J Anesth (1994) 8:1–5

Journal of
Anesthesia

Original articles

Anesthesia mortality and morbidity in Japan: a study of lawsuit cases

YASUHIRO SHIMADA[1] and YOSHIO KATO[2]

[1] Department of Anesthesiology, Nagoya University School of Medicine, 65 Tsurumaicho, Showa-ku, Nagoya, 466 Japan
[2] Medical Malpractice Information Center, 4-16-23, Sakae, Nakaku, Nagoya, 460 Japan

Abstract: To date, there have been no systematic studies on anesthetic accidents in Japan. This study was conducted to clarify the present status of anesthetic accidents by sending a questionnaire to a group of plaintiff's lawyers specializing in medical malpractice. At present, because of manpower shortages, anesthesia is provided by either anesthesia specialists (anesthesiologists) or non-anesthesiologist physicians in Japan. Among 112 lawsuits which involved the use of anesthesia, 64 were analyzed as to the person primarily responsible for administering the anesthesia, the types of anesthesia, the details of major mishaps, and intraoperative monitoring. Of particular note was a large number of deaths from cardiac arrest and hypotension in spinal anesthesia administered by non-anesthesiologists. The results clearly showed that non-anesthesiologists had a substantial incidence of mortality cases among accidents compared with anesthesiologists. Human error was the most frequent cause, but a lack and/or a grave omission of intraoperative monitors was found in non-anesthesiologist-related cases.

Key words: Complication, Anesthesia, Accident, Monitoring, Medicolegal, Questionnaire

Introduction

To date, there have been no systematic studies on anesthetic accidents in Japan, except for a few reports from the Japanese Association of Legal Medicine [1,2] and sporadic case reports of rare anesthetic complications. The Japanese Association of Legal Medicine conducted nationwide studies covering the period from 1960 through 1980 on the deaths associated with medical malpractice [1,2]. During that period, a total of 215 deaths were determined by forensic pathologists to have been associated with anesthesia. Although these were the nationwide studies, they only dealt with cases involving fatal complications investigated by forensic pathologists. The Japan Medical Association has a medical liability insurance and has accumulated cases. However, as yet we have not been given access to those records. The Japan Society of Anesthesiologists has recently prepared an annual inquiry for anesthesia accidents, and it has now been sent to all hospitals with board-certified anesthesiologist on staff. The inquiry put these hospitals under obligation to report cases with critical anesthetic accidents such as cardiac arrest, severe hypotension, and hypoxia necessitating intensive treatment, as well as other critical incidents. The inquiry is expected to give us insight into the causes of anesthetic accidents in about 500 large hospitals where board-certified anesthesiologists are formally employed. However, the inquiry does not cover about 8000 hospitals which do not have a board-certified anesthesiologist on staff.

The present study was undertaken to clarify the present status of anesthetic accidents in Japan by sending a questionnaire to a group of plaintiff's lawyers specializing in medical malpractice. The group recently established a foundation called the "Medical Malpractice Information Center" consisting of 215 lawyers throughout the country, where most medical malpractice cases are being collected.

Materials and methods

A questionnaire was prepared (Table 1) and sent to the 215 lawyers who comprise the Medical Malpractice Information Center in October 1991. A total of 126 lawyers (58.6%) responded and 112 lawsuit cases were obtained. To those who responded to the inquiry, we requested that they send us the anesthesia record, medical and nursing records, and other documents such as expert's reports if the claim had been closed. Of 112 cases, 5 were pain clinic cases and 5 cases were appar-

Address correspondence to: Y. Shimada
Received for publication on February 9, 1993; accepted on March 12, 1993

Table 1. Questionnaire form sent to lawyers of the Medical Malpractice Information Center

Age:	Sex:
Date of Accident:	
Outcome:	1. Died 2. Severe brain damage 3. Slight to moderate brain damage 4. Other
Hospital:	1. Private clinic 2. Private hospital 3. Public hospital 4. University hospital
Operation:	
Anesthesia:	1. General (intubated, mask) 2. Epidural 3. Spinal 4. Local 5. I.V. 6. Other
Anesthetic agents:	
Anesthetist:	1. Anesthesiologist (resident, registered, board-certified) 2. Other (surgeon, ob-gyn, etc.)
Monitors:	1. ECG 2. BP 3. Temp 4. Pulse oximeter 5. Capnometer 6. Other
Time of accident:	1. Induction 2. Endotracheal intubation 3. Maintenance 4. End of anesthesia 5. Post-operative
Details of the case:	

ently not related to anesthesia. An additional 38 cases were excluded due to insufficient records. The remaining 64 cases were used for the present study. The incidences were widely distributed from 1973 to 1991, but 80% occurred after 1980. Thirty of the 64 cases were closed at the time of inquiry.

In this study, anesthetic accidents were categorized as follows: cardiac arrest, hypotension necessitating special therapy, hypoxia necessitating special therapy, and other critical events such as malignant hyperthermia and fulminant hepatitis. The cases were also categorized according to whether the anesthesia was provided by an anesthesiologist (including anesthesia residents, registered anesthesiologists, or board-certified anesthesiologists) or by a non-anesthesiologist physician (such as surgeon or gynecologist).

The search for causes among accidents was primarily an intuitive process. Classification of causes was done according to the method of Cooper et al. [3] and one of the authors (YS) made the judgment.

Results

Basic clinical features of the cases are summarized in Table 2. Twenty of the lawsuits involved anesthesiologists; in the other 44, anesthesia was administered by non-anesthesiologist physicians. Accidents related to spinal anesthesia occurred in half of the non-anesthesiologist-related cases, whereas most of the accidents related to anesthesiologists occurred during general anesthesia. Table 3 shows the distribution of anesthetic accidents according to the types of anesthesia. Of particular note is the incidence of cardiac arrest and hypotension in spinal anesthesia administered by non-anesthesiologists (20 cases).

Table 4 shows the outcome of anesthetic accidents. Severe brain damage denotes a vegetative state. The incidence of mortality among accidents of non-anesthesiologist-related cases was substantially greater than that of anesthesiologist-related cases (63.6% *vs* 45.0%, respectively). This study clearly revealed substandard intraoperative monitoring in Japan (Table 5). In these cases, which occurred between 1973 and 1991, neither a pulse oximeter nor a capnometer were ever used. Even in one case where an anesthesiologist was in attendance, the patient's electrocardiogram (ECG) was not monitored. Intraoperative monitoring was much worse among non-anesthesiologist-related cases: ECG was not monitored in half of these cases, and blood pressure was not monitored in 7 of the 44 cases. Temperature was not monitored in any of the cases. Table 6 shows the

Table 2. Basic features of the cases

	Anesthesiologist-related cases (n = 20)	Non-anesthesiologist-related cases (n = 44)
Age (mean ± SD)	25 ± 21	29 ± 20
Male/female	9/11	24/20
Primary anesthesia		
General	17	16
General + epidural	1	2
Epidural	1	1
Spinal	1	21
Local	0	4

Table 3. Distribution of anesthetic accidents according to types of anesthesia

	Cardiac arrest	Hypotension	Hypoxia	Others
Anesthesiologist-related accidents				
General	11	2	2	2
General + epidural	1	0	0	0
Epidural	0	0	0	1
Spinal	0	1	0	0
Local	0	0	0	0
Total	12	3	2	2
Non-anesthesiologist-related accidents				
General	14	0	0	2
General + epidural	1	1	0	0
Epidural	0	1	0	0
Spinal	15	5	0	1
Local	4	0	0	0
Total	34	7	0	3

Table 4. Outcome of anesthetic accidents

	Anesthesiologist-related cases (%)	Non-anesthesiologist-related cases (%)
Intraoperative death	3 (15.0)	17 (38.6)
Late death	6 (30.0)	11 (25.0)
Severe brain damage	6 (30.0)	10 (22.7)
Slight/moderate damage	4 (20.0)	5 (11.4)
Others	1 (5.0)	1 (2.3)

Table 5. Intraoperative monitors in anesthesia-related accidents

	Anesthesiologist-related cases (%)	Non-anesthesiologist-related cases (%)
ECG	19 (95.0)	20 (45.5)
Blood pressure	20 (100)	37 (84.1)
Temperature	6 (30.0)	0 (0)
Total cases	20	44

Table 6. Major factors of anesthetic accidents

	Anesthesiologist-related cases (%)	Non-anesthesiologist-related cases (%)
Human error	17 (85.0)	40 (90.9)
Omission of monitors	1 (0.5)	21 (47.7)
Anaphylactic shock	0 (0)	4 (9.1)
Machine failure	0 (0)	1 (2.3)
Pipeline disconnection	1 (0.5)	0 (0)
Malignant hyperthermia	0 (0)	2 (2.3)
Fulminant hepatitis	1 (0.5)	0 (0)

Table 7. Associated factors of human error

	Anesthesiologist-related cases	Non-anesthesiologist-related cases
Inadequate airway	8	4
Hypoventilation	1	10
Hypovolemia	1	14
Lack of observation	0	7
Drug overdose	2	2
Deep anesthesia	2	1
Syringe swap	1	0
Other	2	2

major factors of accidents. Two or more causes were counted in a case if both were considered to have contributed to the accident. Human error was the most frequent, but omission of intraoperative monitors was noticeable.

Table 7 shows the distribution of critical incidents of human error according to type of anesthesia provider. Most of the inadequate airway management cases were related to the failure to place endotracheal intubation. In non-anesthesiologist-related hypoventilation cases, there were seven cases where diazepam was used for spinal anesthesia, and the levels used were probably excessive. Non-anesthesiologist-related hypovolemia cases included eight spinal anesthesia cases with severe hypotension and/or cardiac arrest. Lack of observation denotes that there was no one observing the patient's anesthesia during surgery, and this situation was exclusively found in non-anesthesiologist-related cases.

Discussion

In the present study, no attempt has been made to measure the absolute occurrence rate of critical anesthetic accidents in Japan. To date, even the total number of anesthesia or surgical cases has not been investigated, and there has not been a single study to investigate the epidemiology of anesthetic accidents in Japan. In the present study, we tried to identify types of errors and associated factors found in cases of medical malpractice. Similar to the closed claims studies [4–7], the

analysis of lawsuit cases are biased even when they have already been settled or judged. Firstly, this is a retrospective study with all the inherent limitations. Secondly, the date of occurrence of these incidents is widely distributed from 1973 to 1991, and the anesthetic management might not reflect the current situation in Japan. Thirdly, in a study of the reliability of the case reviewers, Caplan et al. [4] concluded that practicing anesthesiologists can produce a cohesive set of judgments when asked to review anesthetic mishaps for basic aspects of clinical care. In the present study, only one of the authors, with more than 20 years' experience in clinical anesthesia and with the Japanese Board of Anesthesiology, assessed and judged the causes of accidents. Finally, this data base includes only cases wherein plaintiff's lawyers decided that the negative outcome was serious enough and there were sufficient grounds to justify filing a lawsuit. Cases which make it as far as the courts are often considered to be the tip of the iceberg. In the vast majority of cases, the patient and/or their family may not even be aware that an accident has occurred, or if they are aware, there may not be enough concrete evidence to support the filing of a lawsuit.

In contrast to studies carried out in the countries where anesthesia is invariably performed by anesthesiologists, this study is unique in that it was conducted in a country where probably 70% of anesthesia is administered by doctors who do not specialize in anesthesia [8]. In the Japanese medical system, basically every physician is allowed to anesthetize patients. However, an anesthesia board program was established in 1963. After either 2 years of anesthesia residency in board-qualified hospitals or anesthetizing 300 cases, any physician can submit the necessary documents to the Japanese Ministry of Health and Welfare (Koseisho) and will be registered as an anesthesiologist (registered anesthesiologist). Currently, we have 9545 registered anesthesiologists, but most of them have other specialities and do not practice anesthesia on a routine basis. An anesthesia specialist in training is required to continue an anesthesia residency program for 3 more years. During that period, the candidate must sit for the written, oral, and clinical examinations administered by the Japan Society of Anesthesiology. After completing all the examinations, the title of board-certified anesthesiologist is conferred. Currently, we have 2755 board-certified anesthesiologists. In this study, we analyzed the anesthetic accidents according to the anesthesia providers: anesthesiologists who specialize in anesthesia practice, including board-certified anesthesiologists, some of the registered anesthesiologists, anesthesia residents, and non-anesthesiologists who specialize in another field of medicine.

The results of this study clearly demonstrate that the non-anesthesiologists had a substantial incidence of serious accidents (Table 3); the incidence of mortality cases among accidents of non-anesthesiologist-related cases was greater than that of anesthesiologist-related cases (63.6% *vs* 45.0%). Another typical finding of this study was the grave omission of adequate monitors in cases with spinal anesthesia performed by non-anesthesiologists. In eight of the cardiac arrest cases during spinal anesthesia, we noticed in the anesthesia and nursing records that bradycardia and cyanosis were the first signs noticed prior to the development of cardiac arrest, and the presence of a pulse oximeter could have prevented the problem. The risk associated with spinal anesthesia has already been pointed out in surveys by the Japanese Association of Legal Medicine [1,2]. Most of the accidents associated with spinal anesthesia occurred in small-sized private hospitals and clinics with only one surgeon and a few nurses present. Human error was found in 89% of the cases as a cause of critical anesthetic accidents. The frequency of human error was in accord with other studies [3,9–11].

The results of this study clearly demonstrate that Japan must establish a system to increase the number anesthesiologists nationwide. However, in the meantime, in light of the large shortage of trained anesthesiologists, we must establish an anesthesia safety standard first to reduce anesthetic accidents accompanied by a lack or total absence of intraoperative monitors [12]. We also propose that a national inquiry into perioperative mortality and morbidity be conducted such as the CEPOD study in Great Britain [13].

In summary, the causes of anesthetic accidents were analyzed in 64 lawsuit cases in Japan. Human error was the most frequent cause, but in spinal anesthesia conducted by non-anesthesiologists, omission of intraoperative monitors was prominent.

Acknowledgments. We should like to thank Dr. J.B. Cooper, Associate Professor, Department of Anaesthesia, Massachusetts General Hospital, and Dr. J.N. Lunn, Reader, Department of Anaesthetics, University of Wales College of Medicine, for helpful criticism. This work was presented in part at the Fifth Meeting of the International Committee for Prevention of Anesthesia Mortality and Morbidity, The Hague, Netherlands, June 26, 1992.

References

1. Wakasugi C, Shikata I (1976) Statistical study of therapeutic deaths for the past 10 years (in Japanese, with English abstract). Jpn J Legal Med 30:391–400
2. Investigation Committee of the Medico-Legal Society of Japan (1983) Reports on medico-legal data from the mass-investigation performed by the Medico-legal Society of Japan (in Japanese, with English abstract). Jpn J Legal Med 37:434–454

3. Cooper JB, Newbower RS, Kitz RJ (1984) An analysis of major errors and equipment failures in anesthesia management: considerations for prevention and detection. Anesthesiology 60:34–42
4. Caplan RA, Ward RJ, Posner K, Cheney FW (1988) Unexpected cardiac arrest during spinal anesthesia: a closed claims analysis of predisposing factors. Anesthesiology 68:5–11
5. Cheney FW, Posner K, Caplan RA, Ward RJ (1989) Standard of care and anesthesia liability. JAMA 261:1599–1603
6. Tinker JH, Dull DL, Caplan RA, Ward RJ, Cheney FW (1989) Role of monitoring devices in prevention of anesthetic mishaps: a closed claims analysis. Anesthesiology 71:541–546
7. Kroll DA, Caplan RA, Posner K, Ward RJ, Cheney FW (1990) Nerve injury associated with anesthesia. Anesthesiology 73:202–207
8. Rosen M, Fujimori M (1985) Maternal mortality and manpower. Comparisons in relation to anaesthetists, obstetricians, and paediatricians in England and Wales and in Japan. Anesthesia 40:892–895
9. Cooper JB, Newbower RS, Long CD, McPeek B (1978) Preventable anesthesia mishaps: a study of human factors. Anesthesiology 49:399–406
10. Keenan RL, Boyan CP (1985) Cardiac arrest due to anesthesia. JAMA 253:2373–2377
11. Gaba DM (1989) Human error in anesthetic mishaps. Int Anesthesiol Clin 27:137–147
12. Eichhorn JH (1989) Prevention of intraoperative anesthesia accidents and related severe injury through safety monitoring. Anesthesiology 70:572–577
13. Campling EA, Devling HB, Hoile RW, Lunn JN (1990) The report of the National Confidential Enquiry into Perioperative Deaths 1990. National Confidential Enquiry into Perioperative Deaths