Letters to the Editor

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
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Study design in valve surgery and outcome

To the Editor:

The article by Grunkemeier and colleagues[1] published in the February 2003 issue of the Journal is clearly an important study demonstrating the role of logistic regression analysis performed on a series of statistical summaries from different institutions. The authors' approach toward such summary of studies may not, however, have offered the solution to the confusion present when trying to answer for differences in complication rates between prosthetic valves. They set out to offer explanations for the heterogeneity among the study series analyzed. However, they did not address any clinical context in their explanation for such diverse outcomes with regard to valve thrombosis, bleeding, and thromboembolism.

A number of questions need to be addressed before reaching such a conclusion from summary of a series. Three important aspects that were not mentioned include the etiology of the valve disease, case mix, and comorbidities. All three factors should be addressed in the context of which valve is superior (St Jude vs CarboMedics) in either mitral or aortic position to that unique patient's heart valve biology. No mention was made of operative variables, including in-hospital reoperative cases and estimated blood loss.

To replace a heart valve with a certain type of prosthesis is a gray zone in the field of surgery, with as yet little evidence-based medicine for a valid argument. Differential understanding, surgical expertise, and institutional experience still remain the main determining factors for definitive decision, except in a clinical trial. A potential drawback of analysis of summary statistics in this case is that it nearly forces the investigator to ask and attempt to answer the wrong question ('Is it better to replace with St Jude or a CarboMedics valve?') rather than to ask who can undergo replacement and, among those, who will benefit from replacement. This requires analysis of individual patient data considered more powerful under all circumstances. It may be more difficult to retrieve such data because it requires the cooperation of several institutions and individuals and determination of common definitions or adjudication thereof. In a similar context, Lim and coworkers[2] in a randomized controlled trial showed that no difference existed between the two valve brands.

When recruiting studies that specifically address the question of mitral or aortic valve replacement, strict and valid inclusion criteria need to be adopted. The articles should include a patient population description, etiology of disease process, level of comorbidity, and surgical technique that are specific and well defined. In other words, the statistical summary should detail type of surgical procedure performed for a specific etiology. Other aspects that should be taken into account include whether the addition of coronary artery bypass or arrhythmia surgery or another valve replacement was performed. Moreover, a more valid and relevant postoperative follow-up will be achieved when including case series that address in detail preoperative assessment of mitral or aortic valve pathophysiology.

Before performing a logistic regression, four essential check points could have been taken into account. First is the etiology of mitral and aortic valve disease. Just as the pathophysiology differs among rheumatic, ischemic, degenerative, and infectious disease, so does the outcome. Ischemic etiology poses a particularly vexing problem. Ischemic normal mitral valve is highly variable. Therefore it is not surprising that results of replacement with what type of prosthesis are variable and controversial. For example, ischemic mitral valve disease is associated more often with diabetes. Diabetes is associated with a hypercoagulable state.[3] So when replacing with either type of prosthesis, the outcome needs to be adjusted for the etiology, not forgetting the comorbidity. The second main point that needs to be addressed is how the subval-

vular tensor apparatus was managed at operation. Left ventricular function is unquestionably related to this. At least in the context of randomized controlled trials, complete preservation of the apparatus results in better left ventricular performance,[4] which also means a lower chance of thrombus and later embolism development.[5] This generates another confounding factor when interpreting the data. Third, the underlying strategy for anticoagulation control should be addressed and controlled for in the inclusion criteria. Finally, the presence or absence of perioperative atrial fibrillation is acknowledged as important by both operating surgeons manufacturers.

It is possible that these factors were considered; however, for the sake of the reader, it is necessary to be include them in the discussion. Such consideration will reduce chance-related outcome and broaden the horizon of the reader when transferring a statistical critique to clinical reality.

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Reply to the Editor:

We thank Dr Shuhaiber and colleagues for their comments on our study comparing two heart valve models on the basis of reports from the literature. In describing the limitations of such comparisons, they give us another opportunity to stress the main purpose of our report, which was to point out precisely these limitations.

The ideal way to compare valve performance across multiple studies is to use risk-adjustment techniques with individual, patient-level data. But only summary, study-level information is available from published reports. We emphasized also that the simple, weighted-average pooling of results within valve types is not appropriate if these results are statistically heterogeneous.

A regression approach that does allow for heterogeneity was used to adjust for some series-level risk factors: the mean, maximum, and completeness of follow-up; bleeding rate, as a surrogate for anticoagulation intensity; mean age; percentage of male patients; year of publication; number of valves; and journal impact factor. Three of the risk factors that Dr Shuhaiber mentions, etiology, surgical technique and atrial fibrillation, were generally not available in these reports.

It can be seen from the plots of linearized rates that by arbitrarily selecting groups of studies, the superiority of either valve in either position for any of the three outcomes studied can be supported. Because there is a tendency to perform these literature comparisons despite the described limitations, we used statistical techniques that can account for some of these limitations. We also stressed the "cautious interpretation" of even the most carefully done comparisons.

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Esophageal perforation during left atrial radiofrequency ablation: Is the risk too high?

To the Editor:

The recent article by Doll and colleagues documents a 1% incidence of esophageal perforation with intraoperative radiofrequency ablation of atrial fibrillation (AF).[1] This observation serves as an important word of caution as we increase the application of surgical ablation and design minimally invasive procedures to treat AF. In our exploration of new approaches to cure AF, we must first follow the edict "do no harm." Although AF is an undesirable and dangerous heart rhythm, we cannot justify major complications in its treatment.

The esophageal injuries described by Doll and colleagues resulted from the application of a heat-based energy source to the left atrial endocardium. In each case, the esophagus, which courses posterior to the left atrium, suffered a burn with resulting esophageal perforation. They note that this complication has occurred with unipolar radiofrequency and microwave energies.[1,2] It is likely that collateral damage in general and esophageal injury in particular will occur occasionally with any heat-based, endocardial approach to AF ablation that lacks precise control of lesion depth and direction.

Safety in AF ablation requires that the depth of tissue injury be controlled during ablation; delivery of energy must be focused and directed to avoid collateral damage. In addition, however, it is generally accepted that efficacy requires transmural atrial lesions. There are several promising modalities that satisfy both of these criteria. Safety may be reliably achieved with bipolar or epicardial energy delivery. Bipolar radiofrequency devices ablate only the tissue between the jaws of the clamp, eliminating the risk of esophageal injury.[3] Epicardial delivery of energy with a shielded, directional catheter is also an attractive option. Epicardial ablation using ultrasound energy may have particular advantages, as this energy source allows reliable creation of a lesion that is 10 mm in depth and design of the ultrasound catheter ensures directional delivery of energy from the epicardium to the endocardium.

As surgeons explore these technologies and devise new procedures to cure AF, we must follow the lead of the group from Leipzig and share our experiences, whether they be favorable or unfavorable. This strategy will facilitate development of effective and safe procedures to ablate AF. And this, in turn, will offer the possibility