# Title: Outcomes after transcatheter aortic valve implantation with a newer-generation balloon-expandable transcatheter heart valve

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## Background

The Myval™ transcatheter heart valve (THV) (Meril Life Sciences Pvt. Ltd., India) is a novel, balloon-expandable valve indicated for the treatment of patients with native severe aortic stenosis (AS).
The Myval-1 study, the first-in-human study, has confirmed.the safety and efficacy of the Myval THV in 30 Indian patients with native severe aortic stenosis [1].

## Aim/hypothesis

To assess the clinical outcomes of the Myval THV in native severe aortic stenosis in a real world setting in a large European heart center

## Methods

In this prospective, single arm, observational, single center study, 120 consecutive patients who underwent transcatheter aortic valve implantation (TAVI) using the Myval THV were analyzed. Clinical outcomes were evaluated at 30 days using Valve Academic Research Consortium-2 criteria. All-cause mortality, stroke, acute kidney injury, major vascular complications, moderate or severe prosthetic valve regurgitation, conduction system disturbances resulting in new permanent pacemaker implantation (PPI) were investigated at 30 days and 12 months.

## References

1. Sharma SK, Rao RS, Chandra P et al.. First-in-human evaluation of a novel balloon-expandable transcatheter heart valve in patients with severe symptomatic native aortic stenosis: the MyVal-1 study. EuroIntervention. 2020;16:421-429.

## Results

| **Echocardiographic measurements N=120** mean ± SD | **Baseline** | **Post-procedure** | **30 Days** |
|---|---|---|---|
| Aortic valve area ($cm^2$) | 0.77 ± 0.18 | 2.97 ± 1.02 | 2.61 ± 0.92 |
| Indexed aortic valve area ($cm^2/m^2$) | 0.41 ± 0.11 | 1.56 ± 0.51 | 1.36 ± 0.44 |
| Mean aortic valve pressure gradient (mmHg) | 36.77 ± 12.99 | 7.84 ± 3.27 | 9.34 ± 4.19 |
| Peak aortic valve pressure gradient (mmHg) | 62.73 ± 20.36 | 15.95 ± 6.16 | 18.81 ± 7.93 |
| Peak aortic valve velocity (m/s) | 3.89 ± 0.64 | 1.95 ± 0.39 | 2.12 ± 0.43 |
| Left ventricular ejection fraction (%) | 51.74 ± 8.20 | 51.86 ± 7.52 | 52.41 ±7.20 |

| **Clinical Events N=120 n (%)** | **30 Days** | **208 ± 130 Days** |
|---|---|---|
| All-cause mortality | 3 (2.5) | 10 (8.33) |
| Cardiac mortality | 2 (1.67) | 4 (3.33) |
| Valve embolization (pop-out) | 2 (1.67) | - |
| All stroke | 4 (3.33) | 4 (3.33) |
| Myocardial infarction | 0 (0) | 1 (0.83) |
| Acute kidney injury | 5 (4.17) | 5 (4.17) |
| Moderate or severe paravalvular leakage | 0 (0) | 0 (0) |
| New permanent pacemaker implantation | 4 (3.33) | 4 (3.33) |
| Vascular and access related complications | 0 (0) | 0 (0) |

## Conclusions

This study confirms good safety and performance outcomes of the Myval THV in patients with native severe symptomatic aortic stenosis ***at 30 days and 6-month follow-up with:***

- Improved valve hemodynamics
- Acceptable rate of new permanent pacemaker implantation (3.33%) and all stroke (3.33%)
- No moderate or severe paravalvular leakage present

| **Baseline Characteristics** | **N=120** n (%) or mean ± SD |
|---|---|
| Age (years) | 80.23 ± 6.31 |
| Body Mass Index ($kg/m^2$) | 28.24 ± 4.64 |
| Male | 64 (53.33) |
| Diabetes Mellitus | 43 (35.83) |
| Hypertension | 85 (70.83) |
| Hypercholesterolemia | 59 (49.17) |
| Coronary Artery Disease | 56 (46.67) |
| Chronic Kidney Disease | 42 (35) |
| COPD | 19 (15.83) |
| Previous CABG | 13 (10.83) |
| Previous Valve Surgery | 3 (2.5) |
| Peripheral Vascular Disease | 17 (14.17) |
| Cerebrovascular Accident | 24 (20) |
| Atrial Fibrillation | 39 (32.5) |
| Previous Pacemaker Implantation | 10 (8.33) |
| STS Score (%) | 2.33 ± 1.14 |
| Euroscore II (%) | 3.53 ± 2.69 |
| **Access Route** | |
| Transfemoral | 107 (89.17) |
| Transapical | 13 (10.83) |

## Clinical implication

Ongoing studies like the LANDMARK trial[1,2] and COMPARE-TAVI[3] will further establish the clinical utility of this next-generation balloon-expandable THV