First-in-Man Implantation of a Tricuspid Annular Remodeling Device for Functional Tricuspid Regurgitation

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Tricuspid regurgitation (TR) is a common finding in patients with left-sided disease, and is associated with poor outcome and predicts poor survival, heart failure, and reduced functional capacity (1). It is common after mitral valve treatment in rheumatic or ischemic mitral regurgitation, if left untreated at the time of mitral surgery. In this subgroup with long-standing TR, managed medically for a long time, surgical correction can be more prohibitive due to the presence of variable degrees of right ventricular (RV) dysfunction, pulmonary vascular disease, and right heart failure. The pre-operative condition of the RV and the severity of secondary renal and hepatic impairment are predictors of limited survival (2,3). Percutaneous procedures may be an attractive alternative to surgery for patients deemed to be high-risk surgical candidates. While the development and clinical use of percutaneous approaches to the aortic valve and mitral valve have been widespread over the past few years, limited data are available about the feasibility and efficacy of percutaneous tricuspid valve (TV) therapies (4,5).

The TriCinch System (4Tech Cardio Ltd., Galway, Ireland) is a percutaneous device designed for TV remodeling, by means of a transfemoral fixation of a stainless steel corkscrew into the anteroposterior TV annulus. The corkscrew is connected through a Dacron band to a self-expanding nitinol stent. By pulling the system towards the inferior vena cava (IVC), the anchoring corkscrew remodels the anteroposterior annulus, and the tension is maintained by fixation of the stent in the IVC. The stent is available in different sizes (27 to 43 mm in diameter, 60 mm in length) to guarantee oversizing in the hepatic region of the IVC (Figure 1). The “first-in-man” patient was a 72-year-old woman with severe functional TR associated with tricuspid annular dilation. She was admitted in New York Heart Association functional class III after 2 episodes of decompensated heart failure in the previous 2 months, presenting with edema of the lower extremities, moderate ascites, jugular venous distension, with moderate liver dysfunction due to hepatitis C (unconjugated bilirubin 2.7 mg/dl) and normal kidney function (creatinine 1 mg/dl, glomerular filtration rate 57.8 ml/min). She had a clinical history of permanent...
atrial fibrillation and prior aortic valve replacement with a bioprosthesis. The STS Score risk of mortality was 5.2% (morbidity or mortality 34.7%). Transesophageal echocardiography revealed grade 4+ TR (with systolic hepatic vein flow reversal, 9 mm lack of coaptation, and septolateral dimension of 46 mm at transthoracic echocardiography [TTE] assessment) (Figure 2), moderate right ventricular dysfunction (tricuspid tissue Doppler imaging systolic velocity 8 cm/s and systolic pulmonary artery pressure 42 mm Hg) with a normal functioning mitral valve, maintained aortic prosthesis function (mean gradient 6 mm Hg), and normal left
ventricular ejection fraction. After multidisciplinary heart team agreement on the transcatheter TV repair option with the TriCinch System, the patient was enrolled in the PREVENT (Percutaneous Treatment of Tricuspid Valve Regurgitation With the TriCinch System; NCT02098200) study. Procedural planning, based on cardiac computed tomography (CT) scan, predicted the safe anchoring area at the level of the anterior tricuspid annulus (between the right coronary artery and anterior leaflet’s hinge) (Figure 3A) and the adequate stent size to be used to guarantee the best vessel oversizing (IVC mean diameter 26 mm, oversizing 60%). The intervention was performed under general anesthesia, fluoroscopy, as well as intracardiac and transesophageal echocardiography guidance. A 10-F intracardiac echocardiography probe was inserted via the left femoral vein and a Judkins right guiding catheter via the left femoral artery to perform right coronary angiography. A 24-F Gore Dry-seal sheath was inserted in the right femoral vein for insertion of the 18-F steerable TriCinch delivery system into the right atrium. The tip of the delivery system was steered toward the target site on the tricuspid annulus. The corkscrew was inserted into the annulus. Any interference with the right coronary artery was ruled out by selective angiography (Figure 3B). The system was tensioned under echo guidance until a reduction in septolateral dimension (intraoperative at transesophageal echocardiography from 41 mm to 38 mm) and in TR grade (from 4+ to 3+) was observed (Figure 4, Online Video 1) and 5-mm coaptation length became evident. The cinching of the tricuspid annulus was maintained by implantation of a 43-mm self-expanding nitinol stent in the IVC between the hepatic veins and the right renal vein (Figure 3C). The procedure was completed uneventfully in 56 min, and the patient was discharged 5 days later, with TTE documenting the maintained remodeling of the TV (TR grade 3+ and septolateral diameter of 40 mm at TTE assessment) and showing the device correctly in place with continued tension on the annulus. At 6-month follow-up, the patient was in good functional status with improved quality of life.

The TriCinch is the first dedicated TV repair device to be evaluated in humans in a prospective trial. The design concept of the TriCinch system was initially based on mimicking the Kay procedure by cinching at the anteroposterior commissure and reducing septolateral dimensions. This first-in-man case demonstrates the feasibility and safety of the percutaneous remodeling of the TV by implanting the TriCinch device, associated with reduction in annular dimensions and TR severity. Although the device only resulted in a modest reduction in TR, this may be sufficient for symptomatic improvement in these patients in whom elimination of TR may be harmful. This also raises the question as to whether the correct
measure of efficacy in patients with severe TR is echocardiographic or symptoms and quality of life. Longer-term follow-up and more patients are required to confirm these initial results and will define the risk–benefit balance of future TR treatment strategies.

**REFERENCES**