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EDITORIAL COMMENT

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Mid- to long-term results following aortic valve replacement using the Mitroflow xeno-pericardial bioprosthesis: somewhat different views from 2 high-volume institutions

Thierry Carrel*

Clinic for Cardiovascular Surgery, University Hospital, University of Bern, Bern, Switzerland

* Corresponding author. Clinic for Cardiovascular Surgery, University Hospital, University of Bern, 3010 Bern, Switzerland. Tel: +41-31-6322375; fax: +41-31-6324443; e-mail: thierry.carrel@insel.ch (T. Carrel).

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The present editorial discusses two papers submitted quite simultaneously and dealing with what is called 'long-term' results of the xeno-pericardial Mitroflow tissue valve in aortic position [1, 2]. Both studies included a large number of patients (>830) operated during a similar time period, between 2005 and 2015, 2003 and 2012, respectively in 2 large institutions in Belgium and Germany.

First of all, the conclusions of the authors sound somewhat different: Lootens and co-authors concluded that the data of their study did not support the concerns on early accelerated structural degeneration of the first-generation Mitroflow bioprosthesis, when used for aortic valve replacement in patients older than 75 years. However, they postulated that limiting the number of small sized prostheses by using a proper implantation technique, would help to reduce the risk of significant patient-prosthesis mismatch as one of the main determinant of early structural valve degeneration (SVD). Ius and co-workers concluded that the former LA/LXA Mitroflow model showed limited long-term durability, but SVD was not associated with worse survival up to 9 years after aortic valve replacement (AVR). Patient age at the time of valve implantation played an important role in the development of SVD. The main recommendation was to wait for longer follow-up until using the new DLA model in patients younger than 75 years.

Interestingly, both groups referred to an age threshold of 75 years in their analysis. As far as the American (2017) and European (2012) Guidelines for the treatment of patients with valvular disease are concerned, the recommendations to consider the implantation of a tissue valve in aortic position significantly differ from those described in both papers [3, 4]. In the 'older' European Guidelines, the minimal age considered adequate to discuss a tissue valve was set between 60 and 65 years (Class of recommendation IIa, level of evidence C) while the more recent American Guidelines use the age of 70 for this purpose.

There is no doubt that uncertainty and debate still exist regarding the type of valve prosthesis for patients between 50 and 70 years of age. Randomized controlled trials with the most modern generation of devices are lacking and newer-generation tissue prostheses may show greater freedom from structural deterioration, especially in the older individual [5].

Independently from what is recommended by the different Guidelines, the choice of the most appropriate valve prosthesis should consider the patient's preferences and result from an in-depth discussion of the indications outweighting all advantages and disadvantages of the mechanical and the biological devices: risk of anticoagulation, potential need and risk of reintervention or reoperation. Of course, since the introduction of the transcatheter aortic valve implantation (TAVI) concept, the use of a transcatheter valve-in-valve procedure has also to be considered for decision making on the type of valve, even though long-term follow-up is not yet available, and some bioprosthetic valves, particularly the smaller-sized valves, are not suitable for a valve-in-valve replacement. And one should keep in mind: a valve-in-valve procedure will always require insertion of a device smaller than the original tissue valve and patient-prosthetic mismatch has to be kept in mind with this strategy.

Of course the threshold of age will be more and more influenced by the possibility to treat the majority of degenerated tissue valves by a transcatheter valve-in-valve procedure. This is the reason why I believe, that the recommendation found in both papers, to use a surgical tissue valve in patients aged 75 or older is no more actual and does also not match with those of the Guidelines and is neglecting the most recent developments in valve technologies.

But let's have a closer look at the 2 papers. The first important comment to both papers should emphasize the fact that neither a mean follow-up of 45 months (Belgian cohort) nor 1 of 6.6 years (German cohort) really represent what could be called a 'long-term' follow-up, especially not when prosthetic durability is one of the main issues. The concept of tissue valves was developed decades ago to mainly avoid life-long anticoagulation. For the majority of patients, it should represent the most definitive option, although nowadays, the concept of valve-in-valve transcatheter implantation is emerging as an acceptable option for patients with SVD. Therefore, a SVD-free survival of approximatively 15–20 years

should reasonably be expected in patients who receive a tissue valve. No way to be satisfied with mean or median follow-up less than 10 years. Recently, Bourguignon and colleagues published long-term data on patients who received the pericardial Carpentier-Edwards valve in aortic position with differentiated rate of SVD and necessity for redo-operation depending on the age at the time of aortic valve replacement [5, 6]. This paper gives the minimal durabilities that are the threshold to surpass!

Overall survival was similar with 64% at 5 years and 43% at 9 years in the Belgian study and 67% and 33% in the German study. However, other mid-term results were surprisingly different in both cohorts: freedom from SVD was 68% at 9 years in the Belgian, but 93.8% at 10 years in the German study. Personally, I cannot explain such huge differences. The main problem of SVD was stenosis in the large majority of patients (38 out 52 in the Belgian group). After stratification, neither the prosthesis model nor the size had a significant predictive value for SVD in one paper but in contrary, smaller prosthetic size was found to be a potential predictive factor for SVD in the German analysis.

For this reason, the authors recommended to limit the number of small prostheses by using a 'proper' implantation technique. What this should be other than a supra-annular positioning is not explained in the text. Not surprisingly, increasing age was found to be a protective factor against SVD in the multivariate analysis of the Belgian cohort.

Altogether the information provided by these 2 papers are interesting, even though there were some weaknesses:

- Again, the mean follow-up of 45 months and 6.6 years was still very short—when compared with the expected durability of competitive tissue valves of 15–20 years.
- During the study period, 2 types of valve were implanted: the LA/LXA model until 2011 and the DLA model later on, that differs from the first one mainly because of the phospholipid reduction treatment with Octanediol. The length of follow-up for both types of valve was highly different and, to my opinion, does not allow a proper comparison.
- Whether redo surgery occurred primarily because of SVD or because of endocarditis is not clear. In fact, it is theoretically possible that endocarditis developed on the base of SVD since a dysfunctional valve would be more proned to endocarditis
- In-hospital mortality was 8% in the German group, this is rather high and would need some clarification. It would have been interesting to receive more information about the average EuroSCORE risk score and the frailty assessment of the respective collectives.

Having said this, the reader feels between the lines that there is most probably still a major concern with the durability of the Mitroflow valve—otherwise one could not explain why the authors of both papers do recommend to use this valve mainly in patients older than 70–75 of age—which once again—does not fit with the recommendations of the AHA/ACC and ESC/EACTS Guidelines.

Conflict of interest: none declared.

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