In Reply—I would like to thank Drs. Introna and Blair for making several interesting comments regarding the reported case of vagotonia and cardiac arrest during a spinal anesthetic. I agree that in most individuals the sympathetic and parasympathetic systems remain remarkably balanced, despite significant blockade of the sympathetic afferent and efferent pathways during spinal anesthesia. Otherwise, as pointed out, completely unopposed vagal tone would lead to asystole in many patients during spinal and epidural anesthesia. However, it appears that in a select group of patients the balance between the sympathetic and parasympathetic systems is not as well-controlled. Even in the absence of spinal anesthesia, these patients can experience significant hypotension and bradycardia when exposed to noxious stimuli. Perhaps these individuals lack the pathways that are responsible for down-regulating the parasympathetic system when sympathetic blockade occurs? Studying heart rate variability in these patients using the methods described by Introna et al. would be interesting. If preoperative abnormalities could be detected or predictive of adverse events during spinal anesthesia, then this technology could be used to identify patients in whom spinal or epidural anesthesia should be avoided.

David N. Thrush, M.D.
Professor
Department of Anesthesiology
University of South Florida
College of Medicine
Tampa, Florida
dthrush@hsc.usf.edu

References

Ethical Issues on Informed Consent and Recruitment for Clinical Trials

To the Editor—Myles et al. have taken on the important task of identifying potential barriers to participation in clinical research in anesthesia. Such data are clearly needed. Despite the need for such data, at least two aspects of this study warrant discussion.

First, whereas the investigators were concerned about the affect of research design on the willingness of patients to participate in clinical trials, some of the hypothetical trials included in their study are ethically troublesome. That is, in most cases, prerandomized trials are arguably unnecessary or unethical. These arguments are largely based on the fact that improved enrollment rates over conventionally randomized studies can only be achieved with prerandomized trials when important ethical principles, such as respect for autonomy, are violated. Therefore, it could be questioned whether group 2 (prerandomization to experimental drug, consent for experimental drug) and group 3 (prerandomization to standard drug, consent for standard drug) should have been included in this study. What would have been the authors' recommendations if the hypothetical recruitment rate in these groups was superior?

Second, the authors suggest that they are conducting empirical research about informed consent for clinical research in anesthesia. Although data regarding the informed-consent process in this context are wanting, this study seems better described as one that focuses on recruitment rather than on informed consent. Regardless, the study itself raises questions about informed consent. According to the consent form that was published with the report, study participants were not informed that they would be randomized to one of five groups (see Explanatory Statement 1, Appendix 1). Information about the study design is clearly an indispensable component of meaningful informed consent. This information is needed to respect the autonomy of the subject to make a decision regarding participation. From the published report, it is unclear why this information was not included. And somewhat ironically, whether meaningful informed consent was obtained in a study reportedly about informed consent!

Thomas Erb, M.D.
Visiting Associate
Department of Anesthesiology
erb00003@mc.duke.edu

Jeremy Sugarman, M.D., M.P.H., M.A.
Associate Professor
Department of Medicine
Duke University Medical School
Durham, North Carolina
sugar001@mc.duke.edu

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