Anesthesia in 1984: How safe is it?

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The methods of gathering information to determine the safety of anesthesia and to establish the risk of mortality and morbidity include anecdotal tales, in-hospital audit and peer review, reports to medical protective societies, retrospective studies, reviews of specific problems and prospective studies. All these methods have limitations and, in particular, do not readily differentiate the anesthetic from the surgical contributions. However, it appears that over the past 30 years the risk of death directly attributable to anesthesia has decreased from 1 in 2680 to about 1 in 10 000. The main causes of death are faulty anesthetic techniques due to human error, drug overdose, coexistent disease and failure of immediate postoperative care. Equipment failure, poor preoperative assessment, halothane-associated hepatitis and malignant hyperthermia, although often cited in the literature, are rarely the cause of problems associated with anesthesia.

Quand on cherche à établir la sécurité de l'anesthésie, il faut aller au-delà de la considération de cas particuliers et tâcher d'en mesurer la mortalité et la morbidité par l'analyse statistique de dossiers hospitaliers, l'étude des rapports des sociétés d'assurance professionnelle, les enquêtes rétrospectives et prospectives, et la recherche de la fréquence d'accidents donnés. Toutes ces méthodes manquent de précision; elles ne départagent notamment pas à première vue le risque anesthésique et le risque chirurgical. Malgré tout, il semble qu'au cours des 30 dernières années la mortalité reliée directement à l'anesthésie soit passée de 1/2680 à environ 1/10 000. Les principales causes de décès sont les fautes de technique dues à la défaillance humaine, le surdosage médicamenteux, les maladies intercurrentes et l'inefficacité des soins post-opératoires immédiats. Bien qu'on en parle souvent dans la littérature, les pannes d'appareils, l'insuffisance des examens pré-opératoires, l'hépatite reliée à l'emploi de l'halothane et l'hyperthermie maligne jouent rarement un rôle significatif dans les ennuis graves qui accompagnent et suivent l'anesthésie générale.

Webster's dictionary defines "safe" as free from "harm, injury or risk".[1] Most studies of anesthesia-related problems[2,3] define "safe" as having a low incidence of death (mortality) and other serious complications (morbidity). Even though mortality is easy to determine (although its causes may not be) morbidity is obscure. Furthermore, investigators recognize the difficulty in separating direct anesthesia-related problems from the surgery for which the anesthesia was required.[4] Other factors include the preoperative state of the patient and the postoperative care. This paper reviews the methods used to determine the mortality and morbidity associated with anesthesia and the changes that have occurred over the past 30 years.

Methods of study

Anecdotal tales

Although there is natural reluctance to publish reports of anesthetic mishaps they appear regularly, primarily in the literature on anesthesia. Usually these reports are of rarities and often bear little relevance to day-to-day practice.[5,6] However, if such a mishap leads to serious complications, further publicity may follow as a result of a medical malpractice suit, a coroner's or medical examiner's inquest, a judge's or attorney general's recommendations, or a publication from a government health regulatory body, which usually relates to either drug or equipment problems. It is difficult to quantify the frequency of such events or to determine if official recommendations are implemented; nevertheless, such reports may lead to more studies.

In-hospital audit and peer review

In most parts of the world it is mandatory to keep a written anesthetic record of events in the operating room and in the immediate postoperative period and to make this information available to internal committees. However, even a superficial review of patients' charts reveals that the records are often incomplete or absent.[7] In institutions where records are properly kept, computerization has made review of the records relatively straightforward.[8] Therefore, death and other major complications can be quantified in relation to the total number of procedures.

Since the incidence of untoward events is low,[9] accurate calculation of the true risk of anesthesia is difficult. Another problem is that complications related to anesthesia may occur in the first postoperative week[10] and not be noted on the patient's record because they are not recognized. Employing people to review patients' postoperative progress[11] circumvents these difficulties, but financial and logistic limitations have prevented most institutions from pursuing this course. Many hospitals use their medical records department to gather such information, often for collation and evalua-

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tion at a provincial level. However, this is usually limited to a review of deaths following anesthesia and surgery. In Alberta, for example, a report for the committee on anesthetic and operating-room deaths of the Alberta Medical Association is required from the surgeon and the anesthetist for all postoperative deaths that occur within a week of operation; either of these practitioners can indicate that death was not related to the surgery or the anesthetic. If this happens it is unlikely that there would be any further investigation unless there are medicolegal proceedings. As a result the data gathered are incomplete and may reflect professional bias. The difficulty with this type of external review is that feedback may not occur when a problem has been identified.

Reports to medical protective societies

Medical protective societies receive information in two ways. First, doctors are encouraged to report incidents that may have potential for litigation; not all of these incidents result in legal proceedings. Second, doctors may need medicolegal advice because they are involved in a lawsuit. Every year the medical protective societies report their "interesting cases". In addition, their medical advisers periodically publish a review of all cases submitted, with an analysis of their relevance to anesthetic practice.[12] As with anecdotal tales, the denominator necessary to calculate the incidence of these mishaps is unknown, but the cases have been investigated in detail because of the litigation aspect.

A review of the anesthetic accidents reported to the Medical Defence Union of the United Kingdom between 1970 and 1977 was published recently.[12] The union represents two thirds of the doctors in the United Kingdom and Eire and some in Australia, Canada and other countries. Of the 277 deaths reported, faulty technique was responsible for almost half (43%). The next most frequent were coexistent disease (in 12%), failure of postoperative care (in 10%) and drug overdose (in 5%); failure of preoperative assessment accounted for only five (2%) of the deaths. Halothane-associated hepatitis was a possibility in 12 of the cases (4%) and malignant hyperthermia in 8 (3%). These two conditions, which are specifically related to anesthesia, accounted for only a very small number of the deaths — totally out of proportion with the publicity they receive. Seventy-one patients survived with cerebral damage, a more serious complication, from a medicolegal standpoint, than death. Of these cases, faulty technique accounted for 61% and "anaesthetist's failure" for 4%. The latter was defined as absence of the anesthetist from the operating room when something went wrong with the patient, an indefensible situation.

Retrospective studies

Retrospective studies are usually initiated when a specific factor has been identified as a possible cause of anesthetic-related problems. However, the relatively low incidence of complications may require collaboration among several centres to obtain sufficient numbers. The limitations of such studies include failure to record significant events at the time of occurrence; lack of knowledge as to what is important at the time of record-making; failure to adequately store records, which leads to loss; the changing pattern of clinical practice; and, in the case of multicentre studies, lack of uniformity of assigned values. Despite these limitations, retrospective studies have been the main method of quantifying safety in anesthetic practice.

An early example of the multicentre retrospective study was that reported by Beecher and Todd[13] in 1954. They collated information from 10 institutions on 599 548 instances in which anesthesia was given from 1948 to 1952. They concluded that the patients had a 1 in 95 chance of dying from the disease that brought them to hospital and a 1 in 2680 chance of an anesthetic-related death (Table I). Another conclusion was that the use of curare markedly increased the risk of an anesthetic-related death, an observation that significantly changed American anesthetic practice. Although Dripps and associates[4] subsequently showed, in a retrospective study of 33 224 patients, that there was no evidence of "an inherent toxicity of muscle relaxants", some reservation about the dosage of these drugs persists in the United States. They also found that there was no difference in the contribution of either spinal or general anesthesia to "surgical mortality".

A good example of the lack of uniformity of assigned values is the definition of death associated with anesthesia. In the study by Marx and colleagues[14] an "anesthetic death" was recorded if the patient died within 7 days after surgery. In the 34 145 patients studied, 1 in 1265 deaths was related to anesthesia and 1 in 1707 was related to postoperative management. By contrast, in the study by Harrison[15] death associated with anesthesia was defined as "occurring during or within 24 hours of anaesthesia or after the failure of a patient, conscious before, to regain consciousness after anaesthesia". In this study the frequency of anesthetic-related death was 1 in 4537 compared with 1 in 3068 in the previous 10 years in the same institution (Table I), which illustrates the changing patterns of medical practice. Two thirds of the deaths caused by anesthesia were attributable to, in decreasing order of frequency, hypovolemia, respiratory inadequacy after the use of muscle relaxants, complications of tracheal intubation and poor postoperative care.

The Association of Anaesthetists of Great Britain and Ireland uses a voluntary reporting system to investigate deaths resulting from anesthesia. Two studies, reported in 1956[17] and 1964,[18] reviewed 1600 cases. Death was due most often to failure to maintain the airway, failure to maintain ventilation, and circulatory difficulties. However, the reporting system was not able to establish incidence.

Table I—Risks of anesthetic-related death

Study	Chance of death
Beecher et al[13]	1 in 2 680
Marx et al[14]	1 in 1 265
Harrison[15]	
1957–66	1 in 3 068
1967–76	1 in 4 537
Lunn et al[9]	1 in 10 000
Hatton et al[16]	1 in 10 000

A similar study, of 745 deaths associated with anesthesia, carried out in Australia between 1960 and 1968[19] indicated that there would be one such death in an anesthetist's lifetime, but that "an average of 4.3 human error near incidents for every one of these deaths" was likely.[20]

On Aug. 10, 1982 *The Times*, London (page 2) stated that "anaesthesia could cost 900 lives each year". This followed a review by the Nuffield Provincial Hospitals Trust for the Association of Anaesthetists of deaths associated with surgical operations in England, Scotland and Wales.[9] The survey was conducted on cases voluntarily reported during 1979 in which death occurred within 6 days of a surgical operation in hospital; however, the study excluded cases in which both the surgeon and the anesthetist agreed that anesthesia was not the cause of death. From these findings, extrapolation to the 3 million anesthetics given yearly in Britain suggested that anesthetic-related mishaps were directly responsible for about 300 deaths and strongly, but not completely, responsible for a further 600 deaths. Thus, the risk of dying solely as the result of such mishap appeared to be about 1 in 10 000[9] (Table I). The main causes of these deaths were faulty anesthetic technique, in 43%, and the inappropriate use of anesthetic agents, in 17%.[9] Another study of deaths reported in 1981 concluded that 43% had "nothing to do with anaesthesia, 41% were partly due to, and 16% were totally due to anaesthesia".[21] However, the authors of these studies cautioned that they knew "neither the incidence of near misses nor the incidence of deaths totally attributable to anaesthesia which may have been suppressed by a negative response from both anaesthetist and surgeon". At the same time as the Nuffield report the results of a French survey of some 200 000 anesthetics were released.[16] The risk of death due totally to anesthetic mishap was found to be 1 in 10 000 (Table I). It is interesting that this appears to be the same as the risk of major complications due to the administration of epidural and spinal anesthetics and to the risk of "halothane-associated hepatotoxicity".[22]

More recently, Cooper and coworkers[23] used a "critical incident" technique to gather voluntary reports from four hospitals of anesthesia-related human error and equipment failure. A total of 1089 preventable critical incidents were reviewed, of which 70 represented problems that led to a "substantive negative outcome". The problems most frequently reported were disconnection of the anesthetic circuit, loss of the gas supply and errors in administering the drugs. However, only 4% of the serious incidents involved equipment failure. The authors concluded that "human error is the dominant issue in anesthesia mishaps". However, it is not possible to determine the incidence of preventable critical events from such a study.

Review of specific problems

Reports of a specific anesthetic problem may appear in the medical press either in the correspondence columns or as a leading article. The problem may also be identified by voluntary reports to drug companies, government agencies such as the Department of National Health and Welfare, the US Food and Drug Administration or Great Britain's Committee on the Safety of Medicines. These agencies and drug companies usually focus on adverse reactions to drugs and only concern themselves with clinical anesthetic practice when the drug in question is either an anesthetic agent or is used during anesthesia. This concern may result in the withdrawal or a change in the use of the drug, either voluntarily by the drug manufacturer[24] or according to an edict by the government.[25] If a drug is not withdrawn or cause and effect are not clear, then a study — a retrospective survey, a review of cases or laboratory testing — is undertaken.

One example of a retrospective survey is the National Halothane Study, which was undertaken by the National Academy of Sciences–National Research Council[26] to study halothane-associated hepatitis and included some 1 million patients in 34 institutions. All patients with massive hepatic necrosis were identified, and the records of those who had received an anesthetic before dying were analysed. Although in most of the patients no obvious relation to the anesthetic could be established, there were seven patients for whom the consensus was that halothane might have been responsible. This represents an incidence of 1 in 10 000 (only some of the patients had received halothane).

The confidential enquiry into maternal mortality in the United Kingdom is an ongoing review of cases. This enquiry investigates, anonymously, every maternal death associated with childbearing and attempts to establish the cause of death. The study is conducted by senior obstetricians and anesthetists, who impartially review the cases. The results of the review are published every 3 years and may lead to major changes in obstetric practice. The most recent study, in 1979, reported that there were some 12 deaths each year in obstetric patients undergoing anesthesia, most resulting from pulmonary aspiration of gastric contents.[27]

Malignant hyperthermia is a rare genetic condition that is reasonably benign until the patient is exposed to certain anesthetic drugs. Then there is a rapid rise in the patient's temperature, with tachycardia, cyanosis, acidosis and muscle rigidity. When this condition is unrecognized, the mortality is about 60%.[28] However, the problem of malignant hyperthermia has been solved by combined clinical observation and laboratory testing. Despite the rarity of malignant hyperthermia, it is now routine to ask patients at the preoperative visit whether any member of their family has died during or after anesthesia in circumstances that might suggest malignant hyperthermia. If the answer is yes, a tentative diagnosis of malignant hyperthermia should be considered. The patient is then referred to a neuromuscular disease clinic, in Canada at the universities of Calgary, Toronto or Ottawa, for muscle biopsy.[29] Thus, it is possible to identify patients at risk and to use an anesthetic that will not trigger malignant hyperthermia.

Prospective studies

A prospective study is probably the best way to investigate medical

problems. However, the design of such a study is not always simple since there must be a working hypothesis, and the necessary tests must be established. In addition, when one is looking for rarities, a large number of patients need to be studied, and the difficulties of collaboration between many centres and the passage of time may obfuscate the results. Finally, prospective trials tend to be more costly than the other methods outlined.

Most prospective trials on anesthesia are small and concentrate on one problem. For example, Fee and colleagues[30] attempted to correlate the anesthetic administered changes in with the results of simple liver function tests following repeat administration of halothane or enflurane. However, despite the cost and time involved, the relatively nonspecific nature of the tests did not allow any firm conclusion. Nevertheless, there is still concern as to whether the various commonly used anesthetic agents have any significant differences with regard to adverse effects when used for the same surgical procedures.

A 2-year multicentre study of general anesthesia in 10 centres in Canada and the United States, organized by the Department of Anesthesia at McMaster University, Hamilton, Ont., is studying three volatile anesthetics — enflurane, isoflurane and halothane — and the most commonly used narcotic in anesthesia, fentanyl citrate. Administration of the various anesthetics and selection of the patients is being done randomly. All possible side effects of these agents are recorded for the first postoperative week. The Department of Epidemiology at McMaster University advises that 25 000 patients is a sufficient number to establish differences, both for major and minor complications. To illustrate the cost of such a study, one centre, the Department of Anaesthesia at the Foothills Hospital, University of Calgary, employs two full-time nurses and a senior medical investigator and requires a minicomputer and the voluntary cooperation of many members of the department. Although the McMaster study may determine the best way to monitor postoperative morbidity and mortality and how to relate this to the anesthetic, it is unlikely that it will provide the final answer, and other work will be needed.

Prediction of risk

From the data gathered by the various methods of study, attempts have been made to predict surgical and anesthetic risk and outcome. Such risk scores have concentrated on a specific disease state (e.g., cardiac or hepatic problems).[31-33] However, the main problem of such scoring systems is the difficulty in differentiating the surgical from the anesthetic component.

"Eyeball" method

The commonest way of predicting risk is at the preoperative visit, when the anesthetist assesses the patient and "determines his or her fitness" to withstand the proposed surgery. The anesthetist assumes that the anesthesia will be uneventful and considers other variables, such as preoperative consultations, knowledge of the surgeon's ability, time of day, experience of the nursing staff, and postoperative facilities. Unfortunately, although the eyeball method may be of comfort to the anesthetist when predicting outcome, it is of little use in comparative studies since it cannot be quantified.

Classification of physical status

The classification of the American Society of Anesthesiologists (ASA) was intended for statistical analysis in the study of outcome according to anesthetic records.[34] However, the ASA classification[35] is a common finding on anesthetic charts and is frequently used by internists in their preoperative consultations. It should be clear that this classification is intended to assess only the physical status of a patient and does not assess surgical or anesthetic risk or postoperative outcome (Table II). Indeed, to make the classification it is not necessary to know the proposed surgery or the age or weight of the patient. Literal interpretation of ASA class 5 means that the patient should not undergo surgery, and yet this classification is used for the critically ill patient who does indeed have an operation.

Conclusion

The title of this paper is "Anesthesia 1984: How safe is it?" A simple answer would be: safer now than 30 years ago. However, this conclusion is based on data from outside Canada. Despite the lack of published figures for anesthetic practice in Canada, there is no reason to believe that they differ greatly from those in the countries described. The incidence of 1 in 10 000 (the apparent risk of dying directly as a result of an anesthetic) is such that, in other contexts, most would find this chance acceptable. However, problems in anesthesia cannot be ignored since the outcome may be extremely serious for the patient. In addition, an account must always be taken of the surgical procedure since it may contribute to and increase, often markedly, the overall risk of death. Nevertheless, when the problem is due to the anesthetic, most mishaps result from the failure of the anesthetist to recognize or cope with a problem. Lesser contributing factors include unexpected reactions of the patient to anesthetic agents and failure of equipment. A disturbing feature of the studies in the past 30 years is that, although mortality has decreased, the causes remain the same. Anesthetists have always rec-

Table II—American Society of Anesthesiologists' classification of physical status[35]*

1. A healthy patient.
2. A patient with a mild systemic disease.
3. A patient with a severe systemic disease that limits activity but is not incapacitating.
4. A patient with an incapacitating systemic disease that is a constant threat to life.
5. A moribund patient not expected to survive 24 hours with or without an operation.

*For an emergency operation the number is followed by an E.

ognized that anesthetic mishaps do occur, and they have made attempts to quantify them and to address possible solutions. For example, specialist qualifications, postgraduate training, inspection of institutions and audit with peer review, both locally and nationally, are believed to be essential, but it remains to be seen if they can be linked to decreased mortality and morbidity. The reports cited here concentrate on mortality. Future studies should be directed towards assessing morbidity, probably the main area of concern given that anesthetic-related death is now rare.

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