

Two-Year Outcomes for Women in the Five-Year SMART Trial

SMART
Trial

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Background

The Small Annuli Randomized To Evolut or SAPIEN Trial (SMART) compares the performance of Evolut and SAPIEN transcatheter aortic valve replacement (TAVR) in patients with severe aortic stenosis and small aortic annuli.¹ These patients, predominantly women (87%), are at risk for impaired valve hemodynamics. At 1 year, women in this trial had similar clinical outcomes with both devices but significantly lower bioprosthetic valve dysfunction (BVD) with Evolut.²

Research Question

For women with a small aortic annulus and severe aortic stenosis who undergo TAVR with Evolut vs SAPIEN, do clinical and hemodynamic outcomes remain similar at 2 years?

SMART Trial Design

Prospective, randomized controlled, post-market trial conducted at 81 sites in 13 countries

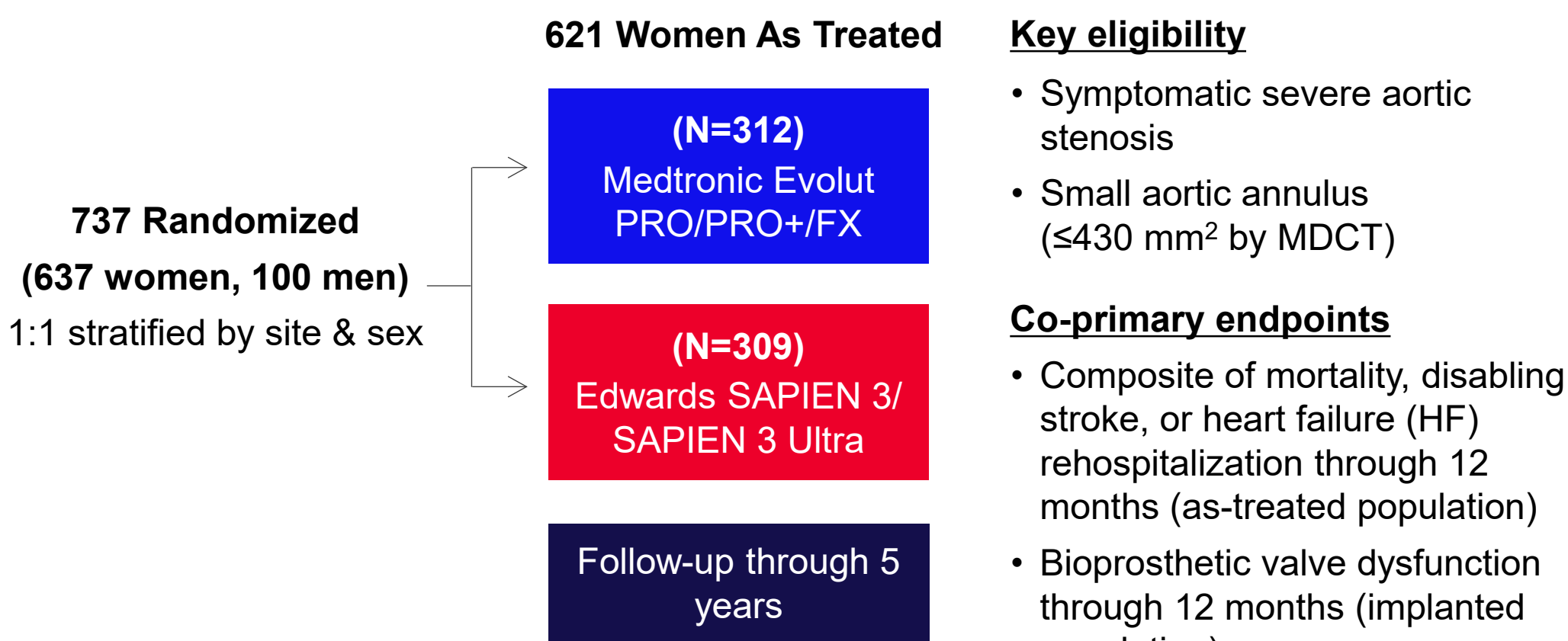


Table 1. Baseline Characteristics

% or mean ± SD	Evolut (N=312)	SAPIEN (N=309)
Age, years	80.2 ± 6.3	80.1 ± 6.0
BSA, m ²	1.7 ± 0.2	1.7 ± 0.2
STS PROM score, %	3.4 ± 1.9	3.3 ± 1.7
NYHA class III/IV	43.6%	40.1%
Diabetes mellitus	27.9%	32.7%
Hypertension	82.7%	87.7%
Chronic lung disease/COPD	16.4%	17.6%
Cerebrovascular disease	12.0%	11.4%
Coronary artery disease	33.0%	37.2%
Prior CABG	2.6%	3.2%
Prior PCI	15.2%	19.5%
Prior myocardial infarction	4.8%	7.1%
Arrhythmia	23.4%	22.7%
Atrial fibrillation/flutter	20.2%	17.8%
History of RBBB	5.8%	6.1%
LVEF at screening (%) (site reported)	61.7 ± 7.2	61.5 ± 8.6
Prior pacemaker	6.7%	5.2%

Table 2. Key Adverse Events at 2 Years

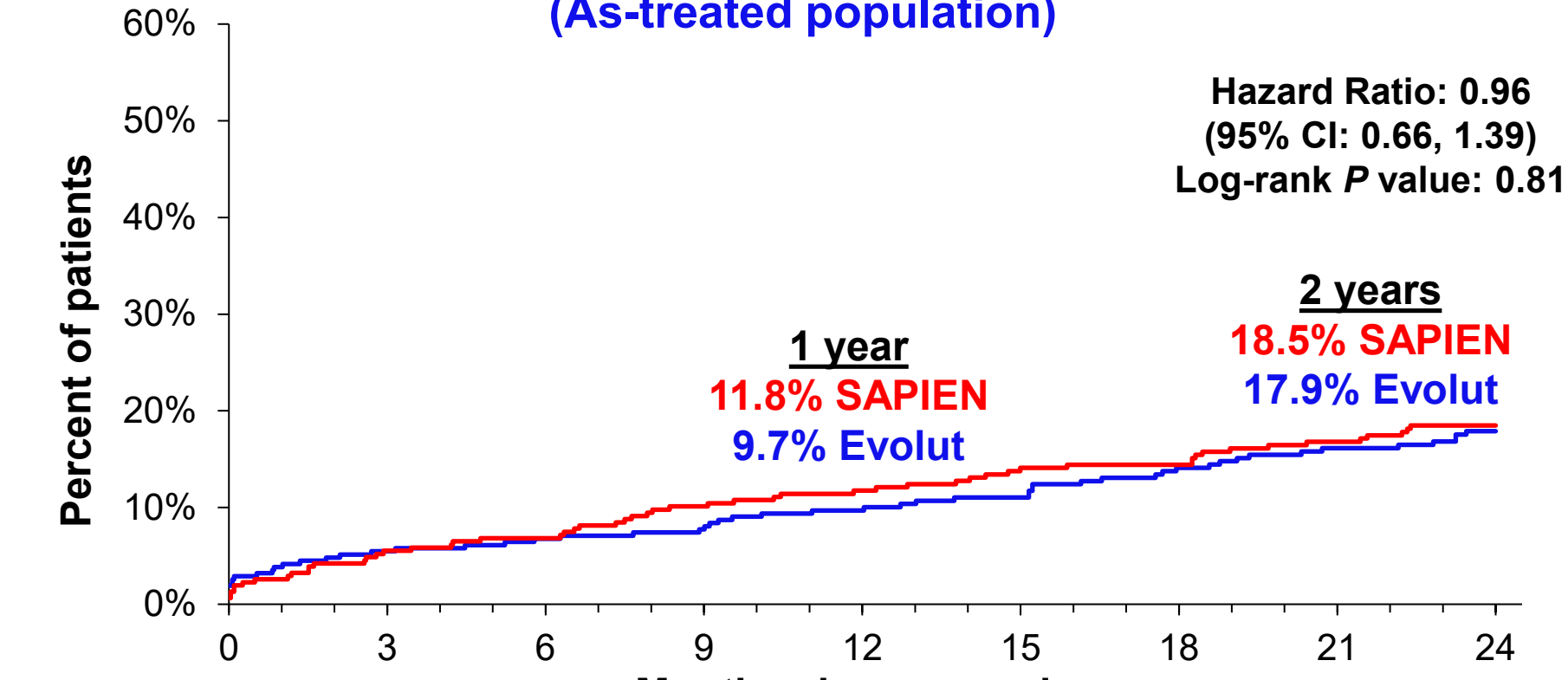
KM%	Evolut (N=312)	SAPIEN (N=309)	Log-Rank P Value
Cardiovascular mortality	7.5%	6.7%	0.77
New pacemaker implant ^a	15.5%	11.0%	0.08
All stroke	7.7%	6.6%	0.53
Transient ischemic attack	1.3%	3.8%	0.07
Prosthetic valve thrombosis	1.2%	4.2%	0.02
Clinical	0.3%	1.5%	0.18
Subclinical	0.9%	2.7%	0.05

^aPatients with pacemaker/ICD at baseline are excluded; site-reported data
Values based on independent Clinical Events Committee adjudication.

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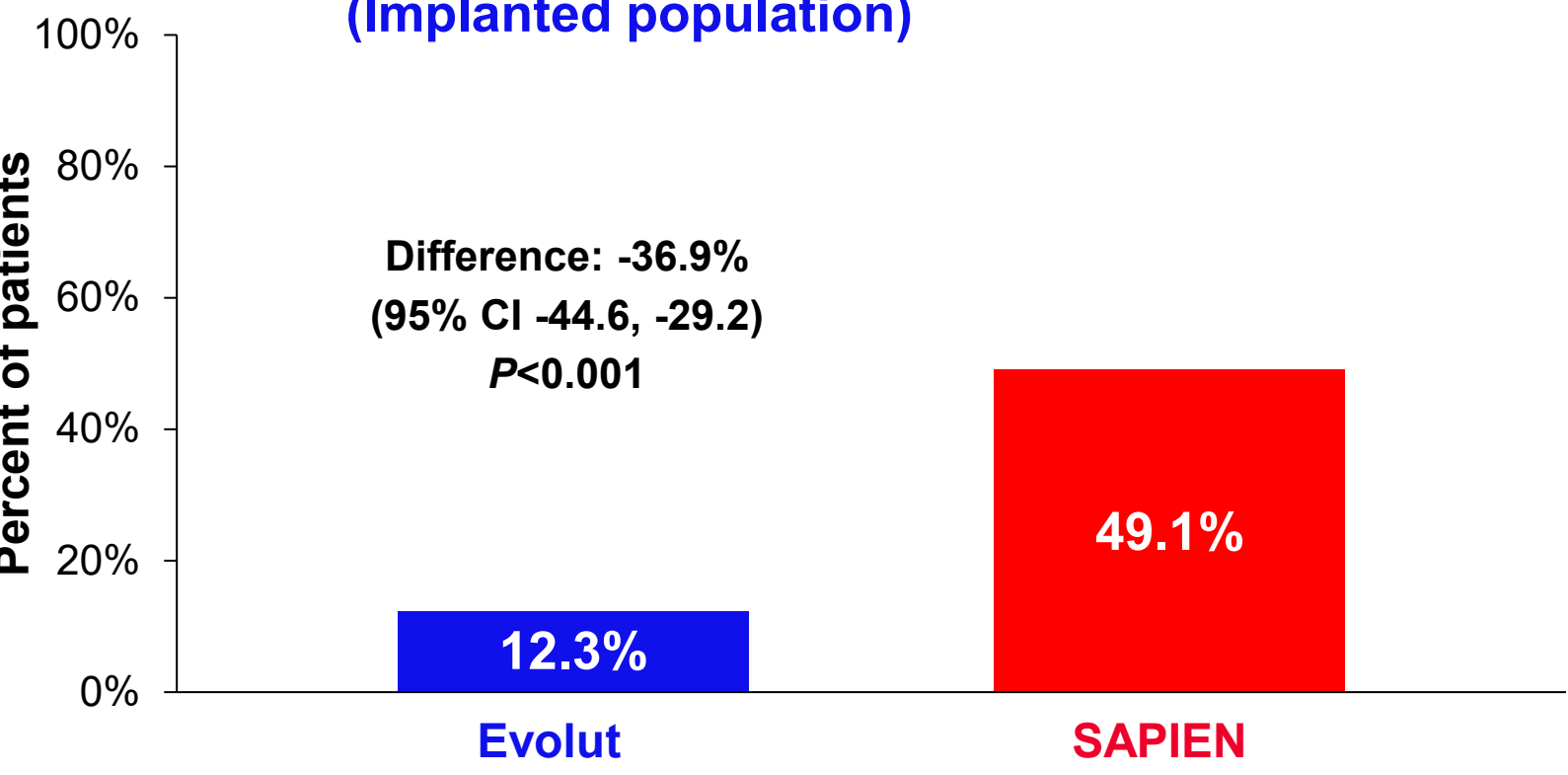
SMART: Co-primary Outcomes and Hemodynamics for Women at 2 Years

Figure 1. Mortality, Disabling Stroke, or HF Rehospitalization (As-treated population)



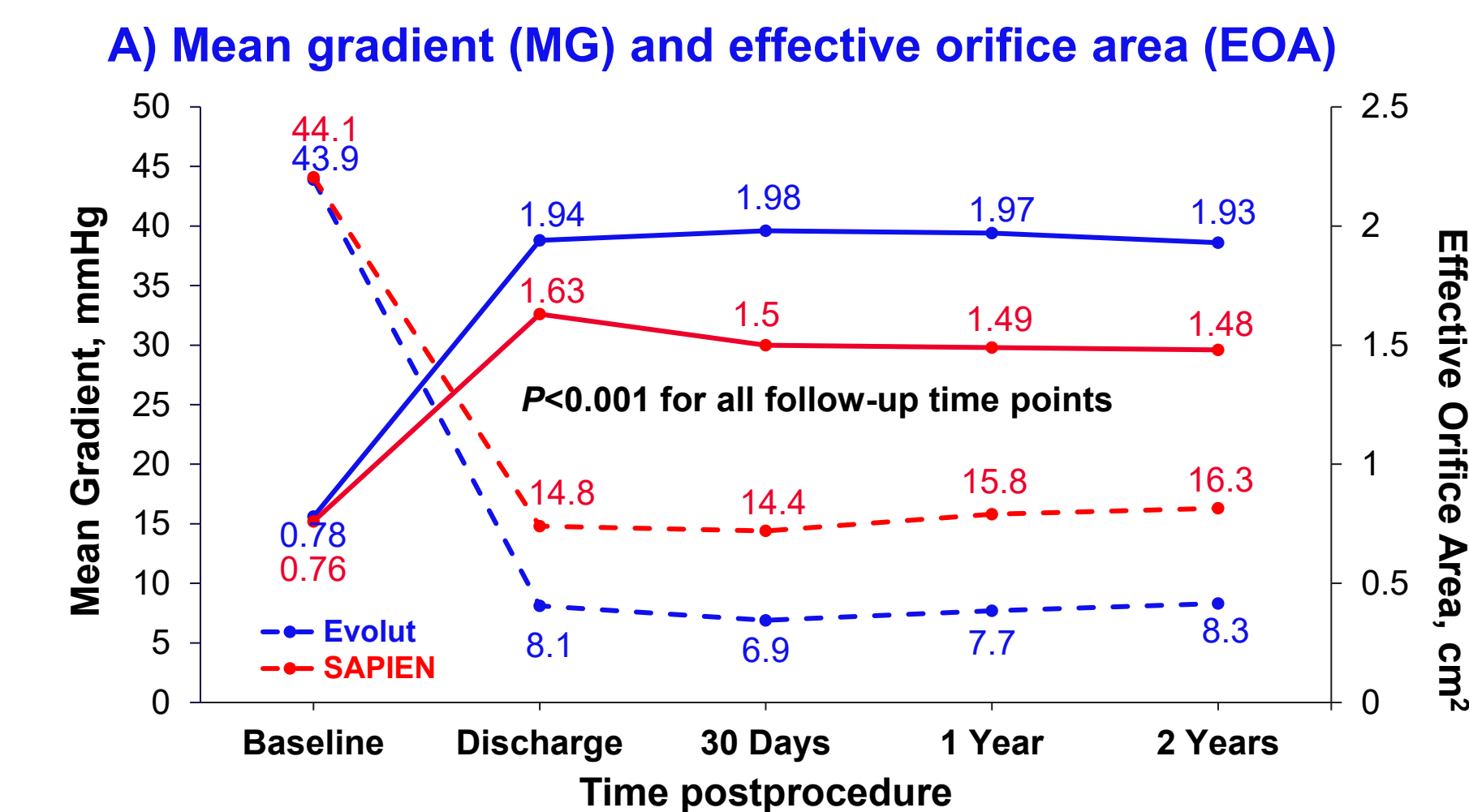
Evolut and SAPIEN showed similar clinical outcomes at 2 years

Figure 2. Bioprosthetic Valve Dysfunction (Implanted population)



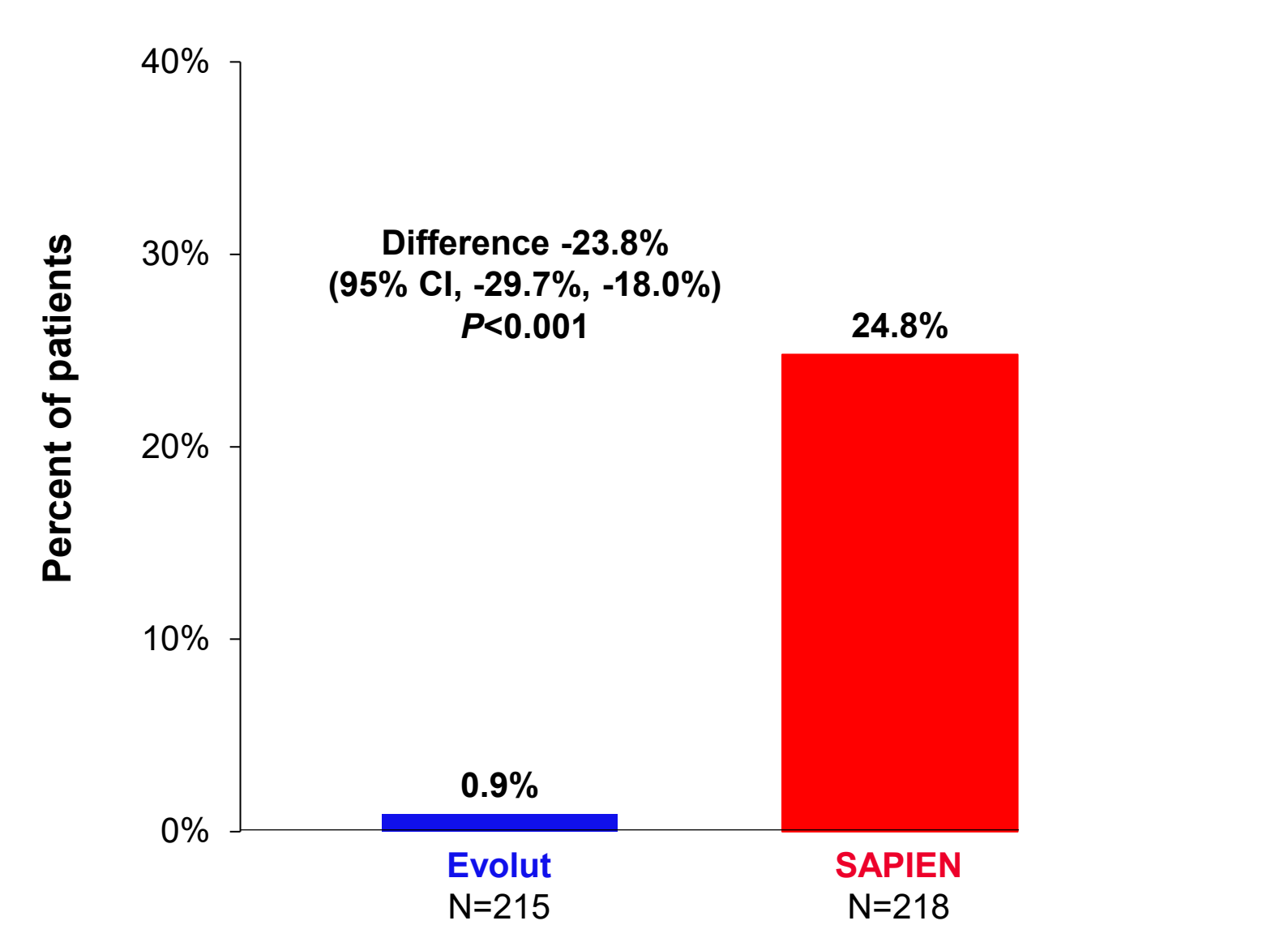
Evolut maintained significantly lower BVD at 2 years

Figure 3. Hemodynamics (Implanted population)



Evolut demonstrated significantly lower mean gradient and larger effective orifice area at all visits

B) Mean gradient ≥ 20mmHg at 2-year visit



Percent of patients with mean gradient ≥ 20 mmHg was significantly lower with Evolut at 2-year visit

Figure 4. Total Aortic Regurgitation (Implanted population)

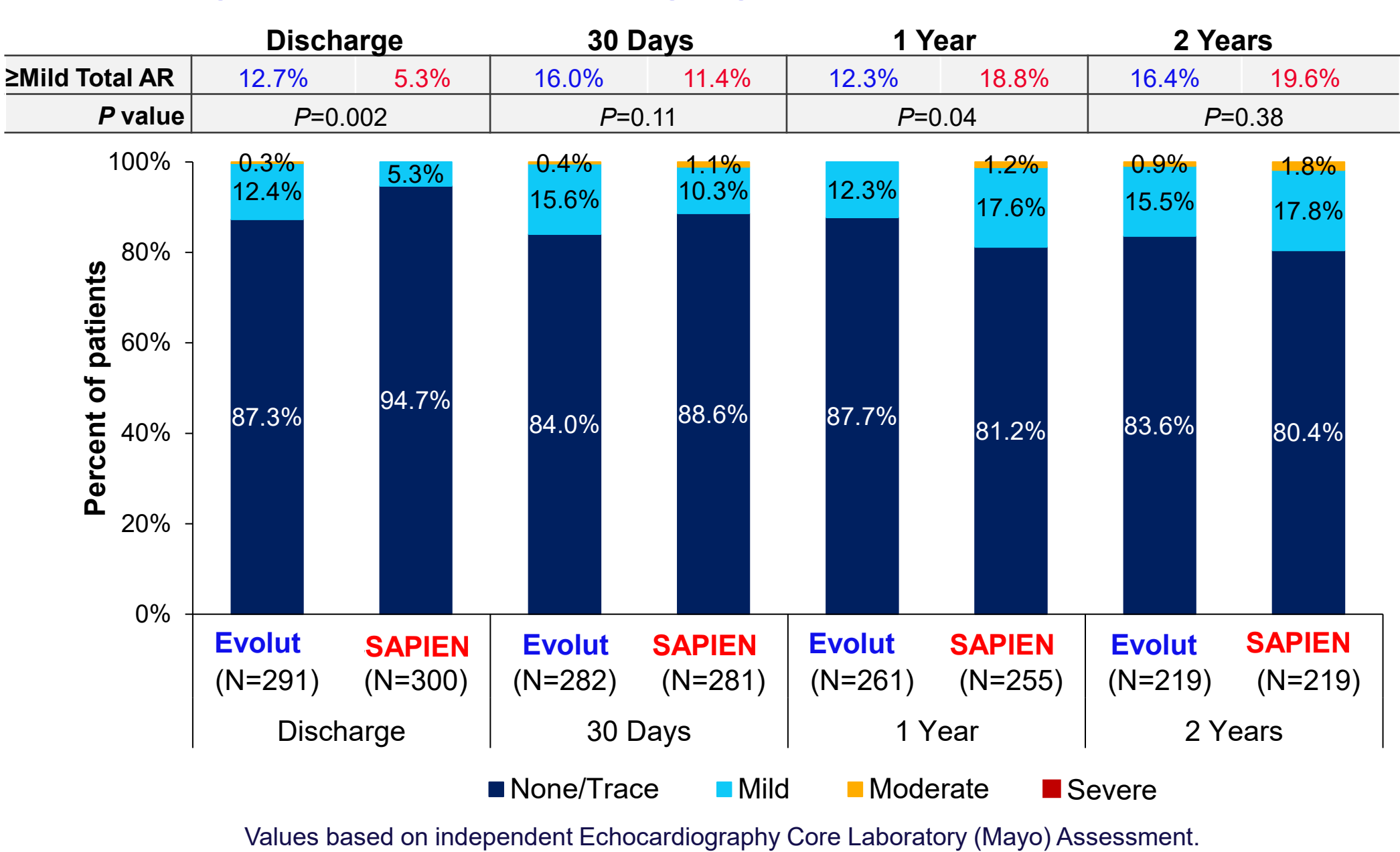
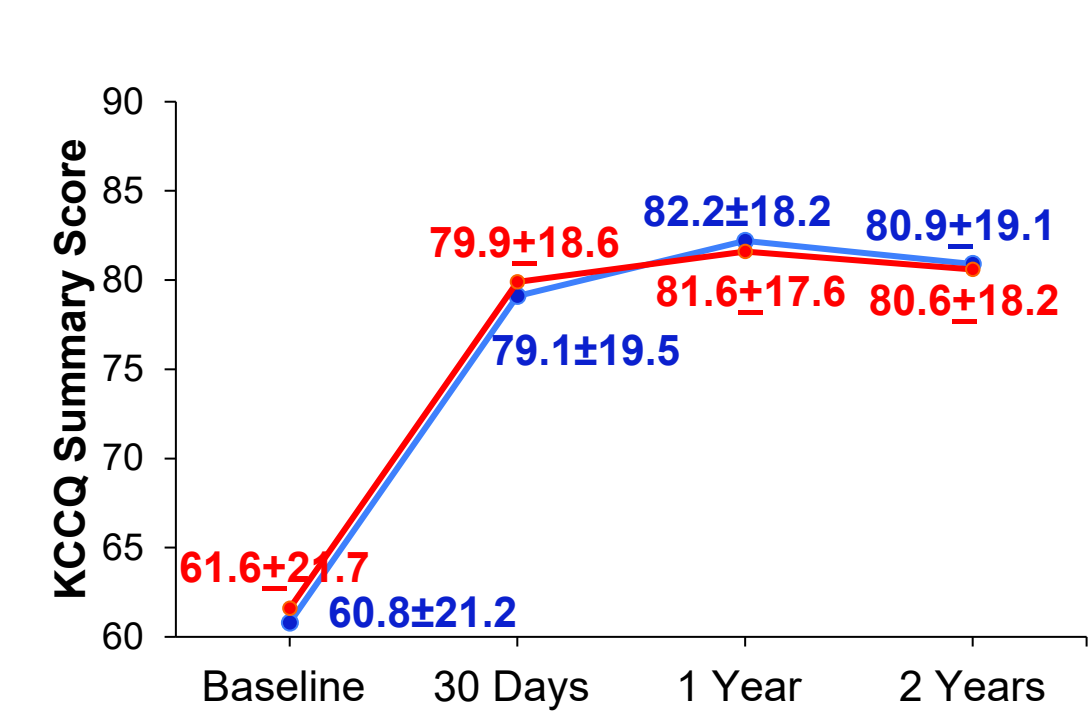
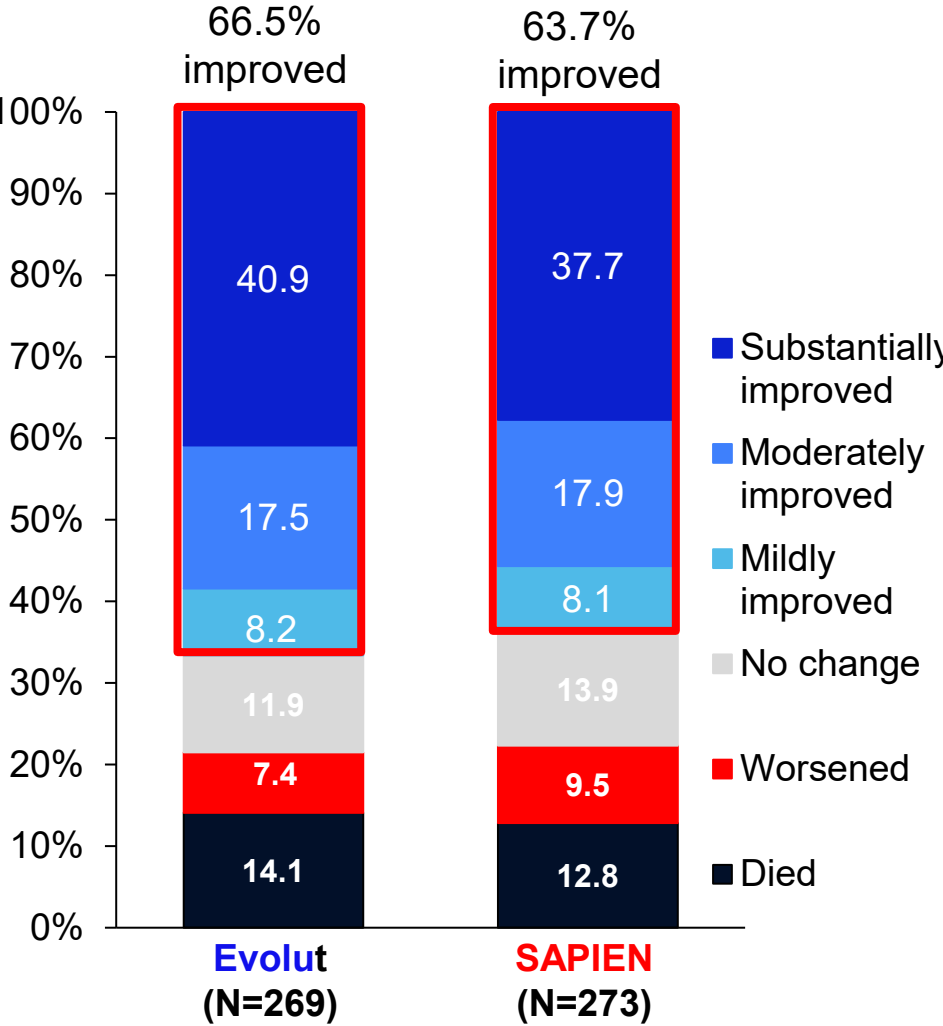


Figure 5. Quality of Life (As-treated population)

A) KCCQ Overall Summary Score



B) KCCQ Ordinal Outcomes



Conclusions

- This post hoc analysis from the randomized SMART trial reports clinical and hemodynamic outcomes for all 621 women enrolled in SMART.
- After 2 years of follow up, we observed similar rates for the clinical outcome composite of death, disabling stroke, or HF rehospitalization between groups.
- The BVD composite endpoint, mean gradient and effective orifice area all continue to demonstrate the superiority of the Evolut platform at 2 years.
- These findings underscore Evolut's hemodynamic advantage compared to SAPIEN and highlight the importance of long-term follow-up through 5 years.

¹Herrmann et al. Self-Expanding or Balloon-Expandable TAVR in Patients with a Small Aortic Annulus. *N Engl J Med*. 2024;390(21):1959-1971.

²Tchétché et al. Transcatheter Aortic Valve Implantation by Valve Type in Women With Small Annuli: Results From the SMART Randomized Clinical Trial. *JAMA Cardiol*. 2024;9:1106-1114.

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