

# Health Status after Transcatheter vs Surgical Aortic Valve Replacement in Low-risk Patients with Aortic Stenosis

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**Citation** *J Am Coll Cardiol* 2019;74:2833–42  
DOI:10.1016/j.jacc.2019.09.007

**Period of study**

- Patient recruitment between March 2016 and October 2019
- Health status checked at baseline, 1, 6 and 12m

## Objectives

- To understand the impact of valve replacement strategy on early and late health status in patients with aortic stenosis (AS) at low surgical risk
- To compare health status outcomes of transcatheter aortic valve replacement (TAVR) vs surgical aortic valve replacement (SAVR) in these patients

## Study design

A prospective study alongside the Placement of Aortic Transcatheter Valves (PARTNER) 3 randomised trial.

## Materials and methods

- 1000 low-risk AS patients were enrolled at 71 sites and 950 were randomised (1:1) to transfemoral (TF)-TAVI using the SAPIEN 3 valve or surgery, in the PARTNER 3 trial.
- The mean age was 73 years, approximately 67% were male, and the mean Society of Thoracic Surgeons risk score was 1.9%
- Disease-specific health status was evaluated at baseline, 1, 6 and 12m, using the Kansas City Cardiomyopathy Questionnaire (KCCQ)
- Generic health status was evaluated using the Medical Outcomes Study Short-Form-36 (SF-36) questionnaire and the Euro QoL (EQ-5D).

## Key results

- At 1 month, TAVR was associated with better health status than was surgery (mean difference in KCCQ 16.0 points)
- At 6 and 12m, health status remained better with TAVR (mean difference in KCCQ 2.6 vs 1.8 points)
- The proportion of patients with an excellent outcome was greater with TAVR than surgery at 6 and 12m

## Limitations of study

- Since the study population was restricted to patients who were treated via TF access, results may not be generalisable to other types of TAVR access routes, or to patients excluded from the PARTNER 3 Trial population, or to types of TAVR prosthesis other than the SAPIEN 3 balloon-expandable valve
- Treatment assignment was unblinded, possibly introducing bias, although this would be unlikely in explaining 12m health status differences
- Durability of these results beyond 12m is untested

## Conclusions

- Among patients with severe AS who are at low surgical risk, substantial improvements in disease-specific and generic health status at 12m was observed in both TAVR and SAVR cohorts
- TAVR was associated with an early benefit over SAVR on all health status measures.
- TAVR was associated with persistent benefits in disease-specific health status at 12m compared with SAVR
- This is the first study to evaluate the effects of TAVR and SAVR on health-related quality of life in patients with severe AS at low surgical risk, and the first randomised trial to demonstrate a persistent health status advantage with TAVR at 6 and 12m
- The KCCQ-defined health status score is derived, in part, from patient perception of physical limitations, symptom frequency, quality of life and social limitations, indicators that are of principal importance to patients, and to any decision regarding their treatment options