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Is BIS Monitoring Cost-Effective?

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***Abstract*—BIS monitoring is a processed electroencephalogram (EEG) technology that is designed to follow the effects that anesthetics and sedatives have on cerebral function. Much is know about the technology, it's utility and limitations. The economic case for widespread utilization of this technology is weak. There appears to be little opportunity to decrease health care cost by either reduction of drug costs or improved practice efficiency. General use of BIS monitoring to reduce the incidence of intraoperative recall (IR) would cost about $10,000 to 25,000 per avoided IR. Total cost to the heath care system would approach one billion US dollars per year, just for use during general anesthetics. More appropriate use of already available drugs and technology would most likely decrease the incidence of IR as effectively, although individual patients who are at high risk for IR may benefit from this technology. However, based on current health care economic standards general use of BIS monitoring does not seem warranted and appears not to be cost-effective.**

I. Introduction

The Bispectral Index Monitor (BIS, Aspect Medical System Inc., Natick, MA) was released for clinical use in October 1996. BIS monitoring is a processed electroencephalogram (EEG) technology that produces a BIS value between 0 and 100. This technology is designed to follow the effects that anesthetics and sedatives have on cerebral function. BIS was originally approved for the monitoring a patient's depth of hypnosis, not anesthesia. Recently, the US Food and Drug Administration (FDA) has approved BIS monitoring for reducing the incidence of intraoperative awareness. From the beginning, there has been considerable controversy associated with the use of this technology, secondary to the manufacturer's aggressive marketing campaign that focused on intraoperative recall (IR), including mass media articles discussing IR. Anesthesiologists strongly objected to these sales tactics. In spite of the fact that BIS monitoring has been available for more than a decade, these initial hard feelings have not abated and there continues to be skepticism and resistance to the use of this technology by some anesthesiologists.

Much is know about the technology, it's utility and limitations.(1-5) The company cites many of the same clinical advantages of BIS monitoring that they had when their product was first released. Aspect claims that using BIS monitoring during an anesthetic will lead to drug savings, faster wake-ups, shorter PACU stays, decreased postoperative nausea and vomiting, and reduced incidence of awareness during anesthesia. While these claims are somewhat supported in the medical literature, there are two basic questions that must be answered. Are these changes in patient outcomes clinically relevant and if so are they cost-effective?

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II. Technology Assessment

Formal technology assessment is often done by large organizations, particularly third party payers. There are also a number of organizations that do their own technology assessments that are available by subscription. The Emergency Care Research Institute, (ECRI, www.ecri.org) is one such organization. Subscribing to these services can be useful, not only for the technology reports but also to gain an understanding of how new medical technologies and therapies are evaluated. Although, formal technology assessment is impractical at the departmental level, the basic principles of this process can be a useful guide for decision-making.

The Blue Cross Blue Shield Insurance Companies have Medical Advisory Committees, which are made up of physicians and community members that make recommendations to the insurer as to whether a medical intervention is accepted medical practice and should be reimbursed. In order for a new technology to meet this standard it must be shown that:

- The technology must have final approval from the appropriate government regulatory bodies
- The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes
- The technology must improve health outcomes
- The technology must be as beneficial as any established alternatives
- The improvement must be attainable outside the investigational setting

A less complex way to think about introducing new technology is to determine what are the expected patient outcomes. A new technology can be expected to improve, worsen, or not change clinical outcomes. The technology will increase, decrease, or not change net resource expenditures, (i.e. cost, efficiency, personnel). If the new practice improves outcomes for the same or less expense the change is cost-effective. Conversely, if the change worsens outcomes for the same or greater cost, it is not cost-effective. Although there are nine possible consequences of a practice change, most commonly a new technology will increase costs and, at times, improve outcomes. This relationship is seen in Figure 1.

If new technology is expected to improve patient outcomes, but at an increased cost, the next step is to decide if the improvement is worth the cost. The metrics "dollars

per life-year-saved" and "dollars per quality adjusted life-year-saved" are the standard by which medical treatments and technologies are measured.(6,7) Simply put, dollars/life-year-saved is the ratio of incremental costs associated with a practice change relative to the estimated incremental life expectancy gains.

Cost-Effectiveness of a Practice Change

COSTS	Patient Outcomes		
	Better	Same	Worse
Higher	maybe	NO	NO
Same	YES	maybe	NO
Lower	YES	YES	maybe

Figure 1: Cost-effectiveness relationship of patient outcomes and cost implications of a practice change. This relationship holds true whether the change is a new drug, procedure, diagnostic strategy, or technology.

For example, the GUSTO study showed that the thrombolytic agent tissue plasminogen activator (tPA) prevented one incremental death for every one hundred acute MI patients treated with tPA as compared to those treated with streptokinase.(8,9) The cost of tPA is about $2,000 more than streptokinase. The actuarial life expectancy of the average patient surviving an acute MI is about ten years. Therefore, the cost of saving one incremental life with tPA, as compared to streptokinase is:

((100 MI pts) * ($2,000)) / (10 yrs of additional life) =
$20,000 / life-year-saved

Currently, technologies are considered to be cost-effective if they cost less than $50,000 to $80,000 per life-year-saved. The foundation for these economic criteria is the cost of renal dialysis, which the United States government decided to fully fund in the 1960's. Since society has determined that it is unacceptable to die of renal disease then other treatments that cost no more than dialysis, in the context of dollars-per-life-year-saved, are *de facto* cost-effective.

III. BIS Monitoring Impact on Practice Economics

One of the attractive features of BIS monitoring is the potential to decrease the cost of delivering an anesthetic. Anesthesiologists have been generally trained to dose their anesthetics based on a patient's hemodynamic responses as well as movement. Many physicians will give themselves and their patients a pharmacologic buffer in order to assure that there is an adequate level of anesthesia. BIS monitoring is thought to give the clinician a better picture of their patient's level of hypnosis, and by extension anesthesia, allowing them to better titrate their medications. If successful, the cost of anesthetics could be decreased and patients would emerge from anesthesia sooner, thereby decreasing the cost of the episode of care.

Many initial studies seemed to support this conjecture. Gan and colleagues showed in a prospective randomized study that use of BIS monitoring to titrate anesthesia with propofol, alfentanil, and nitrous oxide decreased propofol use by 23%, extubation time by 35%, and discharge time from the PACU by 35%.(10) Similar results were seen in a study of patients receiving outpatient tubal ligation being anesthetized with a sevoflurane anesthetic.(11) These and other studies would seem to support the claim that BIS monitoring can reduce the cost of anesthesia thereby offsetting the incremental increase in cost of utilizing this technology.

Unfortunately, the data does not support such a conclusion. Pavlin and colleagues reported their results of a study of 1,580 inpatients who were randomly assigned to receive their anesthesia with or without the use of BIS monitoring.(12) In this study, the authors reported no differences in anesthetic utilization or time in the PACU. In a study of 99 patients undergoing gynecologic laparoscopy that were randomized to receive BIS monitoring the authors reported no significant effect on the ability to fast track outpatients.(13) In a meta-analysis of 11 studies, Liu reported that BIS monitoring had a minimal reduction in the total dose of anesthetics, postoperative nausea and vomiting, and time in the PACU.(14) Liu also reported that BIS monitoring did not decrease time to discharge and caused a net increase in cost by $5.55 per patient. These results are consistent with a Mayo practice management study that determined that the average cost of IV and inhalation anesthetics was $14.62 per procedure, which is less than the cost of the BIS electrodes. In a more recent meta-analysis of 20 studies involving over 4,000 patients, Punjasawadwong reported that BIS monitoring reduced propofol by 1.3 mg/kg/hr and use of volatile anesthetics by 0.17 MAC.(15) These cumulative drug savings are far less then the cost of a BIS electrode. In addition, the authors reported the use of BIS decreased time to eye-opening by 2.43 min, response to verbal command by 2.28 min, time to extubation by 3.05 min, and duration of PACU stay by 6.83 min. These time savings, while statistically significant, can not be translated into the ability of doing additional procedures in the OR suite nor a reduction in recovery room personnel and are therefore, not associated with any incremental cost savings. While many studies show improvements in intermediate measures of outcome, the evidence for the economic benefits of BIS monitoring, in the context of practice management, are substantially lacking.

IV. BIS Monitoring and Awareness During Anesthesia

Intraoperative awareness is an infrequent but potentially devastating complication of general anesthesia. Since neuromuscular blocking agents became ubiquitous in anesthesia practice the risk of awareness during procedures

increased since it was possible to be paralyzed but not anesthetized. This risk is increased in those patients that are unable to mount a sympathetic response to inadequate anesthesia, such as the elderly and patients taking significant doses of Beta-blockers. The reported incidence of intraoperative recall (IR) appears to be 1-2 per thousand anesthetics.(16,17)

Three recent studies have investigated the impact of BIS monitoring on the incidence of IR.(18-20). Ekman and colleagues reported on a prospective study that examined the anesthesia recall rate of 4,945 consecutive patients with BIS monitoring during general anesthesia and compared these results to historic controls of 7,826 consecutive patients(21) from the same medical facility.(20) Patients with BIS monitoring had a recall rate of 0.04% (2 patients) as compared to a rate of 0.18% of those anesthetized without BIS monitoring. In Myles 2004 study 2,463 high-risk patients (e.g. trauma, C-section, CV surgery) were randomized to BIS monitoring.(18) They reported recall rates of 0.16% and 0.89% for the BIS and the control group, respectively. When definite and possible recall was combined, the recall rate was 1.8% and 3.0% in the BIS and control groups, respectively. Most recently, Avidan reported the results of another study of patients at high-risk of recall, similar to that of Myles.(19) This 2008 study of 1,941 high-risk patients randomized to BIS or control reported that both groups had two patients with definite recall, a rate of 0.21%. When definite and possible recall was combined, the recall rate was 0.62% and 0.31% in the BIS and control groups, respectively. It's worth noting that in contrast to the Myles study, in Avidan's methodology the control group received a defined anesthetic designed to decrease anesthesia recall.

The question then, assuming that the reported improvement in IR are achievable in a noninvestigative environment, what is the incremental cost of reducing the incidence of IR and is this expense acceptable? BIS monitoring electrodes cost about $17 each and are disposable devices. The monitor costs about $9,000. If one assumes that the length of life of the device is seven years, that the monitor will be used on four patients per day, 300 days per year, then the depreciated cost of the device would be:

$9,000 / (7 yrs * 300 d/yr * 4 pts/d) = $1.07 per patient

This calculation does not account for the time value of money. Based on these calculations the cost of BIS monitoring is about $18.07 per use.

If BIS monitoring is restricted to only those patients that are at high-risk for IR, averaging the difference between the Myles and Avidan studies, then we could expect to see a reduction from 59 incidents per 10,000 procedures to 18. Then the cost of avoiding IR in high-risk patients would be:

($18.07 * 10,000) / (59 - 18 IR) = $4,410 per avoided IR

If BIS monitoring is utilized on all patients receiving a general anesthetic, using Ekman's results of a reduction from 18 incidents per 10,000 procedures to 4. Then the cost of avoiding IR would be:

($18.07 * 10,000) / (18 - 4 IR) = $11,294 per avoided IR

However, these results may be better than is achievable in a noninvestigative environment, since the clinicians are not part of a study and, therefore, motivated to prevent IR. If Ekman's results are, for example, two times better than achievable in a noninvestigative environment, a result far better than shown in Avidan's study, one would expect a reduction of only 7 incidents of IR per 10,000 anesthetics, then the cost of avoiding IR would be:

($18.07 * 10,000) / (18 - 11 IR) = $25,814 per avoided IR

This is roughly the same cost of avoiding a death from a myocardial infarction with tPA. Of course death and IR are not the same thing. While $20,000 per-life-year-saved is an acceptable expense to avoid death, BIS monitoring may be too expensive a tool for avoiding this complication. When one examines the results of Sebel's study(17) the majority of recalls were auditory, very brief and/or appear to be associated with induction or emergence. Similar results were seen in the Sandin, Myles, Ekman, and Avidan studies(18-21). If BIS monitoring was used on all patients receiving a general anesthetic in the United States health care expenditures would increase by almost one billion US dollars.

Comparing the cost of avoided recall at $11,000 to $25,000 to the cost of accepted medical interventions, one finds, for example, that the cost of CABG surgery for left-main disease and renal dialysis is $8,768 and $40,000 per-life-year-saved, respectively.(22) A value judgment has to be made as to the long-term impact of intraoperative recall has on the individual and how this compares to treatments that avoids death or ameliorates chronic disease.

Avoided recall with BIS monitoring	**$11,294 – $25,814**
CABG for left main disease *	**$8,768**
3-Drug Treatment for HIV§	**$13,000 - $23,000**
PAP Smear Screening*	**$24,011**
Breast Cancer Screening (55-65 yrs)*	**$41,008**
Neonatal ICU (500-999 grams)*	**$77,161**

Cost of avoiding intraoperative recall with BIS monitoring as compared to the cost, in U.S. dollars-per-life-year-saved of accepted medical interventions.
* (6), § (23)

Given these results and the economic implications of an incremental expense of $10-25,000 per avoided IR, is BIS monitoring worth this expense? Spitellie correctly points out that we already know how to avoid IR with long standing tools.(24) Specifically, the proper use of the anesthetic medications, attention to equipment and monitoring, and most importantly the vigilance of the

anesthesiologist. We know that assuring that 0.5-0.75 MAC of a volatile anesthetic is delivered to the patient will greatly decreases the incidence of IR.(25-27) The use of benzodiazepines and other amnestic agents are also important. Assuring that more than adequate doses of induction agents are used if the patient is to be rapidly intubated. Avoiding deep paralysis, which is rarely if ever indicated, so that the patient is able to move if their anesthetic becomes too light. Anesthetic gas analysis, when used, should have their alarms activated to alert the anesthesiologist if the concentration of volatile anesthetic decreases to subanesthetic levels. Such straightforward and common sense steps come at virtually no cost to the patient or the health care system. While this is certainly a value judgment, it would appear that BIS monitoring, in spite of the fact that it may lower the incidence of IR, is not as cost-effective as already established therapies.

V. Conclusion

BIS monitoring has been available for more than a decade and has been investigated more than many medical technologies. The economic case for widespread utilization of this technology is weak. There appears to be little opportunity to decrease health care cost by either reduction of drug costs or improved practice efficiency. The incidence of any kind of intraoperative recall, as reported in the literature, is relatively low, with an incidence of 0.1% to 0.2%. BIS monitoring may reduce this incidence. General use of BIS monitoring to reduce the incidence of IR would cost about $10,000 to 25,000 per avoided IR. Total cost to the heath care system would approach one billion US dollars per year, just for use during general anesthetics. More appropriate use of already available drugs and technology would most likely decrease the incidence of IR as effectively. The decision to use BIS monitoring is best left to individual physicians and the health care facilities where they work. Individual patients who are at high risk for IR may benefit from this technology. However, based on current health care economic standards general use of BIS monitoring does not seem warranted and appears not to be cost-effective.

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