Mini Review

Interventional Cardiology

Aortic bioprosthesis: A critical review

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Abstract

The wide use of bioprostheses in aortic position in younger patients to avoid anticoagulation seems as a solution for thrombosis and embolization. However, this approach generates controversy on considering the life expectancy of these patients compared to documented prosthesis durability, early thrombosis risk, and early degeneration and dysfunction. The balance between offering solutions to old problems and generating new inconveniences is still in dispute.

Keywords: Bioprosthesis • Aortic position • Young patients • Aortic valve replacement • Prosthesis disfunction

Introduction

Anticoagulation after Aortic Valve Replacement surgery (AVR) was a nightmare at the time mechanical prostheses were improving their function and performance, not only regarding hemodynamics but also durability. Bioprostheses arose as a long-awaited breakthrough to avoid life-long anticoagulation with high International Normalized Ratio (INR) targets. Progressively, these valves enhanced their hemodynamic profiles and achieved apparently excellent durability, becoming the mainstream approach [1].

Currently, clinical guidelines suggest that for patients over 50 years of age requiring a prosthesis in the aortic position, the choice of the type of prosthesis should be a shared decision-making process that takes into account patient's values and preferences after a full discussion of the tradeoffs. It is easy to understand that patients would prefer to avoid anticoagulation therapy. If additionally physicians feel confident about the durability of the valves-or trust they can afford an easy solution in case of prosthesis degeneration or disruption-bioprosthesis valves are the usual choice [2-4]. However, this dilemma of choosing between better hemodynamic profiles and durability versus hemorrhage/thrombosis risk is heightened in the population of younger patients with a longer life expectancy, despite the growing use of biological designs [5].

Literature Review

Available data on bioprosthesis durability was recently reviewed by Jørgensen, et al. [4]. In these studies, clinically-significant prosthesis failure was defined as "death caused by prosthesis dysfunction and/or heart failure or the need for reoperation". These endpoints are all clearly defined, with the exception of "need for reoperation". What exactly does "need for redo aortic valve replacement" mean? What does this endpoint state about the clinical condition of these patients? The answer to this question is relevant! Heart failure or death due to prosthetic dysfunction are clear examples of outcomes that appear too late in disease progression to evaluate prosthetic performance, let alone improve survival. Redo operations are generally not conducted in patients with acute heart failure due to prosthetic dysfunction, since reoperation risks are very high in these patients. But on the other hand, early clinical signs and symptoms of mild heart failure are usually not enough to push surgeons and clinical cardiologist to perform

reoperations. Therefore, the need for redo aortic valve replacement is an ambiguous term that does not offer clear information on the clinical status of patients, and almost certainly arrives at advanced stages of prosthetic valve dysfunction. For these reasons, it does not appear to be a good endpoint to evaluate the durability of bioprosthesis [4].

Recently, widespread availability of new cardiac imaging diagnostic tools has loaded the literature with data on bioprosthesis early dysfunction, disruption and/or degeneration, pannus or thrombosis. For example, CardiacTomography (CCT) studies have revealed a startling high incidence of aortic bioprosthesis subclinical thrombosis, which, without proper anticoagulation, may organize creating pannus and permanently jeopardize valve performance [6,7]. An additional problem related to aortic bioprothesis performance is Prosthesis Patient Mismatch (PPM), which is particularly relevant in patients with high body mass indexes and aortic rings diameters below 25 mm, either due to ethnics, sex or obesity [8,9]. Guaranteeing an Effective Orifice Area of flow (EOA) is in itself not a simple task since bioprostheses are handmade, which introduces wide variations across models, brands, and possibly lots, even within the same valve size [10]. Since this broad standard deviation of EOA reported by manufacturers is not taken into account in the current methods used to predict PPM, the selection of an appropriate patient-specific prosthesis size could be unsuitable for many, arousing controversy on its accuracy [11]. Recent studies are reassuring on the fact that these methods do accurately predict the presence of PPM, but not the severity, failing to distinguish between moderate and severe PPM. These studies also suggest that both degrees of PPM accelerate valve degeneration and affect the recovery and reverse remodeling of the left ventricle in less than 5 years after AVR, though in different proportions [12,13].

In our own personal experience as noninvasive cardiologists, we frequently evaluate patients with aortic bioprostheses with increased transvalvular gradients, time-to-peak flow and decreased EOA and Doppler velocity indexes. A systematic evaluation of these patients using CCT revealed prosthetic thrombus within the first year after AVR in a surprisingly high proportion of patients. Though fortunately the EOA and transvalvular gradient values returned to normal with anticoagulation therapy, we were left with the tough decision of either suspending or maintaining anticoagulation, when to avoid it was the main point in choosing bioprostheses over mechanical heart valves. These patients became frustrated by the long-term–and in some cases, permanent–anticoagulation regimens, since their expectations were to avoid anticoagulation at the time of prosthesis selection.

Discussion

Currently, American Heart Association/American College of Cardiology (AHA/ACC) clinical guidelines recommend a yearly echocardiography follow-up starting 5 and 10 years after AVR with bioprostheses, unless clinical signs or symptoms are present. Following these suggestions, it would be nearly impossible to detect early subclinical thrombosis and/or early valve dysfunction [2]. We find only what we seek.

Though we do not count on enough data to identify with precision which patients are at higher risk for early valve thrombosis and/or degeneration, following our personal experience we recommend patients with moderate or severe PPM, severe calcification, history of smoking, dyslipidemia, renal insufficiency, diabetes or history of thrombosis to undergo careful echocardiography examinations every 6 months after postoperative echocardiography to determine the EOA and hemodynamic profile. There is an urgent need for evidence-based clinical guidelines addressing these issues, as well as the duration of anticoagulation therapy when early thrombosis is detected by the combination of echocardiography and CCT examinations [2,7].

Lastly, regarding Transcatheter Aortic Valve Replacement (TAVR), PPM does not appear to be a problem since the hemodynamic profile of these valves is clearly superior to that of surgical bioprostheses. Nevertheless, valve-in-valve interventions in rings diameters below 25 mm without prosthetic valve ring disruption do not exhibit the same excellent hemodynamic performance as implants in native valve rings. Also is well established that calcified, degenerated and stenotic aortic prosthesis have worst results in terms of mortality and morbidity, after valve in valve interventions, in comparison with prosthetic failure due to disruption and/or regurgitation [13]. There is also an abundance of published data suggesting high incidence of early thrombosis in TAVR valves, despite the lack of information on the clinical relevance of such findings. The fact that the durability of TAVR valves has been documented only up to 8 years after implantation should encourage us to be especially cautious on recommending TAVR in young patients with high life expectancies [5,13-15].

Overall, we believe bioprostheses are a remarkable development that still has room from improvement. At present, these heart valves represent a suitable alternative to avoiding anticoagulation for some patients, but introduce many new problems for others [13].

Who are the patients at major risk for developing early and late thrombosis as well as early degeneration should be figured out. Early failure of bioprosthetic aortic valves is a complex and

multifactorial phenomenon. At the present time we can identify some clinical cardiovascular risk factors as predictors for early prosthetic degeneration, as well as, factors related with prosthetic size and designs, but, there are still unclear many others related to inflammatory and thrombotic states that should be pointed out [13-16]. Xenographs, as porcine valves, bovine pericardial stented or stenless, are quite different to autographs and/or allographs (cadaveric aortic valves and Ross procedures pulmonic valves implanted in aortic position) and all of them suffer early calcification and degeneration in young patients [13,15].

The need to improve designs looking for better hemodynamic profiles in surgical bioprosthesis at smaller sizes should be achieved. We believe these issues need to be addressed and that feasible solutions must be available before moving the indication of bioprostheses on to younger people, in which the alleged promises of durability and avoiding anticoagulation with bioprosthesis have to be weighed against the well-known advantages and disadvantages of mechanical designs [14-16].

Conclusion

In conclusion the available bioprosthesis, both surgical and percutaneous, are still in improvement progress. Surgical ones need to improve hemodynamic profiles especially at smaller sizes to avoid patient prosthesis mismatch because this is one of the recognized factors for early degeneration. Percutaneous prosthesis are in rapid development but it is mandatory to demonstrate long term durability. Who are the patients and which are the factors related with higher risk for early prosthetic degeneration and failure are not defined yet, and these seem to be the key for prosthetic selection in the future. Following our personal experience we recommend in patients with moderate or severe PPM, severe calcification, inflammatory disturbs and/or history of thrombosis to undergo careful echocardiography examinations every 6 months after postoperative echocardiography to determine the EOA and hemodynamic profile. Prospective and randomized trials should be conducted before we can go to wider indication of bioprosthesis in younger patients with longer life expectancy as the best treatment option.

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