One-year outcomes after TAVI with balloon-expandable vs. self-expandable valves

Results from the randomized CHOICE trial

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on behalf of the CHOICE investigators

Potential conflicts of interest

Speaker's name: Mohamed Abdel-Wahab

☑ I have the following potential conflicts of interest to report:

Consultant: BOSTON SCIENTIFIC

Honorarium: ABBOTT VASCULAR

Institutional grant/research support: BIOTRONIK, ST. JUDE MEDICAL

Background

- In the first randomized head-to-head TAVI trial, the use of a balloon-expandable valve resulted in a greater rate of device success than the use of a self-expandable valve.
- While mortality at 30 days was comparable, improvement of heart failure symptoms was more frequently observed with the balloon-expandable valve, whereas minor stroke rates were numerically higher.
- Longer-term data are required to further assess valve function and to monitor clinical events.

Abdel-Wahab et al. JAMA 2014;311:1503-14

CHOICE Trial Design

Symptomatic severe aortic stenosis

Assessment by Heart Team

Indication for TAVI (high-risk/inoperable)

Assessment: transfemoral access, anatomic suitability

1:1 randomization

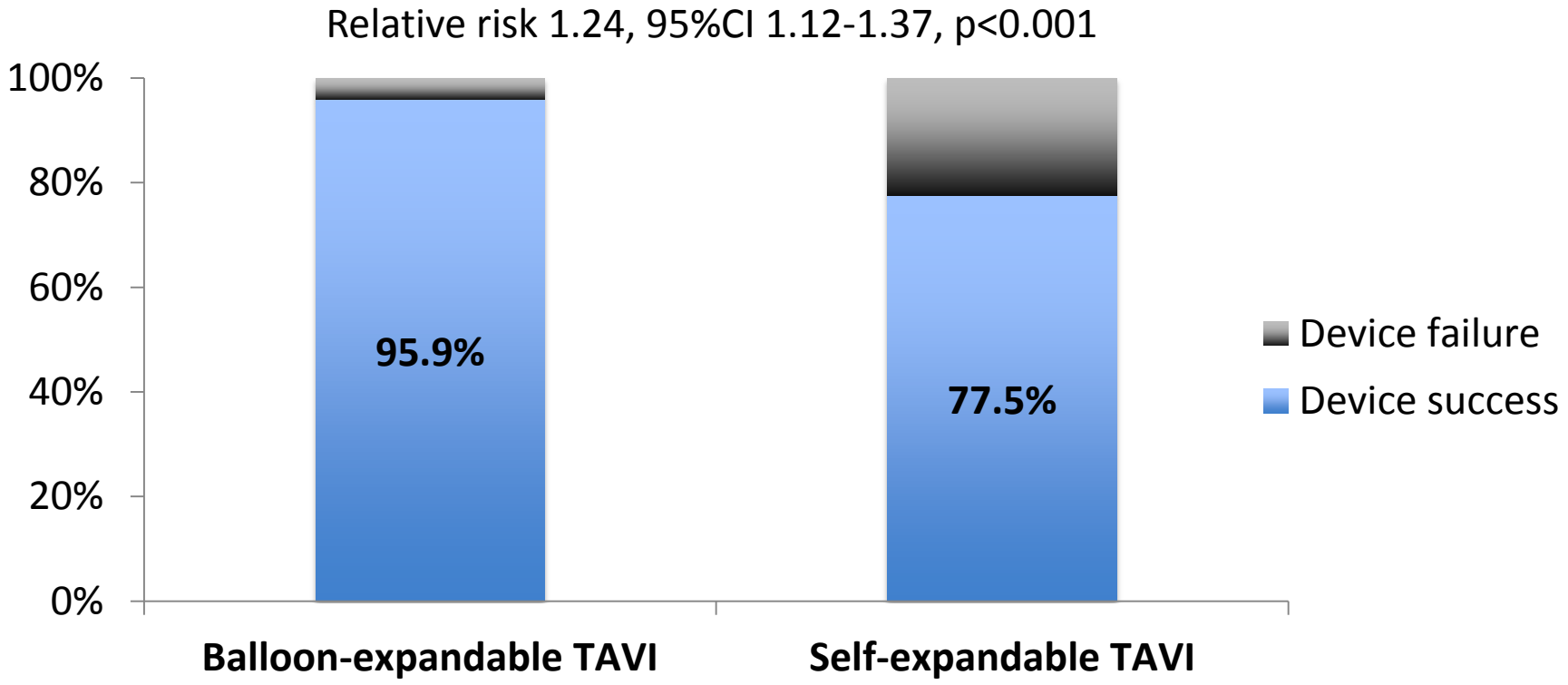
Transfemoral TAVI with a balloon-expandable valve (Edwards Sapien XT)

Transfemoral TAVI with a self-expandable valve (Medtronic CoreValve)

Inclusion and Exclusion Criteria

- Main inclusion criteria
  - Severe symptomatic aortic valve stenosis
  - High risk for surgery
  - Native aortic valve annulus measuring 20-27 mm
  - Suitable transfemoral vascular access
- Main exclusion criteria
  - Native aortic valve annulus < 20 mm and > 27 mm
  - Pre-existing aortic bioprosthesis
  - Cardiogenic shock or hemodynamic instability

Primary endpoint: Device Success



Causes of device failure	Balloon-expandable (n=121)	Self-expandable (n=120)
Unsuccessful vascular access, delivery and deployment	0/121 (0)	0/120 (0)
Incorrect position with implantation of more than one valve	1/121 (0.8)	7/120 (5.8)
Inadequate performance of the prosthetic heart valve		
- Aortic valve area < 1.2 cm^2 or mean aortic valve gradient > 20 mmHg	0/121 (0)	0/120 (0)
- Moderate or severe prosthetic valve regurgitation	5/121 (4.1)	22/120 (18.3)
Total (hierarchical)	5/121 (4.1)	27/120 (22.5)

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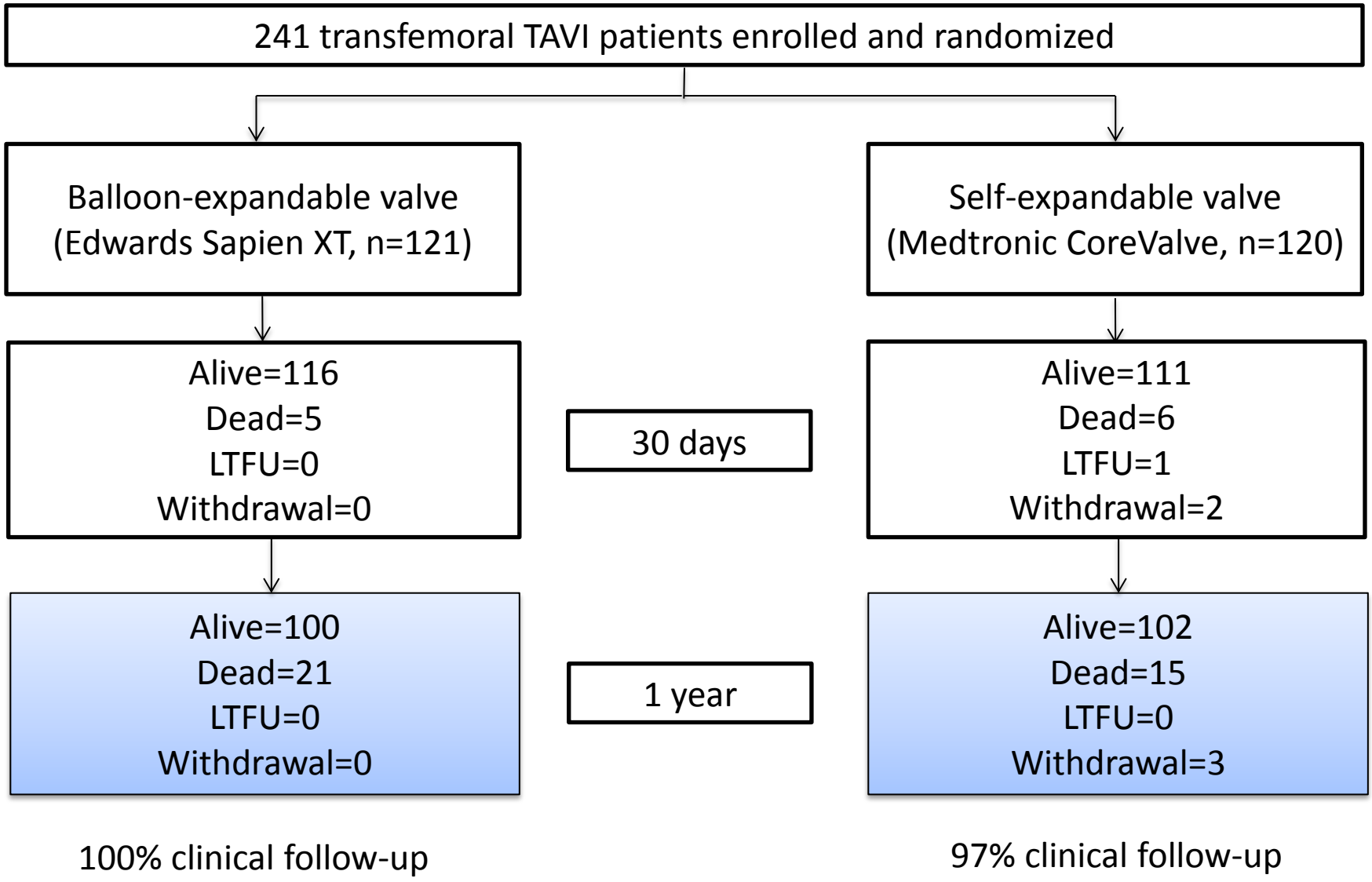
Study Methodology

- All patients were followed for at least 1 year and had clinical visits and echocardiographic evaluations at 6 months and 1 year.
- A clinical events committee blinded to treatment assignment was responsible for adjudicating all endpoints.
- Definitions of the endpoints are identical to those in the original trial (in accordance with the first VARC consensus document).
- Echocardiography was performed on site by an experienced interventional echocardiographer blinded to the echocardiographic findings at discharge and/or 30 days.

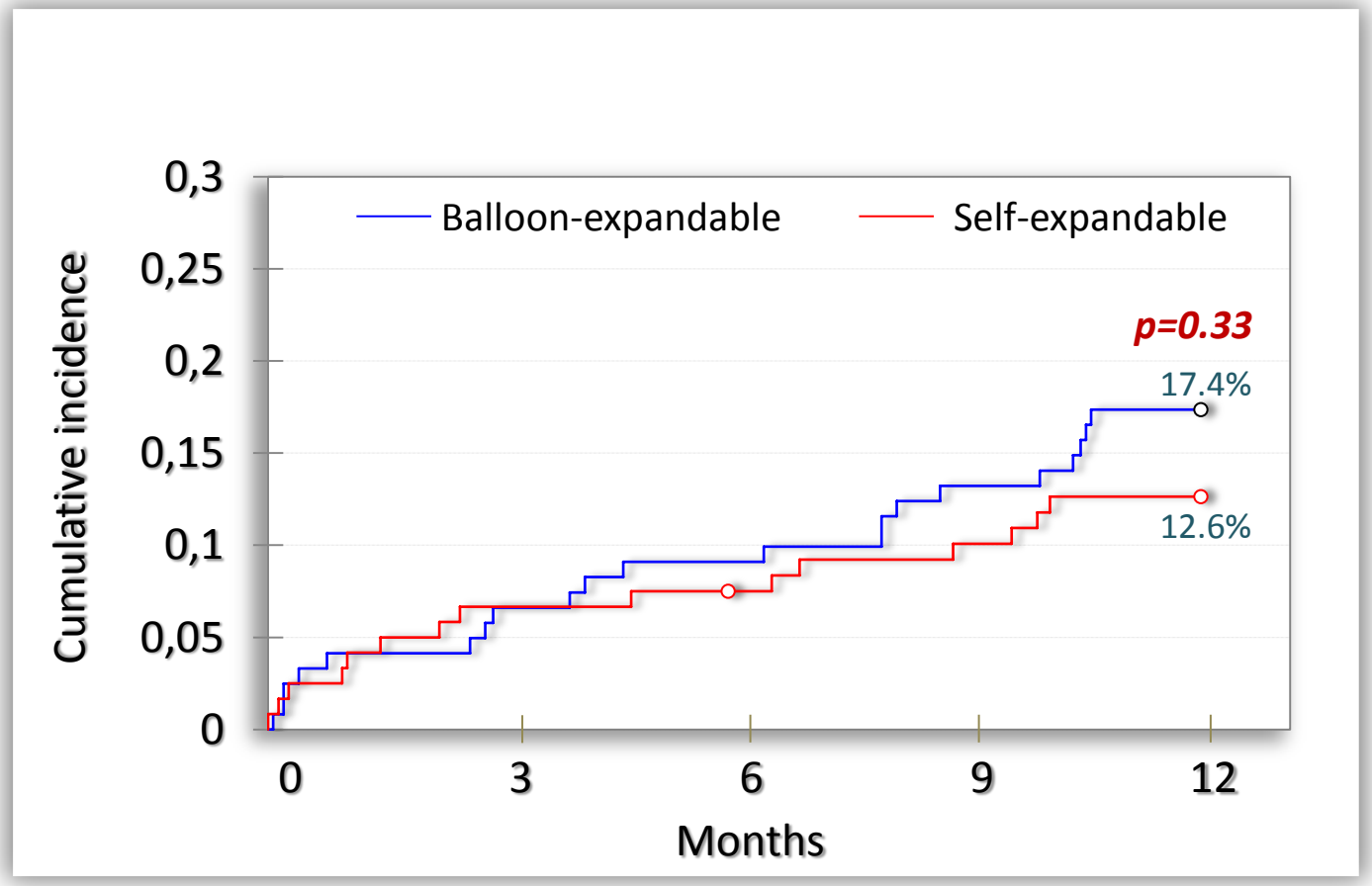
Study Flow


241 transfemoral TAVI patients enrolled and randomized
Balloon-expandable valve (Edwards Sapien XT, n=121)
Self-expandable valve (Medtronic CoreValve, n=120)
Alive=116
Dead=5
LTFU=0
Withdrawal=0
30 days
Alive=111
Dead=6
LTFU=1
Withdrawal=2
Alive=100
Dead=21
LTFU=0
Withdrawal=0
1 year
Alive=102
Dead=15
LTFU=0
Withdrawal=3
100% clinical follow-up
97% clinical follow-up

Key Endpoints at 1-Year

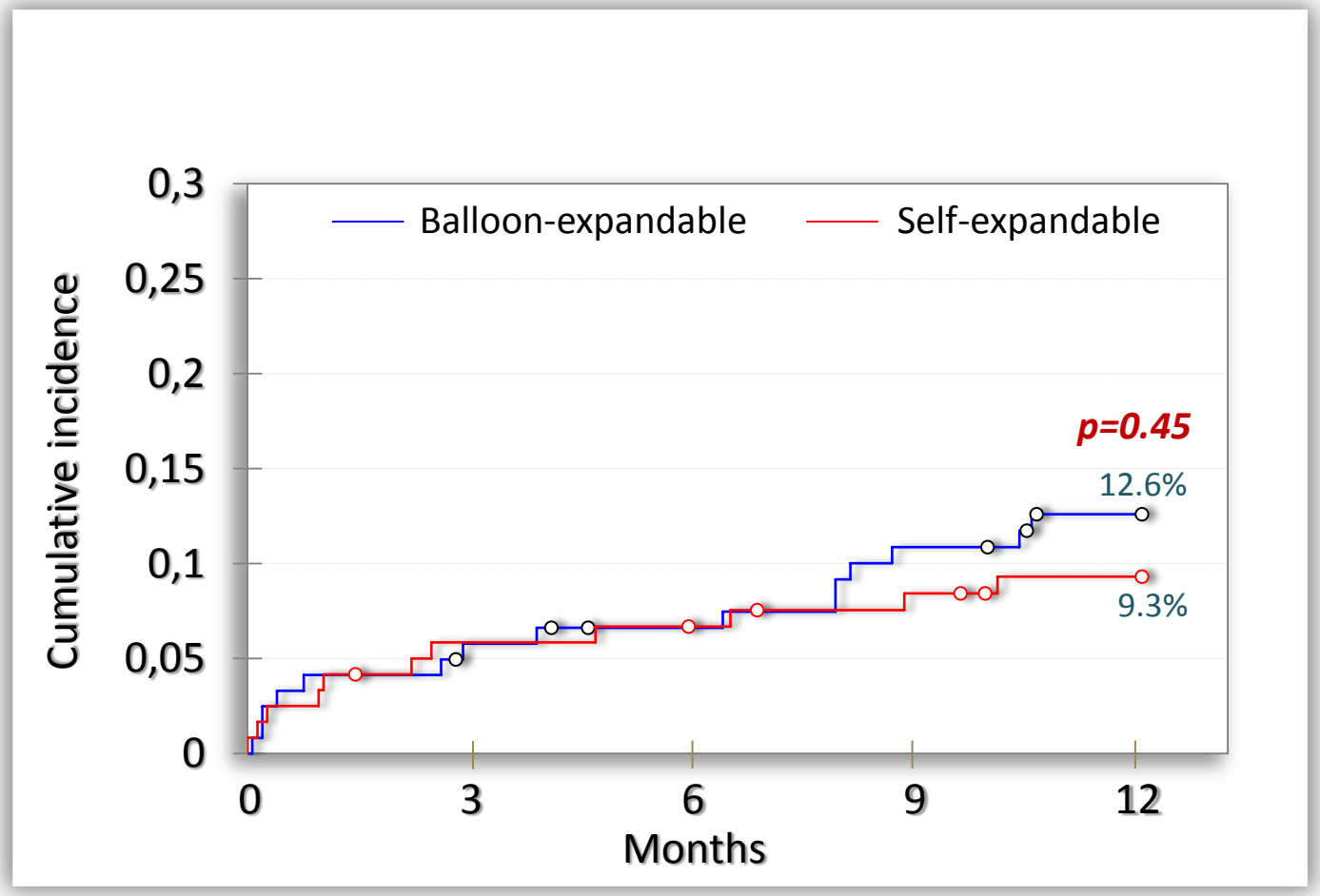
- All-cause and cardiovascular mortality
- Rehospitalization for heart failure
- Stroke
- Functional class improvement
- Echocardiographic parameters of valve function

All-Cause Mortality



No. at risk					
Balloon-expandable	121	114	111	106	100
Self-expandable	120	113	111	106	102

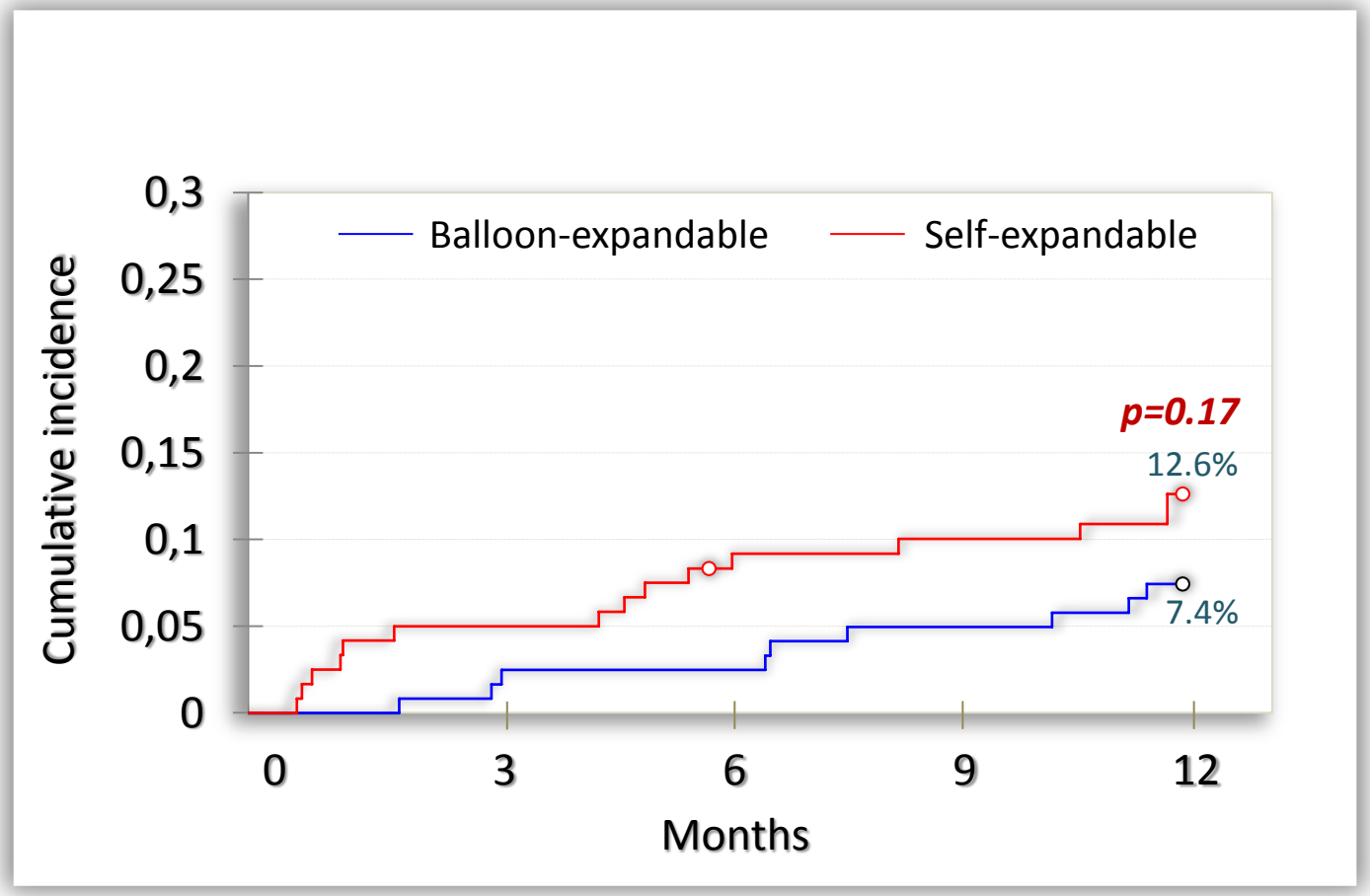
Cardiovascular Mortality



No. at risk

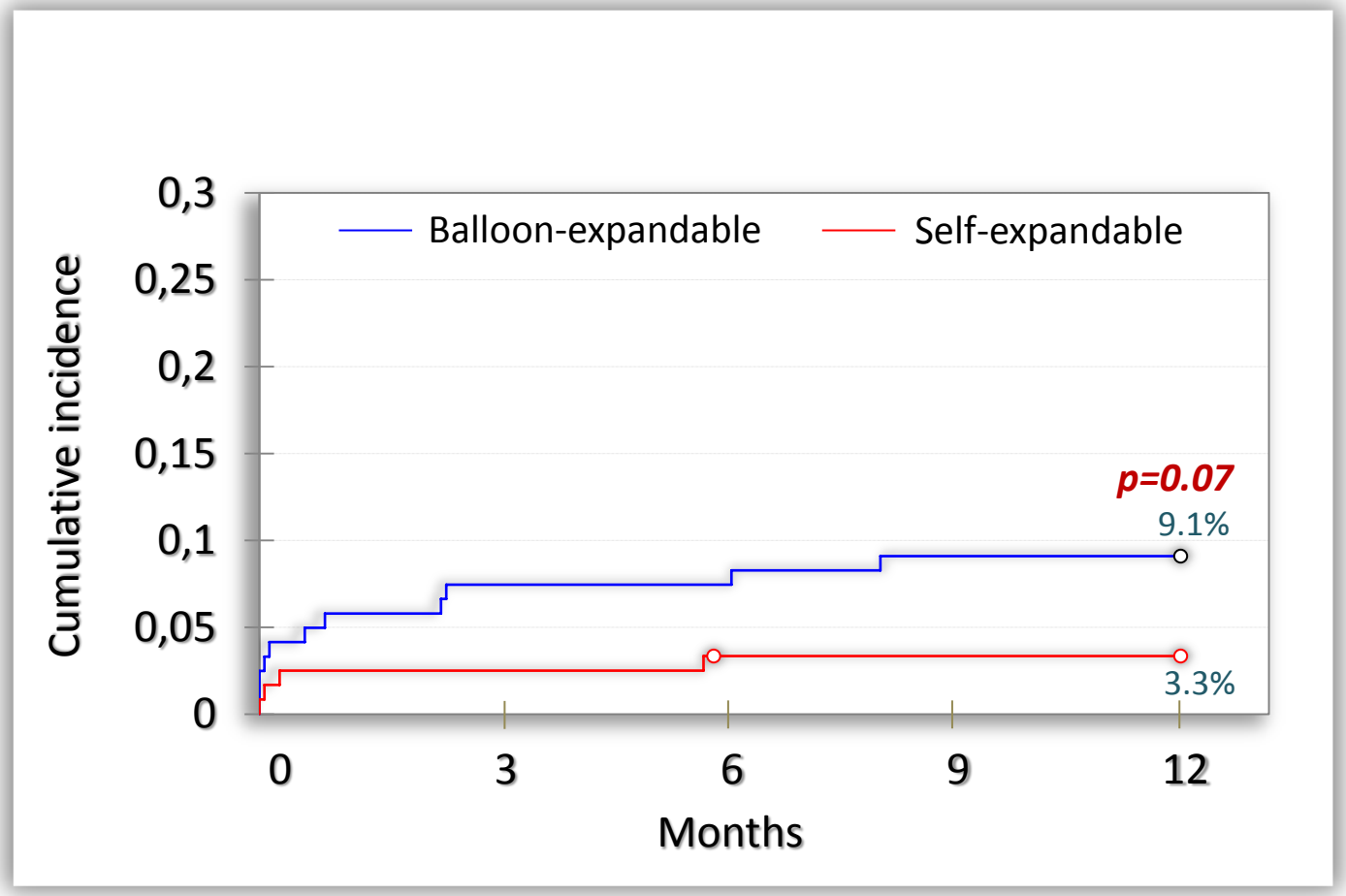
Balloon-expandable	121	114	111	106	100
Self-expandable	120	113	111	106	102

Heart Failure Hospitalization



No. at risk					
Balloon-expandable	121	121	119	116	112
Self-expandable	120	115	110	106	102

Stroke



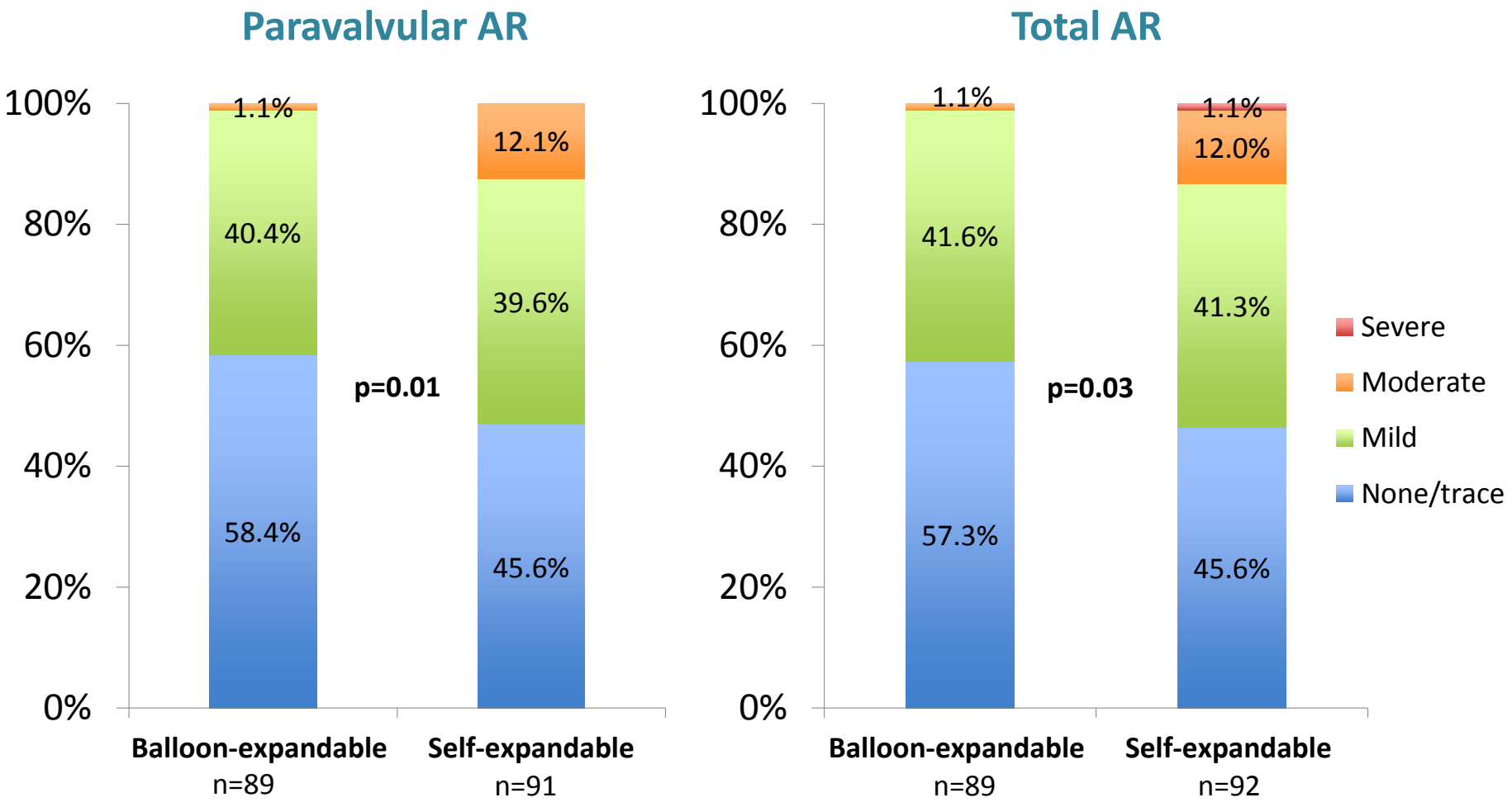
No. at risk					
Balloon-expandable	121	113	113	110	110
Self-expandable	120	118	116	116	113

Other Endpoints

	Balloon-expandable (n=121)	Self-expandable (n=117)	p-value
Myocardial infarction	1/121 (0.8%)	1/117 (0.9%)	1.0
Bleeding			
Life threatening	17/121 (14.0%)	15/117 (12.8%)	0.85
Major	26/121 (21.5%)	17/117 (14.5%)	0.18
Minor	13/121 (10.7%)	9/117 (7.7%)	0.50
Vascular complications			
Major	14/121 (11.6%)	14/117 (12.0%)	1.0
Minor	5/121 (4.1%)	2/117 (1.7%)	0.45
Endocarditis	2/116 (1.7%)	1/111 (0.9%)	1.0
Repeat procedure for valve-related dysfunction	2/121 (1.6%)	3/117 (2.6%)	0.68
New pacemaker	26/111 (23.4%)	38/100 (38.0%)	0.02
Combined efficacy endpoint	24/116 (20.7%)	31/111 (27.9%)	0.22
MACCE	13/121 (10.7%)	8/117 (6.8%)	0.36
NYHA class improvement	82/95 (86.3%)	85/95 (89.5%)	0.66
Quality of life score	65±22	67±20	0.49

Echocardiographic Findings

Aortic Regurgitation at 1 Year



Echocardiographic Findings

Changes in paravalvular leak
Echocardiography at discharge compared to 1 year
(Patients with data at both time points)

Change in PVL grade between discharge and 1 year	Balloon-expandable valve no./total no. (%)	Self-expandable valve no./total no. (%)	p-value*
-2	0/88 (0%)	1/89 (1.1%)	0.98
-1	15/88 (17.0%)	20/89 (22.5%)	
0	58/88 (65.9%)	47/89 (52.8%)	
1	15/88 (17.0%)	21/89 (23.6%)	

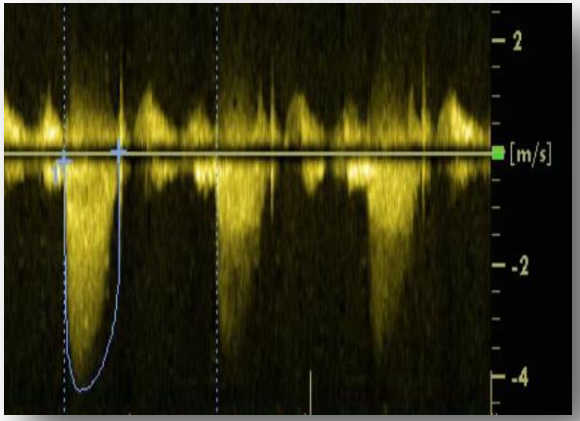
*p-value for comparison between balloon- and self-expandable valves obtained with the Mann-Whitney U test

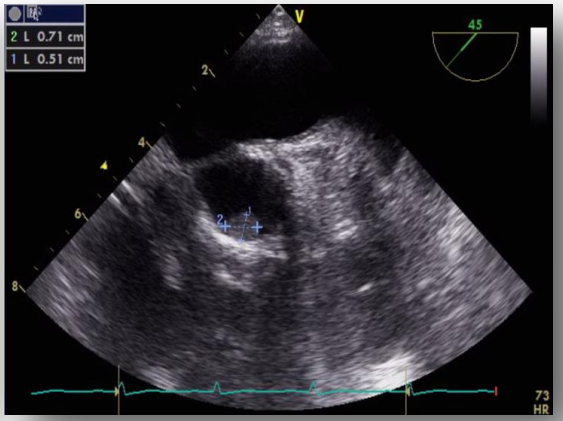
Echocardiographic Findings

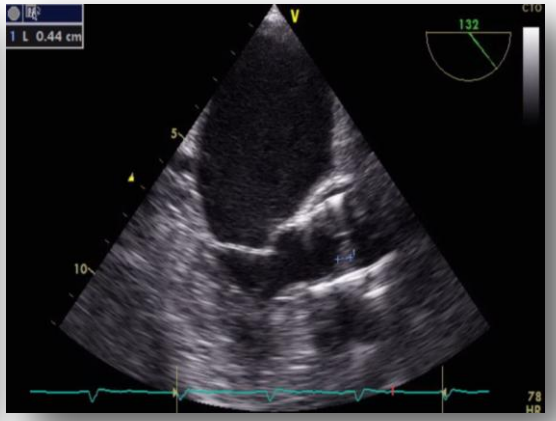
Valve Thrombosis

Balloon-expandable	Self-expandable	p-value
4/116 (3.4%)	0/111 (0.0%)	0.12

- Elevation of mean gradient and reduction of valve area during follow-up, which was not recorded post-procedure (observed between 175 and 203 days after TAVI).
- Echocardiographic evidence of thrombus and/or leaflet thickening and restricted motion.
- Transvalvular gradient normalized with anticoagulant therapy.







Limitations

- Moderate sample size and lack of power to detect differences in clinical outcomes, and thus all observations should be considered hypothesis generating.
- Lack of an echocardiographic core laboratory. However, echocardiographic evaluation of paravalvular leaks following TAVI remains complex and challenging, and differences in grading have been observed within and between different core laboratories.

Conclusions

- Despite the higher device success rate and lower paravalvular regurgitation rate (which remained stable during follow-up) with the balloon-expandable valve, no differences in one-year mortality rates were observed among the CHOICE patients treated with either balloon- or self-expandable valves.
- The numerically higher rate of thromboembolic events with the balloon-expandable valve underscores the necessity of adequately powered large comparative device trials in the TAVI field.