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Transcatheter tricuspid valve repair with a new transcatheter coaptation device for the treatment of severe tricuspid regurgitation - One-year clinical and echocardiographic results

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THEME: Interventions for Valvular Disease
TOPIC(S): Tricuspid / Pulmonary valve

AIMS

To report the first-in-man 1 year clinical and echocardiographic outcomes of a novel trans-catheter device, the FORMA device (Edwards Lifesciences, Irvine, CA), for treating high risk patients with severe tricuspid regurgitation

METHODS AND RESULTS

Patients were treated at two centers in Canada and a center in Switzerland under the conditions of compassionate-care programs. These were the first-in-man procedures performed worldwide. Follow-up was done at 30 days and 1 year and included clinical and echocardiography evaluation. One center performed invasive hemodynamic evaluation at 30 days.

18 patients were treated and completed 30 days follow up, 15 patients completed 1 year follow up. Device implantation was successful in 16 (89%) patients, one device dislocated on day 1 and another patient required conversion to open-heart surgery for right ventricle perforation. There were no deaths by 1 year and rates of re-hospitalization for heart failure were reduced significantly (one event).

In 14 patients with a successful device implantation and 1 year follow up, 79% were in New York Heart Association class I/II ($p<0.001$ compared with baseline), the average 6 minute walk test increased by 72 meters ($p=0.04$) and the KCCQ heart failure score improved by 17 points ($p=0.08$) compared with baseline.

Echocardiography showed a reduction of tricuspid regurgitation from severe in all patients at baseline to moderate or less in 11/16 patients (69%) by 30 days ($p=0.001$) and 4/13 patients (31%) by 1 year ($p=0.02$). The diameters of the tricuspid annulus and the right ventricle were both reduced by 1 year (46 ± 6mm vs. 43 ± 4mm, $p=0.12$; 56 ± 7 vs. 50 ± 5mm, $p=0.01$, respectively).

Hemodynamic evaluation at 30 days of right atrial pressures in 6 patients showed that the mean atrial pressure decreased from 15.2 ± 4.6 mmHg to 11 ± 7.0 mmHg ($p=0.08$) and the atrial systolic V wave from 25.1 ± 7.7mmHg to 16.8 ± 10.3mmHg ($p=0.049$). Cardiac output increased by 1.3 ± 1.9 L/min but this change was not statistically significant.

There were no device infections, pulmonary embolisms or significant arrhythmias noted after discharge in all patients. No late dislocations of the devices were observed. There was one case of thrombus noted on a device at 4 months, in a patient with warfarin treatment for atrial fibrillation and non-therapeutic INR measurements. The thrombus resolved uneventfully with resumption of adequate anti-coagulatio

CONCLUSIONS

Our first-in-man experience with the FORMA device in high risk non-operable patients with severe tricuspid regurgitation shows feasibility with a good mid-term safety profile. 1 year follow up revealed significant clinical improvements and reductions in right ventricular dimensions despite variable success in consistently reducing tricuspid regurgitation.