Patient Awareness During Anesthesia

Safety and Liability Issues

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Overview

The goals of general anesthesia are to prevent the sensation of pain and to produce unconsciousness in patients during the surgical procedure so that they will not remember the operation after they awaken. To accomplish this, a number of powerful anesthetics have been developed. Many surgical procedures also require that the patient's muscles be completely relaxed so that tissues can be adequately seen and safely manipulated by the surgeon. This requires administration of another type of drug in addition to the anesthetic—a muscle paralyzing drug or neuromuscular blocker.

There is the potential for a catastrophic complication when both an anesthetic and a muscle paralyzing drug are given to patients. If the anesthetic dose administered to patients to put them completely to sleep is insufficient, muscle paralysis prevents patients from signaling to the anesthesiologist and surgeon that they are actually awake during surgery. In this situation, patients may be subjected to intense physical and psychological agony without the ability to defend themselves. As a result, they may suffer profound, subsequent, psychological harm.

An inadequate level of anesthesia can be caused by a number of factors, including equipment failure, problems associated with certain surgical procedures, and patient differences in uptake and distribution of the anesthetic agent. The recommended dosages of anesthesia are usually determined in clinical studies of middle-aged men, yet the actual anesthetic dose required for individual patients can vary greatly from that standard dose. As a result, the amount of a particular drug that is sufficient for some patients may be insufficient for others, potentially resulting in patient awareness during surgery.

Estimates of the scope of patient awareness during general anesthesia vary widely. It is conservatively estimated that awareness may occur in 0.2–1% (30,000–150,000) of the approximately 15 million patients who undergo general anesthesia in the United States each year.[1,2] The true incidence of surgical awareness is uncertain because patients usually do not report the experience.

Patients fail to report their experiences for a number of reasons, including feeling embarrassed about discussing their symptoms and questioning their own mental stability. Some patients become convinced that they were merely hallucinating and that surgical awareness could not possibly have occurred. Numerous reports are available, however, that document the terrifying paralysis and helplessness of patients who have experienced surgical awareness. The reports are similar and relay the horror of feeling throat blockage and sometimes pain:

> *"It was like being buried alive."*
>
> *"I was still perfectly lucid when the obstetrician plunged his knife into my abdomen."*
>
> *"All I could feel was terrible, terrible pain. I was...screaming, but no one knew."*

"It hit me when I heard the power saw cutting the bone."

"I remember them splitting my ribs open and I remember the pain."

As these testimonials suggest, awareness during surgery may have an enormous emotional impact on patients. The long-term psychological consequences cannot be overstated. Psychological and emotional problems subsequent to surgical awareness include nightmares, irritability, anxiety, a fear of future surgeries, an unnatural preoccupation with death, and post-traumatic stress syndrome. Psychological dysfunction can subsequently result from these problems and directly impact patients' sexual, marital, and occupational lives.

In addition to its impact on patients, awareness during surgery increasingly exposes medical institutions and healthcare professionals to medicolegal liability. Widespread publicity by both the media and patient advocacy groups has brought the possibility of surgical awareness to the attention of the general public and raised the expectations of what constitutes proper anesthetic treatment. The number of patients reporting surgical awareness is increasing and more patients are expressing anxiety about the possibility of regaining consciousness during surgery.

Perhaps because of this adverse publicity, patients also have become more litigious in cases of psychological trauma resulting from surgical awareness. Less than 10 years ago, there were almost no reports of lawsuits resulting from patient awareness during surgery.[3,4] Today, a significant number of settled anesthesia-related insurance and malpractice claims against medical institutions and anesthesiologists are a result of patient awareness during general anesthesia. In fact, 2–4% of settled claims—with substantial sums paid to the plaintiffs—result from patient awareness and fright that went undetected by the surgical team. The absence of a precise method of detecting and consequently preventing awareness adds considerably to the burden of proving the absence of negligence or liability by the medical defendants. For this reason, most cases involving claims of surgical awareness are settled out of court.

Current practice relies upon a number of indirect methods to ascertain the absence of awareness, but all have substantial limitations. The usefulness of the vital signs—blood pressure and pulse—as indicators of awareness is minimized by the multiple hemodynamic effects of the drugs that are used in surgery. Reliance on standard anesthetic dosage to predict the level of awareness is problematic because of patient variability. The level of concentration of an inhalational anesthetic agent can be measured by analyzing the patient's exhaled breath, but this method is not useful for all types of anesthetics. Intravenous anesthetic concentration can only be estimated using mathematical modeling. For either inhalational or intravenous anesthesia, this information does not reflect consciousness itself or the need for changing anesthetic doses as requirements change during surgery. Other, more quantitative methods, such as the conventional monitoring techniques that are used to evaluate a patient's brain waves—electroencephalograms (EEGs)—also have been limited in effectiveness.

The emotional trauma to the patient of being aware during a surgical procedure, in and of itself, justifies an investment in an appropriate methodology for detecting and

consequently preventing awareness. The emotional and economic consequences to medical institutions and healthcare professionals also can be immense. To protect their patients from the trauma of awareness and to defend themselves from claims of awareness in patients undergoing general anesthesia, it is incumbent upon clinicians and healthcare institutions to adopt more accurate and reliable patient monitoring techniques.

New developments in EEG technology promise to vastly improve the accuracy and confidence of patient monitoring so that the catastrophe of surgery for awake and aware patients can be avoided in the future. Anesthesiologists, nurse anesthetists, surgeons, risk managers, healthcare provider organizations, and—most of all—patients, stand to benefit from a greater level of accuracy in detecting and preventing patient awareness.

Historical Perspective

The ability of patients to have conscious or subconscious thoughts while undergoing general anesthesia has a long history—as long, in fact, as general anesthetic use. Reports of awareness in surgical patients date to the mid-1800s with the introduction of the first general anesthetics—nitrous oxide and diethyl ether. Since body movement and speech were not specifically impaired with these anesthetics, however, the patient was able to respond if he or she were conscious. Thus, in the early days of general anesthesia, patient awareness was not considered a problem. Rather, patient movements or verbalizations were routinely used as clinical indicators of level of awareness, signaling a need to administer additional anesthetic.

The possibility of a patient being aware of surgical events became problematic only with the introduction of neuromuscular blocking agents in the 1940s.[5] These muscle paralyzing drugs completely relax the patient's muscles and ensure that no bodily movement can take place. The use of neuromuscular blocking agents greatly facilitated intubation and surgical practice—particularly thoracic and abdominal surgery—by preventing muscular rigidity and allowing adequate exposure and manipulation of tissues. These agents, however, also created the possibility of situations developing in which patients were experiencing all the physical and psychological agony of a surgical procedure while awake without being able to alert the clinician. Case reports of patients who were conscious during surgical procedures, but unable to communicate, began to appear shortly after the use of neuromuscular blocking agents became commonplace in anesthetic practice.[6,7] Interestingly, the human misery associated with an inability to convey feelings of pain or terror due to a drug-induced paralysis was prophesied by the French physiologist, Claude Bernard, in the late 1800s:

> *"In all ages poetic fictions which seek to arouse our pity have presented us with sensitive beings locked in immobile bodies."*[3]

Common Causes of Patient Awareness

A number of factors can lead to situations in which patients are conscious during surgery **(Table)**. Awareness can result from problems with the anesthetic process, differences in the patient response to the anesthetic, or the nature of the surgical procedure.

Anesthesia Process-Related Factors

The possibility of awareness commonly exists during the transition period between anesthetic induction and maintenance. The effects of the intravenous anesthesia induction agents, such as propofol and thiopental, are not long-lasting.[8] There also is a large variability in the time it takes for different induction agents to be cleared from the body. In a recent study, the duration of unconsciousness induced by a standard dose of thiopental ranged from 2–12 minutes.[9] The effect of propofol ranged from 4–13 minutes. Accordingly, intravenous agents must be closely monitored to ensure that their sedative action does not dissipate before the introduction of an inhalational anesthetic.

Difficulties with tracheal intubation can prolong the period of time that the intravenous induction agents can be relied on

Table: Common Causes of Patient Awareness

Anesthesia Process-Related Factors

- Absent or Inadequate Pre-Medication
- Difficulties During Anesthetic Induction / Intubation
- Equipment Failure
- Inadequate Anesthesia / Anesthetic Failure

Individual Patient Response-Related Factors

- Metabolic Rate
- Obesity
- Age
- Health Status
- Drug or Alcohol Abuse

Special Problems with Certain Surgical Procedures

- Obstetric
- Trauma
- Cardiopulmonary

for the maintenance of unconsciousness, sometimes past the point of their effectiveness, unless additional agent is administered. Redistribution or elimination by the body of the induction agents before sufficient ventilation with the inhalational anesthetic can result in insufficient anesthetic to maintain patient unconsciousness.[10,11]

Defects in the anesthesia delivery equipment or human error in its use also can result in inadequate anesthesia. Improperly calibrated or connected vaporizers may cause a patient to receive inadequate anesthesia during surgery. Leaks in ventilator bellows can cause a loss of anesthetic from the ventilation system or allow oxygen, which is used to compress the bellows, to enter the system and dilute the anesthetic gas mixture.[3,10,12] In addition, reducing the fresh-gas flow rate without adjusting the inspired concentration of the inhalational agent could result in reduced anesthesia and subsequent patient awareness.[12] Likewise, if the unconscious patient is not given adequate breathing air by the anesthesiologist or the mechanical ventilator, the inspired anesthetic gas mixed with the air may be insufficient to ensure adequate anesthesia.[11]

Individual Patient Response-Related Factors

Individual differences in the way anesthetic agents are metabolized, distributed to various tissues (including the brain), and excreted can result in the presence or absence of awareness in different patients who are given the same amount of anesthetic. For example, patients whose tissues break down and excrete anesthetic agents rapidly are more likely to be awake and aware of surgery than patients who metabolize anesthetic agents slowly.

Obesity increases the likelihood of awareness due to altered distribution and uptake of the anesthetic agent. Obese patients often are difficult to intubate as well, which can prolong the interval between induction with intravenous agents and anesthesia maintenance with the volatile anesthetic.[11,13]

The elderly and patients with serious illnesses often receive less-than-optimal doses of anesthetic drugs because of the extra caution taken due to their fragility, and young children are sometimes given less-than-optimal doses under the mistaken assumption that they require less anesthesia than older children.[14]

Alcoholics can be less responsive to the sedative effects of general anesthetics, and similar physiological mechanisms producing anesthetic tolerance are found in chronic abusers of tranquilizers, sedatives, and illicit drugs, such as narcotics, cocaine, and amphetamines.[11,13,15,16]

Special Problems with Certain Surgical Procedures

Special problems achieving the desired depth of anesthesia to prevent awareness are associated with certain surgical procedures. Obstetric procedures, such as cesarean sections, traditionally have been associated with a high incidence of maternal consciousness during surgery, since the

anesthetic dose is kept low deliberately to prevent over-sedation of the baby.[17,18,19] Similarly, patients undergoing surgery following major trauma often have substantially compromised cardiovascular stability that dictates the use of lower-than-standard doses of anesthetics.[12]

The use of intravenous anesthetic agents, specifically high doses of opioid analgesics (i.e., morphine, alfentanil, fentanyl, and sufentanil), provides greater hemodynamic stability to patients than inhalational agents. Therefore, these drugs are often used in cardiopulmonary procedures such as coronary artery bypass surgery.[20,21] Unfortunately, intravenous anesthesia without inhalational agents has been associated with a higher incidence of awareness.[16,21] First, it is difficult to measure the concentration of intravenous anesthetic agents in the patient since they are not eliminated by the lungs. Because of differing clearance rates among patients, there also can be a wide variability between the dosage given and the actual level of intravenous anesthetic in the body, making it difficult to manage the level of anesthesia.

Finally, in recent years, clinicians and healthcare facilities have faced mounting financial pressure to increase efficiency in the operating room and to reduce the patient recovery time from anesthesia. To accomplish this, efforts are being made to reduce excessive anesthesia doses during surgery. For example, many hospitals are implementing "fast-track" cardiac anesthesia programs designed to facilitate earlier recovery after open-heart procedures. One goal of these programs is to allow postoperative patients to begin breathing on their own earlier so that the endotracheal breathing tube can be removed sooner. This early removal of the breathing tube allows the patient to be moved more quickly from the expensive critical care unit to less costly areas of the hospital. The effort to avoid deep anesthesia, however, can increase the risk of underdosing.

In any situation in which a patient is receiving less-than-optimal doses of anesthesia, the possibility exists that a patient is awake and aware of operative events, but has no way of communicating this to the anesthesiologist or surgeon. The lack of an appropriately precise method of monitoring the level of consciousness during surgery while under general anesthesia sets the stage for a situation in which the medical team is not cognizant of a patient's awareness and can result in serious consequences.

Patient Reports of Awareness

Patients have reported recall of just about every aspect of surgical procedures performed under general anesthesia including intubation, skin incision, noises, conversations (both relevant to the surgery and irrelevant), hand and instrument insertion, and suturing.[21]

It is conservatively estimated that awareness may occur in 0.2–1% (30,000–150,000) of the approximately 15 million patients who undergo surgery with general anesthesia in the United States each year.[1,2] When questioned at a recent conference, 50–60% of American anesthesiologists reported that at some time in their practice at least one of their patients had reported experiencing awareness during surgery while under general anesthesia.[1]

Cesarean sections are associated with a particularly high incidence of patient awareness. In a survey conducted by a popular women's magazine, 187 women responded with reports of surgical awareness.[22] Of these reports, 119 (64%) were related to cesarean sections or other obstetric procedures. Pain, either unspecified, or described as "cutting," "ripping," or "tearing" was reported by 56% of the responders. A review of incidence studies shows that 0.4–28% of obstetric patients complained of awareness or dreams while under general anesthesia.[19,23,24] Nitrous oxide / oxygen and nitrous oxide / halothane produce the highest number of these awareness reports.[18,19] A recent study found that if a cesarean section was initiated immediately after intubation, an extraordinary 96.7% of the patients signaled awareness and 80% signaled the perception of pain. If surgery was postponed for two minutes following intubation, 20% of the patients signaled awareness and 6.7% pain.[17]

Patients undergoing emergency trauma surgery also have a high incidence of recall. In one survey, postoperative interviews of 37 trauma patients receiving uninterrupted anesthesia revealed that 11% reported awareness.[25] In cases where anesthesia had to be interrupted to maintain hemodynamic stability, more than 40% of the trauma patients reported awareness.

A high incidence of recall also has been found in patients following cardiopulmonary procedures, such as coronary artery bypass, valve replacement, and defibrillator implantation.[26,27,28] Studies have found that 8.9–25% of patients suffered postoperative recall after cardiopulmonary bypass surgery.[27,28]

Awareness also has been reported in children undergoing surgery. In one study, 5% of children aged 7–11 reported surgical recall.[29] Another study found that 19% of 120 children aged 5–17 reported dreaming during surgery, which suggests cerebral arousal, but does not describe overt awareness.[30]

Since the ability to hear remains longer than the other senses when consciousness is lost, it is not surprising that reports of hearing noises and conversations among the members of the surgical team are quite common

among patients reporting awareness. A number of reports exist, however, documenting recall by patients of the terrifying paralysis and intense helplessness associated with intubation and surgical incision.[31] The recalls are remarkably similar and relay the feelings of "throat blockage," "suffocation," "cutting / tearing pain," and the inability to verbally communicate or move.[31,32] One study found that, of all reports of surgical awareness, 40% of patients were conscious but completely paralyzed prior to, or during, intubation.[33] A number of other studies confirm the high incidence of awareness during this period.[34,35]

Anecdotal reports of patients who have experienced the horror of surgical awareness are seen in popular lay publications. These publications enjoin feelings of sympathy and outrage. In these articles, patients give disturbing accounts of their experiences during surgery with general anesthesia:

> *"It was loud and very clear like cutting wood. I really panicked."*[36]
>
> *"I started to panic. I tried to move to let them know I was awake."*[37]
>
> *"I could hear every tissue tearing like a piece of paper."*[38]

Psychological Consequences of Patient Awareness

The long-term consequences to the patient associated with the trauma of being paralyzed but aware of a surgical procedure due to inadequate anesthesia cannot be overstated. The spontaneous, postoperative recall of surgical awareness can lead to a number of immediate or delayed psychological problems that can be traced back to the previous surgical procedure. Early counseling and honest discussions by the medical staff with patients who have suffered awareness during surgery can help reduce the severity of postoperative psychological and emotional problems.[3,13] If patients are not counseled or counseling is unsuccessful, however, psychological problems, such as fear of subsequent anesthesia or surgery and fear of new pregnancies, can result.

The development of postoperative neuroses is often delayed. The negative sequelae are consistent with those produced by other traumatic events and include recurrent nightmares, irritability and generalized anxiety, a fear of falling asleep, an unnatural preoccupation with death, and a reluctance to discuss the postoperative symptoms or even the possibility of awareness while under anesthesia.[39,40,41]

The Awareness with Anesthesia Research Education (AWARE) support group, formed in 1993, provides information and psychological support for patients and the families of patients who have experienced awareness while under general anesthesia. The organization also campaigns to educate the general public and medical community about the emotional devastation and possible long-term psychological problems associated with surgical awareness. The president and founder of AWARE, Jeanette Tracy, suffers from post-traumatic stress syndrome as a result of surgical awareness. Tracy emotionally recalls surgical awareness and the condescending, negative attitude of her physicians:

> *"As the surgeon started cutting...I thought the left side of my face would blow off my head. They made reference to my physical attributes...what great shape I was in after having two children. To retain my sanity...I screamed as loud as I could in my head."*

She relates her postoperative experience:

> *"[My anesthesiologist] cut me off and said, 'Sometimes the combination of drugs can make you hallucinate, but it was just a dream'.... The surgeon said, 'it's not my problem'...."*[38]

Medicolegal Issues

Patient awareness during surgery increasingly exposes medical institutions and healthcare professionals to medicolegal liability. Paradoxically, improvements in medical practice may contribute to the problem. Anesthetic accidents have been reduced to such a degree by technological advances that the general public believes that anytime one does occur, it must be due to negligence. Half a century ago, surgical risk was much higher, so problems perceived as minor—that is, not life-threatening—were generally accepted without question.

In interviews conducted with postoperative patients as recently as 1992, only 35% of those who had actually experienced awareness in previous surgeries said that they had informed their anesthesiologist.[31] It is highly unlikely that this level of acceptance will continue.

In the last few years, widespread publicity by the media and patient advocacy groups has brought the very real possibility of being conscious while under general anesthesia to the attention of the public. The number of patients who report awareness during surgery has increased over the last few years and more and more patients are expressing fear and anxiety about the possibility of regaining consciousness during surgery.[1,42,43]

Risk Management

As a result of increased consumer-related medical news, the public today has very high expectations of what constitutes proper medical treatment. Patients would not consider consenting to endure a painful surgical procedure while awake. They also have become more litigious in cases of psychological or emotional injury. Claims of anesthetic malpractice resulting from patient awareness are almost always settled out of court or before a verdict is reached. In fact, a review of more than 100 anesthesia-related cases showed that, in a seven-year period, only four had gone to court for settlement.[44]

Those cases that do go to trial usually end in a verdict in favor of the plaintiff, who is portrayed as a helpless victim suffering from the "invisible scars of surgery." In one case, the decision by a jury to rule in favor of the surgical team actually appeared to result more from a lack of credibility of the plaintiff, a drug abuser, than from any evidence presented by the medical defendants that the patient's clinical signs assured unconsciousness.[45] In another case, even though the judge found no negligence on the part of the medical team, he stated that he regretted having to rule for the defendants because he felt great sympathy for the patient.[46]

Medical ethicists are now questioning a number of procedures employed in modern anesthetic practice. In a recent issue of *The Journal of Clinical Ethics*, several physicians argued that their colleagues were using amnestic drugs as a substitute for adequate anesthesia in surgery in a "deceptive manner," in order to fool patients into thinking they had been "spared pain" and surgical awareness, when actually they had been spared only the conscious memory of surgical events.[47] The inference is that some anesthesiologists administer light doses of general anesthesia for a number of reasons (e.g., fast-track procedures, anesthetic risk in certain patients), and give amnestics in a deliberate attempt to avoid the legal ramifications of conscious surgical recall by the patient.

The Committee on Professional Liability of the American Society of Anesthesiologists (ASA) has compiled a data bank of settled or "closed" malpractice claims against medical institutions and anesthesiologists since 1983 that represents about 50% of claims. Reviews of the data from the ASA Closed Claims Project revealed that 4% of anesthesia-related insurance claims resulted from cases of patient awareness and fright, with about one-third of these also reporting feelings of paralysis.[1,42,48] A recent review of the information in the ASA Closed Claims Project database showed that claims were 2% when only patient awareness was included as a complication.[49,50] It is noteworthy, in terms of suits against medical institutions and professionals, that the incidence of patient awareness claims was about the same as for claims of aspiration pneumonia, respiratory distress syndrome, hepatic dysfunction, and back pain.[42]

Anesthetic malpractice cases are litigated on either the basis of breach of contract, a lack of informed consent, or negligence based on the legal doctrine of *res ipsa loquitur*, which literally translates as "it speaks for itself."[51,52] The breach of contract argument often results from an attempt by a physician or nurse to allay the preoperative fears of the patient. Up to 50% of preoperative patients express fear to their physician or nurse of waking up during a forthcoming surgery.[43] Comments meant to calm and reassure the preoperative patient such as, "It's OK, I will make sure that you don't wake up," become evidence for breach of contract in a malpractice suit if the patient does, in fact, experience awareness during surgery.

Possible liability based on the argument of lack of informed consent can occur in cases where the physician or the nurse decides that it would not be in the best interest of the preoperative patient to reveal the possibility of patient awareness during surgery. For example, highly anxious patients, trauma patients, or patients undergoing emergency procedures may not be informed of possible surgical awareness either because time is being spent on more critical measures or the patient is not in any condition to provide informed consent.

The decision not to discuss possible surgical awareness with a preoperative patient may have been based on the best standards of care, but postoperatively it can be used as an argument for medical malpractice by the unhappy patient.[52]

Arguments invoking the doctrine of *res ipsa loquitur* require proof that:

- The anesthetic injury resulted from medical negligence or fault;
- The anesthetic injury was caused by something under the exclusive control of the anesthesiologist; and
- The patient made no voluntary contribution to the injury.

Res ipsa loquitur places the burden of proof on the medical defense.[51] It is extremely hard to successfully defend a physician or nurse in a patient awareness suit involving this doctrine. The third part of the proof of *res ipsa loquitur* is *a priori* since the patient is paralyzed, and consciousness in and of itself implies negligence by the anesthesiologist or nurse anesthetist. Defense-related expert testimony often can be too technical for the jury to appreciate. The judge and jury naturally feel sympathy for the plaintiff, who is perceived as a helpless victim. The attorney for the anesthesia team has the burden of convincing the jury that there is absolutely no possibility that the patient could have been aware of the surgery.[51]

Professional Education

Professional healthcare organizations are beginning to appreciate the need to address the problem of awareness and to develop methods of preventing or alleviating any long-term psychological injuries to patients that result from such awareness.

The ASA recently held panel discussions at national meetings, and an entire issue of a recent ASA newsletter was devoted to the subject of patient awareness during general anesthesia. The American Association of Nurse Anesthetists and other nursing organizations have conducted sessions at conventions addressing the problem of patient awareness during general anesthesia and the importance of professional operating room behavior. AWARE founder Jeanette Tracy often attends these medical conferences to share her horrific experiences during surgical awareness to help educate professional audiences.

Anaesthesia and the *AORN Journal* have published articles on awareness during anesthesia and how to cope with patients who report awareness postoperatively. These publications provide valuable information about possible measures that can be taken by healthcare professionals to prevent or alleviate psychological problems that occur in patients as a result of surgical awareness.

The medicolegal problems associated with patient awareness promise to continue and will probably escalate, considering the increased attention paid to this issue by the media and patient advocacy groups. The most practical way that medical institutions and healthcare professionals can successfully defend themselves in claims of malpractice due to breach of contract, lack of informed consent, or *res ipsa loquitur* is by employing patient monitoring techniques that accurately monitor the level of consciousness in patients undergoing general anesthesia and assist in the detection of awareness. Not using such techniques adds considerably to the burden of proving the absence of liability or negligence by the medical professional or institution in litigation surrounding claims of patient awareness during general anesthesia.

Qualitative Methods of Detecting Awareness

The detection of awareness in a patient who appears to be anesthetized is difficult. This is evidenced by the fact that until the early 1980s, the most commonly used method of assessing whether or not a patient was aware during surgery was the postoperative interview. Since the aim of anesthesia is the prevention of awareness, the postoperative interview is not satisfactory. The development of quantitative methods to detect and monitor the level of consciousness in patients undergoing general anesthesia and assist in the detection of awareness is imperative, but qualitative methods remain the primary techniques in use today.

Ongoing patient assessment by the anesthesiologist or nurse anesthetist is conducted during surgery in an effort to detect and prevent patient awareness. The current practice of monitoring the effects of anesthesia relies heavily upon hemodynamic responses—changes in blood pressure and pulse—and the dose of the anesthetics.[10,53]

Hemodynamic responses are simply not reliable for predicting patient awareness as pulse and blood pressure are not directly indicative of consciousness, and modern anesthetics have varying and sometimes offsetting effects on hemodynamic variables. For example, ketamine anesthesia can increase blood pressure, while halothane decreases blood pressure.[10] In addition, drugs that are used to treat underlying cardiovascular diseases, such as beta-blockers and antihypertensives, can blunt hemodynamic responses markedly.[26] A recent study found that heart rate and blood pressure could not be trusted to consistently respond to the return of consciousness by patients following induction with thiopental.[9] In some patients, the heart rate went up, but in others, it stayed the same or decreased.

Reliance on the effects of "standard" anesthetic dosage presents many problems. Standard dosages are based on the anesthetic needs of average-weight, middle-aged men. These standards may not apply to women, patients of different ages, those with underlying disease, or even all average-weight, middle-aged men. Other factors that affect patients' tolerance of anesthesia include body temperature, differing rates of metabolism, and clearance of anesthetics.[10]

An indirect method of measuring an inhalational anesthetic agent's absorption into the bloodstream through the lungs is to measure the unabsorbed agent in the patient's exhaled air—the expired concentration—but this method is not useful for measuring the effects of all anesthetics. Concentrations of intravenous agents, for example, can only be measured through intermittent blood sampling or estimated by mathematical modeling. In either case, measuring the anesthetic concentration provides no indication of its effects on the patient nor of changing dosage requirements during the course of surgery.

Quantitative Methods of Detecting Awareness

The electroencephalogram (EEG) is known to be affected by anesthesia and the use of neuroactive drugs. It is also affected by physiological changes that occur during surgery such as cerebral ischemia and hypothermia. As a result, unprocessed and computer-processed EEG recordings have been used in an attempt to monitor the level of consciousness of patients under general anesthesia. Computer-processed recordings have included auditory evoked potentials and power spectral analysis.

Unprocessed EEG Monitoring

EEG analysis is one objective indicator of patient awareness during general anesthesia, as there are characteristic EEG changes associated with consciousness and unconsciousness. The EEG can be followed in real time, is appropriately sensitive, and does not require active patient response. The use of raw, unprocessed EEG recordings for monitoring the depth of anesthesia or level of consciousness of patients during surgery, however, is not widespread. For practical utility in the operating room, the unprocessed EEG signal is problematic for several reasons. The EEG signal is complex and difficult to read, requiring a trained and dedicated interpreter.[54] Also, unprocessed EEG recordings are not particularly useful for detecting small changes in the depth of anesthesia.[55] With the lighter anesthetic doses and pervasive use of muscle relaxants in modern surgical practice, it is critical to detect slight changes in anesthetic depth in order to differentiate between unconsciousness and possible patient awareness.

Auditory Evoked Potentials

Unlike the overall EEG signal, which records changes in spontaneous electrical activity of the brain, the evoked potential signal reflects the brain's response to specific sensory stimuli, such as sound. Attempts have been made to use auditory evoked potentials to monitor depth of anesthesia and consciousness.[56,57] Middle latency (i.e., 30–40 Hz) auditory evoked responses show the most promise among evoked techniques as indicators of patient consciousness.[41,58] Auditory evoked potentials, however, are hard to detect and must be extracted from the EEG background; their interpretation is difficult and requires considerable expertise.

Power Spectral Analysis

The EEG signal can be broken down into a series of component sine waves with frequencies ranging from 0–30 Hz. Power spectral analysis represents the signal amplitude (power) of each of the sine wave components as a function of frequency.

Change in the spectral edge frequency—the frequency below which the power spectrum contains 95% of the total power of the EEG—is considered the best of the power spectral analysis techniques for reflecting a patient's level of consciousness.[59,60,61] The spectral edge frequency, however, does not perform reliably when the EEG response to the anesthesia deviates from the typical pattern. Specifically, the spectral edge frequency does not always show a consistent relationship with the dose of the anesthetic, as may be seen when low doses of benzodiazepines are administered.[62,63]

Technological Advances in Monitoring Patient Awareness

The deficiencies of hemodynamic response and conventional brain monitoring techniques for the detection of a patient's level of consciousness under general anesthesia have led to the development of a more refined computer-processed approach to EEG monitoring. This new technology has been shown to correlate well with the level of consciousness in patients undergoing general anesthesia and to assist in the detection of awareness.

Bispectral Analysis

Bispectral analysis is a mathematical method of analysis that examines the relationships or "coupling" among components of the EEG signal. Specifically, it provides a quantitative measure of the synchronization of the EEG signal (i.e., not just frequency and amplitude).

Originally used by geophysicists in the early 1960s to study ocean wave motion, atmospheric pressure changes, and seismic activity, bispectral analysis is an emerging technique for other applications because of the advent of high-speed, low-cost computing. Most recently, it has been applied to EEG analysis with the development of the Bispectral Index™ (BIS).

Bispectral Index

The development of the Bispectral Index has simplified the interpretation of the complex three-dimensional EEG data generated by bispectral analysis. Sophisticated statistical algorithms are applied to the data to generate this simple, real-time, numerical index that correlates with level of consciousness.[64]

The Bispectral Index ranges from 100, indicating that the patient is awake, to zero, indicating a total lack of brain wave activity. The sensitivity of the Bispectral Index makes it possible to detect minute changes in the electrical activity of the brain rapidly and reproducibly. Recent clinical studies have demonstrated its usefulness in monitoring the level of consciousness and in the detection of awareness in patients undergoing general anesthesia.

In a multicenter study involving researchers from several medical research centers at major universities, including Harvard, Duke, Emory, and the University of Pittsburgh, the Bispectral Index was found to assess levels of sedation accurately in subjects undergoing general anesthesia with commonly used anesthetics.[65,66,67] These results were confirmed in studies performed at other clinical institutions.[68,69]

In studies comparing the Bispectral Index with power spectral analysis techniques (e.g., spectral edge frequency, median frequency, and delta, theta, alpha, and beta power bands), the Bispectral Index correlated better with the level of sedation.[65,68] The Bispectral Index also reflected the level of patient sedation more accurately than did the measurement of propofol blood level, and as well as expired isoflurane concentrations.[66] In fact, an almost linear decrease in the Bispectral Index was observed with increases in the level of patient sedation, and it accurately predicted awakening from general anesthesia.[70,71,72] Studies have found that the Bispectral Index accurately tracked the return of consciousness as the anesthetic dose wore off.[9,71,72] Increases in the Bispectral Index anticipated patient emergence from general anesthesia by several minutes.[71]

Conclusion

Each year in the United States, it is estimated that approximately 15 million patients require surgery under general anesthesia. Conservative estimates indicate that 30,000–150,000 of these patients are awake—but unable to communicate—during surgery. While the number of patients that experience surgical awareness may seem small to some, the consequences of even a handful of cases can be enormous, not just in terms of the physical and emotional trauma to these patients, but also in terms of the medical and economic consequences to the clinician and the medical institution. To successfully protect their patients from the horrific experience of surgical awareness and to defend themselves from claims of awareness by such patients, the medical community must adopt more accurate and reliable patient awareness monitoring techniques. Despite substantial efforts over many years, however, there has been little improvement until recently in the accuracy of, or confidence in, such techniques.

New developments in technology such as the Bispectral Index promise to make the detection of patient awareness during surgery more useful and reliable. What is needed is an understanding by the healthcare community of the urgent need to recognize the problem of patient awareness during general anesthesia and to minimize its occurrence. Given the medical community's ethical obligation to protect the patient from unnecessary physical pain and emotional anguish, to say nothing of the economic necessity of avoiding litigation resulting from patient awareness during general anesthesia, it is imperative that new, more-effective methods of addressing this avoidable problem be embraced at the earliest opportunity.

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