Clinical Summary

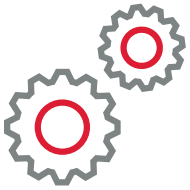
Impact of predilation during transcatheter aortic valve replacement

Insights From the PARTNER 3 Trial

Ternacle J *et al. Circ Cardiovasc Interv*. 2021 Jul;14(7):e010336.

Study aim

To evaluate the impact of predilation during TAVI on clinical outcomes and valve haemodynamics, by utilising the Edwards SAPIEN 3 valve in a low surgical risk population enrolled in the PARTNER 3 Trial.[1]



Methods

In the PARTNER 3 Trial, of the enrolled patients (n=950) underwent TAVI or surgery. TAVI was performed in 52% of the study population (n=495).

The primary end point was a composite of all-cause death, stroke, or rehospitalisation evaluated at 30 days and 1 year after TAVI.

To estimate the effect of predilation and to overcome the absence of randomisation for this additional procedure, a propensity score matching analysis was performed. This resulted in two groups of 202 patients, with balanced baseline characteristics.

To compare the incidence of the primary end point in the predilation and direct groups Kaplan-Meier estimates and log-rank test were used. Association of predilation with the primary end point was also confirmed by an inverse probability of treatment weighting analysis.[1]

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Results

Patient population

Predilation was performed in 286 (58%) of patients and 209 (42%) patients underwent direct TAVI. After matching, mean age (73.2±5.8 in both groups), gender, comorbidities, STS risk score and echocardiographic baseline characteristics were similar in both groups.[1]

Primary outcome

In the matched groups, the primary endpoint was similar in both predilation and direct TAVI groups at 30 days (4.0% vs. 5.0%, respectively; p = 0.629) and 1 year (10.4% vs. 8.4%, respectively; p = 0.516).[1]

At 30 days and 1 year predilation was not associated with the primary endpoint components of all cause death, stroke and hospitalisation.[1]

End point	30 days				1 year			
	Predilation (n=202)	Direct TAVI (n=202)	HR [95% CI]	p value	Predilation (n=202)	Direct TAVI (n=202)	HR [95% CI]	p value
All-cause death, n (%)	1 (0.5)	1 (0.5)	2.00 [0.40–10.90]	>0.99	4 (2.0)	1 (0.5)	2.01 [0.40–11.00]	0.179
Stroke, n (%)	1 (0.5)	2 (1.0)	1.00 [0.20–4.90]	0.563	3 (1.5)	3 (1.5)	1.00 [0.20–5.00]	>0.99
Rehospitalisation, n (%)	6 (3.0)	8 (4.0)	1.12 [0.60–2.30]	0.588	17 (8.4)	15 (7.4)	1.13 [0.60–2.30]	0.725

Adapted from Ternacle *et al*. 2021

Procedural outcomes

Conscious sedation was the main modality of anaesthesia in both the predilation and direct TAVI groups (64.9% vs. 65.3%, p >0.99). The predilation group did not have a higher risk of conversion to general anaesthesia.[1]

When used to enhance haemodynamics, post-dilation is clearly harmful, and strongly associated with post-procedural stroke at 1 year (HR: 8.78 [95% CI, 1.56–49.26], p = 0.014).

Longer procedure times were observed with predilation versus direct TAVI (63.2±45.8 mins vs. 51.4±23.7 mins, respectively; p = 0.001).[1] Total fluoroscopy times were also longer with predilation vs direct TAVI (15.6±7.9 vs. 11.7±5.6 mins, p < 0.001, respectively).[1]

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Conclusions

- Predilation and direct TAVI are safe in patients with low surgical risk and favourable aortic valve anatomy (note, the absence of predilation did not correlate with an increased need for post-dilation)[1]
- Direct TAVI reduces both procedure and fluoroscopy times, being beneficial to both patient and hospital resources[1]
- Nevertheless, predilation may remain useful in specific circumstances. With no significant increased risk in complications[1]

Using data from the PARTNER 3 Trial, this study shows that no predilation with Edwards SAPIEN 3 valve is safe and feasible[1]

Abbreviations

CI:	confidence interval
HR:	hazard ratio
PARTNER:	Placement of Aortic Transcatheter Valves
STS:	Society of Thoracic Surgeons
TAVI:	transcatheter aortic valve implantation

Reference

1. Ternacle J *et al. Circ Cardiovasc Interv.* 2021;14(7): e010336.

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