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Initial Feasibility Study of a New Transcatheter Mitral Prosthesis: The First 100 Patients

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Abstract

Background:

Transcatheter mitral valve replacement (TMVR) is a rapidly evolving therapy. Follow-up of TMVR patients remains limited in duration and number treated.

Objectives:

The purpose of this study was to examine outcomes with expanded follow-up for the first 100 patients who underwent TMVR with the prosthesis.

Methods:

The Global Feasibility Study enrolled symptomatic patients with either primary or secondary mitral regurgitation (MR) who were at high or prohibitive surgical risk. The present investigation examines the first 100 patients treated in this study. Clinical outcomes through last clinical follow-up were adjudicated independently.

Results:

In the cohort (mean age 75.4 ± 8.1 years; 69% men), there was a high prevalence of severe heart failure symptoms (66%), left ventricular dysfunction (mean ejection fraction $46.4 \pm 9.6\%$), and morbidities (Society of Thoracic Surgeons Predicted Risk of Mortality, $7.8 \pm 5.7\%$). There were no intraprocedural deaths, 1 instance of major apical bleeding, and no acute conversion to surgery or need for cardiopulmonary bypass. Technical success was 96%. The 30-day rates of mortality and stroke were 6% and 2%, respectively. The 1-year survival free of all-cause mortality was 72.4% (95% confidence interval: 62.1% to 80.4%), with 84.6% of deaths due to cardiac causes. Among survivors at 1 year, 88.5% were New York Heart Association function class I/II, and improvements in 6-min walk distance ($p < 0.0001$) and quality-of-life measurements occurred ($p = 0.011$). In 73.4% of survivors, the Kansas City Cardiomyopathy Questionnaire score improved by ≥ 10 points.

Conclusions:

In this study of TMVR, which is the largest experience to date, the prosthesis was highly effective in relieving MR and improving symptoms, with an acceptable safety profile. Further study to optimize the impact on long-term survival is needed.

Keywords: mitral; regurgitation; surgery; transcatheter.

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