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SURGEON VERSUS DEVICE IN AORTIC VALVE REPLACEMENT To the Editor:

We believe that in-hospital outcomes after valve replacement are at least partially related to the skill of the surgeon, the choice of valve, and the complexities of perioperative management. From a technical perspective, mechanical valve outcomes are likely to be affected by sizing mismatch in larger patients¹; from a management perspective, mechanical valve outcomes are likely to be affected by the approach to anticoagulation, which is still not well defined.² Surgical and institutional expertise and experience thus still remain important factors affecting outcomes of mechanical versus bioprosthetic valves.

Our study was based on the national cohort and included all patients who received bioprosthetic and mechanical aortic valves. Data on mortality and

FIGURE 1. In-hospital mortalities for mechanical and bioprosthetic aortic valve replacements according hospital valve volume, with patients matched by propensity score within each hospital. Patients were selected from the Nationwide Inpatient Sample in the years 1998 through 2011. Error bars represent the 95% confidence interval.

complications, such as thromboembolism, were included for each treatment modality. We found increased in-hospital mortality associated with mechanical valves relative to bioprosthetic valves, even after adjustment for all known confounders using propensity scores. Further, when patients were propensity score matched within each center, the difference in mortality persisted.³

Hospitals with lower volumes were more likely to use mechanical valves, and it is possible that quality of care in these hospitals is an unmeasured variable. The accompanying editorial written by a respected expert focuses on this aspect of the evidence.⁴ The editorial highlights that surgeon expertise, volume, and anticoagulation protocol for mechanical and biologic valves are important and can serve as surrogate markers for quality of medical care and higher mortality in institutions with lower volumes, including the “failure to rescue” for complications. We believe, however, that persistence of findings after propensity score matching within each center is evidence that factors beyond the facilities’ quality of care levels are responsible for the higher mortality associated with mechanical valves (Figure 1). Even if we assume that there are no other factors, one can still argue that this can also be a device safety issue. When the device technology is complex and requires proper protocols for sizing, placement and management that are more likely to be well implemented in institutions with higher volumes, should we really separate the effect of the device safety from delivery of care? The device manufacturers and regulators need to be aware of the issues affecting implant performance under usual care, and we believe that the complexity of care and the device should be viewed as a package from a device safety and effectiveness perspective.⁵

We also recognize that the safety issues might be related to some specific mechanical valves and not to all devices. The absence of unique device identifiers makes it extremely difficult, if not impossible, to assess manufacturer-specific product performance in the real-world setting.⁶ The Society

of Thoracic Surgeons recently started detailed data collection on devices; the information is incomplete, however, and it will take a long time to achieve enough data and statistical power to detect small differences in valve outcomes. In the interim, we should consider collection of explants and evaluation of autopsy reports to get more information on causes of death and to provide key information for decision making for regulators, patients, and surgeons.

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SURGEONS AND DEVICES IN AORTIC VALVE REPLACEMENT

Reply to the Editor:

Although critical to our understanding of clinical medicine, retrospective study—even with the most refined statistical analysis—is fraught with well-known limitations. Moreover, the limited ability of administrative data to answer clinical questions is legendary. The medical literature is replete with scientifically sound hypotheses supported by robust anecdotal and retrospective data that failed to withstand the scrutiny of prospective randomized evaluation. While our medical colleagues are still trying to sort out the dramatic failures of hormone therapy in postmenopausal women,¹ our own cardiac surgical community is absorbing the failure of statins to affect the progression of aortic valve disease,² and, more recently, the failure of a restrictive blood transfusion strategy to improve

clinical outcomes.³ It is certainly possible that the evolution of devices has rendered earlier prospective, randomized control trials of mechanical versus prosthetic valves irrelevant. However, if it is the valve (or the requisite technical or medical aspects of valve selection) that is specifically driving the observed difference in mortality, then the difference should be reflected specifically in the valve-relatedness of the mortalities observed. In the absence of any such signal, the distinction between valve selection and quality of care will await more convincing data. However, with the emerging success and increasing application of transcatheter aortic valve replacement, the question may well remain unanswered.

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EPIDURALS, INTRAOPERATIVE FLUID ADMINISTRATION, AND HYPOTENSION

To the Editor:

I enjoyed the recent article, “Effect of the amount of intraoperative fluid administration on postoperative pulmonary complications following anatomic lung resections” by Arslantas and colleagues¹ in the January issue of *Journal of Thoracic and Cardiovascular Surgery*.

Our group agrees that all patients undergoing anatomic pulmonary resection should have limited fluid administration because it decreases the number of postoperative pulmonary complications. We have seen substantially greater amounts of fluid administration in patients who receive epidural catheters for pain control, and in recent years have decreased our use of epidural catheters for this reason. Our impression is that the reduced fluid administration as well as the reduced incidence of intraoperative and postoperative hypotension decreases postoperative complication rates.

The study by Arslantas and colleagues¹ noted that epidural use was not significantly different between patients