Hemodynamic Evaluation of Heart Valve Prostheses

Paradigm Shift for Transcatheter Valves?

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The treatment of aortic valve disease is undergoing rapid changes. In addition to conventional valve replacement that has evolved as the gold standard over several decades, transcatheter techniques have been introduced into clinical practice. Whereas the conventional approach offers very precise and safe suturing of standard valves with low failure rates and excellent proven long-term outcomes, transcatheter techniques allow for off-pump beating-heart valve implantations that can even be performed without general anesthesia in some patients. To determine the clinical benefits of transcatheter valve implantation in comparison with conventional aortic valve surgery, randomized trials are required.

Given the lack of data from randomized trials, the study by Clavel et al. (1) in this issue of the Journal is timely and provides insight into the hemodynamic performance of interventional and standard aortic valve implants. Pibarot’s group from Quebec and Webb’s group from Vancouver are pioneers both in the field of hemodynamic assessment of prosthetic heart valves and in transcatheter aortic valve implantations.

Hemodynamic assessment was performed retrospectively on a total of 150 patients, of whom 50 received transfemoral or transapical aortic valve implantation, and the remaining 100 patients received conventional aortic valve replacement using a stented (n = 50) or a stentless (n = 50) xenograft. Of note, 39 of 89 patients with transcatheter valve implantation had to be excluded from the analysis owing to procedural death (9%), death before completing their 6- or 12-month follow-up (14.6%), or incomplete follow-up (20.2%). Similar data were not provided for the stented or stentless valve groups. Groups were matched for standard criteria, including the aortic annulus diameter. Particularly in the stented valve group, a large number (18%) of 19-mm valves, known for high transvalvular gradients, were implanted. Another 40% of patients in the stented group and 34% in the stentless group received 21-mm valves. The smallest transcatheter valve implanted was 23 mm. Conversely, 64% of the patients in the transcatheter group received a 26-mm valve, and only 10% in the stented group and 26% in the stentless group received a 25-mm valve. Clearly, this disproportional selection of implants is related to the oversizing concept. During transcatheter aortic valve implantation, oversizing as much as 2 to 3 mm is usually performed to generate the radial forces required to achieve a stable position of the implant. Not surprisingly, the authors found transvalvular gradients to be lower in the transcatheter group at discharge. Whether a total difference of mean transvalvular gradient of 3 (transcatheter vs. stentless) or 4 mm Hg (transcatheter vs. stented), albeit statistically significant, has any clinical relevance remains unclear at this point. At 1 year, transvalvular gradients remained significantly lower in the transcatheter versus the stented xenograft group, whereas they were equal between the transcatheter and the stentless group, even though the stentless valves had a smaller diameter at the time of implant.

After transcatheter aortic valve implantation, patients had a significantly higher incidence of aortic regurgitation (present in 50% of patients) in comparison with conventional surgery (present in 10% [stented valves] and 12% [stentless valves] of patients, respectively), which persisted largely unchanged throughout the study.

The observed immediate improvement in left ventricular (LV) ejection fraction after implantation in the transcatheter group may most likely reflect that the procedure is performed on the beating nonischemic heart. Despite myocardial protection, surgical implantation on the arrested heart may cause some impairment of ventricular function. However, echocardiography tends to overestimate LV ejection fraction in the presence of aortic regurgitation, which was present in 50% of the transcatheter patients after intervention.

Valve surgery for aortic valve stenosis aims to provide a low transvalvular gradient, induced regression of hypertrophy and recovery of LV function, freedom from paravalvular leak, long-term freedom from structural failure, and long-
term freedom from valve-related reoperation. Most contemporary xenografts offer sufficient hemodynamic improvement to achieve regression of LV hypertrophy, and thus normalize ventricular function even when some residual gradient persists. In this context, the observed differences in mean gradients of 3 and 4 mm Hg for the 3 groups post-operatively may have limited clinical importance. The authors emphasize the high incidence of patient-prosthesis mismatch in the conventionally treated group. The potential impact of patient-prosthesis mismatch on long-term survival remains a matter of lively debate. While some groups support this view, others have not found patient-prosthesis mismatch to be an independent predictor of survival.

The higher incidence of paravalvular leakage in the transcatheter group could, however, become of clinical importance, as paravalvular leakage is known to trigger hemolysis, promote endocarditis, and if moderate to severe, may even cause LV dysfunction. Longer term follow-up is required to determine these outcome parameters.

Common criteria for the hemodynamic evaluation of the performance of aortic valve prostheses have been blood flow velocity, pressure gradients, and effective orifice area. Given the presented data and the data reported from other groups, it is fair to state that transcatheter implants match and may even exceed the hemodynamic expectations for valvular implants, even though the native valve is not replaced but remains in situ.

But there is a price to pay: namely, a high incidence of paravalvular leakage, which can be explained by the differences in the technical approach. Whereas conventional valves can be safely implanted using precise suturing techniques, transcatheter valves are implanted in a sutureless fashion using oversizing to expand a stent at the level of the aortic annulus. The technical constraints posed by the transcatheter technique have promoted a paradigm shift with regard to the hemodynamic assessment of prosthetic heart valves. Cardiac surgeons were educated over the years to judge paravalvular leakage as a complication of surgery. With the event of transcatheter techniques, paravalvular leaks are now considered as acceptable collateral damage intrinsic to the procedure. It is true that trivial and mild paravalvular incompetence in patients with a hypertrophied ventricle is usually well tolerated. As long as a negative impact of the high incidence of paravalvular leakage on long-term results cannot be ruled out, a word of caution is justified.

In the future, aortic valve prostheses designed for transcatheter implantations will have to match standard criteria for accepted quality: in addition to long-term durability, ease of implantation, and safety of positioning, a low incidence and degree of potential paravalvular leakage will be important end points. It is quite clear that—especially when targeting a younger population—the high standards of quality that have evolved with conventional aortic valve surgery will have to be matched by any new transcatheter technique.

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