Reviewer’s report

Title: Is distortion of the bioprosthesis ring a risk factor for early calcification?

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Reviewer: Rafael LLorens

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This article is a continuation of that published by José Rubio in Interact CardioVasc Thorac Surg in 2009 (1) presenting the results of 491 patients over 70 years of age who had Mitroflow A12 bioprostheses implanted between January 1993 and January 2006. Twenty patients had to be reoperated due to structural dysfunction and another twenty-seven patients showed deterioration of the prosthesis. This means that in 9.5% of the patients there was deterioration of the prosthesis that led to the patients having to undergo surgery again or will have to in the coming months. The percentage of patients not requiring surgery again for structural dysfunction was 0.74% patient/year. Macroscopic findings showed sclerosis and calcification of the leaflets. Under X-ray examination it was noted that in 70% of the cases, the right coronary valve was the most affected.

In José Manuel Martínez’s work on a total of 510 patients, corresponding to the same series as José Rubio’s but increased by 19 patients and over a longer period of time, the number of patients requiring re-operation due to structural dysfunction has risen from 20 to 32, an increase of 6.2% over an average period of 70 months (36-98).

In the present article, the findings of José Rubio are observed: the macroscopic examination showed that calcification of the prosthesis was greater in the right coronary valve. A difference was that a 64 Multidetector Computed Tomography study on 4 patients was included in which distortion of the ring and abnormal movement in some of the leaflets were observed. The radiological study the ring was seen to be not circular in shape but irregular.

These results cannot easily be compared to those of Yankah (2), probably the largest series published by a single institution: 1513 patients over a period of 21 years. In that study the absence of reoperation in patients over 70 was 84.8±0.7% at 20 years with a linear incidence of structural dysfunction of 0.34% patient/year.

Martínez’s data confirm in time the results of the same series published in 2009: the A12 Mitroflow prosthesis presents a high incidence of structural failure as a result of fibrosis and calcification in the leaflets, affecting the non-coronary leaflet particularly.

The authors hypothesize that according to results obtained from X-ray and Multidetector Computed Tomography, the deterioration is due to mechanical stress secondary to ring distortion, brought about by suture abrasion on the Dacron ring, causing geometric deformity to the prosthesis.
The pericardium of the Mitroflow prosthesis has a greater incidence of calcification than other bioprostheses (3), partly related to a high level of phospholipids. The conclusion can be taken from Martinez’s article that the incidence of structural failure in the Mitroflow prosthesis, secondary to calcification in the leaflets and particularly in the right coronary leaflet, is higher than that published to date and is related to the mechanical stress it is subjected to. The authors related that stress to the deformation of the prosthesis ring shown by X-ray and MCT. However, the size and shape of the aortic ring vary during the cardiac cycle (4) and these changes do not happen uniformly in the three segments of the ring (5). Neither the stent nor the Mitroflow sewing ring are rigid structures and should bend to the changes in the aortic ring.

It has been shown that the loss of compliance in the aortic wall at the level of the breasts causes increased stress in the leaflets and triggers a chain of changes starting with microstructural modifications and ending in calcification (6). This phenomenon may explain the development of degenerative aortic stenosis or the calcification of the bioprostheses.

Taking into account that all the patients were over 70 and that 97.2% had aortic stenosis, it would seem a logical conclusion that the elasticity of the aortic wall was reduced in these patients.

Nevertheless, that does not explain the differences between this and other published series, therefore work must go on with the clinical evolution and the macroscopic or radiological studies of these patients.

I recommend the authors add demographic information on the patients, such as age, gender, incidence of hypertension, diabetes, smoking, aortic stenosis, renal insufficiency or size of the prosthesis. It would also be of interest to know the percentage the right coronary valve, or the other two, is affected by.

The article is of relevance in the field. It shows a large series of patients suffering from a complication whose mechanism is not well known and that this work has been developed on a hypothesis which must be backed up with further studies.

I recommend the editors publish this paper, after the addition of the abovementioned recommendations. The language is of acceptable quality.


**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

NA