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Epidural Anesthesia and Analgesia in High-risk Surgical Patients. IV.

To the Editor:—In the recent report by Yeager *et al.*,[1] the study was terminated because "the overall complication rate and complication intensity were strikingly higher in group II patients." It seems that the more ethical course would have been to continue the data gathering to make the study even more persuasive by virtue of larger numbers. Since these data would indicate that common present practice may be deficient, it seems to me that terminating the study for the stated reason is indefensible.

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Epidural Anesthesia and Analgesia in High-risk Surgical Patients. V.

To the Editor:—Drs. Yeager, Glass, Neff, and Brinck-Johnsen are to be commended in their attempt to compare the outcome of two fundamentally different anesthetic techniques in high-risk surgical patients.[1]

Key to the interpretation of outcome is the claim that the two study groups were similar. Despite the fact that patients were randomly assigned to the two treatment groups, it is quite possible that, by chance alone, group II included a few extra high-risk patients compared to group I. This dissimilarity could account for some of the differences in outcome rather than anesthetic technique.

In Yeager *et al.*'s study, the most important comparisons of patient characteristics are the ASA physical status classification and the Goldman index, as indicated in their Table 1. I am not sure the statistics used are valid. What is an ASA physical status of 2.79 (±0.55) or a Goldman Index of 9.1 (±6.8)? The ASA physical status classification and the Goldman Index meet the definition of ordinal data, since they represent categories which can be ranked.[2] The numbers are nothing more than a form of shorthand for groups defined clinically,[3] and, although they can be ranked, the "distance" between any two groups or classes may be variable.[2] An ASA physical status or a Goldman Index could easily be given a letter instead of a number. The numbers do not come from a set of continuous data, and it is inappropriate to calculate means, standard deviations, and *P* values using these numbers.[3] Because of this, the reader cannot be sure that group II did not include several more high-risk patients compared to group I.

The authors should present their data so that we can compare the number of high-risk patients having high-

risk surgery in the two groups. An appropriate non-parametric test of statistical significance could have been used to compare the two groups of ordinal data.[2]

Another factor that may have affected the results is the fact that group II patients received highly variable treatments. I consider 50 μg/kg fentanyl anesthesia radically different from "balanced" anesthesia. Yet, all patients in group I received essentially the same treatment. Perhaps the increased morbidity and mortality in group II had some relationship to high-dose narcotic anesthesia.

The conclusion that "some aspect of the anesthetic management of the patients who received EAA acted to improve their overall outcome" may not be valid.[1]

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In Reply:—We appreciate the opportunity to respond to the letters from Drs. Clark, Day, Frumin, Jenkins, and Kehlet. They raise several interesting and important questions.

The first question relates to the design of the study. Dr. Kehlet asks why we included different operative procedures, and why the type of anesthesia given to control patients was not defined by protocol. When we initiated this study, we chose to include different surgical procedures and to allow the anesthesiologist some latitude in deciding how best to care for each patient. This, we believed, would make the control group more representative of current anesthesia practice and the results of the study of greater value to other practitioners.

Were the two treatment groups identical to each other in all relevant regards, so that any observed difference in outcome can be attributed causally to only the difference in treatment? For each possible factor that we thought might be relevant *a priori*, we compared the distributions of the data for each treatment group, and we used randomization to control for all other factors that we did not think were relevant but, in fact, might be. *A posteriori*, the actual data show that comparability was achieved. We included the ASA Physical Status Classification because it is commonly used as a predictor of outcome, despite the fact that it is not applied consistently from one observer to the next,[1] large variability in outcome is observed for any given class, and it was never intended to predict outcome.[2] With regard to the Goldman Index, which was intended to predict cardiovascular morbidity, we have enclosed the distribution data of the two groups (table 1).

TABLE 1. Distribution of Goldman Index

	Group I		Group II	
Value	n	%	n	%
3	7	25	9	36
6	2	7	0	0
8	11	39	10	40
10	1	4	1	4
11	2	7	2	8
14	0	0	1	4
15	3	11	2	8
25	1	4	0	0
33	1	4	0	0
Total	28	100	25	100

Regarding the conduct of the study, study protocol stated that patients with epidural catheters should receive local anesthetic injections to maintain sensory analgesia to the fourth thoracic dermatome until the end of the operation. The epidural narcotic used was morphine. The dose of epidural morphine was dictated by clinical response and not by rigid dosing schedules, which we find to have a high likelihood of undesirable effects, especially incomplete pain relief.

Cause of death in all patients can only be described as multisystem failure. In three of the four patients who died, the decision was finally made to withdraw intensive care support. In one patient, the terminal event was a myocardial infarction with the patient dying in cardiogenic shock. Although we were primarily interested in postoperative morbidity, we included the mortality statistics in the published results simply because the only alternative was to not include them. We pointedly avoided suggesting that the use of epidural anesthesia