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EDITORIAL COMMENT

A Step Forward for Transcatheter Tricuspid Valve Repair*

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Secondary tricuspid valve regurgitation (TR) occurs because of a combination of tricuspid annulus dilatation and leaflet tethering related to right ventricular chamber enlargement. Factors predisposing to secondary TR include chronic atrial fibrillation and pulmonary hypertension, often in the setting of left-sided heart disease. The degree of tricuspid annular dilatation can be extreme and occurs to a greater extent than seen in mitral regurgitation. Consequently, the severity of TR can far exceed the "severe" threshold vena contracta width of >7 mm, leading to the recent recommendation for expanded grading of TR to include "massive" and "torrential" classifications (14 mm to 20 mm and >21 mm, respectively) (1). Despite the poor prognosis associated with unoperated severe TR (2,3), isolated tricuspid valve surgery is uncommonly performed and is associated with increased risk because of comorbidities including prior cardiac surgery, right ventricular dysfunction, advanced age, and frailty (4,5). Accordingly, multiple novel transcatheter tricuspid valve repair systems have been developed and are in various stages of investigation.

The FORMA system (Edwards Lifesciences, Irvine, California) is one of the first transcatheter tricuspid valve repair systems to be used in humans, with initial 30-day results reported in 2015 (6). The FORMA device, distinct from other transcatheter tricuspid valve technologies involving direct annuloplasty or leaflet plication, uses a transcatheter rail anchored in the interventricular groove of the right ventricle to deliver a spacer occupying the center of the dilated tricuspid valve annulus, allowing for leaflet coaptation onto the surface of the spacer, to reduce TR. In this issue of *JACC: Cardiovascular Interventions*, Perlman et al. (7) report the 1-year results of the initial 18 patients who underwent the FORMA procedure. As expected, the severe TR population undergoing the FORMA procedure was older (mean age, 76 years), with 89% having atrial fibrillation and 72% having had previous open heart surgery. It is noteworthy that most patients in the study had very severe TR at baseline, with mean vena contracta width of 12.1 ± 3.3 mm in the overall group, reflecting an extreme disease state.

SEE PAGE 1994

DEVICE SAFETY

The first-generation FORMA device was successfully implanted in 16 (89%) cases, with 1 failure caused by anchor dislodgement within hours of the procedure, and another caused by right ventricular perforation necessitating emergency sternotomy for repair and concomitant tricuspid annuloplasty. There was 1 incidental finding of device thrombosis that resolved with appropriate anticoagulation. Despite the high risk nature of this population surprisingly no deaths occurred in the first year and there were no other major device-related complications. Although the FORMA procedure itself is simple in design, the vulnerability of the thin-walled right ventricle to injury and variability in right ventricular anatomy may explain the observed risks of right ventricular injury and anchor dislodgement. Improvements in patient selection, procedural techniques, and iterative improvements in delivery catheter steerability hold the potential to lower risk of these complications, and/or allow application to patients with more challenging right ventricular anatomy because of

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extreme angulation, prominent trabeculations, or unfavorable pre-existing pacemaker/defibrillator lead location.

DEVICE EFFICACY

In most patients, the FORMA device reduced TR severity by ≥1 grade, with 69% of patients having less than or equal to moderate-severe residual TR at 30 days. A total of 19% of patients experienced further reduction of TR to less than or equal to moderate at 1 year, likely indicating the occurrence of right ventricular reverse remodeling in these patients. Another 19% of patients, however, had recurrent "very severe" TR at 1 year after device implantation, perhaps because of inadequate initial TR reduction, changes over time in device location within the annulus, or progressive annular dilatation. Quantification of TR after the FORMA device has been implanted can be challenging because of distortion of the TR jet and device-related acoustic shadowing. Despite uncertainty about degree of TR reduction, right atrial pressure decreased acutely in almost all patients (mean right atrial pressure reduction from 15 to 12 mm Hg) and invasive right heart catheterization was available in 5 patients at 30-day follow-up, confirming a significant reduction in right atrial pressure and increase in the cardiac index. At 1 year a sustained decrease in right ventricle dimensions coupled with TR reduction were observed in 28% of patients (none of whom had severe pulmonary hypertension at baseline). The addition of a larger spacer device (18 mm) is expected to improve TR reduction in patients with larger effective regurgitant orifice areas, which seem to represent a large proportion of the population considered for transcatheter repair. Significant improvements in quality of life metrics including 6-min walk distance, Kansas City Cardiomyopathy Questionnaire, and New York Heart Association functional class were observed at 6 months and 1 year despite a high prevalence of greater moderate residual TR.

Despite encouraging 1-year data of the early FORMA experience, several questions remain. Because of limitations of color Doppler assessment of TR after FORMA implantation, alternative techniques are needed to measure procedural results. Enhanced 3-dimensional quantitative techniques and indirect methods of assessment, such as hepatic vein Doppler velocities and Doppler-derived left ventricular stroke volume index, may hold promise for assessment of the hemodynamic effects of this device. Whether pre-procedural hemodynamic and anatomic imaging data can predict which patients may benefit most from tricuspid valve repair remains unanswered. Other burning questions include: How much residual TR is acceptable in order to translate to meaningful improvements in clinical outcomes? Which clinical, echocardiographic, and biomarker outcomes should be used to gauge success and at what time points? Can improvements in device design and procedural techniques improve technical success and reduce the risk of right ventricular injury and anchor dislodgement? Continued work in the U.S. Early Feasibility Trial (NCT02471807) and SPACER (Repair of Tricuspid Valve Regurgitation Using the Edwards TricuSPid TraAnsCatheter REpaiR System) trials (NCT02787408) will provide further insight into these important questions. It is likely that long-term data beyond 30 days will be necessary to detect serial improvements that may occur in right ventricular size and function, renal and hepatic function, edema, diuretic requirements, and quality of life. The important data gained from these studies will inform the design of a pivotal randomized controlled trial that better measures the benefit of this exciting new therapy, which promises to open a new door for patients with severe secondary TR.

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