Mortality associated with anaesthesia: a qualitative analysis to identify risk factors

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Summary

From a prospectively defined cohort of patients who underwent either general, regional or combined anaesthesia from 1 January 1995 to 1 January 1997 ($n = 869\ 483$), all consecutive patients ($n = 811$) who died within 24 h or remained unintentionally comatose 24 h after anaesthesia were classified to determine a relationship with anaesthesia. These deaths ($n = 119$; 15%) were further analysed to identify contributing aspects of the anaesthetic management, other factors and the appropriateness of care. The incidence of 24-h peri-operative death per 10 000 anaesthetics was 8.8 (95% CI 8.2–9.5), of peri-operative coma was 0.5 (0.3–0.6) and of anaesthesia-related death 1.4 (1.1–1.6). Of the 119 anaesthesia-related deaths, 62 (52%) were associated with cardiovascular management, 57 (48%) with other anaesthetic management, 12 (10%) with ventilatory management and 12 (10%) with patient monitoring. Inadequate preparation of the patient contributed to 30 (25%) of the anaesthesia-related deaths. During induction of anaesthesia, choice of anaesthetic technique ($n = 18$ (15%)) and performance of the anaesthesiologist ($n = 8$ (7%)) were most commonly associated with death. During maintenance, the most common factors were cardiovascular management ($n = 43$ (36%)), ventilatory management ($n = 12$ (10%)) and patient monitoring ($n = 12$ (10%)). In both the recovery and the postoperative phases, patient monitoring was the most common factor ($n = 12$ (10%) for both). For cardiovascular, ventilatory and other anaesthetic management, human failure contributed to 89 (75%) deaths and organisational factors to 12 (10%). For inadequate patient monitoring, human factors contributed to 71 (60%) deaths and organisational factors to 48 (40%). Other contributing factors were inadequate communication (30 deaths (25%) for all four aspects of the anaesthetic management) and lack of supervision (particularly for ventilatory management). Inadequate care was delivered in 19 (16%) of the anaesthesia-related deaths with respect to cardiovascular management, in 20 (17%) with respect to ventilatory management, in 18 (15%) with respect to patient monitoring and in 23 (19%) with respect to other anaesthetic management.

Keywords *Mortality*: anaesthetic. *Morbidity*: anaesthetic. *Complications*.

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The risk of death in conjunction with surgery and anaesthesia has been studied extensively. It has been suggested that anaesthetic mortality has decreased in the last two decades and is currently very low, ranging from 0.05 to 10 per 10 000 administered anaesthetics [1–7]. However, insight into the contribution of anaesthesia to peri-operative mortality is important to anaesthetists, to enable further improvements in the safety and quality of peri-operative care. Evaluation of peri-operative mortality provides knowledge of the quality of anaesthetic management, allowing preventive measures to be instigated and directing further research.

Over two years, we qualitatively analysed a prospectively collected series of all patients who died within 24 h of undergoing anaesthesia or remained comatose after 24 h to determine the relationship between anaesthesia and peri-operative death or coma. The aim was to assess the appropriateness of anaesthetic care, to identify aspects of the anaesthetic management that were associated with death or coma and to identify contributing factors.

Methods

Study population

A detailed description of study design, methods, organisation and data collection of the main project has been given previously [8]. The current report describes the results of the qualitative analysis of cases recruited as part of a case-control study. In summary, after obtaining institutional and ethical approval, information on all consecutive patients (cases) who died during or within 24 h of anaesthesia (mortality), or remained unintentionally comatose 24 h after anaesthesia (severe morbidity) was collected. The prospectively defined cohort from which the cases arose comprised all patients undergoing either general, regional or combined anaesthesia, from 1 January 1995 to 1 January 1997, in three of the 12 Dutch provinces (namely Zuid-Holland, Utrecht and Gelderland). The number of anaesthetic practices in this area is 51, operating in 64 different hospitals (locations). It is estimated that these hospitals perform approximately one-third to one-half of the total number of anaesthetics performed yearly in The Netherlands (approximately 1.3 million [9]).

Data collection

Data were collected using two structured questionnaires, the 'Hospital Characteristics Questionnaire' and the 'Procedure Questionnaire', and anaesthesia and recovery forms. At the beginning and end of the study period, the Hospital Characteristics Questionnaire with characteristics of the anaesthetic practice (e.g. type and size of hospital, number of anaesthetic procedures performed) was submitted by each participating hospital. Thus, the incidence of mortality and severe morbidity ('overall' and per type and size of hospital) could be estimated, and significant changes in anaesthetic practice documented and accounted for in the data analysis. Immediately following a death or coma, the Procedure Questionnaire and an anonymised anaesthetic and recovery form were submitted to the study centre. The Procedure Questionnaire contained pre-, per- and postoperative factors, a detailed description of the incident by the anaesthetist involved and the cause of death judged by the anaesthetist or obtained after post-mortem. By means of a unique identification number and a local contact person, it was possible for the investigators to ask for additional, patient-specific information. Pre-operative factors included patient-related factors, e.g. age, gender, ASA physical status, medical illnesses and current medication, and anaesthetic factors, e.g. pre-operative assessment and type of premedication. Surgical variables were outpatient status, emergency procedure, and time and duration of procedure. Surgical procedures were classified according to the International Classification of Diseases codes and further classified into 21 families of surgical procedures according to the anatomic site of surgery. Per- and postoperative anaesthetic factors included the presence of medical and paramedical staffing; anaesthetic agents used; type of anaesthetic technique used; characteristics of induction; maintenance and emergence from anaesthesia; availability, checks and use of equipment; postoperative location; staffing; monitoring; and pain medication. Information on anaesthetics administered and the anaesthetic procedure was further extracted from the anaesthesia and recovery form. Identification of patients fulfilling the study criteria was conducted locally. During the study, 11 (25%) anaesthetic practices in 13 hospitals drew on an existing hospital registry to identify eligible patients by daily comparison of the operating room schedule and the registry. These included patients' deaths registries, hospital admission and discharge files, and archives of the local pathology department.

Classification and definitions

Any patient who died or remained unintentionally comatose for whom an anaesthesia-related factor was identified by a panel of experts, and who it was judged would not have died within 24 h or remained comatose after 24 h if he/she had not undergone the procedure, was defined an 'anaesthesia-related' death or coma. In the initial phase of identification of anaesthetic factors, no distinction was made between anaesthetic factors that were preventable, those that could have been improved or those that were non-preventable.

All reported deaths and comas were assigned an overall classification (X–x–y) to determine the proportion of peri-operative deaths and comas that was related to anaesthesia. The overall classification was made in three steps (Appendix 1). The first step was to determine the main related factor (X) for the death or unintentional coma. This could have been anaesthesia (A), surgery (S), the patient (P) or a combination of these (M). The second step was to determine a contributing factor (x). Again, this could have been anaesthesia (a), surgery (s), the patient (p) or a combination of these (m). The third step determined the main related factor (y), scored 1–8 following the approach of Edwards *et al.* [10] (Appendix 1). The classification (X–x–y) obtained as described above was assigned to each case by three different experts, e.g. (X_1–x_1–y_1), (X_2–x_2–y_2) and (X_3–x_3–y_3). The team of classifiers comprised the anaesthetists in the Committee on Morbidity and Mortality ($n = 5$) and a number of anaesthetists trained in each of the nine teaching hospitals in The Netherlands and currently employed outside the study region ($n = 13$). In addition to the applied definition, it was determined in advance that for the purpose of this study, an 'anaesthesia-related death' was a case in which an anaesthetic factor was involved in any of the three groups of factors (i.e. when $X = \text{A}$, $x = \text{a}$ or $y = 1$ or 2), and according to at least two classifiers.

All 'anaesthesia-related deaths' were subsequently discussed in plenary meetings of the Committee and subclassified by applying a Study Subclassification System (Appendix 2a) and the classification of clinical causes of death described by Lunn *et al.* [11] (Appendix 2b). The Study Subclassification System was developed by the Committee, based on existing classification systems [11–34]. The objective was to extract and aggregate information from the anaesthesia-related deaths in a format appropriate to improve quality of (anaesthetic) care. Factors were grouped into those relating to the patient's physiological state (axis I), those relating to the anaesthetic management (axis II), system-related factors (axis III) and contributing factors (axis IV). The aim of using Lunn *et al.*'s classification was not to compare the two systems but to obtain additional information from a clinical perspective. The factors by Lunn *et al.* match different axes of the Study Subclassification System, mostly axes I and II. The anaesthetic phase in which identifiable factors played a role was specified (pre-operative, induction, maintenance, emergence, recovery, postoperative). For each case, more than one factor per axis could be identified, exerting its effect over more than one anaesthetic phase. It was possible that problems on a specific axis did not play a role according to the classifiers, in which case no classification was given for that axis.

Since they describe different aspects of a peri-operative problem, the information on anaesthetic management (axis II), system-related factors (axis III) and contributing factors (axis IV) was combined with factors identified according to Lunn *et al.*'s classification and aggregated into four categories: 1: cardiovascular management, 2: ventilatory management, 3: patient monitoring and 4: other anaesthetic management, for the final presentation of the results.

Results

Four out of 51 eligible anaesthetists refused to participate. The remaining 47 (92%) worked in 60 locations (hospitals). One anaesthetic practice (at two locations) withdrew during the study, resulting in participation of 46 practices (90%) in 58 locations. The participating hospitals were of different type (expressed as referral or teaching function) and size (expressed as number of beds), as summarised in Table 1. Nine had 24-h recovery rooms available and 49 had intensive care units available. Seven were teaching hospitals allied to a University or Medical Faculty and a further eight were teaching hospitals not allied to a University or Medical Faculty.

Overall and anaesthetic 24-h peri-operative mortality

The total number of reported cases was 811, of whom 769 (95%) died within 24 h and 42 (5%) remained comatose, all of the latter dying in hospital. The number of anaesthetics given was 869 483, approximately 31% of the total number of anaesthetics in The Netherlands during the same period. The estimated incidence of 24-h peri-operative death per 10 000 anaesthetics was 8.8 (95% CI 8.2–9.5) and of peri-operative coma was 0.5 (0.3–0.6). There was large variation in 24-h peri-operative mortality between the different types of hospital (Table 2). Forty-three (5.3%) of 811 deaths were judged by all three classifiers to have a relationship with anaesthesia. Per classifier, the relationship with anaesthesia ranged from a classification of A-a-1 to solely an A, a, 1 or 2. Seventy-three (9.0%) were judged by two classifiers to be related to anaesthesia. Three (0.4%) were judged by only one classificator to be related to anaesthesia or were classified as M-m-3, e.g. a combination of patient, surgical and anaesthetic factors, but were considered to have such a relationship with anaesthesia as to be included in the further analysis of the anaesthesia-related deaths. Thus, a total of 119 (15%) cases were judged to have a relationship with anaesthesia. Of these, all died and none remained comatose after 24 h, giving the incidence of anaesthesia-related death as 1.4 (95% CI 1.1–1.6) per 10 000 anaesthetics.

Table 1 Characteristics of participating hospitals. Values are number of hospitals.*

Number of beds and referral or teaching function:	
= 150; non-referral or teaching	6
151–300; non-referral or teaching	9
301–500; non-referral or teaching	17
> 500; non-referral or teaching	12
< 500; referral or teaching	3
> 500; referral or teaching	5
Number of anaesthetics administered during study period:	
2500–5000	3
5000–10 000	7
10 000–15 000	17
15 000–20 000	10
20 000–25 000	4
25 000–30 000	4
30 000–35 000	5
> 35 000	2

*Total number of hospitals (52) is between number of anaesthetic practices (46) and number of locations (58) since some practices operating on different locations submitted information aggregated for the locations, while others distinguished different locations.

Characteristics of peri-operative and anaesthesia-related deaths are given in Table 3. As expected, more peri-operative deaths occurred in the higher ASA categories and in emergency procedures outside working hours.

Anaesthesia-related deaths

Contributing factors to anaesthesia-related deaths are summarised in Table 4. Cardiovascular management, respiratory management and monitoring were the most common.

Cardiovascular management

In all phases of anaesthesia, patient-related problems (Study Subclassification System axis I) most frequently pertained to the cardiovascular system, in 79 (66%) anaesthesia-related deaths (Fig. 1). In 53 (45%) deaths the cardiovascular problems already existed pre-operatively and persisted in subsequent phases, and only in a few cases did they occur first during maintenance or postoperatively (in four (3%) and four (3%) cases, respectively). Post-operative cardiovascular problems were judged to be myocardial infarction in four (3%), left ventricular failure in four (3%) and congestive heart failure in two (2%) anaesthesia-related deaths.

Anaesthetic management (Study Subclassification System axis II) was most often judged to have been inadequate with respect to cardiovascular management (overall in 62 (52%) of cases), in all phases of anaesthesia (Fig. 2; Table 5). It was judged that during induction and maintenance the risk of hypotension was ignored in approximately one-quarter of all anaesthesia-related deaths. In nearly half of the patients, this followed regional (spinal) anaesthesia. Inadequate volume replacement occurred regularly during maintenance, in the recovery and the post-operative period.

System-related factors (Study Subclassification System axis III) did not seem to play an important role in terms of cardiovascular management.

Two-thirds of the cases of human failure (Study Subclassification System axis IV) contributing to anaesthesia-related deaths associated with cardiovascular management occurred during induction or maintenance of anaesthesia (Table 4). Inadequate communication occurred most frequently during maintenance. The organisational factors that were judged to have played a role mainly constituted lack of protocols (for example for ordering blood) or lack of facilities for cardiovascular monitoring.

Table 2 Peri-operative mortality according to type and size of hospital. Values are number (95% CI) per 10 000 anaesthetics or proportion.

	Number of beds and referral or teaching function					
	= 150; non-referral or teaching	151–300; non-referral or teaching	301–500; non-referral or teaching	> 500; non-referral or teaching	< 500; referral or teaching	> 500; referral or teaching
Peri-operative mortality (all hospitals included)	3.9 (2.3–5.6)	3.9 (2.6–5.2)	6.1 (5.1–7.0)	9.6 (8.6–10.8)	11.6 (7.0–16.2)	18.6 (16.5–20.7)
Peri-operative mortality (only hospitals with checking system)			7.8 (4.6–11.0)	18.0 (15.4–20.6)	15.6 (8.9–22.3)	21.4 (18.9–24.0)
Estimated underreporting*			22%	47%	26%	13%

*Estimated by comparing within each hospital category the number of reported deaths and comas for hospitals without checking systems with the number reported for hospitals with checking systems, and expressing the result as a percentage. This assumes that the former hospitals' checking systems were 100% efficient and that hospitals within each category are completely comparable.

Table 3 Characteristics of all deaths and anaesthetic deaths. Values are number (proportion).

	All deaths (*n* = 811)	**Anaesthesia-related deaths (*n* = 119)**
Sex; M/F	499/312	61/58
ASA classification:		
1	18 (2.2%)	7 (5.9%)
2	50 (6.2%)	13 (10.9%)
3	177 (21.8%)	54 (45.4%)
4	246 (30.3%)	3 (27.7%)
5	320 (39.5%)	12 (10.1%)
Postmortum examination	24 (3.0%)	9 (7.6%)
Location of surgery:		
Outpatients operating theatre	1 (0.1%)	0
Day care operating theatre	5 (0.6%)	0
Inpatient operating theatre	805 (99.2%)	119 (100%)
Type of surgery:		
Elective	176 (21.7%)	52 (43.7%)
Nonelective*	119 (14.7%)	34 (28.6%)
Emergency*	516 (63.6%)	33 (27.7%)
Time of procedure:		
08.00–17.00	411 (50.7%)	88 (74.0%)
17.00–23.00	262 (32.3%)	21 (17.6%)
23.00–08.00	138 (17.1%)	10 (8.4%)
Anaesthetic technique:		
General: inhalational	71 (8.7%)	8 (6.8%)
General: total intravenous	237 (29.2%)	21 (17.7%)
General: inhalational + intravenous	376 (46.4%)	41 (34.6%)
General: inhalational + regional	11 (1.4%)	5 (4.2%)
General: intravenous + regional	29 (3.5%)	7 (6.0%)
General: inhalational + intravenous + regional		
Regional: without sedation	7 (0.9%)	0
Regional: with sedation	38 (4.7%)	18 (15.2%)
Sedation only	41 (5.1%)	19 (16.1%)
	1 (0.1%)	0
Location of death:		
Induction room	1 (0.1%)	0
Operating theatre	276 (34.0%)	34 (28.8%)
Recovery unit	15 (1.9%)	7 (5.5%)
Intensive care unit	421 (52.1%)	53 (44.4%)
Ward	82 (10.1%)	22 (18.5%)
Emergency Department	1 (0.1%)	0
Other	15 (1.9%)	3 (2.8%)

*Non-elective = surgical intervention required within 12–24 h; emergency = surgical intervention required immediately/as soon as possible.

Respiratory management

Respiratory disease (Study Subclassification System axis I) existed pre-operatively in 12 (10%) of the anaesthesia-related deaths. In subsequent anaesthetic phases, respiratory problems did not occur very often (Fig. 1).

Approximately 12 (10%) of the anaesthesia-related deaths were associated with inadequate respiratory management (Study Subclassification System axis II) during induction and maintenance, usually inadequate oxygenation (Fig. 2; Table 6). These situations were insertion of a laryngeal mask airway instead of tracheal intubation, administration of a sedative to an agitated hypoxaemic patient and lack of administration of oxygen to a hypoxaemic patient.

System-related factors (Study Subclassification System axis III) did not seem to play an important role, as with cardiovascular management.

Human failure (Study Subclassification System axis IV; Table 4) was most common during induction of anaesthesia, followed by maintenance. Inadequate communication occurred most frequently during induction and maintenance. The organisational factors that contributed to these deaths included lack of a protocol for difficult intubation.

Monitoring

Inadequate monitoring occurred in 12 (10%) anaesthesia-related deaths, most often during maintenance of anaesthesia and postoperatively (Fig. 2). Inadequate monitoring pertained to haematological and serum biochemical parameters, arterial oxygen saturation and the cardiovascular system of patients who were already cardiovascularly compromised. Postoperative monitoring facilities were inadequately provided for eight (8%) patients (cared for in an ordinary ward instead of the recovery unit, or in the recovery unit instead of medium/intensive care units, despite a more appropriate location being available), and were unavailable for another six (5%) patients (no operating theatre available; no recovery facilities outside working hours; no intensive care facilities

Table 4 Contributing factors for different aspects of anaesthetic management in 119 anaesthesia-related deaths. Values are number (proportion).*

	Overall contribution	**Human failure**	**Inadequate communication**	**Lack of supervision**	**Inadequate care**	**Organisational factors**
Cardiovascular management	62 (52%)	92 (77%)	30 (25%)	6 (5%)	19 (16%)	13 (11%)
Ventilatory management	12 (10%)	83 (70%)	36 (30%)	15 (13%)	20 (17%)	15 (13%)
Patient monitoring	12 (10%)	71 (60%)	30 (25%)	6 (5%)	18 (15%)	48 (40%)
Other anaesthetic management	57 (48%)	88 (74%)	30 (25%)	6 (5%)	23 (19%)	14 (12%)

*Totals exceed 100% because more than one factor occurred in individual patients.

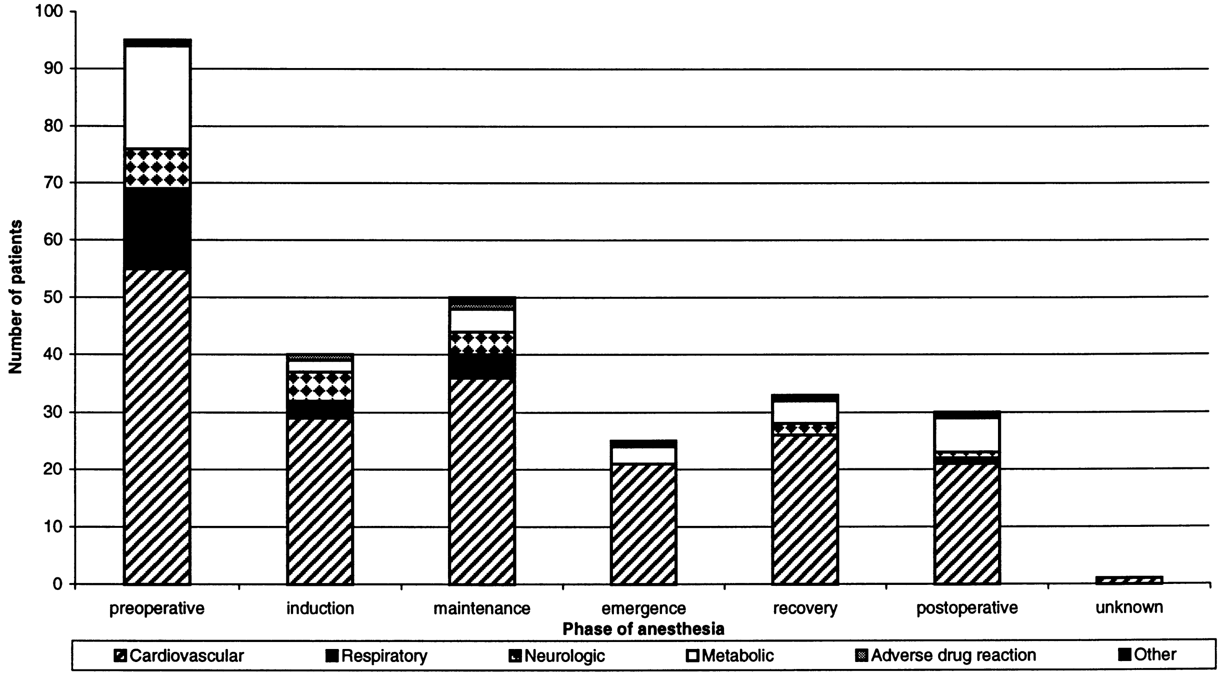

Figure 1 Patient-related problems in 119 anaesthesia-related deaths according to phase of anaesthesia.

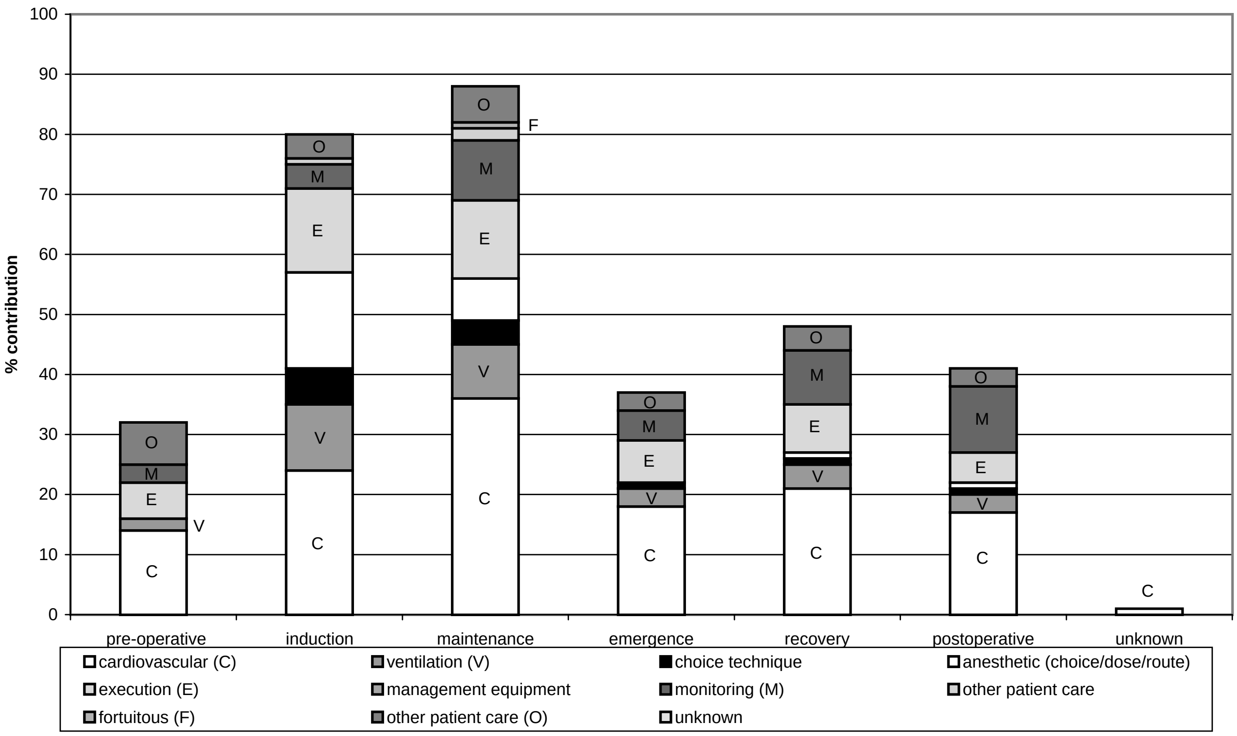

Figure 2 Factors contributing to inadequate anaesthetic management in 119 anaesthesia-related deaths according to phase of anaesthesia.

Table 5 Deficiencies in cardiovascular management in 119 anaesthesia-related deaths, according to phase of anaesthesia. Values are number (proportion).*

	Pre-operative	Induction	Maintenance	Emergence	Recovery	Postoperative
Untreated hypovolaemia	4 (3.4%)	3 (2.5%)	4 (3.4%)	3 (2.5%)	2 (1.7%)	2 (1.7%)
Inadequate volume replacement	4 (3.4%)	3 (2.5%)	9 (7.6%)	3 (2.5%)	6 (5.0%)	7 (5.9%)
Risk of hypotension ignored	3 (2.5%)	28 (23.5%)	27 (22.7%)	8 (6.7%)	9 (7.6%)	5 (4.2%)
Risk of hypertension ignored	1 (1%)	0	0	0	0	0
Ventricular irritability ignored	1 (1%)	1 (1%)	2 (2%)	0	0	0

*Totals exceed 100% because more than one factor occurred in individual patients

Table 6 Deficiencies in respiratory management occurring in 46 out of 119 anaesthesia-related deaths, according to phase of anaesthesia. Values are number (proportion out of 46).

	Pre-operative	Induction	Maintenance	Emergence	Recovery	Postoperative
Inadequate oxygenation	2 (1.7%)	6 (5.0%)	12 (10.1%)	3 (2.5%)	3 (2.5%)	3 (2.5%)
Failure of (re)intubation		4 (3.4%)	1 (1%)		0	0
Failure to maintain an airway		1 (1%)	1 (1%)		0	0
Bronchospasm		1 (1%)	2 (2%)	0	0	0
Aspiration of gastric contents		1 (1%)	1 (1%)	0	0	0
Respiratory failure		0	0	0	0	1 (1%)
Failure to start IPPV*		0	0	0	1 (1%)	0

*IPPV = intermittent positive pressure ventilation.

available). Lack of recovery and postoperative facilities in the latter six deaths was considered an organisational problem to which the timing of the procedure was considered to have contributed. None of the anaesthesia-related deaths was judged to be related to the management of equipment (ventilators or monitors) by the anaesthetist. In one case, equipment (electrocardiography) failed during maintenance of anaesthesia, without direct consequences.

Human failure (Study Subclassification System axis IV; Table 4) mainly comprised the choice of monitoring during maintenance of anaesthesia and selection of the postoperative location by the anaesthetist. Inadequate communication occurred most frequently during induction and maintenance.

Other anaesthetic management

Pre-operative preparation, choice of technique; choice, dose or route of administration of the anaesthetic(s); and performance and execution of anaesthetic actions comprised 'other anaesthetic management' (Study Subclassification System axis II; Table 4; Fig. 2). In nearly one-quarter of the anaesthesia-related deaths the pre-operative preparation had been inadequate. This was directly related to the judgement of the Committee that in eight (7%) deaths surgery should have been postponed and in one case it should have been performed sooner. During induction of anaesthesia, five patients (4%) received an overdose and two (2%) an underdose. An overdose was also considered to have been administered in five (4%) during maintenance and in one in the postoperative period. Propofol was considered in seven deaths to be the wrong choice, given the patients' characteristics and (un)availability of postoperative care. Continuous infusion of propofol was given in two anaesthesia-related deaths. The choice and dose of thiopental was considered suboptimal in two anaesthesia-related deaths.

If a combination of factors pertaining to anaesthetic management was judged to have been associated with death, this was classified under 'anaesthetic performance', for example a combination of choice of technique, monitoring, cardiovascular, respiratory and volume management; inadequate resuscitation; and unawareness of the effect of certain anaesthetic choices or inability to solve ensuing complications. The performance of the anaesthetist was judged to be associated with the anaesthesia-related deaths mainly during induction (15 (13%) deaths) and maintenance (12 (10%) deaths; Fig. 2).

Human failure (Study Subclassification System axis IV; Table 4) mainly occurred during induction and maintenance of anaesthesia. Inadequate communication occurred most frequently during maintenance.

Discussion

In our study, different aspects of anaesthetic management, particularly cardiovascular, were found to play a role in peri-operative comas and deaths, and the most critical phases of anaesthesia were induction and maintenance.

To appreciate these findings, some issues need to be addressed. In studies of anaesthetic factors associated with peri-operative events, there appears to be a shift of focus to include peri-operative morbidity [3, 35–40] and long-term complications [36, 41, 42], and to apply new study methods. The low death rate is one of the reasons. Furthermore, mortality studies may be less effective at providing insight into the quality of care and the economic impact on health services, and other outcomes should also be included [41, 43–49]. Conventional case series, thus far the most frequently applied study design, may not fully appreciate the complicated aetiology of adverse events during anaesthesia nor provide risk estimates for anaesthetic risk factors. The aetiology of adverse events is probably better addressed by relatively new methods like critical incident analyses [28, 30–32, 50, 51] and simulation studies [52, 53]. Recently, clinical trials and follow-up studies have quantified the risk not only of pharmacological factors but also of factors related to anaesthetic management [37–38]. However, we think that qualitative analysis of patients who died or remained comatose peri-operatively, especially a large series of cases obtained from a prospectively defined cohort, can still provide important knowledge.

In the current study, a voluntary reporting system was used. The main drawbacks are selection and under-reporting. We tried to diminish the effect of these two factors by an extensive introductory phase and emphasising throughout the study the importance of submitting all cases fulfilling the study criteria. The aim was to include patients on the basis of a well-defined outcome (death or coma) and to prevent selection only of 'anaesthetic' cases. Furthermore, by emphasizing anonymity, including clearance by the Dutch Health Care Inspectorate, we hoped to avoid preferential submission of non-anaesthetic cases.

Fortunately, throughout the study, 13 hospitals drew on existing registries to compare all patients who underwent surgery and those who died within 24 h. These checking systems may have reduced underreporting. For comatose patients, this was more difficult since this definition is less clear and is subject to personal interpretation. Therefore, it was emphasised that the patient had to be *unintentionally* comatose. Furthermore, intensive care units are not the routine work area of anaesthetists in all hospitals. Half of the hospitals with a checking system also screened the intensive care unit for unintentionally comatose patients. In addition, the hospitals with a checking system were of different type and size. If the results of hospitals of comparable type and size with and without checking systems are compared, it is obvious that hospitals with a checking system submitted more cases. The most likely reason for this difference is underreporting. Finally, since the first anaesthetic mortality studies, there has been no universally accepted definition of anaesthetic death. We applied a workable definition that enabled us to identify anaesthetic factors without implicating fault, guilt or preventability. We agree with Runciman *et al.* [28] and Keats [54, 55] that not all anaesthetic accidents are preventable or even error related; and that the long prevailing bias that anaesthetic deaths are by definition preventable may even have precluded identification of human or system-related risk factors, the prevention of which could have contributed to improvement of quality.

Classification was performed individually to reduce the influence of other opinions, but a substantial number of difficult cases were discussed at meetings. The classification systems we used (Appendix 1) appeared in a recent study by Revicki *et al.* [56] to be reproducible and consistent across different physician raters. We combined these systems to enable the classifiers to refine their opinion. The primary interest was in anaesthetic factors related to peri-operative death. Consequently, any anaesthetic factor judged by a majority vote of a panel of experts to be related to the peri-operative death was of interest. This is in concordance with theories concerning causality which state that every (anaesthetic) factor that is considered a necessary cause for a peri-operative death is relevant to improve safety and quality [57–61]. With the available information, it was not possible to perform error analyses as proposed by Cooper *et al.* [30]. Therefore, a subclassification system (Appendix 2a) was designed to aggregate information from the anaesthetic deaths in a format applicable to improve quality of (anaesthetic) care. In the present study, for all four different aspects of anaesthetic management, it was judged that in approximately 20% of the anaesthesia-related deaths inadequate care was delivered. Closed claims studies have reported delivery of inadequate care in 30% of non-respiratory cases and 76% of respiratory cases [62, 63]. However, in these studies, solely cases for which an insurance claim was filed were studied, representing a biased subset with, by definition, an overestimate of inadequate care.

Recently, anaesthetic mortality was estimated to be as low as 0.05 per 10 000 anaesthetics [1, 2, 6]. However, these results may be biased by study methods (voluntary reporting, closed claims analysis, classification of a small subset), the confusing definitions of 'overall, contributory or total anaesthesia related' or the postoperative observation period. However, we suggest that peri-operative mortality in which *anaesthetic* factors are involved is not as low as these estimates and still constitutes a substantial proportion of peri-operative mortality, given the results of studies since the 1980s and those of our study. Our results are comparable with data from recent studies applying a study method, classification and postoperative observation period similar to ours, in which estimated 24-h peri-operative mortality was 20 per 10 000 anaesthetics and anaesthetic mortality 1.9–7.0 per 10 000 anaesthetics) [5, 14, 18, 64, 65]. The estimates for 24-h peri-operative mortality (2.5–5 per 10 000 anaesthetics) and anaesthetic mortality (0.3–0.7 per 10 000 anaesthetics) are somewhat smaller if reporting is voluntary [12, 13, 15, 17]. In our study, voluntary data collection probably caused significant underreporting. If we restrict our analyses to the hospitals applying a checking system, the estimated peri-operative mortality would be 17.9 per 10 000 anaesthetics. This estimate is, however, somewhat biased towards teaching and referral hospitals. The proportion of peri-operative mortality due to anaesthesia is estimated by our study to be 15%. The range found in the literature is approximately 10–30% [5, 14, 18, 64, 65]. In studies in which preferential selection of anaesthetic cases occurred, the estimated proportion is at the upper range, over 25% [15–17].

From 811 peri-operative deaths, only in seven cases was anaesthesia considered the sole cause of death. In the majority of anaesthesia-related deaths, anaesthesia contributed to the patient's subsequent demise in conjunction with patient-related factors (poor physical condition) and sometimes surgical factors. This is reflected by, for example, the difference in distribution of ASA scores between all peri-operative deaths and the anaesthesia-related deaths. The higher proportion of ASA classification 1–2 in the anaesthesia-related deaths suggests that in these mainly healthy patients no other factor besides anaesthesia could be implicated in contributing to death or coma.

We found 52% of anaesthesia-related deaths to be associated with inadequate cardiovascular management. In previous critical incident studies, cardiovascular management is not cited as frequently to have been associated with an incident, and only fluid management is reported. Two to four per cent of peri-operative incidents are reported to have been related to fluid management, involving human error in 80%, which is comparable to the results of our study [30, 31, 66]. Studies not applying critical incident analyses report failure of control of circulatory homeostasis to contribute in 35–72% of cases [4, 14]. Apparently, cardiovascular management plays a more important role in incidents with serious outcome than in incidents without residual impairment. In the present study, equipment failure seldom occurred (1%). A higher percentage is reported by investigators applying the critical incident technique (14–20%) [30, 31, 34, 50, 66–70]. However, many incidents involving equipment failure may not lead to death or coma. Respiratory management was involved in 10% of our anaesthetic deaths. In recent studies applying comparable study methods, respiratory management contributed to approximately one-quarter of the anaesthesia-related deaths [4, 14, 17]. In critical incident studies, respiratory mismanagement is cited to occur in 17–34% [31, 34, 71]. By nature of the data collection, closed claims constitute a much larger part of respiratory incidents, 50–75% of the claims [62, 63]. In our study, lack of supervision was judged to have contributed for a larger part to ventilatory mismanagement (13%) than to other aspects of anaesthetic mismanagement.

Our data suggest that inadequate preparation may contribute to one-quarter of the anaesthesia-related deaths, against 40–45% in studies with a comparable study design [12, 16, 17]. In the current study, inadequate preparation was partly associated with organisational factors and 'questionable surgery' or 'questionable lack of surgery'. This is an aspect of peri-operative management that pertains to both the anaesthetist and the surgical specialist.

In this study, in three of four aspects of anaesthetic management, human factors contributed over 70% to the anaesthesia-related death. This is comparable with the proportion found by critical incident studies. It has been suggested that the overall contribution of human factors may be much smaller than often cited and the contribution of system-related factors higher [72, 73]. Studies of complex systems (like the anaesthetic practice) have shown that approximately 85–90% may actually reflect deficiencies in the layout and process of the system. Unfortunately, definitions of human or system-related factors are not yet unequivocal. An example in our study may be the finding that 60% of cases of inadequate patient monitoring were considered due to human failure and 40% to organisational factors. For the part that we considered human related, we do not know whether the decision of the anaesthetist not to send a patient to the intensive care unit or recovery unit stemmed actually from unavailability of postoperative facilities. Thus, factors we classified as human related may well have been system related.

In summary, some factors contributing to coma or death were related to anaesthetic management, of which some are incidental findings and some constitute a pattern. The latter especially may be candidates for preventive measures to improve quality and safety. The preventive recommendations that will follow from the results of this study pertain to human (attitude, knowledge, education and supervision) and organisational, i.e. system-related (supervision, facilities) factors. Future research should be directed towards identification of such factors since elimination of system errors may be more important to improve quality than elimination of human errors.

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Appendix 1 Classification system for all peri-operative deaths and unintentional comas lasting more than 24 h after surgery. Each case was given a classification X–x–y where X refers to step I, x to step II and y to step III.

STEP I: Main related factor
- A Anaesthesia related to the event
- S Surgery related to the event
- p Patient related factors related to the event
- M Combination of factors related to the event

STEP II: Contributing factor
- a Anaesthesia contributing to the event
- c Surgery contributing to the event
- p Patient related factors contributing to the event
- m Combination of factors contributing to the event

STEP III: Main related factor (Edwards *et al*. [10])
1. Cases in which it was reasonably clear that death was caused by the anaesthetic agent or technique or administration, or in other ways came directly within the anaesthetist's province.
2. Similar cases to those in category 1, but in which there was some element of doubt as to whether the agent or technique was entirely responsible for the fatal result.
3. Cases in which the patient's death was caused by both the anaesthetic and the surgical technique.
4. Deaths entirely referable to the surgical technique.
5. Inevitable deaths, such as cases of severe peritonitis, but in which anaesthetic and surgical techniques were apparently satisfactory.
6. Fortuitous deaths due to a cause such as pulmonary embolism.
7. Cases which could not be assessed despite considerable data.
8. Cases for which an opinion could not be formed due to inadequate data.

Appendix 2a Study Subclassification System applied to 119 anaesthesia-related deaths.

Patient (I)	Anaesthetist (II)	System (III)	Contributing factors (IV)
Cardiovascular (A): Arrhythmia; cardiac arrest; myocardial infarction; ventricular failure; volume	*Cardiovascular management (A)* Administration of drugs; arterial blood pressure; volume; ventricular function; rhythm	*Failure of personnel (A)* Presence; assistance	*Personal/human failure (A)* Knowledge; skills; experience
Respiratory (B) Inadequate airway; inadequate respiration; pneumothorax	*Respiratory management (B)* Intubation; maintenance of airway; ventilation (choice and maintenance); extubation	*Failure equipment (B)* Presence; functioning	*In contact with others (B)* Communication; supervision
Neurological (C) Cerebrovascular accident; peripheral nerve injury	*Other anaesthetic management (C)* choice of technique	*Failure facilities (C)* Induction room, operating theatre; recovery unit; intensive care unit	*Environment and organisation (C)* Procedures and protocols
Metabolic (D) Electrolytes	*Other anaesthetic management (D)* Anaesthetics (choice, dose, administration)	*other (D)*	*Timing (D)* Day/evening/night; weekend
Adverse drug reaction (E)	*Other anaesthetic management (E)* Performance and implementation	*unknown (E)*	*Training & education (E)*
Other (F)	*Management of apparatus (F)* Monitors; mechanical ventilator; other; check		
Unknown (G)	*Monitor (G)* Vital functions; choice (number and type)		
	Other patient care (H) Positioning the patient		
	No single cause/fortuitous (I) *Other (J)* *Unknown (K)*		

Appendix 2b Clinical causes of death according to Lunn *et al.* [11].

1 **Pre-operative preparation**	20 **Postoperative respiratory failure**
2 Untreated hypovolaemia	21 Neuromuscular
3 Inadequate preparation	22 Failure to start IPPV*
4 Other	23 **Postoperative circulatory failure**
5 Equipment fault	24 Myocardial infarction
6 **Faulty technique**	25 Left ventricular failure
7 Overdose	26 Congestive heart failure
8 Risk of hypotension ignored	27 Other
9 Ventricular irritability ignored	28 **Miscellaneous**
10 Inadequate oxygenation	29 Progress of existing disease
11 Other	30 Not so far listed
12 **Accidents**	31 Questionable surgery
13 Failure of intubation	32 **Inadequate care**
14 Failure to maintain an airway	33 Location
15 Bronchospasm	34 Monitoring
16 Obstructed airway	35 Qualification team
17 Malignant hyperthermia	36 Volume replacement
18 Aspiration of vomit	
19 Other	

*IPPV = intermittent positive pressure ventilation.