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Transcatheter aortic valve-in-mechanical valve replacement: a first-in-human study

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Introduction

Surgical aortic valve replacement has progressed considerably since the 1950s.[1,2] Although mechanical valves offer superior durability, the preference for bioprostheses has increased due to their anticoagulation-free profile.[3] Transcatheter aortic valve implantation (TAVI) is an established therapy for failing bioprostheses,[4,5] but its use in mechanical valve failure remains largely unexplored.[6] This translational investigation evaluates a strategy to intentionally disrupt bileaflet mechanical aortic valves, retrieve embolized disc fragments, and implant a transcatheter valve without open-heart surgery.

Methods

The central hypothesis was that mechanical valve dysfunction in inoperable patients can be treated percutaneously via controlled disc dislodgement followed by TAVI. The secondary hypothesis is that anticoagulation may be replaced by single antiplatelet therapy when no alternative indication exists. The primary endpoint was VARC-3 procedural success; secondary endpoints were mortality, device thrombosis, heart failure readmissions, and bleeding or ischaemic events.

Bench testing demonstrated that snaring the discs failed to dislodge them and blocked their function longer time. On the contrary, disc dislodgement was rapid and feasible with balloon inflation at 2–4 atm. Both large balloons (18 mm) and peripheral balloons (10–14 mm) successfully dislodged the discs without balloon rupture; specifically, peripheral balloons allowed single disc detachment and second disc trapping in position with the implanted balloon-expandable TAVI, suggesting that it might be a better alternative. An animal study was then performed at CNIC (PROEX041.4/24). Large white pigs (60–80 kg) underwent heterotopic mechanical valve implantation (to avoid extracorporeal circulation) or orthotopic implantation (for anatomical fidelity), using commercially available bileaflet valves (Open Pivot™, Regent™, Overline™). After ≈1 month, surviving animals underwent valve-in-mechanical prosthesis (ViMech). Bilateral femoral access was used: one for the Ono Filter™ in the ascending aorta with a balloon positioned inside to fracture the discs and the other for the TAVI device (Myval™ or Evolut™). Once discs dislodgement was confirmed fluoroscopically, the balloon/filter system was withdrawn and TAVI deployed immediately using the mechanical sewing ring as a landmark. Aspirin (100 mg/day) was initiated; vitamin K antagonists were not resumed. Computed tomography (CT) and echocardiography were performed

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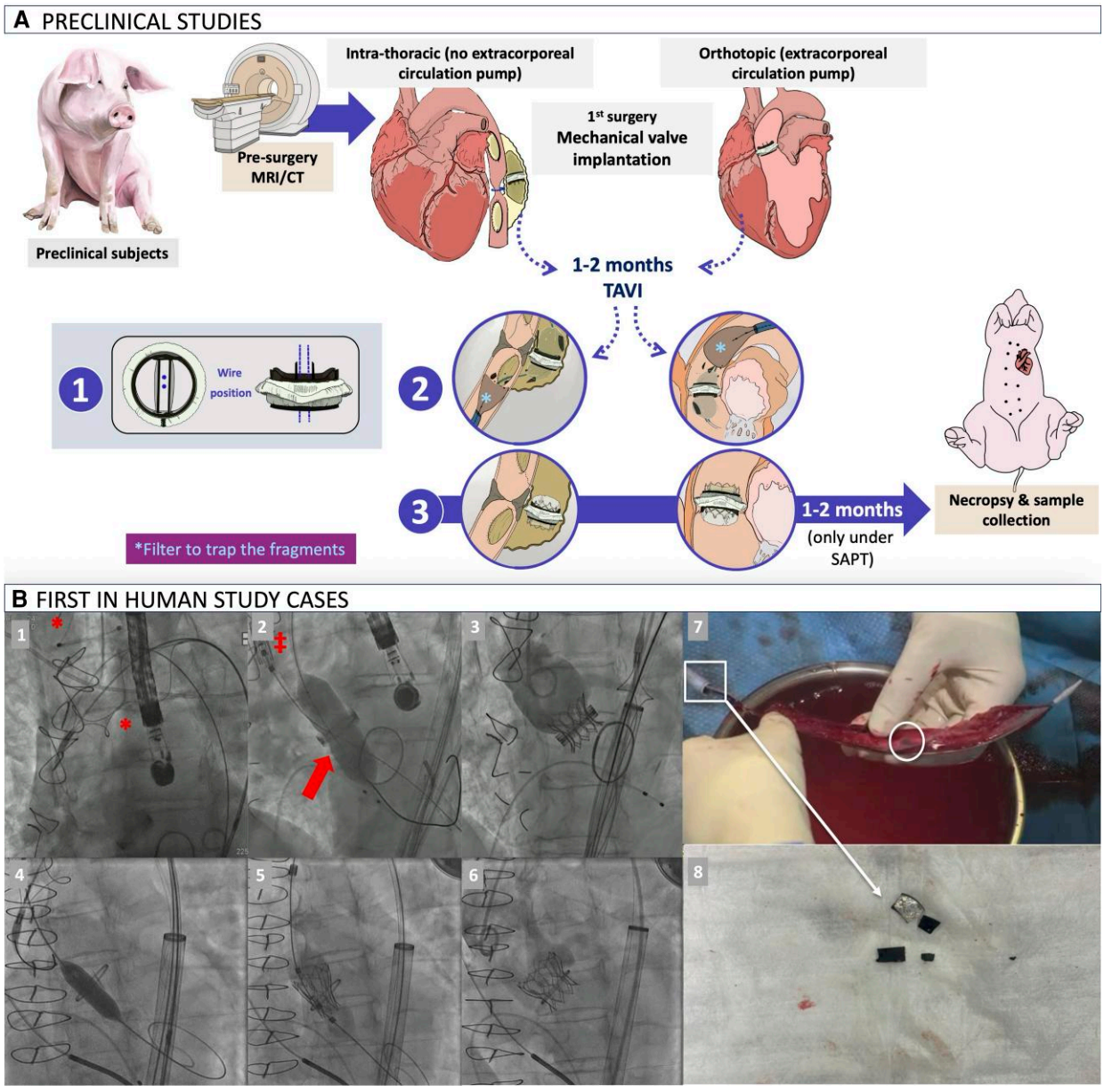

Figure 1 Animal preclinical study (*A*) and first-in-human (*B*). PANEL A: 1: Position of the wires. 2: Position of the filters (left: heterotopic; right: orthotopic). 3: Implanted TAVI device. PANEL B: 1: Two simultaneous filters (*) were used in all cases: FLOWer filter (Aorticlab, Italy) and Sentinel filter (Boston Scientific, US). 2–3: Once the stiff wires were advanced between the discs, valvuloplasty (red arrow) with 18 mm True Dilatation balloon was performed to dislodge the discs while TAVI device was on hold in the ascending aorta (‡) to allow rapid implantation. 4–6: Alternatively, 12 mm peripheral balloon was also used to dislodge only one disc and trap the other disc with the balloon-expandable TAVI. 7–8: The fragments of the discs removed from the body from the filter (white circle) and also from inside the introducer sheath (white square). CT, computed tomography; MRI, magnetic resonance imaging; SAPT, single antiplatelet therapy; TAVI, transcatheter aortic valve implantation

at baseline, pre-TAVI, post-TAVI, and at follow-up; necropsy followed final imaging.

After preclinical evaluation, compassionate-use ViMech-TAVI was undertaken in three inoperable patients. FLOWer™ plus Sentinel™ embolic protection was used in two cases. The FLOWerTM device covers all the aortic arch and is tapered, with smaller distal orifice that was kept within a long sheath to avoid distal migration of the fragments. Informed consent was obtained.

Results

The main preclinical and clinical results are presented in *Figure 1*. Regarding the preclinical experience, eleven heterotopic mechanical valve implantations were performed (mean weight 68.4 ± 8.5 kg). Eight animals (72.7%) survived to transcatheter treatment; three early deaths were mainly anticoagulation-related (one during surgery, two while waiting for the TAVI procedure

under warfarin). ViMech was successful in 7/8 survivors (87.5%), with one failure due to graft angulation. Disc fragments were consistently retrieved. With 18-mm balloons, discs fragmented in 3–4 pieces and with 10-mm balloons, typically 2–3. In some cases, a residual disc was crushed and trapped during TAVI expansion as in the bench testing. One animal died from an access complication; six completed follow-up with good haemodynamic function and no significant regurgitation.

Nine pigs underwent orthotopic implantation; five died intraoperatively from malignant arrhythmias. Two additional animals died from anticoagulation-related bleeding. The remaining two underwent ViMech at 22 and 36 days, with procedural success, but both died shortly after TAVI. Autopsy demonstrated thrombotic material related to under-expansion of the TAVI device within the small (16 mm) mechanical prosthesis, reflecting anatomical constraints of the swine model.

Three first-in-human ViMech-TAVI procedures were performed.

Patient 1: A 75-year-old man with prior Bentall–Bono (25-mm CarboSeal) and disc embolization during endovascular repair. A 24.5-mm balloon-expandable valve was implanted, trapping the remaining disc; the embolized disc lodged in the iliac artery without ischaemia.

Patient 2: A 79-year-old man with prior Bentall and an immobile disc causing heart failure. Disc dislodgement was performed within FLOWer™ + Sentinel™, followed by contralateral balloon-expandable TAVI. A pacemaker was required; no other events occurred.

Patient 3: A 67-year-old woman with three prior cardiac surgeries and a 21-mm St. Jude Masters valve. A 12-mm balloon within the filter dislodged one disc, retrieved *en bloc*; a 21.5-mm balloon-expandable valve trapped the remaining disc.

Anticoagulation was changed to aspirin in the first two patients and to apixaban in the third due to persistent atrial fibrillation. At 6 months all patients were alive and asymptomatic and had normally functioning TAVI devices, with control CT demonstrating lack of leaflet thrombosis, and without other bleeding or ischaemic events.

Main limitations include small sample size, incomplete anatomical correspondence between animal and human models, and absence of a control arm. Testing the hypothesis of alternative antithrombotic management after ViMech will require dedicated investigation in larger populations.

This study provides the first integrated bench-to-animal-to-human demonstration of controlled disc dislodgement enabling transcatheter valve-in-mechanical valve implantation. The technique was feasible in preclinical models and successful in three high-risk patients. While disc removal lowers thrombogenic potential, optimal post-procedural antithrombotic management requires further investigation.

Declarations

Disclosure of Interest

Dr Amat-Santos is proctor for Abbott, Boston Scientific, Medtronic, Meril Life, and Microport.

Data Availability

Data of this paper are available under request.

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Ethical Approval

All procedures were conducted at CNIC, with approval from the institutional and regional ethics committees (PROEX041.4/24), following EU Directive 2010/63/EU.

Pre-registered Clinical Trial Number

Not applicable.

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