Quality of valve prostheses. Are we treating our patients well in the Brazilian National Health System?

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The correction surgery of acquired valvular heart disease is responsible for about 30% of all cardiac operations performed in Brazil and the valve prostheses implantation corresponds to 17.4% of high complexity surgeries using 25% of government resources for the cardiovascular field.

The Unified Health System (SUS) (acronym in Portuguese), accounts for 75% of patients requiring cardiovascular surgery procedures in Brazil, which provides nationally manufactured bioprostheses for the surgical treatment of these patients, represented by the world’s most widely used models with extensive evidence of effectiveness and quality. However, due to the shortage of studies, there is a lack of data about the efficiency and durability of bioprostheses in comparison with the imported bioprostheses, raising questions about the product quality that SUS provides for the treatment of patients with valvular heart disease.

The paper written by Almeida et al. [1], published in this issue (page 326), offers the opportunity to assess the performance of biological prostheses provided SUS and ensure the quality of surgical treatment we are offering to our patients.

A total of 301 patients evaluated in a 20-year follow-up period, the study compared the results between national bioprostheses and mechanical prostheses outcomes in mortality, hemorrhagic events and reoperations in patients undergoing surgery for aortic valve replacement by biological or mechanical substitute in a university hospital that is a reference center for cardiac surgery.

Data from international literature with the studies carried out so far, have shown that the type of prosthesis, whether biological or mechanical, did not determine differences regarding long-term mortality. It also reveals that bleeding events were more strongly related to mechanical prostheses and reoperation for prosthesis dysfunction more frequently in patients with biological substitute after a 5-year follow-up period.

In the study by Adams et al., 5, 10 and 15-year survival after valve replacement surgery for mechanical substitute was 83.90%, 75.40% and 60.20%, respectively, and for biological substitute was 89.30%, 70.40% and 58.40% respectively, with no statistically significant difference in survival of patients in both groups (P = 0.939) during the follow-up period. Thus, the bioprostheses examined in the study had similar performance to that observed in international studies that compared the long-term performance of biological and mechanical prostheses. In addition to that, during Cox regression multivariate analysis, the type of prosthesis remained unassociated with the death outcome (P = 0.556), making the data in this study agree with the current literature.

As expected and consistent with international studies, major bleeding events tended to be more frequent in patients with mechanical substitutes (P = 0.084). In patients with biological substitute there was a higher probability of reoperation, especially after the first 10-year follow-up.

As it was a retrospective and observational cohort study performed in a single center, these data should be confirmed by randomized controlled trials, which constitute the top of the hierarchy of scientific evidence guiding our clinical practice.

Ultimately, from the evidence generated by the new study, the Brazilian cardiac surgeons can be certain that they are using valve prosthesis with a long-term performance comparable to those used throughout the world, performing a high-quality surgery that definitely benefits patients with valve disease in the National Health System.

REFERENCE