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CLINICAL INSIGHTS

PORTICO™ TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM

Portico Valve Demonstrates Consistent Results at Two Years[1]

Low gradients, incidence of CV mortality, disabling stroke, and PVL seen in recent study data

PRESENTATION TITLE

Two Years Outcomes in the Portico I Study[1]

PRINCIPAL INVESTIGATORS

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INTRODUCTION

Two-year results from a prospective, multi-center, non-randomized study of the Portico™ transcatheter aortic valve were presented by Professor Lars Søndergaard, MD of Rigshospitalet in Copenhagen, Denmark.

STUDY DESIGN

The trial enrolled patients at 61 centers in the European Union, Canada, and Australia.

- Included patients with symptomatic, severe aortic stenosis at high risk for surgical aortic valve replacement
- Primary endpoint: all-cause mortality at 1 year
- Secondary endpoints: evaluation of VARC-2 defined events, device performance, change in functional capacity at 30-day, 1-year, and yearly up to 5 years
- Patient follow-up: 30 days, 1, 2, 3, 4, and 5 years

SUMMARY OF RESULTS

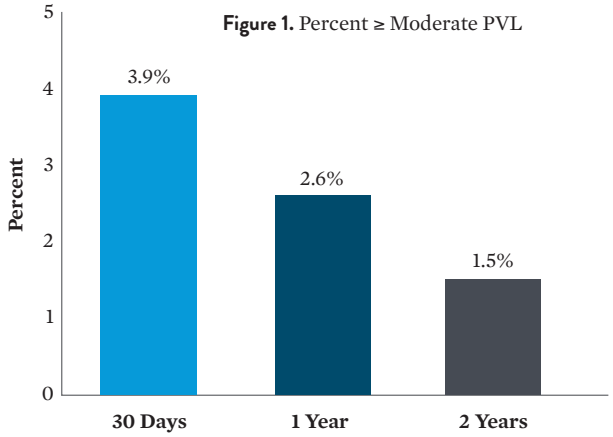
This large, real-world study included 941 participants with 96.0% overall 2-year compliance.

- Mean age 82.4 years
- 63.9% NYHA class III/IV
- Chronic kidney disease present in 30.2%
- Almost one-third (29.6%) had diabetes
- Frailty assessment: 85.2% met ≥1 criterion

Tables 1 and 2 include additional baseline characteristics and procedural data. At two years, safety data remained consistent with earlier reports, transvalvular gradients stayed low, and effective orifice areas were large.

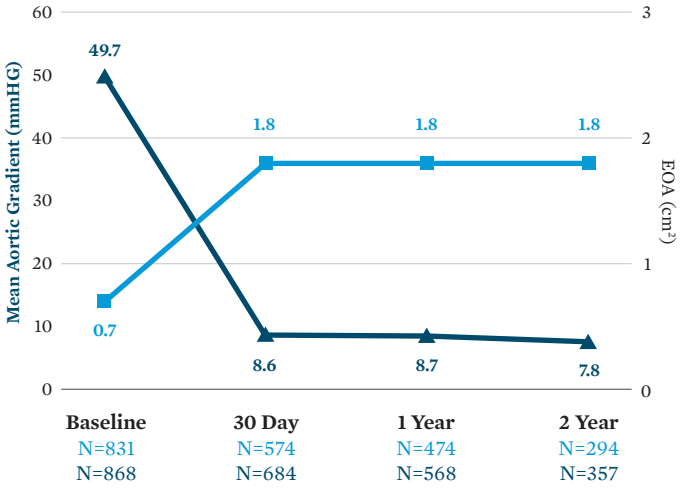
- All-cause mortality 19.7% (See Table 3)
- Cardiovascular mortality 9.6%
- Mean aortic gradient 7.8 (See Figure 2)
- Effective orifice area 1.8

Figure 1. Percent ≥ Moderate PVL



- No severe PVL at 30 days, 1 year, or 2 years

Figure 2. Valve area and mean gradients over 2 years.



Based on core-laboratory assessed echocardiographic data

The Portico valve demonstrated good safety and durability at the 2-year follow-up.

- No severe paravalvular leakage (PVL) was observed (See Figure 1)
- Incidence of disabling stroke was 3.1%
- Freedom from structural valve deterioration 99.1%

The study investigators compared Portico's 2-year results with public data for the Evolut R‡ and Sapien-XT‡ devices. Portico demonstrated low rates of cardiac mortality, disabling stroke, and more-than-mild PVL. (See Table 4)

CONCLUSION

At 2 years, PORTICO I demonstrated:

- Low cardiovascular mortality (9.6%)
- Continued low transvalvular gradient and large effective orifice area
- Low rate of prosthesis-patient mismatch
- Low rate of more-than-mild PVL (1.5%)

Safety and performance outcomes of the PORTICO™ THV remain consistent in this large, real-world study based on early experience.

TABLE 1. SELECT BASELINE CHARACTERISTICS

Characteristic	N=941
Mean Age, years	82.4
Female Gender, %	65.7
NYHA Class III/IV, %	63.9
STS Score (mortality), %	5.8
Frailty Assessments (patients with ≥ 1 criterion met), %	85.2%

TABLE 2. SELECT PROCEDURAL DATA

Characteristic	N=941
Device Success, %	96.0
General Anaesthesia / Conscious Sedation, %	24.4 / 75.5
Implant Depth, mm	5.4
Re-sheathed for repositioning, %	41.5
Fluoroscopy time, min	20.4
Total procedure time, min	76.5

TABLE 3. SELECT 30-DAY, 1- AND 2-YEAR CLINICAL OUTCOMES

VARC-2 Outcome (N=941), %	30 Days**	1 Year†	2-Year†
All-Cause Mortality	2.7	12.1	19.7
CV Mortality	2.4	6.6	9.6
All Stroke	3.0	5.3	7.9
Disabling	1.6	2.2	3.1
Non-Disabling + TIA	1.4	3.1	4.8
Myocardial Infarction	1.6	2.5	3.2
Overall New PM Implantation	17.1	19.5	20.4
Naïve PM*	18.7	21.3	22.3

*In patients with no prior PM; **30-day rates are based on proportion;
†1- and 2-year rates are KM estimates.

TABLE 4. CROSS-STUDY REVIEW OF THREE VALVES AT 2 YEARS

Valve	Portico	Evolut R‡	Sapien-XT‡
Study	Portico I[1]	FORWARD[2]	Partner 2A[4]
Patients, n	941	1040	1011
Cardiac Mortality, %	9.6	11.6	10.1
Disabling Stroke, %	3.1	3.3	6.2
PPI, %	22.3	20.9	11.8
EOA, cm²	1.8	1.9[3]	1.5
Mean Gradient, mmHg	8.7	8.5[3]	10.8
> Mild PVL, %	1.5	6.1[3]	8.2
Severe PPM, %	8.8	N/A	19.4[5]

Yrs, years; PPI, permanent pacemaker implant; PVL, paravalvular leak; PPM, prosthesis-patient mismatch; N/A, not available.

REFERENCE:

1. Søndergaard L, on behalf of the PORTICO I investigators. Two year outcomes in the Portico I study. Presented at: PCR London Valves 2019. November 18, 2019. London, England.
2. Medtronic CV, Luxemburg S.A.R.L.; S. Bleiziffer poster 2-y Outcomes Forward Study
3. 2 Year outcomes of Corevalve *J Am CollCariol* 2015;66:113-21)
4. Edwards Lifesciences, Irvine, CA, USA; Leon MB, Smith CR, Mack MJ, et al *N Eng J Med* 2016;374:1609-20
5. Hahn et al. *Jacc* 2013;61:2541-21

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