Review Articles

Pulse oximetry and capnography in anaesthetic practice: an epidemiological appraisal

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In the evaluation of any medical technology the efficacy, effectiveness, and efficiency must each be considered before routine deployment is recommended. Since the widespread practice of patient monitoring by pulse oximetry and capnography has occurred before the performance of rigorously controlled trials, definitive proof of worth is lacking. The purpose of this review is to appraise critically the effectiveness of this technology. The assessment was performed using concepts developed in epidemiology and community medicine to establish a given factor to be causative to a given outcome. The current literature pertaining to anaesthetic adverse outcomes was reviewed, and the use of monitors evaluated against the criteria of a causal relationship. While the conclusions are based more on the absence of positive data (owing to low frequency of adverse anaesthetic occurrences) rather than negative results, it must be concluded that the effectiveness of such monitoring has yet to be demonstrated. Such a conclusion should not detract from their use, for the role of an individual factor in the complex chain of accident evolution will seldom be demonstrable. Rather, such an appraisal should encourage a clear perspective of the depth of our clinical science, and encourage more rigorous critical evaluation in the future.

Dans l'évaluation de toute technologie médicale l'efficacité, l'opérabilité, et le rendement doivent être considérés avant le déploiement de son emploi de routine. Etant donné que la pratique courante de la surveillance des patients par saturométrie de pouls et capnographie est survenue avant l'accomplissement d'essais rigoureux et contrôlés, la preuve de leur valeur n'est pas encore établie. Le but de cette revue est d'évaluer d'une façon critique cette technologie. L'évaluation fut faite utilisant des concepts développés en épidémiologie et médecine communautaire afin d'établir qu'un facteur donné est responsable d'une certaine issue. La littérature actuelle concernant l'issue anesthésique défavorable fut revue et l'utilisation des moniteurs évaluée afin d'établir la relation de cause à effet. Alors que les conclusions sont basées plus sur l'absence de données positives (à cause de la basse fréquence, des issues anesthésiques défavorables) plutôt que des résultats négatifs, on doit conclure que l'efficacité de ce genre de monitoring demeure encore à être démontrée. Une telle conclusion ne doit pas nous empêcher de les utiliser car le rôle d'un facteur individuel dans une chaîne complexe d'accidents peut être rarement démontré. Cette évaluation devrait plutôt encourager une perspective claire sur notre science clinique et nous encourager à une évaluation plus rigoureuse et critique dans le futur.

Key words
MONITORING: oxygen, carbon dioxide;
EPIDEMIOLOGY.

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The last decade has witnessed many changes in the practice of anaesthesia.[1] Most gratifying has been the demonstration that the safety offered to patients is greater than ever before, while denying nobody the possibility of surgical treatment if there is a chance of benefit. While the magnitude of the death rate attributable to anaesthesia has been a subject of debate,[1,2] few would question that death from anaesthesia has become a rare event. Indeed, when put in perspective with the other factors predicting patient survival after surgery, anaesthesia is no longer a factor, in contrast to patient disease and surgical factors.[3]

When discussing the reasons for this improvement in morbidity and mortality, many factors can be cited. For example, the patients may have changed, with a population of subjects of better preoperative health submitting to

TABLE Estimate of potential risk reduction by monitoring

Origin	Risk (per 10,000)		Risk reduction		Number needed to be treated
	Control	Treated*	Relative	Absolute	
Keenan[19]	0.67	0.00	100%	0.67	14,925
Eichhorn[12]	0.16	0.031	80.6%	0.129	77,519
Tiret[18]	1.25	0.00	100%	1.25	8,000

*Assumes that all cardiac arrests are preventable by universal application of monitoring.

In the Table the following definitions apply: (a) Relative risk reduction: the reduction of adverse events achieved by a treatment, expressed as a proportion of the control rate. (b) Absolute risk reduction: difference in event rates between control and treatment groups. (c) Number to be treated: The number of patients who must be treated to prevent one adverse event (mathematically equal to the reciprical of the absolute risk reduction).

a different profile of surgical procedures.[4] We know that the anaesthetist has changed: in the 1970's 52.1% of 2450 residency positions in anaesthesia in the USA were filled with North American medical school graduates; by 1988 this had risen to 90.9% of 4563 positions.[5] In addition, the training has become longer as specialty requirements increased, and is based more on educational principles than learning through apprenticeship. Standards have been published suggesting how an anaesthetic should be conducted,[6,7] with utilization mandated by some insurance carriers.[8] Even the lawyers claim credit, suggesting but not proving that their adversarial role has served the public well by encouraging a lax profession to improve its practices.[9] In all probability each of these factors has helped, and arguments have been made as to which of the associations is important.[5,10]

The need for justification of monitors

Such a debate should be constructive, and challenge each proponent to advance his or her contributions to improved anaesthetic practice. Unfortunately, this has not always occurred, for financial considerations are soon identified. For example, the adherence to suggested standards of practice may affect individual income if the cost of practice is increased, or if service volume is adversely affected. At the same time there is a cost implication to new technology, and strained hospital resources may be slow to be approved in the absence of documented problems. Anaesthesia may have improved safety to such an extent that future resource allocation will be restricted. It has been suggested that insurance premium reductions should offset any financial impact,[11–13] although it remains speculative whether this will occur,[14] particularly in countries such as Canada where equipment purchase comes out of budgets different from physician liability premiums.

The financial argument against widespread use of new technology can be persuasive. As an example, using the method of Laupachis[15] to estimate the consequences of treatments and the data from three studies of the estimate of adverse outcomes (cardiac arrest or hypoxic injury) from perioperative care[12,18,19] one can construct a table of estimates of benefit expected from monitoring (Table): to save one life in the practice of anaesthesia thousands of patients must be monitored.

In contrast, to put such estimates into the context of the health care system, Laupachis made comparisons of the numbers of patients needed to be treated with technological advances in other fields to prevent one death.[15] For example, to save one life by coronary artery bypass grafting for left main artery disease (five-year survival) six patients need to be treated, for mammography 1,592 women aged 50–59 yr need treatment, while only eight high-risk persons need immunization with hepatitis B vaccine. While such comparisons are of limited use because study methods vary and estimates of "harm" to survivors are not included, they serve to put the cost of care into perspective. Anaesthesia may have become so safe that investment in this service may lack relative cost effectiveness! The main opposition to monitoring is financial (although the potential "harm" done by introducing new technology must also be considered), and cost implications of health care planners must be acknowledged in this era of accountability.

Therefore, there remains a need to generate an argument for the rational use of new monitoring technology. Unfortunately, since the emotional response to non-invasive monitoring by anaesthetists has been so enthusiastic it is difficult to consider a reliable controlled study to justify its universal deployment.[16] Although this may be possible in other countries which have yet to see the widespread application of this technology, the ability to extrapolate the data to North America may be poor. In addition the Hawthorne effect (the change in behaviour consequent to doing a study) may preclude widespread application of study results even in the country of origin.

Anaesthetists must prove that a certain intervention, routine non-invasive monitoring, is a justified preventative measure in anaesthesia. As such, the traditional form of study may not suffice, but methods used in occupational medicine may be helpful. In that specialty it is often important to decide if a given factor is causal to a certain outcome, or whether it is simply an association. Clearly one cannot, in the study of population hazards, change entire populations in a "controlled" fashion and look at the results, for there are too many confounding variables, the ethics of research are violated, and the costs would be prohibitive. The establishment of a causal argument must then rest on more indirect data which, if properly collected and considered, can still lead to a valid conclusion.[17]

For the purpose of this epidemiological review of causal relationships the two non-invasive monitors considered are pulse oximetry and capnography. A third monitor automatically measuring the blood pressure at regular intervals is not considered here as it is simply an extension of what has been done clinically for years. Although it adds accuracy, frequency, and reproducibility to such determinations it does not provide "new information" expected to influence outcomes of care.

The criteria of causation[17]

Strength of the association

The first criterion of causation refers to the strength of the association: the causal relationship of one factor to a given outcome is greater as the magnitude of risk reduction associated with that factor increases. With respect to anaesthetic-related mortality, if the recent death rate of 1:185,000[2] is compared with previous frequencies of approximately 1:10,000,[1] there is an 18-fold improvement in mortality statistics. However, such studies are not comparable since the methodology differs, both in the definition of the time frame for a death to be attributed to anaesthesia, and in the process of deciding the role of the anaesthetic. The studies also differ in the jurisdiction in which care was provided, stretching the validity of comparative conclusions. In addition, we have no information as to whether or not the patients in the British study[2] were monitored with pulse oximetry and capnography in the period studied.

Unfortunately, there are no examples of comparative situations where the frequency of adverse outcomes in the presence of such monitoring can be assessed against comparable care offered in their absence. The widespread use of oximetry and capnography has only occurred in the last five years, and therefore most comparisons are based on historical controls. In addition, differences in practice that accompany the various clinical settings may have a considerable effect on outcome. For example, in France, the incidence of death or brain damage after anaesthesia is given as 1/8000 cases, but the lack of recovery facilities in that country precludes comparison with North American data.[18]

Eichhorn[12] described the influence of monitoring standards on the outcome of care provided by the Harvard teaching hospitals. Before the implementation of their monitoring standards in 1985 they found major intraoperative accidents (death, CNS damage, cardiac arrest) in 11/682,000 cases (0.16/10,000 cases). In contrast, since implementation the rate has been 1/319,000 cases (0.031/10,000 cases), a 5.22-fold improvement. Since the reporting of any adverse outcome to the department was mandatory (even in the absence of litigation) we have assumed that this represents all events occuring at these institutions. While the clinical importance of such a change is encouraging, the results were not statistically significant, nor likely to achieve significance until the year 2030.[10] In addition, since the standards included several items in addition to capnograpy and pulse oximetry one cannot assume any absolute cause-and-effect relationship.

From 1969 to 1985 Keenan *et al.*[19] studied the incidence of unexpected cardiac arrests associated with anaesthesia, and found an incidence of 27/163,240 cases (1.7/10,000). Of these, 11 cases were attributed to intraoperative hypoxaemia (0.67/10,000). Since the adoption of routine monitoring by pulse oximeter there have been no such episodes in 31,000 anaesthetics,[20] whereas one case would have been expected by the laws of probability. Again, the data demonstrated no statistical significance because of the infrequent nature of the event. Furthermore, the definition of what constitutes an arrest attributable to anaesthesia may have changed over the period.

Consistency of the association

The second criterion in a causal argument is the consistency of the observed association: has it been observed by different researchers, in different places, circumstances, and times? Certainly there has been no reported series of a *rising* morbidity associated with anaesthesia in the last decade, and all studies have suggested a favourable improvement or no change in outcome. While the use of claims information to medical defence unions and insurance carriers is biased in its sampling of populations, the data over the years 1970–77 suggest a constant rate of occurrences in Great Britain,[22] although the more recent report[26] suggests there was some improvement. However, since the introduction of the new "standards" to anaesthesia (technology plus guidelines to professional practice) the claims-based premiums for coverage have either decreased as in the United States,[8,23] or remained

constant in the face of increases in other specialties as in Canada.[24,25]

Therefore it would appear that using several methodologies, including in-house audit,[12] national mortality reviews,[2] the review of specific outcomes,[20] or the assessment of frequency of medical-legal consequence there is consistency in the improvement obtained. To date only a few countries have seen widespread application of this monitoring technology, but the influence in other countries will soon be described. However, again, a direct causal relationship to pulse oximetry and capnography to improved outcomes can only at best be inferred.

Specificity of the association

If the association described is limited to specific types of problems, and there is no association demonstrable with other adverse outcomes, then a much stronger argument can be made in favour of causation. It is clear that the two monitors are concerned specifically with the detection of impaired oxygen delivery (oximetry), perhaps due to failure of effective ventilation (capnography). The question then becomes whether these events have been reduced to a greater extent than have other adverse outcomes: if so, their value is supported but, if not, the acknowledged improvement may be a non-specific function of modified physician performance[25] or other reasons.

The principle source of information about adverse outcomes in anaesthesia in North America remains our legal defence organizations. It is heartening to note that in Canada the frequency of "disaster" claims for hypoxic damage has decreased.[24] However, this may be due to two other factors: a change in the number of people having surgery, or a change in the climate of litigation.

The report from the Harvard hospitals[12] does not provide sufficient detail about non-critical or non-hypoxic events, hence the specificity of their conclusions is unknown. However, since 88% of their insurance settlements were related to these disasters, the failure of their premiums to disappear suggests other litiginous events were still occcurring. The closed-claims study of the United States[13] suggested that problems with oxygenation or ventilation accounted for the majority of severe injuries from anaesthesia, and could have been averted in over one-third of instances. In addition, it was these events which caused the most damage, and cost the insurance carrier the most money. The two monitors in question, if used, were considered able to prevent 93% of the avoidable mishaps, although it is impossible to say if increased vigilance would have produced similar results. No data are rendered about the incidence of claims in recent years that do *not* relate to oxygen delivery, making statements of the specificity of the improvements merely speculative.

Temporal relationship of the association

It has already been suggested that the time of introduction of these monitors corresponded to a period of improvement in the outcome from anaesthesia.[12,10] Simultaneously, considerable improvement in mortality rates were reported from Great Britain[2] and Canada[3] independent of the use of this technology. The introduction of these advances during a period of rising performance[5] makes a temporal argument difficult to support. Indeed, the coincidental appearance of written standards of practice, the appearance of new monitoring technology, the introduction of new drugs and techniques, and the desire of both physicians and insurance executives to control rising malpractice rates occurred almost simultaneously.

The only study that specifically attempted to identify the effect of the time of introduction of oximetry on patient outcome was done by Cooper.[27] He sought to define the independent effects of feedback of information about patient outcomes and oximetry on the frequency of operating room events deemed important enough to report to the recovery room. While a general improvement was noted there appeared to be no significant change upon the introduction of oximetry to their operating suites.

Is there a biological gradient?

If it is possible to establish a biological gradient, or a dose–response curve, then the case for causation is strengthened. The detection of hypoxia and hypercapnia does have such a gradient, depending upon the intensity of observation. No anaesthetic is administered without observation of the patient's colour and ventilation, but the acuity can be increased by the use of the new technology.[28,29] While Rao *et al.*[30] suggested that aggressive monitoring may improve the outcome of a certain subset of critically ill subjects, the use of more monitors did not seem to decrease the frequency of complications in a general patient population served in the days before pulse oximetry and capnography.[31] Whether the increased information available through routine monitoring use in all patients will result in improved outcomes is the essence of the current debate, and remains to be demonstrated.

Plausibility

The recommendation of routine use of oximetry and capnography is largely based on the feeling that such monitoring is logical. If the majority of adverse anaesthetic outcomes stem from failures of ventilation or oxygenation then surely earlier detection and action should eliminate their occurrence.

There remain several points of concern. First, no monitor can influence outcome if the response to the signal is blunted. Kestin[32] suggested that the plethora of alarms currently in use in the operating room may result in

intentional disabling, or failure to respond in an appropriate manner. In addition, more monitors could induce a sense of complacency leading to reduced direct observation of the patient, and constrain the practice of anaesthesia to the technical role of observation of electronic devices. Finally, if their routine use is advocated before true benefit is documented, it may adversely affect the ability to negotiate new and better technology in a future period of financial restraint. While these concerns are speculative, they highlight the problem of linearly extrapolating current studies to indicate future population benefit.

There have been studies suggesting that more monitoring may not guarantee a successful outcome. All mechanical devices have an inherent failure rate, due either to technical fault or to an inability to function in all circumstances. With respect to pulse oximetry the failure rate has been reported by Overand[33] to be 1.24% of cases. Unfortunately this often occurred in the sicker patients, and lasted for a mean duration of 75 min (of a mean of 227 min of anaesthesia per case). Cheney[34] has analyzed the closed claims data from 100 cases during which, in spite of the use of oximetry, an adverse event occurred. He suggested that failure to respond to the monitor signal, or failure to continue monitoring into the recovery phase, still leaves patients at risk of tragedy. It was of interest that, although cardiac events still occurred, the oximeter aided the defense of the position that hypoxaemia was not causative, suggesting the technology may prove more useful legally than medically.

Coherence

The cause and effect argument should not conflict with the acknowledged facts of the problem of adverse anaesthetic outcomes. There are no observations about the practice of anaesthesia that do not support the efficacy of these monitors to perform as needed, within the restraints of technical function (they are, for example, affected by ambient light, haemoglobinopathies, and alarm endlessly with cautery). The frequency of these adverse events has been reduced to such an extent that human skills and vigilance may occasionally lapse – in such situations mechanical devices must perform without fault if disaster is to be averted.

Experimental evidence

Is there experimental evidence to suggest that these devices will cause an improvement in outcome? While the critical incident study of McKay[28] suggests that unrecognized hypoxia is more common than assumed, adverse outcomes were not observed. The only published study to date using an experimental design to evaluate pulse oximetry was done in children by Cote.[35] The study was constrained by several methodologic problems, including utilizing intermediate outcome measures (episodes of desaturation) and inadequate statistical power. There appeared to be a benefit in the group monitored by oximetry in that episodes of arterial desaturation were detected earlier; it remains to be demonstrated whether differences in the speed of detection will extrapolate to reduced morbidity or mortality from anaesthesia.

Despite the lack of demonstration of efficacy from randomized controlled trials the use of these monitors has become routine.[16] The unfortunate part of practice is that the integration and response to information is dependent on the person conducting the anaesthetic; the majority of anaesthetic events relate to the failure of that individual.[36] It may be that the ability to improve anaesthetic outcome will not be possible with any technology if we do not simultaneously address the issue of human performance. It is when human consistency breaks down that one needs aid to vigilance: that scenario does not lend itself easily to experimental modelling.

Analogy

In certain circumstances it is appropriate to judge a causal relationship by analogy to other situations. With respect to anaesthesia monitoring there are few parallels in clinical medicine. For example, considerable investment in technology in acute coronary care to improve diagnosic information has not made a significant change in patient outcome.[37] However, in this situation there is little that can be done to treat the diseased coronary artery directly. In anaesthesia, detected events usually have a simple pathophysiological solution. In commercial aviation, a cascade of events of low frequency, if occurring together, can generate a disaster;[38] each piece of aviation technology assists to break this chain of accident evolution. As a final analogy one doubts that the speedometer of an automobile will ever be demonstrated to prevent accidents although its role in assisting safe driving practice is widely accepted. Aids to vigilance deployed in a complex interaction can probably never be proven to possess independent benefit, although their role in supporting improved personal performance cannot be refuted.

Conclusion

There is much to learn about the prevention of anaesthetic disasters, and about the value of the technology in improving the safety of anaesthetic practice. The "proof" that a given device is efficacious is often difficult: to define its effectiveness in large populations may be impossible. Using an argument from the world of epidemiology it is concluded that non-invasive monitoring has not yet been shown to reduce morbidity or mortality due to anaesthesia. Oximetry and capnography have been demonstrated to be efficacious in controlled situations in detecting earlier the type of events judged to be most

harmful during anaesthesia; whether the same can be said of their effectiveness when applied to large populations will await future evaluations.

Epidemiological and medical-legal studies have suggested anaesthetic practice is safer now than ever before, but the contribution of monitoring to this improved performance must remain speculative. That is *not* to say it has lacked an important impact, but merely to limit the emphasis placed on one aspect of practice that occurred simultaneously with other events. Indeed, it would be foolish to ignore monitoring's potential value for lack of "proof," for such may never be forthcoming. Technological progress in diagnostic information systems has been a very visible aspect of the specialty of anaesthesia in the last 20 years, and should be acknowledged appropriately, while keeping the larger picture in perspective. In the future, it may prove more difficult to acquire new forms of technology without proof of efficacy, and the evaluation of such must become a routine part of research and development.

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