The ReTAVI Trial: Clinical Outcomes of Patients Undergoing a Redo-TAVI Procedure

G. Tarantini, R. Parma - *Evaluation of Clinical Outcomes of Patients Undergoing a Redo-TAVI Procedure; a Multicenter Prospective Observational Registry.* Presented at TCT 25th October 2025, San Francisco, USA.

Study design

Prospective Observational Registry

N=150

Follow up:
30d, 1y, 3y, 5y

Device(s) used

Index valve

The SAPIEN platform
30.0%

Core valve/ Evolut
53.1%

ACURATE
14.0%

Other
2.8%

Second valve

SAPIEN 3
SAPIEN 3 Ultra
SAPIEN 3 Ultra RESILIA

Sizes used:
20 mm: 8.4%
23 mm: 39.2%
26 mm: 44.8%
29 mm: 7.7%

Locations

59 sites

Across Europe, Canada and Israel

Patients characteristics

Median Age:
84 years

Median STS score:
7.0%

First prospective, multicenter international registry with patients treated with the SAPIEN 3 platform for THV-in-THV procedures

Proven excellent performance of the SAPIEN 3 platform in THV-in-THV procedures

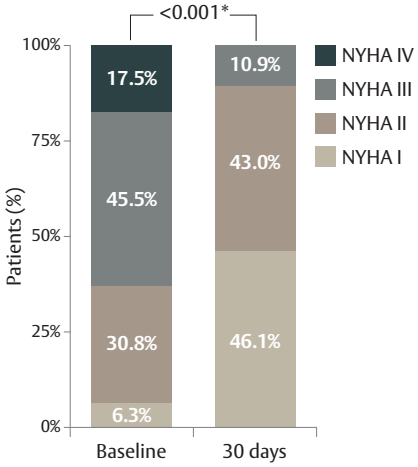
Excellent outcomes for THV-in-THV procedure at discharge and 30 days

Key patient outcomes included (n=143):

VARC-3 Device success	95.0%	
All-cause mortality	Discharge 3.5%	30 days 3.5%
All Stroke	Discharge 0.0%	30 days 0.7%
Pacemaker Implantation	Discharge 5.6%	30 days 6.3%

Significant patient functional status improvement

NYHA Class scores at 30 days (n=143):



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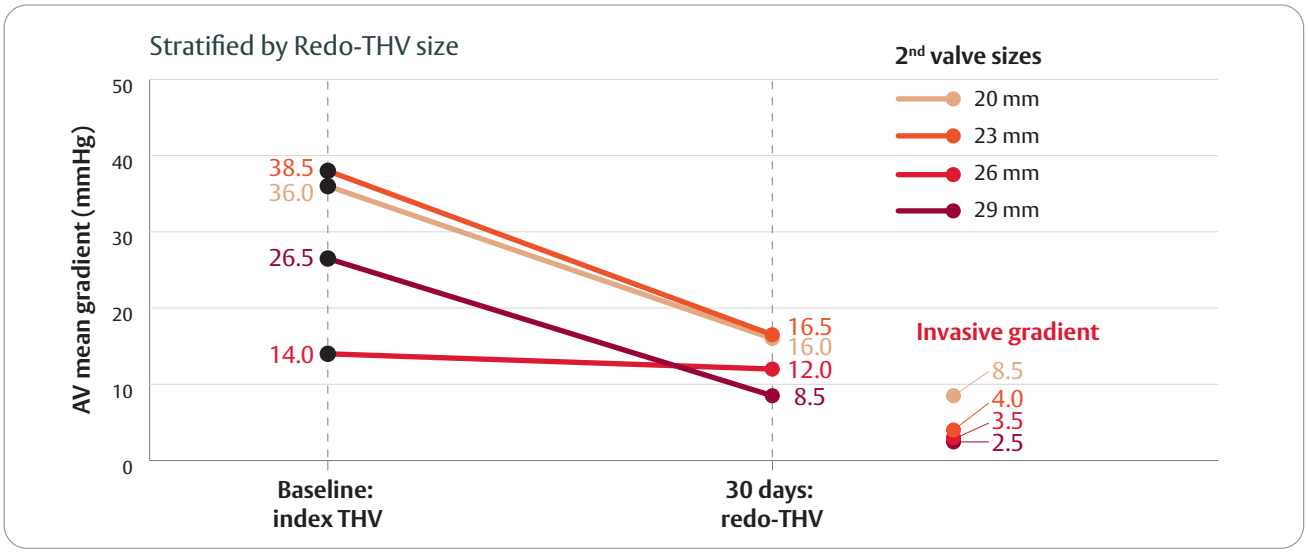
98.6% rate of no coronary obstruction with the SAPIEN 3 platform in studied index valves

	Short index frame (n=46)	Tall index frame (n=97)
Use of coronary protection	22.2%	28.3%

Coronary protection was more used in tall frame valves

Consistent hemodynamic improvement across anatomies, index valve types and sizes

Hemodynamic improvements in all SAPEN 3 platform sizes



The SAPIEN 3 platform demonstrated outstanding regurgitation results

Demonstrating absence of Intra-prosthetic regurgitation (n=143)

Outcomes	30 days
Intraprosthetic regurgitation; *moderate/severe*	0.0 %
Paravalvular regurgitation/leak; *moderate/severe*	0.9 %

The image of the SAPIEN 3 Ultra RESILIA valve in the SAPIEN frame is for illustrative purposes only and does not reflect the study design, which includes other index valves. SAPIEN is an older model that has been discontinued and it is not available for commercial use

Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

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