STRUCTURAL HEART
2020, VOL. 4, NO. S1, 188–189
https://doi.org/10.1080/24748706.2020.1713659



# Evaluation of Balloon Expandable Transcatheter Heart Valve in the Treatment of Severe Symptomatic Native Aortic Stenosis: The First-in-human MyVal-1 Study

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**Objective**: To demonstrate safety and efficacy of the next-generation balloon-expandable CE-approved Myval™ THV in intermediate or high-risk patient population with severe symptomatic native aortic stenosis.

**Methods**: We enrolled 100 patients with severe symptomatic native aortic stenosis and who were at intermediate to high risk for surgery into a first-in-man, prospective, multicentre, single-arm MyVal-1 study. Clinical follow-up was scheduled at 30-day, 6-month, 12-month and annually thereafter up to 5-year. The major safety endpoint was Kaplan-Meier survivorship up to 12-month. Additional safety endpoints were all-cause death and stroke up to 12-month follow-up. The efficacy endpoints were improvement in NYHA functional classification, effective orifice area (EOA), and six-minute walk test from baseline through 12-month follow-up. Furthermore, freedom from major adverse cardiac cerebrovascular and renal event (MACCRE) was assessed at respective follow-up up to 5-year. MACCRE was defined as the composite of cardiovascular death, evidence of prosthetic valve dysfunction, stroke, procedure-associated and/or device-associated adverse cardiac events, or kidney dysfunction. Device success, myocardial infarction, and stroke were defined in accordance with VARC-2 definition.

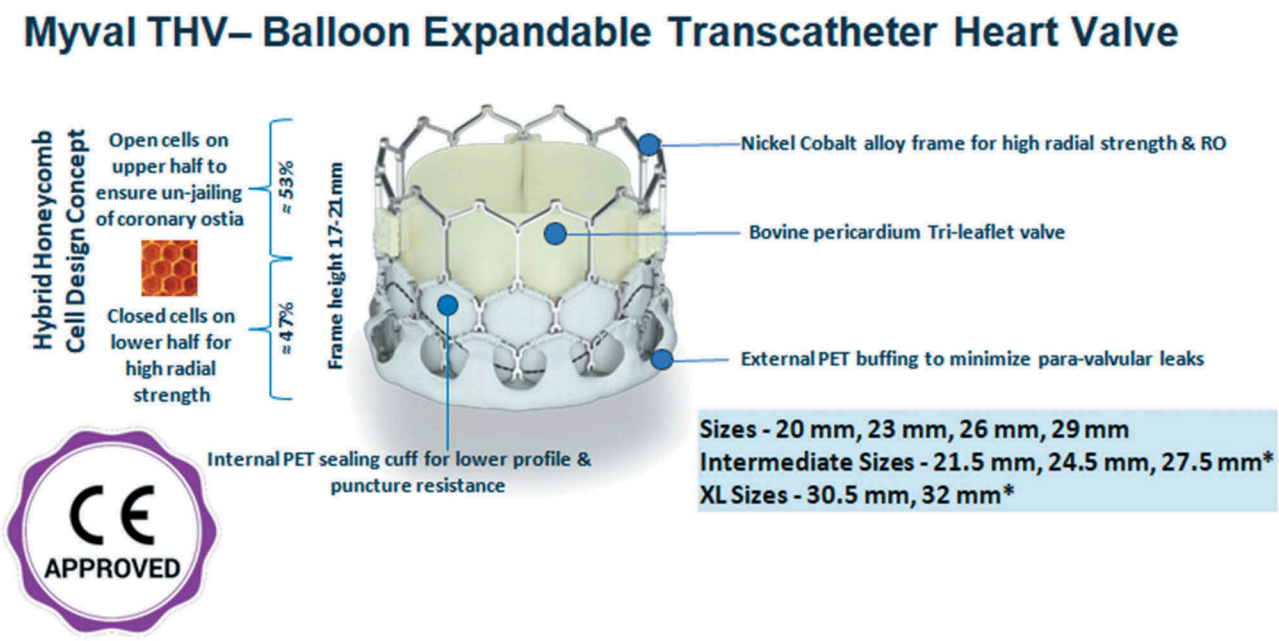
**Results**: The mean STS score of 100 enrolled patients was 5.11 ±1.69%. At one-month post-procedure, there was significant improvement in NYHA functional class, results of six-minute walk test and KCCQ score as compared to baseline. Moreover, EOA, mean and peak aortic-valve gradient, and trans-aortic velocity improved significantly from baseline to discharge through one-month follow-up (Based on the hemodynamic data analysis of initial 30 patients). Three all-cause mortality, one stroke and two permanent pacemaker implantation (one patient had RBBB pre-procedure) were reported at one-month follow-up. The survivorship rate was 97%. [**Echocardiography data of remaining patients is under Corelab analysis and updated hemodynamic data will be presented at conference**].

**Conclusions**: The MyVal-1 study demonstrated favourable safety and efficacy of Myval THV at one-month follow-up. However, long-term follow-up is awaited to further establish the safety and efficacy.

**KEYWORD**: e-P-34

## Disclosure Statement

R. RAO declares a conflict of interest: Proctor for Myval THV Technology. S. SHARMA declares a conflict of interest: External scientific advisors to Meril Life Sciences Pvt. Ltd. P. CHANDRA declares a conflict of interest: Proctor for Myval THV technology. P. GOEL declares a conflict of interest: External scientific advisors to Meril Life Sciences Pvt. Ltd. A. SETH declares a conflict of interest: External scientific advisors to Meril Life Sciences Pvt. Ltd.




*Myval Transcatheter Heart Valve*