

# Structural Heart

## The Journal of the Heart Team

Heart Valve Society 6th Annual Meeting Including  
Abstracts of the ICTEHV Satellite Symposium



ISSN: 2474-8706 (Print) 2474-8714 (Online) Journal homepage: <https://www.tandfonline.com/loi/ushj20>

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

Ravinder Singh Rao, Samin K. Sharma, Praveen Chandra, Gunasekaran Sengottovelu, Prashant Bharadwaj, Pravin Kumar Goel, George Joseph, John Jose, Pratap C Rath, Rajpal K Abhaichand, Rajiv C Nair, Ajit Mallasari S, V.K. Ajith Kumar, Bijulal S, Cholenahally N Manjunath, B. C. Srinivas, T.R. Raghu, Ajaykumar U Mahajan, Ganesh Kumar, Jaspal Arneja, Keyur Parikh, Rajendra Kumar Jain, Shashi Mohan Sharma, Bharat Bhushan Chanana, M.S Hiremath, Jagdish Parikh, Manik Chopra, S. Nagendra Boopathy, Rajneesh Jain, Rony Mathew Kadavil, Rishi Sethi, Sanjay Mehrotra, T. R. Murlidharan, Tarlochan Singh Kler, Vijay Trehan & Ashok Seth

**To cite this article:** Ravinder Singh Rao, Samin K. Sharma, Praveen Chandra, Gunasekaran Sengottovelu, Prashant Bharadwaj, Pravin Kumar Goel, George Joseph, John Jose, Pratap C Rath, Rajpal K Abhaichand, Rajiv C Nair, Ajit Mallasari S, V.K. Ajith Kumar, Bijulal S, Cholenahally N Manjunath, B. C. Srinivas, T.R. Raghu, Ajaykumar U Mahajan, Ganesh Kumar, Jaspal Arneja, Keyur Parikh, Rajendra Kumar Jain, Shashi Mohan Sharma, Bharat Bhushan Chanana, M.S Hiremath, Jagdish Parikh, Manik Chopra, S. Nagendra Boopathy, Rajneesh Jain, Rony Mathew Kadavil, Rishi Sethi, Sanjay Mehrotra, T. R. Murlidharan, Tarlochan Singh Kler, Vijay Trehan & Ashok Seth (2020) Evaluation of Balloon Expandable Transcatheter Heart Valve in the Treatment of Severe Symptomatic Native Aortic Stenosis: The First-in-human MyVal-1 Study, Structural Heart, 4:sup1, 188-189, DOI: [10.1080/24748706.2020.1713659](https://doi.org/10.1080/24748706.2020.1713659)

**To link to this article:** <https://doi.org/10.1080/24748706.2020.1713659>



Published online: 13 Feb 2020.



Submit your article to this journal



View related articles



View Crossmark data



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

Ravinder Singh Rao<sup>a</sup>, Samin K. Sharma<sup>b</sup>, Praveen Chandra<sup>c</sup>, Gunasekaran Sengottovelu<sup>d</sup>, Prashant Bharadwaj<sup>e</sup>, Pravin Kumar Goel<sup>f</sup>, George Joseph<sup>g</sup>, John Jose<sup>g</sup>, Pratap C Rath<sup>i</sup>, Rajpal K Abhaichand<sup>h</sup>, Rajiv C Nair<sup>i</sup>, Ajit Mallasari S<sup>k</sup>, V.K. Ajith Kumar<sup>l</sup>, Bijulal S<sup>l</sup>, Cholenahally N Manjunath<sup>m</sup>, B. C. Srinivas<sup>m</sup>, T.R. Raghu<sup>m</sup>, Ajaykumar U Mahajan<sup>n</sup>, Ganesh Kumar<sup>o</sup>, Jaspal Arneja<sup>p</sup>, Keyur Parikh<sup>q</sup>, Rajendra Kumar Jain<sup>r</sup>, Shashi Mohan Sharma<sup>s</sup>, Bharat Bhushan Chanana<sup>t</sup>, M.S. Hiremath<sup>u</sup>, Jagdish Parikh<sup>v</sup>, Manik Chopra<sup>w</sup>, S. Nagendra Boopath<sup>aa</sup>, Rajneesh Jain<sup>v</sup>, Rony Mathew Kadavil<sup>x</sup>, Rishi Sethi<sup>y</sup>, Sanjay Mehrotra<sup>z</sup>, T. R. Murlidharan<sup>aa</sup>, Tarlochan Singh Kler<sup>ab</sup>, Vijay Trehan<sup>ac</sup>, and Ashok Seth<sup>ad</sup>

<sup>a</sup>Eternal Heart Care and Research Institute Pvt. Ltd., India, Jaipur, Rajasthan, India; <sup>b</sup>Mount Sinai Health System, New York, United States; <sup>c</sup>Medanta-The Medicity, Haryana, India; <sup>d</sup>Apollo Hospital Enterprise Limited, Tamil Nadu, India; <sup>e</sup>Military Hospital Cardio Thoracic Centre, Maharashtra, India; <sup>f</sup>Sanjay Gandhi Post Graduate Institute of Medical Sciences, Uttar Pradesh, India; <sup>g</sup>Christian Medical College & Hospital, Tamil Nadu, India; <sup>h</sup>G. Kuppuswamy Naidu Memorial Hospital, Tamil Nadu, India; <sup>i</sup>Apollo Hospital, Hyderabad, India; <sup>j</sup>Amrita Institute of Medical Sciences, Kerala, India; <sup>k</sup>Madras Medical Mission Hospital, Chennai, India; <sup>l</sup>Sree Chitra Tirunal Institute for Medical Sciences & Technology, Kerala, India; <sup>m</sup>Sri Jayadeva Institute of Cardiovascular Sciences & Research, Karnataka, India; <sup>n</sup>Lokmanya Tilak Municipal Medical College & General Hospital, Maharashtra, India; <sup>o</sup>Dr.L.H.Hiranandani Hospital, Mumbai, India; <sup>p</sup>Arneja Heart and Multispeciality Hospital, Nagpur, India; <sup>q</sup>Care Institute of Medical Sciences, Ahmedabad, India; <sup>r</sup>Krishna Institute of Medical Sciences Hospital, Hyderabad, India; <sup>s</sup>SMS Hospital, Jaipur, India; <sup>t</sup>Maharaja Agrasen Hospital, New Delhi, India; <sup>u</sup>Ruby Hall Clinic, Pune, India; <sup>v</sup>Smt. S R Mehta and Sir K P Cardiac Institute, Mumbai, India; <sup>w</sup>Narayana Multispeciality Hospital, Ahmedabad, India; <sup>x</sup>Lisie hospital, Kerala, India; <sup>y</sup>Lari Cardiology Centre, King George's Medical University, Uttar Pradesh, India; <sup>z</sup>Narayana Institute of Cardiac Sciences, Karnataka, India; <sup>aa</sup>Sri Ramachandra Medical Centre, Chennai, India; <sup>ab</sup>PSRI Heart Institute, New Delhi, India; <sup>ac</sup>Govind Ballabh Pant Hospital, New Delhi, India; <sup>ad</sup>Fortis Escorts Heart Institute, New Delhi, India

**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].

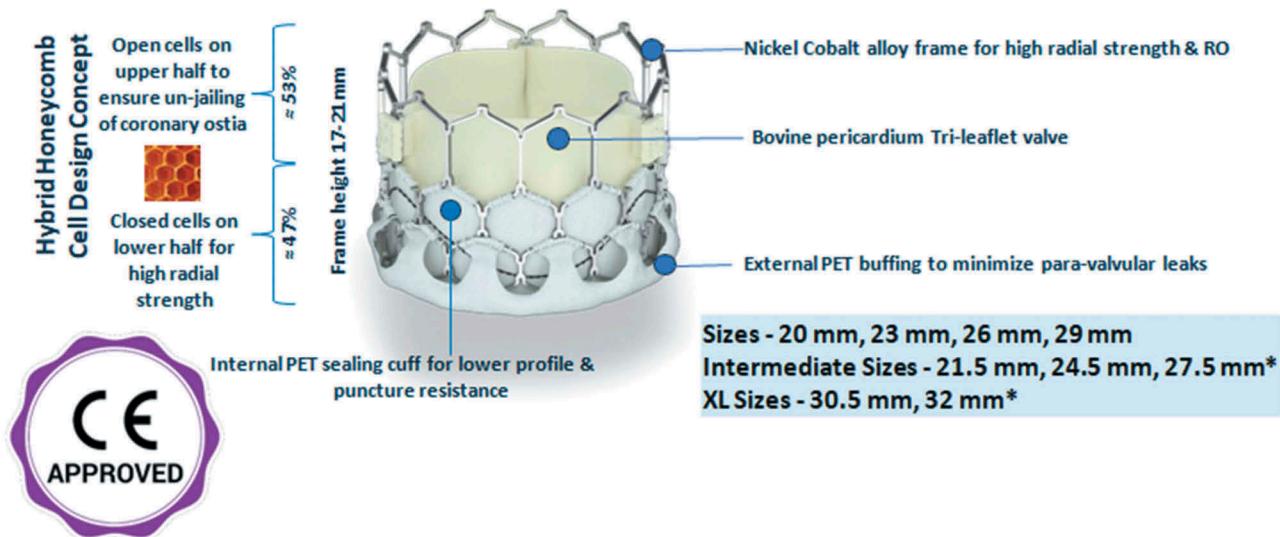
**Conclusions:** The MyVal-1 study demonstrated favourable safety and efficacy of Myval THV at one-month follow-up. However, long-term follow-up is awaited to further establish the safety and efficacy.

**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 THV – Balloon Expandable Transcatheter Heart Valve



Myval Transcatheter Heart Valve