

Analysis of Deaths Related to Anesthesia in the Period 1996–2004 from Closed Claims Registered by the Danish Patient Insurance Association

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Background: Anesthesia is associated with complications, and some of them may be fatal. The authors investigated the circumstances under which deaths were associated with anesthesia. In Denmark, the specialty anesthesiology encompasses emergency medicine, chronic and acute pain medicine, anesthetic procedures, perioperative care medicine, and intensive care medicine.

Methods: The authors retrospectively investigated anesthesia related deaths registered by the Danish Patient Insurance Association.

Results: From 1996 to 2004, 27,971 claims were made by the Danish Patient Insurance Association covering all medical specialties, of which 1,256 files (4.5%) were related to anesthesia. In 24 cases, the patient's death was considered to result from the anesthetic procedure: 4 deaths were related to airway management, 2 to ventilation management, 4 to central venous catheter placement, 4 as a result of medication errors, 4 from infusion pump problems, and 4 after complications from regional blockades. Severe hemorrhage caused 1 death, and in 1 case the cause was uncertain.

Conclusions: Several of the 24 deaths could potentially have been avoided by more extended use of airway algorithm, thorough preoperative evaluation, training, education, and use of protocols for diagnosis and treatment.

IT has become accepted that patients can file a claim if their medical treatment results in an injury or an unexpected side effect. In Denmark, claims from patients regarding medical treatment are considered by the independent Danish Patient Insurance Association (DPIA) introduced in 1992 by the Danish government. The DPIA acts as an impartial agency, with the power to provide financial compensation to patients for injuries sustained during examination or treatment in the healthcare service.¹ As a result, patients can file a claim with the DPIA with the sole purpose of seeking financial compensa-

tion. Based on the DPIA files covering claims from 1996 to 2004, we evaluated the fatal cases related to the fields of anesthesia in Denmark.

In Denmark, the specialty anesthesiology encompasses emergency medicine, chronic and acute pain medicine, anesthetic procedures, perioperative care medicine, and intensive care medicine. The number of anesthetics performed in Denmark per year is estimated to be 400,000.

The aim of this study was to describe the set of claims that resulted from death associated with anesthesia and to identify potential opportunities to improve patient safety.

Materials and Methods

The study used a retrospective design that followed claims for financial compensation as listed in the DPIA database launched in 1996. The claim from a patient comprises a description of the injury (injuries) in addition to the medical record. Each case is registered in the database under a code that identifies the patient and the medical specialty involved.

A claim for financial compensation can be made by the injured patient, the relatives, or the hospital. When a patient files a claim, the hospital is obliged to submit all medical records regarding the case to the DPIA. A lawyer evaluates the claim and may seek advice from medical specialists. Since 2002, cases regarding anesthesia have been handled by a permanently employed anesthesiologist, who provides an evaluation as to whether "best practice" has been followed. Before 2002, a medical specialist without anesthesiology training provided advice for simple claims, and an external consulting anesthesiologist (usually a professor) provided advice for more complex claims.

In general, financial compensation is granted if (1) an experienced specialist would have acted differently; (2) defects in, or failure of the technical equipment were of major concern with respect to the incident; or (3) alternative treatments, techniques, or methods were considered to be more safe and potentially offer the same benefits. At least one of the three conditions must be fulfilled before compensation is granted. In addition, an injury may lead to financial compensation if the injury is rare and more extensive than the patient would be expected to endure. It is important to note that financial compensation can be granted even in claims where no medical errors were made. The lawyer determines, in

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concert with the medical adviser, whether a claim qualifies for financial compensation, and the decision is forwarded to the patient. The compensation is calculated on the basis of the extent of pain and suffering, reduced income, reduced ability to work, and medical expenses, and it is considered whether the injury would be expected to be permanent.

The patient may appeal the decision of the DPIA to the Patient Damage Appeal Board and further to the courts of law.

For each claim, the DPIA creates a patient folder in which the documents of the case are kept. The most important data (sex, age, year, World Health Organization classifications of diseases [International Classification of Diseases], specialty, surgery code, procedures, complications, brief description of the circumstances, place, and so on) are, in addition, transferred to an internal electronic data system.

This review is based on information drawn from the internal data system and from the folders of all implicated patients. We searched the database for claims to injuries related to anesthesia in Denmark in the period from 1996 to 2004. We defined *anesthesia related* as all procedures performed by anesthesiology staff members or patient care in one of the fields of anesthesiology (intensive care medicine, emergency medicine, perioperative care, and pain care units).

All submitted cases resulting in death were chosen for further evaluation. Two anesthesiology specialists then independently evaluated the documents of each of these cases as to whether death was caused by an anesthetic procedure or treatment. Only cases where the patient had died within a period of 3 months from the procedure or patient care were selected. Cases in which the outcome was other than death are described in a previous report.² Cases for further investigation were selected only if both anesthesiologists agreed that the case was anesthesia related. The investigation then included details as revealed in the records: age, sex, medical history, place of incident, circumstances and cause of death, and finally, judgment of preventability. A case was defined as preventable if each of the two anesthesiology specialists found that a complication from a procedure or a complication from specific patient care was considered most likely the cause of death within 3 months and that the complication could have been avoided if guidelines had been followed, or if the use of a specific technique could have prevented the complication.

Results

We found 1,256 cases in the period from 1996 to 2004 where an injury related to the field of anesthesia resulted in a claim. Of these, 43 cases were registered as deaths. The database did not distinguish between those who

died as a result of the complication and those who died from natural causes. All of the files of the 43 cases registered as deaths were thoroughly read and evaluated. By reading the files, it became clear that 13 patients only sustained minor injuries (e.g., dental injuries, skin lesions) and died of natural causes several months after the injury. Two patients became paraplegic after epidural analgesia and died 4 and 6 months after the injury. The cause of death in both cases was considered to be cancer. Two of the claims were directed toward internal medicine and did not involve anesthetic personnel. Two patients sustained hypoxic brain damage but did not die within 3 months. Twenty-four fatal cases were considered by the two anesthesiology specialists to be a result of the anesthetic treatment. These 24 deaths involved 7 adult females, 14 adult males, and 3 children. The procedure related to the fatal outcome happened in the following locations: 13 incidents in an operating theater, 4 in a recovery room, 4 in an intensive care unit, 1 in a department of radiology, 1 in an emergency room, and 1 in the patient's home (table 1).

The causes of the 24 deaths were as follows: 4 deaths were related to airway management (difficult intubations, aspiration, lack of observations), 2 deaths were related to ventilation management (unrecognized pneumothorax, misassembled CPAP system without expiratory valve), 4 deaths were related to administration of drugs or blood (insulin, methohexital, benzodiazepine, or incompatible blood), 4 deaths were related to infusion pump problems, and 4 deaths were related to the placement of central venous catheters. Complications related to regional blockade resulted in 4 deaths (spinal abscess, spinal lesion). Severe hemorrhage caused 1 death, and in 1 case the cause was uncertain (probably amniotic embolus or peripartum cardiomyopathy). We found that 20 of the 24 cases were potentially preventable. The average age of these 20 patients was 46 yr (range, 1-83 yr). The average age for the 4 cases categorized as not preventable was 49 yr (range, 1-79 yr). The average age of all 24 cases was 46 yr (range, 1-83 yr).

The claims for these 24 patients resulted in compensation totaling \$1.1 million (range, \$1,900-107,053).

Discussion

In most of the 24 cases, the critical incident could be identified. We defined a critical incident as the procedure or specific patient care that eventually led to the fatal outcome.

It is important to have an incident reported in as detailed a manner as possible so that the pattern of injury may be understood, the cause of injury analyzed, and lessons from mistakes made widely known in an attempt to reduce the risk of recurrence. Because of the historic

Table 1. Number, Sex, Age, Type of Anesthetic Procedure or Location, History, Cause, and Possible Prevention

No.	Sex and Age, y	Procedure	Location of the Event	History	Preventable
1	M 23	Tracheotomy	Intensive ward	The patient was recovering from a traffic accident and was intubated for several days. After extubation, he developed severe stridor. Tracheotomy was attempted. During this procedure, a via falsa into the mediastinum was made twice before correct placement. A tension pneumothorax was not recognized. Died of bilateral pneumothorax and hypoxemia.	Probably preventable. The pneumothorax was not recognized. Questions of training and senior doctor responsibility could be addressed.
2	F 35	General anesthesia and epidural analgesia for peritoneal lavage	Operating theater	Peritoneal lavage because of peritonitis after gallstone operation. Perioperatively, the patient aspirated using a laryngeal mask airway. Died day 2 postoperatively because of aspiration pneumonia.	Probably preventable. Knowledge of and adherence to the use of tracheal intubation when there is a known risk of aspiration.
3	M 83	General anesthesia for tamponade of urine bladder	Operating theater	After surgery while still orally intubated, the patient was transported to the ICU. In the ICU, he was connected to a misassembled CPAP system without expiratory valve. The patient developed severe bilateral pneumothorax with thoracic subcutaneous emphysema. Shortly thereafter, cardiac arrest developed, and resuscitation was unsuccessful.	Probably preventable. Misassembled CPAP system may be prevented by better construction and instructions of testing before use.
4	M 59	General anesthesia for evacuation of an abscess in the oral cavity	Operating theater	Hospitalized for a suspected dental abscess. Preoperatively, trismus, submental, and submandibular edema was noticed. The patient was anaesthetized (pentothal-suxamethonium), but intubation, insertion of laryngeal mask, or tracheostomy was impossible. Died in the operating theater because of a difficult airway.	Probably preventable. Fiber-intubation to be used on patients with a known difficult airway. Knowledge and adherence to airway management guidelines.
5	M 65	General anesthesia with the use of a laryngeal mask for elective ureteroscopy	Operating theater	The patient had diabetes and cardiac disease and was obese. In the final part of the anesthesia, the patient developed bronchospasm and severe hypoxemia, probably due to aspiration. In the recovery room, the respiratory failure worsened, and the patient was intubated. The following days, he developed multiorgan failure and died.	Probably preventable. Knowledge and adherence to rules of secured airway in patients with known risk of aspiration.
6	M 53	General anesthesia for acute repair of shoulder fracture	Surgical ward	The patient was obese and intoxicated with alcohol. Five hours postoperatively, he was found dead. He had been discharged from the recovery room a few hours earlier. The patient was not under specific observation at the ward.	Probably preventable. Instructions for the postoperative observation and treatment of obese and intoxicated patients should prevail.
7	F 41	General anesthesia for liver transplantation	Operating theater	In relation to attempted placement of a central venous catheter, a bilateral cannulation and perforation of the carotid arteries occurred. Compromised venous return caused the death in combination with hemorrhage in mediastinum. Preoperatively known bleeding disorder. Died intraoperatively of cardiovascular collapse.	Probably preventable by the use of ultrasound for localizing the vein. Extended compression when accidental cannulation occurs in patients with bleeding disorders.
8	F 34	Placement of central venous catheter	Operating theater	The patient had a history of nephropathy. Intended placement of a venous catheter for hemodialysis. A rupture of the subclavian vein occurred while inserting the catheter. The patient was severely hypotensive for 4 h before a hemothorax was discovered. Died of hypoxic brain damage as a result of cardiovascular collapse.	Probably preventable.
9	M 70	Placement of central venous catheter	Operating theater	During anesthesia for acute abdominal aneurism operation, a CVC sheath was placed incorrectly in the carotid artery. The sheath was withdrawn during the operation, and compression was performed in 10 min. Postoperatively, the patient developed signs of hemorrhagic shock. Explorative thoracotomy was performed; 6 l of blood was found in the thoracic cavity, and a lesion in the carotid artery was repaired. Died a few days later due to multiorgan failure.	Probably preventable. When a large-caliber catheter is wrongly placed intraarterially, it should not be withdrawn in the acute phase but rather surgically removed when the patient is stable.
10	M 57	Placement of central venous catheter	Operating theater	A catheter to be used for dialysis was placed in the right internal jugular vein in a patient with an INR of 2.0. A hematoma was observed at the right side of the neck, but no specific measures were undertaken. Six hours later, the patient reported respiratory difficulties. Cardiac arrest developed, and resuscitation was unsuccessful.	Probably preventable. Use of ultrasound for placement of catheter on patients with known abnormal coagulation. When a hematoma develops, careful observation and rapid intervention (surgical) if any signs of compression of trachea are observed.
11	M 75	Spinal analgesia for transurethral resection of the prostate, uncomplicated	Operating theater	Day 5 and 14 postoperatively development of neurologic symptoms and sepsis, respectively. MRI revealed cervical and thoracic abscesses. Died of sepsis at day 24 postoperatively.	Probably not preventable.

(continued)

Table 1. Continued

No.	Sex and Age, y	Procedure	Location of the Event	History	Preventable
12	M 1	General anesthesia and epidural analgesia for elective closure of an intestinal stoma	Operating theater	The child had Down syndrome as well as Hirschsprung disease. Immediately after surgery, it was established that the patient had become tetraplegic. No apparent problems during placement of the epidural catheter at the level of L1–L2. Surgery completed without complications. Postoperatively, MRI showed edema of the medulla spinalis. Died after 2 months from respiratory failure.	Probably not preventable. Although the cause is uncertain, the epidural needle was probably inserted in the medulla spinalis.
13	M 47	General anesthesia combined with epidural analgesia for explorative laparotomy	Operating theater	Postoperatively, an epidural analgesia was performed in the recovery room. After placement of the epidural catheter, 4 ml + 5 ml mepivacaine, 1%, was injected. A few minutes later, cardiac arrest developed, and resuscitation was unsuccessful. The epidural catheter was probably located in the spinal canal.	Probably preventable. Knowledge of and adherence to written procedure for testing of an epidural.
14	M 79	Epidural analgesia for pain treatment	Intensive ward	Admitted to the ICU because of respiratory failure. The patient had fracture of four costae and pneumonia. An epidural was placed for pain treatment. Ten days later, the epidural was withdrawn, and subsequently, he developed paralysis from thoracic level and an epidural abscess was diagnosed. He died 3 months later of pneumonia.	Probably not preventable.
15	M 6	Sedation to treat fever seizures	Patients home	Previously healthy child treated for fever seizures at home by an emergency physician. Within 15 min, the patient received 10 mg diazepam rectally, 20 mg diazepam and 10 mg midazolam intravenously. The airway was not secured, and hypoxemia developed prehospitally. Died from hypoxic brain damage.	Probably preventable by securing the airway when larger doses of sedative are administered.
16	F 72	General anesthesia for hemicolectomy of the right colon	Operating theater	Postoperatively, the patient (blood group A) received 2 units of group B erythrocytes. The patient developed disseminated intravascular coagulation. Died of allogenic incompatible blood transfusion.	Probably preventable. Proper identification of patient and blood type by two caretakers.
17	F 1	General anesthesia for thoracic CT	Radiotherapy department	Recurrent pneumonia was the indication for performing the CT. Methohexital, 8 mg, was intended administered intravenously, but 80 mg was given. A solution of 10% intended for rectal administration was confused with a solution of 1% intended for intravenous administration. Cardiac arrest shortly after the administration, resuscitation was unsuccessful.	Probably preventable. Double check of the intended procedure. Use of drugs in one concentration only.
18	M 49	General anesthesia	Emergency room	The patient was intoxicated with unknown substance after suicide attempt. To obtain a secure airway, he was intubated. For this procedure, he was given a bolus of 2,000 mg thiopental (400 mg was intended). An anesthetist had prepared the thiopental concentration as 125 mg/ml and not as supposed as 25 mg/ml. Immediately after, the patient developed cardiac arrest, and resuscitation was unsuccessful.	Probably preventable. Drugs should be available in only one concentration. Local preparation of drugs should be avoided.
19	M 45	General anesthesia for correction of nasal septum	Recovery room	Postoperative development of pulmonary edema in the recovery room. Treated with nitroglycerine. A bolus of 50 mg nitroglycerine was accidentally given, causing severe hypotension. Died day 2 postoperatively due to cerebral infarction.	Probably preventable. Avoid use of infusion pump with free-flow possibility.
20	M 64	General anesthesia and epidural analgesia for elective abdominal aneurysm surgery	Recovery room	In the postoperative ward, confusion of two correctly connected infusion pumps was made. The first pump infused bupivacaine into an epidural catheter; the second infused dopamine through an intravenous line. A bolus of 5 ml bupivacaine was intended, but instead, a bolus of 5 ml dopamine (21 mg) was given intravenously. The patient died of cardiac infarct.	Probably preventable. Clearly marking of contents of infusion pumps, double checking.
21	M 39	Insulin infusion	Intensive ward	Primarily admitted comatose with seizures and pneumonia to the ICU. The parenteral nutrition was paused, but an insulin infusion continued. Blood glucose was not measured until 6 h later (blood glucose was 0.4 mm). The patient died several days later due to severe cerebral damage.	Probably preventable. Several ways to minimize this problem: education, clearly marked instructions, double checking, and technological coupling of infusion pumps are some suggestions.
22	F 55	General anesthesia for pericardiocentesis	Operating theater	After initiating the anesthesia, the patient was inadvertently given a bolus of 500 mg propofol. A new type of infusion pump was used, and it was adjusted incorrectly. Cardiac arrest occurred and resuscitation was performed, but the patient developed cerebral infarction and died a few days later.	Probably preventable. Before the use of new equipment, all staff should undertake proper education and training.

(continued)

Table 1. Continued

No.	Sex and Age, y	Procedure	Location of the Event	History	Preventable
23	F 39	Spinal analgesia for cesarean delivery	Operating theater	At the end of the operation, the patient developed cardiovascular collapse starting with the following symptoms: cyanosis, seizures, bradycardia, and tachypnea. Shortly before, a bolus of Syntocinon (Novartis Healthcare, Copenhagen, Denmark) was given. Blood loss was estimated to be 1,000 ml. Resuscitation attempts were unsuccessful.	Probably not preventable. Amniotic embolus or peripartum cardiomyopathy was suspected, but postmortem examination did not reveal the cause of death. Association with the use of Syntocinon possible.
24	F 29	General anesthesia for postpartum hemorrhage	Operating theater	Severe vaginal hemorrhage after vaginal delivery. A placental abruption was suspected, and an explorative laparotomy was performed. Twenty-five minutes after induction, the patient developed cardiovascular collapse and died. Uncertainty of total blood loss, probably lesion at uterine collum.	Probably preventable. A large lesion was found postmortem in the uterine collum.

CPAP = continuous positive airway pressure; CT = computed tomography; CVC = central venous catheter; ICU = intensive care unit; INR = international normalized ratio; MRI = magnetic resonance imaging.

nature of the data of the current study, we were not able to perform a complete investigation of each incident, and our statements of the cause are therefore suggestive and may often seem to stop at the front-line level. A contemporary analysis would look deeper and point out causes in the systemic environment as well. In many analyses, critical events are considered preventable.³⁻⁶ To reduce and avoid critical incidents, it is crucial that the anesthesiologist masters the theoretical knowledge, the practical skills, and the equipment used for the various procedures as well as coordination and communication skills.⁷ Likewise, it is important that patient safety measures are considered in the physical and organizational structure of the working environment as well as in the apparatus used.

By examining the 24 incidents, we concluded that death could probably have been prevented in 20 of the 24 cases (table 1). The majority of these deaths can be divided into six categories: airway handling (4 deaths), ventilation handling (2 deaths), central catheter placement (4 deaths), medication errors (4 deaths), regional analgesia (4 deaths), and infusion pump problems (4 deaths). How could these deaths have been avoided?

Regarding airway and ventilation handling, in the current study, the respiratory critical incident differed in each case. Airway problems included one case where the patient developed bronchospasm after extubation probably because of aspiration. Another patient died after aspiration on a laryngeal mask where intubation should have been performed, and one patient died because an airway could not be established. One patient died unattended postoperatively, probably because of airway obstruction. The ventilation incidents included one case where the patient died because ventilation could not be established because the patient had an unrecognized pneumothorax. In another case, hypoxemia and subsequently death was caused by an incorrectly assembled ventilator. To reduce the number of injuries during airway and ventilation management,

there should be more training through simulation, which is a safe means of improving anesthetic skills.⁸⁻¹⁰ Finally, it is essential to have protocols and guidelines for airway and ventilation handling and to use them.

Four patients died after placement of a central venous catheter. The deaths were caused by compression of vital structures by hematomas or hemorrhage. A study from the American Society of Anesthesiologists Closed Claims Database regarding central catheter injuries showed similar serious complications due to central catheter placement.¹¹ The use of sonographic guidance in the placement of central venous catheters is a safe technique because the structures can be visualized and studies have shown very low complication rates when this technique is used.^{12,13} Furthermore, the central venous pressure or a blood gas analysis (also compared with an arterial blood gas analysis) should be obtained before placing a large-bore catheter whenever there is any doubt about correct placement.

Medication errors and infusion pump problems caused in total eight deaths. Two of the deaths resulted when a large unintended bolus of medicine was given by an infusion pump. One of these deaths could have been avoided if an infusion pump with no free-flow possibility had been used. The other case happened because a new infusion pump was used, and the death could probably have been avoided if there had been proper education and training before the use of the infusion pump. Another two of the deaths could have been prevented if drug concentration mistakes had been avoided. Anesthetic drugs should be available in one concentration only, and if drugs are to be prepared, this should be done centrally and not locally in the acute setting. Furthermore, drug mistakes can be reduced with the use of color-coded labels for syringes and education.¹⁴

Four patients died after regional analgesia. We concluded that one of the four deaths could probably have been avoided if guidelines for testing and epidural analgesia had been followed. One study from the American

Society of Anesthesiologists Closed Claims Database regarding cardiac arrest after regional analgesia concluded that two patterns contributed to this occurrence and/or the outcome of these patients. One pattern was the use of sedative, which caused cyanosis and subsequently cardiac arrest. The other pattern was the treatment. The optimal treatment of a cardiac arrest occurring in relation to regional analgesia is positional change (Trendelenburg position) and the use of a potent α agonist.¹⁵ When the combination of regional and general anesthesia is used, the patients' risks increase, and clinicians should be sure that the benefits outweigh these risks.

In general, if the technique had been used properly, if standard procedures had been followed, and finally, if equipment had been provided with patient safety measures, many of the deaths could potentially have been avoided. Lack of knowledge of the equipment ought to be prevented by proper education. Having protocols and guidelines and using them is, in the authors' view, essential.

Our study shows that there is a need for improvement in the safety of anesthesia in Denmark. The incidence of deaths related to anesthetic procedures is unknown. The proportion of deaths and other injuries that lead to a claim for compensation is also unknown. We found 24 deaths resulting in claims during a 9-yr period, and probably 20 of these deaths were considered preventable.

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