Mitral valve repair with an automated suturing device for artificial chordal placement - first-in-human study experience

Objective
The availability of ergonomic and reliable automated technology for remote ePTFE suturing and knot placement through a small thoracotomy can offer additional options for advancing minimally invasive mitral valve repair surgery. The first clinical evaluation regarding the safety and efficacy of this new approach to artificial chord placement is reported.

Methods
After extensive preclinical development and testing, a 12 patient first-in-human clinical trial was approved by the Austrian competent authority (1228/2020) to study a new manually controlled suturing device to place ePTFE chords secured by a customized titanium fastener. The first squeeze of the suturing device lever advances two needles through the targeted leaflet. A second squeeze rearms the device. The third squeeze passes the ePTFE suture through the corresponding papillary muscle. The "knotting" device crimps a titanium fastener and trims suture tails. Outcome parameters include: perioperative and late mortality, adverse events, valve competence, and operative times.

Results
Since August 2021, 11 patients (66±12 years, 5 female, BMI 27.0±4.9kg/m2, EuroSCORE II mean 2.3±1.8%, 7 full sternotomy, 4 lateral thoracotomy, 6 concomitant procedures) received one (n=2) or two (n=9) ePTFE sutures and titanium fasteners as indicated by anatomy and repair strategy along with using a standard annuloplasty ring. Suture placement and knot delivery were easy and intuitive across repair strategies. All patients required only a single aortic cross-clamping to complete mitral valve repair. Four serious adverse events (SAE) occurred: 2 prolonged hospitalizations due to atrial fibrillation, with 1 requiring cardioversion; 1 same-day reexploration for pericardial effusion, with no active bleeding; and 1 rehospitalization 45 days after surgery for suspected urinary tract infection, with endocarditis ruled out. Postoperative mitral regurgitation was absent in 10 patients and trace in 1 patient. No patient required mitral valve reoperation. No mortality was observed during follow-up.

Conclusions
The first-in-human trial revealed excellent short-term clinical outcome results with the novel automated ePTFE suturing and knot replacement devices. No device-related adverse events were observed. Suture placement was possible via open and minimally invasive access. This more automated chordal replacement approach appears applicable to utilization with commonly reported modern mitral valve repair techniques. These sutures can also easily be replaced if required. This system can potentially reduce some of the technical challenges of mitral valve repair.

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