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STRUCTURAL

First-in-Human Transcatheter Tricuspid Valve Repair

30-Day Follow-Up Experience With the Mistral Device

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ABSTRACT

OBJECTIVES This study sought to report short-term results of safety, performance, and efficacy of the Mistral device first-in-human study in patients suffering from severe functional tricuspid insufficiency.

BACKGROUND Patients who suffer from severe tricuspid regurgitation (TR) and who are at high surgical risk have no standard care therapy. Therefore, minimally invasive and safer methods are sought. The Mistral device is an investigational spiral-shaped device intended for percutaneous transcatheter repair. The Mistral device approximates the tricuspid leaflets by grasping together the chordae tendineae of the tricuspid valve.

METHODS Seven patients (4 women; mean age 73.14 ± 7.4 years) with severe (n = 5) and massive (n = 2) symptomatic TR and high surgical risk underwent Mistral tricuspid repair under transesophageal echocardiography guidance.

RESULTS Mistral was successfully implanted in all cases with a single device deployed in 6 patients, with 2 devices deployed in 1 patient. No procedural or 30-day adverse events occurred. TR was reduced by at least 1 grade in all patients. Effective regurgitant orifice area was reduced from median 0.52 cm^2 (interquartile range [IQR]: 0.40 to 0.60 cm^2) at baseline to 0.15 cm^2 (IQR: 0.14 to 0.21 cm^2) at 30 days post-procedure ($p < 0.01$), vena contracta width was reduced from 0.95 cm (IQR: 0.81 to 1.16 cm) to 0.62 cm (IQR: 0.52 to 0.67 cm) ($p < 0.05$), and regurgitant volume decreased from 49.4 ml/beat (IQR: 45.2 to 57.7 ml/beat) to 19.7 ml/beat (IQR: 12.4 to 23.9 ml/beat) ($p < 0.01$). Right ventricular fractional area change improved from 27.0% (IQR: 21.3% to 33.5%) at baseline to 38.5% (IQR: 29.0% to 47.1%) at 30-day follow-up ($p < 0.05$). Significant improvements in New York Heart Association functional class, Kansas City Cardiomyopathy Questionnaire score, and 6-min walk test were observed at 30 days.

CONCLUSIONS Tricuspid valve repair with the Mistral device appears safe and leads to 30-day reduction of tricuspid insufficiency and improvement of right ventricular function and exercise capacity. (J Am Coll Cardiol Intv 2020;13:2091–6)

The tricuspid valve was known for many years as the "forgotten valve." Although percutaneous solutions for treatment of the mitral and aortic valves have been available for several years, there are only very few devices, mostly investigational, with limited experience that are used for treating the tricuspid valve (1).

Functional TR medical treatment mainly includes intravascular volume management and is of limited efficacy. Surgical repair of functional TR is usually done during operations for mitral regurgitation (MR) in patients with left ventricular heart failure (2), which consequently caused right ventricular (RV) enlargement, remodeling, and tricuspid annular

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the *JACC: Cardiovascular Interventions* author instructions page.

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