COMENTÁRIO A ARTIGO CIENTÍFICO

Autor do Comentário a Artigo Científico:
André Cabrita, *fellow* da subespecialidade de Cardiologia de Intervenção na ULS São João

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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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Legenda: eGFR: estimated glomerular filtration rate; GDMT: Guideline-directed medical therapy; LVEF: left ventricular ejection fraction; LVEDD: left ventricular end-diastolic diameter; MR: mitral regurgitation; NYHA: New York Heart Association; TMVR: transmitral valve replacement