



The BIS monitor should be standard in all cardiac operations.

CON

Although it is exceedingly rare with a reported incidence of approximately 0.1-0.2%, awareness is a feared adverse event associated with general anesthesia.¹ This rate may be higher in certain populations, notably patients undergoing obstetric, cardiac and trauma operations. The variable definitions of intraoperative awareness, as well as the fact that routine postoperative visits may not elicit patients' awareness (it is estimated that 35% of cases are detected at delayed postoperative interviewing) make it difficult to assess a true incidence.² Reports of "dreaming" intraoperatively are more common than awareness of actual events, with patients reporting conversations, sensations attributable to surgical/anesthetic maneuvers-also termed as "explicit recall".¹ Of the patients experiencing explicit recall, the true adverse outcome is when they go on to have sequelae such as post-traumatic stress disorder (PTSD) with respect to their intraoperative awareness. While the incidence of PTSD is ill-explored in patients suffering from awareness, not all patients suffering from awareness go on to manifesting this complication.³



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What frustrates clinicians is that despite adequate hemodynamic monitoring with stable vital signs, awareness may still occur. This has led to some advocating the routine use of neurological monitoring to detect a level of sedation, in addition to standard monitoring.^{4,5,6}

The most popular monitor is the Bispectral Index ® (BIS: Aspect Medical Systems, Newton, MA) which is a processed electroencephalogram (EEG) derivative. It functions on a scale of 0-100, with 100 being awake and 0 noting absence of brain activity.⁷ BIS values of below 70 have a "low probability of explicit recall", below 60 "low probability of consciousness" and below 40 a "deep hypnotic state" exists.

Two studies have been published touting that routine use of BIS monitoring reduces the incidence of awareness in patients undergoing general anesthesia.^{5,6} Both of these studies had serious limitations. In Ekman's paper, 4945 patients were prospectively studied for signs of awareness using a BIS monitor and then compared to 7826 patients from a historical control where there was no monitoring. In using a historical control, there are several problems: lack of standardization of anesthetic, difference in standard monitoring techniques (the historical control had a significantly smaller portion of patients that had end-tidal gas monitoring), and no comment regarding the use of beta-blockers (that presumably would be higher in the more recent patient population) which tend to lower BIS values and potentially anesthetic requirements.^{5,8} Additionally, the

authors commented that 20 patients responded postoperatively that they did 'remember something in between', but only 2 had explicit recall. They commented that the historical control also had these "unsubstantiated" reports, but did not quantify them. These 20 patients with these recollections would represent a greater total by >40% when compared with historical controls having recall (n=14)! Finally, the authors suggest that a BIS < 60 indicates that appropriate anesthetic depth has been reached, and the two incidences of awareness both occurred when BIS values were > 60. However, almost 20% of patients in the BIS group had BIS > 60 for 4 minutes or longer during induction, and almost 10% had period of BIS > 60 during maintenance-the vast majority of whom had no recall. How reliable then is that number 60?

In contrast to the historical control model above, Myles' study published later in 2004, was a prospective, randomized, double-blinded protocol.⁶ They found that they had an 82% reduction of awareness in the group using BIS monitors versus a control group (2 reports vs. 11, BIS vs Control groups respectively). This was statistically significant, however, if even one more patient in the BIS group had reported awareness, there would be no statistical significance attached to the monitor. Additionally, one of the reports of awareness occurred at BIS values between 55-59, lower than the 60 advocated by the manufacturer and the authors of the study. When you compared patients who may have had "possible" awareness (with subsequent questioning either ruling them in or out), there was no significant statistical difference between the two groups. Also, the control group had a higher rate of heavy alcohol use, a potentially confounding variable. Finally, both of the above studies were sponsored by Aspect Medical and neither addressed the feared outcome of PTSD after awareness.

It generally has been accepted that cardiac surgery carries an increased risk of awareness.⁹ In contrast to this view, a more recent study by Ranta et al. reported a frequency of awareness with recall of only 0.5% in cardiac surgery patients.¹⁰ They also suggested that the intraoperative use of benzodiazepines is effective in decreasing the incidence of recalled awareness, and experience of awareness is not often traumatizing. Although Myles' study⁶ found 82% reduction of awareness in group using BIS monitor in patients at high risk for intraoperative awareness (including cardiac surgery patients), it is important to keep in mind the factors which can affect the BIS value during cardiopulmonary bypass. For example, Mathew et al. reported the effects of hypothermia on the BIS during cardiac surgery and demonstrated that for every degree reduction in temperature, the BIS value decreased 1.12 units.¹¹

Awareness is so rare that studies have determined that it may not be cost effective to routinely use BIS monitoring.¹² Indeed, even in high-risk populations, the cost may be \$2000 per case prevented.¹²

The BIS monitor is a software program that several parameters can affect. While the software has undergone updates, they have not all been 100% sensitive or specific. Numerous reports of neuromuscular blockade affecting BIS readings inappropriately are in the literature. In fact, even drugs such as nitrous oxide, ketamine and halothane have had reliability issues, with one study commenting that at equipotent doses of sevoflurane or halothane, BIS values were

markedly different. The use of electrocautery in the operating room can also affect BIS values. Finally, baseline abnormalities in EEG waveforms may have effects on accurate BIS values—even brain dead patients have been reported to have spikes in BIS levels.¹³

Recently there has been concern that in patients with BIS values intraoperatively <45 there were higher rates of morbidity and mortality.¹⁴ This has been widely criticized on many fronts, first and foremost this was an observational study that did not control for anesthetics administered, that the number 45 was arbitrarily selected, and furthermore calculations of time spent by patients with BIS levels < 45 were not appropriate.¹⁵ Additionally, the majority of their deaths were attributable to cancer and the impact of general anesthesia on their cancer process is debatable.¹⁵ From a practical standpoint, if clinicians are to aim for a BIS < 55 (as there was awareness in Myles' paper at BIS 55-59), but above 45 as to avoid potential long-term complication- this is a very narrow therapeutic range that may be difficult to maintain throughout an anesthetic.

Media hype and industrial campaigning have heightened the public's interest and fear in intraoperative awareness. However, the use of routine BIS monitoring does not offer clear-cut advantages in the reduction of awareness, nor is it cost effective. Additionally, there is no data that confirms that BIS monitoring reduces the incidence of the sequelae of awareness, namely PTSD. Even the Aspect Medical website states: "Reliance on the BIS alone for intraoperative anesthetic management is not recommended." As technology continues to evolve, there may eventually be a 'sedation' monitor that can be plugged into an electrical outlet. Until then, a vigilant anesthesiologist remains the best monitor in ensuring patient safety.

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(Endnotes)

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