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DABIGATRAN AFTER CARDIAC SURGERY: CAUTION ADVISED To the Editor:

We recently read the interesting study by McKellar and associates¹ evaluating the effectiveness of dabigatran for thromboprophylaxis after implantation of mechanical heart valves. Using a heterotopic aortic valve model, the authors randomized 30 swine to receive dabigatran, enoxaparin, or no anticoagulation after implantation of a mechanical valve conduit. At 30 days, McKellar and associates¹ reported that dabigatran reduced thrombus and platelet deposition on the mechanical valve leaflets without an increase in adverse events.

Several new oral direct thrombin inhibitors are being evaluated as alternatives for long-term anticoagulation because of the widely known difficulties associated with warfarin, including its long half-life and unpredictable dose response. Compared with warfarin, dabigatran has no food or drug interactions, has a rapid onset of action, and does not require blood monitoring.^{2,3} Paradoxically, while lauded for its ease of use, the management of patients receiving dabigatran may be extremely challenging in the setting of active bleeding and coagulopathy. McKellar and colleagues¹ claim that, in contrast to warfarin, dabigatran “could prove safer should emergency surgery be needed.” We respectfully disagree with this statement. There is no known antidote available for dabigatran. Vitamin K and fresh frozen plasma are ineffective, and dialysis may be the only means available to rapidly reverse the anticoagulant effects of dabigatran.^{4,5}

We recently prescribed dabigatran to a 74-year-old woman after coronary

artery bypass graft surgery. The patient had a history of atrial fibrillation and had previously refused warfarin therapy. After surgery, she continued to refuse warfarin, but she agreed to take dabigatran to reduce the risk of stroke and systemic embolism.⁶ Dabigatran was initiated on postoperative day 3 using the lowest possible dose (75 mg twice daily), given the patient’s frailty and mild renal insufficiency. She was monitored in the hospital for 6 additional days before transfer to a rehabilitation facility. A chest x-ray film before discharge noted a very small left pleural effusion. Two days after transfer, the patient returned to hospital with a massive left hemothorax and gastrointestinal bleeding. She was treated with intubation for respiratory distress and placement of a left thoracostomy tube, draining more than 2 L of blood. The patient had evidence of a severe coagulopathy, with an international normalized ratio of 21.5 and a partial thromboplastin time of 161.2. To manage the bleeding, we instituted emergency dialysis, successfully correcting the coagulopathy. After 2 dialysis treatments, the international normalized ratio and partial thromboplastin time were reduced to 1.9 and 47.4, respectively, and the chest and gastrointestinal bleeding had subsided. The patient made a miraculous recovery and was discharged back to rehabilitation 2 weeks later without anticoagulation therapy.

McKellar and associates¹ are to be congratulated for their novel study. Their animal model data suggest that dabigatran may have a role in the thromboprophylaxis of mechanical valves. We would be intrigued to learn whether they have had any clinical experience using dabigatran in patients undergoing cardiac surgery, either for the thromboprophylaxis of mechanical valves or for the anticoagulation of atrial fibrillation. Although our experience is limited to a single case, the outcome was nearly fatal. We would therefore strongly advise caution when prescribing dabigatran

early after cardiac surgery, at least until additional clinical experience accrues.

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DOUBLE RIGHT CORONARY ARTERY OR CONUS ARTERY WITH SEPARATE ORIFICE?

To the Editor:

In their recent Cardiothoracic Imaging article, Chen, Chien, and Lee¹ have applied the term “double right coronary artery”¹ (RCA) in a debatable way.

The anatomic nomenclature for the situation they have described has been better termed “the conus artery: a third coronary artery”²; “conus coronary artery with aortic origin”³; or, more appropriately, “conus artery with separate orifice,” coded as

09.42.18 in the International Pediatric and Congenital Cardiac Code.⁴ This variation appears in 45% of human hearts.^{2,3}

The double RCA is an extremely uncommon coronary artery anomaly with 2 RCAs, coursing toward the right atrioventricular groove, originating marginal branches, terminating by giving off the posterior descending artery in the posterior interventricular groove. It is predominantly seen in male patients and might originate from either single or separate ostia.⁵

We think it is important to standardize the nomenclature in order to have the correct identification of anatomic structures.

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METHODOLOGIC ISSUES REGARDING BACKGROUND MORTALITY IN OBSERVATIONAL STUDIES

To the Editor:

We read with great interest the article "Aortic Valve Replacement: Results and Predictors of Mortality From a Contemporary Series of 2256

Patients," by Di Eusanio and associates,¹ in a recent issue of the *Journal*. We congratulate Di Eusanio and associates on their favorable results after aortic valve replacement (AVR) in octogenarians and on the identification of predictors for postoperative mortality. Some methodologic issues exist, however, concerning the comparison of patient survivals with that of a reference population. The investigators used a static method to compare the 3-year survival for octogenarians who had undergone AVR with the expected survival of an age- and sex-matched regional population and concluded that the survivals were statistically similar ($P = .157$).

Intuitively, it would seem apparent that survival after AVR is unlikely to be comparable to that of the general population. Patients undergoing heart valve replacement are vulnerable to both valve-related and non-valve-related events. In addition, the left ventricle in a patient with aortic valve disease is characterized by progressive accumulation of interstitial myocardial fibrosis and impairment of myocyte ultrastructure, leading to decreased survival. Aortic stenosis has been shown to be an inflammatory process associated with histopathologic changes in the valve leaflets that are similar to those seen in other atherosclerotic diseases, and the presence of calcific valve disease is associated with hypertension, diabetes, and the metabolic syndrome.² A survival comparable to that of the general population can therefore only be achieved by strict selection of patients undergoing AVR, which is the case in the study by Di Eusanio and associates.¹

The major shortcoming in the static comparison method is that a dynamic cohort, in this case the octogenarian study population, is being compared with a static reference cohort from the regional life tables. Changes in the patient group caused by withdrawal at different times make the study cohort dynamic and necessitate a rate adjustment to make the

comparison with the reference cohort more accurate.³⁻⁵ Rate adjustment can be achieved by matching the reference cohort with respect to age, sex, and calendar time at every moment that an event occurs in the study population. The benefit of treatment is overestimated when this mechanism is not taken into account. It would be interesting if Di Eusanio and associates were to compare the survival of the patient group with that of the age-, sex-, and calendar time-matched regional population by means of rate adjustment.

Matching should be performed not only for age and sex but also for other important demographic indicators, such as ethnicity and socioeconomic class.⁵ Unfortunately, these data are seldom available, and consequently comparisons with the general population should be interpreted carefully.

Finally, we question some of the numbers and the corresponding figures in the article. Figure 1 in the article shows a significantly lower survival of patients in New York Heart Association functional class III or IV than of those in class I or II ($P < .001$), whereas in the text a nonsignificant P value of .157 is stated. In addition, Figure 3 in the article shows a 2-year survival of 87.4% for the AVR after 80 years of age group, whereas in the text a 2-year survival of 89.7% is mentioned.

In our opinion, comparison with a reference group should be handled with caution. We suggest the development of specific guidelines to compare an accurately matched population to ensure that all factors are taken into account and that the comparison performed is methodologically correct.

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