

Clinical Summary

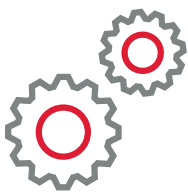
Prosthesis-patient mismatch (PPM) after aortic valve replacement in the PARTNER II Trial and Registry

Ternacle J *et al.* *JACC Cardiovasc Interv.* 2021;14(13): 1466-1477.



Study aim

To compare the incidence and outcomes of PPM after SAVR and TAVI using measured versus predicted EOA.¹



Methods

Patients with symptomatic SAS at intermediate surgical risk from the PARTNER II A Trial and PARTNER II S3i Registry who underwent SAVR and TAVI, respectively, were included in this analysis.

PPM_M was determined by transthoracic echocardiography measured EOA indexed to BSA (EOAi) at 30 days. PPM_p was determined by using normal EOA reference values reported for each valve model and size indexed to BSA (PPM_{p1}) and using normal reference EOA predicted from preprocedural CT annular measures indexed to BSA (PPM_{p2}, TAVI only).

Moderate and severe PPM was classified as:¹

- Moderate = $EOAi >0.65 \text{ cm}^2/\text{m}^2 \leq 0.85 \text{ cm}^2/\text{m}^2$ ($>0.55 \text{ cm}^2/\text{m}^2$ and $\leq 0.70 \text{ cm}^2/\text{m}^2$ if obese: $BMI \geq 30 \text{ kg}/\text{m}^2$)
- Severe = $EOAi \leq 0.65 \text{ cm}^2/\text{m}^2$ (≤ 0.55 if obese)

The primary endpoint was the composite of all-cause death and cardiac rehospitalisation at 5 years.¹



Edwards



Results

Patient population

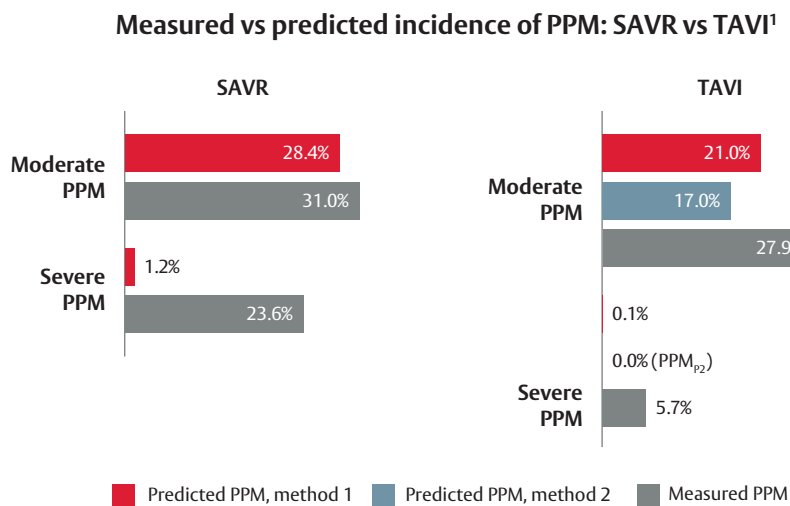
Two-thousand and five patients were included in the analysis; n = 936 from PARTNER II who received SAVR and n = 1,069 from S3i who received TAVI.



Thirty-day echocardiography for PPM_M was available in 726 patients from the SAVR cohort and 954 patients from the TAVI cohort. For PPM_{p1}, 929 patients from the SAVR cohort and 1,069 from the TAVI cohort had known valve model and label size, and were included. For PPM_{p2}, preprocedural CTA data were available for 864 patients from the TAVI cohort.¹

Measured versus predicted incidence of PPM

Incidence of moderate and severe PPM_p was much lower than PPM_M in both SAVR and TAVI groups.



Adapted from Ternacle J, et al. *JACC Cardiovasc Interv.* 2021.

The incidence of severe PPM_{p1} and PPM_M was significantly lower in the TAVI cohort than the SAVR cohort.¹

	SAVR	TAVI	P value
Severe BMI-adjusted PPM _M	23.6%	5.7%	<0.0001
Severe PPM _{p1}	1.2%	0.1%	0.002

Clinical outcomes

At 5 years severe predicted PPM (using reference value) in the SAVR cohort was independently associated with a 3-fold increased risk of all-cause death or rehospitalisation (HR 3.18 [95% CI, 1.69-5.96] p < 0.001).¹ For the TAVI cohort, the association between clinical outcomes at 5 years could not be examined as severe predicted PPM (both through reference value and through CT annular measures) were absent or extremely rare.¹

Moderate PPM was not associated with an increased risk of events when measured by any method in either the SAVR or TAVI cohort.¹





Conclusions

- EOA_i measured by echocardiography overestimates the incidence and severity of PPM following SAVR or TAVI, versus predicted EOA_i¹
- Predicted EOA_i¹
 - Yields a lower rate of PPM compared with measured EOA_i and reveals that ‘true-severe’ PPM is rare (<1.5%) and is virtually absent in the TAVI cohort
 - Was significantly lower for Edwards SAPIEN 3 valve versus SAVR
- There was no association between PPM and clinical outcomes in the Edwards SAPIEN 3 valve group¹

Abbreviations

BMI:	body mass index	PPM:	prosthesis-patient mismatch
BSA:	body surface area	PPMM:	measured prosthesis-patient mismatch
CI:	confidence interval	PPMP1:	predicted prosthesis-patient mismatch, method 1
CT:	computed tomography	PPMP2:	predicted prosthesis-patient mismatch, method 2
CTA:	computed tomography angiography	SAS:	severe aortic stenosis
EOA:	effective orifice area	SAVR:	surgical aortic valve replacement
EOA _i :	indexed effective orifice area	S3i:	PARTNER S3i Registry (part of the PARTNER II Trial)
HR:	hazard ratio	TAVI:	transcatheter aortic valve implantation
PARTNER:	Placement of Aortic Transcatheter Valves		

Reference

1. Ternacle J *et al.* *JACC Cardiovasc Interv.* 2021;14(13): 1466-1477.

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