See Article page 87.

Commentary: Extremely early failure of transcatheter aortic valves—Another warning!

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In this issue of the *Journal*, Park and colleagues¹ from Grand Rapids, Michigan, describe a case of extremely early structural failure of a self-expanding transcatheter aortic valve secondary to leaflet dehiscence. The original implantation was followed by a postdeployment balloon dilatation for residual moderate paravalvular insufficiency. Immediately after the procedure, the valve appeared to be in good condition; 10 months later, however, there was severe aortic regurgitation requiring surgery, during which the prosthesis was shown to have a left cusp avulsion. In their conclusion, Park and colleagues¹ state that “this case should bring to light the potential complications of balloon dilatation on the integrity of transcatheter valve leaflets. Long-term follow up may eventually reveal the effect of balloon valvuloplasty nuances with respect to size, type, and methods on valve durability.”

I assume that the failure of the prosthesis may have been due to off-label manipulation by the balloon. The conclusion of Park and colleagues¹ thus may be appropriate, and this would be a good reason for no further comments; however that assumption may not be certain. But before I get along with this invited commentary, I wish to make a declaration of conflict of interest. With regard to the percutaneous valves, I am still in a “wait and see” mood. Nonetheless, when my mother required treatment for aortic valve stenosis some 5 years ago, I took her to the best transcatheter aortic valve implantation specialist in my country. But then, she was 90 years old!

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CENTRAL MESSAGE

Durability of percutaneous prostheses remains uncertain and is the main obstacle to generalized use. The tissue used in these prostheses, different from surgical prostheses, may cause early failures.

I have been around in cardiac surgery for 4½ decades now, and have implanted all major types of surgical valve prostheses, from mechanical prostheses to bioprostheses, back to mechanical and again to biologic. In those early days, and until recently, the introduction of a new valve in the market took several years from the conception through laboratory and careful human testing, largely because of the very tight Food and Drug Administration requisites. In current times, all the makers come to Europe (where I live) to take advantage of the far less demanding CE mark. And this could be the main factor for what may come and is portrayed by this case report.

If not, let us consider the history of the last decade of percutaneous devices. There are numerous brands and models coming into the market, in the forefront of which are those produced by the main classic manufacturers of surgical heart valves. Some of their brands have gone into the fourth generation of their initial models, each promising to be better than the previous one. This forceful marketing is triggered by the anticipated multimillion-dollar revenues, which are far higher than those ever reached by the production of the classic surgical prostheses (the new percutaneous devices may cost as much as 10 times as much as the surgical ones).

The percutaneous valves derive from the surgical bovine pericardial bioprostheses; you can see that at first look. The only thing different is the stent, they said. Should these

valves therefore be as durable as their predecessors? Wrong; the manufacturers do not tell us that to be able to introduce the valves inside catheters of increasingly lower calibers, they had to choose different and thinner pericardial sheaths. Thinner is potentially less durable, and durability is the potential Achilles' heel of these devices. Catastrophic failure by "simple" balloon manipulation in this case, which was triggered by yet another mode of failure—periprosthetic leakage—attests to their increased fragility.

One of the concepts that the "old fashioned" surgeons (like me) were taught, right from the beginning, was to be respectful (no-touch) of the tissue of the valve and not to distort the whole prosthesis during implantation in the annulus. This is particularly pertinent in the calcified aortic annulus (débride the calcium careful and completely), because that can damage the prosthetic tissues, and distortion of the geometry increases the stress and accelerates wear. Indeed, this advice was reinforced with the introduction of the rapid-deployment valves, which are closer "cousins" of the percutaneous valves. Now, imagine what the squeezing of the valve inside the delivery system, forcefully opening it with a balloon (to non-self-expanding devices), and implanting it within a wholly calcified valve will do!

Earlier, Summers and colleagues² from the Cleveland Clinic discussed 3 mechanisms of early failure of transcatheter aortic valves, each exemplified by the description of a case: valve thrombosis, cusp rupture, and accelerated calcification. I was also asked to comment on that report,³ and I thought that it was a "timely warning." Each one of these modes of failure is also a well-known complication of the classic surgical bioprostheses, usually occurring much later after implantation, although early failures are also known to occur occasionally.

Naturally, there must be many more cases like the one here described by Park and colleagues,¹ but this one is the only one, or one of the few, to get published. The large series of transcatheter aortic valve implantations do not usually report them. A couple of years ago, Bentham and colleagues⁴ reported early failure of percutaneous valves implanted within bioprosthetic tricuspid tissue valve replacements. It will take at least another decade before we know the true longevity of the percutaneous valves. No doubt, there will be some that will last very long times and some that will last very short times, because that is what happens with any device, medical or not, that is mass produced before it is thoroughly conceived and tested.

That is why I will remain skeptical about universally treating aortic stenosis by transcatheter aortic valve implantation and, for the time being, am against advocating this method to my patients younger than 80 years who are otherwise physically and mentally fit. Please, remember that in these circumstances surgical aortic valve replacement can be performed with a mortality less than 1%,⁵ and we already know that the surgical prosthesis will, almost certainly, last for the rest of the patient's life!

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