Chapter 24. The Impact Of Intraoperative Monitoring On Patient Safety

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Background

Until the 1960s, intraoperative monitoring consisted of a blood pressure cuff, electrocardiogram (ECG), stethoscope, and the vigilance of the anesthesiologist. Over the next 2 decades, the array of available monitors burgeoned, and clinical practice varied widely. In 1986, in an effort to improve patient safety, standards for intraoperative monitoring were developed and implemented by the American Society of Anesthesiologists (ASA).[1] They have been almost universally adopted by anesthesia providers in the United States and now form the standard of care in this country. The ASA standards are summarized in Figure 24.1.

Concurrently with the implementation of better monitoring, anesthesia-related mortality has fallen sharply. Proponents of monitoring claim that better monitoring is the reason for improvement in patient safety.[2-4] Others have claimed that advances in knowledge and training combined with the development of safer medications have had as much impact on patient safety as the adoption of monitoring standards.[5,6] In this chapter, we evaluate the evidence linking intraoperative monitoring to patient safety.

Practice Description

Intraoperative monitoring involves the use of mechanical devices to record and display physiologic parameters such as heart rate, blood pressure, oxygen saturation, and temperature. Standard routine monitoring is noninvasive, employing blood pressure cuff, ECG, and pulse oximetry.

Invasive monitors such as arterial and central venous catheters and transesophageal echocardiography may provide more detailed and timely physiologic information, but also pose an increased risk for iatrogenic complications. In practice these monitors are used selectively, and are not reviewed here.

Prevalence and Severity of the Target Safety Problem

Death due to anesthesia has become rare. In one large Canadian study involving 27,184 inpatients who underwent anesthesia, physician review of 115 randomly selected “major events” classified less than 20% as having any anesthetic involvement, with no deaths even partially attributed to anesthesia.[7] In the United States, the mortality due to general anesthesia has been estimated at approximately 5000 deaths per year (in the 1970s),[8] with approximately half that number estimated in the 1980s.[9] Thus, general anesthesia represents the one aspect of health care where the risk of death is low enough to rival the safety record achieved in other high-risk industries such as aviation.[10]

By contrast, morbid events (complications) related to anesthetic care are likely more prevalent and difficult to classify as preventable or unavoidable. Because certain aspects of monitoring may reduce the incidence of morbid events unrelated to anesthesia, assessing the impact of monitoring practices solely on anesthetic outcomes may be inappropriate. For example, detection of a consistent decrease in intraoperative blood pressure may signal unrecognized bleeding, allowing the anesthesiologist to alert the surgeon to this possibility and prompting appropriate management. While intraoperative hemorrhage does not represent an

anesthetic complication, intraoperative blood pressure monitoring can clearly contribute to the overall safety of the surgical patient. Thus, the scope of intraoperative morbidity targeted by anesthetic monitoring practices is much broader than the set of possible complications attributable solely to the administration of anesthesia.[7-9]

Opportunities for Impact

In the United States, there are no mandatory regulations for monitoring practices. However, virtually all anesthesiologists abide by the monitoring standards set forth by the 1986 ASA standards, last modified in 1998 (Figure 24.1). Although these standards were implemented with only speculative evidence of their benefit,[4] few clinicians doubt their merit.

Study Designs

Using a structured MEDLINE search, we identified articles presenting data related to the impact of perioperative monitoring. Many of these studies[11-17] involved Level 4 designs (eg, observational studies without a control group). For instance, several of the articles[11-13,15] reported data from the Australian Incident Monitoring Study and involved analysis of a case series of 2000 incident reports without accompanying controls. Other studies only indirectly pertained to intraoperative monitoring. One study surveyed anesthesiologists regarding their views on the appropriate alarm settings for intraoperative blood pressure monitoring.[18] Another focused on the personnel performing intraoperative monitoring—physician anesthesiologists versus certified nurse anesthetists.[19] We chose not to purse this contentious and intensely political comparison, as few studies have compared the outcomes achieved by these two groups. Moreover, our reviewer team did not include a nurse anesthetist, making any conclusions drawn more susceptible to bias. Of the 3 remaining studies, one involved a non-randomized clinical trial (Level 2), but a Level 3 outcome.[20]

The remaining 2 studies met our inclusion criteria (Chapter 3). One was a retrospective analysis of anesthesia accidents before and after the implementation of monitoring standards (Level 3),[2] and the other used a prospective, randomized, controlled trial design (Level 1) to assess the impact of pulse oximetry on postoperative complications (Level 1 outcome).[21]

Study Outcomes

The 2 studies[2,21] meeting the methodologic inclusion criterion reported morbidity and mortality (Level 1) attributable to anesthesia, ie, a major complication or death occurring in the immediate postoperative period not obviously explained by the patient's underlying condition or the operation itself.

Evidence for Effectiveness of the Practice

Through a review of cases reported to a liability insurer, Eichhorn identified 11 major intraoperative accidents solely attributable to anesthesia among over 1,000,000 cases performed at the nine Harvard hospitals from 1976-1988.[2] Eight of these accidents were judged to be preventable as they were caused by failure to ventilate or to deliver adequate oxygen to the patient. Only one of these accidents occurred after the adoption of monitoring standards in mid-1985, supporting the safety benefit of intraoperative monitoring standards, although the difference in accident frequency was not statistically significant.

In a multicenter, randomized, controlled trial of 20,802 surgical patients, Moller et al[21] studied the impact of perioperative pulse oximetry on patient outcome. Despite the large sample, the authors were unable to show a difference in in-hospital mortality or postoperative

complications. During anesthesia and in the post-anesthesia care unit (PACU), more episodes of hypoxemia and myocardial ischemia were detected in patients monitored with pulse oximetry.[21]

Potential for Harm

Routine noninvasive monitoring carries minimal (although not zero) additional risk for iatrogenic complications from the devices themselves. Current standard of practice requires that they be used in all cases of general or regional anesthesia. However the number of monitors and their concomitant alarms raises the possibility of additional harm. A study of monitor alarms in the intensive care unit (ICU) suggested that monitor alarms might actually reduce quality of care because of their high frequency and low specificity. In this study, an alarm occurred every 37 minutes, and in the majority of cases (72%) no change in management was indicated as a result.[22]

Costs and Implementation

The costs of intraoperative monitors are largely fixed in the acquisition cost of the monitoring device. Incremental patient costs for disposables are minimal.

Comment

The inability of a very large multicenter study[21] to detect a benefit in morbidity and mortality from pulse oximetry—by all accounts the most useful monitor—suggests that the magnitude of benefit may be so small that an adequate study to detect this difference may not be feasible. Along with capnography (carbon dioxide monitoring), pulse oximetry is often cited as the monitoring method most able to detect potential critical incidents early enough to prevent adverse outcomes.[2,6] This conjecture is supported by the ASA Closed Claims Study. Analyzing 1175 claims, the study concluded that the combination of pulse oximetry and capnography "could be expected" to help prevent anesthetic-related morbidity and mortality.[23]

Despite a lack of randomized trial data, the practice of noninvasive intraoperative monitoring has become standard of care. This has resulted from the ASA Monitoring Standards and physicians' faith in the practice based on its face value, along with some confirmatory evidence drawn from incident reporting systems.[11,16,17] As such, it seems likely that future research into intraoperative monitoring will be unable to study approaches that do not include standard, noninvasive monitoring. Future investigation might seek to determine which monitoring methods detect "near misses" more effectively.

Moving beyond non-invasive techniques, there is a great need to identify which specialized monitors provide a safety benefit in selected patient populations. The use of pulmonary artery catheters for monitoring critically ill patients represents a well-known example of a practice with substantial face validity but unclear impact on patient outcomes.[24,25] In addition, new, noninvasive alternatives to invasive monitors (eg, esophageal or spirometry-based cardiac output monitors) may ultimately allow us to obtain the same information at less risk to the patient.

Figure 24.1. ASA standards for basic anesthetic monitoring*

Standard 1: Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care

Standard 2: During all anesthetics, the patient's oxygenation, ventilation, circulation, and temperature shall be continually* evaluated

Oxygenation:

- Oxygen analyzer for inspired gases
- Observation of the patient
- Pulse oximetry

Ventilation:

- Auscultation of breath sounds
- Observation of the patient
- Observation of the reservoir bag
- Capnography (Carbon dioxide monitoring)

Circulation:

- Continuous* ECG display
- Heart rate and BP recorded every 5 minutes
- Evaluation of circulation
- Auscultation of heart sounds
- Palpation of pulse
- Pulse plethysmography
- Pulse oximetry
- Intraarterial pressure tracing

Temperature:

- Monitor temperature when changes are intended, anticipated, or suspected

* The term "continuous" means prolonged without interruption; "continually" means repeated regularly and frequently. ECG indicates electrocardiography; BP, blood pressure.

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