Mid-term follow-up after heart valve replacement with CarboMedics bileaflet prostheses*To the Editor:*

I read with interest the article by de Luca and associates¹ concerning valve replacement with the CarboMedics bileaflet prosthesis, and I commend them for providing valuable information to help surgeons evaluate the recently approved CarboMedics valve (CarboMedics, Inc., Austin, Tex.). The authors have carefully adhered to the published guidelines for reporting valve-related complications² in virtually all areas. The completeness of their follow-up and the detail of their presentation are admirable.

One area of their report has results that appear to be misleading, namely, the presentation of linearized rates of valve-related complications reported for aortic, mitral, and double valve replacement. The presentation of accurate information is important, because on page 1163 of their report the authors state that their incidence of thromboembolic complications is low, at 0.5%/pt-yr, compared with other series. Analysis of the information provided in the *Results* section on page 1160 reveals that the linearized rates calculated for the individual events are probably erroneous. For example, the authors state on page 1160 that thromboembolic events were observed in seven patients. If the cumulative patient follow-up was 478 patient-years, as stated on page 1159, then the linearized rate for thromboembolism would be 1.5%/pt-yr, not 0.5%/pt-yr.

A further difficulty arises when the authors present linearized rates segregated according to valve procedure. Although they do not provide us with a breakdown of the individual events by operative procedure, their report of the linearized rates of thromboembolism for aortic (0.35%/pt-yr), mitral (0.8%/pt-yr), and double valve replacement (0.3%/pt-yr) cannot be correct. Linearized rates for valve-related complications separated according to valve operation must be divided by the patient-years of follow-up for only that valve operation group to accurately represent the linearized rate. The authors appear to have generated a "linearized rate" by dividing the percentage of patients free of an event actuarially by the follow-up interval of 3½ years.

Similar computational errors can be found in the presentations of valve-related death, anticoagulant-related hemorrhage, nonstructural valvular dysfunction, prosthetic valve endocarditis, and incidence of reoperation. In terms of sustaining the high quality of their report, I ask that de Luca and colleagues generate accurate linearized rates for the valve-related complications that they have noted for the combined and separate operative procedures. This information would be valuable for cardiac surgeons who are seeking to generate data³ that allow comparison of the various available prostheses, with an aim toward finding the most appropriate prostheses for their patients.

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REFERENCES

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Reply to the Editor:

We appreciate the opportunity to respond to the comments of Dr. Akins regarding our article.¹ He gave us the benefit of his experience.²

With regard to linearized rates of valve-related complications, data were analyzed by applying the Mantel-Haenszel test included in the program 1L of the BMDP statistical software package (BMDP Statistical Software, Inc., Los Angeles, Calif.).³ This test takes into account the number of events for a given time divided by the number of patients followed up for the same time interval.^{3,4} In our study we assumed a 6-month interval. This type of calculation is presented in our article as the curve at the bottom of each graph. The combined and separate linearized rates presented in our report were obtained with this test, by summing up the patient-year incidences of each time interval divided by the total number of time intervals of follow-up.^{3,4} Moreover, linearized rates of each subgroup of patients were calculated including only the patients undergoing that operative procedure. For all these reasons, they would be better defined as *linearized incidences* than as *linearized rates*, and we apologize not to have mentioned this statistical aspect in our paper.

On the other hand, linearized rates are generated by the number of events divided by the number of patient-years. As requested by Dr. Akins, we list the linearized rates of our population for the valve-related complications that we have noted for the combined and separate operative procedures (Table I). The rates were calculated according to this latter method.

We are grateful to Dr. Akins for raising this statistical issue of our paper that would have been overlooked

Table I. Linearized rates of valve-related complications

Event	Total (%/pt-yr)	MVR (%/pt-yr)	AVR (%/pt-yr)	DVR (%/pt-yr)
NSD	0.6	—	0.5	2
ARH	1	—	1.5	2
TE	1.5	2.9	1	—
Reoperation	0.6	1.7	—	—
PVE	0.2	—	0.5	—
VRD	1.5	1.2	1.5	2

ARH, Anticoagulant-related hemorrhage; AVR, aortic valve replacement; DVR, double (mitral and aortic) valve replacement; MVR, mitral valve replacement; NSD, nonstructural dysfunction; PVE, prosthetic valve endocarditis; TE, thromboembolic events; VRD, valve-related deaths.