Clinical Summary

TAVI in Low-Risk Patients at 5 Years
PARTNER 3 Trial

Mack MJ, et al. Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years. N Engl J Med. 2023 Oct 24. doi: 10.1056/NEJMoa2307447

Study aim

To compare the 5-year outcomes of TAVI with SAPIEN 3 valve and SAVR in patients with ssAS in low surgical risk.

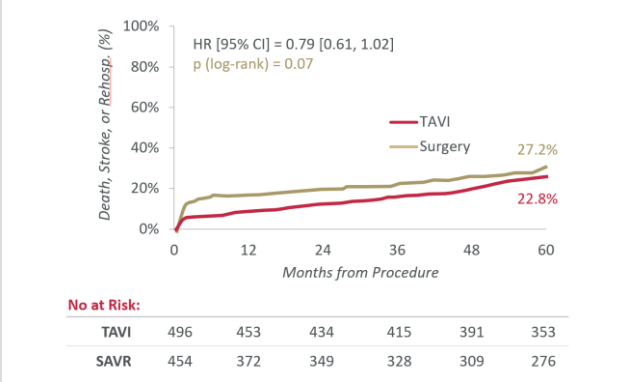
THE PARTNER 3 TRIAL

Methodology

- **PARTNER 3:** 5 years data; Randomized Clinical Trial - patients treated with TF-TAVI or SAVR
- **1000 low surgical risk** patients with ssAS - Average age 73 y.o. – STS score 1.9
- **At 5 years:** 469 patients with SAPIEN 3 valves, 401 patients with surgical valves (70% Edwards)

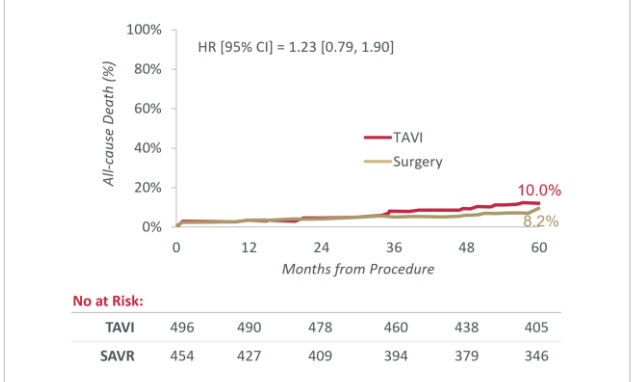
Results

Primary Endpoints:



- **Death, stroke, or rehospitalization*** composite: No significant difference between TAVI and SAVR.
  - **Event-free survival was longer by 103 days in the TAVI cohort.**
- **Win ratio§** - hierarchical composite of death, disabling stroke, non-disabling stroke, and rehosp. days: 1.17 - **22.1% of wins for TAVI and 19% wins for SAVR.** No significant difference.

Mortality:



- **All-cause mortality: No significant difference** between TAVI (10.0%) and SAVR (8.2%).
  - **Vital status sweep**$ reduced the gap between TAVI and SAVR. **TAVI 10.2% vs. SAVR 9.0%.**
  - Mortality differences mainly due to **non-CV deaths** – e.g., Cancers, Covid-19, and Sepsis deaths.

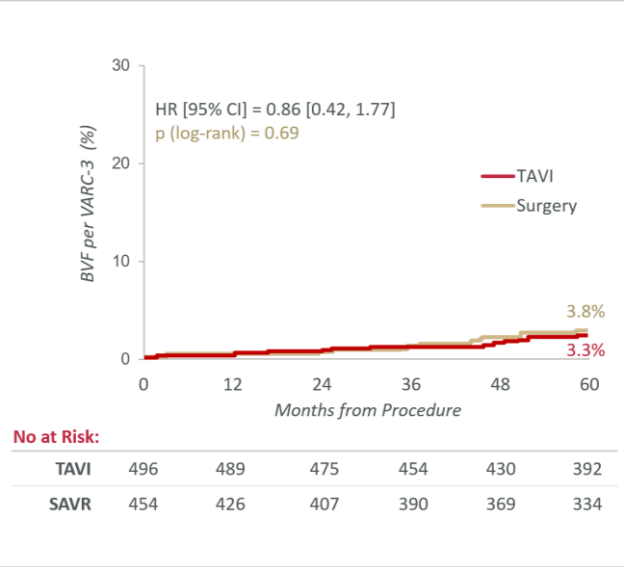
* related to the valve, the procedure, or heart failure / $ vital status sweep: conducted to obtain information about the patients who withdrew or were lost to follow-up § Win ratio: NT × NC paired comparisons - Test (TAVI) or Control (SAVR) wins when specific endpoints happen first over the same follow-up time – the ratio represented n of wins divided by n of loses".

Edwards

Secondary Endpoints:

- No difference was reported for CV deaths, all and disabling strokes, rehospitalization, BVF, and aortic reintervention.
- **Valve thrombosis:** significantly higher in TAVI arm (2.5% vs 0.2% - HR 10.52 (1.37–80.93))
  - **No thrombosis-related death;** TAVI: only 1 thrombosis-related BVF
- **Hemodynamics: Sustained** mean gradient and aortic valve area in both cohorts and in **all SAPIEN 3 valve sizes.**

Bioprosthesis-valve Failure:



BVF Cause[&] (%)	TAVI (N=496)	SAVR (N=454)
SVD	1.4%	2.0%
Endocarditis	0.2%	0.9%
PVL	0.8%	0.2%
Thrombosis	0.2%	0.2%
PPM	0.2%	0%
Undetermined[ǂ]	0.2%	0%

& according to VARC-3 criteria
ǂ The patient had a valve-in-valve reintervention for stenosis

Conclusion

Among patients with ssAS at low surgical risk who underwent TAVI or SAVR, the incidence of the two primary composite endpoints appeared to be similar in the two groups at 5 years of follow-up.

Abbreviations

BVF = Bioprosthesis-valve Failure; **CV** = cardiovascular; **NC**= number of patients on the Control arm (SAVR); **NT**= number of patients on the Test arm (SAPIEN 3); **PVL** = Paravalvular leak; **PPM** = Patient-prosthesis mismatch; **SAVR** = surgical aortic valve replacement; **ssAS** = severe symptomatic aortic stenosis; **SVD** = Structural valve deterioration; **TAVI** = Transcatheter aortic valve implantation; **TF** = transfemoral; **VARC-3** = Valve Academic Research Consortium-3.

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