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The Position of Aspect

To the Editor:—I read with great interest the exchange of opinions regarding “The Media and the BIS Monitor,” which appeared in the June issue of ANESTHESIOLOGY.^{1,2} The letters highlighted some very important issues facing anesthesiologists and Aspect Medical Systems, especially in today’s healthcare environment.

As you indicated in your response to Dr. Katz, Aspect has been very careful about not making specific claims that use of the BIS will reduce the incidence of intraoperative recall. We state in our marketing materials that the BIS Monitor can be used as a tool to “monitor,” “assess,” or “track” the risk of awareness based on results from numerous peer-reviewed publications demonstrating the relationship between BIS and sedation scores, memory function tests, and loss and return of consciousness in volunteers and surgical patients.^{3–13} It is not our intention to suggest that these studies prove that BIS monitoring will reduce the incidence of awareness. In fact, it is very important for anesthesiologists to understand that awareness can still occur when BIS monitors are used, although we believe the data clearly support the observation that awareness is most likely to happen when BIS values are high.

Widespread publicity of awareness cases on national television, news magazines, and newspapers with the resulting reactions of the anesthesia community have represented a significant public relations challenge to Aspect. Our efforts to introduce the BIS to the anesthesia community have relied extensively on sound clinical research published in high-quality journals such as ANESTHESIOLOGY. To date, more than 45 full manuscripts and more than 300 abstracts have been published on BIS. Our sales and marketing programs have always highlighted the demonstrated drug savings and recovery benefits of BIS rather than focusing on prevention of awareness. The perceived benefit to Aspect from awareness-related publicity is overshadowed by the negative impact it has had on our relationship with the anesthesia community, which we have worked so hard to build over the past 13 yr. The letter from Dr. Katz is a good case in point.

I sincerely hope that this letter provides a better understanding of Aspect’s position regarding the issue of awareness and BIS. Perhaps some day it will be possible to conduct a definitive clinical study to evaluate the impact of BIS monitoring on the incidence of awareness (although such a study would require randomization of approximately 50,000 patients to have adequate statistical power*), but until then, the potential efficacy of BIS monitoring in preventing awareness can only be reasonably inferred from the previously cited references. The scientifically demonstrated recovery benefits of BIS monitoring provide the most important reasons for anesthesia providers to consider using this technology.

* Assuming a baseline incidence of awareness of 0.2% in non-monitored patients, in order to detect a 50% reduction in the BIS-Monitored group, with equal numbers of subjects in each group and Alpha = 0.05, Power of 80%, 2-tailed test, 47,022 (23,511 per group) patients would be required.

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CORRESPONDENCE

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In Reply:—Shortly after the appearance of Dr. Katz's letter and my reply, I was contacted, first in writing and then by telephone, by Nassib Chamoun, President and CEO of Aspect Medical Systems (Natick, MA). In an extensive conversation, I reiterated the general concerns expressed in the letters, *i.e.*, that misleading stories in the popular media concerning awareness and the use of the BIS monitor (intentional or otherwise), as well as statements being made directly to anesthesiologists, were creating difficulties for practitioners whose only interest was trying to care for their patients. I also passed on remarks made to me by many anesthesiologists (who I did not identify), indicating a belief that Aspect Medical Systems was somehow connected with such stories. Mr. Chamoun strongly denied any such connection or intent and expressed his concern that such beliefs were damaging the rela-

tionship between the company and the anesthesia community, a relationship that he wished to preserve.

After this conversation, a revised "formal" Letter to the Editor was submitted to our office for publication. That letter is printed here.

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Sevoflurane and Lumbar Cerebrospinal Fluid

To the Editor:—Talke *et al.*¹ recently reported that sevoflurane increases lumbar cerebrospinal fluid pressure (LCSFP) in normocapnic patients undergoing transsphenoidal hypophysectomy. The authors should be congratulated for simply reporting their observations without speculating on the cause of the increase in LCSFP. The authors correctly pointed out that this increase in LCSFP is significant but clinically irrelevant and observed that the increase in LCSFP is at variance to previously reported results from our group.² They also pointed out that our baseline results were obtained during 70% nitrous oxide; therefore, the lack of increase in intracranial pressure with sevoflurane that we observed could be reinterpreted as sevoflurane having the same effect as 70% nitrous oxide. We would like to point out that there are two other interpretations that the authors might have missed: (1) In our study, the intracranial pressure is measured using an intraparenchymal fiberoptic catheter. This is generally considered to be more accurate than LCSFP. Although changes in the latter are valid, factors other than cerebral physiology may be involved. (2) The authors measured baseline LCSFP values during propofol-nitrous oxide anesthesia. Because propofol is a cerebral vasoconstricting agent, whereas sevoflurane is not, a more appropriate interpretation of the authors' data is that LCSFP is higher during sevoflurane anesthesia compared with propofol-nitrous oxide anesthesia.

As published, the title of the article is misleading because it implies

that sevoflurane anesthesia increases LCSFP compared with unanesthetized patients. With all studies, the choice of the control group is critically important and affects the interpretation of the observations.

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