PARTNER 3 Trial Outcomes

Demonstrating the **superiority of SAPIEN 3 TAVI compared with sAVR** in low surgical risk patients*[1,2]

THE PARTNER 3 TRIAL

Patient characteristics[1]

	SAPIEN 3 TAVI	sAVR
Mean age, yr±SD:	73.3±5.8	73.6±6.1
STS** score, %±SD:	1.9±0.7	1.9±0.6
NYHA class III or IV, n (%):	155 (31.2)	108 (23.8)

Low surgical risk patients[1]

Younger and with **fewer comorbidities** than in previous TAVI trials[1,3–5]

Trial design[1]

- **5** Countries
- **71** Centres
- **1000** Patients
- **1:1** Randomisation to **SAPIEN 3 TAVI** or **sAVR**
- **950** Procedures carried out

1 year
Primary endpoint – composite of all-cause death, all stroke, or rehospitalisation (any related to the procedure, the valve, or heart failure)[1]

Trial outcomes

	Risk reduction	SAPIEN 3 TAVI	sAVR
All-cause death, all stroke, or rehospitalisation at 1 year:[1]	**46%** HR 0.54 (95% CI, 0.37 to 0.79; *P*=0.001)	8.5%	15.1%

SAPIEN 3 TAVI superior to sAVR*[1,2,6]

Individual components of primary endpoint:[1,6]

	Risk reduction	SAPIEN 3 TAVI	sAVR
All-cause death:	59% HR 0.41 (95% CI, 0.14 to 1.17; *P*=0.09)	1.0%	2.5%
Stroke:	62% HR 0.38 (95% CI, 0.15 to 1.00; *P*=0.04)	1.2%	3.1%
Rehospitalisation:†	35% HR 0.65 (95% CI, 0.42 to 1.00; *P*=0.046)	7.3%	11.0%

Additional endpoints[1,2,6,7]

	Risk reduction	SAPIEN 3 TAVI at 1 year	sAVR at 1 year
Death or disabling stroke:[1,6]	66% HR 0.34 (95% CI, 0.12 to 0.97; *P*=0.03)	1.0%	2.9%
Rehospitalisation due to heart failure:[7]	61% HR 0.39 (95% CI, 0.16 to 0.94; *P*=0.029)	1.4%	3.6%
Life-threatening or major bleeding:[1,6]	75% HR 0.25 (95% CI, 0.17 to 0.37; *P*<0.001)	7.7%	25.9%
New-onset atrial fibrillation:[1,7]	87% HR 0.13 (95% CI, 0.09 to 0.20; *P*<0.001)	7.0%	40.9%
Moderate or severe paravalvular regurgitation:[6]	No significant difference (*P*=1.0)	0.6%	0.5%
New permanent pacemaker implantation:‡[6]	No significant difference (*P*=0.21)	7.3%	5.4%

Quality of life[2]

Significantly higher KCCQ overall summary score§

TAVI compared to sAVR at:

- 30 days △ = 16.0 (*P* <0.001)
- 6 months △ = 2.6 (*P*=0.002)
- 1 year △ = 1.8 (*P*=0.03)

Recovery time

SAPIEN 3 TAVI showed better recovery time compared with sAVR:[1,6]

Length of hospital stay (median):[1]
3.0 days compared with **7.0**
(*P*<0.001)

Patients discharged to home or self-care:[1,6]
95.8% compared with **73.1%**
(*P*<0.001)

In low-risk patients, the PARTNER 3 Trial proves

SAPIEN 3 TAVI is superior to sAVR on the composite primary endpoint (all-cause death, all stroke, and rehospitalisation)

and multiple pre-specified secondary endpoints at 1 year[1,2,6]

You can give your low-risk patients the lowest-risk procedure with Edwards SAPIEN 3 TAVI

*The PARTNER 3 Trial proved that SAPIEN 3 TAVI is superior to sAVR with regard to the primary endpoint (all-cause death, all stroke, and rehospitalisation) and multiple pre-specified secondary endpoints.[1]
**Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) scores range from 0 to 100%, with higher scores indicating a greater risk of death within 30 days after the procedure. STS-PROM is based on the presence of coexisting illnesses in order to predict 30-day operative mortality. The STS-PROM score equals the predicted mortality expressed as a percentage. Less than 5% of patients in the population on which the STS-PROM algorithm is based had a predicted operative mortality (score) of more than 10%.[1]
† Valve-related, procedure-related, or heart-failure-related.[1]
‡ Including baseline.
§ Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary scores range from 0 to 100, with higher scores indicating fewer physical limitations and a greater feeling of well-being.[1]

Abbreviations:
CI, confidence interval; HR, hazard ratio; KCCQ, Kansas City Cardiomyopathy Questionnaire; NYHA, New York Heart Association; QoL, quality of life; SD, standard deviation; STS-PROM, The Society of Thoracic Surgeons Predicted Risk of Mortality; TAVI, transcatheter aortic valve implantation.

References;
1. Mack MJ, Leon MB, Thourani VH, *et al.* Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med.* 2019;380:1695–1705 and supplementary material. **2.** Baron SJ. Health Status after Transcatheter vs. Surgical Aortic Valve Replacement in Patients with Severe Aortic Stenosis at Low Surgical Risk. Presentation at TCT, September 25–29, 2019; San Francisco, CA, USA. **3.** Leon MB, Smith CR, Mack M, *et al.* Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med.* 2010;363:1597–1607. **4.** Smith CR, Leon MB, Mack MJ, *et al.* Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med.* 2011;364:2187–2198. **5.** Leon MB, Smith CR, Mack M, *et al.* Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med.* 2016;374:1609–1620. **6.** Leon MB, Mack MJ. Partner 3 – Transcatheter or Surgical Aortic Valve Replacement in Low Risk Patients with Aortic Stenosis. Presentation at the American Congress of Cardiology, March 16–18, 2019; New Orleans, LA, USA. **7.** Data on file. Edwards Lifesciences. June 2019.

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