Risk of Anaesthesia – A Review

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Summary
Modern anaesthesia carries a definite although small risk. The risk from general and regional anaesthesia is reviewed, the causes explored, and preventive strategies discussed. Although anaesthesia may never be 100% safe, a knowledge of the risk and causes enables us to work towards this goal.

Key words: Anaesthesia, Complications, Mortality, Morbidity.

Introduction
Many would like to believe that being “put to sleep” carries no risk at all – not even that of an afternoon nap. The idea that if a patient dies or sustains injury, error must have played a causal role, has spawned much legal profit. Juries are led to believe, and indeed often want to believe, that any untoward outcome must be rooted in physician fault.

In most instances, death during anaesthesia is not caused only by the anaesthetist, since both the operative procedure and the underlying disease cause physical and mental stress. The risk associated with the operative or other procedure involves several factors: the patient’s physical status and disease, age and the adequacy of pre-operative preparation and therapy. The urgency and extensiveness of surgery, the methods used during surgery and anaesthesia and the abilities of the surgeon and the anaesthetist contribute also to the total risk.

To quote Tinker and Roberts: “To deduce that anaesthetic risk can and must be nil because there is little or no therapeutic benefit of anaesthesia per se is fallacious. No one educated in the myriad complexities and possible disasters inherent in such separate categories as muscle relaxants, inhaled anaesthetics, local anaesthetics, hypnotics, all the above plus pre-existent medical disease, all the above plus surgical stress and trespass, plus electromechanical monitors and drug delivery systems could rationally conclude that the sum total risk of an anaesthetic could or should be zero. Anaesthesia performed completely in accordance with current accepted standards can still be associated with major morbidity or mortality. However, lack of vigilance and poor judgement certainly do result in ‘anaesthetic death’.”

History
The first anaesthetic death was described by John Snow in his book “On Chloroform and Other Anaesthetics”. The patient, Hannah Greener, died from ventricular fibrillation during chloroform anaesthesia given for an operation on an ingrown toenail.
Studies of Anaesthetic Mortality

Except for the study by Beecher and Todd which reported an incidence of 3.7 anaesthetic deaths per 10,000 anaesthetics, most anaesthetic mortality studies have found rates of approximately one to two deaths per 10,000 anaesthetics. This is despite the fact that different studies have employed different definitions of “anaesthetic death”, used different time periods, and have been in different countries. For example, Harrison studied deaths which occurred within 24 hours of anaesthesia, while Clifton & Hotten considered only deaths during anaesthesia or failure to return to consciousness. However, more recent studies have suggested that anaesthetic death rates may be falling. This will be discussed further later.

At the University Hospital Kuala Lumpur, analyzing data on 125 deaths which occurred in the operating theatre from January 1980 to August 1992, six were found to be ‘mainly due to anaesthesia’. This gives an incidence of six deaths out of about 155,000 anaesthetics, or about 0.39 per 10,000 anaesthetics.

What is an ‘anaesthetic death’? Previously, different authors have defined this differently. In 1984, an international symposium entitled ‘Preventable anaesthetic mortality and morbidity’ held in Boston produced the following definition. Mortality: death which occurred before recovery from the effects of a drug or drugs given to facilitate a procedure or to relieve the pain of a condition, or arising from an incident which occurred while the drugs were effective.

What is the risk from regional anaesthesia? M. Puke et al, quoting 13 studies, arrived at a figure of between 0 and 1 per 10,000 as the frequency of serious complications from regional anaesthesia. In a large series of 500,000 intrathecal, epidural and caudal blocks performed in Sweden from 1980-84, there were 52 serious complications thought to have been the result of the block (Table 1). Although

### Table 1

<table>
<thead>
<tr>
<th>Complications</th>
<th>Epid</th>
<th>Intrath</th>
<th>Caudal</th>
<th>Block+GA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Brain damage</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Cauda equina lesions</td>
<td>12</td>
<td>20</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Spinal/Epidural haematoma</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Subdural haematoma</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Subarachnoid haemorrhage</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Significant paresis</td>
<td>10</td>
<td>7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Purulent meningitis</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Deep local infection</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Somatosensory disturbances</td>
<td>18</td>
<td>21</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Chronic back pain</td>
<td>7</td>
<td>8</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

Note: Cauda equina injury – different kinds of bladder and rectal sphincter dysfunction.

One patient died following epidural anaesthesia with 0.5% bupivacaine. The cause was bradyarrhythmias developing into asystole. The patient had hypertension and was being treated with beta-adrenergic receptor blockers.
the incidence of deaths may possibly be lower than with general anaesthesia, there is still an approximately 1:10,000 incidence of serious complications including death, brain damage, cauda equina lesions and meningitis. Also, an experienced anaesthetist will have to accept a 2.5% accidental dural puncture with epidural anaesthesia. If dural puncture is not discovered, there is a risk of total intrathecal block with local anaesthetic injection. The patient becomes unconscious and develops respiratory and cardiovascular collapse.

Even intravenous regional anaesthesia (Bier’s Block), commonly performed by orthopaedic surgeons and emergency room doctors, has been the cause of deaths as a result of inadvertent cuff release shortly after the administration of the drug.\(^9,24\)

**Maternal Mortality**

Anaesthesia as a cause of maternal mortality in England and Wales fell from 13% of maternal deaths in the triennium 1982-84, to 4.1% of maternal deaths in the triennium 1985-87.\(^10\) The actual decrease in mortality from anaesthetic causes is greater because of increasing number of anaesthetics given for operative procedures. This improvement has been ascribed to increased allocation of anaesthetic resources to obstetrics, increased awareness of the risk of anaesthesia, and increase in appropriately supervised regional anaesthesia.

In the period 1985-87, for the United Kingdom, there were six deaths directly attributable to anaesthesia, plus two late deaths. Six of these eight deaths were due to problems with intubation – there were five cases of misplaced and one of a kinked tracheal tube. The remaining two were due to inhalation of gastric contents at induction in one, and cardiovascular collapse from epidural anaesthesia in a patient with severe aortic incompetence in the other.

The incidence of failed intubation has been found to be higher (1:280) in obstetric patients, compared to surgical patients (1:2,230).\(^11\)

As a result of these findings, there is increasing use of regional anaesthesia for Caesarean section in many countries.

**Regional Versus General Anaesthesia**

**Ophthalmic Surgery**

Almost all cataract operations in the USA are performed under local anaesthesia, and the total hospital stay rarely exceeds two hours. This may be influenced by the fact that medical insurance carriers will not cover inpatient cataract surgery under general anaesthesia except in specified circumstances. In Australia and the United Kingdom, there is an increasing number of cataract operations performed under local anaesthesia.

There is a feeling amongst many doctors that local anaesthesia for eye surgery is 100% safe, and is the solution for those ‘not fit’ for general anaesthesia. Unfortunately, there are few studies comparing the efficacy and anaesthetic and surgical complications with the different anaesthetic methods.\(^12\)

Petrusca\(^k\) and Duncalf\(^4\) compiled overall mortality rates for general anaesthesia and local anaesthesia in ophthalmic surgery and concluded that there is little difference in morbidity and mortality.

Backer et al\(^15\) suggested that local anaesthesia for ophthalmic surgery does not pose special risks for
reinfarction in the patient with a preoperative myocardial infarction. Nicoll\textsuperscript{16}, in a series of retrobulbar blocks, found that one in 375 patients had a central nervous system complication and one in 700 was subject to a life-threatening episode. Hamilton\textsuperscript{17} found an incidence of brain-stem anaesthesia of one in 654 for retrobulbar blocks and none out of 5704 for peribulbar block. Other complications of local anaesthesia for eye operations include fits, scleral perforation, retinal vascular occlusion, optic nerve damage, extraocular muscle paresis, retrobulbar haemorrhage and vasovagal problems\textsuperscript{17}. One death has been recorded in association with peribulbar injection\textsuperscript{18}. Hence, local anaesthesia for eye operations is not without risk.

\textbf{Hip Surgery in the Elderly}

Covert and Fox\textsuperscript{19} reviewed this subject in 1989 and came to the following conclusions. For hip fracture repair, the use of spinal anaesthesia is beneficial in terms of reduced deep vein thrombosis and better oxygenation in the early postoperative period compared to general anaesthesia. However, the use of regional anaesthesia increases the magnitude and frequency of hypotensive episodes. There is no difference in the one-month mortality rate, intraoperative blood loss, and postoperative confusion. For total hip arthroplasty however, regional anaesthesia reduced deep venous thrombosis, pulmonary embolism, and blood loss and may be the preferred technique.

\textbf{Caesarean Section}

As most of the anaesthetic-related maternal mortality is associated with general anaesthesia for Caesarean section, a change to extradural has been advocated. Increasing use has been made of regional anaesthesia for Caesarean section\textsuperscript{20}.

\textbf{High Risk Surgical Patients}

In 1987, Yaeger \textit{et al}\textsuperscript{21} in a randomized controlled trial on 53 high-risk surgical patients, found that patients who received general plus epidural anaesthesia and postoperative epidural analgesia, had a reduction in the incidence of cardiovascular failure, major infectious complications, and overall postoperative complication rate. The control group had comparable surgical “risk”, and received standard anaesthetic and analgesia techniques with epidural anaesthesia/analgesia. The authors concluded that epidural anaesthesia and analgesia exerted a significant beneficial effect on operative outcome in a group of high risk surgical patients.

Regional anaesthesia may benefit patients with prior myocardial infarction undergoing transurethral prostatectomy: the reinfarction rate for spinal anaesthesia has been reported to be less than 1\%, versus 2-8\% for general anaesthesia\textsuperscript{22,23}.

\textbf{The Causes of Anaesthetic Mortality and Morbidity}

Utting\textsuperscript{24} found that out of 750 cases of death and cerebral damage reported to the Medical Defence Union between 1970 and 1982, 469 (62\% or about two-thirds) were thought to be mainly the result of error (Table II). Out of these, a large percentage were associated with the respiratory system – problems with intubation, inhalation of gastric contents, hypoxia, obstructed airway, etc. (Table III).

Keenan and Boyan\textsuperscript{25} reported 27 intra-operative cardiac arrests in 160,000 anaesthetics during a 15 year period, out of which 20 were considered avoidable. Eleven of these were due to respiratory problems, including oesophageal intubation, disconnect, and dislodgement of the tracheal tube. Hence routine pulse oximetry was recommended.
### Table II

<table>
<thead>
<tr>
<th>Cause of 750 cases of death and cerebral damage reported to the Medical Defence Union between 1970-92</th>
<th>(Adapted from Utting24.)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mainly misadventure</strong></td>
<td><strong>Mainly error</strong></td>
</tr>
<tr>
<td>Coexisting disease</td>
<td>Faulty technique</td>
</tr>
<tr>
<td>Unknown*</td>
<td>Failure of postop care</td>
</tr>
<tr>
<td>Drug sensitivity</td>
<td>Drug overdosage</td>
</tr>
<tr>
<td>Hypotension/blood loss**</td>
<td>Inadequate preop assessment</td>
</tr>
<tr>
<td>Halothane hepatic failure</td>
<td>Drug error</td>
</tr>
<tr>
<td>Hyperpyrexia</td>
<td>Anaesthesiologist's failure</td>
</tr>
<tr>
<td>Embolism</td>
<td></td>
</tr>
<tr>
<td>Clot in bypass</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
</tr>
</tbody>
</table>

* What is unknown now may not come into that category in the light of future knowledge.
** Some of the cases of death or damage from hypotension and blood loss might now be considered the result of error, as might some of the cases of halothane hepatic failure.

### Table III

<table>
<thead>
<tr>
<th>Causes of the 326 cases of death and cerebral damage reported to the Medical Defence Union between 1970-82, thought to be the result of errors in technique</th>
<th>(Adapted from Utting24.)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Faulty technique</strong></td>
<td><strong>No. (%)</strong></td>
</tr>
<tr>
<td>Errors assoc. with tracheal intubation</td>
<td>100 (31)</td>
</tr>
<tr>
<td>Misuse of apparatus</td>
<td>75 (23)</td>
</tr>
<tr>
<td>Inhalation of gastric content</td>
<td>47 (14)</td>
</tr>
<tr>
<td>Errors associated with induced hypotension</td>
<td>26 (8)</td>
</tr>
<tr>
<td>Hypoxia</td>
<td>14 (4)</td>
</tr>
<tr>
<td>Obstructed airway</td>
<td>14 (4)</td>
</tr>
<tr>
<td>Accidental pneumothorax/haemopericardium</td>
<td>13 (4)</td>
</tr>
<tr>
<td>Errors assoc. with extradural analgesia</td>
<td>9 (3)</td>
</tr>
<tr>
<td>Use of N\textsubscript{2}O instead of O\textsubscript{2}</td>
<td>7 (2)</td>
</tr>
<tr>
<td>Use of CO\textsubscript{2} instead of O\textsubscript{2}</td>
<td>6 (2)</td>
</tr>
<tr>
<td>Errors assoc. with Bier's block</td>
<td>5 (2)</td>
</tr>
<tr>
<td>Underventilation during anaesthesia</td>
<td>4 (1)</td>
</tr>
<tr>
<td>Use of halothane with adrenaline</td>
<td>4 (1)</td>
</tr>
<tr>
<td>Mismatched blood transfusion</td>
<td>1</td>
</tr>
<tr>
<td>Vasovagal attack</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>326</td>
</tr>
</tbody>
</table>
Taylor et al. collected data from malpractice suits in California involving unexpected cardiac arrests during anaesthesia, and found hypoxia from hypoventilation and low levels of inspired oxygen to be the chief cause of cardiac arrest. Similar studies involving analysis of death or brain damage also implicated hypoxaemia as a common cause.

Keenan reviewed prior studies of anaesthetic mortality, and found that from one-third to two-thirds of those involving death or severe brain damage were the result of hypoxia. This was supported by the Closed Claims Analysis Study which analyzed more than 1,500 malpractice claims against anaesthesiologists in the USA, which noted that the single largest and most expensive category of claims, by cause, was respiratory. Of these, 70% were judged to be preventable with better respiratory monitoring.

As a result of these and other studies, minimal monitoring standards during anaesthesia have been proposed in several countries emphasizing monitoring of oxygenation and ventilation during anaesthesia. Routine use of capnography, pulse oximetry and oxygen analyzers have been implemented in several countries. The Malaysian 'Recommendations for Standards of Monitoring during Anaesthesia and Recovery' which includes the above recommendations was launched in 1993 by the Malaysian Society of Anaesthesiologists.

Has the "Respiratory Safety Revolution" of the 1980's emphasizing respiratory monitoring been translated into safer anaesthesia? Although there is no hard evidence, the following data suggests that this may be so. Keenan and Boyan in 1991 compared the anaesthetic cardiac arrest rate of two decades, from 1969 to 1978, and from 1979 to 1988. Pulse oximetry and capnography were introduced in the second decade. The intraoperative anaesthetic cardiac arrest rate decreased by half – from slightly more than two per 10,000 anaesthetics in the first decade, to one per 10,000 in the second. The decrease was almost entirely due to a decrease in the number of preventable respiratory events. The rates for non-preventable cardiac arrests, and for preventable non-respiratory cardiac arrests, did not change significantly. This would be the expected outcome if the safety initiatives introduced in the second decade, emphasizing respiratory monitoring, were effective.

Two recent studies, one from England in 1987, and the other from Massachusetts in 1989, estimated anaesthetic mortality rates to be 0.05 and 0.15 respectively. These are markedly lower than the one to two per 10,000 in the previous studies. Although it may not be valid to compare studies due to differences in population, definitions, time span and changing practice of anaesthesia, the change is in the right direction.

**Pre-Existing Disease**

For patients with pre-existing disease, the American Society of Anesthesiologists Physical Status Scale first introduced by Saklad in 1941 (Table IV) is still useful to estimate the combined risk of surgery and anaesthesia (Table V). Note that this table shows the overall mortality, not just anaesthetic mortality. It can be seen that postoperative mortality increases as physical status decreases, and that there is a significant increase in mortality between elective operations and those done as emergencies. This serves to remind us that, in the rush to get the emergency patient to the operating room, a hasty preoperative workup – or none at all – may contribute to the mortality statistics.

For the patient with cardiovascular disease scheduled for non-cardiac surgery, risk factors have been examined and a scoring system has been devised by Goldman et al. However, Mangano, in an extensive review of the literature, concluded that there are only two consistently proven preoperative predictors of perioperative cardiac morbidity – recent myocardial infarction less than six months old,
Table IV  
The ASA physical status scale  
(Adapted from Tinker & Roberts3.)

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Healthy patient.</td>
</tr>
<tr>
<td>II</td>
<td>Mild systemic disease, no functional limitation.</td>
</tr>
<tr>
<td>III</td>
<td>Severe systemic disease, definite functional limitation.</td>
</tr>
<tr>
<td>IV</td>
<td>Severe systemic disease that is a constant threat to life.</td>
</tr>
<tr>
<td>V</td>
<td>Moribund patient unlikely to survive 24 hours with or without operation.</td>
</tr>
</tbody>
</table>

Table V  
Mortality rates for each ASA physical status – Elective and emergency procedures.  
(Adapted from Vacanti, Van Houten and Hill37.)

<table>
<thead>
<tr>
<th>ASA rating</th>
<th>*Mortality rate %</th>
<th>*Mortality rate %</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>0.07</td>
<td>0.16</td>
</tr>
<tr>
<td>II</td>
<td>0.24</td>
<td>0.51</td>
</tr>
<tr>
<td>III</td>
<td>1.4</td>
<td>3.4</td>
</tr>
<tr>
<td>IV</td>
<td>7.5</td>
<td>8.3</td>
</tr>
<tr>
<td>V</td>
<td>8.1</td>
<td>9.5</td>
</tr>
</tbody>
</table>

* Note that this is the overall mortality, not just anaesthetic mortality.

and current congestive heart failure. The more recent the previous myocardial infarction, the more likely is reinfarction. Within three months, the reinfarction rate exceeds 30%; at 3-6 months, it is 15%; and after six months, approximately 6%40, 41. Rao42 has challenged this, and has suggested that pre-operative optimization of the patient’s status, aggressive invasive monitoring and therapy, and prolonged ICU stay may significantly reduce reinfarction rates. However, this is controversial, and the cost of implementing such an approach is considerable. Hence, the current recommendation is to postpone non-emergency surgery until six months after a myocardial infarction, and to treat and optimize congestive heart failure before surgery.

Critical Incident Monitoring

Mortality and morbidity studies only pick up the small ‘visible tip of the iceberg’ of clinical anaesthesia mistakes. The ‘critical incident’ technique does not require death or injury to identify errors.
A critical incident is an untoward event that could have led (if not discovered or corrected in time) or did lead to an undesirable outcome, ranging from increased length of hospital stay or permanent disability.

Cooper reported on a series of interviews conducted over a five-year period, with anaesthesiologists and nurse anaesthetists from four hospitals in Boston, USA. 1089 critical incidents were identified involving 1013 patients. Equipment failure and disconnection of breathing circuits or intravenous lines accounted for about a quarter of all reports, but human error was implicated in 74%. Unfortunately, the report failed to include any definition of the term 'error' since on 42 occasions the incident was associated with death or cardiac arrest. Lack of experience was thought to have contributed on more than 37% of occasions.

Preliminary data from the first year of critical incident monitoring at the University Hospital Kuala Lumpur showed that about half (28 out of 58 incidents) involved hypoxia and/or hypoventilation (data yet to be published). This suggests that the use of respiratory monitoring (including oximetry and capnography) may reduce the incidence of accidents and possible morbidity.

**Prevention of Anaesthetic Morbidity and Mortality**

The following aspects need to be looked into.

**Training and supervision.** Staff, including anaesthetists, hospital assistants or paramedics giving anaesthesia, anaesthetic assistants, recovery nurses, and staff in the wards where patients are sent to postoperatively, should be adequately trained. Inadequate experience is associated with anaesthetic critical incidents. This is often compounded by poor supervision. The training of more specialist anaesthetists will improve the quality of anaesthetic care in the country, increasing the proportion of cases done by specialists anaesthetists and also increasing the supervision available for more junior anaesthetists. Where this is not possible in the short term due to lack of staff, for example in East Malaysia, paramedics giving anaesthesia should be adequately trained and supervised. Continuing education programmes, whether voluntary or compulsory, for anaesthetists working outside teaching hospitals should be considered, to ensure that they keep up to date.

**Equipment.** There should be adequate and up to date equipment, including safe anaesthetic machines with oxygen failure alarms, monitoring equipment like pulse oximeters and capnographs, and availability of equipment for difficult intubation and resuscitation. These should be checked prior to use. Other equipment may be necessary depending upon the complexity of surgery and the condition of the patient. The availability of a fibreoptic intubation laryngoscope (and the training of anaesthetists in its use) will reduce the problems of failed intubation and misplacement of double lumen tubes.

**Organizational.** Provision should be made for adequate facilities and staff in the operating room, recovery area, and high dependency/intensive care unit where patients are sent to postoperatively. Rosters should be drawn so that anaesthetists and anaesthetic assistants should have enough rest and sleep and adequate supervision.

**Audit and quality assurance programme.** Besides knowing causes of anaesthetic mortality and morbidity in other centres, it is important to know the local causes in each institution, which may be different depending upon the patient population, the disease pattern and the staffing situation. Hence it is important to conduct local epidemiological studies on this. Each anaesthetic department should have...
its own quality assurance programme, which should include critical incident monitoring, and morbidity and mortality meetings, and audit.

**Pharmacological.** There should be ongoing research into drugs, introduction of new and better drugs, and better knowledge of old drugs. For example, the introduction and use of atracurium and vecuronium has reduced the problem of inadequate reversal of neuromuscular paralysis.

Is it justified to spend hundreds of thousands of ringgit on monitoring equipment and training of specialist anaesthetists to reduce the mortality rate from anaesthesia from 1:10,000 to 1:100,000? Will the same amount spent on public health or other areas save more lives? There is no simple answer to this question. Patients, surgeons and the public would like anaesthesia to be 100% safe. Anyone going to sleep for an operation wants to be certain of waking up at the end of it. Furthermore, the patient who dies solely from an anaesthetic cause is often fit, young, healthy and productive. Hence the prevention of that one death may arguably be more important that the prolongation of several lives of chronically sick patients who may not be productive.

**Conclusion**

The morbidity and mortality produced by anaesthesia is relatively easy to define for specific populations, but this cannot be simply extrapolated to specific individuals. Prediction of risk in an isolated individual remains elusive. Nonetheless, morbidity and mortality studies will permit better consideration by both surgeon and anaesthetist of the options available regarding surgical and non-surgical therapy.

The use of the critical incident technique has greatly aided the assessment of the safety of anaesthesia. By assessing near-misses, it increases the size and extent of the database.

Will anaesthesia ever be 100% safe? There have been suggestions that all death associated with anaesthesia are avoidable. Keats\(^4\) pointed out that so many people are subjected to anaesthesia that one would expect a sudden death to occur from time to time, as in the street. Many cases are anaesthetized who are known to be ill and may not survive. When surgery is mandatory and all possible methods of preventing aspiration are employed, death from aspiration of vomit should not be classed as an error. It is also simplistic to argue that elimination of error would eliminate anaesthetic deaths. For this to be possible it would be necessary to assume a complete knowledge of all drugs and their dangerous side effects and a complete knowledge of how each individual would react. There is no method of introducing new drugs that is completely without risk.

To quote Keats: “To every benefit, there is a risk. The only way to guarantee immunity from risk is to do nothing at all”\(^4\).

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