI>0.70).
[b]1 month, or discharge when 1 month is not available.
[c]Thrombosis and endocarditis are presented as Kaplan-Meier estimate % (# of subject with event) and compared with the log-rank test.

CONCLUSIONS

- In patients **< 75** years of age as compared to surgery TAVI with the self-expanding Evolut bioprosthesis has **similar** all-cause mortality rates, **lower** disabling stroke rates, **no difference** in ≥ moderate PVR, and **significantly better** valve performance at 3 years follow-up.
- Our analysis **supports** the use of TAVI as a treatment option for patients **< 75 years** of age who require valve replacement due to severe aortic stenosis.
- Patients within this study will be followed for **10 years** to provide insight in the long-term outcomes of these 2 approaches.