Transcatheter valve-in-valve implantation into a failed mechanical prosthetic aortic valve: are we looking for trouble?

Domenico D’Amario1,2* and Marco De Carlo3

1Department of Cardiovascular and Thoracic Sciences, Fondazione Policlinico A. Gemelli IRCCS, Via della Pineta Sacchetti, 217, 00168 Rome, Italy; 2Università Cattolica del Sacro Cuore, Via della Pineta Sacchetti, 217, 00168 Rome, Italy; and 3Cardiothoracic and Vascular Department, Azienda Ospedaliero-Universitaria Pisana, Via Paradisa, 2, 56100 Pisa, Italy

Received 14 April 2021; first decision 18 May 2021; accepted 14 June 2021

This editorial refers to ‘First successful transcatheter valve-in-valve implantation into a failed mechanical prosthetic aortic valve facilitated by fracturing of the leaflets: a case report’, by C. Butter et al. doi:10.1093/ehjcr/ytab130.

As the famous Roman poet Horace wrote in his Odes, the ‘aurea mediocritas’ is the attitude to reach a virtuous middle ground between two sinful extremes. This concept might be even glimpsed in the Hippocrates oath: ‘The physician must be able to tell the antecedents, know the present, and foretell the future—must mediate these things, and have two special objects in view with regard to disease, namely, to do good or to do no harm’.

In the present issue of the Journal, Butter et al.1 pushed the boundaries of this notion to the extreme, presenting a unique case of a patient with acute heart failure caused by a dysfunctioning mechanical bi-leaflet aortic valve prosthesis with an immobile disc. How to deal with this clinical conundrum of a fragile patient, haemodynamically unstable with multiple comorbidities, affected by a potentially reversible cause of heart failure?

Since the local Heart Team deemed the patient inoperable due to prohibitive surgical risk, the authors considered plausible the unprecedented option of breaking the mechanical prosthesis with a balloon so as to allow transcatheter valve-in-valve implantation (ViV). In order to make such a risky intervention as safe as possible, the procedure was conceived in two steps: first, a bench test to assess the feasibility and mechanical effects of breaking the prosthesis and second, after a clinical reappraisal and the approval of the Ethical Committee, the first-in-man ViV procedure in a mechanical aortic prosthesis. The intervention was successful and resulted in a fully functional transcatheter aortic valve replacement, with immediate improvement of heart function and early discharge from hospital.

Although the embolic protection of the left main and of the supra-aortic vessels was suboptimal, no major cardiovascular complications occurred. Importantly, at postoperative full-body computed tomography, three large disc fragments were detected in the iliac arteries, not causing symptoms, as far as reported. A summary of the planning and performance of the intervention is represented in Figure 1.

This procedure may inspire awe from a technical standpoint, but also criticism from a clinical and ethical perspective. As physicians, should we consider this procedure a new therapeutic option to be considered or just a prohibitively risky intervention that may have caused serious harm to the patient? From the ethical, clinical, and scientific point of view, all possible aspects should be scrutinized. There are at least a few issues to consider:

1. Were there other options available? According to the data provided, all the possible medical and surgical options were discussed and carefully evaluated by the Heart Team. No other therapeutic options were applicable, and the patient appeared deemed to die from the acute dysfunction of the prosthesis.

2. Was the patient fully informed and aware of the risks of the procedure? When severe acute heart failure is present, providing the patient with exhaustive information on his condition and on the therapeutical options in a comprehensible way is crucial but often very difficult to achieve. Elderly patients, particularly when they are very fragile, in critical conditions, and have already undergone cardiac surgery, may be considered as hopelessly vulnerable and, as such, candidates for ‘extreme’ interventions of unknown efficacy but with definite risks. In this setting, a first-in-man procedure should not be presented to the patient with an overconfident attitude, and all the potential complications should be firstly carefully foreseen and then explained to the patient. Sometimes, especially in the field of interventional cardiology, physicians tend to exaggerate the ability of procedures and devices to cure heart diseases,
focussing on the heart and losing the whole picture of the patient. Therefore, a major effort has to be made to explain to the patient his present condition and its foreseeable evolution in an understandable way, developing communication skills that help to approach the issue of the end of life, as well as to discuss the risk/benefit ratio of a novel interventional approach.

(3) In-depth discussion about what is important to the patient and to his caregivers is decisive to favour a good decision-making process and a patient-centred plan of treatment, allowing clinicians, patients, and families to set their respective goals, avoiding disagreements that could otherwise escalate into ethical/legal conflicts.

(4) Was the procedure carefully planned and all possible complications foreseen and adequately prevented (as far as possible)? The obvious risks of disrupting a mechanical prosthesis are the acute massive aortic regurgitation and the embolization of the disc fragments. In this clinical case, the risk of embolization in the right coronary artery as well as in the left subclavian artery was not adequately prevented, although embolic protection could have been implemented. In addition, a strategy for the detection and retrieval of embolized fragments in visceral arteries could have been planned before the intervention. Such measures could have mitigated the potentially fatal complications of this risky intervention.

In summary, Butter et al. demonstrated unconventional thinking, and, instead of clinging to what is safe and familiar, defied the ‘status quo’ approaching a clinical dilemma with a novel strategy. However, the procedure hereby described was extremely risky and cannot be offered as a generalized therapeutic option and has to be considered unique in its kind rather than rare.

Importantly, although we might think that the implementation of a new interventional technique is largely about carefully planning and performing the procedure, the real success of this clinical case was related to the engagement of the patient and of all the personnel involved in this unprecedented approach to save the patient’s life. Knowing and respecting the patient’s values, informing him on the risks and potential benefits of an unexplored intervention in the context of a critical illness, aligning the care provided with what is most important to the patient, represent the appropriate foundations for innovative procedures such as the one described, which was successful but could have turned out in a disaster.

Given the progressive growth in the number of novel technical options for the treatment of structural heart diseases, scientific societies should consider the opportunity of producing specific guidelines for the implementation of first-in-man interventional procedures. Initial indications in this direction have already been published in the field of pharmacological phase 1 trials.

**Lead author biography**

Dr Marco De Carlo, MD, PhD, FESC, obtained the degree in Cardiology and the PhD *summa cum laude* at the University of Pisa, Italy. Since 2006, he is vice director of the Cardiac Catheterization Laboratory and Professor at the School of Specialization in Cardiology of Pisa University. He has authored 170 scientific papers, with >10,000 citations, including the ESC Guidelines on
Peripheral Artery Diseases. His interests include coronary interventions, transcatheter valvular interventions, and peripheral artery disease. He served as Chairperson of the Working Group on Aorta and Peripheral Vascular Diseases of the ESC, and as member of the ESC Congress Programme Committee.

Conflict of interest: None declared.

References
1. Butter C, Kühnel R-U, Hölschermann F. First successful transcatheter valve-in-valve implantation into a failed mechanical prosthetic aortic valve facilitated by fracturing of the leaflets: a case report. Eur Heart J Case Rep 2021; doi: 10.1093/ehjcr/ytab130.
2. Sibille M, Patat A, Caplain H, Donazzolo Y. A safety grading scale to support dose escalation and define stopping rules for healthy subject first-entry-into-man studies: some points to consider from the French Club Phase I working group. Br J Clin Pharmacol 2010; 70: 736–748.