DEFICIENCY IN COMPARISON OF DATA BETWEEN MECHANICAL VALVE STUDIES To the Editor:

After reading the e-publication of the November 2010 article by Chan and colleagues,¹ we noted comparative data from previously published studies cited or incompletely cited when data were available. Three generic and 2 specific issues should be addressed in the interpretation of the data presented.

First, the guideline document is that of their reference 14 by Akins and associates.² This document, however, does not differentiate major or minor embolic events. The guidelines require reporting of all events.

Second, the term *major thromboembolism* is not defined in the article by Chan and colleagues,¹ nor is it used according to the referenced guideline document.² What does the term *major thromboembolic events* mean? Not having these events defined creates confusion when comparisons are made with other articles, as in Chan and colleagues' Table 3.¹

Third, a thorough review of the article by the authors was not completed, because their references 19 and 24 are identical and calculations of valve-related events are incompletely reported.

Specific issues of concern are comparisons with other publications^{3,4} noted in their Table 3. Chan and colleagues¹ compare major thromboembolic events with those reported by

our group in *The Journal of Heart Valve Disease* in 2004³ for the ATS Medical valve (ATS Medical, Inc, Minneapolis, Minn). Table 3 in their article¹ cites a "major thromboembolic" rate for ATS Medical aortic valve replacement (AVR) of 1.6%/patient-year and a rate for the ATS Medical mitral valve replacement (MVR) of 2.2%/patient-year; however, in our report, major events (permanent neurologic and peripheral embolic events) were 0.7%/patient-year for AVR and 0.4%/patient-year, as shown our Table V.³ Other events reported were transient and minor (minor transient thromboembolic events 12 of 16 for AVR and 6 of 8 for MVR), adhering to guideline recommendations. Thus the *total* thromboembolic events, not the *major* thromboembolic events, were 1.6%/patient-year and 2.2%/patient-year for AVR and MVR, respectively.

Freedom from valve-related mortality was not noted for the ATS valve in Table 3 of Chan and colleagues,¹ but in the article cited,³ valve-related mortality was clearly reported as 0.8% per year for both aortic and mitral positions. Freedoms from valve related-deaths over 5 years were 96% for the ATS Medical AVR and 96% for the ATS Medical MVR. One should not choose to compare some data while ignoring other available data from the same source.

Similarly, in an article by our group published in *The Annals of Thoracic Surgery* in 2005,⁴ the incidences of all thromboembolism-related events were 1.9%/patient-year for St Jude Medical AVR and 2.8%/patient-year for St Jude Medical MVR (St Jude Medical, Inc, St Paul, Minn). Of these thromboembolic events, 195 transient ischemic attacks, 181 strokes, and 85 peripheral events occurred for AVR, and 139 transient ischemic attacks, 122 strokes, and 31 peripheral events occurred for MVR. Thus fewer than half the events cited by Chan and colleagues¹ were actually

"major thromboembolic" events, a further confusing point in their comparison. The incidences for both neurologic and peripheral events were 1.04%/year for AVR and 1.49%/year for MVR.⁴ For neurologic events only, incidences were 0.83%/year for AVR and 1.17%/year for MVR. These numbers differ from the comparison cited by Chan and colleagues.¹

As previously stated, the valve-related mortality was not given in Chan and colleagues' Table 3,¹ even though it is easily found in the reference text (section Patient Survival).⁴ As shown in Table 3 and Figure 2 of our group's article,⁴ there were 230 aortic valve-related deaths during 21,741 patient-years of follow-up, for a valve-related mortality of 1.05%/patient-year. With MVR, 130 valve-related deaths occurred during 10,441 patient-years of follow-up, yielding a valve-related mortality of 1.24%/patient-year.

One must also note that in the definitions of postoperative management by Chan and colleagues,¹ an international normalized ratio (INR) of 2.0 to 3.0 was used for anticoagulation. In the 2005 article by our group,⁴ a prothrombin time of 1½ control was used for the first 15 years of follow-up, and a transition between prothrombin and INR was used during the subsequent 5 years. Only in the last 5 years of the study was INR used exclusively. It is well known that the measurement of prothrombin time for anticoagulation of mechanical heart valves is inferior to that of INR, thus a direct comparison cannot be made without noting the different measurements of anticoagulant management.

In summary, Table 3 of Chan and colleagues¹ misstates data from the literature and adds confusion to the interpretation of valve-related events. This deficiency principally stems from the absence of definitions and the misuse of established criteria for reporting events.

The Editor welcomes submissions for possible publication in the Letters to the Editor section that consist of commentary on an article published in the Journal or other relevant issues. Authors should: • Include no more than 500 words of text, three authors, and five references. • Type with double-spacing. • See <http://jtcvs.ctsnetjournals.org/misc/fora.shtml> for detailed submission instructions. • Submit the letter electronically via jtcvs.editorialmanager.com. Letters commenting on an article published in the JTCVS will be considered if they are received within 6 weeks of the time the article was published. Authors of the article being commented on will be given an opportunity of offer a timely response (2 weeks) to the letter. Authors of letters will be notified that the letter has been received. Unpublished letters cannot be returned.

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Reply to the Editor:

We thank Emery and Krogh for their interest in our study describing the intermediate-term outcomes after aortic valve replacement (AVR) with the On-X valve (On-X Life Technologies, Inc, Austin, Tex).¹ We agree that the reporting of clinical events related to anticoagulation is important; however, the comments of Emery and Krogh must be taken with the following considerations.

In our study, clinical thromboembolic and hemorrhagic events were defined in accordance with current guidelines.² Although the current guidelines do not separate thromboembolic events into major and minor categories, major thromboembolic events have been extensively reported by Jamieson and colleagues.³ Our definition of the term *major thromboembolism* incorporated all major events (cerebral and peripheral, inclusive of reversible ischemic neurologic deficits).

With reference to Table 3 in our original article,¹ there was an error on our part and also an error in the comment by Emery and Krogh. The

major thromboembolic events rates for the ATS prosthesis (ATS Medical, Inc, Minneapolis, Minn) should be 0.7%/patient-year for AVR and 0.4%/patient-year for mitral valve replacement (MVR).⁴ The article about the ATS made no mention of reversible ischemic neurologic deficit events, and it also did not document whether such events were considered minor or major. We mistakenly reported the minor thromboembolic event rates, which Emery and Krogh erroneously stated as the total thromboembolic event rates; however, the article gave the total AVR thromboembolic event rate for the ATS prosthesis as 2.6%/patient-year and the total MVR thromboembolic event rate as 3.0%/patient-year. For the St Jude Medical prosthesis (St Jude Medical, Inc, St Paul, Minn), the major neurologic and peripheral thromboembolic event rates should be 1.04%/patient-year for AVR and 1.49%/patient-year for MVR⁵; here, we mistakenly reported total thromboembolic events. There was, however, no mention of reversible ischemic neurologic deficit events in the thromboembolic event categorization in that article.

The valve-related mortalities were neither reported nor calculated by us in our Table 3.¹ The AVR valve-related mortalities were similar for the On-X and ATS valves at 0.2%/patient-year, whereas the MVR-related mortality was higher for the ATS valve at 0.4%/patient-year. The valve-related mortalities for the St Jude Medical valves were 1.05%/patient-year for AVR and 1.24%/patient-year for MVR.⁵

Emery and Krogh have correctly identified the differences associated with the measurement of prothrombin time versus the international normalized ratio. We did not discuss the impact of using prothrombin time, because this measurement is less commonly used to monitor anticoagulation. Our study involved a relatively recent cohort; anticoagulation in all patients was therefore managed by monitoring the

international normalized ratio, in accordance with the current recommendations from the American Heart Association and the American College of Cardiology.⁶

We therefore believe that our study provides insight regarding the intermediate-term performance of the On-X valve in a relatively large cohort of patients.

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