hydra

Transcatheter Aortic Valve

5 YEAR Outcomes

Hydra CE study

Study Overview

Study Objective:

- To assess the clinical performance and safety of the Hydra Transcatheter Heart Valve (THV) for transfemoral transcatheter aortic valve replacement (TAVR) in the treatment of patients with symptomatic severe aortic stenosis and high or extreme surgical risk.

Design

Prospective, multicenter, single-arm

Population

High/extremely high surgical risk symptomatic severe aortic stenosis

Follow-up Duration

N=157 - **1 Year**
N=54 **- 5 Years**

Multi-Center

1 Year Cohort - 18 Centers
5 Years Cohort - 2 Centers

Primary safety endpoint: All-cause mortality at 30 days

Secondary safety endpoint: All clinical endpoints were evaluated as per Valve Academic Research Consortium (VARC) 2 criteria at 30-day, 1-year, 2-year, 3-year and 5-year follow-up

Study Design



- Patients who provided consent for long-term follow-up (up to 5 years) at recruitment (n=54 patients)

1-year Outcomes[1]

Published in JACC: Cardiovascular Interventions (Impact Factor 11.4)

Number of Patients:
N=157

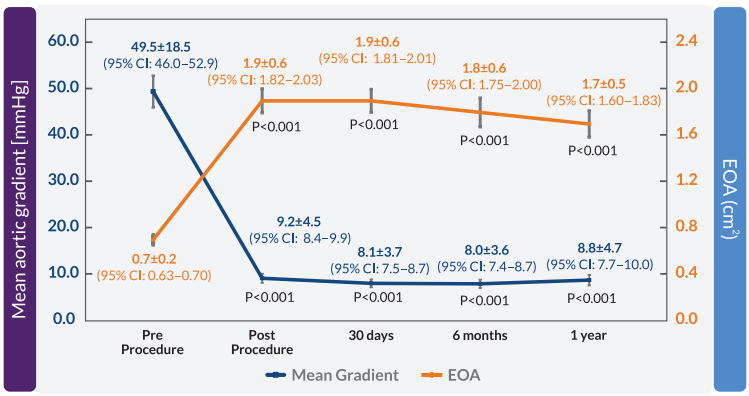
Geography
18 Centers across, Greece, Hongkong, India, Kazakhstan, Poland, Lithuania, New Zealand & Thailand

Results

Variables	At 1 month	At 1 year
All-cause mortality	11 (7.0)	23 (14.6)
Cardiovascular mortality	9 (5.7)	13 (8.3)
Non-cardiovascular mortality	2 (1.3)	10 (6.4)
All stroke	1 (0.6)	1 (0.6)
Disabling	1 (0.6)	1 (0.6)
Nondisabling/Transient ischemic attack	0 (0)	0 (0)
Life-threatening bleeding	3 (1.9)	3 (1.9)
Major bleeding	7 (4.5)	7 (4.5)
Major vascular complication	7 (4.5)	7 (4.5)
Acute kidney injury	1 (0.6)	1 (0.6)
Myocardial infarction	0 (0)	0 (0)
New permanent pacemaker implantation	17 (10.8)	18 (11.5)
In pacemaker naïve patients	17 (11.7)	18 (12.4)

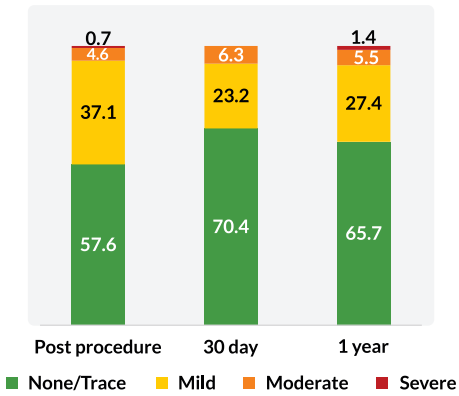
Values are n (%)

Hemodynamic Performance



Stable hemodynamic performance

Paravalvular Leak (%)



Low moderate or severe paravalvular leak

Conclusion

1-year follow-up data from the Hydra CE study demonstrated

- **Favorable 1-year safety & efficacy**
- Achieved **large effective orifice area (EOA)**
- Maintained **single digit transvalvular gradients**
- **Low rates of complications**

5-year Outcomes[2]

Presented @ PCR London Valves 2025

Presenter | Dr. Vilhelmas Bajoras

Number of Patients:
N=54

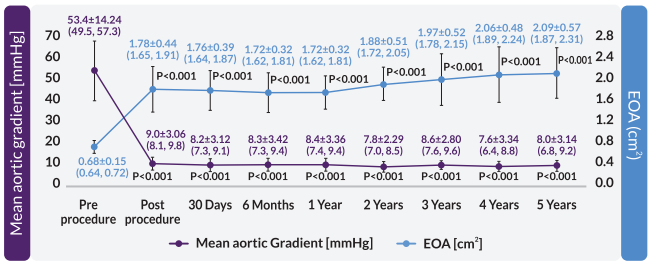
Geography
Poland & Lithuania

Results

Clinical Outcomes (N=54)	5 Years
All-cause mortality, n (%)	13 (24.3%)
Cardiovascular mortality, n (%)	3 (6.0%)
Non-cardiovascular mortality, n (%)	10 (19.4%)
All stroke, n (%)	6 (12.2%)
Disabling stroke, n (%)	2 (4.6%)
Nondisabling/Transient ischemic attack, n (%)	4 (8.0%)
Life-threatening bleeding, n (%)	1 (1.9%)
Major bleeding, n (%)	1 (1.9%)
Major vascular complication, n (%)	2 (3.7%)
Acute kidney injury, n (%)	1 (1.9%)
Myocardial infarction, n (%)	3 (5.6%)
New permanent pacemaker implantation, n (%)	9 (16.7%)
In pacemaker naïve patients, n (%)	9 (19.6%)

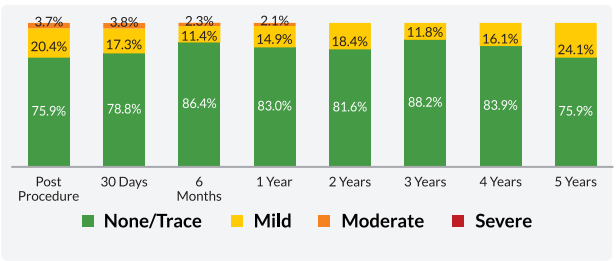
Values are n (%)

Hemodynamic Performance



Progressive enhancement in effective orifice area (EOA) with a significant improvement in the mean aortic valve gradient

Paravalvular Leak (%)



No moderate or severe paravalvular leak (PVL) was observed at the 5 years follow-up

Conclusion

5 years follow-up data from the Hydra CE study demonstrated:

- **Excellent valve durability**
- **Sustained hemodynamic performance** over the long term
- Established **favorable long-term safety and clinical effectiveness** of the Hydra THV
- Observed **low cardiovascular mortality,** contributing to **acceptable 5-year survival rates**
- Reported **low rates of disabling stroke** at 5 years follow-up

Hydra CE study

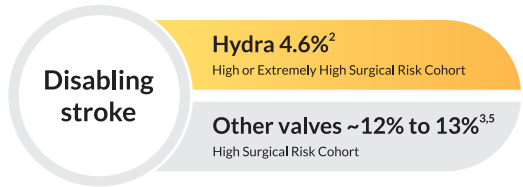
5 YEAR Outcomes

hydra

Key Findings

@ 5 years





	@ 1 year[1] (n=157)	@ 5 years[2] (n=54)
Mean Aortic Gradient	8.4 mmHg ↓	8.0 mmHg ↓
Effective Orifice Area	1.72 cm²	2.09 cm²
Moderate/Severe PVL	6.9%	0 %

- **Excellent long-term valve durability** with sustained 5-year hemodynamic performance
- **Low cardiovascular mortality,** supporting strong long-term survival
- **Low rates of disabling stroke** at 5 years
- **Consistent safety and clinical effectiveness** throughout long-term follow-up

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