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## Complications associated with anaesthesia - a prospective survey in France

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*A prospective survey of complications associated with anaesthesia was carried out in France from 1978 to 1982 in a representative sample of 198,103 anaesthetics performed in 460 public and private institutions chosen at random in the country as a whole. There were 268 major complications associated with anaesthesia occurring during or within 24 hours of anaesthesia (one per 739 anaesthetics), among which 67 were followed by death within 24 hours and 16 by coma persistent after the 24th hour. The incidence of death and coma was one per 2387 anaesthetics. The incidence of death and coma totally attributable to anaesthesia was one per 7924 anaesthetics. Fifty-eight per cent of complications occurred during anaesthesia while 42 per cent were observed during the recovery period. Mortality was lower following complications during anaesthesia than for those during the recovery period. Half of the deaths and cases of coma totally attributable to anaesthesia were due to postanaesthetic respiratory depression. The rate of complications appeared to be dependent upon several risk factors: the patient's age, the number of associated diseases, the pre-operative status, whether the operation was an emergency and the duration of procedure.*

### Key words

COMPLICATIONS: anaesthesia. EPIDEMIOLOGY: anaesthesia, complications.

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Mortality associated with anaesthesia has been extensively studied in several countries<sup>1-9</sup> and there have been a number of recent reports regarding this problem.<sup>10-12</sup> However, some aspects of the previous studies can be criticised, for the following reasons: (1) most of the studies involved only teaching hospitals and consequently did not represent the standard of practice of anaesthesia in the country as a whole; (2) the duration of the surveys was sometimes very long (between five and ten years) and anaesthetic techniques may have changed during the study period; (3) all studies were based on retrospective surveys emphasizing anaesthetic deaths and which permitted only a rough estimation of the overall risk of anaesthesia and of some specific risks related to factors routinely recorded for all patients undergoing anaesthesia; (4) most of the studies focused on anaesthetic deaths and did not include non-lethal complications which may have permanent sequelae or which may increase the duration of hospital stay.

Taking into account these considerations, a prospective survey of complications associated with anaesthesia was conducted in France between 1978 and 1982 by the Institut National de la Santé et de la Recherche Médicale (INSERM). The study was carried out on a representative sample of anaesthetics for which a large amount of information was collected, to determine the overall rate and mortality of complications associated with anaesthesia and to identify risk factors.

### Methods

The study was carried out prospectively on a representative sample of anaesthetics performed in public and private institutions chosen at random in the country as a whole. The field of study included

all anaesthetics, either general or regional, given by, or under the direction of certified anaesthetists. Because of the expected rare occurrence of complications, the size of the sample necessary to carry out this study was estimated to be 200,000. Since the number of anaesthetics performed each year in France was estimated to be at least 2,500,000, at the time of the study, a one-thirteenth sampling rate was held as representative. The selection of institutions included in the study was performed separately for public and private institutions. In each group, they were classified in three categories according to the annual volume (all surgical admissions plus half of obstetrical admissions) of surgical and obstetrical admissions:

- 1 More than 8,000 admissions. These institutions were all included in the sample and the study lasted four weeks;
- 2 From 4,000 to 8,000 admissions. One-half of these institutions were chosen at random and the study lasted twice as long (8 weeks);
- 3 Less than 4,000 admissions. One out of four of these institutions was chosen at random and the study lasted four times as long (16 weeks).

In each category of institution, the sample included one-thirteenth of the total number of anaesthetics given yearly. In order to take into account geographic and seasonal variations, all regions of France were included and in each of them the survey was carried out during two periods, separated by an interval of 6 months ( $2 \times 2$ ,  $2 \times 4$ ,  $2 \times 8$  weeks according to the category of institution).

During these two periods, a detailed questionnaire was completed by the anaesthetist for each anaesthetic performed. In the case of a major complication occurring during the operation or within 24 hours following anaesthesia, whether it appeared to be related to anaesthesia or not, a supplementary questionnaire was completed.

A major complication was defined as any fatal or life-threatening accident or one producing severe sequelae. The outcome of complications was assessed at the 24th hour: (1) death within 24 hours, (2) persistent coma at the 24th hour (3) survival (with or without sequelae). Cases with persistent postanaesthetic coma were examined individually because most were followed by a fatal outcome and taking them into account would thus allow for a more accurate assessment of mortality related to anaesthesia.

To be sure of the accuracy of the number of anaesthetics and deaths reported by the anaesthetists, the schedule of the operating theatre and register of deaths were checked in each institution included in the study. The contribution of anaesthesia to the complications had to be assessed by the anaesthetist involved with the case in the conclusion of each report: nil, partial or total contribution. All reports were then scrutinized by a National Committee of Assessors including anaesthetists who held an academic position, in order to reach its own conclusion about the contribution of anaesthesia to the complication. In the event of a disagreement between the opinions of the anaesthetist and the Committee, the latter was accepted.

The role of anaesthesia was deemed as total when it was the direct cause or a major contributory factor, of the complication. It was partial when the complication was primarily a result of the patient's disease or the surgical procedure but an anaesthetic aetiology could not be entirely excluded. Complications related to anaesthesia (totally or partially) were classified in three groups according to the time of the occurrence: induction of anaesthesia (time interval to ten minutes after the start of the anaesthetic procedure), maintenance of anaesthesia (until the end of surgical procedure), postanaesthetic period (until the 24th hour after the end of surgery). The causes of complications related to anaesthesia were classified according to the mechanism primarily responsible: failure of respiratory homeostasis, failure of circulatory homeostasis, neurologic accident and miscellaneous causes.

In this report, the study of possible risk factors focused on those related to the patient's preoperative status (age, number of associated diseases, ASA physical status) and the characteristics of the procedure (emergency, duration). For each risk factor examined, several relative risks (RR) were assessed by dividing the rate of complications observed, in the different classes of risk, by the rate of complications observed in the class of lowest risk according to the same factor. The value of RR indicates by how much the risk is multiplied between the two classes. The role of the risk factor was tested by the Chi-square test.

## Results

Only two regions (representing nine per cent of total surgical admissions in France) from a total of 21 did

TABLE I Participation rate of institutions in the study

	Sample institutions (number)	Participating institutions (number) (per cent of total)
<i>Public institutions</i>		
>8000 admissions	101	95 (94)
4-8000 admissions	32	32 (100)
<4000 admissions	90	82 (91)
<i>Private institutions</i>		
>8000 admissions	7	7 (100)
4-8000 admissions	32	31 (97)
<4000 admissions	265	213 (80)
<b>Total</b>	<b>527</b>	<b>460 (87)</b>

TABLE II Number of major complications partially or totally related to anaesthesia according to the outcome at 24 hours

Outcome	Partially related	% of total	Totally related	% of total	Total
Death	52	78	15	22	67 (100)
Coma	6	38	10	62	16 (100)
Survival	47	25	138	75	185 (100)
<b>Total</b>	<b>105</b>	<b>39</b>	<b>163</b>	<b>61</b>	<b>268 (100)</b>

TABLE III Incidence of complications partially or totally related to anaesthesia (number of anaesthetics: 198,103)

	Partially related	Totally related	Total
All complications	1:1887	1:1215	1:739
Death	1:3810	1:13207	1:1957
Death and coma	1:3415	1:7924	1:2387

not participate in the study. For institutions included in the sample, there was an 87 per cent participation rate (Table I). It was lowest for small private institutions (80 per cent).

#### *Incidence of complications related to anaesthesia*

Reports were collected for 198,103 anaesthetics. A total of 268 major complications related to anaesthesia occurred during or within 24 hours of anaesthesia. Among these, 67 were followed by death before 24 hours and 16 by coma persistent at the 24th hour, related either to a cerebrovascular accident or to postanoxic encephalopathy (Table II). Anaesthesia was considered as totally responsi-

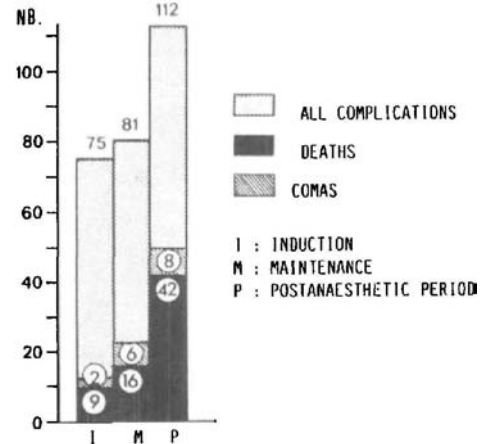


FIGURE 1 Time of occurrence of complications.

ble for the complication in 61 per cent of the cases. However, only 22 per cent of the deaths were totally attributable to anaesthesia (Table II).

The incidence of complications partially or totally related to anaesthesia is shown in Table III. Anaesthesia was totally responsible for one death per 13,207 anaesthetics occurring during the procedure or within 24 hours after the termination of anaesthesia. When including cases with coma, which usually had a fatal outcome, the incidence of deaths and coma totally attributable to anaesthesia was one per 7,924 anaesthetics.

#### *Time of occurrence of complications*

Fifty-eight per cent of complications occurred during anaesthesia (28 per cent at induction and 30 per cent during maintenance) and 42 per cent occurred during the postanaesthetic period (Figure 1). The prognosis was better when the complication occurred during anaesthesia (16 per cent of lethal complications) than during the recovery period (37 per cent of lethal complications).

The delay between the end of the procedure and the occurrence of a postanaesthetic complication was short in most cases: half of the overall complications occurred during the first postanaesthetic hour and 75 per cent within the first five hours. The delay was shorter for complications totally related to anaesthesia than for those which were partially related (Figure 2).

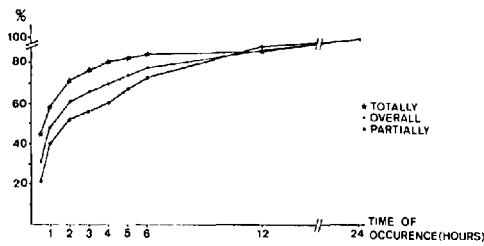


FIGURE 2 Cumulative percentage of postanaesthetic complications according to the delay between the end of the procedure and the time of occurrence.

TABLE IV Causes of complications at induction

	Complications	Death	Coma
<i>Respiratory failure</i>			
Failure of equipment	3	—	—
Complication of intubation	5	—	—
Inhalation of gastric contents	6	—	2
Bronchospasm	4	—	—
<i>Circulatory failure</i>			
Cardiac arrest	18	8	—
Collapse	8	—	—
Anaphylactoid shock	26	1	—
Severe arrhythmias	4	—	—
Complication of peridural anaesthesia	1	—	—
<b>Total</b>	<b>75</b>	<b>9</b>	<b>2</b>

#### Type of complications

At induction, respiratory failure accounted for 25 per cent of the complications, leading to postanoxic encephalopathy in two cases. Mortality related to circulatory collapse and cardiac arrests was high (30 per cent of cases) but more than half of the complications occurred in ASA physical status class III patients. In contrast, most of the cases of anaphylactoid shock (24 of 26) were observed in ASA physical status class I and II patients and only one was followed by death (Table IV).

The complications during maintenance of anaesthesia are summarized in Table V. Two cases of persistent coma at the 24th hour were related to respiratory complications and 16 deaths and four cases of coma were related to circulatory complications. Five patients had delayed symptoms in relation to an anaphylactoid reaction leading to coma in one patient (Table V).

TABLE V Causes of complications during maintenance of anaesthesia

	Complications	Death	Coma
<i>Respiratory failure</i>			
Failure of equipment	1	—	1
Complication of intubation	9	—	1
Inhalation of gastric contents	8	—	—
Bronchospasm	3	—	—
Laryngospasm	3	—	—
Pneumothorax	1	—	—
Respiratory depression	1	—	—
<i>Circulatory failure</i>			
Collapse	10	—	1
Cardiac arrest	22	14	1
Severe arrhythmias	9	1	1
Acute pulmonary oedema	4	1	—
Anaphylactoid shock	5	—	1
Miscellaneous	5	—	—
<b>Total</b>	<b>81</b>	<b>16</b>	<b>6</b>

During the postanaesthetic period, few complications due to failure of equipment or related to intubation were observed. The most common cause was respiratory depression (27 cases, leading to death in seven cases and to coma related to postanoxic encephalopathy in five cases). Almost all of these patients had received narcotic analgesics (26 of 27 patients) and muscle relaxants (21 of 27 patients) during anaesthesia for which antagonists had not been used. Seventy per cent of cases of respiratory depression occurred during the first postoperative hour. Inhalation of gastric contents was also frequently reported (13 cases leading to the death of four patients). Circulatory failure was lethal in half of the cases but most of the patients concerned were in poor condition, making the assessment of the contribution of anaesthesia difficult. One-half of the cardiac arrests occurred suddenly while the others followed a long period of refractory hypotension. Thirteen neurological complications related to cerebrovascular accidents or to head injury were followed by death in four cases and by coma in three cases (Table VI).

#### Complications totally attributable to anaesthesia

The most common causes of complications totally attributable to anaesthesia were anaphylactoid shock, inhalation of gastric contents and postoperative respiratory depression (Table VII). While fatal outcome rarely followed anaphylactoid shock, the

TABLE VI Causes of complications during postanaesthetic period

	Complications	Death	Coma
<i>Respiratory failure</i>			
Failure of equipment	1	1	-
Complication of intubation	2	1	-
Inhalation of gastric contents	13	4	-
Pneumothorax	2	1	-
Respiratory depression	27	7	5
Atelectasis	1	-	-
Bronchospasm	2	-	-
<i>Circulatory failure</i>			
Acute pulmonary oedema	12	2	-
Cardiac arrest	19	16	-
Collapse	4	-	-
Myocardial infarction	7	3	-
Severe arrhythmias	9	3	-
<i>Neurological complications</i>			
	13	4	3
<i>Total</i>	112	42	8

TABLE VII Causes of complications totally attributable to anaesthesia

	Complications	Death	Coma
<i>Respiratory failure</i>			
Failure of equipment	5	1	1
Complication of intubation	16	1	1
Inhalation of gastric contents	27	4	2
Bronchospasm	9	-	-
Pneumothorax	2	-	-
Postanaesthetic respiratory depression	28	7	5
Laryngospasm	3	-	-
<i>Circulatory failure</i>			
Collapse	5	-	-
Anaphylactoid shock	31	1	1
Severe arrhythmias	6	-	-
Cardiac arrest	17	1	-
Acute pulmonary oedema	8	-	-
Miscellaneous	6	-	-
<i>Total</i>	163	15	10

other complications were responsible for most of the deaths and cases of coma totally attributable to anaesthesia.

The outcome of complications totally attributable to anaesthesia was more often lethal when the complication occurred on the wards than in locations where the patients were more closely supervised (Table VIII). This was especially obvious in cases of postoperative respiratory depression,

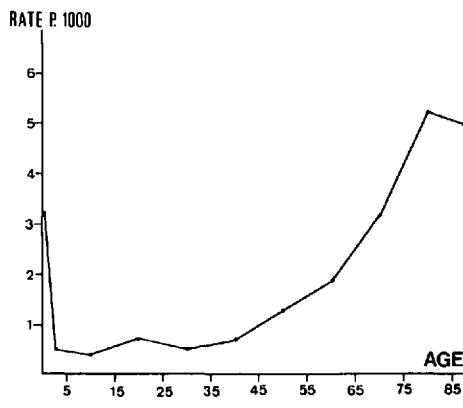


FIGURE 3 Rate of complications related to anaesthesia according to age.

which was lethal in 70 per cent of cases when occurring on the wards versus 29 per cent when occurring in the operating theatre, recovery room or intensive care unit. However, it appeared from the study that half of the patients undergoing anaesthesia were sent directly to the ward at the end of the procedure.

#### Risk factors

##### AGE

The rate of complications varied significantly according to the patient's age. Although higher for children less than one year old, it was very low for children between one and 14 years of age and remained less than 1:1000 up to 45 years of age. Thereafter the rate rose very significantly (Figure 3).

TABLE VIII Outcome of cases with complications totally attributable to anaesthesia, according to the location of occurrence

Location	Complications totally attributable to anaesthesia	Death or coma (%)	Significance
Ward	24	10 (41.7)	p < 0.001
Other (operating theatre, recovery room, ICU)	139	15 (10.8)	
<i>Total</i>	163	25 (15.3)	

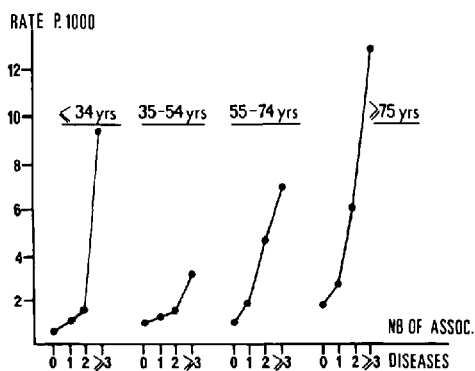


FIGURE 4 Rate of complications related to anaesthesia according to number of associated diseases in different age groups.

#### NUMBER OF ASSOCIATED DISEASES

The rate of complications also appeared to depend on the number of associated diseases: in all age groups, it increased significantly but was more pronounced at the extremes of age. The rate was very high for patients with three or more associated diseases (Figure 4).

#### ASA PHYSICAL STATUS

The rate of complications was very closely related

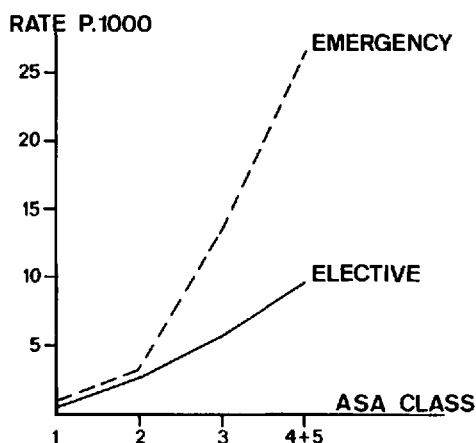


FIGURE 5 Rate of complications related to anaesthesia according to physical status for elective and emergency procedures.

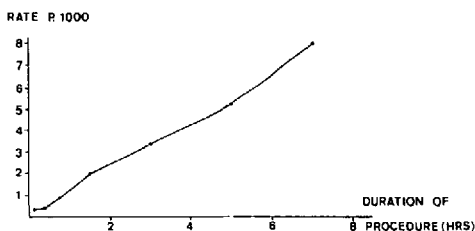


FIGURE 6 Rate of complications related to anaesthesia according to the duration of procedure.

to the patient's physical status. For elective procedures, the rate increased from 0.4:1000 for patients in good condition (ASA class I) to 9.6:1000 for patients in poor condition (ASA classes IV and V). For emergency procedures, this difference was even greater (from 1:1000 to 26.5:1000) (Figure 5).

#### DURATION OF PROCEDURE

The risk of complications increased with the duration of the procedure (Figure 6). Although the rate was low for short operations, it should be noted that 32 complications occurred during procedures lasting less than half an hour. In long operations (more than 8 hours), no complications were observed, probably due to the particular types of operations, such as plastic surgery.

#### RELATIVE RISK ACCORDING TO DIFFERENT RISK FACTORS

Different values of RR for each risk factor are shown in Table IX. Emergency procedures were associated with nearly a threefold increase in the rate of complications, but the highest RR was associated with physical status: the rate of complications was multiplied by 37 between ASA class I patients and ASA class IV and V patients.

#### Discussion

This report is a prospective study of complications associated with anaesthesia. Several advantages can be found, in comparison with retrospective surveys. In retrospective surveys detailed information may be available about the circumstances and the type of anaesthetic accident, but data regarding the preoperative status of the patient may lack objectivity since the report is made after the

TABLE IX Relative risks\* (RR) according to different risk factors

	Rate of complications (per 1000)	Relative risk	Significance
<b>Age (years)</b>			
<1	3.5	8.7	p < 0.001
1-14	0.4	1.0	
15-44	0.6	1.5	
45-54	1.3	3.2	
55-64	1.9	4.7	
65-74	3.2	8.0	
>75	5.2	13.0	
<b>ASA physical status class</b>			
I	0.5	1.0	p < 0.001
II	2.9	5.8	
III	7.2	14.4	
IV, V	18.7	37.4	
<b>Emergency</b>			
No	1.1	1.0	p < 0.001
Yes	2.9	2.6	
<b>Duration of procedure (hours)</b>			
<½	0.4	1.0	p < 0.001
½-1	0.9	2.3	
1-2	2.0	5.0	
2-4	3.4	8.5	
4-6	5.2	13.0	
6-8	8.0	20.0	

\*RR = Ratio between the rates of complications observed in one class of risk and the class of lowest risk of the same factor.

RR = 1 in the class of lowest risk.

accident. Furthermore, retrospective studies are limited to anaesthetics with complications and information for a control population undergoing anaesthesia without complications is scarce because it must be drawn from hospital registration records.

Anaesthetic complications are perhaps reported with less reluctance when every anaesthetic procedure is reported, regardless of whether an accident occurs or not. While a self-administered questionnaire may introduce potential bias in the collection of data it was required by the large volume of the survey. The accuracy of information provided from each institution could be checked for deaths but not for non-lethal complications. Thus, the rate of non-fatal complications is probably underestimated and conversely the overall frequency of mortality of some complications is perhaps overestimated.

The location of this study differs from that of most of the previous studies. With the exception of those reported by Lunn and Mushin<sup>12</sup> and Hovi-Viander,<sup>11</sup> most of the earlier studies were conducted either in teaching hospitals<sup>1-4,6,7,9,10,13</sup> or in private practice.<sup>7</sup> The aim of our study was to evaluate the overall risk of complications related to anaesthesia performed in all institutions, including private, non-teaching and teaching hospitals. The rate of participation was very high, reaching 87 per cent of institutions; most of those refusing to participate were small private institutions in which staff anaesthetists are so few that the completion of questionnaires required by the survey was considered as too time-consuming.

Another important point is the duration of the follow-up of patients after anaesthesia. Lunn and Mushin<sup>12</sup> chose a six-day interval for their study of mortality associated with anaesthesia in Great Britain, considering that anaesthesia may be a contributory factor in deaths which occur more than 24 hours after its administration. However, since all anaesthetics, even those for very short procedures, were included in our study, the length of follow up could not exceed 24 hours after anaesthesia for obvious practical reasons, some patients being day cases. Although severe complications related to anaesthesia may occur despite an uneventful immediate recovery, for example myocardial reinfarction or respiratory problems, many factors unrelated to the anaesthetic are often involved, so the contribution of anaesthesia is not always clearly established. Since we included cases having persistent post-anaesthetic coma at the 24th hour, it is likely that very few deaths totally attributable to anaesthesia were omitted.

The comparison of our results with those from the literature is difficult, because of marked differences in methodology. In the earlier studies the mortality rate partially or totally related to anaesthesia varied from 1:500 to 1:5000 (1:2389 in the present study). Lunn and Mushin<sup>14</sup> reported the mortality rate totally related to anaesthesia to be approximately 1:10,000, whereas the rate of death and coma observed in the present survey was 1:8,000. However, in the British survey, the rate was evaluated from all anaesthetic and non-anaesthetic procedures performed by anaesthetists. Thus, mortality rate is perhaps underestimated. Moreover, only 60 per cent of deaths have been reported and it is possible

that the contribution of anaesthesia to operative death is greater in these non-reported cases.

The present survey allowed us also to evaluate mortality of anaesthetic complications according to the time of their occurrence. A greater number of complications occurred during operation than in the postoperative period but the mortality of the latter was much higher. This fact is likely related to an insufficient number of recovery rooms in France, since about 50 per cent of patients returned directly to the ward after anaesthesia. The prognosis for postanaesthetic complications was worse when these were noted in the ward, compared with those observed in the recovery room. The nature of accidents observed during the induction and the maintenance of anaesthesia holds no surprise when compared with those reported previously in the literature.<sup>1-9,11-13</sup>

One exception which must be mentioned is that of anaphylactoid shock. The incidence was found to be quite high in our survey (1:4600 in patients aged 15 to 65 years). This complication was not reported in the previous studies which focused primarily on anaesthetic mortality. The difference in reporting of this complication may be explained by its low mortality rate. In the present survey, diagnosis of this complication was based on clinical symptoms (arterial hypotension or cardiac arrest following the administration of anaesthetic drugs in absence of overdosage, plus cutaneous manifestations of histamine release, for example erythema or oedema, and bronchospasm), so the rate may perhaps be overestimated. Althesin and succinylcholine were incriminated in most cases.

Analysis of the causes of accidents occurring during the postanaesthetic recovery period shows the frequency and severity of respiratory depression. This cause was found in 50 per cent of deaths totally related to anaesthesia. Many factors can contribute to postanaesthetic respiratory depression. Narcotics, widely used for anaesthesia in France (in 55 per cent of anaesthetics), are considered as the main cause of respiratory depression. The prognosis appears to relate to the availability of a postanaesthetic recovery room since the mortality rate was 70 per cent when the accident occurred on the wards and 29 per cent in the recovery room.

In conclusion, the present study has permitted us to determine the rate and mortality of complications associated with anaesthesia in France and to identify

risk factors. Although the interpretation of the data has to take into account the specific problems of the clinical practice in France, it should be emphasized that one original feature of this survey is the prospective approach to the epidemiology of anaesthetic complications. The prospective methodology used in this study allows a more accurate evaluation of anaesthetic risk. The role played by factors such as age, associated diseases, preoperative status, duration and urgency of operations is confirmed and each of them is assessed. From a prospective survey like this, a multifactorial index of risk could be determined as it has been established for cardiac patients by Goldman *et al.*<sup>15</sup> This point is now being investigated. A better assessment of risk factors should contribute to the improvement in safety of anaesthesia.

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### Résumé

*Une étude prospective des complications liées à l'anesthésie a été réalisée en France, entre 1978 et 1982, à partir d'un échantillon représentatif de 198,103 anesthésies pratiquées dans 460 établissements publics ou privés sélectionnés de façon randomisée sur l'ensemble du territoire. Deux cent soixante huit complications majeures, liées à l'anesthésie et survenues durant l'anesthésie ou les 24 premières heures post-opératoires, ont été observées (1 pour 739 anesthésies). Parmi ces complications, 65 étaient suivies par la mort dans les premières 24 heures post-opératoires et 16 par un coma persistant au-delà des 24 premières heures post-opératoires (la fréquence globale de décès et de comas liés à l'anesthésie était de 1 pour 2,387 anesthésies. La fréquence des décès et des comas totalement liés à l'anesthésie était de 1 pour 7,924 anesthésies). Cinquante huit pour cent des complications sont survenues durant l'anesthésie tandis que 42 pour cent étaient observées durant la période post-anesthésique. La létalité des complications était plus faible pour celles survenant durant l'anesthésie que pour celles observées après l'anesthésie. La moitié des décès et comas totalement liés à l'anesthésie (12 sur 25) était due à la dépression respiratoire post-anesthésique. Les facteurs favorisant les complications de l'anesthésie sont les suivants : âge du patient, nombre des affections associées, état pré-opératoire, caractère urgent de l'intervention, durée de l'intervention.*