2019 euroPCR

Five-year outcomes after TAVI with balloon-expandable vs. self-expanding valves: Results from the CHOICE randomised clinical trial

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Potential conflicts of interest

Speaker's name : Mohamed Abdel-Wahab

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

Receipt of honoraria or consultation fees: Boston Scientific, Edwards Lifesciences, Medtronic

Why this study?

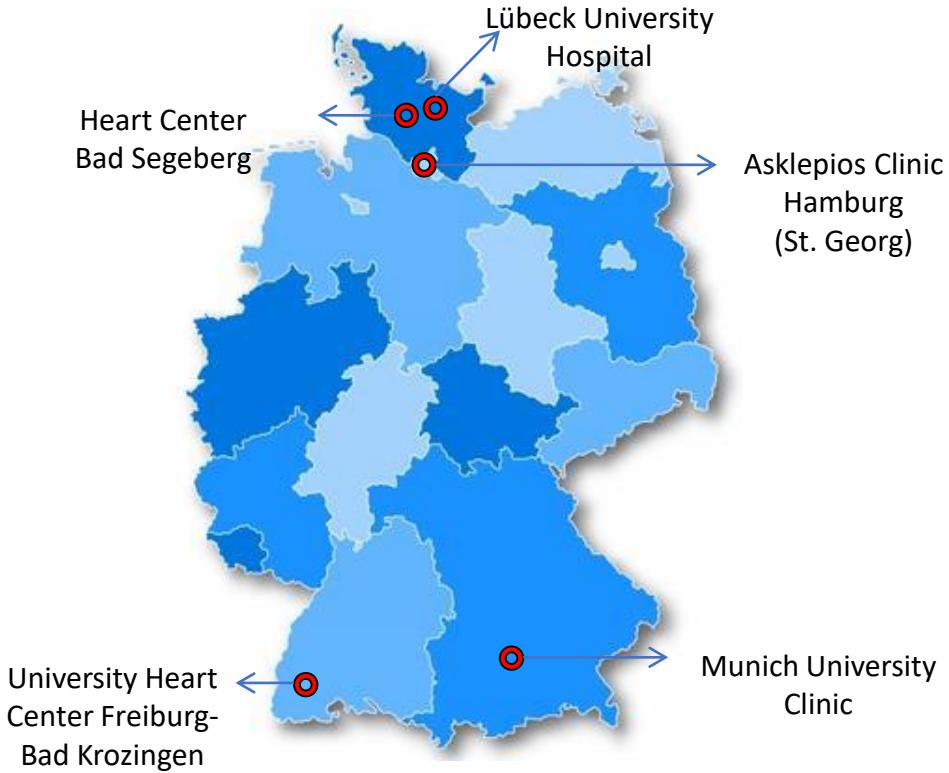
- Transcatheter heart valves used for TAVI can be broadly classified into balloon-expandable and self-expanding devices.
- Both device types have different expansion modes, stent frames and leaflet characteristics, which could translate into differences in hemodynamic function, complication rates and long-term device performance.
- Randomized head-to-head studies between both device technologies are scarce, and no trial has yet reported long-term comparative outcomes beyond one year.

The CHOICE Trial

Objective	To compare early generation balloon-expandable (Sapien XT) and self-expanding (CoreValve) THVs in high-risk native AS patients undergoing TAVI
Primary endpoint	Device success (VARC definition)
Secondary endpoints	Clinical outcome measures at 1 year
Design	Investigator-initiated, industry-independant, prospective, multicenter, randomized trial
Enrolment period	March 2012 – December 2013
Sponsor	Heart Center, Bad Segeberg, Germany

Abdel-Wahab et al. JAMA 2014;311:1503-14 – Abdel-Wahab et al. J Am Coll Cardiol 2015;66:791-800

The CHOICE Trial



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Statistical core lab:
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Funding:
Heart Center, Segeberger Kliniken GmbH, Bad Segeberg, Germany

Primary and secondary outcomes

- Device success was significantly higher with the balloon-expandable device, mainly due to less paravalvular leaks.
- Mortality, stroke and rehospitalization for heart failure were not significantly different at 1 year.

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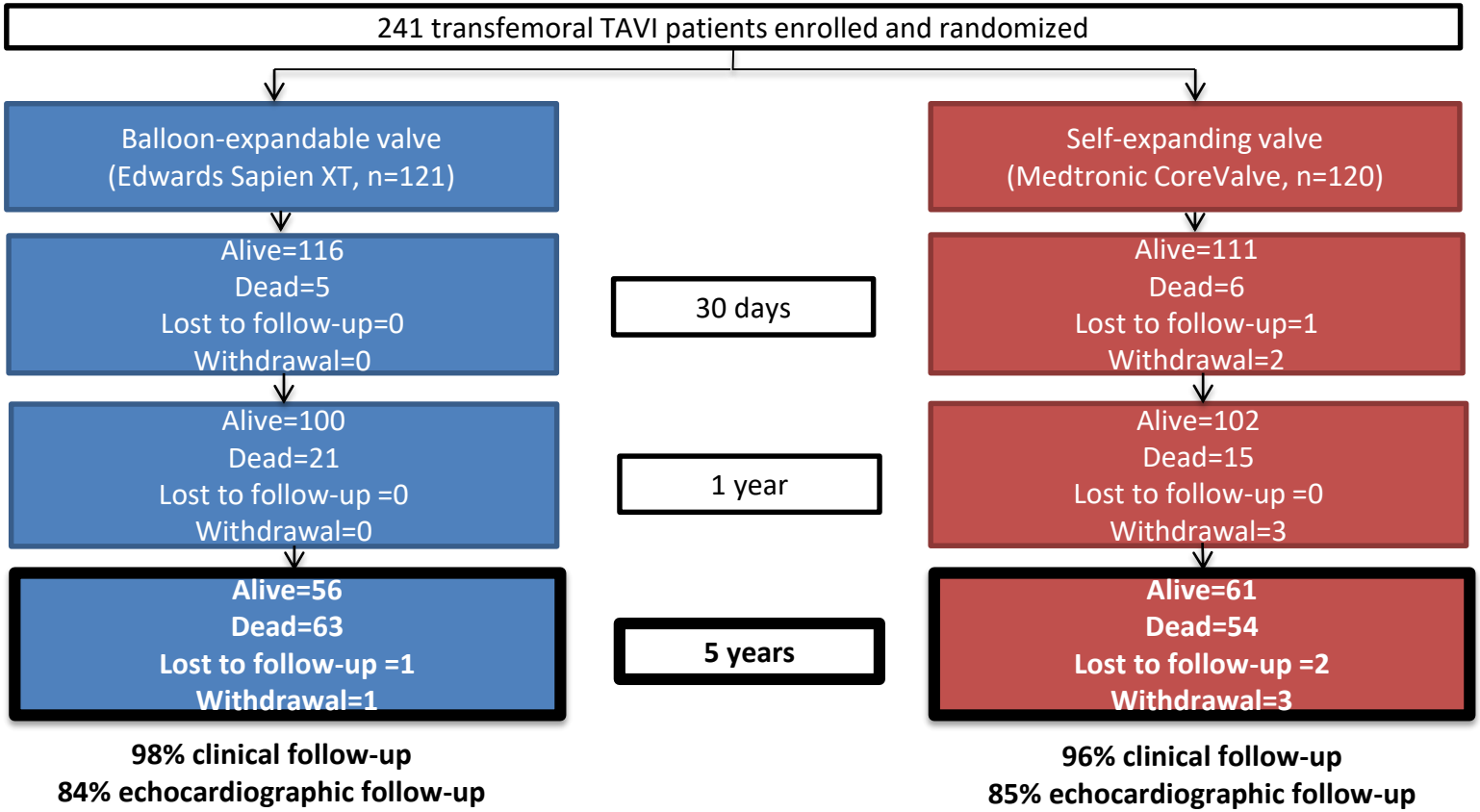
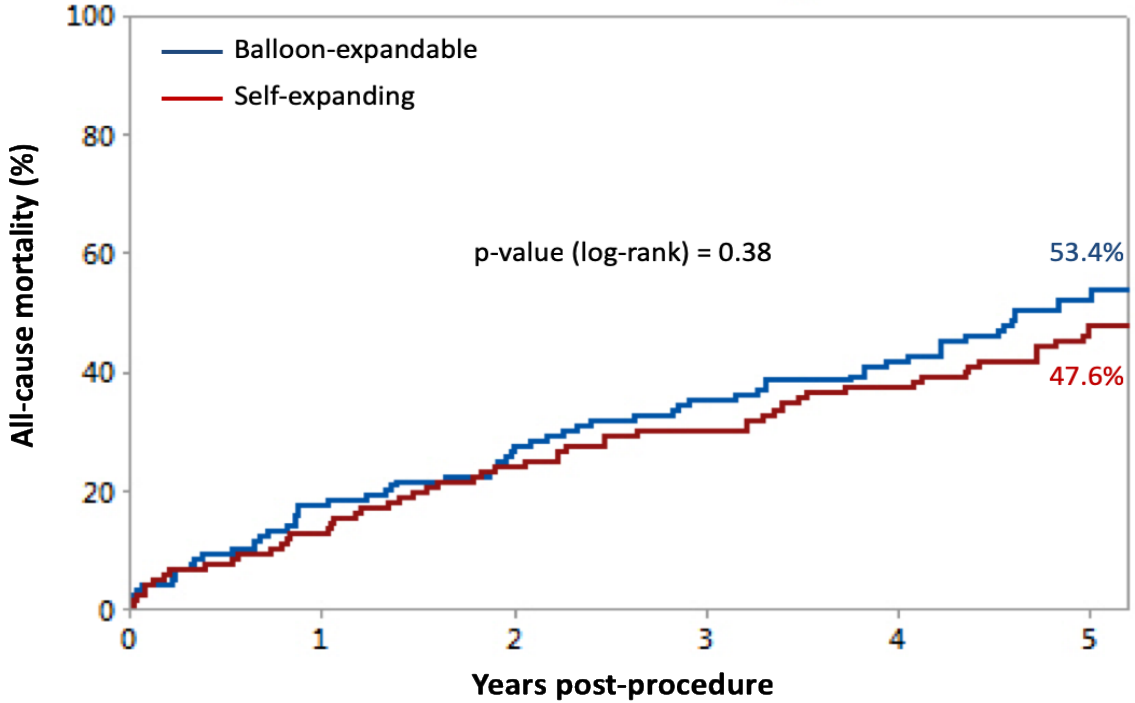
CHOICE long-term: Study flow



5-year endpoints and analysis

- Main endpoints
  - All cause and cardiovascular mortality
  - Stroke, rehospitalization for heart failure
  - Echocardiographic parameters of valve function
  - Valve durability analysis (post hoc, using European consensus criteria)
    - Bioprosthetic valve dysfunction
    - Structural valve deterioration
    - Bioprosthetic valve failure
- Statistical analysis
  - Time-to-event analysis using Kaplan-Meier estimates
  - Analysis adjusted for the competing risk of death for all other outcomes

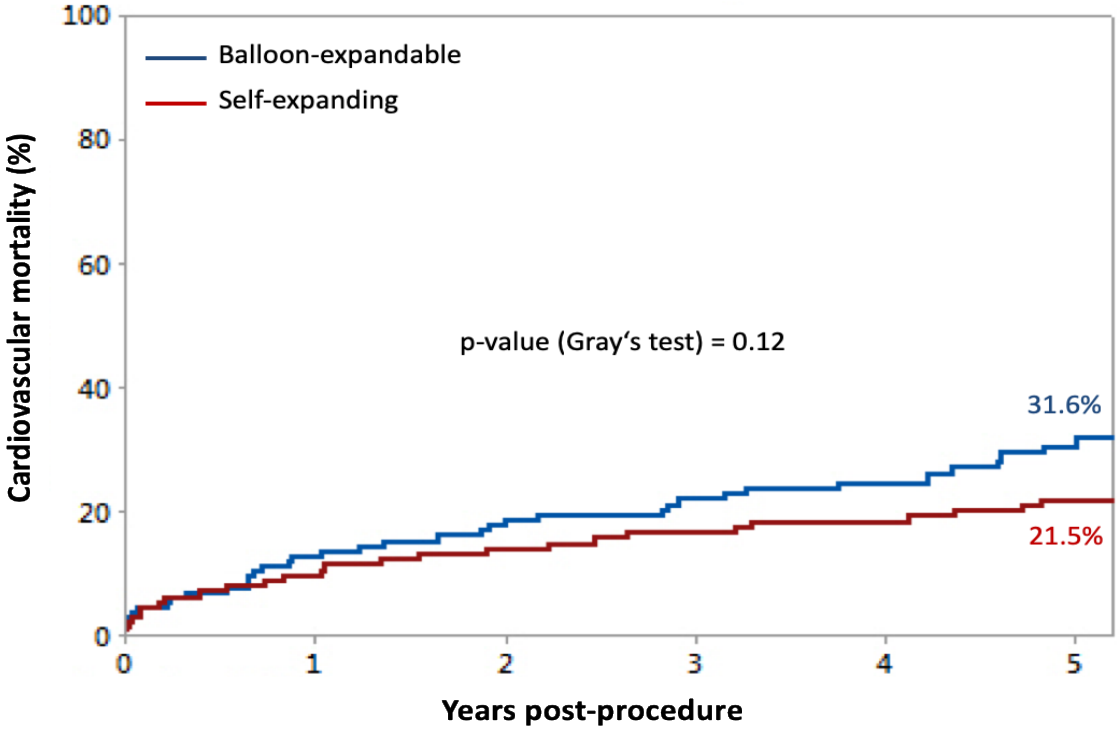
All cause mortality



Number at risk

121	99	87	77	69	46
120	101	87	80	71	42

Cardiovascular mortality



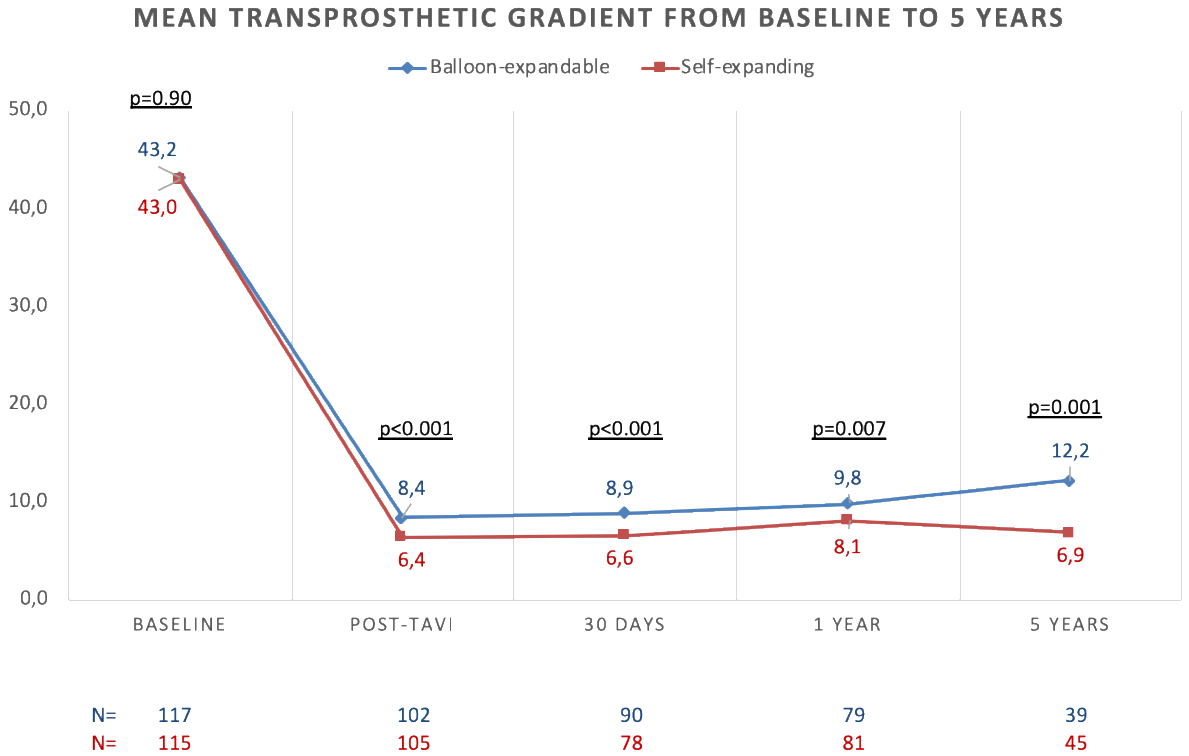
Number at risk

121	99	87	77	69	46
120	101	87	80	71	42

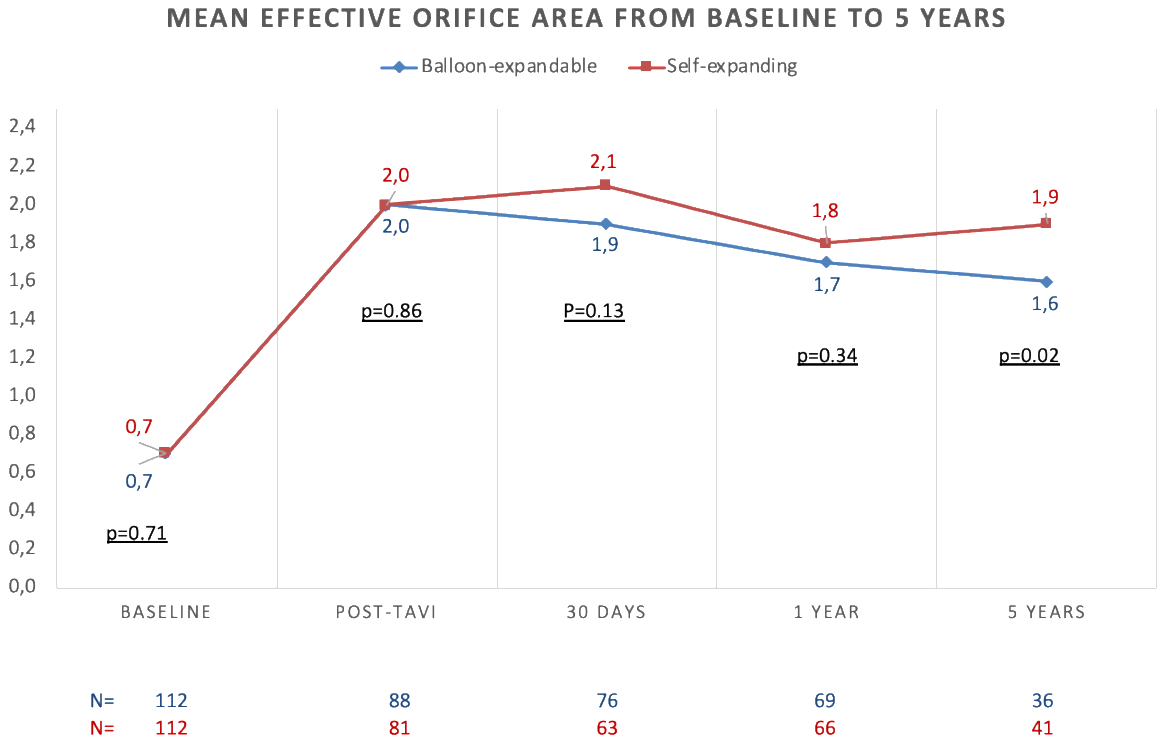
Other clinical endpoints

	Balloon-expandable valve (n=121)	Self-expanding valve (n=120)	p-value
Stroke	21 (17.5%)	19 (16.5%)	0.73
Repeat hospitalization for heart failure	30 (28.9%)	26 (22.5%)	0.75
Myocardial infarction	2 (1.6%)	7 (6.1%)	0.08
Bleeding			
Life threatening	21 (17.3%)	18 (16.2%)	0.77
Major	28 (26.3%)	20 (22.0%)	0.26
Minor	17 (14.3%)	12 (10.4%)	0.37
Vascular complications			
Major	14 (11.6%)	14 (12.1%)	0.89
Minor	5 (4.2%)	3 (2.6%)	0.51
New pacemaker	28 (25.4%)	40 (40.4%)	0.01

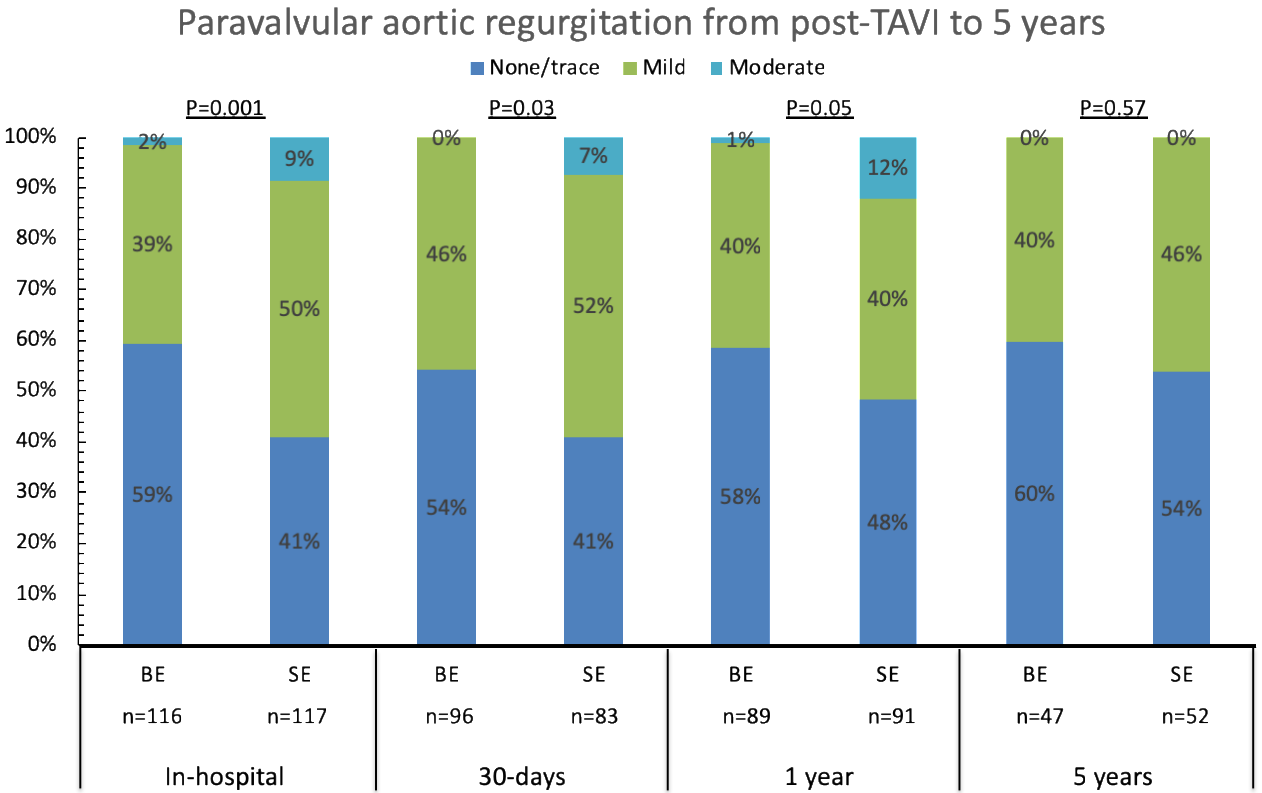
Forward flow hemodynamics



Forward flow hemodynamics



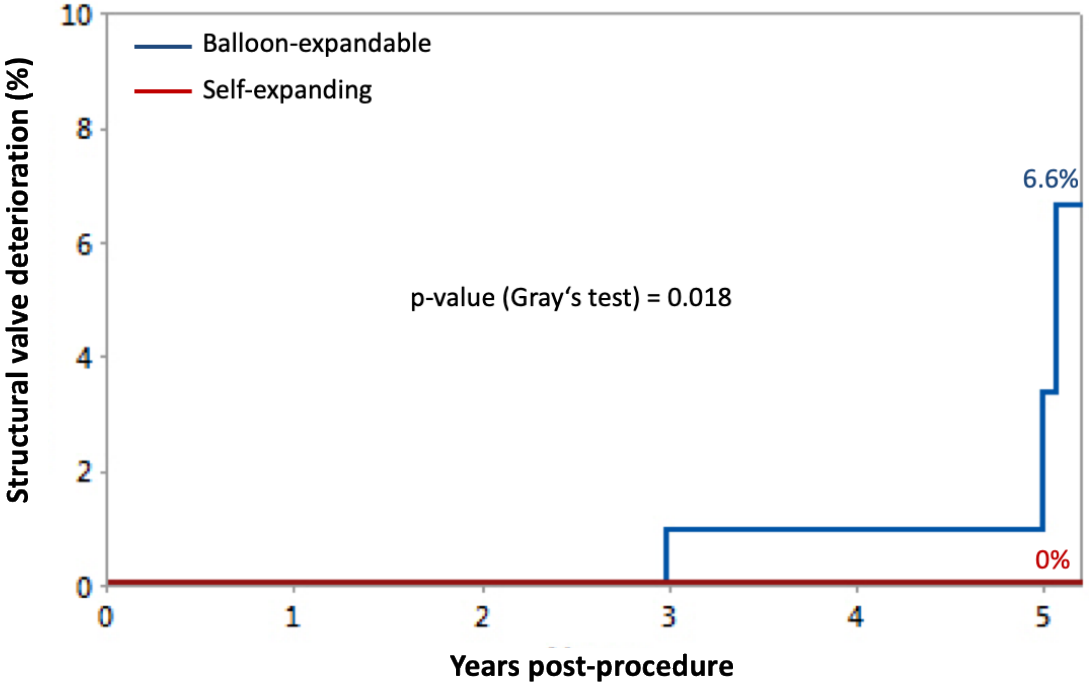
Aortic regurgitation



Bioprosthetic valve dysfunction

	Balloon-expandable valve (n=121)	Self-expanding valve (n=120)	p-value
Bioprosthetic valve dysfunction	28 (22.5%)	26 (20.9%)	0.91
Components			
Structural valve deterioration	6 (6.6%)	0 (0%)	0.018
Moderate SVD	4 (5.6%)	0 (0%)	0.047
Severe SVD	2 (0.9%)	0 (0%)	0.20
NSVD	17 (17.8%)	23 (26.7%)	0.20
Moderate/severe PPM	14 (15.9%)	13 (16.0%)	1.0
Moderate/severe PVL	3 (2.5%)	10 (8.5%)	0.08
Valve thrombosis	6 (7.3%)	1 (0.8%)	0.06
Endocarditis	2 (1.6%)	4 (3.4%)	0.39

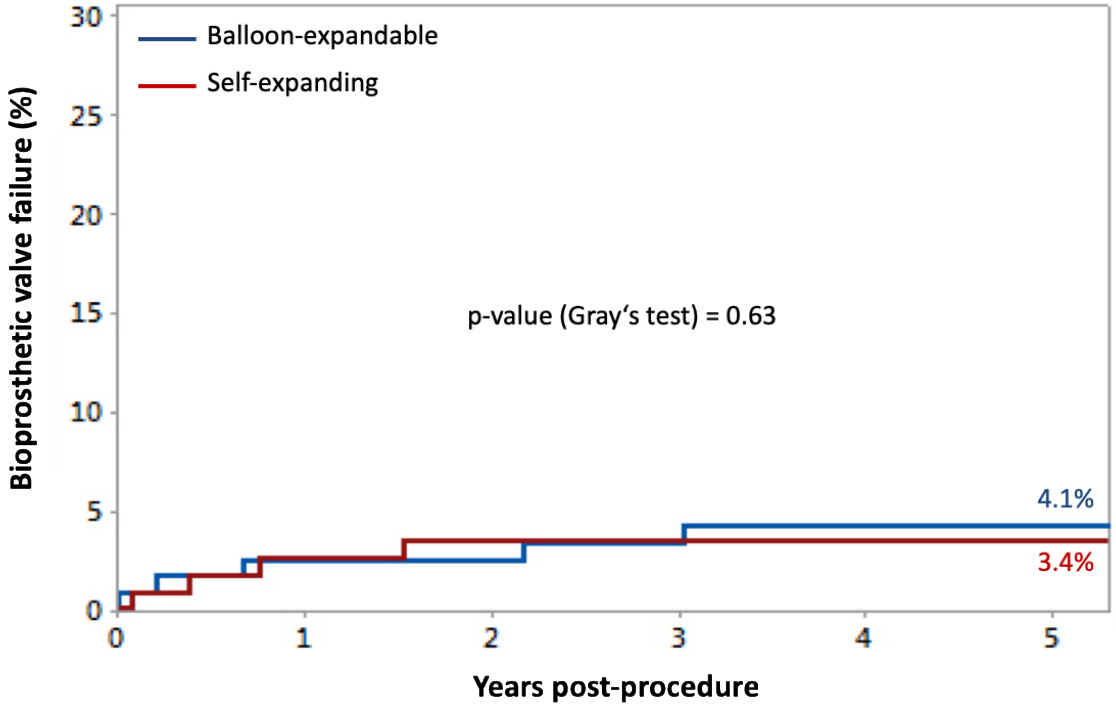
Structural valve deterioration



Number at risk

121	99	87	74	66	42
120	101	87	80	70	42

Bioprosthetic valve failure



Number at risk

121	99	87	77	69	46
120	100	86	79	70	42

Limitations

- Small-sized trial, therefore statistical power for clinical endpoints remains limited
- Durability analysis was post hoc
- Duration of follow-up currently limited to 5 years

The essentials to remember

- This is the first report of long-term (5-year) outcomes of balloon-expandable versus self-expanding THVs from a randomized head-to-head trial.
- The CHOICE trial shows comparative mortality, stroke and rehospitalization rates at 5 years after transfemoral TAVI with the early generation balloon-expandable and self-expanding valves.
- The initial differences in paravalvular leaks were not evident at 5 years.
- Forward flow hemodynamics were superior with the self-expanding device at all time points, particularly at 5 years.
- Subtle differences in clinical valve thrombosis and structural valve deterioration favouring the self-expanding valve need further confirmation.

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