

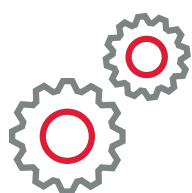
Paravalvular Regurgitation Post-Transcatheter Aortic Valve Replacement in Intermediate Risk Patients: A Pooled PARTNER II Study

Chau KH, et al. *EuroIntervention*. 2021; EIJ-D-20-01293. doi: 10.4244/EIJ-D-20-01293



Study aim

The adverse impact of moderate or high PVR after TAVI is already known. However, the underlying mechanisms that lead to these outcomes are missing. The aim of this post hoc analysis was to determine the mechanism by which PVR leads to worse outcomes.¹



Methods

Patients with symptomatic severe aortic stenosis at intermediate surgical risk from the PARTNER II A Trial and PARTNER S3i Registry who received TAVI, were pooled together in this post hoc analysis.

Transthoracic echocardiogram from 30 days was used to determine PVR severity. With patients divided into those with \leq mild PVR and those with \geq moderate PVR.¹

The endpoints were clinical and echocardiographic outcomes up to 2 years post-TAVI:¹

- Clinical outcomes included all-cause mortality, CV mortality, rehospitalisation, re-intervention and stroke.
- Echocardiographic outcomes were assessed by the mean difference between 30-days (or discharge) and years 1 and 2.



Edwards



Results

Patient population

Of the 947 patients from the PARTNER II A and 1,027 from the S3i cohorts (n = 1,974), 1,856 had \leq mild PVR and 118 had \geq moderate PVR. Of the patients with \geq moderate PVR, 9 had severe PVR.¹

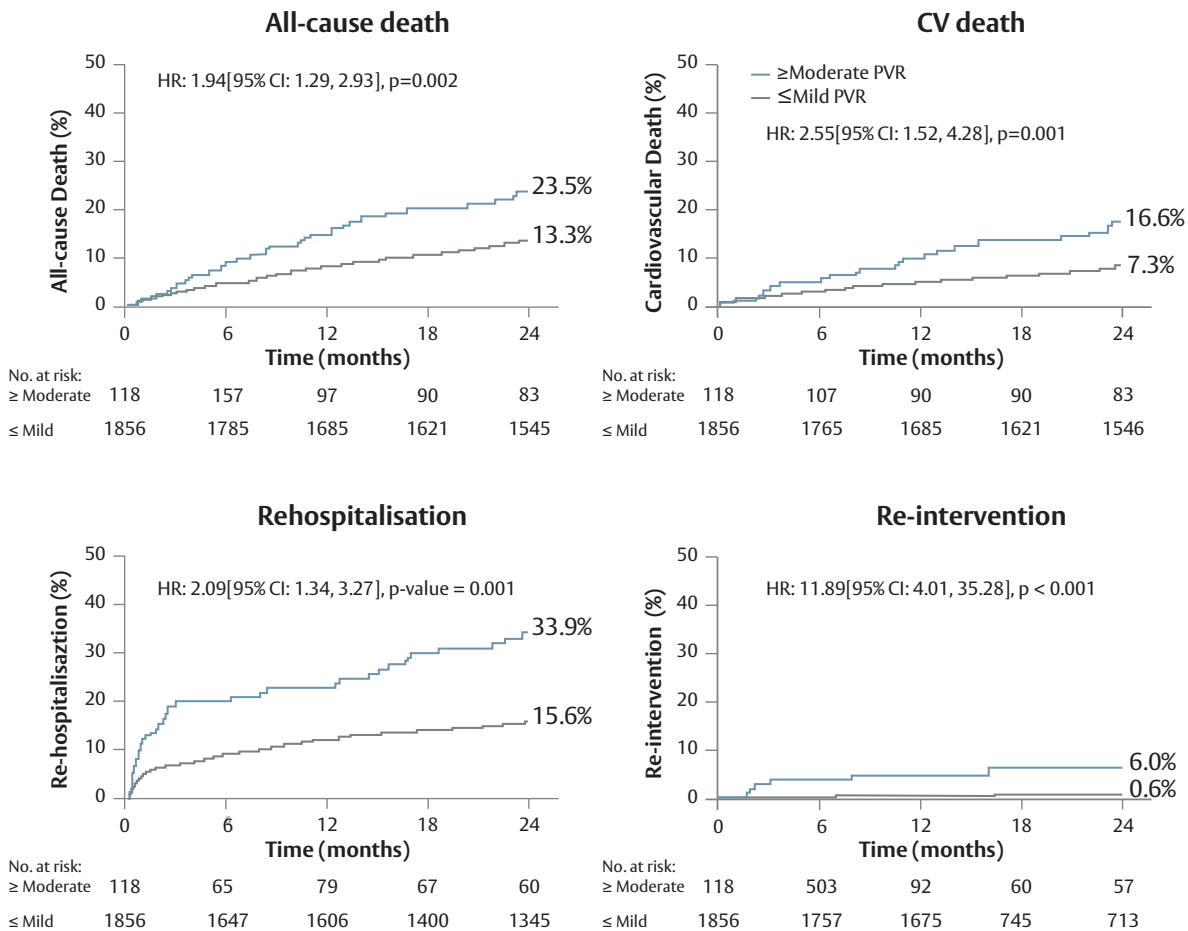


Clinical outcomes

At 2 years patients with \geq moderate PVR had significantly increased risk of all-cause mortality when compared with none/trace PVR patients (HR 1.95 [95% CI, 1.30-2.94] p=0.001). Whereas those with \leq mild PVR did not have significantly increased risk of all-cause mortality versus non/trace PVR patients (HR 1.09 [95% CI, 0.84-1.41] p = 0.53).

A greater than two-fold increased risk of CV death, rehospitalisation and re-intervention at 2 years was observed in patients with \geq moderate PVR versus those with \leq mild PVR patients.

Kaplan-Meier survival curves showing the association of PVR severity with clinical outcomes at 2 years



*Adapted from Chau, et al. 2021.¹

Echocardiographic outcomes

Between 30 days and 1 year \geq moderate PVR was associated with significant echocardiographic changes. Compared with \leq mild PVR, patients with \geq moderate PVR were shown to have:¹

- Greater increases in LV end diastolic and systolic dimensions ($p < 0.001$ and $p = 0.004$, respectively)
- Greater increases in LV end diastolic and systolic volumes ($p < 0.001$ for both measures)
- Greater increases in LV mass indices ($p < 0.001$)
- Greater reduction of LVEF ($p = 0.008$)

These changes continued to progress up to 2 years.¹



Conclusions

- \geq Moderate PVR is associated with an increased risk of all cause and CV mortality, rehospitalisation and re-intervention at 2 years¹
- Adverse cardiac remodelling changes associated with \geq moderate PVR are associated with the worse outcomes¹
- \leq Mild PVR was not associated with increased mortality¹

CI: confidence interval

CV: cardiovascular

HR: hazard ratio

LV: left ventricular

ECMO: extracorporeal membrane oxygenation

LVEF: left ventricular ejection fraction

PARTNER: Placement of Aortic Transcatheter Valves

PVR: paravalvular regurgitation

S3i: PARTNER S3i Registry (part of the PARTNER II Trial)

TAVI: transcatheter aortic valve implantation

Reference

1. Chau KH, et al. *EuroIntervention*. 2021: EIJ-D-20-01293. doi: 10.4244/EIJ-D-20-01293

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

Edwards, Edwards Lifesciences PARTNER, PARTNER II, 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-3373 v1.0

Edwards Lifesciences • Route de l'Etraz 70, 1260 Nyon, Switzerland • edwards.com



Edwards