

PARTNER 3 Trial Outcomes

Demonstrating the superiority of SAPIEN 3 TAVI compared with sAVR in low surgical risk patients^{*1,2}



Patient characteristics¹



	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 patients¹
Younger and with **fewer comorbidities** than in previous TAVI trials^{1,3-5}

Trial design¹



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}

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:[†]

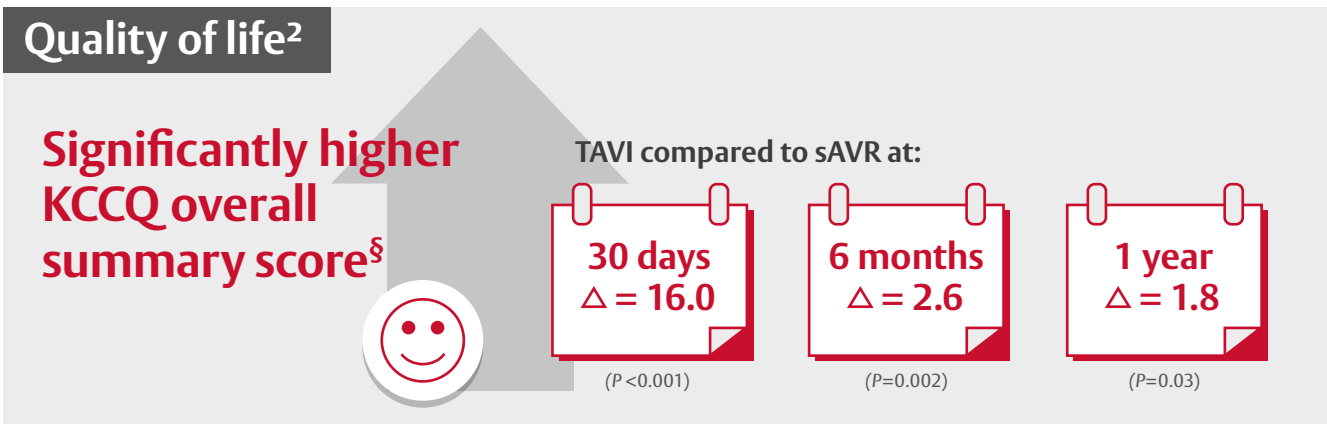
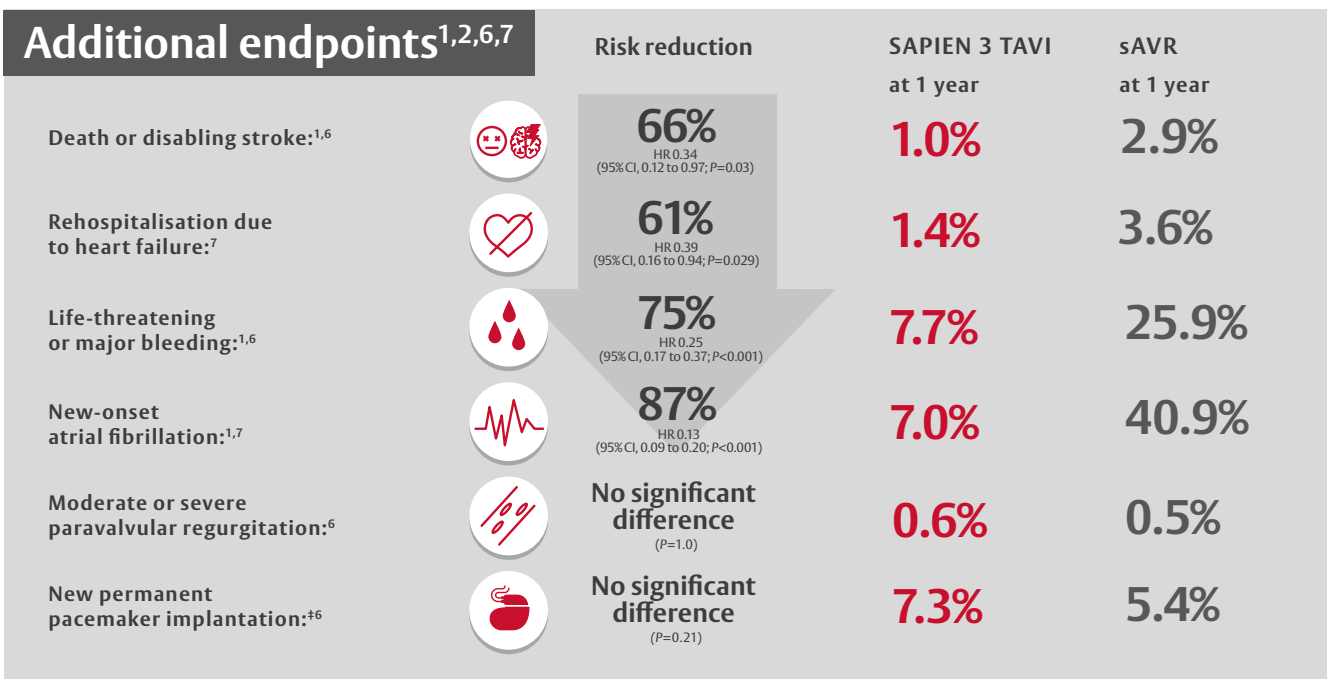


35%

HR 0.65
(95% CI, 0.42 to 1.00; P=0.046)

7.3%

11.0%



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.
 **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%.
 † Valve-related, procedure-related, or heart-failure-related.
 ‡ 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.

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). Edwards devices placed on the European market meet the requirements for bearing the CE marking of conformity.
 Edwards, Edwards Lifesciences, the stylized E logo, Edwards SAPIEN, Edwards SAPIEN 3, PARTNER, PARTNER 3, SAPIEN, and SAPIEN 3 are trademarks or services marks of Edwards Lifesciences Corporation. All other trademarks are the property of their respective owners.
 © 2019 Edwards Lifesciences Corporation. All rights reserved. E10463/11-19/THV
 Edwards Lifesciences • Route de l'Etraz 70, 1260 Nyon, Switzerland • edwards.com

