TCT-633

Treatment of mitral regurgitation in patients with severely impaired left ventricular ejection fraction with the MitraClip system – MVARC outcome

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BACKGROUND Several studies and registers such as EVEREST, ACCESS-EU and PILOT EUROPEAN SENTINEL showed safety and effectiveness of the MitraClip system. However, only limited data exists for patients with MR and severely reduced left ventricular (LV) ejection fraction (LVEF).

METHODS We report our single-centre experience of using the MitraClip system in patients with moderate/moderate-to-severe and severe MR and LVEF <20%. Outcome parameters were classified according to the MVARC criteria. Out of 605 MitraClip procedures performed in 578 patients at our centre between 08/2008 and 11/2015, 29 pts (71 ± 10 years; 26 men; log. EuroSCORE 24 ± 16%; functional MR n=27, degenerative MR n=2; NYHA II, III and IV in 2, 12 and 15 pts, respectively) had LVEF <20%. All pts were on optimal medical treatment. Baseline MR was graded as moderate/moderate-to-severe (n=14) and severe (n=15). Patient comorbidities were atrial fibrillation (n=22; 76%), coronary artery disease (n=18; 62%), renal dysfunction (n=12; 41%), pulmonary hypertension (n=7; 24%). Eight patients (28%) had a CRT system implanted.

RESULTS Mean LVEF was 17 ± 3%, LV end-diastolic diameter 72 ± 8 mm, LV end-systolic diameter 63 ± 9 mm, LV end-diastolic volume 246 ± 76 ml and LV end-systolic volume 205 ± 67 ml. Technical success was 100%. Device success was achieved in 17 pts (59%). Twelve pts had no device success due to persistence of MR >I°. Device time was 77 ± 55 min. The numbers of implanted clips were 1, 2, 3, and 4 in 52% (n=15), 41% (n=12), 3% (n=1), and 3% (n=1), respectively. Right heart catheterization showed an increase in cardiac output from 4.0 ± 1.2 to 5.0 ± 1.3 l/min ($p < 0.0001$) and decrease of left atrial pressure from 16.5 ± 6.2 to 13.1 ± 6.4 mmHg ($p = 0.0032$). There was no stroke, acute kidney injury, major vascular and major bleeding complication after the procedure. Patients were followed for a median of 15.3 (IQR, 7.3-32.7) months. 30 day mortality was 0%.

CONCLUSION Percutaneous treatment of pts with MR and severely impaired LVEF is feasible and safe. This is the first report of MVARC outcome in such a patient population. However, device success rate was relatively low. More data are needed for a general recommendation for treatment option in patients with MR and severely impaired LVEF

CATEGORIES STRUCTURAL: Valvular Disease: Mitral

TCT-634

Feasibility and Efficacy of Transapical Implantation of a Novel Transcatheter Mitral Bio-Prosthesis in a Pig Model

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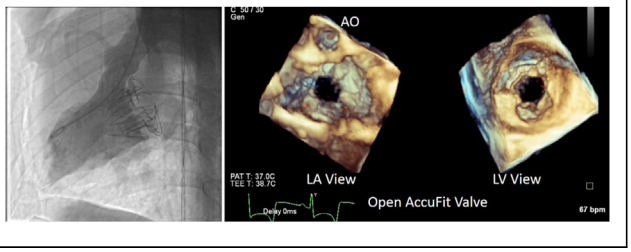
BACKGROUND Transcatheter mitral valve replacement is emerging as a treatment alternative to surgery for high-risk patients with severe mitral regurgitation (MR). This study aimed to evaluate the feasibility and efficacy of a novel self-expanding mitral bio-prosthesis (AccuFit™, SinoMed Inc.) in a swine model.

METHODS The catheter-based AccuFit valves were implanted in 5 swine via transapical access under 3D TEE and fluoroscopic guidance. Follow-up TEE was scheduled at 7, 14 and 30 days after device implantation to evaluate the function of the test valves.

RESULTS The measurements of the native mitral annulus were as follows: mean anteroposterior diameter 25.8±0.6mm, intercommissural diameter 35.3±1.0mm and annulus perimeter 106.4±2.9mm. A size 34mm AccuFit valve was successfully implanted in all 5 animals. Trace paravalvular leak was observed in only 2 of the 5 animals with none in the remaining 3 pigs; no central MR was seen in any animal, the mean transvalvular pressure gradient (MG) was 3.8±1.3mmHg. There was no left ventricular outflow tract obstruction (MG 4.0±1.7mmHg), no aortic regurgitation or coronary artery obstruction (figure). One animal died 10 days after implantation due to anticoagulation over-dose. Adequate position and function of the test valve was observed in the other animals at 1 and 2 weeks by TEE; and the animals will be undergo histological evaluation at 1 month.



CONCLUSION In a healthy swine model, catheter-based transapical implantation of the AccuFit valve is technically feasible, safe and results in a stable and well-functioning mitral bioprosthesis.

CATEGORIES STRUCTURAL: Valvular Disease: Mitral

TCT-635

Transcatheter Mitral Repair With a Sutureless Neochordal Device: Preclinical Experience

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BACKGROUND An animal study was performed to evaluate technical feasibility and performance of a transcatheter mitral neochordae repair system.

METHODS Five adult swines and five adult sheeps underwent left thoracotomy through the third intercostal space. A novel catheter based sutureless chordal replacement implant (Chordart, Coremedic, Biel, Switzerland) was introduced either transcatheter through a 14F sheath in the swine model or open beating heart with CPB support on the sheep model. The posterior mitral leaflet was grasped at the P2 segment, and it was punctured. The implant was delivered to the posterior papillary muscle using echocardiographic, fluoroscopic or visual guidance, on the beating heart. Subsequently the leaflet component was deployed using a flexible delivery system to the central section of the posterior leaflet. Finally, the transcatheter delivery was withdrawn from the working sheath and the atrial purse-string closed. The 5 swines were sacrificed acutely, while the sheeps were sacrificed at 180 days.

RESULTS All animal survived the acute implant. The sutureless chordal replacement implant was successfully implanted in all animals, without side effect noted to the mitral valve and substructure. At necropsy, location of the implant was within a few millimeters of the leaflet free boundary (2.5 ± 3 mm). No leaflet lesion was observed. In 3 animals, papillary muscle fixation element was implanted more than 5mm from the muscle tip but within the targeted papillary muscle. In the 5 long term survivors, the implanted device showed satisfactory healing, no inflammatory or toxicity response, and no chordae dehiscence.

CONCLUSION Transcatheter minimally-invasive, beating-heart implantation of a sutureless neochordae implant is feasible. This approach may be an alternative to open surgical procedures in high risk degenerative MR patients or even in young patients who want to avoid an operation.

CATEGORIES STRUCTURAL: Valvular Disease: Mitral