BIOPROSTHETIC DURABILITY ASSESSMENT: IMPORTANCE OF COMPLETE DATA

To the Editor:

Mykén and Bech-Hansen¹ reported a 20-year experience with the Biocor valve (St Jude Medical, Inc, St Paul, Minn). This study consisted of 1518 aortic valve replacements and 194 mitral valve replacements (MVRs). The predominant area of interest in the report has been the durability of the prosthesis in the mitral position. The article reported on structural valve deterioration (SVD) as determined by explant reoperation. The alternative method of retrospective reporting is to combine SVD by explant reoperation and with SVD by clinical (echocardiographic) evaluation. Mykén and Bech-Hansen¹ reported echocardiographic performance but did not include echocardiographic evaluation in their durability analysis. Only Kaplan–Meier actuarial data analysis was reported, because their objective was to report on prosthesis performance and not performance in a specific population subset (actual cumulative incidence).

Mykén and Bech-Hansen¹ reported promising results with respect to MVR actuarial freedom from explant reoperation for SVD. For patients older than 65 years, the 20-year actuarial freedom from reoperation for SVD in MVR was 88.0%. Two previous reports on MVR freedom from reoperative SVD have illustrated similar results, noting highly satisfactory

15-year durability performance in MVR populations with mean ages of 48 and 49 years.^{2,3} Pomerantzeff and colleagues³ in 2006 reported favorable actuarial freedoms from reoperation for SVD for MVR at 15 years of 88.7% for patients 51 to 60 years old and 84% for patients 61 to 80 years old. Kirali and colleagues² reported in 2001 MVR actuarial freedom from reoperation for SVD of 76.8% at 13 years. An important aspect of the latter publication is that the freedom from SVD for all clinically documented cases was 64.8% at 13 years (39 cases of overall SVD vs 16 reoperative cases). The distinctions in reporting of SVD for MVR by the different definitions are illustrated by Kirali and colleagues.²

Mykén and Bech-Hansen¹ reported that for patients older than 65 years undergoing aortic valve replacement the 20-year actuarial freedom from reoperation for SVD was 92.1%. In 2008, Eichinger and coauthors,⁴ in a separate 20-year publication on the Biocor prosthesis, reported actuarial freedom from reoperation for SVD at 15 years of 90.6% for aortic valve replacement in a cohort of 455 patients (mean age, 72.5 ± 9 years). The actuarial freedom at 15 years for overall SVD was 88.4%. Sixteen of 23 patients with SVD came to reoperation. The actuarial freedom at 20 years from reoperation for SVD was 86.5%. The distinctions in reporting of SVD for aortic valve replacement by the different definitions are illustrated by Eichinger and colleagues.⁴

The comparison of SVDs from various studies must always consider how SVD is reported, either on the basis of explant reoperation or on the basis of a combination of explant reoperation and clinical parameters. The currently approved next generation of the Biocor porcine bioprosthesis, the Epic porcine bioprosthesis, needs durability assessment, preferably combining both methods of reporting SVD, by reoperation explant and by reoperation

explant combined with clinical (echocardiographic) evaluation.

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Reply to the Editor:

We thank Drs Suyker and Leicher for their comments¹ regarding our article reporting 20-year experience of 1712 patients with the Biocor (St Jude Medical, Inc, Minneapolis, Minn) porcine bioprosthesis² and would like to respond. We agree that one would wish for longer mean follow-up; however, our study does not differ significantly from other 20-year studies (Table 1).³⁻⁸ This only reflects the increasing numbers of bioprostheses inserted during this period, a trend for the entire Western world.

Suyker and Leicher¹ are further concerned that reporting actuarial freedom from reoperation for structural valve deterioration (SVD) rather than all SVD may underestimate the impact of SVD. The difficulty is that there is no specific definition of SVD. All bioprostheses are gradually degenerating, and which valves should categorize as affected by SVD? Even if we had a consensus definition, there is difficulty in obtaining

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TABLE 1. Sample of long-term published studies

Valve type	Reference	Mean follow-up (y)	Maximum follow-up (y)	Determination of SVD
Biocor	Mykén and Bech-Hansen ²	6.0 aortic, 6.2 mitral	20	Reoperation for SVD
Mitroflow	Yankah et al ³	4.1	21	Reoperation for SVD
PERIMOUNT	Biglioli et al ⁴	6	18	Prosthesis replacement for SVD
PERIMOUNT	Aupart et al ⁵	5.5	18	Echocardiography indicated by mean gradient >40 mm Hg
Carpentier-Edwards S.A.V. porcine valve	Jamieson et al ⁶	7.8	20	Reoperation and pathology reports from autopsy, or echocardiography in patients with reduced functional class
Hancock II	Borger et al ⁷	7.4 (0–21)	20	Clinically relevant stenosis or regurgitation per echocardiographic documentation or reoperation
PERIMOUNT	Edwards LifeSciences ⁸	9	20	Explant for SVD

SVD, Structural valve deterioration.

echocardiograms for all patients (because of old age and various other reasons). Studies that report freedom from all SVD generally have very few patients reported with SVD who do not undergo reoperation. It thus is most unlikely that their numbers truly reflect all SVD. In our opinion, it is more fair to report SVD leading to reoperation, because it is an objective measurement. Suyker and Leicher¹ have noted the uneven age distribution with time, with older mean age in the last decade than in the first. This reflects a trend in cardiovascular surgery in which the average age of patients receiving heart valves during the past 20 years has increased. As an example from one of your references, Aupart and colleagues⁵ reported a mean age of 72.6 years in 2006. The same group had published in 1996 on the same set of patients with a mean age of 67.5 years.⁹ Suyker and Leicher¹ also comment on incompleteness in our table showing long-term survival and durability outcomes (17–20 years) of large-scale (n > 1000 patients) studies of bioprosthetic heart valves for aortic valve replacement. We have never claimed that this table is complete. As pointed out in our article, it is difficult to compare outcomes in populations with differing baseline characteristics, and different reports rarely include all the same baseline characteristics. With that as a back-

ground, the table only illustrates a snapshot of the available data and was reported as such.

Again, we thank them for their interest in our publication.

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REPLY TO DIFFERENCE IN OUTCOME IN THE TRANSECTION OF THE PULMONARY ARTERY AND VEIN:

To the Editor:

We thank Dr Kamiyoshihara and colleagues¹ for bringing Dhaliwal and colleagues' study² to our attention. The content was both interesting and clinically relevant. Understanding that transection of the main pulmonary artery does not mandate continued resection is an invaluable piece of information, but should only be used when a patient is in extremis, warranting immediate transfer from the operating room.

We disagree with their conclusions concerning vein ligation based on their experience with a single case. Early data suggest that ligation of both the superior and inferior veins results in death.³ However, other studies suggest