CARDIOVASCULAR FLASHLIGHT
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First in human transcatheter COMBO mitral valve repair with direct ring annuloplasty and neochord leaflet implantation to treat degenerative mitral regurgitation: feasibility of the simultaneous toolbox concept guided by 3D echo and computed tomography fusion imaging

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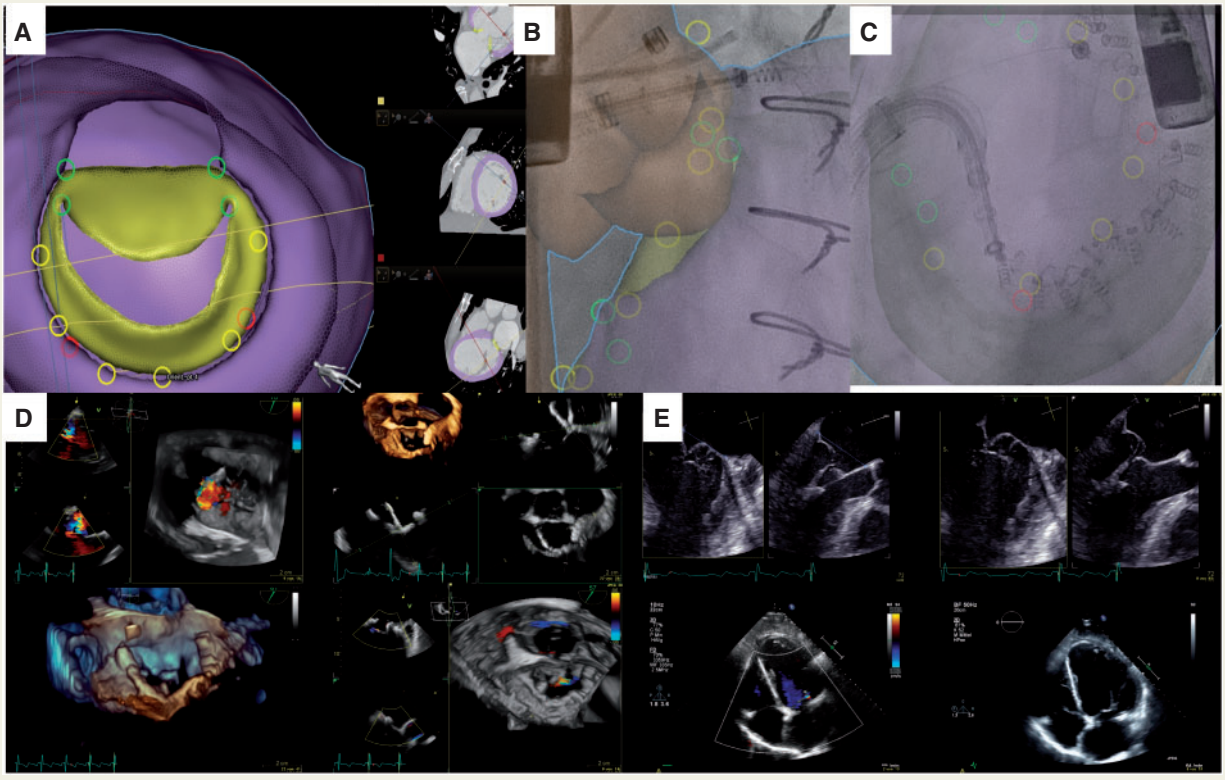
In mitral valve (MV) prolapse with flail leaflet, the combination of surgical repair including annuloplasty and chordal replacement is the current standard of care. Both valvular heart disease guidelines in the USA and Europe published in 2017 acknowledge a future role of transcatheter approaches in non-low-risk patients. We present here a first in human case of a transvenous transcatheter off-pump direct annuloplasty with the Edwards Cardioband system and simultaneous one-staged transapical off-pump transcatheter implantation of three NeoChordae using the NeoChord DS1000 application system to treat a 63-year-old male with a STS-score of mortality of 8% and a logistic EuroScore of 31%. The patient suffered from severe mitral regurgitation due to a chordal rupture on the P2 segment and annular dilatation (anteroposterior diameter of 42 mm) with a leaflet-to-annulus-index (LAI) of 1.02. The risk profile included coronary artery disease with a history of anterior myocardial infarction (*Panel E* and Supplementary material online, *Video S4*) status post-CABG with patent grafts, left ventricle (LV) ejection fraction of 30%, carotid stenosis, NYHA class IV dyspnoea, and a relevant frailty index with cardiac cachexia. The ethics committee and interdisciplinary Heart team (cardiothoracic surgeons, interventional cardiologists, heart failure specialists, and cardiovascular anaesthesiologists) decided for an interventional approach. For pre-procedural planning, the patient underwent a cardiac multiphase (10 phases in one heart cycle) and multi-slice high-resolution computed tomography (CT) scan (*Panel A*). A 3D reconstruction and 3D transoesophageal echocardiography was used to determine the size of percutaneous annuloplasty with the selection of a Cardioband D and the location and number of chordal replacements. The position of the transseptal puncture site, catheter mobility assessment, and anchor position next to the left circumflex artery and mitral trigone was predefined using Osirix Medical and Philips Heart Navigator 3 simulation and fusion tools. The CT scan was calibrated and fused to a pigtail diagnostic catheter in the aortic root with intra-hybrid OR fluoroscopy real-time fusion imaging, and 3D echocardiography was used to guide transseptal puncture and transseptal sheath navigation close to the anatomic left trigone as used in conventional surgical repair approaches. Initial invasive evaluation revealed a systolic blood pressure of 89 mmHg, a left atrial pressure (LAP) mean of 36 mmHg, and a systolic v-wave of 67 mmHg, respectively. Guided by 3D echocardiography employing a multiplanar reconstruction of FlexiSlice (GE Vivid E95 prototype 2018) an Edwards Lifesciences Cardioband size D was fixed from left to right trigone using 15 anchors (6 mm long stainless steel) positioned in a landing zone of 2–3 mm next to the hinge point of the posterior leaflet to the annulus in segments 1 through 3 (*Panel B–D*, Supplementary material online, *Videos S1* and *S2*). After assessment of left coronary artery (LCA) patency the anchors were consecutively released and the Cardioband implanted. A size-adjustment tool (SAT) was connected to the cinching spool, leaving the band uncinched to facilitate chordal implantation. No blood loss was documented in a procedural time of 98 min. Transapical access was obtained through a left side 5th intercostal space mini-thoracotomy in this pre-operated patient. Access site was planned according to the previously reconstructed CT fusion images. The apex was punctured, and a 29-F NeoChord DS 1000 system preloaded with ePTFE chord (Gore, Flagstaff, AZ, USA) was introduced in the left ventricle under 2D and 3D multiplanar echo guidance. Three NeoChords were implanted on the P2.

Following the two repair steps individual reduction by NeoChord tensioning or cinching alone resulted in an improvement to moderate MR only. When both interventional tools were used simultaneous under beating heart conditions by adding a cinching of 5 cm to the Cardioband and consecutive controlled tension to the Neochords a reduction to trivial MR was achieved (*Panel D and E*, Supplementary material online, *Videos S3* and *S4*). Left atrial pressure fell dynamically to 13–16 mmHg and the v-wave was abolished from 67 mmHg to 21 mmHg. Size-adjustment tool was released in the LA and the apex closed with complete cessation of bleeding. Procedure time of chordal implant was 63 min without requiring blood transfusions. The patient was extubated immediately in the OR after the procedure.

Cardiac CT performed within 24 h after the procedure showed no bleeding nor pericardial effusion and correct positioning of all anchors. Echocardiography revealed an improved LAI of 1.28 and coaptation of 4.5 mm after the transcatheter repair and trivial residual MR (*Panel D and E*).



Thus, we report here to our knowledge the first 3D-echocardiography and CT-fusion guided COMBO MV repair procedure combining direct ring annuloplasty and Neochord leaflet repair in a high-risk patient with leading DMR demonstrating the feasibility of the toolbox concept for MV repair with a Heart team approach of cardiologists and cardiac surgeons.

Figure panels: (*A*) Automatic analysis of mitral valve (MV) surgical landmarks including left and right trigonum (upper green dots), medial and lateral end of the MV commissure (lower green), manual delineation of MV hinge points and Edwards Cardioband anchors (yellow dots), position of papillary muscle head displacement (red dots) in annulus and ventricular dilatation due to primary mitral regurgitation (MR) with secondary MR features due to ischaemic post-infarct remodelling (Philips Heart Navigator 3 fusion software). (*B*) Fusion imaging showing important landmarks for anchor positioning including left main coronary (yellow dot), leaflet insertion at the annulus level (yellow), left ventricular myocardium (purple), images are aligned to the hybrid OR fusion cath lab table. (*C*) Fusion imaging showing important landmarks with live overlay to the fluoroscopy system. (*D*) 3D Echo showing severe prolapse with excentric mitral regurgitation in LA view plus 2 chamber view and long axis view. 3D Implantation of the Cardioband covering 75% of the annulus from left to right trigonum and the result after a COMBO treatment of annuloplasty and 3 NeoChords with trace MR. (*E*) 2D Echo showing severe prolapse with chordal elongation and rupture in the upper row and the result after a COMBO treatment of annuloplasty and 3 NeoChords with trace MR in the lower row images. Note the transthoracic echo 6 days post-implant showing LVEF (systole left and diastole right) with apical scar tissue and depiction of both natural chords heading to 2 o'clock papillary muscle and NeoChord to 12 o'clock anterolateral apex.

Supplementary material is available at *European Heart Journal* online.