

SAPIEN 3 Ultra RESILIA valve: 1-year real-world outcomes with significant mortality benefits for patients

Introduction

As TAVI becomes the preferred treatment option for symptomatic severe aortic stenosis even in younger and low-risk patients, lifetime management and valve durability have become paramount for the Heart Team's decision-making on valve selection

Aim

Compare 1-year clinical and echocardiographic outcomes of native TAVI with the SAPIEN 3 Ultra RESILIA valve versus earlier generation SAPIEN 3 and SAPIEN 3 Ultra valves

Study design

Data from US STS/ACC TVT Registry from **over 4,500** propensity-matched pairs (N=4,598)

Key patient demographics (±SD)

Mean age of **76.7 years** (8.8)
STS score of 3.6% (3.5)

Endpoints

Primary: 1-year mortality, stroke and combined mortality or stroke

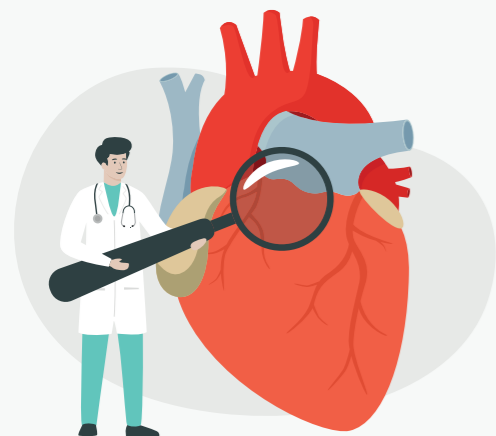
Secondary: Echocardiographic and functional outcomes

Abbreviations

ACC: American College of Cardiology; CI: confidence interval; HR: hazard ratio; KCCQ-OS: Kansas City Cardiomyopathy Questionnaire Overall Summary Score; LT: life-threatening; MVC: major vascular complication; NYHA: New York Heart Association; PVL: paravalvular leak; SD: standard deviation; STS: Society of Thoracic Surgeons; TAVI: transcatheter aortic valve implantation; TVT: transcatheter valve therapy.

Citation

Kini AS, Tang GHL, Yaryura R *et al.* One-year real-world outcomes of TAVR with the fifth-generation balloon expandable valve in the United States. *JACC Cardiovasc Interv.* 2024; doi:10.1016/j.jcin.2024.11.015

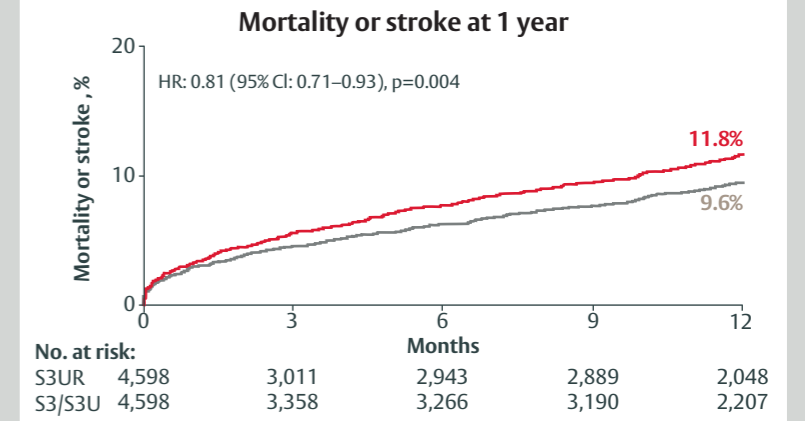
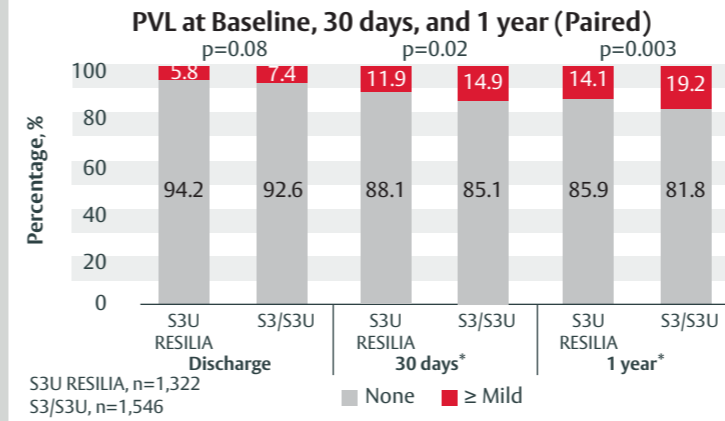


Enhanced clinical and echocardiographic outcomes with the SAPIEN 3 Ultra RESILIA valve: superior performance and reduced complications at 1 year

Multivariable analysis of covariates associated with 1 year mortality

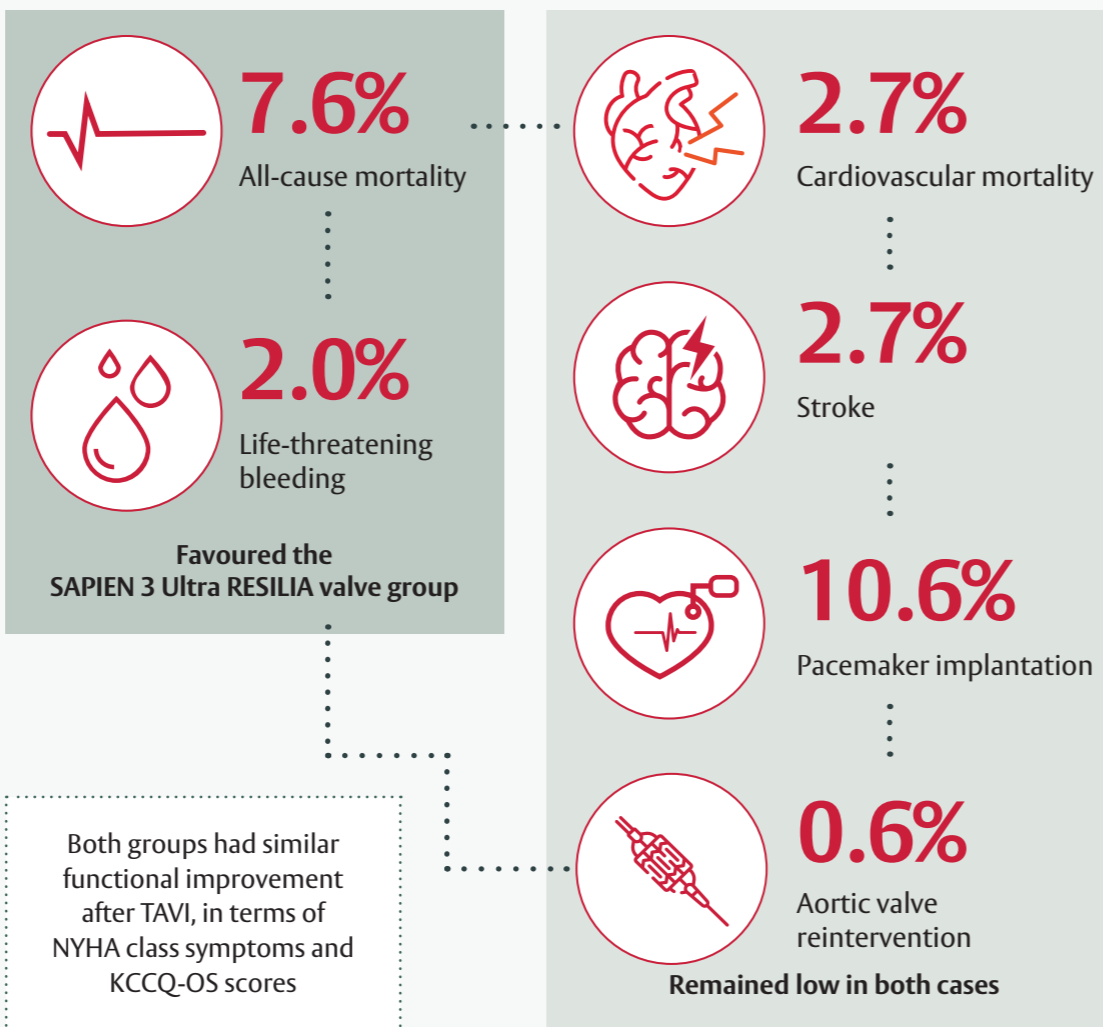
	1 year all-cause mortality	HR (95% CI)	p value
S3U RESILIA vs S3/S3U		0.77 (0.68–0.88)	<0.01
In-hospital LT bleeding		4.29 (3.61–5.10)	<0.01
In-hospital stroke		3.79 (3.14–4.57)	<0.01
In-hospital MVC		2.86 (2.36–3.47)	<0.01
Discharge PVL ≥ mild vs none		1.43 (1.26–1.64)	<0.01

PVL ≥ mild independently associated with increased risk of 1-year mortality

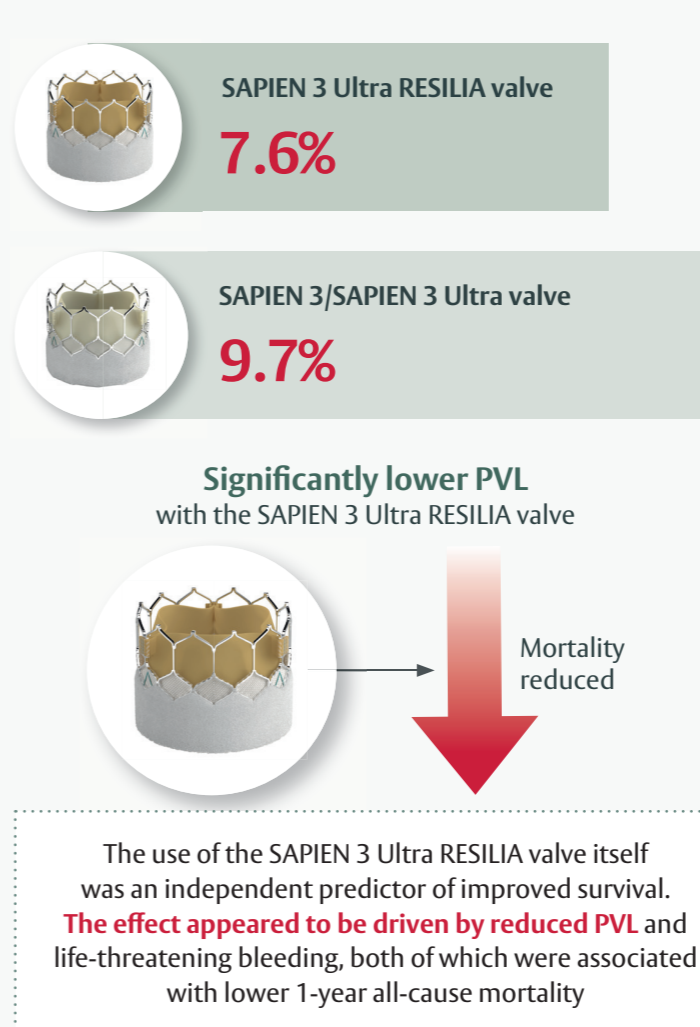


Significantly lower 1-year mortality or stroke for the SAPIEN 3 Ultra RESILIA valve than for the SAPIEN 3 and SAPIEN 3 Ultra valves

Outcomes at 1 year



Mortality benefits



Conclusions

1 Year results of the SAPIEN 3 Ultra RESILIA valve benefitting patients clinical outcomes

The mortality benefit was mainly driven by a **significant reduction in PVL at 30 days and 1 year**

The SAPIEN 3 Ultra RESILIA valve has **strong indications for lifetime management**, including younger, low-risk patients

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