The impact of such an injury on prosthesis durability requires a further investigation.

ACKNOWLEDGEMENTS

The authors are deeply grateful to Hicham Azendour (Faculté de médecine et de pharmacie, Université Mohammed V, Rabat, Morocco) and Witold Styrc (Flashmed, Echtnerach, Luxembourg) for their technical assistance.

Funding

This work was supported by a research grant from Cormove (Ivry le Temple, France).

Conflict of interest: Rachid Zegdi is a stockowner of Cormove, a company that is developing a new percutaneous valve.

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Editorial comment

Pericardial traumatic injury in transcatheter aortic valve implantation

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Keywords: Pathology • Transcatheter aortic valve implantation • Pericardium • Aortic stenosis • Valve disease

Transcatheter aortic valve implantation (TAVI) is a very promising new treatment for native aortic stenosis or failed bioprostheses [1]. Glutaraldehyde xenograft tissue is employed because of its pliability for folding during implantation and minimizing its size in order to reach its final position in the aortic root. In the CoreValve® system, the stent is self-expanding, whereas in the Edwards Sapien, the valve has to be dilated by balloon inflation to approximate the stent to the aortic annulus without suturing, so as to prevent escape of the prosthesis and paravalvular leakage. In the latter procedure the pericardium is crushed against the stent.

Since the operation is relatively easily accomplished with early success, the question arises of whether it might also be indicated in low-risk patients, thus avoiding sternotomy, general anaesthesia, cardiopulmonary bypass and cardiac arrest.

However, in contrast to the traditional surgical implant, TAVI requires cusp crimping and, in the case of the Edwards Sapien, balloon inflation. Both manoeuvres may be responsible for tissue injury. Previous observations by Zegdi et al. have shown evidence of cusp injury following percutaneous aortic valve deployment of the Edwards Sapien [2]. To confirm these preliminary findings, the same group made an experimental study, comparing the severity of traumatic cusp injury in home-made balloon- vs self-expanding valved stents (VS); a non-crimped pericardium was used as a control [3].
According to the authors’ findings, all deployed valves were associated with microscopic lesions, in keeping with traumatic disruption, both in terms of transverse fractures and longitudinal cleavages. Transverse fractures were seen both in balloon- and in self-expanding VS, whereas longitudinal cleavages were more frequently observed in balloon-expanded VS. Crushing and shearing of the pericardium during crimping and deployment are the most plausible causes. They may facilitate plasma and lipid insulation with tearing in the long term, thus affecting durability. These data support and expand the preliminary observations of the same authors [2]. An editorial comment by our group expressed some concern in interpreting these data, due to the limitations of technology used in pathological investigations [4]. However, the new data provided herein by Amahzoune et al. [3] seem to be convincing, even in the absence of macroscopic evidence of lacerations, commissural dehiscences or tears. They support the occurrence of some iatrogenic damage, particularly in balloon-expandable VS. However, in our opinion, the experiment should be repeated in a core lab employing special histological staining, such as picrosirius red, and scanning electron microscopy, to assess collagen waviness and to exclude the artifacts arising from manipulation at histology.

If confirmed, these observations may cast a shadow on the safety of the TAVI procedure in terms of tissue integrity and biological compatibility, although crimping was proven not to influence propensity to cusp calcification in the long term [5].

Glutaraldehyde-fixed pericardium is the best available tissue because of its strength (thick fibrosa) and pliability (elasticity of wavy collagen bundles). If handled gently, as in the current second- and third-generation stented or stentless pericardial valve prostheses, it is not at risk of mechanical failure. Whether this is the case with TAVI—in which the pericardium is exposed to crimping or even crushing, with a potential traumatic injury—is a matter of concern.

According to the findings by Amahzoune et al. [3], the following considerations may be put forward:

(1) Balloon inflation, with pericardium crushing against the stent at the time of deployment, may present a risk of damaging the pericardial fibrosa with cracks and cleavages. Some caution and protection should be applied with a view to preventing or minimizing the trauma.

(2) The pericardium used should be as strong as possible. Bovine pericardium is preferable because it is thicker than equine or porcine ones. Clearly, the porcine aortic valve, which shows thin fibrosa, should be discarded as a bioprosthetic graft in this setting [6].

(3) The burden of crimping is nearly half that of the so-called sutureless bioprosthetic valves. Picrosirius red staining at histology and scanning electron microscopy studies revealed no abnormalities when compared to controls, even following 90 min collapse [7].

A sutureless procedure, other than valve collapse and deployment, implies the removal of the native valve and this may sound in favour of surgical approach, due to fewer potential complications. However, it necessitates extracorporeal circulation, general anaesthesia and cross-clamping, as well as cardiac arrest and cardioplegia, as in traditional aortic valve replacement with annular suturing. Sutureless implantation is an alternative option to surgical replacement, not to TAVI.

TAVI is a ‘compassionate’ therapy, carried out when traditional, surgical aortic valve replacement is prohibitive in terms of risk. Preservation and durability of its biological components should be guaranteed as far as possible before extending indication of TAVI to low-risk surgical patients and dismissing the traditional surgical replacement.

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