

Serious complications related to regional anaesthesia: Study of Greek Courts' Decisions

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Abstract

Background: Regional anaesthesia and analgesia present many advantages. Related complications are few and have been fully described. Information on regional anaesthesia malpractice is lacking in Greece. The objectives of the analysis were to highlight areas of high litigation risk and report the financial impact of claims.

Methods: Published judicial decisions of criminal, civil, administrative and disciplinary content, from 1995 to 2020, were searched in the legal information banks. The court decisions were analysed by an expert in collaboration with the lawyers of the investigation.

Results: A total of 26 court decisions related to complications from regional anaesthesia were found involving 10 cases, which comprised: 8 convictions, 1 referral of the case for a new expert opinion and 1 acquittal. In 6 cases the medical negligence involved complications after epidural anaesthesia and in 2 after subarachnoid anaesthesia. In 1 case there was collective liability of the anaesthesiologist and the obstetrician for negligent homicide and in 7 cases liability of the anaesthesiologist for bodily injuries. The duration of the litigation was 5–16 years.

Conclusions: Analysis of court cases made it possible to identify the causes that led to complications during regional anaesthesia. Informed consent, non-traumatic technique, careful patient selection, adherence to safety rules, and early diagnosis and treatment of complications are essential to avoid permanent injury.

Key words: complications, epidural anaesthesia, spinal anaesthesia, malpractice, regional anaesthesia, medical liability.

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Regional anaesthesia and analgesia in the form of central or peripheral nerve blocks are part of routine practice because of their many advantages [1–4]. However, as with every medical intervention, there are risks of certain complications [5–9]. In the study by Aromaa *et al.*, the incidence of serious complications was 0.45 : 10.000 after spinal and 0.52 : 10.000 after epidural anaesthesia. Factors believed to prevent permanent injury include an atraumatic approach, appropriate patient selection, and timely diagnosis and treatment of complications [10].

Studies of insurance claims related to regional anaesthesia and detailing specific patterns of injury and liability have been published [10–15]. These publications have effectively identified aspects of daily practice relevant to patient safety. The knowledge gained thus far from the analysis of medical malpractice lawsuits has already led to multiple improvements in patient care and safety processes.

Similar information on regional anaesthesia is lacking in Greece, and to our knowledge, the pattern of disputes related to regional anaesthesia and analgesia has not been previously reported. In case of a medical error, the patient can initiate a legal dispute individually, and there is no central system of closed claim analysis documentation.

This study aims to analyse all medical liability claims related to regional anaesthesia and analgesia complications, identify aspects that carry increased litigation risk and report the financial outcome of claims. The course of complications will also be described to further raise awareness among anaesthesiologists.

METHODS

Published judicial decisions of criminal, civil, administrative, and disciplinary content from 1995 to 2020 were searched in the legal information banks "Law", "Sakkoulas online.gr" and "Bank of the Athens

Bar Association" and in legal journals, such as *Nomiko Vima*, *Greek Justice*, *Criminal Chronicles*, and *Criminal Justice*. The following keywords were used: anaesthesiologist, medical liability, civil, criminal, medical error, regional anaesthesia, epidural, subarachnoid, nerve block.

The date of the operation, the duration of the litigation, the causes that led to the adverse outcome and the events of the postoperative course after the complication were recorded. The court decisions were analysed by an expert, a specialist anaesthesiologist, to determine the causes of complications and the correctness of the court decision in collaboration with the lawyers of the investigation. It was checked whether detailed history, informed patient consent, timely medical and surgical treatment, continuous and close follow-up, and compliance with safety rules were addressed and whether all procedures were performed in organized institutions.

RESULTS

A total of 26 court decisions related to complications from regional anaesthesia were found involving 10 cases, comprising 8 convictions, 1 referral of the case for a new expert opinion, and 1 acquittal. Of the 8 cases resulting in convictions, 6 were decided in criminal courts and 2 in civil courts. In addition, one of the criminal cases was also decided at the civil level. Medical negligence involving complications after epidural anaesthesia was found in 6 cases, after subarachnoid anaesthesia in 2 cases, after obstetric anaesthesia in 1 case and after orthopaedic surgery in 1 case. A brief description of the cases is as follows:

1. Epidural anaesthesia for caesarean section. No control dose was administered despite a third booster dose, which was assigned to a nurse. The patient was not immediately monitored afterwards. Catheter migration led to cardiac arrest, resulting in encephalopathy, lower limb spasticity, dysarthria, and severe mental disorder. MRI findings: air bubble in the anterior horn of the left lateral ventricle and in the subarachnoid space in the anterior parietal-frontotemporal region, which was later absorbed. Total duration of litigation: 8 years.
2. Epidural anaesthesia. The patient experienced an electric current sensation during puncture. Due to dural erosion, a spinal haematoma and delayed diagnosis, the patient was transferred to the Neurosurgery Clinic. The patient developed ischaemic myelopathy and arachnoiditis. The haematoma was removed and reoperation for entrapped intracanal fluid collections was performed. The patient was not adequately informed of the potential complications prior to providing consent. Compensation: € 384,000. Total duration of litigation: 8 years.
3. Epidural anaesthesia without complete information or written consent. No control dose or CSF aspiration was performed before dural puncture. The patient experienced an electric current sensation during puncture. The patient suffered from dural erosion and diffuse aseptic arachnoiditis.
4. Full-term parturient with bicuspid aortic valve and symptomatic aortic stenosis. Measurements of the aortic valve area and intervalvular pressure gradient were not reported. Epidural anaesthesia was administered for caesarean section. The patient suffered from cardiac failure and pulmonary oedema, resulting in death. The obstetrician-gynaecologist failed to inform the patient of pregnancy risks. The patient was treated in a private clinic without an intensive care unit, cardiac surgery clinic or cardiologist. The anaesthesiologist and obstetrician-gynaecologist were convicted of manslaughter. The anaesthesiologist was convicted of performing epidural instead of general anaesthesia. Criminal prosecution was terminated in the state council due to a statute of limitations. Total duration of litigation: 8.5 years.
5. Epidural analgesia for caesarean section. The patient experienced an electric current sensation at the lumbar root branches during puncture. There was dural erosion, CSF loss, cauda equina syndrome, and arachnoiditis. Arachnoiditis was a delayed diagnosis. The patient was not provided sufficient information regarding complications before providing consent. Compensation award: € 297,520. Total duration of litigation: 6 years.
6. Spinal anaesthesia for caesarean section. The patient experienced an electric current sensation during puncture. There was left L5–S1 root damage with aesthetic and motor deficits. The patient was not appropriately informed about the complications and no informed consent form was signed. Compensation award: € 146,735. Total duration of litigation: 6 years.
7. Spinal anaesthesia for caesarean section. The patient experienced pain and an electric current sensation during needle insertion. There was L5 root damage. Compensation award: € 76,000. Total duration of litigation: 12 years.
8. Epidural anaesthesia for total knee arthroplasty. There was pain in the right knee during drug administration. MRI findings showed L5/S1 disc disease and vertebral prolapse. The patient did not receive information on the complications before providing consent. Duration of litigation: 6 years.
9. Epidural anaesthesia at the L2/L3 level and catheter placement for caesarean section. The patient

experienced an electric current sensation during needle insertion. The anaesthesia chart was unsigned. The block was inadequate, so the patient also received general anaesthesia. The patient reported difficulty moving the left leg the next day. Damage to the distribution of the sciatic nerve and L5–S1 roots was revealed by electrophysiological testing. MRI showed incipient degeneration of diffuse bulging with pressure effects on the left paired root L5. After the anaesthesiologist received first- and second-degree convictions, the State Council reversed the conviction and requested a new expert opinion and new trial for the following reasons:

- A. The damage could not be attributed to the needle insertion, as only one root or nerve would have been damaged.
- B. The damage could not be associated with disc prolapse, as in this case, only one root would have been affected, the left L5.

According to the international literature, the possibility of a sudden appearance of projection proneness during the birthing process would have been mentioned. The damage appeared to have been

the cumulative result of a combination of factors, including anatomical, mechanical, and temporal, affecting the pressure on the left plexus from the fetal head, the prolonged period before the caesarean section was performed, and the inappropriate positioning of the body for anaesthesia induction. Total duration of the litigation: 16 years.

- 10. Spinal anaesthesia for transurethral prostatectomy in a patient with Parkinson's disease (stage II on the Hoehn and Yahr scale: initial stage of the disease). The patient died from aspiration and respiratory failure syndrome. The experts reported that negligence by the anaesthesiologist could not be substantiated because excessive salivation occurs in patients with advanced (stage IV) Parkinson's disease. The patient fasted from solids and liquids, was fully informed and consented, and had no contraindications, as regional anaesthesia has more advantages than general anaesthesia. Total duration of litigation: 5 years.

Table 1 summarises the type of the cases, type of anaesthesia, the personnel involved, the type of complication and outcome, as well as the result of the litigation.

TABLE 1. Summary of anaesthesia, type of surgery, type of complication and outcome, personnel involved, and litigation result

	Type of anaesthesia	Type of surgery	Complication	Outcome	Personnel involved	Judicial decision
1	Epidural	Obstetrics	Dural puncture, catheter migration	Encephalopathy, lower limb spasticity, dysarthria, and severe mental disorder	Anaesthesiologist, anaesthetic nurse	Conviction
2	Epidural	Obstetrics	Spinal haematoma	Ischaemic myelopathy and arachnoiditis	Anaesthesiologist	Conviction
3	Epidural	Obstetrics	Dural puncture	Arachnoiditis	Anaesthesiologist	Conviction
4	Epidural	Obstetrics	Pulmonary oedema	Death	Anaesthesiologist, obstetrician	First degree conviction, termination of criminal prosecution (statute of limitations)
5	Epidural	Obstetrics	Dural puncture	Arachnoiditis, cauda equina syndrome	Anaesthesiologist	Conviction
6	Spinal	Obstetrics	Dural puncture, electric current sensation	Aesthetic and motor deficits	Anaesthesiologist	Conviction
7	Spinal	Obstetrics	Electric current sensation during puncture	L5 root damage	Anaesthesiologist	Conviction
8	Epidural	Orthopaedic	Pain during drug administration	L5/S1 disc disease and vertebral prolapse	Anaesthesiologist	Conviction
9	Epidural	Obstetrics	Electric current sensation during needle insertion	Damage to the distribution of the sciatic nerve and L5–S1 roots	Anaesthesiologist	First and second-degree conviction, referred to a new trial
10	Spinal	Urologic	Aspiration	Death	Anaesthesiologist	Acquittal

Cases of medical negligence during obstetric regional analgesia involved 8 women, aged 28 to 47 years, with 6 being ASA I, 1 being ASA II and 1 being ASA III. In 1 case, the anaesthesiologist and obstetrician were equally liable for negligent homicide, and in 7 cases, the anaesthesiologist was liable for bodily injuries, including 1 cardiac arrest resulting in severe irreversible encephalopathy, 1 haematoma, 1 diffuse chemical arachnoiditis, 2 cases of subarachnoid arachnoiditis and 3 nerve lesions. In 5 cases, the patients were not fully informed prior to providing consent, and in 2 cases, there was no documentation of the medical procedure. In 3 cases, no CSF aspiration test was performed, nor was the test dose performed, while in 1 case, a medical procedure was assigned to a nurse. In 6 cases, an electric current sensation or pain was felt during drug administration, resulting in nerve damage. In 5 cases, dura meningeal erosion resulted in one case of catheter migration into the subarachnoid space and 4 cases of diffuse arachnoiditis or cauda equina syndrome.

Criteria for the legal conviction of the physicians were as follows:

- a) a delay in diagnosis and treatment;
- b) failure to perform CSF aspiration and/or control the test dose;
- c) noncompliance with safety rules and improper management of the parturient by both the obstetrician and the anaesthesiologist (collective liability);
- d) assigning the administration of epidural doses to a nurse;
- e) lack of informed consent in 6 cases.

The duration of the litigation was 5–12 years and 16 years in the case referred for a new trial by the Council of State. The compensations awarded in 3 civil cases were € 146,000, € 279,520, and € 384,000.

DISCUSSION

The main finding of this court case analysis from 1995 to 2020 is that the number of cases involving complications from regional anaesthesia is relatively small and mainly involves the use of neuraxial blocks in obstetrics. This is contrary to the literature. Staender *et al.* conducted an analysis of closed claims involving the Swiss Society of Anaesthesiology from 1987 to 2008 and found that 54% ($N = 93$) of the claims concerned regional anaesthesia [14]. Moen *et al.* reported that between 1990 and 1999, there were 127 complications of regional anaesthesia in Sweden, with epidural block-related complications being more frequent than subarachnoid anaesthesia-related complications [8].

Aromaa *et al.* found that there were 86 complications from spinal and/or epidural anaesthesia in

Finland from 1987 to 1993 [9]. The differences in our cases compared to those from countries with a smaller population may be explained by the fact that in our survey, there were no claims for mild or moderate injuries [8, 9, 14]. Different legal systems may contribute to this discrepancy. In other countries, such as the United Kingdom, where legal costs are sometimes provided by the state, the potential for low value claims may be even greater [14]. Different attitudes between populations and different patient-doctor relationships may also play an important role. In the United States of America, it has been reported that only 1–3% of affected persons submit a claim for malpractice [6]. However, case analysis is useful in managing care quality and patient safety.

One patient had cardiac arrest during the third booster dose of drugs administered into the subarachnoid space via an epidural catheter, which migrated intrathecally after an unrecognized accidental dural puncture. Epidural catheters are known to be misplaced or migrate into the subarachnoid space, subdural space, vessels, and chest cavities [16–19]. Since migration of epidural catheters can occur at any time during the perioperative period, patients require continuous monitoring to prevent and minimize the risk of related adverse events. In our study, 6 out of 8 patients experienced an electric current sensation or pain during needle puncture or drug administration, suggesting nerve injury or intraneural injection [9]. Additionally, dural erosion was recorded in 5 cases with subsequent generalized arachnoiditis or cauda equina arachnoiditis and an epidural haematoma. Delayed diagnosis contributed to the severity and permanence of complications in these cases. It is worth noting that after dural puncture, there is also the possibility of intrathecal spread of epidural local anaesthetics and opioids [19].

Peng *et al.* reported that one-fifth of anaesthesia claims in Canada were related to regional anaesthesia, there were no deaths reported, and the claim outcomes were favourable in 90% of cases [11]. According to the Third National Audit Project of the Royal College of Anaesthetists of 700,000 cases, the estimated incidence of permanent injury was 1 in 23,500 and that of paraplegia or death was 1 in 50,500 [6]. Moen *et al.* reported that the incidence of epidural haematoma was 25.98% ($n = 33$) and that of cauda equina syndrome was 25.19% ($n = 32$), while permanent neurological damage was observed in 65.93% ($n = 85$) of the 127 regional anaesthesia complications reported [8]. In Auroy's study, out of 40,640 spinal blocks, 32 cardiac arrests were recorded, 7 of which were fatal, while 3 cardiac arrests were reported in 30,413 patients who

received epidural blocks [9]. In Lee *et al.*'s survey of more than one thousand claims related to regional anaesthesia, central neuraxial blockade was used in more than 80% of the cases, both obstetric and non-obstetric. In more than one-third of deaths or brain injury cases, the main catastrophic event was cardiac arrest associated with neuraxial block. The incidence of claims in the obstetric group involving temporary or less severe injuries was 71% and 38% in the non-obstetric group [12].

Szypula *et al.* reported that, of 326 neuraxial claims, 81% ($n = 264$) were associated with epidural anaesthesia, 16.56% ($n = 54$) with subarachnoid anaesthesia and 2.45% ($n = 8$) with combined subarachnoid/epidural anaesthesia. The incidence of claims for nerve damage from epidural anaesthesia was 28.79% ($n = 76$), for inadequate blockade 9.09% ($n = 24$) and 8.71% ($n = 23$) for back pain. Dural erosion was present in 18 ($n = 6.81\%$) claims, epidural haematoma in 8 ($n = 3.03\%$) claims, medication error in 8 ($n = 3.03\%$) claims, and high sympathetic blockade/hypotension in 8 ($n = 3.03\%$) claims [13]. In 4 of the cases, there was no fully informed consent, which abolishes the individual's autonomy and leads to adverse events. This finding should serve as an impetus to anaesthesiologists. The patient's signed informed consent form outlining the potential complications can help exonerate doctors in the event of a complication. On the other hand, a healthy doctor-patient relationship and full communication between the doctor, patient and family members plays an important role [16].

Our research data analysis has some important limitations. Only published court decisions were retrieved; therefore, litigations that are still ongoing were not included in this study. Additionally, cases that were settled outside of court were not identified. The introduction of a closed claims analysis system in Greece could overcome many of the limitations of our research dataset and would be beneficial for anaesthesiologists and patients.

CONCLUSIONS

The analysis of court cases made it possible to identify the causes that led to complications during regional anaesthesia. Knowledge of the causes of events provides the basis for improving outcomes and patient safety. Informed consent, non-traumatic techniques, careful patient selection, adherence to safety rules, and early diagnosis and treatment of complications are essential to avoid permanent injury.

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