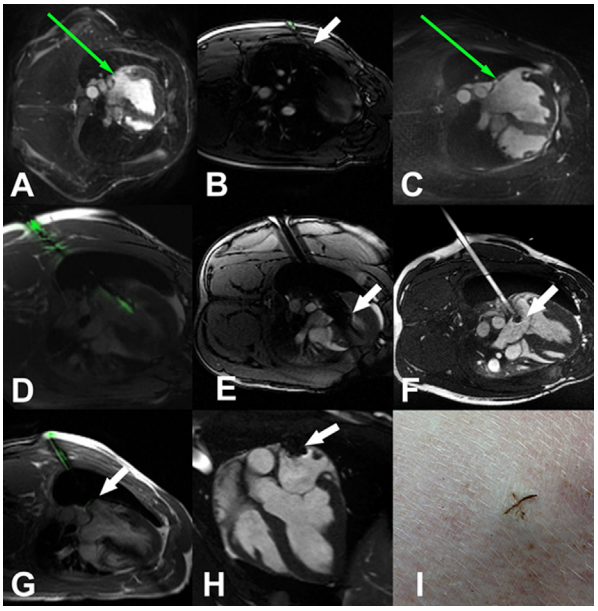

OTHER

CRT-822

Support System of Bioprosthetic Valves With A Heart Shape Commissural Post

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BACKGROUND Bioprosthetic valves fail due to torn leaflets as a result of increased forces applied on the commissural posts during the cardiac cycle. To face this problem a novel Support System (stent) with large openings at the Commissural posts made from acetal copolymer (POM-C) or Titanium has been developed. The hydrodynamic performance and durability of bioprosthetic valves constructed using this stent went under evaluation.

METHODS This stent was initially designed to accommodate aortic and pulmonary valves derived from marine mammal origin (Phoca Groelandica), showing excellent hydrodynamic performance when tested in a steady flow system. The same stent was used to create three trileaflet composite porcine valves of 23mm (titanium), 27mm and 31mm (POM-C) in diameter and one 25mm (titanium) bovine pericardial valve wrapped around the stent. All valves were tested in a steady flow system. The three porcine valves underwent fatigue accelerating testing to define their long term durability.

RESULTS For the porcine valves the peak pressure was measured as 12.5mmHg, 9.1 mmHg and 7.3mmHg for the 23mm, 27mm and for the 31mm valve respectively. The 25mm pericardial valve showed a peak pressure of 5.5mmHg. The durability test showed valve deterioration after 225x106cycles for the 23mm, 265x106 cycles for the 27mm and 240x106 cycles for the 31 mm, values far above the passing standards according to ISO/DIS 5840.

CONCLUSION This novel stent for bioprosthetic valves offers excellent hydrodynamic performance for a variety of biological issues tested and above the standards long term durability, possibly due to the amelioration of forces applied on the commissural posts during the cardiac cycle.

CRT-823

Transcatheter Extra-Cardiac Tricuspid Annuloplasty

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BACKGROUND We designed and built a device that is positioned along the atrioventricular groove in the pericardial space and tightened to modify the geometry of the tricuspid annulus to treat functional tricuspid regurgitation. The device is delivered to the pericardial space from within via trans-atrial puncture.

METHODS 15 swine, including 3 with dilated right heart and functional tricuspid regurgitation, underwent extra-cardiac tricuspid annuloplasty. The pericardial space is accessed with large (12-14Fr) sheaths from a femoral vein, through the right atrium and by puncture through the right atrial appendage. A self-orienting nitinol compression device is then deployed around the atrioventricular groove and tightened to exert compressive force to the free-wall of the tricuspid annulus. The atrial puncture site is closed with an off-the-shelf nitinol closure device.

RESULTS In all 15 animals, trans-atrial pericardial access was uncomplicated and the device was delivered successfully. Tricuspid septal-lateral and antero-posterior dimensions, annular area and perimeter were reduced by 49%, 31%, 59% and 24% ($p<0.001$) respectively. Tricuspid leaflet coaptation length was increased by 53% ($p<0.001$). The degree of annuloplasty correlated closely with the tension delivered to the device ($r2=0.94$, $p<0.001$). Coronary artery compression was not observed in any animal, but a bridge-shaped protection element can be positioned over an underlying vessel to deflect compressive force. 9 animals were survived for mean 9.7days and tricuspid geometric changes were maintained. In the 3 animals with functional tricuspid regurgitation, severity of regurgitation by intracardiac echocardiography was reduced. Small pericardial effusions were observed immediately post-procedure but had completely resolved at follow-up. Post-mortem examination demonstrated fibrotic encasement of the device along the atrioventricular groove and no tissue erosion. There was no evidence of pericarditis or adhesions between visceral and parietal pericardial layers.

CONCLUSION This is the first extra-cardiac structural intervention performed from within via trans-atrial puncture. The degree of tricuspid annuloplasty achieved is comparable to current surgical techniques. The trans-atrial pericardial access port is safely closed with off-the-shelf devices, with no evidence of cardiac tamponade in swine.

CRT-824

Does Angio-Seal Have a Role in Femoral Vascular Closure Following Transcatheter Aortic Valve Replacement?

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BACKGROUND Femoral access closure post transcatheter aortic valve replacement (TAVR) remains challenging. The Perclose ProGlide (PP) device has been utilized in a dual pre-close strategy; however, failure of this technique occurs in approximately 10% of cases. This study examined the utility of Angio-Seal (AS) in selected cases where hemostasis is not achieved with the dual PP alone.

METHODS Patients who received a percutaneous transfemoral TAVR with the use of at least two PP and, given residual bleeding, subsequently received one AS device, were included. This cohort was divided into two groups: a success group (full homeostasis with two PP and one AS), and a failure group (required additional interventions). The baseline and procedural characteristics, in-hospital VARC-2 major and minor vascular access site and bleeding complications, change in hemoglobin of $\geq$3 g/dL, and blood transfusions were compared.

RESULTS A total of 169 patients (57% male, mean 83.7 years) underwent femoral closure with at least two PP followed by one AS. Complete hemostasis was obtained in 140 (83%) cases (Table). In the failure group, there were higher rates of hypertension (systolic aortic pressure 192±28 vs. 129±18 mmHg, $p=0.015$ and diastolic aortic pressure 68±11 vs. 42±15 mmHg, $p=0.050$).

CONCLUSIONS The utility of the AS technique when a pre-close PP strategy fails in patients with difficulty in femoral hemostasis after TAVR is feasible. Even when this strategy fails, hemostasis is achieved with conventional techniques without requiring surgery.

Characteristics	Success Group With Angio-Seal (n=140)	Failure Group With Angio-Seal (n=29)	p-Value
Manual compression	0% (0/140)	14% (4/29)	p<0.001
Additional closure device(s) prior to Angio-Seal	0% (0/140)	7% (2/29)	p=0.020
Balloon cross-over technique	15% (20/137)	29% (8/28)	p=0.009
Total access site percutaneous intervention	7% (7/107)	21% (6/28)	p=0.028
Access site surgical intervention	3% (3/107)	0% (0/29)	p=1.000
Decrease in hemoglobin of $\geq$3 g/dL	8% (9/107)	8% (2/25)	p=1.000
VARC-2 major and minor vascular complications	16% (22/133)	30% (8/27)	p=0.174
VARC-2 major and minor bleeding complications	11% (14/132)	15% (4/28)	p=0.220
Post-procedural blood transfusion	20% (27/135)	39% (11/28)	p=0.028