We also have two minor comments concerning the article by Mashour *et al.*[1] and the accompanied editorial.[8] On the basis of the detailed description on page 719, the most important principle of randomization and the randomized controlled trial paradigm may have been breached; in a randomized trial, the investigator should not know the treatment/intervention allocation before patient recruitment. Or have we misunderstood the procedure? In addition, the editorial included a funny flaw: BIS spectroscopy. Surely, we are not able to *scope* anything with BIS.

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To BIS or Not to BIS

To the Editor:

I read with interest the study by Mashour *et al.*[1] The authors are to be congratulated for having performed this large randomized trial to answer an important question regarding the utility of bispectral index monitor and comparing that to minimum alveolar concentration level alarm system.

There are few points that warrant clarification. First, the author included patients who received total intravenous anesthesia. However, the details of this subgroup of patients were not provided. The method of determining the minimum alveolar concentration level in the no bispectral index total intravenous anesthesia patients, the alarm limits, and the incidence of awareness in these patients were not described.

Second, the inter-rater agreement using Fleiss κ statistic for the three blinded assessments of awareness showed fair agreement (0.25). Can the authors comment on the low level of agreement and provide the confidence interval for κ?

Third, 36% of patients did not have bispectral index data recorded because of technical issues. While this could provide a third arm for comparison, it may also create some bias. Providers who did not receive an alarm might have decreased vigilance as they could have depended on the alarm system. Adding a third arm of routine care in the design might have provided valuable information.

Finally, it would have been interesting to learn more about the 19 definite awareness cases in this large sample which could help in refining the characteristics of high-risk patients.

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In Reply:

We thank Dr. Myles for his thoughtful comments on our editorial[1] and his contribution to the field of anesthesiology in general and comparative effectiveness research (CER) specifically. The points, including the disagreement with our categorization of the discussed trials, are well taken and are representative of a wider discussion about the question of what actually constitutes CER and what methodologies should be used to achieve it.[2,3] Although the most commonly used definition in the United States today is that put forth by the Federal Coordinating Council for Comparative Effectiveness Research in 2009,* it can be argued that principles

* FCCCER (Federal Coordinating Council for Comparative Effectiveness Research). "Report to the President and Congress." Washington, DC: U.S. Department of Health and Human Services, June 2009. Available at: www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf. Accessed January 4, 2013.