

ized to general, spinal, and epidural anesthesia for lower extremity revascularization procedures and found that the overall incidence of acute graft failure was very low (1.6%) and did not significantly vary among the anesthesia techniques. Furthermore, in another study of 423 patients randomized to general, spinal, and epidural anesthesia, Bode *et al.*⁵ found no evidence that regional anesthesia reduced the incidence of major cardiovascular events in a high-risk patient population (86% diabetic patients). One cannot ignore the intensity of monitoring used in their studies by both the anesthesia team (pulmonary and systemic arterial pressure monitoring) and the surgical team (vascular angioscopy and hourly Doppler monitoring), which most likely contributed to their low complication rate, be it in the incidence of acute graft failure or major cardiac complications. One can make a case about the value of intensive hemodynamic monitoring as noted also by Berlauck *et al.*⁵ in these high-risk patients. The studies by Rosenfeld *et al.* and Christopherson *et al.*, despite the great effort by the co-investigators, will remain equivocal at best if they ignore the role of the other key player, namely, the surgeon.

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In Reply:—The role of the surgeon in the overall rate of graft failure in our study was not disregarded, as suggested by Kupeli. Christopherson *et al.* reported that randomization to epidural or general anesthesia was stratified by surgeon, thus eliminating the possibility that experience or referral pattern would be maldistributed between anesthesia groups.¹ Kupeli also overlooked our report of the surgery performed and graft material used. Patients were stratified into low risk (femoral bypass graft and femoral aneurysm repair) and high risk (grafts to the popliteal artery and other distal sites) for occlusion. This resulted in similar numbers of high-risk patients in each group; furthermore, the same number in each high-risk group received synthetic grafts (Christopherson *et al.*, page 429).

Although it may be possible to find lower rates of revascularization in the early postoperative period than reported in our paper, it is also possible to find higher rates. As we stated,¹ our rate of in-hospital reoperation of 13% is within the range reported in the literature.²⁻⁵ Bode *et al.* should be commended for the very low rate of acute graft failure that they found in the study of 307 patients randomized to epidural spinal or general anesthesia.⁶ However, as we explained, (Christopherson *et al.*, page 432) when an outcome occurs rarely, it is usually not possible to find a significant difference between treatment groups even when such a difference exists. With a low rate of graft failure such as reported by Bode *et al.*,⁶ it is improbable that

* Bode RH, Lewis KP: Graft occlusion after peripheral vascular surgery vs. regional anesthesia, *Manual of the Society of Cardiovascular Anesthesiologists*. 1993, pp 244-245.

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they had an adequate sample size to have power to find a significant difference if there was a difference related to type of anesthesia.

We agree with Kupeli that intensive hemodynamic monitoring, such as that reported by both Berlauck *et al.*⁶ and Bode *et al.*⁶ might greatly lower the rate of vascular graft occlusion because of improved flow through the graft. We mentioned this in our discussion (Christopherson *et al.*, page 431). However, invasive hemodynamic monitoring has never been shown to alter patients' tendencies for thrombosis. We showed such an alteration related to anesthesia.⁷ We agree with Kupeli that postoperative vascular graft occlusion is a complex phenomenon that may be caused by the difficulty of the procedure, the skill of the surgeon, the use of synthetic rather than natural vein grafts, and blood flow through the graft. Despite these contributions to graft occlusion, the type of anesthesia and its attendant effects on hemostatic function also appear to be very important determinants, as shown by us⁷ and Tuman *et al.*²

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Factors Affecting Outcome in Patients Undergoing Peripheral Vascular Surgery: II

To the Editor:—The authors of the recent articles comparing general *versus* epidural anesthesia and analgesia for lower extremity vascular surgery are to be commended for the rigorous study they performed.^{1,2} It is, however, of concern that protocol failures (patients assigned to epidural anesthesia but given general anesthesia) were treated differently in the analysis of one part compared to the other part, though they involved some of the same patients. In the first part of the study, assessing morbidity and mortality, protocol failures were treated as epidural anesthesia, whereas in the second part of the study investigating etiologic factors, protocol failures were treated as general anesthesia patients. I am curious as to the authors' rationale. Would a more consistent treatment of protocol failures have altered their results? This is pertinent as it appears that three of the patients having protocol failure suffered morbidity, one died, one developed cardiac ischemia, and one required limb amputation, all of which were outcome variables in the first part of the study.

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In Reply:—In all clinical trials, it is necessary first to report results according to treatment assignment, that is, according to the group to which patients were randomized.¹ This is because it is always possible that there may be some inherent risk caused simply by being assigned to a particular treatment group and that this risk may be

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overlooked by investigators. For instance, in this study, as soon as investigators knew patients were randomized to epidural anesthesia, hypertension may have been treated differently compared to patients randomized to general anesthesia. Patients about to receive regional anesthesia would be expected to have a sympathectomy; therefore,