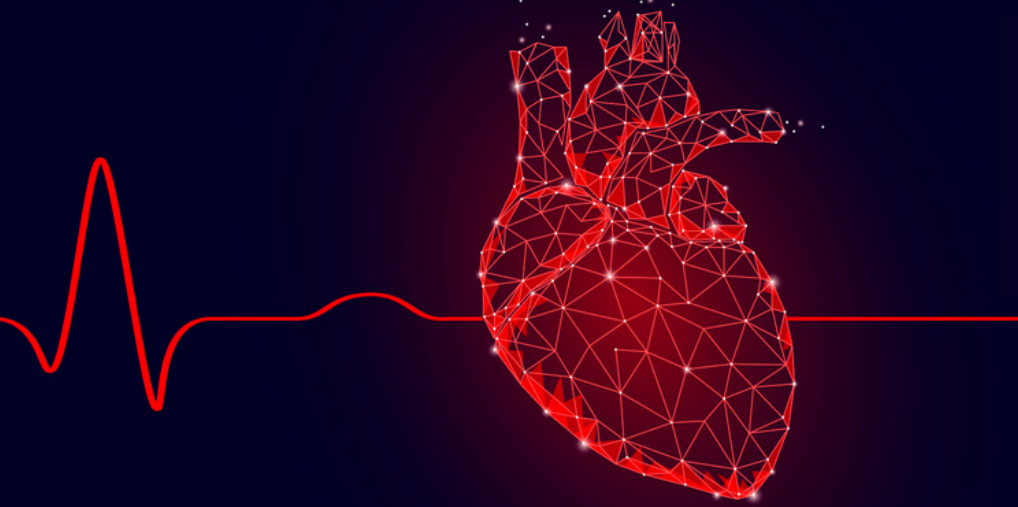




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Percutaneous transcatheter valve replacement in individuals with mitral regurgitation unsuitable for surgery or transcatheter edge-to-edge repair: a prospective, multicountry, single-arm trial (ENCIRCLE trial)

Population	Intervention	Comparison	Outcomes
299 patients with symptomatic MR ≥3+, NYHA ≥II, GDMT optimized for at least 30 days, unsuitable for surgery or commercially available transcatheter treatment options due to clinical, anatomic, or technical considerations Key exclusion criteria: • LVEF < 25% • LVEDD ≥ 75 mm • Need for other valvular intervention in next 12 months • Irreversible, severe pulmonary hypertension • Severe right ventricular dysfunction • eGFR < 30 mL/min/1.73m2	TMVR with Sapien M3 system • Transseptal sytem • Single-arm study • Follow-up: 30 days, 6 months, 1 year, and annually through 5 years	Performance Goal of 45% at 1-year No comparator group was directly available for this patient population Performance goal was based on event rates from the optimized medical therapy arm of RCTs (COAPT trial, MITRA-FR trial) investigating mTEER intervention available at the time of trial design	• The primary endpoint of a non-hierarchical composite of all-cause mortality or heart failure hospitalization was achieved at 1 year with results significantly better than the performance goal (25.2% vs 45%) • <1% all-cause mortality at 30 days • 96% achieved MR 0/1+ at 1 year • Patients treated with the SAPIEN M3 system had significant improvements in health status, including an 18-point increase in KCCQ-OS score at 1 year

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