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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 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,

long-acting vasodilators would not be given intravenously to control blood pressure, which would be expected to decrease with the regional technique. Thus, it is possible that patients were put at some risk because of differences in initial treatment of high blood pressure.

The paper by Christopherson *et al.*[2] provides the initial analysis of outcomes from the study. Therefore, analysis in that paper is intentionally to treat. A second statistical analysis was performed in which the patients who were randomized to epidural anesthesia but who received general anesthesia were assigned to the general anesthesia group. Changing groups for these four patients did not alter any of the major outcomes of the trial.

The study by Rosenfeld *et al.*[3] is not the primary analysis, and therefore, it is permissible to analyze by treatment administered rather than by randomization. Since Rosenfeld *et al.* were studying mechanisms of perioperative thrombosis, the most rational and appropriate analysis is by treatment administration rather than treatment assignment. This provides a more accurate assessment of anesthetic effects on changes in fibrinolysis.

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Factors Affecting Outcome in Patients Undergoing Peripheral Vascular Surgery: III

To the Editor:—The conclusion by Christopherson *et al.*[1] that ". . . epidural anesthesia is associated with a lower incidence of reoperation for inadequate tissue perfusion and therefore may be advantageous for this surgical population" is rather noncompelling. Of concern are the data in table 2 that demonstrate that above-the-ankle amputation was not decreased in a statistically significant manner in patients before discharge, nor was the 6-month vascular surgery outcome (amputation, regrafting, or thrombectomy) altered in patients who received epidural *versus* general anesthesia. Furthermore, the authors never state whether the patients were matched for the severity of their vascular disease.

In summary, I will find it very difficult to alter my clinical practice until more convincing data is forthcoming on the matter.

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