Clinical Summary:

Real-World Outcomes for the Fifth Generation Balloon Expandable Transcatheter Heart Valve in the United States

Stinis CT, Abbas AE, Teirstein P, et al.
J Am Coll Cardiol Intv. Mar 07, 2024.

Objective

This study compared SAPIEN 3 Ultra RESILIA transcatheter heart valves (THV) to SAPIEN 3 THV / SAPIEN 3 Ultra THV for procedural, in-hospital, and 30-day clinical and echocardiographic outcomes after transcatheter aortic valve replacement (TAVR).

Key Outcomes

- SAPIEN 3 Ultra RESILIA THV is associated with excellent procedural outcomes and low complication rates:
  - 1.4% 30-day mortality
  - 1.8% 30-day all stroke
  - 94% of patients discharged directly to home
- A statistically significant reduction in paravalvular leak (PVL) for the 29 mm SAPIEN 3 Ultra RESILIA valve as compared to the 29 mm SAPIEN 3 valve, with low rates of PVL across all Edwards TAVR platforms
- SAPIEN 3 Ultra RESILIA THV is associated with both significantly lower mean gradients and higher calculated aortic valve areas as determined by echocardiography compared to SAPIEN 3 THV / SAPIEN 3 Ultra THV at both discharge and 30 days

Methods

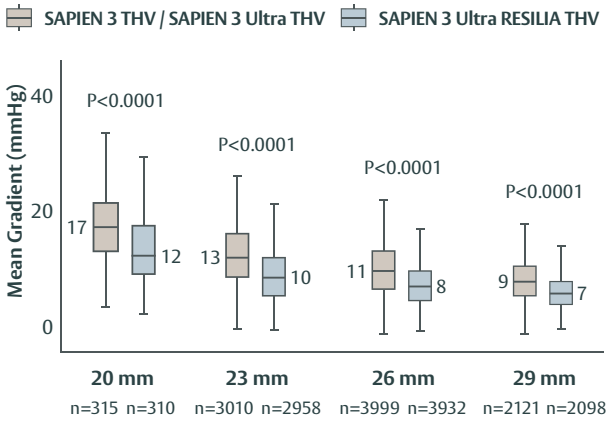
- The study included patients in the TVT registry who underwent TAVR between January 1, 2021, and June 30, 2023, with a SAPIEN 3 Ultra RESILIA THV or SAPIEN 3 THV / SAPIEN 3 Ultra THV. A total of 160,853 patients were identified after exclusions:
  - 150,539 SAPIEN 3 THV / SAPIEN 3 Ultra THV patients
  - 10,314 SAPIEN 3 Ultra RESILIA THV patients
- The propensity score matching successfully paired 10,312 patients with SAPIEN 3 Ultra RESILIA THV to patients with SAPIEN 3 THV / SAPIEN 3 Ultra THV
- Baseline STS scores were similar for each matched cohort (SAPIEN 3 THV / SAPIEN 3 Ultra THV: 3.5 ± 3.1, SAPIEN 3 Ultra RESILIA THV: 3.6 ± 3.5)
- Endpoint: clinical and echocardiographic outcomes at hospital discharge and at 30 days

Results

At discharge

Measure	SAPIEN 3 THV / SAPIEN 3 Ultra THV	SAPIEN 3 Ultra RESILIA THV	p-value
No or trace PVL	92.6%	94.2%	P<0.0001
Mild PVL	7.2%	5.6%	P<0.0001
Mean gradients (mmHg)	12.0 ± 5.7	9.2 ± 4.6	P<0.0001
Aortic valve area (cm^2)	1.9± 0.6	2.1 ± 0.7	P<0.0001

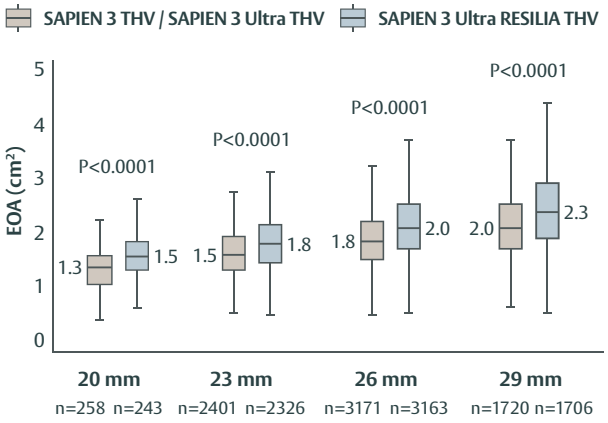
Figure 1. Discharge Mean Gradient



Edwards

Results, continued

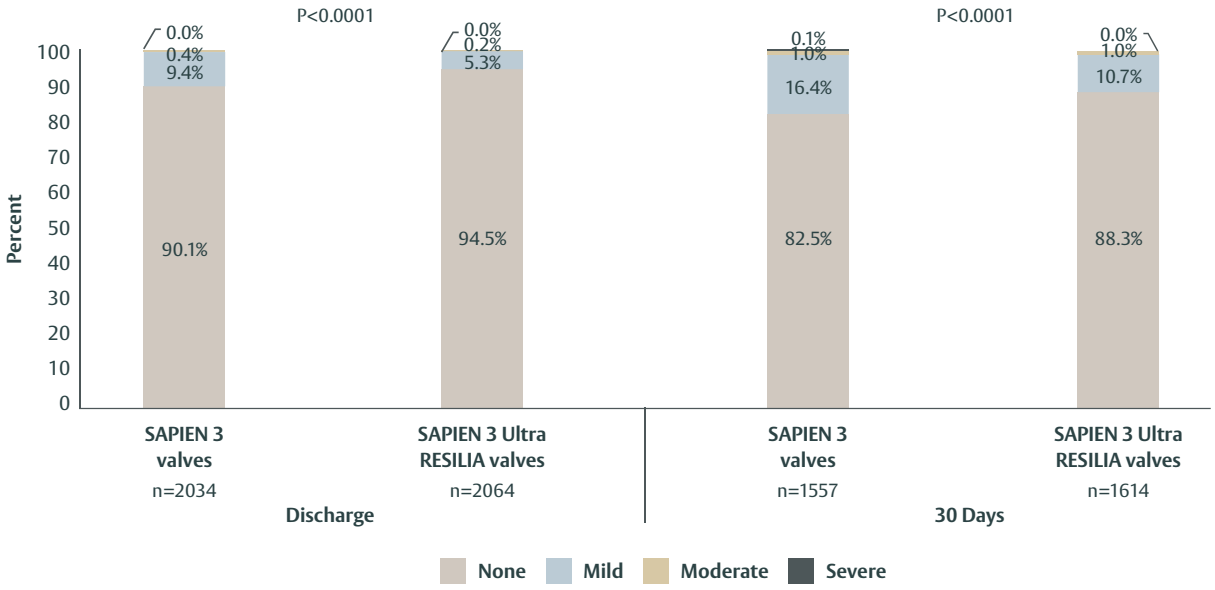
Figure 2. Discharge Effective Orifice Area



At 30 days

Measure	SAPIEN 3 THV / SAPIEN 3 Ultra THV	SAPIEN 3 Ultra RESILIA THV	p-value
All-cause death	1.8%	1.4%	P=0.05
Cardiac death	1.1%	0.8%	P=0.052
Stroke	1.6%	1.8%	P=0.44
New permanent pacemaker	7.7%	8.3%	P=0.13
Any readmission	7.7%	8.5%	P=0.04
No or trace PVL	86.4%	87.9%	P=0.006
Mild PVL	12.9%	11.4%	P=0.005

Figure 3. Incidence and severity of PVL at discharge and at 30 days after for patients undergoing TAVR with 29 mm SAPIEN 3 Ultra RESILIA valves and 29mm SAPIEN 3 valves in matched cohorts



Conclusions

In this large real-world study across more than 10,000 propensity-matched patients treated at >800 sites, the SAPIEN 3 Ultra RESILIA valve demonstrated:

- A statistically significant reduction in PVL for the 29 mm SAPIEN 3 Ultra RESILIA valve as compared to the 29 mm SAPIEN 3 valve, with low rates of PVL across all Edwards TAVR platforms
- Significantly lower echo-derived mean gradients and larger effective orifice areas across all four valve sizes
- Low rates of all-cause mortality, stroke, life-threatening bleeding, and permanent pacemaker implantation at 30 days, with no compromise in these excellent outcomes when compared to SAPIEN 3 THV / SAPIEN 3 Ultra THV

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