

## Letters to the Editor

**Early Structural Valve Deterioration of the Mitroflow Aortic Bioprosthesis: Will the New Anticalcification Treatment Change Anything?****Degeneración estructural precoz de la prótesis aórtica Mitroflow: ¿cambiará algo con el nuevo tratamiento anticalcificante?****To the Editor,**

We read with great interest the article published in your journal by Díaz et al.<sup>1</sup> on structural degeneration of the Mitroflow aortic bioprosthesis. The authors describe a large series of patients who underwent aortic valve replacement with the last models, 12A and LX, of the Mitroflow bioprosthesis prior to the introduction of anticalcification therapy. They report a high cumulative incidence of structural valve degeneration (SVD).

Although several authors had already warned of the probable early degeneration of these bioprostheses, it was not until 2014 when the French group of Sénage et al.<sup>2</sup> rigorously demonstrated a high cumulative incidence of SVD (8.4%) with these models in the first 5 years after implantation. These same authors also showed a worrying pattern of accelerated degeneration in a substantial proportion of patients with SVD, defined as a gradient increase of > 25 mmHg in just 12 months. Such findings are very uncommon in patients older than 65 years.

Subsequently, the French National Medicines Agency launched an investigation. Their findings, published in 2016, recognized the existence of early degeneration of Mitroflow prostheses, but the agency recommended not to proceed to withdrawal of the device from the market as it was still an option for patients with a very narrow annulus.<sup>3</sup>

The British government went further and recommended locating all carriers of the small (19 or 21 mm) LX model with highest risk of SVD for clinical assessment and early echocardiography (within 5 years of implantation).<sup>4</sup>

The findings of the study by Díaz et al.<sup>1</sup> not only confirm a higher incidence of cases of SVD in the first 5 years after implantation, but also point to an exponential growth in new cases in subsequent years of follow-up. These results are also consistent with a series, also published recently, in another hospital with a large number of patients in Spain implanted exclusively with the Mitroflow LX model.<sup>5</sup>

In July 2011 in Europe and later in January 2013 in Spain, the new model of the Mitroflow prosthesis (DL) was brought onto the market. Anticalcification therapy, known as phospholipid reduction treatment (PRT), based on rinsing the pericardial tissue with phospholipids after fixing with glutaraldehyde, is applied to this model. Subsequently, after some design modifications, but without any changes in the treated biological material, it became known as CROWN PRT.

In our hospital, we started to implant the Mitroflow PRT (DL) device early in 2013. Despite the high expectations generated by

Mosquera et al.<sup>6</sup> in A Coruña, who found a significant reduction in SVD with the device with the new treatment, we now have 2 cases of early valve degeneration after a total of 110 implantations. Both were in a device 23 mm in diameter, and only 1 had a maximum postoperative gradient > 30 mmHg.

In line with conventional wisdom that prevention is better than cure, the best approach when studies such as this one are published is to carefully select the patients to receive the prosthesis, assess whether they have the identified risk factors for SDV (eg, patient-prosthesis mismatch, prosthesis diameter of 19 mm, age, metabolic syndrome) and await a later model of the valve that will offer better outcomes.

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