

CORRESPONDENCE

Letters to the Editor

Percutaneous Aortic Valve Replacement With the CoreValve Prosthesis

We read with interest the recent article of Grube et al. (1) dealing with percutaneous aortic valve implantation. They reported the experience from 3 centers using the second and third generations of the CoreValve prosthesis (CoreValve Inc., Irvine, California) in 86 consecutive patients. The acute device success was high (88%), and the 30-day mortality was low (12%) in these surgically high-risk patients with mean pre-procedural logistic Euroscores of 21.7%. Hemodynamically, the mean transvalvular gradient dropped from 43.7 to 9.0 mm Hg with a concomitant improvement in the New York Heart Association functional class.

We would like to comment on these results and also ask for some clarifications regarding their data.

When reporting data after aortic valve implantation, one would expect to have information regarding the aortic prosthetic valve area and the rate of prosthesis–patient mismatch. One cannot be satisfied by the transvalvular gradient alone, knowing that a high proportion of patients with left ventricular systolic dysfunction were included in the study. These data are important because they will allow comparison among percutaneous valves themselves and with the surgically implanted prosthetic valves, thus improving the information given to patients.

In the same way, we regret that the post-procedural incidence and severity of perivalvular leakage were not detailed as was the case for the pre-procedural intravalvular regurgitation.

We were surprised that exclusion criteria did not include bicuspid aortic valves. In our experience, stent deployment may be impaired in bicuspid aortic stenosis (2), a condition with an incidence that can reach 50% of the surgically operated patients (3). Furthermore, in the series of Cribier et al. (4), all of the native aortic valves were tricuspid.

We were also surprised by the high rate of procedural valve dilations after valve implantations (28% of the 76 valve implantations) to achieve good stent expansions. We wonder if this high rate of subsequent dilation reflects undiagnosed bicuspid aortic stenosis.

Information regarding major bleeding is lacking (a rate of 24% has been reported in a previous study [5]). Likewise, the peripheral vascular complications and their management were not reported. One would like to know whether their incidence was dependent on the type (open [with a cut down] or closed) of vascular access during the procedure.

Atrioventricular block is a classic complication after surgical aortic valve replacement. It seems that it is also the case after percutaneous valve implantation. Data regarding this complication in the series should also be provided.

Finally, there is actually only one available size of CoreValve, with a 21-mm bioprosthesis implanted within the stent frame (2). As researchers, we do not understand how proper sizing could be

achieved in patients with aortic annulus diameters ranging from 20 to 27 mm. Mismatch will inevitably lead to leaflet distortion or restriction (Rachid Zegdi, personal communication, December 2006), with a potential negative impact in the long term.

Although many points of the study require further clarification, we would like to thank the authors for their important work and contribution to this important new field of interventional therapy.

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Please note: Dr. Zegdi is a stock owner in a company (Coremove) developing a new percutaneous valve.

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Reply

We would like to thank Dr. Zegdi and colleagues for their interest in our article (1) and would like to address the raised questions as follows: 1) the valve area increased from $0.60 \pm 0.16 \text{ cm}^2$ to $1.67 \pm 0.41 \text{ cm}^2$ post-CoreValve implantation, as suggested by the marked decrease of the mean transvalvular gradient. A direct comparison of the valve areas after standard surgery versus percutaneous replacement carries a caveat. Prosthetic valves are surgically implanted and function either intra-annularly or supra-annularly, whereas the CoreValve is designed to be placed intra-annularly but function supra-annularly. Therefore, whereas the frame anchors and adapts to the annulus

size within its design parameters, the functional valve area of the CoreValve device is a constant factor at a 22-mm diameter for the smaller valve and 24 mm for the larger valve. Obviously this does not result in a relevant increase of the gradient as demonstrated in our series. 2) We would like to emphasize that in the results section of the article, a detailed description of the degree of post-procedural paravalvular leaks is provided. Severe (grades 3+ or 4+) regurgitation was not observed during follow-up. Furthermore, there were no patients with congenitally known bicuspid aortic valves. 3) Some of the patients have had functionally bicuspid valves due to strong calcification of the cusps. However, in our view, this does not present a contraindication for this procedure as long as a successful balloon pre-dilation of the native valve is considered to be feasible and is successful to prepare a landing zone for the percutaneous bioprosthesis. 4) The relatively high rate of post-dilation of this early series may be explained by the fact that during the first period of the study only the small valve (26-mm inflow for patients with a 20- to 23-mm annulus) was available, and some valves were undersized. Also, during the early phase of the study, investigators were less comfortable with the notion of giving the self-expanding frame some time to "adapt to the annulus," and post-dilations were more common. Of note, at the end of the reported study phase, the larger valve (29-mm inflow for patients with a 24- to 27-mm annulus) became available, which explains the 20- to 27-mm annulus range of the total cohort. 5) In addition, likely due to the smaller device size (21- and 18-F, respectively), there were no severe peripheral vascular complica-

tions or major bleedings to report. It should be noted that with this 18-F device, standard interventional pre-closing techniques are commonly applied, thus obviating the need for surgical access or repair. 6) Finally, we acknowledge that the issue of the need for permanent pacemakers is not unlike surgical aortic valve replacement patients, and we will be reporting in our next publication on the incidence of complete atrioventricular block and the need and rationale of pacemaker implantation in this high-risk octogenarian population.

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