Meril
More to Life

Dafodil
Pericardial Bioprosthesis

Dafodil™-1 Trial: 3-year Outcomes

Clinical safety and performance of Dafodil™ pericardial bioprosthesis for replacing diseased native or prosthetic aortic or mitral valves in patients with advanced valvular heart disease (VHD)

Dafodil™-1 Trial study design

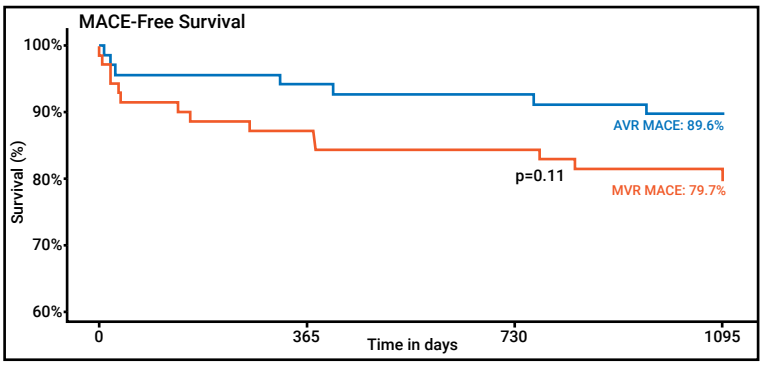
Prospective, multi-center, first-in-human clinical trial

- In this study, between July 2017 and July 2019, 136 patients (aortic: 67 and mitral: 69) were enrolled from 19 centers in India (with mean age—AVR group: 60.2 ± 8.3 years and MVR group: 49.7 ± 14.4 years).
- **Inclusion Criteria:** Patients age ≥18 years with advanced VHD with significant aortic/ mitral stenosis or regurgitation, or combined aortic/mitral valve disease (stenosis and regurgitation) requiring aortic valve replacement (AVR) or mitral valve replacement (MVR) with or without concomitant valve surgery and having surgical risk scores <4%.
- **Primary Endpoints:** (Post-procedure (discharge), 1 month, 6 months, 1 year, 2 years and 3 years):
  (i) Major adverse cardiovascular events (MACE), defined as a composite of all-cause mortality, MI, and stroke.
  (ii) Cardiovascular mortality.

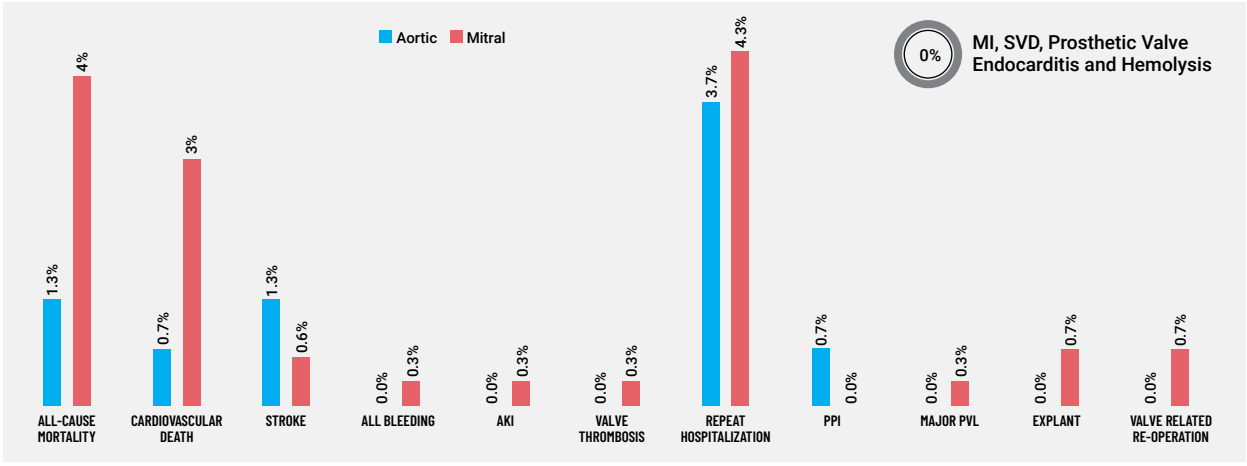
Primary Endpoint

The MACE rate at 3-year follow-up was 2.3% per 100 patient-years in AVR group and 4.7% per 100 patient-years in MVR group

KAPLAN–MEIER ESTIMATES OF MACE-FREE SURVIVAL IN AVR AND MVR GROUPS



3-year Primary and Secondary Outcomes



Hemodynamic Performance (Baseline vs. 3 year FU)

		AVR group (n=67)	MVR group (n=69)
Mean Pressure Gradient (mmHg)	Baseline	51.2±24.1	8.8±5.0
	3-year	11.1±6.0	4.4±1.7
Effective Orifice Area (cm^2)	Baseline	0.9±0.6	0.7±0.4
	3-year	1.8±0.4	1.1±0.4

- There was significant improvement in New York Heart Association functional class and mean SF-12 scores in both groups

AVR Vs. MVR Group (At 3-year)

MACE	Valve thrombosis	Valve-related re-operation
2.3% vs 4.7%	0% vs 0.3%	0% vs 0.7%

- The Dafodil™ -1 trial demonstrated satisfactory outcomes of clinical safety, hemodynamic performance, and quality-of-life metrics.
- Additionally, no incidence of structural valve deterioration and very low rates of valve thrombosis during the 3-year follow-up period of Dafodil™ -1 first-in-human trial indicated acceptable valve durability up to three years and similar outcomes are warranted for longer follow-ups.

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Hiremath CS, et al. Frontiers in Cardiovascular Medicine. 2024 May 30;11:1393762