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EARLY DEGENERATION OF THE ST JUDE MEDICAL TRIFECTA BIOPROSTHETIC AORTIC VALVE: A PROBLEM OF

THE LEAFLETS OR OF THE STENT?

To the Editor:

The development of new aortic valvular bioprosthetic devices is a very important issue in light of the increasing demand for these models for younger patients who want to avoid oral anticoagulation and maintain a better quality of life. Moreover, the prospect of a subsequent catheter-based valve-in-valve therapy plays an even more important role in this new trend in decision making.

If we are to implant these devices in younger and younger patients, the aspect of long-term durability becomes central in the development of the new models. With regard to this issue, we read with interest the article by Goldman and colleagues.¹ They reported on a prospective, multicenter trial in which 710 patients operated on for aortic valve disease received the novel Trifecta (St Jude Medical, St Paul, Minn) aortic valve prosthesis. The valve shows very favorable hemodynamic results even for small implants, but there are aspects that we believe should be discussed more closely.

During the study period, 15 valves had to be explanted for valve dysfunction (4 cases of nonstructural dysfunction and 11 structural valve failures), and these explantations were not further elaborated on in the text. When we implanted the Trifecta valve in our institution, we encountered several cases in which, during manipulation of the valve in the root during positioning or knotting, deformation of 1 or more struts led to distortion of the valve, which in turn led to severe central leakage. This leakage necessitated early explantation of the device, which was performed during the same session as the implantation. One might then speculate whether a smaller degree of stent distortion, not sufficient to lead to very early valve dysfunction and thus

immediate explantation, may have had an effect on a possible premature degeneration of the prosthesis. If this were the case, what would be an adequate means of detecting such distortion intraoperatively? Would it be justified to recommend explantation of these prostheses with mild central incompetence under intraoperative echocardiographic control? It would be interesting to know whether Goldman and colleagues¹ have encountered this phenomenon during their experience, particularly in patients with early degeneration.

In addition, there is another consideration in association with the implantation of these prostheses in young patients. Although this prosthesis allows a favorable hemodynamic profile even when small sizes are implanted, would it still be better to carry out an annular enlargement and use a larger implanted prosthesis to allow a subsequent valve-in-valve procedure, such as would not be possible with a size 21 or smaller valve?

Giuseppe Santarpino, MD

Steffen Pfeiffer, MD

Department of Cardiac Surgery

Paracelsus Medical University

Nuremberg, Germany

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BIGGER VALVE SIZE IS NOT ALWAYS BETTER

Reply to the Editor:

In their letter to the Editor, Drs Santarpino and Pfeiffer question whether early dysfunction of the Trifecta valve (St Jude Medical, St Paul, Minn) is due to the leaflets or stent and whether implantation of a small valve size should be avoided. In our study, stent deformation may have contributed to an early explant in 4 cases, whereas in 11 cases leaflet dysfunction due to calcification, fibrous thickening, or pannus formation was the primary contributing factor.¹ Although there are multiple factors that can contribute to valve dysfunction, our results demonstrate that the Trifecta valve exhibits excellent durability over 6 years of follow-up.

On the basis of our experience, the Trifecta valve is uniquely suitable for implantation in patients with a small aortic root. The best clinical outcomes occur when the valve is appropriately sized to match the aortic annulus and anatomy of the sinotubular junction. When encountering an aorta with a narrow root, attention must be given to not

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S.G. is a consultant to St Jude Medical, Edwards Lifesciences, LSI, and Abbott.

deform the stent during implantation because it may result in altered hemodynamic performance.²

Despite notice from the manufacturer, some surgeons may attempt to oversize the Trifecta valve with the thinking that implanting the biggest possible valve may have the best chance of achieving a successful clinical outcome, with relief of aortic obstruction, regression of left ventricular mass, and avoidance of patient–prosthesis mismatch. These cases typically represent the early learning curve with using the valve and have the potential to result in an unfavorable clinical outcome. Oversizing may result in shifting of the leaflet hinge point and causing incomplete leaflet opening with reduced hemodynamic performance.³

To ease the implant procedure, the manufacturer has introduced a next-generation Trifecta valve with Glide Technology. The new valve is identical in design to the prior valve with the exception of having a more slender conical holder with a softer sewing cuff that conforms more easily to the annulus and minimizes suture drag (Figure 1). The holder has internal backstops that protect the stent posts from deforming during valve insertion. In addition, the base of the valve has an additional titanium band that provides enhanced fluoroscopic visibility and valve protection.

An aortic root enlargement with the Trifecta valve is rarely needed to achieve the desired hemodynamic performance and not recommended because it requires a longer operative time and may be associated with increased operative risk.⁴ Performing a root enlargement merely for the sake of being able to perform a valve-in-valve procedure at a later date cannot be justified, because a valve-in-valve procedure carries the risk of an elevated postprocedure gradient, and in general redo aortic valve replacements can be performed safely with minimal risk.⁵ A valve-in-valve procedure is more appropriate for older patients with high surgical risk who are unlikely to require another operation. The Trifecta valve has excellent hemodynamic

FIGURE 1. Trifecta valve with Glide Technology (St Jude Medical, St Paul, Minn) aortic valve with holder. The holder has internal backstops (arrow) that protect the stent posts from deforming.

performance, particularly in smaller valve sizes, and cardiac surgeons confronted with a small aortic root should be aware that oversizing of the valve is not beneficial and that aortic root enlargement is rarely needed to avoid patient–prosthesis mismatch.

Scott Goldman, MD
Division of Cardiovascular Surgery
Lankenau Hospital
Wynnewood, Pa

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