

Survey of Anesthesia-related Mortality in France

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Background: This study describes a nationwide survey that estimates the number and characteristics of anesthesia-related deaths for the year 1999.

Methods: Death certificates from the French national mortality database were selected from the International Classification of Diseases, Ninth Revision codes using a variable sampling fraction. Medical certifiers were sent a questionnaire (response rate, 97%), and the anesthesiologist in charge was offered a peer review (acceptance rate, 97%). Files were reviewed to determine the mechanism of each perioperative death and its relation to anesthesia. Mortality rates were calculated using the number of anesthetic procedures estimated from a national 1996 survey and compared with a previous (1978–1982) nationwide study.

Results: Among the 4,200 certificates analyzed, 256 led to a detailed evaluation. The death rates totally or partially related to anesthesia for 1999 were 0.69 in 100,000 (95% confidence interval, 0.22–1.2 in 100,000) and 4.7 in 100,000 (3.1–6.3 in 100,000), respectively. The death rate increased from 0.4 to 55 in 100,000 for American Society of Anesthesiologists physical status I and IV patients, respectively. Rates increased with increasing age. Although concerns regarding aspiration of gastric contents remain, intraoperative hypotension and anemia associated with postoperative ischemic complications were the associated factors most often encountered. Deviations from standard practice and organizational failure were often found to be associated with death.

Conclusion: In comparison with data from a previous nationwide study (1978–1982), the anesthesia-related mortality rate in France seems to be reduced 10-fold in 1999. Much remains to be done to improve compliance of physicians to standard practice and to improve the anesthetic system process.

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ANESTHESIA is commonly regarded as a high-risk activity. Many experts acknowledge however that “very impressive” safety improvements have been made in this field,^{††,‡‡} leading some investigators to conclude that anesthesia-related mortality has decreased in the previous two decades. The scientific basis supporting this opinion has been questioned because of variable methodology and operational definitions to evaluate the trends.^{3,4} No large-scale study has been performed at the national level to confirm whether the anesthesia-related death rate has indeed decreased. In France, reliable data on anesthesia-related mortality have been collected by the National Institutes of Health and Medical Research for the period 1978–1982.⁵ Many safety procedures have been adopted since this period, leading the French Society of Anesthesia and Intensive Care to conduct a national survey in cooperation with the National Institutes of Health and Medical Research to estimate the number and characteristics of anesthesia-related deaths in France for the year 1999. A previously published calculation of the number of anesthetic procedures performed in France in 1996 was used to estimate anesthesia-related mortality rates for 1999.⁶ Events associated with death were also analyzed.

Materials and Methods

Number of Anesthesia-related Deaths

The survey and subsequent data analysis were performed between 2001 and 2003. The number of anesthesia-related deaths was estimated by sampling the 537,459 French death certificates for 1999 (except deaths from French overseas territories). A sample of these certificates was then analyzed, and when necessary, the certifiers (*i.e.*, physicians who had filled out the medical part of the death certificate) and anesthesiologists involved were queried about the case.

A list of all International Classification of Diseases, Ninth Revision (ICD-9) codes⁷ that might relate to anesthesia care or anesthesia-related complications was created, and then that list was used to identify death certificates worthy of review. Complete analysis of ICD-9 codes was performed by three anesthesiologists and three epidemiologists (nosologists) to identify and select all aforementioned codes. A group named “interventional deaths,” including (1) all codes that suggest any relation with an anesthetic and (2) all codes describing any complication related to any medical, obstetric, or surgical or interventional procedure (including endoscopic procedures), was created. In addition, any death certificate that was detected during encoding process

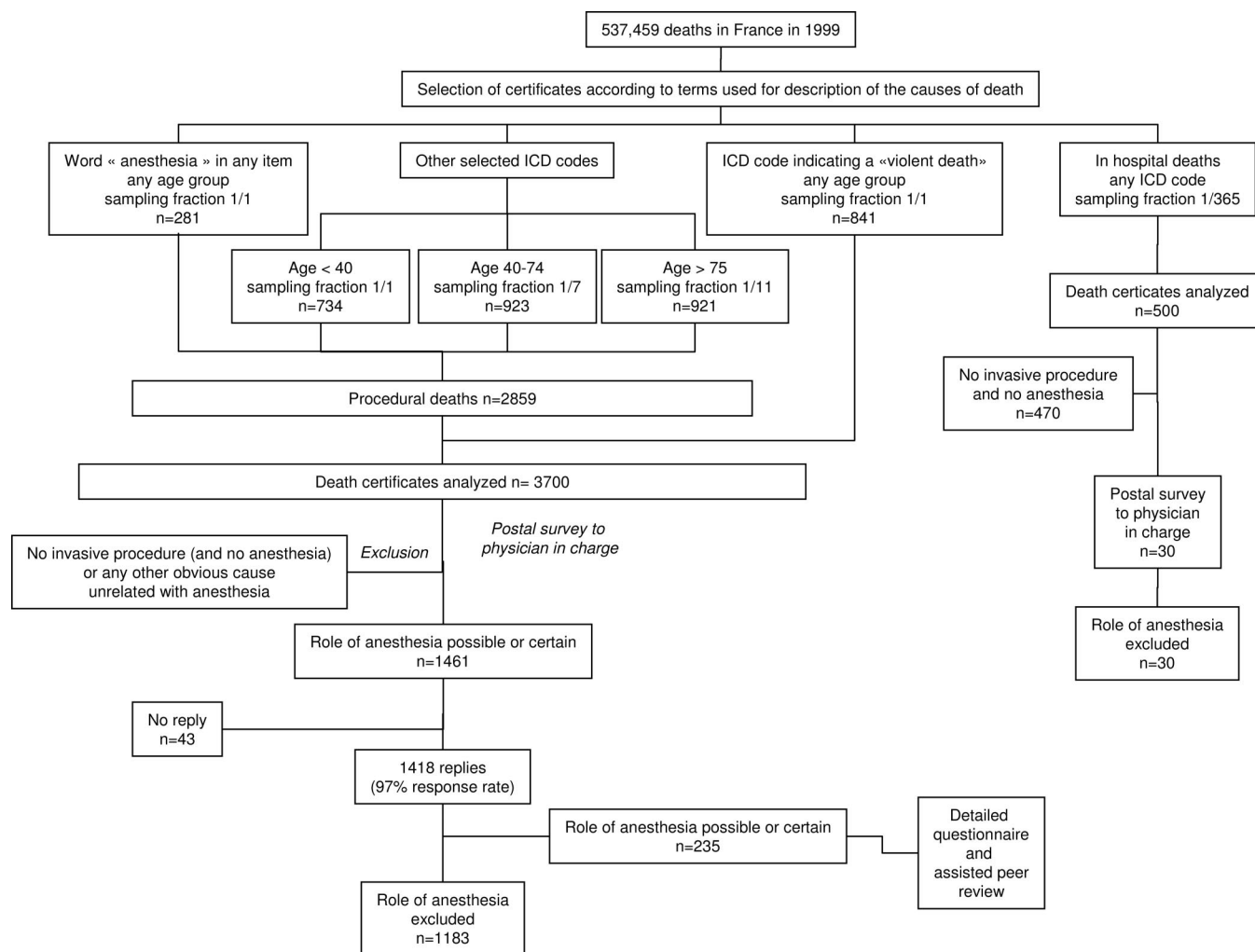


Fig. 1. Organization of the study. Part 1: Analysis of death certificates and of selected questionnaires sent to physicians who signed the death certificates. ICD = International Classification of Diseases, Ninth Revision.

and in which a surgical, endoscopic, or obstetric procedure was mentioned (whether or not the patient's death was related to this procedure) was added. Another group named "violent death," including in-hospital deaths secondary to an external cause (ICD-9 codes: trauma, traffic accident, falls, other types of accidents, and so on), was created.

Among these certificates, a sample was drawn by stratified randomization using the following sampling fractions. For interventional deaths, the sampling fraction (SF) was 1/1 when the medical certifier had suggested that anesthesia had played a role (*i.e.*, the word *anesthesia* mentioned in any item of the form) ($n = 281$); for other interventional deaths, the SF was 1/1 for patients aged younger than 40 yr ($n = 734$), 1/7 for those aged 40–74 yr ($n = 923$), and 1/11 for those aged 75 yr or older ($n = 921$); for violent deaths, the SF was 1/10 ($n = 841$). These various SFs were chosen to obtain the largest number of anesthesia-related deaths. In addition, we randomly selected certificates of 500 patients who had died in the hospital (SF = 1/365; $n = 500$) but in which

preselected ICD-9 codes had not been found by the initial triage. This last selection was aimed to verify whether interventional deaths could have been missed.

Three anesthesiologists independently surveyed all the death certificates selected ($n = 4,200$). They excluded from further analysis death cases based on the four preestablished following criteria (cases were excluded only when all three experts agreed): (1) Anesthesia is never associated with the procedure mentioned (*e.g.*, overdose of IV opiate in a drug addict patient); (2) the medical history totally explained why death occurred, whatever the anesthesiologist might have done; and (3) a long event-free interval between the procedure and the event leading to death was ascertained (fig. 1). For the remaining certificates, each medical certifier was sent a questionnaire ($n = 1,491$). The questionnaire asked the certifier to provide the reason, type, and date of the procedure; the type of anesthetic procedure used, if any; the associated diseases and the American Society of Anesthesiologists (ASA) physical status; a chronologic description of events and complications that had led to

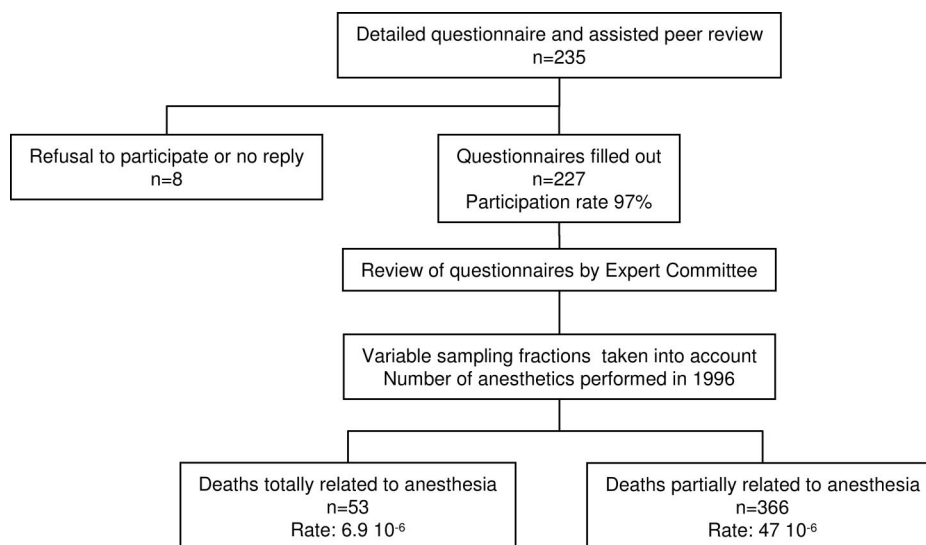


Fig. 2. Organization of the study. Part 2: Detailed questionnaires and main results.

death; where the death occurred (operating room, post-anesthesia care unit, intensive care unit, or any other unit); and contact information about the physician having the best knowledge of the case (the certifier may not be well aware of the patient's history). The response rate to this questionnaire was 97% (1,452 of 1,491 cases), although reminders were necessary for some certifiers who did not answer the first query. When any additional information was believed to be necessary, the certifier was sent another query.

A committee of experts independently analyzed the returned questionnaires and resolved any discrepancy in interpretation of the case by collective discussion. The expert committee was composed of the three experts who had formerly reviewed the medical certificates and of three other experts suggested by the French Society of Anesthesia and Intensive Care Board from a list of officers. For cases for which the role of anesthesia could not be eliminated (*i.e.*, the procedure performed or the health status of the patient could not in itself explain the death) ($n = 235$), the anesthesiologist involved in the procedure suspected to have been the primary event leading to death was asked to undergo a peer review through an interview where the details of the case were discussed (fig. 2). Peers were anesthesiologists working in a separate country area and who had volunteered to participate in the process. The peers had previously been trained by the expert committee during at least one session, where the goals of the study were explained, practical information on how to fill out the questionnaire was given, and guidance to solve delicate communication problems with their colleague were discussed. Specifically, when a different opinion emerged about any aspect of the analysis of the file that could not be solved by discussion, peers were asked to add a personal comment on the questionnaire before sending it rather than to try to convince their colleague to accept a different

view. Each peer anesthesiologist met his or her colleague in the institution where the anesthetic event had occurred and spent 2 to 3 h together to fill out the questionnaire. The form (52 pages) was made of multiple-choice questions describing in detail the patient's history, the case and the events until death, and open questions to which the anesthesiologist involved could answer by providing personal input and opinion. A colleague was asked to participate when the original anesthesiologist was not available (5% of cases). Each peer anesthesiologist was involved in not more than three interviews. Participation of the peers was uncompensated (reimbursement for travel expenses only). In situations where conclusion could not be obtained with the available information, the expert committee could confidentially ask the peer in charge of the case for additional data or could request a complementary analysis by an external academic expert. A copy of any relevant data from the medical file (particularly the anesthesia sheet) was attached and sent to the expert committee for review. Confidentiality was ensured at each step (excluding any patient, physicians, hospital, and city detail). The acceptance rate for the peer review was 97% (227 of 235 cases), sometimes after several phone calls and/or letters.

The experts separately analyzed each questionnaire and then discussed their personal views until obtaining complete concordance on each case. For each file, six items were recorded to summarize the case:

1. Provide a clinically pertinent summary of the case.
2. Identify the pathophysiologic process that best described the sequence of events. A graphical representation of the main pathophysiologic processes that could be encountered was prepared beforehand and applied to each case (fig. 3).
3. Identify if any deviation from rules, standards, or recommendations had occurred. To prepare this

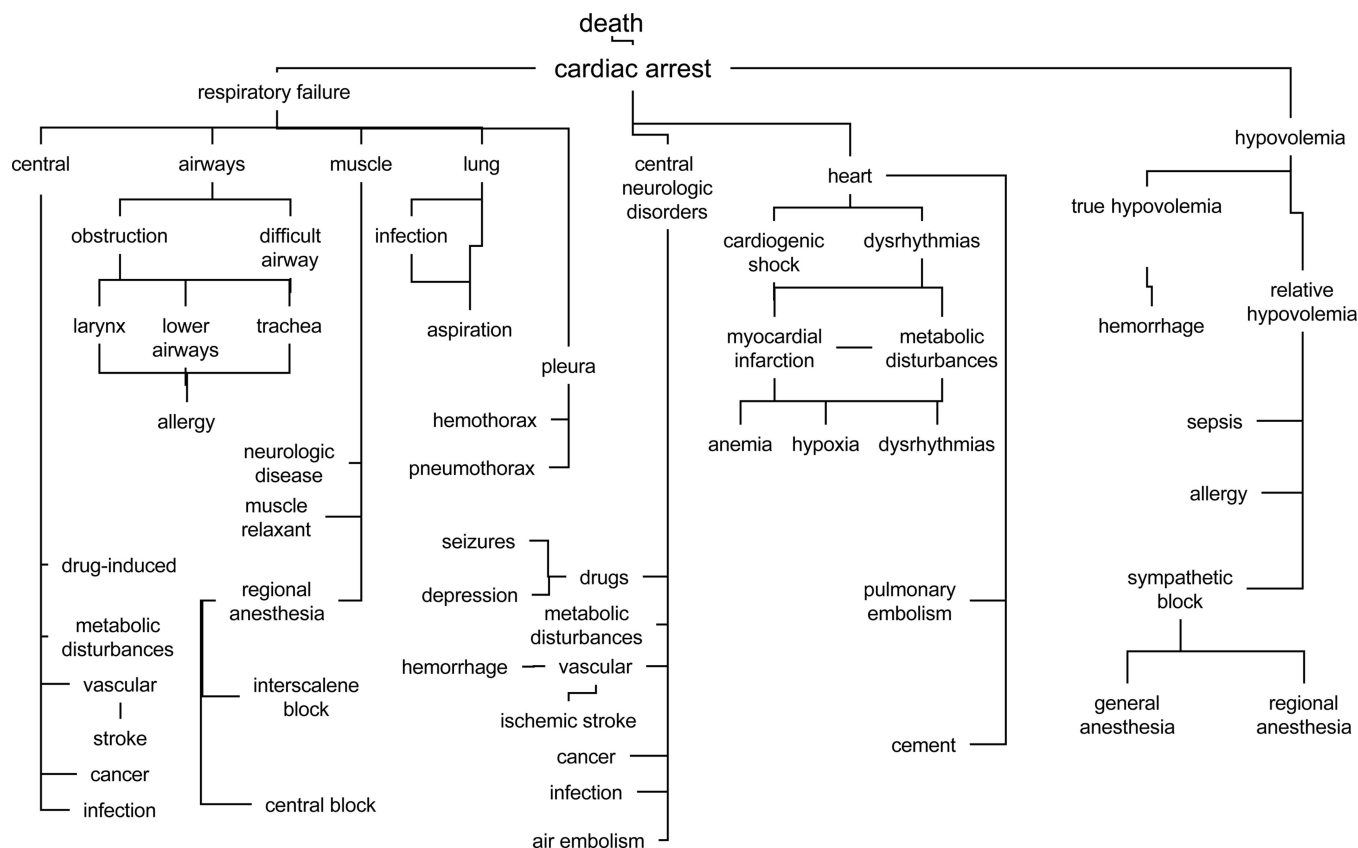


Fig. 3. Pathophysiologic description ("tree") of main events leading to deaths totally and partially related to anesthesia.

step, a detailed list of all existing recommendations that apply to French Anesthesiology practice was established by the investigators. Additional deviations were included (even though they could not be related to any published guidelines) if all three experts agreed that practice was obviously inadequate in comparison with contemporary practice at the time of the event. Deviations were retained only they were believed to have played a role in the process of death.

4. Describe the root causes that could be noted from questionnaire analysis or through discussion with the anesthesiologist involved. These causes were described using a simplified classification based on current frameworks for analyzing risk and safety in clinical medicine⁸ and were searched in seven fields: institutional context, organizational and management, work environment, team, staff, tasks, and patient factors.
5. Determine the causal role of anesthesia in the process leading to death using a three-point scale where 0 means "not anesthesia related" (which includes deaths totally explained by surgery or comorbidities and deaths explained by surgery or comorbidities in which anesthetic care could have played only a minor role), 1 means "partially related to anesthesia" (*i.e.*, deaths explained by surgery or comorbidities but in which the role of anesthetic care was not minor), and 2 means "totally related" (*i.e.*, deaths exclusively explained by anesthetic care). For the purpose of the

study, anesthesia was defined as a medical specialty taking care of the patient in the operating room and the postanesthesia care unit but also involved in the perioperative process including blood transfusion, analgesic techniques, and thromboembolic prophylaxis during the first 2 or 3 postprocedural days. Only anesthetic procedures performed by anesthesiologists or under their supervision were considered. Anesthetic procedures performed in intensive care units or in resuscitation ambulances were excluded.

6. Describe how reliable the conclusions were, using a two-class (high-low) stratification.

This final six-point summary had been previously tested using cases obtained from a pilot study, by a group of 22 anesthesiologists not involved in the analysis process.

Number of Anesthetic Procedures

The number of anesthetic procedures performed in 1999 was estimated by a national survey conducted in 1996 from a sample of 62,000 anesthetic procedures performed in all French hospitals and clinics.⁶ The estimated number of anesthetic procedures was 7,756,121 (95% confidence interval, 7,375,054–8,137,188), of which 12% were performed in patients classified as ASA physical status of 3 or greater, and 27% were performed in patients older than 65 yr.⁶

Statistical Analysis

The total number of anesthesia-related deaths was estimated by taking into account the two-stage sampling with unequal selection probabilities. The Horvitz-Thompson estimator was used for each total. Weights were the inverse of the observed instead of the theoretical sampling fraction to partially adjust for the non-response bias. A finite population correction was used. Confidence intervals of totals were estimated by adding variances of each stratum. The annual estimation was then calculated by taking into account the notion of rare events (Poisson distribution).

The mortality rate was estimated as the ratio of the population total of anesthesia-related deaths estimated from that survey and the population total of anesthetic procedures estimated from the 1996 survey. The variance of each ratio was estimated by using the Taylor linearization method.⁹

Statistical analyses were performed by using Stata Statistical Software (Release 7.0 for Windows; Stata Corporation, College Station, PA), in particular by using the specific (svy) commands for survey data.

The variation in reliability (high – low) of anesthesia accountability was evaluated in a complementary analysis in which the relation with anesthesia was increased by one step for low-reliability cases to avoid underestimation in cases for which an agreement between expert opinions was difficult to reach and for which we remained unsure of our analysis (*i.e.*, nonrelated cases with low reliability were classified as partially related, and partially related cases with low reliability were classified as anesthesia related).

Results

Characteristics of patients who died and circumstances and types of surgery are summarized in table 1. The estimated rate of deaths totally related to anesthesia was 0.69 in 100,000 anesthetic procedures (95% confidence interval, 0.2–1.2 in 100,000) in the whole population, *i.e.*, 1 death for every 145,500 anesthetic procedures (fig. 2).

The estimated rate of deaths partially related to anesthesia was 4.7 in 100,000 anesthetic procedures (3.1–6.3 in 100,000), *i.e.*, 1 death for every 21,200 anesthetic procedures. The estimated rate of deaths partially and totally related to anesthesia was 5.4 in 100,000 anesthetic procedures (3.7–7.1 in 100,000), *i.e.*, 1 death for every 18,500 anesthetic procedures.

Additional analysis in which the reliability of the relation between anesthesia and death was explored led to the following “corrected” rates: rate of deaths totally related to anesthesia: 1.2 in 100,000 (0.6–1.8 in 100,000); rate of deaths partially related to anesthesia: 5.3 in 100,000 (3.6–7.1 in 100,000); and rate of deaths

Table 1. Characteristics of Patients Who Died, and Circumstances and Types of Surgery Associated with Death

	n	Confidence Interval	%
Sex			
Men	233	140–326	56
Women	186	96–275	44
Age			
1–66 yr	114	76–152	27
67–75 yr	104	55–153	25
76–81 yr	112	46–178	27
82–92 yr	89	28–150	21
ASA physical status			
I	18	11–25	4
II	113	48–178	27
III	232	128–337	56
IV	56	4–108	13
Comorbidities*			
Heart disease	326	207–444	78
CAD	152	62–242	
Hypertension	141	65–217	
Arrhythmia	55	12–98	
Respiratory	99	37–161	24
Diabetes	36	3–72	9
Others	134	56–212	32
Emergency procedures	196	96–296	47
< 1 h	5		
1–6 h	30		
6–24 h	57		
24–48 h	104		
Scheduled procedures	223	140–306	53
Anesthetic techniques			
General	308	203–413	74
Regional	111	35–187	26
Spinal	107		
Epidural	4		
Others	0		
Surgery			
Orthopedics	209	97–310	50
Abdominal	101	43–158	24
Vascular	42	6–79	10
Urology	33	2–65	8
Others	21	1–47	5
Nonsurgical procedure	13	6–18	3

* The sum may be greater than 419 and 100% because several comorbidities may be found in a single case.

ASA = American Society of Anesthesiologists; CAD = coronary artery disease.

partially and totally related to anesthesia: 6.5 in 100,000 anesthetic procedures (4.6–8.4 in 100,000).

The mortality rate increased with age and ASA physical status as shown in table 2. The 95% confidence intervals of mortality rates in the highest and the lowest categories of age or ASA score did not overlap. Forty-two percent of the deaths totally or partially related to anesthesia occurred within 24 h of the procedure; 23% of patients died later than 72 h after the procedure. The event leading to death occurred during induction of anesthesia in 12% of the deaths totally or partially attributable to anesthesia, during maintenance for 26%, in the postanesthesia care unit for 22%, and after the recovery period for 40%.

Pathophysiologic mechanisms associated with death are described using a tree presentation in figure 4, the

Table 2. Rates of Deaths Totally or Partially Related to Anesthesia According to Age and ASA Physical Status

	Mortality Rate per 100,000 Anesthetic Procedures	95% Confidence Interval
Age		
0–7 yr	0.60	0.12–3.2
8–15 yr	1.20	0.30–3.2
16–39 yr	0.52	0.24–0.93
40–74 yr	5.20	2.7–8.1
≥ 75 yr	21.00	8.3–34.0
ASA physical status		
I	0.40	0.12–0.81
II	5.0	1.6–9.1
III	27.0	12.0–44.0
IV	55.0	1.1–130.0

ASA = American Society of Anesthesiologists.

width of each bar representing the relative importance of the mechanism. Overall, three main situations were identified: coronary artery disease and perioperative ischemia often triggered by anemia, true hypovolemia (associated with hemorrhage), or relative hypovolemia and aspiration of gastric contents.

Types of deviations from standard practice are presented in table 3. In 2% of cases partially or totally related to anesthesia, no deviation was found, whereas for all other patients, at least one cause of substandard practice was identified. In 56% of cases, more than four deviations were recorded. For deviations occurring during

induction of anesthesia, the use of a too-large dose was found by experts in 38% of cases. In nearly 60% of urgent abdominal surgery procedures, a rapid sequence induction technique was not correctly performed. Inadequate management of hypotension was identified in 39% of substandard intraoperative care.

One or several root causes grouped in seven arbitrarily defined fields (institutional context, organizational and management, work environment, team, staff, tasks, and patient factors) were identified in 91% of cases (table 4). Deficiencies in teamwork that could have promoted the occurrence of the event leading to death or could have played an aggravating role (and might have led to death) were found by experts in more than half of the cases. Overall, the most frequently encountered root causes were related to scheduling of surgical activity, deficiencies in communication between caregivers, and inadequate matching between necessary resources (human, technical, or logistic).

Discussion

In the current survey, an anesthesia-related mortality rate (totally or mainly related) of 5.4 in 100,000 anesthetic procedures (95% confidence interval, 3.7–7.1 in 100,000) was observed. The mortality rate increased with advancing age and with more impaired ASA physical status. Although airway management and postopera-

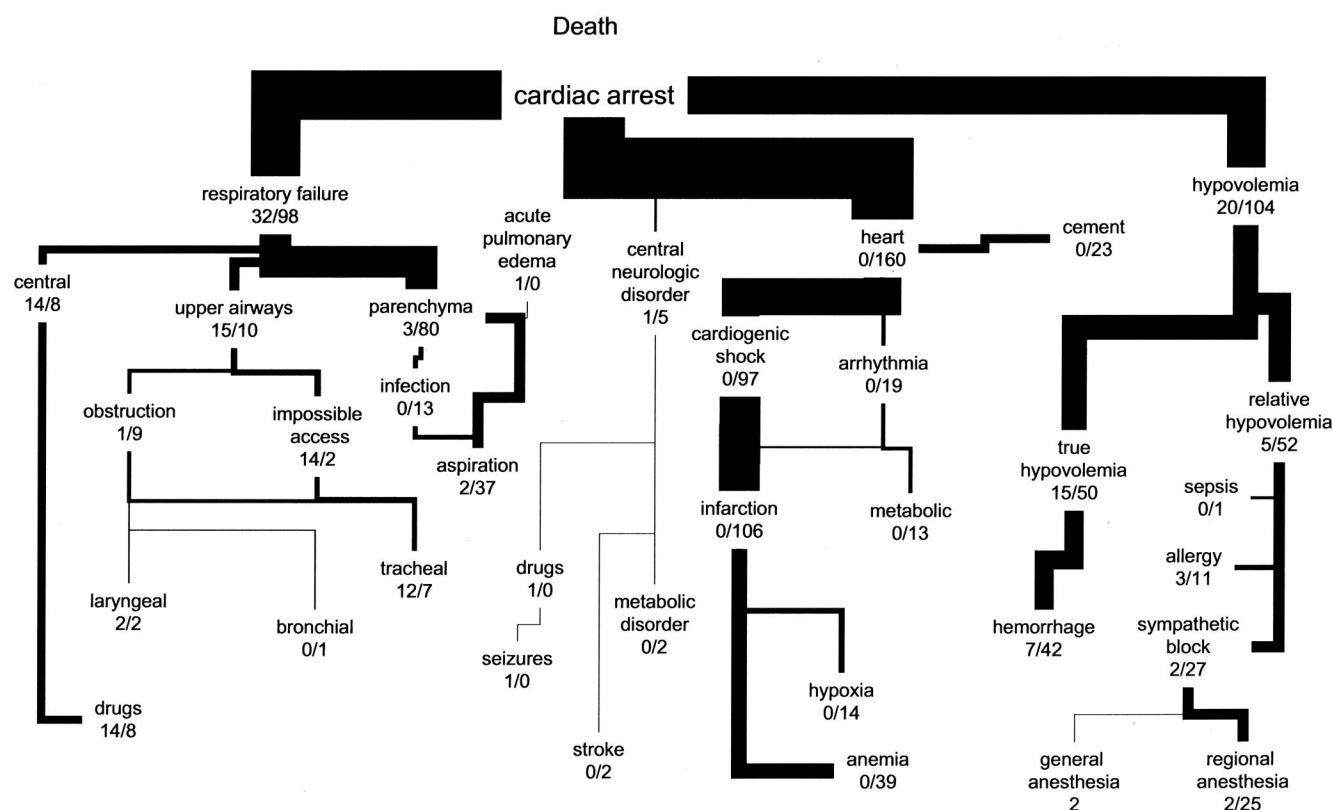


Fig. 4. Pathophysiologic description ("tree") of main events leading to deaths totally and partially related to anesthesia. The width of each line indicates the relative contribution of a given mechanism (number of cases totally related/partially related to anesthesia).

Table 3. Deviations from Rules, Standards, or Recommendations Identified for Deaths Totally and Partially Related to Anesthesia

Deviation	Relative Incidence of Deviations Identified, %	Deaths Associated with Occurrence of Each Deviation, %
Intraoperative care	18	46
Management of hypotension	5	
Diabetes mellitus	7	
Resuscitation cardiac of arrest	4	
Others	2	
Preanesthetic assessment and preparation	16	38
Preanesthetic assessment	10	
Patient optimization of underlying sickness	6	
Postoperative care	13	42
Management of postoperative analgesia	10	
Postoperative management of blood loss	2	
Miscellaneous	<1	
Intraoperative management of blood loss	12	37
Anesthetic induction technique	11	34
Substandard induction technique (patient at risk of aspiration of gastric contents for example)	6	
Overdosing	4	
Allergy in patients with known risk	1	
Management of anesthesia	9	26
Anesthesia information system	6	19
Monitoring in the postanesthesia care unit	5	14
Others	3	11
Intraoperative monitoring	3	10
Surgical technique	2	7
Inadequate healthcare structure	2	6
Total	100	—

tive respiratory complications remained important causes, no deaths related to hypoxia during recovery or equipment problems were found. Intraoperative hypotension and anemia are now the most important concerns associated with the occurrence of postoperative myocardial ischemia and infarction. Prudent comparison with the nationwide 1978–1982 survey suggests a 10-fold decrease in anesthesia mortality rate within this 20-yr time frame.

Anesthesia-related deaths are rare events and are difficult to study. The identification of such rare events by the longitudinal follow-up of a cohort study would require inclusion of millions of anesthetized patients. For practical and methodologic reasons, such a study is unrealistic. Furthermore, a specific registry of postanesthetic deaths does not exist in hospitals and clinics in France. By contrast, it is mandatory to report all deaths to the national mortality database using death certificates, which ensures exhaustiveness. Each death certificate described a mean of 3.3 causes or contributing factors, and this minimized the risk of missing cases. However, the large number of 537,459 death certificates obliged us to consider many steps in our sample selection. To avoid underestimation, the selection process was based on nonrestrictive criteria at the initial step. The primary step discarded only certificates for which any relation with surgery or anesthesia could be obviously ruled out (e.g., death due to multiple metastases with a primary cancer treated by surgery years before). To minimize the risks related to misinterpretation of the

causes described in the death certificate, three experts independently performed the initial selection. We excluded cases in which the medical history totally explained why death occurred, whatever the anesthesiologist might have done. These cases mainly included very sick patients undergoing high-risk surgery. In these situations, death was not due (partially or totally) to anesthesia but to the underlying disease. Had the study been devoted to human error, these cases should not have been excluded because anesthesiologists' errors may occur more easily during urgent and stressful care.

Any case for which the slightest concern arose regarding the role of anesthesia was kept for further analysis, even if concern arose for only one of the three experts. The response rate at any step of the study process was extremely high, and this also minimizes the risk of underestimation. The large communication campaign preceding the study might have contributed to the high acceptance rate.

The initial selection process was validated by reviewing a sample of 500 hospital deaths in which no preselected ICD-9 codes were found and no surgical or anesthesia-related death was found in this additional sample. Finding no event in a sample does not, however, necessarily mean that the event can never occur. Statistical analysis suggests that our underestimation, if any, was small. By taking the upper limit of the 95% confidence interval and applying this information to the whole database studied, it was found that a maximum error of 6.7% could have occurred. That is, the worst scenario

Table 4. Framework of Factors (Root Causes) Associated with Death

Domain of Investigation	Relative Contribution of Each Domain in the Dysfunctions Observed, %*	Root Causes by Domain of Investigation	Relative Contribution of Root Causes in Each Domain, %
Institutional context	27	Inappropriate healthcare structure	37
		Inappropriate hospital architecture	31
		Funding problems	32
		Total	100
Organizational and management factors	26	Inadequate patient orientation	38
		Inappropriate night call organization	11
		Inadequate surgical scheduling	31
		Production pressure	20
		Total	100
Work environment factors	44	Administrative and managerial support	14
		Staffing level vs. skills	5
		Availability/use of equipment†	81
		Total	100
Team factors	62	Written communication	20
		Oral communication	36
		Supervision and seeking help	44
		Total	100
Individual (staff) factors	51	Experience/competence	89
		Judgment/analysis	11
		Total	100
Task factors	27	Availability and use of protocols	82
		Task design/clarity of structure	18
		Total	100

* The sum may be greater than 100% because several causes may be found in a single case. † Mainly point-of-care hemoglobin monitoring (75%) and ST-segment monitoring (11%).

would be that we studied only 93.3% of all in-hospital deaths. With the hypothesis that the proportion of anesthetic deaths in this additional 6.7% sample would be similar to that of the whole database, we would thus have missed less than one anesthetic death.

Another limitation might come from the different periods used to measure the number of anesthetic procedures and anesthesia-related mortality (1996 *vs.* 1999). The error, if any, again seems minimal because data from the French Ministry of Health providing the number of procedures and their type do not show any increase in anesthetic activity during this small time frame.^{10,11} A small reduction is even suggested, between 1% and 5%, depending on the parameter used to estimate surgical activity. However, this bias would lead to a slight overestimate of anesthetic deaths.

Defining causes and consequences in a healthcare process as well as defining precisely the cause of death is an extremely difficult and complex task. Summarizing the mechanisms of death in a single word, as often found in previous studies,^{4,12–15} is overly simplistic, explaining why we have decided to present data using a pathophysiologic tree in which the main factors associated with death are described. This presentation also avoids counting the same case several times.

Moreover, for a given final outcome, the healthcare process might have been very different and highly variable actions and process deviations might be seen. Conversely, a given dysfunction (genotype) might lead to complications with highly variable clinical presentation

(phenotype).¹⁶ To help describe factors associated with poor outcomes, we searched in our cases the most important root causes, using a classification inspired from Vincent *et al.*⁸ It is obvious, however, that because cases were analyzed long after the event had occurred and because all participants were not interviewed, our root cause analysis is only a rough estimate, and it cannot be guaranteed that all human and system factors that contributed to the poor outcome were disclosed.

Another difficulty that was faced is hindsight bias (which should be differentiated from outcome bias). Hindsight bias is indeed the exaggerated extent to which individuals indicate they would have predicted the event beforehand.^{3,17} Reduction of this bias is difficult, but one way could be to systematically ask people to consider all other possible solutions that could explain what happened and how it happened. The pathophysiologic tree was also built and tested beforehand to reduce hindsight bias.

The various causes of medical complications and their complexity are factors that limit the use of traditional statistical tools and explain why expert opinions are used. This is why we structured case analysis in well-separated steps, in which the decision to link the event with anesthesia was the final one. Differentiation between “deaths partially related to anesthesia” and deaths not related to anesthesia “in which anesthetic care could have played only a minor role” was indeed often difficult. We tried to take into account this difficulty by asking experts to indicate how reliable their decision

was. For low-reliability cases, the causal relation with anesthesia was increased by one level in a complementary analysis, with the voluntary aim at causing overestimation rather than underestimation. Again, this analysis showed that errors produced by a change in classification, if any, would have only slightly modified the results.

Because we sought information from anesthesiologists involved in candidate cases long after the event had occurred, recall bias might be a problem. Arguably, they may not have had further contact with the patients after their anesthetics and might not even have been aware that some of them had died. Besides their likely inability to recall relevant detail not mentioned on their anesthetic record is the likelihood that they might readily associate the adverse events (e.g., hypotension) with the subsequent death, without recognizing that similar events occur commonly in patients who do not die. To reduce this bias, a copy of the most important medical documents (made anonymous during the on-site visit) was made available to the experts. Moreover, at each time significant disagreement between the anesthesiologist involved and the peer anesthesiologist (who reviewed the case) was noticed, additional questions from the expert committee were transmitted to the peer by the research assistants.

The rate of deaths totally related to anesthesia was close to other published values.^{4,12,14} Several traditional causes of death were identified, but consequences of hemorrhage and anemia played a role that was found to be disturbing. It was indeed estimated from this survey that nearly 100 deaths occur perioperatively in France each year as the result of inadequate blood management. Surprisingly, more deaths partially related to delayed or absent blood transfusion were observed, and only a small proportion of complications occurred after an episode of transfusion, emphasizing the safety of today's blood transfusion. In many cases, point-of-care monitoring of hemoglobin was not used to estimate blood loss, although it is likely that these inexpensive devices were already available in most hospitals at that time. Blood loss associated with delayed or absent blood transfusion caused intraoperative hypotension and hypovolemic shock but also postoperative myocardial ischemia and infarction in patients with preexisting coronary artery disease. Our analysis indeed suggested that thresholds used by the physicians in charge were sometimes lowered too much, leading to delayed or absent transfusion in cases where experts believed it would have been necessary. It is difficult to determine the role of the current, more restrictive guidelines for blood transfusion and the persisting reluctance to use blood transfusion that had been generated by the human immunodeficiency virus epidemics in the occurrence of these complications related to delayed transfusion.

Respiratory complications, although less frequently associated with death, remain a significant problem. The

role of aspiration of gastric contents remains disturbing but comparable to the rate found in previous studies.¹⁸ This is especially concerning because in the French 1978–1982 survey, aspiration of gastric contents was also a prominent cause of death or brain damage from a respiratory complication (40%), and audits of practice showed at the same period that important recommendations regarding prophylaxis of aspiration were not followed by many French anesthetists.¹⁹ Although more recent surveys performed in France and assessing obstetric anesthesia practices suggest that deviations are now much less common in this field,²⁰ substandard care remains for patients undergoing urgent abdominal surgery, which has been shown to be the current most common situation in which aspiration occurs.^{21,22}

Root causes were found in the majority of the files that were analyzed. As mentioned previously, this analysis likely leads to an underestimate of the real role of system dysfunction, because files were analyzed long after the event and only one actor was interviewed. Even with this important limitation, our data confirm that errors are not confined “at the sharp end” but result from the often unforeseeable combination of human and organizational failures in the presence of some weakness or gap in the system's many barriers and safeguards.^{23,24} This has also been suggested in a recent anesthesia mortality study²⁵ which showed that an adequate anesthetic management process can positively influence anesthesia-related mortality. Barriers to implementing patient safety systems should be alleviated by introducing a formal culture of safety in the operating room environment.²⁶ Other actor-centered improvements are needed. For example, one can remain perplexed when trying to understand the following: Why did experienced physicians use such large doses of anesthetic agents in elderly patients while pharmacodynamic changes associated with aging are so well known? Why did experienced physicians inadequately treat hypotension and not use direct vasoconstrictors when ephedrine was clearly ineffective?²⁷ Maintenance of competence and medical education, as well as implementation of a safety culture, are needed to improve anesthesia safety.

The evolution over the past decades of the rate of mortality related to anesthesia is a matter of controversy.⁴ One of the main causes of this controversy is that it is difficult to compare the various study methods and their results. Few data are available within the same country. In France, a study performed between 1978 and 1982 examined the role of anesthesia-related mortality and found 1 death totally related to anesthesia for 13,200 anesthetic procedures,⁵ yielding a rate of anesthesia deaths of 7.6 in 100,000. Therefore, the current study suggests that the anesthesia-related mortality rate has decreased 10-fold in France during the past 20 yr. Because these rates may be confounded by a change in the characteristics of the population anesthetized, compari-

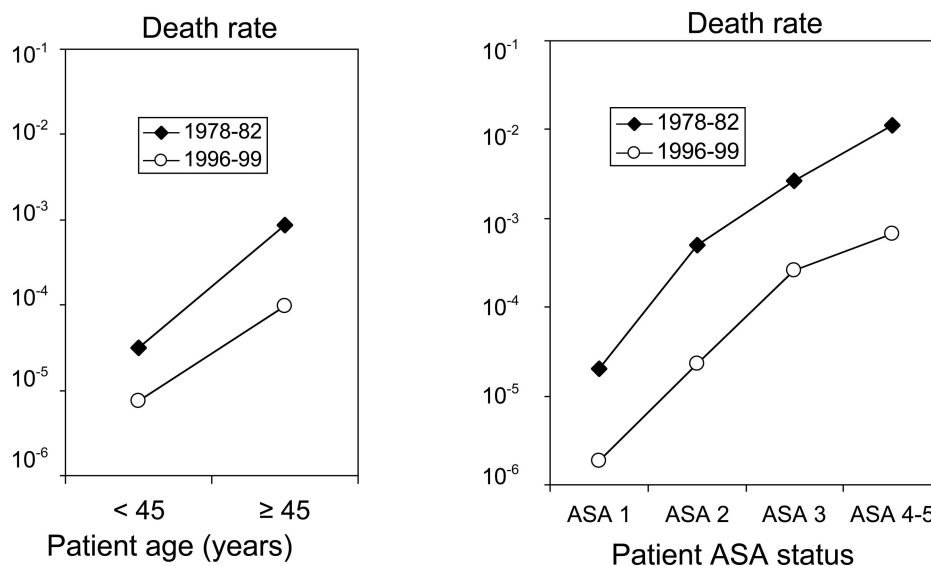


Fig. 5. Comparison of death rates between the two French studies (1978–1982 vs. 1996–1999) for different ages (*left*) and different American Society of Anesthesiologists (ASA) physical statuses (*right*).

son of rates in ASA physical status III and IV patients permits more accurate analysis and also confirms this significant decline between the two periods (fig. 5). Because the rate of ASA physical status III and IV patients has also increased severalfold in the more recent study and given the fact that these patients are not undergoing preferentially low-risk procedures, concluding that anesthesia-related mortality has declined overall seems sound (fig. 5).

This decline is observed in two surveys designed to estimate the annual nationwide number of both anesthetic procedures and anesthesia-related deaths. Both surveys included only anesthetic procedures that were performed by anesthesiologists or under their supervision, whereas procedures performed in intensive care units or ambulances were excluded. The definitions of deaths related to the anesthetic procedure were also similar. The participation rates of French anesthesiologists in both surveys were very high: 87% in 1978–1982 and 94% in 1999. External validation was performed in both surveys to estimate the completeness of the data collection. Because anesthesia is performed in France only by specialists in formally approved structures (hospitals and clinics), there is a low risk that cases might have been missed in either survey. Finally, because thromboprophylaxis is part of the anesthesiologist's role in France, those deaths believed to be due to postoperative thromboembolism were included among anesthesia-related deaths in the 1999 study, although they were not in the 1978–1982 survey. This might have included a significant bias (overestimated rate in the 1999 study) in the computation of anesthesia-related deaths. This is unlikely, however, because we did not observe any case for which pulmonary embolism was a factor in our sample.

In 1978–1982, only deaths occurring during the first

24 h after surgery were included in the analysis. By contrast, deaths occurring long after the anesthetic procedure were included in the 1999 analysis. Because 58% of the deaths occurred more than 24 h after surgery in the 1999 study, there was a relative underestimation of the anesthesia-related deaths in 1978–1982, and this reinforces our conclusions. Moreover, the increased number of guidelines now in place allows for a more precise classification of substandard practices. Although the willingness to attribute causality to anesthesia might have changed between the two study periods (it is difficult to be certain which direction the bias is in), we believe that underestimation was more likely in the previous survey. The role of human error is a factor that was not considered 20 yr ago and is more likely to influence judgment of experts in the current survey (toward an increased role of anesthesia care in the process leading to death). Moreover, in the current era, more data are available that tend to strengthen certain explanations. Therefore, today, if there is a case of difficult intubation but the patient later dies, the pulse oximetry and capnography data might prove that oxygenation and ventilation were maintained throughout. In the previous era, such cases might be assumed to be due to anesthesia care, even though the physiologic connection might not have been there.

Beside the decreased mortality rate, qualitative trends also appear. Hypoxia during the recovery period and the variable conditions of recovery monitoring, which was often found in 1978–1982, was not observed in 1999. Several factors likely contribute to this decline. Some are universal, *i.e.*, introduction of pulse oximetry²⁸ and use of modern anesthetics with more rapid offset,²⁹ but some are specific to this country. Results from the 1978–1982 survey were discussed with French healthcare authorities, and this led to the promulgation of a series of

laws centered on anesthesia care in 1985–1994.^{30,31} Postanesthesia care units and postprocedural stay in these units became mandatory in every surgical institution while supervision personnel and monitoring techniques were defined.

In conclusion, taking into account the numerous limitations of this study, we found that the overall rate of anesthesia-related mortality is currently 5.4 in 100,000 but increases in ASA physical status III and IV patients. Comparison of these data with a previously performed survey in the same country suggests a 10-fold decrease in the rate of anesthesia-related deaths.

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