# **Clinical Summary**

# 5-year outcomes comparing surgical versus transcatheter aortic valve replacement in patients with chronic kidney disease

Garcia S et al. JACC Cardiovasc Interv. 2021;14(18):1995 – 2005.



To assess 5-year cardiovascular, renal, and bioprosthetic valve durability outcomes in patients with sAS and CKD who received SAVR or TAVI.<sup>1</sup>



A subgroup of patients at intermediate-risk with moderate and severe CKD (eGFR 45–59.9 mL/min/1.73 m² to eGFR 15–44.9 mL/min/1.73 m², respectively) from the PARTNER 2A Trial and PARTNER S3i Registry were analysed. The eGFR was calculated using the MDRD equation using creatinine values obtained prior to the SAVR or TAVI procedure.<sup>1</sup>

The primary endpoint was a composite of death, stroke, rehospitalisation and new haemodialysis (major adverse cardiovascular and renal events) 5 years after SAVR or TAVI with Edwards SAPIEN XT valve or Edwards SAPIEN 3 valve.¹ The five-year incidence of VARC-3 defined SVD, BVF and SVD-related BVF was the secondary endpoint.¹





# **Patient population**

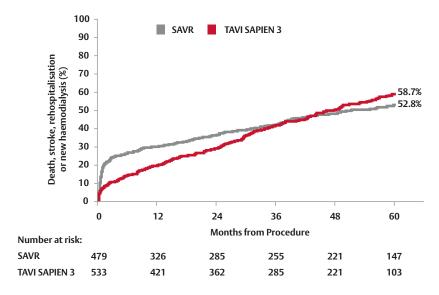
2,940 patients at intermediate risk from PARTNER II A and S3i had available baseline eGFR. Of these, moderate or severe CKD was present in 479 SAVR patients (52.1%) and 1,045 TAVI patients (51.6%; n = 512 Edwards SAPIEN XT valve and n = 533 Edwards SAPIEN 3 valve).



### **Primary outcome**

At 5 years, the composite primary endpoint was similar for SAVR and Edwards SAPIEN 3 valve (52.8% vs 58.7%, respectively. HR: 1.01 [95% CI, 0.84-1.22] p = 0.89). This result remained after propensity score matching.<sup>1</sup>

Kaplan-Meier curve comparing rates of the primary endpoint in patients with severe AS and moderate to severe chronic kidney disease treated with SAVR and TAVI Edwards SAPIEN 3 valve<sup>1</sup>

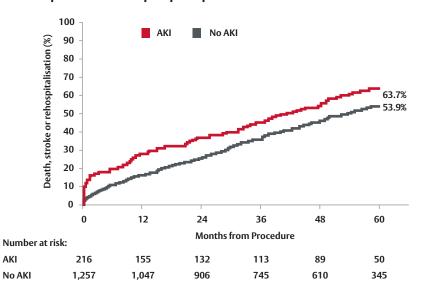


### **Renal outcomes**

Perioperative AKI was more common with SAVR than TAVI between 0 and 1 month, occurring in 26.3% and 10.3% of patients respectively (p < 0.001).<sup>1</sup>

AKI after AVR was also independently associated with increased risk for mortality, stroke, and rehospitalisation after 5 years versus no AKI after AVR (HR 1.38 [95% CI, 1.14-1.66] p < 0.001).<sup>1</sup>

Kaplan-Meier curve comparing the composite rate of death, stroke or rehospitalisation at 5 years on the basis of whether patients developed perioperative AKI<sup>1</sup>



# **Durability**

At 5 years, Edwards SAPIEN 3 valve had comparable valve durability with SAVR:1

- All-cause BVF was 0.8% and 2.4% for SAVR and TAVI SAPIEN 3 valve, respectively (p = 0.1)
- SVD-related BVF = 0.3% and 0.0% for SAVR and TAVI SAPIEN 3 valve, respectively (p = 0.99)



- In patients with sAS and CKD, SAVR and Edwards SAPIEN 3 valve had similar 5-year risks of:1
  - Death
  - Stroke
  - Rehospitalisation
  - Progression to haemodialysis
- AKI was more common after SAVR than TAVI<sup>1</sup>
- Valve durability was comparable between SAVR and Edwards SAPIEN 3 valve<sup>1</sup>

# **Abbreviations**

AKI:	acute kidney injury	PARTNER:	Placement of Aortic Transcatheter Valves
AVR:	aortic valve replacement	S3i:	PARTNER S3i Registry (part of the PARTNER II Trial)
BVF:	bioprosthetic valve failure	sAS:	severe aortic stenosis
CI:	confidence interval	SAVR:	surgical aortic valve replacement
CKD:	chronic kidney disease	SVD:	structural valve deterioration
eGFR:	estimated glomerular filtration rate	TAVI:	transcatheter aortic valve implantation
HR:	hazard ratio	VARC:	Valve Academic Research Consortium
MDRD:	Modification of Diet in Renal Disease		

# Reference

1. Garcia S et al. JACC Cardiovasc Interv. 2021;14(18):1995 – 2005.

This document is a summary of the presentation by Dvir D, at TCT CONNECT 2020. The full presentation is available at: https://www.tctconnect.com/interventional-cardiology-in-the-era-of-covid-19/

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 meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

Edwards, Edwards Life sciences, Edwards SAPIEN, Edwards SAPIEN XT, Edwards SAPIEN 3, PARTNER, PARTNER II, SAPIEN, SAPIEN XT, and SAPIEN 3 and the stylized E logo are trademarks or service marks of Edwards Lifesciences Corporation. All other trademarks are the property of their respective owners.



© 2022 Edwards Lifesciences Corporation. All rights reserved. PP--EU-3376 v1.0