Risk Management and Quality Assurance in Anesthesia

An Essay

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in Anesthesiology

By

Eman Galal Hassanein

M. B, B. Ch

Supervised by

Prof.Dr.Mohammed Saeed Abd El-Aziz

Professor of Anesthesiology and Intensive Care
Faculty of Medicine – Ain Shams University

Dr. Sameh Michel Hakim

Assistant Professor of Anesthesiology and Intensive Care
Faculty of Medicine – Ain Shams University

Dr. Fady Adib Abd EL-Malek

Lecturer of Anesthesiology and Intensive Care
Faculty of Medicine – Ain Shams University

Faculty of Medicine
Ain Shams University
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Introduction

The term “risk management” has been coined to describe the financial and economic aspects of business or professional activity. So “risk” is recognized as certain activities predictably leading to a degree of loss. This risk then becomes the subject of efforts to plan to pay for the loss and to try to reduce the likelihood and/or magnitude of loss. Thus there has been an attempt to control or “manage” the known risk ***(Holzer, 1984).***

Minimizing adverse outcome of anesthesia care is the goal of risk management in anesthesia. Because anesthesia care is facilitative rather than therapeutic, the outcome of anesthesia care has been traditionally measured in terms of absence of complications ***(Keats, 1990).***

Patient safety in the peri-operative period is a major focus for the specialty of anesthesia, and it is now a prominent concept in the whole healthcare system. Anesthesiologists almost exclusively focus on safety and quality issues in the operating theatre. Anesthesia and surgery are serious invasions on the physiologic stability of the human body. Careful monitoring of the patient during and after surgery allows the anesthesiologist to identify problems early, when they can still be corrected. Proper monitoring of the patient can reduce the risks involved in anesthesia and surgery ***(Leape et al., 2002).***

Classic risk management involves 4 steps ***(Pierce, 1989).***

- Identification of the problem (actual or potential injury or loss).
- Assessment and evaluation of the problem (determining the cause of injury or loss).
- Resolution of the problem (modification or elimination of the cause, by change of the practice, procedures, equipment, or behavior).
- Follow up on the resolution (to verify the desired result and to ensure continued effectiveness).

Risk management will help prospectively reduce liability exposure, taking into account features of the medico-legal system. In any case, awareness of medico-legal implications is clearly necessary and case precedents have revealed specific factors that make the defense against a malpractice suit more difficult. Risk management strategies are intended to promote optimal care thus, to minimize the likelihood and severity of malpractice suits ***(Keats, 1990).***

Aim of the study

The aim of this study is to review current literature pertaining to risk management in anesthesia practice including issues related to the patient, the anesthesiologist and the operating environment.

Chapter (1)

Standard Anesthesia Practice, Minimum Monitoring and Records Keeping

The presence of an appropriately trained and experienced anesthesiologist is the main determinant of patient safety during anesthesia. However, human error is inevitable, and many studies of critical incidents and mortality associated with anesthesia have shown that adverse incidents and accidents are frequently attributable, at least in part, to error by anesthesiologists **(Buck et al., 1992).**

Monitoring will not prevent all adverse incidents or accidents in the peri-operative period. However, there is substantial evidence that it reduces the risks of incidents and accidents both by detecting the consequences of errors, and by giving early warning that the condition of a patient is deteriorating for some other reason **(Keenan and Boyan, 1991).**

The introduction of routine monitoring in anesthesia coincided with numerous improvements in clinical facilities, training and other factors likely to affect patient outcomes. The progressive reduction in anesthesia-related morbidity and mortality is therefore linked to instrumental monitoring by association rather than proof from prospective randomized trials **(Thompson and Mahajan, 2006).**

The overwhelming view is that such studies would today be unethical and the circumstantial evidence that is already available indicates clearly that the use of such monitoring improves the safety of patients. Consequently, it is appropriate that the AAGBI "The Association of Anesthesiologists of Great Britain and Ireland" should make clear recommendations about the standards of monitoring which anesthesiologists generally must use **(Thompson and Mahajan, 2006).**

New monitoring modalities such as those describing depth of anesthesia have not yet become established as 'routine' and the opportunity exists to critically evaluate their utility before general introduction. A clear distinction may reasonably be made between consensus based recommendations for 'core' monitoring and requiring that new monitoring techniques be shown by clinical trials to improve patient outcomes (**Thompson and Mahajan, 2006).**

The Anesthesiologist's Presence during Anesthesia

An anesthesiologist of appropriate experience must be present throughout general anesthesia, including any period of cardiopulmonary bypass. Using clinical skills and monitoring equipment, the anesthesiologist must care for the patient continuously. The same standards must apply when an anesthesiologist is responsible for a local/regional anesthetic or sedative technique for an operative procedure **(Association of Anesthesiologists of Great Britain and Ireland, 2002).**

When there is a known potential hazard to the anesthesiologist, for example during imaging procedures, facilities for remotely observing and monitoring the patient must be available.

Accurate records of the measurements provided by monitors must be kept. It has become accepted that core data (heart rate, blood pressure and peripheral oxygen saturation) should be recorded at intervals no longer than every five minutes, and more frequently if the patient is clinically unstable. It is recognized that contemporaneous records may be difficult to keep in emergency circumstances. Electronic record keeping systems are now available. It is likely that their use will become routine **(Association of Anesthesiologists of Great Britain and Ireland, 2002).**

Local circumstances may dictate that handing over of responsibility for patient care under anesthetic may be necessary. If so, hand-overtime must be sufficient to apprise the incoming anesthesiologist of all information concerning the patient's anesthesia and the time and details must be noted in the anesthetic record. Very occasionally, an anesthesiologist working single-handedly may be called upon to perform a brief life-saving procedure nearby. Leaving an anesthetized patient in these circumstances is a matter for individual judgment. If this should prove necessary, the surgeon must stop operating until the anesthesiologist returns. Observation of the patient and monitoring devices must be continued by a trained anesthetic

assistant. Any problems should be reported to available medical staff **(Association of Anesthesiologists of Great Britain and Ireland, 2002).**

Standards of monitoring

The AAGBI regards it as essential that certain core standards of monitoring must be used whenever a patient is anesthetized. These minimum standards should be uniform irrespective of duration, location or mode of anesthesia:-

1. The anesthesiologist must be present and care for the patient throughout the conduct of an anesthetic
2. Monitoring devices must be attached before induction of anesthesia and their use continued until the patient has recovered from the effects of anesthesia.
3. The same standards of monitoring apply when the anesthesiologist is responsible for a local /regional anesthetic or sedative technique for an operative procedure.
4. A summary of information provided by monitoring devices should be recorded on the anesthetic record. Electronic record keeping systems are now recommended.
5. The anesthesiologist must ensure that all equipment has been checked before use. Alarm limits for all equipment must be set appropriately before use. Audible alarms must be enabled during anesthesia.

6. These recommendations state the monitoring devices which are essential and those which must be immediately available during anesthesia. If it is necessary to continue anesthesia without a device categorized as 'essential', the anesthesiologist must clearly note the reasons for this in the anesthetic record. In hospitals employing Anesthetic Practitioners (APs), this responsibility may be delegated to an AP supervised by a consultant anesthesiologist in accordance with guidelines published by the Royal College of Anesthesiologists.

7. Additional monitoring may be necessary as deemed appropriate by the anesthesiologist.

8. A brief interruption of monitoring is only acceptable if the recovery area is immediately adjacent to the operating theater. Otherwise monitoring should be continued during transfer to the same degree as any other intra- or inter-hospital transfer.

9. Provision, maintenance, calibration and renewal of equipment is an institutional responsibility.

10. Anesthesiologists must ensure that they are familiar with all equipment that they intend to use and that they have followed any specific checking procedure recommended by individual manufacturers. More complex equipment will require more formal induction and training in its use **(Association of Anesthesiologists of Great Britain and Ireland, 2007).**

Monitoring the anesthetic equipment

It is the responsibility of the anesthesiologist to check all equipment before use as recommended in *Checking Anesthetic Equipment* **(Association of Anesthesiologists of Great Britain and Ireland, 2007).**

Oxygen Supply: The use of an oxygen analyzer with an audible alarm is essential during anesthesia. It must be placed in such a position that the composition of the gas mixture delivered to the patient is monitored continuously. The positioning of the sampling port will depend on the breathing system in use.

Breathing Systems: During spontaneous ventilation, observation of the reservoir bag may reveal a leak, disconnection, high pressure or abnormalities of ventilation. Carbon dioxide concentration monitoring will detect most of these problems. Capnography is therefore an essential part of routine monitoring during anesthesia.

Vapor Analyzer: The use of a vapor analyzer is essential during anesthesia whenever a volatile anesthetic agent is in use.

Infusion Devices: When any component of anesthesia (hypnotic, analgesic, muscle relaxant) is administered by infusion, the infusion device unit must be checked before use. Alarm settings and infusion limits must be verified and set to appropriate levels before commencing anesthesia. It is essential

to verify that these drugs are delivered to the patient. The infusion site should be secure and preferably visible.

Alarms: The default alarm settings incorporated by the manufacturer are often inappropriate and the anesthesiologist must review and reset the upper and lower limits as necessary. Audible alarms must be enabled when anesthesia commences. When intermittent positive pressure ventilation is used during anesthesia, airway pressure alarms must also be used to detect excessive pressure within the airway and also to give warning of disconnection or leaks. The upper and lower alarm limits must be reviewed and set appropriately before anesthesia commences. Provision, maintenance, calibration and renewal of equipment are institutional responsibilities **(Association of Anesthesiologists of Great Britain and Ireland, 2007).**

MONITORING THE PATIENT

During anesthesia, the patient's physiological state and depth of anesthesia need continual assessment, Monitoring devices and clinical observation. Appropriate clinical observations may include mucosal color, pupil size, response to surgical stimuli and movements of the chest wall and/or the reservoir bag. The anesthesiologist should undertake palpation of the pulse, auscultation of breath sounds and, where appropriate, measurement of urine output and blood loss. A stethoscope must always be available, **(Association of Anesthesiologists of Great Britain and Ireland 2007).**

Monitoring Devices

The following monitoring devices are essential to the safe conduct of anesthesia. If it is necessary to continue anesthesia without a particular device, the anesthesiologist must clearly record the reasons for this in the anesthetic record **(Association of Anesthesiologists of Great Britain and Ireland**, **2007).**

A - Induction and Maintenance of Anesthesia:-

1. Pulse oximeter.
2. Non invasive blood pressure monitor.
3. Electrocardiograph.
4. Airway gases: oxygen, carbon dioxide and vapor.
5. Airway pressure.

The following must also be available;

- A nerve stimulator whenever a muscle relaxant is used.
- A means of measuring the patient's temperature.

During induction of anesthesia in children and in uncooperative adults it may not be possible to attach all monitoring before induction. In these circumstances monitoring must be attached as soon as possible and the reasons for delay recorded in the patient's notes **(Association of Anesthesiologists of Great Britain and Ireland, 2007).**

B - Recovery from Anesthesia:-

A high standard of monitoring should be maintained until the patient is fully recovered from anesthesia. Clinical observations must be supplemented by the following monitoring devices:

1. Pulse oximeter.
2. Non-invasive blood pressure monitor.

The following must also be immediately available:

- Electrocardiograph.
- Nerve stimulator.
- Means of measuring temperature.
- Capnograph.

If the recovery area is not immediately adjacent to the operating theatre, or if the patient's general condition is poor, adequate mobile monitoring of the above parameters will be needed during transfer. The anesthesiologist is responsible for ensuring that this transfer is accomplished safely **(Association of Anesthesiologists of Great Britain and Ireland, 2007).**

C - Additional Monitoring:-

Some patients will require additional, mainly invasive, monitoring, e.g. vascular or intracranial pressures, cardiac output, or biochemical variables. Specific devices designed to monitor loss of consciousness using adaptations of either surface EEG monitoring or auditory evoked potentials have become available. However, their routine use has yet to be fully considered as part of our recommended minimum monitoring standards. The American Society of Anesthesiologists (ASA)

recently published a report from a task force set up to assess the use of brain function monitoring to prevent intra-operative awareness **(Practice Advisory for Intra-operative Awareness and Brain Function Monitoring, Task Force Report. *Anesthesiology*, 2006).** This report summarized the state of the literature and reported the opinions derived from task force members, expert consultants, open forums and public commentary. It concluded that "brain function monitoring is not routinely indicated for patients undergoing general anesthesia, either to reduce the frequency of intra-operative awareness or to monitor depth of anesthesia." It was the consensus of the task force that the decision to use a brain function monitor should be made on a case-by-case basis by the individual practitioner for selected patients. The task force reported that patients have experienced intra-operative awareness in spite of monitored values which would imply an adequate depth of anesthesia. The AAGBI endorses the views of the ASA taskforce **(Association of Anesthesiologists of Great Britain and Ireland, 2007).**

D - Regional Techniques & Sedation for Operative Procedures:-

Patients must have appropriate monitoring, including a minimum of the following devices **(Association of Anesthesiologists of Great Britain and Ireland, 2007);**

1. Pulse oximeter.
2. Non-invasive blood pressure monitor.
3. Electrocardiograph

MONITORING DURING TRANSFER WITHIN THE HOSPITAL

It is essential that the standard of care and monitoring during transfer is as high as that applied in the controlled operating theatre environment and that personnel with adequate knowledge and experience accompany the patient. The patient should be physiologically as stable as possible on departure. Prior to transfer, appropriate monitoring must be commenced. Oxygen saturation and arterial pressure should be monitored in all patients and an ECG must be attached.

Intravascular or intracranial pressure monitoring may be necessary in special cases. A monitored oxygen supply of known content sufficient to last the maximum duration of the transfer is essential for all patients. If the patient's lungs are ventilated, expired carbon dioxide should be monitored continuously. Airway pressure, tidal volume and respiratory rate must also be monitored when the lungs are mechanically ventilated **(Wallace PGM, 1999).**

ANESTHESIA OUTSIDE HOSPITAL

Association's view is that the standards of monitoring used during general anesthesia, regional analgesia and sedation should be exactly the same in all locations **(Association of Anesthesiologists of Great Britain and Ireland, 2007).**