

Patient injuries in response to anaesthetic procedures: cases evaluated by the Danish Patient Insurance Association

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Background: In response to medical treatment, side-effects may occur and the patient may be injured. In Denmark, a patient is entitled to raise a claim for financial compensation and the validity of the claim which, based on defined criteria, is decided by the independent Patient Insurance Association (PIA). In this study, we investigated the files of the patients who were given financial compensation because of an injury caused by an anaesthetic procedure. We wanted to find the sort of injuries and the anaesthetic procedures involved and the size of financial compensation.

Methods: A retrospective study of the PIA database from 1996 to 2002 concerning the speciality anaesthesiology.

Results: From 1996 to 2002, 18,917 patients made a claim and out of these 916 files were related to anaesthetic procedures, of which 374 cases resulted in financial compensation. In the same period, it is estimated that the total number of anaesthetic procedures was approximately 400,000 per year in Denmark. The primary causes for financial compensation were nerve lesions in response to regional anaesthesia (epidural, spinal, peripheral nerve blockade; $n = 132$), body positional-related injuries ($n = 100$), complications due to intravascular catheters or needles ($n = 39$) and teeth damage during airway handling

($n = 31$). After anaesthesia, 12 patients' brain functions were impaired probably as a result of prolonged peri-operative hypotension and hypoxaemia. Death occurred in 21 cases. The average financial compensation was 21,500 euros (0.3% of the total amount from all cases) and in 13 cases the injury induced severe patient disability and therefore the compensation was above 1 million Dkr. equal to 150,000 euros.

Conclusion: In the 6-year period 1996–2002, 374 patients were given in total 8.0 million euros in financial compensation for an injury caused by an anaesthetic procedure. Some anaesthetic complications may result in severe disability whereby the financial compensation to the suffering patients is high. In this study, we estimate that approximately ~ 0.2% of all patients receiving anaesthesia may develop complications that entitle them to financial compensation.

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IT has become accepted that patients complain if the medical treatment is associated with an injury or an unexpected side-effect. In Denmark, complaints from patients about medical treatment are considered by the independent Patient Insurance Association (PIA) introduced in 1992. The PIA is based on a law as an impartial administrative agency, with the power to provide patients financial compensation for injuries suffered during examination or treatment in the health care service (1). As a result, patients can raise a claim to the PIA with the sole purpose of seeking financial compensation. Based on the PIA files from 1996 to 2002, we evaluated cases related to anaesthesia, which led to a financial compensation.

Methods

The study employed a retrospective design which followed claims for financial compensation as listed in the PIA database, which was launched in 1996. The claim from a patient encompasses a description of the injury (injuries) in addition to the medical record (2). Each case is registered in the database under codes that identify the patient and the medical speciality involved. All files concerning anaesthesia were identified and cases resulting in a decision on compensation were grouped according to the procedure, i.e. related to airway management, epidural or spinal analgesia, peripheral nerve blockade, infections, and vascular catheters in addition to

injuries due to positioning. Unexpected deaths related to anaesthesia were also considered. Several cases from 2003 to 2005 were still under consideration and we therefore focussed on claims from 1996 to 2002. Cases with a compensation exceeding 1 million Dkr equal to about 150,000 euros were selected for individual presentation.

Either the injured patient or the hospital can make a claim for financial compensation. When a patient fills a claim, the hospital is obliged to submit all medical records related to the case to the PIA. The claim is evaluated by a lawyer who may seek advice from medical specialists. Cases made after 2002 were handled by an anaesthesiologist, who provided an evaluation as to whether 'best practice' had been followed whereas prior to 2002 advice was provided by a non-anaesthesiology specialist. In general, financial compensation is granted if: (i) the 'best' specialist would have acted differently, (ii) defects in, or failure of the technical equipment had not occurred, or (iii) other treatments, technique or methods were considered to be safer. At least one of the three conditions needs to be fulfilled. 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. The lawyer determines, in 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 and a reduced ability to work and whether the injury is permanent.

Results

In the 6-year period 1996–2002, the PIA evaluated 18,917 claims of which 916 were related to the anaesthetic procedures and 374 cases (Table 1) resulted in financial compensation due to an injury. One case was related to two separate injuries. It is estimated that the total number of anaesthetic procedures in the period 1996–2002 were approximately 400,000 per year in Denmark. This means that a claim was made after 1 of 2500 anaesthetics and financial compensation was awarded after 1 of 6500 anaesthetics in Denmark during this time period.

The most common cause of injury was nerve lesion, infection, haematoma, headache or hearing loss followed by epidural, spinal anaesthesia or peripheral nerve blockade ($n = 132$). The majority of these patients developed a permanent nerve injury resulting in pain, incontinence of the bladder or

rectum or motor function impairment, and in a small number of these patients the procedure resulted in paraplegia.

Injury related to positioning of the patient resulted in financial compensation in 100 cases. These cases were separated in to several groups: compartment syndrome ($n = 1$) and Whiplash ($n = 8$), chronic pain in the neck or back ($n = 8$). However, the majority suffered from impaired nerve function of the ulnar nerve ($n = 30$), the brachial plexus ($n = 11$), the radial nerve ($n = 7$) and the peroneal nerve ($n = 7$).

Injuries related to airway management ($n = 40$) were dominated by a broken tooth ($n = 31$), injuries of the vocal chords, jaw and tongue were also noted. In a few cases, the airway management resulted in aspiration and failure to maintain pulmonary gas exchange and consequently caused hypoxaemia.

Beside infection caused by a needle or an intravascular catheter, five patients developed a systemic infection where the infective agent or the source of infection was not established or could not be proven. For example, one patient developed chronic liver failure as a result of a hepatitis C infection, which was suspected to be by transmission of virus from the former patient in the operating theatre but that could not be proven. Intravascular catheters beside infection caused injuries to the vessels, nerves or skin ($n = 24$).

Minor head injuries were seen in a few patients: after surgery one patient fell on the floor while being moved from the operative couch to the bed. Likewise, an accidental head injury occurred in another three patients. After anaesthesia, 16 patients (brain injuries as a result of anaesthesia or apoplexy) had reduced cognitive ability and even severe brain damage, the cause of which was predominantly related to prolonged peri-operative hypoxaemia or hypotension, although in a few cases it was caused by a stroke. One of the patients had a stroke (emboli) caused by a broken catheter. Twenty-one deaths were registered after anaesthesia. According to this registry there was 1 death per 100,000 anaesthetics in Denmark during this 6-year period.

Financial compensation was awarded to patients who had a cardiac arrest (two patients), anaphylactic shock (one patient) and urine incontinence (three patients). One patient had an eye injury and severally damaged teeth caused by an infusion bottle of saline being accidentally dropped on their face. In order to maintain the patients' body heat during surgery, they are covered by electrical blankets. Five of the claims reviewed in this study were the result of faulty electrical blankets which overheated and caused skin burn lesions.

Table 1

An overview of all patients who received compensation (374 patients)

Complication	Number	Total compensation in euros
Epidural/spinal injuries/peripheral nerve blockade (<i>n</i> = 67)		
Medullar lesion	22	311,152
Nerve root lesions	45	786,739
Spinal analgesia injuries (<i>n</i> = 31)		
Hearing loss	1	12,257
Headache	7	42,523
Nerve injuries	12	252,394
Infection	4	129,118
Other	7	53,780
Epidural analgesia injuries (<i>n</i> = 34)		
Nerve injuries	12	228,754
Infection	16	503,243
Epidural haematomas	1	20,886
Dura mater injury	4	172,850
Other	1	3,302
Injuries due to positioning (<i>n</i> = 100)		
Compartment syndrome	1	4,044
Whiplash	8	386,068
Shoulder injuries	2	10,538
Spine/Back injuries	8	284,436
Eye injuries	2	33,498
Plexus brachialis injuries	11	207,530
N. thoracicus longus injuries	4	62,107
N. medianus injuries	3	17,319
N. ulnaris injuries	30	231,771
N. radialis injuries	7	34,476
Other over extremity injury	4	42,065
N. ischiadicus injuries	4	70,589
N. peroneus injuries	7	37,692
Other under extremity injury	4	30,288
Other positioning injuries	5	72,435
Deaths due to anaesthesia (<i>n</i> = 21)	21	766,974
Brain injuries due to anaesthesia (<i>n</i> = 12)	12	1,306,626
Infection caused by anaesthesia (<i>n</i> = 5)		
Hepatitis C	1	132,266
Hepatitis toxic/viral	3	15,658
Sepsis	1	3,350
Complications due to needle lesions (<i>n</i> = 39)		
Lesions to arteries	3	19,523
Lesions to veins	2	51,314
Infections	15	382,792
Haematomas	4	71,691
N. recurrence injuries	5	138,550
Skin lesions	4	13,367
Other	6	92,105
Complications caused by airway management (<i>n</i> = 40)		
Aspiration	3	18,634
Injuries to vocal chords	1	7,379
Tooth injury	31	99,875
Injuries to the jaw or tongue	3	8,256
Other	2	5,291
Urine incontinence (<i>n</i> = 3)	3	71,826
Apoplexy (<i>n</i> = 4)	4	536,845
Burns (<i>n</i> = 5)	5	9,926
Cough with surgical consequence (<i>n</i> = 2)	2	8,756
Cardiac arrest (<i>n</i> = 2)	2	8,550
Awareness during anaesthesia (<i>n</i> = 1)	1	3,045
Anaphylactic shock (<i>n</i> = 1)	1	36,775
Others (headache, dizziness, tinnitus, concussion of the brain) (<i>n</i> = 7)	7	173,754

Listed are the types of complications, number and the compensation in euros.

The total cost of the claims was 8.0 million euros corresponding to an average compensation of 21,500 euros per case. In 13 of the cases the individual compensation exceeded 150,000 euros (Table 2). In these latter patients the injury was related to severe hypoxaemia during airway obstruction, major side-effects caused by spinal and epidural analgesia, nerve lesions as a result of inappropriate positioning, or prolonged peri-operative

hypotension, defined as mean arterial pressure of 40–50 mmHg lasting at least 20 min.

Discussion

This retrospective study demonstrates that both mild to severe patient injuries may occur in response to anaesthesia. This can be a side-effect to the medication and procedures used, but it can also

Table 2

Description of the 13 patients who each received more than 150,000 euros in compensation

	Gender	Age (years)	Anaesthesia	History	Injury	Comp (euros)
1	F	50	Spi/GA	Spi converted to GA. Hypotension during the major part of anaesthesia	Reduced strength in the left side of the body. Reduced vision, headache and bladder/rectum paresis. MR scan showed cerebral thrombosis.	336,408
2	F	32	GA	Severe bronchospasm during awakening from the anaesthesia. Development of hypoxemia and cardiac arrest.	Severe brain damage and suffering from multiple handicaps.	247,200
3	F	57	GA/Epi	Epi placed when the patient was in GA. No loss of resistance.	Paralysis of the legs. MR scan showed oedema of the spinal cord.	219,585
4	F	28	GA	Anaesthesia for Caesarean section. The anaesthesia apparatus was misassembled and expiration was impossible.	Severe brain damage and suffering from multiple handicaps.	212,323
5	F	52	GA/Epi	Hypotension during the major part of anaesthesia.	Reduced power of concentration and difficulties with speech.	199,899
6	M	47	Epi	Epi was in use for 15 days and 5 days after epi-infusion terminated symptoms developed.	Paralysis of the legs and bladder/rectum paresis.	192,214
7	M	50	GA	Anaesthesia to bronchoscopy.	Severe pain in the neck post-operatively. Too much traction during anaesthesia was seen as the cause.	181,434
8	F	47	GA	Laryngeal mask to a patient with peritonitis. Aspiration during anaesthesia.	Reduced power of concentration.	158,836
9	F	30	GA/Epi	Epi with 1 day post-operative development of paresis in the left leg.	Paresis in the left leg. MR scan showed no abnormalities.	157,380
10	M	53	Spi	Spi with development of post-operative symptoms.	Loss of control of the legs, impotence, incontinence and hearing loss.	157,166
11	M	17		Extubated at the intensive ward. Epistaxis after extubation.	Development of hypoxaemia and cardiac arrest. Severe brain damage and suffering from multiple handicaps.	154,630
12	F	48	GA/Epi	Epi in use for 11 days post-operatively.	Paralysis in the legs 4 weeks post-operatively. MR scan revealed an epidural abscess.	154,579
13	F	48	GA/Epi	Hypotension during the major part of anaesthesia.	Post-operative reduced strength in both legs.	153,851

F, female; M, male; GA, general anaesthesia; Epi, epidural analgesia; Spi, spinal analgesia; MR, magnetic resonance; Comp, compensation.

be due to defected equipment or improper handling of the patient. In these cases the independent Danish Patient Insurance Act determined that the patients were entitled to compensation and the highest compensations were provided to patients for whom anaesthesia was complicated by prolonged peri-operative hypotension or airway failure with secondary severe marked hypoxaemia. In Denmark, the total number of anaesthetic procedures is approximately 400,000 per year. Thus financial compensation was sought by 0.4% and granted to 0.2% of those patients who underwent anaesthesia.

The Danish Patient Insurance Association

Before the PIA was introduced, financial compensation for injuries caused by medical treatment was governed by the non-statutory principle of liability known as the *culpa principle*. The physician was liable only for the injury sustained if it was a result of a negligent act or an omission made by the physician. Through the 1970s and 1980s, it became clear that the *culpa principle* was ineffective for patient injuries and consequently the PIA was introduced and funded by the government. The number of claims submitted to the PIA has increased each year, probably because patients are encouraged to seek financial compensation (3). The payment from the PIA has increased from 3.1 million euros in 1992 to 32 million euros in 2002 (3).

In the present study, the complication risks appear to be rather low. Another study found that 1–2% of patients were harmed by negligent care (4) but only 1% of injured patients appear to seek compensation at the PIA (5).

Complications

Respiratory incidents are more likely to result in death or permanent injury compared with other incidents and therefore the highest financial compensations were granted to patients who had injuries caused by severe hypoxaemia (6). Previous research has found that adverse respiratory events are the largest source of injury and resulted in a high number of poor outcomes in healthy patients undergoing elective surgery (7–9). A similar study encompassing 222 medico-legal claims involving anaesthesiology found that 35% of the anaesthetists in a medical indemnity organization had previously had a claim made against them (10). The predominant claim was dental injury with other complications/injuries being awareness during surgery, coronal enquiries, nerve palsies and circulatory arrest.

In the present study, respiratory failure was related to several factors including the intubation phase; in

one case hypoxaemia was caused by an incorrectly assembled respiratory machine and in another patient bronchospasm occurred after extubation. To reduce the number of injuries during airway management there should be more training through simulation, which is safe and improves anaesthetic skills (11–13). Peri-operative hypotension is a well-known side-effect of anaesthetic drugs and in most cases cerebral autoregulation maintains a constant blood flow to the brain over a wide range of blood pressures. However, in three patients blood pressure was thought to be below the lower level of cerebral autoregulation and peri-operative cerebral ischaemia probably resulted in the reported injury (14). Near-infrared spectrophotometry can be used to evaluate changes in cerebral oxygenation and a decrease in oxygenation reflects a decrease in regional cerebral blood flow and is therefore a useful tool for monitoring during anaesthesia (15). Consequently, the critical level of hypotension, below which cerebral blood flow might be challenged, can be easily assessed during anaesthesia (16,17).

Injuries as a result of inappropriate positioning of the patient comprise 100 patients and cover various nerve/muscle and joint injuries caused by pressure or retraction. Although a few of these patients might have had a pre-existing unrecognized peripheral nerve lesion, the majority of the patients were healthy without any risk factors associated with neuropathies (e.g. diabetes or alcohol abuse). The most common injury was lesion of the ulnar nerve as previously reported (18). Prevention remains the mainstay of the management of positioning injuries. Although the majorities of these lesions typically recover over time, a small number do not recover and therefore give rise to disability (19). The use of intra-operative protective padding as well as securing the patients position seem to be important factors in preventing these injuries (20).

The cause-effect relationship mentioned in this article is to be reviewed with some reservations because it is not always clear-cut. Patients underlying condition and other procedures performed at the same time as the anaesthetic procedures may cover some important issues about origin of the injury.

Often when an injury occurs, the focus has been, and continues to be, on finding the individual to blame and hold responsible. While it is easy to blame an individual for an injury, research indicates that more often than not, errors are caused by breakdowns in the system, not of the individual (21,22). This conclusion has been found in other high performance and complex systems such as

aviation and nuclear power stations. In this study, we have not made an in-depth analysis of the fault issue. Despite this we found that improving the system would prevent many of the described injuries (equipment improvements, standardized procedures, checks, training, etc.).

We have shown that anaesthesia procedures are not without risks. The exact number of complications as a result of anaesthesia is not known but the present study estimated that approximately ~ 0.2% of all patients receiving anaesthesia may develop complications that entitle them to financial compensation. A previous study demonstrated that the compensation rates could potentially be 100-fold higher than they are currently, as the majority of patients suffering from complications do not raise a claim (5). Errors and near-misses occur every day and studies suggest that errors in the use of medication are the leading cause of adverse anaesthetic-related events (23,24). Fortunately, most of such errors are inconsequential and this is probably the reason only a few drug errors are represented in this study (25–27). Furthermore, the number of drug errors in anaesthesia can be and some places already have been reduced significantly by the use of colour-coded labels for syringes and education (27).

Patients suffering from various complications as a result of anaesthesia in Denmark have since 1992 had the opportunity to seek the PIA for compensation and there is a trend for an increasing number of patients seeking compensation. In the future, the amount of money being paid for compensation may rise considerably.

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