Thirty-Day Outcomes Following Transfemoral Transseptal Transcatheter Mitral Valve Replacement: Intrepid™ TMVR Early Feasibility Study Results

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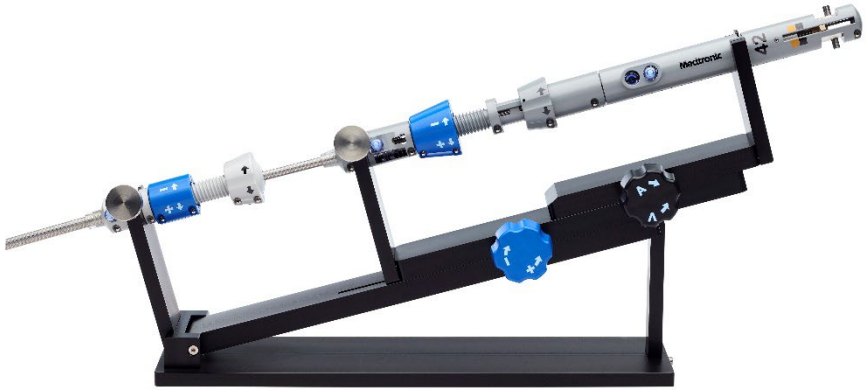
Intrepid™ TMVR System

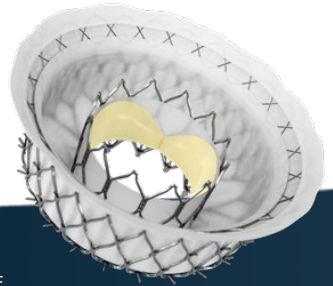
Intrepid™ TMVR Delivery System

- Transfemoral access with dilator and 35-Fr sheath
- Cradle and delivery catheter with familiar transeptal MV maneuvers



Intrepid™ Valve Design

- Conformable outer stent anchors without leaflet capture
- Circular inner stent with 27 mm tri-leaflet bovine pericardial valve; symmetrical design without need for rotational alignment
- 42- & 48-mm valves currently and 54-mm valve in development
- Identical valve design used in transapical studies

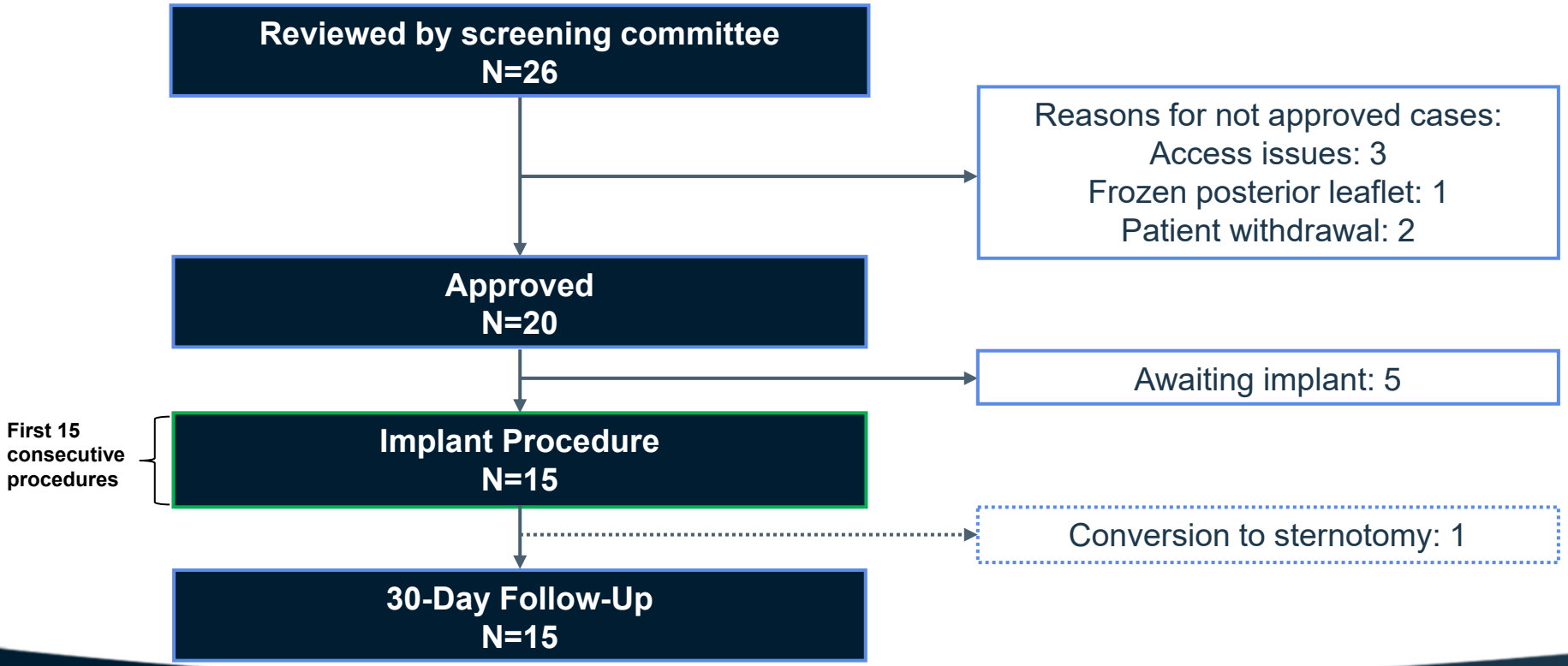


Study Overview

- Prospective, multicenter, non-randomized early feasibility study
- Clinical and echo outcomes according to MVARC criteria[1]
- External physician screening committee
- Protocol-specified echo acquisition reviewed by an echo core laboratory (Mayo Clinic, Rochester, MN)
- Independent CEC adjudication of safety events

[1]Stone, et al. JACC 2015; 66(3):308-21

Patient Screening and Enrollment



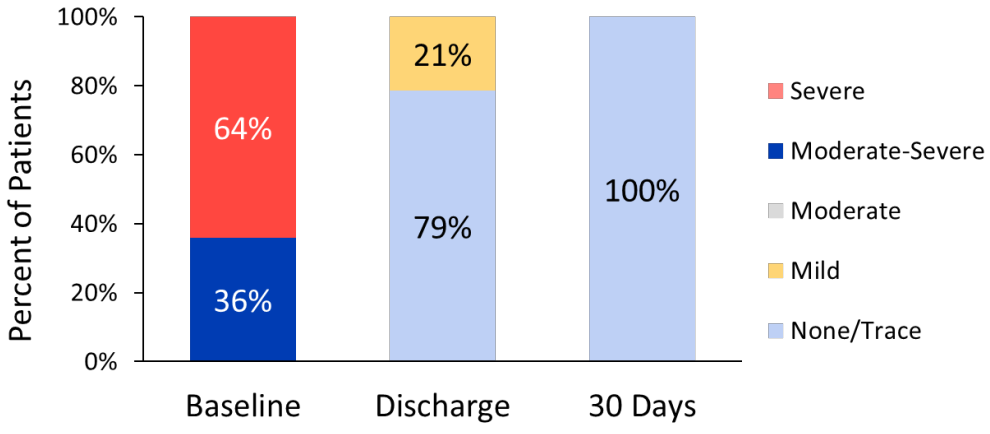
30-Day Clinical Outcomes

30-Day clinical outcomes (N=15)	# of patients
All-cause mortality	0
Stroke or transient ischemic attack	0
Reoperation (or reintervention)	0
New pacemaker implantation	0
≥Stage 2 acute kidney injury	0
≥ MVARC major bleeding events	7
Major vascular complications*	6
Cardiovascular rehospitalization (related to minor vasc. complication)	1

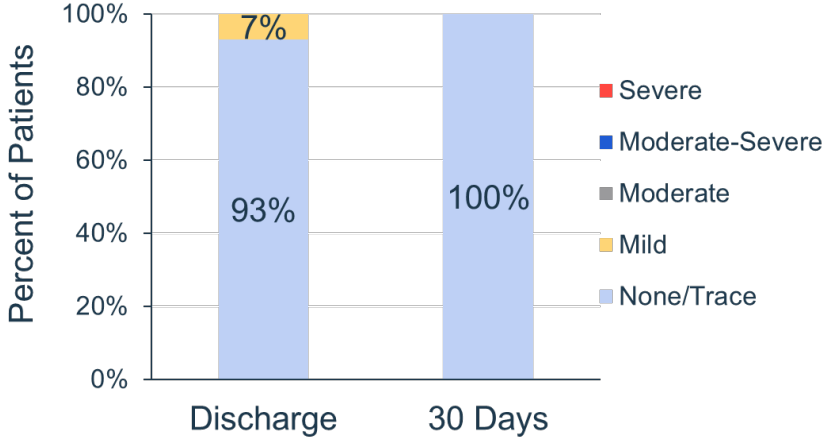
Values reported as number of patients with event. *Six access-site complications. Anticoagulation regimen of 5 of 6 patients with major vascular complications included antiplatelets and warfarin

30-Day Echocardiographic Outcomes (N=14)

Mitral Regurgitation

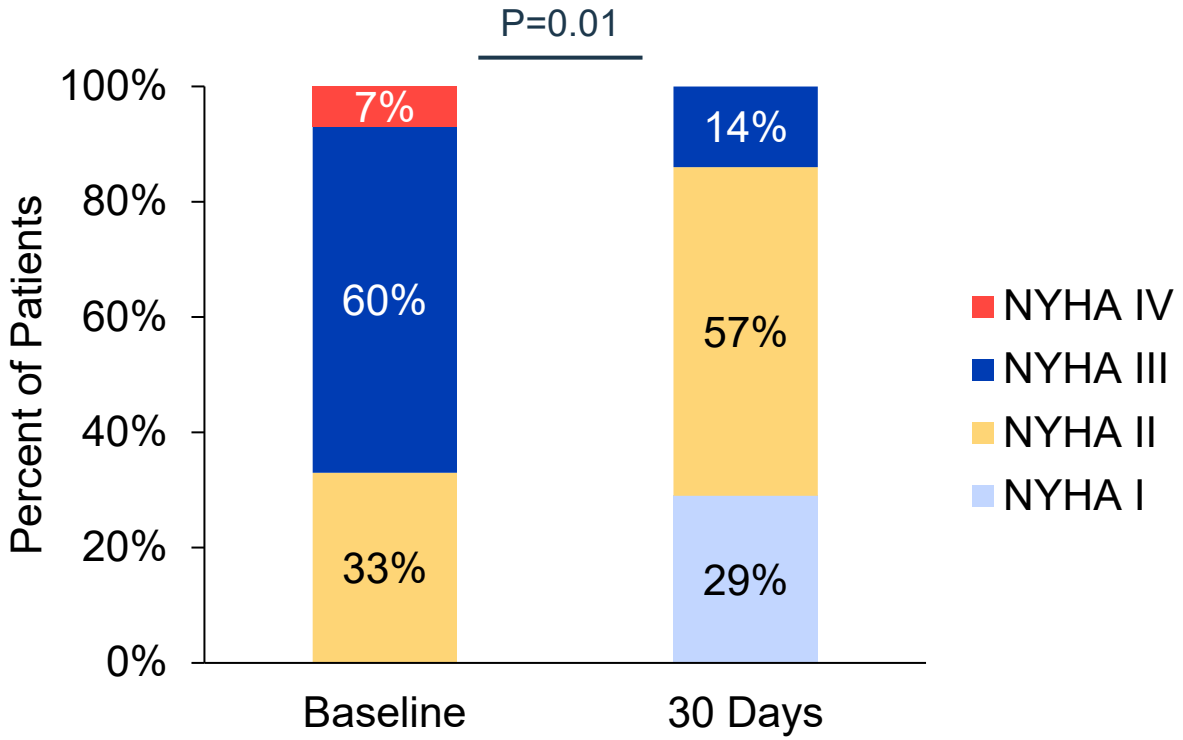


Paravalvular Leak



30-Day Functional Outcomes (N=15)

NYHA Classification



Summary

30-day results from the Intrepid TMVR Transfemoral Early Feasibility Study demonstrate:

- No mortality, stroke, reintervention, or new pacemaker implantation
- ~50% patients with ≥ major bleeding events (largely due to access site major vascular complications)
- Favorable hemodynamics with almost complete elimination of MR at 30 days
- Improved NYHA class