Awareness during anesthesia with subsequent recall is a relatively rare complication occurring at an incidence of 1–2 cases per thousand (1, 2). Yet it excites substantial interest amongst the lay population as well as medical practitioners. Why is that?

When one considers the denominator, it is apparent that a large number of patients are affected annually. Over 20 million general anesthetics are administered annually in the USA (3). If the incidence of awareness is 0.2%, then there will be 40,000 awareness cases per annum.

Awareness is not always a trivial experience. Often, patients suffer adverse sequelae in terms of a post traumatic stress disorder (PTSD). The frequency of pain, anxiety or delayed neurotic symptoms in paralyzed patients who suffer awareness may be as high as 78% (1). The symptoms can persist for a long time. Two years after the original study, nine of the patients described previously (1) were contacted (4). Four of the nine were still severely disabled by their psychological symptoms.

Another reason why awareness excites interest is that it may lead to litigation against the anesthesia personnel. Cases of awareness with recall represent from 1.9% (5) to 12.2% (6) of all malpractice claims against anesthesia personnel.

Awareness following anesthesia is a significant source of worry to patients. Over 50% of patients express preoperative anxiety about awareness (compared with 65% anxiety for postoperative pain and 34% for death) (7). It is also a significant source of dissatisfaction after anesthesia (8).

The question that I would pose in this editorial is: Is there an effective monitor for awareness during anesthesia and, if so, should we use it?

This editorial accompanies an article by Ekman and colleagues (9) demonstrating a significant reduction in the incidence of awareness when BIS monitoring is used. Prior to this study, there was only anecdotal evidence that high BIS values are associated with awareness with recall (10), although others have suggested that awareness can occur with BIS < 50 (11). This contention was subsequently disproven (12).

The findings are remarkable and, to my knowledge, represent the first demonstration that any anesthesia monitoring technology has led to a reduction in adverse outcome, with the incidence of awareness being reduced by 77% in this study compared with retrospective data (1). It should be noted that the two cases of awareness reported in this study had BIS > 60 at the time of awareness. Had the authors maintained BIS < 60 during these cases, we may infer that there may have been no cases of awareness. However, such a retrospective study falls short of our ‘gold standard’ of a prospective randomized study. It is possible that there was a change in anesthetic practice in the institutions between the original study (1) and the current investigation.

Unfortunately, we are unlikely to have a definitive prospective randomized study of the general surgical population to help us resolve this issue because such a trial is unrealistic. Since awareness during anesthesia is such a low-frequency event, power analysis suggests that, if the incidence is 0.1% and BIS monitoring produces a 50% reduction in incidence, then almost 41,000 patients would need to be included in the prospective randomized trial (13). Such a large prospective trial is unrealistic. What, then, is the supporting evidence for the conclusion from Ekman’s study (9) that BIS-guided anesthesia reduces the incidence of awareness?

There are data from unstimulated patients who are allowed to recover consciousness while paralyzed, where awareness is assessed using the isolated...
 forearm technique (IFT) (14). In one such study (15), patients recovered consciousness with a mean BIS of 80 for propofol and 81 for thiopental induction. In patients maintained at BIS 60–70, 66% of patients gave an unequivocal response to the IFT, suggesting awareness, with 25% reporting conscious recall after recovery (16). When an appropriate conditional response is used for the IFT, it appears that awareness generally occurs with BIS greater than 60 in unstimulated patients. It is important to note that these studies were all performed on anesthetized patients prior to surgery, without substantial noxious stimulation. It would generally be unethical to intentionally allow awareness to occur during surgery.

O’Connor and colleagues suggested that an appropriate study (in lieu of a large double-blind study) to establish the utility (or otherwise) for BIS monitoring in awareness detection would be a prospective randomized study in a high-risk group of patients (13). Such a study has now been completed (17) and provides further supporting evidence.

In a multicenter prospectively randomized study of 2500 high-risk patients (e.g. cardiac surgery, cesarean section, trauma surgery), where BIS was guided in the treatment group to 40–60, there was an 82% reduction in the incidence of awareness. This is remarkably similar to the 77% reduction in awareness reported by Ekman (9). Together, these studies provide strong evidence that BIS monitoring reduces the incidence of awareness.

It has also been suggested that using BIS monitoring to reduce awareness is not cost effective (13, 18). Moreover, no comprehensive analysis of any anesthesia monitoring technology has proven that technology to be cost effective. Also, no other anesthetic monitoring technology has been shown to reduce the incidence of adverse outcomes (let alone be cost effective!). Even use of pulse oximetry does not reduce the incidence of cardiovascular, respiratory, neurologic or infectious complications following anesthesia (19). The cost effectiveness argument for BIS monitoring may never be made, but apart from reducing the incidence of awareness, several other beneficial outcomes for the patient have been demonstrated including reduced anesthetic requirement, faster and clearer recovery (20) and reduced incidence of postoperative nausea and vomiting (21).

Kalkman and Drummond suggested that using BIS or similar technology to guide the administration of anesthesia may actually increase the incidence of awareness (22). Their concern is that in guiding the anesthetic too close to the consciousness threshold in order to improve wake up or reduce anesthetic requirements, a greater number of patients may receive inadequate anesthesia and the incidence of awareness may be increased. The study from Ekman (9) in this journal and that of Myles (17) effectively refute that argument.

It is important for the clinician to realize that attaching a BIS monitor per se will not alter the incidence of awareness. It is important to look at the data from the monitor critically and treat the patient appropriately based on the monitor. It is noteworthy that the two patients in this study who were aware had BIS values higher than the intended upper limit for the study (9).

The article by Ekman (9) and the study by Myles (17) provide good evidence that BIS-guided anesthesia will reduce the incidence of awareness. The technology also has other patient benefits as described above (20). Should the technology be used routinely? I believe that it should. To quote Orkin and colleagues: ‘While aids to vigilance cannot independently engender greater safety (i.e. improved outcome), their use provides comforting backup to clinical observation, allows dedication of attention to other matters, and reassures our fallible reasoning with on line data during critical periods of the anesthetic’ (23). Although these words were written about pulse oximetry, they apply equally well to BIS. There is now sufficient evidence that appropriate use of BIS significantly reduces the incidence of awareness during anesthesia.

The Food and Drug Administration in the USA also shares this view. They have recently given clearance for the indication that ‘The use of BIS monitoring . . . may be associated with the reduction of awareness with recall in adults during general anesthesia’.

References

8. Myles PS, Williams DL, Hendrata M, Anderson H, Weeks AM. Patient satisfaction after anaesthesia and surgery:

Address:
Peter S. Sebel, MBBS, PhD, MBA
Department of Anesthesiology
Emory University School of Medicine
69 Jesse Hill Jr. Drive, SE
Atlanta, Georgia 30303
USA
e-mail: peter_sebel@emoryhealthcare.org